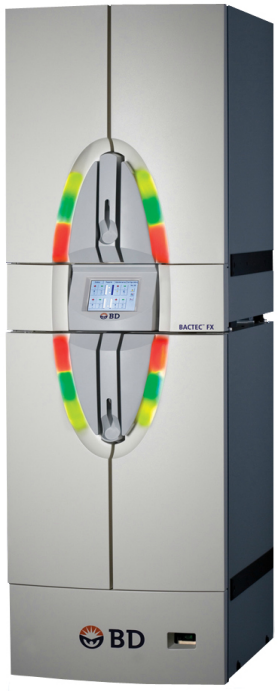
BD BACTEC™ FX

Instrument User's Manual



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Change History

Revision	Date	Change Summary
13	2023-12	Added details on Lot Expiration feature, and added supporting screenshots; Added information on PHI window once instrument is powered on; Added information on Satellite Blood Culture BD Synapsys™ interactions. Added new Error messages and updated existing error message details.
14	2024-03	Updated the LED lights information to Yellow (Amber); Updated Product Name Throughout the document as per Product name Harmonization; Updated Symbols glossary; Made typographical and formatting updates.
15	2024-09	Updated Product name throughout the manual; Added Yellow button statement and updated picture in "Test Display" section; Made additional typographical and formatting updates.

Table of Contents

1 – Introduction

1.1 Intended Use

The BD BACTEC™ FX is designed for the rapid detection of bacteria and fungi in clinical specimens, blood, and blood products. Samples are drawn from patients or bagged blood/blood products and injected directly into BD BACTEC™ Culture Vials, which are placed into the instrument for incubation and testing.

Additional Information

The BD BACTEC™ FX is automated and provides qualitative results.

1.2 Principles of the Procedure

When microorganisms are present in culture vials, they metabolize nutrients in the culture medium, releasing carbon dioxide into the medium. A dye in the sensor at the bottom of the vial reacts with CO_2. This modulates the amount of light that is absorbed by a fluorescent material in the sensor. A photo detector at each station measures the level of fluorescence, which corresponds to the amount of CO_2 released by organisms. Then the measurement is interpreted by the system according to preprogrammed positivity parameters.

At system start-up, the onboard computer performs self-diagnostics and downloads operating instructions to the drawer rows. Then the instrument(s) automatically begin testing. Light Emitting Diodes (LEDs) behind the vials illuminate the rows, activating the vials' fluorescent sensors. After a warm-up period, the instrument's photo detectors then take the readings. A test cycle of all rows is completed every 10 minutes. Positive cultures are immediately flagged by an indicator light on the front of the instrument, an audible alarm, and are displayed on the LCD display.

When positive vials are identified, the lab technologist pulls them from the instrument for confirmation of results, and for isolation and identification of the organism.

This is an example:

Figure 1-1 shows the growth and detection process.

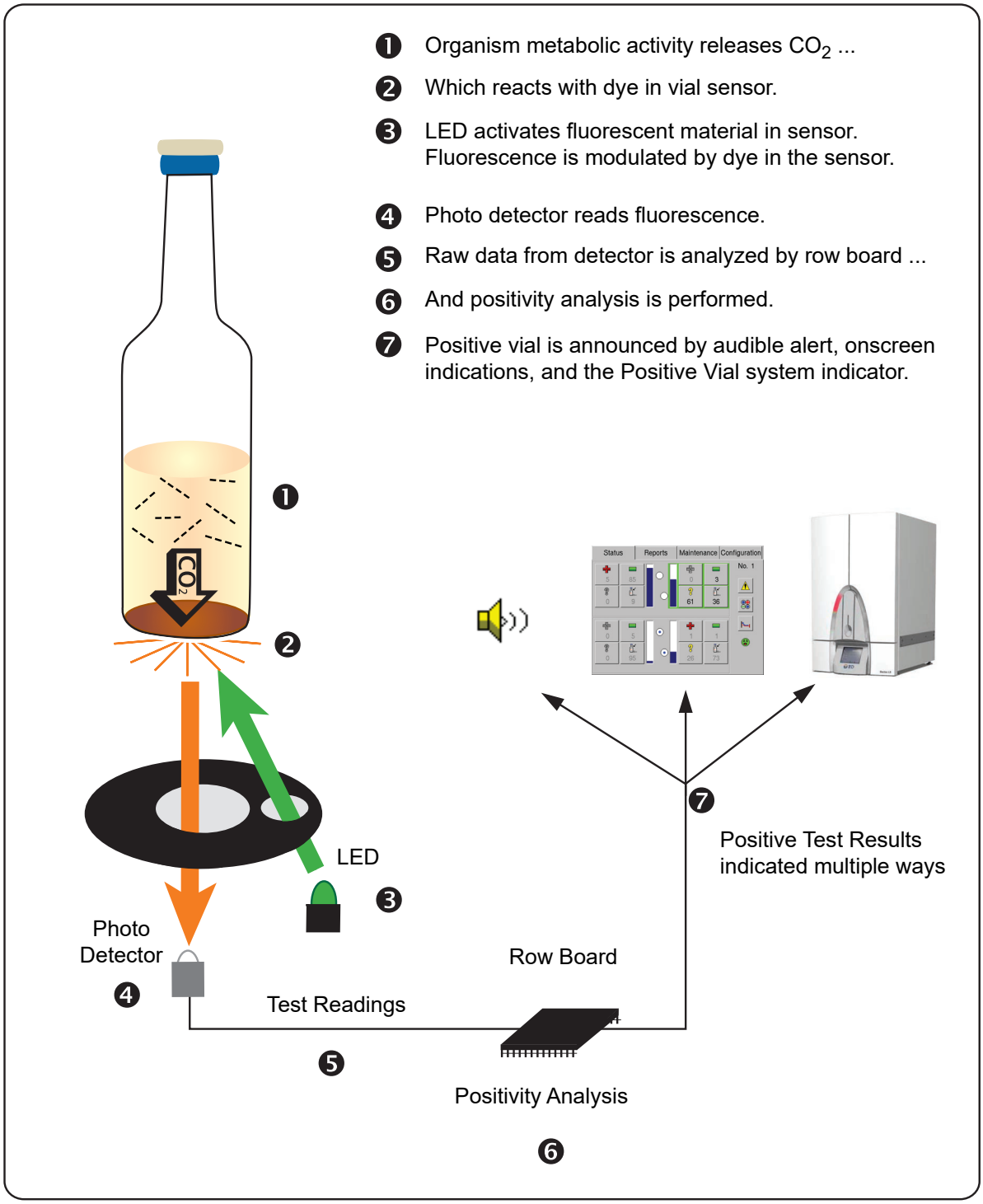


Figure 1-1 – BD BACTEC™ FX Fluorescent Technology

1.3 System Overview

The BD BACTEC™ FX instrument (BD BACTEC™ FX Top and BD BACTEC™ FX Bottom instruments) provides the following major features:

- Modular instrument design permits flexibility to accommodate laboratory needs
- Sliding drawers provide increased vial density, saving laboratory floor space
- Graphical user interface with color display and touchscreen provides ease of use
- Real-time vial presence sensors located in each vial station provide immediate feedback on vial insertion and removal from stations
- Agitation provides additional enhancement of organism growth and detection
- The ability to mix bacterial, fungal, and mycobacterial cultures within a module or system is accomplished by varying the medium type
- Can be connected to a BD EpiCenter™ workstation for enhanced instrument reporting and data management capabilities. Standalone instruments can be connected to a compatible Laboratory Information System (LIS).

1.3.1 Instrument Overview

The BD BACTEC™ FX instrument is an automated system for detecting the presence of microorganisms in clinical samples, blood, and blood products. Inoculated vials are placed in one of the drawers in the instrument, each of which contains a 10 x 10 array of vial stations. When the drawers are closed, vials in protocol are monitored for microbial metabolic activity over time by measuring the fluorescence levels from a specially designed sensor in the vial. This is performed by the measurement subsystem. The algorithm subsystem analyzes the signals from the measurement subsystem to determine if evidence of microbial growth (i.e., positivity) is present. Agitation is performed by the agitation subsystem, which enhances organism growth. Data storage and examination is managed through a data management subsystem. Stations are rendered unusable due to an alert condition such as an incubation failure, agitation failure, or measurement system failure.

The user interface subsystem encompasses all instrument functions pertaining to instrument workflow, primarily inserting vials into the instrument for testing, and subsequent removal of positive and final negative vials. Demographic information can be entered into the system and reported out. Vial information can be entered via a barcode reader, designed for one-handed operation, or can be entered manually via an onscreen keyboard. Vials are associated to a particular station by the process of inserting the vial into a station immediately after scanning the vial; this activates the station's vial presence sensor. You can view information about vials processed by the instrument, request printed reports, or communicate with a BD EpiCenter™ system. Indicator LEDs on the front of the instrument and others above each station convey status information. The instrument provides confirmatory audio and visual feedback at the completion of each workflow transaction.

The instrument system has two basic configurations, a Single or a Stack. A Stack consists of the BD BACTEC™ FX Top and the BD BACTEC™ FX Bottom instruments. Multiple Stacks/Singles can be linked together with a BD EpiCenter™ system to create a larger installation with full connectivity between modules. The measurement compartments of the two instruments are identical, but the electronics bay of the BD BACTEC™ FX Top instrument contains a display and touchscreen and a computer and interface module which controls and collects data from both BD BACTEC™ FX Top and the BD BACTEC™ FX Bottom instruments. Both units contain a barcode scanner which is used to scan a unique sequence number to identify the vial and the medium type, and a user applied (optional) accession label for tracking specimens.

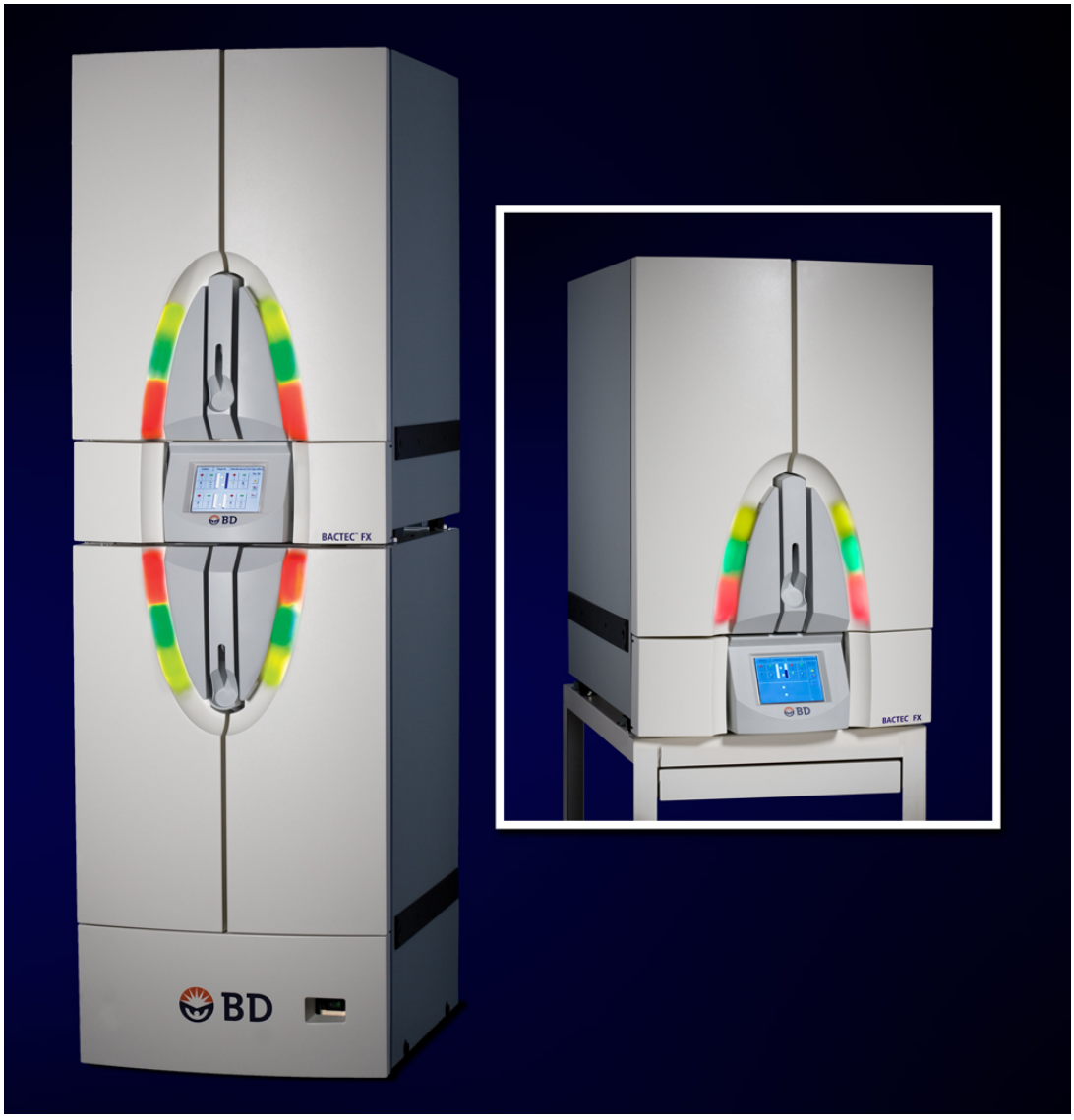


Figure 1-2 – BD BACTEC™ FX Stack (BD BACTEC™ FX Top and BD BACTEC™ FX Bottom Instruments) and Single (BD BACTEC™ FX Top Instrument)

1.3.2 Control Electronics

The instrument has several controllers that are responsible for control and analysis of the following:

- Temperature measurement and control
- Built-In-Test functions
- Agitation motor control
- Positivity analysis
- Illuminating station and system indicators
- Monitoring vial presence and door open sensors
- System communications
- User interface

1.3.3 Incubation Subsystem

The incubation subsystem is designed to maintain the temperature of the contents of any culture vial in any station at 35.0 ± 1.5 °C. The temperature is achieved by forced air convection over the media vials. Each drawer is a separately controlled incubation zone. Each zone contains blowers, heaters and temperature sensors. The incubation system brings in a percentage of external make up air, monitors the temperature of that air, and mixes it with a certain percentage of recirculating air. It then heats that air according to the zone's temperature setpoint and actual temperature measurements.

1.3.4 Vial Agitation

Vial stations are agitated so that their fluid contents achieve a homogeneous distribution of nutrients and microbial by-products. Vials are arranged in separate row modules that are coupled by a gang linkage to a motor. The motor causes each row module to agitate over a range of 0° to 20° relative to horizontal.

1.3.5 Measurement Subsystem

The measurement subsystem activates the sensor in the bottom of a media vial optically. The measurement consists of illuminating the sensor with an LED and collecting fluorescent light back from the sensor with a photo detector. The collected data is processed, normalized and compensated for thermal variation. Measurement is performed and processed by the Row Board.

1.3.6 Vial Presence Sensing

Each station has a vial presence sensor that immediately detects the insertion or removal of vials. This allows users to place vials in any location, or to assign stations through Vial Entry. Station indicators immediately reflect the changed status. Vial presence sensing is performed by the Row Board.

1.3.7 Station Indicators

LED indicators (shaped like crescents) located above vial stations indicate vial status and are illuminated when a drawer is opened. Station indicators are controlled by the Row Board.

1.3.8 LCD and Touchscreen

The display is a 6.4" diagonal color Liquid Crystal Display. It is covered by a touchscreen that enables you to perform actions and operations simply by touching buttons and fields shown on the screen.

1.3.9 USB Port/Flash Drive

Two standard USB ports are located behind the front bezel of the top (or Single) instrument. The front ports are used primarily to save files to, and update system software from flash media.

1.3.10 Audible Alarm

An audible alarm provides notification of system alerts and positive vials. The default setting for the audible alarm is 60 dB(A). The maximum setting is 85 dB(A). Loudness settings for positive vials are set in the Configuration display and are indicated by numbers from 1 (softest) to 10 (loudest). A jack on the rear of the instrument enables connection of an optional remote alarm unit.

1.3.11 Barcode Scanners

A barcode scanner is located on the mullion of each instrument. The scanner is designed to allow one-handed vial barcode scanning by providing a bottle rest to assist in positioning and bottle rotation. The barcode scanner is used to scan vial sequence and user-provided accession barcodes.

> NOTE
>
> Accepted barcode symbologies include Code 128, Codabar, Code 39, and Interleaved 2 of 5.

1.3.12 Software and Operation Overview

The Liquid Crystal Display (LCD) presents all the information needed to monitor instrument and station status, to enter and remove vials, set up the instrument, print reports, and perform routine instrument maintenance. The information is presented in the form of icons that graphically represent the information (such as a clock to indicate the current time), text buttons, or a combination of icons and text.

Operations you perform at the instrument can be initiated by opening a drawer and scanning a vial ("vial activated workflow") or can be initiated by selecting buttons, tabs, and fields on the LCD touchscreen ("screen activated workflow"). Routine operations, such as entering vials and removing positive vials, are initiated from the Status display. A Reports tab provides access to the built-in BD BACTEC™ FX reports, while Maintenance and Configuration tabs provide access to these functions.

Positivity analysis (algorithm subsystem)

Algorithms determine vial positivity (i.e., the detection of microbial growth). Multiple algorithms are used to test for vial positivity. Some algorithms are medium specific for greater sensitivity.

If a sequenced vial has not triggered a positivity algorithm by the end of the defined protocol length, and there are no instrument error conditions that would prevent accurate detection of positives, the vial is declared a negative vial, however, positivity algorithms continue to be applied until the vial is removed from the instrument.

Database

The database maintains the test measurements for each vial, vial identification and association data, and patient demographic information. Data is stored in the BD BACTEC™ FX database in both standalone and BD EpiCenter™ configurations. In addition, associated instrument errors, and operating conditions (e.g., test times, instrument temperature, etc.) are stored in the database.

The database stores vial results for up to 60 days after removal from the instrument (readings are maintained for up to 14 days).

1.3.13 Media Overview

Several media are available for use with the BD BACTEC™ FX instrument (BD BACTEC™ FX Top and BD BACTEC™ FX Bottom instruments). These include:

BD BACTEC™ Standard/10 Aerobic/F Culture Vials

Recommended for 3.0 to 10.0 mL (8.0 to 10.0 mL optimal) blood volume.

BD BACTEC™ Plus Aerobic/F Culture Vials

Contains resins for antibiotic neutralization. Recommended for use in adult populations due to higher blood volume capacity and resins. Recommended for 3.0 to 10.0 mL (8.0 to 10.0 mL optimal) blood volume.

BD BACTEC™ Standard Anaerobic/F Culture Vials

Recommended for 3.0 to 7.0 mL (5.0 to 7.0 mL optimal) blood volume.

BD BACTEC™ Peds Plus™/F Culture Vials

Optimized for use with pediatric patients and for low blood volume specimens. Recommended for 1.0 to 3.0 mL (range of 0.5 to 5.0 mL). Contains resins for antibiotic neutralization.

BD BACTEC™ Plus Anaerobic/F Culture Vials

Contains resins for antibiotic neutralization. Recommended for use in adult populations due to higher blood volume capacity and resins. Recommended for 3.0 to 10.0 mL (8.0 to 10.0 mL optimal) blood volume.

BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials

Non-resin medium containing the blood lysing agent saponin. Provides improved time-to-detection and recovery in comparison to standard anaerobic medium. The lysis of red cells provides additional nutrients for microbial growth and reduced blood background. The lysis of white cells releases phagocytized organisms. Recommended for 3.0 to 10.0 mL (8.0 to 10.0 mL optimal) blood volume.

BD BACTEC™ Myco/F Lytic Culture Vials

Specialized medium for the detection of fungi and mycobacteria from blood and sterile body fluids. Recommended for 1.0 to 5.0 mL (3.0 to 5.0 mL optimal) blood volume. A supplement may be required for use with non-blood specimens.

BD BACTEC™ Mycosis IC/F Culture Vials

Selective culture medium specifically designed for the recovery of fungi from blood culture specimens. Accepted specimen volume range is 3.0 to 10.0 mL. (This product is not for sale in USA.)

BD BACTEC™ Platelet Aerobic/F Culture Vials

Recommended for 4.0 to 8.0 mL of platelets (Leukocyte Reduced Apheresis and Leukocyte Reduced Whole Blood Concentrates).

BD BACTEC™ Platelet Anaerobic/F Culture Vials

Recommended for 4.0 to 8.0 mL of platelets (Leukocyte Reduced Apheresis and Leukocyte Reduced Whole Blood Concentrates).

Each medium type has default test protocol duration (modifiable in the Lab Configuration display). The default protocol can be overridden on each vial entered in the instrument.

1.3.14 Built-In Test

When power is first applied to the instrument, each of the major subsystems performs its native built-in-test (BIT) to ensure proper operation. Any failure of a component test is considered a fatal error for the measurement system, and no measurement cycles will be initiated.

1.3.15 Testing Overview

The instrument acquires light readings, temperature, and dark readings for each station of each drawer once every 10 minutes. If a drawer is opened during the data acquisition cycle, the cycle is aborted. When the drawer is closed the test cycle restarts after one minute.

After readings for stations are acquired, the instrument applies normalization to improve signal accuracy, and temperature compensation to minimize the impact of temperature transients on data.

After normalization and temperature compensation, the instrument applies signal conditioning algorithms to improve overall data quality.

Next, data for stations is tested for signal quality with a series of Built-In-Tests. These tests determine whether data is to be used for positivity processing, and whether fault conditions exist in stations that would render them unusable.

The final step in the testing process is the application of positivity algorithms to determine whether a culture contains evidence of microbial growth. The instrument uses general positivity algorithms as well as algorithms specific to each medium type to optimize positivity analysis.

1.4 Use of this Manual

This user's manual is designed as an integral part of instrument operation for technologists, supervisors, and other trained laboratory personnel who operate and maintain the BD BACTEC™ FX instrument on a regular basis. Every attempt has been made to include all information that would be required during normal use and maintenance of the system. Should a question arise which is not answered in this manual, please contact the following parties:

- Technical Service and Support: In the United States contact BD at 1.800.638.8663 or bd.com. For regions outside of the United States, contact your local BD representative or bd.com.

  EU Only: Users shall report any serious incident related to the device to the Manufacturer and National Competent Authority
  Outside EU: Contact your local BD representative for any incident or inquiry related to this device.

- International contacts are listed in Section 9. Contact your local BD representative or bd.com.

Other documentation required for proper system operation includes:

BD BACTEC™ Media Package Inserts – These documents contain important information on the use, storage, inoculation, performance, and limitations of each type of BD BACTEC™ medium. They are included with each carton of media, and are available upon request from BD Technical Service and Support.

BD EpiCenter™ System Help – The online Help utility provided with the BD EpiCenter™ system provides comprehensive instructions on the operation of BD EpiCenter™ and the BD BACTEC™ FX instrument within BD EpiCenter™.

1.5 Conventions

1.5.1 User Interface

Screen buttons are shown in bold (e.g., select **Save** or select **OK**).

System prompts and messages are shown in a monospaced typeface (e.g., `Report By does not apply`).

Various displays are named in initial capital letters (e.g., Vial Entry display). Fields are shown as they appear on the displays (e.g., Accession).

1.5.2 Symbols and Connections Used on the Equipment

The following symbols and connections are used on the BD BACTEC™ FX instrument:

Figure 1-3 – Front Connections

At center of photo, 9-pin serial connector (top); two USB connectors (middle); power switch (bottom)

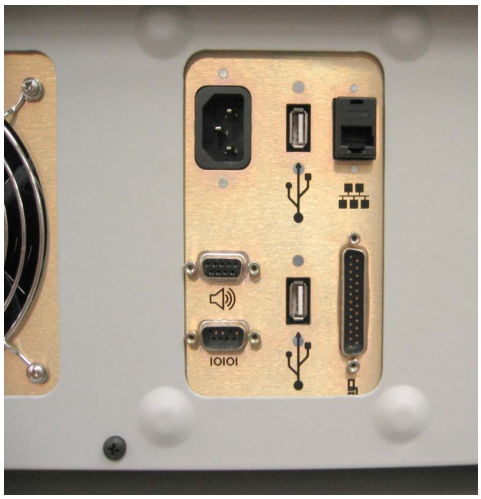


Figure 1-4 – BD BACTEC™ FX Top Instrument Rear Connections

Clockwise from top left: AC Power connector; USB connector; Network (BD EpiCenter™) connector; Stack connector; USB connector; Serial (LIS) connector; Remote Alarm connector

Figure 1-5 – BD BACTEC™ FX Bottom Instrument Rear Connections

AC Power connector (top); Stack connector (bottom)

Figure 1-6 – Biohazard Symbol

1.5.3 Notes, Cautions, and Warnings

Throughout this manual, important information is presented in boxes offset from the regular text, and is labeled as either a NOTE, CAUTION, or WARNING. These messages are formatted as shown below and bear the following significance:

NOTE

Important information about instrument use worthy of special attention is presented as a NOTE.

CAUTION

Information on an activity which potentially could cause damage to the instrument is presented as a CAUTION.

WARNING

INFORMATION ON AN ACTIVITY WHICH POTENTIALLY COULD CAUSE INJURY TO THE USER IS PRESENTED AS A WARNING.

Dispose of all used reagents and any other contaminated disposable materials following procedures for infectious or potentially infectious waste. It is the responsibility of each laboratory to handle solid and liquid waste according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

2 – Installation

2.1 General

This section provides specifications for installation and setup of the BD BACTEC™ FX instrument. The following major topics are included:

- Instrument Specifications
- Instrument Installation
- Software Setup

WARNINGS

PROTECTION PROVIDED BY THIS EQUIPMENT MAY BE IMPAIRED IF THE EQUIPMENT IS USED IN A MANNER NOT CONSISTENT WITH THE INSTRUCTIONS IN THIS MANUAL.

THE AIR INTAKE AND OUTPUT AREAS ON THE BD BACTEC™ FX INSTRUMENT MUST REMAIN UNOBSTRUCTED AT ALL TIMES. RESTRICTED AIR FLOW MAY CAUSE EXCESSIVE TEMPERATURES IN THE INSTRUMENT, WHICH CAN AFFECT TEST RESULTS AND POSSIBLY CAUSE HARDWARE MALFUNCTIONS. INTAKE AND OUTPUT AREAS ARE SHOWN IN FIGURE 2-1.

Figure 2-1 – Air Intake (Left) and Output (Right)

Air is output (exhausted) from same location in BD BACTEC™ FX Top and BD BACTEC™ FX Bottom instruments.

2.2 Instrument Specifications

Physical Dimensions	Single Instrument	Stack (BD BACTEC™ FX Top and BD BACTEC™ FX Bottom Instruments)
Height	93.9 cm (37.0 in)	198.7 cm (78.25 in)
Width	62.2 cm (24.5 in)	62.2 cm (24.5 in)
Depth	86.9 cm (34.25 in)	86.9 cm (34.25 in)
Clearance (rear, left, right)	1.3 cm, 0 cm, 0 cm	1.3 cm, 0 cm, 0 cm
Clearance (front)	68.6 cm (27.0 in)	68.6 cm (27.0 in)
Weight (empty)	187.5 kg (413.4 lb)	384.8 kg (848.4 lb)
Weight (Full Glass Bottles)	220.4 kg (485.9 lb)	451 kg (994.2 lb)
Weight (Full Plastic Bottles)	202.9 kg (447.3 lb)	416 kg (917.1 lb)
Stand weight	63.5 kg (140 lb)	N/A
Counterweights (countertop, unanchored)	47.6 kg (105 lb)	N/A

Electrical Requirements	
Input Voltage	100–240 VAC ± 10%
Peak Current	8 amperes
Input Line Frequency	50/60 Hz
Power	800 W
Heat	450 Btu/hr

Environmental Requirements	
Non-Operating Storage	
Temperature	-17.8 to 65 °C (0–149 °F)
Humidity	10–90% RH, non-condensing
Operating Conditions	
Temperature	18.0–30.0 °C (64.4–86 °F)
Humidity	25–80% RH for temperatures ≤30.0 °C (86 °F) Maximum dew point 26.1 °C for temperatures >30.0 °C (86 °F)

Environmental Requirements	
Locations	Level Surface; No direct sunlight; No direct heat or other external air source; No high humidity, dust, temperature extremes, or corrosive or explosive vapors or gases
Noise @ 1 m	58 dBA using ANSI Type 2 sound meter
Altitude	Evaluated for safety to 2,000 m
Other	
Instrument shall withstand thermal decontamination at 65 °C for 10 hours.	
The instrument shall withstand paraformaldehyde treatment as used for mycobacterial decontamination.	
Use of earthquake anchoring technique and kit will be provided with instruments as required by local ordinances. The instrument anchorage system shall be pre-approved for installation in California hospitals and labs by the California Office of Statewide Health Planning and Development (OSHPD).	
Installation Category II and Pollution Degree 2 as per IEC 664.	

2.2.1 EMC compliance information

The BD BACTEC™ FX instrument (BD BACTEC™ FX Top and BD BACTEC™ FX Bottom instruments) have been evaluated to and conforms to the IEC 61326-2-6 standard for Electromagnetic Compatibility (Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment).

The system is not intended to be used with any accessory or cable not provided or directed for use by BD. Use of accessories or cables not specified by BD can result in reduced electromagnetic compatibility performance.

The system should be installed such that it is not directly adjacent to or stacked with other electrical devices. If constraints do not allow for spacing between devices, both the BD BACTEC™ FX instrument and the other device or devices should be monitored to verify that operation is not affected. In the event that changes in operation are observed, including motion or processing errors, please contact the BD service department immediately.

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

This equipment is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.

Portable RF communication equipment including external antennas can affect medical electrical equipment. As such, these should be used no closer than 30 cm (12 inches) to any part of the system, including any cable specified BD. Disregarding this can result in reduced electromagnetic compatibility performance.

2.3 Instrument Installation

2.3.1 Site Preparation

The BD BACTEC™ FX instrument is installed only by BD representatives.

WARNINGS

DO NOT ATTEMPT TO LIFT OR MOVE THE INSTRUMENT. CONTACT BD FOR INFORMATION ON MOVING THE INSTRUMENT.

TIP HAZARD! DO NOT LEAN OR PLACE WEIGHT ON THE INSTRUMENT DRAWERS WHILE THEY ARE OPEN.

THE SINGLE INSTRUMENT, WHEN INSTALLED WITHOUT THE COUNTER WEIGHTS, MUST BE SECURED TO THE MOUNTING SURFACE BY YOUR LOCAL BD REPRESENTATIVE.

The BD BACTEC™ FX instrument should be installed in an area that is free from undue vibration, direct sunlight, high humidity, dust, temperature extremes, external air sources, and corrosive or explosive vapors or gases.

The system will operate within specifications in room temperatures from 18.0–30.0 °C (64.4–86.0 °F). Relative humidity should be 25–80% (non-condensing) for temperatures less than or equal to 30.0 °C (86.0 °F). The maximum dew point for operation is 26.1 °C for temperatures over 30.0 °C.

No clearance is required on the left or right sides of the instrument, however a minimum of 1.3 cm is required at the rear. If the instrument is placed against a wall that protrudes, make sure you allow sufficient space for personnel to access the drawer opposite the protruding wall.

Environments that exceed these limits could adversely affect the performance of the system components.

The incubation system should maintain its temperature to within plus or minus 1.5 °C of the temperature controller's setting (35 °C). This accuracy can be assured only if the room temperature meets the requirements given above.

The BD BACTEC™ FX instrument shall be positioned such that both the power switch and AC power input are easily accessible to the operator at all times. Means for disconnection of the device is to unplug supply cord from mains circuit.

The BD BACTEC™ FX instrument must be electrically connected to earth-ground at all times. To ensure that the power cord and outlet strip have the required electrical current ratings, only use the cord and power strip supplied with the unit, or as provided by BD.

2.4 Software Setup

The instrument ships with all setup parameters preset to factory default values. However, before using the instrument for culture testing, you should review the setup parameters to see if they are suitable for your laboratory. These parameters are set in the Configuration function, and are grouped as follows:

- Lab (e.g., language, test protocol duration, etc.)
- Reports (Lab name, etc.)
- Instr(ument) (e.g., Instrument number, barcode readers, etc.)
- LIS (communications) (for standalone configurations only)
- Time (Time and Date Format, etc.)

To access the configuration function, from the Status display (Figure 2-2), select the **Configuration** tab. The last configuration display that was accessed appears. Field values can be changed by selecting the arrows (▲/▼), drop-down arrows, radio buttons, or checkboxes next to them.

Any changes to configuration parameters are in effect from the time of the change forward.

To cancel your changes, select the **Undo** button.

You cannot access Configuration displays in an instrument that is in degraded mode.

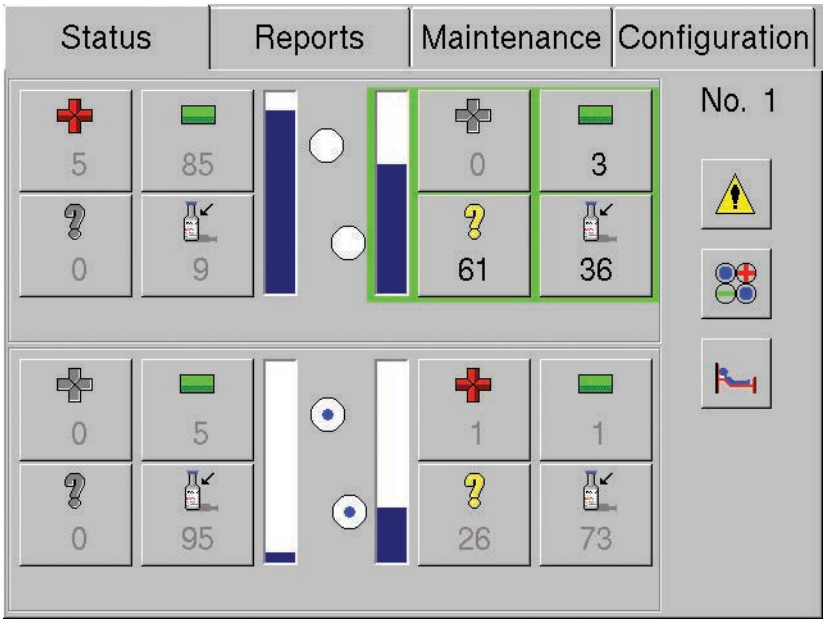


Figure 2-2 – Status Display

To save configuration changes, select **Save** (shown below).

To enter a password, select the password field to display the onscreen keyboard (see Section 3.10).

Figure 2-3 – Password Window

Enter the Supervisor password (default: BACTECFX). Select **ENTER and then OK** to enter the password.

2.4.1 Lab Configuration

Lab Configuration enables you to set values that are unique to how your laboratory functions. Such discretionary values include media protocol lengths, accession barcoding enable/disable, language, etc. See Media Protocols.

Workflow Window:

Accession Barcode Enable/Disable 

> NOTE
>
> Accepted barcode symbologies include Code 128, Codabar, Code 39, and Interleaved 2 of 5.

Select whether Accession Barcoding is enabled (checked) or disabled (unchecked) by toggling the white box to check on or off. The default setting is enabled (checked). When Accession Barcoding is enabled, the system turns on the barcode reader for an accession barcode to be scanned during certain activities and interprets any non-vial-sequence barcode scan as an accession. The accession barcode may not both begin with the numbers “44” AND be 12 digits long, which is the format of a vial sequence barcode.

Accessions can always be entered in the Culture – Vial display regardless of whether accession barcoding is enabled or disabled.

In a BD EpiCenter™ configuration, enabling Accession Barcoding at one instrument enables the feature for all instruments.

Batch Negative Removal Enable/Disable 

Select whether Batch Negative Removal is enabled (checked) or disabled (unchecked) by toggling the white box to check on or off. The default setting is enabled (checked). When Batch Negative Removal is enabled, you can remove all final (out-of-protocol) negative vials without scanning the individual labels during the Negative (vial) Removal activity. When batch removal is disabled, you must scan the vial sequence barcode for each negative vial that is removed.

In a BD EpiCenter™ configuration, enabling Batch Negative Removal at one instrument enables the feature for all instruments.

Show Related Vials Enable/Disable 

Select whether Show Related Vials is enabled (checked) or disabled (unchecked) by toggling the white box to check on or off. The default setting is disabled (unchecked). When Show Related Vials is enabled, all vials in the same drawer that are related to the current positive vial being removed (i.e., vials with the same accession number) are flagged by station indicators that correspond to their status (Ongoing, Negative, etc.).

In a BD EpiCenter™ configuration, enabling Show Related Vials at one instrument enables the feature for all instruments.

Language/Locale Window:

Language 

Select the language for screen displays and instrument reports. The default setting is English. To see the available selections, select the **Down Arrow** button to the right of the field. You can choose from the following language selections:

Deutsch
English
Español
Français
Italiano
Japanese

In a BD EpiCenter™ configuration, selecting a language at one instrument selects that language for all instruments.

Country

Select a country or ISO (international) to automatically select a corresponding time and date format. The default setting is United States. To see the available selections, select the **Down Arrow** button to the right of the field. You can choose from the following selections:

Select Locale	Date Format	Time Format
ISO	yyyy-mm-dd	HH:MM
Danmark	dd-mm-yyyy	HH.MM
Suomi	dd.mm.yyyy	HH:MM
France	dd/mm/yyyy	HH:MM
Deutschland	dd.mm.yyyy	HH:MM
Greece	dd/mm/yyyy	HH:MM
Italia	dd/mm/yyyy	HH.MM
Nederland	dd Mmm yyyy	HH:MM
España	dd/mm/yyyy	HH:MM
Sverige	yyyy-mm-dd	kl HH.MM
United Kingdom	dd/mm/yyyy	HH:MM
United States	mm/dd/yyyy	hh:MM am/pm
Japan	yyyy-mm-dd	HH:MM
dd = day; mm = numeric month; Mmm = alphabetic month; yyyy = year; HH = hours (24-hour clock); hh = hours (12-hour clock); MM = minutes		

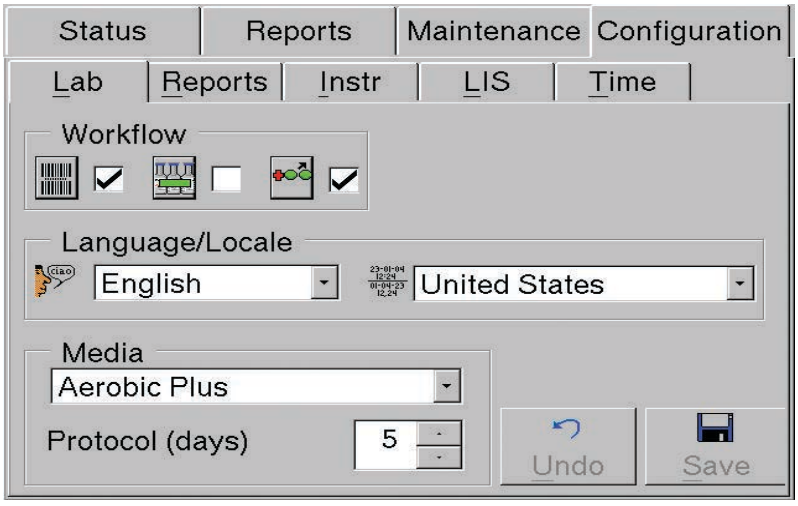


Figure 2-4 – Lab Configuration Display

In a BD EpiCenter™ configuration, selecting a country (locale) at one instrument selects that locale for all instruments.

Media Window:

Media configuration is used to set default protocol values for each medium type you will be using for culture testing. The default protocol value is entered automatically when that medium type is scanned during the Vial Entry operation. If no medium type is entered for a vial (e.g., an anonymous vial or replacement barcode), the default instrument protocol of 5 days is used.

To modify default media values, refer to the field requirements listed below. When changes are complete, select **Save**.

Media

To select a medium type, select the **Down Arrow** button to the right of the field. You can choose from the following medium selections:

Type	Codes	Protocols Available	Default Protocol
Aerobic Plus	92	3–30	5
Anaerobic Plus	93	3–30	5
Anaerobic Lytic	65	3–30	5
Myco Lytic	88	3–42	42
Mycosis I/C	06	3–42	14
Peds Plus	94	3–30	5
Platelet Aerobic	5A	3–14	7
Platelet Anaerobic	5B	3–14	7
Standard Aerobic	60	3–30	5
Standard Anaerobic	91	3–30	5

Protocol (days)

Select the **Up** or **Down Arrow** to increase or decrease the value in the field. Available protocol lengths are shown in the table above. Each laboratory should set its protocol lengths based on its own policies and conditions.

In a BD EpiCenter™ configuration, selecting a protocol at one instrument selects that protocol for all instruments.

Configuration – Lab Buttons:

Undo button 

Select to clear changes and return to saved values. Only active if field values are changed and are not saved.

