BD FACSPresto™ Near-Patient CD4 Counter

REF 651000

Instructions For Use

IVD CE

23-12808-02
11/2014

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Regulatory information

For In Vitro Diagnostic Use.

FCC information

WARNING: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTICE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his or her own expense. Shielded cables must be used with this unit to ensure compliance with the Class A FCC limits. This Class A digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations. Cet appareil numérique de la classe A respecte toutes les exigences du Réglement sur le matériel brouilleur du Canada.

History

Revision	Date	Change made
23-12808-00	3/2014	Initial release
23-12808-01	4/2014	Updated cover to add catalog number.
23-12808-02	11/2014	Updated accessories list and solar panel details.

Contents

1

Introduction

This chapter covers the following topics:

Product documentation

Introduction

This topic describes the available documentation for the BD FACSPresto™ Near-Patient CD4 Counter (the instrument) and other system components. All users should read this information.

Documents

- **BD FACSPresto Near-Patient CD4 Counter Instructions For Use (IFU).** This guide describes how to use the instrument with the other system components. It includes directions on how to set up the system, run process controls and samples, and manage results and reports.
- **BD FACSPresto Near-Patient CD4 Counter Safety and Limitations Guide.** This guide provides descriptions of safety and warning labels, general system hazards, specific risks, and electrical and biological hazards.
- **BD FACSPresto Near-Patient CD4 Counter Quick Reference Guide.** This guide gives a quick workflow for using the system.
- **BD FACSPresto Cartridge Instructions For Use (IFU).** This guide includes technical information about the BD FACSPresto™ cartridge, the CD4/%CD4/Hb cartridge.

More information

- Technical assistance (page 7)
- Instrument specifications (page 87)

Technical assistance

Introduction

This topic describes how to get technical assistance.

Contacting technical support

If assistance is required, contact your local BD Biosciences technical support representative or supplier. Visit our website, bdbiosciences.com, for up-to-date contact information.

When contacting BD Biosciences, have the following information available:

- Product name and serial number
- Any error messages
- Details of recent system performance

More information

- Instrument reference (page 75)
- Troubleshooting (page 76)

Safety symbols used in this guide

Introduction

This topic describes the safety symbols used in this guide.

Safety symbols

The following safety symbols are used in this guide to alert you to potential hazards.

Symbol[a]	Meaning
	Caution. Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Biological hazard
	Electrical hazard
	Mechanical hazard, pinch points

a. Although these symbols appear in color on the instrument, they might be printed in black and white; their meaning remains unchanged.

More information

- See the *BD FACSPresto Near-Patient CD4 Counter Safety and Limitations Guide* for safety information and symbol definitions for the system.

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System overview

This chapter covers the following topics:

About the system

Introduction

This topic describes how the BD FACSPresto system works.

Intended use

The BD FACSPresto Near-Patient CD4 Counter is an automated system for in vitro diagnostic use in performing the direct enumeration of CD4 absolute count, CD4 percentage of lymphocytes, and hemoglobin concentration in human whole blood.

System overview

The BD FACSPresto system consists of the following:

- BD FACSPresto instrument package containing:
  - Portable instrument
  - Power supply
  - Adapter cords
  - Instrument cover
  - Work station
  - Thermal printer paper
  - USB flash drive
- BD FACSPresto Cartridge package containing:
  - BD FACSPresto Cartridges
  - BD™ Disposable 100 µL Pipets

Optional accessories include:

- BD FACSPresto Cartridge Kit containing:
  - BD FACSPresto Cartridge package
  - BD FACSPresto Finger Stick Sample Collection Kit containing:
    - BD Microtainer® Contact-Activated Lancets
    - Tempo Sterile Alcohol Pads
    - Nonwoven Sponges

    - Sheer Plastic Bandages, Sterile, Hypoallergenic, Non-latex
- BD FACSPresto Instrument Carrying Case
- BD FACSPresto Solar Charge Kit (includes solar panel, solar generator, and power supply)
- BD FACSPresto Solar Generator (includes solar generator and power supply)
- BD FACSPresto Car Battery Charge Adapter
- BD FACSPresto™ Thermal Printer Paper

Contact BD Biosciences for ordering information.

Hardware

The instrument is based on fluorescence photomicroscopy and light absorbance detection on a multicolor platform. Light emitting diodes (LEDs) shine on, or through, a sample, and the resulting signal is captured through a microscope lens and emission filter, or a spectrometry system, onto a digital camera chip.

Reagents

Each test uses one cartridge. The cartridge contains dried reagents. Human whole blood from either a capillary or venipuncture specimen is added into an inlet port on the cartridge. Three assays are performed within the same cartridge to give CD4 absolute count, percentage of $CD4^+$ T cells among the lymphocytes (%CD4), and total hemoglobin (Hb) concentration.

Software

The software is integrated into the instrument. Use the touchscreen to operate the instrument. The software algorithms perform automatic calculation of the absolute CD4 count, %CD4, and Hb concentration. The results display on the screen, print, and can be exported.

More information

- System components (page 12)
- Power requirements (page 89)
- Software overview (page 19)

- BD FACSPresto Cartridge IFU

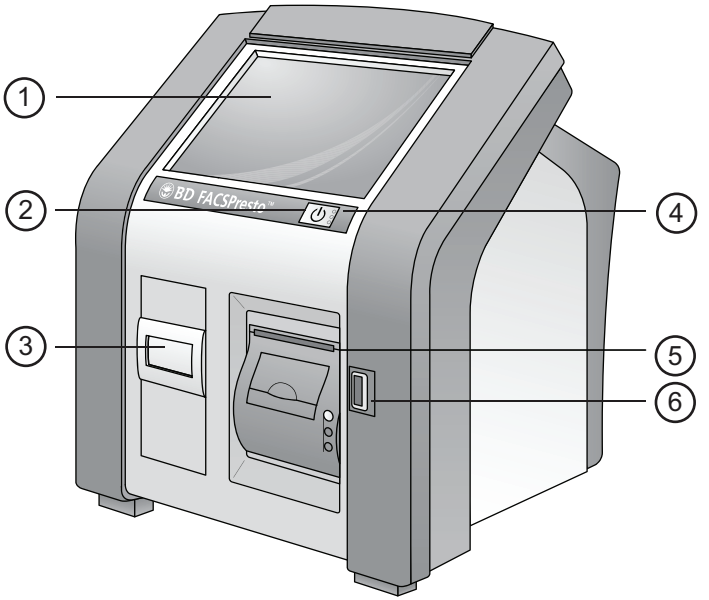
System components

Introduction

This topic describes the BD FACSPresto system components. Before operating the system, you should familiarize yourself with the names, locations, and functions of the various system components.

Instrument front view

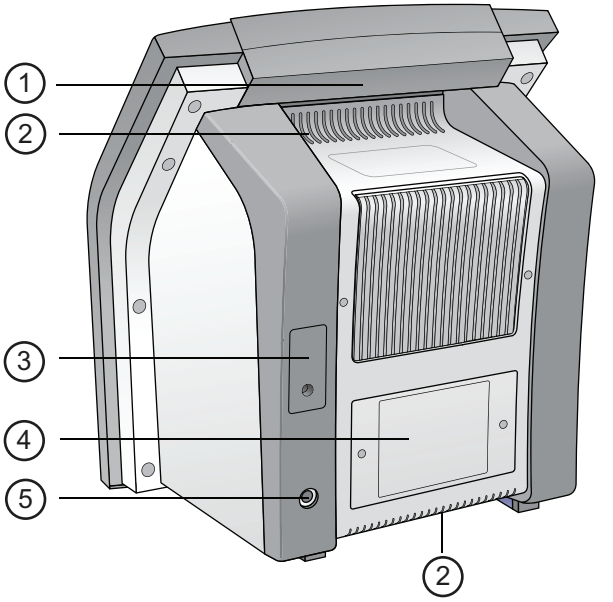
User interface components are located on the front of the instrument.



No.	Component	Description
1	Touchscreen	Display for operating the instrument.
2	Power button	Button used to turn the instrument on or off.
3	Cartridge door	Door that automatically opens when you need to insert or remove the cartridge. Do not manually open the cartridge door.
4	Standby LEDs	Lights that: • Are on if the instrument is on. • Are off if the instrument is off. • Blink if the instrument is running on battery power only and not in use for 21 minutes or more.
5	Printer	Prints QC and test results.
6	USB port	Port for exporting patient results and upgrading the software.

Instrument rear view

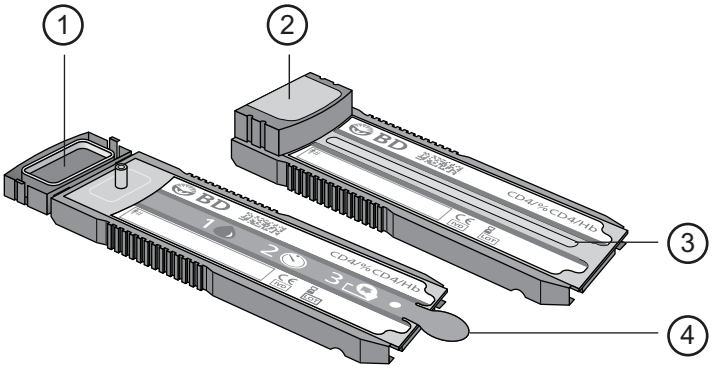
Power, service, and identification components are located on the rear of the instrument.



