BIOMÉRIEUX

BIOFIRE® SPOTFIRE®
Connectivity User Guide

PIONEERING DIAGNOSTICS

TABLE OF CONTENTS

1. Introduction 5
   - 1.1 Purpose of the Document 5
   - 1.2 Reference Documents 5
2. System & Software Overview 6
   - 2.1 System Description 6
   - 2.2 Software Description 6
   - 2.3 Supported Functionality by Interface Type 6
3. Point of Care Testing (POCT01-A2) Interface 8
   - 3.1 Interface Description 8
     - 3.1.1 Messaging Format 8
     - 3.1.2 Data Transfer 8
   - 3.2 Configuring the POCT01-A2 Interface 8
     - 3.2.1 Initial Preparation 9
     - 3.2.2 POCT01-A2 Interface Configuration Requirements 9
     - 3.2.3 Validate POCT01-A2 Interface 11
   - 3.3 POCT Operator Management Settings 12
     - 3.3.1 View Point-of-Care Operator Lists 16
     - 3.3.2 Login Management Settings for Point-of-Care Operators 17
   - 3.4 Remote Management of SPOTFIRE Settings 18
     - 3.4.1 Updates to System Date and Time 19
4. XML Interface 20
   - 4.1 Interface Description 20
   - 4.2 Messaging Format 20
   - 4.3 Configuring an XML Interface 20
     - 4.3.1 Initial Preparation 20
     - 4.3.2 XML Interface Configuration Requirements 21
     - 4.3.3 Validate XML Interface 24
5. HL7 Interface 25
   - 5.1 Interface Overview 25
   - 5.2 Messaging Format 25
   - 5.3 Data Transfer 25
     - 5.3.1 Unidirectional Communication Mode 25
     - 5.3.2 Bidirectional Communication Mode 26
   - 5.4 Test Order Review 26
   - 5.5 Configuring the HL7 Interface 29
     - 5.5.1 Initial Preparation 29

5.5.2 HL7 Interface Configuration Requirements 30
5.5.3 Validate HL7 Interface 32
6. Using the SPOTFIRE Connectivity Software 33
6.1 View Interface Status 33
6.2 Managing the Interface Configuration 34
6.2.1 Export Interface Configuration 35
6.2.2 Import Interface Configuration 35
6.2.3 Clearing Interface Configuration 37
6.3 Transmitting Test Results 39
6.3.1 Transmit from Patient Test Results 40
6.3.2 Transmit from Test Report 42
6.3.3 View Transmission Status from Audit Log 44
6.4 Configure Result Processing Settings 46
6.4.1 Automatic Result Processing 47
6.4.2 Send Start Test Notifications 48
6.4.3 Send Failed Results 49
6.4.4 Send Control Melt Temperatures (T_m) 50
6.5 Diagnostics 51
6.6 System Notifications 53
7. Troubleshooting 55
7.1 General Troubleshooting 55
7.2 POCT01-A2 Interface 56
7.3 XML Interface Configuration 57
7.4 HL7 Interface Configuration 59
7.5 Data Bundles 60
8. Technical Support Contact Information 61

Document Revision History

Document Number	Revision Description	Associated SPOTFIRE Software Version(s)	Release Date
BFR0001-6608-01	Initial release of the document.	BIOFIRE® SPOTFIRE® Software v4.0.2.0	2023-04-27
BFR0001-6608-02	Updated for the SPOTFIRE System Software 2023 release.	BIOFIRE® SPOTFIRE® Software v4.1.0.0	2024-03-07
BFR0001-6608-03	Updated for the SPOTFIRE System Software 2024 release.	BIOFIRE® SPOTFIRE® Software v4.2.0.0	06/2024

1. Introduction

1.1 Purpose of the Document

The purpose of this document is to provide information about how to interface a BIOFIRE® SPOTFIRE® System with a Data Manager (e.g., Observation Reviewer, Laboratory Information System, or middleware) using the BIOFIRE® SPOTFIRE® Connectivity Software.

The following information is covered in this document:

- Overview of the SPOTFIRE System and software
- Description of the Point-of-Care Testing (POCT01-A2) interface
- Description of the XML and HL7 interfaces used for LIS connectivity
- Instructions for interfacing a SPOTFIRE System with a Data Manager
- Instructions for using the SPOTFIRE Connectivity Software
- Instructions for troubleshooting the SPOTFIRE Connectivity Software and interfaces

Note: The BIOFIRE SPOTFIRE System will be referred to as SPOTFIRE throughout this document.

1.2 Reference Documents

The following documents are referenced in this user guide. To obtain copies of them, contact bioMérieux Technical Support. Refer to the contact information in section 8.

- BFR0001-5795: *BIOFIRE® SPOTFIRE® POCT01-A2 Interface Driver Development Guide*
- BFR0002-*3721: BIOFIRE SPOTFIRE XML Interface Driver Development Guide*
- BFR0002-*3956: BIOFIRE SPOTFIRE HL7 Interface Driver Development Guide*
- BFR0001-9777: *SPOTFIRE® Connectivity Mapping Guide*
- BFR0001-1641: *BIOFIRE® SPOTFIRE® System Operator's Manual*

2. System & Software Overview

2.1 System Description

The BIOFIRE® SPOTFIRE® System is an automated in vitro diagnostic (IVD) device intended for use with FDA-cleared or approved IVD BIOFIRE® SPOTFIRE® Panels. SPOTFIRE is intended for use in combination with assay-specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. SPOTFIRE interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR (nmPCR) in a closed system. The resulting PCR products are evaluated using assay-specific DNA melting analysis. The SPOTFIRE System automatically determines the results and provides a test report. SPOTFIRE integrates sample preparation, nucleic acid amplification, detection, and data analysis into one platform, and is designed to process samples and deliver results in about 25 minutes.

The SPOTFIRE System is composed of one to four SPOTFIRE Modules connected to one SPOTFIRE Control Station running the SPOTFIRE Software. The first Module is placed on top of the Control Station, and subsequent modules are added as desired (up to four). Each SPOTFIRE Module can be randomly and independently accessed to run a reagent pouch.

Refer to BFR0001-1641: *BIOFIRE® SPOTFIRE® System Operator's Manual* for more information about the system.

2.2 Software Description

The SPOTFIRE System is controlled by Windows®-based software running on the SPOTFIRE Control Station. The software provides workflow guidance allowing an operator to perform a molecular diagnostic test on any of the connected Modules, then display the test result data to operators utilizing an integrated computer with touch screen. The software is also used to manage operators, system configurations, customer QC processes, and connected devices (e.g., printers).

The software also provides the SPOTFIRE System with the ability to connect with a Data Manager using one of the following interfacing options:

1. **POCT01-A2 Interface**: A bidirectional transfer of XML-formatted data from the SPOTFIRE System to a Data Manager based on the CLSI POCT01-A2 standard.
2. **XML Interface**: A unidirectional XML file transfer or transfer of structured text from the SPOTFIRE System to a Data Manager.
3. **HL7 Interface**: A unidirectional or bidirectional transfer of structured data from the SPOTFIRE System to a Data Manager using Health Level 7 (HL7) v2.5.1 based on the CLSI AUTO16 standard.

IMPORTANT: The software can only be configured to use one of these interfacing options at a time. The SPOTFIRE Control Station must be connected to a network to support data transfer to and from the Data Manager. The Data Manager must be also accessible from the same network as the SPOTFIRE.

2.3 Supported Functionality by Interface Type

The table below identifies key functionality supported by each of the three interfacing options in SPOTFIRE:

Functionality	POCT01-A2 Interface (TCP/IP POCT01-A2)	XML Interface (HTTP Client, FTP Server, Local Folder, LIS Shared Folder, Network Shared Folder)	HL7 Interface (MLLP)
Electronic reporting of patient test results (section 6.3)	✓	✓	✓
Electronic reporting of QC test results (section 6.3)	✓	✗	✗
Test Order Review (section 5.4)	✗	✗	✓
Start Test Notifications (section 6.4.2)	✗	✓	✓
Remote management of device operators (section 3.3)	✓	✗	✗
Remote management of device settings (section 3.4)	✓	✗	✗
Automatic Result Processing (section 6.4.1)	✓	✓	✓
Send Failed Results (section 6.4.3)	✓	✓	✓
Send Control Tm (section 6.4.4)	✓	✓	✓

3. Point of Care Testing (POCT01-A2) Interface

The purpose of this section is to describe the POCT01-A2 interface and provide detailed configuration instructions.

3.1 Interface Description

The POCT01-A2 protocol defines a set of conversations, topics, and messages that can be electronically exchanged between one or more SPOTFIRE devices and a centralized Point-of-Care Data Manager server.

Major functions supported by the POCT01-A2 protocol include:

- Electronic reporting of patient and QC test results
- Electronic reporting of SPOTFIRE device events
- Remote management of SPOTFIRE device operators
- Remote management of SPOTFIRE device settings

Refer to BFR0001-5795: *BIOFIRE® SPOTFIRE® POCT01-A2 Interface Driver Development Guide* for more information about the POCT01-A2 and specific conversation workflows.

3.1.1 Messaging Format

Messages exchanged between the SPOTFIRE Connectivity Software and the Data Manager are formatted according to the CLSI POCT01-A2 standard, referenced below:

- Clinical and Laboratory Standards Institute. Point-of-Care Connectivity; Approved Standard – Second Edition. CLSI document POCT1-A2 [ISBN 1-56238-616-6]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006.

Different messages are used to support each of the different use cases supported by the POCT01-A2 interface.

For a complete list of messages that can be sent from or received by SPOTFIRE via the POCT01-A2 interface, or for information about how each of the different messages are structured and formatted, refer to BFR0001-5795 *BIOFIRE® SPOTFIRE® POCT01-A2 Interface Driver Development Guide*.

3.1.2 Data Transfer

Data transfer via the POCT01-A2 interface is performed using a Transmission Control Protocol (TCP/IP) connection between the SPOTFIRE (client) and Data Manager (server). Once established, the TCP connection is persistent and will remain active until terminated by SPOTFIRE or the Data Manager (e.g., due to a system restart or similar downtime event).

Refer to BFR0001-5795: *BIOFIRE® SPOTFIRE® POCT01-A2 Interface Driver Development Guide* for more information about how the software uses TCP/IP to transfer data.

3.2 Configuring the POCT01-A2 Interface

This section describes the process of setting up the POCT01-A2 interface between a SPOTFIRE and a Data Manager. The process consists of three general steps:

1. Initial preparation between SPOTFIRE and your institution's Data Manager.

2. Configure the POCT01-A2 interface.
3. Validate the interface from the Data Manager server.

Each of these steps is detailed in the subsections that follow and should be performed in order.

3.2.1 Initial Preparation

Perform the steps listed below before attempting to configure the POCT01-A2 interface in SPOTFIRE.

1. Verify that the Point-of-Care Data Manager you wish to interface with offers a SPOTFIRE-compatible POCT01-A2 device driver.

   Note: If your Data Manager does not offer a SPOTFIRE-compatible driver, bioMérieux support may provide additional assistance to the Point-of-Care vendor for the development of a driver.

2. Determine your institution's local networking and security requirements. Your institution may require a cybersecurity questionnaire or security review to be completed prior to connecting the SPOTFIRE to your local network. Additionally, IT personnel may be required to ensure network firewalls will permit TCP/IP traffic between the SPOTFIRE System and the Data Manager.
3. Connect the SPOTFIRE to the local network. For more information, refer to BFR0001-1641: *BIOFIRE® SPOTFIRE® System Operator's Manual.*
4. Install and configure the SPOTFIRE device driver on the Data Manager server. The device driver must be configured and available from the same hostname/IP address and port number used to configure the POCT01-A2 interface in SPOTFIRE. Contact your Point-of-Care vendor representative for assistance.

Once the above steps are complete, proceed to the next section.

3.2.2 POCT01-A2 Interface Configuration Requirements

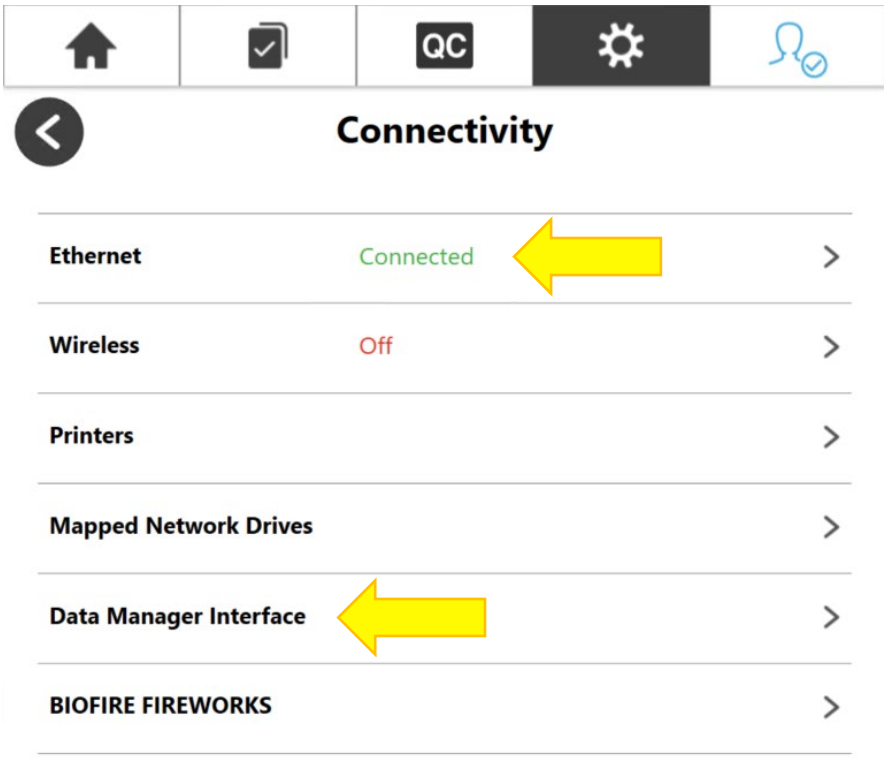
The SPOTFIRE Connectivity Software provides two ways to configure the POCT01-A2 interface:

1. Manually creating a new configuration.
2. Loading the configuration settings via file import (using a previously exported configuration file).

The steps included in this section describe how to create a new configuration. Refer to the instructions in section 6.2.2 to configure via file import.

Complete the following steps to configure the POCT01-A2 interface in SPOTFIRE:

1. Log into SPOTFIRE as an Administrator operator.
2. From the SPOTFIRE toolbar, select the **Settings** tab.
3. Select the **Connectivity** option from the Settings menu.
4. Ensure the SPOTFIRE is connected to the local network.



Either the **Ethernet** or **Wireless** options in the Connectivity menu should display "Connected". Refer to BFR0001-1641: *BIOFIRE® SPOTFIRE® System Operator's Manual* for information on connecting the SPOTFIRE to your institution's local network.

5. Select the **Data Manager Interface** option from the Connectivity menu.

   IMPORTANT: The **Data Manager Interface** option is only available to Administrator operators.

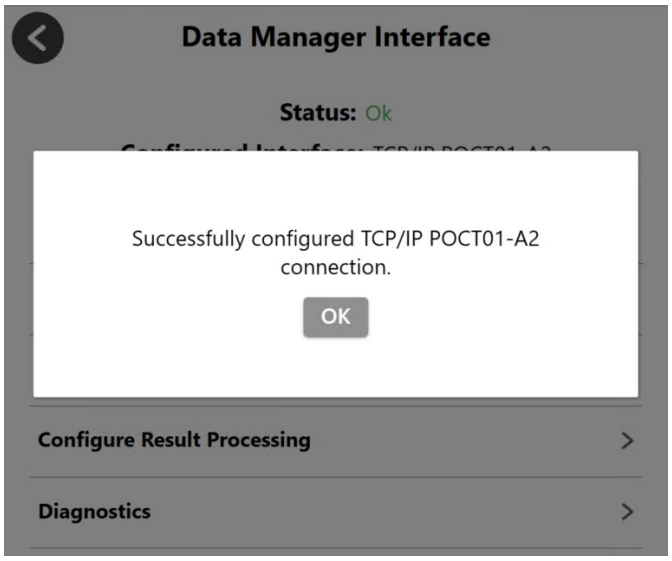
6. Select the **Configure Interface** option from the **Data Manager Interface** screen.
7. Select "TCP/IP POCT01-A2" from the **Selected Interface** dropdown menu.
8. Enter the following information to configure the TCP/IP POCT01-A2 Interface:

Field	Description
Host	The IP address or hostname of your institution's Data Manager server.
Port	The TCP/IP port number the Data Manager server is listening on. A numeric value between 1-65535 must be provided.

9. Select **Save**.

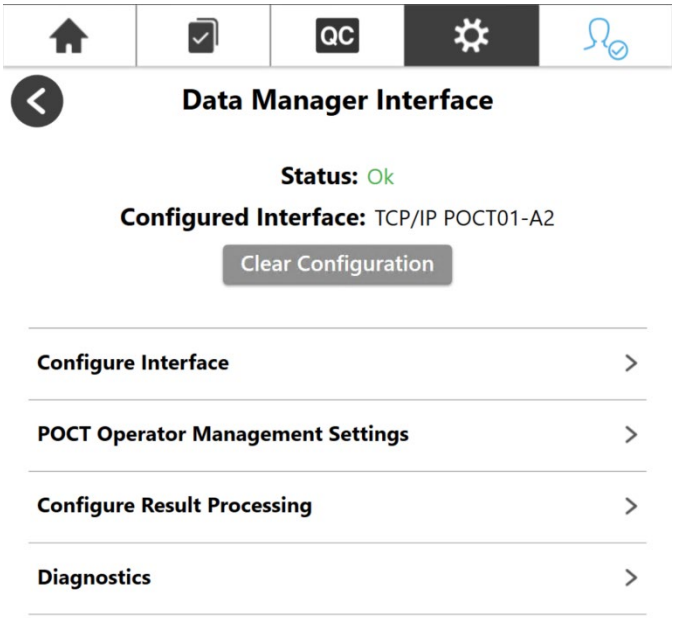
   Upon **Save**, the SPOTFIRE Connectivity Software attempts to establish a TCP/IP connection with the Data Manager using the **Host** and **Port** settings provided**.**

   Note: For more information about background processes and data exchanges occurring between SPOTFIRE and the Data Manager while the POCT01-A2 connection is being established, refer to BFR0001-5795: *BIOFIRE® SPOTFIRE® POCT01-A2 Interface Driver Development Guide.*



10. Click **OK** on the dialog shown above to complete interface configuration.

    Note: Refer to section 5 for help troubleshooting problems establishing the POCT01-A2 connection.



    The software automatically returns the operator to the **Data Manager Interface** screen upon successful connection. The **Status** field updates from “Not Configured” to “Ok”. The **Configured Interface** field updates from “None” to “TCP/IP POCT01-A2”.