Save button 

Select to save changes. When the Enter Password window appears, select the blank password field. Enter the Supervisor password with the onscreen keyboard, then select **ENTER**, followed by **OK**.

2.4.2 Reports Configuration

Reports configuration enables you to set up printing and reports parameters. See Figure 2-5.

In a BD EpiCenter™ configuration, modifications made to the Reports configuration settings are used by all instruments.

Printer Selection Window:

Printer

Select the arrow next to the blank field under Printer Selection to choose the system printer. You can choose **No Printer**, **Network Printer*** (not available in BD EpiCenter™ configuration), **BD EpiCenter™ Printer**, or **USB Printer***. If you choose **Network Printer**, the IP field appears. **BD EpiCenter™ Printer** appears only if the instrument is connected to a BD EpiCenter™ system. It is the default selection in a BD EpiCenter™ configuration.

*For Vx Works instruments only.

> NOTE
>
> Incompatible printer may cause system malfunction.
>
> If your printer is not listed, contact BD.

IP (Address)

For a Network Printer*, enter the IP (Internet Protocol) address of the printer. The default IP address is 192.168.2.150. This field does not appear if BD EpiCenter™ Printer is selected as the printer.

*For Vx Works instruments only.

QC Auto Report Window:

Time

To set the time for the Maintenance QC Report (Section 5.4.9) to automatically print, select **Set**. The default value is the current system date/time. Refer to Section 2.4.5 for instructions on setting time.

Disable checkbox

To disable automatic printing of the QC Report, select the **Disable** checkbox. The default setting is disabled (checked). The checkbox only disables automatic printing; the report can still be printed by request from the Reports menu.

Custom Fields Window:

Organization 1 / Organization 2

Enter the desired name for your laboratory or hospital. There are two lines of text available, each of which accepts up to 25 characters. Select in the Organization 1 field to access the onscreen keyboard (see Section 3.10) to enter the desired hospital or laboratory name. When the first line is complete, select **Enter**. Select in the Organization 2 field to use the keyboard to enter the second line of text.

The Organization information prints at the top of reports.

Configuration – Reports Buttons:

Undo button 

Select to clear changes and return to saved values. Only active if field values are changed and are not saved.

Save button 

Select to save changes. When the Enter Password window appears, select the blank password field. Enter the Supervisor password with the onscreen keyboard, then select **ENTER**, followed by **OK**.

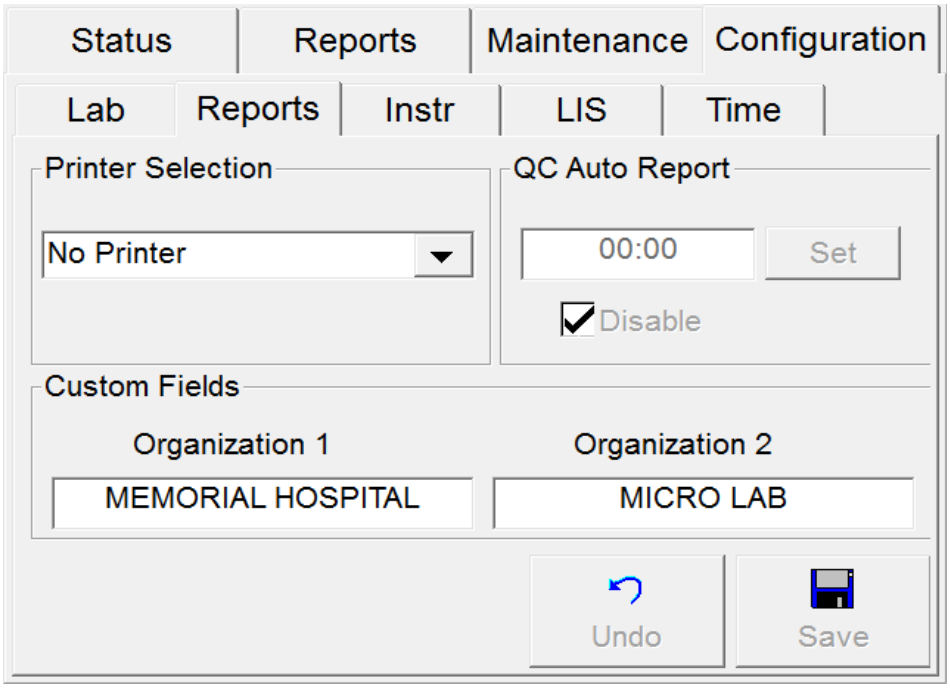


Figure 2-5 – Reports Configuration Display

2.4.3 Instr(ument) Configuration

Instrument configuration settings are unique to each individual instrument within a stack or workgroup. See Figure 2-6.

To modify default instrument values, refer to the field requirements listed below. When changes are complete, select **Save** and enter the Supervisor password.

Instrument No.

Select the instrument identification number. The default setting is 1. To increase or decrease the instrument number, select the **Up** or **Down Arrow** to increase or decrease the value in the field. You can choose a number from 1 to 99. If there is only a single instrument at your location, you should leave this value set at 1. Instrument number appears in report headers.

Instrument numbers must be unique in a BD EpiCenter™ configuration.

Barcode Reader Radio Buttons

This field enables or disables the instrument barcode readers in an instrument stack. To enable the top barcode reader only, select the **Top** radio button. To enable the bottom barcode reader only, select the **Bottom** radio button. To enable both barcode readers, select the **Both** radio button. (When **Both** is selected, the barcode reader associated to the currently open drawer is active.)

If there is only a single instrument at your location, only the Top selection is available.

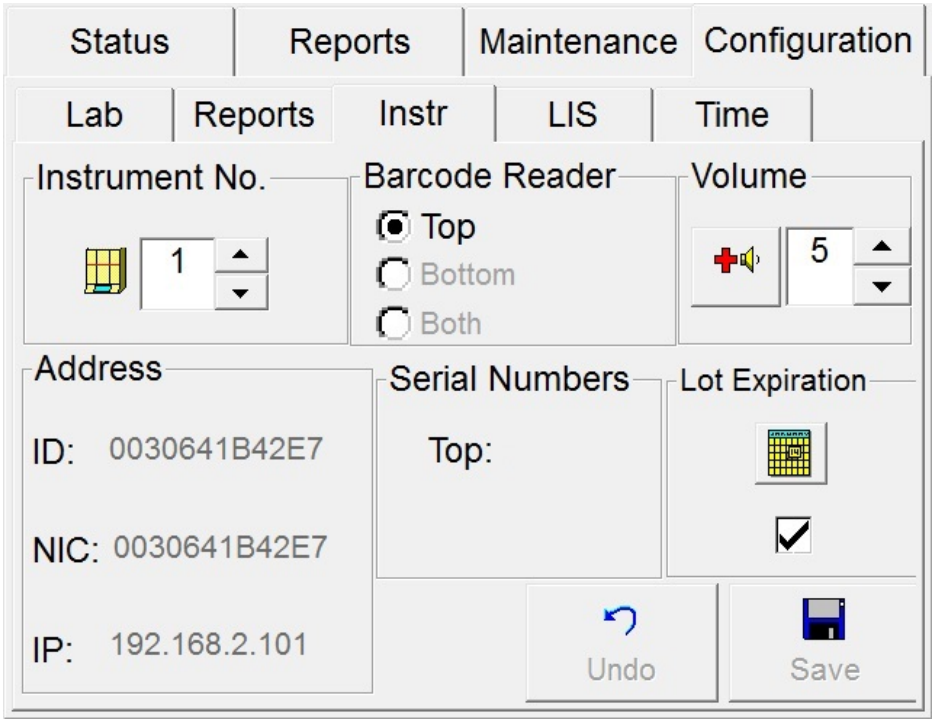


Figure 2-6 – Instrument Configuration Display

Volume 

Select the volume of the instrument's Positive Vial audible alarm. The default setting is 5, which is at the middle of the volume range. To increase or decrease the volume, select the **Up** or **Down Arrow** to increase or decrease the value in the field from 1 (softest) to 10 (loudest).

To hear a sample of the current volume, select **Volume**.

This setting also affects the volume of the optional Remote Alarm unit.

The volume of other instrument audible alarms is controlled by the system software and cannot be adjusted.

Address

Read-only fields showing network configuration information. ID shows the original MAC address of the Network Interface Card in the instrument. NIC shows the current MAC address of the Network Interface Card in the instrument. IP shows the Internet Protocol address for the instrument.

Serial Numbers

Read-only fields showing the instrument Serial Numbers. This number is set at instrument installation. Top represents the high instrument in the stack, and Bottom represents the low instrument. If there is only one instrument, only Top is shown.

Configuration – Instrument Buttons:

Undo button 

Select to clear changes and return to saved values. Only active if field values are changed and are not saved.

Save button 

Select to save changes. When the Enter Password window appears, select the blank password field. Enter the Supervisor password with the onscreen keyboard, then select **ENTER**, followed by **OK**.

Lot Expiration

This field enables or disables lot number and expiration date tracking.

NOTE

This feature requires a 2D barcode scanner which is only available on newer instruments. Any instrument with a serial number below T10985 or B10293 may require a hardware upgrade for this feature to work properly.

2.4.4 LIS Configuration

LIS configuration enables you to set up communications with a Laboratory Information System (LIS). Communications should only be enabled/disabled by a BD representative.

To modify default values, refer to the field requirements listed below. When changes are complete, select **Save**.

LIS Window fields:

Disabled radio button

To disable all communications with the LIS, select the **Disabled** radio button. This button is selected by default.

Enabled radio button

To enable communications with a compatible LIS system, select the **Enabled** radio button. Check the settings in the Port Parameters, Physical Layer, LIS Options, and BD Modem™ windows to complete the setup.

Port Parameters Window fields:

Com Port

Select the **Drop-down Arrow** to select the desired com port. Only configured com ports appear in the drop-down box.

Baud

Select the **Drop-down Arrow** to select the desired baud rate. Select **1200**, **2400**, **4800**, **9600** (default), or **19.2k**.

Parity

Select the **Drop-down Arrow** to select the method of parity check used in serial communications with the LIS. Select **No Parity** (default), **Odd Parity**, or **Even Parity**.

Data Bits

Select the **Drop-down Arrow** to select the number of data bits used in serial communications with the LIS. Select **7** or **8** (default).

Stop Bits

Select the **Drop-down Arrow** to select the number of stop bits used in serial communications with the LIS. Select **1** (default) or **2**.

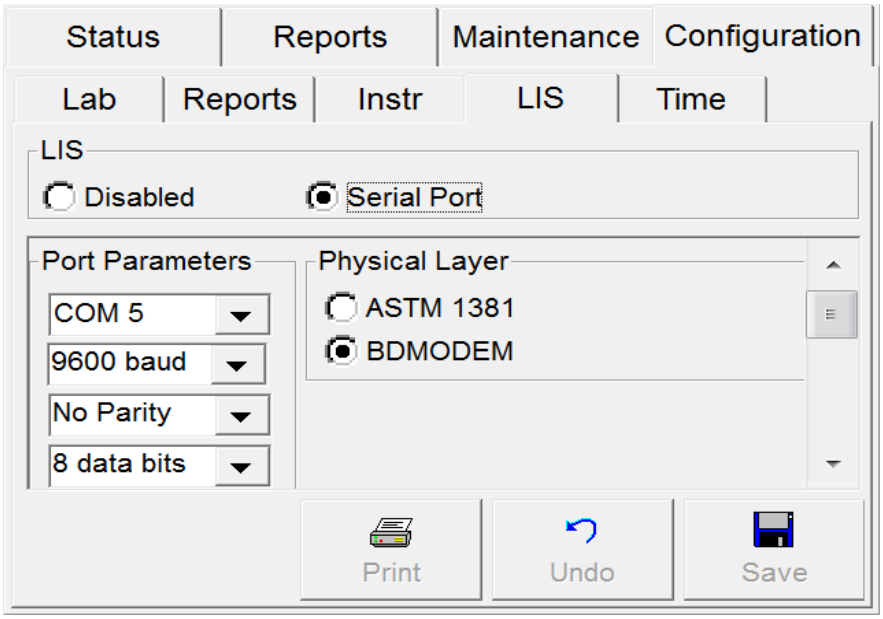


Figure 2-7 – LIS Configuration Display

Physical Layer Window fields:

ASTM 1381 radio button

Select **ASTM 1381** to use the ASTM 1381 LIS Communications protocol for communications with the BD BACTEC™ FX instrument. Refer to the LIS Vendor Interface Document for additional information.

BDMODEM radio button

Select **BDMODEM** to use the BD Modem™ Communications protocol for communications with the BD BACTEC™ FX instrument. The default value is enabled (when LIS communications is enabled). Refer to the LIS Vendor Interface Document for additional information.

LIS Options Window fields:

Upload Pos Results checkbox

Select the checkbox to enable the upload of positive results. Uploading negative results is automatically enabled, however uploading positive results is optional and must be enabled here. Results for orphan vials are not uploaded. The default value is unchecked.

LIS Solicited Result checkbox

Select the checkbox to enable Solicited Results. In Solicited Mode, results are uploaded by the BD BACTEC™ FX instrument ONLY when requested by the LIS. In Unsolicited mode (unchecked), the instrument uploads results to the LIS automatically (default setting) whenever a vial status changes. In unsolicited mode, The BD BACTEC™ FX instrument still responds to requests from the LIS for results (solicitations). If the system is configured for unsolicited processing, the LIS must always be ready to receive data from the BD BACTEC™ FX instrument.

Vial Tracking checkbox

This checkbox appears only if the LIS Solicited Results checkbox is unchecked (disabled).

Select the checkbox to enable Vial Tracking. Vial Tracking uploads the following status information for non-orphan vials in the system:

- new vials that are entered or identified at the instrument
- removal of positives, negatives, and related vials
- pulled positives that are reentered
- vials that are relocated to a different station

The information is uploaded from the time the vial is entered into the instrument until it is removed as a positive or final negative. In order to enable Vial Tracking, communications must be set for unsolicited processing. The default value is unchecked.

If Vial Tracking is disabled, only the final result is uploaded.

Log Comms checkbox

The Log Comms function is designed to assist BD representatives in troubleshooting LIS communications problems. It enables the representative to record low-level communications messages in a separate file on a USB flash drive. Log Comms can only be enabled when LIS Communications is enabled. The default value is unchecked.

Forced Upload checkbox

This field appears only if the LIS Solicited Results checkbox is unchecked (disabled).

The Forced Upload function is designed to assist BD representatives in troubleshooting LIS communications problems. When this function is enabled and saved, the Culture display features a Send button (in place of the Save button) that enables the representative to send recalled vial/culture data to the LIS. If vial/culture information is modified, the Save button reappears. The default value is unchecked.

<CR><LF> checkbox

This field appears only if BDMODEM is selected.

- Select the <CR><LF> checkbox to terminate a record, making it easy to read the record on some displays or printouts.
- Uncheck the checkbox to use <CR> to terminate a record. All logical records defined in the ASTM protocol are terminated by a Carriage Return <CR>.

Host Query Mode drop-down box

This field appears only if the LIS Solicited Results checkbox is unchecked (disabled).

Select the **Drop-down Arrow** next to the Host Query mode field to drop down the mode selection box. Then select the desired mode.

In Host Query mode, the instrument can request demographic information from the LIS for new specimens and vials entered/logged in at the instrument. In order to enable Host Query, Accession Barcoding must be enabled, and the communications must be set for unsolicited processing.

Host Query field offers the following modes:

MANUAL – the instrument only requests demographic information from the LIS when manually requested by the user.

SINGLE – the instrument requests demographic information from the LIS each time a vial-specimen is entered or logged in.

AUTO – the instrument requests demographic information from the LIS at the automatic report time.

DISABLED – Host Query mode is disabled (default)

ASTM 1381 Window

The ASTM 1381 window appears only when ASTM 1381 is selected in the Physical Layer window.

ASTM Packed Frames checkbox

Check this checkbox to enable ASTM packed frames. Uncheck the checkbox to disable ASTM packed frames.

BD Modem™ Window fields:

The BD Modem™ window appears only when BDMODEM is selected in the Physical Layer window.

The first two fields are used to determine where specific data is in the LIS record.

New Sequence Position checkbox

The default setting is checked.

Hospital Service Field (33) checkbox

The default setting is checked.

9000 Legacy Mode

The default setting is unchecked.

The following fields are used to define the expected characters in LIS messages.

SOH

The default setting is 0x01.

EOT

The default setting is 0x04.

ACK

The default setting is 0x06.

NAK

The default setting is 0x15.

CAN

The default setting is 0x18.

SYN

The default setting is 0x16.

LIS Communications Buttons:

Undo button 

Select to clear changes and return to saved values. Only active if field values are changed and are not saved.

Save button 

Select to save changes. When the Enter Password window appears, select the blank password field. Enter the Supervisor password with the onscreen keyboard, then select **ENTER**, followed by **OK**.

Print button 

This button appears only if Log Comms is enabled.

Select to print all the LIS messages in the Event Log. The messages include the time stamp when the message was generated.

2.4.5 Time Configuration

Time and date configuration settings can only be changed in a standalone configuration. Time and date may not be changed in a BD EpiCenter™ configuration.

To modify default values, refer to the field requirements listed below. When changes are complete, select **Save**. See Figure 2-8.

Date/Time Window:

Date 

The current date is shown next to the calendar icon. To change the date, select **Set** at the right of the Date/Time window, and refer to the instructions below.

Time 

The current time field is shown next to the clock icon. To change the time, select **Set** at the right of the Date/Time window, and refer to the instructions below.

Set Button

Select **Set** to display the Set Date and Time window (Figure 2-9). To set or change the date, select the **Up** or **Down Arrow** in the Month, Day, or Year field. To set the time, select the **Up** or **Down Arrow** in the Hour or Minute field. For USA locations, select the **a.m./p.m. Drop-down Arrow** to select either value. Select **OK** when complete to set the new Date/Time. Select **Cancel** to exit the window without changing the date or time.

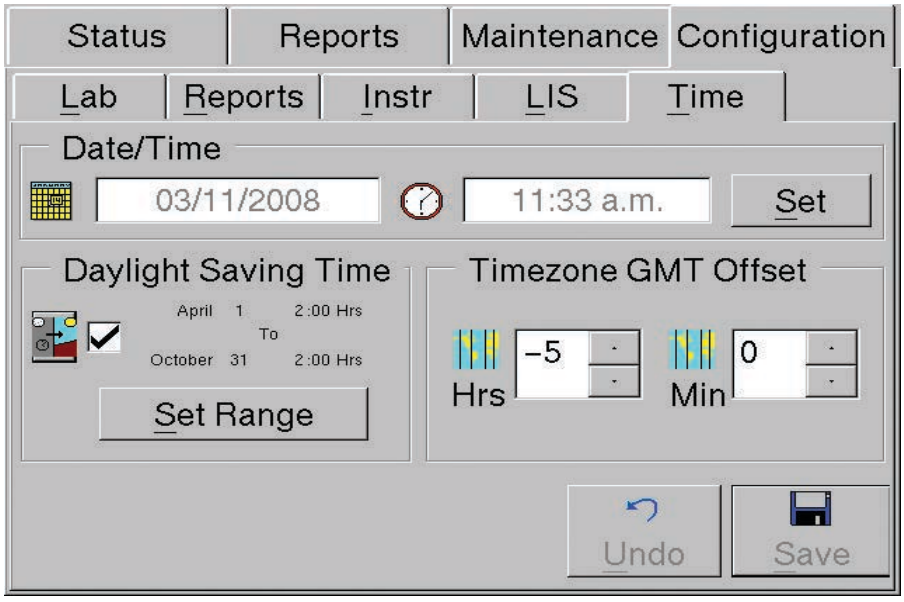


Figure 2-8 – Time Configuration Display

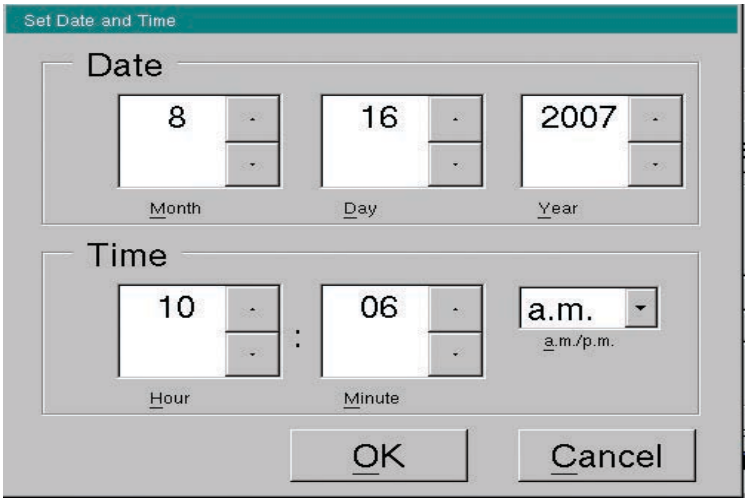


Figure 2-9 – Set Date and Time Window

Daylight Saving Time Window:

Daylight Saving Time checkbox 

The Daylight Saving Time field is represented by a day/night icon with an arrow between the two. Select whether the system clock is automatically set forward 1 hour for Daylight Saving Time (checked) or is set at Standard Time (unchecked). The default value is Standard Time (unchecked).

Set Range button

To set the date range during which Daylight Saving Time is active, select **Set Range**. In the Start DST window, select the **Up** or **Down Arrow** in the Month, Day, and Hour value you want to set for the beginning of Daylight Saving Time. In the End DST window, select the **Up** or **Down Arrow** in the Month, Day, and Hour value you want to set for the end of Daylight Saving Time. The Start and End dates/times are shown to the right of the icon.

When the clock reaches the **From** date/time, the time automatically advances 1 hour. When the clock reaches the **To** date/time, the time automatically decreases 1 hour.

Timezone GMT Offset Window:

H(ou)rs/Min(utes) 

The Timezone Offset field is represented by a map icon. To change the time zone offset, select the **Up** or **Down Arrow** to increase or decrease the value in the Hrs (Hours) or Min(utes) field. This value is your time zone difference from GMT (Greenwich Mean Time).

Select negative integers if you are west of the Prime Meridian and east of the International Date Line. Select positive integers if you are east of the Prime Meridian and west of the International Date Line. Hours values can be from –14 to 14; minutes values can be from 0 to 59.

The default value is –5 hours 0 minutes (USA Eastern Time Zone).

Configuration – Time Buttons:

Undo button 

Select to clear changes and return to saved values. Only active if field values are changed and are not saved.

Save button 

Select to save changes. When the Enter Password window appears, select the blank password field. Enter the Supervisor password with the onscreen keyboard, then select **ENTER**, followed by **OK**.

3 – Controls and Indicators

3.1 General

This section describes the meaning and use of the controls and indicators of the BD BACTEC™ FX instrument.

The overall layout of the instrument and most of the controls and indicators are shown in Figure 3-1. Some components are illustrated in figures accompanying the related text. Figure 3-1 shows an instrument “stack” (a two-instrument system). Single instrument installations (“singles”) feature controls and indicators that are identical to the top instrument in a stack.

The following controls and indicators are discussed:

- Power Switch
- System Indicators
- Drawer Handles
- Barcode Scanner
- LCD/Touchscreen
- Station Indicators
- USB Ports
- Audible Tones and Alarms
- Onscreen Keyboard
- Digital Thermometer
- Remote Alarm
- Printer

WARNING

ALL USERS SHOULD BECOME THOROUGHLY FAMILIAR WITH ALL CONTROLS AND INDICATORS BEFORE ATTEMPTING TO OPERATE THE INSTRUMENT.

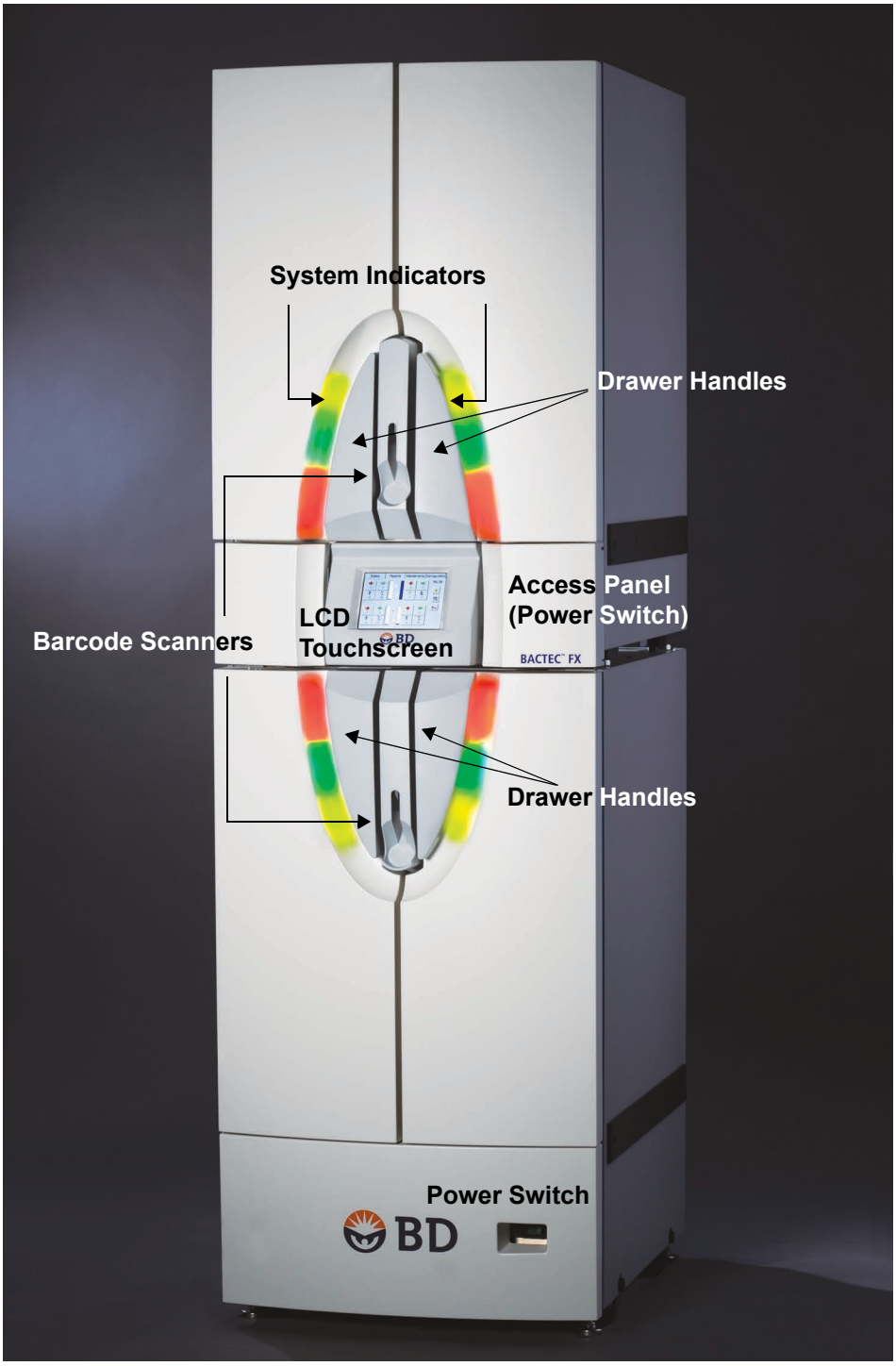


Figure 3-1 – BD BACTEC™ FX Instrument Layout - Stack (BD BACTEC™ FX Top and BD BACTEC™ FX Bottom Instruments)

3.2 Power Switch

3.2.1 Location

Each instrument (BD BACTEC™ FX Top and BD BACTEC™ FX Bottom instruments) has its own power switch.

The BD BACTEC™ FX Top instrument's power (On/Off) rocker switch is on the front of the instrument, behind the access panel to the right of the LCD/Touchscreen.

The BD BACTEC™ FX Bottom instrument's power switch is on the front of the instrument, at bottom right.

See Figure 3-1 for power switch locations. See Figures 3-2 and 3-3 for Upper and Lower instrument power switch close-ups.

3.2.2 Operation

When in the "O" (Off) position, power is removed from the instrument. When in the "|" (On) position, the switch illuminates green and power is applied to the instrument. Power must be turned On for the incubation and testing modules to work. For normal operation, the power should remain On at all times except during some maintenance procedures.

Figure 3-2 – Upper Instrument Power Switch

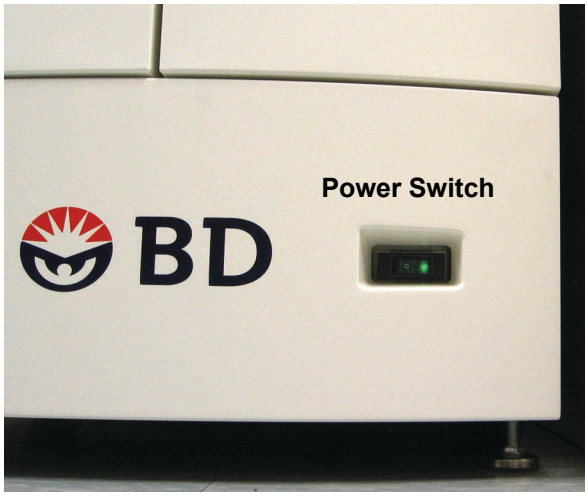


Figure 3-3 – Lower Instrument Power Switch

3.3 System Indicators

3.3.1 Location

Each instrument (BD BACTEC™ FX Top and BD BACTEC™ FX Bottom instruments) has its own set of system indicators.

The system indicators are located on the front of the instrument, at the bottom center of the BD BACTEC™ FX Top instrument, and at the top center of the BD BACTEC™ FX Bottom instrument. An array of LED lamps projects onto the door and is easily visible from across a room.

See Figure 3-1 for system indicator locations.

3.3.2 Indication

The system indicators inform you of various states of the instrument, as shown below.

Indicator Color	State	Meaning
Yellow (Amber) – light in unison for instrument	On	System Alert (Indicator remains on until the condition is corrected/addressed.) See Section 7 for additional information.
Yellow (Amber) – pulsing	On	Instrument is in isolation mode. Stack is not communicating to the main computer.
Green – one each for left and right drawers	On	Out-of-protocol negative vial (Indicator remains lit until all negative vials are removed through the **remove negative** vials activity.)
Red – one each for left and right drawers	On	Positive vial (Indicator remains lit until all positive vials are removed through the **remove positive** vials activity.)

3.4 Drawer Handles

3.4.1 Location

The drawers are designed to be grasped by handles to the right and left of the mullion, where the system indicator lights are projected.

See Figure 3-1 for drawer handle locations.

When a drawer is opened, agitation of all rows in the open drawer ceases immediately, and any measurements in progress are aborted.

3.4.2 Operation

Grasp the drawer handle and pull the drawer out completely.

When closing a drawer, be sure you push it completely closed and the drawer locks closed. A tone confirms the drawer closing.

Avoid opening the drawer unnecessarily. Drawers should not remain open longer than 10 minutes.

If a drawer remains open longer than 10 minutes, a tone sounds. You may acknowledge the alert message or close the drawer to silence this tone. If a drawer is slightly ajar, a loud continuous tone sounds to alert you to the condition. This tone continues until the drawer is fully opened or fully closed.

3.5 Barcode Scanner

3.5.1 Location

Each instrument (BD BACTEC™ FX Top and BD BACTEC™ FX Bottom instruments) has its own barcode scanner.

The BD BACTEC™ FX Top instrument's barcode scanner is on the front of the instrument, at the bottom center of the mullion.

The BD BACTEC™ FX Bottom instrument's barcode scanner is on the front of the instrument, near the top center of the mullion.

See Figure 3-1 for barcode scanner locations. Figure 3-4 shows a barcode scanner turned on.

3.5.2 Operation

> NOTE
>
> Accepted barcode symbologies include Code 128, Codabar, Code 39, and Interleaved 2 of 5.

The scanner turns on when the instrument is ready to read a barcode. To scan a barcode, place the vial in the recessed area below the scanner. If necessary, slowly turn the vial until the acknowledgment beep sounds (indicating that the barcode was scanned successfully).

Figure 3-4 – Upper Barcode Scanner (On)

3.6 LCD/Touchscreen

3.6.1 Location

The Liquid Crystal Display (LCD) is located at the bottom center of the BD BACTEC™ FX Top instrument's front panel. It contains the displays that present information to you and the on-screen buttons that allow you to perform routine operations.

The LCD is shown in Figure 3-1.

3.6.2 Operation

After the instrument completes its startup process, the Status Display appears. Other displays appear as you perform various operations.

The LCD is programmed to automatically dim after 60 minutes of inactivity. To return the brightness to normal, tap the screen lightly anywhere or open a drawer.

More information on displays is presented in Section 5.

3.7 Station Indicators

3.7.1 Location

Each accessible station has a set of LED indicators that inform you of the station or vial's status. The status indicators are located above each station.

Station indicators are defined in the table below. Figure 3-5 shows the actual station indicators.

3.7.2 Indication

The color (red, green, or yellow [amber]) and state (on, flashing, or off) indicate the conditions shown in the table below for a given station.

Indicator Color	State	Meaning
Red	Flashing	Positive vial
Green	Flashing	Negative vial
Yellow (Amber)	Flashing	Anonymous vial
Red/Yellow (Amber) (alternating)	Flashing	Positive Anonymous vial
All indicators	Off	Ongoing vial / Unusable station
Green	On	Available station

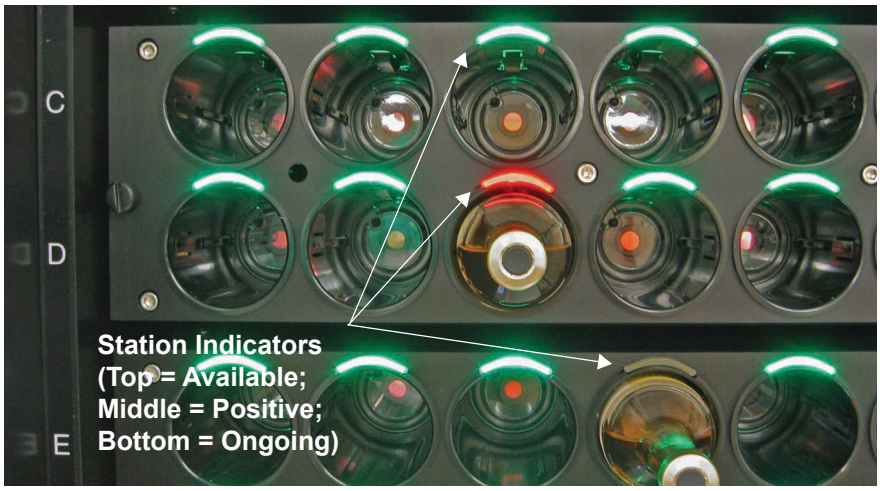


Figure 3-5 – Station Indicators

3.8 USB Ports

The USB ports are located on the front of the BD BACTEC™ FX Top instrument, behind the access panel at the bottom right.

Their primary purposes are to enable saving data to a flash memory USB drive, and to perform software updates when they are released.

Note that a local printer should be connected to the instrument's rear USB port.

3.9 Audible Tones and Alarms

A variety of sounds are generated by the BD BACTEC™ FX instrument as you perform operations. Each of the sounds is unique and designed to keep you informed about various operational states of the instrument.

Type	Example	Sound
Activity complete	All negative vials were removed	High pitch tone repeated 3 times
Activity error	Did not scan accession barcode after scanning sequence barcode and placing vial in instrument when Accession Barcoding is enabled	Single high beep
Anonymous	Anonymous vial entered	Short buzz sound
Barcode scan	A vial sequence number was scanned	Single medium beep
Drawer ajar	The drawer is not completely closed	Two tones, high then low frequency, repeating until drawer is fully opened or fully closed
Drawer closed	Drawer is closed	Mechanical latching sound
Positive vial	A positive vial has been detected	Pulsing fading sound, repeating
System alert	Temperature alert	Single high beep, some are repeating
Vial entry	A vial was entered into a station	High pitch blip or chirp sound

3.10 Onscreen Keyboard

Fields that accept alphanumeric information (e.g., Accession, Password) activate an onscreen keyboard that enables you to input characters into the various fields.

To access the onscreen keyboard, select the field. In alphanumeric fields, the alphabetic keyboard (caps) opens. If a numeric field is selected, the numeric keyboard opens.

The following keyboards can be accessed:

- NUM -- Numeric
- CAPS -- Alphabetic (toggles between UPPERCASE and lowercase letters)
- EXTND -- International characters (accented, extended character set)

To switch between keyboards, select the key at the bottom corresponding to the desired character set.

To enter text or numbers, select the desired characters. The text is shown in the white box at the top of the keyboard display. Then select **ENTER**.

To erase one or more characters, select **BACKSPACE**.

To move the cursor left without erasing, select **LEFT**.

To move the cursor right without overtyping, select **RIGHT**.

To exit the keyboard display, select **ESC**.

To enter the text into the field, select **ENTER**.

The keyboard display is shown in Figure 3-6.

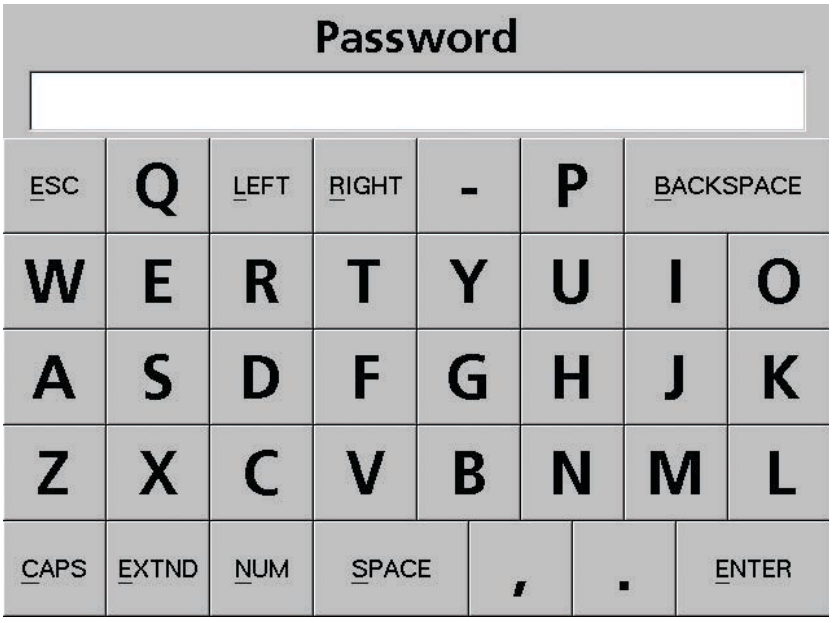


Figure 3-6 – Keyboard Display (CAPS shown)

3.11 Digital Thermometer

The digital thermometer eliminates many of the problems associated with a liquid in glass thermometer, such as hazardous materials and column separation.

To activate a new thermometer, pull out the plastic tab from the battery compartment and remove the plastic sheath.

The thermometer is now ready to use and may be inserted into any rack location that will not interfere with the barcode reader or its cable.

When the thermometer is not being read, turn it off by pressing the On/Off button. This will prolong the battery life.

NOTE

Erratic readings, a faint display, or no display are all indicators that the battery must be replaced. The battery can be replaced without removal from the vial. Use a screwdriver to remove the battery cap by turning the cap counterclockwise approximately 1/4 turn. Turning the cap more than 1/4 turn may damage the cap. Replace the exhausted battery with a new 1.5 volt, silver oxide, size 393 battery. Make certain the positive (+) side is visible. Replace the battery cap. Do not over tighten the cap.

Figure 3-7 – Digital Thermometer

3.12 Remote Alarm

The BD Remote Alarm unit is a small box that sounds an audible alarm when critical System Alerts occur, and when positive vials are detected. Controls and indicators are described in the operating instructions, furnished separately.

3.13 Printer

For an explanation of controls and indicators on the printer, refer to the manufacturer's operating instructions, furnished separately.

Note that a local printer should be connected to the instrument’s rear USB port.

4 – Operation

4.1 General

This section provides instructions for routine operation of the BD BACTEC™ FX instrument. The following major topics are discussed:

- Using the Instrument
- Daily Maintenance
- Collecting and Preparing Specimens
- Entering Vials
- Recalling, Entering, and Modifying Data
- Testing Vials
- Printing Reports
- Removing Positive, Negative, and Ongoing Vials
- Responding to Alarms and Errors
- Power Failures
- Operation with a BD EpiCenter™ System

These topics are offered in a general order which might fit the workflow of the average laboratory. Some operations (such as printing reports) may be done at your convenience. Other operations, like monitoring the instrument for new positives and alarm conditions, should be ongoing throughout the day.

This section is designed to provide general instructions. More detailed information on system displays is presented in Section 5.

