

 **BD FACSLyric™ System**
Instructions for Use

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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 Règlement 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.

EC information

The BD FACSLyric™ system is for in vitro diagnostic use. The system is CE marked in compliance with Regulation (EU) 2017/746 and Directive 2006/42/EC.

Electromagnetic compliance

The BD FACSLyric™ 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.

History

Revision	Date	Change made
23-21284-00	2019-02	Initial release (in English only).
23-21284-01	2020-04	Updated from software version 1.3 to 1.4. IFU expanded to cover both BD FACSuite™ and BD FACSuite™ Clinical applications (instead of just BD FACSuite™).
23-21284-02	2020-12	Version updated to 1.5 including modified handling of high-sensitivity fluidics mode, FCS file concatenation, and updates to worklist and gating user interface.
23-21284(03)	2021-07	Clarified bleach concentration as a percentage of sodium hypochlorite. Renamed "Technical assistance" topic in Chapter 1 to "Contact information" and added subtopic "Reporting serious incidents". Changed EU authorized representative. Changed publication part number and date formats.
23-21284(04)	2021-10	Added Swiss authorized representative.
23-21284(05)	2023-10	Updated legal manufacturer address. Added EU importer and Swiss importer addresses. Added reference to Directive 2006/42/EC. Changed maximum particle size in Principle of Operation from 150 µm to 50 µm. Added more detail about errors, warnings, and notifications in QC reports. Added catalog IDs to title page. BD FACSuite™ and BD FACSuite™ Clinical applications updated to v1.6.

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Introduction

This chapter includes the following topics:

- [About this guide \(page 10\)](#)
- [Symbols in this guide \(page 11\)](#)
- [Contact information \(page 12\)](#)
- [Intended use \(page 12\)](#)
- [Cybersecurity guidelines \(page 13\)](#)
- [Limitations \(page 14\)](#)

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.

The software that controls the BD FACSLyric™ system features two applications:

- The BD FACSuite™ Clinical application supporting BD IVD assays
- The BD FACSuite™ application supporting BD IVD Single Color Reagents and user-defined panels, which need to be verified and validated by the user

The following chapter applies to the BD FACSuite™ Clinical application for BD IVD assays only:

- [BD IVD assays \(page 167\)](#)

The following chapters apply to the BD FACSuite™ application only:

- [Experiment basics \(page 57\)](#)
- [Data acquisition in an experiment \(page 69\)](#)
- [Data analysis in an experiment \(page 91\)](#)
- [Experiment settings \(page 99\)](#)

To provide a visual reminder of which application you are running, the color theme in the graphical user interface (GUI) of the software is application-specific: green for the BD FACSuite™ Clinical application and blue-gray for the BD FACSuite™ application. Most of the content in this guide applies to both applications. For screenshot examples that are applicable to both, this guide uses the blue-gray color theme from the BD FACSuite™ application.

Additional help

In the BD FACSuite™ and BD FACSuite™ Clinical applications, 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™** or **About BD FACSuite™ Clinical** (depending on the application) displays version information and the unique device identifier (UDI) for the software.

- Click **Reference** to open the *BD FACSLyric™ Reference System* in a separate window. Internet access is not required to access this content.

The *BD FACSLyric™ 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™ 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™ 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 system is intended for use as an in vitro diagnostic device for identification and enumeration of human cell subsets for flow cytometry.

Intended user statement

The BD FACSLyric™ flow cytometer system is intended for laboratory professional use.

Cybersecurity guidelines

Introduction

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

BD FACSuite™/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™ application is C:\ProgramData\BD\FACSuite\BD Backup and 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™ 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™/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™/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™/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

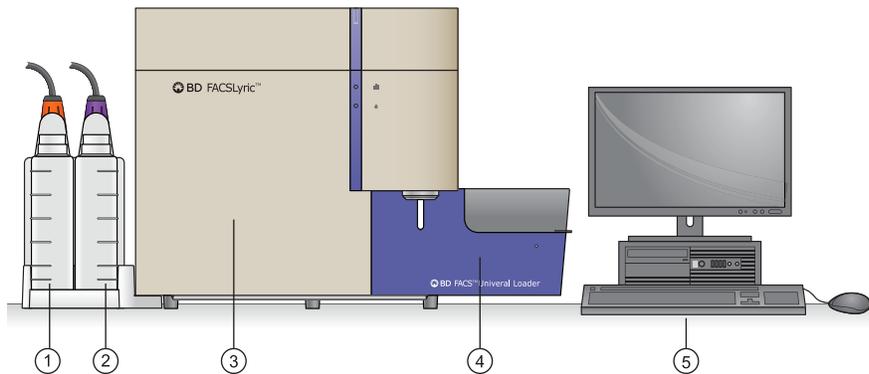
This chapter includes the following topics:

- [System overview \(page 16\)](#)
- [Cytometer overview \(page 20\)](#)
- [Optical components \(page 22\)](#)
- [Fluidics components \(page 24\)](#)
- [System options and upgrades \(page 27\)](#)
- [Software overview \(page 28\)](#)
- [About the Home page \(page 30\)](#)
- [Software components \(page 33\)](#)
- [Daily workflow \(page 35\)](#)

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.



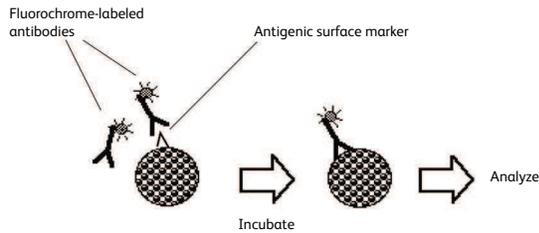
No.	Description
1	Waste tank
2	Sheath tank
3	BD FACSLyric™ cytometer
4	BD FACS™ Universal Loader (optional)
5	Workstation with BD FACSuite™ and BD FACSuite™ Clinical applications. Note that the workstation for newer BD FACSLyric™ systems is more compact than shown in the illustration and, as a result, 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

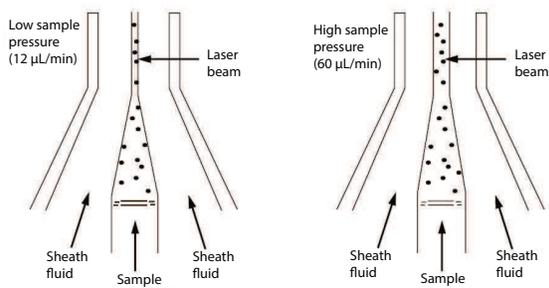
The BD FACSLyric™ system, using flow cytometry, identifies and enumerates cell subsets. Flow cytometry is a technology that simultaneously measures and then analyzes multiple physical characteristics of single particles, usually cells, as they flow in a fluid stream through a beam of light. The properties 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.

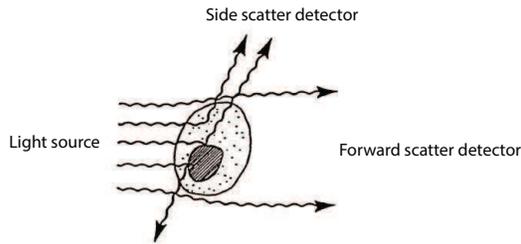


The fluidic system is vacuum-driven, which draws the sheath fluid and the sample into the system rather than pushing it through using positive pressure. This approach enables the fluid to be drawn from a nonpressurized sheath and sample vessels. This method avoids potential issues surrounding the pressurization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

Three laser configurations provide the ability to analyze up to 12 colors (14 parameters). A unique heptagon detector array ensures that the correct filters and mirrors are installed.

The vacuum-driven fluidics, along with a uniquely designed flow cell and sample injection tube, provide reliability and good signal resolution. The BD FACSuite™ application includes high, medium, and low flow rates. In addition, a special high-sensitivity fluidics mode makes it easier to detect dimly stained particles. In the BD FACSuite™ Clinical application, flow rate is fixed by the BD IVD assay and cannot be changed.

Note: High-sensitivity fluidics mode should not be used with BD IVD applications.

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. The Loader can also handle multiple types of microtiter plates, including deep-well plates. Plates should not be used for BD IVD assays. A barcode reader verifies the ID on tube racks, plates, 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 and plates 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™ 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 FACFlow™ 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.

In the BD FACSuite™ application, User-Defined assays can be used as a starting point for creating customized experiments and reports.

More information

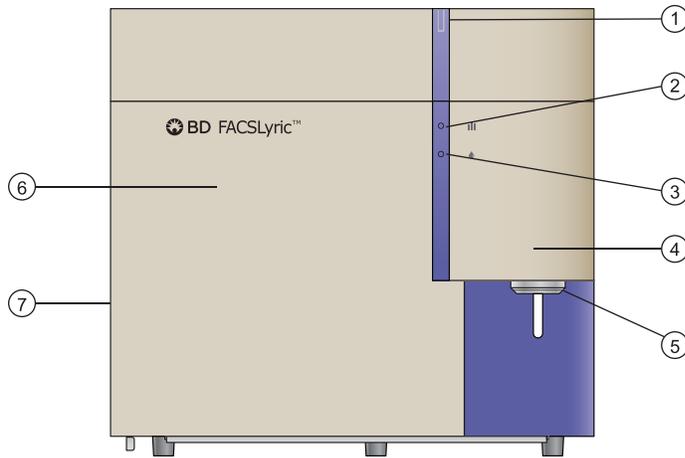
- [Cytometer overview \(page 20\)](#)
- [System options and upgrades \(page 27\)](#)
- [Software overview \(page 28\)](#)

Cytometer overview

Main components

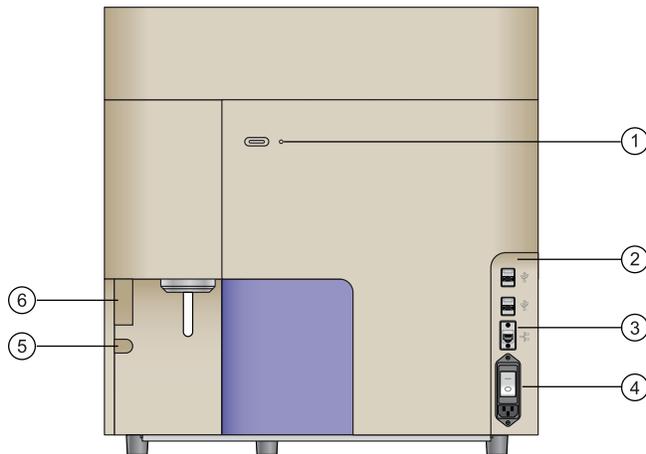
The locations of the main components of the cytometer, including the status indicators, are shown in the following figures.

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	<ul style="list-style-type: none"> • Sheath fluid low • Waste tank almost full
	Red	<ul style="list-style-type: none"> • 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)

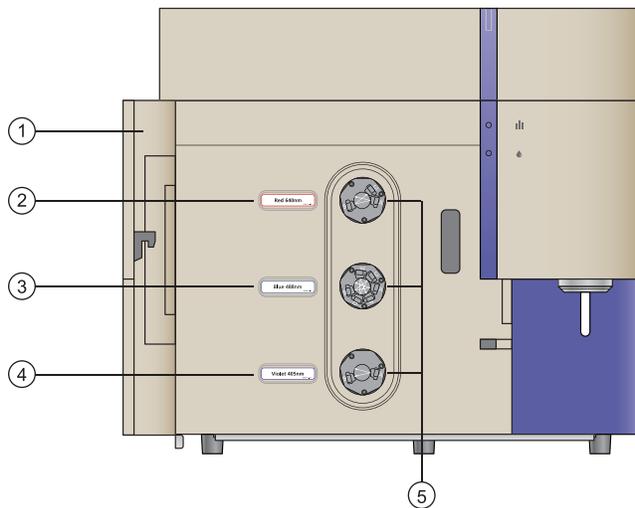
More information

- [Optical components \(page 22\)](#)
- [Fluidics components \(page 24\)](#)
- [System options and upgrades \(page 27\)](#)
- See Laser and detector configurations in the *BD FACSLyric™ 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

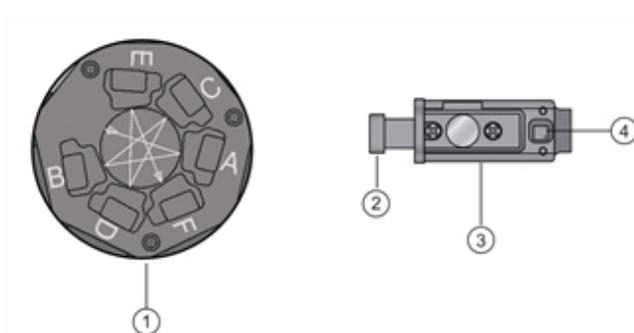
Heptagon detector arrays

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

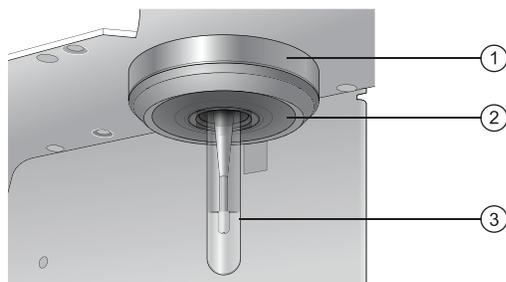
- [Fluidics components \(page 24\)](#)
- [System options and upgrades \(page 27\)](#)

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

Condition	Status
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

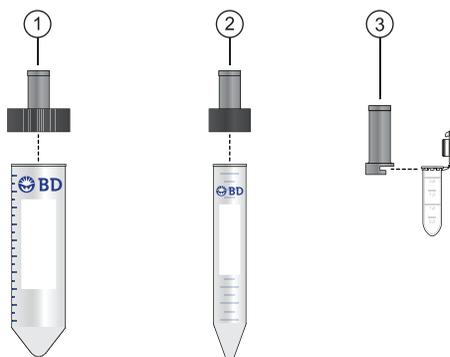
Only the following tubes have been qualified for use on the manual tube port on the cytometer. For optimal performance in reducing carryover when using 5-mL tubes, it is important to ensure that the wash probe does not make contact with the sample by filling to 0.5 mL or less, and to take care when loading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

Note: Only qualified 5 ml tubes should be used with BD IVD assays. Other sizes of tubes should not be used.

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
Falcon 15-mL (when used with adapter)	14 mL
Falcon 50-mL (when used with adapter)	45 mL
Eppendorf® 2-mL (when used with adapter)	1.5 mL

Tube adapters

You can use 15-mL, 50-mL, and Eppendorf 2-mL tubes by installing a tube adapter. The 15-mL and 50-mL adapters screw onto the tops of the tubes. The Eppendorf adapter slides onto the tube from the side.



No.	Description
1	50-mL adapter
2	15-mL adapter
3	Eppendorf 2-mL adapter

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 \(page 232\)](#)
- [System options and upgrades \(page 27\)](#)

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 and plates to the BD FACSLyric™ system for acquisition. Note: Plates should not be used with BD IVD assays. See BD FACS™ Universal Loader overview (page 178) .
	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 <i>BD FACSLyric™ Reference System</i> .
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.
	Cubitainer	Sheath fluid can also be supplied from a BD FACFlow™ 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 <i>BD FACSLyric™ Reference System</i> .
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).
	BD FACS™ Workflow Manager	BD FACS™ Workflow Manager software is a data management system that also provides an interface solution to an LIS/LIMS (available in Europe only).

Software overview

Introduction

This topic provides an overview of the basic features and functionality of the BD FACSuite™ and BD FACSuite™ Clinical applications that control 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 and experiments 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.

Experiments and assays

In the BD FACSuite™ application, you can measure and analyze samples using either assays or experiments. Both formats organize and specify the conditions for acquisition and analysis for tubes.

Use assays when you want to run a specific protocol or analysis on samples repeatedly. Assays are run as entries in a worklist, which provides batch acquisition and analysis. Use experiments to test studies and different samples, and to develop protocols. Experiments are exploratory and highly customizable. You can define the properties of each tube and create custom tube settings and apply them to other tubes. You can refine an experiment and then save it as an assay to set the test protocols.

While assay protocols are predefined to target specific data (markers, populations, fluorochromes, etc) and look for specific results, you can modify plots, gates, and other worksheet or report elements for an assay. Worklists and assays provide administrative control capabilities such as e-signature and audit trails.

In experiments, data can be displayed in a worksheet or report using any combination of plots or histograms. In the application, worksheets and reports are live data portals and continuously display current data. You can acquire data and then analyze it by gating populations of interest, displaying statistics, and adding expressions. You can create custom, formatted reports that include the details you want to analyze and present in a final lab report.

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 or plates 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 experiments, worklists, and in setup and QC. For example, you can assign a tube setting to an experiment, or 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
- Experiment 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.

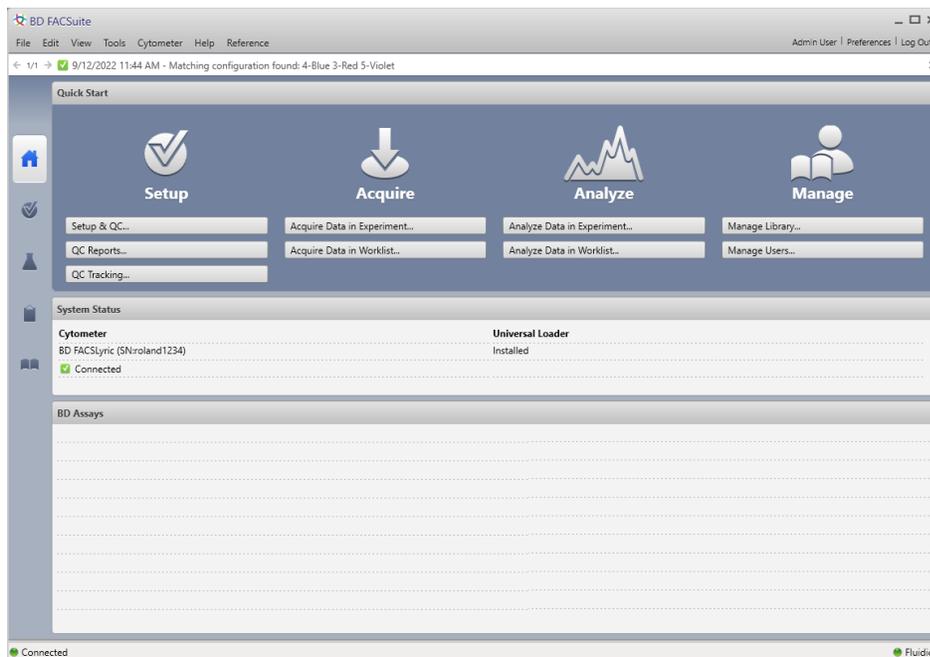
About the Home page

Introduction

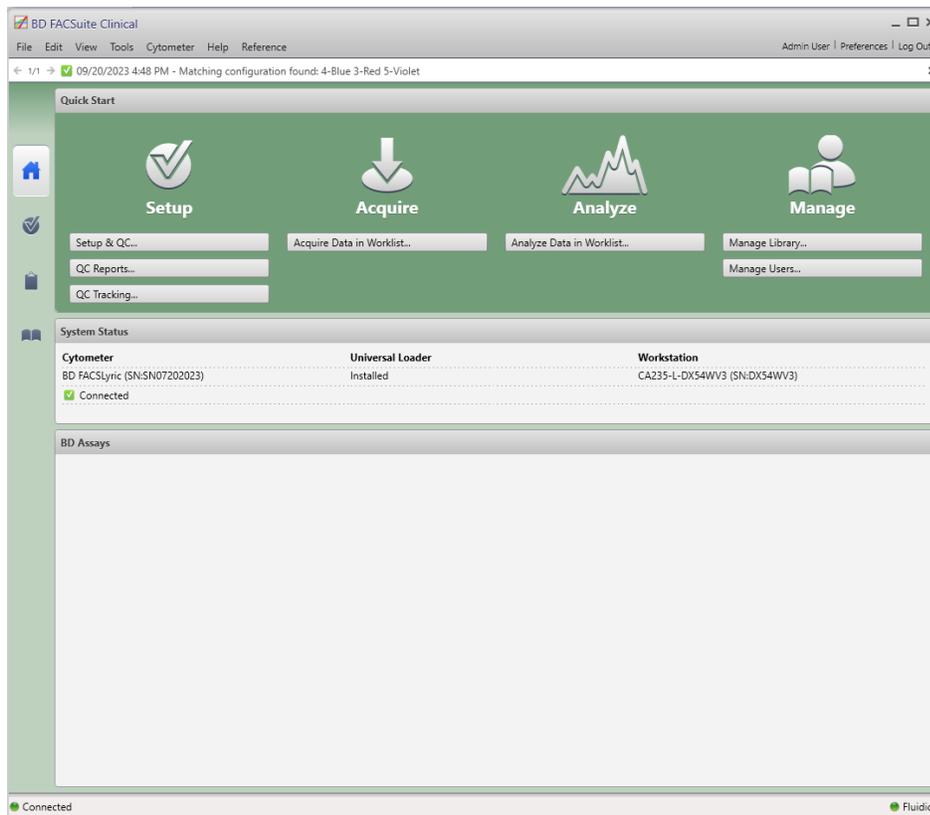
The Home page is the default starting page. This page includes the following sections:

- **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 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™ application Home page:



BD FACSuite™ Clinical application Home page:



Quick Start shortcuts

The following table describes the available Quick Start shortcuts.

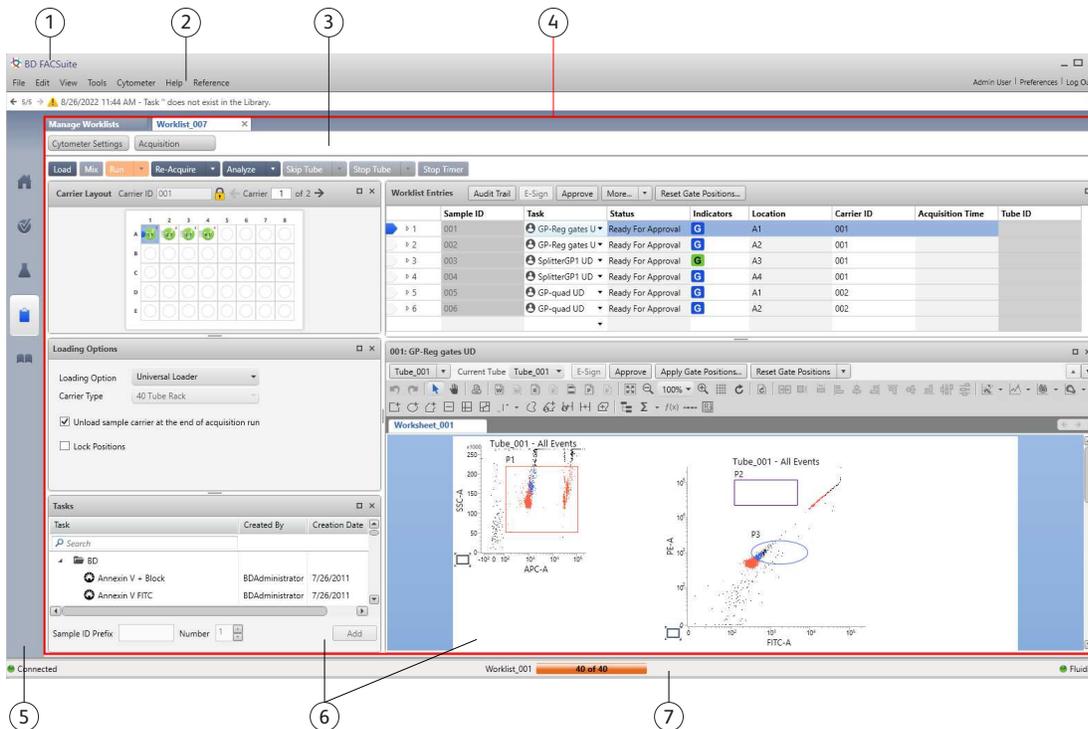
Shortcut	Task	Description
	Setup & QC	Opens the Setup & QC workspace and displays the Setup & QC tab.
	Setup & QC Report	Opens the Setup & QC workspace and displays the QC Report tab.
	QC Tracking	Opens the Setup & QC workspace and displays the QC Tracking tab.
	Acquire Data in Experiment	Opens the Experiment workspace and displays a new experiment.
	Acquire Data in Worklist	Opens the Worklists workspace and displays a new worklist.
	Analyze Data in Experiment	Opens the Experiment workspace and displays the Experiment Management tab.
	Analyze Data in Worklist	Opens the Worklists workspace and displays the Worklists Management tab.

Shortcut	Task	Description
	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.
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, experiments, 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.

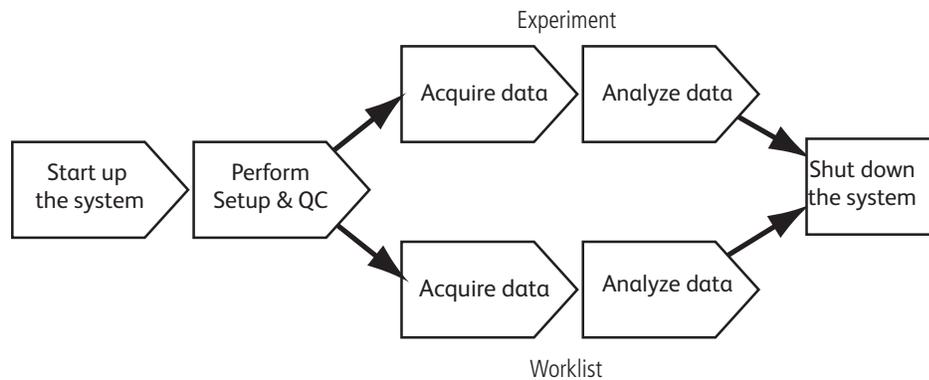
Menu	Description
File	This menu includes specific tools and items for the current window or workspace. Choices include importing, exporting, printing, saving, and managing specific workspaces (for example, opening a worklist).
Edit	This menu includes Cut, Copy, Paste, Delete, Undo, Redo, and other editing 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 <i>BD FACSLyric™ Reference System</i> . 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 \(page 28\)](#)

Daily workflow

The following diagram shows the typical daily workflow for the BD FACSLyric™ system when using the BD FACSuite™ application.



The following diagram shows the typical daily workflow when using the BD FACSuite™ Clinical application for BD IVD assays.