3.2.3 Validate POCT01-A2 Interface

Upon successful configuration of the POCT01-A2 interface in SPOTFIRE, ensure that data to and from the Data Manager is being successfully received and sent. Perform any additional validation procedures recommended by your Data Manager administrator. Additionally, validate the interface using test procedures that meet the appropriate standards for CLIA and other applicable laboratory accrediting agencies.

3.3 POCT Operator Management Settings

When the POCT01-A2 interface is configured, admins have two options for managing operators on the SPOTFIRE System. These options are controlled by the **Operator Management Source** setting:

1. **Local**: All operator accounts are created, maintained, or deleted using the SPOTFIRE Software's built-in operator management features. Local operator management is enabled by default and remains the default even after the POCT01-A2 interface is configured.
2. **Point-of-Care**: All operator accounts are created, maintained, or deleted remotely by the Data Manager via the POCT01-A2 interface. This option must be manually enabled by an Administrator from the Data Manager user interface.

Note: The SPOTFIRE Administrator ("SFAdmin") operator account remains active regardless of the **Operator Management Source** setting and cannot be modified or deleted by the Data Manager.

SPOTFIRE maintains Local and Point-of-Care operator information in two separate databases. This allows Administrators to flexibly toggle between the Local and Point-of-Care settings without impacting stored operator account data.

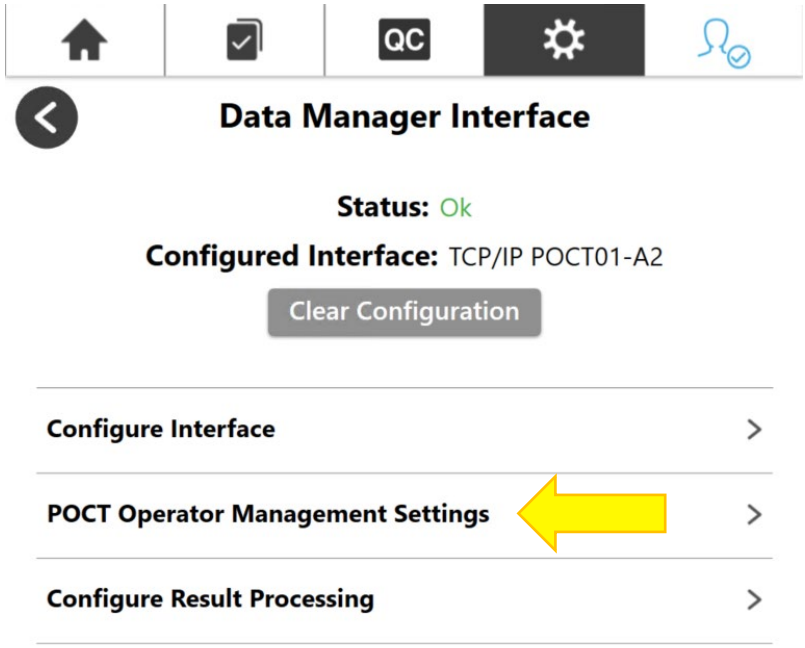
For example, if the Point-of-Care operator management setting is enabled, all local operator accounts are de-activated and can no longer be used to login to the SPOTFIRE. At that point, operators must login using account credentials provided by the Data Manager.

If the setting is then reverted back to Local, all prior local operator accounts are restored and any operator accounts created by the Data Manager are de-activated. In either case, the Local and Point-of-Care account data remains separate and intact within their respective databases.

IMPORTANT: Before enabling Point-of-Care operators, verify that your institution's Data Manager is configured to support SPOTFIRE operators via the POCT01-A2 interface.

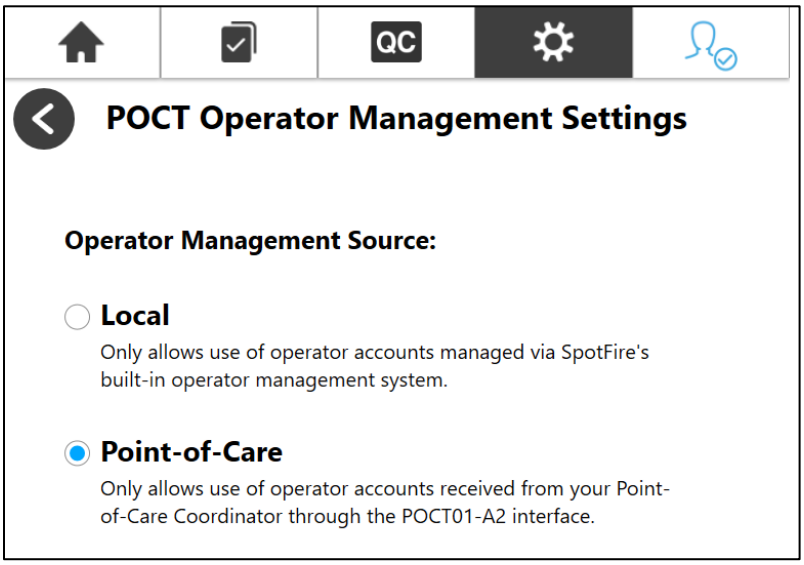
The following instructions describe how to enable the Point-of-Care option for operator management:

1. Select the **POCT Operator Management Settings** option from the Data Manager Interface screen.



IMPORTANT: By default, **POCT Operator Management Settings** are disabled if the POCT01-A2 interface is **not** currently configured.

2. Select the **Point-of-Care** option.



3. Select **OK** on the Warning prompt to confirm and acknowledge the following as a result of changing the **Operator Management Source**:
    a. Administrator options to add, update, or delete operators locally will be disabled.

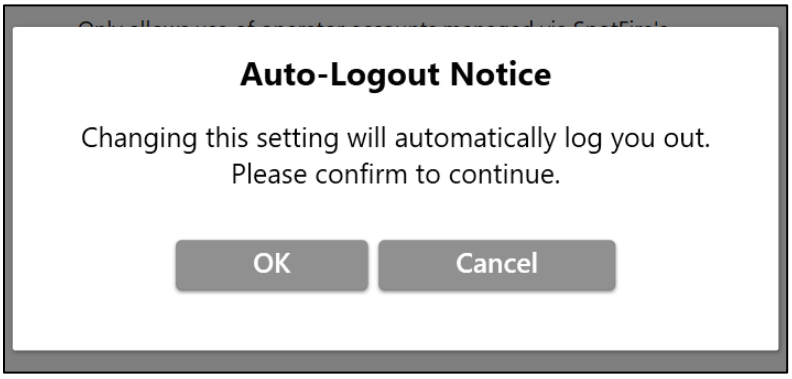
b. Password Recovery settings will be disabled for all operators *except* the SPOTFIRE Administrator (“SFAdmin”).

c. Local operators may be restored at a later time.

Alternatively, operators may select **Cancel** to retain Local operator management settings.

IMPORTANT: Changing the **Operator Management Source** setting will automatically log out the current operator *unless* the SPOTFIRE Administrator (“SFAdmin”) is currently logged in.

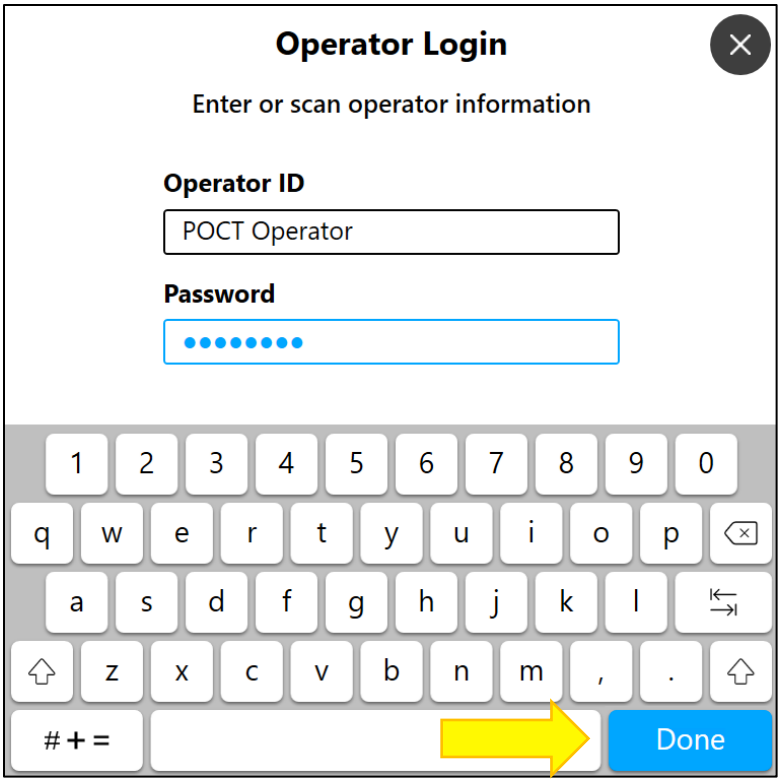
4. If applicable, select **OK** on the *Auto-Logout Notice* to confirm (not applicable if logged in as “SFAdmin”).



Alternatively, the **Cancel** button may be selected to retain the current **Operator Management Source** setting.

5. Upon automatic log out, select the **Log In** option from the SPOTFIRE toolbar.

6. Use the on-screen keyboard to enter the **Operator ID** and **Password** assigned by your institution’s Data Manager, then select **Done.**



The SPOTFIRE Software authenticates the **Operator ID** and **Password** values against the operator credentials provided by the Data Manager.

Alternatively, operators may also scan a barcode if **Barcode Badge Access** is enabled on the SPOTFIRE System and barcode IDs are issued by your institution. Scanned barcodes must match the values provided by the Point of Care Data Manager if the **Operator Management Source** is set to Point-of-Care. Otherwise, locally managed barcodes will not be recognized if they differ from the values provided by the Data Manager. Refer to BFR0001-1641: *BIOFIRE® SPOTFIRE® System Operator's Manual* for more information on barcodes and other login management options.

If operators are unable to log in after the Operator Management Source setting is changed to Point-of-Care, refer to your institution's POC system administrator to verify your account credentials. Additionally, the SPOTFIRE Administrator ("SFAdmin") may log in at any time to revert the **Operator Management Source** setting, as needed.

IMPORTANT: It is **strongly** encouraged that administrators ensure POCT-managed operator lists are refreshed whenever the POCT01-A2 interface is configured to a new Host. This action requires the Data Manager to transmit a Complete Operator List Update message (OPL.R01) to the SPOTFIRE device when the connection to the new Host is established. This will prevent obsolete operator profiles associated with the former Host (if any) from being used to login to the SPOTFIRE device. Consult with your institution's POC system administrator for additional information.

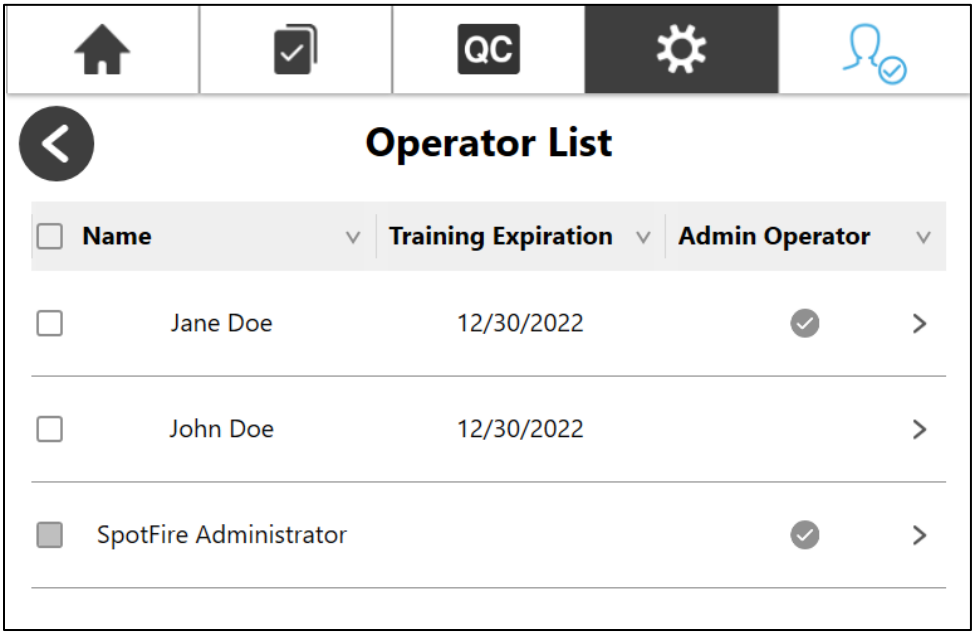
Note: Updates to SPOTFIRE Operator Lists via the POCT01-A2 are not currently recorded in the SPOTFIRE Audit Log.

Note: Point-of-Care managed operators can successfully log into SPOTFIRE even if the POCT01-A2 interface is currently disconnected (e.g., in an Error status). The **Operator Management Source** setting will not automatically revert back to Local if the POCT01-A2 interface disconnects.

3.3.1 View Point-of-Care Operator Lists

To view operator lists received from the Data Manager after the **Operator Management Source** setting is changed to Point-of-Care:

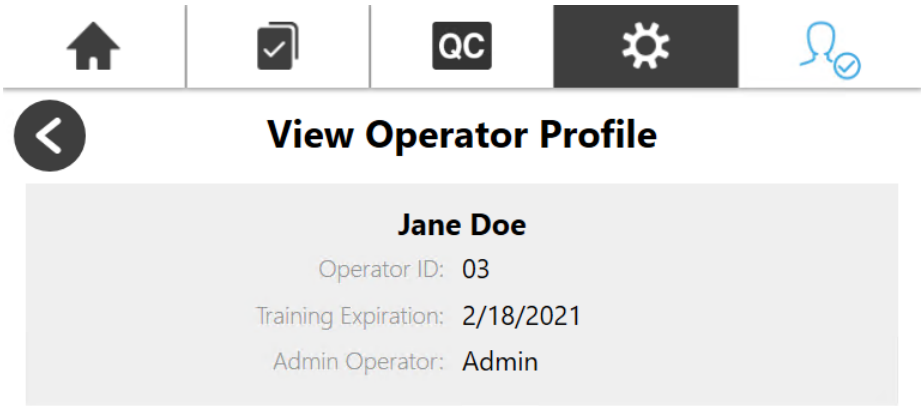
1. Log in to SPOTFIRE as an administrator and select the **Settings** tab from the SPOTFIRE toolbar.
2. Select the **Operator Management** option.
3. Select the **Operator List** option.



Note: The SPOTFIRE Administrator (“SFAdmin”) is a locally managed account that remains permanently active and cannot be modified or removed by the Data Manager via the POCT01-A2 interface.

The Operator List displays all active operators received from the Data Manager. Select any operator from the list to view that operator’s details.

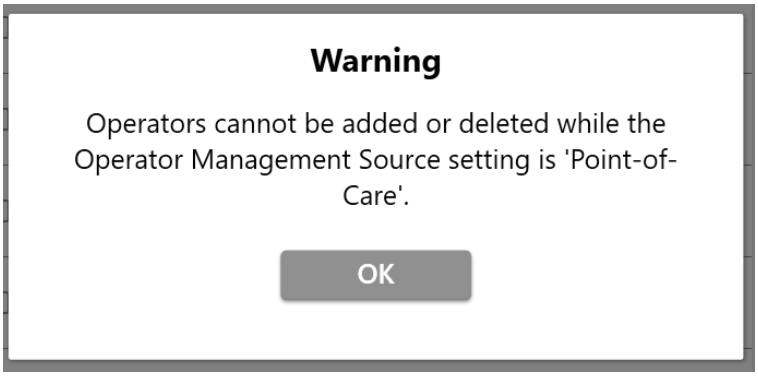
Operator profiles are displayed as read-only and cannot be modified while the **Operator Management Source** is set to Point-of-Care, as shown below:



If no operator accounts display in the Operator List (other than the SPOTFIRE Administrator), it is probable that the Data Manager has not provided any operator accounts via the POCT01-A2 interface. Refer to your institution's POC administrator to ensure that operator accounts are being transmitted to the SPOTFIRE System. Additionally, refer to section 7.2 for troubleshooting steps if the Operator List is missing or incomplete.

Note: If SPOTFIRE encounters a problem while attempting to process operator account data from the Data Manager, the software will automatically transmit a Device Events message to inform the Data Manager of the problem. For additional information on Device Events messages, refer to BFR0001-5795: *BIOFIRE® SPOTFIRE® POCT01-A2 Interface Driver Development Guide.*

IMPORTANT: Operators cannot be locally added or deleted using the SPOTFIRE Software while the **Operator Management Source** is set to Point-of-Care. Attempting to select the **Add Operator** or **Delete Operator** buttons on the *Operator List* screen will result in the following warning prompt:

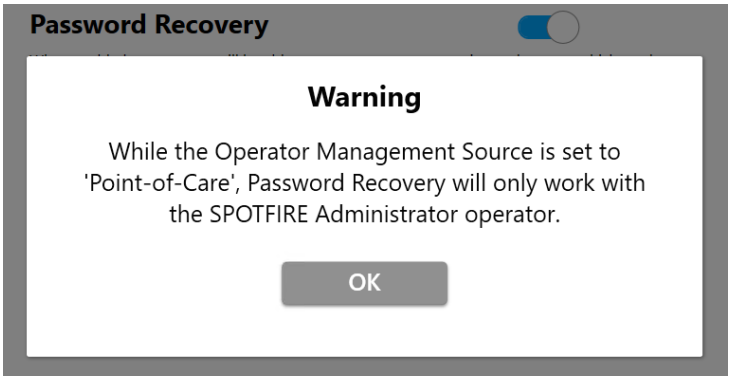


3.3.2 Login Management Settings for Point-of-Care Operators

While the **Operator Management Source** is set to Point-of-Care, the following features on the *Login Management* screen (located within *Settings* → *Operator Management*) will apply to the SPOTFIRE Administrator ("SFAdmin") operator **only**:

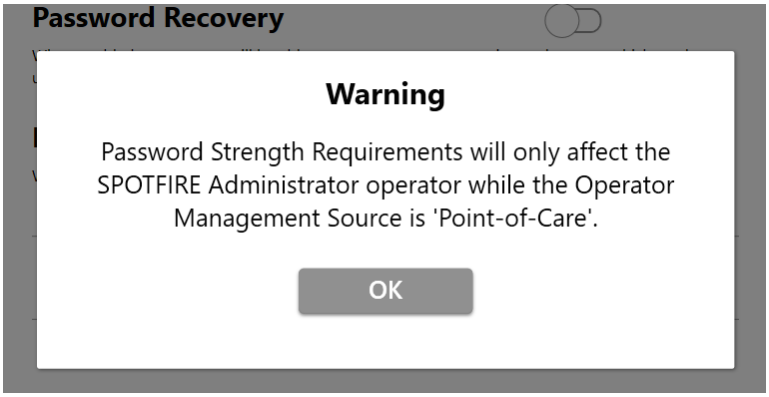
- **Password Recovery**

  Attempting to enable or disable the Password Recovery setting displays the following warning prompt:



- **Password Strength Requirements**

  Attempting to update Password Strength Requirements displays the following warning prompt:



Point-of-Care operators that require password assistance should contact their institution's POC system administrator.