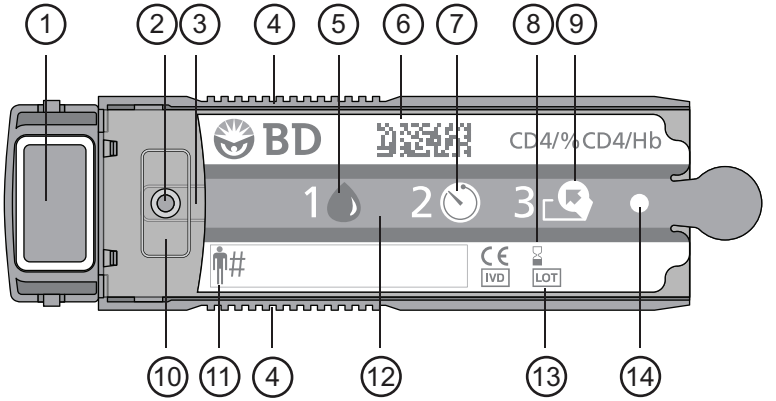
No.	Component	Description
1	Lift handle	Handle used to move the instrument.
2	Air vent	Enables air flow into and out of the instrument.
3	Service port	Used by BD personnel only to service the instrument.
4	Asset tag plate	Removable plate for instrument identification.
5	Power port	Port for connecting the adapter cord to the instrument.

BD FACSPresto cartridge

The BD FACSPresto cartridge, the CD4/%CD4/Hb cartridge, is a unit-dose disposable device that contains all the reagents that are needed to test one sample or specimen. Use one cartridge per specimen. Use only BD FACSPresto cartridges with the instrument.



No.	Component	Description
1	Cap (open)	Enables blood addition.
2	Cap (closed)	Protects blood in the cartridge.
3	Channel	Shows blood in the cartridge.
4	Channel protector	Protects blood in the cartridge from light.

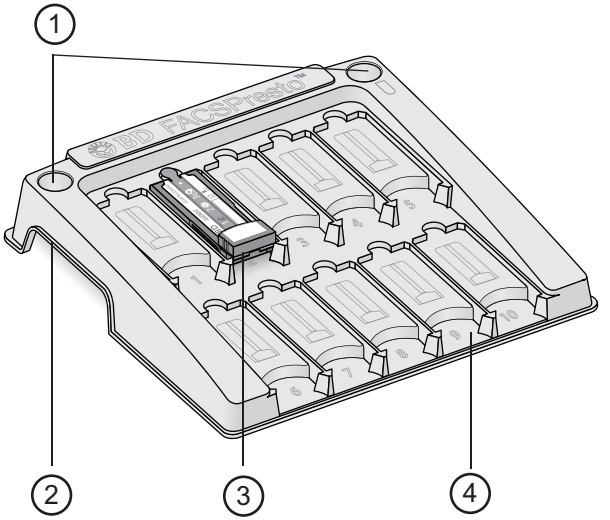


No.	Component	Description
1	Cap	Covers the inlet port and acts as a biohazard-containment mechanism.
2	Inlet port	Receives blood or process control into the cartridge using the pipet or finger stick method.
3	Channel	Allows you to view the blood or process control in the cartridge before closing the cap.
4	Ridges	Place to hold the cartridge.
5	Add blood	Indicates the step to put blood into the cartridge.
6	Barcode	Scanned by the instrument to identify each cartridge.
7	Incubate	Indicates the step to incubate the sample in the cartridge.
8	Expiration date	Date by which the cartridge must be used.
9	Remove channel protector	Indicates the step to remove the channel protector before inserting the cartridge into the instrument.

No.	Component	Description
10	Containment zone	Catches blood or process control that overflows from the inlet port.
11	Patient number	Indicates the space to write the patient ID or process control information before putting blood or process control into the cartridge. Do not write on any other part of the cartridge.
12	Channel protector	Protects the sample in the cartridge from light and dirt during incubation. The channel protector must be removed before inserting the cartridge into the instrument.
13	Lot number	Identifies the cartridge's lot number. There are multiple cartridges per lot.
14	Fill indicator	Indicates the sample in the cartridge. The fill indicator should be full of blood or process control.

BD FACSPresto work station

The BD FACSPresto work station can hold up to 10 cartridges during incubation. The slots are numbered. Place the cartridge in the slot as shown in the following figure. You can monitor the incubation times using the on-board timer.



No.	Component	Description
1	Tube or pen holders	Hold tubes or pens.
2	Handle	Handle used to hold and carry the work station.
3	Cartridge	BD FACSPresto cartridge.
4	Cartridge slot	Slot used to hold a cartridge.

More information

- About the system (page 10)
- Setting the on-board timer (page 34)

Software overview

Introduction

This topic describes the software for the BD FACSPresto instrument and how to use it.

About the touchscreen

Press the tabs and buttons on the touchscreen to use the software. Avoid using sharp objects on the screen because they can damage the screen.

Welcome screen and navigation tabs

After you turn the instrument on, the welcome screen opens. Press a navigation tab to adjust settings, perform tasks, and get help on using the instrument.

No.	Tab name or Icon	Description
1	On-board Timer	Use to set a timer for each cartridge's incubation period.
2	Run Test	Use to run samples.
3	Results	Use to view test results. You can search, print, and export test results.
4	Quality Control (QC)	Use to run instrument QC and process controls.

No.	Tab name or Icon	Description
5	Settings	Use to set the date, time, display brightness, volume, Hb units, lab name, operator names, and process control information.
6	Help	Use to view instructional videos.
7	Battery charge indicator	Icon that shows the remaining battery power.
8	Time and date	Shows the time and date as specified in the Settings tab.

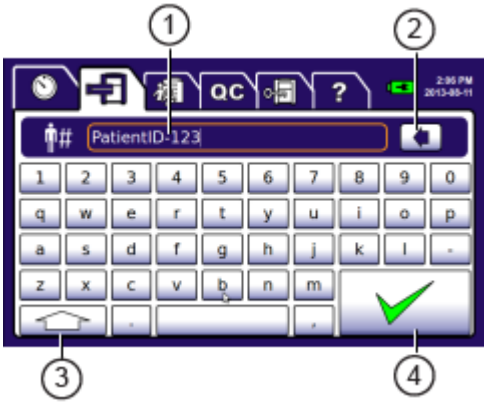
Battery charge indicator

The following table describes the battery charge indicator on the upper right of the screen. The fill and color of the indicator show the remaining battery power.

Icon	Description
	The fill is completely green when the battery is fully charged. On a fully charged battery, the instrument can run for up to 6 hours without being plugged into an electric source.
	The fill is green when there is more than 25% battery power remaining.
	The fill is yellow when there is less than 25% battery power remaining.
	The fill is red when there is not enough power to complete a sample run.
	The fill is green and a plug icon indicates that the battery is charging when the instrument is connected to an AC power source.

Keyboard

A keyboard opens when your input is needed. An example of the keyboard used for entering the patient ID is shown in the following figure.



No.	Button
1	Patient ID
2	Backspace
3	Caps Lock
4	Accept

Navigation buttons

The following table describes the basic buttons in the software.

Button	Description
	Increases the setting in a field (for example, setting the date).
	Decreases the setting in a field (for example, setting the time).
	Returns to the previous screen.
	Cancels the selected action.

More information

- Settings tab (page 30)

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Instrument setup

This chapter covers the following topics:

Instrument setup, startup, and shutdown

Introduction

This topic describes how to set up, start up, and shut down the instrument.

Instrument setup

The instrument must be operated in a facility protected from environmental elements such as rain, dust, etc.

To set up the instrument:

1. Remove the instrument from the box.
2. Remove the instrument from the plastic bag.

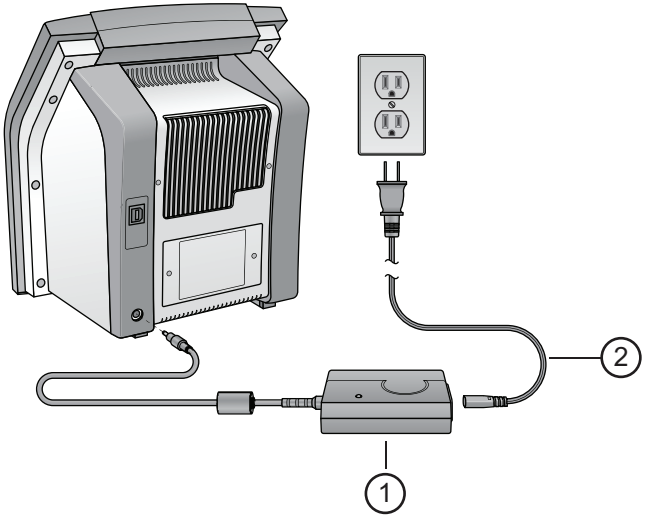
   Keep the instrument packaging. Use the packaging to pack the instrument in case you need to return it to BD Biosciences for service.
3. Place the instrument on a level surface, a minimum of 1.27 cm (0.5 in.) away from the wall.
4. Remove the tape from the cartridge door.
5. Plug the power supply into the instrument.
6. Plug the adapter cord for your country into the power supply.
7. Plug the adapter cord into a wall electrical outlet, car battery charge adapter, solar generator, or other electric source, as shown in the following sections.

   Note: Use only the adapter cords, power supply, car battery charge adapter, solar charge kit, or solar generator provided by BD Biosciences.

   Note: Before running the instrument on battery power only, fully charge the battery. Plug the instrument into a wall electrical outlet, or fully charged car battery charge adapter or solar generator, for 6 hours.

Power connection using a wall electrical outlet

The following figure shows the power connection using a wall electrical outlet.



