



BIOFIRE® SPOTFIRE®

Connectivity User Guide

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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., point-of-care coordinator 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 and capabilities
- 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 the POCT01-A2 interface

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 6.

- BFR0001-5795: *BIOFIRE® SPOTFIRE® POCT01-A2 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 configure a Point of Care Testing (POCT01-A2) interface with a connected data manager. Upon successful configuration, the POCT01-A2 interface allows the SPOTFIRE System to bi-directionally communicate with the data manager.

The SPOTFIRE Control Station must be connected to a network to support data transfer to and from the connected data manager. The data manager must be also accessible from the same network as the SPOTFIRE.

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 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 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. Contact your Point-of-Care vendor representative for assistance.

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

3.2.2. Configure the POCT01-A2 Interface

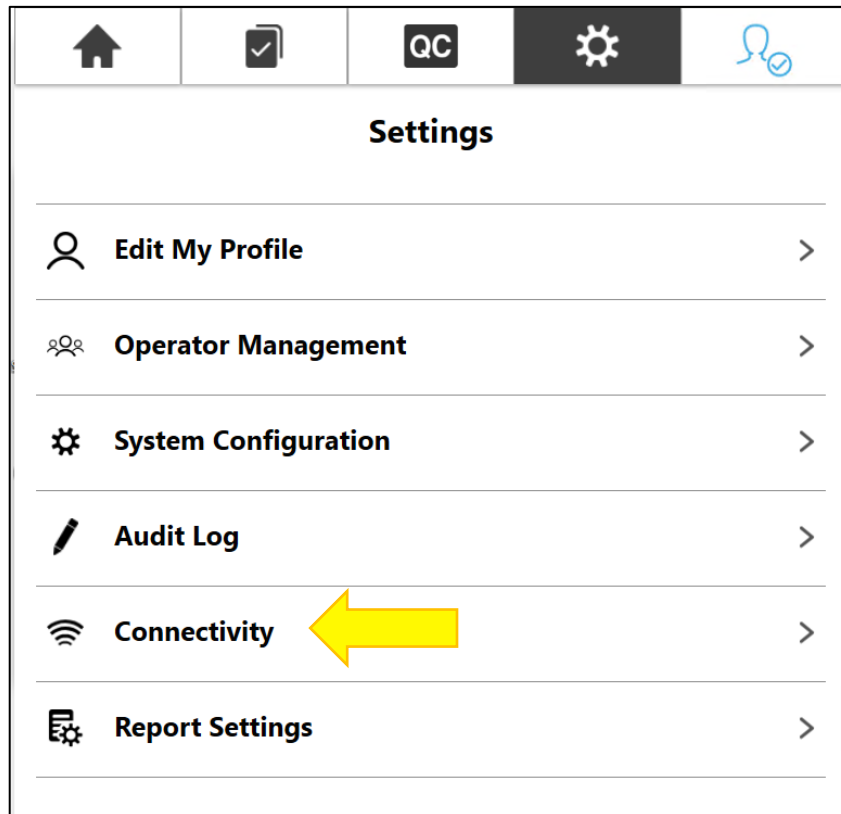
The SPOTFIRE Connectivity Software provides two ways to configure the POCT01-A2 interface:

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 4.2.2 to configure via file import.

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

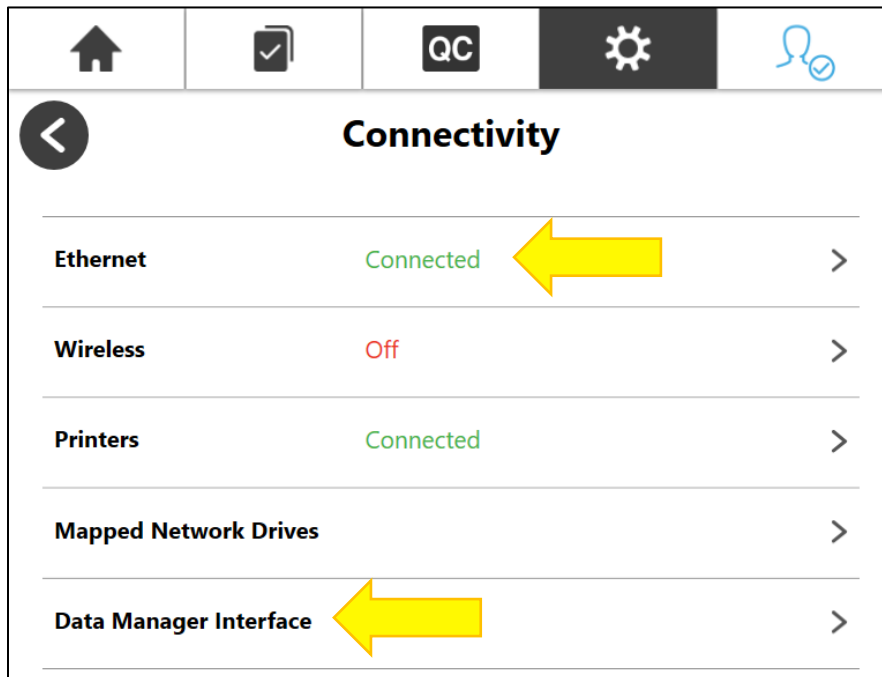
1. From the SPOTFIRE toolbar, select the **Settings** tab.
2. Select the **Connectivity** option from the Settings menu.



3. Ensure the SPOTFIRE is connected to the local network.

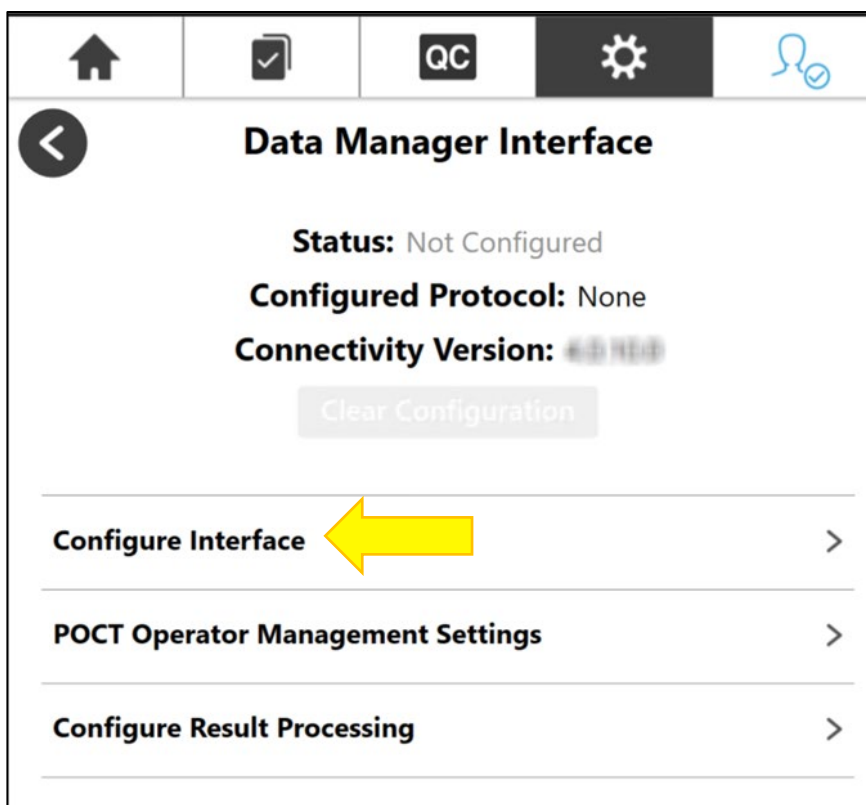
Either the **Ethernet** or **Wireless** options in the Connectivity menu should display “Connected”. Refer to BFR0001-1641: *BIOFIRE® SPOTFIRE® System Operator’s Manual* for information on connecting the SPOTFIRE to your institution’s local network.

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



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

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



6. Use the on-screen keyboard to enter the following information on the **Configure Interface** screen.

Field	Description
Selected Interface	Defaults to "TCP/IP POCT01-A2". No other options are currently available.
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.

Configure Interface

Selected Interface: TCP/IP POCT01-A2 ▼

Import

Export

Host: 172.24.18.57

Port: 3000

1 2 3 4 5 6 7 8 9 0

q w e r t y u i o p

a s d f g h j k l

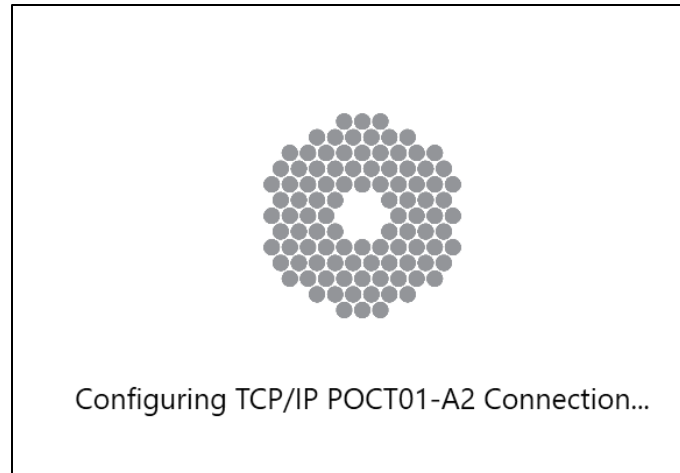
z x c v b n m , .

