BD FACSLyric™ Clinical System

Instructions for Use

REF 662875
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23-19938(05)
2023-10
English

℞ Only IVD

This English document contains the original instructions.

Laser safety information
Class 1 Laser Product.

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.

NOTE: "Harmful interference" is defined in 47 CFR § 2.1 by the FCC as follows: Interference which endangers the functioning of a radio-navigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the International Telecommunication Union (ITU) Radio Regulations.

Electromagnetic compliance
The FACSLyric™ Clinical system complies with standard IEC 61326-2-6:2020, emission and immunity requirements. This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments. This equipment is designed for use in a professional healthcare facility environment. It is likely to perform incorrectly if used in a home healthcare environment. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference. The electromagnetic environment should be evaluated prior to operation of the device. Do not use this device in proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these can interfere with proper operation.

Graphical symbols website:
bd.com/symbols-glossary

History

Revision	Date	Change made
23-19938-00	2017-07	Initial release

Revision	Date	Change made
23-19938-01	2019-04	Added electromagnetic compliance statement. Revised for 12-color system and BD FACSuite™ Clinical application v1.3.
23-19938-02	2019-10	Updated for BD FACSuite™ Clinical application v1.4: changes in the user interface for audit trails, auto-approve, auto-export/print options; using the BD FACS™ Universal Loader when creating reference settings and during daily clean; changes in the Universal Loader user interface; and setting operator permissions.
23-19938-03	2020-08	Removed reference to BD FACSDuet™ integration preferences.
23-19938-04	2020-12	Version updated to BD FACSuite™ Clinical v1.5 including FCS file concatenation and updates to worklist and gating user interface.
23-19938(05)	2023-10	Clarified bleach concentration as a percentage of sodium hypochlorite. Changed maximum particle size in Principle of Operation from 150 µm to 50 µm. Renamed "Technical assistance" topic in Chapter 1 to "Contact information" and added subtopic "Reporting serious incidents". Updated intended use statement. Added more detail about errors, warnings, and notifications in QC reports. Changed publication part number and date formats. Updated legal manufacturer address. Added catalog IDs to title page. Added addresses of Australian and New Zealand distributors. BD FACSuite™ Clinical application updated to v1.6.

Contents

1

Introduction

This chapter includes the following topics:

About this guide

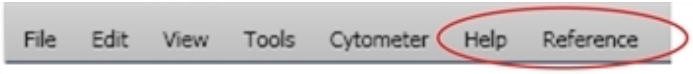
In this guide

This guide provides information for setting up and running the BD FACSLyric™ system. The guide includes:

- Introductory information about system hardware and components, a basic overview of the software, and instructions about preparing the system for use.
- Instructions for performing daily quality control, basic acquisition, and analysis of flow data using the software.
- Instructions for maintaining the system and information about the optional BD FACS™ Universal Loader.

Additional help

In the BD FACSuite™ Clinical application, you can use the Help or Reference menus to access additional information.



- Click **Help** to view the product documentation, including this manual and the *BD FACSLyric™ System Safety and Limitations Guide*. Help documents are provided in PDF format, and you can set a system preference for which language is displayed. Clicking **About BD FACSuite™ Clinical** displays version information and the unique device identifier (UDI) for the software.
- Click **Reference** to open the *BD FACSLyric™ Clinical Reference System* in a separate window. Internet access is not required to access this content.

  The *BD FACSLyric™ Clinical Reference System* is a comprehensive collection of information that includes all content from this guide and additional concepts, procedures, and reference information about the cytometer and software.

You can use the table of contents, interactive links, or the search tool to locate topics of interest. Search results are displayed in a familiar web search format to help you find information quickly.

Use the print tools to print individual topics or to print entire sections as formatted PDF files.

Training

BD recommends that operators complete device-specific training offered by the manufacturer before using the system.

Symbols in this guide

Introduction

The following table describes the symbols used in this guide.

Safety symbols

Symbol	Meaning
	Caution. Identifies a hazard or unsafe practice that could result in data loss, material damage, minor injury, severe injury, or death.
	Biological hazard
	Electrical hazard
	Laser hazard
	Mechanical hazard, pinch points

Contact information

Introduction

This topic describes how to contact BD Biosciences.

Before contacting technical support

Try the following options for answering technical questions and solving problems:

- Read the section of this guide specific to the operation you are performing.
- Read topics about related information, which are listed in the *More Information* section (at the bottom of each topic).
- Search the troubleshooting topics in the *BD FACSLyric™ Clinical Reference System* for solutions to problematical system behaviors.

When contacting technical support

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

When contacting BD, have the following information available:

- Product name, part number, and serial number
- Software application and version number
- Any error messages
- Details of recent system performance
- A system health report. See topics about generating one in the *BD FACSLyric™ Clinical Reference System*.

Reporting serious incidents

EU Only: Users should report any serious incident related to the device to the Manufacturer and National Competent Authority.

Outside EU: Contact your local BD representative for any incident or inquiry related to this device.

Intended use

Intended use statement

The BD FACSLyric™ flow cytometer is intended for use as an in vitro diagnostic device for the following:

- Immunophenotyping using up to six fluorescence detection channels and two light scatter channels using a blue (488-nm) and a red (640-nm) laser.

- Enumeration of residual white blood cells (rWBCs) in leucoreduced blood products.

It is intended for use with in vitro diagnostic (IVD) assays and software that are indicated for use with the instrument.

Cybersecurity guidelines

Introduction

For network-connected workstations, the following recommendations should be considered.

BD FACSuite™ Clinical application guidelines

- In **User Management Settings**, configure the options for **Lockout Attempts**, **Password Expiration**, and **Password Expiration Warning** to require users to regularly change their passwords.
- Use a complex password of at least 8 characters with the full set of alphanumeric characters and special symbols.
- All users should have their own User ID and IDs should not be shared.
- Users should be given Administrator privileges only if their duties require that level of access (to create users, for example).
- Software backups should be performed on a regular basis to secure storage external to the workstation, and to allow a restore to be performed. The default backup directory on the BD FACSLyric™ workstation for the BD FACSuite™ Clinical application is C:\ProgramData\BD\FACSuite Clinical\BD Backup.
- As software updates including security updates are made available, these updates should be applied in a timely manner.
- Install antivirus software per company IT policy and periodically scan hard drives.
- Do not enter sensitive patient information, such as patient name and social security number, into keywords and other text fields in the software. Doing so could expose this sensitive patient information to unintended use.

Microsoft® Windows® OS guidelines

- Password options for the Microsoft Windows operating system should be configured as required to meet organizational IT standards, including password complexity, password expiration, limits on attempts to guess users' passwords, and password reuse rules.
- Administrative access to the Windows operating system should be given only to users that require such access (to perform backups, for example).
- Windows operating systems security updates should only be applied if they have been reviewed and approved by BD Biosciences. Non-approved updates can affect the correct functioning of the system.
- Remote access to the workstation should only be enabled if it is required.
- For more information about operating system configuration and additional tools, see the document *Information Security Guidelines, BD Biosciences Workstations*, available on bdbiosciences.com.

Limitations

Fluidics modes

The BD FACSLyric™ system has a high-sensitivity fluidics mode that should not be used with BD IVD assays.

Sample carriers

The BD FACSLyric™ system with the BD FACS™ Universal Loader option has the capability of using tube racks that can include 30 or 40 tubes. The Loader can also handle plates, but plates should not be used with BD IVD assays. Always refer to the reagent package insert for sample carrier requirements.

System requirements

You must have Microsoft Windows Administrator access to install the BD FACSuite™ Clinical and BD FACSuite™ Clinical applications.

If you are installing the software on a standalone workstation, we recommend that the computer meets the following minimum requirements:

- Intel® Pentium® Quad Core processor. The BD FACSuite™ Clinical/BD FACSuite™ Clinical application v1.6 is validated for the HP® Z2 G9, HP® Z2 G5, and HP® Z2 mini G4 workstations only.
- Microsoft Windows 64-bit version.
- 8 GB of RAM.
- Hard drive with at least 50 GB of free space.
- PDF-capable printer. The BD FACSuite™ Clinical application renders content to PDF before sending it to a directly connected or networked printer. Any printer that supports PDF format can be used to print from the BD FACSuite™ Clinical application.
- Google Chrome™ browser for proper display of the system documentation.
- Software, such as Adobe® Acrobat® Reader®, for reading PDF files.

2

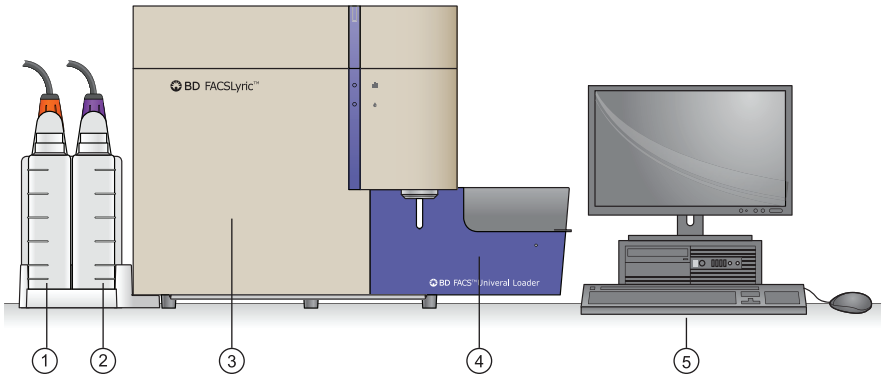
About the system

This chapter includes the following topics:

System overview

About the system

The BD FACSLyric™ system includes the BD FACSLyric™ cytometer, the optional BD FACS™ Universal Loader (Loader), and workstation that runs the software. The system also includes setup beads and reagents. All of these components combine to create an integrated system designed for use in a wide variety of clinical applications.



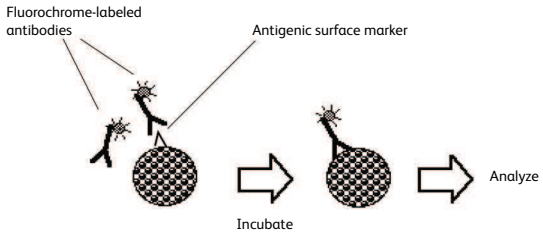
No.	Description
1	Waste tank
2	Sheath tank
3	BD FACSLyric™ cytometer
4	BD FACS™ Universal Loader (optional)
5	Workstation with BD FACSuite™ Clinical application. Note that the workstation for newer BD FACSLyric™ systems is more compact than shown in the illustration and, as a result, the monitor cannot be placed on top of it.

The BD FACSLyric™ flow cytometry system acquires and analyzes particles or cells in a liquid suspension. Antibodies to specific cell proteins are labeled with a fluorescent dye and incubated with the cell suspension. The suspension flows through the cytometer and is interrogated by a laser which excites the fluorescent antibodies. The fluorescence is captured and the resulting data is analyzed to reveal information about the cells. Multiple antibodies, each labeled with a different dye, can be used in a single tube to simultaneously identify different cell populations.

Principle of operation

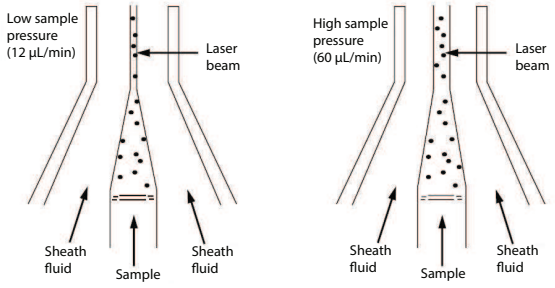
The BD FACSLyric™ system, using flow cytometry, identifies and enumerates cell subsets. Flow cytometry is a technology that simultaneously measures and then analyzes multiple physical characteristics of single particles, usually cells, as they flow in a fluid stream through a beam of light. The properties measured include a particle's relative size, relative granularity or internal complexity, and relative fluorescence intensity. An optical-to-electronic coupling system determines these characteristics by recording how the cell or particle scatters incident laser light and emits fluorescence.

A fluorochrome is conjugated to an antibody and used to identify a particular cell type based on the individual antigenic markers of the cell.



In a mixed population of cells, different fluorochromes can be used to distinguish different cell populations. The staining pattern of each population, combined with forward-scattered light (FSC) and side-scattered light (SSC) data, can be used to identify which cell populations are present in the sample and to count their relative percentages.

The stained sample is carried in a fluid stream through the laser beam. Any suspended particle or cells from 0.2 to 50 micrometers in size is suitable for analysis. The design of the flow chamber causes the sample core to be focused in the center of the sheath fluid. Based on principles relating to laminar flow, the sample core remains separate but coaxial within the sheath fluid. The flow of the sheath fluid accelerates the particles and restricts them to the center of the sample core. This process is known as hydrodynamic focusing.

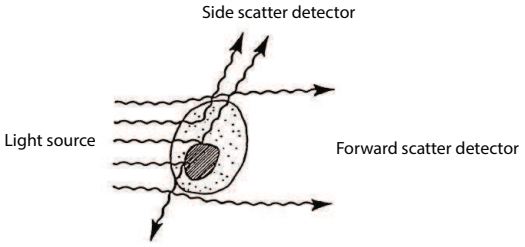


The fluidic system is vacuum-driven, which draws the sheath fluid and the sample into the system rather than pushing it through using positive pressure. This approach enables the fluid to be drawn from a nonpressurized sheath and sample vessels. This method avoids potential issues surrounding the pressurization of sample tubes and also avoids the use of complicated syringe drive mechanisms.

When the particles pass through the laser beam, they scatter laser light. The extent of the scattering depends on the physical properties of each particle. The scattered light is differentiated into two categories:

- Forward-scattered light (FSC) provides a measure of cell size and shape. It is a measurement of mostly diffracted light, which is detected just off the axis of the incident laser beam in the forward direction. FSC is detected by a photodiode.
- Side-scattered light (SSC) provides a measure of the complexity of the cytoplasm. It is a measurement of refracted light that occurs at any interface within the cell where there is a change in refractive index. SSC is collected at approximately 90 degrees to the laser beam by a collection lens, which is redirected by a beam splitter to the appropriate detector.

Pictorial representation of FSC and SSC:



Correlated measurements of FSC and SSC can allow for differentiation of cell types in a heterogeneous population.

Photodetectors convert the light signals to electronic signals that in turn are converted into digital channel numbers for display on a data plot. BD currently used two types of photodetectors:

- Photodiodes, used to detect FSC signals
- Photomultiplier tubes (PMTs), used to detect fluorescence and SSC signals

Once the light signals (photons) strike one side of the PMT or the photodiode, they are converted into a proportional number of electrons, which results in a voltage pulse. The pulse reaches maximum amplitude when the particle is in the center of the beam, which corresponds to where the maximum amount of scatter or fluorescence occurs. As the particle leaves the beam, the pulse amplitude drops back to the baseline.

An analog-to-digital converter (ADC) converts the voltage pulse to a digital channel number. This number is then transferred to the computer and displayed in an appropriate position on a data plot and stored by the computer system.

BD FACSLyric™ cytometer

The BD FACSLyric™ cytometer is a compact flow cytometer. Several hardware options and upgrades can be used to customize the system for different applications.

The vacuum-driven fluidics, along with a uniquely designed flow cell and sample injection tube, provide reliability and good signal resolution.

BD FACS™ Universal Loader

The Loader is an optional automated loading system that delivers samples to the BD FACSLyric™ cytometer for acquisition. It is designed for walkaway operation.

The Loader offers various settings to resuspend and mix samples. It can draw from 12 x 75-mm tubes in 30- and 40-tube racks.A barcode reader verifies the ID on tube racks, and individual tubes in 30-tube racks. A built-in imaging system provides safety checks, such as verifying the correct rack type and tube layout, and ensuring that tubes were loaded correctly.

Workstation

The system is shipped with a workstation that includes a monitor, keyboard, and mouse. The workstation runs the BD FACSuite™/BD FACSuite™ Clinical application and other software, which controls the cytometer. The workstation comes equipped with the following software:

- Microsoft® Windows® 10 operating system, 64-bit compatible
- BD FACSuite™ Clinical version 1.6 or later, comprising the BD FACSuite™ application and the BD FACSuite™ Clinical application

The workstation requires a security key that plugs into a USB port to run the software.

Sheath and waste tanks

Several tank sizes are available depending on the sample throughput and needs of individual laboratories. The standard 5-L capacity sheath and waste tanks are located to the left side of the cytometer in a dock that can be disconnected from the cytometer. Optional 10-L extended-use tanks are also available. Level sensors alert you when fluid levels are low (sheath) or high (waste). Additionally, for high-volume labs, a BD FACSFlow™ cubitainer can be used to supply sheath fluid.

Beads, reagents, and assays

BD® CS&T Beads are used to check the cytometer performance and automatically make adjustments, ensuring consistent values from day to day.

Note: Ensure that you use the BD® CS&T Beads designed specifically for your BD FACSLyric™ IVD system.

BD® FC Beads are used to set up reference settings, which are valid for 60 days.

BD IVD assays are available as separate modules that can be used with BD IVD kits to support clinical applications. Worksheets with plots and gates are already set up for acquisition, analysis, and reporting.

More information

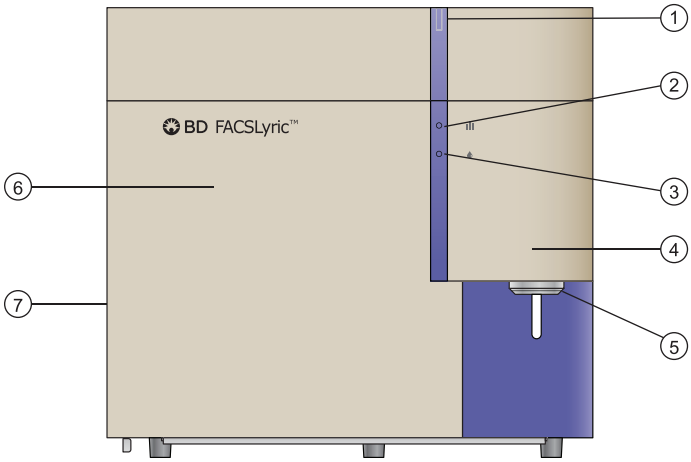
- Cytometer overview (page 22)
- System options and upgrades (page 28)
- Software overview (page 29)

Cytometer overview

Main components

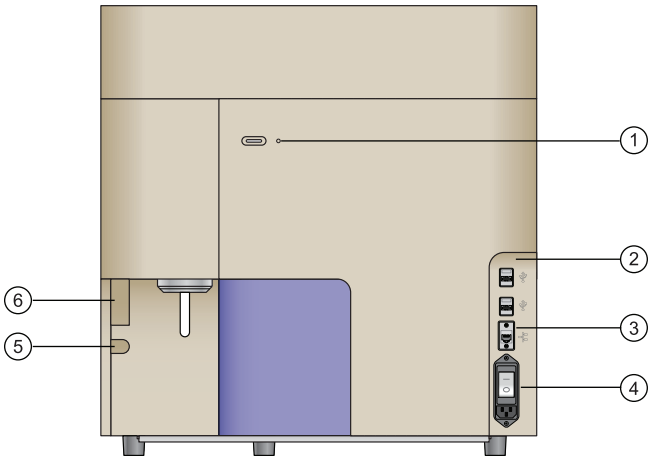
The locations of the main components of the cytometer, including the status indicators, are shown in the following figures.

Cytometer front view



No.	Description
1	Cytometer status indicator
2	Acquisition status indicator
3	Fluidics status indicator
4	Sample injection tube (SIT) door
5	Manual tube port
6	Heptagon detector arrays, behind front door
7	Access door for sheath filter on left side of cytometer

Cytometer right-side view



No.	Description
1	Cytometer power button
2	Connector panel
3	Ethernet connector for workstation
4	AC power circuit breaker
5	Captive screw for front door
6	Grip area for front door

Status indicators

When the system is started, indicators display different conditions to show the system's status. The functions of the status indicators are described in the following table.

Indicator	Condition	Status
Cytometer status	Green	Ready for operation
	Solid amber	Fault condition
	Blinking amber	Warming up
	Red	System inoperable
Cytometer power button	Amber	Power is off to all major subsystems
	Green	Power is on
	Blinking green	Shutdown process has started
Acquisition status	Off	Not previewing or acquiring sample
	Blinking blue	Previewing or acquiring sample

Indicator	Condition	Status
Fluidics status	Off	Ready
	Blinking amber	• Sheath fluid low • Waste tank almost full
	Red	• Sheath fluid empty • Waste tank full • Waste tank disconnected

Cytometer configurations

The BD FACSLyric™ system is available in the following configurations.

Lasers	Number of colors
2 lasers (blue, red)	4 color (3-1)
2 lasers (blue, red)	6 color (4-2)
3 lasers (blue, red, violet)	8 color (4-2-2)
3 lasers (blue, red, violet)	10 color (4-3-3)
3 lasers (blue, red, violet)	12 color (4-3-5)

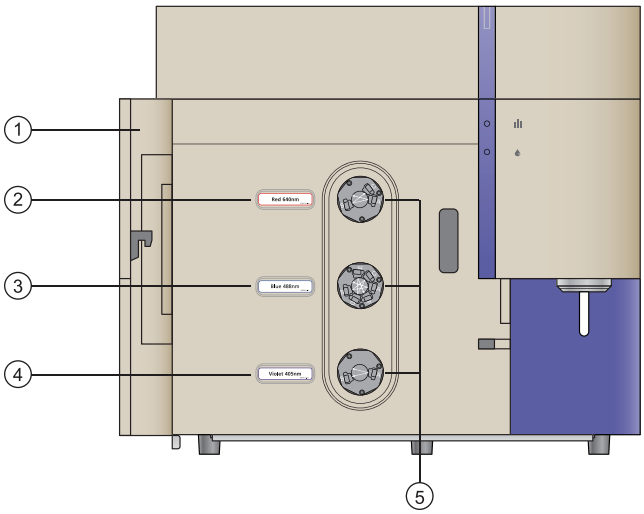
More information

- Optical components (page 25)
- Fluidics components (page 26)
- System options and upgrades (page 28)
- See Cytometer Configurations in the *BD FACSLyric™ Clinical Reference System*

Optical components

Location of optical components

The optical compartment is located on the front of the cytometer, behind the front door. The heptagon arrays for each laser are accessible when the door is open. The following figure shows the locations of the optical components.



No.	Description
1	Front door in open position
2	Red laser (640 nm)
3	Blue laser (488 nm)
4	Violet laser (405 nm)
5	Heptagon detectors, one for each laser

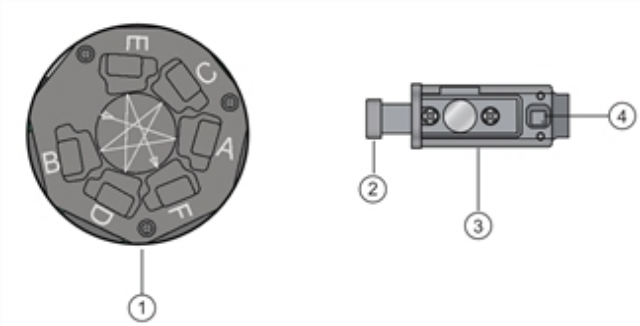
Heptagon detector arrays

The heptagon detector arrays contain the filters, mirrors, and photomultiplier tubes (PMTs) for each laser. There is a separate heptagon for each laser.

Filter holders

For all channels, there is a removable filter holder. The filter holder has an ID chip that identifies the holder to the system so the software can confirm that the correct filter holder is in place.

The following figure shows a heptagon and a filter holder.



No.	Description
1	Heptagon
2	Handle
3	Filter holder
4	ID chip

Location of lasers

The system lasers and beam-steering optical components are located at the top of the cytometer, under the top cover. There is no user access to the laser area.

More information

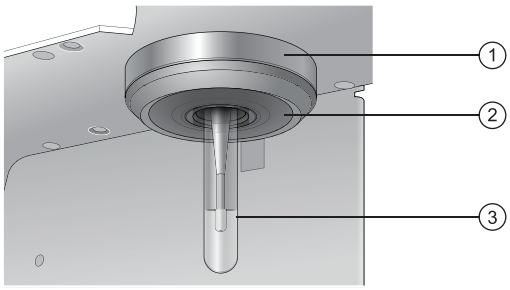
- Fluidics components (page 26)
- System options and upgrades (page 28)

Fluidics components

Manual tube port

The manual tube port is located on the right front of the cytometer. A circular LED indicator at the base of the port turns green when the system is ready to accept a tube.

The following figure shows the manual tube port.



No.	Description
1	Manual tube port
2	LED status indicator
3	Tube loaded on port

The following table describes the conditions and status of the LED status indicator.

Condition	Status
Solid green	Ready to accept a tube
Blinking green	Error, SIT moving down without a tube present
Solid amber	SIT flush in progress, do not load a tube
Off	Tube is loaded

Sample injection tube (SIT)

The sample injection tube (SIT) aspirates sample from a tube or a well and delivers it to the flow cell.

Qualified tubes

Only the following tubes have been qualified for use on the manual tube port on the cytometer. For optimal performance in reducing carryover when using 5-mL tubes, it is important to ensure that the wash probe does not make contact with the sample by filling to 0.5 mL or less, and to take care when loading tubes into position on the manual port.

Tube type	Maximum volume
Falcon® 5-mL (12 x 75-mm) polystyrene	2 mL
Falcon 5-mL (12 x 75-mm) polypropylene	2 mL
BD Trucount™ 5-mL (12 x 75-mm)	2 mL

Sheath filter

The sheath filter is located on the left side of the cytometer behind the access door. The sheath filter should be changed every 3 months.

More information

- Replacing the sheath filters (page 164)
- System options and upgrades (page 28)

System options and upgrades

Introduction

The BD FACSLyric™ system options and available upgrades are listed and described in the following table.

Category	Option	Description
System hardware	BD FACS™ Universal Loader	The Loader is an optional automated loading system that mixes samples and delivers tube racks to the BD FACSLyric™ system for acquisition. See BD FACS™ Universal Loader overview (page 112).
	Handheld barcode reader	The handheld barcode reader plugs into the USB port on the system computer workstation and reads most current barcode standards. See the topic about the barcode reader in the *BD FACSLyric™ Clinical Reference System*.
Optics	Laser upgrades	Upgrade a 2-laser to a 3-laser system. The number of colors on a 2-laser system can be upgraded from a 4-color system to a 6-color system. For a 3-laser system, upgrades are available up to 12 colors from any lower-color configuration.
Fluidics	Large fluidics tanks (10-L capacity)	The optional large volume sheath and waste tanks do not have a dock and are normally stored on the floor. See topics about the fluidics tank options in the *BD FACSLyric™ Clinical Reference System*.
	Cubitainer	Sheath fluid can also be supplied from a BD FACSFlow™ cubitainer by using an optional adapter.
Remote diagnostics	BD Assurity Linc™ software	BD Assurity Linc™ software is a highly secure remote systems management service that connects BD instruments and BD technical support personnel. Using the BD Assurity Linc™ Agent, BD support personnel can securely access your workstation (with your approval) through an enterprise server and diagnose problems remotely. See the topic about BD Assurity Linc™ software in the *BD FACSLyric™ Clinical Reference System*.
Assays	BD IVD assays	Contact your BD representative for a current list of available BD assays.
Laboratory Information System/Laboratory Information Management System (LIS/LIMS)	BD FACSLink™ software	BD FACSLink™ software provides an interface solution to an LIS/LIMS (available worldwide).

Software overview

Introduction

This topic provides an overview of the basic features and functionality of the BD FACSuite™ Clinical application that controls the BD FACSLyric™ cytometer and the optional BD FACS™ Universal Loader.

The software is used to operate the instrument, acquire samples, and analyze the data. Quality control performance, tracking, and reporting are streamlined and automated. Routine tasks such as startup and shutdown can be programmed to occur automatically.

Setup and QC

The software provides comprehensive tools to run QC and to set up the cytometer on a daily basis to maintain precise and reproducible results and ensure consistent performance.

The setup and QC procedures use BD® CS&T Beads to measure and adjust cytometer PMT voltages. This ensures that target values for the cytometer and the assays are maintained.

As part of the QC tracking function, Levey-Jennings charts are generated daily. Use these charts to track and set acceptance criteria for various performance parameters. QC reports are generated to help document and track the system performance over time.

BD IVD assays

In the BD FACSuite™ Clinical application, you can measure and analyze samples using BD IVD assays. Assays are run as entries in a worklist, which provides batch acquisition and analysis.

BD IVD assays are predefined to target specific cell populations. The data displays during preview and acquisition, and the plots with algorithm gates on the lab report are designed for specific results. The gates can be adjusted, but the gating hierarchy and other report elements cannot be changed.

The e-signature function can be enabled; the audit trail function is automatically enabled. When enabled, the e-signature function requires that one or more authorized persons sign the report. Up to three e-signatures can be configured. The audit trail tracks changes to entries and keeps a log.

Worklist

The worklist is a set of tasks to be performed. It organizes the tasks and their associated tubes, status, and other information into entries. Each task in an entry includes an assay or fluidics (cleaning or maintenance) procedure.

Using the worklist, you can acquire tubes in entries, display acquisition data, perform analysis on the acquired data, and export data automatically based on your preferences.

With the BD FACS™ Universal Loader option, you can load tube racks and run worklists in a more automated manner.

Library

The library stores and manages shared resources and assay properties. Resources include assays, beads, reagents, keywords, labels, and tube settings. You can import, add, edit, and delete some resources.

Resources are used as elements in worklists and in setup and QC. For example, you can assign a keyword to an entry in a worklist.

Rearranging and restoring the workspace

You can rearrange the workspace to fit your specific workflow and application needs. You can also restore the default layout in all workspaces:

- Setup and QC workspace
- Worklist workspace
- Library workspace

To restore a workspace layout, select **View > Restore Default Layout**. If the workspace is already using the default layout, the command will be grayed out and disabled.

