



# BACTEC FX40 System™

## Service Training Manual

### System Operation

#### Module A



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## System Operation

### Overview:

This topic provides a system operation overview for the BACTEC™ FX40 Instrument.

### Topics:

The following Topics are covered in this Module:

- Topic 1: User Interface
- Topic 2: User Workflow
- Topic 3: Reports
- Topic 4: Isolation Mode
- Topic 5: User Maintenance
- Topic 6: System Alerts
- Topic 7: System Operation Exercises

#### Materials Required:

- BACTEC™ FX40 Instrument
- System Software
- BALTTI0585 BACTEC FX Station Qualification Procedure
- Calibrator Vials Catalog #441476



## Topic 1: User Interface

User sessions with the instrument can be initiated by selecting the appropriate function from the touch screen or by opening an instrument door. The system software will recognize a door opening event via the Door Ajar Sensor.

User initiated workflow begins when the user selects an icon associated with the vial workflow to be performed via the touch screen. Once the workflow has been activated, the user will perform the appropriate actions until the workflow is exited.

Once an instrument door is opened, the user can initiate vial activated workflow or workflow via one of the icons on the tablet computer. Vial activated workflow begins when the user scans a vial sequence number or removes a vial. When a door is opened, vial status indicators adjacent to each station inform the user of the status of each vial.

The user may activate the workflow associated with a particular vial by removing the vial from the instrument. For vial entry, the user may activate the vial login workflow by scanning the vial sequence number barcode and then placing the vial in an available station.

The BACTEC FX40 instrument incorporates the following:

- Red, Green, and Amber LEDs on each instrument door indicate positive vials, negative vials or system alerts, respectively. Tricolor LEDs on each station indicate the station status (**Figure 1**).
- A tablet computer displaying both graphic and text, allows the user to perform actions by touching buttons and fields shown on the screen.
- An emulated keyboard for alpha/numeric input that is also capable of providing international characters.
- A barcode scanner to read vial sequence numbers and/or accession numbers.
- USB ports to connect printer, barcode scanner.
- An audible alarm from tablet computer.
- Two rack subassemblies per instrument capable of testing 10 vials per row (20 per assembly).
- A serial port LIS data transmission.
- A serial port for connecting remote alarm.



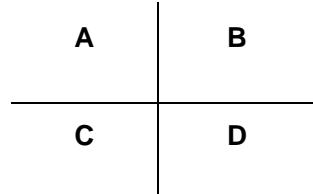
Figure 1



### System Configuration

BACTEC FX40 is provided in the following system configurations: 1) as standalone instrument, 2) interconnected a local cluster of up to 4 instruments. In both cases, they are controlled by one Tablet Computer.

A single instrument is designated as instrument A. In a cluster, additional instruments are designated, B, C, and D (maximum of 4 instruments in a cluster, **Figure 2**).



**Figure 2**

Each instrument has its own serial number. However cluster is numbered as a collective. A lab with three clusters would have tablet computers number 1, 2 and 3.

## Instrument Layout

Instrument is divided into rows and columns of stations. Rows are lettered A-D from top to bottom. Columns are numbered 1-10 from left to right as you face the open drawer.

There are 40 stations per instrument. The stations are identified by: CC-I-RSS, which CC = instrument Cluster, I = FX40 Instrument designation, and RSS = Row and Station.

Ex: 01-B-D8 points to the first cluster, instrument B, row D and the eighth station column.

## Instrument Access

Each instrument can be opened by grasping and pulling a door handle. There is no locking mechanism to restrict user from opening multiple instruments within the same cluster.

## Station Status Indicators

Above each station is a tricolor LED indicator to display the station status. Each station status condition is outlined in **Table 1**.

TABLE 1 STATION STATUS	
VIAL STATUS	LED COLOR
POSITIVE	« FLASHING » RED
NEGATIVE (END OF PROTOCOL)	« FLASHING » GREEN
ONGOING	NONE
ANONYMOUS ONGOING	« FLASHING » AMBER
ANONYMOUS POSITIVE	« FLASHING » AMBER/RED
AVAILABLE	STEADY GREEN
BLOCKED STATION	NONE, STATION BLOCK SHOULD BE INSTALLED
BLOCKED STATION ON BLOCK/UNBLOCK SCREEN	STEADY RED
UNUSABLE STATION VIALS	STEADY RED, WHEN "NOW" HAS BEEN

**TABLE 1 STATION STATUS**

PARTIALLY SEATED VIALS	SELECTED IN OPEN DOOR MESSAGE FOR UNUSABLE STATIONS AND OPEN DOOR MESSAGE FOR PARTIALLY SEATED VIALS
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### Barcode Scanner

A barcode scanner is connected to instrument. It turns on when the instrument is ready to read a bar code. To scan a bar code, place the vial below the scanner. If necessary, slowly turn the vial until the acknowledgement beep sounds indicating that the bar code was scanned successfully.

Note that there is only one barcode scanner for an FX40 cluster with multiple instruments.

**NOTE:** Scan order (accession/sequence) does not matter

### Status Display

The Status display is the main display shown when no other operation has been initiated or is in progress (**Figure 3**). It is the initial display that appears when the system starts up or restarts. This screen provides notebook tabs to access Status, Reports, Maintenance or Configuration. This screen provides the visual interface to the instruments.

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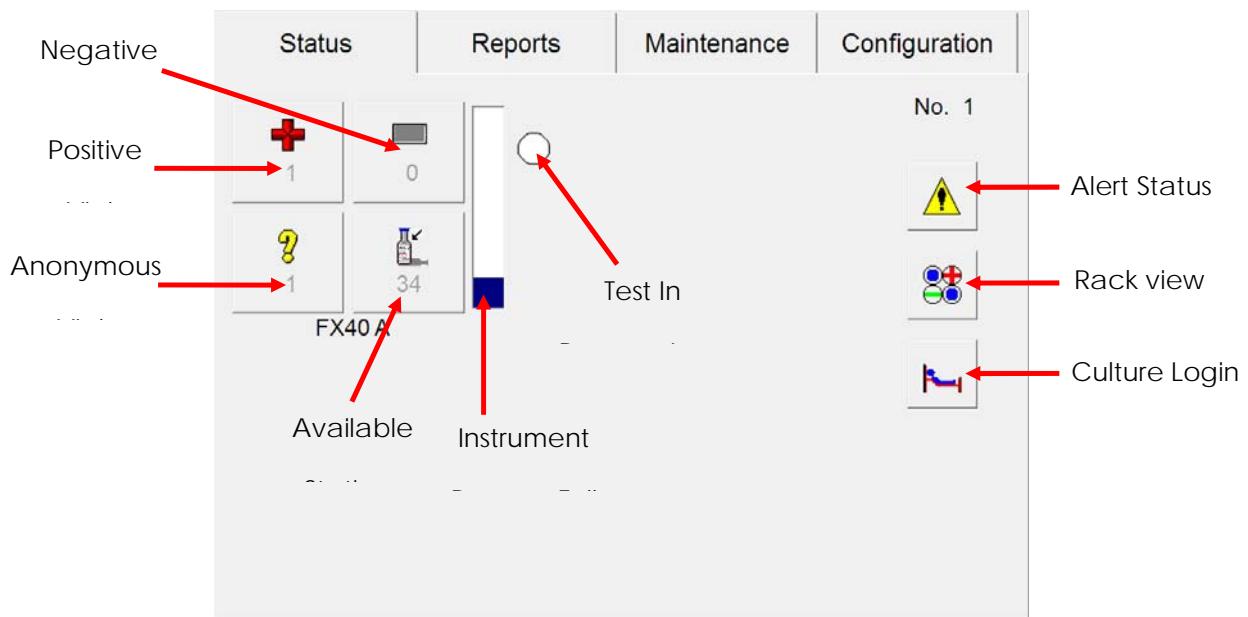


Figure 3

### Alert Status

The system alert display, shows a list of system alerts that have occurred (Workflow alerts are not displayed). The display can be accessed by pressing the alert

button . The last 100 alerts are shown in the display, from the most recent (top) to oldest (bottom). The list is updated dynamically.

Any active alerts are indicated by an exclamation point at the left side of the display (**Figure 4**). Active alerts cannot be deleted from the list until the condition has been cleared.

To view a message in the detail window or delete a message, access the alert list, tap the message, select info to view more detail or delete to clear the message.

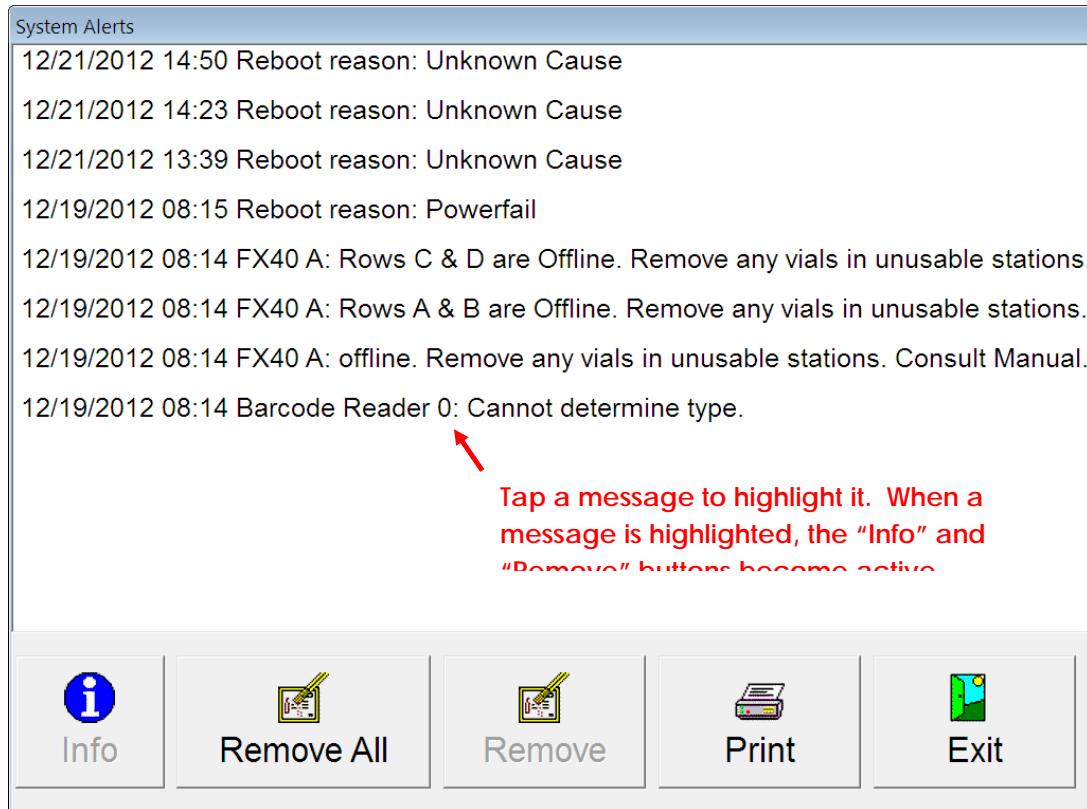


Figure 4

### View Stations Display

The View Stations display (**Figure 5**) appears when you tap the view stations button



This display shows the status of each station. View Stations is updated dynamically as vial statuses change.

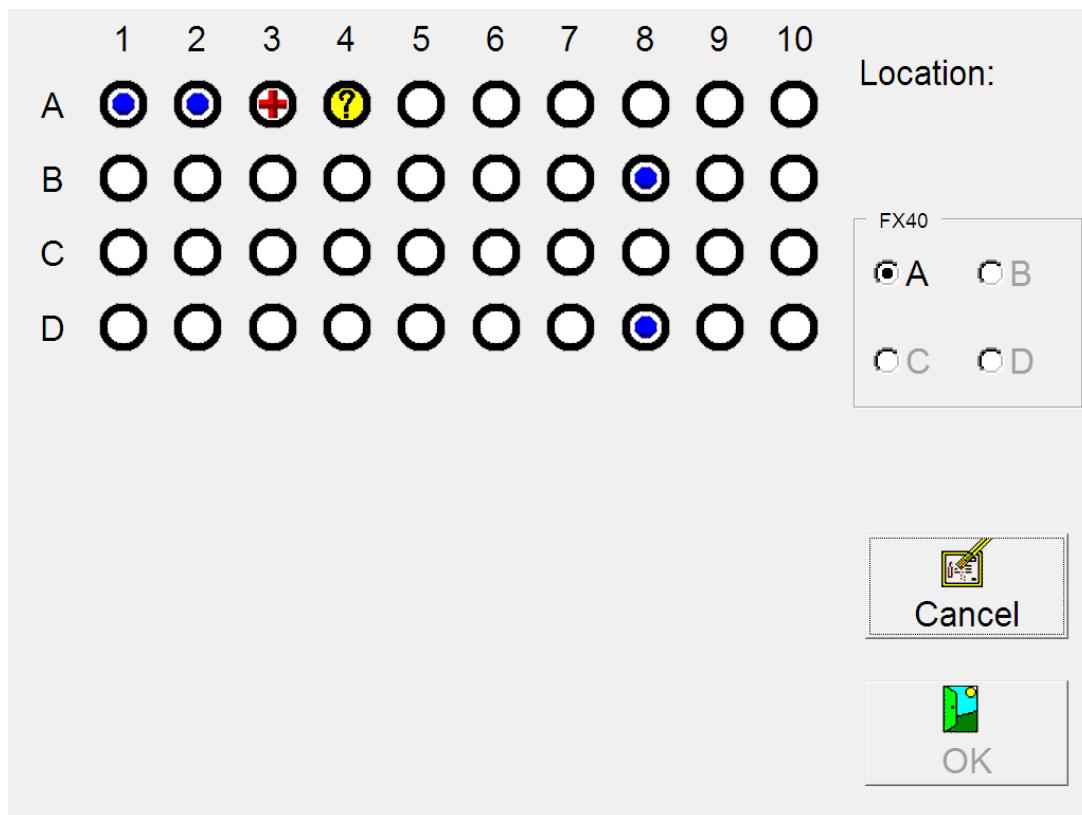


Figure 5

**Table 2** describes the station statuses.

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	anonymous ongoing vial (yellow background)		anonymous positive vial (red background)
	ongoing station		available station
	positive station		negative station
	blocked station		unusable station – station has been blocked by the instrument because of a temperature, measurement, or agitation failure

Table 2

## Culture

The culture button  allows access to patient related information for any specimen. Information can be searched by patient, specimen or vial. (**Figure 6**).

Patient	Specimen	Vial	
	Patient ID: <input type="text" value="959595959"/>		
	Patient Name: <input type="text" value="Doe, John"/>		
+ Accession	Date	Time	
747474664			
 Disassoc	 Save	 Clear	 Exit

Figure 6



## Reports Menu

The Reports Menu (**Figure 7**) enables you to select reports to be printed.

To access the Reports Menu, tap the “Reports” tab. To print a report, highlight the desired report(s) by tapping it in the menu, then tap the “Print” button.

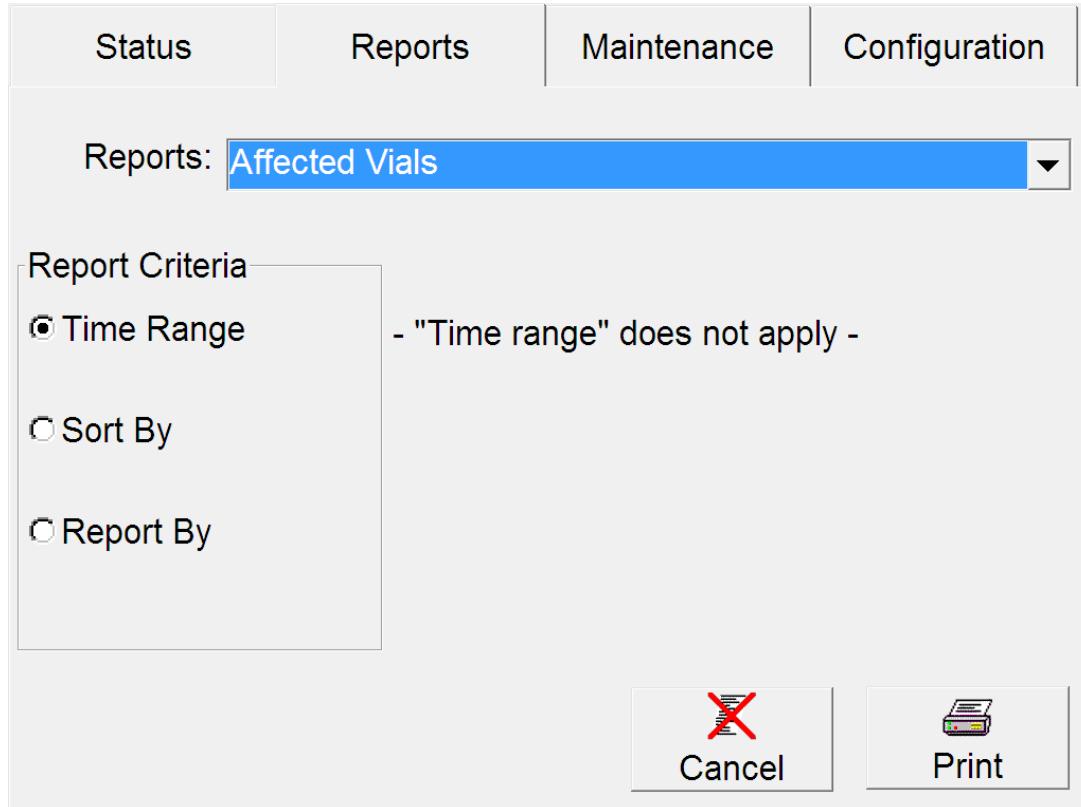


Figure 7

**Maintenance Screen**

Each day simple maintenance procedures (Figure 8) should be performed. The best time to perform maintenance is first thing in the morning, but it may be done at any time.

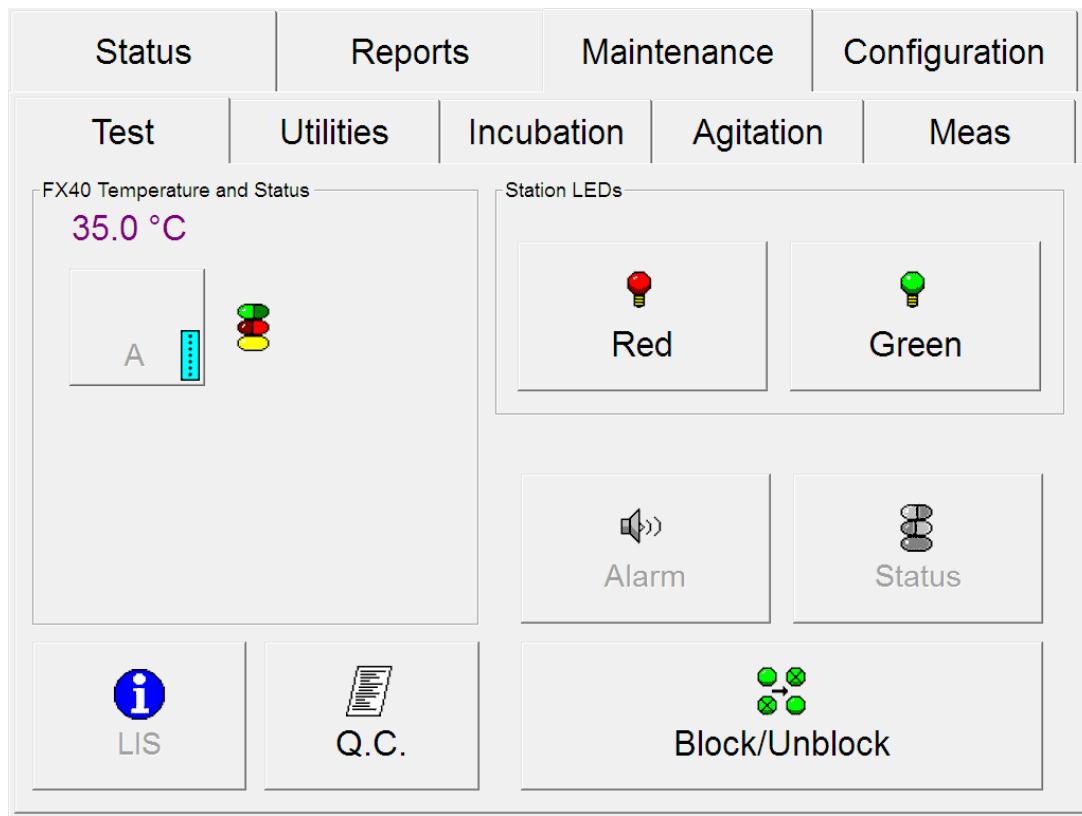
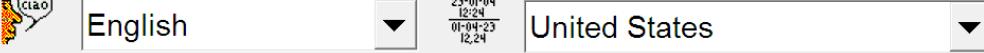


Figure 8

## Configuration Screen

The Configuration Screen (**Figure 9**) allows configuration parameters for laboratory-specific usage.

Status	Reports	Maintenance	Configuration	
Lab	Reports	Instr	LIS	
Workflow				
				
Language/Locale				
				
Media				
				

**Figure 9**

The following parameters can be configured to customize workflow.  
The parameters are grouped as follows:

### Lab

Time and Date Format

Language

Accession Bar code/Enable or Disable

Batch Negative Removal Enable/Disable

Show Related Vials Enable/Disable

Country

Media Protocol length (days)

### **Reports**

Reports Configuration enables you to set up printing and reports parameters.