4.2 Using the Instrument

4.2.1 Touchscreen, Fields, and Buttons

The Liquid Crystal Display (LCD) presents all the information needed to monitor instrument and station status, to enter and remove vials, set up the instrument, print and customize reports, and perform some routine instrument maintenance. The information is presented in the form of icons that graphically represent the information (such as a clock to indicate the current time), text buttons, or a combination of icons and text.

Many of the operations you perform at the instrument are initiated by selecting buttons, tabs, and fields on the LCD itself. These buttons, tabs, fields are discussed, display by display, in Section 5. Do not use pens or sharp implements to select the touchscreen; this can cause damage to the screen. You can use your fingertip or fingernail for greater precision, or a pencil eraser to select buttons on the screen without causing damage.

4.2.2 Power On

Instrument is powered on by pressing the power button. Once the instrument is turned on, acknowledge the PHI window. Once acknowledged, the Status Screen is displayed.

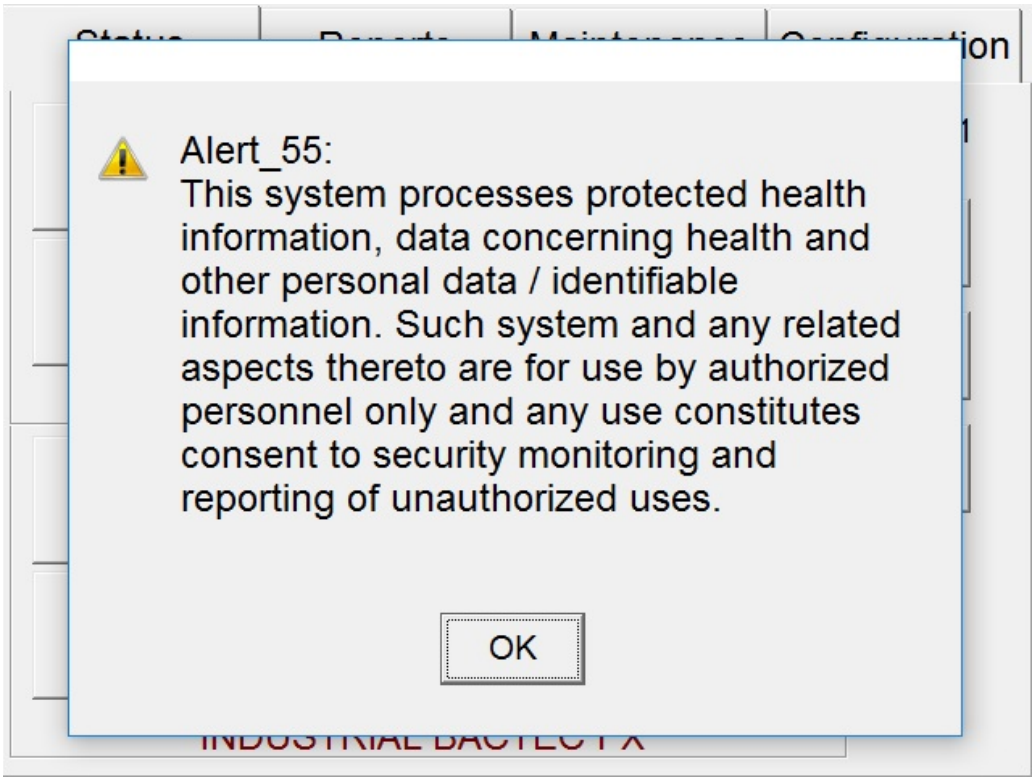


Figure 4-1 – PHI window

4.2.3 Status Display

The Status display is the main display shown when no other operation has been initiated or is in progress. It is the initial display that appears when the instrument starts up or restarts.

The Status display is shown in Figure 4-2. It provides a quick overview of testing status, station availability, and vial statuses such as positive, negative, and anonymous (see Section 4.2.5 for more information about vial statuses).

Once a drawer is opened, you can initiate the major instrument activities from the Status display. Vial Entry, **remove positive** vials, **remove negative** vials, and Identify Anonymous Vials can be initiated for any drawer in the instrument or current stack. (Each of the activities is discussed in greater detail later in this section.) Demographic information (accession only in BD EpiCenter™ configuration) can be added to vial records in the Culture display, accessed through the **Culture** button. The Drawer View display (Figure 4-4), accessed by selecting **Drawer view**, shows the status of each station in a representational view of the drawer. Finally, a list of System Alerts can also be reviewed by selecting **System Alerts**.

The Vial Entry (Figure 4-3), Identify Anonymous, Positive Removal, and Negative Removal activity displays present station counts for the current drawer for Positive, Negative, Blocked, Ongoing, Anonymous, and Available Stations.

Section 5 provides more detailed information about the Status display.

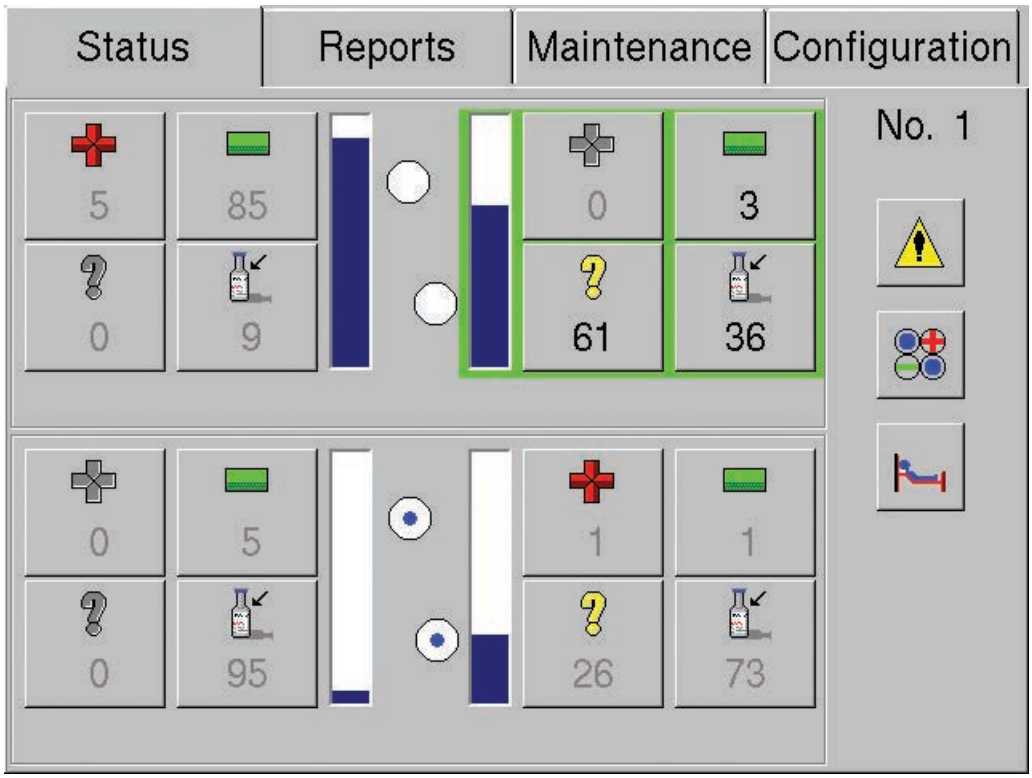


Figure 4-2 – Status Display

4.2.4 Instrument and Drawer Layout

Instruments are provided either as singles, which are countertop individual instruments with LCD; as stacks, which are two modules stacked on top of each other (only the top has an LCD); or a combination of the two.

Singles are numbered individually, and each instrument has two drawers: A and B.

Stacks are numbered as a collective. Each stack has four drawers: A, B, C, and D. Drawers are lettered across the top then across the bottom:

A	B
C	D

Drawers are divided into columns and rows of stations. Columns are numbered 1–10 from left to right and rows are lettered A–K from top to bottom, excluding I. This provides a total of 100 stations for each drawer. Thus, a single has 200 stations; a stack has 400 stations available for cultures (minus any stations used for temperature QC vials).

The Drawer View display (Figure 4-4) shows the drawer's column and row numbering. An open instrument drawer is shown in Figure 4-5.

Stations are designated by Instrument – Drawer – RowColumn (II-D-RCC). Therefore a station designated 03-B-G8 would be in instrument number 3, the top right drawer, row G and the eighth column.

4.2.5 Vial and Station Statuses and States

Vials can have both a status and a state, but it is the status that conveys information about the presence or absence of microbial growth (or the practical availability of a station). The states are used for reporting purposes only.

The Vial Entry (Figure 4-3), ID Anonymous, Positive Removal, and Negative Removal displays (activity displays) present counts for the current drawer for the following statuses/states: Positive, Negative, Blocked/Unusable, Ongoing, Anonymous, and Available. These statuses/states appear at the top right area of the display, with icons representing statuses/states.

The Drawer View display (Figure 4-4), accessible through the Drawer View button on the Status display, shows the status of each station in the drawer in a representational view of the drawer. Drawer View is a useful alternative to physically opening the drawer to view all the station/vial statuses in the drawer.

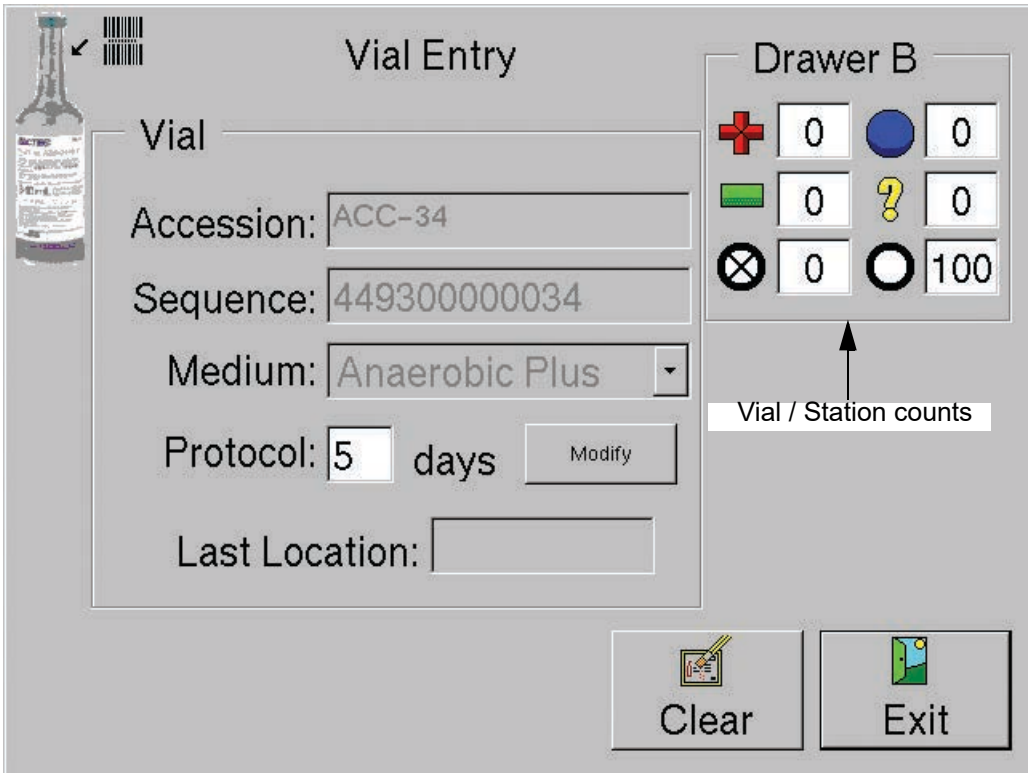


Figure 4-3 – Vial Entry Display

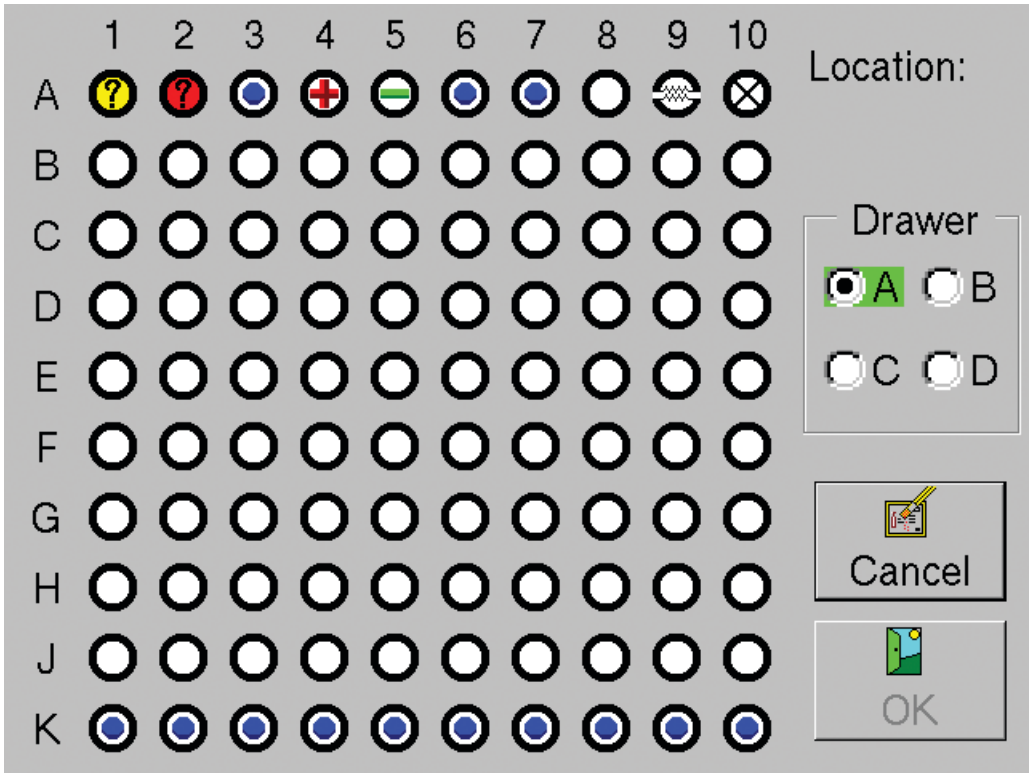


Figure 4-4 – Drawer View Display

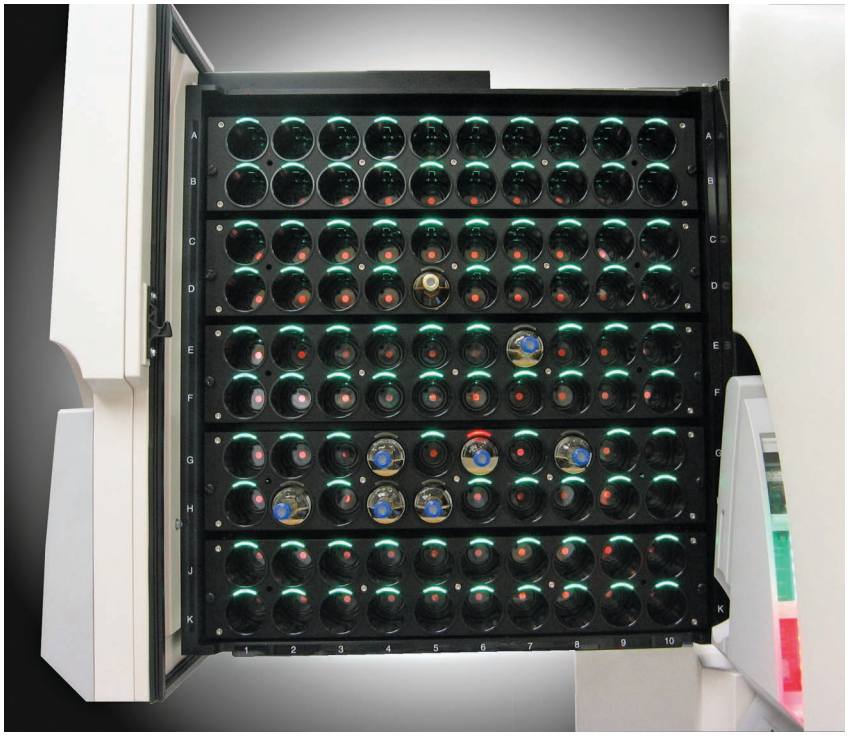


Figure 4-5 – Instrument Drawer (open)

Vial and station statuses in the Drawer View display are:

Status	Icon	Meaning	How Indicated
Available		There is no vial in station	Station Indicators: GREEN **vial entry** icon in color on Status display **vial entry** button active on Status display when drawer is opened Available counter on activity displays
Blocked		User has manually blocked station	Station Indicators: OFF Blocked counter on activity displays
Negative		Vial completed protocol with no evidence of positivity For Manual Negative: User forced vial negative in Culture display	Station Indicators: FLASHING GREEN **remove negative** vials icon green on Status display **remove negative** vials button active on Status display when drawer is opened Negative Vial System indicator lights Negative counter on activity displays
Ongoing		Vial is in instrument and is in protocol	Station Indicators: OFF Ongoing counter on activity displays
Pending	N/A	Vial information has been entered but vial has not been physically scanned into the instrument	No instrument indication; can see on reports and Culture display
Positive		Instrument has detected evidence of microbial growth For Manual Positive: User forced vial positive in Culture display For Anonymous Positive: see below	Station Indicators: FLASHING RED or FLASHING YELLOW (AMBER) / RED (alternating) – Anonymous Positive **remove positive** vials icon red on Status display **remove positive** vials button active on Status display when drawer is opened Message box on screen Positive Vial audible alarm sounds Positive Vial System indicator lights Positive counter on activity displays
Unusable		Instrument has detected a hardware problem with the station; ongoing vials must be moved to good stations	Cracked circle superimposed on existing status icon Blocked counter on activity displays

The vial states are:

State	Icon	Meaning	How Indicated
Anonymous	 (Ongoing)  (Positive) ? (Report)	Vial was physically placed in instrument without its barcode sequence number being scanned Test results are collected while it is in instrument and general positivity criteria are applied	Station Indicators: FLASHING YELLOW (AMBER) --Ongoing FLASHING YELLOW (AMBER) / RED (alternating) --Positive Anonymous vial tone plays when vial is placed in station without scanning **identify anonymous vials** icon yellow on Status display **Identify Anonymous Vials** button active on Status display when drawer is opened Anonymous counter on activity displays On reports, shown as a question mark next to the Status
Current		Vial is in instrument	Reports only, shown as a vial next to the Status

4.3 Daily Maintenance

Each day several simple maintenance procedures should be performed. The best time to perform maintenance is first thing in the morning, but it may be done at any time you find convenient.

The following procedures should be performed:

1. Check the paper supply to the printer. If the paper supply is low or exhausted, replace the paper as explained in the operating manual furnished separately.
2. Select the **Maintenance** tab. The Test display appears.
3. Select the **Q.C.** button to print the Maintenance QC Report.
4. Open drawer A. Then select the **Red** button to illuminate the red station indicators. Record any station that does not illuminate red.
5. Next select the **Green** button to illuminate the green station indicators. Record any station that does not illuminate green.
6. Check and record the temperature on the temperature QC vial.
7. Repeat Steps 3 through 5 for each of the drawers in the system.
8. Close the drawer.
9. Select the **Alarm** button to verify that the audible alarm is functioning.
10. Finally, select the **Status** button to illuminate the system status indicators. Both sides of all the indicators (yellow [amber], red, and green) should illuminate. If any indicator does not light, contact your local BD representative for service.
11. Information can be recorded on the Maintenance QC Report.

Blocking Stations

If any of the station indicators does not light, the station should be blocked and the vial should be moved to an available station using the Vial Entry activity.

To block a station:

1. Open the correct drawer.
2. From the Test display, select **Block/Unblock**.
3. The Block/Unblock display appears.
4. Select the station to block in the display. Repeat for additional stations to be blocked.
5. Remove any vial from the station.
6. Insert station plugs.
7. Enter the removed vials into available stations with the Vial Entry activity (Section 4.5).
8. If you inadvertently block a station with a vial in it, the instrument tests the vial as an anonymous vial. Be sure to use vial entry to move any vial in that station to a new station.
9. The Maintenance QC Report lists the blocked stations.

4.4 Collecting and Preparing Specimens

WARNING
PATHOGENIC MICROORGANISMS, INCLUDING HEPATITIS VIRUSES AND HUMAN IMMUNODEFICIENCY VIRUS, MAY BE PRESENT IN CLINICAL SPECIMENS. "STANDARD PRECAUTIONS"[1-4] AND INSTITUTIONAL GUIDELINES SHOULD BE FOLLOWED IN HANDLING ALL ITEMS CONTAMINATED WITH BLOOD AND OTHER BODY FLUIDS.

[1] CLINICAL AND LABORATORY STANDARDS INSTITUTE. 2005. APPROVED GUIDELINE M29-A3. PROTECTION OF LABORATORY WORKERS FROM OCCUPATIONALLY ACQUIRED INFECTIONS, 3RD ED. CLSI, WAYNE, PA.
[2] GARNER, J.S. 1996. HOSPITAL INFECTION CONTROL PRACTICES ADVISORY COMMITTEE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION. GUIDELINE FOR ISOLATION PRECAUTIONS IN HOSPITALS. INFECT. CONTROL HOSPITAL EPIDEMIOL. 17:53-80.
[3] U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. 1999. BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES, HHS PUBLICATION (CDC), 4TH ED. U.S. GOVERNMENT PRINTING OFFICE, WASHINGTON, D.C.
[4] DIRECTIVE 2000/54/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 18 SEPTEMBER 2000 ON THE PROTECTION OF WORKERS FROM RISKS RELATED TO EXPOSURE TO BIOLOGICAL AGENTS AT WORK (SEVENTH INDIVIDUAL DIRECTIVE WITHIN THE MEANING OF ARTICLE 16(1) OF DIRECTIVE 89/391/EEC). OFFICIAL JOURNAL L262, 17/10/2000, P. 0021-0045.

Collection - Patients

Specimens should be collected aseptically from the patient and inoculated into the vials. Refer to the *Media Package Insert* for specific recommendations on specimen collection. Vials should be labeled and sent to the laboratory at once.

Collection - Platelets

Platelets should be collected aseptically from the bagged unit and inoculated into the vial. Refer to the *Media Package Insert* for specific recommendations. Vials should be labeled and placed in machine at once.

Preparation

At least one aerobic culture vial and one anaerobic vial should be prepared. To prepare a vial, remove the plastic flip cap and clean the exposed rubber septum with 70% isopropyl alcohol. Use a separate swab for each vial. Inoculate the vial with the appropriate volume of sample (refer to the *Media Package Insert* for specific information on vial inoculation).

4.5 Entering Vials

To enter vials in the instrument, select a drawer where there are available stations. (The number of available stations is shown below the vial entry icon on the Status display.)

Then follow one of the methods described below.

Vial Entry can be initiated in one of two ways:

Method 1 (Vial Activated)

- Select a drawer that has available stations, and open that drawer.
- The barcode scanner turns on.
- Scan a vial sequence barcode label.
- The Vial Entry display appears and the Sequence, Media, and default Protocol are automatically entered.
- If you did not scan the Accession, scan or enter it now (sequence and accession can be scanned in any order).
- If lot number and expiration date tracking are enabled, scan the 2D barcode containing the information.
- To change the protocol, select **Modify**, then select the **Up Arrow** to increase or down arrow to decrease the protocol length.
- Place the vial into an available station (solid green indicator).

Method 2 (Icon Activated)

- Select a drawer that has available stations, and open that drawer.
- Select **vial entry** on the Status display.
- The Vial Entry display appears and the barcode scanner turns on.
- Scan the vial sequence barcode label.
- The Sequence, Media, and default Protocol are automatically entered.
- If lot number and expiration date tracking are enabled, scan the 2D barcode containing the information.
- If you did not scan the Accession, scan or enter it now.
- To change the protocol, select **Modify**, then select the **Up Arrow** to increase or down arrow to decrease the protocol length.
- Place the vial into an available station (solid green indicator).

Note that for both methods, the Vial Entry process is not completed until the scanned vial is placed into an available station. That is when the vial database is updated with the new vial data. The Vial Entry tone signifies that the Vial Entry process for that vial is complete.

The barcode scanner will not turn on if the instrument does not detect the previously scanned vial being fully inserted into a station.

When a vial is placed into the last available station in a drawer, the Activity Complete tone sounds (3 beeps). To continue entering vials, select another drawer with available stations.

Vial Entry cannot be performed in an instrument in Isolation mode (Win FX), or an instrument in degraded mode in a BD EpiCenter™ configuration.

Inserting Vials in the Instrument

Before inserting vials from clinical specimen into the stations, visually inspect all vials for evidence of microbial growth. Evidence of microbial growth includes dark or black blood in non-lytic aerobic media (the blood in ongoing non-lytic aerobic vials will be bright red in color), hemolysis, turbidity, and excess gas pressure (causing the vial septum to bulge outward). All such vials should be treated as positives; they should be Gram stained and subcultured.

Before inserting platelet vials into the stations, visually inspect all vials for evidence of microbial growth which may include excessive turbidity and/or excess gas pressure (causing the vial septum to bulge outward). All such vials should be treated as positives; they should be Gram stained and subcultured.

If you accidentally place a vial into a blocked station, the vial entry tone does not sound and the barcode scanner remains off. You must remove the vial from the station and reenter it with the Vial Entry activity. Blocked stations are not tested.

After all vials have been inspected and inserted in stations, close the drawer.

A vial presence sensor immediately senses the insertion of a vial in a station and the instrument updates the station LED indication and the status shown on the LCD.

Once vials are placed in their stations, BD recommends that you do not move them to other stations.

Avoid opening the drawer unnecessarily. Drawers should not remain open longer than 10 minutes.

WARNING

VIALS SHOULD BE HANDLED WITH EXTREME CARE AT ALL TIMES. MAKE SURE ALL VIALS ARE FULLY INSERTED INTO THE STATIONS BEFORE CLOSING THE DRAWER.

Login

> NOTE
>
> Good clinical practice dictates that for optimal performance, blood culture vials should be sent to the laboratory as soon as possible upon collection.
>
> Delays in entering blood culture vials into continuous-monitoring blood culture instruments may delay or impede detection of growth.
>
> M47-A Vol. 27 No. 17, "Principles and Procedures for Blood Cultures; Approved Guideline."

Complete instructions on entering vial, specimen, and patient data is provided in Section 4.6. You can log in demographic data at any time you find convenient.

Anonymous Vial Entry

Vials can be placed into available (GREEN indicator) stations without being scanned into the instrument. Vials that are not scanned into the instrument are called anonymous vials. Anonymous vials are recognized by the instrument when they are placed in stations, but are assigned an unknown medium type and default protocol of 5 days. Anonymous vials are evaluated with general positivity criteria. They cannot use the specific positivity criteria tied to the characteristics of the medium since the instrument does not know the medium type.

BD recommends that at some point you identify these anonymous vials to the system using the ID(entify) Anonymous vials activity. The instrument is able to apply medium specific positivity criteria when the medium type is known, and can apply these specific criteria to collected test readings. In addition, the protocol is adjusted, if necessary, to the default for that medium type once the vial is identified.

Ongoing anonymous vials that reach the end of their protocol must be identified before the instrument will assign a Negative status.

If an instrument in a BD EpiCenter™ configuration is in degraded mode, vials can only be entered as anonymous vials until communications with BD EpiCenter™ are re-established.

> NOTE
>
> Once an anonymous vial has been placed in the instrument, do not remove the vial and reenter it without identifying it (ID Anonymous activity). All test readings are discarded if you remove the vial without identifying it.

To identify anonymous vials:

- Select a drawer that has anonymous stations, and open that drawer.
- Remove a vial from a FLASHING YELLOW (AMBER) or FLASHING YELLOW (AMBER) / FLASHING RED (alternating) station, or select **Identify Anonymous** on the Status display.
- The ID Anonymous display appears and the barcode scanner turns on; Station and Status information for the vial are shown.
- Scan the vial sequence barcode label.
- The Sequence, Medium, default Protocol, and TIP (Time in Protocol) or TTD (Time to Detection) are automatically entered.
- Scan or enter the Accession (if accession barcoding is enabled).
- If lot number and expiration date tracking are enabled, scan the 2D barcode containing the information.
- To change the protocol select **Modify**, then select the **Up Arrow** to increase or **Down Arrow** to decrease the protocol length.
- If you are returning the vial to the instrument, place it in the FLASHING GREEN station (station from which the vial was pulled). If you are not returning the vial to the instrument, select **Save**. You must do one or the other to retain the vial information.
- Add the desired demographic information in the Culture display(s).

You cannot identify anonymous vials in an instrument that is in degraded mode.

4.6 Recalling, Entering, and Modifying Data

4.6.1 General

Patient is the top level of the instrument database record. A patient record consists of a mandatory Patient ID and optional Patient Name.

You cannot create patient records at the instrument with no accessions or vials attached.

Accessions can exist in the database without being attached to patient records. If there are no vials attached to the accessions, they are called orphan demographics.

Vials can exist unattached to accessions. These are called orphan vials.

Note that in a BD EpiCenter™ configuration, you cannot enter Patient ID or Patient Name at the instrument. However, you can recall patient records by these fields. Also, you cannot enter Hospital Service or Collection Date/Time at the instrument. This operation can only be performed at the BD EpiCenter™ system.

4.6.2 Vial Data

Recalling vial records by location:

From the Status display, select **Culture**. 

The Culture – Patient display appears.

Select the **Vial** tab to access the Culture – Vial display.

Select the blank Location field.

Select the station in the Drawer View display.

Select **OK**.

The desired vial record appears.

or

From the Status display, select **Drawer View**. 

Select the desired station.

Select **OK**.

The desired vial record appears.

Recalling vial records by sequence:

From the Status display, select **Culture**. 

The Culture – Patient display appears.

Select the **Vial** tab to access the Culture – Vial display.

Scan vial sequence number or manually enter it with the onscreen keyboard (select the Sequence field to access the keyboard).

The desired vial record appears.

Associating vials to an accession:

From the Status display, select **Culture**. 

The Culture – Patient display appears.

Select the **Specimen** tab to access the Culture – Specimen display.

In the Accession field, enter the desired accession.

Scan the vial sequence barcode you want to attach.

Select **Save** to save the association.

Only new sequence numbers or existing orphan (sequence unattached to an accession) sequence numbers can be attached.

Disassociating vials:

If a vial record contains an accession number, it is considered associated to that accession. The disassociate function enables you to break the link between a vial and an accession number.

To disassociate an accession from a vial:

From the Status display, select **Culture**. 

The Culture – Patient display appears.

Select the **Vial** tab to access the Culture – Vial display.

Scan the sequence number of the vial.

Select **Disassoc(iate)** to disassociate the vial from the accession number.

Note that the **Disassoc(iate)** button is active only if there is an accession number saved for that vial. If the button is grayed out, there is no associated accession number.

To manually enter a medium type (e.g., a replacement barcode):

Recall the desired vial record in the Culture – Vial display.

For media type 99 replacement barcodes, select the arrow next to the `Unknown` medium type and select the correct medium type. (You can also select the medium type during Vial Entry or ID(entify) Anonymous.

Select **Save** to save the information.

Modifying vial protocol:

Recall the desired vial record in the Culture – Vial display.

If the protocol is eligible for change, the **Modify** button (next to the Protocol field) is enabled.

Select **Modify** and select the desired protocol by selecting the **Up** or **Down Arrow**. You can set the protocol length from 3 to 42 days depending on the medium type.

Select **Save** to save the information.

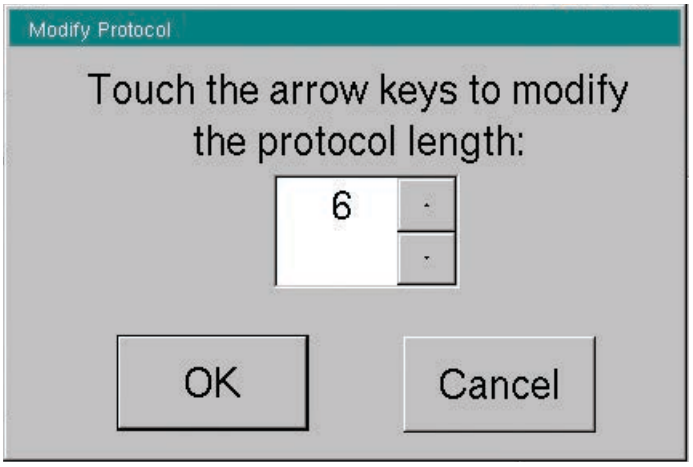


Figure 4-6 – Modify Protocol Window

Protocols cannot be extended beyond 14/30/42 days (depending on medium type). To test a culture longer than the protocol maximum, apply a spare media barcode label to the vial and use Vial Entry to enter it as a new vial.

Changing vial status:

Recall the desired vial record in the Culture – Vial display.

Select the **Drop-down Arrow** next to the Status field.

Select the desired status by selecting it in the drop-down box.

Select **Save** to save the information.

4.6.3 Specimen Data

Note that in a BD EpiCenter™ configuration, you cannot enter Hospital Service or Collection Date/Time at the instrument. This operation can only be performed at the BD EpiCenter™ system.

Recalling specimen records:

From the Status display, select **Culture**. 

The Culture – Patient display appears.

Select the **Specimen** tab to access the Culture – Specimen display.

Select in the Accession field. The onscreen keyboard appears.

Enter accession number, then select **ENTER**.

The desired specimen record appears.

Adding specimen data:

Recall the desired specimen record in the Culture – Specimen display.

To enter a hospital Service, select in the Service field.

The onscreen keyboard appears.

Enter the Service from which the specimen was collected, then select **ENTER**.

To enter a Collection Date/Time, select **Set**. In the Set Date and Time window, select the **Up** or **Down Arrow** in the Month, Day, or Year field. To set the time, select the **Up** or **Down Arrow** in the Hour or Minute field. For USA locations, also select the **a.m./p.m. Drop-down Arrow** to select a.m. or p.m. Select **OK** when complete to set the Date/Time.

Select **Save** to save the information.

Modifying specimen data:

You can modify hospital Service and Collection Date/Time in a specimen record.

Recall the desired specimen record in the Culture – Specimen display.

- To modify the hospital Service, select the Service field.

  The onscreen keyboard appears.

  Enter the Service from which the specimen was collected, then select **ENTER**.

  Select **Save** to save the information.

- To modify the Collection Date/Time, select **Set**. The Set Date and Time window appears.

  To set the date, select the **Up** or **Down Arrow** in the Month, Day, or Year field you want to set.

  To set the time, select the **Up** or **Down Arrow** in the Hour or Minute field you want to set. For USA locations, also select the **a.m./p.m. Drop-down Arrow** to select the new value.

  Select **OK** when complete to set the Date/Time.

  Select **Save** to save the information.

Disassociating specimens from patient records:

Recall the desired patient record (see below, **Recalling patient records**).

In the specimen window, select the specimen to be disassociated. Only one specimen can be disassociated at a time.

Select **Disassoc(iate)**. When the message appears, select **Yes** to complete the disassociation.

If all specimens are disassociated from the patient record, the patient record is removed from the database.

Note that in a BD EpiCenter™ configuration, you cannot disassociate a specimen from a patient record. This operation can only be performed at the BD EpiCenter™ system.

Disassociating vials from specimen records:

Recall the desired specimen record in the Culture – Specimen display.

In the vial window, select the vial to be disassociated.

Select **Disassoc(iate)**. When the message appears, select **Yes** to complete the disassociation.

That vial is disassociated and becomes an orphan.

4.6.4 Patient Data

Note that in a BD EpiCenter™ configuration or in a standalone configuration with LIS enabled, you cannot enter or edit Patient ID or Patient Name at the instrument. In a BD EpiCenter™ configuration, this operation can only be performed at the BD EpiCenter™ system. In a standalone configuration with LIS enabled, this operation can only be performed at the LIS system.

Adding patient data:

From the Status display, select **Culture**. 

The Culture – Patient display appears (in Search mode). You cannot add patient information to the display while it is in Search mode.

Select the **Vial** tab. The Culture – Vial display appears.

Recall the desired vial record.

Select the **Specimen** tab. The Culture – Specimen display appears.

Select **Add**. The Culture – Patient display appears (in Add mode).

Select in the Patient ID field to enter patient identification. The onscreen keyboard appears. Type the patient ID and then select **ENTER**. You can enter up to up to 16 characters, excluding the following:

* [ ] | ? !

To add an optional patient name, select the Patient Name field. The onscreen keyboard appears. Type the patient name and then select **ENTER**. You can enter up to 40 characters, excluding the following:

* [ ] | ? !

You may use any name format you prefer, but BD recommends a consistent naming convention to make subsequent searching less problematic. Last name, first name works well for many laboratories.

Select **Save** to save the patient data.

Recalling patient records:

You can recall patient data either by patient name or patient ID.

Recalling a patient record by patient name:

From the Status display, select **Culture**. 

The Culture – Patient display appears.

Select the Patient Name field. The onscreen keyboard appears.

Type the patient's name and then select **ENTER**.

The desired patient's record appears.

If you aren't certain of the spelling, enter a few characters and search for a portion of the name. For example, if you have saved the patient name of Doe, John, to locate the record, you can enter Doe or Do and select **ENTER**. More characters narrow the search; fewer characters expand it in case you are not sure of spelling.

If you enter no characters, the search returns all patient records with *blank* patient names. It does *not* return *all patient names*.

If there is more than one match for a patient name search, the Select Patient window pops up (Figure 4-7). Highlight the desired patient by selecting that line, then select **OK** to recall the patient record. If there are more than 50 matches on the search, a message prompts you to narrow your search criteria.

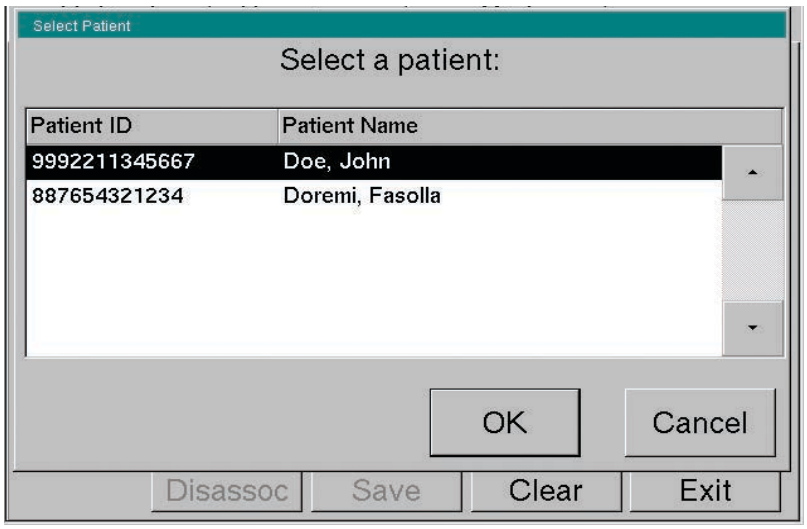


Figure 4-7 – Select Patient Window

Recalling a patient record by the patient ID:

From the Status display, select **Culture**. 

The Culture – Patient display appears.

Select in the Patient ID field.

The onscreen keyboard appears.

Enter the entire patient ID, then select **ENTER**. (You cannot enter a partial Patient ID to recall a patient record.)

The patient record is displayed.

Modifying patient data:

Only the patient name can be modified after a patient record is saved. The patient name can also be changed to blank.

To modify the patient name:

Recall the desired patient record.

Select in the Patient Name field. The onscreen keyboard appears. Type the new patient name and then select **ENTER**.

Select **Save** to save the patient data.

Changing a Patient ID:

You cannot directly change a patient ID. However, you can disassociate a Patient ID from any associated vials, and then associate the correct Patient ID/Name to the vials.

First follow the steps above in Section 4.6.3, in the section called, Disassociating specimens from patient records. Do this for each accession attached to the patient record. When the last accession is disassociated from the patient, the patient record is deleted from the database.

Next, follow the steps at the beginning of this section, Adding patient data.

Select **Save** to save the patient data.

4.7 Testing Vials

Vial testing in the BD BACTEC™ FX instrument is automatic and is interrupted only by drawer openings and/or some system alert conditions. Test cycles are initiated every 10 minutes. A minimum of 1 hour of test results is required in order for any vial to be declared positive.

Measurement cycles in the BD BACTEC™ FX Top and BD BACTEC™ FX Bottom instruments of a stack are independent of each other. Testing in drawers is independent also.

Positive vials are indicated immediately upon detection as described in Section 4.9.

In Isolation mode, the instrument continues to acquire readings from vials. However, positivity analysis does not occur until the instrument re-establishes communication with the main computer. In a BD EpiCenter™ configuration, an instrument in degraded mode continues to incubate, agitate, and test vials.

4.8 Printing Reports

The following reports can be selected for printing:

- Affected vials
- Alert List
- Contaminant Vials

- Culture Summary
- Current Inventory
- Current Negatives
- Current Positives
- Loaded Vials
- Maintenance QC Report
- No Growth Accession
- Orphan Vials
- Partial Seated Stations
- Pending Report
- Unloaded Negative Vials
- Unloaded Positive Vials
- Unloaded Vials

Reports cannot be printed at an instrument in degraded mode in a BD EpiCenter™ configuration.