More information

- [System startup and shutdown \(page 37\)](#)
- [Daily setup and QC \(page 43\)](#)
- [Data acquisition in an experiment \(page 69\)](#)
- [Data analysis in an experiment \(page 91\)](#)
- [About the worklist \(page 114\)](#)
- [Maintenance \(page 223\)](#)

3

System startup and shutdown

This chapter includes the following topics:

- [Performing system startup \(page 38\)](#)
- [Performing manual system shutdown \(page 39\)](#)
- [Performing automated system shutdown \(page 40\)](#)

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 the [Setting system preferences \(page 202\)](#).

Required materials

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

- BD FACSTyric™ 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™** icon or **BD FACSuite™ Clinical** icon to start the application.
 - 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 \(page 226\)](#)
- [Emptying the waste tank \(page 227\)](#)
- [Setting system preferences \(page 202\)](#)

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 \(page 40\)](#).

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**.

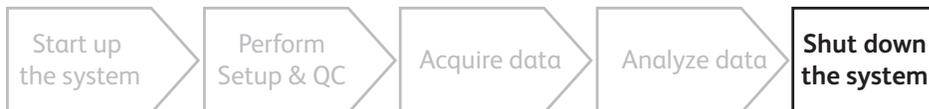
The Power button blinks green for a few seconds, then power to the system turns off and the Power button turns amber.

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 \(page 38\)](#)
- [Performing automated system shutdown \(page 40\)](#)

Performing automated system shutdown



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 information about setting cytometer schedule preferences in the *BD FACSLyric™ Reference System*.

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

	Sample ID	Task	Status	Indicators	Location
▶ 1	001	User-Defined A: ▼	Ready		A1-A2
▶ 2		Perform SIT Flush ▼	Ready		
▶ 3	002	UL Assay UD ▼	Ready		A3
▶ 4		Perform SIT Flush ▼	Ready		
▶ 5	003	User-Defined A: ▼	Ready		A4-A5
▶ 6		Perform SIT Flush ▼	Ready		
▶ 7	004	UL Assay UD ▼	Ready		A6
▶ 8		Perform SIT Flush ▼	Ready		
▶ 9	005	UL Assay UD ▼	Ready		A7
▶ 10		Perform Daily Clear ▼	Ready		A8-B1
▶ 11		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™ Reference System*.

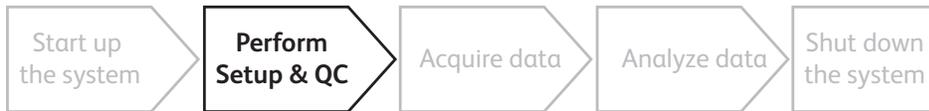
4

Daily setup and QC

This chapter includes the following topics:

- [Daily setup and QC workflow \(page 44\)](#)
- [Running daily performance QC \(page 44\)](#)
- [Selecting and viewing Performance QC favorites \(page 46\)](#)
- [About the Setup and QC workspace \(page 48\)](#)
- [About QC reports \(page 50\)](#)

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 experiments or worklists.

More information

- [Running daily performance QC \(page 44\)](#)
- [About the Setup and QC workspace \(page 48\)](#)
- [About QC reports \(page 50\)](#)

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™ Reference System*.

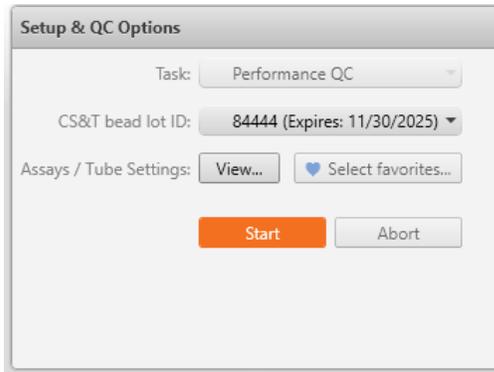
Procedure

To run daily performance QC:

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

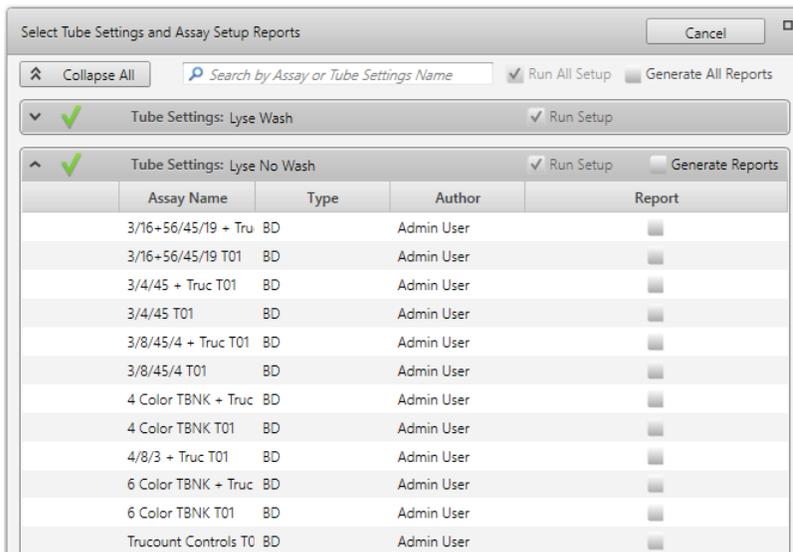
The Setup & QC workspace opens.

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.

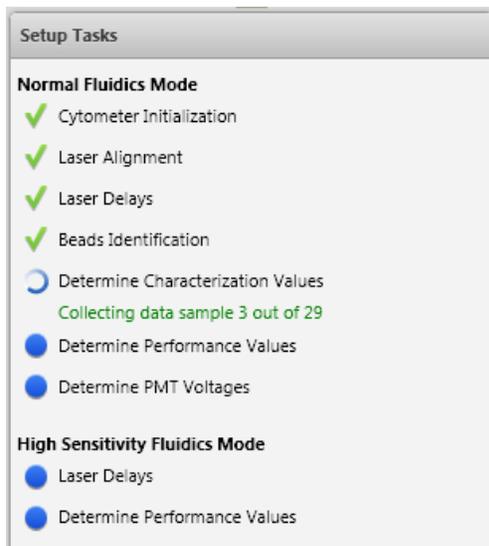
8. Load the tube of BD[®] CS&T Beads onto the manual tube port.

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

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

The details for the application-supported 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™ application including High Sensitivity Fluidics mode:



Note: High Sensitivity Fluidics Mode is only available in the BD FACSuite™ application and is disabled by default. An Administrator can change this setting if required.

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™ Reference System*.

Note: If the setup task passes with warnings or notifications, refer to [About QC reports \(page 50\)](#) and the troubleshooting section in the *BD FACSLyric™ 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 \(page 48\)](#)
- [Importing or adding a CS&T or FC bead lot \(page 217\)](#)
- [About QC reports \(page 50\)](#)
- [Setting setup and QC preferences \(page 203\)](#)

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. The maximum number of PQC favorites that you can select depends on the PQC running mode:

- Ten tube settings when running PQC in Normal Sensitivity mode only
- Five tube settings when running PQC in both Normal and High Sensitivity mode (High sensitivity mode is only available in the BD FACSuite™ application)

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

Adding tube settings to PQC favorites

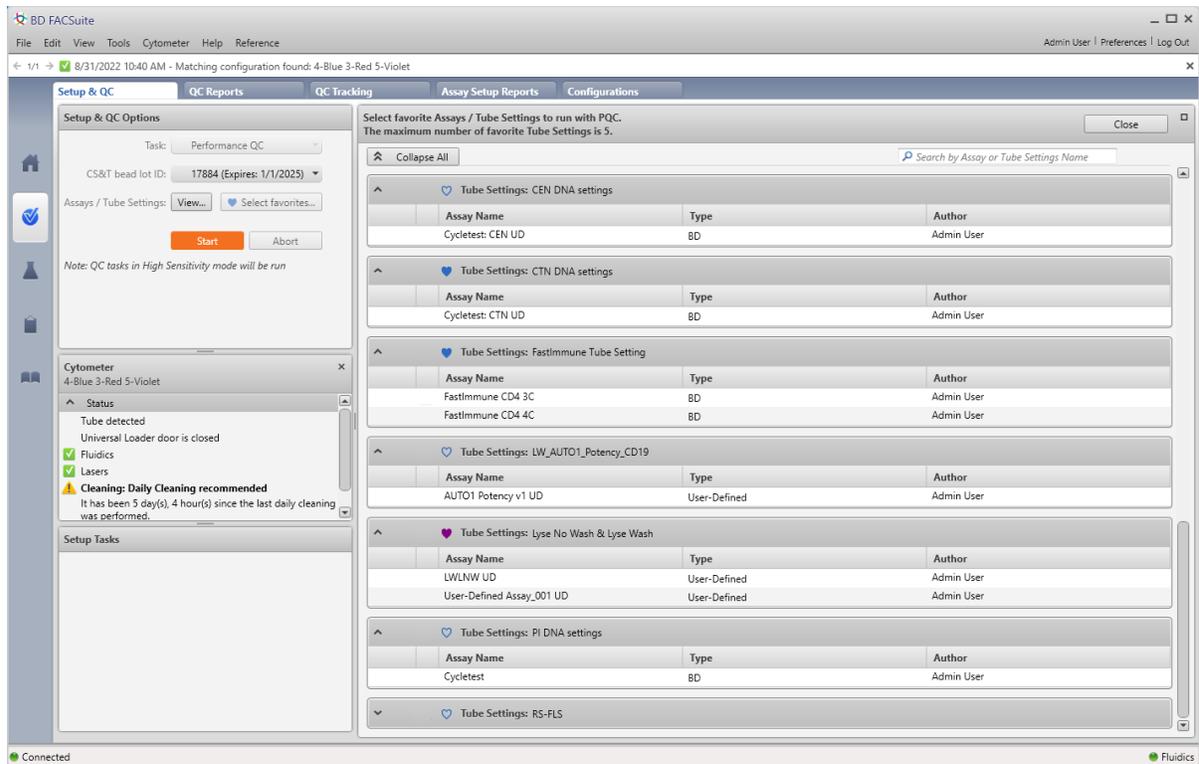
A **Select favorites...** button is displayed in the Setup & QC Options panel on the Setup & QC tab. To select tube settings and their associated assays to be included in the PQC task:

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.

For a User-Defined tube setting, its availability as a PQC favorite depends on the shared status of the tube setting and the Setup & QC preferences. If the preferences are set up so that favorite tube settings are defined for all users, a tube setting can only be selected as a PQC favorite if the tube setting is shared. If the preferences are set up so that favorite tube settings are defined for the individual user, a tube setting can be selected as a PQC favorite if the tube setting is shared or if the logged in user name corresponds to the tube setting author. For details about Setup & QC preferences, see [Setting setup and QC preferences \(page 203\)](#). For details about shared and author properties for tube settings in the Library, refer to the *BD FACSLyric™ Reference System*.



Assay Name	Type	Author
Tube Settings: CEN DNA settings		
Cycletest: CEN UD	BD	Admin User
Tube Settings: CTN DNA settings		
Cycletest: CTN UD	BD	Admin User
Tube Settings: FastImmune Tube Setting		
FastImmune CD4 3C	BD	Admin User
FastImmune CD4 4C	BD	Admin User
Tube Settings: LW_AUTO1_Potency_CD19		
AUTO1 Potency v1 UD	User-Defined	Admin User
Tube Settings: Lyse No Wash & Lyse Wash		
LWLNW UD	User-Defined	Admin User
User-Defined Assay_001 UD	User-Defined	Admin User
Tube Settings: PI DNA settings		
Cycletest	BD	Admin User
Tube Settings: RS-FLS		

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

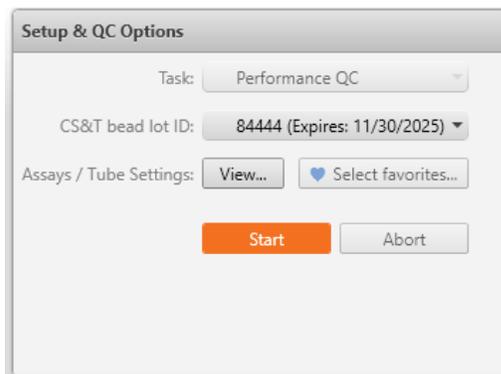
The Setup and QC workspace includes multiple tabs that you use to perform different setup and quality control tasks, view reports, and track QC over time. You can also view or modify the cytometer optical configuration.

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

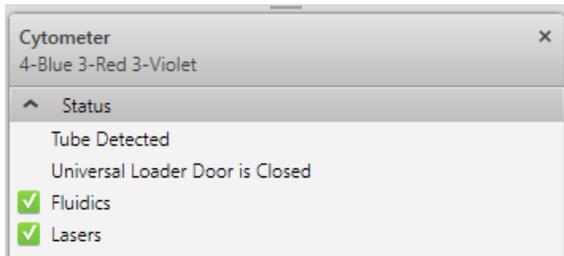
Setup & QC tab

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. Separate reports for each fluidics mode (normal and high sensitivity¹) are generated for each setup and QC task.

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

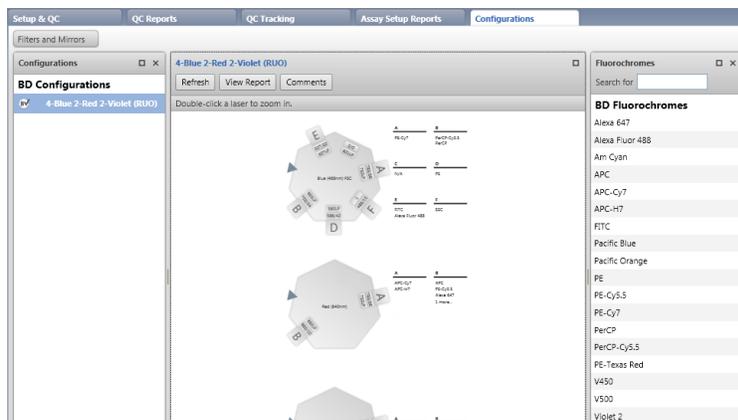
In the Assay Setup Reports tab, the Assay Setup Reports table lists all of the reports that are generated when you perform assay and tube settings setup.

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.

Configurations tab (BD FACSuite™ application)

Use the Configuration tab to view the current cytometer configuration and the details for each laser and detector.

¹ In the BD FACSuite™ application, high-sensitivity mode is an option that can be set by the Administrator under Tools > Setup and QC Preferences.



You can assign fluorochromes to detectors, and view, print, and export configuration reports.

More information

- [Running daily performance QC \(page 44\)](#)
- [About QC reports \(page 50\)](#)

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.

Each time a procedure is completed, a report is generated for each supported fluidics mode. 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™ 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 (x10 ³)	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 (x10 ³)	110.1	55.0 - 107.3	Value is outside of +/- 3SD alarm limits
Violet-V500-C Qr (x10 ³)	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

Section	Field	Description
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
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

Section	Field	Description
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- μ m beads
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

Field	Description
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- μ m 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 \(page 205\)](#).

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 \(page 44\)](#)
- [About the Setup and QC workspace \(page 48\)](#)

5

Experiment basics

This chapter applies to the BD FACSuite™ application only, and includes the following topics:

- [About the experiment \(page 58\)](#)
- [Using the Manage Experiments tab \(page 60\)](#)
- [About tube properties \(page 62\)](#)
- [About experiment panels \(page 63\)](#)

About the experiment

Introduction

This topic describes experiments, the Experiment workspace, and provides typical workflow steps for creating, editing, and saving experiments. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

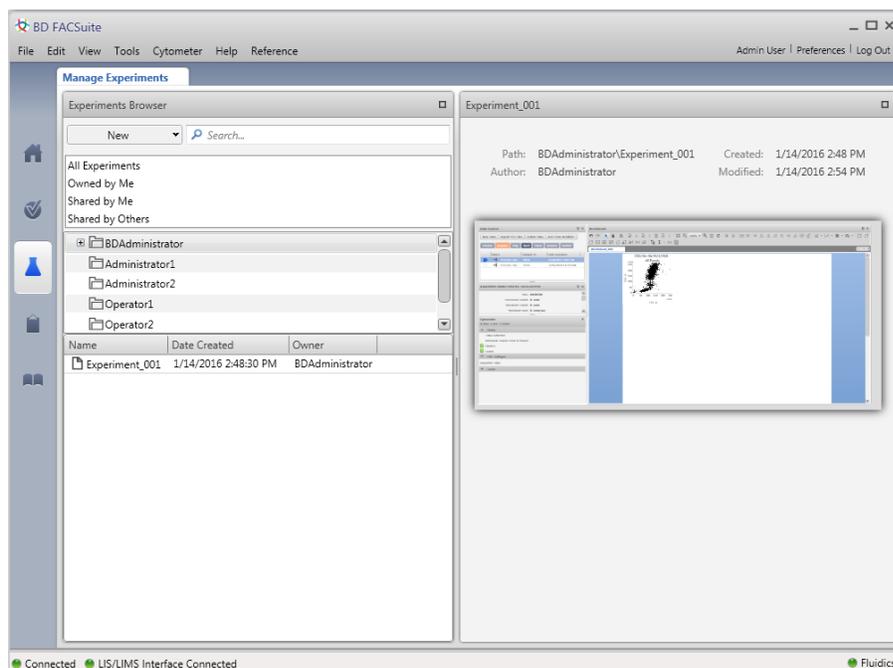
This workflow includes only the basic required elements for creating and acquiring data in an experiment using BD default settings. See [Using the Manage Experiments tab \(page 60\)](#) for more information about optional features and functions.

About the Experiments workspace

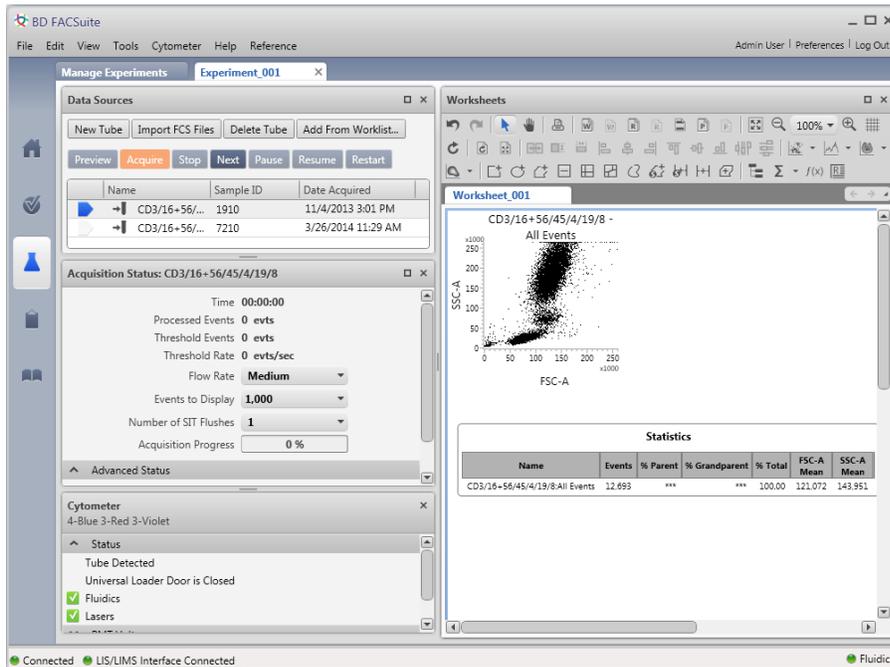
The Experiments workspace includes the Manage Experiments tab and Experiment tabs, which represent an open experiment.

To open the Experiments workspace, click the **Experiments** icon on the navigation bar.

Use the Manage Experiments tab to create new experiments, preview and open existing experiments, organize experiments, filter and search for experiments, and share them with other users. Use the BD FACSuite™ menus to rename, import, or export experiments.



Use a named Experiment tab, such as Experiment_001, to develop your experiment, adjust settings, set properties, acquire and visualize tube data, and analyze the data using different analysis tools. A separate tab is created for each open experiment.



About experiment folders

The Experiments Browser panel in the Manage Experiments tab displays experiment folders. Each user has a default experiment folder identified by the user login name. You can create an unlimited number of subfolders and organize different experiments within your default experiment folder.

You can rename experiments and folders, move experiments from one subfolder to another, and delete, share, or make experiments private.

Locating existing experiments

Experiments are located in your user folder(s) and are listed by experiment name and creation date. Private experiments are accessible only by their author. Shared experiments are accessible by all users.

If your folders include numerous subfolders with many experiments, you can search individual folders to locate experiments. Click a folder, type an experiment name, number, date, or owner in the Search field and press **Enter**.

If you cannot find a specific experiment, the experiment might not be shared. See your Administrator or the experiment author for more information.

More information

- [About experiment panels \(page 63\)](#)
- [Using the Manage Experiments tab \(page 60\)](#)
- [Experiment building workflow \(page 73\)](#)

Using the Manage Experiments tab

Introduction

This topic describes how to open, save, and delete experiments, and how to change sharing settings. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

Opening the Experiment workspace

To open the Experiment workspace:

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

The Manage Experiments tab opens in the Experiment workspace.

Saving an experiment as a different experiment

To save an experiment (Save As) as a different experiment:

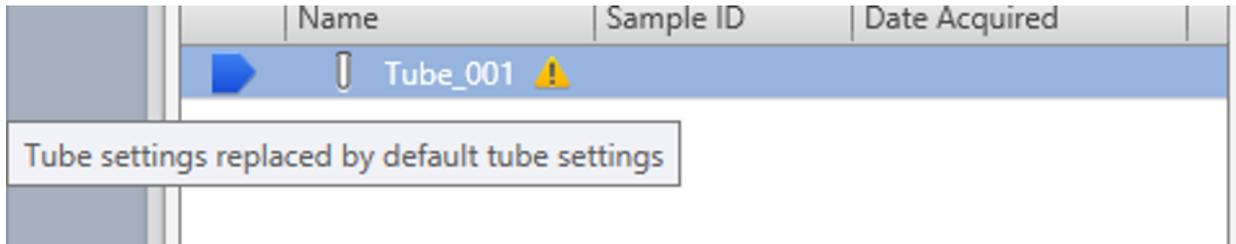
1. In the **Experiments Browser**, right-click an experiment, then select **Save As**.

A **Save Experiment As** dialog opens.

2. In the **Experiment Name** field, type a new experiment name.
3. (Optional) If you want to save the experiment properties, plots, gates, and other worksheet elements, but not the tube data, select the **Save Experiment without Data** checkbox.
4. Click **OK** to save a copy of this experiment with a new name.

Changing sharing settings

Experiments are private by default. Only Administrators or experiment owners (authors) can change share settings. Once an experiment is shared by the author, all users can modify, rename, or export the experiment. Changes are saved to the original, shared experiment. Only Administrators or experiment owners (authors) can delete an experiment. If a user tries to use shared tube settings from a deleted experiment, the system will alert the user and indicate that they have been replaced by default tube settings.



Shared experiments are listed in the **Shared by Me** and **Shared by Others** folders. Private experiments are listed only in the **All Experiments** and **Owned by Me** experiment folders.

To change the share setting for an experiment:

1. In the **Experiments Browser**, right-click an experiment and select **Make Private** or **Share**.

Exporting experiments

Export experiments so that you can import them onto a different BD FACSLyric™ workstation or to back up experiments as a part of your specific data management process.

To export an experiment:

1. In the **Experiment** workspace, click the **Manage Experiments** tab.
2. In the **Experiments Browser**, click an experiment folder.
3. Right-click an experiment.
4. Select **Export Experiments**, then select one of the following options:
 - **With Data.** Saves all tube properties, instrument settings, worksheets, reports, and acquired data.
 - **Without Data.** Saves tube properties, worksheets, and reports. Select this option when you are creating tubes you want to reuse.

The Browse For Folder dialog opens.

5. Navigate to a target export folder.
6. Click **OK** to export the file.
7. View the status bar to confirm that the files have exported successfully.

More information

- [About the experiment \(page 58\)](#)
- [Creating and opening an experiment \(page 70\)](#)

About tube properties

Introduction

As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

Tube properties define the identity and details for each tube and determine how tube data is acquired and displayed. Tube properties can be modified at any time before you acquire a tube. It can be useful to set some tube properties before you preview data (for example, selecting tube settings or adding labels), while other properties should be modified after plots and gates are created (for example, acquisition stopping rules).

Tube properties

The following table describes the tabs in the Tube Properties dialog.

Tab	Description
General	Use this tab to view or modify the tube name, tube ID, or sample ID, select tube settings, and view other descriptive information about the tube. See Setting general tube properties and applying tube settings (page 81)
Parameters	Use this tab to change the current parameter names, area, height, and width, PMT voltages, and thresholds for the tube. See Viewing and adjusting cytometer settings (page 78)
Spillover Values	Use this tab to view or modify the compensation matrix for the current tube. You do not need to modify this matrix for typical daily use. See Modifying the compensation matrix (page 80)
Reagents	Use this tab to select labels and lot IDs for fluorochromes used in this tube. See Editing single-color reagent labels (page 84)
Keywords	Use this tab to view and assign keywords and set keyword values to the selected tube. See Assigning and editing keywords (page 85)
Acquisition	Use this tab to set acquisition stopping rules. See Setting acquisition stopping rules (page 86)

More information

- [Experiment building workflow \(page 73\)](#)
- [Modification of tube properties for multiple tubes \(page 83\)](#)

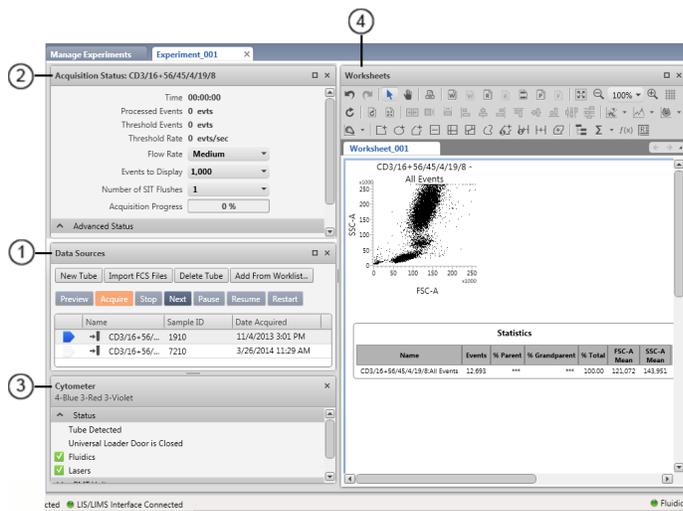
About experiment panels

Introduction

This topic describes the different panels in the Experiment tab and how to use them to build, modify, and run experiments. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

About the Experiment tab

When you create a new experiment or open an existing experiment in the Manage Experiments tab, a new Experiment tab opens.