No.	Component
1	Power supply
2	Adapter cord

Power connection using a car battery charge adapter

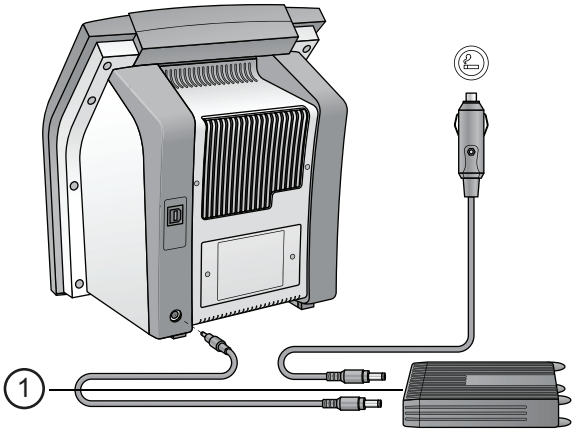
To connect power to the instrument using a car battery charge adapter:

1. Plug the car battery charge adapter directly into the car's cigarette lighter receptacle.

   Do not plug any adapters or splitters into the cigarette lighter receptacle.

2. Make sure the LED light on the car battery charge adapter lights up. You might need to turn the car's ignition switch to the On position or turn the engine on.

3. Plug the car charge battery adapter into the instrument.



No.	Component
1	LED light

Do not use the instrument in a car with a running engine.

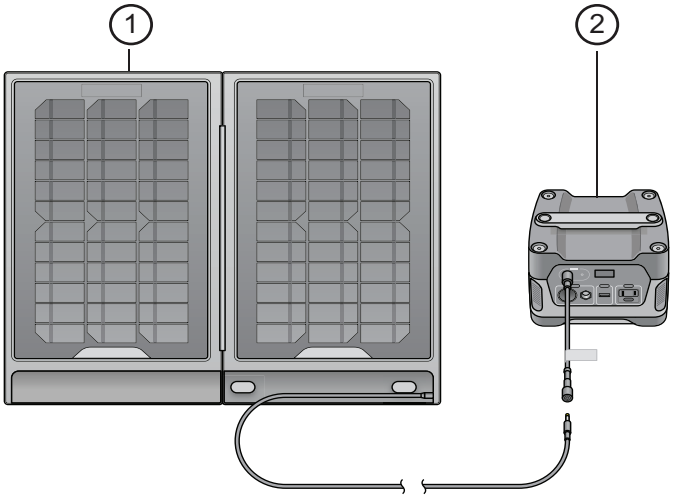
Note: You can also use the car charge battery adapter to charge the solar generator.

Power connection using a solar charge kit

To connect power to the instrument using a solar charge kit:

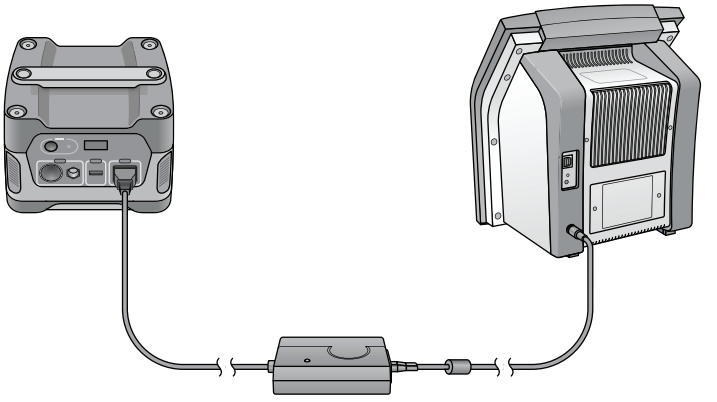
1. Connect the solar panel to the solar generator.

The solar panel needs 11–22 hours to fully charge the solar generator, depending on the sun.



No.	Component
1	Solar panel
2	Solar generator

2. Plug the solar generator into the instrument.



When not in use, plug the solar generator into a wall electrical outlet or other electric source. This ensures that the solar generator is charged for the next use.

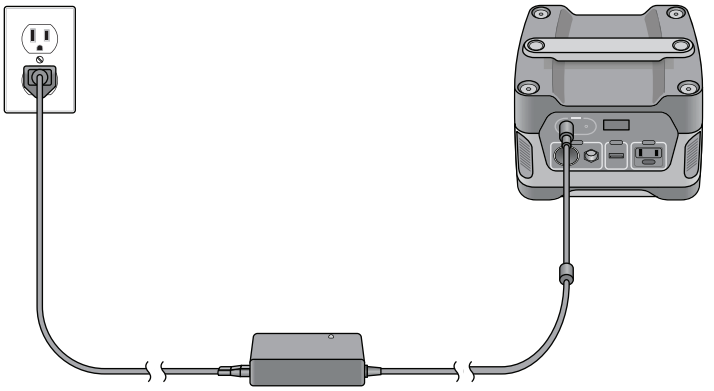
Power connection using a solar generator

The solar generator can be used without the solar panel, as another power supply.

To connect power to the instrument using the solar generator:

1. Plug solar generator into a wall electrical outlet or car charge battery adapter.

   For a full charge of the solar generator, keep it plugged in for 6 hours.



2. Connect the solar generator and instrument.

Instrument startup

Press the power button on the front of the instrument to turn it on.

Instrument shutdown

Turn the instrument off when it is not in use. If the instrument is running on battery power only and not in use for 35 minutes, it automatically shuts down. You should turn the instrument off at least one time per day. Place the instrument cover over the instrument when it is not in use.

To turn the instrument off:

1. Press the power button on the front of the instrument.

   A confirmation screen opens.

2. Press **Accept**.

More information

- Power requirements (page 89)
- Instrument front view (page 12)
- Car battery charge adapter instructions for use
- Solar charge kit and solar generator instructions for use
- Solar generator instructions for use

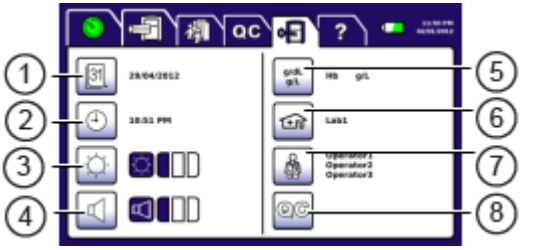
Instrument settings

Introduction

This topic describes how to set up the instrument before you run samples, and how to change the settings later. The first time you start the instrument, specify the date, time, display brightness, volume, Hb units, lab name (optional), operator names (optional), and process control information.

Settings tab

The following figure shows the screen with the Settings tab selected.



No.	Button
1	Date
2	Time
3	Display brightness
4	Volume
5	Hb Units
6	Lab Name
7	Operator
8	Quality Control

Setting the display

To set up the instrument display:

1. Press the **Settings** tab.
2. Press a button to change one of the following settings:
   - Date (year/month/day)
   - Time
   - Display brightness
   - Volume, from high to mute
   - Hb units for the total hemoglobin result. Select grams per deciliter (g/dL) or grams per liter (g/L).
   - (Optional) Lab. Press Backspace to delete the default setting. Enter a lab name from 0–15 characters.
   - (Optional) Operator-1, Operator-2, or Operator-3. Press Backspace to delete the default setting. Enter an operator name from 0–15 characters. If this field is left blank, the setting reverts to the default setting.
   - Quality Control. Opens the Process Control Settings screen. See Entering process control information (page 45).
3. Press **Accept** to accept a setting.

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4

Instrument use

This chapter covers the following topics:

Setting the on-board timer

Introduction

This topic describes how to set the on-board timer.

About incubation

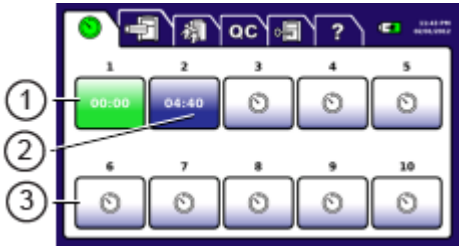
Incubation time is the amount of time you must wait after putting blood or process control into the cartridge, before inserting the cartridge into the instrument. Incubate each cartridge for at least 18 minutes, but no longer than 2 hours.

About the on-board timer

Use the on-board timer while the cartridge is in the BD FACSPresto work station. There are 10 timers, one for each cartridge slot in the work station. Each timer is pre-programmed with the minimum incubation time.

On-board Timer tab

The following figure shows the screen with the On-board Timer tab selected.



No.	Button
1	Incubation complete
2	Remaining incubation time
3	Incubate

Procedure

To set the on-board timer:

1. Press the **On-board Timer** tab.
2. Press the timer that corresponds to the numbered slot containing the cartridge on the BD FACSPresto work station.

   The timer starts at 18 minutes and shows the minutes and seconds remaining until incubation is complete. It turns green when complete.

   If another screen is open when the timer completes, the icon on the On-board Timer tab turns green and the instrument beeps.
3. (Optional) Press a green timer to reset it.

More information

- BD FACSPresto work station (page 17)

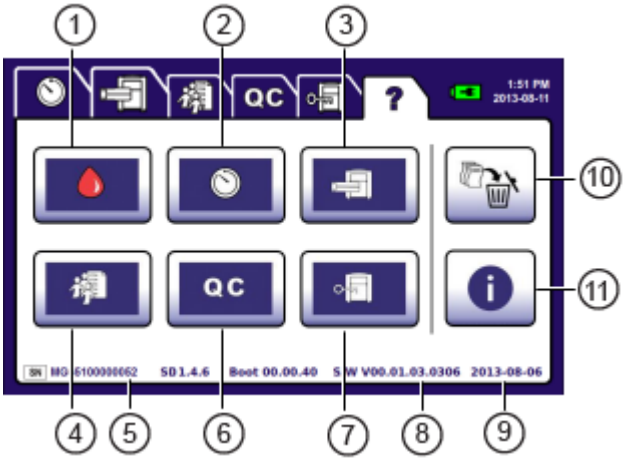
Watching the instructional videos

Introduction

This topic describes how to watch the instructional videos from the Help tab. The videos provide training on workflow tasks.