### **Instr**

The configuration is unique to each individual instrument within a cluster or workgroup. The following can be configured from the Instrument tab:

Instrument No.

Volume

FX40 Serial Numbers

Network Address

### **LIS**

Enables you to set up communications to a Laboratory Information System (LIS).

### **Time**

May be changed in a standalone instrument setup.

## Topic 2: User workflow

### Vial Entry

**NOTE:** Ensure all vials are seated prior to door closure

- Open the instrument door, the barcode scanner will activate.
- Touch the <VIAL ENTRY> icon on the Status display or simply scan the vial sequence and accession number.
- The vial entry workflow screen will be displayed.
- When the vial sequence is scanned, the sequence number, media type and protocol length is displayed.
- The available station LEDs inside the instrument will illuminate solid green.
- Place the vial into any available station (illuminated solid green).
- Workflow screen clears, Vial Entry sound is played, and station LED is turned off.
- (Instrument associates accession and sequence numbers with station location).
- Repeat process for each vial to be entered.
- Close instrument door.

**NOTE:** Do not place the vial into a station not illuminated (blocked station or station with non-functioning LEDs).

**NOTE:** Vial sequence and accession numbers can be entered manually at the Culture screen.

**Resolutions to typical problems during Vial Entry:****Correcting an Orphan Vial During Vial Entry**

- If during Vial Entry, a vial sequence is scanned and a vial is placed into the instrument without scanning (or typing) an accession number, the following message will appear: "Vial was entered without accession; accession can be added at the Culture Screen".
- Note vial station.
- Touch <OK>.
- Remove vial.
- "Unexpected vial removed" message displayed, station LEDs turn off.
- Touch <NO>.
- Message appears telling the user to scan the vial and return it.
- Scan sequence and accession – make sure that both fields are populated.
- Place the vial into the station flashing green (Information is associated to the vial, not the station).

**Previously Entered Vials:**

- If the vial was previously entered in the instrument that is open and it has been less than 20 minutes since the vial was removed, the last station that it was in will be illuminated flashing green. Return the vial to the station that is flashing green.
- Greater than 20 minutes but less than 5 hours algorithms start again due to sensor technology. Vial will go back in same station location.
- If the vial has been out of the instrument for 20 minutes or more, return the vial to the station that is flashing green. All other available station LEDs will be lit steady green.

**Ongoing (non-positive orphan)**

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- Obtain station location of orphan vial from Current Inventory Report or Orphan Report.
- Open instrument door where orphan is located.
- Remove orphan vial.
- Message appears to scan sequence to return or cancel to remove.
- Scan sequence and accession. Station that it was pulled from illuminates flashing green. The vial information is displayed.
- Return vial to the flashing green station.

**Positive Orphan**

- Obtain station location of orphan vial from Current Inventory Report or Orphan Report.
- Open instrument door where orphan is located.
- Remove positive orphan vial (flashing red in station noted on Current Inventory Report) now in positive removal workflow.
- Scan sequence.
- Exit Remove Positive workflow.
- Shut drawer.
- Touch <Culture> from the Status Screen.
- Touch Vial tab.
- Scan sequence.
- Scan accession.
- Accession is backlit.
- Touch <SAVE> button.
- The remaining positive station LEDs are turned on.

**If an ongoing vial is accidentally pulled during Positive Removal:**

- Station LEDs are turned off.
- A message is displayed “Unexpected vial pulled” ; sequence for the pulled vial is displayed.
- Message displayed asking if the intent is to remove the vial “Remove?”
- Touch <NO>.
- Message is displayed to scan the sequence to return the vial.

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- o The barcode reader is turned on.
- o Scan the vial sequence.
- o Vial Entry workflow screen is displayed.
- o The sequence and vial information is displayed.
- o The station the vial was pulled from is illuminated flashing green.
- o Return the vial to the indicated station (information is associated to the vial, NOT to the station).
- o Touch the <Exit> and note the Remove Positive workflow is now active.

### Correcting an Anonymous Vial During Vial Entry

If during Vial Entry, the accession only is scanned (not the vial sequence), and the vial is placed into an available station, the Anonymous Entry sound will be played. A message will be displayed stating that an anonymous vial cannot have an accession.

- o Touch <OK>, then exit.
- o Touch ID Anonymous on the Status screen.
- o Pull vial from station with flashing amber LED.
- o Barcode scanner turns on.
- o Scan both sequence and accession.
- o Place the vial into the station with flashing green LED.
- o Touch <exit> to exit ID Anonymous workflow and return to Vial Entry.

### Change Protocol Length Workflow

- o Go to the Culture Screen.
- o Select the Vial Tab.
- o Touch Location.
- o Drawer View appears.
- o Select location of vial for which protocol length needs to be changed.
- o Select modify.
- o Select # of days.
- o Touch SAVE.

### Positive Removal

**NOTE:** If there are anonymous vials in the instrument, do NOT perform this workflow until all anonymous vials have been resolved.

### Scanned Positive Removal

- Touch the <Positive> to activate the Scanned Positive removal workflow.
- Remove Positive workflow screen is displayed, only the positive station LEDs are illuminated flashing red.
- Pull a positive vial.
- Station LEDs are turned off, the vial information is displayed on workflow screen, the barcode reader is turned on.
- Scan the sequence number for the vial.
- Accession need not be scanned. If the accession is accidentally scanned, the instrument will wait for the sequence scan.
- Information is cleared from the screen.
- The barcode reader is turned off.

### Disassociate/Re-associate Workflow

- Make note of location of vial(s) to be disassociated.
- Go to the Culture Screen.
- Touch the Vial Tab.
- Touch Location.
- Drawer view will appear.
- Select vial location to be disassociated.
- Press OK.
- Press Disassociate.
- Select Yes.

- o Select accession.
- o Type in correct accession.
- o Touch SAVE.

If vial has already been removed before they notice, obtain sequence number of vial.

- o Go to the Culture Screen.
- o Touch the Vial Tab.
- o Scan or manually enter sequence of vial that needs to be disassociated.
- o Vial information will be displayed.
- o Press Disassociate.
- o Select Yes.
- o Select accession field.
- o Type in correct accession.
- o Touch SAVE.

### **Partially Seated Vials**

Alert\_09: One or more stations has had a measurement failure or has had a vial presence switch failure.

- o Open instrument door to resolve error(s).
- o Press OK.
- o Open carefully - partially unseated vial(s) inside!
- o Message displayed: Push vials in to reseat. Press OK when done.
- o Select NOW.
- o DO NOT PULL ANY VIALS.
- o Fully seat vials in stations with lit LEDs – there will be no audible sound, or, there may be the sound of an anonymous vial insertion if the vial was out of the station so far that the station sensor thought the vial was “removed.”

- o Close instrument door and check for anonymous vials. If anonymous vials exist, resolve anonymous vials through ID anonymous workflow.

**NOTE:** Once the vial is fully seated in the station, the partially seated error message will not clear until an instrument reading has completed for that drawer (instrument reads occur every 10 minutes).

If fully seating the vial corrects the error, the error message will disappear after a reading has completed. If the partially seated error persists after there has been an instrument read for that rack, a bad station may be the source of the partially seated error. The user should block the station and move the vial to another usable station.

- o Open instrument door.
- o Partially seated vial – remove Now/Later.
- o Select Now and note station location.
- o Touch the <Exit> on the workflow screen.
- o Go to Maintenance Screen.
- o Select Test Tab.
- o Block station in question (touch the <block/unblock> on the bottom of the test tab).

When the station is blocked, a message will be displayed to remove any vial in the station, insert a station plug, and return the vial through vial entry workflow. Move vial to an available location through vial entry (scanning in sequence and accession).

### Removing Vials (two methods)

#### Removing Negative Vials after Completion of Protocol

**NOTE:** Do NOT perform this workflow if there are anonymous vials in the drawer. All anonymous vials must be resolved first.  
Anonymous vials accidentally pulled will lose their data.

**NOTE:** The Bactec FX will not call anonymous vials negative.

Anonymous vials must be identified through ID Anonymous before they can go out of protocol as negative.

### Batch Negative Removal

- Open the instrument door.
- Touch the <Negative> to activate the Negative removal workflow.
- Remove Negative workflow screen is displayed.
- Only the negative station LEDs are illuminated flashing green.
- Pull a negative vial.
- Station LEDs remain on.
- The vial information is displayed on workflow screen.
- Barcode reader is not turned on.
- Continue removing negative vials until all vials with flashing green LEDs are removed. Triple beep (workflow complete) will play.

If a completed protocol vial is accidentally left in the instrument, it will not create an error. Simply remove the vial at a later time

### If an ongoing vial is accidentally pulled during Negative Removal:

- Station LEDs are not turned off.
- A message is displayed "Unexpected vial", sequence is displayed
- Set the vial aside – message displayed contains vial information – match to the correct vial to set aside.
- Touch OK.
- Return the vial through Vial Entry after the remove negative workflow has been exited.
- Touch the <Vial Entry>.
- Scan the sequence for the vial, Vial information is on the screen.  
The last station that the vial was pulled from illuminates flashing green. If the vial has been out of the instrument for less than 20 minutes, the remaining stations are not lit. If the vial has been out of the instrument for more than 20 minutes, the last location

will be flashing green and the other available stations are illuminated steady green

- o Return the vial to the station that is flashing green.

### Non Batch Negative Removal

- o Touch the <Negative> to activate the Negative removal workflow.
- o Remove Negative workflow screen is displayed, only the negative station LEDs are illuminated flashing green.
- o Pull a negative vial.
- o Station LEDs are turned off, the vial information is displayed on workflow screen, the barcode reader is turned on.
- o Scan the sequence number for the vial.
- o Accession need not be scanned. If the accession is accidentally scanned, the instrument will wait for the sequence scan.
- o Information is cleared from the screen.
- o The barcode reader is turned off.
- o The remaining negative station LEDs are turned on.

### ID Ongoing Anonymous Vial

- o Open the instrument door and touch the "?" to activate ID anonymous workflow.
- o The anonymous station LEDs are illuminated flashing amber.
- o The ID Anonymous workflow screen is displayed.
- o Pull an ongoing anonymous vial (flashing amber LED).
- o Other station LEDs turn off, the barcode reader is turned on.
- o The anonymous information is displayed on the workflow screen.
- o Scan the sequence and the accession for the anonymous vial.
- o Information is displayed on the workflow screen, the protocol length is based on the sequence and medium.
- o Return the vial to this station flashing green.
- o LEDs are turned off, seen is cleared.
- o The remaining anonymous vial station LEDs are turned on.

**NOTE:** If an anonymous vial is removed (anonymous workflow opens), the vial sequence must be scanned into the instrument before placing the vial back into the instrument. If an anonymous vial is removed and placed back into the instrument without scanning the vial sequence, the protocol will be restarted for that vial. If an anonymous vial is removed and not identified, all electronic data will be lost for that vial. The vial should be returned to the same station. Only the last location will be lit flashing green. If the vial has been out of the instrument for more than 20 minutes (unlikely in the ID Anonymous situation), then the last location will be lit flashing green and all other available station LEDs will be lit steady green.

### ID Positive Anonymous Vial

- Open the instrument door and touch the "?" to activate ID anonymous workflow.
- The anonymous station LEDs are illuminated flashing amber.
- The positive anonymous station LEDs are illuminated flashing red/amber.
- The ID Anonymous workflow screen is displayed.
- Pull a positive anonymous vial (flashing red/amber LED).  
Message ID01: Positive-Anonymous pulled.
- Scan sequence and touch <Save> to ID and remote. <OK>
- Touch <OK> on the message.
- The message box is closed, the barcode reader is turned on
- The positive anonymous information is displayed on the workflow screen.
- Scan the sequence and the accession for the anonymous vial.
- Information is displayed on the workflow screen, the protocol length is based on the sequence and medium.
- The station from which the vial was pulled is illuminated flashing green.
- Information is saved to the database, screen is cleared.
- Remaining anonymous station LEDs are turned on.

### Unable to Resolve Anonymous Vial

- Vial is removed from the instrument (in ID anonymous workflow).
- User unable to resolve anonymous.
- Touch <RETURN> button.
- Message will appear.
- Insert vial to continue measuring anonymously or touch cancel to discard all readings.
- The station from which the vial was removed will flash. User may return the anonymous vial to the flashing station, or insert the anonymous vial into any available station.

### Plots

- To plot a vial, tap the "plot" button on the Culture – Vial display.
- In the Drawer View display that appears, select the desired station, then tap the "okay" button.
- You are returned to the Culture – Vial display. Tap the "plot" button again to display the plot.

## Blocking Stations/Unblocking Stations

A station should be blocked if the station LED is out, the vial presence switch is not working (the instrument does not “sense” a vial’s insertion), the reading is bad, or other possible failures.

### Blocking Stations:

- Open the instrument door containing the station to be blocked (door must be open to block station).
- Touch the <Block/Unblock> icon on the Test screen of the Maintenance tab.
- When the drawer is open, blocked stations in the drawer will be illuminated steady red.
- Touch the icon that represents the station to block. (Note: already blocked stations will display as a circle containing an “X”).
- When the icon to block a station is touched, the station LED will be illuminated steady red. A message will be displayed stating that the station has been blocked. There will also be a message stating that the user should remove any vial in that station and insert a station plug.

A vial that is in a station that has been blocked MUST be removed since it will be marked as removed in the database and will not receive any readings. A vial that has been removed should be returned through the Vial Entry workflow. After removal of a vial from a blocked station, the user should insert a station plug or supplied alternative.

- Repeat this process to block additional stations.

If the user accidentally blocks a station containing a vial and then immediately unblocks the station, the vial must be removed from the station and returned through the Vial Entry workflow.

If the user accidentally places a vial into a blocked station, the vial must also be removed and returned through the vial entry workflow.

If the user sees an unusable station (cracked egg) on the drawer view, the user should place a station plug in that station to ensure that a vial is not accidentally inserted into that station.

Unblocking Stations:

- Touch the <Block/Unblock> icon on the Test screen of the Maintenance tab.
- Open the drawer containing the station to be unblocked.
- When the drawer is open, blocked stations in the drawer will be illuminated steady red. Blocked stations will display on the screen as a circle containing an "X".
- Touch the station to unblock.
- Remove the station plug (or supplied alternative) or vial (most likely temperature vial).
- Repeat for additional stations to unblock.

**Alert List**

- To view the FX40 Alert List: From the Main Status Screen, touch <Alert> Icon (yellow triangle with exclamation point).

Active alerts are designated by an exclamation point (!). After an alert becomes inactive, the exclamation point will disappear from the alert list. After all active alerts have been resolved; the System Alert Icon will no longer be illuminated amber. An alert may be removed from the alert list only if the alert is inactive.

The Alert List can be printed from the Reports tab as well as the Alert List screen. The following alerts are critical.

- Instrument X: Agitation failure.
- Instrument X: Incubation failure.
- Instrument X: Temperature under set point.
- Instrument X: Temperature over set point.
- Instrument X: Temperature sensor fault
- Instrument X: Blower motor failure.
- Instrument X: One or more stations have had a measurement failure or have had a vial presence switch failure.
- Upgrade error.
- FX40 'X' offline. Remove any vials in unusable stations. Consult manual.
- Instrument X: Measurement system is offline.
- Instrument X contains a vial with a reading gap. Consult manual.
- FX40 'X' Rows A & B are offline. Remove any vials in unusable stations. Consult manual.
- FX40 'X' Rows C & D are offline. Remove any vials in unusable stations. Consult manual.

## Unusable Station Workflow and Affected Vials

Some system alerts may eventually result in unusable stations and/or "affected" vials. Not all unusable stations will contain vials that are "affected". Vials considered "affected" will usually, but not always, be located in unusable stations.

- Remove all vials that are in unusable stations. The workflow is batch - no need to scan vials.
- Check the affected vial report that was just printed. For optimal recovery, subculture all affected vials.
- For each vial that was removed from an unusable station, go to vial entry and return vial to instrument by scanning in sequence and accession. Place each returned vial into an available station (lit steady green). Vials should be returned within 5 hours.
- Block all unusable stations.

Only sequenced vials will be lit during the remove unusable station workflow. Any anonymous vial that is in an unusable, unlit station should NOT be pulled during this workflow because all information for the anonymous vial will be lost. After completion of unusable vial workflow, check the Main Status Screen for anonymous vials. If anonymous vials are present, print Maintenance QC Report or Drawer View Status screen to locate the anonymous vial(s). The indicator on the drawer status screen will be anonymous vial signified by "?" (Anonymous) and a "cracked egg" (unusable station). Initiate ID Anonymous workflow and identify the anonymous vial. If there are no available/usable stations in that drawer, press SAVE and EXIT. Return the identified anonymous vial to another drawer in the instrument through Vial Entry. If there are available usable stations in the drawer where the anonymous vial is originally located, those stations will be lit once the vial is identified. Place the identified vial into one of the available, usable stations (no need to press SAVE).

**NOTE:** If the anonymous vial appeared on the Affected vials report, it is recommended that the vial be sub cultured for optimal recovery before returning to the instrument.

### Affected Vials in Usable Station

In certain cases, a system alert resulting in unusable stations and affected vials can resolve on its own (i.e. temp out of range). When the system alert resolves, the yellow system light will disappear from the center oval and the audible warning will cease. The stations may no longer be considered unusable, and the user will not receive any warnings regarding unusable stations. The alert, however, will remain in the Alert List until it is removed from the viewable alert list by the user. A user should always view the alert list if the yellow triangle with the exclamation point is present on the Main Status screen. Anytime the user sees a critical alert (listed in the Alert List Workflow in this training manual (Incubation / Temperature Failure, Measurement System Failure, Agitation Failure Reading Gap, Drawer offline, etc.), the user should print an Affected Vials report. For optimal recovery, subculture all affected vials before returning them to the instrument (must be returned within 5 hours). After appropriately addressing alerts in the Alert List, the user should touch the "Remove All" button to clear the Alert List. This will facilitate management of the alert list: the alert icon on the Main Status screen will become grayed-out (rather than yellow), indicating that there are no active alerts.

### Saving Electronic Data and Log files to USB Key – Perform 2X per Week

- From the Main Status Screen, touch Maintenance.
- Select Utilities screen.
- Insert a USB key into one of the USB ports of tablet computer.
- Touch <SAVE DB and LOG> icon to save the database and the log
- When the database and log have been saved, two messages will be displayed:
- Database saved. Touch OK
- Event Log saved. Touch OK

If the USB key is bad or full, a backup failure message will be displayed.

**The log files saved will be:**

**Event Log** (example LSPM0110529.txt – where “L” indicates “Log”, “SPM011” indicates the serial number of the instrument, and “0529” indicates today’s date).

**Alert List** (example ASPM0110529.txt – where “A” indicates “Alert”, “SPM011” indicates the serial number of the instrument, and “0529” indicates today’s date).

**Communication Log** (example CommLogSPM011.bvr – where “CommLog” indicates the “Communication Log” and “SPM011” indicates the serial number of the instrument).

Assert log (example AssertStackSnapshot.bin ).

**Operating System Log** (example VxMsgSPM011.txt – where “VxMsg” indicates , “SPM011” indicates the serial number of the instrument, and “0529” indicates today’s date).



## Topic 3: Reports

To access Reports menu, tap the "Reports" tab. To print a report, highlight the desired report(S) by tapping it in the Reports dropdown list. Then tap the "Print" button.

**Available reports are listed below:**

### Affected Vials

Lists vials that have experienced either a failure in the instrument's incubation subsystem, or an extended gap in test readings within the last 30 days.

Grouped into 2 report sections:

Incubation Failures

Reading Gap Failures.

**NOTE:** Print if unusable station vials are present, print if reading gap vials are present.

### Alert List

Lists the latest 100 instrument alerts.

### Contaminant Vials

Lists all the vials in the database that have been marked as contaminant.

### Culture Summary

Lists total counts for contaminant, positives, and negative cultures, as well as percent of total cultures for each of these counts.

### Current Inventory

Lists all the vials in all the instrument's stations.

**NOTE:** Print to use in ID anonymous and to accession orphan vials.

### **Current Negatives**

Lists all the negative vials (out-of-protocol and manual negatives) in all the instrument's stations.

### **Current Positives**

Lists all the positive vials (instrument positive, manual positive and anonymous positive) in all the instrument's stations.

### **Loaded Vials**

Lists all the vials (sequenced and anonymous) that have been loaded in the instrument during a selected time period. The default time period is from midnight of yesterday.

### **Maintenance QC Report**

Provides a report on drawer temperature set points and blocked stations. Provides spaces for you to log user verification and maintenance activities (such as verifying station and system LED indicators). This report will print automatically.

### **No Growth Accession**

Lists all the accessions whose related vials show no growth (and are not marked manual positive) in the selected time interval.

### **Orphan Vials**

Lists all the vials in the instrument's database that have no accession number.

### **Partially Seated Stations**

Lists all the vials that the instrument believes are partially seated (not fully inserted in their stations).

**Pending Report**

Lists all the vials that have been logged in at the Culture display but have not been placed in the instrument yet (orphan demographics) or have come from the LIS and not been entered yet.

**Unloaded Negative Vials**

Lists all the sequenced negative vials (out-of-protocol negative and manual negative) that have been removed from the instrument in a specified time period and have not been reentered. The default will capture all unloaded negatives from midnight of the previous day; can be configured to go back 60 days.