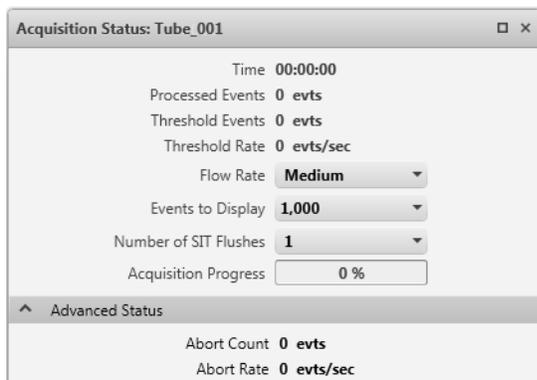
The Experiment tab represents an experiment and includes the following panels:

No.	Description
1	Data Sources
2	Acquisition Status
3	Cytometer Settings
4	Worksheets and reports

You can drag the panels to organize them in any order within the workspace, or click to minimize panels to maximize display space.

About the Acquisition Status panel

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



This panel is open by default. You can show or hide this panel. When you hide (close) the panel, an Acquisition Status button is displayed in a toolbar at the top of the Experiment tab. Click the button to display the panel.

Acquisition data displays each time you preview or acquire data. The display is refreshed (cleared) each time you preview or acquire a tube. You can also click to expand Advanced Status to display the acquisition abort count and abort rate.

You can select the following options in this panel.

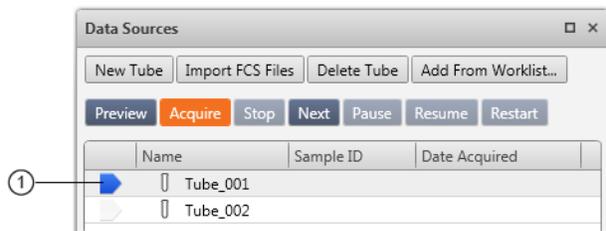
Option	Description
Flow Rate	Select the rate (low, medium, high, or high sensitivity) that the sample flows through the flow cell in the instrument. High and medium flow rates are typically used for immunophenotyping experiments and to increase event throughput. Lower flow rates are typically used when high precision is required (for example, DNA experiments) to measure slight variations in fluorescence. The high-sensitivity fluidics mode slows the sample and sheath flow. If selected in an experiment, high-sensitivity fluidics mode must be enabled in the Setup and QC Preferences. Note: High-sensitivity fluidics mode should not be used in clinical applications.
Events to Display	Select the maximum number of events to display in plots.
Number of SIT Flushes	By default, one SIT flush is performed after acquisition completes and after you remove the tube from the manual tube port. Increase the number of flushes when extra cleaning is required between acquisitions to reduce sample carryover.

If you create another tube using the **Next** button in the Data Sources panel, all the settings in the Acquisition Status panel remain the same unless you change them.

If you create another tube using the **New Tube** button in the Data Sources panel, only **Events to Display** remains the same; **Flow Rate** and **Number of SIT Flushes** revert to default values.

About the Data Sources panel

Use the Data Sources panel to add and delete tubes and FCS files for acquisition and analysis. You can right-click tubes to set tube properties, duplicate tubes, create tube settings, and create reference settings. The run pointer indicates which tube is being previewed or acquired, and which tube's data is applied to a plot.



No.	Description
1	Run pointer

The Data Sources table displays the tube name, sample ID, and acquisition date. If the tube settings associated with the tube are deleted, a warning icon is displayed to the right of the tube name. The icon is removed when you change the tube settings. The following table describes the buttons in the Data Sources panel.

Button	Description
New Tube	Click to add a new tube to the list. A new default tube has the default Lyse/Wash (LW) or Lyse/No-Wash (LNW) tube settings. You can select the default tube settings from the experiment preferences.
Import FCS Files	Click to display a dialog where you can select FCS files to import for analysis.
Delete Tube	Select a tube or tubes in the list, then click this button to delete the tube.
Add From Worklist	Click to select tubes from a worklist and add them as tubes in an experiment. See Creating and adding tubes (page 73) .
Preview	Click to start the sample flow and to populate plots with event data. This does not record event data.
Acquire	Click to start the sample flow (if not already previewing) and record event data to an FCS file.
Stop	Click to stop the sample flow and the current preview or acquisition.
Next	Click to set the run pointer to the next tube in the Data Sources table. You can also click this button to add tubes. Note that this is the equivalent of duplicating without data. See Creating and adding tubes (page 73) .
Pause	Click during preview to pause the sample flow and event counters and timers. If this feature is used, avoid pausing for longer than 2 minutes.
Resume	Click to resume a paused preview.

Button	Description
Restart	<p>During preview, click to clear the counters and timers. This clears the acquisition data without pausing the fluid flow.</p> <p>During acquisition, click to delete acquired events, clear counters and timers, and clear the progress bar. This clears the acquisition data without pausing the fluid flow.</p>

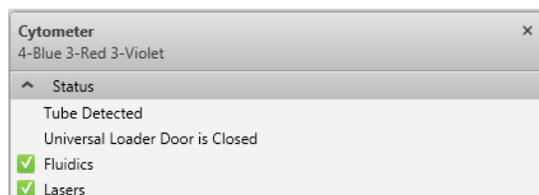
About the Cytometer Settings panel

Use the Cytometer Settings panel to view system status, run cleaning protocols, adjust PMT voltages, and view laser delay and area scaling. This panel includes the following sections:

- Status
- PMT Voltages
- Lasers

Status

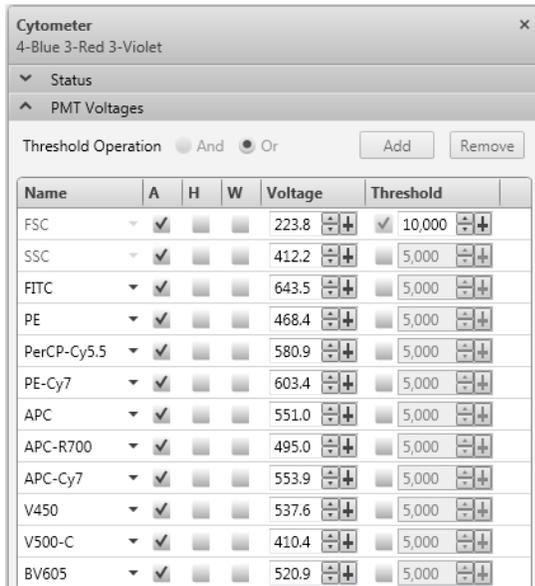
The Status section displays the system status, including real-time status for the SIT, fluidics, and lasers. This section also indicates when you need to run system cleaning protocols.



A checkmark indicates a ready status. You can click the arrow icon in the **Status** title bar to expand or collapse this section.

PMT Voltages

Use the PMT Voltages section during preview to select the area, height, width, and adjust the voltage and threshold for scatter or fluorescence parameters. You can also add or remove parameters.



If you are using the default tube settings and then adjust PMT voltages or other cytometer settings, the changes apply only to the current tube. If you want to reuse adjusted settings for additional tubes, especially outside the current experiment, create a new tube setting.

In the PMT Voltages section, you can perform the following actions. Select a parameter by clicking to the right of the threshold control.

Button	Description
Threshold Operation	Select And or Or to specify how multiple thresholds are combined logically.
Add	Adds a new parameter to the PMT Voltages table. Click the arrow to select a fluorochrome.
Remove	Removes the selected parameter from PMT Voltages table.
Parameter (Name column)	Displays a list of available parameters. You can select the fluorochrome by clicking the arrow.
A (Area), H (Height), and W (Width)	A (Area) is the default parameter that measures the entire voltage pulse. H (Height) is the peak of the voltage pulse, and W (Width) is the amount of time taken for the event to pass through the laser (multiplied by a constant).
Voltage	Adjusting the voltage changes the amount of sensitivity used by the PMT to view events. <ul style="list-style-type: none"> Click the up and down arrows to adjust the value in increments of 1 V. Ctrl+click the up and down arrows to adjust the value in increments of 10 V. Drag the slider to adjust the voltage value in any increment.

Button	Description
Threshold	<p>An electronic threshold on a parameter is used to eliminate unwanted events. Only events with parameter values above the threshold are acquired. Select the checkbox to enable the threshold for the parameter.</p> <ul style="list-style-type: none">• Click the up and down arrows to adjust the value in increments of 100.• Ctrl+click the up and down arrows to adjust the value in increments of 10.• Drag the slider to adjust the voltage value in any increment.

You can click the arrow icon in the PMT Voltages title bar to expand or collapse this section.

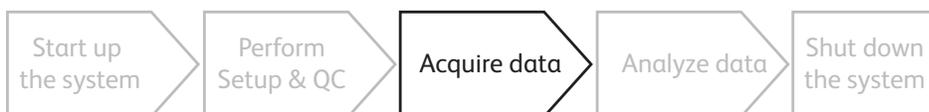
6

Data acquisition in an experiment

This chapter applies to the BD FACSuite™ application only, and includes the following topics:

- [Data acquisition workflow \(page 70\)](#)
- [Creating and opening an experiment \(page 70\)](#)
- [Experiment building workflow \(page 73\)](#)
- [Creating and adding tubes \(page 73\)](#)
- [Creating plots and gates \(page 75\)](#)
- [Viewing and adjusting cytometer settings \(page 78\)](#)
- [Modifying the compensation matrix \(page 80\)](#)
- [Setting general tube properties and applying tube settings \(page 81\)](#)
- [Modification of tube properties for multiple tubes \(page 83\)](#)
- [Editing single-color reagent labels \(page 84\)](#)
- [Assigning and editing keywords \(page 85\)](#)
- [Setting acquisition stopping rules \(page 86\)](#)
- [Acquiring data in an experiment \(page 87\)](#)

Data acquisition workflow



Introduction

This topic describes the typical workflow stages you need to complete to build an experiment and acquire data. This is also the workflow for creating an assay, which allows for data acquisition in the worklist. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

Typical workflow

Perform the following typical workflow stages for acquiring data in an experiment.

Stage	Description
1	Create a new experiment or open an existing experiment. See Creating and opening an experiment (page 70) .
2	Build an experiment. See Experiment building workflow (page 73) .
3	Acquire data. See Acquiring data in an experiment (page 87) .
4	(Optional) Save, export, or print the experiment. See Using the Manage Experiments tab (page 60) .

More information

- [Daily workflow \(page 35\)](#)
- [Performing system startup \(page 38\)](#)

Creating and opening an experiment

Introduction

This topic describes how to create new experiments and how to open existing experiments. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

You can have several experiments open at the same time. This allows you to compare acquired data from different experiments.

Creating a new experiment

To create a new experiment:

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

The Manage Experiments tab opens in the Experiments workspace.

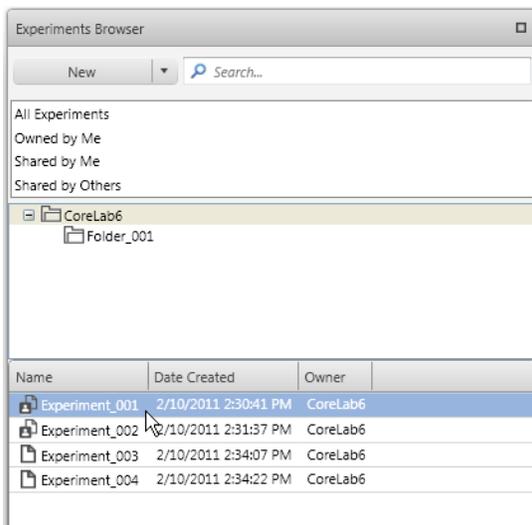
2. In the **Experiments Browser** panel, click your default folder or subfolder.
3. Click **New**.

A new experiment opens. The new experiment name and creation date are displayed in the Experiments Browser, and a new tab opens in the Experiments workspace.

Opening an existing experiment

To open an existing experiment:

1. In the **Experiments Browser**, click your experiment folder or click an experiment subfolder to display the available experiments.



2. (Optional) Click an experiment to display a snapshot of the experiment in the **Experiment Preview** panel.
3. Double-click an experiment to open the experiment in the **Experiments** workspace.

Opening multiple experiments

To open multiple experiments at the same time:

1. In an experiments folder, Ctrl+click each experiment that you want to open.
2. Right-click, then select **Open Experiment**.

All selected experiments open as individual tabs.

Creating a new experiment from an assay

If you want to modify a current BD assay or a User-Defined assay, you can create a new experiment from the assay, modify the experiment, then create an assay from the modified experiment.

To create a new experiment from an assay:

1. Click the **Manage Experiments** tab.
2. Perform either of the following operations:
 - From the menu bar, select **File > New Experiment from Assay**.
 - In the Experiments Browser panel, click the drop-down selector on the **New** button and then select **New from Assay...**

The Select an Assay dialog opens. The dialog includes a Search control and an expandable list structure. If the User-Defined assay repository includes folders and subfolders, the folder structure will be reflected in the expandable list structure.

3. Use the Search control or navigate the expandable list to find the required assay.
4. Click the assay in the list, then click **OK**.

The new experiment is displayed in the Experiments Browser and the new experiment opens.

If you intend to modify an existing User-Defined assay and want to retain the same assay name, you can overwrite the original by creating an assay with the same name (but only if the original assay in the library does not have Shared status).

See [Creating a User-Defined assay from an experiment \(page 94\)](#).

Next steps

- If you want to create new tubes or delete existing tubes in your experiment, continue with [Experiment building workflow \(page 73\)](#).
- If your experiment has the correct tubes, plots, gates and properties, you can acquire tubes, re-acquire existing tubes, or analyze the data. See [Acquiring data in an experiment \(page 87\)](#).

More information

- [About the experiment \(page 58\)](#)

Experiment building workflow

Introduction

This topic provides the basic workflow for building an experiment. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

Typical workflow

Perform the following typical workflow stages for building an experiment.

Stage	Description
1	Determine the experiment settings strategy.
2	Adjust cytometer settings as needed. See Viewing and adjusting cytometer settings (page 78) .
3	(Optional) Create tube settings and reference settings as needed. See Creating tube settings (page 100) and Creating default reference settings (page 101) .
4	Add tubes (if needed) with default tube settings, or apply existing tube settings. See Creating and adding tubes (page 73) .
5	Create and modify worksheet, reports, plots, and create gates and statistics views. See Creating plots and gates (page 75) .
6	(Optional) Create a User-Defined assay from the experiment. See Creating a User-Defined assay from an experiment (page 94) .

More information

- [Using the Manage Experiments tab \(page 60\)](#)

Creating and adding tubes

Introduction

This topic describes how to create tubes in the Data Sources panel by adding or duplicating tubes. This topic also describes how to delete tubes from an experiment. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

Working with tubes

When you create a new experiment, one default tube is displayed in the Data Sources panel.

To work with tubes, complete one of the following options in the **Data Sources** panel:

To...	Then do this...
Create a new tube.	<ol style="list-style-type: none"> 1. Click New Tube. <p>A new default tube is displayed. The Lyse/Wash (LW) or Lyse/No-Wash (LNW) tube settings are applied to all default tubes.</p>
Add tubes from entries in a worklist.	<ol style="list-style-type: none"> 1. Click Add From Worklist. <p>The Add Tubes From Worklist dialog opens.</p> <ol style="list-style-type: none"> 2. Select one of the following: <ul style="list-style-type: none"> • Under Entries, click a worklist entry, then click Add Selected Entry Tubes. • Under Entries, click a worklist entry. Under Tubes, click individual tubes that are displayed in the entry, then click Add Selected Tubes.
Use the Next button to add tubes	<ol style="list-style-type: none"> 1. Click Next to move the run pointer to the next tube. <p>If you click the last tube in the list, and then click Next, a new duplicate tube without data is created and the run pointer moves to the tube.</p>
Duplicate tubes with or without data	<ol style="list-style-type: none"> 1. Before you can duplicate with data, acquire the tube. See Acquiring data in an experiment (page 87). 2. In the tube list, right-click the tube you want to duplicate. 3. Select one of the following: <ul style="list-style-type: none"> • Duplicate with data. A duplicate tube is added to the list with the same tube name and includes all data that is associated with the source tube. • Duplicate without data. A duplicate tube is displayed with a new name and includes all tube properties and settings except the acquired data.
Clear data in a tube	<ol style="list-style-type: none"> 1. Right-click a tube and select Clear Tube. <p>All associated tube data is deleted and associated plots or statistics are cleared.</p>
Delete a tube	<ol style="list-style-type: none"> 1. Click a tube in the list. 2. Click Delete.

Next step

- After you add tubes to the experiment, create plots on a worksheet to visualize tube data. See [Creating plots and gates \(page 75\)](#).
- If you want to adjust tube properties before creating plots, see [Setting general tube properties and applying tube settings \(page 81\)](#), and [Modification of tube properties for multiple tubes \(page 83\)](#).

Creating plots and gates

Introduction

As with other topics in this chapter, this topic applies to the BD FACSuite™ application only. This topic describes how to create plots and basic gates. Gates allow you to identify cells of interest, display these cells graphically in plots, and classify events into populations which are used to calculate statistics.

Additional gate types including logical, interval, quadrant, adaptive, and trainable (BD Elastigate™) gates are described in the *BD FACSLyric™ Reference System*.

About worksheets and reports

Worksheets and reports provide a canvas to lay out analysis elements such as plots, statistics, and text. You use the Worksheets toolbar to add and adjust analysis elements. Reports differ from worksheets because reports allow the use of an E-Signature box, are shown as part of the report delay time, and are available for auto-printing and exporting.

Before you begin

- It is helpful to create tubes before you create plots associated with the tubes.
- (Optional) You can also set tube properties before you begin, or at any time before you acquire the tube. See [Setting general tube properties and applying tube settings \(page 81\)](#).

Creating a plot

When you create a new experiment, one default tube is displayed in the Data Sources panel and one default plot is displayed in the worksheet.

When you create additional plots, the plots display the default plot title and parameter names. You can modify the plot title and select different parameters for each axis after you create the plot.

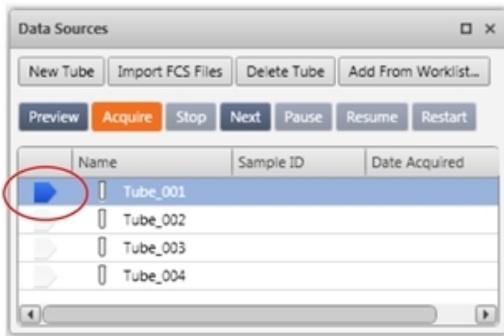
To create a plot:

1. Open an experiment.
2. (Optional) Click **Toggle Grid** on the **Worksheets** toolbar to enable the grid.

A grid on the worksheet provides guidelines for plot size and placement.

3. Click a plot tool on the **Plot** toolbar.
4. Click in the worksheet to create the plot.
5. Continue to add plots for your scatter and fluorescence parameters as needed.

The primary data source determines which tube is associated with a plot or plots in the worksheet. If the run pointer is selected as the primary data source (default), all plots display data from the tube that is indicated by the run pointer.



You can change the primary data source for a plot from the run pointer to a specific tube if needed.

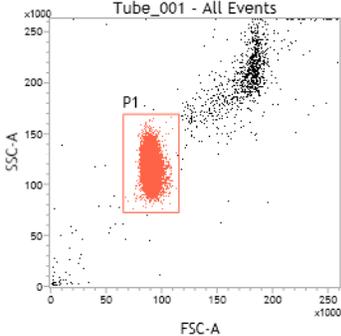
Modifying plot parameters

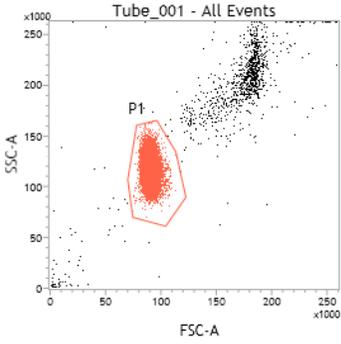
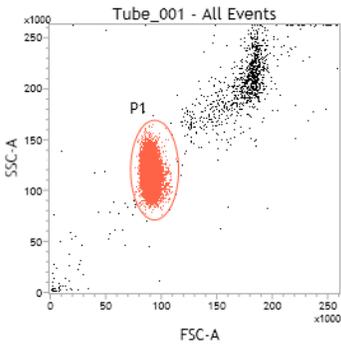
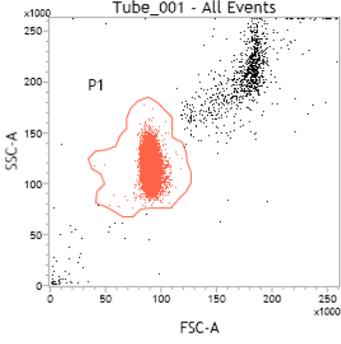
To modify plot parameters:

1. Select a plot in a worksheet.
2. Right-click the x-axis parameter label, then select a parameter from the list.
3. Right-click the y-axis parameter label, then select a parameter from the list.

Drawing gates

The following table describes how to draw basic gates in plots.

To draw a...	Then do this...
Rectangle gate 	<ol style="list-style-type: none"> 1. Click this tool on the Worksheet toolbar. 2. Click in the plot and drag diagonally to create and size the rectangle around specific events in the plot. 3. Release the mouse button to set the gate. 

To draw a...	Then do this...
<p data-bbox="201 239 344 268">Polygon gate</p> 	<ol data-bbox="380 239 1383 420" style="list-style-type: none"> 1. Click this tool on the Worksheet toolbar. 2. Click in the plot to specify a starting point. A vertex is displayed. 3. Move the cursor to another position and click to add another vertex. Repeat this step to create a minimum of three vertices around specific events in the plot. 4. Click the first vertex or double-click to set the last vertex to close the gate. 
<p data-bbox="201 827 344 856">Ellipse gate</p> 	<ol data-bbox="380 827 1416 940" style="list-style-type: none"> 1. Click this tool on the Worksheet toolbar. 2. Click in the plot and drag diagonally to create and size the ellipse around specific events in the plot. 3. Release the mouse button to set the gate. 
<p data-bbox="201 1352 344 1381">Freehand gate</p> 	<ol data-bbox="380 1352 1416 1486" style="list-style-type: none"> 1. Click this tool on the Worksheet toolbar. 2. In the plot, click and hold the mouse button, then move the cursor to draw a freehand shape around specific events. 3. Release the mouse button to set the gate. 

New gates are added to the hierarchy and are applied to all tubes within the experiment. The population hierarchy is updated to identify the new population.

Next step

- If a tube contains acquired data, new plots automatically display data.
- If you are working with un-acquired tubes, plots remain empty until you preview or acquire the tube to populate the plots with data. Continue by acquiring data.

More information

- [Modifying the compensation matrix \(page 80\)](#)
- [Setting general tube properties and applying tube settings \(page 81\)](#)
- See topics about plots in the *BD FACSLyric™ Reference System* for more information about plot types and tools, and creating and modifying plots.
- See topics about modifying tube properties in the *BD FACSLyric™ Reference System*.

Viewing and adjusting cytometer settings

Introduction

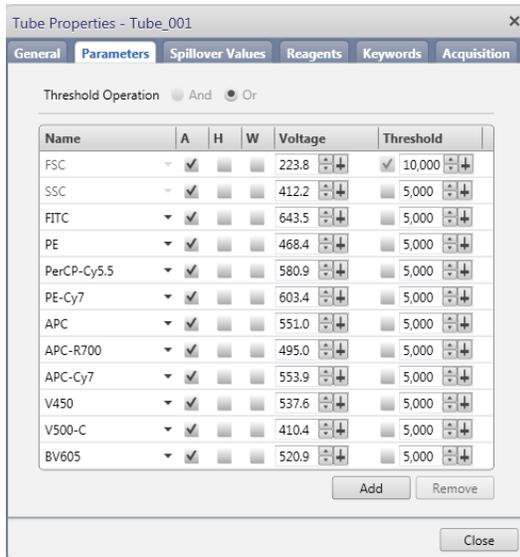
This topic describes how to view the tube parameters for area, height, width, window extension, area scaling factors, laser delay, PMT voltages, and threshold settings. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

You can then adjust these settings in the Cytometer panel. Adjust the cytometer settings for a tube to optimize the sample brightness and place the events on scale.

Viewing tube parameters

To view tube parameters for a tube:

1. In the **Data Sources** panel, set the run pointer to the tube you want to modify (for example, *Tube_001*).
2. Double-click the run pointer, or right-click the tube and select **Properties** to open the **Tube Properties** dialog.
3. Click the **Parameters** tab.



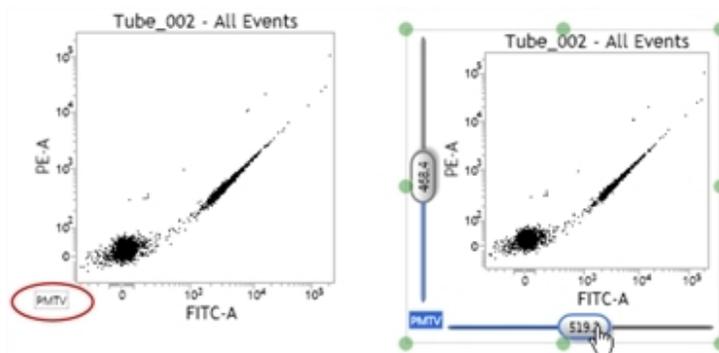
This tab displays only the parameters that are set for the current tube or an acquired tube.

Adjusting cytometer settings

Perform the following adjustments as needed before or after you create gates in a plot.

To adjust the cytometer settings:

1. Preview the data. See [Previewing data \(page 87\)](#).
2. Adjust the PMT voltages as needed to put all populations on scale.
 - a. In a plot, click the **PMTV** button in the lower-left corner of the plot to enable the data sliders.



- b. Drag the slider control for each axis parameter in the plot.

The PMTV value is displayed on the slider control.

- c. Click the **PMTV** button again to disable the slider control.
3. Select a threshold operation as needed.
4. Select a checkbox to enable a threshold, then adjust the threshold value as needed.