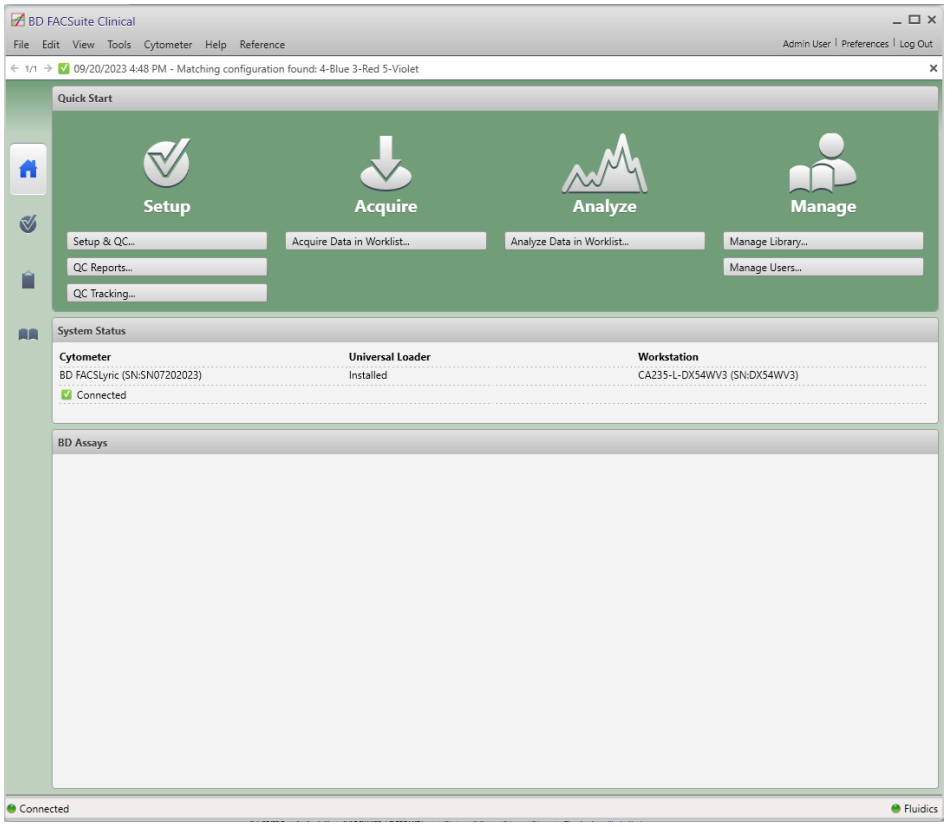
About the Home page

Introduction

The Home page is the default starting page. This page includes the following sections:

- **Quick Start** At the top of the Home page, displays shortcuts for the most commonly used workflows or operations.
- **System Status** In the center of the Home page, displays the current status and serial numbers of the system for the fluidics, lasers, LIS/LIMS connection status (if applicable), all system components, and the connection status. It also displays all installed options.
- **BD Assays** In the lower section of the Home page, displays the list of currently installed BD IVD assays and their version numbers. In the BD FACSuite™ Clinical application, the window also displays the Unique Device Identifier (UDI) associated with each BD IVD assay.

BD FACSuite™ Clinical application Home page:



Quick Start shortcuts

The following table describes the available Quick Start shortcuts.

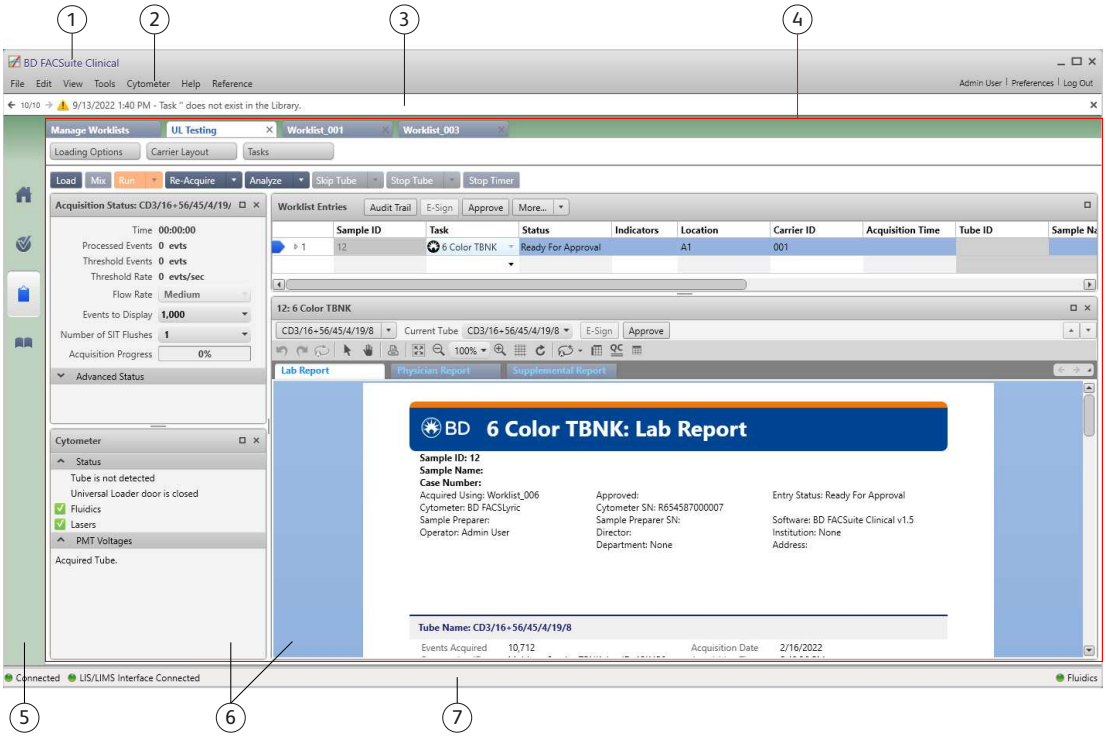
Icon	Button	Description
	Setup & QC	Opens the Setup & QC workspace and displays the Setup & QC tab.
	QC Reports	Opens the Setup & QC workspace and displays the QC Reports tab.
	QC Tracking	Opens the Setup & QC workspace and displays the QC Tracking tab.
	Acquire Data in Worklist	Opens the Worklists workspace and displays a new worklist.

Icon	Button	Description
	Analyze Data in Worklist	Opens the Worklists workspace and displays the Manage Worklists tab.
	Manage Library	Opens the Library workspace and displays the categories of library resources.
	Manage Users	(Administrator and ITStaff users only) Opens the User Management dialog and displays the list of users.

Software components

Window components

The software windows consist of the following components.



No.	Description	Function
1	Title bar	Displays the software product name and the standard window controls (minimize, maximize, close).
2	Menu bar	See the next section.

No.	Description	Function
3	Message bar	Located at the top of the window (below the Menu bar), displays system messages.
4	Workspaces	Contain the panels, fields, tables, and tools required for a specific function. Individual workspaces are provided for setup and QC, worklists, and the library.
5	Navigation bar	Located at the left side of the window. Click the navigation bar icons to open the different workspaces.
6	Panels	Contain the tools, fields, and options for performing specific, detailed functions required for a workspace. You can maximize, minimize, or reposition most panels on the screen.
7	Status bar	Located at the bottom of the window, displays the current cytometer connection status, fluidics status, and an acquisition progress bar. Also includes status of the LIS/LIMS connection, if installed.

Menu bar

The menu bar displays the following software menus.

Menu	Description
File	This menu includes specific tools and items for the current window or workspace. Choices include importing, exporting, printing, saving, and managing specific workspaces (for example, opening a worklist).
Edit	This menu includes Cut, Copy, Paste, Delete, Undo, Redo, and other editing tools.
View	This menu includes display control items.
Tools	This menu includes user management, preferences, administration, tracking, and setup items.
Cytometer	This menu includes cytometer cleaning, instrument information, and control items.
Help	This menu includes documentation in PDF format and basic software information.
Reference	This menu includes the *BD FACSLyric™ Clinical Reference System*. Use the Reference System to view and search for information on using the system.
User profile (username)	This menu item opens the My Profile dialog. Use this dialog to manage your login password and user profile information.
Preferences	This menu item opens the Preferences dialog. Use this dialog to set preferences.
Log Out	This menu item logs the current user out of the software.

More information

- Software overview (page 29)

Daily workflow

The following diagram shows the typical daily workflow for the BD FACSLyric™ system.

More information

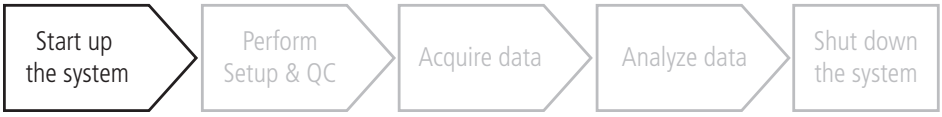
- System startup and shutdown (page 35)
- Daily setup and QC (page 41)
- About the worklist (page 54)
- Maintenance (page 155)

3

System startup and shutdown

This chapter includes the following topics:

Performing system startup



Introduction

This topic describes how to perform the normal system startup procedure. You can also set up a pre-programmed time and day to start the system automatically.

See information about setting cytometer schedule preferences in Setting system preferences (page 134).

Required materials

The following list describes the required materials for daily operation of the system.

- BD FACSFlow™ sheath fluid
- Bleach of 5% sodium hypochlorite concentration for the waste tank
- Deionized (DI) water
- BD® CS&T Beads

Prerequisite

Before first use, inspect the instrument for any cracks, breaks, or dents that might have occurred during shipment. If you see any damage, do not use the instrument. Call your BD technical support representative.

Procedure

To start up the system:

1. Turn on the power to the system by pressing the Power button.

   The Power button turns green when system power is on.

2. Wait 20 minutes for the system to warm up before starting any acquisition work.
3. Log in to the software.

   a. Double-click the **BD FACSuite™ Clinical** icon to start the software.
   b. Enter a username and password.
   c. Acknowledge you read and understood the statement on the login screen and select the checkbox.
   d. Click **OK**.
4. Verify that the software is connected to the cytometer by looking for the green **Connected** status icon in the lower-left corner of the workspace.
5. Check the fluid levels.

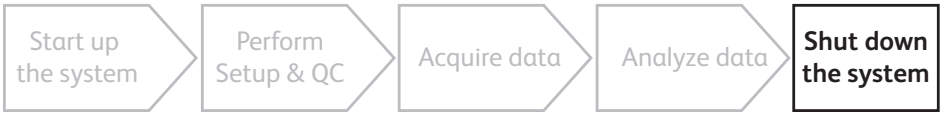
a. Check the sheath tank to ensure that there is enough sheath fluid to perform your work.
b. Check the waste tank to ensure there is adequate capacity.

6. Verify that the fluidics system is ready by looking for the green **Fluidics** status icon in the lower-right corner of the workspace.

More information

- Refilling the sheath tank (page 158)
- Emptying the waste tank (page 159)
- Setting system preferences (page 134)

Performing manual system shutdown



Introduction

This topic describes the manual system shutdown procedure. Use this procedure to manually perform the daily cleaning and shutdown of the system.

Alternatively, you can program the system to shut down automatically. See Performing automated system shutdown (page 38).

Required materials

- 1 tube containing 2 mL of bleach solution diluted to 0.5% sodium hypochlorite
- 1 tube containing approximately 3 mL of DI water
- Disposable towels or wipes

Procedure

To manually shut down the system:

1. From the menu bar, select **Cytometer > Daily Clean**.

   The Daily Clean dialog opens.

2. Place a tube containing 2 mL of bleach solution (0.5% sodium hypochlorite) on the manual tube port, then click **Continue**.

3. When prompted, place a tube containing approximately 3 mL of DI water on the manual tube port, then click **Continue**.

   The dialog closes after the tube is unloaded from the manual tube port.

4. Load a tube containing 2 mL of DI water on the manual tube port.

Always leave a tube of DI water on the manual tube port whenever the system is not in use.

5. Clean external surfaces.

   a. Wipe down the external surfaces of the cytometer and work area.
   b. Dispose of the used cleaning materials in biohazard containers.

6. From the menu bar, select **Cytometer > Shutdown**.

   The Cytometer Shutdown dialog opens.

7. Click **Yes**.

   The Power button blinks green for a few seconds, then power to the system turns off and the Power button turns amber.

8. Log out of the software.

   a. From the right side of the menu bar, click the **Log Out** button.
   b. In the confirmation dialog, click **Yes**.

More information

- Performing system startup (page 36)
- Performing automated system shutdown (page 38)

Performing automated system shutdown

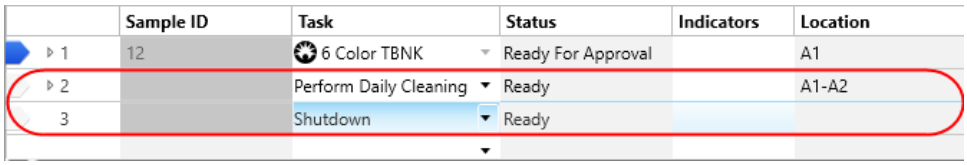
Start up the system | Perform Setup & QC | Acquire data | Analyze data | **Shut down the system**

Introduction

This topic describes how to automate the process for shutting down the system by adding cleaning and shutdown entries to a worklist and then running that worklist using the Loader.

You can also set a preference to shut down the system after a specified length of idle time. See Setting cytometer schedule preferences (page 134).

The following figure shows a sample worklist with cleaning and shutdown entries added.



	Sample ID	Task	Status	Indicators	Location
1	12	6 Color TBNK	Ready For Approval		A1
2		Perform Daily Cleaning	Ready		A1-A2
3		Shutdown	Ready		

Procedure

To run an automated shutdown using a worklist:

1. Prepare a tube containing 2 mL of bleach solution diluted to 0.5% sodium hypochlorite and a tube containing approximately 3 mL of DI water.
2. Place the tubes in a 30- or 40-tube rack. Do not use a plate.
3. Create a worklist with a Daily Clean and Shutdown as the last tasks.
4. Run the worklist.

   When the worklist is finished, the system power turns off.

5. Place a tube of DI water on the manual tube port.

   A tube containing 2 mL of DI water should be loaded on the manual tube port whenever the system is not in use.

More information

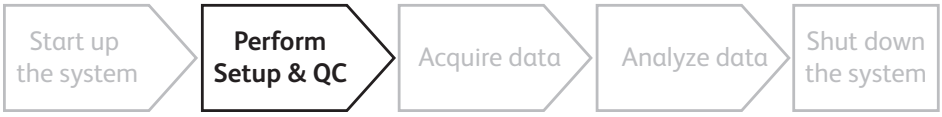
- For details about creating cleaning and shutdown entries in a worklist, see topics on adding fluidics cleaning or shutdown to a worklist in the *BD FACSLyric™ Clinical Reference System*.

4

Daily setup and QC

This chapter includes the following topics:

Daily setup and QC workflow



Daily setup and QC tasks

Perform the daily performance QC task each day before you acquire and analyze data using worklists.

More information

- Running daily performance QC (page 42)
- About the Setup and QC workspace (page 46)
- About QC reports (page 47)

Running daily performance QC

Introduction

This topic describes how to run daily performance QC.

A typical performance QC should take approximately 5 to 10 minutes if the BD® CS&T Beads have already been prepared.

As a part of performance QC, Lyse/Wash and Lyse/No-Wash tube settings are updated through assay and tube settings setup. All assays using these tube settings are therefore updated, and reports can be generated. For more information on these settings, see the *BD FACSLyric™ Clinical Reference System*.

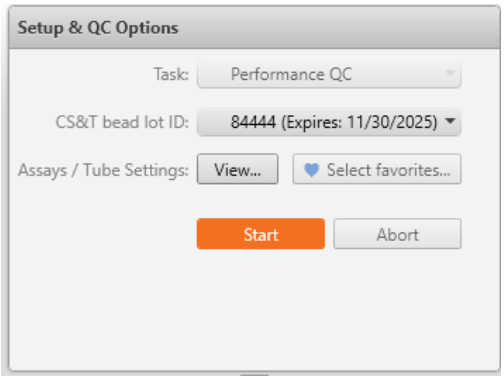
Procedure

To run daily performance QC:

1. Prepare a tube with BD® CS&T Beads according to the directions in the instructions for use for the beads.
2. On the navigation bar, click **Setup & QC**.

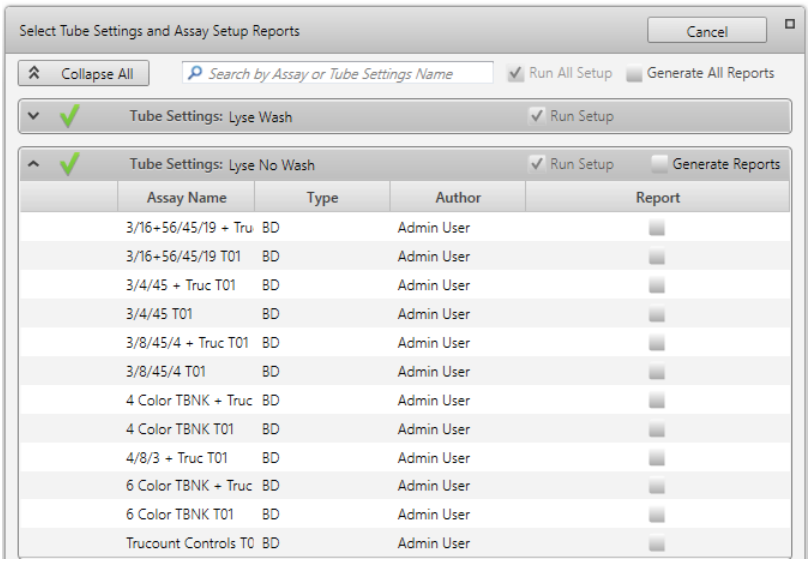
   The Setup & QC workspace opens.

3. In the **Setup & QC Options** panel, verify that **Performance QC** is selected.



4. Verify that the correct CS&T bead lot ID is selected.
5. To view the assays that will be included in the daily performance QC task, click **View** next to the **Assays / Tube Settings** prompt.

   The panel opens similar to the following:



6. In the **Report** column, select the assays for which a report is desired.

   The reports reflect the results of assay and tube settings setup.

7. In the **Setup & QC Options** panel, click **Start**.

   The Load Tube dialog opens.

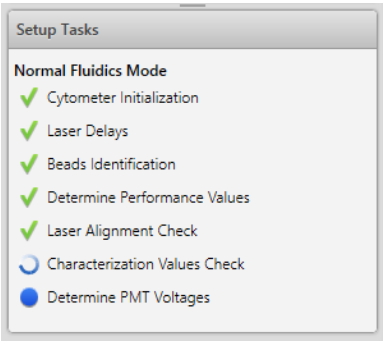
8. Load the tube of BD® CS&T Beads onto the manual tube port.

   The system detects the tube and prompts for confirmation of its contents.

9. Click **Continue** to initiate the setup tasks.

   The details for normal fluidics modes are displayed in the Setup Tasks panel. A checkmark indicates that a step in the task has been completed.

Setup Tasks dialog for the BD FACSuite™ Clinical application:



When all tasks are complete, the system displays a dialog to unload the tube.

10. Unload the tube from the manual port.

    A dialog opens and indicates whether the task completed successfully.

    Caution! If the setup tasks did not pass, we recommend that you do not proceed. Instead, see topics on failed setup tasks in the Troubleshooting section of the *BD FACSLyric™ Clinical Reference System*.

    Note: If the setup task passes with warnings or notifications, refer to About QC reports (page 47) and the troubleshooting section in the *BD FACSLyric™ Clinical Reference System* for more information and recommended solutions.

11. Click **Yes** to view the performance QC report or click **No** to close the dialog.

More information

- About the Setup and QC workspace (page 46)
- Importing or adding a CS&T or FC bead lot (page 149)
- About QC reports (page 47)

Selecting and viewing Performance QC favorites

The Performance QC (PQC) task automatically includes all assays using Lyse Wash and Lyse No Wash tube settings. PQC favorites let your most commonly used other tube settings be included in the PQC task so that you do not need to run a separate setup task for these tube settings on a daily basis. A maximum of 10 PQC favorites can be selected.

Note: The volume of CST beads must be sufficient to complete PQC including all favorite assays selected.

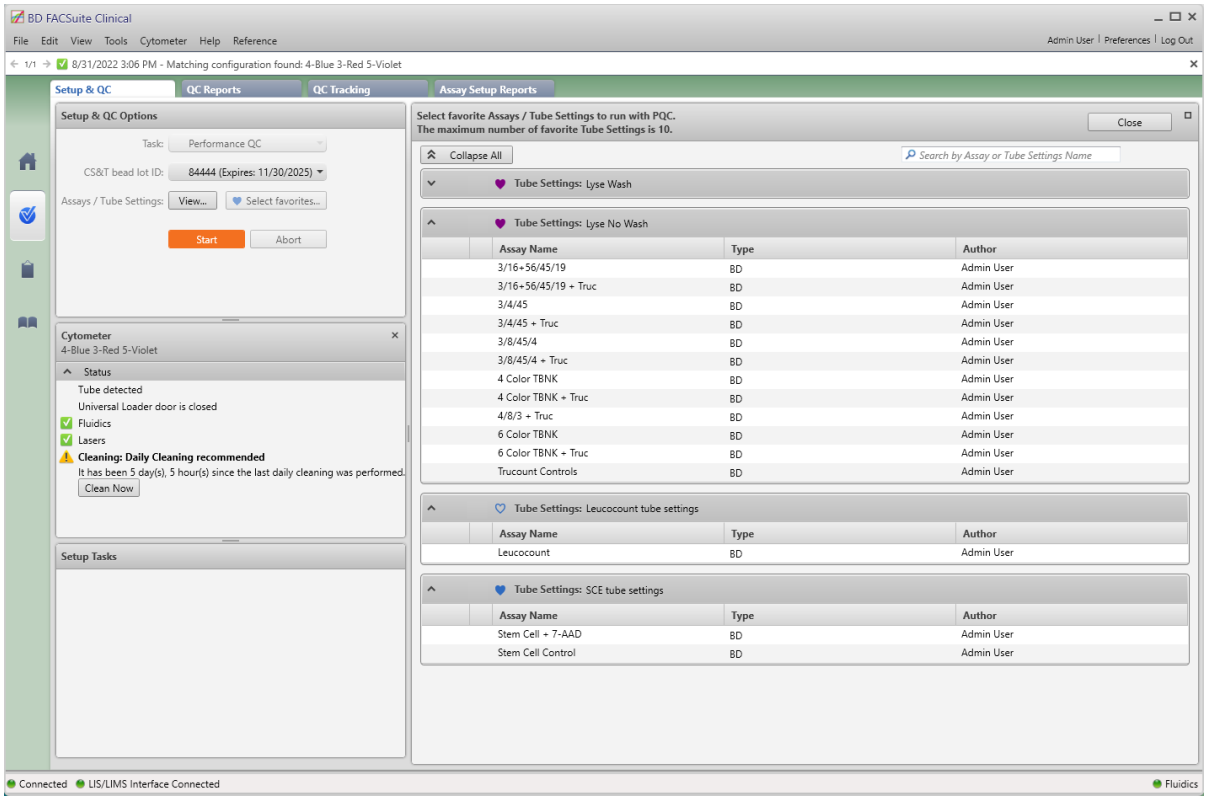
Adding tube settings to PQC favorites

A **Select favorites...** button is displayed in the Setup & QC Options panel on the Setup & QC tab. To select tube settings and their associated assays to be included in the PQC task:

1. Click **Select favorites...**.

   The panel on the right displays a table for each available tube setting.

   Every BD tube setting is available for selection as a PQC favorite independent of Setup & QC preferences.



   A heart-shaped Favorites icon in the header of each table indicates its PQC favorites status. A solid purple Favorites icon denotes a Lyse Wash or Lyse No Wash tube setting that cannot be edited. These tube settings are always included in the PQC task. If the Favorites icon is a filled solid cyan color, it is selected as a PQC favorite and the corresponding tube settings will be included in the PQC task. If only the outline of the Favorites icon is colored, the corresponding tube settings will not be included in the PQC task.

2. Click a cyan-colored heart-shaped Favorites icon in a table header to select or deselect the corresponding tube settings as a PQC favorite.

Viewing tube settings that are included in the PQC task

A **View...** button is displayed in the Setup & QC Options panel on the Setup & QC tab. To view tube settings and their associated assays that are included in the PQC task:

1. Click **View...** in the Setup & QC Options panel.

   The panel to the right displays a table for each of the tube settings included in the PQC task. A heart-shaped Favorites icon is displayed in each table header. The Favorites icon is solid purple for Lyse Wash and Lyse No Wash tube settings that are always included in the PQC, and the color is solid cyan if the tube setting is selected as a PQC favorite.

About the Setup and QC workspace

Introduction

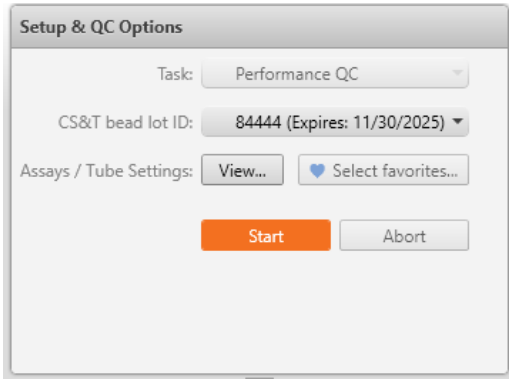
The Setup and QC workspace includes multiple tabs that you use to perform different setup and quality control tasks, view reports, and track QC over time.

To open the Setup and QC workspace, click Setup & QC on the navigation bar.

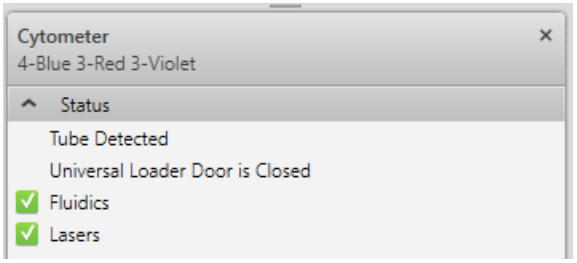
Setup & QC tab

The Setup and QC tab includes the following panels:

- **Setup & QC Options** Use this panel to select setup and QC tasks, select CS&T bead lots, view and select assays and tube settings to be added in addition to those that use LW/LNW settings, and start or abort setup and QC operations.



- **Cytometer** This panel displays the current cytometer configuration and the current cytometer status. The status area displays the system status (including information for a tube loaded on the manual tube port), fluidics, and lasers. This panel also indicates when you need to run system cleaning protocols.



- **Setup Tasks** This panel displays real-time status of setup and QC task steps. Green checkmarks indicate completed steps.

QC Reports tab

In the QC Reports tab, the Reports panel lists all of the reports that are generated when you perform a characterization, performance, or laser setup QC task, or a bead lot transfer.

Reports contain details about the system, detector settings, lasers, setup bead lots, and cytometer settings, as well as warnings, errors, and notifications. Click a report in the table to view, print, or export the report.

QC Tracking tab

Use the QC Tracking tab to view performance values in Levey-Jennings charts and to set the alarm ranges and scales. Levey-Jennings charts are used to track the instrument performance over time.

Assay Setup Reports tab

In the Assay Setup Reports tab, the Assay Setup Reports table lists all of the reports that are generated when you perform assay and tube settings setup.

Reports contain details about the assay-specific instrument settings, cytometer configuration, setup bead lot, and user, as well as warnings or errors. Click a report in the table to view, print, or export the report.

More information

- Running daily performance QC (page 42)
- About QC reports (page 47)

About QC reports

Introduction

This topic describes the content of the QC reports. You can access these reports in the Setup & QC workspace, in the QC Reports tab.

QC report content

QC reports contain information about the system, detector settings, lasers, setup bead lots, cytometer settings, and warnings, errors, and notifications relevant to the task. They are generated after characterization QC, performance QC, laser setup, and bead lot transfers.

The status is listed in the Reports panel as either Passed or Failed. Items that have passed might include a status icon indicating that there are warnings or notifications, despite the Passed status.

System information

The top section displays the cytometer type, name, configuration, serial number, options, last characterization and QC date, and user and institution identity.

Summary

This section displays pass/fail status. Pass status is indicated by the word *PASSED*. Fail status is indicated by the word *FAILED*.

Errors, warnings, and notifications

If an error, warning, or notification is generated from the characterization QC, the following information will be displayed in a table for review.

Section or field	Description
Parameter	Name of parameter with error
Value	Current value of the parameter
Range	Expected value range for the parameter
Message	Reason for the warning

Errors

If the status is Failed, an Errors section is created in the report to highlight the issue. Red text indicates the out-of-range or expired values. Refer to the troubleshooting section in the *BD FACSLyric™ Clinical Reference System* for more information.

Example from a QC Report:

SUMMARY: FAILED

ERRORS

Parameter	Value	Range	Message
Blue-PE-Cy7 Linearity (±2%) Min Channel	539	<= 500	Value exceeds allowable maximum of 500

DETECTOR SETTINGS

Lot Info	Detector				PMT		Bright Bead			Mid Bead		Dim Bead		Linearity (±2%)		Resolution			
	Name	Mirror	Filter	Position	Voltage at LW Settings	Slope of Gain	Median at LW Settings	Median at QC Settings	%rCV	Median at QC Settings	%rCV	Median at QC Settings	%rCV	Min Channel	Max Channel	Sensitivity	Electronic Noise RSD	Qr (x10^3)	Br
LASER: Blue (Wavelength = 488nm)																			
X	FSC	-	-	FSC	241.5	0.0040	17,965	120,597	1.2	120,504	1.2	24,729	1.3	N/A	N/A	327	N/A	N/A	N/A
X	SSC	10	488/15	E	427.3	8.2348	125,949	121,251	2.3	121,977	2.2	56,382	1.8	N/A	N/A	1,417	N/A	N/A	N/A
X	FITC	507LP	527/32	D	512.8	8.7878	15,689	100,835	2.1	2,683	10.1	573	23.9	175	229,303	496	19.9	58.6	87
X	PE	560LP	586/42	C	464.4	8.5975	22,450	101,128	1.6	2,157	7.4	452	21.2	84	230,511	1,108	18.6	573.8	154
X	PerCP-Cy5.5	665LP	700/54	B	608.2	8.8680	36,448	97,895	2.8	2,497	12.1	497	27.8	171	229,906	319	19.9	27.1	68
X	PE-Cy7	752LP	783/56	A	662.1	8.8327	15,334	98,541	4.7	2,281	27.3	553	59.6	**539**	227,680	520	18.6	28.5	17
LASER: Red (Wavelength = 640nm)																			
X	APC	660/10	660/10	C	520.2	8.6874	48,690	100,727	2.1	2,066	9.8	357	24.3	132	230,028	563	19.4	46.8	34
X	APC-R700	705LP	720/30	B	496.3	8.5010	22,215	99,799	2.1	3,040	7.5	788	14.4	124	228,289	150	19.4	17.7	66

Warnings

Warnings are displayed with Passed status to highlight when the current values have changed by 50% since characterization QC. Red text indicates out-of-range or expired values.

