BDDSSGFS7422 Rev. 06

BD MAX™

Service Manual

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Table of Contents

1 Introduction

This service manual introduces the BD MAX system. The BD MAX service manual is for BD associates and contains information needed to support BD MAX system.

This section acquaints BD associates with an overview of the instrument, control systems, parts identification, and important principles.

The BD MAX service manual is intended for:

- System Support Specialists
- Field Service Engineers
- Phone Support Engineers
- Network Specialists.

1.1 System Description

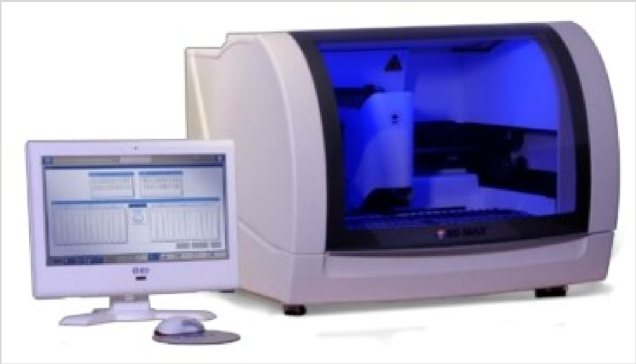

Fig: BD MAX™ instrument with All-In-One (AIO)

The BD MAX System is composed of:

- Instrument
- Peripherals
- Reagents.

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Fig: Instrument Interior

The BD MAX Instrument is capable of:

- Independent nucleic acid extraction and purification
- Polymerase Chain Reaction (PCR) amplification using thermal cycling across 24-lanes per cartridge
- Real-time detection of amplification products
- Identification of each sample buffer tube by external barcode reader
- Worklist verification by internal barcode reader
- Fluorescence detection at up to **5 nm**, allowing multiplex reactions
- Qualitative, quantitative and melt curve analysis.

The BD MAX instrument contains the following modules:

- Temperature control/heating subsystem to control thermal cycling
- Liquid handling head (pipettor) to transfer samples from sample buffer tubes to the Unitized Reagent Strips (URS)
- Onboard PCR reader to read and evaluate amplification and to detect curves and report results.

1.1.1 Liquid Handling Head

The liquid handling head performs all sample transfers. It features a pipettor to transfer fluids.

- The pipette head consists of four nozzles that move as a single unit. Each of the four nozzles can be opened or closed independently.
- The head also includes sensors to detect when tips have not been successfully picked up or ejected. When at rest, the robotic arm sits at the middle rear of the instrument interior.

- The barcode reader attached to the pipette head is capable of reading linear and 2D barcodes.
  - In a typical run, barcodes are read for the URS, PCR Master Mix Tube, Extraction Reagent Tube, Sample Buffer Tube, and PCR Cartridge. The Master Mix and Extraction disposables are furnished as snap-in tubes.
- In addition to the pipette head sensors, the liquid handling head contains the X-YZ pipettor drive, pump, valve manifold, pipette interface barrels, and pipette detection and ejection assembly.

1.1.2 Reader

The reader unit consists of four major subsystems:

- Pressure System
- Cartridge Alignment System
- Thermal System
- Optical Reader System.

All the necessary thermal cycling for the run is performed by the on-board thermal system.

Five fluorescence channels are available on each of the two on-board readers.

Wavelength Name (Excitation / Emission)	Dye Examples
475 / 520	FAM
530 / 565	VIC
585 / 630	Cal Red / ROX
630 / 665	Cy5
680 / 715	Cy5.5

Each lane in the PCR amplification cartridge is read during each PCR cycle. Excitation light is directed into the PCR chamber for each cartridge lane, and the emitted fluorescent signals are read with a fluorescence detector.

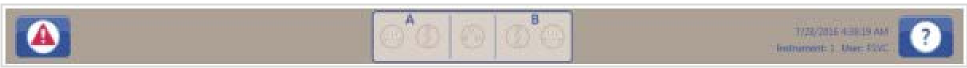
1.1.3 Computer and Instrument Software

The system is operated using an All-In-One **(AIO)** computer that contains the instrument software. The software is responsible for instrument control, self-calibration,data analysis and storage.

The user interface is navigated with point-and-click icons (keyboard and mouse), or the AIO computer touchscreen. Basic displays include:

- **Log In/Log Out:** User names and passwords are required to access assigned functions.
- **Unlock Door:** Provides access to instrument interior.
- **Start (run):** Initiates an instrument run.

Located at the top of the screen, the **Status Bar** shows the alert indicator, rack/robot/reader status (dynamically updated), current user, USB/LIS status and date/time.



Located at the bottom of the screen, the **Menu Bar** offers access to the major functions listed below.

- **Run:** Adds samples to the Worklist (log in samples), creates a PCR Only run, defines tests (open system only), and creates a list of active consumables.
- **Status:** Shows step-by-step Run Status information in the form of messages, status bars, and timers that update dynamically, showing run progress.
- **Results:** View and manage run results.
- **Configuration:** Manages user accounts, selects the language used in displays and reports, sets a default printer, imports new Assays, and sets up communication with external devices, (e.g., a Laboratory Information System **(LIS)**).
- **Reports:** Prints individual reports from the instrument, including positivity reports.
- **Maintenance:** View software versions, event log and block lanes.

Note: If the touchscreen becomes unresponsive, perform a soft reboot.

1.1.4 Peripherals

System peripherals used with the BD MAX system include:

Fig: System Peripherals

1. AIO Computer
2. Sample Racks
3. Keyboard
4. Mouse
5. Handheld 2-D Barcode Scanner
6. Printer

Note: Components such as printers or keyboards may change over time depending on OEM support and availability.

Keyboard, Mouse, and 2-D Barcode Scanner

- The keyboard and mouse enable data entry and navigational displays.
- A hand-held barcode scanner enables scanning of sample tube barcodes, accession barcodes, lot number barcodes.

Sample Rack

- Only BD MAX sample racks fit onto the BD MAX instrument deck.
- Each sample rack holds up to 12 URS and 12 sample buffer tubes. Two racks can be placed onto the instrument deck for each run.
- Each sample rack has 3 banks. Each bank is composed of 4 adjacent rows. Each row accommodates a URS and its associated sample buffer tube. Samples within a bank are processed simultaneously by the 4-nozzle pipette head.

Options:

- Pre-warm Heater. Used only with BD MAX assays requiring a pre-warm step.

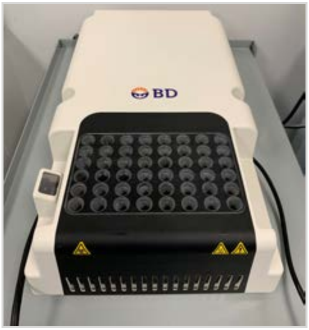


Fig: Pre-warm Heater

- Uninterruptable Power Supply **(UPS)**. The recommendations are online UPS with a line transformer. Regions outside the USA source their own. Regions outside the USA source their own.

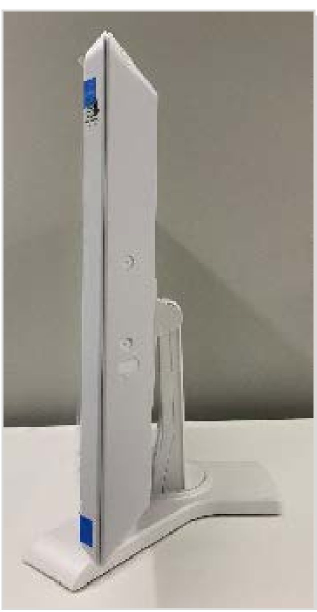
Configuration	Power
Online with line transformer	220-24 volts
AIO with BD MAX	2.6 KVA
AIO	800VA

All-In-One Computer

Part Description	H6 S20 SSD All-In-One
Spare Part Number	443686
Minimum Software/Image Req.	SW v5.20 & Image v2.20
Windows Version	Windows 10

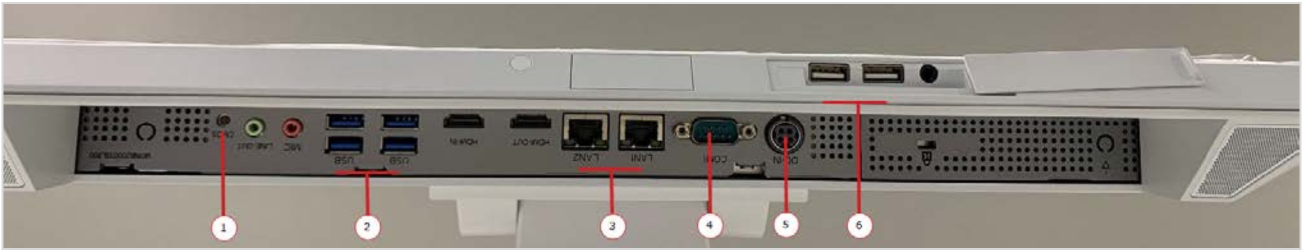
For AIO replacements: Once the Intel H6 AIO stock is depleted, customers that need a new AIO will be forced to upgrade to Windows 10 and a compatible software.

1. Night light (not enabled for BD MAX)
2. Brightness (descrease)
3. Brightness (increase)
4. Menu
5. Touch Power Button (touch and hold to power down)



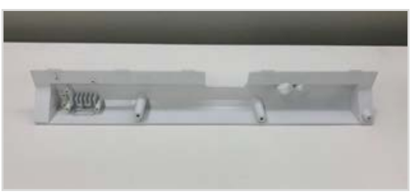
Side ports, Power button, and SAS button on the rear do not serve any major function.

Note: The AIO does not have any physical buttons for volume control. The volume can still be adjusted through the Configuration and System sub-tab in the BD MAX software.



1. CMOS reset; Micro switch for factory reboot in case of boot up issues
2. USB 3.0; Printer, Pre-warm, Keyboard, Mouse
3. LAN/Serial: LIS/Remote connectivity
4. LAN/Serial: LIS/Remote connectivity
5. Power; AIO power supply
6. USB 2.0; MAX-AIO USB Cable, USB for file export/import

Note:
The AIO may come with a cable cover for the undercarriage (below). This should NOT be used because it will put too much stress on the cables.



Power Supply

Each AIO will come with a new power supply. The power supply for the previous AIO variants is compatible with the H6 S20 SSD AIO as well.

Stylus

The provided stylus is optional.

Menu

The menu button on the AIO enables the user to adjust a few settings. The Menu button itself is used to access the Menu and Select an option. The brightness adjust buttons also function as toggle buttons when the menu is open. There is no need to adjust the menu options for routine function.

The following Menu options are available:

- Brightness/Contrast
  - Contrast adjust
- Options
  - Information: Shows resolution, refresh rate, and product details
  - Menu Language: Changes language of BIOS menu
  - Factory Default: Resets monitor to original settings (no function)
- Turn off the panel (This will cause the monitor to “sleep”. This will not affect the instrument.)
- Display Mode Switch
  - PC/Monitor: Selecting Monitor will cause the user to log out and restart the screen, but will not impact a run.

1.2 System Level

The BD MAX consists of two major systems:

- **Magnetic Extraction/Separation system**:
  - Both extractors are identical in appearance and performance.
  - Fully independent of each other.
- **Amplification/Detection system**:
  - Both the readers and heater MUX boards on sides A and B are identical in appearance and performance.
  - Fully independent of each other.

BD MAX can run extraction/PCR on the left (side A), the right (side B), or on both at the same time.

> **Note:** In Open System, the BD MAX is capable of running either Extraction or PCR independently. It can also perform two additional processes known as Melt and Quantization.

This section reviews BD MAX systems in the following order:

"Parts Identification" on page 23

"Control System" on page 27

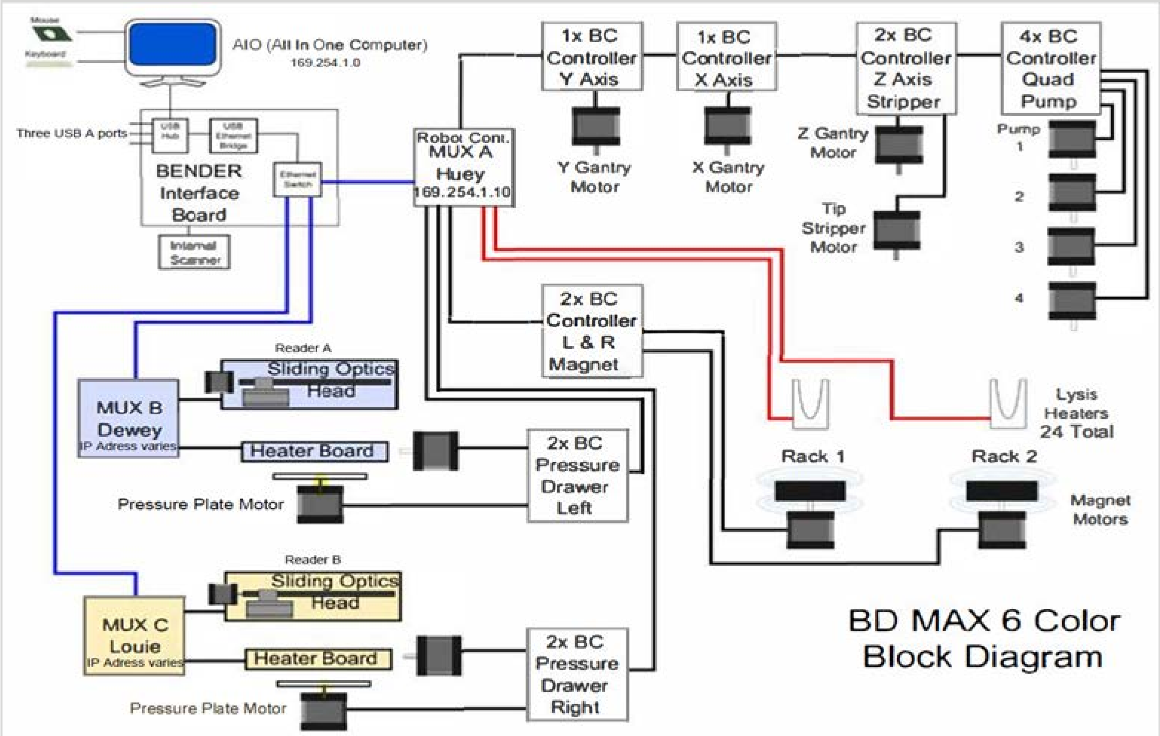
"Robot System (Gantry)" on page 28

"Extraction System " on page 39

" PCR Reader System" on page 41.

1.2.1 Parts Identification

The following diagram represents the BD max internal connections. The colored lines identify the links between the boards.

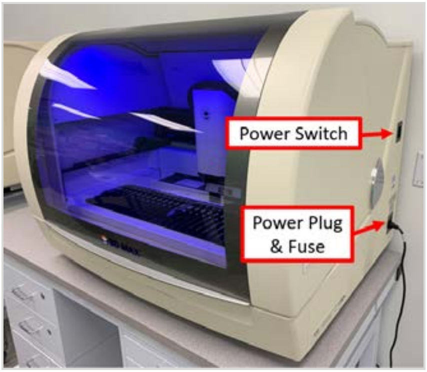


External Components

Refer to "Peripherals" on page 17 for information on external components.

Exterior View

The power plug and switch for the BD MAX are located on the rear right side of the instrument. The power connector has two built in two removable fuses.



- The lower left side of the instrument has a panel with one Type B USB port and three Type A USB ports. The Type B USB port is for connecting the All-In-One to the instrument.

- The three type A USB ports are connected to an internal USB hub on the Bender board, which is daisy-chained through the Type B USB port back to the AIO.

Interior View

The inside of the BD MAX has:

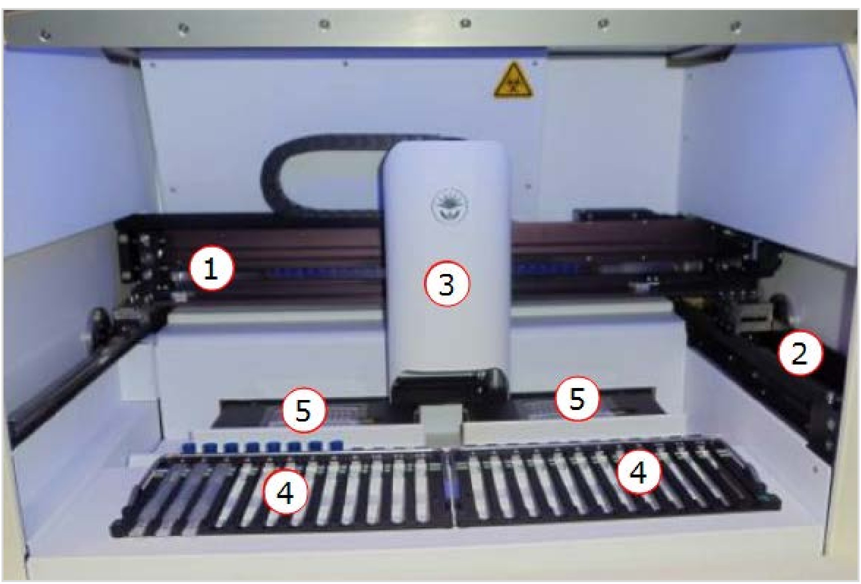


Fig: BD Max interior view

1. X-Gantry Assembly
2. Y-Gantry Assembly
3. Z-Gantry Assembly
4. Sample Racks (12 channels each; Side A and Side B)
5. PCR Card Readers (Side A and Side B)

Under the Skins

Several modules are visible when the instrument skins are removed.

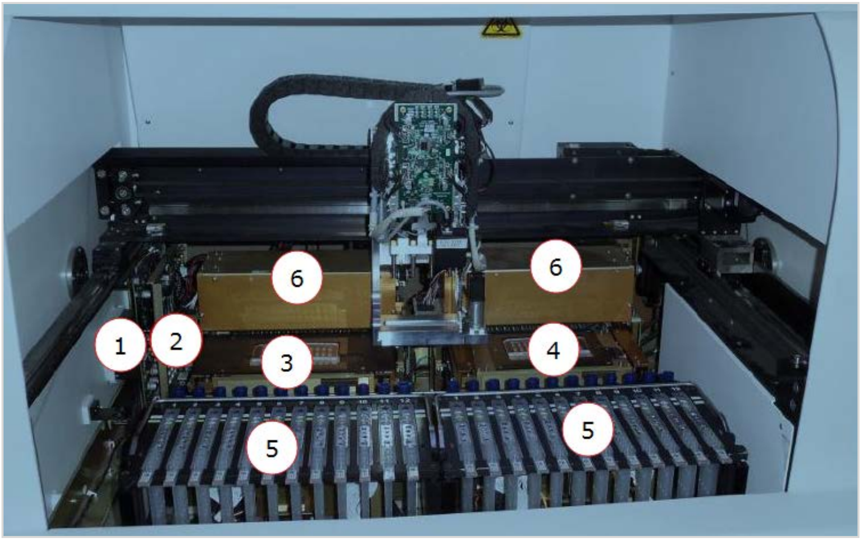
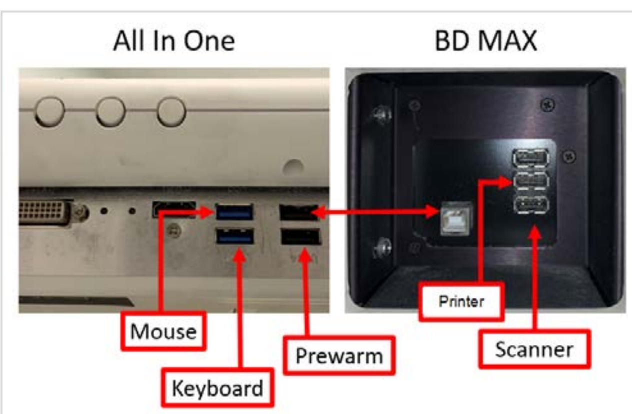


Fig: BD MAX - skins removed

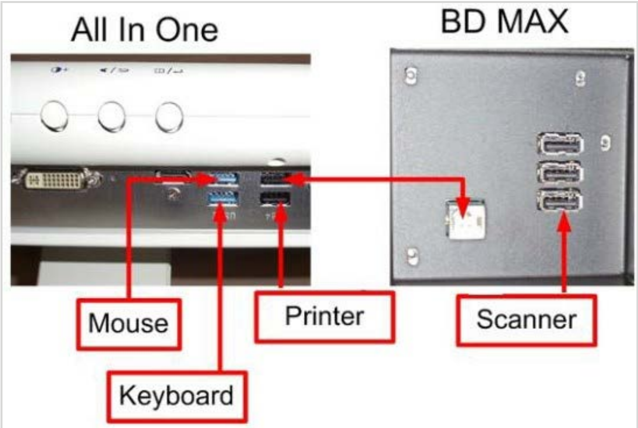
1. Bender Interface board
2. Robot Controller (Huey) MUX board
3. Reader A (Dewey) MUX board /Heater board
4. Reader B (Louie) MUX board /Heater board
5. MAG LYSIS Extractor assemblies (not visible; beneath the Sample Racks)
6. Sliding Reader modules

BD MAX System Connections

For instruments **with a Pre-warm Heater**, connect according to the following figure:



For instruments **without a Pre-warm Heater**, connect according to the following figure:



1.2.2 Control System

The control system consists of the external AIO computer and the internal bender board within the instrument.

Bender Board

The AIO communicates with the bender board inside the instrument via an A/B USB cable. The bender board contains a USB hub, a USB-to-Ethernet bridge, and an ethernet switch for the internal local area network (LAN).

- All external communications with the All-In-One pass through the bender board. The internal LAN is propagated from the bender board ethernet hub through the liberty board to each of the three individual MUX boards (Robot Controller, Reader a Controller, Reader B Controller).
- The bender board is mounted on the far left side of the instrument and attaches to the Liberty interconnect board via a 150 pin connector. The I/O ports on the back of the board project through the left side facade, where they are externally accessible.

MUX Boards

Three MUX boards are connected to the bender board via Ethernet; these control all instrument actions.

- **Robot Controller**(Huey) MUX board controls Lysis heaters and all motors with two exceptions: motors on the optics read heads of Reader A and Reader B.
- **Reader A** (Dewey) MUX board controls Reader A Optics head motor, the optics module within the optics head, and all PCR and valve heaters on the heater board.
- **Reader B** (Louie) MUX board controls Reader B Optics head motor, the optics module within the optics head, and all PCR and valve heaters on the heater board.

Motor Controllers

With the exception of the optical read head motors, all motors are serially controlled by the robot controller (Huey) MUX board through their respective Blue Cobra motor controllers.

There are seven motor controllers and 14 motors (excluding the Optical Read Head motors):

- **Extractor 2x Blue Cobra** controls both the left and right extractor motors that raise and lower the magnets.
- **Reader A 2x Blue Cobra** controls the pressure and tray drive motors on Reader A.
- **Reader B 2x Blue Cobra** controls the pressure and tray drive motors on Reader B.
- **X-Gantry controller box** controls the X-Axis drive motor.
- **Y-Gantry controller box** controls the Y-Axis drive motor.
- **Z-Controller board** controls the Z-Axis drive motor and the tip stripper drive motor.
- **Quad Pump board** controls the four fluid pumps mounted on the Z-Gantry.

1.2.3 Robot System (Gantry)

The basic robot gantry consists of three motorized axes: X, Y, and Z. It also has a tip sensor/stripper assembly with a single motor and a quad pump assembly with four motors.

All motor axes are controlled by the Robot Controller MUX board. The Robot Controller MUX board is part of the internal instrument LAN and receives commands from the AIO via the bender board.

The Robot Controller runs scripts based on the data received. These scripts control the robot gantries.

> **Note:** The reader pressure motor and tray drive motor are controlled by the motor controller and could be considered part of the robot.

1.2.3.1 X-Gantry

The X-Gantry controls the movement of the Z Head in the left (-X) and right (+X) directions. It has a range of 0 to approximately 5000 steps. The entire X-Gantry slides back and forth in the Y direction on a simple rail mounted to the left side of the instrument frame, while the right side of the X-Gantry is actually moved by the Y-Gantry.

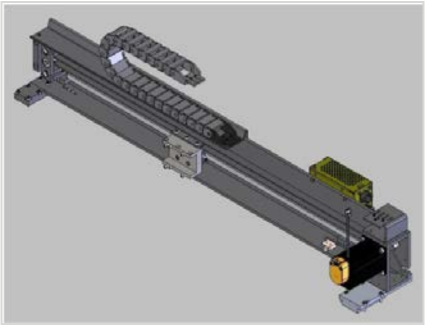


Fig: X-Gantry

The entire assembly is held on by eight bolts, four on the left and four on the right. Control cables are routed to the X-Gantry via a plastic chain assembly which is part of the Y-Gantry.

Another plastic chain, which is part of the X Gantry, routes the control and power signals to the Z-Gantry.

The X-Gantry assembly consists of a mounting frame holding the following components:

- X Drive stepper motor with optical encoder
- 1X Blue Cobra X/Y motor controller
- X Rail on which the Z-Gantry mounting plate rides
- Z-Gantry mounting plate
- X-Gantry Drive Belt
- Idler assembly
- Left and right hard stops for maximum and minimum physical x movement
- Left and right micro switches for minimum and maximum software movement
- Hall effect sensor for the X home

The X-Gantry stepper motor provides the motive force for the Z-Gantry mounting bracket along the x-axis. The stepper motor is mounted to the right front of the X-Gantry. A toothed drive sprocket and belt ensure accurate movement of the Z-Gantry. An optical encoder is mounted to the rear of the stepper motor. The motor and encoder are one assembly.

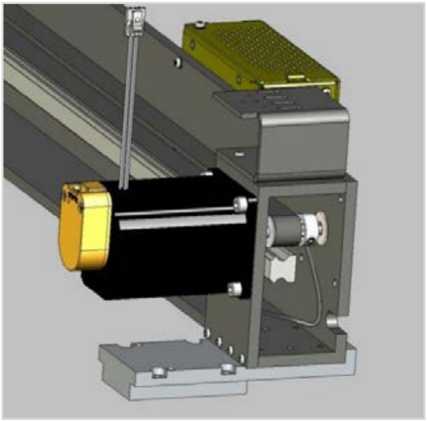


Fig: X-axis controller on the X-Gantry

The X-axis controller (1x BC Controller) is mounted to the rear of the X-Gantry. It receives and executes movement commands from the Robot Controller MUX board. In turn, it sends back to the Robot Controller MUX board:

- Limit Switch Status
- Home Sensor Status
- Encoder Status.

When the X-axis is homed, the encoder value is set to zero. The encoder on the back of the motor counts the steps moved in relation to the home sensor zero position. The Gantry is moved for a specific amount of time, and then the encoder results are compared to expected results.

The X-Controller is contained in its own case, which is mounted to the rear of the X-Gantry.

The communications cable from the Z-Gantry runs through the plastic chain and connects to the left side of the case (from front of instrument).

A second communications cable runs from the right side of the case to the Y Controller case mounted on the Y-Gantry.

The X-Gantry left and right limit switches, and the home position Hall effect sensor are attached to the right side of the X-Controller case.

> **Note:** The left and right limit switch connectors are identical. They are identified on the controller by a **plus** (right) and **minus** (left) sign.

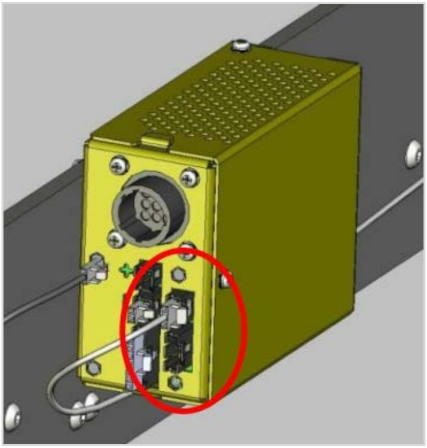
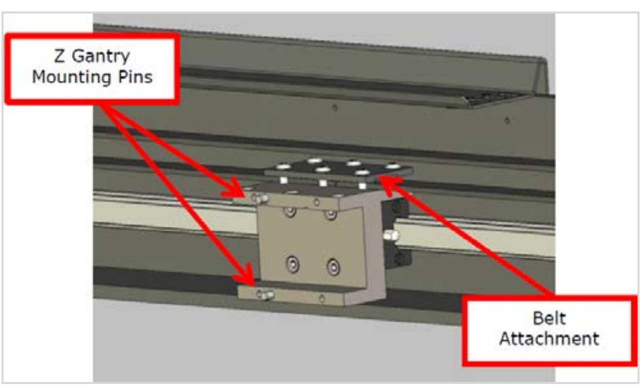


Fig: Limit switches and Hall effect sensor

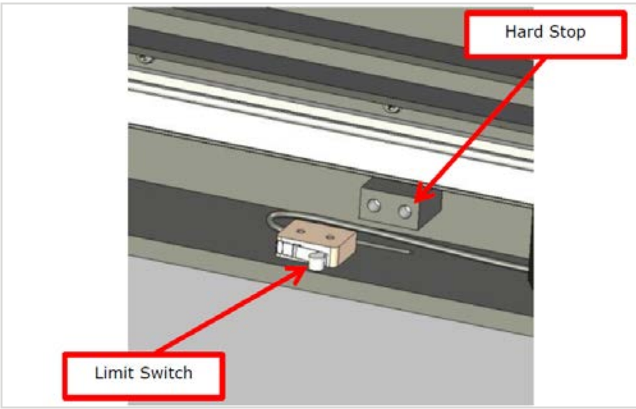
Fig: Rotary switch

The X-Controller and Y-Controller are identical. X or Y status is set by a small rotary switch mounted on the left side of the case. There are also three status lights on this side of the controller. The X-Controller is a field replaceable module.

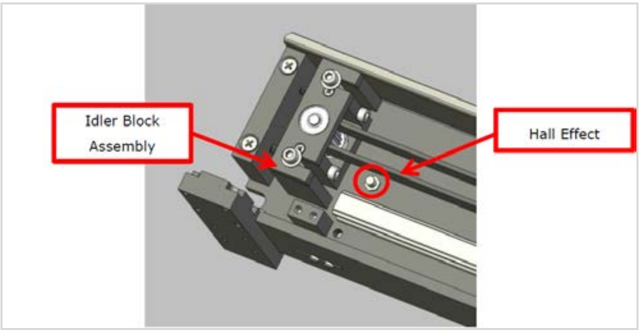


The Z-Gantry assembly attaches to the X-Gantry via a bracket. It is initially positioned with two guide pins, and then secured with four Allen head screws.

The bracket is mounted to a slide carriage that travels on a horizontal X-Rail. The belt drive is attached to the top of the bracket. The stepper motor moves the belt, which in turn moves the slide block along the rail, setting the X position of the Z-Head.



Stop blocks mounted to the left and right provide a physical limit for x-axis travel of the Z-Gantry. Within these physical stops are left and right limit micro switches that provide a signal when the Z-Gantry mounting bracket has reached the end of its x-axis travel.



Mounted on the left side, next to the idler block, is the home position Hall Effect Sensor. All x-axis positioning is measured in step from this sensor.

The idler block assembly is used to tension the belt drive. Two horizontally mounted Allen screws are used to move the assembly right or left. Two additional Allen head screws are used to lock the assembly in place once it is adjusted.

1.2.3.2 Y-Gantry

The Y-Gantry is made up of the same basic parts as the X-Gantry. The arrangement of components and assemblies is different. The Y-Gantry is on the right side of the instrument. There is also a simple rail on the left side. The X-Gantry rides on both the Y-Gantry rail and the simple rail.

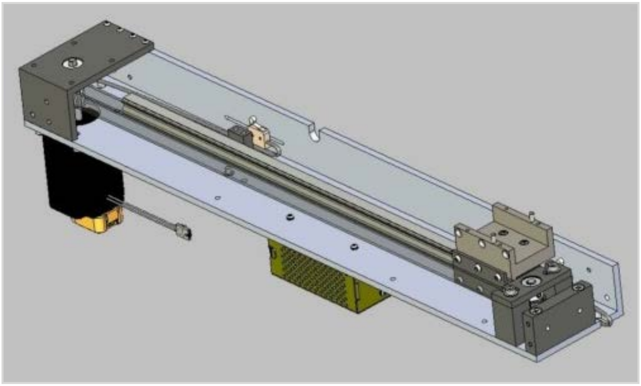
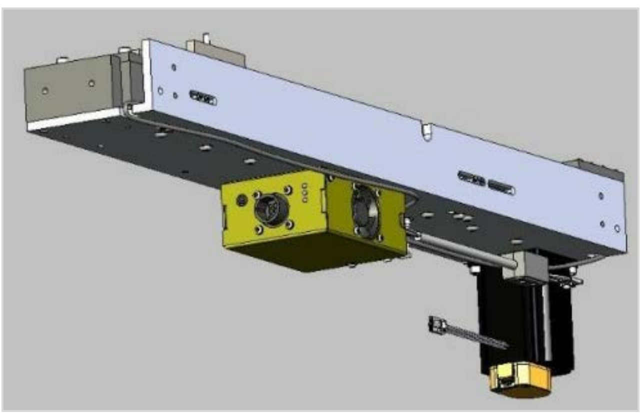


Fig: Y-Gantry

The Y-Gantry moves the X-Gantry forward (+) and backward (-) setting the Y position of the Z-Gantry. The controller cable from the X-Gantry controller passes to the Y-Gantry controller through a plastic chain.

Another plastic chain routes signals and power from the Y-Gantry to the Liberty board. From the Liberty board, the controlling signals are passed to the Huey MUX board.



1.2.3.3 Z-Gantry

The Z-Gantry assembly is mounted to a bracket that rides along a rail on the X-Gantry. It consists of the following sub-assemblies:

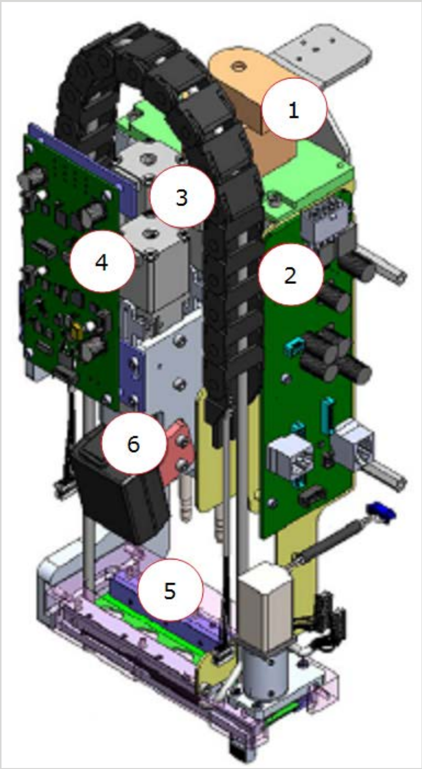


Fig: gantry

1. Z height stepper motor and optical encoder
2. Z-Head Blue Cobra stepper motor controller board
3. Four displacement pumps
4. Quad pump control board
5. Pipette tip stripper assembly
6. 2D barcode scanner

The Z-Gantry assembly is secured to the X-Gantry bracket with four Allen screws and two pins. The Z-Head assembly is moved left and right by the X-Gantry drive belt. The Z-Gantry alone controls the vertical or Z-position of the Quad pump assembly.

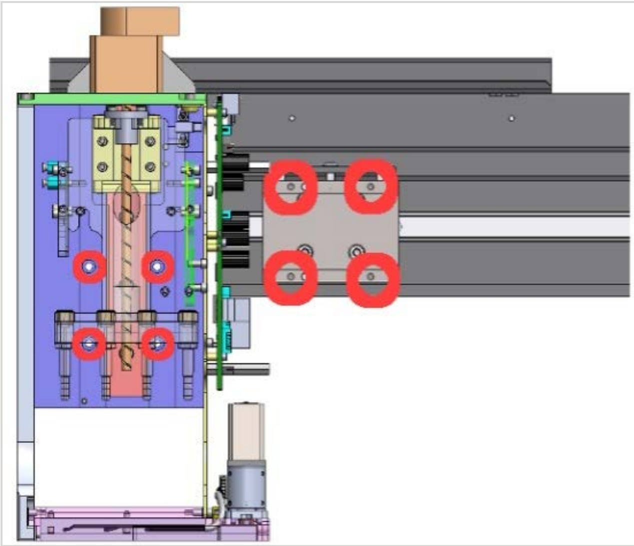


Fig: Stepper motors Z-Gantry Assembly

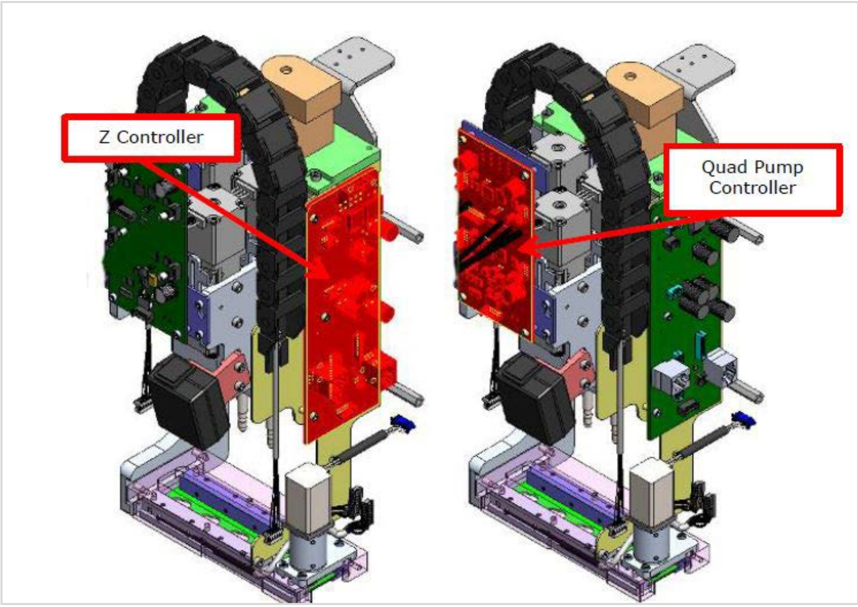
Six stepper motors are mounted to the Z-Gantry assembly.

- The Z-Axis drive and stripper assembly drive are controlled by the Z-Controller board mounted on the right side of the Z-Gantry.
- The four pump motors are controlled by the pump control board mounted on the front of the Z-Gantry.

The Z-Gantry is connected sequentially to the Robot Controller MUX board through both the X and Y Blue Cobra controller modules and the Liberty board.

The Z-Stepper motor turns a threaded shaft moving a bracket up and down along a vertical rail. Mounted to the back plate is an optical sensor that sets the home or zero position of the pump assembly.

All movements are stepper counts from home or zero position. Positive (+) Z-movement is downward, and negative (-) Z-movement is upward.

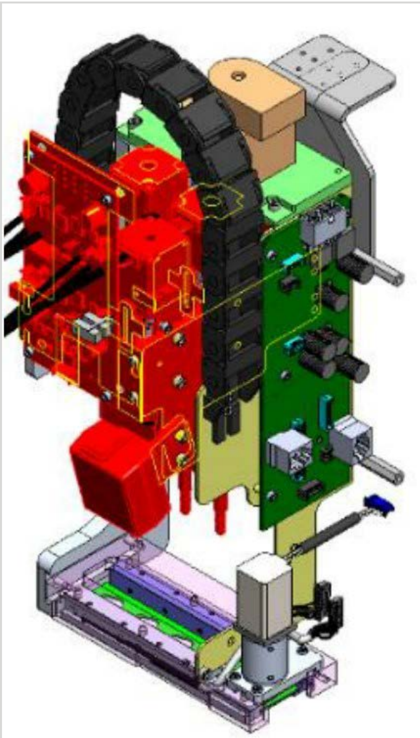


The displacement pump assembly mounts to the Z-Drive bracket.

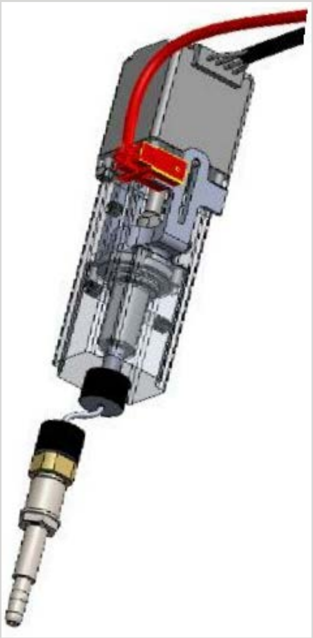
The Z-Gantry contains four independent pumps:

- The pumps are field replaceable parts that consist of a stepper motor paired to a volume displacement piston.
- While all four pumps are connected to the pump control board, each pump/nozzle configuration operates independent of the other three units.
- Each pump has its own optical home sensor. The pump control board moves each pump a specific number of steps based on the zero position set by this home sensor.

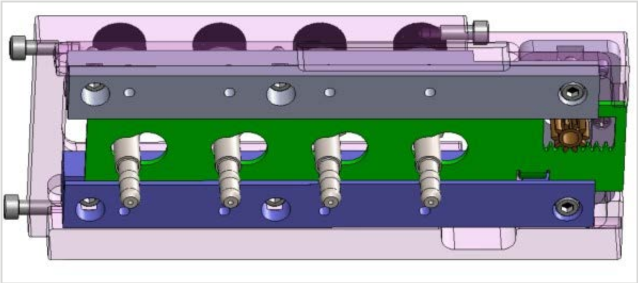
The air output of each pump is connected to its respective nozzle via a plastic tube and two ferrules with built-in ratchets. Inside the ferrules at both ends of each tube is a compression fitting. The ferrules are hand tightened until the ratchet engages, ensuring an air tight seal while preventing damage from over tightening.

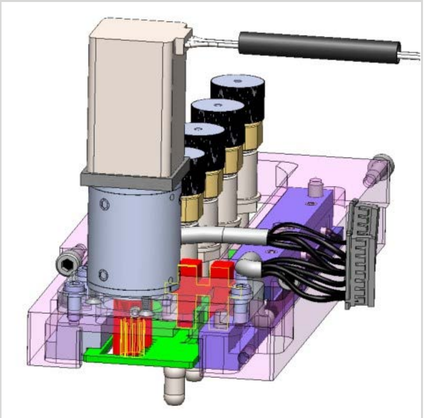


The pipette stripper motor drives the pipette stripper assembly left and right to remove pipette tips. An optical sensor sets the home position of the stripper plate. The Z-Controller directs the stripper motor to drive and position the stripper plate based on the home sensor position.



The pipette tip passes throughout the wide area of a key-shaped hole when the tips are picked up. To remove tips, the pipette assembly is lowered until the tips are below the stripper plate. The stripper plate then moves to the left. The left side of the key hole is narrower than the width of the top of the pipette tip, so that when the pipette assembly is raised, the tips are forced off the pipette nozzles.

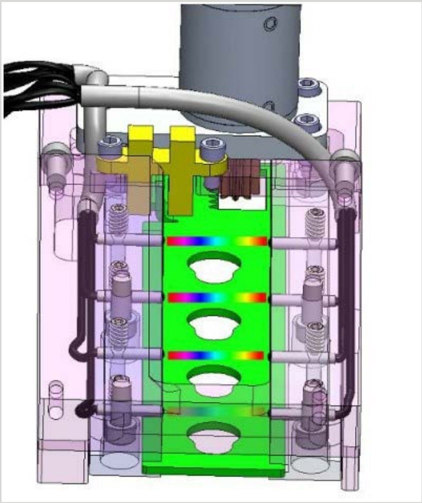




Optical sensors are mounted along the sides of the assembly that detect pipette tips and fluid levels within the tips.

The tips are detected based on the presence of the filter in the tip which blocks the signal received by the sensors. The Z-offset of the filter location differs between large and small tips, allowing the instrument to distinguish between tip types.

Fluid in the tips absorbs energy from the light beam, reducing the intensity. Fluid level is determined by the Z-position of this drop off.



The 2-D barcode scanner is mounted to the front plate of the displacement pump manifold assembly and is connected directly to the DB9 connector on the top of the Robot Controller MUX board. It does not connect to the Z-Head 3x Blue Cobra board.

1.2.4 Extraction System

The BD MAX has two identical Extractor (Mag/Lysis) modules:

- The left or A Assembly
- The right or B Assembly

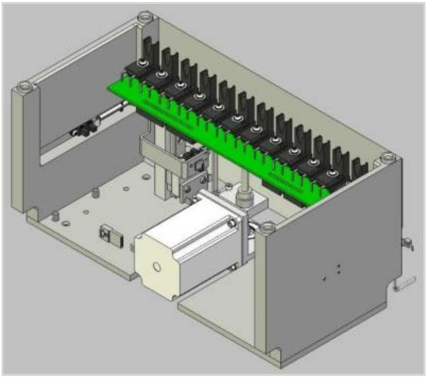
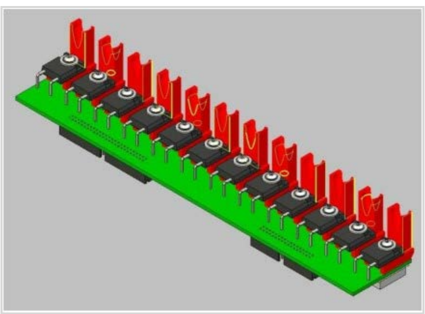


Fig: Extractor (Mag/Lysis) module

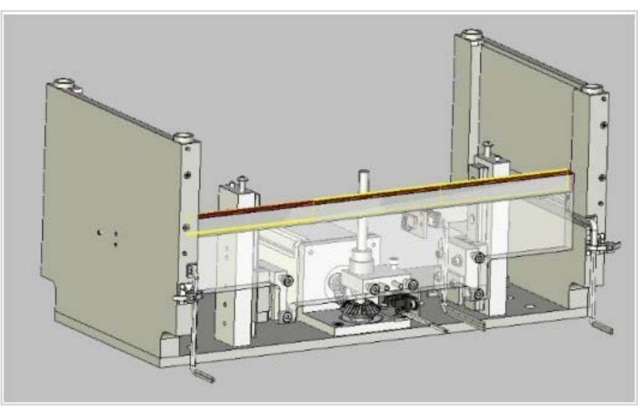
Lysis is accomplished by means of 12 heaters mounted to the Heat block (Gort Board). Between the two assemblies, there are a total of 24 individual lysis heaters.

- Each heater has a resistive thermal device to provide temperature information.
- The lysis heaters are controlled by and communicate with the Robot Controller MUX board, which in turn exchanges information with the AIO via the bender board.

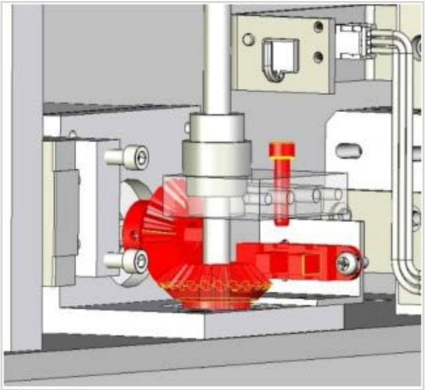


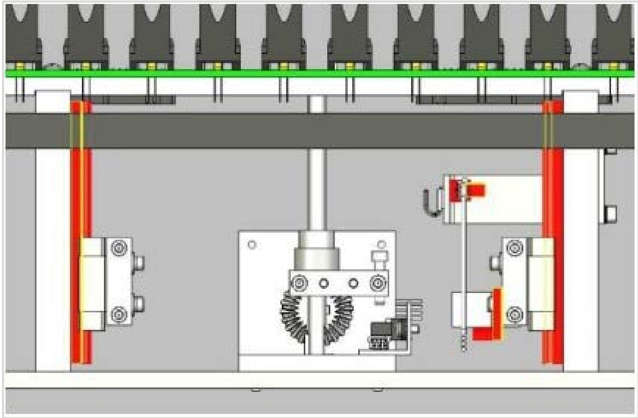
The magnetic extraction assembly consists of a row of rare earth magnets secured to an armature that is driven by a stepper motor through a screw drive shaft.

The stepper motor axis is horizontal and provides power through two 45° gears that are mounted at right angles to each other.



In the original design, there are two optical interrupt sensors - one for the **home** (down) position and one for the **limit** (up) position.





The magnet drive stepper motor is controlled by a 2x Blue Cobra motor controller, which receives instructions form the Robot Controller MUX board. The 2x Blue Cobra is mounted horizontally just above the base plate on lower front right side of the instrument.

1.2.5 PCR Reader System

Two PCR readers mounted in the BD MAX™ Instrument:

- The left hand or A Reader Assembly
- The right hand or B Reader Assembly

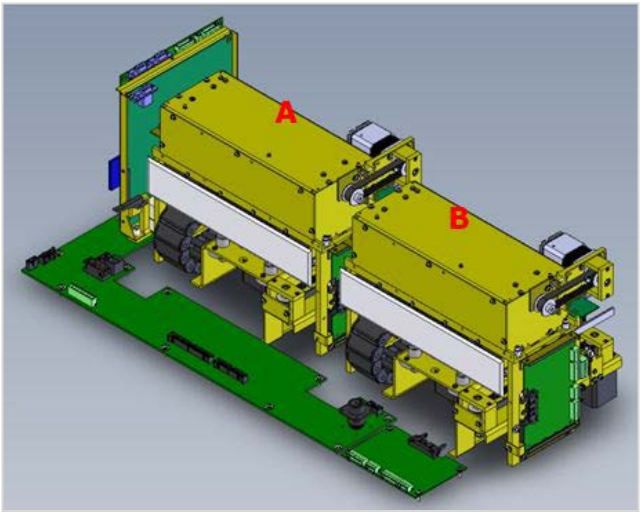


Fig: PCR Reader system

Each reader is functionally identical and consists of several modules:

- Six color optics reader (only five colors are populated)
- Twenty-four channel PCR heater
- Associated assemblies and modules to control the reader and generate PCR sample data.

The six color reader is a modular assembly that includes:

- Optical Read Head module contains the optics head and drive
- Reader Drawer assembly contains the Heater/MUX assembly
- Drawer Drive assembly
- Pressure assembly
- 2x Blue Cobra motor controller PCB.

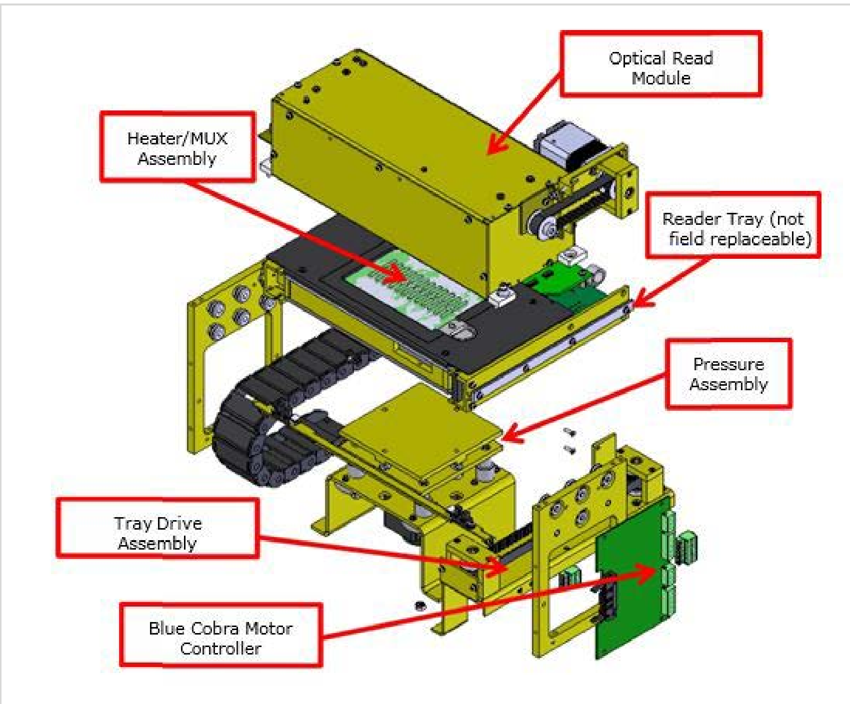


Fig: Six color reader modular assembly

1.2.5.1 Optics Reader Module

The Optics Reader Module (Sliding Read Head) consists of an **optics head** and **stepper motor**. The optics head stepper motor is controlled directly from the Reader MUX board (Dewey or Louie) with no intermediate Blue Cobra controller. There is a single home limit optical flag sensor located on the right side of the housing. Belt tension is set by two screws on the stepper motor mount plate.

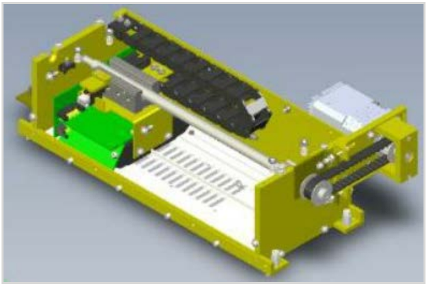


Fig: Optics Reader Module (white /yellow line)

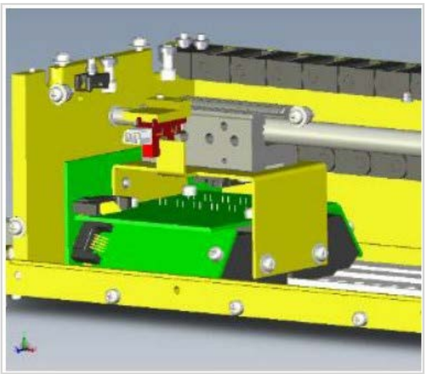


Fig: Home Position of Optics Head

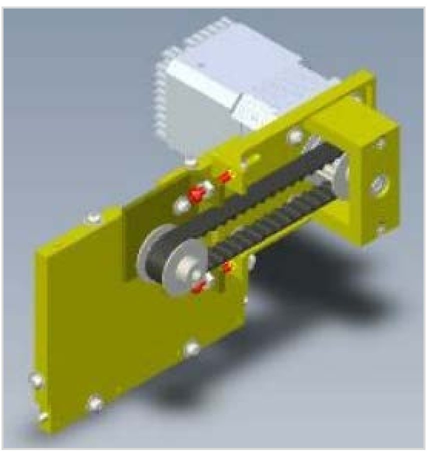


Fig: Stepper Motor

A built-in normalizer plate is located under the home position of the optics head. At the start of each read cycle the normalizer validates that the optics head is functioning normally.

The stepper motor moves the optics head to the next lane after each read. The MUX board uses step count to position the optics head correctly over the lanes to be read.

1.2.5.2 Reader Drawer Assembly

The drawer assembly consists of the **drawer frame** and a **Heater/MUX module**.

The Heater/MUX module consists of the PCR heater board mounted on top and the MUX board mounted underneath. The module is field replaceable, while the drawer assembly itself is not.

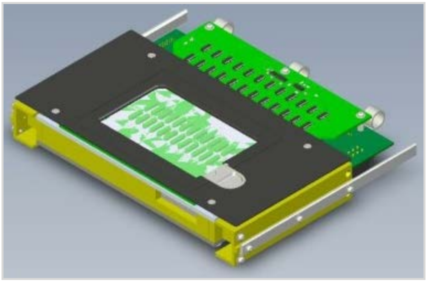


Fig: Drawer Frame and Heater/MUX module

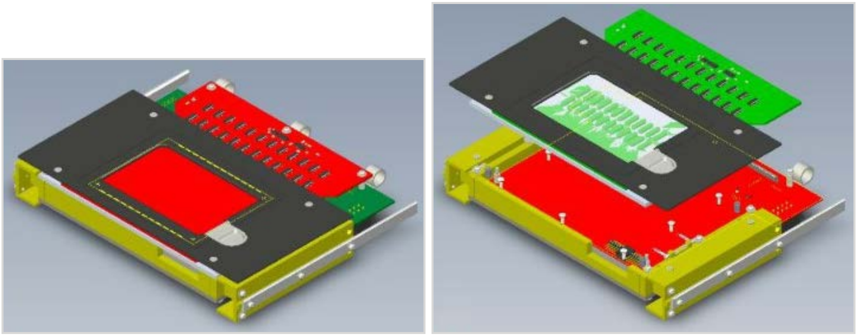


Fig: PCR Heater board mounted on top and the MUX board mounted underneath

Note: The PCR Heater board should not be separated from the MUX board in the field.

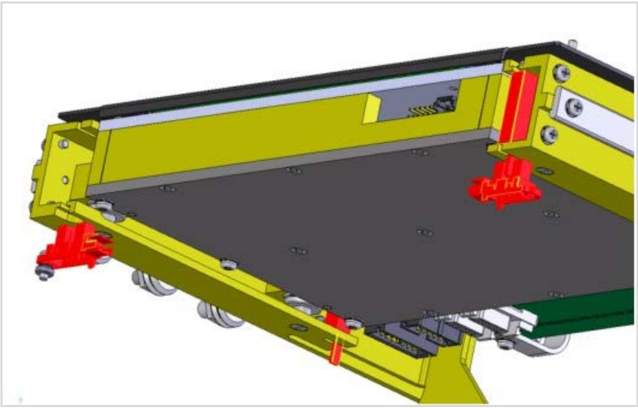


Fig: Flags that trigger frame mounted optical flag sensors

There are two posts/flags, front right and rear left (in red above) that trigger frame mounted optical flag sensors, indicating the open and closed positions of the drawer.

1.2.5.3 Drawer Drive Module

The Drawer Drive module consists of a stepper motor controlled from the readers 2x Blue Cobra board. A metal Z-plate attaches the belt drive to the rear right of the reader drawer assembly.

The 2x Blue Cobra uses the frame mounted optical flag sensors to determine drawer position and control the stepper motor.

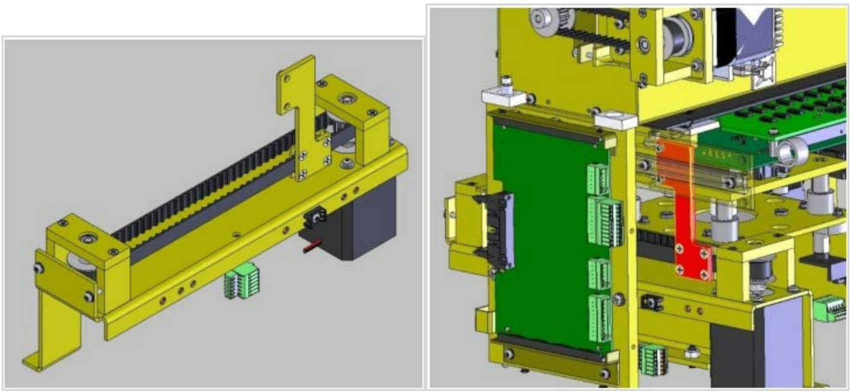


Fig: Drawer drive module

1.2.5.4 Pressure Plate Motor Module

The pressure plate motor module is controlled by the reader assembly 2x Blue Cobra. A flag sensor sets the 0 or (home) position. Step count from the home position determines the travel of the pressure plate and the amount of pressure applied to the drawer assembly.

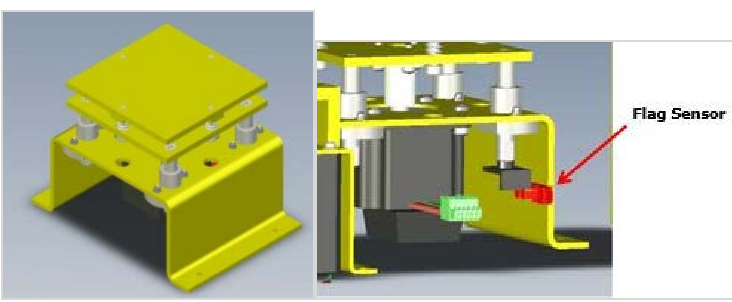


Fig: Pressure plate motor module

1.2.5.5 2X Blue Cobra (Motor Controller)

Each reader assembly has a 2x Blue Cobra motor controller card mounted to the left side. This motor controller controls the drawer drive and the pressure plate motors.

A 2x Blue Cobra Motor Controller is mounted to the right of the Liberty board and controls the extractor magnet motors.

Input from the Robot Controller MUX board is attached to the locking connector at the front of the 2x Blue Cobra cards. There are two sets of two input /output connectors at the rear of the card, one for each controlled motor, its encoder, and control circuitry.

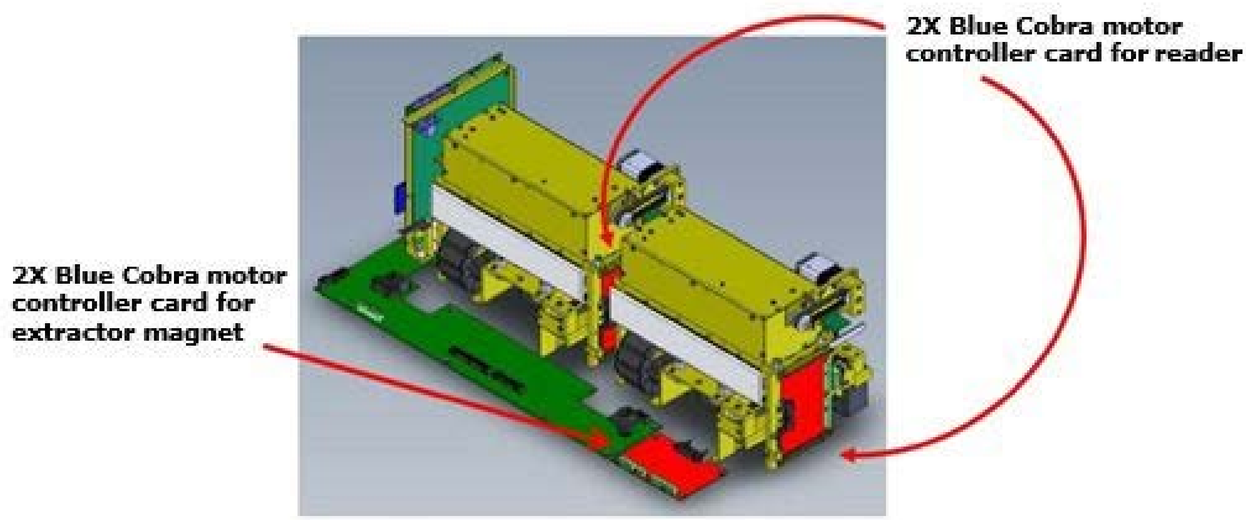


Fig: 2X Blue Cobra motor controller

The Robot Controller MUX board sends movement commands to the Blue Cobra, which then runs the motor for the specified time period. The output from the motor encoder is then read and compared to what the encoder count should be at the end of the movement.

All three 2x Blue Cobra Motor Control Board are the same. The boards are programmed for their specific position and task via multiple on-card jumpers and rotary switches.

1.3 Important Principles

This section describes principles that are important operating principles of the BD MAX.

"In-vitro Diagnostics (IVD)" on page 46

"DNA or TNA Extraction" on page 48.

1.3.1 In-vitro Diagnostics (IVD)

The BD MAX System is intended for in vitro diagnostic **(IVD)** use in performing FDA cleared or approved nucleic acid testing in clinical laboratories. The BD MAX System is capable of automated extraction and purification of nucleic acids from multiple specimen types, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR.

Open System (OS)

Used in conjunction with compatible extraction kits and reagents, the BD MAX System can automate:

- extraction and purification of nucleic acids from multiple specimen types
- amplification and detection of target nucleic acid sequences for use in clinical, industrial, and research settings.

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- extraction and purification of nucleic acids from multiple specimen types
- amplification and detection of target nucleic acid sequences for use in clinical, industrial, and research settings.

Features (IVD and OS)

The BD MAX can process and analyze up to 24 specimens per run (OS = up to 48 specimens in a PCR only run).

Each BD MAX™ Sample Buffer Tube gets an individual barcode, which is scanned by an external barcode reader and verified against the system Worklist by an internal barcode reader. This ensures traceability throughout extraction and PCR.

Other features of the BD MAX are:

- Real-time PCR with two 24-lane microfluidic PCR readers.
- Dedicated multi-color optics.
- IVD assays which contain all reagents required for extraction, purification, amplification and detection of specific target analytes.
- OSUser-Defined Protocols (UDPs) for:
  - Nucleic acid extraction and purification only.
  - PCR amplification and detection only.
  - Nucleic acid extraction and purification, followed by PCR amplification and target detection.

IVD Assay Workflow (Extraction and Components)

The workflow for IVD Assay consists of a number of steps:

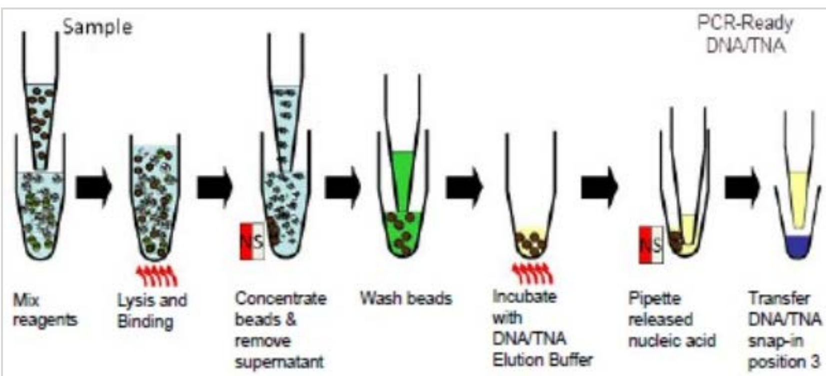
1. Specimens are introduced into sample buffer tubes per package insert instructions.
2. Scanned barcode-labeled sample buffer tubes are placed into a sample rack.
3. Sample information is entered via the keyboard or by external barcode reader. Tests election is made using the BD MAX system software.

4. The appropriate number of URS needed for the run are placed and securely seated in the sample rack.
5. Foil-sealed dried extraction tubes and PCR reagent tubes are snapped into the appropriate positions on each URS.
6. A BD MAX PCR cartridge is placed into a drawer located behind each respective sample rack.
7. After extraction, the purified nucleic acid is mixed with the master mix, including probes and primers. The instrument then transfers the PCR-ready sample into the sample injection port of the appropriate lane on the BD MAX PCR cartridge.
8. After all programmed samples are loaded, the drawer containing the BD MAX PCR cartridge is drawn into the reader where automated PCR amplification and detection is performed.

1.3.2 DNA or TNA Extraction

Sample analysis and DNA/TNA extraction take place in each unitized reagent strip.

- The lysis and extraction process are presented schematically.
- The red wavy arrows represent heat applied to the reaction tube by the heater module.



- The gray and red box (labeled N">S represents a bar magnet that is raised and lowered to come into close proximity to the reaction tube of each unitized reagent strip loaded within the sample rack.

DNA /TNA Extraction Work flow

1. To start the process, the instrument transfers a fixed volume of the prepared sample to the extraction tube to rehydrate the extraction reagents.
2. After rehydration, the mixture is transferred to the reaction tube.
3. When applicable, heat is applied to the reaction tube and the cells in the sample are analyzed, releasing DNA /TNA. DNA /TNA present in the sample binds to magnetic beads that have been coated with a proprietary nucleic acid affinity matrix.

4. The magnetic bar is raised to immobilize the DNA/TNA bound by the magnetic beads. Supernatant is aspirated from the tube.
    a. The magnet is lowered, releasing the magnetic beads. DNA/TNA wash buffer is added to the tube to remove any non-specifically bound material.
    b. The magnet is raised, thereby immobilizing the DNA/TNA bound magnetic.
    c. Supernatant is removed from the tube and the magnet is lowered.
    d. DNA/TNA elution buffer is added to the reaction tube and the tube is heated to release bound nucleic acids from the magnetic beads.
    e. The magnet is raised, immobilizing the beads.
5. The released DNA/TNA is transferred from the reaction tube to snap-in tube position 3 of the unitized reagent strip, where it is prepared for PCR analysis.

1.3.2.1 IVD Assay (Reagents/Kit Components)

BD MAX IVD Assay Kits contain all the reagents required for analyte detection including:

- Lyophilized BD MAX Extraction Reagent
- BD MAX Sample Buffer Tubes
- BD MAX Master Mix (reagent containing analyte specific probe and primers)
- BD MAX Unitized Reagent Strips (URS)

BD MAX Assay-Specific Master Mix contains a complete lyophilized PCR reagent mix for DNA detection containing assay specific probe and primer along with a probe and primer to amplify and detect an internal process control present in the extraction reagent.

BD MAX extraction reagent provided in each IVD Assay kit contains magnetic beads coated with proprietary DNA affinity matrix and an internal process control.

- Formulations are designed to optimize DNA extraction based upon sample type.
- The extraction reagent contains the following items dried-down in foil-sealed snap-in tubes:
    - Enzymes and reagents necessary for lysis and extraction
    - Sample Processing Control (SPC) DNA and beads

BD MAX Sample Buffer Tubes associated with each IVD Assay Kit are formulated for the sample type being processed.

Unitized Reagent Strips contain the following items or open positions to be used for DNA extraction and purification:

- 4 pipette tips: 1 mL tips (2 each) + 175 µL tips (2 each)
- Buffer Solutions (Wash, Elution and Neutralization)

- Reaction tube
- Open position for the extraction tube
- Open position for the Master Mix Tube (1 or 2 depending on assay)
- Conical Tube
- Waste Reservoir

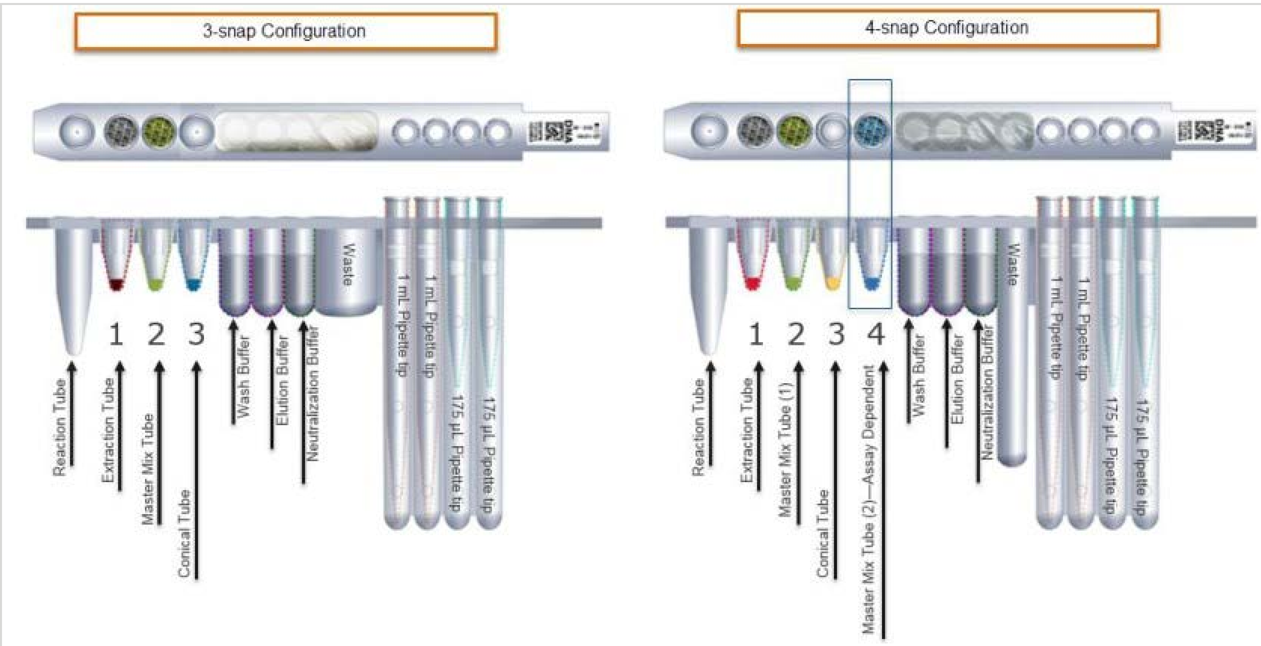


Fig: 3-snap Sample Rack (white/yellow lines)

Fig: 4-snap Sample Rack (white/yellow/blue lines)

- BD MAX PCR Cartridges incorporate a proprietary microfluidic design that enables PCR amplification and detection when used in the BD MAX System.

- The micro-fluidic disposable cartridge has 24 lanes which are organized into groups of 12, Top and Bottom rows.The PCR cartridge has a bar code similar to the reagents and unitized reagent strips.
- The bar code is read when a run starts to validate if the cartridge has been used before, and if so, which lanes (Top and Bottom) are available.

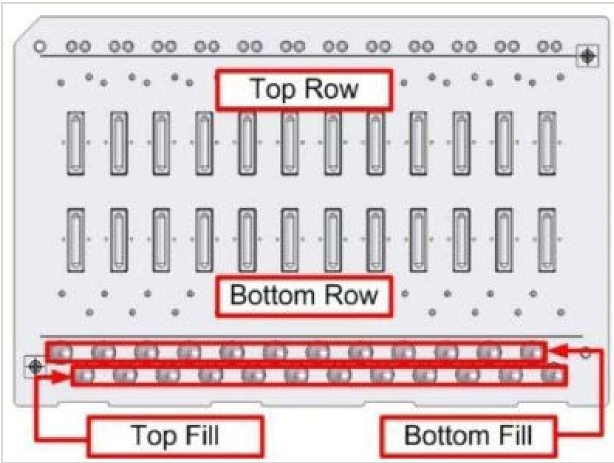


Fig: PCR Cartridge

Each of the 24 lanes consists of:

- Inlet (sample is injected into port)
- Outlet (Exhaust vent)
- Micro-fluidic channel
- Micro valves (wax; used for sealing the reaction chamber)
- PCR (Reaction) Chamber.

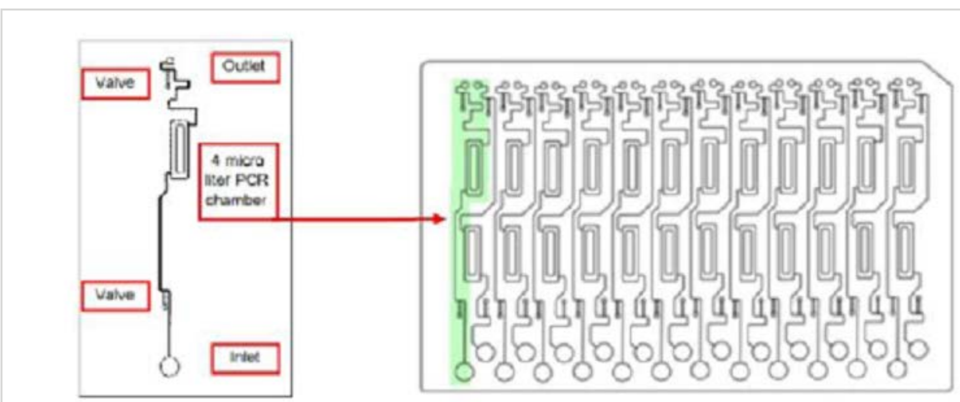


Fig: Single Lane (left; magnified view) and PCR Cartridge (right; 24 Lanes)

1.3.2.2 Open system Workflow (Extraction & Components)

Protocols for a variety of open system test applications can be defined by the user. These protocols can be designed for nucleic acid extraction only, PCR amplification and detection only, or for full process (extraction, amplification, and detection).

The following summarizes the steps, components, and theory of operation associated with performance of a full process protocol on the BD MAX system.

1. Specimens are introduced into sample buffer tubes according to package insert instructions.
2. Scanned barcode-labeled sample buffer tubes are placed into a sample rack.
3. Sample information is entered via the keyboard or by external barcode reader.
4. The appropriate number of URS needed for the run are placed securely and seated in the sample rack.
5. Foil-sealed dried extraction tubes are snapped into the appropriate positions on each URS.
6. Foil-sealed master mix reagent tubes and/or liquid reagents, as required for the UDP, are snapped into the appropriate positions on each URS.
7. A BD MAX PCR cartridge is placed into a drawer located behind each respective sample rack.
8. The UDP is selected for each applicable test location and the run is started.
9. Verification of sample buffer tubes, URS, and reagents begin, followed by the extraction and purification process.
10. The purified nucleic acid is mixed with master mix, including probes and primers. The instrument then transfers the PCR-ready sample into the sample injection port of the appropriate lane on the BD MAX PCR cartridge.
11. The drawer containing the BD MAX PCR cartridge is drawn into the reader where automated PCR amplification and detection is performed.

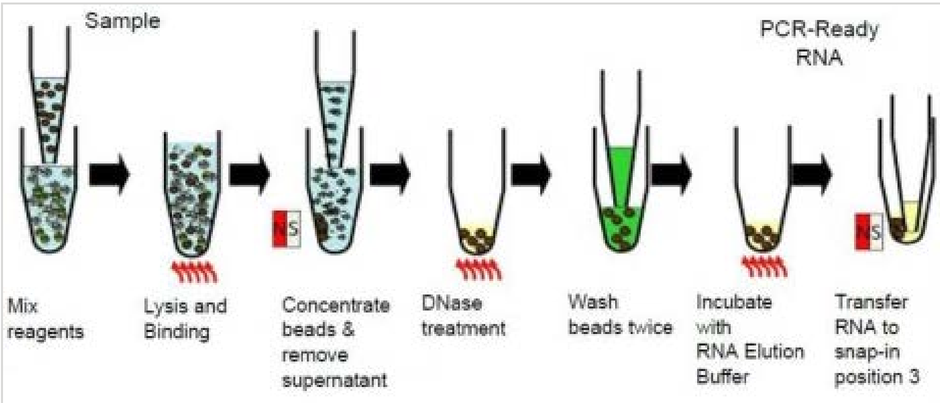
The DNA or TNA extraction process for open system is exactly the same as it is for IVD.

1.3.2.3 RNA Extraction

The RNA extraction process is very similar to the DNA /TNA extraction process and is presented schematically below:

- Sample lysis and RNA extraction take place in each URS.
- The red arrows represent heat that is applied to the reaction tube by the heater module.
- The gray and red box (labeled NS) represents a bar magnet that is raised and lowered to come

into close proximity to the reaction tube of each URS loaded within the sample rack.



RNA Extraction workflow

1. The instrument transfers a fixed volume of the prepared sample to the extraction tube to rehydrate the extraction reagents.
2. After rehydration, the mixture is transferred to the reaction tube.
3. Heat is applied to the reaction tube and the cells in the sample are lysed, releasing RNA. RNA present in the sample binds to magnetic beads which have been coated with a proprietary RNA affinity matrix.
   - The magnetic bar is raised to immobilize the nucleic acid bound by the magnetic beads. Supernatant is aspirated from the tube.
   - The magnet is lowered, releasing the magnetic beads.
4. DNase is added to the tube to degrade the DNA present.
   - The magnet is raised; thereby immobilizing the RNA bound magnetic beads.
   - Supernatant is removed from the tube and the magnet is lowered.
5. RNA wash buffer is added to the tube to wash the beads. The magnet is raised and the supernatant containing cellular debris is removed.
6. RNA elution buffer is added to the reaction tube and the tube is heated to release bound RNA from the magnetic beads.
   - The magnet is raised, immobilizing the beads.
7. The released RNA is transferred from the Reaction Tube to snap-in tube position 3 of the URS, where it is prepared for PCR analysis.

1.3.2.4 Open System Reagents

DNA Kits - BD MAX reagents available for Open System tests:

- **BD MAX DNA Extraction Kits (DNA ExK)** contain BD MAX™ extraction reagents, BD MAX sample buffer tubes and BD MAX™ DNA URS required for extraction and purification of DNA from samples prior to PCR analysis.
  - Each BD MAX DNA ExK contains magnetic beads coated with proprietary DNA affinity matrix.
  - Formulations are designed to optimize DNA extraction based upon sample type.
  - The extraction reagent contains enzymes and reagents necessary for lysis and extraction, the sample processing control (SPC) DNA, and beads dried-down in foil-sealed snap-in tubes.

BD MAX sample buffer tubes associated with each ExK are formulated for the sample type being processed.

BD MAX DNA URS contains pipette tips, solutions, a reaction tube, and a waste reservoir for DNA extraction and purification.

- The URS features open positions for addition of extraction and PCR reagents.
- BD MAX DNA Master Mix Kit (MMK) with Sample Processing Control (DNA MMK {SPC}) contains complete PCR reagent mix for DNA, along with primers and a Cy5.5- labeled TaqMan® probe, which is used to amplify and detect a SPC present in the Extraction Reagent.

BD MAX DNA MMK, is a complete PCR reagent mix for DNA.

BD MAX PCR cartridges incorporate a proprietary microfluidic design that allows for PCR amplification and detection when used in the BD MAX system.

> **Note:** DNA ExK have the same configuration as IVD Assays. The PCR cartridge is the same as the one used for IVD Assays.

RNA Kits - BD MAX reagents available for Open System tests:

- **Preparation Reagent Tubes, BD MAX DNase Reagent and BD MAX RNA URS:** are required for extracting and purifying RNA from samples prior to PCR analysis.
- **BD MAX RNA extraction reagent** is provided in each RNA extraction kit contains magnetic beads coated with proprietary RNA affinity matrix. Formulations contain enzymes and reagents necessary for lysis and extraction of RNA and lyophilized beads contained in foil-sealed snap-in tubes.
- **BD MAX DNase reagent**
- BD MAX RNA URS contain pipette tips, solutions, a reaction tube and waste reservoir for RNA extraction and purification. The URS features open positions for the addition of extraction, DNase and PCR reagents.

TNA Kits - BD MAX reagents are available for Open System tests:

- **BD MAX TNA Extraction Kits (TNA ExK)** contain BD MAX extraction reagents, BD MAXsample buffer tubes and BD MAX TNA URS required for extraction and purification of TNA from samples prior to PCR analysis.
- **BD MAX TNA extraction reagent** is provided in each ExK Kit contains magnetic beads coated with proprietary nucleic acid affinity matrix. Formulations are designed to optimize TNA extraction based upon sample type. The extraction reagent also contains enzymes and reagents necessary for lysis and extraction, an RNA SPC, and beads dried-down in foil-sealed snap-in tubes.
- BD MAX sample buffer tubes is provided in each ExK Kit are formulated for the sample type being processed.
- **BD MAX TNA URS** contains pipette tips, solutions, a reaction tube and waste reservoir for nucleic acid extraction and purification. The unitized reagent strip features open positions for addition of extraction and PCR reagents.

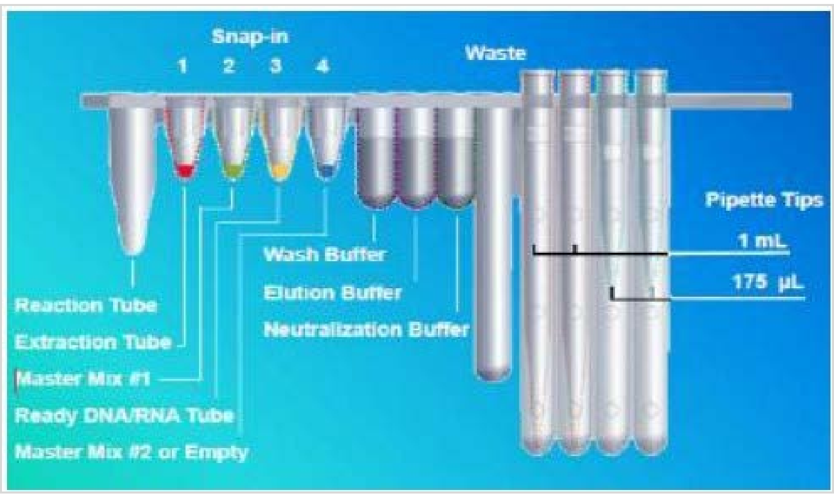


Fig: TNA Unitized Reagent Strip (typical example; 4-snap format)

- BD MAX TNA Master Mix Kit (TNA MMK) is a complete PCR reagent mix for TNA.
- BD MAX TNA Master Mix Kit with Sample Processing Control (TNA MMK {SPC}) is a complete PCR reagent mix for TNA, along with primers and a Cy5.5-labeled TaqMan® probe which are used to amplify and detect a SPC present in the extraction reagent.

1.4 Safety Considerations

1.4.1 Electrical Safety

The BD MAX instrument and pre-warm heater (optional) use electrical voltage and power levels that are potently lethal. During normal operations these voltages are internal to the instrument and do not present a hazard. However, while testing, troubleshooting, and performance maintenance, it is necessary to remove parts of the instrument enclosure, thereby exposing electrically charged circuits. While working on the instrument, observe electrical safety precautions.

1.4.2 Mechanical Safety

The BD MAX instrument contains numerous movable parts:

- During normal operation, moving parts are enclosed either behind a fixed cover or a door that serves as a barrier and shields the operator (or Service Engineer) from coming in contact with that moving part.
- During normal instrument operation, the moving parts and assemblies present no danger to the operator or Service Engineer.

Note: During troubleshooting, preventative maintenance and/or engineering testing post repair, it may be necessary to remove instrument panels or assembly covers, thereby exposing the instruments movable parts.

- Use caution and adhere to all required mechanical safety precautions as outlined for this instrument platform.

Warning: Only BD certified personnel should perform maintenance on the BD MAX™ and pre-warm.

1.4.3 Electrostatic Discharge (ESD)

The BD MAX instrument and pre-warm heater contain electrostatic sensitive electronic components.

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Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

When servicing the instrument, proper Electrostatic Discharge **(ESD)** protection must be utilized to prevent possible damage to sensitive components.Failure to follow proper ESD precautions can induce intermittent and/or catastrophic failures.

The use of a Portable Field Service Static Kit such as those manufactured by 3M™ is recommended when servicing the BD MAX™ instrument and pre-warm heater.

This kit provides a wrist strap and a coil cable, a ground strap and a portable anti-static mat for servicing and staging components.

Replaceable electronic modules should be stored and transported in an ESD shielded container or bag. Ideally, components should only be opened on a grounded ESD work surface to minimize risk of electrostatic damage.

1.4.4 Personal Protective Equipment (PPE)

Personal Protective Equipment **(PPE)** is worn to minimize exposure to serious workplace injuries and illnesses that may result from contact with chemical, radiological, physical, electrical, mechanical, or other hazards. PPE equipment may include items such as:

- Gloves
- Safety Glasses
- Shoes
- Earplugs or Muffs
- Hard Hats
- Respirators
- Coveralls
- Vests
- Full Body Suits.

All PPE should be safely designed and constructed, maintained in a clean and reliable fashion, and fit comfortably to encourage use when needed.

- Improperly fitted PPE can make the difference between being safely covered or dangerously exposed.
- Where engineering, work practice and administrative controls are not feasible or do not provide sufficient protection, BD must provide PPE to their associates and ensure its proper use.

BD is obligated to train each associate required to use PPE on:

- When it is necessary and what kind
- How to properly put it on, adjust, wear and remove
- Equipment limitations
- Care, maintenance, useful life, and disposal

Using the Compliance to Capability **(C2C)** system, BD Service Associates are required to train on specific safety curricula that includes, but is not limited to:

- PPE Standard Training
- Bloodborne Pathogens Training
- BD Corporate and BDDS specific safety policies and procedures that directly affect Service Associates.

1.5 Dangerous Procedure Warnings

Throughout the service manual, important information is presented in boxes offset from the regular text and is labeled as a Note, a Caution, or a Warning. These messages are formatted as shown below and bear the following significance:

Note: Important information about system that requires special attention is presented as a Note.

Caution: Information on an activity which potentially could cause the application to malfunction is presented as a Caution.

Warning: Information on an activity which potentially could cause injury to the user is presented as a Warning.

1.6 EHS & Onsite Protocol

1.6.1 Best Practices for Minimizing Molecular Contamination

One of the advantages of PCR is its exquisite sensitivity. More than 10 million copies of RNA or DNA molecules can be synthesized starting with small fragments from a few copies of target sequence in as few as 32 amplification cycles.

While the sensitivity level works in the lab's favor, it can create problems if care is not taken to avoid environmental contamination with other templates and amplicons (amplified DNA/RNA products from a previous amplification) that may be present in the lab work area.

These environmental contamination issues can result in the wrong template being amplified during test, which can lead to false positive results.

1.6.2 Molecular Contamination Sources

Sources of contamination may include, but are not limited to:

- Products of amplification reactions (e.g, amplicons) or positive quality control samples (contain DNA fragments or plasmids of the target organism)
- DNA or RNA extracted from patient samples
- Reagents contaminated with molecular primers, probes or enzymes
- Biohazardous waste generated during testing (e.g, test disposables, used gloves/lab coats).

Molecular contamination may be present on, but is not limited to:

- Instrument Surfaces
- Instrument Peripherals
- Laboratory Benches
- Laboratory Personnel (e.g, due to failure to change gloves or lab coats, failure to clean lab surfaces and instruments with appropriate cleaning/decontamination solutions).

1.6.3 Service Engineer Preparation

PPE Use:

- Always wear disposable Nitrile gloves when working on the instrument, peripherals and reagents.

> **Note:** Avoid Latex gloves where possible. Latex allergies and incompatibility with some BD molecular assay reagents is possible.

- Always wear a disposable lab coat that is buttoned up to prevent soiling of clothing and to reduce risk of amplicon material being transferred with you upon departure from the lab.
- Use eye protection where the potential for flying debris, acid or base reagents and other splashing hazards exit, and any time eyes may be exposed to hazards.
- Use foot coverings if so indicated by the facility.
- Adherence to universal precautions when servicing an instrument is a key responsibility for all BD Associates.
- Refer to the appropriate C2C training modules or contact your team leader, supervisor or manager for additional information or training on the use of universal precautions.

1.6.4 Minimize Potential for Molecular Contamination

- Minimize clutter (e.g., packaging, shipping crates and tools) around the instrument and work area during a service call.
- Clean /decontaminate with the appropriate cleaning solutions.
- Use disposable Nitrile gloves and change gloves frequently when working on the instrument, handling peripherals or testing reagents, especially if they become soiled or wet.
- Use disposable laboratory spill pads (chucks /diapers) or toweling on lab bench surfaces when laying out tools and parts to be used during the service activity.
- Use disposable lab coats and change daily or if soiled or wet.
- Limit customer interaction with the work area while performing service related tasks. Customers may pick up dust and dirt particles that carry amplicons and transfer them to other areas of the lab before any cleaning has been performed.
- Notify responsible laboratory personnel (Clinical Laboratory Scientist, Supervisor) when the service activity has been completed.
- Request the laboratory personnel responsible for the molecular area clean and/or decontaminate instrument work surfaces, to clean up the peripherals and work areas (e.g, lab benches) before resuming patient testing.

> **Note:** Environmental monitoring is recommended to ensure that the instrument, peripheralsand laboratory testing areas are clean prior to resuming patient testing.

1.6.5 Clean and Decontaminate Tools and Equipment

Clean and decontaminate service tools and equipment before and after use on an instrument.

Refer to "Instrument Decontamination" on page 85 for enhanced safety practices and procedures for treatment of potentially contaminated equipment, components, and tools.

Service Tools and Equipment

Clean tools, equipment, and tool cases used for a service call to eliminate the possibility of amplicon contamination transfer from one area to another and from one facility to another. Refer to the procedures and recommended decontamination solutions to clean service tools and equipment.

2 Installation

This section details the general requirements, the required prerequisites, and procedures to install the BD MAX.

2.1 Site Survey Requirements

Before installing the BD MAX, consider the following:

"Clearance Requirements" on page 62

"Electrical Requirements" on page 63

"Environmental Specifications" on page 64

"Environmental Impact" on page 64

"Special Site Requirement" on page 64.

2.1.1 Clearance Requirements

An instrument requires no additional backside clearance other than space for cabling and may be installed flush to the wall. It is recommended that **8 feet (2.44 m)** of bench space be available to accommodate monitor, keyboard, mouse, UPS, and printer.

Instrument		In Shipping Container
Height	28.5 in (72.4 cm)	32.0 in (800.0 cm)
Width	37.0 in (93.9 cm)	38.0 in (96.5 cm)
Depth	29.7 in (75.5 cm)	38.0 in (96.5 cm)
Weight	250 lb. (114 kg)	350 lb. (159 kg)

Installation Notes:

- Front clearance requires a minimum of **30 inches (76.2 cm)**.
- When placing an Instrument on a counter top, the counter top must be able to accommodate the instrument depth of **22 inches (55.9 cm)** to the front feet.
- With the door open, the instrument requires a vertical clearance of **33 inches (83.9 cm)**.

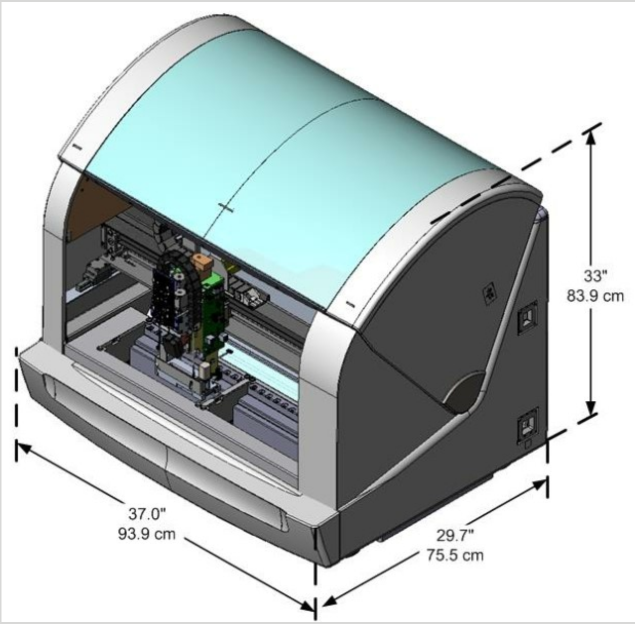


Fig: BD MAX Instrument Clearance Schematic

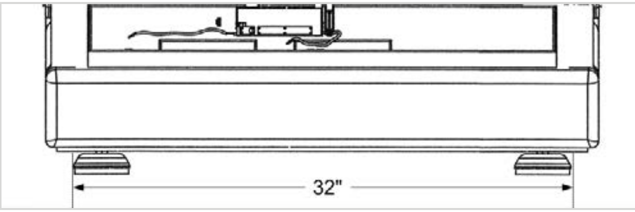


Fig: Feet - Width

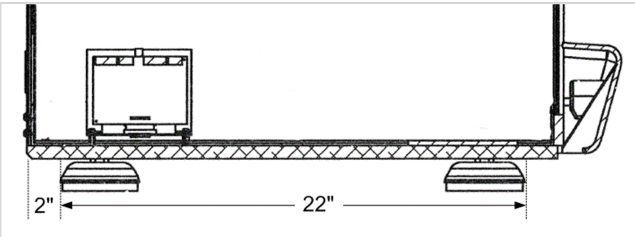


Fig: Feet - Depth

2.1.2 Electrical Requirements

Input Voltage	100 -117 VAC or 200-240 VAC
Input Current	14.0 amperes, nominal @ 115VAC, 60Hz
Input Line Frequency	47- 53 Hz or 57- 63 Hz

2.1.3 Environmental Specifications

Non-Operating Storage	
Temperature	-20°C to 65°C (-4° to 149°F)
Humidity	10% to 90% RH, non-condensing
Operating Conditions	
Temperature	18° to 30°C (64.4°F to 86°F)
Humidity	20% to 80% RH non-condensing for temperatures up to 29.0°C (84.2°F).
Locations	Level surface, no direct sunlight, no direct heat or other external air source, no high humidity, dust, extreme temperatures or corrosive or explosive vapors or gases.
Altitude	Evaluated for safety to 2,000 m

2.1.4 Environmental Impact

Noise Produced at 1 m	65 dBA using ANSI type 2 sound meter
Heat Produced	1700 BTU/hr (including UPS, All-In-One Computer, Printer) **excludes Pre-warm Heater**

2.1.5 Special Site Requirement

Consider an UPS connected to an emergency back up outlet.

Refer to "Pre-installation Checklist" on page 585 for general requirements.

2.2 Pre-installation Procedure

This section provides information and documentation to ensure installation requirements for the BD MAX System are met prior to shipment . A site inspection, to verify that customer can meet these requirements, will primarily be the responsibility of the instrument Sales Representative or the Sales Account Manager, with occasional follow-up by a Field Service Engineer.

Materials

- Tape Measure
- Level

Requirements

The BD MAX system should be installed on a level surface in an area that is free from undue vibration, external air flow, direct sunlight, direct heat, high humidity, dust, extreme temperatures, corrosive or explosive vapors or gases.

- **Staging Requirements:** Based on the planned, final location of the instrument, the transport route inside the building should be considered to ensure smooth transport of the instrument from the loading site or staging area, where the instrument is unloaded. Space for the customer to store parts, peripherals, waste receptacles, reagents, etc will also need to be considered.
- **Environmental Requirements:** The tables below provide specific Environmental, Electrical and Clearance requirements for the BD MAX instrument.

Table: Environmental Requirements

Non-Operating Storage	
Temperature	-20°C to 65°C (-4°F to 149°F)
Humidity	10% to 90% RH, non-condensing
Operating Conditions	
Temperature	18°C to 30°C (64.4°F to 86°F)
Humidity	20% to 80% RH non-condensing for temperatures up to 29.0°C (84.2ºF).
Locations	Level surface, no direct sunlight, no direct heat or other external air source, no high humidity, dust, extreme temperatures or corrosive or explosive vapors or gases.

Table 1: Electrical Requirements

Input Voltage	100 -117 VAC or 200-240 VAC
Input Current	14.0 amperes, nominal @ 115VAC, 60Hz
Input Line Frequency	47-53 Hz or 57-63 Hz

In Europe only: step-down transformer, dedicated 16 Amp line, and/or 220-240V UPS may be needed. Check that the input current 16.0 Amperes is nominal @ 220-240 VAC 50 Hz.

Document: BDDSSGFS7422 Doc Type: ZIP Status: Released EFFECTIVE
Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

Note: BD recommends a 15 amp dedicated circuit for each BD MAX instrument.

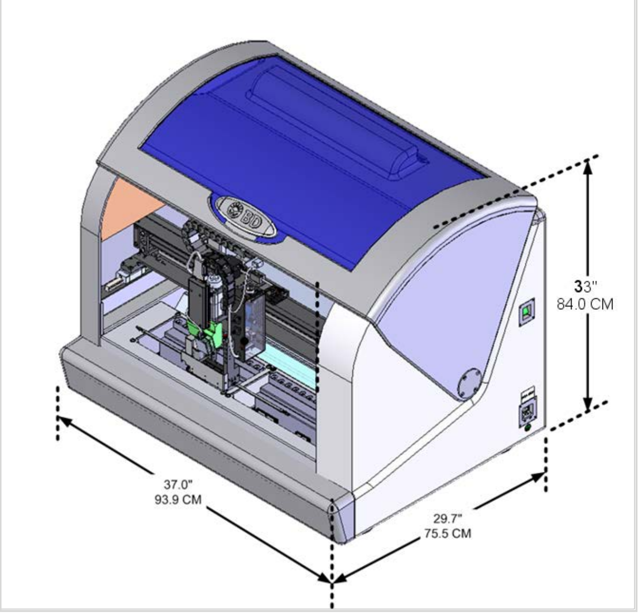
Table 2: Clearance Requirements

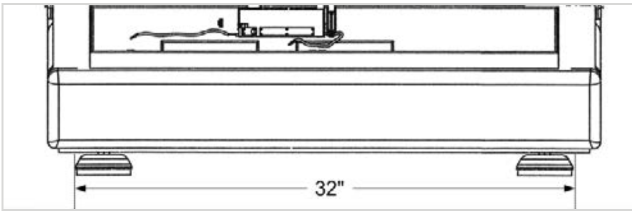
Instrument		Shipping Container
Height	33.0” in (84.0 cm)	40.0 in (102.0 cm)
Width	37.0 in (93.9 cm)	48.0 in (122.0 cm)
Depth	29.7 in (75.5 cm)	37.0 in (94.0 cm)
Weight	250 lb (114 kg)	300 lb (137 kg)

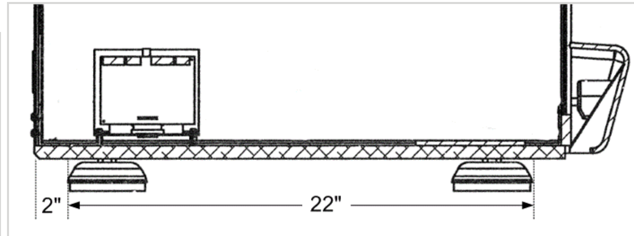
An instrument requires no additional backside clearance other than space for cabling and may be installed flush to the wall. The recommended bench space is 8 feet, to accommodate monitor, keyboard, mouse, and printer.

Front clearance will require a minimum of 30 inches (76.2 cm). Height clearance will require a minimum of 33 inches (84.0 cm). When placing an instrument on a counter top, the counter top must be able to accommodate the instrument depth (24 inches from rear of instrument to front feet).

Note: The AIO Monitor Arm Mount adds an additional ~5.5 inches to the width of the instrument. Positioning the arm wider will require additional space.







- **LIS Requirements:** The BD MAX communicates with the Laboratory Information System (LIS) using the ASTM protocol and standards.

  The BD MAX uses a DB9 (serial) port for LIS. Standard LIS connections commonly use either an RJ-45 jack or a DB9 serial connector. The connector type needs to be identified, so a RJ45 adapter can be provided if required.
- **Assurity LINC:** The BD MAX can connect to Assurity Linc. Currently an external computer connects to the BD MAX via the All-In One Ethernet port. Internet access is required for Assurity Linc to function.
- **PRE-Warm Station:** The BD pre-warm station is an optional component and connects to the BD MAX via USB. The dimensions of the pre-warm station are: 21″ (54 cm) deep, 12″ (31 cm) wide, and 5.5″ (14 cm) high.

  Clinical trial sites and certain assays may require the use of pre-warm stations.

Pre-Installation Checklist

> **Note:** The checklist is an optional tool available for use to ensure adherence to the procedure and should not be used exclusively to drive full compliance with procedural directives.

If applicable:

1. Copy the BD MAX™ "Pre-installation Checklist" on page 585.
2. Complete the Pre-Installation Checklist on your BD-issued laptop by typing the appropriate information into the text fields and checking all required checkboxes. The checklist may also be printed and completed manually, if necessary.
3. N/A any blank fields.
4. If checklist is used and uploaded to ServiceMax, a BD representative must sign and date for verification of completion.
5. Once the checklist has been signed by the customer and the BD Representative, changes or edits to the checklist are prohibited.
6. Return the checklist to the appropriate Field Service Manager.

7. These conditions must be met prior to the installation date.
8. Inform the customer of any required environmental changes or concerns.

2.3 Installation Procedure

Materials/References

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

- "Qualification Run" on page 322
- Level
- Assorted Hand Tools
- BD MAX System Software (SAP# 443584)

Warning: The BD MAX instrument uses electrical voltage and power levels that are potentially lethal. During normal operations these voltages are internal to the instrument and do not present a hazard. However, while testing, troubleshooting, and performing maintenance it is sometimes necessary to remove parts of the instrument enclosure exposing electrically charged circuits. When the High Voltage symbol appears in this procedure, use safety precautions.

Warning: The BD MAX instrument contains Electro Static Discharge (ESD) sensitive components. When servicing the instrument, ESD protection must be utilized to prevent possible damage to sensitive components. Failure to follow ESD precautions can induce intermittent and/or catastrophic failures. When the ESD Discharge symbol appears in this procedure, use caution and ESD procedures.

Unpacking the Instrument

1. Cut the band securing the cardboard box, containing the BD MAX, to the pallet. Cut the band securing the other equipment shipped with the instrument.
2. Open the top of the cardboard box and remove the two pieces of packing foams and plastic wraps.

3. Lift the cardboard box off the palette to access the BD MAX instrument.
4. Open the other boxes and inventory/inspect items:
    a. BD MAX Post Wave 1 instrument with Power Cord and A/B USB Cable
    b. All-In-One Computer Monitor With Power Cord
    c. UPS With Power Cord
    d. Printer with Power Cord and A/B USB Cable
    e. Peripherals: Keyboard, Scanner, Mouse
    f. Optional: Pre-warm Station with Power Cord and USB Cable
    g. Optional: AssurityLinc™ box with Power Cord, 2 Ethernet Cables and Cable Adapters as required.
    h. Report any discrepancies to the supervisor.
5. The BD MAX sits unsecured on a custom pallet. When lifting the instrument off the pallet, do not lift by the front skirt. The BD MAX has standard BD instrument screw in handles to use while lifting. Handles can be ordered if needed.

Monitor Arm Mount Installation (optional)

1. Place the BD MAX instrument into its final location.
    1. The instrument cannot be moved once the arm mount is installed.
    2. Remove the front skin.
    3. Adjust the BD MAX feet to the minimum height of 1.6”.
        1. The large bracket will not fit if the BD MAX is too low.
2. Confirm with the customer on which side of the BD MAX the AIO should be placed.
    1. The arm mount can be placed on either side of the BD MAX. Orient the large white bracket so that the pocketed side will be on the desired side for the AIO (Fig. 1).

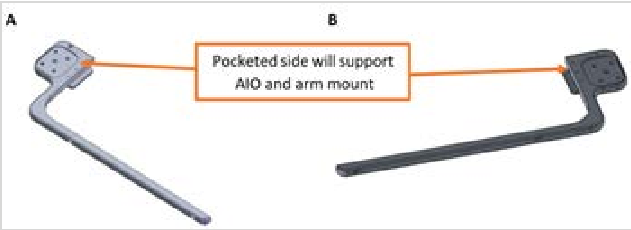


Figure 1: Large white bracket orientation; (A) AIO on left of BD MAX, (B) AIO on right

3. Use the supplied hardware to connect the large white bracket to the arm (Fig. 2).
    1. There are four 1/4”-20 x 1” socket head screws supplied within the hardware that is used to connect the arm to the bracket.
    2. Place the monitor arm onto the pocketed groove of the large white bracket.
    3. The bolts are installed from the bottom of the arm through the bracket.

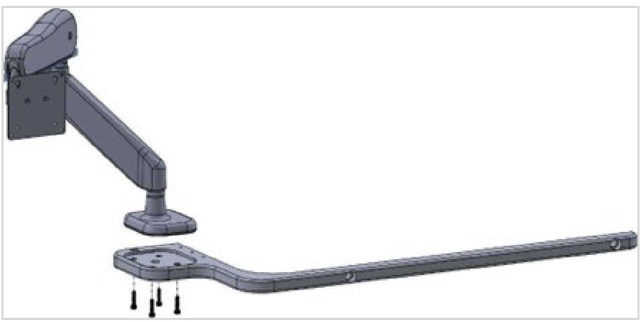


Figure 2: Joining arm mount to large white bracket for left side orientation

4. Connect the white tab to the large bracket (Fig. 3).
    1. There are three more 1/4”-20 x1”socket head allen screws.

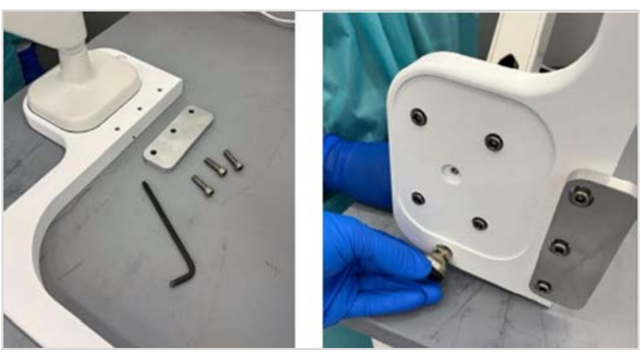


Figure 3: White tab hardware – white for production (reverse for right side AIO)

5. Install the foot onto the large bracket.
    1. Place the swivel leveling mount (foot) underneath the back hole of the large white bracket and insert the knurled head thumb screw (Fig. 3-4).

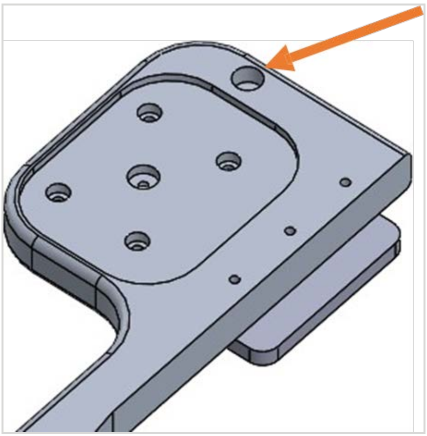



Figure 4: Hole for knurled head thumb screw assembly (foot) (reverse for right side AIO)

6. Mount the large bracket onto the BD MAX. **Be careful not to lift the BD MAX**.
    1. Use the two 3/8” – 16 x 2.5” socket head cap screws to install the large white bracket into the front base of the instrument. This is where the lifting handles typically are used.
    2. Ensure that the large white bracket is biased upwards.
        1. Push the bracket upwards when tightening the 3/8” screws at the front of the BD MAX). The tab should be flush against the side support strut (Fig. 5).

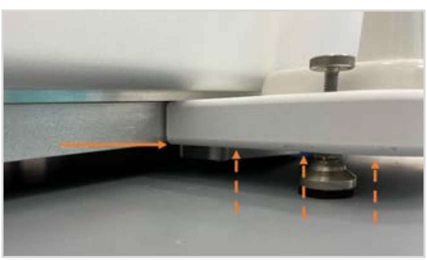


Figure 5: Tab (production version is white) flush against the large bracket and BD MAX base plate

7. Adjust the instrument and arm mount height.
    1. Level the BD MAX and adjust the feet of the instrument as needed.
    2. Level the large white bracket using the thumb screw (foot) until it presses the tab on the bracket against the bottom of the instrument (Fig. 5).
8. Install the VESA mount onto the AIO.
    1. There are four M4x8 Phillips head mounting screws (Fig. 6) – **tighten all the way down**.

2. The VESA mount is not critical to the security of the mount/monitor arm, but provides additional space for the power, COM1, LAN, and HDMI connections beneath the AIO.

Figure 6: VESA mount on back of AIO

9. Assemble the keyboard mount.
    1. Use the three #10-32 x 7/16” flat head mounting screws in the center of the base (Fig. 7).

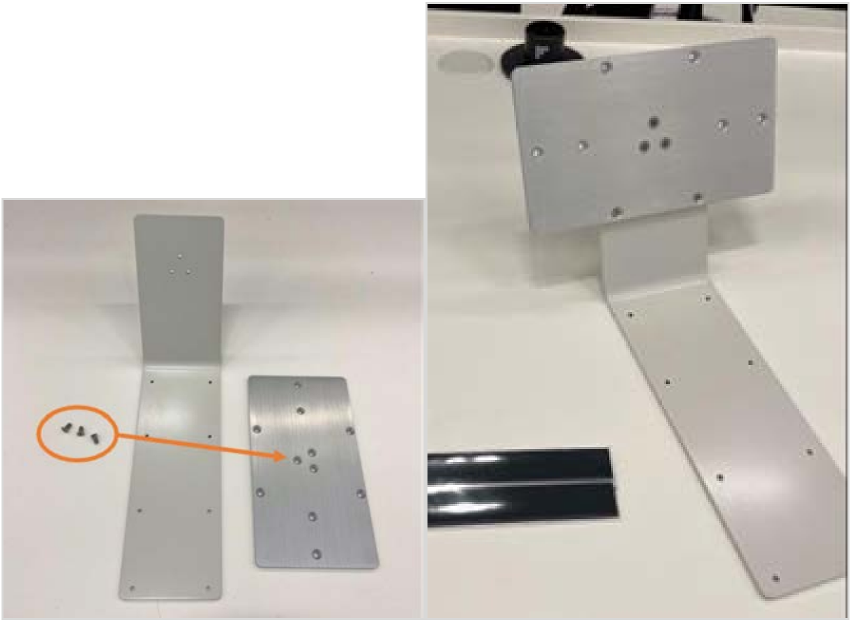


Figure 7: Keyboard mount assembly

b. Mount the Wireless Touch Pad Keyboard.

  i. The wireless touch pad keyboard is connected to the tray below the AIO via Velcro on the back of the keyboard (Fig. 8).

  ii. Velcro pieces may need to be cut to fit on the keyboard mount.

  iii. When applying the velcro, stick both pieces to the keyboard mount or keyboard and remove the plastic film. Then press the entire keyboard on the keyboard mount to secure the velcro to the other side.

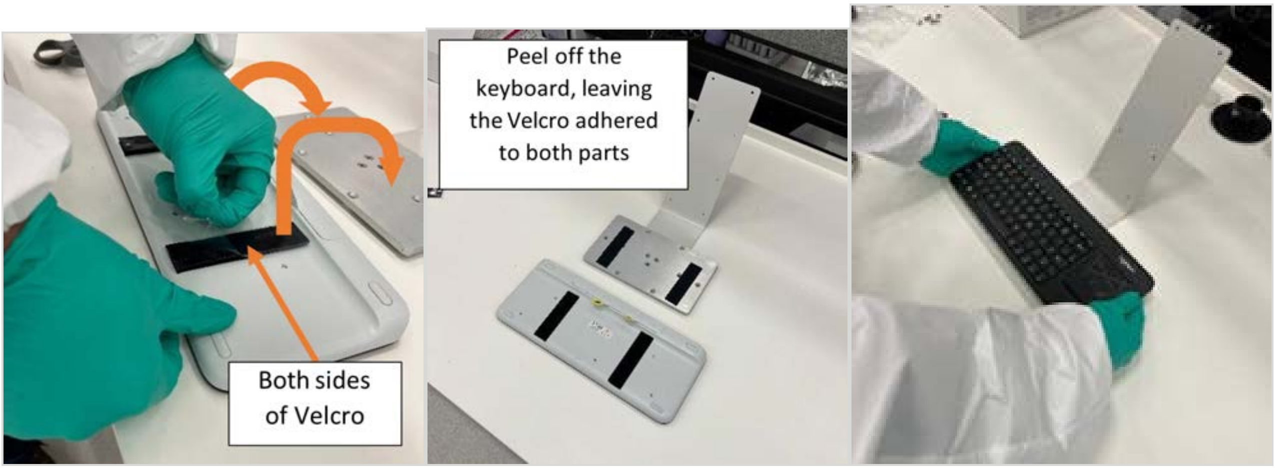


Figure 8: Mounting the Wireless Touch Pad Keyboard

c. Use two M4x12mm Phillips head mounting screws to loosely fasten the keyboard mount to the back of the VESA mount/AIO assembly. Use the top two holes on the keyboard mount.

  i. Leave partially unthreaded to hook onto the arm mount plate (Fig. 9).

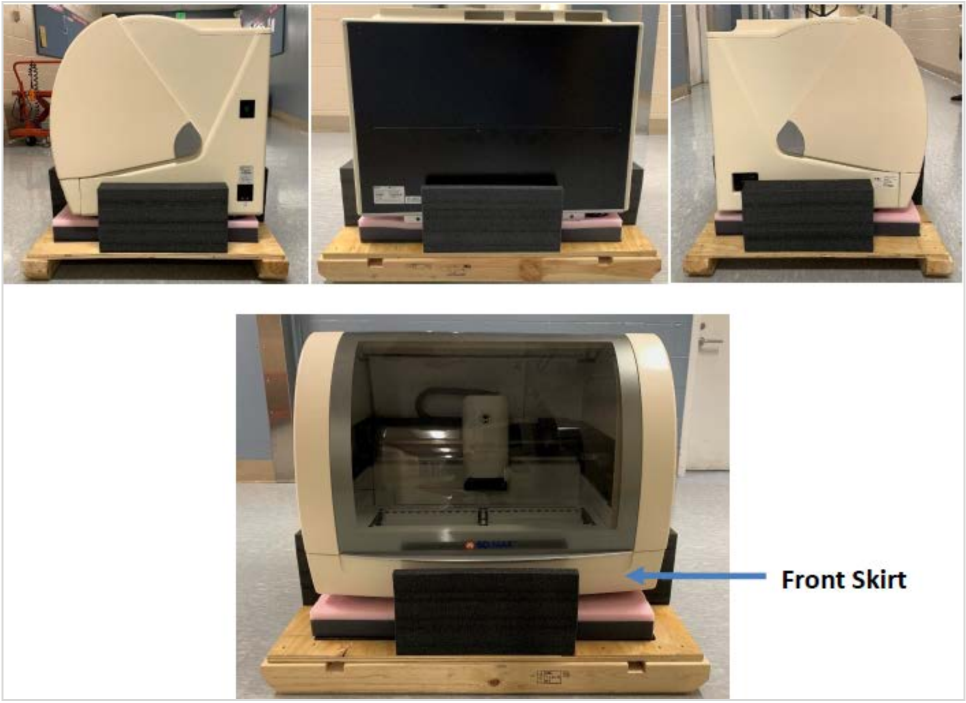
Figure 9: Keyboard mount assembly and mount to monitor arm bracket

10. Mount the AIO, VESA mount, keyboard mount assembly on to the arm mount.
    1. Position the arm in the upright position when mounting/removing the AIO.
    2. Fasten the remaining two Phillips screws (12mm) (Fig. 9).
11. Adjust the arm counterbalances.
    1. Adjust the tension of the arm joints using the set screws beneath the "elbow" (1/8") and "wrist" (5/32") of the arm. (Clockwise to tighten) (Fig. 10)
        1. The user should be able to move the AIO monitor arm without shaking the MAX.
        2. Ensure the monitor arm stays stationary when left alone. If the monitor arm falls down on its own, the tension needs to be tighter.

Figure 10: Cable duct (left) and two tension screws in the "elbow" (middle) and "wrist" (right).

12. Connect AIO cables and organize with cable ducts in the monitor arm (Fig. 10).

> **Note:** Follow standard install procedures to complete the installation of the instrument and AIO computer.



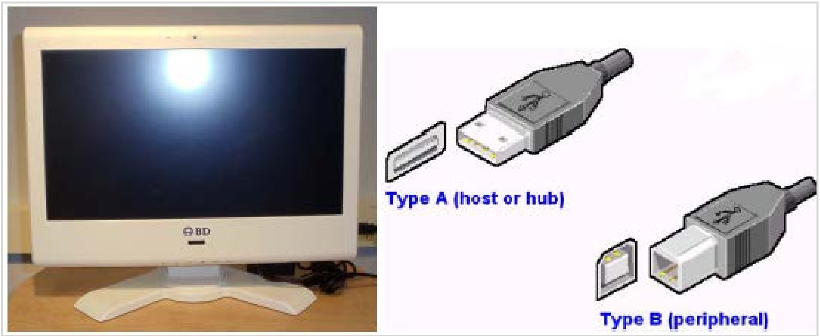
Transporting and Positioning the Instrument

1. The BD MAX weighs more than 200 lbs (91 Kg). Either use a mechanical lift or at least four people to move the instrument. Lift the instrument using the handles. **Do not lift the instrument by the front skirt.**
2. Move the instrument to its final position in the lab, and remember the All-In-One monitor requires a 150 cm by 85 cm space. Reinstall the front skirt. The instrument will be leveled in a later step.

Instrument Setup

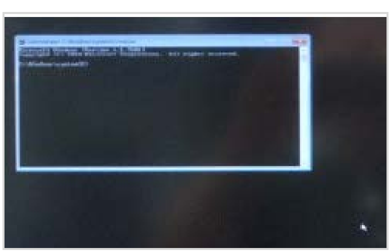
1. Set up the Uninterrupted Power Supply (UPS).
2. Connect the UPS to a wall outlet. Press the power button on the front of the UPS to turn it on.
3. Ensure the BD MAX instrument is turned off, and subsequently install the power cord between the instrument and the UPS.
4. Ensure the AIO is turned off, and then install the power cord between the UPS and the AIO. Connect the B side of the A/B USB cord to the instrument and the A side to one of the AIO bottom ports. See"AIO USB Cable" on page 353.

> **Note:** For H5 or H6 AIOs, do not use the blue USB ports (USB 3) for the AIO USB cable.



5. Check that the correct time and date are set on the All-In-One and adjust if needed.
6. If a Pre-warm station was shipped, connect its power cord and connect it to the instrument with the provided USB cord. Do not connect the Pre-Warm Station to the UPS. Plug it directly into an outlet.
7. Ensure the BD MAX instrument is turned off, and then install the power cord between the instrument and the UPS. Turn on the UPS.

8. Connect the peripherals to the instrument. If the All-In-One has blue 3.0 USB ports, make sure to plug the mouse and keyboard into them.
9. **Turn on the AIO only.**
   a. If the AIO boots up to a command shell, follow the latest service bulletin and image, if necessary, to install the software.

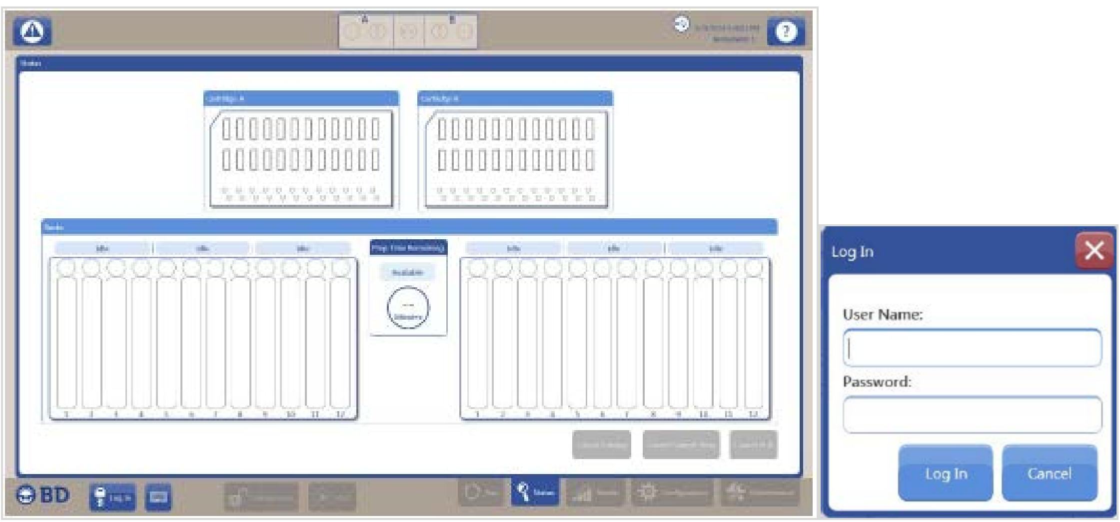


> **Note:** The latest BD MAX software may have a newly associated image. Always refer to the latest software release service bulletin to ensure proper installation.

b. After verifying the proper image, navigate to the USB drive and double click on the most recent BD MAX System software MSI file. This will install the BD MAX System Software. This will take approximately five minutes. Once the install is finished, the BD MAX GUI will start.

10. If a window opens saying a script version mismatch has been detected, select **Cancel**.

11. Once the the All-In-One boots to the BD MAX screen, log in with user name **FSVC** and password **halley**. The password is case sensitive.



12. The Robot IP Address is **169.254.1.10. Reader A and Reader B**IP addresses both start with **169.254.XX.XXX**. The last two digits (XX.XXX) can be retrieved by using WireShark. Look inside the instrument for an excerpt of the Design History File, which provides the three IP address settings. For instructions to use WireShark and to verify IP addresses, refer to "Obtain MUX IP (WireShark)" on page 413.
13. Go to **Maintenance > Tasks**. Enter the IP addresses and ensure the ports are set to 1929 and click **Save**.

14. Power on the BD Max instrument and wait to be connected.
15. On the menu bar, select **Unlock Door** and open the door.
16. Remove all packing and shipping material:
    a. Remove six gantry lock clamps and the rubber pieces under them. Two each on the left and right Y-Rails, holding the X-Gantry in place, and two on the X-Rail holding the Z-head Assembly in place (Refer the below image for instrument serial numbers less than CT3000).

    Fig: Serial numbers less than CT3000

    b. Remove six gantry locks, two each on the left and right Y-Rails, holding the X-Gantry in place, and two on the X-Rail holding the Z-head Assembly in place (Refer the below image for instrument serial numbers equal to or greater than CT3000).

Fig: Serial numbers equal to or greater than CT3000

17. Cut the cable tie securing the pump assembly to the stripper assembly. Remove the nozzle block from the Z-Head.
18. Remove the foam padding sitting in front of the reader drawers.

> **Note:** The instruments are shipped with the drawer covers loose for easy removal. After the instrument initializes without issue, tighten the drawer covers.

19. Cut the blue tape and remove the pink foam around the cable underneath the X-motor controller.

> **Caution:** Make sure you do not cut the cable!

20. Remove the protective tape from the mirror.
21. Place two racks into the instrument. Place a level on the racks. If the instrument is not leveled, adjust from the feet of the instrument.
22. Check that the Z-Gantry is perpendicular to the racks and the readers:
    a. Place the rack calibration plate into position.
    b. Lower the Z-Gantry until the nozzles touch the plate.

c. No nozzle should be more than **0.0015 inch (0.038 mm)** higher than the other nozzles.

23. Click **Home All Motor** from **Maintenance > Tasks.**
24. Verify that all new sample racks fit in the BD MAX and are correctly registered by the rack sensors and the BD MAX software.
25. Perform "Gantry Alignment " on page 508.
26. Report any discrepancies to your supervisor and note it in your service report.

Verification:

1. Perform the Qualification Run 5.3.3
2. Verify that the Results match the qualification verification table.

> **Note:** The checklist is an optional tool available for use to ensure adherence to the procedure and should not be used exclusively to drive full compliance with procedural directives.

If applicable:

1. Complete a copy of the Installation Checklist for the customer Installation Checklist A.2
2. Submit copies of the Installation Checklist and run reports with the service report.

> **Verification:** After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

2.4 Install at the New Location

A full PM will be required after the facility's relocation/move.

Follow the "Installation Procedure" on page 68

2.4.1 Relocation Move Procedure

Procedure:

This procedure applies to all personnel performing service on BD MAX systems worldwide. This document provides additional information and assumes knowledge of basic system operation, maintenance, and troubleshooting techniques.

1."Pre-installation Procedure" on page 64 is required before the relocation.

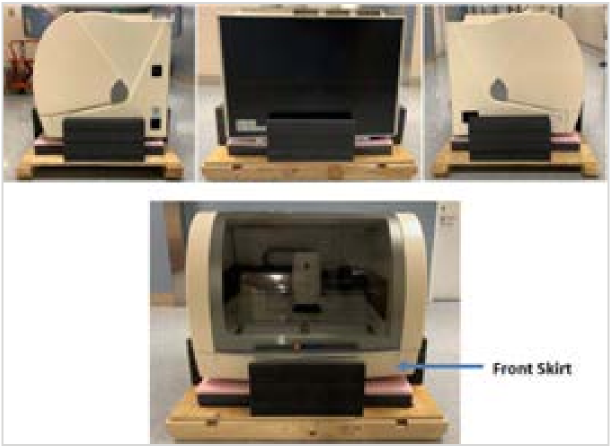
The section provides information and documentation to ensure installation requirements for the BD MAX System are met before moving. A site inspection to verify that the customer can meet these requirements will primarily be the responsibility of the instrument Sales Representative or the Sales Account Manager, with occasional follow-up by a Field Service Engineer.

2. Pre-installation Checklist is available in the service manual, "Pre-installation Checklist" on page 585.

2.4.2 Prepare the BD Max Instrument

1. Perform Home all Motors.
2. Open the door.
3. Power OFF the BD Max instrument.
4. Perform Instrument Decontamination 3.1
5. Install six gantry lock clamps and the rubber pieces under them. Two each on the left and right Y-Rails, holding the X-Gantry in place, and two on the X-Rail holding the Z-Gantry Assembly in place (Refer to the below image for instrument serial numbers less than CT3000).

6. Install six gantry locks, two each on the left and right Y-Rails, holding the X-Gantry in place, and two on the X-Rail holding the Z-Gantry Assembly in place.
7. Carefully Secure the Z-Gantry.
8. Place the cable tie securing the pump assembly to the stripper assembly. Remove the nozzle block from the Z-Gantry.
9. Secure the blue tape and remove the pink foam around the cable underneath the X-motor controller.
10. Close the drawer assembly.
11. Place the foam padding sitting in front of the reader drawers.
12. Remove the front filter.
13. Install the four transport Max handles.
14. The BD MAX weighs more than 200 lbs (91 Kg). Use a mechanical lift or at least four people to move the instrument. Lift the instrument using the handles. Do not lift the instrument by the front skins.
15. Place the Instrument on the transport pallet, use the original transport Material, and install the front filter.
16. Secure the instrument to the Pallet.



17. Remove the four transport Max handles.
18. Install the front filter.
19. Close the BD Max door.
20. Move the instrument to its final position in the lab.

2.4.3 Prepare the AIO

1. Perform Database Backup 1 and Logs Backup 2.

2. Power OFF the AIO
3. Disconnect the AIO from The UPS.
4. Disconnect all external connections to the AIO
    1. Printer, hand Barcode Scanner, Pre-warm (If used), Keyboard, and Mouse.
5. Pack and protect all the external components from being transported carefully.
6. Pack and protect the AIO carefully.

Document: BDDSSGFS7422 Doc Type: ZIP Status: Released EFFECTIVE
Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

3 General Procedures

3.1 Instrument Decontamination

Decontamination Procedure

It is recommended to perform a number of rounds of cleaning. It is recommended that external BD MAX™ System surfaces are cleaned before internal surfaces.

Please pay attention; some parts must never be cleaned with hydrogen peroxide or sodium hypochlorite, and only 70% isopropanol should be used in the table below.

Never spray cleaning agents near or inside the BD MAX™ System.

> **Note:** The decontamination is a process the customer will perform on the BD Max before the de-installation, relocation, or move.

Preparations for Decontamination

Clean personal protective equipment (PPE), i.e., lab coat, gloves, etc., should be worn to clean the lab. Any used PPE should be cleaned or discarded accordingly.

BD MAX™ sample racks should be taken out of the BD MAX™ System, and all used reagents and consumables, such as PCR cartridges, should be discarded according to the Instructions for Use.

