

BD Phoenix™ AP

Instrument User's Manual



CE **IVD** **R_x Only**

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EC REP

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1 - Introduction

1.1 Intended Use

The BD Phoenix AP instrument is designed for use with the BD Phoenix system. It is intended to standardize ID broth tube inoculum, add AST indicator to the AST broth tube and transfer an aliquot of ID broth to AST broth tubes, as required for preparing samples for use on the BD Phoenix system, which performs identification and susceptibility testing.

1.2 Operation Overview

The BD Phoenix AP instrument provides BD Phoenix sample preparation including automated inoculum standardization, precise fluid transfer and barcode driven panel login.

The BD Phoenix AP instrument is able to support two fully utilized BD Phoenix 100 instruments, enabling enough sample processing to fill both instruments within a 4.5 hour period. This design allows the processing of 200 Gram negative or Gram positive tube sets in 4.5 hours. The instrument can prepare ID-only, AST-only, Emerge (AST136) or ID/AST broth tube sets.

To use the BD Phoenix AP instrument make a heavy suspension of the test isolate in BD Phoenix ID broth. Measurement of this concentration by the technologist is not required. The BD Phoenix AP instrument is designed to handle a broad starting density, anywhere between 0.20 and 4.00 McFarland.

Optimized workflow includes labeling the initial suspension with a BD EpiCenter barcode that combines both the lab accession number and isolate number. The barcode is used to electronically link the BD Phoenix panel with the appropriate patient isolate. Alternate workflows using a Laboratory Information System (LIS) can also be used.

After a short vortex and removal of the cap, the BD Phoenix ID broth is placed into the BD Phoenix AP Sample rack along with an uncapped BD Phoenix AST broth tube. This procedure can be repeated for up to five isolates per Sample rack. While processing a rack, the BD Phoenix AP instrument can also queue up to three additional racks for processing. Likewise, up to three racks can be ejected into the output belt without requiring user intervention.

To begin the automated process, one or more racks is placed on the Input Queue. The processing is started using the BD Phoenix AP instrument touchscreen. The rack is indexed into the instrument then the BD Phoenix AP instrument will automatically:

- Add the BD Phoenix AST indicator to the AST broth tubes
- Resuspend the ID broth to prepare accurate nephelometry
- Determine the initial density utilizing a highly sensitive turbidity measurement system
- Adjust the McFarland density by adding ID fluid with a highly accurate peristaltic pump and pipetting excess liquid to the waste container
- Transfer an aliquot of ID broth to the BD Phoenix AST broth tubes in the Sample rack
- Program the result of the process into the Sample rack's memory using Radio Frequency Identification (RFID) technology for proper interpretation by the BD Phoenix instrument

Within approximately 7 minutes, the BD Phoenix AP instrument completes all of the tube sets in the Sample rack, readying the samples for inoculation into the appropriate BD Phoenix panels.

Specimen login is performed at a BD EpiCenter workstation using a combination of barcodes, RFID, and touchscreen. By simply placing the processed rack in the BD Phoenix AP Inoculation Station, the BD EpiCenter system can be updated to reflect the rack results and the BD Phoenix AP instrument information is transferred to the BD Phoenix/BD EpiCenter database. After batch login of the rack information, the user pours the inoculum into the BD Phoenix panels and caps the panels to complete the Inoculation Station procedure. From here, the user places the panels into the BD Phoenix 100 instrument.

1.3 Instrument Overview

The BD Phoenix AP instrument contains the following major components:

- Rack Handling Module – Rack Conveyors move Sample racks from Input Queue to the Processing Chute to the Output Queue; multiple sensors detect the location of Sample racks on the instrument and display their location as they are processed by the instrument
- Dispenser Module – a peristaltic pump that controls dispensing of ID Broth to ID broth tubes
- Pipettor Module – performs dispense and mixing operations, acquires and disposes of pipette tips, and dispenses waste liquid to the waste bottle; liquid levels are monitored by the use of conductive tips
- Nephelometer – for determination of inoculum density
- Fluidics Control Module – tracks the volume of ID Broth, AST Indicator, waste liquid
- Drawer – provides user access to consumable items, such as ID Broth, AP AST Indicator, pipette tips, and waste liquid and waste tip receptacles
- Sample rack – rack into which ID and AST Broth tubes are loaded for processing on the instrument. Sample racks come in two varieties. Original sample racks containing 2 rows of 5 wells can be used to prepare tubes to inoculate combination panels (ID/AST), ID only panels and AST only panels. A newer rack has an additional row of 5 wells and can be used to prepare the 3 broth tubes (ID Broth, AST broth, and AST 4.5 mL) used to inoculate Emerge (AST 136) panels, as well as, continuing to prepare all the other standard panel types (see below) supported by the older rack.
- AP Inoculation Station – station into which you load the completed Sample racks and BD Phoenix panels for upload of rack status to BD EpiCenter, clearing the rack RFID tag, panel login, and inoculating the BD Phoenix panels
- Inoculation insert for the AST 4.5 mL tubes. Insert fits into the docking station and provides posts to raise 5 AST 4.5 mL tubes within the new AP Rack
- RFID Read/Write Module – writes the following data to the RFID tag: sample status, initial turbidity values, final turbidity values, QC data (Nephelometer verification results, Nephelometer calibration results, Pipettor verification run, Dispense calibration results), instrument number, "Rack Processed" flag
- Instrument Software – accessed through a LCD Touchscreen; icon-based Graphical User Interface (GUI); monitors consumable volumes/quantities and expiration timers, Sample racks, and run status in real time; displays instrument alerts; presents setup and maintenance functions/displays

1.3.1 Test Disposal Overview

- BD Phoenix Standard panels include:
- ID only panels - The ID side of the panel (51 wells) contains substrates used for determining bacterial identification, and the AST side (85 wells) is empty. Gram Positive (PID) or Gram Negative (NID) inoculation preparation is performed in BD Phoenix AP, but broth suspensions used to inoculate Strep ID or Yeast ID panels can only be prepared and inoculated manually.

- Combination ID/AST panels - The ID side contains substrates used for determining bacterial identification and the AST side contains antimicrobials for antimicrobial susceptibility testing. Gram Positive (PMIC/ID) or Gram Negative (NMIC/ID) inoculation preparation is performed in BD Phoenix AP, but broth suspensions used to inoculate Strep ID/AST panels can only be prepared and inoculated manually.
- AST only panels - The ID side of the panel is empty and the AST side contains antimicrobials for antimicrobial susceptibility testing. Gram Positive (PMIC) or Gram Negative (NMIC) inoculation preparation is performed in BD Phoenix AP, but broth suspensions used to inoculate Strep AST only panels (SMIC) can only be prepared and inoculated manually.
- Emerge (AST136) panels (nonstandard) - The panel contains wells for antimicrobial susceptibility on both the 51-well and 85-well sides. Gram Positive (PMIC) or Gram Negative (NMIC) inoculation preparation is performed in BD Phoenix AP, but Strep Emerge panels can only be prepared and inoculated manually.
- Inoculation Reagent Tubes
- ID Broth (4.5 mL) - ID broth tubes contain fluid used to inoculate the ID side of ID only and Combination ID/AST panels. The 4.5 mL volume is required to fill the ID side of panels. The ID broth can also be used to prepare AST broth suspensions to inoculate Emerge panels or AST only panels.
- Inoculum Broth (2.2 mL) - Inoculum broth is used to prepare AST broth suspensions for Emerge panels only, prepared on AP. This broth cannot be used in panels containing ID tests (combination ID/AST or ID only panels) because the volume of liquid is too low to fill the ID side of a BD Phoenix panel.
- The lower volume in the tube facilitates preparation of a bacterial suspension of sufficient turbidity to inoculate panels (≥ 0.25 McFarland) when there are few isolated colonies to work with. (This broth can also be used to inoculate AST only panels manually, but cannot be processed by the AP for these panels)
- AST Broth Tubes
- AST Broth (8 mL) - This AST broth tube contains sufficient volume to fill the AST side (85 wells) of BD Phoenix panels.
- AST Broth (4.5 mL) - This AST broth tube contains sufficient volume to fill the 51-well side of Emerge panels. This broth can only be used with the AP system. To fill Emerge panels manually, follow the procedure described in the BD Phoenix User's Manual in Section 4 using two AST broth (8 mL) tubes.



Figure 1-1 – BD Phoenix AP System



Figure 1-2 – BD Phoenix AP Consumables

Clockwise from top left: waste tip bin; BD Phoenix AP AST Indicator; waste liquid bottle; pipette tip tray; ID broth solution; Dispense Tubing set



Figure 1-3 – BD Phoenix AP Inoculation Station

Sample rack is shown at front of Inoculation Station. Top image shows 2-row rack; bottom image shows 3-row rack.

1.4 Use of this Manual

This user's manual is designed as a reference tool for technologists, supervisors, and other personnel who operate and maintain the BD Phoenix AP instrument on a regular basis. Every attempt has been made to include all information which would be required during normal use and maintenance of the instrument. Should a question arise which is not answered in this manual, please contact the following parties (USA):

All product related questions, in North America:

☎ Technical Services 1–800–638–8663

International contacts are listed in Section 11.

Other documentation required for proper instrument operation includes:

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 Phoenix AP module within BD EpiCenter.

BD Phoenix System User's Manual – This manual provides complete instructions on use of the BD Phoenix 100 microbiology instrument.

1.5 Conventions

1.5.1 Buttons, Icons, and Displays

Screen buttons and icons are always identified by lowercase letters in quotes, and the words “button” or “icon” (e.g., “start” button). Display names are shown in Title Case text, describing the display's function (e.g., Calibrate Nephelometer display).

1.5.2 Symbols and Connections Used on the Equipment

The following symbols and connections appear on the BD Phoenix AP instrument:



Figure 1-4 – Symbols/Connections Used on the BD Phoenix AP Instrument (A)

Left side at rear: Power Connection and Power Switch



Figure 1-5 – Symbols/Connections Used on the BD Phoenix AP Instrument (B)

Right side at front: USB port and Serial Port (for BD use only)







	Biohazard		Electrical Hazard
	Refer to accompanying documentation (specifically, the User's Manual)		Protective Conductor Terminal
	AC Voltage		DC Voltage

Figure 1-6 – Symbols/Connections Used on the BD Phoenix AP Instrument (C)

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.

2 - Installation

2.1 General

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

- Instrument specifications (Section 2.2)
- Instrument installation (Section 2.3)
- Software setup (Section 2.4)
- Software installation (Section 2.5)

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.**

2.2 Instrument Specifications

Physical Dimensions	
Height	61 cm (24 in)
Width	91.5 cm (36 in)
Depth	81.5 cm (32 in)
Clearance (left, right)	7.6 cm (3 in)
Clearance (rear)	2.5 cm (1 in)
Clearance (front)	40.7 cm (16 in) minimum 91.5 cm (36 in) recommended
Weight	90.7 kg (200 lb) empty

Electrical Requirements	
Input Voltage	100–240 VAC
Peak Current	6.3 A
Input Line Frequency	50/60 Hz
Power	150 VA
Leakage Current	< 500 µA
Input Voltage (Inoculation Station)	5 VDC, USB powered
Peak Current (Inoculation Station)	100 mA, USB powered
Heat	
	500 BTU

Environmental Requirements	
Non-Operating Storage	
Temperature	-17.8–65 °C (0–149 °F)
Humidity	20–90% Relative Humidity, non-condensing
Operating Conditions	
Temperature	20–30 °C (68–86 °F)
Humidity	20–90% Relative Humidity, non-condensing
Locations	Area that is free from undue vibration, direct sunlight, high humidity, dust, temperature extremes, external air sources, and corrosive or explosive vapors or gases
Noise @ 1 m	62 dBA during operation
Altitude	0–2,240 m (0–7,350 ft)
Other	
Decontamination: withstands 65 °C Dry Heat for 10 hours	
Installation Category II and Pollution Degree 2 as per IEC 664	
Hereby, Becton, Dickinson and Co. declares that this BD Phoenix AP System is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.	

2.3 Instrument Installation

2.3.1 Site Preparation

The BD Phoenix AP instrument is installed only by BD representatives.

WARNING

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

The BD Phoenix AP 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 between 20–30 °C (68–86 °F). Relative humidity should be 20–90% non-condensing.

7.6 cm (3 in) clearance is required on the left or right sides of the instrument and 10.2 cm (4 in) is required at the rear, 40.7 cm (16 in) clearance is required in the front of the instrument to open the drawer, however 91.5 cm (36 in) is recommended.

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

2.4 Software Setup

Before using the instrument for preparation of ID/AST broth tubes, 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:

- Set date and time
- Set inoculum density
- Set rack aging timer
- Set audible alert volumes
- Set the LCD backlight brightness
- Set instrument number

At the top of the Configuration menu, the Configuration icon is shown. The current time and date and the inoculum density setting are also shown.

To access the Configuration menu:



From the Idle display, tap the “configuration” button

To access any configuration display, tap the associated button.

Field values can be changed by tapping the arrows (up/down), drop-down arrows, radio buttons, or checkboxes next to them.

To save your changes, tap the “save” button, then tap the “exit” button to return to the Idle display.



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

To cancel your changes, tap the “exit” button and tap it again at the “exit without saving” confirmation display.

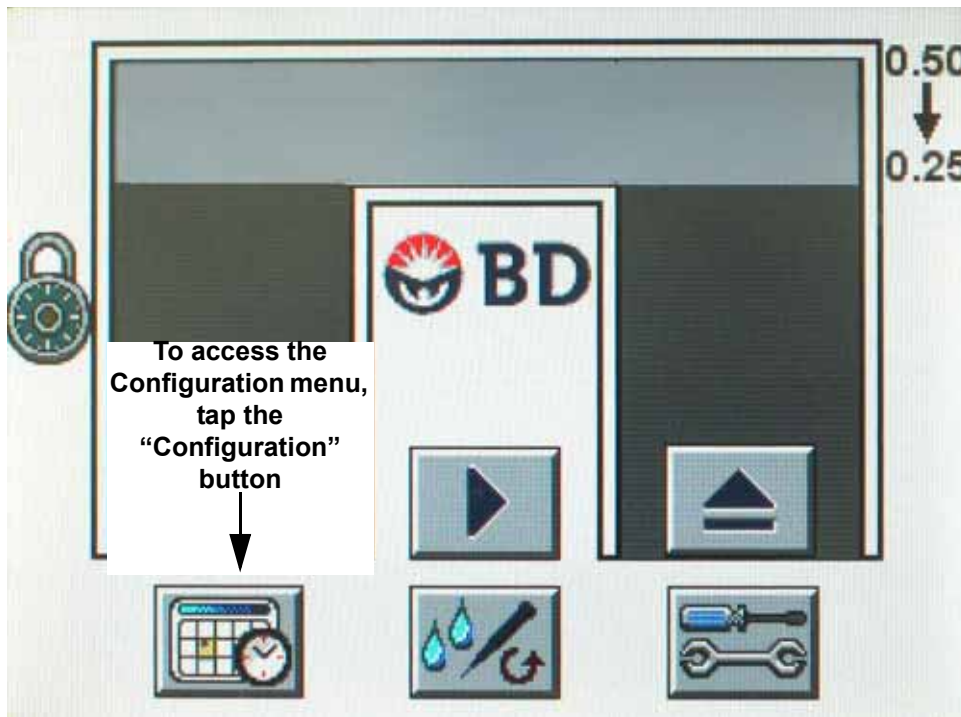


Figure 2-1 – Idle Display

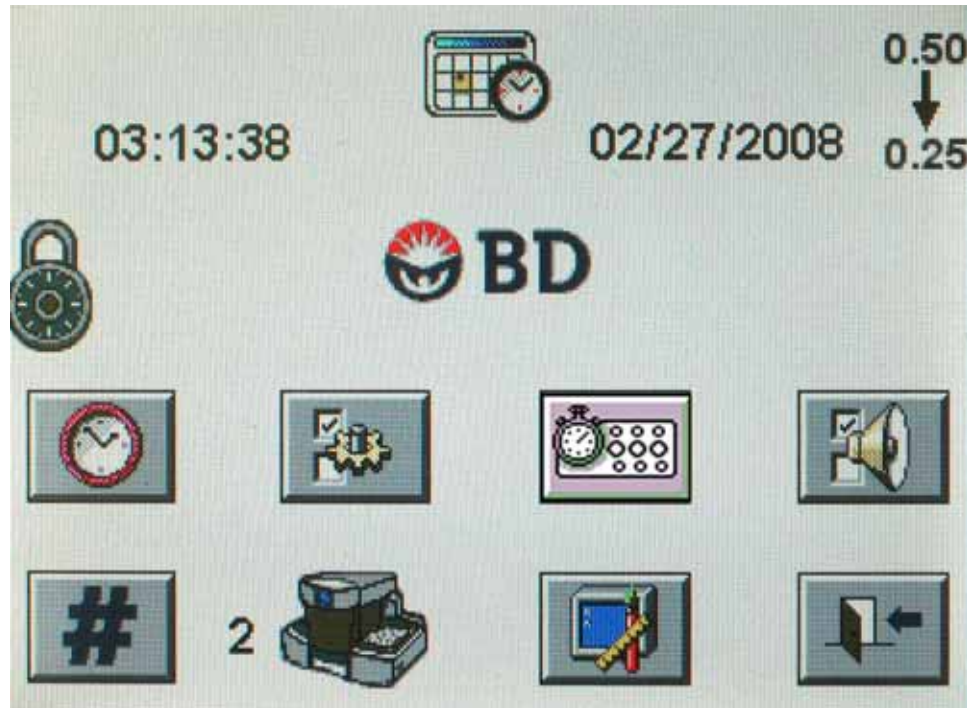


Figure 2-2 – Configuration Menu

2.4.1 Set Date and Time

The Set Date and Time function allows you to set values for month, day, year, hour, minute, and seconds. The time setting uses a 24-hour clock (e.g., 4:00 p.m. is shown as 16:00).

The date and time should be set to match the date and time at the BD EpiCenter system. If the respective clocks are not synchronized, the BD EpiCenter system generates warning messages.

There is no automatic adjustment for Daylight Saving Time. To adjust the time for DST, set the clock forward or backward one hour on the appropriate date.

To access the Set Date and Time display:



From the Idle display, tap the “configuration” button



From the Configuration menu, tap the “set date and time” button

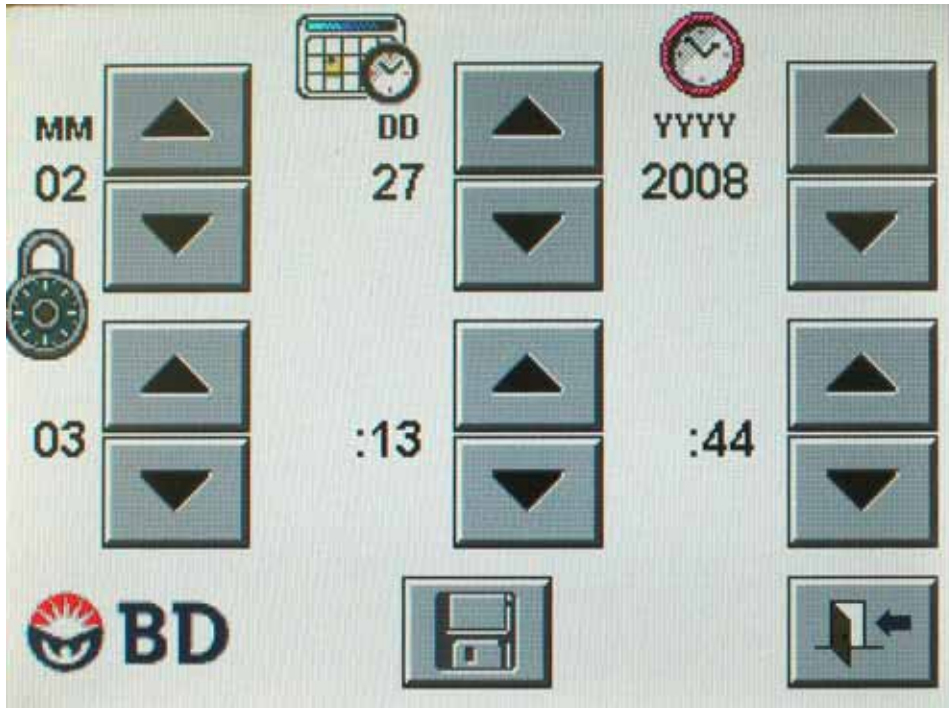
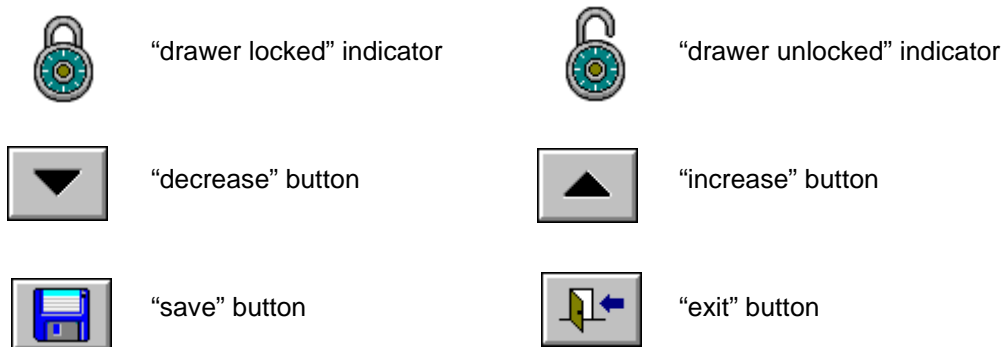


Figure 2-3 – Configuration – Set Date and Time

Each field value is shown to the left of the “increase”/“decrease” button set. In the top row, MM indicates the Month; DD indicates the Day; and YYYY indicates the Year. In the second row, the leftmost value is Hours; the middle value is Minutes; and the rightmost value is Seconds.

Set Date and Time Icons and Buttons:



To increase a value, tap the increase button to the right of the field. To decrease a value, tap the “decrease” button. When the highest value is reached, the counter wraps around to the lowest value (e.g., 59 minutes wraps around to 00 minutes).

The “save” button is disabled (grayed out) until a change is made to one of the field values.

To save the date and time, tap the “save” button.

To exit the display, tap the “exit” button.

2.4.2 Set Inoculum Density

The Set Inoculum Density display allows you to set the default McFarland density for ID broth tubes. You can choose 0.25 or 0.50 McFarland. A checkbox allows you to enable the Fallback option of 0.50 to 0.25. When the Fallback option is enabled, the instrument will adjust the density to 0.25 McFarland if the starting concentration of the ID broth tube is less than 0.50 McFarland.

Refer to the *BD Phoenix System User's Manual* (Appendix F) for a listing of taxa claims for each inoculum density.

To access the Set Inoculum Density display:



From the Idle display, tap the “configuration” button



From the Configuration menu, tap the “set inoculum density” button

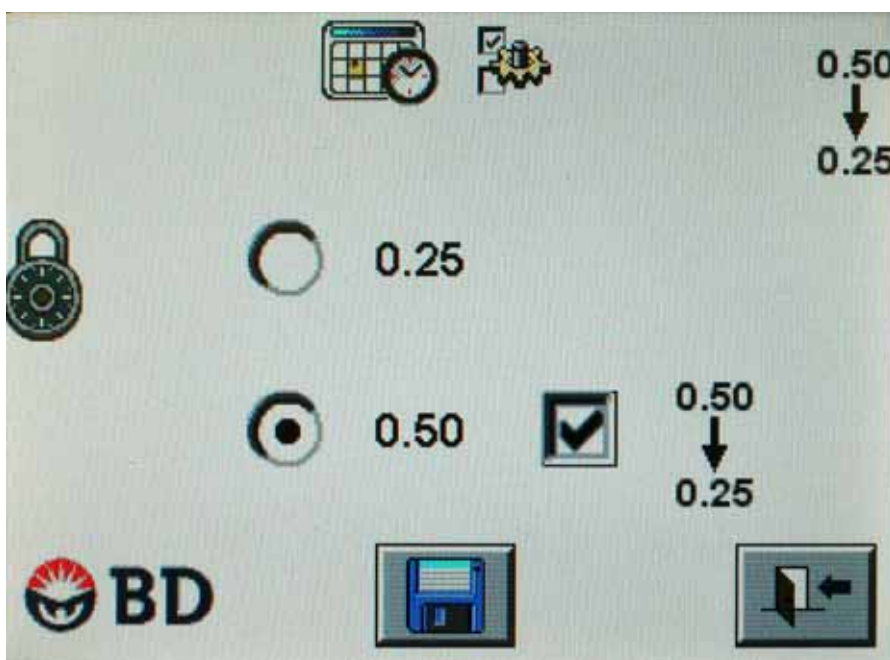


Figure 2-4 – Configuration – Set Inoculum Density

To select a density of 0.25 McFarland, tap the radio button to the left of the 0.25 value. The instrument will adjust the density to a value between 0.20 to 0.30 McFarland.

To select a density of 0.50 McFarland, tap the radio button to the left of the 0.50 value. The instrument will adjust the density to a value between 0.50 to 0.60 McFarland.

To enable the Fallback setting of 0.50 to 0.25, first select the 0.50 McFarland inoculum density, then tap the checkbox to right of the density.

The “save” button is disabled (grayed out) until a change is made to one of the field values.

To save the inoculum density settings, tap the “save” button.

To exit the display, tap the “exit” button.

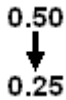
Set Inoculum Density Icons and Buttons:



“drawer locked” indicator



“drawer unlocked” indicator



“fallback” checkbox



“save” button



“exit” button

2.4.3 Set Rack Aging Timer

The Set Rack Aging Timer display allows you to set the amount of time (5 to 25 minutes) for an audible alert to occur indicating that inoculated tubes are about to expire. This alert is intended as a reminder that ID and AST broth tubes must be used to inoculate BD Phoenix panels within certain time limits (30 minutes after inoculation of AST broth tubes, 60 minutes after processing of ID broth tubes).

The Rack timer can be set in increments of 5 minutes.

The timer represents the time left (remaining) before the timer expires.

When the rack timer expires, a Workflow Error is generated and an audible tone (not configurable) sounds. In addition, the rack icon turns red on the Run Status and Rack Status displays. The tubes in these racks should not be used to inoculate panels.