**Unloaded Positive Vials**

Lists all the sequenced positive vials (instrument positive and manual positive) that have been removed from the instrument in a specified time period and have not been reentered. The default will capture all unloaded positives from midnight of the previous day; can be configured to go back 60 days.

False positives will not appear on this report they are returned to the instrument and are therefore not unloaded. False positive vials must be returned to the instrument within 5 hours.

**Unloaded Vials**

Lists all the sequenced vials that have been removed from the instrument in a specified time period and have not been reentered.



## Topic 4: Isolation Mode

Isolation mode is the state that exists when communication between BACTEC FX40 instrument and the tablet PC is lost. Isolation mode is designed to enable the instrument to continue to collect vial readings. However, Isolation mode is not intended to enable routine workflow such as entering vials through Vial Entry, removing positive and negative vials, identifying anonymous vials, etc. Since positivity analysis occurs at the tablet PC, no vials transition to Positive or Negative status while the system is in Isolation mode.

Please note the following conditions about Isolation mode:

- In an FX40 cluster with multiple instruments, each instrument can be in Isolation mode independent of the other.
- The tablet PC handles the transition of each instrument into and out of Isolation mode independently.
- In Isolation mode, no station status indicators will be lit when you open the instrument door, since routine workflow is not supported.
- The tablet PC displays error when communication is lost with instrument. The button for operating the isolated instrument will be disappeared once you acknowledge the error. This serves as a reminder that a specific FX40 instrument is not communicating with tablet PC.
- When communication is reestablished, the instrument and tablet PC will both return to Directed mode (normal operating state). During the transition, data collected by the instrument while in Isolation mode is transferred to the tablet PC and processed. Vial positivity is assessed at this time for all vials that are still in the instrument when recovering from Isolation mode.

## Isolation Mode System Indicators

Indicator Color	State	Meaning
Amber	Pulsing	Instrument is not communicating with the tablet PC
Green	Off	Both green and red system indicators are off while the system is in isolation mode, regardless of the presence of positive or negative vials
Red	Off	

## Isolation Mode Operation

Vial Examination: A vial can be pulled from its station for examination. When a vial is pulled, the station's green indicator blinks. This is to guide you to return the vial to the same station.

Vial Removal: A vial can be removed from instrument by pulling it from its station and close the door. When a vial is removed during Isolation mode, all data collected is discarded.

Vial Entry: A vial can be entered into any empty station. Instrument begins data collection and processes that data as anonymous vial when the data is uploaded to tablet PC in Isolation Recovery mode.

## Isolation Mode Troubleshooting

Isolation mode can be caused by

- Tablet PC malfunction
- Power or communication cable disconnected
- FX40 user interface stopped working

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## Topic 5: User maintenance

### Required Daily User Maintenance:

Print the Maintenance QC report.

Test Red LEDs, test Green LEDs

Read the Temperature, temperatures should read  $35^{\circ}\text{C} \pm 1.5^{\circ}\text{C}$ .

Test Status Indicators

Test the alarm.

View Alert List; critical alerts are listed in a separate alert list document.

Print Current Inventory Report.

Print Orphan Report.

ID all patient anonymous vials (if any).

Add Accessions to Orphans (if any).

BACTEC FX40 filters should be at least inspected monthly.



## Topic 6: System Alerts

This topic discusses error messages and codes which appear when the system encounters a known problem. These messages are listed in alphabetical order, along with possible causes of the error and corrective actions.

**NOTE:** These alerts are listed in the System Users Manual and all references within the table on the following pages refer to the users manual.

## MODULE A

Error Number	Message	Possible Cause(s)	Corrective Action(s)
<b>SYSTEM ALERTS</b>			
00	Drawer X: Incubation failure.	Instrument incubation is over 40° C for more than 60 continuous seconds.	<p>Reboot instrument.</p> <p>Stations are marked as Unusable.</p> <p>Refer to Section 7.3.2 for additional information on dealing with Unusable stations.</p> <p>Any vials in the affected row(s) are marked as "Affected Vials." Refer to Section 7.3.3 for instructions on Affected Vials.</p> <p>Contact BD.</p>
02	Drawer X: Temperature under setpoint.	Instrument incubation is more than 1.5° C under setpoint temperature for more than 180 continuous minutes from power up, or 60 continuous minutes after power up. Room may be too cold.	<p>Alert clears if temperature returns within range for 5 continuous minutes or if instrument is rebooted.</p> <p>Stations are marked as Unusable.</p> <p>Refer to Section 7.3.2 for additional information on dealing with Unusable stations.</p> <p>Any vials in the affected row(s) are marked as "Affected Vials." Refer to Section 7.3.3 for instructions on Affected Vials.</p> <p>Verify that room temperature is within specification (Section 2).</p>
03	Drawer X: Temperature over setpoint.	Instrument incubation is more than 1.5° C over setpoint temperature (but less than 40° C) for more than 60 continuous minutes. Room too warm. Air filters dirty.	<p>Alert clears if temperature returns within range for 5 continuous minutes or if instrument is rebooted.</p> <p>Verify that room temperature is within specification (Section 2).</p> <p>Check/clean air filters.</p> <p>Stations are marked as Unusable.</p> <p>Refer to Section 7.3.2 for additional information on dealing with Unusable stations.</p> <p>Any vials in the affected row(s) are marked as "Affected Vials." Refer to Section 7.3.3 for instructions on Affected Vials.</p>
04	Drawer X: Temperature sensor fault.	Sensor temperature has deviated from QC temp sensor by more than 1.0° C for more than 5 minutes.	Alert clears if temperature returns within range for 5 continuous minutes or if instrument is rebooted.

## MODULE A

Error Number	Message	Possible Cause(s)	Corrective Action(s)
05	Drawer X: Blower motor failure.	A Blower Motor Failure is detected if it fails to start after 3 consecutive retries. When a Blower Motor Failure is detected the heater for the affected instrument is turned off.	Alert clears if instrument is rebooted. Stations are marked as Unusable. Refer to Section 7.3.2 for additional information on dealing with Unusable stations. Any vials in the affected row(s) are marked as "Affected Vials." Refer to Section 7.3.3 for instructions on Affected Vials.
06	Instrument using default system configuration parameters.	The instrument has booted and is using default values for the system parameters. System parameters are set (and/or reset to the defaults) on the Startup-Configuration display (accessed by BD representatives only).	Message is informational. Check all system parameters to insure that they meet your laboratory's requirements.
07	Event Log Reinitialized.	Set during startup when the instrument detects corruption in the event log.	Alert clears when instrument creates new event log.
08	Alert List Reinitialized.	Set during startup when the instrument detects corruption in the alert list.	Alert clears when instrument creates new alert list.
09	One or more stations has had a measurement failure or has had a vial presence switch failure. Open drawer to resolve error(s).	Instrument has detected a condition that could represent a measurement failure or partially seated vial.	Alert clears when the instrument detects that the failure no longer exists. Make sure all vials are fully seated in the stations. If alert does not clear, block the station and contact BD. Stations are marked as Unusable. Refer to Section 7.3.2 for additional information on dealing with Unusable stations. Move vials in the indicated stations within 40 minutes of the set time of this alert to prevent them from becoming Affected Vials.

## MODULE A

Error Number	Message	Possible Cause(s)	Corrective Action(s)
11	Printer offline.	The printer's "pending" queue is temporarily full. The printer is turned off. The print cable is unplugged. The connection to the hub is disconnected. The print server is turned off. The hub power supply is disconnected. The instrument is offline in a Workgroup.	Check all conditions listed at left. Any queued reports should print when error is corrected.
16	EpiCenter Communications failure.	This alert is detected when EpiCenter is configured and cannot be reached.	Alert clears itself when communication with EpiCenter is reestablished.
17	LIS Server not responding to uploads.	This alert is detected when LIS is configured and cannot be reached.	Alert clears itself when communication with LIS is reestablished.
18	LIS interface offline.	Alert is set when LIS library returns any of errors below to the Fx application.  LIS_SYSTEM_ERROR: UNSUPPORTED_CONFIG:  LIS_ASSERT_ERROR: DEBUG_PROBLEM:	Communications problem between instrument and LIS system. Refer to the BD LIS Interface specification.
21	Upgrade error.	There was a problem with a software upgrade.	Reboot the instrument with the software upgrade flash media in the USB flash drive. If error recurs, contact your local BD representative.
22	X EDB offline.	Occurs when the rack is unable to communicate with the main instrument computer board.	Reboot instrument. Stations are marked as Unusable. Refer to Section 7.3.2 for additional information on dealing with Unusable stations. Move vials in the indicated stations within 60 minutes of the set time of this alert to prevent them from becoming Affected Vials.

## MODULE A

Error Number	Message	Possible Cause(s)	Corrective Action(s)
23	Drawer 'X' offline. Remove any vials in unusable stations. Consult Manual.	Occurs when the rack is unable to communicate with the main instrument computer board.	Reboot instrument. Stations are marked as Unusable. Refer to Section 7.3.2 for additional information on dealing with Unusable stations. Move vials in the indicated stations within 40 minutes of the set time of this alert to prevent them from becoming Affected Vials.
25	Drawer X: Measurement System offline.	Agitation failure has set the measurement system to offline after three consecutive failures to stop at the read position.	Reboot instrument. Stations are marked as Unusable. Refer to Section 7.3.2 for additional information on dealing with Unusable stations. Move vials in the indicated stations within 10 minutes of the set time of this alert to prevent them from becoming Affected Vials.
26	Drawer open too long.	The door has been open for longer than 10 minutes.	Close the door. Allow it to remain closed for at least 30 minutes. NOTE: If door is not closed within 40 minutes of the time that it is opened, all vials in instrument are marked as "Affected Vials." Refer to Section 7.3.3 for instructions on Affected Vials.
30	The instrument has lost connectivity to the server database.	The instrument has lost communications with the BD EpiCenter master database.	Instrument enters a degraded mode of operation. See Section 4.12.2 for information on degraded operations.
31	Database Object Reinitialized.	An individual reading or a reading collection is corrupted.	A sector on the flash drive is corrupted or a bad checksum is encountered on a reading object or collection. One or more readings have been lost. Message is informational. If 4 consecutive readings become corrupted, then a reading gap will occur and the vial will automatically become affected.
32	Barcode Reader n: Cannot determine type.	Instrument cannot communicate with barcode reader to determine the barcode reader's type.	Communication attempt continues every two minutes until successful communication with the barcode reader is established.

## MODULE A

Error Number	Message	Possible Cause(s)	Corrective Action(s)
33	Program download failure.	Set when a microprocessor download fails to complete successfully.	Reboot instrument.
36	Reboot Reason.	<p>Message sent to System Alert display only (Info detail window).</p> <p>Instrument has rebooted for one of the following causes:</p> <ul style="list-style-type: none"> <li>1. Unknown Cause</li> <li>2. Software Upgrade Initiated</li> <li>3. Software Upgrade Completed</li> <li>4. Powerfail</li> <li>5. Power Interrupted</li> <li>6. Software Assert</li> <li>7. Watchdog Timeout</li> <li>8. Software Fault</li> <li>9. Invalid WD Count</li> <li>10. Syscall Failure</li> <li>11. OSBDPL Fatal</li> <li>12. Downgrade Not Allowed</li> <li>13. Assert at Interrupt Level</li> <li>14. Invalid Reason Code</li> <li>15. Stack Fault</li> </ul>	<p>If error recurs, contact BD.</p> <p>For Reasons 4 and 5, if power is lost for more than 40 minutes, all vials in the instrument are marked as "Affected Vials." Refer to Section 7.3.3 for instructions on Affected Vials.</p>
37	Drawer X: Agitation Failure.	Agitation outside of normal range. Agitation has been re-started 4 consecutive times. (Preceded by 4 occurrences of Alert 47.)	<p>Alert is cleared when the instrument determines that the agitation speed is within range.</p> <p>Stations are marked as Unusable. Refer to Section 7.3.2 for additional information on dealing with Unusable stations.</p> <p>Move vials in the indicated stations within 40 minutes of the set time of this alert to prevent them from becoming Affected Vials.</p>

## MODULE A

Error Number	Message	Possible Cause(s)	Corrective Action(s)
38	Drawer X: Contains a vial with a reading gap. Consult manual.	The reading gap evaluator determines when a vial has a reading gap greater than 40 minutes or the algorithms have not processed readings for 40 minutes. This alert is reported each time a different vial with a reading gap is detected in that instrument.	Any vials in the affected row(s) are marked as "Affected Vials." Refer to Section 7.3.3 for instructions on Affected Vials.
40	Reminder – The drawer has been open too long.	Caused when the door is still open every 5 minutes after Alert 26 has been reported and acknowledged.	Close the door. NOTE: If door is not closed within 40 minutes of the time that it is opened, all vials in instrument are marked as "Affected Vials." Refer to Section 7.3.3 for instructions on Affected Vials.
41	NTP server unavailable: clocks may not be synchronized.	Set when the network client cannot get a response to a time synchronization request.	Make sure all network cables are plugged in.
44	BACTEC FX and EpiCenter times are not synchronized.	The instrument has determined that its time is not synchronized with the EpiCenter Time Service.	Make sure all network cables are plugged in.
46	Database recovery file invalid.	This will only cause (potentially) the last transaction before the power failure to be rolled back. A new recovery file will be created.	Message is informational. No action necessary.
47	Drawer X: Agitation Re-Started	Agitation speed is outside of normal range, or failed to stop at a sensor or see a sensor for 10 continuous seconds. A Drawer Open, Measurement scan or Power failure resets 4 times consecutively.	Alert is reported on System Alerts display and report only. Alert is cleared when agitation speed returns within range. If this message recurs frequently, contact BD for service.

## MODULE A

Error Number	Message	Possible Cause(s)	Corrective Action(s)
49	Drawer X Rows A & B are Offline. Remove any vials in unusable stations. Consult Manual.	When the Drawer Control Board fails to communicate with the Row Board that controls rows A and B, the Row Board is marked offline.	Reboot instrument. Stations are marked as Unusable. Refer to Section 7.3.2 for additional information on dealing with Unusable stations. Move vials in the indicated stations within 40 minutes of the set time of this alert to prevent them from becoming Affected Vials.
50	Drawer X Rows C & D are Offline. Remove any vials in unusable stations. Consult Manual.	When the Drawer Control Board fails to communicate with the Row Board that controls rows C and D, the Row Board is marked offline.	Reboot instrument. Stations are marked as Unusable. Refer to Section 7.3.2 for additional information on dealing with Unusable stations. Move vials in the indicated stations within 40 minutes of the set time of this alert to prevent them from becoming Affected Vials.
51	Drawer X Rows E & F are Offline. Remove any vials in unusable stations. Consult Manual.	When the Drawer Control Board fails to communicate with the Row Board that controls rows E and F, the Row Board is marked offline.	Reboot instrument. Stations are marked as Unusable. Refer to Section 7.3.2 for additional information on dealing with Unusable stations. Move vials in the indicated stations within 40 minutes of the set time of this alert to prevent them from becoming Affected Vials.
52	Drawer X Rows G & H are Offline. Remove any vials in unusable stations. Consult Manual.	When the Drawer Control Board fails to communicate with the Row Board that controls rows G and H, the Row Board is marked offline.	Reboot instrument. Stations are marked as Unusable. Refer to Section 7.3.2 for additional information on dealing with Unusable stations. Move vials in the indicated stations within 40 minutes of the set time of this alert to prevent them from becoming Affected Vials.
53	Drawer X Rows J & K are Offline. Remove any vials in unusable stations. Consult Manual.	When the Drawer Control Board fails to communicate with the Row Board that controls rows J and K, the Row Board is marked offline.	Reboot instrument. Stations are marked as Unusable. Refer to Section 7.3.2 for additional information on dealing with Unusable stations. Move vials in the indicated stations within 40 minutes of the set time of this alert to prevent them from becoming Affected Vials.

## MODULE A

Error Number	Message	Possible Cause(s)	Corrective Action(s)
<b>Barcode Messages</b>			
BC01	Invalid medium type. Reenter barcodes.	A vial sequence number was scanned or entered and the media type is not defined in the instrument	Make sure the correct vial barcode or replacement vial barcode is scanned; only original BD vial sequence or BD-supplied replacement barcodes can be used for sequence numbers. If vial sequence number is entered manually, be careful to enter it correctly. Tap "OK" to remove the message box.
BC03	Invalid sequence. Reenter barcodes.	The vial sequence number was entered or scanned that does not meet the defined parameters (e.g., it is too long, too short, has incorrect digits)	Make sure the correct vial barcode or replacement vial barcode is scanned; only original BD vial sequence or BD-supplied replacement barcodes can be used for sequence numbers. If vial sequence number is entered manually, be careful to enter it correctly. Tap "OK" to remove the message box.
BC05	Invalid accession. Reenter barcodes.	An accession number was entered that does not meet the defined parameters. It could contain illegal characters such as : * ? [ ] ! #   or it could have too many digits. You could also have scanned a sequence already, and then scan another sequence when the instrument is expecting an accession barcode scan.	Enter a valid accession number, up to 20 characters that does not contain the following characters : * ? [ ] ! #   Tap "OK" to remove the message box.
<b>Culture Screen Messages</b>			
CS01	Patient ID not found.	You entered a patient ID that is not in the database. The value you entered is shown at the top of the message box.	Make sure Patient ID is entered correctly and completely. You cannot enter a partial ID to recall patient information.

## MODULE A

Error Number	Message	Possible Cause(s)	Corrective Action(s)
CS02	Patient name not found.	You entered a patient name or portion of a patient name that is not in the database. The value you entered is shown at the top of the message box.	Try entering only the first portion of the name if you tried entering the whole name.
CS03	Too many patients found. Please refine search.	A Patient Name search matched more than 50 entries in the database.	Try to enter more characters to narrow the search results.
CS15	Disassociate sequence from accession?	You have pressed the "Disassoc(iate)" button on the Culture – Vial display. The sequence and accession are shown at the top of the message box.	Tap "Yes" to confirm the disassociation. Tap "No" to cancel the disassociation.
CS21	One or more reports have been cancelled.	Appears if you respond "Cancel" to a print request.	Message is informational.
CS22	Report has been sent to the printer.	On the Plot display, the "print" button was pressed. Also generated when you respond "Yes" to message WE35, or when printing is requested for non-oversize reports.	Message is informational. Tap "OK" to remove the message box and print the report.
CS23	Disassociate specimen from patient?	You have pressed the "Disassoc(iate)" button on the Culture – Patient display. The sequence and accession is shown at the top of the message box.	Tap "Yes" to confirm the disassociation. Tap "No" to cancel the disassociation.
CS24	Sequence scanned already associated with accession. Must disassociate on Vial tab before reassociating.	Message occurs if you scan any non-sequence barcode (other than one matching the displayed accession) or a sequence that is already associated to a different accession number.	A vial can only be attached to one accession number.
<b>ID Anonymous Messages</b>			

## MODULE A

Error Number	Message	Possible Cause(s)	Corrective Action(s)
ID01	Positive-Anonymous pulled. Scan sequence and touch <Save> to ID and remove.	A positive anonymous vial was pulled from a station. The station is shown at the top of the message box.	Scan the vial sequence barcode. Tap the "Save" button to save the identification if you are keeping the vial out of the instrument. If you are returning the vial, place it in the FLASHING GREEN station and do not tap the "Save" button.
ID02	The instrument has lost connectivity to the server database. Vial cannot be identified now and must be returned anonymously to maintain readings. Touch Cancel to discard all readings.	An anonymous vial was pulled from a station in an instrument that is in degraded mode.	Place the vial back into the same station to continue testing the vial anonymously. Or tap the "cancel" button or close the door to discard all readings.
ID05	Vial pending identification. All readings will be lost.	This is displayed when <Discard> is selected on the Identify Anonymous Screen.	Tap the "OK" button to discard the vial's readings. Tap the "Cancel" button to cancel the Discard operation.
ID09	Removed vial is anonymous. Identify?	An anonymous vial is pulled when a display other than ID Anonymous is displayed.	Tap "Yes" to identify the anonymous vial. The ID Anonymous display appears. Tap "No" if you do not want to identify the anonymous vial. Additional message(s) provide further instructions.
ID10	Vial has been out of the instrument too long. The vial's protocol will be restarted and it should be subcultured. Consult Manual. <OK>.	The vial barcode sequence scanned belonged to a known vial which was removed from the instrument more than 5 hours (reentry window) ago.	If the vial is placed back in the instrument, it is treated as a new vial. If this occurs during ID Anonymous activity, the vial maintains all the test readings and information associated to the anonymous vial, but the previous sequence information is discarded.
ID12	Re-insert vial to continue measuring anonymously or touch cancel to discard all readings.	Occurs if you respond "No" to message ID09, or if you tap the "Return" button on the ID Anonymous display.	Vial continues as anonymous if you place it back in the station. Previous test readings are retained and testing continues. If you tap "Cancel" in response to the message, the vial becomes a newly entered anonymous vial.

