BD FACSLink™ LIS Interface Solution User's Guide

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Regulatory information

BD FACSCanto, BD FACSCanto II, and BD FACSCalibur are Class 1 Laser Products.

BD FACSCanto, BD FACSCanto II, BD FACSCalibur, BD FACS™ SPA II, and BD FACS SPA III are for In Vitro Diagnostic Use.

History

Revision	Date	Change made
647062 Rev. A	4/2009	New document
23-11040-00 Rev. A	9/2009	Added information to support V1.1 driver.
23-11546-00 Rev. A	5/2010	Added information to support V1.2 driver.
23-13042-00 Rev. 01	3/2011	Added information to support V1.3 driver.
23-14537-00	5/2013	Updated for Windows 7.

Contents

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Introduction to the BD FACSLink LIS Interface Solution

This section includes these topics:

About the BD FACSLink LIS Interface Solution

Introduction

This topic describes the hardware and software that BD FACSLink™ LIS Interface Solution (BD FACSLink) supports and Data Innovations Instrument Manager software compatibility and requirements.

Description

BD FACSLink is a software application that uses Data Innovations Instrument Manager software and the BD FACSLink driver to read BD Multiset™, BD™ HLA-B27, BD FACSCanto™ clinical, and BD FACSDiva™ software result files into ASTM and HL7 formats, and to transfer the results data to laboratory information systems (LIS).

Worklists in Data Innovations Instrument Manager are compatible with the following BD products:

- BD FACSCanto clinical software, version 2.2 and later
- BD FACSDiva software, version 6.x and later
- BD FACSCalibur™ instrument
- BD FACS™ Sample Prep Assistant II (SPA II) instrument and software
- BD FACS™ Sample Prep Assistant III (SPA III) instrument and software

BD FACSLink allows the lab manager to review and designate which test results are released to the LIS. BD FACSLink provides a readable audit trail file for traceability between the original files and the transferred results files.

Instrument Manager compatibility

BD FACSLink has the same system and compatibility requirements as Data Innovations Instrument Manager software.

See the Data Innovations Instrument Manager *Help* for a specific list of system requirements and compatibilities.

Requirements

Data Innovations Instrument Manager software must be installed on a dedicated network server and networked to BD workstations.

- The BD workstation EXP and CSV results directories must be accessible on the network and have read/write permissions.
- The network administrator should indicate the base result location by using UNC paths, not Windows® drive letter mapping (for example, C drive).
- Store all exported BD FACSLink worklist files in a network shared folder accessible by the BD workstation.

Full operation of BD FACSLink requires installation of the BD FACSLink driver and the BD Global Configuration File (GCF). If the GCF is not installed, the BD FACSLink customized user interface will not be configured.

Documentation

Introduction

This topic describes the information that is available in this guide and provides information on additional resources for using BD FACSLink.

In this guide

This guide provides instructions for getting started with BD FACSLink. It does not include information about installing the software on a network server, configuring the server or instrument, or operating extended features of Data Innovations Instrument Manager.

Related publications

For detailed user information, see the Data Innovations Instrument Manager documentation included on the software CD, or Data Innovations Instrument Manager *Help*.

Several quick reference guides are available to provide information on the setup workflows necessary for BD FACSLink to access and transfer files created in BD FACSDiva software and BD FACSCanto clinical software. For information on BD FACSLink workflows when using BD panels with BD FACSCanto clinical software (with or without SPA II or SPA III) and using custom panels with BD FACSDiva software (with or without SPA II or SPA III), see the following quick reference guides:

- *Quick Reference Guide for Setting Up Custom Panels Used with the BD FACSLink LIS Interface*
- *Quick Reference Guide for Using Custom Panels with BD FACS SPA and BD FACSDiva Software and the BD FACSLink LIS Interface*
- *Quick Reference Guide for Using Custom Panels with BD FACSDiva Software and the BD FACSLink LIS Interface*
- *Quick Reference Guide for Using BD Panels with BD FACS SPA and BD FACSCanto Clinical Software and the BD FACSLink LIS Interface*
- *Quick Reference Guide for Using BD Panels with BD FACSCanto Clinical Software and the BD FACSLink LIS Interface*

The quick reference guides can be found on the License and Drivers CD and on our website at bdbiosciences.com/resources.

Limitations

Introduction

This topic describes the product limitations.