The BD MAX™ System, BD MAX™ sample racks surfaces should only be cleaned with a validated cleaning solution for the specific area as listed in table 2. Follow cleaning solutions by wiping with a lint-free cloth dampened with deionized (DI) water and then with 70% alcohol.

> **Note:** Do not use 3% hydrogen peroxide from a bottle that has been open for longer than 8 days.

> **Note:** It is recommended while cleaning the inside of the system to place unused PCR cartridges in the cartridge drawers to protect the glass surfaces from any accidental splattering of abrasive or corrosive cleaning agents.

Document: BDDSSGFS7422 Doc Type: ZIP Status: Released EFFECTIVE
Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

Recommended areas to be cleaned and appropriate solution.

External Areas	Cleaning Solution	Follow with DI Water
Wipe BD MAX™ sample racks	• 1% sodium hypochlorite • 3% hydrogen peroxide • DNA AWAY, or disinfecting wipes containing 1% sodium hypochlorite	✓
Wipe BD MAX™ System sides and door handle	• 1% sodium hypochlorite • 3% hydrogen peroxide • DNA AWAY, or disinfecting wipes containing 1% sodium hypochlorite	✓
Wipe Transparent door	• alcohol (70% isopropanol) • or glass cleaner	×
Wipe Pre-warm racks and heater (if used)	• 1% sodium hypochlorite • 3% hydrogen peroxide • DNA AWAY • or disinfecting wipes containing 1% sodium hypochlorite	✓
Wipe touchscreen monitor (if used)	• alcohol (70% isopropanol)	×
Wipe keyboard (if used)	• 1% sodium hypochlorite • 3% hydrogen peroxide • DNA AWAY • or disinfecting wipes containing 1% sodium hypochlorite	✓

Internal Areas and Action	Cleaning Solution	Follow with Water
Wipe white/skins parts inside BD MAX™	• 1% sodium hypochlorite • 3% hydrogen peroxide	✓

Internal Areas and Action	Cleaning Solution	Follow with Water
	• DNA AWAY • or disinfecting wipes containing 1% sodium hypochlorite	
Wipe Mirror	• alcohol (70% isopropanol) • or glass cleaner	×
Wipe PCR Drawer	• ONLY alcohol (70% isopropanol)	×

3.2 Environmental Monitoring

All **routine work should stop** if there are indications that contamination is present in the lab. To determine if (and where) contamination is present, samples may be taken from the lab environment and/or BD MAX™ System and tested with the relevant test on the BD MAX™. BD recommends performing environmental monitoring procedures regularly.

The environmental monitoring should be carried out after all the daily cleaning has been completed; please refer to the BD MAX™ System User's Manual for more information on daily, weekly, and as-needed cleaning. The sampling of the areas listed in the table can be done using any cotton or synthetic-tipped sterile swabs.

1. A swab is dipped into molecular-grade water.
2. The area is swabbed using a broad sweeping motion see Table.
3. The swab is expressed into a Sample Buffer Tube corresponding to the assay of interest and then processed according to the Instructions for Use.
4. A Sample Buffer Tube can also be left open during the day and tested to check for the presence of airborne contaminants.

Note: Sterile swabs must be expressed and must not be snapped and left in sample buffer tubes.

Note: It is also good practice to include a test of the water used for wetting the swabs.

Areas of the BD MAX™ System and in the lab may be swabbed.

Area	
1	White part inside BD MAX™
2	BD MAX™ door handle
3	BD MAX™ monitor touchscreen (if used)
4	BD MAX™ keyboard and mouse
5	BD MAX™ sample racks
6	BD MAX™ pre-warm racks and heater (if used)
7	Bench surrounding platform
8	Working area/bench/biosafety cabinet
9	Molecular-grade water

Note: Locations may be added or modified according to your laboratory setup and needs.

Additional areas of the laboratory environment can be included in the environmental monitoring to assess the extent of the contamination and highlight what other areas in and around the lab may need to be decontaminated. The list below consists of the most, but not all, common areas:

1. Ancillary items include pipettors, vortex, tube racks, timers, pens, etc.
2. Laboratory door handles
3. Bench surfaces other than working and platform benches
4. Outside surfaces and handles of refrigerator/freezer/cupboards
5. Light switches
6. Taps and/or sink areas
7. Laboratory chairs
8. Laboratory flooring, walls

Decontamination will require thorough cleaning of the lab environment and the BD MAX™ System. While cleaning, avoid spreading contamination by using clean clothes or towels and changing between distinct areas such as parts of instruments, bench/worktops, door handles, etc.

If environmental monitoring was performed first, these results could indicate where contamination may be concentrated and where cleaning should be more intense.

Use a dampened lint-free cloth or towel to wipe down recommended areas with the appropriate cleaning agent see table 3.1 so the area is visibly wet (glistening) and leave to dry, then wipe down with water – except for areas that are cleaned with alcohol.

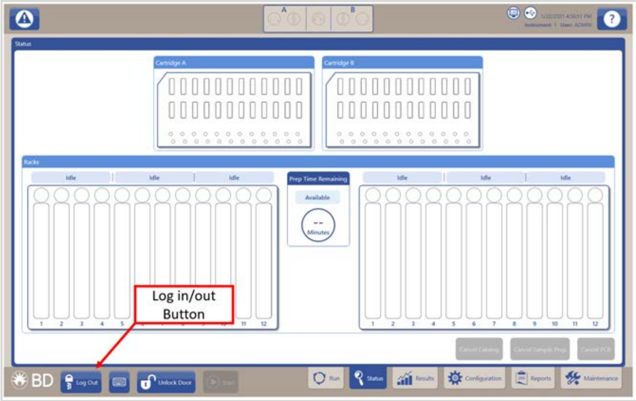
4 IT Connectivity

4.1 Operating System

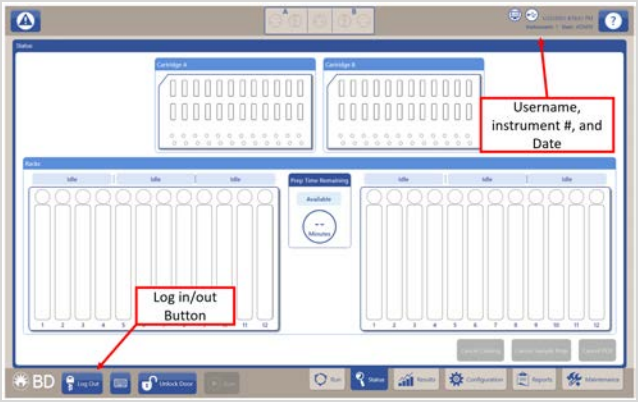
When the AIO computer is turned ON, it automatically starts the system application. During normal operations, the user is never exposed to nor has access to the underlying embedded Operating System (OS).

4.1.1 User Login Screen

The User workflow is initiated by selecting **Log In** on the menu bar, which opens the **Log in** window.



All instruments initially have an administrative account called **ADMIN** with the password **ADMIN** (all uppercase).



Note: In some cases, customers might have changed the admin account or password. In that case, log in using the built-in maintenance account. The customer cannot change this account.

During field service visits to customer sites, log into the **Maintenance** account as user **FSVC** (upper- or lower case), and the password **halley** (lowercase) to gain extra privileges and access to the embedded OS commands necessary for servicing the instrument.

When logged in as the **FSVC** user, the **Field Service** sub-tab under the **Maintenance** becomes available. This contains various maintenance programs and commands.

A successful log in changes the **Log In** button to **Log Out**, and the name of the curent user appears in the status bar at the upper right of the screen.

If logged in using **FSVC**, the **Service Mode** watermark appears. This watermark also appears if any of the environmental variables are modified.

Note: Never leave an instrument in **Service Mode** at a customer site. Always return the instrument to normal operations.

4.1.2 Common User Interface Elements

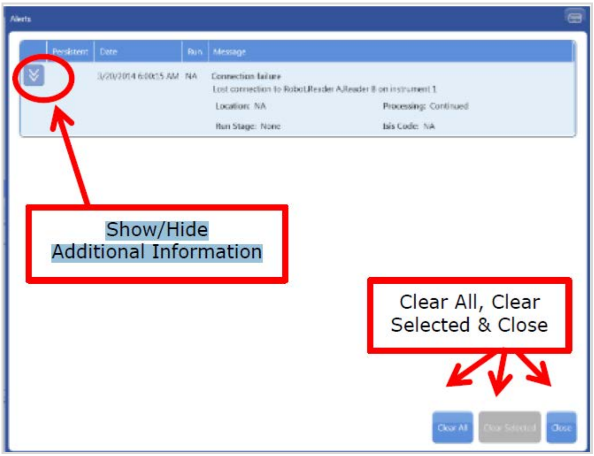
Several elements appear on every screen of the user interface:

- A **System Alert** icon appears in the upper left corner of every screen. When the triangle flashes red, there are new system alerts. Clicking on this icon opens the **Alerts** window.

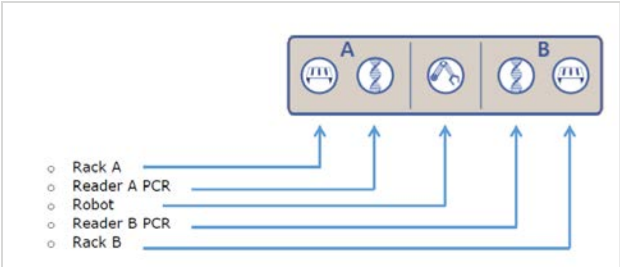
The **Alerts** window displays current alert messages. These messages stay in the **Alert** window until cleared. Persistent alerts remain until they are resolved.

To clear an Alert:

1. Click the **drop down** arrow (to the left of each alert) to see more details.
2. Select any of the three buttons at the bottom right to **Clear All** alerts, **Clear Selected** alerts, or to **Close** the **Alert** window.

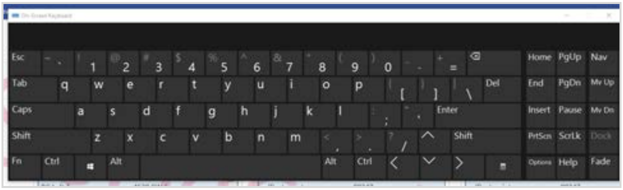


- The top center section of the screen contains multifunction indicators that show when a particular sub system is running and when that sub system has an issue.

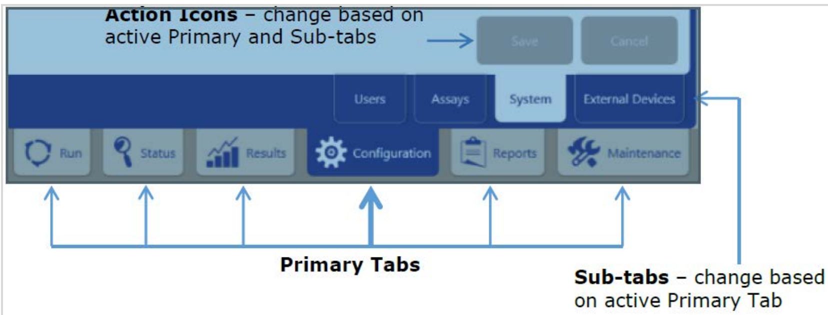


- The BD Logo at the lower left of the screen is selectable and initiates software shutdown options for the AIO computer. This option is only available when logged in.
- A virtual keyboard is also available to the right of the **Log In/Log Out** button.

- The touch screen and virtual keyboard allow operation of the All-In-One without an external keyboard, mouse, or other pointing devices.



- The tabs at the bottom right provide access to various categories of user software. When a tab is active, sub-tabs and action icons appear just above.



- Center bottom of the screen is the **Unlock Door** and **Start Run** Icons.

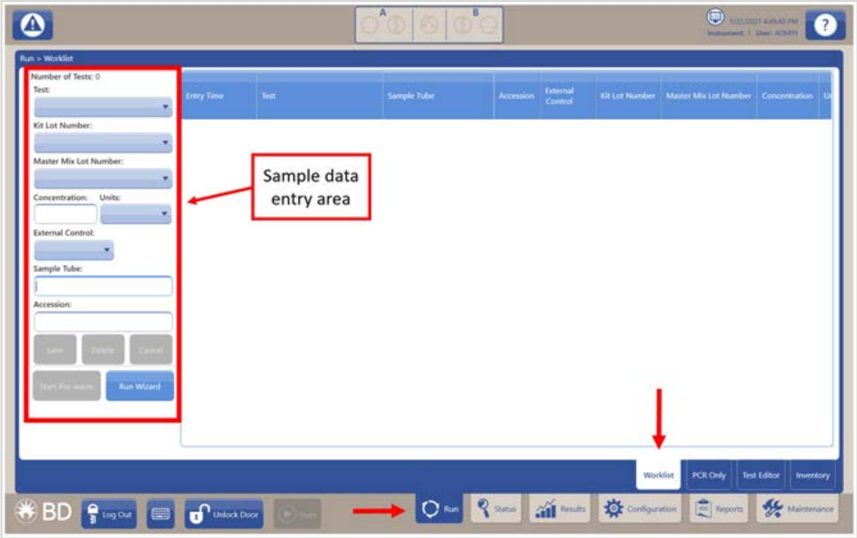
- The availability of start icon (active or active) depends on the state of the instrument.

4.2 Maintenance Interface

The maintenance interface offers:

4.2.1 Run Tab

Select the **Run** tab to set up and run samples. The **Run** tab has four sub tabs.



4.2.1.1 Work List Sub-tab

Work List enters sample, patients, and reagent information. This process is referred to as creating a work list, which is a high-level list of instructions telling the system the sample types being run and the lanes being used. It also tracks bar codes from the sample buffer tubes, external controls, and lot numbers of consumable reagents being used.

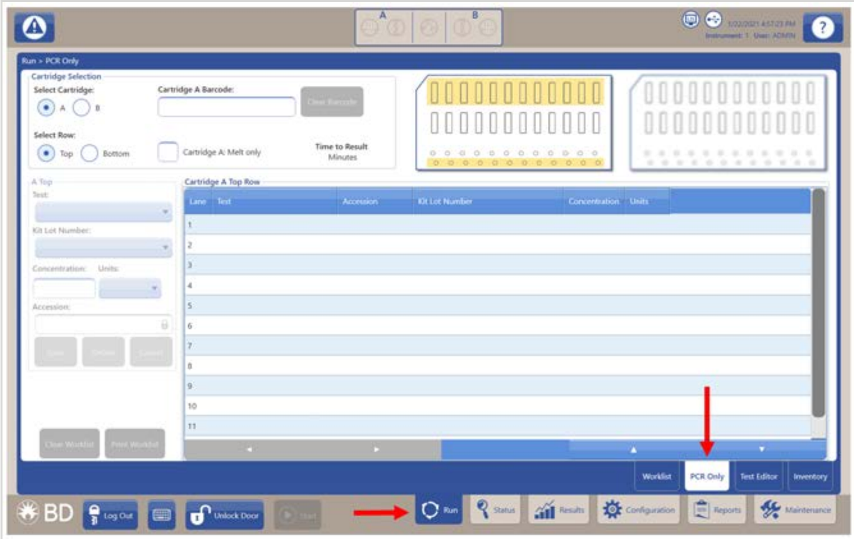
There are two different Work List modes:

- **24 Sample Work List**: Allows 1 to 24 samples to be set up. The operator must assign samples to specific locations programed for each sample rack.
  - The 24 Sample Work List is a carryover from the former Operating System (Linux).
  - Not commonly used since the transition to the Windows OS.
- **2000 Sample Work List**: Automates and reduces some of the prep work done prior to a run. The operator loads reagents into the racks. The 2000 Sample Work List is now the preferred work list taught in Applications training.

The BD MAX scans the sample buffer tubes and automatically assigns samples from the active sample list.

4.2.1.2 PCR Only Sub-tab

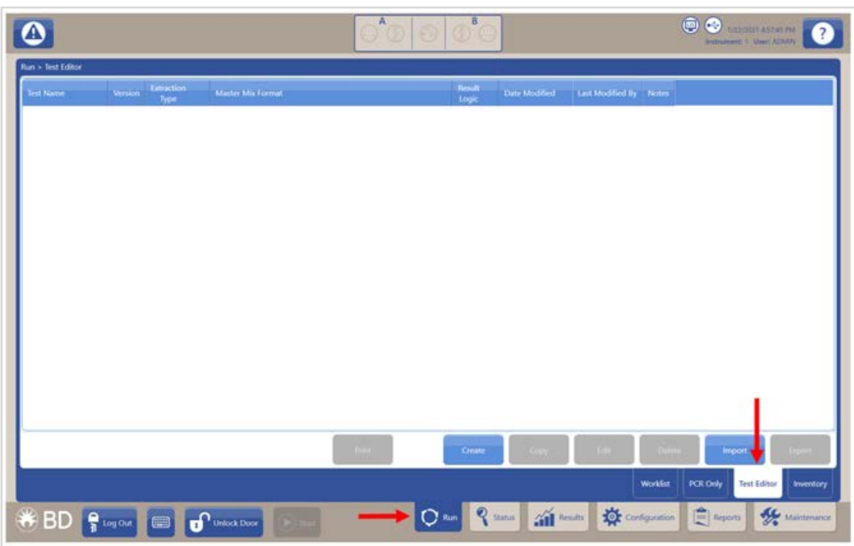
This is similar to the work list. The difference is that no extraction is performed on a PCR only run. It is assumed that the user has manually performed the extraction process and loaded the samples into the test cartridge.



Note: PCR Only is an open system mode of operation. It cannot be used for IVD assay testing.

4.2.1.3 Test Editor Sub-tab

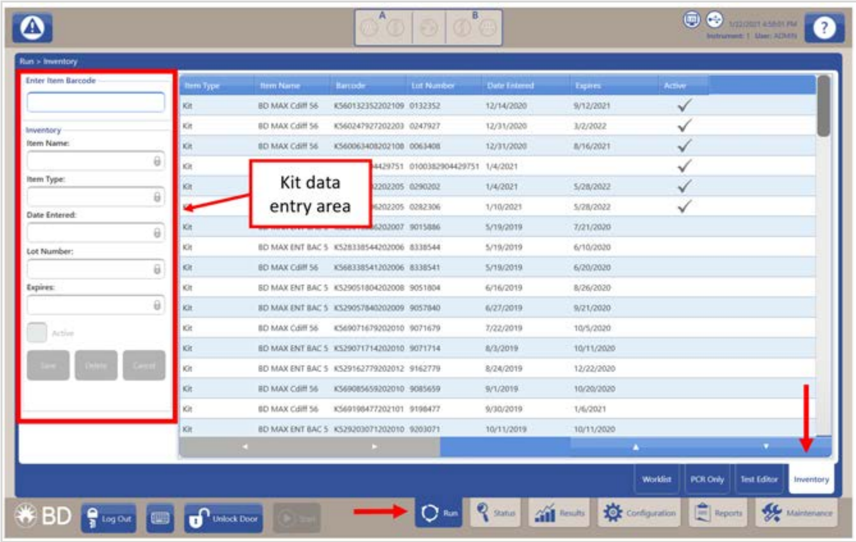
The **Test Editor** sub-tab is for research and open systems. When used for research, the customer can program specific extraction and PCR parameters not covered by any existing FDA approve assay.



Non-FDA tests are created using the sub tab. These tests can be saved as User Defined Protocols (UDP) files.

4.2.1.4 Kit Inventory Sub-tab

The **Kit Inventory**sub-tab is used to scan and record the information from the label and barcode on the reagent kit box which contains lot number information.

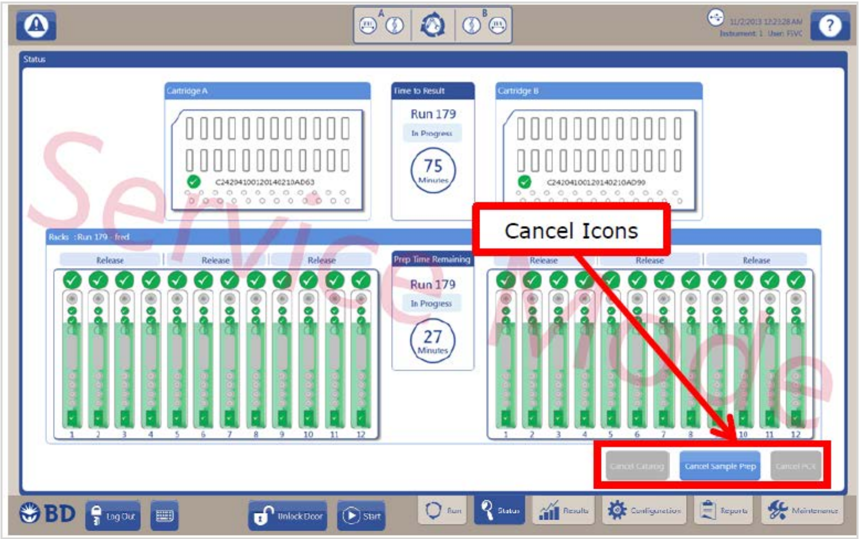


Kit lot numbers can be scanned into the system and can be set to **Active**or **Inactive**.

Only active kits appear in the **Work List** sub-tab.

4.2.2 Status Tab

Selecting the **Status** tab opens the section of user software that monitors the progress of an ongoing run and does not have any sub-tabs.



Consumable Tracking

During consumable checks, the bar codes of reagents and disposables are scanned by the internal barcode scanner. The status of reagents and consumables is displayed as green (pass), yellow (second usage of multi-use cartridge), or red (failed).

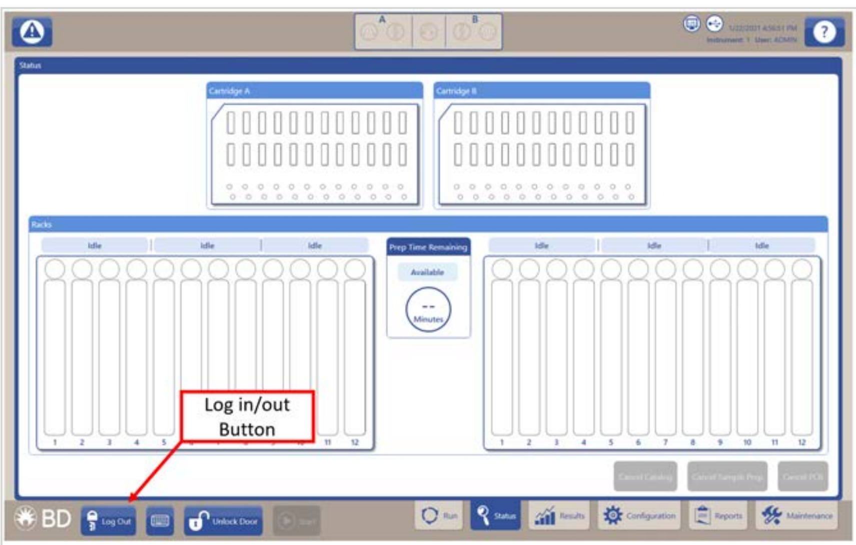
Reagent and consumable failures can be caused by previously used consumables, expired reagents, and mismatched reagents and consumables. Run progress is also monitored from this screen by green bars that fill each sample lane and Cartridge track as the run progresses.

Action icons that can cancel stages of a run: **Cancel Catalog**, **Cancel Sample Prep**, or **Cancel PCR**.

4.2.3 Results Tab

The **Results**tab is used to display **Run**Data. There is one sub-tab.

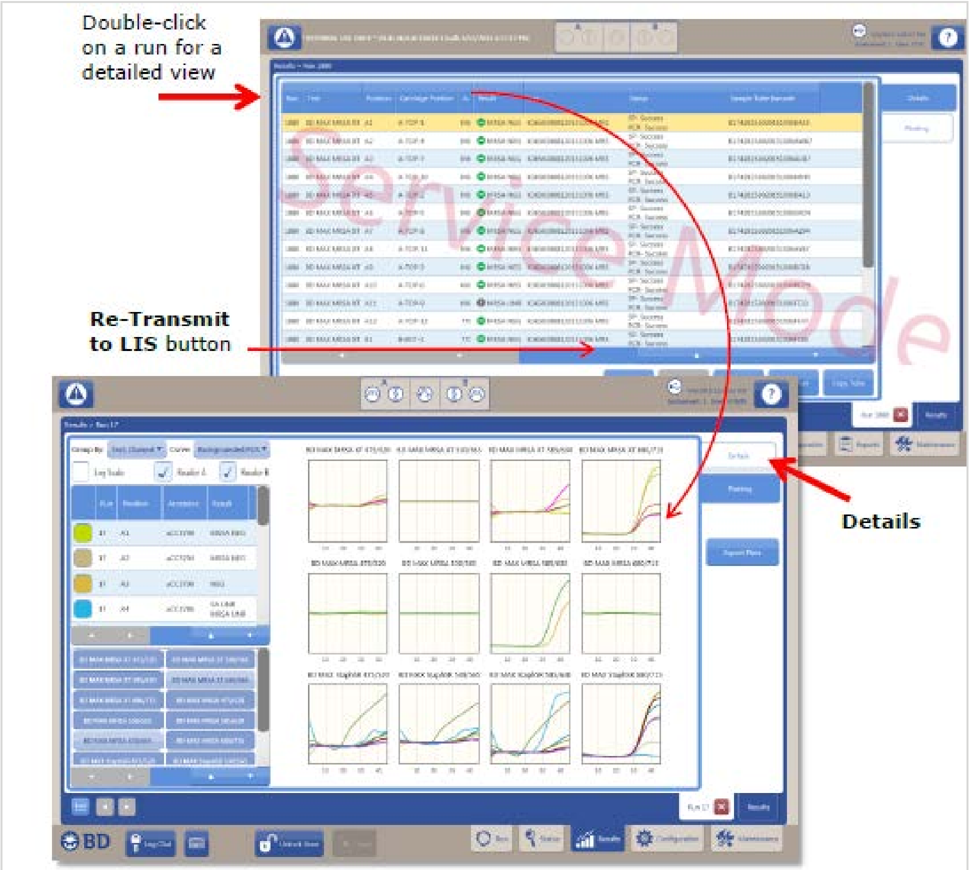
Runs are listed by run number.**Search Criteria** fields are found along the left side of the screen. A row of buttons just above the sub-tab contains buttons including **Export**, **View**, and **Print** of results for the selected run.



The **Results** tab can be used to review current run results as well as past run results. Reviewing past instrument performance can be helpful in diagnosing current problems.

When a run is selected, **Print**, **Copy Run** and **Copy Tube**icons become active.

Document: BDDSSGFS7422 Doc Type: ZIP Status: Released EFFECTIVE
Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential



Double-clicking a run opens the selected run and reveals:

- **Details** displays run results
- **Plotting** displays run plots.

For software versions 4.50 and above:

To re-transmit results, highlight the desired test and click **Re-transmit to LIS**.

Note: IND, INC, UNR and invalid accession numbers are not re-sent to the Laboratory Information System (LIS).

4.2.4 Configuration Tab

Use the Configuration Tab to configure the following:

"Users Sub-tab" on page 98

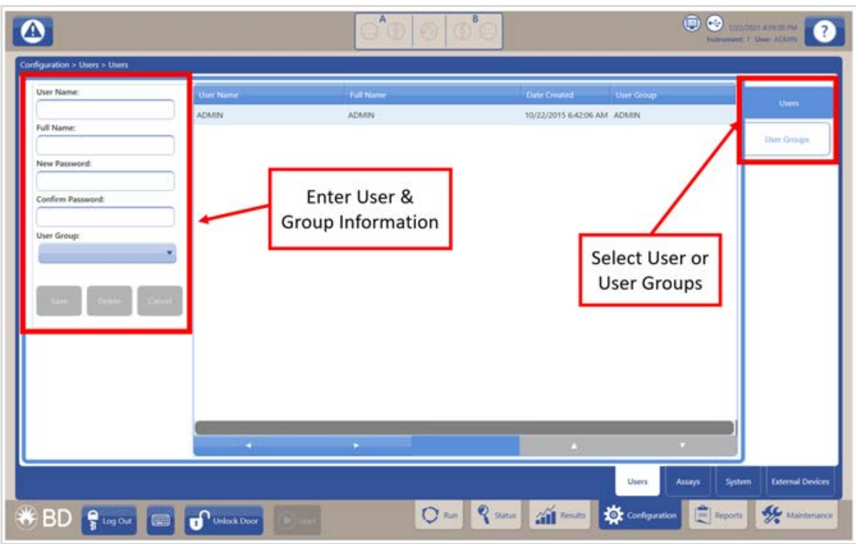
"Assays Sub-tab" on page 98

"System Sub-tab" on page 99
"Environmental Variables Pane" on page 100
"Display Options Pane" on page 106.

4.2.4.1 Users Sub-tab

The users sub-tab is used for creating both **Users**and **User Groups**:

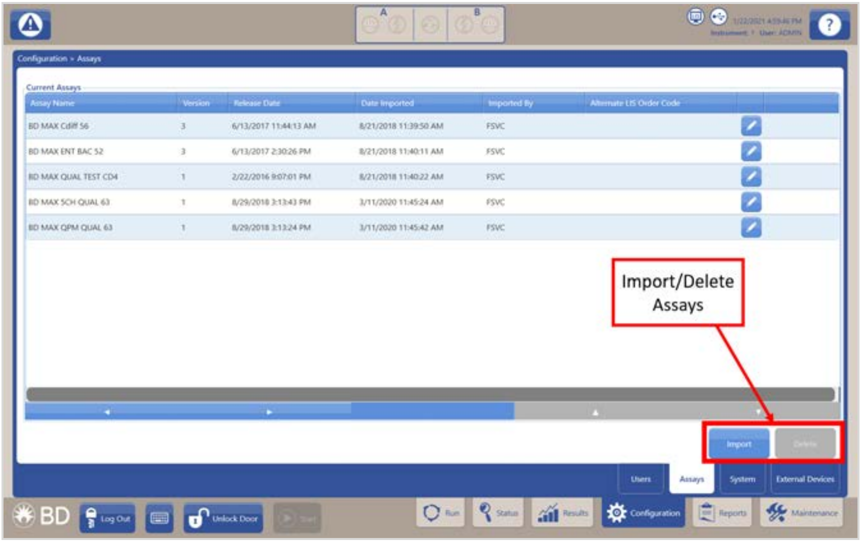
- Users can be assigned permissions on the instrument directly.
- The Groups concept allows separate groups to be created for specific tasks with specific permissions.



> **Note:** Generally, it is easier to create groups with specific permissions and then assign the user to the group related to that access level and function.

4.2.4.2 Assays Sub-tab

Selecting the **Assays** sub-tab allows you to import or delete official BD approved FDA/CE cleared assays.



The assay files must be at the top level of a USB flash Drive. The instrument automatically reads the drive when it is plugged in.

Selecting the **Import** icon displays a list of assay files on the flash drive.

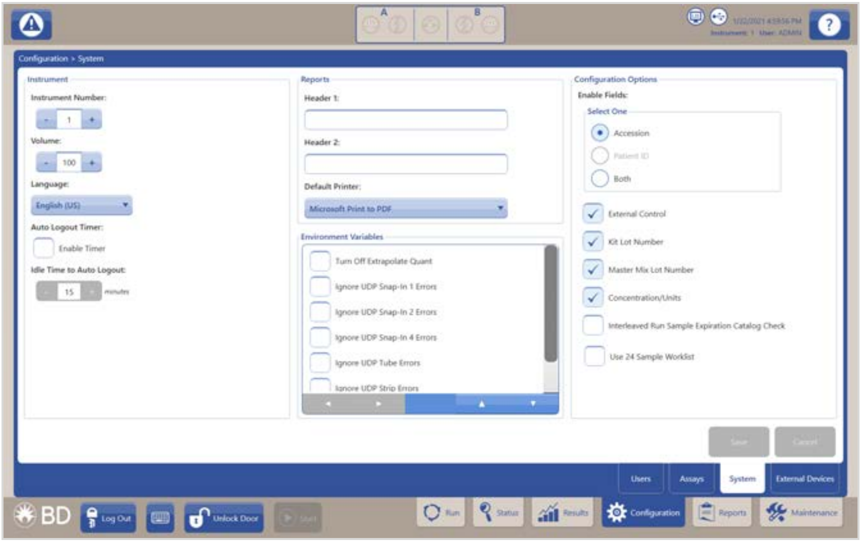
Selecting an assay already on the instrument enables the **Delete** icon, which enables deletion of an installed assay.

> **Note:** An Assay Definition File (ADF) that is imported onto a BD MAX instrument using the Windows Operating System (OS) automatically replaces previous versions of the ADF, leaving only the most up-to-date assay choice. The Windows OS does not allow for duplicate ADFs to be loaded onto a BD MAX AIO.

4.2.4.3 System Sub-tab

The System Sub-tab offers:

- An instrument pane
- A reports pane.



Instrument Pane

Located on the left side of the screen, the Instrument Pane includes the following parameters:

- Instrument Number
- Volume
- Language
- Auto Log Out Time
- Idle Time to Auto Log out: This feature logs off a user once the elapsed idle time has expired.

Reports Pane

The Reports Pane, found at the top center, includes:

- Header 1 and header 2 fields control the headers on printed reports. Typically, these include lab name, doctor name.
- Default printer requires printer drivers be installed first for those printers to be listed as options in the drop-down.

4.2.4.4 Environmental Variables Pane

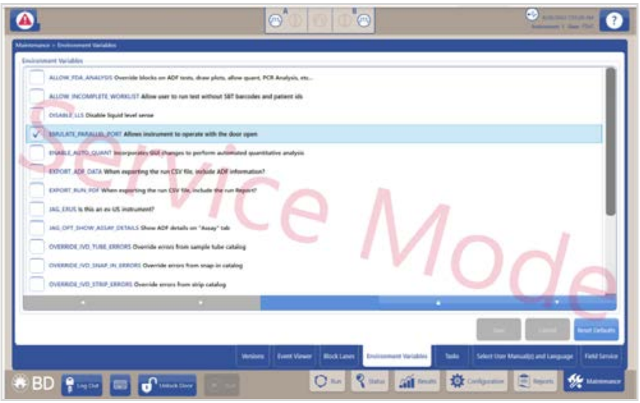
The FSVC user has access to a number of environment variables that are not visible to the customer.

Emulate Parallel Port

The EMULATE_PARALLEL_PORT environmental variable enables the FSVC user to operate the BD MAX instrument and start runs with the door open. Usually the instrument will not allow internal components to move when the door is open for safety reasons, but this environmental variable bypasses that.

This can make internal components (nozzles, liquid level sensing, gantry rails, trays, etc) more visible and accessible for troubleshooting/observing while the instrument is running.

When logging out of Service Mode, be sure to disable EMULATE_PARALLEL_PORT. This is not allowed for customer use.



Display Run Metrics and Y-Axis

> **Note:** The customer can request to enable **DISPLAY_RUN_METRICS and/or DISPLAY_ YAXIS_VALUES**, but must sign a letter agreement. The Letter Agreement is attached, but can also be found in the appendix of the service bulletin for the associated software version. This only applies to instruments that are running SW V5.00A or greater.

Field Service Engineer Enabling Environmental Variables

1. Obtain and print the **"BD MAX Customer Activation of Software Features Letter Agreement" on page 105** .
2. Review the letter with the user.
3. Obtain the user signature on the letter before moving forward.
4. Generate a scanned copy of the signed letter.
5. Attach the scanned copy of the letter at the **Installed Product** level under **Notes and Attachments**.

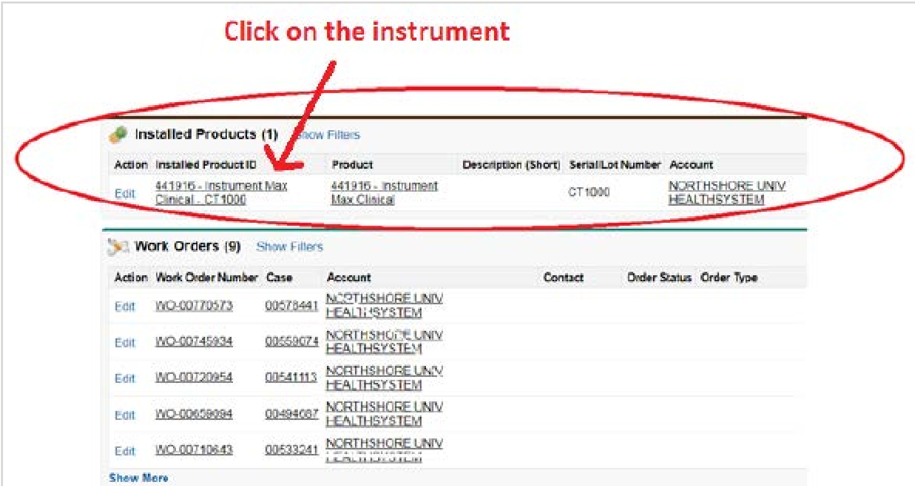


Fig: ServiceMax Screenshot of Installed Products Section. Select the instrument

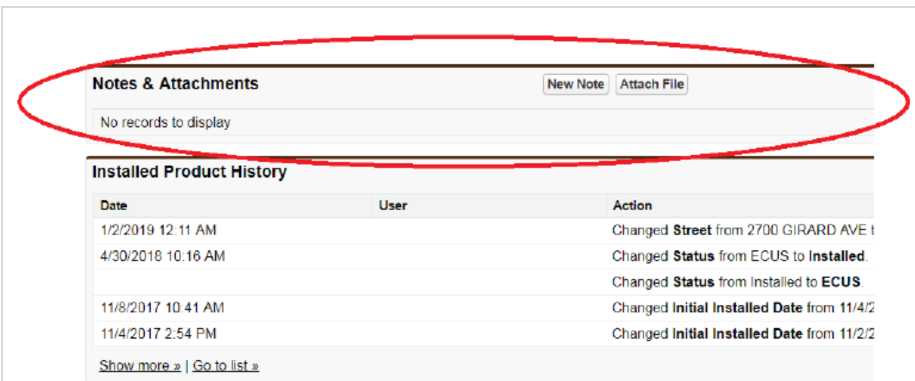
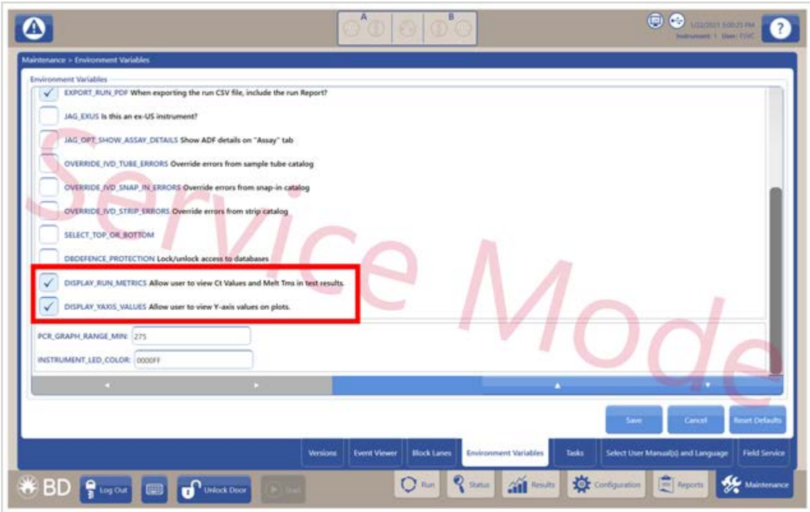


Fig: Scroll down on the Installed Product page to find the Notes and Attachments section

6. Go to **Maintenance**, then **Environment Variables** and locate the **DISPLAY_RUN_ METRICS and DISPLAY_YAXIS_VALUES** at the bottom of the Environment Variable list.



DISPLAY_RUN_METRICS and DISPLAY_YAXIS_VALUES

7. Enable **DISPLAY_RUN_METRICS and/or DISPLAY_YAXIS_VALUES**
   a. Enabling **DISPLAY_RUN_METRICS** will display the Ct value and/or the Melt temperature depending on the assay type.
   b. Enabling **DISPLAY_YAXIS_VALUES** will display the Y axis scale.

> **Note:** The next step (8) is VERY IMPORTANT.

8. Ensure that **ALLOW_FDA_ANALYSIS** is disabled.

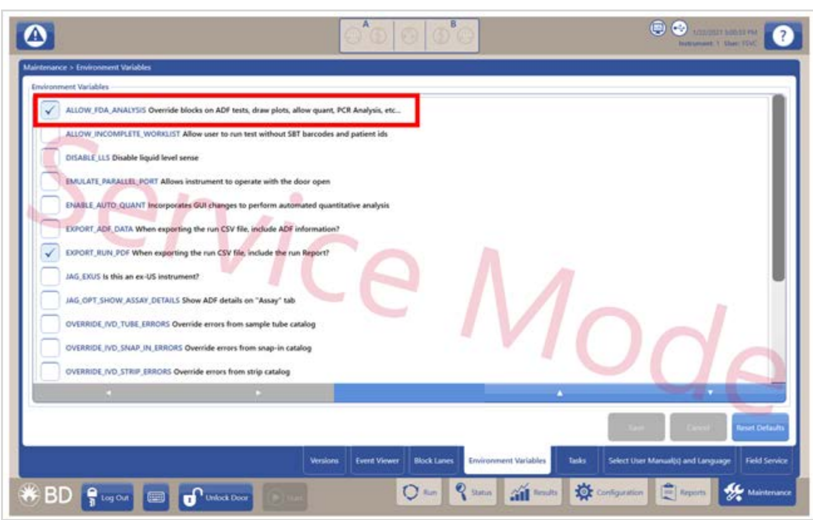


Fig: ALLOW_FDA_ANALYSIS must be disabled

9. Log in as non-FSVC user and verify that the user can view the Ct value, Melt temperature, and/or Y axis scale without the Service Mode watermark.

10. Select **SW V5.04A with RunMetricsYAxis enabled** (or for other appropriate SW version) attribute in ServiceMax. For instructions on how to select attributes, refer to **BDLS7318 ServiceMax Attribute Update** Procedure.

Molecular Application Specialist Enabling Environmental Variables

11. Perform all steps described in section above, except for step 5 and step 10.
12. Provide a copy of the attached letter signed by the customer (BD MAX Customer Activation of Software Features Letter Agreement) and instrument serial number to your local Customer Support Center or FSE counterpart and instruct them to complete the following steps in ServiceMax:
    a. Attach the scanned copy of the signed letter in ServiceMax (Reference: step 5).
    b. Select **SW V5.04A with RunMetricsYAxis enabled** (or for other appropriate SW version) attribute in ServiceMax. For instructions on how to select attributes, refer to BDLS7318 ServiceMax Attribute Update Procedure.

BD MAX Customer Activation of Software Features Letter Agreement

This Letter Agreement between Becton, Dickinson and Company, through its BD life Sciences - Diagnostic Systems business unit ("BD") and the customer identified in the signature block below ("Customer") is entered into as of the date this letter Agreement is signed by both parties.

BD acknowledges and Customer represents and warrants that end user access to raw data or any other data that a component of results generated from in vitro diagnostic systems typically utilized by manufacturers in support of designing, developing and validating in vitro diagnostic (IVD) tests, may be useful for a range of non-diagnostic activities including, but not limited to, ensuring adequate user-based laboratory quality control, public health reporting requirements, and conducting user-defined research studies ("Underlying Data"). Underlying Data includes, but not limited to, metrics such as Ct values generated from IVD tests conducted on the BD MAX™ System.

Upon the explicit request of the Customer set forth below, BD consents to provide Customer with access to Underlying Data generated on the instruments with the respective serial numbers listed below previously acquired from BD. Customer represents and warrants that Underlying Data will not be used to over-rule or change the manufacturer reported diagnostic IVD result provided by the IVD test and will be used **only** for purposes of user-defined research or laboratory quality control. **CUSTOMER REPRESENTS AND WARRANTS THAT IT SHALL USE THE INSTRUMENTS IN A MANNER CONSISTENT WITH THE APPLICABLE LABELING. ANY USE OF THE INSTRUMENTS IN VIOLATION THEREOF, OR USE OUTSIDE THE SCOPE OF THE CLEARANCE AND/OR APPROVAL BD RECEIVED FROM THE US FOOD AND DRUG ADMINISTRATION, OR OTHER APPLICABLE LOCAL REGULATORY AUTHORITY, IS AT THE CUSTOMER'S SOLE AND EXCLUSIVE RISK.** FURTHER, CUSTOMER SHALL DEFEND AGAINST AND INDEMNIFY BD FOR ANY LOSS, DAMAGES, OR LIABILITY, INCLUDING REASONABLE ATTORNEYS' FEES, RESULTING FROM ANY THIRD PARTY CLAIM OR ANY GOVERNMENT ACTION AGAINST BD ("CLAIM") TO THE EXTENT ARISING FROM CUSTOMER'S BREACH OF ITS REPRESENTATIONS, WARRANTIES AND COVENANTS UNDER THIS LETTER AGREEMENT.

Customer represents that it has controls in place to ensure that only its personnel that have a need to access Underlying Data for user-defined research, public health reporting requirements, or

Letter Agreement page 1 of 2

BD-52226 IDS Customer Activation of Software Features Letter Agreement laboratory quality control will have access. Customer also represents that it will notify personnel of Customer's obligations hereunder.

Customer acknowledges and agrees that BD may at any time without notice to Customer revoke Customer's access to the Underlying Data.

Each party has caused this Letter Agreement to be signed by an authorized representative on the date set forth below.

Instrument(s)

Location(s):	Serial Number(s):	Date(s) Configured:

Parties

Customer:	BD: Becton, Dickinson and Company, through its BD Life Sciences - Diagnostic Systems unit
Address:	7 Loveton Circle Sparks,
	Maryland 21152-0999
Agreed to by (Lab Director, or equivalent, minimum) (Signature):	Agreed to by (BD authorized representative) (Signature):
Title (Print):	Title (Print):
Date (Print):	Date (Print):

Letter Agreement page 2 of 2

BD-52226 IDS Customer Activation of Software Features Letter Agreement

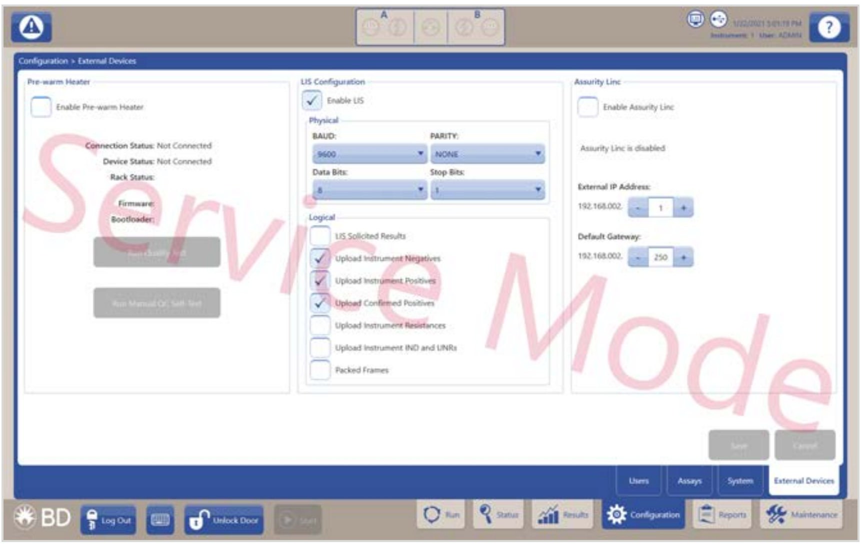
4.2.4.5 Display Options Pane

The following elements of the parameter set appear in a work list:

- Use **Accession**, **Patient ID** and both radio buttons to turn on or off editing of these items.
- Select or clear **External Control**, **Lot Number**, and **Concentration/Units** to switch those on or off.
- **24 Sample Work List** turns off the **default 2000 Sample Work List** and reverts back to the work list previously used on the Linux Operating System BD MAX instrument.

> **Note:** The Linux OS has been discontinued for Microsoft Windows OS.

4.2.4.6 External Devices Sub-tab



The **External Devices** sub-tab controls connections to external devices.

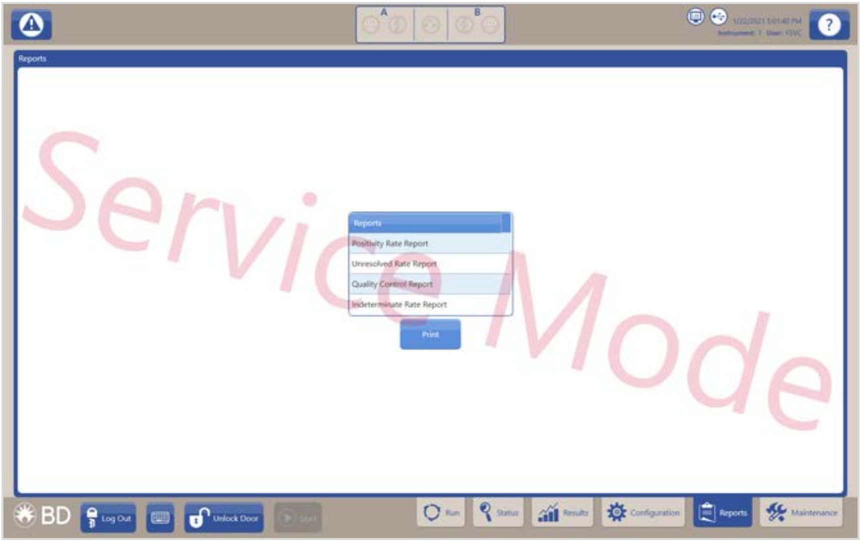
- The Pre-Warm Heater Pane enables an optional USB Pre-warm Heater and allows it to be tested.
- The LIS Configuration Pane sets and configures LIS.
- The Assurity Linc™ Pane (optional) is Ethernet based and uses the **RJ45 port**.

4.2.5 Reports Tab for Users

For software version V4.50 and above, the **Reports** tab allows the Field Service Engineer (FSE) to generate an **Indeterminate Rate Report**.

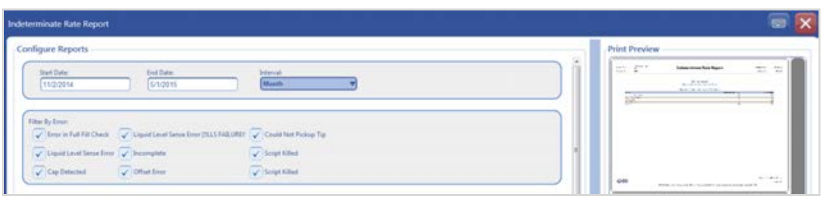
The **Indeterminate Rate Report** is available only in **Service Mode**.

A user logged in as **Admin** only sees the **Positivity Rate Report** and the **Quality Control Report**.



To generate an **Indeterminate Rate Report**:

1. Select that **Reports** option.
2. Click **Print**.
3. Filter the date, **Date** filter at the top to set a date range or for intervals by week, month, or quarter.
4. Use the **Filter by Error** Pane to select to include or exclude move errors from the report.



Indeterminate Rate Report(Filter by Error)

The Indeterminate Rate Report is displayed next to the Filter by Error Pane. It shows:

- A summary of the error, affected samples out of all samples run, along with error rates.
- A graph of the percentage of IND results by error over time. The interval of the time adjustable by week, month or quarter.
- A chart displaying each individual Indeterminate results with errors, to include error date, run ID, the error, rack position, sample strip positive, sample cartridge position, pump number, and assay.

The Indeterminate Rate Report can be printed or exported onto a USB drive if needed, and is a key factor in diagnosing instrument performance problems.

4.2.6 Maintenance Tab

The Maintenance tab has the following sub-tabs:

"Versions Sub-tab" on page 109

"Event Viewer Sub-tab" on page 110

"Block Lanes Sub-tab" on page 111

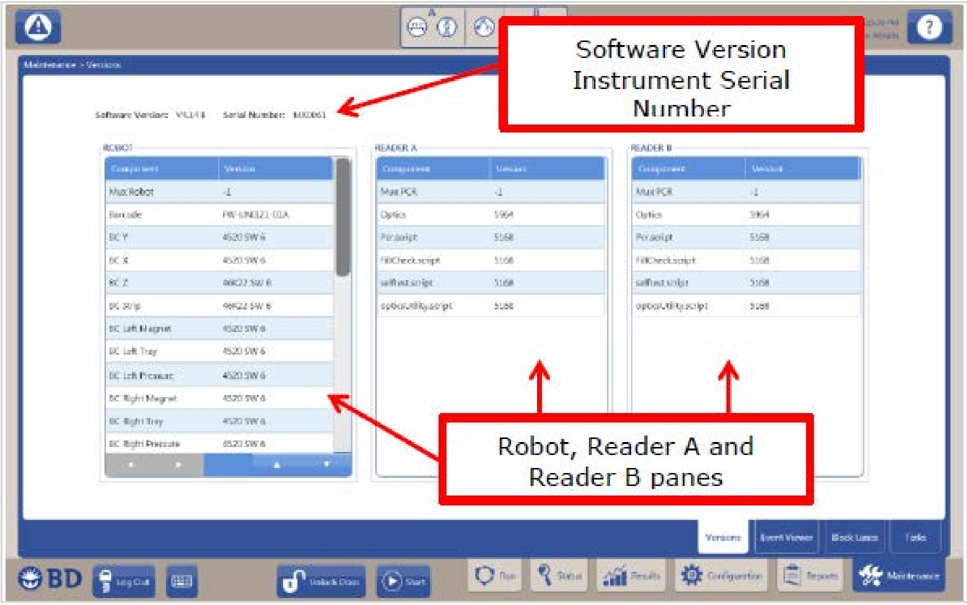
"Tasks Sub-tab" on page 114

"Field Service Sub-tab" on page 116

4.2.6.1 Versions Sub-tab

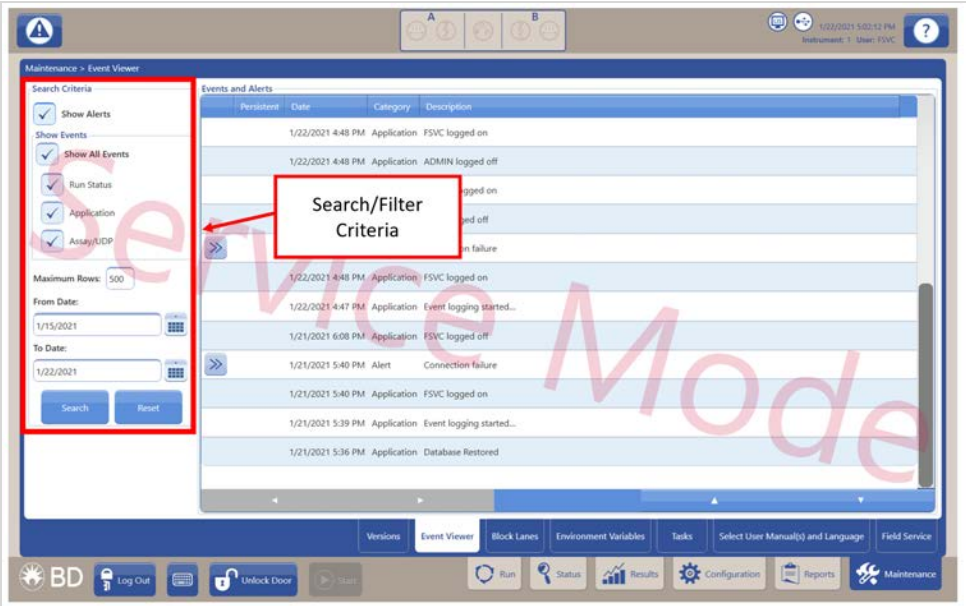
The Versions sub-tab shows:

- Current BD MAX software version and instrument Serial Number as set in the user software.
- The **Robot**, **Reader A**, and **Reader B** panes that list components and their MUX Script Version numbers.



4.2.6.2 Event Viewer Sub-tab

The **Event Viewer** sub-tab provides sorting and filtering tools for an event lot of every instrument action.



4.2.6.3 Block Lanes Sub-tab

The **Block Lanes**sub-tab allows blockage of specific lanes or an entire reader/rack.

This is used, for example, with a heater problem related to a specific lane where the customer does not want lab technicians using that lane. Alternately, there may be a problem with an entire reader.

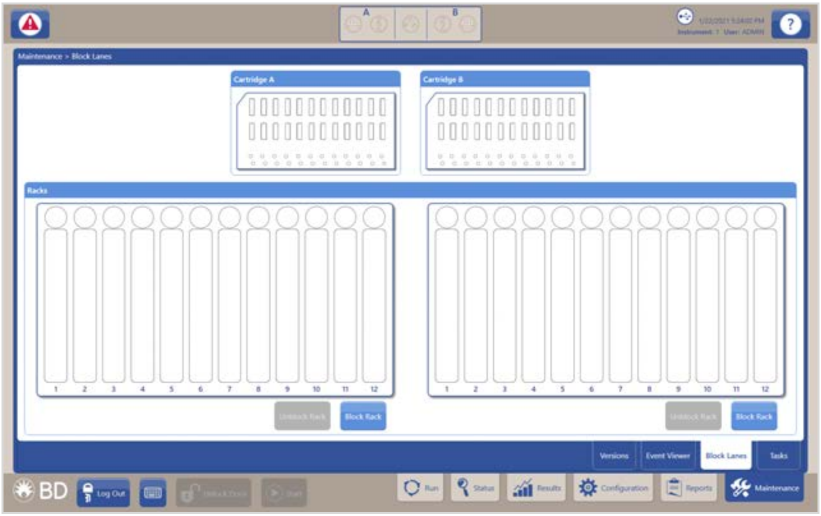
Blocking prevents processing in blocked lanes while permitting processing in others.

Block Affected Lanes or Racks

> **Note:** This note applies to Table 1 in "Qualification Run" on page 322. It is qualification failure of the lane and not the failure of the entire BD MAX system if a lane fails due to PCR heater warnings or heater timeout errors. It is a specific event and the FSE may choose to block the affected lanes and/or racks.

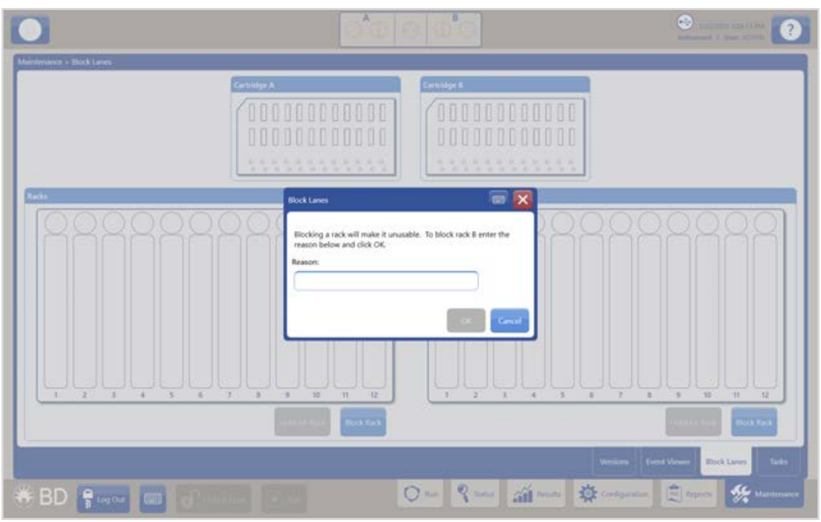
1. Log into **FSVC** mode.
2. Navigate to **Maintenance** > **Block Lanes**.

3. To block a rack, press **Block Rack**.



4. To block a lane, press the desired lane in a rack. To block multiple lanes, repeat the step for each lane individually.
5. Enter the reason for blocking the rack or lane, and press **OK**. The rack or lane is now unusable.

> **Note:** Lane not passing qualification could be stated as reason.



6. To unblock a lane, select the blocked lane and press **OK** on the **Block Lanes** overlay. The lane is now usable.

7. To unblock a rack or multiple lanes, press **Unblock Rack**. The rack is now usable.

> **Note:** Create a follow-up work order in **ServiceMax**. State the reason and indicate lanes and/or racks that are blocked. Note the part number needed to complete the work order.

4.2.6.4 Tasks Sub-tab

The **Tasks** sub-tab includes five panes (sections):

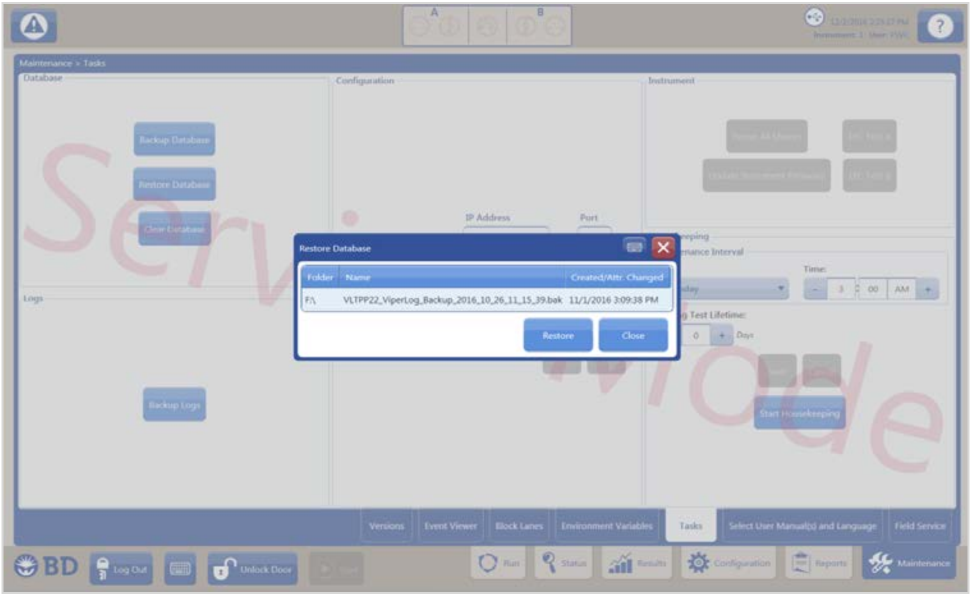
- Database Pane: Backup Database (download) to a USB key, **Restore Database** (upload) from a USB key.
- Logs Pane: **Logs Pane**, **Backup Logs** (download) to a USB key.
- Configuration Pane: When logged in as the **FSVC**user, the FSE can set up IP Addresses and Port Numbers.
- Instrument Pane: Home All Motors (Init script), Update Instrument Firmware (does not require software re-install)
- Housekeeping Pane: Sets automated execution of maintenance tasks such as disk defragmentation and backups.

Database and Log Panes

System software version 4.50 and greater supports:

- database backup,
- database restoration,
- log file backup
- software upgrades using a zip format.

When database and log files are saved to a USB flash drive, a folder with the instrument serial number as the name, is created on the USB drive. The log file and database are in zip format and protected with the password **halley**.



Restore Database supports both zipped and unzipped database files, so files need not be unzipped before restoring. Once the **Restore** button is pressed, a listing of database backup files appear in the USB drive.

Housekeeping Pane

The housekeeping function allows configuration of the **Maintenance Interval** and **Pending Test Lifetime**.

The default Day/Time setting is Sunday at 3:00 AM.

The Pending Test Lifetime interval configures the maximum number of days (0-999) that pending sample tubes remain in the worklist. The default value is 0, which means sample tubes are not deleted.

The **Start Housekeeping** button manually executes this feature.

> **Note:** The Pending Test Lifetime configuration does not apply to the 24 sample or PCR worklists.

Tasks performed during housekeeping are described in the table.

Housekeeping Task	Description	Interval
Disk Defrag	This task runs Disk Defragment on the D: drive.	Weekly
Rebuild Database Indices	This task maintains database efficiency. Each table is adjusted and captured in the log identified by the REORGANIZE and REBUILD messages.	Weekly

Housekeeping Task	Description	Interval
Database Backup	This task performs a daily backup to the D:/Backup directory (see figure below). This backup file combines the configuration and main SQL databases into one backup file that is complete and may be restored through the maintenance screen. Each file contains the instrument serial number and day. **7 days** of backups are maintained and overwritten after a week.	Daily
Purge old log files	This task removes any log files **>28 days old.**	Daily

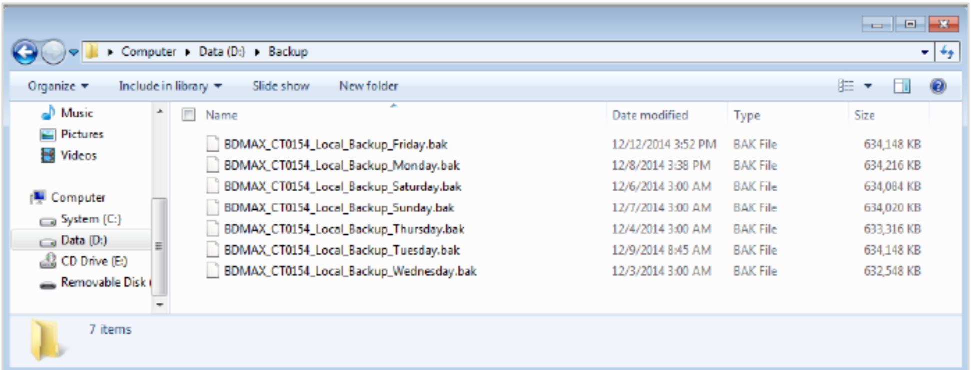
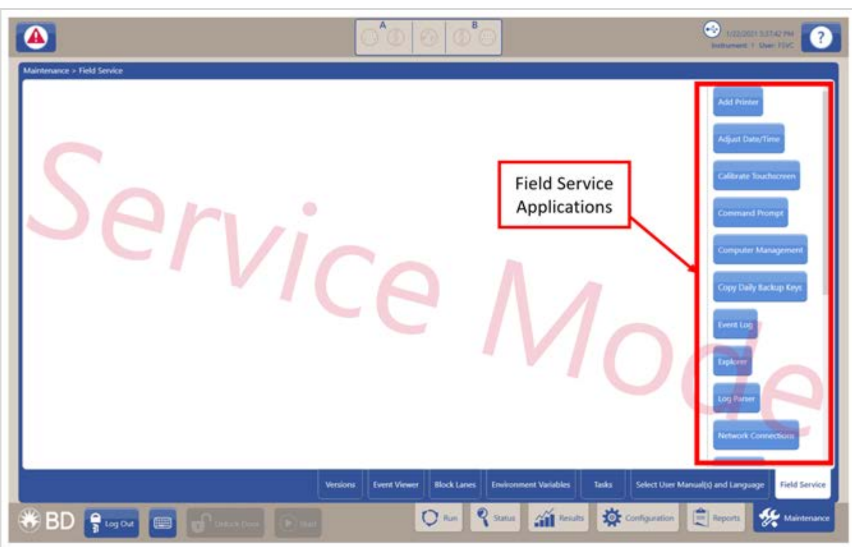


Fig: Example of a Daily Backup Directory

4.2.6.5 Field Service Sub-tab

The **Field Service** tab is located in the **Maintenance Screen** tab, but is only visible when logged in as **FSVC**.



A scrolling box of buttons along the right hand side of the screen allows access to the underlying elements of the operating system, or to third party software that is part of the base install. Applications include standard Windows-based computer management applications as well as some vender, third party, and BD exclusive applications.

Add Printer

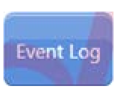
Opens the MS Windows **Add Printer** Wizard.

> **Note:** A printer CANNOT be added to the BD MAX when write filtering is turned ON. Printer drivers cannot be saved to the C drive during this action.

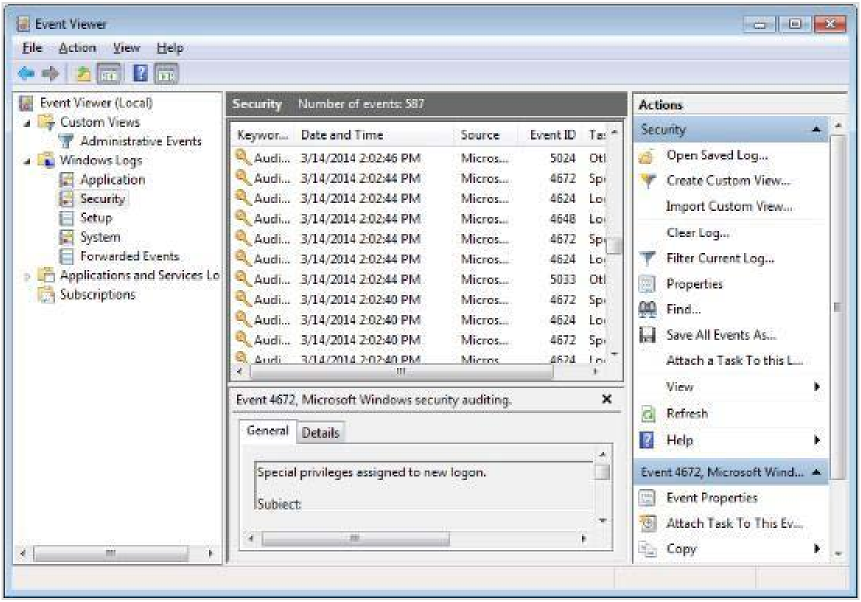
Computer Management

Opens the standard MS Windows Computer Management Window.

Event Log

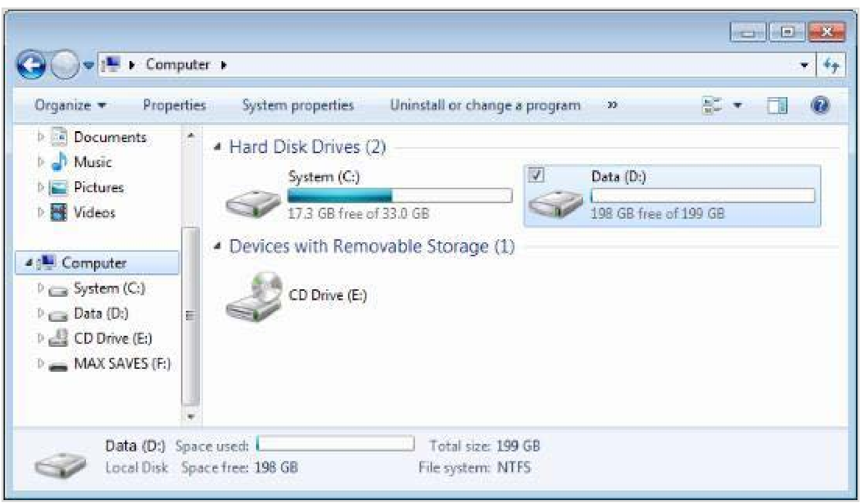


Opens the standard windows event viewer, which is used for tracking Operating System messages (not the instrument event log).



Explorer

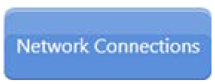
Opens the standard MS Windows File Explorer program.



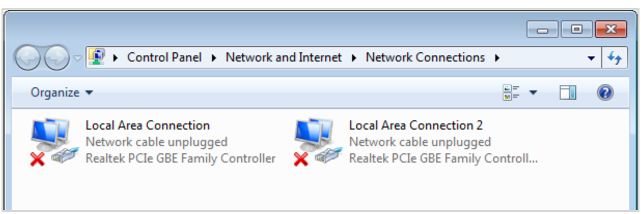
Log Parser

Opens a BD Utility to select and view instrument log files. This tool includes built-in sorting and filtering tools.

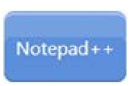
Network Connection



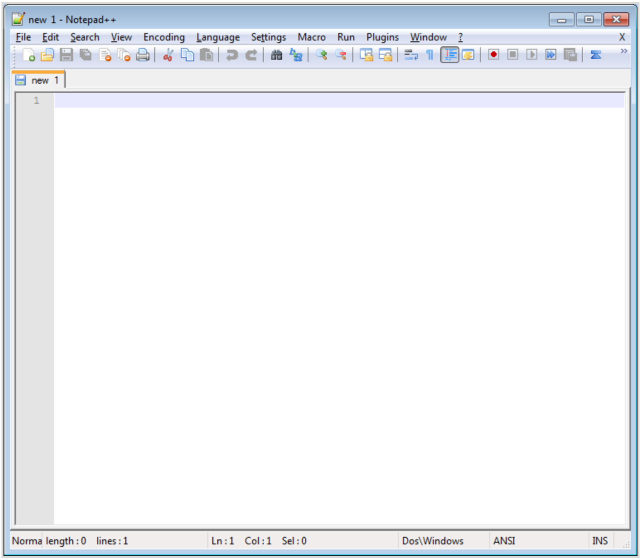
Opens the standard MS Windows Network Connection Window.



Notepad ++

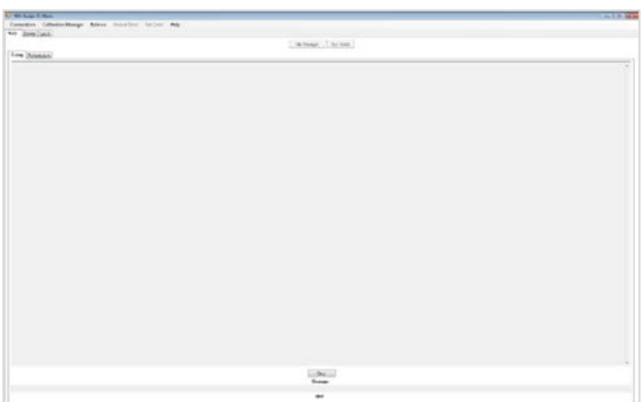


Opens a third-party multi-file text editor.



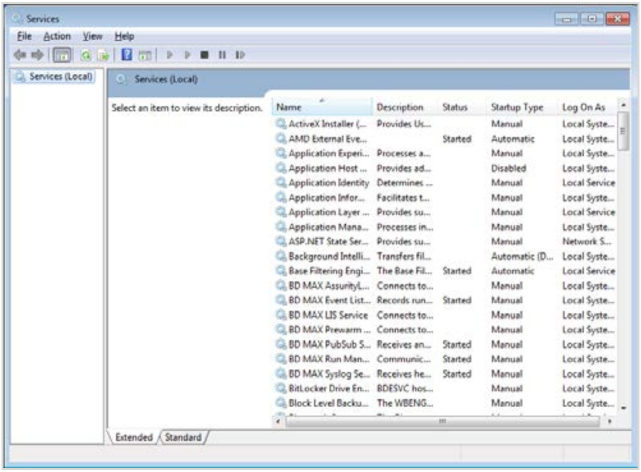
Script-O-Matic

Opens a BD utility for running MUX board scripts for testing and troubleshooting the instrument.



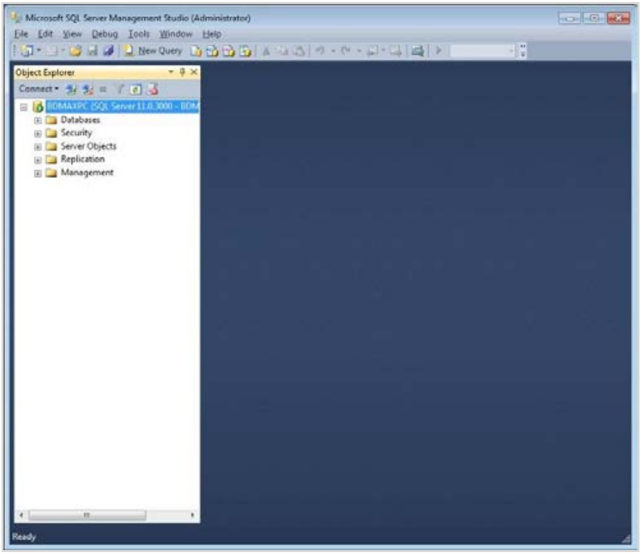
Services

Opens the standard MS Windows service manager utility program.



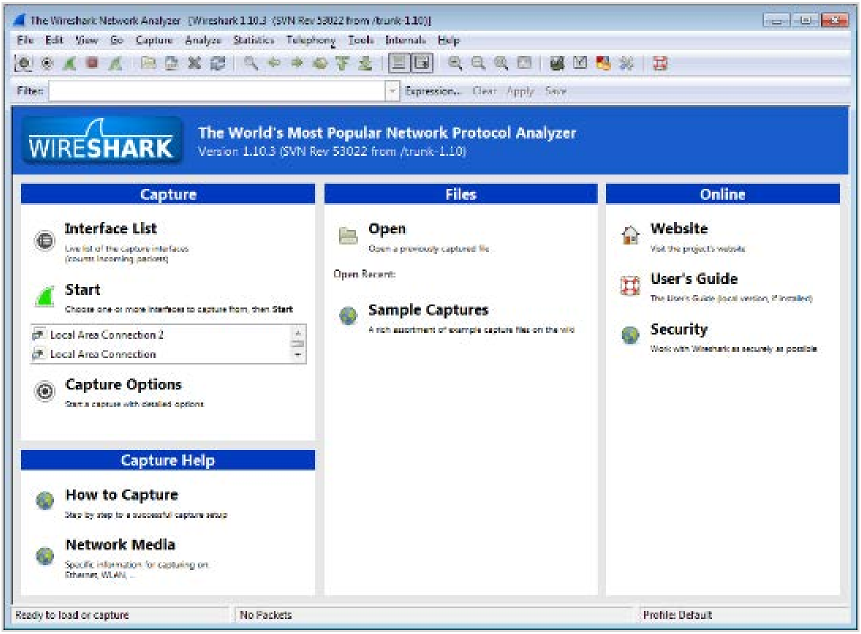
SQL Server Manager

Opens the Microsoft **SQL Server Manager**. Use this utility to view the database.



Wireshark

Opens the third party **Wireshark Network Monitor and Analyzer**.



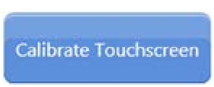
Adjust Date/Time

Opens the MS Windows **Date and Time** Manager.

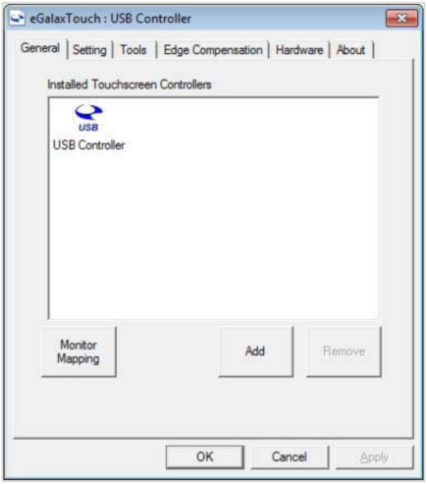
Note: Due to issues with users changing the **Date and Time** setting, this feature is no longer a user option.

Warning: Avoid adjusting the time forward. Significant adjustment may result in serious risk and compromised results due to misreferenced data - fill check, normalization, etc.

Calibrate Touch Screen



Accesses the vendors screen calibration utility, a third party program used for aligning the touch screen to the graphics display.



Command Prompt

Opens the standard MS Windows Command Line Tool.

4.3 Remote Connectivity

BD AssurityLinc™ Overview

BD AssurityLinc™ Remote Service system connectivity is available for use with the BD MAX™ System and configurable through the BD MAX™ Graphical User Interface (GUI).

The BD AssurityLinc™ remote service system monitors key parameters of the BD instrument systems and has the ability to be programmed to automatically send error alerts to the BD Service and Support Center.

BD AssurityLinc™ Gateway is designed to minimize security exposure. The OS, is hardened with enhanced security tools such as write filters and file base write settings. These protect the gateway system image by blocking all writes to the OS boot drive and protects the file level by redirecting to RAM overlay cache.

The application, hardware and network settings are locked down. The Microsoft Windows® firewall is configured to keep the BD AssurityLinc™ device safe from malicious software such as viruses and malware. This controls which applications have permission to run, what devices can be installed, and the traffic flow. There are no input devices such as a keyboard or mouse connected to the system when in normal operation.

BD AssurityLinc™ security works with proxy servers for outbound internet access. The local agent software initiates all communication to the enterprise. There are typically little to no changes required to customer network infrastructure.

4.4 RSS Integration

For RSS installation and configuration, please refer to RSS Manual BDDSSGFS7424.

4.4.1 Intuition Parser Overview

This installation manual for Intuition Parser is for BD associates' usage and contains information to support BD DS Remote Support Services (RSS).

4.4.1.1 System Description

The Intuition Parser is a BD created parser that works on BD DS Remote Support Services (RSS) for the BD Max. The Intuition Parser will assist the BD Max SMEs and technical support team in gathering more reliable data and metrics from the instrument for further help in diagnosing and troubleshooting the instruments.

4.4.1.2 Procedure Warnings

Throughout this service manual, important information is presented separately and labeled as a Note, a Caution, or a Warning. Below are examples of these procedural information sections.

Note: Important system information worthy of special attention is presented as a Note.

Caution: Information on a step that could cause the software or configuration to malfunction is presented as a Caution.

Warning: Information on a step that could cause injury to the associate or negatively affect patient testing and/or results is presented as a Warning.

Document: BDDSSGFS7422 Doc Type: ZIP Status: Released EFFECTIVE
Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

4.4.1.3 Environmental Health and Safety (EHS) and Onsite Safety Protocols

Becton Dickinson is committed to provide all authorized individuals on BD property with a safe environment in which to work, and proper tools with which to do the work. Please refer to the safety procedures that pertain to the region, locale, and facility. The on-site safety protocols must address safety requirements and safe environments at the customer site.

4.4.1.4 Scope Summary

The installation scope is briefly explained in the diagram below to show you where will the parser reside on BD Max instrument.

4.4.1.5 Installation

This section contains the procedures to install the Intuition Parser on all BD Max devices.

4.4.1.6 Requirements

Requirements listed here should be gathered before the on-site visit or the remote session request. The BD associate performing the Intuition parser installation should be certified to maintain the BD Max advanced knowledge is required to access restricted parts of the software.

4.4.1.7 Documentation

BALTFS0172 – Installation Procedure for Intuition Parser Ver 1.4.

4.4.1.8 Software

Note: Download the software from the BD Life Sciences File Repository. Check the site for the latest version.

- The latest revision of the BD Intuition Parser Ver 1.4 installer package.
- Instrument machines/devices are operating on Microsoft Windows 10 and above.
- The Bomgar client installer package.
- The BeyondTrust™ client installer package.

4.4.1.9 Supported Instruments

- BD Max
- Epicenter/Gateway/NUC

4.4.1.10 Information

RSS Software must be installed and configured for the instruments at the customer location. The instrument's status in RSS Dashboard must be shown as “online”.

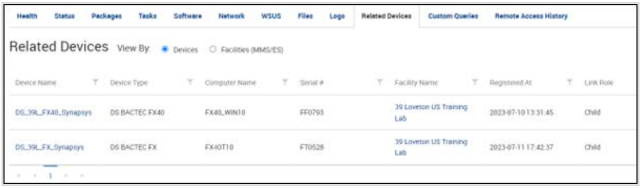
4.4.1.11 Prerequisite for all Windows AIO

Before installing the Intuition Parser, this parser is intended to be used with Windows 10 operating system and above.

Some instruments may require a Microsoft Net 4.7.2 installer to be installed. Please refer to ("Checklists" on page 584) at the end of the documents for more information.

4.4.2 Intuition Parser Installation

Note: For instruments that are connected to an Epicenter, like FX and FX40, make sure the configuration using the RSS Configuration has been completed and you can see the related devices on the RSS page of the Epicenter device.



4.4.2.1 Intuition Parser Installation on the NUC

Installed on the Epicenter or Gateway connected to FX and FX40 instruments.

1. Download the latest Intuition parser file from BD Life Sciences File Repository.

   Max IntuitionInstaller.zipfrom the BD Life Sciences File Repository or copy-paste this link:

   [Intuition Parser Max - All Documents (sharepoint.com)]

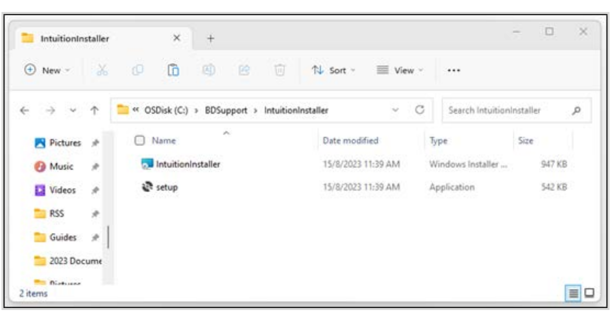
2. Transfer the file onto the Epicenter.

   1. If you are accessing the instrument using remote access or Bomgar/ BeyondTrust™ use the File Transfer on Bomgar/BeyondTrust and transfer the file to the BD Software or BD Support folder that is in the C or D drive.

   2. If you are accessing the instrument directly, you can transfer the file via a USB stick or by accessing the SharePoint link.

      Note: Refer to (Appendix A, p.41) on accessing the DS Epicenter or DS Gateway

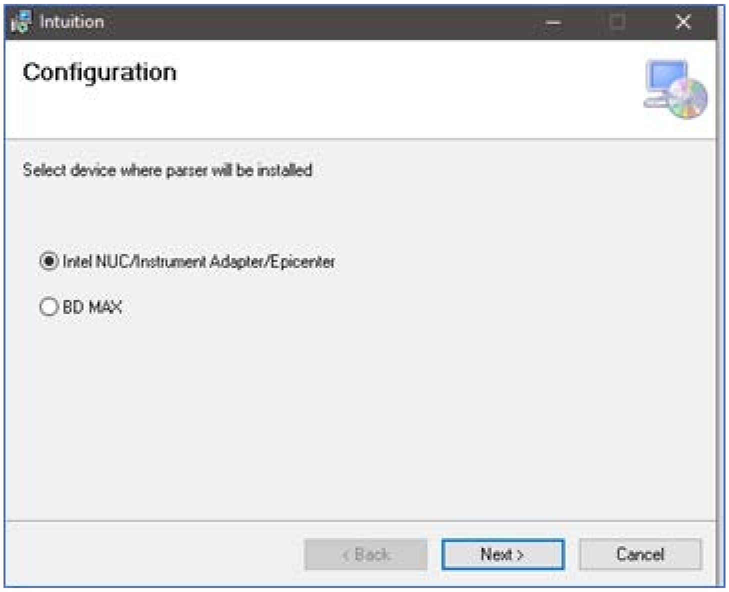
3. Extract the latest Intuition parser zip file.

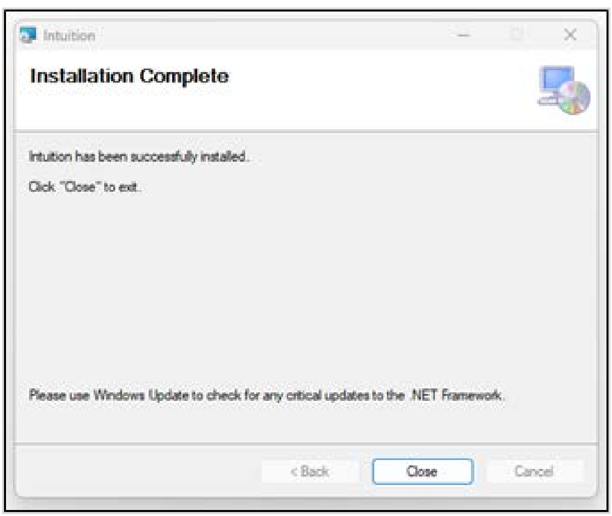
4. Right-click on the **Setup** file and click on **Run As Administrator**.

Document: BDDSSGFS7422 Doc Type: ZIP Status: Released EFFECTIVE
Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

5. On the configuration page, choose in the device type you are configuring (Select Epicenter for Bactec FX and Bactec FX40) and click **Next**.

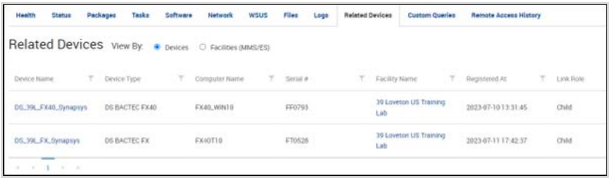


6. The parser will be installed and wait until you have received the confirmation windows like below. Click **Close** to exit.

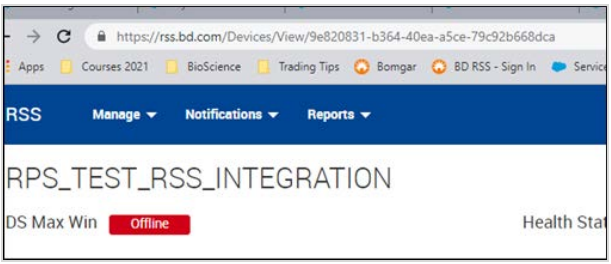


4.4.2.2 Intuition Parser Configuration (Epicenter/ Gateway)

1. Go to https://rss.bd.com/ and search for the devices that are connected to the Epicenter. Or from the Epicenter page, click on the **Related Devices** tab and select the device that you will be configuring the parser



2. Proceed to copy the Atlas Key for the instrument. In the example below, we are copying the Atlas Key for a BD Max device.

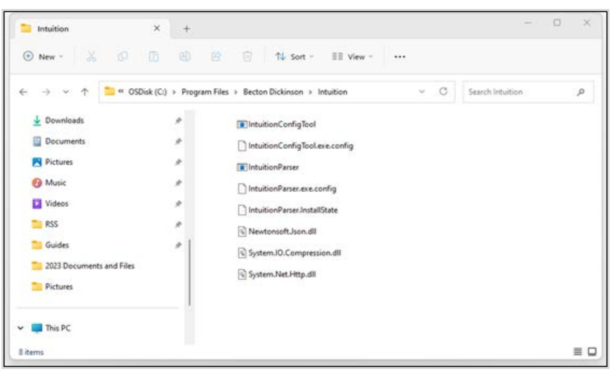


Example: https://rss.bd.com/Devices/View/9e820831-b364-40ea-a5ce-79c92b668dca

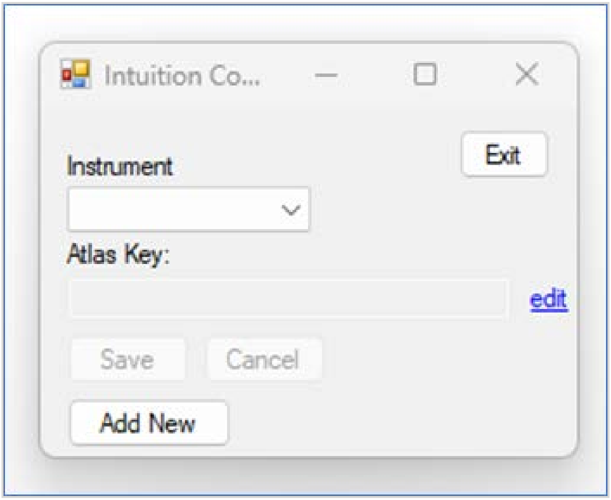
Atlas-Key: 9e820831-b364-40ea-a5ce-79c92b668dca

3. On the **Epicenter**, go to this location to configure the parser: **C:\Program Files\Becton Dickinson\Intuition**

4. Right-click the **IntuitionConfigTool.exe** and click on the **Run as Administrator**.

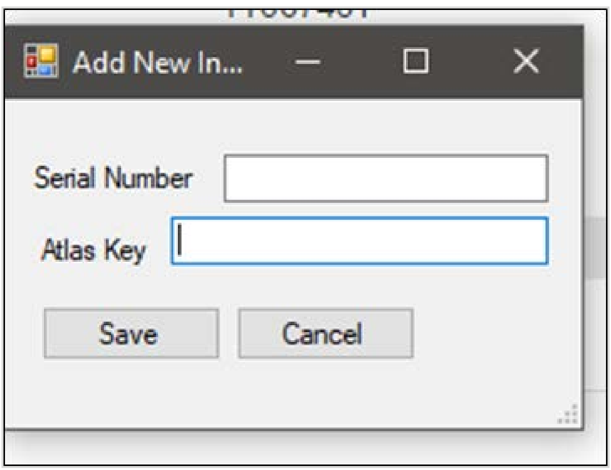


5. Click on **Add New**.

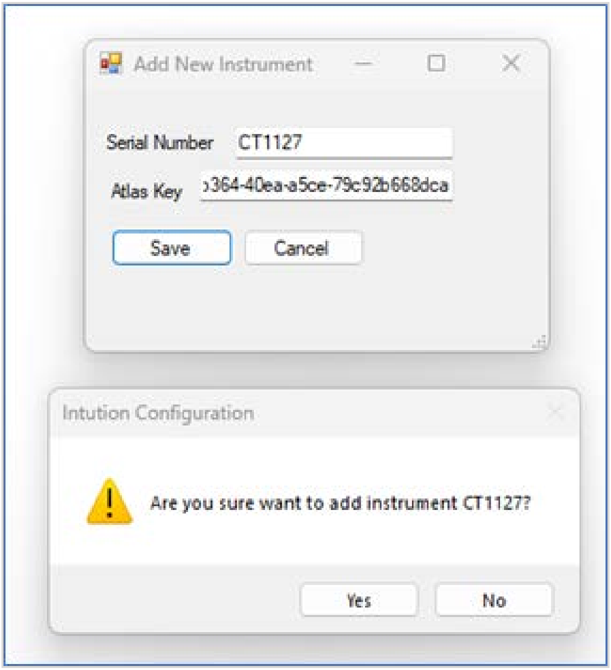


6. Paste the **Atlas Key** copied at Step 2 here and insert the device serial number.

> **Note:** The device serial number that will be inserted here will be the same as the information of the device from the Service Max, for example FT1234.

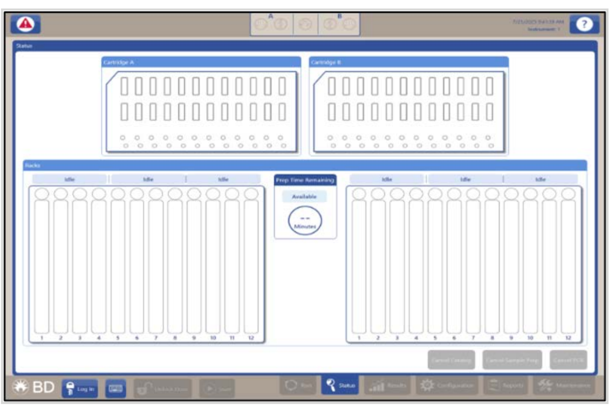


7. Enter the serial number ie: CT1127 and click on **Save**. Click **Yes** to confirm.

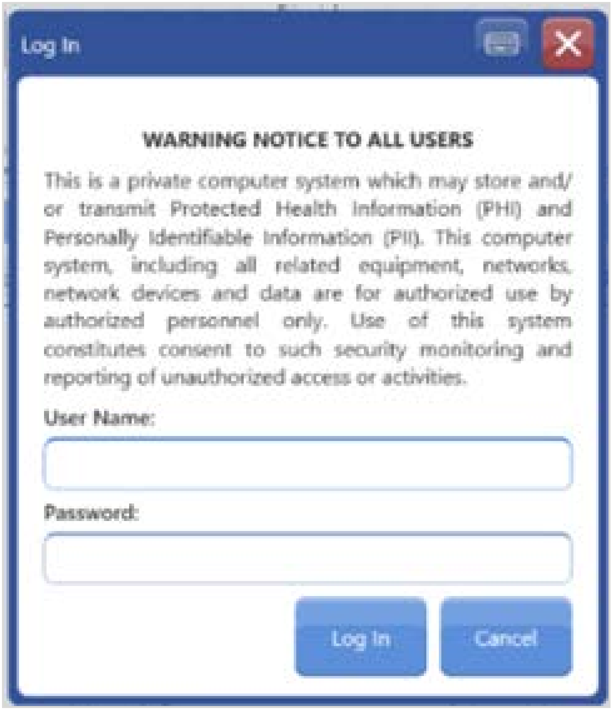


4.4.2.3 Intuition Parser Installation on the BD Max

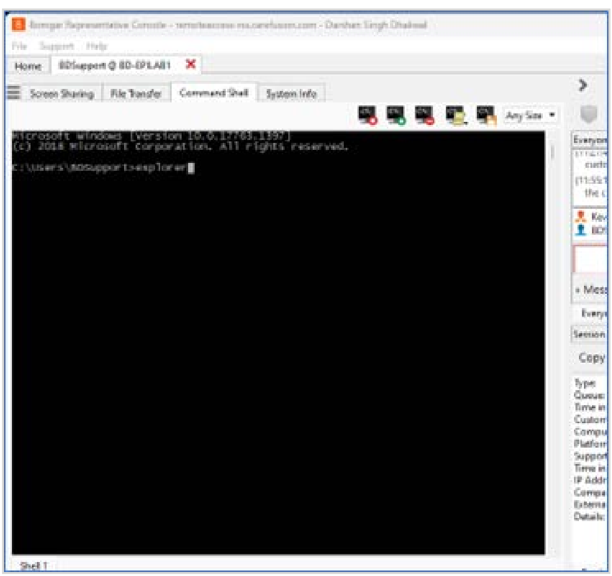
1. Log into the BD Max device.



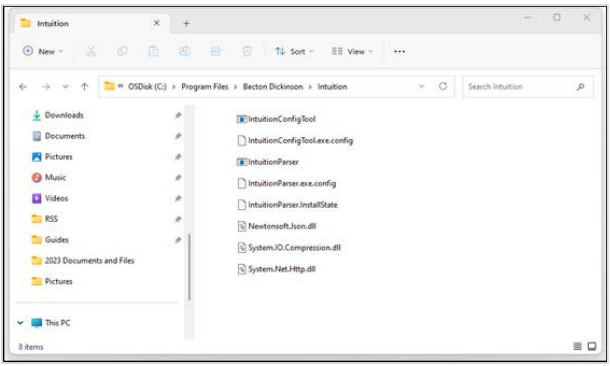
2. Press the **Login** button at the bottom left corner of the screen to display the Login screen.



3. Login into the application using the **FSVC user name** and **password**.
4. Navigate to the **Maintenance** tab **> Field Services>** and click on the **Explorer** button.
5. Alternatively if you are remotely using Bomgar/Beyond Trust, open the **Command Shell** and type "**explorer**". This will bring up a Windows Explorer on the screen.

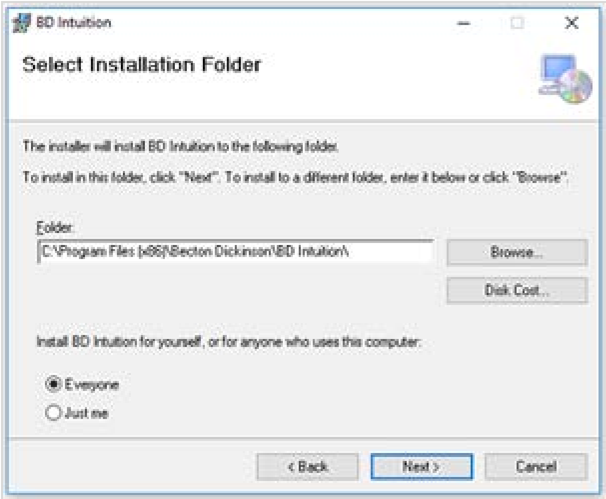


6. Download the Intuition Parser from the repository location to your computer and transfer it to the BD Max device.
7. Use the **File Transfer** on Bomgar, if you are accessing the instrument using remote access or Bomgar/ BeyondTrust, and transfer the Intuition Parser installation folder into the C:\BD Software or BDSupport located in the C drive and extract the files.
8. If you are accessing the instrument manually, kindly transfer the file to the same folder.
9. Once the Intuition Parser folder is extracted, right-click the **setup.exe** and click on **Run as Administrator**.

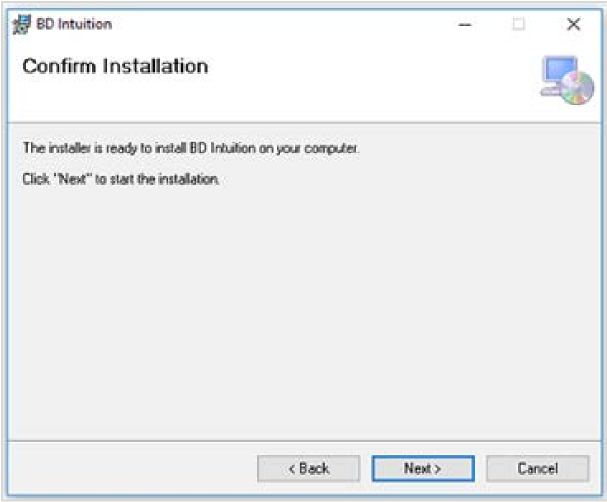


10. The instruments may prompt you to install Microsoft Net 4.7.2 installer. Please refer to ("Installer .NET Framework 4.7.2" on page 607) at the end of the documents for more information.
11. Click on **Next**.

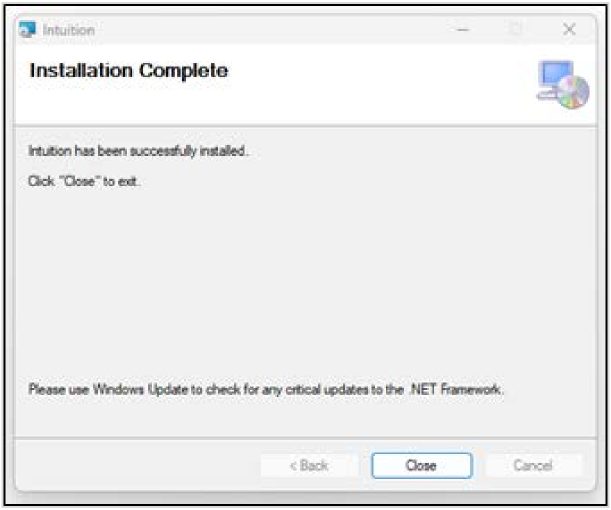
12. For select destination folder, leave it under the default location, select for **Everyone** and click **Next**.



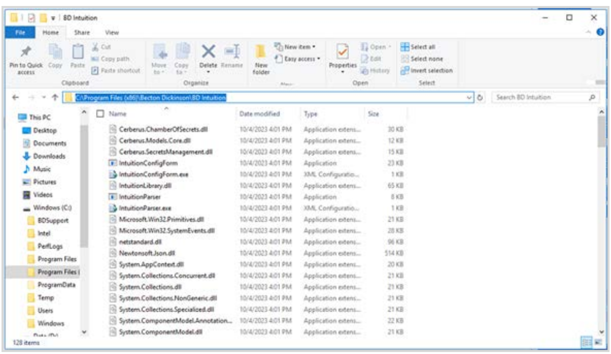
13. On the confirmation screen, click **Next** to start the installation.



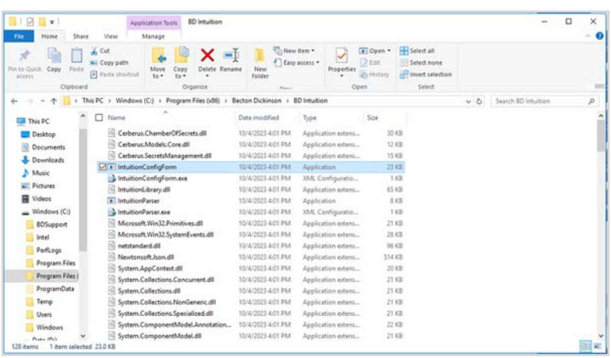
14. The installer will now install the parser. Once completed, you will receive the confirmation below. Select **Close** to close the installer.



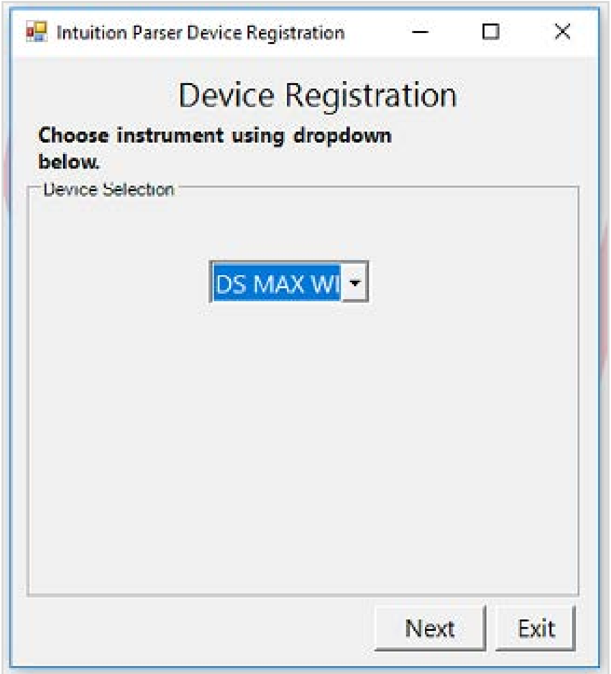
15. Go to the destination folder located here.



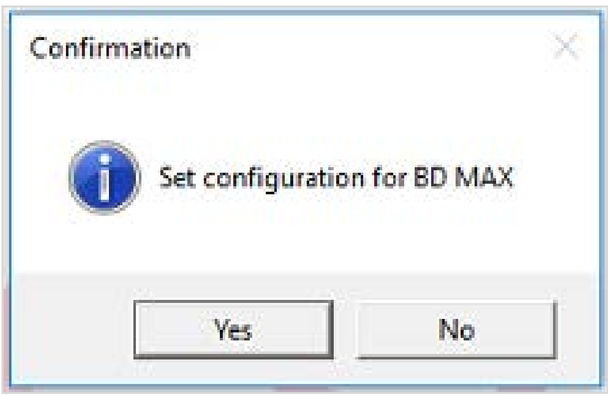
16. Right-click and **Run as Administrator** for the **IntuitionConfigForm**.



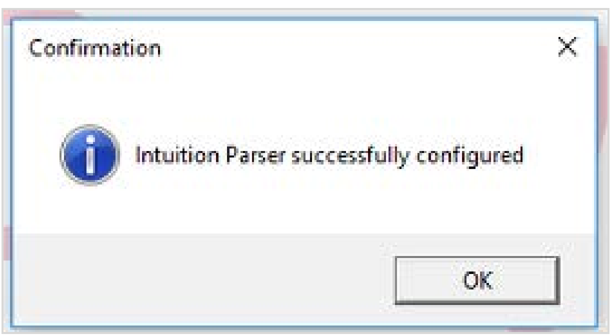
17. On the **Intuition Parser Device Registration** screen, select the device type: **DS BD Max Win** and select **Next**.



18. On the **Confirmation** page, select **Yes**.



19. Click **OK** to close the Confirmation dialog box.

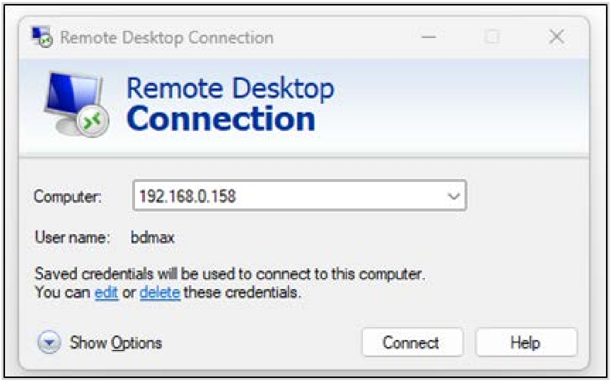


4.4.2.4 Intuition Parser Installation on the BD Max via Epicenter

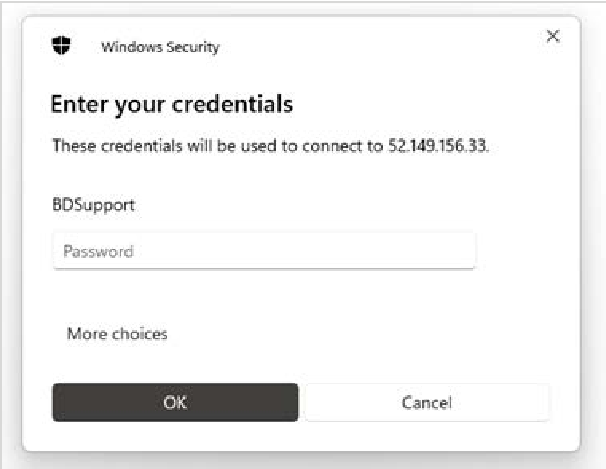
Several BD Max instruments are connected to an Epicenter and can only be accessed through the Epicenter system. This is followed by connecting to the instrument using RDP (Remote Desktop Connection) session. This section will highlight the steps that can be used using a remote tool (Bomgar/Beyond Trust).

> **Note:** Assuming the RSS on the BD Max have been configured using the RSS Configuration Tool on the Epicenter.

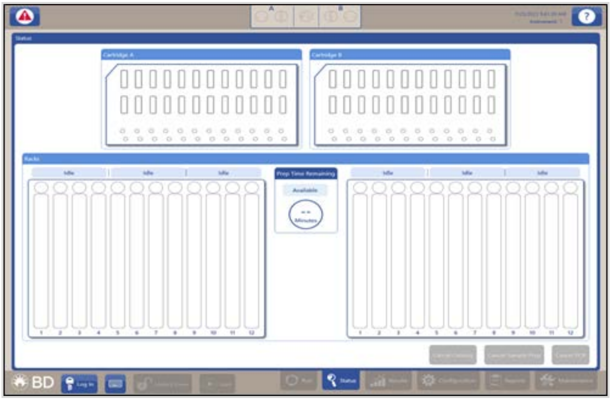
1. Login into the Epicenter using remote tool or in person.
2. Using the windows search icon, search for RDP (Remote Desktop Connection) and type in the IP Address of the BD Max device.



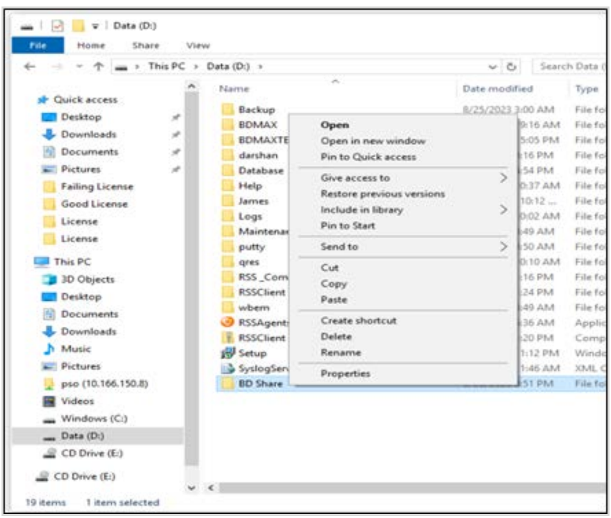
3. Click **Connect** and enter the login information of the BD Max device.



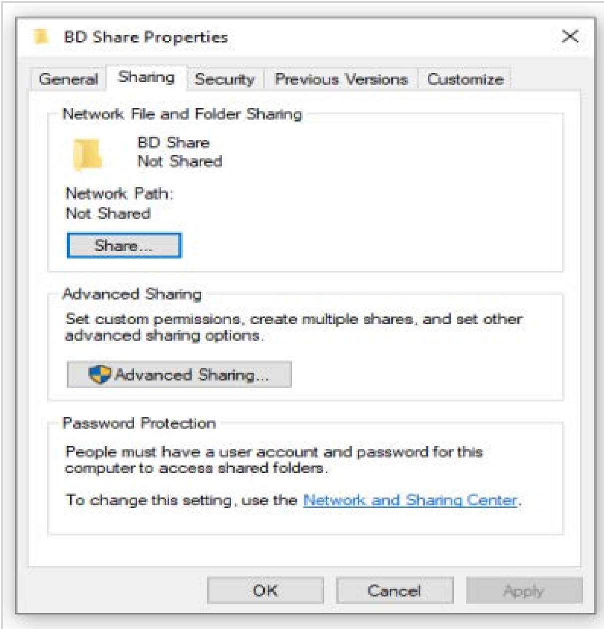
4. You will be logged into the BD Max instrument, from here follow the steps to login using the service login ID and password.



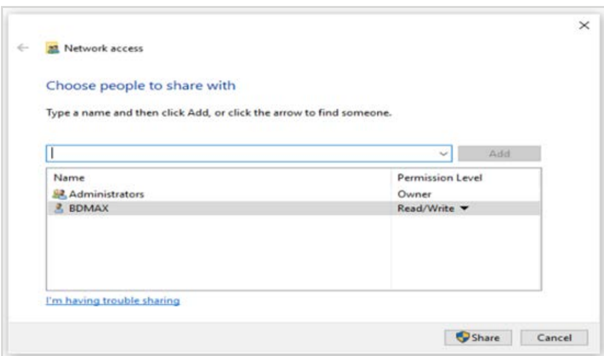
5. Navigate to the **Maintenance** tab **> Field Services>** and click on the **Explorer** button.
6. Under the "D" Drive, create a new folder and name it as **BD Share**.
7. Right-click on the folder and click **Properties**.



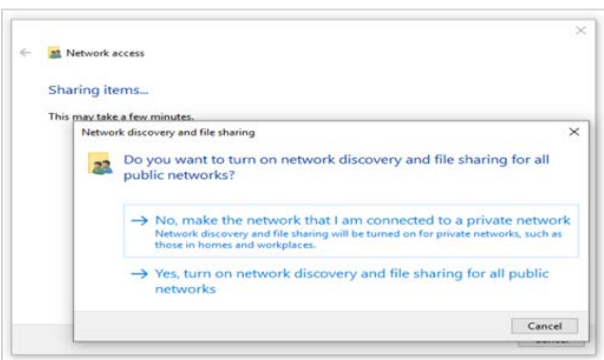
8. Click on the **Sharing** tab and proceed to click on the **Share** button.



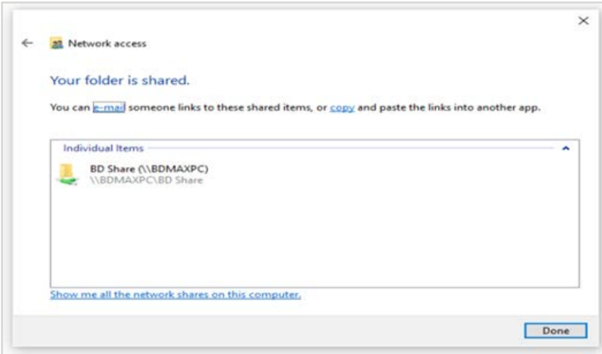
9. Click on **Share**.



10. If you received the notification/pop-up below, choose the first option - **Make the network I connected to a private network.**



11. Click on **Done** once the folder is shared.



12. You can access this folder from the Epicenter by searching for **Run** command and entering the IP address of the BD Max. Type in **** followed by the IP address of the instrument., i.e., \\192.168.2.55

13. Copy the Intuition Parser Installer into this folder.

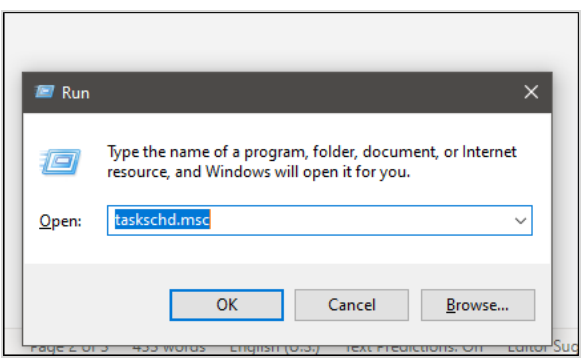
14. Run the installation steps referring to "Intuition Parser Installation on the BD Max" on page 131 from steps nine onwards.

    Verification

Three steps confirmation process if the parser is installed successfully on the device (BD Max or Epicenter/Instrument Adapter/Intel NUC)

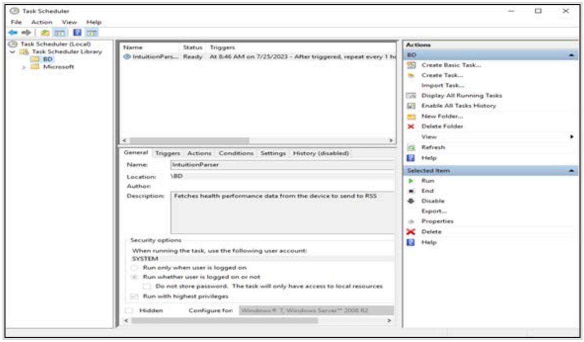
1. Intuition Parser in Task Scheduler

1. Open **Task Scheduler** where the parser is installed. You can do this by using the shortcut " Windows key + r" Copy the text and click **OK** to open Task Scheduler.



2. You can also type in the Windows Explorer search bar taskschd.msc.

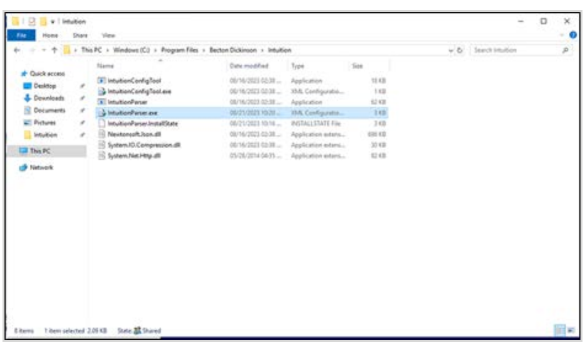
3. Expand the Task Scheduler Library in the newly opened Task Scheduler window if necessary. There should be a BD folder created.



4. Click on the folder and there should be a task with the name “**IntuitionParser**” with **Ready** status.
5. The task will do an initial run 1 minute after running the setup batch script. After 1 minute, ensure the last run result has been completed successfully with a 0x0 status code.
6. If the status has not been updated, click the **Refresh** button in the right pane under Actions and check the status again. Proceed to click **RUN** for the Intuition Parser for the first run.

2. Intuition Parser in Configuration File

1. On the Epicenter/Instrument Adapter/Intel NUC or the BD MAX, go to the location below: C:\Program Files\Becton Dickinson\Intuition
2. If it has successfully installed, you will see a list of programs in this folder. Right click on the IntuitionParser.exe.config file and choose to edit/open with a notepad.



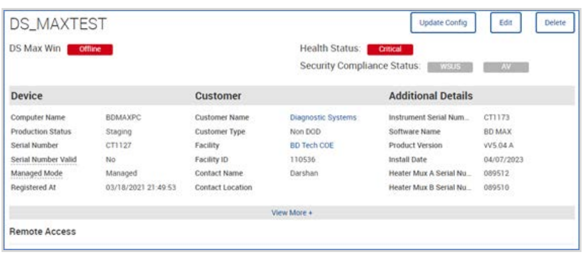
3. Under the instrument, the value will be shown as the devices installed, followed by the

atlas key.

```
IntuitionParser.exe - Notepad
File  Edit  Format  View  Help
<?xml version="1.0" encoding="utf-8"?>
<configuration>
  <configSections>
    <section name="FxSettings" type="System.Configuration.NameValueSectionHandler" />
    <sectionGroup name="EpicenterSettings">
      <section name="AttachedInstruments" type="System.Configuration.NameValueSectionHandler" />
    </sectionGroup>
  </configSections>
  <appSettings>
    <add key="Instrument" value="epi" />
    <add key="RssDatahubApiConnectionParameters" value="Ip=127.0.0.1;Port={0}" />
    <add key="ClientSettingsProvider.ServiceUri" value="" />
  </appSettings>
  <FxSettings>
    <add key="logFilePath" value="tmp\log.txt" />
  </FxSettings>
  <EpicenterSettings>
    <AttachedInstruments>
      <add key="FFPP03" value="08c78e67-031c-4fa6-bf7c-e4362046c8fb" />
      <add key="FT4824 F83098" value="ad71a6ed-2832-46b8-8963-058649f36ef3" />
    </AttachedInstruments>
  </EpicenterSettings>
  <connectionStrings>
    <add name="epi" connectionString="Data Source={0};Initial Catalog=EpiCenter_SQL;Persist Security Info=Tr
    <add name="max" connectionString="Data Source={0};Initial Catalog=BDMAX_SQL;Persist Security Info=True;I
  </connectionStrings>
  <startup>
    <supportedRuntime version="v4.0" sku=".NETFramework,Version=v4.5.2" />
  </startup>
```

3. **Intuition Parser in RSS Dashboard**

   1. Proceed to login to https://rss.bd.com and search for the device such as BD Max.
   2. You will notice a new section at the device page level called **Additional Details**.

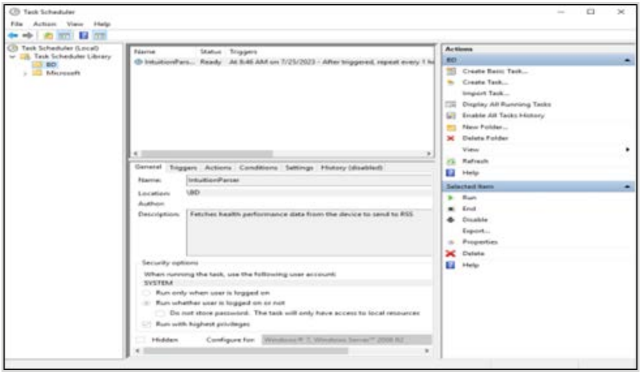


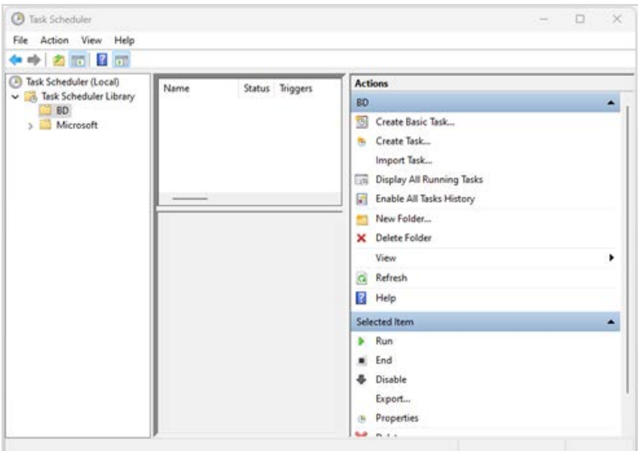
   3. For some off the devices, it will take around 8-12 hours to be able to see the changes on the RSS Dashboard page.

4.4.3 Intuition Parser Removal

4.4.3.1 Task Schedule

On the **Task Scheduler** page, right-click on the **Intuition Parser** that was created and choose **Delete**. This will stop the parser from running on the devices.



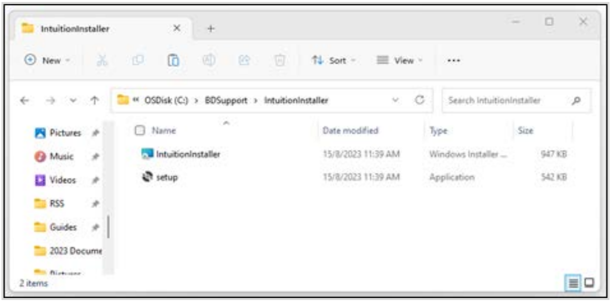


4.4.3.2 Control Panel

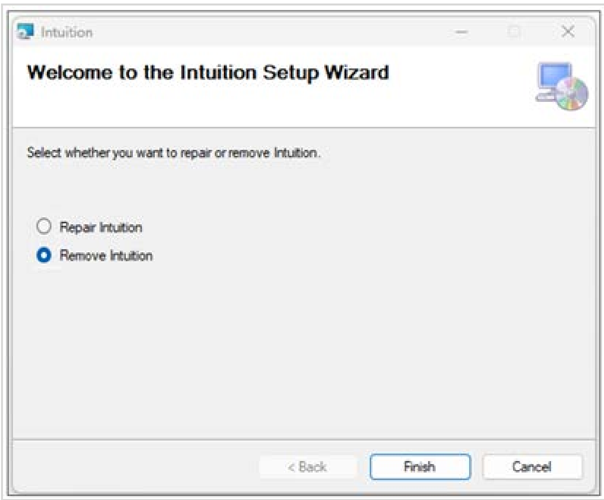
1. Search on the taskbar, enter **Control Panel**, and select it from the results.
2. Select **Programs > Programs and Features**.
3. Search for **Intuition**
4. Press and hold (or right-click) on the program and select **Uninstall** or **Uninstall/Change**.

4.4.3.3 Setup Folder

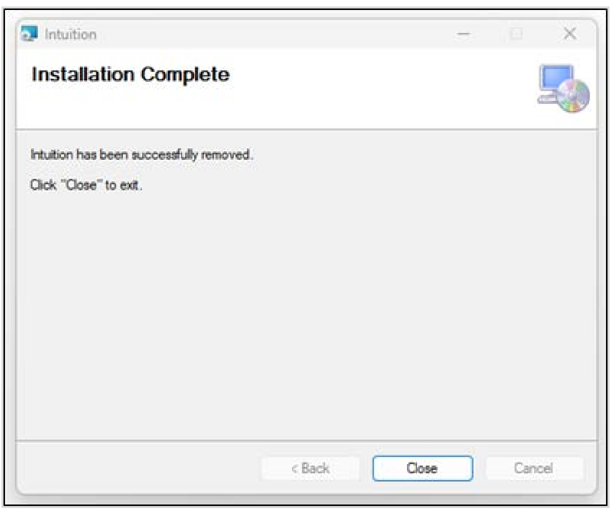
1. You can also remove the Intuition Parser from the setup file. Click on the **setup.exe** file again.



2. Click on the **Remove Intuition** option or **Repair Intuition** option and click on **Finish**.



3. Wait until the confirmation page appears. Click **Close**.



Verification:

1. Return to the folder and confirm the Intuition Parser was removed.

4.5 Synapsys Integration

This section details the general requirements, the required prerequisites, and procedures to integrate Synapsys.

4.5.1 Prerequisites

Before configuring BD Synapsys on the BD MAX, the following prerequisites must be met:

BD MAX

- Install (at a minimum) BD MAX System Software V6.10A & Windows 10 image V2.33A on the BD MAX.

AIO Synapsys

- Minimum Synapsys requirement is V5.10.
- Complete the BD Synapsys installation according to the BD Synapsys Service Manual BDDSSGFS7406.
- Identify the Synapsys FQDN (Fully Qualified Domain Name). Have this ready for use in "Enabling BD Synapsys on BD MAX" on page 146.

> **Note:** The Synapsys FQDN will be specific for each customer and originate from Synapsys.

Example from our test environments here at BD.

Environment	IP & Domain Name (FQDN)
max-syn-vm1	10.35.68.30 max-syn-vm1
maxplorersqa	10.35.68.27 maxplorersqa

4.5.2 Enabling BD Synapsys on BD MAX

Update Hosts File:

1. Navigate to the **Maintenance > Field Service tab** and select **Explorer**.
   1. Locate the hosts file in the following file pathway: Windows (C:)\Windows\System32\drivers\etc\hosts
   2. Open the hosts file in Notepad.
2. Type in the **IP Address** and **Synapsys URL/Application Server Hostname (FQDN)** of the Synapsys environment you are trying to connect to at the bottom of the hosts file as shown below.
3. Save the file and close.

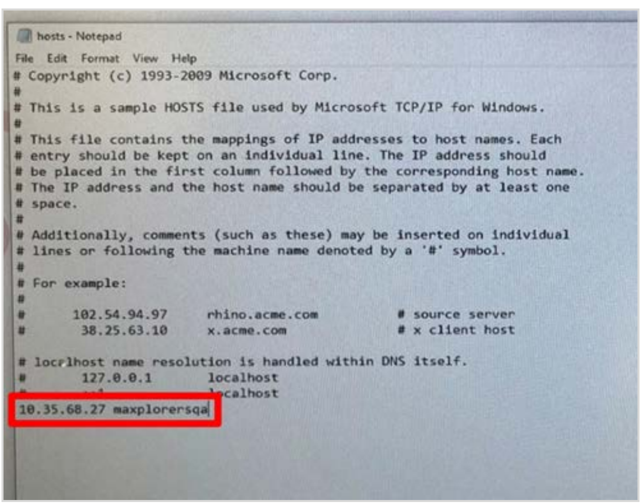


Fig: Example updated hosts file with Synapsys IP (10.35.68.27) & host name (maxplorersqa)

4.5.2.1 Connecting Synapsys and BD MAX

1. If connecting one BD MAX to Synapsys, continue to step 2. If connecting multiple BD MAXs to Synapsys, perform the following steps to set a unique BD MAX AIO Hostname:
   1. Navigate to the **Maintenance > Field Service tab** and select **Task Manager**.
   2. Click **More Details** at the bottom left of the Task Manager screen.

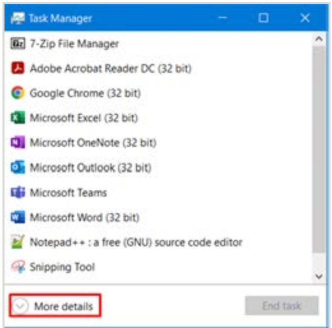


Fig: More Details on Task Manager

3. In the top menu bar, click **File > Run New Task**. Then, type "control" in the text box and click **OK**

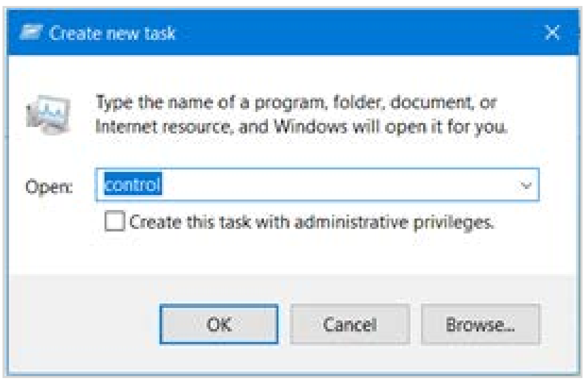


Fig: Running new "control" task

4. On the Control Panel screen, change the **View By** option to Large or Small icons.

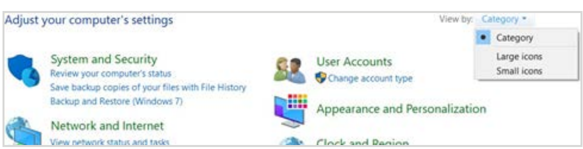


Fig: Changing view of Control Panel

5. Select the **System** option in Control Panel.

6. On the **System** screen, select the **Change Settings** option under the Computer Name, domain, and workgroup settings section.