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Error Number	Message	Possible Cause(s)	Corrective Action(s)
ID13	Vial pending identification. Discard all readings and exit workflow?	Occurs if you tap the "Exit" button on the ID Anonymous display, with information related to a pulled vial on the screen.	Tap "Yes" to exit the ID Anonymous display. All readings to date for the vial are discarded. Tap "No" to cancel the Exit operation and continue identifying anonymous vials.
ID14	Vial cannot be identified with this sequence. Duplicate sequence exists. Consult Manual.	The instrument has determined that the sequence number you just scanned belongs to a different vial.	A vial swap has occurred. For optimal recovery, both vials should be subcultured. To reenter vials, use the Vial Entry activity.
<b>Maintenance Utilities Messages</b>			
UTIL01	Database saved!	A save operation was completed successfully (Maintenance – Utilities – Save DB).	Message is informational.
UTIL02	Database save failed!	A save operation was not completed successfully. Flash drive could be full, or the file system on the drive could be corrupted.	Retry the save operation. If error recurs, retry the operation with a new flash drive.
UTIL03	Event log saved!	A save operation was completed successfully (Maintenance – Utilities – Save Log).	Message is informational.
UTIL04	Event log save failed!	A save operation was not completed successfully. Flash drive could be full, or the file system on the drive could be corrupted.	Retry the save operation. If error recurs, retry the operation with a new flash drive.
UTIL07	Verify there is a valid Bactec FX Software Upgrade disk in the instrument. Press "Yes" to continue with the Upgrade.	You have entered a valid password to upgrade the instrument software.	Insert the software update flash drive into the USB port and tap "Yes" to continue.

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Error Number	Message	Possible Cause(s)	Corrective Action(s)
UTIL10	Did not find a valid Bactec FX Software Upgrade disk.	The flash drive in the USB port does not contain updated BACTEC FX instrument software.	Locate the correct flash drive for the instrument software update and insert it in the USB port. If the flash drive is labeled correctly (indicates correct software update version), contact BD for a new software update flash drive.
UTIL11	Password incorrect, please reenter.	The current Password was entered incorrectly.	Enter the correct current password.
UTIL12	Confirmation of new password failed. Try again.	A different password was entered in the New password and Confirm password fields.	Enter the same password in both New password and Confirm password fields.
UTIL13	Password successfully changed.	The new password entered was accepted.	Message is informational.
UTIL14	Downgrading to an older version of BACTEC FX System Software is not allowed. Please Remove BACTEC FX System Software device from USB port.	You attempted to install an older version of software than what is currently on the instrument.	Installing an older version of instrument software is not permitted.
UTIL15	Software Upgrade completed. Please Remove BACTEC FX System Software device from USB port.	Upgrade of system software completed successfully.	Message is informational. Remove the flash drive from the USB port.
<b>Vial Entry Messages</b>			
VE01	Vial out of instrument for longer than recommended time. Algorithms and Protocol will be restarted when vial is returned. Consult Manual.	You attempted to reenter a vial that has been out of the instrument for more than 5 hours (Ongoing, Positive, or Negative). The sequence and status are shown at the top of the message box.	Vial should be subcultured. Vial may be reentered into instrument, but is treated as a new vial. Existing readings are discarded.

## MODULE A

Error Number	Message	Possible Cause(s)	Corrective Action(s)
VE06	Vial entered with no accession. Accession can be entered at Culture Screen.	Accession barcoding is enabled and you only scanned a vial sequence number prior to placing the vial in the station. The sequence and station are shown at the top of the message box.	Message is informational. The accession number can be entered at any time in the Culture – Vial display. Tap "OK" to continue.
VE13	Anonymous vials cannot be entered with an accession. Accession discarded.	A vial was placed in a station and only the accession barcode was scanned.	If an accession barcode is scanned, a vial sequence number must be scanned also. To enter an anonymous vial, do not scan any barcodes. Tap "OK" to remove the message box.
VE16	One or more vials entered anonymously while the instrument was off.	One or more vials were placed in the instrument during a power failure or when an instrument was offline.	Message is Informational. Tap "OK" to remove the message box.
VE17	Last known status of sequence scanned was POSITIVE.	During Vial Entry or ID Anonymous, a sequence number for a positive vial is scanned.	Message is informational. Vial becomes Ongoing if reentered after the 20 minute peek window (but within 5 hours of removal), otherwise the vial remains Positive. Positivity analysis restarts at time of reentry although original Start of Protocol is retained.
VE18	The vial's last known status is POSITIVE. Would you like to change the status to ONGOING when the vial is re-inserted?	A positive vial is being re-entered into the instrument within 20 minutes of its removal.	Tap the "Yes" button to return the vial as ONGOING. Tap the "No" button to return the vial as POSITIVE.
<b>Vial Removal Messages</b>			
VR01	Vial has a manually entered sequence. Please visually verify for removal. Correct sequence?	Appears if a related vial with a manually entered sequence is removed during Positive Removal activity. The sequence, station, and status are shown at the top of the message box.	Compare the actual vial sequence number to the one shown at the top of the message box. If the 2 numbers are identical, tap the "Yes" button. If the numbers are not identical, tap the "No" button.

## MODULE A

Error Number	Message	Possible Cause(s)	Corrective Action(s)
VR02	Scan sequence or touch Cancel.	Appears when a related vial is removed during Positive Removal activity.	Scan the sequence number and place the vial in the instrument.
VR04	One or more vial(s) removed while the instrument was off.	You removed one or more vials while the instrument is offline or power was off. When the instrument is back online, message appears.	Message is informational. Tap "OK" to remove the message box.
VR07	Vial removed due to blocked station. Insert station plug.	You blocked a station with a positive, negative, or ongoing vial. When a station is blocked, no more tests are performed on a vial in that station, so if there is a vial in the station, it must be moved for testing to continue.	Use Vial Entry to move the vial to a new station. Plug the blocked station to prevent use.
<b>Workflow Exception Messages</b>			
WE02	Unexpected vial pulled. Remove?	You have pulled a vial that doesn't correspond to the current activity (e.g., pulling a vial that is not positive during Positive Removal, pulling any vial during Vial Entry, etc.). The sequence, station, and status are shown at the top of the message box.	Tap "Yes" to remove the scanned vial named in the message box. Tap "No" to place the vial back in the instrument. WE03: Scan sequence to return or touch Cancel to accept removal message then appears.
WE03	Scan sequence to return or touch Cancel to accept removal.	Appears if you respond "No" to WE02: Unexpected vial pulled. Remove?	To return the vial to the instrument, scan the vial sequence number and place the vial in an available station. To remove the vial, tap "Cancel."

## MODULE A

Error Number	Message	Possible Cause(s)	Corrective Action(s)
WE04	Unexpected sequence scanned. Can you scan correct sequence?	Appears if you scan an unexpected vial after a WE03: Scan sequence to return or touch cancel to accept removal (e.g., you remove a positive vial then inadvertently scan another vial's sequence number). Appears if you scan an unexpected sequence during an activity; the sequence scanned does not match the sequence in the database for the station/vial.	If you reply "Yes" then the WE03 : Scan sequence to return or touch cancel to accept removal message reappears. If you reply "Cancel," then a WE06: Unverified sequence. Return through Vial Entry workflow message appears. To return the unexpected vial, tap the "Yes" button in this message.
WE05	Sequence was manually entered. Visually verify for return. Verified?	The vial sequence number of the vial being removed and/or entered was entered manually via the onscreen keyboard. The sequence is shown at the top of the message box.	Compare the actual vial sequence number to the one shown at the top of the message box. If the 2 numbers are identical, tap the "Yes" button. If the numbers are not identical, tap the "No" button.
WE06	Unverified sequence. Return through Vial Entry workflow. Consult Manual.	Appears if you respond "No" to WE04 or "Cancel" to VR02. Also occurs if you respond "Wrong" when verifying a manually entered sequence number.	When the current activity is complete, use the Vial Entry activity to enter the vial into the instrument. Note any additional messages that appear at that time about vial status.
WE07	The instrument has lost connectivity to the server database. Vial may only be returned anonymously.	An ongoing vial was pulled from an instrument in degraded mode in an EpiCenter configuration.	Return the vial to the station from which it was removed to continue to test the vial anonymously. Identify the vial when communications with EpiCenter are reestablished.
WE14	Exit with vial information pending on screen. Exit?	Message appears if you tap the "Exit" button without saving data on Vial Entry, or if you exit Positive or Negative Removal display without scanning a pulled vial or confirming the sequence number of a manually entered vial.	Tap "Yes" to exit without saving the data. Tap "No" to return to the display with data retained on the display. Then tap "Save" to save the data.

## MODULE A

Error Number	Message	Possible Cause(s)	Corrective Action(s)
WE16	Only one instrument may be open at a time while performing vial workflows.	You opened a second instrument door.	Only one instrument can be open for vial entry /removal or maintenance activities.
WE17	Sequence scanned belongs to vial in station above. Consult Manual!	A known vial sequence number is scanned for a vial currently in the instrument. Vial may have been removed when instrument was offline. Vials may have been swapped. The sequence and station are shown at the top of the message box.	For optimal recovery, subculture both vials (the scanned vial and the one in the station named in the message). You may also apply a replacement barcode to either or both vials and reenter them with Vial Entry to continue testing.
WE20	Accession does not match previously associated accession. Accession can be disassociated at Culture Screen.	During Vial Entry or ID Anonymous, you scan or enter an accession and vial sequence number, but the sequence belongs to a different accession.	To change the accession, go to Culture – Vial display and disassociate the vial from the accession number. Then enter the correct accession number. Tap "OK" to remove the message box.
WE21	Vial sequence is a replacement barcode. Select a medium type.	Replacement vial barcode labels have a generic medium type of "99." The system performs optimally when the correct medium type is known for a given vial.	Select the medium type by tapping the Media field and tapping the correct medium type in the dropdown box. Tap "OK" to remove the message box.
WE24	Remove any vial from station and insert plug.	Appears when an empty station is blocked using Block/Unblock utility.	Insert a station plug to prevent inserting a vial in the blocked station. Tap "OK" to remove the message box.

## MODULE A

Error Number	Message	Possible Cause(s)	Corrective Action(s)
WE28	Unexpected vial pulled during batch removal.	The system lights stations of all negative stations when batch removal is enabled and the Remove Negative vials activity is initiated. If a sequenced vial is removed from a station that is not illuminated, this message appears. The vial sequence number, accession, station, and status are shown in the message box.	Tap "OK" to remove the message box. Use the Vial Entry activity to return the vial if you did not intend to remove it.
WE29	Anonymous vial pulled unexpectedly during batch removal. Readings discarded.	The system lights stations of all negative stations when batch removal is enabled and the Remove Negative vials activity is initiated. If an anonymous vial is removed from a station that is not illuminated, this message appears. The station and status are shown in the message box.	Accumulated test readings are discarded. Tap "OK" to remove the message box. Note the location and status of the vial that is displayed at the top of the message box. Continue removing negative vials. Vial should be subcultured and reentered with the Vial Entry activity.
WE30	Positive vial(s) present.	Positive vial has been detected; message appears when instrument detects first positive vial in an instrument, when offline instrument goes online again, or after power is cycled. The instrument is shown at the top of the message box. Message is displayed for each instrument where the first positive detection occurs.	Tap "OK" to remove the message box and silence the Positive Alarm tone. Remove positive vials.
WE31	Drawer contains sequenced vials that are in unusable stations. Consult Manual. Remove Vials?	An instrument that contains sequenced vials in unusable stations was opened.	Refer to Section 7.3.2 for additional information.



## MODULE A

Error Number	Message	Possible Cause(s)	Corrective Action(s)
WE34	Drawer selected is currently offline. Information shown may not be up-to-date.	Appears if an instrument that is offline is selected in Drawer View or Block/ Unblock Stations display. The instrument, a station, or a row board could be what is offline.	Message is informational. Vial or station statuses may be different from what is shown on the display because the instrument cannot communicate with the offline instrument.
WE35	Report size estimate is greater than 50 pages. Print Report?	The instrument has calculated the approximate size of the report to be more than 50 pages.	To accept the message, tap the "Yes" button. Tap "No" to cancel the print request.
WE36	Drawer contains anonymous vials that are in unusable stations. Print Affected Report and Identify vials through Id Anonymous workflow. Consult Manual.	An instrument that contains anonymous vials in unusable stations was opened.	Use the ID Anonymous activity to identify any vials in the instrument. When identifying anonymous vials in this scenario, be sure to either tap the "Save" button after identification to move them to another instrument, or place the vials in another station in the instrument that is lit steady green.
WE53	Drawer contains one or more vials that are partially seated. Fully insert Vials!	The instrument has determined that a vial may be partially seated in the station. Message is displayed when the door is first opened and each time it is subsequently opened, until a measurement occurs that clears the "partial insertion" condition.	Refer to Section 7.3.4 for additional information.
WE56	One or more drawers is ajar. Please close or fully open any drawer(s).	The door sensor has detected that the door is not fully closed.	Push door fully closed.
WE57	Database under-write – displayed data not current. Please change data again and reattempt save.	While you were attempting to enter a new vial, identify an anonymous vial, or change vial or specimen information, another process changed information for that vial or specimen.	Your current modifications are not saved. On the Culture display, recall the vial/accession and modify the desired information again.

## MODULE A

Error Number	Message	Possible Cause(s)	Corrective Action(s)
WE58	Vial can no longer be found in the database and cannot be viewed or modified. Consult manual.	This will be displayed if the user has attempted to modify a vial that has been deleted by Epi since the time it was recalled on the Culture screen.	Message is informational. No activity is possible since the vial is no longer resident in the database.
WE59	Vial last known to be in station shown above, which is offline. Is this the same vial?	Sequence vial is removed from a degraded mode instrument or offline row and inserted via Vial Entry into an online instrument.	Tap "Yes" to remove the vial from the old (offline) location. Place the vial into the online instrument to continue testing the vial in its current protocol. Tap "No" to re-enter the vial sequence number (in case sequence was entered incorrectly).
WE60	Vial currently residing in an offline instrument and cannot be modified. Consult manual.	In an EpiCenter configuration, you tried to modify a vial in the Culture display (e.g., disassociate or associate accession, change protocol length, select media type (if replacement vial), change status) if the vial resides in an instrument which is currently offline.	You cannot modify information for a vial that is in an offline instrument.
WE61	Vial removed from station shown above is positive.	Message occurs when a removed vial is called POSITIVE. This will likely be the result of an anonymous vial being identified and "saved" (i.e. not returned to the instrument). Algorithms are re-run on the vial with the newly identified media type, and if more sensitive than the general algorithm, could cause a positive result.	Message is informational. Vial is already removed from the instrument.
WE62	Restoring connection to database. Please wait	The instrument and EpiCenter systems are reconciling their databases.	Message is displayed while the reconciliation process is in progress. Message is removed when the reconciliation process is complete.

## Topic 7: System Operation Exercises

This topic provides a review and exercises for Module A.

### MODULE A TOPIC 6 EXERCISES

1. What does flashing Red/Amber on a station represent?
2. How many vials can a BACTEC FX40 full cluster hold?
3. How would you initiate vial activated work flow?
4. What tabs would you access to activate accession bar coding?
5. What does the blue dot on the status screen represent?
6. What screen would you access to change a media protocol length?
7. Define "AFFECTED VIAL"?
8. What steps would you take to clear an alert 09?
9. If an Alert 50 were issued, would it be necessary to remove the vials?
10. What would be the file name of the training instrument event log saved today?
11. Review the Status screen.
  - Alert Status
    - What does the exclamation point at the beginning of the alert mean?
  - Drawer View
    - What does this ICON represent? 
  - Culture Login

---

#### MODULE A TOPIC 6 EXERCISES

- What 3 tabs are on this screen?

12. Review the Reports screen.

13. Review the Maintenance screen.

14. Review the Configuration screen.



# BACTEC FX40 System™

## Service Training Manual

### System Overview

### Module B



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## System Overview

### Overview:

This topic provides a system overview of the BACTEC™ FX40 Instrument.

### Topics:

The following Topics are covered in this Module:

- Topic 1: System Overview
- Topic 2: Instrument Subsystems
- Topic 3: Software Overview

#### Materials Required:

- BACTEC™ FX40 Instrument
- Module Specifications



## Topic 1: System Overview

The FX40 instrument is a BACTEC FX derivative instrument design for price sensitive, low volume emerging market labs. The instrument will leverage the design of BACTEC FX measurement system and FX "Vial Activated Workflow". An adjacent tablet computer will run the FX40 user interface software. A total of 4 FX40 instrument modules can be connected to the tablet computer for increased capacity.

The measurement system subassembly, the same subassembly used in BACTEC FX instrument, holds 20 vials in a 2 x 10 array. Two of these measurement system subassemblies shall be incorporated in an FX40 instrument.

A total of four FX40 instrument modules can be connected to the user interface tablet computer for increased capacity. Two FX40 instruments may be stacked together for user convenience and to reduce the amount of required bench top space.

**Figure 1** shows a functional description block diagram.

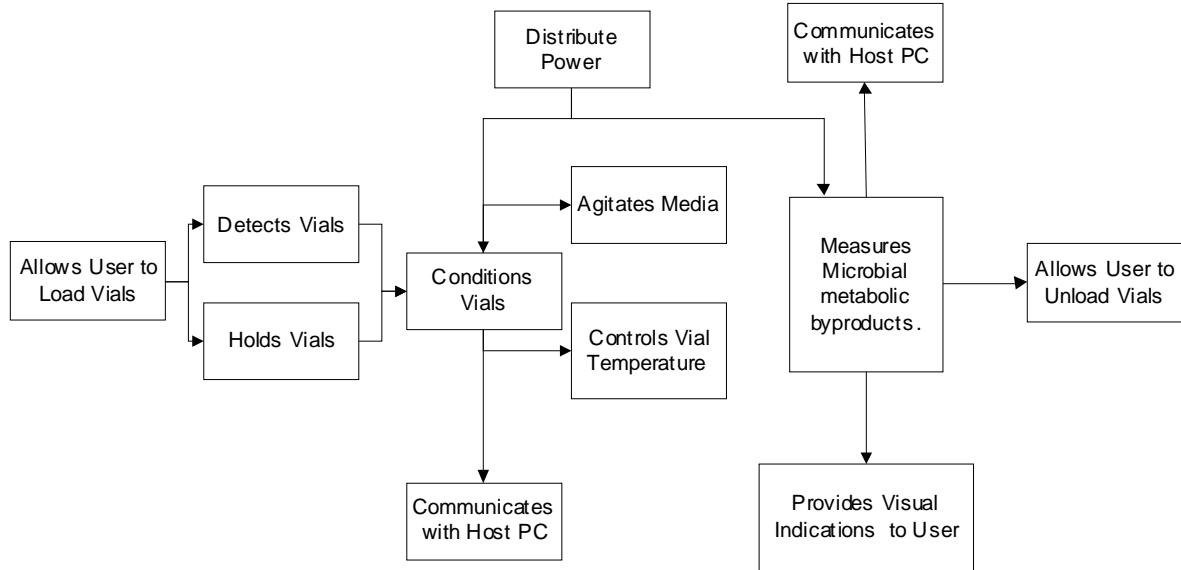
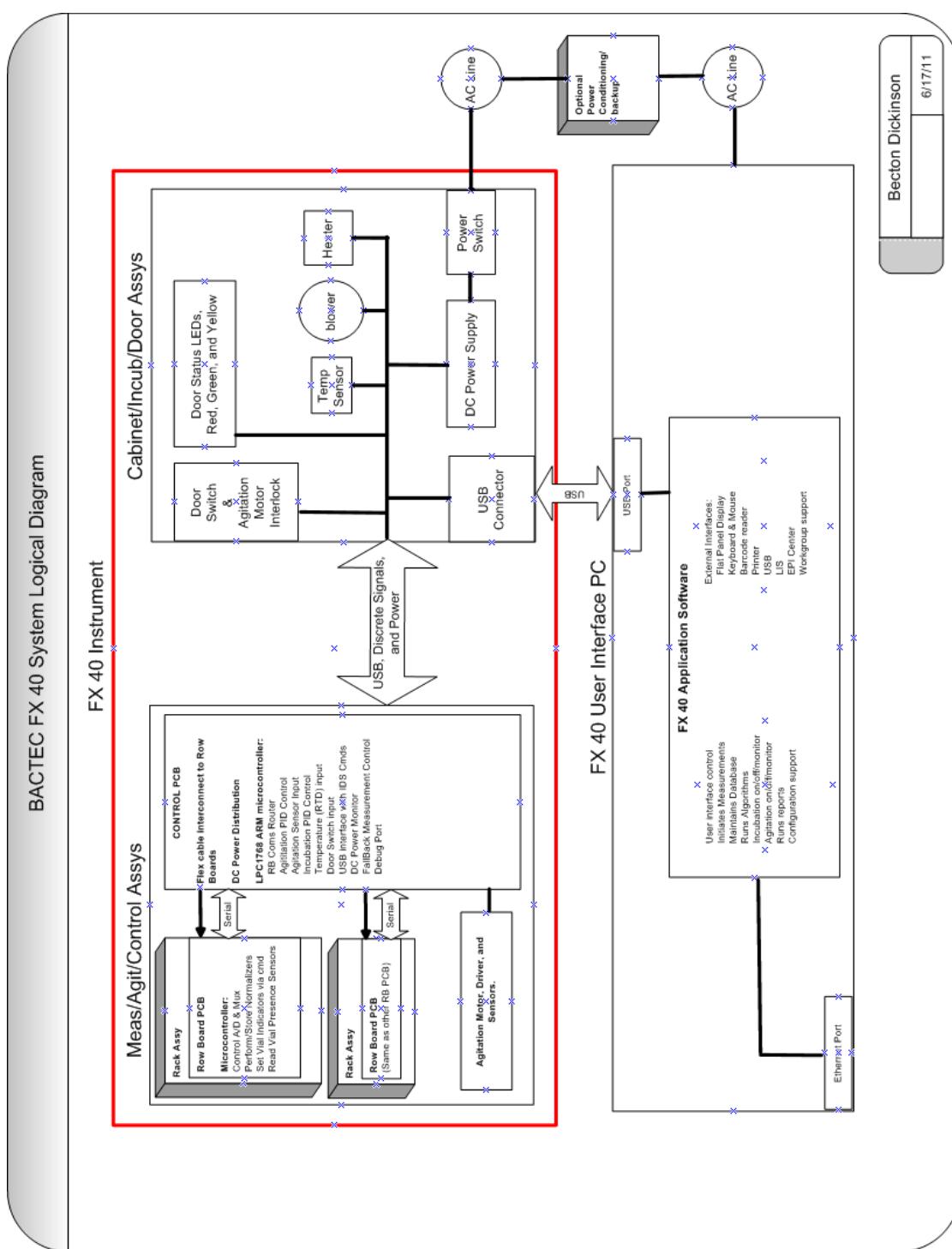