Help tab

The following figure shows the Help tab's video selection screen.



No.	Component	Description
1	Add Blood	Video on collecting samples.
2	Incubate	Video on setting the on-board timer for a cartridge's incubation period.
3	Run Test	Video on running samples.
4	Results	Video on exporting test results.
5	Serial number	Serial number of the instrument.
6	Quality Control (QC)	Video on running instrument QC and process controls.

No.	Component	Description
7	Settings	Video on setting the date, time, display brightness, volume, Hb unit, lab name, operator names, and process control information.
8	Software version	Software version installed on the instrument.
9	Date	Date of software version.
10	Delete All	Button for deleting all test results.
11	Copyright information	Opens the Copyright information screen for the instrument. Press the Back button to return to the Help tab's video selection screen.

The following figure shows the Help tab after you have selected a video.

No.	Button
1	Stop
2	Rewind
3	Back
4	Play or Pause
5	Fast Forward

Procedure

To watch the instructional videos:

1. Press the **Help** tab.
2. Select a video in the video selection screen.

   The selected video starts playing.
3. Press **Pause**, **Fast Forward**, **Rewind**, **Stop**, or **Play** to control the video.
4. Press **Back** to return to the video selection screen.

More information

- Deleting test results (page 72)

Upgrading the software

Introduction

This topic describes how to upgrade the instrument software.

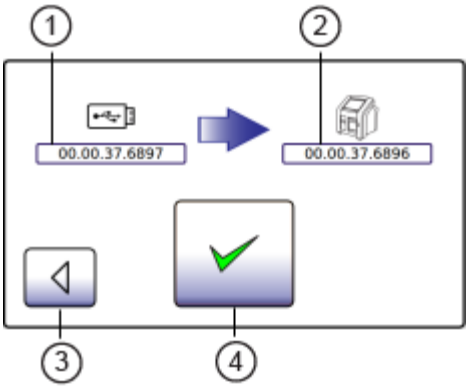
If a software upgrade is available, you are provided with a USB flash drive that contains the new software version.

Procedure

To upgrade the software:

1. Turn off the instrument.
2. Insert the USB flash drive into the USB port on the front of the instrument.
3. Turn on the instrument.

The software upgrade screen opens.

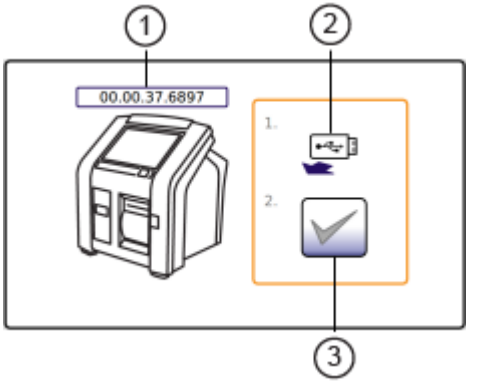


No.	Component
1	Software version on the USB flash drive
2	Current software version on the instrument
3	Back
4	Accept

If you do not want to upgrade the software on the instrument, press Back. The Welcome screen opens and the current software version starts.

4. To upgrade the software to the software version on the USB flash drive, press **Accept**.

The software upgrade proceeds. When the software upgrade completes, the following screen opens.



No.	Component
1	Upgraded software version on instrument
2	Remove the USB flash drive
3	Accept

5. Remove the USB flash drive.
6. Press **Accept**.

   The instrument turns off.

   When you turn on the instrument, the upgraded software version starts.

More information

- Instrument startup (page 28)
- Instrument shutdown (page 29)
- Instrument front view (page 12)
- Welcome screen and navigation tabs (page 19)

5

Quality and process control

This chapter covers the following topics:

Quality and process control overview

Introduction

This topic provides information on running instrument quality control (QC) and process controls.

About instrument QC

Instrument QC is a test to make sure that your instrument is operating properly. It automatically runs, and the results print, every time the instrument turns on.

About process controls

Process controls are liquid control materials that are processed like patient samples to monitor the performance of the system. Self-validated process controls may be run using the instructions in this chapter.

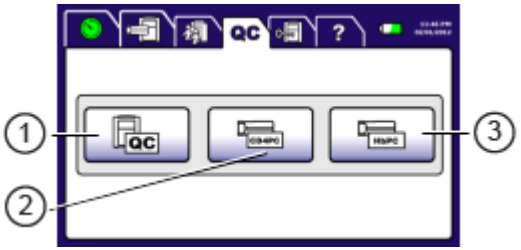
Workflow for process controls

The workflow for running process controls includes these stages.

Stage	Description
1	Entering process control information (page 45)
2	Preparing process controls (page 50)
3	Running process controls (page 53)

QC tab

The following figure shows the screen with the QC tab selected. From the QC tab, you can run instrument QC, and CD4 and Hb process controls.



No.	Button
1	Instrument QC
2	CD4 Process Control
3	Hb Process Control

More information

- To run QC manually, see Running instrument QC (page 44).
- BD FACSPresto Cartridge IFU

Running instrument QC

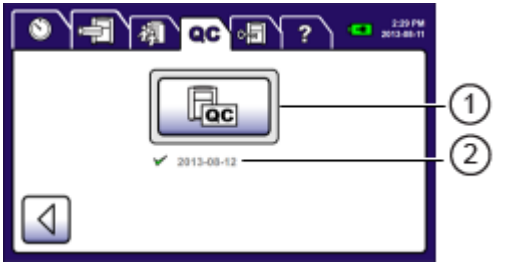
Introduction

This topic describes how to manually run instrument QC.

Procedure

To run instrument QC:

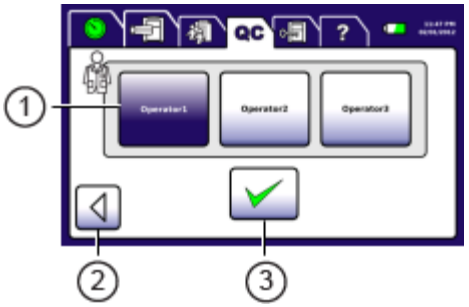
1. Press the **QC** tab.
2. Press **Instrument QC**.



No.	Button or field
1	Instrument QC
2	Date instrument QC was last performed

The Instrument QC Operator screen opens.

3. Select your operator ID and press **Accept**.



No.	Button
1	Operators
2	Back
3	Accept

A progress screen opens. When instrument QC is complete, the instrument beeps 3 times, a results screen opens, and the results automatically print.

4. Press **Accept**.

Entering process control information

Introduction

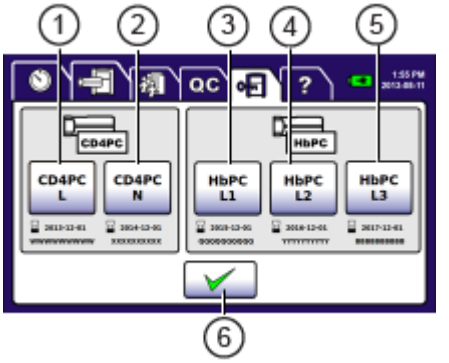
This topic describes how to enter process control information. Enter the following information for each new lot of process controls:

- CD4 low count (includes CD4 percentage)
- CD4 normal count (includes CD4 percentage)
- Hb Level 1 concentration
- Hb Level 2 concentration
- Hb Level 3 concentration

See the documentation that came with your process controls for the lot number, expiration date, and range values.

Process Control Settings screen

The following figure shows the screen with the QC button in the Settings tab selected. From this screen, you can define the process control settings.



No.	Button
1	CD4 Low Count
2	CD4 Normal Count
3	Hb Level 1 Concentration
4	Hb Level 2 Concentration
5	Hb Level 3 Concentration
6	Accept

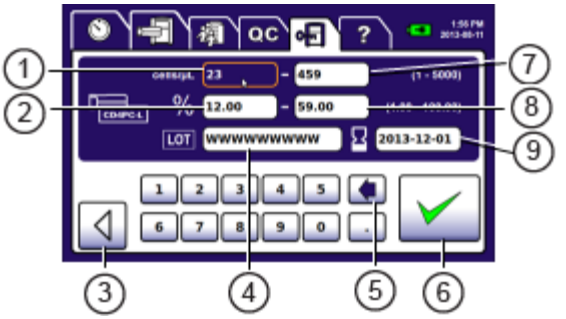
Defining CD4 process control settings

To define the CD4 process control settings:

1. Press the **Settings** tab.
2. Press **QC**.

   The Process Control Settings screen opens.
3. Press **CD4PC L**.

The CD4PC Low Settings screen opens.



No.	Field or Button
1	Lower Limit CD4 Count
2	Lower Limit CD4 Percentage
3	Back
4	Lot Number
5	Backspace
6	Accept
7	Upper Limit CD4 Count
8	Upper Limit CD4 Percentage
9	Expiration Date

4. Press the **Lower Limit CD4 Count** field on the left and enter a value (according to the process control documentation) with up to four digits with no decimal places.
5. Press the **Upper Limit CD4 Count** field on the right and enter a value.
6. Press the **Lower Limit CD4 Percentage** field on the left and enter a value (according to the process control documentation) with up to four digits including two decimal places.