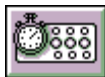
Example: To be alerted when 5 minutes remain in the timer, set a value of 5 minutes.

For ID-only tubes, the timer fires when 55 minutes have expired; for ID/AST tubes, the timer fires when 25 minutes have expired

To access the Set Rack Aging Timer display:



From the Idle display, tap the “configuration” button



From the Configuration menu, tap the “set rack aging timer” button

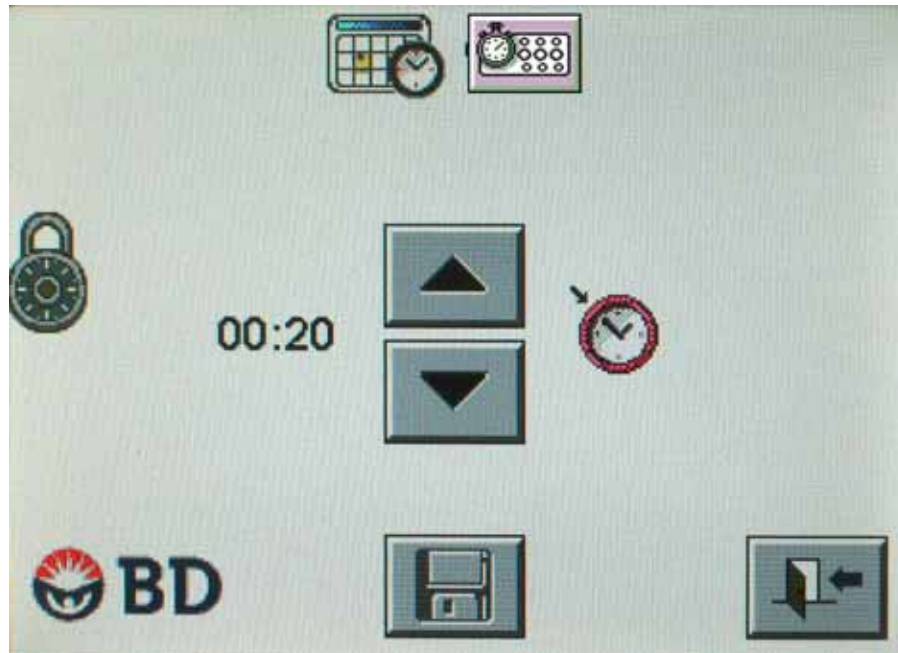


Figure 2-5 – Configuration – Set Rack Aging Timer

Set Rack Aging Timer Icons and Buttons:



“drawer locked” indicator



“drawer unlocked” indicator



“decrease” button



“increase” button



“save” button



“exit” button

To increase the timer, tap the “increase” button.

To decrease the timer, tap the “decrease” button.

The current timer value is shown to the left of the “increase” and “decrease” buttons.

The “save” button is disabled (grayed out) until a change is made to the field value.

To save the rack timer setting, tap the “save” button.

To exit the display, tap the “exit” button.

2.4.4 Set Audible Alerts

The Set Audible Alerts display allows you to adjust the volume (or disable) alert sounds for 5 different instrument events/conditions:

- rack completed;
- rack aging timer;
- system and workflow alerts;
- consumables issues (volume, quantity, or stability);
- Output Queue full.

These settings have no effect on the display of error codes or other non-audible Instrument responses to error conditions.

The non-configurable Rack timer volume setting (not shown) equals that of the configurable Rack timer volume setting. The minimum volume of the non-configurable Rack timer audible alert is 4.

To access the Set Audible Alerts display:



From the Idle display, tap the “configuration” button



From the Configuration menu, tap the “set audible alerts” button

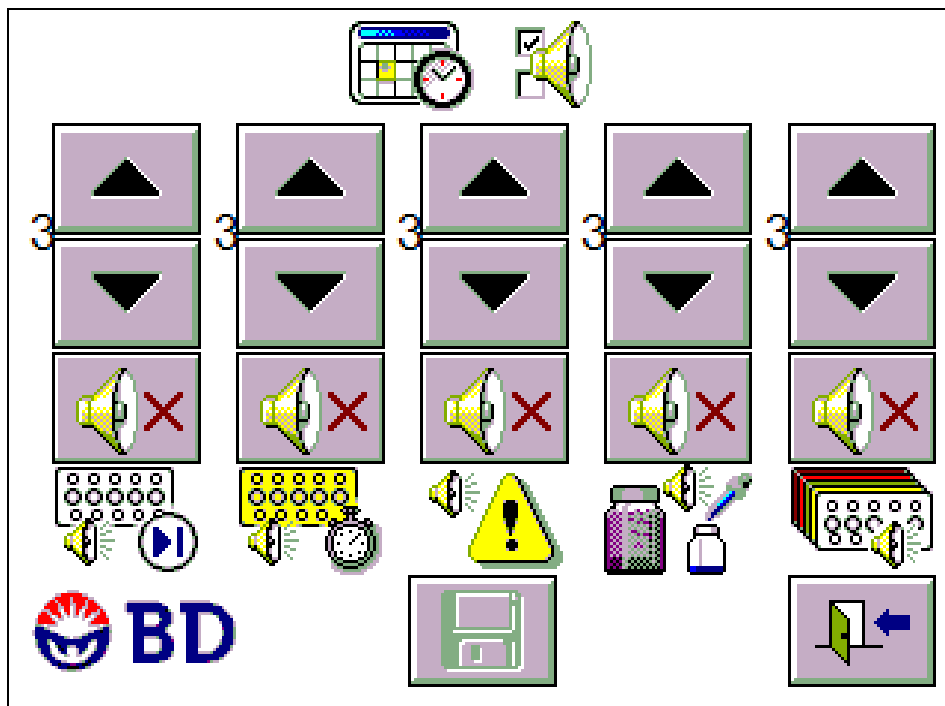





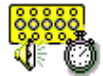







Figure 2-6 – Configuration – Set Audible Alarm Volumes

Set Audible Alerts Icons and Buttons:

	“audible alert on” indicator/button		“audible alert muted” indicator/button
	“decrease” button		“increase” button
	“rack completed” alert		“rack aging timer” warning
	“system/workflow alert” alert		“consumables issue” alert
	“output queue full” alert		“save” button
	“exit” button		

To increase the volume, tap the “increase” button.

To decrease the volume, tap the “decrease” button.

To mute an alert, tap the “audible alert on” button. The icon changes to “audible alert muted.”

To un-mute an alert, tap the “audible alert muted” button. The icon changes back to “audible alert on.”

The current volume is shown to the left of the “increase” and “decrease” buttons.

When the highest value is reached, the counter wraps around to the lowest value (e.g., the 9 setting wraps around to the 1 setting)

The “save” button is disabled (grayed out) until a change is made to the field value.

To save the alert volume settings, tap the “save” button.

To exit the display, tap the “exit” button.

2.4.5 Set Instrument Number

Set Instrument Number display allows you to set a unique number to identify each BD Phoenix AP instrument (up to 9). The instrument number value is stored on the RFID tag in the rack to identify the instrument that prepared the ID/AST broth tubes in a particular rack.

If you have more than one BD Phoenix AP instrument, you should set a unique instrument number at each instrument.

To access the Set Instrument Number display:



From the Idle display, tap the “configuration” button



From the Configuration menu, tap the “set instrument number” button

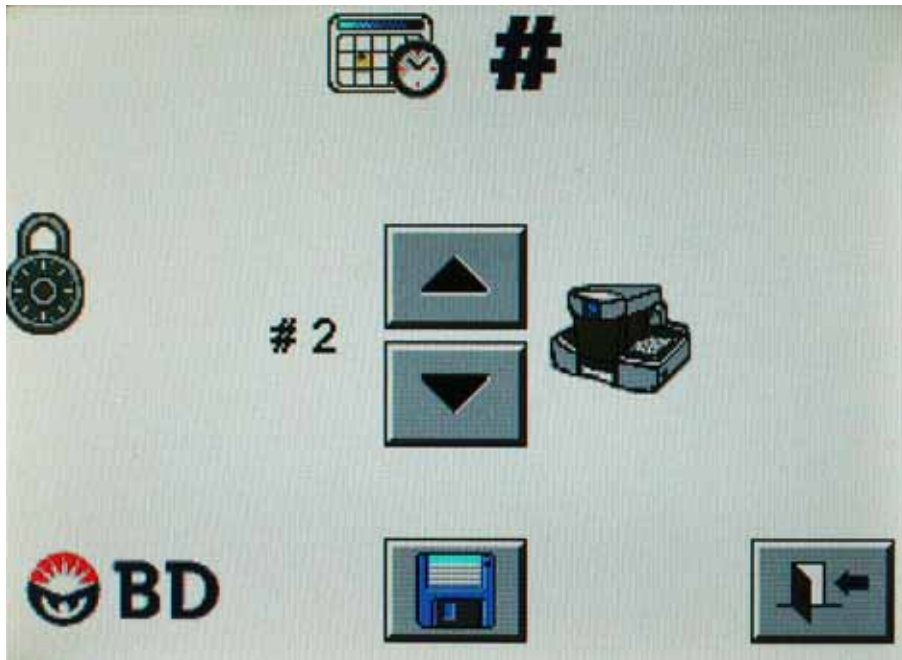
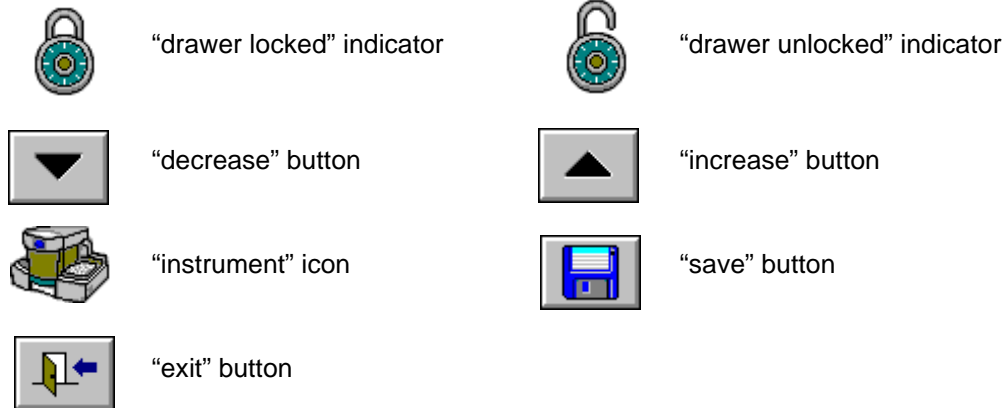


Figure 2-7 – Configuration – Set Instrument Number

Set Instrument Number Icons and Buttons:

To increase the instrument number, tap the “increase” button.

To decrease the instrument number, tap the “decrease” button.

The current instrument number is shown to the left of the “increase” and “decrease” buttons.

When the highest value is reached, the counter wraps around to the lowest value (e.g., the 9 setting wraps around to the 1 setting)

The “save” button is disabled (grayed out) until a change is made to the field value.

To save the instrument number, tap the “save” button.

To exit the display, tap the “exit” button.

2.4.6 Set Display Brightness

The Set Display Brightness allows you to adjust the backlight brightness of the LCD/Touchscreen. There are 9 brightness settings.

The LCD display dims after 30 minutes of inactivity. To reactivate the LCD backlight, tap the screen.

To access the Set Display Brightness display:



From the Idle display, tap the “configuration” button



From the Configuration menu, tap the “set display brightness” button

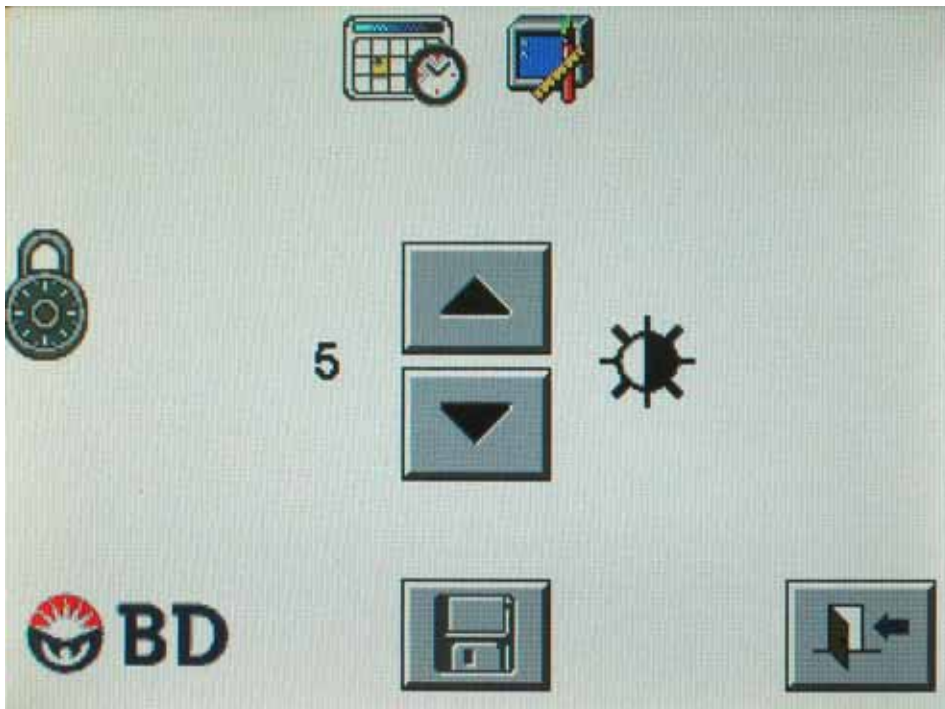
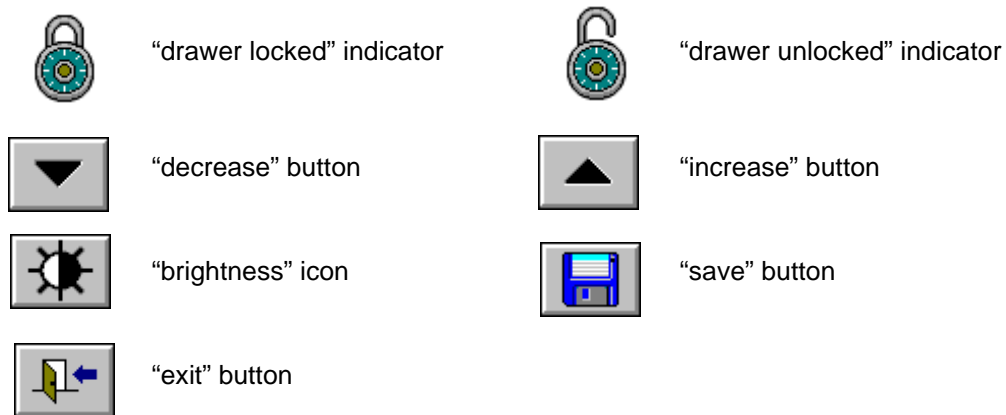


Figure 2-8 – Configuration – Set Display Brightness

Set Display Brightness Icons and Buttons:



To increase the brightness, tap the “increase” button.

To decrease the brightness, tap the “decrease” button.

Each time the “increase” or “decrease” button is touched, the display changes immediately to the new setting.

The current setting number is shown to the left of the “increase” and “decrease” buttons.

When the highest value is reached, the counter wraps around to the lowest value (e.g., the 9 setting wraps around to the 1 setting)

The “save” button is disabled (grayed out) until a change is made to the field value.

To save the brightness, tap the “save” button.

To exit the display, tap the “exit” button.

2.5 Software Installation

For instructions on installing software updates, refer to Section 6.3.4 – Software Upgrade Function.

3 - Controls and Indicators

3.1 General

This section describes the meaning and use of the controls and indicators of the BD Phoenix AP 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.

The following controls and indicators are discussed:

- Power Switch
- Power Indicator
- Drawer Handle
- LCD/Touchscreen
- Data Ports
- Audible Tones and Alarms
- Icon, Button, and Indicator Colors

WARNING

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

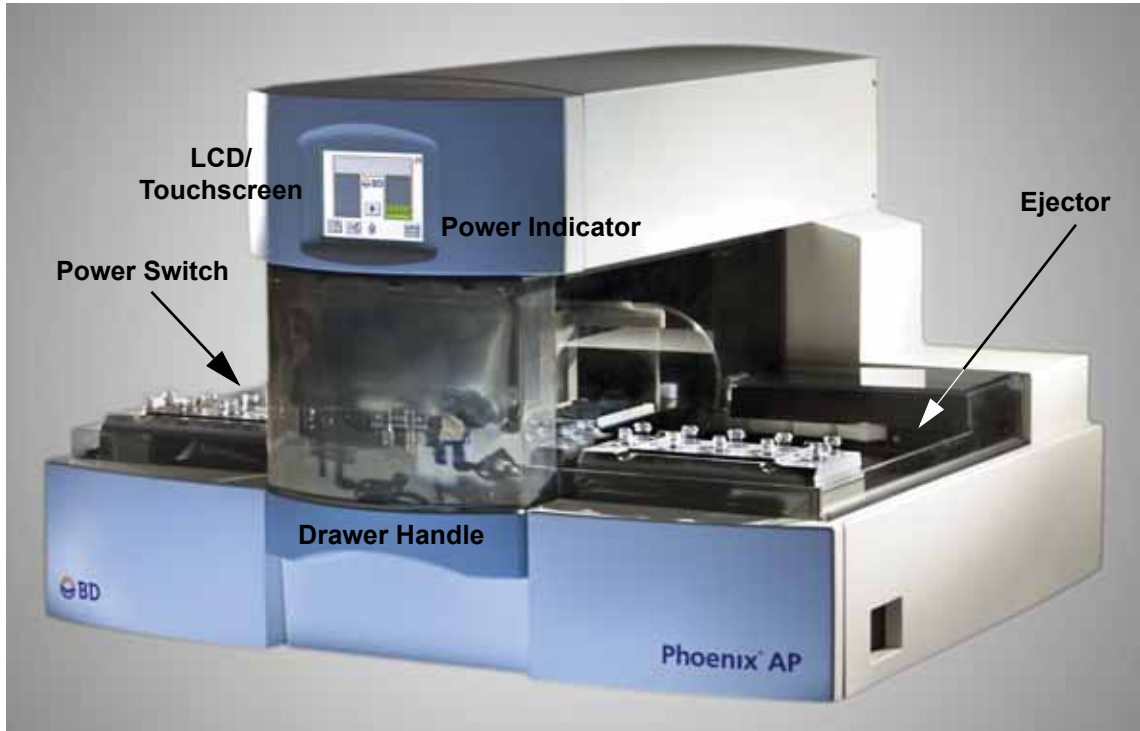


Figure 3-1 – BD Phoenix AP instrument Layout

3.2 Power Switch

The system power (On/Off) rocker switch is located on the left side at the rear of the instrument. When in the Off (O) position, power is removed from the instrument. When in the On position (I) power is applied to the instrument. During normal operation, power should remain on at all times except when performing some maintenance procedures.

See Figure 3-2.



Figure 3-2 – Power Switch

3.3 Power Indicator

The power indicator is located on the front of the instrument, to the lower right of the LCD/ Touchscreen. When extinguished, power is removed from the instrument. When illuminated green, power is applied to the instrument.

See Figure 3-3.



Figure 3-3 – Power Indicator

3.4 Drawer Handle

See Figure 3-1 for drawer handle location. The drawer is electromagnetically latched to prevent it from being opened during instrument operation. The drawer must first be unlocked by the user tapping the “lock/unlock drawer” button on the Maintenance menu. The drawer unlocks automatically when you access the Consumables menu and before the instrument self-test.

To open the drawer, grasp the drawer handle and pull the drawer out completely.

3.5 LCD/Touchscreen

The Liquid Crystal Display (LCD) and Touchscreen is located at the top center of the 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/Touchscreen is shown in Figure 3-1.

During the startup process and self-test, the Startup display appears. When the startup process is complete, the Idle display appears. Other displays appear as you perform various operations.

Do not use pens or sharp implements to tap the touchscreen; this can cause damage to the screen. You can use your fingertip or fingernail for greater precision, or a pencil eraser to tap buttons on the screen without causing damage.

The LCD is programmed to automatically dim after 30 minutes of inactivity. To return the brightness to normal, just tap the screen lightly anywhere.

More information on displays is presented in Section 5.

3.6 Data Ports

There are two data ports on the right side of the BD Phoenix AP instrument, at the front. The port on the left is a USB port, used for installing software upgrades and saving the event log to flash media. The port on the right is a serial port. It is only used by BD Field Service personnel.



Figure 3-4 – USB and Serial Ports

3.7 Audible Tones and Alerts

Numerous different sounds are generated by the BD Phoenix AP instrument as you perform operations. Each of the sounds is unique. These tones are designed to keep you informed about various operational states of the instrument.

Type	Example	Sound
System Error	Nephelometer fails calibration	High then low tones
Rack complete	A Sample rack has completed preparation and is in the Output Queue	Muted high then low tones
Output Queue full or rack indexing problem	There are 3 Sample racks in the Output Queue	High then low tones in minor key
Consumables/waste need attention	Waste liquid bottle is full	Low then high tones
Rack aging timer (warning)	The rack aging timer has reached the user time setting	2 high fast tones (volume is user-controlled)
Rack aging timer (alarm)	The rack aging timer has exceeded the expiration time	2 high fast tones (fixed volume)

3.8 Icon, Button, and Indicator Colors

Many icons have different components that change color to indicate different statuses for the condition they represent.

Refer to Section 5 for charts showing all the icons on each display with their various color indications.

4 - Operation

4.1 General

This section describes the routine operation of the BD Phoenix AP instrument. The following major topics are discussed:

- Using the Instrument Interface (Section 4.2)
- Storage and Handling (Section 4.3)
- Workflow Summary (Section 4.4)
- Preparing the Instrument (Section 4.5)
- Preparing the Sample Rack (Section 4.6)
- The BD Phoenix AP Run (Section 4.7)
- Responding to Alarms and Errors (Section 4.8)
- Post-Run Activities (Section 4.9)
- Power Failures (Section 4.10)

4.2 Using the Instrument Interface

The Liquid Crystal Display (LCD) presents all the information needed to view instrument status and operate the instrument. The information is presented on screens with icons that represent instrument operations. The display presents information, progress bars, and prompts for the operation currently being performed. The screen is touch-sensitive, meaning you can simply touch or tap the button or icon on the screen itself to perform the associated action.

As you initiate instrument activities, the messages in the main body of the display guide you through the operations, and new buttons may appear that present additional options. All the icon definitions and buttons are presented in Section 5. Do not use pens or sharp implements to tap the touchscreen; this can cause damage to the screen. You can use your fingertip or fingernail for greater precision, or a pencil eraser to tap buttons on the screen without causing damage.

Functions which cannot be performed (buttons or icons) are “grayed out.”

4.3 Storage and Handling

BD Phoenix Panels: Panels are individually pouched and packaged in a box of 25. Panels must be stored unopened at room temperature (15–25 °C). Do not refrigerate or freeze. Visually inspect the packaging for holes or cracks in the foil package. Do not use if the packaging appears to be damaged. Do not use the panel if there is no desiccant or if the desiccant pouch is torn. If stored as recommended, the panels will retain expected performance until the date of expiration. A package of closures is included with each box of panels.

BD Phoenix ID Broth and BD Phoenix Inoculum broth (tubes): Tubes are packaged as 100 tube packs. Visually inspect the tubes for cracks, leaks, etc. Do not use if there appears to be a leak, tube or cap damage or visual evidence of contamination (i.e., haziness, turbidity). Do not use tubes that are scratched or damaged (e.g. wavy surface) because they may not read properly in the instrument. Store BD Phoenix ID broth tubes at 2–25 °C. Expiration dating is shown on the tube label.

BD Phoenix AP ID Broth (bulk): Bag is packaged as five 800 mL bags. Visually inspect the bag for cracks, leaks, etc. Do not use if there appears to be a leak or visual evidence of contamination (i.e., haziness, turbidity). Store BD Phoenix AP ID Broth (bulk) at 2–25 °C. Expiration dating is shown on the bag label. The ID Broth (bulk) must be replaced every 30 days.

BD Phoenix AST Broth tubes (8 mL and 4.5 mL): Tubes are packaged as 100 tube packs. Visually inspect the tubes for cracks, leaks, etc. Do not use if there appears to be a leak, tube or cap damage or visual evidence of contamination (i.e., haziness, turbidity). Store BD Phoenix AST Broth tubes at 2–25 °C. When not in use, the broth should be stored away from direct light. Expiration dating is shown on the tube label.

BD Phoenix AP AST Indicator (15 mL): The indicator is packaged as a package of 10 bottles. Visually inspect the bottle for cracks, leaks, etc. Do not use if there appears to be a leak, bottle or cap damage, or any change from a dark blue color. Store the BD Phoenix AP AST Indicator at 2–8 °C. Each bottle contains enough solution to test up to 150 panels. Expiration dating is shown on the box and bottle label and is for unopened bottles. An opened bottle will be stable for up to 5 days if stored on the instrument (20–30 °C).

4.4 Workflow Summary

An overview of the workflow for a run is as follows:

User Preparation

- Check/load consumable supplies in the BD Phoenix AP instrument and log replacements in the Tip/Liquid Consumables displays.
 - BD Phoenix AP ID Broth solution
 - BD Phoenix AP AST Indicator
 - Waste liquid bottle
 - Pipette tips
 - Waste tip bin
 - Dispense Tubing set
- Print and label ID Broth tubes with accession barcodes (see BD EpiCenter system help for complete instructions).
- Inoculate the ID broth tube with a bacteria sample to a level that is visually at or above the desired inoculum density of 0.25 McFarland or 0.50 McFarland.
- Recap and vortex the tubes.
- For Standard BD Phoenix panels, uncap and load the inoculated ID broth tube and an uninoculated AST broth tube into a Sample rack and place on the instrument's Input Queue. The Rack can contain 1–5 ID broth tubes and 0–5 AST broth tubes.

or

For Emerge (AST136) panels, uncap and load the inoculated ID/Inoculum broth tube and uninoculated AST broth tubes (8 mL and 4.5 mL) into a 15-well sample rack and place on the instrument's Input Queue. The proper position for AST 4.5 mL tubes is labelled on the rack.

- Tap the “start” button.

Instrument Operations

At this point automated operations begin.