+=

Save

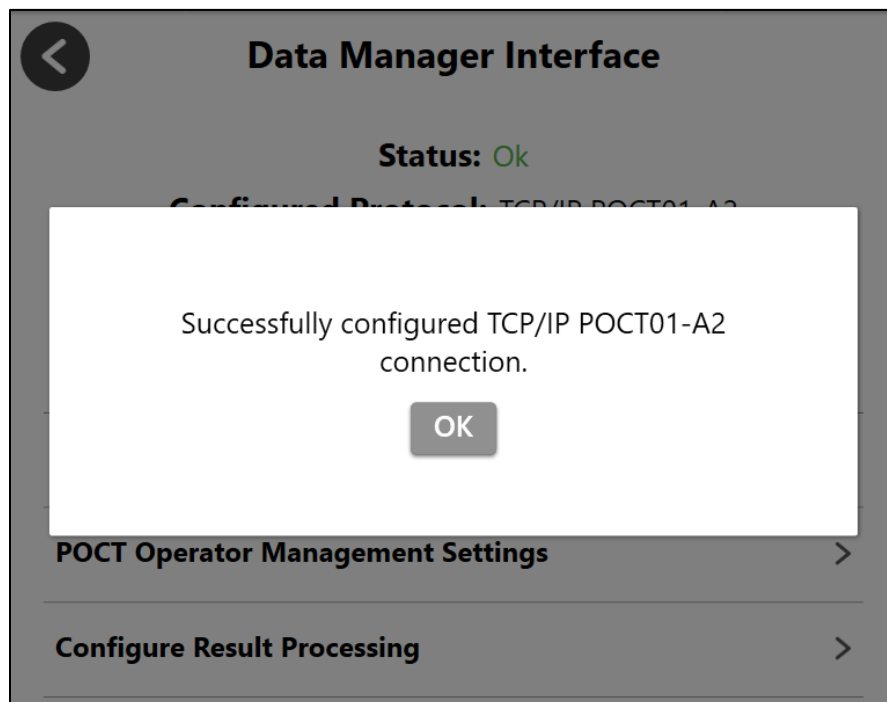
7. Select **Save**.

Upon **Save**, the SPOTFIRE Connectivity Software attempts to establish a TCP/IP connection with the Data Manager using the **Host** and **Port** settings provided. The dialog shown below displays while SPOTFIRE communicates with the Data Manager to complete the connection.



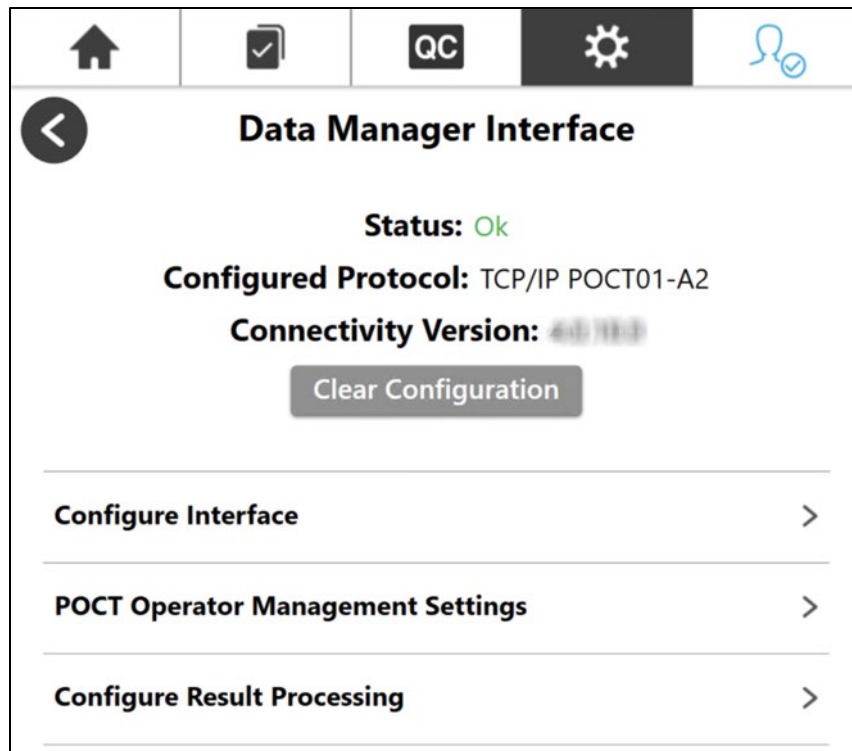
Note: For more information about background processes and data exchanges occurring between SPOTFIRE and the Data Manager while the POCT01-A2 connection is being established, refer to BFR0001-5795: *BIOFIRE® SPOTFIRE® POCT01-A2 Interface Driver Development Guide*.

The following dialog message displays after the POCT01-A2 connection is successfully configured.



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

8. Select **OK** to complete the POCT01-A2 interface configuration.



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 Protocol** field updates from “None” to “TCP/IP POCT01-A2”.

3.2.3. Validate Interface from Data Manager

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.

4. 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:

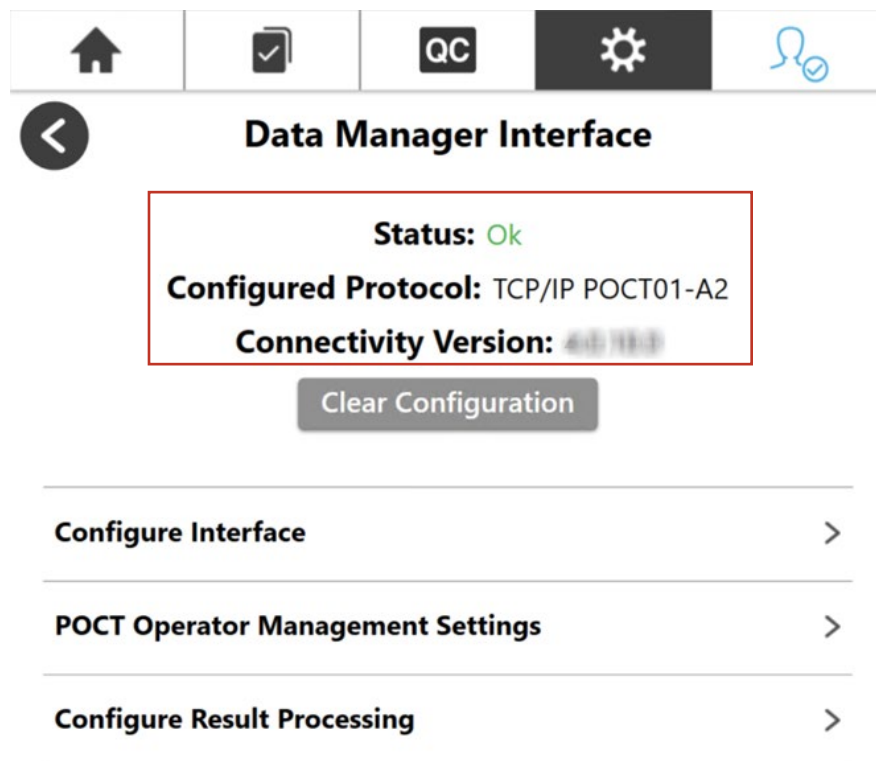
- Viewing the current status of the POCT01-A2 interface
- Managing the current POCT01-A2 interface configuration
- Importing or exporting the POCT01-A2 interface configuration settings
- Configuring POCT Operator Management Settings
- Configuring Result Processing settings, including:
 - Automatic Result Processing
 - Send Failed Results
 - Send Control melting temperatures (T_M)

Note: A POCT01-A2 interface must be currently configured in order to access and configure POCT Operator Management and Configure Result Processing settings. If the POCT01-A2 interface has not been configured, please refer to section 3.2.

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

4.1. View the Status of the POCT01-A2 Interface

The status of the POCT01-A2 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. Refer to section 3.2 for help configuring the interface.
Error	A connection error has been detected and communication with the Data Manager has been disrupted. Refer to section 5 for troubleshooting steps.

Configured Protocol displays the current data transfer protocol being used. Currently, “TCP/IP POCT01-A2” is the only protocol supported by the SPOTFIRE Connectivity Software. The **Configured Protocol** will display as “None” if no interface is currently configured.

The **Connectivity Version** displays the version of SPOTFIRE Connectivity Software currently installed on the SPOTFIRE System.

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.

4.2. 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.

4.2.1. 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.

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

The screenshot shows the 'Data Manager Interface' with a top navigation bar containing icons for home, checkmark, QC, settings, and a user profile. The interface displays 'Status: Ok' in green, 'Configured Protocol: TCP/IP POCT01-A2', and 'Connectivity Version: 4.0.18.3'. A 'Clear Configuration' button is present. Below this is a list of options: 'Configure Interface', 'POCT Operator Management Settings', and 'Configure Result Processing', each with a right-pointing chevron. A large yellow arrow points to the 'Configure Interface' option.