Example from a QC Report:

SUMMARY: PASSED

WARNINGS

Parameter	Value	Range	Message
Violet-V450 Bright Bead %rCV for Normal Mode (Laser Alignment Check)	1.9	<= 1.9	Value exceeds allowable maximum of 1.9

Out-of range value in **DETECTOR SETTINGS** table:

Lot Info	Detector				PMTV at LW Settings		Bright Bead			Linearity (±2%)		Resolution			
	Name	Mirror	Filter	Position	Actual	Δ	Median at LW Settings	Median at QC Settings	% rCV	Min Channel	Max Channel	Sensitivity		Qr (x10³)	Br
												Actual	% Diff		
LASER: Red (Wavelength = 640nm)															
X	APC-Cy7	752LP	783/56	A	543.6	0.4	69,862	100,094	1.7	148	226,337	125	-1	37.0	179
LASER: Violet (Wavelength = 405nm)															
X	V450	448/45	448/45	E	528.2	-0.7	8,558	100,327	**1.9**	165	224,768	224	2	294.4	1,980
X	V500-C	500LP	528/45	D	441.2	-0.3	31,139	100,649	1.8	148	235,133	198	19	138.7	838
X	BV605	606/36	606/36	C	447.1	-0.4	6,113	100,850	2.4	114	227,320	3,084	8	543.2	18
X	BV711	715/50	715/50	B	509.3	0.0	32,056	99,600	3.1	162	236,646	2,083	3	160.7	5
X	BV786	755LP	755	A	561.7	0.4	57,430	101,395	4.5	126	231,451	1,501	-1	64.8	3

Notifications

Notifications are displayed for the following reasons:

- Indicated values are outside of Levey-Jennings alarm ranges. Review Levey-Jennings plots to see if the instrument performance is changing over time.
- No value: values that could not be calculated because the baseline does not have the corresponding measurement.

Note: Notifications alone do not indicate a problem with the instrument. The information is provided to encourage evaluation of the Levey-Jennings plots.

Example from a QC report:

SUMMARY: PASSED

NOTIFICATIONS

Parameter	Value	Range	Message
Violet-V450 Qr (x10³)	110.1	55.0 - 107.3	Value is outside of +/- 3SD alarm limits
Violet-V500-C Qr (x10³)	73.4	28.0 - 69.0	Value is outside of +/- 3SD alarm limits
Violet-BV711 PMT Voltage	548.3	551.4 - 571.9	Value is outside of +/- 3SD alarm limits
Violet Laser Delay Trigger on FSC	-36.30	-36.18 - -33.88	Value is outside of +/- 3SD alarm limits
Violet Laser Delay Trigger on Fluorescence	-36.32	-36.19 - -33.90	Value is outside of +/- 3SD alarm limits

Detector settings for performance QC Report

This table displays information that is displayed in the performance QC reports.

Section	Field	Description
Detector	Name	Name for the detector
	Mirror	Name of the mirror used with the detector
	Filter	Description of wavelengths transmitted
	Position	Location of the filter holder with mirror
PMTV at LW Settings	Actual	Measured PMT voltage
	Delta	Delta from characterization QC value
Bright Bead	Median at LW Settings	Median fluorescence intensity (MFI) value of the specific beads at LW settings
	Median at QC Settings	MFI value of the specific beads at QC settings
	%rCV	Percent robust coefficient of variation of the bright beads
Linearity	Min Channel	The lower end of the linear range for the detector
	Max Channel	The upper end of the linear range for the detector
Resolution	Sensitivity Actual	The ratio of the MFI of the bright bead to two times the standard deviation of noise of a given detector
	Sensitivity % Diff	Percent difference from characterization QC value
	Qr	Relative fluorescence detection efficiency, used for describing the light collection efficiency of a detector
	Br	Relative optical background signal, used for tracking the optical background noise levels in a detector

Detector settings for characterization QC Report

This table displays information that is displayed in the characterization QC reports.

Section	Field	Description
Detector	Name	Name for the detector
	Mirror	Name of the mirror used with the detector
	Filter	Description of wavelengths transmitted
	Position	Location of the filter holder with mirror

Section	Field	Description
PMT	Voltage at LW Settings	Measured PMT voltage at LW settings
	Slope of Gain	Slope of the PMT voltage vs brightness for bright beads (log MFI vs log PMT voltages)
Bright Bead	Median at LW Settings	Median fluorescence intensity (MFI) value of the specific beads at LW settings
	Median at QC Settings	MFI value of the specific beads at QC settings
	%rCV	Percent robust coefficient of variation of the bright beads
Mid Bead	Median at QC Settings	MFI value of the specific beads at QC settings
	%rCV	Percent robust coefficient of variation of the mid beads
Dim Bead	Median at QC Settings	MFI value of the specific beads at QC settings
	%rCV	Percent robust coefficient of variation of the dim beads
Linearity	Min Channel	The lower end of the linear range for the detector
	Max Channel	The upper end of the linear range for the detector
Resolution	Sensitivity	The ratio of the MFI of the bright bead to two times the standard deviation of noise of a given detector
	Electronic noise rSD	Robust standard deviation (rSD) of the electronic noise in the particular detector, used to predict the minimum acceptable signal levels required for the best attainable resolution and sensitivity for the system
	Qr	Relative fluorescence detection efficiency, used for describing the light collection efficiency of a detector
	Br	Relative optical background signal, used for tracking the optical background noise levels in a detector

Laser settings

The measurements shown in this section of the report are cytometer-dependent.

Section	Field	Description
Laser		Laser name
Position		Location of each laser
Delay	Trigger on FSC	Laser delay values when thresholding on FSC
	Trigger on Fluorescence	Laser delay values when thresholding on fluorescence
Area Scaling Factor		Area scaling factors that are determined by setting area and height values equally on the bright 3-µm beads

Section	Field	Description
Power (mW)	Actual	Laser power measured in milliwatts
	Spec	Laser power specification in milliwatts
Current (mA)	Actual	Laser current measured in milliamperes
	Spec	Laser current specification in milliamperes

Info

This section displays information on the setup beads and the cytometer settings that were used.

Field	Description
Bead Lot ID	Setup bead identifier on the kit label
Expiration date	Date after which the bead activity is not guaranteed
Window extension	The amount of time added to collect the signal pulse below the threshold
FSC Area Scaling Factor	Area scaling factor that is determined by setting the FSC area and height values on the bright 3-µm beads

Comments

The Comments section displays comments that were previously added to the report. Click the Comments icon to add a new comment to the report.

Linearity results

This section of the report shows linearity plots for each detector. They are included only if the preference is turned on. See Specifying report preferences (page 136).

A detector's linear range is determined by measuring the MFI ratio of bright beads to mid beads across the detector's dynamic range. The ratio values from the middle of the range, which is known to be linear, are averaged and compared against individual ratios. If the difference between the measured ratio and the averaged ratio is greater than 2%, the results are not considered linear.

More information

- Running daily performance QC (page 42)
- About the Setup and QC workspace (page 46)

5

Worklist overview

This chapter includes the following topics:

About the worklist

Introduction

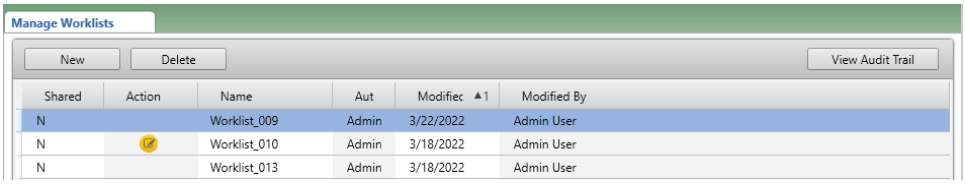
Samples are acquired and data is analyzed using a worklist. A worklist is a list of tasks to be performed for sample acquisition and analysis. Tasks include the assays being run and other operations such as daily clean, SIT flush, and shutdown. The worklist organizes multiple entries, which include sample IDs, tubes, tasks, status, and other information about the sample.

You can acquire individual entries, tubes, or an entire worklist, then perform individual sample analysis or batch analysis.

To open the Worklists workspace, click the Worklists icon on the navigation bar, or click either the Acquire Data in Worklist or Analyze Data in Worklist shortcuts on the home page.

Manage Worklists tab

The Worklist workspace includes the Manage Worklists tab, which contains a list of all worklists.



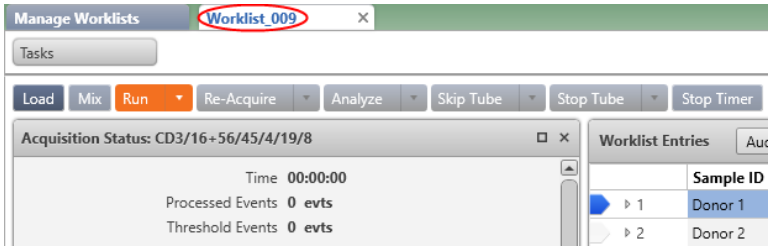
Use the **Manage Worklists** tab to create new worklists, delete worklists, view the worklist audit trail, open existing worklists, and share worklists with other users. Use the menu bar to create, rename, import, and export worklists. The Action column displays actions needed for worklists, such as approval required or acquisition required.

Audit Trail tab

Open the **Audit Trail** tab by clicking **View Audit Trail** in the **Manage Worklists** tab. The **Audit Trail** tab, if active, is always displayed next to the **Manage Worklists** tab. Besides maintaining an audit trail of current and deleted worklists, a worklist can be opened from the list of worklists on the **Audit Trail** tab. This can be advantageous on systems containing a large number of worklists because the list of worklists can be filtered and sorted.

Worklist tabs

Each worklist opens in a separate tab.



Use the worklist tabs to build your worklist, and acquire and analyze data.

More information

- Using the Manage Worklists tab (page 55)
- Working with the worklist manager audit trail (page 89)

Using the Manage Worklists tab

Introduction

Use the **Manage Worklists** tab to create new worklists, delete worklists, view the worklist audit trail, open existing worklists, and filter, search, and share worklists with other users.

Creating a worklist

To create a worklist:

1. On the navigation bar, click **Worklists**.

   The **Manage Worklists** tab opens.

2. Click **New**.

   The new worklist opens in a new tab in the Worklist workspace.

Opening a worklist

To open a worklist:

1. On the navigation bar, click **Worklists**.

   The **Manage Worklists** tab opens.

2. In the **Manage Worklists** tab, double-click a worklist in the table.

   The worklist opens in a new tab in the Worklist workspace.

Importing a worklist

To import a worklist from a folder:

1. On the navigation bar, click **Worklists**.

   The **Manage Worklists** tab opens.

2. From the menu bar, select **File > Import Worklist**.

   The Import Worklist dialog opens.

3. Navigate to the folder that contains the worklist you want to import and select the worklist.
4. Click **Open**.

   The worklist is displayed in the Worklist table.

Viewing worklist outstanding actions

If a worklist has outstanding actions that need to be performed on it, the **Action** column under the **Manage Worklists** tab displays one or more of the following status icons:

Icon	Action status
	Not all entries have been acquired.
	Not all entries have been approved.
	Unable to send test result to LIS/LIMS.

Deleting a worklist

Deleting a worklist makes the data files associated with the worklist inaccessible in the database. When you delete a worklist, the entry run packages (ERPs) for the worklist are automatically exported to the default export folder (as defined in worklist preferences). You can navigate to the export folder to locate and import the ERPs.

Worklist owners (authors) who are Operator users can change or delete only their worklists. Administrators can change or delete all worklists.

To delete a worklist:

1. Select a worklist.
2. If the worklist contains an LIS test order, make sure that the BD FACSLyric™ system is connected to the LIS. Otherwise, you will not be able to delete the worklist.
3. Click **Delete**.

The Delete Worklist dialog opens, which prompts for confirmation of the operation and displays a text box to enter a reason for deletion.

4. For auditing reasons, type a reason for deleting the worklist. Entering a reason may be required or optional, depending on your worklist preferences. See Setting the worklist deletion preferences (page 139).
5. Click **Yes**.

   The worklist is deleted.

Exporting a worklist

To export a worklist:

1. In the **Manage Worklists** tab, select a worklist.
2. From the menu bar, select **File > Export Worklist > With Data**.

   The Export Worklist path dialog opens.

3. Navigate to an export target folder.
4. (Optional) Modify the name of the worklist.
5. Click **Save**.

Opening the worklist Audit Trail tab

1. On the navigation bar, click **Worklists**.

   The **Manage Worklists** tab opens.

2. Click **View Audit Trail**.

   The **Audit Trail** tab displays next to the **Manage Worklists** tab. If tabs for individual worklists are open, they are redisplayed to the right of the **Audit Trail** tab.

More information

- About the worklist (page 54)

About the Worklist Entries table

Introduction

Within the Worklist tab, the Worklist Entries table organizes multiple entries to be acquired or analyzed, and displays status and other information about each entry. The Worklist Entries table is where you add, modify, and select entries.

About entries and tubes

The worklist is a set of entries which are specific to your samples. Each entry is either a fluidic task or an assay. Sample IDs must be entered for assay tasks, but not for fluidic tasks.

Each entry has an ID number. Each tube within an entry is a child of the entry. For example, if the entry number is 1, then the tube numbers are 1.1, 1.2, and 1.3.

Entries are collapsed by default, but can be expanded to show the tubes in each entry.

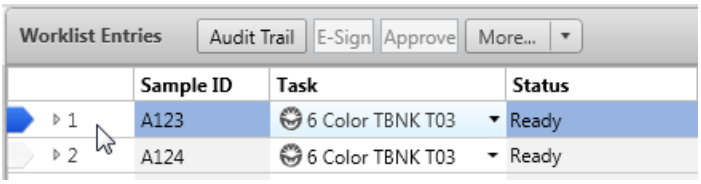
You can drag entries in the Worklist Entries table to change the run order.

Selecting entries and tubes

You can select one or more entries or tubes in a worklist. Any actions selected from the Worklist Entry Control toolbar are applied to all selected entries.

To select an entry:

1. Click between the entry number and the Sample ID column.



   You can select multiple entries by holding down the Shift key to select a range of entries, or the Ctrl key to select individual entries.

To select a tube:

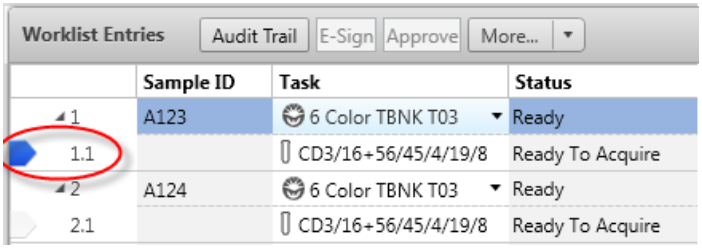
1. Expand an entry by clicking the arrow next to the entry number.
2. Click between the tube number and the Sample ID number.

   You can select multiple tubes by holding down the Shift key to select a range of tubes, or the Ctrl key to select individual tubes.

About the run pointer

The run pointer is used to select:

- Which entry to display in the Entry Details panel.
- Which entry an acquisition run starts with (only when you select Run from Pointer).



Worklist Entries table columns

The Worklist Entries table includes the following columns. Some columns in the worklist will be displayed only when running certain assays.

Column	Description
Sample ID	Each entry for an assay task requires a sample ID. You can specify a sample ID by typing in the Sample ID column for an entry, or by clicking in the column and scanning a barcode.
Task	A task is an action that is performed when you run a worklist. Tasks can be assays or fluidics actions. The list of installed assays is displayed by the task selector in the Task column. Assays consist of one or more tubes. When you add a task in the Task column, all tubes associated with the task are added to the entry. Fluidics tasks include: • Perform Daily Cleaning • Perform SIT Flush • Shutdown
Status (entry)	The current entry status is displayed in the Status column. • **Ready**. Indicates that the entry will be acquired during the worklist run. • **Not Ready**. Indicates that the entry does not have a sample ID or task, or another requirement of the assay is not met. Mouse over the status to view the condition that is not met. • **Incomplete**. Indicates that the acquisition of the entry has not been completed. • **Ready For Approval**. Indicates that the entry has been acquired and requires approval. This is displayed when automatic approval is disabled for the assay (default), or after modification of the entry removes the Approved status. • **Approved**. Indicates that the entry has been approved. This is displayed when automatic approval is enabled for the assay, and when no QC messages that trigger the Needs Review status are included in the report. It is also displayed when an entry has been approved manually. • **Needs Review**. Indicates that there are QC messages for the entry that indicate what should be reviewed before the entry is approved. This status requires manual approval.

Column	Description
Status (tube)	The current tube status is displayed in the Status column. • **Ready to Acquire**. Indicates that the tube is ready to be acquired and has all required information. • **Complete**. Indicates that the tube has been acquired. • **Stopping Criteria not met**. Indicates that there were insufficient events to meet the stopping rule.
Indicators	A worklist entry that allows gate sizes and positions to be modified displays a gating control status icon:
	All matching gates are at their last applied positions.
	All matching gates are at their last applied positions and the entry was the source of the last applied positions.
	At least one of the matching gates is different from last applied gate positions.
	A worklist entry with e-signature enabled displays an e-signature status icon:
	Worklist entry requires at least one e-signature before approval.
	Acquisition and sign-off is complete and the worklist entry is ready to be approved.
	The worklist entry may also display LIS/LIMS interface status:
	Entry created from an LIS/LIMS Interface test order.
	Results queued for transmission to LIS/LIMS interface.
	Results sent to LIS/LIMS Interface
	Unable to send results to LIS/LIMS Interface.
Location	The tube location on the Loader rack specified for the entry.
Carrier ID	The sample carrier ID for the entry. You can select different sample carrier types using the Loading Options panel. You can select a specific carrier using the Layout View panel.
Acquisition Time	The date and time of acquisition for the data file.
Tube ID	The ID number of the tube.
Sample Name	The name of the sample.
Case Number	The case number of the sample. This value can be configured on the LIS/LIMS server.
Trucount Lot ID	The lot ID for the BD Trucount™ Tube. Only used with assays that use BD Trucount™ Tubes.
Beads Per Pellet	The number of beads per pellet in the BD Trucount™ Tube. Only used with assays that use BD Trucount™ Tubes.

Column	Description
Keyword 1	The value for Keyword 1. This can be used to put additional information on the lab report. This value can be configured on the LIS/LIMS server.
Keyword 2	The value for Keyword 2. This can be used to put additional information on the lab report. This value can be configured on the LIS/LIMS server.
WBC (x1000)	White blood cell count, in thousands. Only used with assays that do not use BD Trucount™ Tubes.
Lymphs (%)	Percentage of lymphocytes. Only used with assays that do not use BD Trucount™ Tubes.
Lymphs (x1000)	Lymphocyte count, in thousands. Only used with assays that do not use BD Trucount™ Tubes.

Note: Other assay-specific keywords may be displayed to the right of the Tube ID column.

Printing a worklist

To print a worklist:

1. Open the worklist you want to print.
2. From the menu bar, select **File > Print > Worklist**.

   The Print dialog opens.

3. Complete your typical printing procedure.

Note: The selected printer must be capable of accepting input in PDF format.

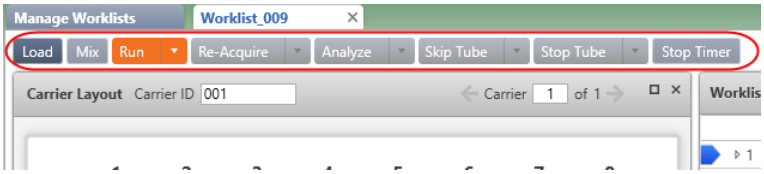
More information

- BD FACS™ Universal Loader (page 111)
- Defining sample carrier layouts (page 116)

About the Worklist Controls bar

Introduction

The Worklist Controls bar is displayed at the top of the Worklist tab and includes options for different worklist acquisition, analysis, and stopping actions.



Worklist controls

The following table describes the worklist controls.

Control	Description
Load/Unload	Click to load or unload the sample carrier (tube rack) with the Loader.
Mix	Click to perform mixing actions on the sample carrier (based on default sample carrier preferences).
Run	Click to start an acquisition run of unacquired entries or tubes, or to start an analysis run of previously acquired entries. Click the arrow to select options (Run All, Run from Pointer, or Run Selected). A worklist run begins with preview mode, then begins acquiring after the Acquisition Delay Timer expires.
Re-Acquire	Click to re-acquire any previously acquired entries or tubes. Click the arrow to select options (Re-acquire Selected, Re-acquire All, or Re-acquire from Pointer).
Analyze	Click to start a batch data analysis run of previously acquired entries. Click the arrow to select options (Analyze All, Analyze from Pointer, or Analyze Selected).
Skip Tube	Click to skip a tube during an acquisition or analysis run. Click the arrow to select to skip entries or sample carriers.
Stop Tube	Click to stop a tube immediately. Click the arrow to select to stop the run after a tube completes or after an entry completes.
Stop Timer/Resume	**Before acquisition** During preview mode, the Stop Timer button controls the Acquisition Delay Timer. Click this button to manually stop the timer countdown and pause the worklist in preview mode before acquisition begins. You can stop the timer if you need to make adjustments. If you make changes to instrument settings, a dialog prompts you to select how to apply the changes to the other entries in the worklist. **After acquisition** After acquisition, the Stop Timer button controls the Report Delay Timer. The report displays data from an acquired entry until the timer expires. You can click Stop Timer (before time expires) to continue viewing the report and making adjustments. You can adjust the duration of the Acquisition and Report Delay timers in the Preferences dialog.

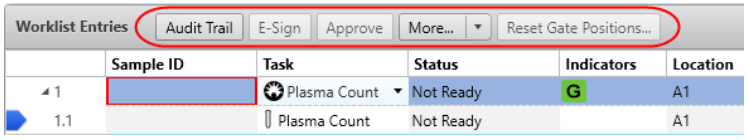
More information

- Worklist run options (page 76)
- Setting worklist preferences (page 138)
- See the *BD FACSLyric™ Clinical Reference System* for topics about using the layout view with the worklist.

About worklist entry controls

Introduction

The controls at the top of the Worklist Entries table allow you to perform actions on selected worklist entries.



Worklist entry controls

Clicking the Approve, Audit Trail, or E-Sign control applies the next logical action to some or all of the selected entries based on the state of the entries. For example, if any of the selected entries are ready for approval, then clicking the Approve control approves all entries which are ready for approval.

This following table describes what each control does when you click it, based on the status of the selected entries.

Control	When...	Then...
Approve	One or more selected entries are ready for approval	Click this button to approve any entries that are ready for approval. Entries not ready for approval are unaffected.
Audit Trail	To view the log	Click this button to view the **Audit Trail Report**.
	An audit trail item in a worklist entry requires a reason for change	After clicking this button: • Select one or more entries that require a description in the **Reason** column of the audit report. • Click the button **Provide Reason for Change** to open the dialog. • Type the reason for change. The same change text will be applied to each selected entry.
E-Sign	An entry has E-Signature enabled	Click to open the E-Signature dialog.

Control	When...	Then...
More	NA	Click to select one of the following actions: • Assign Keywords • Show/Hide Columns One or more entries must be selected for the following functions to be enabled: • Export Entry Run Packages • Export Results • Export FCS Files • Export Assay Reports • Print Assay Reports • Send Results to LIS/LIMS • Delete
Reset Gate Positions	This control only displays if the current worklist contains at least one entry using an assay with the **Apply Gate Positions** attribute enabled. It is only enabled when acquired entries are not in the **Approved** state and gates are not in their last applied positions.	Click to display a dialog that allows you to select the tubes where positions and sizes of gates need to be reset to their last applied positions. Applying gate positions using this button results in the audit trail text "Gate positions were reset to last applied gate positions" for each affected assay in the worklist. The user can overwrite the audit trail text on a per-assay basis.

More information

- Working with worklist-entry audit trails (page 95)
- Using E-Signature (page 97)

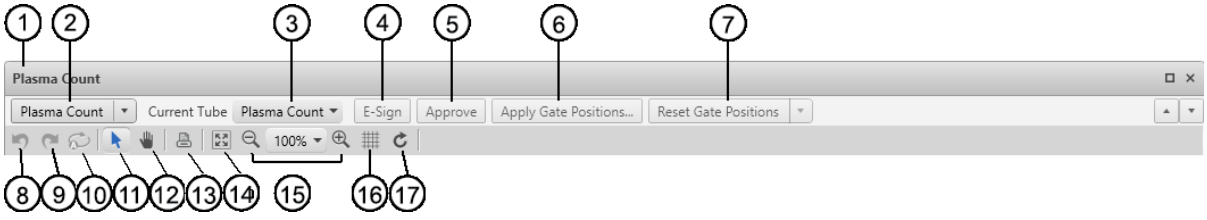
About Entry Details panel controls

Introduction

The controls in the Entry Details panel allow you to display data from a specific tube, approve an entry, and print a report, as well as adjust how the report is displayed on the screen.

Entry Details panel controls

The following figure shows the controls in the Entry Details panel.



The following table describes the controls in the Entry Details panel.

No.	Description
1	Displays the sample ID and assay used to create the report.
2	Click to view the tube properties for that tube.
3	Displays the current tube selected by the run pointer.
4	Click to apply an e-signature to the entry, when enabled.
5	Click to approve the entry, when enabled.
6	Only shown if the assay for the worklist entry allows gates to be repositioned and resized. Click to set the gate positions in this entry as the *Gating Control* for the assay.
7	Only shown if the assay for the worklist entry allows gates to be repositioned and resized. A drop-down arrow allows selection between **Reset to Applied Gate Positions** and **Reset to Assay Default Gate Positions**. The former is only enabled if the entry has not been approved and the gates are not in their last applied positions. Click to reset the gates to the last applied positions. The latter is only enabled if the gate positions of the current entry differ from the assay default positions.
8	Click to undo the last action.
9	Click to redo the last action.
10	Click to re-run the gating algorithms.
11	Click to change to Select mode.
12	Click to change to Navigate mode.
13	Click to print the current tab to a PDF-capable printer.
14	Click to make the report fit the pane below.
15	Click to zoom in or zoom out.
16	Click to view a grid in the report background.
17	Click to toggle the layout of multiple pages between horizontal (side by side) and vertical (top to bottom).

More information

- Reviewing reports (page 87)

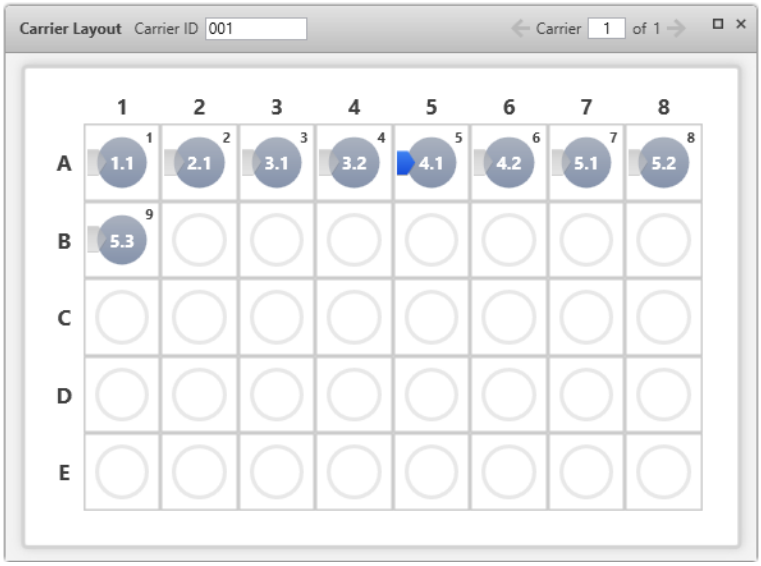
About Worklist panels

Introduction

The worklist workspace is made up of a series of panels that can be expanded, collapsed, or closed. When closed, the panel names are displayed as buttons across the top of the worklist workspace.

Carrier Layout panel

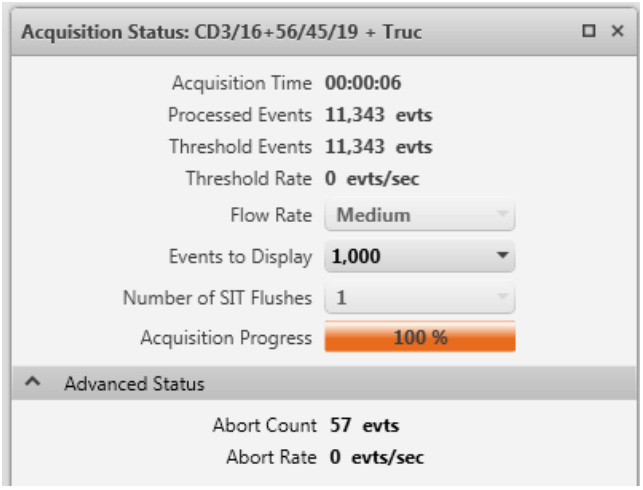
The Carrier Layout panel displays the carrier ID of the tube rack and the tube layout. The order of tubes is based on their order in the worklist. You can right-click in the layout to display properties of the rack.



If you are using the Loader, you can use the Carrier Layout panel to view tubes as they are ordered in the worklist. Carriers can be locked, which means that the physical tube position will not change, regardless of the acquisition order. If a carrier is not locked, modifying the position of entries in the worklist also modifies the physical tube location. Carriers are automatically locked when acquisition starts.