5. Select area, height, and width parameters as needed.
6. Click **Stop** to stop previewing.

More information

- [Acquiring data in an experiment \(page 87\)](#)
- See topics about changing the primary data source for a plot in the *BD FACSLyric™ Reference System*.
- See topics about populations and the population hierarchy in the *BD FACSLyric™ Reference System*.

Modifying the compensation matrix

Introduction

This topic describes how to view or modify the spillover matrix for your tube using the Spillover Values tab in the Tube Properties dialog. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

About the compensation matrix

The spillover matrix is automatically recalculated any time you adjust the PMT voltages for a tube.

If you apply tube settings that do not have associated reference settings, the matrix is calculated using the spillover values (SOVs) from the Lyse/Wash reference settings.

If you apply tube settings that have an associated reference setting, the matrix reflects the measured SOVs created with the reference settings.

If the calculated SOVs work for your samples, you do not need to modify this matrix.

Procedure

To modify the SOVs matrix for a tube:

1. In the **Data Sources** panel, set the run pointer to the tube you want to modify (for example, *Tube_001*).
2. Double-click the run pointer, or right-click the tube and select **Properties** to open the **Tube Properties** dialog.
3. Click the **Spillover Values** tab.

The matrix displays the SOVs associated with the acquired tube or the values that will be used when a tube is acquired. The table shows how much of the row (for example, FITC parameter) is spilling over into the column (for example, PE parameter).

4. Select the **Enable Compensation** checkbox to analyze with compensated data, or clear the checkbox to analyze with uncompensated data.
5. (Optional) Edit the SOVs as needed.

The goal is to ensure that a single-positive population and the negative population are centered. For example, for a plot with FITC vs PE, the FITC mean on the y-axis should not be higher or lower than the negative-population mean.

- a. Locate the row on the left, then move right across the table until you locate the intersecting column.

↓ Intro From →	FTTC	PE	PerCP-Cy5.5	PE-Cy7	APC	APC-R700	APC-Cy7	V450	V500-C	BV605	E
FTTC	100.00	1.10	0.02	0.17	0.01	0.03	0.04	0.02	5.28	0.00	0
PE	15.60	100.00	0.09	1.71	0.01	0.01	0.02	0.02	1.01	2.31	0
PerCP-Cy5.5	3.14	23.23	100.00	1.15	1.71	6.48	0.11	0.02	0.45	4.98	0
PE-Cy7	0.29	1.80	17.35	100.00	0.21	1.50	1.54	0.01	0.05	0.56	0
APC	0.00	0.01	1.34	0.03	100.00	6.70	6.55	0.00	0.01	0.11	0
APC-R700	0.00	0.00	7.38	0.09	18.20	100.00	1.44	0.00	0.00	0.02	0
APC-Cy7	0.00	0.00	6.60	7.32	15.22	66.30	100.00	0.00	0.00	0.02	0
V450	0.17	0.03	0.08	0.03	0.03	0.00	0.13	100.00	6.36	19.89	0
V500-C	3.88	0.47	0.10	0.05	0.03	0.00	0.12	17.57	100.00	1.56	0
BV605	0.64	13.20	0.05	0.14	0.07	0.01	0.04	0.90	15.76	100.00	0
BV711	0.09	0.57	5.27	30.09	0.06	0.45	0.42	0.00	0.02	0.17	1
BV786	4.17	28.89	0.01	0.39	0.00	0.00	0.01	0.00	0.36	0.67	0

- b. Type a new value (0.00 to 1000.00) in the table, or click the up and down arrows to adjust the value.

If you adjust the values in this matrix, the values are applied to the current tube. If you want to reuse these values, you need to save modified reference settings. Use the Reset button to undo changes to the matrix. Use the Apply to Tubes button to copy the SOV matrix from one tube in the experiment to another.

6. Click **Close**.

More information

- [Saving modified reference settings \(page 109\)](#)
- [Viewing and adjusting cytometer settings \(page 78\)](#)
- [Editing single-color reagent labels \(page 84\)](#)

Setting general tube properties and applying tube settings

Introduction

This topic describes how to set general tube properties using the General tab in the Tube Properties dialog and how to apply different tube settings from the library. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

Setting general tube properties

To set general properties for a tube:

1. In the **Data Sources** panel, double-click the run pointer, or right-click a tube and select **Properties** to open the **Tube Properties** dialog.

The Tube Properties dialog opens in the General tab.

2. In the **Tube Name** field, use the current default name or type a new tube name.
3. (Optional) In the **Tube ID** field, type a tube ID or click in the field and scan a barcode.
4. (Optional) In the **Sample ID** field, type a sample ID or click in the field and scan a barcode.

Information for the following read-only fields is displayed when you acquire a tube:

- Total Events (acquired for this tube)
- Acquisition Date

- Cytometer Name (the cytometer that was used for acquisition)

Applying existing tube settings

When you create a new tube, the default tube settings are applied—Lyse/Wash (LW), or Lyse/No-Wash (LNW), based on the Experiment preferences. This section describes how to apply a different tube setting from the library.

See [Creating tube settings \(page 100\)](#).

To apply existing tube settings:

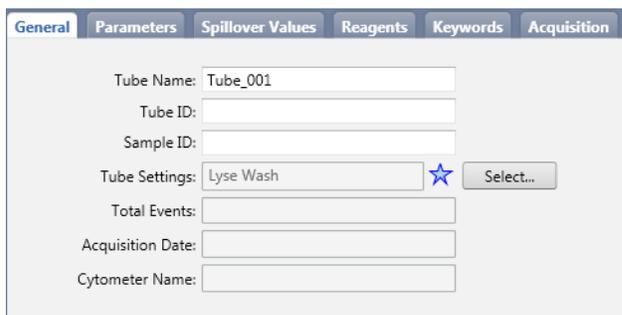
1. In the **General** tab, click **Select** in the **Tube Settings** field.

The Select Tube Setting dialog opens.

2. Select a tube setting in the list.
3. Click **Select**.

The tube settings are applied to the current tube.

If you modify any values that are part of a tube setting, a star icon is displayed in the Tube Settings field indicating that you have modified tube settings. The application automatically calculates modified SOVs based on the SOV column and modified tube settings.



The screenshot shows a software interface with a tabbed menu at the top: General (selected), Parameters, Spillover Values, Reagents, Keywords, and Acquisition. Below the tabs, there are several input fields: Tube Name (containing 'Tube_001'), Tube ID, Sample ID, Tube Settings (containing 'Lyse Wash' and a blue star icon), Total Events, Acquisition Date, and Cytometer Name. To the right of the Tube Settings field is a 'Select...' button.

If you select a different tube setting, you will undo your current modified values and the star will be removed. If you want to save these modified settings for future use, create tube settings prior to selecting a different tube setting.

More information

- [Modification of tube properties for multiple tubes \(page 83\)](#)
- [Viewing and adjusting cytometer settings \(page 78\)](#)

Modification of tube properties for multiple tubes

Introduction

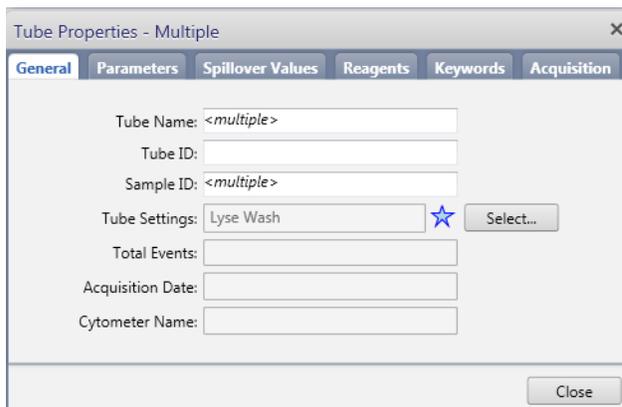
This topic describes how to modify tube properties for multiple selected tubes. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

You can select multiple tubes and modify certain tube properties simultaneously. The properties that can be modified are those for which the fields in the dialogs are enabled for editing. If a field is not enabled, it will be dim and you cannot click in the field.

Rules for tube property fields

The general rules for fields that are enabled are:

- If the values are the same between the selected tubes, then the actual value displays in the field.
- If the values are different between the selected tubes, then the field displays *<multiple>* or *<m>*.



Details for Tube Properties tabs

The Tube Properties tabs have different behaviors depending on which one you are trying to modify for multiple selected tubes. The following table describes what you can and cannot modify when multiple tubes are selected.

Tab	Description
General	Tube name, tube ID, sample ID, and tube settings are editable if all the tubes are unacquired.
Parameters	PMTVs and threshold can be edited for multiple tubes if all the tubes are unacquired.
Spillover Values	Compensation takes into account labels, parameters, and lot IDs to determine which values are editable.
Reagents	All of the fields in this tab are editable for multiple tubes.
Keywords	All of the fields in this tab are editable for multiple tubes.
Acquisition	All of the fields in the Stopping Rules sub-tab are editable for multiple tubes.

More information

- [Setting general tube properties and applying tube settings \(page 81\)](#)
- [Viewing and adjusting cytometer settings \(page 78\)](#)
- [Creating tube settings \(page 100\)](#)

Editing single-color reagent labels

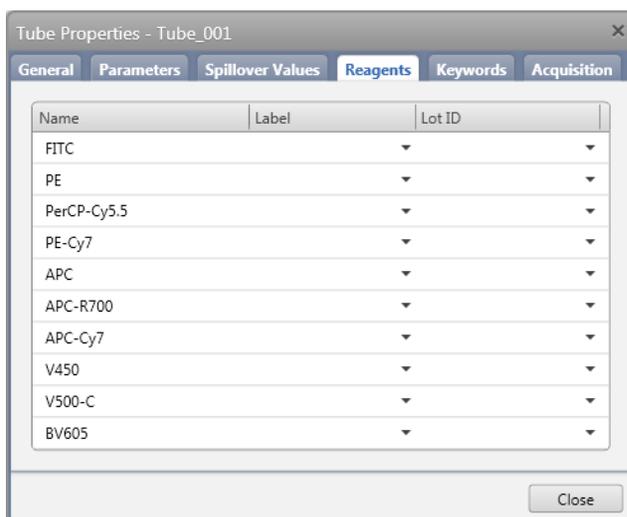
Introduction

This topic describes how to view or edit single-color reagent labels for available fluorochrome parameters in a tube. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

Procedure

To edit single-color reagent labels for available fluorochrome parameters in a tube:

1. In the **Data Sources** panel, set the run pointer to the tube you want to modify (for example, *Tube_002*).
2. Right-click the tube and select **Properties** to open the **Tube Properties** dialog.
3. Click the **Reagents** tab.
4. In the **Label** column for each parameter, select an available reagent label.



Note: You cannot add a fluorochrome as a reagent label.

5. If your reagents require lot-specific SOVs (usually for tandem fluorochromes), select a lot ID from the **Lot ID** column.

You must add reagents to the Library before you can use them. The values in the Library Reagents workspace populate the lot ID list.

If you do not select a lot ID from the list, then the generic SOVs are used.

Assigning and editing keywords

Introduction

This topic describes how to view or assign keywords to a tube and how to modify keyword values using the Keywords tab in the Tube Properties dialog. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

About keywords

Keywords are unique fields for storing information in files. They are used to identify particular data elements, both required and optional, and can be added to tubes in an experiment. Keywords can include information such as dilutions and cell or sample types.

Before you begin

In the library, create any new keywords that you plan to assign to tubes.

Assigning new keywords to a tube

To assign a new User-Defined keyword to a tube:

1. In the **Data Sources** panel, set the run pointer to the tube you want to modify (for example, *Tube_001*).
2. Double-click the run pointer, or right-click the tube and select **Properties** to open the **Tube Properties** dialog.
3. Click the **Keywords** tab.
4. Click **Assign Keywords**.

The Assign Keywords dialog opens.

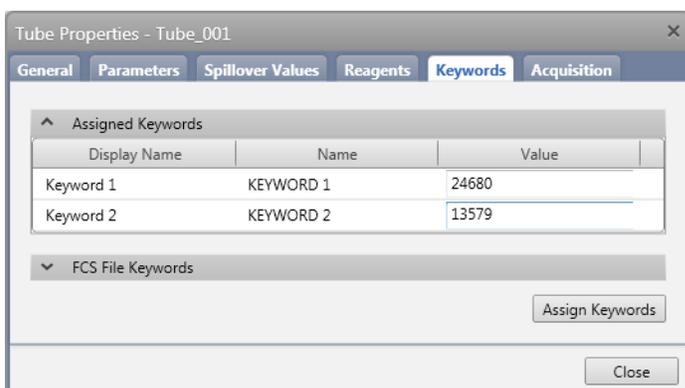
5. In the **Assign** column, select the checkboxes for keywords you want to assign to the tube.

To locate or view detailed information on the keywords, you can perform the actions in the following table.

To...	Then do this...
Filter keywords by name or display name	<ol style="list-style-type: none"> 1. In the Keyword Filter field, type the name or display name criteria. 2. Press Enter.
View the properties of a keyword	<ol style="list-style-type: none"> 1. Click Keyword Properties. 2. Select a keyword in the list to view its properties.

6. Click **OK**.

The assigned User-Defined keywords are displayed in the tab.



Changing values for assigned keywords

To change values for keywords assigned to a tube:

1. In the **Tube Properties** dialog, click the **Keywords** tab.
Any currently assigned User-Defined keywords are displayed.
2. Click the User-Defined keyword you want to modify.
3. Click the **Value** field for that keyword and type a new value or select a new value from the menu.

More information

- [Running a worklist \(page 139\)](#)
- See the Keywords section in *BD FACSLyric™ Reference System* for more details on keywords.

Setting acquisition stopping rules

Introduction

This topic describes how to set acquisition stopping rules using the Acquisition tab in the Tube Properties dialog. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

If you want to assign a specific gate or gates to use as storage or stopping criteria, these gates must first be created before setting acquisition properties.

Setting acquisition stopping rules for a tube

To set acquisition stopping rules for a tube:

1. In the **Data Sources** panel, set the run pointer on the tube you want to modify (for example, *Tube_001*).
2. Double-click the run pointer, or right-click the tube and select **Properties** to open the **Tube Properties** dialog.
3. Click the **Acquisition** tab.

4. If the experiment has multiple worksheets, click and select a worksheet in the **Worksheet to Display during Acquisition** field.
5. In the **Storage Gate** field, click and select an existing gated population if you want to use a gate as the storage gate.

A storage gate identifies which data is stored when the tube is acquired. If you select a gate for a subpopulation (P1, P2, etc), only events from that subpopulation are stored in the FCS file.

6. In the **Stopping Rules** tab, define the acquisition stopping rules.

BD FACSuite™ application always uses a combination of a time stopping rule and a gate criteria rule using an OR operator. Use **Time Stopping Rule** to change the time criteria. Use **Create Gate Criteria** and **Combine Gate Criteria** and **Apply Rule** to change and apply the gate criteria. The current acquisition stopping rules are displayed under **Applied Stopping Rule**.

More information

- [Setting general tube properties and applying tube settings \(page 81\)](#)
- See the *BD FACSLyric™ Reference System* for more details on stopping rules.

Acquiring data in an experiment

Introduction

This topic describes how to preview and acquire data in an experiment. You can acquire data in an experiment as long as the experiment has at least one tube. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

About previewing data

Previewing data is the process of starting the sample flow and displaying event data. Previewing does not record data. While previewing, you can adjust the PMT voltages and modify the tube properties.

This example describes previewing data from a single (manually loaded) tube using the run pointer as the primary data source. See topics about changing the primary data source for a plot in the *BD FACSLyric™ Reference System*.

Before you begin

Create plots in the worksheet before you preview tube data.

Previewing data

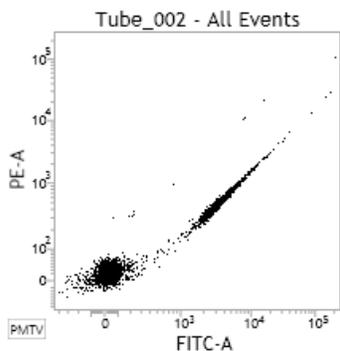
To preview data in a specific tube:

1. Load a tube on the manual tube port.
2. In the **Data Sources** panel, set the run pointer to the tube you want to preview (for example, *Tube_002*).
3. Click **Preview**.

During preview, the run pointer remains blue and displays an activity indicator.

	Name	Sample ID
	Tube_001	
	Tube_002	
	Tube_003	
	Tube_004	

Data is displayed in the plots.



Once data is displayed in plots, you can adjust the cytometer settings and draw gates to identify populations of interest.

See [Viewing and adjusting cytometer settings \(page 78\)](#).

Acquiring data

To acquire data in an experiment:

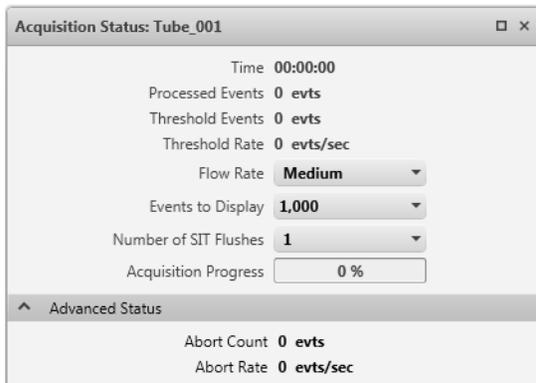
1. Complete the previewing procedure and adjust gates and cytometer settings as needed.
2. Click **Acquire**.

During acquisition, the run pointer turns orange and displays an activity indicator.

	Name	Sample ID
	Tube_001	
	Tube_002	
	Tube_003	
	Tube_004	
	Tube_005	

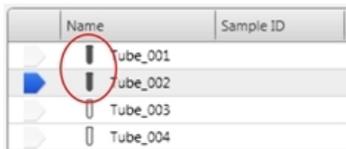
Acquisition continues until the stopping rules (defined in the Tube Properties dialog) are satisfied.

The acquisition status is displayed in the Acquisition Status panel.



During acquisition, you can click Stop to manually stop acquisition, or click Restart to clear the current acquisition.

When acquisition is complete, the tube icon displays as a filled tube to indicate that data has been acquired.



3. Click **Next** to move the run pointer to the next tube.

If no next tube exists, a new tube (duplicate without data) is created and the run pointer moves to the tube.

Next step

After you acquire data, you can analyze the data immediately, or open the experiment later to analyze it.

More information

- [Data analysis workflow \(page 92\)](#)
- [Creating and opening an experiment \(page 70\)](#)
- [Experiment building workflow \(page 73\)](#)

7

Data analysis in an experiment

This chapter applies to the BD FACSuite™ application only, and includes the following topics:

- [Data analysis workflow \(page 92\)](#)
- [Exporting and printing experiment worksheets and reports \(page 92\)](#)
- [Creating a User-Defined assay from an experiment \(page 94\)](#)
- [Updating a User-Defined assay \(page 96\)](#)

Data analysis workflow



Introduction

This topic describes the workflow for analyzing data acquired in an experiment. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

About analyzing experiments

When you create an experiment, you can preview data and perform basic analysis by adding plots and drawing gates to define populations.

You can perform analysis on the workstation that is connected to the cytometer or from a remote workstation with BD FACSuite™ application and exported FCS files.

Typical workflow

Perform the following tasks to analyze data in an experiment.

Stage	Description
1	Open an existing experiment or import an experiment on a remote workstation. See Creating and opening an experiment (page 70) .
2	Create and modify reports. See these topics in the <i>BD FACSLyric™ Reference System</i> : <ul style="list-style-type: none"> • Modifying experiment worksheets and reports • Setting and modifying the report header and footer
3	(Optional) Export or print reports. See Exporting and printing experiment worksheets and reports (page 92) .
4	(Optional) Save the experiment as an assay. See Creating a User-Defined assay from an experiment (page 94) .

Exporting and printing experiment worksheets and reports

Introduction

This topic describes how to print or export worksheets or reports. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

Exporting in PDF format allows you to archive a page separately from the experiment. If your experiment includes multiple worksheet or report tabs, you must select each and export them separately.

Note: If an exported or printed worksheet or report shows *** for a statistic, its value was not calculated. To fix this issue, force recalculation by moving the run pointer or closing and reopening the worklist or experiment. Confirm that the statistic shows a real value in place of *** and then repeat the export or print operation.

Exporting a worksheet or report

To export:

1. Open an experiment.
2. Select the desired worksheet or report by clicking the tab.
3. From the menu bar, select **File > Export To PDF**.

The Save As dialog opens.

4. Navigate to the folder where you want to export the page.
5. Type a file name.
6. Click **OK**.

Printing a worksheet or report

To print:

1. Select the desired worksheet or report by clicking the tab.
2. Click the **Print Current Tab** tool.
3. Preview the report and make sure that all analysis items are in the print area of the page.
4. Select **Print** on the **Print Preview** menu bar.
5. Complete your typical printing process.

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

Previewing a worksheet or report

To preview:

1. Select the desired worksheet or report by clicking the tab.
2. From the menu bar, select **File > Print**.
3. Preview the report and make sure that all analysis items are in the print area of the page.

You can print to a PDF-capable printer from the preview window using the Print button on the Print Preview menu bar.

Creating a User-Defined assay from an experiment

Introduction

This topic describes how to create a User-Defined assay from an experiment. User-Defined assays are used as templates in worklists to complete the same work on multiple samples. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

About saving experiments

Experiments are automatically saved as you make changes to them. Creating a User-Defined assay from an experiment allows the assay to be used in the worklist, and is useful when you or others must repeat an experiment often. The User-Defined assays provide uniform cytometer settings and format.

Some properties and parameters which are expected to be constant over time become permanent in the assay.

If you want to edit these properties or parameters, you can create an experiment from the assay, modify it, then save it as a User-Defined assay again with the same name or a new name.

If a tube uses a fluorochrome that is not contained in the tube settings of that tube, then the assay cannot be created. Create tube or reference settings in order to create the assay.

Before you begin

- If you create a report in the experiment, you can use auto-printing and auto-exporting. You select these options in the assay properties.
- If you are using statistics and auto-export or sending results to an LIS or LIMS, you need to define the properties for the statistics.

Procedure

To create a User-Defined assay from an experiment:

1. Build or open an experiment in the **Experiment** workspace.

See [Creating and opening an experiment \(page 70\)](#).

2. From the menu bar, select **File > Create Assay**.

The Create Assay dialog opens.

3. In the **Name** field, type a name for the new User-Defined assay.

If you intend to modify an existing User-Defined assay and want to retain the same assay name, you can overwrite the original by creating an assay with the same name. Note that you cannot overwrite BD assays, nor can you overwrite “Shared” assays.

4. (Optional) In the **Assay description** field, type a description of any details you want to document for the assay.

5. (Optional) Expand the Folder Assignment drop-down list to select a folder or subfolder where the assay is to be assigned.

Note: Creation and management of folders can be performed from a context menu displayed by right-clicking **User-Defined** in the Assays section of the Library. For details, refer to the *BD FACSLyric™ Reference System*.

6. (Optional) Select a report to display in the **Report to display after entry run** list.

This sets the default report that opens after the worklist runs.

7. Click **OK**.

The User-Defined assay is added to the library.

More information

- See topics about working with private and shared library resources in the *BD FACSLyric™ Reference System* for more information about sharing User-Defined assays.
- [Specifying assay properties \(page 213\)](#).

Updating a User-Defined assay

This feature allows an assay to be modified without needing to create a brand new assay. Assay updates allow minor modifications. An update cannot be performed on an assay after making any of the following changes:

- Changing the assay name
- Switching, adding, or removing parameters or changing their A/W/H properties
- Applying different labels
- Changing the number of tubes

Note: An assay with changed PMT voltages or threshold values can still be updated.

Before you begin

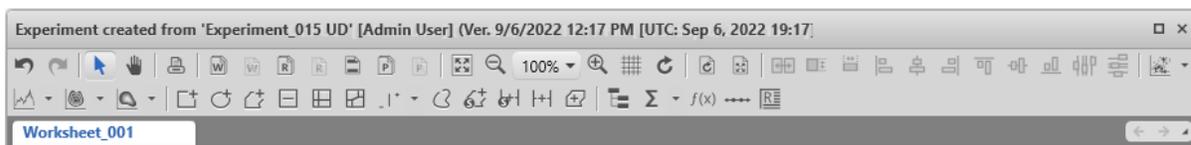
Check whether the assay that you want to modify was created in BD FACSuite™ version 1.6 or an earlier version:

- Examine the list of User-Defined assays in the Library. If the information for the assay in the Version column indicates a date and time, the assay was created or last modified in BD FACSuite™ version 1.6 or later. If the information in the version column is "Initial version", the assay was created or last modified in BD FACSuite™ version 1.5 or earlier.

Procedure

To update an assay:

1. Open the **Experiments** workspace and select the **Manage Experiments** tab.
2. If the array was created or modified using BD FACSuite™ version 1.6 or later, open the associated experiment, if the experiment exists on the instrument. To aid in identification of the existing experiment, its worksheet header will identify the assay.



3. If no experiment on the instrument was used to create or modify the assay that you want to update, or the assay was imported from a BD FACSuite™ database version earlier than 1.6:
 - a. Select **File > New Experiment from Assay...**
 - b. In the User-Defined list in the Select an Assay dialog box, select the assay that you want to modify.
4. Make the required modifications to the assay. For example, to change a PMT value, right-click the selected tube, and run **Create Tube Settings...** from the context menu.
5. Select **File > Update Assay**.

6. Complete the information identified by the prompts in the Update Assay dialog box and click **OK** to complete the operation.

The change history for the assay will contain a new entry for the update and the header of the experiment worksheet will indicate the updated version of the assay, given by time and date.

8

Experiment settings

This chapter applies to the BD FACSuite™ application only, and includes the following topics:

- [Creating tube settings \(page 100\)](#)
- [Creating default reference settings \(page 101\)](#)
- [Creating user-defined reference settings \(page 103\)](#)
- [Viewing tube and reference settings in the library \(page 109\)](#)
- [Saving modified reference settings \(page 109\)](#)

Creating tube settings

Introduction

This topic describes how to adjust the position and brightness of the positive population and how to create tube settings. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

A tube must contain at least two fluorochromes to create tube settings.

Before you begin

- Prepare a tube of BD® CS&T Beads according to the instructions in the technical data sheet.
- Run performance QC.