To print a report:

1. Select the **Reports** tab.
2. Highlight the desired report by selecting it in the menu.
3. Select the desired criteria (Time Range, Sort By, Report By).
4. Select **Print**.

Refer to Section 5.4 for additional information and sample reports.

4.9 Removing Positive, Negative, and Ongoing Vials

Positive and Negative Vials

Many positive cultures will be detected in the first 24 hours after inoculation. However, ongoing vials must still be kept for several days to ensure maximum recovery. With the BD BACTEC™ FX instrument, vials are typically held for 5 days (except Myco/F Lytic, Mycosis IC/F, Platelet Aerobic/F, and Platelet Anaerobic/F culture vials) before they are discarded as negative. Each laboratory should set the protocol length based on its own policies and conditions. Protocol length can be from 3 to 42 days, depending on medium type.

You should perform a subculture and a Gram stain from each positive vial. In most cases, organisms can be identified and a preliminary report can be made to the physician. Preliminary antimicrobial susceptibility (AST) and identification (ID) procedures may also be set up from fluid in the culture vials. The results from these preliminary tests should be confirmed by using standardized laboratory procedures.

In a BD EpiCenter™ configuration, you can remove Negative and Positive (but not related) vials from an instrument in degraded mode.

Single Negative Vial Removal vs. Batch Vial Removal

The instrument can be configured for either single negative vial removal or batch negative removal. This option is set up in the Configuration – Lab display.

For Single Vial Removal, each negative vial that is removed must be scanned to confirm its removal.

For Batch Vial Removal, vials do not have to be scanned. Vial presence sensors immediately sense the removal of a vial and update the station LED indication and the status shown on the LCD.

Vial Reentry

> NOTE
>
> For optimal time to detection and recovery, it is recommended that vials remain in their original station throughout the protocol. See table below.

<table>
<tr><th>Time the vial is out of the instrument</th><th>Does BD recommend subculturing before vial reentry?</th><th colspan="2">Is positivity analysis restarted?</th><th colspan="3">Is protocol restarted?</th></tr>
<tr><td rowspan="3">≤20 minutes</td><td rowspan="3">No</td><td>If reentered into the same workgroup</td><td>No</td><td colspan="2">If same workgroup</td><td>No</td></tr>
<tr><td rowspan="2">If moved to a different workgroup</td><td rowspan="2">Yes</td><td rowspan="2">If different workgroup</td><td>If BD EpiCenter™</td><td>Yes</td></tr>
<tr><td>If BD Synapsys™</td><td>No</td></tr>
<tr><td rowspan="3">>20 minutes and <5 hours</td><td rowspan="3">Yes</td><td colspan="2" rowspan="3">Yes</td><td colspan="2">If same workgroup</td><td>No</td></tr>
<tr><td rowspan="2">If different workgroup</td><td>If BD EpiCenter™</td><td>Yes</td></tr>
<tr><td>If BD Synapsys™</td><td>No</td></tr>
<tr><td rowspan="3">≥5 hours</td><td rowspan="3">Yes</td><td colspan="2" rowspan="3">Yes</td><td colspan="2">If same workgroup</td><td>Yes</td></tr>
<tr><td rowspan="2">If different workgroup</td><td>If BD EpiCenter™</td><td>Yes</td></tr>
<tr><td>If BD Synapsys™</td><td>Yes</td></tr>
</table>

Use the Vial Entry activity to reenter vials. If the vial is still in the database, the Vial Entry display shows the existing information, including the previous station. A reentered vial should be placed in its previous station, which illuminates FLASHING GREEN (if the drawer is open and the station is unoccupied).

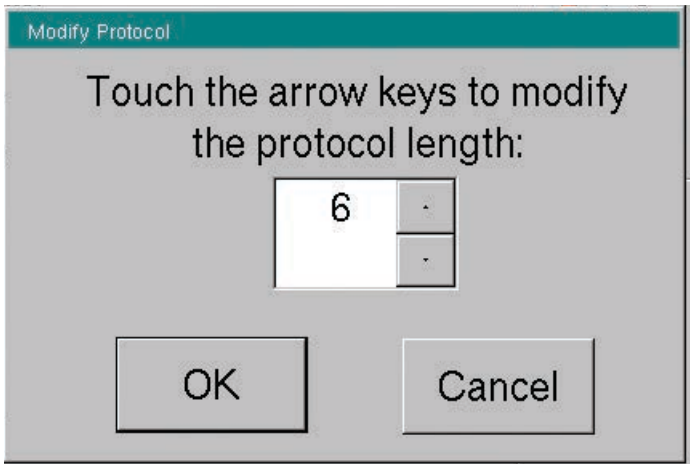


Figure 4-8 – Modify Protocol Window

When reentering a NEGATIVE vial that has been out of the instrument for less than 5 hours, the protocol length should be extended beyond the vial's Time In Protocol to reenter it as Ongoing. If you do not extend the vial's protocol length, the status transitions back to Negative after the third reading.

To adjust the protocol length of a reentered vial, select **Modify** and select the desired protocol by selecting the **Up Arrow** (increase protocol). You can set the protocol length up to 30/42 days (depending on medium type).

Protocols cannot be extended beyond 14/30/42 days (depending on medium type). To test a culture longer than the protocol maximum, apply a spare media barcode label to the vial and use Vial Entry to enter it as a new vial.

Satellite Blood Culture BD Synapsys™ interactions

Due to the critical nature of blood culture testing, and for optimal time to detection, laboratories aim to minimize the time between collecting the patient specimen and placing the bottle into the instrument to initiate incubation. In physically distributed facilities, the transfer time to a main laboratory facility may be long, resulting in delayed bottle entry. To support the goal of rapid start of incubation, BD BACTEC™ FX instrument may be placed in remote testing locations closer to the site of patient specimen collection. The BD Synapsys™ Informatics Solution provides a feature that will allow a bottle that is moved from one remote instrument to another, to continue the culture protocol. No user action is required in BD Synapsys™ Informatics to enable remote blood culture protocol continuation.

Refer to the *BD Synapsys™ User's Manual* for additional information.

Notification of positive and negative vials:

The system notifies you of new positive cultures in several ways:

- Positive Vial audible alarm sounds (first positive in drawer only)
- Station Indicators: FLASHING RED or FLASHING YELLOW (AMBER) / RED (alternating) – Anonymous Positive
- Message box appears on screen (first positive in drawer only)
- Positive vial system indicator for that drawer illuminates
- On the Status display, the **positives** icon is active (color is red, not grayed out) and the number of positive vials in the drawer is shown

Out-of-Protocol Negatives are indicated by the following:

- Negative vial system indicator for that drawer illuminates
- On the Status display, the **negatives** icon is active (color is green, not grayed out) and the number of negative vials in the drawer is shown
- Station Indicators: FLASHING GREEN

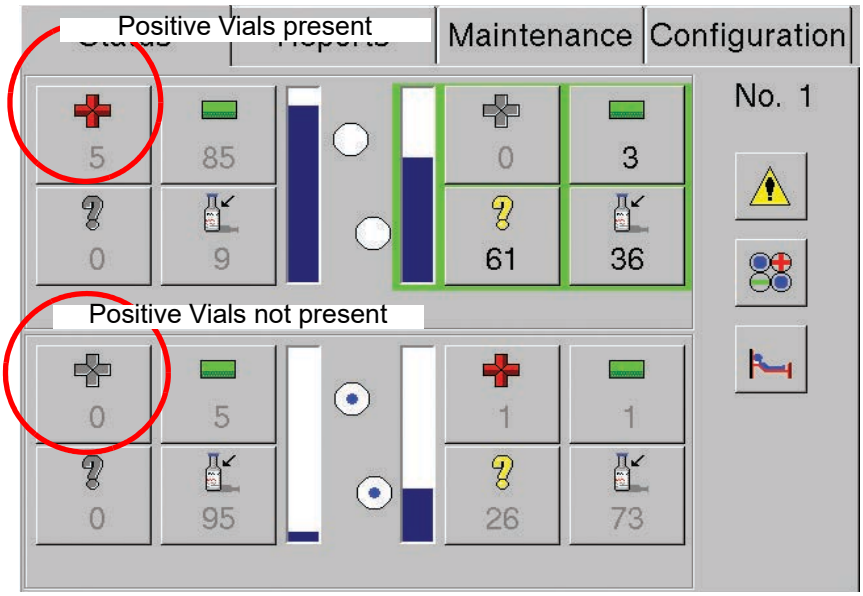


Figure 4-9 – Status Display

Removing positive vials:

Select a drawer that has positive stations, and open the drawer by pulling it out.

- The barcode scanner turns on.
- All positive, final negative, available, and anonymous (all variations) are indicated by the appropriate lit or flashing station indicators.
- Remove a vial from a FLASHING RED (positive) or FLASHING YELLOW (AMBER) / FLASHING RED (Anonymous Positive) station, OR

  Select **Remove Positives** on the Status display.
- The Positive Removal display appears. (If an anonymous positive vial was removed, the ID Anonymous display appears. Scan the sequence and accession for the anonymous positive vial and select **Save**. Then select **Exit** to return to the Positive Removal display.)
- Scan the vial sequence barcode (note that only positive stations remain illuminated after this). You must scan each positive vial you pull in order for the instrument to re-light positive stations.

  If that vial sequence number was entered manually, the system asks you to verify that the sequence number is correct. You must manually confirm that the sequence number on the vial is the same as the one shown on the screen, and select **Verified**. If the sequence numbers do not match, select **Wrong**.

- If the Show Related Vials function is enabled in configuration, the LEDs of vials with the same accession number illuminate GREEN (in the current drawer), and the Culture – Specimen display shows the related vials in the Vial Window (not applicable to Positive/ Anonymous vials).

  In a BD EpiCenter™ configuration, the instrument cannot Show Related Vials when it is in degraded mode.

  Remove any related vials if desired, and either confirm or scan the sequence number, depending on the system prompt. When you have finished removing related vials, select **Exit** to return to the Positive Removal display.

- Counters on the display are updated dynamically as vials are removed.
- When all positives are removed from the drawer, the Activity Complete tone sounds (or when the Culture – Specimen display is exited, if related vials are shown).

Removing negative vials:

Select a drawer that has negative stations, and open the drawer by pulling it out.

- The barcode scanner turns on.
- All positive, final negative, and anonymous (all variations) are indicated by the appropriate flashing station indicators.
- **For Single Vial Removal**
  - Select **Remove Negatives** on the Status display, OR
  - Remove a vial from a FLASHING GREEN (negative) station and scan it.
  - The Negative Removal display appears.
  - Remove and scan all the negative vials. (If any vial sequence numbers were entered manually, the system asks you to verify that the sequence number is correct. You must manually confirm that the sequence number on the vial is the same as the one shown on the screen, and select **Verified**. If the sequence numbers do not match, select **Wrong**.)
- **For Batch Vial Removal**
  - Remove the negative vials from the FLASHING GREEN stations. These vials do not have to be scanned (and the scanner does not turn on). Any vials left in the instrument remain in the database as negatives.
- Counters on the display are updated dynamically as vials are removed.
- When all negatives are removed from the drawer, the Activity Complete tone sounds.

Forcing vials positive or negative:

If the vial is Ongoing, Positive, or Negative, you can manually change the status to positive (Manual Positive) or negative (Manual Negative).

To force a vial positive or negative:

1. From the Status display, select **Culture**. 
2. Go to the Culture – Vial display.
3. Scan or type in the sequence number of the vial. (You can also select the Location field and select a vial from the Drawer View display to recall the vial information.)
4. Select the Status field.

5 Select **Manual Positive** or **Manual Negative**.

6 Select **Save** to save the new status. 

Removing Ongoing Vials:

Ongoing vials may be removed for up to 5 hours and they retain their Start of Protocol.

For optimal performance, ongoing vials should not be removed from the instrument. In situations when they must be removed, such as reconciling labeling and accessioning, the vial must be returned to the instrument within 20 minutes in order to retain all data.

There is no special process to remove an ongoing vial. Remove the desired vial from the station. A vial presence sensor immediately senses the removal of a vial and the instrument updates the station LED indication and the status shown on the LCD.

Use the Vial Entry activity to reenter the vial. If the vial is still in the database, a message appears, and you can reenter the vial by following the instructions in the message. In addition, the Vial Entry display shows the existing information, including the previous station. The vial's previous station illuminates FLASHING GREEN (if the drawer is open and the station is unoccupied), and the vial should be returned to this station. However, a reentered vial can be placed in any available station (solid green indicator).

4.10 Responding to Alarms and Errors

When the system encounters an alert or error condition, the error message is displayed on the screen. Some alerts are only written to the system event log or alert list. In general, system alerts represent fault conditions that the instrument encounters; and activity (workflow) errors occur when some action you have performed was not what the system expected. In most cases, you can usually perform the correct action without exiting the current activity.

Messages are listed in Section 7.2 and are sorted by the error code. The table suggests some possible causes of errors and alerts, and provides possible corrective actions.

CAUTION

If the recommended corrective actions do not solve the problem, contact BD.

System alerts can be viewed and printed in the System Alerts display. Refer to Section 5.3.5.

4.11 Power Failures

When power to the system is lost, the instrument displays a message that power has been lost and initiates an orderly shutdown of the user interface. The system restarts automatically when power is restored. All data is saved in NVRAM (non-volatile Random Access Memory) and is maintained when power is lost.

If power is lost for more than 40 minutes, to ensure maximum recovery it is recommended that all vials in the affected instrument(s) be subcultured. To avoid the burden of manually subculturing vials in a power outage, the instrument can be connected to an emergency power line.

Vials may be accessed during power failures by simply pulling the drawer open. If you move or remove any vials while power is removed, messages will be generated when the instrument resumes power. Keep track of vials removed during power failures to assist in resolving these messages.

If any persistent alerts are displayed when power is lost, the alert is redisplayed when power is restored.

4.12 Operation with a BD EpiCenter™ System

4.12.1 Normal Operations

In a BD EpiCenter™ configuration, the instrument and BD EpiCenter™ system routinely exchange information on instrument status, vial statuses, and test readings. Typically current information can be viewed at either the instrument or the BD EpiCenter™ system.

Only a few operations are different in a BD EpiCenter™ configuration.

Vial Operations

Vial Entry is always performed at the instrument. Most demographics are entered at BD EpiCenter™ system because the demographic data resides in the BD EpiCenter™ master database.

Readings for anonymous vials are not transferred from the instrument to the BD EpiCenter™ system until the vial is identified. Vial status is transferred.

Readings and status information for vials using replacement barcodes where the medium type has not been selected are not transferred from the instrument to the BD EpiCenter™ system until the medium type is selected.

Pending vials are not transferred to the BD EpiCenter™ system.

When Show Related Vials is enabled, the Positive Vial Removal display shows related vials located in (or removed from) any instruments in the BD EpiCenter™ configuration.

Vial sequence numbers must be unique in a BD EpiCenter™ configuration.

System Alerts

The System Alerts display shows alerts only for the instrument at which the display is being viewed.

Drawer View

The Drawer View display shows only stations for the instrument at which the display is being viewed.

Culture Displays

In normal operation, Culture displays show information on related vials that reside in (or were removed from) any instrument in the BD EpiCenter™ configuration.

Demographic Data

Demographic data is not needed for Platelet samples.

Reports

You can configure the instrument to print reports at the BD EpiCenter™ printer. When multiple reports are queued for printing, the print order cannot be guaranteed.

Reports can be printed from the instrument and will contain data only for that instrument. Reports with data from all instruments should be requested at the BD EpiCenter™ system.

Instrument Configuration

Instrument date and time settings and GMT Offset are controlled by the BD EpiCenter™ system and cannot be set at the instrument.

Each instrument in a BD EpiCenter™ configuration must use the same values for the following fields:

- Protocol
- Accession Barcode Enable/Disable
- Batch Negative Removal Enable/Disable
- Show Related Vials Enable/Disable
- Language
- Country/Locale (Country)
- Daylight Saving Time Range
- Timezone GMT Offset

The above fields can be set/modified at any instrument in the BD EpiCenter™ configuration. The other instruments in the system are updated by the BD EpiCenter™ system.

Instrument numbers must be unique in a BD EpiCenter™ configuration.

LIS configuration is disabled when BD EpiCenter™ is enabled. The instrument data can be conveyed to a LIS system through the BD EpiCenter™ system.

All instruments in a BD EpiCenter™ configuration must use the same version of instrument software.

Maintenance

The Host Query button on the Maintenance – Test display is disabled when BD EpiCenter™ is enabled.

4.12.2 Isolation Mode

Isolation mode is the state that exists when communication between the BD BACTEC™ FX instrument and a stack is lost. Isolation mode is designed to enable the stack 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 main computer, no vials transition to Positive or Negative status while the system is in Isolation mode.

Readings will continue to be taken by the stack(s) while in Isolation Mode, however only the last 5 days' worth of readings will be sent to the main computer once communications have been re-established. If the stack remains in Isolation Mode for more than 5 days, readings will be lost and a Reading Gap Error may occur.

Please note the following conditions about Isolation mode related to system operation:

- Isolation mode will continue to collect readings until communications with the UIPC is re-established. However, only the most recent 5 days' worth of readings are maintained. It is strongly suggested that an instrument not remain in Isolation Mode for a time period greater than 5 days, failure to do so may result in Reading Gap errors.
- Each stack can be in Isolation mode independent of the other stack; however this would be a rare condition.

- The main computer handles the transition of each stack into and out of Isolation mode independently.
- In Isolation mode, when you open the instrument door no station status indicators are lit. Routine workflow is not supported in Isolation mode; see Isolation Mode Operation below for supported operations.
- The main computer displays errors when communication is lost with the stack. Once you acknowledge the error, the buttons for operations at the isolated instrument (e.g., **Remove Positives** button, **vial entry** button, etc.) do not appear. This serves as a reminder that the BD BACTEC™ FX stack (BD BACTEC™ FX Top and BD BACTEC™ FX Bottom instruments) and main computer are not communicating.
- The stack(s) and main computer both return to Directed mode (normal operating state) from Isolation mode when communication between the two is reestablished. During the transition, data collected by the stack(s) while in Isolation mode is transferred to the main computer and processed. Vial positivity is assessed at this time for all vials that remain in the instrument when recovering from Isolation mode.
- The time required to complete Isolation Mode recovery will vary depending upon the number of vials in the system and the length of time that the instrument was in Isolation Mode.

Isolation Mode System Indicators

Indicator Color	State	Meaning
Yellow (Amber)	Pulsing	Instrument is not communicating with the main computer
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

Only the following operations are supported while the system is in Isolation mode:

- Vial Examination: A vial can be pulled from its station for examination. When a vial is pulled, the station's green indicator blinks. The blinking green indicator is intended to guide you to return the vial to the same station, which allows data collection for the vial to continue. If you pull a second vial (from a different station), or place a new vial into a different station before the first pulled vial is placed back in its original station, the first pulled vial is considered to have been removed from the instrument.

  Be very careful when examining vials while the instrument is operating in Isolation mode. If a removed vial is accidentally placed in a different station than the one with the flashing green station indicator, the vial is treated as removed and a new anonymous protocol is initiated for the vial in its new station. All data collected for the vial while in its original station during Isolation mode is discarded. Even if the vial is later identified as the original vial, the lost data will not be recovered and the bottle will have a data gap.

- Vial Removal: A vial can be removed from the instrument by pulling it from its station and closing the door, or inserting /pulling a vial in a different station. All data collected for a vial during Isolation mode is discarded when that vial is removed. The instrument assumes that you removed the vial to perform a subculture, and data collection by the instrument is no longer required. Do not return any vial removed from an instrument while the instrument is in Isolation mode to that instrument or any other instrument.

- Vial Entry: You can enter a new vial into any empty station. The instrument begins data collection on the new vial and processes that data as an anonymous vial when the data is uploaded to the main computer in Isolation Recovery mode.

Isolation Mode Troubleshooting

Isolation mode can be caused by the following conditions:

- Main computer malfunction
- BD BACTEC™ FX user interface has stopped working

To return to normal Directed mode, cycle power on the main computer and wait for the Main Status screen to be displayed. Depending upon the state that the user interface was in, the reboot process may take 5 minutes before the application is restarted. If the power cycle does not correct the problem, contact your local BD representative.

4.12.3 Degraded Mode Operations

If a BD BACTEC™ FX instrument loses communication with the BD FX master database, a system alert 30 is generated and the instrument enters a degraded mode of operation. In degraded mode, only the following operations can be performed:

- Remove positive vials (but not related vials)
- Remove negative vials (not batch removal)
- Opening a drawer causes only the Positive (including Positive Anonymous) and Negative stations to illuminate
- View System Alerts (not print)
- View Status and Drawer View displays
- Vials continue incubation, agitation, testing, and determination of results
- Instrument continues to monitor its state of health and generate applicable alerts
- Enter anonymous vials
- Maintenance functions except changing password, QC Report print

You cannot perform the following operations:

- Enter vials with Vial Entry
- Remove or view related vials
- View Culture displays
- Access Vial display by selecting a station in Drawer View display
- View vial plots
- Identify Anonymous vials
- Print reports
- Change passwords
- Adjust Configuration settings

Avoid moving vials in instruments that are in degraded mode. Avoid placing vials in degraded mode instruments unless it is the only instrument with available stations.

Culture displays showing information on related vials that reside in a degraded mode instrument are flagged with an **offline** indicator. No modifications can be made to these vials in the Specimen or Vial tab.

When communications are reestablished, the instrument and its master database are reconciled and the instrument resynchronizes with BD EpiCenter™, updating any changes that have occurred at each system. This includes statuses for sequenced vials, instrument status, and test readings. When the reconciliation is complete, operations that were disabled (e.g., Vial Entry, Identify Anonymous) become enabled again.

5 – Reference

5.1 General

This section presents reference material on the BD BACTEC™ FX instrument user interface. All the screens, icons, reports, and functions in the user interface are described in the order in which they are accessed from the Status display. The following information is presented:

- Status Display
- Reports Menu
- Maintenance
- Configuration

5.2 Software Tree

The following is a hierarchical list of all displays/functions in the instrument. The sections where these activities are discussed in detail are noted in parentheses.

Status Display (5.3)
- Positive Removal Display (5.3.1)
- Negative Removal Display (5.3.2)
- ID(entify) Anonymous Display (5.3.3)
- Vial Entry Display (5.3.4)
- System Alerts Display (5.3.5)
- Drawer View Display (5.3.6)
- Culture – Patient Display (5.3.7)
- Culture – Specimen Display (5.3.8)
- Culture – Vial Display (5.3.9)
- Plot Display (5.3.10)

Reports Menu (5.4)
- Affected Vials (5.4.1)
- Alert List (5.4.2)
- Contaminant Vials (5.4.3)
- Culture Summary (5.4.4)
- Current Inventory (5.4.5)
- Current Negatives Report (5.4.6)
- Current Positives Report (5.4.7)
- Loaded Vials (5.4.8)
- Maintenance QC (5.4.9)
- No Growth Accession (5.4.10)
- Orphan Vials (5.4.11)
- Partially Seated Stations (5.4.12)
- Pending (5.4.13)
- Unloaded Negative Vials (5.4.14)
- Unloaded Positive Vials (5.4.15)
- Unloaded Vials (5.4.16)

Maintenance (5.5)
Test Display (5.5.1)
Block/Unblock Stations Display (5.5.2)
Utilities Display (5.5.3)
Upgrade Software (5.5.3.1)
Save DB and Log (5.5.3.2)
Save Log (5.5.3.3)
Reboot (5.5.3.4)
Change Password (5.5.3.5)
BD Utilities (5.5.3.6)

Configuration (5.6)
Lab (5.6.1)
Reports Display (5.6.2)
Instrument Display (5.6.3)
LIS Display (5.6.4)
Time (5.6.5)

5.3 Status Display

The Status display provides general information about system and station status.

The following operations can be initiated from the Status display:

- View System Alerts
- Access Drawer View display
- Access Culture displays
- Access Positive Removal, Negative Removal, Identify Anonymous, or Vial Entry activities for an open drawer

The following status information is shown:

- Open drawer (highlighted by a green box)
- Instrument number
- Number of positive, negative, anonymous, and available vials/stations, updated dynamically
- Testing status (active/inactive)
- Approximate drawer full status
- Communications status with LIS or BD EpiCenter™ system

See Figure 5-1 for a sample Status display.

The screen is divided into areas that represent the instrument drawers. The icons within each represented drawer are grayed out if there are no vials/stations that correspond to the activity. Offline drawers are not shown on the display.

Added counts for a drawer may total more than 100 stations because a vial or station may be tallied in more than one area (e.g., a positive anonymous vial counts as 1 anonymous vial and as 1 positive vial).

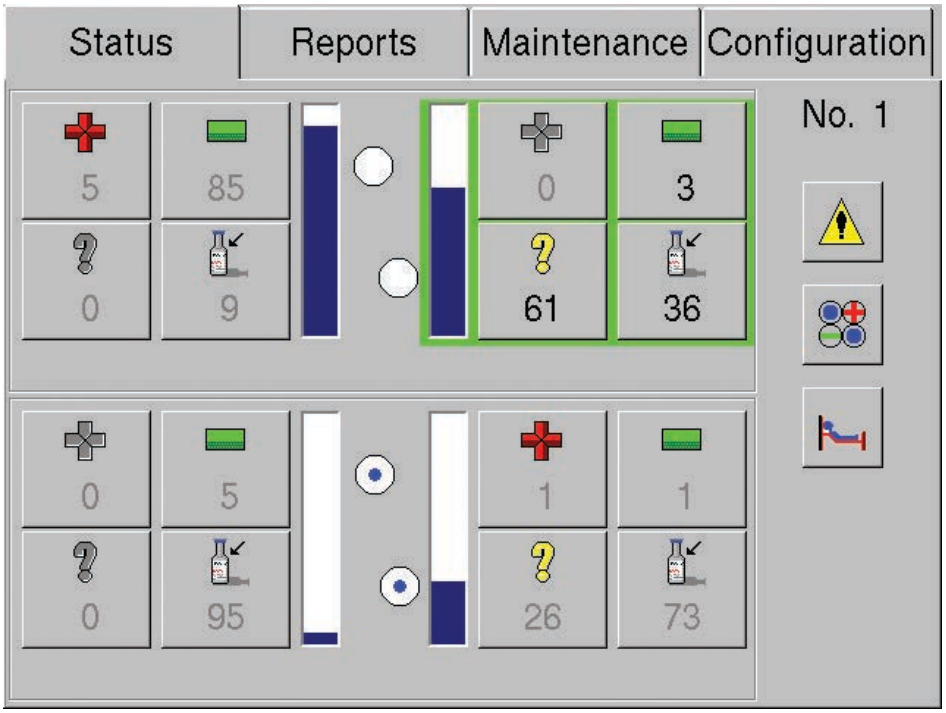
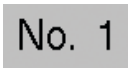


Figure 5-1 – Status Display

Status Display Buttons and Indicators:

	**Remove Positives** button/ Positive Vial indicator		**Remove Negatives** button/ Negative Vials indicator
	**Identify Anonymous** button/ Anonymous Vials indicator		**Vial Entry** button/ Available Stations indicator
	Testing indicators When the circle is empty, no testing is occurring. When the circle is filled, testing is in progress.		Drawer Full indicator Blue portion indicates how much of the drawer is occupied by positive, negative, anonymous (all states), and ongoing vials, as well as blocked and unusable stations. White portion indicates how much of the drawer is available.
	**System Alert** button If enabled, select to access: System Alert display (5.3.5)		**Culture** button Select to access: Culture - Patient display (5.3.7) Culture - Specimen display (5.3.8) Culture - Vial display (5.3.9)

	**Remove Positives** button/ Positive Vial indicator		**Remove Negatives** button/ Negative Vials indicator
	**Drawer View** button Select to access: Drawer View display (5.3.6)	 	BD EpiCenter™ Enabled/healthy indicator BD EpiCenter™ Enabled/unhealthy indicator
	Instrument Number	  	LIS Enabled/healthy indicator LIS Enabled/unhealthy indicator LIS enabled/unknown status indicator

5.3.1 Positive Removal Display

The Positive Removal display appears when you initiate the remove positive vials activity, either by pulling a positive vial or by selecting **Remove Positives**. It provides information about the positive vial that was scanned, and enables you to view a list of vials related to the current one (if Show Related Vials is enabled in Configuration – Lab).

You are informed of positive vials by the following:

- RED System indicator illuminated
- Station indicators: FLASHING RED; or FLASHING YELLOW (AMBER) / RED (alternating) – Anonymous Positive
- Remove Positive vials indicator/button on Status display
- Positive vial audible alarm sounds
- Message box on screen
- Positive counter on activity displays

See Figure 5-2 for a sample positive removal display.

To access Positive Removal:

- Open a drawer and remove a positive vial, or
- Open a drawer and select **Remove Positives** on the Status display 

Positive Removal Fields:

Accession

Read-only field that shows the accession number of the vial.

Sequence

Read-only field that shows the vial barcode sequence number.

Medium

Read-only field that shows the medium type.

TTD

Read-only field that shows the Time to Detection, in days; hours; minutes. Time to Detection is calculated as the amount of time between the vial's Start of Protocol and when it is declared positive by the instrument. Time in Protocol is shown for Manual Positive vials.

Location

Read-only field that shows the station number from which the positive vial was removed.

Drawer X (where X is the current drawer)

Counters for positive vials (+), negative vials (–), blocked/unusable stations (⊗), ongoing vials (●), anonymous vials (?), and available stations (O).

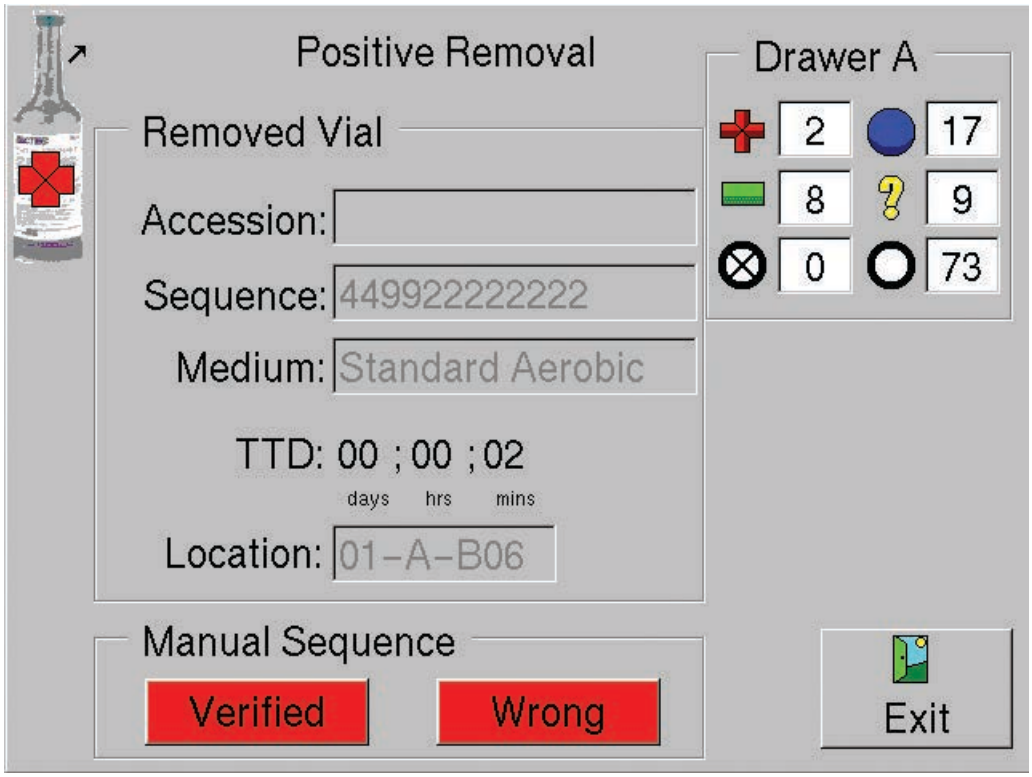


Figure 5-2 – Positive Removal Display

Manual Sequence window appears only if vial sequence number was originally entered manually (via onscreen keyboard)

Positive Removal Buttons:

Verified button

Appears only if the vial sequence number was entered manually. Select to confirm to the system that the displayed vial sequence number is correct.

Wrong button

Appears only if the vial sequence number was entered manually. Select to inform the system that the displayed vial sequence number is incorrect. Message WE06 then appears (see Section 7). Related vials are not shown if you select the wrong button.

Exit button 

Select to exit the display and return to the Status display.

5.3.2 Negative Removal Display

The Negative Removal display appears when you initiate the remove negative vials activity, by scanning a negative vial barcode sequence number, removing a negative or manual negative vial from a station, or by selecting **Remove Negatives**. It provides information about the negative vial that was scanned.

You are informed of negative vials by the following:

- GREEN System indicator illuminated
- Station indicators: FLASHING GREEN
- Remove Negative vials indicator/button on Status display
- Negative counter on activity displays

See Figure 5-3 for a sample negative removal display.

To access Negative Removal:

- Open a drawer and remove a negative vial, or
- Open a drawer and select **Remove Negatives** on the Status display 

Negative Removal Fields:

Accession

Read-only field that shows the accession number of the vial.

Sequence

Read-only field that shows the vial barcode sequence number.

Medium

Read-only field that shows the medium type.

TIP

Read-only field that shows the Time in Protocol, in days; hours; minutes. Time in Protocol is calculated as the amount of time between the vial's Start of Protocol and the current time.

Location

Read-only field that shows the station number from which the negative vial was removed.

Drawer X (where X is the current drawer)

Counters for positive vials (+), negative vials (–), blocked/unusable stations (⊗), ongoing vials (●), anonymous vials (?), and available stations (O).

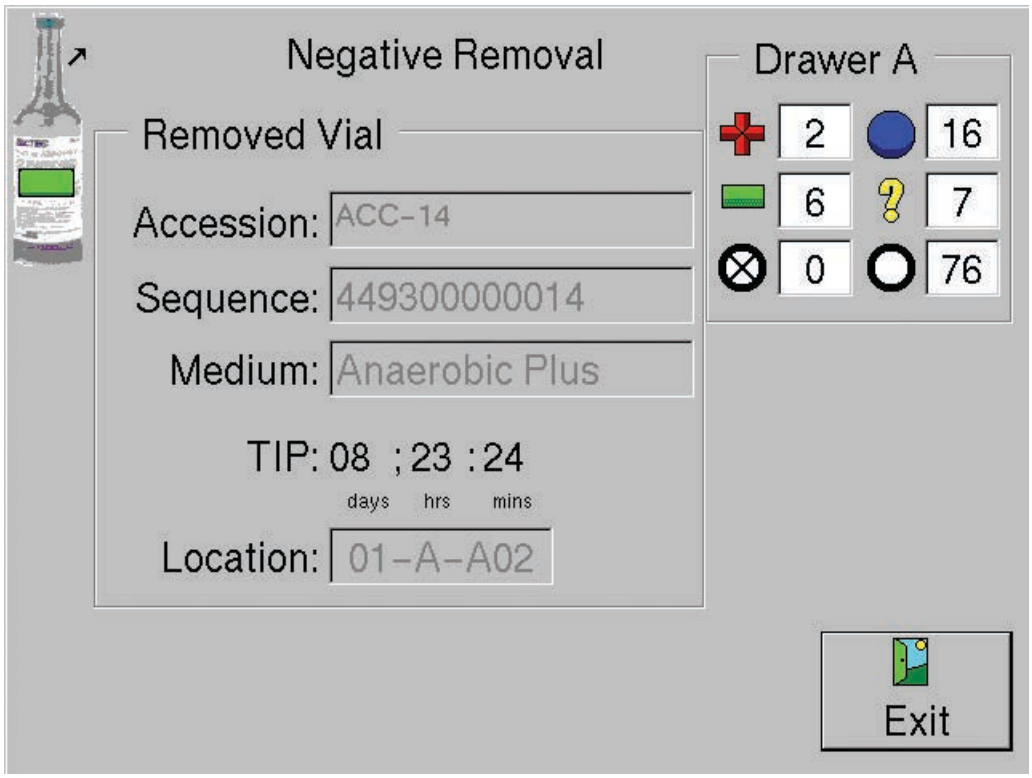


Figure 5-3 – Negative Removal Display

Negative Removal Buttons:

Verified button

Appears only if the vial sequence number was entered manually and Batch Removal is disabled. Select to confirm to the system that the displayed vial sequence number is correct.

Wrong button

Appears only if the vial sequence number was entered manually and Batch Removal is disabled. Select to inform the system that the displayed vial sequence number is incorrect. Message WE06 then appears (see Section 7).

Exit button 

Select to exit the display and return to the Status display.

5.3.3 ID(entify) Anonymous Display

The ID Anonymous display enables you to identify ongoing anonymous and positive anonymous vials. You are informed of anonymous vials by the following:

- Station indicators: FLASHING YELLOW (AMBER) – Ongoing Anonymous
  FLASHING YELLOW (AMBER) / RED (alternating) – Positive Anonymous
- Identify Anonymous Vials button active on Status display
- Anonymous counter on activity displays

In order to complete the identification process, you must place the vial into an available station or select **Save** if the vial is to be kept out of the instrument (e.g., a Positive Anonymous vial you have just identified).

Anonymous vials do not go out of protocol (Negative) until they are identified.

You cannot identify anonymous vials in an instrument that is in degraded mode.

See Figure 5-4 for a sample ID Anonymous display.

To access ID Anonymous:

- Open a drawer and remove a FLASHING YELLOW (AMBER) or FLASHING YELLOW (AMBER) / FLASHING RED vial, or
- Open a drawer and select **Identify Anonymous** on the Status display 

ID Anonymous Fields:

Accession

Scan or type in the accession number [up to 20 alphanumeric characters, excluding the following:

* ? [ ] ! # |

Accession number cannot be 12 digits long AND begin with the numbers "44."

Sequence

Scan or type in the vial barcode sequence number located on the vial label. Sequence number is a 12-digit number beginning with "44."

Medium

If the sequence number is scanned or typed in, the medium type is automatically entered in this field. You have to manually select a medium from the drop-down box for medium type "99" (replacement barcode).

Status

The current status of the vial. Statuses include: Ongoing, Positive. These statuses are explained in Section 4.2.5.

Protocol

The default protocol for the medium type entered is shown. To change this protocol, select **Modify** and refer to that information below.

Lot Expiration

This field shows lot number and expiration date of the vial.

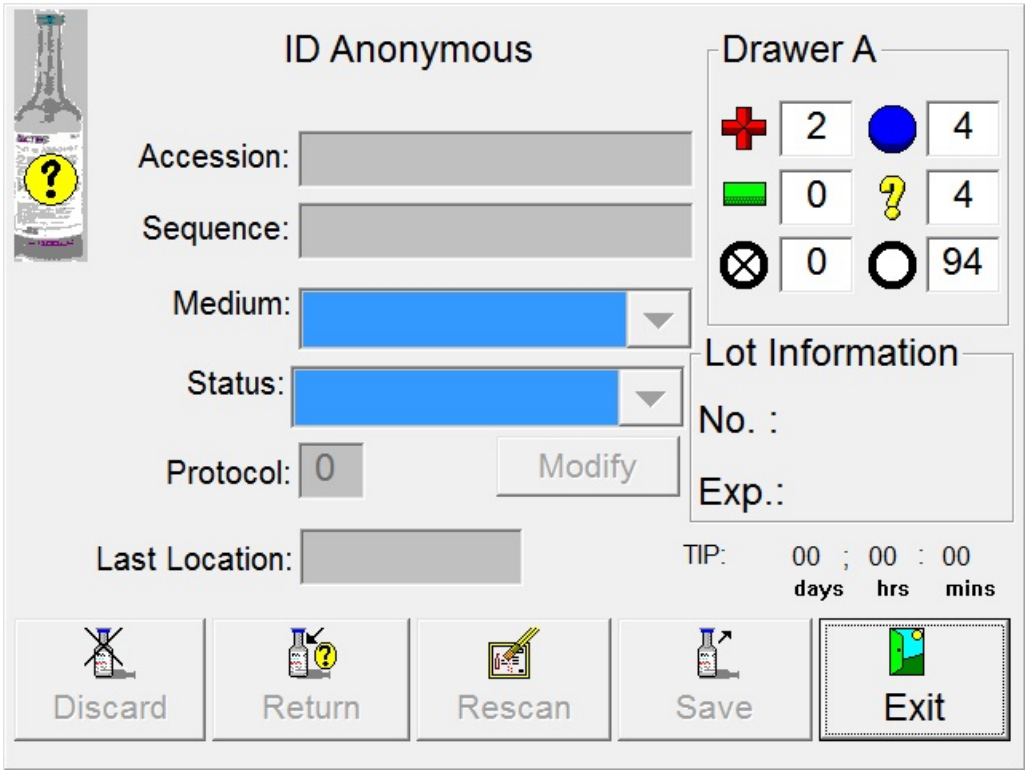


Figure 5-4 – ID Anonymous Display

Last Location

This field shows the station number from which the anonymous vial was removed.