Figure 1

**Figure 2** shows a System Logical Diagram.



**Figure 2**

**Figure 3** shows a physical connection diagram.

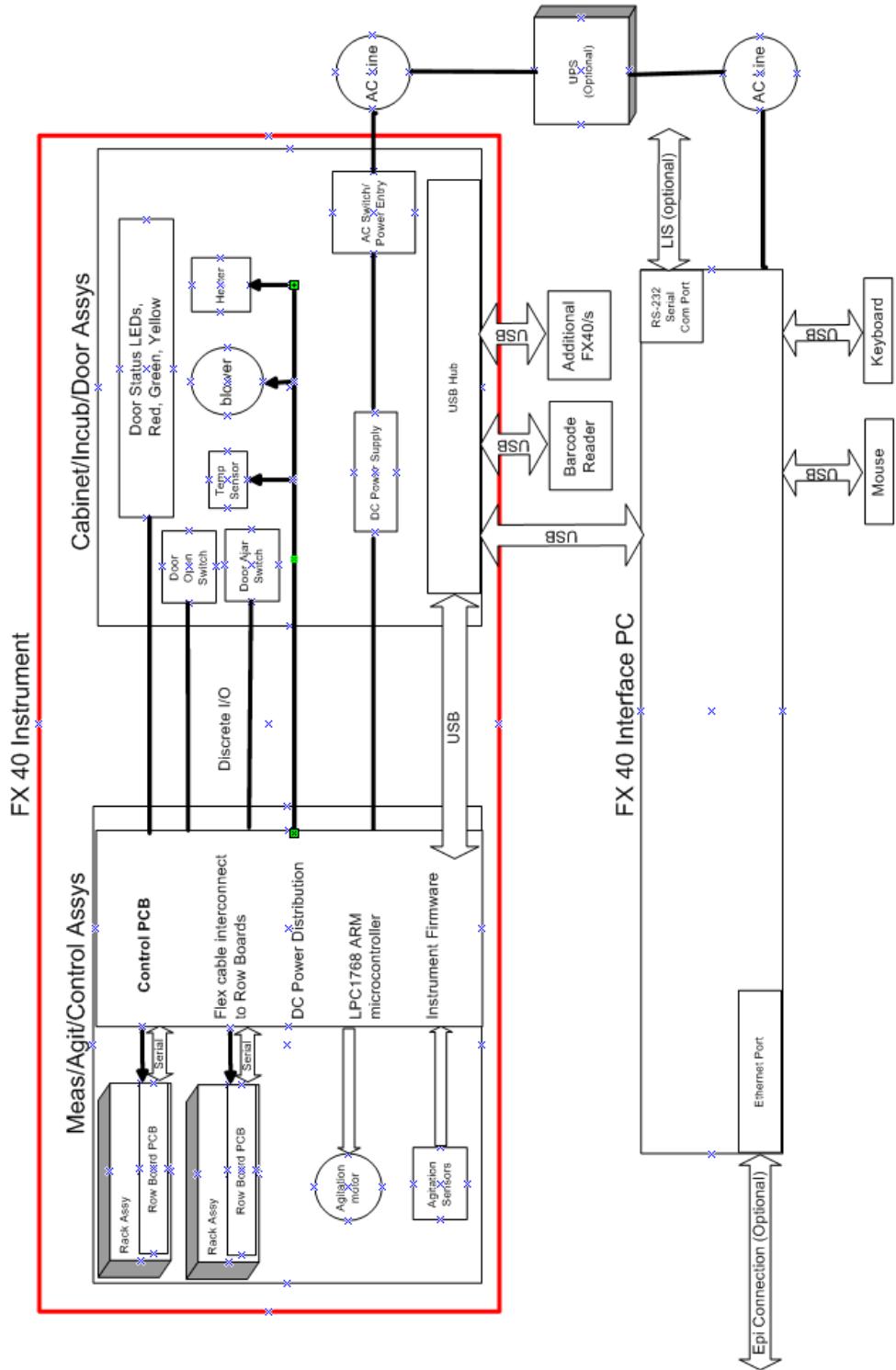


Figure 3

Figure 4 shows an FX40 cluster connection diagram

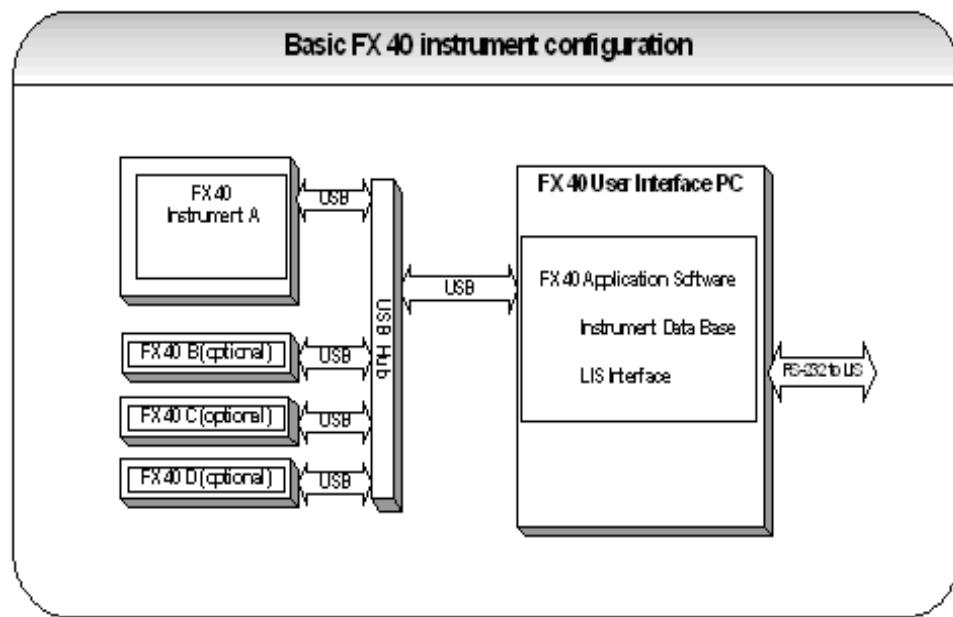


Figure 4

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## Topic 2: Instrument Subsystems

### Incubation Subsystem

The incubation subsystem contains the following components: heater plate, blower assembly and RTD (**Figure 5**). It regulates the temperature of the media vials to the set-point temperature (35°C). This historically has been achieved by forced air convection over the media vials. This subsystem uses an RTD located at the back of the cabinet to sense temperature. Heat is then generated by a heater plate. This heated air is circulated inside the cabinet through a blower assembly. The whole incubation mechanism is controlled by FX40 Control Board.

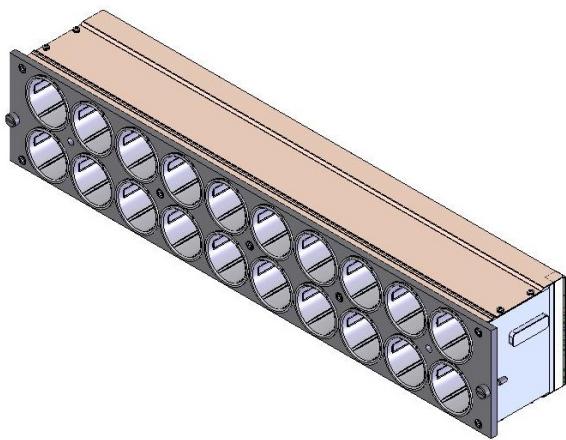
The cabinet is wrapped with foams to prevent heat lost.



**Figure 5 Heater Plate (top left), RTD (top right), Blower Assembly (bottom)**

### Measurement Subsystem

The measurement subsystem is achieved by reusing the BACTEC FX Vial Storage Racks (**Figure 6**). This assembly includes the Row Board PCB mounted on back. This PCB contains the 20 photo diode detection circuits and one on-board microprocessor.



**Figure 6 BACTEC FX Vial Storage Rack**

The measurement subsystem optically interrogates the sensor in the bottom of a media vial (**Figure 7**). The interrogation consists of exciting the sensor with an LED, collecting fluorescent light back from the sensor with a photo detector, and collecting data from a temperature sensor located in close proximity to the excitation LED. The collected data is processed, normalized and compensated for thermal variation.

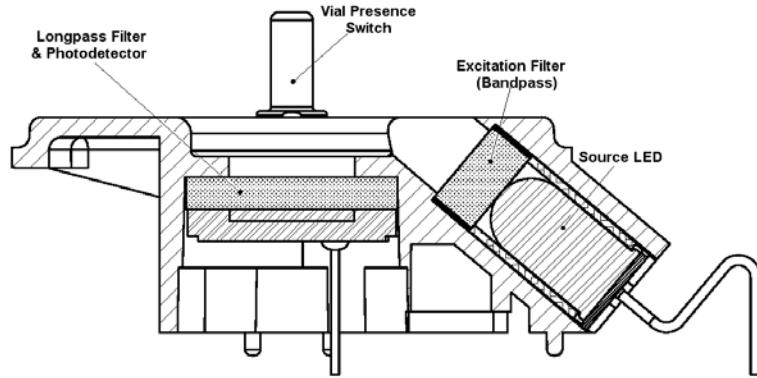


Figure 7 Station Bottom

Each station in the vial storage rack contains a vial presence switch to detect vial insertion and removal (Figure 8). Each station also includes a station status indicator. The indicator LEDs produce visible light at the front of the station via a crescent shaped light pipe. Vial presence slotted optical switches and station indicator LEDs are all located on the Row Board PCB.

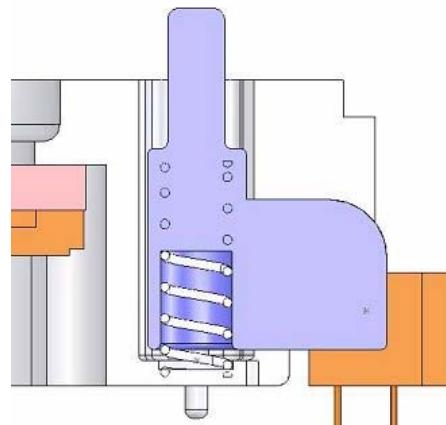


Figure 8 Vial Presence Switch

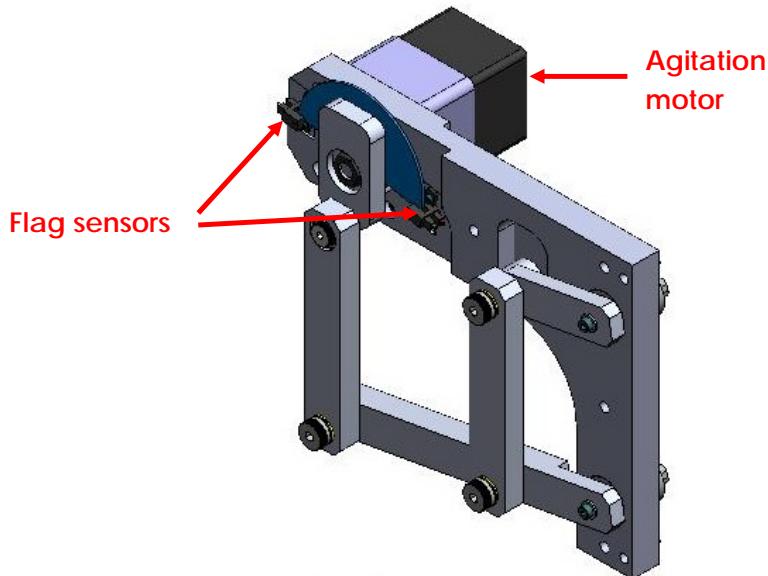
More details about measurement subsystem can be found in BACTEC FX Service Training Manual.

### Agitation Subsystem

The agitation subsystem contains the following components: step motor, two flag sensors and metal linkages (**Figure 9**). Its main function is to rock the vial storage racks back and forth between 0° and 20° relative to horizontal. The two vial storage racks are coupled by a gang linkage to a motor. The rotary action of the motor is converted to a linear reciprocation of the linkage, which is then converted to the 20° oscillation. The 0° and 20° positions are monitored by two flag sensors, with signals returned back to FX40 Control Board. When instrument door is opened, door ajar sensor will return signal to FX40 Control Board such that racks will be stopped at 0°.

A vial seated in the FX 40 will have its fluid contents agitated to facilitate a homogeneous distribution of nutrients and microbial byproducts.

The entire agitation subsystem is assembled and aligned in factory. Hence it is replaced as a module.



**Figure 9 Agitation Subsystem**

### Door Subsystem

The door contains visible instrument indicators to convey top level instrument status to the user. The status colors are red for positive vials, green for negative vials, and amber to alert the customer to other instrument conditions requiring operator intervention.

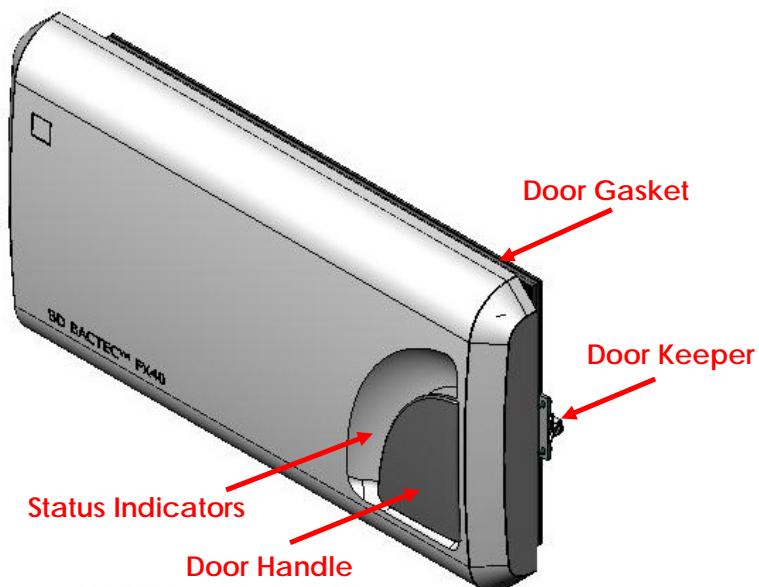


Figure 10 Door Subsystem

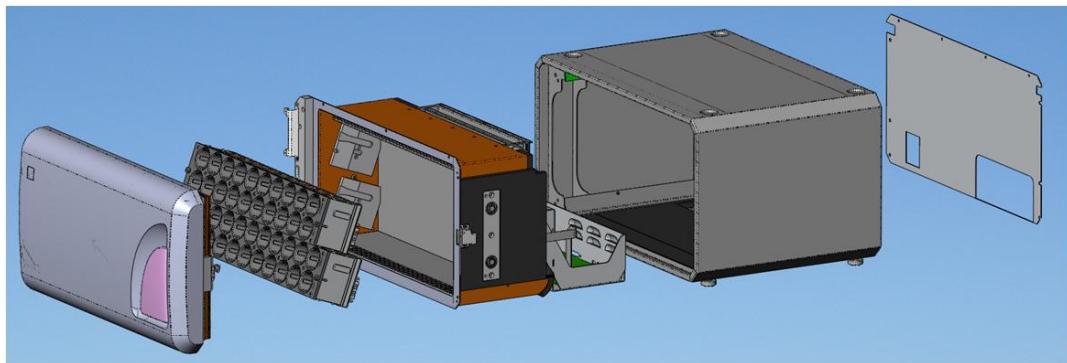
The door hinges are located on the left side of the instrument. When open, the door does not hinder the removal/insertion of vials. The door also opens wide enough for removal/installation of the vial storage racks. When closed, the door provides a light tight seal so that the sensitive photodiode circuits on the row board PCB are not affected by ambient light. Also, when closed, the door minimizes heat transfer between the incubated instrument interior and the external room air.

### Cabinet/Structural Subsystem

The Cabinet/Structural subsystem is defined as the physical assembly that houses all major subsystems and assemblies (**Figure 11**). This structure is built with rigidity and structural integrity to withstand the forces and stresses of stacking instruments, shipping, door open/closing, vial insertion/removal,

etc... Similar to the door subsystem, the cabinet must provide a light tight enclosure for the measurement system. Also, the cabinet contains air circulation ducting as part of the incubation subsystem to provide an even distribution of temperature within the instrument.

In principle, instrument is designed such that all service can be performed from front. The inner chassis assembly can be pulled out in order to service the attached components. In addition, the back panel can be removed separately, that allows access to cabinet components from back.



**Figure 11 Cabinet/Structural Subsystem**

### Control PCB Subsystem

This microprocessor based circuit board has many responsibilities as it forms part of the incubation and agitation subsystems as well as numerous independent functions. The S/W architecture and communication protocol, in addition to other BD products, has been used in microprocessors on the BACTEC FX. This includes the microprocessor on the Vial Storage Rack.



### Topic 3: Software Overview

System software is pre-installed in the tablet computer, under Windows 7 environment. Software user interface is the same as current FX. This instrument software is designed to be user installable through external USB flash drive. System software, database and configuration parameters are all located in the internal memory of tablet computer.





# BACTEC FX40 System™

## Service Training Manual

### Module Replacement

#### Module C



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## Module Replacement

### Overview:

This topic provides Module Replacement Procedures for the BACTEC™ FX Instrument.

### Topics:

The following Topics are covered in this Module:

- Topic 1: Electro Static Discharge (ESD)
- Topic 2: Module Replacement Instructions
- Topic 3: Module Replacement Exercises

#### Materials Required:

- BACTEC™ FX40 Instrument
- ESD ground strap & bench/field mat
- Common Hand Tools
- DVM



## Topic 1: Electro Static Discharge (ESD)

The BACTEC FX40 instrument contains Electro Static Discharge (ESD) sensitive electronic components. When servicing the instrument proper ESD protection must be utilized to prevent possible damage to these sensitive components. Failure to follow proper ESD precautions can possibly induce intermittent and/or catastrophic failures.

The use of a Portable Field Service Static Kit such as those manufactured by 3M™ (**Figure 1**) is recommended when servicing BACTEC FX40 instrumentation. This kit provides a wrist strap & coil cable, ground strap and a portable anti-static mat for servicing & staging components. Any replacement electronic modules should be stored and transported in an ESD shielded container or bag. These components ideally should only be opened on a grounded ESD work surface.

The Universal Anti-Static Icon (**Figure 2**) is used throughout BACTEC FX40 service documentation. PCB's are often labeled with this icon as an additional warning where ESD protection should be utilized. Proper use of ESD protection is assumed when performing service tasks on BACTEC FX40 instrumentation.



3M™ Portable Field Service Kit 8501 provides effective static protection in a compact package for the electronics field technician. The entire kit folds to a size that fits easily into most tool cases. Two pockets sewn into the work surface provide storage for the cords.

**Figure 1**



**Figure 2**

## Topic 2: Module Replacement Instructions

This Topic provides detailed instructions on replacing modules in the BACTEC FX40 instrument. An effort was made to condense these instructions by referring to previously described instructions whenever possible.

The instructions below are listed in no particular order.

**WARNING:** Testing of clinical vials should never be interrupted for greater than 40 minutes under any circumstances. To ensure maximum recovery, it is recommended that all vials in the instrument system be subcultured when system testing has been interrupted for longer than 40 minutes.

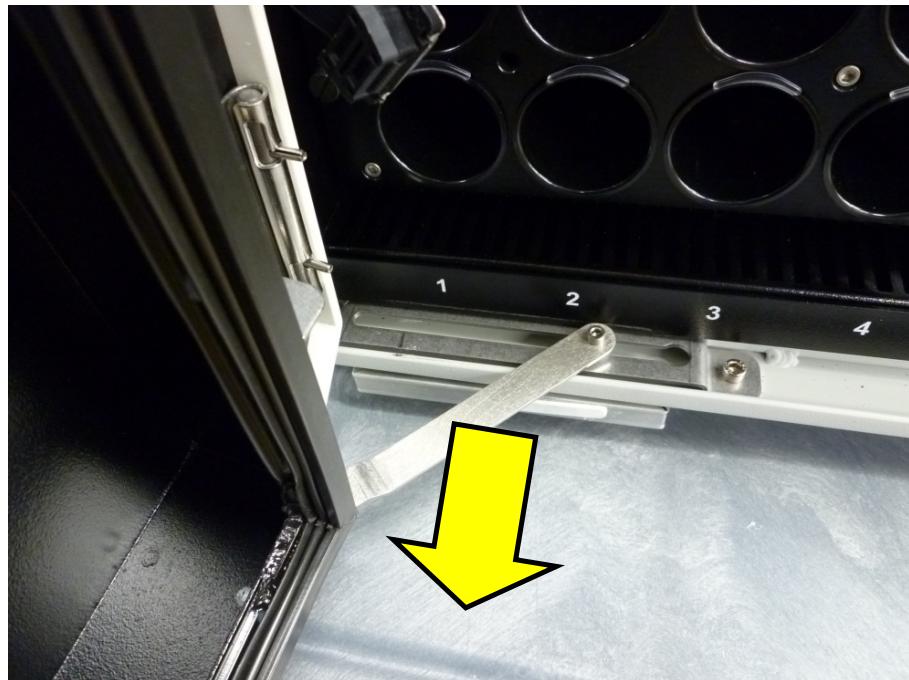
**CAUTION:** Proper use of ESD protection is assumed when performing service tasks on BACTEC FX40 instrumentation.