7. Press the **Upper Limit CD4 Percentage** field on the right and enter a value.
8. Press the **Lot Number** field and enter the lot number for the process control (1–10 characters).
9. Press **Accept**.
10. Press the **Expiration Date** field and press **Up** or **Down** to set the year, month, and day.
11. Press **Accept**.

    The Expiration Date screen closes.
12. Press **Accept** on the **CD4PC Low Settings** screen to save all the entered data for the low count process control.

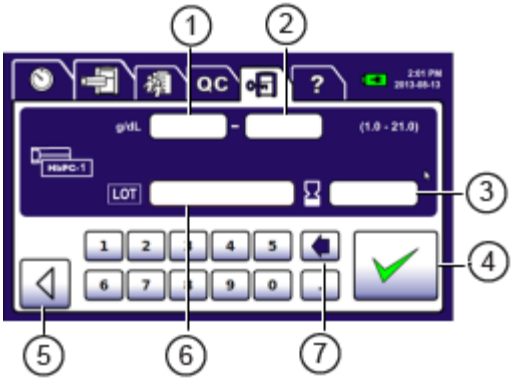
    The CD4PC Low Settings screen closes.
13. Press **CD4PC N** on the **Process Control Settings** screen.
14. Repeat steps 4 to 12 for the normal count process control.

Defining Hb process control settings

To define the Hb process control settings:

1. Press **HbPC L1** on the **Process Control Settings** screen.

The HbPC Level 1 Settings Screen opens.



No.	Field or Button
1	Lower Limit HbPC Concentration
2	Upper Limit HbPC Concentration
3	Expiration Date
4	Accept
5	Back
6	Lot Number
7	Backspace

2. Press the **Lower Limit HbPC Concentration** field and enter a value (according to the process control documentation) with up to three digits including one decimal place.
3. Press the **Upper Limit HbPC Concentration** field and enter a value.
4. Press the **Lot Number** field and enter the lot number for the process control (1–10 characters).
5. Press **Accept**.

   The Lot Number screen closes.

6. Press the **Expiration Date** field and press **Up** or **Down** to set the year, month, and day.
7. Press **Accept**.

   The Expiration Date screen closes.
8. Press **Accept** on the **HbPC L1 Settings** screen to save all the entered data for the Hb Level 1 process control.

   The HbPC Level 1 Settings screen closes.
9. Repeat the previous steps for the HbPC L2 and L3 settings.
10. Press **Accept** on the **Process Control Settings** screen when you are finished entering data for the process controls.

Next step

Preparing process controls (page 50)

More information

- Settings tab (page 30)

Preparing process controls

Introduction

This topic describes how to prepare the process controls using the cartridges. Running process controls is optional.

Required materials

- Pipet
- Cartridge
- Process control reagent

Before you begin

- Prepare the process controls according to their accompanying instructions for use.
- Open the cartridge package. Write the process control name on the cartridge. Face the inlet port up. You must use the cartridge within 30 minutes of opening the package.

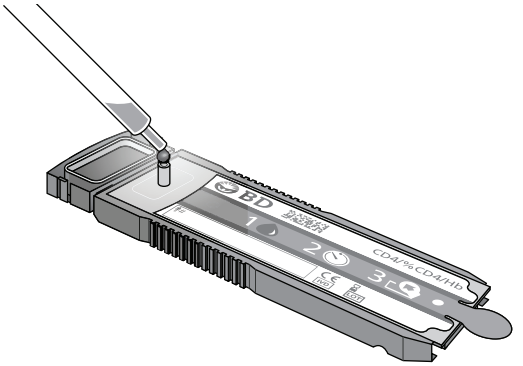
Procedure

Perform this procedure for the CD4 low count, CD4 normal count, CD4 percentage, Hb low concentration, Hb normal concentration, and Hb high concentration.

To prepare process controls:

1. Carefully dispense the process control into the inlet port of the cartridge. Hold the cartridge by its ridges only.
2. Make sure the process control reaches the top of the inlet port.

   Make sure the cartridge is level, with the barcode side up, at all times. Make sure that process control appears in the part of the channel not covered by the channel protector, next to the containment zone.



3. Close the cartridge cap securely. Make sure both latches on the cap snap closed.

Caution: Biological! If necessary, use a cloth dampened with bleach diluted to 0.5% sodium hypochlorite concentration to clean excess process control outside the containment zone. Be careful to not contaminate the inlet port or introduce any debris into the underside of the cartridge. Do not smear, contaminate, or damage the barcode. If you drop the cartridge into a contaminated area, discard the cartridge into a biohazardous waste container and start over with a new cartridge.

4. Set the on-board timer. See Setting the on-board timer (page 34).
5. Make sure the fill indicator is full.

   Some process controls might be difficult to see in the cartridge. Check the fill indicator carefully.
6. Place the cartridge, barcode side up, on the work station.

Next step

Running process controls (page 53)

More information

- BD FACSPresto work station (page 17)
- About process controls (page 42)
- BD FACSPresto cartridge (page 15)

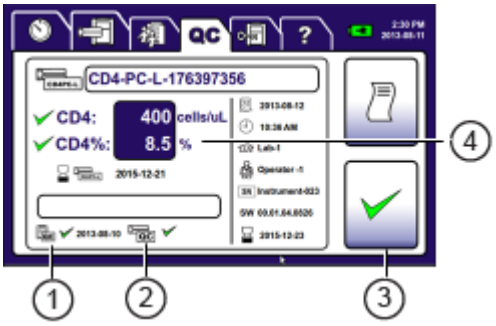
Running process controls

Introduction

This topic describes how to run process controls.

Process Control Results screen

The following figure shows the screen with process control results.



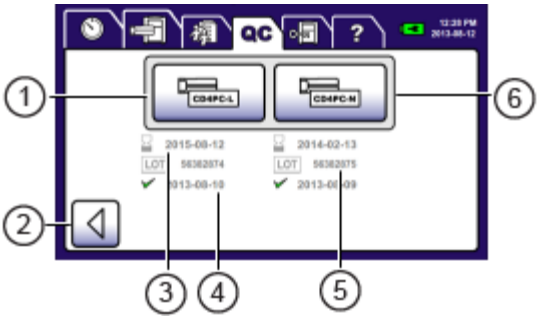
No.	Field or button
1	Instrument QC Result
2	Cartridge QC Result
3	Accept
4	Process Control Results

Procedure

To run process controls:

1. Press the **QC** tab.
2. Press **CD4PC.**

The CD4 Process Control Selection screen opens.



No.	Field or Button
1	Process Control Low
2	Back
3	Expiration date for process controls
4	Date of last process control run
5	Lot number for process controls
6	Process Control Normal

3. Press **CD4PC-L.**

   The CD4 ID Confirmation screen opens.

4. If the process control information is correct, press **Accept**.

   The Process Control Operator screen opens.

5. Insert the cartridge.

   See Inserting the cartridge (page 65).

   The process control is processed and a progress screen opens. When the process is complete, the Process Control Results screen opens and the results print.

6. Press **Accept** to close the results screen.

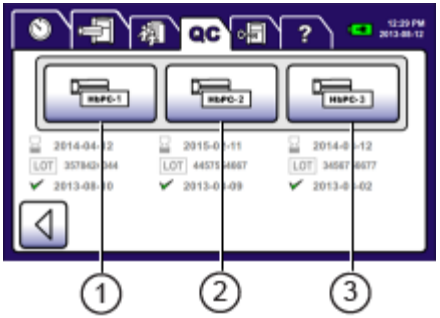
7. Remove the ejected cartridge within 30 seconds.

   If you do not remove the cartridge within 30 seconds, the cartridge goes back into the instrument. If this happens, press Open door and remove the ejected cartridge.

   The CD4 Process Control Selection screen opens.

8. Press **CD4PC-N**.
9. Repeat steps 3 to 7 for the CD4 normal count process control.
10. Press **HbPC** in the **QC** tab.

    The Hb ID Confirmation screen opens.



No.	Button
1	Hb Process Control 1
2	Hb Process Control 2
3	Hb Process Control 3

11. Repeat steps 3 to 7 for **HbPC L1**, **HbPC L2**, and **HbPC L3**.

    You can now process samples.

More information

- QC tab (page 43)
- Entering process control information (page 45)
- Process Control Results screen (page 53)

- Running samples (page 64)
- Troubleshooting (page 76)

6

Sample processing

This chapter covers the following topics:

Sample processing overview

Introduction

This topic describes the workflow for preparing a capillary or venipuncture blood sample using the cartridge and instrument.

Workflow

The workflow for sample processing includes the following stages.

Stage	Description
1	Preparing a capillary blood sample (page 58) or Preparing a venipuncture blood sample (page 61)
2	Running samples (page 64)
3	Inserting the cartridge (page 65)
4	Managing test results (page 70)

Preparing a capillary blood sample

Introduction

This topic describes how to collect a capillary blood specimen using a finger stick, and how to add the specimen into the cartridge.

Required materials

- Cartridge
- Alcohol pad
- Nonwoven sponge
- Lancet
- Bandage

Before you begin

- Open the alcohol pad package.
- Remove the cover on the lancet.
- Open the bandage package.
- Open the cartridge package. Write the patient ID on the cartridge. Face the inlet port up. You must use the cartridge within 30 minutes of opening the package.