Limitations

BD Biosciences delivers software and workstations that are intended for running the instruments supplied by BD Biosciences. It is the responsibility of the buyer/user to ensure that all added electronic files including software and transport media are virus-free. If the workstation is used for Internet access or purposes other than those specified by BD Biosciences, it is the buyer/user's responsibility to install and maintain up-to-date virus protection software. BD Biosciences does not make any warranty with respect to the workstation remaining virus-free after installation. BD Biosciences is not liable for any claims related to or resulting from the buyer/user's failure to install and maintain virus protection.

BD Biosciences is not responsible for the development, validation, or support of features or functions of Data Innovations Instrument Manager software, other than the BD FACSLink driver option.

Technical support

Introduction

This topic describes how to obtain assistance from BD Biosciences technical support.

Contacting technical support

If assistance is required, contact your local BD Biosciences technical support representative or supplier. Visit our website at bdbiosciences.com for up-to-date information. For system support from within the US, call 877.232.8995.

When contacting BD Biosciences, have the following information available:

- Product name, part number, and license number
- Any error messages
- Details of recent system performance

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Using BD FACSLink

This section includes these topics:

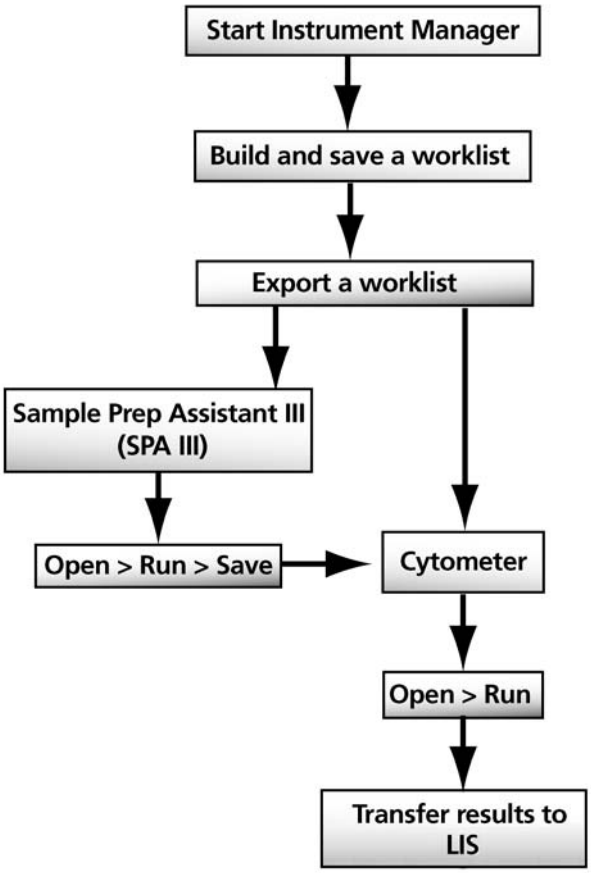
BD FACSLink workflow

Introduction

This topic shows a typical BD FACSLink workflow.

Typical workflow

Your facility's standard operating procedure might require a different workflow. This information is provided as an example.



Workflow overview

The following table lists the tasks that need to be performed each time you transfer files to the LIS using BD FACSLink.

Stage	Procedure
1	Starting Instrument Manager (page 11)
2	Opening the BD FACSLink window (page 12)
3	Building a worklist (page 16)
4	Exporting a worklist (page 21)
5	Transferring results to the LIS (page 22)

Starting Instrument Manager

Introduction

This topic describes how to start and log on to Data Innovations Instrument Manager.