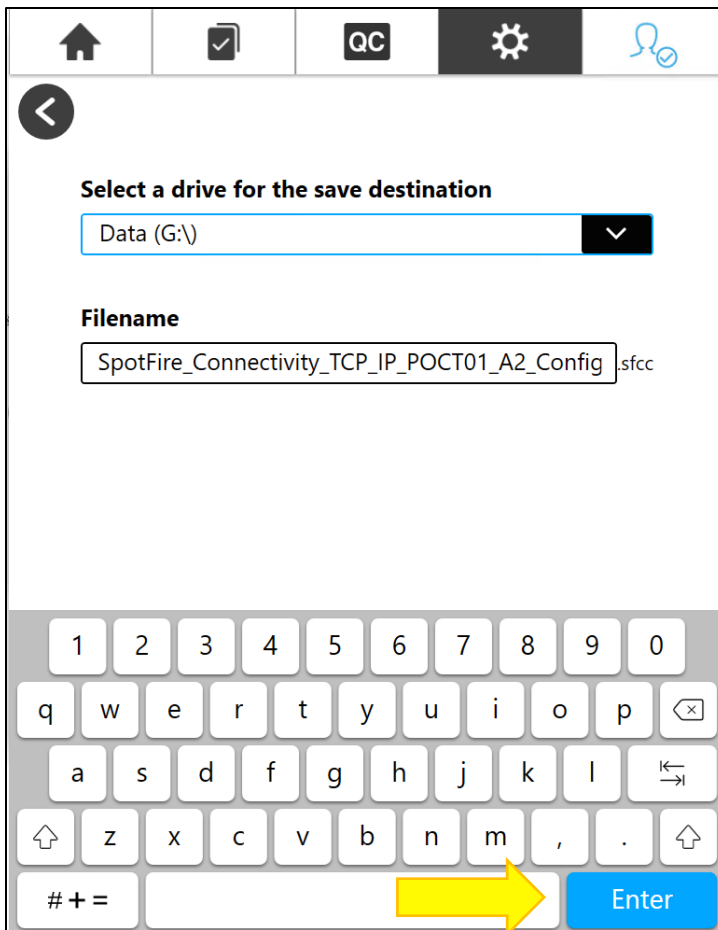
2. Select the **Export** button.

The screenshot shows the 'Configure Interface' dialog box. It has a top navigation bar with icons for home, checkmark, QC, settings, and a user profile. The dialog displays 'Selected Interface:' with a dropdown menu showing 'TCP/IP POCT01-A2'. To the right of the dropdown are 'Import' and 'Export' buttons. Below the dropdown are 'Host:' and 'Port:' fields with input boxes containing '172.24.16.43' and '3000' respectively. A large yellow arrow points to the 'Export' button.

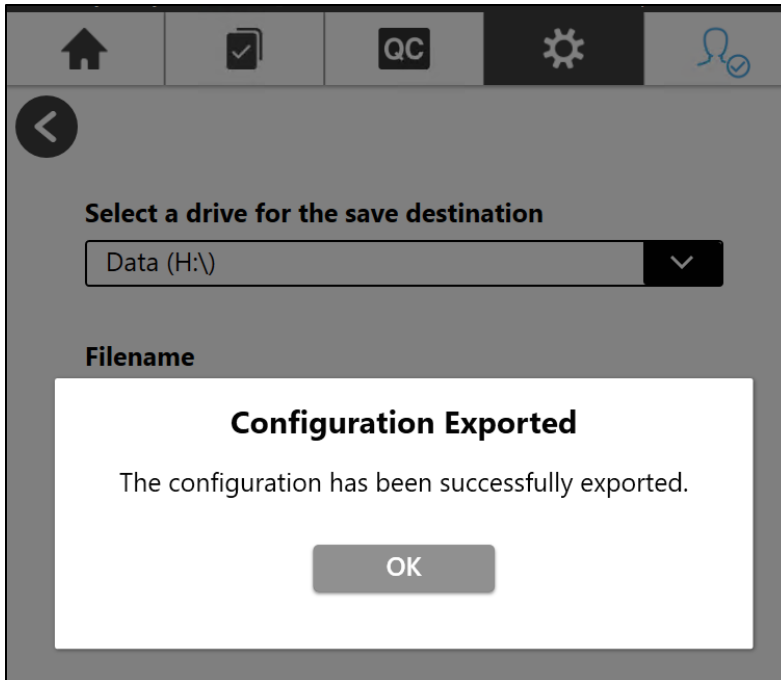
3. **Select a drive for the save destination** using the dropdown menu provided.
4. (optional) Edit the export **Filename**, as desired.

Note: The software defaults the **Filename**, as follows:
SPOTFIRE_Connectivity_TCP_IP_POCT01_A2_Configuration_<YY-MM-DD>_<hh-mm-ss>_<SPOTFIRE Control Station Serial Number>.sfcc

5. Select **Enter** to export.



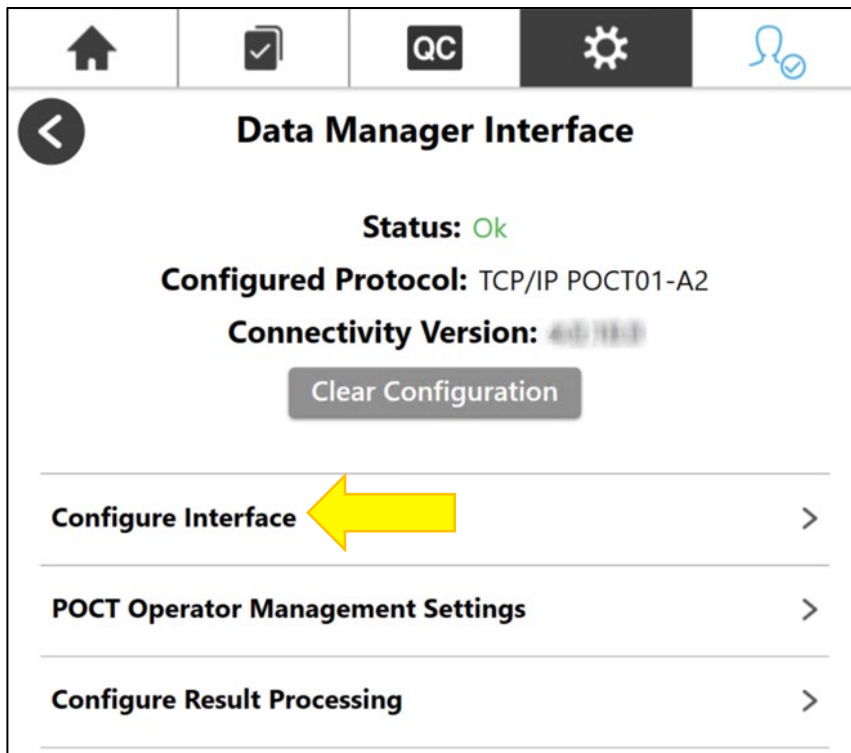
6. Select **OK** to complete file export.



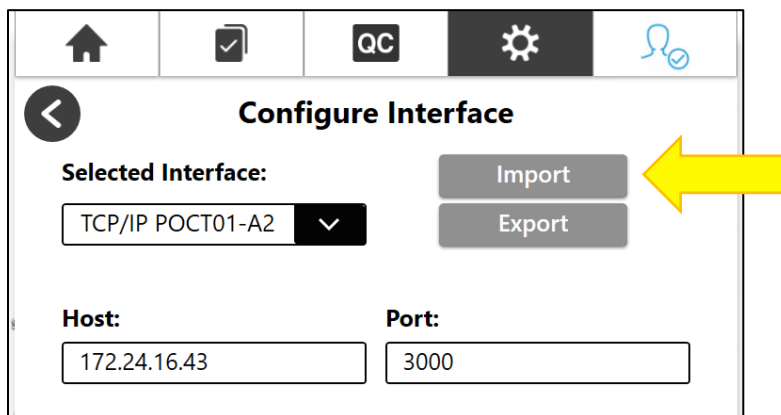
4.2.2.Import Interface Configuration

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

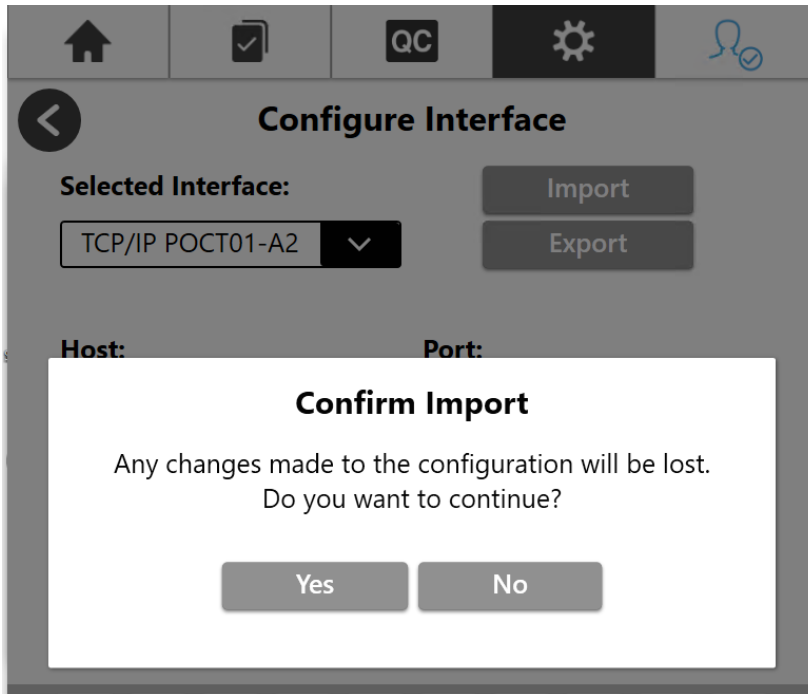
1. Place a previously exported interface configuration file (.sfcc) onto the root directory of a removable USB or mapped network drive accessible to the SPOTFIRE.
2. Select the **Configure Interface** option from the **Data Manager Interface** screen.