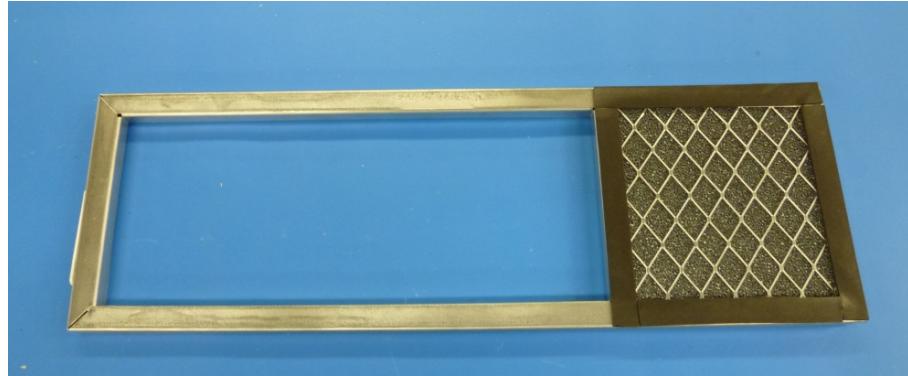
**CAUTION:** Ambient light entering the instrument may cause erroneous readings, including errors and/or false positives. Ensure gaskets are always maintained in good conditions.

**WARNING:** The BACTEC FX40 instrument should only be serviced by trained authorized personnel and assumes proper safety precautions are observed.

**Incubation Air Filter**

There is one incubation filter for each BACTEC FX40 instrument. It resides at the lower left corner. To remove it, first open instrument door and pull the filter out (**Figure 3**). Black rubber sealing (**Figure 4**) is added on the metal frame in order to achieve optimum cooling to internal components. This rubber sealing should always be facing up when the filter is installed back to instrument.

**Figure 3**



**Figure 4**

#### **Accessing Instrument from Back**

In principle, BACTEC FX40 is designed such that all instrument service can be performed from front. If laboratory environment is allowed, we can also carry out a portion of instrument service from back. In this case, the back cover must be removed.

1. Remove two rubber bumpers (**Figure 5**, red arrows).
2. Remove ten M5 hex screws (**Figure 5**, yellow arrows).
3. The back cover can now be taken off (**Figure 6**).
4. Reassemble by reversing the above steps.

## MODULE C



Figure 5



Figure 6

### LED Indicator PCB Assembly

The LED Indicator PCB Assembly resides in the door handle. The whole replacement process is performed from front.

1. Open the instrument door.
2. Remove five M4 hex screws located at the door left side (**Figure 7**, yellow circles).
3. Carefully take out the door handle (**Figure 8**).
4. Unplug cable connecting to LED Indicator PCB.
5. Slide out the LED Indicator PCB Assembly. It's a set of three small PCBs connected by thin wires.
6. Reassemble by reversing the above steps.

**CAUTION:** Ensure those connecting wires are not pressed and damaged when assembling the LED indicator PCB Assembly and door handle.

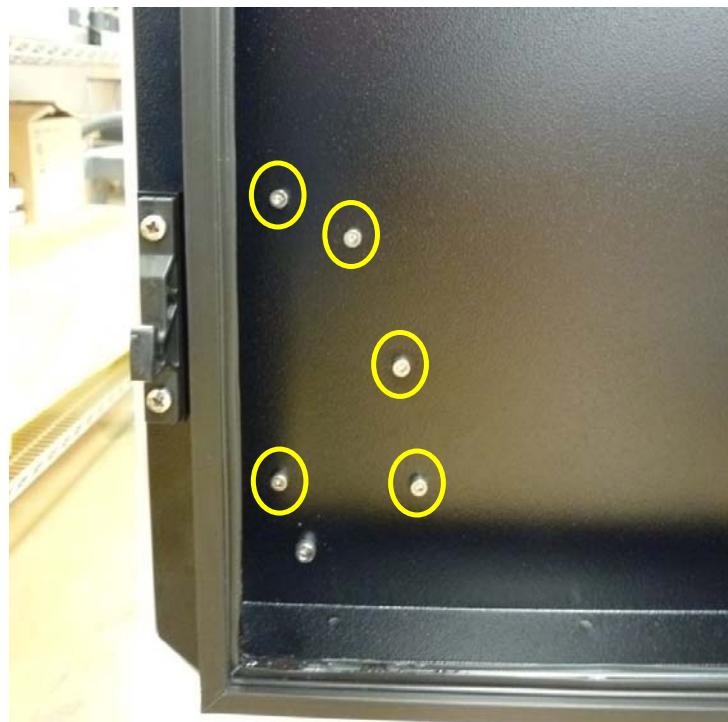


Figure 7



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**Figure 8****Door Assembly**

1. Disconnect the LED cable (**Figure 9**, yellow circle).
2. Release four springs on the door hinges.
3. Carefully remove the whole door assembly by sliding the door stay to right (**Figure 10**).
4. Reassemble by reversing the above steps. **Note:** Some adjustments may be required in order to align door latch back to keeper.

**CAUTION:** Do not apply excessive force to door assembly. Otherwise, it may bend the door stay assembly.

**CAUTION:** Door gasket is not supplied as a separate spare. If it is damaged, the whole door assembly should be replaced.



Figure 9

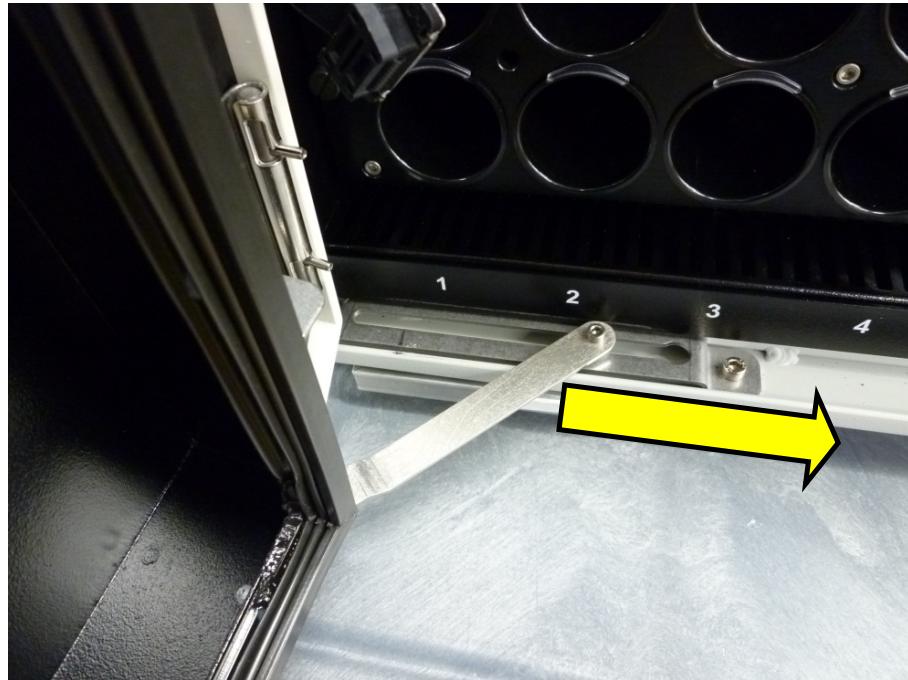


Figure 10

### Vial Storage Rack

BACTEC FX40 uses the same Vial Storage Rack as BACTEC FX, and thus it follows the same replacement procedure.

Each spare Vial Storage Rack is calibrated and tested in factory. Calibration data is stored locally on each rack and uploading this data is not required. **Note:** It is still necessary to notify software when a rack is replaced.

1. Ensure the rack to be replaced is empty.
2. Open the instrument door.
3. Loosen the two thumb screws on both sides with a flat head screwdriver.
4. Grasp the rack and pull forward, in order to release it from the back connector. Extra care should be taken to avoid hitting vials in the other rack.
5. Reassemble by reversing the above steps.

6. Turn on the software Diagnostic feature.
7. Under the Maintenance Menu, select BD Utilities (**Figure 11**) / Change Rack (**Figure 12**).
8. Select the appropriate rack replaced from the Change Rack menu (**Figure 13**).
9. Recycle power to instrument and tablet computer.
10. Turn off the software Diagnostic feature.
11. Allow instrument to run several test cycles and ensure no error conditions are encountered.

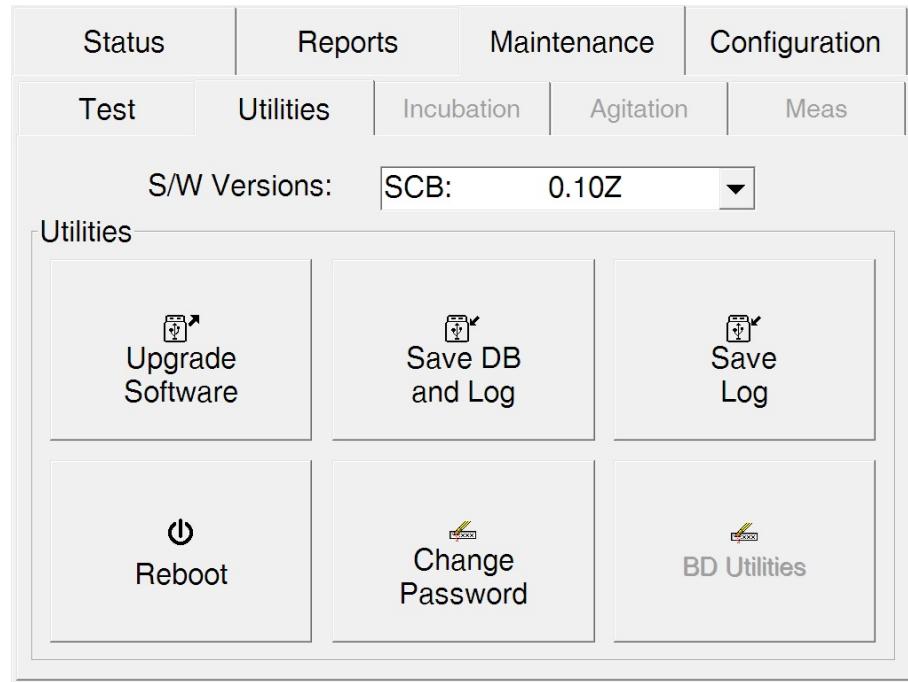


Figure 11

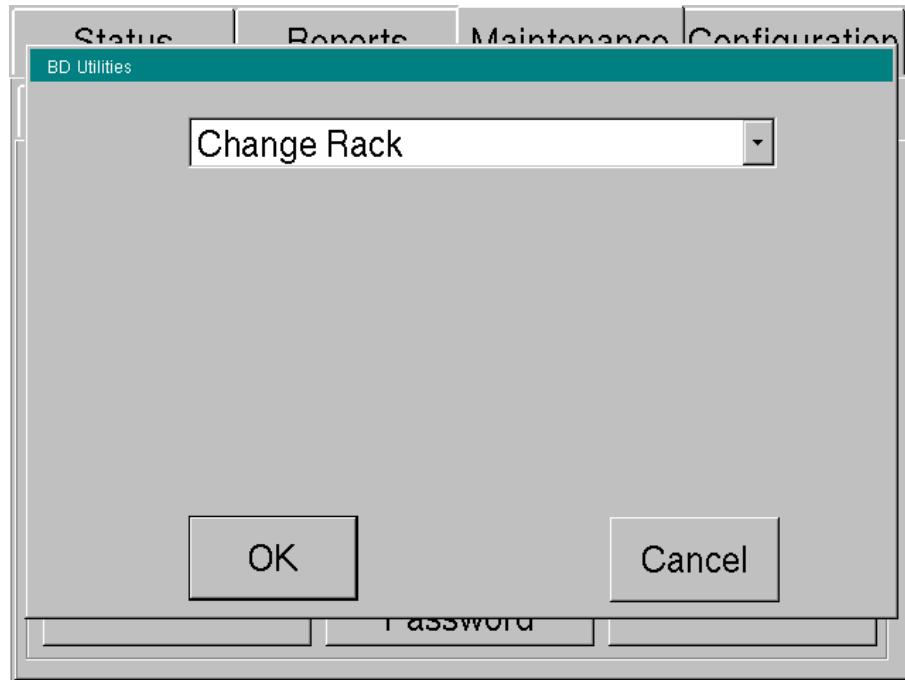


Figure 12

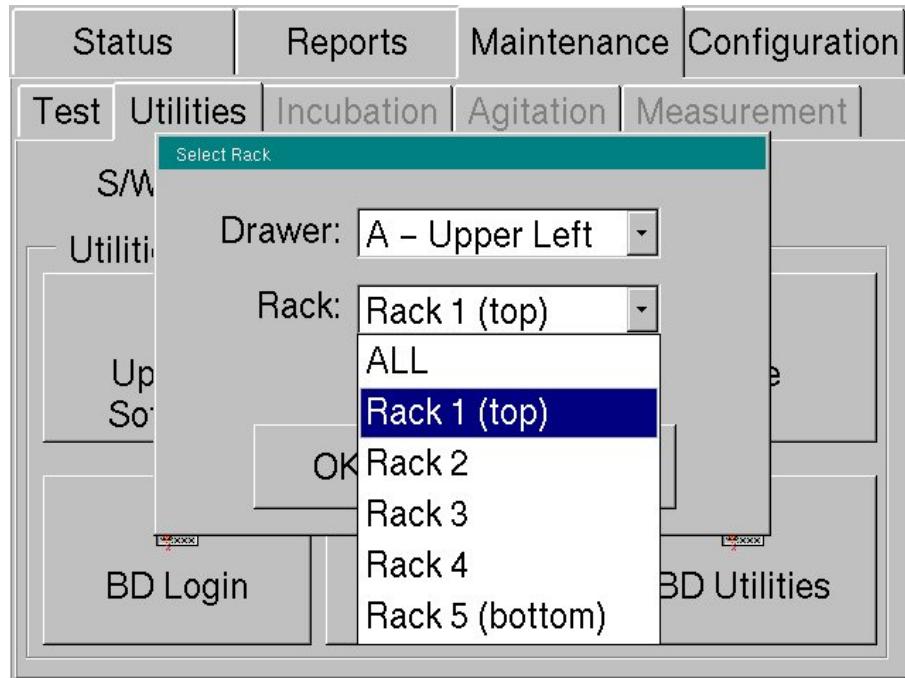


Figure 13

### RTD Assembly

The replacement of RTD Assembly can be performed from front. Thus, it is not required to take out the Inner Chassis Assembly to carry out this service.

1. Remove the two racks from instrument (**Figure 14**).
2. Remove the right side sample drawer driveplates. Each of them is secured by two M4 hex screws.
3. Disassemble the interconnect board at the back of each driveplate. It is secured by two shoulder screws.
4. Remove three M5 hex screws that hold the inner back wall.
5. Pass the interconnect boards and flat cables through the openings on inner back wall (**Figure 15**).
6. Take out the inner back wall.
7. Unplug the RTD cable from row interconnect assembly.
8. Remove two M3 hex screws that secure the RTD.
9. Lower the RTD and carefully take it out (**Figure 16**).
10. Reassemble by reversing the above steps.



Figure 14

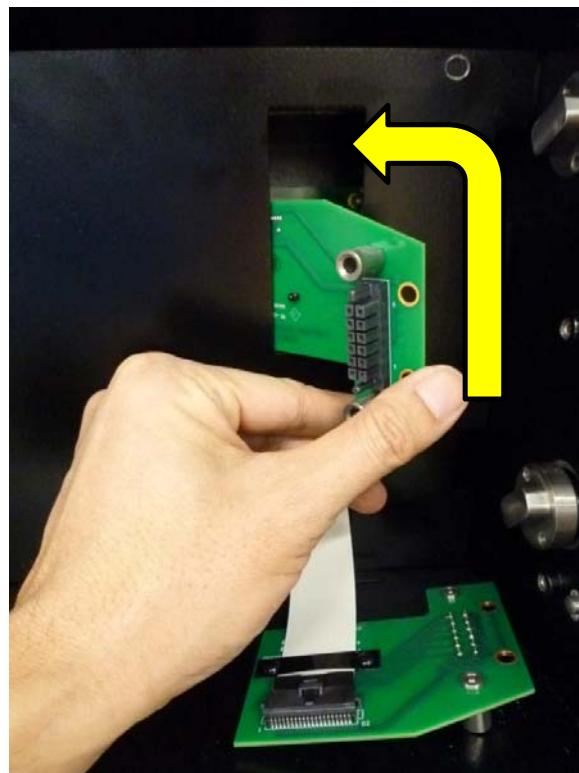


Figure 15



Figure 16

### Row Interconnect Assembly

The row interconnect assembly can be accessed with the inner back wall removed. It is disassembled by:

1. Unplug the RTD cable.
2. Unplug the ribbon cable that connects to FCB.
3. Remove four M3 hex screws that secure the whole assembly.
4. The row interconnect assembly is free to take out (**Figure 17**).
5. Reassemble by reversing the above steps.

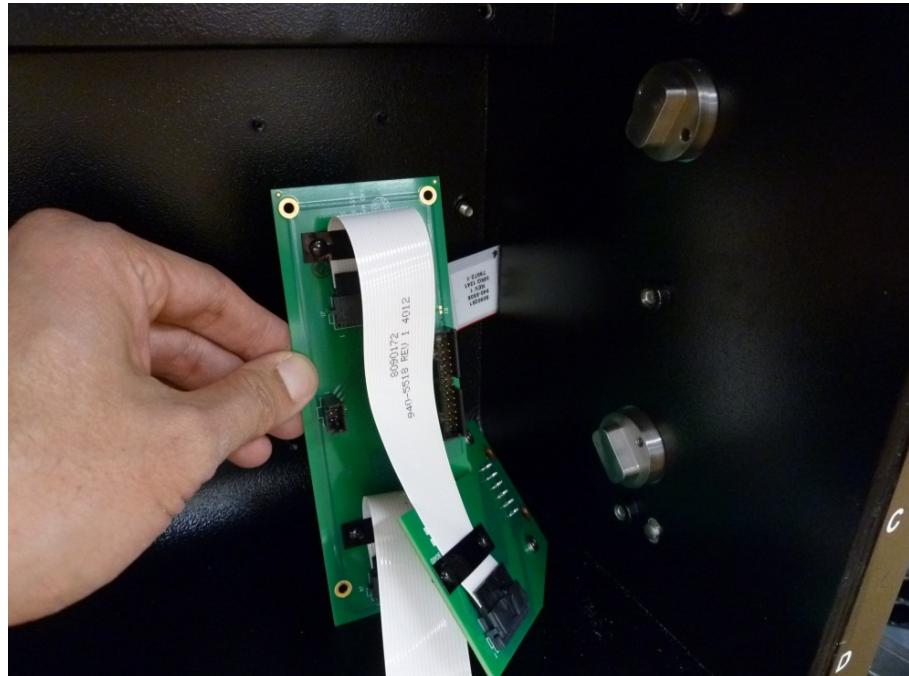


Figure 17

### Inner Chassis Assembly

**CAUTION:** Taking out the Inner Chassis Assembly may probably take more than 40 minutes. Transfer all vials to other instruments to ensure on-going tests will not be affected.

1. Remove the door assembly.
2. Remove seven M4 hex screws that secure the inner chassis assembly to main cabinet structure (**Figure 18**, yellow circles).
3. Insert the chassis removal tool to rack B.
4. Pull the whole inner chassis assembly out slowly (**Figure 19**). Upper part of cabinet may be slightly purged down and obstruct the movement of inner chassis assembly.
5. When pulling the chassis out, be careful not to damage those cables on both sides (**Figure 20**).
6. Once the inner chassis assembly is taken out, we can reach all FX40 internal components.
7. Reassemble by reversing the above steps. **Note:** When pushing the chassis in, pay extra care to those cables on both sides.

**WARNING:** The whole Inner Chassis Assembly (with racks) weighs approximately 40 lbs. It is necessary to apply proper OH&S practice when handling this module. Weight can be reduced by 12 lbs after removing the two racks.