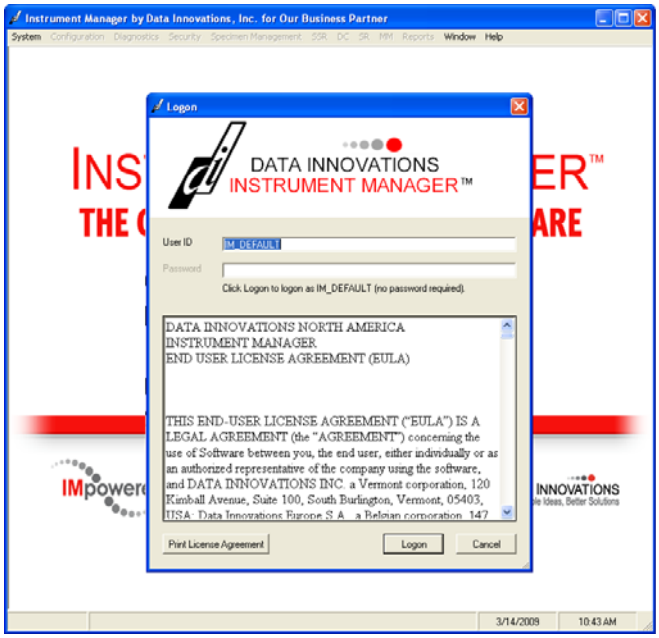
Starting and logging on

Note: Depending on how your system is configured, an administrator may be required to log on.

To start Instrument Manager and log on:

1. Double-click the **Instrument Manager** icon on the desktop.

   The Instrument Manager window and the Logon dialog open.



2. In the **User ID** field, type a user ID.
3. In the **Password** field, type a password.

   If this field is disabled (gray), no password is required. The IM_ADMIN user account does not require a password.

4. Click **Logon**.

   The Status Display window opens.

5. If the **Status Display** window does not open, reopen the **Status** dialog by selecting **System > Status** in the **Instrument Manager** window.

Logging off

To log off Instrument Manger:

1. In the main **Instrument Manager** window, select **System > Logoff**.

   A confirmation dialog opens.

2. Click **Yes** to log off.

Opening the BD FACSLink window

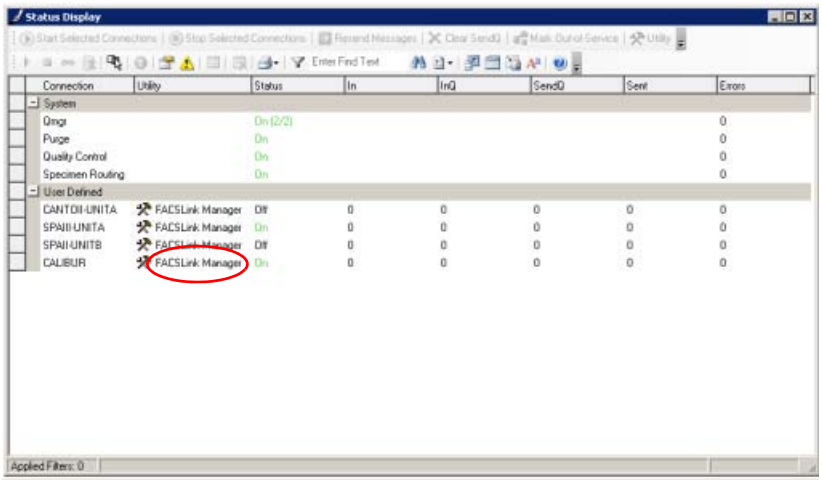
Introduction

This topic describes the BD FACSLink window and how to open it.

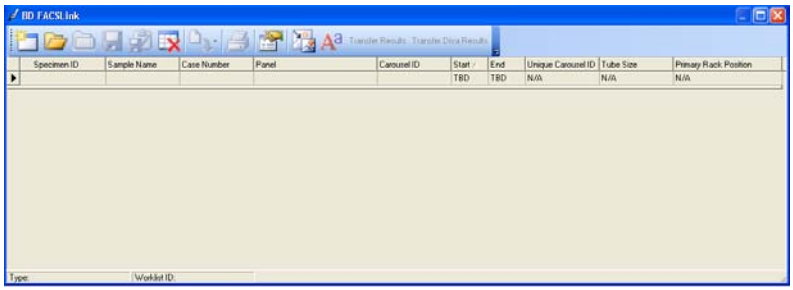
Procedure

To open the BD FACSLink window:

1. In the **Status Display** dialog, click **FACSLink Manager** for the appropriate instrument in the **Utility** column.



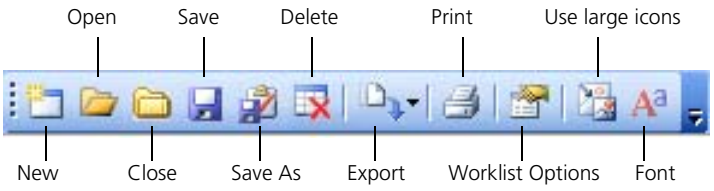
The BD FACSLink window opens.



You need to open an existing worklist, or create a new one.