Acquisition Status panel

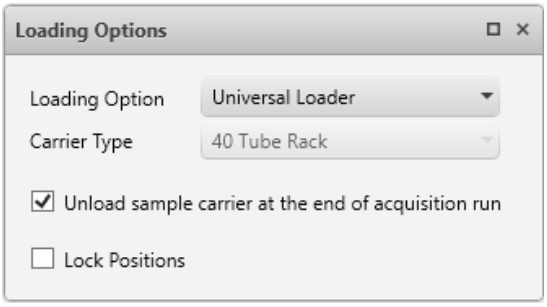
Use the Acquisition Status panel to view real-time status for time, event counts, and aborts. You can also set events to display and SIT flush options specific to an acquisition.



The settings apply to the entire worklist except for the number of SIT flushes, which applies to the current tube only. Also, the assay can control the number of SIT flushes per tube. Changing the number of SIT flushes in the worklist Acquisition Status panel overrides the assay value for the current tube.

Loading Options panel

Use the Loading Options panel to select the carrier type, loading mode (manual or Universal Loader), whether to automatically unload the carrier at the end of a run, and whether to lock the positions of tubes. The default is defined by the Loader preferences.

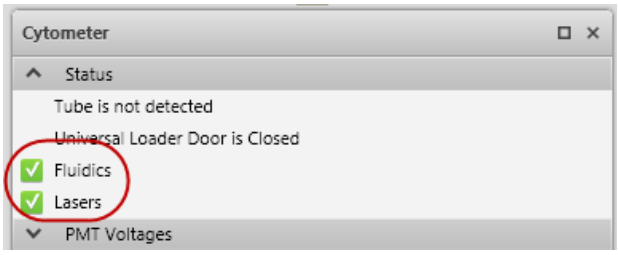


Selecting the Lock Positions checkbox maintains the physical location of the target tubes—even if you re-order or add new entries in the worklist. This can be helpful when you are manually preparing samples to run using the Loader. Note that you cannot unlock the positions for a worklist once you lock them.

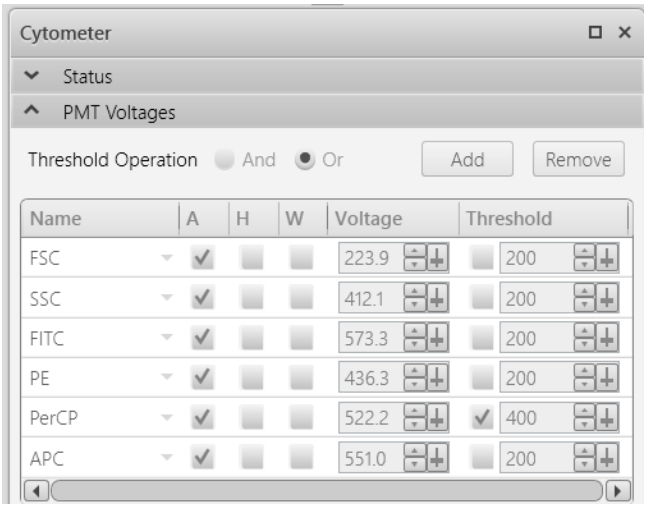
Cytometer panel

Use the Cytometer panel to view system status, run cleaning protocols, and adjust PMT voltages.

The Status section displays the system status, including real-time status for the manual tube port, Loader, fluidics, and lasers. A checkmark indicates a ready status. This section also indicates when you need to run system cleaning protocols.



Use the PMT Voltages section to view and adjust PMT voltages and adjust the threshold.



During preview mode, you can adjust threshold and PMT voltages (as applicable) and the system will automatically adjust spillover values (SOVs).

6

Data acquisition

This chapter includes the following topics:

Data acquisition overview

About data acquisition

Acquisition consists of creating or opening a worklist, adding keywords, then running the worklist to acquire data from samples.

Workflow stages

Perform the following workflow to acquire data using a worklist.

Stage	Description
1	Open an existing worklist, or create a new worklist and create new entries. See Creating a worklist (page 71).
2	(Optional) Assign keywords to entries and tubes. See topics about assigning keywords in the *BD FACSLyric™ Clinical Reference System*.
3	Run the worklist. See Running a worklist (page 74).

More information

- Worklist run options (page 76)
- Re-acquiring entries in a worklist (page 79)

Creating a worklist

Introduction

This topic describes how to create a worklist from scratch. You can also open an existing worklist and make modifications or start by importing saved entry run packages into the worklist. An entry run package includes all information needed to replicate an entry in a different worklist, including acquired data.

In addition to manually adding entries to a worklist, you can add entries from LIS/LIMS test orders or import entry run packages (ERPs).

Creating a worklist

To create a worklist:

1. In the **Manage Worklists** tab, click the **New** button.

   A blank worklist opens in a new tab.

2. Add entries to the worklist by doing one of the following:

   - Use the **Worklist Entries** table to type a sample ID or scan a barcode in the **Sample ID** column. In the **Task** column, select an assay or fluidics task.
   - Use the **Tasks** panel to select one or more tasks to add. You can specify how many of each task you want to add. For each entry, type a sample ID or scan a barcode in the Sample ID column.

   Note: A Sample ID is not required for fluidics tasks.

   All tubes associated with the task(s) are added to each entry.

3. (Optional) Assign keywords to an entry or tube.

   See topics about assigning keywords to entries or tubes, and working with audit trails in the *BD FACSLyric™ Clinical Reference System*.

4. Modify the loading options in the **Loading Options** panel as needed.
5. Save the worklist by selecting **File > Save.**

Adding entries from an LIS or LIMS

BD FACSLink™ software is used to communicate with an LIS (laboratory information system) or LIMS (laboratory information management system) and can access sample information for use in building worklists.

To add entries from an LIS/LIMS to the worklist:

1. In the **Worklist Preferences** dialog, verify that there is a connection to the LIS or LIMS.

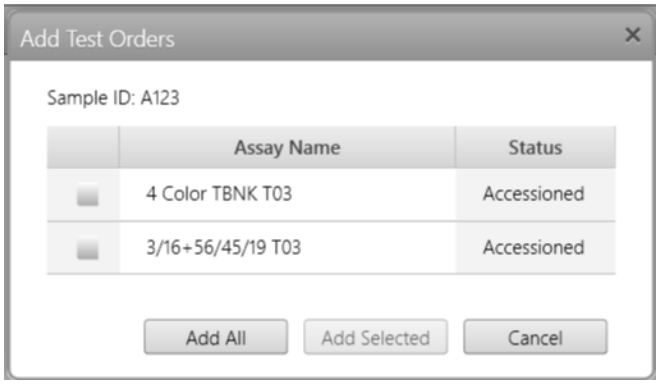
   Check the application lower status bar for the status of the LIS/LIMS connection.

2. In the **Worklist Entries** table, type in the field or scan a barcode to enter a sample ID in the **Sample ID** column.

   The sample and assay are added as a task in the Worklist Entry table.

   If multiple test orders are available for the sample ID, or if the order is already accessioned, the Add Test Orders dialog opens with the Sample ID and the requested test orders.

3. If necessary, in the **Add Test Orders** dialog, select the assay(s) and click **Add Selected** or **Add All**.



   The Worklist Entries table now displays the samples and assays from the LIS/LIMS with a LIS/LIMS status icon in the Indicators column.

4. For each entry, verify that the information entered for each sample ID (for example, sample name and case number) is correct, and that the correct task is assigned.

Note: If a tube ID is provided in an entry received from the LIS/LIMS interface, the ID will not be editable.

Saving a worklist

Worklists are automatically saved as you add entries, make changes, or when you close the worklist.

To save without closing:

1. Select **File > Save.**

Renaming a worklist

To rename a worklist:

1. Select **File > Rename.**
2. Type a new name, then click **OK.**

If you create a new worklist, you need to create at least one entry before you can rename the new worklist.

More information

- See the *BD FACSLyric™ Clinical Reference System* for more information about sorting, exporting, and deleting worklists, the Layout View panel, and entry run packages.

Running a worklist

Introduction

This topic describes how to acquire samples using the worklist.

About worklist run order

Acquisition is performed in the order that entries are listed in the worklist. However, you can run the worklist entries in a different order based on the acquisition status of the tubes and where you set the run pointer. Once you start a worklist run, you cannot re-order tubes or entries during acquisition unless you first stop the run.

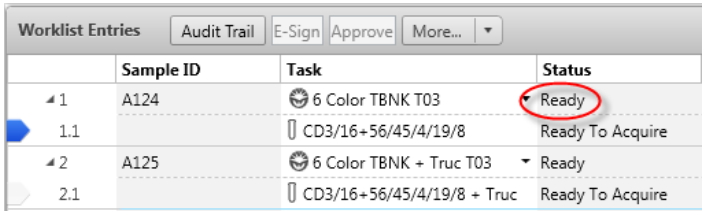
Before you begin

- Set or verify your worklist preferences for acquisition delay and report delay timers, exporting, and printing in Worklist preferences.
- Set or verify your assay report and results export preferences in the library.
- If you include cleaning tasks, make sure that the tube racks include a tube with bleach diluted to 0.5% sodium hypochlorite and a tube with DI water in the locations identified in the Layout View.

Running a worklist

To run a worklist:

1. Verify that the **Status** column displays Ready for all entries.



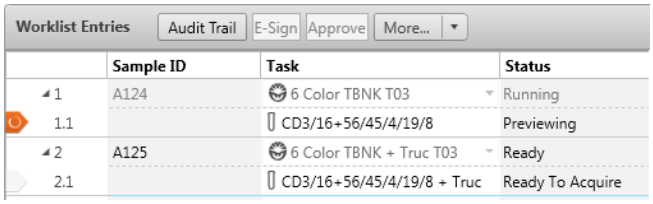
2. In the **Worklist Controls** bar, click **Run All** to run the entire worklist from the beginning, or click the arrow on the **Run All** button to select a different run option.

   If you select Run from Pointer, acquisition begins with the tube where the run pointer is set. If you select Run Selected, acquisition begins with the first of the selected entries.

3. Load the first tube or sample carrier.

   - (Loader) When prompted, place the carrier onto the Loader tray, then click **Continue** in the **Add Carrier** dialog.
   - (Manual loading) When prompted, ensure that the LED light on the manual tube port is green, then gently place a tube onto the manual tube port, pressing the top of the tube onto the gasket until you feel a click. To reduce carryover, take care to prevent splashing on the wash probe when loading tubes.

   The worklist run starts, indicated with a circle on the run pointer.



As acquisition progresses, the Acquisition Status panel displays the time, events, and an acquisition progress bar. Events are displayed in the acquisition report.

4. If necessary, adjust voltages, threshold, or SOVs.

   a. Click **Stop Timer** on the **Worklist Controls** bar.

      This stops the acquisition delay timer, but sample is still being aspirated into the cytometer.

   b. Adjust the threshold and FSC, SSC, and PMT voltages, or adjust SOVs.

      You cannot modify both SOVs and threshold/voltages.

      Note: A QC message is added to the lab report if you adjust instrument settings or modify compensation.

   c. Click **Resume**.

      The Apply Changes dialog opens.

   d. Select how to apply the adjusted instrument settings, then click **OK** to start acquisition.

5. (Optional) Make adjustments to gates.

   a. Click **Stop Timer** when the lab report is displayed after the tube has been acquired.
   b. Examine each gate and make adjustments as necessary.
   c. Click **Resume** to continue to the next entry.

   Repeat steps 4 and 5 as applicable for all tubes in the entry.

6. Follow the prompts to load subsequent tubes or carriers.

   - (Loader) If selected in the Loading Options panel, the Loader will automatically unload after the last sample in the carrier has been acquired. If not, click **Unload** and remove the first carrier, then load the next carrier and click **Load.**
   - (Manual tube loading) When prompted, take care to avoid sample transfer to the wash probe when removing the first tube from the manual tube port. To minimize carryover, remove the tube promptly after acquisition. Be sure to wait until the LED light on the manual tube port turns green before loading the next tube. This allows the system to complete a SIT flush.

   Acquisition continues until the last entry has been acquired.

Running part of a worklist

If you don't want to run the entire worklist from start to finish, you can perform one of the following actions.

To...	Then do this...
Run from a specific entry or tube and all subsequent tubes	1. Set the run pointer to a specific entry or tube. 2. Click the arrow next to the **Run All** button and select **Run from Pointer.** The worklist starts with the specified tube or entry, then runs all subsequent tubes in the worklist.
Run a specific entry or tube in the worklist	1. Select either entries or tubes. The entries or tubes do not need to be adjacent in the worklist. 2. Click the arrow next to the **Run All** button and select **Run Selected.** The worklist starts with the selected tube or entry and continues with the next selected entry or tube in the worklist.

More information

- Worklist run options (page 76)
- Re-acquiring entries in a worklist (page 79)
- About the Worklist Controls bar (page 61)
- Setting worklist preferences (page 138)
- See the *BD FACSLyric™ Clinical Reference System* for topics about modifying tube properties and approving entries in a worklist.

Worklist run options

Optional tasks while running the worklist

You can perform the following additional tasks while running the worklist.

To...	Then do this...
Pause the worklist in preview mode	1. Click **Stop Timer** to manually stop the acquisition delay timer countdown and pause the worklist in preview mode. While the timer is paused, you can adjust PMT voltages and thresholds, or SOVs. 2. If you make changes, click **Resume** to open the Apply Changes dialog. 3. Select how you want to apply the changes to the worklist, then click **OK**. Acquisition resumes according to tube type and preferences.

To...	Then do this...
Review the entry once the report is populated with data	After acquisition, the report displays data from an acquired entry until the timer expires. The Stop Timer button controls the report delay timer. 1. Click **Stop Timer** (before time expires) to continue viewing the report and modify the analysis. 2. Click **Resume** to allow the worklist to move to the next entry.
View the reports for an entry after a worklist run	1. After acquisition, set the run pointer to an entry to manually display the reports. Click the arrow buttons on the right side of the toolbar in the Entry Details panel to view results for the previous or next entry.
View tube properties	1. If needed, expand an entry to view the tubes for that entry. 2. Set the run pointer to a tube in the **Worklist Entry** table. 3. Right-click next to the tube number and select **Tube Properties.**
View stopping rules	1. Open the tube properties for a tube. 2. Click the **Acquisition** tab and then click the **Stopping Rules** tab.
Print spillover values matrix for a tube	1. Open the tube properties for a tube. 2. Click the **Spillover Values** tab. 3. Click **Print**. The Print dialog opens. 4. Select a PDF-capable printer and complete your typical printing procedure.

Skipping tubes, entries, and carriers

You can skip tubes, entries, or carriers during a worklist run. If you skip during preview, then no data is saved. If you skip during acquisition, then an FCS file is saved, but the stopping criteria will not be met.

To skip tubes, entries, and sample carriers during a worklist run, complete one of the actions in the following table.

To...	Then do this...
Skip a tube in a worklist	1. Click **Skip Tube.** The tube where tube pointer is set will be skipped.
Skip an entry	1. Click the arrow on the **Skip Tube** button and select **Skip Entry.**
Skip a carrier	This applies only to systems using the Loader. 1. Click the arrow on the **Skip Tube** button and select **Skip Sample Carrier.**

Stopping a worklist run

You can stop a worklist run at any time. If you stop a run during preview, then no data is saved for the current tube. If you stop a run during acquisition, then an FCS file is saved for the current tube, but the stopping criteria will not be met.

To stop the worklist run, complete one of the actions in the following table.

To...	Then do this...
Stop the worklist immediately	1. Click **Stop Tube.**
Stop the worklist after the current tube completes	1. Click the arrow next to the **Stop Tube** button and click **Stop After Tube Completes.**
Stop the worklist after the current entry completes	1. Click the arrow next to the **Stop Tube** button and click **Stop After Entry Completes.** The tube with the run pointer completes, then the worklist run stops.

Re-acquiring entries in a worklist

About FCS files for entries and worklists

Entries and tubes can be re-acquired using the Re-acquire options.

After an entry or tube is re-acquired, the new FCS file is saved along with the previous FCS file. Each file is date and time stamped.

Procedure

To re-acquire entries in a worklist, complete one of the actions in the following table.

To...	Then do this...
Re-acquire an entire worklist	1. Click **Re-Acquire All.** This re-acquires all tubes in the worklist that have an FCS file.
Re-acquire from a specific starting point	1. Set the run pointer to a specific tube or entry. 2. Click the arrow next to the **Re-Acquire All** button, then click **Re-Acquire from Pointer.** This re-acquires the current tube and all subsequent tubes in the worklist which have an FCS file.
Re-acquire specific entries or tubes	1. Ctrl+click to select specific tubes that have an FCS file. The selected entries or tubes do not have to be adjacent. However, you cannot select a mix of tubes and entries. 2. Click the arrow next to the **Re-Acquire All** button, then click **Re-Acquire Selected.**
Restart a partially acquired tube	1. Select the tube that was stopped. 2. Click the arrow next to the **Re-Acquire All** button, then click **Re-Acquire Selected.**

More information

- Data analysis overview (page 86)
- Worklist run options (page 76)

Concatenating FCS files

About FCS file concatenation

FCS files may need to be concatenated to record sufficient events of interest to allow a scientifically or clinically meaningful analysis of a test sample. There are multiple scenarios and reasons why you may not be able to acquire sufficient events of interest in a single FCS file. These include:

- Stopping the instrument mid-acquisition during long acquisitions (e.g. for rare populations) to clear or prevent clogging and then acquire further events from the same tube that was being acquired at the time that acquisition was stopped.
- Due to incomplete RBC lysis, a bad sample preparation, or a medical condition where the number of cells of interest are unexpectedly reduced in a sample, the usual stopping criteria of 100,000 events or 5 minutes may stop the acquisition before sufficient events of interest have been acquired. In such cases, re-acquisition may be needed to record as many events as possible from the remaining sample.

Note: FCS file concatenation is subject to the following constraints:

- Concatenation of acquired and re-acquired data can only be performed if concatenation is enabled in the assay being used.
- The assay constraint also applies to assays used in imported Entry Run Packages (ERPs). In addition, concatenation is only enabled if the ERP supports FCS 3.1 or later.
- For imported FCS files, concatenation is disabled regardless of the concatenation configuration in the assay.

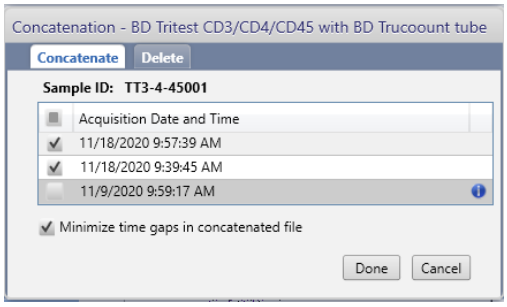
Concatenation Procedure

To concatenate acquired and re-acquired samples for an entry in a worklist:

1. Set the run pointer to the tube where samples have been re-acquired.
2. Right-click in the Worklist Entries cell containing the run pointer to display the context menu.
3. Select the **Concatenation** menu item.

   The system displays a Concatenation dialog.
4. Select the samples to concatenate.

   Note: After you select the first FCS file for concatenation, the BD FACSuite™ Clinical application checks that other FCS files for the sample are compatible. If an FCS file is not compatible with the first selected item, selection of the file will be disabled and an information icon will be displayed next to it. Clicking the icon will display the reasons why the two FCS files are incompatible for concatenation purposes. Possible reasons include different Performance QC date, PMT voltage changes, and different spillover values.



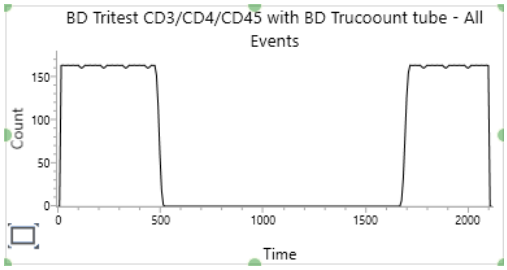
5. If a relatively long period has elapsed between acquisitions in comparison to the combined acquisition times, click **Minimize time gaps in concatenated file**.

6. Click **Done** to concatenate the selected files.

   The message bar displays the message "Concatenated file successfully created".

7. (Optional) To confirm that the FCS files have been concatenated as expected, add a time-based histogram to the worksheet or any other plot with a Time parameter for the x-axis.

   Example:



The FCS filename of the composite file, after running the **File > Export > FCS Files** command, will end with the suffix concat*nnn*.fcs where *nnn* is a 3-digit integer that increments by one for each concatenation operation.

Handling of keyword values in concatenated FCS files

The following table lists how common keywords are handled in concatenated FCS files.

Keyword	Application to concatenated FCS file
$OP	Name of person logged in when the file was created.
OPERATOR EMAIL	Email address of person logged in when file was created.
Last_Modifier	Name of person logged in when the file was created.
Last_Modified	Date and time the file was created.
GUID	The GUID in the composite file is auto-generated and is not the same as any of the values in the component FCS files.
$FIL	The filename of the composite file is auto-generated and is not the same as any of values in the component FCS files.

Keyword	Application to concatenated FCS file
AUTOBS	At the time of concatenation, the AUTOBS keyword will match the tube properties. If scaling is set after concatenation, the AUTOBS value will be true if biexponential autoscaling was selected or false if biexponential scaling is set manually.
$BEGINDATA	Value reflects the address of the first event data in the composite file. However, if the size of the file exceeds the default limit of 99,999,999 bytes, the Begin Data value given in the header segment will remain at zero.
$ENDDATA	Value reflects the address of the last event data in the composite file. However, if the size of the file exceeds the default limit of 99,999,999 bytes, the End Data value given in the header segment will remain at zero.
$COM	If there are no comment values in the files concatenated into the composite file, there will be no keyword value. If the comments are the same in each of the component files, the $COM value will be the same as the value shown in a single component file. If one or more $COM values differ between component files, the $COM value in the composite file will be concatenated values (including duplicates) of the component files in the order that they were acquired, separated by a suitable separator character.
$WELLID	If the files concatenated into the composite file were all acquired manually, there will be no $WELLID value in the composite file. If at least one of the concatenated files was acquired using the loader, the $WELLID in the composite file will be the same as the value in the concatenated file or files acquired using the loader.
$DATE	Value reflects the $DATE value from the first acquired component FCS file.
$TOT	Value reflects the sum of all $TOT values in the concatenated component files.
$ABRT	Value reflects the sum of all $ABRT values in the concatenated component files.
ORIGINALITY	Value is data modified.
PnBS	Value will match that of the tube properties at time of acquisition of the component FCS files.
PnMS	Value will match the tube properties at the time of concatenation.
PnDISPLAY	Value will match current tube properties.
CONCATENATIONSOURCEINFO	Value will be the GUID, $BTIM, and $ETIM data from each of the concatenated component files in acquisition order. The three keywords from each component file will be comma-separated, and the pipe character will separate the combined keyword values from each component file.
User-Defined keywords	If a User-Defined keyword is the same in each of the component files, the value in the composite file will be the same as the value shown in a single component file. If one or more of the values differ between component files, the value in the composite file will be concatenated values (including duplicates) of the User-Defined keyword in the component files in the order that they were acquired, separated by a suitable separator character.

Keyword	Application to concatenated FCS file
QCMESSAGES QCMn	Contain a list of all the QC messages in the source files minus duplicates. Where a message is duplicated, the timestamp will be taken from the first occurrence of the message. The messages will be in timestamp order. In a report, QC messages are re-ordered by priority (high priority first) as the primary sort order and timestamp as the secondary sort order.

More information

- Specifying assay properties (page 143) for details about viewing or setting concatenation preferences.
- For details about keywords, refer to the *BD FACSLyric™ Clinical Reference System*.

Deleting Concatenated FCS files

Note: Approved concatenated files cannot be deleted. Only files that have not yet been approved can be deleted. Deletion of concatenated files is permanent.

To delete a concatenated FCS file:

1. Set the run pointer to the tube where FCS files were concatenated.
2. Right-click in the Worklist Entries cell containing the run pointer to display the context menu.
3. Select the **Concatenation** menu item.

   The system displays a Concatenation dialog.
4. Click the **Delete** tab.
5. Select the FCS file or files to delete from the displayed list.

   An information icon is displayed beside each list entry, indicating the acquisition dates and times recorded in the concatenated file.
6. Click **Delete** to permanently delete the selected files.

   The message bar displays the message "Concatenated file(s) deleted".

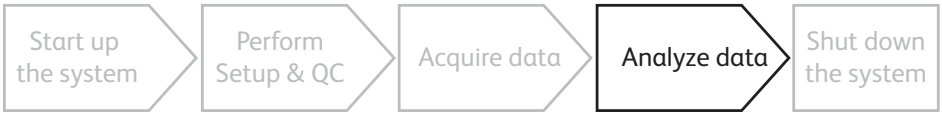
   The audit trail for the worklist records the deleted FCS file and the associated tube name.

7

Data analysis

This chapter includes the following topics:

Data analysis overview



About data analysis

[1] After entries have been acquired, perform analysis by reviewing reports, adjusting gates, approving entries, and e-signing reports. Entries can be automatically exported and printed before approval if the assay is set to do so in the Library. Approve an entry to send results to the LIS or LIMS according to the assay properties and preferences.

You can analyze any individual entry or tube that has been acquired, or use batch analysis to analyze all acquired entries in a worklist.

Batch analysis in worklists is an automated process that results in automatically generated lab and physician reports and statistics files that can optionally be exported. Batch analysis allows you to increment files and print automatically.

Acquisition and batch analysis cannot run simultaneously for the same worklist.

Analysis workflow

The following table describes the analysis workflow stages.

Stage	Description
1	Review lab and physician reports, and modify instrument settings (as permitted). See Reviewing reports (page 87).
2	Approve the results. See topics about approving entries in a worklist in the *BD FACSLyric™ Clinical Reference System*.
3	E-sign reports. See Using E-Signature (page 97).

More information

- Working with worklist-entry audit trails (page 95)
- Running batch data analysis (page 98)

[1] Worksheet analysis features are only available in the BD FACSuite™ application.

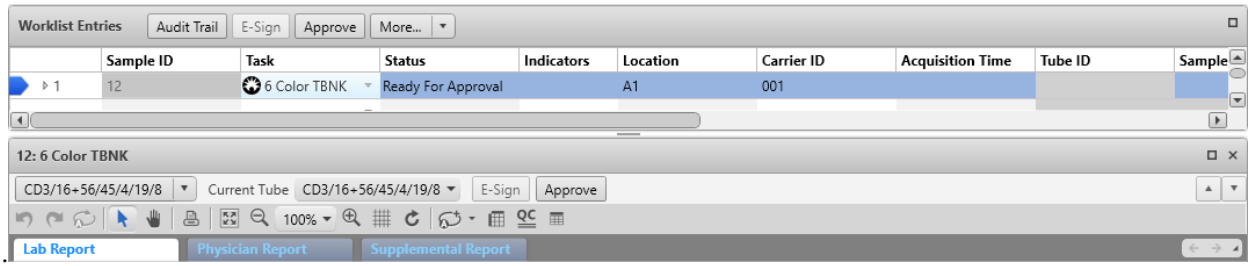
Reviewing reports

Introduction

Reports are included for each assay. The plots and results table automatically populate with data when you acquire or analyze a worklist. Reports are automatically saved with the worklist.

Reports are displayed in the Entry Details panel based on where the run pointer is set. The plots and statistics are populated with the acquired data.

You can review the plots during acquisition or once acquisition is complete. We recommend that you inspect all plots to verify that all gates include the appropriate populations. Review the lab, physician, and any supplemental reports, as necessary.



Procedure

To review reports:

1. If necessary, open the worklist that you want to review.

   The status of each entry is displayed in the Status column.

2. Set the run pointer to view the reports for that entry in the Entry Details panel.
3. Click the tab for the report you want to view.
4. Visually inspect the plots and verify that all gates fully encompass the appropriate populations, or adjust if necessary.
5. Review the following:

   - QC results (for BD assays only)
   - QC messages
   - Cross-tube results
   - Results summary (for BD assays only)

6. Click **Approve** to approve the entry.

   Approving an entry triggers the automatic export, printing, and sending of results to the LIS or LIMS according to the assay properties and preferences.

   Note: An assay property can be set up for auto-approval, where automatic export will occur without needing

to manually approve the entry. This option is only available if e-signatures are not required.

7. Repeat steps 2 through 6 for the remaining entries.

More information

- Data analysis overview (page 86)
- Approving entries in a worklist (page 88)
- Using E-Signature (page 97)
- Specifying report preferences (page 136)
- Setting worklist printing preferences (page 143)

Approving entries in a worklist

Introduction

This topic describes how to approve entries after analysis.

Approving an entry triggers the automatic export, printing, and sending of results to the LIS or LIMS according to the assay properties and preferences.

Entry approval status

After an entry is acquired in a worklist, the Status column displays one of the following status messages.

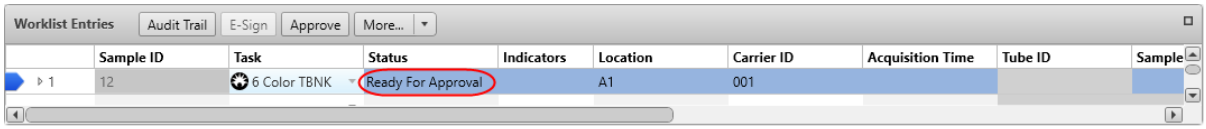
Status message	Condition
Approved	This message is displayed when automatic approval is enabled for the assay and there are no errors reported for this entry, or when you manually approve the entry.
Ready For Approval	This message is displayed when automatic approval is disabled for the assay and when no errors are reported for this entry.
Needs Review	This message is displayed when there is an error with the entry, including a QC message which requires review.

If your laboratory workflow requires manual approval of an entry, you can manually approve it. You can also save a worklist without approving, then return to the worklist at a later time and finalize the status.