- The instrument feeds the Sample rack into the Processing chute.
- For the ID sample, the instrument measures the turbidity with the onboard Nephelometer, dilutes and mixes the sample to the desired inoculum density, transfers excess sample volume to waste, and confirms the turbidity.
- For the AST sample, the Instrument transfers the AP AST Indicator into the AST broth tubes, transfers a portion of the ID sample into the tube, and mixes the sample. The ID sample volume for the AST broth tubes (8 mL) is 25 μ L for 0.50 McFarland density and 50 μ L for the 0.25 McFarland density. The ID sample volume for the AST 4.5 mL tube is adjusted appropriately for the lower volume of AST broth.
- After the samples are prepared, the instrument records the status of the instrument and of each set of tubes, sounds a tone (if configured) indicating that the process is complete, and moves the Sample rack into the Output Queue.

Post-Run Activities

- Remove the Sample rack from the Output Queue and place it on the BD Phoenix AP Inoculation Station for RFID data upload to BD EpiCenter.
- Login and scan the tubes (see BD EpiCenter system help for complete instructions).
- Prepare BD Phoenix panels by pouring the appropriate broth into the appropriate side of the panel (refer to the BD Phoenix System User's Manual for complete instructions).
- Load BD Phoenix panels into BD Phoenix instrument.

4.5 Preparing the Instrument

Materials Required:

- BD Phoenix ID Broth tubes
- BD Phoenix AP ID Broth solution
- BD Phoenix AST Broth tubes
- BD Phoenix AP AST Indicator
- BD Phoenix AP pipette tips
- Waste liquid bottle with funnel
- Waste tip bin
- Sample racks
- Calibrator tube set
- Dispense tubing set (monthly replacement)



Figure 4-1 – BD Phoenix AP Consumables

Clockwise from top left: waste tip bin; BD Phoenix AP AST Indicator; waste liquid bottle; pipette tip tray; ID Broth solution; Dispense Tubing set

Instrument Preparation:

When an instrument is first set up, all consumables must be loaded. Consumables are depleted (and some expire) at different times and rates. The BD Phoenix AP instrument tracks consumable usage and displays consumable status and alerts when items require replacement. The instructions below advise you to “check/load” consumable items: for an initial setup, the items should be loaded; for subsequent instrument runs, consumables should be checked and replaced if needed.

Refer to Figure 4-2 for locations of consumables.

- 1 Verify that the instrument power is on.
- 2 From the Idle display, tap the “consumables” button.



To log replacement of liquid consumables: tap the “liquid consumables” button.



The drawer is automatically unlocked.

- 3 Grasp the drawer handle and open the drawer.
- 4 Check/load the AP AST Indicator. Unscrew the cap and place the bottle in position. Place the cap in the cap holder. AP AST Indicator may be left in the instrument for up to 5 days. The instrument will not use the last 6 mL of solution in the bottle.

NOTES

Leave the cap on the AP AST Indicator until just before use.

Do not attempt to use the remaining solution or combine it with new AP AST Indicator.

- 5 Check/load the Dispense Tubing set. (For detailed instructions on loading this item, refer to Section 6.4 – Dispense Tubing Set Replacement.)

(Reminder: if you loaded a Dispense Tubing set, you must calibrate the Dispense Pump. Refer to Section 6.3.7 for additional instructions.)

- 6 Check/load the ID Broth solution. To load the bag, hang it on the hooks with the label toward the front of the instrument, with the blue clamp toward the left side of the instrument. Make sure the clamp is closed.

Join the ID Broth solution tube to the Dispense Tube by pushing them together and twisting to the right. Unclamp the blue clamp.

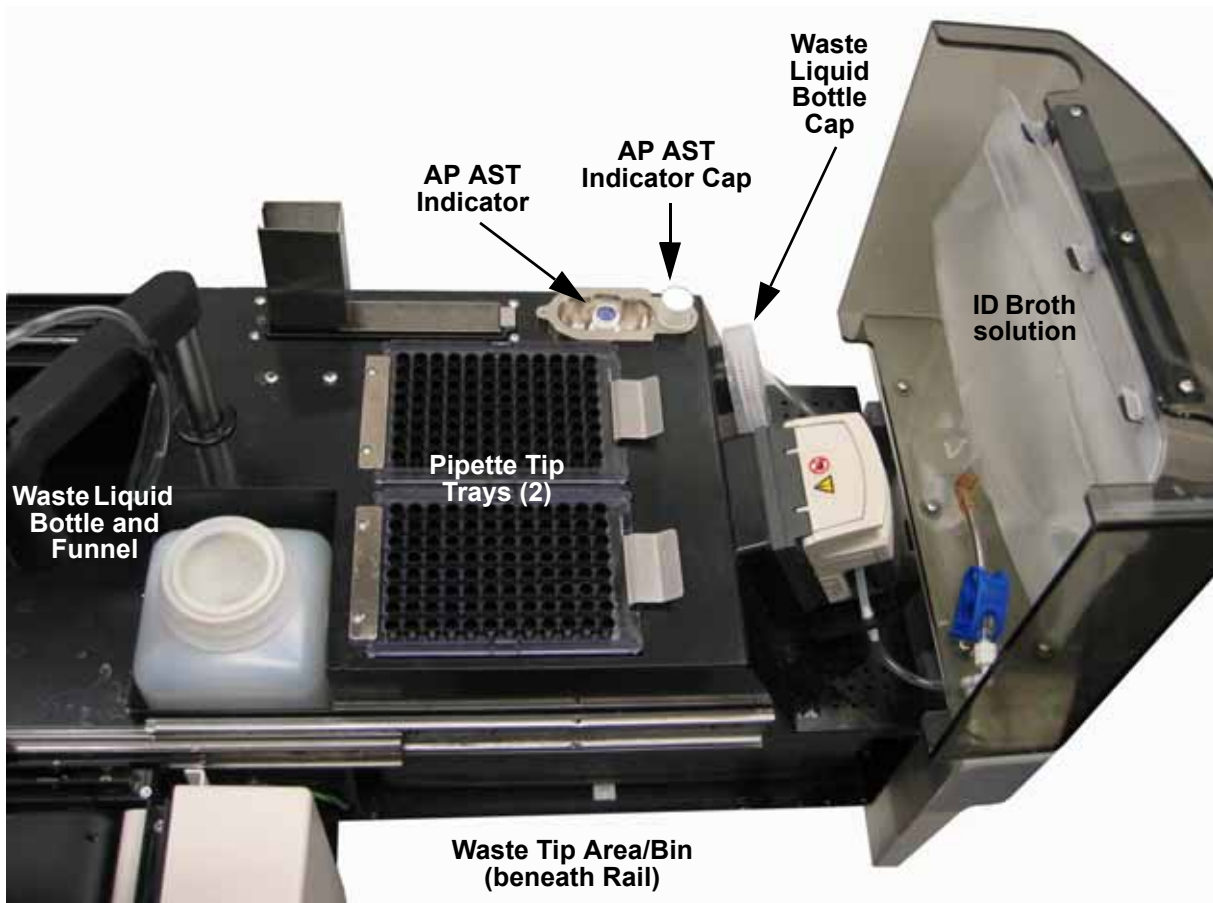


Figure 4-2 – Consumable Setup (open drawer viewed from left side)

- 7 Check/load a waste liquid bottle. Recap the full bottle (leave the funnel in place). Dispose of the waste liquid with biohazard waste.

Unscrew the new bottle lid and place it in the front holder. Waste liquid bottles should not be reused.

Make sure the waste liquid funnel is in the waste liquid bottle.

- 8 In the Liquid Consumables display, tap the “reset” button for the consumables that you added/replaced: ID Broth, AP AST Indicator, and the waste liquid bottle (note that actual icon appearance may differ based on current status).



To “undo” the replacement and return the counter to its previous state, tap the “reset” button again before saving.

Tap the “save” button to save the updated information.

- 9 Return to the Consumables menu by tapping the “exit” button.
 10 To log replacement of tip consumables: tap the “tip consumables” button.

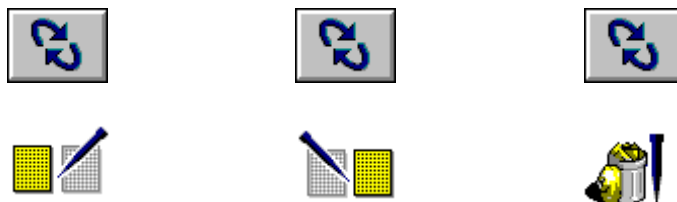


- 11 Check/load BD Phoenix AP pipette tips (black). To load a tip tray, place the rear notch under the chrome bar, carefully lower the tip tray into place, and push the front latch down. The instrument holds 2 trays of pipette tips. (Note that if only the left tray is low on tips, it is not necessary to replace the tip tray. The instrument automatically switches to the right tip tray when the left tray is depleted.)
 12 Check the waste tip chute and clear any tips from the chute if they are stuck.

If needed, carefully remove and discard waste tip bin with biohazard waste. Be careful not to spill tips from the bin.

Always make sure you replace the old bin with a new waste tip bin in the waste tip area.

- 13 In the Tip Consumables display, tap the “reset” button for the consumables that you added/replaced: the left pipette tip tray, the right pipette tip tray, and the waste tip bin (note that actual icon appearance may differ based on current status).



To “undo” the replacement and return the counter to its previous state, tap the “reset” button again before saving.

Tap the “save” button to save the updated information.

- 14 Tap the “exit” button to return to the Consumables menu. Tap the “exit” button again to return to the Idle display.
 15 Tap the “maintenance” button to access maintenance functions.



- 16 Close the drawer.
- 17 Lock the drawer by tapping the “lock/unlock drawer” button.



- 18 Run the Daily Check. From the Idle display, tap the “maintenance” button.



From the Maintenance menu, tap “daily check” button.



Place the dedicated Calibration rack on the Input Queue. (See Section 6.3.1 for information on setting up a dedicated Calibration rack.)

Tap the “start” button.



The Daily Check is performed and the Calibration rack is sent to the Output Queue at completion. (See Section 6.3.1 for more information on the Daily Check.)

Results for the Daily Check are:



Passed



Failed

If the Daily Check fails, a message is generated and a nephelometer calibration operation is required. Refer to Section 6.3.9, for additional instructions.

Take the completed Calibration rack to the BD Phoenix AP Inoculation Station to upload the results.

- 19 Prepare the Sample racks. Refer to Section 4.6 for additional instructions.

4.6 Preparing the Sample Rack

4.6.1 Isolate Selection for ID Broth Tubes

The BD Phoenix system is not for use directly with clinical specimens. Only pure culture isolates of aerobic and/or facultatively anaerobic Gram negative and Gram positive organisms are acceptable for testing. The test isolate must be a pure culture. It is recommended that cultures be 18–24 hours old. The BD Phoenix AP instrument should not be used for preparation of tubes for inoculation of BD Phoenix Strep panels (SMIC or SMIC-ID) or Yeast ID panels. For AST testing in the BD Phoenix system, isolates recovered from non-selective media are recommended. It is recommended that media containing antibiotics not be used for organisms to be tested in the BD Phoenix system except those specifically claimed in the table below. Selective media may inhibit some strains of bacteria, therefore caution must be used when selecting isolated colonies from these media. Use isolates from a blood agar plate such as Trypticase Soy Agar with 5% Sheep Blood. Other recommended media are included in the table below:

Recommended Media	Approved Use	
	ID	AST
Trypticase Soy Agar with 5% Sheep Blood	Yes	Yes
Bromthymol Blue (BTB) Lactose Agar	Yes ¹	Yes
BBL™ CHROMagar™ Orientation	Yes	Yes ²
Chocolate Agar	Yes	Yes
Columbia Agar with 5% Horse Blood	Yes	Yes
Columbia Agar with 5% Sheep Blood	Yes	Yes
Columbia CNA Agar with 5% Sheep Blood (Gram positives)	Yes	X
Cystine-Lactose-Electrolyte-Deficient (CLED) Agar	Yes ³	Yes
Dey/Engley (D/E) Neutralizing Agar (Gram negatives)	Yes	X
Eosin Methylene Blue (Gram negatives)	Yes	Yes
Hektoen Enteric Agar (Gram negatives)	Yes	X
MacConkey Agar (Gram negatives)	Yes	Yes
Phenylethyl Alcohol Agar (Gram positives)	Yes	X
Trypticase Soy Agar without Blood	Yes	X
Trypticase Soy Agar with Lecithin and Tween 80	Yes	X
Xylose Lysine Desoxycholate Agar (Gram negatives)	Yes	X
<p>¹ The use of Bromthymol Blue Lactose Agar with Gram positive organisms should be restricted to Staphylococci for both the 0.5 and 0.25 GP systems.</p> <p>² The use of CHROMagar Orientation may produce false susceptibility results when testing erythromycin with Gram positive organisms. Antimicrobial susceptibility test results should be confirmed using Trypticase Soy Agar with 5% Sheep Blood.</p> <p>³ The use of Cystine-Lactose-Electrolyte-Deficient Agar with Gram positive organisms should be restricted to Staphylococci for the 0.25 GP system.</p>		

WARNINGS

OBSERVE ESTABLISHED PRECAUTIONS AGAINST MICROBIOLOGICAL HAZARDS THROUGHOUT ALL PROCEDURES. ALL SPECIMENS SHOULD BE HANDLED ACCORDING TO CDC-NIH RECOMMENDATIONS, CLSI GUIDELINES, OR LOCAL INSTITUTION GUIDELINES FOR ANY POTENTIALLY INFECTIOUS HUMAN SERUM, BLOOD, OR OTHER BODY FLUIDS. PRIOR TO DISCARDING, STERILIZE SPECIMEN CONTAINERS AND OTHER CONTAMINATED MATERIALS BY AUTOCLAVING.

IN ADDITION TO WEARING GLOVES, THE USE OF DISPOSABLE LAB COATS OR GOWNS AND PROTECTIVE GLASSES OR GOGGLES IS RECOMMENDED WHEN WORKING AROUND THE INSTRUMENT.

4.6.2 Rack Preparation Procedure

Materials Required:

- BD Phoenix ID Broth tube
- BD Phoenix AST Broth tubes
- BD Phoenix AP Sample rack
- Specimen ID labels generated by BD EpiCenter workstation or LIS (optional)

Materials Required but Not Provided:

- Gram Stain Reagents
- Nonselective Culture Plated Media (see Figure 4-2)
- Sterile Cotton Swabs, Inoculation Loops or Needles
- Incubators
- Biohazard Disposable Container
- Vortex Mixer
- Personal Protection Equipment (e.g., gloves, disposable lab coats, protective goggles/glasses, etc.)

Procedure:

- 1 Confirm the Gram stain reaction of the isolate before proceeding with the inoculum preparation for use in the BD Phoenix AP instrument.
- 2 Label a BD Phoenix ID broth tube and AST broth tubes (if needed) with the specimen number generated by the BD EpiCenter workstation (see BD EpiCenter system help for additional information).

An ID broth tube is required for preparing ID-only panels, ID/AST panels, and AST broth tubes. AST broth tubes are required for preparing ID/AST, AST-only, and Emerge panels.

An ID broth or Inoculum broth tube may be used for preparing the Emerge panels on the BD Phoenix AP Instrument only.

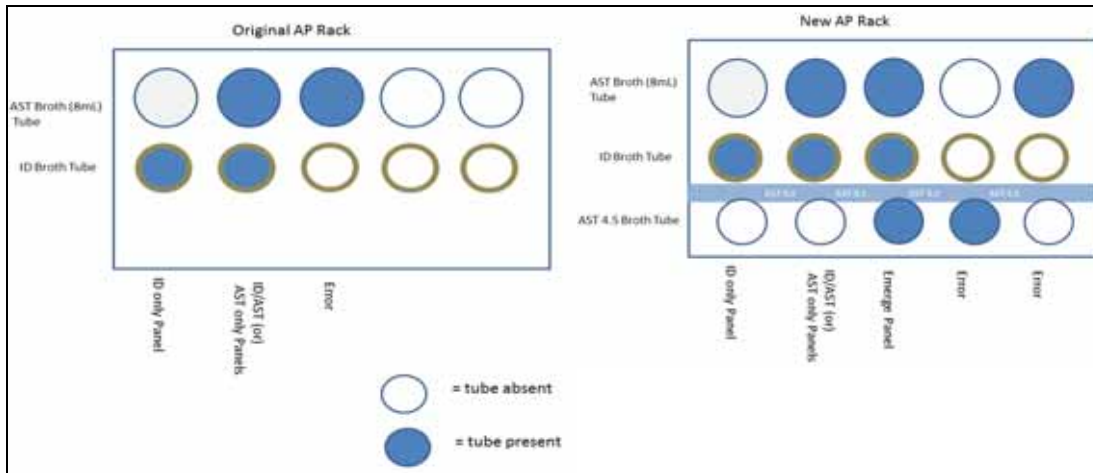
- Place the tubes on the Sample rack for the panel type/rack being used, as shown in the diagrams below.

Place the ID broth tube in the grey ringed wells on the rack.

Place the 8 mL AST broth tubes in the rear row.

For the 15-well racks, place the 4.5 mL AST broth in the front row of the rack, labeled "AST 4.5".

The Inoculum broth is only used in the 15-well rack for preparing Emerge panels. Place these tubes in the grey ringed wells in the center row of the rack. You can load up to 5 sample sets on each Sample rack.



WARNING**STANDARD PRECAUTIONS**

CONSIDER ALL ORGANISMS AS POTENTIALLY INFECTIOUS AND HANDLE ACCORDING TO STANDARD MICROBIOLOGICAL PRACTICES, SPECIAL PRACTICES, AND SAFETY EQUIPMENT RECOMMENDED FOR BIOSAFETY LEVEL 2 (BSL-2) CONTAINMENT¹.

BSL-2 PRACTICES INCLUDE, BUT ARE NOT LIMITED TO THE FOLLOWING:

- **WEAR GLOVES AND LAB COAT WHEN HANDLING POTENTIALLY INFECTIOUS MATERIAL OR CONTAMINATED INSTRUMENT COMPONENTS. WEAR ANY OTHER PERSONAL PROTECTIVE EQUIPMENT ACCORDING TO LOCAL POLICY.**
- **DECONTAMINATE WORK SURFACES AFTER COMPLETION OF WORK AND AFTER ANY SPILL OR SPLASH OF POTENTIALLY INFECTIOUS MATERIAL WITH APPROPRIATE DISINFECTANT.**
- **DECONTAMINATE ALL CULTURES, STOCKS, AND OTHER POTENTIALLY INFECTIOUS MATERIALS BEFORE DISPOSAL USING AN EFFECTIVE METHOD.**
- **PERFORM ALL PROCEDURES TO MINIMIZE THE CREATION OF SPLASHES AND/OR AEROSOLS.**
- **LABORATORY EQUIPMENT SHOULD BE ROUTINELY DECONTAMINATED, AS WELL AS, AFTER SPILLS, SPLASHES, OR OTHER POTENTIAL CONTAMINATION.**
- **SPILLS INVOLVING INFECTIOUS MATERIALS MUST BE CONTAINED, DECONTAMINATED, AND CLEANED UP BY STAFF PROPERLY TRAINED AND EQUIPPED TO WORK WITH INFECTIOUS MATERIAL.**
- **EQUIPMENT MUST BE DECONTAMINATED BEFORE REPAIR, MAINTENANCE, OR REMOVAL FROM THE LABORATORY.**
- **DECONTAMINATE AND DISPOSE OF ALL POTENTIALLY CONTAMINATED MATERIALS AS REGULATED MEDICAL WASTE IN ACCORDANCE WITH LOCAL, STATE, AND FEDERAL REGULATIONS.**

¹ Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. 2007. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, US Government Printing Office, Washington, DC.

Web site: <http://www.cdc.gov/OD/ohs/biosfty/bmb15/bmb15toc.htm>



Figure 4-3 – Sample Rack

Top image shows 2-row rack; bottom image shows 3-row rack.

- 4 Using aseptic technique, pick colonies of the same morphology with the tip of a sterile cotton swab (do not use a polyester swab) or a wooden applicator stick from one of the recommended media.
- 5 Suspend the colonies in the labeled BD Phoenix ID broth tube. Be sure to express the swab against the side of the tube to remove excess fluid.
- 6 Cap the tube and vortex for five seconds.
- 7 **Remove all broth tube caps** and load tubes into the Sample rack.
- 8 Verify that there are no obstructions on the Input Queue.

Place the Sample rack squarely in the Input Queue of the BD Phoenix AP instrument. Make sure the handle is fully lowered on the rack after placement. You can place up to 3 Sample racks in the Input Queue. Use caution during rack transport and when placing the rack on the Input Queue to avoid spills.

- 9 To begin the run, tap the “start” button. Refer to Section 4.7 for additional information on the run.

Do not tap the “start” button if you have not yet run the Daily (Nephelometer) Check. Refer to Step 18 in the Instrument Preparation section.

NOTE

Un-standardized bacterial suspension in ID Broth must be processed by the BD Phoenix AP instrument within 2.5 hours of preparation.

4.7 The BD Phoenix AP Run

4.7.1 Run Overview

After you tap the “start” button, the BD Phoenix AP run begins. The Idle display changes to the Run Status display (Figure 4-5).

Next the instrument checks the RFID tag to verify that the rack was previously uploaded/cleared at the BD Phoenix AP Inoculation Station.

The pipettor then picks up AP AST Indicator and adds 40 µL into each AST broth tube.

The instrument reads the ID broth tubes and adjusts the density by removing inoculum and adding ID broth from the ID Broth solution.

The instrument transfers ID solution to AST broth tube and mixes.

NOTE

Panels must be inoculated within 30 minutes of the time that the AST broth inoculum is prepared.

If any consumable items become depleted (or nearly depleted) such that the run cannot continue, an alert is generated and you are given the opportunity to add the needed consumable to complete the run.

When tube preparation is complete, the instrument moves the Sample rack to the Output Queue and signals that the Rack is complete with an audible tone (configurable).

4.7.2 Run Status

Run status can be monitored in the Run Status display. The Run Status display shows the following information:

Drawer locked/unlocked indicator at left.

Inoculum density setting at top right.

Sample racks as they progress from the Input Queue to the Processing Chute to the Output queue. The color of the rack indicates the status: White for racks that have not yet been processed, Red for expired racks, Yellow for racks whose aging alert has been exceeded, and Green for Rack Aging Timer good.

Consumable status along the bottom of the display.

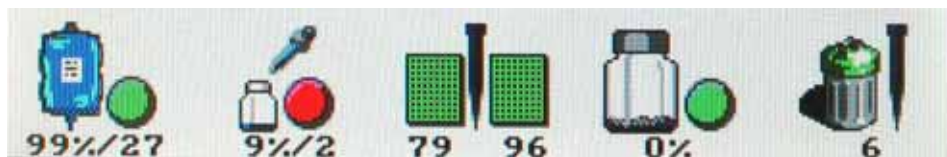


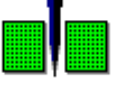




Figure 4-4 – Consumable Status area of Run Status Display

 xx%/nn	ID Broth Dot Color: Red for Volume <10% of capacity OR time remaining on stability timer =0 days; Yellow for Volume 10–30% of capacity OR time remaining on stability timer £ 2 days; Green (shown at left) for Volume >30% of capacity AND time remaining on stability timer >2 days Number below icon represents percentage of Broth remaining/days remaining (out of 30)
 xx%/nn	AP AST Indicator Dot Color: Red for usable volume <10% of capacity OR time remaining on stability timer =0 days; Yellow for usable volume 10–30% of capacity OR time remaining on stability timer £ 1 day; and Green (shown at left) for usable volume >30% of capacity AND time remaining on stability timer >1 day Number below icon represents percentage of indicator remaining/days remaining (out of 5)
 aa bb	Pipette Tips: left tray, right tray color: Red for Tip quantity remaining <10% of tray capacity; Yellow for Tip quantity remaining 10–30% of tray capacity; and Green (shown at left) for Tip quantity remaining >30% of tray capacity Number below icon represents number of tips remaining in each tray
 xx%	Waste Liquid Bottle Dot Color: Red for Volume >90% of capacity; Yellow for Volume 70–90% of capacity; Green for Volume <70% of capacity Number below icon represents percentage full
 nn	Waste Tip Bin lid color: Red for Tip quantity discarded >90% of capacity; Yellow for Tip quantity discarded 70–90% of capacity; and Green for Tip quantity discarded <70% of capacity Number below icon represents quantity of waste tips in the bin

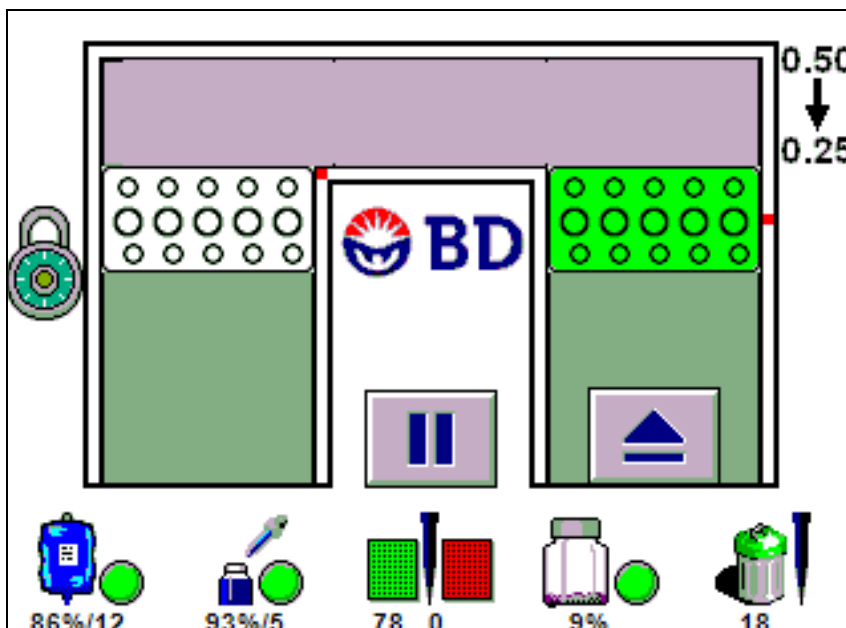


Figure 4-5 – Run Status Display

4.7.3 Pausing or Aborting a Run

To **pause a run**, from the Run Status display, tap the “pause” button.