BD FACSLink toolbar

The following figure describes the tools on the BD FACSLink toolbar.



Use the toolbar to perform the following functions.

Tool	Function
New	Selects an instrument type and creates a new, blank worklist file.
Open	Opens an existing worklist file.
Close	Closes the open worklist without saving.
Save	Saves the current worklist with a default name.
Save As	Saves the current worklist with a different name.
Delete	Deletes a worklist.
Export	Exports the current worklist to a connection or an instrument. Exported worklists are saved with the date and time stamp.
Print	Prints the current worklist.
Worklist Options	Use to import BD FACSDiva custom panels and to configure control samples for the worklist.
Use large icons	Makes the toolbar icons larger.
Font	Use to modify the font in the worklist.

Opening and closing worklists

Introduction

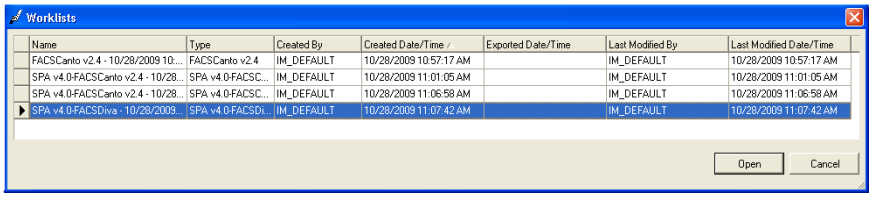
This topic describes how to open and close worklists using the BD FACSLink window.

Opening a worklist

To open an existing worklist:

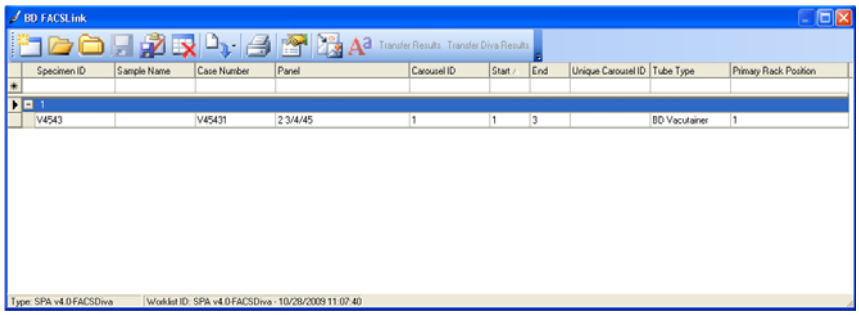
1. In the **BD FACSLink** window, click **Open** on the toolbar.

The Worklists dialog opens.



2. Select a worklist from the list, then click **Open**.

The worklist opens.



Closing a worklist

To close an open worklist:

1. In the **BD FACSLink** window, click **Close** on the toolbar.

The worklist closes.

More information

- About worklist data columns (page 14)
- Building a worklist (page 16)
- Exporting a worklist (page 21)

About worklist data columns

Introduction

This topic describes the data column contents and provides guidelines for data columns and specific worklist types.

Data columns

The following tables describes the contents of the data columns in the worklist.

Value	Description
Specimen ID	Enter an ID or scan an ID with a barcode reader.
Sample Name	Patient name. This data column is populated by the LIS. You can view or edit a patient name associated with the current specimen ID. If the specimen ID is configured as a QC specimen in BD FACSLink, the QC specimen name will be added to the worklist. See Defining control samples (page 17).
Case Number	This is a case number based on the specimen ID plus an incremental number. This data column is populated by the LIS. You can enter a case number or allow the software to automatically assign it.

Value	Description
Panel	Select a single panel. If multiple panels are required, you can select them using the Panel Selection dialog. If the specimen ID is configured as a QC specimen in BD FACSLink, the QC panel will be added to the worklist. See Defining control samples (page 17). SPA connections might only have a single panel ordered for a specific specimen ID in a single worklist.
Carousel ID	Enter a value after entering the first specimen ID of a new worklist. If the current carousel is full, enter a new carousel ID. You can build multiple carousels at the same time using different carousel IDs.
Start	The first tube position for a selected panel.
End	The last tube position for a selected panel.
Unique Carousel ID	(SPA worklists only.) Enter a unique ID to be used with the worklist. If your unique ID contains special characters, they are not included in the file name of your exported worklist.
Tube Size	(SPA v3.0 worklists only.) Select a tube size.
Tube Type	(SPA v4.0 or later worklists.) Select a tube type.
Primary Rack Position	(SPA worklists only.) Enter the primary rack position.