Manually approving an entry

To manually approve an entry:

1. Select one or more entries that have a Needs Review or Ready For Approval status.



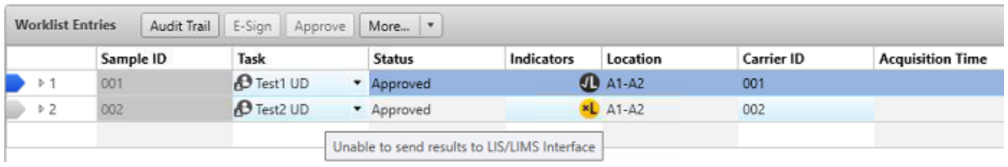
2. Do one of the following:

   - To approve one or more entries, select the entries, then click the Worklist Entries **Approve** button.
   - To approve only the currently selected entry, click the **Approve** button in the Entry Details panel.

   Approval triggers the export and printing of reports, as well as the automatic export, printing, and release of results to the LIS or LIMS.

Confirming results are sent via the LIS/LIMS interface software

Approve the entries you want to send manually or by using automatic approval in the assay properties. Confirm that the results were successfully transmitted to the LIS/LIMS interface software by checking for the confirmation LIS/LIMS status icon in the entry. The following example shows the LIS/LIMS indicators for successful and unsuccessful transmission.



Viewing the LIS/LIMS interface test results history log

To view the LIS/LIMS interface test results history:

1. From the main menu, select **Tools > LIS/LIMS Interface Test Results History**.

   The LIS/LIMS Interface Test Results History log displays all entries that have been sent to the LIS or LIMS or are in queue. You can sort the columns and delete entries from the table.

More information

- Using E-Signature (page 97)
- Data analysis overview (page 86)

Working with the worklist manager audit trail

The worklist manager audit trail provides a list of active and deleted worklists and displays the audit trail of a selected worklist. A worklist audit trail provides full traceability of the worklist to provide a permanent record of

creation, renaming, and deletion events associated with both the worklist and its entries. A separate audit trail is maintained for each worklist entry. If an entry is created or deleted, it is recorded at the worklist level.

Accessing the worklist manager audit trail

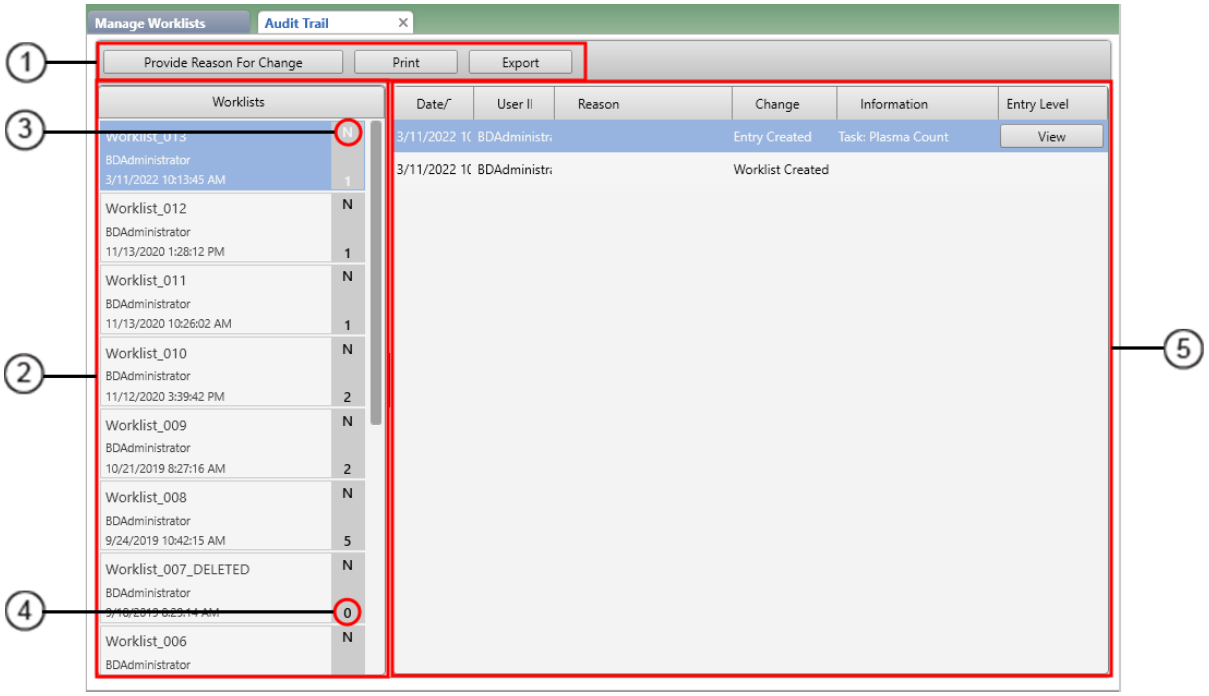
To view the audit trail:

1. On the navigation bar, click **Worklists**.

   The Manage Worklists tab opens.

2. Click **View Audit Trail**.

   An Audit Trail tab is displayed next to the Manage Worklists tab. The tab is automatically selected.



No.	Description
1	Audit trail action controls
2	Worklists panel
3	Worklist shared status (Y = shared, N = private)
4	Number of worklist entries
5	Audit information for the worklist selected in the Worklists panel (2).

3. To view the audit trail information for a particular worklist, select the worklist from the list in the left panel. Administrators and Supervisors can see all worklist audit trails. Operators can only see their own and shared worklist audit trails.

   Auditing information about the creation, deletion, renaming, and sharing of the worklist is displayed in the right panel. The worklist audit trail also contains line items that track the creation and deletion of the worklist entries. If a worklist is saved as another worklist, the audit trail for the new worklist will contain a line item where the Change parameter indicates "Worklist Saved" instead of "Worklist Created". The Information parameter also indicates the name of the original worklist. Similarly, if a worklist is imported from an FCS, ERP, or BD FACSDuet™ Sample Preparation System, the Change parameter in the first (bottom) line item indicates "Worklist Imported" instead of "Worklist Created".

   Note: If you import a previously shared worklist, the imported worklist is not shared, and this status is reflected on its tile in the Worklists panel. Nevertheless, an item in the audit trail for the new worklist keeps a record of the previous shared action.

Accessing a worklist-entry audit trail from the worklist audit trail

1. Select the worklist in the worklist manager audit trail as detailed in Accessing the worklist manager audit trail (page 90).

2. Click the **View** button associated with the entry creation.

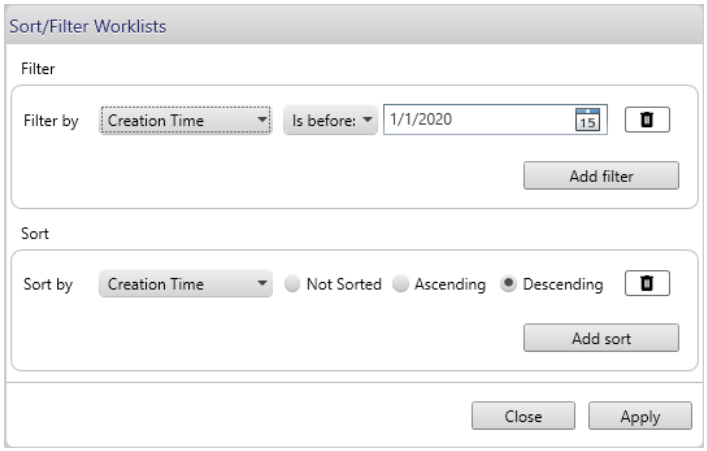
   Note: The View button for an entry is disabled if the worklist entry has been deleted, and the View buttons for all entries are disabled if the worklist has been deleted. However, worklist preferences can be set up so that the audit trail reports for the worklist and its entries are automatically exported when the worklist is deleted.

Filtering and sorting the worklists in the Worklists panel

To filter or sort the worklists shown in the Worklists panel on the Audit Trail tab:

1. Click the **Worklists** button at the top of the panel.

   The Sort/Filter Worklists dialog opens.



2. If filtering the worklists:

a. In the drop-down list next to the Filter by prompt, select one of the following worklist parameters:

   - Worklist Name
   - Author
   - Creation Time
   - Is Shared
   - Is Deleted

b. Click the next control to the right to specify the filter constraint. The list of options available depends on the selection made in step 2a.

   - For the text options (Worklist Name and Author) the available constraints are **Begins with:**, **Equals:**, **Contains:**, and **Ends with:**.
   - For the calendar option (Creation Time) the constraints are **Is before:**, **Equals:**, or **Is After:**.
   - For the binary options (Is Shared and Is Deleted) an **Is True** checkbox is displayed.

c. The user interface element for specifying the filter criterion also depends on the selection made in step 2a.

   - For the text options, enter the criterion in the text box.
   - For the calendar option, open the calendar and select a date or type the date into the Select a date field in month-number/day-number/year-number format (for example, the format for 2nd January, 2020 is **1/2/2020**).
   - For the binary options, the **Is True** checkbox can be checked to select True, cleared to select False, or shaded to select Don't Care.

d. You can apply multiple filters. Click **Add Filter** to add another Filter by line and repeat steps 2a through 2c on the new filter line.

e. If you want to clear a filter, click the Delete icon on the far right of the associated Filter by line.

f. If you want to sort as well as filter the worklist, continue to step 3. Otherwise, click the **Apply** button at the bottom-right of the dialog.

3. If sorting the worklists:

    a. Select a worklist parameter from the drop-down list next to the Sort by prompt. The available parameters are the same as for filtering.

    b. Click an option button to select a sort ordering option (**Not Sorted**, **Ascending**, or **Descending**).

    c. If desired, add another level of sort by clicking the **Add sort** button and repeating steps 3a and 3b on the new Sort by line.

    d. If you want to clear a sort level, click the Delete icon on the far right of the associated Sort by line.

    e. Click the **Apply** button at the bottom-right of the dialog to complete the operation.

Editing items in a worklist audit trail report

The only parameter that can be edited in a worklist audit trail item is the Reason parameter, which logs the reason for change.

To add a reason for change to items in the audit trail:

1. Select one or more items in the audit trail. Multiple items can be selected by simultaneously pressing the Shift or Ctrl key and clicking.

2. Click **Provide Reason For Change**.

    The application displays a Reason for Change dialog.

    Under the Please provide a reason for audited modifications label, a table lists the selected worklist items that do not already have a reason for change.

3. In the text box under the Enter Reason prompt, type the reason for change. The text will be added to the Reason parameter for all items listed in the table.

4. Click **OK** to complete the operation and close the Reason for Change dialog.

Once information has been entered for the Reason parameter, it cannot be overwritten and the Provide Reason For Change button is disabled for that item in the worklist audit trail.

Printing a worklist audit trail report

To print the creation and deletion details for a worklist and its entries:

1. Select the worklist in the worklist manager audit trail as detailed in Accessing the worklist manager audit trail (page 90).
2. Click **Print**.

   The application displays a Worklist Audit Trail Print Preview window.
3. On the toolbar at the top of the preview window, click the Printer icon.

   The application displays a Print dialog box.
4. In the Print dialog, select a pinter and click **Print**.

Exporting a worklist audit trail report

A worklist audit trail report can be either exported directly from the worklist audit trail or by using the preceding "Printing a worklist audit trail report" subtopic.

If using the preceding procedure, click **Export** in step 3 instead of the Printer icon. The application displays a Save As dialog instead of the Print dialog, which you can use to save the worklist audit trail report in PDF format. You cannot save the audit trail reports for the worklist entries using this method.

To export a worklist audit trail report directly:

1. Select the worklist in the audit trail as detailed in Accessing the worklist manager audit trail (page 90).
2. Click **Export**.

   The application opens an Export Audit Trail Report dialog, displaying the contents of the default export directory. The file extension is set up according to worklist preferences—see Setting worklist audit trail export preferences (page 142). If the preferences are set up to save the audit trail reports of the worklist entries along with the report for the worklist itself, the dialog will be set up for a ZIP file extension. Otherwise the dialog is set for a PDF file extension for the worklist audit trail report only.

   Note: After a worklist has been deleted, the audit trails for the associated worklist entries are no longer accessible. You can set up worklist preferences to automatically export the audit trail reports for a worklist and its entries when the worklist is being deleted.
3. If desired, change the filename in the text box beside the File name prompt.
4. Click **Save** to complete the export operation and to close the Export Audit Trail Report dialog.

Accessing a worklist from the worklist manager audit trail

A worklist can be accessed from the Audit Trail tab as an alternative to accessing the worklist from the Manage Worklists tab. The advantage of using this method to access the worklist is that the worklists shown in the Worklists panel on the Audit Trail tab can be filtered and sorted, making it easier to find if your system contains a large number of worklists.

1. Select the **Audit Trail** tab if it is not already selected.
2. Optionally, filter and sort the worklists.
3. Double-click the worklist title displayed in the Worklists panel.

   Note: If you attempt to open a deleted worklist, the application will display the following error message: "The selected worklist cannot be opened as it is no longer available".

Removing deleted worklists from the worklist manager audit trail

One of the worklist preferences allows you to specify whether or not deleted worklists can be removed from the worklist manager audit trail—see Setting worklist audit trail export preferences (page 142). These preferences allow deleted worklists to be removed after a minimum retention period, which can be set between 30 and 180 days, in 30-day increments.

To remove worklists in the audit trail that have been deleted for longer than the minimum retention period:

1. Perform a backup of the database using the BD FACSuite™ Clinical Backup and Restore utility. Otherwise, removal of items from the audit trail is irreversible.
2. Select the **Audit Trail** tab if it is not already selected.
3. On the application menu, select **Edit > Remove Deleted Worklist Audit Trail(s)**.

   The application displays a dialog with a backup warning and that audit trails for worklists deleted by a specified date, set by the retention period, will be removed from the worklist manager audit trail. You will be prompted as to whether you wish to proceed.
4. Click **Yes** to complete the operation and to close the dialog.

Working with worklist-entry audit trails

About worklist-entry audit trails

Audit trails track changes to worklist entries. Any changes that affect the data (for example, modifying instrument settings, changing keyword values, or changing gate locations) are listed as changes in the audit trail report. Audit trails are automatically enabled for all entries in all worklists.

The following information is tracked for each change:

- Date and time of changes
- User ID
- Details of the changes

Requiring the user to provide the reason for change can be enabled or disabled on a per-assay basis. Once an entry in a worklist has been acquired or modified, its reason-for-change requirement can no longer be changed, even if the reason-for-change requirement of the corresponding assay is subsequently modified.

Providing a reason for change

When a reason for change requirement is enabled and a modification is made, a yellow **A** (Audit) icon is displayed in the Indicators column for the modified worklist entry. The icon remains until you provide a reason for change.

To provide a reason for change:

1. Select the entry in the Worklist Entries table, click **Audit Trail** and, in the Audit log, click the **Provide Reason for Change** button.

   The Reason for Change dialog opens.

2. Under Enter Reason, type a reason for changing the selected entry.
3. Click **OK.**

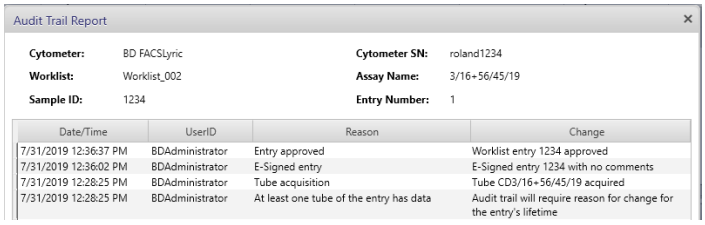
   The reason is added to the audit trail report and the Audit icon is removed.

Reviewing the audit trail report

To review the audit trail report:

1. Select an entry in the worklist.
2. Select **Audit Trail.**

   The Audit Trail Report dialog opens.



   The audit trail report displays the history of changes and the reason for each change.

Alternatively, access a worklist-entry report from the worklist manager audit trail:

1. If the Audit Trail tab is not showing next to the Manage Worklists tab, click **View Audit Trail** on the Manage Worklists tab.

2. On the **Audit Trail** tab, select the worklist of interest from the Worklists panel.

3. In the worklist audit trail displayed in the right panel, click the **View** button associated with the worklist entry of interest.

Printing the audit trail report

To print the audit trail report:

1. Click **Print** in the lower-right corner of the dialog.

   The Audit Trail Viewer Print View dialog opens.

2. Click the **Print** icon.

   The system Print dialog opens.

3. Select a PDF-capable printer and complete your typical printing procedure.

Exporting the audit trail report

To export the audit trail report as a PDF:

1. Click **Export** in the lower-right corner of the Audit Trail Report dialog.

   The Export Audit Trail Report dialog opens.

2. Provide a meaningful name in the **File name** text box and click **Save**.

   The PDF is exported to the default worklist reports folder.

Note: Setting up an assay to automatically export/print applies to the audit trail reports as well as other assay reports.

More information

- Approving entries in a worklist (page 88)
- Using E-Signature (page 97)
- For details about setting audit trail preferences in an assay, refer to the *BD FACSLyric™ Clinical Reference System*

Using E-Signature

Introduction

E-signature allows you to electronically sign reports. When E-signature is enabled for an assay, the signature box is displayed at the bottom of the report and an E-Signature icon showing a yellow E is displayed in the Indicators column for the entry.

E-Signature is an assay property that can be enabled in the library.

E-signing a report

To e-sign a report:

1. Select an entry, then click the **E-Sign** button.

   The E-signature dialog opens.

2. Select a user ID.
3. Type your password.
4. (Optional) Enter any comments.
5. Click **Sign.**

   The E-signature icon in the Worklist Entries table turns green, and the E-signature box at the bottom of the report displays the signer's user ID, date and time, and comments that were entered.

   If you modify the gate position, keywords, or any other settings that affect the data after you e-sign the report, the report is automatically un-signed and must be e-signed again.

More information

- Approving entries in a worklist (page 88)
- Data analysis overview (page 86)
- For instructions on enabling E-Signature, see "Editing assay properties" in the *BD FACSLyric™ Clinical Reference System*.

Running batch data analysis

Introduction

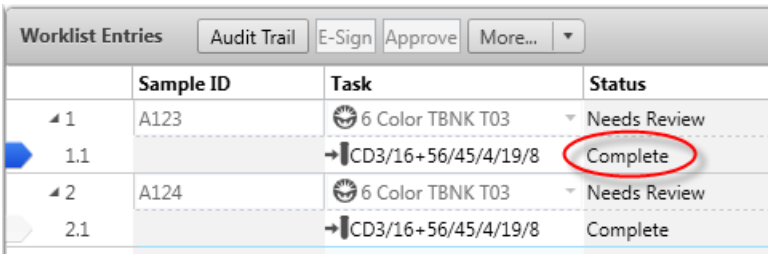
Batch analysis allows you to automatically export and print all items in a worklist that have already been approved. To begin batch analysis, you need to have acquired data from at least one entry or tube. Analysis is performed only on entries or tubes that have an associated FCS file. Tubes that do not have an FCS file are skipped.

Running batch analysis on selected entries or tubes

To run batch analysis on selected entries or tubes:

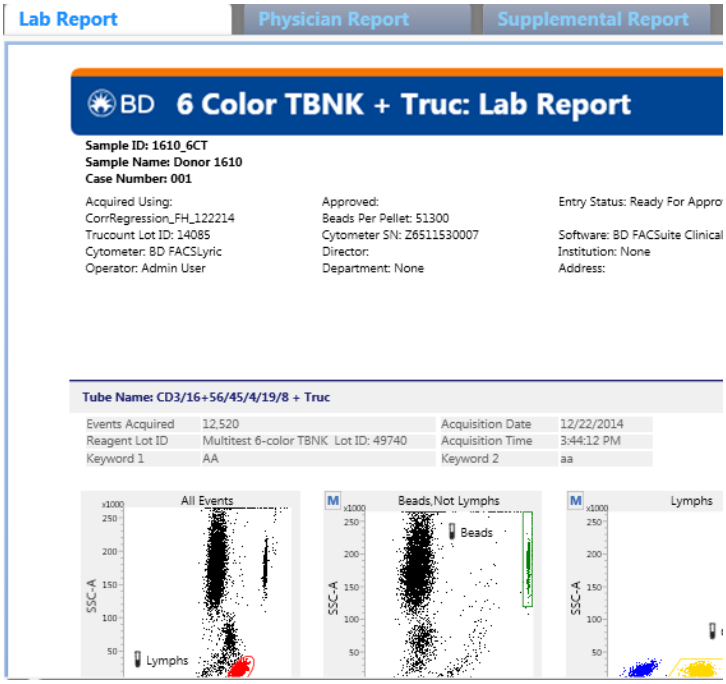
1. Click an entry or tube in the worklist that has been acquired and includes an FCS file.

   This is indicated by a Complete status in the Status column for the entry or tube, as well as a black tube icon in the Task column.



2. Click **Analyze** on the worklist control bar.

   The analysis preview opens in the lab report.



3. (Optional) Click **Stop Timer** to pause the run and make any changes.

   Click **Resume** to resume the run.

   When all entries have been run, results are automatically generated, and reports and statistics files are printed or exported according to assay preferences.

Running batch analysis on an entire worklist

To run batch analysis on an entire worklist:

1. Click **Analyze** on the worklist control bar.

   Batch analysis begins and analyzes entries and tubes with acquired data.

8

BD IVD assays

This chapter covers the following topics:

Overview of BD IVD assays

Introduction

BD IVD assays are designed for use only with the BD FACSuite™ Clinical application and the appropriate process controls.

Contents

Each assay contains the following elements:

- Predefined tubes for samples or controls
- Tube settings and keywords
- Acquisition properties and stopping rules
- Lab report with plots, gates, results, and QC messages
- Physician report with reportable results
- Supplemental report (for selected assays)

Workflow

The following table describes the workflow for running BD IVD assays.

Stage	Description
1	Create an assay worklist. See Creating an assay worklist (page 102).
2	Prepare controls or samples for the assay according to the directions in the product kit's Instructions For Use.
3	Acquire the samples. See Data acquisition (page 69).
4	Analyze the data. See Data analysis (page 85).

Creating an assay worklist

Before you begin

- Verify that the lot information for the reagents and BD Trucount™ Tubes (if applicable) that you are using matches the information entered into the library.
- Verify that all QC required for the IVD assays was performed and passed within the last 24 hours.
- For assays that do not use BD Trucount™ Tubes, obtain complete blood counts (CBCs) from a hematology analyzer for all samples. The application uses the WBC count and percent lymphocytes, or the lymphocyte

count, to calculate absolute counts.

- Prepare and stain your samples according to the reagent instructions for use (IFU).

Procedure

To create an assay worklist:

1. Open an existing worklist, or create a new one.
2. In the worklist, type a sample ID for the first entry.
3. Select an assay from the **Task** menu.
4. If you selected an assay without a BD Trucount™ Tube, enter one of the following in the designated keywords field(s) in the worklist:

   - WBC (x1000) and percent lymphocytes
   - Lymphocyte count (x1000)

WBC (x1000)	Lymphs (%)	Lymphs (x1000)
<no value>	<no value>	<no value>

   Note: If you enter values in all three keyword fields, the application checks to ensure that WBC x % lymphocytes is equal to the lymphocyte count. If the calculation is incorrect, the absolute count results are suppressed.

5. Repeat step 2 through 4 for the remaining samples.
6. Save the worklist with a unique name.

More information

- Creating a worklist (page 71)
- Running a worklist (page 74)
- Worklist run options (page 76)

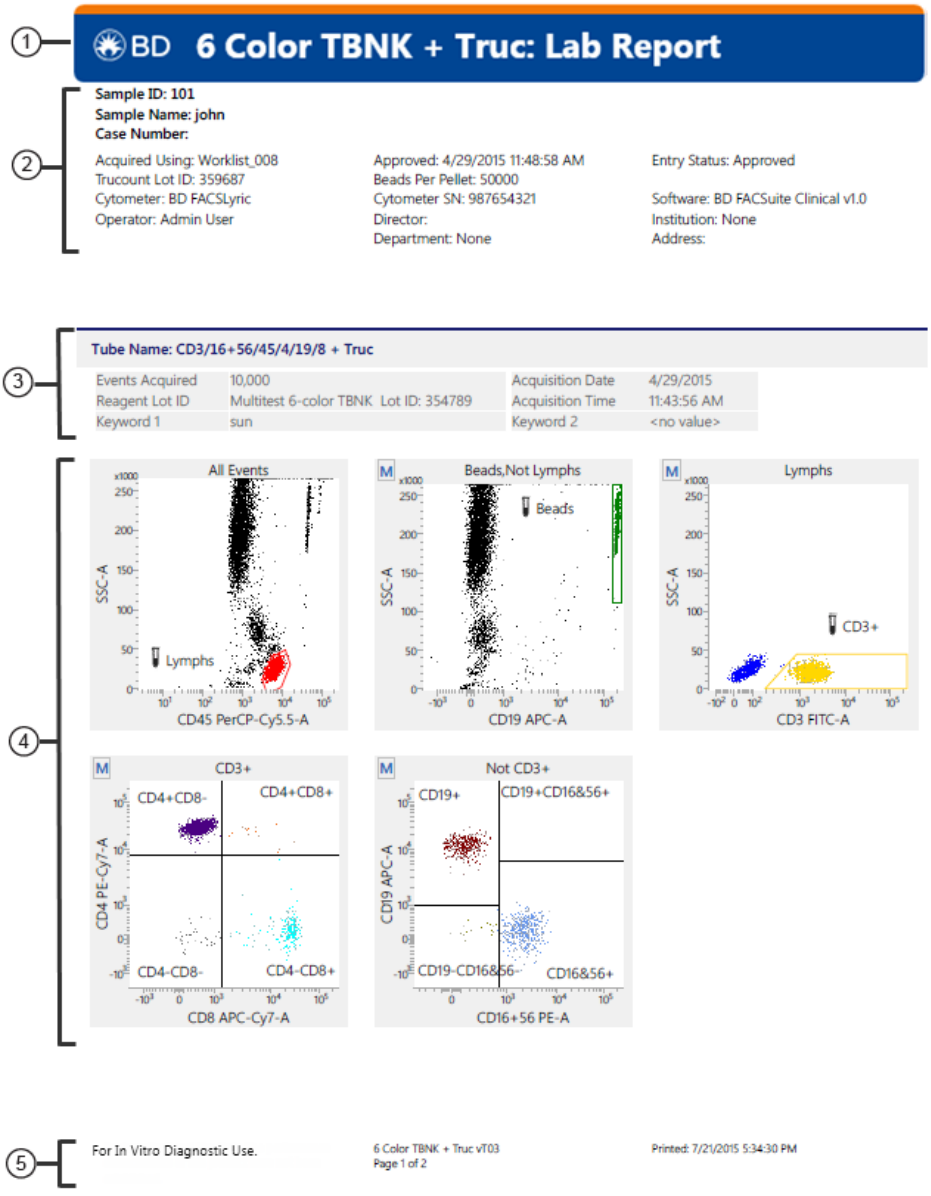
About lab reports

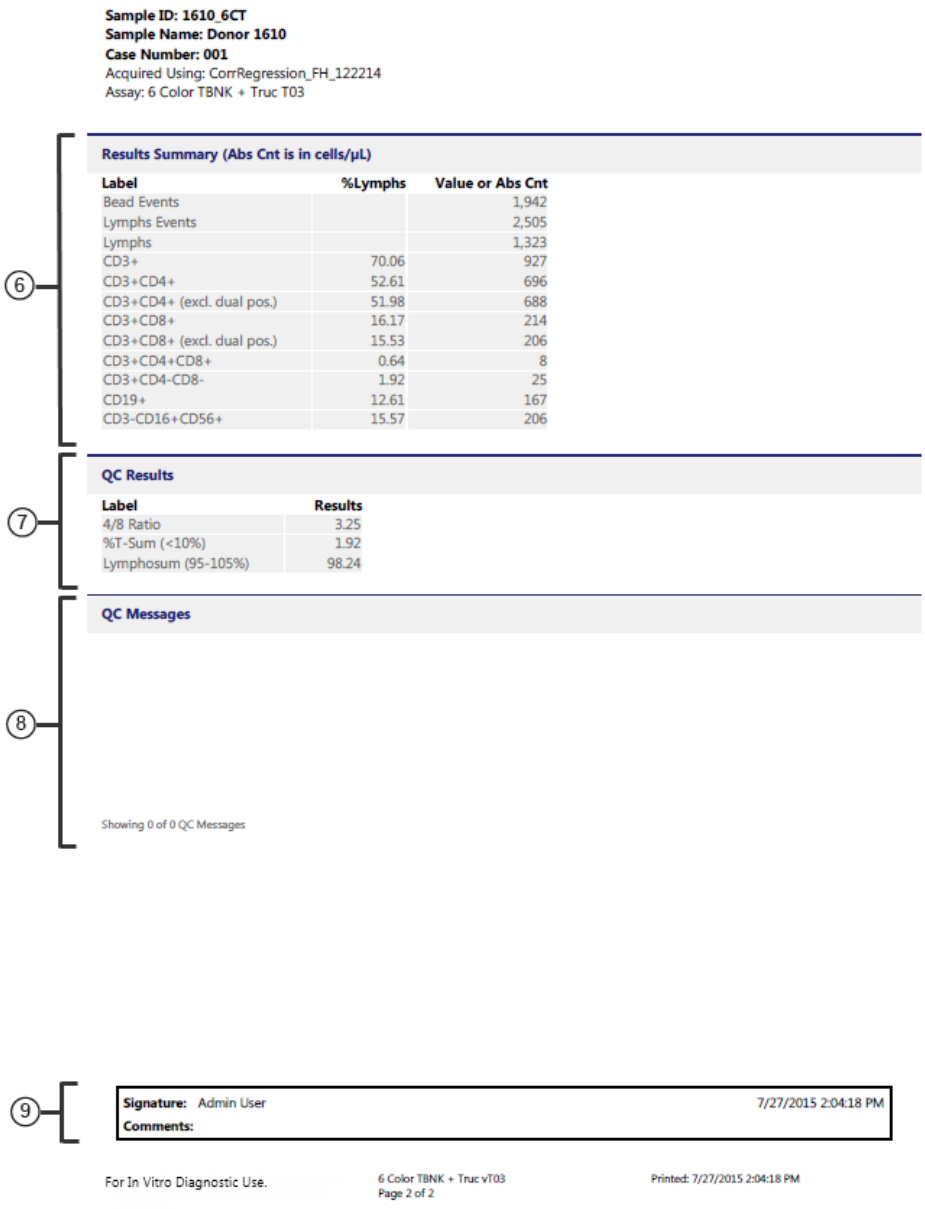
Introduction

The lab report summarizes data analysis of the stained sample. The following is an example lab report for the 6 Color TBNK + Truc assay. The table contains a description of the elements in the report.