Optimizing the positive population

To optimize the position and brightness of the positive population:

1. Create a new experiment.
2. In the **Data Sources** panel, select a tube, or add a new tube.
3. Load a tube of your sample onto the manual tube port.
4. Click **Preview** to start the sample flow and preview the data.
5. In the **Acquisition Status** panel, adjust the flow rate or fluidic mode as needed.
6. In the **PMT Voltages** panel, adjust the PMT voltages and threshold as needed.

Creating tube settings

The following procedure describes the typical method for creating tube settings without measured SOVs. Creating tube settings is available only for tubes without data. If your tube has data, duplicate it without data or clear the tube (by right-clicking in the Data Sources panel).

To create tube settings:

1. Right-click the tube and select **Create Tube Settings**.

The Create Tube Settings wizard opens.

2. The **CS&T lot ID** field displays the BD CS&T bead lot to be used for this tube setting.

If you want to use a different bead lot, click and select a different BD CS&T bead lot. If the appropriate lot is not listed, add the lot to the library.

3. Load a tube of BD® CS&T Beads onto the manual tube port.
4. Click **Acquire**.

When acquisition completes, the BD FACSuite™ application checks that the PMT voltages and thresholds will pass subsequent tube settings setup.

5. If the PMT voltage and threshold check fails, the application will display an error message. In this case, readjust the PMT voltage and thresholds for the sample so that the BD[®] CS&T Beads are also on scale and over the minimum threshold. Then restart this procedure from step 1.

If the PMT voltage and threshold check passes, the Name and Description dialog opens.

6. In the **Tube Settings Name** field, type a meaningful name.
7. (Optional) In the **Description** field, type a meaningful description that helps to differentiate between similarly named tube settings.
8. Click **Finish**.

The new tube settings are saved in the library.

More information

- See Tube settings overview in the *BD FACSLyric™ Reference System*.
- [Importing or adding a CS&T or FC bead lot \(page 217\)](#)

Creating default reference settings

Introduction

This topic describes how to create reference settings using the Create Reference Settings wizard. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

Note that if your system uses multiple optical configurations, each configuration requires its own default reference settings.

Before you begin

- Make sure the kit information for your BD[®] FC Beads is entered into the FC Bead reagent section in the library.
- Make sure that bead lots for BD[®] CS&T Beads and BD[®] FC Beads are current.
- Prepare the BD[®] CS&T Beads according to the instructions in the technical data sheet.
- Prepare BD[®] FC Beads according to the instructions in the technical data sheet.
- Prepare BD[®] CompBeads according to the instructions in the technical data sheet.
- Ensure that the performance QC is current.

The default LW/LNW reference settings are created by a BD Field Service Engineer when the BD FACSLyric™ system is installed for the first time, or when a system is reconfigured.

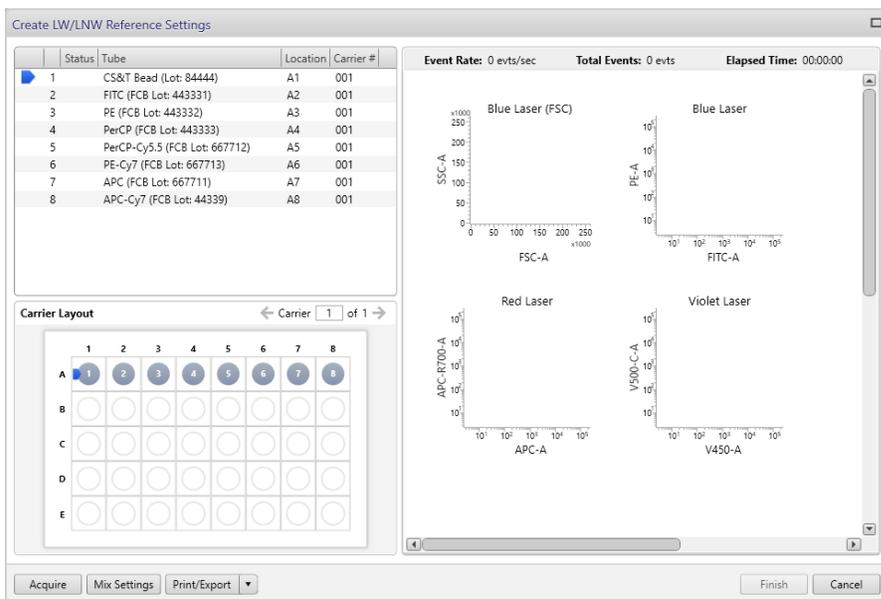
A user with Administrator privileges can create new default LW/LNW reference settings if needed.

Note: Creating these new settings affects the performance of the system and must be done carefully. Make sure to follow the instructions for the beads to insure that the new settings are accurate.

Using the BD FACSTM Universal Loader

To create new default LW/LNW reference settings using the BD FACSTM Universal Loader:

1. On the navigation bar, click **Setup & QC**.
2. Select **Create LW/LNW Reference Settings** from the **Task** menu.
3. For **Loading Option**, select **Universal Loader**.
4. Select the **Carrier Type** corresponding to the tube capacity of the rack that you are using.
5. Verify that you have selected the correct Lot ID numbers for the BD® FC Beads you will be using.
6. Click **Start** to open the **Create LW/LNW Reference Settings** dialog. Panels on the left of the dialog indicate how the tube rack needs to be loaded. For example, if a **BD® FC Beads 7-Color Kit** was selected in step 5 and a **40 Tube Rack** was selected in step 4, the panels would appear as follows:



7. Load the BD® CS&T Beads and BD® FC Beads into the tube rack as specified in the tube-identifier and **Carrier Layout** panels on the left of the **Create LW/LNW Reference Settings** dialog. Place the rack in the Loader and close the Loader door.
8. (Optional) Change the default values for mix settings by clicking the **Mix Settings** button. Default value for initial mixing is 4 seconds at 1,400 rpm and then 10 seconds at 1,250 rpm every 4 minutes thereafter.
9. (Optional) Click **Print/Export** to print or export as a PDF file the carrier layout and list of tube names.
10. Click the **Acquire** button to create the LW/LNW settings.

Once all the tubes have been acquired, a message displays to confirm that the new settings have been successfully created.

11. (Optional) To print or export the acquisition results, click the drop-down arrow on the **Print/Export** button, and select **Worksheets**. The Print/Export Worksheets option can only be selected after acquisition is complete. After the BD FACSuite™ application has generated the report, from the toolbar in the Print/Export Worksheets window, select **Print** (to select and send to a printer) or **Export** (to select and save a PDF file).

Note: If printing, the selected printer must be capable of accepting input in PDF format.

12. Click **Finish**.

Using the manual tube port

To create new default LW/LNW reference settings using the manual tube port:

1. On the navigation bar, click **Setup & QC**.
2. Select **Create LW/LNW Reference Settings** from the **Task** menu.
3. Verify that you have selected the correct Lot ID numbers for the FC Beads you will be using.
4. For **Loading Option**, select the **Manual** loader.
5. Click **Start**.

The Create LW/LNW Reference Settings dialog opens.

6. Click **Acquire**.

The Load Tube dialog opens.

7. Load the BD[®] CS&T Beads on the cytometer and click **Continue**.

The system detects the tube, and the process begins.

8. Follow the on-screen instructions to load each sample tube of BD[®] FC Beads.

The on-screen instructions display which tube should be loaded in the exact order required by the application. Note that by default the application asks for all the colors available in the system configuration and depends on the FCB kit configuration.

Once all the BD[®] FC Beads tubes have been acquired, a message displays to confirm that the new settings have been successfully created.

9. (Optional) Click **Print/Export** to print/export the a snapshot of the plot displays for each tube recorded during data acquisition.
10. Click **Finish**.

Creating user-defined reference settings

Introduction

This topic describes how to create user-defined reference settings from existing tube settings. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

Setting tube properties

To create user-defined reference settings:

1. Create a new experiment.
2. In the **Data Sources** panel, click an existing tube or add a new tube.

3. Right-click the tube and select **Properties**.

The Tube Properties dialog opens.

4. In the **Tube Settings** field, select appropriate tube settings as a starting point: **Lyse Wash**, **Lyse No Wash**, or previously created User-Defined tube settings.
5. Close the **Tube Properties** dialog.
6. Preview the tube data and modify the cytometer settings.
7. Right-click the tube and select **Create Reference Settings**.

The Create Reference Settings wizard opens.

8. Type a name in the **Reference Settings Name** field. The reference settings will be stored in the library, separated into new tube settings of the same name and SOVs. You can also type the name of an existing User-Defined tube setting, to override that setting in the library.
9. (Optional) Add a description using up to 300 characters to help differentiate between similarly named tube settings.
10. Click **Next** to continue.

The **Create Reference Settings** wizard displays a window that prompts for the **CS&T Bead Lot ID**, provides a tube-loading option, and displays a **Control Tubes** table.

Select the controls and lot IDs that will be used to create Reference Settings.
Click Add or Delete to modify which tubes to run.

CS&T Bead Lot ID: 84444 (Expires: 11/30/2019) Loading Option: Universal Loader
Carrier Type: 40 Tube Rack

Fluorochrome	Control Type	Label	Lot ID	Unstained
FITC	FC Beads	Generic	443331 (9/19/2020)	-
PE	FC Beads	Generic	443332 (9/14/2020)	-
PerCP-Cy5.5	FC Beads	Generic	667712 (9/14/2020)	-
PE-Cy7	FC Beads	Generic	667713 (9/14/2020)	-
APC	FC Beads	Generic	667711 (9/14/2020)	-
APC-H7	FC Beads	Generic	443344 (9/30/2020)	-

Drag fluorochromes to re-order. Use CTRL/SHIFT keys for multi-selection.

Add Delete

Previous Next Cancel

11. The **CS&T Lot ID** field displays the bead lot used for the latest performance QC. If you want to use a different bead lot, click and select a different entry.
12. For **Loading Option**, select between **Universal Loader** and **Manual**. If you select **Universal Loader**, select the **Carrier Type** corresponding to the tube capacity of the rack that you are using.

Selecting control tubes

The Control Tubes table displays the fluorochromes of the beads included in each BD[®] FC Beads kit. Control types include: BD[®] FC Beads, BD[®] CompBeads, and fluorescence controls.

- **BD[®] FC Beads** FC beads are supplied by BD.
- **BD[®] CompBeads** These particles include two separate beads, a negative bead and a capture bead. These beads need to be stained with the specific antibodies for fluorochromes that are being added to the

reference setting. You can choose to have a separate unstained tube or add the negative bead to the positive capture beads.

- **Fluorescence control (FC).** These controls are user-defined fluorescent control particles that can be cells, beads, or anything else (for example, nuclei for DNA staining). They can have a separate unstained tube or include unstained particles in the stained tube. This is useful when the fluorochrome/dye of interest is stained on a specific particle other than BD[®] FC Beads or BD CompBeads particles.

To define control tubes:

1. In the **Label** column, select to use a generic or specific label.

Generic labels apply to any antibody or label. Use Specific labels when compensation requirements are different between labels (for example, for tandem dyes). The available selection is based on the reagents in the library. For example, you must create CD3 PE-Cy7 reagent to select CD3 as a label for PE-Cy7. BD[®] FC Beads can only define generic controls.

2. In the **Lot ID** column, select a lot ID if you want to designate a specific reagent lot ID for the fluorochrome label combination.

The available selection is based on the fluorochrome and reagent already selected. For example if you select PE-Cy7; CD3, only lot IDs for that reagent are available.

Defining the label and lot ID creates a lot-specific SOV column in the SOV matrix. This can be necessary for tandem reagents, for example, because the reagent emission can change from lot to lot.

In the following example, PE-Cy7 and APC-H7 fluorochromes are changed to BD CompBeads that are tandem reagents with lot-specific SOVs.

Fluorochrome	Control Type	Label	Lot ID	Unstained
FITC	FC Beads	Generic	443331 (9/19/2020)	-
PE	FC Beads	Generic	443332 (9/14/2020)	-
PerCP-Cy5.5	FC Beads	Generic	667712 (9/14/2020)	-
APC	FC Beads	Generic	667711 (9/14/2020)	-
PE-Cy7	CompBeads	CD4	12345 (12/31/2019)	-
APC-H7	CompBeads	CD8	23456 (12/31/2019)	-

3. In the **Unstained** column, select an unstained control type:

- **Blank** Leave this column blank if your tube contains both positive and negative controls. No unstained control tube is created.
- **Unstained** Select this when you have one unstained tube you plan to use as a universal negative control and your remaining tubes contain only positive controls. A universal unstained control tube (specific to the control type) is created.
- **Fluorochrome-Unstained** Select this when you have an unstained tube you plan to use as a negative control only for a specific fluorochrome. An unstained control tube for the specific fluorochrome is created.

4. (Optional) If you want to add new fluorochromes or control types:

- a. Under **Control Tubes**, click **Add** to add a new fluorescence control.
- b. In the **Fluorochrome** column, select a fluorochrome for the new control tube.
- c. In the **Control Type** column, select the control type (FC Beads, FC, or CompBeads).
- d. Repeat steps 1 to 3 for each added control.

Once the controls have been added, you can reorder them using drag and drop. The order of the controls is persistent for the Update Reference Settings and Add Fluorochromes tasks.

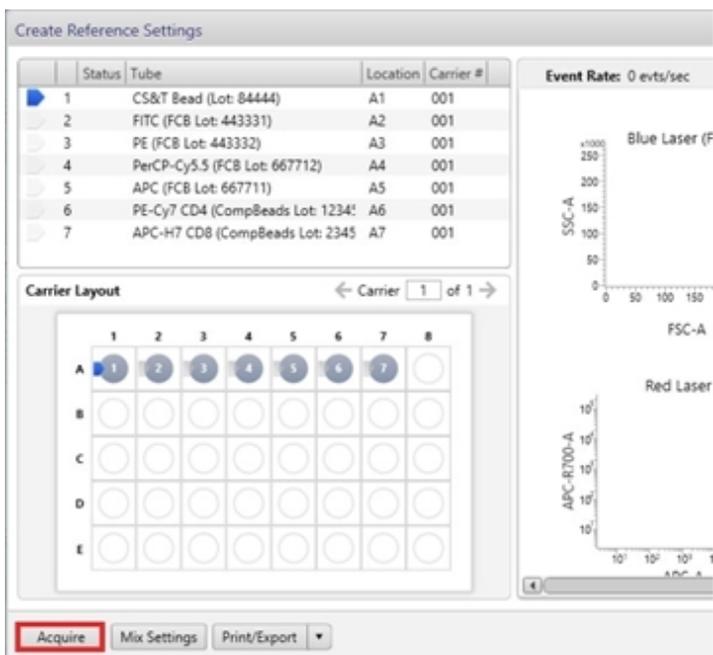
5. Click **Next**.

The next wizard page displays a list of control tubes to acquire.

Acquiring control tubes using the BD FACST™ Universal Loader

To acquire the control tubes using the BD FACST™ Universal Loader:

1. Place the BD® CS&T Beads and control beads into the tube rack as shown in the left two panels of the **Create Reference Settings** dialog.



2. (Optional) Change the default values for mix settings by clicking the **Mix Settings** button. Default value for initial mixing is 4 seconds at 1,400 rpm and then 10 seconds at 1,250 rpm every 4 minutes thereafter.
3. (Optional) Click **Print/Export** to print or export as a PDF file the carrier layout and list of tube names.
4. Click **Acquire** and, when prompted, put the carrier onto the Loader and close the Loader door. After dismissing the **Load Carrier** dialog, acquisition starts automatically.

As the acquisition of each tube completes, a provisionally colored checkmark is displayed in the tube status and **Carrier Layout** panels (green for success and red for failure). When prompted, after acquisition of all tubes is complete, remove the carrier from the loader and click **Continue**.

Note: SOV recalculations are performed after acquisition of all tubes is complete. This can change the success/failure status for individual tubes.

- (Optional) To print or export the acquisition results, click the drop-down arrow on the **Print/Export** button, and select **Worksheets**. The Print/Export Worksheets option can only be selected after acquisition is complete. After the BD FACSuite™ application has generated the report, from the toolbar in the Print/Export Worksheets window, select **Print** (to select and send to a printer) or **Export** (to select and save a PDF file).

Note: If printing, the selected printer must be capable of accepting input in PDF format.

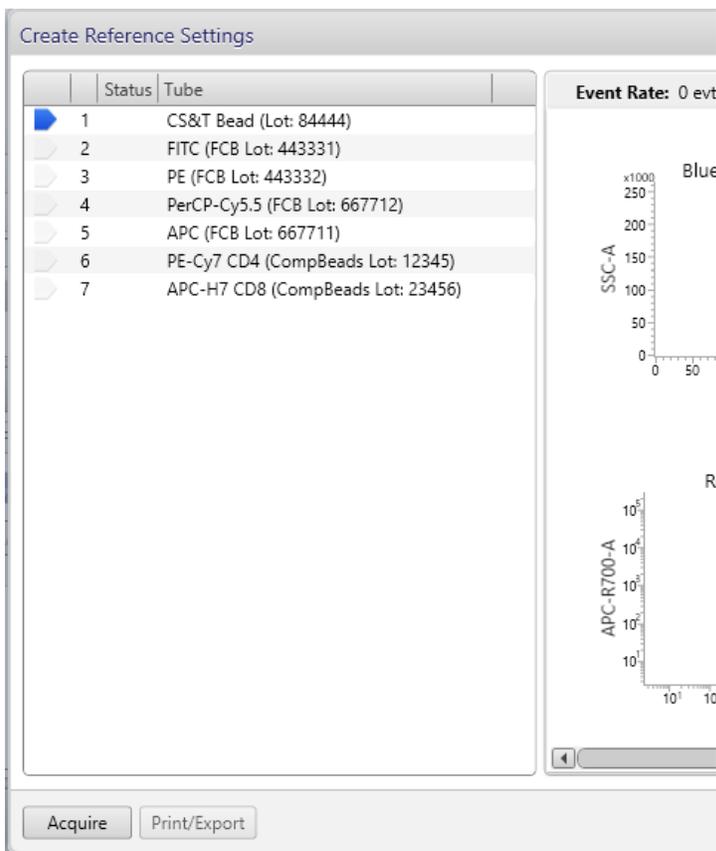
- Click **Finish**.

The BD FACSuite™ application saves the tube settings and SOVs that comprise the reference settings into the library.

Acquiring control tubes using the manual tube port

To acquire the control tubes using the manual tube port:

- Click **Acquire**.



- When prompted, load the indicated tube onto the manual tube port.

When the acquisition of the tube completes, a green checkmark is displayed.

- When prompted, unload the indicated tube from the manual tube port.
- Repeat steps 2 and 3 until all of the tubes have been acquired.
- Click **Finish**.

The BD FACSuite™ application saves the tube settings and SOVs that comprise the reference settings into the library.

More information

- [Creating tube settings \(page 100\)](#)
- See Reference settings overview in the *BD FACSLyric™ Reference System*.

Viewing tube and reference settings in the library

Introduction

This topic describes how to view tube and reference settings in the library. As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

Procedure

To view the settings:

1. In the **Library** panel, double-click **Tube Settings**, then click **User-Defined**.

The BD FACSuite™ application displays a **Tube Settings** table in a large panel to the right of the **Library** panel. Entries in the table that are reference settings are indicated by an X in the **Reference Settings** column.

2. Click an entry in the **Tube Settings** table.

The tube settings for the selected entry in the Tube Settings table display in a panel below the table.

Reference settings are split into tube settings and spillover values, which appear under separate tabs in the lower panel.

3. (Optional) Print tube settings or SOVs:

- a. Click the **Tube Settings** or **Spillover Values** tab.
- b. Click **Print**.

The print dialog includes a toolbar that allows you to change the print layout and to either send the data to a PDF-capable printer or export the data to a PDF file.

More information

- [Creating tube settings \(page 100\)](#)
- [Creating default reference settings \(page 101\)](#)
- [Creating user-defined reference settings \(page 103\)](#)

Saving modified reference settings

Introduction

This topic describes how to save modified reference settings when you adjusted compensation but did not modify the cytometer settings (PMT voltages, thresholds, window extension, flow rate, or area scaling factors). As with other topics in this chapter, this topic applies to the BD FACSuite™ application only.

Example of the correct use of Save Modified Reference Settings

Saving modified reference setting works correctly for the tube (shown in the following figure) if the reference settings have been applied to the tube and then adjustments to the fluorochromes were made (FITC and PE in this example).

Reagents		
Name	Label	Lot ID
FITC	CD4	12345
PE	CD45	21345
PerCP-Cy5.5		
PE-Cy7		
APC		
APC-Cy7		
V450		
V500		

The FITC and PE labels and lot IDs in the Tube Properties dialog match what was in the Create Reference Settings dialog. The rest of the parameters use the generic SOVs from when the reference settings were created.

Procedure

To save modified reference settings:

1. In the **Data Sources** panel, click a tube and apply tube settings to the tube.
2. Right-click the tube and select **Properties**.
3. Click the **Spillover Values** tab. If necessary, delete any non-lot specific labels assigned to the parameters for which you will be adjusting compensation.
4. Adjust the compensation values as needed and click **Close**.
5. Right-click the tube, then select **Save Modified Reference Settings**.

The Save Modified Reference Settings dialog opens.

6. In the **Reference Setting Name** field, type a name for the reference settings that are being modified.

If you began with LW/LNW reference settings, then you must give them a new name.

7. (Optional) In the **Description** field, type a meaningful description to help differentiate between similarly named reference settings.
8. Click **Finish**.

If you do not update the name for the reference settings other than LW or LNW, the Save Settings dialog opens.

9. Click **Yes** to overwrite the existing reference settings, or click **No** to enter a new name and create new reference settings.

The modified reference settings are saved in the library with their associated tube settings and adjusted SOVs.

10. Add any deleted labels back to the tube properties.
11. Acquire tubes or create an assay that will use the modified reference settings.

More information

- [Creating default reference settings \(page 101\)](#)

9

Worklist overview

This chapter includes the following topics:

- [About the worklist \(page 114\)](#)
- [Using the Manage Worklists tab \(page 116\)](#)
- [About the Worklist Entries table \(page 118\)](#)
- [About the Worklist Controls bar \(page 122\)](#)
- [About worklist entry controls \(page 123\)](#)
- [About Entry Details panel controls \(page 125\)](#)
- [About Worklist panels \(page 126\)](#)
- [Working with the worklist manager audit trail \(page 155\)](#)

About the worklist

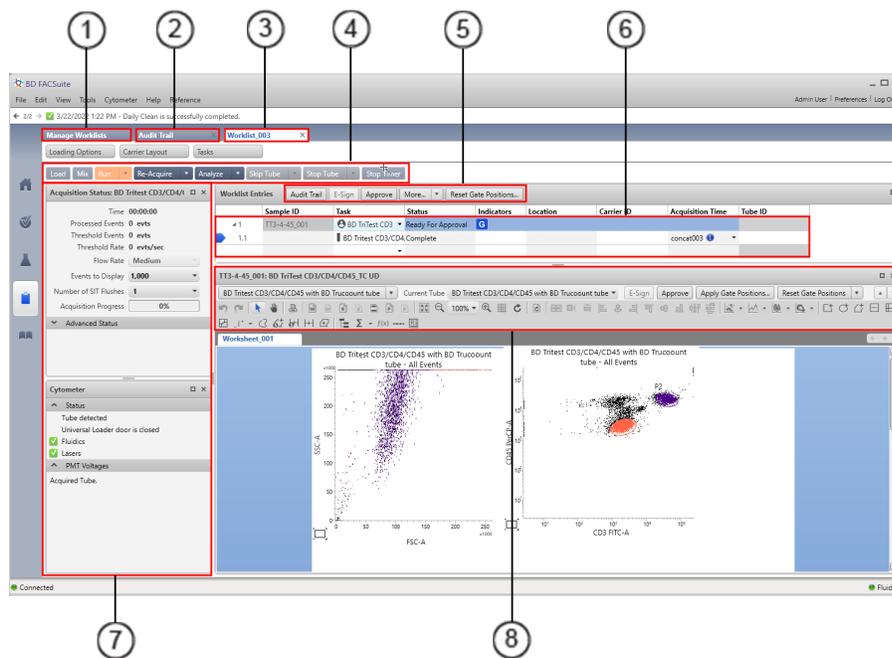
Introduction

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.

Worklists workspace



No.	Description
1	Manage Worklists tab
2	Audit Trail tab
3	Worklist tab
4	Worklist controls bar
5	Worklist entry controls
6	Worklist entries table

No.	Description
7	Worklist panels
8	Entry Details panel controls

Manage Worklists tab

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



Shared	Action	Name	Author	Modified Date	Modified By
N	👍	Worklist_003	Admin User	3/22/2022	Admin User
N	👎	Worklist_001	Admin User	3/22/2022	Admin User
N	👍👎	Worklist_004	Admin User	3/4/2022	Admin User

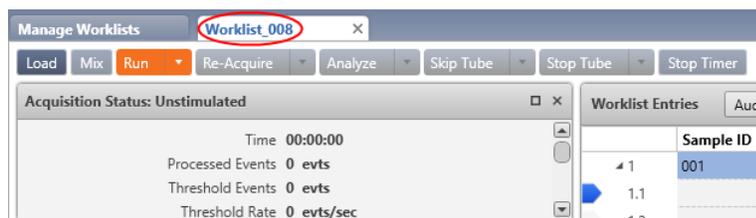
Use the **Manage Worklists** tab to create new worklists, delete worklists, view the worklist audit trail, open existing worklists, and share worklists with other users. Use the menu bar to create, rename, import, and export worklists. The Action column displays actions needed for worklists, such as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



Sample ID
001
1.1
1.2

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

More information

- [Using the Manage Worklists tab \(page 116\)](#)
- [Working with the worklist manager audit trail \(page 155\)](#)

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 \(page 208\)](#).
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 \(page 114\)](#)
- See these topics in the *BD FACSLyric™ Reference System*:
Setting worklist preferences, Sharing a worklist, Sorting worklists in the table, and Defining search criteria.

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.

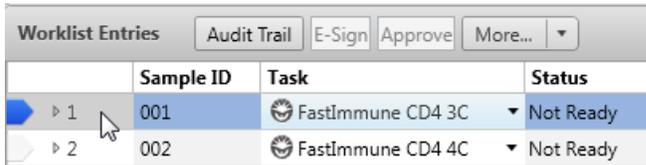
You can drag entries in the Worklist Entries table to change the run order.