Initially, the “waiting” (hourglass) icon appears as the instrument completes the current action in progress and disposes of any pipettor tips. Then the Pause display appears (Figure 4-6).

To **abort a run and clear the Processing chute**, from the Pause display, tap the “stop” button.



Alternatively, you can continue the run by tapping the “start” button, or replace consumables by tapping the “consumables” button.

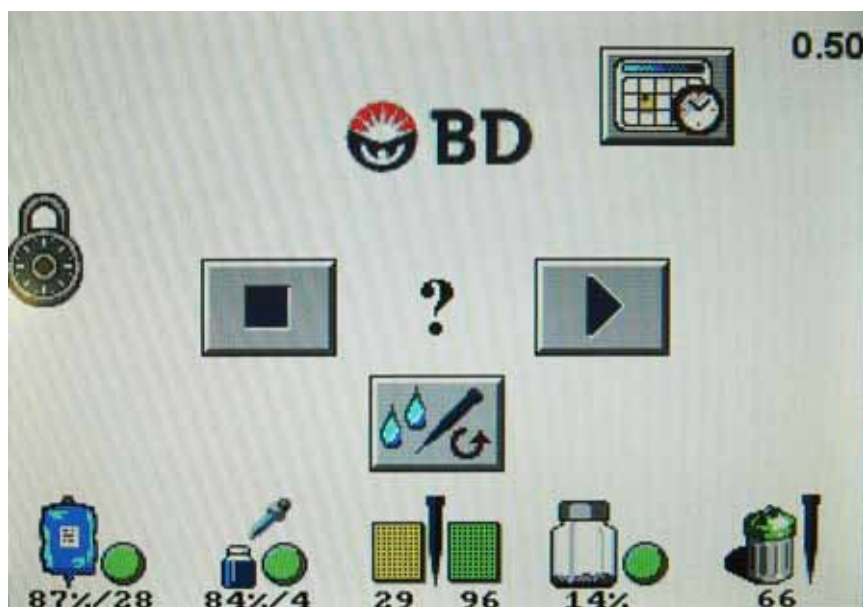
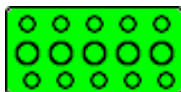


Figure 4-6 – Pause Display

4.7.4 Viewing Rack Status

From the Run display, tap a “rack” button (if color is other than white) to check the status of any Rack that is in process or completed.



The Rack Status display (Figure 4-7) shows the initial McFarland reading below the rack. The final status (normally the target density) is shown below the tube icons (see table below). White tube icons represent tubes not yet processed or not present; Red indicates that a tube was not successfully prepared; and Green indicates that the target suspension was achieved.

The Rack Aging Timer for panel inoculation counts down at the top of the display.

Tube status symbols are shown in the table below:

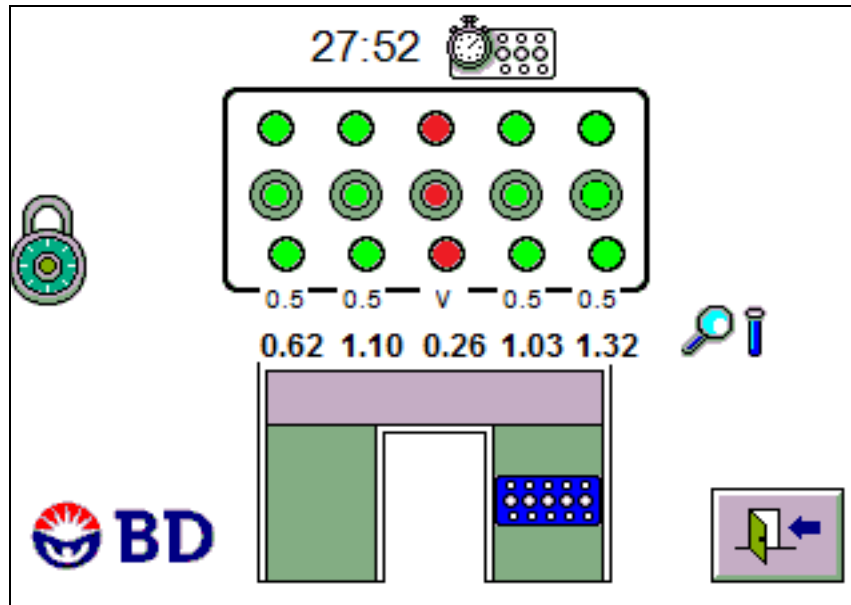


Figure 4-7 – Rack Status Display

Blue rack icon indicates location of rack on instrument.

Symbol	Meaning
?	Sample error
!	Instrument error
^	Initial inoculum density too high
v	Initial inoculum density too low
0.25 or 0.5	Target density (achieved)
x.yz	Initial inoculum density

4.7.5 Tip Search Display

Throughout operations the Instrument tracks tip position and counts and confirms tip acquisitions. If the robot tries unsuccessfully to acquire tips 3 times in succession, the instrument sounds an alert tone and the Tip Search display appears (see Figure 4-8).

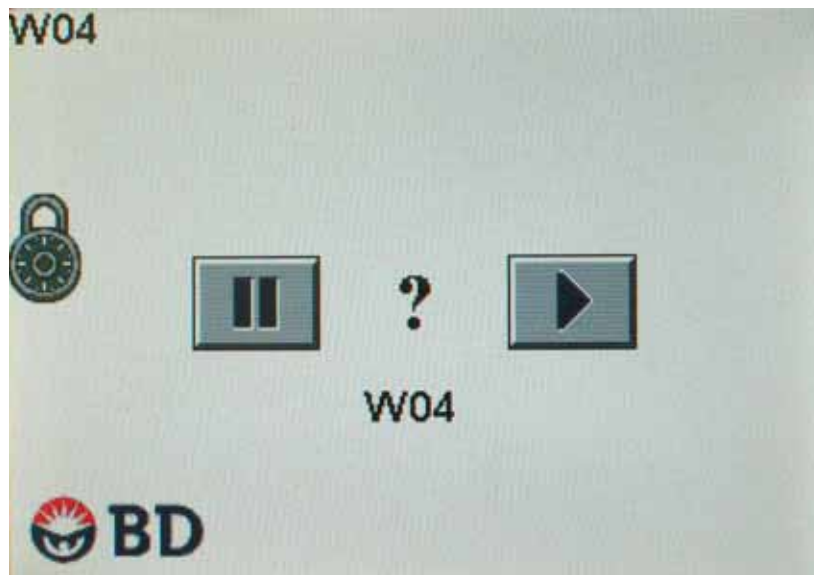


Figure 4-8 – Tip Search Display

The “pause” and “start” buttons appear at the center of the display.

To stop the tip search and go to the Tip Consumables display, tap the “pause” button.

To continue the tip search, tap the “start” button. The screen returns to the Run Status display.

Tip search stops when one of the following conditions are met:

- a tip is acquired
- you press the “pause” button on the Run Status display
- the pipettor cycles through both trays back to the starting point of a new tray pair (tray 1, position 1). If this occurs, a workflow alert is generated.

4.8 Responding to Alarms and Errors

As you perform activities at the BD Phoenix AP instrument, and as testing progresses, instrument alerts and errors may occur. Different types of alerts and errors are flagged by error codes and/or audible tones.

CAUTION

When the instrument notifies you of alerts and errors, you should immediately respond to the condition.

The highest priority active error code is shown at the center of the Idle and Run Status displays. Initially, the error code flashes until you acknowledge the error. To acknowledge the error and silence any associated audible alert, tap the error code. In most cases the code displayed disappears when it is acknowledged.

Some error codes remain active until you take corrective action. In addition, some error codes require corrective action by BD. For information on possible causes of error codes and corrective actions, refer to Section 7.2.

When more than one error code is active, when you clear the first code, the next one appears (along with any associated audible alert). You can acknowledge subsequent codes by tapping them on the screen.

To view a listing of all active error codes, from the Idle or Run Status display, tap and hold the error code that is currently being displayed. When you release, the Active Alerts display appears. The listing includes dates and times that the errors occurred. See Section 5.6 for additional information.

All the alert and workflow codes are discussed in detail in Section 7.2. The audible tones are discussed in Section 3.6.

4.9 Post-Run Activities

4.9.1 Upload Rack Data

- 1 Remove each completed Sample rack from the Output Queue.
- 2 Take the completed Sample rack to the BD Phoenix AP Inoculation Station to upload the information to BD EpiCenter and clear the rack status.



Figure 4-9 – Sample Rack in BD Phoenix AP Inoculation Station at BD EpiCenter Workstation

Three-row rack shown

4.9.2 Preparing BD Phoenix Panels

Materials Required:

- BD Phoenix panels
- BD Phoenix ID Broth tube or Phoenix Inoculum Broth tube
- BD Phoenix AST Broth tube(s)
- BD Phoenix Panel closures
- BD Phoenix AP Inoculation Station

Procedure:

- 1 Select the appropriate BD Phoenix panel for inoculation.
- 2 Examine the pouch, and do not use the panel if the pouch is punctured or opened. Remove the panel from the pouch. Discard the desiccant. Do not use the panel if there is no desiccant or if the desiccant pouch is torn.

NOTE

Panels must be inoculated within 2 hours of being removed from the pouch.

- 3 Perform the panel scanning operation at the BD EpiCenter system. (Refer to the BD EpiCenter system help for detailed instructions.)
- 4 Place the panel on the Inoculation Station with the inoculation ports on top and the pad on the bottom.
- 5 For standard BD Phoenix panels, pour the ID broth tube inoculum into the fill port on ID side of the panel (51-well side). Allow the fluid to traverse down the tracks before moving the panel. If you are using an AST (only) panel, it is not necessary to inoculate the ID side of the panel.

Pour the AST broth inoculum into the fill port on AST side of the panel (85-well side). Allow the fluid to traverse down the tracks before moving the panel.

or

For Emerge panels, pour the 4.5 mL AST broth tube located in the front row into the 51-well side of the panel. Allow the fluid to traverse down the tracks before moving the panel.

Pour the AST broth (8 mL) tube located in the back row into the 85-well side of the panel. Allow the fluid to traverse down the tracks before moving the panel.

NOTE

ID broth tubes used for preparing Emerge panels cannot be used to fill the ID side of a BD Phoenix panel.

- 6 Retain the ID broth tube for a recommended purity check.

- 7 Before placing panel closure check for residual droplets of inoculum on the edge of the fill ports. If a droplet is present remove the droplet with absorbent material. The used absorbent material must be decontaminated before discarding.
- 8 Snap on the panel closures. Make sure that the closures are fully seated. Use 2 closures regardless of panel type.
- 9 Visually inspect panels to be sure each of the wells is full. Look at both sides of the panel. Make certain that the wells are not overfilled. If any of the wells are unfilled or overfilled, inoculate a new panel.

NOTES

- Panels must be loaded into the BD Phoenix 100 instrument within 30 minutes of inoculation.
- Panels must be kept in the Inoculation Station after inoculation until the excess fluid has been completely absorbed by the pad.
- Panels should stay vertical in the caddy until loaded.
- Inoculated panels should be handled with care. Avoid knocking or jarring the panel.

4.10 Power Failures

In some circumstances, when power to the instrument is cycled, the instrument unlocks the drawer and displays a W01 alert, along with the “start” button. If the W01 display appears, before tapping the “start” button, verify that the robots are in a safe position (see Figure 4-10). If one of the robots is not in position, turn power off, move the robot arm to the safe position (shown below), and turn the power back on.

CAUTION

You must verify robot positions and correct them if necessary to avoid possible instrument damage.

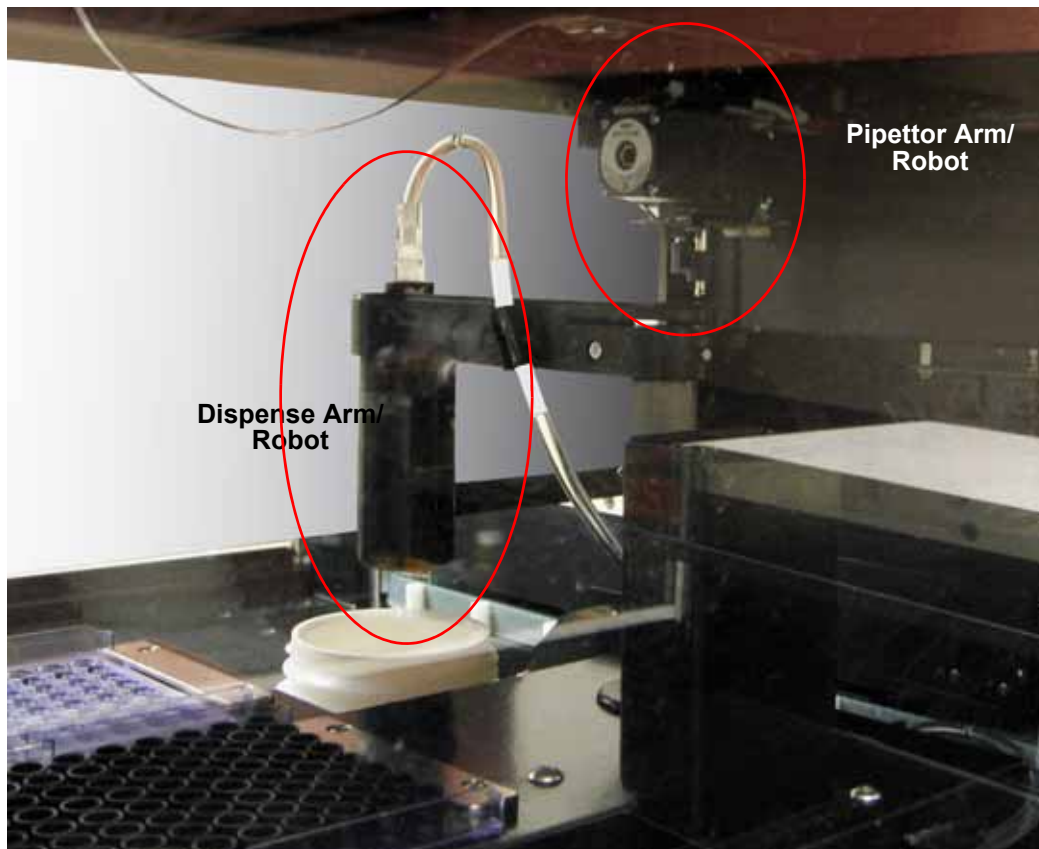


Figure 4-10 – BD Phoenix AP Robot Safe Positions

Dispense robot is over waste liquid bottle; pipettor robot is at left rear

If the W01 alert does not appear, simply tap the “start” button to initiate the startup process.

When power is cycled, the instrument writes this information to the log file, with the date and time.

All instrument configuration settings are retained in the event of a power failure.

The status of any racks in progress or completed is retained and recorded on the RFID tag in the rack. Racks that were in progress are ejected to the Output Queue. These racks should be taken to the BD Phoenix AP Inoculation Station so that their status may be uploaded to BD EpiCenter and the rack state can be cleared.

Any Rack Timers in progress are updated when power is reapplied to the instrument, and expired timers generate the appropriate alert notification. Any tips that might be present on the pipettor are ejected to the waste tip bin.

NOTES

- Do not attempt to manually remove tips after a power failure unless an error code resolution advises this action. Do not attempt to manually pipette fluids after a power failure.
- Do not rerun a partially processed Sample rack through the instrument unless you replace the AST tubes.

5 - Reference

5.1 General

This section presents reference material on the BD Phoenix AP instrument user interface. The following information is presented:

- Software tree (Section 5.2)
- Startup display (Section 5.3)
- Idle display (Section 5.4)
- Configuration menu (Section 5.4.1)
- Consumable menu (Section 5.4.2)
- Maintenance menu (Section 5.4.3)
- Run Status display (Section 5.5)
- Pause display (Section 5.5.1)
- Rack Status screen (Section 5.5.2)
- Active Alerts display (Section 5.6)

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.

Startup Display (Section 5.3)

Idle Display (Section 5.4)

Configuration Menu (Section 2.4)

Set Date/Time Display (Section 2.4.1)

Set Inoculum Density Display (Section 2.4.2)

Set Rack Aging Timer Display (Section 2.4.3)

Set Audible Alerts Display (Section 2.4.4)

Set Instrument Number Display (Section 2.4.5)

Set LCD Brightness Display (Section 2.4.6)

Consumable Replacement Menu (Section 5.4.2)

Liquid Consumables Display (Section 5.4.2.1)

Tip Consumables Display (Section 5.4.2.2)

Maintenance Menu (Section 6.3)

Daily Nephelometer Check (Section 6.3.1)

Lock/Unlock Drawer function (Section 6.3.2)

Save Log File (Section 6.3.3)

Update Software (Section 6.3.4)

Move Rack/Belt (Section 6.3.5)

Pipettor Verification (Section 6.3.6)

Calibrate Dispense Pump (Section 6.3.7)

Calibrate Nephelometer (Section 6.3.8)

Self-Test function (Section 6.3.9)

Purge/Prime Dispense Pump function (Section 6.3.10)

Run Status Display (Section 5.5)

Pause Display (Section 5.5.1)

Rack Status Display (Section 5.5.2)

Active Alerts Display (Section 5.6)

5.3 Startup Display

Whenever power to the instrument is cycled (off then on), the Startup display appears.

In some circumstances, the instrument unlocks the drawer and displays a W01 alert, along with the “start” button. If this display appears (Figure 5-1), before tapping the “start” button, verify that the robots are in a safe position (see Figure 4-10).

If the W01 alert does not appear, simply tap the “start” button to initiate the startup process.



Figure 5-1 – Startup Display with W01 Alert

CAUTION

If the W01 code appears, you must verify robot positions and correct them if necessary to avoid possible instrument damage. Figure 4-10 shows proper robot positions.

During instrument startup, the instrument locks the drawer, performs a self-test, and initializes various instrument components. Progress of the operation is shown in a progress bar at the bottom of the display (see Figure 5-2). When initialization and self-test are complete, the Idle display (Section 5.4) appears.

If the self-test completes successfully, the Idle display appears and the “start” button is enabled for initiating Sample rack processing.

If the self-test encounters any problems, the Idle display appears and the appropriate error code is reported. The “start” button is disabled until the error condition is corrected.

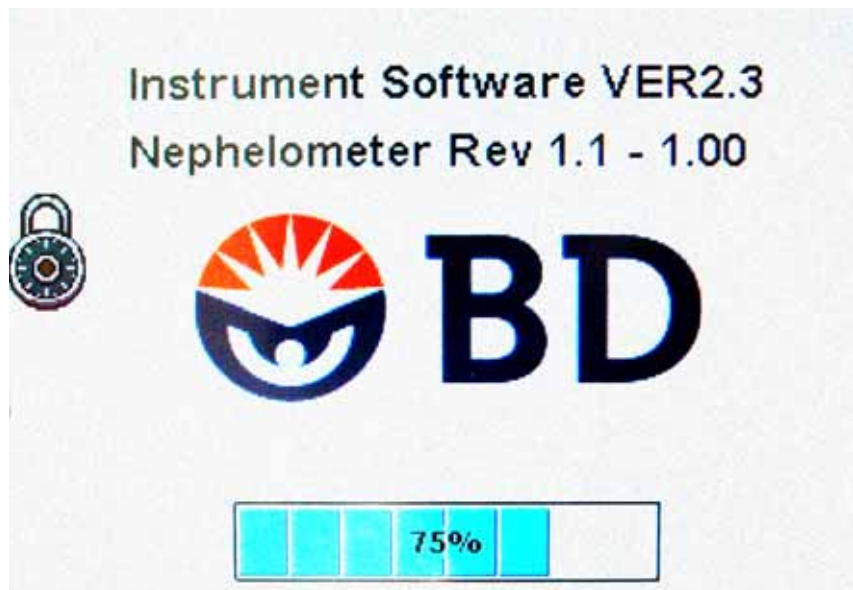


Figure 5-2 – Startup Display with Progress Bar

5.4 Idle Display

The Idle display appears when the instrument completes the initialization and self-test processes. When a sample run is initiated, the Idle display automatically transitions to the Run Status display. When all Sample racks have completed processing, the screen returns to the Idle display.

The Idle display shows a representation of the Input Queue, Processing Chute, and Output Queue, along with the positions of any Sample racks on those locations. The default inoculum density is shown at top right. The drawer status (locked/unlocked) is shown at the left of the display. The highest priority error code (if any exist) appears below the BD logo. Buttons to access other functions and screens appear toward the bottom of the display.

The following functions can be performed or accessed from the Idle display (Figure 5-3):

- Start a Run – The instrument starts processing any Sample racks in the Input Queue or resumes processing any rack that was paused during processing.
- Eject Rack – Move Rack onto the Output Queue.
- Access Rack Status display to view detailed information for in-process or completed racks. Refer to Section 5.5.1 for additional information.
- Configuration – Set up instrument parameters such as Instrument number, date and time, etc. Refer to Section 2.4 for additional information.
- Access consumables replacement displays. Refer to Section 5.4.2 for additional information.
- Maintenance Activities – Perform various instrument verification and calibration functions, as well as the Daily Check. Refer to Section 6.3 for additional information.

Idle Display Icons and Buttons:









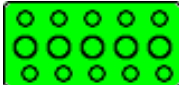
	“drawer locked” indicator		“drawer unlocked” indicator
	“start” button – tap to begin or resume a run		“eject” button – tap to move Sample rack on Output Queue (disabled while rack is in process)
	“waiting” indicator		“configuration” button
	“consumables” button		“maintenance” button
	“rack” button – tap to access Rack Status display		



Figure 5-3 – Idle Display

5.4.1 Configuration Menu

The Configuration menu is discussed in detail in Section 2.4.

5.4.1.1 Set Date and Time

Refer to Section 2.4.1.

5.4.1.2 Set Inoculum Density

Refer to Section 2.4.2.

5.4.1.3 Set Rack Aging Timer

Refer to Section 2.4.3.

5.4.1.4 Set Audible Alerts

Refer to Section 2.4.4.

5.4.1.5 Set Instrument Number

Refer to Section 2.4.5.

5.4.1.6 Set Display Brightness

Refer to Section 2.4.6.

5.4.2 Consumables Menu

The Consumables menu enables you to access displays for viewing and resetting liquid and tip consumable counters/timers. See Figure 5-4.

The instrument automatically unlocks the drawer when you access the Consumables menu. The “exit” button is disabled until the drawer is closed. If a consumable is exhausted during operation resulting in a workflow error (e.g., W02, W03, etc.), the “exit” button is disabled until the condition is addressed (consumable is replaced or waste container is emptied), the counter is reset, and the changes are saved.

To access the Consumables menu:



From the Idle display, tap the “consumables” button

Consumables Menu Icons and Buttons:



“drawer locked” indicator



“drawer unlocked” indicator



“liquid consumables” button



“tip consumables” button



drawer open indicator



drawer closed indicator



“exit” button



Figure 5-4 – Consumables Menu

5.4.2.1 Liquid Consumables Display

The Liquid Consumables display enables you to reset the counters/timers for the instrument's liquid consumables. This includes the ID Broth solution, the BD Phoenix AP AST Indicator, and the Waste Liquid Bottle. Each item is reset independently. See Figure 5-5.

In the main body of the display, each type of liquid consumable is represented by an icon (see Icons and Buttons table below). Above each liquid consumable icon is a "reset" button that enables you to reset the counter/timer for that item. Above the "reset" button for the liquid consumable the available percentage (of the total) is shown. Below the liquid consumable icon the timer (if applicable) for days remaining (in timer) is shown.

To reset a counter and timer (both values are reset together), tap the "reset" button above the liquid consumable icon you want to reset.

To undo the reset operation, tap the "reset" button again to return to the previous counter/timer value.

To save any changes, tap the "save" button.

If any timer reaches 0, the instrument disables the "start" button on the Idle display, and no runs can be initiated.

If you exit the display without resetting any consumable items, a reminder display appears (see Figure 5-6). To return to a Consumables display to reset an item, tap the "reset" button; to exit without resetting any consumables, tap the "exit" button.

When you exit the display, the drawer is locked, a waiting screen with hourglass icon is displayed, the pipettor and Dispense arm are homed, the Dispense arm performs a priming sequence if the ID Broth counter was reset, and the display then proceeds to the Idle display.