3. Select the **Import** button.



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

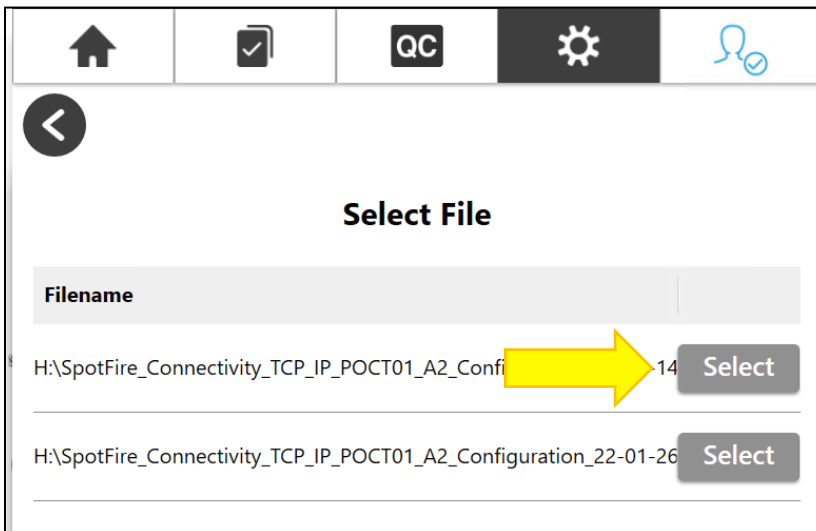


Operators may alternatively select **No** to cancel import and return to the previous screen.

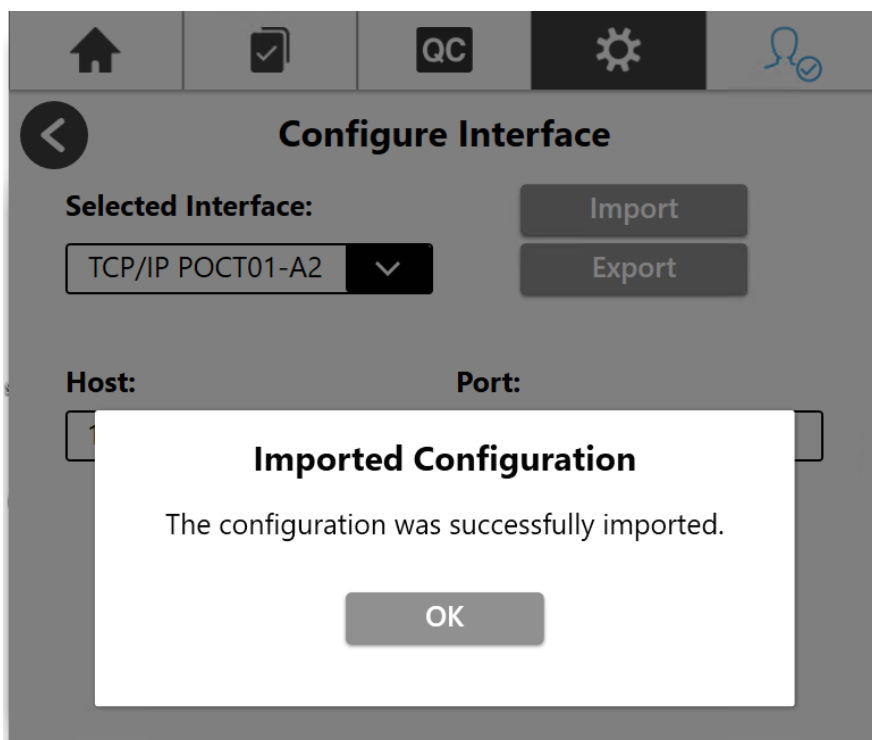
5. Locate the desired import file in the list provided.

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

6. Press the **Select** button corresponding to the appropriate file.



7. Select **OK** to complete file import.



8. Verify the imported **Host** and **Port** values on the **Configure Interface** screen.
9. Select **Save** to initiate a new connection to the Data Manager.

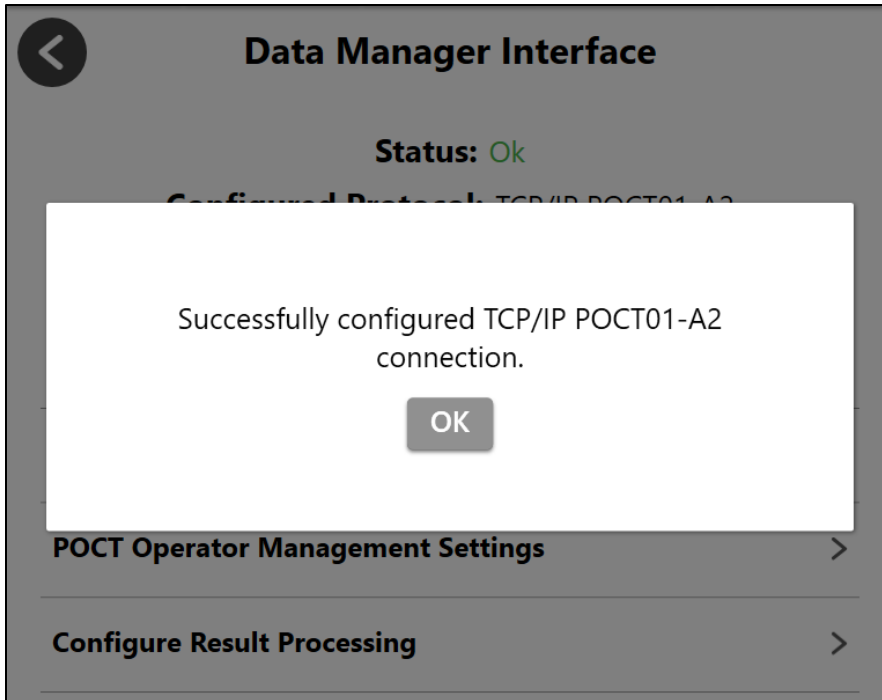
Configure Interface

Selected Interface: TCP/IP POCT01-A2 Import Export

Host: 172.24.16.43 **Port:** 3000

Save

The following dialog message displays after the POCT01-A2 connection is successfully configured.



10. Click **OK** to close dialog and return to the **Data Manager Interface** screen.

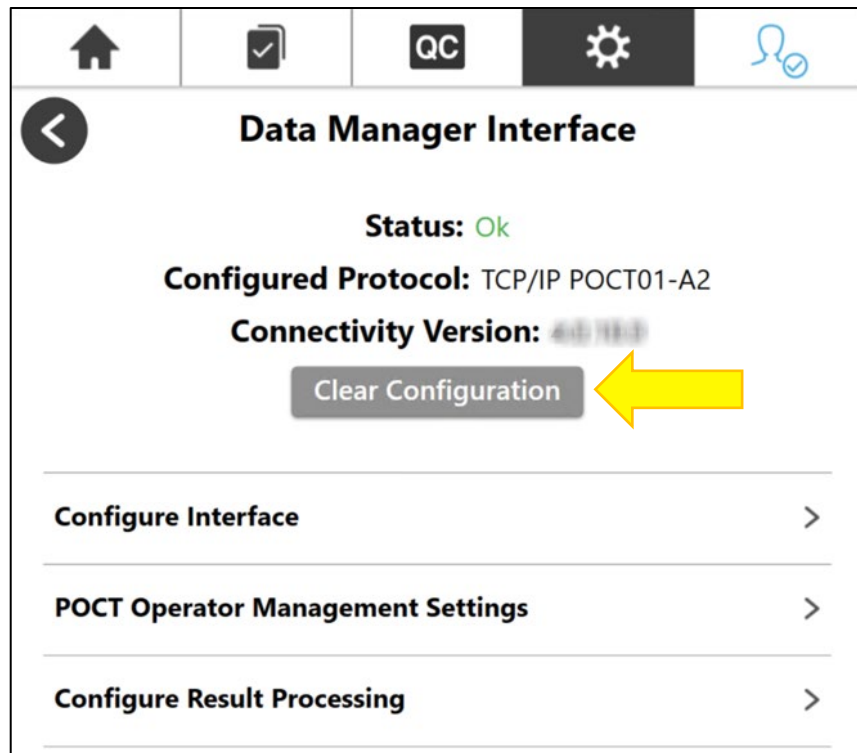
4.2.3. Clearing Interface Configuration

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 4.2.1 for details on exporting interface configuration settings.