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.



Worklist Entries			
	Sample ID	Task	Status
▶ 1	001	FastImmune CD4 3C	Not Ready
▶ 2	002	FastImmune CD4 4C	Not Ready

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:

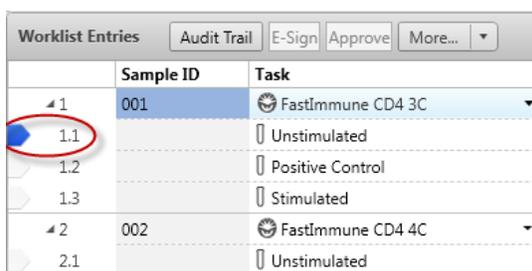
1. Expand an entry by clicking the arrow next to the entry number.
2. Click between the tube number and the Sample ID number.

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:

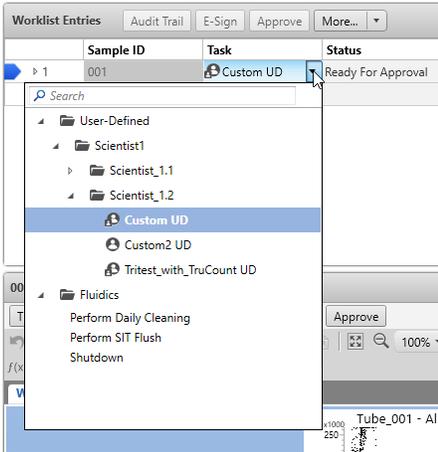
- Which entry to display in the Entry Details panel.
- Which entry an acquisition run starts with (only when you select Run from Pointer).



Worklist Entries			
	Sample ID	Task	
◀ 1	001	FastImmune CD4 3C	▼
◀ 1.1		Unstimulated	
◀ 1.2		Positive Control	
◀ 1.3		Stimulated	
◀ 2	002	FastImmune CD4 4C	▼
◀ 2.1		Unstimulated	

Worklist Entries table columns

The Worklist Entries table includes the following columns.

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. By default, autonumbering is enabled and a sample ID is added when you select a task. By default, in the BD FACSuite™ application, autonumbering is enabled and a sample ID is added when you select a task.
Task	<p>A task is an action that is performed when you run a worklist. Tasks can be assays or fluidics actions.</p> <p>The list of installed assays is displayed by the task selector in the Task column. For the BD FACSuite™ application, if the assays are organized into folders in the User-Defined repository in the Library, the task selector reflects the folder structure accordingly. The task selector automatically accounts for any subsequent changes in the folder assignment of the selected assay.</p>  <p>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.</p> <p>Fluidics tasks include:</p> <ul style="list-style-type: none"> • Perform Daily Cleaning • Perform SIT Flush • Shutdown
Status (entry)	<p>The current entry status is displayed in the Status column.</p> <ul style="list-style-type: none"> • 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)	<p>The current tube status is displayed in the Status column.</p> <ul style="list-style-type: none"> • 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	<p>A worklist entry that allows gate sizes and positions to be modified displays a gating control status icon:</p> <ul style="list-style-type: none">  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. <p>A worklist entry with e-signature enabled displays an e-signature status icon:</p> <ul style="list-style-type: none">  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. <p>The worklist entry may also display LIS/LIMS interface status:</p> <ul style="list-style-type: none">  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 or the well location on a plate ^a specified for the entry.
Carrier ID	<p>The sample carrier ID for the entry.</p> <p>You can select different sample carrier types using the Loading Options panel. You can select a specific carrier using the Layout View panel.</p>
Acquisition Time	The date and time of acquisition for the data file.
Tube ID	The ID number of the tube.
^a Well locations should not be used for BD IVD assays	

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.

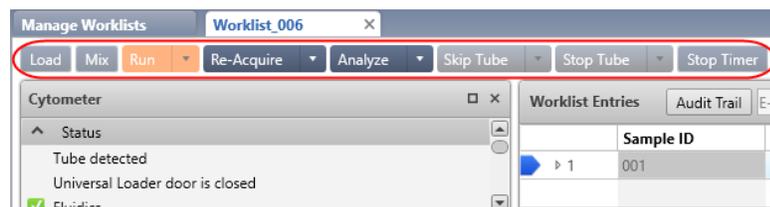
More information

- [BD FACS™ Universal Loader \(page 177\)](#)
- [Defining sample carrier layouts \(page 183\)](#)

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 or plate ^a) 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, or wells ^a . 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.

Control	Description
Stop Timer/Resume	<p>Before acquisition</p> <p>During preview mode, the Stop Timer button controls the Acquisition Delay Timer.</p> <p>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.</p> <p>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.</p> <p>After acquisition</p> <p>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.</p> <p>You can adjust the duration of the Acquisition and Report Delay timers in the Preferences dialog.</p>
<p>^a Plates should not be used with BD IVD assays.</p>	

More information

- [Worklist run options \(page 141\)](#)
- [Setting worklist preferences \(page 207\)](#)
- See the *BD FACSLyric™ 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.

Sample ID	Task	Status	Indicators	Location
TT3-4-45_001	BD TriTest CD3	Ready	G	A1
1.1	BD Tritest CD3/CD4, Ready To Acquire			A1

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	<p>After clicking this button:</p> <ul style="list-style-type: none"> • 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. <p>The same change text will be applied to each selected entry.</p>
E-Sign	An entry has E-Signature enabled	Click to open the E-Signature dialog.
More	NA	<p>Click to select one of the following actions:</p> <ul style="list-style-type: none"> • Assign Keywords • Show/Hide Columns <p>One or more entries must be selected for the following functions to be enabled:</p> <ul style="list-style-type: none"> • Export Entry Run Packages • Export Results • Export FCS Files • Export Assay Reports • Print Assay Reports • Send Results to LIS/LIMS • Delete
Reset Gate Positions	<p>This control only displays if the current worklist contains at least one entry using an assay with the Apply Gate Positions attribute enabled.</p> <p>It is only enabled when acquired entries are not in the Approved state and gates are not in their last applied positions.</p>	<p>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.</p> <p>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.</p>
Update Assay Version	This control only displays if the current worklist contains sample data and the associated assay has been updated since the sample was acquired or partially acquired. This control applies to the BD FACSuite™ application only.	<p>Click to apply changes to the already-acquired worklist.</p> <p>Note: After performing this operation, you cannot re-acquire data in the worklist.</p>

More information

- [Working with worklist-entry audit trails \(page 161\)](#)
- [Using E-Signature \(page 163\)](#)

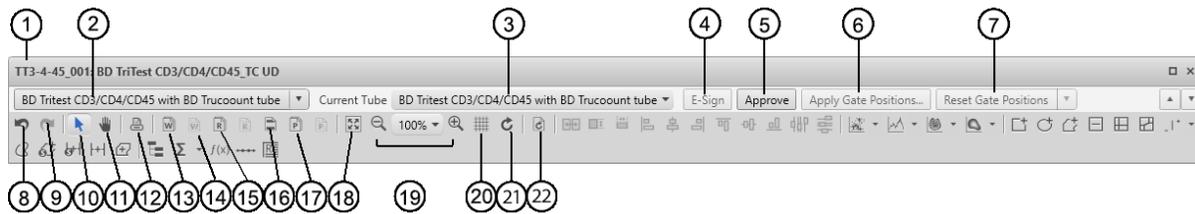
About Entry Details panel controls

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 or worksheet, overwriting the name of the Entry Details panel.
2	Click to view the tube properties for that tube.
3	Click to select which tube to view.
4	Click to apply an e-signature to the entry, if enabled.
5	Click to approve the entry, if enabled.
6	Only shown if the assay for the worklist entry allows gates to be repositioned and resized. Click to apply the gate positions in this entry to other entries in this worklist that use the same assay.
7	Only shown if the assay for the worklist entry allows gates to be repositioned and resized. 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.
8	Click to undo the last action.
9	Click to redo the last action.
10	Click to change to Select mode.
11	Click to change to Navigate mode.
12	Click to print the current tab to a PDF-capable printer.

No.	Description
13	Click to add a new worksheet.
14	Click to delete the currently selected worksheet.
15	Click to add a new report.
16	Click to edit the header and footer (BD FACSuite™ application only).
17	Click to add a new page (BD FACSuite™ application only).
18	Click to make the report fit the pane below.
19	Click to zoom in or zoom out.
20	Click to view a grid in the report background.
21	Click to toggle the layout of multiple pages between horizontal (side by side) and vertical (top to bottom).
22	Click to change page orientation between landscape and portrait (BD FACSuite™ application only).

More information

- For details about gates, see [Drawing gates \(page 76\)](#).
- [Reviewing reports \(page 151\)](#)

About Worklist panels

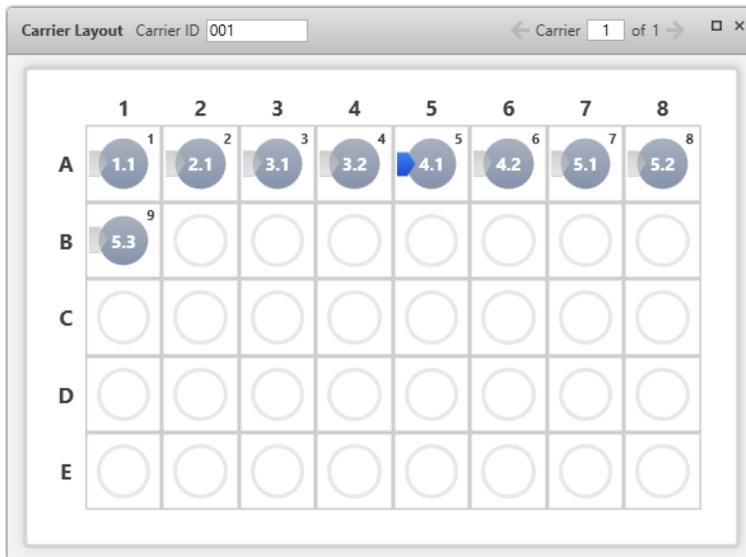
Introduction

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 or plate¹ and the tube or well 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.

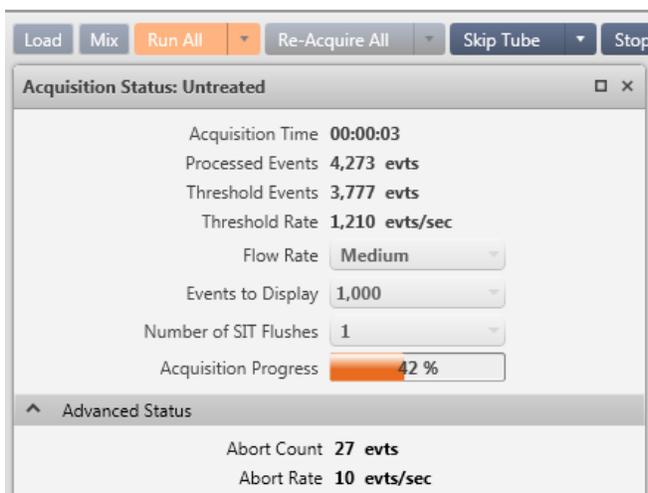
¹Do not use plates with well layouts with BD IVD assays.



If you are using the Loader, you can use the Carrier Layout panel to view tubes and wells 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.

The fluidic mode controls the speed that the combination of sheath and sample passes through the flow cell in the instrument. These modes include:

- Normal (uses low, medium, or high flow rates)
- High-sensitivity (uses a flow rate that obtains a better separation between the negative and positive fluorescence populations)

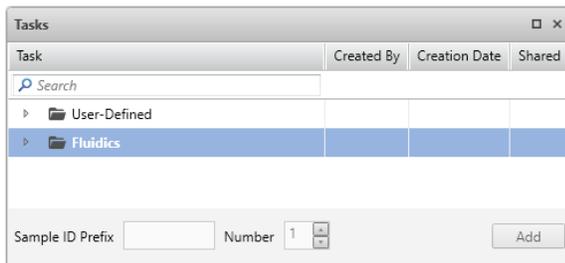
High-sensitivity mode should not be used for BD IVD applications.

Flow rates (low, medium, or high) determine the rate that the sample flows through the flow cell in the instrument.

Note that you cannot apply different fluidic modes to separate entries within the same worklist. Changing from one fluidic mode to another causes the cytometer settings to recalculate and requires time for the fluidics to stabilize.

Tasks panel

The Tasks panel allows you to add multiple entries of a task at once. It includes a Search control that allows you to search for a task by typing part or all of its name.

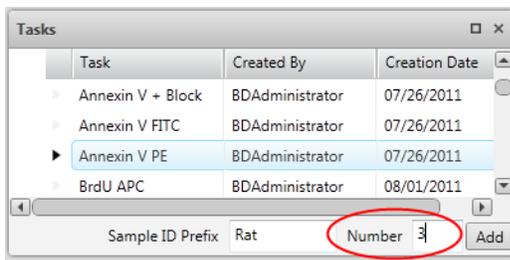


You can select one or more tasks to add at once. You can also specify how many of each selected task to add to the worklist.

In the BD FACSuite™ application, you can also designate a sample ID prefix to be added to the beginning of the sample ID. Sample ID auto numbering needs to be enabled if you are using the prefix.

The tasks selected in the Task panel can be added to the worklist either by clicking **Add** in the Tasks panel or by dragging and dropping the selected tasks into the Worklist Entries panel.

In the example, a prefix is entered and three tasks are added.

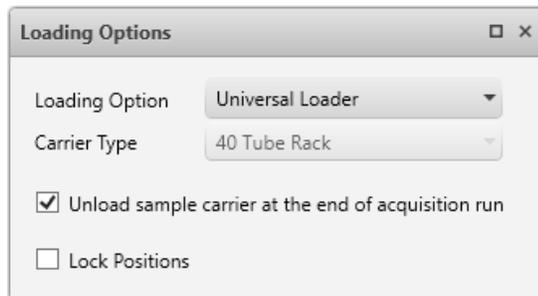


Worklist Entries			
	Sample ID	Task	Status
▶ 1	Rat_001	Annexin V PE	Ready
▶ 2	Rat_002	Annexin V PE	Ready
▶ 3	Rat_003	Annexin V PE	Ready

For the BD FACSuite™ application, if the assays are organized into folders in the User-Defined repository in the Library, the task selector in the Tasks panel reflects the folder structure accordingly.

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 or wells. The default is defined by the Loader preferences.

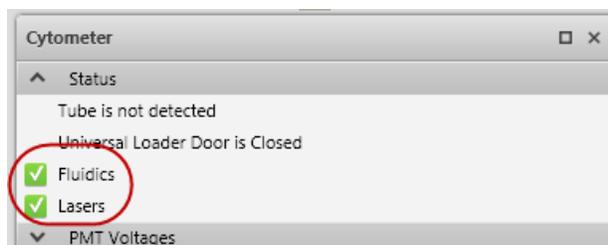


Selecting the Lock Positions checkbox maintains the physical location of the target tubes or wells—even if you re-order or add new entries in the worklist. This can be helpful when you are manually preparing samples to run using the Loader. Note that you cannot unlock the positions for a worklist once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

Cytometer panel

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

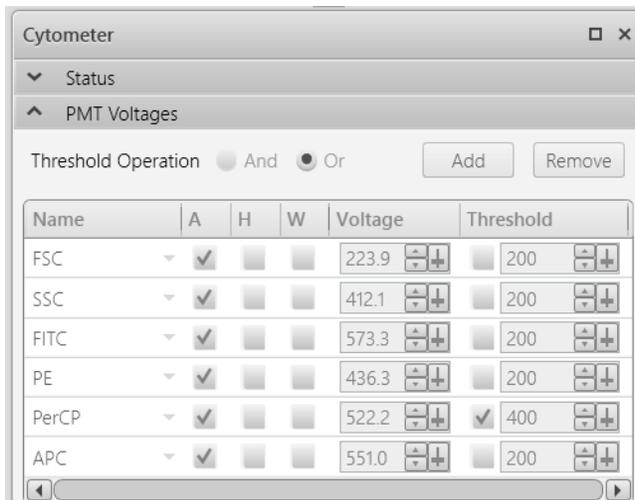
The Status section displays the system status, including real-time status for the manual tube port, Loader, fluidics, and lasers. A checkmark indicates a ready status. This section also indicates when you need to run system cleaning protocols.



Use the PMT Voltages section to indicate whether or not to collect data for area (A), height (H), width (W)¹; view and adjust PMT voltages; and adjust the threshold.

In the BD FACSuite™ application, you can also add or remove parameters before you run a worklist.

¹Area, height, and width options are available in the BD FACSuite™ application only.



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

10

Data acquisition in a worklist

This chapter includes the following topics:

- [Data acquisition overview \(page 132\)](#)
- [Creating a worklist \(page 133\)](#)
- [Excluding tubes from acquisition before running a worklist \(page 136\)](#)
- [Running a worklist \(page 139\)](#)
- [Worklist run options \(page 141\)](#)
- [Re-acquiring entries in a worklist \(page 143\)](#)
- [Concatenating FCS files \(page 144\)](#)
- [Deleting Concatenated FCS files \(page 147\)](#)

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 133) .
2	(Optional) Assign keywords to entries and tubes. See topics about assigning keywords in the <i>BD FACSLyric™ Reference System</i> .
3	Run the worklist. See Running a worklist (page 139) .

More information

- [Worklist run options \(page 141\)](#)
- [Re-acquiring entries in a worklist \(page 143\)](#)

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. If autonumbering is enabled in the BD FACSuite™ application, the sample ID is automatically entered after you add a task.

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™ Reference System*.

4. Modify the loading options in the **Loading Options** panel as needed.
5. If the worklist is in the BD FACSuite™ application, modify worksheet or report elements, instrument settings, or SOVs (as permitted by the assay type or your user privileges).
6. Save the worklist by selecting **File > Save**.

Adding entries from an LIS or LIMS

BD FACSLink™ software or BD FACS™ Workflow Manager 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.

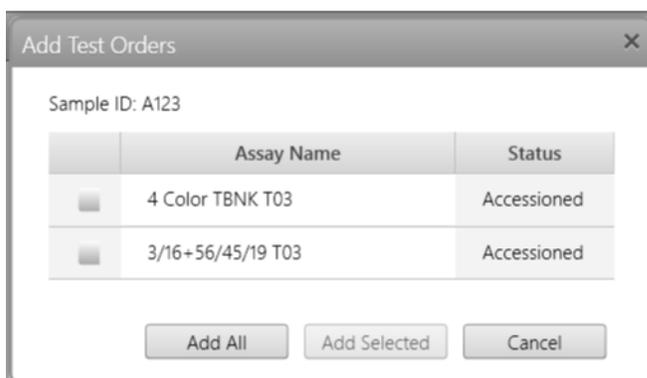


2. In the **Worklist Entries** table, type in the field or scan a barcode to enter a sample ID in the **Sample ID** column.

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.

Sample ID	Task	Status	Indicators	Location	Carrier ID	Acquisition Time	Tube ID
123SC	Copy of 3P_3T_1*	Ready	+L	A1-A3	001		

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

Excluding tubes from acquisition before running a worklist

Worklists that include one or more multitube worklist entries can have one or more tubes in an entry excluded from acquisition. This feature is subject to the following restrictions:

- The assay associated with the worklist entry is a User-Defined assay, not a BD assay, and not imported from an FCS file.
- The assay property **Allow excluding tubes from acquisition** is enabled in the Library—see [Specifying assay properties \(page 213\)](#).
- The tubes in the worklist entry have not yet been acquired.
- Not all tubes in a worklist entry are excluded from acquisition.

If you run a worklist with entries containing excluded tubes or excluded wells on a plate on the BD FACSTM Universal Loader, excluded tubes or wells are removed from the carrier layout. No gaps are left in the carrier layout for excluded tubes or wells.

If you run a worklist containing excluded tubes using the manual port, you will not be prompted to load excluded tubes.

Excluding tubes from a single worklist entry

1. Open the worklist:
 - a. Click **Worklists** in the navigation bar to open the Manage Worklists window.
 - b. In the Manage Worklists tab, double-click the worklist of interest to open it in a separate tab.
2. Open a worklist entry that has not yet been acquired.
3. If excluding a single tube, open the context menu by right-clicking in the first column of the subentry for the tube to be excluded from acquisition.
4. If excluding multiple tubes in a worklist entry, but not all of them, select the first tube by clicking in its leftmost column, select other tubes by holding the Ctrl key and clicking in their leftmost columns, and then right-click to display the context menu.
5. Select **Exclude** from the context menu.

For each excluded tube, an Excluded icon showing a tube with a red line through it is displayed in the Task

column. Also, the same Excluded icon is displayed in the leftmost column of the parent worklist entry.

	Sample ID	Task	Status	Indicators	Location	Carrier ID	Acquisition Time	Tube
▶ 1	001	Experiment_X	Ready		A1	001		
▶ 1.1		Tube_001	Excluded					
▶ 1.2		Tube_002	Ready To Acquire		A1	001		
▶ 2	002	Experiment_X	Ready		A2-A3	001		
▶ 3	003	Experiment_X	Ready		A4-A5	001		

An entry will be added automatically in the Change column of the audit trail report indicating the tube or tubes that were excluded. For example, "The following tube(s) were excluded from acquisition: Tube_001".

Excluding corresponding tubes in other worklist entries

Once you have set up the tube exclusions in one worklist entry, if the entry has not yet been acquired, you can then use it as a template for excluding corresponding tubes in other unacquired worklist entries created from the same experiment:

1. Right-click in the leftmost column of the worklist entry containing one or more excluded tubes that you want to use as a template for exclusions in other worklist entries.
2. Select **Apply Excluded Tubes...** from the context menu.

The application displays the Apply Excluded Tubes dialog, which allows you to select the worklist entries where you want the corresponding tubes to be excluded from acquisition.

3. Select the entry or entries where the tube exclusions are to be applied.

Note: If tube exclusions are applied to an entry where tube exclusions have already been applied, the previously applied exclusions will be overwritten. In other words, the included and excluded tubes will correspond to the settings in the template entry selected in step 1.

4. Optionally, add a reason for change to be added to the audit trail report for the selected entries.

Apply Excluded Tubes

Apply excluded tubes from entry 1, task 'Experiment_XX1 UD'

Tubes to be excluded from acquisition: Tube_001

Tubes to be acquired: Tube_002

Select entries to apply i Existing tube exclusions will be overwritten.

	Sample ID
<input checked="" type="checkbox"/>	2 002
<input type="checkbox"/>	3 003

Audit trail reason for change for selected entries

To exclude corresponding tubes excluded from worklist entry 1

Apply Close

5. Click **Apply** to complete the operation or **Close** to cancel it.

Clearing tube exclusions from a worklist entry

This operation can only be performed if the tubes in the worklist entry have not yet been acquired.

To clear the exclusion for one or more tubes in an open worklist:

1. If clearing the exclusion for a single tube, open the context menu by right-clicking in the first column of the subentry for a tube where you want the current exclusion to be cleared.
2. If clearing the exclusion for more than one tube in a worklist entry, select the first tube by clicking in its leftmost column, select other tubes by holding the **Ctrl** key and clicking in their leftmost columns, and then right-click to display the context menu.
3. Select **Clear Excluded** from the context menu.

An entry will be added automatically in the Change column of the Audit Trail Report identifying the tube or tubes where the exclusions were cleared. For example, "Previously excluded tube(s) were included for acquisition: Tube_001".

Alternatively, if you want to clear all tube exclusions from a worklist entry:

1. Right-click in the first column of the worklist entry where you want to clear the tube exclusions.
2. Select **Clear All Excluded Tubes** from the context menu.

An entry will be added automatically in the Change column of the Audit Trail Report with the text "All tubes were included for acquisition".

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.

	Sample ID	Task	Status
1	001	Annexin V PE	Ready
1.1		Untreated	Ready To Acquire
1.2		Treated	Ready To Acquire

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.

Worklist Entries				
	Audit Trail	E-Sign	Approve	More... ▾
	Sample ID	Task	Status	
1	001	Annexin V PE	Running	
1.1		Untreated	Previewing	
1.2		Treated	Ready To Acquire	

As acquisition progresses, the Acquisition Status panel displays the time, events, and an acquisition progress bar. Events are displayed in plots in the acquisition report and, in the case of the BD FACSuite™ application, in the worksheet.

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.
 - 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.
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	<ol style="list-style-type: none"> 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. <p>The worklist starts with the specified tube or entry, then runs all subsequent tubes in the worklist.</p>
Run a specific entry or tube in the worklist	<ol style="list-style-type: none"> 1. Select either entries or tubes. <p>The entries or tubes do not need to be adjacent in the worklist.</p> <ol style="list-style-type: none"> 2. Click the arrow next to the Run All button and select Run Selected. <p>The worklist starts with the selected tube or entry and continues with the next selected entry or tube in the worklist.</p>

More information

- [Worklist run options \(page 141\)](#)
- [Re-acquiring entries in a worklist \(page 143\)](#)
- [About the Worklist Controls bar \(page 122\)](#)
- See the *BD FACSLyric™ Reference System* for topics about worklist preferences, 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	<ol style="list-style-type: none"> 1. Click Stop Timer to manually stop the acquisition delay timer countdown and pause the worklist in preview mode. <p>While the timer is paused, you can adjust PMT voltages and thresholds, or SOVs.</p> <ol style="list-style-type: none"> 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. <p>Acquisition resumes according to tube type and preferences.</p>
Review the entry once the report is populated with data	<p>After acquisition, the report displays data from an acquired entry until the timer expires. The Stop Timer button controls the report delay timer.</p> <ol style="list-style-type: none"> 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.

To...	Then do this...
View the reports for an entry after a worklist run	<ol style="list-style-type: none"> 1. After acquisition, set the run pointer to an entry to manually display the reports. For the BD FACSuite™ application, the run pointer also displays the worksheets. <p>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.</p>
View tube properties	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 1. Open the tube properties for a tube. 2. Click the Spillover Values tab. 3. Click Print. <p>The Print dialog opens.</p> <ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 1. Click Skip Tube. <p>The tube where tube pointer is set will be skipped.</p>
Skip an entry	<ol style="list-style-type: none"> 1. Click the arrow on the Skip Tube button and select Skip Entry.
Skip a carrier	<p>This applies only to systems using the Loader.</p> <ol style="list-style-type: none"> 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 \(page 150\)](#)
- [Worklist run options \(page 141\)](#)

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:

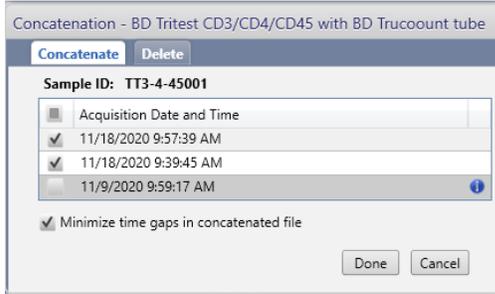
1. Set the run pointer to the tube where samples have been re-acquired.
2. Right-click in the Worklist Entries cell containing the run pointer to display the context menu.
3. Select the **Concatenation** menu item.