7. On the **Computer Name** tab, click **Change**.

8. In the **Computer Name** text box, enter the new BD MAX AIO hostname. Click **OK** once completed.

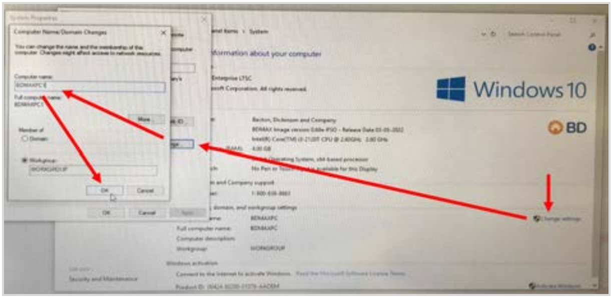


Fig: Updating the BD MAX AIO Computer name (hostname).

2. In this example, changing to “BDMAXPC1” :
    1. A warning message appears that the PC needs to reboot for changes to take effect. Click **OK** on the warning message and click **OK** on the **System Properties** screen.
    2. Once the BD MAX AIO has rebooted, log in with the FSVC account.
    3. A message will appear asking if you want to reboot now, select **Reboot Now**.
3. Connect the ethernet cable for Synapsys into the **LAN2** port in the AIO.
    1. RSS connections should always go in LAN1.

    Fig: LAN2 Port for Synapsys ethernet cable
4. In the **BD MAX GUI**, navigate to the **Maintenance > Field Service** tab and select **Command Prompt**.
5. Type **“ipconfig /all”** in the command shell and press **Enter**. The MAX FQDN is one of the following:
    1. **(PREFERRED)** Static IPv4 Address (**ex:** https://10.3.135.54)

    Fig: ipconfig output and MAX FQDN (IPv4)

    1. Dynamic IP Address (DHCP)
        1. If the customer provides a DHCP, it is recommended to use the AIO Hostname (**ex:**https://BDMAXPC)
6. Record the BD MAX FQDN (used in step 7. The BD MAX AIO Hostname will be visible as well if needed. Navigate to the **Configuration > External Devices** tab and locate the **“LIS/Synapsys Configuration”** column.
7. Navigate to the **Configuration > External Devices** tab and locate the **“LIS/Synapsys Configuration”** column.
    1. Select the **“Synapsys”** radio button.
    2. Enter the **IP address** (from step 6) in **MAX FQDN** and the domain name of the Synapsys environment (from Prerequisites > Synapsys) you are attempting to connect

to in the **Synapsys FQDN** textbox.

> **Note:** This needs to match the Synapsys host name entered into the hosts file

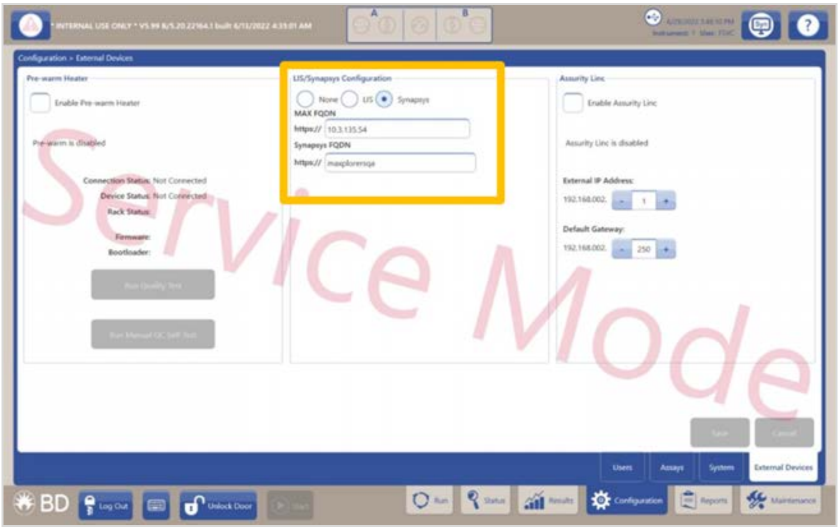
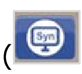
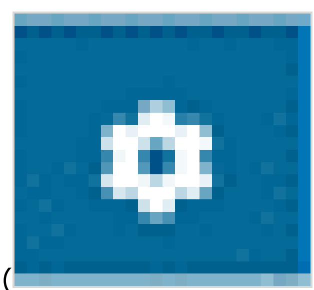


Fig: LIS/Synapsys Configurations with populated Synapsys radio button and example MAX/Synapsys FQDNs

8. Press **Save** in the lower right corner and reboot the BD MAX AIO.
9. Once back online, log into the BD MAX AIO and confirm that the **Synapsys** icon () is now visible in the top right corner.
10. Log into the Synapsys Application using the **SynapsysAdmin** login credentials (can be acquired from the regional KeePass database, from the Synapsys Cloud site, or from a regional Informatics Specialist).
11. Navigate to **Configurations** ()**> Instruments**.

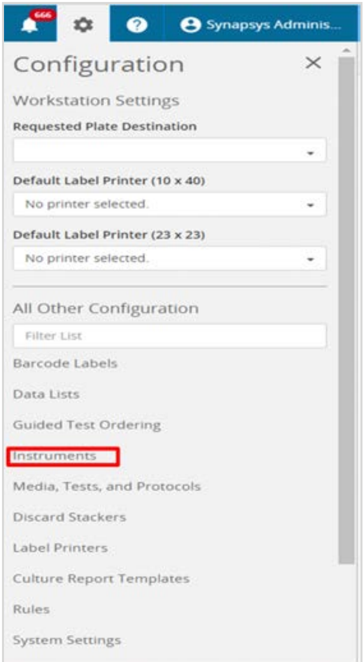


Fig: Configurations > Instruments

12. In the **Instruments Configuration** screen, select the **Add an Instrument** (

) button.

13. In the **Instrument Definition Name** dropdown box, choose the **MAX** option.

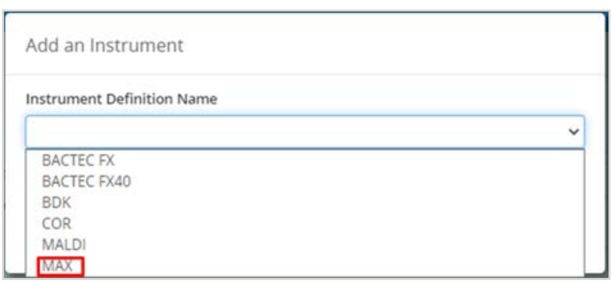


Fig: Adding BD MAX instrument to Synapsys

14. In the **User Label** box, enter a **Unique Identifier** for the BD MAX AIO. This can be the hostname of the BD MAX AIO or a lab-specific name that can be used to quickly identify the Instrument.

15. 2. In the **URL Address** box, enter the **BD MAX FQDN** from step 3 (i.e., https://<MAXFQDN>)

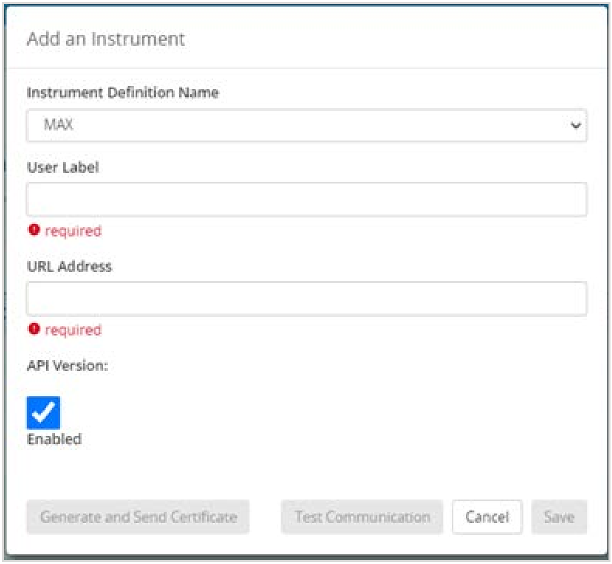


Fig: Assigning User Label and URL Address for connected BD MAX

16. Click the **Generate and Send Certificate** button. During this process Synapsys will generate a security certificate and transfer it over to the BD MAX AIO. Once received, the certificates will be installed on the BD MAX AIO in certlm.msc. Once the certs are installed, the BD MAX Synapsys service will restart.
    1. If successful, you will receive a green box indicating the process completed successfully.
    2. If unsuccessful, you will receive a red box indicating the process was not completed. Ensure that all the BD MAX configurations were correctly configured. The BD MAX AIO has a unique hostname. If multiple BD MAXs are connecting to Synapsy, ensure the network connection between Synapsys and the BD MAX AIO is working properly.
17. Once you receive the green box, click the **Test Communication** button to verify connectivity between Synapsys and the BD MAX AIO.
    1. If successful, you will receive a green box verifying connectivity.
    2. If unsuccessful, you will receive a white box indicating the connection was not successful. Ensure that all the BD MAX configurations were correctly configured. The BD MAX AIO has a unique hostname. If multiple BD MAXs are connecting to Synapsys, ensure the network connection between Synapsys and the BD MAX AIO is working properly.
18. Once the Test Communication process is completed successfully, click **Save** to save your BD MAX instrument in Synapsys.

4.5.3 Rules Setup Guidance for BD MAX Results

BD MAX Assay results are delivered in the Molecular Result 2 Field. For assays with multiple target types, all targets are delivered in this field. For example, a CTGCTV2 with negative results for the all targets would deliver as CT NEG/GC NEG/TV NEG. Sample results which indicate a failure to complete PCR: IND and INC will only deliver a single result for the full assay. For this reason, the Molecular Result 2 Field result can be used for general rules about incomplete sample handling across assays.

For assays with multiple targets, there are also fields for each individual target. For example, the CTGCTV assay also has the fields CT Result, GC Result, and TV result, each containing the result for that specific assay. These fields are useful for creating rules governing specific results per target.

The Trigger Event for all rules should be Non-Media Protocol Updated and the Enabled box should be checked.

4.5.4 To Create BD MAX Rules for Sending Results without Review

The rules governing specific Molecular Result types should all include "Criteria" IF statements that:

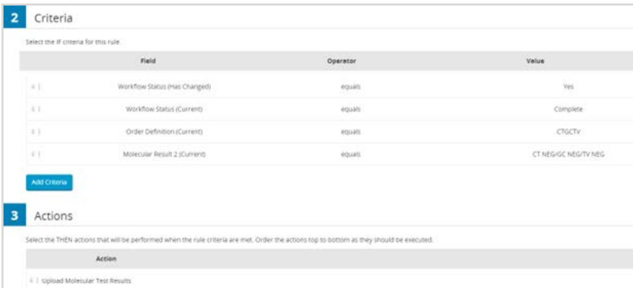
- Workflow Status (**Has Changed**) equals **Yes**
- Workflow Status (**Current**) equals **Complete**
- Order Definition (**Current**) equals {**Assay Targeted by Rule**}

These criteria ensure that the rule will only trigger once at the point when the test for that sample has completed and that the rule will not accidentally be applied to results for other assays or from other instruments.

The Action for these rules should be Upload Molecular Test Results.

Additional Criteria can be added based on the needs of the customer.

For example: If only results with all negative targets should be sent automatically, a criteria can be added for Molecular Result 2 (Current) for all negative results.

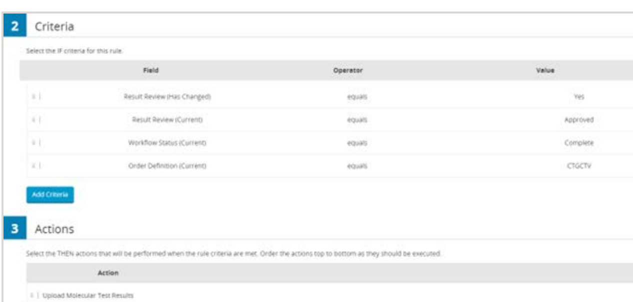


4.5.5 To Create BD MAX Rules for Sending Results after Review

Rules intended to send results after review should be based on the Result Review Status (Has Changed) criteria rather than the Workflow Status (Has Changed). If the customer only wants results that they have approved to send to the LIS, the Result Review Status (Current) should equal Approved. These rules should all contain the following:

- Result Review Status (**Has Changed**) equals **Yes**
- Result Review Status (**Current**) equals **Approved**
- Workflow Status (**Current**) equals **Complete**
- Order Definition (**Current**) equals **Assay Targeted by Rule**

These rules should also include the Upload Molecular Test Results Action.



Any result types that the customer does not want to review should be included in an additional rule using one of the options below.

Option 1: Send results automatically

Any result types that do not need result review and should be sent to the LIS can be set up in a rule like the one described in the "To Create BD MAX Rules for Sending Results without Review" on page 152. The result types that should be sent automatically without review should be included as a “Molecular Result” Criteria.

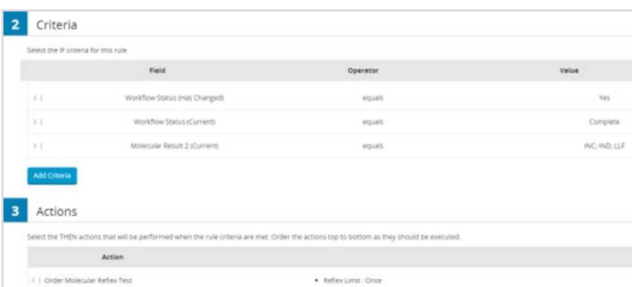
Option 2: Automatically set the result review status to Approved

A rule requiring result review to send test results can be paired with a rule that automatically sets the Review Status of certain result types to “Reviewed” so that they are sent right away to the LIS.

4.5.6 To Create BD MAX Rules for Reflex Testing on Processing Failure Across Assays

Rules intended to create a new reflex order so that an HPV sample can be reloaded should all contain the following Criteria:

- Workflow Status (**Has Changed**) equals **Yes**
- Workflow Status (**Current**) equals **Complete**
- Molecular Result 2 (**Current**) equals **INC;IND;LLF**



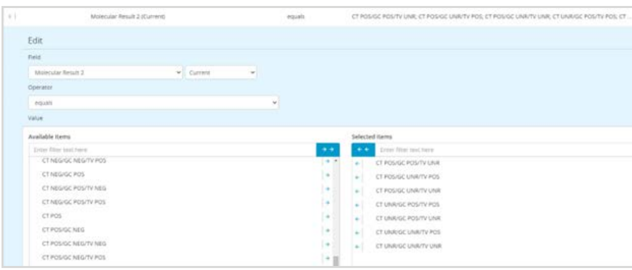
4.5.7 To Create BD MAX Rules for Reflex Testing Based on Result Type

Rules intended to create a new reflex order so that a BD MAX sample can be reloaded should all contain the following Criteria:

- Workflow Status (**Has Changed**) equals **Yes**
- Workflow Status (**Current**) equals **Complete**
- Order Definition (**Current**) equals **Assay Targeted by Rule**

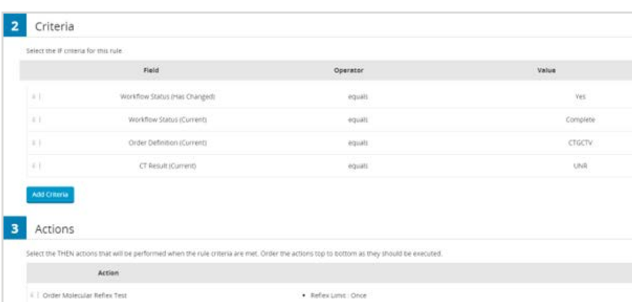
Because BD MAX assay results are sent in multiple fields, reflexing based on result type can be done in two ways.

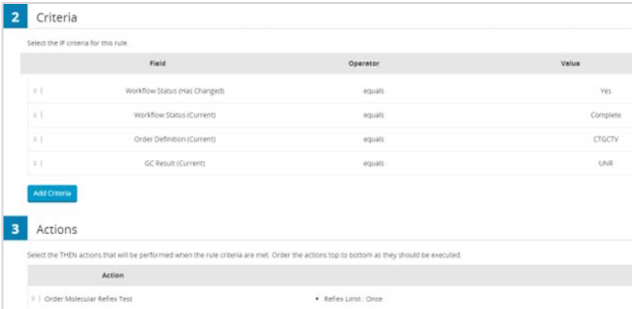
The Molecular Results 2 field can be used to create one rule that applies to all possible result combinations of results for an assay, which should lead to reflex testing. For example, if CTCGTV2 tests should reflex on any target resulting in a UNR, all result combinations including UNR should be selected.



The action for this rule should be Order Molecular Reflex Test.

Alternatively, an individual rule can be set up for each target, which addresses the reflect criteria for that specific target. For example, for CTGCTV, three individual rules with criteria for the CT Result, GC Result, and TV Result fields can be created.





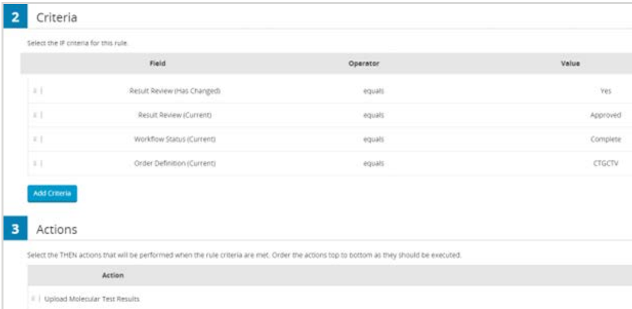
When using this strategy to create rules, it is important that the Reflex Limit is set to Once so that samples with UNRs for multiple targets do not lead to the creation of multiple reflex test orders.

4.5.8 To Create BD MAX Rules for Reflex Testing Based on Review

Rules intended to create reflex tests for results that do not pass review should all contain the following Criteria:

- Result Review (**Has Changed**) equals **Yes**
- Result Review (**Current**) equals **Rejected**
- Workflow Status (**Current**) equals **Complete**
- Order Definition (**Current**) equals **Assay Targeted by Rule**

The Action for this rule should be “Order Molecular Reflex Test.”



Rules of this type should be paired with a rule like the examples from the "To Create BD MAX Rules for Sending Results after Review" on page 153 section of this document so that the Molecular Result types that are reviewed by the customer are not sent to the LIS prior to review.

4.5.9 BD MAX Synapsys Connection Troubleshooting

- Refer to the BD Synapsys Quick Reference Troubleshooting Guide.
- Synapsys icon can be used to notify Synapsys that BD MAX is ready to receive orders in the queue
- Verify physical connections on BD MAX and Synapsys sides.

4.6 BD MAX MDR-TB Fitness Test Instrument Qualification Procedure

Procedure for performing an MDR-TB Fitness Test during instrument troubleshooting, Mux/Reader replacement, or installation for customers running BD MAX MDR-TB Assay. This includes the initial field action items to facilitate troubleshooting procedures.

Materials:

Item	Part Number	QTY	Description
BD MAX MDR TB 70 ADF	NA	NA	Use the latest version of the released ADF.
BD MAX Software	NA	NA	MAX software version 5.14A and above
BD MAX MDR-TB Assay Kit	443878	2	Assay reagent kit
MDR-TB Resistance	444522	2	2 kits of 24 each

Item	Part Number	QTY	Description
QC Tool			
BD PCR Cartridge	437519	1	Box of 24 cartridges
BD MAXTM STR (Sample Treatment Reagent)	443806	12	Each STR contains 8 mL reagent

Warnings and Precautions

Personal protective equipment such as powder-free nitrile gloves, safety glasses, and lab coats should be worn throughout the entire procedure.

Warning: The MDR-QC Tool is a set of set of sample buffer tubes that contain positive TB target. Only trained BD Personal can use and perform the test. Standard laboratory procedure to prevent environmental contamination must be followed.

Note: Expired reagents will generate false values and erroneous results. Verify and confirm all reagents, including the STR and QC Tool are not expired before dates before use.

Note: Prior run the MDR-TB Tool, the instrument should be qualified with the QPM and the 5 Chanel Qualification Kit.

Procedure:

1. **BD MAX Qualification**

   a. The MDR-TB fitness test should be performed in conjunction with other qualification tests and after

   Note: The MDR-TB fitness test should only be executed after the instrument passes instrument qualification tests (5CH and QPM).

2. **QC Tool Preparation**

   a. Document reagent lot numbers and expiration dates in "Attachment A: MDR-TB Assay Fitness Test" on page 165.

   b. Gloves must be changed before manipulating reagents and cartridges.

c. For each Heater/MUX assembly to be tested, uncap 12 MDR-TB QC Tools.

> **Warning:** Add 0.5ml water and 1mL of STR to each QC Tool tube using a transfer pipette.

d. Cap tubes with septum caps.

e. Invert QC Tools 10 to 20 times.

f. Place QC Tools in the BD MAXTM sample rack (**Figure 1**).

g. Place the Sample Tubes into the specimen rack with barcode labels facing outward (this makes scanning Sample Tubes easier during sample login)

h. **Change gloves**.

Figure 11: BD MAXTM sample rack

3. **MDR-TB Strip Preparation**

a. For each Heater/MUX, remove 12 MDR-TB assay unitized reagent strips (URS) and gently tap the strips against a hard surface to release any trapped air at the bottom of each tube and to ensure all the liquid is at the bottom of each tube.

b. Observe there are two long tips with filters next to the waste reservoir and two short tips with filters next to the URS barcode. Check to make sure the tips are properly positioned.

c. For each Heater/MUX, add 12 Extraction tube snap-ins **labeled E**7 to Snap-in 1 Position signified with a white line, 12 MM1 snap-ins **labeled E6** to Snap-in 2 Position signified with a green line and 12 MM2 snap-ins **labeled E5** to Snap-in 4 Position signified with a blue line.

i. Check that tubes are properly sealed.

ii. Check that the extraction component in each tube is intact.

iii. Check that the tubes are placed in the URS in the right orientation (tapered end down) and position.

iv. See **Figure 2** below of a properly prepared URS setup.

d. Final inspection of all consumables.
   i. Make sure all snap-in tubes are correctly snapped.
   ii. Make sure the buffer in the strips does not contain air bubbles or that the liquid is stuck to the foil.
   iii. Make sure the correct tips are in the strip.
e. Place racks and cartridges into the BD MAX™ instrument.

Figure 12: MDR-TB Fitness Test sample rack layout ready for processing.

4. **Run Management**

a. Power up the instrument and AIO.
b. Login with "**FSVC**" and Password. (see **Figure 3**).

Figure 13: BD MAX All-in-one login screen.

c. Check and record the software version in Attachment A Table 5. This information can be found by going to **Versions** tab and in the upper left corner is the **Software Version** (see **Figure 4**)

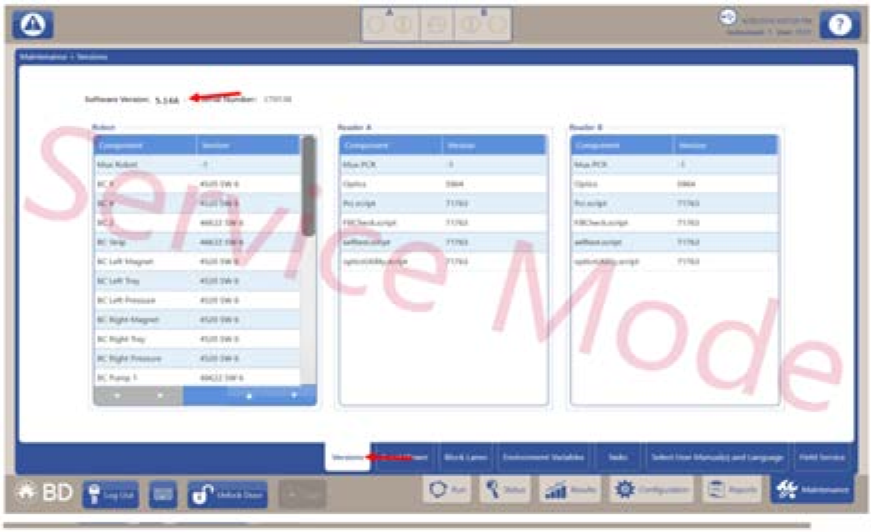


Figure 14: Software version window

d. Load "BD MAX MDR TB 70" ADF, or latest version, if it is not already installed:

i. Insert the USB key with the ADF file on the root drive into the AIO.

ii. Click on the **Configuration** tab to open the Configuration window, then select the **Assays** tab (**Figure 5**).

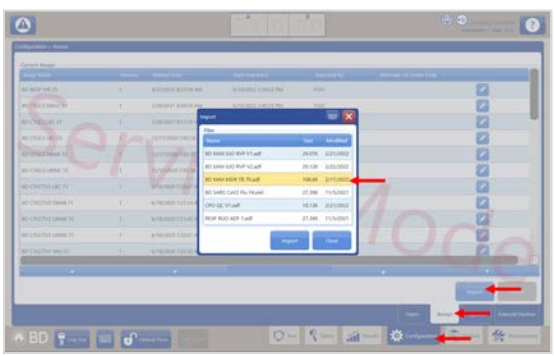


Figure 15: Import ADF

iii. In the Assays window, click on **Import**.

iv. Select "BD MAX MDR TB 70" from the file and click **Import**, then **OK**.

v. Record the ADF file name and version in "5. Preparation and identification of the testing" on page 167.

e. Execute the run

i. Go to **Run** and **Inventory** (see **Figure 6**)

ii. Update the inventory information.

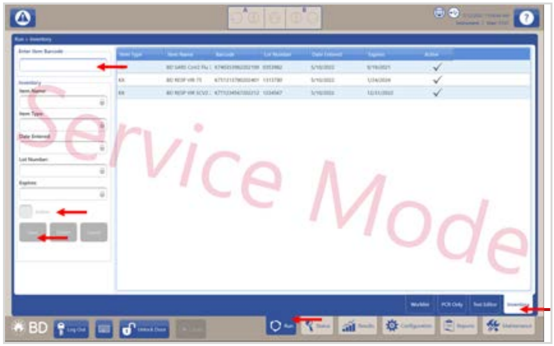


Figure 16: Kit Inventory

iii. Go to **Run** and **Worklist** (see **Figure 7).**

iv. Select the BD MAX MDR TB 70 and Kit lot.

v. Scan the MDR-TB QC Tool tube barcode.

vi. Depending on the worklist configuration Accession and Patient ID must be entered.

vii. Repeat the last two steps 24 times for a full run.

viii. Close the instrument door and press the **Start** button. A complete run of 24 samples will take approximately 3 hours and 40 minutes to complete.

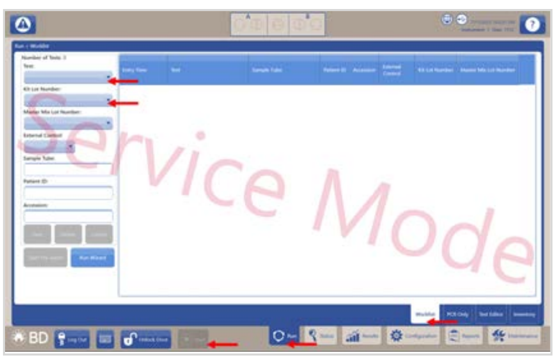


Figure 17: Assay run interface.

5. **Post-Run Review**

1. At the end of the run, examine the cartridges to evaluate the cartridge filling.

    1. Label used cartridges as "Instrument #+RUN # + Heater/Mux side".

    2. **Evaluate the Top and Bottom row cartridge filling.** All the lanes in both rows must be completely filled as "Good Fill". See **Figure 8**. If bubbles or partial fills are observed, record the cartridge lane position in the Comments section of Attachment A, perform the initial field action following to the latest version of the

BDDSSGFS7422 BD MAX Service Manual, and repeat the run if required (see Acceptance Criteria).

Figure 18: Cartridge example after the run showing both good and bad (bubbles) fills.

2. At the end of the run, examine, the unitized reagent strip (URS).
    1. Remove the test strips from the sample rack.
    2. For each strip, check that all foil covers of reservoirs and snap-ins are pierced.
    3. The Reaction tube will have a smear of magnetic particles along one side of the wall.
    4. The liquid levels should be like those shown in **Figure 9**.

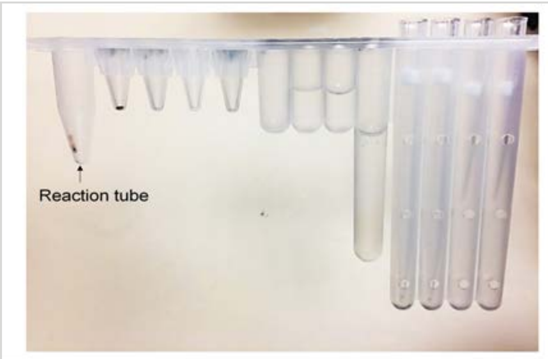


Figure 19: A picture of an MDR-TB strip following the run

    5. Any consumable errors (i.e., incorrect buffer levels, foil not pierced, magnetic beads in snap position 2, 3, or 4) should be recorded in the "Attachment A: MDR-TB Assay Fitness Test" on page 165 Comments section.
        a. Perform Initial Field Service Action following the BDDSSGFS7422 BD MAX

Service Manual.

b. Repeat the test if required (see Acceptance Criteria).

6. Data Analysis

a. Activate the following configuration on Maintenance/environmental variables.

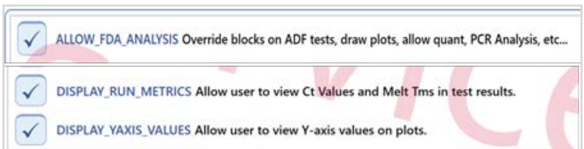


Figure 20: Maintenance/Environmental variables reference

b. Export the raw data (.csv) and the PDF on the USB key.

c. Expected results:

Position Test Name SP Status Kit Lot	Sample Tube PCR Status Cartridge Barcode	Patient ID Accession Master Mix Lot	Result	Ct 475/520 Melt 475/520	Ct 530/565 Melt 530/565	Ct 585/630 Melt 585/630	Ct 630/665 Melt 630/665	Ct 680/715 Melt 680/715
A1 BD MAX MDR TB 70 Success K70916274420200301	B22907463420200318BE76 Success C2490086082021012AD60	-- 01 --	MTB Detected RIF Resistance NOT Detected INH Resistance NOT Detected	31.5 26.5 -- --	-1.0 35.8 63.0 --	-1.0 -1.0 68.6 70.1	-1.0 -1.0 61.6 68.1	-1.0 -1.0 63.0 66.0
A2 BD MAX MDR TB 70 Success K70916274420200301	B22907463420200318BE38 Success C2490086082021012AD60	-- 02 --	MTB Detected RIF Resistance NOT Detected INH Resistance NOT Detected	31.5 26.7 -- --	-1.0 35.3 63.0 --	-1.0 -1.0 68.6 70.1	-1.0 -1.0 61.6 68.1	-1.0 -1.0 63.6 65.5
A3 BD MAX MDR TB 70 Success K70916274420200301	B22907463420200318AT67 Success C2490086082021012AD60	-- 03 --	MTB Detected RIF Resistance NOT Detected INH Resistance NOT Detected	31.6 26.8 -- --	-1.0 35.0 63.5 --	-1.0 -1.0 69.1 70.1	-1.0 -1.0 62.1 68.1	-1.0 -1.0 63.6 65.5
A4 BD MAX MDR TB 70 Success K70916274420200301	B22907463420200318AF56 Success C2490086082021012AD60	-- 04 --	MTB Detected RIF Resistance NOT Detected INH Resistance NOT Detected	30.5 26.4 -- --	-1.0 34.4 63.8 --	-1.0 -1.0 69.1 70.3	-1.0 -1.0 62.6 68.1	-1.0 -1.0 63.6 66.0

Ct
Tm

Figure 21: Expected Results from testing

d. Review results and record atypical results (Any result calls that are different from the expected results are considered atypical results) in "Attachment B: MTB Results Table" on page 173. Also, complete " 8. katG Channel Results Table" on page 169.

7. Acceptance Criteria

a. IND, INCs, samples with bubbles/partial fills in the top lanes of cartridges, or samples with consumable errors associated with katG results should not be included in the data analysis. IND and INC should undergo standard troubleshooting and sample repeat in the same bank.

b. For each Heater/Mux, if there is one or zero **atypical result**, then the Heater/Mux meets acceptance criteria and can be used for the MDR-TB assays if there are no other IND/INCs, bubbles/partial fills or consumable errors.

c. For each Heater/Mux, if there are two or more **atypical results** the heater/MUX does not meet acceptance criteria and a repeat test should be performed. Following the procedure above, the MDR-TB Assay will be tested again on that Heater/MUX.

d. Upon repeat.

i. Upon repeating the Bank, after an error occurs and there are one or zero atypical results, the Heater/Mux meets acceptance criteria and can be used with the MDR-TB Assay if there are no IND/INCs, bubbles/partial fills, or consumable errors.

ii. Upon repeating the Bank, after an error occurs and there are two or more atypical results, and the Heater/Mux fails to meet acceptance criteria. Follow the appropriate regional escalations path to escalate the issue.

iii. See the table below for the positions reported in the PDF report and the associated cartridge lane position.

Position in PDF Report	A or B 1	A or B 2	A or B 3	A or B 4	A or B 5	A or B 6	A or B 7	A or B8	A or B 9	A or B 10	A or B 11	A or B 12
Cartridge position	1	4	7	10	2	5	8	11	3	6	9	12

iv. Consult the latest version of the BDDSSGFS7422 BD MAX Service Manual to determine the root of the error generated in the Run; consult the event viewer for more information.

v. Repeat the samples in the same bank with IND, INCs, bubbles/partial fills, or consumable errors after executing the field actions.

4.6.1 Attachment A: MDR-TB Assay Fitness Test

1. Identification of the BD MAX instrument tested	
Instrument Identification	Repeat Testing: Yes ☐ No ☐

2. Material and solutions	**Lot number**	**Expiration date**
STR(443806)		
PCR Cartridge (437519)		
BD MAXTM MDR-TB kit (443878)		
MDR-TB Resistance QC Tool (444522)		

3. Preparation of MDR-TB Resistance QC Tools
Reconstitute MDR-TB Resistance QC Tools with 0.5ml of water and 1mL of STR using the transfer pipet supplied with the MDR-TB Kit.
Close the QC Tools with septum caps.
Invert the QC Tools 20 times.
Place QC Tools in the BD MAX sample rack.
Change gloves.

4. Assembly of components for unitized reagent strips (URS)
For each Heater/MUX, remove 12 MDR-TB assay URS and gently tap the strips against a hard surface to release any trapped air at the bottom of each tube and to ensure all the liquid is at the bottom of each tube.
Observe there are two long tips with filters next to the waste reservoir and two short tips with filters next to the URS barcode.
Place the URS into the BD MAX™ sample rack. Pull the URS out from the sample rack to ensure all the URS are aligned.
Identify and put the following components in the strips: • Extraction tube (snap 1 position) • Master Mix 1, M22 (snap 2 position) • Master Mix 2, M23 (snap 4 position)

5. Preparation and identification of the testing		
Identify and place the PCR cartridges in the BD MAX™ System(s).		
Identification of the BD MAX™	Software version	Run number
Select the ADF and version of the tested assay:		

6. Set-up and initiation of the BD MAX™
Insert the racks in the BD MAX™ System.
Verification of cartridges and strips: «snap-in» and tips (presence and position).
Scan the kit barcode into the inventory.
Go to **RUN** and **Worklist** to select the test and scan the QC tool barcode.
Close the door and start the assays by clicking on **Start**.

7. Save and analyze the data
Export the raw data (.csv) and the PDF report using the USB key.
Look for error codes, if present. Refer to "Diagnostics and Troubleshooting" on page 372.
Print and attach the PDF report file to this document.
Complete **Table 8** below using data from the printed PDF report to determine if acceptance criteria are met.
Update the attribute in ServiceMax.

8. katG Channel Results Table				
		Cartridge Positions of valid katG results reported as "INH Resistance Detected" or "INH Resistance UNREPORTABLE" or "MTB UNR" or "MTB Not Detected" (A)	Cartridge Positions of erroneous * katG results associated with "INH resistance detected" or "INH Resistance UNREPORTABLE" or "MTB UNR" or "MTB Not Detected" (B)	Interpretation of Data (Circle Conclusion)
Heater/MUX A NA ☐	Test 1 ☐ Test 2 ☐	ATOP1 ☐	ATOP1☐	If the total number of cartridge positions with valid katG results (A) is ≤1 and the total number of cartridge positions with erroneous katG result (B) ≥ 1:Perform initial field action following Troubleshoot according to the latest version of the BDDSSGFS7422 BD MAX Service Manual based on the error codes and then repeat samples (B)in the same lanes. Use a new form and report with current valid data.

8. katG Channel Results Table				
				Test 1: If A ≤1 katG results and B = 0: Pass. If A ≥2 katG results, perform Test 2 using a new form. **Test 2:** If A ≤1 katG results and B = 0: Pass. If B ≥2 katG results: Fail/ replace Heater/Mux
		ATOP2 ☐	ATOP2 ☐	
		ATOP3 ☐	ATOP3 ☐	
		ATOP4 ☐	ATOP4 ☐	
		ATOP5 ☐	ATOP5 ☐	
		ATOP6 ☐	ATOP6 ☐	
		ATOP7 ☐	ATOP7 ☐	
		ATOP8 ☐	ATOP8 ☐	
		ATOP9 ☐	ATOP9 ☐	
		ATOP10 ☐	ATOP10 ☐	
		ATOP11 ☐	ATOP11 ☐	
		ATOP12 ☐	ATOP12 ☐	

Heater/MUX B NA ☐	Test 1 ☐ Test 2 ☐	BTOP1 ☐	BTOP1☐	If the total number of cartridge positions with valid katG results (A) is ≤1 and the total number of cartridge positions with erroneous katG result (B) ≥ 1: Perform initial field action following Troubleshoot according to the latest version of the BDDSSGFS7422 BD MAX Service Manual based on the error codes and then repeat samples (B) in the

				same lanes. Use a new form and report with current valid data. **Test 1**: If A ≤1 katG results and B = 0:Pass If A ≥2 katG results: Perform Test 2 using a new form **Test 2:** If A ≤1 katG results and B = 0:Pass If B ≥2 katG results:Fail/ replace Heater/Mux
		BTOP2 ☐	BTOP2 ☐	
		BTOP3 ☐	BTOP3 ☐	
		BTOP4 ☐	BTOP4 ☐	
		BTOP5 ☐	BTOP5 ☐	
		BTOP6 ☐	BTOP6 ☐	
		BTOP7 ☐	BTOP7 ☐	
		BTOP8 ☐	BTOP8 ☐	
		BTOP9 ☐	BTOP9 ☐	
		BTOP10 ☐	BTOP10 ☐	
		BTOP11 ☐	BTOP11 ☐	
		BTOP12 ☐	BTOP12 ☐	

9. Comments:

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

4.6.2 Attachment B: MTB Results Table

Expected Results	Channel	WT Tm Range	Record atypical result	Record temperature	Lane	Pump
MTB detected (WT)	MM1: 475/520 MM2: 530/565	NA NA				
INH resistance not detected	KatG MM1 530/585	60.0-74.0				
	inhA pr MM1 585/630	65.1-79.1				
RIF resistance not detected	MM1 630/665 (R4)	58.1-72.1				
	MM1 680/715 (R1)	61.0-75.0				
	MM2 (585/630) (R2)	66.6-80.6				
	MM2 (630/665)	65.3-78.3				
	MM2 (680/715)	62.5-76.5				

5 Maintenance

This section details the procedures for maintaining the BD MAX. Proper maintenance is necessary for the BD MAX to produce consistent quality slides. If neglected, the instrument performance may deteriorate over time.

5.1 Preventive Maintenance

This section provides information on performing preventive maintenance on the BD MAX instrument.

BD MAX™ System User's Manual References:

- International Windows Version - **Document No. 8089570**
- US Open System Windows Version - **Document No. 8089571**
- US Open System Windows Version -**Document No. 8089571**

> **Note:** For service compliance reasons, always confirm that the document is the most current revision available in SAP. Contact the BD MAX System Support Specialist (SSS) or Technical Education Specialist for additional information if needed.

Associated Procedures:

"PM Checklist" on page 594.

"Qualification Run" on page 322.

"Qualification Checklist" on page 597

Materials

Item	SAP	Qty
PM Kit	435253	1
Service Alignment Tool Kit	441998	1
Qualification Kit (1 backup)	444048	2
Load Cartridge Test Kit	445028	1
Box of 24 Cartridges	437519	1
Calibration Plate	435251	1
Calibration Plate 6 Color	435256	1
Multi Meter		
#10 Torx Security driver		
Assorted Hand Tools (Metric and Standard)		
Ultra-fine Scotch-Brite Pad (7448 or equivalent)		

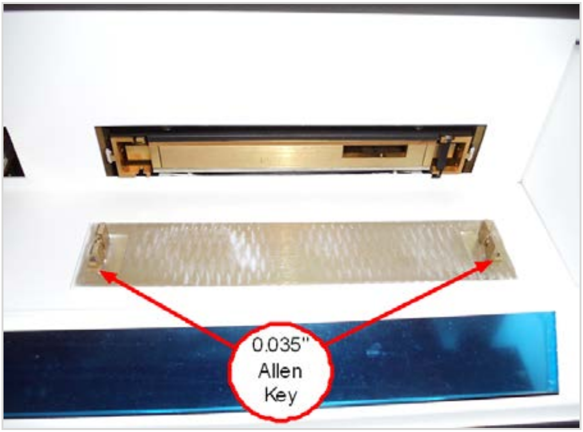
Warning: The BD MAX instrument uses electrical voltage and power levels that are potentially lethal. During normal operations, these voltages are internal to the instrument and do not present a hazard. However, while testing, troubleshooting, and performing maintenance, it is sometimes necessary to remove parts of the instrument enclosure exposing electrically charged circuits. When the High Voltage symbol appears in this procedure, use safety precautions.

Warning: The BD MAX instrument contains Electro Static Discharge (ESD) sensitive components. When servicing the instrument, ESD protection must be utilized to prevent possible damage to sensitive components. Failure to follow proper ESD precautions can induce intermittent and/or catastrophic failures. When the ESD Discharge symbol appears in this procedure, use proper ESD techniques.

Note: All warnings and cautions should be observed while servicing BD MAX instrumentation. All discrepancies should be documented in Service Max and service personnel should always reference the latest service bulletins.

Procedure

1. Open the instrument door and turn off the power to the instrument.
2. Use the black nozzle block to keep the tips raised when moving the robot.
3. Remove the front skirt by lifting it upwards at both ends and pulling away from the instrument. The front skirt contains the input air filter. Clean the air filter. If the filter (SAP 435226) is damaged, make arrangements to replace it.
4. Remove the upper waterfall with the following steps:
   a. Ensure the instrument power is turned off
   b. Remove both tray covers using the 0.035” Allen key from the PM kit.

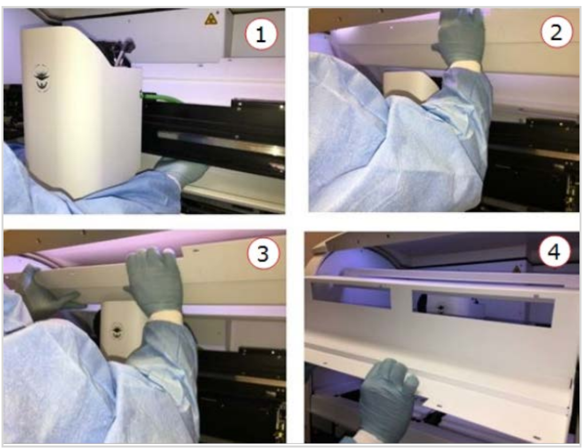


   c. Remove the five T10 torx screws from the top back of the rear upper reader cover.

   d. Remove the two white nylon thumb screws just in front of the mirror and on the left and right sides.

e. Push the trays all the way in and pull the X gantry all the way to the front of the instrument.

f. Slowly lift up the rear upper waterfall, moving the robot towards the back of the instrument as the cover it is rotated over the top of the robot.

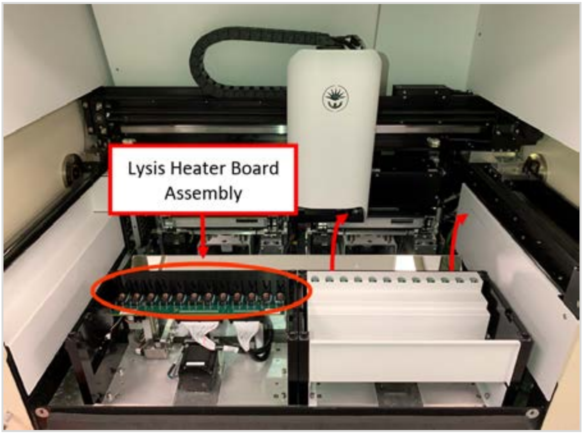


5. Remove the lower waterfall with the following steps:

   a. Remove the left and right front screws.

   b. Push the robot to the back of the instrument.

c. Lift the front of the lower reader cover until the rear lip rotates below the mirror.
d. Slowly lift the cover up and towards you, removing it from the instrument.



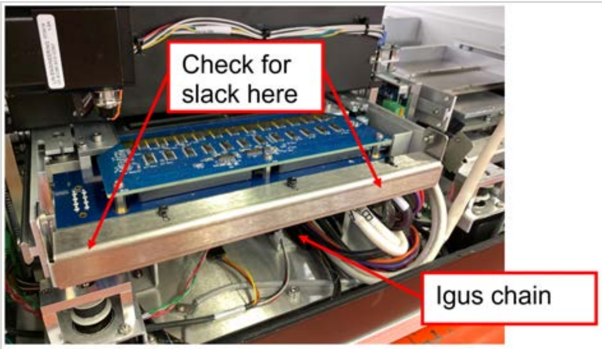
Warning: Static Sensitive Circuits and Dangerous Voltages are exposed once the covers are removed. Use appropriate ESD and Electrical Safety practices

6. Remove each reader and use a lint-free cloth to clean the glass heater surface and the reader aperture plate for each reader. When cleaning, go along the aperture plate. Do not touch either the aperture plate or the Heater glass surface with your hands. Be careful not to damage the surface of the heater boards. Use denatured alcohol to remove more stubborn material.

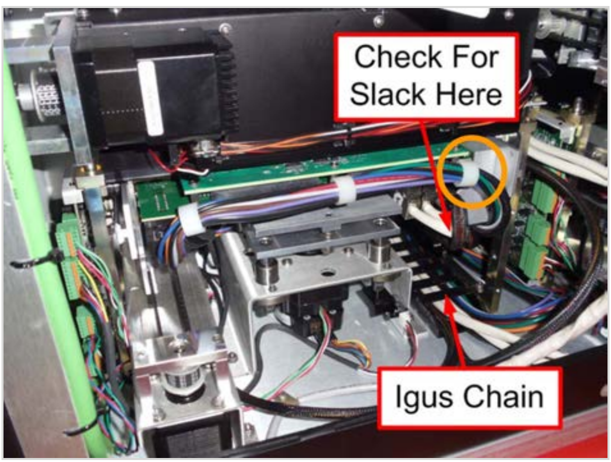
7. Inspect moving parts for wear and loose hardware. If there is extensive wear and/or damage, make arrangements for replacements.

- Tighten the 1/8 inch and 5/32 inch hex screws securing the door to each side wall.
- Tighten the screws on and around each tray, especially near the rails.

8. Check the heater MUX boards' cable tension by moving the drawers in/out and up/down. The heater mux should fall straight down and rest on the metal tray. Observe if the cables and Igus chain are interfering with drawer movement and that the connections are secure.



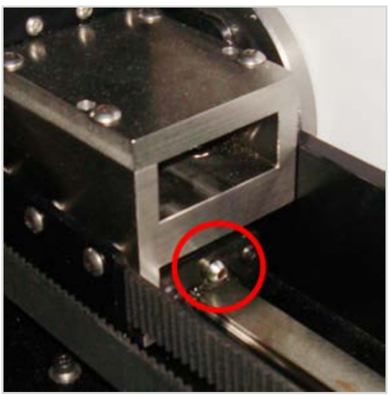
9. For instruments with the white heater mux cable loops, check that the cables are not preventing the heater mux from moving up/down freely. Removing the cable loop (circled in orange) above the SCSI cable connections can alleviate tension.



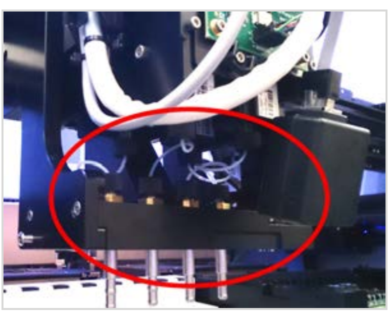
10. If any strain or movement interference is noted, adjust the cable slack and positioning while moving the drawers in/out and up/down. Check the condition of the cable to make sure there are no signs of damage.
11. Inspect the rails for any signs of oxidation.
    a. Remove any oxidation with an ultra-fine Scotch-Brite pad.
    b. Clean off any residue with a lint free cloth.

12. Lubricate moving parts:
    a. Manually lubricate all rails with the lithium bearing grease. Make sure the back and front parts of the Y- and X-gantry rails are well lubricated, as these parts are outside of the Y- and X-axis travel and do not get lubrication during normal operations.
    b. Pack the bearing carriages for the X- and Y- axis with the disposable grease gun (1 to 2 pumps). There are four of these, one on each side of the X gantry, that lubricates the Y-rails and one on the Z-Gantry that lubricates the X-rail.

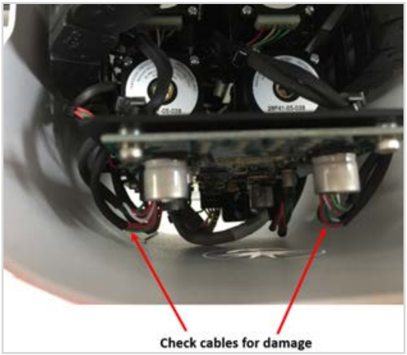
    Note: Please change gloves before proceeding.

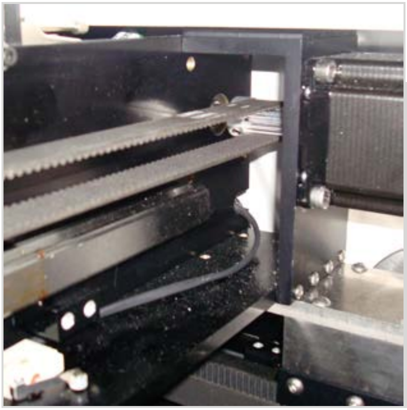
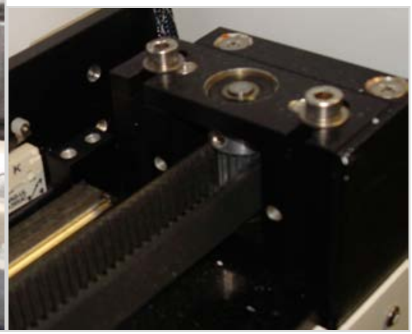
13. Check the extractor magnet alignment for both sets of magnets.
14. Check all airline connections on the Z-Head.
    a. Make arrangements to replace any worn or damaged air lines.
    b. Hands tighten as necessary.

15. Inspect cables on the Z-head for damage. Ensure they are not rubbing on the Z-head façade.



16. Inspect Motor belt drive gears and idler gears on the X- and Y- gantries. If there is extensive wear and/or damage, make arrangements for replacements.
17. Visually inspect the X- and Y- gantry drive belts. If there is extensive wear and/or damage (tears, cracks, etc), make arrangements for replacements.

18. Check all rack sensors (SAP 435222) and ensure edges are not worn down or broken. If a sensor is broken or damaged, replace as needed.
19. Perform extractor magnet alignment (see "Extractor Magnet Alignment" on page 513).
20. Check overall cleanliness of instrument interior and exterior.
    a. DO NOT use canned or compressed air to clean out the instrument.
    b. Use a portable vacuum cleaner, lint free clothes, and denatured alcohol to clean the inside of the instrument if necessary.
21. Turn instrument power on and measure the Power Supply Voltages on the Liberty board test points in front of the left reader as per next Table.

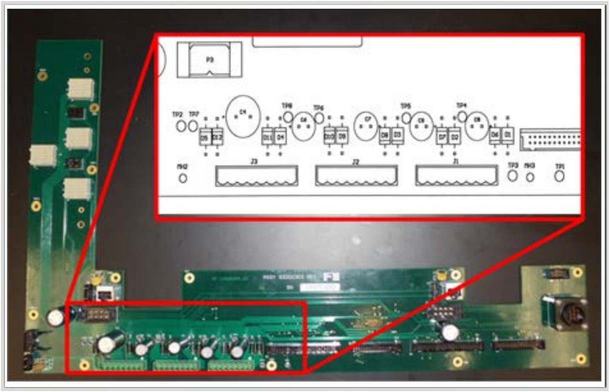
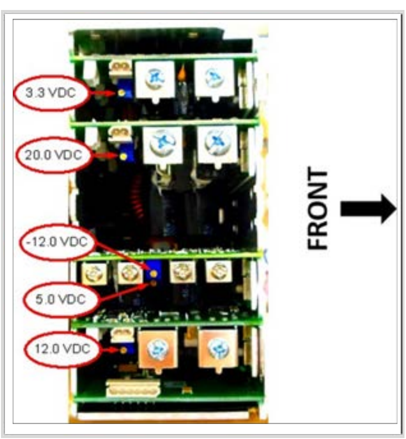


Table : Test points

TP1 (GND) – TP3 (11.4Vdc to 12.6Vdc)
*TP1 (GND) – TP4 (5.13Vdc to 5.17Vdc)
*TP1 (GND) – TP5 (3.47Vdc to 3.49Vdc)
TP1 (GND) – TP6 (-11.4Vdc to -12.6Vdc)
TP2 (GND) – TP7 (19.0Vdc to 21.0Vdc)
TP2 (GND) – TP8 (22.8Vdc to 25.2Vdc)

*Critical values

22. Adjust all out of specification voltages. See figure 8 for location of voltage adjustment potentiometers.



23. Re-assemble the instrument and remove the black nozzle block.

24. Perform gantry alignment using the calrack.script

Verification

Perform the following Verifications:

a. "Self-Test " on page 474.

- Confirm all parameter PASS at the end of the table.

b. "CatalogWin.Script" on page 488

- Confirm the Barcodes are read with one clear Beep in the designated marked area.

c. "Load Cartridge Check" on page 500.

- Visual confirmation: The PCR cartridges are full.

d. "Empty Fill Check Errors" on page 454.

- Confirm the values are below 350. Cleaning is required if the range is 350 to 450.

e. "Procedure Normalizer Ratio Check" on page 492.

- Confirm there is no renormalized message on the text. If needed, perform "Procedure Reader Normalization" on page 495.

f. Perform full qualification run. Refer to "5-Channel Qualification Test" on page 325.

> **Verification:** After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.1.1 General Health Check

The purpose of the **General Health Check** is to check the overall performance of the instrument.

> **Note:** Detailed procedures are available in previous sections of the Service Guide.

1. Perform Backup database 6.4.13 Database.
2. Note down system configuration under 4.2.4.3 system sub-tab.
3. External devices configuration 4.2.4.6

   Backup:

   The IPs address and port numbers.

LIS configuration

Synapsys configuration.

Prewarm connection.

Backup all UDP from the customer.

4. Perform the following verifications on the side or sides required and note any difference from the expected results.

   Power system verification:

   Power Supply Voltage Adjustments 5.2.1

   Detection:

   EFC. 6.10.4.1. Clean if needed (**Use only Alcohol 70% and DI water**)

   Muxes Selftest. 6.4.6

   Ratio verification 6.4.10.2

   PCR temperature test. 6.4.5

   Pressure Plate setings 6.4.8

   Reader tray position 6.4.4

   Lysis Heater Test 6.4.7

   Robotics

   Z-Gantry Stall Script 6.4.1.19 (If the difference from steps is more than 10 steps, consider to re-clean the z Gantry and/or replace the Z Motor)

   Gantry alignment 5.1.3.2

   Extractor Magnet Alignment 6.4.17

   Magnet Height Correction 6.4.18

Verification:

1. Run the QPM 5.3.3, programmed for four samples on the A side and four samples on the B side.
2. Determine the aspiration and dispensing on the cartridge. Visual observation is required.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

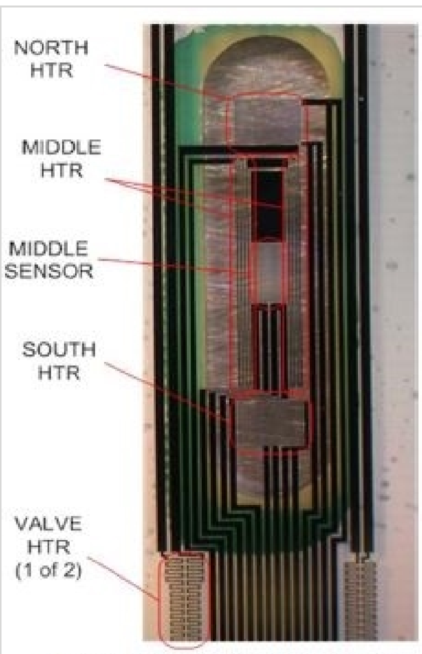
5.1.2 Heater MUX Board Maintenance

The heater MUX assembly is within the reader drawer and includes two printed circuit boards, a control board and a heater wafer board (the glass PCR heater surface on which the cartridges are placed).

Background

A study on premature failures of the heater MUX assembly showed some type of corrosive or mechanical damage that was evident across approximately 85% of the failed returned heater MUX assemblies.

Working in conjunction with the manufacturer of the board, BD has confirmed that exposure of the heater MUX board to chemical cleaning agents such as 1% Sodium hypochlorite solution (bleach) and hydrogen peroxide can damage the traces resulting in the heater failure.



New Heater Board without Damage

The damage often manifests over a long period of time and is not easily visible to the naked eye; usually requiring a microscope to visualize it. Improper cleaning of the heater wafer board, even if only intermittently, may result in the long-term and irreversible damage to the board.

Below is a picture taken from under the microscope of a damaged heater board.

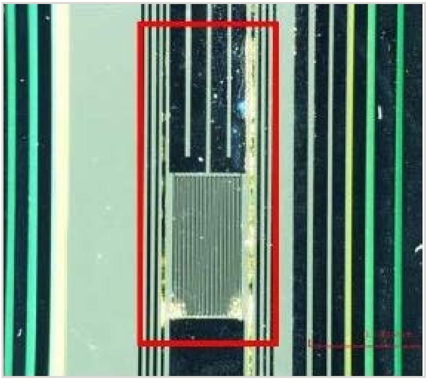


Fig: Heater Board with damage due to bleach use (in red rectangle area)

Fig: Heater Board with corrosive damager (enlarged)

The site used 1% Sodium hypochlorite to wipe down the glass surface.

The corrosion caused the heater traces to short. Electricity could no longer flow, resulting in a failure of the affected heater lanes and PCR heater errors.

Procedure

Cleaning of the PCR cartridge drawers: Clean only when there is a foreign object, dirt or dust visibly present using a lint -free cloth.

1. Use a lint-free cloth.
2. Dampen the cloth using **ONLY** 70% Isopropyl alcohol (IPA).
3. Using very light pressure, wipe the glass surface in a single direction (DO NOT wipe back and forth).
4. When visiting customer sites for PM or in response to Heater MUX complaints, be sure to remind the customer of this procedure.

5.1.3 Lubrication

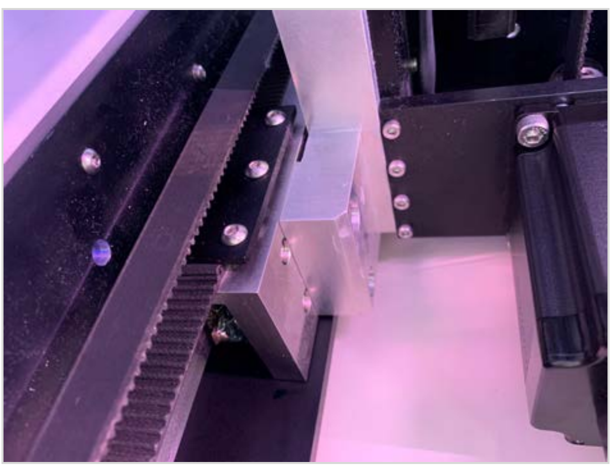
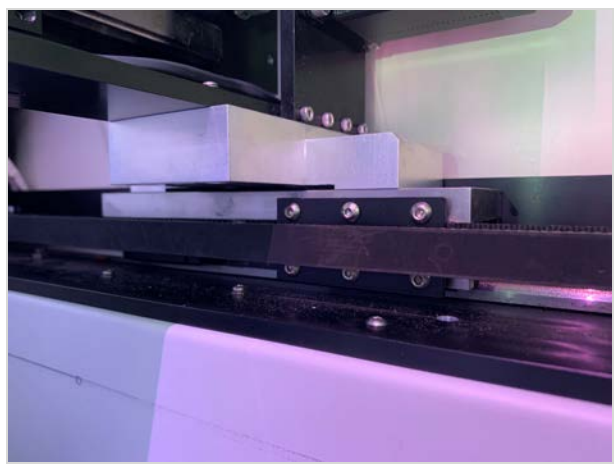
Several moving parts on the BD MAX instrument require periodic lubrication; these are outlined in the PM procedure. This section describes lubrication of the X-, Y- and Z-Gantries.

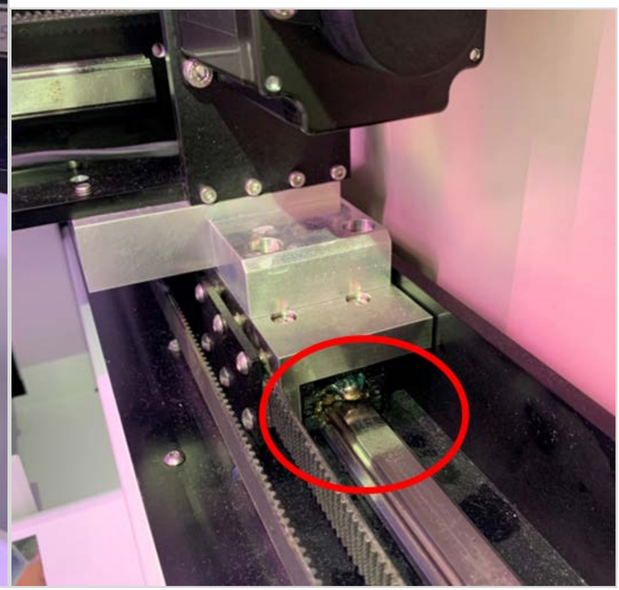
Grease from BD MAX PM Kit **(SAP Catalog No. 435253)**. This is the only acceptable and approved grease /lubricant. Other lubricants such as silicon oil should not be used.

5.1.3.1 X/Y-Gantry Lubrication

1. The X and Y Gantries are lubricated with a high quality medium weight lithium bearing grease. The BD MAX PM Kit includes disposable applicator.
2. There are three or four zirc fittings (depending on the serial number of the instrument).
   - **MX** and **CM** series instruments have **three zirc fittings**.
   - **CT** and **CR** series instruments have **four zirc fittings**.

   The zirc fittings are provided for lubrication of the slide rails and carriages for the X and Y Gantries:
   - **One** on the left Y-Gantry carriage
   - **Two** on the right Y-Gantry carriage (only **one** on MX, CM series instruments)
   - **One** on the X-Gantry carriage.

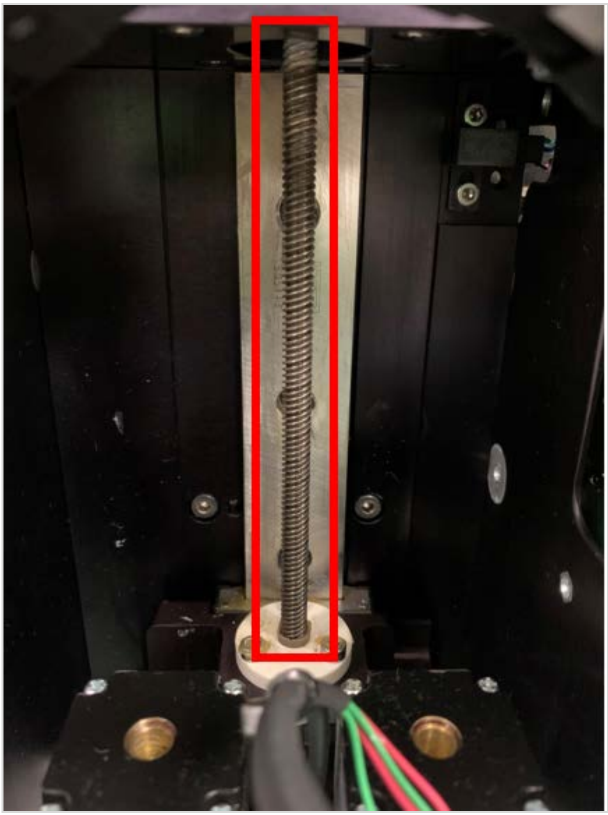


3. Manually lubricate the ends of all rails with a light coating of grease.

> **Note:** Do not over-lubricate the slides. Two pumps from the disposable grease applicator in the PM kit are sufficient for each slide. These are the areas of the rails where the gantry carriages do not move, and these are not lubricated by gantry travel.

5.1.3.2 Z-Gantry Lubrication

1. Completely remove the old grease and clean the lead screw before applying any new grease.
2. Use a high quality, light weight, white Lithium grease to lubricate the **Z**-Axis threaded drive shaft.
3. Thinly spread a small amount over the threads (about the size of a pea).
4. Move the **Z**-head up and down several times to evenly distribute the lubricant.



5.1.4 Discoloration Gantry Rails

Discoloration may be observed on the gantry rails. This is generally caused by insufficient lubrication of gantry carriage bearings. Exposure to cleaning chemicals and other environmental factors may also discolor gantry rail ends. Use the following materials and procedure to clean discoloration from the gantry rails.

Document: BDDSSGFS7422 Doc Type: ZIP Status: Released EFFECTIVE
Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

Required materials

- Scotch-Brite 7448
- Lint Free Wipes
- Alcohol
- Lithium bearing grease from PM Kit.

Procedure

1. Use the Scotch-brite pads to clean the oxidation from the rails.
2. Wipe down the rails with the lint free wipes that have been dampened with alcohol to remove any residue.
3. When the rails are clean and dry, apply a thin coat of grease by hand.

5.1.5 X/Y-Gantry Belt Tension

Required materials:

- Tension Rite Belt Frequency Meter (443969)
- Tension Rite Belt Frequency Meter User Manual.

References:

- BALTEC0271, BD MAX™ instrument manufacturing procedure for belt tension
- IDSLID-10119, Calibration System.

Procedure

1. Replace the instrument belt:
   a. Adjust the belt tension based on feel and past experience.
   b. Use the meter to fine tune the belt tension.
2. Record the serial number of the belt tension meter in **Work Order** notes.
   a. The belt tension frequency meter does not require annual calibration. It must be verified before use.
   b. Each meter should be labeled according to **IDSLID-10119**.
3. Remove the included tuning fork found in the case with the frequency meter. A target frequency is found near the handle of the tuning fork.
4. Record the target frequency in the **Work Order** notes.

5. Turn on the belt frequency meter.
6. Ensure that the meter is set to Hz. Use the up or down buttons to adjust the setting of the meter. The setting is visible on the left side of the readout window.

   If the display does not read **zero (0)** after changing from a force value to Hz it will not affect the value given by the meter.
7. Lightly strike the end of the tuning fork against a hard surface and hold steady approximately **1/2 inches** away from the optical sensor.

   > **Note:** Tap tip of the tuning fork on a hard surface and then hold steady in front of optical sensor at a distance of 1/2 inches. The meter will measure a frequency of 250Hz thus demonstrating that it is in calibration.
8. A reading is displayed on the Belt Frequency Meter while steadily holding the vibrating tuning fork close to the sensor.
   a. Record this number in **Work Order**. This helps verify the correctness of the meter operation.
   b. If this number is not within the acceptable range specified in the **Tension Rite Belt Frequency Meter User's Manual**, the meter must be removed from service.
9. Verify or store the meter's settings
   a. The meter settings are dependent on the mass and span of the belt being measured. Place the settings as in the table into the meter's for ease of use.

      > **Note:** Check the settings before each use.

Memory Location	Belt	Span Setting	Mass Setting
MEM1	X Gantry	0.812	0.034
MEM2	Y Gantry	0.572	0.034

b. To check these values, press the button of the memory location you wish to check. Then, press:
- The span button to check the span.
- The mass button to check the mass.

c. To adjust a setting, for example to set the **X-Gantry (MEM 1)** span setting,while holding down the span button use the up and down buttons to get to 0.812.

d. Release the span button. Press the **MEM 1** button and two beeps will confirm that your setting has been stored.

e. Repeat steps if necessary until your settings are correct for the assembly being built.

10. Press the **Down** button to change the meter's units to pounds (Lbs). The units are visible in the left portion of the display.
11. Select the memory settings for the belt being tested. Before testing the X Gantry select **MEM1** and before testing the Y Gantry, select **MEM2**.
12. Use the **Span** and **Mass** buttons to confirm that the appropriate values have been stored in that memory location.
13. Pluck the belt as if plucking a guitar string with a finger.
14. While the belt is vibrating, hold the meter's optical sensor approximately **1/2 - 1 inches** away from the center of the belt.

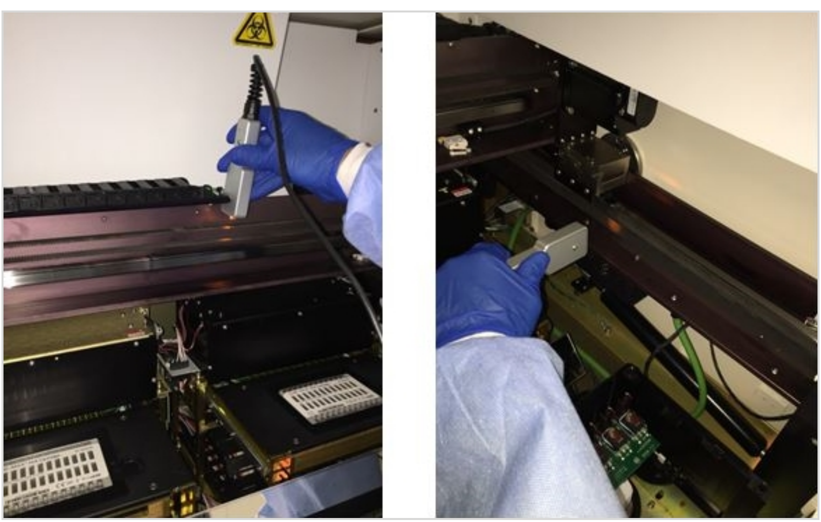


Fig: Checking X-Gantry belt tension (left) and Y-Gantry belt tension (right)

15. The meter displays the value quantifying the belt tension.
16. Adjust the belt tension accordingly and recheck until the tension is within the specified range.

BELT	Tension Range
X-Gantry	20.0 ± 2.0 lbs (9.0 ± 0.8 kg)
Y-Gantry	20.0 ± 2.0 lbs (9.0 ± 0.8 kg)

5.1.6 Long Term BD Max Shut Down

All instruments with a Long Term Shutdown (More than 30 days).

A full PM needs to be performed.

Verification:

"Preventive Maintenance" on page 174.

Perform three "Qualification Run" on page 322.

Verification: All serviced/installed instrument shall be verified to perform as intended after servicing/installation activities. Results of inspection(s) and test(s) performed during servicing / installation activities shall be documented in Service Management System, as required.

5.2 Corrective Maintenance

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.1 Power Supply Voltage Adjustments

Measure and adjust power supply voltages.

Required materials

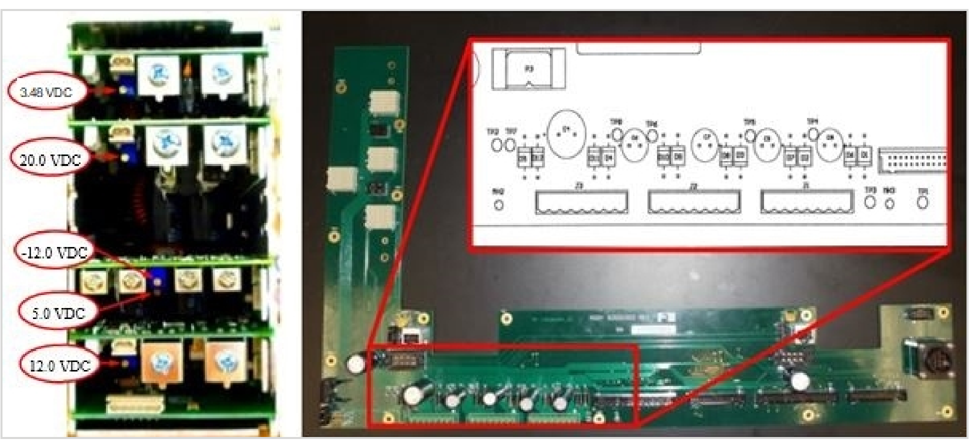
- Digital Multimeter
- #10 Torx
- 9/16 inch socket

The most appropriate areas to measure voltages on the BD MAX are the test points on the Liberty Board. Verify voltages:

- TP1 (GND) – TP3 (11.4Vdc to 12.6Vdc)
- **TP1 (GND) – TP4 (5.13Vdc to 5.17Vdc)***
- **TP1 (GND) – TP5 (3.47Vdc to 3.49Vdc)***
- TP1 (GND) – TP6 (-11.4Vdc to -12.6Vdc)
- TP2 (GND) – TP7 (19.0Vdc to 21.0Vdc)
- TP2 (GND) – TP8 (22.8Vdc to 25.2Vdc)

*Critical values

> **Note:** Power Supplies are behind the rear top left panel. See "Instrument Skins" on page 197 for skin removal instructions. Adjusting voltages requires the power supply be leaning forward for free access to its top.



Adjust accordingly using the small potentiometers accessed from the top of the power supply.

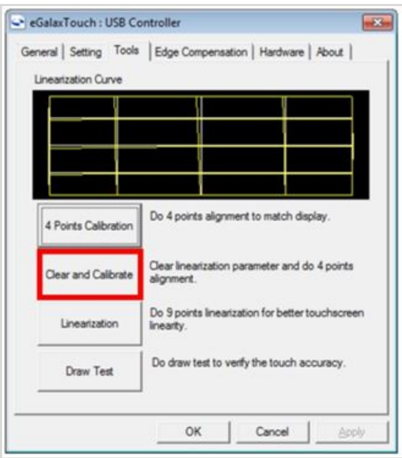
5.2.2 All-In-One Screen Calibration/Linearization

Accurately align the BD MAX All-In-One Touch Screen to the graphical interface. There are two types of calibration:

1. **Four Point Calibration** uses touch points corresponding to each corner of the screen and is generally sufficient to calibrate the screen.
2. **Nine Point Calibration** uses touch points corresponding to the 4 corners, the middles of each side, and the screen center; it is used when Four Point Calibration does not succeed.

Procedure:

1. Log in as user **FSVC**.
2. Click **Calibrate Touch Screen** from the **Maintenance Field Service** screen. This opens the **eGalax Touch USB Controller** window.
3. Click to open the **Tools** tab.
4. Click **Clear and Calibrate** to clear all previous settings and allow you to do a four point calibration.



5. Starting in the lower right corner, press and hold the center of the red target icon, releasing once the icon turns blue.

> **Note:** For ease of use, use a stylus of some sort rather than a finger.

6. Continue on to the next red target icon until all four corners have been programmed. The new calibration data is saved upon completion.

7. Check the accuracy of the screen cursor by touching the screen at several different points.

8. If there are discrepancies, click **Linearization** and complete the Nine Point Calibration in the same manner as the Four Point Calibration.

Verification:

1. Restart the AIO
2. Select several menu options and confirm the software responds to the touching commands.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.3 Screen Capture

Specific screen images from the BD MAX can be captured for use in troubleshooting, training and educational materials.

Refer to **Technical Service & Support Data Download Procedure** for instructions on handling patient data.

Required materials

USB Flash Drive

Procedure

1. Set up the screen shot to be captured.
2. Insert the USB device into the AIO.
3. Press **F10** and wait for 10 seconds. The image is saved to the USB device as a**.png** file.

Verification:

1. Confirm in the external PC/Laptop the file is stored in a folder at the top level of the USB drive.
2. Confirm file names include the instrument serial number as well as the date (yyyy-mmdd) and time (hhmmss), seconds are included in the name to minimize the chance of overwriting an image.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.4 Instrument Skins

With the exception of the Z-Head and select parts of the Gantry assemblies, some instrument skins must be removed for repair and/or replacement activities.

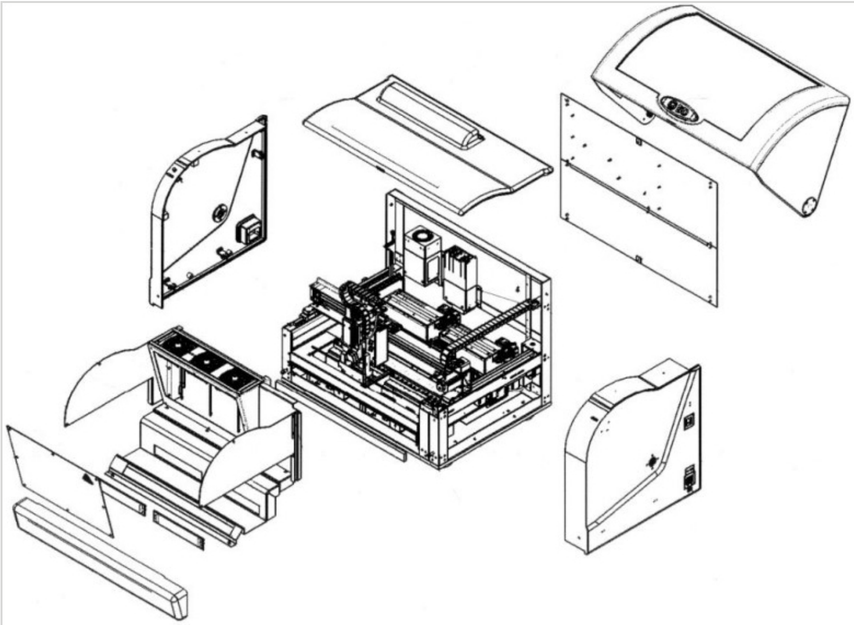
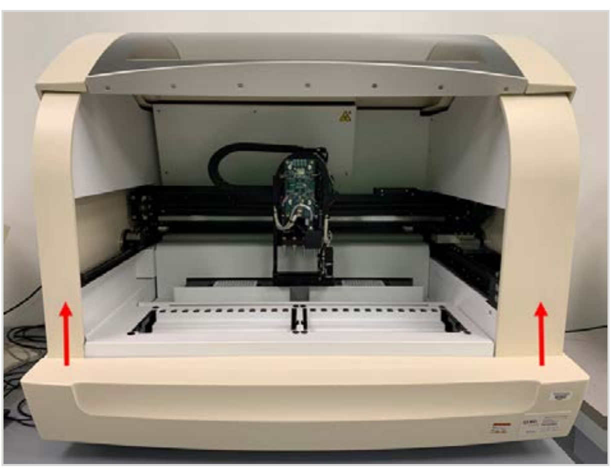


Fig: BD MAX Exploded View - Skins and Panels pulled away

> **Note:** Before performing any actions in this chapter, one is required to wear PPE. At a minimum, disposable Nitrile gloves, disposable lab coats, eye protection is required, in addition to any adherence with the customer site. Ensure proper ESD protection when working with sensitive electronic components (e.g., boards). Use universal precautions at customer sites as the instrument may contain **target**.

5.2.4.1 Skins Removal

1. Open the BD MAX door.



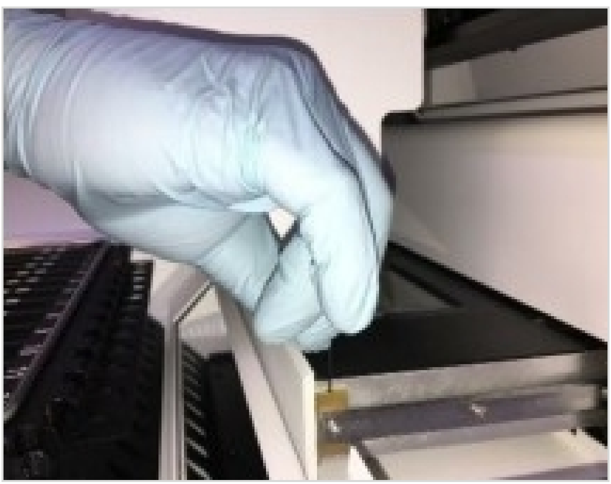
2. Push up on both ends of the skin, pulling the catches off the posts, and then pull the skin away from the instrument.

5.2.4.2 Upper Reader Cover Removal

1. Remove the two nylon screws that connect the lower and upper covers.

2. Remove the five **#10 Torx** screws from the rear portion of the **Upper Reader Cover**.

3. Use a **0.035 inch** hex key to remove the outer drawer facade from both drawers. Then push the drawers all the way in.



4. Move the robot gantry to the front of the instrument.
5. Lift the rear section of the Upper Reader Cover and rotate it over the robot gantry.
6. Push the robot gantry towards the back of the instrument while rotating the cover over the top.

Front Panel Assembly (445345)

> **Note:** Use only the Allen Key provided in the PM Kit or specific Allen key with **0.035 inch**.

The legacy Front Panel Assembly has two 0.035-in screws. Instructions for removal and installation are found in the BD MAX Service Manual (BDDSSGFS7422).

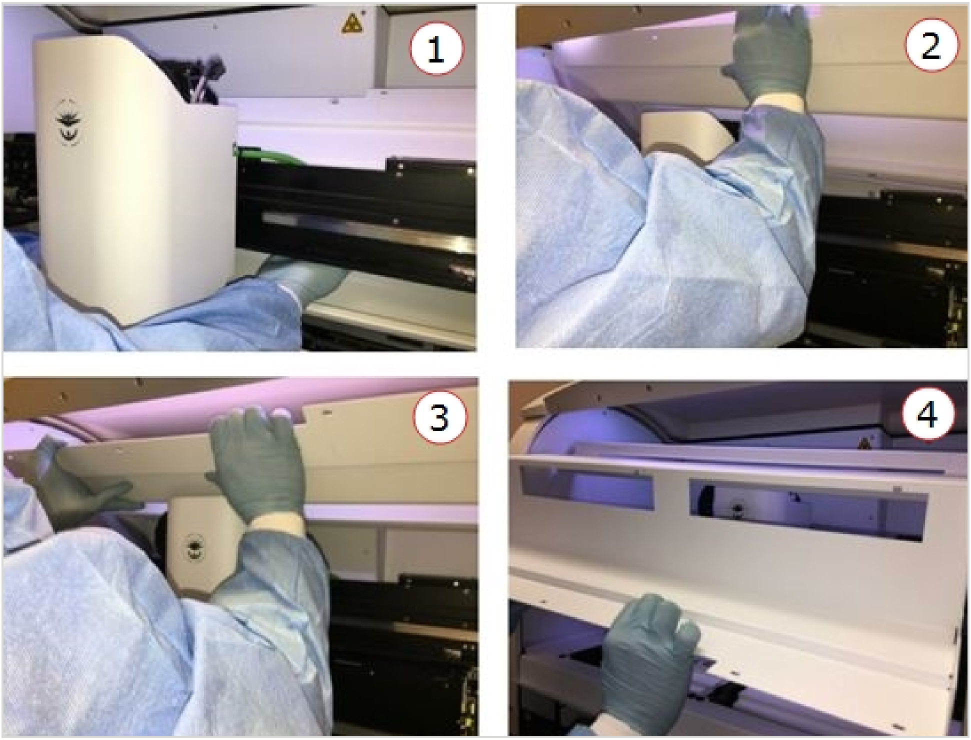
Fig: Front Panel Assembly (Legacy)

Front Panel Assembly MAX PLUS (445346)

The New Front Panel Assembly is installed and removed the same as the legacy version but has two 1/16-in screws instead. The old and new front panel assemblies are specifically designed for the old and new PCR trays, respectively, and are not interchangeable. The part is included from BD MAX CT3050 inclusive.

Fig: Front Panel Assembly (MAX PLUS)

7. Remove the cover from the instrument.



Facade 2X Reader Assay MOD MAX Spare

Instructions for removal and installation are found in the BD MAX Service Manual (BDDSSGF7422). After installation, complete the post-install verification "Facade 2X Reader Rack MAX Spare" on page 214.

5.2.4.3 Lower Reader Cover Removal

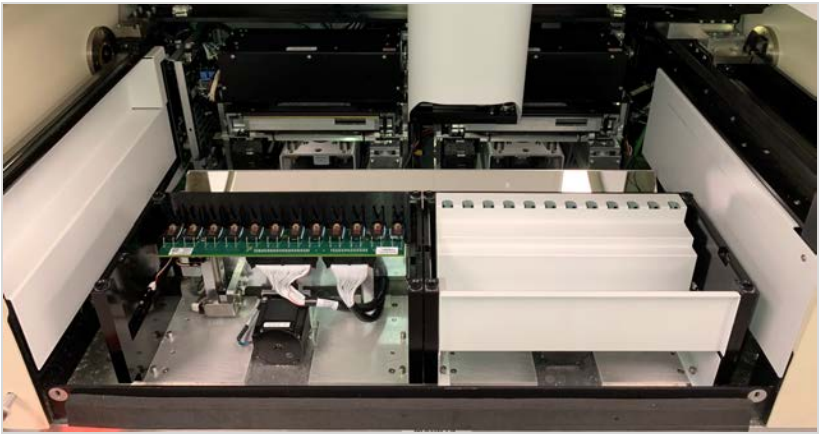
> **Note:** The upper reader cover and front skirt must be removed before the lower reader cover can be removed.

1. Once the front skirt is removed, remove the two **#10 Torx** head screws from the lower right and left sections of the Lower Reader Cover.
2. Tilt the front of the Lower Reader Cover upwards to free the rear lip and pull it out of the instrument.

5.2.4.4 Lysis Cover Removal

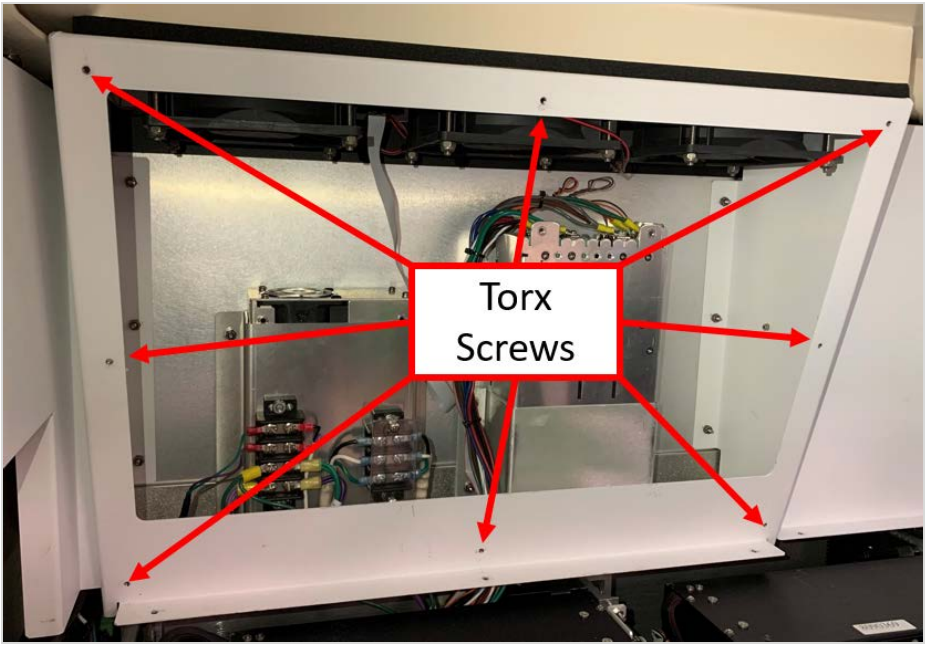
Note: The Lower Reader Cover must be removed before the Lysis covers can be removed.

1. Lysis Covers are removed by lifting them straight up about **1 inch**, then tilting them slightly forward to clear the Lysis Heater board assembly.



5.2.4.5 Fan/Power Supply Cover Removal

1. Remove the eight **#10 Torx** screws from the cover, and then tilt the panel forward to remove the cover.



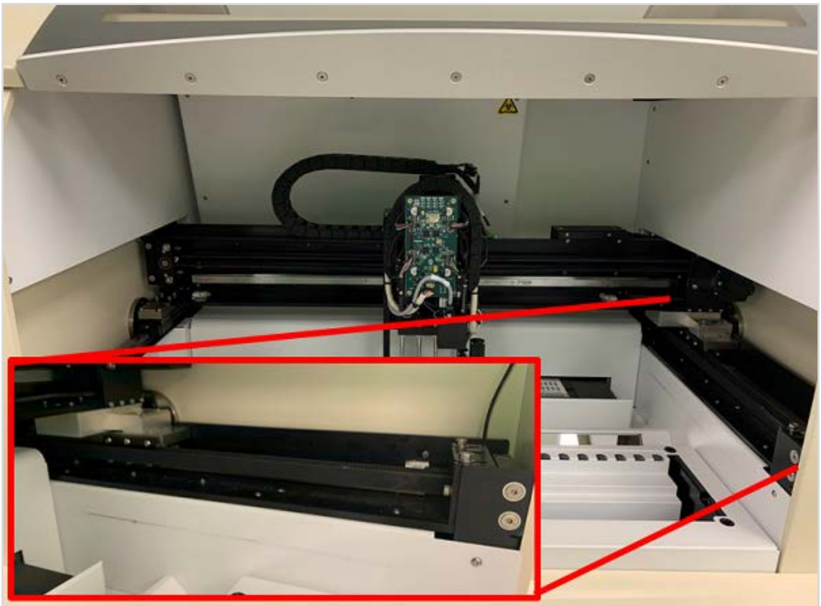
5.2.4.6 Right Guard Removal

1. Remove the five **#10 Torx** screws.

   Three are fastened to the horizontal support rail and two are fastened to the vertical support rail.

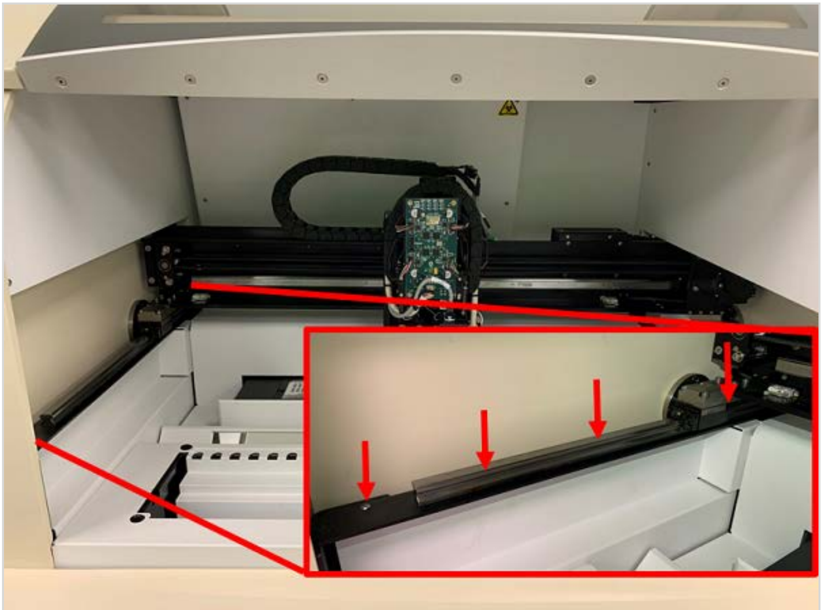
2. Hold the guard while removing the fasteners (which drops when all the fasteners are removed).

Warning: There are no guards on the underside of the fans. Ensure power to the instrument is secured before removing the Fan Duct Cover. **Do not work in this area** unless power is secured.



5.2.4.7 Left Guard Removal

1. Remove the four **#10 Torx** screws fastened to the horizontal support rail. Hold the guard while removing the fasteners to prevent it from falling.



5.2.4.8 Door and Nitrogen Gas Spring Repair

Required Tools

- Magnetic Bowl
- 0.035” Allen wrench
- T10 Torx Screwdriver
- Channellocks (Tongue-and-groove pliers)
- 5/32” Allen T-handle
- 1/8” Allen wrench (Ball end)
- Loctite

Note: At least 2 FSEs are required to perform this repair

Removing Door Procedure

1. Open the BD MAX Door and power down the system.
2. Remove the following skins:
   a. Front skirt
   b. Tray covers
   c. Upper reader cover

d. Lower reader cover
e. Lower right panel

Fig: Necessary skins removed

Caution: When working a door that is not supported by the gas spring, have another FSE hold the door up so that he door does not fall down.

3. Disconnect the ball joint between the gas spring and arm damper (See Appendix 1).

Note: The gas spring (444782) is loaded with ~40lbs of force. It is easier to disconnect the gas spring using channellock pliers with the door completely open.

Caution: The tray drive housing and mirror are very sharp. Use extreme caution.

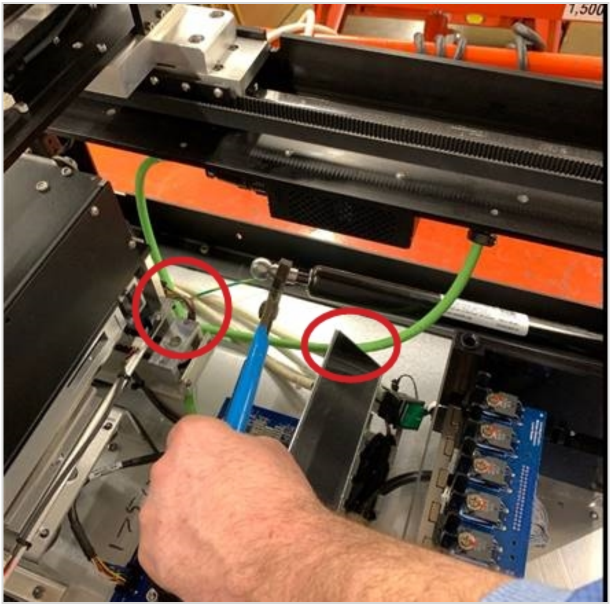


Fig: Using channellocks to grip gas spring – (left) unloaded; (right) loaded. The tray drive housing and mirror, circled in red, are very sharp. Always wear proper PPE when servicing a BD MAX in ordinary field settings.

Disengaging RIGHT side

4. Slowly push the Z-gantry to the back of the instrument to expose the main screw securing the right side door hinge. Unscrew using a 5/32” Allen wrench.

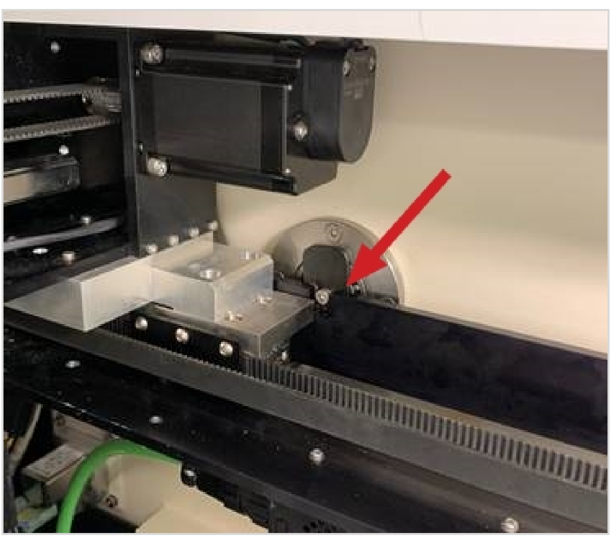
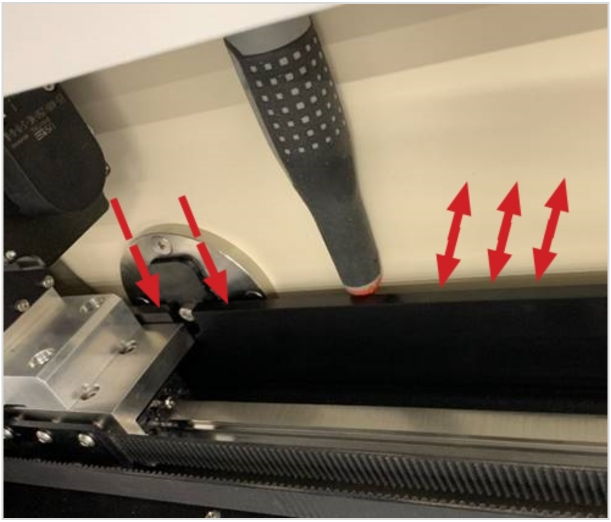


Fig: Exposed main screw (5/32”) on right side

5. Disengage arm damper from 2 door hinge pins and remove downward. You may need to use a rubber screw driver to spread the right side wall away from the Y-Gantry for enough space

to slide out the arm damper. Remove the flat washer as well.



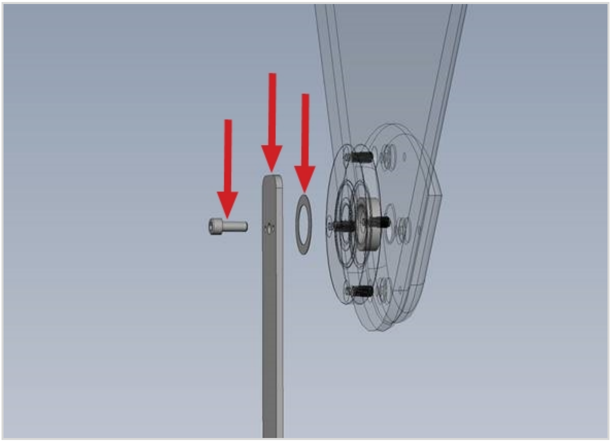


Fig: Push out the side wall out by a few mm to slide out arm damper and flat washer

LEFT SIDE

6. Remove the left side screw with a 1/8" Allen wrench (ball-end). The Y-rail makes it difficult for a straight wrench to fit. Remove the retaining washer (black)

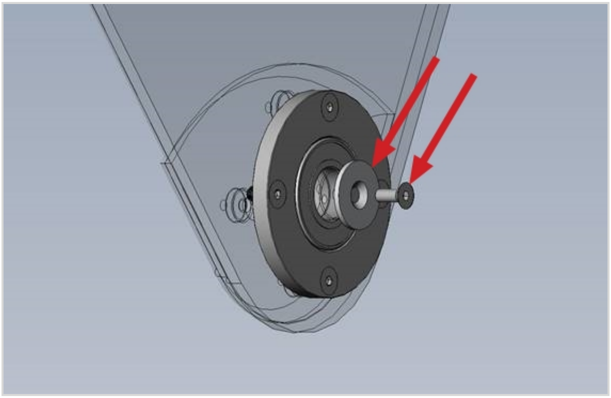


Fig: Ball-end Allen wrench needed to remove left side screw and retaining washer (black)

7. Once the left and right side hinges are unscrewed and hardware are removed, the door sides can be pulled outward to disengage the side wall bearings. **(2 PEOPLE!**)
   a. Be careful not to flex too much that the door cracks
   b. There are black spacer rings on each side of the door that may fall out. Remove these as well (see "Parts Map" on page 212).

Installing the Door - Engaging door onto side wall bearings

1. Carefully spread the wings of the door to fit it over the instrument.
2. Before sliding the hinges into the bearing, install two black spacer rings on each side. This should be between the instrument side wall and the door. (See Appendix 2)
3. With the spacer rings in place, slide the hinges into the side wall bearings.
4. Secure the door all the way open. The door should be loosely fixed to the instrument, but will still fall down without connecting the gas spring.

Securing RIGHT side (see "Parts Map" on page 212).

5. Install the ball joint and hex nut to the bottom of the arm damper.

Fig: Ball joint installed in arm damper. Hand tighten all the way

6. Stick the flat washer on the outside of the arm damper where it will interface with the door hinge and bearing (See Appendix 3). Use a small dab of grease.

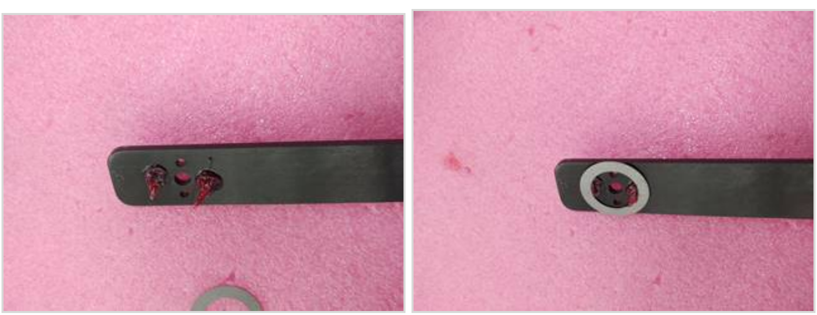


Fig: Small dab of grease to stick flat washer on arm damper

7. Hold open the side wall from the Y-Gantry again so the arm damper can slide up and align with the two pins on the door hinge.

Caution: The flat washer should be as centered as possible. Crushing this washer can damage the door pins and compromise the door.

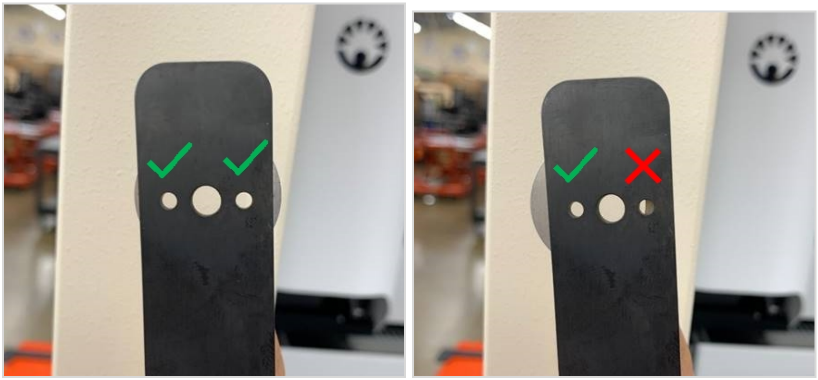


Fig: Correct (left); Incorrect (right). Ensure flat washer is centered BEFORE tightening screw

8. Tighten the main 5/32” Allen screw after installing/aligning the arm damper and flat washer. Use Loctite.
9. To re-connect the gas spring-arm damper ball and socket joint, it is easiest to use the channellock plier to engage the gas spring by a few inches (as shown in Fig on page 208) and have another set of hands press the arm damper ball into the socket joint.

   There should be an audible “snap” into place.

> **Note:**
> Be sure the green communications cable is on the inside of the instrument to avoid interfering with the door.
>
> Also be sure that the wires in the back are clear of the arm damper.

Securing LEFT side

10. From the inside of the instrument, add the following hardware in order:
    a. Black retaining washer
    b. 1/8” Allen screw w/ Loctite
11. Re-install the instrument skins.

Post-Install Verification

1. Clean any excess grease.
2. Account for all hardware and tools.
3. Visually inspect the door hinge when opening and closing the door.

   The user should not be able to fit his/her hand underneath the door and into the instrument when the door is closed.

4. Run Home All Motors to verify all basic components are communicating and functioning correctly and skins are not interfering with instrument movement.
5. Instrument qualification is not required.
6. Document the use of this procedure in the work order.

Parts Map

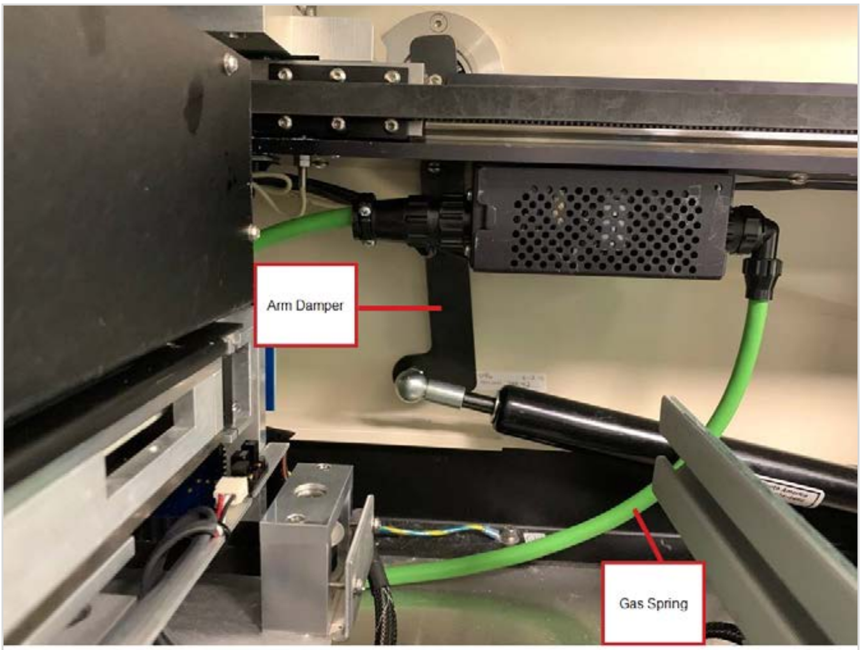


Fig: Parts - Arm Damper-Gas Spring Connection

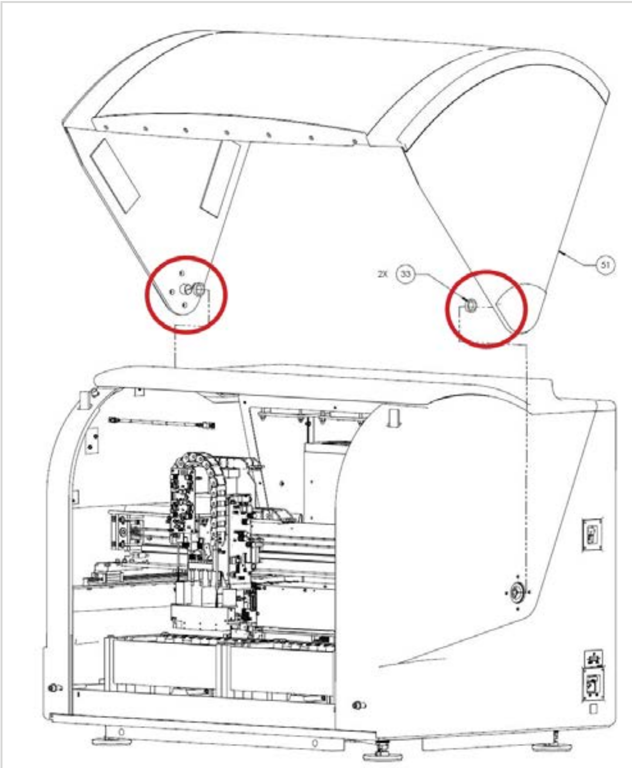
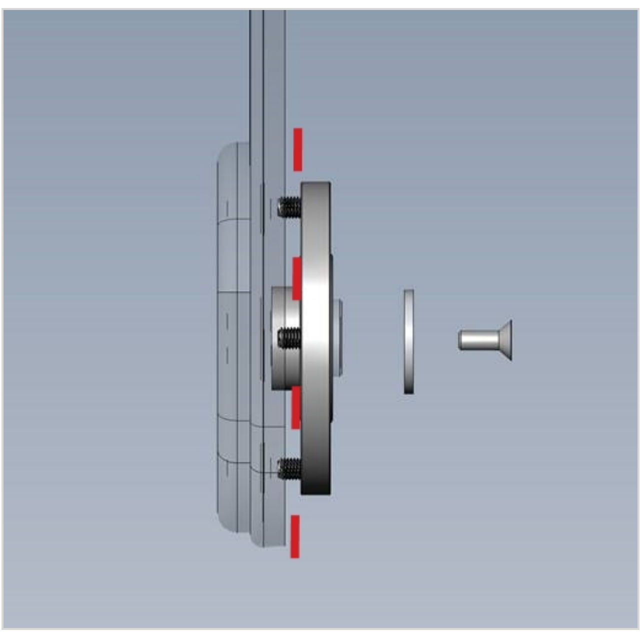


Fig: Black Spacer Rings (for even air gap between side wall and door)



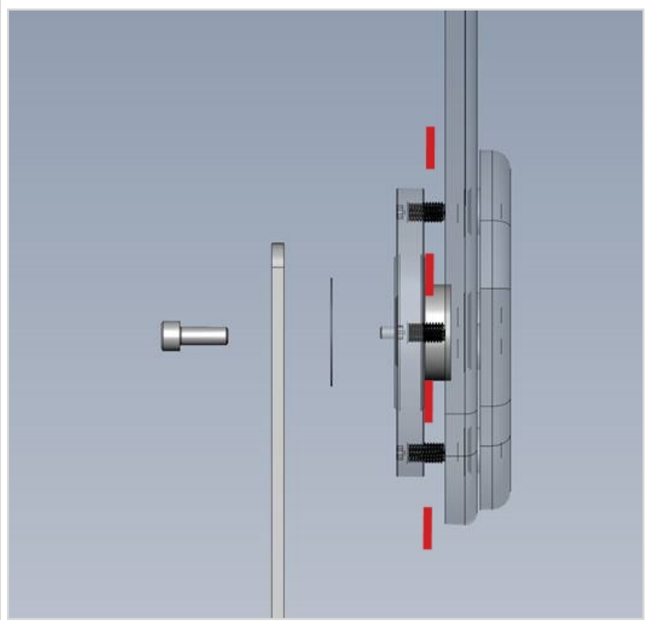


Fig: Left and right side Door hinge and Securing Hardware (red dotted line represents hidden side walls)

5.2.4.9 Verification after Remove/Replacement

1. Visual verification that each cover is secure.
2. Perform Home all Motors.
3. Confirm that there are no abnormal noises/vibrations from the X, Y, and Z Gantry during Home all Motors.
4. No Internal noise from the instrument during Home all Motors.
5. Confirm the Racks sit properly in the Lysis assemblies.
6. Verify the door opens and closes properly.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.4.10 Facade 2X Reader Rack MAX Spare

Instructions for removal and installation are found in the BD MAX Service Manual (BDDSSGF7422). After installation, complete the post install verification below.

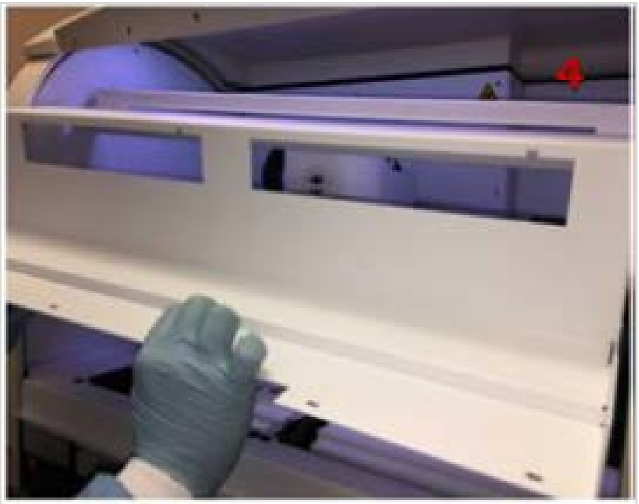
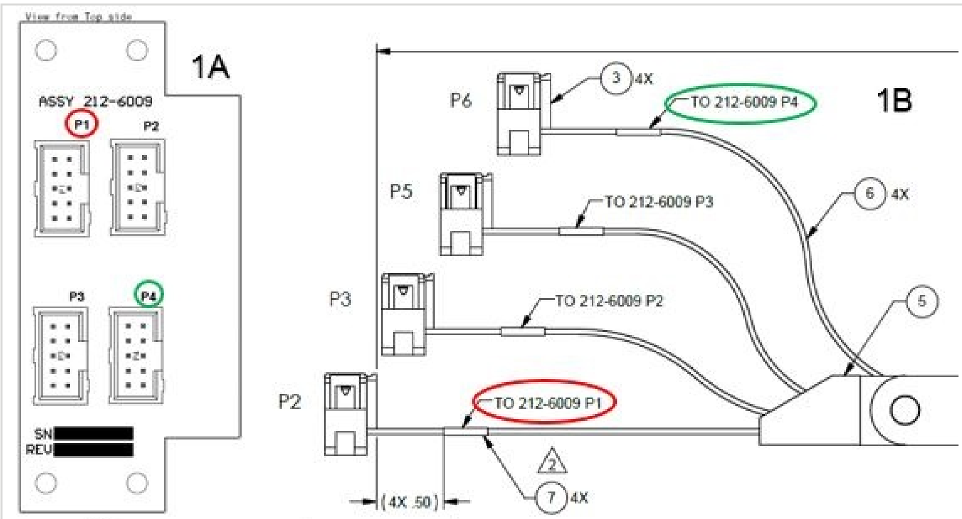


Fig: Facade 2x Reader Rack MAX Spare

5.2.5 Reader Assemblies Replacement

The Sliding Readhead Assembly is shipped with updated packaging to reduce the risk of shipping damage. Each assembly is placed into an anti-static bag that will be placed in custom fitting foam insert and box.



> **Note:** Observe the green and red circles on 1A and 1B. If a reader connector on 1A, such as P1, is dislodged, the corresponding connector on 1B, such as TO 212-6009 P1, replaces it.

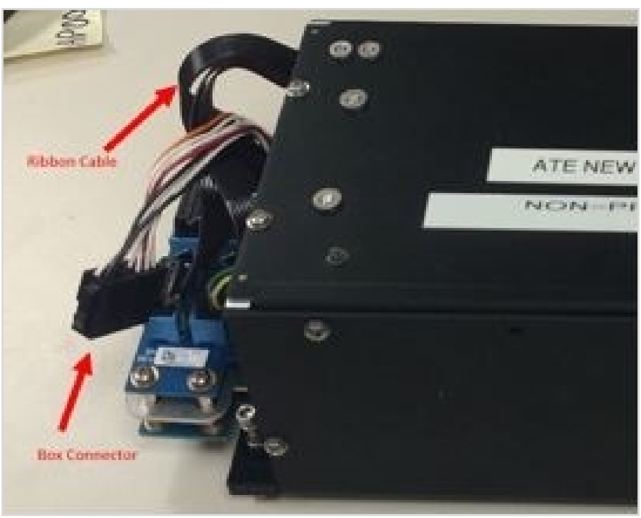
5.2.5.1 Sliding Readhead Assembly

Pre-installation step:

1. Open the box, remove the foam insert and then the **Sliding Readhead Assembly** from its box or static bag and lay it flat on the work surface as shown in the figure (A through D).

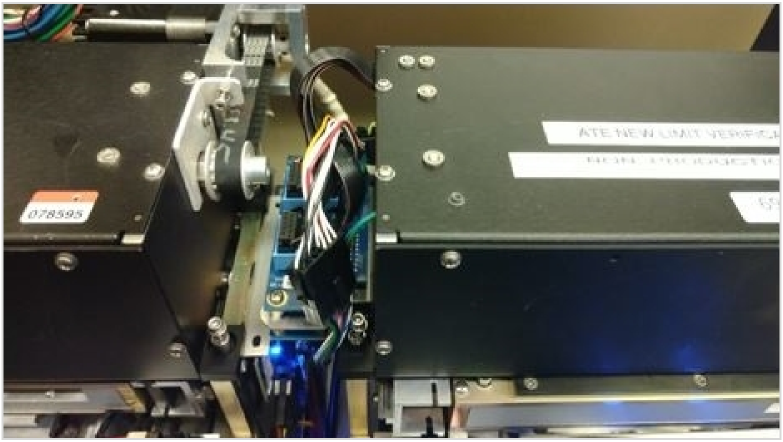
Installation steps:

> **Note:** The **Box Connector** is no longer seated within a sheet metal side bracket. Ensure that the **Box Connector** for the detector motor is fed through the looped ribbon cables.



1. Feeding the **Box Connector** cable underneath the **Ribbon** cable. Ensure that the **Box Connectors** cables are prevented from making contact with the adjacent reader.
2. Install the **Sliding Readhead Assembly**.
    a. Route the **Box Connector** and mate the cable assemblies.
    b. Tighten the four captive Allen screws at each corner of the reader and ensure that the reader does not wobble. Loose screws may cause pressure issues and poor heating that may affect PCR.

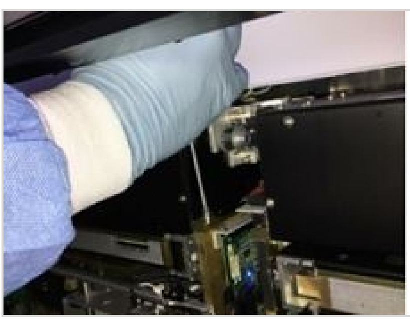
> **Note:** The bottom interconnect PCBA has a designator for both **A** and **B SCSI** cable just as the previous configuration.



3. After installing the new reader, perform the reader health check and update instrument firmware (Refer to "Reader Normalization " on page 490 and "Software/Firmware Update" on page 407).

5.2.5.2 Reader Module Removal

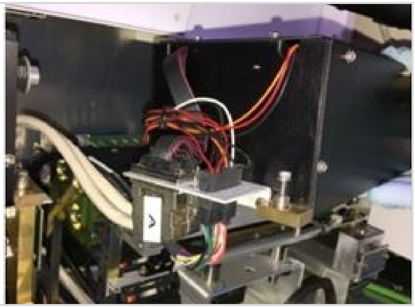
1. Loosen the four captive **Allen**head screws (one in each corner) that hold the sliding **Reader** module to the **Reader** frame.



2. Lift and tilt the sliding reader backwards slightly until you see the three cables on the left hand side. Note the orientation of the **A** and **B** cables. The **B** cable attaches to the inside connector, and the **A** cable attaches to the outside connector.

> **Warning:** Reversing the A and B cables will damage the assembly.

3. Disconnect the three cables and remove the sliding reader module from the instrument.

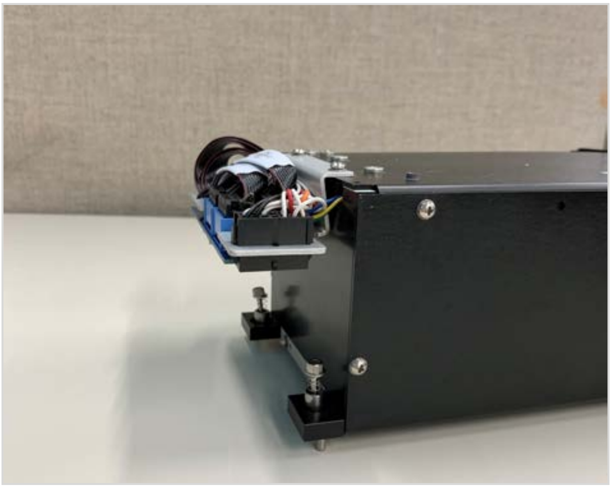
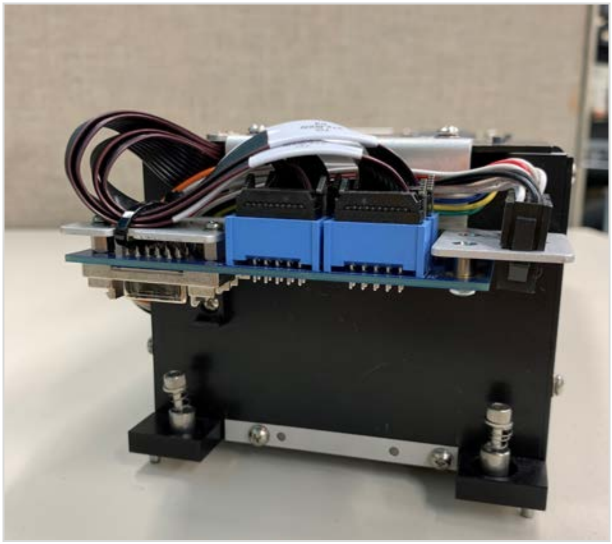



4. If a **Sliding Read Head** is replaced, make sure to update the firmware and perform the reader health check. Refer to "Software/Firmware Update" on page 407 and "Reader Normalization " on page 490.

> **Warning:** Do not power on the instrument when either of the two readers are unplugged or removed. This may significantly damage the system.

5. Install the **Sliding Readhead Assembly**. Route the **Box Connector** and mate the cable assemblies.

> **Note:** The new reader configuration combines the side PCB and sheet metal plate higher up on the side of the reader. The box connector will also connect into the plate. The reader installation procedure does not change.

5.2.5.3 New Revised Reader Configuration

The Sliding Readhead Assembly has been updated to contain four 10-position headers and matching interconnect PCBs that allow backwards compatibility. This update was required because the crimp style connector paired with the Optical Cable Assembly is obsolete. The configuration installation procedure for the Sliding Readhead Assembly are similar to the old Reader configuration installation procedure.

> **Note:** The revised Sliding Readhead Assembly configuration begins with **Reader serial number 79810**.

Verification:

1. Perform Update Instrument Firmware Update 6.3.3.6
2. Procedure EFC Check, 6.4.10.1,
3. Perform Normalizer Ratio Check 6.4.10.2
4. If required, Perform Reader Normalization 6.4.10.3
5. Procedure EFC Check, 6.4.10.1,
6. Perform Normalizer Ratio Check 6.4.10.2
7. Perform Instrument Qualification 5-Channel Qualification Test 5.3.3
8. Review the acceptance criteria in the qualification protocol Table.

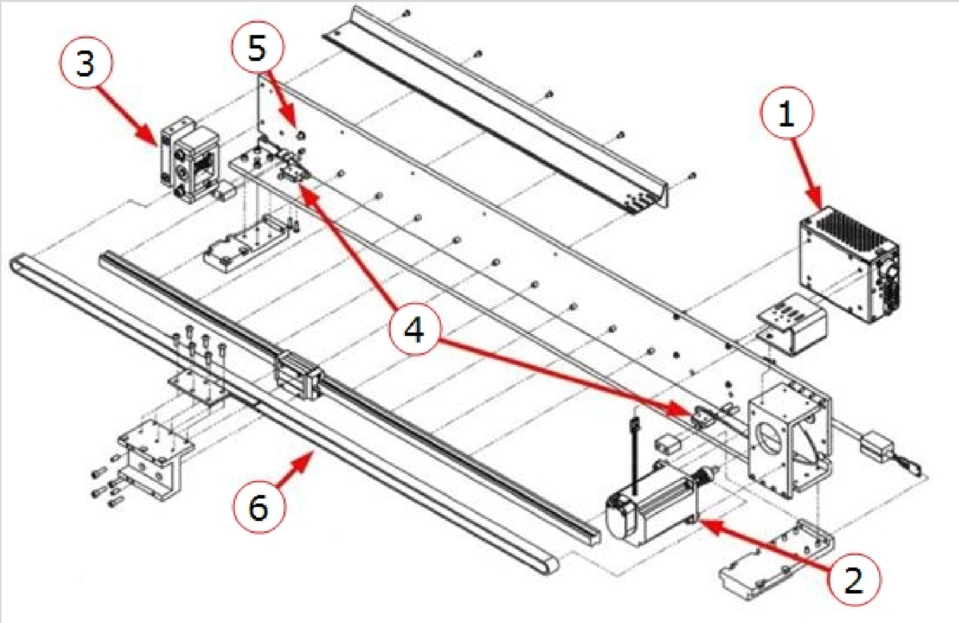
> **Verification:** After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.6 X-Gantry

The **X-Gantry** runs across the instrument with its left side riding on a simple rail and its right side riding on the **Y-Gantry** carriage.

> **Note:** The **Y-Gantry** is on the right side of the instrument. The right guard needs to be removed to work on the **Y-Gantry**. While its configuration is different, replacing parts is accomplished the same way as the **X-Gantry**.

There are several components that can be replaced on the X-Gantry.



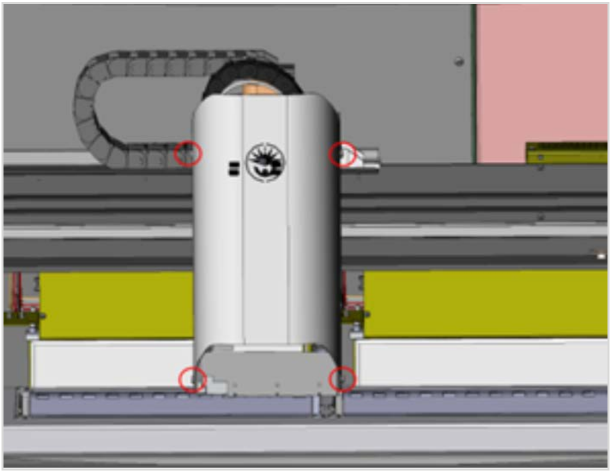
1. X-Gantry Blue Cobra Controller
2. Stepper Motor
3. Idler Assembly
4. Limit Switches
5. Hall Effect Home Sensor
6. Drive Belt

Note: The stepper motor and idler assembly is the same for both the X-Gantry and the Y-Gantry.

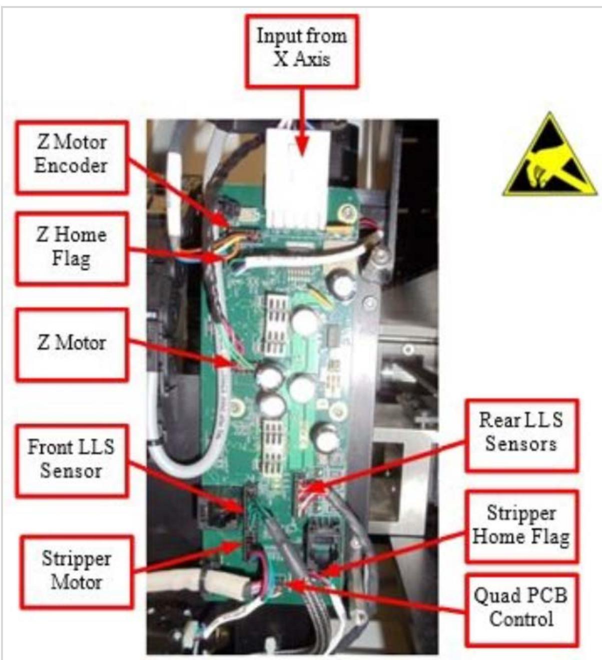
5.2.6.1 Gantry Blue Cobra Controller

The X-Gantry Controller Assembly is held in place by four Phillips head screws and seven connectors.

1. Power off the BD Max instrument
2. Remove the Gantry cover skin.



3. Disconnect all cables attached to the Cobra controller board.



4. Remove of screws that secure the board to the Gantry chassis.
5. Install and secure the New Board.
6. Connect all cables to the board.
7. Place the Gantry Cover.
8. Power On the BD Max instrument.

> **Warning:** Do not initialize the instrument.

9. Perform the "Software/Firmware Update" on page 407.
10. Perform the "Gantry Alignment " on page 508.
11. Perform "Cataloging" on page 404.

Verification:

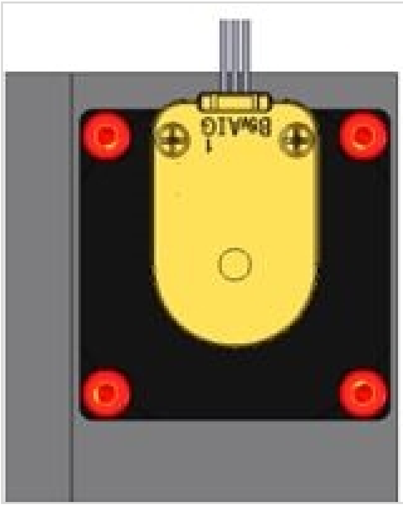
> **Verification:** After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

1. Perform the QPM section of the "Qualification Run" on page 322.

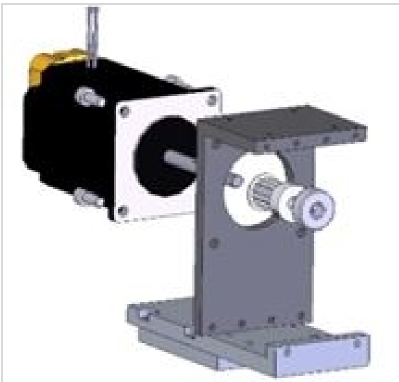
5.2.6.2 X-Gantry Stepper Motor

The X-Gantry stepper motor is located on the right side of the X-Gantry and consists of the motor and an encoder (attached to the end of the motor).

1. Remove the four **4 mm** hex head screws that secure the motor to the X Gantry (highlighted in red).
2. Disconnect the **Encoder** cable from the motor.



3. Disconnect the **Motor Cable** form the **Gantry Controller** assembly. (A cable tie holds the cable in place on the backside of the gantry.)
4. Pull the motor from the X-Gantry. (If necessary, the motor may be tipped slightly to loosen the drive belt enough to get the drive gear past it.)
5. Loosen the two inset Allen screws securing the drive gear to the shaft.



5.2.6.3 Idler Assembly

Required Materials:

- 4mm Allen Head Key
- TensionRite Belt Frequency Meter (443969)
- Loctite 222

Procedure

The idler assembly is located at the left side of the X-Gantry. Follow the steps of the installation procedure ("Installation Procedure" on page 68) to set up the instrument, connect and configure the AIO Computer, and unlock and open the instrument door. Remove all packing and shipping material.