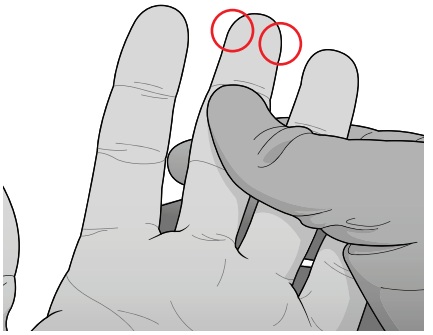
Procedure

To prepare a capillary blood sample:

1. Prepare for puncture by increasing blood flow to the fingers.

   Ask the patient to extend his or her arm towards the floor and shake and squeeze his or her hand. If the patient's hand is cold, use a warming device or run the hand under warm water.

2. Firmly squeeze the base of the patient's fingers.
3. Select either the middle or ring finger, and clean the fingertip with an alcohol pad. Let the alcohol dry.
4. Place the tip of the lancet on the circled area of the finger, as shown in the following figure. Push the lancet to puncture the finger.



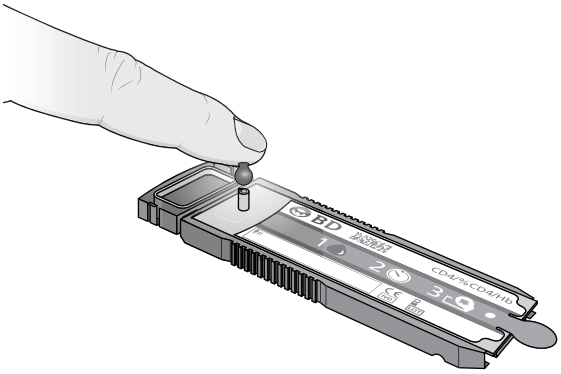
5. Discard the lancet into a biohazardous sharps waste container.
6. Wipe away the first drop of blood with the sponge.

The initial drop might contain tissue fluids that may dilute the sample.

7. Wait until a large drop of blood forms.
8. Apply the blood to the inlet port of the cartridge.

   Hold the cartridge by its ridges only.

   Squeeze and hold the finger to maintain blood flow until blood reaches the top of the inlet port. Make sure the cartridge is level, with the barcode side up, at all times. Make sure that blood appears in the part of the channel not covered by the channel protector, next to the containment zone.



9. Apply the sponge and a bandage to the patient's finger to stop excess bleeding.
10. Close the cartridge cap securely.

Make sure both latches on the cap snap closed.

Caution: Biological! If necessary, use a cloth dampened with bleach diluted to 0.5% sodium hypochlorite concentration to clean excess blood outside the containment zone. Be careful to not contaminate the inlet port or introduce any debris into the underside of the cartridge. Do not smear, contaminate, or damage the barcode. If you drop the cartridge into a contaminated area, discard the cartridge into a biohazardous waste container and start over with a new cartridge.

11. Set the on-board timer. See Setting the on-board timer (page 34).
12. Make sure the fill indicator is full.
13. Place the cartridge, barcode side up, on the work station.

Next step

Running samples (page 64)

More information

- BD FACSPresto work station (page 17)
- BD FACSPresto cartridge (page 15)

Preparing a venipuncture blood sample

Introduction

This topic describes how to add a previously collected venipuncture blood specimen into the cartridge.

Required materials

- Pipet
- Cartridge
- BD Vacutainer® EDTA tube containing room temperature blood

Before you begin

Open the cartridge package. Write the patient ID on the cartridge. Face the inlet port up. You must use the cartridge within 30 minutes of opening the package.

Procedure

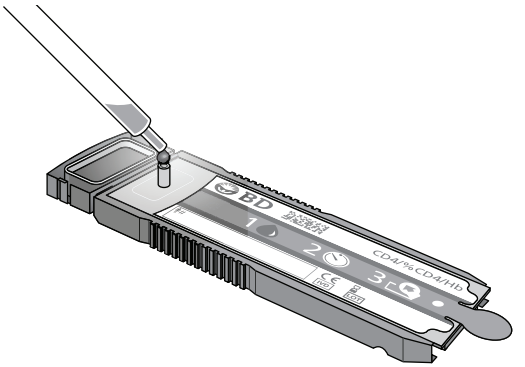
To prepare a venipuncture sample:

1. Invert the tube 10 times to mix the contents well.
2. Use the pipet to obtain the specimen.

   Use one pipet per specimen.
3. Gently squeeze the bulb on the pipet to form a drop of blood on the tip of the pipet.
4. Carefully dispense the specimen into the inlet port.

   Hold the cartridge by its ridges only.

   Make sure the blood reaches the top of the inlet port. If necessary, gently squeeze the bulb on the pipet to dispense more blood. Make sure the cartridge is level, with the barcode side up, at all times. Make sure that blood appears in the part of the channel not covered by the channel protector, next to the containment zone.



5. Discard the pipet into a biohazardous waste container.

6. Close the cartridge cap securely. Make sure both latches on the cap snap closed.

Caution: Biological! If necessary, use a cloth dampened with bleach diluted to 0.5% sodium hypochlorite concentration to clean excess blood outside the containment zone. Be careful to not contaminate the inlet port or introduce any debris into the underside of the cartridge. Do not smear, contaminate, or damage the barcode. If you drop the cartridge into a contaminated area, discard the cartridge into a biohazardous waste container and start over with a new cartridge.

7. Set the on-board timer. See Setting the on-board timer (page 34).
8. Make sure the fill indicator is full.
9. Place the cartridge, barcode side up, on the work station.

Next step

Running samples (page 64)

More information

- BD FACSPresto work station (page 17)
- BD FACSPresto cartridge (page 15)

Running samples

Introduction

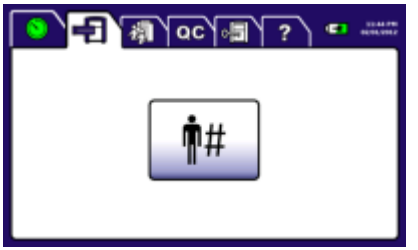
This topic describes how to run samples from the Run Test tab.

You cannot start a run if the instrument has a low battery. You cannot turn off the instrument during a run.

Procedure

To run samples:

1. Make sure the cap on the cartridge is closed.
2. Press the **Run Test** tab.
3. Press **Patient ID**.



4. Enter the patient's ID and press **Accept**.

   The Confirm Patient ID screen opens.
5. Press **Accept**.

Next step

Inserting the cartridge (page 65)

More information

- Keyboard (page 21)

Inserting the cartridge

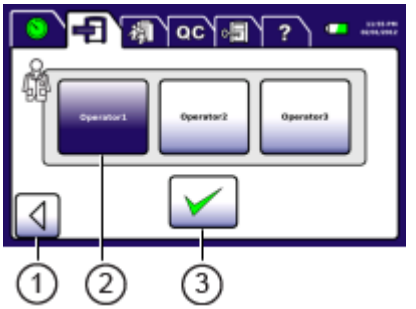
Introduction

This topic describes how to insert the cartridge into the instrument.

Procedure

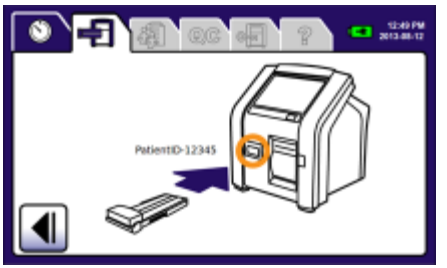
To insert the cartridge:

1. Select your Operator ID and press **Accept**.



No.	Button
1	Back
2	Operator ID
3	Accept

The cartridge door on the instrument opens.



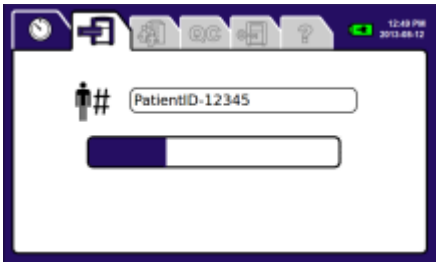
Note: If possible, complete the following two steps within 30 seconds.

2. Remove the channel protector from the cartridge. Do not touch the cartridge except for the closed cap.
3. Hold the cap with the channel facing upwards. Insert the prepared cartridge into the cartridge door, as shown in the following figure.

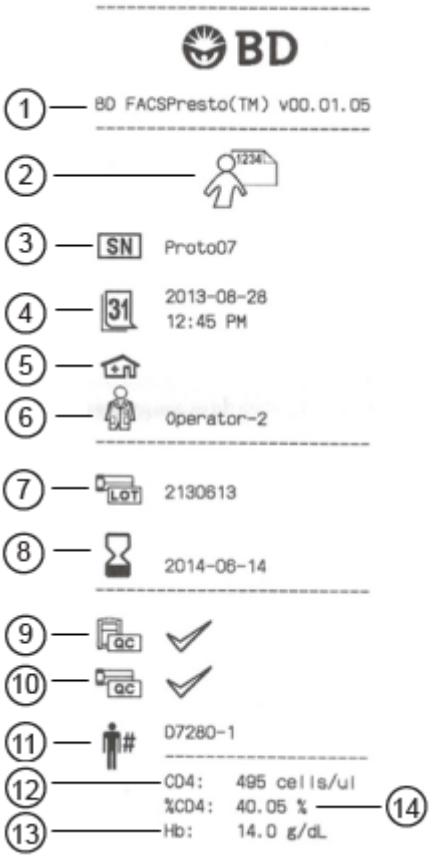
The cartridge clicks in place. The cartridge door closes. If the cartridge door closes before you insert the cartridge, press Open Door.

No.	Button
1	Open Door
2	Cancel

The sample is processed and a progress screen opens. Typically, a sample takes 4 minutes to process.



When the process is complete, the instrument beeps 3 times, the results appear on the screen, and automatically print.