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™ 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.

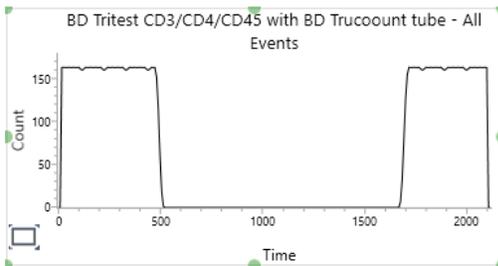


5. If a relatively long period has elapsed between acquisitions in comparison to the combined acquisition times, click **Minimize time gaps in concatenated file**.
6. Click **Done** to concatenate the selected files.

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 `concatnnn.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.

Keyword	Application to concatenated FCS file
\$FIL	The filename of the composite file is auto-generated and is not the same as any of values in the component FCS files.
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 \(page 213\)](#) for details about viewing or setting concatenation preferences.
- For details about drawing plots and keywords, refer to the *BD FACSLyric™ 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.

11

Data analysis in a worklist

This chapter includes the following topics:

- [Data analysis overview \(page 150\)](#)
- [Working with assay reports \(page 151\)](#)
- [Reviewing reports \(page 151\)](#)
- [Approving entries in a worklist \(page 152\)](#)
- [Working with the worklist manager audit trail \(page 155\)](#)
- [Working with worklist-entry audit trails \(page 161\)](#)
- [Using E-Signature \(page 163\)](#)
- [Running batch data analysis \(page 165\)](#)

Data analysis overview



About data analysis

After entries have been acquired, perform analysis by reviewing reports and worksheets¹, adjusting plots and 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 worklists¹ is an automated process that results in automatically generated reports and statistics files that can be optionally 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 reports and worksheets, and modify analysis elements or instrument settings (as permitted). See Reviewing reports (page 151) .
2	Approve the results. See topics about approving entries in a worklist in the <i>BD FACSLyric™ Reference System</i> .
3	E-sign reports. See Using E-Signature (page 163) .

More information

- [Working with worklist-entry audit trails \(page 161\)](#)
- [Running batch data analysis \(page 165\)](#)

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

Working with assay reports

About assay reports

Reports must be created in an experiment. When you create a User-Defined assay from an experiment, the report is included in the new assay. If your assay includes a report, the plots and statistics automatically display data when you acquire or analyze a worklist.

If you are using a BD IVD assay, reports are included in the assay. The plots and statistics automatically populate with data when you acquire or analyze a worklist.

If you want to modify an assay report, you must create a new experiment from the assay, modify the report, then re-create a new User-Defined assay from the modified experiment. When you create an experiment from a BD-defined assay, the reports and data are removed. When you create an experiment from a User-Defined assay, the report and data are included.

More information

- [Experiment building workflow \(page 73\)](#)
- [Creating a User-Defined assay from an experiment \(page 94\)](#)

Reviewing reports

Introduction

Reports are already defined for each BD IVD assay. In the BD FACSuite™ application, you can also create reports for User-Defined assays. 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.



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:
 - Plots
 - Gates
 - Statistics
 - QC results (for BD assays only)
 - QC messages
 - 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 \(page 150\)](#)
- [Approving entries in a worklist \(page 152\)](#)
- [Using E-Signature \(page 163\)](#)
- [Specifying report preferences \(page 205\)](#)
- [Setting worklist printing preferences \(page 212\)](#)

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.

Sample ID	Task	Status	Indicators	Location	Carrier ID	Acquisition Time	Tube ID
001	1T_1G_1R UD	Ready For Approval	G E	A1	001		

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.

Sample ID	Task	Status	Indicators	Location	Carrier ID	Acquisition Time
001	Test1 UD	Approved	DL	A1-A2	001	
002	Test2 UD	Approved	xL	A1-A2	002	

Unable to send results to LIS/LIMS Interface

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 \(page 163\)](#)
- [Data analysis overview \(page 150\)](#)

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.

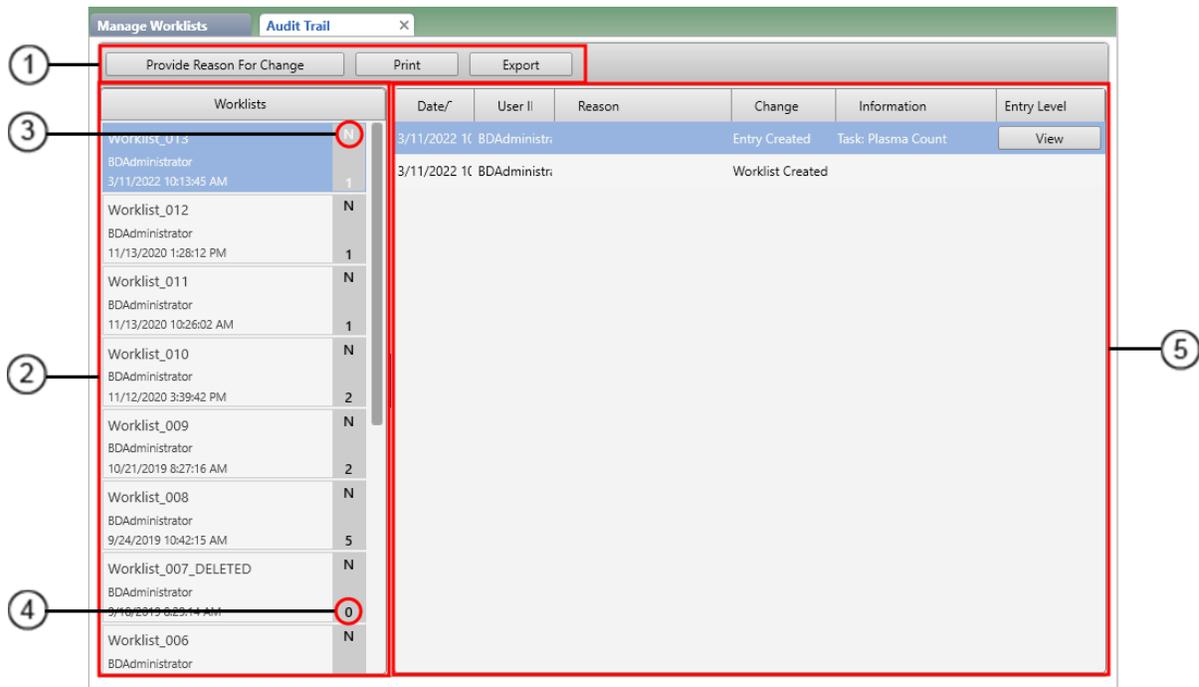
2. Click **View Audit Trail**.

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

Example of worklist manager audit trail in the BD FACSuite™ application:

Worklists	Date	User	Reason	Change	Information	Entry Level
Worklist_005 BDAdministrator 3/4/2022 8:59:37 AM	3/4/2022 8:5	BDAdminist		Entry Created	Sample ID: 003	View
Worklist_004_DELETED BDAdministrator 3/1/2022 4:12:09 PM	3/4/2022 8:5	BDAdminist		Entry Created	Sample ID: 002	View
Worklist_003 BDAdministrator 11/6/2020 2:55:54 PM	3/4/2022 8:5	BDAdminist		Entry Created	Sample ID: 001	View
Worklist_002 BDAdministrator 11/6/2020 1:05:09 PM				Worklist Created		
Worklist_001 BDAdministrator 11/6/2020 1:05:19 PM						

Example of worklist manager audit trail in the BD FACSuite™ Clinical application:



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).

- 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 \(page 155\)](#).
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 \(page 155\)](#).
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 printer 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 \(page 155\)](#).
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 \(page 211\)](#). 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 \(page 211\)](#). 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™ 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.

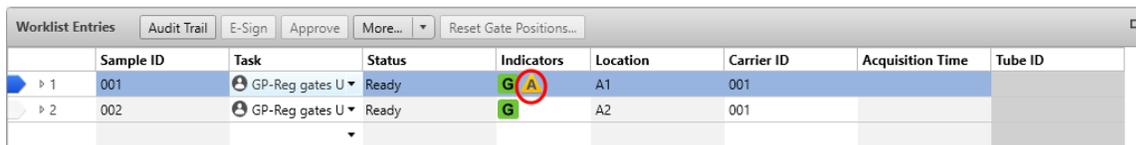
The following information is tracked for each change:

- 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.



	Sample ID	Task	Status	Indicators	Location	Carrier ID	Acquisition Time	Tube ID
> 1	001	GP-Reg gates U	Ready	G A	A1	001		
> 2	002	GP-Reg gates U	Ready	G	A2	001		

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.

Date/Time	UserID	Reason	Change
8/1/2019 9:02:16 AM	BDAdministrator	The entry was modified	Audit trail will require reason for change for the entry's lifetime
8/1/2019 9:02:16 AM	BDAdministrator	Change of Gate Vertices	
8/1/2019 9:02:01 AM	BDAdministrator	Task assigned to entry	Assigned task's audit trail requires reason for change for user actions that impact results
8/1/2019 9:02:01 AM	BDAdministrator	Task assigned to entry	Task assigned: 6-color Stimulation_RA UD
8/1/2019 9:02:00 AM	BDAdministrator	Entry created	Entry created

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 \(page 152\)](#)
- For details about setting audit trail preferences in an assay, refer to the *BD FACSLyric™ 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.



Sample ID	Task	Status	Indicators	Location	Carrier ID	Acquisition Time	Tube ID
001	1T_1G_1R UD	Ready	G E	A1	001		

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, worksheet or report layout¹, or any other analysis elements or settings that affect the data after you e-sign the report, the report is automatically un-signed and must be e-signed again.

¹Worksheet analysis and report layout preferences are available in the BD FACSuite™ application only.

More information

- [Approving entries in a worklist \(page 152\)](#)
- [Data analysis overview \(page 150\)](#)
- For instructions on enabling E-Signature, see “Editing assay properties” in the *BD FACSLyric™ Reference System*.

Running batch data analysis

Introduction

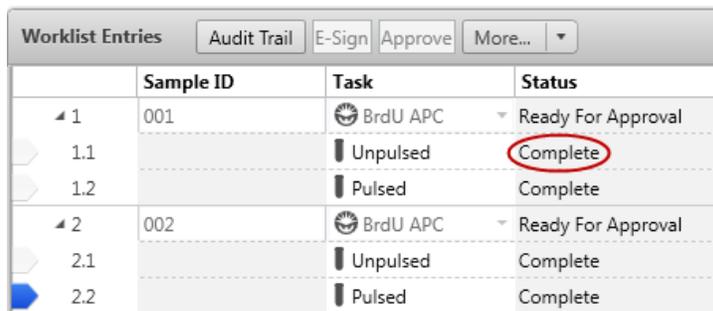
Batch analysis allows you to automatically export and print all items in a worklist that have already been approved. To begin batch analysis, you need to have acquired data from at least one entry or tube. Analysis is performed only on entries or tubes that have an associated FCS file. Tubes that do 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.



Worklist Entries			
Audit Trail E-Sign Approve More... ▾			
	Sample ID	Task	Status
◀ 1	001	🕒 BrdU APC ▾	Ready For Approval
▶ 1.1		🕒 Unpulsed	Complete
▶ 1.2		🕒 Pulsed	Complete
◀ 2	002	🕒 BrdU APC ▾	Ready For Approval
▶ 2.1		🕒 Unpulsed	Complete
▶ 2.2		🕒 Pulsed	Complete

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

The analysis preview opens in the 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.

12

BD IVD assays

This chapter covers the following topics:

- [Overview of BD IVD assays \(page 168\)](#)
- [Creating an assay worklist \(page 168\)](#)
- [About lab reports \(page 170\)](#)
- [About physician reports \(page 172\)](#)
- [About supplemental reports \(page 174\)](#)

Note: BD IVD assays are for use in the BD FACSuite™ Clinical application only.

Overview of BD IVD assays

Introduction

BD IVD assays are designed for use only with the BD FACSuite™ Clinical application 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 168) .
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 in a worklist (page 131) .
4	Analyze the data. See Data analysis in a worklist (page 149) .

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 \(page 133\)](#)
- [Running a worklist \(page 139\)](#)
- [Worklist run options \(page 141\)](#)

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.

① **BD 6 Color TBNK + Truc: Lab Report**

②

Sample ID: 101 Sample Name: john Case Number:	Acquired Using: Worklist_008 Trucount Lot ID: 359687 Cytometer: BD FACSLyric Operator: Admin User	Approved: 4/29/2015 11:48:58 AM Beads Per Pellet: 50000 Cytometer SN: 987654321 Director: Department: None	Entry Status: Approved Software: BD FACSuite Clinical v1.0 Institution: 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

The flow cytometry analysis consists of several plots:

- All Events:** Scatter plot of SSC-A vs CD45 PerCP-Cy5.5-A. A red gate is drawn around the lymphocyte population.
- Beads, Not Lymphs:** Scatter plot of SSC-A vs CD19 APC-A. A green gate is drawn around the bead population.
- Lymphs:** Scatter plot of SSC-A vs CD3 FITC-A. A yellow gate is drawn around the CD3+ lymphocyte population.
- CD3+:** Quadrant plot of CD4 PE-Cy7-A vs CD8 APC-Cy7-A. Quadrants are labeled CD4+CD8-, CD4+CD8+, CD4-CD8-, and CD4-CD8+.
- Not CD3+:** Quadrant plot of CD19 APC-A vs CD16+56 PE-A. Quadrants are labeled CD19+, CD19+CD16&56+, CD19-CD16&56-, and CD16&56+.

⑤

For In Vitro Diagnostic Use.	6 Color TBNK + Truc vT03 Page 1 of 2	Printed: 7/21/2015 5:34:30 PM
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Sample ID: 1610_6CT
Sample Name: Donor 1610
Case Number: 001
 Acquired Using: CorrRegression_FH_122214
 Assay: 6 Color TBNK + Truc T03

Results Summary (Abs Cnt is in cells/ μ L)		
Label	%Lymphs	Value or Abs Cnt
Bead Events		1,942
Lymphs Events		2,505
Lymphs		1,323
CD3+	70.06	927
CD3+CD4+	52.61	696
CD3+CD4+ (excl. dual pos.)	51.98	688
CD3+CD8+	16.17	214
CD3+CD8+ (excl. dual pos.)	15.53	206
CD3+CD4+CD8+	0.64	8
CD3+CD4-CD8-	1.92	25
CD19+	12.61	167
CD3-CD16+CD56+	15.57	206

QC Results	
Label	Results
4/8 Ratio	3.25
%T-Sum (<10%)	1.92
Lymphosum (95-105%)	98.24

QC Messages	
Showing 0 of 0 QC Messages	

Signature: Admin User Comments:	7/27/2015 2:04:18 PM
--	----------------------

For In Vitro Diagnostic Use.

6 Color TBNK + Truc vT03
Page 2 of 2

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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 \(page 151\)](#)

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

①  **BD 6 Color TBNK + Truc: Physician Report**

② **Sample ID: 101**
Sample Name: john
Case Number:

Approved: 4/29/2015 11:48:58 AM Director: Institution: None
 Department: None Tel: Address:
 Email: admin@bd.com

③ Acquisition Date: 4/29/2015 Acquisition Time: 11:43:56 AM

④ **Results Summary (Abs Cnt is in cells/ μ L)**

Label	Results
Lymphs Abs Cnt	1,891
CD3 %Lymphs	64.66
CD3+ Abs Cnt	1,222
CD3+CD4+ %Lymphs	54.40
CD3+CD4+ Abs Cnt	1,028
CD3+CD4+ %Lymphs (excl. dual pos.)	53.76
CD3+CD4+ Abs Cnt (excl. dual pos.)	1,016
CD3+CD8+ %Lymphs	9.59
CD3+CD8+ Abs Cnt	181
CD3+CD8+ %Lymphs (excl. dual pos.)	8.95
CD3+CD8+ Abs Cnt (excl. dual pos.)	169
CD3+CD4+CD8+ %Lymphs	0.63
CD3+CD4+CD8+ Abs Cnt	12
CD3+CD4-CD8- %Lymphs	1.31
CD3+CD4-CD8- Abs Cnt	25
CD19+ %Lymphs	17.00
CD19+ Abs Cnt	321
CD3-CD16+CD56+ %Lymphs	17.67
CD3-CD16+CD56+ Abs Cnt	334
4/8 Ratio	5.67

⑤ **Signature:**

⑥ **Comments:**

⑦ For In Vitro Diagnostic Use. 6 Color TBNK + Truc vT03 Printed: 7/21/2015 5:38:19 PM
 Page 1 of 1

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 \(page 151\)](#)

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**

Supplemental Report

Sample ID: 101

Sample Name: john

Case Number:

Acquired Using: Worklist_008

Trucount Lot ID: 359687

Cytometer: BD FACSLyric

Operator: Admin User

Approved: 4/29/2015 11:48:58 AM

Beads Per Pellet: 50000

Cytometer SN: 987654321

Director:

Department: None

Entry Status: Approved

Software: BD FACSuite Clinical v1.0

Institution: None

Address:

②

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

Events Acquired 10,000

Reagent Lot ID Multitest 6-color TBNK Lot ID: 354789

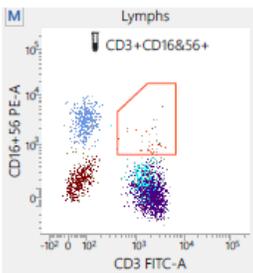
Keyword 1 sun

Acquisition Date 4/29/2015

Acquisition Time 11:43:56 AM

Keyword 2 <no value>

③



④

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

⑤

⑥

For Research Use Only. Not for use in diagnostic or therapeutic procedures.

6 Color TBNK + Truc vT03
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13

BD FACS™ Universal Loader

This chapter includes the following topics:

- [BD FACS™ Universal Loader overview \(page 178\)](#)
- [Sample carrier specifications \(page 180\)](#)
- [Placing carriers into the Loader \(page 182\)](#)
- [Defining sample carrier layouts \(page 183\)](#)
- [Cleaning the Loader \(page 184\)](#)

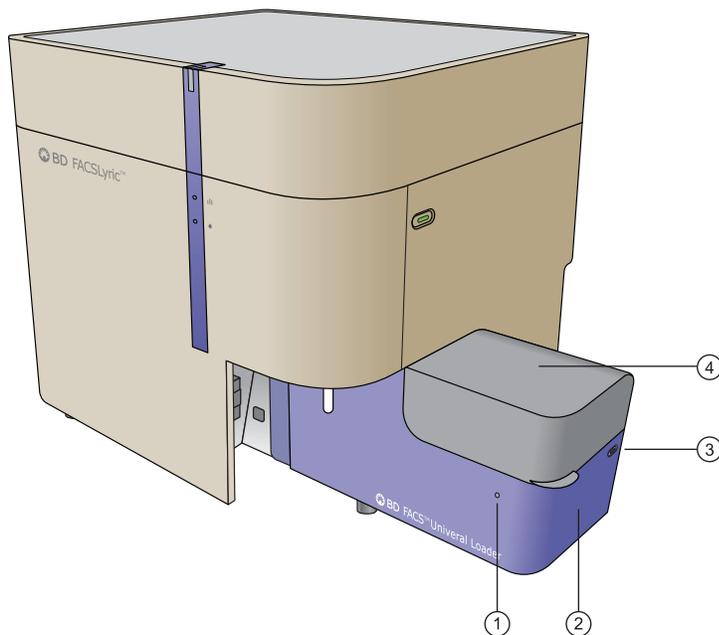
BD FACSTM Universal Loader overview

About the Loader

The BD FACSTM Universal Loader is an optional automated loading system that mixes samples and delivers tube racks and plates¹ 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

¹Plates should not be used with BD IVD assays.

Status indicator

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

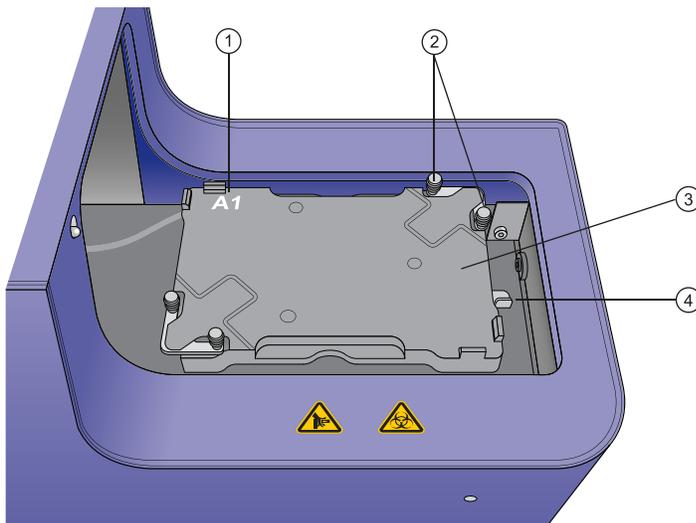
Condition	Status
Off	Ready to operate Note: If main power to the system is off, this indicator is off.
Blue	Cover is locked and system is running
Blinking blue	Loading or unloading
Red	Error condition

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
- Lids on plates

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.

Note: Plates should not be used with BD IVD assays.

- Do not use any plates, tubes, or racks that are not listed as compatible carriers. See [Sample carrier specifications \(page 180\)](#).
- Do not use black plates.
- 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 \(page 182\)](#).
- 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 and wells 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

Carrier type for tubes ^a	Recommended minimum volume (μL)	Maximum volume (μL)
^a For polystyrene, polypropylene, and BD Trucount™ Tubes.		

Carrier type for plates ^a	Bottom geometry	Material ^b	Recommended minimum volume (μL)	Maximum volume (μL)
BD 96 standard height	Round	PS	55	200
BD 96 standard height	Flat	PS	55	200
BD 96 standard height	Round	PP	55	200
BD 96 standard height	Conical	PP	55	200
384 standard height	Flat	PS	40	75
96 half deep	Conical	PP	55	500
96 deep	Conical	PP	55	1,000
96 matrix tube rack	N/A	N/A	55	700
96 filter bottom	N/A	PS	150	200
^a Plates should not be used with BD IVD assays.				
^b PS = polystyrene, PP = polypropylene				

Barcode reading

The system can read barcodes on plates, 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™ Reference System* for more information about barcode scanning and barcode labels.
- See Loader preferences in the *BD FACSLyric™ Reference System* for more information about setting preferences for the Loader.

Placing carriers into the Loader

Procedure

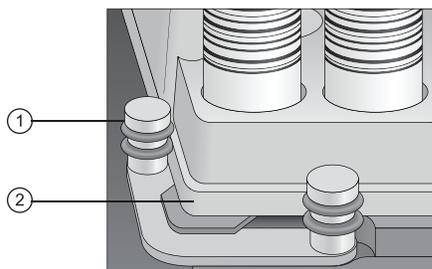
To place a carrier into the Loader:

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

See [Carrier type compatibility \(page 180\)](#).

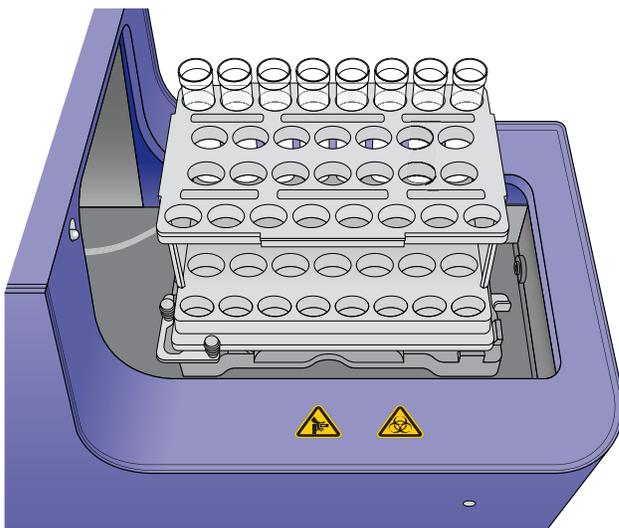
2. Open the cover.
3. Install the carrier into the carrier nest with the carrier centered on the nest.

This is especially important with heavier carriers such as tube racks, deep-well plates, 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 \(page 180\)](#)

Defining sample carrier layouts

Introduction

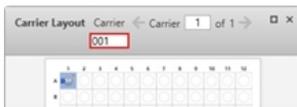
This topic describes how to define sample carrier layouts for a worklist. This applies only to systems that include the Loader option.

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:

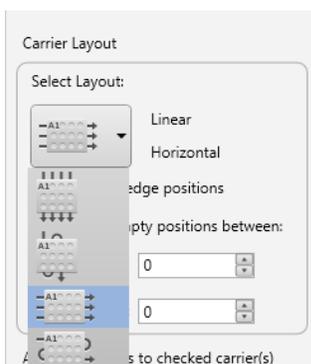
1. In the **Loading Options** panel, in the **Carrier Type** field, click and select a carrier type (for example, *40 Tube Rack*).
2. (Optional) In the **Carrier Layout** panel, change the three-digit carrier ID in the text box.



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

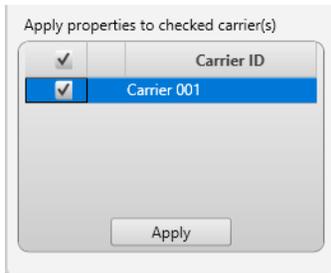
The **Layout Settings for Carrier** dialog opens.