Perform the additional steps below to verify that the tension setting screws of the gantries are properly secured.

Refer to the detail figure below and the drawings of the X and Y Gantries on the following page. The X-gantry idler block is found on the left side of the instrument. The Y-gantry idler block is found in the front right corner of the instrument.

Follow these steps for each of the two gantry idler blocks:

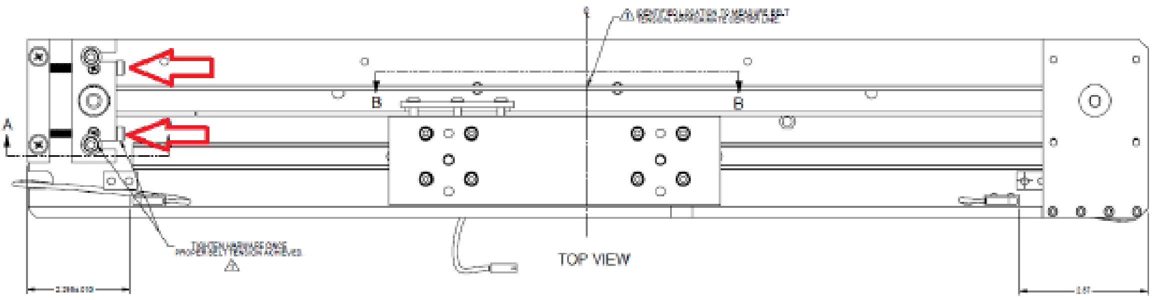
1. Remove **only one** of the screws identified by the red arrows. Apply Loctite 222 to the threads and re-insert the screw back into the idler block until it is flush to the mating face. Turn the

screw 1/2 turn beyond "finger tight".

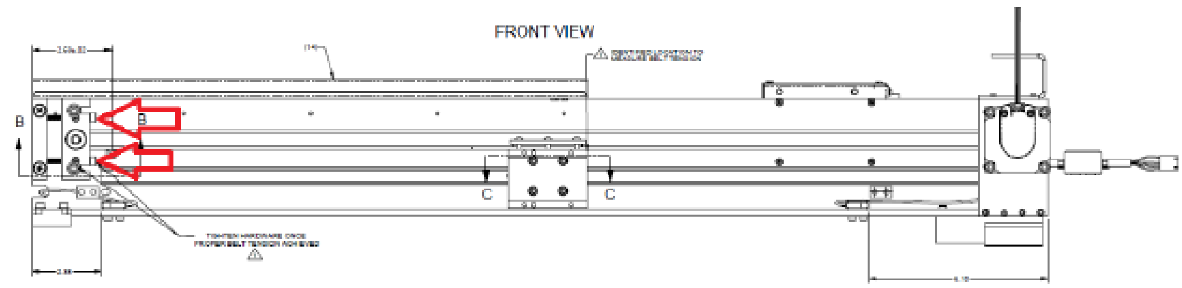
2. Repeat this step with the second screw of the idler block identified by the red arrows.
3. Verify that gantry belt tension has remained within 20lbs ±2lbs by following the belt tension procedure "X/Y-Gantry Belt Tension " on page 190.
4. Repeat these steps for the Y-Gantry.

Follow the remaining steps to complete the installation procedure.

Fig: Gantry Screws Details



Y Gantry Assembly



X Gantry Assembly

When replacing the idler assembly, loosely insert all locking screws. Then tighten after the tension has been adjusted.

> **Note:** Apply loctite on the cover and mounting screws. Both the Tension Adjustment screws now require Loctite at installation.

5. Power On the BD Max instrument.

> **Warning:** Do not initialize the instrument.

6. Perform the "Software/Firmware Update" on page 407
7. Perform the "Gantry Alignment " on page 508
8. Perform "Cataloging" on page 404

Verification:

> **Verification:** After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

1. Perform the QPM section of the "Qualification Run" on page 322

5.2.6.4 X Limit Sensor

- The right-hand limit switch sets the maximum travel of the Z-Gantry along the X-Gantry and connects to the controller socket marked with a plus sign (+) on the X Cobra Controller.
- The limit switch on the left sets the minimum travel distance, and connects to the controller socket with a minus sign (-).
- The limit switches are mounted horizontally through slots on the bottom of the X-Gantry by two screws.

Procedure:

1. Power off the BD Max.
2. Measure the actual position of the limit sensor, the distance from the sensor to the frame, and the distance from the sensor to the end chassis.

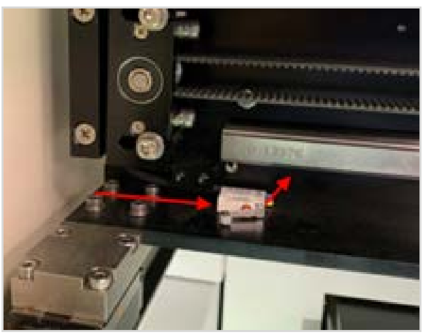


Fig: Limit switch left

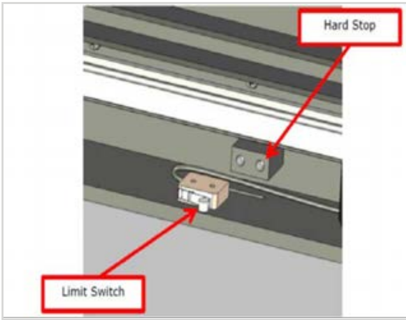


Fig: Limit switch right

Recommendation: Mark the around actual position before being replaced. The sensor on the left side is located after the Hall Effect Sensor; at the replacement, confirm the Limit sensor is 1 mm after the Hall Effect Sensor (Red in the next photo).

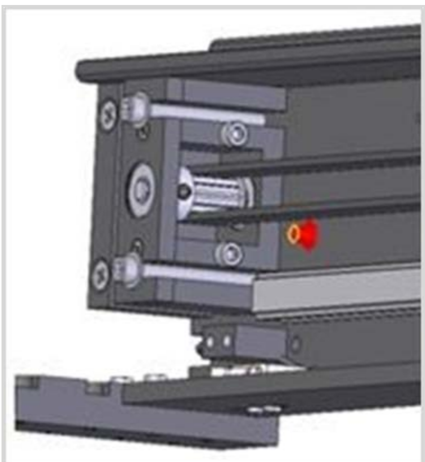
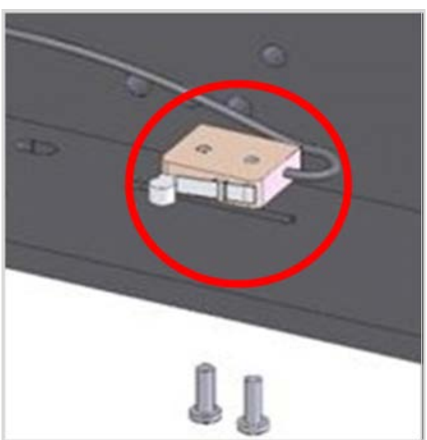


Fig: Left to the end of the chassis and front to the frame

3. Remove the two screws that secure the sensor.



4. Disconnect the cable connected to the X Cobra Controller.
5. Place the new sensor in the same position as the previous sensor.
6. Secure the sensor.
7. Power on the BD Max.
8. Perform the "Gantry Alignment " on page 508.
9. Perform the "Cataloging" on page 404.

Verification:

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

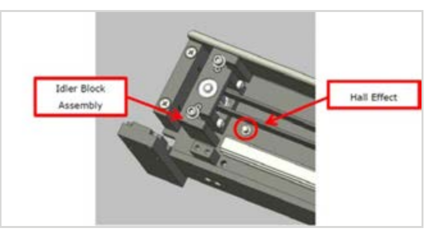
1. Perform the QPM section of the "Qualification Run" on page 322.

5.2.6.5 HALL Effect Sensor

The HALL Effect sensor is not adjustable. It marks the Z-Gantry's home (or zero) position.

- Two nuts on the front and back hold the sensor in place. It connects to the three-pin jack on the controller assembly.

Note: When replacing the HALL Effect sensor, ensure that it is adjusted low enough, so the Z-Gantry does not strike it.

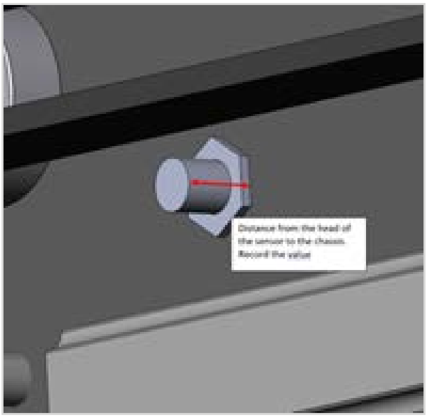


Tools

- Standard FSE tools
- Calibrate caliper

Procedure:

1. Open the BD Max Door.
2. Power of the BD Max instrument.
3. Move the gantry totally to the right.
4. Move the x-rail totally to the front.
5. Measure the distance from the head of the sensor to the x-rail chassis.



6. Remove the nut that secures the sensor from the back of the x-rail.
7. Disconnect the sensor cable from the X cobra controller.

8. Cut all claps that secure the cable to the chassis.
9. Install the nuts in the new sensor and place the top nut in the same position as the removed sensor.
10. Install the new sensor.

Verify the nut installed has the same value measured in step 5.

11. Install the rear nut that secures the sensor to the chassis.
12. Secure the cable with plastic clamps in the same positions as before.
13. Connect the cable to the X cobra controller.
14. **Manually, with very slow movement,** move the Gantry to the sensor and verify the gantry is not touching the sensor.
15. Place the gantry in the center of the x-rail.
16. Power on the BD Max instrument.
17. Perform Home All Motors.
18. Perform the "Gantry Alignment " on page 508.
19. Perform "Empty Fill Check Errors" on page 454.

Verification:

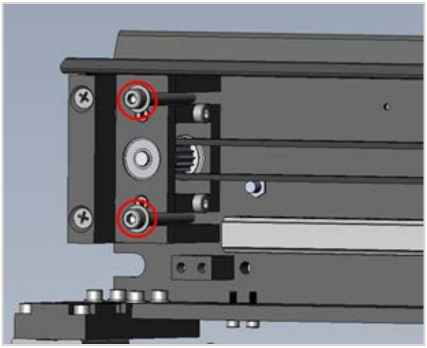
Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

1. Perform the QPM section of the "Qualification Run" on page 322.

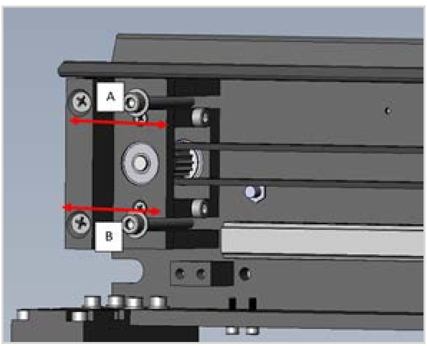
5.2.6.6 Drive Belt

The two ends of the drive belt are secured to the Z mounting by a plate affixed with six screws.

1. Open the BD Max Door.
2. Power of the BD Max instrument.
3. Remove the two security screws that secure the Idle on the left side of the rail.



4. Move the x-rail totally to the front.



5. Remove the adjustable screws from the Idler. At this point, the belt will be free to be removed.
6. Remove the gantry assembly from the chassis.
7. Remove the six screws that secure the belt to the frame.

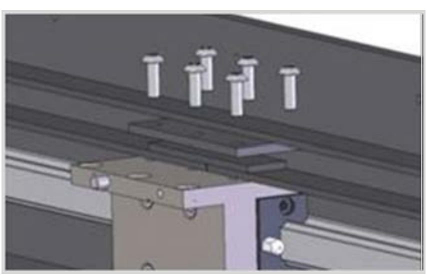


Fig: Tension is adjusted at the idler assembly.

Verification

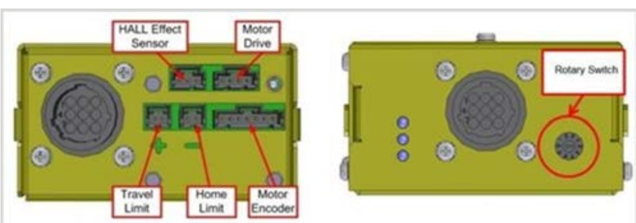
Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

1. Perform "Instrument Firmware Update " on page 416 (if the Cobra XY controller 443682 was replaced.)
2. Home all Motors.
3. Perform "Gantry Alignment " on page 508
4. Perform "CatalogWin.Script" on page 488
5. Perform the "5-Channel Qualification Test" on page 325

5.2.6.7 XY Blue Cobra Controller

The X/Y Cobra Controller Assembly is held in place by four Phillips head screws and seven connectors.

1. Power off the BD Max instrument.
2. Disconnect the two connectors for the control cable pass through.



3. Disconnect the two limit switch cables, the Hall Effect sensor cable, encoder and motor connector cable.
4. Remove 4 Phillips head screws securing the controller to the x/y -Cobra Controller
5. When installing a new controller assembly, verify that the rotary switch is set to the same number as the one removed and reload firmware.
6. The rotary switch on the X-motor controller should be set to 1, and the Y-motor controller should be set to 0.

Note: When replacing the Cobra Controller assembly, ensure that it is adjusted to the correct rotatory switch. **Perform the firmware upgrade with the wrong configuration will de-programed all 7 Cobra controllers in the instrument.**

7. Power On the BD Max instrument.

Caution: Do not initialize the instrument.

8. Perform the "Software/Firmware Update" on page 407
9. Perform the "Gantry Alignment " on page 508
10. Perform the"Cataloging" on page 404

Verification:

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

1. Perform the QPM section of the "Qualification Run" on page 322

5.2.6.8 Y Limit Switches

Required Tools

- Magnetic Bowl
- 0.035” Allen wrench

- T10 Torx Screwdriver
- 4.Channellocks (Tongue-and-groove pliers)
- 5/32” Allen T-handle
- 1/8” Allen wrench (Ball end)
- Loctite
- Calipers

Note: Two FSEs are required to complete this procedure.

Procedure:

1. Open the BD MAX Door and power down the system.
2. Remove the following skins and instrument door per the procedure outlined in the BD MAX Service Manual (BDDSSGFS7422).
    a. Front skin
    b. Tray covers
    c. Upper reader cover
    d. Lower reader cover
    e. Lower right panel
3. Remove the top cover skin
    a. From inside, remove the four screws that secure the top cover of the BD Max. See the Figures below for the location of the screws.

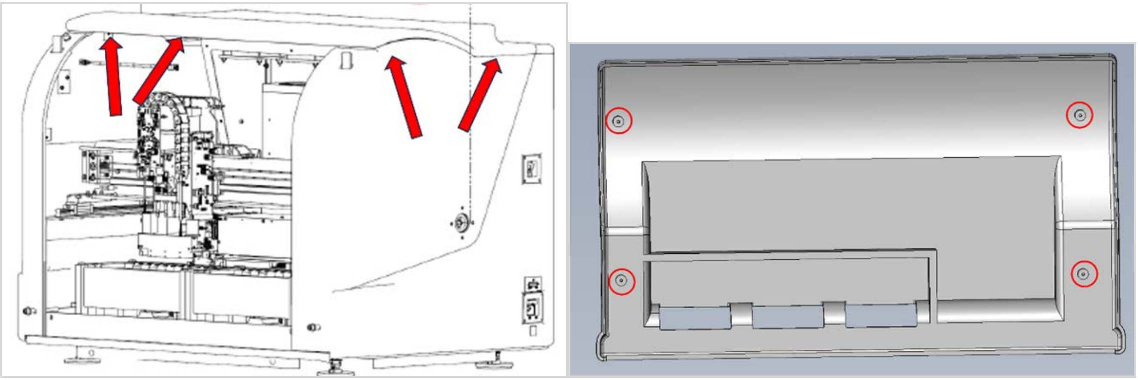


Fig: Front and top view of screw location for the top cover skin

4. Remove the right-side skin.
   a. The right-side skin is secured by 2 screws.

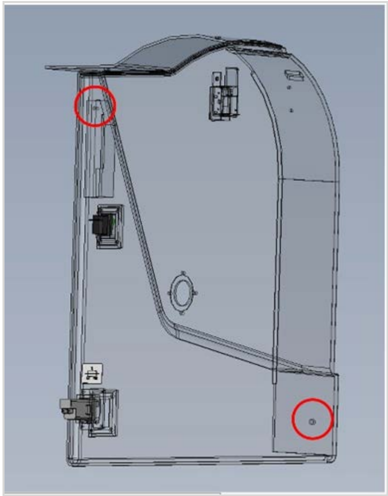


Fig: Location of screws in the right side skin

   b. Measure the distance from the chassis to the extrema of the screw. This distance needs to be recorded to be the same after installing the right side.

Fig: Measurement point for right side skin screw

   c. Disconnect the cables from the main power switch and power input filter.

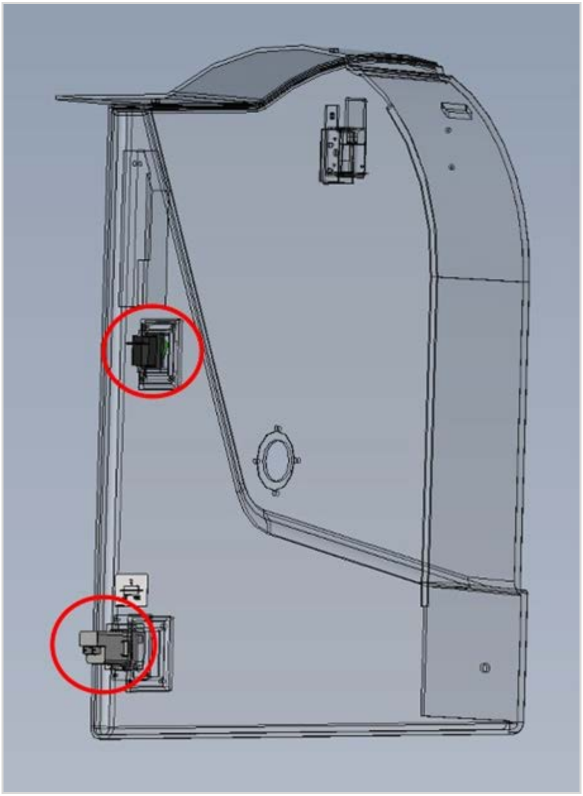


Fig: Location of the main power switch ad power input filter.

d. Carefully slide up the right side skin.

5. Limit Sensor Replacement.

a. Measure with the distance from the sensor to the hold sensor. Record that distance to be the same after the sensor replacement.

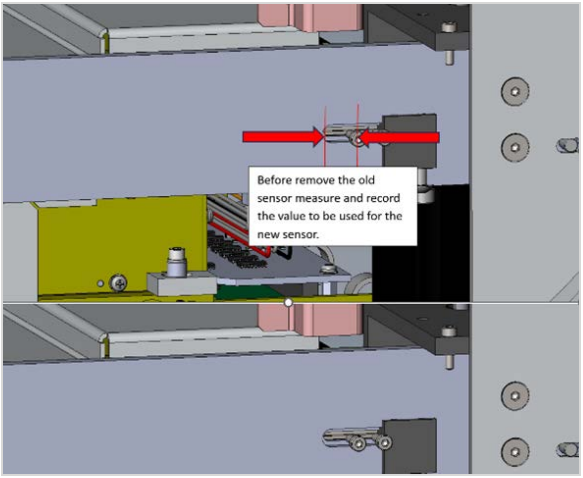


Fig: Distance measurement

b. Remove the two screws that secure the sensor to the rail.

c. Disconnect the sensor from the Cobra controller.

d. Cut the secure ties that secure the cable to the rail.

e. Remove the defective sensor.

f. Install the new sensor. Tie the sensor to the rail in the same position as recorded in step 5a.

g. Connect the sensor to the Cobra controller.

h. Secure the cable to the rail.

> **Note:** Do not over-tighten the sensor screw, which can crack the sensor and damage the functionality.

6. Install the right-side Skin.
   a. Follow the reverse procedure to remove the right-side skin.
   b. Verify all cables are connected to the power switch and input filter.
7. Verification
   a. Verify the right side is fixed to the base, and that the front screw is at the same distance as measured in step 4b.
8. Install the top cover BD Max.
   a. Place the top cover and verify all 4 holds match with the cover screws.
   b. Secure the top cover with the screws.

> **Note:** Do not over-tight the screws, that can break or damage the top cover.

9. Clean any excess grease.
10. Account for all hardware and tools.
11. Visually inspect the door hinge when opening and closing the door. a. The user should not be able to fit his/her hand underneath the door and into the instrument when the door is closed.
12. Connect the power cable to the input plug on the side Skin.
13. Power on the BD Max

14. Run Home All Motors to verify all basic components are communicating and functioning correctly and skins are not interfering with instrument movement.
15. Verify the sensor functionality.
16. Perform the Calrack.script.

Verification:

> **Verification:** After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

1. Verify visually the top cover matches with the side skins and that they are symmetric to the sides.
2. Reinstall the remaining skins and instrument door per the procedures outlined in the BD MAX Service Manual (BDDSSGFS7422).

Post-Install Verification

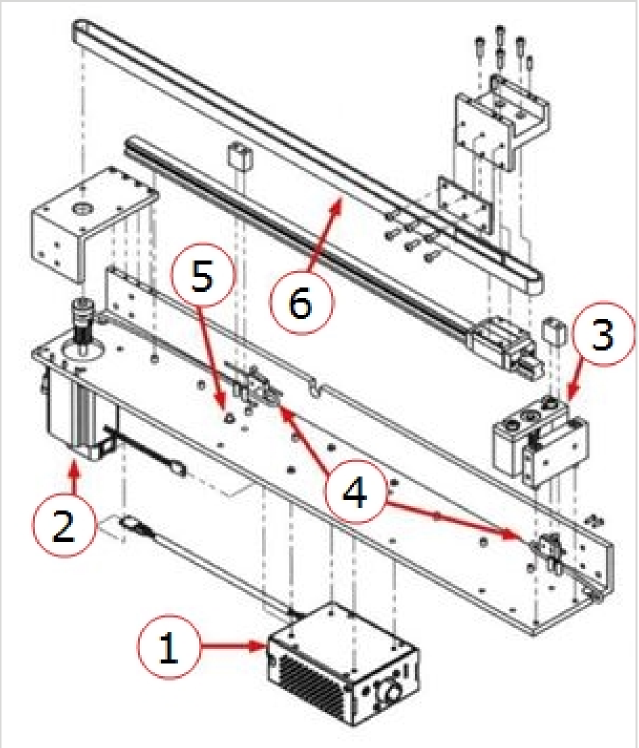
1. Perform Home All Motors.
2. Perform "Empty Fill Check Errors" on page 454 for side A and side B.
3. Perform the QPM section of the "Qualification Run" on page 322.

5.2.7 Y-Gantry

The Y-Gantry runs from front to back of the instrument along the right side. The two left hand facades must be removed for proper access to the Y-Gantry. While its configuration is different, the Y-Gantry consists of the same parts as the X-Gantry.

The same steps and processes are used to remove the various parts on the Y-Gantry:

Document: BDDSSGFS7422 Doc Type: ZIP Status: Released EFFECTIVE
Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential



1. X-Gantry Blue Cobra Controller
2. Stepper Motor
3. Idler Assembly
4. Limit Switches
5. Hall Effect Home Sensor
6. Drive Belt

Note: Apply loctite on the cover and mounting screws. Both the Tension Adjustment screws now require Loctite at installation.

Verification

Warning: DO NOT perform or select Home All Motors, before the firmware update is finished.

1. Perform"Instrument Firmware Update " on page 416 (If the Cobra XY controller 443682 was replaced.)
2. Home all Motors.
3. Perform "Gantry Alignment " on page 508.

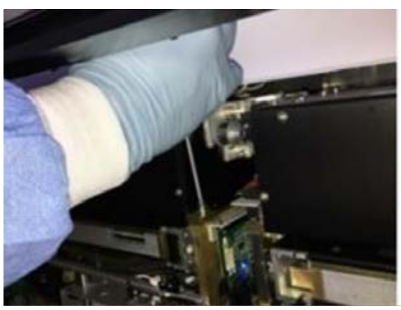
4. Perform "CatalogWin.Script" on page 488.
5. Perform the QPM verification of the "5-Channel Qualification Test" on page 325.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.8 Windows MUX Board Replacement

Procedure

1. Power off the BD Max
2. Remove the Power Cable.
3. Remove all internal Skins. Refer to "Instrument Skins" on page 197.
4. Remove the reader A assembly secure by Loosening the four captive Allen head screws (one in each corner) that hold the sliding Reader. 5.2.5.2.




5. Disconnect all three cables that connect the Reader to the Heater Mux assembly.
6. Remove the six Phillips head screws that secure the Heater MUX module to the Reader drawer.
7. Avoid backing out the screw out of the cover itself.
8. Move the Mux to the right side to create space to remove the Windows MUX board. The Windows MUX board is mounted to the left of Reader A. Disconnect the serial cable on top of the Windows MUX board. The Reader A sliding read head should be de-installed to provide more working room before removing this card.

9. Install the replacement board in reverse steps from step 8 to step 3.

> **Note:** All Windows MUX boards are configured to be with the IP 169.254.1.10.

10. Edit/update the IP address in the Maintenance/task screen.

11. Connect the power Cable.
12. Power On the BD Max instrument.

> **Warning:** DO NOT perform or select Home All Motors.

13. Perform Instrument Firmware Update. Refer to "Instrument Firmware Update " on page 416.

> **Warning:** At the time the software is performing the instrument Firmware Update, do not interfere or perform and task on the BD Max or AIO, any interference cold corrupt the firmware update.

14. Perform the following adjustments in the sequence recommended below:

Verification:

1. Update the IP address to 169.254.1.10.
2. Perform pressure plate setting procedure. Refer to "Pressure Plate Setting " on page 484.
3. Update instrument firmware.
4. Perform the Reader Tray position procedure. Refer to "Reader Tray Position " on page 469
5. Perform Gantry Alignment. Refer to "Gantry Alignment " on page 508.
6. Go to "CatalogWin.Script" on page 488.
7. Perform EFC. If the empty fill check fails at the test, go to "Flashing the GORT board (Lysis Heater)" on page 411.
8. Perform full instrument qualification as per "Qualification Run" on page 322.
9. Confirm results. Refer to "5-Channel Qualification Kit Result Review Table" on page 331.

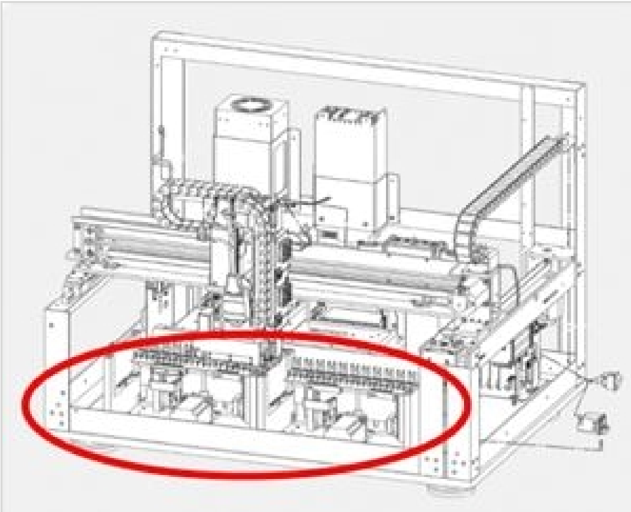
> **Verification:** After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.9 Lysis or Mag Extractor Assemblies

The instrument has two **Extractor (Lysis or Mag)** assemblies, located in the front of the instrument underneath the **Lower Reader Cover**.

Replaceable parts include:

- Entire Lysis/Mag Separation Assembly
- Heat Block Module (GORT Board)

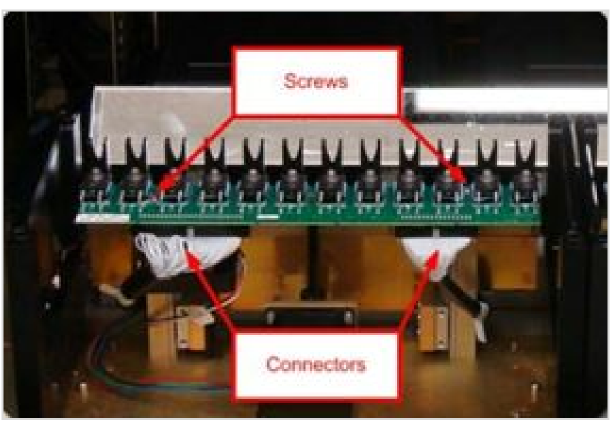


To access the **Lysis** or **Mag Assembly**, remove the **Lower Reader Cover** and the corresponding Lysis covers.

> **Note:** The **Heater** block module can be removed by itself with the **Lysis or Mag Separation** assembly remaining in place.

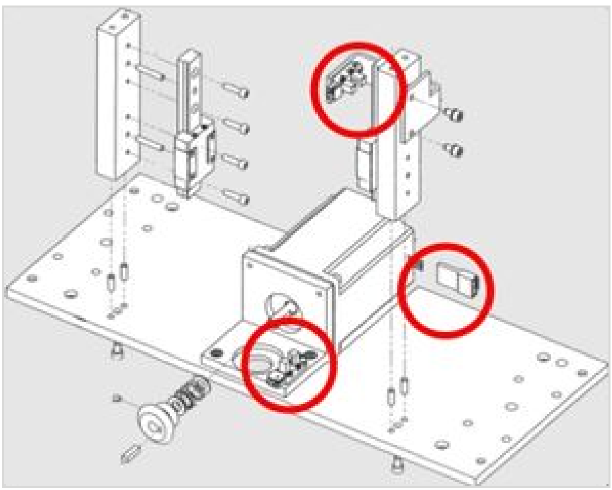
5.2.9.1 Heater Block (GORT Board) Module Removal

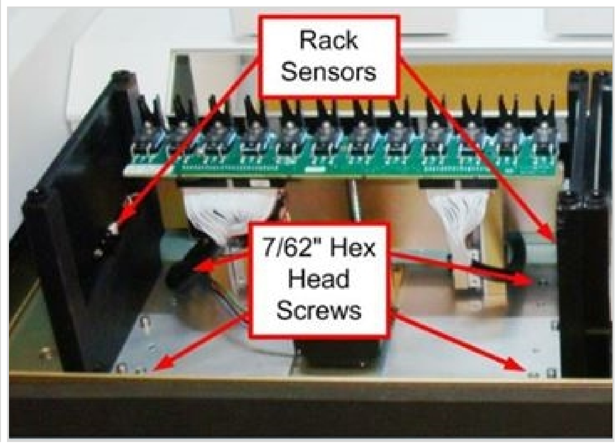
1. Remove the two Philips head screws that hold the **Heater Block** Assembly in place.
2. Disconnect the two **Lysis Heater** ribbon cables form the board.
3. Remove the board from the instrument.



5.2.9.2 Lysis or Mag Assembly Removal

1. Use an **Allen** wrench to remove four **7/64 inch** hex head screws holding the module in place. **Loctite 222MS** is used on the threads of these fasteners.
2. Remove the cover of the wiring tray directly behind the **Lysis or Mag** module.
3. There are seven wiring harnesses connecting the module to the instrument. Several of these connectors are physically located in the wiring tray behind the **Mag/Lysis** Assembly and the cover needs to be removed to access them.
4. Disconnect two **Lysis** heater connectors (if the **Heater Block Assembly** has not been previously removed).
5. Disconnect the two **Magnet** travel sensors, the home connector, and the limit connector.





6. Disconnect the two **Rack** detection sensor connectors.
7. Disconnect the motor control connector.
8. Remove the four **7/62 inch** hex head screws.
9. Remove the **Lysis** or **Mag** module.

5.2.9.3 Replacing the Left Side Wall of the Mag Lysis Assembly

Required materials:

- Mag/lysis assembly left side wall (Part Number: 444099)
- Phillips head screwdriver
- 7/64” Allen wrench
- #10 Torx bit driver
- Loctite adhesive

- Rack calibration plate (Part Number: 435251)
- Reader calibration plate (Part Number: 435256)

Procedure

1. Power off and unplug the instrument.
2. Remove the skirt, the upper reader cover, the lower reader cover, and the lysis cover.

> **Note:** For removal instructions, refer to "Skins Removal " on page 198and "Lysis Cover Removal" on page 203.

3. Disconnect both the Gort board cables from the mag/lysis assembly.

> **Note:** Newer assemblies have tabs that can be pushed outward to pop out the connector. Older style assemblies are disconnected by pulling the cable out of the harness. On older style assemblies, grab the cable attachment point with both hands and remove gently to avoid damaging the connection.

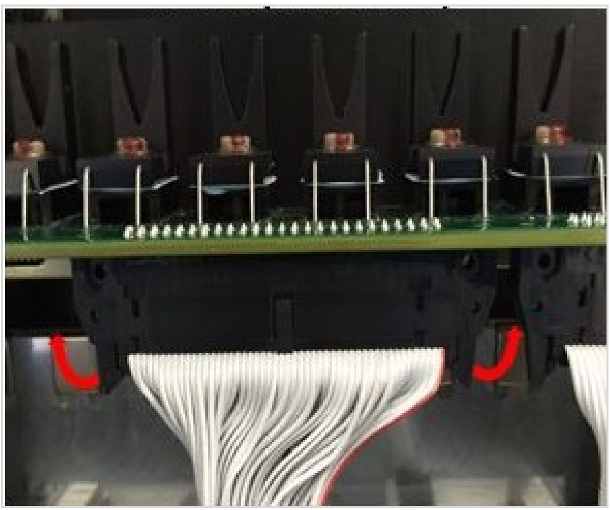


Fig: New Style Assembly

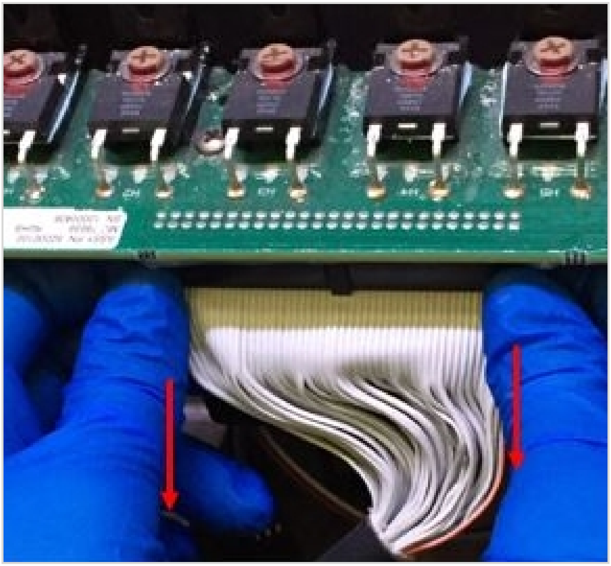
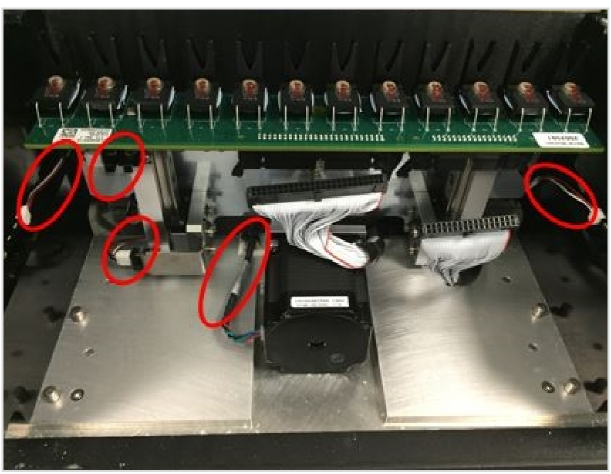


Fig: Old Style Assembly

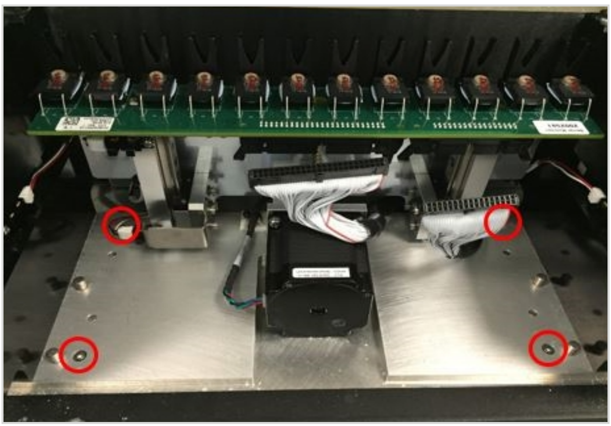
4. Disconnect the left and right side wall sensors, the flag home sensor, the upper limit sensor and the motor from the instrument.

> **Note:** Some mag/lysis assemblies do not have an upper limit sensor for the home flag.



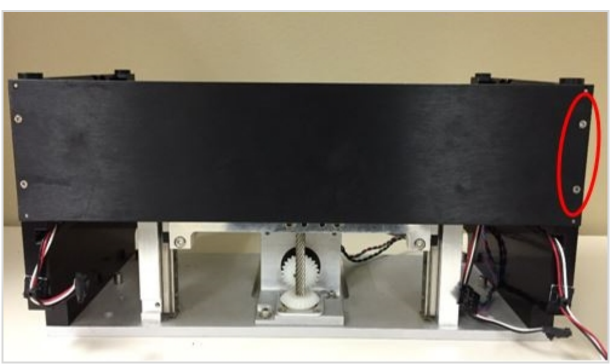
> **Note:** The wires are connected to the instrument by a wiring harness in the wire guide located behind the mag/lysis assembly (see image below). **DO NOT** disconnect the wiring directly from the sensors or motor. Label the connectors in the instrument to avoid improper rewiring later.

5. Remove the four **7/64** inch head screws securing the Mag/Lysis assembly to the instrument.



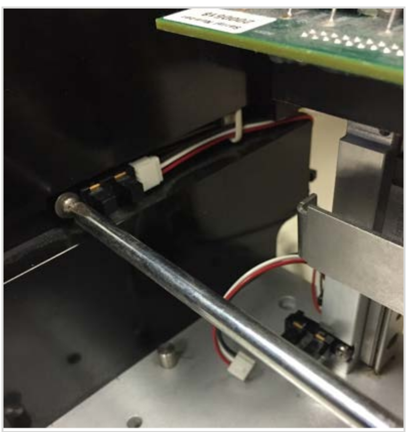
6. Lift the Mag/Lysis assembly out of the instrument and place on bench top.
7. Remove the two small Phillips head screws securing the back plate to the side wall.

> **Note:** Do not drop and lose screws.



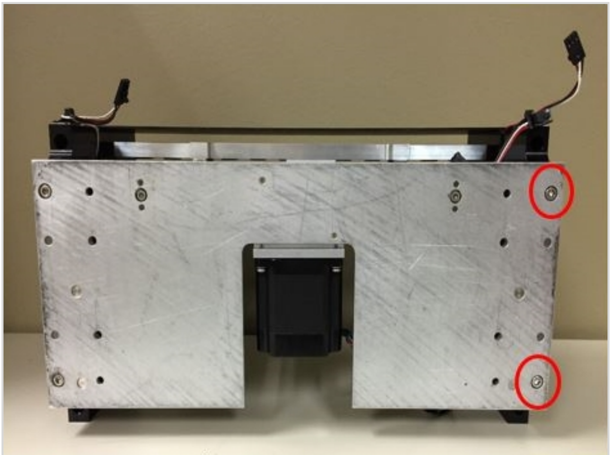
8. Using diagonal cutters, remove the zip tie holding the left rack sensor cable to the rear of the left wall, if present.

9. Use a Philips head screw driver to remove the screw holding the sensor to the left side wall and remove the sensor. Place the sensor and screw aside to attach to the new side wall.



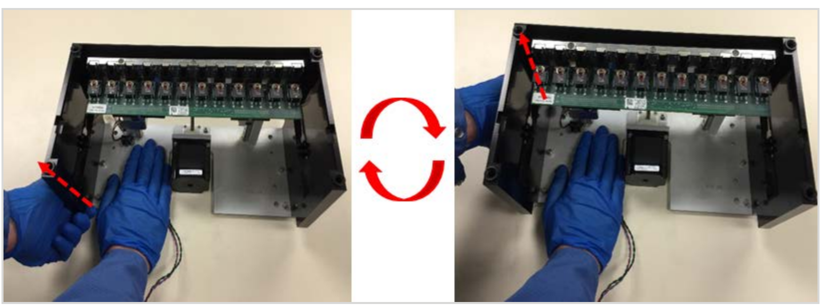
10. Remove the two **7/64** inch head screws securing the side wall on the underside of the Mag/Lysis assembly.

> **Note:** Save the screws for use in installing the new wall.

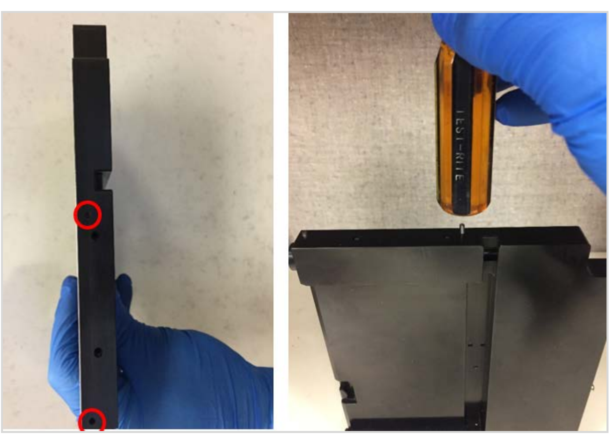


11. Pull upwards on the side wall to remove it from the Mag/Lysis base plate.

Note: The wall is pinned in place and requires force to remove. Place one hand firmly on the base and alternate pulling upwards on each end of the wall works to loosen it from the base.

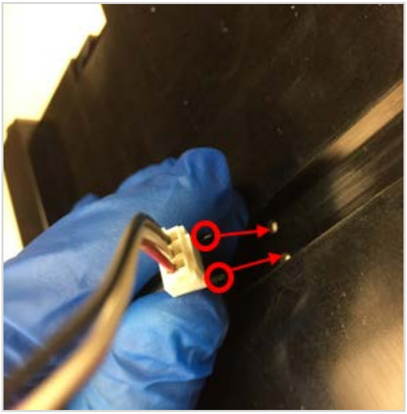
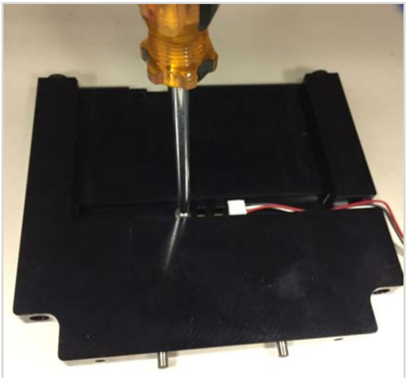


12. Using the rear end of the screw driver, or a small mallet, tap the small metal pins into the smaller two holes on the rear face of the new left side wall.

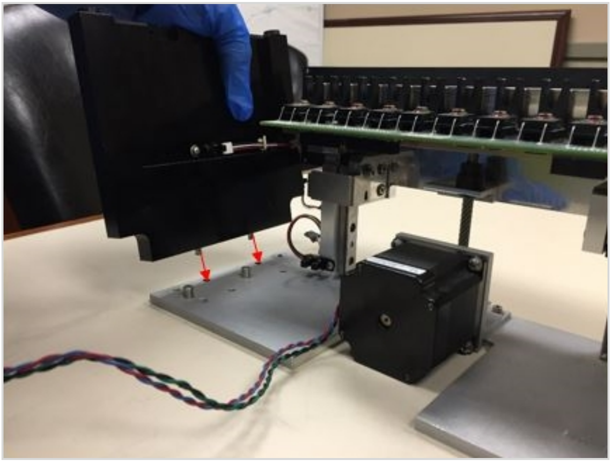


13. Use a Phillips head screw driver to attach the sensor to the new side wall with the screw removed from the old side wall.

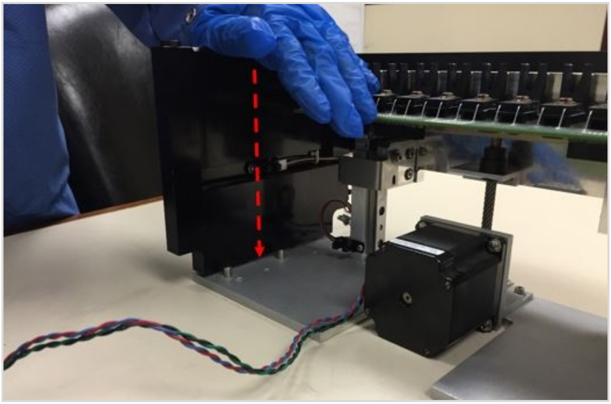
Note: Align pins on the sensor with small holes in the side wall as shown.

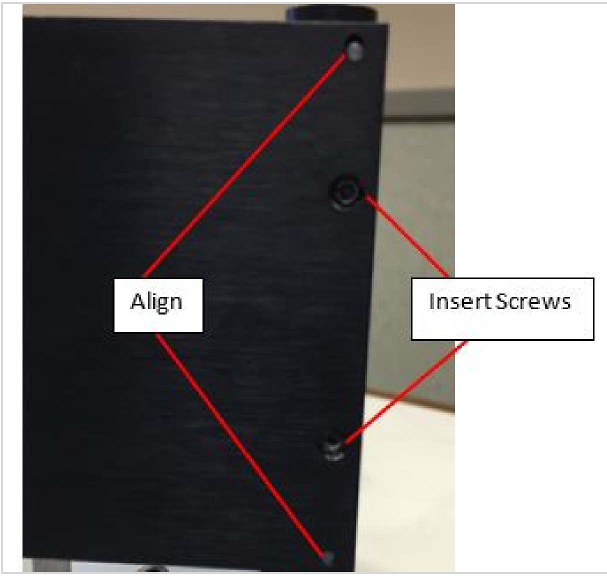
14. To install the new side wall on the mag/lysis assembly, lower it onto the base plate, ensuring that the holes on the bottom of the side wall align with the pins on the base.



15. With pins aligned in the guide holes, press firmly on top of the side wall until the bottom of the wall is flush with the base of the assembly.



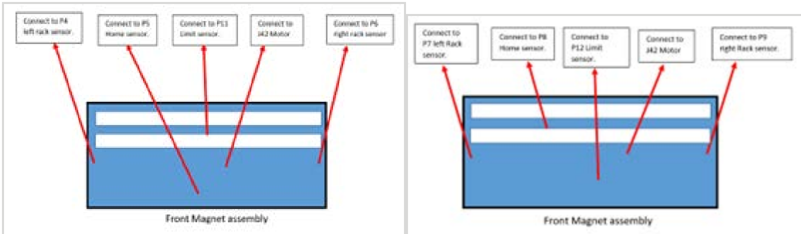
16. Ensure that pins on the rear of the side wall align with the holes in the back plate of the assembly. Replace the small Philips head screws that secure the back plate to the wall.



17. Replace the two **7/64** inch head screws on the underside of the base securing the wall to the base. Apply Loctite to secure the screws.
18. Reinstall the mag/lysis assembly in the Max instrument using the four 9/64inch head screws, applying Loctite to secure the screws, and reconnecting the left and right side sensors, the flag home sensor, the flag upper limit sensor, the motor, and both Gort board cables.
19. Connect the sensor cables to the correspondent connector.

Note: All 4 connectors are not clearly labeled, is recommended to mark to connectors to ensure are the connectors are properly connected.

For reference:



20. Power ON the BD Max instrument.
21. Wait for the BD Max to be connected to the AIO.
22. Verify with a piece of paper or plastic screwdriver that each rack sensor is properly connected.
23. Perform Home all Motors.
24. Perform "Extractor Magnet Alignment" on page 513.
25. Install all previously removed instrument skins in the BD Max.

Verification:

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

1. Perform the"Empty Fill Check Errors" on page 454 to confirm pass-in values.
2. Perform full instrument qualification as per"5-Channel Qualification Test" on page 325.
3. Confirm the results with the "5-Channel Qualification Kit Result Review Table" on page 331.
4. Verify the brown magnet beads aren’t transferred to the next Master Mix.

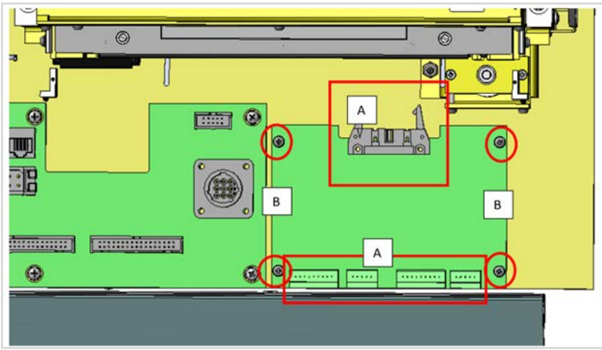
5.2.10 Circuit Card Assemblies

5.2.10.1 Extractor Motor Controller

The Extractor Motor Controller is mounted directly to the right of the Liberty board (backplane) and in front of the right or B reader. It is held in place by four screws.

Procedure:

1. Disconnect the cables Label A.
2. Remove all four screws. Label B



Verification:

1. Perform the "Instrument Firmware Update " on page 416.

Warning: At the time the software is performing the instrument Firmware Update, do not interfere or perform and task on the BD Max or AIO, any interference cold corrupts the firmware update.

2. Perform Home All Motors
3. Perform "Procedure Empty Fill Check" on page 491.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.10.2 Huey MUX Board

The Huey MUX board is mounted to the left of Reader A. The Reader A sliding read head should be de-installed to provide more working room before removing this card.

The Huey MUX board has one standard DB9 connector plugged into the top of the card.

At the bottom of the card there are two tabs, one towards the front and one towards the back of the instrument.

- These are used to lift the card straight out and insert the card straight into the **three 150 pin connector sockets** on the Liberty board.

After changing the **Huey MUX** board, update the IP address and update firmware.

- Both reader pressure plate step counts must be reset.
- The step count values are written on the base plate in front of each reader and are reset through Script-O-Matic.

The Robot should then be aligned.

Note: These connectors are fragile and easily damaged. Take care when removing and inserting any card with these types of connectors, or damage may result.

Document: BDDSSGFS7422 Doc Type: ZIP Status: Released EFFECTIVE
Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

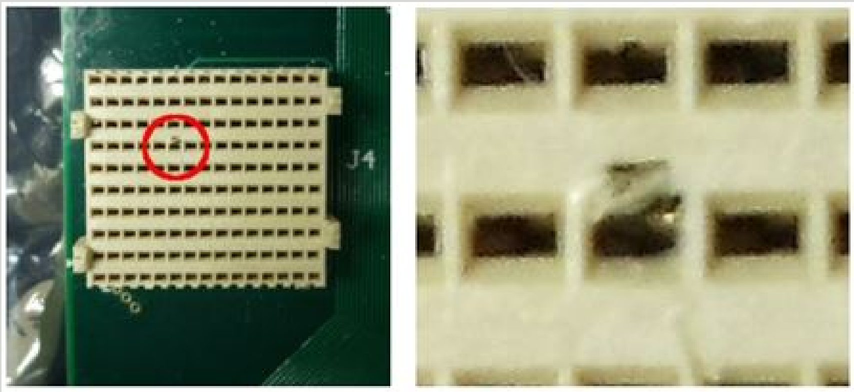


Fig: Example of damaged connector

Note: Re-enter the pressure plate value into the calibration table after HUEY MUX board is replaced. Refer to "Pressure Plate Setting " on page 484 for more information on adjusting pressure plate values.

Verification:

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

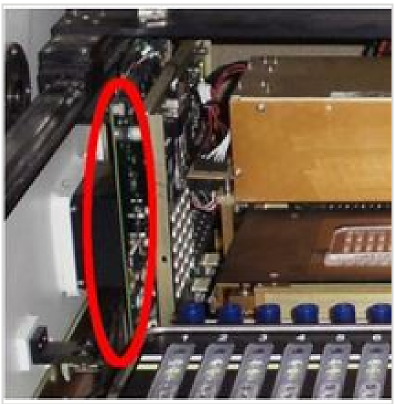
1. Perform "Qualification Run" on page 322 in the side the Mux was replaced.

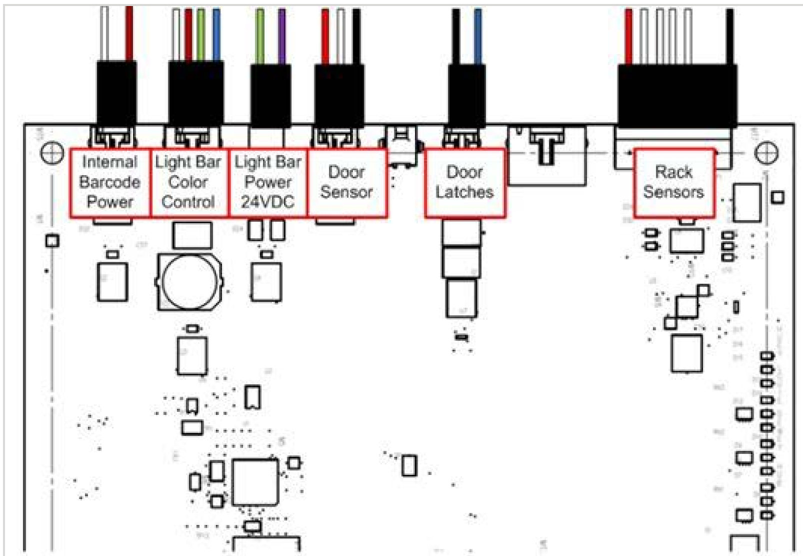
5.2.10.3 Bender Board

The Bender board is located on the far left of the instrument. First to facilitate the removal of this board, the A Reader and Windows Mux board should be de-installed.

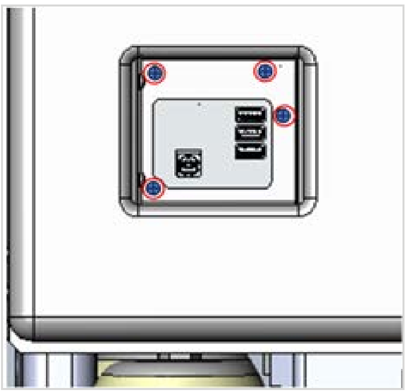
1. Open the door and keep open.
2. Power off the BD Max
3. Disconnect the power cable.
4. Disconnect any external USB devices from the instrument.
5. From the top of the Bender board, disconnect the:

a. Green rack sensor connector
b. Two-pin connector for the door latches
c. Three-pin door sensor connector
d. Two-pin light bar power connector
e. Four-pin light bar control connector
f. Two-pin internal scanner/barcode power connector

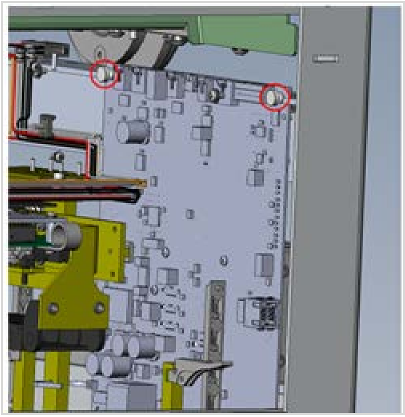




6. Remove the four screws from the faceplate that attaches to the outer left side of the instrument.



7. Remove the two white thumb screws at the top of the Bender board.



8. Pull the Bender board up and slightly backward to free it from the 150-pin connector and clear the left-side I/O port.

> **Note:** Be aware that the I/O cover plate is now loose.

9. Carefully Remove the card.
10. Reverse the removal process to reinstall the new Board.

> **Warning:** When replacing the Bender board ensure that it is aligned correctly - so as not to damage the 150 pin connector on the Liberty board.

11. Connect the power Cable.
12. Power On the BD Max.
13. Perform "Instrument Firmware Update " on page 416.

> **Warning: DO NOT** perform or select Home All Motors

14. Perform "Instrument Firmware Update " on page 416.

> **Warning:** At the time the software is performing the instrument Firmware Update, do not interfere or perform and task on the BD Max or AIO, any interference cold corrupt the firmware update.

Verification:

1. Visually Confirm the internal light Bar illuminates.
2. Confirm the AIO connects to the BD Max.

3. Verify the functionality if the printer and/or handheld barcode scanner is connected.
4. Perform "Procedure Empty Fill Check" on page 491.
5. Verify with a piece of paper or plastic screwdriver that each rack sensor is properly connected.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.10.4 Replacement Liberty Board 435233

Note: The Replacement Liberty Board is also referred to as Motherboard in the Manual.

Procedure:

1. Open the door.
2. Power off the BD Max
3. Remove the power cable.
4. Disconnect the USB cable that connects the AIO and other USB cables on the side.
5. Remove the Skin Removal 5.2.4.1
6. Remove the Windows Mux Board Replacement 5.2.8
    a. The Windows Mux board is mounted to the left of Reader A.
    b. The Reader A sliding read head should be de-installed to provide more working room before removing this card.
    c. The Windows MUX board has one standard DB9 connector plugged into the top of the card.
    d. At the bottom of the card, there are two tabs, one towards the front and one towards the back of the instrument.
    e. These are used to lift the card straight out and insert the card straight into the three 150-pin connector sockets on the Liberty board.

7. Remove the Bender board. 5.2.10.3

> **Note:** To facilitate the removal of this board, the A Reader and Windows/MUX board should be de-installed first.

8. Disconnect any external USB devices from the instrument.

9. From the top of the Bender board, disconnect the:

    a. Green rack sensor connector

    b. Two-pin connector for the door latches

    c. Three-pin door sensor connector

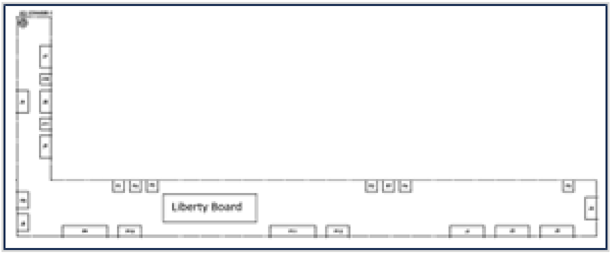
    d. Two-pin light bar power connector

    e. Four-pin light bar control connector

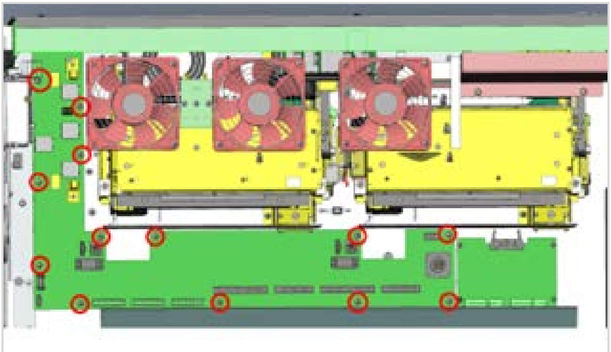
    f. Two-pin internal scanner power connector

10. Disconnect all cables from the Liberty board connectors.

11. Verify that each cable is correctly identified.



12. Remove all 13 screws that secure the board to the frame.

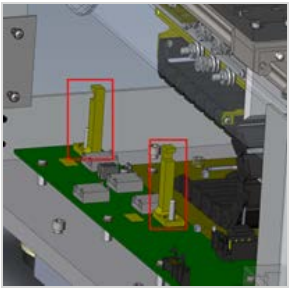


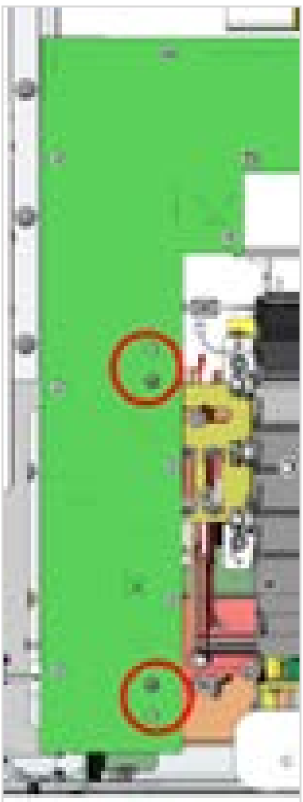
13. Remove the Liberty board.

14. Remove the board clamps from the replaced board and install them in the replacement board.

> **Note:** The new board will not come with the clamps.

15. Removing the two screws that secure the board.

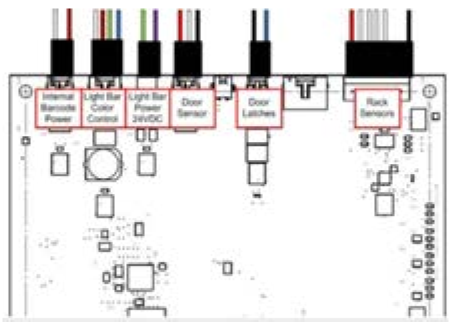




16. Place the replacement Liberty board in the frame.
17. Connect the cables to the liberty board.

> **Note:** Confirm all cables are securely connected. Verify no cables are under the board.

18. Install the bender board.
19. From the top of the Bender board, connect the:
    a. Green rack sensor connector
    b. Two-pin connector for the door latches
    c. Three-pin door sensor connector
    d. Two-pin light bar power connector
    e. Four-pin light bar control connector
    f. Two-pin internal scanner power connector.



20. Install the Windows Mux Board.
21. Connect the serial cable.
22. Connect the power cable.
23. Connect the USB cable that connects the AIO and other USB cables on the side.
24. Power on the BD Max.

Verification:

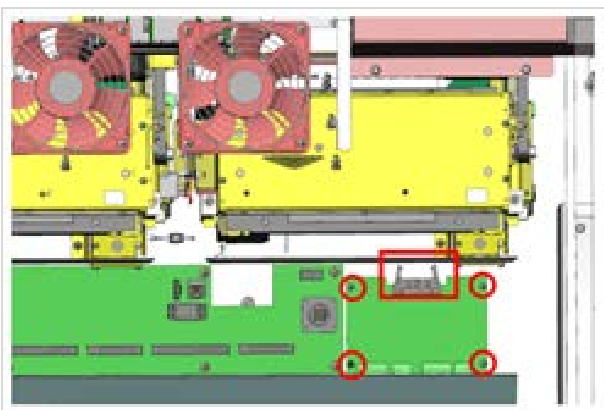
1. Perform the Power Supply Voltage Adjustments 5.2.1.
2. Perform Home All Motors.
3. Perform EFC 6.4.10.1.
4. Perform Lysis Heater Test 6.4.7.
5. If A Reader was removed, perform the 5-Channel Qualification Test 5.3.3 on the A side.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.10.5 Replacement PCB 2X MTR MAG DRV WIN (Dual Cobra Controller)

Procedure:

1. Open the door.
2. Power off the BD Max.
3. Perform "Skins Removal " on page 198.
4. Disconnect the cable on the right side.
5. Remove the four screws that secure the board.



6. Install the replacement board.
7. Install all internal Skins - "Skins Removal " on page 198.
8. Power on the BD Max.

Warning: DO NOT perform or select Home All Motors.

9. Perform "Instrument Firmware Update " on page 416.

Warning: At the time the software is performing the instrument Firmware Update, do not interfere or perform and task on the BD Max or AIO, any interference cold corrupt the firmware update.

10. Perform Home all Motors.

Verification

1. Perform "Lysis Heater Test" on page 482.
2. Perform "Procedure Empty Fill Check" on page 491.
3. Perform the QPM verification - "5-Channel Qualification Test" on page 325.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.11 Extractor Magnet Update and Alignment

Alignment of the magnets on the Extractor Module is critical to proper sample preparation, which in turn affects the ability of the BD MAX to obtain usable and repeatable PCR results.

Requirements

- Magnet Alignment Tool T212-1002-011 (8090622)
- Magnet Alignment Tool T212-009-001 (8088449)
- Set of Allen wrenches
- Phillips screw driver

Note: Reboot both the instrument and the All-In-One after exiting from Script-O-Matic.

5.2.11.1 Extractor Versions

Depending on the BD MAX Model designation, serial number, recent repairs and/or BD MAX upgrades, the instrument may have either a 3 magnet or 12 magnet Extractor Assembly.

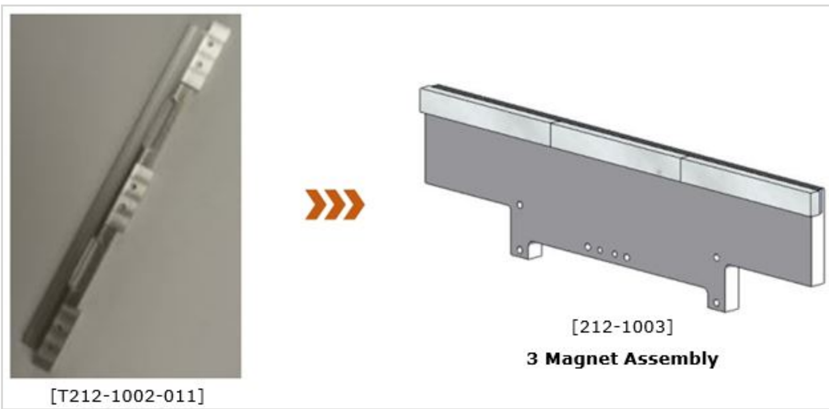
Note: The 12 Magnet Extractor Assembly [212-1006] is now the standard on all BD MAX™ instruments being produced. Eventually, the entire BD MAX install base will be converted from the 3 magnet version to the 12 magnet version.

Main differences between the 3 magnet and 12 magnet are:

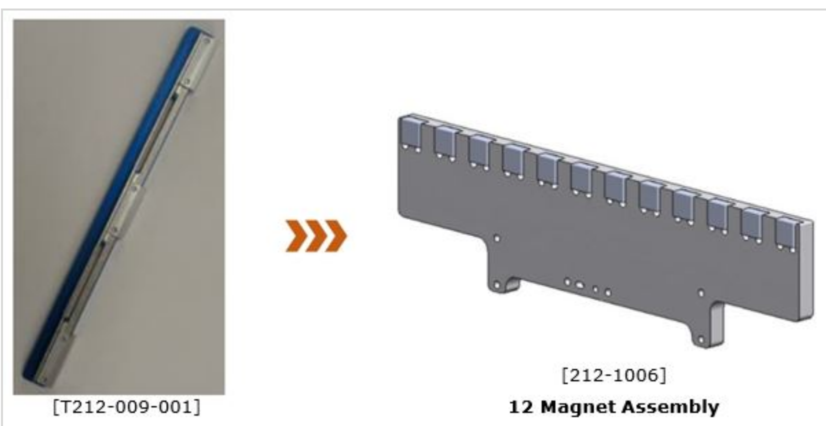
- Type of **Magnet Holder Assembly** installed (3 versus 12 magnets)
- Adjustment to **Gort Board** connectors

While the alignment procedure is similar in both Magnet Extractor Assemblies, the alignment tool used to perform the task is different.

- Version 212-1003 Magnet Holder Assembly (original 3 magnet version) requires the T212-1002-011 (8090622) Magnet Alignment Tool.



- Version 212-1006 12 Magnet Holder Assembly requires the T212-009-001 (8088449) Magnet Alignment Tool.



- Alignment must be checked on both Extractor modules by carefully raising the magnet sub-assembly by hand.

5.2.11.2 Extractor Magnet Update

Procedure to perform the extractor magnet upgrade from the 3 magnet configuration to the new 12 magnet configuration.

Required Materials

- Blue Magnet Alignment Tool (T212-009-001)
- Kit 12 Magnet Replacement MAX 6 (**SAP Catalog No. 443900**)
- **7/64** inch Allen Wrench
- **3/32** inch Allen Wrench
- #10 Torx Security Screwdriver

Procedure

1. Remove the upper and lower waterfall covers of the instrument to gain access to the **Mag/Lysis** assembly.
2. Remove the **Mag/Lysis** assembly by disconnecting the cables and removing the four screws at the base of the assembly with the **7/64** inch Allen wrench.

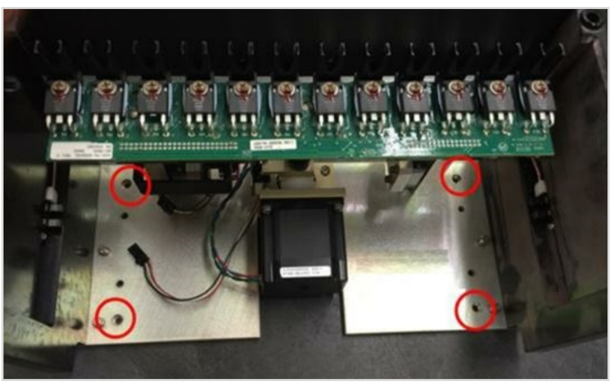


Fig: Removing the mag/lysis assembly from the instrument

3. Place the **Mag/Lysis** assembly on a flat surface, with the back side facing up.

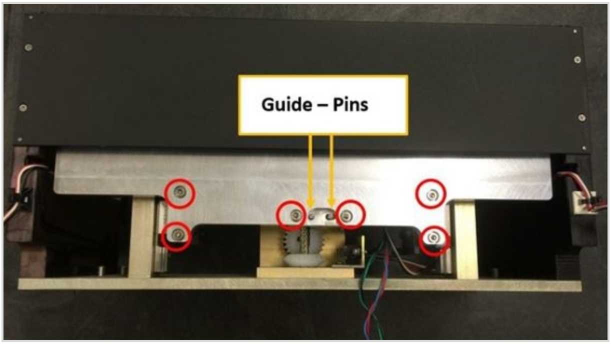


Fig: Mag/lysis assembly with back side facing up

4. With the 7/64 inch Allen wrench, remove the six screws that holds the magnet assembly in place.
5. Remove the 3 magnet assembly by lifting it out of the two guide-pins in the center. Be careful not to bend the lead screw in the center back.
6. Install the new 12 magnet assembly and tighten the six screws back.
7. Align the magnet assembly using the blue magnet alignment tool T212-009-001.
8. Install the Mag/Lysis assembly back into the instrument.
9. Perform steps 2 through 8 for the Mag/Lysis assembly on the other side to update the extractor magnet.
10. Run the **init.script** from Script-O-Matic or the **Home All Motors** from **Tasks** to ensure the magnets are working properly.
11. Perform one qualification run.

Verification:

> **Verification:** After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

1. Perform the QPM section of the "Qualification Run" on page 322

5.2.12 BD MAX 24V Power Supply

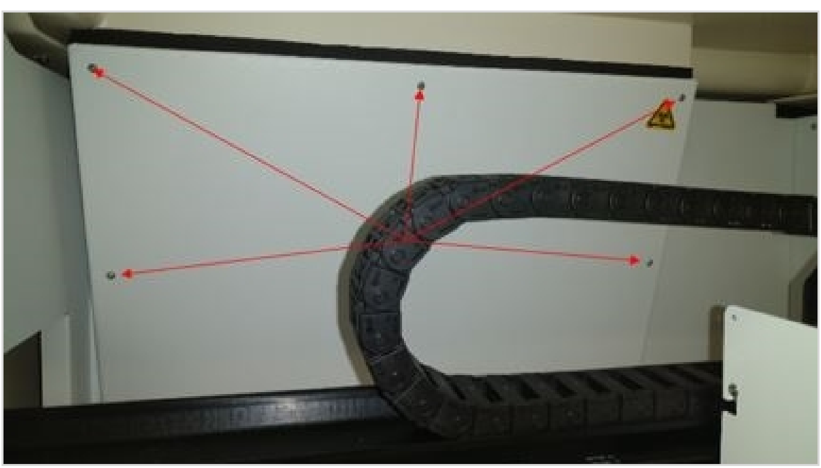
Note: Instruments with serial number CT1114 and below have the old power supply.

Required Materials

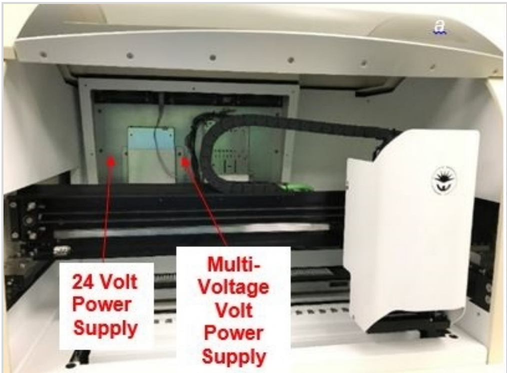

5.2.12.1 Removing the Old Power Supply

To remove the old power supply:

1. Remove power and unplug power cable from the BD MAX instrument. With the instrument unplugged, toggle the power switch to de-energize capacitors.
2. Remove all eight **T10** screws from access panel to access both the **24V** and multivoltage power supplies.

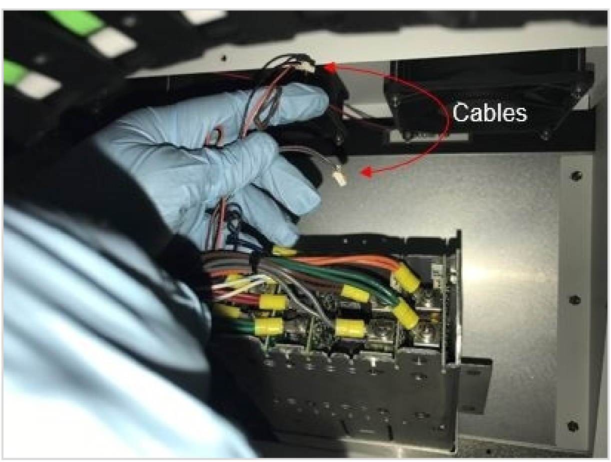
   

3. Remove the **5/16** inch nuts from the support bracket of the multi-voltage (right) power supply.

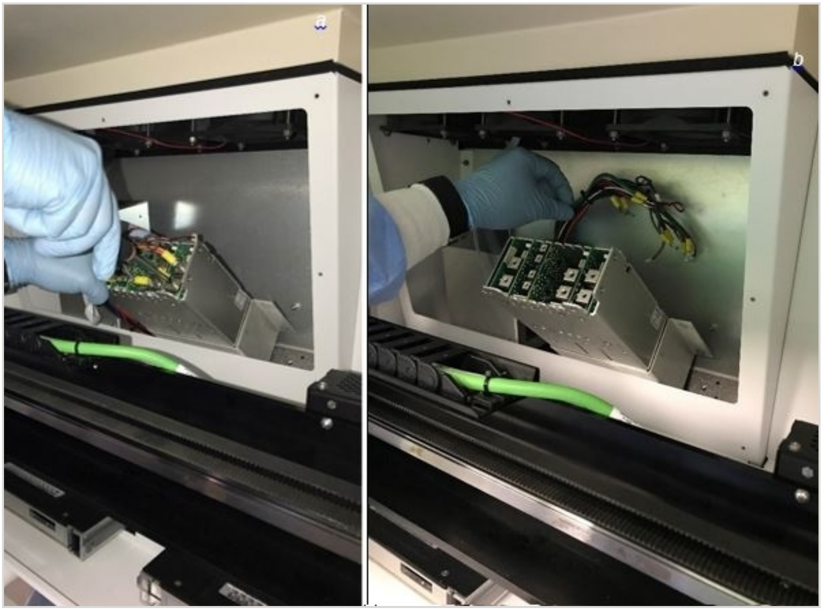


4. Gently tilt the multi-voltage power supply towards the front of the instrument as shown in the image.

5. Remove connectors from the multi-voltage power supply.

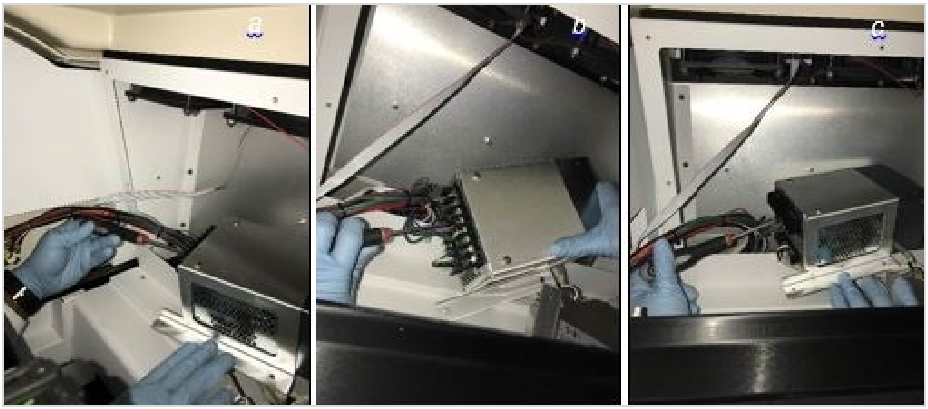


6. Use a Philips screwdriver to remove the terminals from the multi-voltage power supply.



7. Remove the cable ties with wire cutter.

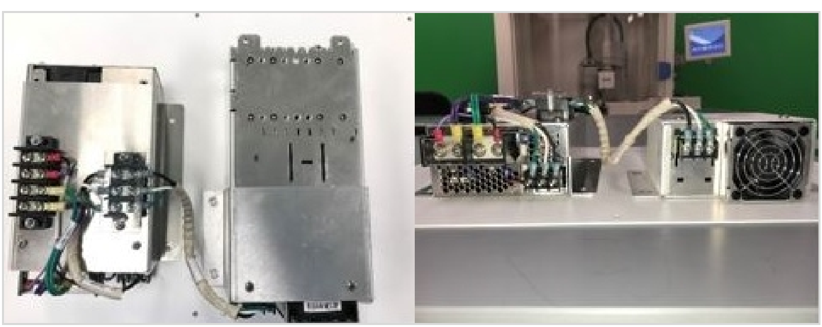
8. Remove the **5/16** inch nuts and tilt the power supply towards the front of the instrument. Remove the power cables from the terminals of the **24V** power supply with Philips screw driver.



9. Remove both power supplies from the instrument.

   For top and side view of the obsolete **24V** power supply configuration:

   For top and side view of new **24V** power supply configuration:



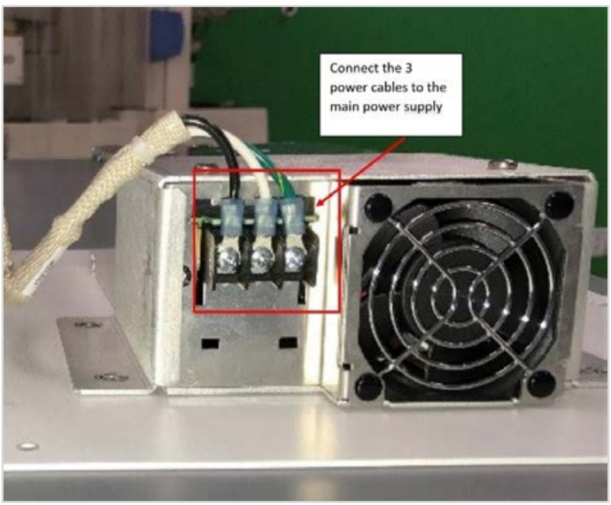
5.2.12.2 Installing the New Power Supply

The New Power Supply is compatible as a total replacement with all BD Maxes.

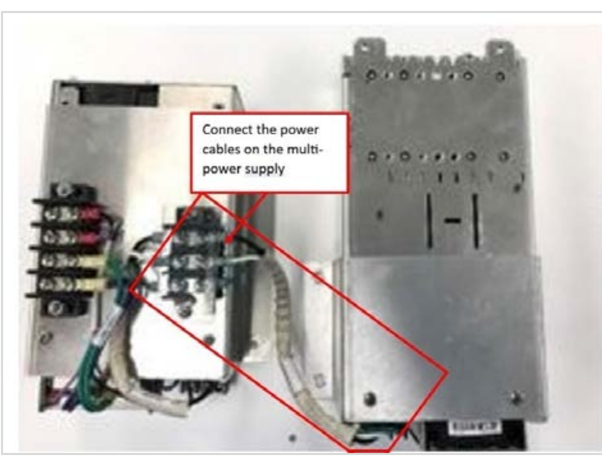
1. Open the door.
2. Power OFF the BD Max.
3. Unplug the power cord.
4. Use a Philips screwdriver, mount the 24 multi-voltage power supply in the back panel, and secure the two bottoms 5/16 inch nuts on the support bracket.

   Note: If the cable is attached to the multi-power supply, disconnect before mounting.

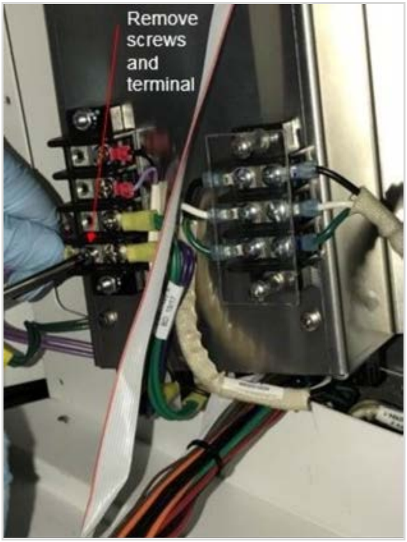
5. Connect the power cables on the bottom of the Main Power Supply.



6. Secure the Main power supply in the back panel.
7. Connect the power cable from the main power supply to the multi-power supply with a Philips screwdriver.

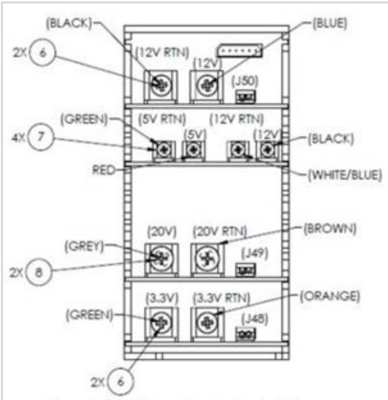


8. With a Philips screwdriver, remove the four screws on the left-hand side of the four position terminal strip.

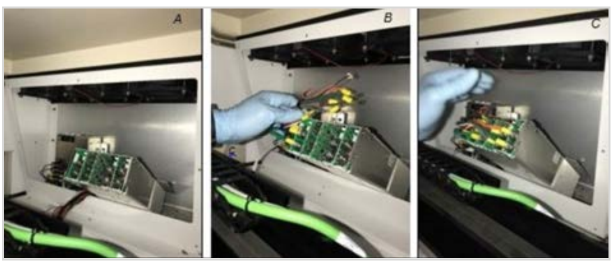


9. The cables are color-coded for easy installation. Install green and purple cables onto terminal block by placing screws into the ring terminal and mounting cables onto the terminal block.

10. Use a Philips screwdriver to install the cable harness onto the multi-voltage power supply by color.



11. Tilt the multi-voltage power supply towards the front of the instrument for easier installation of individual ring hooks and power supply cables.



12. Tighten and install remaining 5/16 inch nuts on both the 24V and multi-voltage power supplies. Apply tie wraps in the same locations as with the older power supply.

13. Reinstall the power supply access panel with all eight T10 screws.

> **Note:** Check or adjust the power supply test points on the liberty board when power supply is replaced.

14. Connect the power cord.
15. Power on BD Max System.

Verification:

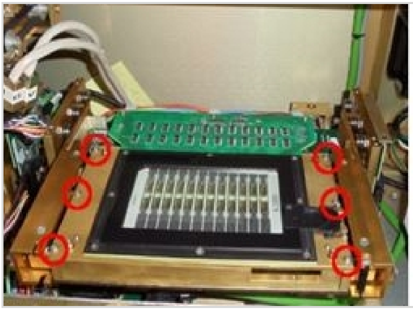
1. Perform Home All Motors.
2. Perform "Power Supply Voltage Adjustments" on page 193.
    a. Verify the voltages on the liberty board and power supply voltage adjustments.
    b. Confirm the voltages are in the range.
3. Perform the full "5-Channel Qualification Test" on page 325.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.13 Heater MUX Module

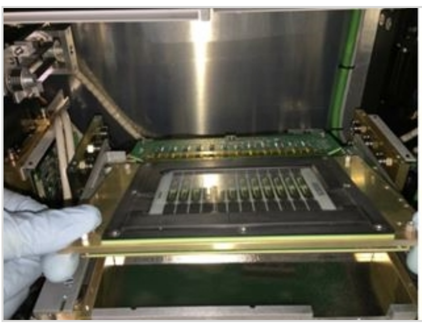
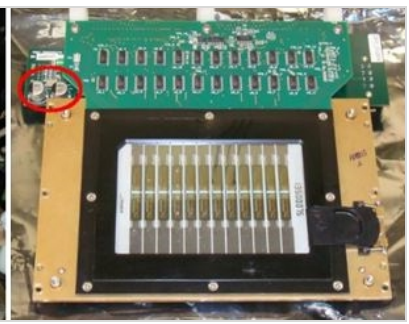
1. Remove the Sliding Read Head Assembly according to "Reader Module Removal" on page 217.
2. Loosen the four captive slot screws that hold the black cover to the **Heater MUX module**, and then remove. Pulling up slightly on the black cover while loosening the screws will help avoid backing out the screw out of the cover itself.


3. Remove the six Phillips head screws that secure the **Heater MUX module** to the **Reader** drawer.

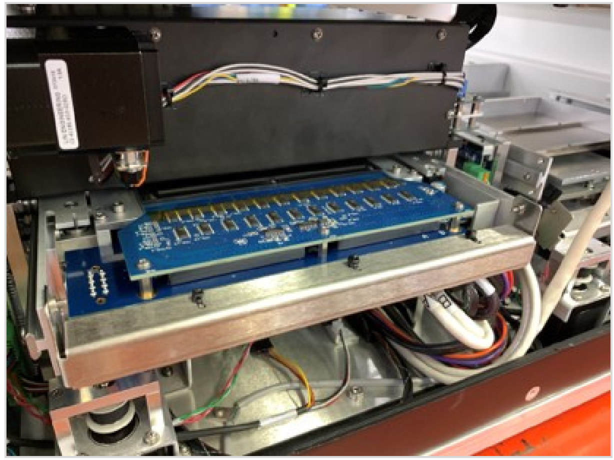
4. Carefully lift the **Heater MUX module** out of the **Reader** drawer.

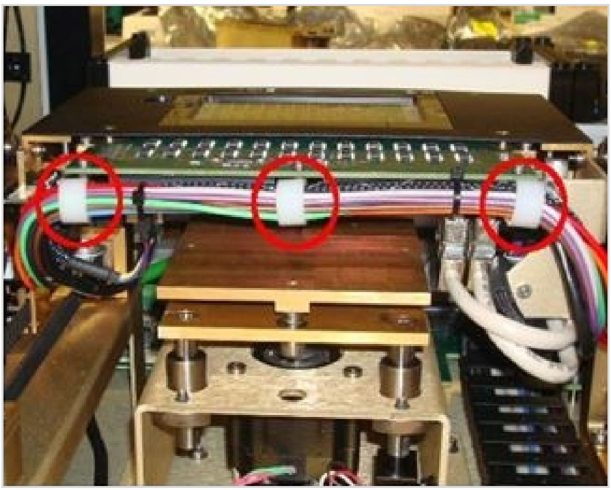
> **Warning:** There are two surface mount capacitors on the top of the **Heater MUX** module. When inserting or removing the module, be aware of the metal edge on the left rear of the **Reader** drawer. The two capacitors can be broken off the board by the metal edge if not careful.

5. From the back of the instrument, remove the wire bundles form the wire guides on the back of the **Heater MUX module.**

> **Note:** When looking from the front of the instrument, the left side cable loop on the back of the heater MUX can be removed permanently. New instruments (beginning with CT1653, excluding CT1654) introduce a new cable bracket, in which the cables are secured with cable ties.





6. Disconnect the cables from the underside of the board. Pay attention to the orientation of the **A** and **B** cables. The **A** cable attaches to the inside connector. Remove the **Heater MUX board.**

Warning: Reversing the **A** and **B** cables will damage the assembly.

7. When installing a new **Heater MUX board**, update the new IP address and firmware. Refer to "Obtain MUX IP (WireShark)" on page 413 for updating IP address. Refer to section"Software/Firmware Update" on page 407 for firmware update.
8. After replacing a heater MUX, check cable tension so that the heater mux will rest on the metal tray and not on the cables. Check pressure settings and tighten screws on the tray.

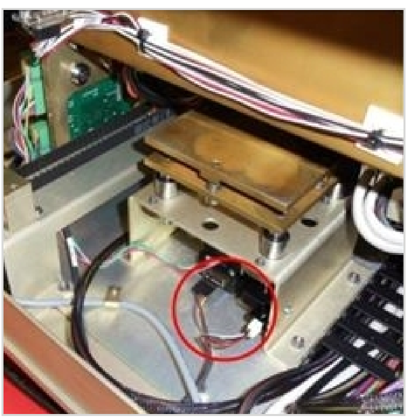
Verification:

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

1. Perform the "Qualification Run" on page 322 in the side the Heater Mux was replaced.

5.2.13.1 Reader Pressure Motor Module

1. To remove the pressure motor from the reader, first remove the instrument's lower back panel.
2. Disconnect the encoder/limit switch cable from the assembly.
3. Disconnect the motor power cable from the reader motor controller card.
4. Remove the four nuts holding the assembly in place.
5. Pull the reader drawer all the way out.
6. Lift and remove the assembly.

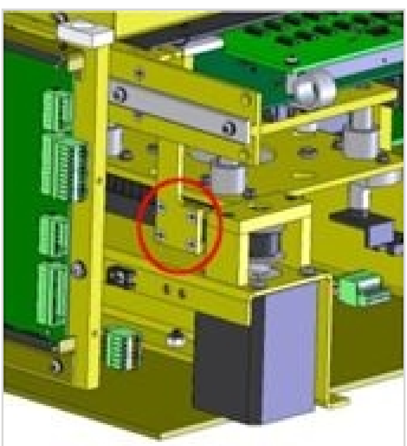


5.2.13.2 Reader Tray Drive Assembly

1. Remove the **two screws** attaching the assembly to the reader frame.

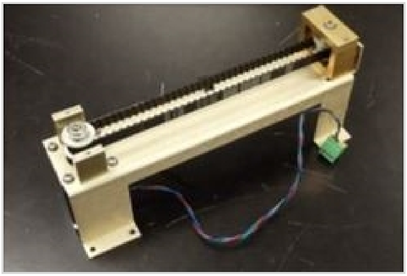
Note: The **Reader** motor controller may need to be moved slightly to access the screw

2. Remove the **two nuts** securing the inside of the assembly to the base plate.
3. Disconnect the **motor drive** from the Reader motor controller.



4. Remove the **four screws** holding the drive bar to the drive belt.

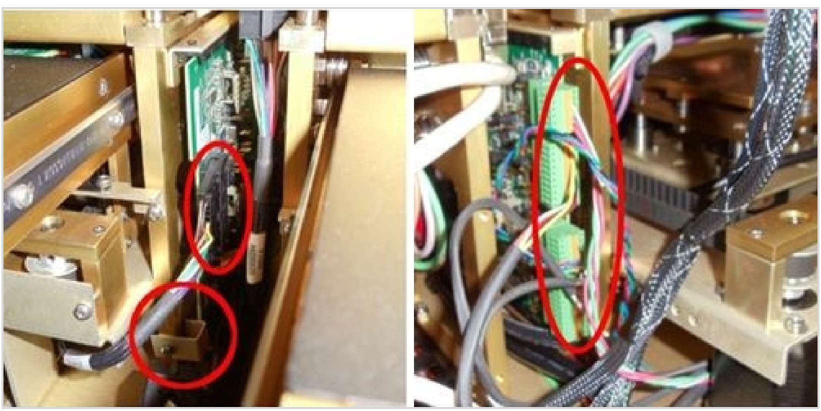
5. Remove the **Reader Tray Drive** Assembly.



5.2.13.3 Reader 2x Motor Controllers

The controller card is held in place by a retaining clip and slides out the front.

1. Unscrew and remove the retaining clip.
2. Disconnect the controller cable from the front of the board.
3. Disconnect the two sets of motor and encoder cables from the back of the card.
4. Remove the card.



> **Note:** The 2x Blue Cobra motor controllers are physically the same part. Their function is set by on-board jumpers and rotary switches. Verify that the jumpers and switch settings of the new card match those of the card being removed.

5.2.14 Robot Assemblies Replacement

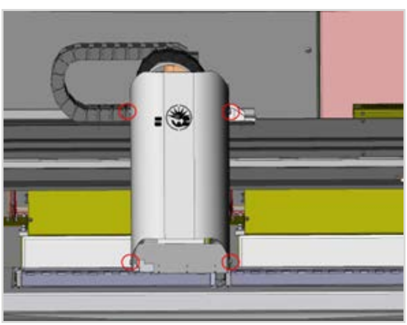
5.2.14.1 Z-Head Gantry Assembly

The Z-Head Gantry attaches to the X-Gantry. The Z-Head Assembly consists of the following replaceable parts:

- Barcode scanner
- Stripper assembly
- Stripper Motor
- 4 Quad Pumps
- Z-Controller PCB
- Quad Pump Controller PCB
- Air Lines
- Z-Gantry motor

5.2.14.2 Z-Head Assembly Removal

1. Unlock and open the BD Max door.
2. Power off the BD Max.
3. Unplug the power cord on the BD Max.
4. Loosen the four screws (two on each side) that secure the **Z-Shield**, and then remove the **Z-Shield**.



5. Remove the four 3 Philips screws that secure the chain to the head of the Z-Gantry.
6. Remove the clamp that secures the chain to the frame.
7. Disconnect the two cables on the top of the Gantry.

8. The Z-Gantry is secured to the X-Gantry by four 2.5mm Allen screws and two pins.
9. Move the Z-Head way up and use a 2.5 mm Allen wrench to remove the bottom screws.
10. Move the Z-Head to the bottom position and, while holding the Gantry, remove the top two screws with a 2.5 mm Allen wrench.
11. Remove the Gantry assembly from the rail.
12. Install the replacement Gantry assembly in reverse from step 8 to step 4.

Warning: Place a new clamp to secure the cables on top of the head Gantry.

13. Connect the power cord.
14. Power on the BD Max.

Warning: DO NOT perform or select Home All Motors.

15. Perform Instrument Firmware Update. Refer to "Instrument Firmware Update " on page 416.

Warning: At the time the software is performing the instrument Firmware Update, do not interfere or perform a task on the BD Max or AIO. Any interference could corrupt the firmware update.

Verification:

1. Perform Home All Motors.
2. Perform QPM on the rack A and B that link to the replaced Pump. Refer to "5-Channel Qualification Test" on page 325.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.14.3 Z-Gantry Quad Pump Removal

The quad pump head had has four pumps, one for each nozzle. Each pump can be removed individually.

From the front of the instrument. The left rear pump goes to nozzle **1**, the left front pump goes to nozzle **2**, the right rear pump goes to nozzle **3**, and the left front pump goes to nozzle **4**.

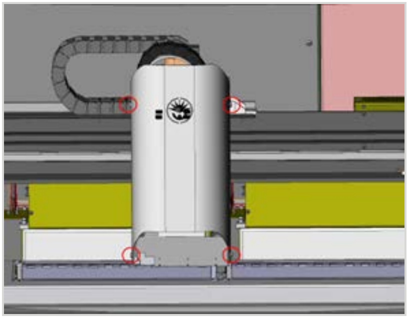
1. Disconnect the air nozzle from the bottom pump, then disconnect the pump and sensor connector from the quad pump control board.

2. Remove the **two Allen head screws** securing the pump to the side of the instrument.

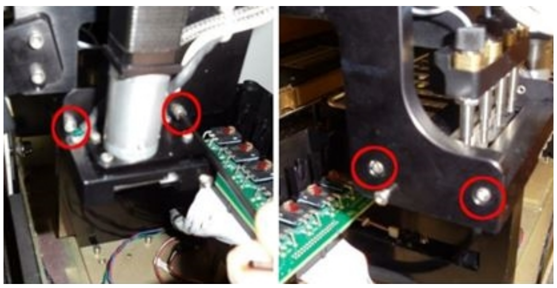
3. Remove the pump from the instrument.

5.2.14.4 Z-Gantry Stripper Assembly Removal

1. Unlock and open the BD Max door.
2. Power of the BD Max.
3. Unplug the power cord on the BD Max.
4. Loosen the four screws (two on each side) that secure the Z-Shield, and then remove the Z-Shield.
5. Remove the four T10 Head screws securing the X-Gantry chain to the Z-Gantry.



6. Disconnect the cable from the stripper to the Cobra controller board.
7. Remove the four Allen screws that secure the stripper to the Gantry assembly.



8. Install the new stripper assembly by securing with the four screws.
9. Install the Z-Shield, and secure it with the four screws.
10. Connect the power cable on the BD Max.
11. Power on the BD Max.

> **Warning:** DO NOT perform or select Home All Motors.

12. Perform the "Software/Firmware Update" on page 407.

> **Warning:** At the time the software is performing the instrument Firmware Update, do not interfere or perform and task on the BD Max or AIO, any interference cold corrupt the firmware update.

13. Perform Home All Motors.

Verifications:

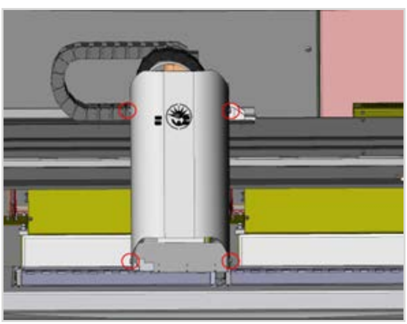
1. Perform QPM on the rack A and B who link to the replaced Pump, refer to "5-Channel Qualification Test" on page 325.

2. Confirm the stripper picked up and eject all tips.

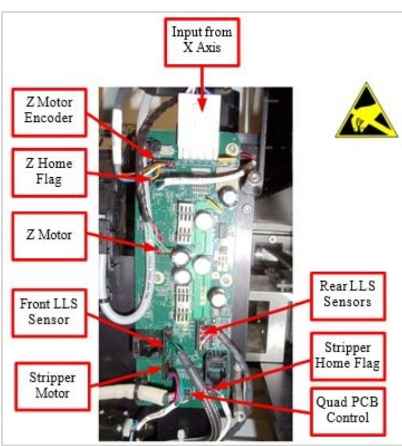
Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.14.5 Z-Controller Removal

1. Unlock and open the BD Max door.
2. Power of the BD Max.
3. Unplug the power cord on the BD Max.
4. Loosen the four screws (two on each side) that secure the Z-Shield, and then remove the Z-Shield.
5. Remove the four T10 Head screws securing the X-Gantry chain to the Z-Gantry.



6. Carefully disconnect all cables attached to the Z-controller board.



7. Remove all six Allen screws that secure the Z-controller to the frame.
8. Install the new board and secure it with the six Allen screws.
9. Connect all cables to the z-Controller board.
10. Install the Z-Shield, and secured with the four screws.
11. Connect the power cable on the BD Max.
12. Power on the BD Max.

> **Warning:** DO NOT perform or select Home All Motors.

13. Perform the "Software/Firmware Update" on page 407.

> **Warning:** At the time the software is performing the instrument Firmware Update, do not interfere or perform and task on the BD Max or AIO, any interference cold corrupt the firmware update.

14. Perform Home All Motors.
15. Perform the Gantry calibration.

Verifications:

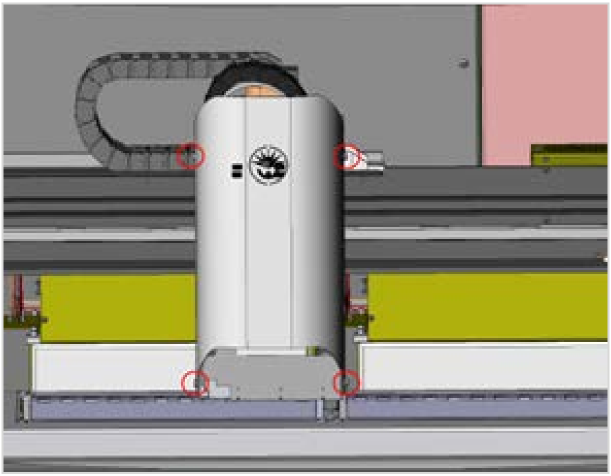
1. Perform"Procedure Empty Fill Check" on page 491.
2. Perform "Z-Gantry Stall Script" on page 450.
3. Perform QPM on the rack A and B that link to the replaced Pump, refer to "5-Channel Qualification Test" on page 325.

> **Verification:** After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

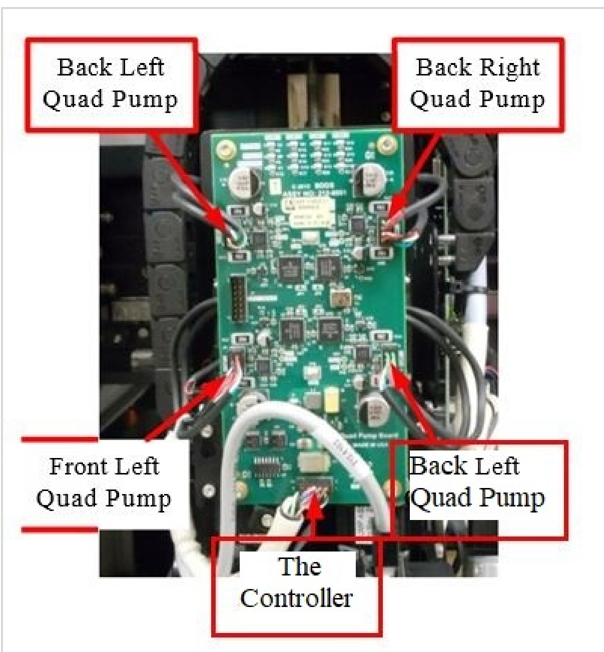
5.2.14.6 Quad Pump Controller Removal

1. Unlock and open the BD Max door.
2. Power of the BD Max.

3. Unplug the power cord on the BD Max.
4. Loosen the four screws (two on each side) that secure the **Z-Shield**, and then remove the Z-Shield.
5. Remove the four T10 Head screws securing the **X-Gantry chain** to the **Z-Gantry**.



6. Carefully disconnect all pump cables and the power command from the Quad Pump controller.



7. Remove all four Allen screws that secure the Quad Pump-controller to the frame.
8. Install the new board and secure it with the four Allen screws.

9. Connect all cables to the Quad Pump Controller board.
10. Install the Z-Shield, and secure it with the four screws.
11. Connect the power cable on the BD Max.
12. Power on the BD Max.

> **Warning:** DO NOT perform or select Home All Motors.

13. 10. Perform the "Software/Firmware Update" on page 407.
14. At the time the software is performing the instrument Firmware Update, do not interfere or perform and task on the BD Max or AIO, any interference cold corrupt the firmware update.
15. Perform Home All Motors.

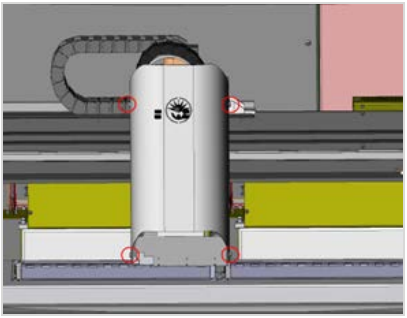
Verifications:

1. Perform Pump Aspiration and Dispense Check, refer to "Read the Run Report " on page 443.
2. Perform QPM on the rack A and B who link to the replaced Pump, refer to "5-Channel Qualification Test" on page 325.

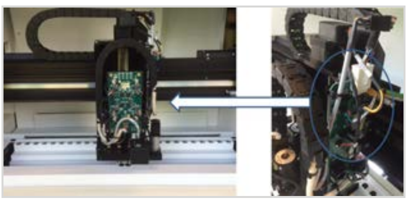
> **Verification:** After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.15 Replacing the Z-Robot Motor

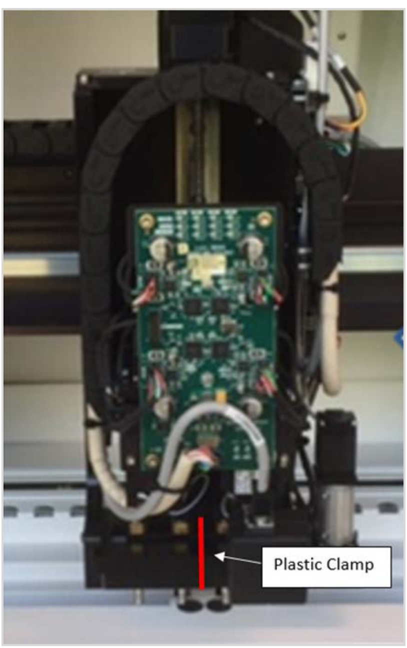
1. Unlock and open the BD Max door.
2. Power of the BD Max.
3. Unplug the power cord on the BD Max.
4. Loosen the four screws (two on each side) that secure the **Z-Shield**, and then remove the Z-Shield.
5. Remove the four T10 Head screws securing the **X-Gantry** chain to the **Z-Gantry**.
6. Move the gantry to the front of the BD Max.



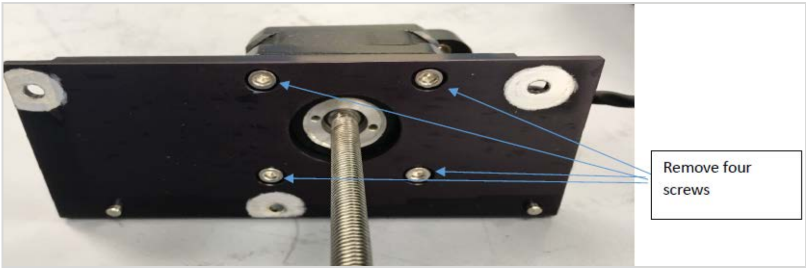
7. Carefully disconnect all cables connected to the z-Motor in the Z-controller board.
    a. Disconnect the motor power from the Z robot blue cobra board.
    b. Disconnect the encoder cable from the motor.
8. Remove any cables that might impede removing the top of the robot.



9. Remove three 7/64 screws from the top of the robot to uninstall the Z motor.
10. **Use a cable tie to secure the internal pumps to the chassis.**This is to avoid the damage or breaking the Z-Home sensor.



11. Pull the bracket and motor straight up while holding the robot base.
12. Remove that **four screws** from the underside of the bracket using **2.5 mm Allen key**.



13. Install new motor and shaft.
14. Install four screws to secure the motor to the bracket.
15. Reinstall the bracket to the robot base.
16. **Remove cable tie used to secure pumps to the chassis.**
17. Move the robot up and down a few times to ensure easy up/down movement.
18. Connect the motor and encoder cables.
19. Install the Z-Shield, and secured with the four screws.
20. Connect the power cable on the BD Max.
21. Power on the BD Max.

Warning: DO NOT perform or select Home All Motors.

22. Perform the Update Firmware Update 6.3.3.6.

Warning: At the time the software is performing the instrument Firmware Update, do not interfere or perform and task on the BD Max or AIO, any interference cold corrupt the firmware update.

23. Perform "Z-Gantry Stall Script" on page 450.
24. Perform "Gantry Alignment " on page 508.
25. Perform Home All Motors.

Verifications:

1. Perform "5-Channel Qualification Test" on page 325 on the racks A1 A5 A6 A12 and B1 B5 B6 B12. Visual observation is required to verify the new motor picked up and ejected the tips.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.16 Replacement Cable Assembly Door Sensor

1. Open the Door. Power On the BD Max.
2. Power on the AIO.
3. Log in **Service Mode** a. Select **Maintenance**, **Field Service**.
4. Locate and open **Script-O-Matic** a. On top of the new windows, select the **Unlock Door option** . (This will bypass the hall effect sensor)

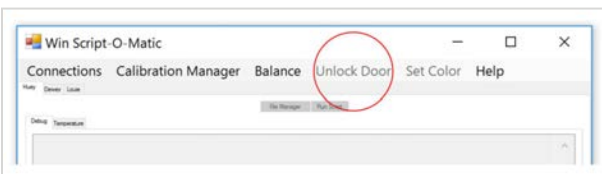


Fig: Script-O-Matic Unlock Door button

5. Open the door completely.
6. Shut down the AIO and power off the BD MAX.

Removing the door hall effect sensor

1. Remove the front Skin from the BD MAX (Refer to "Skins Removal " on page 198).
2. Carefully move the z gantry to the front-right side of the BD MAX and using a T10 Torx screw driver to remove the power supply cover (eight T10 screws). This opens access to three more T10 screws that secure the upper left side panel.
3. Remove the upper left side panel (five T10 screws) that secure this panel in place.
   a. Be careful when removing these screws so that the panel and hardware do not fall down or drop into the cracks. Loose hardware can lead to electrical shorts and further instrument damage.

b. Be sure to account for any dropped hardware before proceeding.

c. Using a ratchet handle may help for removing the screws.

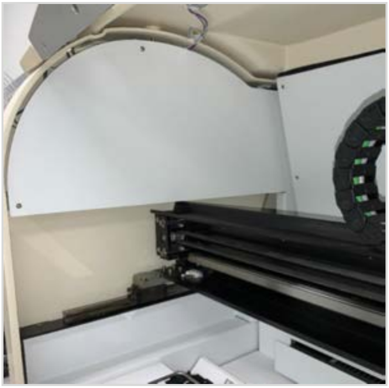


Fig: Upper Left Panel

Fig: Three hidden screws for the left side panel

Warning: Three hidden screws for the left side panel.

4. The door hall effect sensor is located on the left and towards the front of the BD MAX, behind the door solenoid. Remove the lower hex nut (14mm) from the bottom of the sensor and disconnect the black connector attached to the sensor to pull the sensor out. The upper hex nut may be difficult to access.

Fig: Hall Effect Sensor location

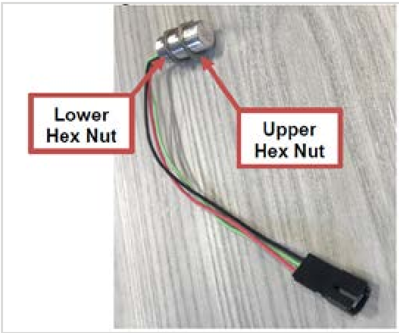


Fig: The Lower Hex Nut is on the cable side of the hall effect sensor.

Installing the door hall effect sensor

1. Before installing the new sensor, adjust the upper 14mm hex nut so that it protrudes from the top of the instrument **0.42in±0.05in** (10.7mm±1.3mm). Measure with a calibrated caliper.
2. This includes the width of the upper hex nut. It is easiest to install the lower hex nut after feeding the new sensor into the BD MAX frame.

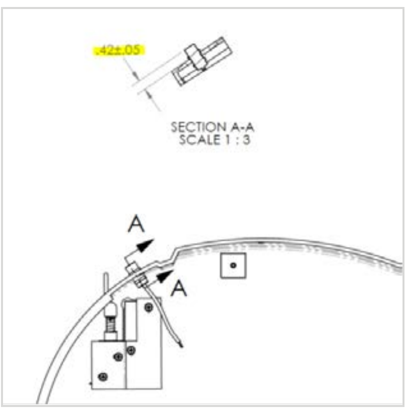


Fig: The upper part of the door hall effect sensor should protrude 0.42in±0.5in (10.7mm±1.3mm)

3. Feed the new sensor into the frame and install the lower 14mm hex nut to tighten the hall effect sensor in place. Be careful that the sensor does not continue to rotate as the lower nut is being tightened in place. The protruding height of the sensor is critical to the function of the sensor.
   a. The lower portion that protrudes out the bottom of the instrument should be approximately 0.45in (11.4mm).
   b. The BD MAX frame is about 5mm thick.

Fig: The lower part of the sensor should protrude about 0.45in to ensure the outer portion is the right distance from the door.

4. Connect the black cable connector.
5. Re-install the upper side panel, power supply cover, and front skins on the BD MAX.
6. Close the door.
7. Power on the BD Max.
8. Power on the AIO.

Verification

1. Log-in as ADMIN i. Verify the Service Mode isn't present on the AIO.
2. Test the door sensor functionality by click in the open-door bottom in the main menu.
3. The door should open and activate the solenoid, 1.5 min after the solenoid will close.

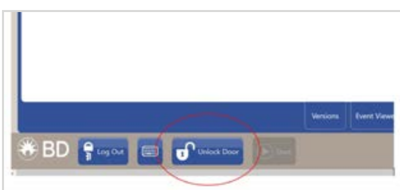
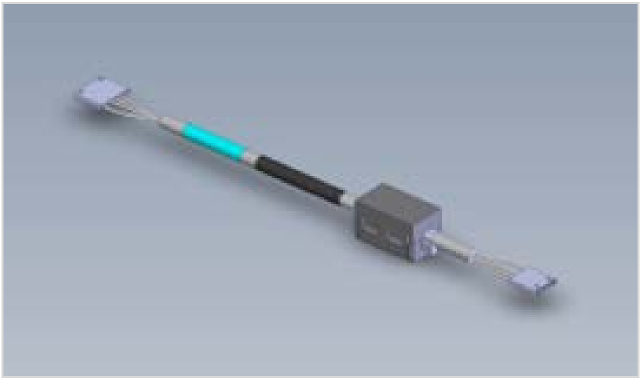


Fig: Unlock Door Button

> **Verification:** After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.17 Cable Assay X-Y Enconder (444762)

Procedure



1. Open the door.
2. Power off the BD MAX instrument.
3. Remove the Power Cable.
4. Manually open the drawers.
5. Remove the right-side lower skin.
6. Remove the five T10 screws that secure the skin to the X-Y rail.
7. Cut the cable tie that secures the cable to the frame.
8. Disconnect the cable from the head of the motor, (a small clip secures the connector to the motor head).

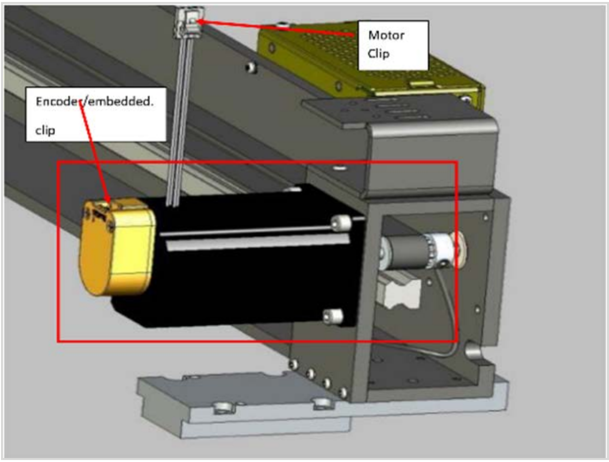


Fig: Motor and encoder

9. Disconnect the other side of the cable at the Y cobra controller.

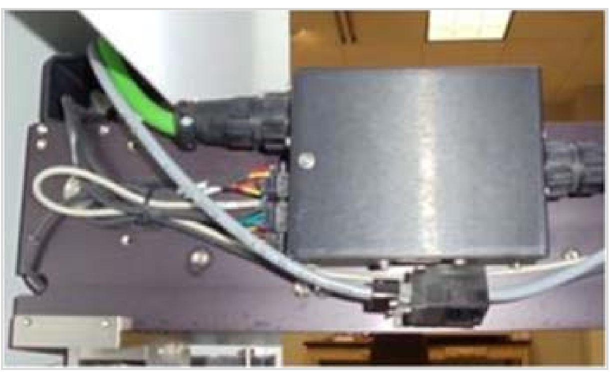


Fig: COBRA controller connections

10. Tie the cable with the cable ties in the exact locations as before.
11. Install the new cable in reverse sequence from steps 5 to 10, reconnect the cable, secure the cable to the frame, and replace the skins.
12. Connect the power cable.
13. Power ON the BD Max.
14. Perform home All Motors.

Replacement of the Cable Assy X-Y Encoder

1. Move the Gantry assembly completely to the left side of the BD MAX.
2. Cut the cable ties that are securing the cable to the X rail.
3. Disconnect the cable from the head of the motor (A small clip secures the connector to the motor head).
4. Disconnect the cable from the cobra controller.

Fig: Motor and encoder

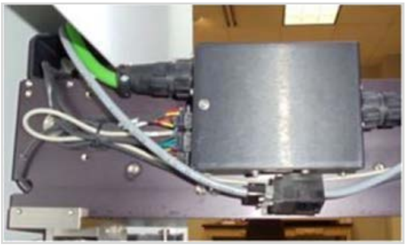


Fig: COBRA controller connections

5. Install the new cable.
6. Tie the cable to the same point as the replaced cable.
7. Install all skins removed.

Verification:

1. Perform "Gantry Alignment " on page 508.
2. Perform "CatalogWin.Script" on page 488.
3. No qualification is required after installation.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.18 Splash Guard MAX Spare

Procedure

1. Open the door.
2. Power off the BD MAX instrument.
3. Unplug the Power cable.
4. Manually open the drawer.
5. Loosen the four captive slot screws that hold the black splash guard to the Heater MUX module and then remove them.
6. Pulling up slightly on the splash guard while loosening the screws will help avoid backing out the screw.

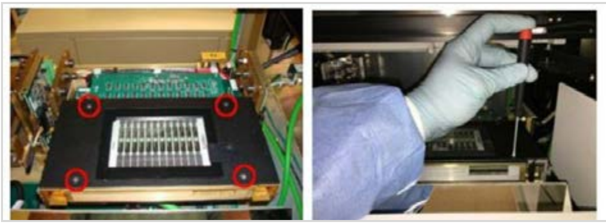


Fig: Location of the four screws holding the splash guard

7. Install the new splash guard using the four captive slot screws.
8. Visually confirm the splash guard is correctly sitting on the Heater MUX and that all four screws are correctly tightened.
9. Plug the power cable.
10. Power on the BD Max
11. Perform Home All Motors.

Verification:

1. Perform EFC (on sides A and B)"Empty Fill Check Errors" on page 454
2. No qualification is required.

> **Verification:** After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.19 Internal Fasteners MAX Spare

This spare is composed of several screws used in various applications on the BD MAX. The screws not used after ordering should be kept in the FSE toolkit for future use. Below, the location where each screw is used is described. Instructions for removal and installation, the related components are found in the BD MAX Service Manual (BDDSSGFS7422). After installation, complete the post installation verification as described in the Service Manual or in this Service Bulletin. The part number will contain the components listed below.

Screw	Quantity	Use
SCREW BUT HD TX SS BO 6-32UNCX.38L	Qty. 8	• Power Supply access panel • Z-Gantry cover • Upper Reader cover • Internal facades
SCREW BUT HD TX SS 6-32UNC .38L	Qty. 10	Back panel cover
SCREW BUT HD TX SS 6-32UNC .50L	Qty. 6	Secure Heater MUX module to the Reader drawer
SCREW KNRL HD NYL 6-32UNC .250L	Qty. 2	Secure the X and Y cobra drives to the rails
Nylon Plastic Snap-In Panel Plugs	Qty. 4	Connect upper and lower covers Lyse covers

5.2.20 Wire Duct Assembly Reader

Procedure:

Accessing the Wire Duct Assembly

1. Open the door.
2. Power of the instrument.
3. Disconnect the power Cable.
4. Remove the following "Instrument Skins" on page 197.

   Note: It is possible to remove the wire duct assembly from the front of the instrument, but it is more difficult and at least requires removal of the Reader and Heater MUX on that side as well.

   Recommended: Remove the following parts for additional space: If servicing side A: Windows Mux Board and Bender Board.

5. If the rear is not accessible, remove:
   a. Reader
   b. Heater MUX Board

   Warning: Be aware of the flag sensor in the pressure assembly to prevent accidental damage.

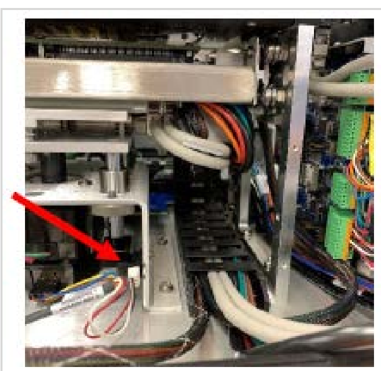


Fig: Pressure assembly flag sensor

Document: BDDSSGFS7422 Doc Type: ZIP Status: Released EFFECTIVE
Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

Removing the Wire Duct Assembly

1. Cut cable ties.
2. Cut ties along Heater MUX cable bracket – Cables 4, 5, 6
3. Cut ties along the base plate – Cables 4, 5, 6
4. You may also need to cut the cable ties from neighboring cables for enough space to route and secure other cables properly.)

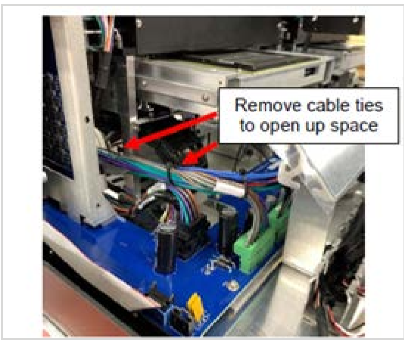
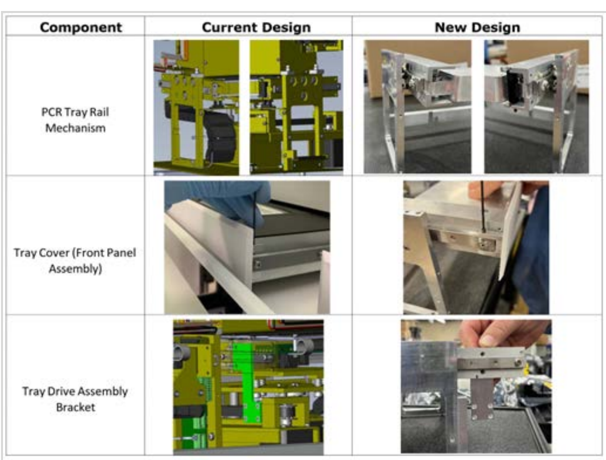


Fig: Removing additional cable ties for space to work

5. Disconnect cables.
6. Be patient and methodical. This may require going back and forth from the front and rear of the instrument, if accessible.
7. Remove the existing wire duct assembly.
8. Remove the two silver Philips screws from the tray.

> **Note:** The instruments with the CT3050 and above will have the new tray mechanism. Refer to the"PCR Tray Design Update" on page 355



Component	Current Design	New Design
PCR Tray Rail Mechanism		
Tray Cover (Front Panel Assembly)		
Tray Drive Assembly Bracket		

9. Remove the two black Philips screws from the base plate (2 black Philips screws).

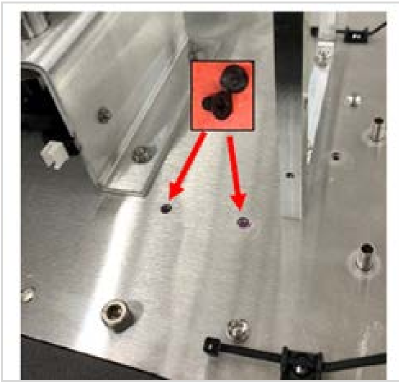


Fig: Base plate screws to be removed

10. Carefully pull out the cable assembly.

Installing the Wire Duct Assembly

1. Feed the Wire Duct Assembly beneath the tray. This is easiest from the back of the instrument, if available.
2. Using Loctite, screw down Wire Duct Assembly into the base plate. These two black Philips screws only engage a few threads.
3. Screw in the Wire Duct Assembly bracket, which mounts to the tray.

> **Note:** It may be easier to use a right-angle Philips wrench Connect cables.

4. Install the Heater MUX cable bracket.
5. Four Philips screws (two on each end).

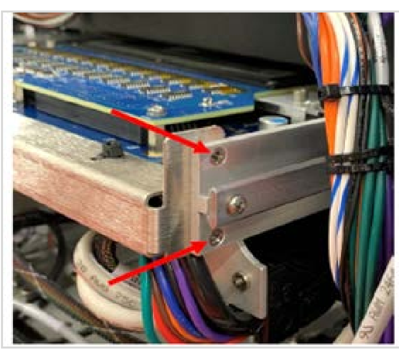


Fig: Heater MUX cable bracket screws (these are on each side)

6. Feed in cables 4, 5, and 6 and secure with three zip ties.

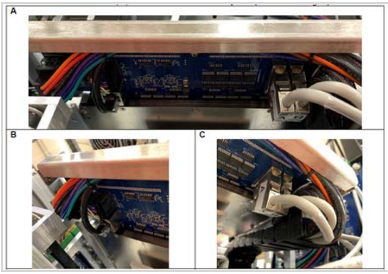


Fig: Heater MUX cable routing from instrument rear. (A) Neatly tucked cables; (B) Cables 4, 5, and 6 connecting in heater MUX board, away from the wire duct side; (C) Cables 1, 2, and 3A/B plugging directly into heater MUX

7. Loosely secure the cable ties.

> **Note:** There are two cable tie mounts on the base plate for securing cables 4, 5, and 6 from the "lower" outlet – one at the back of the instrument and one by the liberty board ports.

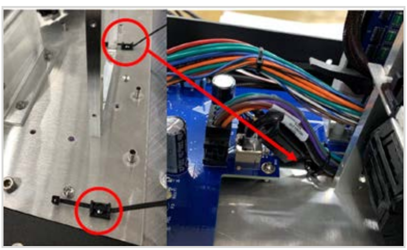


Fig: Base plate cable mounts for cables 4, 5, and 6

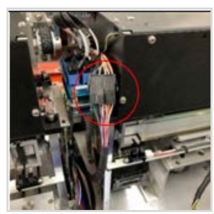
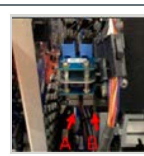
8. Adjust cable tension to ensure the heater mux can fall flat on the tray.
9. You should hear the heater MUX board fall flat on the tray when no upward force is applied.
10. If cables are pushing upward or tugging on the heater mux board/tray, then pressure and/or movement issues can arise.
11. Tighten cable ties and cut loose ends.
12. Install instrument skins.
13. Connect the power cable.
14. Power on the instrument.

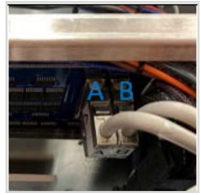
Verification

1. Perform "Gantry Alignment " on page 508.
2. Perform "Reader Tray Position " on page 469.
3. Perform the"Self-Test " on page 474.
4. Perform "Procedure Normalizer Ratio Check" on page 492.
5. Perform the "Power Supply Voltage Adjustments" on page 193.
6. Perform a site qualification according to the site where the cable was replaced. "5-Channel Qualification Test" on page 325

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

Additional connection references

Cable	Reference
CABLE ASSY MUX24 TO OPT POS SNSR EXT (1)	
CABLE ASSY MTR CNTRL INTERFACE (2)	
A/B SCSI cables (3) (Front view)	

Cable	Reference
A/B SCSI cables (4) (Rear view)	

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.21 Gantry Cable Set MAX Spare

Procedure

1. Open the door.
2. Power off the BD MAX instrument.
3. Unplug the power cable.
4. After unplugging the power cable, switch the power switch on and off to discharge any residual energy.
5. Follow the instructions in Section 5.2.4 for the removal of instrument skins to remove all skins, including internal skins and the back skins. The sides and door do not need to be removed.
6. Follow steps 5.2.4.1 to 5.2.4.4, and 5.2.4.6.
7. Use the security T10 to remove the back Black lower skins.
8. Disconnect the cables on the Windows and bender board and follow the cable chain to cut all plastic clamps.

Fig: Location of the four screws holding the splash guard

9. Remove the ground protection on the base of the BD MAX.

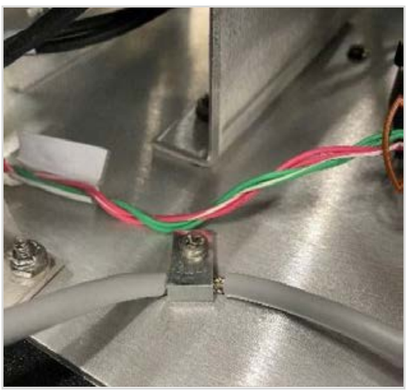


Fig: Ground protection

10. Remove all screws to secure the Igus chain to the chassis.

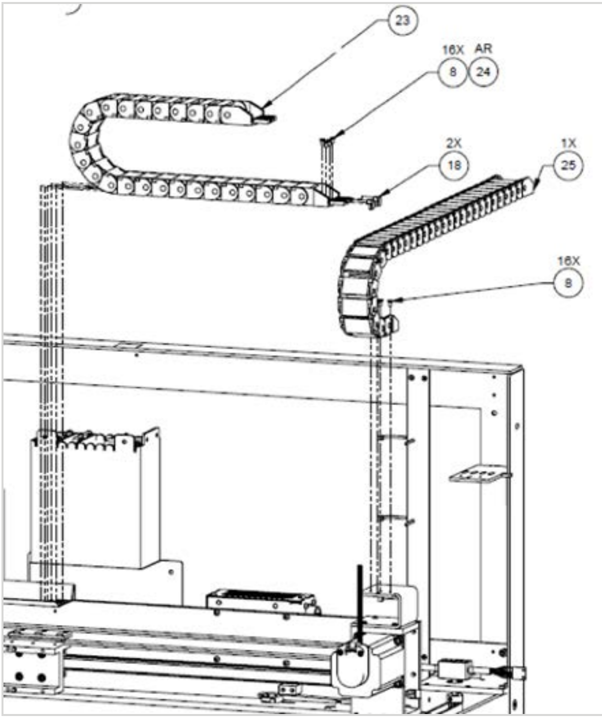


Fig: Screws securing the Igus chain

11. Disconnect the chain from the Z-Gantry.

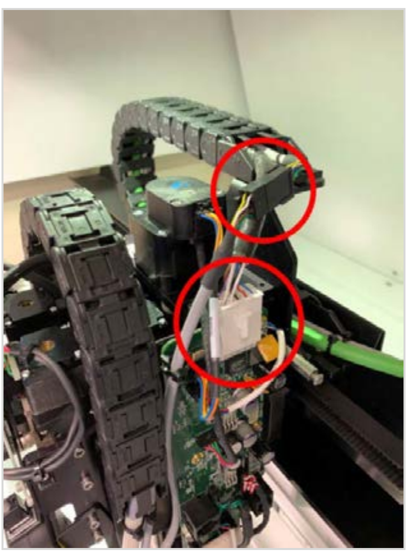


Fig: Disconnection points between the Igus chain and Z-Gantry head.