Data column guidelines

- The same specimen ID, sample name, and case number cannot be present in one carousel for SPA III or BD FACSCalibur worklists.
- SPA III worklist uniqueness is defined by the combination of the following columns: Unique Carousel ID, Carousel ID, Sample ID, Sample Name, and Case Number. This allows the same sample ID to be added with different tests in two different carousels in one worklist.
- The same specimen ID, sample name, and case number cannot be present in a BD FACSCanto worklist.
- Two rows with the same specimen ID cannot be present in one carousel for a SPA II worklist.
- If more than one panel is added from the same specimen ID, the previously selected panel is highlighted (yellow) in the Panel Selection dialog.
- A control sample needs to be defined in BD FACSLink before it can be used in a worklist. See Defining control samples (page 17) for information.

Building a worklist

Introduction

This topic describes worklist types and how to select a worklist type and build a worklist with BD pre-defined panels. This topic also describes how to save a worklist.

Before you begin

The BD FACSLink driver and Data Innovations Instrument Manager are designed to allow data input using a barcode scanner. Information that is linked to a barcode should populate data entry columns when you scan a barcode.

Some barcode scanners' default settings require you to scan, then press the >, Enter, or Tab keys to populate the data columns. See your barcode scanner documentation for information about configuring your scanner to automatically populate the data immediately after a scan.

Instrument worklist types

You can only select an instrument worklist type that supports the specific instrument connection. For example, BD FACSCanto clinical software v2.2 worklists require an established BD FACSCanto v2.2 connection.

Worklist types include the following:

- FACSCalibur (BD™ Worklist Manager software v5.2.1 and 6.0.2)
- FACSCanto v2.2
- FACSCanto (BD FACSCanto clinical software 2.4 and later)
- SPA v3.0.1-FACSCalibur
- SPA-FACSCalibur (SPA software v4.0 and later)
- SPA-FACSCanto v2.2 (SPA software v4.0 and later)
- SPA v3.0.1-FACSCanto (BD FACSCanto clinical software v2.4 and later)
- SPA v3.0.1-FACSCanto v2.2
- SPA-FACSCanto (SPA software v4.0 and later)
- FACSDiva (BD FACSDiva software v6.0 and later)
- SPA v3.0.1-FACSDiva
- SPA-FACSDiva (SPA software v4.0 and later)

Worklist restrictions

- **SPA-BD FACSDiva and BD FACSDiva.** You can only bring one carousel into a BD FACSDiva experiment when using SPA-FACSDiva worklist types.
- **SPA 3.0.1-BD FACSDiva.** You can only specify one panel for each sample ID.
- **BD FACSDiva worklist.** You can have multiple instances of the same sample ID, but the combination of the sample ID and panel must be unique.

Defining control samples

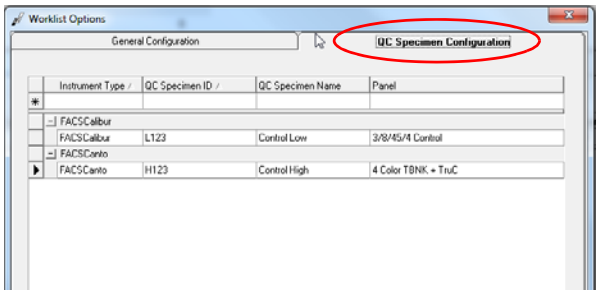
Enter control information for each control lot. When building a worklist, when you enter or scan a specimen ID with no pending orders, BD FACSLink checks the configured QC specimen IDs for a match and automatically populates the worklist for the associated QC specimen ID and panel.

To define control samples:

1. Click **Worklist Options** on the toolbar.

The Worklist Options dialog opens.

2. Click the **QC Specimen Configuration** tab.



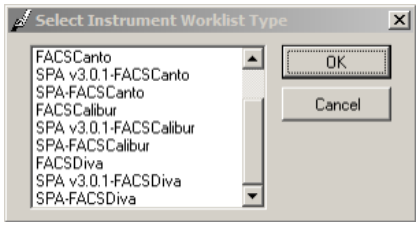
3. Enter the following information to define the QC specimen. All fields are required.
   - Select the instrument from the **Instrument Type** menu.
   - Enter the QC specimen ID.
   - Enter the QC specimen name.
   - Select the panel (available once an instrument is selected).
4. Click **OK**.