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

- The Loader can be used for creating or updating reference settings. For details, see the following:
 - [Creating default reference settings \(page 101\)](#)
 - [Creating user-defined reference settings \(page 103\)](#)
- For details about using the BD FACS™ Universal Loader when updating reference settings or adding fluorochromes to a reference setting, see the *BD FACSLyric™ 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 \(page 39\)](#)

14

User management

This chapter includes the following topics:

- [Managing user accounts \(page 188\)](#)
- [Managing departments \(page 189\)](#)
- [Managing users \(page 191\)](#)
- [Managing role permissions \(page 193\)](#)
- [Working with the user management audit trail \(page 196\)](#)

Managing user accounts

Introduction

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

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™ 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 189)
Add or edit user profiles	Managing users (page 191)
User roles and managing role permissions	Managing role permissions (page 193)
Set the password policy for users	Topics about setting user login and password policies in the <i>BD FACSLyric™ Reference System</i> .
Export or import user accounts	Topics about importing and exporting users in the <i>BD FACSLyric™ Reference System</i>

More information

- [Setting administration preferences \(page 201\)](#)

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 \(page 188\)](#)
- [Managing users \(page 191\)](#)

Managing users

Introduction

This topic describes how Administrator and ITStaff users can add new users in the BD FACSuite™ and BD FACSuite™ Clinical applications 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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 \(page 188\)](#)
- [Managing departments \(page 189\)](#)

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
	Access Experiments Workspace	Yes	Yes	No	Yes
	Edit Shared Status	Yes	Yes	No	Yes
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 201) .
	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 199) . 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 213) .
	Access Experiments Workspace	–
	Edit Shared Status	–

Category	Task	Notes
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	For the BD FACSuite™ application, modifiable tube properties are items on the Spillover Values tab and the following items on the Acquisition tab: <ul style="list-style-type: none"> • Worksheet to Display during Acquisition • Storage Gate • Items on the Stopping Rules subpanel For the BD FACSuite™ Clinical application, only the Create Gate Criteria properties (Gate and Events) on the Acquisition tab can be modified.
	Rename Worklists with Data	–
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 \(page 188\)](#)
- [Managing departments \(page 189\)](#)

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**.

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Preferences

This chapter includes the following topics:

- [Preferences overview \(page 200\)](#)
- [Setting administration preferences \(page 201\)](#)
- [Setting system preferences \(page 202\)](#)
- [Setting setup and QC preferences \(page 203\)](#)
- [Setting experiment preferences \(page 207\)](#)
- [Setting worklist preferences \(page 207\)](#)
- [Specifying assay properties \(page 213\)](#)

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, Experiments, 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.
Experiments	These preferences define the default tube settings for experiments.
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™ Reference System*

Setting administration preferences

Introduction

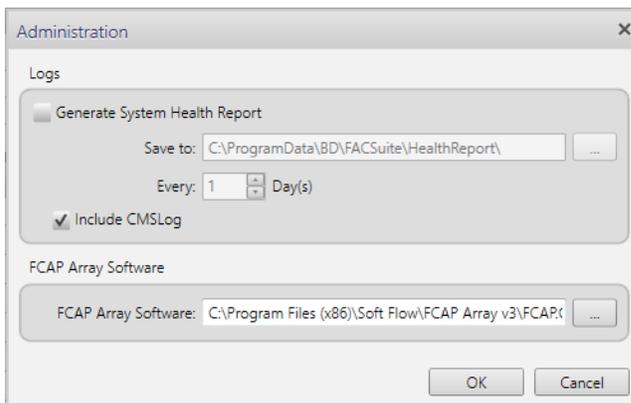
This topic describes how administrators can set administration preferences. By default, the user account roles with these administration privileges are Administrator, Supervisor, and ITStaff. Administration preferences are global settings that specify where files are saved and when the system health 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 \(page 200\)](#)

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. 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.

The screenshot shows two sections of a configuration dialog. The top section, titled "Cytometer Startup Schedule", has a checked checkbox for "Preprogrammed Startup". Below it are seven rows for days of the week: Monday, Tuesday, Wednesday, Thursday, Friday, Saturday, and Sunday. Each row contains a checkbox, a text input field, and a clock icon. The bottom section, titled "Cytometer Shutdown Schedule", has a checked checkbox for "Preprogrammed Shutdown" and a dropdown menu set to "8" with the label "Hours After Cytometer Idle". A note below reads: "Note: If Worklist automated run mode is enabled the time will be set to a minimum of 8 hours. Adjust time as needed when disabling Worklist automated run mode."

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 \(page 200\)](#)

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 and user-defined 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) and user-defined reference settings.

Note that controls created with BD CompBeads or user-defined fluorescence controls do not contribute to the reference setting expiration. The expiration is calculated based on the last updated date for the individual FC Beads in each setting.

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

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

Setting the high-sensitivity fluidics mode preference

High-sensitivity mode is only available in the BD FACSuite™ application. By default, high-sensitivity fluidics mode is excluded when performing setup and QC tasks.

To change the fluidics mode preference:

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 Fluidics Mode section, click the **Include High Sensitivity** checkbox to include or exclude high-sensitivity fluidics mode.

Note: The system will display an error message if you attempt to run an experiment that has tube settings with flow rate set to high-sensitivity mode, and high-sensitivity Characterization QC (CQC) and Performance QC (PQC) tasks have never been run, or if previously run CQC/PQC tasks have expired.

Note: Changing preferences for high-sensitivity mode will clear the performance QC favorites settings, due to changed resource requirements and assay selection constraints. To add assays that have their own tube settings to the daily performance QC again, see [Selecting and viewing Performance QC favorites \(page 46\)](#).

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 \(page 46\)](#).

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.

The image shows a dialog box titled "Export Options". It contains two rows of controls. The first row is for "Automatic Export Location" and the second is for "Manual Export Location". Both rows have a text input field containing "C:\BD Export\Setup\Reports", a "Browse..." button, and a "Reset to BD Default" button.

- 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.

The image shows a table titled "Parameters" with three columns: "Laser", "X Axis", and "Y Axis". The "Blue" laser row is selected. A dropdown menu is open for the "X Axis" of the "Blue" laser, showing a list of parameters: FITC, PE, PerCP-Cy5.5, and PE-Cy7. The "Y Axis" for the "Blue" laser is "PE". The "Red" laser has "FSC" for X Axis and "APC-R700" for Y Axis. The "Violet" laser has "SSC" for X Axis and "V500-C" for Y Axis.

Laser	X Axis	Y Axis
Blue	FITC	PE
Red	FSC	APC-R700
Violet	SSC	V500-C

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 \(page 200\)](#)
- [Selecting and viewing Performance QC favorites \(page 46\)](#)
- For Loader and mix preferences, refer to the Preferences section in the *BD FACSLyric™ Reference System*.

Setting experiment preferences

Introduction

This topic describes how to set experiment preferences. Experiment preferences can be set for each user and apply to all experiments created and run by that user.

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

Procedure

To set experiment preferences:

1. Click the **Experiments** tab.
2. In the **Default Tube Settings** field, select a tube setting from the list.
3. Continue with additional preferences, or click **OK** to save your preferences and close the dialog.

More information

- [Preferences overview \(page 200\)](#)

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 autonumber preference for sample IDs

You can select a worklist preference that enables automatic generation of sample IDs for worklist entries. This automatically assigns a sample ID when adding an entry manually or by adding tasks from the Worklist task panel. Autonumbering is enabled by default.

To set the autonumber preference for sample IDs:

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 Sample ID Assignment, select the **Autonumber Sample ID** checkbox.

The first auto-generated sample ID will be 001. The next one will be 002, and so on.

If you change the sample ID to 100 for the first entry, then the next one will be 101, and so on.

5. Click **OK** to close the Preferences 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™, the default export location is C:\BD Export\Reports\Worklist. 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™ or 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.

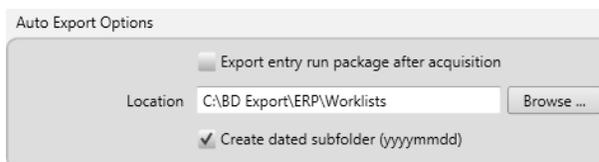
Setting entry run package export preferences

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.

- 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*.

- 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).

The screenshot shows a dialog box titled "Naming Format". It contains four dropdown menus for selecting naming elements: "Worklist Name", "Entry Number", "Sample ID", and "None". Below these is a "Delimiter" dropdown set to "Underscore", and a checked checkbox for "Autonumber starting with" followed by a spinner box set to "1". At the bottom, an example field shows "Worklist Name_001_Sample ID_001.cerp" with the text "Example based on the selected choices" to its left.

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

- 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™ and BD FACSuite™ Clinical applications, the FCS standard is 3.1.

To set FCS export preferences:

- From the menu bar, select **Tools > Preferences**.
- In the Preferences dialog, click the **Worklist** tab.
- In the Worklists tab, select **Export > FCS**.
- 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.
- In the **Location** field, specify the folder where to export the FCS files. Click the **Browse** button to display the Browse for folder dialog.
- 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 *BDEExport\FCS\Worklists* and the checkbox is selected, then the folder location becomes: *BDEExport\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**.

- 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 \(page 208\)](#).

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.

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

Setting worklist printing preferences

To set worklist printing preferences:

- In the Worklists tab, select **Print**.
- 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.
- 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 \(page 114\)](#)
- [Working with the worklist manager audit trail \(page 155\)](#)
- For Loader and mix preferences, refer to the Preferences section in the *BD FACSLyric™ Reference System*.

Specifying assay properties

About assay properties

Assay properties specify results approval, LIS/LIMS options, report print, export, and E-signature options. BD FACSuite™ also allows lot IDs to be assigned to each tube to enable lot-specific compensation. 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 or **User-Defined**.

The BD Assays window displays a list of installed BD assays. The User-Defined Assays window displays a list of User-Defined 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. The User-Defined Assays panel allows tubes to be excluded from an acquisition before running a worklist using the assay. To enable this feature, select the **Allow excluding tubes from acquisition** checkbox.
 - e. 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.
 7. Remove or add any statistics, keywords or expressions for 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. (Optional) Click the **Send to LIS** tab and select from **Keywords & Expressions** and **Statistics**¹.
10. Remove any keywords, expression results, or statistics that you do not want to send to your LIS/LIMS.
11. (Optional for the BD FACSuite™ application) Click the **Assign Lot ID** tab and select specific lots and labels for lot-specific compensation. This is only for tubes with labels assigned. Use the Assign Lot buttons to select a lot for all tubes, or use the individual drop-down menu to select per tube.
12. To save all changes, click **Done**.

More information

- [Creating and opening an experiment \(page 70\)](#)
- [Creating a User-Defined assay from an experiment \(page 94\)](#)
- For more details about editing assay properties, refer to the Library section in the *BD FACSLyric™ Reference System*.
- [Setting worklist preferences \(page 207\)](#)

¹Statistics are only available in the BD FACSuite™ application.

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Periodic Setup and QC

This chapter includes the following topics:

- [Cytometer Setup and QC overview \(page 216\)](#)
- [Importing or adding a CS&T or FC bead lot \(page 217\)](#)
- [QC tracking overview \(page 218\)](#)
- [Setting Levey-Jennings charts preferences \(page 220\)](#)

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 \(page 44\)](#).

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 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. In the BD FACSuite™ application, the task also updates the user-defined 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. In the BD FACSuite™ application, the task also adds the fluorochromes to the user-defined 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 \(page 50\)](#)
- See the *BD FACSLyric™ 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™ 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 220) .

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 <i>BD FACSLyric™ Reference System</i> .
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 <i>BD FACSLyric™ Reference System</i> .

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

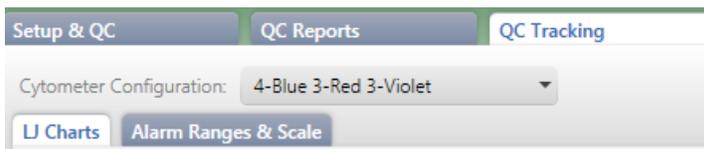
To set data display preferences for LJ reports:

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

The Setup & QC workspace opens.

2. Click the **QC Tracking** tab.

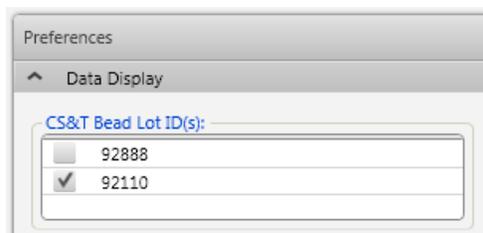
3. In the **Cytometer Configuration** field, select an available cytometer configuration from the list.



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. If high sensitivity fluidics mode is enabled in the **Tools > Preferences** menu, the LJ Charts Preferences panel includes **Fluidics Mode** options. Select between **Normal** and **High Sensitivity**.
8. Under **Filter by Date Range**, select a date filtering preference.
9. Under **Filter By Status**, select a status filtering preference.
10. Under **X-Axis Label**, select a label preference.

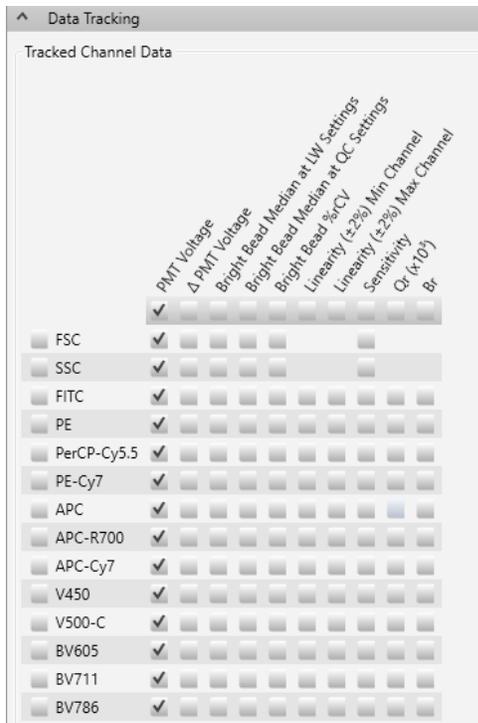
Setting data tracking preferences

To set data tracking preferences for LJ reports:

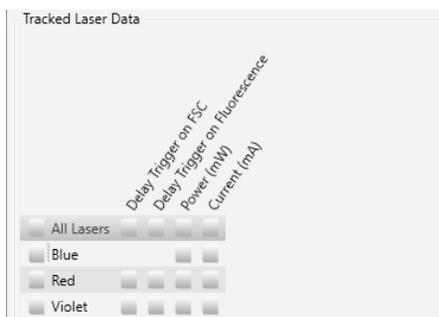
1. On the navigation bar, select **Setup & QC**.

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.

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Maintenance

This chapter includes the following topics:

- [Maintenance overview \(page 224\)](#)
- [Running the daily clean procedure \(page 224\)](#)
- [Refilling the sheath tank \(page 226\)](#)
- [Emptying the waste tank \(page 227\)](#)
- [Performing the monthly clean procedure \(page 229\)](#)
- [Replacing the sheath filters \(page 232\)](#)
- [Managing your database \(page 234\)](#)
- [Archiving procedure for worklists \(page 236\)](#)
- [Archiving procedure for experiments \(BD FACSuite™ application only\) \(page 237\)](#)
- [Performing disk cleanup \(page 238\)](#)
- [Decommissioning the instrument \(page 238\)](#)

Maintenance overview

Daily maintenance

Daily maintenance is part of the shutdown procedure.

Procedure	When
Running the daily clean procedure (page 224)	Daily
Performing manual system shutdown (page 39)	Daily

Unscheduled maintenance

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

Procedure	When
Refilling the sheath tank (page 226)	As needed
Emptying the waste tank (page 227)	As needed

See topics about unscheduled maintenance in the *BD FACSLyric™ 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 229)	Monthly
Replacing the sheath filters (page 232)	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 \(page 225\)](#).
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 \(page 24\)](#)
- [Performing manual system shutdown \(page 39\)](#)

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.

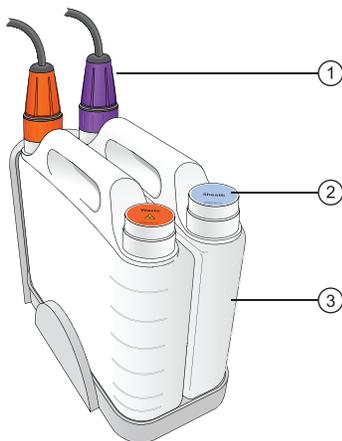
The sheath and waste tanks must be placed at a level even with, or below, the cytometer. Placing the tanks higher than the cytometer can cause uncontrolled siphoning.

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 FACSTow™ 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 \(page 232\)](#)
- [Fluidics components \(page 24\)](#)
- [Emptying the waste tank \(page 227\)](#)

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.

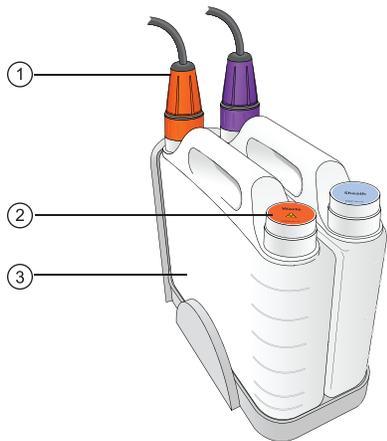
The sheath and waste tanks must be placed at a level even with, or below, the cytometer. Placing the tanks higher than the cytometer can cause uncontrolled siphoning.

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 \(page 24\)](#)
- [Refilling the sheath tank \(page 226\)](#)

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 FACSTFlow™ sheath fluid to fill the sheath tank (5 L or 10 L)

Procedure



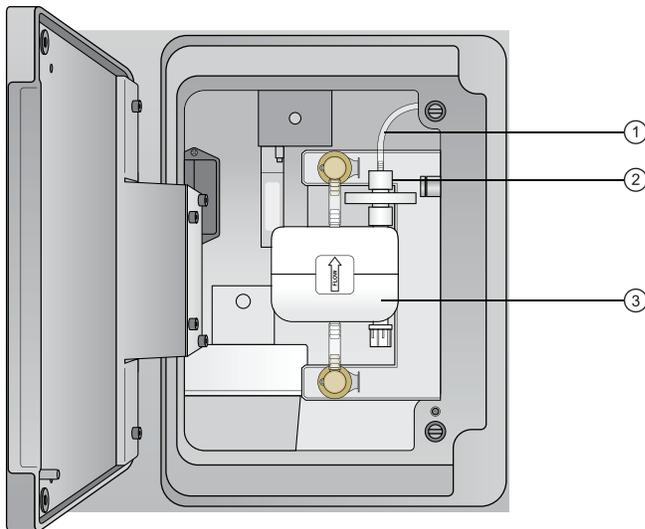
Caution! All biological specimens and materials can transmit potentially fatal infection. To prevent exposure to biohazardous agents, expose waste container contents to bleach of 5% sodium hypochlorite concentration to 10% of total volume before disposal. Dispose of waste in accordance with local regulations. 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.



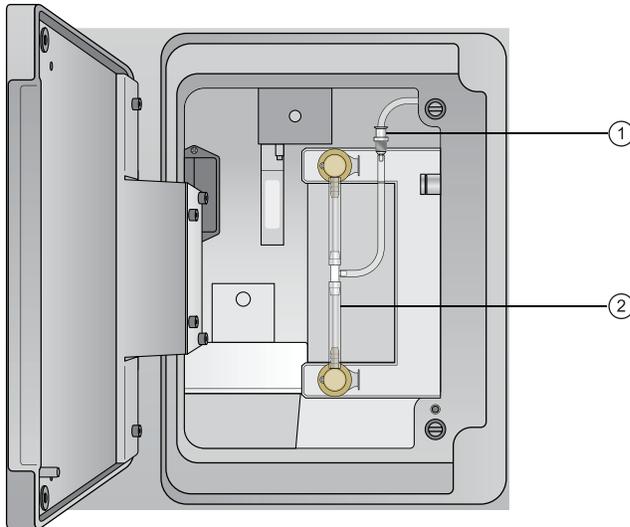
No.	Description
1	Vent line
2	Vent line connector nut
3	Sheath filter

- 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 \(page 24\)](#)
- [Replacing the sheath filters \(page 232\)](#)

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

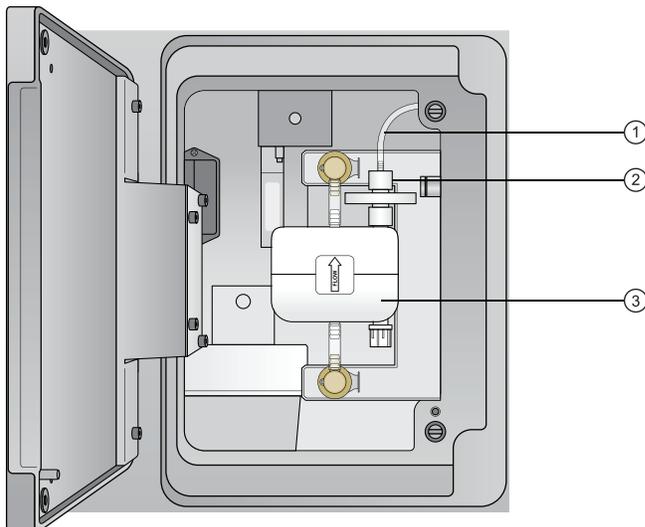
Replacing the sheath filter

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.

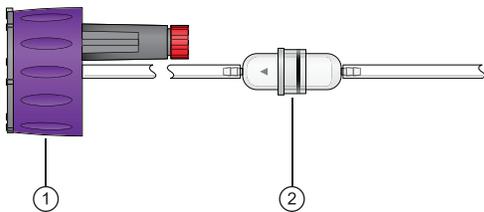
10. Close the door and resume normal operation.
11. Select **Cytometer > Maintenance > Replace Sheath Filter**.
12. Enter the information about the new filter, then click **OK**.

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 \(page 24\)](#)
- [Refilling the sheath tank \(page 226\)](#)

Managing your database

Introduction

This topic describes the tasks involved in managing your database. The BD FACSuite™ Backup and Restore utility allows you to back up and restore your database. Two utilities are provided: the BD FACSuite™ Backup and Restore Utility and the BD FACSuite™ Clinical Backup and Restore Utility.

About the Backup and Restore utility

Use the appropriate Backup and Restore utility to back up or restore all data that is stored in the BD FACSuite™ application database or 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 experiment and 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.

Since the Experiment and Worklist workspaces save FCS files to different locations, these folders are handled separately when the backup is created.

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. Start the **BD FACSuite™ Backup and Restore** or **BD FACSuite™ Clinical Backup and Restore** by clicking the corresponding utility icon on the desktop, depending on which application database you want to back up.
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.

Note: Worklists containing a large number of entries with BD Elastigate™ assay tasks will take significantly more time to back up than other worklists. This is because training data sets are stored in each BD Elastigate™ assay.

5. Click **Finish** to close the window.

Restoring a backup set

To restore a backup set:

1. Click the **BD FACSuite™ Backup and Restore** or **BD FACSuite™ Clinical Backup and Restore** utility icon on the desktop, depending on which application database you want to restore.
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™ Backup and Restore** or **BD FACSuite™ Clinical Backup and Restore** utility icon on the desktop, depending on which application database backup image you want to delete.
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 \(page 224\)](#)
- To create a backup set from the Windows command line, refer to the BD FACSuite™ or 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 BD FACSuite™ and/or BD FACSuite™ Clinical 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\Worklists\Deleted Worklists** or **C:\ProgramData\BD\FACSuite Clinical\Worklists\Deleted Worklists**, according to which application worklist was archived 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.

Archiving procedure for experiments (BD FACSuite™ application only)

Introduction

Experiments 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.

Experiments should be archived to a known location, preferably not on the hard drive of the BD FACSLyric™ workstation.

Procedure

To archive experiments not actively in use:

1. Perform a BD FACSuite™ database backup and export it to a known location, preferably not on the hard drive of the BD FACSLyric™ workstation.
2. Navigate to the **Manage Experiments** workspace.
3. Select the experiments you would like to archive.
4. In the **File** menu, select **Export Experiments > With Data** to export the selected experiments to the desired known location.
5. Confirm that the files were successfully exported.
6. In the **Edit** menu, select **Delete** to delete the selected experiments that have been exported.
7. Exit the BD FACSuite™ application.
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\Experiments\Deleted Tubes** 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 experiments from the archive, use the Import Experiment functionality to import the desired experiment(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™ or 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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BD FACSLyric™ technical specifications

This section includes the following topics:

- [Software and data specifications \(page 240\)](#)
- [Physical specifications \(page 240\)](#)
- [Transportation and storage \(page 241\)](#)

Technical specifications

Software and data specifications

Parameter	Value
Software	BD FACSuite™ and BD FACSuite™ Clinical applications version 1.6
Operating system	Microsoft Windows 10
Data resolution	Uncompensated data has a range of 0 to 262143, which is 18 bits
FCS format	FCS 3.1 for export

Physical specifications

Parameter	Value
Indoor or outdoor use	Indoor use only.
Pollution degree	2—For use in a laboratory environment.
Operating temperature	The cytometer has an operating range between 15 °C (59 °F) and 30 °C (86 °F). We recommend that the lab temperature fluctuate less than 5 °C within a day for best operation.
Humidity	The operating humidity tolerance is between 15% and 85% relative humidity (non-condensing).
Barometric pressure	The operating barometric pressure is at least 0.8 atmosphere. This corresponds to an altitude lower than 2000 m (6,561 feet).
Dimensions (W x D x H)	
Cytometer	63.3 x 57.9 x 57.9 cm (24.93 x 22.8 x 22.8 in.)
Cytometer with standard tanks	85.2 x 57.9 x 57.9 cm (33.5 x 22.8 x 22.8 in.)
Cytometer with standard tanks and Loader	107.2 x 57.9 x 57.9 cm (42.2 x 22.8 x 22.8 in.)
See the <i>BD FACSLyric™ Site Preparation Guide</i> for additional information on dimensions and clearances.	
Weight	Cytometer: 56.02 kg (123.5 lb) Loader: 13.2 kg (29 lb)
Voltage	100–240 ±10% VAC The BD FACSLyric™ system is an IEC (International Electrotechnical Commission) overvoltage category II device.
Frequency	50–60 ±10% Hz

Parameter	Value
Mains outlet current rating	15 A
Power	900 W total: 200 W (cytometer and Loader) + 500 W (workstation) + 200 W (BD-provided monitor).
Heat dissipation	Less than 498 BTU/hour at ambient temperature with the cytometer and Loader running.
Noise	Less than 55 dBA over 8 hours under normal operating conditions with the cytometer and Loader running.

Transportation and storage

This product does not require any special environmental conditions (for example, cold chain) for transport or storage.

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