All other features on the *Login Management* screen—including **Automatic Logout** settings and **Barcode Badge Access**—remain applicable to all operators while the Operator Management Source is set to Point-of-Care.

3.4 Remote Management of SPOTFIRE Settings

When the POCT01-A2 interface is configured, the connected Data Manager has the option to remotely enable/disable select settings on the SPOTFIRE System. This allows the Data Manager to manage and synchronize settings across several SPOTFIRE devices without having to manually log in and configure settings on each individual device. SPOTFIRE system settings can be remotely updated via two methods:

- **Automatic**: The Data Manager automatically applies system settings when the POCT01-A2 connection with SPOTFIRE is established.
- **On Demand**: The Data Manager applies system settings at any point *after* the POCT01-A2 connection is established (at the discretion of the POC system administrator).

The following are SPOTFIRE System settings that can be remotely managed by a Data Manager via the POCT01-A2 interface:

- **Automatic Logout:** Sets the amount of time after which an operator is automatically logged out due to system inactivity. When enabled, the system inactivity interval is also set (1, 2, 5, 10, or 15 minutes).
- **Barcode Badge Access**: When enabled, allows operators to log in using an associated scanned barcode (instead of Operator ID and Password credentials).
- **Initial Lot Lockout**: When enabled, new pouch lots cannot be run without passing positive and passing negative QC tests.
- **Automatic Result Processing**: When enabled, newly completed test results are automatically transmitted to the Data Manager (refer to section 6.4.1 for additional information).
- **Send Failed Results**: When enabled, failed test results may be transmitted to the Data Manager (refer to section 6.4.3 for additional information).
- **Send Control T_m:** When enabled, internal process control melting temperatures are included in transmitted test results (refer to section 6.4.4 for additional information).

Admin operators retain the ability to overwrite any SPOTFIRE System settings applied by the Data Manager via the POCT01-A2 interface.

Note: Updates to SPOTFIRE System settings via the POCT01-A2 are not currently recorded in the Audit Log.

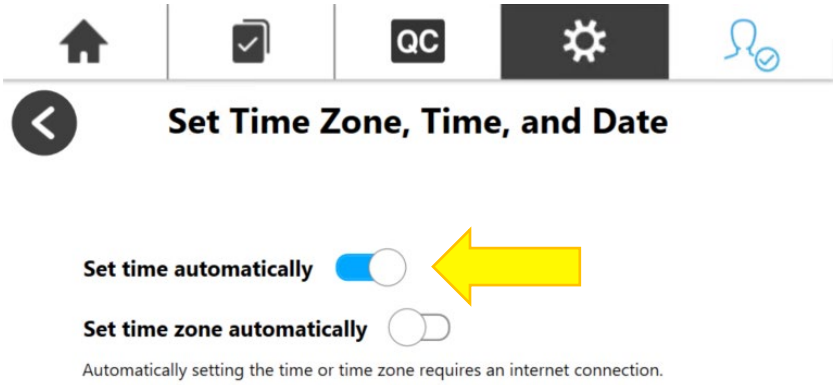
3.4.1 Updates to System Date and Time

The POCT01-A2 interface also allows the connected Data Manager to remotely update system date and time on the SPOTFIRE computer. This feature allows the Data Manager to more easily reconcile date/timestamps on the messages it receives from SPOTFIRE, as well as synchronize date and time settings across a fleet of connected devices.

Admin operators retain the ability to overwrite updates to system date or time initiated by the Data Manager via the POCT01-A2 interface.

There are two scenarios where system date/time may **not** be remotely updated by the Data Manager via the POCT01-A2 interface:

1. One or more patient or QC tests are in progress. The software only permits updates to date/time settings when all connected SPOTFIRE instrument modules are idle.
2. **Set time automatically** setting is enabled, as shown below (setting found under Settings > System Configuration > Date and Time). In this scenario, system date/time values are acquired from the customer's local network.



For additional information about Set Time Directive messages and protocol, refer to BFR0001-5795: *BIOFIRE® SPOTFIRE® POCT01-A2 Interface Driver Development Guide*.

4. XML Interface

The purpose of this section is to describe the SPOTFIRE System's XML interfacing options and provide detailed instructions for configuring the interface.

4.1 Interface Description

An XML interface can be used to electronically transfer test results form a SPOTFIRE System to a Data Manager. The XML interface supports the use of any the following communication protocols for transfer of the XML-formatted electronic reports across a network:

- File Transfer Protocol (FTP Server)
- Hypertext Transfer Protocol (HTTP Client)
- Local Folder protocol (SMB)
- LIS Shared Folder protocol (SMB)
- Network Shared Folder protocol (SMB)

Refer to BFR0002-3721-*BIOFIRE SPOTFIRE XML Interface Driver Development Guide* for additional information regarding how the SPOTFIRE Connectivity Software implements each of the protocols listed above to support data transfer.

4.2 Messaging Format

When an XML interface is configured, the SPOTFIRE Software formats patient test results into a proprietary XML format defined by BIOFIRE. Refer to BFR0002-3721-*BIOFIRE SPOTFIRE XML Interface Driver Development Guide* for additional information about the XML electronic report format.

4.3 Configuring an XML Interface

This section describes the process of setting up an XML interface between SPOTFIRE and a Data Manager. The process consists of three general steps:

1. Initial preparation between SPOTFIRE and your institution's Data Manager.
2. Configuring the interface.
3. Validate the interface from the Data Manager server.

Each of these steps is detailed in the subsections that follow and should be performed in order.

4.3.1 Initial Preparation

Perform the steps listed below before attempting to configure an XML interface in SPOTFIRE.

1. Verify that the Data Manager you wish to interface with offers a SPOTFIRE-compatible device driver supporting transfer of XML electronic reports.

   Note: If your Data Manager does not offer a SPOTFIRE-compatible driver, bioMérieux support may provide additional assistance to your institution's LIS or middleware vendor for the development of a driver.

2. Determine your institution's local networking and security requirements. Your institution may require a cybersecurity questionnaire or security review to be completed prior to connecting the

SPOTFIRE to your local network. Additionally, IT personnel may be required to ensure network firewalls will permit TCP/IP traffic between the SPOTFIRE System and the Data Manager.

3. Connect the SPOTFIRE to the local network. For more information, refer to BFR0001-1641: *BIOFIRE® SPOTFIRE® System Operator's Manual.*
4. Install and configure the SPOTFIRE device driver on the Data Manager server. Contact your LIS or middleware vendor representative for assistance.

Once the above steps are complete, proceed to the next section.

4.3.2 XML Interface Configuration Requirements

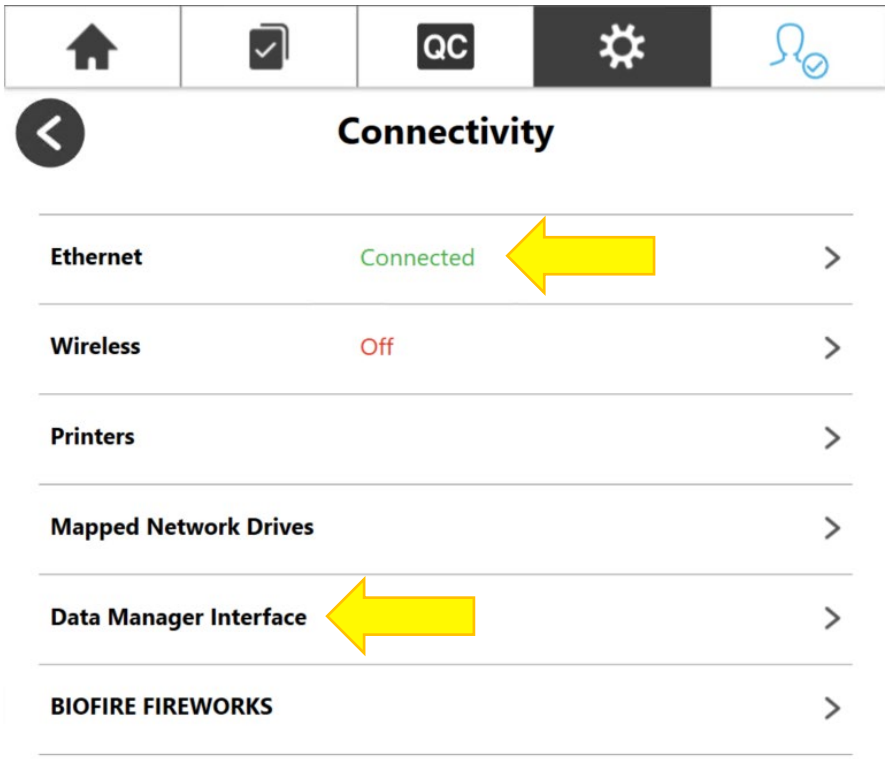
The SPOTFIRE Connectivity Software provides two ways to configure an XML interface:

1. Manually creating a new configuration.
2. Loading the configuration settings via file import (using a previously exported configuration file).

The steps included in this section describe how to create a new configuration. Refer to the instructions in section 6.2.2 to configure via file import.

Complete the following steps to configure an XML interface in SPOTFIRE:

1. Log into SPOTFIRE as an Administrator operator.
2. From the SPOTFIRE toolbar, select the **Settings** tab.
3. Select the **Connectivity** option from the Settings menu.
4. Ensure the SPOTFIRE is connected to the local network.



Either the **Ethernet** or **Wireless** options in the Connectivity menu should display “Connected”. Refer to BFR0001-1641: *BIOFIRE® SPOTFIRE® System Operator’s Manual* for information on connecting the SPOTFIRE to your institution’s local network.

5. Select the **Data Manager Interface** option from the Connectivity menu.

   IMPORTANT: The **Data Manager Interface** option is only available to Administrator operators.

6. Select the **Configure Interface** option from the **Data Manager Interface** screen.

7. Select one of the following XML interfacing options from the **Selected Interface** dropdown:

   - FTP Server
   - HTTP Client
   - LIS Shared Folder
   - Local Folder
   - Network Shared Folder

   NOTE: Refer to section 3.2.2 and 5.5.2 for TCP/IP POCT01-A2 and MLLP configuration requirements, respectively.

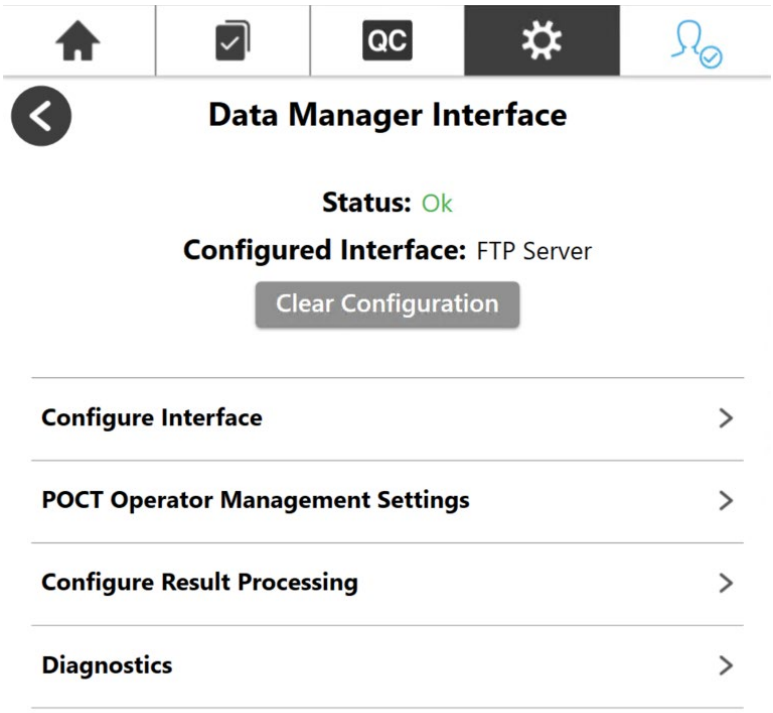
8. Enter the following information corresponding to the **Selected Interface**:

Selected Interface	Field	Description
FTP Server	**Login**	User account login for the FTP site hosted on the SPOTFIRE control station via Windows Internet Information Services (IIS). Alphanumeric characters only; 32 characters or fewer.
	Password	User account password for the FTP site. 127 characters or fewer.
	Confirm Password	Must exactly match the Password value.
HTTP Client	**Connection Type**	One of the following options must be selected: • HTTP • HTTPS
	Server URL	URL for the Data Manager server. Value must be a valid HTTP v1.1. URL. The URL scheme (http://, https:// is pre-populated based on the selected Connection Type).
LIS Shared Folder	**Folder Path**	Folder location on the Data Manager server where XML electronic reports files are deposited. Values should be expressed as: \\<IP address or host name>\<Folder path> 200 characters or fewer.

LIS Shared Folder	**Username**	User account name for accessing the Folder Path on the Data Manager server. 127 characters or fewer; value cannot contain spaces.
	Password	User account password for accessing the Folder Path on the Data Manager server. 127 characters or fewer.
Local Folder	**Driver Letter**	A list of available fixed or removable drives on the SPOTFIRE control station. The C:\ drive is selected by default.
	Folder Path	Folder location on the SPOTFIRE control station where XML electronic reports files are deposited. 200 characters or fewer.
Network Shared Folder	**Folder Path**	Network folder location where XML electronic reports files are deposited. 200 characters or fewer.
	Domain	Name of the network domain.
	Username	User account name for accessing the network Folder Path. 127 characters or fewer; value cannot contain spaces.
	Password	User account password for accessing the network Folder Path. 127 characters or fewer.

9. Select **Save.**

   Upon **Save**, the SPOTFIRE Connectivity Software attempts to establish a connection with the Data Manager based on the configuration settings provided.



The software automatically returns the operator to the **Data Manager Interface** screen upon successful connection. The **Status** field updates from “Not Configured” to “Ok”. The **Configured Interface** field updates from “None” to the name of the Selected Interface (e.g., FTP Server).

4.3.3 Validate XML Interface

Upon successful configuration of an XML interface in SPOTFIRE, ensure that test results sent from the SPOTFIRE System are received and processed by the Data Manager, as expected. In addition, perform any local validation procedures of the interface.

5. HL7 Interface

The purpose of this section is to describe the SPOTFIRE System's HL7 interface and provide detailed instructions for configuring the interface.

5.1 Interface Overview

An HL7 interface can be used to transfer test information, including test results, between the SPOTFIRE System and a Data Manager.

The HL7 interface conforms to the CLSI AUT016 standard and is implemented in accordance with revision 10 of the Pathology and Laboratory Medicine Technical Framework (referred to as the IHE PaLM TF throughout this document) published by IHE International, Inc. Specifically, the HL7 interface was developed in accordance with the Laboratory Analytical Workflow (LAW) Profile portion of the IHE PaLM TF. The HL7 interface supports a set to use cases defined in the LAW Profile and only supports query mode. Refer to BFR0002-3956: *BIOFIRE SPOTFIRE HL7 Interface Driver Development Guide* for more details.

Data-transfer protocols, communication modes, and messaging formats supported by the HL7 interface are described in the sections below.

5.2 Messaging Format

When the HL7 interface is configured, messages exchanged between the SPOTFIRE Connectivity Software and the connected Data Manager are formatted according to the HL7 v2.5.1 standard, in accordance with the LAW Profile and the IHE PaLM TF. Refer to BFR0002-*3956: BIOFIRE SPOTFIRE HL7 Interface Driver Development Guide* for more details about the message format and contents.

5.3 Data Transfer

The HL7 interface uses the Minimum Lower Layer Protocol (MLLP) to transfer structured data sets between the SPOTFIRE System and Data Manager across a network. Refer to BFR0002-3956: *BIOFIRE SPOTFIRE HL7 Interface Driver Development Guide* for more information about how the software uses MLLP to transfer data.

MLLP supports both unidirectional and bidirectional communication modes, which are described in the subsections below.

5.3.1 Unidirectional Communication Mode

The SPOTFIRE Connectivity Software can be configured to communicate in unidirectional mode when the HL7 interface is configured. In unidirectional communication mode, the software will transfer test results from the SPOTFIRE System to a Data Manager, at which point, the Data Manager is expected to only respond with an acknowledgement message confirming receipt.

In unidirectional communication mode, the software will not query the Data Manager for a test order and does not expect to receive any test order information from the Data Manager. In addition, the Test Order Review feature is not available when the HL7 interface is configured for unidirectional communication (refer to section 5.4 for more information).

5.3.2 Bidirectional Communication Mode

The SPOTFIRE Connectivity Software can alternatively be configured to communicate in bidirectional mode with a Data Manager when the HL7 interface is configured. Bidirectional communication mode enables the following functionality:

1. Upon entry of the sample ID when starting a patient test on the SPOTFIRE System, the software queries the Data Manager for a test order associated with the sample ID.
2. In response to the query, the Data Manager can send SPOTFIRE the test order information associated with the sample to be tested. The SPOTFIRE Connectivity Software then displays the test order information received from the Data Manager to the SPOTFIRE operator prior to starting the patient test. In addition, the SPOTFIRE compares the test order information received from the Data Manager against the test information entered by the operator on the SPOTFIRE. See section 5.4. for details.

   IMPORTANT: In order for the SPOTFIRE Connectivity Software to verify the test order information, the sample ID entered by the SPOTFIRE operator must match the corresponding specimen container ID defined by the Data Manager (case sensitivity applies).
3. Upon completion of the patient test, the SPOTFIRE Connectivity Software sends the test results to the Data Manager with the associated test order information.

5.4 Test Order Review

When the HL7 interface is configured for bidirectional communication, the SPOTFIRE Connectivity Software provides the ability for the SPOTFIRE operator to confirm that the right test is performed on the right sample. This is accomplished through the Test Order Review feature in the software. Specifically, the Test Order Review feature performs the following:

- Compares the test information input by the operator in the SPOTFIRE Software with the test order information from the Data Manager during initiation of a new patient test.
- Displays the results of the comparison for the operator to verify before the patient test starts.