Example lab report

The following is an example of a BD clinical report.





No.	Element	Description
1	BD banner	Displays the assay name and report type.
2	Report header	Lists information about the sample, the BD Trucount™ Tubes (if applicable), the logged-in user, the system, and the date and time the report was approved.
3	Tube header	Displays information about the tube and its acquisition. If the assay was run without BD Trucount™ Tubes, the WBC count, lymphocyte percentage, and lymphocyte count are displayed for each entry.
4	Analysis plots	Displays the plots with gates.

No.	Element	Description
5	Report footer	Displays the assay name, print date and time, regulatory status of the results, and the report page number.
6	Results summary table	Summarizes the results for each tube acquired.
7	QC results	Displays the 4/8 ratio, %T-Sum value, and lymphosum values with recommended ranges.
8	QC messages	Displays all QC messages that were generated during the run.
9	E-signature	Displays the electronic signature and any comments added by the reviewer, if applicable.

More information

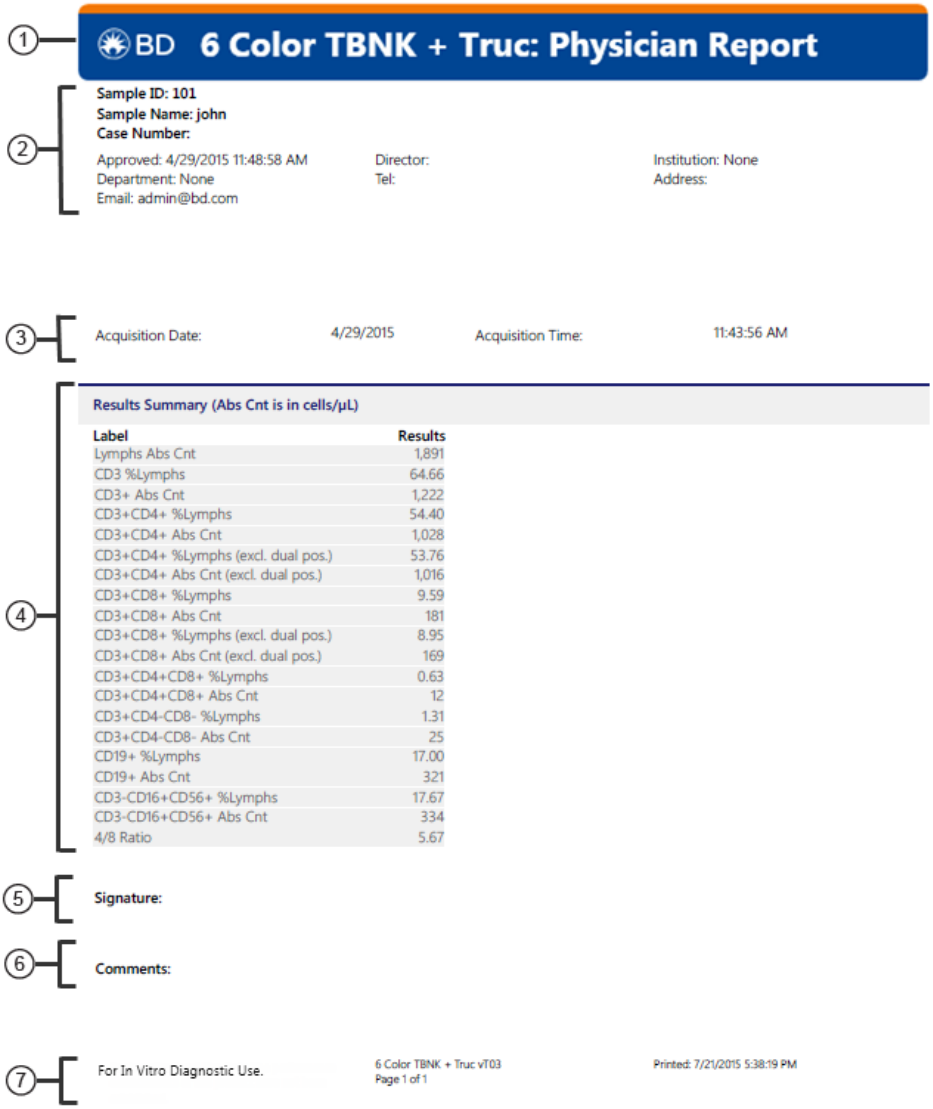
- Reviewing reports (page 87)

About physician reports

Introduction

The physician report contains a results summary table and provides space to write comments and sign the report.The following is an example physician report for the 6 Color TBNK + Truc assay. The table contains a description of the elements in the report.

Example physician report



No.	Element	Description
1	BD banner	Displays the assay name and report type.
2	Report header	Lists information about the sample, the date and time the report was approved, and institution information.
3	Acquisition information	Displays the tube name (for some assays), and acquisition date and time.
4	Results summary table	Summarizes the results for each tube acquired.
5	Signature	Provides space to sign the report.

No.	Element	Description
6	Comments	Provides a space for comments.
7	Report footer	Displays the assay name, print date and time, regulatory status of the results, and the report page number.

More information

- Reviewing reports (page 87)

About supplemental reports

Introduction

The following is an example supplemental report for the 6 Color TBNK + Truc assay. The report displays the analysis plot and results of the $CD3^{+}CD16^{+}CD56^{+}$ population. The table contains a description of the elements in the report.

Caution! The information in the supplemental report is for Research Use Only. Not for use in diagnostic or therapeutic procedures.

No.	Element	Description
1	BD banner	Displays the assay name.
2	Report header	Displays the report type. Lists information about the sample, the BD Trucount™ Tubes (if applicable), the logged-in user, and the system at the time of acquisition.
3	Tube header	Displays information about the tube and its acquisition. If the assay was run without BD Trucount™ Tubes, the WBC count, lymphocyte percentage, and lymphocyte count are displayed for each entry.
4	Analysis plot	Displays the CD3 vs CD16+CD56 plot with gate.
5	Supplemental information	Displays the percent lymphocytes and absolute counts in cells/µL of the $CD3^{+}CD16+CD56^{+}$ population. Caution: The supplemental information is not for diagnostic use.
6	Report footer	Displays the assay name, print date and time, regulatory status of the results, and the report page number.

1

BD 6 Color TBNK + Truc

2

Supplemental Report

Sample ID: 101
Sample Name: john
Case Number:

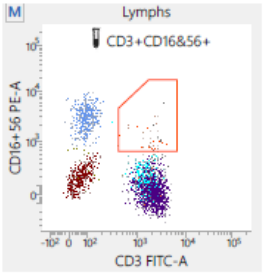
Acquired Using: Worklist_008	Approved: 4/29/2015 11:48:58 AM	Entry Status: Approved
Trucount Lot ID: 359687	Beads Per Pellet: 50000	
Cytometer: BD FACSLyric	Cytometer SN: 987654321	Software: BD FACSuite Clinical v1.0
Operator: Admin User	Director:	Institution: None
	Department: None	Address:

3

Tube Name: CD3/16+56/45/4/19/8 + Truc

Events Acquired	10,000	Acquisition Date	4/29/2015
Reagent Lot ID	Multitest 6-color TBNK Lot ID: 354789	Acquisition Time	11:43:56 AM
Keyword 1	sun	Keyword 2	<no value>

4



5

Supplemental information. Not intended for diagnostic use. (Abs Cnt is in cells/µL)

Label	Results
CD3+CD16+CD56+ %Lymphs	1.47
CD3+CD16+CD56+ Abs Cnt	28

6

9

BD FACS™ Universal Loader

This chapter includes the following topics:

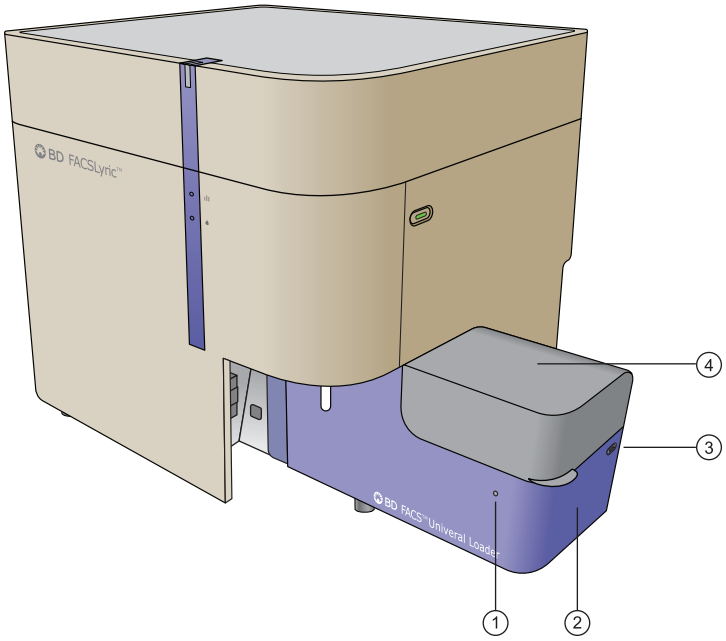
BD FACS™ Universal Loader overview

About the Loader

The BD FACS™ Universal Loader is an optional automated loading system that mixes samples and delivers tube racks to the BD FACSLyric™ cytometer for acquisition. The Loader can be included as an option on a new system or it can be ordered and installed at a later time by a BD field service engineer.

External components

The following figure shows the location of the Loader's external components.



No.	Description
1	Status indicator
2	Loader
3	Eject button
4	Cover

Status indicator

The status indicator uses illumination and color to show the status of the Loader.

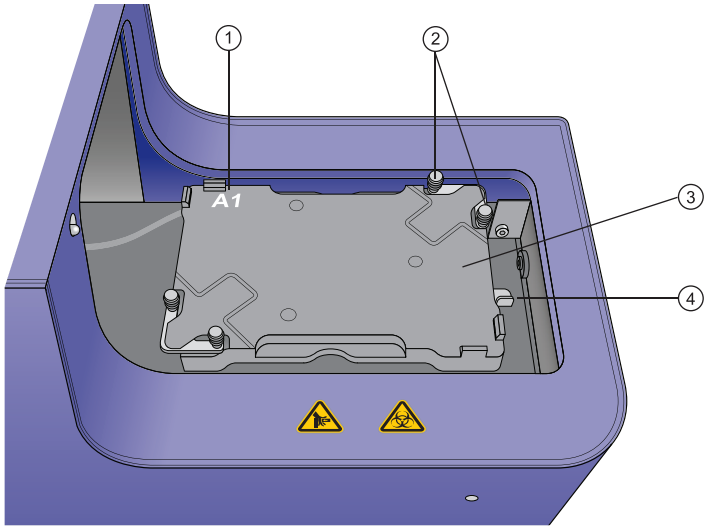
Condition	Status
Off	Ready to operate **Note:** If main power to the system is off, this indicator is off.
Blue	Cover is locked and system is running
Blinking blue	Loading or unloading
Red	Error condition

Eject button

The Eject button should be used if there is a problem during operation. Pressing this button stops acquisition and moves the carrier out to the loading position.

Internal components

The following figure shows the location of the internal components.



No.	Description
1	A1 location
2	Gripper mechanism
3	Carrier nest
4	Carrier release lever

Overhead imaging system

The Loader has an internal overhead imaging system that can detect:

- The presence and location of tubes in racks
- The correct type and orientation of carriers

Only compatible carriers can be used for this system to work.

Recommendations for using the Loader

Follow these recommendations to ensure that the Loader operates correctly.

- Do not use any tubes or racks that are not listed as compatible carriers. See Sample carrier specifications (page 114).
- Keep the top surface of tube racks clean so that the camera imaging system works properly.
- Inspect the flange, upper lip, and barcode label on all tube racks for signs of wear and replace them if excess wear is found. See Placing carriers into the Loader (page 115).
- Inspect the numbers on the top surface of tube racks to make sure they are legible and not faded.
- Keep all barcode labels clean and dry.
- Do not use CONTRAD® detergents for any cleaning procedures when using the Loader.
- Do not autoclave tube racks.
- When using the Loader, leave a tube of DI water on the manual tube port.

Sample carrier specifications

Carrier type compatibility

The following tables list the carrier types that are compatible with the Loader. The tube racks are available only from BD.

For information on part numbers and additional details on compatible carriers, see the BD FACSLyric™ section of the BD website.

The minimum and maximum volumes for tubes are shown. Volumes below the minimum may need additional diluent to resuspend the sample. Using volumes above the maximum could result in cross-contamination and spillage during mixing.

Carrier type for tubes [a]	Recommended minimum volume (µL)	Maximum volume (µL)
30-tube rack (12 x 75 mm)	100	2,000
40-tube rack (12 x 75 mm)	100	2,000
[a] For polystyrene, polypropylene, and BD Trucount™ Tubes.		

Barcode reading

The system can read barcodes on tube racks and individual tubes in 30-tube racks. To confirm the identification of racks, the barcode must first be entered into the Carrier ID field in the Layout View of the worklist.

To confirm the identification and correct location of tubes in racks, the barcodes must first be entered into a worklist with the handheld barcode reader or entered into the Tube ID column manually. Then the readers in the Loader can confirm that the correct barcode has been recognized.

More information

- See topics about barcode label specifications in the *BD FACSLyric™ Clinical Reference System* for more information about barcode scanning and barcode labels.
- See Loader preferences in the *BD FACSLyric™ Clinical Reference System* for more information about setting preferences for the Loader.

Placing carriers into the Loader

Procedure

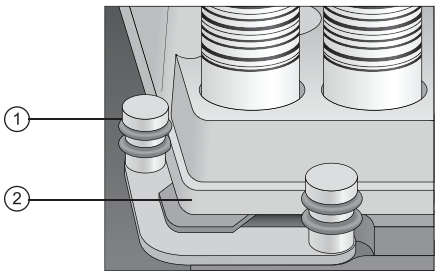
To place a carrier into the Loader:

1. Verify that the carrier type you are using is compatible with the Loader.

   See Carrier type compatibility (page 114).

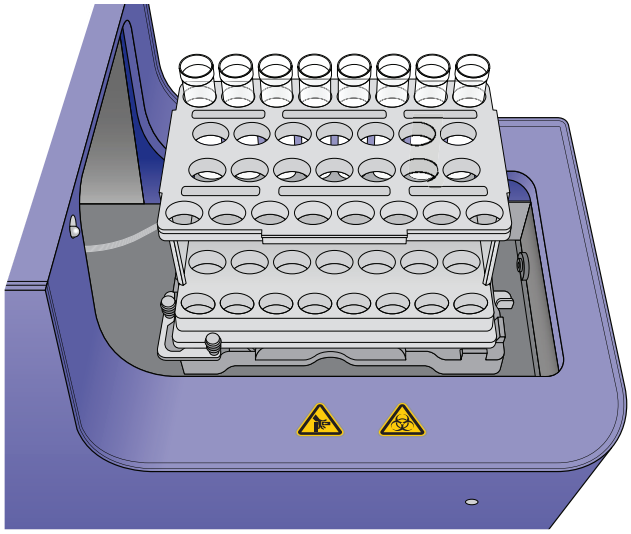
2. Open the cover.
3. Install the carrier into the carrier nest with the carrier centered on the nest.

   This is especially important with heavier carriers such as tube racks and matrix tube racks. Make sure that the flange along the perimeter of the carrier is held securely in the gripper mechanisms, as shown in the following figure. The grippers close automatically when the Loader cover is closed.



No.	Description
1	Gripper mechanism
2	Flange

The following figure shows a tube rack loaded onto the nest.



More information

- Sample carrier specifications (page 114)

Defining sample carrier layouts

Introduction

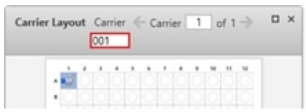
This topic describes how to define sample carrier layouts for a worklist. This applies only to systems that include the Loader option.

You need to perform this procedure only if you want to define a layout different from the default. The default is set as a preference in the Preferences dialog. Layouts are saved with a worklist.

Defining a carrier layout

To define a carrier layout:

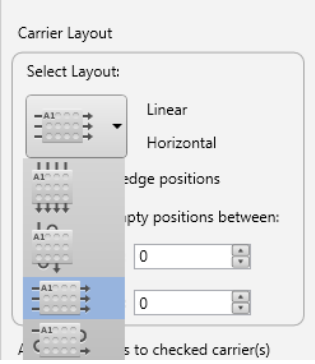
1. In the **Loading Options** panel, in the **Carrier Type** field, click and select a carrier type (for example, *40 Tube Rack*).
2. (Optional) In the **Carrier Layout** panel, change the three-digit carrier ID in the text box.



3. In the **Carrier Layout** panel, right-click the carrier diagram and select **Display Layout Settings...**

   The **Layout Settings for Carrier** dialog opens.

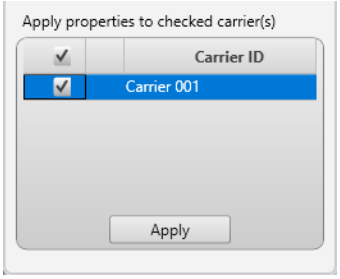
4. Under **Carrier Layout,** click the drop-down arrow and select a linear vertical, serpentine vertical, linear horizontal (factory default), or serpentine horizontal layout.



5. (Optional) Make the following selections:

   - If you do not want to include the tubes on the horizontal or vertical edges, select the **Don't use edge positions** checkbox.
   - Select the number of empty positions in the layout between each tube.
   - Select the number of empty positions in the layout between worklist entries.

6. (Optional) If you have defined multiple carriers in the worklist, use the **Apply properties to checked carrier (s)** table to apply the carrier settings to all or selected carriers. The checkbox in the table header controls the property settings for all carriers simultaneously.



7. Click **Apply**.

Note: If you change the layout in a worklist, the change is tracked in the worklist audit trail.

Changing barcode settings

To enable or disable barcode reading:

1. Right-click the carrier diagram in the **Carrier Layout** panel and select **Display Barcode Settings...**
2. To read the carrier barcode label during loading, select the **Read Carrier Barcode Label** checkbox.
3. For 30-tube racks only, select or clear the **Read Tube Barcode Labels** checkbox, as needed.

More information

- For details about using the BD FACS™ Universal Loader when updating reference settings or adding fluorochromes to a reference setting, see the *BD FACSLyric™ Clinical Reference System*.

Cleaning the Loader

Introduction

This topic describes how to clean the Loader. It is a good practice to perform this cleaning daily.

Required materials

- Bleach solution, diluted to 0.5% sodium hypochlorite, in a squirt-type bottle
- DI water
- Disposable towels or wipes

Caution

Caution! Do not use a spray bottle to spray the bleach solution because the mist can get into areas and can cause problems. Instead, use a squirt-type (squeeze) bottle to distribute the solution.

Caution! All biological specimens and materials can transmit potentially fatal infection. Use proper precautions and wear suitable protective clothing, eyewear, and gloves. Dispose of waste in accordance with local regulations.

Procedure

To clean the Loader:

1. Apply the bleach solution to a disposable towel, then wipe down the following areas:
    - Top surface of the carrier nest
    - Inside surfaces of the cover
    - Outside surfaces of the cover
    - Outside surfaces of the Loader chassis
2. Use the DI water on the same areas to remove the bleach, then wipe them dry with a towel.
3. Dispose of used cleaning materials following biohazard precautions.

For any major spills of liquids down into the interior of the Loader, contact BD technical support.

More information

- Performing manual system shutdown (page 37)

10

User management

This chapter includes the following topics:

Managing user accounts

Introduction

This topic describes the user management tools in the BD FACSuite™ Clinical application.

Administrator and ITStaff user accounts can use the User Management window to create and manage user accounts in the software, as well as manage and assign corresponding departments to user accounts and create passwords. A user management audit trail records when users are created and deleted.

User account types

The software includes the following user account types:

- **Administrator**: This account can administer and manage all accounts (except BD Service) and, by default, has complete access to instrument functions and data.

  The system includes a special preinstalled default Administrator account with user ID **BDAdministrator**, which is assigned to a user with first name of **Admin** and last name of **User**. This account cannot be locked, and the password will never expire, cannot be modified, and cannot be deleted. However, the account can be activated or deactivated by a user with an **ITStaff** role.

  A regular account of this type for a specific user can access and edit Operator user accounts and other regular Administrator accounts including role change.

- **Supervisor**: This role has full control of the instrument functions and data, except that it does not have access to the User Management window to create and manage user accounts.
- **ITStaff**: This account can administer and manage all accounts (except BD Service), can control Setup & QC and Worklist preferences, and can view the list of assays in the Library and edit their Reports properties, but has no access to other instrument functions and data.

  The system includes a special preinstalled default ITStaff account with user ID **ITStaff**, which is assigned a first name of **IT** and last name of **Staff**. This account cannot be deactivated by anyone except the default Administrator account, **BDAdministrator**. It can neither be locked nor can its role be changed by any other user. The **BDAdministrator** account can reset its password. Only the default **ITStaff** account can change its own profile details but, even in this case, the Status and Role cannot be changed. The default **ITStaff** account can change the **ITStaff** role permissions.

  A regular account of this type for a specific user can be created and activated or deactivated by the **BDAdministrator** or **ITStaff** account. It cannot be activated/deactivated by a regular user-specific account with the Administrator role. It cannot be locked by any other user/role, but can lock itself out if it exceeds the allowed limit for wrong passwords. The **BDAdministrator** or **ITStaff** user can reset the password. A regular **ITStaff** account can only be edited by the account itself or the default **ITStaff** user.

- **Operator**: This account can only edit its own profile with certain limitations.

  See topics about managing a profile in the *BD FACSLyric™ Clinical Reference System*.

About the User Management window

The User Management window can be accessed only by Administrator user accounts. The window is divided into two panels: a Master panel that displays a table of current users and user information, and a Details panel for creating or editing information about the user.

User management tasks

The following table lists the user management tasks.

To...	See...
Add or edit the department that is associated with a user	Managing departments (page 121)
Add or edit user profiles	Managing users (page 123)
User roles and managing role permissions	Managing role permissions (page 125)
Set the password policy for users	Topics about setting user login and password policies in the *BD FACSLyric™ Clinical Reference System*.
Export or import user accounts	Topics about importing and exporting users in the *BD FACSLyric™ Clinical Reference System*

More information

- Setting administration preferences (page 133)

Managing departments

Introduction

This topic describes how to manage departments by adding, editing, and deleting their information.

Departments must be created before you can assign users. This is an Administrator or ITStaff task.

Adding new departments

To add a new department:

1. From the menu bar, select **Tools > User Management**.

   The User Management panel opens.

2. In the **Departments** tab, click **New**.

   The New Department detail panel displays at the bottom of the tab.

3. Enter values in all required fields and optional fields, as needed.

All values are alphanumeric text. All fields have a 30-character limit, except the Address field, which has a 40-character limit, and the URL field, which has a 200-character limit.

4. (Optional) Add information to the **custom text 1** and **custom text 2** fields if needed.

   a. Click the **Settings** tab.
   b. Under **Custom Department Fields**, click a field and type the information to be displayed in the corresponding fields in the New Department detail panel.
   c. Click the **Department** tab.

   The custom text fields are displayed in the New Department detail panel.

5. Click **Done** to add the new department settings to the table.

Editing departments

To edit a department:

1. In the **Departments** tab, select a department to edit.

   The Department detail panel displays at the bottom of the tab.

2. Click **Edit**.
3. Edit the information as necessary.
4. Click **Done**.

Deleting a department

To delete a department:

1. In the **Departments** tab, select the department to delete.

   You can only delete one department at a time. All users must be deleted from a department before a department can be deleted.

2. Click **Delete**.

   The Delete Department dialog opens.

3. Click **Yes** to confirm the deletion.
4. The department is deleted.

More information

- Managing user accounts (page 120)
- Managing users (page 123)

Managing users

Introduction

This topic describes how Administrator and ITStaff users can add new users in the BD FACSuite™ Clinical application and edit their information later.

Users must be assigned to a department in an institution. The value for the department and institution can be **None**.

Adding a new user

To add a new user:

1. From the menu bar, select **Tools > User Management**.
2. In the **Users** tab, click **New**.

   The **New User** detail panel opens at the bottom of the tab.

3. Enter values for all required fields, and the optional fields as needed.

   Values are alphanumeric text.

In the field...	Enter the value for...
First Name (Required)	First name for the user (1–20 characters).
Last Name (Required)	Last name for the user (1–20 characters).
User ID (Required)	A user ID for the user (1–25 characters), must be unique.
Title	The user's job title.
Status	A status for the user: • **Active.** For users who are granted access to the software. • **Inactive.** For users who are no longer granted access to the software. • **Locked.** For active users with expired passwords, or users who have exceeded the maximum number of failed login attempts.
Department (Required)	A department for the user, as defined in the Departments tab. The value can be None.
Institution (Required)	An institution for the user, as defined in the Departments tab. If the Department value is None, then the Institution value is None. Because the valid values for this field depend on the Department, this field is only enabled after a Department has been selected.
Phone	A phone number for the user.
Email	An email address for the user (must be 1–60 characters and include the @ symbol and a period).

In the field...	Enter the value for...
Role	A role for the user: • **Administrator** • **Operator** (default) • **ITStaff** • **Supervisor**
Password Expiration Date	The date that the user password expires, set in number of days. This is a calculated value. Password details are defined in the Settings tab. The field is set to "Not Applicable" if the password expiration days in the user settings is set to **NEVER**. When a new user is created, the field will display "Not Applicable" because the password is temporary and the user needs to modify the password.
Temporary Password (Required)	A temporary (initial login) password. Administrators can type specific passwords (case-sensitive, 8–16 characters, no spaces, and at least one of each of the following: lowercase, uppercase, number, and a special character), or generate a random password by clicking Generate Password. At first login, the user is prompted to enter a new password.
Notes	Any notes to document history, or other descriptions of the new user (maximum of 250 characters).

4. (Optional) Add information to the **custom text 1** and **custom text 2** fields if needed.
   a. Click the **Settings** tab.
   b. Under **Custom User Profile Fields**, click a field and type the information to be displayed in the corresponding fields in the User detail panel.
   c. Click the **Users** tab.

   The new user profile field is displayed in the User detail panel.
5. Click **Done** to save the new user to the **Users** table.

Editing user details

To edit user details:

1. In the **Users** tab, select a row in the **Users** table.
2. Click **Edit**.
3. Edit the information as needed.
4. Click **Done**.

Note: The **BDAdministrator** account can activate/deactivate the default **ITStaff** account and reset its password. Other profile details of the default **ITStaff** account can only be modified by the default **ITStaff** account itself.

Note: Any regular user with the **ITStaff** role can activate/deactivate the **BDAdministrator** account, but cannot modify any of its other profile details.

Resetting a user password

To reset a user password:

1. In the **Users** tab, select a row in the **Users** table.
2. Click **Edit**.
3. In the **User** detail panel, click **Generate Password** to generate a random password, or type a new password in the **Temporary Password** field.
4. (Optional) Click the **Settings** tab to view the password policies.
5. Click **Done**.

Making users inactive

To make a user inactive:

1. In the **Users** tab, select a row in the **Users** table.
2. Click **Edit**.
3. In the **User** detail panel, select **Inactive** in the **Status** menu.
4. Click **Done**.

   The user status becomes inactive in the Users table and access is denied.

More information

- Managing user accounts (page 120)
- Managing departments (page 121)

Managing role permissions

Introduction

This topic describes how an Administrator or ITStaff user can view, set, and print permissions for all user roles. These settings are global, and changes affect all users in their respective roles. The role permissions are constrained by the default permissions for that role. In other words, permissions can be edited to further constrain the permissions for a role, but permissions cannot be added to a role that does not exist in the default for that role. For example, access to Setup and QC workspace cannot be added to the ITStaff role. The following table shows the default permissions for each role.

Permission		Role			
Category	**Task**	**Administrator**	**Supervisor**	**ITStaff**	**Operator**
Administration	Manage Admin Activities	Yes	Yes	Yes	No
	Manage User Management	Yes	No	Yes	No

Permission		Role			
Category	**Task**	**Administrator**	**Supervisor**	**ITStaff**	**Operator**
System Preferences	Edit System Preferences	Yes	Yes	Yes	Yes
	View System Preferences	Yes	Yes	Yes	Yes
Assays	Edit Assay Properties	Yes	Yes	Yes	No
Data & Worklists	Apply Gate Positions	Yes	Yes	No	Yes
	Delete Worklists/Entries with Data	Yes	Yes	No	Yes
	Modify Entry Tube Properties	Yes	Yes	No	Yes
	Rename Worklists with Data	Yes	Yes	No	Yes
Setup and QC	Access Setup and QC Workspace	Yes	Yes	No	Yes
	Run Laser Setup	Yes	Yes	No	No

If a task is not self-explanatory, the following table provides notes for clarification.

Category	Task	Notes
Administration	Manage Admin Activities	Enables/disables the menu item **Tools > Administration**. See Setting administration preferences (page 133).
	Manage User Management	This permission setting is fixed as defined by the default for the role given in the preceding table. The task cannot be disabled from the Administrator and ITStaff roles.
System Preferences	Edit System Preferences and View System Preferences	See Preferences (page 131). For the ITStaff role, access is limited to Setup & QC Reports and Worklists Automation/LIS or LIMS preferences.
Assays	Edit Assay Properties	See Specifying assay properties (page 143).
Data & Worklists	Apply Gate Positions	Enables/disables both the **Apply Gate Positions** and **Reset Gate Positions** buttons on the Worklist Entry Details panel.
	Delete Worklists/Entries with Data	–
	Modify Entry Tube Properties	Only the Create Gate Criteria properties (**Gate** and **Events**) on the Acquisition tab can be modified.
	Rename Worklists with Data	–

Category	Task	Notes
Setup and QC	Access Setup and QC Workspace	–
	Run Laser Setup	–

Viewing and setting role permissions

1. From the menu bar, select **Tools > User Management** or click the **Manage Users...** button in the **Quick Start** panel on the home page.
2. Click the **Role Permissions** tab.
3. Select a user role from the **Edit permission(s) for** drop-down list. Selectable user roles are **Administrator**, **ITStaff**, **Operator**, and **Supervisor**.