Selecting an instrument worklist type

To select an instrument worklist type:

1. In the **BD FACSLink** window, click **New** on the toolbar.

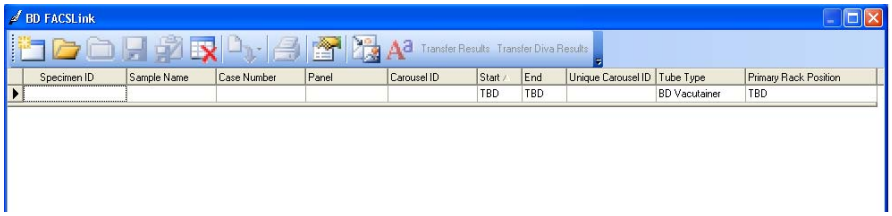
The Select Instrument Worklist Type dialog opens.



The list of worklist types and version that appears is based on the currently established instrument connections. Only instrument worklist types that support the specific instrument connection appear in this list.

2. Select the instrument worklist type and version in the list, then click **OK**.

   A new worklist opens.

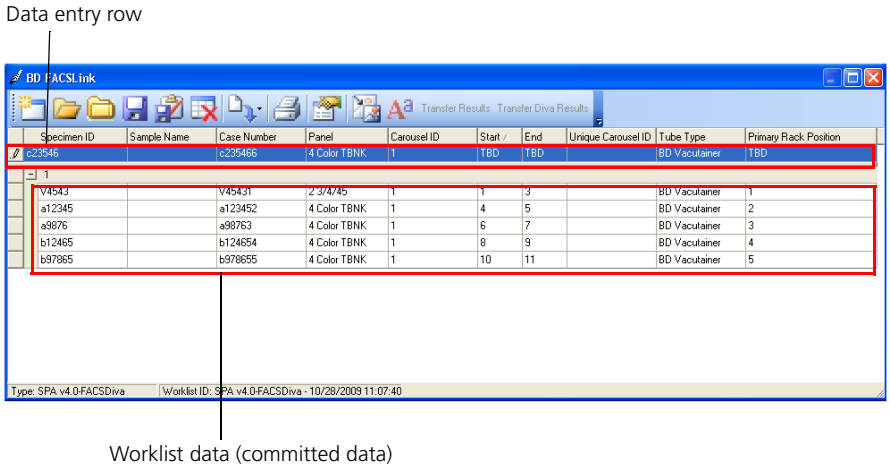


Adding data into data columns

To add data into data columns:

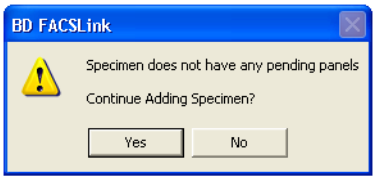
1. Manually enter the specimen ID into the **Specimen ID** data column in the data entry row, or scan the specimen ID to populate the data columns with data from the LIS.

   Always enter your specimen ID in the data column before you enter data in any other data column.



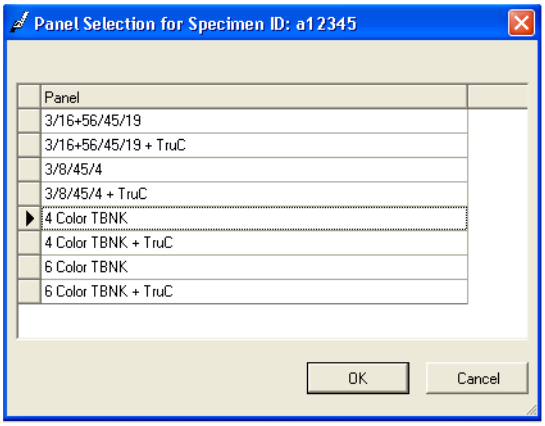
   See About worklist data columns (page 14) for details about each data column.

   After you enter the specimen ID, the following dialog opens if there is no existing information or work request for this specimen ID in the LIS, or if the specimen ID is not a pre-defined QC sample is FACSLink.



2. Click **Yes** to continue adding the specimen.

   - If the specimen has pending panels associated with it, the panel data populates the Panel column. Continue with step 5.
   - If a specimen does not have any pending panels associated with it, the Panel Selection for Specimen ID dialog opens.