TIP or TTD

Read-only field that shows the Time in Protocol (for ongoing vials) or Time to Detection (for positive vials), in days; hours: minutes.

Time in Protocol is calculated as the amount of time between the vial's Start of Protocol and the current time (if in the instrument) or removal time (if removed from the instrument).

Time to Detection is calculated as the amount of time between the vial's Start of Protocol and when it is declared positive by the instrument.

Drawer X (where X is the current drawer)

Counters for positive vials (+), negative vials (–), blocked/unusable stations (⊗), ongoing vials (●), anonymous vials (?), and available stations (O).

ID Anonymous Buttons:

Modify button

Select to bring up a window enabling you to change the vial's protocol length. This changes the protocol only for the current vial. To change the default protocol for a medium type, go to the Configuration – Lab display.

To modify the protocol, select the **Up Arrow** to increase the protocol. To decrease the protocol, select the **Down Arrow**. When the desired protocol appears, select **OK**. To exit the window without changing the protocol, select **Cancel**.

You can change a protocol up until the maximum protocol for that medium type is reached. Negative vials whose protocol is extended become Ongoing. Ongoing vials whose protocol is reduced and that go out of protocol become Negative when they receive their first test after reentry into the instrument.

Discard button 

Select to clear the information on the display and remove it from the database.

Return button 

Select to retain information for this vial in the database and return the vial to the instrument anonymously.

Rescan button 

Select to clear the sequence and accession (if scanned) on the display but retain the rest of the information for the pulled vial. Useful if an unintended vial was scanned during the ID Anonymous operation.

Save button 

Select to save the information on the display for vials that are *not* going to be reentered immediately into the instrument (e.g., to stain and subculture a Positive Anonymous vial you have just identified).

Exit button 

Select to exit the display and return to the Status display.

5.3.4 Vial Entry Display

The Vial Entry display is used for entering vials into the instrument. The display shows information about the vial currently being entered and about the current drawer.

Typically you access Vial Entry to scan one or more new vials to enter them into the instrument. The information for each scanned vial appears on the display.

To save the current information, place the vial into an available station.

To clear the display without saving any information, select **Clear**.

Vial Entry cannot be performed at an instrument in degraded mode in a BD EpiCenter™ configuration.

See Figure 5-5 for a sample Vial Entry display.

To access Vial Entry:

Open a drawer and scan a new vial sequence or accession barcode, or

Open a drawer and select **Vial Entry** on the Status display 

Vial Entry Fields:

Barcoding icon  

At the top left of the display either a single-height or double-height barcode appears. The single-height barcode indicates that only sequence barcode scans are accepted on the Vial Entry display (i.e., Accession Barcoding is disabled). The double-height barcode indicates that both sequence and accession barcode scans are accepted (i.e., Accession Barcoding is enabled). Accession barcoding is enabled/disabled in the Configuration – Lab display.

Accession

Scan or type in the accession number, up to 20 alphanumeric characters, excluding the following:

* ? [ ] ! # |

Accession number cannot be 12 digits long AND begin with the number “44.” The barcode scanner does not turn on for accession scanning if accession barcoding is disabled in Configuration – Lab.

Sequence

Scan or type the vial barcode sequence number located on the vial label. Sequence number is a 12-digit number beginning with “44.”

Medium

If the sequence number is scanned or typed, the medium type is automatically entered in this field. If the sequence number contains the code for a replacement media label (##**99**########), you can select this field and select the appropriate medium from a drop-down list of configured media.

Lot Expiration

This field shows lot number and expiration date of the vial.

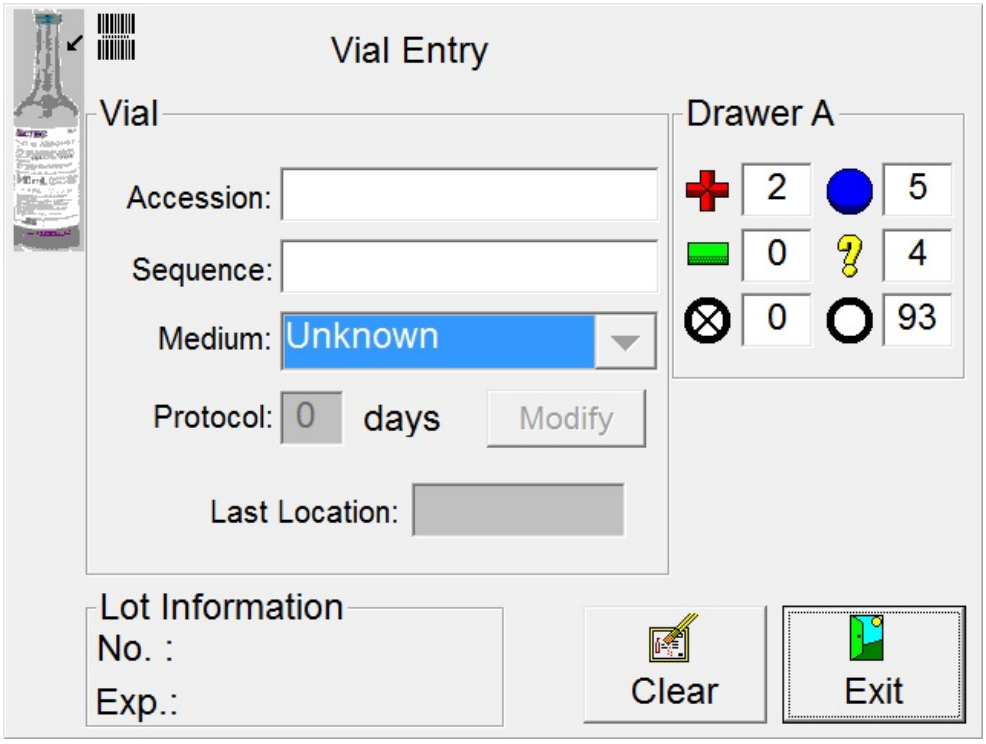


Figure 5-5 – Vial Entry Display

Protocol

The default protocol for the medium type entered is shown. To change this protocol, select **Modify** and refer to that information below.

Last Location

If the vial was previously entered in the instrument, this field shows the station number from which the vial was removed. If you have scanned a new vial (pending status), or an unknown sequence number, the field remains blank.

Drawer X (where X is the current drawer)

Counters for positive vials (+), negative vials (–), blocked/unusable stations (⊗), ongoing vials (●), anonymous vials (?), and available stations (O).

Vial Entry Buttons:

Modify button

Select to bring up a window enabling you to change the vial's protocol length. This changes the protocol only for the current vial. To change the default protocol for a medium type, use the Configuration – Lab display.

To modify the protocol, select the **Up Arrow** to increase the protocol. To decrease the protocol, select the **Down Arrow**. When the desired protocol appears, select **OK**. To exit the window without changing the protocol, select **Cancel**.

You can change a protocol up until the maximum protocol for that medium type is reached. Negative vials whose protocol is extended become Ongoing. Ongoing vials whose protocol is reduced, and that go out of protocol, become Negative when they receive their first test after reentry into the instrument.

Clear button 

Select to clear the information currently on the display. This enables you to not save the information for the current vial.

Exit button 

Select to exit the display and return to the Status display.

5.3.5 System Alerts Display

The System Alert display shows a list of system alerts that have occurred. (Workflow messages are not displayed.) The last 100 alerts are shown in the display, from the most recent (top) to oldest (bottom). The list is updated dynamically.

You can print the alert listing, delete the entire listing, or delete individual alerts. Any currently active alerts are indicated by an exclamation mark at the left side of the display. Active alerts cannot be deleted from the listing until the alert condition is cleared.

To select a message to view a detail window or delete the message, select the message in the scrollable alert window. Alerts still print on the Alert List report even if they are removed from the display.

The System Alerts button is grayed out when there are no alerts to display.

See Figure 5-6 for a sample System Alerts display.

To access System Alerts:

From the Status display, select **System Alerts** 

System Alerts Buttons:

Info button 

Active if a single message is highlighted, inactive if no message or more than one message is highlighted.

Select to pop up a read-only detail window showing the time that the alert occurred, the time that the alert was cleared (if applicable), and the full text of the alert message.

Remove All button 

Select to delete all the non-active messages from the list. This button is always active.

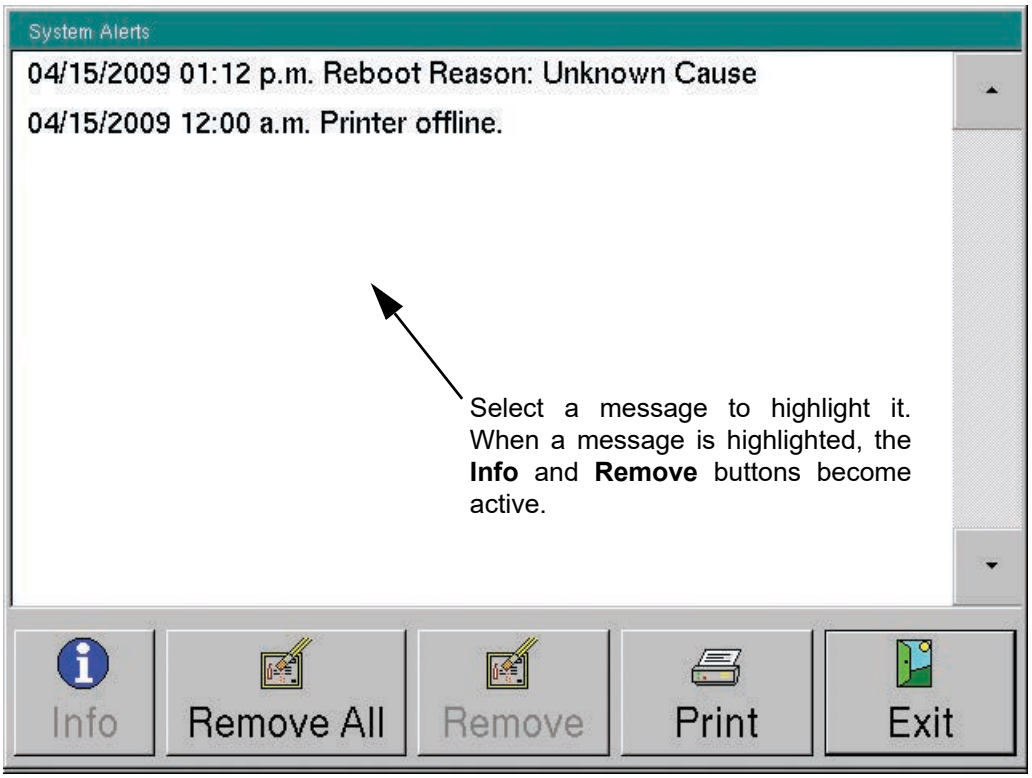


Figure 5-6 – System Alerts Display

Remove button 

This button is active if a message is highlighted, inactive if no message is highlighted. To select a message for deletion, select the message in the list. To select multiple messages, tap each one you want to select. To deselect a message that is selected, tap the message again. You cannot delete active alerts.

Tap to delete the highlighted message(s) from the list.

Print button 

Select to print the Alert List report. The report contains the latest 100 system alerts in the instrument database, even if the alerts have been removed from the System Alerts display. Reports cannot be printed at an instrument in degraded mode in a BD EpiCenter™ configuration.

Exit button 

Select to exit the display and return to the Status display.

5.3.6 Drawer View Display

The Drawer View display appears when you select the Drawer View button on the Status display. It provides an iconic view of all the drawer's stations, showing the status of each station. Drawer View is updated dynamically when vial statuses change.

You can access the Culture – Vial display from Drawer View by selecting the station then selecting **OK.**

See Figure 5-7 for a sample Drawer View display.

To access Drawer View:

From the Status display, select the **Drawer View** button 

Drawer View Fields:

Station statuses

The following station statuses are shown:

	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

Location

Read-only field showing the current selected station. That station is also highlighted with a gray box surrounding it. To select a Location (station), tap the station in the left portion of the display.

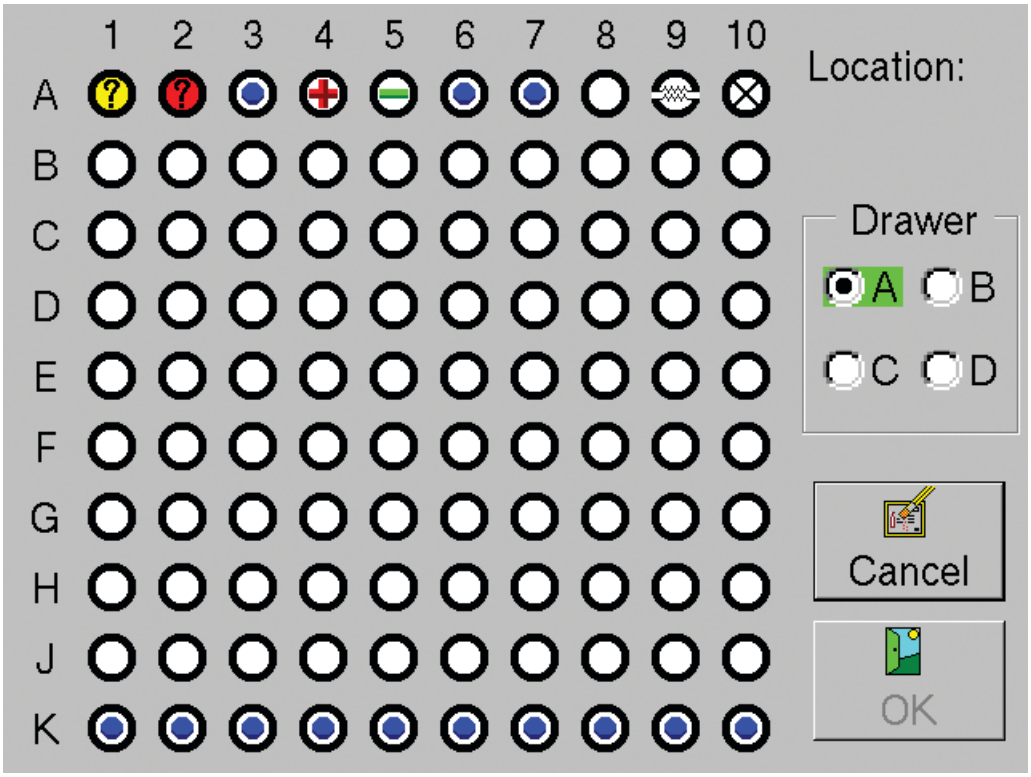


Figure 5-7 – Drawer View Display

Drawer View Buttons:

Drawer radio button

Selected drawer is indicated by filled in radio button. Any currently open drawer is highlighted in green. To select a different drawer, select the empty radio button to the left of the letter (A, B, C, D).

Cancel button 

Select to exit the display and return to the Status display.

OK button 

Select to access the Culture – Vial display for the station shown in the Location field.

5.3.7 Culture – Patient Display

Culture – Patient appears when you select Culture from the Status display. It shows patient related information for any specimens. Culture – Patient is primarily intended for searching for specimens attached to a particular patient record. These functions can be performed:

- Recall all specimen records for the entered patient ID
- Disassociate an accession from the patient record (see Disassoc(iate) button below)
- Change a patient name

When the Culture – Patient display is first accessed, it is in search mode (indicated by Search icon at top left of the display. To locate the desired information, select either the Patient ID or Patient Name field and enter the characters to search for via the onscreen keyboard. For Patient ID, you must enter the whole ID. For Patient Name, you can enter a partial name. Select **Enter** to exit the Keyboard display and execute the search. You cannot search if you do not enter characters in the Patient ID or Patient Name field.

Any specimen records appear in the Specimen window (bottom half of display). Initially, the first specimen record is highlighted. You can select the Specimen or Vial tabs to see additional information on the highlighted specimen.

When new information is added, or a field is changed, the field name appears highlighted until the information is saved.

The barcode readers are disabled when the Culture – Patient display is in use.

When LIS is enabled, the Culture – Patient display is confined to Search mode.

Note that in a BD EpiCenter™ configuration, you cannot enter Patient ID or Patient Name at the instrument. Also you cannot disassociate a specimen (accession) from a Patient ID. These operations can only be performed at the BD EpiCenter™ system.

You cannot access Culture displays in an instrument that is in degraded mode.

To access Culture – Patient:

From the Status display, select **Culture** 

Culture – Patient Display Fields:

Patient ID

Select the blank field to access the onscreen keyboard. Enter up to 16 characters, excluding the following:

* [ ] | ? !

Once the record is saved, the Patient ID cannot be modified.

Patient ID cannot exist without associated vials/specimens. Patient ID can exist without a Patient Name.

Patient Name

Select the blank field to access the onscreen keyboard. Enter up to 40 characters, excluding the following:

* [ ] | ? !

You cannot enter a Patient Name without a Patient ID attached.

Specimen Window, showing the following read-only information (left to right, for each specimen associated to the patient record)

Positive vial indication (+ indicates at least one associated positive/manual positive vial)

Accession

Date

Time

Culture – Patient Display Buttons/Icons:

Search Mode indicator 

A binocular icon appears at the top left of the display when it is in search mode.

Add Mode indicator 

A patient icon with a plus sign appears at the top left of the display when it is in add mode.

This icon appears only when BD EpiCenter™ communications is disabled.

Disassoc(iate) button 

Select to disassociate a specimen (accession) from the patient record. The specimen to be disassociated must be selected in the Specimen Window. If all specimens are disassociated from the patient record, the record is removed from the database.

This button is active only when BD EpiCenter™ communications is disabled.

Save button 

Select to save any new or modified information to the database.

Clear button 

Select to clear the information currently on the display (all 3 tabs).

Exit button 

Select to exit the display and return to the Status display.

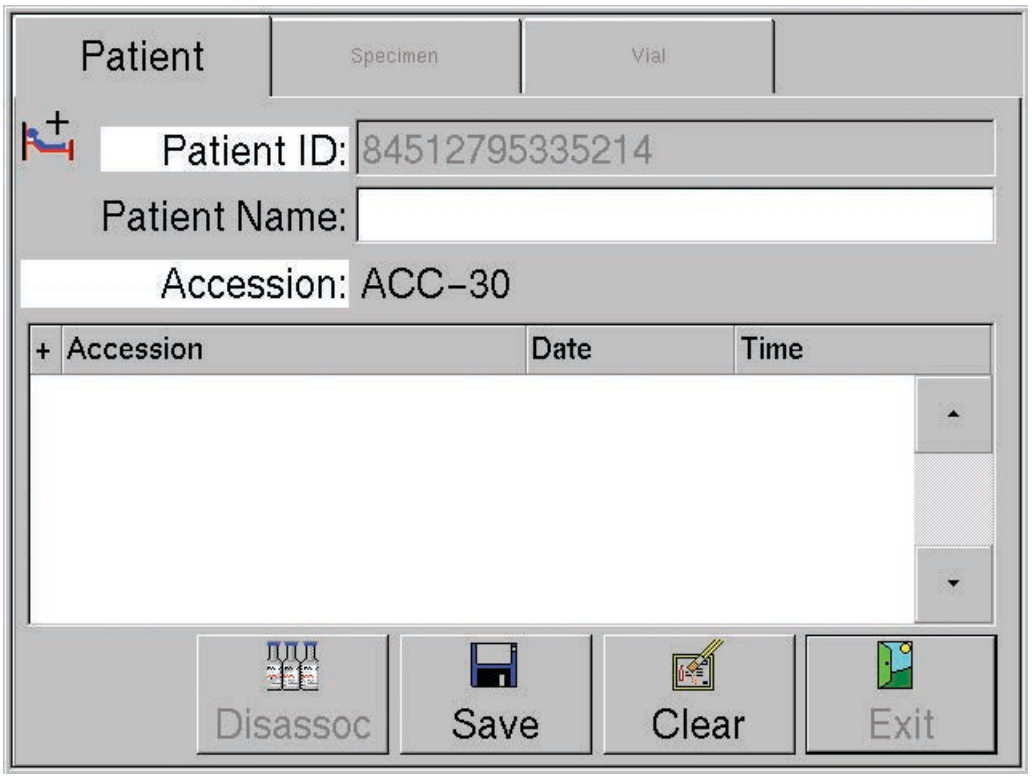


Figure 5-8 – Culture – Patient Display (add mode)

Highlighted field names indicate information that is added or changed.

5.3.8 Culture – Specimen Display

The Culture – Specimen display enables you to add or recall information on specimens (accessions). The following functions can be performed:

- Recall a specimen to add or modify information
- Disassociate a vial from an accession number (see Disassoc(iate) button below)
- Associate vials (scannable sequence numbers) to an accession number
- Create specimen record and add patient information at the Culture – Patient tab

Culture – Specimen can be accessed from either the Culture – Patient or Culture – Vial tab when you select the Specimen tab from one of those displays.

Any specimen records appear in the Specimen window (bottom half of display). Initially, the first specimen record is highlighted. Select the **Specimen** or **Vial** tabs to see additional information on the highlighted specimen.

When new information is added, or a field is changed, the field name appears highlighted until the information is saved.

Note that in a BD EpiCenter™ configuration, you cannot enter Hospital Service or Collection Date\Time at the instrument. This operation can only be performed at the BD EpiCenter™ system.

You cannot access Culture displays in an instrument that is in degraded mode.

To access Culture – Specimen:

From the Status display, select **Culture** 

From the Culture – Patient display, select the **Specimen** tab

Culture – Specimen Display Fields:

Accession

For a new specimen record, enter up to 20 alphanumeric characters, excluding the following:

* ? [ ] ! # |

Accession number cannot be 12 digits long AND begin with the number "44."

Once it is saved, an accession number cannot be changed.

An accession can be saved with no vials attached.

To recall a specimen record, enter an existing accession number. You must enter the whole accession number.

Collection Date\Time

Enter the date and time when the specimen was collected. See Set button below.

Service

Select the field to access the onscreen keyboard. Enter up to 6 characters excluding the following:

* ? [ ] ! # |, to designate the hospital service or ward.

Vial Window, showing the following read-only information (left to right, for each vial associated to the accession)

Pending changes (* indicates vial association is pending a save to the database)

Sequence

Location (last known station number; `Removed` if vial is no longer in instrument; `Pending` if vial has never been placed in instrument; `Offline` if vial was last known to be in a degraded mode instrument or an offline row or drawer)

Status (last known status: see Section 4.2.5)

Culture – Specimen Display Buttons:

Set button

Select to bring up a window enabling you to set the vial's collection date and time. The Set Date and Time window appears. Refer to Section 2.4.5 for instructions on setting date and time.

This button is active only when BD EpiCenter™ communications is disabled.

Add button 

Select to add patient data to the displayed specimen record. This button is active only when an orphan accession is displayed and when BD EpiCenter™ communications is disabled.

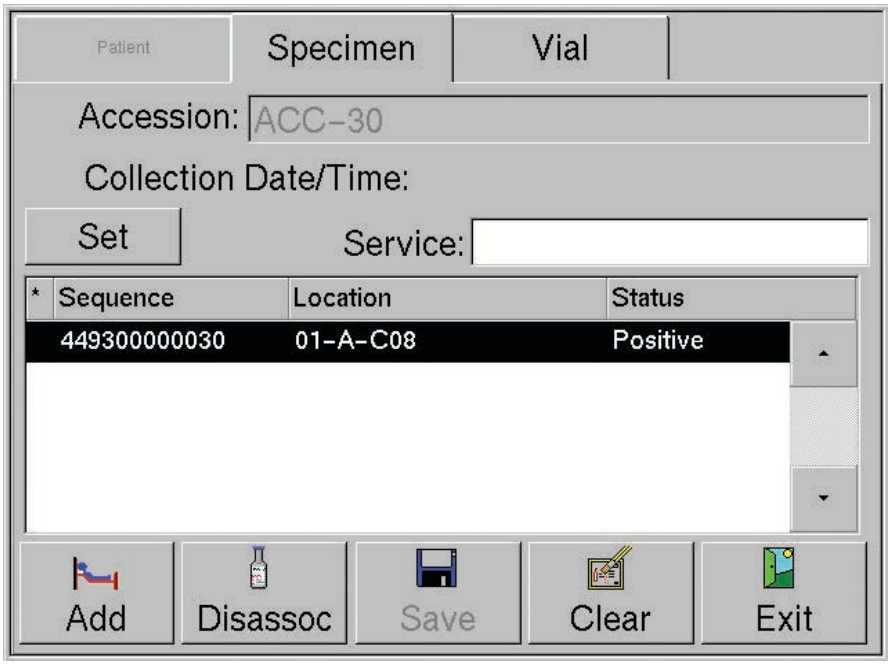


Figure 5-9 – Culture – Specimen Display

Disassoc(iate) button 

Select to disassociate the current vial (sequence) from the accession number. The vial to be disassociated must be selected in the Vial window.

Save button 

Select to save any new or modified information to the database.

Clear button 

Select to clear the information currently on the display (all 3 tabs).

Exit button 

Select to exit the display and return to the Status display.

5.3.9 Culture – Vial Display

The Vial tab on the Culture display is primarily used to view or enter information about individual vials, and to perform specialized functions related to vials. The following functions can be performed:

- Add information for a new vial (see field requirements below)
- Recall a vial to add or modify vial information (scan or type in the vial sequence number to recall data)
- Disassociate a vial from an accession number (see Disassoc(iate) button below)
- Associate an orphan vial to an accession number
- Force a vial manually positive or negative (see Status below)
- View or print a vial plot (see Plot button below)

When new information is added, or a field is changed, the field name appears highlighted until the information is saved.

You cannot access Culture displays in an instrument that is in degraded mode.

See Figure 5-10 for a sample Culture – Vial display.

To access Culture – Vial:

From the Status display, select **Culture** 

From the Culture – Patient display, select the **Vial** tab

or

From the Status display, select **Drawer View** 

In the Drawer View display, select the desired station

Select **OK**

Culture – Vial Display Fields:

Accession

Scan or type in the accession number up to 20 alphanumeric characters, excluding the following:

* ? [ ] ! # |

Accession number cannot be 12 digits long AND begin with the number "44."

Sequence

Scan or type in the vial barcode sequence number located on the vial label. Sequence number is a 12-digit number beginning with "44."

Medium

If the sequence number is scanned or typed in, the medium type is automatically entered in this field. If a replacement barcode is scanned (medium type 99), the correct medium type can be selected by selecting the arrow next to the `Unknown` medium type, and selecting the correct medium type.

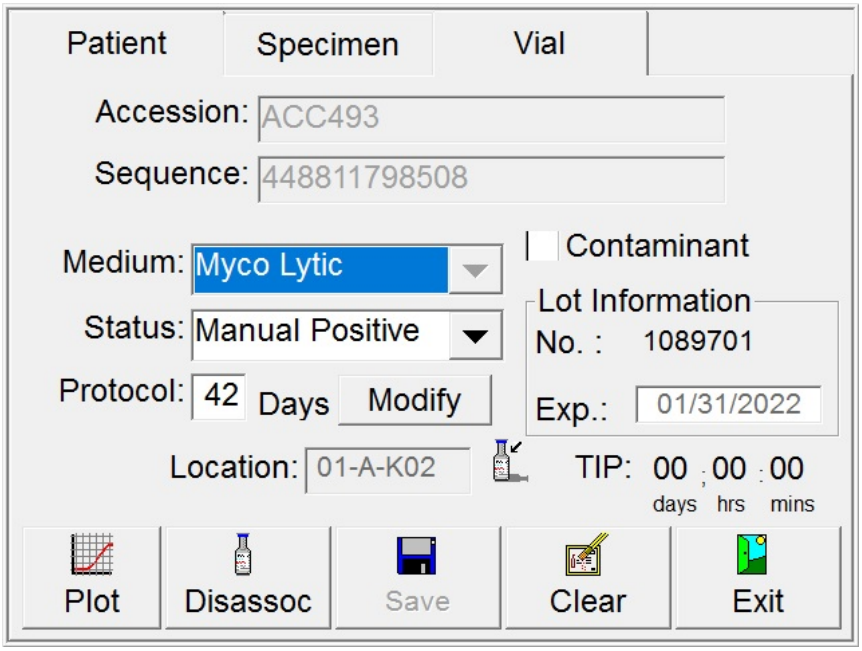


Figure 5-10 – Culture – Vial Display

Status

The current status of the vial. Statuses include: Pending, Ongoing, Positive, Negative. These statuses are explained in Section 4.2.5. In addition, you can select Manual Positive or Manual Negative in the drop-down box if you have determined through offline testing that a vial is positive or negative.

Contaminant checkbox

If the vial status is Positive or Manual Positive and the state is not Anonymous, this checkbox appears. Check the box to indicate that testing has confirmed that the organism is a contaminant. The default value is unchecked.

Protocol

The default protocol for the medium type entered is shown. To change this protocol, select **Modify** and refer to that information below.

Location

This field shows the last known station for the vial. If the vial is still in the instrument, it shows the current station (see In Instrument indicator below). If the vial has been removed from the instrument, it shows the last known station.

If no vial has been recalled (all fields blank), you can select the Location field and select a vial from the Drawer View display to recall the vial information.

Offline indicator 

When this icon appears between the Location and TIP/TTD fields it indicates that the vial is currently in a drawer or row that is offline.

In Instrument indicator 

When this icon appears between the Location and TIP/TTD fields it indicates that the vial is currently in the instrument.

TIP or TTD

Read-only field that shows the Time in Protocol (for all vials other than Positive or Pending status) or Time to Detection (for positive vials), in days; hours: minutes.

Time in Protocol is calculated as the amount of time between the vial's Start of Protocol and the current time (if in the instrument) or removal time (if removed from the instrument).

Time to Detection is calculated as the amount of time between the vial's Start of Protocol and when it is declared positive by the instrument.

Lot Expiration

This field shows lot number and expiration date of the vial.

Culture – Vial Display Buttons:

Modify button

Select to bring up a window enabling you to change the vial's protocol length. This changes the protocol only for the current vial. To change the default protocol for a medium type, go to the Configuration – Lab display.

To modify the protocol, select the **Up Arrow** to increase the protocol. To decrease the protocol, select the **Down Arrow**. When the desired protocol appears, select **OK**. To exit the window without changing the protocol, select **Cancel**.

The button is enabled only if the vial is eligible to have its protocol changed (i.e., the vial is not anonymous or is not an `Unknown` media type).

Plot button 

Select to generate a plot or graphical display of test readings for a station. See Plot Display below for additional information.

Disassoc(iate) button 

Select to disassociate the current vial from the accession number.

Save button 

Select to save any new or modified information to the database.

Clear button 

Select to clear the information currently on the display (all 3 tabs).

Exit button 

Select to exit the display and return to the Status display.

5.3.10 Plot Display

The Plot display enables you to generate a line graph, or plot, of the test readings of a specified non-pending station. Both Fluorescence units and Positivity are shown on the graph.

Plot displays all test readings for a vial that are stored in the database.

The interpretation of plot graph information is not to be substituted for established laboratory procedures for determining the final positive or negative status of a culture.

To plot a vial's readings, select the **Location** field on the Culture – Vial display. In the Drawer View display that appears, select the desired station, then select **OK**. You are returned to the Culture – Vial display. Select **Plot** to display the plot.

You can plot vials for up to 14 days after their removal from the instrument.

You cannot access the Plot Display in an instrument that is in degraded mode.

See Figure 5-11 for a sample Plot display.

To access Plot:

- From the Status display, select **Culture** 
- From the Culture – Patient display, select the **Vial** tab
- Enter a vial sequence number in the Sequence field, or select the Location field and select a station from the Drawer View display by tapping it, then selecting **OK** (note that you may plot any vial that is still in the database, provided its status is not Pending)
- From the Culture – Vial display, select **Plot** 

Plot Display Fields:

Accession

Read-only field that shows the accession number of the vial.

Sequence

Read-only field that shows the vial barcode sequence number. If the vial is Anonymous, the value "`Anonymous`" is shown as the sequence number.

Last Loc(ation)

Read-only field that shows the most recent station number to which the vial was/is assigned.

Plot readings

Fluorescence units and Positivity readings are plotted on the y-axis (vertically). Readings are indicated by red x's and are labeled Fluorescence. Positivity is indicated by blue squares. These readings occur every 10 minutes unless testing or communications is interrupted (e.g., by a door opening).

The values for units shown will vary among different patients, media types, volumes of inocula, etc.

The x-axis represents time. Time is shown as days; hours (dd;hh). The number of days and hours may vary depending on whether the data must be compressed due to the length of the protocol.

When a vial is declared positive, it is shown by the positivity line (blue squares) jumping from low to high across the Fluorescence readings.

Medium

Read-only field that shows the medium type. If the medium type is unknown, the vial is either Anonymous, or a replacement sequence barcode was entered for the vial.

Status

Read-only field that shows the current status of the vial. Statuses include: Ongoing, Positive, Negative, Manual Positive, or Manual Negative. A vial with a Pending status cannot be plotted.

SOP

Read-only field that shows the Start of Protocol date and time.

TIP or TTD

Read-only field that shows the Time in Protocol (for ongoing and negative vials) or Time to Detection (for positive vials), in days; hours: minutes (dd; hh: mm).

Time in Protocol is calculated as the amount of time between the vial's Start of Protocol and the current time (if in the instrument) or removal time (if removed from the instrument).

Time to Detection is calculated as the amount of time between the vial's Start of Protocol and when it is declared positive by the instrument.

Plot Display Buttons:

Print button 

Select to print the displayed plot. Once you print the plot, the button is disabled until you exit and re-enter a Plot display.

The Plot Report is essentially a printout of the Plot display, printed in landscape mode, with the addition of the following items at the top of the page: Hospital information (if configured), the Instrument number, Software version, and Date/Time the plot was printed.

Exit button 

Select to exit the plot display and return to the Culture – Vial display.

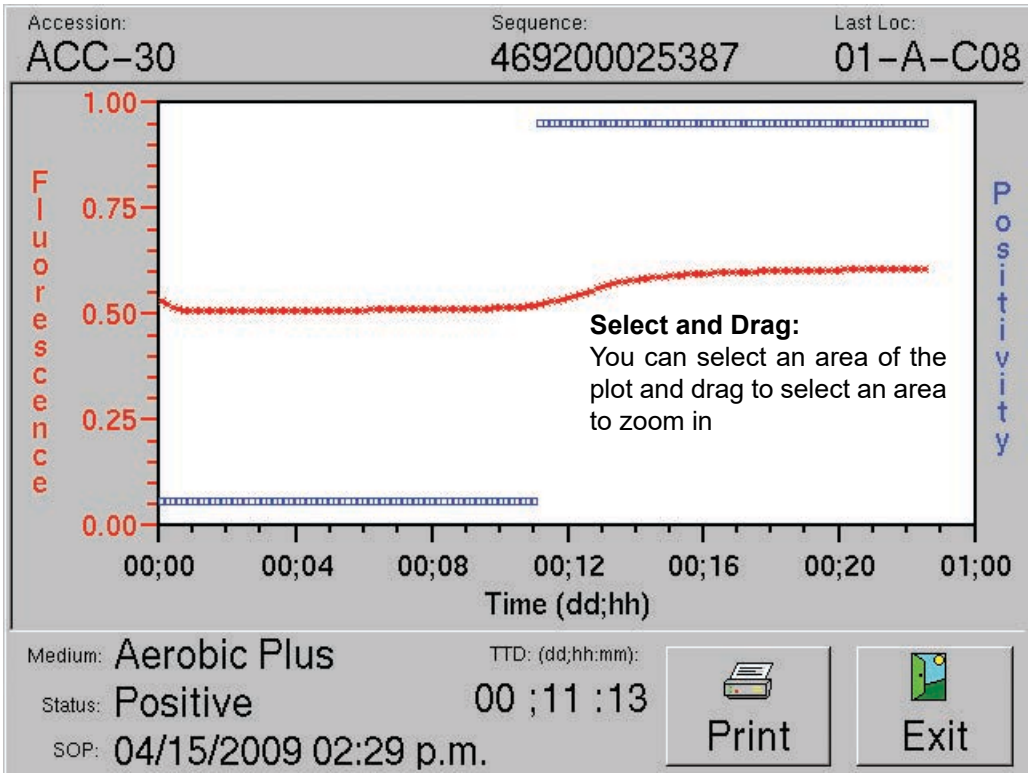


Figure 5-11 – Plot Display

5.4 Reports Menu

The Reports Menu enables you to select reports to be printed. To access the Reports menu, select the **Reports** tab. The display in Figure 5-12 appears.

The following reports are available:

- Affected Vials (5.4.1)
- Alert List (5.4.2)
- Contaminant Vials (5.4.3)
- Culture Summary (5.4.4)
- Current Inventory (5.4.5)
- Current Negatives Report (5.4.6)
- Current Positives Report (5.4.7)
- Loaded Vials (5.4.8)
- Maintenance QC (5.4.9)
- No Growth Accession (5.4.10)
- Orphan Vials (5.4.11)
- Partially Seated Stations (5.4.12)
- Pending (5.4.13)
- Unloaded Negative Vials (5.4.14)
- Unloaded Positive Vials (5.4.15)
- Unloaded Vials (5.4.16)

Each of the reports is discussed in greater detail in the sections shown above.

The instrument retains culture data for 60 after an accession's last vial is removed. After 60 days, the instrument purges vial data. If there is no data in the database that meets the reporting criteria, the message "`No Data Available to Report`" is printed in the body of the report. If a report contains a vial residing in a station, drawer, or instrument that is offline, that line of the report is flagged and the message "`* - Indicates Latest Reported Data from Currently Offline Station`" is shown on the relevant pages of the report.

The instrument calculates the approximate size of the report before printing. If the instrument estimates a report to be more than 50 pages, a message box appears. To print the report, you must respond **Yes** to the initial WE35 message, then respond **OK** on the resulting CS22 message box.

Reports cannot be printed at an instrument in degraded mode in a BD EpiCenter™ configuration. Reports only contain information for the instrument at which they are requested. For system-wide data, you should print the report from the BD EpiCenter™ system (if configured).

To print a report:

- Access the Reports menu by selecting the **Reports** tab
- Highlight the desired report by selecting it in the menu
- Select the desired Time/Sort/Report criteria
- Select **Print** 

A message box confirms that the report has been spooled to the printer.

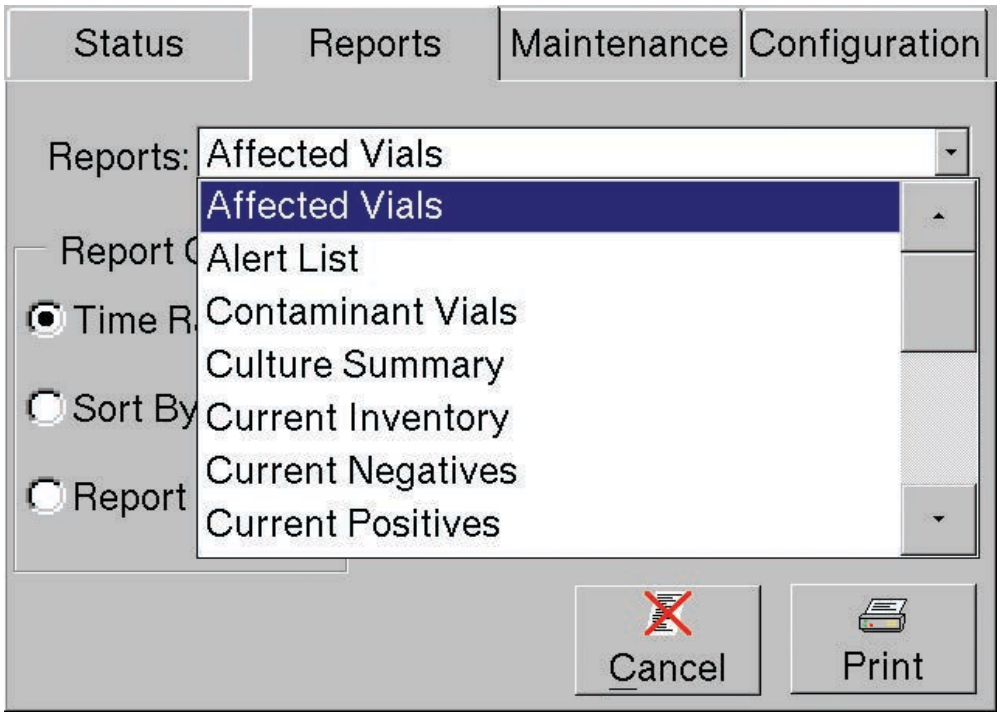


Figure 5-12 – Reports Menu (initial list)

General Selection Criteria:

Different reports have different criteria for selecting the data to be reported (filtering) or for sorting and/or organizing that data. If a specific criterion is not applicable to the selected report, the screen indicates "`Time Range/Sort By/Report By does not apply`."