No.	Description
1	Product and software version
2	Results type. Patient results are shown in this example. Other result types are process controls, and instrument QC.
3	Instrument serial number

No.	Description
4	Date and time of test
5	Lab
6	Operator
7	Cartridge lot number
8	Cartridge expiration date
9	Instrument QC result
10	Cartridge QC result
11	Patient number
12	CD4 absolute count
13	Hemoglobin concentration
14	CD4 percentage of lymphocytes

Note: For process control results, the process control lot number and process control expiration date are also listed in the results.

4. Press **Accept.**

   The cartridge door opens and the results screen closes.

5. Remove the ejected cartridge within 30 seconds.

   If you do not remove the cartridge within 30 seconds, the cartridge goes back into the instrument. If this happens, press Open Door and remove the ejected cartridge.

6. Press **Accept**.

7. Dispose of the used cartridge using proper precautions and in accordance with local regulations.

More information

- Troubleshooting (page 76)
- Managing test results (page 70)

- *BD FACSPresto Near-Patient CD4 Counter Safety and Limitations Guide*

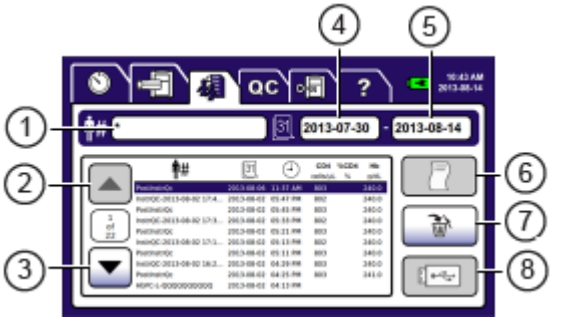
Managing test results

Introduction

This topic describes how to search, filter, print, delete, and export test results. Press the Results tab to manage the test results.

Results tab

The following figure shows the screen with the Results tab selected.



No.	Button
1	Patient ID
2	Up
3	Down
4	Start Date
5	End Date
6	Print
7	Delete
8	USB

Searching for test results

To search for test results:

1. Press **Up** or **Down** to scroll through the test results.

Filtering test results

You can filter test results by patient ID, date, or both. To filter test results by both patient ID and date, perform both of the following procedures.

To filter test results by patient ID:

1. Press the **Patient ID** field.
2. Enter the patient's ID.

   If you do not know the exact patient ID, use an asterisk (*). For example, if you are searching for a patient ID that begins with 123, enter: 123*. If you are searching for a patient ID that ends with 123, enter: *123. If you are searching for a patient ID that contains 123, enter: *123*.
3. Press **Accept**.

   If you are also filtering by date, perform the following procedure.

To filter test results by date:

If you are filtering by date only, the Patient ID field should contain the default value of an asterisk (*) only.

1. Press the **Start Date** field.
2. Press **Up** or **Down** to select the start date for the filter.
3. Press **Accept**.
4. Press the **End Date** field.
5. Press **Up** or **Down** to select the end date for the filter.
6. Press **Accept**.

Printing test results

You can print only one test result at a time.

To print a test result:

1. Select a test result.
2. Press **Print**.

Deleting test results

Before you delete a test result, you should export it to a USB flash drive. You should delete all test results from the instrument before sending the instrument to BD Biosciences for service.

To delete a test result:

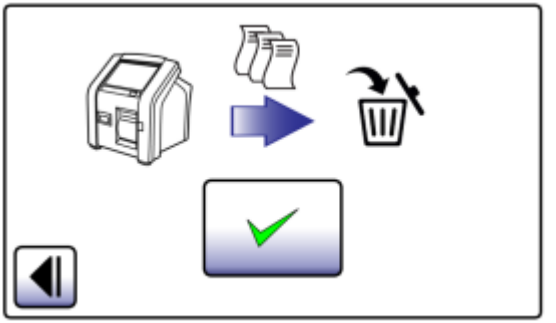
1. Select a test result.
2. Press **Delete**.

   A confirmation screen opens.
3. Press **Delete**.

To delete all test results:

1. Press the **Help** tab.
2. Press **Delete All**.

   A confirmation screen opens.



3. Press **Accept**.

   To confirm all results are deleted, press the Results tab.

Exporting test results

The instrument can store up to 12,000 results in its internal memory. Results include sample runs, QC runs, and process control runs. If the instrument exceeds 12,000 results, it deletes the oldest result. To back up your results, export them to a USB flash drive.

To export test results:

1. Filter the test results that you want to export. To export all test results, leave the asterisk (*) in the **Patient ID** field.
2. Insert a USB flash drive into the USB port on the front of the instrument.
3. Press **USB**.

   The USB button is not active unless a USB flash drive is properly inserted into the USB port.
4. (Optional) Enter a new file name for the results. The file name should be different from other file names on the USB drive.

   The file name can contain 0–30 characters.
5. Press **Accept**.
6. In the confirmation screen, press **USB**.

   To cancel the export, press Back.

   The file is saved in a comma-separated value (CSV) file format in a *Results* folder on the USB flash drive.

   If the export was successful, the Results tab appears.

More information

- Instrument front view (page 12)
- Troubleshooting (page 76)
- Technical assistance (page 7)
- Help tab (page 36)

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7

Instrument reference

This chapter covers the following topics:

Troubleshooting

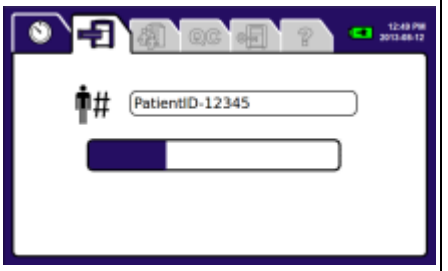
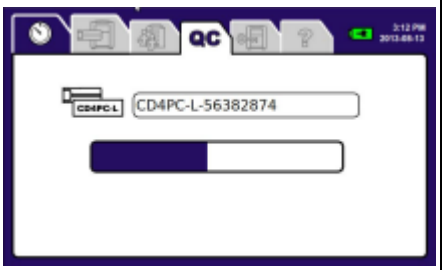
Introduction

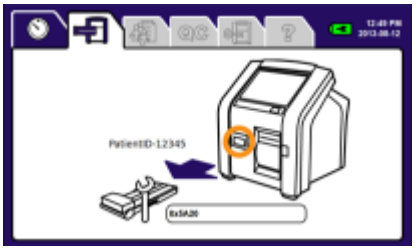
This topic describes how to troubleshoot problems with the instrument. Error screens alert you to issues with the hardware, software, and cartridge. If additional assistance is required, contact your local BD Biosciences technical support representative or supplier.

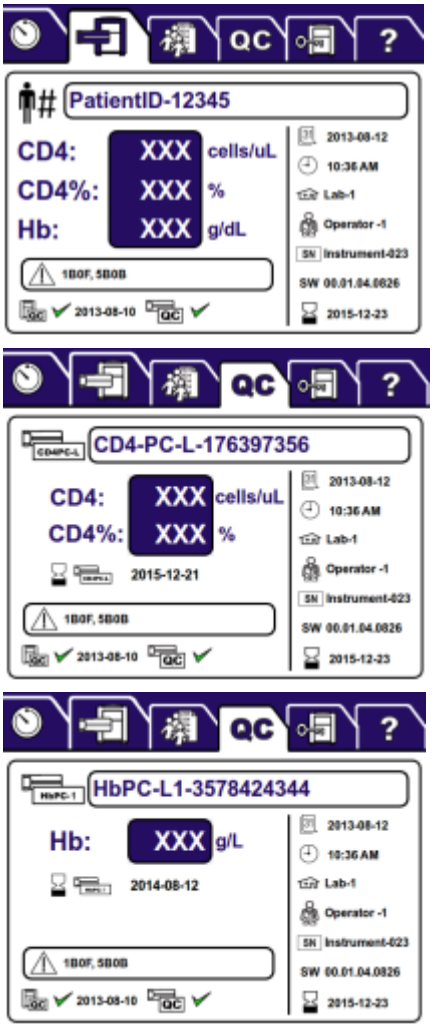
Errors

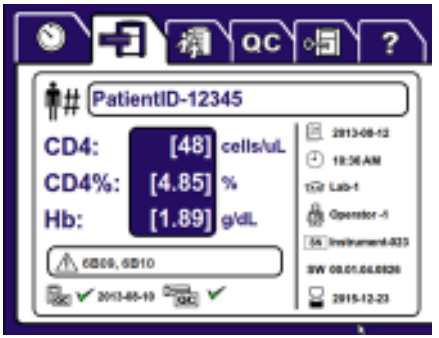
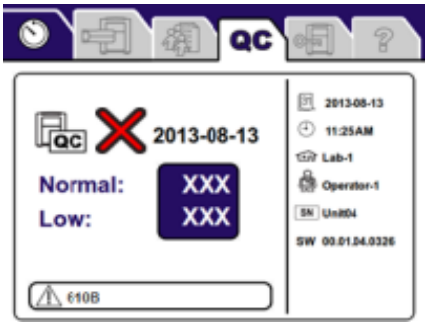
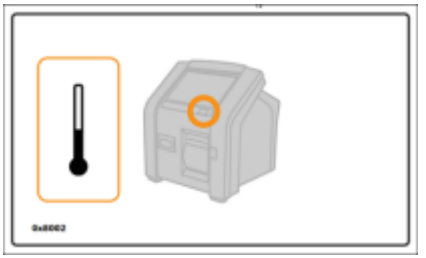
The following table describes possible errors and recommended solutions. Note the error code on the screen. For technical support, BD Biosciences might ask for this code.