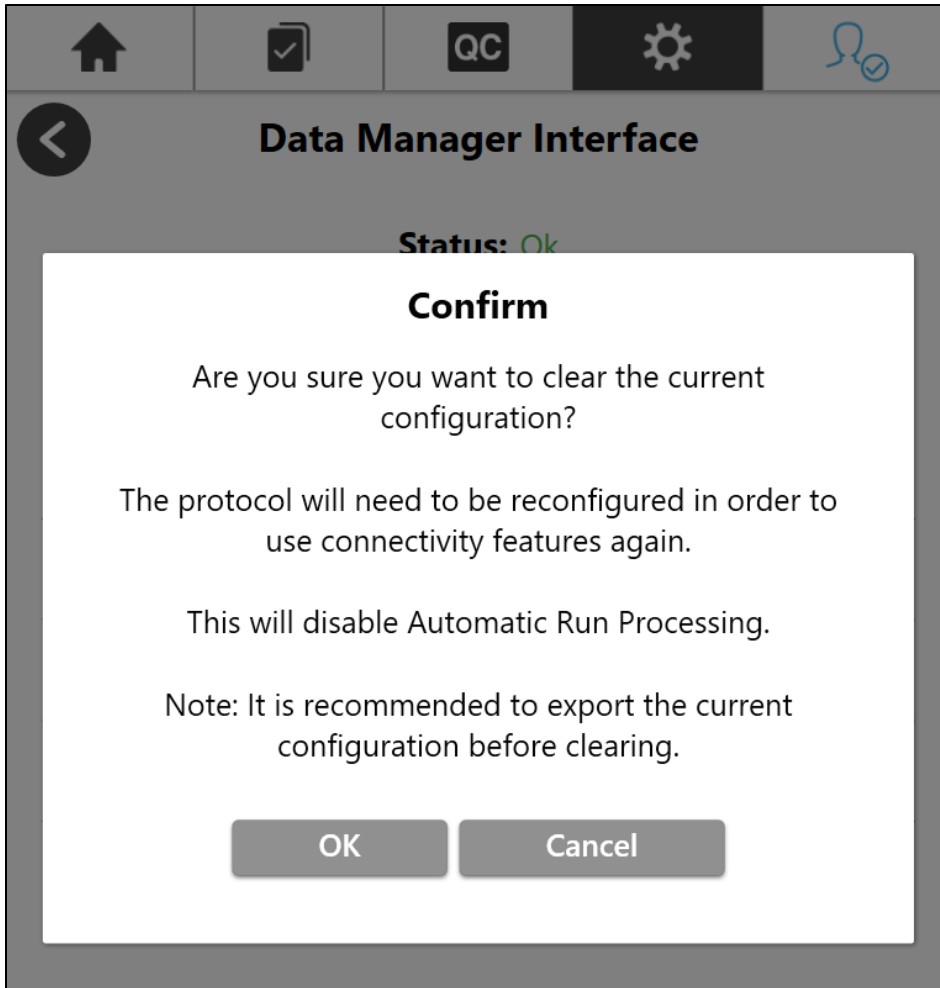
Follow the steps listed below to clear the current Data Manager Interface configuration:

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



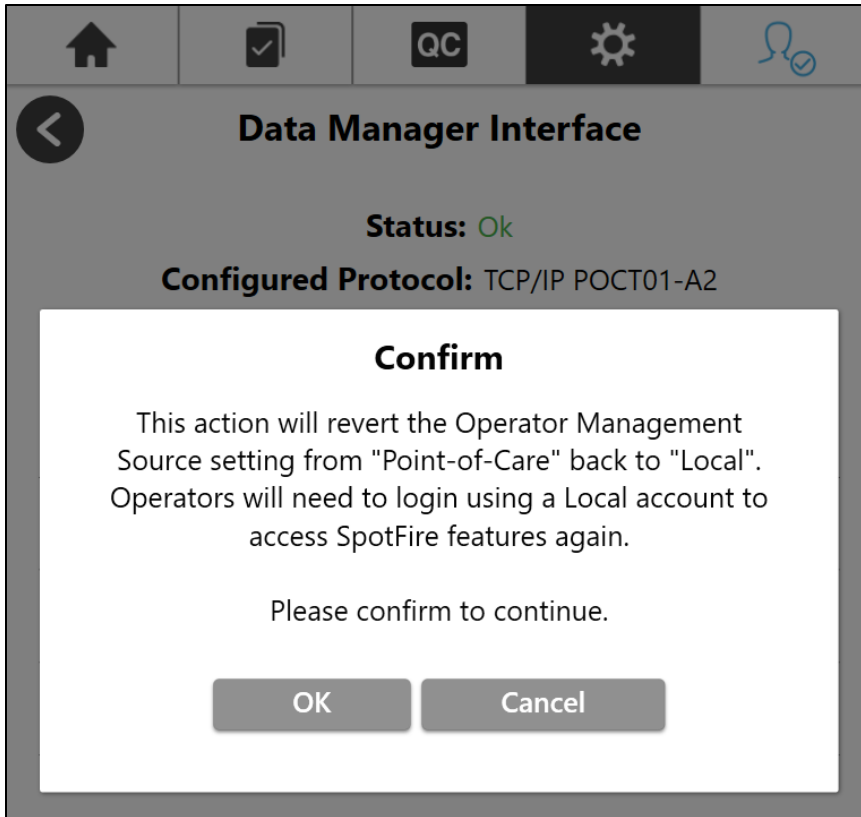
Note: The **Clear Configuration** button activates only if an interface is currently configured.

2. Select **OK** on the confirmation prompt (shown below) to confirm the action.



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

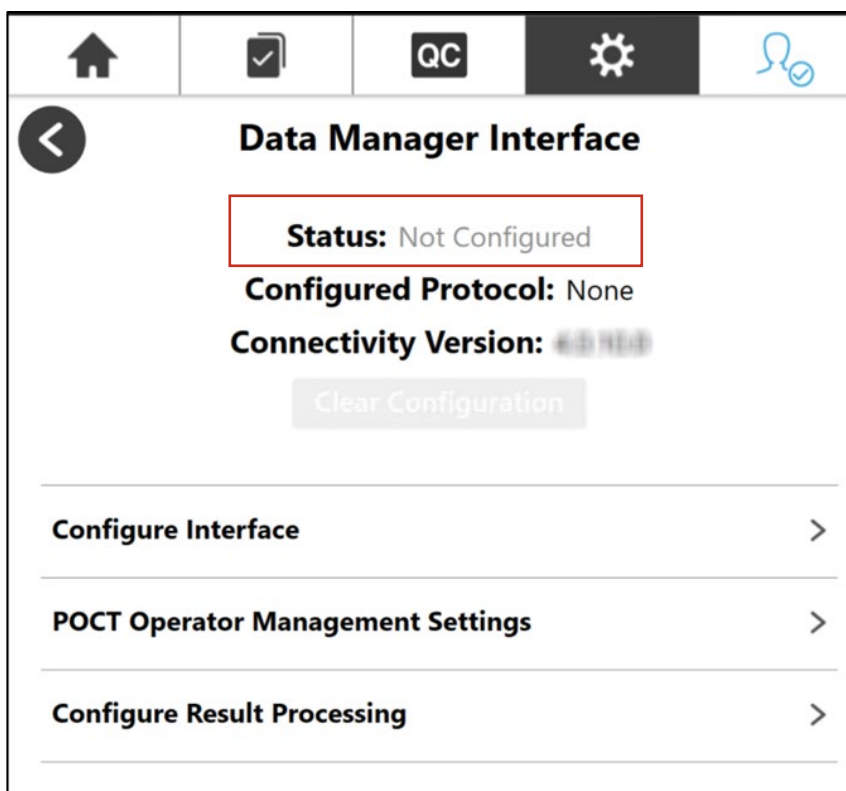
3. If applicable, select **OK** on the confirmation prompt below to revert the Operator Management Source setting to "Local".



Note: This step applies only if the Operator Management Source setting was previously set to "Point-of-Care". For more information on Operator Management Source selection, refer to section 4.5.

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 Protocol** updates to "None".



4.3. Transmitting Test Results

The SPOTFIRE Connectivity Software allows patient and QC test results associated with completed pouch runs to be automatically or manually sent to the connected Data Manager. Instructions for enabling/disabling **Automatic Result Processing** on the SPOTFIRE System are provided in section 4.3.1. 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 (or QC) Test Results screen(s).