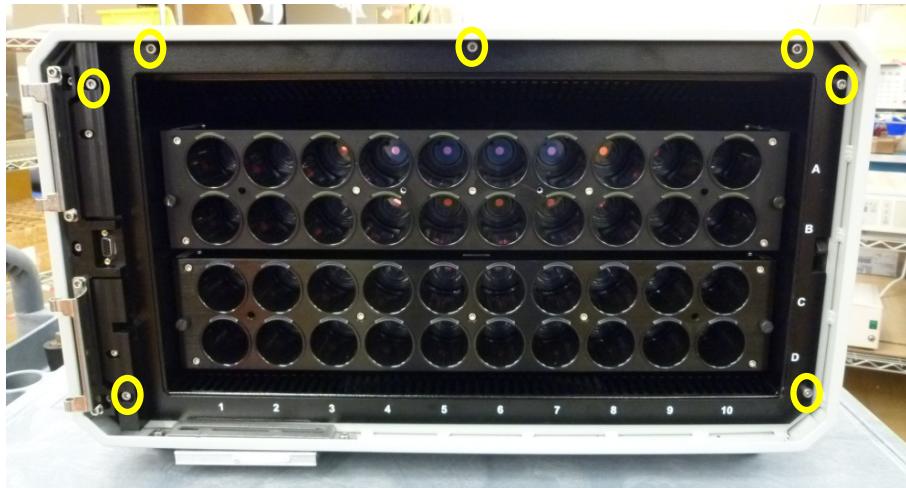


Figure 18



Figure 19



Figure 20

Electronics assembly is the rear part of Inner Chassis Assembly. It contains the following components:

1. FX40 Control Board (FCB)
2. Power Supply
3. Cooling Fan
4. Power Entry Assembly

In principle, those components can be serviced either from front or back. If instrument service is going to be performed from front, it is mandatory to pull out the entire Inner Chassis Assembly

### **FX40 Control Board (FCB)**

The FCB resides at the Electronics Assembly.

1. Unplug eleven cables that connect to FCB
2. Remove six M3 hex screws that secure the FCB.
3. Carefully lift up the FCB.
4. Reassemble by reversing the above steps.

**WARNING:** Ensure each connector is connected properly prior to powering up the instrument. Improper connections may cause permanent damage to FCB.

**WARNING:** Never remove the battery pack from FCB when instrument is powered off.

Table 1 outlines the detail connections on FCB.

Connector	Module connected
-----------	------------------

J5	DOOR LED BOARD
J7	BLOWER ASSEMBLY
J8	COOLING FAN
J10	HEATER BAR
J11	AGITATION MOTOR
J12	ROW INTERCONNECT PCB ASSEMBLY
J18	OPTICAL SENSOR 0 DEGREE
J19	DOOR LATCH ASSEMBLY
J20	OPTICAL SENSOR 20 DEGREE
J21	DOOR AJAR SENSOR
J22	POWER SUPPLY

Table 1

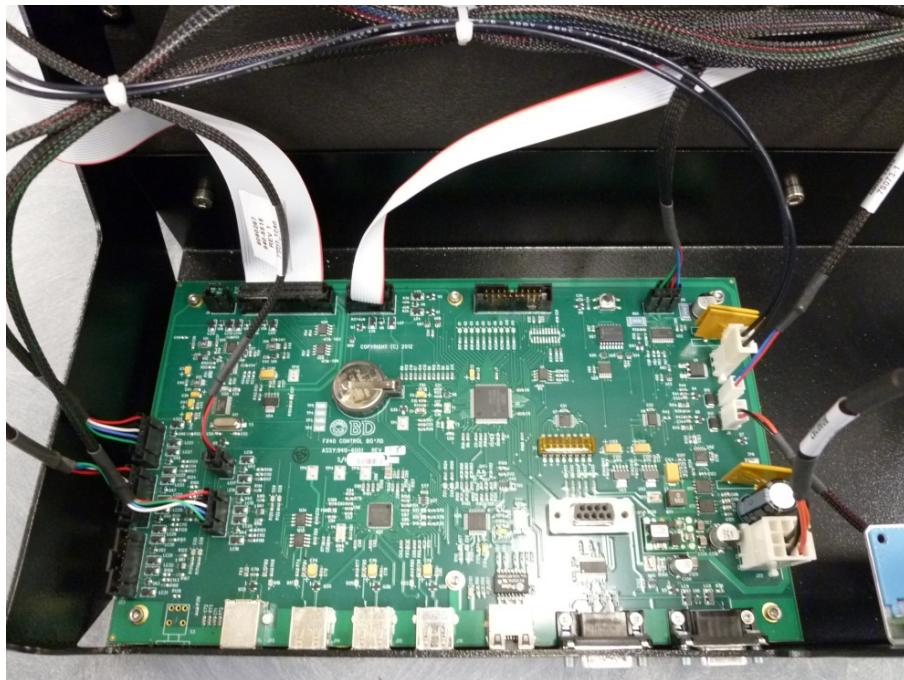


Figure 21

## Power Supply

The power supply resides at the electronics assembly. Unlike those power supplies used in other BD instrumentations, there is no pot on this component to adjust the output voltage.

1. Unplug J22 from FCB.
2. Unplug the cable coming from Power Entry Assembly.
3. Remove four Philips screws that secure the power supply.
4. Carefully lift up the FCB.
5. Reassemble by reversing the above steps.

## Power Entry Assembly

The Power Entry Assembly resides at the electronics assembly. It holds two 5A fuses that protect the instrument from power surge. Replacing fuses is a simple procedure, and should be performed from the back of instrument.

1. Unplug the cable that is connected to power supply.
2. Disconnect the ground cables from instrument chassis. It is secured by nuts, flat washers and locking washers.
3. Remove two M3 hex screws that secure the Power Entry on electronics assembly.
4. Press on both top and bottom clips to slot out the Power Entry Assembly.
5. Reassemble by reversing the above steps.

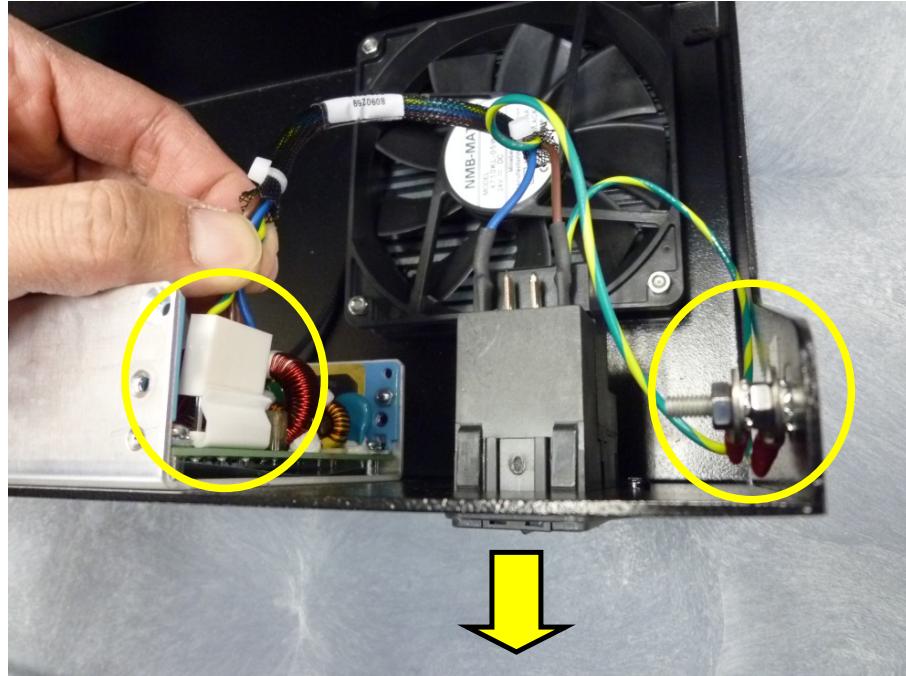


Figure 22

### Cooling Fan

The cooling fan resides at the Electronics Assembly, right above the Incubation Air Filter. It operates continuously to keep the instrument internal components running at an optimum temperature.

1. Unplug J8 from FCB.
2. Remove four nuts that secure the Cooling Fan.
3. Remove one M5 hex screw right above the Cooling Fan (**Figure 23**).
4. Carefully lift up the Cooling Fan. **Note:** There may be fiction between Cooling Fan and the threads.
5. Reassemble by reversing the above steps.

**CAUTION:** The Cooling Fan power cable should be routed to FCB from left side.



Figure 23

### Door Latch Assembly

The Door Latch Assembly resides at the right side wall of Inner Chassis Assembly. Its cable is connected to FCB, and thus it is required to pull out the Inner Chassis Assembly for service or replacement.

1. Unplug J19 from FCB.
2. Cut the appropriate cable ties that secure those cable routing to FCB.
3. Remove four M3 hex screw that hold the Door Latch Assembly. (**Figure 24**).
4. Reassemble by reversing the above steps. **Note:** Fine alignment to Keeper Assembly is required to ensure proper closing of instrument door.



Figure 24

### Blower Assembly

The Blower Assembly resides in the middle of Inner Chassis Assembly. It is required to pull out the Inner Chassis Assembly prior to replacing the Blower Assembly.

1. Unplug J7 from FCB.
2. Cut the appropriate cable ties that secure those cable routing to FCB.
3. Remove three M3 hex screws that hold the Blower Assembly on top (**Figure 25**, red circles).
4. Remove three M3 hex screws that hold the Blower Assembly on bottom (**Figure 25**, yellow circles).
5. Carefully lift up the Blower Assembly (**Figure 26**).
6. Reassemble by reversing the above steps.

**WARNING:** Touching the blower wheel, bearing or other internal components may deform the Blower Assembly. Minor defect may already enough to create

excessive noise during instrument operation.



Figure 25

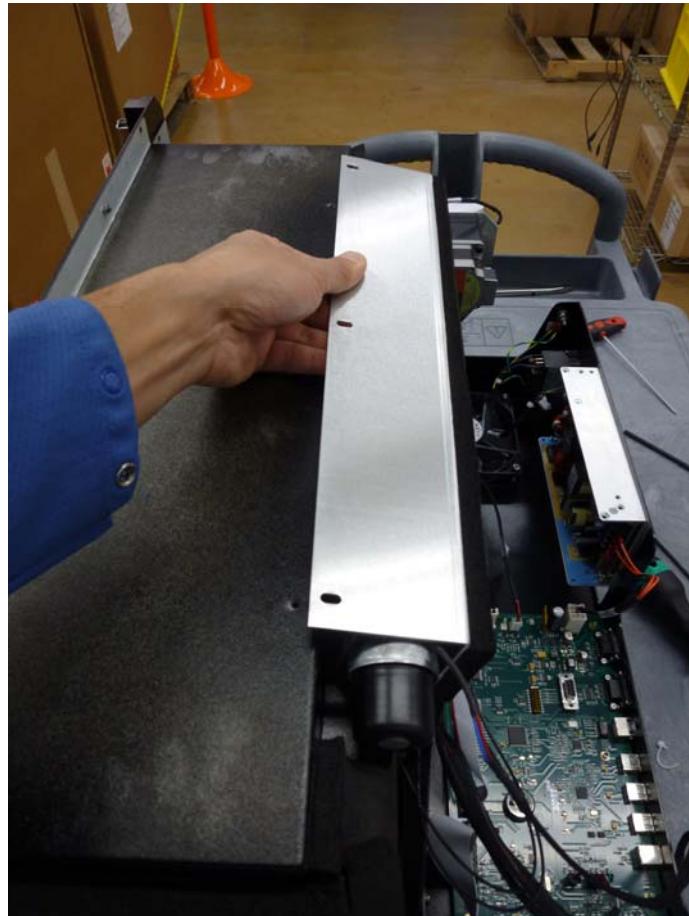


Figure 26

### Heater Bar

The Heater Bar resides right below the Blower Assembly. It is required to pull out the Inner Chassis Assembly prior to replacing the Heater Bar.

1. Unplug J10 from FCB.
2. Cut the appropriate cable ties that secure those cable routing to FCB.
3. Remove two M5 hex screws that secure the Heater Bar (**Figure 27**).
4. The insulation foam is blocking the path. Tear off that piece of foam to make room for the Heater Bar (**Figure 28**).
5. Carefully slide the Heater Bar out.

- 
6. Reassemble by reversing the above steps.

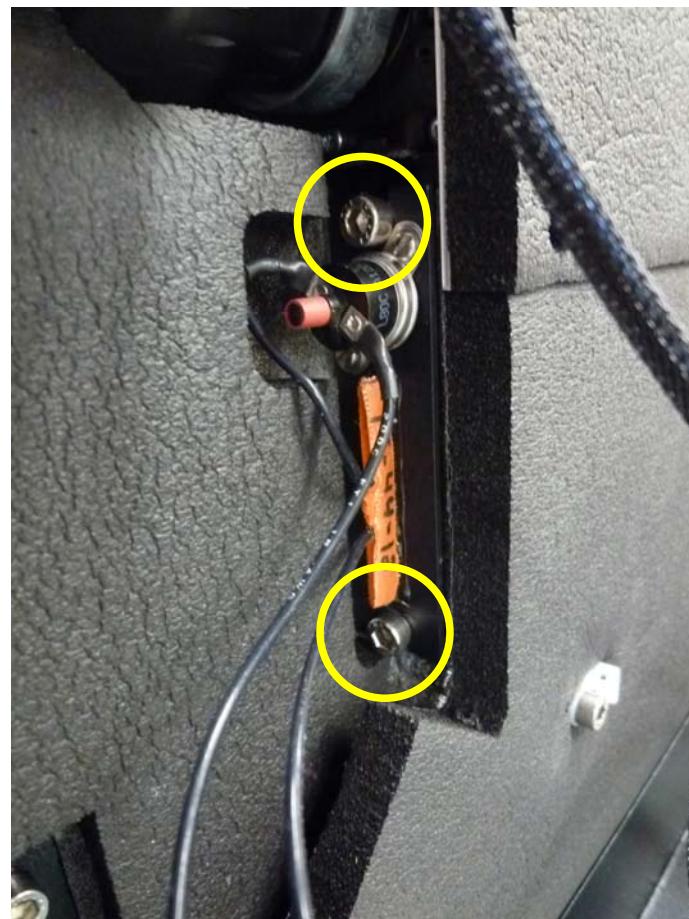


Figure 27

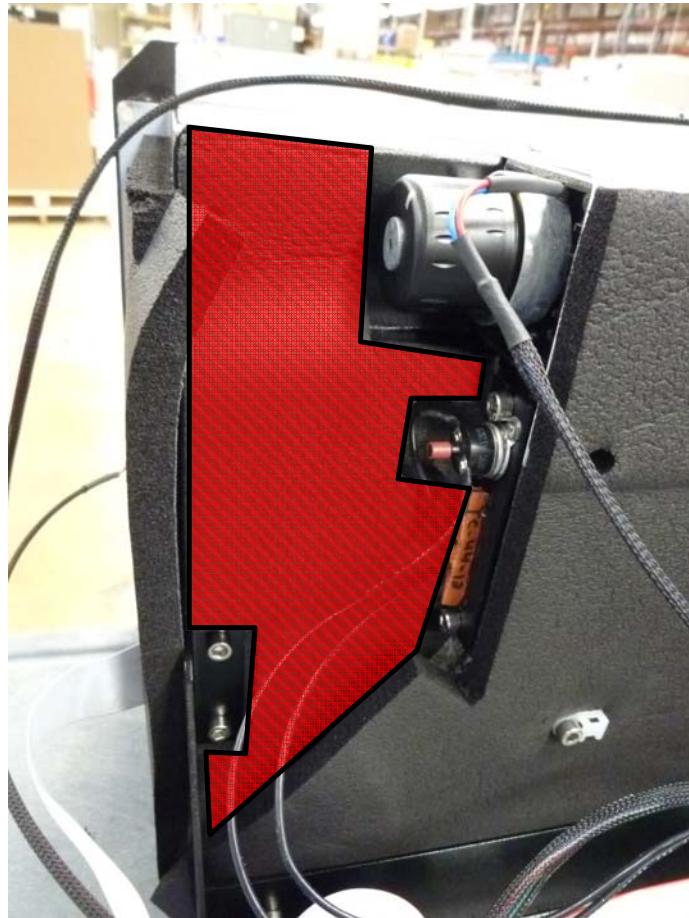


Figure 28

### Agitation Assembly

The Agitation Assembly resides at the left side wall of Inner Chassis Assembly. It contains Agitation Motor, Agitation Linkage Bars, and two Optical Sensors. The Agitation Assembly is replaced as a module. Nevertheless, the two Optical Sensors can be replaced separately if they are broken. Adjustment of sensor position with reference to eccentric flag is required to ensure proper agitation angles.

It is required to pull out the Inner Chassis Assembly prior to performing any service on Agitation Assembly.

1. Remove the two racks from instrument.
2. Remove the left side sample drawer driveplates. Each of them is secured by two M4 hex screws.
3. Unplug J11, J18 and J20 from FCB.
4. Cut the appropriate cable ties that secure those cables routing to FCB.
5. Remove four M6 hex screws that secure the Agitation Assembly (**Figure 29**).
6. Carefully pull the whole Agitation Assembly out. **Note:** This component is heavy.
7. Reassemble by reversing the above steps.

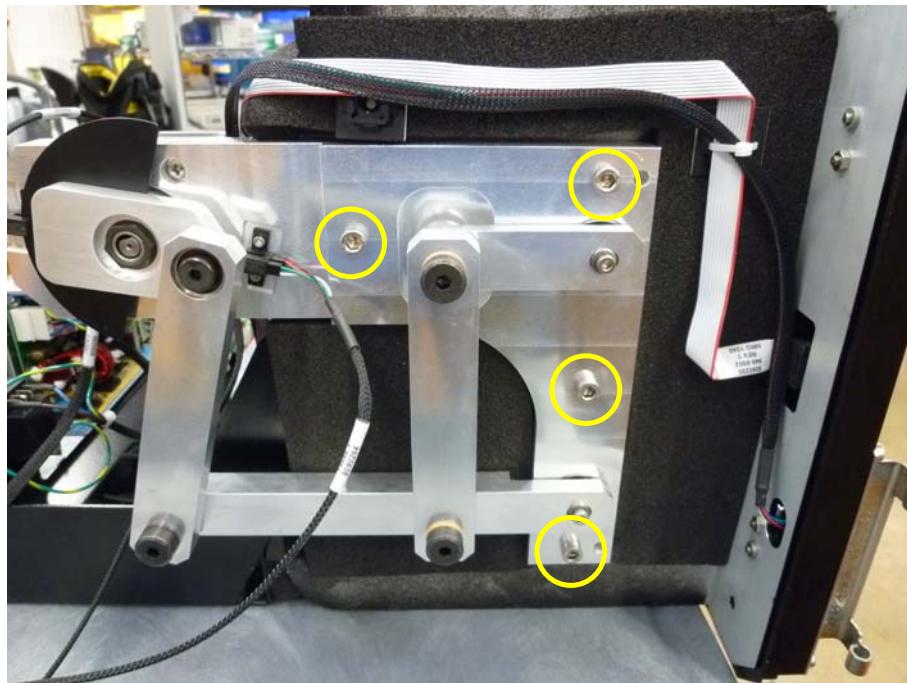


Figure 29

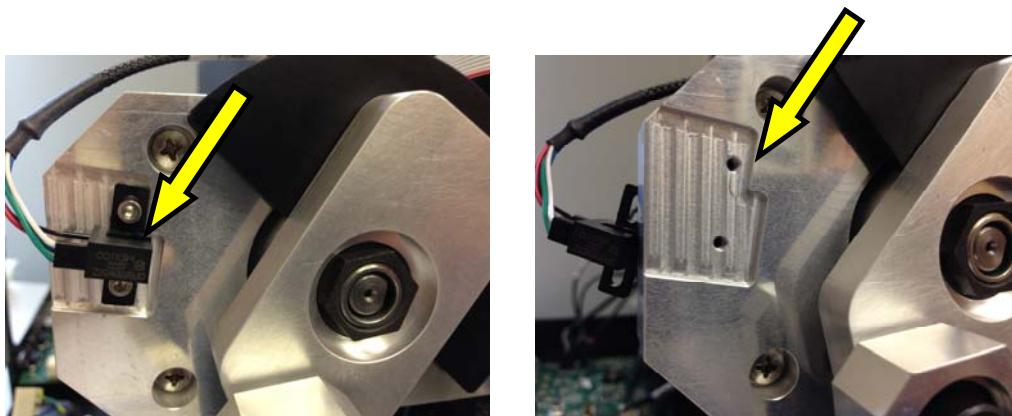
**WARNING:** Agitation Motor is assembled and aligned in factory. It requires dedicated service tools for this process. Do not attempt to take out the

Agitation Motor during field service.

The 20 degree Optical Sensor is located on the left, while the 0 degree Optical Sensor is located on the right (**Figure 30**). They are both connected to FCB to return signal for agitation positions. When replacing a new Optical Sensor, it must be flushed firmly to the edge of metal frame assembly. This will provide correct 0 degree and 20 degree position signals.

Agitation cycle works as follows:

1. At the beginning, racks are maintained at 0 degree. Right Optical Sensor is blocked while left Optical Sensor is unblocked (**Figure 31**).
2. When racks are moving upwards, right Optical Sensor is kept interrupted (**Figure 32**).
3. When racks reach 20 degree, right Optical Sensor is unblocked while left Optical Sensor is blocked (**Figure 33**).
4. When racks are moving downwards, left Optical Sensor is kept interrupted (**Figure 34**).
5. This mechanism will repeat continuously.