The following criteria may be used (depending on the report):

Time Range

Enables you to select a starting and ending date for the report. This is a data filtering parameter, meaning it allows you to restrict what information is reported.

Sort By

Enables you to select an alternate sort order (up to 2) for the report. The default sort order is by Accession, then by Sequence. This parameter provides flexibility in organizing the report data.

The instrument presents sorted information (with demographic sort criteria) in the following groups: anonymous vials first, then orphan vials, then vials with sequence numbers/ accessions.

Report By

Enables you to select filters based on field contents for the information reported (such as specific media types, hospital services, etc.). Only one report by criterion can be chosen each time the report is printed.

5.4.1 Affected Vials

The Affected Vials Report 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. These affected vials are grouped into 2 report sections: Incubation Failures, and Reading Gap Failures. Both sections always print when the report is requested. Anonymous vials are included only while they are in the instrument. All sequenced vials are included in the report, even if they are removed. The report prints in landscape mode. The report provides the following information:

Header: Selection/Sorting/Reporting Criteria, Hospital Information (if configured), Instrument Number, Instrument Software Version, Report Title, type of failure that affected the vials (Incubation Failure or Reading Gap Failure), and Date and Time Printed

Body of Report: (columns from left to right): Accession, Patient Name (30 characters), Patient ID, Sequence, Test*/Protocol, Status*, State (column not labeled, body of report shows: ? for anonymous, vial icon for current, or blank for removed/pending), Service, Location, TIP/TTD (Time in Protocol for negatives and manual positives, Time To Detection for positives), "was Positive" indicator (plus sign [+] at end of line indicates that a vial that is not currently Positive previously had a positive result)

* See Section 11 for Glossary.

Applicable Selection Criteria:

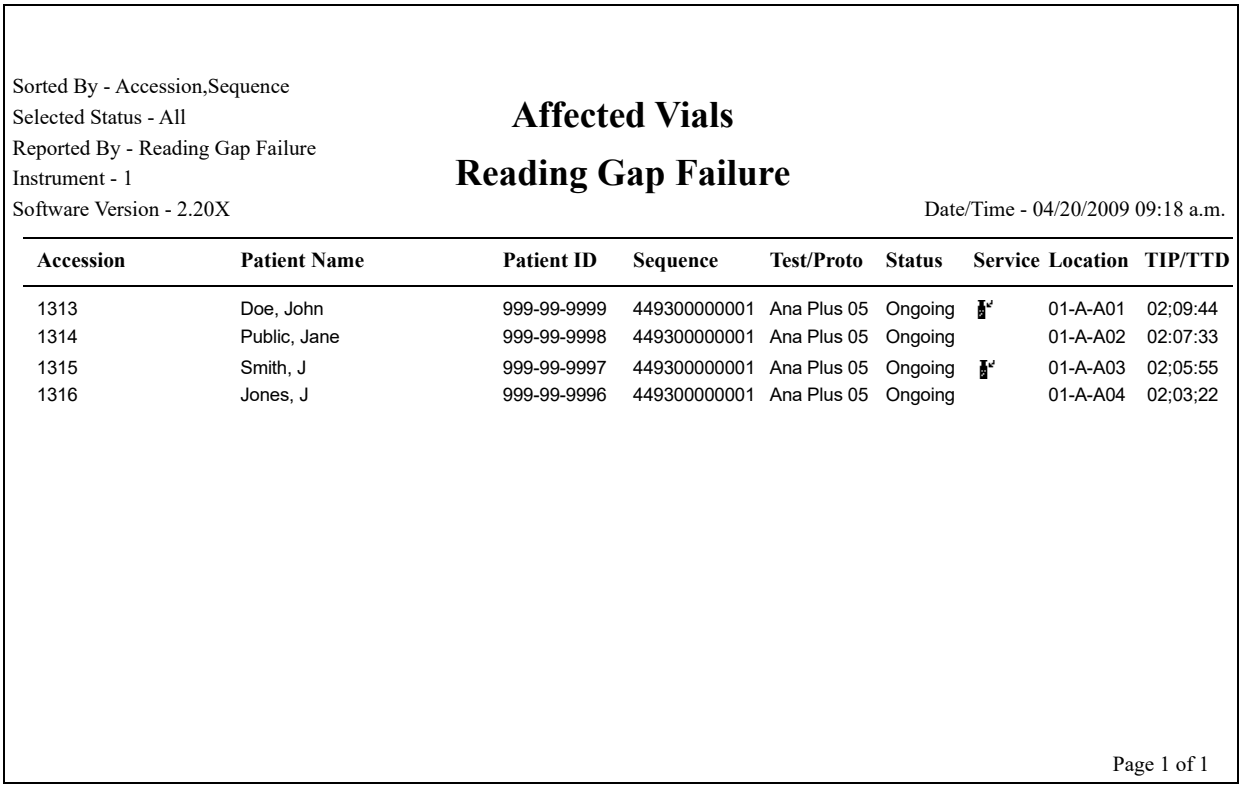
Sort By

See Figure 5-13 for a sample Affected Vials report.

To print an Affected Vials Report:

1. From the Status display, select the **Reports** tab to access the Reports menu.
2. Select the desired report in the menu.
3. Select the desired report criteria by selecting the radio button next to the criteria.

   Sort By: Choose 1st and 2nd Sort By field of either: Accession, Hospital Service, Media (alphabetic), Patient ID, Patient Name, Sequence, Start of Protocol, Location, Status, or None. The default sort order is by Accession, then by Sequence.
4. Select **Print** to print the report.



Sorted By - Accession,Sequence
Selected Status - All
Reported By - Reading Gap Failure
Instrument - 1
Software Version - 2.20X

Affected Vials

Reading Gap Failure

Date/Time - 04/20/2009 09:18 a.m.

Accession	Patient Name	Patient ID	Sequence	Test/Proto	Status	Service	Location	TIP/TTD
1313	Doe, John	999-99-9999	449300000001	Ana Plus 05	Ongoing		01-A-A01	02;09:44
1314	Public, Jane	999-99-9998	449300000001	Ana Plus 05	Ongoing		01-A-A02	02:07:33
1315	Smith, J	999-99-9997	449300000001	Ana Plus 05	Ongoing		01-A-A03	02;05:55
1316	Jones, J	999-99-9996	449300000001	Ana Plus 05	Ongoing		01-A-A04	02;03;22

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Figure 5-13 – Sample Affected Vials Report (Reading Gap portion only)

5.4.2 Alert List

The Alert List report lists the latest 100 instrument alerts. The report provides the following information:

Header: Hospital information (if configured), Instrument Number, Instrument Software Version, Report Title, and Date and Time Printed

Body of Report (columns from left to right): Message ID number, Time that the Alert occurred (Set Time), Time that the Alert was cleared (Clear Time), Description of the Alert

Applicable Selection Criteria:

N/A

See Figure 5-14 for a sample Alert List report.

To print an Alert List Report:

1. From the Status display, select the **Reports** tab to access the Reports menu.
2. Select the desired report in the menu.
3. Select **Print** to print the report.

Instrument - 1

Alert List

Software Version - 1.00X

Date/Time - 09/22/2007 09:18 a.m.

ID	Set Time	Clear Time	Description
!38	09/21/2007 11:19 a.m.	09/21/2007 11:19 a.m.	Drawer A: Contains a vial with a reading gap. Consult manual.
26	09/20/2007 03:42 p.m.	09/20/2007 03:43 p.m.	Drawer A: Drawer open too long.
11	09/20/2007 02:31 p.m.	09/20/2007 02:31 p.m.	Printer offline.

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Figure 5-14 – Sample Alert List Report

5.4.3 Contaminant Vials

The Contaminant Vial Report lists all the vials in the database that have been marked as "contaminant." The report prints in landscape mode. The report provides the following information:

Header: Selection/Sorting/Reporting Criteria, Hospital Information (if configured), Instrument Number, Instrument Software Version, Report Title, and Date and Time Printed

Body of Report (columns from left to right): Accession, Patient Name (30 characters), Patient ID, Sequence, Test*/Protocol, Status*, State (column not labeled, body of report shows: ? for anonymous, vial icon for current, or blank for removed/pending), Service, Location, TIP/TTD (Time in Protocol for negatives and manual positives, Time To Detection for positives), "was positive" indicator (plus sign [+] at end of line indicates that a vial that is not currently Positive previously had a positive result)

* See Section 11 for Glossary.

Applicable Selection Criteria:

Time Range Sort By

See Figure 5-15 for a sample Contaminant Vials report.

To print a Contaminant Vials Report:

1. From the Status display, select the **Reports** tab to access the Reports menu.
2. Select the desired report in the menu.
3. Select the desired report criteria by selecting the radio button next to the criteria.

   Time Range: Select the **From:** and **To:** buttons to select the start and end times (Start of Protocol). The default time range is from midnight yesterday.

   Sort By: Choose 1st and 2nd Sort By field of either: Accession, Hospital Service, Media (alphabetic), Patient ID, Patient Name, Sequence, Start of Protocol, Location, Status, or None. The default sort order is by Accession, then by Sequence.
4. Select **Print** to print the report.

Sorted By - Accession,Sequence
Selected Status - All
Reported By - Contaminant:
Instrument - 1
Software Version - 2.20X

Contaminant Vials

From 04/20/2009 12:00 a.m. To 04/20/2009 09:19 a.m. Date/Time - 09/22/2009 09:18 a.m.

Accession	Patient Name	Patient ID	Sequence	Test/Proto	Status	Service	Location	TIP/TTD
1313	Doe, John	999-99-9999	449300000001	Ana Plus 05	Ongoing		01-A-A01	02;09:44
1314	Public, Jane	999-99-9998	449300000001	Ana Plus 05	Ongoing		01-A-A02	02:07:33
1315	Smith, J	999-99-9997	449300000001	Ana Plus 05	Ongoing		01-A-A03	02;05:55
1316	Jones, J	999-99-9996	449300000001	Ana Plus 05	Ongoing		01-A-A04	02;03;22

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Figure 5-15 – Sample Contaminant Vials Report

5.4.4 Culture Summary

The Culture Summary report lists total counts for contaminant, positive, and negative cultures, as well as percent of total cultures for each of these counts.

To qualify for inclusion, cultures must have a state of Removed (all vials related by accession number must be removed from the instrument), be within the selected date and time range, and have a final status of positive, manual positive, negative, manual negative, or be ongoing and removed from the instrument.

A culture is considered a contaminant, positive, or negative based on the following criteria:

Contaminant – when all of the positive/manual positive vials within the accession are marked as contaminant.

Positive – if the accession contains at least one positive or manual positive vial that is not marked as a contaminant.

Negative – when all the vials in the accession are either negative, manual negative, or ongoing/ removed from the instrument.

The report provides the following information:

Header: Selection/Sorting/Reporting Criteria, Hospital Information (if configured), Instrument Number, Instrument Software Version, Report Title, and Date and Time Printed

Body of Report (columns from left to right): Positive (number of cultures and percent), Negative (number of cultures and percent), Contaminant (number of cultures and percent), and total number of Cultures

Applicable Selection Criteria:

Time Range Report By

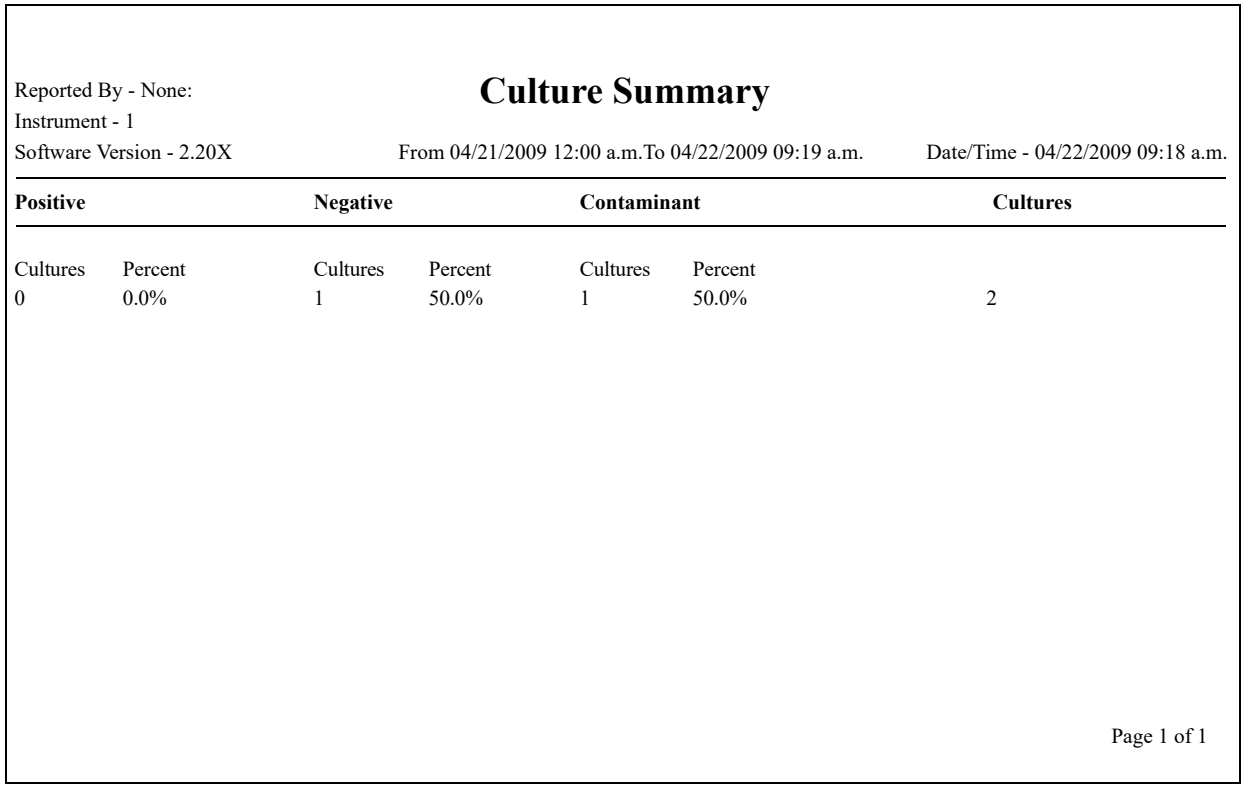
See Figure 5-16 for a sample Culture Summary report.

To print a Culture Summary Report:

1. From the Status display, select the **Reports** tab to access the Reports menu.
2. Select the desired report in the menu.
3. Select the desired report criteria by selecting the radio button next to the criteria.

   Time Range: Select the **From:** and **To:** buttons to select the start and end times. The default time range is from midnight 45 days ago.

   Report By: primary selection: None, Media, Hospital Service. If a criteria other than None is selected, any Media or Hospital Services that have been used in patient/specimen records appear in the secondary selection field. The default values are All Media and Hospital Services.
4. Select the **Print** button to print the report.



Reported By - None:
Instrument - 1
Software Version - 2.20X

Culture Summary

From 04/21/2009 12:00 a.m.To 04/22/2009 09:19 a.m.

Date/Time - 04/22/2009 09:18 a.m.

Positive		Negative		Contaminant		Cultures
Cultures	Percent	Cultures	Percent	Cultures	Percent	
0	0.0%	1	50.0%	1	50.0%	2

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Figure 5-16 – Sample Culture Summary Report

5.4.5 Current Inventory

The Current Inventory Report lists all the vials in all the instrument's stations. The report prints in landscape mode. The report provides the following information:

Header: Selection/Sorting/Reporting Criteria, Hospital Information (if configured), Instrument Number, Instrument Software Version, Report Title, and Date and Time Printed

Body of Report (columns from left to right): Accession, Patient Name (30 characters), Patient ID, Sequence, Test*/Protocol, Status*, State (column not labeled, body of report shows: ? for anonymous, vial icon for current, or blank for removed/pending), Service, Location, TIP/TTD (Time in Protocol for negatives and manual positives, Time To Detection for positives), “was positive” indicator (plus sign [+] at end of line indicates that a vial that is not currently Positive previously had a positive result)

* See Section 11 for Glossary.

Applicable Selection Criteria:

Sort By Report By

See Figure 5-17 for a sample Current Inventory Report.

To print a Current Inventory Report:

1. From the Status display, select the **Reports** tab to access the Reports menu.
2. Select the desired report in the menu.
3. Select the desired report criteria by selecting the radio button next to the criteria.

   Sort By: Choose 1st and 2nd Sort By field of either: Accession, Hospital Service, Media (alphabetic), Patient ID, Patient Name, Sequence, Start of Protocol, Location, Status, or None. The default sort order is by Accession, then by Sequence.

   Report By: primary selection: None, Media, Hospital Service, State (vial), Status. If a criteria other than None is selected, any Media, Hospital Services, Statuses, and vial States that are contained in patient/specimen records appear in the secondary selection field. The default value is the first item in the secondary selection field.
4. Select **Print** to print the report.

Sorted By - Accession,Sequence
Selected Status - All
Reported By - None:
Instrument - 1
Software Version - 2.20X

Current Inventory

Date/Time - 04/20/2009 09:18 a.m.

Accession	Patient Name	Patient ID	Sequence	Test/Proto	Status	Service	Location	TIP/TTD
1313	Doe, John	999-99-9999	449300000001	Ana Plus 05	Ongoing		01-A-A01	02;09:44
1314	Public, Jane	999-99-9998	449300000002	Ana Plus 05	Ongoing		01-A-A02	02:07:33
1315	Smith, J	999-99-9997	449300000003	Ana Plus 05	Ongoing		01-A-A03	02;05:55
1316	Jones, J	999-99-9996	449300000004	Ana Plus 05	Negative		01-A-A04	05;03;22 +

+ - Indicates a reentered instrument-positive vial

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Figure 5-17 – Sample Current Inventory Report

5.4.6 Current Negatives Report

The Current Negatives Report lists all the negative vials (out-of-protocol and manual negatives) in all the instrument's stations. The report prints in landscape mode. The report provides the following information:

Header: Selection/Sorting/Reporting Criteria, Hospital Information (if configured), Instrument Number, Instrument Software Version, Report Title, and Date and Time Printed

Body of Report (columns from left to right): Accession, Patient Name (30 characters), Patient ID, Sequence, Test*/Protocol, Status*, State (column not labeled, body of report shows: ? for anonymous, vial icon for current, or blank for removed/pending), Service, Location, TIP/TTD (Time in Protocol for negatives and manual positives, Time To Detection for positives), “was positive” indicator (plus sign [+] at end of line indicates that a vial that is not currently Positive previously had a positive result)

* See Section 11 for Glossary.

Applicable Selection Criteria:

Sort By Report By

See Figure 5-18 for a sample Current Negatives Report.

To print a Current Negatives Report:

1. From the Status display, select the **Reports** tab to access the Reports menu.
2. Select the desired report in the menu.
3. Select the desired report criteria by selecting the radio button next to the criteria.

   Sort By: Choose 1st and 2nd Sort By field of either: Accession, Hospital Service, Media (alphabetic), Patient ID, Patient Name, Sequence, Start of Protocol, Location, Status, or None. The default sort order is by Accession, then by Sequence.

   Report By: primary selection: None, Media, Hospital Service, State (vial). If a criteria other than None is selected, any Media, Hospital Services, and vial States that are contained in patient/specimen records appear in the secondary selection field. The default values are All Media and Hospital Services, and Current and Anonymous States.
4. Select **Print** to print the report.

Sorted By - Accession,Sequence
Selected Status - Negative
Reported By - None:
Instrument - 1
Software Version - 2.20X

Current Negatives

Date/Time - 04/22/2009 09:18 a.m.

Accession	Patient Name	Patient ID	Sequence	Test/Proto	Status	Service	Location	TIP/TTD
1313	Doe, John	999-99-9999	449300000001	Ana Plus 05	Negative		01-A-A01	02;09:44
1314	Public, Jane	999-99-9998	449300000001	Ana Plus 05	Negative		01-A-A02	02:07:33
1315	Smith, J	999-99-9997	449300000001	Ana Plus 05	Negative		01-A-A03	02;05:55
1316	Jones, J	999-99-9996	449300000001	Ana Plus 05	Negative		01-A-A04	02;03;22

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Figure 5-18 – Sample Current Negatives Report

5.4.7 Current Positives Report

The Current Positives Report lists all the positive vials (instrument positive, manual positive, and anonymous positive) in all the instrument's stations. The report prints in landscape mode. The report provides the following information:

Header: Selection/Sorting/Reporting Criteria, Hospital Information (if configured), Instrument Number, Instrument Software Version, Report Title, and Date and Time Printed

Body of Report (columns from left to right): Accession, Patient Name (30 characters), Patient ID, Sequence, Test*/Protocol, Status*, State (column not labeled, body of report shows: ? for anonymous, vial icon for current, or blank for removed/pending), Service, Location, TIP/TTD (Time in Protocol for negatives and manual positives, Time To Detection for positives), “was positive” indicator (plus sign [+] at end of line indicates that a vial that is not currently Positive previously had a positive result)

* See Section 11 for Glossary.

Applicable Selection Criteria:

Sort By Report By

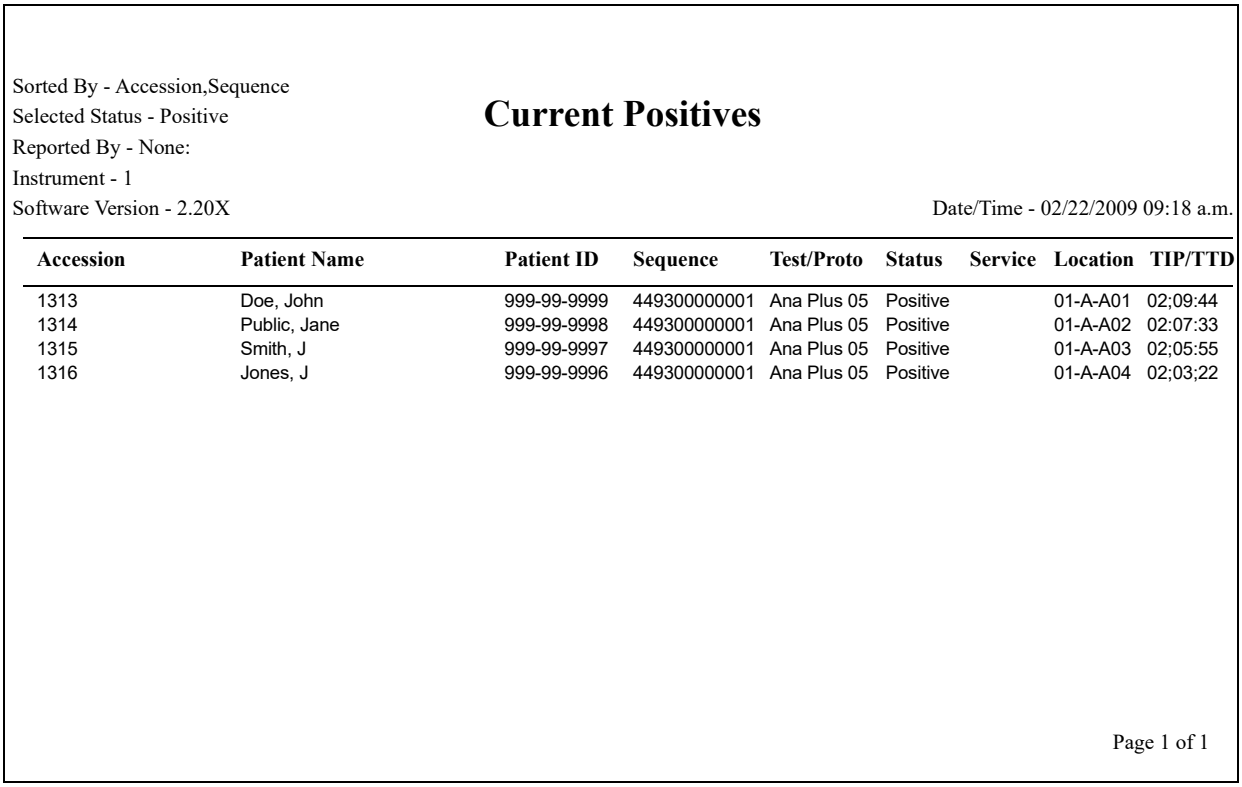
See Figure 5-19 for a sample Current Positives Report.

To print a Current Positives Report:

1. From the Status display, select the **Reports** tab to access the Reports menu.
2. Select the desired report in the menu.
3. Select the desired report criteria by selecting the radio button next to the criteria.

   Sort By: Choose 1st and 2nd Sort By field of either: Accession, Hospital Service, Media (alphabetic), Patient ID, Patient Name, Sequence, Start of Protocol, Location, Status, or None. The default sort order is by Accession, then by Sequence.

   Report By: primary selection: None, Media, Hospital Service, State (vial). If a criteria other than None is selected, any Media, Hospital Services, and vial States that are contained in patient/specimen records appear in the secondary selection field. The default values are All Media and Hospital Services, and Current and Anonymous States.
4. Select the **Print** button to print the report.



Sorted By - Accession,Sequence
Selected Status - Positive
Reported By - None:
Instrument - 1
Software Version - 2.20X

Current Positives

Date/Time - 02/22/2009 09:18 a.m.

Accession	Patient Name	Patient ID	Sequence	Test/Proto	Status	Service	Location	TIP/TTD
1313	Doe, John	999-99-9999	449300000001	Ana Plus 05	Positive		01-A-A01	02;09:44
1314	Public, Jane	999-99-9998	449300000001	Ana Plus 05	Positive		01-A-A02	02:07:33
1315	Smith, J	999-99-9997	449300000001	Ana Plus 05	Positive		01-A-A03	02;05:55
1316	Jones, J	999-99-9996	449300000001	Ana Plus 05	Positive		01-A-A04	02;03;22

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Figure 5-19 – Sample Current Positives Report

5.4.8 Loaded Vials

The Loaded Vials Report 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. The report prints in landscape mode. The report provides the following information:

Header: Selection/Sorting/Reporting Criteria, Hospital Information (if configured), Instrument Number, Instrument Software Version, Report Title, and Date and Time Printed

Body of Report (columns from left to right): Accession, Patient Name (30 characters), Patient ID, Sequence, Test*/Protocol, Status*, State (column not labeled, body of report shows: ? for anonymous, vial icon for current, or blank for removed/pending), Service, Location, TIP/TTD (Time in Protocol for negatives and manual positives, Time To Detection for positives), "was positive" indicator (plus sign [+] at end of line indicates that a vial that is not currently Positive previously had a positive result)

* See Section 11 for Glossary.

Applicable Selection Criteria:

Time Range Sort By Report By

See Figure 5-20 for a sample Loaded Vials Report.

To print a Loaded Vials Report:

1. From the Status display, select the **Reports** tab to access the Reports menu.
2. Select the desired report in the menu.
3. Select the desired report criteria by selecting the radio button next to the criteria.

   Time Range: Select the **From:** and **To:** buttons to select the start and end times (Start of Protocol). The default time range is from midnight yesterday.

   Sort By: Choose 1st and 2nd Sort By field of either: Accession, Hospital Service, Media (alphabetic), Patient ID, Patient Name, Sequence, Start of Protocol, Location, Status, or None. The default sort order is by Accession, then by Sequence.

   Report By: primary selection: None, Media, Hospital Service, State (vial), Status. If a criteria other than None is selected, any Media, Hospital Services, vial States, and Statuses that are contained in patient/specimen records appear in the secondary selection field. The default values are All Media, Hospital Services, States, and Statuses.
4. Select **Print** to print the report.

Sorted By - Accession,Sequence
Selected Status - All
Reported By - None:
Instrument - 1
Software Version - 2.20X

Loaded Vials

From 04/21/2009 12:00 a.m. To 04/22/2009 09:19 a.m. Date/Time - 04/22/2009 09:18 a.m.

Accession	Patient Name	Patient ID	Sequence	Test/Proto	Status	Service	Location	TIP/TTD
					Ongoing?		01-A-A03	02;05:55
1313	Doe, John	999-99-9999	449300000001	Ana Plus 05	Ongoing		01-A-A01	02;09:44
1314	Public, Jane	999-99-9998	449300000001	Ana Plus 05	Ongoing		01-A-A02	02:07:33
1316	Jones, J	999-99-9996	449300000001	Ana Plus 05	Positive		01-A-A04	02;03;22

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Figure 5-20 – Sample Loaded Vials Report

5.4.9 Maintenance QC

The Maintenance QC Report provides a report on drawer temperatures and blocked stations, and provides spaces to log user verification and maintenance activities (such as verifying station and system LED indicators). The report typically prints on one page, but if needed the information may continue on a second page. The report provides the following information:

Header: Hospital Information (if configured), Instrument Number, Instrument Software Version, Report Title, and Date and Time Printed

Body of Report: Instrument Serial Number, Drawer Setpoint Temperature, Drawer QC Thermometer Reading (user entry), Internal Green/Red LED Pass/Fail (user entry), Blocked (and unusable) Stations, External Yellow (Amber)/Red/Green Drawer Indicator Pass/Fail (user entry), Audible Alert Pass/Fail (user entry), Filters Change/Date (user entry), Comments (user entry), Technologist/Date (user entry)

Applicable Selection Criteria:

N/A

See Figure 5-21 for a sample Maintenance QC Report.

To print a QC Report:

1. From the Status display, select the **Reports** tab to access the Reports menu.
2. Select the desired report in the menu.
3. Select **Print** to print the report.

Maintenance QC Report

Instrument - 1
Software Version - 1.00X
Date/Time - 04/15/2009 09:18 a.m.

Upper Serial Number LJK001

A	Pass	Fail	B	Pass	Fail
Temperature 35.0 (33.5 - 36.5)			Temperature 35.0 (33.5 - 36.5)		
QC Thermometer Reading _____	_____	_____	QC Thermometer Reading _____	_____	_____
Internal Green LEDs	_____	_____	Internal Green LEDs	_____	_____
Internal Red LEDs	_____	_____	Internal Red LEDs	_____	_____

Lower Serial Number LJK002

C	Pass	Fail	D	Pass	Fail
Temperature 35.0 (33.5 - 36.5)			Temperature 35.0 (33.5 - 36.5)		
QC Thermometer Reading _____	_____	_____	QC Thermometer Reading _____	_____	_____
Internal Green LEDs	_____	_____	Internal Green LEDs	_____	_____
Internal Red LEDs	_____	_____	Internal Red LEDs	_____	_____

Unusable/Blocked Stations*

A	B	C	D
F01 F02 G01 G02			

*All stations have been verified for proper operation since the last automatic QC report except those listed above, if any.

		Pass	Fail
External System Yellow Indicator	A	_____	_____
	B	_____	_____
	C	_____	_____
	D	_____	_____
External System Red Indicator	A	_____	_____
	B	_____	_____
	C	_____	_____
	D	_____	_____
External System Green Indicator	A	_____	_____
	B	_____	_____
	C	_____	_____
	D	_____	_____
Audible Alert		_____	_____

Filters Checked - Yes _____No _____ Date _____

Filters Changed - Yes _____No _____ Date _____

Comments _____

Technologist _____Date _____

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Figure 5-21 – Sample Maintenance QC Report

5.4.10 No Growth Accession

The No Growth Accession Reports list all the accessions whose related vials show no growth (and are not marked manual positive) in the selected time interval. The time intervals are:

24 hours (Start of Protocol is at least 24 hours ago and less than 48 hours ago)

48 hours (Start of Protocol is at least 48 hours ago and less than 72 hours ago)

72 hours (Start of Protocol is at least 72 hours ago and less than 96 hours ago)

96 hours (Start of Protocol is at least 96 hours ago and less than 120 hours ago)

120 hours (Start of Protocol is at least 120 hours ago and less than 144 hours ago)

144+ hours

The report prints in landscape mode. To be included in the report, vials must be within the time interval specified, be in the instrument at the time the report was requested (or have been removed on the same calendar day as the report request), and they cannot have a manual positive or positive status.

The report provides the following information:

Header: Selection/Sorting/Reporting Criteria, Hospital Information (if configured), Instrument Number, Instrument Software Version, Report Title, and Date and Time Printed

Body of Report (columns from left to right): Accession, Patient Name (30 characters), Patient ID, Sequence, Test*/Protocol, Status*, State (column not labeled, body of report shows: ? for anonymous, vial icon for current, or blank for removed/pending), Service, Location, TIP/TTD (Time in Protocol for negatives and manual positives, Time To Detection for positives), "was positive" indicator (plus sign [+] at end of line indicates that a vial that is not currently Positive previously had a positive result)

* See Section 11 for Glossary.

Applicable Selection Criteria:

Time Range Sort By Report By

See Figure 5-22 for a sample No Growth Accession Report.

To print a No Growth Accession Report:

1. From the Status display, select the **Reports** tab to access the Reports menu.
2. Select the desired report in the menu.
3. Select the desired report criteria by selecting the radio button next to the criteria.

   Time Range: Select the radio button next to the desired Report Interval (24 [default], 48, 72, 96, 120, or 144 hours+)

   Sort By: Choose 1st and 2nd Sort By field of either: Accession, Hospital Service, Media (alphabetic), Patient ID, Patient Name, Sequence, Start of Protocol, Location, Status, or None. The default sort order is by Accession, then by Sequence.

   Report By: primary selection: None, Media, Hospital Service. If a criteria other than None is selected, any Media or Hospital Services that have been used in patient/specimen records appear in the secondary selection field. The default values are All Media and Hospital Services.
4. Select **Print** to print the report.

Sorted By - Accession,Sequence
Selected Status - All
Reported By - None:
Instrument - 1
Software Version - 2.20X

No Growth Accession

Report Interval - 72 Hours

Date/Time - 04/22/2009 09:18 a.m.

Accession	Patient Name	Patient ID	Sequence	Test/Proto	Status	Service	Location	TIP/TTD
1313	Doe, John	999-99-9999	449300000001	Ana Plus 05	Ongoing		01-A-A01	03;09:44
1314	Public, Jane	999-99-9998	449300000001	Ana Plus 05	Ongoing		01-A-A02	03:07:33
1315	Smith, J	999-99-9997	449300000001	Ana Plus 05	Ongoing		01-A-A03	03;05:55
1316	Jones, J	999-99-9996	449300000001	Ana Plus 05	Ongoing		01-A-A04	03;03;22

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Figure 5-22 – Sample No Growth Accession Report

5.4.11 Orphan Vials

The Orphan Vials Report lists all the vials in all the instrument's database that have no accession number. The report prints in landscape mode. The report provides the following information:

Header: Selection/Sorting/Reporting Criteria, Hospital Information (if configured), Instrument Number, Instrument Software Version, Report Title, and Date and Time Printed

Body of Report (columns from left to right): Accession, Patient Name (30 characters), Patient ID, Sequence, Test*/Protocol, Status*, State (column not labeled, body of report shows: ? for anonymous, vial icon for current, or blank for removed/pending), Service, Location, TIP/TTD (Time in Protocol for negatives and manual positives, Time To Detection for positives), “was positive” indicator (plus sign [+] at end of line indicates that a vial that is not currently Positive previously had a positive result)

* See Section 11 for Glossary.

Applicable Selection Criteria:

Sort By

See Figure 5-23 for a sample Orphan Vials Report.

To print an Orphan Vials Report:

1. From the Status display, select the **Reports** tab to access the Reports menu.
2. Select the desired report in the menu.
3. Select the desired report criteria by selecting the radio button next to the criteria.

   Sort By: Choose 1st and 2nd Sort By field of either: Accession, Hospital Service, Media (alphabetic), Patient ID, Patient Name, Sequence, Start of Protocol, Location, Status, or None. The default sort order is by Sequence.
4. Select **Print** to print the report.

Sorted By - Accession,Sequence
Selected Status - Orphan
Reported By - None:
Instrument - 1
Software Version - 2.20X

Orphan Vials

Date/Time - 04/22/2009 09:18 a.m.

Accession	Patient Name	Patient ID	Sequence	Test/Proto	Status	Service	Location	TIP/TTD
			449300000001	Ana Plus 05	Ongoing		01-A-A01	03;09:44
			449300000001	Ana Plus 05	Ongoing		01-A-A02	03:07:33
			449300000001	Ana Plus 05	Ongoing		01-A-A03	03;05:55
			449300000001	Ana Plus 05	Ongoing		01-A-A04	03;03;22

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Figure 5-23 – Sample Orphan Vials Report

5.4.12 Partially Seated Stations

The Partially Seated Stations Report lists all the vials that the instrument believes are partially seated (not fully inserted in their stations). The report prints in landscape mode. The report provides the following information:

Header: Selection/Sorting/Reporting Criteria, Hospital Information (if configured), Instrument Number, Instrument Software Version, Report Title, and Date and Time Printed

Body of Report (columns from left to right): Accession, Patient Name (30 characters), Patient ID, Sequence, Test*/Protocol, Status*, State (column not labeled, body of report shows: ? for anonymous, vial icon for current, or blank for removed/pending), Service, Location, TIP/TTD (Time in Protocol for negatives and manual positives, Time To Detection for positives)

* See Section 11 for Glossary.

> NOTE
>
> The Partially Seated Stations Report provides only station information, not vial information, since the scan is not confirmed by vial entry.

Applicable Selection Criteria:

N/A

See Figure 5-24 for a sample Partially Seated Stations Report.

To print a Partially Seated Stations Report:

1. From the Status display, select the **Reports** tab to access the Reports menu.
2. Select the desired report in the menu.
3. Select **Print** to print the report.

Sorted By - Accession,Sequence
Selected Status - All
Reported By - None:
Instrument - 1
Software Version - 2.20X

Partially Seated Stations

Date/Time - 04/22/2009 09:18 a.m.

Accession	Patient Name	Patient ID	Sequence	Test/Proto	Status	Service	Location	TIP/TTD
							01-A-A01	

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Figure 5-24 – Sample Partially Seated Stations Report

5.4.13 Pending

The 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). The report prints in landscape mode. The report provides the following information:

Header: Selection/Sorting/Reporting Criteria, Hospital Information (if configured), Instrument Number, Instrument Software Version, Report Title, and Date and Time Printed

Body of Report (columns from left to right): Accession, Patient Name (30 characters), Patient ID, Sequence, Test*/Protocol, Status*, State (column not labeled, body of report shows: ? for anonymous, vial icon for current, or blank for removed/pending), Service, Location, TIP/TTD (Time in Protocol for negatives and manual positives, Time To Detection for positives), “was positive” indicator (plus sign [+] at end of line indicates that a vial that is not currently Positive previously had a positive result)

* See Section 11 for Glossary.

Applicable Selection Criteria:

Sort By Report By

See Figure 5-25 for a sample Pending Report.

To print a Pending Report:

1. From the Status display, select the **Reports** tab to access the Reports menu.
2. Select the desired report in the menu.
3. Select the desired report criteria by selecting the radio button next to the criteria.

   Sort By: Choose 1st and 2nd Sort By field of either: Accession, Hospital Service, Media (alphabetic), Patient ID, Patient Name, Sequence, Start of Protocol, Location, Status, or None. The default sort order is by Accession, then by Sequence.

   Report By: primary selection: None, Media, Hospital Service. If a criteria other than None is selected, any Media or Hospital Services that have been used in patient/specimen records appear in the secondary selection field. The default values are All Media and Hospital Services.
4. Select **Print** to print the report.

Sorted By - Accession,Sequence
Selected Status - All
Reported By - None:
Instrument - 1
Software Version - 2.20X

Pending Report

Date/Time - 04/22/2009 09:18 a.m.

Accession	Patient Name	Patient ID	Sequence	Test/Proto	Status	Service	Location	TIP/TTD
1313	Doe, John	999-99-9999	449300000001	Ana Plus 05	Pending			
1314	Public, Jane	999-99-9998	449300000001	Ana Plus 05	Pending			
1315	Smith, J	999-99-9997	449300000001	Ana Plus 05	Pending			
1316	Jones, J	999-99-9996	449300000001	Ana Plus 05	Pending			

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Figure 5-25 – Sample Pending Report

5.4.14 Unloaded Negative Vials

The Unloaded Negative Vials Report 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 report prints in landscape mode. The report provides the following information:

Header: Selection/Sorting/Reporting Criteria, Hospital Information (if configured), Instrument Number, Instrument Software Version, Report Title, and Date and Time Printed

Body of Report (columns from left to right): Accession, Patient Name (30 characters), Patient ID, Sequence, Test*/Protocol, Status*, State (column not labeled, body of report shows: ? for anonymous, vial icon for current, or blank for removed/pending), Service, Location, TIP/TTD (Time in Protocol for negatives and manual positives, Time To Detection for positives), “was positive” indicator (plus sign [+] at end of line indicates that a vial that is not currently Positive previously had a positive result)

* See Section 11 for Glossary.

Applicable Selection Criteria:

Time Range Sort By Report By

See Figure 5-26 for a sample Unloaded Negative Vials Report.