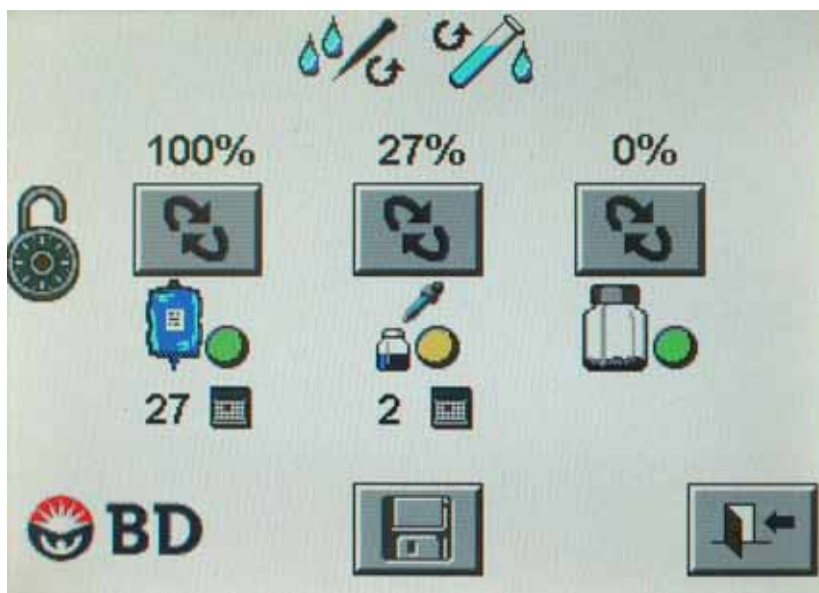


Figure 5-5 – Liquid Consumables Display

To access the Liquid Consumables display:



From the Idle display, tap the “consumables” button



From the Consumables menu, tap the “liquid consumables” button

Liquid Consumables Display Icons and Buttons (general):



“drawer locked” indicator



“drawer unlocked” indicator



“reset” button



“days remaining” timer















“save” button



“exit” button

Liquid Consumables Display Volume/Timer Indicators:

 <p>“ID broth” indicator Number below icon represents percentage of Broth remaining/days remaining (out of 30)</p>		Volume >30% of capacity AND time remaining on stability timer >2 days
		Volume 10–30% of capacity OR time remaining on stability timer £ 2 days
		Volume <10% of capacity OR time remaining on stability timer = 0 days
 <p>“AP AST Indicator” indicator Number below icon represents percentage of indicator remaining/days remaining (out of 5)</p>		Volume >30% of capacity AND time remaining on stability timer >1 day
		Volume 10–30% of capacity OR time remaining on stability timer £ 1 day
		Volume <10% of capacity OR time remaining on stability timer = 0 days
 <p>“waste liquid bottle” indicator Number below icon represents percentage full</p>		Volume <70% of capacity
		Volume 70–90% of capacity
		Volume >90% of capacity

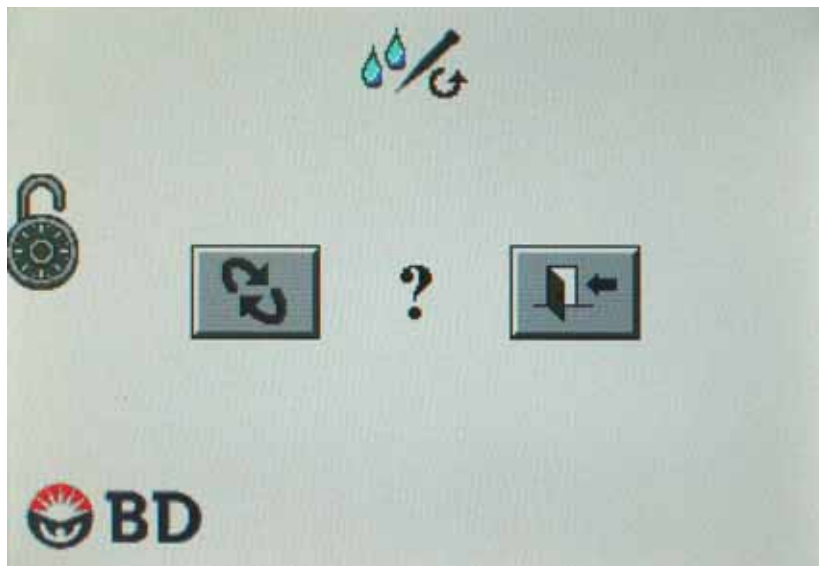


Figure 5-6 – Consumables – Exit without Resetting Display

To return to a Consumables display to reset an item, tap “reset” button; to exit without resetting any consumables, tap the “exit” button.

5.4.2.2 Tip Consumables Display

The Tip Consumables display enables you to reset the counters for the instrument’s pipette tip consumables. This includes two pipette tip trays and the Waste Tip bin. Each item is reset independently. See Figure 5-7.

In the main body of the display, each type of tip consumable is represented by an icon (see Icons and Buttons table below). Above each tip consumable icon is a “reset” button that enables you to reset the counter for that item. Above the “reset” button for the pipette tips, the number of pipette tips remaining is shown. Above the waste tip bin icon, the number of pipette tips in the waste bin is shown.

To reset a counter, tap the “reset” button above the tip consumable icon you want to reset.

To undo the reset operation, tap the “reset” button again to return to the previous counter value.

To save any changes, tap the “save” button.

If both tip counters reach 0, the instrument disables the “start” button on the Idle display, and no runs can be initiated.

If you exit the display without resetting any consumable items, a reminder display appears (see Figure 5-6). To return to a Consumables display to reset an item, tap the “reset” button; to exit without resetting any consumables, tap the “exit” button.

When you exit the display, the drawer is locked, a waiting screen with hourglass icon is displayed, the pipettor and Dispense arm are homed, the Dispense arm performs a priming sequence if the ID Broth counter was reset, and the display then proceeds to the Idle Mode screen.

To access the Tip Consumables display:

From the Idle display, tap the “consumables” button



From the Consumables menu, tap the “tip consumables” button

Tip Consumables Display Icons and Buttons (general):

“drawer locked” indicator



“drawer unlocked” indicator



“reset” button


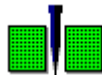
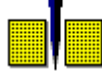
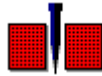






“save” button



“exit” button

Tip Consumables Display Volume Indicators:

 <p>“pipette tip tray” indicator (note that left and right trays can be different colors) Number below icon represents number of tips remaining in each tray</p>		Tip quantity remaining >30% of tray capacity
		Tip quantity remaining 10–30% of tray capacity
		Tip quantity remaining <10% of tray capacity
 <p>“waste tip bin” indicator Number below icon represents quantity of waste tips in the bin</p>		Tip quantity discarded <70% of capacity
		Tip quantity discarded 70–90% of capacity
		Tip quantity discarded >90% of capacity

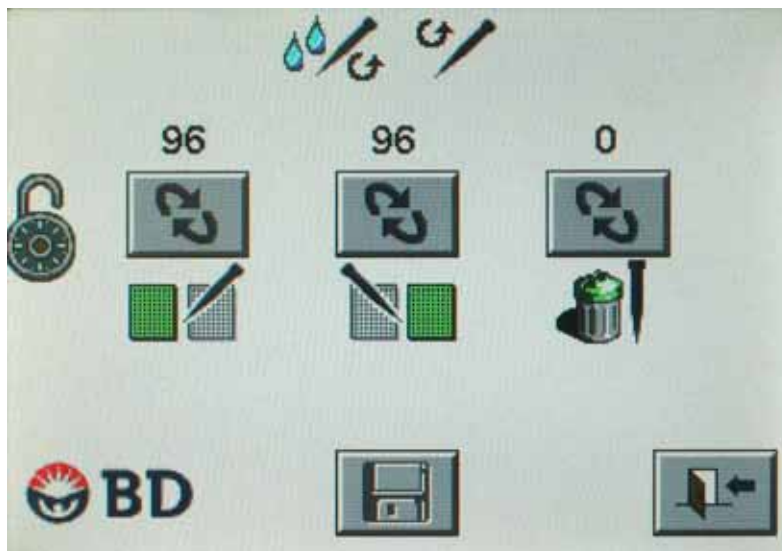


Figure 5-7 – Tip Consumables Display

5.4.3 Maintenance Menu

The Maintenance menu is discussed in detail in Section 6.3.

5.4.3.1 Daily Nephelometer Check Display

Refer to Section 6.3.1.

5.4.3.2 Lock/Unlock Drawer Function

Refer to Section 6.3.2.

5.4.3.3 Save Log File Function

Refer to Section 6.3.3.

5.4.3.4 Update Software Function

Refer to Section 6.3.4.

5.4.3.5 Move Rack Display

Refer to Section 6.3.5.

5.4.3.6 Pipettor Verification Display

Refer to Section 6.3.6.

5.4.3.7 Calibrate Dispense Pump Display

Refer to Section 6.3.7.

5.4.3.8 Self-Test Function

Refer to Section 6.3.8.

5.4.3.9 Calibrate Nephelometer Display

Refer to Section 6.3.9.

5.4.3.10 Purge/Prime Dispense Pump Function

Refer to Section 6.3.10.

5.5 Run Status Display

The Run status display appears when the Instrument is processing samples. The display shows a representation of the Input Queue, Processing Chute, and Output Queue. Any racks located on these belts are shown with color-coded status icons. Current inoculum density is shown at top right; drawer locked/unlocked status is shown on the left of the display; consumable status is shown at the bottom of the display. Buttons at the center of the display enable you to pause a run or to clear the belts of racks. In addition, any racks that have begun processing (green color) can be tapped to access the Rack Status display for that rack. The highest priority error code (if any exist) appears below the BD logo.

The Run Status display enables you to:

- Pause a run in progress
- Resume a paused run
- Abort a paused run
- View current active alert code
- Access Rack Status display for a rack that has begun processing
- View consumable status

See Figure 5-8.

To access the Run Status display:



From the Idle display, tap the “start” button

The first rack on the Input Queue begins processing, and the display automatically changes to the Run Status display.

Run Status Display Icons and Buttons:



“drawer locked” indicator



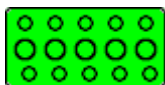
“drawer unlocked” indicator



“pause” button – tap to pause a run



“eject” button – tap to move Sample rack on Output Queue (disabled while rack is in process)















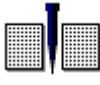
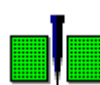
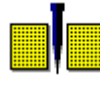
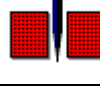




“rack” button – tap to access Rack Status display

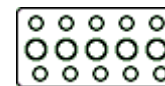
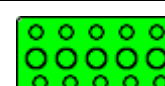
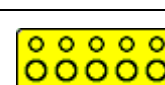



“waiting” indicator

Run Status Display Consumables Indicators:

 <p>“ID broth” indicator Number below icon represents percentage of Broth remaining/days remaining (out of 30)</p>		Volume >30% of capacity AND time remaining on stability timer >2 days
		Volume 10–30% of capacity OR time remaining on stability timer £ 2 days
		Volume <10% of capacity OR time remaining on stability timer = 0 days
 <p>“AP AST Indicator” indicator Number below icon represents percentage of indicator remaining/days remaining (out of 5)</p>		Volume >30% of capacity AND time remaining on stability timer >1 day
		Volume 10–30% of capacity OR time remaining on stability timer £ 1 day
		Volume <10% of capacity OR time remaining on stability timer = 0 days
 <p>“waste liquid bottle” indicator Number below icon represents percentage full</p>		Volume <70% of capacity
		Volume 70–90% of capacity
		Volume >90% of capacity

 <p>“pipette tip tray” indicator (note that left and right trays can be different colors) Number below icon represents number of tips remaining in each tray</p>		Tip quantity remaining >30% of tray capacity
		Tip quantity remaining 10–30% of tray capacity
		Tip quantity remaining <10% of tray capacity
 <p>“waste tip bin” indicator Number below icon represents quantity of waste tips in the bin</p>		Tip quantity discarded <70% of capacity
		Tip quantity discarded 70–90% of capacity
		Tip quantity discarded >90% of capacity

	Rack has not begun processing
	Rack aging warning has <i>not</i> been exceeded
	Rack aging warning has been exceeded
	Rack aging alarm has been exceeded

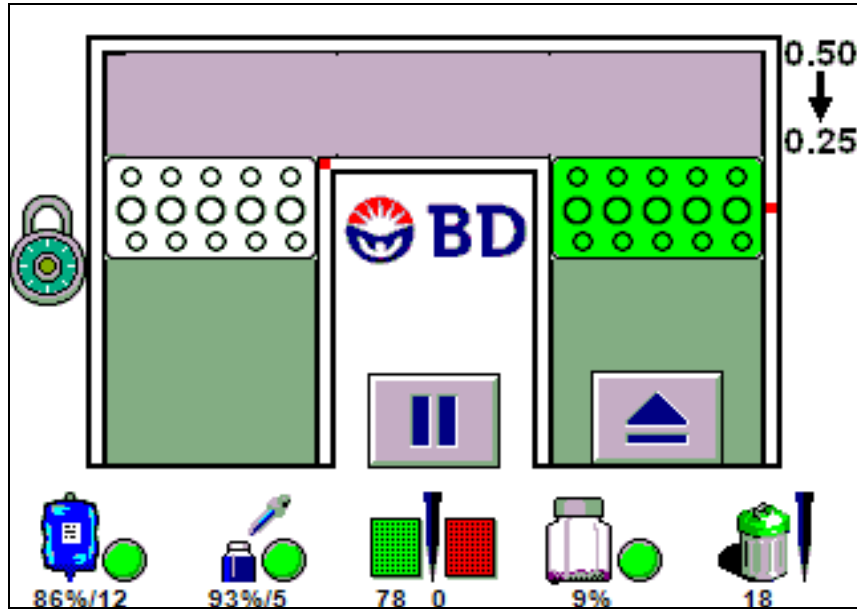


Figure 5-8 – Run Status Display

5.5.1 Pause Display

The Pause display appears when you tap the “pause” button from the Run Status display.

It enables you to stop (abort) a run, continue processing a run, access the Configuration functions (e.g., inoculum density setting or audible alert volume settings), or access the Consumables menu. See Figure 5-9.

Consumable status icons at the bottom of the display are explained in Section 5.5.

To access the Pause display:



From the Run Status display, tap the “pause” button

The “waiting” (hourglass) icon appears as the instrument completes the current action in progress. Then the Pause display appears

Pause Display Icons and Buttons:



“drawer locked” indicator



“drawer unlocked” indicator



“stop” button – tap to abort a run



“start” button – tap to continue a run



“configuration” button



“consumables” button



Figure 5-9 – Pause Display

5.5.2 Rack Status Display

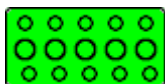
The Rack Status display shows detailed information about a selected rack. Racks are selected in the Run Status display or Idle display by touching the desired rack button. See Figure 5-10.

The top left of the Rack Status display shows the highest priority active error code if any exist. The top center of the display shows the remaining processing time. If the rack contains AST tubes, the time shown represents time remaining in the 30-minute window (from the time that the ID Broth is inoculated into the AST tube until panel inoculation); if there are no AST tubes, the time represents time remaining in the 60-minute window (from the completion of the final nephelometer confirmation reading for the first ID tube until panel inoculation).

At the center of the display is a representation of the rack. Color coded circles show the status of each tube being processed. At the bottom of the rack, the final status of the tube is shown (either a density reading or other status icon). (See tables below for color and status icon meanings.) Just below the rack the initial nephelometer readings are shown.












Drawer locked/unlocked status is shown on the left of the display. At the bottom of the display, a representation of the Input Queue, Processing Chute, and Output Queue appears. The position of the current rack being viewed is shown by a blue rack icon.

To access the Rack Status display:



From the Idle or Run Status display, tap a “rack” button

Rack Status Display Icons and Buttons:

	"drawer locked" indicator		"drawer unlocked" indicator
	"selected rack" icon		AST tube: no tube present or tube not yet completed processing
	AST tube: successfully prepared		AST tube: <i>not</i> successfully prepared
	ID tube: no tube present or tube not yet completed processing		ID tube: successfully prepared
	ID tube: <i>not</i> successfully prepared	?	Sample error
		^	Initial inoculum density too high
		v	Initial inoculum density too low
		!	Instrument error
		0.25 or 0.5	Target density (achieved)
		x.yz	Initial inoculum density
	"initial inoculum density" indicator		"exit" button

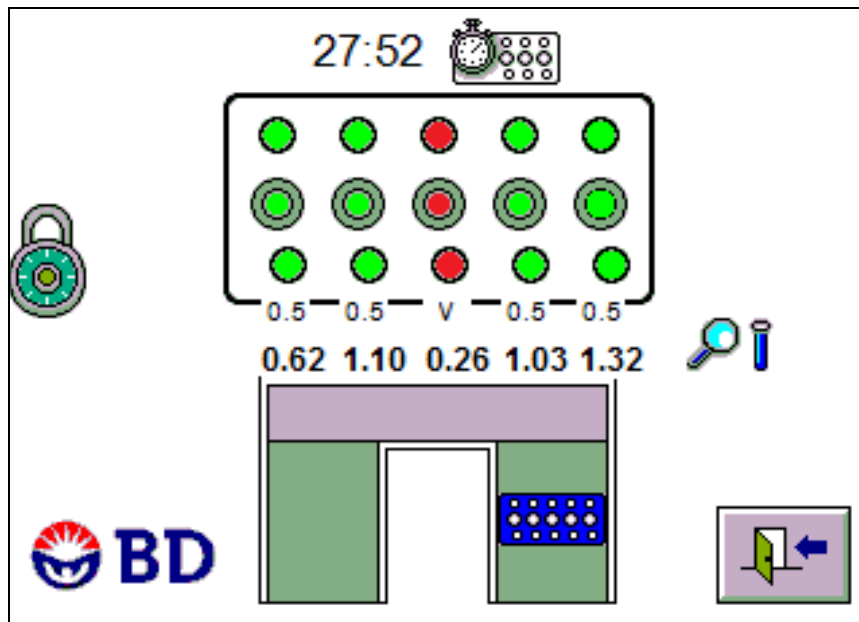


Figure 5-10 – Rack Status Display

5.6 Active Alerts Display

The Active Alerts display shows any active error or workflow codes that exist in the instrument. The codes are shown in order of priority (see Section 7.2). The list can be navigated using the up and down arrows to the right of the listing. See Figure 5-11.

Alerts are displayed in an assigned color. The color corresponds to the following types of errors:

- Red System Fatal Errors
- Purple Mechanical Jam or Processing Errors
- Blue Non-fatal Alerts
- Black General Notifications

To Access the Active Alerts Display:

- E17 From the Idle or Run Status display, touch and hold the error code (E17 shown as example) for 2+ seconds; when you release, the Active Alerts display appears

Active Alerts Icons and Buttons:

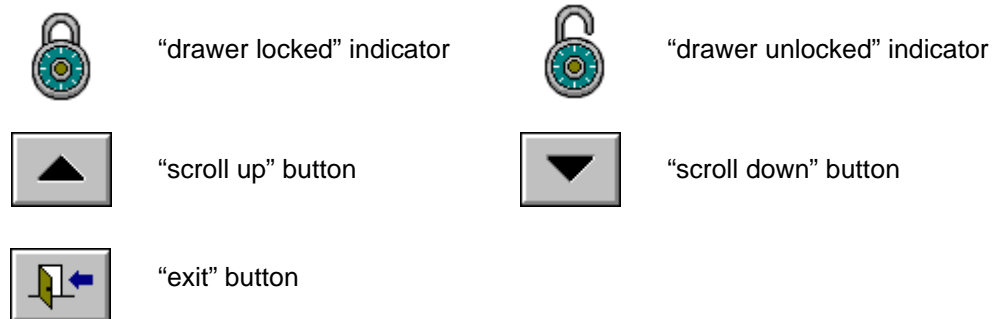


Figure 5-11 – Active Alerts Display

6 - Maintenance

6.1 General

The BD Phoenix AP instrument requires little maintenance from the user to provide reliable performance. Periodic maintenance activities are shown in the chart below. 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

THE BD PHOENIX AP INSTRUMENT CONTAINS NO USER-SERVICEABLE PARTS. ALL MAINTENANCE AND REPAIR OTHER THAN THE PROCEDURES DESCRIBED IN SECTION 6 MUST BE PERFORMED BY BD QUALIFIED SERVICE PERSONNEL.

FOR TROUBLESHOOTING INSTRUMENT PROBLEMS, POWER SHOULD BE REMOVED AND THE POWER CORD SHOULD BE DISCONNECTED FOR SAFETY, UNLESS YOU ARE INSTRUCTED TO LEAVE POWER ON.

Interval	Activity
Daily	Check Consumables
	Daily Nephelometer Check
Weekly	Calibrate Dispense Pump
Every 30 days	Replace Dispense Tubing Set
	Clean Tip Chute
Every 3 months	Calibrate Nephelometer
Annually	BD Preventive Maintenance

6.2 Daily Maintenance

6.2.1 Check Consumable Status

Before initiating any runs, you should check the status of the consumable items. Replacing consumables that are low or exhausted before the run begins can prevent delays in completing a run and possibly exceeding a rack expiration timer.













To check consumable status, from the Idle display, tap the “consumables” button.



To check liquid consumables: tap the “liquid consumables” button.



In the Liquid Consumables display, check the status of ID Broth, AP AST Indicator, and the waste liquid bottle.

 <p>“ID broth” indicator Number below icon represents percentage of Broth remaining/days remaining (out of 30)</p>		Volume >30% of capacity AND time remaining on stability timer >2 days
		Volume 10–30% of capacity OR time remaining on stability timer £ 2 days
		Volume <10% of capacity OR time remaining on stability timer = 0 days
 <p>“AP AST Indicator” indicator Number below icon represents percentage of indicator remaining/days remaining (out of 5)</p>		Volume >30% of capacity AND time remaining on stability timer >1 day
		Volume 10–30% of capacity OR time remaining on stability timer £ 1 day
		Volume <10% of capacity OR time remaining on stability timer = 0 days
 <p>“waste liquid bottle” indicator Number below icon represents percentage full</p>		Volume <70% of capacity
		Volume 70–90% of capacity
		Volume >90% of capacity

Replace any consumables that are in the red range to avoid interruptions to the day's runs.

If you replace any items, be sure to tap the "reset" button, then tap the "save" button to save the updated information.




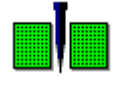
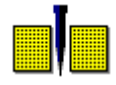
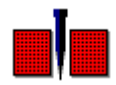




Return to the Consumables menu by tapping the "exit" button.



To check tip consumables, tap the "tip consumables" button.



In the Tip Consumables display, check the status of the left pipette tip tray, the right pipette tip tray, and the waste tip bin.

 <p>"pipette tip tray" indicator (note that left and right trays can be different colors) Number below icon represents number of tips remaining in each tray</p>		Tip quantity remaining >30% of tray capacity
		Tip quantity remaining 10–30% of tray capacity
		Tip quantity remaining <10% of tray capacity
 <p>"waste tip bin" indicator Number below icon represents quantity of waste tips in the bin</p>		Tip quantity discarded <70% of capacity
		Tip quantity discarded 70–90% of capacity
		Tip quantity discarded >90% of capacity

Replace any consumables that are in the red range to avoid interruptions to the day's runs. Note that for tip replacement, if only the left tray is yellow/red, it is not necessary to replace the tip tray. The instrument automatically switches to the right tip tray when the left tray is depleted.

If you replace any items, be sure to tap the "reset" button, then tap the "save" button to save the updated information.



6.2.2 Run Daily Nephelometer Check

Each day before starting any runs you must run the Daily Nephelometer Check.

Refer to Section 6.3.1 – Daily Nephelometer Check for additional instructions.

6.3 Maintenance Menu Activities

Most of the items on the Maintenance menu represent "as needed" and/or periodic maintenance activities. The following operations can be performed:

- Daily Nephelometer Check display (Section 6.3.1)
- Lock/Unlock Drawer function (Section 6.3.2)
- Save Log File function (Section 6.3.3)
- Update Software function (Section 6.3.4)
- Move Rack/Belt display (Section 6.3.5)
- Pipettor Verification display (Section 6.3.6)
- Calibrate Dispense Pump display (Section 6.3.7)
- Calibrate Nephelometer display (Section 6.3.8)
- Self-Test function (Section 6.3.9)
- Purge/Prime Dispense Pump function (Section 6.3.10)

The Maintenance menu display shows the instrument software version, drawer locked/unlocked indicator, and a counter for the number of tube sets processed. At the bottom center of the display, the drawer status (open or closed) indicator appears and is updated dynamically.

Most maintenance activities require the drawer to be locked to perform. Activities that cannot be performed in the current drawer state (locked or unlocked) are grayed out. To access disabled activities, tap the "lock/unlock drawer" button to lock the drawer.










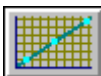





Sections where the Maintenance operations are described are shown in the bullet list above.

To access the Maintenance Menu:



From the Idle display, tap the "maintenance" button

Maintenance Menu Icons and Buttons:

	“drawer locked” indicator		“drawer unlocked” indicator
	“daily check” button		“lock/unlock drawer” button
	“save log file” button		“update software” button
	“move rack/belt” button		“pipettor verification” button
	“calibrate dispense pump” button		“calibrate nephelometer” button
	“self-test” button		“purge/prime dispense pump” button
	drawer open indicator		drawer closed indicator
	“exit” button		

6.3.1 Daily (Nephelometer) Check

The Daily Check is used to verify the accuracy of the Nephelometer. The Daily Check is performed with a dedicated Calibration rack containing calibrator tubes. The instrument verifies the turbidity of the tubes in the rack.

If all the tubes are within the nephelometer’s specifications, the Daily Check passes. If any tube is out of range, the Daily Check fails. Pass/Fail status is shown on the right side of the display. Any tubes that fail the Daily Check are indicated in red in the rack representation at the center of the display. The target density is shown below the tube and the actual McFarland density that is read is shown below the rack.

Acceptance criteria for Nephelometer verification are:

- 0.25 McFarland calibrator tube – 0.23–0.27 McFarland
- 0.50 McFarland calibrator tube – 0.45–0.55 McFarland
- 1.00 McFarland calibrator tube – 0.90–1.10 McFarland
- 4.00 McFarland calibrator tube – 3.60–4.40 McFarland

Progress of the Daily Check is shown in a progress bar at the bottom of the display.

To abort a Daily Check, tap the “stop” button. The display returns to the Maintenance menu.

If the Daily Check fails, the Nephelometer Calibration may assist in clearing the system alert condition. However, the Daily Check must be performed successfully to clear the system alert. If the Daily Check does not pass, contact BD.

To access the Daily Check display:



From the Idle display, tap the “maintenance” button



From the Maintenance menu, tap the “daily check” button

Daily Check Icons and Buttons:



“drawer locked” indicator



“drawer unlocked” indicator



“start” button



“stop” button



“passed” indicator



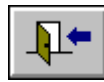
“failed” indicator



“tube passed” indicator



“tube failed” indicator



“exit” button

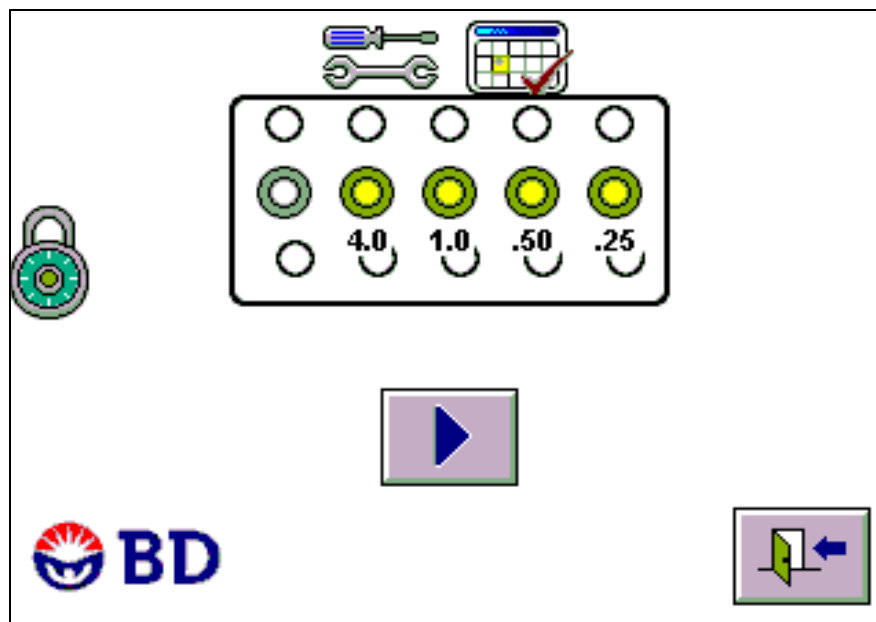


Figure 6-1 – Daily (Nephelometer) Check Display

Preparing a Calibration Rack:

- 1 Take a normal Sample rack.
- 2 Check the Calibrator tubes' Expiration Date. If the date has expired, use a new set of Calibrator tubes.