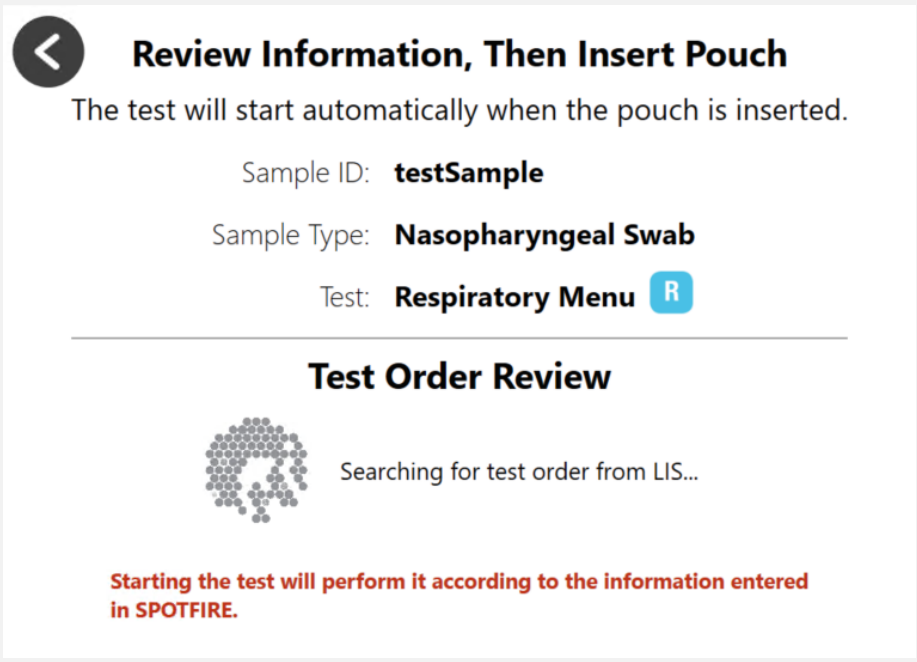
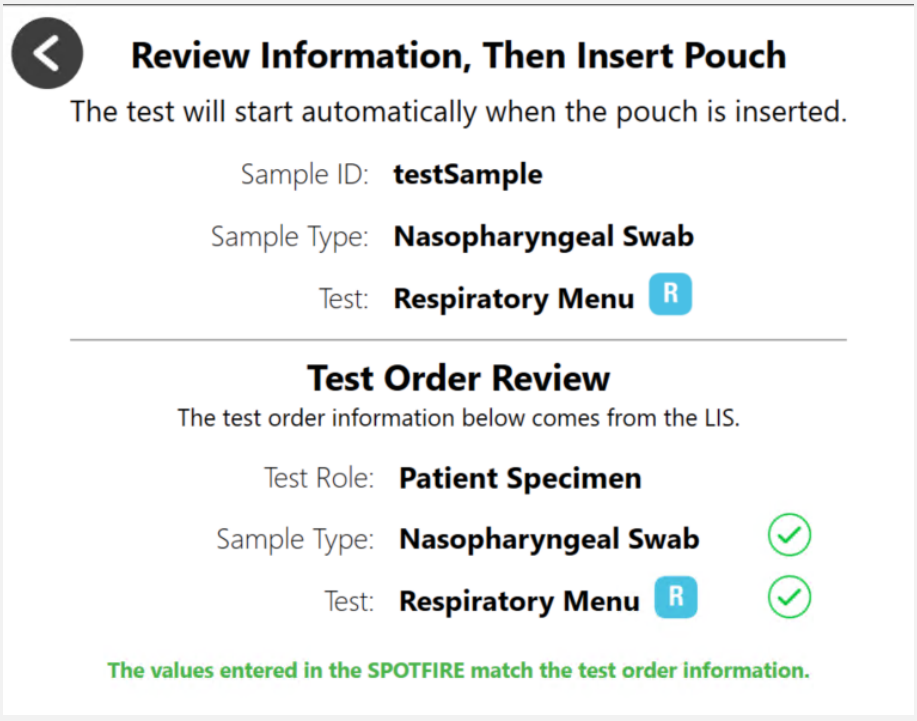
The table below defines the test order information that is compared as part of the Test Order Review feature:

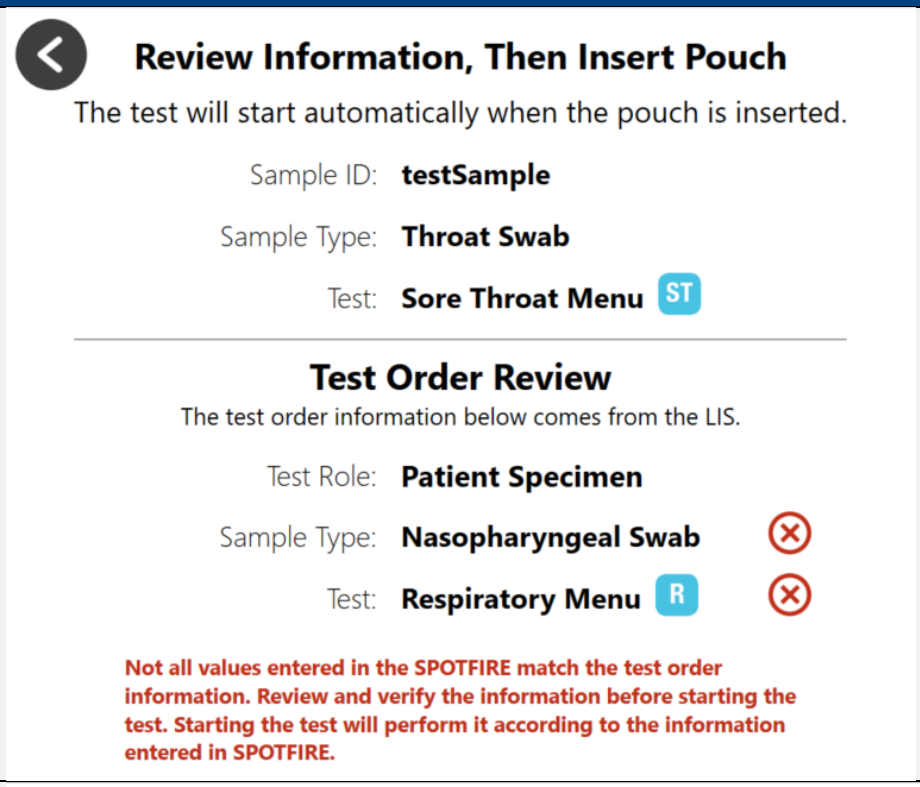
Value	Description
Test Role	The test role indicates whether the sample on which the test will be performed is a patient specimen or a QC specimen. The test role is displayed for informational purposes only and does not correspond with an input in the SPOTFIRE Software.
Test	The test indicates which IVD BIOFIRE Panel test was ordered to be performed on the sample (e.g., BIOFIRE Respiratory/Sore Throat Panel). The test received from the Data Manager corresponds with the pouch type from the SPOTFIRE Software.
Sample Type	The sample type indicates the type of sample on which the test will be performed (e.g., Nasopharyngeal Swab). The sample type received from the Data Manager corresponds with the sample type selection in the SPOTFIRE Software.

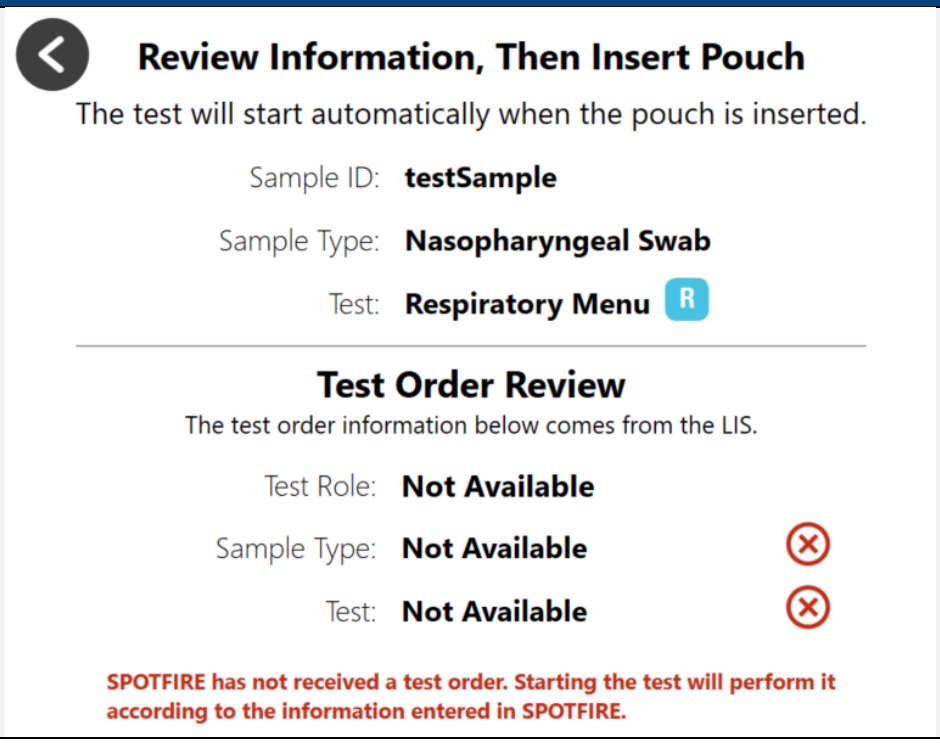
5.4.1.1 Test Order Review User Interface

The SPOTFIRE Software displays any test order information received from the Data Manager in the Test Order Review section of the *Review Information, Then Insert Pouch* view immediately prior to starting a patient test.

The Test Order Review section dynamically updates in the following scenarios:

Scenario	Test Order Review User Interface
The SPOTFIRE Software is searching for a test order from the Data Manager that corresponds with the sample ID entered by the operator.	
The SPOTFIRE Software receives test order information from the Data Manager that corresponds with the sample ID entered by the operator and matches all the inputs in the SPOTFIRE Software.	

Scenario	Test Order Review User Interface
The SPOTFIRE Software receives test order information from the Data Manager that corresponds with the sample ID entered by the user, but it does not match one or more inputs in the SPOTFIRE Software.	
The SPOTFIRE Software receives a message from the Data Manager indicating that a test order does not exist in the Data Manager for the corresponding sample ID.	

Scenario	Test Order Review User Interface
The SPOTFIRE Software does not receive a message from the Data Manager in response to its query.	

The patient test will always be performed according to the inputs entered by the SPOTFIRE operator. Verifying both sources of information against each other, however, allows the operator to make any changes to the test inputs on the SPOTFIRE System before starting the patient test.

IMPORTANT: Patient tests can be started on the SPOTFIRE system immediately upon insertion of the pouch regardless of the Test Order Review results.

5.5 Configuring the HL7 Interface

Perform the steps listed below before attempting to configure an HL7 interface in SPOTFIRE.

5.5.1 Initial Preparation

Perform the steps listed below before attempting to configure an HL7 interface in SPOTFIRE.

1. Verify that the Data Manager you wish to interface with offers a SPOTFIRE-compatible device driver supporting HL7 data transfer.

   Note: If your Data Manager does not offer a SPOTFIRE-compatible driver, bioMérieux support may provide additional assistance to your institution's LIS or middleware vendor for the development of a driver.

2. Determine your institution's local networking and security requirements. Your institution may require a cybersecurity questionnaire or security review to be completed prior to connecting the SPOTFIRE to your local network. Additionally, IT personnel may be required to ensure network firewalls will permit TCP/IP traffic between the SPOTFIRE System and the Data Manager.

3. Connect the SPOTFIRE to the local network. For more information, refer to BFR0001-1641: *BIOFIRE® SPOTFIRE® System Operator's Manual.*

4. Install and configure the SPOTFIRE device driver on the Data Manager server. The device driver must be configured and available from the same hostname/IP address and port number used to configure the HL7 interface in SPOTFIRE. Contact your LIS or middleware vendor representative for assistance.

Once the above steps are complete, proceed to the next section.

5.5.2 HL7 Interface Configuration Requirements

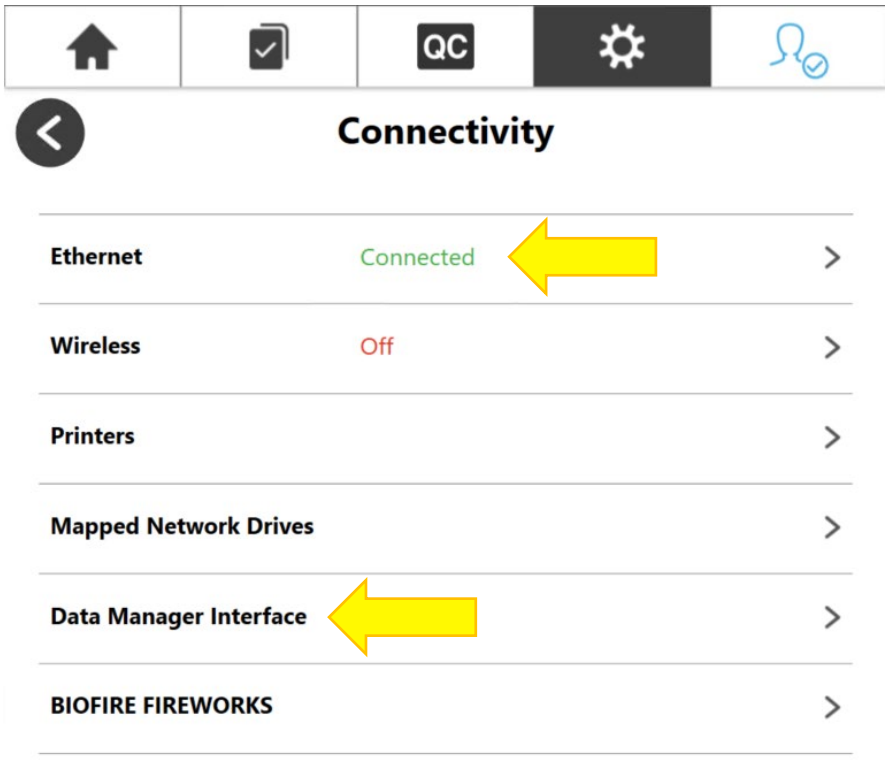
The SPOTFIRE Connectivity Software provides two ways to configure an HL7 interface:

1. Manually creating a new configuration.
2. Loading the configuration settings via file import (using a previously exported configuration file).

The steps included in this section describe how to create a new configuration. Refer to the instructions in section 6.2.2 to configure via file import.

Complete the following steps to configure an HL7 interface in SPOTFIRE:

1. Log into SPOTFIRE as an Administrator operator.
2. From the SPOTFIRE toolbar, select the **Settings** tab.
3. Select the **Connectivity** option from the Settings menu.
4. Ensure the SPOTFIRE is connected to the local network.



Either the **Ethernet** or **Wireless** options in the Connectivity menu should display “Connected”. Refer to BFR0001-1641: *BIOFIRE® SPOTFIRE® System Operator’s Manual* for information on connecting the SPOTFIRE to your institution’s local network.

5. Select the **Data Manager Interface** option from the Connectivity menu.

   IMPORTANT: The **Data Manager Interface** option is only available to Administrator operators.

6. Select the **Configure Interface** option from the **Data Manager Interface** screen.

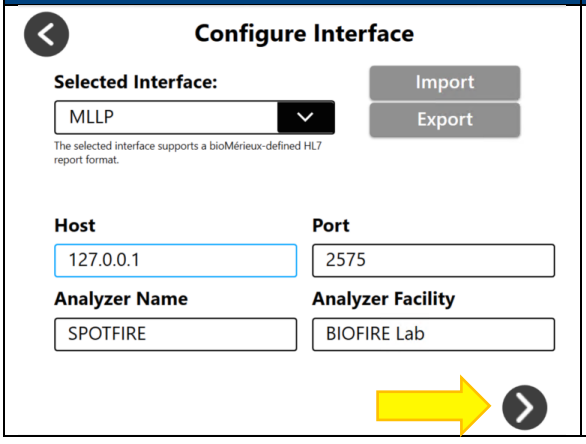
7. Select "MLLP" from the **Selected Interface** dropdown menu.

8. Enter/select the following information to configure the MLLP connection:

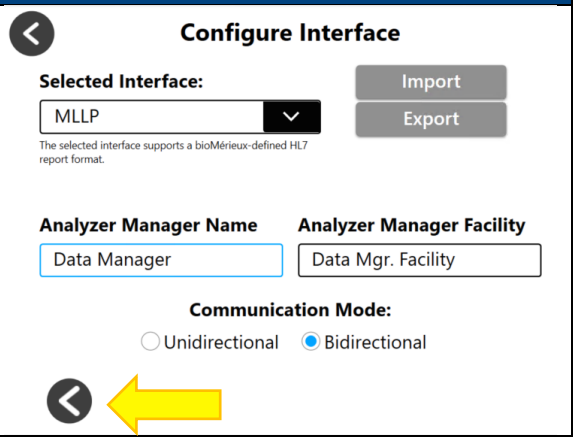
Field	Description
Host	The IP address or hostname of your institution's Data Manager server.
Port	The TCP/IP port number the Data Manager server is listening on. A numeric value between 1-65535 must be provided. Default value is "2575".
Analyzer Name	Name of the analyzer from which test results will be sent (e.g., SPOTFIRE). Default value is "SF". 20 characters or fewer.
Analyzer Facility	Name of the facility in which the analyzer is located. 20 characters or fewer.
Analyzer Manager Name	Name of the analyzer manager (i.e., Data Manager) in which test results will be received. 20 characters or fewer.
Analyzer Manager Facility	Name of the facility in which the analyzer manager is located. 20 characters or fewer.
Communication Mode	Select from the following options: • Bidirectional (default) • Unidirectional

IMPORTANT: Due to limited space on the **Configure Interface** screen, the fields listed above are displayed in different views. Select the ❯ and ❮ buttons (as shown below) to toggle between these two views:

View #1

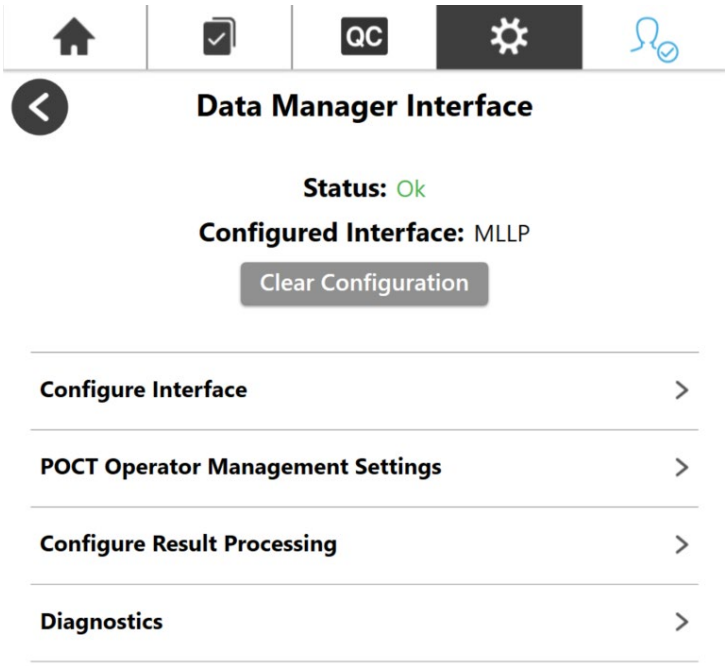


View #2



9. Select **Save.**

   Upon **Save**, the SPOTFIRE Connectivity Software attempts to establish a connection with the Data Manager based on the configuration settings provided.