Note: The instructions below demonstrate steps for transmitting patient test results, but the same steps may be used to transmit QC test results.












4.3.1. 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** detail screen.

				
Patient Test Results 				
<input type="checkbox"/>	Date ▾	Operator ▾	Panel ▾	Sample ID ▾
<input type="checkbox"/>	2/11/2022 10:12 AM	SpotFire Administrator	 	000123569 >
<input type="checkbox"/>	2/11/2022 10:11 AM	SpotFire Administrator		000123458 >
<input type="checkbox"/>	2/11/2022 10:10 AM	SpotFire Administrator		000123457 >
<input type="checkbox"/>	2/11/2022 10:08 AM	SpotFire Administrator		000123456 >



3. Select the **Options** button at the bottom of the selected report.

Respiratory Panel - IUO

PCR Test

Run Date:
02/11/2022 10:10

Sample ID:
000123457

Operator:
SpotFire Administrator

Results:

NEGATIVE

Bacteria

- Bordetella parapertussis*
- Bordetella pertussis*
- Chlamydia pneumoniae*
- Mycoplasma pneumoniae*

Viruses

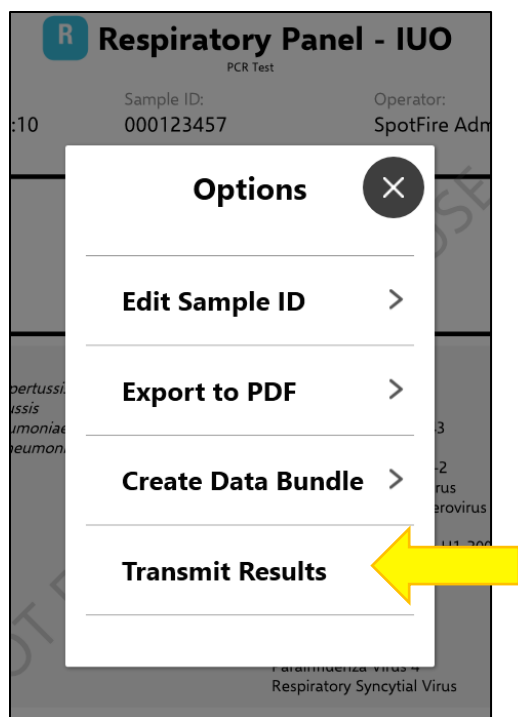
- Adenovirus
- Coronavirus 229E
- Coronavirus HKU1/OC43
- Coronavirus NL63
- Coronavirus SARS-CoV-2
- Human Metapneumovirus
- Human Rhinovirus/Enterovirus
- Influenza A Virus
 - Influenza A Subtype H1-2009
 - Influenza A Subtype H3
- Influenza B Virus
- Parainfluenza Virus 1
- Parainfluenza Virus 2
- Parainfluenza Virus 3
- Parainfluenza Virus 4
- Respiratory Syncytial Virus

Print

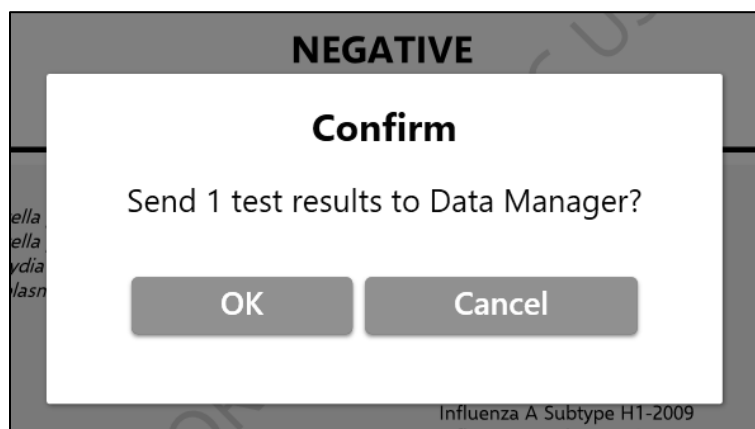
Show

Options

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

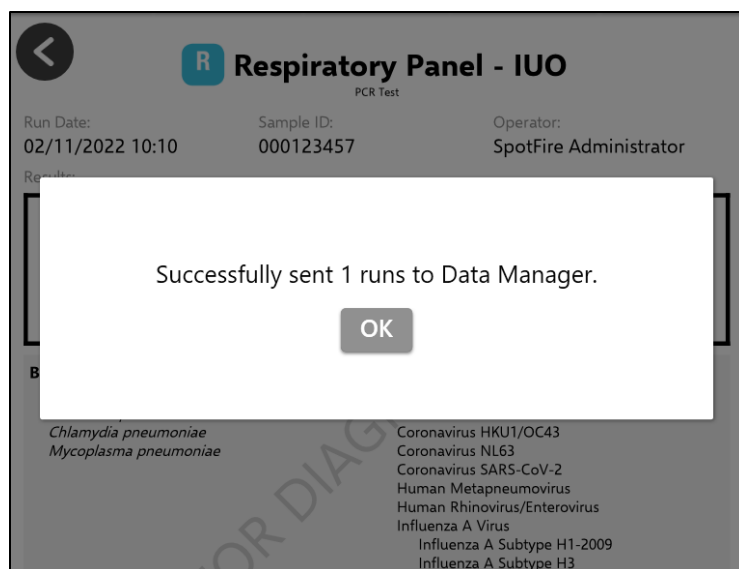


5. Select **OK** to confirm transmission to the connected Data Manager.

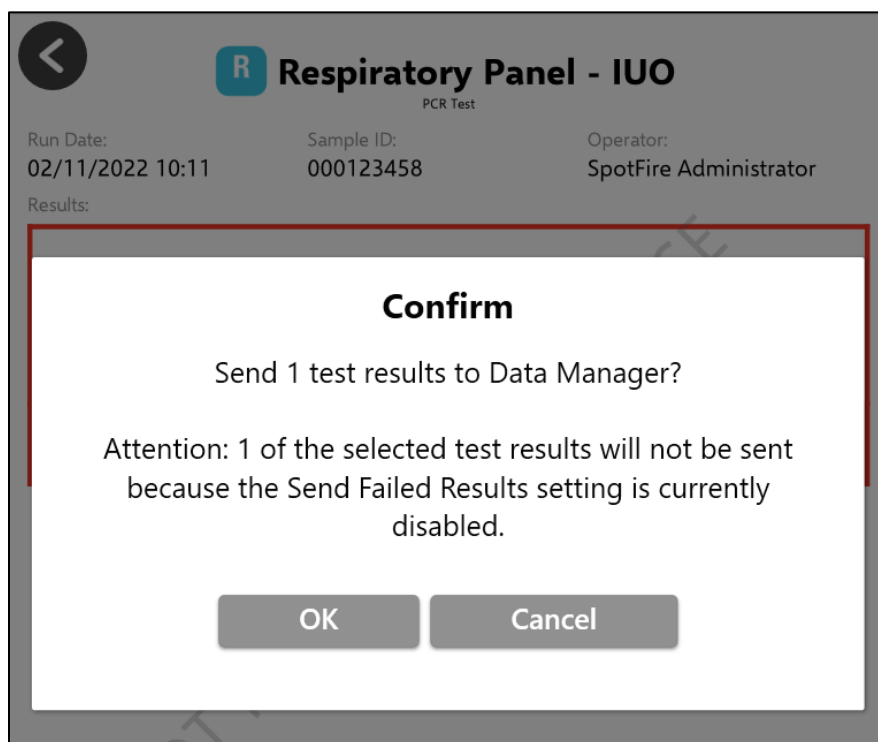


Alternatively, operators may select **Cancel** to return to the **Test Report** screen without transmitting.