Place the Calibrator tubes in the Sample rack as indicated in Figure 6-1.

The caps of the Calibrator tubes should not be removed.

- 3 Place a "Calibration" sticker on the corner of the rack.



- 4 Take the rack to the BD EpiCenter workstation and program it for Calibration use (see BD EpiCenter system help for information on programming racks).
- 5 Use this dedicated Calibration rack for Daily Nephelometer Check and the Calibrate Nephelometer function (every 3 months).
- 6 Leave the Calibrator tube set in the Calibration rack.

Required Materials:

- Calibration rack

Procedure:

- 1 Access the Daily Check display as described above.
- 2 Place the Calibration rack on the Input Queue. The caps of Calibrator tubes should not be removed.
- 3 Tap the "start" button.



- 4 The Daily Check is performed and progress of the operation is shown in a progress bar at the bottom of the display.
- 5 To abort the process, tap the "stop" button.



- 6 When the Daily Check is complete, the Sample rack is sent to the Output Queue.
- 7 Results for the Daily Check are:



Passed



Failed

- 8 If the Daily Check passes, take the completed Daily Check Sample rack to the BD Phoenix AP Inoculation Station to upload the results. Remove and return the Calibration rack to storage. Tap the “exit” button to return to the Maintenance menu.
- 9 If the Daily Check fails, a system alert is generated. A Nephelometer Calibration can be accessed directly from the Daily Check display by tapping the “nephelometer calibration” button at the top right of the display. Refer to Section 6.3.8.
- 10 After the Nephelometer Calibration is complete, run the Daily Check again to clear the system alert.

6.3.2 Drawer Lock/Unlock Function

The “drawer lock/unlock” function switches the state of the drawer’s electromagnetic lock. If the drawer is locked, tapping the button unlocks the drawer. If the drawer is unlocked, tapping the button locks the drawer.

The drawer must be locked for most Maintenance functions to be initiated. Unlocking the drawer disables Pipettor and Dispense arm motion-based activities.

To Lock/Unlock the drawer:



From the Idle display, tap the “maintenance” button



From the Maintenance menu, tap the “lock/unlock drawer” button

The icon at bottom center of the display indicate the status of the drawer (open or closed).

6.3.3 Save Log File Function

The Save Log File function enables you to save the instrument’s internal error/event log to flash media. This function is most useful to provide information for service personnel to troubleshoot instrument malfunctions.

To save the log file to flash media:



From the Idle display, tap the “maintenance” button

Insert a BD-supplied flash drive in the USB port on the right side of the instrument



From the Maintenance menu, tap the “save log file” button

The file copy process begins immediately after the button is pressed.

Progress of the operation is shown in a progress bar at the bottom of the display.

Error codes are generated if there is insufficient space on the flash media or if the operation fails to complete successfully. Refer to Section 7.

6.3.4 Software Upgrade Function

The Software Upgrade function enables you to upgrade the instrument software to a new version. New software is provided on USB flash media.

To update the instrument software:



From the Idle display, tap the “maintenance” button

Insert the BD-supplied software update flash media in the USB port on the right side of the instrument



From the Maintenance menu, tap the “update software” button

The instrument verifies that a valid software update is present on the flash media, then it begins the update process.

Progress of the operation is shown in a progress bar at the bottom of the display.

When the update is complete, the instrument is rebooted.

Error codes are generated if the flash media does not contain a valid software update file or if the operation fails to complete successfully. Refer to Section 7 for additional instructions.

CAUTION

Do not remove the USB flash media during the update process. Failure to follow this instruction could render your instrument inoperable.

6.3.5 Move Rack/Belt Display

This Move Rack/Belt display enables you to clear the instrument of Sample racks or to rotate the conveyor belts for cleaning. The Input Queue belt, Processing Chute belt, and Output Queue belt may be operated independently.

To access the Move Rack/Belt display:

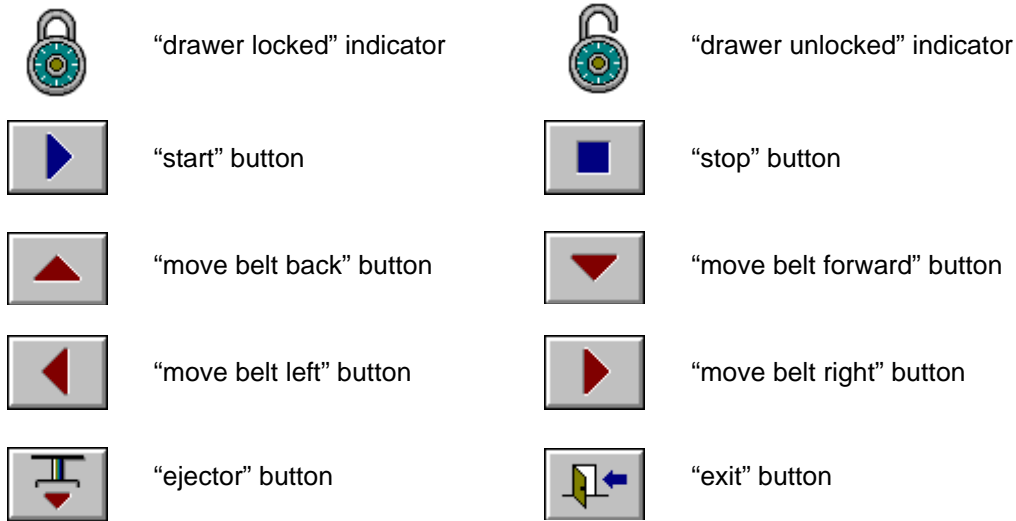


From the Idle display, tap the “maintenance” button



From the Maintenance menu, tap the “move rack/belt” button

Move Rack Icons and Buttons:



Moving belts and racks:

To clear all detected Sample racks from the Input Queue to the Output Queue, tap the "start" button.

To stop the movement of belts and/or Sample racks, tap the "stop" button.

To move the Input Queue or Output Queue belt one half-cycle to expose the opposite side for cleaning, tap the "move belt back" or "move belt forward" button.

To move the Processing Chute belt one index position, tap the "move belt left" or "move belt right" button.

To move a Sample rack from the right end of the Processing Chute to the Output Queue, tap the "ejector" button.

If any Sample racks in the Instrument are causing conflict in movement, the "move belt" buttons are disabled to prevent damage to the instrument.

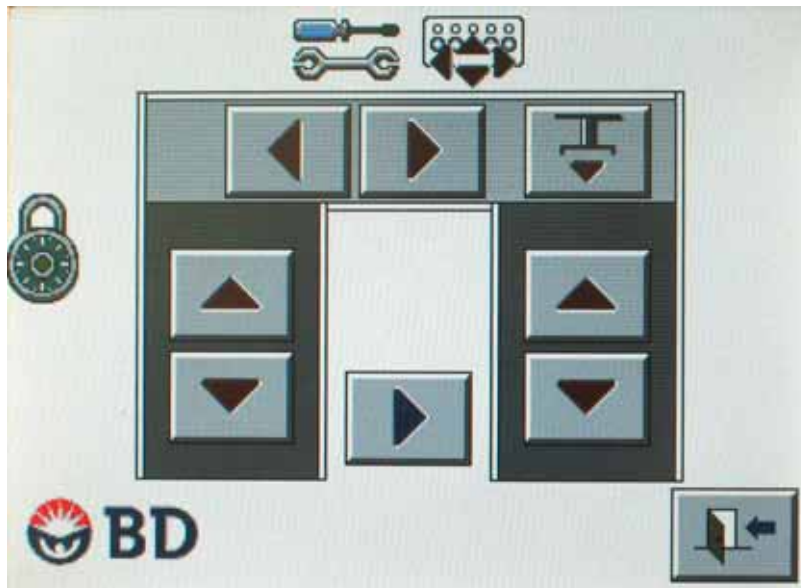


Figure 6-2 – Move Rack Display

6.3.6 Pipettor Verification Display

The pipettor can be verified by the user as needed.

The Pipettor Verification display enables you to check the accuracy of the pipettor. To verify pipettor accuracy, you uncap and pre-weigh 5 AST and 3 ID broth tubes, or 10 AST and 5 ID broth tubes (Emerge panel users) then place them in a Sample rack as shown in the display (Figure 6-3). Another ID tube must be emptied and filled to 4.5 mL with deionized water. After the pipetting operations are completed, reweigh the tubes. If the difference is within the specified tolerance, the pipettor's accuracy has been verified.

To access the Pipettor Verification display:



From the Idle display, tap the “maintenance” button



From the Maintenance menu, tap the “pipettor verification” button

Pipettor Verification Icons and Buttons:



“drawer locked” indicator



“drawer unlocked” indicator



“start” button



“stop” button



“pipetting completed successfully” indicator



“pipetting did not complete successfully” indicator



“exit” button

Required Materials:

- Non-Emerge panel users
 - 5 AST broth tubes
 - 3 ID broth tubes
- Emerge panel users
 - 5 AST broth tubes
 - 5 AST 4.5 mL broth tubes
 - 5 ID broth tubes
- Deionized water
- Sample rack
- Analytical balance (capable of measuring to four decimal places [0.0001 grams])

Procedure:

- 1 Access the Pipettor Verification display as described above.
- 2 For non-Emerge panel users: Set up 5 AST broth tubes and 3 ID broth tubes in a Sample rack as shown on the display (Figure 6-3).
For Emerge panel users: Set up 5 AST broth tubes, 5 AST 4.5 mL broth tubes, and 5 ID broth tubes in a Sample rack as shown on the display (Figure 6-3).
- 3 Remove each tube individually from the rack, remove the cap, weigh the tube, and record the weight to 4 decimal places. (The ID tube in the middle of the rack does not have to be weighed.)
- 4 Add 4.5 mL (\pm 10%) of deionized water to the ID tube in the middle of the rack, designated in blue in the Pipettor Verification display (Figure 6-3).
- 5 Return the tubes to the Sample rack.
- 6 Tap the “start” button to begin pipetting operations.



- 7 For non-Emerge panel users, the instrument dispenses 25 μ L, 50 μ L, and 40 μ L of deionized water into the tubes in several passes. Progress of the operation is shown in a progress bar at the bottom of the display.
For Emerge panel users, the instrument dispenses 22.5 μ L, 25 μ L, 28.1 μ L, 50 μ L, and 40 μ L of deionized water into the tubes in several passes. Progress of the operation is shown in a progress bar at the bottom of the display.
- 8 To abort the process, tap the “stop” button.



- 9 When pipetting is complete, the Sample rack is moved to Output Queue.

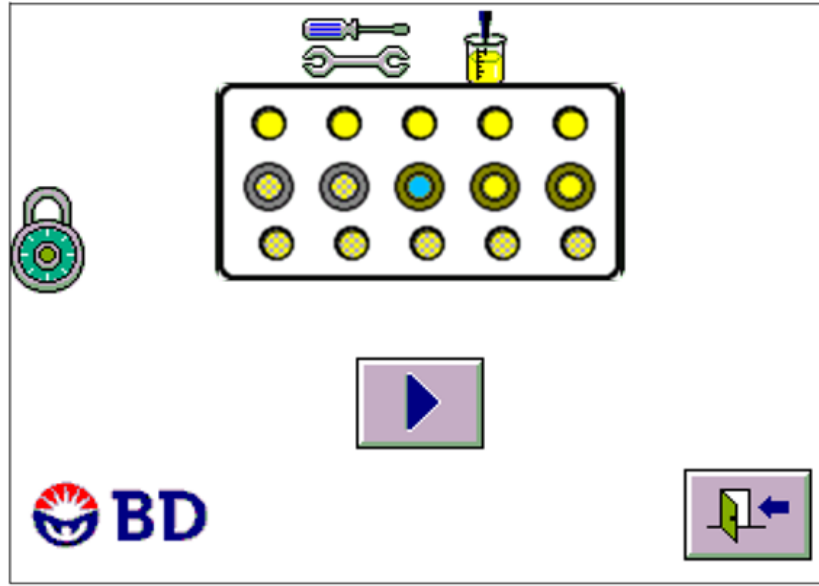


Figure 6-3 – Pipettor Verification Display

Place 2 preweighed ID tubes in yellow locations (non-cross-hatch pattern); place deionized water in blue location; place 5 pre-weighed AST tubes in rear row.

For Emerge panel users, place 2 additional pre-weighed ID tubes in cross-hatch pattern yellow locations in the middle row; place 5 pre-weighed AST 4.5 mL broth tubes in front row.

- 10 Results of the pipetting operations are:



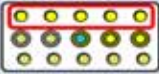






Pipetting completed successfully



Pipetting did not complete successfully

- 11 If the pipetting operation completes successfully, reweigh all tubes (except the leftmost ID tube) and record the weights.
- 12 Take the Sample rack to the BD Phoenix AP Inoculation Station to upload status to BD EpiCenter. At BD EpiCenter, in the BD Phoenix AP Instrument QC History (Pipettor Verification grid), select Pass or Fail to indicate the results obtained from manually weighing the tubes (acceptable tolerances are shown below).

13 The weight difference for the tubes should be:

Tube	Position	Weight Difference
AST		0.040 ± 0.004 g
ID		Does not matter
ID		0.050 ± 0.005 g
ID		0.025 ± 0.0025 g
ID		0.050 ± 0.005 g
ID		0.0281 ± 0.0028 g
AST		0.0225 ± 0.0023 g

6.3.7 Calibrate Dispense Pump Display

The Calibrate Dispense Pump display enables you to calibrate the Dispense Pump. This function should be performed weekly, as well as after the Dispense Tubing Set is replaced.

The Calibrate Dispense Pump function dispenses broth into empty ID broth tubes, verifies the volumes dispensed, and adjusts the Dispense Pump based on the results.

To access the Calibrate Dispense Pump display:















From the Idle display, tap the “maintenance” button



From the Maintenance menu, tap the “calibrate dispense pump” button

Calibrate Dispense Pump Icons and Buttons:

	“drawer locked” indicator		“drawer unlocked” indicator
	“start” button		“stop” button
	“reset” button		“days remaining” timer
	days remaining on Dispense Tubing set timer >2 days		days remaining on Dispense Tubing set timer £ 2 days
	Dispense Tubing set timer expired indicator		“passed” indicator
	“failed” indicator		“exit” button

Required Materials:

- 2 ID broth tubes (empty)
- Sample rack

Procedure:

- 1 Access the Calibrate Dispense Pump display as described above.
- 2 Take 2 ID broth tubes, remove the caps, and empty the contents.
- 3 Set up the ID broth tubes in a Sample rack as shown on the display (Figure 6-4).
- 4 Tap the “start” button to begin calibration.



- 5 The instrument dispenses ID broth into the tubes, verifies the volumes dispensed, and makes any needed calibration adjustments to the Dispense Pump. Progress of the operation is shown in a progress bar at the bottom of the display.
- 6 To abort the process, tap the “stop” button.



- 7 When the process is complete, the Sample rack is moved to Output Queue.

8 Results of the calibration are:



Calibration completed successfully



Calibration did not complete successfully

9 If you replaced the Dispense Tubing Set, tap the “reset” button to reset the 30-day timer.



10 Tap the “save” button to save the updated information.



11 If the calibration fails, a system alert is generated, and you cannot initiate any sample tube preparation runs until the Dispense Pump is successfully calibrated.

12 Take the Sample rack to the BD Phoenix AP Inoculation Station to upload status to BD EpiCenter.

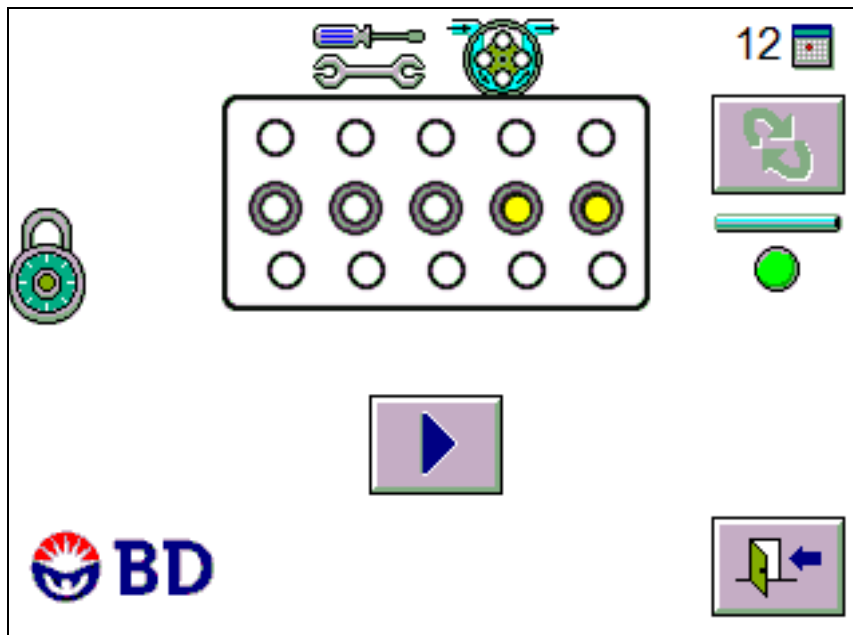


Figure 6-4 – Calibrate Dispense Pump Display

6.3.8 Self-Test Function

The Self-Test function causes the instrument to perform its startup self-test and initialization routines. This is useful if the instrument appears to be having a problem but is not reporting an error code.

To initiate the self-test function:



From the Idle display, tap the “maintenance” button



From the Maintenance menu, tap the “self-test” button

The self-test process begins immediately after the button is pressed. The self-test verifies operation of Pipettor robot motions/sensors; dispense pump motions/sensors; Dispense Robot motions/sensors; Input conveyor motions/sensors; Output conveyor motions/sensors; Processing Chute conveyor motions/sensors; Pipettor pump and sensors; Rack ejection mechanism/sensors; and communications with the RFID Reader/Writer, Nephelometer, and RS-232/USB module.

The display transitions to the Startup display (Section 5.3).

If the self-test completes successfully, the Idle display appears and the “start” button is enabled for initiating Sample rack processing.

If the self-test encounters any problems, the Idle display appears and the appropriate error code is reported. The “start” button is disabled until the error condition is corrected.

6.3.9 Calibrate Nephelometer Display

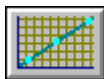
The nephelometer should be calibrated every 3 months.

The Calibrate Nephelometer display enables you to calibrate the nephelometer as part of routine maintenance or to correct the error condition resulting from a failed Daily Check.

To access the Calibrate Nephelometer display:

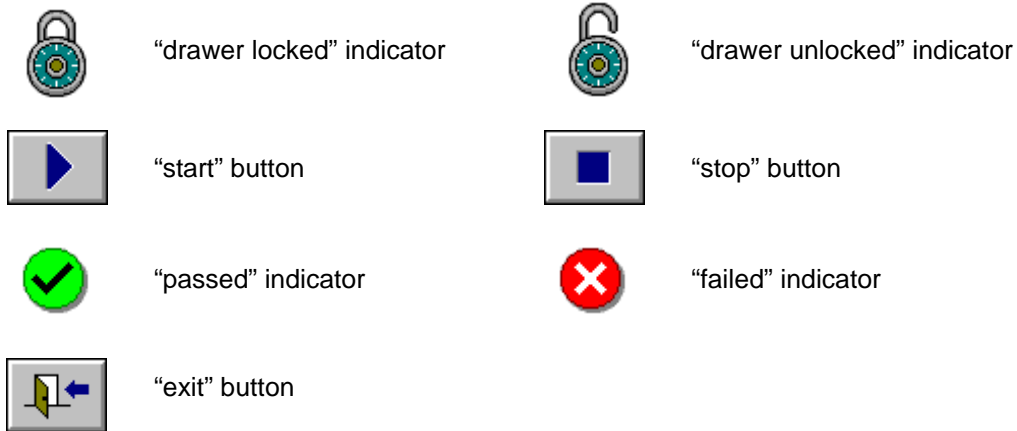


From the Idle display, tap the “maintenance” button



From the Maintenance menu, tap the “calibrate nephelometer” button

Calibrate Nephelometer Icons and Buttons:



Required Materials:

- Calibration rack

Procedure:

- 1 Access the Calibrate Nephelometer display as described above.
- 2 Place the Calibration rack on the Input Queue.

Check the Calibrator tubes' Expiration Date. If the date has expired, replace the Calibrator tubes.

Examine all Calibrator tubes for scratches, smudges, or cracks. Do not use any tube that is scratched or cracked. If a tube is smudged, remove the smudge with a damp lint-free cloth before proceeding.

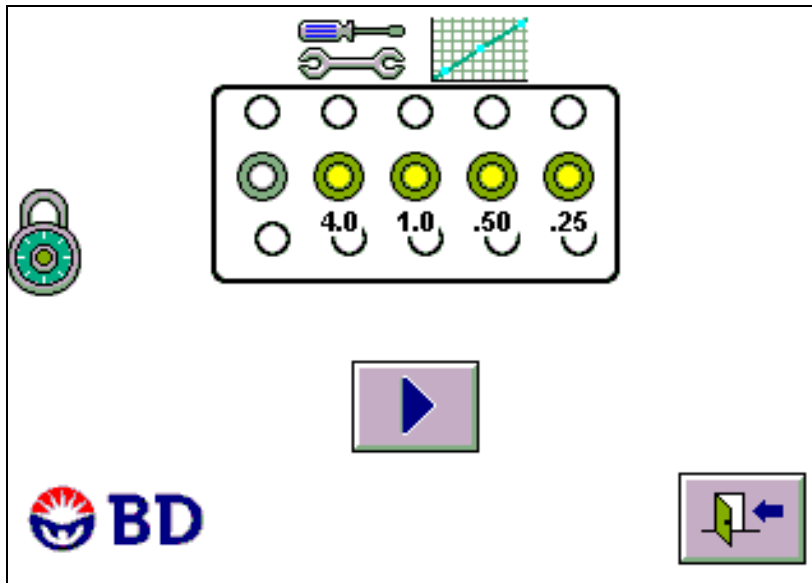


Figure 6-5 – Calibrate Nephelometer Display

- 3 Tap the “start” button.



- 4 The nephelometer calibration is performed and progress of the operation is shown in a progress bar at the bottom of the display.
- 5 To abort the process, tap the “stop” button.



- 6 When the nephelometer calibration is complete, the Sample rack is sent to the Output Queue.
- 7 Results for the nephelometer calibration are:



Passed



Failed

- 8 If the nephelometer calibration passes, take the completed Calibration rack to the BD Phoenix AP Inoculation Station to upload the results.
- 9 Perform the Daily Check as described in Section 6.3.1.
- 10 Remove and return the Calibration rack to storage. Tap the “exit” button to return to the Maintenance menu.
- 11 If the nephelometer calibration fails, a system alert is generated. Refer to Section 7 for additional information.

6.3.10 Purge/Prime Dispense Pump Function

The Purge/Prime Dispense Pump function purges air from the Dispense Tubing set and primes ID broth to the dispenser. This function may be used when changing the Dispense Tubing set to help avoid ID Broth leakage.

To initiate the Purge/Prime Dispense Pump function:



From the Idle display, tap the “maintenance” button



From the Maintenance menu, tap the “purge/prime dispense pump” button

The Dispense arm moves over the waste liquid bottle and begins to pump after the button is pressed. When the operation completes, the Maintenance menu appears.

6.4 Changing the Dispense Tubing Set

The Dispense Tubing set **must** be replaced every 30 days.

Removing the old tubing:

Wear gloves and a gown/lab coat when performing this procedure. It is possible that there could be minor leakage from the tube being removed. Failure to follow these instructions could result in spilling ID Broth inside the instrument.

This procedure must be performed with the instrument power on.

- 1 From the Idle display, tap the “maintenance” button.
- 2 From the Maintenance menu, tap the “lock/unlock drawer” button to unlock the drawer.
- 3 Open the drawer.
- 4 Close the blue clamp on the ID Broth solution output tube.
- 5 Hold the ID Broth solution output tube LUER-LOK, and twist and pull the Dispense Tube LUER-LOK to remove it from the ID Broth solution. Lay the Dispense Tube LUER-LOK down.
- 6 Close the drawer.
- 7 From the Maintenance menu, tap the “lock/unlock drawer” button to lock the drawer.
- 8 Run the Purge/Prime Dispense Pump function from the Maintenance menu to clear the ID Broth from the Dispense Tube.
- 9 From the Maintenance menu, tap the “lock/unlock drawer” button to unlock the drawer.
- 10 Open the drawer.
- 11 Push down, twist and pull to unlock and remove the Dispense Tube tip from the Dispense arm at the back of the reagent drawer.
- 12 Feed the tube under the Dispense arm, and remove the tube from the clip on the rear of the drawer.
- 13 Remove the Tube Set from the clips on the right side of the drawer.
- 14 Open the Dispense pump by pulling the lid up and towards the rear of the instrument. Remove the old tubing, noting how it lays within the groove inside the Dispense pump. You will need to remove the two square locators on the tube from the locator tube clips on both sides of the Dispense pump.
- 15 Dispose of old tubing.



Figure 6-6 – Dispense Tubing Set in Packaging

Installing the new tubing:

- 1 If you are changing the ID Broth solution at the same time, hang the new bag on the three clips at the top of the drawer's front panel. Make sure that the output tube of the ID Broth solution is facing the left side of the instrument.
- 2 Remove the new Dispense Tubing set from the bag by peeling it open from the top.

Avoid touching the Dispense Tubing set tip to instrument surfaces prior to inserting it into the Dispense arm.