12. Disconnect all cables attached to the Liberty board and 2X Motor Drive Max6 board.

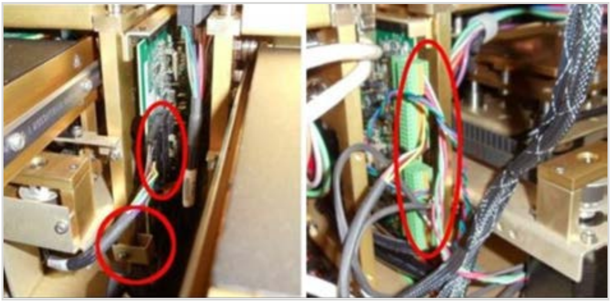


Fig: Disconnection points of cables on the Liberty board and 2X Motor Drive Max6 board.

13. Disconnect the cables on the Y Cobra controller board.

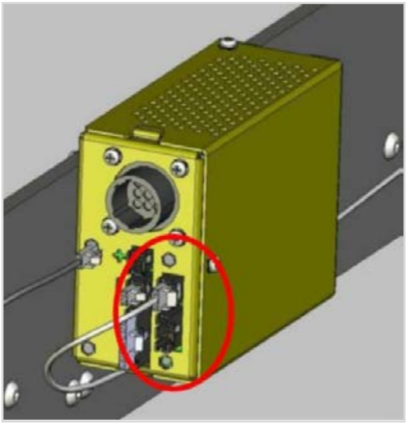


Fig: Disconnect cables on Y Cobra controller board

14. Disconnect the Cables on the X Cobra controller board.

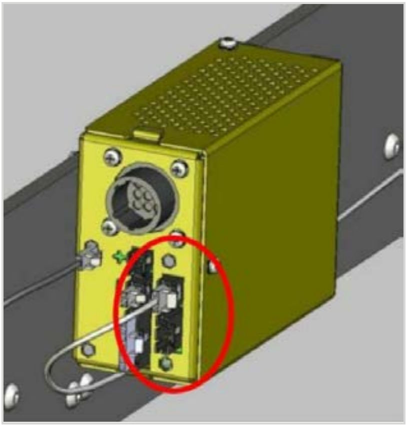


Fig: Disconnect cables on x Cobra controller board

15. Remove the Y-Cable Chain from the front of the BD MAX.

Fig: Direction to move the Y rail

16. Install the new Y-Cable Chain following the steps above in reverse order.

Verification.

1. Home all motors.
2. Perform EFC on sides A and B 6.4.10.1.
3. Complete Gantry alignment 6.4.15.
4. Complete CatalogWin.script 6.4.9.
5. Perform Pump Aspiration and Dispense check 6.4.16.
6. No qualification run is needed following this part replacement.

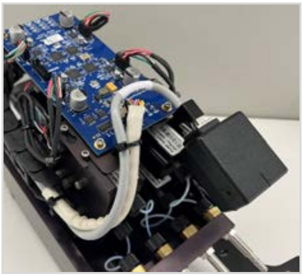
> **Verification:** After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.22 Cable Chain Assembly

Procedure

1. Open the door.
2. Power OFF the BD Max.

3. Unplug the power cord.
4. Accessing the Z-Cable Chain.
5. Remove the Z-Gantry Shield
6. Removing the Z-Cable Chain
7. Unplug the two connections on each side of the cable chain.



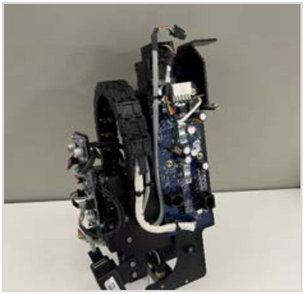


Fig: Z-Cable Chain Connections – two on each side

8. Remove the two Phillips (four total) on each side of the cable chain.
9. The spacers on each side do not need to be removed.

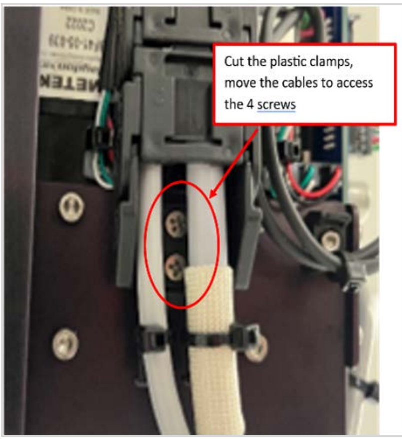


Fig: Locations of screws to remove to remove the Cable Chain

10. Cut the cable ties that secure the cable chain to the Z-Gantry.
11. Remove the Cable chain from the Gantry.

Fig: Z-Cable Chain

12. Installing the Z-cable Chain.
    a. Install the Z cable Chain following the removal steps in reverse.
    b. Power on the BD MAX instrument.
13. Perform Home All Motors

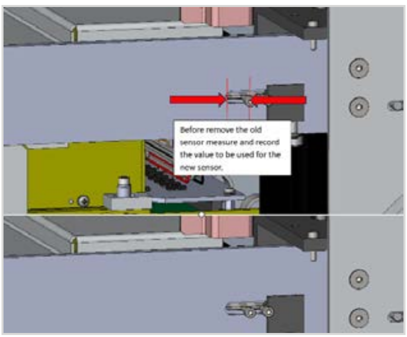
Verification

1. Complete "Gantry Alignment " on page 508.
2. Complete "CatalogWin.Script" on page 488.
3. Perform "Pump Aspiration and Dispense Check" on page 511.
4. No qualification run is needed following this part replacement.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.23 X-Y Limit sensor replacement

1. Power OFF the BD Max
2. Remove the Power Cable.
3. Follow the "Skins Removal " on page 198 to access the sensor. The skins to remove it will differ in what sensor will be replaced.
   a. The Y sensors require the right side removal.
   b. The X sensor do not require any Skins removal.
4. Measure the distance from the sensor to the hold sensor. Record that distance to be the same after the sensor replacement.

5. Remove the two screws that secure the sensor to the rail.
6. Disconnect the sensor from the Cobra controller
7. Cut the secure tides that secure the cable to the rail.
8. Remove the defective sensor.
9. Install the new sensor. Tide the sensor to the rail in the same position as recorded in point 1.
10. Connect the sensor to the Cobra controller.
11. Tide the cable to the secure tides.
12. **Note:** Do not over-tighten the sensor screw, which can crack the sensor and damage the functionality.
13. Connect the power cable.
14. Power on the BD Max

15. Perform Home All Motors.

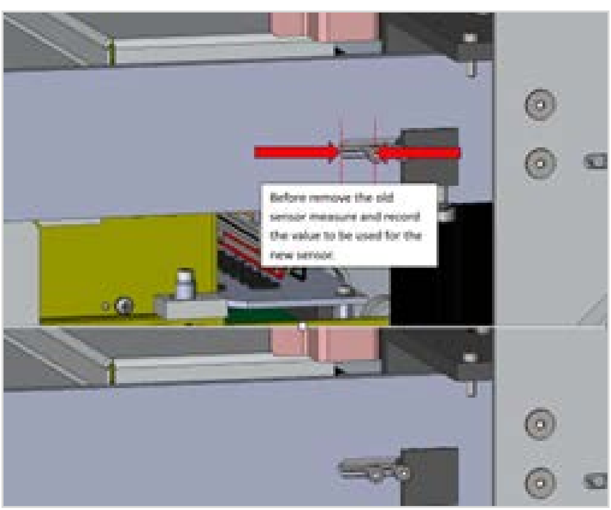
Verification:

1. Perform the Gantry Alignament.
2. Perform the CatalogWin.script.
3. Perform the QPM on the "5-Channel Qualification Test" on page 325 on A1to A4 and B1 to B4 to confirm the replacement.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.24 Cable Assembly Y Front Limit MAX 6

1. Follow "Instrument Skins" on page 197 to remove all internal skins on the BD Max.
2. Remove the top filter cover, refer to "Left Guard Removal" on page 205.
3. Remove Door, refer to "Facade 2X Reader Rack MAX Spare" on page 214.
4. Remove the right side skin.
5. Measure the distance from the sensor to the hole at sensor. Record that distance to be the same after the sensor replacement.



6. Remove the two screws that secure the sensor to the rail.
7. Disconnect the sensor from the Cobra controller
8. Cut the cable ties that secure the cable to the rail.
9. Remove the defective sensor.
10. Install the new sensor. Secure the sensor to the rail in the same position as recorded in step 5.
11. Connect the sensor to the Cobra controller.
12. Tie the cable to secure the cable.

> **Note:** Do not over-tighten the sensor screw, which can crack the sensor and damage the threads.

13. Follow the reverse procedure on the Remove the right-side Skin.
14. Verify all cables are connected to the power switch and input filter.
15. Connect the power cable.
16. Power ON the BD Max.
17. Perform Home all motors.

Verification:

1. Verify the right side is fixed to the base and that the front screw is in the same distance as measured on steps 5 and 10.

> **Verification:** After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

Install the top cover BD Max

1. Place the top cover and verify all four holds match with the cover screws.
2. Tie the screws to secure the top cover.
3. Do not over-tight the screws that can break or damage the top cover.

Verification:

1. Verify visually the top cover matches with the side skin and that they are symmetric to the sides.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

Installing the Door

1. Engage door onto side wall bearings.
2. Carefully spread the wings of the door to fit it over the instrument.
3. Before sliding the hinges into the bearing, install two black spacer rings on each side. This should be between the instrument side wall and the door.

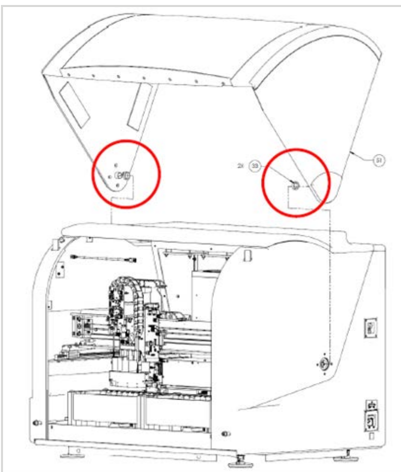


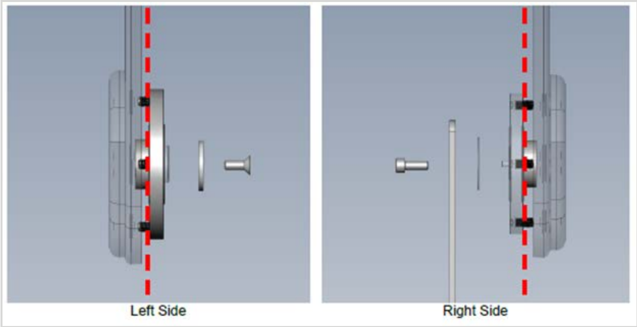
Fig: Black Spacer Rings (for even air gap between side wall and door)

4. With the spacer rings in place, slide the hinges into the side wall bearings.
5. Secure the door all the way open. The door should be loosely fixed to the instrument but will still fall down without connecting the gas spring.

Securing the RIGHT side

BD MAX Door Hinge and Securing Hardware

(Red dotted line represents hidden side walls)



1. Install the ball joint and hex nut to the bottom of the arm damper.

Fig: Ball joint installed in arm damper. Hand tighten all the way.

2. Stick the flat washer on the outside of the arm damper where it will interface with the door hinge and bearing. Use a small dab of grease.
3. Hold open the side wall from the Y-Gantry again so the arm damper can slide up and align with the two pins on the door hinge.

> **Note:** The flat washer should be as centered as possible. Crushing this washer can damage the door pins and compromise the door.

4. The flat washer is on the opposite side of the ball joint.

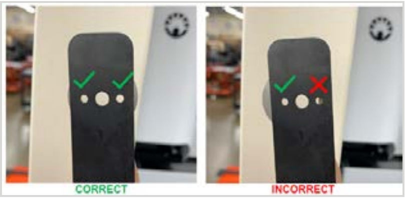


Fig: Ensure flat washer is centered BEFORE tightening that screw.

5. Tighten the main 5/32” Allen screw after installing/aligning the arm damper and flat washer. Use Loctite.
6. To re-connect the gas spring-arm damper ball and socket joint, it is easiest to use the channel lock pliers to engage the gas spring by a few inches and have another set of hands press the arm damper ball into the socket joint.

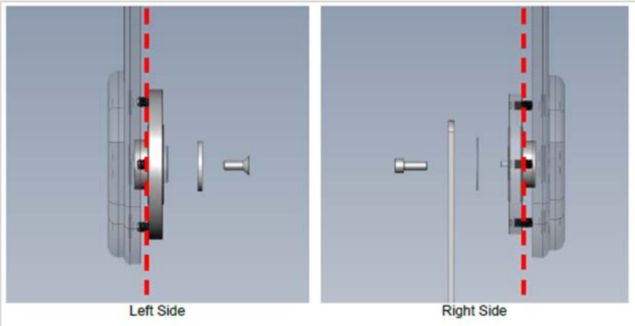
VERIFICATION

1. There should be an audible “snap” into place.

> **Note:** Be sure the green communications cable is on the inside of the instrument to avoid interfering with the door. Also be sure that the wires in the back are clear of the arm damper.

> **Verification:** After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

Securing LEFT side



1. From the inside of the instrument, add the following hardware in order:
   a. Black retaining washer
   b. 1/8” Allen screw w/ Loctite
2. Re-install the instrument skins.
3. Clean any excess grease.
4. Power on the BD Max.
5. Run Home All Motors.
6. Connect the power cable.

Verification

1. Visually inspect the door hinge when opening and closing the door.
2. The user should not be able to fit his/her hand underneath the door and into the instrument when the door is closed.
3. Perform Home All Motors to verify all basic components are communicating and functioning correctly and that skins are not interfering with instrument movement.
4. Perform the Gantry Alignment "Gantry Alignment " on page 508.
5. Perform EFC for side A and side B "Procedure Empty Fill Check" on page 491.
6. Home All Motors.
7. No qualification is required.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.2.25 X-Gantry Rail Adjustment

Materials

Item	Part Number	QTY	Description
Gauge Block Set	N/A	1	Will need resolution of at least 0.001-in and range from about 0.825-in to 0.845-in. This should be purchased by the engineer. Reference only set is acceptable for occasional use.
Allen Key Set	N/A	1	3mm - For newer BD MAX
Phillips Screw Driver	N/A	1	For older BD MAX

Item	Part Number	QTY	Description
BD MAX Calibration Plates	435251 (Rack) 435256 (Tray)	1	For Gantry Alignment
Feeler Gauge	N/A	1	Nozzle touch off spec is 0.0015-in
5-Channel Qualification Kit	444048	1	For troubleshooting and verification

Confirm before Adjusting X-Gantry Rail

1. Tip pickup/drop and/or bubble issues are isolated to either Bank 1 or 6.
2. Diagnostics and troubleshooting results suggest the ambient lighting, gantry alignment, racks, and z-gantry components (stripper assembly, LLS sensors, z-motor, pumps, PCBs, etc) are most likely NOT the root cause. Load cartridge (LC_UDP.script) may be used to visually verify a tip pickup/drop issue.
3. Issues are biased towards one side of the Bank (ex: anomalies are mostly on nozzle 1 and 2).
4. Door is open and instrument is powered down.

Procedure

Images below will depict the adjustment for Bank 6, where tip issues were observed on nozzle 1 (Strip B9).

Determine if the rail should be raised or lowered

1. Open the Door.
2. Power off the BD MAX instrument.
3. Follow Table 1 below to determine if the rail should be adjusted up or down.

Table 1. Raising or lower the X-rail depends on the specific bank and error locations on each nozzle.

Majority of Anomalies	Bank 1 (A1-A4)	Bank 6 (B9-B12)
Nozzle 1 and 2	**Lower** by 0.005-in	**Raise** by 0.005-in
Nozzle 3 and 4	**Raise** by 0.005-in*	**Lower** by 0.005-in

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Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

Note: Raising Bank 1 could require remounting of the gantry to reconcile steps added to the touch off, which happens on Bank 3 and 6.

Measure the starting height

1. Locate the approximate point of the rail that is secured by a screw.
2. Using a stack of gauge blocks, determine the initial height of the X-gantry rail. The initial height is the largest stack of gauge blocks which fit with no resistance.
   a. The fit can be tight. Do not use excessive force.
   b. This is generally around 0.830-in, but can vary for each instrument.

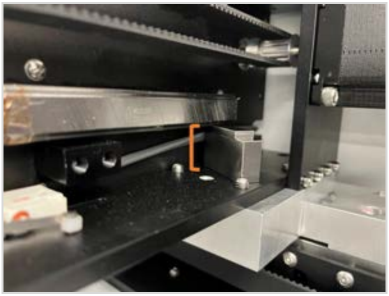


Fig: Measuring initial x-rail height at the end of interest

3. Before loosening any screws, verify that all other screws are tight.
4. Loosen the last screw that is securing the X-rail.

Fig: Right side fastener (bank 6) for newer systems

5. Do not loosen any other screws and be careful not to strip the screws. It is best to have a replacement with Loctite 222 on hand.

Incrementally adjust height

> **Note:** If the problem (tip pickup/drop or bubbles) does not improve, further troubleshooting may be complicated by an uneven x-rail. It is important to keep track of exactly what has been done.

1. With the x-rail fastener loosened, raise/lower the x-rail by 0.005-in.
   a. Slide in a new stack of gauge blocks with the appropriate 0.005-in adjustment.
   b. While using hand force to push/pull the x-rail to meet the gauge block height, tighten the fastener behind the x-rail.
   c. The change can be as small as one Z motor step (observed after calibration), but this can make a difference. A bubble level will not have the resolution to visualize the change.
2. Remove any tools, gauge blocks, etc. from the instrument.
3. Power on the BD Max instrument
4. Perform Home all Motors.

Post-Adjustment Verification

1. Perform **Gantry Alignment** with "Gantry Alignment " on page 508.
   a. Verify that there are no significant changes.
   b. Verify nozzle gaps.
2. Perform "5-Channel Qualification Test" on page 325 and assess the results for improvement.
   a. Enable the EMULATE_PARALLEL_PORT environmental variable to operate with the door open.
   b. Closely observe the tip and liquid handling throughout the sample preparation and load cartridge steps.
   c. If issues persist, another 0.005-in adjustment may be necessary.
      i. Generally, this should not require more than 0.010-in of adjustment.
3. Record the use of this procedure in the work order.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.3 Qualification Run

Note: Check latest service bulletins before proceeding with qualification to ensure compliance with the latest procedures.

A qualification run tests overall system operation.

1. Refer to **Qualification Checklist** to perform field qualification on BD MAX.
2. The qualification kit is designed specifically to test and validate instrument condition, repairs, and adjustments. It provides an operational efficiency and verifies instrument performance.

Note: This example demonstrates how to set up a run for instrument verification. Refer to **BD MAX™ User's Manual** for information on preparation and execution of test runs.

Before running a qualification run, it is recommended to run other scripts to verify specific functionality.

- Home All Motors
- Magnet Alignment
- Tray Alignment
- Calrack
- Load Cartridge Test
- Lysis Heater Test
- Empty Fill Check Test (both sides)
- Norm Ratio Check

5.3.1 CD4 Qualification Requirements

Materials:

- Qualification Kit - **SAP Catalog No. 442975** (contains 24 tests)

> **Note:** The CD4 Qualification Kit is no longer manufactured. The 5-Channel Qualification (444048) is always the preferred method of instrument qualification.

- Micro Fluidic Cartridges – **SAP Catalog No. 437519** (comes in a box of 24)
  Personal Protective Equipment (PPE); as required by BD Service policies/procedures. In addition, please check with the laboratory for any additional PPE requirements specific to that facility.

Time:

- ~ 0.25 Hours Set Up
- ~ 2 Hours Run Time
- ~0.25 Hours Cleanup.

5.3.2 CD4 Qualification System Setup

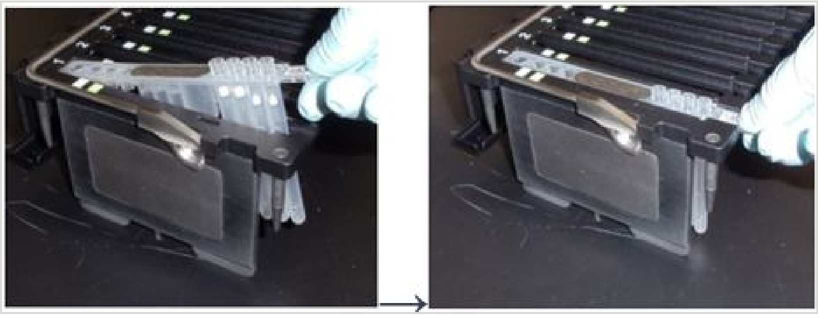
> **Note:** The CD4 qualification will eventually be obsoleted and superseded by the 5-channel qualification.

1. Ensure to have enough tests available from a non-expired qualification kit.
2. Insert 12 USR into each specimen rack, one at a time.

   There is a socket with a leaf spring in front of the lane numbers at the end of the lane slot:

   a. Place the test strip in the lane at an angle.
   b. Push the far end of the test strip into the socket.
   c. Lower the end with the barcode into the lane slot and pull back to set the test strip.

   The leaf spring helps keep the strip in the correct position.



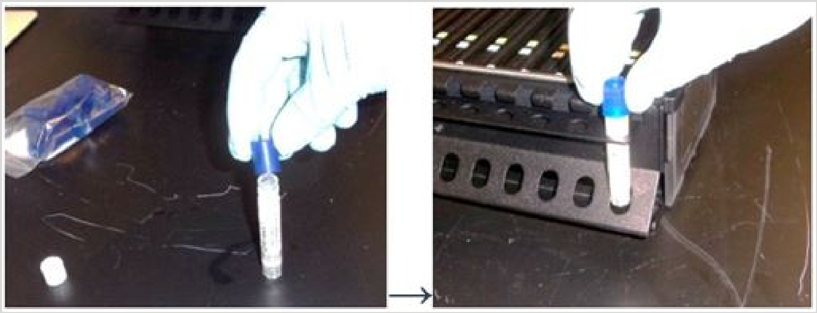
3. Once the strips are seated, add the Extraction and Master Mix (MM) PCR snap into each strip. There are color coded bars on the rack that match the foil covering the snap-in.

   Ensure that the snap-ins are aligned to the correct color bar.

   > **Note:** Updated Sample Racks have an additional blue line for a 2nd MM for this procedure. The blue line and empty location on the URS can be ignored since Cdiff Qualification Kits do not have a 2nd MM.

4. Push down on each snap-in until it snaps into place. Ensure none of the snap-ins are loose.

5. Remove the caps from each Sample Buffer Tubes (SBT) to be used.
6. Replace the caps with the septum caps that came in the qualification kit.
7. Place the SBT into the sample rack with the 1D barcode facing out.



8. Inspect all consumables:
   - Ensure the cartridges and strips do not have any bubbles.
   - The URS have correct number of tips with filter in them.

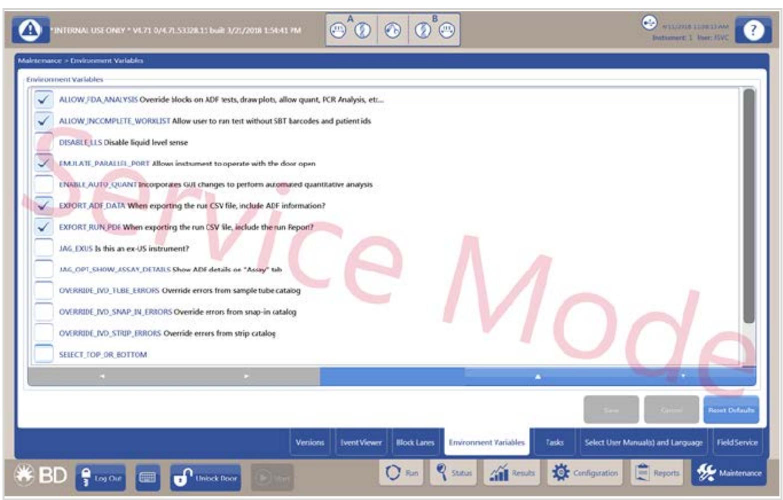
5.3.3 5-Channel Qualification Test

Quad Point Melt (QPM) Qualification Run:

The 5 Channel qualification is the latest qualification method, which provides more rigorous testing of the instrument and supersedes the previous CD4 qualification.

1. Click on **Maintenance** tab and then the Environmental Variables tab. Check the following items and click **Save**:
   a. Allow FDA Analysis.
   b. Allow Incomplete Worklist.
   c. Export Assay Definition files (ADF) Data.
   d. Export Run PDF.
   e. Select Top or Bottom.

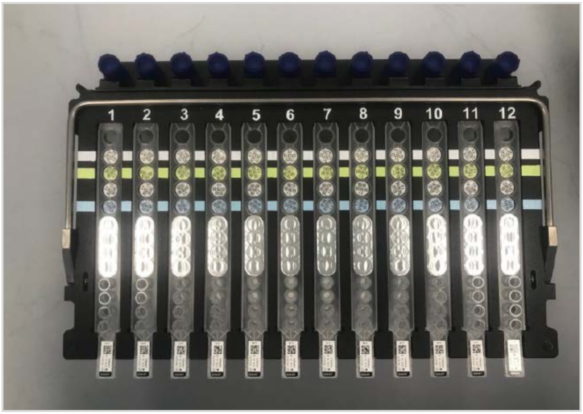
   Note: If running software version 5.0, ensure that DB defense is NOT enabled.

2. Obtain the **5 Channel Qualification Kit**, containing Unitized Reagent Strips (URS), Extraction Tubes, EBP Master Mix Tubes, Positive Control Tubes, QPM Master Mix Tubes, Sample Buffer Tubes, Septum Caps, and four 24 well micro fluidic cartridges.
3. Record the kit and cartridge lot and expiration dates in **Qualification Checklist**.
4. Put on PPE (i.e. gloves, safety goggles, lab coat, etc).
5. Add **24 URS** to two rack assemblies.
   a. Check the fluid levels in each strip and tap the strips against a surface, releasing any trapped air at the bottom of each tube.
   b. Check that tips are properly positioned.

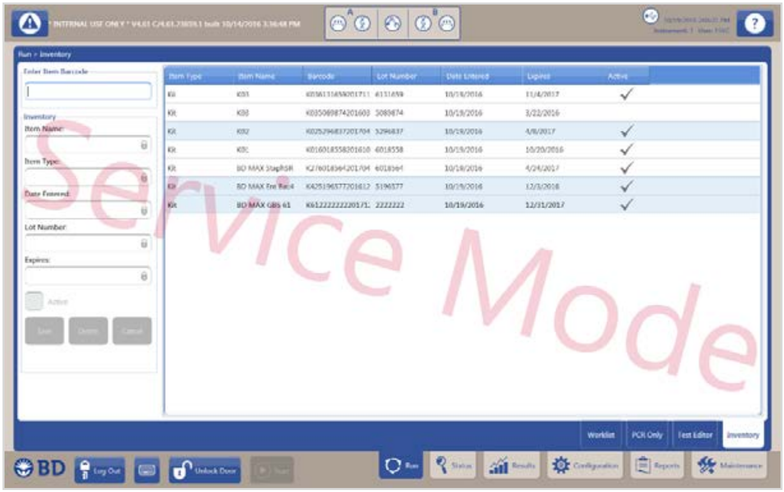
6. Add 24 Extraction Tubes **labeled B2** to the white line position on the rack.
    a. Check that tubes are properly sealed and that the extraction cake is intact and in the right orientation (tapered end down).
    b. Snap the tubes into the racks.
7. Add 24 EBP Master Mix Tubes **labeled E9** from the green pouch to the green line position on the racks.
    a. Check that tubes are properly sealed.
    b. Snap the tubes into the racks.
8. Add 24 Positive Control Tubes **labeled E4** to the snap 3.
    a. Check that tubes are properly sealed.
    b. Snap the tubes into the racks.
9. Add 24 QPM Master Mix Tubes **labeled F3** from the blue pouch to the blue line position on the rack.
    a. Check that tubes are properly sealed.
    b. Snap the tubes into the racks
10. Add 24 Sample Buffer Tubes to the racks.
    a. Check that there is fluid in the tubes.
    b. Add the blue pierceable Septum caps to the tops of the tubes.

> **Note:** This rack setup will be used for two runs on the MAX. Do not dispose of the **URS** or **sample buffer tubes** until Section 3.

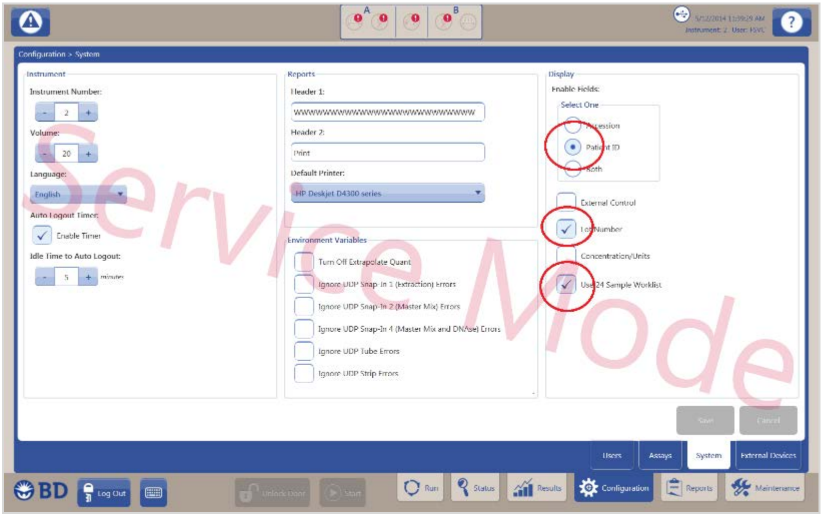


11. Load the latest ADFs files **BD MAX QPM QUAL 63** and **BD MAX 5CH QUAL 63** to the instrument.
12. Record the ADF file names and versions in Remarks section of the **Qualification Checklist**.

13. Click on **Run** , then **Kit Inventory**.
    a. Scan the consumable barcode to the **Enter Kit Barcode** line.
    b. Check **Active**. Then click **Save**.



14. Go to **Configuration** tab then System tab. Note the current settings for reference later. Select **Patient ID**, **Use 24 Sample Worklist** and **Lot Number** in the system configuration screen. Click **Save**.



15. Click the **Run** tab, then **Worklist**.
    a. Select **BD MAX QPM QUAL 63** under the Test column for all 24 lanes.
    b. Select the appropriate **Kit Lot Number**.
    c. Ensure all rows are auto populated. Any row that has an error from a previous run will not populate. To clear error: Click **Maintenance**, then **System Error Summary** and then **Acknowledge Error**.
16. Load both A and B racks, and PCR cartridges into the instruments.
17. Inspect all consumables (Cartridges and strips to ensure no bubbles, correct tips and the cartridges have clear and open lanes).
18. Close the door and press **Start**. The QPM will take approximately **49 minutes to complete**.
19. After the QPM run is complete, click the **Results tab**, and open the run to observe if there are any Evaluates. If evaluates are present, refer to the "5-Channel Qualification Kit Result Review Table" on page 331.
20. Examine the cartridge. The reaction chambers in all lanes must be completely filled with no bubbles.
21. complete **Enteric Bacterial Panel (EBP) Qualification Run**.

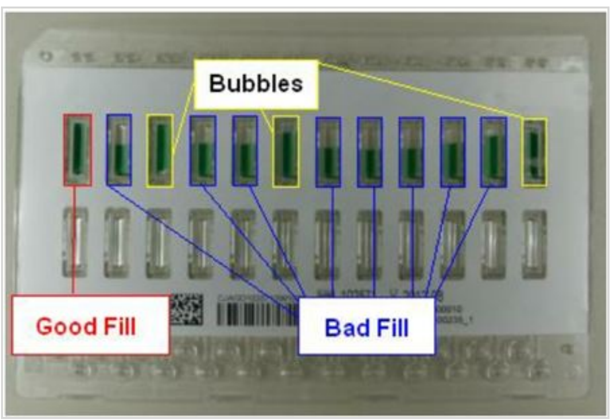
Enteric Bacterial Panel (EBP) Qualification Run:

1. Click on **Maintenance** tab at bottom of screen.
    a. In the **Environmental Variables** tab, ensure uncheck **Allow Incomplete Worklist**.
    b. Click **Save**.

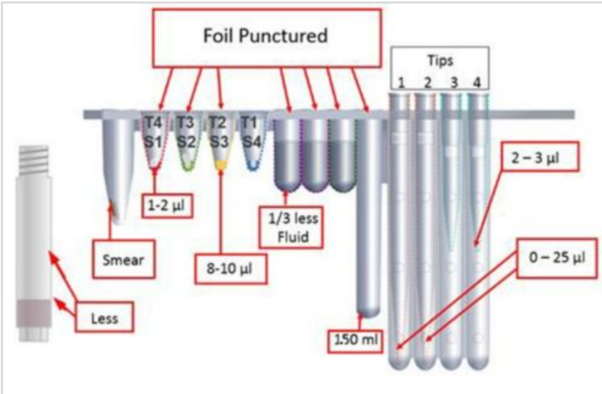
2. Click the **Run** tab, then **Worklist**.
   a. Select **BD MAX 5CH QUAL 63** under the Test column for all 24 lanes.
   b. Select the appropriate Kit Lot Number.
   c. Ensure all rows are auto populated. Any row that has an error from a previous run will not populate. To clear error: Click **Maintenance**, then **System Error Summary** and then **Acknowledge Error**.
3. Scan the bar codes of the sample buffer tubes. Enter numbers 1 through 24 under the Patient ID column.
4. Place **two new PCR cartridges**. Do not replace the consumables on the racks.
5. Close the door and press **Start**.
6. After the EBP run is complete, refer to "Post System Run Review " on page 329.

5.3.4 Post System Run Review

1. At the end of the run, examine the cartridge. The reaction chambers in all lanes must be completely filled with no bubbles.



2. Remove and examine the test strips.
3. Check that all foil covers of reservoirs and snap-ins are pierced.
   a. The **Reaction** tube will have a smear of particles along one side.
   b. The extraction snap in may have a small amount of particles and up to 1 - 2µL liquid in the bottom.
   c. The **Wash Reservoir** will have 1/3 less liquid remaining than the other reservoirs.
   d. The **Waste Reservoir** will have approximately 1 to 1.5mL (depending on assay) of liquid with no solids.
   e. **Tip 4** may have 2 - 3µL of fluid present. Tips 1 and 2 may have up to 25µL present.



4. Navigate to the **Results** tab, and open the run to review the Results against "5-Channel Qualification Kit Result Review Table" on page 331.
5. If one or more samples fail, document what failed in the checklist **Qualification Checklist** under the Comments.
   a. Perform Initial Field Service Action.
   b. Then, perform follow up run.
6. If sample passes, document the result in **Qualification Checklist**. If sample results still fail, document the result in **Qualification Checklist**. Do not turn the instrument over to the customer.
7. Do not leave reagents from qualification at customer site- remove or destroy them.

> **Note:** The new qualification kit contains target DNA. Use standard laboratory practices when removing used strips and sample buffer tubes from the racks. Clean racks according to standard laboratory procedures.

8. Be sure to reconfigure the system configuration screen back to its prior settings before returning the instrument to the customer. Please make sure that the worklist type (24 Sample or 2000 Sample) is back to its original setting.
9. Go to **Maintenance**, then **Environmental Variables**, and reset to **Default**.

5.3.5 5-Channel Qualification Kit Result Review Table

Error	Acceptable Criteria	Initial Field Service Action	Follow-Up Run	Final Field Service Action
Quad Point Melt (Required to Run before EBP)				
[cartridge row][channel] EVALUATE Description: PCR heater exceeded set tolerances [±2] (530nm/565nm OR 585nm/630nm OR 630nm/665nm) OR [±3] (475nm/520nm) *Note optic 680/715nm data is not evaluated as a part of the QPM	0 Evaluate results	• Check for no fills, partials, and bubbles in cartridge. • If no other errors present, clean the MUX glass wafer where the cartridge sits then conduct Heater MUX Self-Test and PCR.script. • Complete a reader health check. Renormalize or replace reader as needed. • Complete follow up run.	Only rerun specific bank of suspect lane	Replace heater/MUX board ONLY if same lane triggers error
EBP Qualification				
No Amp on > 2 Lanes WITHIN Rack and Row; on Color [color] [cartridge row] Description: Error triggered only if >2 lanes on the same reader and channel	0 Evaluate results	• Check Strip for magnet beads • Check cartridge for no fills, partial fills, and bubbles • Perform general health check in Service Guide Troubleshooting Section. In addition, perform the following: 1. Check magnet position and	Only rerun specific bank of suspect reader	Replace reader ONLY if same reader triggers error

Error	Acceptable Criteria	Initial Field Service Action	Follow-Up Run	Final Field Service Action
		alignment 2. Review/Adjust Pressure Settings. Confirm values in the instrument match with the calrack table. If not, adjust the values by editing the calrack table. 3. Check Cartridge for Debris 4. Perform reader tray alignment. 5. Check the PCR tray drive assembly screws.		
IC No Amp [cartridge row] Description: Error triggered only if in channel Cy5.5 (680nm/715nm) If "No Amp on >2 Lanes" error also raised, overlook error	0 Evaluate results	• Check Strip for magnet beads • Check cartridge for no fills, partial fills, and bubbles • Perform general health check in Service Guide Troubleshooting Section. In addition, perform the following: 1. Check magnet position and alignment 2. Review/Adjust Pressure Settings. Confirm values in the instrument match with the calrack table. If not, adjust the	Only rerun specific bank of suspect lane	Escalate through your Regional Escalation Process.

Error	Acceptable Criteria	Initial Field Service Action	Follow-Up Run	Final Field Service Action
		values by editing the calrack table. 3. Check Cartridge for Debris 4. Perform reader tray alignment. 5. Check the PCR tray drive assembly screws.		
Target NO Amp on Color [color] [cartridge row] Description: Error triggered only if in channels 530nm/565nm OR 585nm/630nm OR 630nm/665nm OR 475nm/520nm If "No Amp on >2 Lanes" error also raised, overlook error	0 Evaluate Results	• Check Strip for magnet beads • Check cartridge for no fills, partial fills, and bubbles • Perform general health check in Service Guide Troubleshooting Section. In addition, perform the following: 1. Check magnet position and alignment 2. Review/Adjust Pressure Settings. Confirm values in the instrument match with the calrack table. If not, adjust the values by editing the calrack table. 3. Check Cartridge for Debris 4. Perform reader tray alignment. 5. Check the PCR tray drive	Only rerun specific bank of suspect lane	Escalate through your Regional Escalation Process

Error	Acceptable Criteria	Initial Field Service Action	Follow-Up Run	Final Field Service Action
		assembly screws.		
Liquid Level Sense Error	1 Evaluate Result **with** septum Caps	• Examine consumables for abnormalities such as low sample buffer fill volumes • Check to see if errors correspond to a specific pump • Check pump cables/flag/connectors and liquid level sensors • Run Pump check from MAX PowerOn.script • Clean and test the Photo and Receiver sensors	Only rerun specific bank of suspect lane **without** septum caps • An acceptable result for the follow up run is 0 Evaluate Results **without** septum caps	Escalate through your Regional Escalation process.
Error in Full Fill Check Description: Full fill check without amplification	1 Evaluate Results	• Check cartridge for no fills, partial fills, and bubbles • Check consumables for consistent fluid level across all strips • Inspect pump cables/flags/connectors and sensors • Run calrack.script to check alignment • Perform tray alignment as per Service Guide. Check the four	Only rerun specific bank of suspect lane	Escalate through your Regional Escalation process.

Error	Acceptable Criteria	Initial Field Service Action	Follow-Up Run	Final Field Service Action
		drive train screws which holds the belt drive and z-bracket. • Run load cartridge script to verify • Gantry maintenance: clean the grease, and keep clean without re-greasing.		
Normalizer on Color [color] Too Noisy Description: Normalization noise error	0 Evaluate Results	• On affected side, Perform Reader Health check and if required, perform reader normalization	On affected side, perform Full Qualification run to include QPM and EBP	Replace reader
PCR Heater Warning Description : PCR heater exceeded set tolerances	0 Evaluate Results	• Run MUX self-test (also known as PCR self-test.) • Run PCR.script.	Only rerun specific bank of suspect lane	Replace heater/MUX board ONLY if same lane triggers error
Step Loss on Axis Z; [how many] Steps Description : Lost more than 15 steps on the Z axis	0 Evaluate Results	• Refer to Motor Issues section and run Motor Script as per the troubleshooting section. • Be sure to check Z for motor step loss and get encoder values. o If motor script fails, refer to the Motor Issues section to determine whether to replace the motor	Rerun an EBP qualification run on both sides	Replace Gantry if test fails.

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Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

Error	Acceptable Criteria	Initial Field Service Action	Follow-Up Run	Final Field Service Action
		(encoder included) and/or cables. o If motor script passes, then run Z-Gantry binding test as per the Service Guide Troubleshooting section. As part of the Z-gantry binding test, run strip positions 1, 6, and 11 only to verify the Z-movement. • Perform Z-gantry maintenance: clean the grease, and keep clean without re-greasing.		
Step Loss on Axis [X|Y]; [how many] Steps Description : Lost more than 3 steps on the X/Y axis	0 Evaluate Results	• Check belt tensions and set screw • Verify gantry components are tight • Check if encoder cable is plugged in. • Check tip sensors. • Refer to Motor Issues section and run Motor Script as per the troubleshooting section • Be sure to check X and Y for motor step loss and get encoder values. If motor script fails, refer to the Motor Issues section to determine whether to replace the	Rerun an EBP qualification run on both sides	Escalate through your Regional Escalation process.

Error	Acceptable Criteria	Initial Field Service Action	Follow-Up Run	Final Field Service Action
		motor (encoder included), and/or the cables.		
Ct %CV > 5%; [percent]% ACROSS RUN Description : Ct variation higher than expected across banks / readers	0 Evaluate Results	• Check Strip for magnet beads • Check cartridge for no fills, partial fills, and bubbles • Perform general health check in Service Guide Troubleshooting Section. In addition, perform the following: 1. Check magnet position and alignment 2. Review/Adjust Pressure Settings. Confirm values in the instrument match with the calrack table. If not, adjust the values by editing the calrack table. 3. Check Cartridge for Debris 4. Perform reader tray alignment. 5. Check the PCR tray drive assembly screws. Evaluate resulting curves	Rerun an EBP qualification run on both sides	Escalate through your Regional Escalation process.
Ct %CV > 5% on Color [color]; [percent]% WITHIN Rack and Row	0 Evaluate Results	• Check Strip for magnet beads • Check cartridge for no fills, partial	Only rerun specific rack	Escalate through your Regional

Error	Acceptable Criteria	Initial Field Service Action	Follow-Up Run	Final Field Service Action
[cartridge row] Description : Ct variation higher than expected within same bank / reader		fills, and bubbles • Perform general health check in Service Guide Troubleshooting Section. In addition, perform the following: 1. Check magnet position and alignment 2. Review/Adjust Pressure Settings. Confirm values in the instrument match with the calrack table. If not, adjust the values by editing the calrack table. 3. Check Cartridge for Debris 4. Perform reader tray alignment. 5. Check the PCR tray drive assembly screws. Evaluate resulting curves		Escalation process.
Could not Pickup Tip Description : Tip pickup failure on rack A/B	0 Evaluate Results	• Check alignment by running Calrack script • Inspect tips for deformities • Check Nozzles alignment, tightness, position • Clean and test the Photo and	Rerun an EBP qualification run on both sides	Escalate through your Regional Escalation process.

Error	Acceptable Criteria	Initial Field Service Action	Follow-Up Run	Final Field Service Action
		Receiver sensors		
Heater Timeout Warning Description : Lysis heater hardware issue	0 Evaluate Results	• Check cables • Perform Lysis Heater test • If possible, reconfigure GORT Board by flashing Refer to Software/Firmware Update section in Service Guide.	On affected side, perform an EBP qualification run	Replace GORT board and perform Full qualification run to include QPM and EBP
PCR Detector Motor Failure Description : Reader detector motor issue	0 Evaluate Results	• Check all connections to the reader. • If loose connections, then secure. • Run EFC to confirm motor failure. If EFC fails, replace reader. If EFC passes, re-run Quad Point Melt to see if motor loses steps. • If error persists, then replace Reader on affected side. • Perform Reader Health check and if needed, perform reader normalization.	On affected side, perform Full Qualification run to include QPM and EBP	Escalate through your Regional Escalation process.
Errors Not Generated in Run Report				
Barcode Issues				
Cataloging Issue with Sample Tube Description: This condition is not generated in the run report and will	[0] Error/Run	• Run CatalogWin script. • Clean the mirror according to the	Run Catalog Script	Escalate through your Regional Escalation

Document: BDDSSGFS7422 Doc Type: ZIP Status: Released EFFECTIVE
Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

Error	Acceptable Criteria	Initial Field Service Action	Follow-Up Run	Final Field Service Action
occur during catalog		cleaning procedures. • Realign barcode and allow instrument to re-catalog. • Replace all consumables if not readable. • Record lot number, and ensure complaint is opened against consumable.		Process.
Cataloging issue with Snap ins Description: This condition is not generated in the run report and will occur during catalog	[0] Error/Run	• Run CatalogWin script. • Realign barcode and allow instrument to re-catalog. • Replace all consumables if not readable. • Record lot number, and ensure complaint is opened against consumable.	Run Catalog Script	Escalate through your Regional Escalation process.
Additional Issues				
Reader Saturation	N/A	• Disregard error	N/A	N/A
Instrument Connection Loss During Run Description: This condition is not generated in the run report and will generate an Alert	0 Evaluate Results	• Verify that the MAX is connected to the black USB in AIO. • Review log files. • Refer to "Troubleshoot a Run" on page 403	Perform Full Qualification run to include QPM and EBP	Escalate through your Regional Escalation process.

Document: BDDSSGFS7422 Doc Type: ZIP Status: Released EFFECTIVE
Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

Error	Acceptable Criteria	Initial Field Service Action	Follow-Up Run	Final Field Service Action
Error in Empty Fill Check Description: Empty fill check without amplification. This condition is not generated in the run report and will occur during catalog	0 Evaluate Results	• Perform reader health check and reader normalization as needed • Check cartridge for debris • Clean glass heater cover • Clean reader Aperture Plate • Perform tray alignment as per Service Guide. • Check the four drive train screws which holds the belt drive and Z-bracket.	On affected side, perform Full Qualification run to include QPM and EBP	Escalate through your Regional Escalation process.
Error in Results Processing	0 Evaluate Results	• Check physical connections (especially on readers and heater mux assemblies). • Check/replace AIO USB cable.	Repeat the qualification run	Escalate through your Regional Escalation process.

5.4 Upgrades

5.4.1 Fixed Magnet Assembly Installation - Version 2

This section describes installation of the Fixed Magnet Assembly Version 2 on BD MAX. The Fixed Magnet Assembly is is a passive enhancement used to capture magnetic beads that have carried over during the extraction process to the elution tube in the Unitized Reagent Strip.

The information in this section applies for the installation of version 2 of the Fixed Magnet Assembly. See "Fixed Magnet Assembly Installation - Version 1" on page 345 for installation instructions for version 1 of the Fixed Magnet Assembly.

Required materials:

Item	Part Number	QTY	Description
Fixed Magnet Assembly Kit	445219	1	Fixed Magnet Assembly v2 (2) Plastic screw hole covers (4)
7/64 inch Allen Key	NA	1	Normal tool on FSE Toolkit
0.035 inch Allen Key	NA	1	Normal tool on FSE Toolkit

Note:
Do not lift Fixed Magnet Assembly by the black magnet bar. This can bend the part.

Procedure

1. Remove skins:
    a. 2 Tray covers
    b. Upper Reader Cover
    c. Lower Reader Cover
    d. Lysis Cover
2. Remove two 7/64 inch screws from the base plate. The screws in the new Fixed Magnet Assembly v2 will fill these screw holes.

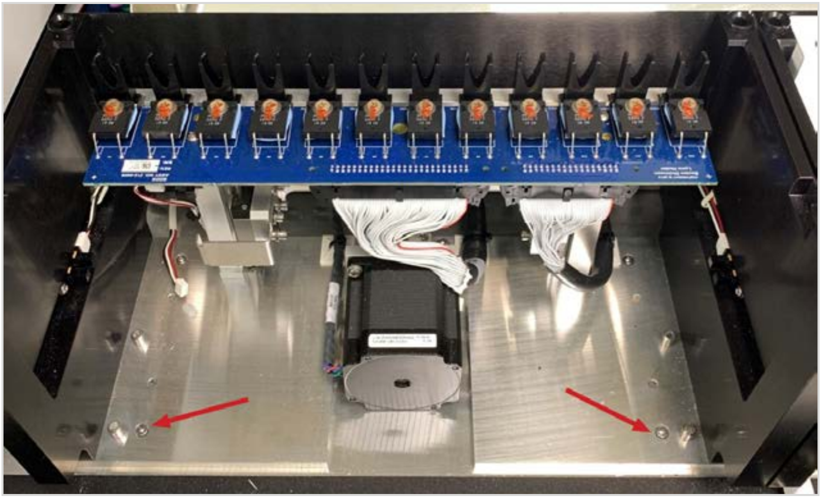


Fig: Mag-lysis screw holes

3. Place the new Fixed Magnet Assembly v2 in place of the old lysis cover. The side walls should fit over the existing alignment pins.

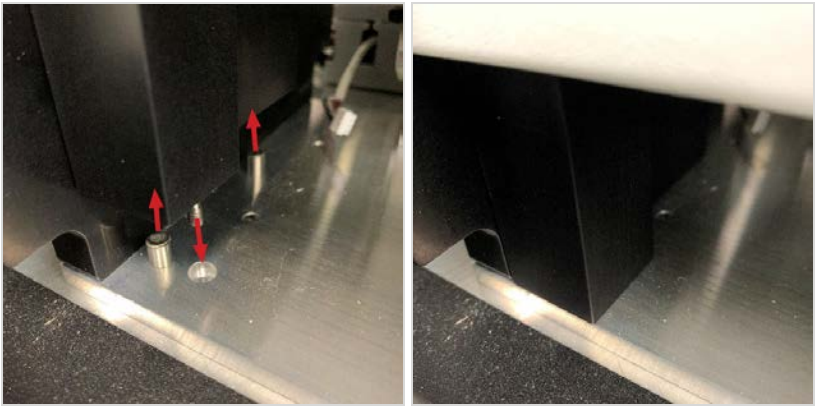


Fig: Fixed Magnet Assembly v2 fit on alignment pins and screw hole

4. Tighten the two 7/64 inch captive screws in the Fixed Magnet Assembly using a standard L-key.
5. Press in the two white plastic buttons to cover the screw holes.

Fig: Plastic button covering screw hole on **right** side

6. Repeat the steps above to install the Fixed Magnet Assembly version 2 on the other side of the BD MAX.

Post-Install Verification

1. Load a rack into the instrument and verify that the black magnet bar of the Fixed Magnet Assembly aligns with the snap-3 position (blue bar on the sample rack)

Fig: BD MAX Sample Rack loaded above new Fixed Magnet Assembly version 2

2. Update the Fixed Magnet Assembly Service Max Attribute to **Version 2 (445219)**.

5.4.2 Fixed Magnet Assembly Installation - Version 1

This section describes installation of the Fixed Magnet Assembly Version 1 to the lysis cover skin. The Fixed Magnet Assembly is used to capture magnetic beads that have carried over during the extraction process to the elution tube.

Required materials

Item	Part Number	QTY	Description
Fixed Magnet Assembly Kit	444877	1	Positioning Tool (1) Fixed Height Magnet Tool (1) Fixed Magnet Assembly (2) Bronze Bushings (4) Shoulder Screws (3)
2.5mm Allen Key	NA	1	Normal tool on FSE Toolkit
2mm Allen Key	NA	1	Normal tool on FSE Toolkit
Calibrated 6in Calipers	NA	1	Normal tool on FSE Toolkit

Procedure

1. Insert 3 bronze bushings and 2 shoulder screws into the fixed magnet assembly positioning tool.

   Note: The kit contains 1 spare of the bronze bushing and shoulder screw.

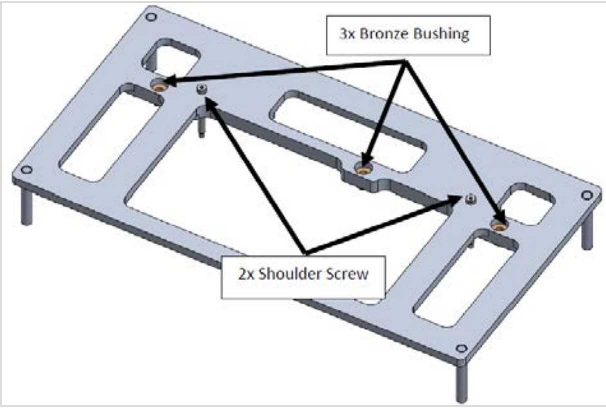
   

   Fig: Fixed magnet assembly positioning tool, pointing out the position where the bronze bushings and shoulder screws are inserted

2. Using a 2 mm hex key, secure the fixed magnet assembly to the 2 shoulder screws. Make sure the bottom of the shoulder is flush on top of the magnet assembly base.

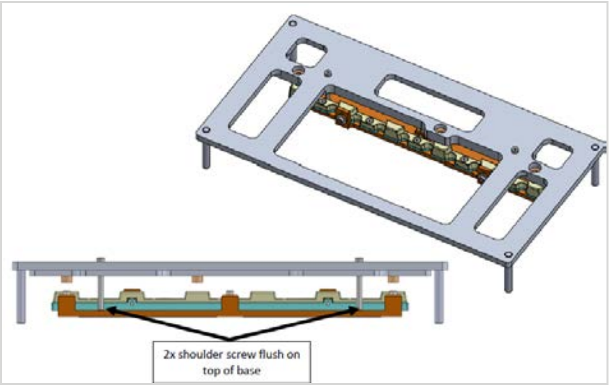
   

   Fig: Top and side view of the fixed magnet assembly positioning tool, with the fixed magnet assembly attached using the shoulder screws

3. Remove the 2x liner from the very high bond (VHB) tape on the bottom of the magnet assembly.

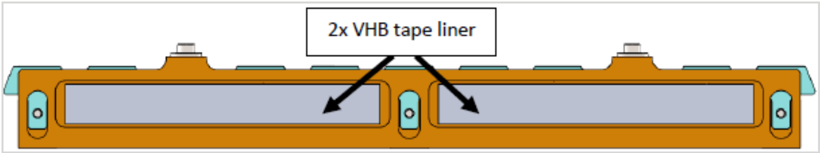


Fig: Underside view of the fixed magnet assembly, indicating the VHB tape

4. On the BD MAX instrument, make sure the white lysis cover is installed over the mag/lysis assembly. Insert the magnet position tool with the magnet assembly into the mag/lsysis assembly in the orientation shown.

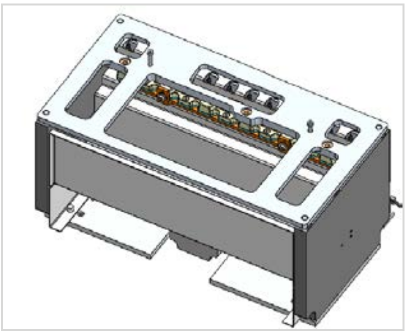


Fig: Fixed magnet assembly and positioning tool on the mag/lysis assembly

5. Once the tool is fully seated on the mag/lysis columns, firmly press the magnet assembly base down onto the lysis cover so the tape will adhere.

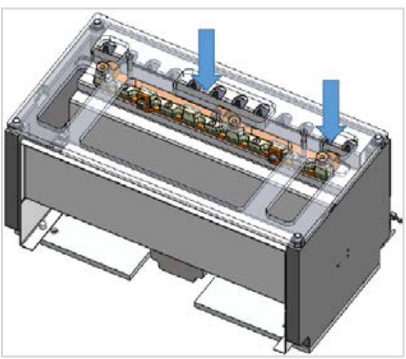


Fig: Firmly press the positioning tool down to adhere the fixed magnet assembly to the mag/lysis cover

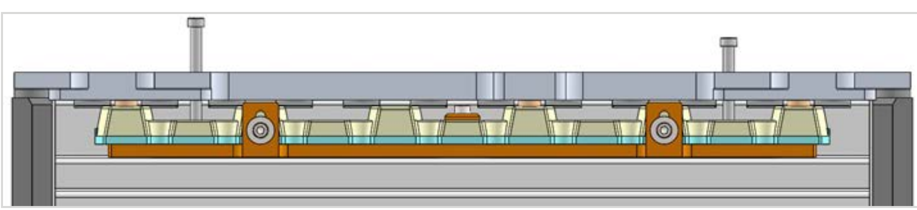


Fig: Fixed Magnet Assembly adhered to the mag/lysis assembly, side view

6. After pressing, note the height of the bronze bushings relative to the top of the magnet position tool.
   a. Place your finger on top of each bushing to feel if it is flush. If the bushings are not flush with the top of the positioning tool, the fixed magnet assembly height will need to be adjusted. When adjusting the fixed magnet assembly height, it is important to observe the bushing visually and using tactile feedback.
   b. As the magnet assembly is adjusted, the bushings will move up and should be flush with the top of the tool once the magnet assembly is in the correct position.
   c. It is possible to continue moving the magnet assembly up and lift up the positioning tool so be sure to observe the bushing movement during the adjustment and stop once it is flush.

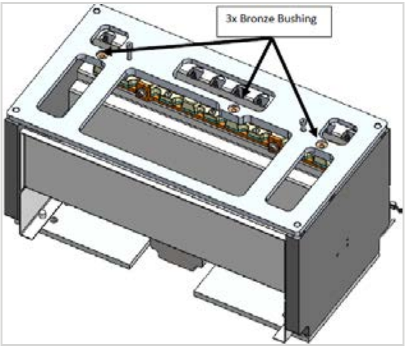


Fig: Top view of the positioning tool, showing the bronze bushing **not** flush with the top of the positioning tool

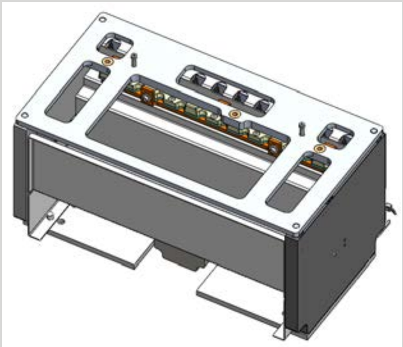


Fig: Top view of the positioning tool, showing the bronze bushing flush with the top of the positioning plate

7. To adjust the height of the magnet, use a 2.5 mm hex key to loosen the two front screws in the fixed magnet assembly. This will allow the top portion of the assembly to move up and down.

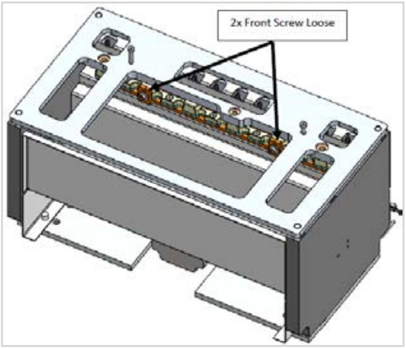


Fig: Top view of the positioning tool with fixed magnet assembly, indicating the location of the 2 front screws that should be loosened to adjust magnet height

8. Use a 2.5 mm hex key to incrementally turn the left, middle, and right rear screws in the magnet assembly clockwise until the bronze bushings are flush with the top of the tool. Make sure that the positioning tool remains seated properly on the mag/lysis column.

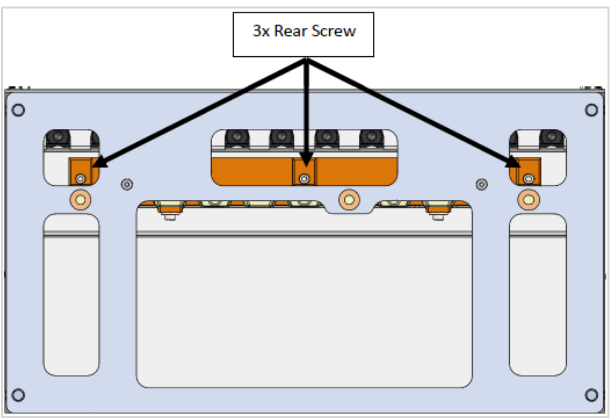


Fig: Top view of the positioning tool with fixed magnet assembly, indicating the location of the 3 rear screws on the fixed magnet assembly that can be adjusted to bring the bronze bushings flush with the positioning tool

9. Confirm that all three bronze bushings are flush with the top of the tool and confirm that the tool is still seated directly on top of the mag/lysis column bushings. If it is not fully seated, lower the magnet height as needed. The fixed magnet assembly will be installed on the MAX at this point.

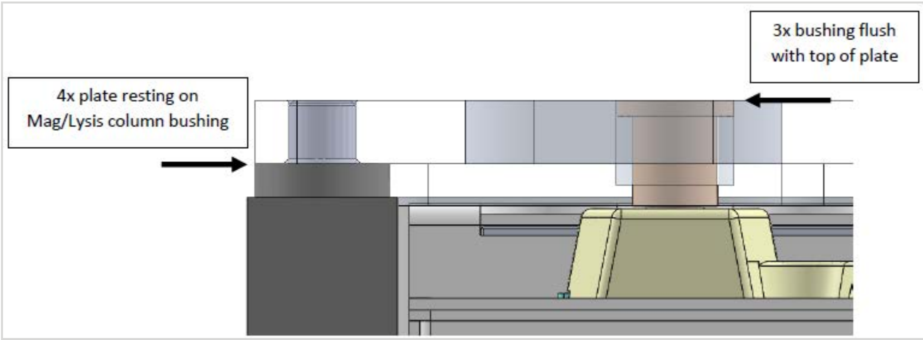


Fig: Side view of the positioning tool fully seated on the mag/lysis column and bronze bushings flush

10. Remove the positioning tool with a 2 mm hex key. Unscrew the shoulder screws that are attached to the magnet assembly.

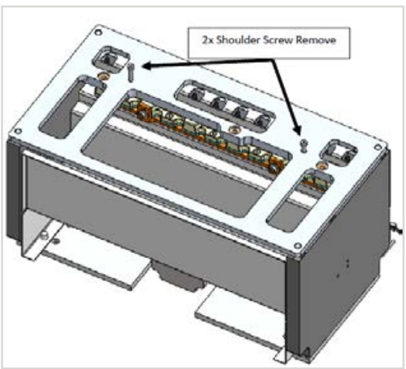


Fig: Top view positioning tool indicating the 2 shoulder screws that have to be removed to remove the positioning tool from the fixed magnet assembly

11. Remove the magnet position tool from the mag/lysis.

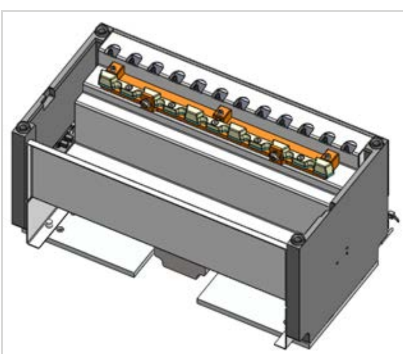


Fig: Side view of the installed fixed magnet assembly

12. Place a MAX rack in the mag/lysis and then place the Fixed Height Magnet Tool in lane 2 of the rack in the orientation shown with the openings to the right side and push it all the way

back.

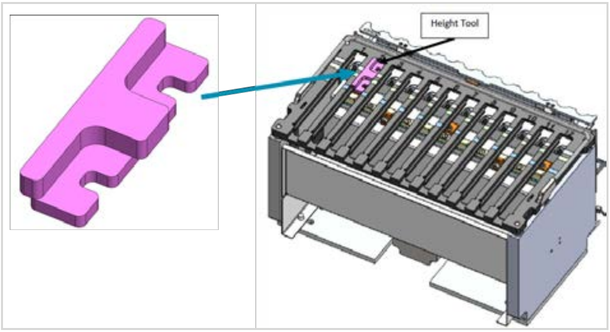


Fig: Fixed height magnet tool (left) and top view of the fixed height magnet tool in place on lane two of a MAX rack in the mag/lysis assembly (right)

13. Zero the calipers and place the end on the URS mounting surface and nearby flush surface of the height tool. Slide the calipers until the end touches the top of the bridge of the magnet assembly. **The measurement should be 13.4 + 1 mm**.

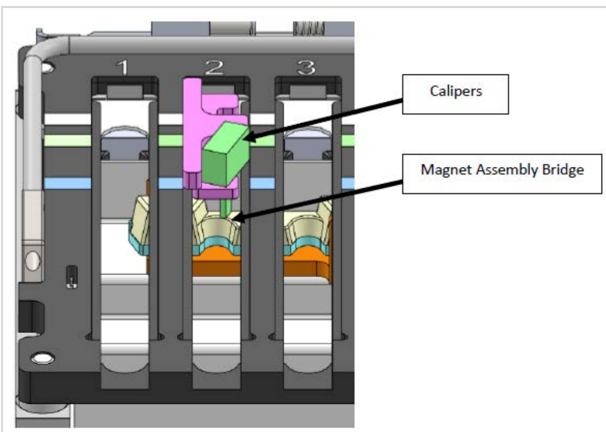


Fig: Top view of the MAX rack - placement of the calipers

14. Repeat steps 13 and 14 for lane 6 with the magnet height tool in the same orientation with the openings to the right and pushed all the way back.
15. Repeat steps 13 and 14 for lane 11 with the height tool rotated with the openings to the left and pushed all the way back.

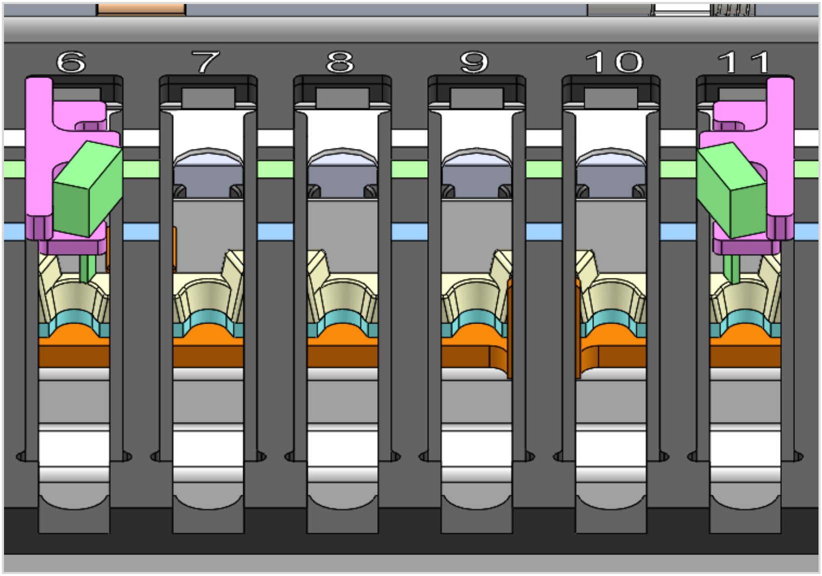


Fig: Top view fixed height magnet tool in place on lanes six and eleven of a MAX rack in the mag/lysis assembly

16. If the measurement is out of range, remove the rack and adjust the magnet assembly height by turning the rear screws. A full turn of the screw is 0.5 mm.

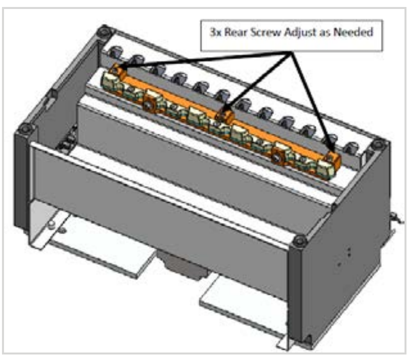


Fig: Three rear screws - to be adjusted if caliper measurement is out of tolerance

17. Once the measurements are within 13.4 + 1 mm, use a 2.5 mm hex key to tighten the two front screws of the magnet assembly. Use care to ensure the magnet assembly height does not move up while tightening the screws.

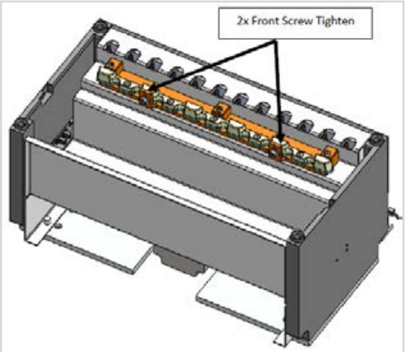


Fig: Two front screws - tighten after caliper check

18. After the fixed magnet assembly is installed, complete the above steps for the second assembly.
19. Update the Fixed Magnet Assembly Service Max Attribute to **Version 1 (444877)**.

5.4.3 AIO USB Cable

This section describes the recommended steps for installation of the BD MAX AIO USB Starter Kit. Tidy cable management is critical to avoiding communication issues due to external interferences.

Table: AIO USB Starter Kit (SAP 445228 /445228) Contents

Item	Quantity	Description
Armored USB Cable	1	3 meters long
Cable Mounts	5	N/A
Cable Ties	5	N/A

This AIO USB Starter Kit will be added into the BD MAX Starter Kit (SAP 443362) to replace the previous 6ft USB 2.0 Cable.

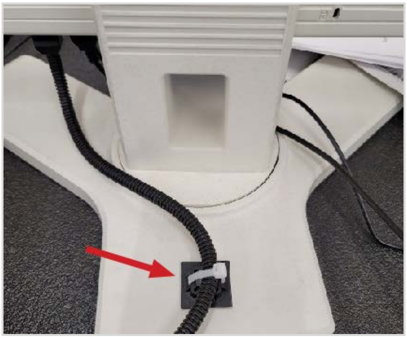
Required Materials

- Alcohol wipes
- Pliers/wire cutter

Procedure

⚠ Do NOT tie USB cable with power cable.

1. Clean surfaces prior to sticking the cable mounts in place.
2. Connect USB cable into the AIO.
3. Using the cable mount and cable tie, secure the cable onto the AIO. Recommended placement:



4. If the AIO is on the left side of the BD MAX, tie excess cable as shown in picture below using the cable mounts and cable ties. Leave enough slack in the cable to avoid excessive pressure, but remain tidy.

5. If the AIO is on the right side of the BD MAX, place cable mount as shown below and secure the cable by using a cable tie. Leave enough slack in the cable to avoid excessive pressure, but remain tidy.

6. If there is excess cable, make loops, as shown below, before inserting cable into the BD MAX.

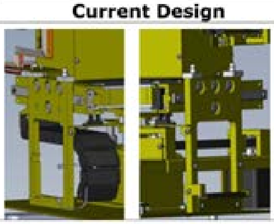
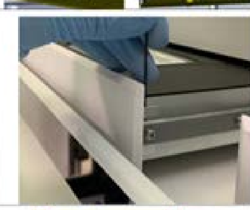
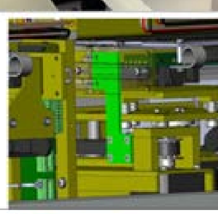
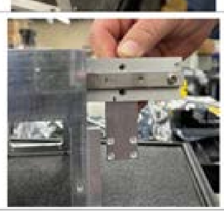
5.4.4 PCR Tray Design Update

The BD MAX™ PLUS features a new PCR tray design that will improve stability, alignment, pressure distribution, and overall robustness. This update will introduce new spare parts, but can utilize the same general service procedures as the current design.

The new tray assembly is not backwards compatible so two different assemblies and sets of spare parts will be maintained in the field.

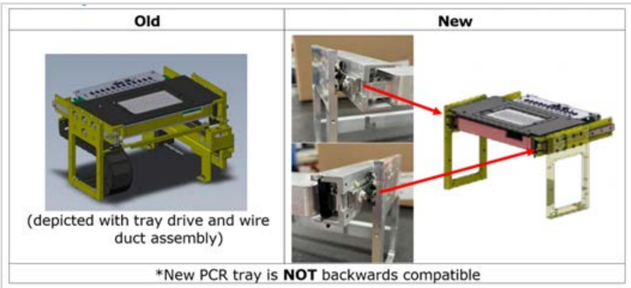
Current & New

Summary

Component	Current Design	New Design
PCR Tray Rail Mechanism		
Tray Cover (Front Panel Assembly)		
Tray Drive Assembly Bracket		

PCR Tray Updates

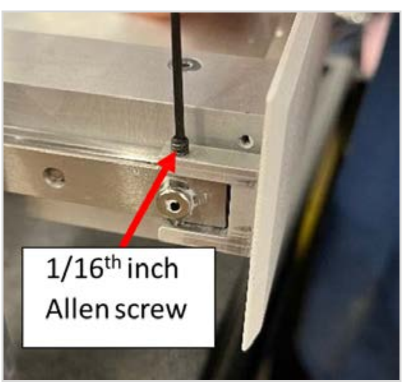
PCR Tray Rail Mechanism



- Update
  - Conversion from 6 wheels to linear slide on each side
- Service Notes
  - NO GREASING REQUIRED
  - Existing BD MAX cannot be upgraded with new tray

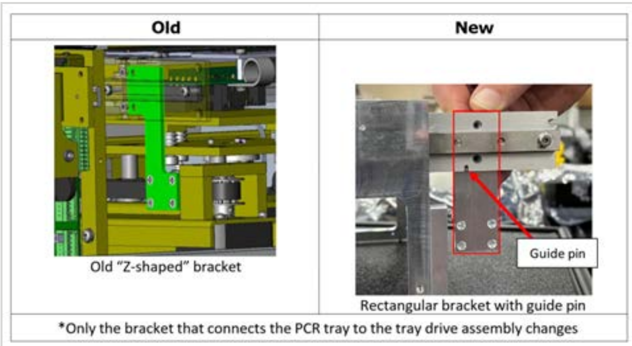
Tray Cover (Front Panel Assembly)

- Update
  - New bracket design
  - Larger set screw (**1/16 inch**) on each side



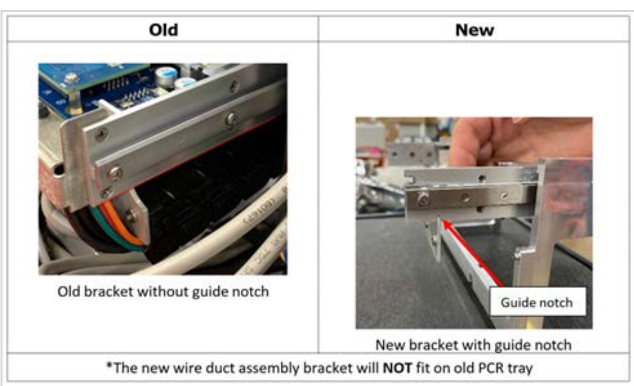
- Service Notes
  - New spares will be created for both old AND new tray cover
  - Old and new tray covers are not interchangeable

Tray Drive Assembly Bracket



- Update
    - New bracket to connect tray drive assembly and PCR tray
    - Guide pin introduced to PCR tray
- Service Notes
    - New spare tray drive assembly (444739) will be created (the actual drive assembly is the same)
    - Both old AND new spares will be maintained
    - Same screws (Phillips) are used for the old AND new tray drive assembly bracket

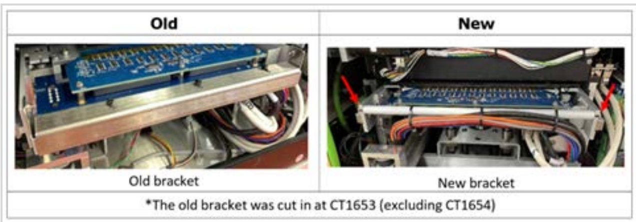
Wire Duct Assembly Bracket



- Update
    - New bracket to connect wire duct assembly and PCR tray
    - Guide notch in PCR tray introduced to PCR tray

  - New wire duct assembly igus chain
- Service Notes
  - Old and new wire duct assemblies are not interchangeable

Heater MUX Cable Bracket



- Update
  - New low-profile bracket for cable routing behind Heater MUX
  - Secured by one pan head Phillips screw and washer on each side
- Service Notes
  - Orientation matters! The “shorter” end should be on the bender board side of the BD MAX

  - Cable ties loop through bracket to restrain cables
  - Ensure cables do not hit the back of the BD MAX
  - Ensure the heater MUX is able to freely move up and down before securing cables

Verification

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

1. Perform Gantry Alignment "Gantry Alignment " on page 508
2. Perform "Reader Tray Position " on page 469
3. Perform the "Self-Test " on page 474
4. Perform "Procedure Normalizer Ratio Check" on page 492
5. Perform the "Power Supply Voltage Adjustments" on page 193
6. Perform a site qualification according to the site where the cable was replaced. "5-Channel Qualification Test" on page 325

5.5 Peripheral

5.5.1 ZBA Handheld Barcode Reader

Replacement

1. Unplug Handheld Barcode Reader from the USB port.
2. Plug in the replacement Handheld Barcode Reader.
   a. Wait for the three consecutive beeps to confirm the barcode handle is connected to the software.

Verification:

1. Scan a few sample tubes to confirm the proper functionality of the Handheld barcode Reader.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.5.2 ZBA Handheld Barcode Reader Configuration

Handheld Barcode Reader Identification:

Identify the version and reprogram according to the type of hand-held barcode reader.

There are two different styles of ZBA barcode readers. The hand-held barcode reader style can be identified by looking at the background flash and internal engine.

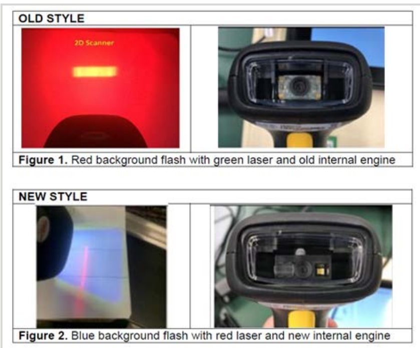


Figure 1. Red background flash with green laser and old internal engine

Figure 2. Blue background flash with red laser and new internal engine

5.5.2.1 Reprograming the Old Handheld Barcode Reader

Follow these steps to reconfigure the hand-held barcode reader.

1. Print the following barcode configuration code to reprogram the old hand-held barcode reader.

HID (PC) with CRLF SUFFIX

Scan codes from top to bottom in sequence (1-10)

1	USB HID (PC)
2	Clear All Suffixes
3	Add Suffix
4	9
5	9
6	0
7	D
8	0
9	A
10	Save

Fig: ZB3062 2D-Barcode Scanner set-up for BD Max

2. Plug in the hand-held barcode reader in a free USB port. There will be a “beep” indicating the reader has initialized.

3. Scan the barcodes from 1 to 10. Each scan will be followed with a “beep” sound to confirm the reading.

5.5.2.2 In Case of a Reading Mistake or Wrong Sequence

1. If barcodes are scanned, missing or wrong order, use the factory reset barcode below and start over.

   Only Scan if necessary

2. Follow step 1 to 3 "Reprograming the Old Handheld Barcode Reader" on page 360 to reconfigure the hand-held barcode.

5.5.2.3 Reconfiguring the New Handheld Barcode Reader

Print and scan the following barcode reader configuration codes to reprogram the new handheld barcode reader.

1	ZB3062USB-BDMAX default setting: • HID (PC) with CRLF SUFFIX Suffix CR & LF
2	Enable Aztec symbology

Note: When scanning the small 2D barcodes on sample buffer tubes, holding the scanner at a slight downward angle can help.

Verification:

1. Scan a few sample tubes and cartridges to confirm the proper functionality of the Handheld barcode Reader.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.5.3 Printer Installation

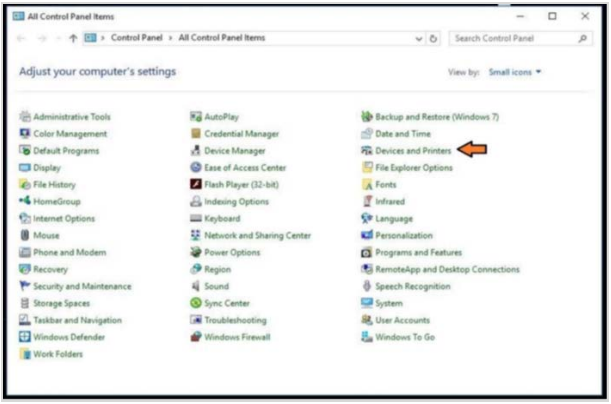
Note: Do not install any software provided by the CD or USB included with the printer. Only the auto configuration in the software will be the correct configuration.

Refer to the last software installation service Bulletin.

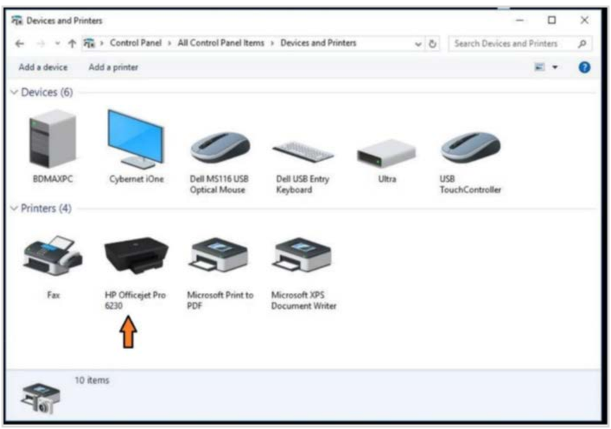
1. Log in **FSVC**.
2. Select Maintenance/Field Service/Command Prompt.

3. Power up the HP Officejet Pro 6230 Printer and plug in the USB cable to the AIO at the designated USB port. Consult the Service Manual for the AIO port designated for the printer.
4. Type the command **control** on the AIO Command Prompt screen that will open the Control Panel on the system.

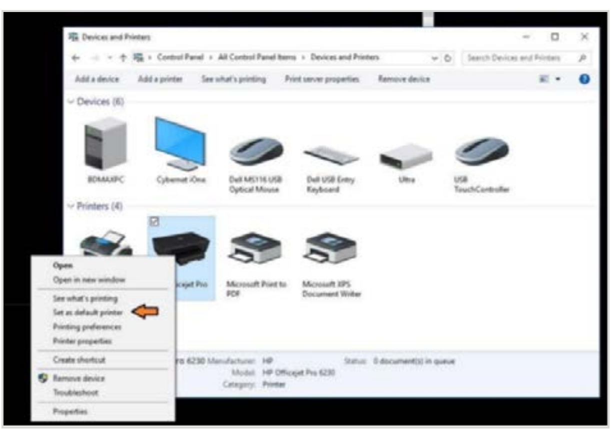
5. Select **Devices and Printers** on the Control Panel.



6. The printers list should display the printer model that has been connected. In this example, the printer is **HP Officejet Pro 6230**.



7. Right-click on the printer and select the **Set as Default Printer** option from the drop-down menu list.



8. If a printer is removed, be sure to restart the system software.

9. Log out of the **FSVC**.

10. Log as **ADMIN**.

Verification:

1. Select the **RESULTS** and print one full report; the printer should print in 1.5 min a full report.
2. No qualification is required.

Printers For EMEA

> **Note:** Do not install any software provided by the CD or USB included with the printer. Only the Autoconfiguration in the software will be the correct configuration.

1. Contact the Regional Expert to receive the latest printer driver and configuration.
2. Use only a validate printer on the BD Max instrument.

Verification:

1. Select the **RESULTS** and print one full report..
2. Timing for printing:
   a. After the PDF will be generate in the BD-Max, will be send to the printer.
   b. Send the information to the print in blocks 10 sec.
   c. Start to print 10 sec.
   d. First page in 15 sec.
   e. Set of two pages every 15 sec.
3. Total time for print a report, 1:5 min.

> **Verification:** After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

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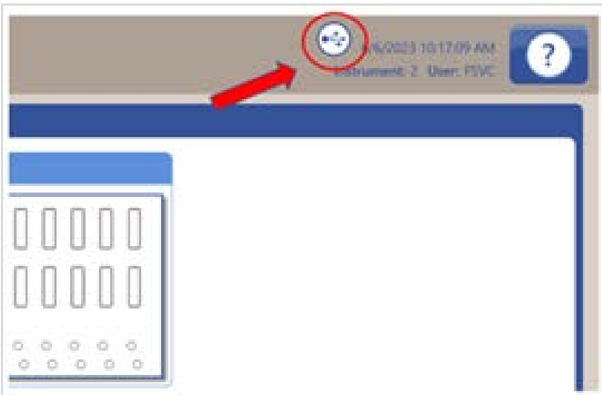
5.5.4 USB Flash Drive Spare

External USB Connectivity and Usage

1. The backup database will be stored by the customer and kept with the instrument.

   > **Note:** The USB will be used only for performing database and log backups, any other files can't be stored on the USB.

2. Wait for the USB symbol to appear on the BD Max software.



3. The following action can be performed with the USB plug-in on the FSVC user:

   a. Perform **Backup Database**.

   b. Restore Database.

   c. Backup Logs.

4. Database Pane: Backup Database (download) to a USB key, Restore Database (upload) from

a USB key.

Database and Log Panes:

1. System software version 4.50 and greater supports:
   a. Database backup,
   b. Database restoration,
   c. Backup logs.
2. When database and log files are saved to a USB flash drive, a folder with the instrument serial number as the name, is created on the USB drive. The log file and database are in zip format and protected with the BD Max password.

Backup Database:

1. Select backup database.
2. Wait for the backup finished.
3. The time to complete the backup is relative to the size of the database, timing can be from 1 minute to 40 minutes, wait until the following Pop up windows close.

4. Backup Completed.

5. Remove the USB from the BD Max.
6. The backup ZIP folder will be created on the USB with the CT serial number.

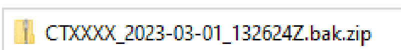
CTXXXX_2023-03-01_132624Z.bak.zip

Restore Database

1. Select the instrument database to be restored in the folder with the CT serial number.

> **Note:** Many databases from the instrument can be stored in one USB, select the database according to the dates to restore.

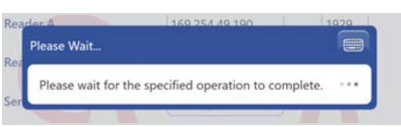
2. The software was asked to confirm the selected database will be restored.
3. Select the database.



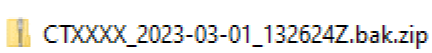
4. Wait for the process finished.
5. The time to complete the Restore the Database is relative to the size of the database, timing can be from 1 minute to 40 minutes, wait until the following Pop up windows close.
6. The BD max software will restart back to the main screen for Log-in.

Backup Logs

1. Select **Backup Logs**.
2. Wait for the backup finished.
3. The time to complete the backup is relative to the size of the database, timing can be from 1 minute to 40 minutes, wait until the following Pop up windows close.



4. The backup ZIP folder will be created on the USB with the CT serial number.



5. The zip folder will contain the CSV files with the backups for the last 30 days.

6. To open the Excel files, use the BD Max password.

VERIFICATION:

1. Visual confirmation is required to:
   a. Check the USB symbol to appear on the BD MAX software.

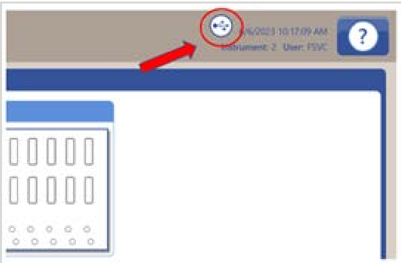


Fig: Icon indicating USB is connected to the BD MAX AIO

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

5.6 BD MAX Load Cartridge Test Kit

Purpose:

In order to prevent extraneous use of a BD MAX Qualification kit (5-channel Qualification test, part number 444048) solely for completing Load Cartridge testing, the BD MAXTM Load Cartridge Test is a new spare part that will allow for the use of the Qualification kit to complete both the Load Cartridge script and instrument qualification.

This procedure provides instructions to run both the Load Cartridge Test Kit and instrument qualification with the Load Cartridge Test and "5-Channel Qualification Test" on page 325.

The Load Cartridge Test Kit is multi-use and is used in combination with a BD MAX Qualification kit (444048).

The BD MAX Load Cartridge Test Kit contains the following:

- 200 conical Tubes
- 192 Pipette Tips (175uL)

Scope:

This applies to all Field Service Engineers serving BD MAX instruments using the Load Cartridge script on the instrument.

Materials:	SAP	Qty	Description
BD MAX Load Cartridge Test Kit	445028	1	Test Kit
BD MAX Qualification Kit	444048	2	5-channel Qualification Kit. Second kit for possible repeat testing.
24 Lane Cartridges	437519	1	Box of 24 cartridges

Procedure:

Setting up the URS for Load Cartridge testing and completing testing.

1. When completing the Load Cartridge script, follow the procedure as outlined in section 7.10 of the BD MAX Service Training Guide with the following modifications:
    1. Obtain and use proper protective equipment (i.e. gloves, safety goggles, lab coat, etc).
    2. Prior to step one, remove the needed number of conical tubes from the Load Cartridge Test Kit. For example, if testing 4 lanes, 4 conical tubes will be needed.
    3. Snap in one conical tube into position 4 of the URS.
    4. Continue with the Load Cartridge Test procedure as outlined in the Service Training Guide.
    5. After completing Load Cartridge Test, do not discard the URS.

Completing Qualification runs

1. Prepare the URS used for Load Cartridge testing to be used during qualification testing.
   1. After Load Cartridge testing is completed, carefully remove and discard the conical tube from the URS.

      Note: Be careful to avoid splashing from the conical tube.

   2. Next, remove the tip in position 4 and discard.
   3. From the Load Cartridge Test Kit, insert a tip in position 4.
   4. Continue setting up the Qualification kit according to the "5-Channel Qualification Test" on page 325.
   5. Retain the remainder of the Load Cartridge Test Kit for future use.

6 Diagnostics and Troubleshooting

This section provides information on routine troubleshooting procedures.

The possible causes and potential corrective actions are listed below each error code and error message. If the error message is not corrected by the corrective action, contact BD Technical Support for assistance.

6.1 Error Codes and Messages

Error Code	Error Description	Possible Cause(s)
0X0	Success	Script ran to completion successfully. Message is informational.
0X1	Exit Failure	General failure not otherwise classified.
0X2	Exit Assert	Internal software error caused script to exit.
0X3	Script Killed	Script failure due to external or operator error. Example causes include: • Starting new run when instrument is still in PCR • Turning instrument off while running
0X4	Script not Found	GUI tried to launch a script that is not found on the MUX board.
0X5	Bad Magic Number	Error caused by firmware not pushed correctly.
0X6	Script Aborted	User aborted a run. Message is informational.
0X7	Robot Calibration Table Failure	Failure in the robot calibration table.
0X9	Invalid Parameters	Parameter string did not match any in script table.

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Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

Error Code	Error Description	Possible Cause(s)
		Normally caused by user-defined protocol not built or entered correctly.
0X8	No Parameters Specified	No parameters were specified in script.
0XA	Mixed Parameters	DNA and RNA were mixed on the same bank.
0XB	Motor Failure	Robot motor communication failure. Failure to connect to the computer.
0XC	Could not Drop Tip	Instrument failed to drop tips in 2 tries.
0XD	Could not Pickup Tip	Instrument failed to pick up tips in 3 tries.
0X10	Heater Timeout Warning	One or more lysis heater did not heat up to temperature within the specified time. Usually caused by lysis heater hardware issue.
0X11	Optics Failure	LED detected by normalizer is out of range or non-existent.
0X12	Optics Restarted	Optics restart exceeded 10 tries. This indicates a communication issue.
0X13	File not Found	Failed to find XML parameter file.
0X14	Syntax Error	Syntax error in XML parameter file.
0X15	Motion Timeout	Timeout on motor movement Communication exists but motor did not reach assigned position within specified time.
0X16	Limit Hit	Robot reached limit switch on axis. Indicates home sensor failure since the instrument hit home sensor before hitting limit switch.
0X17	Offset: Normalizer detection for LED X failed	Failed to adjust position for offset 2 times. This indicates a motor encoder problem.
0X18	Cap Detected	Instrument detected cap on sample buffer tube.
0X19	PCR Valve Failure	PCR valve heater failure causing micro fluidic cartridge to fail sealing.
0X1A	PCR Heater Warning	PCR heater exceeded set tolerances.

Error Code	Error Description	Possible Cause(s)
0X1B	PCR Detector Motor Failure	Detector motor position exceeded encoder tolerance. Reader Detector motor issue.
0X1C	CORE/USER Mismatch	Core system ID and timestamp mismatch.
0X1D	Liquid Level Sense Error	Detected liquid level error in the tip.
0X1E	Error in Full Fill Check	Cartridge fill check reading was under threshold.
0X1F	Error in Empty Fill Check	Cartridge fill check reading was under threshold. The instrument detected fluid in the cartridge when it should be empty.
0X20	PCR Reader Saturation	Saturated reading; readings are out of the reader's limit. Amplification too high or reader failure.

6.2 Hardware Troubleshooting

Hardware troubleshooting includes:

6.2.1 Pre-warm Temperature Verification

The test ramps up the six heaters in the pre-warm to 120ºC, reads the temperatures to confirm they are within range, and then cools them down.

There are **two Resistance Temperature Detectors (RTD)** for each of the six heaters to read their temperature.

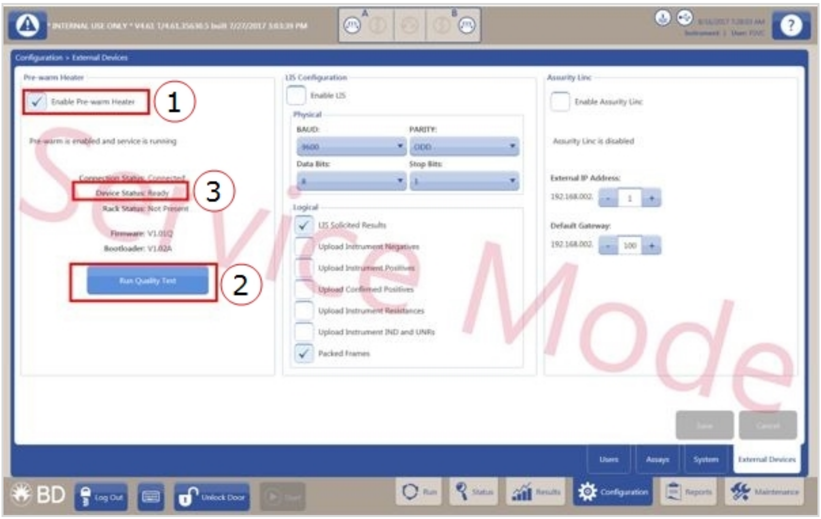
- The **first RTD** is the **primary RTD** that controls how hard the heaters need to drive to reach their desired temperature.
- The **second RTD** is the **QC RTD**. It is only used to monitor the heater temperature and confirm that the primary RTD works correctly.

The QC test compares the two RTD values. If the values are within an acceptable range of the target temperature, the QC test passes.

Procedure

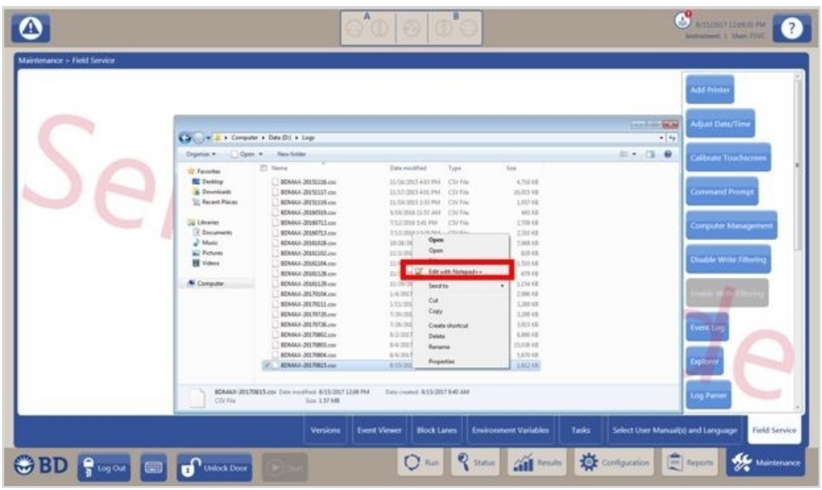
1. Make sure the Pre-warm is connected and powered on.

   > **Note:** Log in to the BD MAX **FSVC** Mode. Go to the **Configuration** tab, and select **External Devices**.

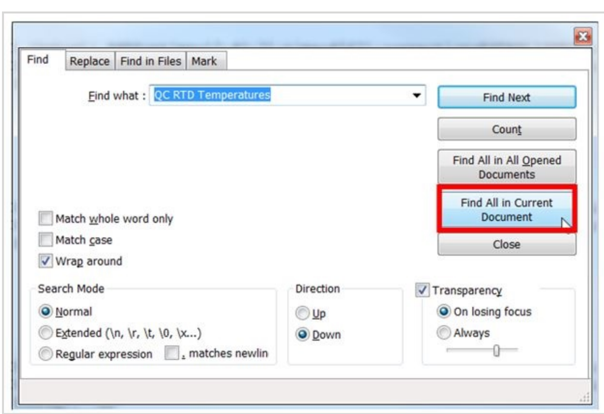
   

2. Make sure that the **Enable Pre-warm Heater** check box is selected. If not, select it and press **Save**. Refer to box 1 in the above image.
3. Verify that the rack is not installed, as the quality test only runs when the rack is removed. Click **Run Quality Test**. Refer to box 2 in the above image.
4. **The QC test takes about 30 minutes to run.**While the test is running, the screen display **Device Status:** Running Quality Test.
5. When the QC test is complete, the screen displays **Device Status Ready**. Refer to box 3 in the above image.
6. Enter the logs by clicking on the **Maintenance** tab, **Field Service**, and then **Explorer** once the QC test is complete.

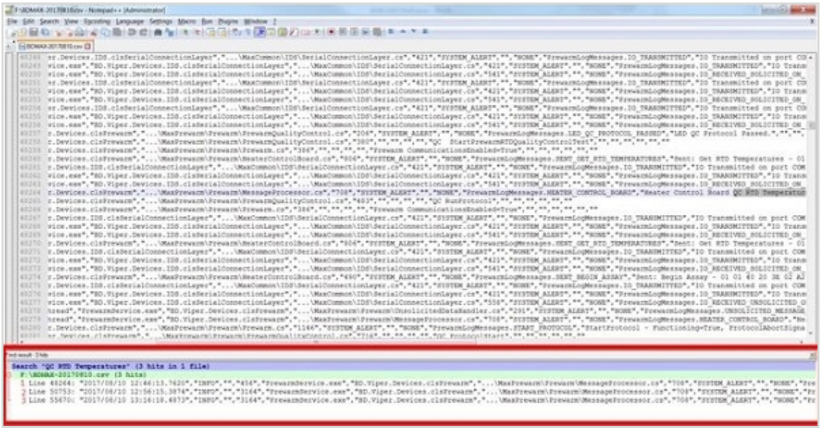
7. Navigate to **D:\Logs,** right-click on today's log file, and click **Edit with Notepad++.**



8. Once in the log file, hit **CTRL+F**, search for the phrase **QC RTD Temperatures** and click on **Find All in Current Document**.



9. The search should come up with three hits at the bottom of the page. Refer to the lines 1, 2, and 3 boxed in below image.



   - The first hit is the temperature of the QC RTDs, printed to the logs before the QC test starts.
   - The second hit is the temperature of the QC RTDs printed to the logs after the heaters are driven to **120ºC**, the target temperature of the QC test.
   - The third hit is the temperature of the QC RTDs printed after the heaters have cooled back down again.

10. Double-click on the **second** instance, which will automatically take you to where that phrase appears in the log file.

11. Scroll to the right until you can see the below information. The underlined information shows the temperatures of the **Primary RTDs** and the **QC RTDs**. The Primary RTD values are 5 lines above the QC RTD values.

12. The Pre-warm functions correctly when both the Primary and QC RTDs temperatures are **± 2.5 degrees** of the target temperature. Since the target is **120º C** for the QC test, all twelve values (underlined in Fig.7) should be between **117.5º C** and **122.5º C**.
13. Depending on the information needs of customer for validations or lab requirements, record temperatures for both the Primary and QC RTDs the acceptable **± 2.5 degrees** range. Record the values in Tables.
14. Attach a scanned copy of Table 1 and Table 2 to the work order. Share with the customer if requested.

Table: QC RTD Temperature Table

Primary RTD Temperature	Recorded Value	Acceptable Range	Pass/Fail
1		117.5º -122.5ºC	
2		117.5º -122.5ºC	
3		117.5º -122.5ºC	
4		117.5º -122.5ºC	
5		117.5º -122.5ºC	
6		117.5º -122.5ºC	

Table: QC RTD Temperature Table

QC RTD Temperature	Recorded Value	Acceptable Range	Pass/Fail
1		117.5º -122.5ºC	
2		117.5º -122.5ºC	
3		117.5º -122.5ºC	
4		117.5º -122.5ºC	
5		117.5º -122.5ºC	
6		117.5º -122.5ºC	
FSE Name: ---------------- Signature: ----------------- Date: -----------------------			

6.2.2 Interpret Run Results

Run results are generally classified as five possible outcomes.

In each sample run there are multiple elements being amplified, the targets and the internal control. The targets are the actual DNA/RNA amplicons that the test was designed to detect. The internal control consists of a known sample of DNA/RNA present in the extraction snap in and their corresponding primers and probes located in the Master Mix (PCR) snap in.

Internal Control is different from an External Control.

- An **External Control** is a known negative or positive sample used to validate overall instrument performance.
- The **Internal Control** is in each approved assay and is only used to validate that particular test performed correctly.

Positive results: are achieved when the target amplifies, regardless of whether the internal control amplifies or not. A positive result on the target confirms the existence of the target DNA/RNA in the sample.

Negative result: only occurs when the target DNA/RNA does not amplify and the internal control does amplify. The internal control validates that the run completed correctly and there is no target DNA/RNA in the sample.

Unresolved (UNR) results: occur only if neither the target nor the control amplifies. Because the control did not amplify, the absence of target DNA/RNA cannot be confirmed. Unresolved results tend to point towards an assay or workflow issue.

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Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

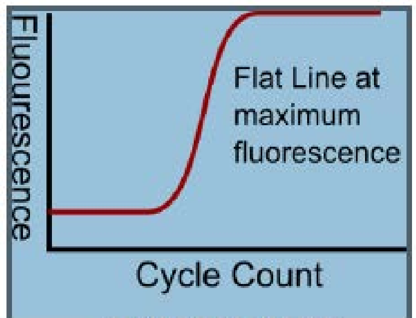
Indeterminate (IND) results: occur if any sort of error is detected during a run. The sample that experienced the error is classified as indeterminate. Basically, the affected lane cannot be confirmed because an error occurred. Indeterminate results normally point towards an instrument problem.

Incomplete results: occur when one of the steps in a run does not come to successful completion. It usually causes runs to abort.

6.2.2.1 Saturated Results

An overabundance of target DNA causes a florescence that becomes too intense for the reader to measure. As a result the graph reaches the peak displaying Saturation. The Saturation can also be observed on a defective reader.

Saturation can also be accompanied by shaky curves and early CT. Such result requires additional investigation. A qualification test can be run and compared to the suspect results to help isolate the problem.

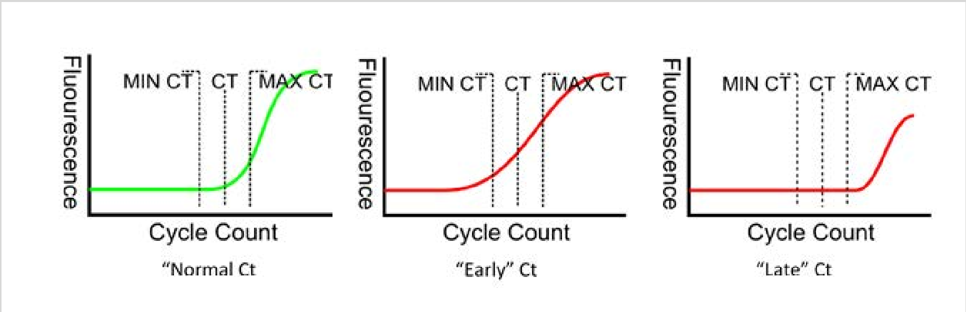


Saturated Curve

6.2.2.2 Early and Late Cycle Threshold [Ct]

Assay results are determined by Cycle Threshold (Ct) value which is the point on the amplification curve that the signal begins to amplify.

> **Note:** The expected Ct Cycle Count for each BD MAX™ assay is defined in the Assay Definition File (ADF) and is a fixed value; users cannot adjust IVD assay Cycle Counts. **In the graphic examples below, CT represents Ct.**



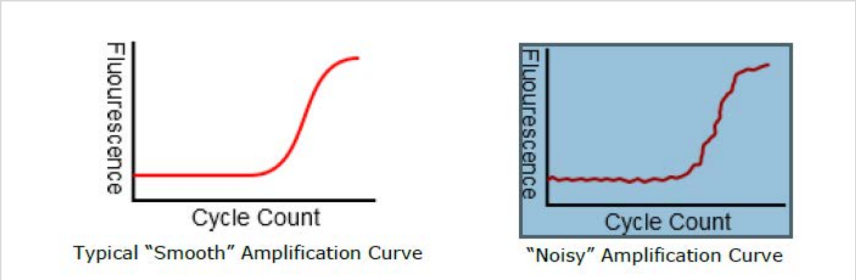
The minimum and maximum acceptable Ct is set by the ADF. If the Ct point is outside of this range, the results might be interpreted as no amplification and reported as a failure.

- **Early Ct** occurs on an earlier cycle.
- **Late Ct** occurs on a later cycle.

Early Ct of target and late Ct of control are common on assays like GBS, which use enriched samples. In these cases, the sample overwhelms the control; the ADF for this assay specifies greater minimum/maximum Ct values.

6.2.2.3 Noisy Curves

Amplification curves are typically smooth in appearance as seen in the below images. On occasion, at least one of the color channel appears to be noisier than is expected resulting in a **Noisy** amplification curve.



This issue is typically limited to a single color channel, affecting a single row (PCR Cartridge Top or Bottom), located on a single reader in an instrument. In rare instances, the issue can extend to multiple colors and the Top and Bottom rows of the PCR Card.

Cleaning: While unlikely, it is possible that this issue can be caused by foreign matter (dust, biologics, etc.) on the aperture plate of the reader or on the heater tray. The aperture plate of the reader can be cleaned using a combination of canned air to clear the apertures, and isopropyl alcohol to wipe away any residue on the plate. The heater tray can be cleaned using isopropyl alcohol.

Data analysis: Some diagnosis can be done by examining the data in question. By identifying the prevalence of the issue, the responsible part of the assembly can typically be pinpointed using the following breakdown.

> **Note:** It can be difficult to discern a noisy and non-noisy curve where amplification has not occurred.

Single Lane on 1-5 channels: if the noise is limited to one lane, it is unlikely that this is an issue with the active parts of the reader assembly. Check that the aperture plate and heater tray are cleaned, and verify that there is not a chemistry issue in that lane. This type of issue should be resolvable in the field.

Single Channel: If the noise is limited to a single channel, the retaining ring on one of the lenses (excitation or emission) has likely come loose. This issue will exist on all lanes and requires replacement of the sliding read head.

All Channels, All Lanes: If the noise is prevalent on all channels, the reader chassis has typically come loose for some reason.

CSV: By looking at the csv data for the runs in question using excel, it is possible to perform some level of analysis. The [PCR Background Data] and the [Raw PCR Data] are of interest in this case. Each section contains either 120 or 60 columns (1 or 2 readers used) with the number of rows equal to the PCR cycles in the test. Each column represents a single PCR lane in a single color channel. By comparing a line plot of a column from the [PCR Background Data] and its corresponding column in the [Raw PCR Data], it is possible to determine if the noise was present in the original detected data, or if it was introduced in the normalization process. This information can be useful in identifying the responsible part during the repair process.

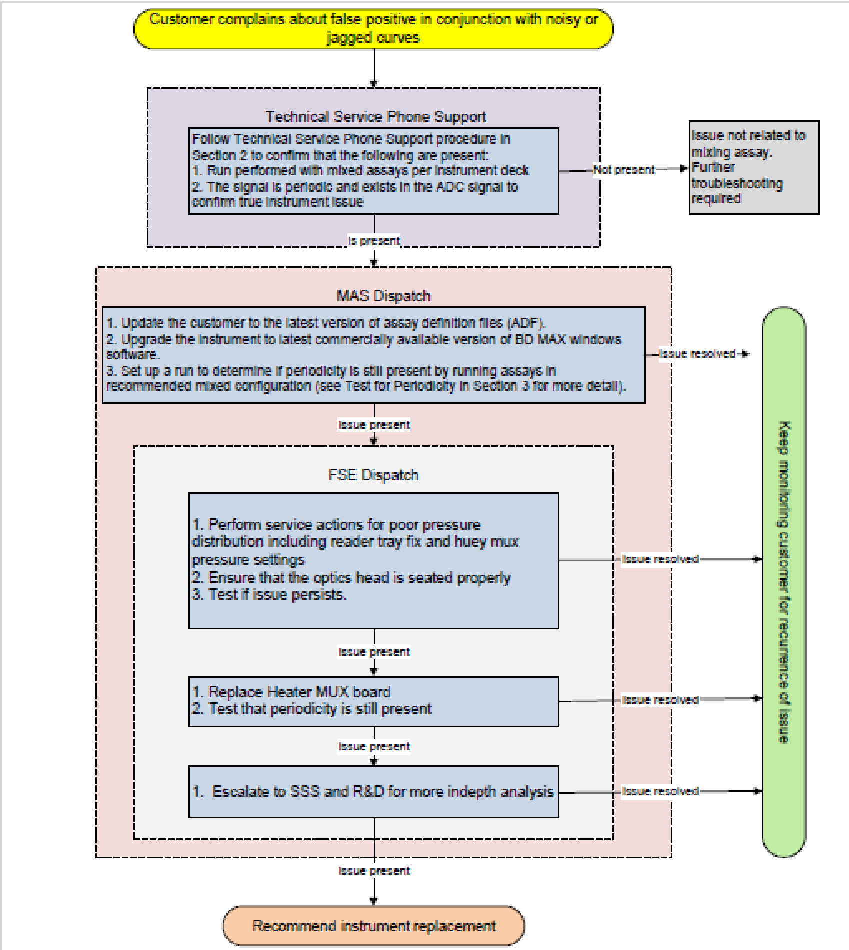
6.2.2.4 False Positive Complaints with Noisy Curves

When running multiple assays on the MAX™, a poor pressure distribution across the cartridge could lead to results with periodic optical signal.

- The poor pressure distribution prevents the cartridge from properly contacting the heater.
- This, in conjunction with a neighboring lane running a different assay and heating at a different time interval, causes the heater to slightly under-heat the lane.
- A small decrease in temperature of the assay results in an increase in signal.

The periodic signal varies based on the timing of the assays run, but when the fluorescence of the lane is read while neighboring lane is in a denature step (high temperature), the periodic signal is strongest.

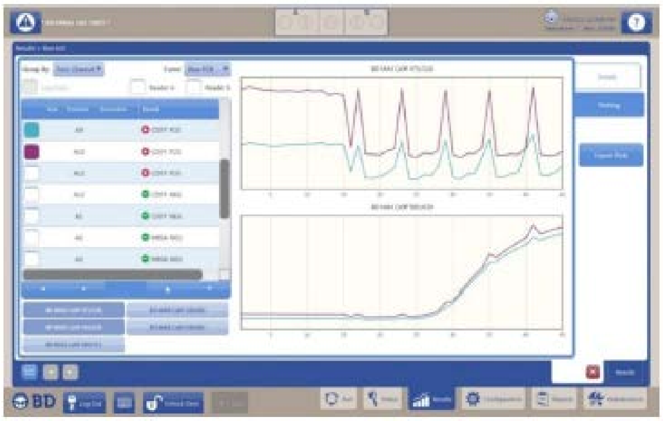
If **False Positive Complaints** are observed in **Conjunction** with **Noisy Curves**, follow the action steps provided below:



6.2.2.5 Procedure for False Positive Result with Noisy Curves

1. Customer files complaint for false positive in conjunction with noisy or jagged curves.
2. Obtain database, CSV and/or run report from the test result in question.
3. Confirm that within the same rack, there was a mix of assays from different assay group.
4. Access the report on the AIO, look at the curves in Raw PCR mode and identify saw-tooth shaped curves (see Plot 1). This corresponds to growing signals in the background curve

mode (see Plot 2).



Plot 1: False Positive due to saw-tooth raw signal in Raw PCR mode

Plot 2: False Positive due to saw-tooth raw signal in Background PCR mode

6.2.2.6 False Positives in Mixed Assay Runs

When running multiple assays on the BD MAX, a poor pressure distribution across the cartridge could possibly lead to results with periodic optical signal.

- The poor pressure distribution prevents the cartridge from properly contacting the heater.
- This, in conjunction with a neighboring lane running a different assay and heating at a different time interval, causes the heater to slightly under-heat the lane.
- A small decrease in temperature of the assay results in an increase in signal.
- The periodic signal varies based on the timing of the assays run, but when the fluorescence of the lane is read while neighboring lane is in a denature step (high temperature), the periodic signal is strongest.

6.2.3 Pre-warm Heater Error Handling

For the following BD MAX™ pre-warm issues, use the following decision trees:

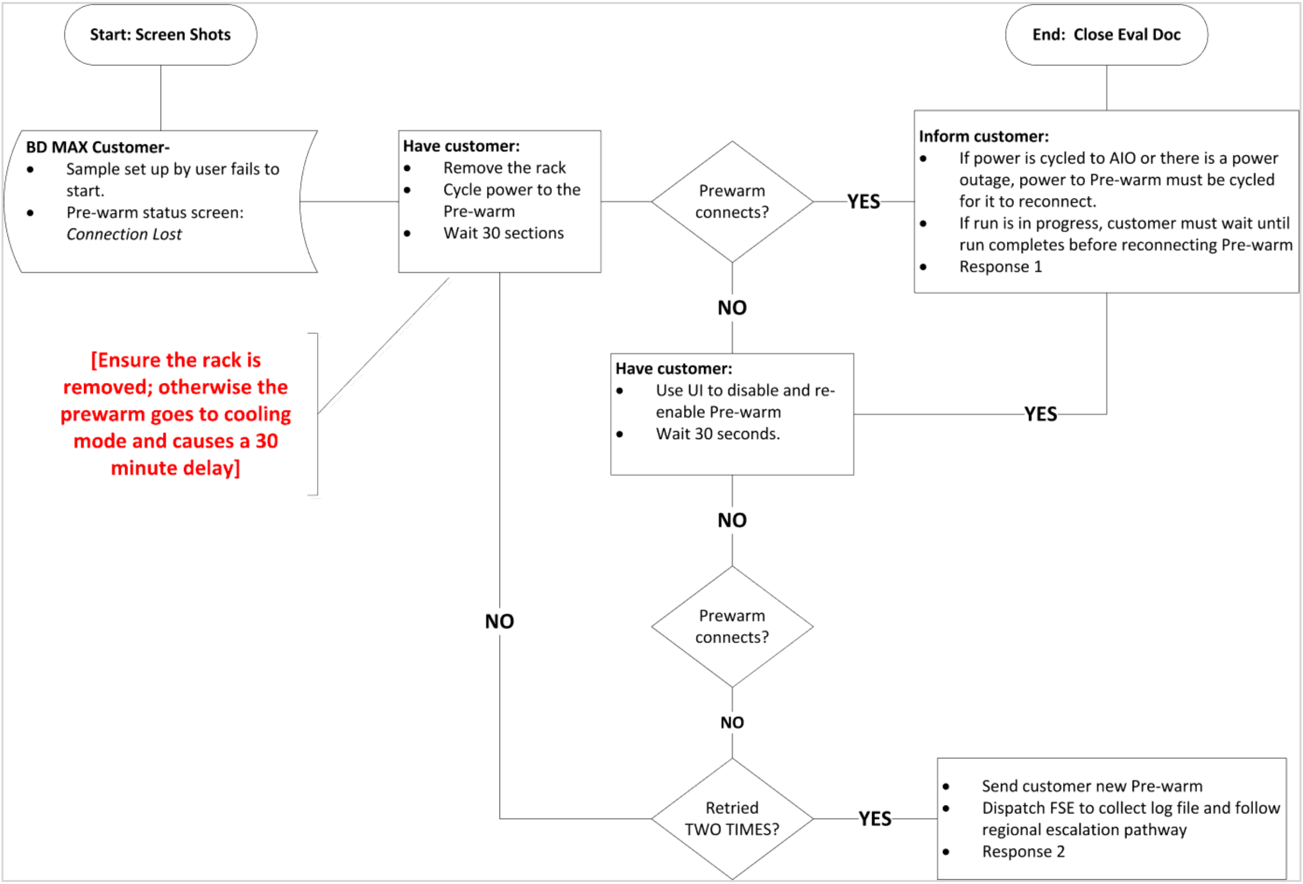


Fig: User Sample Set Up Fails / Pre-warm Status Screen – Lost Connection

Sample set-up by user FAILS to start

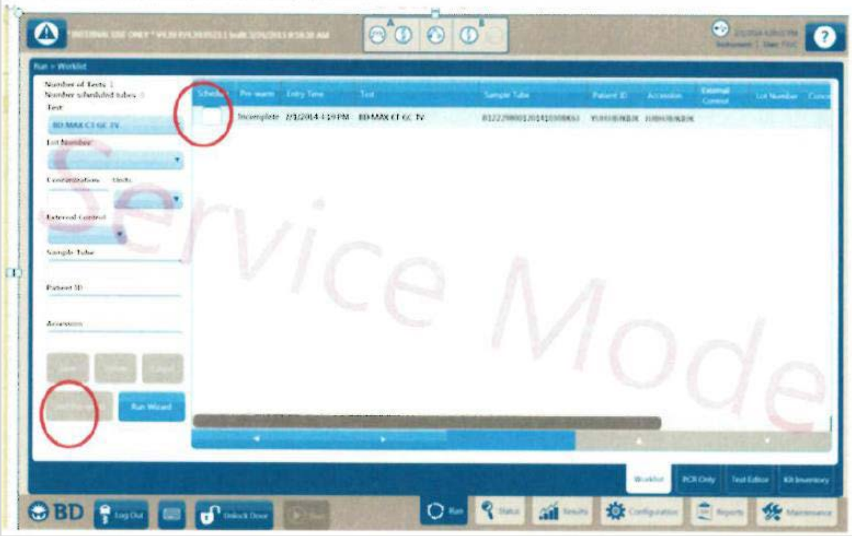


Fig: Sample set-up by user FAILS to start

Prewarm status screen – Connection Lost

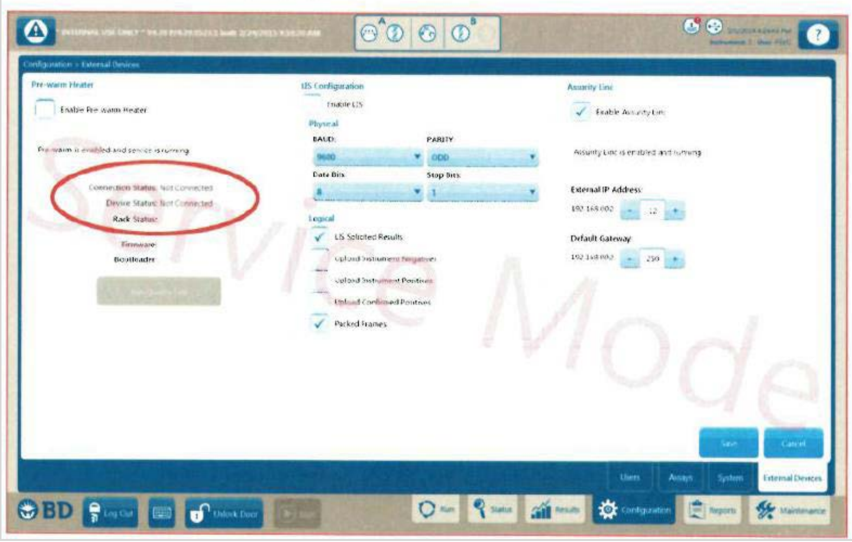
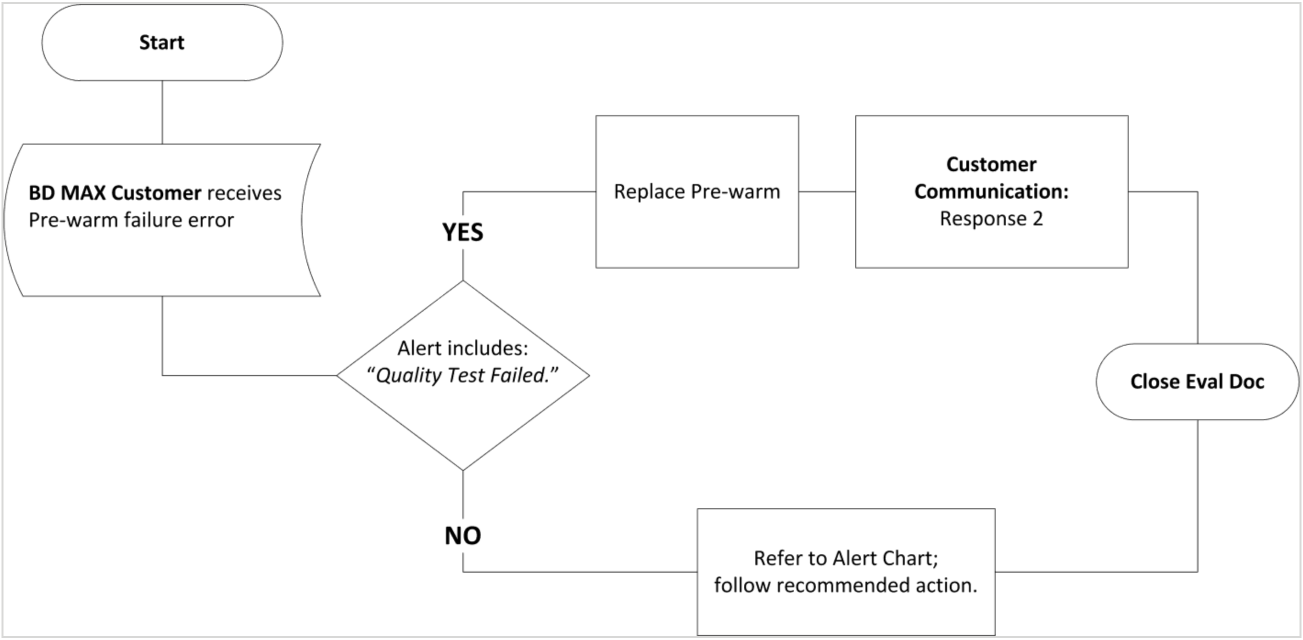


Fig: MAX Pre-warm Failure/Error



Alert Text displays

Alert Text	Recommended Action
Pre-warm failed. Please restart the pre-warm cycle with the scheduled tubes.	Retry Pre-warm.
Pre-warm Quality Test failed. Contact BD Field Service.	Replace Pre-warm station.
Pre-warm failed. Caution samples may be hot!	Let samples cool before using.
Allow the pre-warm rack to cool before handing the samples.	
Pre-warm failed but the samples are still usable. Caution samples may be hot! Allow the pre-warm rack to cool before handing samples.	Attempt QC Test. Attempt heating on new or different Pre-warm station.
A Pre-warm Quality Test is required. Remove the rack from the Pre-warm heater and press the Run Quality test on the Configuration External Devices screen.	Attempt QC Test.

Pre-warm Customer Complaint

Pre-warm station complaints which are provided are to be used with the decision trees for troubleshooting. The outcome of the decision tree indicates which response to use, either Response 1 or Response 2.

> **Note:** The decision tree should be in addition to the normal language used when dealing with customer complaints.

Customer Communication

- **Response 1 (if it solves the issue):** BD is aware of this issue with the Pre-warm stations and we are currently working on a resolution to address this. In the interim, please use the method we just went over as a work around if this error happens again. If you find this does not fix the issue in the future, please call Technical Services. We apologize for the inconvenience this has caused you.
- **Response 2 (if it doesn't solve the issue):** BD is aware of this issue with the Pre-warm stations and we are currently working on a resolution to address this. In the meantime, we will send you a new Pre-warm station immediately. We will include a return label in the shipment, please use this to send back your malfunctioning Pre-warm station. We apologize for the inconvenience this has caused you.

6.2.4 Reclosing Septum, Cap Rack Upgrade

> **Note:** Do NOT discard original parts before completing upgrade and verifying functionality.

1. Using the provided 1/16 inch hex tools (hex key or plastic handled Torque tool), remove the **front three screws** (**red circle**), which fix the leaf spring plate attached to the rack. **Do not remove the SBT holder screws (blue X)**. When removing the spring leaf screws, apply torque slowly to prevent stripping.

   > **Note:** A standard socket wrench with a ratcheting handle and 1/16 inch hex bit can also be used to remove very tight screws. If not available in their tool kit, FSEs can purchase the 1/16 inch hex bit and use for the upgrade. The hex bit is not required to complete the upgrade, but strongly recommended.

   If a screw cannot be removed due to corrosion, reinsert original screws that were already removed and order respective replacement racks (part number 444807).

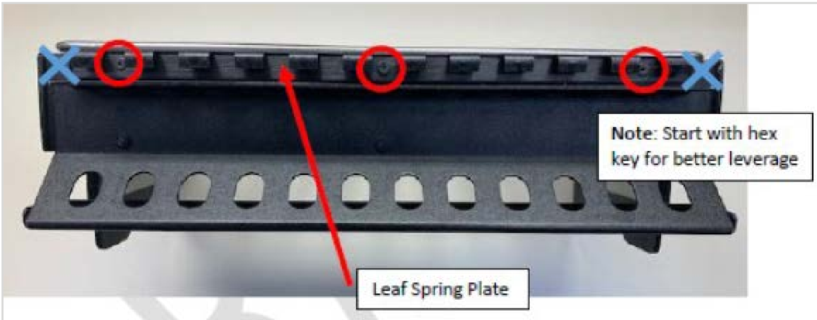


Fig: Front of current rack configuration showing screws to be removed using the hex tool or screwdriver in the rack upgrade kit.

2. Rotate the rack and remove the three screws on the underside using the 1/16 inch hex tools provided. Once again, slowly torque the screws to prevent stripping from occurring.

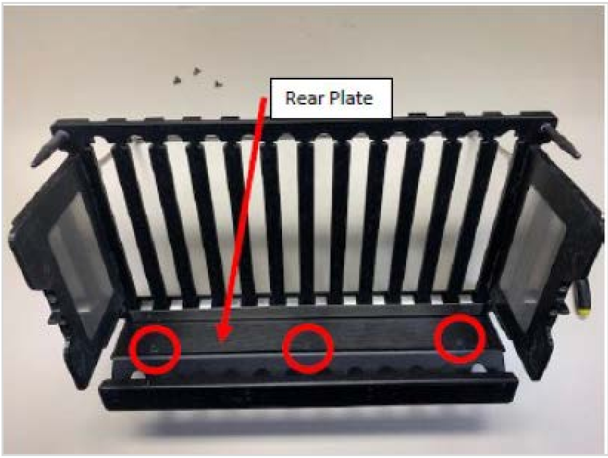


Fig: Underside of current rack configuration showing screws to be removed using the hex tool or screwdriver in the rack upgrade kit

3. Remove the back plate and the leaf spring pieces from the rack. Keep these parts to the side until the upgrade is complete. Clean surfaces with alcohol wipe to remove debris from old Loctite, bleach, etc.

Fig: Rack without rear plate and leaf spring pieces

4. Position the Self-locking tab onto the rack as shown below: Curved portion on top and centered on the middle screw hole.

Fig: Front views of rack with self-locking tab installed

5. Align the center screw hole on the Slide Locking Mechanism with the center screw hole on the rack. Center the Self-locking tab in the recessed area of the Slide Locking Mechanism as shown.

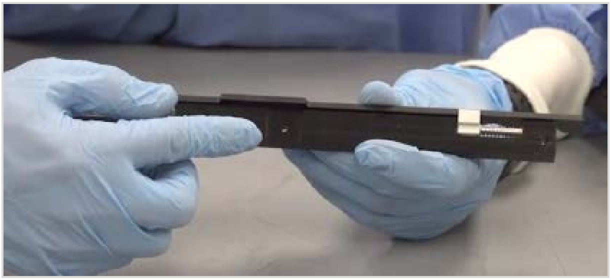


Fig: Slide Locking Mechanism with operator indicating the center screw hole.

Fig: Slide locking mechanism aligned with the self-locking tab on the rack.

Fig: Front view of the rack with the slide locking mechanism in place.

Note: Only use the screws provided in the upgrade kit, these are required due to their additional thread length.

6. Snap open the cap on the provided tube of Loctite. Place a droplet of the Loctite 242 onto the base of each provided screw. Ensure that the self-locking tab is still aligned. Starting with the center screw, use the provided hex tools to secure the screws into the rack (three screws per rack).

Fig: Loctite 242

Fig: Front of current rack configuration showing screws to be replaced using the hex tool or screwdriver in the rack upgrade kit.