   The software automatically returns the operator to the **Data Manager Interface** screen upon successful connection. The **Status** field updates from “Not Configured” to “Ok”. The **Configured Interface** field updates from “None” to “MLLP”.

5.5.3 Validate HL7 Interface

Once the HL7 interface is configured, verify that the messages transferred between the SPOTFIRE System and the connected Data Manager are sent and received as expected. In addition, ensure the test results from the SPOTFIRE System are received and processed by the Data Manager and perform any local validation procedures of the interface.

6. Using the SPOTFIRE Connectivity Software

This section describes how to use features offered through the SPOTFIRE Connectivity Software. The SPOTFIRE Connectivity Software can be accessed by selecting the **Data Manager Interface** option from the Settings > Connectivity menu. These features include:

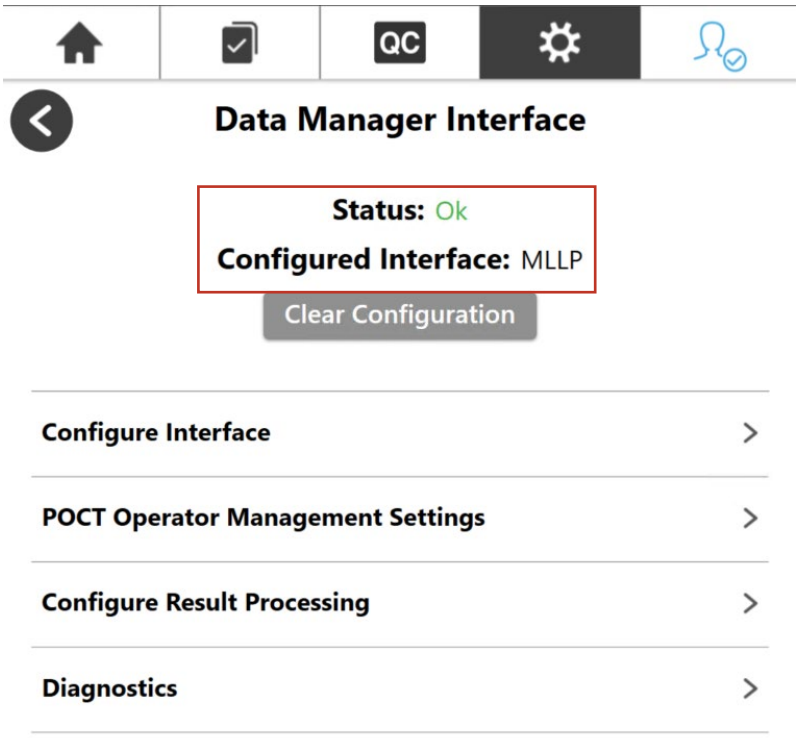
- Viewing the status of the currently configured interface
- Managing the current interface configuration
- Importing or exporting the interface configuration settings
- Configuring POCT Operator Management Settings (applies to the POCT01-A2 interface only)
- Configuring Result Processing settings, including:
    - Automatic Result Processing
    - Send Start Test Notifications (not applicable to the POCT01-A2 interface)
    - Send Failed Results
    - Send Control melting temperatures (T_m)
- Interface diagnostics

IMPORTANT: The Data Manager Interface screen is only accessible to Administrator operators.

6.1 View Interface Status

IMPORTANT: The instructions below apply regardless of the Configured Interface (e.g., TCP/IP POCT01-A2, MLLP, FTP Server, etc.).

The status of the currently configured interface is shown on the **Data Manager Interface** screen.



Status displays the currently operational status of the interface. Possible values include **Ok**, **Not Configured**, or **Error**. The following table provides a description of each status.

Status	Description
Ok	The Data Manager Interface is configured and a stable connection with the Data Manager is established.
Not Configured	The Data Manager Interface is not configured and there is no connection with the Data Manager.
Error	A connection error has been detected and communication with the Data Manager has been disrupted. Refer to section 7 for troubleshooting steps.

Configured Interface displays the current interface being used (e.g., TCP/IP POCT01-A2, MLLP, FTP Server, etc.). The **Configured Interface** will display as “None” if no interface is currently configured.

Note: The SPOTFIRE Connectivity Software is packaged as part of the SPOTFIRE System Software and cannot be installed, uninstalled, or upgraded separately from other software components.

6.2 Managing the Interface Configuration

The SPOTFIRE Connectivity Software provides the following options to help operators manage interface settings after initial configuration.

1. Export Interface Configuration settings
2. Import Interface Configuration settings
3. Clear Interface Configuration settings

Instructions for each of these options are provided in the following sections.

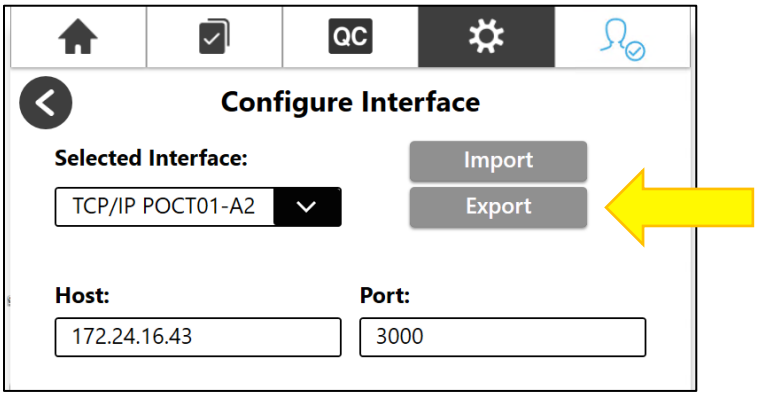
6.2.1 Export Interface Configuration

The software provides operators the option to export current Data Manager Interface settings to an external file. This option is useful in scenarios where the same configuration settings need to be shared and applied to multiple SPOTFIRE devices (i.e., multiple SPOTFIRE devices all need to connect to the same Data Manager server).

IMPORTANT: The SPOTFIRE System must have access to a removable (e.g., USB) or mapped network drive in order to export configuration settings. Ensure a USB is inserted into the SPOTFIRE Control Station, or a mapped network drive is available, prior to performing the steps below.

IMPORTANT: The instructions below apply regardless of the Configured Interface (e.g., TCP/IP POCT01-A2, MLLP, FTP Server, etc.).

1. Select the **Configure Interface** option from the **Data Manager Interface** screen.
2. Select the **Export** button.



3. **Select a drive for the save destination** using the dropdown menu provided.
4. (optional) Edit the export **Filename**, as desired.

   Note: The software defaults the **Filename**, as follows:

   SPOTFIRE_Connectivity_<Configured Interface>_Configuration_<YY-MM-DD>_<hh-mm-ss>_<SPOTFIRE Control Station Serial Number>.<file extension>

   The file extension will equal one of the following values based on the **Selected Interface**:

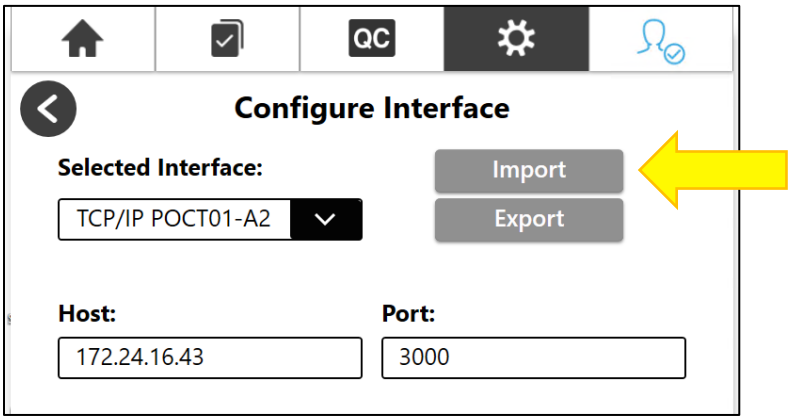
   - *.sfcc (applies to the TCP/IP POCT01-A2 interface only)*
   - *.flc (all other interfaces)*
5. Select **Enter** to export.
6. Select **OK** to acknowledge the file export.

6.2.2 Import Interface Configuration

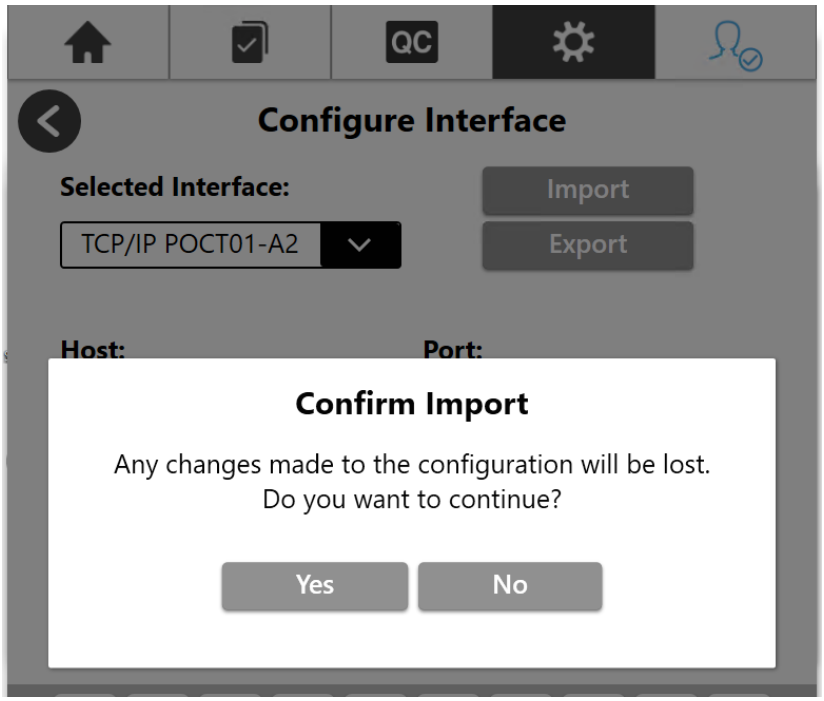
The software provides operators the option to import Data Manager Interface settings onto the SPOTFIRE System using a previously exported configuration file (*.sfcc* or *.flc*). This option provides an alternative way for operators to either configure an interface for the first time, or to modify an existing configuration.

IMPORTANT: The instructions below apply regardless of the Configured Interface (e.g., TCP/IP POCT01-A2, MLLP, FTP Server, etc.).

1. Place a previously exported interface configuration file (*.sfcc* or *.flc*) onto the root directory of a removable USB or mapped network drive accessible to the SPOTFIRE.
2. Select the **Configure Interface** option from the **Data Manager Interface** screen.
3. Select the **Import** button.



4. Select **Yes** on the Confirm Import dialog to confirm that current configuration settings (if any) will be removed.

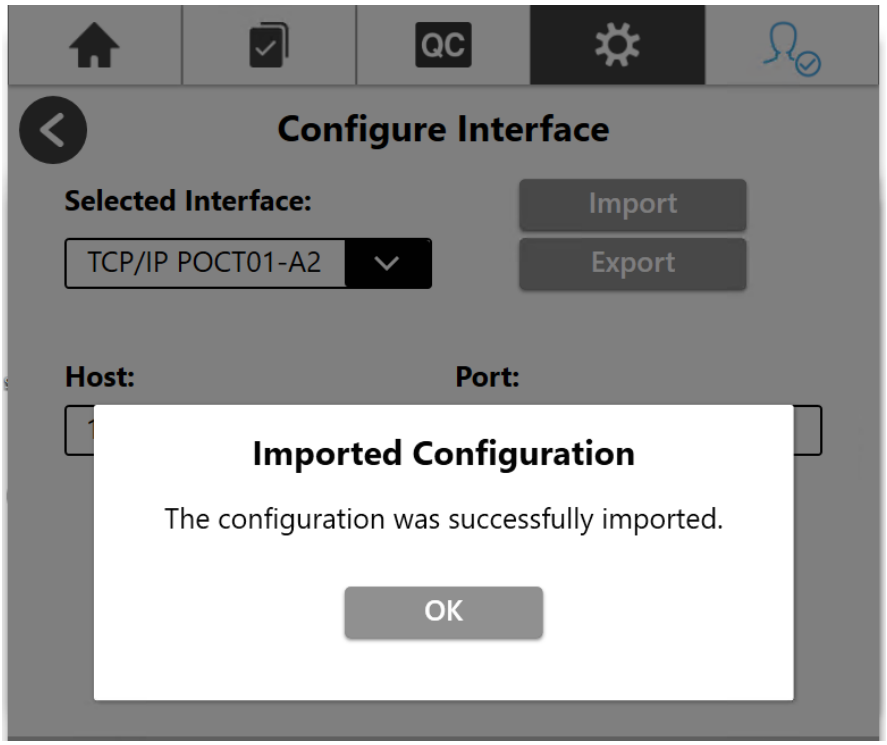


Operators may alternatively select **No** to cancel import and return to the previous screen.

5. Locate the desired import file in the list provided.

Note: The software automatically renders the list shown below based on valid configuration files found on all available removable and mapped drives.

6. Press the **Select** button corresponding to the appropriate file.
7. Select **OK** to acknowledge the imported configuration.



8. Verify the imported values on the **Configure Interface** screen.
9. Select **Save** to initiate a new connection to the Data Manager.
10. Click **OK** to acknowledge the new connection and log and return to the **Data Manager Interface** screen.

6.2.3 Clearing Interface Configuration

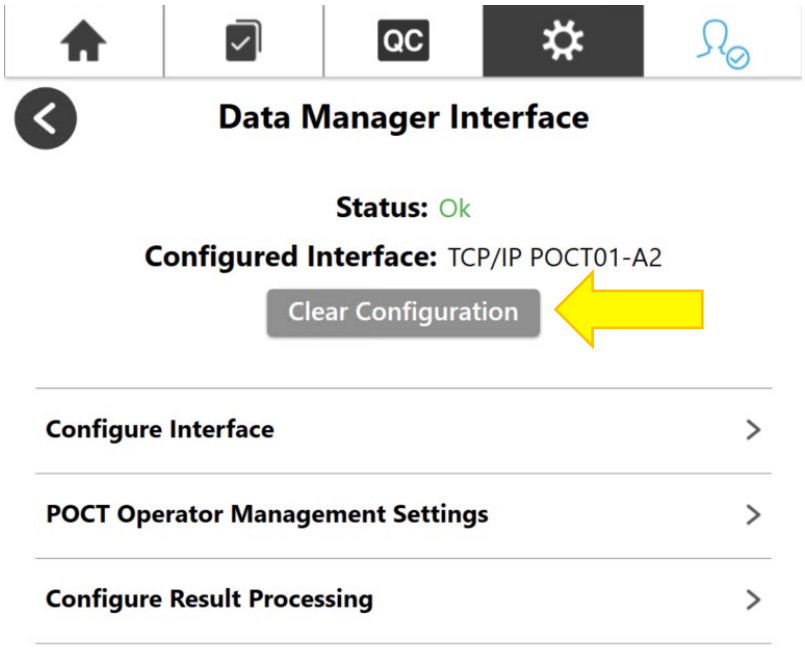
The software provides operators the option to clear (or de-configure) the current Data Manager Interface configuration. This option may be useful in scenarios where the current Data Manager has relocated to a different server, is communicating on a new port, or has been replaced entirely. Clearing the configuration may also be used to disable (or turn off) connectivity features on the SPOTFIRE System.

Note: Before clearing, it is recommended that operators export their current configuration interface settings to an external file. Refer to section 6.2.1 for details on exporting interface configuration settings.

Follow the steps listed below to clear the current Data Manager Interface configuration:

IMPORTANT: The instructions below apply regardless of the Configured Interface (e.g., TCP/IP POCT01-A2, MLLP, FTP Server, etc.) unless noted otherwise.

1. Select the **Clear Configuration** button displayed on the Data Manager Interface screen.



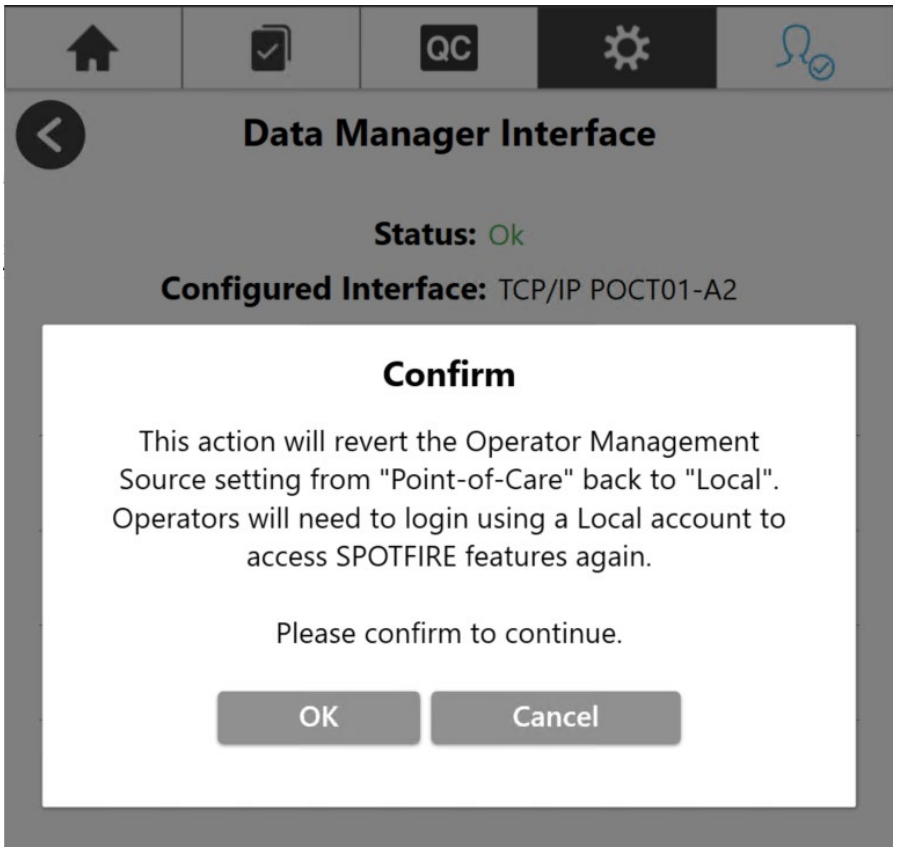
Note: The **Clear Configuration** button activates only if an interface is currently configured.