   The following steps are only applicable if you want to modify the permissions.
4. Click the **Edit** button.
5. Set or clear the checkboxes for tasks in each category as required. For details, see the preceding tables. To restore all tasks for a category to the default for the selected role, set the checkbox in the table head corresponding that category.
6. Click the **Done** button.

   If any changes were made in the task permissions, the system displays an Apply Permissions dialog.
7. Click **Save** to change the permissions or **Cancel** to cancel the operation.

Printing permissions for all user roles

1. From the menu bar, select **Tools > User Management** or click the **Manage Users...** button in the **Quick Start** panel on the home page.
2. Click the **Role Permissions** tab.
3. Click the **Print** button to display the Role Permissions Report Print Preview window.
4. To print the report, click the Print icon in the toolbar of the Print Preview window.

   The Windows print dialog opens, which allows you to select a printer and print the report.
5. To save the report in PDF format, click **Export** in the toolbar of the Print Preview window.

   The Windows Save As dialog opens, which allows you to select a directory, specify the filename, and save it.

More information

- Managing user accounts (page 120)
- Managing departments (page 121)

Working with the user management audit trail

All user management activities are logged in the user management audit trail. The system automatically creates a line entry in the audit trail with the following parameters:

- Date/Time: When the activity was performed to a granularity of 1 second.
- User ID: The ID of the user performing the activity.
- Reason: The reason for change. For most activities, this information is automatically provided by the system.
- Change: A description of the change. This information is always automatically provided by the system.

The system does not provide a "reason for change" for all user management activities. For example, if a user's password is changed—both when a temporary password is provided by an Administrator or IT Staff member (with ITStaff role permission), and when the user changes the password after logging in with the temporary password—the Reason parameter is left blank for both events. The user interface for the audit trail includes a Provide Reason for Change button to allow the blank Reason parameters to be entered manually in this case.

As with all other user management functions, the audit trail can only be accessed and modified by a user with Administrator or ITStaff role permissions.

Reviewing the audit trail report

To review the audit trail report:

1. From the menu bar, select **Tools > User Management** or click the **Manage Users...** button in the Quick Start panel on the home page.
2. Select the **Audit Trail** tab.

Providing a reason for change

The only property in an audit trail entry that can be edited is a blank Reason property. Most entries cannot be edited because the reason for change is automatically provided by the system as the user management activity is performed. Once a reason for change has been entered into an entry, it can no longer be edited and the Provide Reason for Change button is disabled.

To edit an entry that has a blank Reason property:

1. Click the **Provide Reason for Change** button at the top of the window above the audit trail entries.

   The application displays a Reason for Change dialog box.
2. In the **Enter Reason** text box, type the reason for change.
3. Click **OK** to complete the operation and close the dialog box or **Cancel** to close the dialog box without making any changes.

Printing the audit trail report

To print the audit trail report:

1. Click **Print** at the top of the audit trail window.
2. The application displays a print preview window, called User Management Audit Trail Report Print Preview.
3. Click the Print icon on the toolbar at the top of the print preview window.

   The system Print dialog opens.
4. In the dialog, select a PDF-capable printer and click **Print**.

Exporting the audit trail report

To export the audit trail report to a PDF-formatted file:

1. Select and execute one of the following substeps:

   - To preview and save the report, click **Print** at the top of the audit trail window and then click **Export** on the toolbar in the User Management Audit Trail Report Print Preview window.
   - To save the report without previewing, click **Export** at the top of the audit trail window.

   The system Save As dialog opens.
2. Select a directory, provide a meaningful name in the **File Name** text box, and click **Save**.

11

Preferences

This chapter includes the following topics:

Preferences overview

Introduction

This topic describes what preferences are and how they are managed.

About preferences

Preferences specify administration settings, display options, schedules for automatic actions, notifications, and other functions. They include settings for the System, Worklist, Setup & QC, and BD FACS™ Universal Loader. Once set, preferences persist until modified.

The ability to edit preferences is defined by your assigned role. Administrators can set and edit preferences for all users, but operators can set and edit only their user-defined preferences.

You can access the Preferences dialog by selecting Tools > Preferences.

Types of preferences

The following table describes the various preferences.

Preference	Description
Administration	Controls connected systems and software, and generates a system health report.
System	These global preferences set system startup and behavior, programmed startup and shutdown, and other general system settings.
Setup & QC	These preferences set automatic printing for Setup and QC reports, exported file locations, QC expirations, QC dot plot parameters for specific cytometer configurations, and Universal Loader preferences for any reference-setting tasks.
Worklist	These preferences set the acquisition and report delay timers, define exported file names and locations, define how worklist deletion impacts the worklist audit trail, set printing options, and set Universal Loader default preferences for new worklists. The LIS/LIMS connection information is set here as well.

More information

- See topics about preferences in the *BD FACSLyric™ Clinical Reference System*

Setting administration preferences

Introduction

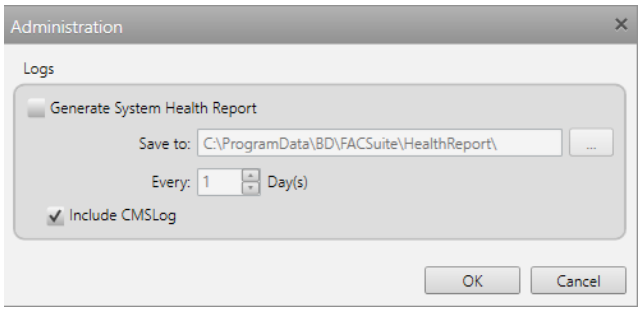
This topic describes how administrators can set administration preferences. By default, the user account roles with these administration privileges are Administrator, Supervisor, and ITStaff. Administration preferences are global settings that specify where files are saved and when the system health reports are generated for the cytometer.

Procedure

To set administration preferences:

1. From the menu bar, select **Tools > Administration**.

   The Administration dialog opens.



2. Under **Logs**, select the **Generate System Health Report** checkbox to automatically create system health reports.
3. (Optional) Specify a different destination folder for system health reports.

   a. Click the **Browse** button to open the **Browse for Folder** dialog.
   b. Select a folder and click **OK**.
4. Enter or select a value in the **Every x Day(s)** field to specify the frequency for generating system health reports.

   The default schedule is every 30 days.

5. Select the **Include CMSLog** checkbox to include the Cytometer Management Service (CMS) Log in the System Health Report.

   This log contains information about the hardware and firmware details in the system and can be helpful when trying to diagnose problems with the system.

6. Click **OK** to save your administration preferences and close the dialog.

More information

- Preferences overview (page 132)

Setting system preferences

Introduction

This topic describes how to set the system general preferences.

These preferences are global and are applied to all users. We recommend that only administrators or lab supervisors set these preferences.

Setting system general preferences

This procedure describes how to set the system general preferences for the default startup view, a notification type to indicate completion of a task, language selection, and information that displays on assay and Setup and QC reports.

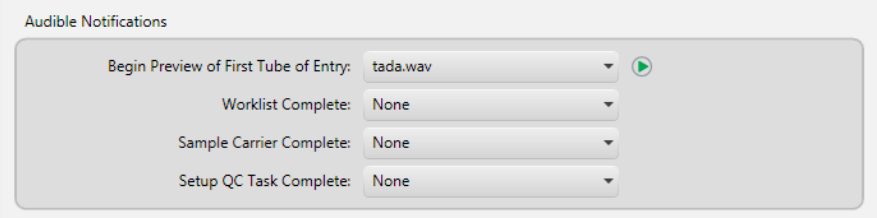
To set the system general preferences:

1. From the **System** tab, select **General** in the left panel.
2. Under **Startup**, select a default startup view from the **Default Startup View** menu.

   The selected workspace is displayed when the software opens.

3. Under **Audible Notifications**, select a sound for each notification type, or leave the value as **None**.

   (Optional) Click the Play button (triangle to the right of the field) to hear the selected sound for each notification type.



4. Under **Print Options**, select the paper size for your printer.
5. Under **Language for Help and BD Assay Reports,** select the language for the Help and the Lab and Physician reports.

   You must restart the software for the language changes to take effect.

6. Continue with additional preferences, or click **OK** to save your preferences and close the dialog.

Setting cytometer schedule preferences

This procedure describes how to specify the cytometer shutdown and automatic startup schedules. Setting shutdown sets the time that the cytometer can stay idle before the system shuts down. Setting preprogrammed startup sets the times when the system automatically starts. When the schedules are set, the cytometer automatically starts at the scheduled time and shuts down after the defined idle time.

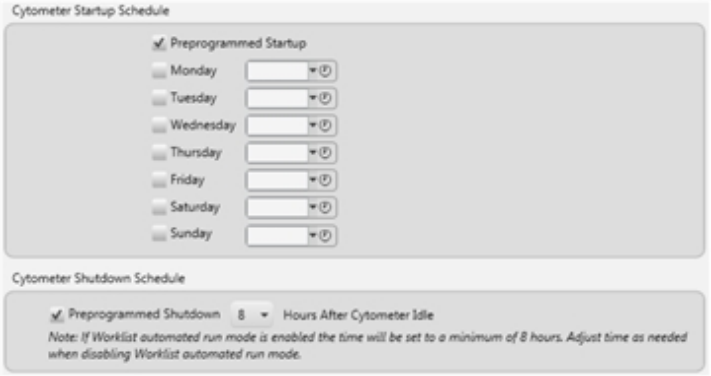
The default setting is unprogrammed (manual).

To set cytometer schedule preferences:

1. In the **System** tab, select **Hardware** in the left panel.
2. Under **Cytometer Startup Schedule**, select the **Preprogrammed Startup** checkbox.

   The Startup Schedule fields are enabled.

3. Specify the startup days and times by selecting checkboxes for the days and then entering times. You can also use the current time icon (clock at right side of field) to set the time to the current time.



4. Under **Cytometer Shutdown Schedule**, select the **Preprogrammed Shutdown** checkbox.

   The Hours After Cytometer Idle field is enabled.

5. Specify the length of time that the system can be idle before shutting down (1–24 hours).
6. Continue with additional preferences, or click **OK** to save your preferences and close the dialog.

More information

- Preferences overview (page 132)

Setting setup and QC preferences

Introduction

This topic describes how to specify setup and QC preferences.

Since most of these preferences are associated with each user ID, you can customize them without affecting other users.

When setting a preference for an export folder, everyone using the system should have access to write to that folder.

Setting expiration preferences

This procedure describes how to specify the expiration preferences for characterization QC, performance QC, and LW/LNW reference settings. This task is available only to Administrators, although Operators can view the settings. See the following table for the maximum time for each setting's expiration.

To set expiration preferences:

1. From the menu bar, select **Tools > Preferences**
2. In the Preferences dialog, click the **Setup & QC** tab.
3. Select the **General** option.
4. Under the Expiration Options section, enter the expiration durations for characterization QC, performance QC, and LW/LNW (default reference settings).

Item	Expiration limit
Performance QC	24 hours
Characterization QC	6 months
Lyse/wash and lyse/no-wash settings	60 days

5. Continue with additional preferences, or click **OK** to save your preferences and close the dialog.

Setting user scope of performance QC favorites

Favorite tube settings can be common to all users or can be customized for individual users. By default, the settings are common to all users. If the scope is common to all users, only public assays can be selected as favorites. If the scope is user-specific, assays that are private to a user can be selected as a favorite by that user. Change the user scope as follows:

1. From the menu bar, select **Tools > Preferences**
2. In the Preferences dialog, click the **Setup & QC** tab.
3. Select the **General** option.
4. Under the Performance QC Favorites section, click the **All users** or **Individual user** option, as desired.

   Note: Changing from **Individual user** to **All users**, will deselect the current performance QC favorites. The performance QC favorites will need to be set up again for all users. For details, see Selecting and viewing Performance QC favorites (page 44).

Specifying report preferences

This procedure describes how to specify setup and QC preferences for printing reports and including linearity charts in characterization QC reports.

To specify setup and QC report preferences:

1. From the menu bar, select **Tools > Preferences**
2. In the Preferences dialog, click the **Setup & QC** tab.
3. In the left panel, click **Reports**.
4. Select the **Automatically print Setup & QC reports** checkbox to automatically print the setup and QC report, once it is generated, on the default printer. The default printer must be capable of accepting input in PDF format.
5. Select the **Include linearity charts in the Characterization QC reports** checkbox to include linearity charts in the characterization QC report.

   This selection is available to users with Administrator or Supervisor permissions only.
6. Continue with additional preferences, or click **OK** to save your preferences and close the dialog.

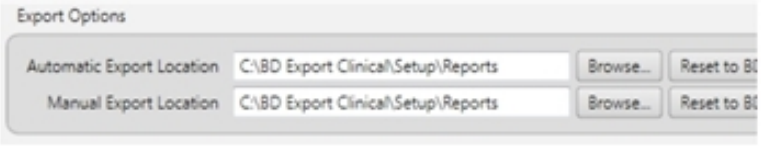
Specifying file export locations

This procedure describes how to specify the file locations for the file types generated during setup and QC. Default locations can be specified for both automatically and manually exported files.

To specify file locations:

1. From the menu bar, select **Tools > Preferences**
2. In the Preferences dialog, click the **Setup & QC** tab.
3. In the left panel, click **Reports**.
4. In the **Export Options** section, specify a file location (storage) path for each generated file type.

   a. Click the **Browse** button to display the **Browse For Folder** dialog.



   b. Select a folder and click **OK**.

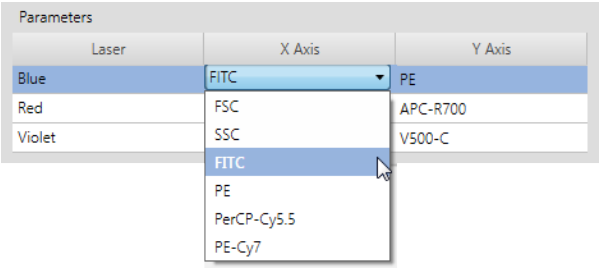
   The new file path with the new folder name is displayed.
5. Continue with additional preferences, or click **OK** to save your preferences and close the dialog.

Setting dot plot parameter preferences

This procedure describes how to specify the default x and y dot plot parameters for each installed laser on the system for viewing during setup and QC.

To set dot plot parameter preferences:

1. From the menu bar, select **Tools > Preferences**
2. In the Preferences dialog, click the **Setup & QC** tab.
3. Select **Dot Plot Parameters** in the left panel.
4. In the **Cytometer Configuration** field, select a cytometer configuration from the list.
5. In the **Parameters** table, double-click any parameter in the **X Axis** or **Y Axis** column to enable editing.



6. Select a different parameter for the other axis.

   Plots display these parameters during characterization QC and performance QC for this configuration.

7. Continue with additional preferences, or click **OK** to save your preferences and close the dialog.

Universal Loader preferences

The Universal Loader preferences for Setup & QC tasks can be set independently from Universal Loader preferences for worklists.

More information

- Preferences overview (page 132)
- Selecting and viewing Performance QC favorites (page 44)
- For Loader and mix preferences, refer to the Preferences section in the *BD FACSLyric™ Clinical Reference System*.

Setting worklist preferences

Introduction

This topic describes how to set preferences for running a worklist, details for exporting entry run packages, FCS files and results, and printing options.

Since these specific preferences are associated to each user ID, you can customize them without affecting other users.

When setting a preference for an export folder, everyone using the system should have access to write to that folder.

Setting worklist acquisition preferences

To select worklist acquisition preferences:

1. From the menu bar, select **Tools > Preferences**
2. In the Preferences dialog, click the **Worklists** tab.
3. From the left panel, select **General**.
4. Under Acquisition Delay Timer:

    a. Enter a value in the **Preview for** field to set how long to preview. This is the time to update PMT voltages and move gates before data is acquired.

    b. Select one of the following options:

    - **Use timer for the first tube in each entry (audible alarm will sound)**
    - **Use timer for all tubes**

5. Under Trucount Acquisition Delay Timer, enter a value in the **Preview for** field to set how long to preview.

    The minimum delay time for assays using BD Trucount™ Tubes is 17 seconds.

6. Under Report Delay Timer, in the **Preview for** field, enter a delay value.

    This time is the duration that the report is displayed before the next tube or entry acquisition is started.

7. Continue with additional preferences, or click **OK** to save your preferences and close the dialog.

Setting the worklist deletion preferences

To control the impact of worklist deletion on the worklist audit trail:

1. From the menu bar, select **Tools > Preferences**.
2. In the Preferences dialog, click the **Worklist** tab.
3. Select **General** from the left panel.
4. Under Worklist Deletion, set or clear the checkboxes for **Require Audit Trail reason to delete worklist(s)** and **Automatically export worklist and entry level audit trail reports on deletion of worklist**, as needed. If you elect to automatically export audit trail reports on worklist deletion, you can select the export location and whether or not dated subfolders will be created. For BD FACSuite™ Clinical, the default export location is C:\BD Export Clinical\Reports\Worklist.

Setting up the LIS/LIMS Interface connection

To configure LIS/LIMS connection preferences:

1. From the menu bar, select **Tools > Preferences**.
2. In the Preferences dialog, click the **Worklist** tab.

3. Select **General** from the left panel.
4. Under LIS/LIMS Interface Connection, enter the following information in the appropriate fields. Contact the person responsible for the LIS/LIMS interface server at your location for this information.
   - Username
   - Password
   - TCP/IP address for the LIS/LIMS server
   - Port number assigned to your instrument
5. Click the **Test Connection** button to ensure that the BD FACSuite™ Clinical application can connect to the LIS/LIMS server.

   An LIS/LIMS interface connected message displays in the status bar when the connection is active.

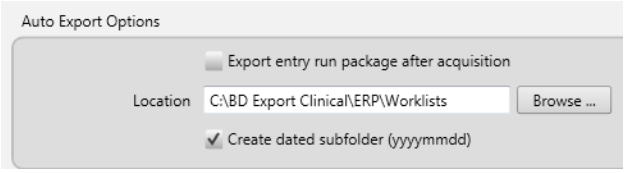
Setting entry run package export preferences

An entry run package includes all the information needed to replicate an entry in a different worklist. This includes acquired data.

To set entry run package export preferences:

1. From the menu bar, select **Tools > Preferences**.
2. In the Preferences dialog, click the **Worklist** tab.
3. In the Worklists tab, select **Export > Entry Run Package** to view the export options.

   Under Auto Export Options, select the **Export Entry Run Package after acquisition** checkbox to automatically export the entry run package, the FCS file, and metadata, which are generated and saved to the specified folder location when the entry status is Approved.

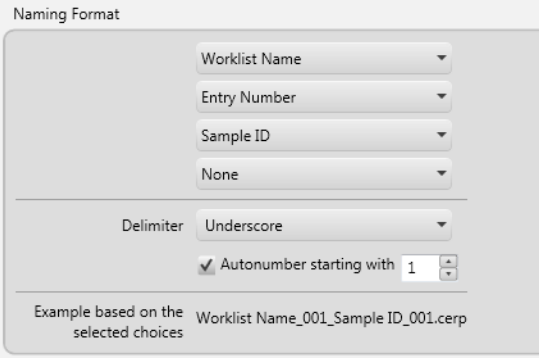


4. In the **Location** field, specify the folder where the exported entry run packages are stored. Click the **Browse** button to display the Browse for folder dialog.
5. If you want to create separate dated folders for exported files, select the **Create dated subfolder** checkbox.

   A folder with the current date in *yyyymmdd* format is added to the Location field. For example, if the folder location field is *BDExport\ERP\Worklists* and the checkbox is selected, then the folder location becomes: *BDExport\ERP\Worklists\20110701*.
6. Under Naming Format, click one or more name fields, then select a naming element.

   The naming elements you select are displayed in the Example based on selected choices field as an example. The selections are used in setting the name of the entry run package.

Note: Tube or assay names with prohibited Windows OS file name characters, such as CD3\CD4, will be replaced by a dash (for example CD3-CD4).



7. Click the **Delimiter** field and select a delimiter to display between naming elements in the file name.
8. Select the **Autonumber starting with** checkbox to add auto numbering to the file name.

   The example field shows an example of the resulting name (for example, *Worklist Name_001_Sample ID_001*).

9. Continue with additional preferences, or click **OK** to save your preferences and close the dialog.

Setting FCS export preferences

An FCS file is a file that contains the raw data. In the BD FACSuite™ Clinical application, the FCS standard is 3.1.

To set FCS export preferences:

1. From the menu bar, select **Tools > Preferences**.
2. In the Preferences dialog, click the **Worklist** tab.
3. In the Worklists tab, select **Export > FCS**.
4. Under Auto Export Options, select the **Export FCS after acquisition** checkbox to automatically export the FCS file that is generated when you run a worklist.
5. In the **Location** field, specify the folder where to export the FCS files. Click the **Browse** button to display the Browse for folder dialog.
6. If you want to create separate dated folders for exported files, select the **Create dated subfolder** checkbox.

   A folder with the current date in *yyyymmdd* format is added to the Location field. For example, if the folder location field is *BDExport\FCS\Worklists* and the checkbox is selected, then the folder location becomes: *BDExport\FCS\Worklists\20110701*.

7. Under Naming Format, click one or more name fields, then select a naming element.

   The naming elements you select are displayed in the Example based on the selected choices. The selections are used in setting the name of the FCS file.

   Note: Tube or assay names with prohibited Windows OS file name characters, such as CD3\CD4, will be replaced by a dash (for example CD3-CD4).

8. Click the **Delimiter** field and select a delimiter to display between naming elements in the file name.

   The example field shows an example of the resulting name.

9. Continue with additional preferences, or click **OK** to save your preferences and close the dialog.

Setting result export preferences

Results are generated by running entries in a worklist. One CSV file is created for the worklist. The file contains a column header row that contains the sample ID, assay name, export date, and the name of each exported result from all assay tasks in the worklist.

To set result export preferences:

1. From the menu bar, select **Tools > Preferences**.
2. In the Preferences dialog, click the **Worklists** tab.
3. In the Worklists tab, select **Export > Results**.
4. Under Auto Export Options, select the **Automatically export results** checkbox to automatically export the results.
5. In the **Location** field, specify the folder where the results are to be exported. Use the **Browse** button to display the Browse for folder dialog.
6. If you want to create separate dated folders for results files, select the **Create dated subfolder** checkbox.
7. Continue with additional preferences, or click **OK** to save your preferences and close the dialog.

Setting worklist audit trail export preferences

When exporting a worklist audit trail report by clicking **Export** in the worklist manager audit trail, you can opt to automatically include the audit trail reports for the worklist entries. You can also elect to allow removal of deleted worklists from the worklist manager audit trail after a minimum retention period.

1. From the menu bar, select **Tools > Preferences**.
2. In the Preferences dialog, click the **Worklists** tab.
3. Select **Export > Audit Trail**.
4. If you want to include the audit trail reports for the worklist entries along with the report for the worklist itself, then under Worklist Manager Audit Trail Options, check the **Include worklist and entry level audit trail reports in export folder** checkbox. In this case, when directly exporting an undeleted worklist in the worklist manager audit trail, the reports are bundled together into a ZIP file. By default, the checkbox is cleared, and the export is a single PDF file corresponding to the report for the worklist only.

   Note: The export of an audit trail report for a deleted worklist will not include entry-level audit trail reports, so only a single PDF file will be exported. You can set up worklist preferences to ensure audit trail reports for the worklist entries are automatically exported along with the worklist audit trail report when a worklist is deleted. For details, see Setting the worklist deletion preferences (page 139).

Note: Exporting the report for *any* worklist using Print > Export in the worklist manager audit trail will only export the report for the worklist shown in the Print Preview window as a single PDF file. Entry-level audit trail reports will not be included using this export method.

5. To allow removal of deleted worklists from the worklist manager audit trail, under Remove Worklist Audit Trail Options, select the **Allow removal of deleted worklist audit trail(s)** checkbox. By default, if you select this option, worklists deleted at least 30 days ago can be removed from the audit trail after 30 days. You can increase the minimum retention period up to 180 days, in 30-day increments, from the drop-down list labeled “Worklist Audit Trail Days to Retain”.
6. Continue with additional preferences, or click **OK** to save your preferences and close the dialog.

Setting worklist printing preferences

To set worklist printing preferences:

1. In the Worklists tab, select **Print**.
2. Under Print Options, select the **Automatically print report for entries** checkbox to automatically print a report to the default printer when the entry status is approved. The default printer must be able to accept input in PDF format.
3. Continue with additional preferences, or click **OK** to save your preferences and close the dialog.

Universal Loader preferences

The Universal Loader preferences for worklist tasks can be set independently from Universal Loader preferences for setup & QC tasks, but the options in each case are the same.

More information

- About the worklist (page 54)
- Working with the worklist manager audit trail (page 89)
- For Loader and mix preferences, refer to the Preferences section in the *BD FACSLyric™ Clinical Reference System*.

Specifying assay properties

About assay properties

Assay properties specify results approval, LIS/LIMS options, report print, export, and E-signature options. Assay properties are set by a user with Administrator or a Operator privileges. Once set, assay properties persist until modified.

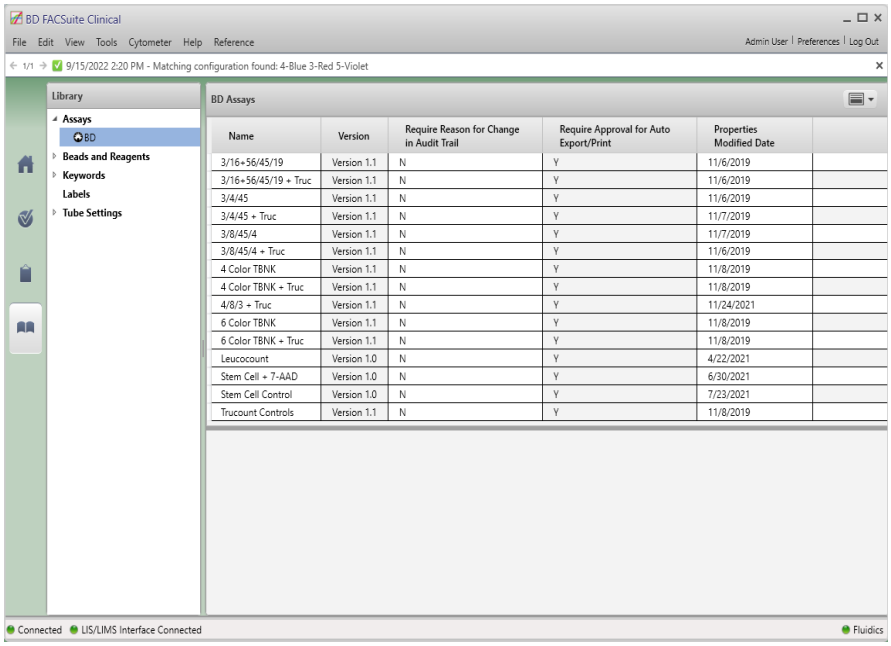
Assay properties, together with worklist preferences, define the behavior of your system when running an assay. However, worklist preferences take precedence over assay properties.

Procedure

To specify assay properties:

1. In the library, double-click **Assays,** and then click the **BD** icon.

   The BD Assays window displays a list of installed BD assays.



2. In the **Name** column, select an assay and right-click the entry.
3. Enable/disable the features **Require Reason for Change in Audit Trail** and **Require Approval for Auto Export/Print** as required.
4. With the assay still selected, click **Edit**.
5. Click the **General** tab. Depending on the user permissions, some or all of the fields may be read-only.

   a. If you want to automatically approve results without review, select the **Automatically Approve** checkbox.

      Note: Automatic approval is disabled if certain QC messages are generated during acquisition or if e-signatures are required for one or more reports.

   b. To allow gate positions and sizes to be modified and applied to other samples using the same assay, select the **Apply gate positions** checkbox.

      Note: Automatic approval is disabled if the "Apply gate positions" attribute is set.

   c. For each assay tube, select the number of **Tube SIT Flushes** in the range 1–6.

   d. Select the **Allow Concatenation** checkbox if the events of interest are so rare that there may not be sufficient to be of value in one acquisition.
6. Click the **Export Results** tab.

By default, all keywords and expressions for the assay are selected for export to the CSV file. Statistics are not available for export.

7. Remove any keywords or expressions that you do not want to export.
8. Click the **Reports** tab, and select print, export, and E-signature options for the reports. Up to three E-signatures can be specified for each report.
9. Click the **Send to LIS** tab.

   By default, all expressions for the assay are selected. Statistics are not available.

10. Remove any keywords or expression results that you do not want to send to your LIS/LIMS.
11. To save all changes, click **Done**.

More information

- For more details about editing assay properties, refer to the Library section in the *BD FACSLyric™ Clinical Reference System*.
- Setting worklist preferences (page 138)

12

Periodic Setup and QC

This chapter includes the following topics:

Cytometer Setup and QC overview

Introduction

This topic describes periodic setup and quality control (QC) procedures for the cytometer.

Use the Setup & QC workspace to perform these tasks. After you perform setup and QC tasks, you can view the results summary or view a detailed report of the task.

For information about daily setup and QC tasks, see Daily setup and QC workflow (page 42).

Periodic setup and QC tasks

The following setup and QC tasks should be performed only as needed.