3. Select a panel from the list.

   You cannot include BD pre-defined panels with user-defined panels in a SPA worklist.

4. Click **OK**.

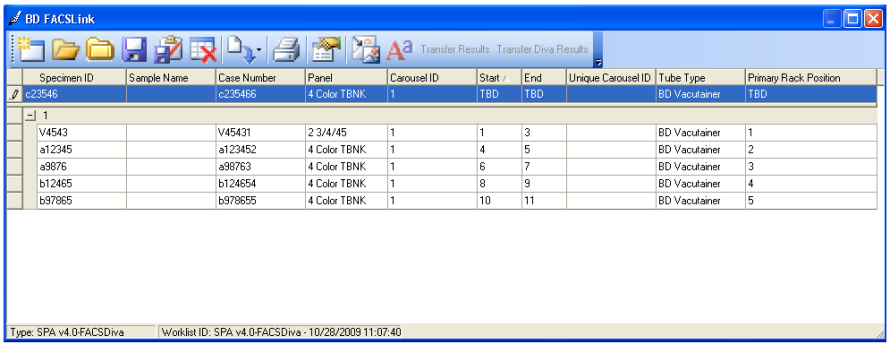
5. Add or modify data in the other data columns as appropriate, or delete single rows of data.

   To delete a row of data from the data entry row, select the row, then press Delete on the keyboard. The row is deleted.

6. If you require a custom data criterion as the case number in this worklist, see Exporting a worklist (page 21) for more information.

7. Press Enter in a data column in the data entry row to commit the data to the worklist.

   The data is committed and the worklist row appears.

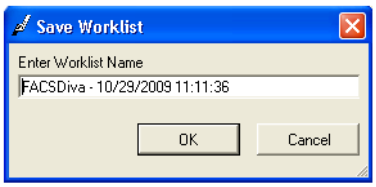


Saving a worklist

To save a worklist:

1. Click **Save** on the toolbar to save the new worklist.

The Save Worklist dialog opens. The worklist name is automatically generated.



2. (Optional) Enter a new name in the **Enter Worklist Name** field.
3. Click **OK** to save the worklist.

Deleting a worklist

To delete an entire worklist:

1. Click the **Delete** tool on the toolbar.

The Worklists dialog opens.

2. In the list of worklists, select the worklist you want to delete.
3. Click **Delete**.

   The worklist is deleted.

More information

- About worklist data columns (page 14)
- Exporting a worklist (page 21)

Exporting a worklist

Introduction

This topic describes how to export a worklist.

Requirement

Store all exported BD FACSLink worklist files in a network shared folder accessible by the BD workstation.

Exported worklist size for each connection

Worklists for SPA II, SPA III, and BD FACSCalibur connections can include only one carousel. BD FACSCanto worklists can hold up to 200 samples or five carousels. For BD FACSDiva worklists, you can export only one carousel at a time.

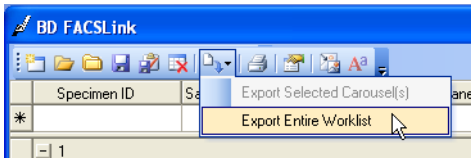
If the BD FACSLink worklist includes more carousels than the BD workstation worklist can contain, the worklist is split into multiple worklists when exported. For example, a worklist that contains two carousels in BD FACSLink splits into two worklists when exported for a BD FACSCalibur connection.

Procedure

To export a worklist:

1. In the **BD FACSLink** window, click **Export** on the toolbar.

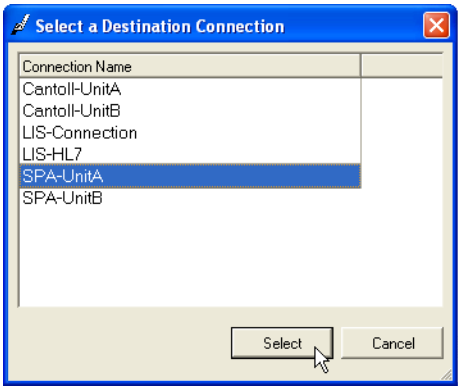
2. Select **Export Entire Worklist** from the menu.



   The **Select a Destination Connection** dialog opens.

3. In the **Connection Name** list, select a connection and click **Select**.

   The worklist is exported and a dialog opens indicating that the worklist is queued for export.