2. Select **OK** on the confirmation prompt to confirm the following as a result of clearing the configuration:

   - The Data Manager Interface must be re-configured in order to resume use of connectivity features in the future.
   - The **Automatic Result Processing** setting will be automatically disabled (refer to section 6.4.1 for more information).

   Note: Operators may alternatively select **Cancel** to retain the current configuration and return to the Data Manager Interface screen.

3. (conditional) Select **OK** on the confirmation prompt below to revert the **Operator Management Source** setting to “Local”.



Note: This step applies only if TCP/IP POCT01-A2 is configured AND the Operator Management Source setting was previously set to “Point-of-Care”. For more information on Operator Management Source selection, refer to section 3.3.

Note: Operators may alternatively select **Cancel** to retain the current Data Manager Interface configuration and Operator Management Source setting.

4. Upon confirmation, verify the **Status** updates to “Not Configured” and the **Configured Interface** updates to “None”.

6.3 Transmitting Test Results

The SPOTFIRE Connectivity Software allows patient test results to be automatically or manually sent to the connected Data Manager. The software can be configured to automatically send test results upon test completion using the **Automatic Result Processing** setting, as described in section 6.4.1. The sections below provide instructions for manually transmitting completed test results.

There are two options for manually transmitting test results to a Data Manager:

1. A single test result can be transmitted from the *Test Report* screen.
2. One or more test results can be selected and transmitted from the *Patient Test Results* screen.

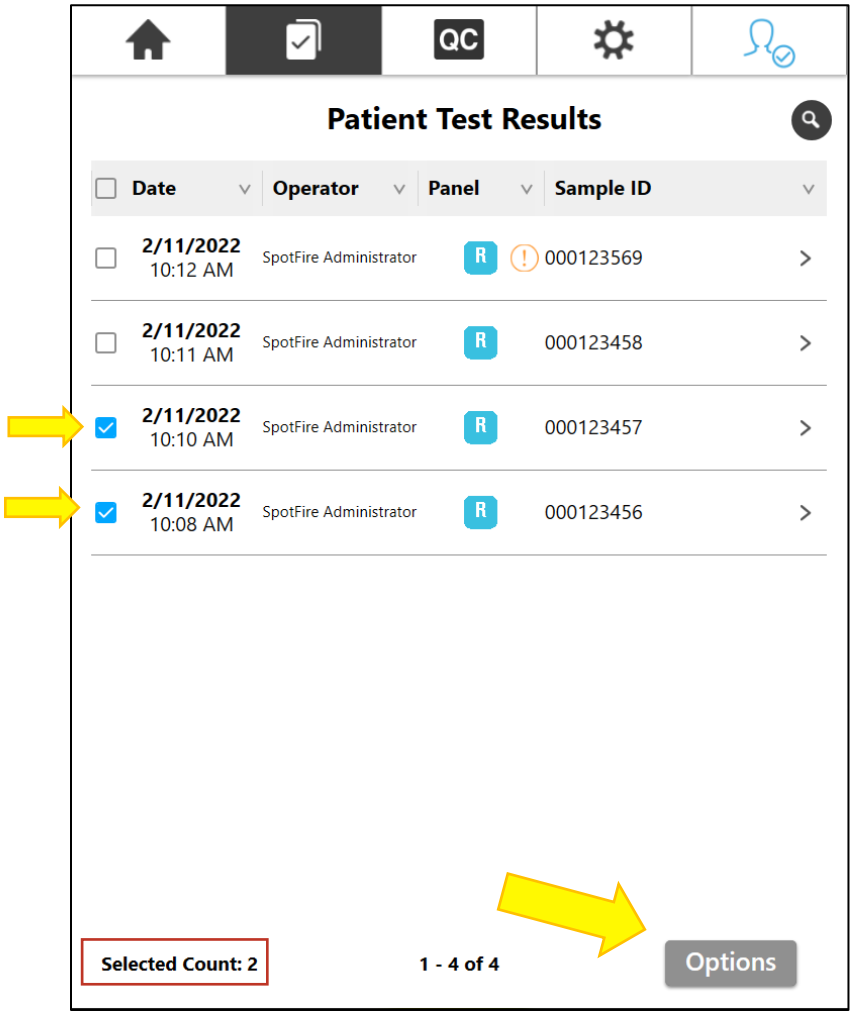
IMPORTANT: QC test results can also be transmitted to a connected Data Manager **only if** the POCT01-A2 interface is configured. Transmission of QC test results is not currently supported for XML or HL7 interface. The instructions below illustrate steps for transmitting patient test results, however, these instructions also apply when transmitting QC test results (accessible from the QC Tab > QC Tests > QC Test Results).

6.3.1 Transmit from Patient Test Results

Complete the following steps to manually transmit one or more results from the *Patient Test Result* screen.

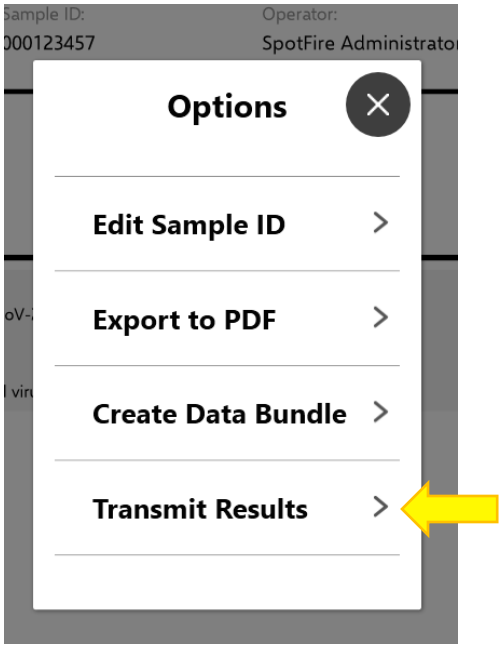
1. Select the Patient Results Tab from the SPOTFIRE toolbar.

2. Scroll and select the checkboxes corresponding to any of the test results listed on the *Patient Test Results* screen.



The **Selected Count** displays at the bottom of the screen to indicate the number of test results currently selected.

3. Select **Options**.
4. Select **Transmit Results** from the **Options** menu.

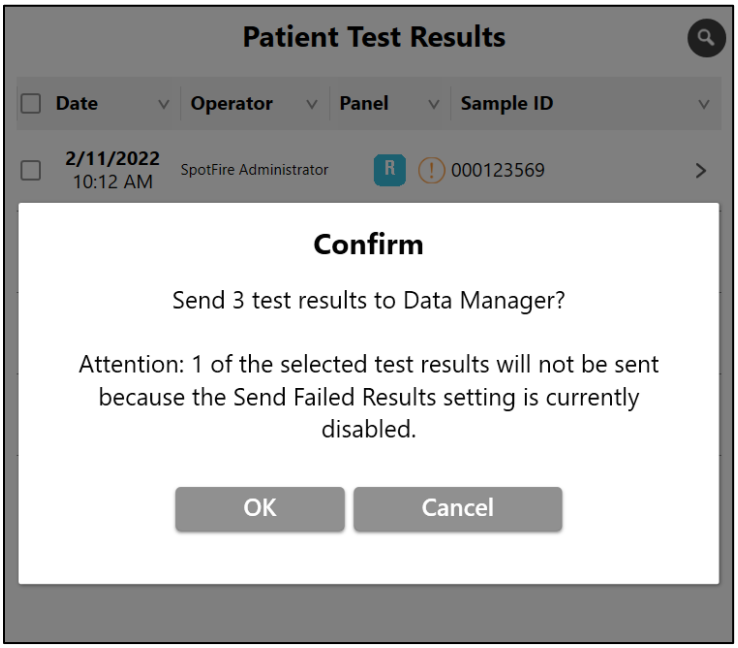


5. Select **OK** to confirm transmission of selected test results to the Data Manager.

   Alternatively, operators may select **Cancel** to return to the *Patient Test Results* screen without transmitting.

6. Select **OK** to acknowledge transmission, when prompted.

IMPORTANT: If any of the selected tests did not successfully complete as a result of a software error, internal control failure, etc. and the **Send Failed Results** setting is currently disabled, the software displays the following prompt when attempting to transmit to the Data Manager:



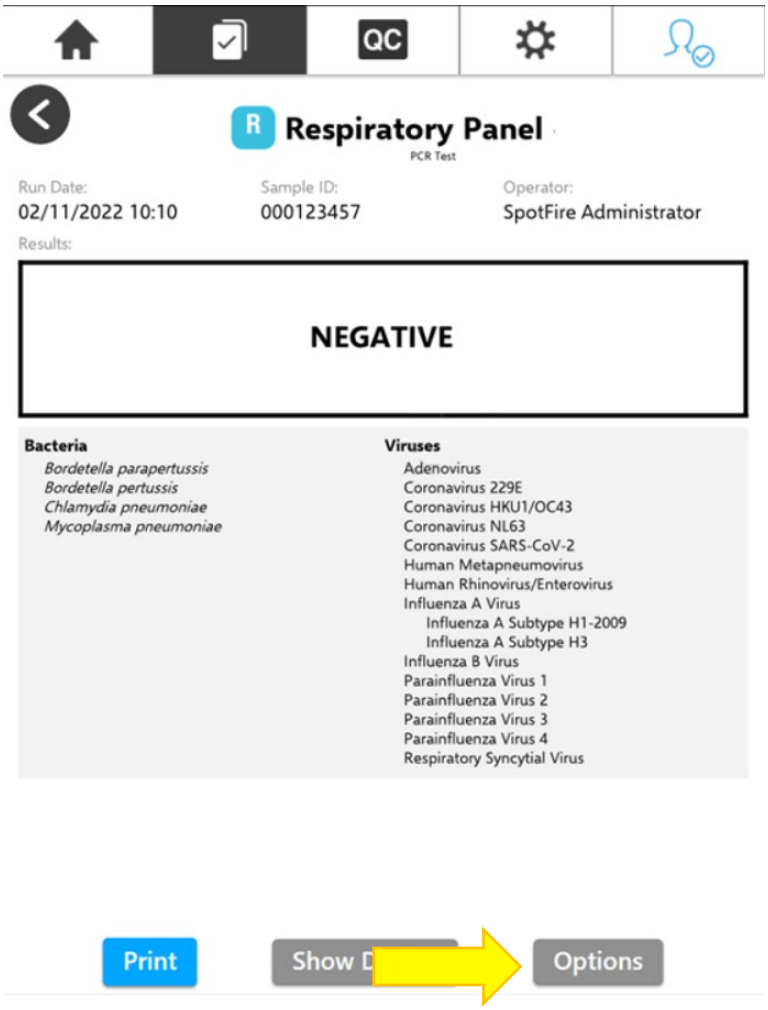
In this scenario, selecting **OK** transmits only the selected test results that completed successfully. Refer to section 6.4.3 for more information about the **Send Failed Results** setting.

6.3.2 Transmit from Test Report

Complete the following steps to manually transmit a test result from the *Test Report* screen.

1. Select the Patient Results Tab from the SPOTFIRE toolbar.

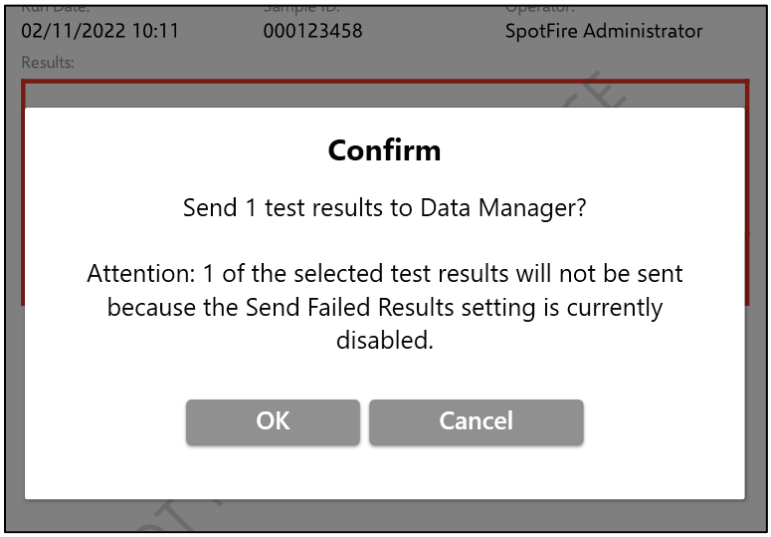
2. Scroll and select any listed test result, as desired, to view the corresponding test report.
3. Select the **Options** button at the bottom of the selected report.



4. Select **Transmit Results** from the **Options** menu.
5. Select **OK** to confirm transmission to the connected Data Manager.

   Alternatively, operators may select **Cancel** to return to the **Test Report** screen without transmitting.
6. Select **OK** to acknowledge test result transmission and return to the **Test Report** screen.

IMPORTANT: If the selected test did not successfully complete as a result of a software error, internal control failure, etc. and the **Send Failed Results** setting is currently disabled, the software displays the following prompt when attempting to transmit to the Data Manager:



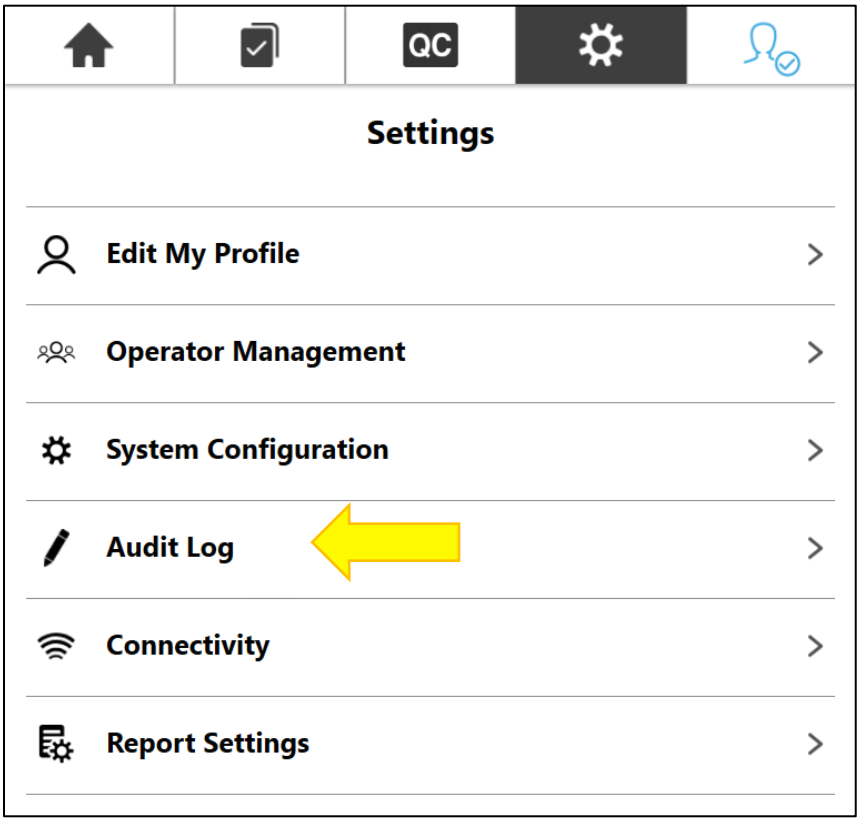
Refer to section 6.4.3 for more information about the **Send Failed Results** setting.

6.3.3 View Transmission Status from Audit Log

Transmission status for all automatically or manually transmitted test results are recorded in the SPOTFIRE Audit Log. The Audit Log indicates if a test result transmitted successfully to the Data Manager or if the transmission failed.

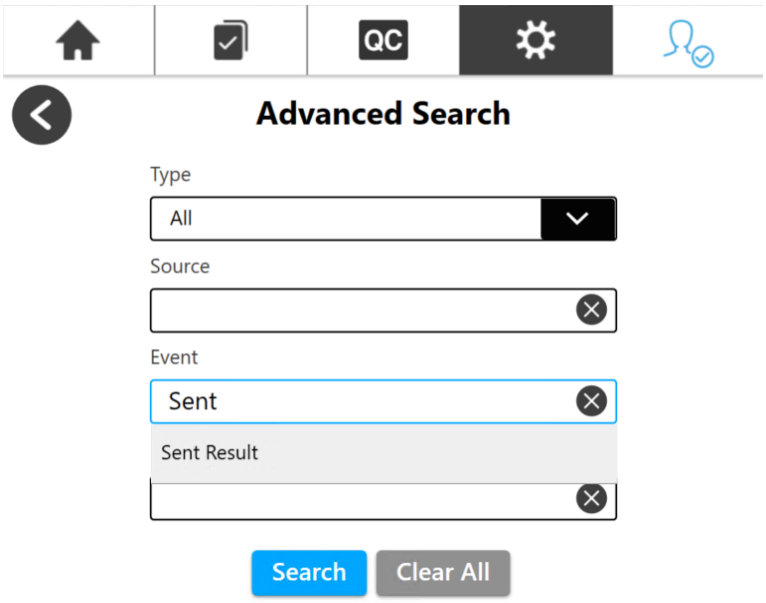
The following section provides instructions for using the Audit Log to view the status for any previously transmitted test results. Refer to BFR0001-1641 *BIOFIRE® SPOTFIRE® System Operator's Manual* For details about other types of events that are recorded in the Audit Log.

1. Select the **Settings** icon from the main toolbar, then select **Audit Log** from the menu provided.

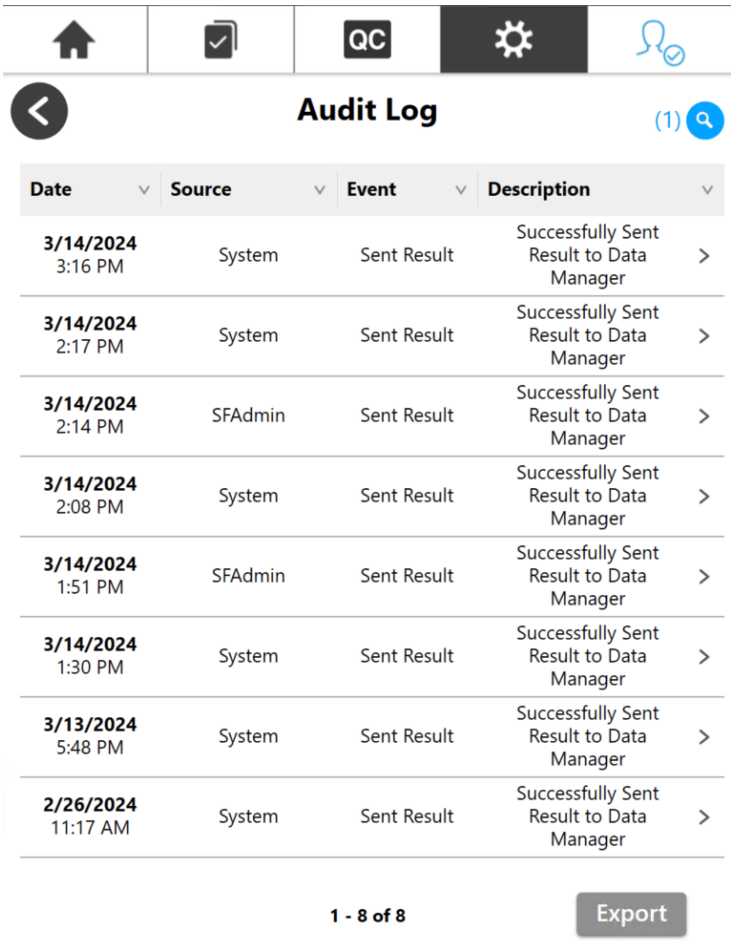


SPOTFIRE system, module, and operator events are displayed in a scrollable summary list. By default, events are sorted by date/time (most recent on top). Transmissions to the Data Manager appear in the list with an **Event** type of "Sent Run".