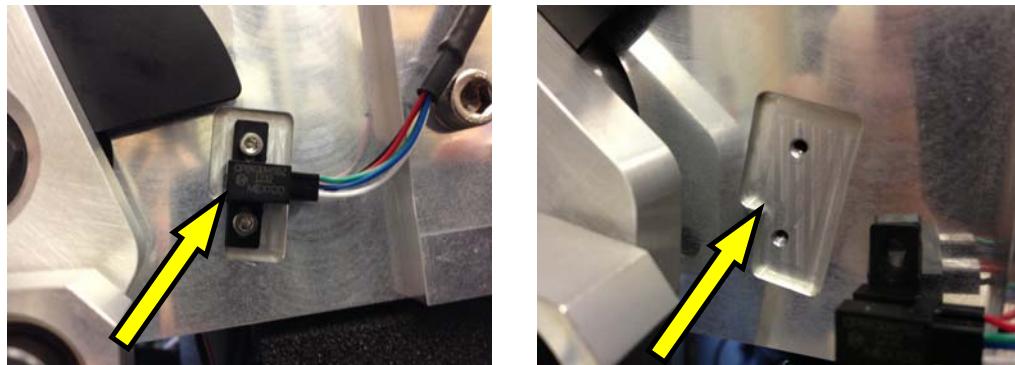


Figure 30

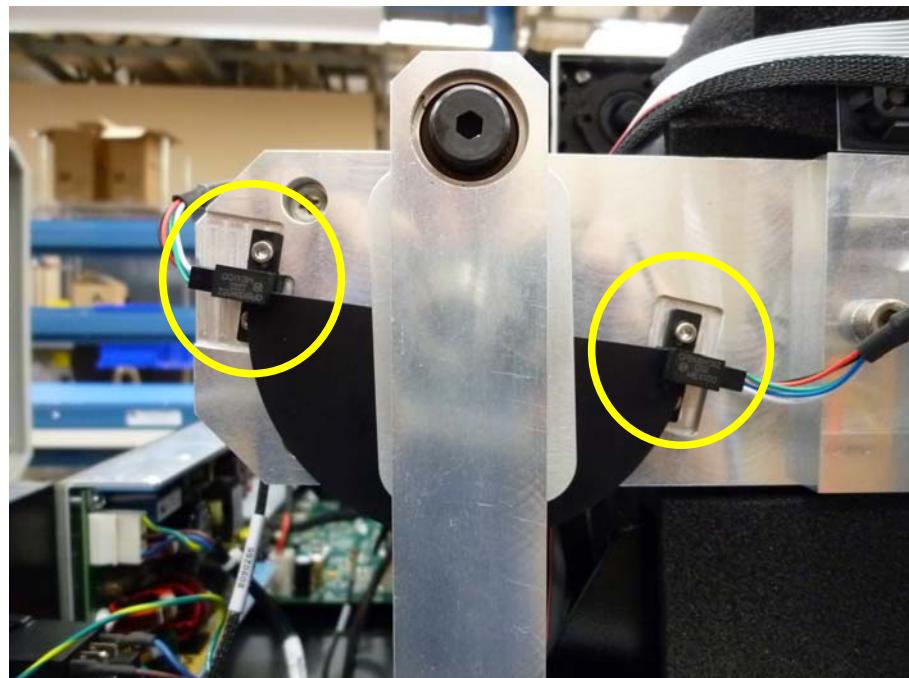


Figure 31

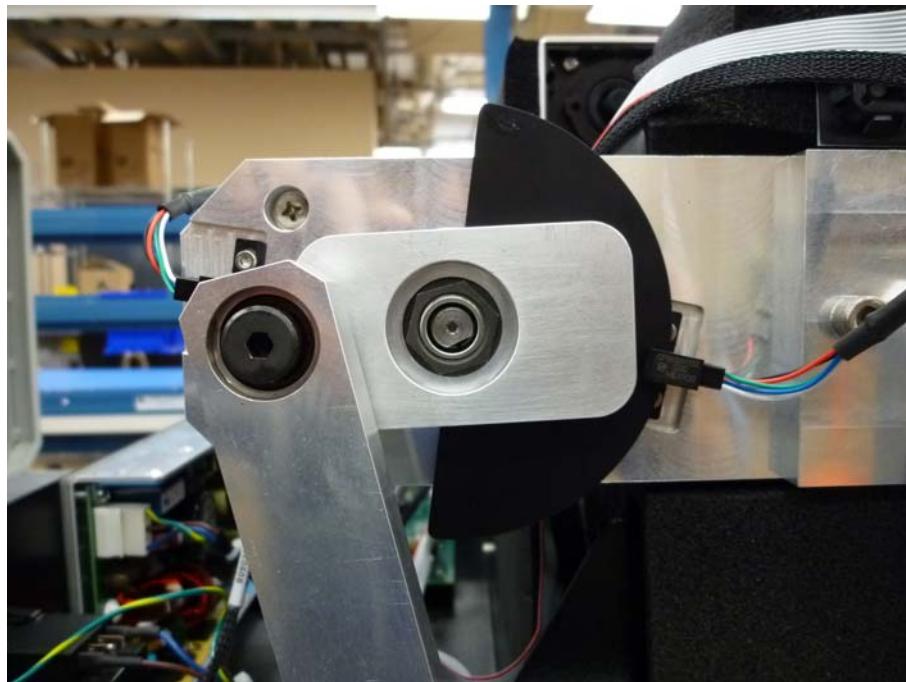


Figure 32

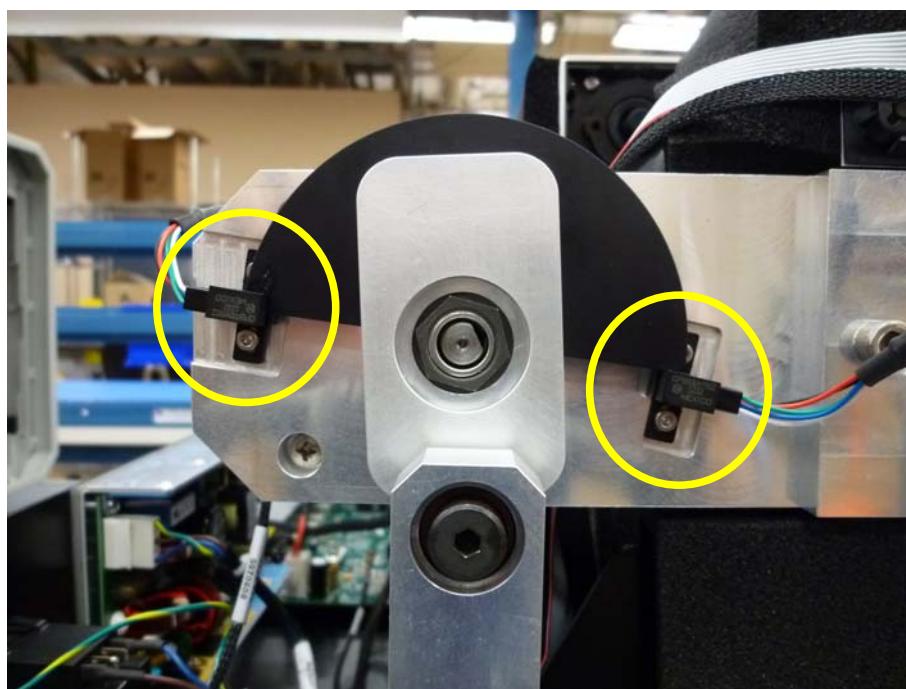


Figure 33

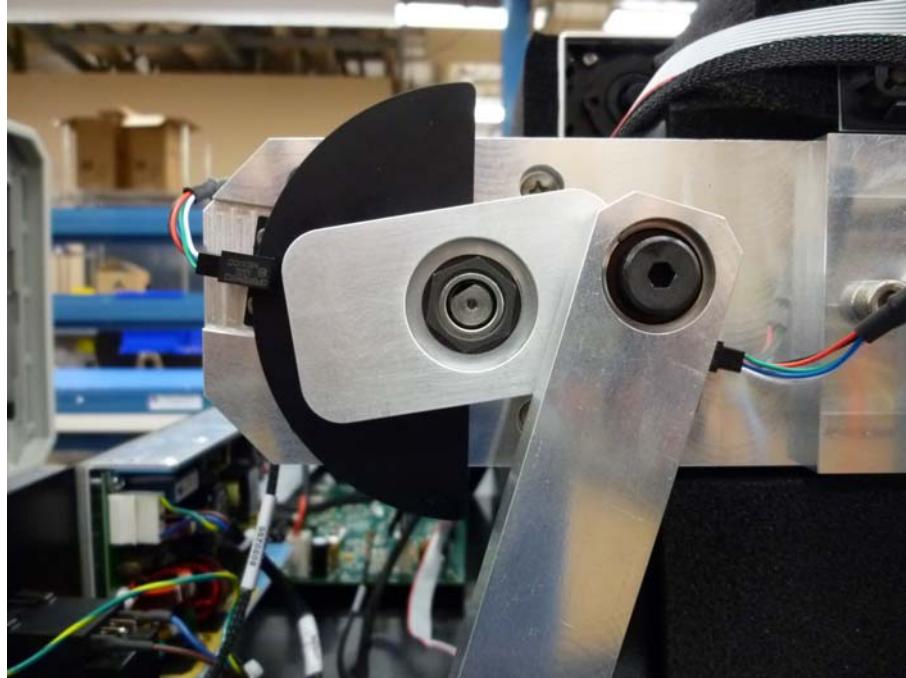


Figure 34

### Door Ajar Sensor

The Door Ajar Sensor resides in the Hinge Assembly. It is required first to remove the Hinge Assembly prior to replacing the Door Ajar Sensor.

1. Unplug J21 from FCB.
2. Cut the appropriate cable ties that secure those cable routing to FCB.
3. Remove three hex screws that hold the Hinge Assembly (**Figure 35**).
4. Carefully take out the Hinge Assembly. Note that the LED cable is still connected.
5. Remove two M2.5 hex screws that hold the Door Ajar Sensor (**Figure 36**).
6. Take out the Door Ajar Sensor by pulling the cable through a hole in Inner Chassis Assembly.
7. Reassemble by reversing the above steps.

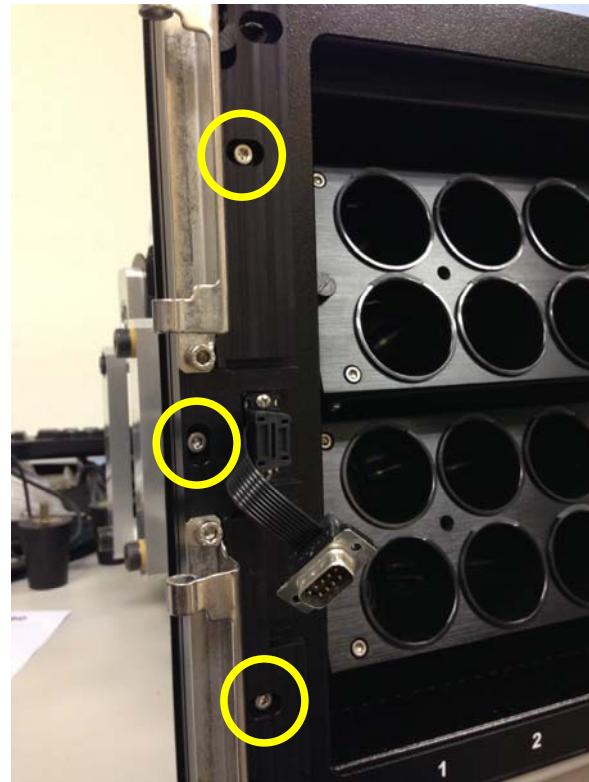


Figure 35

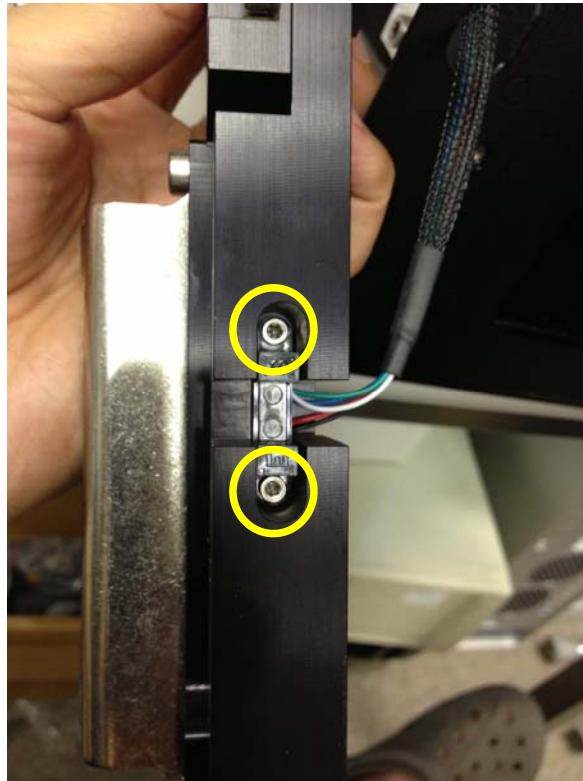


Figure 36

### Door Assembly Alignment Procedure

When reassembling Door Assembly or Hinge Assemble, the latch and keeper may be out of alignment. To re-align the door, loose the screws as and manually move the Hinge Assembly horizontally and vertically until the latch and keeper are properly aligned.

## Topic 3: Module Replacement Exercises

This topic provides an opportunity to identify components and assemblies in the instrument. Optionally, other assemblies may be disassembled. These Exercises are listed in a particular order and should be followed. Refer to the Module Replacement Instructions in Topic 2 whenever disassembling or reassembling the instrument.

### MODULE C TOPIC 3 EXERCISES

1. Identify, remove, replace and clean the Incubation Air Filter in the instrument.

### MODULE C TOPIC 3 EXERCISES

2. Access the Electronics Assembly from back and identify the modules below:
  - Identify the Power Entry Assembly.
  - Replace fuses in the Power Entry Assembly.
  - Identify the Power Supply.
  - Remove the Power Supply.
  - Reinstall the Power Supply.
  - Identify the FX40 Control Board (FCB).
  - Remove the FCB.
  - Reinstall the FCB.
  - Identify the Cooling Fan.

### MODULE C TOPIC 3 EXERCISES

- Remove the Cooling Fan.
- Reinstall the Cooling Fan.

### MODULE C TOPIC 3 EXERCISES

3. Access the Door Assembly:

- Remove the Door Assembly.
- Reinstall the Door Assembly.
- Identify the LED Indicator PCB Assembly.
- Remove the LED Indicator PCB Assembly.
- Reinstall the LED Indicator PCB Assembly.
- Realign Door Assembly to ensure proper closing.

**MODULE C TOPIC 3 EXERCISES**

4. Access the instrument cabinet from front and identify the modules below:

- Identify the Vial Storage Racks.
- Remove one Vial Storage Rack.
- Reinstall Vial Storage Rack.
- Identify the RTD Assembly.
- Remove the RTD Assembly
- Reinstall the RTD Assembly
- Identify the Row Interconnect Assembly
- Remove the Row Interconnect Assembly.
- Reinstall the Row Interconnect Assembly.

**MODULE C TOPIC 3 EXERCISES**

5. Access the Inner Chassis Assembly and identify the modules below:

- Remove the Inner Chassis Assembly.
- Identify the Blower Assembly.
- Remove the Blower Assembly.
- Reinstall the Blower Assembly
- Identify the Heater Bar.
- Remove the Heater Bar.

**MODULE C TOPIC 3 EXERCISES**

- Reinstall the Heater Bar.
- Identify the Door Latch Assembly.
- Remove the Door Latch Assembly.
- Reinstall the Door Latch Assembly.
- Identify the Agitation Assembly.
- Remove the Agitation Assembly.
- Reinstall the Agitation Assembly.
- Identify the two Optical Sensors.
- Remove the two Optical Sensors.
- Reinstall and realign the two Optical Sensors.
- Reinstall the Inner Chassis Assembly.

### MODULE C TOPIC 3 EXERCISES

6. Access the Tablet Computer:

- Identify all cable connections.
- Replace a new Tablet Computer.
- Configure the Tablet Computer for an existing system.



# BACTEC FX40 System™

## Service Training Manual

Installation, Qualification, Maintenance & Troubleshooting

### Module D



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## Installation, Qualification, Maintenance & Troubleshooting

### Overview:

This topic outlines Field Service Procedures for the BACTEC™ FX40 Instrument.

### Topics:

The following Topics are covered in this Module:

- Topic 1: Pre-Installation
- Topic 2: Installation/Qualification
- Topic 3: Preventive Maintenance Inspection
- Topic 4: Eventlog Utilities
- Topic 5: Diagnostics
- Topic 6: Troubleshooting

#### Materials Required:

- BACTEC™ FX40 Instrument
- USB Data Key
- BALTFS0230 BACTEC FX40 Pre-Installation Procedure
- BALTFS0231 BACTEC FX40 Installation Procedure
- BALTFS0232 BACTEC FX40 PMI Procedure



## Topic 1: Pre-Installation

BALTFS0230 BACTEC FX40 Pre-Installation Procedure is a controlled document describing the pre-installation process. This document should be utilized during every pre-installation of BACTEC FX40 instrument.

**IMPORTANT:** Special considerations are required for European installations. Instrument weight could be an issue due to older building structures and local regulations. Refer to EUR\_NGB-001BACTEC FX Installation Configurations for detailed information.

### MODULE D TOPIC 3 EXERCISES

1. Overview BALTFS0230 BACTEC FX40 Pre-Installation Procedure.



## Topic 2: Installation/Qualification

### INSTALLATION/QUALIFICATION

BALTFS0231 BACTEC FX40 Installation Procedure is a controlled document describing the installation and qualification process. This document should be utilized during every installation of the BACTEC FX40.

#### MODULE D TOPIC 3 EXERCISES

2. Overview BALTFS0231 BACTEC FX40 Installation Procedure.



### Topic 3: Preventive Maintenance Inspection

BALTFS0232 BACTEC FX40 PMI Procedure is a controlled document describing the PMI process. This document should be utilized during every PMI of the BACTEC FX40.

#### MODULE D TOPIC 3 EXERCISES

3. Overview BALTFS0232 BACTEC FX40 PMI Procedure.



## Topic 4: Eventlog Utilities

### Viewing the EVENTLOG

The EVENTLOG of BACTEC FX40 can be downloaded from **Maintenance** menu, **Utilities** screen (Figure 1). After pressing Save Log button, files will be transferred automatically to the inserted USB flash drive. Those files are pure text format and can be examined through any Windows text editor.

A\_FFxxxx\_xxxx

L\_FFxxxx\_xxxx

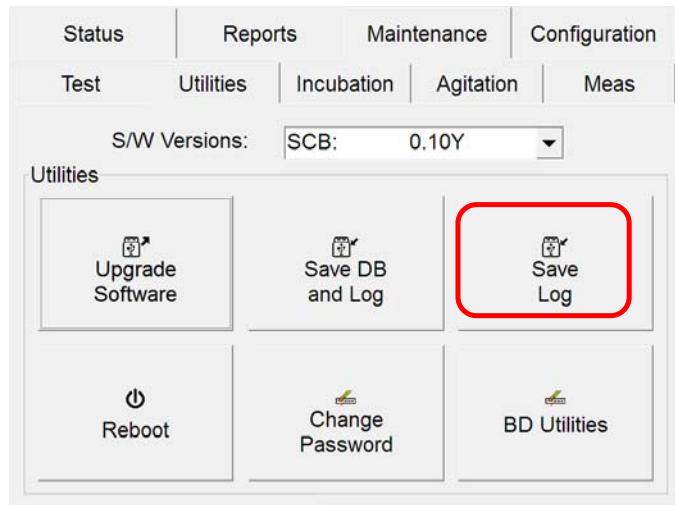


Figure 1

### MODULE D TOPIC 3 EXERCISES

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MODULE D TOPIC 3 EXERCISES

4. Download log files to an USB flash drive and examine with a text editor.



## Topic 5: Diagnostics

The BACTEC FX40 has some diagnostic features built into the instrument **Maintenance** menu. They can be activated by the following procedure.

When those diagnostic features are activated, the Incubation, Agitation and Meas screens can be accessed. Also, the BD Utilities button is enabled (**Figure 2**).

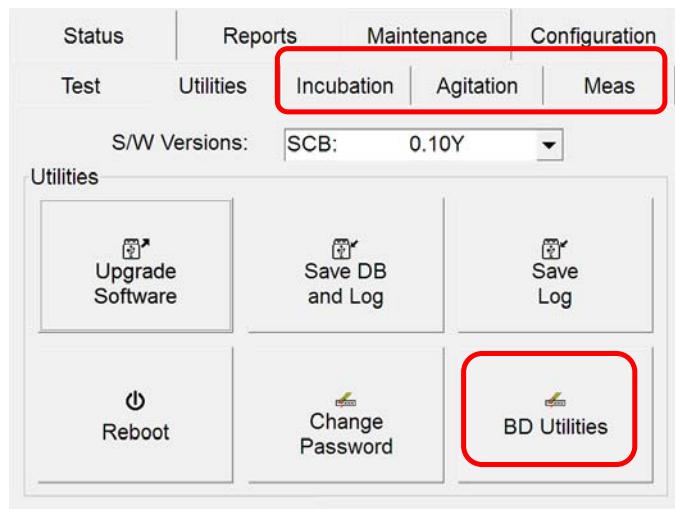


Figure 2

The following are features included in BD Utilities:

### MODULE D TOPIC 3 EXERCISES

5. Review the diagnostic features in the maintenance menu.



## Topic 6: Troubleshooting

Roll back Startup Configuration screen.

Write s/n to FX40 control board

### MODULE D TOPIC 3 EXERCISES

6. Review the Service Bulletins.