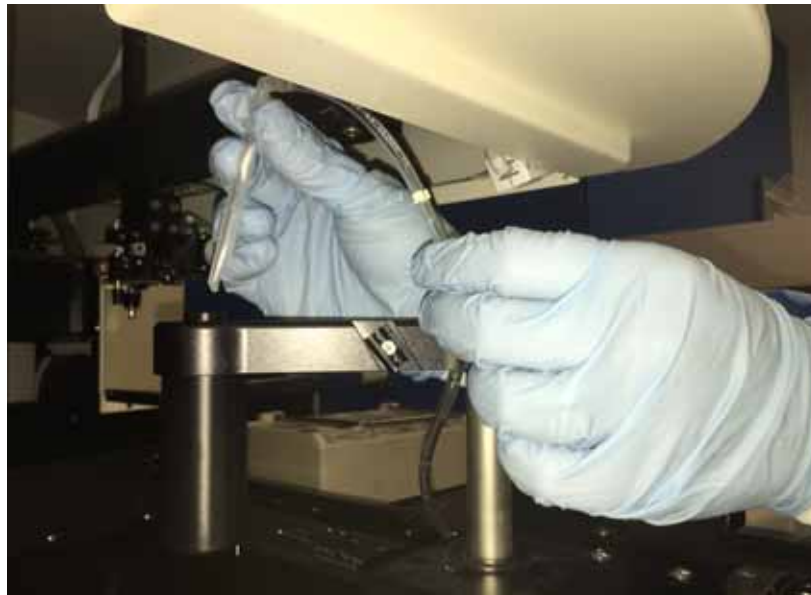


Figure 6-7 – Inserting the Dispense Tip

- 3 As you insert the Dispense tip into the Dispense arm, insure that the top of the Dispense tip is pointed slightly to the rear of the Dispense arm.

Insert the Dispense Tubing set tip into the Dispense arm while pushing down and twisting to the right to secure.

When the Dispense tip is in place, the elbow of the tubing should be facing toward the right side of the instrument.

Failure to orient the tip properly will result in over-spray onto the instrument deck.

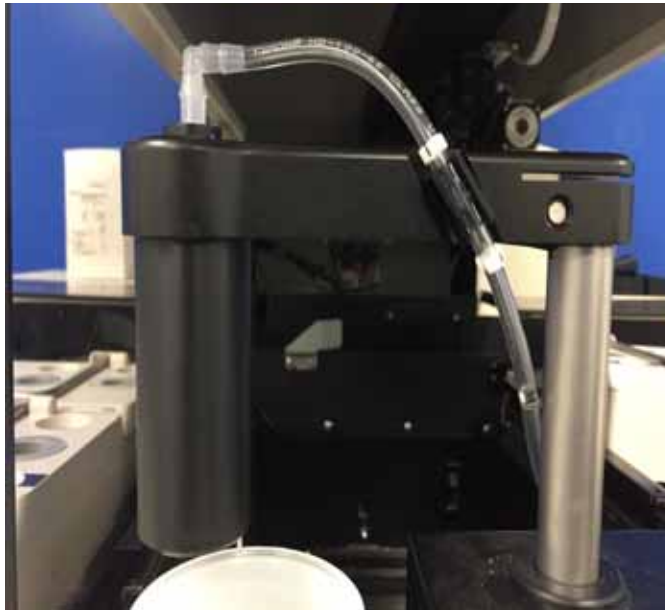


Figure 6-8 – Correct Orientation of Dispense Tip

- 4 Push the tubing into the clip on the front of the Dispense arm. Be sure to align the white marks on the tubing above and below the Dispense arm clip.



Figure 6-9 – Inserting Tube on Dispense Arm

- 5 Feed the tubing **under** the Dispense arm.
- 6 Push the tubing into the clip on the rear of the reagent drawer.

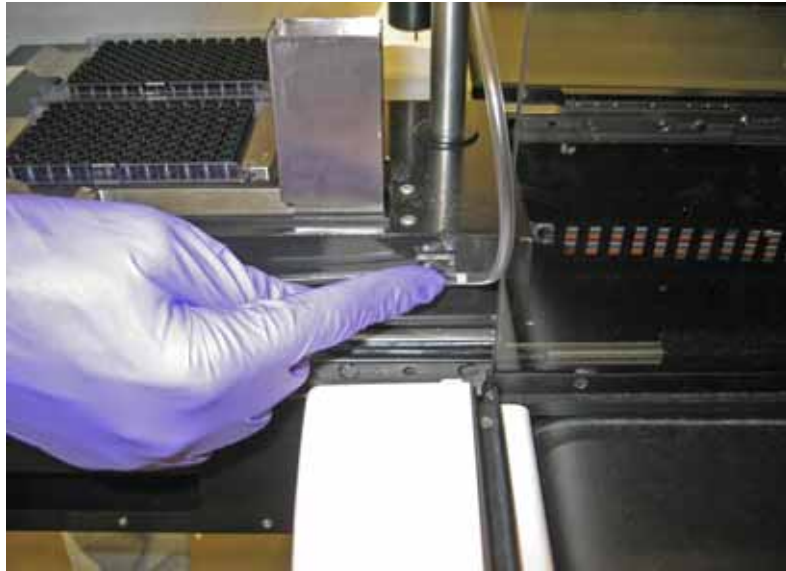


Figure 6-10 – Inserting Tubing into Side Clips

- 7 Run the tubing along the right side of the reagent drawer, pushing the tubing into the two clips on the side. There are white locator marks on the tubing to indicate where the tubing is inserted into clips.
- 8 Find the square locators on the Dispense Tubing. Lay the portion of the tube within the locators in the groove on the inside of the Dispense pump. Fit the locators into the locator clips on each side of the bottom of the Dispense pump. You will have to stretch the tube slightly. Close the Dispense pump.

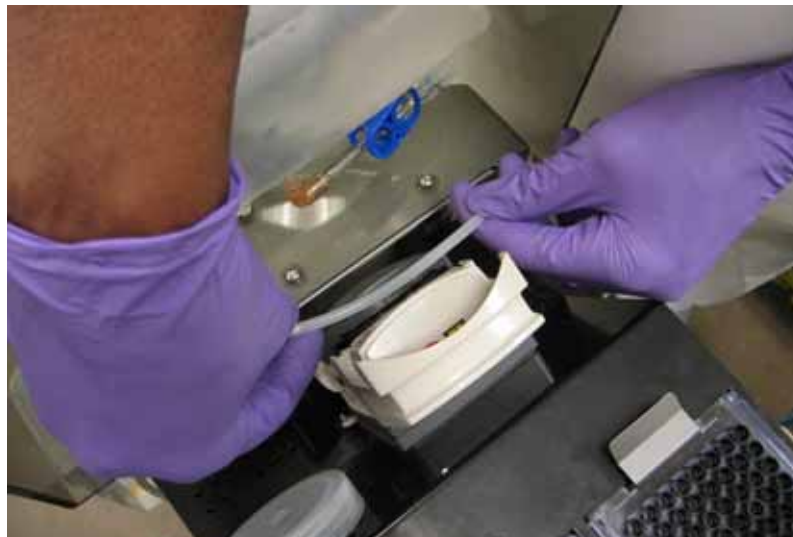


Figure 6-11 – Inserting Dispense Tubing Set in Dispense Pump



Figure 6-12 – Inserting Dispense Tubing Set Locators

- 9 If you are replacing the ID Broth solution at the same time as the Dispense Tubing change, remove the end cap from the ID Broth solution output tube.
- 10 Join the ID Broth solution tube to the Dispense Tubing by pushing them together and twisting to the right.



Figure 6-13 – Connect ID Broth Solution to Dispense Tubing Set

- 11 Open the blue clamp on the ID Broth solution output tube.
- 12 Close the drawer and perform the Calibrate Dispense Pump function (Section 6.3.7).
- 13 Verify the correct orientation of the dispense tip by observing the ID broth dispenses into the waste liquid bottle. If ID broth dispenses outside of the waste liquid bottle, turn off the instrument immediately and contact your local BD representative.

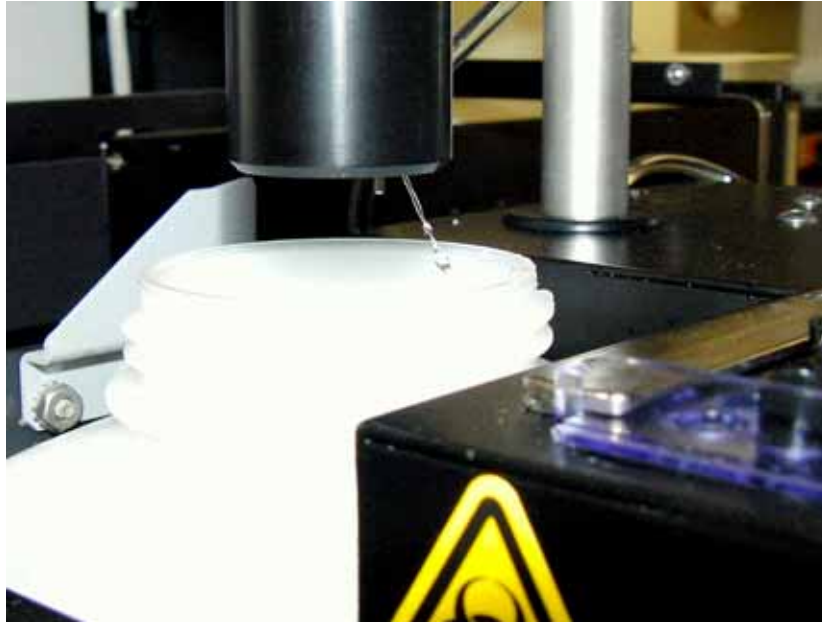


Figure 6-14 – Correct Dispense into Waste Liquid Bottle

6.5 Routine Cleaning

The BD Phoenix AP instrument should be cleaned regularly and should be decontaminated after spills, splashes, or obvious contamination. Always wear appropriate personal protective equipment while performing cleaning activities.

Do not clean the pipette tip adapter.

WARNING

STANDARD PRECAUTIONS

CONSIDER ALL ORGANISMS AS POTENTIALLY INFECTIOUS AND HANDLE ACCORDING TO STANDARD MICROBIOLOGICAL PRACTICES, SPECIAL PRACTICES, AND SAFETY EQUIPMENT RECOMMENDED FOR BIOSAFETY LEVEL 2 (BSL-2) CONTAINMENT¹.

BSL-2 PRACTICES INCLUDE, BUT ARE NOT LIMITED TO THE FOLLOWING:

- WEAR GLOVES AND LAB COAT WHEN HANDLING POTENTIALLY INFECTIOUS MATERIAL OR CONTAMINATED INSTRUMENT COMPONENTS. WEAR ANY OTHER PERSONAL PROTECTIVE EQUIPMENT ACCORDING TO LOCAL POLICY.
- DECONTAMINATE WORK SURFACES AFTER COMPLETION OF WORK AND AFTER ANY SPILL OR SPLASH OF POTENTIALLY INFECTIOUS MATERIAL WITH APPROPRIATE DISINFECTANT.
- DECONTAMINATE ALL CULTURES, STOCKS, AND OTHER POTENTIALLY INFECTIOUS MATERIALS BEFORE DISPOSAL USING AN EFFECTIVE METHOD.
- PERFORM ALL PROCEDURES TO MINIMIZE THE CREATION OF SPLASHES AND/OR AEROSOLS.
- LABORATORY EQUIPMENT SHOULD BE ROUTINELY DECONTAMINATED, AS WELL AS, AFTER SPILLS, SPLASHES, OR OTHER POTENTIAL CONTAMINATION.
- SPILLS INVOLVING INFECTIOUS MATERIALS MUST BE CONTAINED, DECONTAMINATED, AND CLEANED UP BY STAFF PROPERLY TRAINED AND EQUIPPED TO WORK WITH INFECTIOUS MATERIAL.
- EQUIPMENT MUST BE DECONTAMINATED BEFORE REPAIR, MAINTENANCE, OR REMOVAL FROM THE LABORATORY.
- DECONTAMINATE AND DISPOSE OF ALL POTENTIALLY CONTAMINATED MATERIALS AS REGULATED MEDICAL WASTE IN ACCORDANCE WITH LOCAL, STATE, AND FEDERAL REGULATIONS.

¹ Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. 2007. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, US Government Printing Office, Washington, DC.

Web site: <http://www.cdc.gov/OD/ohs/biosfty/bmb15/bmb15toc.htm>

BD Phoenix AP instrument surfaces may be cleaned with a solution containing 0.5% sodium hypochlorite (10% solution of chlorine bleach containing at least 5% sodium hypochlorite). Alternatively, an EPA-registered bactericidal disinfectant that is prepared and used according to the manufacturer's label instructions may be used. After the appropriate contact time (2 minutes for bleach), wipe surfaces with a cloth or paper towel moistened with tap water to remove any residue. Wipe Plexiglas with a dilute solution of a mild liquid dishwashing detergent.

Examine the following areas and wipe with a cloth or paper towel moistened with disinfectant if obvious contamination is evident. Potential biohazardous areas exist in the waste related locations illustrated in Figure 6-13.

The following cleaning procedures may be used.

- 1 Remove the Waste Liquid bottle and clean the inside of the waste bottle reservoir.
- 2 Remove and discard the waste tip bin. Wipe the waste bin area with disinfectant solution.
- 3 Remove the Waste Tip Chute and soak for 5 minutes in 10% bleach solution. Rinse with plenty of water.
- 4 Wipe down the Inoculation Station and Sample rack with disinfectant.

CAUTIONS

- Do not submerge the Sample rack in disinfectant or liquid of any kind.
- Do not clean the pipette tip adapter.

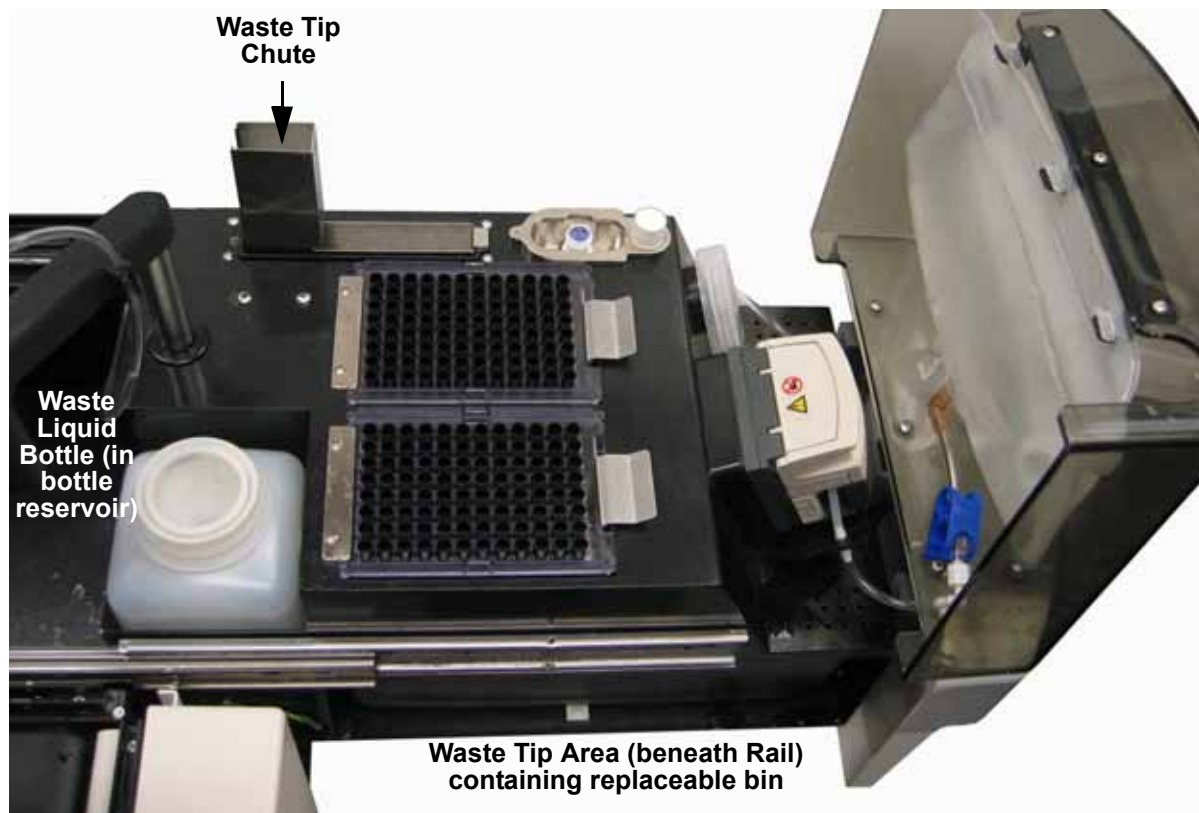


Figure 6-15 – Potential Hazardous Waste Locations

6.6 Decontamination

6.6.1 Decontamination after a Spill

In the event of a spill in or on the BD Phoenix AP instrument, the priority should be to limit the extent of the spill, and then to decontaminate the affected areas.

Do not clean the pipette tip adapter.

General Instructions:

- 1 Absorb the contaminated spill and discard as biohazardous waste.
- 2 Moisten an absorbent cloth or paper toweling with 10% bleach solution, wringing it out until damp but not dripping wet.
- 3 Apply the solution to the affected area until glistening wet. Allow to air dry.
- 4 Once dry, dampen a clean cloth with water and wipe down the affected surfaces. Allow to air dry.

Specific Instructions:

If the spill is on one of the belts, this procedure must be performed with the instrument power on.

- 1 Hold the cloth or toweling on the belt and use the Move Rack/Belt function (Section 6.3.5) on the Maintenance menu.
- 2 Press the “move belt back/forward” button. Move the cloth from side to side while the belt is moving to moisten all areas of the belt.
- 3 Press the “move belt back/forward” button a second time to completely decontaminate the belt.
- 4 Allow to air dry.
- 5 Repeat procedure using water to remove any disinfectant residue.

If the spill occurs inside the drawer, follow general instructions above. If possible, avoid allowing the bleach solution to come in contact with the Dispense arm.

WARNING

IF A TUBE BREAKS OR A JAM OCCURS WHILE A BD PHOENIX ID TUBE OR BD PHOENIX AST TUBE IS IN THE RACK HANDLING MODULE OR WHILE A BD PHOENIX ID TUBE IS IN THE NEPHELOMETER, CONTACT BD FIELD SERVICE IMMEDIATELY. DO NOT ATTEMPT TO CLEAR THE JAM.

6.6.2 Decontamination before Repair, Maintenance, or Removal from the Laboratory

The BD Phoenix AP instrument must be decontaminated before repair, maintenance, or removal from the laboratory. Contact BD Field Service for instructions.

7 - Troubleshooting

7.1 General

7.1.1 Instrument Service

If your BD Phoenix AP 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 a local BD representative (contact numbers are listed in Section 11).

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.

7.1.2 Non-Alert Errors

The BD Phoenix AP instrument has numerous sensors to detect error conditions throughout the instrument. When one of these sensors detects a problem, a system or workflow alert is typically generated.

If you notice any conditions that seem to indicate a problem, but that do not generate any error codes, contact BD with this information.

For troubleshooting instrument problems, power should be removed and the power cord should be disconnected for safety, unless you are instructed to leave power on.

CAUTION

Any pipette tip that is not discarded into the pipette waste tip chute should be considered contaminated and discarded appropriately. The area should be cleaned per the recommendations in Section 6.5. Any jam in the pipette waste tip chute should be cleared immediately.

7.2 Error/Alert Messages

As you perform activities at the BD Phoenix AP instrument, and as testing progresses, instrument alerts and errors may occur. Different types of alerts and errors are flagged by error codes and/or audible tones.

CAUTION

When the instrument notifies you of alerts and errors, you should immediately respond to the condition.

When the system encounters an error condition, the error code is displayed in the center of the screen and written to the log file. The highest priority active error code is shown at the center of the screen.

A listing of all active alert/error codes can be viewed by tapping and holding the “alerts” icon at the center of the Idle display for 2 seconds. When you remove your finger from the screen, the Active Alerts display appears.

There are two main types of alerts and errors.

- System errors relate to instrument operations; they cause the audible alarm tone to sound. The alert tone can be stopped by tapping the error code on the screen. Tapping the alert code acknowledges the alert condition. In some cases, clearing the code requires corrective action by BD.
If there are additional active error codes, they are shown when the previous code is cleared from the display.
- Workflow errors generally happen as a result of some unexpected action you perform, rather than a “fault” condition in the instrument.

Alerts are listed in numerical order in the table below, with W (Workflow) codes first and E (Error) codes second. The priority of the alert/error code is shown in parentheses after the error code number. The table suggests some possible causes of errors and alerts, and provides possible corrective actions.

Alerts are displayed in an assigned color on the Active Alerts display. The color corresponds to the following types of errors:

- Red System Fatal Errors
- Purple Mechanical Jam or Processing Errors
- Blue Non-fatal Alerts
- Black General Notifications

Errors marked with an asterisk trigger Message number 15020 at the BD EpiCenter system.

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

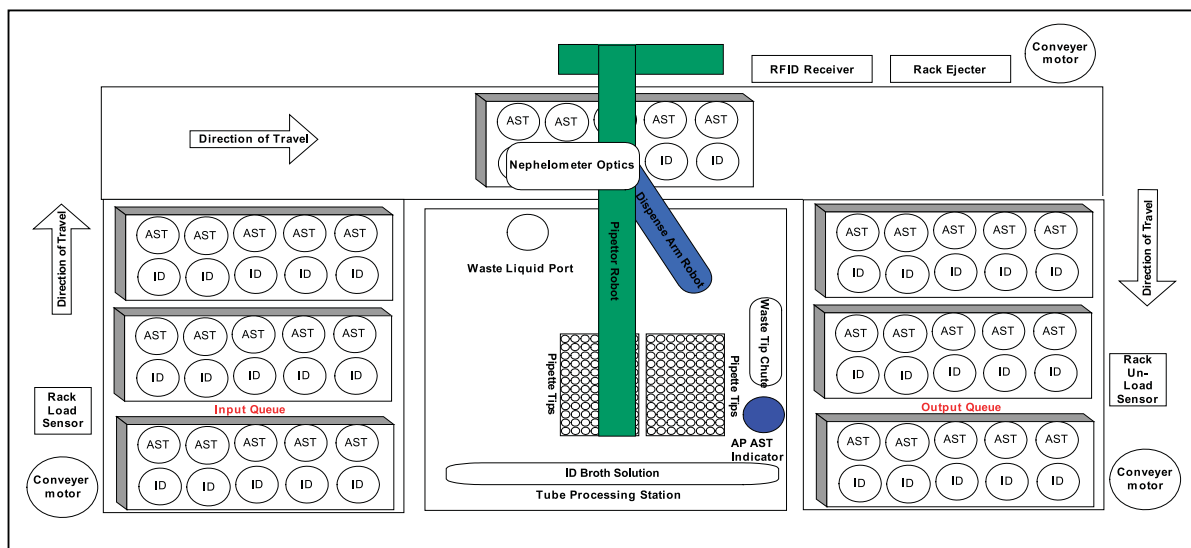


Figure 7-1 – Troubleshooting Components

Shown with 2-row rack. Troubleshooting components are identical with 3-row rack.

Error Number	Description	Possible Cause(s)	Corrective Action(s)
W01 (82)	Check robot positions	Instrument cannot verify that Dispense Robot arm and Pipettor Robot arm are in safe positions (i.e., that they will not collide with each other when operation resumes)	Verify the position of the pipettor and Dispense arm. If either is not in the correct position, turn power off, move the robot arm to the correct position (see Figure 4-10), and turn the power back on. If you have manually moved the Robot arms, make sure they are in the proper positions (see Figure 4-10), and tap the “start” button.
W02 (60)	Insufficient ID Broth for next sample	Available ID Broth volume is low.	Replace the ID broth solution as described in Section 4.5. Reset the ID broth solution counter in the Liquid Consumables display (Section 5.4.2.1).
W03 (61)	Insufficient tips for next rack or sample	Available pipette tips are low.	Add pipette tips as described in Section 4.5. Reset the Pipette Tip counter in the Tip Consumables display (Section 5.4.2.2).

Error Number	Description	Possible Cause(s)	Corrective Action(s)
W04 (62)	Tips not where expected	The instrument was unable to find any pipette tips where it thought they should be.	If either pipette tip tray contains tips, tap the "start" button to continue the tip search. If both tip trays are depleted, add pipette tips as described in Section 4.5. Reset the Pipette Tip counter in the Tip Consumables display (Section 5.4.2.2). Make sure you reset the counters when (and only when) you replace the pipette tip trays.
W05 (63)	No tips found after W04	No tips were found after a previous W04 error occurred and you tapped "start" to continue the tip search.	Add pipette tips as described in Section 4.5. Reset the Pipette Tip counter in the Tip Consumables display (Section 5.4.2.2).
W06 (64) W07 (65)	Insufficient AST Indicator for next Rack	The AP AST Indicator volume is low. The instrument does not use the last few mL of AP AST Indicator due to the potential concentration of the reagent.	Add AP AST Indicator as described in Section 4.5. Reset the AP AST Indicator counter in the Liquid Consumables display (Section 5.4.2.1).
W08 (66)	Waste liquid bottle too full for next sample	The waste liquid bottle is full.	Recap full bottle (leave the funnel in place). Dispose of the waste liquid with biohazard waste. Add a new, empty waste liquid bottle (with funnel) as described in Section 4.5. Reset the Waste Liquid counter in the Liquid Consumables display (Section 5.4.2.1).
W09 (67)	Waste liquid bottle level not where expected	Unexpected waste liquid detected in waste liquid bottle.	Check the rack status to see where processing left off. Recap full bottle (leave the funnel in place). Dispose of the waste liquid with biohazard waste. Add a new, empty waste liquid bottle (with funnel) as described in Section 4.5. Reset the Waste Liquid counter in the Liquid Consumables display (Section 5.4.2.1).