7. Perform a functional verification to confirm successful upgrade.
   a. To ensure that new assembly is functioning, slide the tube Z-restraint to the left and pivot upwards to open the lid (refer to image below). This ensures there are no obstructions have prevented opening. The Z-restraint should remain in the "open" position for clear tube loading.

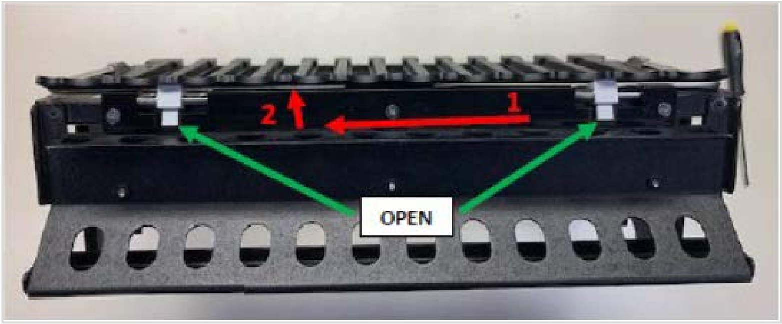


Fig: Front of an upgraded rack assembly showing the Z-tube restraint, where the gray slide locks are in the open position. To open the Z-tube restraint, first slide the Z-restraint to the left and then pivot up.

b. Press the Self Locking Tab located on the underside of the rack. Acceptance criteria is met if the plate engages the Z-restraint to the "closed" position. If the rack does not function properly, ensure that the self-locking tab was aligned properly during installation. If the rack does not function properly, de-install the new configuration, install the old configuration and order a replacement rack.

> **Note:** Failure to verify Self Locking Tab functionality can result in a hard failure where Z-gantry runs into rack if the hinge is left opened and the tab does not properly engage.

c. Ensure that the Sample buffer tube holder is not loose and tighten the two screws at the far ends if necessary.

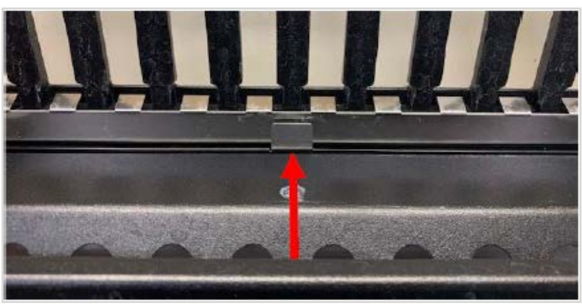


Fig: Underside of the upgraded rack indicating the self-locking tab.

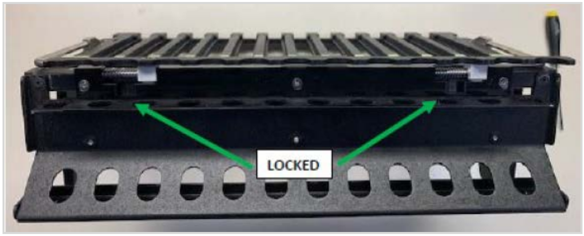


Fig: Front of the upgraded rack showing the gray slide locks in the locked position.

8. For racks successfully completing the upgrade and functional test, indicate in work order notes the number of rack upgrades completed and complete the attribute in ServiceMax. For the ServiceMax attribute, there are three options: Not complete, Complete or Ordered New Racks.

Fig: ServiceMax attribute completed for the RSC Rack Upgrade.

6.2.5 Missing or Tilted Racks

Missing or tilted rack errors prevent a run from starting, and these are recorded in the event log.

Causes

There are two optical sensors on the left and right sides of each extractor. These sensors detect a projection on the bottom of the left and right side of a rack. There are four possible conditions for theses sensors:

- **Rack missing** Neither sensor active
- **Rack Present** Both sensors active
- **Rack Tilt Right** Right sensor inactive, Left sensor active
- **Rack Tilt Left** Sensor inactive, Right sensor active

Troubleshooting

For rack tilt or rack missing errors perform the steps below:

1. Cycle Power to the BD MAX instrument.
2. Log on as **FSVC** and go to the event viewer.
3. Use a piece of paper to block each one of the optical rack detect sensors one at a time. This should show a change on the event log when each one is active. Example is **Rack A absent**,

Rack B tilt right or **Rack A absent**, **Rack B tilt left**. If you block a sensor and see no change on the event log, then the sensor or cable is bad.

4. Place a rack without strips in the system and check to see what the event log says. Ensure the tab at the bottom of the rack is blocking the optics sensors. If not, you may need to replace the rack or re-align the sensor.

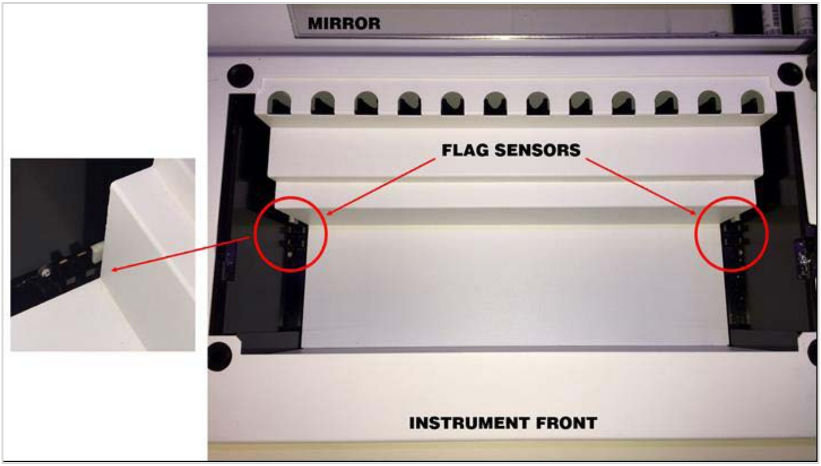
6.2.6 Rack Sensors Repair

Required materials:

- Flag sensor (**SAP Catalog No. 435222**)
- Phillips screwdriver

Procedure

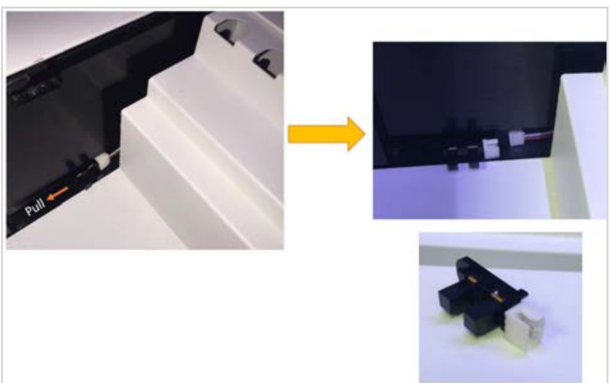
1. Before replacing the rack flag sensors, please check which flag sensor is damaged by looking at the rack icon at the top of the screen.



2. There are two rack flag sensors located on each side of the Mag/Lysis assembly.

3. To replace the flag sensor, remove the screw with a Phillips screwdriver.

4. After removing the screw, pull the flag sensor outward to disconnect it from the connector.



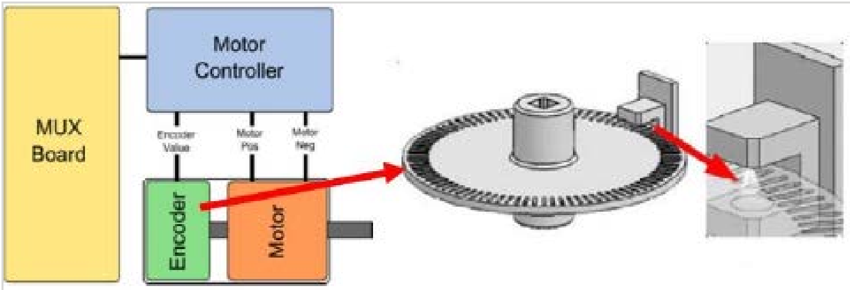
> **Note:** It is easier to remove the flag sensor from the connector if some pressure is applied on the other side to hold the cable down while pulling the flag sensor out.

5. Connect the new flag sensor into the connector, and tighten the screw back.
6. Verify by placing a rack into the Mag/Lysis assembly and ensure that there is no Rack Tilt Error displayed on the AIO.

6.2.7 Motor Issues

The robot gantry system on the BD MAX instrument uses fourteen servo motors and seven motor controller PC boards.

These motors, through their respective motor controllers, are controlled by scripts installed on the Robot (Huey) MUX board. The Robot MUX board receives instructions and sends data to and from the All-In-One PC via the Bender board.



Additionally, most motors also have an optical encoder attached that provides position and movement information.

Some also have limit sensors and/or home flags. These can be mechanical, optical, or magnetic in nature.

To troubleshoot motor issues, the **motor.script** is used from the Robot (Huey) MUX board through Script-O-Matic.

Refer to the following sections when troubleshooting motor issues:

"Motors and Commands Table" on page 397

"Essential Motor Script Commands Table" on page 398

"Motor Encoder Vault Table" on page 399

"Causes" on page 399.

6.2.7.1 Motors and Commands Table

Motor/Axis	Controller	Sensor
X Axis	X Controller	Neg Limit, Home, Pos Limit
Y Axis	Y Controller	Neg Limit, Home, Pos Limit
Z Axis	Z Controller	Home
Stripper	Z Controller	Home
Pump 1 – 4	Quad Pump Controller	Home
Left Pressure	Reader A Controller	Home
Right Pressure	Reader B Controller	Home
Left Tray	Reader A Controller	Neg Limit, Pos Limit

Document: BDDSSGFS7422 Doc Type: ZIP Status: Released EFFECTIVE
Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

Motor/Axis	Controller	Sensor
Right Tray	Reader B Controller	Neg Limit, Pos Limit
Left Magnet	Extractor Controller	Neg Limit, Pos Limit
Right Magnet	Extractor Controller	Neg Limit, Pos Limit

6.2.7.2 Essential Motor Script Commands Table

Command	Argument	Description
moveabs or ma	motor, value	Moves motor to an absolute position based on home position.
moverel or mr	motor, value	Moves motor a relative number of steps based on the current position.
getpos	motor	Returns the current position where the instrument thinks the motor is at.
getstatus, orgs	motor	Returns the axis limit and home flag status; neg limit, home, pos limit.
getstate	motor	Returns if the motor is on (1) or off (0).
setstate	motor, value	Turns a motor on or off (1 = on, 0 = off)
getencoder	motor	Returns current motor encoder value
setvalves	motor, value	Turn on/off tray sensors (0 = on, 255 = off)
home	motor	Moves motor to its home position
homeallaxes		Homes all motor axes.
initmotors		Turns on all motors
initmotor	motor	Turns on specified motor
loadcaltable		Loads calibration table for utilizing commands
editcaltable		Allows changes to x, y coordinates
movebank	bank number	Once calibration table is loaded, moves the X Gantry to set positions (banks 0 to 5)
moveto	strip location	Once calibration table is loaded, moves the Y Gantry to set position (see help for list of strip locations)
movez	z-axis location	Once calibration table is loaded, moves the pipette head

Command	Argument	Description
		to defined heights (see help for list of z-axis location)
ejecttray	ltray, rtray	Opens the left or right drawer.
closetray	ltray, rtray	Closes the left or right drawer.
help		Displays the list of commands for motor script

6.2.7.3 Motor Encoder Vault Table

Motor	Motor Command	#Steps (getpos)	Encoder Value (getencoder)
X axis	X	1000	4000(±2)
Y axis	Y	1000	4000(±2)
Z axis	Z	1000	8000(±4)
Stripper	STRIP	1000	N/A
Left Tray	LTRAY	500	N/A
Right Tray	RTRAY	500	N/A
Left Pressure	LPRES	1000	2000(±2)
Right Pressure	RPRES	1000	2000(±2)
Left Magnet	LMAG	1000	N/A
Right Magnet	RMAG	1000	N/A
Pump 1	PUMP1	-1000	-1000
Pump 2	PUMP2	-1000	-1000
Pump 3	PUMP3	-1000	-1000
Pump 4	PUMP4	-1000	-1000

6.2.7.4 Causes

Several failure modes and error codes are associated with motor movement.

Error Code	Description	Possible Cause(s)
0XB	Motor Failure	Robot motor communication failure. Failure to connect

Error Code	Description	Possible Cause(s)
		to the computer.
0X15	Motion Timeout	Timeout on motor movement Communication exists but motor did not reach assigned position within specified time.
0X16	Limit Hit	Robot reached limit switch on axis. Indicates home sensor failure since the instrument hit home sensor first before hitting limit switch.

6.2.7.5 Troubleshooting

1. Connect to the Robot MUX board through Script-O-Matic, and launch the **motor.script**.
2. Once the script starts, enter **loadcaltable** to load the robot calibration table stored on the Robot MUX board.

   There are two motor movement modes: **Absolute** and **Relative**.

   - **Absolute motion** moves a motor based on the home position for that axis. For example, if I moved X to an Absolute position of **500**, no matter where X was it would move to home **+500**.
   - **Relative motion** moves a motor based on its current location. For example if X was at **500**, then moving X to a relative position of **500** would place X at **1000**.
3. To troubleshoot an axis:
   a. Check that you are able to connect in Script-O-Matic.
   b. The MUX board lights.
   c. The Motor Controller lights are on.

   Any of these could indicate a possible power issue or a bad board.
4. Perform several basic movement and status checks (using X as an example, substitute the correct axis).

   Look for issues with home and limit sensors or errors in position. Failure to move, unusual noises, or odd smells could indicate a bad motor. Positional errors and jerky motion could indicate a bad controller or encoder.

   > **Note:** The encoder is part of the motor.

   a. Check the motor state and turn on if necessary:

   ```
   getstate x
   ```

`setstate x 1`

b. Home the motor and check if its status is home or neg limit:

`home x`

`gs x`

c. Move the axis both absolute and relative and check the position:

`getpos x`

`ma x 1000`

`mr x -500`

d. Turn on one motor versus all motors:

`initmotor x`

`initmotors broadcast`

e. Move the y-axis to a set position on the test strip:

`moveto wash`

`moveto waste`

5. If the axis has a positive limit, move the motor and test it. If there are issues with the home position or limits, the sensors could be bad.

Note: Reboot both the instrument and the All-In-One after exiting from Script-O-Matic.

6.2.8 Printer Issues

The HP Office Jet 6100 printer is replaced with the HP Office Jet Pro 6230. Printing with HP Office Jet Pro 6230, resulted in reports printed in ascending order, face up. When the reports were picked up, the pages were in reverse order (last page on top, first page on bottom). The printer's preference requires adjustment and the printer driver resolution needs to be lowered to avoid incomplete report printing.

6.2.8.1 Delete Old Printer / Install New Printer

Remove the old printer driver before installing the new printer.

1. Log in as **FSVC.**
2. Navigate to **Maintenance > Field Service**, and disable write filtering. The All-In-One should reboot.
3. Navigate to **Maintenance**, then **Field Service**, and click the **Explorer** button.

4. Navigate to Control Panel by clicking on the **Open Control Panel** button.
5. After Control Panel opens, go to **View by**: and select **Large** icons from the drop down menu, as shown in (see below):
6. Click on **Administrative Tools**, then double-click on **Print Management**.

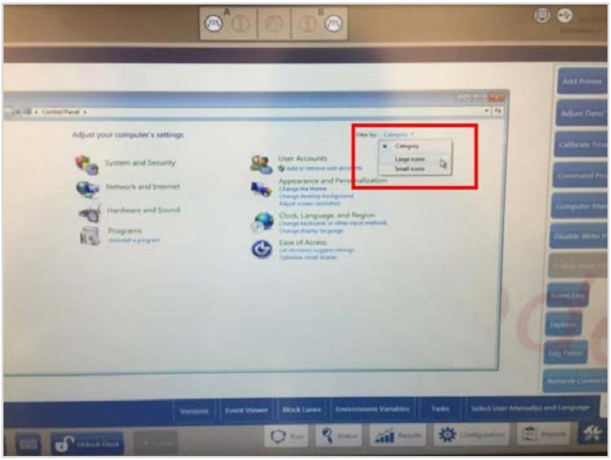


Fig: Control Panel

7. Navigate into **All Printers** and All **Drives**, and delete both the old printer and the old printer driver (see below).

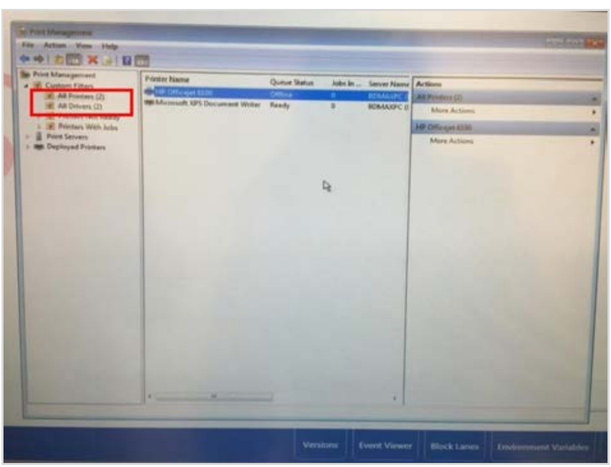


Fig: Print Management: All Printers and Drivers

8. After deleting both the printer and the driver, close the **Control Panel** and reboot the AIO.
9. Log in and navigate to **Field Service**. Add the new printer using the **Add Printer** button.
10. Select the **HP Officejet 6200 series** driver in the preinstalled driver list.

6.2.8.2 Set Printer Preference for Page Order

1. Ensure that **Write Filtering** is disabled.
2. Navigate to **Maintenance**, then **Field Service** and then **Explorer**.
3. Select **Open Control Panel** from the menu bar.
4. Select Administrative Tools, then double-click on **Print Management**.
5. Select **All Printers** from the left column.
6. Right-click on the newly installed printer (HP Office Jet 6200 series) and select **Properties**.
7. On the **General** tab, click the **Preferences** button.
8. On the **Advanced** tab, under **Layout Options**, change the **Page Order** to Back to Front.
9. Navigate back to **Maintenance**, then **Field Service**, enable write filtering and allow the AIO to reboot.

6.2.8.3 Set Printer Quality to Reduce Resolution

Modify the print quality to reduce resolution, queued print document size, and increase printing speed:

1. Disable **Write filtering**.
2. Access the printer properties through **Control Panel**, then **Administrative**, then **Tools**, then **Print management**, and then **All printers**.
3. Right-click on the printer to be modified (HP Office-jet 6200 series) and click on **Properties**.
4. On the **General** tab, click **Preferences**.
5. On the **Paper/Quality** tab, change Print Quality to **Fast Normal**. Verify that the resolution is at the lowest (preferably **300 dpi**). The exact location and options for this setting may differ based on the model of printer.
6. Apply the new setting and enable **Write Filtering**.

> **Note:** These settings reset to default if the printer is plugged into a different USB port, a new printer is installed or if the settings are applied with Write Filtering enabled. Ensure that printer is not plugged into a USB port on the instrument.

6.2.9 Troubleshoot a Run

The standard run consists of four major parts. Knowing the problem part can help narrow the number of suspect assemblies. The four major parts of the run are:

- Consumable Identification
- Sample Preparation (Extraction)
- Load the Cartridge
- PCR

6.2.9.1 Break Down the Run

The AIO computer contains the OS and the user software and does not actually perform sample preparation (Sample Prep).

Through the bender board, the AIO directs the Huey MUX board to run a series of scripts that perform all the sample preparation steps.

To troubleshoot:

1. An engineer can run these scripts individually (instead of a four hour qualification run).
2. Must know the association between a sample preparation part and a script.

6.2.9.2 Cataloging

- The actual run starts with the **CatalogWin.script** Looking in the log file, the entry for this appears as:**Running 'CatalogWin.script' built from 'Catalog.k'**
- The **CatalogWin.script** scans the 2D/1D barcodes on all the consumables and validates that they are correct for the run type and that they have not been used before.
- If the **CatalogWin.script** completes successfully, it writes the consumable information to the instrument database. The BD MAX™ then considers all the consumables as used. If a run is aborted after this happens, the consumables (used or not) generate a cataloging error if used again.
- The **CatalogWin.script** needs to be run from **Bank 3**, can be run at any time through Script-O-Matic, and its output appears in the Debug window. Bank 2 is used for seeing if the consumable catalogs. Bank 3 is used to capture the image to see if the barcode images are within the field of vision.
- The **CatalogWin.script** moves to each set of bar codes and attempts to read them in groups of three. The internal scanner beeps for each bar code read. At each position there should be three distinct beeps when checking the sample buffer tubes and the strips. For checking the Snap-ins, there should be six distinct beeps from each position. Each cartridge should generate one beep.
- When reading the cartridges, the command given to the scanner is **SCEMSK08**. The Gantry is moved to the correct positions, and the barcodes scanned.

This can be found in the log file:

```
SCEMSK08[ACK].
[. . .]
<C24227500120141001BA55>SCETRG[ACK].
[. . .] <C24227500120141001BA18>SCETRG[ACK].
```

Next the strips are read using the `SCEMSK01` command, which can be tracked in the log file as:

```
SCEMSK01[ACK].
[. . .] <S01227100120130517CA42,S01227100120130517CA41,S01227100120130
517CA40>SCETRG[ACK].
[. . .]
<S01227100120130517CA51,S01227100120130517CA50,S01227100120130
517CA43>SCETRG[ACK].
[. . .] Up to 24 strips in groups of three…
```

The command for Snap-ins is `SCEMSK02` and the command for Sample buffer tubes is `SCEMSK04`.

6.2.9.3 Sample Preparation

There are several different sample preparation scripts that take parameters input from the assay definition file. For Open Systems, input is taken from the test editor or UDP file.

These scripts control lysing and mixing of the sample, including everything up to the actually loading the cartridge. It is generally not run on its own unless under direction of R&D for specific objectives. Use the **motor.script**instead to verify motor movements, and **max_power_on_4SNAP.script** for verifying the pump head, both of which take much less time to perform.

Several different scripts can be used for sample prep. For example the **SP_MRSA_CDIFF.script** is for MRSA and CDIFF, while GBS uses the **SP_GBS.script**.

6.2.9.4 Break Down Load Cartridge and PCR

At this point the sample DNA has been extracted and is almost ready for PCR. During the Load Cartridge steps, the prepared DNA sample is combined with the various primers, probes, and DNA segments, and other chemicals and enzymes that are used during PCR. This is then transferred to the cartridge where thermal cycling and PCR are performed.

6.2.9.5 Refresh the AIO GUI if Frozen at the Run

If the AIO is frozen in the run, wait for the instrument to finish the run (the time will be displayed on the Run screen) and use the following exact combinations on the keyboard:

- Reboot the GUI on the H6, then press **Ctrl-Alt-F4**, not **Alt-F4**.
- Reboot the GUI on the S20-H6 with the new Keyboard, then press the following combination **Shift-Alt-F4**.

6.3 Software Troubleshooting

Software troubleshooting includes common errors as :

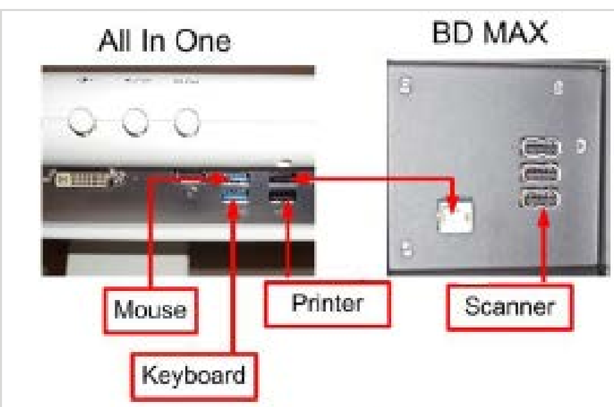
- Cannot connect to one or more internal MUX boards.
- Cannot find instrument.

In each instance, the AIO computer is unable to communicate with one or more parts of the BD MAX system.

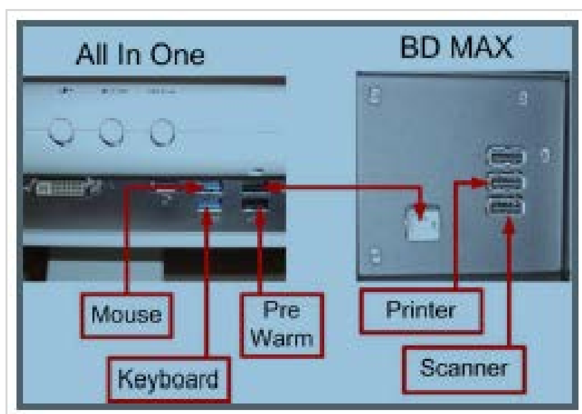
6.3.1 Causes

The AIO connects via USB to the instrument. The bender board in the instrument then bridges the USB to the Local Area Network (**LAN**).

A problem in the LAN results in only one MUX board failing. If all MUX boards **fail**, it may be a problem with the USB part of the system.



Without Pre-warm Heater



With Pre-warm Heater

6.3.2 Troubleshooting

1. Ensure the cables are plugged in completely and the pins are not bent.
2. Always power on the instrument before All-In-One.
3. Verify that the IP Addresses are correct when any of the MUX boards are changed.
4. Check if the firmware has been upgraded.
5. Ensure the software has been upgraded in a brand new instrument, if installed. If not, you may see a message **Unable to receive version/calibration**.
6. Check the A/B USB cable that connects the All-In-One to the instrument.
7. Ensure the internal scanner cable is firmly connected to the scanner and to the top of the Z-Gantry.
8. Try connecting though Script-O-Matic.
9. Try pinging the MUX boards from the command line.
10. If the problem is with all three MUX boards and the USB cable is good, check the AIO or bender board to determine if it is the source of the problem.
11. If the problem is only with one MUX board, then that MUX board may be the problem.

6.3.3 Software/Firmware Update

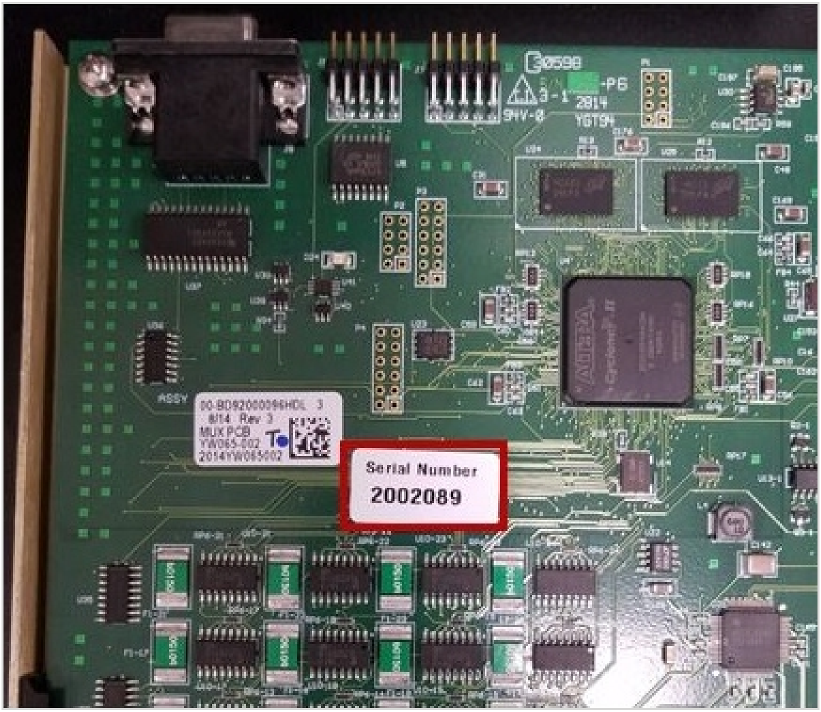
6.3.3.1 Reprogramming or Flashing the Huey MUX Board

Required materials:

- T10 Torx screwdriver
- 0.035 inch hex key
- USB to DB9 cable
- Gantry Alignment plates (435251 and 435256)
- Tray alignment tool (T92000287-100)
- 0.002 inch feeler gauge
- PUTTY software program loaded on BD laptop

Procedure

1. Power down and refer to "Upper Reader Cover Removal" on page 199 to access the DB9 connection on the top of the Huey PCB. Inspect the front of the Huey MUX board to locate and record the serial number.

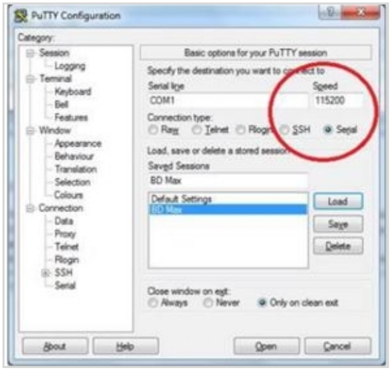


2. Remove the DB9 on top of the **Huey** MUX board and connect the laptop to the **Huey** MUX board with either a DB9 serial cable or a USB to serial cable.

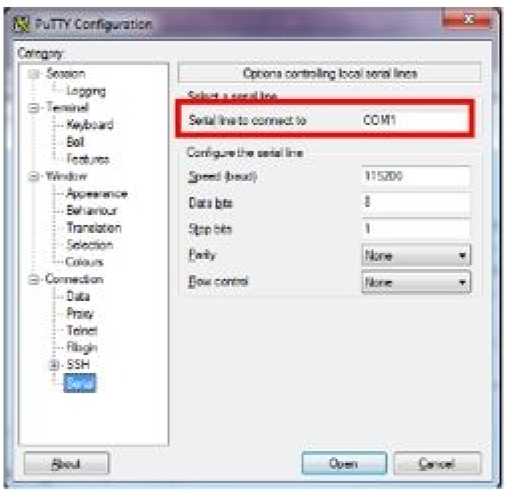
USB to serial cable

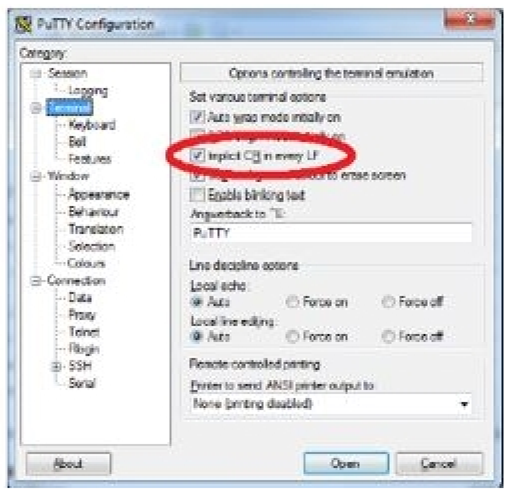
DB9 serial cable

3. Start **Putty.exe** and enter the settings as indicated in the images.
    a. Change the connection type from **SSH** to **Serial**, and set the speed to **115200**.



    b. Ensure that the communication port is set correctly on the laptop and **Putty.exe.**The communication port is in the **Device Manager** on the laptop.
    c. Ensure that the settings on **Putty.exe** are as indicated in the images.





    d. Click **Open** to activate **Putty.exe.**
    e. Turn on the BD MAX™ instrument.
    f. Within **3 seconds**, press any key on the laptop to start the program.

> **Note:** The commands entered will not be displayed.

4. Enter **19** for **Format file system**.
5. Enter **17** for **Initialize file system**.

    It is normal for the BD MAX instrument to be flashing red.

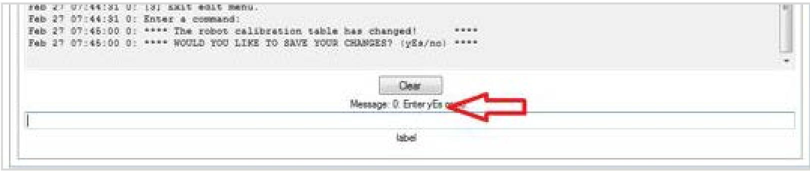
6. Enter **1** for **Set serial number**.

7. Enter the serial number captured in **Step 2** and press **Enter**.
8. Enter **21** for **Set MAX and IP address**.

SETTINGS	
MAC	20
MAC	48
MAC	4C
MAC	00
MAC	02
MAC	10
IP	169
IP	254
IP	1
IP	10

9. Enter **31** for **Exit and reboot.**
10. Disconnect cable and reconnect the instrument DB9 to the top of the **Huey** PCB.
11. Power cycle both the instrument and AIO.
12. Log in as **FSVC**.
13. Go to **Maintenance >Tasks** and if needed, update the IP address for **Reboot** to be **169.254.1.10.**.
14. Select the **Maintenance** tab then **Task** tab and select **Update Instrument Firmware**.
15. You will see **UPDATE COMPLETE** displayed on the screen when the process completes. Power cycle the instrument once prompted.
16. Launch **Script-O-Matic** and connect to the Huey board.
17. Perform **Gantry Alignment (Calrack.script)**.
18. Launch **motor.script**
19. Type `loadcaltable` in the command line and press **enter.**
20. Type `editcaltable` in the command line and press **enter.**
21. Enter **2** for Change cartridge pressure position.
22. Enter the value written in the instrument for each side and press enter.
23. Enter **3** for **Exit** edit menu.

24. The screen be prompted with **Would you like to save your changes?** (yEs/no)". Type `yEs`.



25. Perform **Reader Tray Position**. Refer to "Reader Tray Position " on page 469.
26. Re-install all skins reversing the steps taken to remove the skins.
27. Perform **Gantry Alignment (Calrack.script)**. Refer to "Gantry Alignment " on page 508
28. Perform and complete "Qualification Run" on page 322 & "Qualification Checklist" on page 597.

6.3.3.2 Flashing the GORT board (Lysis Heater)

A GORT PCB (lysis heater) needs to be flashed when:

1. There is a failure or error initializing the BD MAX™ instrument.
2. During new install the board did not get flashed in manufacturing.
3. Unable to reload firmware.

If the below error is displayed when running an **init.script** or during start-up, flash the GORT board following the procedure listed below. The Putty command can be run from either a USB drive or from the laptop.

Error message = ASSERTION RED ALERT: ./stackcontrol.c:332motorcommand: "errcode==BC_ERR_OK" failed!

Motorcommand: bank: 0, addr: 0, cmd: BD_SET_START_SPEED, arg: 55496, err: NOT INITIALIZED

> **Note:** Power off the instrument and remove the serial cable from the Huey MUX that is being used by the scanner. Remember to reconnect this cable when the procedure is completed.

Putty can be launched in different ways:

- From the USB drive
- From the laptop
- Unzipped to the D drive of the AIO.

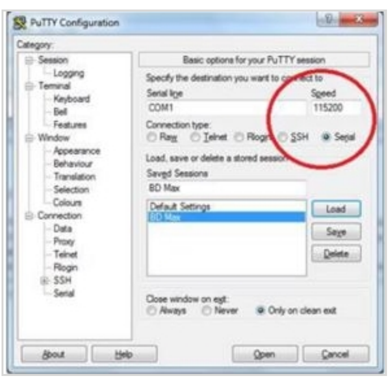
6.3.3.3 Troubleshooting

1. Shut down the power on the instrument.
2. Disconnect the USB cable from All-In-One to the instrument.
3. Remove the DB9 on top of the Huey MUX board and connect the laptop to the Huey MUX board with either a DB9 serial cable or a USB to serial cable.

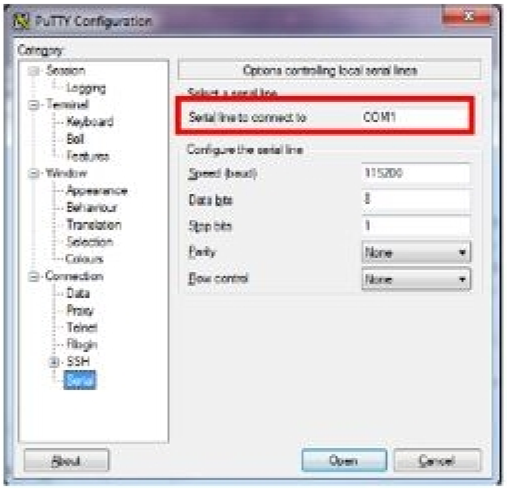
USB to serial cable

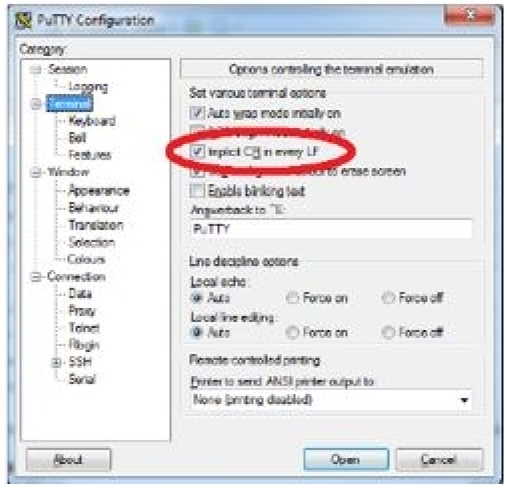
DB9 serial cable

4. Start **Putty.exe** and enter setting as shown.
   a. Change the connection type from **SSH** to **Serial**, and set the **speed 115200**.



b. Ensure that the communication port is set correctly on the laptop and **Putty.exe**.





5. Ensure that Putty is the active window, and turn on the BD MAX™ instrument.
6. Within **3 seconds**, press any key on your laptop to enter program.
7. Select **option [10]: Heater Calibration** by typing in **10** and press **Enter**
8. Answer **YES** by selecting **[1]**. Commands will not be displayed.
9. When complete, select **option [9]: Print Heater Calibration** to view calibration data.
10. Values for **0 – 23** should be displayed on the chart. This represents the 24 lanes on the GORT board.
11. Exit the software, turn the instrument off, and disconnect laptop to the Huey board.

Note: Reboot both the instrument and the All-In-One after exiting from Script-O-Matic.

6.3.3.4 Obtain MUX IP (WireShark)

When MUX boards are shipped with an IP address on the package, or if the IP addresses of the MUX boards get erased during re-imaging of the AIO, the IP addresses can be obtained and entered back into the AIO as mentioned below:

For BD MAX running the windows software, use WireShark to obtain the IP addresses of the MUX boards:

1. Log in as **FSVC** user.
2. Navigate to the Field Service screen under **Maintenance**.
3. Click the **WireShark** to launch it.

4. Double-click the **Local Area Connection** to search for the **IP address 169.254.0.1.**

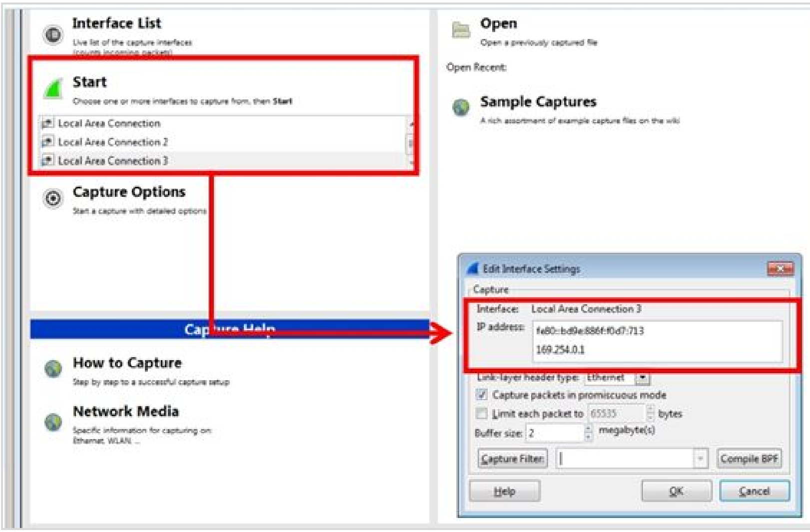
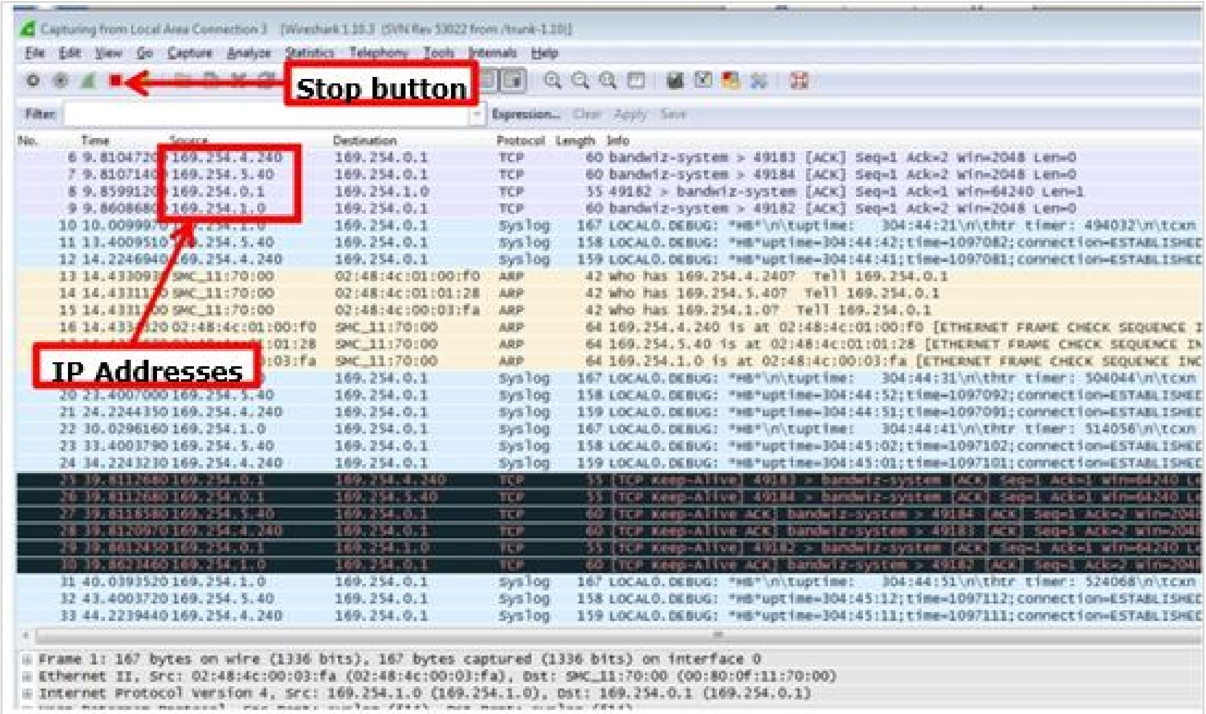


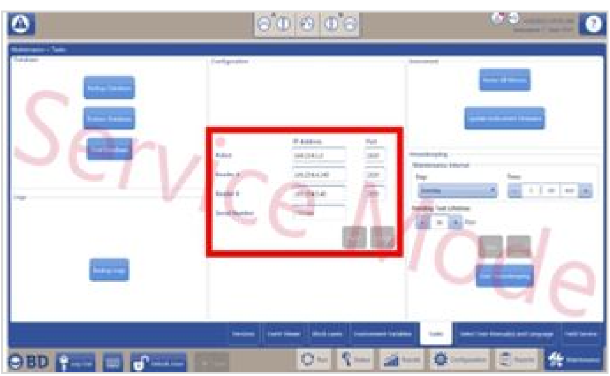
Fig: WireShark

5. Highlight the Local Area Connection and click **Start**. **WireShark** starts pulling IP addresses from all **3** MUX boards.
6. Let **WireShark** run for a while click **Stop** to stop it.At this point, 4 sets of IP address are now available.
   - One for the **AIO**, which should always be **169.254.0.1 or 169.254.xxx.1**
   - One for the **Huey/robot MUX board**, which should always be **169.254.1.10 or 169.254.1.xxx.**

- Two for the left and right heater MUX boards (Dewey and Louie).



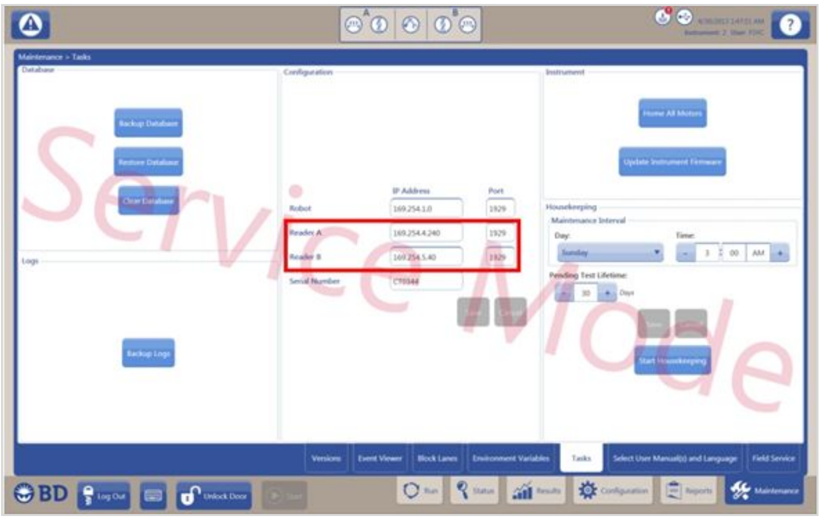
7. Write down the IP addresses and exit the window without saving.
8. To enter the IP addresses, navigate to the Task screen under Maintenance tab.
9. Enter the appropriate IP address and press **Save** to save the changes.



6.3.3.5 Verify MUX Board IP Addresses

Unlike the IP address of Huey MUX boards, there is no way for engineers to identify the IP addresses of the Dewey MUX from the Louie MUX board just by looking at the IP addresses. This is the same in both the Linux and Windows Operating Systems. Although there are various methods for verifying the MUX board IP addresses, the method proposed here allows engineers to identify the Dewey MUX IP from the Louie MUX IP without having to take the instrument apart.

1. If you have two sets of IP address and do not know which is for left reader (Dewey) and which is for the right reader (Louie), take a guess and enter them into the IP address box under the **Tasks** subtab.
2. Click **Save** to save the changes.



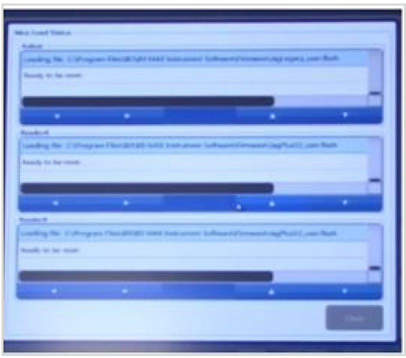
3. Navigate to the **Field Service** screen under **Maintenance** tab.
4. Click on the **Script-O-Matic** button to launch **Script-O-Matic** and select Dewey.
5. Click on the **Run Script** button and select the **fillcheck.script** from the **Drop Down** menu.
6. Select **OK** to execute the run without entering any parameters. This forces an empty fill check.
7. Look through the opening for the left (Dewey) drawer. There should be multicolor lights reflecting off the back of the drawer assembly.
8. If you do not see multicolor lights, look in the right drawer. If you see them then the IP address for Dewey and Louie are backwards. If you do not see lights at all, then the IP address for Dewey is wrong.
9. Run the same **fillcheck.script** on the right (Louie) reader to check the IP address for Louie.

6.3.3.6 Instrument Firmware Update

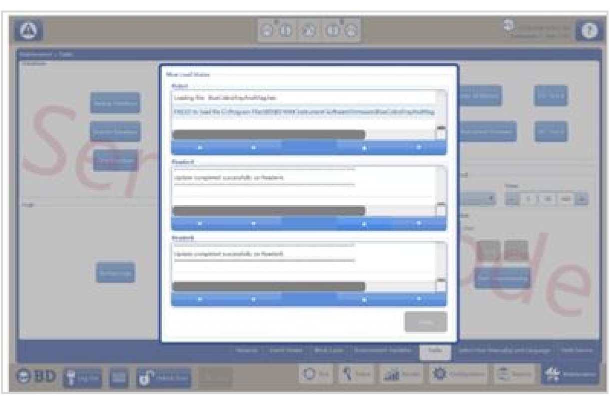
An instrument firmware update is needed after any motor controller replacement. It is important to perform the instrument firmware update steps correctly. Improper power cycling during the process can lead to corrupted firmware and motor failures.

Procedure

1. Log into the AIO as **FSVC** user and with the password **halley**.
2. Go to **Maintenance**, then **Tasks** and then click the **Update Instrument Firmware** button to push firmware to the MUX boards manually.
3. The BD MAX™ System software updates the MUX board firmware, which can take fifteen to twenty minutes. **Be patient and do nothing**. Do **NOT** power cycle or restart anything until this is complete. Wait for the **Update Complete Message** on all MUX boards. When the update is complete, the **Close** button becomes available. Click to **Close**.
4. Cycle power to the instrument and the AIO before proceeding. If you do not cycle power, you will receive an Optics Failure when doing a qualification run.



5. Log into the computer as the **FSVC** user with password **halley**. Test the instrument connection by running home all motors button on the **Maintenance** screen and then select the **Tasks** tab several times in a row. The MUX boards should stay connected and the instrument should perform the initialization process each time the button is pressed. If not, return to step 1.



> **Note:** The door must be closed to perform Home All Motors.

6. If the Instrument Firmware Update freezes or if one of the files failed to load:
   a. Enter **ALT+F4** to exit the program.
   b. Go to **Maintenance >Field Service >Script-O-Matic**. Launch Script-O- Matic and **close** it. By launching Script-O-Matic, the RunManagerService.exe (the program that pushes the firmware) closes. This is important. The **RunManagerService.exe** must be closed. If this program is not closed and you power cycle the instrument, you will get motor control failures.

   c. Power cycle the BD MAX™ instrument to verify all connections and PCBs are seated correctly. Reboot the AIO.
   d. Run **Update Instrument Firmware** again (Repeat steps 1-5).
   e. If the **Update Instrument Firmware** fails again, check the following:
      - Are the IP addresses correct?
      - Check all connections. Ensure there is no partial cable connection issues. Check if the cables are completely seated and there are no bent pins.
      - Go to **Script-O-Matic** and use the motor.script to check if each motor can be initialized.
      - Check the voltages on the Liberty board.
      - Escalate to Regional Expert or Global Service.

6.3.3.7 Connection Failure

Heater MUX (Dewey and Louie)

1. Verify correct IP addresses (using WireShark utility).
   a. Confirm IP addresses. (Refer Chapter 6 section titled Verify MUX board IP addresses in BD MAX Service Guide Rev05).
2. Confirm only BD supplied cables being used (ex. No daisy-chained cables).
3. Reseat Bender and Huey boards.

4. Confirm LAN connections for Liberty and bottom of MUX boards.
5. Refer to420
6. If error persists replace Heater MUX board, refer to "Huey MUX Board " on page 253 for module replacement instructions.

6.3.3.8 All-In-One Windows Image

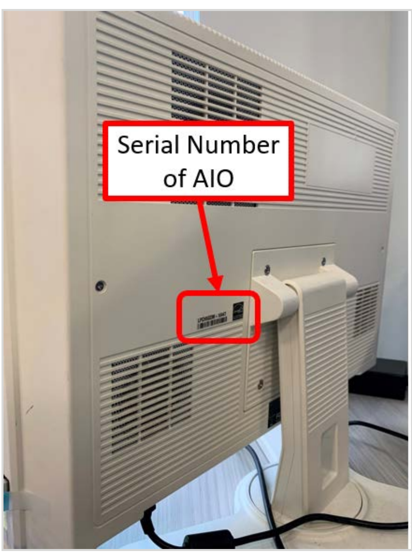
The AIO Windows image contains the following:

Video card on the AIO

- The new All-In-One Windows image key has been updated to include new driver for the new video card on the All-In-One computer. **The new image key is compatible with both the new and the old H6 video card.** The **H5** section of the image for the video card does not change.

Location of Putty

- On the new Windows image, the location of the program Putty has also been moved from C:/ drive to the D:/ drive for both H5 and H6 section of the image.
- Different versions of H6 can be identified by the serial number located at the back of the All-In-One computer (see below).



- Serial number of **old H6** starts with **LPCH6XXX-XXXXX**. For these, use the Windows image key with **Date/Version: 2014-04-08 or 2015-07-08.**

- Serial number of **new H6** starts with **MEDH6XXX-XXXXX**. For new H6, use the Windows image key with **Date/Version: 2015-07-08 only**.

> **Warning:** If an old Windows image key is loaded onto a new H6, the GUI appears enlarged (i.e. too big to fit on the screen) and does not enable log-in.

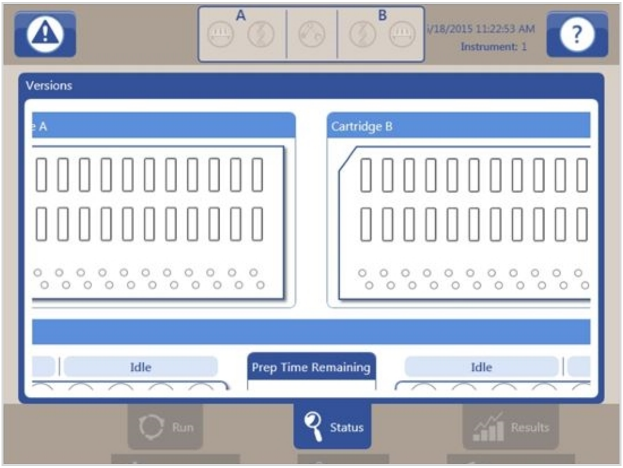


Fig: Enlarge GUI indicating Wrong Image Key was loaded

Required Materials

8 GB or greater USB drive

- Copy the MAX Wanna Cry patch folder available onto a USB drive. The patch can be found on the SharePoint 365 site.

6.3.4 Troubleshoot Optics Error

Re-upload Optics_Server2.ihex

1. Check all cables and connections on both the reader and the MUX. Optics error could be caused by a single intermittent connection in any of the high density reader connections.
2. Re-upload **Optics_Server2.ihex** to the reader (see instructions following step 3 for details).
3. Replace the reader if the above operation is not successful.

Optics error observed on the BD MAX

1. Log in as **FSVC**.
2. Start Script-O-Matic.

3. Connect to either Dewey or Louie depending on the reader that requires reprogramming.
4. Click on the **File Manager** button at the top.
5. Review the list of scripts.
6. If the **Optics_Server2.ihex** is in the list of files, select the file by clicking on the file name and then delete it by pressing the **Delete** button.

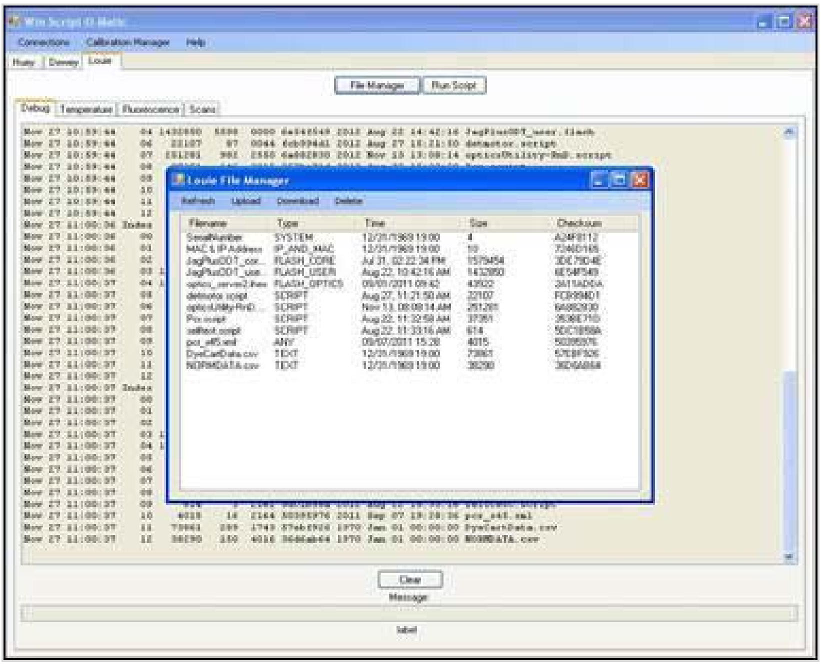


Fig: File Manager Screen with Optics_Server2.ihex

7. Press the **Upload** button and navigate to the following directory:C:\Program Files\BD\BD MAX Instrument Software\Firmware
8. In the **File of Type** drop down, choose **Flash Optics** and the file **Optics_Server2.ihex** displays. Select **Optics_Server2.ihex** and upload it to the MUX.

> **Note:** The upload operation may take up to one minute to complete and for theselected file to appear in the file manager.

9. After the file has appeared in the file listing window, close the file listing dialog window and cycle power to the instrument.

6.3.5 Screen Capture

Specific screen images from the BD MAX can be captured for use in troubleshooting, training and educational materials.

Refer to **Technical Service & Support Data Download Procedure** for instructions on handling patient data.

Required materials

USB Flash Drive

Procedure

1. Set up the screen shot to be captured.
2. Insert the USB device into the AIO.
3. Press **F10** and wait for 10 seconds. The image is saved to the USB device as a**.png** file.

Verification:

1. Confirm in the external PC/Laptop the file is stored in a folder at the top level of the USB drive.
2. Confirm file names include the instrument serial number as well as the date (yyyy-mmdd) and time (hhmmss), seconds are included in the name to minimize the chance of overwriting an image.

> **Verification:** After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

6.4 System Troubleshooting

This section describes system troubleshooting for the BD MAX.

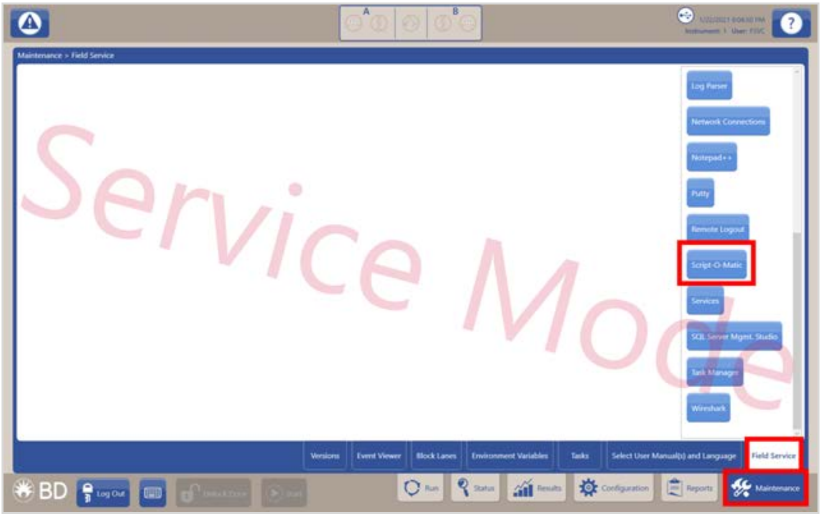
6.4.1 Script-O-Matic

Script-O-Matic is one of the main diagnostic tools available on the BD MAX platform. It is stored on the BD MAX system drive and is run without any external systems or components. The Script-O-Matic interface allows the engineer to access low level programs (referred to as scripts) that reside on the MUX boards and that allow the engineer to exercise and align different instrument sub systems independently. All operations that occur during a normal run can be simulated and performed to aid in troubleshooting.

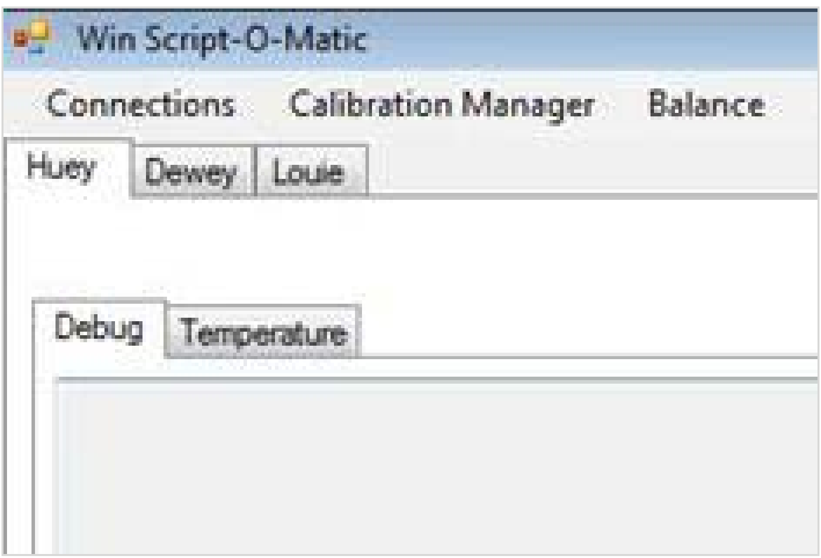
6.4.1.1 Start Script-O-Matic and View Connections

Script-O-Matic is only available when logged in as **FSVC**.

1. To access it, go to **Maintenance > Field Service**.



2. Select **Connections** in the upper left to view the Connect window.

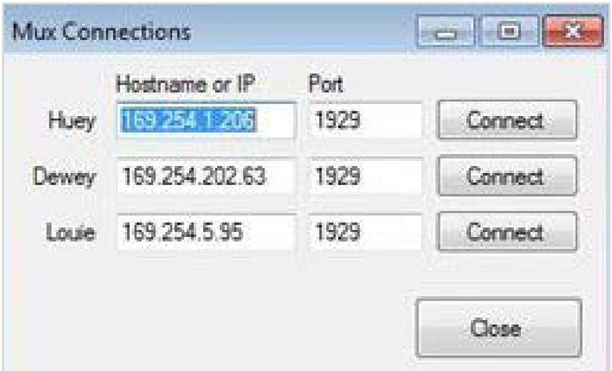


   IP addresses and Port numbers are already entered. Port numbers should always be set to **1929**.

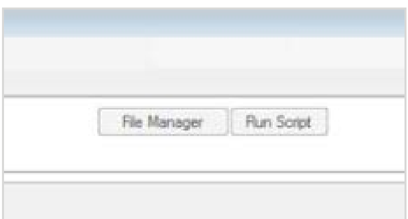
3. Click on each **Connect** button located to the right side of the window.

   After a successful connection, the button name changes to **Disconnect**.

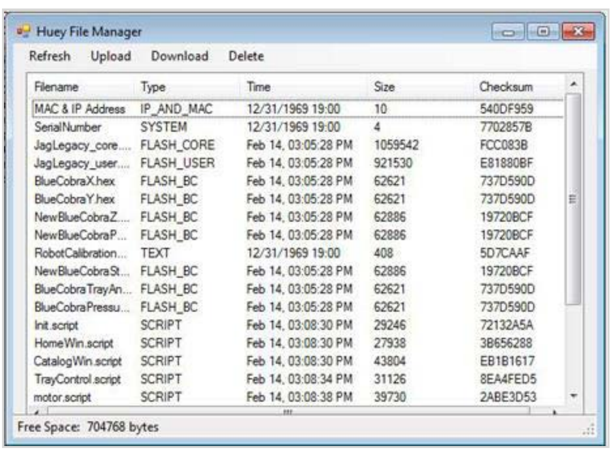
4. After connecting to all three MUX boards, select **Close**.



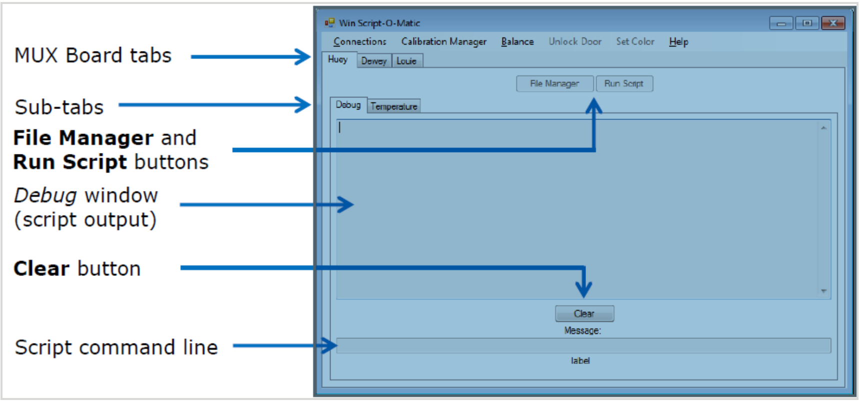
5. From the main Script-O-Matic window, select the **File Manager** button. A new file manager window opens.



6. A new File Manager window opens. View the uploaded, download scripts and files of the specified MUX board and delete the files on the specified MUX board.



6.4.1.2 The Script-O-Matic Interface

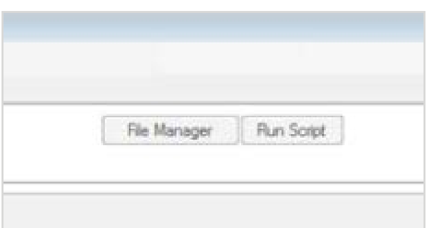


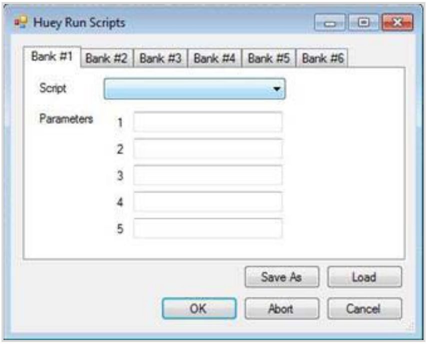
The tabs below the menu bar correspond to the MUX boards.

- Always ensure that the correct MUX board tab is selected.
- A second row of sub-tabs changes based on the MUX board selected, but generally defaults to the Debug tab (unless a different tab is called out in specific processes and procedures).
- Debug window (script output) appears as the large text block in the center.
- A **Message** field at the bottom accepts script commands.
- The **Clear** button clears the Command Line.

6.4.1.3 Run a Script

To run a script, select the correct MUX board tab and click **Run Script**. The [MUX Board] run scripts window appears.





1. Robot and Reader script windows are slightly different, but each uses the same process to launch a script.
2. Select the **bank** or **lane** to run the script, and then select an option from the **Script** drop - down. Enter any required parameters in the spaces provided, and then click **OK** to launch the script.
3. Once the configuration is set up, use **Save As** to save and **Load** to load a saved script startup configuration.
4. If a particular script cannot be found on the MUX board, manually upload it using the **Script-O-Matic File Manager.**

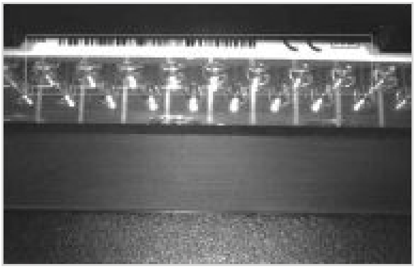
   Scripts on the AIO: **C:\Program Files\BD\BD MAX Instrument Software\Scripts**

6.4.1.4 Catalog Failure Potential Root Causes

There are currently two issues that could potentially cause PCR cartridge cataloging errors:

- Drawer on one side is coming out further than the drawer on the other side.
- Some of the PCR Cartridges leave a barcode label printed in a **higher position.**

These issues cause the barcode to fall outside of the field of view. The steps in the following section provide instructions on how to adjust the drawer sensor flag to the tray out position.



6.4.1.5 Corrective Action

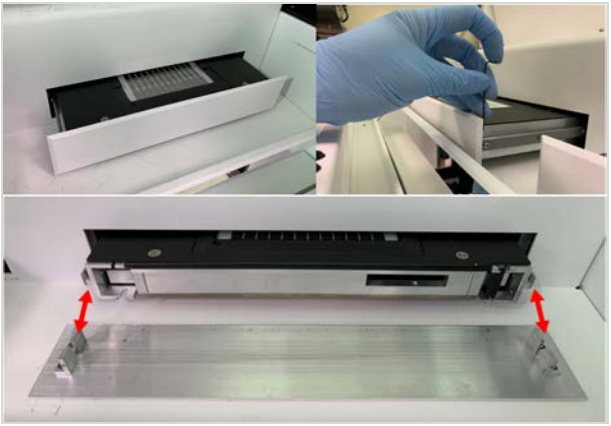
Instructions to correct the drawer sensor flag to the tray out position:

Note: The Instruments with the CT3050 and above will have the new tray Mechanism. Refer to "PCR Tray Design Update" on page 355.

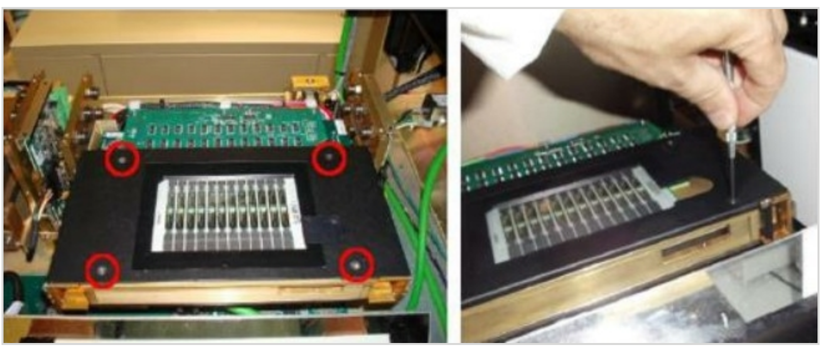
Upper Reader Cover Removal

1. Power off the instrument, then remove the two nylon screws that connect the lower and upper covers. Remove the upper reader cover.

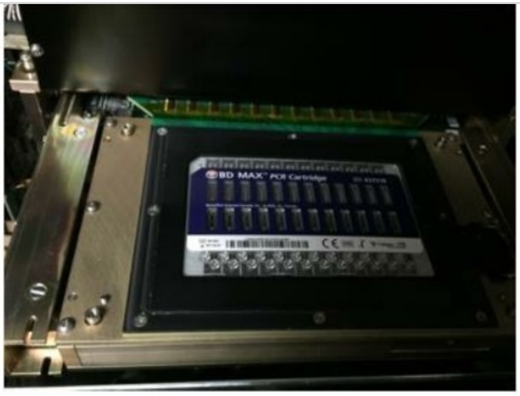
2. Remove the five **#10 Torx** screws from the rear portion of the upper reader cover.
3. Remove the outer drawer facade from both drawers with a **0.035 inch** hex key. Once the drawer facades are removed, push the drawers all the way in.



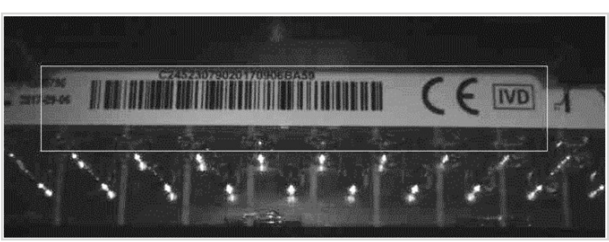
4. Move the robot gantry to the front of the instrument.
5. Lift the rear section of the upper reader cover and rotate it over the robot gantry. Push the robot gantry towards the back of the instrument while rotating the cover over the top. Remove the cover from the instrument.
6. Disconnect and remove the reader from the instrument.
7. Remove the black cover on the Heater MUX board by loosening the four captive slot screws.



8. Carefully pull the tray forward to access the rear tray sensor flag. Verify that the rear tray sensor flag (open-tray position flag on the rear left of the tray) is at the rearmost position in its adjustment slot.
   a. If the flag is already at the rearmost position, go directly to step 5.
   b. If the flag is not at the rearmost position, proceed to step 4 to adjust the flag sensor.



9. Adjust the rear tray flag to the rearmost position in the slot.
   a. Rear tray flag is located at the left rear corner of the Heater MUX board in front of two capacitors. Loosen the screw shown in the image above.
   b. Slide the flag to the rear most position without rotating the flag. Do not leave the flag post overhanging beyond the adjustment slot. The entire square top surface of the post must sit completely under the adjustment slot and must not stick out.
   c. Use a **0.004 inch** feeler gauge to prevent interference between the flag post and the lower board of the MUX board assembly. Hold the gauge between the flag post and the lower board of the MUX board assembly while tightening the adjustment screw. This prevents the flag post from touching the board’s rear edge and prevents from turning a corner of the rear flag post tight against the MUX board. **Ensure that the flag is not hitting the PCB.**
   d. Use a feeler gauge, to leave a gap between the flag post and the MUX board.
10. In Script-O-Matic, reteach the instrument using **Calrack.script** first.
11. Verify any adjustments resulted in an aligned image using **Catalogwin.script** from bank 3.



12. If successful alignment is achieved at this point, jump to step 14. If adjusting the tray sensor flag to the rear most position did not resolve the issue, continue with the next step.
13. If the instrument is still failing cataloging and the flag is already moved to the rearmost position, turn the flag **180°** and put it back to the position it was found at.
14. Check to ensure that there is no interference between the flag post and the lower board of the MUX board assembly.
15. Check the alignment by running **CatalogWin.script** prior to installing the cover(s) and skin (s) back.

    Note: The upload operation may take up to one minute to complete and for the selected file to appear in the file manager.

16. Reinstall the drawer facades.
17. Open and close the tray 10 times to verify that the drawer does not collide with the mirror when the drawer is in the open position. Verify that there is a gap between the drawer façade and the mirror.
18. Once the cartridge tray position is adjusted, reinstall the covers and perform **calrack.script**.
19. Capture image of the adjusted alignment and attach image to service report.
20. Perform qualification run for both the top and bottom rows on the side that was adjusted.

6.4.1.6 Tray Control

1. Run TrayControl script. For side A, enter **LEFT** field 1.
    a. For side B, enter **RIGHT** in field 1. Enter **IN** in field.

    Note: These words are case-sensitive.

2. Click **OK**. This will close the chosen tray and engage the pressure plate.
    a. Confirm that the pressure plate moves up, and that the tray cannot be moved when the pressure plate is engaged.
    b. If the tray is loose when the pressure plate is engaged, then ensure that the drive train screws are tight. If the tray continues to be loose, then either the pressure motor or motor controller needs replacement.

6.4.1.7 Fill Check

The first time the **FillCheck.script** is run it is referred to as the Empty Fill Check. It scans the cartridges for fluorescence and, if high levels of fluorescence are detected, it assumes that the cartridge has been used. In the log file the start of the script is recorded as: **Running 'FillCheck.script' built from 'FillCheck.k'**

> **Note:** After empty fill check, the tray control script is run again to lower the pressure heads.

6.4.1.8 Test for Periodicity

6.4.1.8.1 Material

1. Obtain test strips from 2 different assay kits to perform a mixed run on the reader or side in question. Ensure that the assays come from different groups (see Assay Groups table below). If possible, use the assays that were present in the run that the false positive result occurred due to saw-tooth wave in raw signal.

Group	IVD Assays
I	Cdiff
II	MRSA, StaphSR, MRSA XT, CT/GC/TV
III	III Enteric Bacterial Panel, Enteric Parasite Panel

6.4.1.8.2 Setup a Full Run on the Side Where the False Positive was Observed

1. Perform two full runs (2 full racks each containing 12 strips) of the MAX Vaginal Panel Assay per the instructions.

Setup the Run

Run 1		
Strip	**Cartridge Lane**	**Assay**
1	1	EVP
2	4	xEBP
3	7	EVP

Run 1		
Strip	**Cartridge Lane**	**Assay**
4	10	xEBP
5	2	xEBP
6	5	EVP
7	8	xEBP
8	11	EVP
9	3	EVP
10	6	xEBP
11	9	EVP
12	12	xEBP

Run 2		
Strip	Cartridge Lane	Assay
1	1	Cdiff
2	4	EVP
3	7	Cdiff
4	10	EVP
5	2	EVP
6	5	Cdiff
7	8	EVP
8	11	Cdiff
9	3	Cdiff
10	6	EVP
11	9	Cdiff
12	12	EVP

2. All samples should be blank.Record bubbles and partial fills for each run in the diagram(s) below.

   Fig: MVP Run 1 (Side A/B):

   Fig: MVP Run 2 (Side A/B):

6.4.1.8.3 BD MAX MVP Data Review

1. Export the BD MAX database(s) for the BD MAX MVP runs to a USB drive.
2. Using the validated Results Reprocessor tool, extract the results metrics for the BD MAX MVP runs to a CSV file.
3. Open the CSV file generated in the last step.
4. Open the CSV file generated in the last step.
5. Enable filtering of the table by using the Data -> Filter option on the Excel ribbon.

Document: BDDSSGFS7422 Doc Type: ZIP Status: Released EFFECTIVE
Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

6. Using the filter drop-down option, select only Cartridge Positions listing BOT (bottom) locations AND excluding the samples in positions A1, A2, B1 and B2 (spiked with ZeptoMetrix controls).

> **Note:** This requires the use of two filter options.

7. Copy the ROX EP results into an individual column per reader on a new sheet in the Excel spreadsheet, assuring that only the filtered values are copied and not any of the hidden rows.

8. Use the following formula on the entire range of copied / pasted data, making sure to replace "SELECT RANGE OF DATA HERE" with the range of the copied / pasted data set (e.g. - "A2:A49"). This calculation determines the expected percentage of EP metrics to exceed the threshold of "100"=(1-NORMDIST(100,AVERAGE(SELECT RANGE OF DATA HERE),STDEV.P (SELECT RANGE OF DATA HERE),TRUE))

Result	Action
Less than or equal to 5.6%(x <= 0.056 as displayed in Excel)	Instrument is passing with no additional review required
Greater than 5.6% but less than 8.6% (0.056 < x < 0.086 as displayed in Excel)	Management review to be performed prior to release of instrument
Equal to or greater than 8.6% (x > 0.086 as displayed in Excel)	Instrument is considered higher risk of producing nuisance result metric errors

> **Note:** Certain INDs may be caused by consumable-related issues. For example, a torn blue silicone septum cap may cause a Liquid Level Sense (LLS) indeterminate (IND) result. These non-instrument issues may be dispositioned and the associated data excluded, provided these non-instrument-related failures are documented in this Deviation Waiver.

Cgla False Positive Screen:

- ZERO Cgla False Positive Results (PASS)
- Acceptance Criteria NOT Met (FAIL)

Document in "Periodicity Test " on page 600.

6.4.1.8.4 BD MAX MVP C. Group EP Metrics Screen

- Result Metric Z-Score <= 5.6% (PASS)
- Result Metric Z-Score > 5.6% AND <= 8.6% (REVIEW)
- Result Metric Z-Score > 8.6% (FAIL)

6.4.1.9 No Fills

The occurrence of a no fill has typically been associated with pump/airline issue, alignment issues, or Z-Gantry binding issues, or defective tips.

No Fill Checks typically appear to be close to zero on the fluorescence graphs.

- Check the database for instances where the Full Fill Check fluorescence is equivalent to the Empty Fill Check fluorescence. (See the example of a no fill fluorescence curve below.)

To troubleshoot **No Fill Checks**, it is necessary to review past runs and look for a pattern of no fills. Next the fluid handling during a run must be observed carefully to identify where fluids is not being properly transferred.

If a customer is experiencing Full Fill Checks when running one sample, run the Z-Gantry stall script.

> **Note:** Refer to "Z-Gantry Stall Script" on page 450.

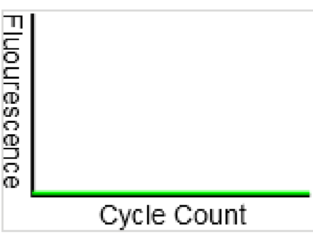
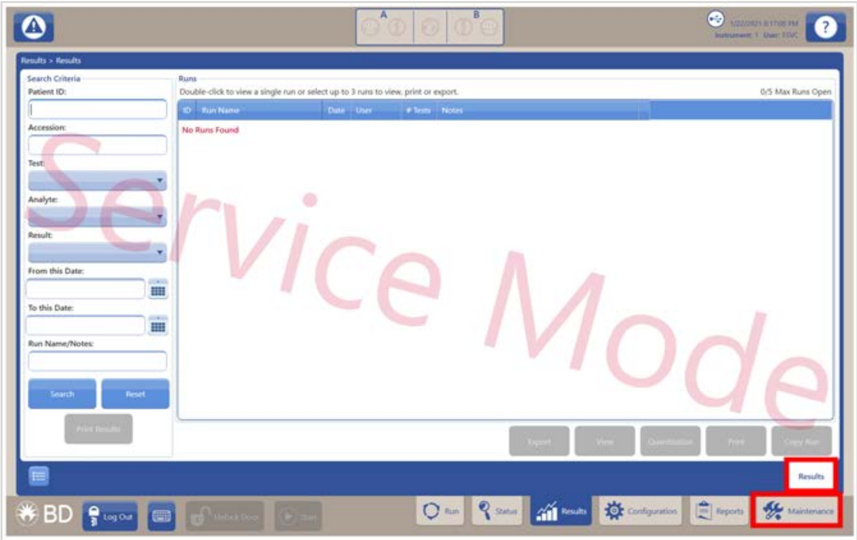


Fig: No Fills

6.4.1.10 Find Run Data

Run data can be pulled from the **Results** tab.



The left hand side of the **Results** tab screen contains a search box.

The right hand side of the screen contains a box that displays completed runs that meet the criteria set in the search box.

With no criteria selected in the search box, all runs are displayed.

6.4.1.11 Search Criteria

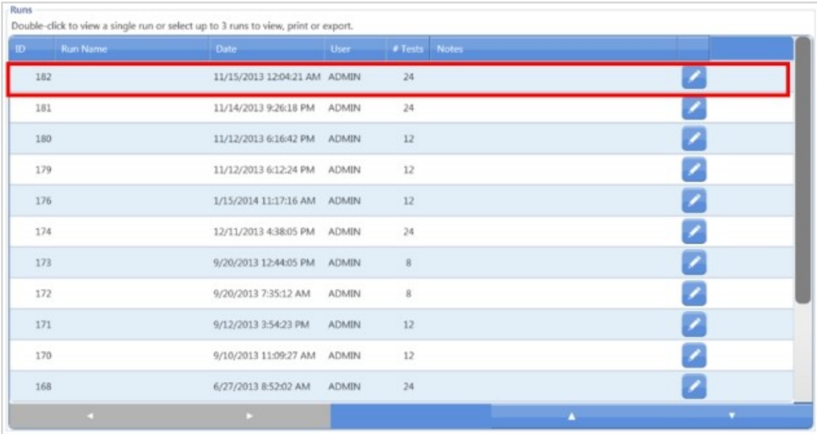
The **Search Criteria** box can filter displayed runs using several parameters like **Patient ID** and **Accession**.

- Useful parameters for servicing the instrument include **Date,** Range, **Test** and **Result**.
- **From this Date** and **To this Date** limit the runs displayed to the dates supplied. For example, when a customer complains about issues from the April 16th to the present.
- The **Test** refers to the Assays loaded on the instrument for example, the customer is having issues with just the MRSA test.
- The **Result** filter allows sorting by, POS, NEG,INC, UNR, IND.
- After setting filter criteria, click **Search** to display results in the **Run** window.

6.4.1.12 Select a Run

The example below is on search for all BD MAX Qualification (Qual) Tests.

1. Select a run to activate buttons under the **Run** window, then click **View**.

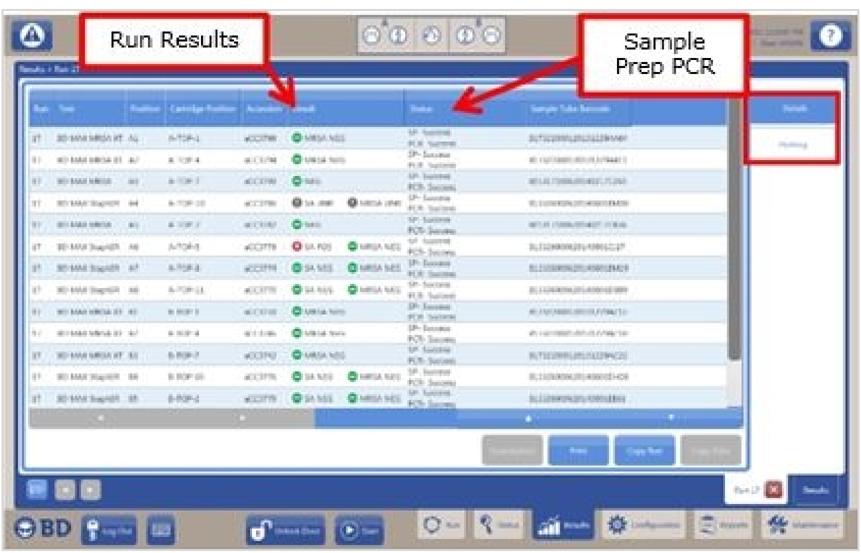


Note: Double-clicking on the run also activates the **View** mode.

6.4.1.13 Run Results Screen

When a run opens, a new sub-tab displays with the run number in the **Details** view. Use the side tabs to switch between **Details** and **Plotting**.

The **Details** view shows each sample's rack and cartridge position, Sample Prep (SP) PCR status, and results.



The **Plotting** view shows plots for each sample by rack lane.

Results can be filtered by:

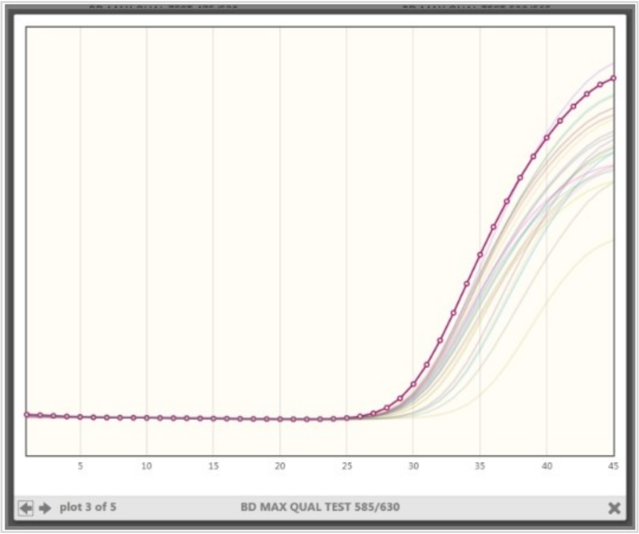
- Reader
- Color
- Individual lane

> **Note:** Each parameter can be turned off and on.

Grouping options that can be selected for reviewing run curves:

- Test
- Channel
- Position
- Positives

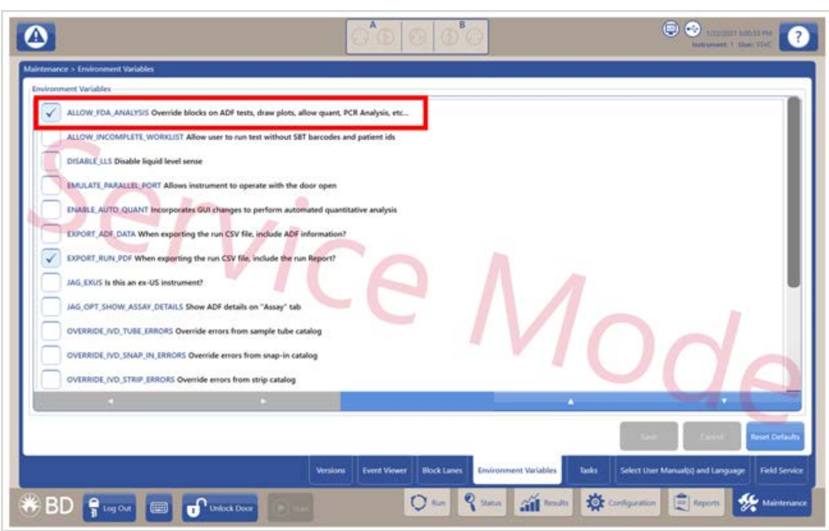
Selecting an individual graph opens a larger version of that graph. When the larger graph is displayed, individual lanes can be selected and highlighted.



There are several different types of curves:

- **Backgrounded PCR** – This is the default setting. This setting shows background corrected readings adjusted to have the same starting point.
- **Raw PCR** – This setting shows normalized raw readings.
- **Color Compensated PCR** – This setting shows curves with spectral crosstalk compensation applied.
- **ADC PCR** – This setting shows the un-normalized raw counts from the reader and is only available when the ALLOW_FDA_ANALYSIS environmental variable is checked.

In **Service Mode**, go to **Maintenance >Environmental Variables**.



Check **ALLOW_FDA_ANALYSIS** and click the **Save** button.

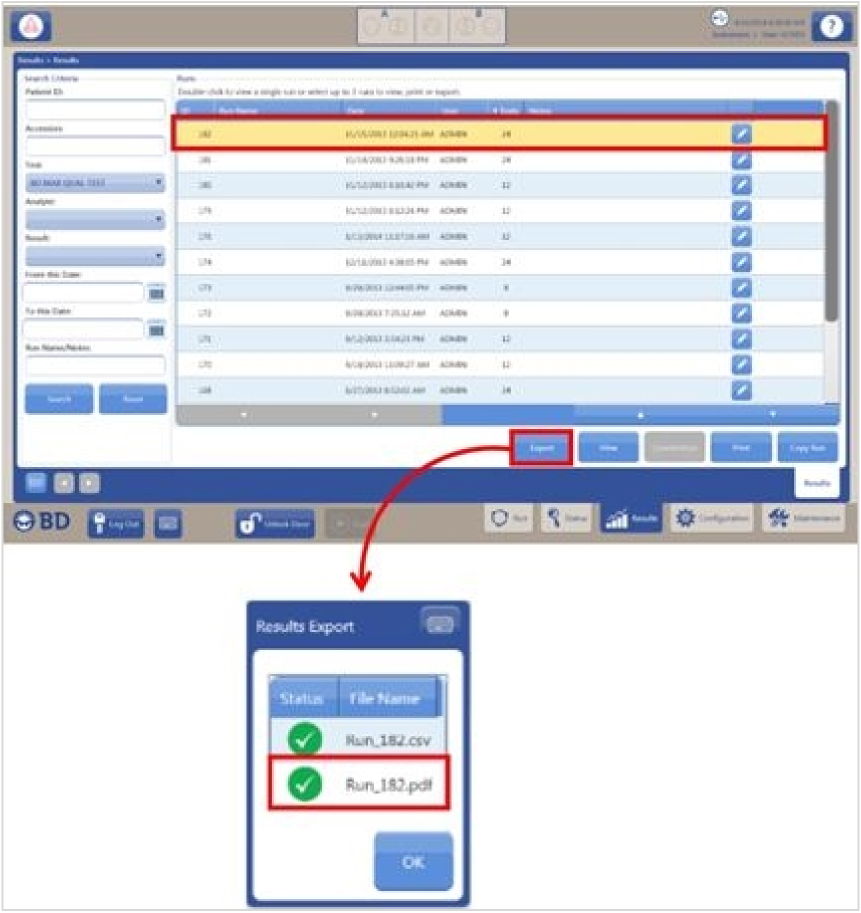
6.4.1.14 PDF File

PDF files are electronic versions of the run information that can be sent to the printer or downloaded to a thumb drive.

6.4.1.15 Acquire PDF Files

PDF files are acquired from the **Results** screen. Select a run and press **Export**. The BD MAX™ automatically detects a USB thumb drive and exports the PDF file there.

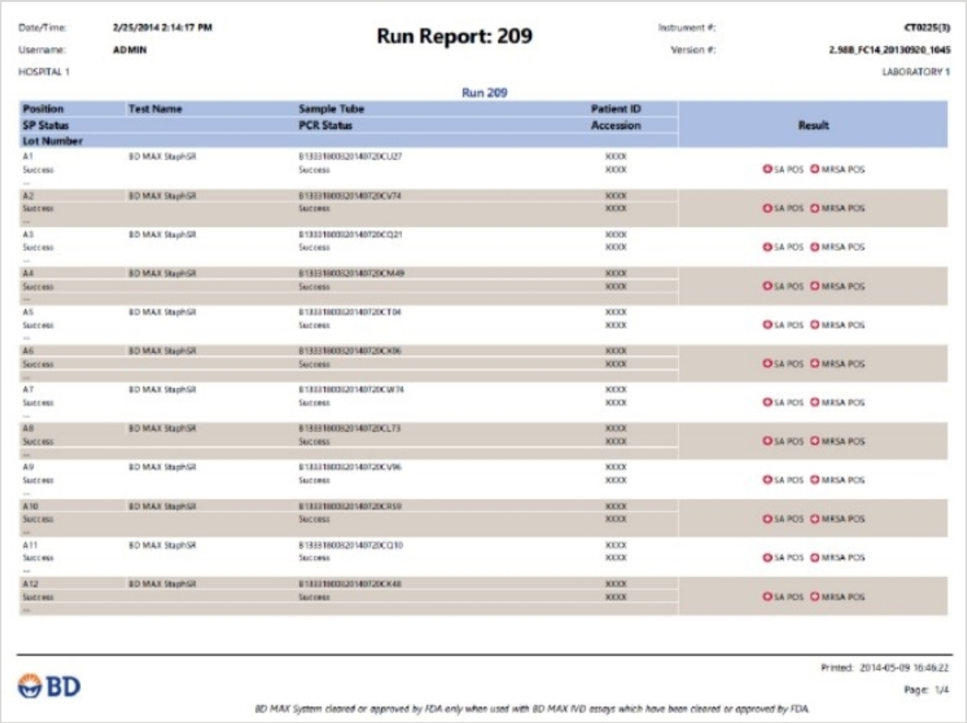
The file size is approximately between**200KB and 250 KB**.



6.4.1.16 Read the Run Report

The **Run Report** PDF shows the sample that were run and their results.

- The header includes **Date /Time, User name, Instrument** serial number, and software version.
- The report body lists test type and results for each lane.
- Review multiple **Run Reports** for patterns, noting how nozzles and cartridge lanes correspond with their rack lanes.



Date/Time: 2/25/2014 2:14:17 PM
Username: ADMIN
HOSPITAL 1

Run Report: 209

Instrument #: CT0225(3)
Version #: 2.98B_FC14_20130920_1045
LABORATORY 1

Run 209

Position SP Status Lot Number	Test Name	Sample Tube PCR Status	Patient ID Accession	Result
A1 Success ---	BD MAX StaphSR	B13331800320140720CU27 Success	XXXX XXXX	SA POS MRSA POS
A2 Success ---	BD MAX StaphSR	B13331800320140720CV74 Success	XXXX XXXX	SA POS MRSA POS
A3 Success ---	BD MAX StaphSR	B13331800320140720CQ21 Success	XXXX XXXX	SA POS MRSA POS
A4 Success ---	BD MAX StaphSR	B13331800320140720CM49 Success	XXXX XXXX	SA POS MRSA POS
A5 Success ---	BD MAX StaphSR	B13331800320140720CT04 Success	XXXX XXXX	SA POS MRSA POS
A6 Success ---	BD MAX StaphSR	B13331800320140720CX06 Success	XXXX XXXX	SA POS MRSA POS
A7 Success ---	BD MAX StaphSR	B13331800320140720CW74 Success	XXXX XXXX	SA POS MRSA POS
A8 Success ---	BD MAX StaphSR	B13331800320140720CL73 Success	XXXX XXXX	SA POS MRSA POS
A9 Success ---	BD MAX StaphSR	B13331800320140720CV96 Success	XXXX XXXX	SA POS MRSA POS
A10 Success ---	BD MAX StaphSR	B13331800320140720CR59 Success	XXXX XXXX	SA POS MRSA POS
A11 Success ---	BD MAX StaphSR	B13331800320140720CQ10 Success	XXXX XXXX	SA POS MRSA POS
A12 Success ---	BD MAX StaphSR	B13331800320140720CK48 Success	XXXX XXXX	SA POS MRSA POS

BD

Printed: 2014-05-09 16:46:22
Page: 1/4

BD MAX System cleared or approved by FDA only when used with BD MAX IVD assays which have been cleared or approved by FDA.

6.4.1.17 CSV Files

A Comma Separated Values (**CSV**) file contains both high level run results and the more detailed data points generated by the run. It can be opened in most spreadsheet programs.

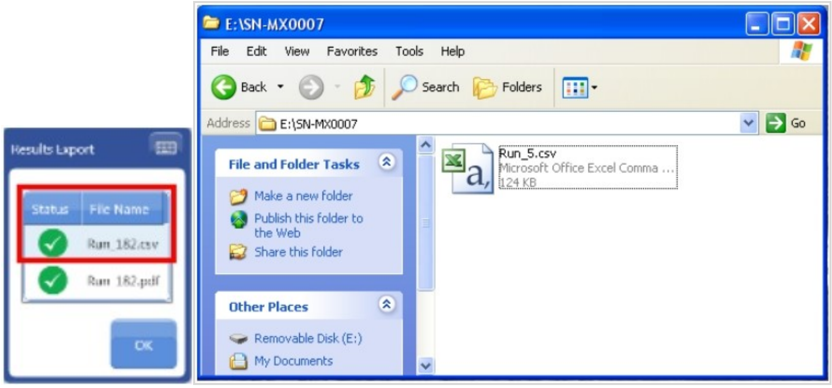
CSV files are small and easy to email, and so are often the initial data retrieved from a customer site.

Acquire CSV Files

Like PDFs, CSV files are acquired via the **export** option on the **Results** screen.

The **CSV** file and **PDF of the run** are exported at the same time.

1. Insert a USB drive into the All-In-One to collect the CSV file.
2. A folder is automatically created on the USB drive named with the instrument serial number.
3. The CSV and PDF files are saved inside the folder and named by run number.

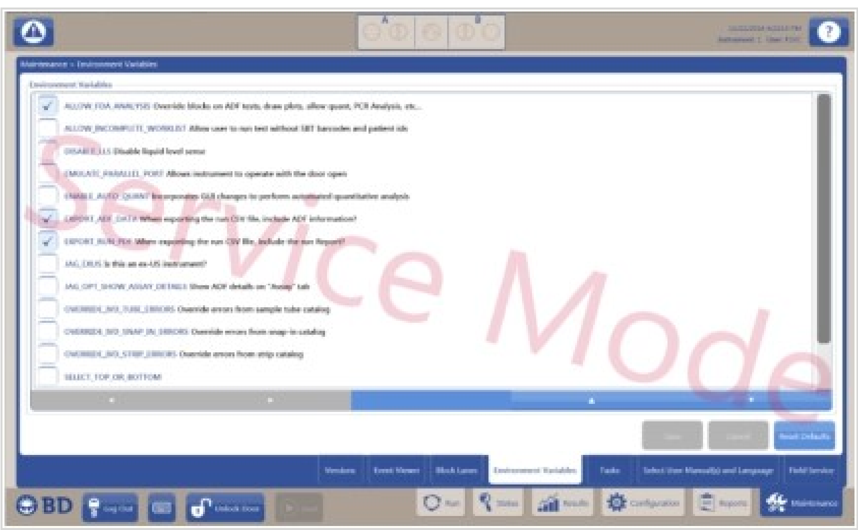


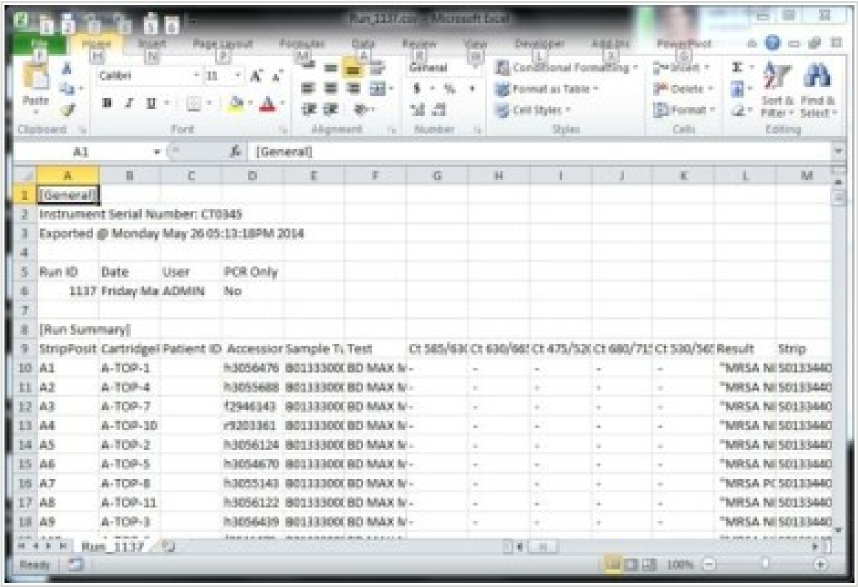
View CSV File in Excel

Log files are stored as CSV files and may be viewed in Microsoft Excel.

The following environmental variables allow for extra options. It is recommend for troubleshooting.

- **ALLOW_FDA_ANALYSIS** – checking this environmental variable exports the BANCS metric used for results calling.
- **EXPORT_ADF_DATA** – checking this environmental variable exports the details of the ADF.





The **General** section at the top provides overall run information.

General - Instrument Serial Number: CT0345			
Exported @ Monday May 26 05:13:18PM 2014			
Run ID	Date	User	PCR Only
1137	Friday May 09 05:36:28AM 2014	ADMIN	No

The **Run Summary** section lists run results by lane with details by column. Particularly useful columns include:

- Strip Position
- Cartridge Position
- Test
- Result
- Prep Status
- PCR Status

Run Summary					
Strip Position	Cartridge Position	Patient ID	Accession Number	Sample Tube ID	Test
A1	A-TOP-1		h3056476	B01333000420140728RP38	BD MAX™ MRSA

Run Summary					
A2	A-TOP-4		h3055688	B01333000420140728QJ30	BD MAX™ MRSA
A3	A-TOP-7		f2946143	B01333000420140728RU02	BD MAX™ MRSA

PCR Detector Settings show the gain and exposure settings for each color channel on both sliding read heads.

PCR Detector Settings			
Position	Color	Gain (Percent)	Exposure (ms)
A1	585/630	25	100
A2	585/630	25	100
A3	585/630	25	100
A4	585/630	25	100
A5	585/630	25	100
A6	585/630	25	100
A7	585/630	25	100
A8	585/630	25	100
A9	585/630	25	100

The **PCR Data** section shows normalized PCR results for each color channel on both sliding reader heads.

PCR Data					
Cycle	A1: 585/630	A2: 585/630	A3: 585/630	A4: 585/630	A5: 585/630
1	2230.44	2178.1	2107.33	2165.65	2081.71
2	2226.12	2171.61	2099.03	2158.66	2075.74
3	2223.72	2166.59	2099.74	2156.85	2081.95
4	2224.12	2172.56	2101.8	2158.61	2078.91
5	2215.68	2158.49	2086.51	2151.03	2069.66

- The first column contains the cycle count, with the number of counts depending on the assay being tested. For example, GBS has 50 while MRSA has 45.

- Additional columns show optical data for each cycle scan.
  - Labeled by the lane and the color channel wave lengths, these values are representative.
  - Values are shown using ADC (Analog Digital Conversion), which does not directly correspond to any external measurement value.

Other Data Sections

Other data sections include similar data but represented differently. These include:

- Crosstalk Corrected Data
- Background Data
- Raw Data

The **Normalizer Data** section provides normalizer values scanned at the beginning of each pass.

PCR Normalizer Data					
Cycle	A1: 585/630	A2: 585/630	A3: 585/630	A4: 585/630	A5: 585/630
1	192445	192445	192445	192445	192445
2	192353	192353	192353	192353	192353
3	192389	192389	192389	192389	192389
4	192267	192267	192267	192267	192267
5	192856	192856	192856	192856	192856
6	193006	193006	193006	193006	193006
7	192820	192820	192820	192820	192820
8	193318	193318	193318	193318	193318
9	193236	193236	193236	193236	193236
10	193518	193518	193518	193518	193518

- Since only one optics head is used to scan all samples, only one normalizer value is scanned each cycle.

  > **Note:** Normalizer values (**NVs**)are the same across a color. For example on Cycle 1, all the 585/630 values are the same on reader A.

- Normalizer values should be consistent through a run, with no large jumps or changes from one cycle to another.

The **MELT** data sections are similar to PCR data sections. MELT is available on the BD MAX, and may be used at open system sites. The MDR-TB and Quad Point Melt assays also utilize and contain MELT data.

The **Version Data** section shows version numbers for user software and software loaded on the MUX boards.

The **Optics/Normalization Parameters** section shows the optics normalization parameters for each sliding reader head.

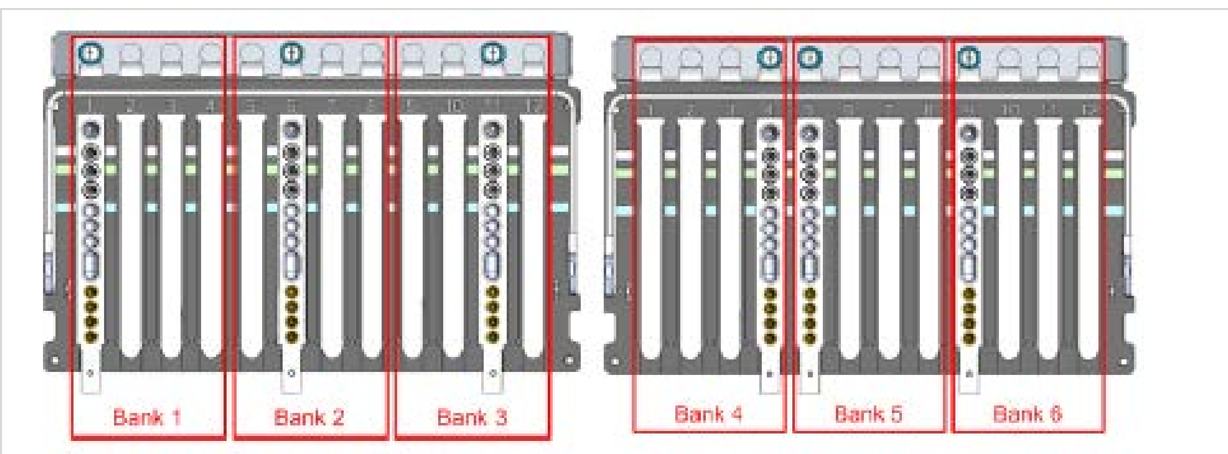
6.4.1.18 Single Sample per Bank Test

Tools and materials

Item	SAP Catalog No.	QTY	Description
Service Kit	444048	1	Qualification Kits
24 Lane Cartridges	437519	1	Box of 24 PCR Cartridges

Procedure

1. Load two racks with one **Qualification** sample per bank (see example in diagram below). It does not matter which spot within the bank the sample goes, as long as there is only one sample per bank.



2. Insert cartridges into both readers. Set up the run in the **Work List** and start it.
3. Watch the fluid handling during the run. Pay special attention to fluid handling during the **Load Cartridge** part of the run.
   - Watch specifically for the Z-Gantry not going down far enough to aspirate and dispense fluid from the test strip or cartridge. If this happens, then there are issues with Z-Gantry

binding.

4. Once **Load Cartridge** has finished, the run can be aborted. If no **Z-Gantry** issues are observed, then the Z-Gantry is functioning normally and the instrument can be turned over to the customer.

5. If no **Z-Gantry** issues are observed, then the Z-Gantry is functioning normally and the instrument can be turned over to the customer.
   - If **Z-Gantry** binding is observed, conduct a run with two to four strips in several banks. If **the Z-Gantry** binding does not repeat, then it is specific to single sample per bank runs.
6. Once **Load Cartridge** is finished the run can be aborted.
7. The current fix for this type of Z-Gantry binding during a single sample per bank run is to replace the Z-Gantry.

   Note: In this instance, the customer can still run normally with multiple samples per bank.

   - If any Z-Gantry binding was observed, ensure a complaint is created and then contact your supervisor for direction on how to proceed.

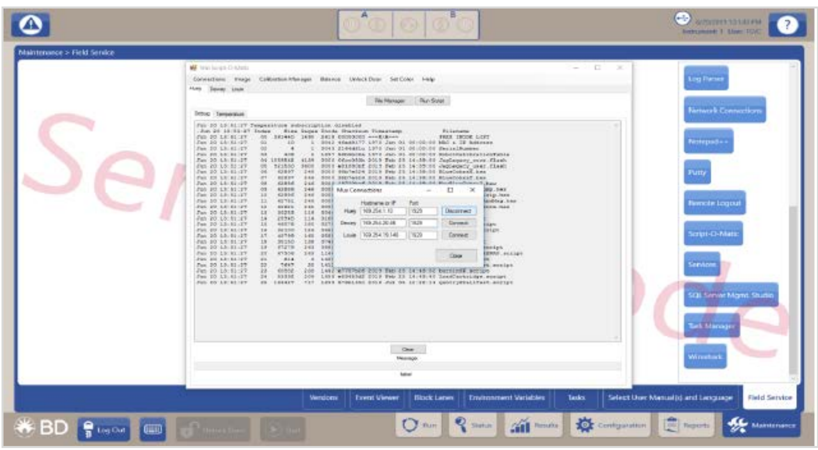
6.4.1.19 Z-Gantry Stall Script

1. Download the **gantryStallTest.script** file to a USB drive.
   a. Access the file at the Electronic File Transfer (EFT) site.
   b. Go to **/IDS-WWTS(RW)/Molecular/BD MAX/Scripts**.
   c. To request access to the EFT, refer to **BDLS7607**.

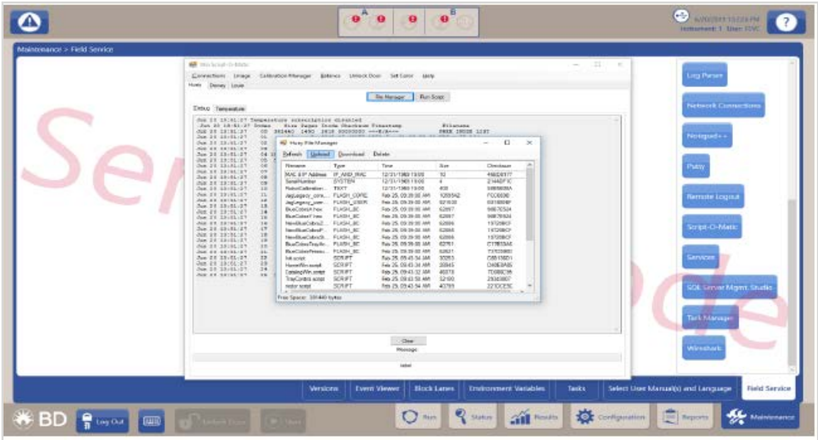
   https://bd1.sharepoint.com/sites/BDDSBDBGPS/BDDSGPS/BDDS%20Software%20Download/Forms/AllItems.aspx?id=%2Fsites%2FBDDSBDBGPS%2FBDDSGPS%2FBDDS%20Software%20Download%2FMax%2FScripts

2. Log into the BD MAX Instrument as **FSVC**.

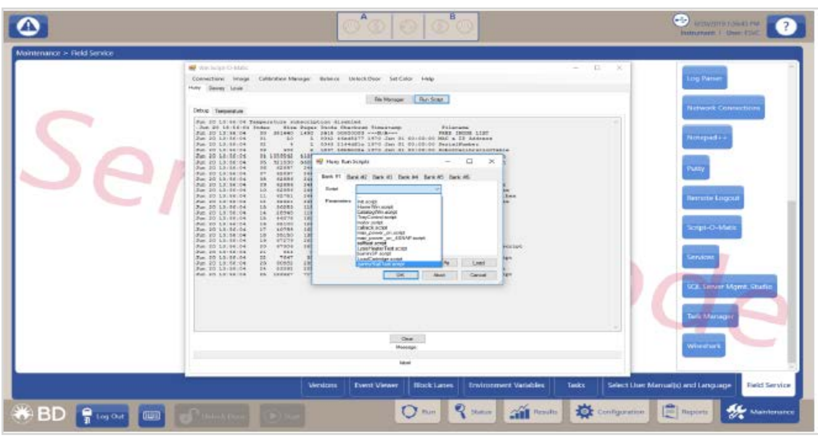
3. Insert your USB key with the **gantryStallTest.script** file into the AIO.
4. Navigate to the **Maintenance -> Field Service** tab and start **Script-O-Matic**.
5. Connect to the **Huey MUX** via the Connections dialog box.



6. Navigate to the **File Manager** dialog box and look for any files on the MUX named **gantryStallTest.script**. If this file exists, delete it from the Huey MUX.



7. Using the **Upload** tab of the **File Manager** dialog box, click **Open**to upload the **gantryStallTest.script** to the Huey MUX from the USB
   - Close the **File Manager** dialog box when the upload completes. Make sure the file type is **script**.
8. Using the **Run Script** button in Win Script-O-Matic, select the **gantryStallTest.script** from the drop-down menu.



9. When the script starts execution, it will prompt for a serial number. Enter the **Z-Gantry serial number (without any spaces)** and press **ENTER**.
   - The serial number for the Z-Gantry is a 6-digit number that can be found on the top of the Z-Gantry.

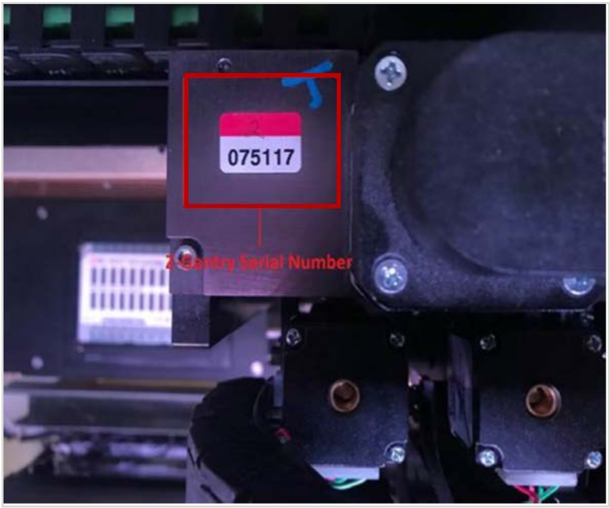


Fig: Z-Gantry serial number

10. The script will initialize the robot and then go through a series of touchoff attempts. **Do not turn the instrument off during this time and allow the instrument approximately 10 minutes to complete this operation.** When the instrument has completed its stall testing, it will home the Z-Gantry, compile its results and upload them to the AIO and exit the script.
    - Passing results = continue troubleshooting.
    - Fail results =
        - Lightly clean grease from the spindle of the **Z-axis**
        - Rerun **gantryStallTest.script**.
        - If you receive a second failure, replace the Z-Motor (see "Robot Assemblies Replacement" on page 280).
11. When the script has completed, navigate to the **File Manager** dialog box and delete the script named **gantryStallTest.script**.
12. Close **Script-O-Matic**.
13. Under the **Maintenance -> Field Service** tab, open an **Explorer** window and navigate to the directory titled **d:\maintenance**. Locate the newest file in this directory titled **GANTRYSTALL_SERIALNUMBER_DATE_TIME.CSV where SERIALNUMBER** where the serial number of the instrument (e.g. - "CT0123"), and DATE / TIME are the current date and time.
14. Copy this file to the removable USB drive and close the **Explorer** window.
15. Attach the file to your **Servicemax** report.
16. **Log out** of the instrument.

6.4.1.20 Empty Fill Check Errors

An **Empty Fill Check** error occurs when the Optical Reader detects an abnormally high level of fluorescence in what should be an empty cartridge.

Empty Fill Check Fluorescence error is based on the level of fluoresce present at the 585/610 (ROX) optics channel detector. Note that the emitter on this channel produces orange light with a wavelength of 585 nanometers, and the detector looks for fluorescence at a wave length of 610 nanometers.

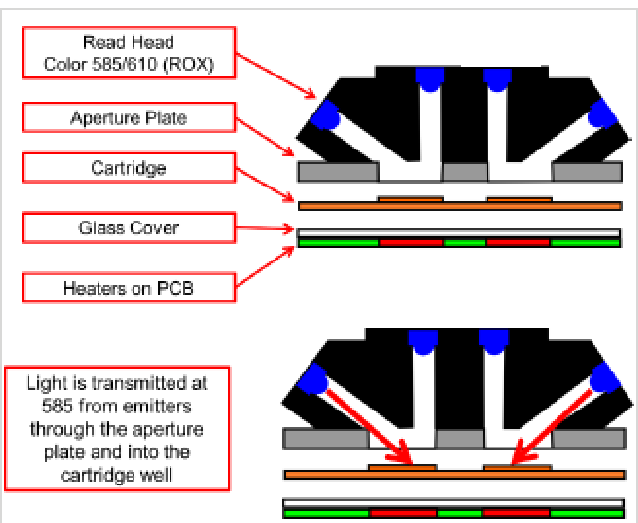
This channel is referred to as **585/610 channel one** in CSV files, and as **channel zero** in log files, **Script-O-Matic**, and database.

Fill Check Error Causes

The purpose of an Empty Fill Check error is to detect previously used cartridges. Since the BD MAX record's cartridge barcodes in its database this is usually not an issue at sites with a single BD MAX. However, if a site has multiple BD MAX instruments, then this can become an issue.

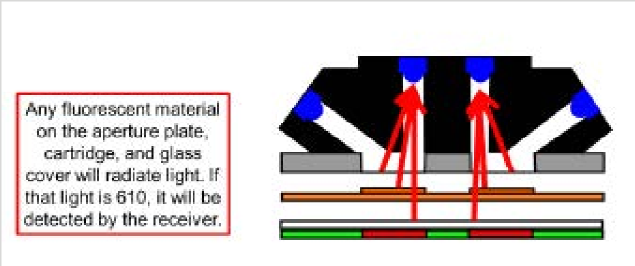
In the case of unused cartridges, Empty Fill Check errors can be related to one or more of several different issues. Sometimes this is referred to as a stacking error.

Looking at a cross section of the Optics system there are multiple elements that can come into play for this type of error. The diagram shows the various parts that can be involved during an Empty Fill Check.



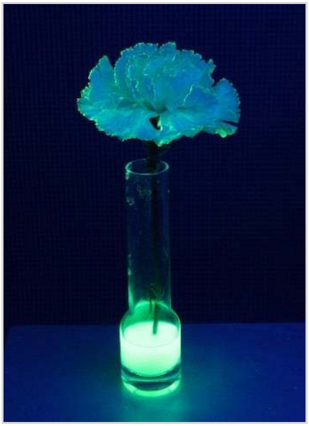
When an Empty Fill Check is performed, the Optics emitters transmit light at a wavelength of 585 nanometers. This light is going to illuminate the aperture plate, the cartridge chamber being tested, and the glass plate covering the heater elements below the cartridge.

Any stray foreign substances located on the optics head, aperture plate, cartridge, or glass heater cover can cause fluorescence at 610 nm. Additionally, fluorescence from all sources is added to get the total fluorescence.



Almost any material can produce fluorescence when exposed to light of various frequencies. For instance, an ordinary flower under a black (Ultra Violet) light can glow.

- During the day time and in normal lighting, this fluorescence is not visible because it is much dimmer than the light we see by.
- Put the object in a dark room and illuminate it with light of a specific wave length and it appears to glow. This is what can happen with foreign substances inside the BD MAX reader. In the dark they can be made to emit fluorescence when the channel emitters are turned on.



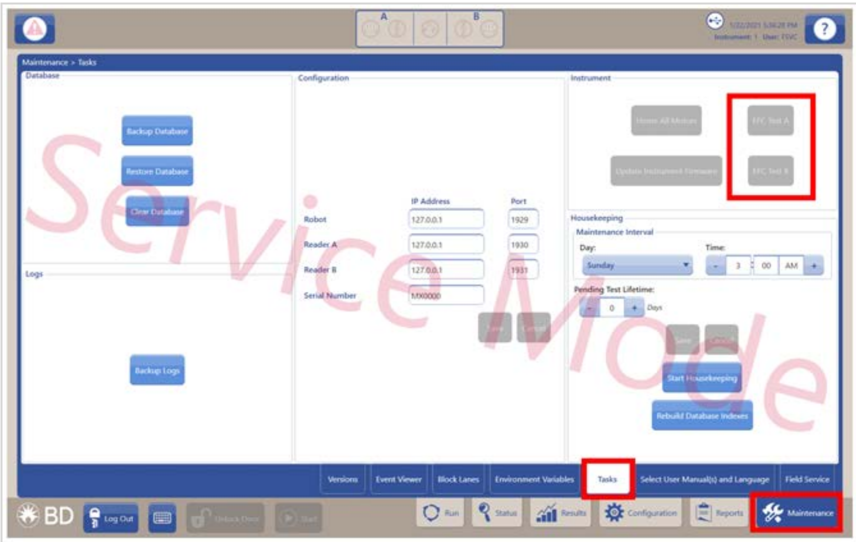
Empty Fill Check is conducted after Cataloging and prior to the start of sample preparation.

Conditions that may create **Empty Fill Checks** are listed below, a single condition or combination of these conditions may lead to an Empty Fill Check being displayed on the BD MAX instrument:

- Debris on the Reader Aperture plate.
- Debris on the Heater/MUX glass plate.
- PCR Cartridges that are dirty or have too much natural fluorescence (i.e. plastic has some fluorescence associated with it).
- PCR Cartridges that have already been used for assay testing.

Troubleshoot with Empty Fill Check Test Function

For **software version V4.50 and up**, the **Empty Fill Check Test** function is available for improving service efficiency. The **Empty Fill Check Test** allows Field Service personnel to check the fluorescence reading of an empty cartridge right from the GUI.



The **EFC Test A** and **EFC Test B** buttons can be found under the Task Sub-tab and is only available when logged in as **FSVC** user. Test buttons are disabled when the door is open, when there is an ongoing run, or when the Home All Motor is executing.

The following steps are performed when the **Empty Fill Check Test**is executed:

- The cartridge is scanned.
- The tray is closed and the pressure plate is raised.
- Fill check is performed.
- The pressure plate is lowered and the tray opens.
- The results are displayed in a report.

When test is completed, the results are shown on a report in the test window. This result may be viewed, exported as PDF onto a USB drive, or printed. Once the test window is closed, the report cannot be recalled.

When the test is completed, the results for all **24** lanes are displayed in a bar graph format. Lanes in gray color represents known/used lanes, and lanes in blue color represent unknown/unused lanes. The values displayed on the Y-axis are normalized value multiplied by the AF, and the **red threshold line of 450** is displayed across the bar chart. In addition to the fluorescence value, the report also contains the instrument serial number, software version, reader tested, and cartridge barcode.

- In the figure above, **lanes 1, 4, 7 and 10** are shown in Grey color, meaning that they have been used and are known to the database. **Lanes 9, 10, 11, and 12** on the bottom row were blocked during the test and are shown in blue color, meaning they are unknown in the database. The remaining lanes are all unused lanes and are under the threshold of **450**.

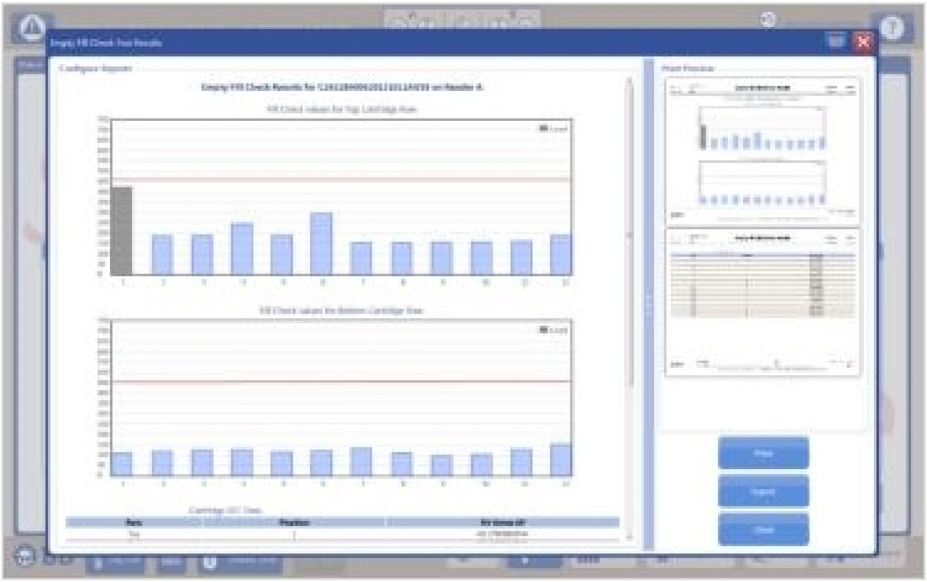
To run the Empty Fill Check Test:

1. Log in as **FSVC** user.
2. Navigate to the **Task** screen under **Maintenance** tab.
3. Select either the **EFC Test A** button for testing Reader A or **EFC Test B** button for testing Reader B.
4. Place a new PCR Cartridge in the reader you wish to test.
5. Select the appropriate **EFC Test** button to execute the test.
6. When test is started, an EFC Test window displays.

   > **Note:** Do not close the window; closing the window at this time terminates the test.

7. When the test completes, a report is generated and displayed. The report can also be printed or exported as a PDF. Once the window is closed, the report cannot be recalled.

8. Log out of service mode and verify the service watermark is no longer present prior to returning the instrument to the customer.



6.4.1.21 Bead Carryover

Bead carryover is observed in the elution steps, this can lead to a variety of errors in reported results; leaving beads in the waste chamber, snap 3, or possibly in the PCR cartridge lanes.

Causes

There are basically four causes of bead carryover:

- **Gantry Alignment issues**: causing the tips to come down into the magnetic particles on the side of the reaction tube, when the magnets are up, and draw some of them up.
- **Magnet issues** (alignment or range of motion): reducing the force exerted on the magnetic particles with some not being pulled to the side of the reaction chamber, and consequently being transferred.
- **Work flow**: sample strip set up issues causing incomplete re hydration and mixing.
- **Sample type issues**: some sample types are more difficult to extract properly.

Bead Carry Over Troubleshooting

1. Evaluate the log files and event logs for any patterns that may occur over several runs.
2. Also look for motor cycle and step errors. This could indicate problems with specific motors or motor controllers.

3. Observe alignment of pipette tips during a run, paying particular attention to how centered the tips are in the reaction tube. Recalibrate the gantries if this is observed.
4. Remove the instrument skins and raise the magnets. Check the magnet alignment. Realign if necessary.
5. Watch workflow, ensure strips and samples are inserted properly and in the correct positions.
6. Observe that reagents inside the sample tubes are properly settled.
7. Bead carryover has been observed with plasma (sample matrix) during extraction reconstitution. Clumps of beads do not reconstitute due to the fibrinogen and proteins in the sample matrix binding to the surface of the beads and causing agglutination and not reconstituting in solution.

For example: [This has also been recently observed in other tough sample matrices such as nasopharyngeal swab or Bronchial lavage. Low wash buffer volume can also increase bubbling during mixing and subsequent loss of beads].

6.4.1.22 Liquid Level Sense

A Liquid Level Sense (**LLS**) error only occurs when the BD MAX aspirates from the Sample Buffer Tube during the early part of Sample Preparation. This is the only time that the BD MAX™ checks liquid levels in the tips because this is basically the only time a sufficient volume of fluid that can be detected is aspirated. If the **LLS** sensor system does not detect a fluid level in the large number one tip that is within tolerance, a **LLS** is flagged.

The pipette tips punctures the septum cap and then aspirates fluid from the sample tube. As the tip is lifted out of the strip, the tip detect sensors are looking for the presence of a filter tip, an empty portion of the plastic tip, and fluid filled portion of the tip.

The position of the transition between plastic and liquid with respect to the filter position is correlated to the volume present in the tip. A reading above **150** indicates plastic and a reading below **135** indicates liquid.

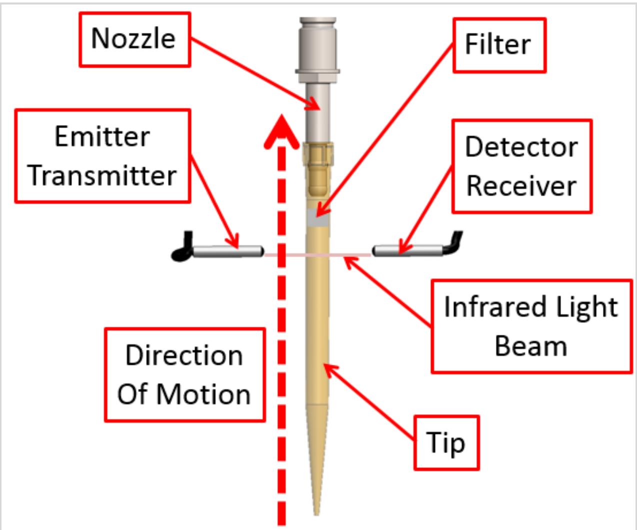
If an error is generated:

- The tips will go back into the sample tube.
- The tip that failed will be dispensed into the tube.
- The z head will move back and forth in the x and y direction in a "+" pattern.
- The tip that failed will try aspirating the fluid again.
- All 4 tips will be scanned again.

LLS Error Causes

The LLS sensor system works by transmitting a beam of infra-red light from an emitter to a receiver, through the tip; this is the same system used for tip detection.

As the tip is moved up (negative Z direction) the light beam is blocked by the nozzle and filter. It passes almost full strength through the translucent material the tip is made of. When passing through fluid, a portion of the infrared energy is absorbed by the fluid yielding a lower reading.



The LLS check starts just below the filter in the large tip.

- As the tip is pulled up by the Z-Gantry, the intensity of the infra-red light beam that passes through the tip is measured.

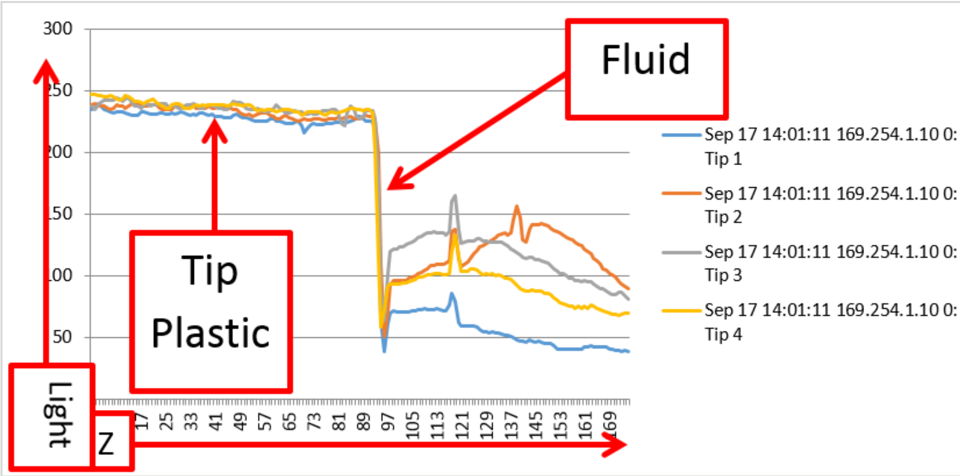
The Z position is noted when a drop in intensity occurs.