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:

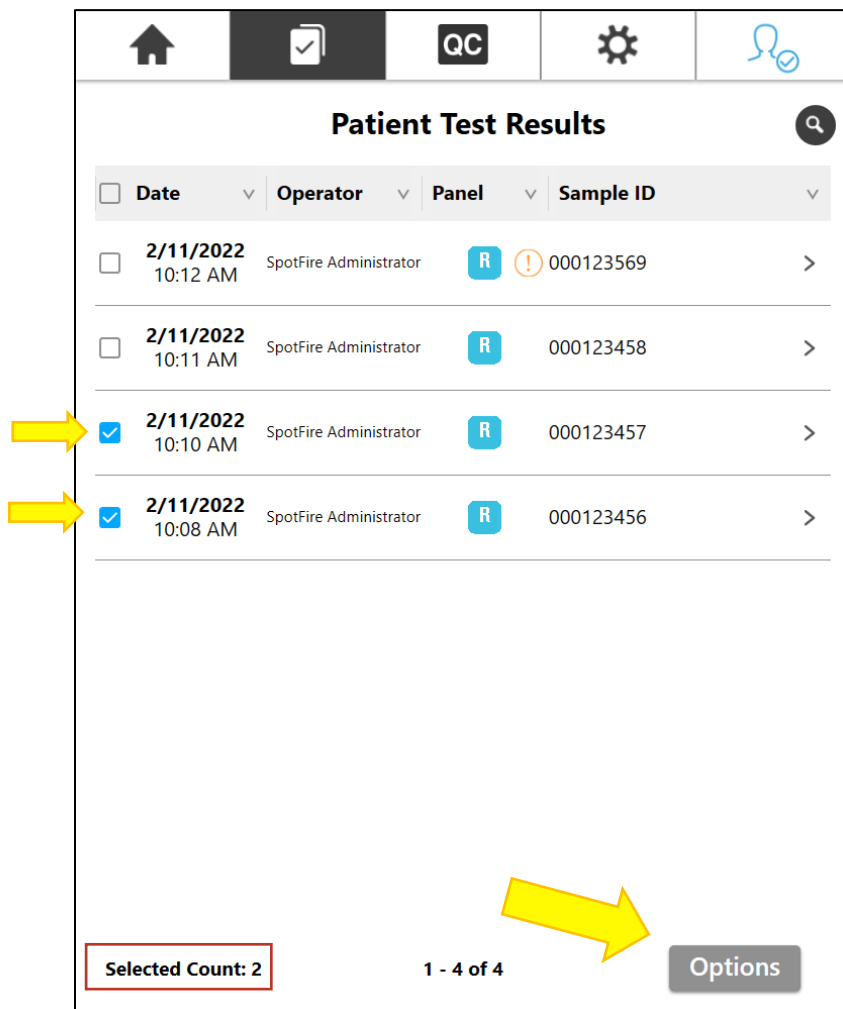


Refer to section 4.3.2 for more information about the **Send Failed Results** setting.

4.3.2. Transmit from Test Results

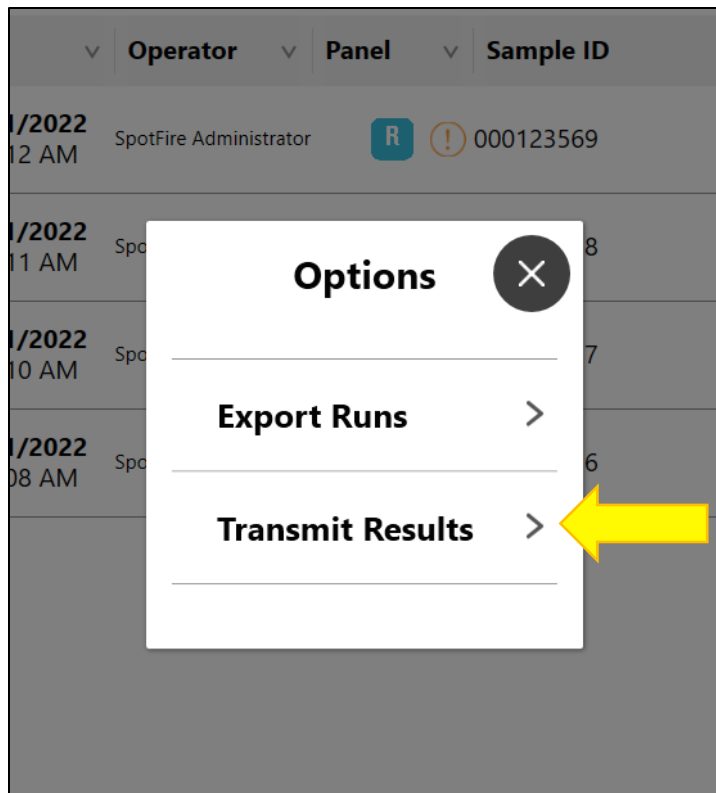
Complete the following steps to manually transmit one or more results from the **Patient** or **QC Test Results** screens.

1. Scroll and select the checkboxes corresponding to any of the test results listed on the **Test Result** summary screen.

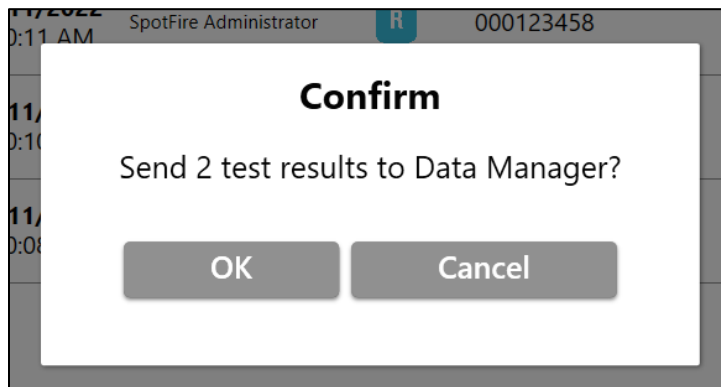


The **Selected Count** displays at the bottom of the screen to indicate the number of test results currently selected.

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

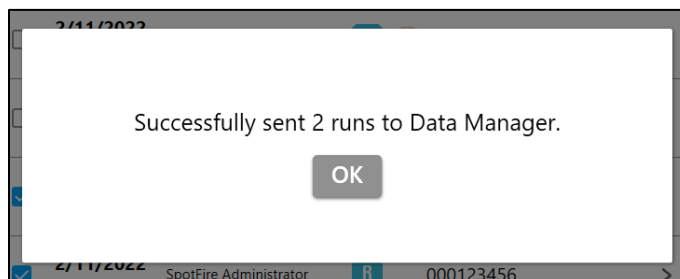


4. Select **OK** to confirm transmission of each selected test result to the Data Manager.

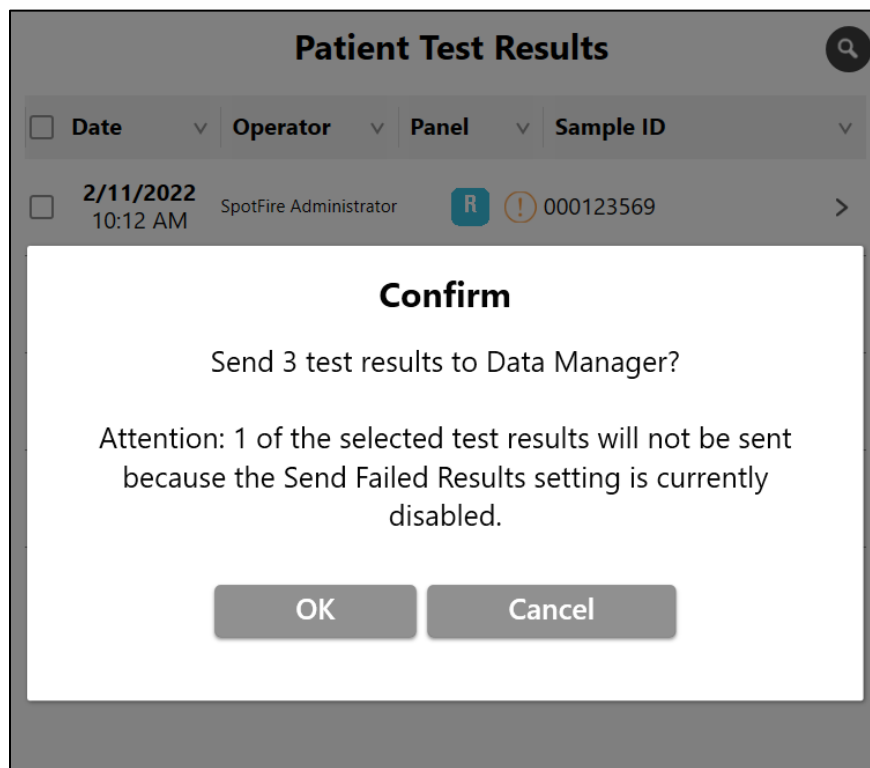


Alternatively, operators may select **Cancel** to return to the **Test Results** summary screen without transmitting.

5. Select **OK** to acknowledge transmission.



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:



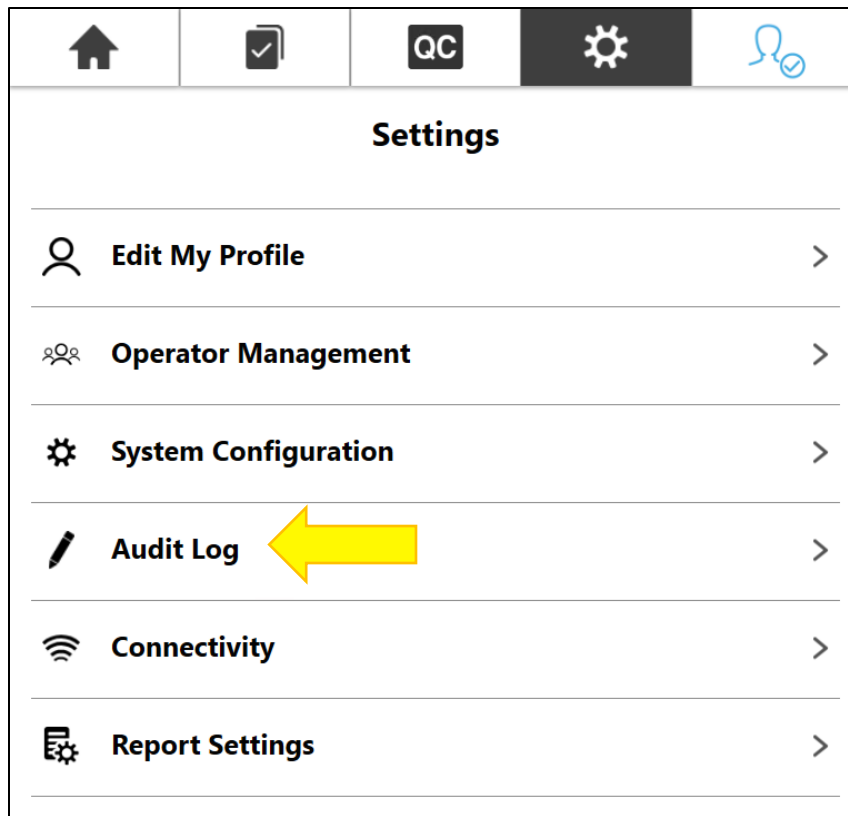
In this scenario, selecting **OK** transmits only the selected test results that completed successfully. Refer to section 4.3.2 for more information about the **Send Failed Results** setting.