Setup and QC task	Purpose	User role
Import or add a a CS&T bead lot (done in the library)	As bead lots near their expiration date, new bead lots will need to be added to the system for use. You can import bead lot ID information from the BD website or add bead lot ID information by scanning the bead lot file card in a kit.	Administrator Supervisor Operator
Assay and tube settings setup	Run assay and tube settings setup to determine the PMT voltages needed to meet the median fluorescence determined by the tube target values in the tube settings. This is completed automatically for LW and LNW tube settings as part of performance QC, but is available to run separately.	Administrator Supervisor Operator
CS&T bead lot transfer	The CS&T bead lot transfer ensures consistency across bead lots by comparing the old lot to the new lot. Existing tube settings and reference settings can be used without additional work.	Administrator Supervisor Operator
Characterization QC	This task establishes the measured cytometer performance baseline that is used for all subsequent performance QC runs. Characterization QC is performed at installation and every six months. Characterization QC should not be performed with bead lots for which the bead lot transfer task has not been completed. The existing tube settings and reference settings may no longer be accurate.	Administrator Supervisor
Update reference settings	This task updates either the default LW or LNW reference settings.	Administrator Supervisor
Setup Cleanup	This task purges Performance QC reports that are older than a specified number of days, which by default is 30. Make sure that you back up the database using the Backup and Restore utility before starting this task.	Administrator Supervisor
Add fluorochromes	This task adds new secondary fluorochromes and lot-specific fluorochromes to the LW or LNW reference settings.	Administrator Supervisor Operator

Setup and QC task	Purpose	User role
Laser setup	This task initiates an automatic re-alignment of the lasers, followed by performance QC to update settings. Run this procedure if the laser alignment check fails during performance QC, or if the %rCV is out of range.	Administrator Supervisor

More information

- About QC reports (page 47)
- See the *BD FACSLyric™ Clinical Reference System* for more information about periodic set and QC tasks.

Importing or adding a CS&T or FC bead lot

Introduction

This topic describes how to import or add a new CS&T or FC bead lot prior to your existing lot expiring.

Importing CS&T and FC bead lots

Import CS&T and FC bead lots if you do not have the optional barcode reader. CS&T and FC bead lot files can be downloaded from the BD website. See the information included in the BD® CS&T Beads or BD® FC Beads kit for the specific URL, and instructions for downloading bead lot files.

To import a CS&T or FC bead lot:

1. On the navigation bar, click **Library**.

   The Library workspace opens.

2. In the **Library** panel, double-click **Beads and Reagents,** then click **CS&T** or **FC Beads**, as applicable.

   The bead information is displayed in the upper-right panel.

3. From the menu bar, select **File > Import**.

   The Import dialog opens.

4. Navigate to the bead lot file location and select the appropriate bead lot file.
5. Click **Open**.

   The new bead lot file is displayed in the table. The Import confirmation dialog opens if there are warnings or errors.

Adding a new CS&T or FC bead lot

To add a new CS&T or FC bead lot using the barcode reader:

1. On the navigation bar, click **Library**.

   The Library workspace opens.

2. In the **Library** panel, double-click **Beads and Reagents,** then click **CS&T Beads** or **FC Beads** as needed.
3. In the **CS&T Bead Lots** or **FC Bead Lots** table, click **Scan barcode** and scan the new bead lot barcode card inside the BD® CS&T Beads kit or BD® FC Beads kit.

   The information is automatically displayed in the Bead Lots table.

More information

- For more information on transferring CS&T bead lots, see the *BD FACSLyric™ Clinical Reference System*.

QC tracking overview

Introduction

This topic describes the tasks needed to set up and view Levey-Jennings charts, which are used to track QC results.

About QC tracking

Using the QC Tracking tab, you can set the performance values you want to display in the Levey-Jennings (LJ) charts. LJ charts and reports provide a visual display of instrument performance over time. Time is plotted on the x-axis. A data point is plotted, indicating its position relative to the mean.

When the system is functioning at peak performance, the variability will be small, within one standard deviation (SD). If the performance declines, the variability and SD range will increase.

Only Administrators can set alarm and scaling ranges, but any user can choose which data to view.

QC tracking tasks

The following QC tasks can be performed as needed.

QC tracking task	Description	For more information
Set Levey-Jennings chart preferences	These preferences determine which set of data is displayed in LJ charts and reports based on different filters including bead lot, date range, and filter status. These preferences are specific to each user ID.	See Setting Levey-Jennings charts preferences (page 152).

QC tracking task	Description	For more information
Setting alarms and scaling ranges	The alarm and scaling ranges for LJ charts and reports determine which alarm criteria are used and how the performance data is scaled in LJ charts and reports. This determines when to flag data points as out of range in reports.	See topics on setting alarms and scaling ranges in the *BD FACSLyric™ Clinical Reference System*.
Viewing Levey-Jennings reports	Levey-Jennings reports contain information about the system, detector settings, lasers, setup bead lots, and cytometer settings.	See topics on Levey-Jennings reports in the *BD FACSLyric™ Clinical Reference System*.

Setting Levey-Jennings charts preferences

Introduction

This topic describes how to set the data display and tracking preferences for Levey-Jennings (LJ) charts and reports. These preferences are specific to the user currently logged in.

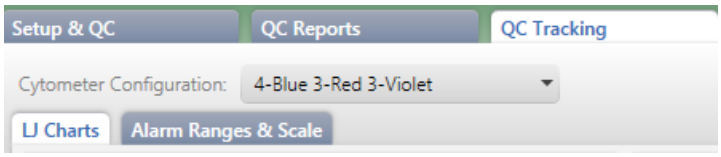
Setting data display preferences

To set data display preferences for LJ reports:

1. On the navigation bar, select **Setup & QC**.

   The Setup & QC workspace opens.

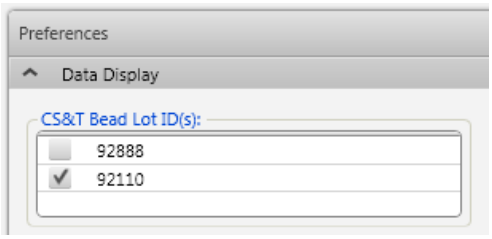
2. Click the **QC Tracking** tab.
3. In the **Cytometer Configuration** field, select an available cytometer configuration from the list.



4. Click the **LJ Charts** tab.

   The LJ Charts tab opens with a Preferences panel on the left and a Charts panel on the right.

5. In the **Preferences** panel, click and expand the **Data Display** box to view the list of preferences.



6. In the **CS&T Bead Lot ID(s)** field, select a bead lot ID.
7. Under **Filter by Date Range**, select a date filtering preference.
8. Under **Filter By Status**, select a status filtering preference.
9. Under **X-Axis Label,** select a label preference.

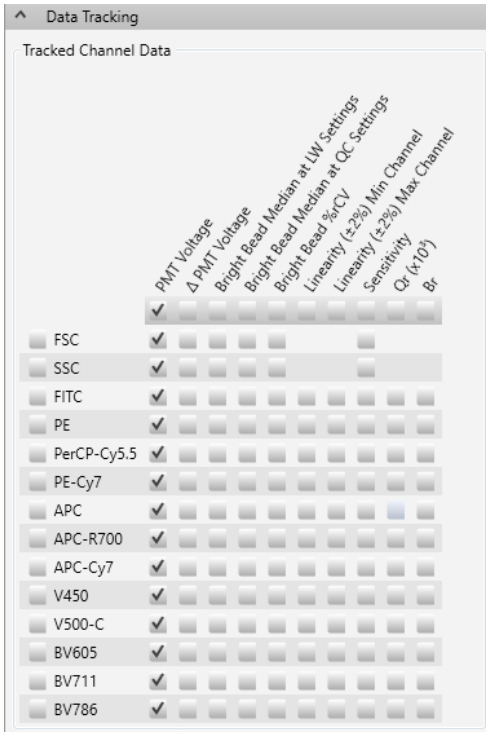
Setting data tracking preferences

To set data tracking preferences for LJ reports:

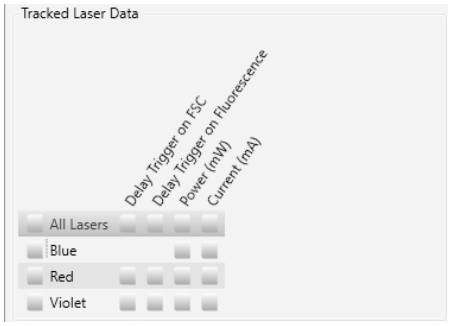
1. On the navigation bar, select **Setup & QC**.

   The Setup & QC workspace opens.

2. In the **QC Tracking** tab, click the **LJ Charts** tab.
3. In the left panel, click and expand the **Data Tracking** section to view the list of performance measurements.



4. Under **Tracked Channel Data**, select an option checkbox to display the channel data you want to view in an LJ chart, either using the controls for columns, rows, or individual checkboxes.
5. Under **Tracked Laser Data**, select an option checkbox to display the laser data you want to view in an LJ chart, either using the controls for selecting all lasers, columns, rows, or individual checkboxes.



As measurements are selected for display, their corresponding LJ charts are displayed in the Charts panel.

6. Complete any of the following actions as needed:

   - Click **View Report** to view the selections in a sample report.
   - Click **Comments** to add a comment to the report.
   - Use the icons on the top right of each chart to copy or zoom in on the charts individually.
   - Use the slider to the right of the Charts panel to vary the zoom of the panel.

13

Maintenance

This chapter includes the following topics:

Maintenance overview

Daily maintenance

Daily maintenance is part of the shutdown procedure.

Procedure	When
Running the daily clean procedure (page 156)	Daily
Performing manual system shutdown (page 37)	Daily

Unscheduled maintenance

The following table lists unscheduled maintenance that you might have to perform.

Procedure	When
Refilling the sheath tank (page 158)	As needed
Emptying the waste tank (page 159)	As needed

See topics about unscheduled maintenance in the *BD FACSLyric™ Clinical Reference System* for information about additional maintenance procedures.

Scheduled maintenance

Scheduled maintenance should be performed according to the following table.

Procedure	When
Performing the monthly clean procedure (page 162)	Monthly
Replacing the sheath filters (page 164)	Every 3 months

Running the daily clean procedure

Introduction

This topic describes how to run the daily clean procedure. This procedure is part of the daily system shutdown. You can also use this procedure to clean the system whenever it is needed.

Required materials

- 2 mL of bleach solution diluted to 0.5% sodium hypochlorite
- 3 mL of DI water

Caution! Do not use the same tube repeatedly for DI water or bleach during the daily clean procedure. Repeated use can cause wear on the tube, and resulting particles can damage the tube sensor in the manual tube port or BD FACS™ Universal Loader.

Procedure using the manual tube port

To run the daily clean procedure using the manual tube port:

1. From the menu bar, select **Cytometer > Daily Clean**.

   The Daily Clean dialog opens.

2. Make sure that the **Universal Loader** checkbox is clear. To use the loader, see Procedure using the universal loader (page 157).
3. Place a tube containing 2 mL of bleach solution (0.5% sodium hypochlorite) on the manual tube port, then click **Continue**.
4. When prompted, place a tube containing approximately 3 mL of DI water on the manual tube port, then click **Continue**.
5. When prompted by the system, unload the DI water from the manual tube port.

   The dialog closes when the process is complete.

Note: You must complete this entire procedure. If the procedure is interrupted or not completed, the system prevents any other actions from happening. This is to avoid the possibility of bleach remaining in the fluidics path.

Procedure using the universal loader

To run the daily clean procedure using the universal loader:

1. From the menu bar, select **Cytometer > Daily Clean**.

   The Daily Clean dialog opens.

2. Make sure that the **Universal Loader** checkbox displays a checkmark and the appropriate option button is set for the size of tube rack that you will use.
3. Place the tubes of bleach solution and DI water on the tube rack according to the instructions given in the dialog, then click **Continue**.

   The dialog closes when the process is complete.

More information

- Fluidics components (page 26)
- Performing manual system shutdown (page 37)

Refilling the sheath tank

Introduction

This topic describes how to check the sheath fluid level, illustrates sheath tank components, and describes how to refill the sheath tank.

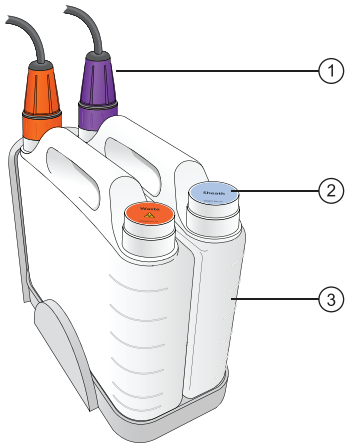
The sheath and waste tanks must be placed at a level even with, or below, the cytometer. Placing the tanks higher than the cytometer can cause uncontrolled siphoning.

Checking the sheath fluid level

The standard sheath tank is translucent so you can visually check the fluid level. In addition, a message in the software alerts you when the tank is close to empty and starts a 10-minute timer. You must refill the tank before the 10 minutes elapses to avoid acquisition being interrupted. The system stops operation when the timer expires.

Sheath tank components

The following figure shows the parts of the standard sheath tank.



No.	Description
1	Connector
2	Filler cap
3	Standard sheath tank in dock

Required materials

- BD FACSFlow™ sheath fluid to fill the sheath tank (5 L or 10 L, depending on which tank is being used). Do not use sheath fluid with surfactant.

Procedure

To refill the sheath tank:

1. Disconnect the connector from the sheath tank by turning it counter-clockwise.

   The following figure shows the connector disconnected from the tank.

2. Remove the sheath tank from the dock and take it to a filling station.
3. Remove the filler cap and fill the tank with BD FACSFlow™ sheath fluid.
4. Re-install the filler cap and place the tank in the dock.
5. Re-install the connector and turn clockwise to tighten it.

More information

- Replacing the sheath filters (page 164)
- Fluidics components (page 26)
- Emptying the waste tank (page 159)

Emptying the waste tank

Introduction

This topic describes how to check the waste tank level, illustrates the waste tank components, and describes how to empty the waste tank.

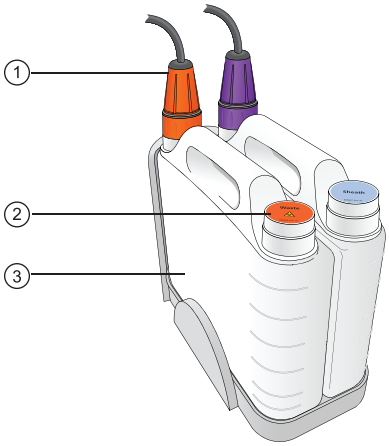
The sheath and waste tanks must be placed at a level even with, or below, the cytometer. Placing the tanks higher than the cytometer can cause uncontrolled siphoning.

Checking waste tank level

The standard waste tank is translucent so you can visually check the fluid level. In addition, a message in the software alerts you when the tank is close to full, and starts a 10-minute timer. If the tank is not emptied within 10 minutes, the system prevents further operation.

Waste tank components

The following figure shows the parts of the standard waste tank.



No.	Description
1	Connector
2	Filler cap
3	Standard waste tank in dock

Required materials

- Enough bleach solution of 5% sodium hypochlorite concentration to fill 10% of volume of waste tank

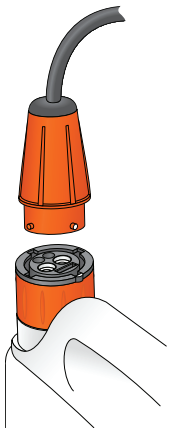
Procedure

Caution! All biological specimens and materials can transmit potentially fatal infection. To prevent exposure to biohazardous agents, expose waste container contents to bleach (10% of total volume) before disposal. Dispose of waste in accordance with local regulations. Use proper precautions and wear suitable protective clothing, eyewear, and gloves.

To empty the waste tank:

1. Verify that the system is not processing any samples.
2. Disconnect the connector from the waste tank by turning it counter-clockwise.

   The following figure shows the connector disconnected from the tank.



3. Remove the tank from the dock and take it to a dumping station.
4. Remove the filler cap and empty the tank.

   Hold the tank at an angle as you empty it and pour slowly to avoid splashing the contents.

5. Add bleach to the tank to fill 10% of the volume.
6. Re-install the filler cap and install the tank in the dock.
7. Re-install the connector and turn clockwise to tighten it.

More information

- Fluidics components (page 26)
- Refilling the sheath tank (page 158)

Performing the monthly clean procedure

Introduction

This topic describes how to perform the monthly clean procedure. This procedure should be performed at least once per month. It can be performed more often if the system is heavily used or if any contamination is suspected.

Description

The monthly clean procedure rinses the fluidics system with a bleach solution, followed by another rinse with DI water and sheath fluid. The procedure takes about 20 minutes to complete.

Required materials

- 2 mL of bleach solution diluted to 0.5% sodium hypochlorite
- 3 mL of DI water
- 2 L of bleach solution diluted to 0.5% sodium hypochlorite
- Sheath filter bypass assembly
- BD FACSFlow™ sheath fluid to fill the sheath tank (5 L or 10 L)

Procedure

Caution! All biological specimens and materials can transmit potentially fatal infection. To prevent exposure to biohazardous agents, expose waste container contents to bleach of 5% sodium hypochlorite concentration to 10% of total volume before disposal. Dispose of waste in accordance with local regulations. Use proper precautions and wear suitable protective clothing, eyewear, and gloves.

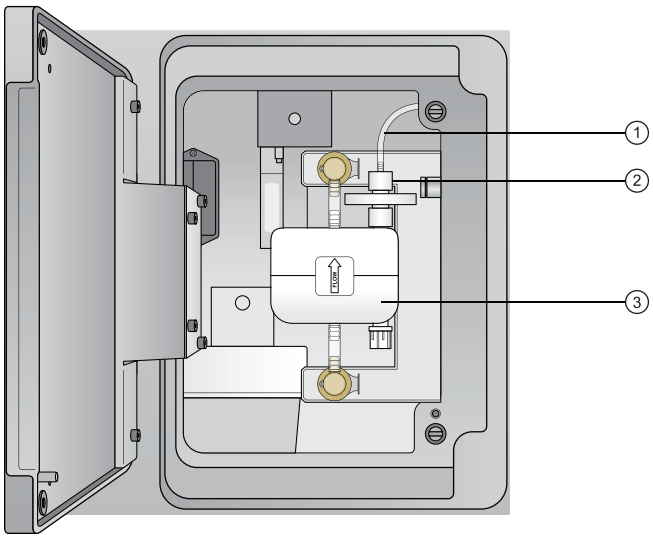
To perform the monthly clean procedure:

1. Verify that the system is in idle mode (not acquiring or performing any other fluidic task).
2. From the menu bar, select **Cytometer > Monthly Clean**.

   The Monthly Clean dialog opens.

3. Load a tube with 2 mL of bleach solution (diluted to 0.5% sodium hypochlorite) onto the manual tube port.
4. Fill a tank with 2 L of bleach solution.

   - We recommend using an extra tank dedicated to bleach (diluted to 0.5% sodium hypochlorite) for this procedure. If you have this tank, remove the connector from the sheath tank and install it on the dedicated bleach tank.
   - If you do not have a dedicated bleach tank, then empty the sheath fluid from the sheath tank and fill it with bleach solution diluted to 0.5% sodium hypochlorite.
5. Empty the waste tank.
6. Remove the sheath filter and store it carefully for putting it back in place at the end of this procedure.



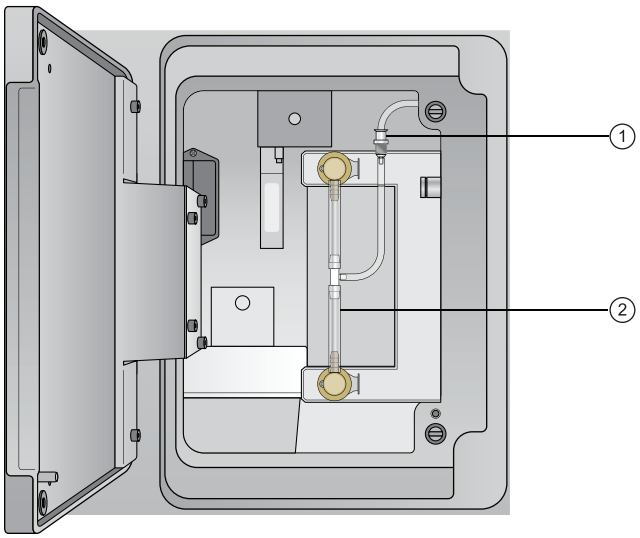
No.	Description
1	Vent line
2	Vent line connector nut
3	Sheath filter

a. Open the door on the left side of the chassis.
b. Disconnect the vent line on the top of the filter by unscrewing the connector nut.
c. Press the quick-disconnect tabs at the top and bottom of the filter and remove the filter from the chassis.

7. Install the sheath filter bypass assembly onto the two quick-connects and the vent line connector.

Caution! Installing the bypass assembly is a critical step. Failure to do this can damage the system.

The bypass assembly is shown installed in the following figure.



No.	Description
1	Vent line connector nut
2	Bypass assembly installed

8. Click **Continue** in the dialog to start the cleaning process.

   A progress bar in the dialog shows the status of the process.

9. When the bleach cycle is done, remove the tube that contained bleach and replace it with a tube containing 3 mL of DI water.
10. Remove the bleach tank and connect the sheath tank.

    - If you are using a dedicated bleach tank, disconnect it and install the connector on the sheath tank.
    - If you are not using a dedicated bleach tank, empty any remaining bleach from the sheath tank, rinse it thoroughly with DI water, and refill it with sheath fluid.

11. Click **Continue** to continue the cleaning process.

    A message is displayed when the process is complete, and the software records the time and date of the completed procedure.

12. Remove the bypass assembly and re-install the sheath filter.
13. Select **Cytometer > Fluidics > Purge Sheath Filter** and run this command twice to remove any air bubbles that might have formed during the process.

    You can also tap the filter gently to help remove bubbles.

More information

- Fluidics components (page 26)
- Replacing the sheath filters (page 164)

Replacing the sheath filters

Introduction

This topic describes how to replace the sheath filter on the side of the cytometer. It also describes how to replace the sheath supply-line filter in the sheath tank. You should replace these filters every three months.

Required materials

- 1 new sheath filter
- 1 new sheath supply-line filter

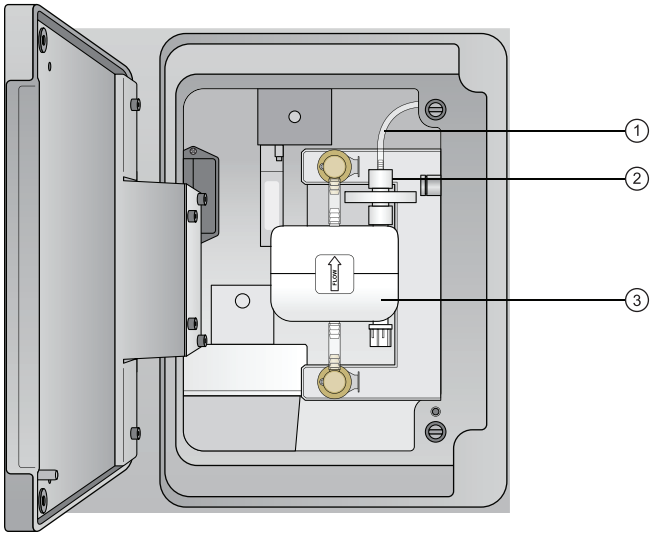
Replacing the sheath filter

To change the sheath filter:

1. Verify that the system is in idle mode (not acquiring or any other fluidic mode).
2. Open the door on the left side of the chassis.

   You might have to move the fluidics tanks dock if it is positioned next to the cytometer.

3. Disconnect the vent line on the top of the filter by unscrewing the connector nut.



No.	Description
1	Vent line
2	Vent line connector nut
3	Sheath filter

4. Press the quick-disconnect tabs at the top and bottom of the filter and remove the filter from the chassis.
5. Discard the used filter.
6. Install a new filter assembly, with the flow arrow pointing up, by inserting each end into the connectors.
7. Reconnect the vent line on the top of the filter by screwing on the connector nut.
8. Select **Cytometer > Fluidics > Purge Sheath Filter** to bring sheath fluid into the new filter.

   This process takes about one minute to complete.

9. Repeat step 8 to fill the filter.

   You should see fluid in the vent line when it is done.

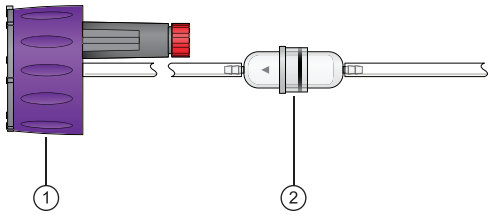
10. Close the door and resume normal operation.
11. Select **Cytometer > Maintenance > Replace Sheath Filter**.
12. Enter the information about the new filter, then click **OK**.

Replacing the sheath supply-line filter

The sheath supply-line filter is located inside the sheath tank in the tube that draws up the sheath fluid.

To change the sheath supply-line filter:

1. Disconnect the connector from the sheath tank by turning it counter-clockwise.
2. Remove the base connector from the sheath tank by unscrewing it and pulling out the connector and supply-line assembly that includes the supply tube and the filter.
3. Place the connector and supply-line assembly on clean, lint-free disposable towels so that you can work on it.
4. Twist open the supply-line filter holder and pull it apart to access the filter. See the following figure.



No.	Description
1	Base connector
2	Supply-line filter holder

5. Remove the used filter and install a new filter.
6. Push the two halves of the filter holder back together and twist to close it.
7. Place the supply-line assembly back into the sheath tank and screw on the base connector until it is secure.

More information

- Fluidics components (page 26)
- Refilling the sheath tank (page 158)

Managing your database

Introduction

This topic describes the tasks involved in managing your database. The BD FACSuite™ Clinical Backup and Restore utility allows you to back up and restore your database

About the Backup and Restore utility

Use the Backup and Restore utility to back up or restore all data that is stored in the BD FACSuite™ Clinical application database, along with all FCS files located in the application-defined directories.

With this utility, you can create a single backup set which contains a backup of the database, along with worklist FCS files. The utility maintains backup sets indefinitely. It displays how much disk space each set is taking and how much disk space is left. You can discard existing backup sets to free up space.

You can also use any backup set to restore the database and FCS files. When you restore, you erase any new data created since the backup was created.

Creating a new backup set

To create a new backup set:

1. Click the **BD FACSuite™ Clinical Backup and Restore** utility icon on the desktop.
2. (Optional) If you want to store the backup files to a mapped network drive:
   a. Click **Change Settings**.
   b. On the Settings pane, click the ... button beside Backup Directory.
   c. In the Browse For Folder pane, right-click **Network**.
   d. From the context menu, select **Map network drive...**.
   e. In the Map Network Drive pane, select a drive letter, type in the network path to the backup folder, and then click **Finish**.
   f. In the Browse For Folder pane, select the mapped network drive and click **OK**.
   g. On the Settings pane, click **OK**.

   Note: If backup to a network drive fails, the backup will be stored locally.
3. Click **Back Up**.

   The Back Up window opens, indicating the required disk space. If the estimated space required is greater than the amount available, the software prompts you to free up additional space and try again.
4. Verify that adequate disk space is available and click **Back Up**.

   The backup process starts and displays a progress bar. A completion dialog is displayed and indicates success or failure. If the backup succeeds, the timestamp of the new backup is provided. If the backup fails, the reason is indicated.
5. Click **Finish** to close the window.

Restoring a backup set

To restore a backup set:

1. Click the **BD FACSuite™ Clinical Backup and Restore** utility icon on the desktop.
2. Select the backup set to restore.
3. Click **Restore**.

The **Restore** window opens, indicating the timestamp of the selected backup set and the required disk space. If the estimated space required is greater than the amount available, the system prompts you to free up additional space and try again.

The estimated space required takes into account the files that will be removed during the process, and it is possible that this number could be negative. In that case, 0 KB is used.

4. Select one of these actions:

   - **Back Up and Restore**
   - **Restore**

   A confirmation dialog is displayed. The restore process begins and displays a progress bar. A completion dialog is displayed and indicates success or failure.

5. Click **Finish** to close the window.

Deleting a backup set

To delete a backup set:

1. Click the **BD FACSuite™ Clinical Backup and Restore** utility icon on the desktop.
2. Select the backup set to delete.
3. Click **Delete**.

   A confirmation dialog is displayed to verify that the selected backup set needs to be deleted.

4. Click **OK**.

More information

- Maintenance overview (page 156)
- To create a backup set from the Windows command line, refer to the BD FACSuite™ Clinical Reference System.

Archiving procedure for worklists

Introduction

Worklists that are no longer being used should be archived at least once per month, or more frequently as defined by lab-validated procedures. This will allow the software to perform optimally.

Worklists should be archived to a known location, preferably not on the hard drive of the BD FACSLyric™ workstation.

Procedure

To archive worklists not actively in use:

1. Perform a database backup and export it to a known location, preferably not on the hard drive of the BD FACSLyric™ workstation.
2. Navigate to the **Worklist Management** page.
3. Select the worklists you would like to archive.
4. In the **File** menu, select **Export Worklist > With Data** to export the selected worklists to the desired known location.
5. Confirm that the files were successfully exported.
6. In the **Edit** menu, select **Delete** to delete the selected worklists that have been exported.
7. Exit the software.
8. To show hidden files and folders in Windows 10:
    a. In the **Search** box, type *Show hidden files and folders*, then press **Enter**.
    b. In the **View** tab, select **Show hidden files and folders,** then click **OK**.
9. Navigate to **C:\ProgramData\BD\FACSuite Clinical\Worklists\Deleted Worklists** and delete the contents of that directory.
10. Perform a database backup again and export it to a known location, preferably not on the hard drive of the BD FACSLyric™ workstation.

If you need to retrieve one or more of the worklists from the archive, use the Import Worklist functionality to import the desired worklist(s) from the archiving location.

Performing disk cleanup

Introduction

During normal operation, the software generates intermediate files in your local temporary folder. We recommend running the Disk Cleanup tool on a regular basis to scan your disks to find and remove unnecessary temporary files to free up some disk space.

Procedure

To run disk cleanup:

1. Close the BD FACSuite™ Clinical application, if it is open.
2. In Windows 10, click the bottom-left **Start** button, type *administrative* and click **Administrative Tools,** and then press **Enter**.
3. Double-click **Disk Cleanup**.
4. In the **Disk Cleanup** dialog, select the **Temporary files** checkbox if it is not selected.
5. Click **OK**.

   A confirmation dialog opens.

6. At the prompt, **Are you sure you want to permanently delete these files?** select **Delete Files**.

Decommissioning the instrument

Instrument disposal and parts removal

A BD Field Service Engineer is required to perform any necessary decontamination and safe removal and disposal of the instrument, or any of its non-consumable parts or accessories.

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