- This Z position corresponds to a specific volume of fluid **+/- 20 µL.**

Check the location of the filter within the tip.

Issues that can lead to LLS errors:

- Incorrect aspiration volume caused by pump or air Line Issues.
- Incorrect aspiration caused by consumable issues.
- Dirty, blocked, or bad sensors.



LLS Troubleshooting

1. Search previous run history for LLS errors. Compare LLS errors from different runs. Looking for any commonality between nozzles. If the LLS issues are occurring on specific nozzles, this indicates issues with that position and effectively narrows the search for a root cause.

Nozzle	1			2			3			4		
Cartridge Lane	1	2	3	4	5	6	7	8	9	10	11	12
Rack Strip	1	5	9	2	6	10	3	7	11	4	8	12

2. The best way to validate fluid handling issues is to observe fluid transfers during a run. Look for correct and matching volumes to be picked up across all nozzles.
   a. Fluid handling can also be observed by using the **Pump Check** option of the **max_power_on_4SNAP.script.** Performing load cartridge test is another way to observe fluid handling.
   b. If there is an issue with fluid handling then the issue resides with either the airlines or the pump for that nozzle.

   > **Note:** Bent tips may indicate an issue with the Z Gantry.

3. Check the LLS sensors in the stripper assembly for obstructions, foreign material, or other issues.
   a. Try cleaning the sensors with a Kim Wipe dampened with isopropyl alcohol.
   b. Test the sensors with the motor.script using the following commands:
   `setfluideepot z` press enter
   `getfluidsensors z` press enter

4. This generates a message **ffffffff.** This is a hexadecimal number. There are eight f responses, grouped by two for each nozzle giving a range of 0 to 255 decimal. Acceptable results for each nozzle are **ff** or **fe**.

   Example of acceptable output: `fffefffe`
5. This generates a message **ffffffff.** This is a hexadecimal number. There are eight f responses, grouped by two for each nozzle giving a range of 0 to 255 decimal. Acceptable results for each nozzle are **ff** or **fe**.

   Example of acceptable output: `fffefffe`
6. If a nozzle sensor is blocked by a piece of paper then the **ff** should be replaced with a **00** or very low value.

   Example of nozzle 2 blocked: `ff00ffff`
7. If all sensors are malfunctioning then it could be an issue with the stripper assembly, the Z controller, or the cable connection between the two assemblies. Try reseating the cables first. Then replacing the stripper assembly. If the Z controller is bad there are likely additional issues as well. In the absence of additional issues, the Z controller should be the last part replaced.
8. Validate that the customer is using approved reagents and consumables. If a consumable or reagent issue is suspected, forward the Lot Number information for investigation.

Note: Reboot both the instrument and the All-In-One after exiting from Script-O-Matic.

6.4.1.23 Tip Pick Errors

Tip Detection

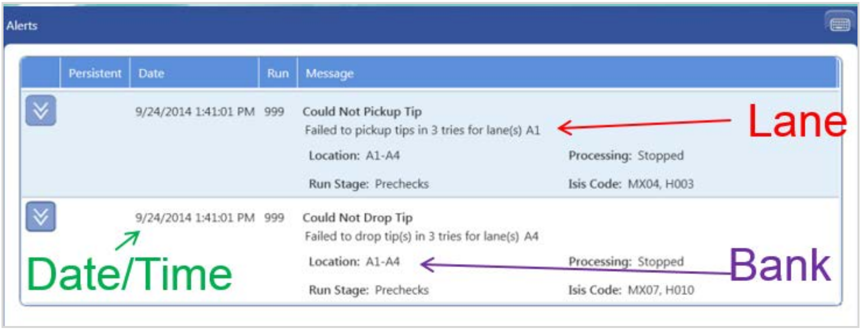
When a tip is picked up by the instrument, the tip detect sensors are activated. As the tip is lifted out of the strip, the sensors scan the tip looking for:

- The presence of the pipette tip adapter on any of the 4 lanes.
- The presence and location of the filter. This determines if the tip is a small or large tip.
- An appropriate gap between the pipette tip adapter and the filter.
- If it does not detect the tip, it will re-try 3 times.

After the pipette tip is stripped off of the z-head, they are scanned again to ensure that there are no tips present.

All the tip scan data is recorded onto the log files for every tip pick-up or drop off as well as any retries.

Tip pick errors includes **Could not pick up tip error**, **Could not drop off tip error**, and a run that did not complete for a bank, and 4 consecutive samples that resulted in an IND. Tip pick errors can be observed in the Alert Summary.



You can look for patterns in the Run History.

- Go to Run Results and filter the Result by IND.
- What is the frequency of the error?
- Does it repeat on the same deck?
- Does it repeat on the same bank?
- Does it repeat on the same lane in the bank?

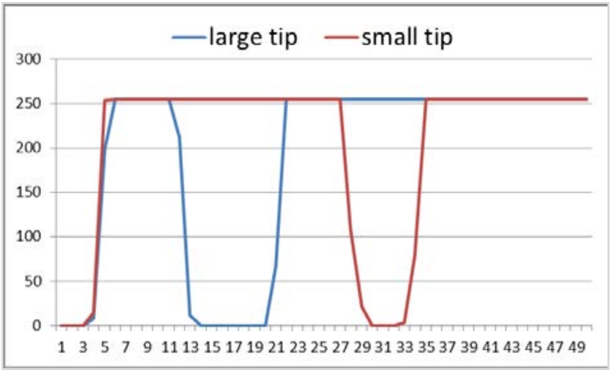
Check the log file:

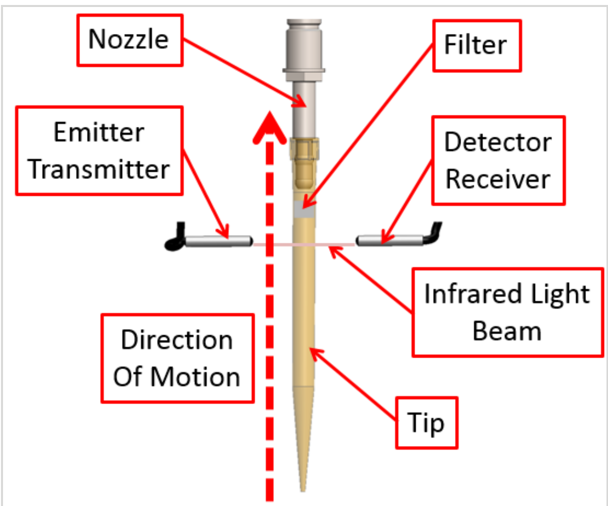
1. Save the log files from the instrument
2. Open the .CSV file.
3. Go to the time of error (from the alert screen on the AIO) or search column M for the term "could not".

```
169.254.1.10:0 Local0 (Informational): 5: Tip 1, 0, 0, 0, 0, 255, 255, 255, 255, 255, 255, 255, 255, 255, 255, 255, 255, 2
169.254.1.10:0 Local0 (Informational): 5: Tip 2, 0, 0, 0, 11, 230, 255, 255, 255, 255, 255, 255, 255, 255, 255, 255, 255,
169.254.1.10:0 Local0 (Informational): 5: Tip 3, 0, 0, 0, 5, 183, 255, 255, 255, 255, 255, 255, 255, 255, 255, 255, 255, 2
169.254.1.10:0 Local0 (Informational): 5: Tip 4, 0, 0, 0, 10, 239, 255, 255, 255, 255, 255, 255, 255, 255, 255, 255, 255,
169.254.1.10:0 Local0 (Informational): 5: Could not pickup Tip 1 on bank 6 location TIPS4. Trying again.
```

4. Copy and paste the sensor output to another sheet and plot it out.
5. The sensor output is the intensity of light seen by the sensor. The signal ranges from 0-255.

   If the nozzle is detected, the signal should be less than 16 and it also indicates that the sensors are working/functional.
6. Confirm that the filter is present and it is from correct tip size (large vs. small).
   - The signal for the large tip is 11-18.
   - The signal for the small tip is 24-32.





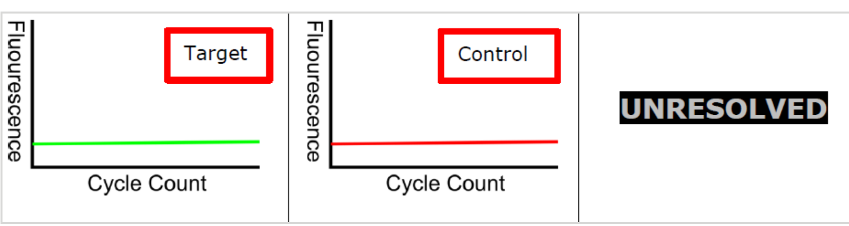
Tip Pick Error Causes

Sensor Failure	• **Observation:** consistent failures on a lane in the bank. • **Solution:** Check the sensors are working in Script-O-Matic. Clean the sensors off with isopropyl alcohol.
Z-Gantry Tilt	• **Observation:** errors on first or last strip in the bank. • **Solution:** Re-calibrate robot and ensure that there is no gap between nozzles and plate during touch-off.
Z-Gantry/ Stripper Assembly Interactions	• Observations: scratch marks on the nozzles. • Solution: Confirm that the stripper assembly can reach limits in the motor script.
Z-Gantry Binding	• **Observation:** Occurs when only 1 or 2 strips are run in a bank. • **Solution:** check for resistance in the Z-head with motor un-

	plugged and instrument off. Run **Z-Gantry Stall** script.
Rack Issues	• **Observation:** Racks do not sit down in the instrument and/or are damaged. The façade is sticking up above the rack grommets. Strips do not spring back in the racks. • **Solution:** Adjust skins and verify that mag/lysis assembly is not uneven. Use a level or watch the touchoff step in **calrack.script** to verify that the rack is able to sit flat and is level with the Z-gantry. Replace the rack.
Robot Calibration	• **Observation:** Typically occurs on a consistent bank or deck. • **Solution:**Repeat calrack.script to ensure that the alignment does not change with subsequent calibrations. Re-calibrate the instrument.
Undersized Nozzle	• **Observation:** Always occurring on one of the 4 lanes in the bank. • **Solution:** Measure the nozzle and replace.
Consumables	• **Observation:** This happens sporadically at a low rate or specific tied to an assayor lot number. Logs confirm the other tips are being picked up. • **Solution:** Record the kit lot number and file a consumables complaint.

6.4.1.24 Unresolved Results (UNR)

An Unresolved Result (**UNR**) occurs in an IVD assay for a sample when there is no system error and both the target and Internal Control DNA results have no amplification.



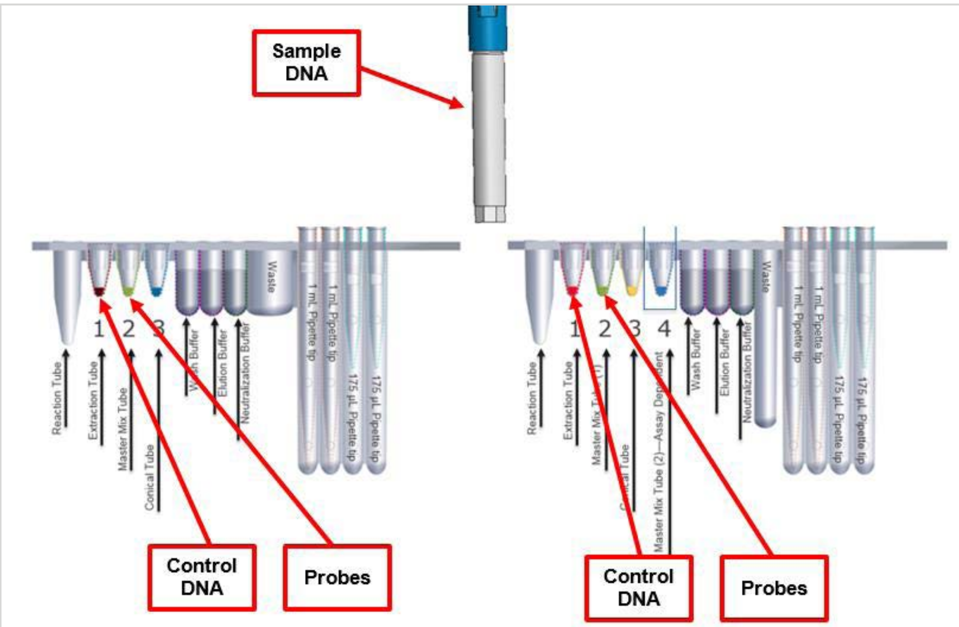
> **Note:** A UNR is a result and not an error, so it only shows up in run results.

Causes

What is important to remember about unresolved results is that no system error has occurred. This means that the cartridge chamber for the lane was filled and passed the Full Fill Check, so fluid was successfully transferred from the URS to the PCR Cartridge.

Therefore, the issue resides in sample mixing (Sample Buffer Tube), reagent condition (Control DNA and Probes), alignment, or an unreported instrument error.

> **Note:** Understanding where the DNA and Probes come from are critical in order to understand how to troubleshoot this type of problem.



> **Note:** The GBS IVD assay only reports Indeterminate (IND) results. So any Unresolved (UNR) results on a GBS assay are reported as IND.

All Target DNA comes from the sample (SBT). If a sample is negative, there is no target DNA amplification. Control DNA comes from the extraction snap-in and should always be present in an IVD assay. Probes come from the PCR or Master Mix snap-in (MM1 in 3-snap URS, MM1 or MM2 in a 4-snap URS) and should always be present.

During the initial mixing, the control DNA, along with the magnetic particles should be transferred to the reaction tube for extraction. At the end of this process the extracted DNA (target and control) is suspended in a high PH buffer solution.

This high PH buffer solution is neutralized in the Number 3 snap-in. From there it is transferred to the PCR snap in, then the cartridge.

Because probes get transferred to the cartridge, we assume that portion of the run performed correctly. This leaves us with four possibilities:

- The solution was not properly neutralized, leaving the pH high enough to inhibit growth. Insufficient DNA was transferred from the reaction tube.
- The reagents are outdated or have been incorrectly stored.
- There was an issue that did not show up as a system error.

UNR Troubleshooting

1. Verify that the reagents being used are not expired and that they have been stored correctly.
2. Review past runs looking for a pattern to where the UNR results are occurring.
3. Observe the cartridges after a run to ensure there are no bubbles in the affected lanes. If there are bubbles this could indicate uneven pressure during PCR or a drawer home flag alignment issue.
4. Look for bead carryover on the strip. If there are magnetic beads anyplace other than the reaction tube this could indicate a problem with alignment of the magnets or the robot. It could also indicate incomplete hydration in the extraction snap-in.
5. Observe a run; note any deviations from standard fluid level transfers. This could indicate a pump/airline issue and either incorrect sample transfer or incorrect neutralization. Also look for any alignment issues.

If Qual Runs and negative sample runs perform correctly, then something in the sample may be inhibiting DNA growth.

6.4.1.25 Procedure

1. Back up customer database under **Maintenance > Tasks**.
2. Record system configuration under **Configuration > System**.
3. Record the LIS configuration under **Configuration > External Devices**.
4. Turn off power to the instrument.
5. Check the heater **MUX boards' cables** for tension by moving the drawers in/out and up/down. Observe if the cables and **Igus chain** interfere with drawer movement.
6. If strain or interference is noted, adjust the cable slack and positioning while moving the drawers in/out and up/down. Check the condition of the cable to ensure there are no signs of damage.

Document: BDDSSGFS7422 Doc Type: ZIP Status: Released EFFECTIVE
Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

7. Clean the following components:
   a. Mirror
   b. Aperture plate
   c. Heater MUX glass plate
   d. Barcode reader
   e. Stripper assembly
   f. Inside/outside of instrument
8. Check all connectors and cables to ensure secure connection.
9. Power on the instrument.
10. Run the Load Cartridge Test.
11. Perform Reader Health Check (Empty Fill Check Test and Normalizer Ratio Check). If needed, perform Reader Normalization.

    Note: Save the CSV output file on your region's share drive. The CSV output file is located at D:\maintenance\NormRation.csv.

12. Check magnet alignment on both sides of the instrument; if needed, adjust magnets using the alignment tool.
13. Perform the following tests from Script-O-Matic:
    a. Heater MUX Self-test
    b. Pump Check
    c. Lysis Heater Check
    d. Liquid Level sensor check
    e. **CatalogWin.script** (if needed)
    f. Encoder values from **motor.script**
    g. Pressure plate value setting
14. Check voltages of power supply.
15. If needed, perform robot alignment from Script-O-Matic.
16. Record the following on your service report:
    a. Software version, image version, and size of the drives.
    b. If needed, record serial number of major assemblies (reader, Heater MUX board, etc.).

6.4.1.26 Tools

- T10 Torque screwdriver
- .004 inch Feeler gauge
- #1 Phillips screwdriver

6.4.1.27 Load Cartridge

The **loadcartridge.script** transfers fluid between the test strip and the cartridge. Like sample preparation, there are several different load cartridge scripts like - **loadcartridge.script** and **LC_UDP.script**. The script used is determined by the protocol being run.

6.4.1.28 Full Fill Check

The **FillCheck.script**is run on some assays as a full fill check. The purpose is to detect that the cartridge has indeed been filled by looking for fluorescence values that exceed the threshold levels by a predefined factor.

6.4.2 PCR Test

After the cartridge has been loaded, Dewey and Louie control the actual PCR (**Pcr.script**). Parameters for PCR come from either the test editor or the assay definition file.

6.4.3 Eject Cartridge

Finally, the **EjectCartridge.script** runs at the end of the run to open the drawers.

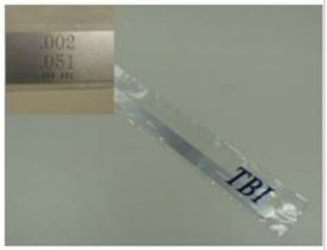
6.4.4 Reader Tray Position

The front flag controls positioning of the cartridge inside the reader. This procedure sets software offset for proper positioning of the flag.

> **Note:** The Instruments with the CT3050 and above will have the new tray Mechanism. Refer to "PCR Tray Design Update" on page 355.

Required materials

- Drawer alignment tool (T92000287-100)
- 0.002 inch feeler gauge

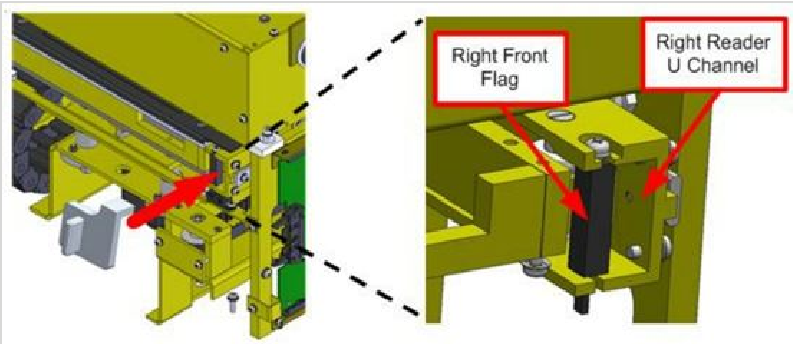


> **Note:** Ensure the customer has been upgraded to BD MAX™ System Software Version 4.60A or above.

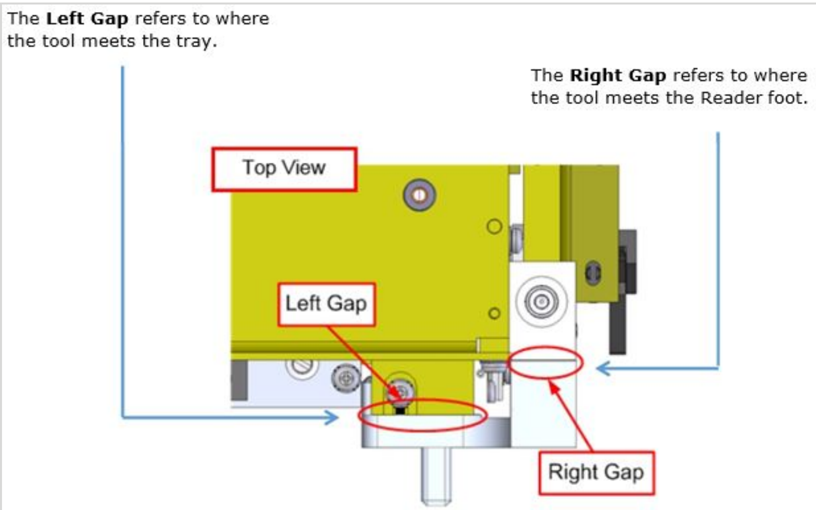
Procedure

1. Remove the tray covers and the rear reader cover.
2. Run the **init.script** from **Script-O-Matic** to turn on the motors.
3. Run **motor.script**.
4. Enter **loadcaltable** and then **printcaltable**.
5. The numbers next to LTRAY and RTRAY are the original tray offset values. Record these values for future reference.
6. From the dropdown menu, select **max_power_on_4SNAP.script** to move the tray to the **IN** position.
7. Run the Set MAX 6 Tray Home Position, option 16. Press **0** to check the **left tray** and **1** to check the **right tray**.
8. The tray you have selected will move in to a position where the tray cover can be removed. Remove the covers, or press **Enter** if it is already removed.
9. You will get a message about adjusting the home flag. Ignore this message for now and press **Enter** so the drawer goes to its home position.
10. Place the block tool (T92000287-100) in the reader U channel on the right side of the tray you are checking.
    - If you are viewing from the right side of the reader tray frame, the front flag is mounted in a **U-Channel**.

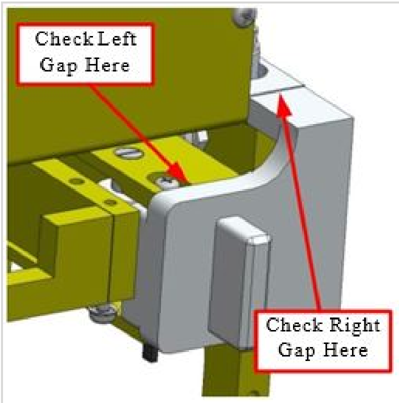
- Confirm that it is seated properly into the channel.



11. The block should fit securely around the front flag. If the block does not sit well in the channel, check the home flag to see if it is rotated. If the flag is rotated, straighten the flag and try again.
12. Hold the block on the middle handle and apply pressure evenly to lightly push the block up against the tray and the reader. Do not force the tool into place, as this might change drawer position.
13. Locate the two gap Positions as shown below. Looking down from the top, the **left gap** is located where the tool meets the tray and the **right gap** is where the tool meets the reader.



14. If there is a **right gap**, this means the tray is too far OUT (away from the reader). If there is a **left gap**, this means the tray is too far IN (towards the reader).



15. Using the **0.002 inch feeler gauge**, check if the tool is flush at the U-channel **left gap** as well as at the Reader foot **right gap**. Ideally there should be no gap at either location.
16. **If there are gaps**, follow the on-screen instructions to enter jog values and incrementally move the tray. Negative values move the tray IN (towards the reader) and positive values move the tray back OUT (away from the reader). The script only allows for the tray to be moved inwards overall, relative to its starting home position.
17. If there is a **right gap**, to to step 17a below. If there is a **left gap**, go to step 17b.
    a. If there is a right gap, that means the tray is too far out. Enter a negative value to move the tray in. If you go too far, and the a left gap appears (meaning the tray is now too far in) you can enter positive values to move the tray back out. Continually recheck the gaps as you jog the tray by lightly pushing the block against the reader and tray, and using the feeler gauge to confirm how big the gap is.
    b. If there is a left gap at the home position, then the tray is too far in. Because the script only allows the tray to be moved inward, you will need to adjust the home flag to change the home position of the tray. Press **q** to quit, then **Enter**, then **q** again to start over from the beginning. Follow the prompts as before, but this time, stop when you reach the message about adjusting the home flag. The home flag is also called the "right front flag". It can be moved by loosening the Philips screw and moving it along its slot. Move the home flag as far back as possible (towards the reader) and press **Enter**. Now, when the tray goes back to its home position, there should be a right gap, meaning the tray is now too far out. Go through the alignment procedure again and jog the tray inwards as needed.
18. Jog the tray inwards until there is no gap at either location. The tray is aligned correctly when the feeler gauge **will not slip** between either the two gaps.
19. Use **q** to exit when done. The drawer will open and close.
20. Recheck the gaps after the drawer moves. If the gaps are correct press **q** to quit. If not, press **r** to retain the tray and repeat the jogging process.

21. After adjusting both drawers, write down the final job value for the left and right tray. These are the new tray alignment offset values.
22. Enter 3 to save the new jog values and exit. Then enter 23 to exit **max_power_on_4SNAP.script.**
23. If the reader tray flags are adjusted, perform "Gantry Alignment " on page 508. The gantry alignment is dependent on the opened tray position.

6.4.5 PCR Heater Test

This test simulates both PCR heater and PCR optics operations during a PCR only run, and allows testing and monitoring of the reader without resorting to a full run.

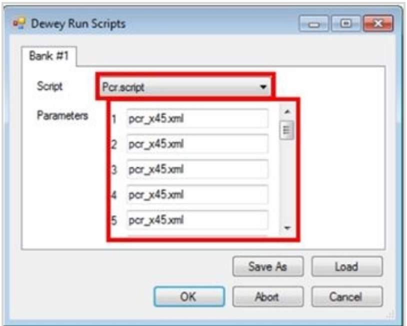
Required materials

1 Micro Fluidic Cartridge per side – SAP Catalog No. 437519 (comes in a box of 24)

Procedure

1. Using Script-O-Matic, run the **init.script** from the Robot MUX board (Huey).
2. Use the **File Manager** for the Reader (Dewey or Louie) being tested to verify that the **pcr_x45.xml** file has been uploaded to that MUX board.
3. Place a cartridge in one of the readers and, using Script-O-Matic, launch the **max_power_on_4SNAP.script** from the Huey MUX board.

4. Select option **[8]**: Prepare for Optics Check and press **Enter**. Follow the instructions in the Debug window.
5. Enter the number corresponding to the reader to be tested and press **Enter**. Wait while the drawer closes and the pressure plate is raised.
6. Use the Debug window for the Reader being tested to launch the **PCR.Script**.
   Enter **pcr_x45.xml** for each parameter **(1 to 24)** and then click **OK**.
7. Enter **pcr_x45.xml** for each parameter **(1 to 24)** and then click **OK**.

8. From the **Reader Debug** window, select the **Temperature** sub-tab to view **Heater board performance**.
9. Verify that all lanes are plotting data.
   - A flat line in any graph indicates a failure.
   - **Two Valve Heaters** run first to seal the cartridge chambers.
   - **Three PCR Heaters** per lane run through **45 thermal cycles**. While the PCR heaters may start at different temperatures, by the end of the first cycle they should be identical.
10. From the **Reader Debug** window, select the Optics Sub-tab to view reader optics performance.
    - Since no samples are being used, the optics data should plot as a mostly straight line.
    - Watch for large deviations or no track.
11. Click **Abort** on the Launch Scripts window to end the script.
12. **Launch Init.Script** from the Robot MUX to set the **PCR** readers back to home position and then remove the cartridge.

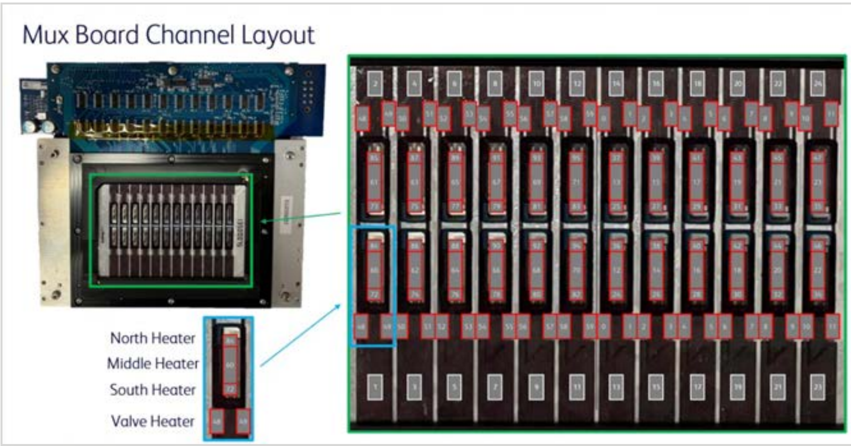
    > **Note:** Reboot both the instrument and the All-In-One after exiting from **Script-O-Matic**.

6.4.6 Self-Test

This test is run on Dewey and Louie for checking heater lanes on the heater MUX boards. This is done by sending current through the heater lanes. Results are either pass or fail.

> **Note:** If a **PCR.script** has just been run on the instrument, allow it 10 minutes to cool down before running the **selftest.script**.

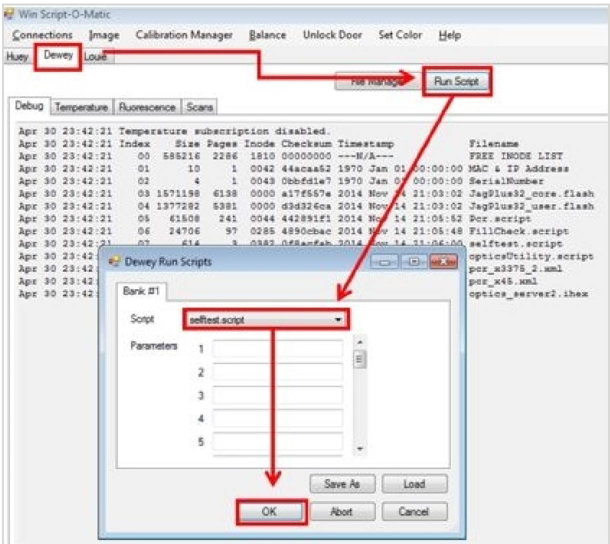
In the selftest.script output, the heaters are numbered based on the type of heater and location. The north, middle, and south heaters are responsible for heating the sample in the PCR cartridge. The valve heaters melt the wax deposits to seal the microfluidic channels on both sides.



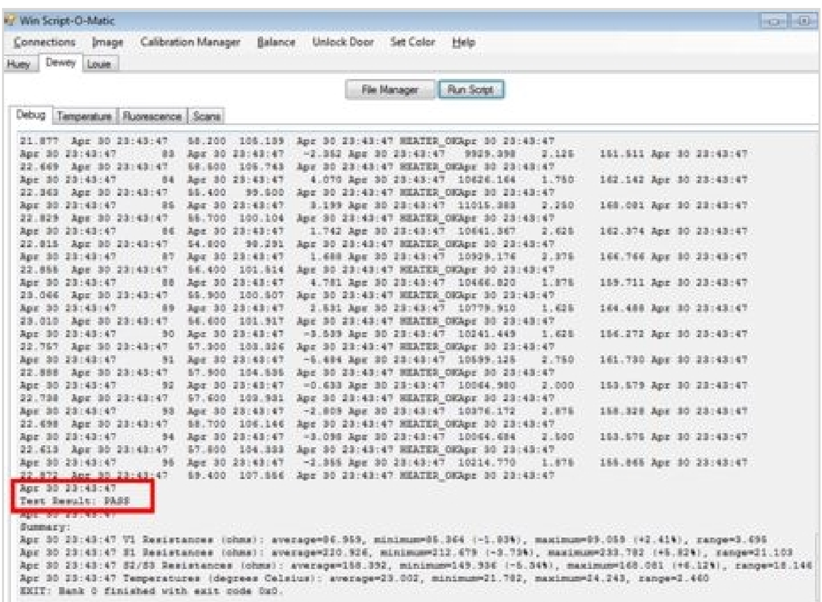
6.4.6.1 Procedure

1. Log in as **FSVC** user.
2. Navigate to the **Field Service** screen under **Maintenance** tab.
3. Click the **Script-O-Matic** button to launch Script-O-Matic.
4. In Script-O-Matic, select either Dewey or Louie.
5. Click on **Run Script** and select **selftest.script** from the drop-down menu.

6. Click **OK** to execute the run.



7. When the self-test is completed, results are displayed at the end of the Debug window.



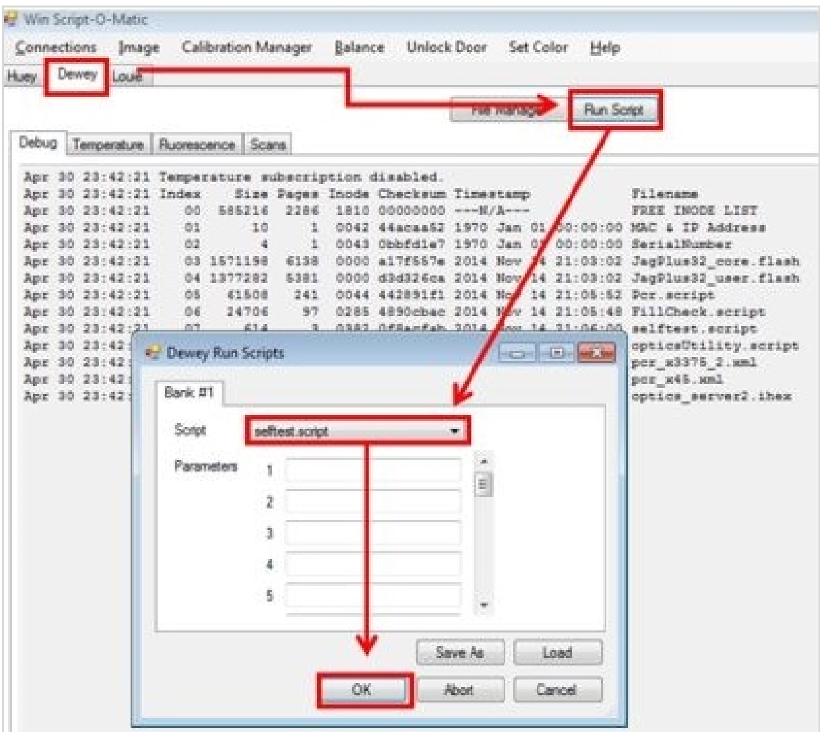
8. Test result shows as either **PASS** or **Fail**.
   - If the result returned is **FAIL**, the heater MUX board must be replaced.

> **Note:** Reboot both the instrument and the All-In-One after exiting from Script-O-Matic.

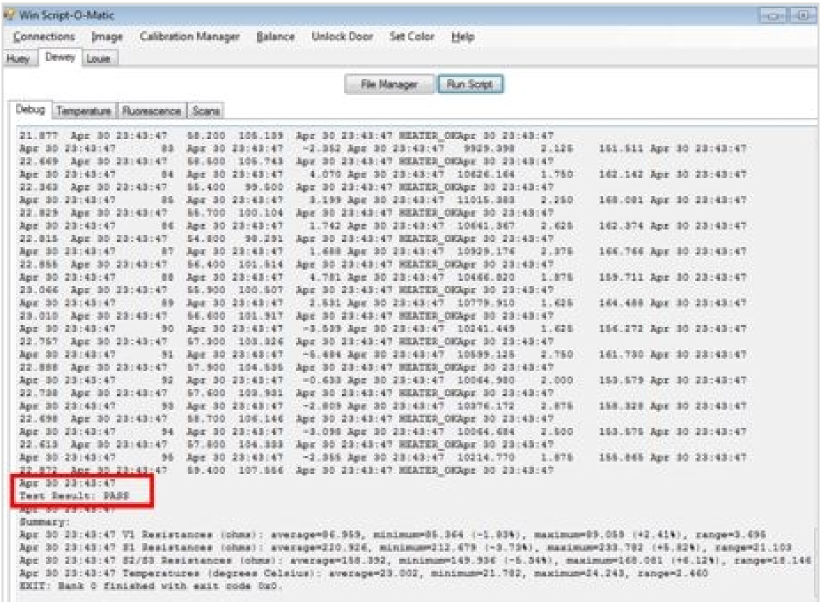
6.4.6.2 Ambient Temperatures for PCR Self-Test

Procedure for performing the Ambient Temperatures for PCR Self-Test:

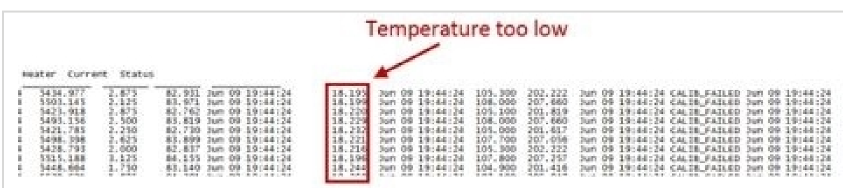
1. Before performing self-test, ensure that the ambient temperature is between **18°- 30°C**.
2. Log in as **FSVC** user.
3. Navigate to **Maintenance > Field Service**.
4. Select the **Script-O-Matic** button to launch **Script-O-Matic.**
5. In **Script-O-Matic**, connect to **Dewey**.
6. From the **Dewey** tab, click on **Run Script** and select **selflest.script** from the drop down menu.
7. Click **OK** to execute the run.



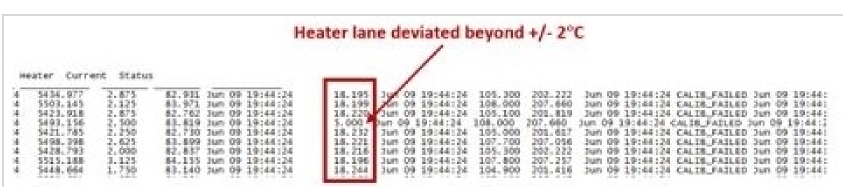
8. When the self-test is complete, results are displayed at the end of the **Debug** window.



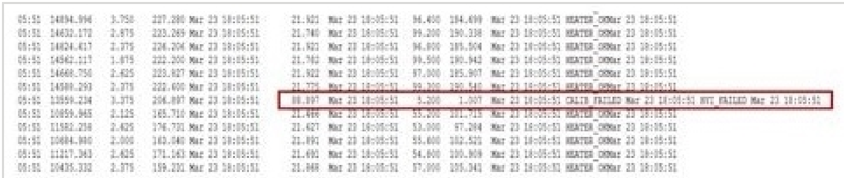
9. The test results are either **PASS** or **FAIL**.
10. If the self test results **FAIL**, check if the ambient temperature column is at least **18°C**. The ambient temperature limits for the self test script are **20°C – 30°C**. Ambient temperature related failures are caused by either a cold laboratory where the ambient laboratory temperature is below **18°C** or by a problem with an individual heater lane.
    a. Do **NOT** replace the heater/MUX board if:
        - The ambient temperature is below 20°C **AND** all of the ambient temperature measurements recorded by the self test are within **± 2°C** of each other.



    b. Replace the heater/MUX board if:
        - If an ambient temperature is below 20°C **AND** one or more individual heater lanes deviates beyond **± 2°C**.



- If the self test failed for reasons other than the ambient temperature being below **20°C**.



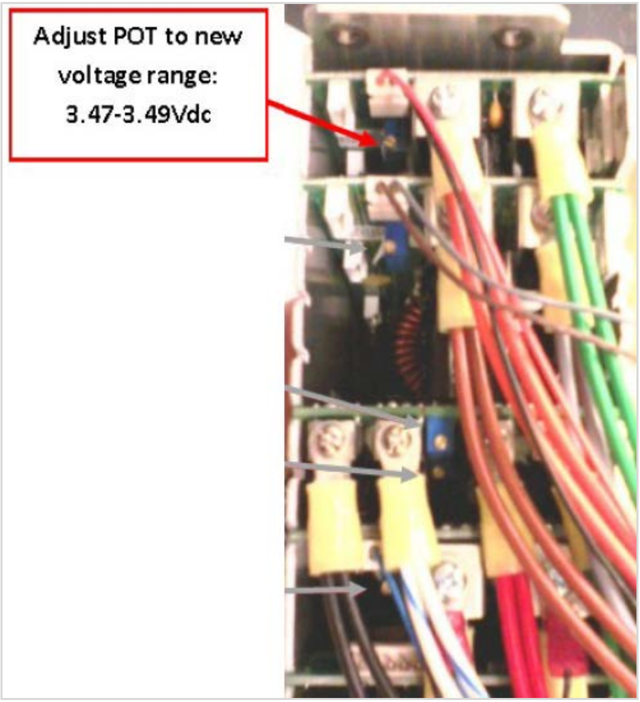
6.4.6.3 Heater MUX TP1-TP5 Voltage Adjustment

Heater MUX TP1-TP5 Voltage Adjustment

The voltage measured at the TP1(GND)-TP5 test point on the PCB mother board (also known as the liberty board) has changed. This change has been implemented to address the “timer stuck at 1 minute” issue where the BD MAX system becomes unresponsive during PCR. The new voltage range is as follows:

TP1 (GND)-TP5 (3.47Vdc to 3.49Vdc)

At the next service visit, per the procedure described in the BD MAX Service Training Guide (Rev 5), pages 287-289, the voltage at this test point should be adjusted to within the new range using the small potentiometers accessed from the top of the power supply. The new range will be updated in the next revision of the BD MAX service manual. Below show the location of the potentiometers and test points.



View of the power supply and potentiometers. Red arrow indicates which potentiometer (POT) should be adjusted. Grey arrows indicate locations of other potentiometers which have retained their voltage ranges as outlined in the service manual.

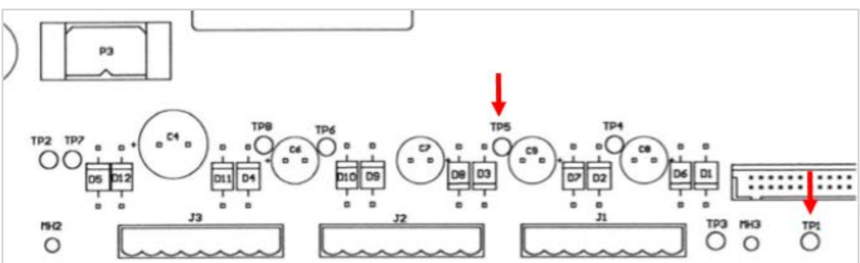


Fig: Ground and Testing locations on the Liberty Board (TP1 and TP5 indicated)

6.4.6.4 Heater MUX Resistance Check

This section describes how to do a selftest resistance check to determine if the heater MUX voltages should be adjusted. Do the selftest when a heater MUX board exhibits heater valve warnings.

> **Note:** This does not apply to new installs. That means that no additional voltage checks are required during installation of new or refurbished MAX instruments.

Procedure

Depending on the heater MUX resistance values, the power supply voltage, measured at the TP2 (GND) – TP7 test points on the PCB motherboard (Liberty board), should be set differently. The steps below describe how to identify the proper voltage setting. A multimeter/voltmeter is not needed to measure the resistance.

1. Power down the instrument and make sure the instrument has been powered OFF for at least 10 minutes to let it cool down completely.
2. Power up the instrument and immediately perform the selftest.script on Dewey in Script-O-Matic:
   a. Locate channels **0-11** and **48-59** (boxed in blue in Fig) and verify that the resistance values (boxed in red in Fig) are all less than **95 ohms** at **ambient temperature** (boxed in green in Fig).
   b. If any of the resistance values are greater than or equal to **95 ohms**, then set the 20V power supply to within 20.98-21.00Vdc.

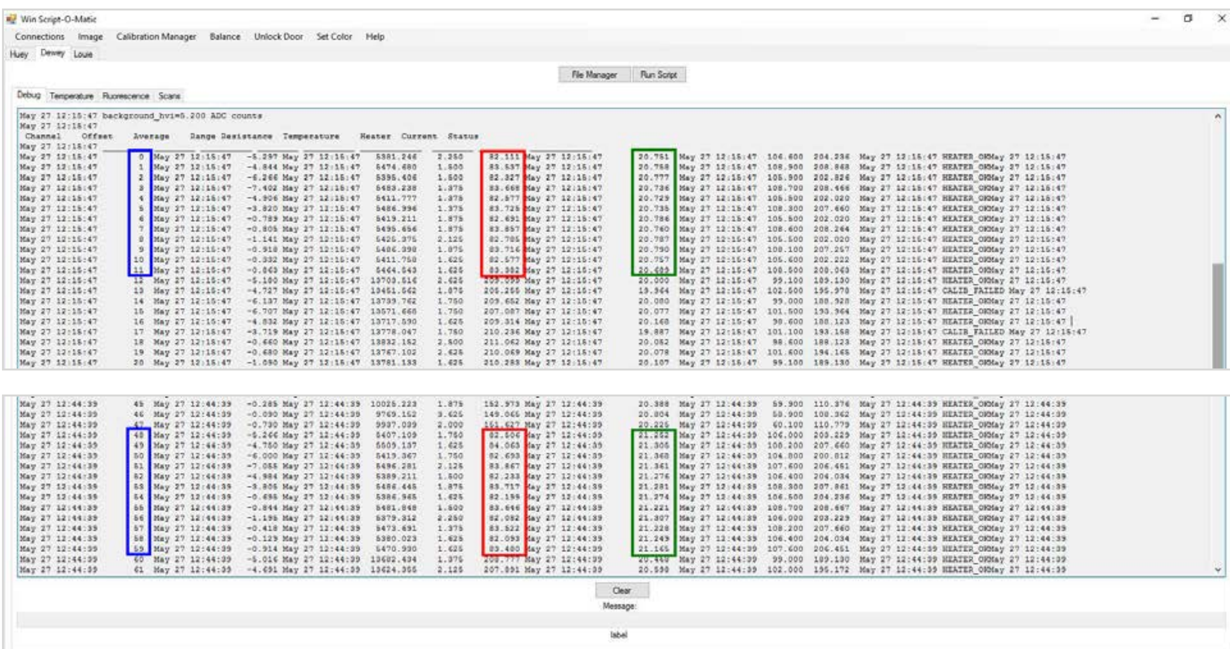


Fig: View of Dewey selftest.script output. The blue, red, and green boxes denote channels 0-11 and 48-59, corresponding resistance values, and ambient temperature, respectively. In this example, all relevant resistance values are below 95 ohms so the voltage should remain at approximately 20V

3. Perform selftest.script on the Louie side of the instrument, the same as the previous step. Table 1 below shows the appropriate voltage setting for each combination of resistance values, acquired from selftest.script.

a. If Dewey and Louie have resistance values that are all below 95 ohms, verify that the power supply is set to nominal 19.99-20.01Vdc and adjust if needed.
b. Only adjust the voltage to 20.98-21.00Vdc if relevant resistance values on either Dewey or Louie are greater than or equal to 95 ohms.

Table: Voltage settings for selftest.script Resistance Combinations

		Dewey (A) selftest.script	
		Ch 0-11 and 48-59 resistance < 95 ohms	Ch 0-11 and/or 48-59 resistance ≥ 95 ohms
Louie (B) selftest. script	Ch 0-11 and 48-59 resistance < 95 ohms	19.99-20.01Vdc	20.98-21.00Vdc
	Ch 0-11 and/or 48-59 resistance ≥ 95 ohms	20.98-21.00Vdc	20.98-21.00Vdc

Note: If selftest.script fails, be sure to check the ambient temperature column for values below 20°C. If the ambient temperature is below 20°C and all other ambient temperature measurements recorded by the selftest are within ±2°C, do not replace the heater MUX board. Be sure to always consult your regional expert to avoid any unnecessary replacements.

6.4.7 Lysis Heater Test

The Lysis Heater Check (LysisHeaterTest.script) is used to verify proper function of the Heater Block (GORT board). This script turns on the lysis heaters, heating up to 89°C and holding that temperature. Observing the temperature plots and inserting a temperature probe on the lysis heaters will confirm proper heating.

Requirements

Temperature probe (optional)

Procedure

1. Open Script-O-Matic and connect to Huey, Dewey, and Louie.
2. From the Huey tab, select **Run Script**.
3. Select init.script and then the OK button.
4. From the Huey tab, select LysisHeaterTest.script for all desired banks.
5. Select **OK** to start the test.

6. Select the **Temperature** tab to observe the temperature plots.
   - Observe the temperature reaches and holds at 89±3°C.
7. End the lysis heater test:
   a. From the Huey tab, select **Abort** for all desired banks.
   b. Disconnect from all boards
   c. Close Script-O-Matic.
8. Execute the LysisHeaterTest.script after connecting to Huey.

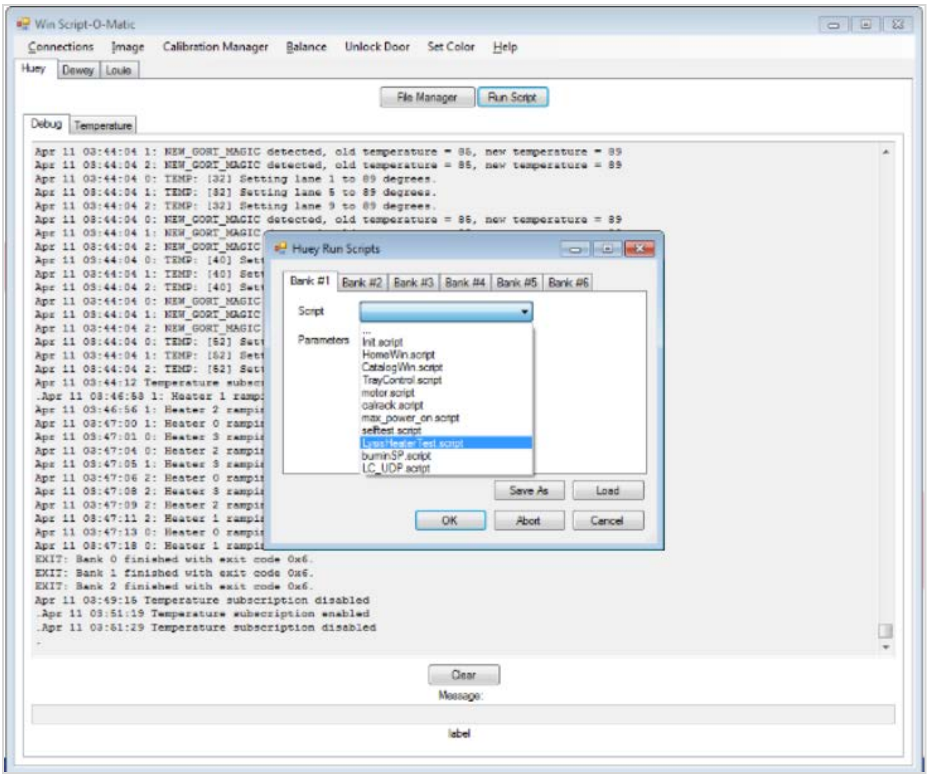


Fig: Execute the LysisHeaterTest.script

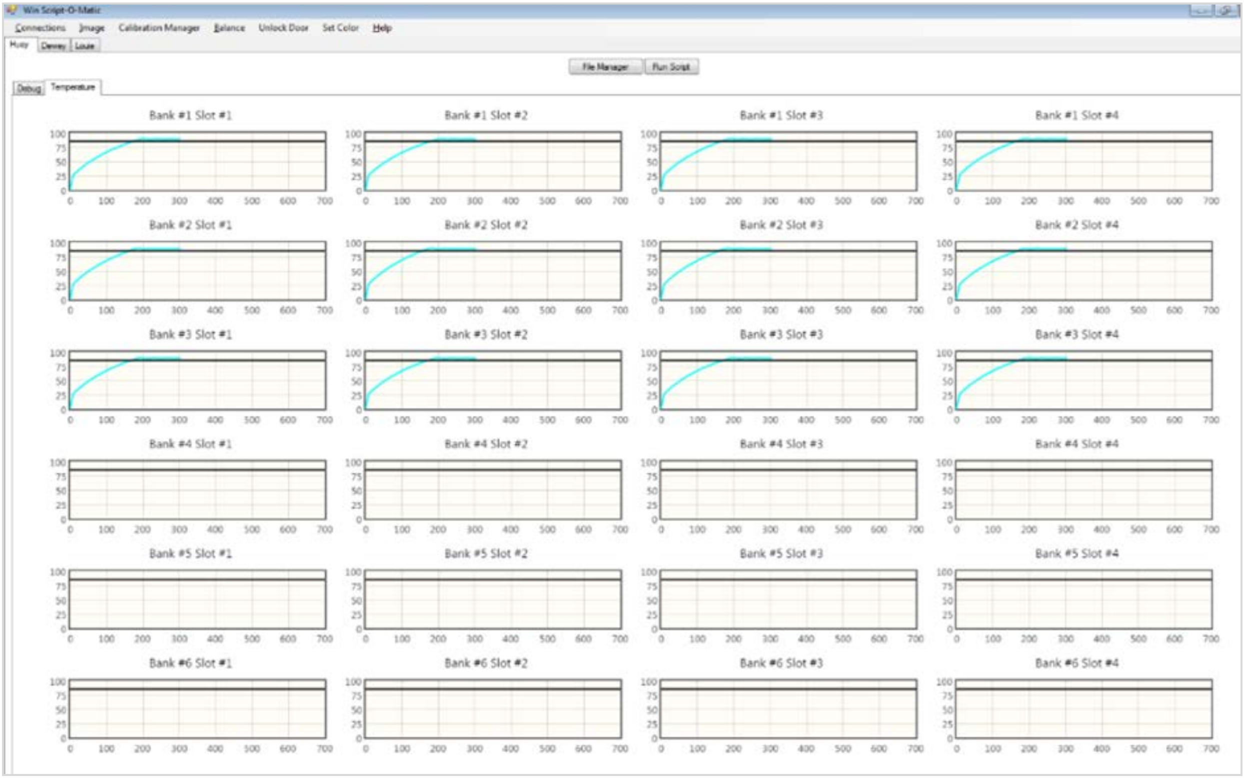


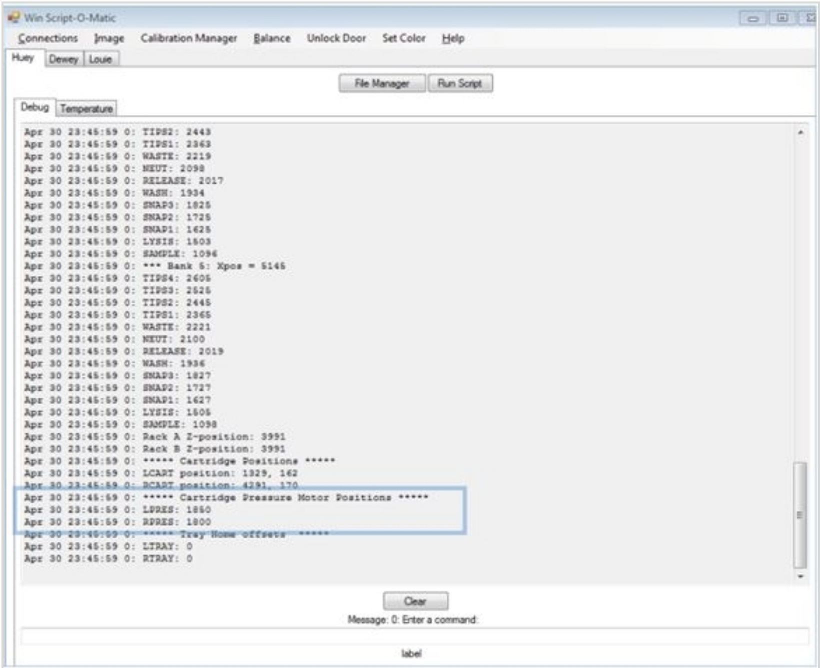
Fig: Lysis heater temperature plots will update live and display the temperature profile over time

6.4.8 Pressure Plate Setting

Each time the Huey MUX board is replaced, the left and right Cartridge Pressure Plate settings default to a value **1700**. Therefore, engineers are required to check the pressure plate values and adjust, if necessary.

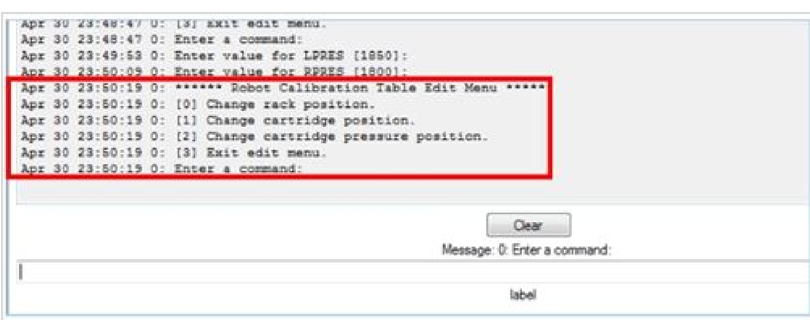
Procedure

1. Log in as **FSVC** user.
2. Navigate to the Field Service screen under **Maintenance** tab.
3. Click the **Script-O-Matic** button to launch Script-O-Matic.
4. In Script-O-Matic, click **Run Script** under Huey.
5. From the drop down menu, select **motor.script** and click **OK** to execute the script.
6. Type in **loadcaltable** and press **Enter**
7. Type in **printcaltable** and press **Enter**. This displays the calibration table showing the left and right cartridge pressure motor position.

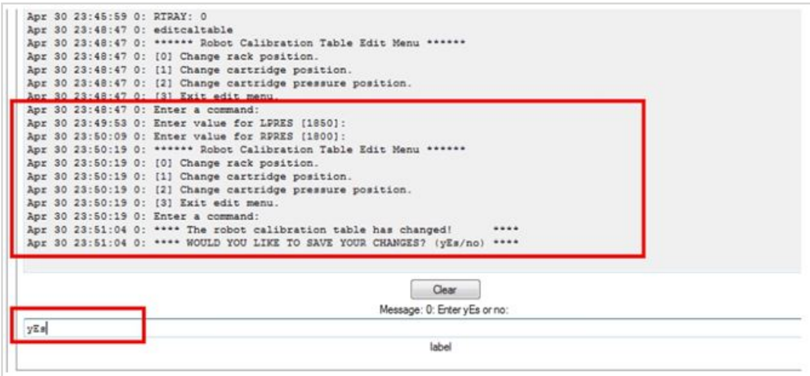


8. Verify that the value shown for the **LPRES** and **RPRES** matches the value written inside the instrument. The example below shows **LPRES = 1700** and **RPRES = 1600**.

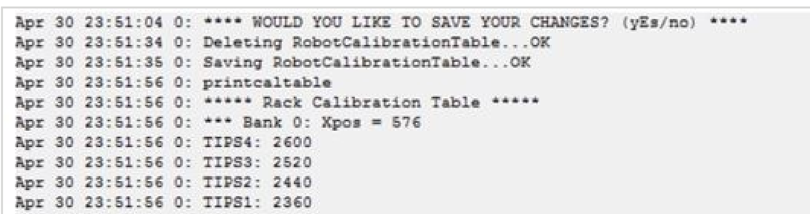
9. To change the value of the pressure plate setting, type in **editcaltable** and press **Enter**. This action brings up the **Robot Calibration Table Edit Menu**.
10. Type **2** to select **Change Cartridge Pressure** position, and press **Enter**.



11. When prompted for the LPRES, enter **RPRES**.
12. Following the instructions in the **Debug** window, enter the corresponding values for the pressure plates, type **yEs** (exactly as shown), and press **Enter** to save the changes.



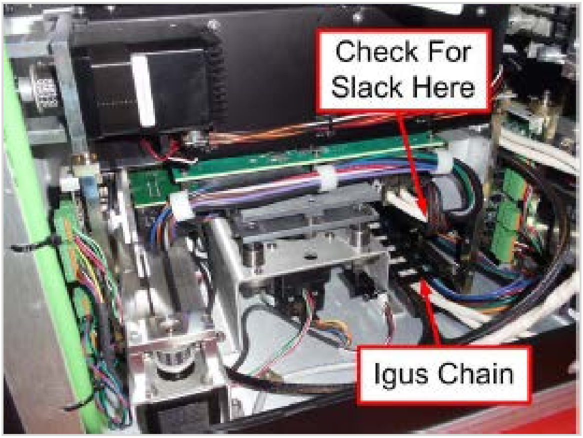
13. After saving, return to calibration table again by typing in **printcaltable** and pressing **Enter**.
14. Verify that the changes took effect.



Note: Reboot both the instrument and the All-In-One after exiting from Script-O-Matic.

6.4.8.1 Cable Tension Check

1. Power off the instrument and close the trays.
2. Check the cable bundle behind the **Heater MUX** assembly for cable tension by physically moving the tray up and down and confirming that it can move freely along the bearings. Be sure to reach and test the back portions of the **Heater MUX** assembly, don't just test the motion from the front.
3. If there is resistance:
   a. Carefully loosen the cables at the back of the tray. These cables are held at the back of the MUX board with three plastic clips. To loosen the tension remove the bundle from the clips and carefully pull on the cables in the IGUS chain for more slack. Be sure replace the bundle in the clips after loosening is complete.



b. Check the rear home flag (in the back-left corner of the Heater/MUX assembly) and confirm it is not interfering with any components on the circuit board. If it is, use a Philips head screwdriver to loosen the flag, move it away from the component it is interfering with, and then re-tighten the screw.

> **Note:** If this flag position is changed, tray alignment (the next step in this procedure) must be performed afterward.

Heater MUX Cable Bracket

Instruments with serial number CT1653 and greater (excluding CT1654) are produced with this cable bracket to mitigate uneven pressure on the heater MUX by redirecting cable tension to the tray assembly. This does not change the install/replacement procedure for heater MUX boards. Cables should have enough slack to comfortably plug into the boards with ease, while remaining neatly tucked into the bracket.

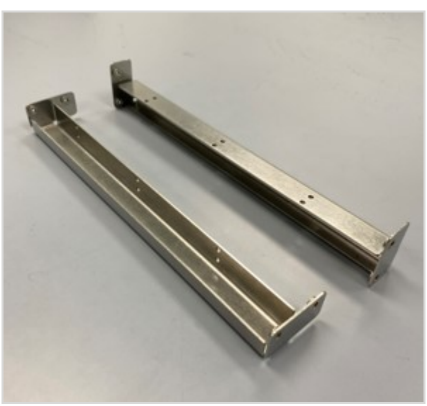


Fig: MUX Cable Bracket

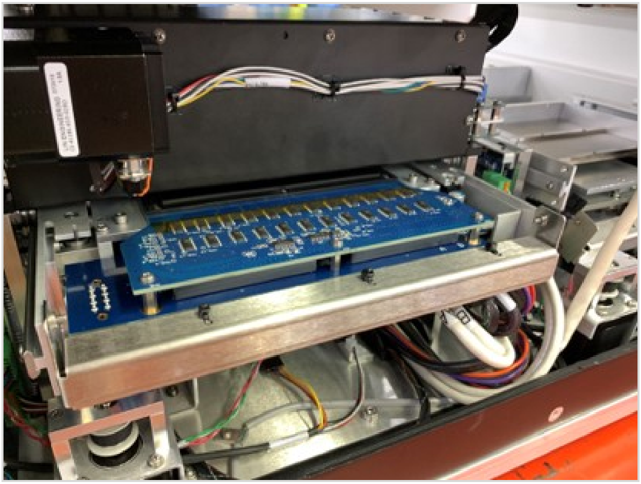


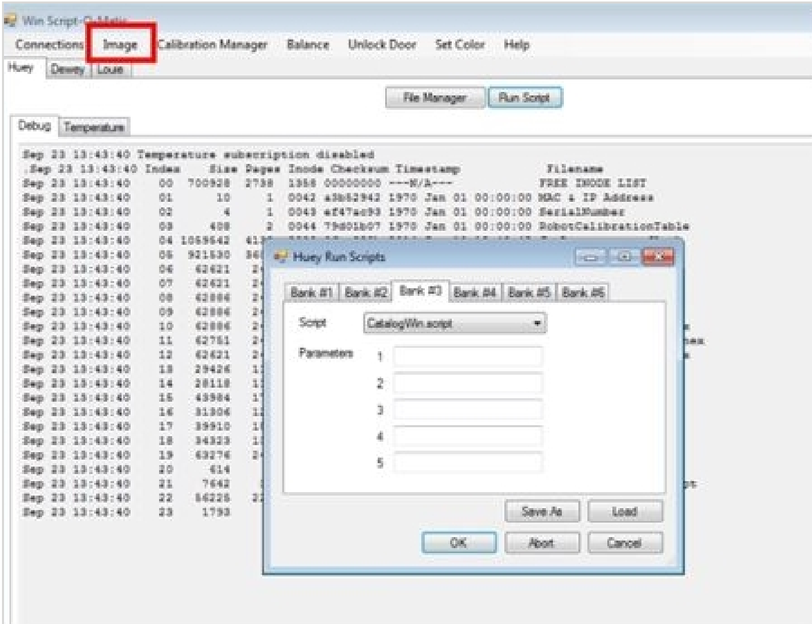
Fig: MUX Cable Bracket Installed

6.4.9 CatalogWin.Script

The **CatalogWin** script allows capture of images of what the barcode scanner is reading at each catalog location. This helps service engineers troubleshoot cataloging errors by inspecting the images of the reagent barcodes and verifying that the barcodes are aligned properly within pre-defined areas.

Procedure

1. Log in as **FSVC** user
2. Navigate to the Field Service screen under **Maintenance** tab.
3. Click on the **Script-O-Matic** button to launch Script-O-Matic.
4. Once in Script-O-Matic, go under **Huey** and click on the **Run Script** button.
5. Navigate to **Bank #3**, select **CatalogWin.script** from the drop down menu, and press **OK** to launch the script. The script will move the Z-Gantry to each cataloging location and pause.



6. Click the **Image** button located at the top of the window **Script-O-Matic** application window to take an image of the reagent barcode.

> **Note:** Image process may take up to **30 seconds** after clicking the image button without acknowledgement to complete.

7. A beep indicates that image was taken by the barcode reader and then the image displays.
8. Inspect the image to verify that the barcodes are aligned properly within the white box or is completely visible in the field of view (**FOV**) of the image taken. If the barcodes are out of the FOV, loosen the two screws holding the barcode reader and title the barcode reader towards the bottom of the gantry. Retighten the screws and retake the image.

9. Once the review of the image is complete, close the image, and press **Enter** to move the robot to the next cataloging location.

   If the barcode is not inside the **white box** (faint rectangular outline at top center of picture), the drawer-out flag sensor may need adjustment.

10. Once the barcode images has been verified, go to **Run Script** and hit the **Abort** button.

> **Note:** Reboot both the instrument and the All-In-One after exiting from **Script-O-Matic**.

6.4.10 Reader Normalization

Definitions

- **MUX**: Multiplexer – Used in reference to the various subsystem components within a BD MAX system. Within the BD MAX there are three MUX boards: Huey, Dewey and Louie. Dewey and Louie MUXes contain identical hardware and are responsible for PCR heater and optics control on the left and right sides of the instrument, respectively.

- **Green Card**: Solid green cartridge used to normalize optics (700002941).
- **Red Card**: Solid red cartridge used to normalize optics (700002940).
- **IP Address**: Internet Protocol Address – A four number identifier, each of which contains one to three digits, with a single dot (.) separating each number or set of digits (e.g. – 192.168.12.145) that is used to address the various boards within the BD MAX system.

Required Materials

- Handheld 2D Barcode Scanner (**SAP# 443391**)
- NormRatio.sql file (**placed on the global SharePoint site**)
- 1x USB Thumb Drive (**≥1GB**)
- 1x Empty BD MAX PCR Cartridge (**SAP# 437519**)
- 1x Set of BD MAX Reader Normalizer Cards (**SAP# 443685**)

6.4.10.1 Procedure Empty Fill Check

1. Log in as Field Service.
    a. Press the **Log In** button.
    b. Enter **FSVC** in the **User Name** field.
    c. Enter the Service Password in the Password field.
2. Select the **Maintenance** tab.
3. Select the **Tasks** tab.
4. Insert the USB Thumb Drive into the BD MAX instrument All-In-One.
5. Place an Empty BD MAX PCR Cartridge on the left Reader Tray.
6. Close the instrument door.
7. Press **EFC Test A** and wait for the report to be generated.
8. Press the **Export** button to save the report to the Thumb Drive.
9. When the left tray is ejected, unlock and open the instrument door.
10. Move the empty BD MAX PCR Cartridge to the right Reader Tray
11. Close the instrument door.
12. Press **EFC Test B** and wait for the report to be generated.
13. Press the **Export** button to save the report to the Thumb Drive.
14. When the right tray is ejected, unlock and open the instrument door.
15. Remove the empty BD MAX PCR Cartridge.

16. Using a BD Laptop, open each Empty Fill Check report and review the report for the following potential issues:
    a. One or two lane(s) that exceeds the threshold – this may be indicative of contamination either on the surface of the Heater / MUX board or in/around the reader aperture. Attempt cleaning of the Heater / MUX board and/or outside of the reader with optical grade lint-free cleaning cloths such as lens paper and 70% isopropyl alcohol.
    b. If any cleaning is needed, go back to step 7 and repeat the Empty Fill Check on the side (s) that was/were cleaned.
    c. If, after cleaning, one or more of the values fall outside of the established threshold on the User Interface, follow your regional escalation process to speak to your regional specialist as the reader or Heater/MUX may need to be replaced.
    d. If a series of lanes (e.g. – the entire upper or lower row) are near or exceeding the threshold this may be indicative of a problematic cartridge lot. If possible, attempt to re-run the Empty Fill Check procedure with a different cartridge lot.

6.4.10.2 Procedure Normalizer Ratio Check

Warning: DO NOT advance to this section until Step 1 - Empty Fill Check is complete. If a reader is replaced and this section is executed prior to running the Empty Fill Check, you will receive invalid results for this portion of the reader normalization process resulting in un-necessary re-normalization or replacement of readers.

Note: Check to ensure that the date and time on the instrument is correct. The date and time shown on the AIO must be correct before proceeding or the software may load the incorrect normalization tables after normalization is completed.

Navigate to D: drive and check if the D:\maintenance folder exists. If it doesn't, create a folder in D: drive with the name "maintenance".

1. Press the **Log In** button.
    a. Enter **"FSVC"** in the **User Name** field.
    b. Enter the Service Password in the Password field.
2. Place a USB into the side of the AIO containing the file named **NormRatio.sql**.
3. The NormRatio.sql file can be found on the global SharePoint site; found under **Global Product Support > Software and Workstation Image > Software > Max > Service Software**.
4. Select the **Maintenance** tab.

5. Select the **Field Service** tab.
6. Using the scroll bar on the right side of the screen, scroll down and press the **SQL Server Mgmt.** Studio button. This operation will launch Microsoft SQL Server Management Studio, allowing access to the instrument database.
7. When the Connect to Server window appears, press the Connect button (or press **ENTER** to continue).
8. From the main menu, select **File > Open > File (CTRL + O).**
9. Verify that the file filter drop down reads "SQL Server files (*.sql)".
10. Navigate to the USB and find the file named **NormRatio.sql** and press the Open button. The SQL query for calculating the reader Normalizer Ratios will open within the application.
11. Press **F5** to execute the SQL query.
    - The query results will be displayed in a results table with the following columns (see screenshot and section definitions).
    - The **NormRatio.sql** query will generate a CSV output file of the results that were displayed to the screen.
    - This file will be stored in the following location: **D:\maintenance\NormRatio.csv**.

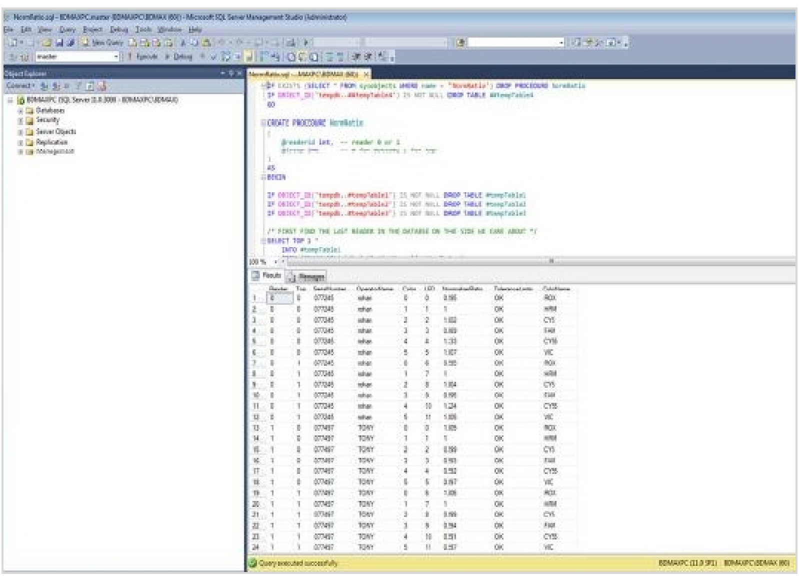


Fig: ReaderNorm.SQL file executed

- **Reader**

  0 – Reader A; **1** – Reader B
- Top

  0 – Bottom LEDs; **1** – Top LEDs
- **Serial Number** - the reader Serial Number

- **Operator Name** - the operator that last renormalized the given reader
- Color

  0 – ROX

  1 – Unused

  2 – Cy5

  3 – FAM

  4 – Cy5.5

  5 – VIC
- LED

0	ROX Bottom	6	ROX Top
1	Unused Bottom	7	Unused Top
2	Cy5 Bottom	8	Cy5 Top
3	Fam Bottom	9	FAM Top
4	Cy5.5 Bottom	10	Cy5.5 Top
5	VIC Bottom	11	VIC Top

- **Tolerance Limits**

  OK – The given optics channel meets acceptable normalizer ratio limits.**RENORMALIZE** – The given optics channel has drifted and requires renormalization.
- Color

ROX	585
Cy5	630
FAM	475
Cy5.5	680
VIC	530

12. If any of the values in the **ToleranceLimits** column read **RENORMALIZE**, proceed to **Reader Normalization** for the given reader. If **BD MAX Reader Normalizer Cards** (SAP# 443685) are not available, consider reader replacement.
13. Close SQL Server Management Studio.

6.4.10.3 Procedure Reader Normalization

Preparation

- Wear latex gloves while handling normalization cartridges to prevent and minimize the transfer of oils and debris to the surface of the normalization card, which may affect the signal intensity readings.
- Verify the calibration date on the normalizer cards. The date of manufacture/test is printed on each normalizer card (YY-MM-DD). Verify that the cards have not expired before use. Do not use cards that are older than 1-year from the date of manufacture. Record the normalizer card serial number in the work order notes.
- When not being used in this normalization procedure, the normalization cards should be stored and kept in an air-tight and light resistant envelope or container at all times.
- Inspect the normalization cards for any signs of damage or contamination. This may include melted areas of the card, scratches, marks, dust, debris, or residue. If the cartridges are dirty, clean the areas around the label with a damp, non-abrasive cloth wetted with water.

> **Note:** Do not expose the cartridges to bleach or solvent based cleaners other than limited exposure to Isopropyl alcohol (less than 99%).

> **Note:** If the card shows visible damage or contamination that cannot be easily removed with a damp, non-abrasive cloth, replace the normalization card prior to executing this procedure.

Normalization Procedure

1. Press the **Log In** button.
   a. Enter **FSVC** in the User Name field.
   b. Enter the Service Password in the Password field.
2. Select the **Maintenance** tab.
3. Select the **Field Service** tab.
4. Using the scroll bar on the right side of the screen, scroll down and press the **Script- O-Matic** button to launch Script-O-Matic.
5. When Script-O-Matic launches, press the **Connections** button from the main menu.
6. If renormalizing Reader A, press the middle **Connect** button to connect to Dewey. If renormalizing Reader B, press the last **Connect** button to connect to Louie.
7. Press the **Close** button to close the MUX Connections window.

8. If renormalizing Reader A, select the **Dewey** tab. If renormalizing Reader B, select the **Louie** tab.
9. If the instrument door is closed, press the **Unlock Door** button in Script-O-Matic.
10. Press the **Run Script** button.Select opticsUtility.script from the Script drop-down menu and press OK to continue. If the opticsUtility script is not displayed in the drop-down menu, stop, andfollow the Global Escalation Process and escalate to the System Support Specialist. Click on the text entry field in the **Win Script-O-Matic** screen and type **2** and **ENTER** to select **Field Normalization**.

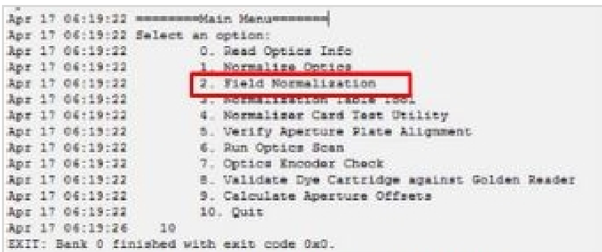


Fig: Field Normalization in Script-O-Matic

11. When prompted **Enter target side (dewey/louie)**, type dewey for the left side or type louie to select the right side of the instrument. Then press ENTER.
12. When prompted **Verbose Mode?**? [Y/N] (Default = N), press **ENTER** without entering any text to select non-verbose mode by default.

> **Note:** Verbose mode does not affect the method used to determine the normalization constants. This mode provides the ability to output informational messages that may be useful for Engineering to debug and root cause any potential problems with the Normalization routine.

13. When prompted **Enter the Operator Name**, enter your full name and press **ENTER**.
14. Remove the Red Normalizer card from its protective pouch and place it, label side up, on the desired MUX.
15. When prompted, scan the 2D barcode on the card label using a 2D barcode scanner. Characters from the barcode will be displayed in the user entry field. After scanning the barcode, wait several seconds until all characters have been displayed.
16. If the script does not advance automatically, it may be necessary to press **ENTER** after scanning the label to continue.
17. If the barcode fails to scan, contact your Regional Support Specialist.

> **Note:** Some 2D barcode scanner models will automatically press **ENTER** . With these models, the script will advance automatically.

Fig: Barcode example highlighting 2D barcode

18. When the tray opens, return the Red Normalizer card into its protective pouch and close the zippered seal on the pouch.
19. Remove the Green Normalizer card from its protective pouch and place it (label side up) on the desired MUX.
20. Scan the 2D barcode on the card label.

> **Note:** Failures must be accepted prior, or else the drawer will not open.

21. When the tray opens, return the Green Normalizer card into its protective pouch and close the zippered seal on the pouch.
    a. If **no warning messages** are displayed after the Green Normalizer card has been ejected, enter **Y** when prompted "Do you want to write normalizer data to the optics head? [Y/N]" to write the new normalization values to the optics head and **jump to Step 23** below; otherwise, continue to the next step.
    b. If warning messages are displayed, follow the instructions in "Handling Normalization Errors and Warnings" on page 498 to clear each warning from the screen. **If any warning indicates an AF value greater than the upper AF limit, cancel the Normalization; the reader should be replaced at the end of this procedure.** Follow Table 10 below. Only the assays using the channel that are out of limit will be affected. The other can continue to be processed.
22. Enter **Y** and **ENTER** when prompted **Do you want to write normalizer data to the optics head? [Y/N]** and then enter a **Y** and **ENTER** again when prompted **Are you sure you want to write normalizer data to the optics head? [Y/N]**.
23. The script should returns to the optics **Utility.script** Main Menu.
    a. If you wish to renormalize the other reader at this point, type **2** and **ENTER** to select **Field Normalization** then repeat Steps 11 through 26.
    b. If wish to exit, type **10** and press **ENTER** to exit the optics **Utility.script**.
24. Proceed with Instrument Qualification following "Qualification Run" on page 322

6.4.10.4 Handling Normalization Errors and Warnings

WARNING – AF for led X out of bounds!

Observe each Attenuation Factor (AF) warning. Review each AF warning against the table below and press **ENTER**to continue past each warning.

> **Note:** The reader should be replaced if any AF value for and LED exceeds the Upper Maximum for that LED in the table below.

Table: Optical Channel AF Limit

Optic Channel	LED Number	Upper AF Limit
ROX	0 and 6	2.00
Cy5	2 and 8	2.00
FAM	3 and 9	1.50
CY5.5	4 and 10	2.00
VIC	5 and 11	1.50

WARNING – N for led X out of bounds!

Look at each normalizer value (**NV**) warning. If the normalizer value has fallen below the lower Limit or higher limit, **accept and proceed with the normalization** (The normalization will correct the values to the normal). pay extra attention to the subsequent qualification runs. Then, observe the qualification runs for EVALs due to a color channel being too noisy.

Linearity Warning

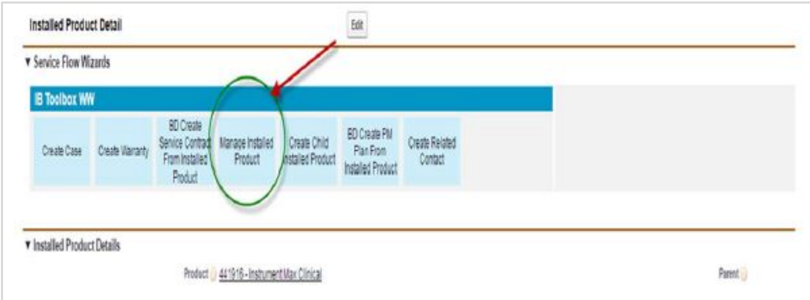
Linearity warning can either be caused by loose hardware, bad control board, bad home sensor, or dirty normalizer card/tray. If Linearity Warning occurs, clean the tray and normalizer card, properly secure all cable connections, and then try renormalizing again. If the same warning appears again, then replace the reader. If the error does not return, then the reader can be left as is and proceed with qualification.

6.4.10.5 Tracking in ServiceMax

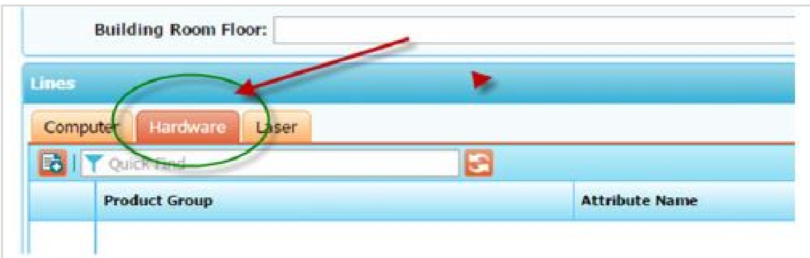
> **Note:** An attribute is now in ServiceMax to track the instrument that have Reader Ratio performed, and Reader Normalization.

Follow these instructions to utilize this attribute:

1. Navigate to installed product detail – select **Manage Installed Product** in The Service Flow Wizard.



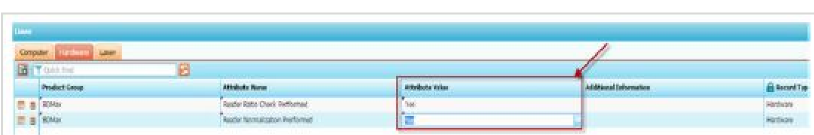
2. Scroll down to the bottom of the page and select the **Hardware** tab.



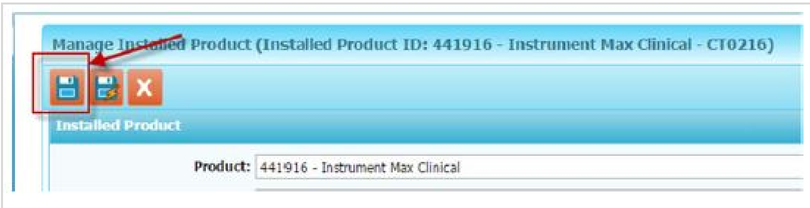
3. Click the **Add** a row icon, then click the **drop-down**, and then select **BD MAX** for the **Product Group** field.

4. After the BD MAX Product Group has been selected; then select the attribute name **Reader Ratio Check Performed** and **Reader Normalization Performed** in the scroll down.

5. Then select the attribute value **Yes** or **No**.



6. Then select navigate to the top of the page and click **Save**.



6.4.11 Load Cartridge Check

Use the **LC_UDP.script** (**Load Cartridge User Defined Protocol**) to validate the proper transfer of fluid from the strip to the PCR cartridge. By entering the proper parameters, the Load Cartridge step of a run can be performed separate from Sample Prep and PCR, which saves approximately two hours.

The Load Cartridge Test can be completed with the Load Cartridge Kit (445028) to avoid wasting snap ins and tips in an entire qualification kit.
Requirements

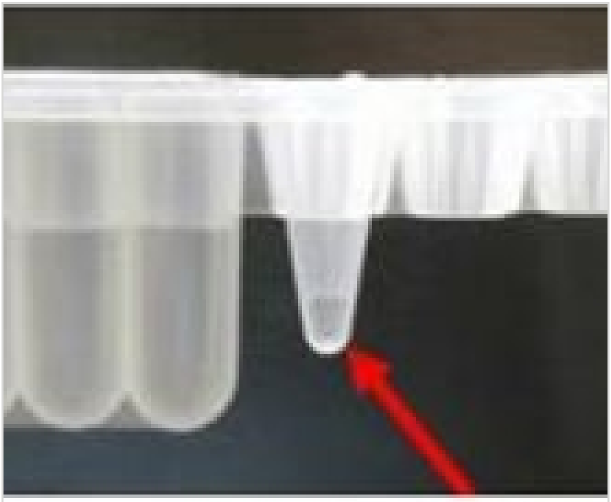
- Up to **24** Strips from BD MAX™ Instrument Qualification Kit (**SAP Catalog No.444048; standard BD MAX™ kit size**)
- **1** or **2** Micro Fluidic Cartridges (**SAP Catalog No. 437519; box of 24**)
- Load Cartridge Test Kit (**445028**)

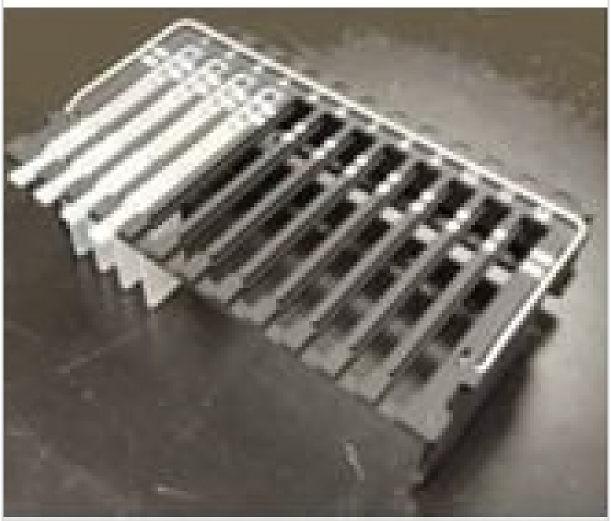
Run Load Cartridge Test in Script-O-Matic

Use one test strip for each lane being tested. In this example, four lanes are tested.

1. Obtain and use proper protective equipment (i.e. gloves, safety goggles, lab coat, etc).
2. Remove the needed number of conical tubes from the Load Cartridge Test Kit. For example, if testing 4 lanes, 4 conical tubes will be needed.
3. Snap in one conical tube into position 4 of the URS.
4. After completing Load Cartridge Test, do not discard the URS.
5. Add approximately **25 µL** of fluid to the third or empty snap in that is pre mounted on the strip.
6. Examine each URS to ensure that there are no bubbles in the snap-in; t URS should also contain a small, **175 µL** pipette tip, in the number **four** position of the strip. The **LC_UDP.script** attempts to pick up **12 µL** from this snap in and transfer it to the PCR cartridge.
7. Place the rack with the prepared Unitized Reagent Strips into the instrument.
8. Place a PCR cartridge in the corresponding reader.

9. From Script-O-Matic, run an **init.script** to initialize the instrument before performing this test.





10. Select the LC_UDP.script from the Robot (Huey) MUX board for each bank to be run.
    - Bank 1 is A1 to A4
    - Bank 2 is A5 to A8
    - Bank 3 is A9 to A12
    - Banks 4 to 6 repeat on the B side.
11. Use the arrow to the left of the bank number to open up the additional options.
    - There are five lanes.
    - The first four correspond to the four rack strips (example in bank 1, Lane 1 is A1, lane 2 is A2, lane 3 is A3, and Lane 4 is A4).

- The fifth Lane is used to determine top or bottom cartridge row. If left blank it defaults to **TOP** row. Typing in the word **BOTTOM** selects the bottom cartridge row.

12. From the right hand drop down menu select DNA-1 Type3 (E1TYPE3) for each lane being tested
13. Continue to enter each strip position to be tested. Once complete, select the **Launch** icon.
14. When the script is launched, the Z head moves and picks up **12 µL** of fluid with the **#4 small tip** from the number three snap. It then moves to the cartridge and aspirate the fluid into the corresponding micro fluidic channels.
15. Observe that the correct volume is picked up and transferred and that the associated cartridge chambers are properly filled.

> **Note:** Reboot both the instrument and the All-In-One after exiting from Script-O-Matic.

Run Empty Fill Check in GUI

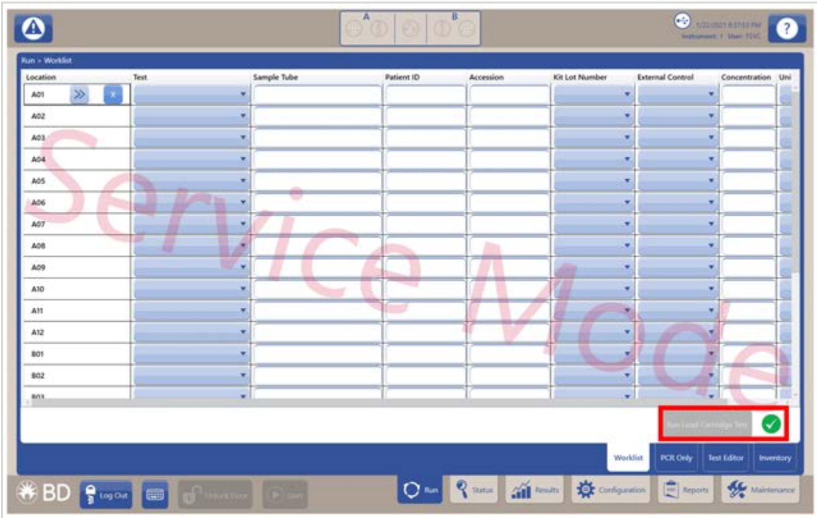
For **software version V4.50 and above**, the **Load Cartridge Test** function allows the FSE to run the **Load Cartridge Test** right from the instrument GUI.

The test:

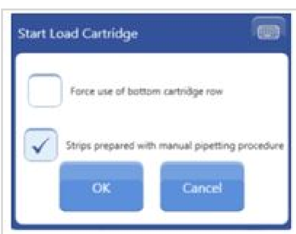
- Performs an **Empty Fill Check;**
- Does **not** include a run ID for the load cartridge test.
- Does **not** add data to the Result screen
- Defaults to using the cartridge top row (but has an option to use the bottom row);
- Defaults to manual pipette mode (but when unselected the test runs a shortened sample prep script).

The **24 Sample Worklist** mode must be enabled for the **Load Cartridge Test** to run in the GUI.

1. Log in as **FSVC** user.
2. Navigate to the **Worklist** screen under the **Run** tab
3. Check if any pending tests are configured and backup the database if so.
4. Navigate to the **System** screen under the **Configuration** tab.
5. Under Display Options, check the Use 24 Sample Worklist box and click Save.
6. Navigate to the **Environmental Variables** screen under the **Maintenance** tab, enable the variable **Allow Incomplete Worklist** and click **Save**. This allows a worklist to be configured without sample buffer tube barcodes and patient ID number.



7. From the **Worklist** screen, set up the reagents in the instrument and configure the run.
8. Select the **Run Load Cartridge Test** button located at the lower right side of the screen.
9. When the **Start Load Cartridge** window appears, select the desired parameters and click **OK**.



10. Observe the instrument as the instrument performs the load cartridge process.

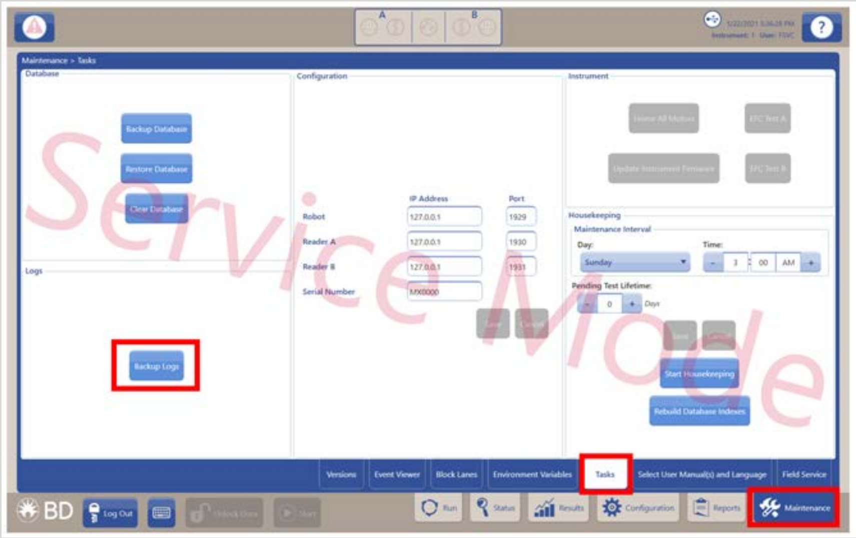
> **Note:** If the worklist had pending tests, restore the database once Load Cartridge Test completes.

11. Navigate to the **Environmental Variables** screen under the **Maintenance** tab and reset the environmental variables to default.
12. Configure the worklist back to the customer's initial format.
13. Log out of the system as **FSVC** user and verify that the Service watermark is no longer present on the screen.

6.4.12 Log Files

Acquire Log Files

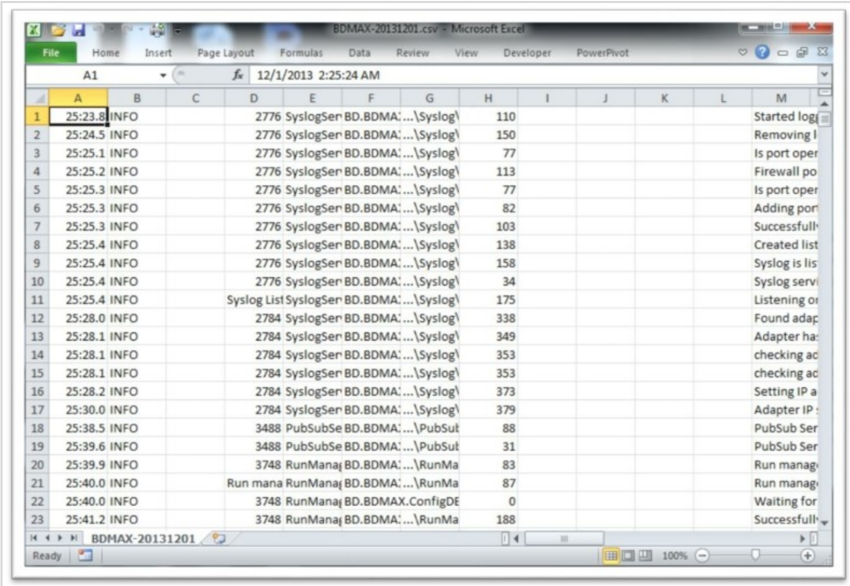
BD MAX log files are downloaded and stored as CSV files. They can be obtained from the **Maintenance >Tasks** screen. In the lower right is the screen.



> **Note:** Connect a USB key to the All-In-One and click the **Backup Logs** to save the log files. The CSV files are broken up by date.

Read Log Files

Find the correct date and right-click on the file. Use the **Open with Menu** option and open the file in MS Excel.



BDMAX-20131201.csv - Microsoft Excel

A1 | 12/1/2013 2:25:24 AM

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	25:23.8	INFO		2776	SyslogSer	BD.BDMA:	...\Syslog\	110					Started log
2	25:24.5	INFO		2776	SyslogSer	BD.BDMA:	...\Syslog\	150					Removing l
3	25:25.1	INFO		2776	SyslogSer	BD.BDMA:	...\Syslog\	77					Is port oper
4	25:25.2	INFO		2776	SyslogSer	BD.BDMA:	...\Syslog\	113					Firewall po
5	25:25.3	INFO		2776	SyslogSer	BD.BDMA:	...\Syslog\	77					Is port oper
6	25:25.3	INFO		2776	SyslogSer	BD.BDMA:	...\Syslog\	82					Adding por
7	25:25.3	INFO		2776	SyslogSer	BD.BDMA:	...\Syslog\	103					Successfull
8	25:25.4	INFO		2776	SyslogSer	BD.BDMA:	...\Syslog\	138					Created list
9	25:25.4	INFO		2776	SyslogSer	BD.BDMA:	...\Syslog\	158					Syslog is lis
10	25:25.4	INFO		2776	SyslogSer	BD.BDMA:	...\Syslog\	34					Syslog servi
11	25:25.4	INFO		Syslog List	SyslogSer	BD.BDMA:	...\Syslog\	175					Listening or
12	25:28.0	INFO		2784	SyslogSer	BD.BDMA:	...\Syslog\	338					Found adap
13	25:28.1	INFO		2784	SyslogSer	BD.BDMA:	...\Syslog\	349					Adapter ha:
14	25:28.1	INFO		2784	SyslogSer	BD.BDMA:	...\Syslog\	353					checking ac
15	25:28.1	INFO		2784	SyslogSer	BD.BDMA:	...\Syslog\	353					checking ac
16	25:28.2	INFO		2784	SyslogSer	BD.BDMA:	...\Syslog\	373					Setting IP a
17	25:30.0	INFO		2784	SyslogSer	BD.BDMA:	...\Syslog\	379					Adapter IP :
18	25:38.5	INFO		3488	PubSubSe	BD.BDMA:	...\PubSut	88					PubSub Ser
19	25:39.6	INFO		3488	PubSubSe	BD.BDMA:	...\PubSut	31					PubSub Ser
20	25:39.9	INFO		3748	RunManag	BD.BDMA:	...\RunMa	83					Run manag
21	25:40.0	INFO		Run mana	RunManag	BD.BDMA:	...\RunMa	87					Run manag
22	25:40.0	INFO		3748	RunManag	BD.BDMAX.ConfigDE		0					Waiting for
23	25:41.2	INFO		3748	RunManag	BD.BDMA:	...\RunMa	188					Successfull

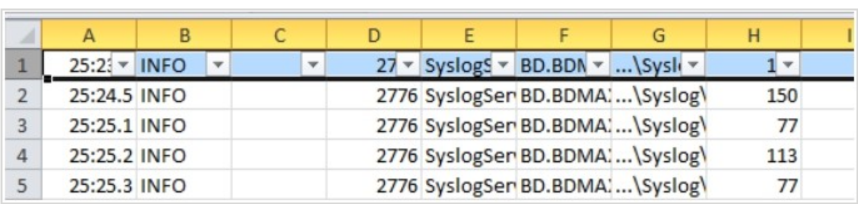
BDMAX-20131201

Ready 100%

Select the first row, click the **Data** menu, and then click the **Filter** icon. This activates **drop down** arrows for every column and enables filtering of log file data.

Note: Since each log file covers just one date, there is no date column.

Column A reflects the time of day. Actual Log File entries are in Column M.



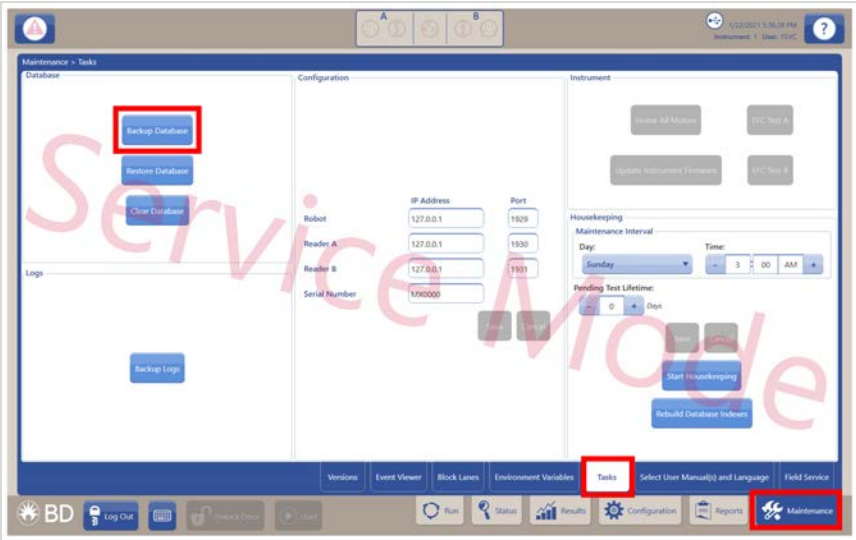
	A	B	C	D	E	F	G	H
1	25:2:	INFO		27	SyslogS	BD.BDN	...\Sysl	1
2	25:24.5	INFO		2776	SyslogSer	BD.BDMA:	...\Syslog\	150
3	25:25.1	INFO		2776	SyslogSer	BD.BDMA:	...\Syslog\	77
4	25:25.2	INFO		2776	SyslogSer	BD.BDMA:	...\Syslog\	113
5	25:25.3	INFO		2776	SyslogSer	BD.BDMA:	...\Syslog\	77

6.4.13 Database

The BD MAX database is downloaded and stored as a MS Sequel Server database.

Acquire the Database

To acquire, insert a USB key, then open the **Maintenance >Tasks** screen and click **Backup Database**.



> **Note:** Opening a database requires a computer with MS Sequel Server installed. All BD MAX™ Windows-based All-In-Ones have this installed.

Read Database

The easiest way to read a database is to use the restore function on a BD MAX™ All-In- One. The SQL Server on the All-In-One can be used to review the data.

- When the database is open, MS Sequel Server displays content in multiple panes.
- The left pane contains a list of database tables located under **Database >BDMAX_ SQL>Tables**. Right-click a table to display the top 100 entries and the MS SQL query.
- The top center pane displays the SQL and allows you to modify it.
- The bottom center pane lists the data results derived from the SQL.

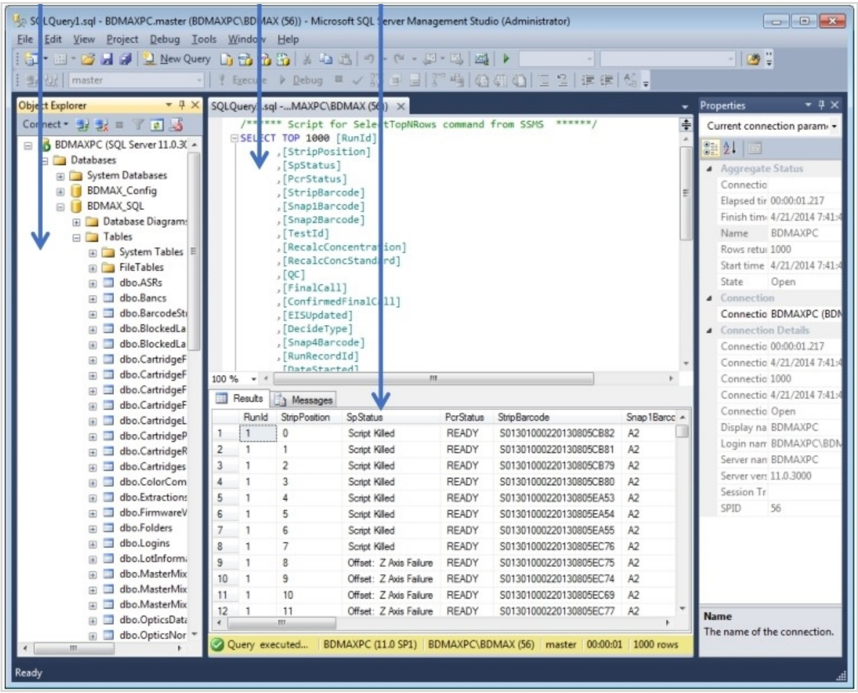


Fig: Sample Database

6.4.14 Initialization Test

This test is used to validate operation of various mechanical movement systems of the BD MAX™ Instrument and to re-home the instrument motors. Depending on how the test is run, feedback is reported in the Script-O-Matic Debug window and/or in the messages log file.

Initialization

When sample prep starts, the first script run is **init.script** as:

Running'Init.script'builtfrom'Init.k'

When the **init.script** runs, it homes all motors and sets the BD MAX™ instrument to the start position.

The **init.script** is run quite often as it validates the home sensors and sets the robot to a good known position.

Run Initialization from User Mode

1. Open the **Maintenance** Tab, **Tasks** Sub-tab.
2. Select **Home All Motors**; the instrument performs an initialization.
3. View results in the log file.

Run Initialization from FSVC Mode

1. Start **Script-O-Matic** and connect to the Robot (Huey) MUX board.
2. Refresh the directory in the **Scrip-O-Matic** File Manager.
3. From any bank, launch the **init.script.** Initialization runs and then the script exits back to the Script-O-Matic interface.
4. View results in the **Script-O-Matic Debug** window.

Review Initialization Results

Initialization writes the same information to both the Script-O-Matic Debug window and the messages log file.

Following initialization, review results and confirm:

1. All motors initialized successfully:
   - Gantry Motors; Y, X, Z
   - Strip Motor, Pumps 1, 2, 3, and 4
   - Left and Right Reader Tray and Pressure plate
   - Left and Right Extractor Magnets.
2. Homing All Motors
   - Y-Gantry moved 500 steps
   - Left and right trays moved to 5000 steps
   - X-Gantry moved to position 2860
   - Moving Left and right Magnets to position 2050
   - Investigate any discrepancies using the motor script.

6.4.15 Gantry Alignment

The Gantry alignment adjustments to the robot are made in eight locations and adjustment values are used to calculate all deck positions.

Use the **calrack.script**, which is resident on the Huey MUX board, to align the robot and the two calibration plates (SAP Catalog No. 435251 and 435256).

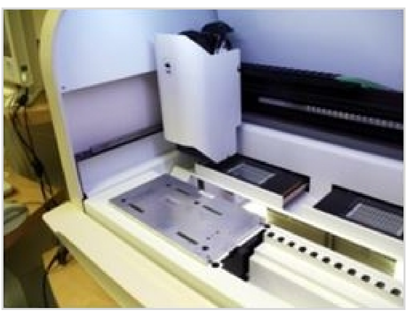
Required materials

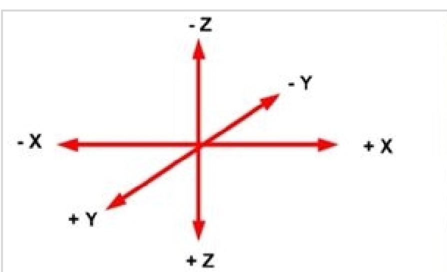
- Rack calibration plate
- Reader calibration plate.

Note: Do NOT perform gantry alignment (calrack), using consumables and racks.

Launch Calrack Script

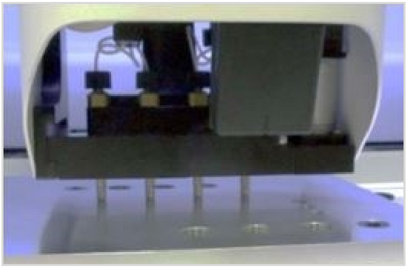
1. Use **Script-O-Matic** to select and launch the **calrack.script** from the **Huey MUX board**.
2. Follow the instructions that appear in the **Script-O-Matic Debug** window.
3. Once the **calrack.script** places the rack calibration in the left rack position, press **Enter**.The robot moves the Z-Gantry over the left side slots on the rack calibration plate.
4. Log the X and Y position by entering an axis and a number.
   - Negative numbers move to the left and back.
   - Positive numbers move to the right and forward.
5. Align the left Z-Gantry nozzle with the center of the insert on the left edge of the rack calibration plate.





6. When satisfied with the positioning, enter a **q**; the Z-Gantry moves to the slots on the other side of the rack calibration plate.
7. Use the same procedure to align the right Z-Gantry nozzle with the center hole of the right insert.
8. When satisfied with the positioning, enter a **q** to advance to the Z-Height check
9. The Z-Gantry moves towards the center of the rack calibration plate and lowers the nozzle tips while monitoring the motor current. When the nozzle tips touch the plate and can no longer move down and the motor current changes, the encoder value where this happens becomes the Z-Height for the left rack position.

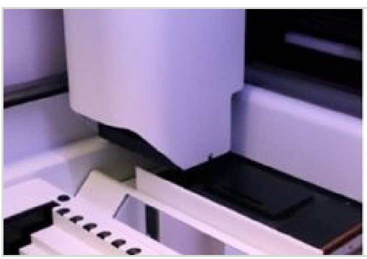
10. While the nozzle tips are on the calibration plate, ensure that all tips touch the plate and the Z-Head is parallel to the calibration plate. All four nozzles should be within 0.0015 inches of the calibration plate.



> **Note:** This step is automatic, requiring no manual intervention.

11. Press the **q** key when the **calrack.script** has finished the Z height adjustment.
12. The **calrack.script** moves the Z-Gantry out of the way to the **X=0 & Y=0** position, and moves the gantry to the right rack side of the calibration plate. The script then performs the calibration for the right rack and then for the left rack.

> **Note:** Readers use a different calibration plate with only one calibration point.

13. When the Z-Gantry moves over the left reader, the Z-Height is zero with the pump/manifold assembly at the top of its movement.
14. If necessary, enter **Z 4000** to move the Z-Head down closer to the plate.
15. The nozzles are now close enough to the plate to do an accurate calibration.
16. Calibrate the left reader to the left rack in the same manner, aligning the left nozzle tip to the center hole of the insert.

> **Note:** There is no Z-Height check for the readers.

17. Repeat the process for the right hand reader.
18. Once the right hand reader is calibrated, the **calrack.script** writes the new calibration values to the instrument and exits.

6.4.16 Pump Aspiration and Dispense Check

The Pump Check is used to verify proper operation of the liquid handling system on the BD MAX™ by aspirating two different volumes of liquid using two different tip sizes.

BD MAX System Software Version 4.70 and above:

A Pump Check is run from the **max_power_on_4SNAP.script** on the Robot (Huey) MUX board:

- The pump check test draws **900 µL** from a sample buffer tube and holds it for **60 seconds**.
- During this time, the tips are inspected for leakage and even fill levels across all nozzles at high volumes of fluid.
- The pump check also draws **10 µL** for comparison across all four nozzles of even pump aspiration at low volumes.

Requirements

4 Strips from BD MAX™ Qualification Kit (**SAP Catalog No. 444048**)

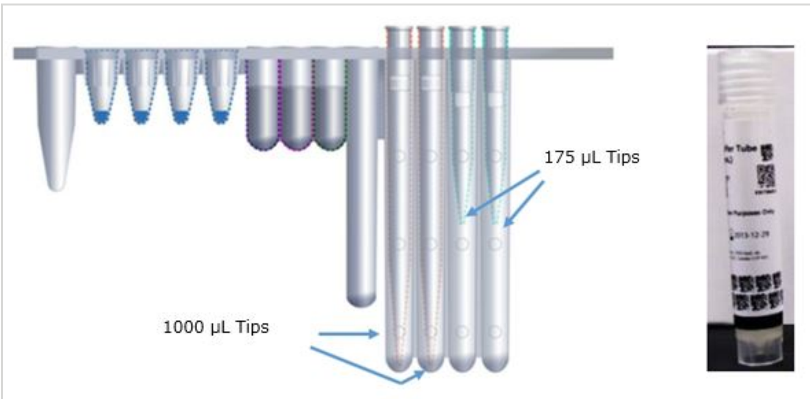
4 Sample Buffer tubes from BD MAX™ Qualification Kit (**SAP Catalog No. 444048**)

Procedure

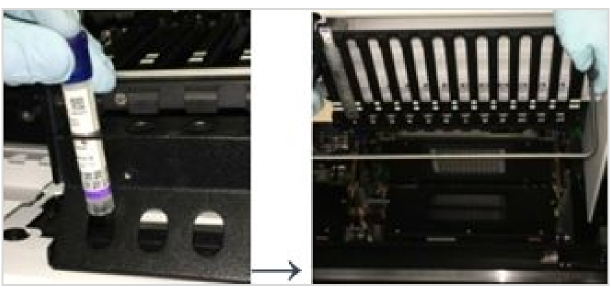
1. Remove the Z-Gantry facade (review **Module Replacement** for instructions) in order to observe the fluid levels in each tip.
    - Blank test strips and sample buffer tubes are normally used for this test. It is important that tips one and four be present in the strip and that the sample tubes being used have at least **1500 µL** in them. If using strips and tubes from a Qualification Kit, both requirements are met.

> **Note:** In the event that only expired reagents are available, they can be used for this test. Sample Buffer Tubes (**SBTs**) are prefilled with **1.5** mL of fluid.

2. Load **four** blank test strips in the first four lanes of a sample rack. Ensure there is a **1000 µL** tip in the tip storage closest to the reader and a **175 µL** tip furthest from the reader.



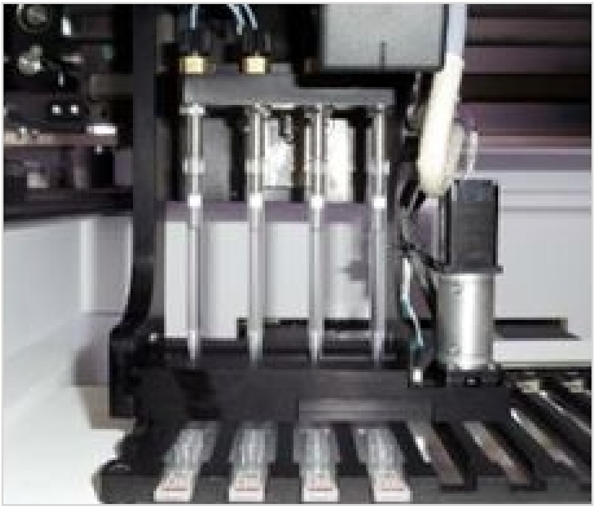
3. Place the tube in the first four rack positions.
4. Load the rack into the left side of the instrument.



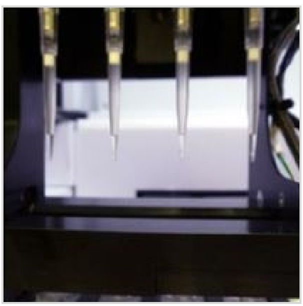
5. From Script-O-Matic, start the **max_power_on_4SNAP.script** from the Huey MUX board.
6. Select **Option [0]** to initialize the system.
7. Select **Option [4]** to home all motors.
8. Select **Option [6] Pump Check** and follow the instructions displayed in the Debug window.
   - The instrument picks up four **1000 µL** tips and aspirates **900 µL (0.9 mL)** of fluid from the sample tubes.

   Observe to confirm that all tips pick up similar volumes of fluid.
   - The fluid is held for **60 seconds** to permit examination for leaks. Continue after the **60 seconds** has expired.

- **900 µL (0.9 mL)** of liquid is dispensed to the waste container on each test strip.

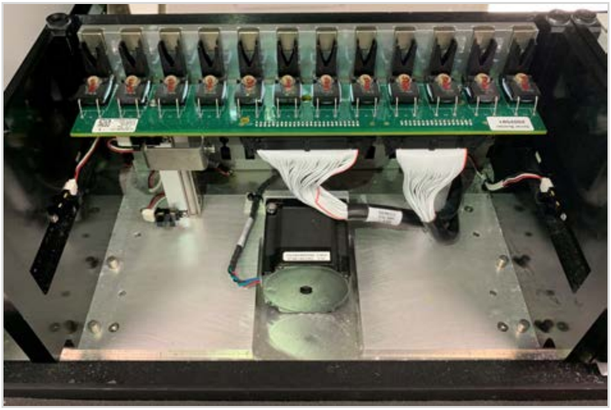


9. Inspect the tips to ensure all are all empty.
10. Press **ENTER** on the keyboard.
    - The **1000 µL** tips are returned and the **175 µL** tips are picked up. **10 µL** of fluid is drawn from the waste.
11. Inspect the tips to ensure sure they picked up similar volumes of liquid.
12. If any part of the pump test fails, examine the air lines and pumps for signs of wear.
13. Repeat as necessary. Repeated failures necessitate replacement of air lines and/or pumps.



6.4.17 Extractor Magnet Alignment

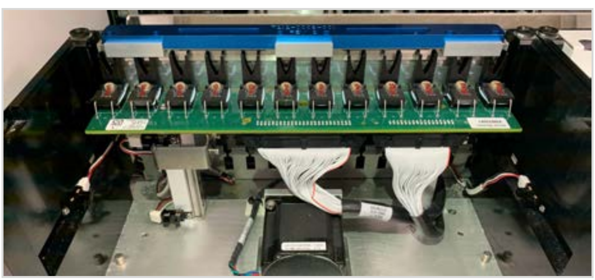
1. Carefully raise the magnet assembly by hand. To do this, pull up on the magnet holder while turning the white gear manually. Raise the magnets until the top of the magnets are even with the top of the heaters on the Gort board (Heater Block) sub-assembly.



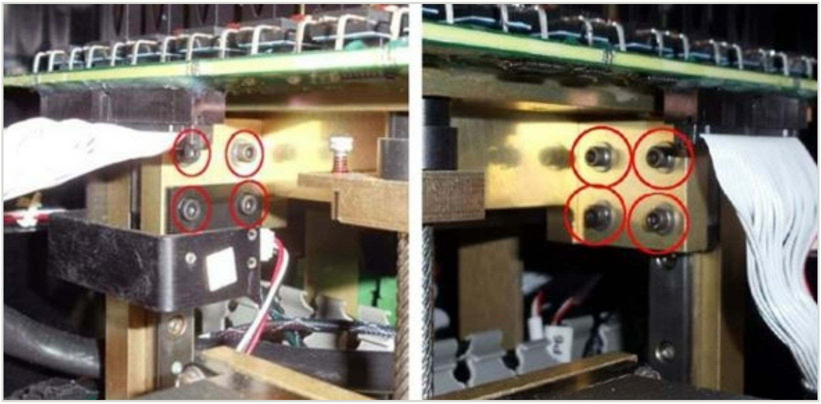
2. Insert the magnet alignment tool between the Gort Board Heaters and the Magnets. Ensure that you are using the correct tool number according to the magnet assembly version (3-magnet or 12-magnet).

   Note: If aligning the newer style assembly, DO NOT STRIKE any of the 12 magnets, as it may cause them to become loose from their fixtures).

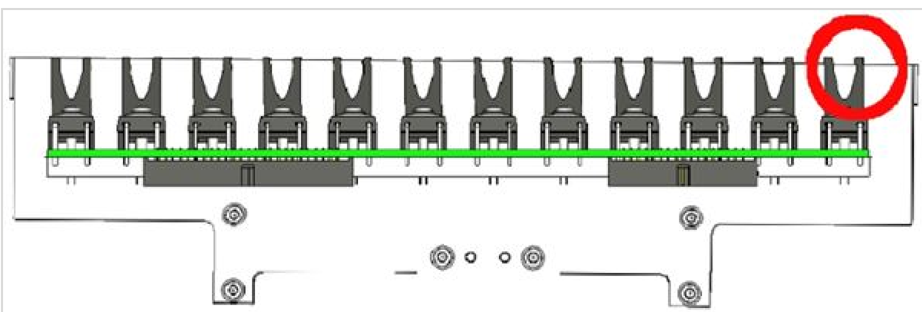
3. Slide the alignment tool to each end of the magnet sub assembly and try lifting it out.
   - If there is no frictional resistance, the magnets are too far from the heat blocks.
   - If the magnet alignment tool could not fit in, the magnets are too close from the heat blocks.

4. To adjust the gap between the magnet and the heat blocks, loosen the **8 screws** by **½ turn**, with the **3/32 inch Allen wrench**. There are **4 Allen screws** on each side, as shown in picture below.



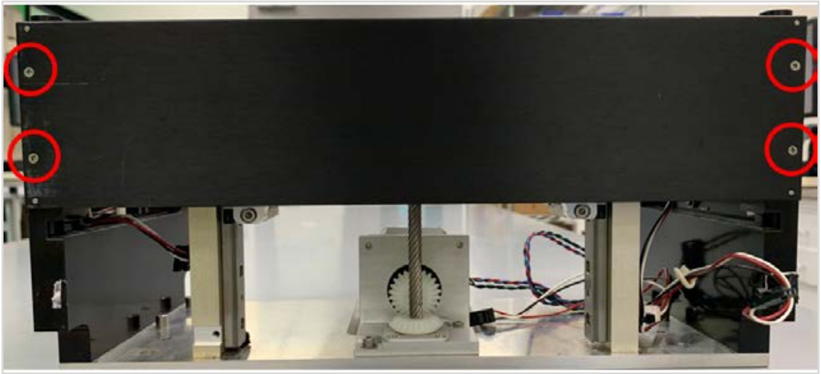
5. By moving the magnet, adjust the gap between the magnets and the heat blocks until the tool fits snuggly and only a slight bit of resistance is felt when lifting the tool.
6. When finish adjusting the gap, tighten the eight Allen head screws.
7. Gently raise the magnets until they touch the bottom of the rear part of the alignment tool
8. Check to see that the magnet assembly is level with the Gort heater blocks.
9. Check the entire length of the Magnet Assembly by moving the alignment tool from one end of the assembly to the other. If the alignment tool touches the magnet assembly on both sides then they are leveled.
   - If there is a gap on one side, the magnets need to be rotated slightly.



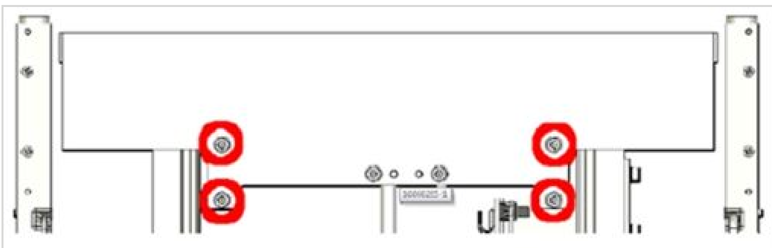
10. To rotate the magnet assembly, take out the Phillips screws to remove the back plate of the extractor module.

    If the back plate cannot be removed, move the magnet assembly down until you have access to the Allen screws.

Document: BDDSSGFS7422 Doc Type: ZIP Status: Released EFFECTIVE
Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

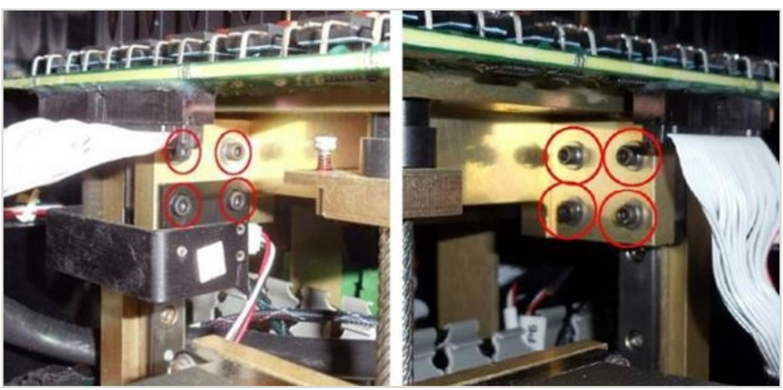


a. Loosen the **four Allen screws** on the back of the magnet sub assembly by **½ turn** and adjust the angle. There is only around **1/16** inch of play. After the magnet level is adjusted, tighten the screws and reinstall the extractor back plate.



b. Slide the alignment tool to each end of the magnet sub assembly and try lifting it out. If there is no frictional resistance, the magnets are too far from the heat blocks.

c. Loosen by **½ turn** the **eight Allen screws** shown (four on each side).



d. Moving the alignment tool to the left and right sides of the magnets, adjust the gap between the magnets and the heat blocks until the tool fits snuggly, i.e., with only slight resistance when lifting the tool. Verify that the magnets are in line with the GORT board heaters and are not tilted, using a level.

e. Tighten the eight Allen screws.

11. After aligning both extractor magnets, re-assemble the instrument.

12. Run the **init.script** from Script-O-Matic to ensure the magnets are working properly.

6.4.18 Magnet Height Correction

To provide BD service personnel worldwide with instructions on checking and **setting the height of the magnet assembly** during replacement of the magnets within the maglysis assembly and when contribution of magnet position to UNR results or instrument failures is suspected.

Required Materials

- Calibrated Calipers: Product #8647A82 from McMaster-Carr or equivalent
  - Measuring Range: **4 inches or greater**
  - Measuring Increments: **0.001 inches**
  - Accuracy: **±0.001**
  - Must be properly labeled with calibration sticker. Info should be entered into BMRAM by the regional calibration expert.
- 2.5 mm Allen Wrench
- 7/64 inch Allen Wrench.

Procedure

1. Remove necessary skins for procedure. In this step, you will be removing the **skirt, upper reader cover, lower reader cover, and lysis cover**. Refer to section "Instrument Skins" on page 197 to remove skins.
2. While the instrument is powered off, disconnect the left Gort Board Cable on both of the Mag/Lysis assemblies.**Note:** Ensure to grab the cable attachment point with 2 hands and remove gently to avoid damaging the connection.

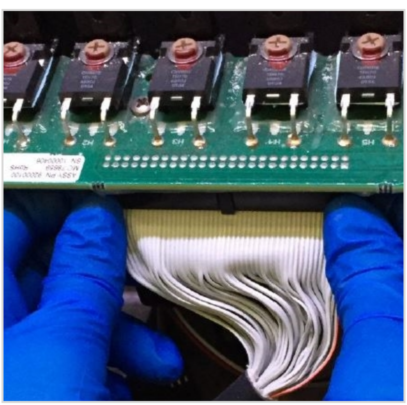


Fig: Removing the Gort Board Cable

3. Verify the Magnet Position. In this step, you will measure the distance between the magnets and the top of the heater block at 1100 motor steps (critical position in the workflow) using a caliper.
4. From the main **Script-O-Matic** window click **Run Script** while in the **Huey** tab.
5. From the **Huey Run Scripts** window click on the drop down box in the **Bank #1** tab.
6. Select **motor.script** from the list.
7. Run the motor to home and up to 1100 steps by following the steps below:

   > **Note:** The scripting below is for the left mag assembly, substitute rmag for the right

   a. Type **initmotor lmag** and press **ENTER** to initiate the motor.
   b. Type **setstate lmag 1** and press **ENTER**.
   c. Type **home lmag** then press **ENTER**.
   d. Type **ma lmag 1100** then press **ENTER**.
8. Measure and record the distance from the top of the Heater Block on the Gort Board to the corresponding magnet on the magnet holder.
9. Open the calipers and place the measuring head of the caliper against the top of the magnet assembly with the length of the caliper behind the **3rd heater block** from the left and the reading face of the calipers oriented towards the back of the instrument.

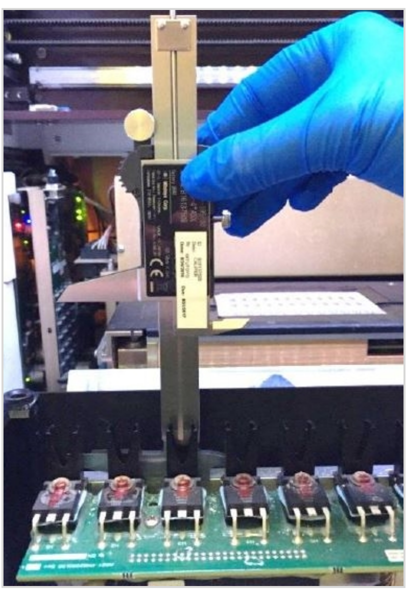
   

   Fig: Starting Position of Calipers (Front View)
10. Make sure that the caliper head is flat against the magnet surface and the body of the caliper is up against the heater block.

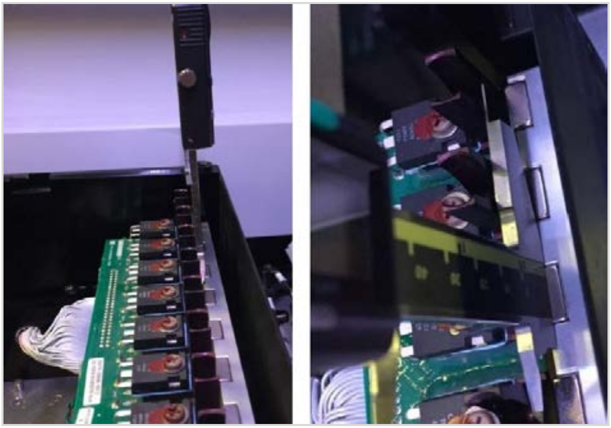


Fig: Caliper Position and Orientation side (on Left) and Back View (on Right)

11. Slide the body of the caliper to the top of the heater block by holding the plastic display and pressing downwards until the sliding portion of the caliper makes contact with the top of the heater block.

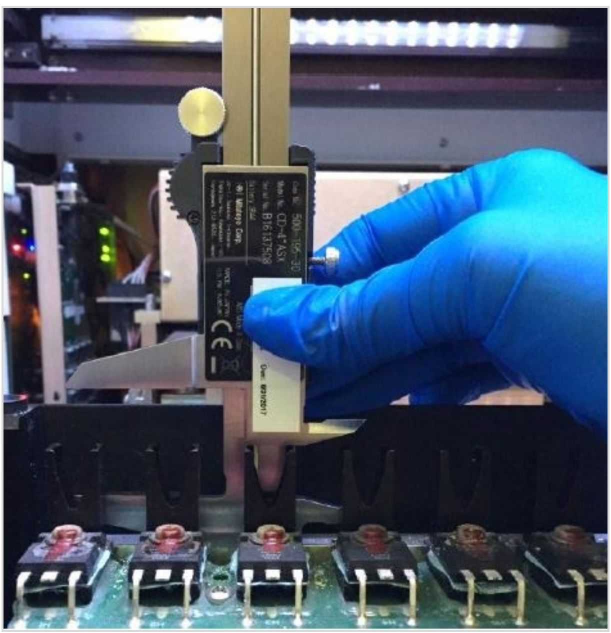


Fig: Caliper Measuring Position

12. Tighten down the set screw on the caliper so the reading is not affected by the pull of the magnets when removing the calipers.