To print an Unloaded Negative Vials Report:

1. From the Status display, select the **Reports** tab to access the Reports menu.
2. Select the desired report in the menu.
3. Select the desired report criteria by selecting the radio button next to the criteria.

   Time Range: Select the **From:** and **To:** buttons to select the start and end times. The default time range is from midnight yesterday.

   Sort By: Choose 1st and 2nd Sort By field of either: Accession, Hospital Service, Media (alphabetic), Patient ID, Patient Name, Sequence, Start of Protocol, Location, Status, or None. The default sort order is by Accession, then by Sequence.

   Report By: primary selection: None, Media, Hospital Service. If a criteria other than None is selected, any Media or Hospital Services that have been used in patient/specimen records appear in the secondary selection field. The default values are All Media and Hospital Services.
4. Select **Print** to print the report.

Sorted By - Accession,Sequence
Selected Status - Negative
Reported By - None:
Instrument - 1
Software Version - 2.20X

Unloaded Negative Vials

From 04/21/2009 12:00 a.m. To 04/22/2009 09:19 a.m

Date/Time - 04/22/2009 09:19 a.m.

Accession	Patient Name	Patient ID	Sequence	Test/Proto	Status	Service	Location	TIP/TTD
1313	Doe, John	999-99-9999	449300000001	Ana Plus 05	Negative		01-A-A01	03;09:44
1314	Public, Jane	999-99-9998	449300000001	Ana Plus 05	Negative		01-A-A02	03:07:33
1315	Smith, J	999-99-9997	449300000001	Ana Plus 05	Negative		01-A-A03	03;05:55
1316	Jones, J	999-99-9996	449300000001	Ana Plus 05	Negative		01-A-A04	03;03;22

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Figure 5-26 – Sample Unloaded Negative Vials Report

5.4.15 Unloaded Positive Vials

The Unloaded Positive Vials Report 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 report prints in landscape mode. The report provides the following information:

Header: Selection/Sorting/Reporting Criteria, Hospital Information (if configured), Instrument Number, Instrument Software Version, Report Title, and Date and Time Printed

Body of Report (columns from left to right): Accession, Patient Name (30 characters), Patient ID, Sequence, Test*/Protocol, Status*, State (column not labeled, body of report shows: ? for anonymous, vial icon for current, or blank for removed/pending), Service, Location, TIP/TTD (Time in Protocol for negatives and manual positives, Time To Detection for positives), “was positive” indicator (plus sign [+] at end of line indicates that a vial that is not currently Positive previously had a positive result)

* See Section 11 for Glossary.

Applicable Selection Criteria:

Time Range Sort By Report By

See Figure 5-27 for a sample Unloaded Positive Vials Report.

To print an Unloaded Positive Vials Report:

1. From the Status display, select the **Reports** tab to access the Reports menu.
2. Select the desired report in the menu.
3. Select the desired report criteria by selecting the radio button next to the criteria.

   Time Range: Select the **From:** and **To:** buttons to select the start and end times. The default time range is from midnight yesterday.

   Sort By: Choose 1st and 2nd Sort By field of either: Accession, Hospital Service, Media (alphabetic), Patient ID, Patient Name, Sequence, Start of Protocol, Location, Status, or None. The default sort order is by Accession, then by Sequence.

   Report By: primary selection: None, Media, Hospital Service. If a criteria other than None is selected, any Media or Hospital Services that have been used in patient/specimen records appear in the secondary selection field. The default values are All Media and Hospital Services.
4. Select **Print** to print the report.

Sorted By - Accession,Sequence
Selected Status - Positive
Reported By - None:
Instrument - 1
Software Version - 2.20X

Unloaded Positive Vials

From 04/21/2009 12:00 a.m. To 04/22/2009 09:19 a.m

Date/Time - 04/22/2009 09:18 a.m.

Accession	Patient Name	Patient ID	Sequence	Test/Proto	Status	Service	Location	TIP/TTD
1313	Doe, John	999-99-9999	449300000001	Ana Plus 05	Positive		01-A-A01	03;09:44
1314	Public, Jane	999-99-9998	449300000001	Ana Plus 05	Positive		01-A-A02	03:07:33
1315	Smith, J	999-99-9997	449300000001	Ana Plus 05	Positive		01-A-A03	03;05:55
1316	Jones, J	999-99-9996	449300000001	Ana Plus 05	Positive		01-A-A04	03;03;22

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Figure 5-27 – Sample Unloaded Positive Vials Report

5.4.16 Unloaded Vials

The Unloaded Vials Report lists all the sequenced vials that have been removed from the instrument in a specified time period and have not been reentered. The report prints in landscape mode. The report provides the following information:

Header: Selection/Sorting/Reporting Criteria, Hospital Information (if configured), Instrument Number, Instrument Software Version, Report Title, and Date and Time Printed

Body of Report (columns from left to right): Accession, Patient Name (30 characters), Patient ID, Sequence, Test*/Protocol, Status*, State (column not labeled, body of report shows: ? for anonymous, vial icon for current, or blank for removed/pending), Service, Location, TIP/TTD (Time in Protocol for negatives and manual positives, Time To Detection for positives), "was positive" indicator (plus sign [+] at end of line indicates that a vial that is not currently Positive previously had a positive result)

* See Section 11 for Glossary.

Applicable Selection Criteria:

Time Range Sort By Report By

See Figure 5-28 for a sample Unloaded Vials Report.

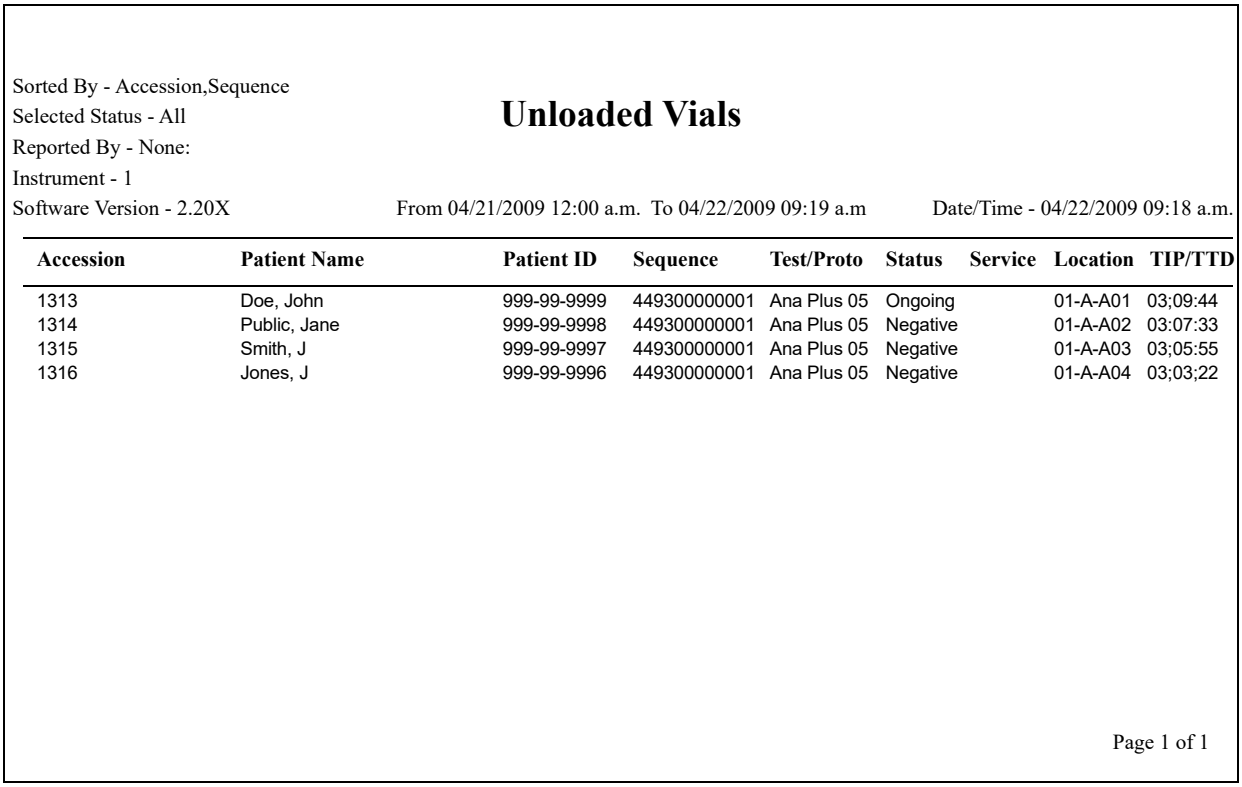
To print an Unloaded Vials Report:

1. From the Status display, select the **Reports** tab to access the Reports menu.
2. Select the desired report in the menu.
3. Select the desired report criteria by selecting the radio button next to the criteria.

   Time Range: Select the **From:** and **To:** buttons to select the start and end times. The default time range is from midnight yesterday.

   Sort By: Choose 1st and 2nd Sort By field of either: Accession, Hospital Service, Media (alphabetic), Patient ID, Patient Name, Sequence, Start of Protocol, Location, Status, or None. The default sort order is by Accession, then by Sequence.

   Report By: primary selection: None, Media, Hospital Service. If a criteria other than None is selected, any Media or Hospital Services that have been used in patient/specimen records appear in the secondary selection field. The default values are All Media and Hospital Services.
4. Select **Print** to print the report.



Sorted By - Accession,Sequence
Selected Status - All
Reported By - None:
Instrument - 1
Software Version - 2.20X

Unloaded Vials

From 04/21/2009 12:00 a.m. To 04/22/2009 09:19 a.m

Date/Time - 04/22/2009 09:18 a.m.

Accession	Patient Name	Patient ID	Sequence	Test/Proto	Status	Service	Location	TIP/TTD
1313	Doe, John	999-99-9999	449300000001	Ana Plus 05	Ongoing		01-A-A01	03;09:44
1314	Public, Jane	999-99-9998	449300000001	Ana Plus 05	Negative		01-A-A02	03:07:33
1315	Smith, J	999-99-9997	449300000001	Ana Plus 05	Negative		01-A-A03	03;05:55
1316	Jones, J	999-99-9996	449300000001	Ana Plus 05	Negative		01-A-A04	03;03;22

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Figure 5-28 – Sample Unloaded Vials Report

5.5 Maintenance

When you select the **Maintenance** tab, the Maintenance – Test display appears. Maintenance Test and Utilities functions are always available for use except as noted below.

5.5.1 Test Display

The Test display enables you to perform daily instrument maintenance tests. You can check the status of all the LEDs and the audible alarm, and print or reprint a Maintenance QC Report.

To access the Test display, select the **Maintenance** tab. The system goes right to the Test display. From any other Maintenance tab, select the **Test** tab to access the Test display.

See Figure 5-29 for a sample Test display.

To access Maintenance – Test:

From the Status display, select the **Maintenance** tab

Test Buttons:

Drawer A/B/C/D Indicator

A green box around the drawer indicates the drawer that is currently open.

Red button 

Select to illuminate all the red station LEDs in the drawer for 5 seconds. If any of the red LEDs does not illuminate, block the station and note it on your Maintenance QC Report. A drawer must be open for this button to be active. Otherwise the button is grayed out.

Yellow button 

Select to illuminate all the yellow (amber) station LEDs in the drawer for 5 seconds. If any of the yellow (amber) LEDs does not illuminate, block the station and note it on your Maintenance QC Report. A drawer must be open for this button to be active. Otherwise the button is grayed out.

Green button 

Select to illuminate all the green station LEDs in the drawer for 5 seconds. If any of the green LEDs does not illuminate, block the station and note it on your Maintenance QC Report. A drawer must be open for this button to be active. Otherwise the button is grayed out.

Alarm button 

Select to sound the audible alarm. All drawers must be closed for this button to be active. The alarm sounds for 2.5 seconds at the middle volume setting, pauses, and repeats. If the alarm does not sound, note this in your Maintenance QC Report and contact BD.

Status button 

Select to illuminate all the system status indicators for 5 seconds. All drawers must be closed for this button to be active. If any of the LEDs does not illuminate, note it on your Maintenance QC Report and contact BD.

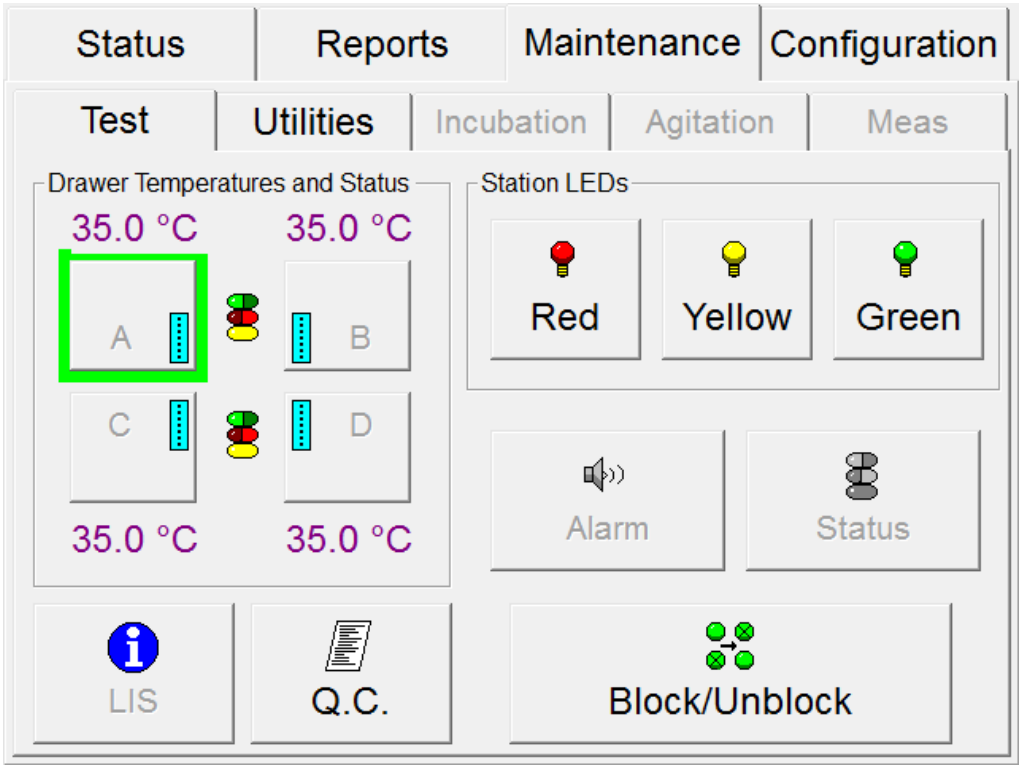

Figure 5-29 – Maintenance – Test Display

LIS Host Query button 

Select to send a query to the LIS system requesting demographic information for orphan vials in the instrument.

This button is disabled in a BD EpiCenter™ configuration.

Q.C. (report) button 

Select to print/reprint the Maintenance QC Report.

This button is disabled when the instrument is in degraded mode.

Block/Unblock button 

Select to access the Block/Unblock stations display. Refer to Block/Unblock Stations Display below.

5.5.2 Block/Unblock Stations Display

The Block/Unblock Stations display enables you to block (remove from service) and unblock (return to service) stations in the drawers. Blocking a station might be advised, for example, when a station indicator does not light.

To access the Block/Unblock Stations display, from the Maintenance – Test display, select **Block/Unblock**.

To block or unblock one or more stations, make sure the drawer where the station is located is open. To block a station, select the desired stations in the display, and follow any instructions in pop-up message/alert windows. The blocked station is shown with a ⊗ station icon. To unblock a station, select a blocked station. When blocking/unblocking is complete, select **Exit**.

Refer to Section 6.2.2.1 for additional instructions.

See Figure 5-30 for a sample Block/Unblock Stations display.

To access Maintenance – Block/Unblock:

- From the Status display, select the **Maintenance** tab
- From the Maintenance – Test display, select **Block/Unblock** 

Block/Unblock Station Fields:

Station statuses

All station statuses are shown.

Location

Read-only field showing the last blocked/unblocked station. That station is also highlighted with a gray box surrounding it.

Block/Unblock Stations Buttons:

Drawer

Selected drawer is indicated by filled in radio button. The currently open drawer is highlighted in green. To select a different drawer for viewing, select the empty radio button to the left of the letter (A, B, C, D). Only stations in the currently open drawer can be blocked/unblocked.

Exit button 

Select to exit the Block/Unblock display and return to the Maintenance – Test display.

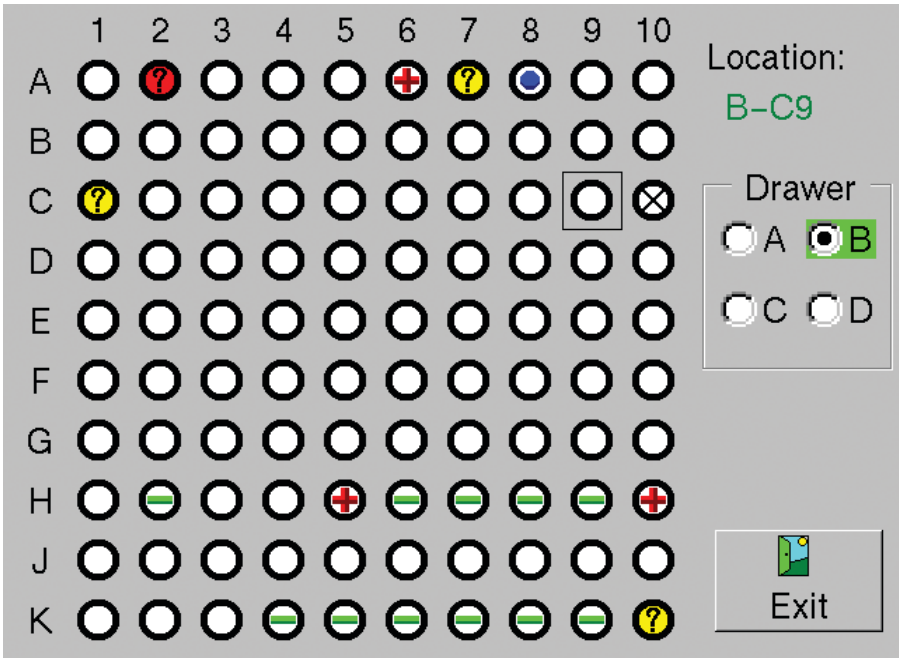

Figure 5-30 – Block/Unblock Stations Display

5.5.3 Utilities Display

To access Maintenance – Utilities:

- From the Status display, select the **Maintenance** tab
- From the Maintenance – Test display, select the **Utilities** tab

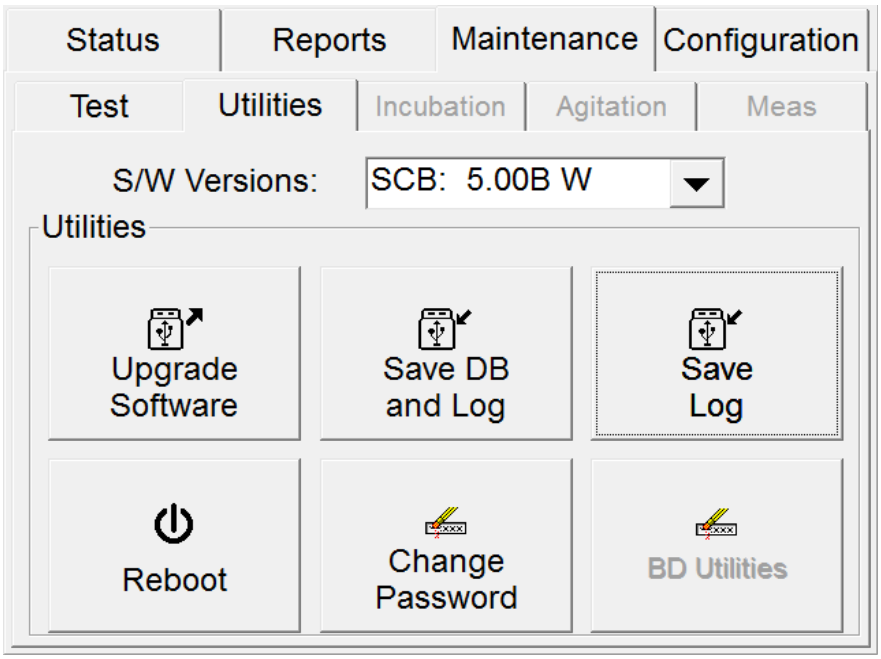

Figure 5-31 – Utilities Display

5.5.3.1 Upgrade Software

There is no associated display for the Upgrade Software utility. For information on upgrading software, refer to Section 6.4.1.

5.5.3.2 Save DB and Log

There is no associated display for the Save DB and Log utility. For information on saving the database and log files, refer to Section 6.4.2.

5.5.3.3 Save Log

There is no associated display for the Save Log utility. For information on saving log files, refer to Section 6.4.3.

5.5.3.4 Reboot

The Reboot function allows you to reboot the main FX computer. This function can be used to restore communications between the main computer and the instrument stacks if needed. Lost communications is indicated with a flashing amber system indicator on the instrument door.

To reboot the instrument, select **Reboot**. A confirmation message asks if you want to reboot the application. Select **Yes** to reboot, or select **No** to cancel the reboot. A message window confirms that you select **Yes** when the confirmation message appears.

5.5.3.5 Change Password

The Change Password utility enables you to change the Supervisor password that is required for saving Configuration changes.

You cannot change passwords in an instrument that is in degraded mode.

To access Change Password:

- From the Status display, select the **Maintenance** tab
- From the Maintenance – Test display, select the **Utilities** tab
- From the Utilities menu, select **Change Password** 

Change Password Fields:

Old Password

Select the blank field to access the onscreen keyboard. Enter the existing Supervisor password, then select **ENTER**.

New Password

Select the blank field to access the onscreen keyboard. Enter the new password, then select **ENTER**. Passwords can be up to 20 characters. Passwords cannot be blank (no characters) and they cannot be all spaces. Passwords are case sensitive.

Confirm Password

Select the blank field to access the onscreen keyboard. Enter the new password a second time, then select **ENTER**.

Change Password Buttons:

OK button

Select **OK** to save the new password and return to the Maintenance – Test display.

Cancel button

Select to exit the Change Password window without saving the new password.

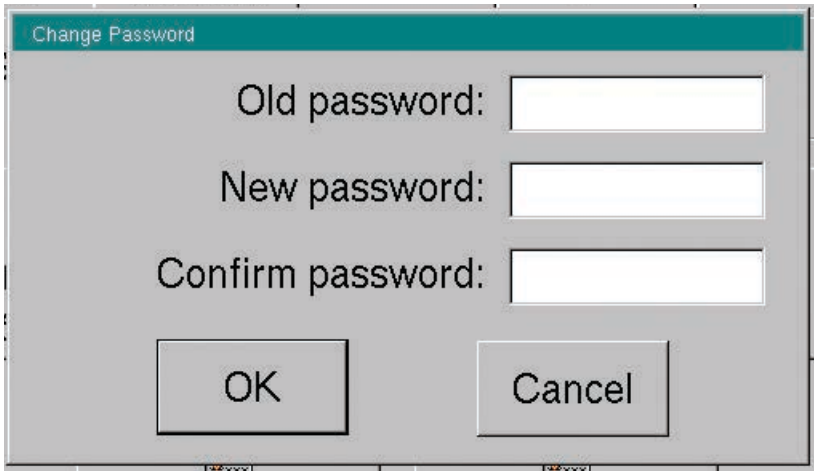

Figure 5-32 – Change Password Window

5.5.3.6 BD Utilities

This function is for BD use only.

5.6 Configuration

You cannot access Configuration displays in an instrument that is in degraded mode.

5.6.1 Lab

Refer to Section 2.4.1 for detailed information on the Configuration - Lab display.

5.6.2 Reports Display

Refer to Section 2.4.2 for detailed information on the Configuration - Reports display.

5.6.3 Instrument Display

Refer to Section 2.4.3 for detailed information on the Configuration - Instrument display.

5.6.4 LIS Display

Refer to Section 2.4.4 for detailed information on the Configuration - LIS display.

5.6.5 Time

Refer to Section 2.4.5 for detailed information on the Configuration - Time display.

6 – Maintenance

6.1 General

The BD BACTEC™ FX instrument requires little maintenance from the user to provide reliable performance. Daily activities include checking the following items: station, system, and audible indicators; instrument temperature; and printer paper supply. All other procedures are on an as needed basis. Once every 12 months, preventive maintenance is required to be performed by BD authorized service personnel.

WARNING

ALL MAINTENANCE AND REPAIR OTHER THAN THE PROCEDURES DESCRIBED IN THIS SECTION MUST BE PERFORMED BY QUALIFIED SERVICE PERSONNEL. NONCOMPLIANCE WITH THIS WARNING MAY RESULT IN PERSONAL INJURY OR INSTRUMENT MALFUNCTION.

6.2 Routine Maintenance

6.2.1 Daily Maintenance

Each day, several simple maintenance procedures should be performed. The best time to perform maintenance is first thing in the morning, but it may be done at any time you find convenient.

The following procedures should be performed:

1. Check the paper supply to the printer. If the paper supply is low or exhausted, replace the paper as explained in the operating manual furnished separately.
2. Select the **Maintenance** tab. The Test display appears.
3. Select **Q.C.** to print the Maintenance QC Report.
4. Open drawer A. Then select the **Red** button to illuminate the red station indicators. Record any station that does not illuminate red.
5. Next select the **Yellow** button to illuminate the yellow (amber) station indicators. Record any station that does not illuminate yellow (amber).
6. Next select the **Green** button to illuminate the green station indicators. Record any station that does not illuminate green.
7. Check and record the temperature on the temperature QC vial.
8. Repeat steps 3–5 for each of the drawers in the system.
9. Close the drawer.
10. Select **Alarm** to verify that the audible alarm is functioning.
11. Finally, select **Status** to illuminate the system status indicators. Both sides of all the indicators (yellow [amber], red, and green) should illuminate. If any indicator does not light, contact your local BD representative for service.
12. Information can be recorded on the Maintenance QC Report.

6.2.2 As Needed Maintenance

6.2.2.1 Blocking Stations

Stations should be blocked if either station indicator fails to light during Daily Maintenance; or if the station does not correctly detect vial removals and insertions; or to reserve the station for a temperature QC vial.

Insert a station plug into any stations that you block AND stations that the instrument marks as unusable (cracked egg icon in Drawer View display).

Any vial that is in a station that is being blocked must be removed since it will be marked as removed in the database and will not be tested.

If you accidentally place a vial into a blocked station, you must remove the vial from the station and reenter it with the Vial Entry activity.

To block a station:

1. Open the correct drawer.
2. From the Test display, select **Block/Unblock**.
3. The Block/Unblock display appears.
4. Select the station to block in the display. Repeat for additional stations to be blocked.
5. Remove any vial from the station.

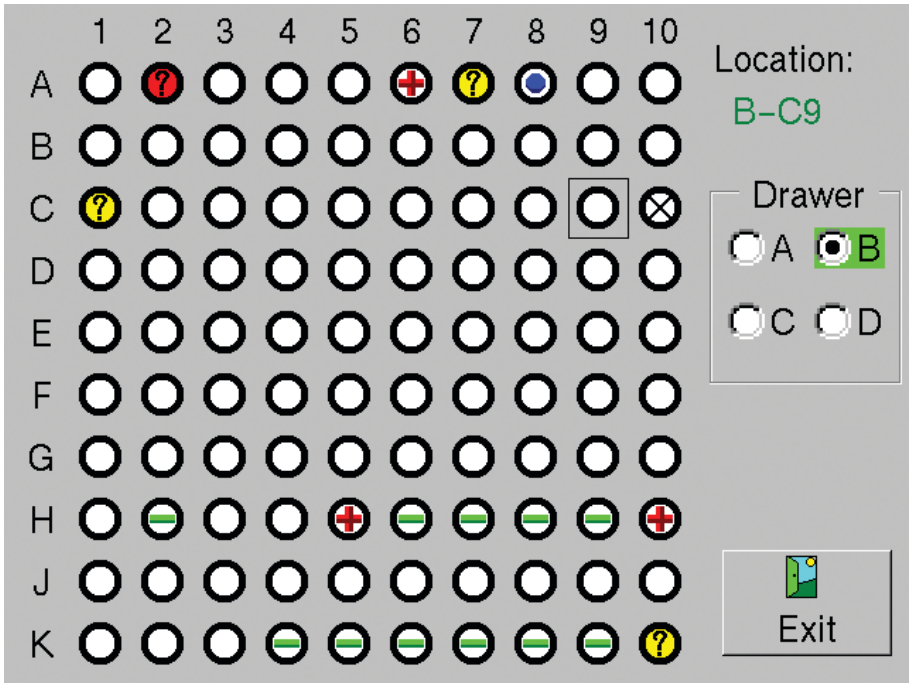

Figure 6-1 – Block/Unblock Stations Display

6. Insert a station plug.
7. Enter the removed vials into available stations with the Vial Entry operation (Section 4.5).
8. If you inadvertently block a station – and even if you immediately unblock it – the instrument will no longer test the vial that was assigned to that station. Be sure to use Vial Entry to move any vial in that station to a new station.
9. The Maintenance QC Report lists the blocked stations.

6.2.2.2 Unblocking Stations

To unblock a blocked station:

1. From the Test display, select **Block/Unblock**.
2. The Block/Unblock display appears.
3. Make sure the correct drawer is open (highlighted in green).
4. Blocked stations are shown with a ⊗ station icon.
5. Select the blocked station in the display that you want to unblock.
6. Repeat for additional stations to be unblocked.
7. Select **Exit** to return to the Maintenance – Test display.

6.2.3 Cleaning Air Filters

All filters should be checked monthly. If needed, filters should be cleaned/replaced (see below, Cleaning the air filters:).

If the instrument's environment is especially dusty, the air intake filters should be checked periodically and cleaned or replaced if needed. These filters must remain clean and unobstructed; restricted airflow from dirty filters may cause the instrument interior to reach excessive temperatures, which can affect results and possibly cause hardware malfunctions or failures. The filters can be cleaned and reused.

Each instrument has two filters: one is located behind the bottom faceplate on the left side (electronics bay), and the others are located at the top edge of the cabinets (cabinet air). They can be removed without tools.

See Figures 6-2a through 6-5.

Cleaning the air filters:

1. Wash dirty filters in a bactericidal disinfectant.
2. Place them on paper towels and dry them thoroughly (if you are going to reuse them immediately).
3. To save time, you can replace dirty filters with a spare clean set. Wash, dry, and set aside the removed dirty filters for the next filter replacement.

Removing the electronics bay filters (Figures 6-2a and 6-2b):

1. The top electronics bay filter is located behind an access door just to the left of the LCD Touchscreen.
2. Pivot the access door outward away from the instrument. The door opens like a left-hinged door.
3. To remove the filter, lift it up slightly, and then pivot the bottom outward. Lower the filter out of the filter housing.
4. To insert a clean filter, place the top edge under the top lip of the mounting bracket. Slide the filter up, pivot the bottom in toward the mounting bracket, and lower the filter into place.
5. The bottom electronics bay filter is located behind the bottom panel on the lower instrument.
6. To remove the panel, grasp both edges and pull the panel away from the instrument. The panel should pop off with light to moderate force.
7. To remove the filter, lift it up slightly, and then pivot the bottom outward. Lower the filter out of the filter housing.

8 To insert a clean filter, place the top edge under the top lip of the mounting bracket. Slide the filter up, pivot the bottom in toward the mounting bracket, and lower the filter into place.

9 Align the bottom panel with the instrument and select the panel on both sides to reattach it.

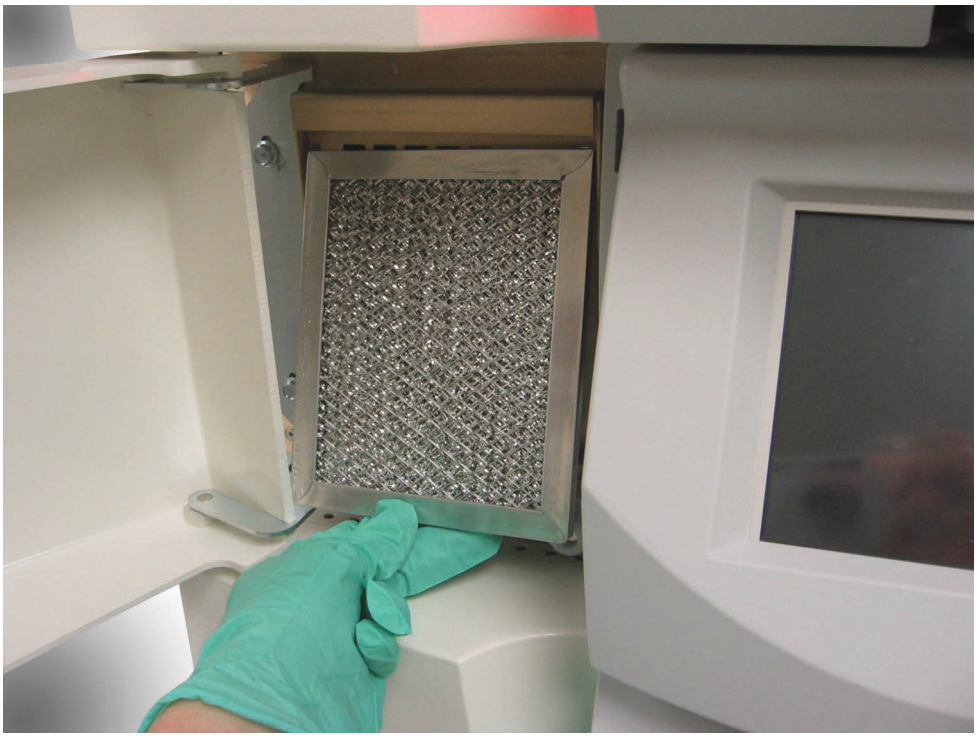

Figure 6-2a – Removing the Top Electronics Bay Filter

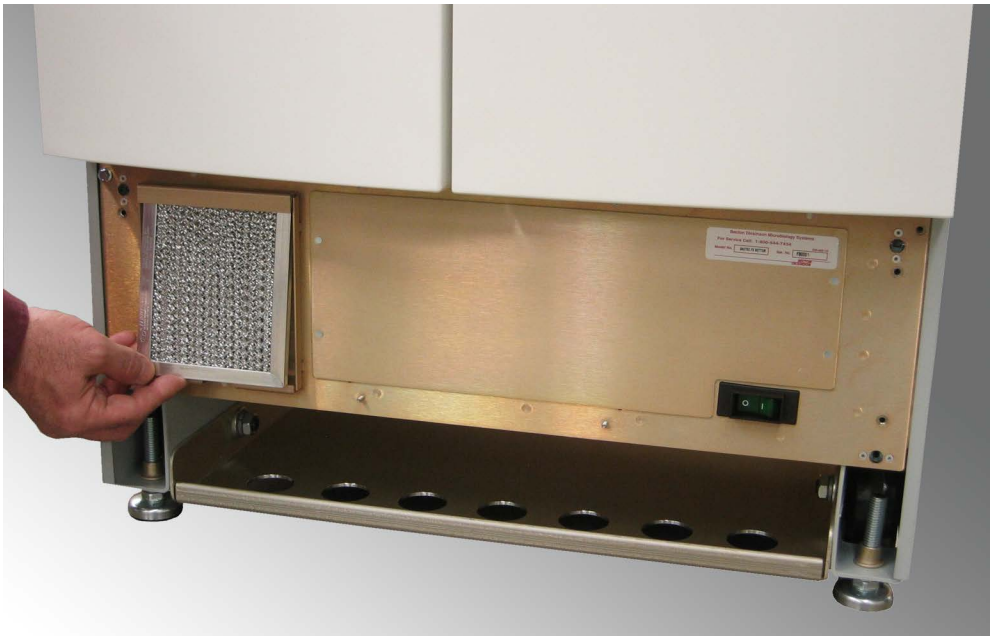

Figure 6-2b – Removing the Bottom Electronics Bay Filter

Removing the top cabinet air filter (Figure 6-3):

1. The top cabinet air filter is located at the top front of the upper instrument. To reach the filter for removal, a stable stepladder should be used.
2. Two small tabs are located on the top edge of the filter. Locate and grasp the tabs.
3. Pull the filter up out of the instrument.
4. To insert a clean filter, align it with the slot from which it was removed and push it down into place.

Figure 6-3 – Top Cabinet Air Filter (shown partially removed)

Removing the bottom cabinet air filter (Figure 6-4):

1. The bottom cabinet air filter is located at the top front of the lower instrument. Because the lower instrument has an instrument atop it, it is accessed differently from the upper instrument.
2. Pivot the access door to the left of the LCD Touchscreen outward away from the instrument. The door opens like a left-hinged door.
3. Pivot the access door to the right of the LCD Touchscreen outward away from the instrument. The door opens like a right-hinged door.
4. Next the LCD Touchscreen bezel must be removed. Figure 6-4 shows both access doors open and the LCD bezel in place.
5. Grasp the bezel at both sides. Gently but firmly pull straight out. The bezel will pop free with light to medium force.
6. Figure 6-5 shows both access doors open, the LCD bezel removed, the filter tabs upward, and the filter partially removed.
7. The tabs for removing the cabinet air filter are located at the top edge of the filter, a short distance from each edge.
8. To remove the filter, grasp the tabs and pull the filter up out of the instrument.

9 To replace the filter, align it with the slot from which it was removed and push it down into place.

10 Align the pins in the LCD bezel with the holes in the instrument, and push the bezel back into place. Select all four corners of the bezel to make sure it is in place.

11 Close the access doors to the left and right of the LCD Touchscreen.

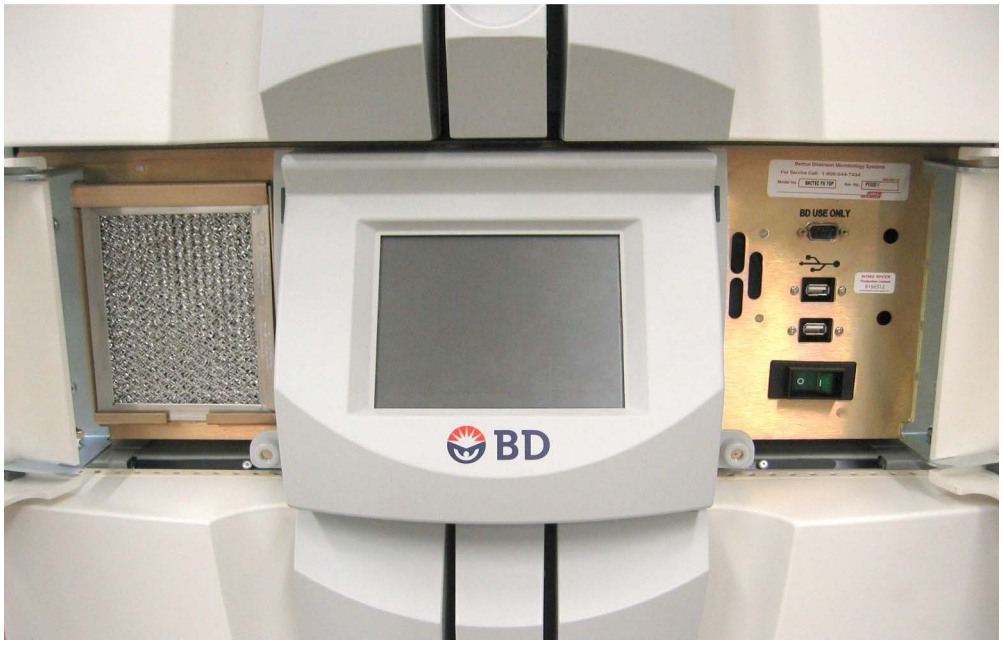

Figure 6-4 – Bottom Cabinet Air Filter (LCD bezel in place, access doors open)

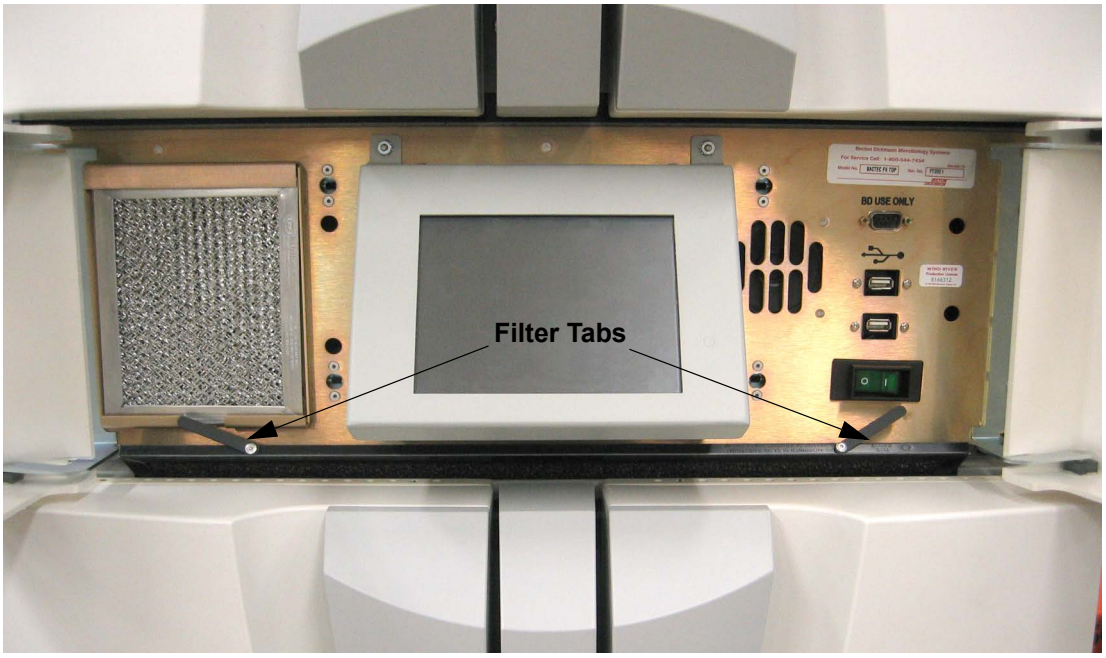

Figure 6-5 – Bottom Cabinet Air Filter (LCD bezel removed, filter partially removed)

6.2.4 Replacing Vial Barcode Labels

Extra vial sequence barcode labels are included in the instrument start-up kit. These labels can be used to replace damaged or unreadable labels on culture vials. The barcode labels contain sequence numbers that uniquely identify each vial.