2. Select the  icon in the upper-right of the **Audit Log** screen to filter on Sent Run events.
3. Start typing "Sent Result" into the **Event** field on the *Advanced Search* screen. A list of available **Event** types dynamically displays based on the operator input, as shown in the figure below:



4. Select **Search** to view a list of matching Audit Log entries, as shown below:



5. Select any of the events listed in the Audit Log to view the corresponding Audit Entry Information.

The *Audit Entry Information* screen displays the following information for Sent Result events:

- **Operator ID**: Displays only for manually transmitted test results.
- **Date**: Date and time of transmission.
- **Description**: Indicates whether the transmission succeeded or failed.
- **More Information**: Identifies the Pouch Serial Number and Sample ID associated with the transmitted test result.

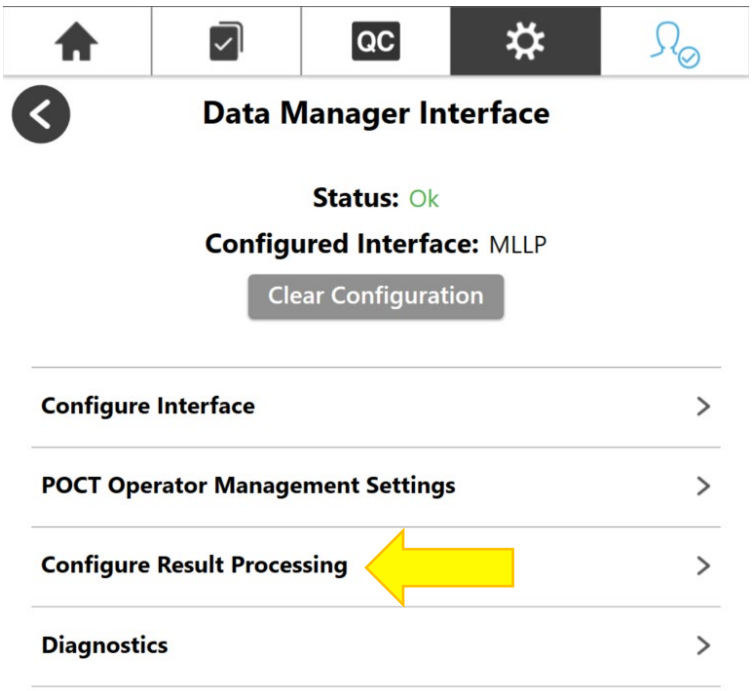
6.3.3.1 Additional Audit Log Events

In addition to test result transmission, the following connectivity-related events are also displayed in the SPOTFIRE Audit Log:

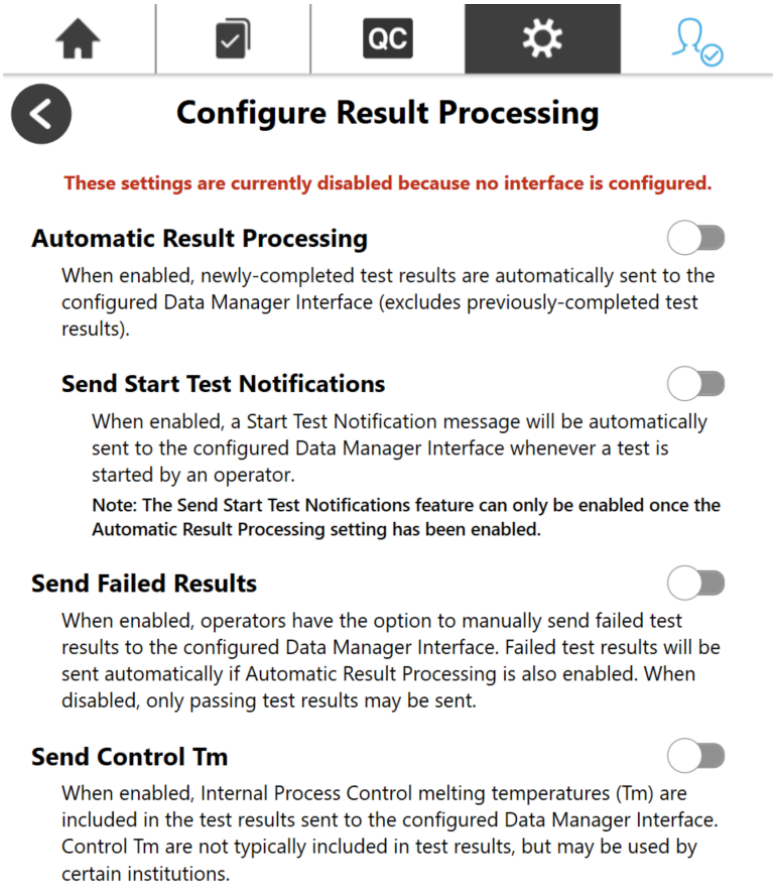
- Configuration of a new interface.
- Updates to an existing interface configuration.
- Receipt of test order information from a connected Data Manager (applies only if a bidirectional HL7 interface is configured).
- Receipt of an unsupported HL7 message type from a connected Data Manager (applies only if a bidirectional HL7 interface is configured).

6.4 Configure Result Processing Settings

The SPOTFIRE Connectivity Software provide configurable settings allowing operators to customize how test results are transmitted. These settings are available to SPOTFIRE administrators by selecting the **Configure Result Processing** option from the *Data Manager Interface* menu.



Settings on the **Configure Result Processing** screen can be updated only when a Data Manager Interface is currently configured. The settings become locked when the Data Manager Interface **Status** is "Not Configured", as shown below:



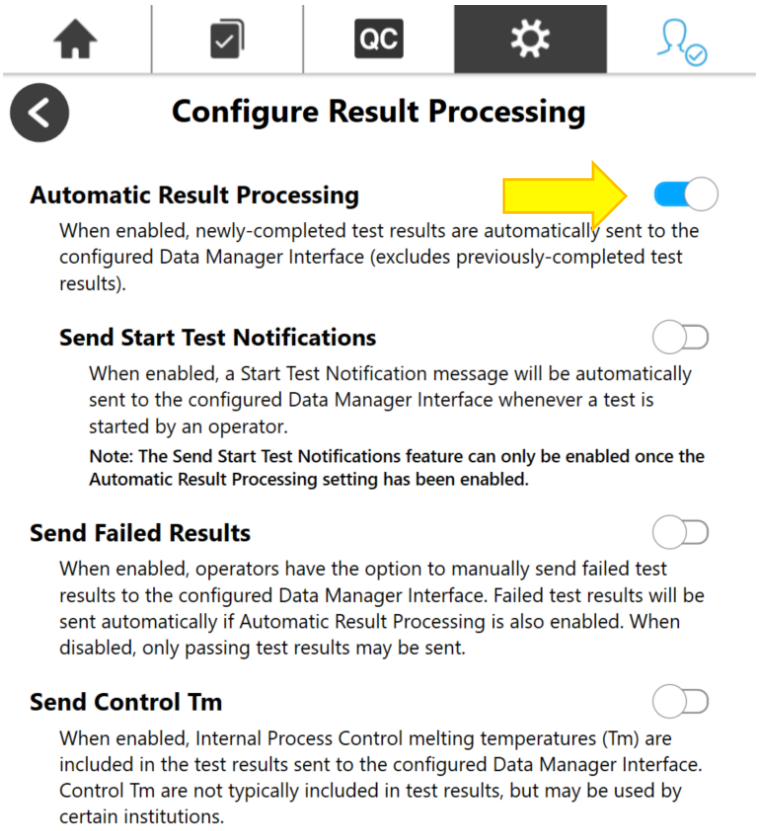
After the Data Manager interface is configured, all the settings provided on the **Configure Result Processing** screen become unlocked and can be enabled or disabled by a SPOTFIRE Administrator.

Note: Alternatively, if the POCT01-A2 interface is configured, a connected Data Manager has the ability to remotely update these settings via the POCT01-A2 interface. These remote updates are triggered when the Data Manager sends a SPOTFIRE Device Settings message to the SPOTFIRE System. Refer to section 3.4 for a complete list of SPOTFIRE Device Settings that may be enabled/disabled via the POCT01-A2 interface. Additionally, refer to BFR0001-5795: *BIOFIRE® SPOTFIRE® POCT01-A2 Interface Driver Development Guide* for more information about Device Settings messages and associated protocols.

Note: All settings on the **Configure Result Processing** screen are disabled by default.

6.4.1 Automatic Result Processing

The **Automatic Run Processing** setting, when enabled, allows future test results to be automatically sent to the Data Manager as tests complete on any connected SPOTFIRE modules. Any test results that completed prior to enabling the **Automatic Result Processing** setting must be transmitted manually, if necessary. Refer to section 6.3 for instructions on manually transmitting test results.



When **Automatic Result Processing** is enabled, test results are typically sent to the Data Manager within two (2) minutes of test completion, though transmission times may be slower during periods of high network activity.

The transmission status for all automatically processed test results is recorded in the SPOTFIRE Audit Log. Refer to section 6.3.3 for more information about using the SPOTFIRE Audit Log.

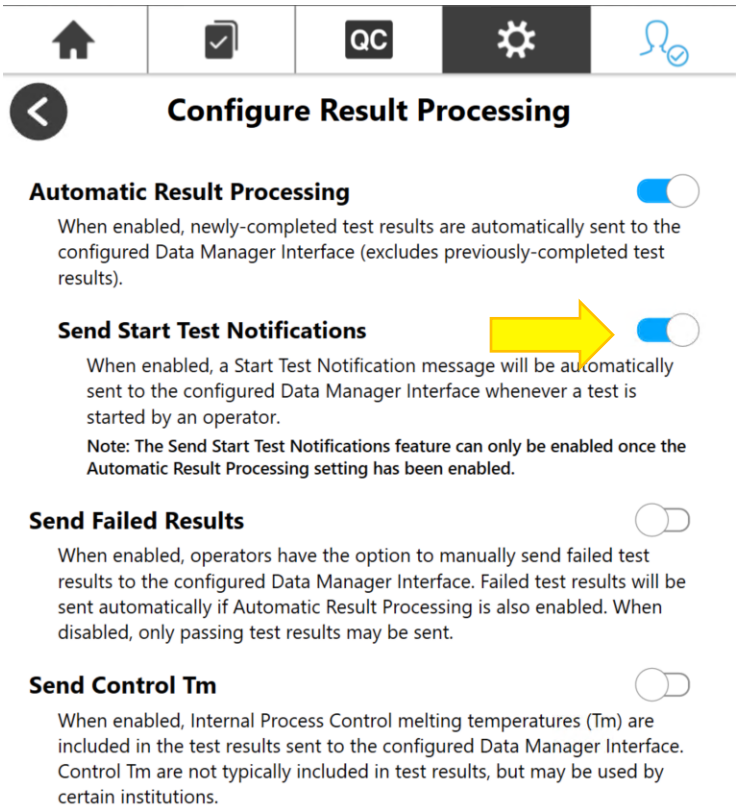
If a test result initially fails to transmit, the SPOTFIRE Connectivity Software will automatically retry the transmission two (2) additional times before failing. Any test results that fail to transmit during automatic processing may be manually processed by an operator at a later time.

Note: The software will automatically disable the **Automatic Result Processing** setting when the Data Manager interface configuration is cleared. Refer to section 6.2.3 for more information about clearing the interface configuration.

6.4.2 Send Start Test Notifications

IMPORTANT: The **Sent Start Test Notifications** setting is not available when the POCT01-A2 interface is configured.

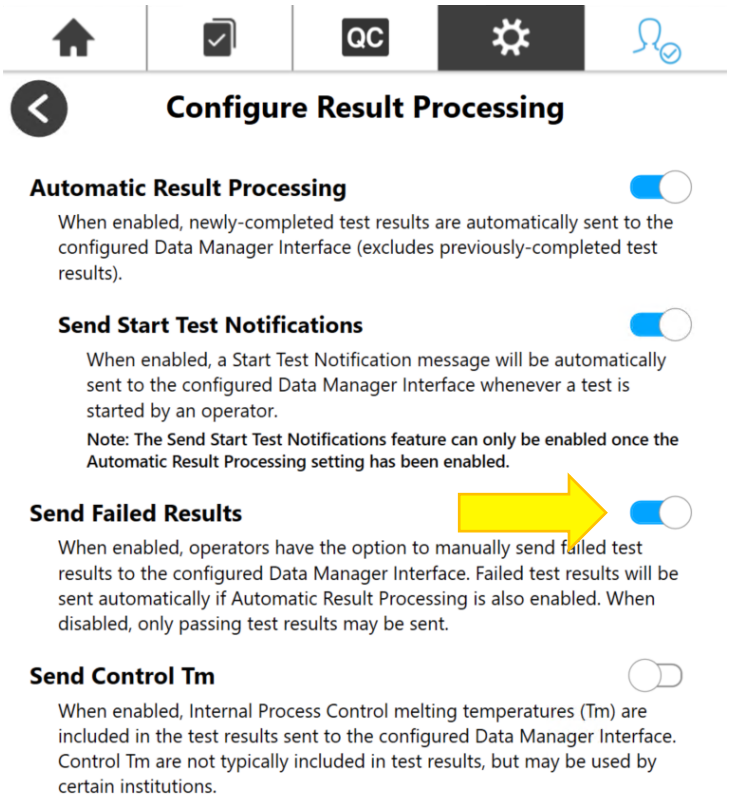
The **Send Start Test Notifications** setting, when enabled, transmits a notification message to the connected Data Manager when a new patient test has started on a connected SPOTFIRE module. The notification identifies the type of test being performed, the sample type being tested against, and the date/time the test is expected to complete.



The **Send Start Test Notifications** setting can only be enabled when the **Automatic Result Processing** setting is also enabled. If **Automatic Result Processing** is disabled (or the current interface configuration is cleared), the **Send Start Test Notifications** setting is automatically disabled and remains in locked state until **Automatic Result Processing** is later re-enabled.

6.4.3 Send Failed Results

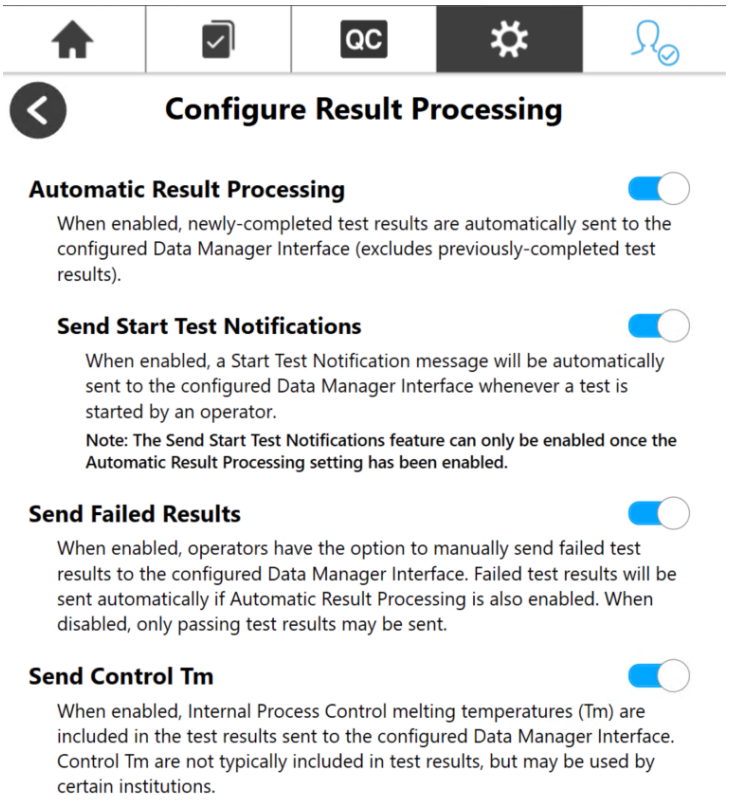
The **Send Failed Results** setting, when enabled, allows test results with a failure result code to be sent to the Data Manager. Failed test results may occur as a result of an aborted test, or software or instrument error.



When enabled, any failed test results may be sent manually to the Data Manager, or automatically if the **Automatic Result Processing** setting is also enabled.

6.4.4 Send Control Melt Temperatures (T_m)

The **Send Control T_m** setting, when enabled, allows internal process control results (e.g., RNA, PCR2) and melting temperatures (T_m) detected during testing to be included in test results sent to the Data Manager.



When the **Send Control T_m** setting is enabled, internal process control results are reported only if the patient test was completed. Similarly, control T_m results are reported only if the patient test was completed with a passing pouch result.

Note: Control results and T_m values are not typically included in test results but may be desired by certain institutions. Reported units of measure for T_m values are based on the Unified Code for Units of Measure (UCUM) coding standard.

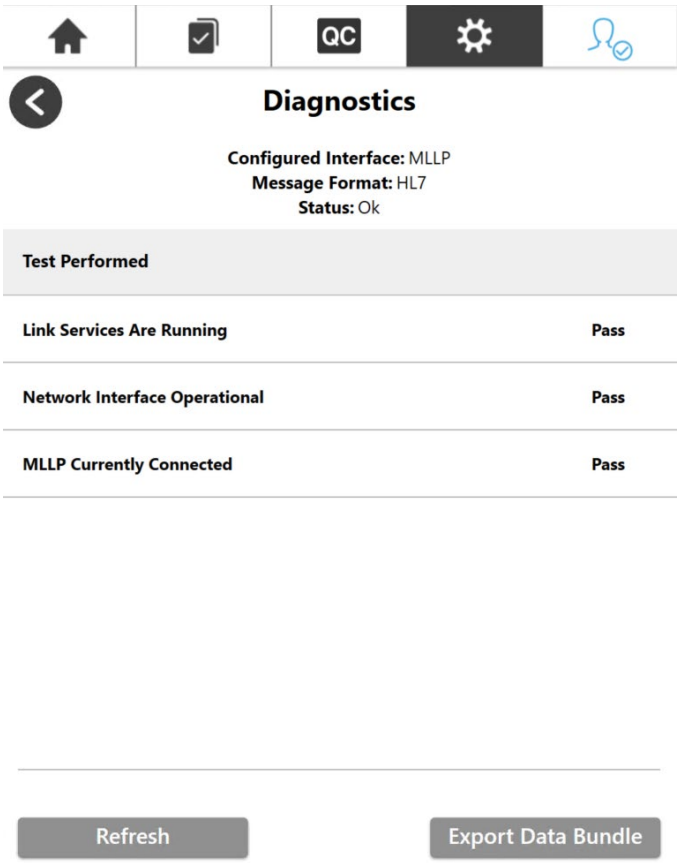
6.5 Diagnostics

The SPOTFIRE Connectivity Software provides a **Diagnostics** feature designed to assist operators with troubleshooting potential problems with the local network and/or interface to the connected Data Manager. Diagnostic information displayed in the software will vary depending on which interface (e.g., TCP/IP POCT01-A2, MLLP, FTP Server, etc.) is configured or if an interface is configured at all.