4. Click **OK** to close the dialog.

More information

- Opening and closing worklists (page 13)
- Building a worklist (page 16)

Transferring results to the LIS

Introduction

This topic describes how to transfer results to the LIS.

Before you begin

If you are using:

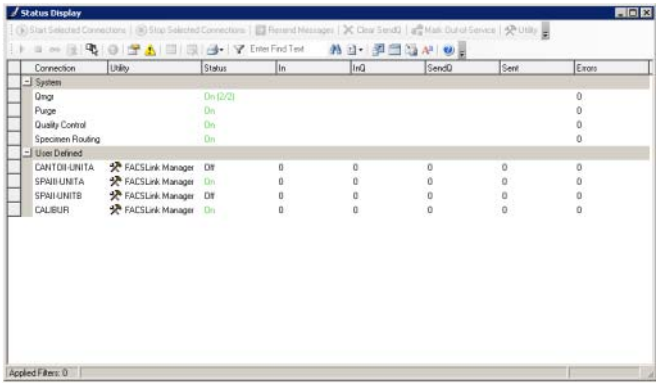
- BD FACSCanto clinical software, review the laboratory reports.
- BD FACSDiva software, perform batch analysis.

Procedure

To transfer results to the LIS:

1. Double-click the **Instrument Manager** icon on the desktop.
2. Enter your user ID and password, and click **Logon**.

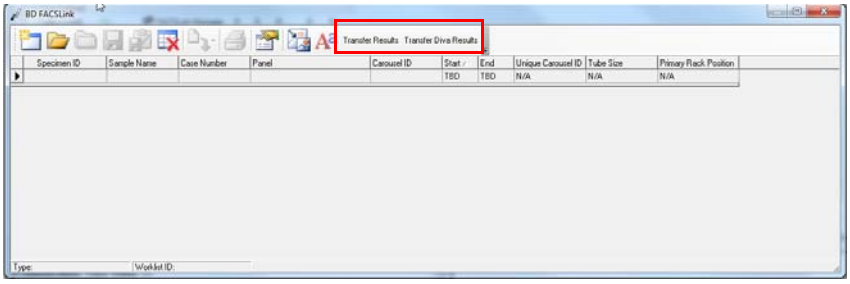
   The Status Display dialog opens.



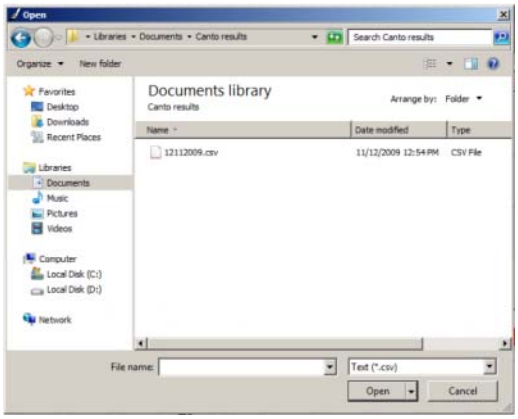
3. Click the appropriate instrument in the **Connection** column.
4. Click **FACSLink Manager** for the selected instrument in the **Utility** column.

   The BD FACSLink window opens.
5. Click the appropriate transfer option on the toolbar:
   - To transfer BD FACSDiva results, click **Transfer Diva Results**.

- To transfer all other results, click **Transfer Results**.



Windows Explorer opens displaying the results files.



6. Select the file to transfer and click **Open**.

   The results transfer and a dialog opens confirming the transfer.

7. Click **OK** to close the dialog.

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3

Troubleshooting

This section includes this topic:

Software issues

Introduction

This topic describes possible software problems and how to correct them.

Error messages

The following table lists possible software errors and solutions.

Error message	Problem description	Possible solution
Unable to open file:<value>	A file to be read cannot be opened.	Make sure that the file exists on the server in the instrument folder.
File not selected to be processed.	The Load Result button was clicked and a worklist has not been selected to be processed.	Select a worklist, then click **Load Result** again.
File selected does not have <value> file type	The Load Result button was clicked and a file with an incorrect extension was selected to be processed.	Select an appropriate worklist, then click **Load Result** again.
Thin client license exceeded	All available thin client licenses are open.	Close another instance, or wait for another licensed user to close their thin client.
Barcode scanner error	The barcode scanner does not scan the barcode.	Make sure that the Caps Lock, Shift, and Control keys are off on the keyboard.