Error Number	Description	Possible Cause(s)	Corrective Action(s)
W10 (68)	Waste Tip Bin too full for next sample	The waste tip bin is too full for the pipettor to eject another tip.	Remove and discard waste tip bin with sharps/biohazard waste. Insert a new waste tip bin in the waste tip area. Reset the Waste Tip Bin counter in the Tip Consumables display (Section 5.4.2.2).
W11 (69)	Waste Liquid Bottle missing.	The instrument cannot detect a waste liquid bottle.	Add a new, empty waste liquid bottle as described in Section 4.5. Reset the Waste Liquid counter in the Liquid Consumables display (Section 5.4.2.1). If waste liquid bottle is present when the message occurs, contact BD.
W12 (50)	Sample Aging Alert - Warning	5–25 minutes (per your Configuration setting) remain before the Rack Aging timer expires.	Process the Sample rack (upload at the AP Inoculation Station, label and login panels, inoculate panels, and place them in the BD Phoenix instrument) before the sample expires. If this message occurs frequently, you may want to decrease the amount of time in the Rack Aging Timer (Section 2.4.3).
W13 (51)	Sample Aging Alert - Alarm	Rack Aging timer has expired.	Dispose of all ID/Inoculum and AST Broth tubes in the affected rack. Prepare fresh ID/Inoculum broth tubes and start a new run.
W14 (58)	Output Queue is full when in-process Sample rack is ready to eject	The Output Queue holds a maximum of 3 Sample racks.	Remove Sample racks from the Output Queue and process them at the BD Phoenix AP Inoculation Station.
W15 (70)	ID Broth timer expired	The stability timer for the ID broth solution has expired.	Replace the ID broth solution as described in Section 4.5. Reset the ID broth solution counter in the Liquid Consumables display (Section 5.4.2.1).
W16 (71)	Dispense Tubing set timer expired	The stability timer for the Dispense Tubing set has expired.	Replace the Dispense Tubing set as described in Section 6.4 – Dispense Tubing Set Replacement.

Error Number	Description	Possible Cause(s)	Corrective Action(s)
W17 (72)	AP AST Indicator stability timer expired	The stability timer for the AP AST Indicator has expired.	Replace AP AST Indicator as described in Section 4.5. Reset the AP AST Indicator counter in the Liquid Consumables display (Section 5.4.2.1).
W18 (73)	Time mismatch	The current system date/time is less than stored date/times.	Contact BD.
W19 (74)	After a dispense, the level in an ID/Inoculum tube is out of bounds	Fluid level in ID/Inoculum tube is not within defined tolerance.	Check/replace ID broth solution if bag is empty. Check for pinches or kinks in Dispense tubing set. Check/release clamp in Dispense tubing set. Calibrate Dispense pump (Section 6.3.7). Replace ID broth solution and calibrate Dispense pump. If the problem persists, contact BD.
W20 (75)	Tubes missing or in incorrect positions for Maintenance functions	The ID or ID/AST broth tubes needed for the requested Maintenance operation were not loaded in the Sample rack properly.	Observe the display and set up tubes as shown on the display and as explained in Section 6.3.
W21 (83)	Missing USB flash media	The USB flash media has not been inserted in the USB port or is damaged.	Check/reinsert flash media in USB port. Reformat flash media as FAT32 on a PC and retry the operation. If message recurs, use new BD-supplied flash media for the operation.
W22 (52)	Rack not processed at BD Phoenix AP Inoculation Station	The Sample rack that is currently being processed was not previously uploaded/cleared at the BD Phoenix AP Inoculation Station. Malfunction of the BD Phoenix AP Inoculation Station.	Take the Sample rack to the BD Phoenix AP Inoculation Station to upload the rack's status and clear the information on the RFID tag. If problem recurs, contact BD.

Error Number	Description	Possible Cause(s)	Corrective Action(s)
W23 (59)	No Rack detected when Processing Chute is being loaded	The Sample rack was loaded improperly on the instrument (backwards, not positioned on the Input Queue correctly, etc.	Remove Sample rack and replace on the Input Queue. Make sure the rack is seated squarely on the belt with ID/Inoculum broth tubes in grey ringed wells on the rack, AST broth (8 mL) tubes in rear and AST (4.5 mL) if used in the front of the rack.
W24 (84)	Insufficient USB capacity for log file download	The log file being downloaded to flash media is too large for available space on the media.	Use a new BD-supplied USB flash media drive. Reformat flash media as FAT32 on a PC and retry the operation.
W25 (86)	Racks on instrument before start of a Maintenance operation	The instrument detected a Sample rack on the Processing Chute or Output queue when a Maintenance operation was requested.	Remove all Sample racks from the instrument before beginning any Maintenance Menu activities.
W26 (87)	Tube initial fluid level issue for Maintenance operation	Fluid was detected in a tube during a Dispense Pump calibration operation.	To calibrate the Dispense pump, follow the procedure in Section 6.3.7 – Calibrate Dispense Pump Display.
W27 (48)	Nephelometer confirmation reading is greater than initial reading	Sample not vortexed or homogeneous. Problem with tube or sample.	If problem recurs frequently, contact BD.
W28 (49)	Level sense in ID tube shows overflow. Retry is in progress	The instrument initially detected an ID tube volume that was too high. The instrument is attempting to repeat the level sense test.	If problem recurs frequently, contact BD.
W29 (54)	Attempt to process calibrator rack	The instrument detected a calibrator rack on the Processing Chute when normal rack processing was requested.	Use correct rack type for the activity.
W30 (55)	Attempt to calibrate with regular rack	The instrument detected a normal sample rack on the Processing Chute when a Daily nephelometer check was requested.	To perform the nephelometer check, follow the procedure in Section 6.3.1. Take the sample rack to the BD Phoenix AP Inoculation Station and program the RFID tag as a calibrator rack.

Error Number	Description	Possible Cause(s)	Corrective Action(s)
W31 (56)	Incorrect tube placement for Emerge processing	ID/AST broth tubes were loaded in the Sample rack incorrectly.	Set up tubes as explained in Section 4.6.2.
E01 (76)	Power loss during a run	Instrument power was cycled when a run was in progress.	Verify the position of the pipettor and Dispense arm. If either is not in the correct position, move it to the correct position (see Figure 4-10). Remove racks from the Input Queues, Processing Chute, and Output Queues. Tubes in any racks in progress are set to ! (error) status. Tubes in error status must be re-run.
E02 (39)	ID Sample Tube initial fill volume too low	The volume of ID broth or the inoculum broth in the ID tube is too low. The instrument cannot process the tube. Sensor malfunction.	Prepare a new ID or inoculum broth tube. Be sure to express the swab against the side of the tube to remove excess fluid. If problem persists or recurs, contact BD.
E03* (33)	Rack still detected in Processing Chute	Processing chute indexing belt is jammed. Foreign object is impeding motion of the belt. Sensor malfunction.	Check rack positions. Remove the Input Queue cover. Check the belt for obstructions, foreign objects, or Sample rack that is impeding motion. Clear any obstructions. Reposition Sample racks in the Input Queue. Replace the Input Queue cover. If problem persists or recurs, contact BD.
E04* (38)	No Sample rack detected at eject point	Processing chute indexing belt is jammed. Foreign object is impeding motion of the belt. Sensor malfunction.	Check the belt for obstructions, foreign objects, or Sample rack that is impeding motion. Reboot the instrument.

Error Number	Description	Possible Cause(s)	Corrective Action(s)
E05* (34)	Rack still detected in chute after ejection	Ejector malfunction. Foreign object is impeding motion of the Output Queue belt. Sensor malfunction.	Check the Ejector and Output Queue belt for obstructions, foreign objects, or Sample rack that is impeding motion. Verify that the Output Queue belt is able to move (use Move Rack/Belt function [Section 6.3.5]). Manually remove any Sample rack that may be stuck at the head of the Output Queue. If problem persists or recurs, contact BD.
E06 (40)	ID Sample Tube initial fill volume too high	The volume of ID broth in the ID/Inoculum tube is too high. The instrument cannot process the tube. Sensor malfunction or alignment problem.	Prepare a new ID/Inoculum broth tube. If problem persists or recurs, contact BD.
E07 (42)	AST Sample Tube initial fill volume out of spec	The volume of broth in the AST tube is incorrect. The instrument cannot process the tube. Sensor malfunction.	Replace the AST tube. If problem persists or recurs, contact BD.
E08 (46)	ID Sample above target turbidity after dilution	The instrument attempted 3 times to achieve the target density and failed. There may be clumps of organism that are not uniform.	Re-vortex the sample and run it again. If problem recurs, prepare a new ID/Inoculum broth tube. If problem persists, contact BD.

Error Number	Description	Possible Cause(s)	Corrective Action(s)
E09 (47)	ID Sample is below target turbidity after dilution	<p>The instrument attempted to achieve the target density and failed.</p> <p>There may be clumps of organism that are not uniform.</p> <p>Fallback option is disabled.</p>	<p>If target density was 0.50 McFarland, enable Fallback option of 0.50 → 0.25 (Section 2.4.2) and rerun ID broth tube, or add colonies to the ID/Inoculum broth tube and rerun, or prepare a new ID/Inoculum broth tube.</p> <p>A setting of 0.25 McFarland is not appropriate for Gram positive rods. The AST tube must be replaced.</p> <p>If the problem recurs, calibrate the Dispense Pump (Section 6.3.7); perform Pipettor Verification (Section 6.3.6), and calibrate the Nephelometer (Section 6.3.8).</p> <p>If the problem persists, contact BD.</p>
E10 (41)	After a dispense/aspirate cycle, level in ID/Inoculum broth tube is too high.	Possible problem with Dispense Pump or Pipettor.	<p>Physically examine the fill volume of the ID/Inoculum broth tube. If the fluid level is near the top, contact BD.</p> <p>Check the Nephelometer for a possible spill. If there is any fluid in the well, contact BD.</p>
E11 (89)	Drawer forcefully opened.	<p>The drawer was opened by the user without releasing the door lock.</p> <p>Drawer lock malfunction.</p>	<p>Close the drawer.</p> <p>Reboot the instrument.</p> <p>Do not attempt to physically open the drawer during instrument startup or operation without first pausing the run and/or using the Drawer Lock/Unlock function in the Maintenance menu.</p> <p>If problem persists or recurs, contact BD.</p>

Error Number	Description	Possible Cause(s)	Corrective Action(s)
E12* (16)	Drawer opened during operation	The drawer was opened during instrument operation. Drawer lock malfunction.	<p>Close the drawer.</p> <p>Do not attempt to open the drawer during operation.</p> <p>To address a situation or condition within the instrument while it is in operation, tap the “pause” button to stop the current operation, and then tap the “lock/unlock drawer” button on the Maintenance menu to release the drawer lock.</p> <p>If you did not attempt to open the drawer without first pausing the run and unlocking it, contact BD.</p> <p>If problem persists or recurs, contact BD.</p>
E13* (20)	Ejector does not fully retract at startup	Ejector malfunction. Foreign object is impeding motion of the Ejector. Sensor malfunction.	<p>Remove the Output Queue cover.</p> <p>Check the Ejector for obstructions, foreign objects, or Sample rack that is impeding motion.</p> <p>Manually remove any Sample rack that may be stuck at the head of the Output Queue.</p> <p>Reboot the instrument.</p> <p>If problem persists or recurs, contact BD.</p>
E14* (21)	Ejector does not fully retract during operation	Ejector malfunction. Foreign object is impeding motion of the Ejector. Sensor malfunction.	<p>Remove the Output Queue cover.</p> <p>Check the Ejector for obstructions, foreign objects, or Sample rack that is impeding motion.</p> <p>Manually remove any Sample rack that may be stuck at the head of the Output Queue.</p> <p>Reboot the instrument.</p> <p>If problem persists or recurs, contact BD.</p>

Error Number	Description	Possible Cause(s)	Corrective Action(s)
E15* (22)	Output Queue belt did not move when commanded	Output belt is jammed or slipping. Foreign object is impeding motion of the belt. Sensor malfunction. Motor malfunction.	Remove the Output Queue cover. Check the Output Queue belt for obstructions, foreign objects, or Sample rack that is impeding motion. Clear any obstructions. Replace the Output Queue cover. If problem recurs, reboot instrument. If problem persists, contact BD.
E16* (23)	Input Queue belt did not move when commanded during operation	Input belt is jammed or slipping. Foreign object is impeding motion of the belt. Sensor malfunction. Motor malfunction.	Remove the Input Queue cover. Check the Input Queue belt for obstructions, foreign objects, or Sample rack that is impeding motion. Clear any obstructions. Replace the Input Queue cover. If problem recurs, reboot instrument. If problem persists, contact BD.
E17* (24)	Processing chute index belt doesn't index as expected at startup	Index belt is jammed. Foreign object is impeding motion of the belt. Sensor malfunction.	Check the Input Queue belt for obstructions, foreign objects, or Sample rack that is impeding motion. Clear any obstructions. If problem recurs, reboot instrument. If problem persists, contact BD.
E18* (25)	Processing chute index belt doesn't index as expected during operation	Index belt is jammed. Foreign object is impeding motion of the belt. Sensor malfunction.	Check the Input Queue belt for obstructions, foreign objects, or Sample rack that is impeding motion. Clear any obstructions. If problem recurs, reboot instrument. If problem persists, contact BD.
E19* (26)	Pipettor step loss at startup	The pipettor robot arm came into contact with something unexpectedly and couldn't move. Instrument out of alignment.	Examine the pipettor robot arm for any obstructions in its path. Reboot instrument. If problem persists or recurs, contact BD.

Error Number	Description	Possible Cause(s)	Corrective Action(s)
E20* (27)	Pipettor step loss during operation	The pipettor robot arm came into contact with something unexpectedly and couldn't move. Instrument out of alignment.	Examine the pipettor robot arm for any obstructions in its path. Reboot instrument. If problem persists or recurs, contact BD.
E21* (28)	Dispense robot arm step loss at startup	Dispenser robot arm came into contact with something unexpectedly and couldn't move. Instrument out of alignment.	Examine the dispenser robot arm for any obstructions in its path. If problem persists or recurs, contact BD.
E22* (29)	Dispense robot arm step loss during operation	Dispenser robot arm came into contact with something unexpectedly and couldn't move.	Examine the dispenser robot arm for any obstructions in its path. If problem persists or recurs, contact BD.
E23* (30)	Dispense Pump step loss at startup	Possible debris in Dispense Pump.	Open Dispense Pump, check for/clear debris or other obstructions. If problem persists, call BD.
E24* (31)	Dispense Pump step loss during operation	Possible debris in Dispense Pump.	Open Dispense Pump, check for/clear debris or other obstructions. If problem persists, call BD.
E25* (36)	RFID write failure	Bad RFID module in rack or in instrument.	Try using a different rack. If problem recurs, the instrument RFID module is likely defective. Contact BD. If problem does not recur, the Sample rack is likely defective. Discontinue using that Sample rack and contact BD for a replacement rack.
E26* (37)	RFID read failure	Bad RFID module in rack or in instrument.	Try using a different rack. If problem recurs, the instrument RFID module is likely defective. Contact BD. If problem does not recur, the Sample rack is likely defective. Discontinue using that Sample rack and contact BD for a replacement rack.

Error Number	Description	Possible Cause(s)	Corrective Action(s)
E27* (17)	ID/Inoculum broth tube is stuck in the Nephelometer	A sensor detects a tube stuck in the Nephelometer.	Leave power on. Do not attempt to move or remove the Sample rack or the stuck tube. Contact BD for service.
E28* (18)	Pipette tip was dropped	The instrument has detected that the pipettor dropped a pipette tip. Any sample prep in progress is aborted.	Open drawer and locate the dropped tip. Dispose of the tip in the waste tip chute. If problem recurs, contact BD.
E29* (19)	Pipette tip failed to eject	The instrument has detected that it was unable to eject a pipette tip from the pipettor. The tip may be defective. Pipettor may need adjustment.	Open drawer and pull off the tip. Dispose of the tip in the waste tip chute. If problem recurs, contact BD.
E30 (44) E31 (45)	Nephelometer problem	There is a problem with the nephelometer.	The current tube goes into an error state (! status). Rerun the tube set. If problem recurs, contact BD.
E32 (77)	Nephelometer fails Daily Check	There is a problem with calibrator tube. There is a problem with nephelometer.	Any runs are disabled until the problem is corrected. Calibrate the nephelometer (Section 6.3.8). Run the Daily Check (Section 6.3.1) with the same tubes used for the nephelometer calibration. Clean the calibration tubes with isopropyl alcohol wipes. Make sure the calibration tube set has not expired. Make sure the calibration tubes are set up in the proper order for both the calibration and the daily check.

Error Number	Description	Possible Cause(s)	Corrective Action(s)
E33 (78)	Nephelometer fails calibration	There is a problem with calibrator tube. There is a problem with nephelometer.	Check/clean the calibration tubes with isopropyl alcohol wipes. Make sure the calibration tube set has not expired. Make sure the calibration tubes are set up in the proper order for both the calibration and the daily check. Calibrate the nephelometer (Section 6.3.8). If you have used new calibration tubes for the calibration or for the daily check, rerun the operation with the prior calibrator tube set. If you are using old calibrator tubes, rerun the operation with a new calibrator tube set. Run the Daily Check (Section 6.3.1) with the same tubes used for the nephelometer calibration. If problem recurs, contact BD.
E34 (79)	Dispense Tubing set calibration out of range	Dispense pump calibration failed. This could be due to a problem with the tubing, the Dispense pump, or another component.	Verify that the tubing set is installed correctly (Section 6.4). Verify that the Dispense pump is closed, that the blue clamp has been opened, that the ID broth solution is not empty, etc. Rerun the Dispense Pump calibration operation (Section 6.3.7). Replace the Dispense tubing set. If problem persists, contact BD.
E35* (2) E36* (32) E37* (5) E38* (6) E39* (12)	Electronics/software error	Various causes.	Reboot the instrument. Save the log file (Section 6.3.3). Contact BD.
E40* (7) E41* (8)	A problem with the flash media occurred	Defective flash media. Flash media removed during read/write operation.	Repeat the operation with new flash media. Do not remove the flash media during any read/write operations. The progress bar on the screen indicates when read/write operations are occurring.

Error Number	Description	Possible Cause(s)	Corrective Action(s)
E42 (85)	A problem occurred during a software update	Defective flash media. Flash media removed during read/write operation.	Reboot the instrument. Save the log file (Section 6.3.3). Contact BD.
E43 (80)	Electronics/software error	Various causes.	Reboot the instrument. Save the log file (Section 6.3.3). Contact BD.
E45* (13)	Bad reading from nephelometer	There is a problem with the sample. There is a problem with the nephelometer.	The current tube is skipped. Processing of other tubes continues. Redo the current ID tube. If problem recurs, contact BD.
E46* (14)	Nephelometer error	There is a problem with the sample. There is a problem with the nephelometer.	The current tube is skipped. Processing of other tubes continues. Redo the current ID tube. If problem recurs, contact BD.
E47* (15)	Ambient light leak	Instrument panel is not in place. Instrument location is too bright.	Do not place instrument in direct sunlight, or in excessively bright light sources. If problem recurs, contact BD.
E48 (88)	Calibration problem	There is a problem with calibrator tube(s). There is a problem with the nephelometer.	Check/clean the bottom of the calibration tubes with isopropyl alcohol wipes. Make sure the calibration tube set has not expired. Make sure the calibration tubes are set up in the proper order for both the calibration and the daily check. Calibrate the nephelometer (Section 6.3.8). If you have used new calibration tubes for the calibration or for the daily check, rerun the operation with the prior calibrator tube set. If you are using old calibrator tubes, rerun the operation with a new calibrator tube set. Run the Daily Check (Section 6.3.1) with the same tubes used for the nephelometer calibration. If problem recurs, contact BD.

Error Number	Description	Possible Cause(s)	Corrective Action(s)
E49* (3) E51* (4)	Electronics/software error	Various causes.	Reboot the instrument. Save the log file (Section 6.3.3). Contact BD.
E52 (90)	ID fill mode: tube not empty	During a dispense pump calibration, the instrument detected liquid in an ID tube that should have been empty.	Repeat the calibration. Make sure the ID broth tubes are empty.
E53* (35)	Pipettor pump step loss	Possible problem with the pipettor pump.	If error recurs, contact BD.
E54* (9) E55* (10) E56* (11)	Electronics/software error	Various causes.	Reboot the instrument. Save the log file (Section 6.3.3). Contact BD.
E57 (43)	ID Sample Tube final volume out of spec	The final volume of ID broth in the ID broth tube is incorrect.	Prepare a new ID broth tube. Perform Pipettor Verification (Section 6.3.6). Calibrate the Dispense Pump (Section 6.3.7). If problem persists or recurs, contact BD.
E58 (81)	Electronics/software error	Various causes.	Reboot the instrument. Save the log file (Section 6.3.3). Contact BD.
E59* (91)	Instrument misalignment suspected	The instrument initially detected ID tube volumes that were too high for 3 tubes in the same Sample rack. The instrument seems to be out of alignment.	If problem recurs frequently, contact BD.
E60 (53)	RFID tag has obsolete format	The Sample rack RFID tag is not properly formatted.	Try using a different Sample rack. Take the problem rack to the BD Phoenix AP Inoculation Station and reprogram it. If problem recurs, contact BD.
E61(57)	Invalid rack version or type	The Sample rack RFID tag is not properly formatted.	Try using a different Sample rack. Take the problem rack to the BD Phoenix AP Inoculation Station and reprogram it. If problem recurs, contact BD.

Error Number	Description	Possible Cause(s)	Corrective Action(s)
E99 (1)	System error	An unexpected error occurred.	Reboot the instrument. Save the log file (Section 6.3.3). Contact BD.

8 - Performance and Limitations

8.1 Performance

A study was performed to demonstrate the accuracy of the final concentration of ID Broth inoculum prepared by the BD Phoenix AP Instrument. Replicates of quality control strains of various species were prepared at multiple initial inoculum concentrations within the allowable range per manufacture instructions. These preparations were then placed on the BD Phoenix AP and set to produce final concentrations of 0.5 or 0.25 McFarland. The BD Phoenix AP final inoculum was then compared to the average BD PhoenixSpec reading. Statistical analysis was performed to calculate the mean, standard deviation, and coefficient of variation across all samples for each final inoculum concentration. The standard deviation and coefficient of variation show that the BD Phoenix AP met expected performance criteria.

		Average BD PhoenixSpec Reading of BD Phoenix AP Prepared Inoculum			
AP Setting	AP McFarland Target	N	AVG	S.D.	%CV
0.25	0.20–0.30	135	0.28	0.02	5.5
0.50	0.50–0.60	135	0.58	0.03	4.9

8.2 Limitations

A Gram stain test is required for the selection of the appropriate BD Phoenix panel types. Accurate identification and/or AST results may not be made without this test.

Use only well-isolated bacterial colonies from one of the recommended primary isolation media. Use of mixed colonies could result in inaccurate identification and/or AST interpretations.

The BD Phoenix AP instrument should not be used for preparation of tubes for inoculation of BD Phoenix Strep panels (SMIC or SMIC-ID) or Yeast ID panels.

9 - Limited Warranty

This warranty gives you specific legal rights. Additionally, you may have other rights that vary from region to region.

The BD Phoenix AP instrument 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 such as printer cartridges, paper, or filters) 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 Phoenix™ AP Instrument User's Manual*.

Any damage to a BD Phoenix AP 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.

10 - International Contacts

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11 - Software Update Log

Whenever you receive a software update, please take a moment to log it below. This can assist you and BD personnel in identifying software revision levels, potential software problems, etc.

Date Received	Software Version	Date Installed	Installed By	Notes

12 - Replacement Parts

Catalog Number	Item
246001	BD Phoenix™ ID Broth
246003	BD Phoenix™ AST Broth, 8 mL
246005	BD Phoenix™ Inoculum Broth
246006	BD Phoenix™ AP AST Indicator
246011	BD Phoenix™ AST Broth, 4.5 mL
440911	BD PhoenixSpec™ Calibrator Kit
441355	BD PhoenixSpec™ 0.25 Calibrator
441356	BD PhoenixSpec™ 0.5 Calibrator
441402	Barcode Printer
441506	Upgraded Barcode Reader
443459	Login Station AP
448012	BD Phoenix™ AP ID Solution
448013	BD Phoenix™ AP Tip Waste Bin
448014	BD Phoenix™ AP Waste Liquid Bottle
448015	BD Phoenix™ AP Pump Tubing
448017	BD Phoenix™ AP Inoculation Station
448019	BD Phoenix™ AP Rack
448027	BD Phoenix Bench-Top Anchoring Kit
448029	BD Phoenix Floor Anchoring Kit
448032	BD Phoenix™ AP Quick Reference Guide
448033	BD Phoenix™ AP User's Manual
448034	BD Phoenix™ AP Software Update
448038	BD Phoenix™ AP Pipette Tips

13 - Glossary

Term	Definition
ambient temperature	temperature of the room where the instrument is placed
AST	Antimicrobial Susceptibility Testing
barcode	Machine-readable marking as part of the panel label which uniquely identifies that panel.
ID	Microbial Identification
inoculation station	The BD Phoenix AP inoculation station holds five BD Phoenix panels at the appropriate angle for optimal fill. The station also holds 10 broth tubes total, two per organism tested. One tube is for Identification, the other for AST.
inoculum density	Setting for desired McFarland turbidity of ID/Inoculum Broth. The instrument can be set for 0.25 McFarland, 0.50 McFarland, or for a Fallback setting of 0.50 → 0.25 McFarland. If the instrument cannot achieve 0.50 McFarland, it dilutes the sample to 0.25 McFarland when the Fallback setting is selected.
input queue	Belt on the left side of the instrument where Sample racks are loaded for processing
output queue	Belt on the right side of the instrument where Sample racks are ejected after processing
BD Phoenix AST indicator	An oxidation-reduction indicator used to signify microbial metabolism in the BD Phoenix panels. The indicator changes from blue to pink as initial reduction occurs. Further reduction causes the indicator to change from pink to colorless.
processing chute	Area at the rear of the instrument between the Input and Output queues. This is where ID and AST tubes are prepared and measured.
reboot	To restart; to cycle power off and on.
RFID	Radio Frequency IDentification. A small chip located in the rack that stores information about the tubes processed and the instrument state. The following is stored: initial turbidity values, final turbidity values, Nephelometer verification results, Nephelometer calibration results, Pipettor verification, Dispense calibration results Instrument number, Rack Processed flag, a unique tag identifier.
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."