To run Diagnostics on the current interface:

1. Login to SPOTFIRE as an Administrator and navigate to the *Data Manager Interface* screen (Settings > Connectivity > Data Manager Interface).
2. Select the **Diagnostics** option.

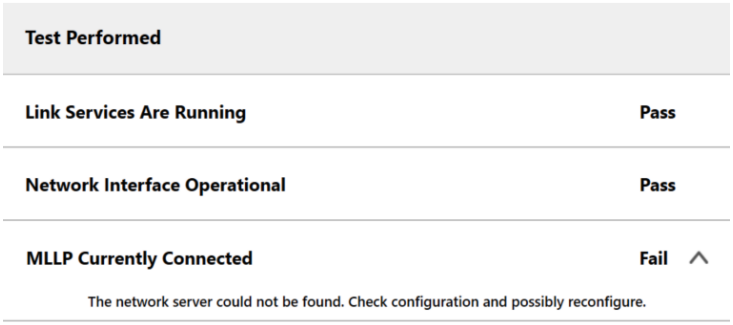
   The SPOTFIRE Connectivity Software will automatically perform a series of tests specific to the currently-configured interface and display the results in a diagnostic report, as shown below:



The diagnostic report displays the following:

- **Configured Interface** (e.g., TCP/IP POCT01-A2, MLLP, FTP Server, etc.)
- Applicable **Message Format** (e.g., POCT, HL7, XML)
- Interface **Status** (i.e., Ok, Error, Not Configured)
- List of **Tests Performed** (varies by interface)

Each **Test Performed** is displayed with a “Pass” or “Fail” result. Failing tests, if any, will also display a brief description of the problem with possible troubleshooting procedures. This additional information can be hidden by selecting the ^ icon corresponding to the failing test.



3. (optional) Select the **Refresh** button to rerun diagnostic tests and generate a new diagnostic report, as needed.

4. (optional) Select the **Export Data Bundle** button to save the diagnostic report as part of a System Data Bundle. Refer to section 7.5 for more information on Data Bundles.

6.6 System Notifications

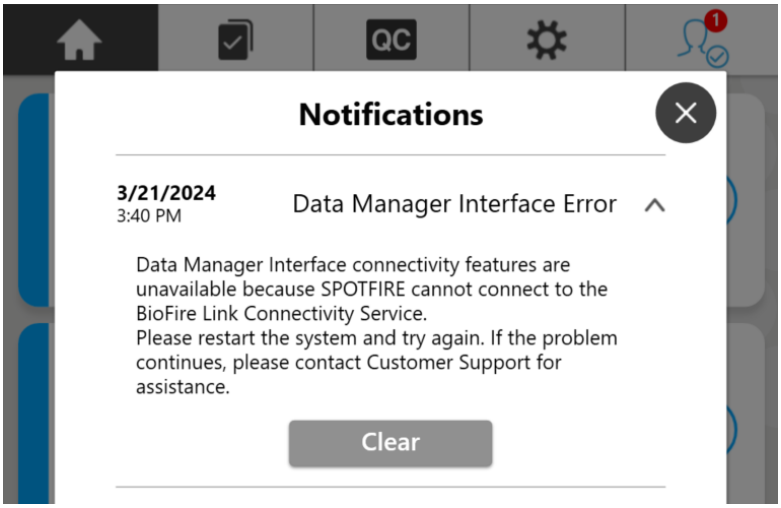
The SPOTFIRE Connectivity Software will display a system notification when essential connectivity services (i.e., the BioFire Link Connectivity Service) are unavailable or not running on the Windows operating system.

When this occurs, a 1 icon will display in the Access Control tab of the SPOTFIRE System Toolbar, as shown below:

To view the system notification:

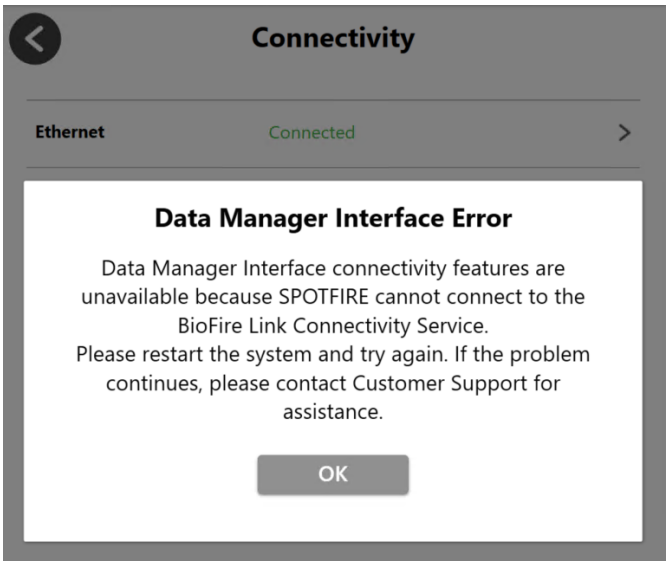
1. Select the Access Control tab from the SPOTFIRE System Toolbar.
2. Select the **Notifications** option:

   The software displays the notification date/time and a summary description in a pop-up dialog.
3. Select the ⌄ icon to expand the notification and display more detailed information:



4. Select the **Clear** button to remove the system notification, or alternatively, select the ⊗ icon close the dialog without removing the notification.

IMPORTANT: The same notification will re-appear after being cleared if problems with the connectivity services persist. Attempting to access the **Data Manager Interface** screen while the BioFire Link Connectivity Service is unavailable will result in the following error:


Connectivity
Ethernet
Connected
Data Manager Interface Error
Data Manager Interface connectivity features are unavailable because SPOTFIRE cannot connect to the BioFire Link Connectivity Service.
Please restart the system and try again. If the problem continues, please contact Customer Support for assistance.
OK

7. Troubleshooting

7.1 General Troubleshooting

The following table provides troubleshooting steps that can be used to resolve problems when using the SPOTFIRE Connectivity Software. These steps apply for **all** interfaces.

Issue	Troubleshooting Steps
Cannot import interface configuration settings	1. Verify that the interface configuration file (.sfcc or .flc) exists in the root directory of an available removable (e.g., USB) or mapped network drive. 2. Verify the interface configuration file has the correct values defined. 3. If the problem persists, export a data bundle and contact BIOFIRE Technical Support.
Cannot export interface configuration settings	1. Verify that all required fields contain valid values on the Configure Interface screen. 2. Verify that a removable (e.g., USB) or mapped network drive is available. 3. Check the destination drive/folder properties to ensure that Write access is allowed. 4. If the problem persists, export a data bundle and contact BIOFIRE Technical Support.
Data Manager Interface Status displays “Error”	1. Run diagnostics and follow any troubleshooting steps provided. 2. Verify your institution’s Data Manager is currently online and operational. 3. Verify the SPOTFIRE System is currently connected to the local network (Wireless or Ethernet). 4. Clear the current interface configuration (refer to section 6.2.3). 5. Re-configure the interface. 6. If the problem persists, export a data bundle and contact BIOFIRE Technical Support.
Unable to transmit completed test results to Data Manager	1. Verify your institution’s Data Manager is currently online and operational. 2. Verify the SPOTFIRE System is currently connected to the local network (Wireless or Ethernet). 3. Verify the **Automatic Result Processing** setting is enabled on the Configure Result Processing screen (refer to section 6.4.1), if applicable. 4. If attempting to transmit failed test results, verify the **Send Failed Results** setting is enabled on the Configure Result Processing screen (refer to section 6.4.3). 5. Verify the Run Tracker Service is running on the Windows OS. For more information about accessing the Windows OS on SPOTFIRE, refer to BFR0001-1641: *BIOFIRE® SPOTFIRE® System Operator’s Manual.* 6. If the problem persists, export a data bundle and contact BIOFIRE Technical Support.

Issue	Troubleshooting Steps
Data Manager Interface is not accessible in Connectivity menu	1. Verify your operator profile has Administrator permissions. For more information about operator permissions in SPOTFIRE, refer to BFR0001-1641: *BIOFIRE® SPOTFIRE® System Operator's Manual.* 2. Restart the SPOTFIRE control station. 3. Verify the BioFire Link Connectivity Service is running on the Windows OS. For more information about accessing the Windows OS on SPOTFIRE, refer to BFR0001-1641: *BIOFIRE® SPOTFIRE® System Operator's Manual.* 4. If the problem persists, export a data bundle and contact BIOFIRE Technical Support.
Cannot update Configure Result Processing settings	1. Verify that the Data Manager Interface is currently configured. 2. Configure the Data Manager interface, if needed. 3. If the problem persists, export a data bundle and contact BIOFIRE Technical Support.
Link Services Running test fails (when running Diagnostics)	1. Restart the SPOTFIRE control station. 2. Rerun diagnostics. 3. Verify the BioFire Link Connectivity Service is running on the Windows OS. For more information about accessing the Windows OS on SPOTFIRE, refer to BFR0001-1641: *BIOFIRE® SPOTFIRE® System Operator's Manual.* 4. If the problem persists, export a data bundle and contact BIOFIRE Technical Support.
Network Interface Operational test fails (when running Diagnostics)	1. Verify the SPOTFIRE System is currently connected to the local network (Wireless or Ethernet). 2. Configure connection to local network, as needed. For more information about connecting SPOTFIRE to a local network, refer to BFR0001-1641: *BIOFIRE® SPOTFIRE® System Operator's Manual.* 3. Restart the SPOTFIRE control station. 4. Rerun diagnostics. 5. If the problem persists, export a data bundle and contact BIOFIRE Technical Support.

7.2 POCT01-A2 Interface

The following table provides troubleshooting steps that can be used to resolve possible issues with the POCT01-A2 interface. BFR0001-5795: *BIOFIRE® SPOTFIRE® POCT01-A2 Interface Driver Development Guide* may be referenced in conjunction with the table below for more information about the interface.

Issue	Troubleshooting Steps
POCT01-A2 connection cannot be established	1. Verify your institution's Data Manager has a SPOTFIRE-compatible POCT01-A2 driver installed and fully configured. 2. Verify the SPOTFIRE System is currently connected to the local network (Wireless or Ethernet). 3. Verify the Host and Port values on the Configure Interface screen in SPOTFIRE match the IP address/hostname and TCP/IP port number the Data Manager is listening on. 4. Check with your institution's IT personnel to ensure that network firewalls permit TCP/IP traffic to the Data Manager host and port.
Missing/incomplete Operator List	1. Verify your institution's Data Manager is configured to transmit operator account information to SPOTFIRE. 2. Verify the **Operator Management Source** is set to Point-of-Care on the POCT Operator Management Settings screen. 3. Verify the PoctOperatorService is running on the Windows OS. For more information about accessing the Windows OS on SPOTFIRE, refer to BFR0001-1641: *BIOFIRE® SPOTFIRE® System Operator's Manual.*

7.3 XML Interface Configuration

The following table provides troubleshooting steps that can be used to resolve diagnostic test failures when an XML interface is configured. BFR0002-3721: *BIOFIRE® SPOTFIRE® XML Interface Driver Development Guide* may be referenced in conjunction with the table below for more information about the interface.

Interface	Issue	Troubleshooting Steps
FTP Server	*FTP Service Running* test fails	1. Restart the SPOTFIRE control station. 2. Rerun diagnostics. If the issue persists, proceed to the next step. 3. Reconfigure the FTP server interface while also verifying the correct credentials are entered. Refer to the instructions in section 4.3.2. 4. Rerun diagnostics again. 5. If the issue still persists, save the report by exporting a data bundle and contact BIOFIRE Technical Support.
	FTP Site Configured test fails	1. Reconfigure the FTP server interface while also verifying the correct credentials are entered. Refer to the instructions in section 4.3.2. 2. Rerun diagnostics. 3. If the issue persists, save the report by exporting a data bundle and contact BIOFIRE Technical Support.
	FTP User Configured test fails	1. Reconfigure the FTP server interface while also verifying the correct credentials are entered. Refer to the instructions in section 4.3.2. 2. Rerun diagnostics. 3. If the issue persists, save the report by exporting a data bundle and contact BIOFIRE Technical Support.

Interface	Issue	Troubleshooting Steps
	FTP File Downloaded test fails	1. Restart the SPOTFIRE control station. 2. Rerun diagnostics. If the issue persists, proceed to the next step. 3. Reconfigure the FTP server interface while also verifying the correct credentials are entered. Refer to the instructions in section 4.3.2. 4. Rerun diagnostics again. 5. If the issue persists, export a data bundle and contact BIOFIRE Technical Support.
	IIS Permissions test fails	1. Export a data bundle and contact BIOFIRE Technical Support.
HTTP Client	*HTTP Server Responding* test fails	1. Verify the SPOTFIRE System is currently connected to the local network (Wireless or Ethernet). 2. Rerun diagnostics. 3. If the test failed again, contact your institution's Data Manager support personnel to verify that their HTTP server is available and accepting POST requests. 4. If the issue persists, export a data bundle and contact BIOFIRE Technical Support.
LIS Shared Folder	*LIS Host Available* test fails	1. Verify the SPOTFIRE System is currently connected to the local network (Wireless or Ethernet). 2. Rerun diagnostics. 3. If the issue persists, reconfigure the LIS Shared Folder interface while also verifying the correct credentials are entered. Refer to the instructions in section 4.3.2. 4. Rerun diagnostics. 5. If the issue persists, export a data bundle and contact BIOFIRE Technical Support.
	Credentials Found for LIS Shared Folder test fails	1. Reconfigure the LIS Shared Folder interface while also verifying the correct credentials are entered. Refer to the instructions in section 4.3.2. 2. Rerun diagnostics. 3. If the issue persists, export a data bundle and contact BIOFIRE Technical Support.
	LIS Shared Folder Permissions Valid test fails	1. Verify the SPOTFIRE System is currently connected to the local network (Wireless or Ethernet). 2. With assistance from your institution's Data Manager support personnel, verify that the shared folder has read and write access for the user credentials provided. 3. Rerun diagnostics. 4. If the issue persists, reconfigure the LIS Shared Folder interface while also verifying the correct credentials are entered. Refer to the instructions in section 4.3.2. 5. Rerun diagnostics again. 6. If the issue persists, export a data bundle and contact BIOFIRE Technical Support.

Interface	Issue	Troubleshooting Steps
Local Folder	*Local Folder Permissions Valid* test fails	1. With assistance from your institution's Data Manager support personnel, verify that the local folder has read and write access for the SpotFire user account. 2. Rerun diagnostics. 3. If the issue persists, export a data bundle and contact BIOFIRE Technical Support.
Network Shared Folder	*Network Shared Folder Host Available* test fails	1. Verify the SPOTFIRE System is currently connected to the local network (Wireless or Ethernet). 2. Rerun diagnostics. 3. If the issue persists, reconfigure the Network Shared Folder interface while also verifying the correct credentials are entered. Refer to the instructions in section 4.3.2. 4. Rerun diagnostics. 5. If the issue persists, export a data bundle and contact BIOFIRE Technical Support.
Network Shared Folder	*Credentials Found for Network Shared Folder* test fails	1. Reconfigure the Network Shared Folder interface while also verifying the correct credentials are entered. Refer to the instructions in section 4.3.2. 2. Rerun diagnostics. 3. If the issue persists, export a data bundle and contact BIOFIRE Technical Support.
	Network Shared Folder Permissions Valid test fails	1. Verify the SPOTFIRE System is currently connected to the local network (Wireless or Ethernet). 2. With assistance from your institution's Data Manager support personnel, verify that the shared folder has read and write access for the user credentials provided. 3. Rerun diagnostics. 4. If the issue persists, reconfigure the Network Shared Folder while also verifying the correct credentials are entered. Refer to the instructions in section 4.3.2. 4. Rerun diagnostics again. 5. If the issue persists, export a data bundle and contact BIOFIRE Technical Support.

7.4 HL7 Interface Configuration

The following table provides troubleshooting steps that can be used to resolve diagnostic test failures when the HL7 interface is configured. BFR0002-3956: *BIOFIRE® SPOTFIRE® HL7 Interface Driver Development Guide* may be referenced in conjunction with the table below for more information about the interface.

Issue	Troubleshooting Steps
MLLP Connected test fails	1. Verify the SPOTFIRE System is currently connected to the local network (Wireless or Ethernet). 2. If the issue persists, reconfigure the MLLP interface while also verifying the correct Host and Port values. Refer to the instructions in section 5.5.2. 3. If the issue persists, export a data bundle and contact BIOFIRE Technical Support.

7.5 Data Bundles

If problems persist after performing the troubleshooting steps provided in the previous section, or if you encounter an issue not currently listed, it is recommended to create a System Data Bundle and contact BIOFIRE Technical Support. Contact information is provided in the next section.

IMPORTANT: The SPOTFIRE System must have access to a removable (e.g., USB) or mapped network drive in order to create and export a System Data Bundle. Ensure a USB is inserted into the SPOTFIRE Control Station, or a mapped network drive is available, before attempting to create a System Data Bundle.

For more information about creating System Data Bundles in SPOTFIRE, refer to BFR0001-1641: *BIOFIRE® SPOTFIRE® System Operator's Manual*.

8. Technical Support Contact Information

bioMérieux is dedicated to providing the best customer support available. If you have any questions or concerns about this process, please contact your local bioMérieux representative or authorized distributer.

NOTE FOR CUSTOMERS WITHIN THE EUROPEAN UNION (EU): Any serious incident that has occurred in relation to the SPOTFIRE device must be reported to a local bioMérieux sales representative and the competent authority of the Member State in which the user and/or the patient is established.

bioMérieux, Inc.
515 Colorow Drive
Salt Lake City, Utah 84108
USA
1-801-736-6354
1 800 735 6544
www.biomerieux.com

BFR0001-6608-03