Note that if you replace a vial barcode label, when you enter that vial into the instrument (either through Vial Entry or through Identify Anonymous), it asks you to select a media type. This enables the system to apply media-specific positivity criteria to the vial.

Required materials:

- Spare barcode label

To apply a new barcode label:

1. Ensure that the area where the defective label is located is clean and dry. If the old label is wrinkled or creased, peel off as much as possible to make a smooth surface on which to apply the new label.
2. Peel off the new barcode label. Verify that the new label is printed clearly and that no smears, smudges, or other markings obstruct the lines of the barcode.
3. Align the new label with the old label, and press the new label into place, being careful not to create any bubbles or ridges in the barcode area.
4. Be sure to select the correct medium type in the Culture – Vial display. This enables the instrument to apply media-specific positivity criteria to test readings.

6.2.5 Cleaning and Decontamination

A situation requiring biological decontamination of one or more stations can occur if a vial should leak or break while in the instrument. The priority in this situation is to first limit the extent of the contamination and then to decontaminate the station(s) and other accessible instrument areas receiving the spill. If the spill extends into regions of the instrument not accessible for topical decontamination, or if it involves a broken vial, contact BD Technical Service (USA) for further instructions (1.800.638.8663).

The solution recommended to clean the affected surfaces should be at least a 10% household bleach solution. All surfaces must be thoroughly washed with the freshly prepared bleach solution, so that the surfaces are glistening wet. If you are not sure of the extent of the contamination, thoroughly wash the exposed portions of the drawer rack and cabinet with the freshly prepared bleach solution.

WARNING

ALL PORTIONS OF THE BODY THAT COULD POSSIBLY COME INTO CONTACT WITH THE AFFECTED INSTRUMENT SURFACES MUST BE COMPLETELY COVERED BEFORE BEGINNING THE DECONTAMINATION PROCESS.

PATHOGENIC MICROORGANISMS, INCLUDING HEPATITIS VIRUSES AND HUMAN IMMUNODEFICIENCY VIRUS, MAY BE PRESENT IN CLINICAL SPECIMENS. "STANDARD PRECAUTIONS"[1-4] AND INSTITUTIONAL GUIDELINES SHOULD BE FOLLOWED IN HANDLING ALL ITEMS CONTAMINATED WITH BLOOD AND OTHER BODY FLUIDS.

[1-4] IBID.

CAUTION

Do not use organic solvents such as cyclohexane, benzene, or alcohol when cleaning the station lens. Such materials can cause degradation of the lens sealing gasket or the lens itself.

Required materials:

- 10% bleach solution
- Personal protection equipment, including gloves, gown, eye protection (e.g., face shield, goggles, etc.)
- Gauze pads or paper towels
- Tap water

Cleaning procedure:

1. Wear gloves and a gown, completely covering any body surfaces that could possibly come into contact with the affected instrument surfaces.
2. Turn off power to the instrument. Unplug the instrument power cord before proceeding.
3. Completely absorb the contaminated spill (gauze pads are most effective).
4. Apply the bleach solution to the affected surfaces, so that the surfaces are glistening wet. Let stand for approximately 15 minutes.
5. Absorb the applied solution with gauze pads or paper towels.
6. Dampen a clean cloth with water. Wipe down the decontaminated surfaces.
7. Thoroughly dry all wet surfaces.
8. Discard all cleanup materials with biohazardous waste.

6.3 Maintenance – Test

For operational information on the Maintenance – Test functions, refer to Section 4.3. For reference information, refer to Section 5.5.1.

6.4 Maintenance – Utilities Menu

The Maintenance – Utilities menu provides access to the following functions:

- Upgrade Software – update the instrument software to a new version
- Save DB and Log – save the vial database and event log to a USB flash drive
- Save Log – save the event log (only) to a USB flash drive
- Change Password – change the default/existing password required to save configuration changes
- Reboot – restart the instrument's main computer
- BD Utilities – for BD use only

Maintenance – Utilities Fields

S/W Versions

Drop-down list shows the current versions of instrument software modules. These modules include the System Control Board (SCB), the Electronics Drawer Board (EDB), the Drawer Control Board (DCB), the IMM Communications Micro (ICM), and the Row Board (RB).

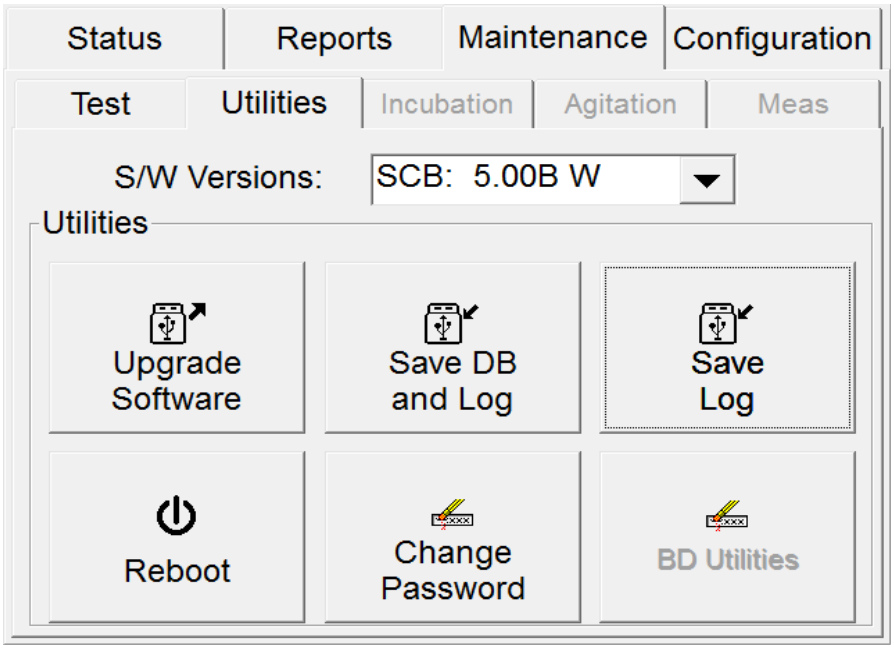

Figure 6-6 – Maintenance – Utilities Menu

6.4.1 Upgrade Software

1. Open the access panel to the right of the LCD Touchscreen.
2. Insert the flash drive containing the software update in the USB port.
3. Select **Upgrade Software**.
4. When the Enter Password window appears, select the blank password field. Enter the Supervisor password with the onscreen keyboard, then select **ENTER**, followed by **OK**.
5. To continue with the software upgrade, select **Yes** in the UTIL07 message box. To cancel the installation, select **No**.

6 The screen blanks and the instrument then reboots. The new software loads as the instrument reboots.

7 When the UTIL15 message appears, the update process is complete. Remove the USB flash drive.

6.4.2 Save DB and Log

To save the vial database and event log files to a flash drive:

1 Open the access panel to the right of the LCD Touchscreen.

2 Insert a flash drive in the USB port.

3 Select **Save DB and Log**.

4 The Busy icon appears.

5 When complete, two messages appear. Select **OK** in each message box.

6.4.3 Save Log

To save the event log files to a flash drive:

1 Open the access panel to the right of the LCD Touchscreen.

2 Insert a BD-supplied flash drive in the USB port.

3 Select **Save Log**.

4 The Busy icon appears.

5 When complete, a message appears. Select **OK**.

6.4.4 Reboot

To reboot the BD BACTEC™ FX instrument application/main computer:

1 Select **Reboot**. A confirmation message asks if you want to reboot the application.

2 Select **Yes** to reboot, or select **No** to cancel the reboot. A message window confirms that you select **Yes** when the confirmation message appears.

6.4.5 Change Password

To change the password:

1 Select **Change Password**.

2 The password window appears.

3 Enter the current password in the Old Password field.

4 Enter the new password in the New Password field.

5 Repeat the new password in the Confirm Password field.

6 Select **OK**.

If the same password has been entered in the New Password and Confirm Password fields, and the new password conforms to the requirements, a message appears confirming that the password was changed.

For additional information, refer to Section 5.5.3.5.

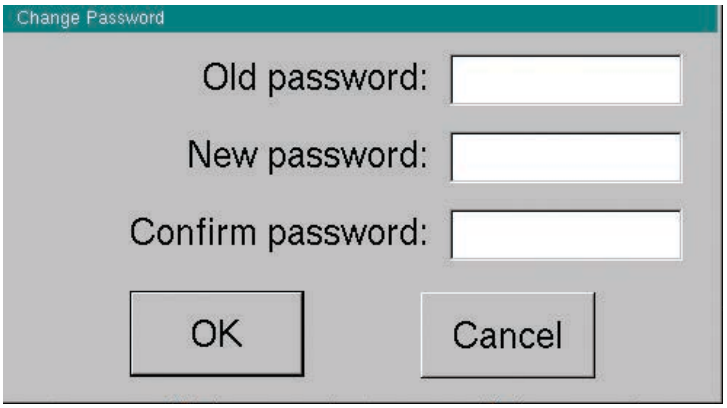

Figure 6-7 – Change Password Window

6.4.6 BD Utilities

This function is for BD use only.

7 – Troubleshooting

7.1 General: Instrument Service

If your BD BACTEC™ FX instrument malfunctions or operates unusually in any way, you may initially attempt to solve the problem by following the recommendations in this section. All other servicing attempts will terminate the responsibility of the manufacturer under the terms of the warranty.

If you cannot repair a system malfunction, contact your local BD representative. Contact numbers are listed in Section 9.

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

7.2 Error/Alert Messages

CAUTION

When the instrument notifies you of alerts and errors, you should immediately respond to the condition.

When the system encounters an alert or error condition, the error is usually displayed in a message box on the screen (some alerts are only written into the system alert list).

There are several different types of alerts and errors, and they behave in slightly different ways.

- Most system alerts appear in message boxes (some are only sent to the System Alert Display).
- Most system alerts cause the System indicator to illuminate until the alert is cleared; some alerts only have to be acknowledged (e.g., select **OK**) for the indicator to turn off.
- Most system alerts cause the audible alarm tone to sound; some alerts sound continuously (typically, when the problem must be addressed before operations can continue), some alerts sound a single tone. The continuous tone can be stopped by selecting **OK**. This may not clear the alert condition itself.
- All system alerts are sent to the System Alert Display and print on the Alert List Report (latest 100 alerts). As more than 100 alerts accumulate in the instrument's alert list, the older ones age out of the list.
- Some message boxes can clear themselves from the display; others are not cleared until you acknowledge them (e.g., select **OK**).
- Activity errors appear in message boxes and do not cause the system alert indicator to light. They are not sent to the System Alert Display. Activity errors generally happen as a result of some unexpected action you perform, rather than a fault condition in the instrument.

The table of messages below suggests some possible causes of errors and alerts, and provides possible corrective actions.

CAUTION

If the recommended corrective actions do not solve the problem, contact BD.

System alerts can be viewed and printed in the System Alerts display. Refer to Section 5.3.5.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
System Alerts			
00	Drawer X: Incubation failure.	Drawer incubation is over 40 °C for more than 60 continuous seconds.	Reboot instrument. 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. Contact BD.
02	Drawer X: Temperature under setpoint.	Drawer 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.	Alert clears if temperature returns within range for 5 continuous minutes or 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. Verify that room temperature is within specification (Section 2).

Error No.	Message	Possible Cause(s)	Corrective Action(s)
System Alerts			
03	Drawer X: Temperature over setpoint.	Drawer 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.	Alert clears if temperature returns within range for 5 continuous minutes or if instrument is rebooted. Verify that room temperature is within specification (Section 2). Check/clean air filters. 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.
04	Drawer X: Temperature sensor fault.	Drawer 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.
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 drawer 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 ensure 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.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
System Alerts			
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.
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.
13	Database Reinitialized.	Set during startup when the instrument detects corruption in the database.	Alert clears when the instrument reinitializes the database and eliminates the corruption.
14	Time offset (SESC) will inhibit the movement of vials between instruments. Contact BD.	A time mismatch has occurred between multiple instruments.	This error is set and cleared automatically. Contact your local BD representative if error persists/ recurs.
15	Contains a vial which may have a reading gap due to an invalid time offset (SESC). Consult manual.	Most likely cause is that a vial was moved between instruments with mismatched time offsets.	Any vials with reading gaps are marked as Affected Vials. Refer to Section 7.3.3 for instructions on Affected Vials.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
System Alerts			
16	EpiCenter Communications failure.	This alert is detected when BD EpiCenter™ is configured and cannot be reached.	Alert clears itself when communication with BD 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.
20	AC Power is lost.	The main computer has been without AC power for more than 60 seconds.	If power is not restored within 60 seconds of the main computer detecting power loss, the main computer performs an orderly shutdown of the user interface.
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 drawer 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.
23	Drawer 'X' offline. Remove any vials in unusable stations. Consult Manual.	Occurs when the drawer 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.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
System Alerts			
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 drawer has been open for longer than 10 minutes.	Close the drawer. Allow it to remain closed for at least 30 minutes. NOTE: If drawer is not closed within 40 minutes of the time that it is opened, all vials in drawer 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 4.12.3 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 four 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 2 minutes until successful communication with the barcode reader is established.
33	Program download failure.	Set when a microprocessor download fails to complete successfully.	Reboot instrument.
34	Watchdog Timeout Failure, Notify Becton Dickinson.	An error occurred in the main computer software.	Reboot the main computer using the Maintenance > Utilities > Reboot function.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
System Alerts			
36	Reboot Reason.	Message sent to System Alert display only (Info detail window). Instrument has rebooted for one of the following causes: 1. Unknown Cause 2. Software Upgrade Initiated 3. Software Upgrade Completed 4. Power Fail 5. Power Interrupted 6. Software Assert 7. Watchdog Timeout 8. Software Fault 9. Invalid WD Count 10. Syscall Failure 11. OSBDPL Fatal 12. Downgrade Not Allowed 13. Assert at Interrupt Level 14. Invalid Reason Code 15. Stack Fault 16a. Allocation Fault (Vx Works only) 16b. System Maintenance (NgbOnWin only) 17. Reboot Button Pressed 18. Application Restarting to Complete Software Upgrade 19. Upgrade Completed	If error recurs, contact BD. 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.
37	Drawer X: Agitation Failure.	Agitation outside of normal range. Agitation has been re-started four consecutive times. (Preceded by four occurrences of Alert 47.)	Alert is cleared when the instrument determines that the agitation speed is within range. 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.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
System Alerts			
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 drawer.	Any vials in the affected row(s) are marked as Affected Vials. Refer to Section 7.3.3 for instructions on Affected Vials.
39	Drawer X: A temporary agitation failure has occurred.	Agitation failure caused by drawer not being fully closed.	Open and close the drawer, and then power the instrument OFF and back ON. Contact BD.
40	Reminder – The drawer has been open too long.	Caused when the drawer is still open every 5 minutes after Alert 26 has been reported and acknowledged.	Close the drawer. NOTE: If drawer is not closed within 40 minutes of the time that it is opened, all vials in drawer 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	BD BACTEC FX and BD EpiCenter times are not synchronized.	The instrument has determined that its time is not synchronized with the BD 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 only. 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 four 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.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
System Alerts			
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.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
System Alerts			
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.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
Barcode Messages			
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. Select **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. Select **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: * ? [ ] ! # | Select **OK** to remove the message box.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
Culture Screen Messages			
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.
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.	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.	Select **Yes** to confirm the disassociation. Select **No** to cancel the disassociation.
CS21	One or more reports have been canceled.	Appears if you select 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. Select **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.	Select **Yes** to confirm the disassociation. Select **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.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
ID Anonymous Messages			
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. Select **Save** 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 select Save.
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 select **Cancel** or close the drawer 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.	Select **OK** to discard the vial's readings. Select **Cancel** 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.	Select **Yes** to identify the anonymous vial. The ID Anonymous display appears. Select **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.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
ID Anonymous Messages			
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 select Return 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 select **Cancel** in response to the message, the vial becomes a newly entered anonymous vial.
ID13	Vial pending identification. Discard all readings and exit workflow?	Occurs if you select Exit on the ID Anonymous display, with information related to a pulled vial on the screen.	Select **Yes** to exit the ID Anonymous display. All readings to date for the vial are discarded. Select **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.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
Maintenance Utilities Messages			
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 select **Yes** to continue.
UTIL10	Did not find a valid BACTEC FX Software Upgrade disk.	The flash drive in the USB port does not contain updated BD 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.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
Maintenance Utilities Messages			
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.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
Vial Entry Messages			
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.
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. Select **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. Select **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 a drawer was offline.	Message is informational. Select **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 reentered into the instrument within 20 minutes of its removal.	Select **Yes** to return the vial as ONGOING. Select **No** to return the vial as POSITIVE.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
Vial Entry Messages			
VE19	The Vial's medium is expired and results may be unreliable.	Expired vial is scanned.	Message is informational. Select OK to remove the message box.
VE21	Vial entered with no lot or expiration information. To include this information please remove and re-scan the vial.	A vial was placed in a station and only the accession number and sequence number were scanned.	Message is informational. Select OK to remove the message box.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
Vial Removal Messages			
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 two numbers are identical, select **Yes**. If the numbers are not identical, select **No**.
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. Select **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.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
Workflow Exception Messages			
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.	Select **Yes** to remove the scanned vial named in the message box. Select **No** to place the vial back in the instrument. WE03: Scan sequence to return or select **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, select **Cancel.**
WE04	Unexpected sequence scanned. Can you scan correct sequence?	Appears if you scan an unexpected vial after a WE03: Scan sequence to return or select 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 select **Yes,** then the WE03: Scan sequence to return or select **Cancel** to accept removal message reappears. If you select **Cancel**, then a WE06: Unverified sequence. Return through Vial Entry workflow message appears. To return the unexpected vial, select 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 two numbers are identical, select **Yes**. If the numbers are not identical, select **No**.
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 a BD 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 BD EpiCenter™ are reestablished.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
Workflow Exception Messages			
WE14	Exit with vial information pending on screen. Exit?	Message appears if you select Exit 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.	Select **Yes** to exit without saving the data. Select **No** to return to the display with data retained on the display. Then select **Save** to save the data.
WE16	Only one drawer may be open at a time while performing vial workflows.	You opened a second drawer.	Only one drawer 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 drawer 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. Select **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 selecting the Media field and selecting the correct medium type in the dropdown box. Select **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. Select **OK** to remove the message box.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
Workflow Exception Messages			
WE28	Unexpected vial pulled during batch removal.	The system lights 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.	Select **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 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. Select **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 a drawer, when offline drawer goes online again, or after power is cycled. The drawer is shown at the top of the message box. Message is displayed for each drawer where the first positive detection occurs.	Select **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?	A drawer that contains sequenced vials in Unusable Stations was opened.	Refer to Section 7.3.2 for additional information.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
Workflow Exception Messages			
WE34	Drawer selected is currently offline. Information shown may not be up-to-date.	Appears if a drawer that is offline is selected in Drawer View or Block/Unblock Stations display. The drawer, a station, or a row board in a drawer 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 drawer.
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, select **Yes**. Select **No** to cancel the print request.
WE36	Drawer contains anonymous vials that are in unusable stations. Print Maintenance QC Report or view Drawer Status screen to locate vials, then identify using ID Anonymous workflow. Consult Manual.	A drawer that contains anonymous vials in Unusable Stations was opened.	Use the ID Anonymous activity to identify any vials in the drawer. When identifying anonymous vials in this scenario, be sure to either select **Save** after identification to move them to another drawer, or place the vials in another station in the drawer 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 drawer 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 drawer sensor has detected that the drawer is not fully closed.	Push drawer 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.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
Workflow Exception Messages			
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 BD EpiCenter™ 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.	Select **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. Select **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 a BD 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 BD 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.

Error No.	Message	Possible Cause(s)	Corrective Action(s)
Workflow Exception Messages			
WE63	Drawer is experiencing an agitation problem and cannot take readings.	Four retry attempts to resume agitation have failed. (See System Alert 37) Unrecoverable issue with agitation system.	Move all vials to another drawer. Contact BD.

7.3 Unusable Stations, Affected Vials, and Partially Seated Vials

7.3.1 General

Certain system alerts represent conditions where the instrument is uncertain whether test readings are accurate or that the instrument hardware is functioning within specifications. When these alerts occur, any stations in rows or drawers where instrument function is in question are marked as Unusable. As soon as the drawer containing Unusable Stations is opened, a message box (WE31) appears and provides the opportunity to move the vials from Unusable Stations to good stations.

BD strongly recommends that you respond to these messages immediately, and follow the instructions below for Unusable Stations. If vials are left in Unusable Stations for more than 40 minutes, the vials become marked as Affected vials. For optimal recovery, all Affected vials should be subcultured.

Certain conditions also alert the instrument to the possibility of Partially Seated vials. When these conditions occur, a message box (WE53) appears and asks you to physically verify that vials in the indicated stations are seated. BD strongly recommends that you respond to this message immediately. If a vial is in fact partially seated, then the condition can be corrected immediately by fully inserting the vial. If the station is malfunctioning, then you can move the vial from the bad station to a good station before the vials become Affected.

7.3.2 Unusable Stations

When certain system alert conditions are detected, the hardware associated with those stations is determined to be out of specification. These stations are marked as Unusable to prevent incorrect test readings from being used for positivity analysis.

When Unusable Stations are detected, a message box appears (WE31) that enables you to process the stations now or later. If there are only anonymous vials in the Unusable Stations, message WE36 appears instead and instructs you to print the Unusable Station Report and to identify the anonymous vials.

If you select Later, the message box closes and the normal station indicator patterns light. The next time the drawer is opened, the message reappears.

BD strongly recommends that you address the WE31 message by responding as soon as possible and following the procedure below. Because the message occurs when the station is Unusable, then test readings are no longer being acquired for positivity analysis. When 40 minutes of missed readings occurs, the vials are marked as Affected, and for optimal recovery we recommend that all such vials be subcultured. To avoid this, respond to the Unusable Station message as soon as possible.

To address a WE31 Unusable Station message box:

1. Select **Later** in the message box. Close the drawer.
2. View the System Alert display and print the Alert List report.
3. Print the Affected Vials Report.
4. Open the same drawer, and select **Later** in the message box.
5. The station indicators change to their normal status indications (Positive, Negative, Anonymous, etc.).
6. If there are any positive vials in the drawer, select **Remove Positives** on the Status display.
7. Remove all positive vials using the positive removal activity (Section 4.9).
8. When all positive vials are removed, the instrument beeps 3 times to indicate that this activity is complete.
9. Select **Exit** to return to the Status display.
10. If there are any negative vials in the drawer, select **Remove Negatives** on the Status display.
11. Remove all negative vials using the negative removal activity (Section 4.9).
12. When all negative vials are removed, the instrument beeps 3 times to indicate that this activity is complete.
13. Select **Exit** to return to the Status display.
14. If there are any anonymous vials in the drawer, select **Identify Anonymous** on the Status display.
15. Identify all anonymous vials using the ID Anonymous activity (Section 4.5). If there are no available stations in the current drawer, select **Save** to save the identification. Use Vial Entry to reenter the vials in a drawer with available stations when you are done identifying anonymous vials. (Perform Step 26 for these vials if you are going to return them to the instrument immediately.)
16. When all anonymous vials are identified, the instrument beeps 3 times to indicate that this activity is complete.
17. Close the drawer, wait a moment, and reopen the drawer.
18. Message WE31 appears again.
19. Select **Later** in the message box.
20. Observe the Status display. If any of the vials identified in steps 14 through 16 have gone out of protocol, repeat steps 10 through 13.
21. Close the drawer, wait a moment, and reopen the drawer.
22. Message WE31 appears again.
23. Select **Now** in the message box. When you select **Now**, the display shown in Figure 7-1 appears.
24. Remove vials with the RED (solid) LEDs from their stations.
25. Because you earlier removed all positive and negative vials, what remains are ongoing vials.
26. Before returning the ongoing vials to good stations, check the vials' sequence numbers against the Affected Vial Report that you printed. For optimal recovery, subculture all affected vials before returning to them to usable stations.
27. Use the Vial Entry activity to return the vials to good stations (Section 4.5). Vials should be returned within 5 hours.
28. Block all Unusable Stations (Section 6.2.2.1).

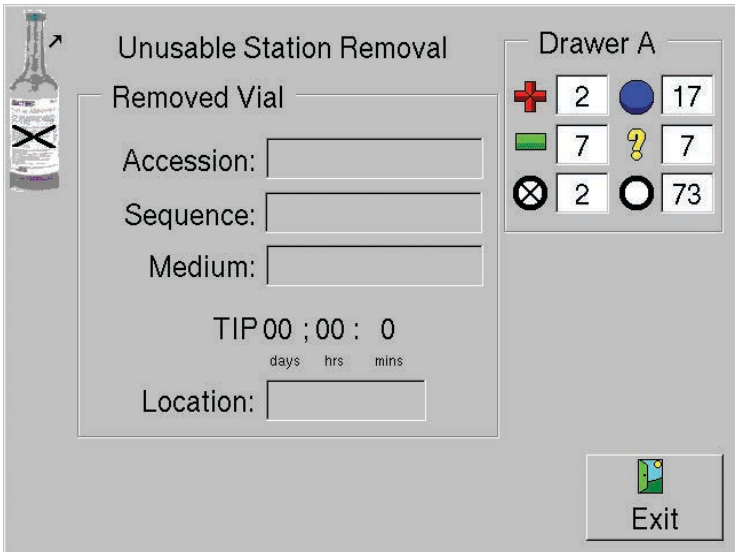

Figure 7-1 – Unusable Station Removal Display

7.3.3 Affected Vials

In some cases, a system alert resulting in Unusable Stations and affected vials can resolve on its own (e.g., an out-of-range temperature). When the system alert clears, the yellow (amber) system indicator extinguishes and the audible alarm stops. The stations may no longer be considered Unusable.

It is important to review the System Alert display when the indicator is yellow (amber) (indicating active alerts). Any time you see a critical alert (Incubation/Temperature Failure, Measurement System Failure, Agitation Failure, Reading Gap, Drawer offline, etc.), you should print an Affected Vials Report. This report lists all vials within the last 30 days that the instrument has marked as Affected.

For optimal recovery, subculture all affected vials before returning them to the instrument. Vials should be returned to the instrument within 5 hours. After appropriately addressing alerts in the Alert List, select **Remove All** to clear the System Alert display of any inactive alerts.

7.3.4 Partially Seated Stations

When a WE53 message box appears, certain conditions within the instrument have led it to believe that one or more vials may be partially seated in the station.

The message box provides the opportunity to deal with the partially inserted vials now or later.

If you select Later, the message box closes and the normal station indicator patterns light. The next time the drawer is opened, the message reappears.

BD strongly recommends that you address the WE53 message as soon as possible by selecting Now. Because the message occurs when test readings are outside of specifications, they may indicate a potential problem with a vial or with a station, so resolving the situation as soon as possible is advisable. When you select Now, the display shown in Figure 7-2 appears.

To address a WE53 Partially Seated Vial message box:

1. Select **Now** in the message box.
2. Push the vials with the RED (solid) LEDs into their stations. There may be no audible sound, or, there may be the sound of an anonymous vial insertion if the vial was out of the station far enough that the station sensor thought the vial was removed.

3 Close drawer and check for anonymous vials. If anonymous vials exist, identify them using the ID Anonymous activity.

4 Close the drawer and wait for a test cycle to occur (indicated on Status display).

5 When the test cycle is complete, open the drawer again.

6 If message WE53 does not recur, the Partial Seated Station condition is resolved.

7 If the message recurs, one of two causes is likely: either the station is bad, or the vial sensor is bad.

8 Block the recurring "Partial Seated" station by following the procedure in Section 6.2.2.1.

9 Use Vial Entry to enter the vial into a new station.

10 If message WE53 does not recur in the new drawer, the original station (the one you blocked in Step 8) was bad.

11 If the message recurs, a problem may exist with the vial. For optimal recovery, you should subculture that vial, incubate it offline, and subculture or visually inspect for positivity daily. A terminal subculture may also be performed.

12 If the error is a result of a bad vial sensor, unblock the station (Section 6.2.2.2) you blocked in Step 8, since it was not the cause of the Partial Seated Station error.

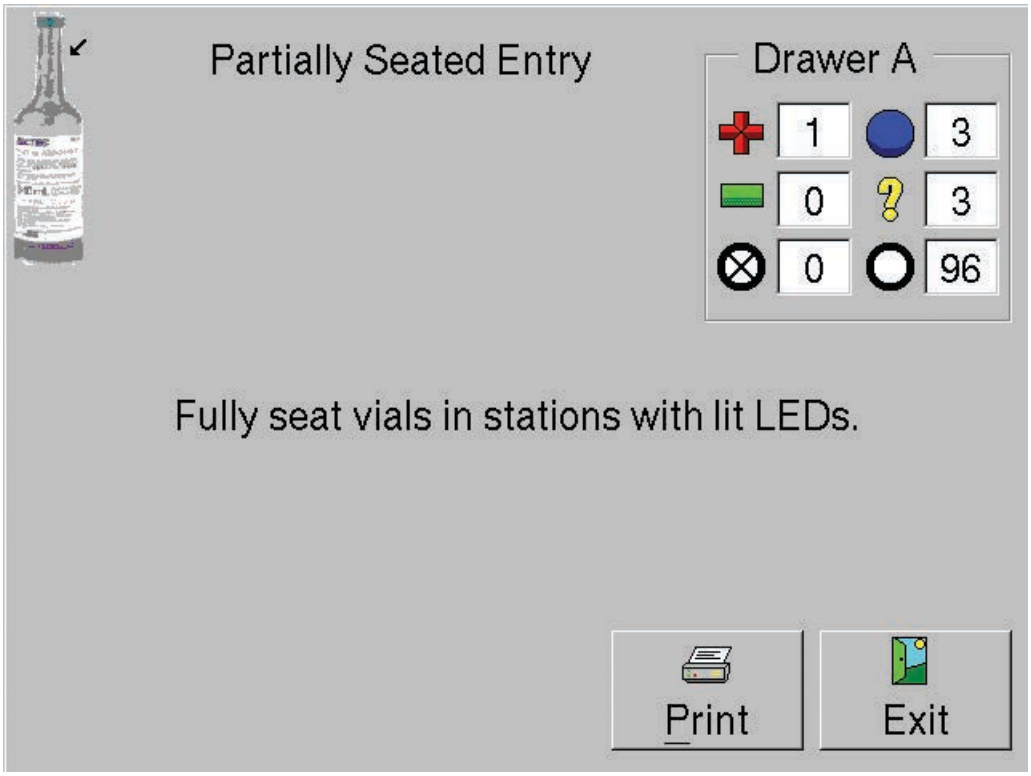

Figure 7-2 – Partial Seated Entry Display

7.4 Barcode Scanner

If the barcode reader for the top (or bottom) instrument in a stack malfunctions, the barcode reader for the other instrument can be configured to scan vials for the entire stack.

1. Select the **Configuration** tab.
2. Select the **Instr(ument)** tab and locate the Barcode Reader field.
3. If the Top instrument's barcode reader has malfunctioned, select the **Bottom** radio button. If the Bottom instrument's barcode reader has malfunctioned, select the **Top** radio button.
4. Select **Save** and enter the Supervisor password when prompted.

Contact BD immediately to have the inoperable barcode reader repaired by your local BD representative.

8 – Limited Warranty

This warranty gives you specific legal rights. Additionally, you may have other rights that vary by region.

The BD BACTEC™ FX instrument (BD BACTEC™ FX Top and BD BACTEC™ FX Bottom instruments) is warranted to the original purchaser to be free from defects in materials and workmanship for a period of one year following installation. BD's sole responsibility under this warranty shall be to repair or replace any instrument or its components (except for expendable supplies) which under normal operating conditions, prove to be defective within one year of delivery.

BD will furnish new or remanufactured components upon its option. All replacements shall meet new part specifications and shall be warranted as above for the remainder of the one year period. Replaced components become the property of BD.

It is understood that the equipment covered by this Agreement has been installed in accordance with the recommendations and instructions in the BD BACTEC™ FX Instrument User’s Manual.

Any damage to a BD BACTEC™ FX instrument resulting from the insertion or removal of cables that connect this instrument to systems other than those approved or supplied by BD or the failure of the owner to maintain reasonable care and precautions in the operation and maintenance of the system will void this warranty and terminate the obligations of the manufacturer as stated herein.

This warranty is in lieu of all other warranties, whether express or implied, including but not limited to, warranties of merchantability, or fitness for a particular use. In no event will BD be liable for indirect, incidental, special or consequential damages regardless of whether BD has been advised of such.

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	BR	0800 5911 055

10 – Replacement Parts

Catalog Number	Item
440809	Air Filters, Cabinet
441370	Thermometer, Temperature QC (digital)
441398	BD BACTEC™ FX Software Update Kit
441407	Printer, USB
441519	Flash Drive, USB, Blank
445516	Plug, Bad Station (10)
445518	Tray, Vial (2)
445529	Barcode Labels, Replacement

11 – Glossary

Term	Definition
accession	any number that is not exactly 12 digits starting with the numbers “44” (this is the format of a vial sequence number; any other barcode is interpreted by the instrument as an accession number)
activity displays	Vial Entry, Positive Removal, Negative Removal, IDentify Anonymous displays; so named because they represent the main user activities
Affected vial	vial that resided in a station where an Incubation Failure was detected; or a vial with a gap in test readings (reading gap) that exceeds a threshold defined as potentially affecting positivity interpretation
algorithm	mathematical formula that is used to interpret readings from the measurement system to determine if microbial growth has occurred or is occurring
ambient temperature	temperature of the room where the Instrument is placed
Anonymous vial	vial entered into the instrument without a sequence number
blocked station	station that was blocked by user; the vial presence sensor is no longer active in a blocked station, and no test readings are saved
contaminant	means of flagging a positive culture to indicate that the isolate is thought to be clinically insignificant
culture	all of the vials within an accession
degraded mode	in a BD EpiCenter™ configuration, when a BD BACTEC™ FX instrument loses communication with the BD EpiCenter™ master database, it enters a degraded mode of operation; only limited operations can be performed
demographic data	data that is associated to the patient, including: Accession, Patient Name, Patient ID, Collection Date/Time, Hospital Service
End of Protocol	date and time when defined testing protocol for vial has been reached; if left in instrument, vial testing continues
GMT	Greenwich Mean Time (now referred to as UCT or Universal Coordinated Time)
home position	the position the racks are placed in when a drawer is opened; this position is near 0°.
Hospital Service	field to identify the service or ward from which the specimen was collected
in protocol	a vial that is within its defined testing protocol (between Start and End of Protocol); an Ongoing vial

Term	Definition
location	synonym for station
manually entered vial	vial whose sequence number was entered using the onscreen keyboard
medium, media	culture vial for use in the BD BACTEC™ FX instrument; current media types include: Type — Code — Abbreviation shown on reports Aerobic Plus — 92 — Aer Plus Anaerobic Plus — 93 — Ana Plus Anaerobic Lytic — 65 — Ana Lytic Myco Lytic — 88 — Myco Lytic Mycosis/IC — 06 — Mycosis I/C Peds Plus — 94 — Peds Plus Platelet Aerobic — 5A — Aer Plt Platelet Anaerobic — 5B — Ana Plt Standard Aerobic — 60 — Std Aer Standard Anaerobic — 91 — Std Ana
message, message box	message that is displayed on the screen that provides information to the user (compare to system alert)
Negative, Negative vial	vial that has reached the end of its protocol without triggering any positivity algorithm
offline	not communicating (e.g., if a drawer is offline, it is not communicating with the main instrument application; if LIS is offline, it is not communicating with the instrument)
Ongoing vial	vial still within its protocol that has not yet tripped any positivity algorithms
orphan	orphan vial: a vial that has no accession; orphan accession: an accession that has no patient data orphan demographics: patient/specimen data where the associated vial has not been placed in the instrument
orphan demographics	demographic data that exists in the database without being associated to a vial
Orphan vial	vial that exists in the database with no associated accession number
out of protocol	a final Negative vial; however, if left in instrument, vial testing continues
patient id	field that allows up to 16 characters to uniquely identify a patient
patient name	field that allows up to 40 characters that represents the patient's name
peek window	20-minute window where a removed vial must be reentered in order to retain its status and readings
pending vial	vial that exists in the database with no Start of Protocol; such vials have never been placed in the instrument

Term	Definition
Positive culture	accession that contains at least one positive or manual-positive vial and at least one positive vial that is not marked as a contaminant
Positive vial	vial that has triggered at least one positivity algorithm
Positive Anonymous vial	vial with no sequence number that has triggered at least one positivity algorithm
reading gap	condition where no readings have been taken or saved for at least 40 minutes
reentry window	5-hour window during which a removed vial can be reentered in order to continue its protocol
Related vial	vials are related that have the same accession number; typically used to identify all vials that originate from the same collected specimen
replacement barcode	vial sequence with a medium type of 99; a barcode designed to replace the original vial sequence barcode if it is damaged or unreadable by the barcode scanner
sensor	in a vial, the material at the bottom of the vial is called the sensor; it contains a dye that reacts with carbon dioxide released by organisms as a by-product of metabolic activity; the dye modulates the amount of fluorescence emitted by material in the sensor; the system analyzes the measured fluorescence to determine if the culture is positive
sequence	barcode to identify BD BACTEC™ culture vials; barcode value is exactly 12 digits and starts with 44; the third and fourth digits contain the medium type; the last 8 digits identify the vial
Sequenced vial	vial that has an associated sequence number (i.e., is not anonymous)
Start of Protocol	date and time when the vial is first placed in the instrument; value is used to calculate End of Protocol, Time in Protocol, and Time to Detection
station	format is Instrument-Drawer-RowColumn (nn-L-Lnn, where n is for number and L is for letter)
Status	vial status; statuses include: Type — Abbreviation shown on reports Positive — Positive Negative — Negative Ongoing — Ongoing Manual Positive — Man Pos Manual Negative — Man Neg Pending — Pending
test	see media
TIP	Time in Protocol: calculated from time of entry into the instrument (the vial's Start of Protocol) until the current time (if in the instrument) or removal time (if removed from the instrument), in the format of days;hours:minutes (DD;HH:MM)

Term	Definition
TTD	Time to Detection: calculated from the time of first entry into the instrument (the vial's Start of Protocol) until the instrument declares the vial as positive, in the format of days;hours:minutes (DD;HH:MM); does not apply to manual positive vials
Unusable Stations	station that has been determined during internal testing of the instrument to not be within the acceptable tolerances, generally indicative of an instrument failure such as an agitation, incubation, or measurement failure; stations are counted as blocked
vial presence sensor	each station contains a vial presence sensor that detects vial insertions and vial removals.
vial sequence	see sequence
vial status	see status

11.1 Symbols Glossary

There are several symbols used on the instrument. Those symbols and their meanings are shown below:

US Customers only: For symbol glossary, refer to bd.com/symbols-glossary.

Symbol	Symbol Title
	Manufacturer
EC REP	Authorized representative in the European Community
REF	Catalogue number
IVD	In vitro diagnostic medical device
R_x Only	This only applies to US: “Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.”
	Biological Risks
	Caution
	Temperature limit
	Consult *instructions for use* or consult electronic *instructions for use*
	Date of manufacture
CE	CE marking; Signifies European technical conformity
SN	Serial number
	Do not use if package is damaged and consult *instructions for use*
CH REP	Authorised representative in Switzerland
	Importer

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