Fig: Tightening the Set Screw

13. Remove the calipers by grabbing above the plastic display and pulling straight up. Read and record measurement for reference.

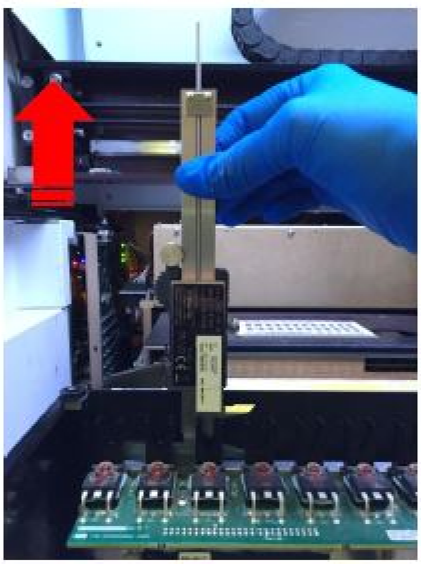


Fig: Removing the Calipers

14. Repeat the previous 3 steps (12 -14) at the 6th and 10th heater block, counting from the left.

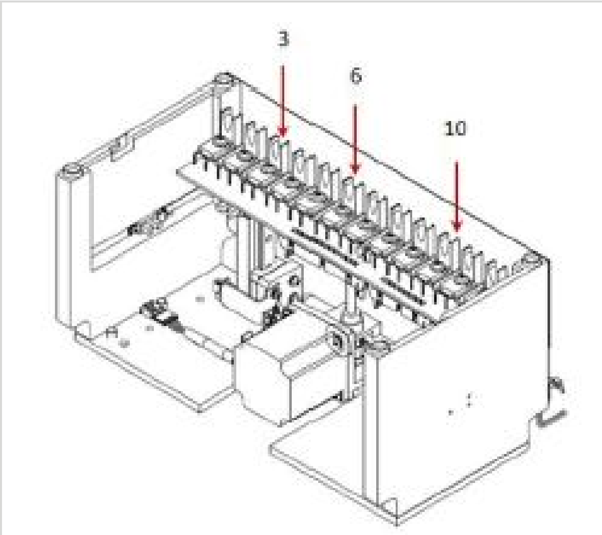


Fig: Measurement Locations for Heater Blocks 3, 6, and 10

If all 3 measurements fall within this range [.905 in. ± .020 in. (.885 in. - .925 in.)], no further action is required:

a. Power off the instrument; reconnect the Gort Board Cables to the Maglysis Assemblies and re-install the instrument skins.
b. Complete all required documentation (including calibration serial number of the caliper used to perform the measurements).

If any or all of the three measurements DO NOT fall between .905 in. ± .020 in. (.885 in. - .925 in.), follow the instructions in this section to set proper magnet position:

a. Adjusting the magnet position flag is only done if the magnets are found to be out of specification at one of the three measured locations. You will be setting the height of the magnet assembly when the flag trips the home sensor.

> **Note:** If Extractor Magnet Alignment using the blue magnet tool has not already been performed, perform it now. For detailed instructions refer to "Extractor Magnet Alignment" on page 513 in this service manual.

b. Adjust the position of the home flag to correct the magnet height. If the instrument has the newer style home flag utilizing a silver colored steel flag, as shown in below image, follow these steps:

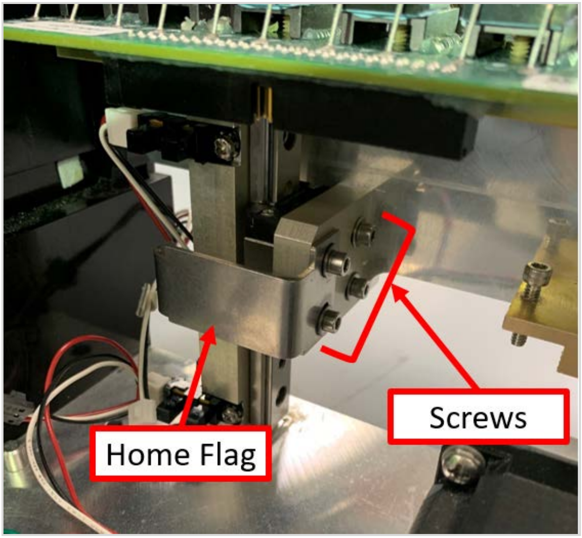
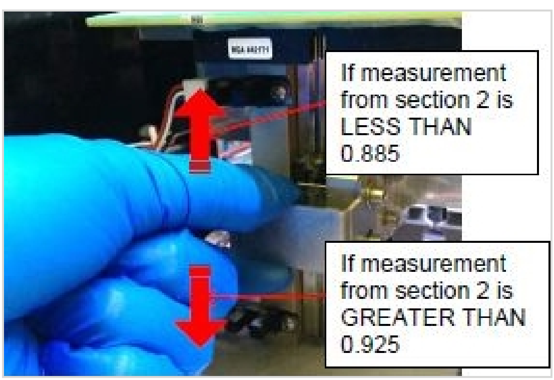


Fig: New Style Home Flag

i. If the reading for the magnet height is less than 0.885 inch, then the flag needs to be moved upwards. If the reading for the magnet height is greater than **0.925** inch, then the flag needs to be moved downwards.
ii. While holding the flag in place, loosen the screws holding the flag (see below image) slightly using the **2.5 mm Allen wrench** so that the flag is able to move along its slotted holes.
iii. Adjust the flag in the necessary direction such that the difference between the initial measurement and the target measurement is **.905 inch**. The flag should be near the middle of its adjustment range rather than near the top or bottom.



iv. Tighten down the screws. Proceed to Check Magnet Assembly Alignment.

If the instrument has the older style MagLysis Flag utilizing a screw directly in front of the motor, as shown in the below image follow these steps:

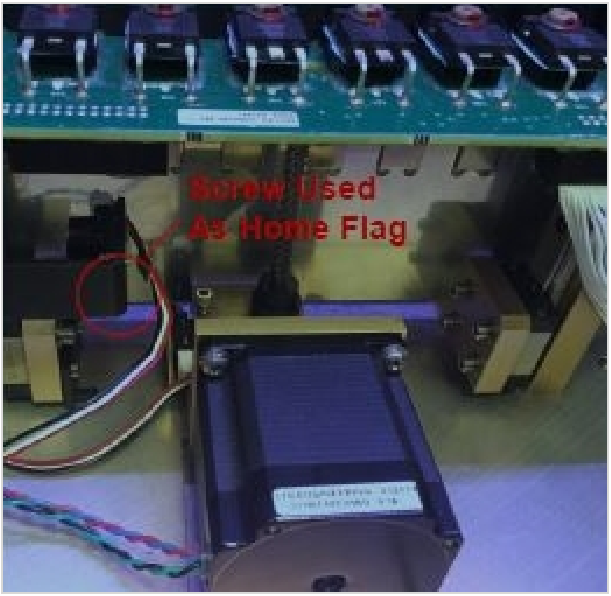
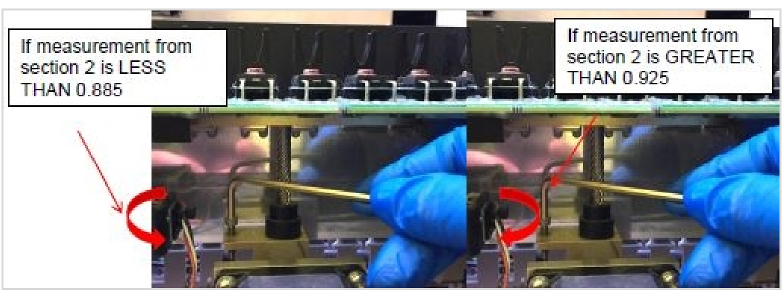


Fig: Old Style Home Flag

a. If the reading for the magnet height is less than **0.885 inch**, then the screw needs to be turned **counter clockwise**. If the reading for the magnet height is **greater than 0.925 inches**, then the screw needs to be turned **clockwise**.



b. Adjust the screw using the **7/64inch** Allen Wrench.

> **Note:** If any or all of the three measurements is not between .905” ± .020”(.885” - .925”), repeat required steps until the measurements meet specification. If there is a defect or damage to the Mag/Lysis assembly which prevents the ability to properly adjust the magnets, follow the procedure for defective parts to be issued a replacement assembly.

6.4.19 ResultsReprocessor Tool

The ResultsReprocessor tool extracts pertinent run metrics from a BD MAX database into a csv file that is stripped of all PHI (Protected Health Information).

Use the ResultsReprocessor tool to assist in troubleshooting and data analysis without transferring PHI. This tool is not meant to be shared with customers.

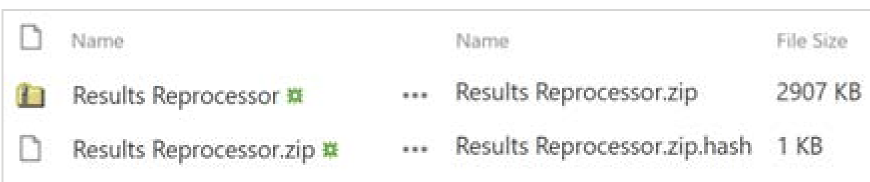
You need access to the Electronic File Transfer (EFT) site. To request access to the EFT, refer to BDLS7607.

Materials:

- 1 USB key; ResultsReprocessor folder will be downloaded onto the USB key.

Procedure:

1. Download the **ResultsReprocessor** folder onto a USB key. Copy the entire folder as one package since all files are needed to run the application.
    1. Access the folder at the Electronic File Transfer (EFT) site.
    2. Go to: SharePoint/IDS Documents/Molecular/BD Max/Service Software/Result Reprocessor:

2. Log into the BD MAX instrument as **FSVC**.
3. Insert the USB and navigate to **Maintenance > Field Service > Explorer**.
4. Locate the USB and open the **ResultsReprocessor** folder.

> **Note:** Do not execute the ResultsReprocessor while the instrument is running.

5. Double-click the **ResultsReprocessor** application.

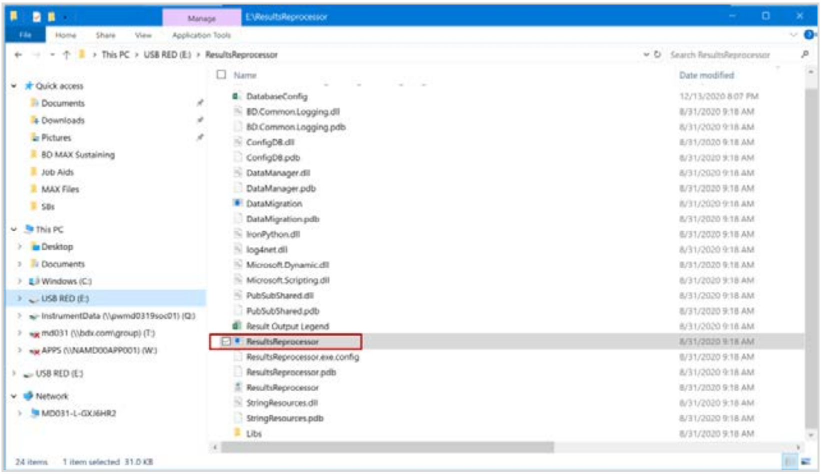


Fig: Run the ResultsReprocessor.exe application, not the ResultsReprocessor.exe.config or"ResultsReprocessor.pdb file

6. The command prompt opens and database processing starts.
7. Beginning with Run 1, the tool will sequentially extract key run data from each individual test result, while stripping all PHI.

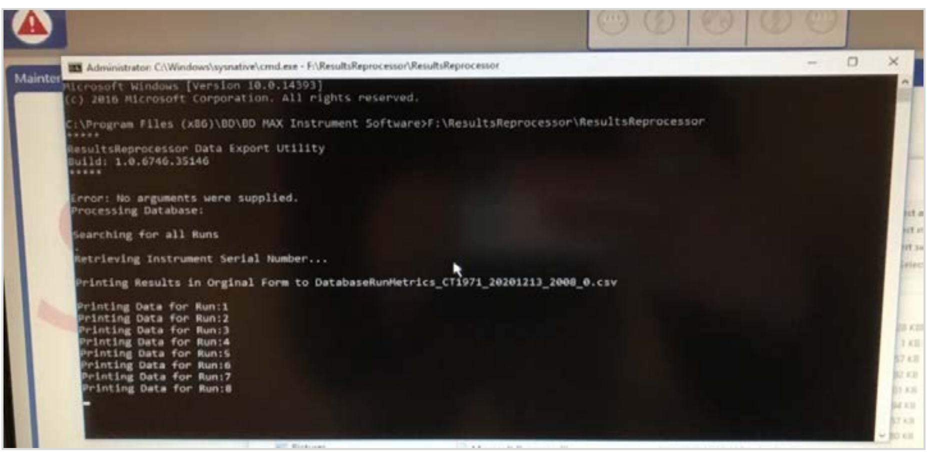


Fig: Running the ResultsReprocessor

8. After the last run is processed, the command prompt will display **Report output complete!** and automatically close the command prompt upon completion.

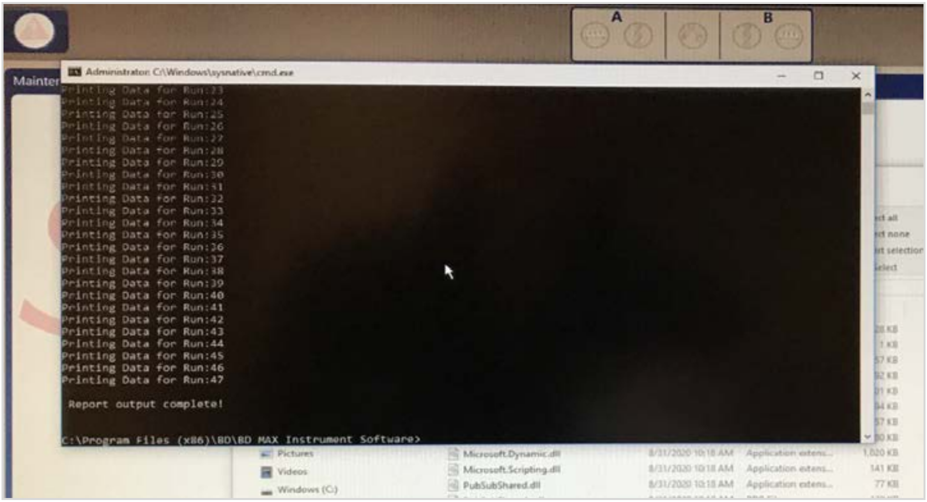


Fig: Completion of the ResultsReprocessor

> **Note: If the tool fails** to complete, then delete the entire ResultsReprocessor folder and go back to step 1 to re-download from the EFT site. If it fails again, escalate to Global Service.

9. After the **Report output complete!** message pops up, the complete output of the ResultsReprocessor tool will be available in the ResultsReprocessor folder and named with the following nomenclature – **DatabaseRunMetrics_[Serial #]_[Date]_[Time].csv**.
10. The **DatabaseConfig.csv** file will be appended with the date/time stamp and instrument serial number upon use of the tool.

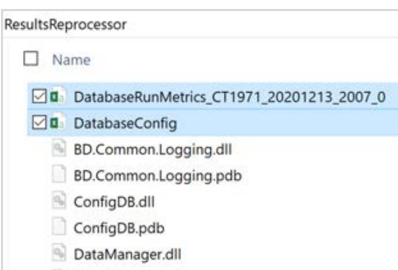


Fig: Output files form executing the ResultsReprocessor application

6.4.20 All In One Computer Troubleshooting

This procedure describes the process for ensuring the communication ports are assigned properly to enable LIS connectivity and proper order upload/download via LIS. UAR1 should be assigned to COM1.

This procedure applies to BD MAX instruments using the H6 S20 SSD AIO since the LIS port is set to COM1 in the BD MAX software.

This procedure must be completed at installation and after re-imaging new AIOs. Refer to the latest service bulletins on installing BD MAX Images and System Software (SW 5.20 and greater).

Fig: H6 S20 SSD All-In-One computer without BD branding on shell

This procedure will **not** apply to old variants of the AIO.

> **Note:** If previous data is available, be sure to backup the database and log files before troubleshooting.

Procedure

1. Make sure that no USB keys are connected during this process
2. If software has already been installed, log in as fsvc (password: halley) and open Explorer via the Field Service tab.
3. Navigate to **Control Panel > All Control Panel Items**.

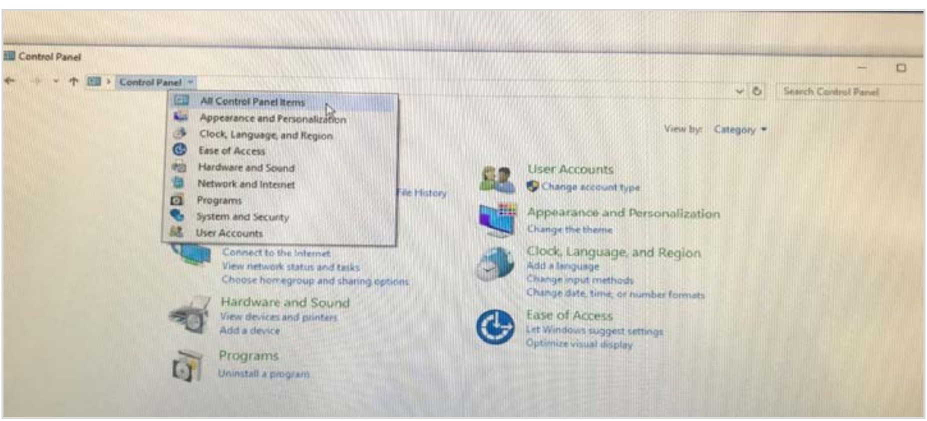


Fig: Field Service > Explorer > Control Panel > All Control Panel Items

4. Select Device Manager.

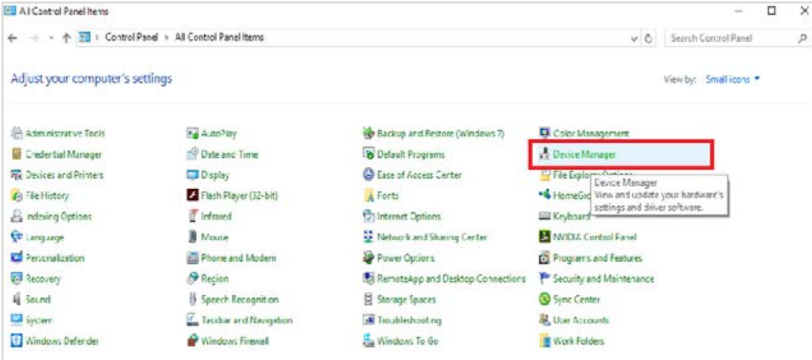


Fig: Selecting Device Manager

5. Expand **BDMAXPC -> Ports (COM & LPT)**.

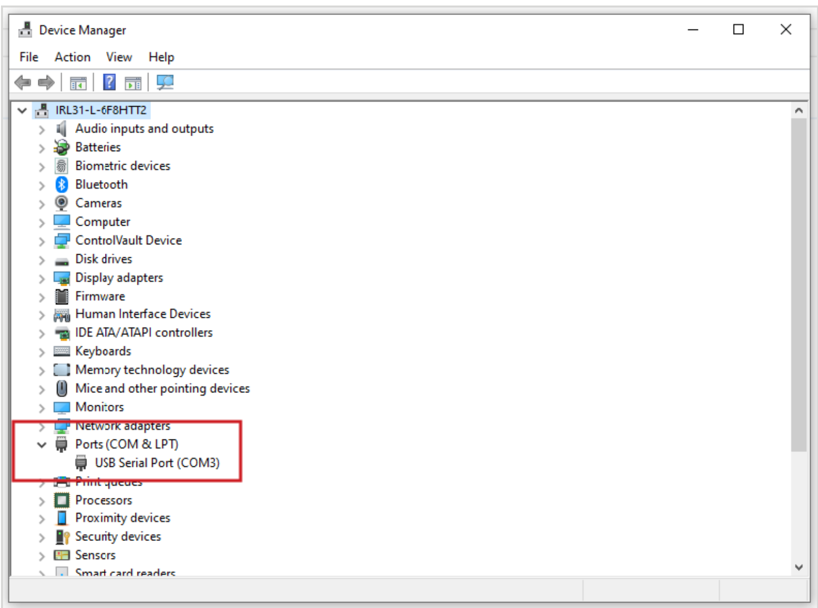


Fig: Communication Ports

6. Right-click on the Port containing **COM1** and select **Properties**.

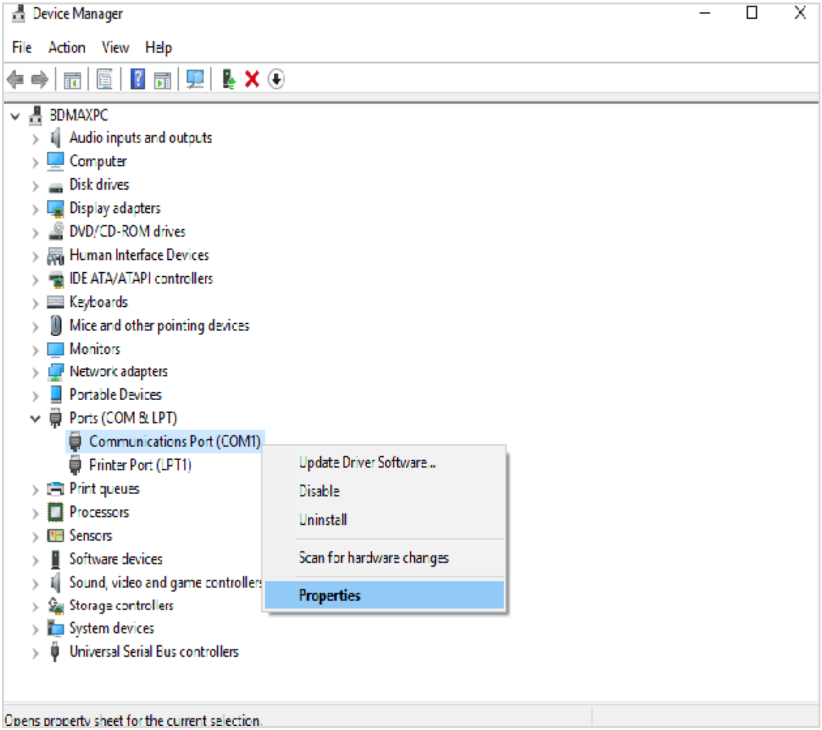


Fig: Selecting COM Port Properties

7. Navigate to the **Port Settings** tab and click **Advanced...**.

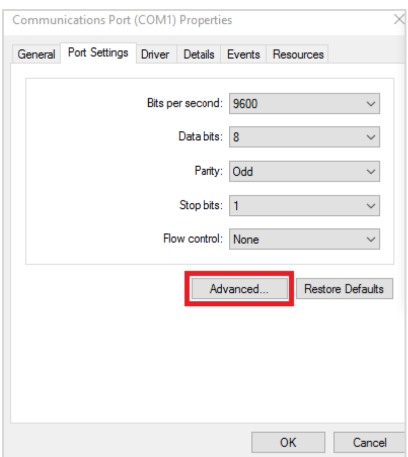


Fig: Selecting Advanced COM Port Properties

8. Select **COM20** in the COM Port Number drop-down list.

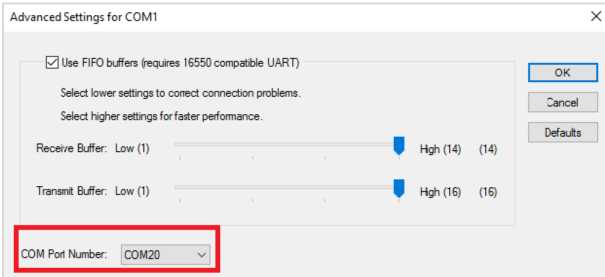


Fig: Changing COM Port Number

9. Click **OK** in the Advanced Settings for COM1 window.
10. Click **OK** in the Communications Port (COM20) Properties window.
11. In Ports (COM & LPT) right-click on any Communications Port and select **Properties**.
12. Navigate to the **Details** tab.
13. Select **BIOS device name** in the Property drop-down list.
14. Note the Value. If the Value does not contain **UAR1** repeat steps 11-13 for other COM Ports.

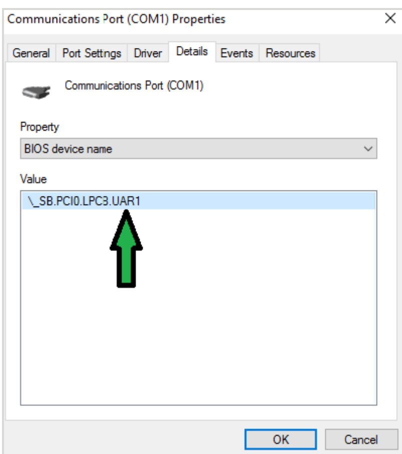


Fig: BIOS Device Name

15. Navigate to the **Port Settings** tab and click **Advanced...**.
16. Select **COM1** in the COM Port Number drop-down list
17. Click **OK** in the Advanced Settings for COM<COM Port Number> window.
18. Click **OK** in the Communications Port (COM1) Properties
19. Close the Device Manager
20. If any Device Manager settings were changed, restart the AIO before proceeding.

6.4.20.1 Additional Checks

Additional AIO troubleshooting checks:

"Unable to open COM…"

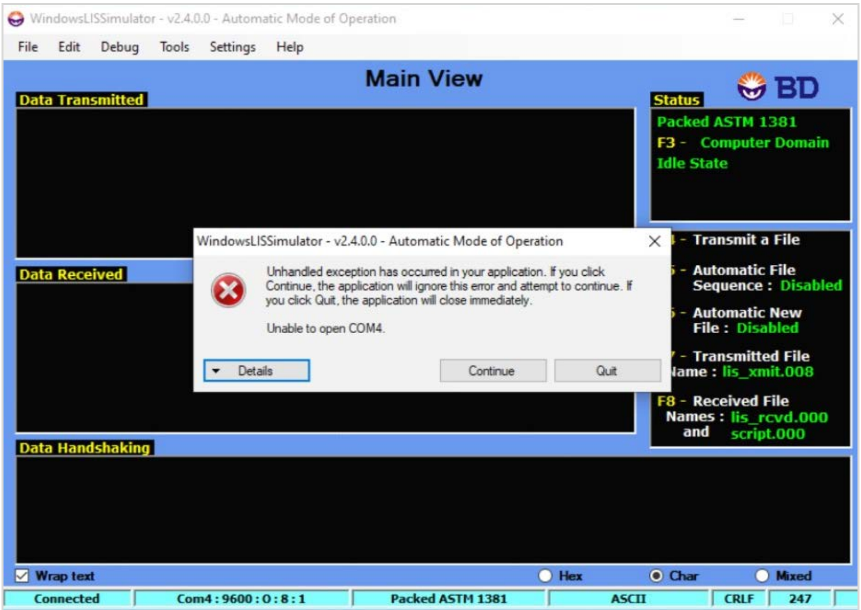


Fig: Unable to open COM error

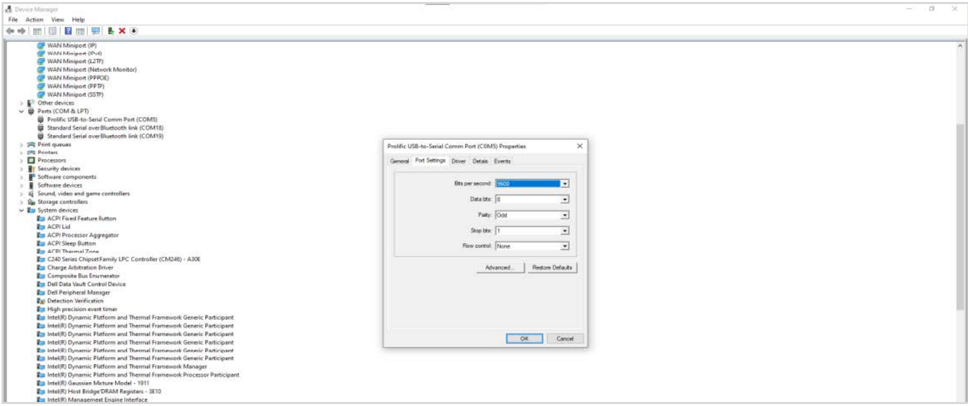
Often due to mismatch of COM ports on Laptop/PC and Application within it.

- Check if COM1 is being used by other application. For example, if two instances of LIS application are open, both of them try to use the same port.
- When the LIS cable is plugged in, the device manager should show the "Prolific USB-to-Serial Comm Port(COM(#))".
- If any Device Manager settings were changed, restart the AIO before proceeding.

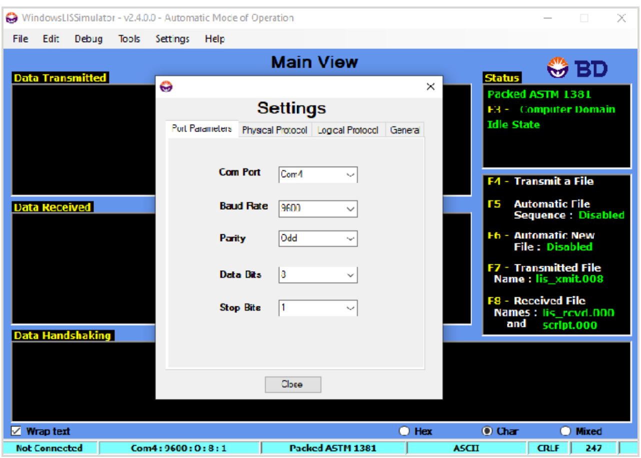
Physical Port Settings Match

- Physical LIS Configurations should match on all four locations. (If any changes are made, restart AIO before proceeding):

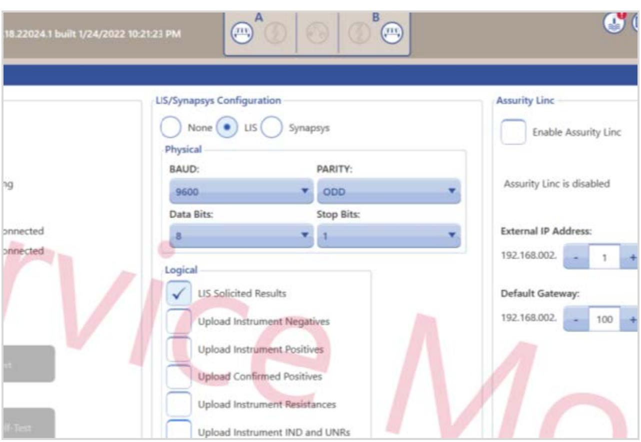
LIS application hosted Laptop/PC Device Manager & AIO Device Manager



LIS Simulator



BD MAX > External Devices > Physical LIS Configurations



6.4.20.2 General Troubleshooting

This applies to previous AIO variants as well

Note: If previous data is available, be sure to backup the database and log files before troubleshooting

Soft Reboot – for GUI freeze events

- To perform a soft reboot of the AIO and software, press the **ALT+F4** on the keyboard.
- This will not affect the instrument, even if it is in the middle of a run.
- The user will need to log in again

Power Cycle

- Attempt a power cycle of the AIO and instrument.
- Turn on the instrument first and then the AIO.

Reimage/Upgrade Software

- Follow the associated service bulletin to reimage the AIO.
- After reimaging, **wait until the command prompt pops up** before inserting the SW key.
- This will clear the database.

CMOS Reset

Repeatedly press the CMOS micro switch in the undercarriage of the AIO to perform a factory reset of the AIO. If the software does not load, follow these steps:

- Press **DEL** during boot up to access setup.
- Toggle to the **BOOT** tab.
    - Change boot mode select to “Legacy”
    - Disable the fast boot
    - Ensure secure boot is disabled
- Press **F10** to save and exit. The AIO should then boot up the image and software.

6.5 ZBA Handheld Barcode Reader Configuration

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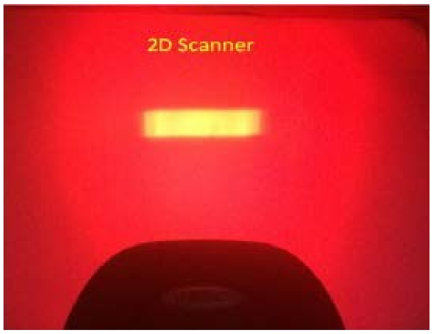
Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

ZB3062 2D-Barcode Scanner set-up for BD MAX

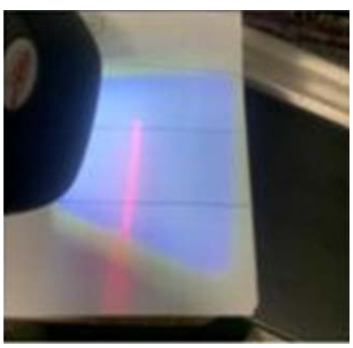
HID (PC) with CRLF SUFFIX

Scan codes from top to bottom in sequence (1-10)

1	USB HID (PC)
2	Clear All Suffixes
3	Add Suffix
4	9
5	9
6	0
7	D
8	0
9	A
10	**Save**



new



Only Scan if necessary

ZB3062USB-BDMAX default setting:

HID (PC) with CRLF SUFFIX

Suffix CR & LF

The handheld barcode scanner can be reconfigured to troubleshoot scanning issues before replacing. Instructions for reconfiguring the scanner are also found in the packaging insert of the 443809 spare part.

Scanners: 500008071 / 443809 - For configuring the scanner (per image a)

1. Connect scanner USB connector to active USB port.

2. Scan the barcode.

   Standard Product Default Settings

   HID default CR Aztec, 30ms, Trigger mode, no limit

   Enable Codabar, No S/S, Enable Code93, Enable MaxiCode, Enable Data Matrix reverse, Code128 CD Redundant 2

3. Disconnect scanner from USB port.
4. Reconnect scanner to USB port (this will force software drivers to update).

Note:
Rebooting the system may be required for instrument/computer to recognize the scanner.

Illumination=White LED with Red aiming line.

For configuring the scanner (per image b)

1. Connect scanner USB connector to active USB port.

2. Scan the barcode.

3. Disconnect scanner from USB port.
4. Reconnect scanner to USB port (this will force software drivers to update).

Note:
Rebooting the system may be required for instrument/computer to recognize the scanner.

Illumination=White LED with Red aiming line.

7 Service Parts

This section describes corrective maintenance procedures and replacement of reader assemblies.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

7.1 Parts Replacement Action Table

Part / Component Replaced	Required Actions
Reader assembly 443364, 44336409	• Perform Update "Instrument Firmware Update " on page 416 • Perform "Procedure Empty Fill Check" on page 491 • Perform Normalizer. • Ratio Check, "Procedure Normalizer Ratio Check" on page 492 • Perform "5-Channel Qualification Test" on page 325 on the side the Reader was replaced. • Review the acceptance criteria in the qualification protocol "5-Channel Qualification Kit Result Review Table" on page 331
Dewey or Louie heater MUX boards spare 443688, 44368809	• Update IP Address "Obtain MUX IP (WireShark)" on page 413 • Update "Instrument Firmware Update " on page 416

Part / Component Replaced	Required Actions
	• Perform "Procedure Empty Fill Check" on page 491 • Perform the"Self-Test " on page 474 • Perform "PCR Heater Test" on page 473 • Perform "5-Channel Qualification Test" on page 325 on the side the Mux was replaced. • Review the acceptance criteria in the qualification protocol "5-Channel Qualification Kit Result Review Table" on page 331.
Huey MUX board spare 443364	• Update IP Address 169.254.1.10. • Update "Instrument Firmware Update " on page 416. • Edit the pressure plate values "Pressure Plate Setting " on page 484 • Perform/Edit the drawer values "Reader Tray Position " on page 469. • Perform the 6.4.9 CatalogWin.Script • Perform the lysis temperature check "Lysis Heater Test" on page 482. • Perform gantry alignment "Gantry Alignment " on page 508. • Perform Instrument Qualification"5-Channel Qualification Test" on page 325. • Review the acceptance criteria in the qualification protocol "5-Channel Qualification Kit Result Review Table" on page 331.
Pumps assembly z-gantry spare 443334	• Update "Instrument Firmware Update " on page 416.

Part / Component Replaced	Required Actions
	• Perform "Gantry Alignment " on page 508. • Perform 4 QPM in the bank 1 and 4. • Visually follow the pipetting sequence. • Visually confirm the 4 pumps aspirate and dispense with the same volume.
Bender board spare 443687	• Update "Instrument Firmware Update " on page 416. • Confirm all 3 muxes connect to the Script-O-Matic. • Perform "Cataloging" on page 404. • Perform "Procedure Empty Fill Check" on page 491. • Visually verify the internal LEDs are on and blue. • Verify door functionality.
Hand barcode reader scanner spare 443809	• Confirm the Hand barcode reader initialized at the time is connected to the USB port. • Perform Barcode scan. • Verify the barcode read with the scanner match the sample tube barcode.
Door hall sensor	• Log in ad ADMIN. • Visually verify the “Unlock Door” button is Blue in the AIO. • Press Unlock door. • Confirm after opening the door the Unlock door bottom is gray for 10 seconds.
Stripper assembly spare 443342	• Update "Instrument Firmware Update " on page 416.

Part / Component Replaced	Required Actions
	• Perform "Gantry Alignment " on page 508. • Perform the QPM section on "5-Channel Qualification Test" on page 325 from point 1 to 20. • Verify the instrument picks up the tips and successfully loads the cartridge. • No errors on tips detection or failure to drop the tips.
All other non-functional skins parts replacement including panels, screws, spare 445338	• Follow the skin remove and replacement instruction "Instrument Skins" on page 197 to verify the replaced skin is well positioned. • Confirm the skin installed is tide and secure.
Computer controller MAX6 spare AIO replacement spare 443686	• Verify the AIO connected with the BD Max using the "Installation Procedure" on page 68. • If required, proceed with last service bulletin for BD Max software installation. • Print a report to confirm the printer's performance. • Home all robotics. • Perform "Procedure Empty Fill Check" on page 491.
Fuse 15A 250V FA IEC 5 X 20MM MAX6 spare 435104	• Remove the power cable from BD Max. • Shut down the AIO. • Change the power switch to the off position. • Confirm the AIO is ON. • Confirm the BD Max is ON. • Perform "Power Supply Voltage Adjustments" on page 193.

Part / Component Replaced	Required Actions
	• Verify the voltages "Power Supply Voltage Adjustments" on page 193. • Perform Home all robotics.
Cover Fan Duct MAX6 Spare 435109	• Power off the BD Max instrument. • Remove the power cable from BD Max. • Remove the 8 TOR 10 screws that secure the cover fan duct. • Install the new cover fan duct. • Tide all 8 TOR 10 screws. • Connect the power cable. • Power on the BD Max. • Perform Home all robotics. • No Internal noise from instrument at the Home of all robotics.
Facade inner right MAX6 spare 435110	• Verify the facade inner right side is secure. • Verify the cover fan duct MAX6 is secure with the 8 TOR 10 screws. • Verify the Home all robotics pass. • Visual verification, all covers are secure. • Confirm no noise from the Y arm at the Home all robotics. • No Internal noise from instrument at the Home all robotics
Facade inner left MAX6 spare 435111	• Verify the facade inner left side is secure. • Visual verification, all covers are secure. • Perform Home all robotics. • Confirm no noise from the Y arm at the

Part / Component Replaced	Required Actions
	Home all robotics. • No Internal noise from instrument at the Home all robotics.
Guard left MAX6 spare 435112	• Verify the guard left MAX6 spare side is secure. • Visual verification, all covers are secure. • Perform Home all robotics. • No Internal noise from instrument at the Home all robotics.
Guard right MAX6 spare 435113	• Verify the guard right MAX6 spare side is secure. • Visual verification, all covers are secure. • Visual verification, all covers are secure. • No Internal noise from instrument at the Home all robotics.
Cable assembly lysis motor MAX6 spare 435130	• Perform Home all robotics. • Verify the home all robotics pass. • Perform the 5CQK "5-Channel Qualification Test" on page 325 on the side the cable was replaced.
Keyboard USB W PS/2 ADP MAX6 spare 435119	• Power on the AIO. • Select the RUN Tab, type in the sample identification sample ID and text. • Confirm the numeric tab is active.
Mouse optical wired MAX6 spare 435121	• Power on the AIO. • Navigate with the optical mouse in several tabs to confirm the functionality. • Confirm the mouse pontes is present and

Part / Component Replaced	Required Actions
	move with the mouse.
Printer MAX6 spare 444336	• Refer to the lattes software installation service bulletin to confirm the printer installation procedure. • Confirm the printer driver is correct for the installed printer. • Print one report to confirm the printer configuration in color.
Wire harness ASSY AC power MAX6 spare 435132	• Follow "BD MAX 24V Power Supply" on page 267 to removing the Old Power Supply to remove the harness. • Power on BD Max System. • Perform "Power Supply Voltage Adjustments" on page 193. • Verify the voltages on the liberty board, "Power Supply Voltage Adjustments" on page 193. • Confirm the voltages are on the range. • Perform the 5CQK "5-Channel Qualification Test" on page 325 on the side the cable was replaced.
Cooling fan assembly MAX6 spare 435133	• Power off the BD Max System. • Remove the internal skin, "Skins Removal " on page 198. • Power on the BD Max. • Verify the fans are starting and increase the fan speed increase at the power on. • Perform home all robotics. • Perform "PCR Heater Test" on page 473.

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Part / Component Replaced	Required Actions
	• "Lysis Heater Test" on page 482. • Perform the 5CQK "5-Channel Qualification Test" on page 325) on the side the cable was replaced.
PCB Z cntrl gantry w fd win MAX6 spare 443690	• Update "Instrument Firmware Update " on page 416. • Perform the "CatalogWin.Script" on page 488t. • Perform "Z-Gantry Stall Script" on page 450. • Perform gantry alignment "Gantry Alignment " on page 508. • Perform QPM from the "5-Channel Qualification Test" on page 325.
Liberty board assembly spare 435233	• Perform the "Power Supply Voltage Adjustments" on page 193. • Perform home all robotics. • Perform "Procedure Empty Fill Check" on page 491 verification. • Perform"Lysis Heater Test" on page 482. • If readers was removed perform the 5CQK "5-Channel Qualification Test" on page 325.
Idler unit assembly MAX6 spare 435145	• Perform "Cable Tension Check" on page 486. • Login on the scrip-o-matic. • Perform "Gantry Alignment " on page 508. • Perform "CatalogWin.Script" on page 488. • Perform Home all robotics.
Wire harness assy rack sensor MAX6 spare	• Power off the BD Max System.

Part / Component Replaced	Required Actions
435154	• Remove the internal skin, "Skins Removal " on page 198. • Perform "Rack Sensors Repair" on page 395. • Power on the system. • Confirm the racks symbol are without racks. • AIO desktop. • Place the racks on sides A and B. • Verify the racks are detected by the 4 sensors on the status bar.
PCB 2X mtr cntrl rdr right win MAX6 spare 443691	• Power off the BD Max System. • Remove the internal skin, "Skins Removal " on page 198. • Remove the board. • Power On the BD Max system. • Perform "Instrument Firmware Update " on page 416. • Home all robotics. • Perform "Reader Tray Position " on page 469 on A-side. • Perform "Gantry Alignment " on page 508. • Perform "CatalogWin.Script" on page 488. • Verify the home all robotics pass. • Perform the 5CQK "5-Channel Qualification Test" on page 325 on the replaced side B.
PCB 2X MTR CNTRL RDR LEFT WIN MAX6 SPARE 443692	• Power off the BD Max System. • Remove the internal skin, "Skins Removal " on page 198.

Part / Component Replaced	Required Actions
	• Remove the board. • Power On the BD Max system. • Perform "Instrument Firmware Update " on page 416. • Home all robotics. • Perform "Reader Tray Position " on page 469 on A-side. • Perform "Gantry Alignment " on page 508. • Perform "CatalogWin.Script" on page 488. • Verify the home all robotics pass. • Perform Perform the 5CQK"5-Channel Qualification Test" on page 325 on the replaced side A.
Nitrogen gas spring spare 444782	• Log in ad ADMIN. • Visually verify the **"Unlock Door"** button is Blue in the AIO. • Press Unlock door. • Confirm after opening the door the Unlock door bottom is gray for 10 seconds.
PC board assy 2x motor drive MAX6 spare 443684	• Power off the BD Max System. • Remove the internal skin, "Skins Removal " on page 198. • Remove the board. • Power On the BD Max system. • Perform "Instrument Firmware Update " on page 416. • Home all robotics. • Perform "Lysis Heater Test" on page 482.

Part / Component Replaced	Required Actions
	• Perform "Procedure Empty Fill Check" on page 491. • Perform the QPM verification"5-Channel Qualification Test" on page 325.
Normalizer tools MAX6 sparee 443685	• Verify the manufactory date on the cards. • Confirm is less of one year before usage.
Gantry assy z axis win MAX6 spare witch gantry cover spare 443683	• Power On the BD Max system. • Perform "Instrument Firmware Update " on page 416. • Home all robotics. • Perform "Gantry Alignment " on page 508. • Perform "CatalogWin.Script" on page 488. • Perform the QPM verification "5-Channel Qualification Test" on page 325.
PCB z cntrl gantry w fd win MAX6 spare 443689	• Power On the BD Max system. • Perform "Instrument Firmware Update " on page 416. • Home all robotics. • Perform "Gantry Alignment " on page 508. • Perform "CatalogWin.Script" on page 488. • Perform the QPM verification "5-Channel Qualification Test" on page 325.
Cooling fan assembly MAX6 spare 435153	• After power on the BD Max instrument, wait 3 minutes and confirm the Fans increase the speed. • Perform "Instrument Firmware Update " on page 416. • Home all robotics.

Part / Component Replaced	Required Actions
	• Perform the QPM verification "5-Channel Qualification Test" on page 325.
Belt syn splice 3mm pitch MAX6 spare 435103	• Home all robotics. • Perform "Gantry Alignment " on page 508. • Perform "CatalogWin.Script" on page 488. • Perform the QPM verification "5-Channel Qualification Test" on page 325.
Cable assembly y front limit MAX6 spare 435250	• Power on the BD Max. • Perform "Gantry Alignment " on page 508. • Perform "Reader Tray Position " on page 469. • Run Home All Motors to verify all basic components are communicating and functioning correctly and skins are not interfering with instrument movement. The next test is to verify the sensor functionality. • Perform the Calrack.script. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B.
Cable assembly door sensor MAX6 spare 435160	• Power on the BD MAX. • Verify the AIO and BD MAX are connected. • Select Unlock Door. • Confirm the door opens. • Confirm the Door open tab is gray and inactive. Close the door. • Confirm the Door open tab is blue and active.
Tray drive assembly drive MAX6 spare 435213	• Power On the BD Max.

Part / Component Replaced	Required Actions
	• Edit the caltable with the pressure values. • Perform"Reader Tray Position " on page 469. • Run Home All Motors to verify all basic components are communicating and functioning correctly and skins are not interfering with instrument movement. • Perform the Calrack.script. • Perform "Instrument Firmware Update " on page 416 for side A or side B, according to the side replaced. • Perform the QPM verification "5-Channel Qualification Test" on page 325, according to the side replaced.
Cable assembly door solenoid MAX6 spare 435161	• Power On the BD MAX. • Verify the AIO and BD MAX are connected. • Select Unlock Door. • Confirm the door opens. • Confirm the Door open tab is gray and inactive. • Close the door. • Confirm the Door open tab is blue and active.
Motor assembly xy axis MAX6 spare 435216	• Power On the BD Max system. • Perform "Instrument Firmware Update " on page 416. • Perform "X/Y-Gantry Belt Tension " on page 190. • Perform "Reader Tray Position " on page

Part / Component Replaced	Required Actions
	469. • Perform "Gantry Alignment " on page 508. • Home all robotics. • Perform "CatalogWin.Script" on page 488. • Perform the QPM verification on "5-Channel Qualification Test" on page 325.
Barcode reader pump head MAX6 spare 435219	• Power On the BD Max system. • Perform "Gantry Alignment " on page 508. • Home all robotics. • Perform "CatalogWin.Script" on page 488. • Align the Reader pump to fit on the square areas on "CatalogWin.Script" on page 488. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B.
Mirror assembly MAX6 spare 435220	• Power off the BD Max System. • Remove the internal skin, "Skins Removal " on page 198. • Mark the actual mirror base position as reference to reinstall. • Remove all screws who fix the mirror base. • Install the new mirror. • Home all robotics. • Perform "Gantry Alignment " on page 508. • Perform "CatalogWin.Script" on page 488. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B.
Wiring harness power supply MAX6 spare	• Confirm the BD Max is ON.

Part / Component Replaced	Required Actions
435221	• Perform "Power Supply Voltage Adjustments" on page 193. • Verify the voltages. "Power Supply Voltage Adjustments" on page 193. • Perform home all robotics. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B. • Perform the "5-Channel Qualification Test" on page 325.
Belt syn splice axis 3MM MAX6 spare 435224	• Power on the BD Max system. • Update "Instrument Firmware Update " on page 416. • Perform "X/Y-Gantry Belt Tension " on page 190. • Perform "Reader Tray Position " on page 469. • Perform "Gantry Alignment " on page 508. • Home all robotics. • Perform "CatalogWin.Script" on page 488. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B. According to the side, the cable is replaced.
Belt syn splice X axis 3MM MAX6 spare 435225	• Power on the BD Max system. • Update "Instrument Firmware Update " on page 416. • Perform "X/Y-Gantry Belt Tension " on page 190. • Perform "Reader Tray Position " on page 469.

Part / Component Replaced	Required Actions
	• Perform "Gantry Alignment " on page 508. • Home all robotics. • Perform "CatalogWin.Script" on page 488. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B. According to the side, the cable is replaced.
Switch power MAX6 spare 435227	• Power on the BD Max. • Change the power switch to the off position. • Confirm the AIO is ON. • Confirm the BD Max is ON. • Perform "Power Supply Voltage Adjustments" on page 193. • Verify the voltages. "Power Supply Voltage Adjustments" on page 193. • Perform home all robotics.
Cable assembly gantry MAX6 spare 435231	• Power on the BD Max system. • Perform "Gantry Alignment " on page 508. • Home all robotics. • Perform "CatalogWin.Script" on page 488. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B. According to the side, the cable is replaced.
Cable assy pressure motor MAX6 spare 435234	• Power on the BD Max system. • Home all robotics. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B.
Cable assembly X right limit MAX6 spare 435238	• Power on the BD Max system.

Part / Component Replaced	Required Actions
	• Perform "Gantry Alignment " on page 508. • Home all robotics. • Perform "CatalogWin.Script" on page 488. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B. According to the side, the cable is replaced.
Cable assembly X left limit MAX6 spare 435239	• Power on the BD Max system. • Perform "Gantry Alignment " on page 508. • Home all robotics. • Perform "CatalogWin.Script" on page 488. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B. According to the side, the cable is replaced.
Cable assembly X home MAX6 spare 435240	• Power on the BD Max system. • Perform "Gantry Alignment " on page 508. • Home all robotics. • Perform "CatalogWin.Script" on page 488. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B. According to the side, the cable is replaced.
Cable assembly Y home MAX6 spare 435241	• Power on the BD Max system. • Perform "Gantry Alignment " on page 508. • Home all robotics. • Perform "CatalogWin.Script" on page 488. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B. According to the side, the cable is replaced.
Chain assembly Y cable MAX6 spare 435242	• Power on the BD Max system.

Part / Component Replaced	Required Actions
	• Perform "Gantry Alignment " on page 508. • Home all robotics. • Perform "CatalogWin.Script" on page 488. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B. According to the side, the cable is replaced.
Cable able drawer limit switch MAX6 spare 435243	• Power on the BD Max system. • Perform "Gantry Alignment " on page 508. • Home all robotics. • Perform "CatalogWin.Script" on page 488. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B. According to the side, the cable is replaced.
Cable assy lysis heater power MAX6 spare 435246	• Power on the BD Max System. • Perform the "Lysis Heater Test" on page 482. • Perform home all robotics.
Cable lysis motor sensor MAX6 spare 435249	• Power on the BD Max System. • Perform the "Lysis Heater Test" on page 482. • Perform home all robotics.
LLS stripper assy z-gantry MAX6 spare 441912	• Power on the BD Max system. • Update "Instrument Firmware Update " on page 416. • Perform "Gantry Alignment " on page 508. • Home all robotics. • Perform "CatalogWin.Script" on page 488.

Part / Component Replaced	Required Actions
	• Perform "Procedure Empty Fill Check" on page 491 for side A and side B. According to the side, the cable is replaced.
Motor assy z-gantry MAX6 spare 443333	• Power on the BD Max system. • Update "Instrument Firmware Update " on page 416. • Perform "Z-Gantry Stall Script" on page 450. • Perform "Gantry Alignment " on page 508. • Home all robotics. • Perform "CatalogWin.Script" on page 488. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B. According to the side, the cable is replaced.
Cable assembly z encoder 212-5101 MAX6 spare 443336	• Power on the BD Max system. • Perform "Gantry Alignment " on page 508. • Home all robotics. • Perform "CatalogWin.Script" on page 488. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B. According to the side, the cable is replaced.
Cable optical switch z home MAX6 spare 443337	• Power on the BD Max system. • Perform "Gantry Alignment " on page 508. • Home all robotics. • Perform "CatalogWin.Script" on page 488. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B. According to the side, the cable is replaced.

Part / Component Replaced	Required Actions
GORT board MAX6 spare 443547	• Power on the BD Max system. • Update "Instrument Firmware Update " on page 416. • Perform "Extractor Magnet Alignment" on page 513. • Perform "Flashing the GORT board (Lysis Heater)" on page 411 • Perform Home all robotics. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B. According to the side, the board is replaced. • Perform the "5-Channel Qualification Test" on page 325. According to the side, the board is replaced.
MAG lysis assembly MAX6 spare -LYSIS MAG separation assy 443549	• Power on the BD Max system. • Update "Instrument Firmware Update " on page 416. • Perform "Extractor Magnet Alignment" on page 513. • Perform Home all robotics. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B. According to the side, the board is replaced. • Perform the "5-Channel Qualification Test" on page 325. According to the side, the board is replaced.
X/Y motor controller assay WIN MAX6 spare 443682	• Configure the rotatory switch according to X or Y controller. • Power on the BD Max system. • Update "Instrument Firmware Update " on

Part / Component Replaced	Required Actions
	page 416. • Perform "Gantry Alignment " on page 508. • Home all robotics. • Perform "CatalogWin.Script" on page 488. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B. According to the side, the cable is replaced.
Fixed magnet assembly v2 spare 445219	• Power on the BD Max system. • Update "Instrument Firmware Update " on page 416. • Perform "Extractor Magnet Alignment" on page 513. • Perform Home all robotics. • Perform "Procedure Empty Fill Check" on page 491 for side A and side B. • According to the side, the board is replaced. • Perform the "5-Channel Qualification Test" on page 325. According to the side, the board is replaced.

Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

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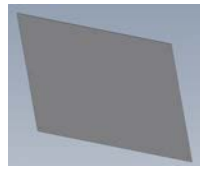
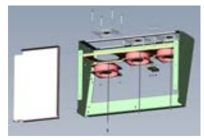
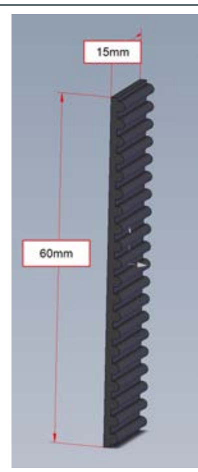
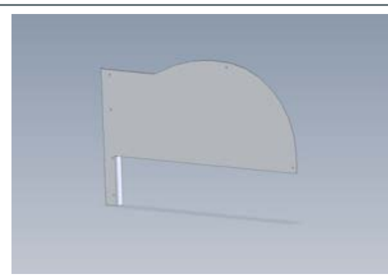
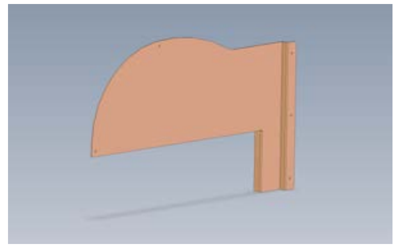
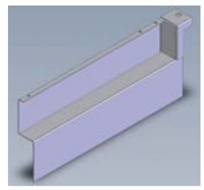
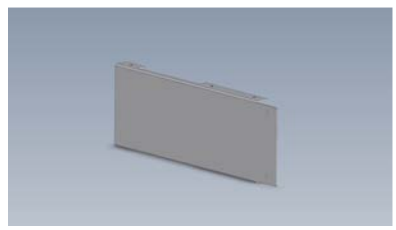
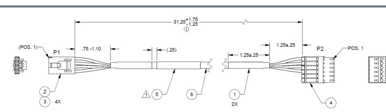
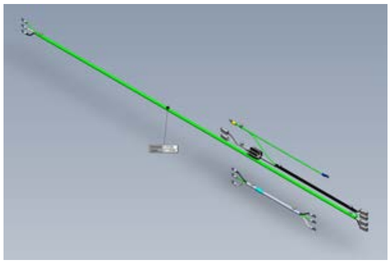
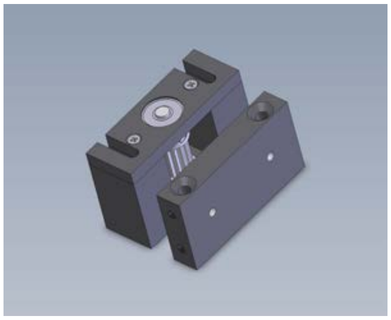
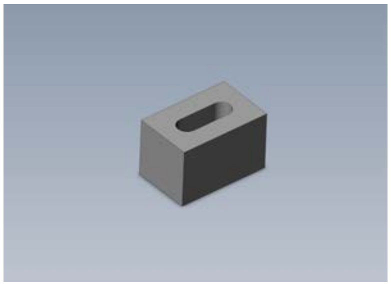
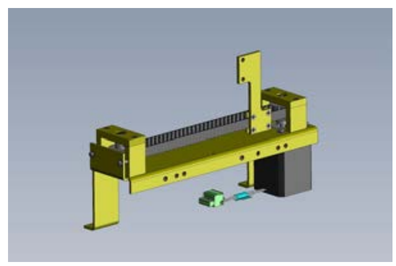
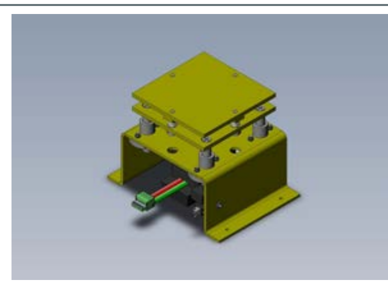
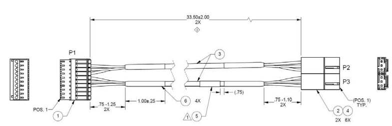
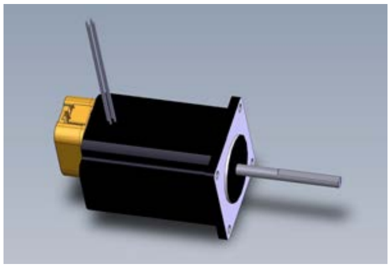
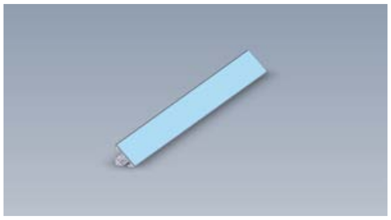
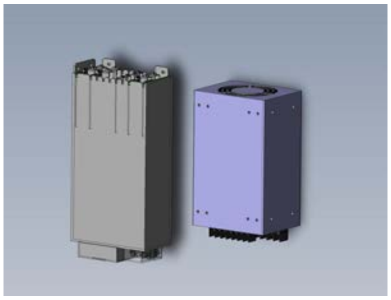
7.2 Parts List

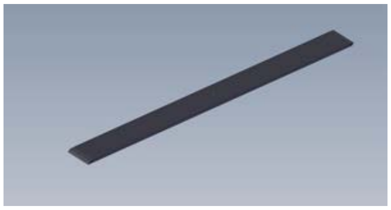
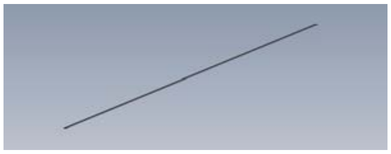
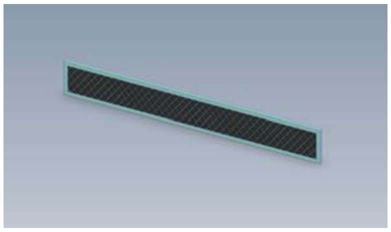
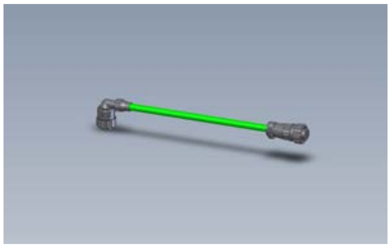
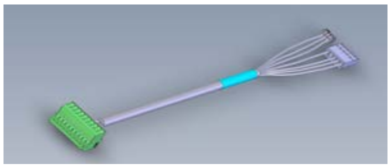
Part number	Description	Image (if available) and notes
435109	COVER FAN DUCT MAX6 SPARE	
435133	COOLING FAN ASSEMBLY MAX6 SPARE	
435102	MANUAL CUSTOMER TRAINING BD MAX GBS	
443328	COMPUTER CONTROLLER MAX6 SPARE	Replaced by 443686.
435103	BELT SYN SPLICE 3MM PITCH MAX6 SPARE	
435104	FUSE 15A 250V FA IEC 5 X 20MM MAX6 SPARE	
435110	UPPER RIGHT PANEL	

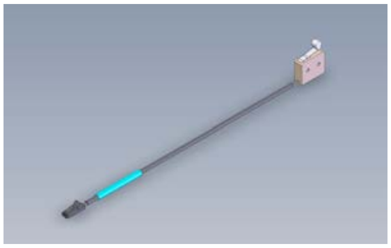
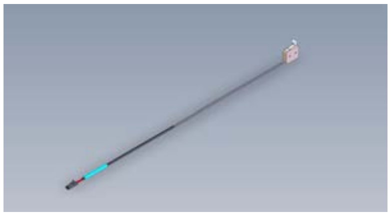
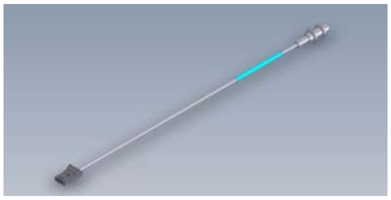
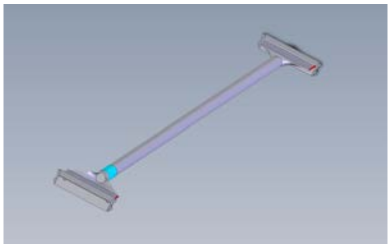
Part number	Description	Image (if available) and notes
435111	UPPER LEFT PANEL	
435112	GUARD LEFT MAX6 SPARE	
435113	GUARD RIGHT MAX6 SPARE	
435117	SCANNER LASER BARCODE GREY MAX6 SPARE	Replaced by 443809. Also contained in 445275
435119	KEYBOARD USB W PS/2 ADP MAX6 SPARE	
435120	MOUSE OPTICAL WIRED MAX6 SPARE	
435121	PRINTER MAX6 SPARE	
435123	PCB ASSEMBLY MUX MAX6 SPARE	Replaced by 443693, effective from Dec 2017. Use 435123 until inventory is available
435130	CABLE ASSEMBLY LYSIS MOTOR MAX6 SPARE	 Detailed drawing: "435130 - CABLE ASSEMBLY LYSIS MOTOR MAX6 SPARE" on page 578

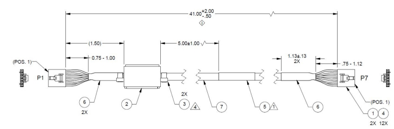
Part number	Description	Image (if available) and notes
435132	WIRE HARNESS ASSY AC POWER MAX6 SPARE	
435145	IDLER UNIT ASSEMBLY MAX6 SPARE	X+Y Axis Pulleys 
435154	WIRE HARNESS ASSY RACK SENSOR MAX6 SPARE	
435159	CABLE OPTOISOLATER ADAPTER MAX6 SPARE	
435160	CABLE ASSY DOOR SENSOR LEFT MAX6 SPARE	
435161	CABLE ASSEMBLY DOOR SOLENOID MAX6 SPARE	
435202	BLOCK NOZZLE PROTECTION	
435206	MOUSE OPTICAL WIRED MAX6 SPARE	In FSL List for US Service. Replaced by 443692
435207	PC BOARD ASSY 2X MOTOR	In FSL List for US Service. Replaced

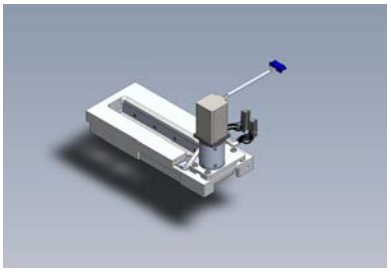
Part number	Description	Image (if available) and notes
	DRIVE MAX6 SPARE	by 443684, effective from Dec 2017. Use 435207 until inventory is available
435210	CONTROLLER XY ASSEMBLY MAX6 SPARE	Blue Cobra X or Y. 443682 is the new part number to be ordered, effective from Dec 2017. Use 435210 until inventory is available
435211	HEATER MUX ASSEMBLY MAX6 SPARE	443688 will be shipped (windows version). The repaired version remains 43521109
435213	TRAY DRIVE ASSEMBLY MAX6 SPARE	Belt and Motor that open/close the drawer 
435214	PRESSURE MOTOR ASSEMBLY MAX6 SPARE	
435215	CABLE ASSY LYSIS MOTOR SENSOR MAX6 SPARE	 Detailed drawing: "435215 - CABLE ASSY LYSIS MOTOR SENSOR MAX6 SPA" on page 578

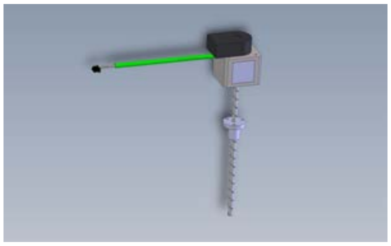
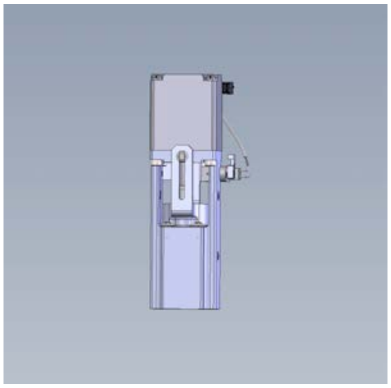
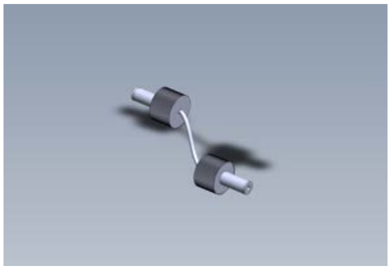
Part number	Description	Image (if available) and notes
435216	MOTOR ASSEMBLY XY AXIS MAX6 SPARE	
435217	PC BOARD ASSY FAN CONTROL MAX6 SPARE	
435219	BARCODE READER PUMP HEAD MAX6 SPARE	
435220	MIRROR ASSEMBLY MAX6 SPARE	
435221	WIRING HARNESS POWER SUPPLY MAX6 SPARE	Both power supplies and harness 
435222	SENSOR FLAGS MAX6 SPARE SET OF 10	Rack tilt, Tray, Magnet and Reader sensor
435223	MOTOR STEPPER FOR READER MAX6 SPARE	

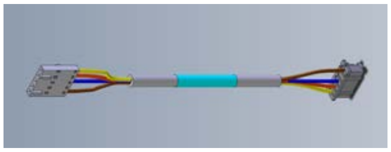
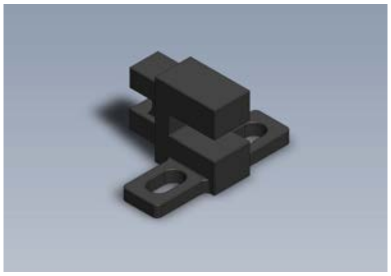
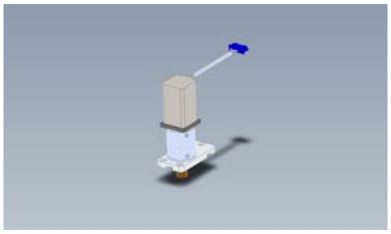
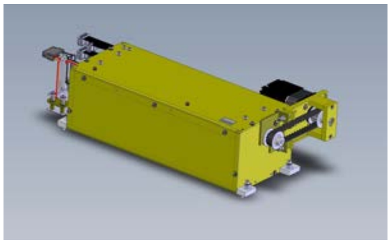
Part number	Description	Image (if available) and notes
435224	BELT SYN SPLICE Y AXIS 3MM MAX6 SPARE	
435225	BELT SYN SPLICE X AXIS 3MM MAX6 SPARE	
435226	FILTER FRONT MAX6 SPARE	
435227	SWITCH POWER MAX6 SPARE	
435228	PC BOARD 2X MOTOR RIGHT READ MAX6 SPARE	Blue Cobra Tray and Pressure Plate. Replaced by 443691
435231	CABLE ASSEMBLY GANTRY MAX6 SPARE	
435233	PC BOARD MOTHER BOARD MAX6 SPARE	PCB Mother Board or Liberty Board
435234	CABLE ASSY PRESSURE MOTOR MAX6 SPARE	

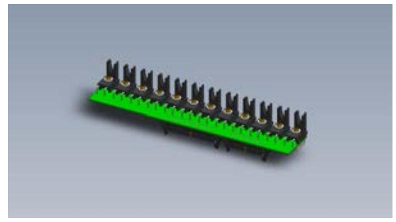
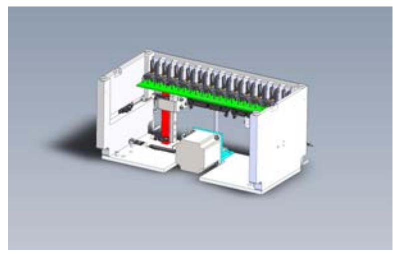
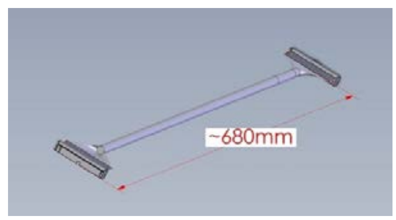
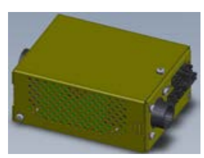
Part number	Description	Image (if available) and notes
435238	CABLE ASSEMBLY X RIGHT LIMIT MAX6 SPARE	
435239	CABLE ASSEMBLY X LEFT LIMIT MAX6 SPARE	
435240	CABLE ASSEMBLY X HOME MAX6 SPARE	
435241	CABLE ASSEMBLY Y HOME MAX6 SPARE	
435242	CHAIN ASSEMBLY Y CABLE MAX6 SPARE	
435243	CABLE DRAWER LIMIT SWITCH MAX6 SPARE	
435246	CABLE ASSY LYSIS HEATER POWER MAX6 SPA	

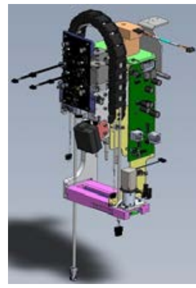
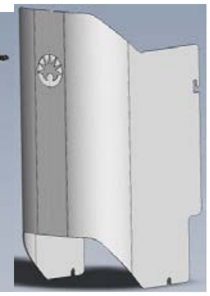
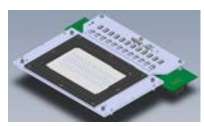
Part number	Description	Image (if available) and notes
435248	CONTROLLER LYSIS MAG MOTOR MAX6 SPARE	
435249	CABLE LYSIS MOTOR SENSOR MAX6 SPARE	 Detailed drawing: "435249 - CABLE LYSIS MOTOR SENSOR MAX6 SPARE" on page 578
435250	CABLE ASSEMBLY Y FRONT LIMIT MAX6 SPARE	
435251	PLATE CALIBRATION MAX6 SPARE	
435253	KIT PMI MAX6	
435256	PLATE CALIBRATION 6 COLOR MAX6 SPARE	
435257	TOOL ALIGNMENT YOKE SETTING MAX6 SPARE	
437519	BD CARTRIDGE PCR 24 EA	Active and ordered during Install/PM/repair
441187	TEST TOOL OPTICAL PLATE FAM ASSEMBLY	
441188	TEST TOOL OPTICAL PLATE ROX ASSEMBLY	
441436	PACKAGING SET MAX6 SPARE	
441520	MANUAL CUSTOMER TRAINING MRSA	
441881	TUBE RACK 16MM BD MAX	
441882	TUBE RACK 13MM BD MAX	
441911	GANTRY ASSEMBLY Z AXIS MAX6 SPARE	Replaced by 443683

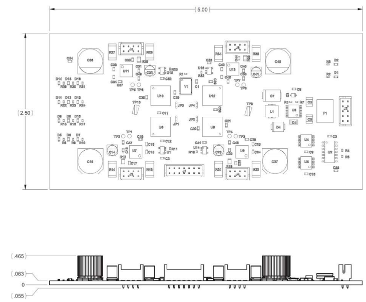
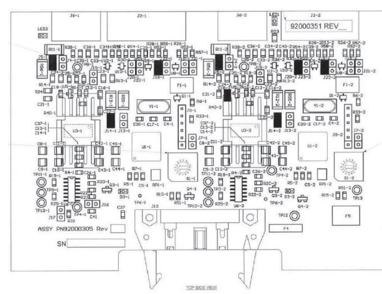
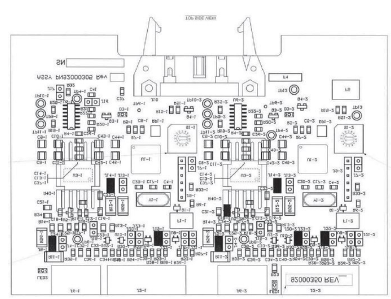
Part number	Description	Image (if available) and notes
441912	LLS STRIPPER ASSY Z GANTRY MAX6 SPARE	
441934	SAMPLE RACK PREWARM MAX6	
441937	UPS POWER SUPPLY NORTH AMERICA MAX	
441938	MANUAL OPERATORS IVD MAX PACKAGED	
441939	MANUAL OPERATORS INTERNATIONAL MAX PKGD	
441942	MANUAL OPERATORS OSR MAX PACKAGED	
441946	SOFTWARE MAX ASSAYS PACKAGED	
441947	SOFTWARE MAX PACKAGED	Replaced by 443584
441985	LATCH ASSEMBLY RIGHT MAX6 SPARE	
441986	LATCH ASSEMBLY LEFT MAX6 SPARE	
441987	TOOL DOOR UNLOCK MAX6 SPARE	
441998	KIT FIELD SERVICE ALIGNMENT TOOLS MAX6	
442975	KIT BD MAX INSTRUMENT QUALIFICATION RUO	This kit is no longer manufactured. The preferred qualification kit is the 5-Channel Qualification Kit (444048).
443159	KIT PREWARM MAX6	

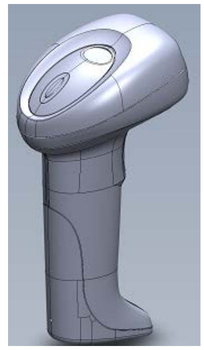
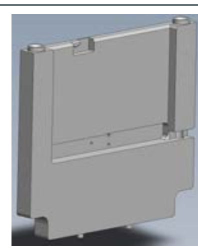
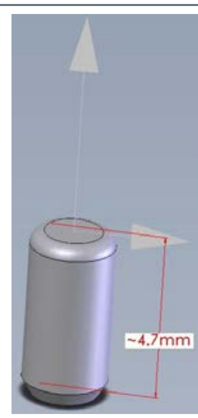
Part number	Description	Image (if available) and notes
443326	KIT SERVICE PACK UPGRADE MAX6	
443329	CABLE OPTICAL SWITCH STRIPPER MAX6 SPARE	
443330	PC BOARD ASSY BENDER MAX6 SPARE	Bender communications USB. Replaced by 443687
443333	MOTOR ASSY Z GANTRY MAX6 SPARE **Note:** This part number includes Base Teflon Block.	
443334	PUMP ASSEMBLY Z GANTRY MAX6 SPARE	Pump. In FSL List for US Service 
443335	TUBING AND FITTING Z GANTRY MAX6 SPARE	This is a kit of 4 eaches. In FSL List for US Service 

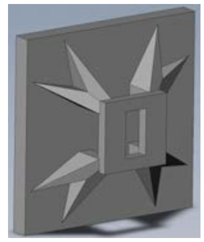
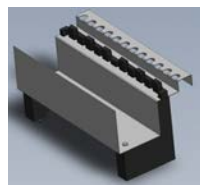
Part number	Description	Image (if available) and notes
443336	CABLE ASSEMBLY Z ENCODER 212-5101 MAX6 SPARE	
443337	CABLE OPTICAL SWITCH Z HOME MAX6 SPARE	
443338	FACADE Z GANTRY MAX6 SPARE	
443339	CABLE CHAIN Z ASSEMBLY MAX6 SPARE	
443340	CABLE X CHAIN ASSEMBLY MAX6 SPARE	
443341	SET OF CABLES LEVEL SENSING MAX6 SPARE	
443342	MOTOR ASSEMBLY STRIPPER MAX6 SPARE	
443364	READER ASSEMBLY MAX6 SPARE	
443365	KIT VORTEXER WITH VIAL HOLDERS MAX6	
443412	HEAT SEAL BLOCKS MAX6	

Part number	Description	Image (if available) and notes
443413	HEAT SEAL PAPER 54 WELLS MAX6	
443547	GORT Board MAX6 Spare	
443549	MAG LYSIS ASSEMBLY MAX6 SPARE - LYSIS MAG SEPARATION ASSY CABLE ASSY LYSIS HEATER SENSOR	In FSL List for US Service  
443584	BD MAX WINDOWS SOFTWARE PACKAGED	Replaces 441947. System software is available for download
443682	XY MOTOR CONTROLLER ASSY WIN MAX6 SPARE	Replacement for 435210, effective from Dec 2017 
443683	GANTRY ASSY Z AXIS WIN MAX6 SPARE GANTRY COVER	Replacement for 441911, effective from Dec 2017

Part number	Description	Image (if available) and notes
		 
443685	NORMALIZER TOOLS MAX6 SPARE	Effective from Dec 2017
443686	PC ALL IN ONE WINDOWS MAX6 SPARE	443328 is discontinued Note: Inserted 25th Jan 2017 and again in Dec 2017
443687	BENDER BOARD WIN MAX6 SPARE	Replaces 443330, effective from Dec 2017
443688	HEATER MUX ASSY WIN MAX6 SPARE	Replacement for 435211 
443689	PCB Z CNTRL GANTRY W FD WIN MAX6 SPARE	Replaces 443331, effective from Dec 2017 
443690	PC Board Quad Pump Z Gantry MAX6 Spare	Replacement for 443332, effective from Dec 2017

Part number	Description	Image (if available) and notes
		 Detailed Drawing:" 443690 - PC BOARD QUAD PUMP Z GANTRY MAX6 SPARE" on page 580
443691	PCB 2X MTR CNTRL RDR RT WIN MAX6 SPARE	Replacement for 435228, effective from Dec 2017  Detailed drawing: "443691 - PCB 2X MTR CNTRL RDR RT WIN MAX6 SPARE" on page 581
443692	PCB 2X MTR CNTRL RDR RIGHT WIN MAX6 SPARE	Replacement for 435206, effective from Dec 2017  Detailed drawing: "443692 - PCB 2X MTR CNTRL RDR RIGHT WIN MAX6 SPARE" on page 582

Part number	Description	Image (if available) and notes
443693	PCB ASSEMBLY MUX WIN VER MAX6 SPARE	Huey
443809	HD BARCODE SCANNER	
443969	BELT FREQUENCY METER MAX6 SPARE	
443990	Kit 12 Magnet Replacement MAX6 Spare	
444099	MAG LYSIS Column Left MAX6 SPARE MAG LYSIS COLUMN LEFT PIN DOWEL CABLE MOUNT	
		

Part number	Description	Image (if available) and notes
		
444805	Rack Upgrade Kit	Material to upgrade 4 racks
444807	Locking Hinge Rack Assembly Single	Replacement part number for 443551
444808	Locking Hinge Rack Assembly 4-Pack	Replacement part number for 443550
445219	Fixed Magnet Assembly v2	
445228	Cable USB 2.0 A/B 3M MAX6 SPARE	
445268	Monitor Arm Installation Kit	
445275	HD Barcode Scanner Stand Kit	
445276	HD Scanner Stand Accessory	
445277	Wireless Touchpad Keyboard Accessory	
43521109	HEATER MUX ASSEMBLY MAX6 REPAIRED	This is the repaired version of 435211 and 443688
44191209	LLS STRIPPER ASSY Z GANTRY MAX REPAIRED	This is the repaired version of 441912. In FSL List for US Service
44336419	Reader Assy MAX Repair RoHS	In FSL List for US Service. 44336409 is superseded by 44336419
44368309	GANTRY ASSY Z AXIS WIN MAX6 REPAIRED	Repaired Version of 443683
44368809	HEATER MUX ASSY WIN MAX6	Repaired Version of 443688

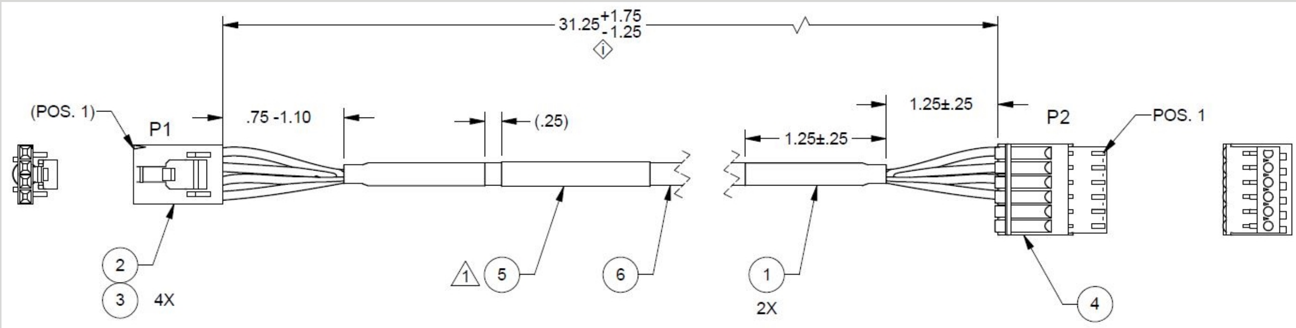
Part number	Description	Image (if available) and notes
	REPAIRED	
444786	WIRE DUCT ASSY READER MAX6 SPARE	For legacy, MAX bellow the CT3037 
444785	WIRE DUCT ASSY READER GEN2 MAX6 SPARE	For BD Max CT3038 and above. The chain connections have been updated to the new version 
445345	FRONT PANEL ASSEMBLY MAX SPARE	For legacy MAX below the CT3037 
445346	FRONT PANEL ASSEMBLY MAX PLUS SPARE	For BD Max CT3038 and above 
444762	CABLE ASSY X-Y ENCODER MAX6 SPARE	The cable connects the X/Y motor to the cobra controller.
445344	USB FLASH DRIVE SPARE	Spare USB drive with 13GB spare for Backups on BD Max Part of the BD Max start-up Kit.
445343	SPLASH GUARD MAX SPARE	
445342	GANTRY CABLE SET MAX SPARE	A set of cables from the Z Cobra controller are sent to the top of the Gantry.
443339	Z-CABLE CHAIN ASSEMBLY MAX6 SPARE	Cables from the top of the gantry to the Liberty and bender board.

Part number	Description	Image (if available) and notes
445341	FAÇADE 2X READER MAX SPARE	
445340	FAÇADE 2X RACK ASSY MOD MAX SPARE	
445338	INTERNAL FASTENERS MAX SPARE	Set of replacement screws for several components on the BD Max: Qty. 8 SCREW BUT HD TX SS BO 6-32UNCX.38L Qty. 10 SCREW BUT HD TX SS 6-32UNC .38L Qty. 6 SCREW BUT HD TX SS 6-32UNC .50L Qty. 2 SCREW KNRL HD NYL 6-32UNC .250L Qty. 4 Nylon Plastic Snap-In Panel Plugs
444782	SPRING NITROGEN GAS MAX6 SPARE	

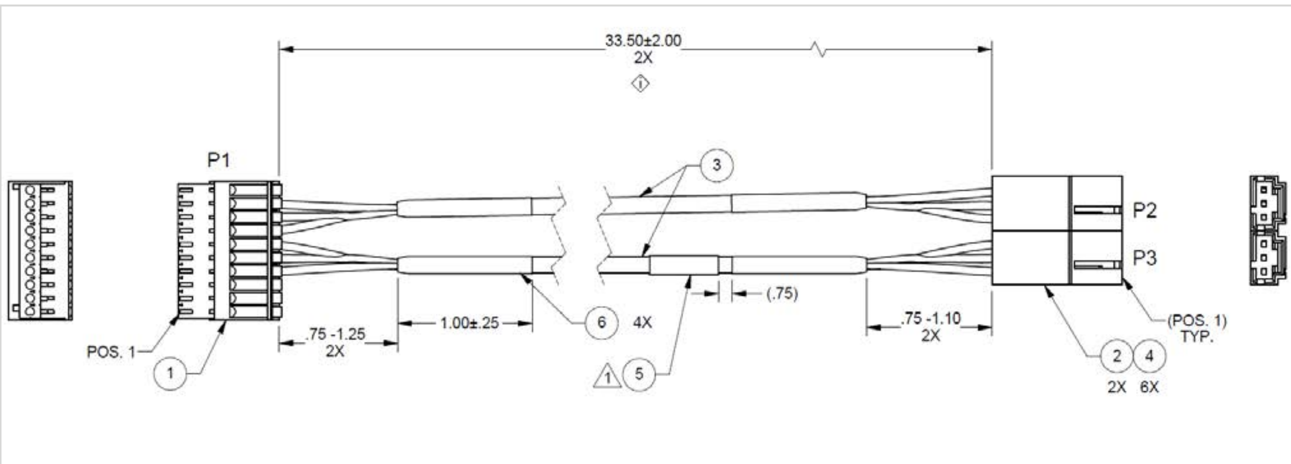
7.3 PCB and cables - detailed drawings

This section provides a number of detailed parts drawings.

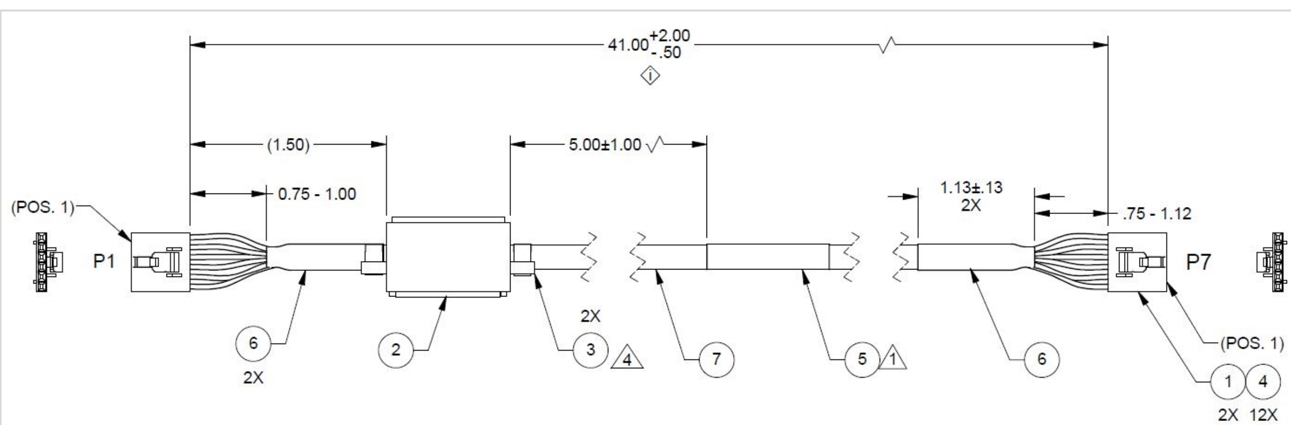
435130 - CABLE ASSEMBLY LYSIS MOTOR MAX6 SPARE



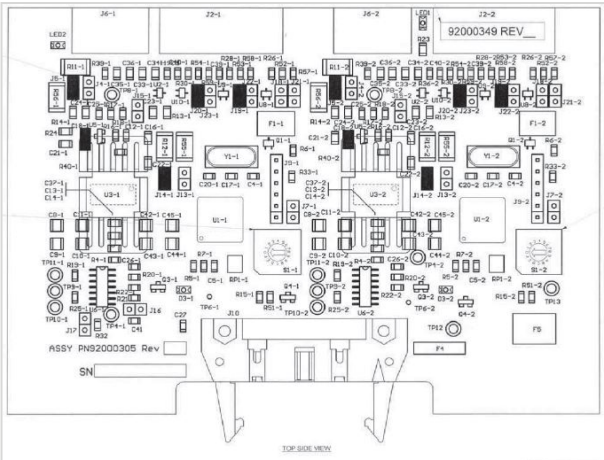
435215 - CABLE ASSY LYSIS MOTOR SENSOR MAX6 SPA



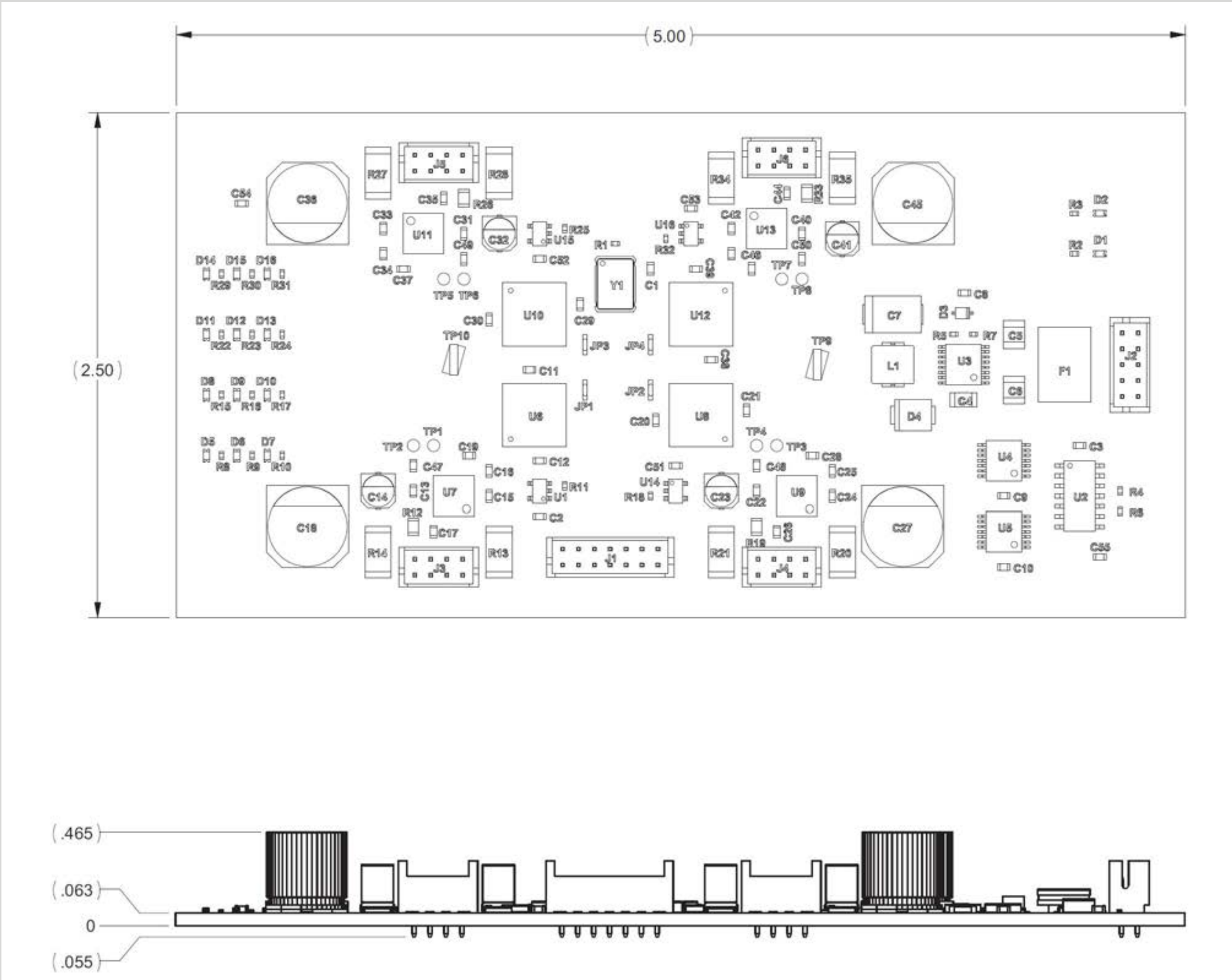
435249 - CABLE LYSIS MOTOR SENSOR MAX6 SPARE



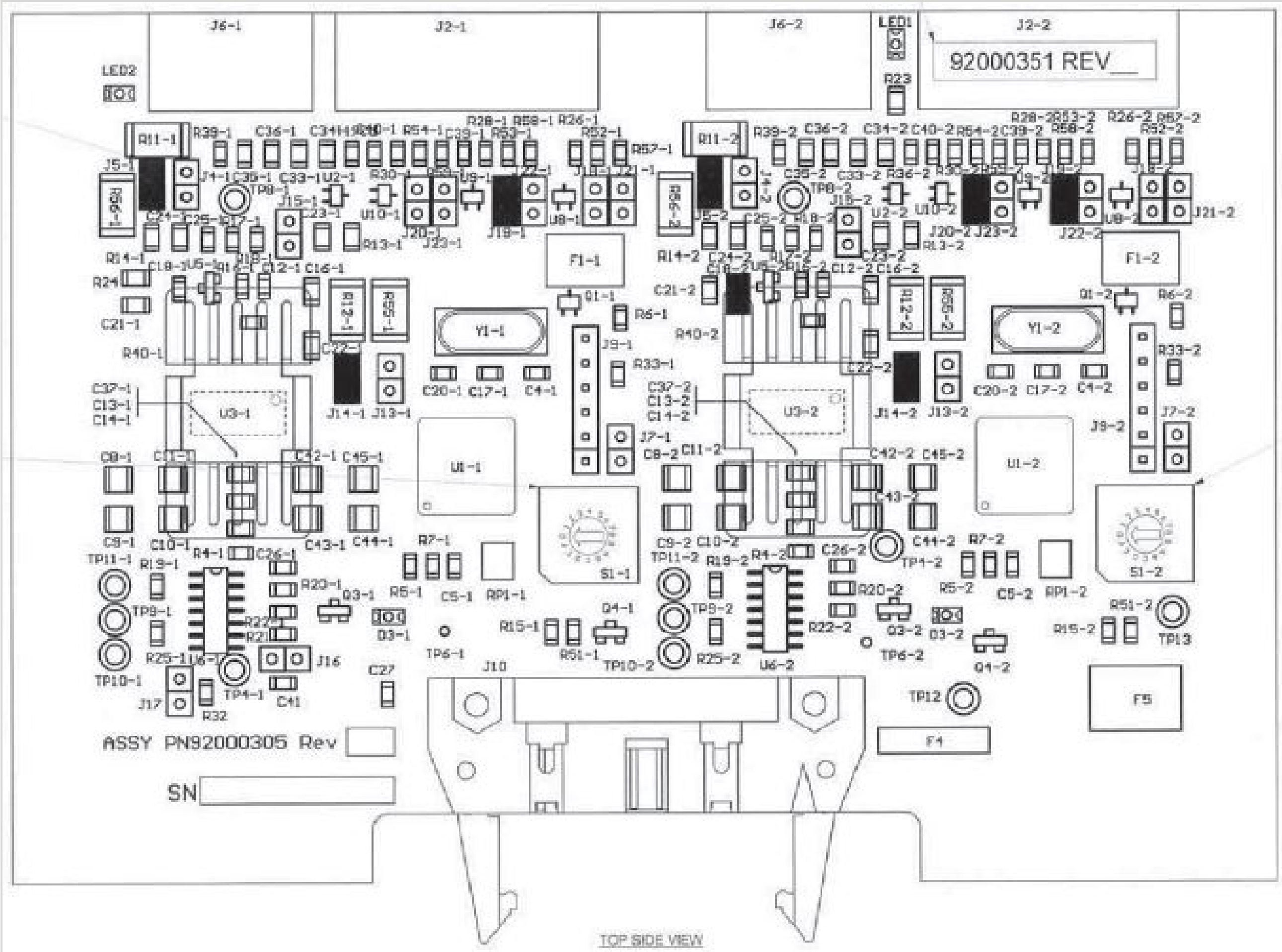
443684 - PCB 2X MTR CNTRL MAG DRV WIN MAX6 SPARE



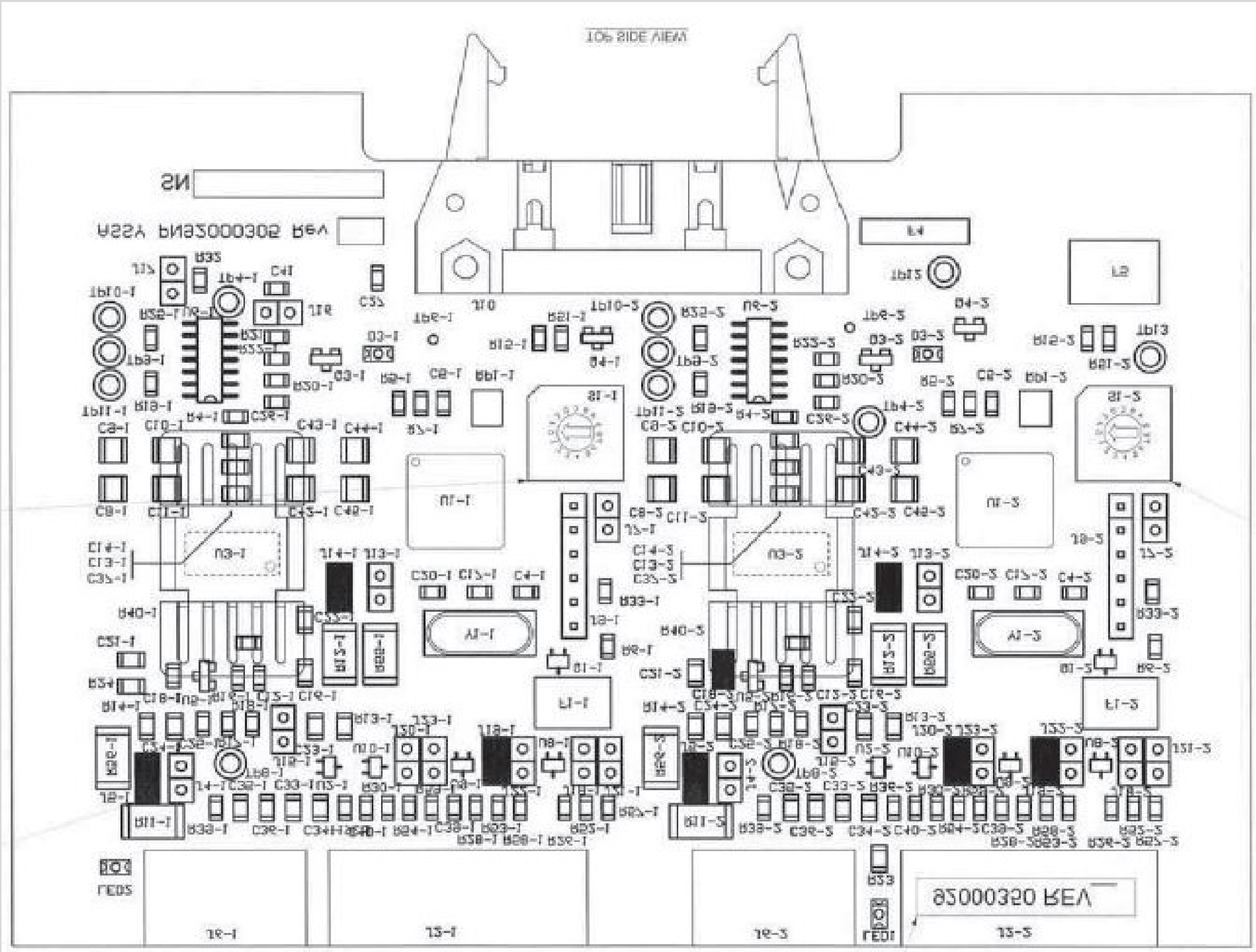
443690 - PC BOARD QUAD PUMP Z GANTRY MAX6 SPARE



443691 - PCB 2X MTR CNTRL RDR RT WIN MAX6 SPARE



443692 - PCB 2X MTR CNTRL RDR RIGHT WIN MAX6 SPARE



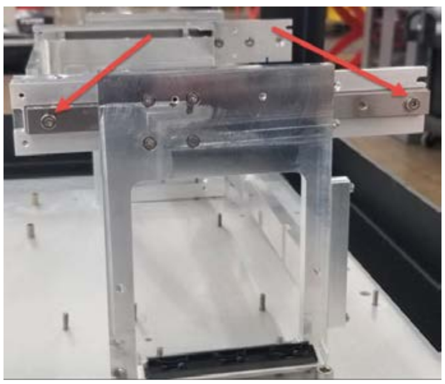
7.4 BD MAX Plus Tray Drive Linear Rail Screw Removal

Materials

Item	Part Number	Qty	Description
2.5mm Allen Key	N/A	1	Normal tool on FSE Toolkit
T10 Torx Screw Driver	N/A	1	
1/16-inch Allen Key	N/A	1	
BD MAX Qualification Kit	444048	2	1 as backup

Procedure

1. Open the BD MAX door and power down the instrument.
2. Remove skins to access the PCR drawers:
    a. Front Skirt
    b. 2 Front Panel Assemblies (Tray Cover)
    c. Façade 2X Reader (Upper Reader Cover)
    d. Façade 2X Rach Assy (Lower Reader Cover)
    e. Rear back panel
3. Remove and discard the four 2.5mm Allen screws from each of the trays as shown.



Verification: After the Service/Installation activities have been completed, perform the specified verification to ensure the product performs as intended. Ensure that applicable results and inspection(s) have been documented per the instructions within the Service Manual. Complete the Technician sign-off statement accordingly within the Service Management System.

Post-Repair Verification

1. Perform alignment of the Reader Tray Position ("tray alignment").
2. Reinstall the instrument skins.
3. Perform qualification on the site where the tray assembly is replaced.
4. Document use of this procedure in the work order.

Appendix A Checklists

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Valid From: 06-Aug-2025 To: 31-Dec-9999 Doc Part: EN Revision: 06 Change #: 500000385034
Print Date: 06-Aug-2025 21:05:02 GMT Daylight Time Usage: Production Usage Version: F Classification: Confidential

A.1 Pre-installation Checklist

The checklist is an optional tool available for use to ensure adherence to the procedure and should not be used exclusively to drive full compliance with procedural directives.

Account:	Location:
Contact title:	Contact name:
Telephone:	Contact email:
BD MAX serial number:	SW version:
Caliper serial number:	Caliper expiration date:

Environmental Requirements

Confirm Non-Operating Storage

Description	Y	N	NA
Does the customer agree to an area that meets temperature -20 °C to 65 °C (-4 °F to 149 °F)?			
Does the customer agree to an area that meets 10% to 90% Relative Humidity, non-condensing?			

Confirm Operating conditions

Description	Y	N	NA
Does the Customer agree to an area that meets temperature requirements 18 °C to 30 °C (or 64.4 °F to 86 °F)?			
Does the Customer agree to an area free that meets 20% to 80% Relative Humidity, non-condensing?			
Does the Customer agrees to an area free from undue vibrations?			
Does the Customer agrees to an area free from direct sunlight? **Note:** Pre-warms should not be stored in direct sunlight.			
Does the Customer agrees to an area free from dust?			
Does the Customer agrees to an area free from extreme			

Description	Y	N	NA
temperatures?			
Does the Customer agrees to an area free from corrosive or explosive vapors and gases?			
In Europe only: Is there adequate space for step-down transformer, dedicated 16 Amp line, and/or 220-240V UPS?			

Clearance Recommendations

Confirm MAX Instrument Clearance Requirements

Description	Y	N	NA
Is there at least 8 feet bench space to accommodate monitor, keyboard, mouse and printer?			
Is there front clearance of 30 inches or 76 cm?			
Is the bench space able to accommodate the instrument depth of 24 inches or 61 cm (from rear of instrument to front feet)?			
Is the bench space able to accommodate the instrument height of 33 inches or 84 cm?			
Is the bench space able to accommodate the instrument width of 37 inches or 94 cm?			
Is the bench space able to accommodate the weight of 250 lb or 114 kg?			
Confirm Pre-warm Clearance Requirements, if required. Otherwise, select N/A, and please explain in the “N/A” comments section.			
Is the bench space able to accommodate a **depth** of 21 inches or 54 cm?			
Is the bench space able to accommodate a **width** of 12 inches or 31 cm?			
Is the bench space able to accommodate a height of 5.5 inches or 14 cm?			

Electrical Requirements

Confirm MAX Instrument Electrical Requirements.

Description	Y	N	NA
Is the Input Voltage 100 - 117 VAC or 200 - 240 VAC?			
Is the Input Current 14.0 Amperes, nominal @ 115 VAC, 60 Hz?			
In Europe only: Is the Input Current 16.0 Amperes Yes No N/A nominal @ 220-240 VAC 50 Hz? BD recommends a 15A dedicated circuit for the instrument. Additional outlets will be required for accessories. (1 outlet for printer, 1 outlet for pre-warm heater, if required.)			
Is Input Line Frequency: 47 - 53 Hz or 57 - 63 Hz?			

Staging Requirements

Confirm MAX Instrument Staging Requirements

Description	Y	N	NA
Is a loading dock accessible?			
Is a staging area available to remove the instrument from the crate?			
Is there a clear route to the installation location?			
If an elevator is required, is one available adequate for instrument movement? If elevator is not required, select N/A.			
Is there adequate space available for on-site parts storage?			
Is there enough room for peripherals (printer, UPS, etc.)?			
Are there enough power and/or emergency receptacles for the entire system? A minimum of 5 receptacles may be needed.			
Additional cables are needed? (If **YES**, note which cables are needed, below. If **NO**, select **NO**.) Please note which additional cables are needed below:			
Does customer acknowledge responsibility of certifying bench support (if applicable)? If not applicable, select N/A.			
How many instruments are being installed? Specify number:			

Responsibilities

Confirm BD Responsibilities versus Customer Responsibilities.

Description	Y	N	NA
Will **BD** provide a forklift to remove instrument from crate?			
Will **BD** provide Crate and packaging removal?			
Will **BD** provide and test all equipment?			
Will **BD** provide customer training?			
Will the **customer** be responsible to make sure HVAC/Environmental Requirements are met?			
Will the **customer** be responsible to ensure that electrical requirements are met?			
Will the **customer** be responsible for LIS - drop near instrument?			

LIS Assessment

Confirm LIS Assessment.

Description	Y	N	NA
Will the customer use or plan to use the LIS capability of the BD MAX™? (If No, please select N/A for remaining questions and then please explain in the "N/A" comments section.)			
Does the customer currently have any BD instruments connected to LIS? (Note: These instruments do not need to necessarily be MAX)			
If the customer has a current LIS vendor, complete fields below. Otherwise, select N/A.			
Vendor Name:			
Version:			
Contact Name:			
Support Capabilities:			

Description	Y	N	NA
Did you verify that the customer has a copy of the Yes No N/A newest version of the BD LIS Vendor Interface Document (L-005933)?			
Has the customer been made aware of the RS -232 cable configuration specification for LIS connectivity?			

Remote Support

Understand Remote Support Capabilities.

Description	Y	N	NA
Will the customer be utilizing remote support or have the remote support capabilities?			
Did the customer receive requirements for remote support?			

Comments

If N/A was selected as an option for any of the above questions, please justify in the space below.

N/A Justification

General comments

FSE & Customer Signature

	Print	Signature	Date
BD Field Service Engineer (FSE)			
Customer			

A.2 Installation Checklist

The checklist is an optional tool available for use to ensure adherence to the procedure and should not be used exclusively to drive full compliance with procedural directives.

Account:	Location:
Contact title:	Contact name:
Telephone:	Contact email:
BD MAX serial number:	SW version:
Caliper serial number:	Caliper expiration date:

Instrument receipt

Confirm that the instrument was properly transported.

Description	Y	N	NA
Did you confirm that the Shockwave Indicator is not activated?			
Did you confirm that the Tip n Tell indicator is not activated?			
Did you confirm that all materials on BOM are accounted for ?			
Did you make sure that packaging material is properly disposed?			

Instrument placement and installation

Confirm that all requirements for the instrument location are acceptable.

Note: The All-In-One monitor requires a 150 cm by 85 cm space.

Description	Y	N	NA
Is instrument location prepared?			
Is work surface leveled?			
Is instrument leveled?			
Did you perform an inspection of the Instrument, All-In-One, and Peripherals?			
Did you properly install the Universal Power Supply (UPS)?			

Description	Y	N	NA
Note: Instrument and AIO should be connected to the UPS, and all peripheries to the same ground and phase (This recommendation is for 3 phases power distribution.)			
Did you perform an Instrument and All-In-One Installation? **Note:** Please make sure the correct time and date are set.			
Did you properly install the Mouse, Keyboard, and Scanner?			
Did you properly install the printer?			
Did you remove the shipping hardware material?			

Instrument Start Up

Confirm Robot IP addresses.

Description	Y	N	NA
Did you set the Robot (Huey) IP address?			
Did you set the Reader A (Dewey) IP address?			
Did you set the Reader B (Louie) IP address?			
Did you confirm that Reader A (Dewey) and Reader B (Louie) IP address are correct via the Empty Fill Check (EFC)?			
Did you perform Reader Health?			
Did you **verify** Magnet Height, Depth, and Tilt?			
Did you **adjust** Magnet Depth and/or Tilt? **Note:** If you selected **Yes**, please perform magnet height adjustment (Refer to the next item in this checklist).			
Did you **adjust** Magnet Height?			

Qualification

Qualify the instrument.

Description	Y	N	NA
Did you perform a Qualification Run MAX Instrument Qualification Procedure on both top and bottom cartridge? The Run must pass the criteria ("Qualification Run" on page 322)			
Did both Runs 1 and 2 pass qualification as per the criteria ("Qualification Run" on page 322)? If additional runs were performed, please note the outcome of the run(s) in the remarks section.			
Remarks:			

Finalization

Confirm that the instrument and workplace are clean.

Description	Y	N	NA
Was cleaning required?			
Did you record pertinent info on the work order, if needed?			

Comments

If N/A was selected as an option for any of the above questions, please justify why in the space below.

N/A Justification

General comments

FSE & Customer Signature

	Print	Signature	Date
BD Field Service Engineer (FSE)			
Customer			

A.3 PM Checklist

The checklist is an optional tool available for use to ensure adherence to the procedure and should not be used exclusively to drive full compliance with procedural directives.

Account:	Location:
Contact title:	Contact name:
Telephone:	Contact email:
BD MAX serial number:	SW version:
Multi Meter Serial Number:	Multi Meter Expiration Date:
Caliper serial number:	Caliper expiration date:

Instrument Inspection

Confirm all parts/functions of instruments are functioning properly.

Description	Y	N	NA
Did you verify all moving parts are working?			
Did you verify airline connections are tight?			
Did you perform Calrack?			
Did you verify Magnet Height, Depth and Tilt?			
Did you adjust Magnet Height?			
Did you adjust Magnet Depth and/or Tilt?			
Did you inspect the X, Y, and Z gantries and ensure they are functioning properly?			
Did you verify that the time and date on the All-In- One is correct?			
Are ADF files updated to the latest version?			
Did you visually verify the belt condition?			
After verifying, did you have to set, replace, remove and/or loosen the belt?			
If belt adjustments were required, did you use the belt frequency meter?			

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Description	Y	N	NA
Did you check the Heater MUX boards' cables for tension by moving the drawers in and out & up and down?			
Did you perform self-test on Dewey and Louie?			
Did you perform load cartridge test?			
Did you perform CatalogWin Test?			
Did you check the condition of the Rack Flag sensors?			
Did you check and verify the Hinge door screw at the door?			
Did you verify that the power supply voltages are within the specification stated in the Preventive Maintenance Procedure?			
Did you perform qualification according to Qualification Run procedure?			
Did you check the normalizer ratios?			
If renormalization is required?			
If renormalization is required, did you perform renormalization successfully? If not required, please select N/A.			
Did you upgrade the instrument to the latest SW Version? If No, please explain in Remarks below.			
Remarks:			
Did you update all ServiceMax attributes as needed?			

Cleanings

Check instrument cleanliness.

Description	Y	N	NA
Did you check and verify that the instrument and the area outside of the instrument is clean?			
Did you clean the air filter? If not required, select No.			

Comments

If N/A was selected as an option for any of the above questions, please justify why in the space below.

N/A Justification

General comments

FSE & Customer Signature

	Print	Signature	Date
BD Field Service Engineer (FSE)			
Customer			

Document: BDDSSGFS7422 Doc Type: ZIP Status: Released EFFECTIVE
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A.4 Qualification Checklist

Refer to the qualification procedure "Qualification Run" on page 322.

The checklist is an optional tool available for use to ensure adherence to the procedure and should not be used exclusively to drive full compliance with procedural directives.

Account:	
Location:	
Country:	
Contact title:	Contact Name:
Telephone:	Contact Email:
MAX Serial Number:	Software version:
Multimeter Serial Number:	Multimeter Expiration Date:
Caliper Serial Number:	Caliper Expiration Date:

Installation Qualification	Y	N	N/A
Are there any signs of damage to the instrument?			
Are there any signs of damage to the peripherals?			
Is the instrument level?			
Is the instrument free from direct sunlight and ventilation?			
Does the GUI screen appear when powering up the instrument?			

Operational Qualification

Operational Qualification - Initialization	Y	N	N/A
Initialize motors.			
Did you successfully home all motors? If No, please comment in Remarks section below.			
Remarks:			

Performance Qualification	Y	N	N/A
Check 24 Sample Test Runs.			
Did you check the cartridge for fill issues?			
Did you add all your Qualification results to your work order?			
Please note Qualification Kit Lot number			
Please note Cartridge Kit Lot number			

All Requirements must be met. If N/A was selected for any of the above items, please justify why in the space below.

N/A Justification:

General Comments:

BD FS Signature and Date:	Customer Signature and Date
Signature:	Signature

BD FS Signature and Date:	Customer Signature and Date
Date:	Date:

A.5 Periodicity Test

Reader Serial Number: ________________ Heater Mux Serial Number: ____________

Task	Completed By	Date
BD MAX EVP/xEBP Data Review Verify that there is no non-reportable results produced by the thermal crosstalk and no false results produced by the normalizer response drift on targets on ROX channel (Norivius and Human Astrovirus on EVP, Vibrio and Shigella (Shig) on xEBP lanes).		
NoV False Positive Screen: ☐ ZERO NoV False Positive Results ☐ One or more Nov False Positive Results		
hAstV False Positive Screen: ☐ ZERO hAstV False Positive Results ☐ One or more hAstV False Positive Results		
Vibrio False Positive Screen: ☐ ZERO Vibrio False Positive Results ☐ One or more Vibrio False Positive Results		
Shig False Positive Screen: ☐ ZERO Shig False Positive Results ☐ One or more Shig False Positive Results		

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Reader Serial Number: _______________ Heater Mux Serial Number: ___________

Task	Completed By	Date
1. Perform two full runs (2 full racks each containing 12 strips) of the MAX Vaginal Panel Assay per the instructions in the previous section. 2. All samples should be blank. 3. Record bubbles and partial fills for each run in the diagram(s) below. MVP Run 1 (Side A/B): MVP Run 2 (Side A/B):		
BD MAX MVP Data Review 4. Export the BD MAX database(s) for the BD MAX MVP runs to a USB drive. 5. Using the validated Results Reprocessor tool, extract the results metrics for the BD MAX MVP runs to a CSV file. 6. Open the CSV file generated in the last step. 7. Enable filtering of the table by using the Data -> Filter option on the Excel ribbon.		

<table>
<tr><th>Task</th><th>Completed By</th><th>Date</th></tr>
<tr><td>
8. Using the filter drop-down option, select only Cartridge Positions listing BOT (bottom) locations AND excluding the samples in positions A1, A2, B1 and B2 (spiked with ZeptoMetrix controls).

Note: This requires the use of two filter options.

9. Copy the ROX EP results into an individual column per reader on a new sheet in the Excel spreadsheet, assuring that only the filtered values are copied and not any of the hidden rows.

10. Use the following formula on the entire range of copied / pasted data, making sure to replace "SELECT RANGE OF DATA HERE" with the range of the copied / pasted data set (e.g. - "A2:A49"). This calculation determines the expected percentage of EP metrics to exceed the threshold of "100" (as defined in Appendix B). =(1-NORMDIST(100,AVERAGE (SELECT RANGE OF DATA HERE),STDEV.P (SELECT RANGE OF DATA HERE),TRUE))

11. Review the result against the table below for corresponding follow-up activity.
<table>
<tr><th>Result</th><th>Action</th></tr>
<tr><td>Less than or equal to 5.6%(x <= 0.056 as displayed in Excel)</td><td>Instrument is passing with no additional review required</td></tr>
</table>
</td><td></td><td></td></tr>
</table>

<table>
<tr><th>Task</th><th>Completed By</th><th>Date</th></tr>
<tr><td>
<table>
<tr><th>Result</th><th>Action</th></tr>
<tr><td>Greater than 5.6% but less than 8.6% (0.056 < x < 0.086 as displayed in Excel)</td><td>Management review to be performed prior to release of instrument</td></tr>
<tr><td>Equal to or greater than 8.6% (x > 0.086 as displayed in Excel)</td><td>Instrument is considered higher risk of producing nuisance result metric errors</td></tr>
</table>
</td><td></td><td></td></tr>
<tr><td>BD MAX MVP C. Group EP Metrics Screen:
☐ Result Metric Z-Score <= 5.6% (PASS)
☐ Result Metric Z-Score > 5.6% AND <8.6% (REVIEW)
☐Result Metric Z-Score > 8.6% (FAIL)</td><td></td><td></td></tr>
<tr><td>BD MAX MVP Data Review:
Note: Certain INDs may be caused by consumable related issues. For example, a torn blue silicone septum cap may cause a Liquid Level Sense (LLS) indeterminate (IND) result. These non-instrument issues may be dispositioned and the associated data excluded provided these non-instrument related failures are documented in this Deviation Waiver.</td><td></td><td></td></tr>
<tr><td>Cgla False Positive Screen:
☐ ZERO Cgla False Positive Results (PASS)
☐ Acceptance Criteria NOT Met (FAIL)</td><td></td><td></td></tr>
</table>

Comment(s):____

Appendix B Document References

B.1 Accessing the Epicenter/Instrument Adapter/Intel NUC

a. EpiCenter Reference Guide. https://bdsmx.my.salesforce.com/kA11W000000083n

b. EpiCenter Password. https://teams.microsoft.com/l/channel/19%3a3e5f0c4f977e46998222e1ecefe9d7f4%40thread.tacv2/General?groupId=2f4ed1c1-c1c9-4181-83e7-3df210050012&tenantId=94c3e67c-9e2d-4800-a6b7-635d97882165

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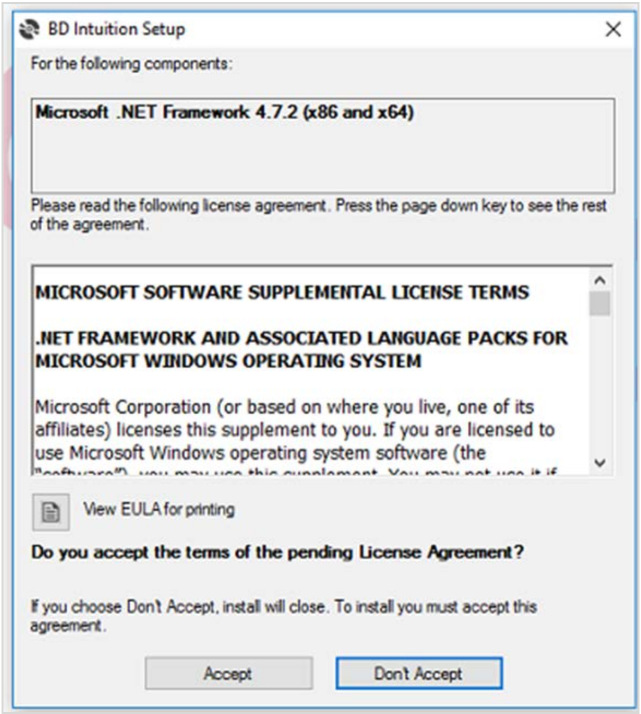
B.2 Installer .NET Framework 4.7.2

The Installer may prompt you to a Microsoft .NET Framework 4.7.2 update.



1. Click on **Accept** and follow on screen prompts to install the .NET framework.
2. Reboot the machine once the installation is completed.

Revision History

Rev 6 change summary details (Release 08/2025)

Replacement table

- Reader's replacement updated
- Stripper assembly spare updated

Procedures

- 5.2.8 Windows MUX Board Replacement
- 6.3.3.1 Reprogramming or Flashing the Huey MUX Board
- 6.4.15 Gantry Alignment
- Updated images in procedures
- Corrected Gantry replacement 5.2.14.2 Z-Head Assembly Removal
- Fixed typo errors
- Updated 7.4 BD MAX Plus Tray Drive Linear Rail Screw Removal. Image added
- Updated 5.1 Preventive Maintenance
- Updated the quality document number 5.1.5 X/Y-Gantry Belt Tension
- Added the spring Nitrogen gas Max6 spare 444782
- Updated 1.6.5 Clean and Decontaminate Tools & Equipment
- Corrected table on Attachment A: MDR-TB Assay Fitness Test
- Add missing pictures on the Periodicity test. 6.4.1.8.2
- Set up a Full Run on the Side where the False Positive was
- Replaced in the Table of contents, module 5.2.5
- Replaced pictures on 5.2.5.1 Reader Assembly
- Added note on 5.2.10.4 Replacement Liberty Board 435233
- Replaced PM pictures with gloves
- Added text in 1.2.1 Parts Identification

Documentation updates

- Replaced the obsolete BALTQP1101 for the DSLID-10119 in 5.1.5
- Updated the 1.6.5 procedure, removed reference to (BALTFS0060)
- Updated 1.2.1 Parts replacement Block

Rev 5 change summary details (Release 08/2024)

Service bulletin information and procedural updates to Installation, Care and Maintenance, Diagnostics and Troubleshooting, and Service Parts

- BDDSFSSB6958-51 BD MAX Synapsys Setup
- BDDSFSSB6958-55 BD MAX PCR Tray Design Update
- BDDSFSSB6958-57 BD MAX AIO Arm Mount
- BDDSFSSB6958-58 BD MAX X-Rail Adjustment
- BDDSFSSB6958-63 XY limit sensor replacement
- BDDSFSSB6958-65 MDR-TB Fitness Test Instrument Qualification Procedure

Minors Typo corrections: Change on Skirt to Skins

- Updated the installation Procedure
- 2.4 Install new location relocation/Move
- Updated the normalization procedure
- Updated the Results Reprocessor information
- New AIO Installation procedure to be added at the installation
- 6.2.9.5 Refresh the AIO GUI if frozen at the run
- Long Term BD Max Shut Down
- Updated the LLs Testing documentation
- Corrected the PRES and RPRES values
- 6.2.7.3 Motor Encoder Vault Table
- LPRES and RPRES values

Updated the spare parts list

- 443690 updated the board diagrams
- 443692 Updated PCB 2X MTR CNTRL RDR RIGHT WIN MAX6 SPARE
- 445345 Front Panel Assembly
- 445346 Front Panel Assembly MAX PLUS

Procedures updates

- MDR-TB Assay Fitness Test checklist
- MTB Results Table
- 2.3 Verification Update
- 3.1 Instrument decontamination

- 4.3 Remote connectivity
- 4.4 RSS Integration
- 4.4.1 Intuition Parser Installation
- 4.4.2 Intuition Parser Installation
- 4.4.3 Intuition Parser Removal
- 4.5 Synapsys Integration
- 4.6 BD MAX MDR-TB Fitness Test Instrument Qualification Procedure
- 5.1 Verification Update
- 5.2.6.1 Gantry Blue Cobra Controller
- 5.2.6.2 X-Gantry Stepper Motor
- 5.2.6.3 Idler Assembly
- 5.2.6.4 Limit Switches Left and Right X Rail
- 5.2.6.5 HALL Effect Sensor
- 5.2.6.6 Drive Belt
- 5.2.6.7 X/Y Blue Cobra Controller
- 5.2.6.8 Y Limit Switch
- 5.2.16 Replacement Cable assembly door sensor
- 5.2.17 Cable Assy X-Y Encoder
- 5.2.18 Splash Guard MAX Spare
- 5.2.19 Internal Fasteners Max spare
- 5.2.4.9 Façade 2X Reader Rack Max Spare
- 5.2.8 Windows MUX Board Replacement
- 5.2.9 Circuit Card Assemblies
- 5.2.10.3 Bender Board
- 5.2.13.1 Reader Pressure Motor Module
- 5.2.13.2 Reader Tray Drive Assembly
- 5.2.13.3 Reader 2x Motor Controllers
- 5.4.4 PCR Tray Design Update
- 5.5 BD MAX Load Cartridge Test Kit

New Appendix

- A.5 Periodicity Test
- A6 Document Reference NUC installations link to the shared drive

- A7 .NET Framework 4.7.2

New spare parts update

- 443690 update the board diagrams
- 444786 WIRE DUCT ASSY READER MAX6 SPARE
- 444785 WIRE DUCT ASSY READER GEN2 MAX6 SPARE
- 445345 FRONT PANEL ASSEMBLY MAX SPARE
- 445346 FRONT PANEL ASSEMBLY MAX PLUS SPARE
- 444762 CABLE ASSY X-Y ENCODER MAX6 SPARE
- 445338 INTERNAL FASTENERS MAX SPARE
- 445340 FAÇADE 2X RACK ASSY MOD MAX SPARE
- 445341 FACADE 2X READER MAX SPARE
- 445342 GANTRY CABLE SET MAX SPARE
- 445343 SPLASH GUARD MAX SPARE
- 445344 USB FLASH DRIVE SPARE

Parts replacements

- Updated the 7.1 Parts Replacement Action Table
- Add validation protocols for all spare parts replacements
- Include quality notification at the end of the parts replacements

QP29 Validations Procedures

- 5.1.1 General Health Check
- 2.3 Installation Procedure
- 5.2.2 All-In-One Screen Calibration/Linearization
- 5.2.3 Screen Capture
- 5.2.4.9 Verification after remove/replacement
- 5.2.5.3 New Revised Reader Configuration
- 5.2.7 Y-Gantry
- 5.2.8 Windows MUX Board Replacement
- 5.2.9 Lysis or Mag Extractor Assemblies
- 5.2.10.1 Extractor Motor Controller
- 5.2.10.3 Bender Board
- 5.2.10.4 Replacement Liberty Board

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- 5.2.10.5 Replacement PCB 2X MTR CNTRL MAG DRV WIN
- 5.2.12.2 Installing the New Power Supply
- 5.2.14.2 Z-Gantry Assembly Removal
- 5.2.14.3 Z-Gantry Quad Pump Removal
- 5.2.14.4 Z-Gantry Stripper Assembly Removal
- 5.2.14.5 Z-Controller Removal
- 5.2.14.6 Quad Pump Controller Removal
- 5.2.15 Replacing the Z-Robot Motor
- 5.2.16 Replacement Cable assembly door sensor
- 5.2.18 Splash Guard MAX Spare
- 5.2.20 Wire Duct Assembly Reader
- 5.2.21 Gantry Cable Set MAX Spare
- 5.2.22 Cable Assy X-Y Enconder
- 5.2.23 X-Y Limit sensor replacement
- 5.2.25 X-Gantry Rail adjustment
- 5.5.1 ZBA Handheld Barcode Reader
- 5.5.2 ZBA Handheld Barcode Reader Configuration
- 5.5.3 Printer Installation
- 5.5.5 USB Flash Drive Spare

Rev 4 change summary details (Release 03/ 2023)

- Added standardized optional checklist verbiage to all checklists

Rev 3 change summary details (Release 02/ 2023)

- Formatted the manual to standardized styles to align with KLA and BDB docs
- Parts list updated
- Door Removal Procedure
- Emulate Parallel Port, Heater MUX Heater Layout
- Lysis Heater Test
- BD MAX Customer Activation of Software Features Letter Agreement
- BDDSFSSB6958-36 BD MAX Fixed Magnet Assembly