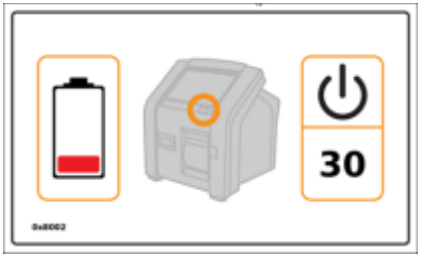
Error displayed	Possible causes	Recommended solutions
	A critical failure requires you to stop operating the instrument.	1. If there is a USB flash drive in the USB port, remove it. 2. If there is a cartridge stuck in the cartridge door, do not attempt to remove it. If possible, make sure the cap is closed. 3. Press the power button until the instrument turns off. 4. Press the power button to turn on the instrument. – If there is a cartridge in the instrument, a screen with the Open Door button appears. – Press Open door. – Remove the cartridge. 5. If the error persists, contact BD Biosciences.
	The printer is out of paper.	Add printer paper.
	There is a paper jam.	1. Open the printer door. 2. Fix the paper jam. 3. Close the printer door.
	The printer door is open.	Close the printer door.

Error displayed	Possible causes	Recommended solutions
	The printer does not respond and requires service.	Contact BD Biosciences.
	The battery does not charge and requires service.	Contact BD Biosciences.
 	The sample or process control run has stopped.	1. Wait 2 minutes. 2. If the progress bar does not move, press the power button until the instrument turns off. 3. Press the power button to turn on the instrument. A screen with the Open Door button appears. 4. Press Open Door. The cartridge is ejected. 5. Remove the cartridge. 6. Follow the instructions in Running samples (page 64).

Error displayed	Possible causes	Recommended solutions
  • This error might appear in the Run Test tab. • The instrument ejects the cartridge.	The instrument cannot read the barcode or channel.	1. Make sure the channel protector is removed from the cartridge. 2. Clean the barcode label or channel. 3. Re-insert the cartridge into the instrument. 4. If the error persists, prepare a new cartridge.
	There is not enough blood or process control in the cartridge.	1. Make sure the channel is full of blood or process control. If it is not full, prepare a new cartridge. 2. Re-insert the cartridge into the instrument. 3. If the error persists, prepare a new cartridge.

Error displayed	Possible causes	Recommended solutions
	Results are not shown.	If the error code is 6B16 or 6102: 1. Re-run instrument QC. 2. Insert the cartridge into the instrument again. If you get the same error screens, prepare a new cartridge. For other error codes, insert the cartridge into the instrument again. If you get the same error screens, prepare a new cartridge.

Error displayed	Possible causes	Recommended solutions
	Results are out of the validated range.	Consult the lab manager.
	Instrument QC does not show results.	1. Press the power button until the instrument turns off. 2. Press the power button to turn on the instrument. 3. If the error persists, contact BD Biosciences.
	The instrument temperature is outside its operational range.	1. Make sure the air vents are unobstructed. 2. Press the power button until the instrument turns off. 3. Wait for the instrument to return to its operational range. 4. Press the power button to turn on the instrument. 5. If the instrument does not turn on, contact BD Biosciences.

Error displayed	Possible causes	Recommended solutions
	The instrument temperature is outside its operational range, and will shut down in the number of seconds specified on the screen.	1. Make sure the air vents are unobstructed. 2. Wait for the instrument to return to its operational range. 3. Press the power button to turn on the instrument. 4. If the instrument does not turn on, contact BD Biosciences.
	The instrument has low battery power, and will shut down in the number of seconds specified on the screen.	1. Plug the instrument into a wall electrical outlet or other electric source. 2. Press the power button to turn on the instrument. 3. If the instrument does not turn on, contact BD Biosciences.
	The instrument is running on battery power only and has not been used for 35 minutes. It will shut down in the number of seconds specified on the screen.	Touch the screen. If the instrument turns off, press the power button to turn it on.

Error displayed	Possible causes	Recommended solutions
	The USB flash drive is not present.	Insert the USB flash drive into the USB port.
	The USB flash drive is not inserted correctly.	Remove and insert the USB flash drive into the USB port again.
	The USB flash drive is full.	Insert the USB flash drive into a PC and remove some files. Or Insert another BD USB flash drive into the USB port.
	The USB flash drive is not functioning.	Insert another BD USB flash drive into the USB port.
	The USB port is not functioning.	Contact BD Biosciences.

More information

- Technical assistance (page 7)
- Changing the printer paper (page 85)
- Instrument setup, startup, and shutdown (page 24)
- Instrument specifications (page 87)

Maintenance, transportation, and disposal

Introduction

This topic describes the maintenance procedures that should be performed on the instrument and work station when necessary. It also describes how to transport and how to dispose of the instrument.

Maintaining the instrument

To maintain the instrument:

- Turn off the instrument when it is not in use.
- Cover the instrument with the included instrument cover when it is not in use.

There are no user-serviceable parts. Contact BD Biosciences for technical assistance.

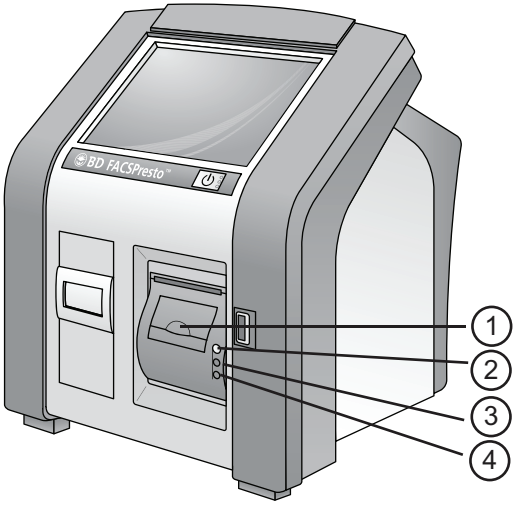
Cleaning the instrument or work station

As needed, clean the outside of the instrument or work station with a cloth dampened with either bleach diluted to 0.5% sodium hypochlorite concentration or 70% isopropyl alcohol. If service is required, clean the instrument before returning to BD Biosciences.

Changing the printer paper

To change the printer paper:

1. Lift the printer door latch.

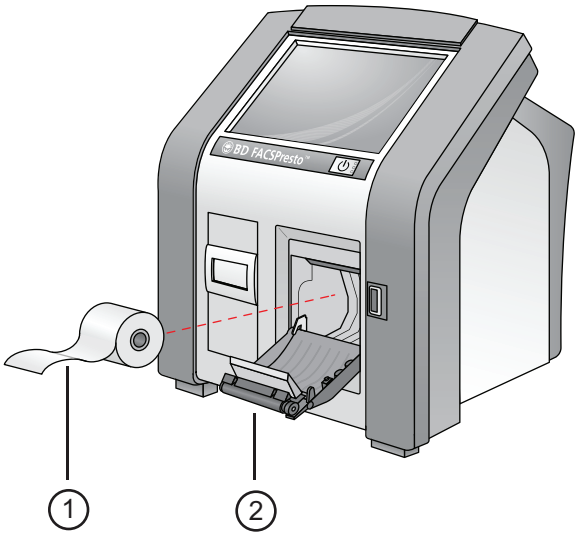


No.	Component
1	Printer door latch.
2	Button to eject paper from printer.
3	Green light means the printer is ready to print.
4	Red light means the printer is out of paper or the printer door is open.

   The printer door opens.

2. Remove the old paper roll.
3. Detach the end of the paper from the new paper roll.

4. Insert the new paper roll into the printer, as shown in the following figure.



No.	Component
1	Paper roll
2	Printer door

5. Close the printer door.

Caution: Mechanical! Use caution when opening or closing the printer door. Do not place your fingers or hands between the printer door and instrument. The top of the printer door can injure your hands or fingers.

6. Push the latch on the printer door.

   The latch snaps in place and the light is green if the paper is inserted into the printer correctly.

Transporting the instrument

To transport the instrument, pack it in its original shipping box. You can also use the carrying case, which is an optional accessory.

Disposing of the instrument

Separate collection of waste at the end of life as required by European Directives. Dispose of in accordance with the applicable country regulation.

More information

- Instrument shutdown (page 29)
- Technical assistance (page 7)
- Troubleshooting (page 76)

Instrument specifications

Introduction

This topic describes the instrument specifications. The instrument complies with EN 61010-01: 2010.

Instrument specifications

Item	Description
Height	28.5 cm (11.22 in.)
Width	25.9 cm (10.20 in.)
Depth	25.1 cm (9.88 in.)
Weight	6 kg (13.23 lb)
Power Supply	100–240 VAC, 50–60 Hz
Instrument Power	3.3 A, 18.5 ±1 VDC

Item	Description
Operating and Storage Environment	Temperature at ≤2,500 meters above sea level • Operating: 10°C–40°C (50°F–104°F) • Storage: 0°C–50°C (32°F–122°F)
	Humidity: 10%–95% non-condensing
	Vibration: Do not operate the instrument near a running vortexer, centrifuge, or microcentrifuge.
Heat Dissipation	Up to 25 watts

More information

- Product documentation (page 6)
- BD FACSPresto Cartridge IFU

Power requirements

Introduction

This topic describes the power requirements necessary for the instrument to operate uninterrupted in any location worldwide.

Requirements

The instrument uses battery or electrical power. The power supply connects the instrument and adapter cord.

Region	Frequency requirements (Hz)	Voltage requirements (VAC)
Africa	50	220 ±10%
Europe	50	230 ±10%
India	50	230 ±10%
Japan	50–60	100 ±10%
North America	60	125 ±10%
United Kingdom	50	230 ±10%

More information

- Instrument setup, startup, and shutdown (page 24)

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