4.3.3. View Transmission Status

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.

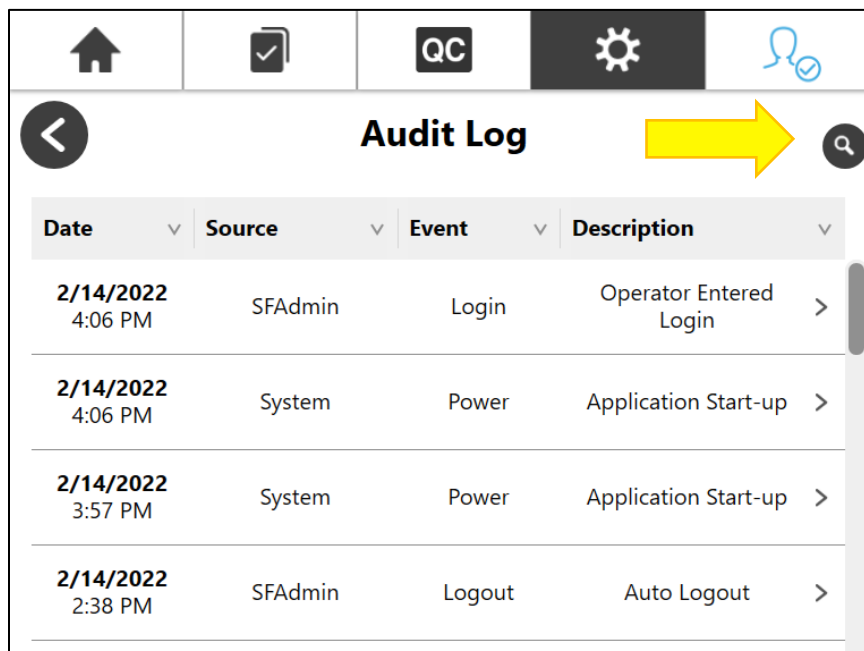
The following section provides instructions for using the Audit Log to view the status for any previously transmitted test results. Refer to BFR0001-1641 *BIOFIRE® SPOTFIRE® System Operator's Manual* For details about other types of events that are recorded in the Audit Log.

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 **Advanced Search** icon in the upper-right of the **Audit Log** screen to filter on Sent Run events.



3. Start typing “Sent Run” 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:

The screenshot shows the 'Advanced Search' interface. At the top is a navigation bar with icons for Home, Checklist, QC, Settings, and a user profile. Below the navigation bar is a back arrow icon and the title 'Advanced Search'. The form contains three input fields: 'Type' with a dropdown menu set to 'All', 'Source' with a clear button (X), and 'Event' with a clear button (X). The 'Event' field is active, showing a dropdown list with 'Sent' and 'Sent Run' (highlighted in blue). At the bottom are 'Search' and 'Clear All' buttons.

4. Select **Search**.

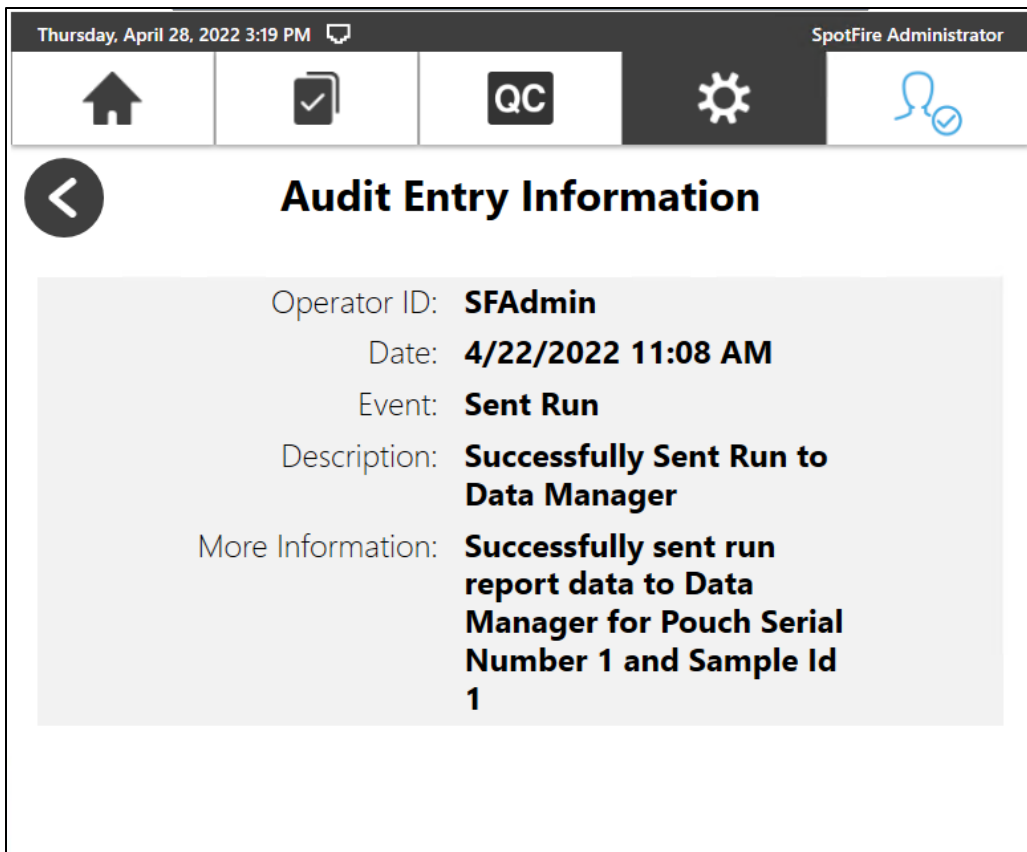
This screenshot shows the 'Advanced Search' screen after the 'Event' field has been updated to 'Sent Run'. The 'Type' field remains 'All', 'Source' is empty, and 'Date(s)' is empty. A large yellow arrow points to the 'Search' button, indicating the next step in the process.

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

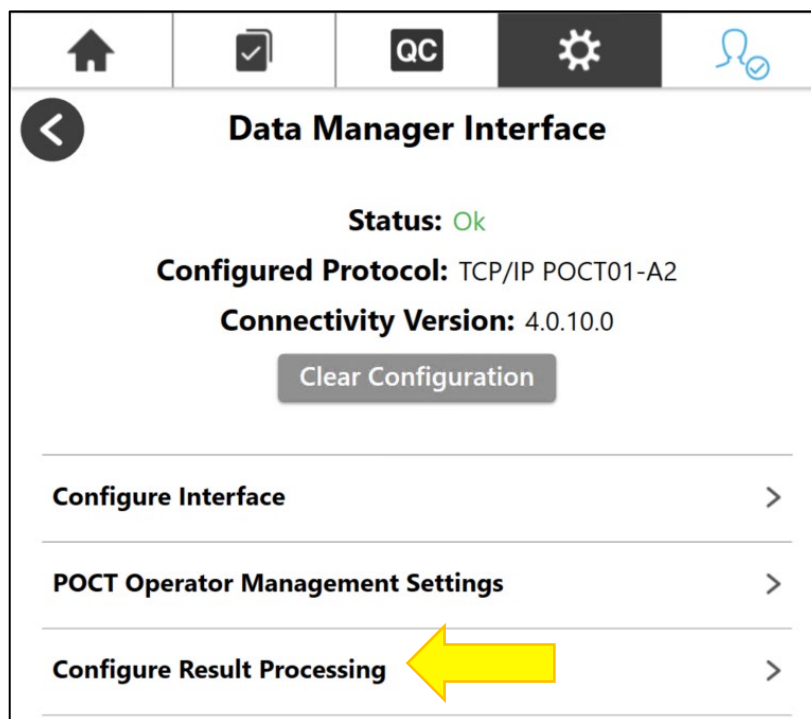
	Audit Log			(1)
Date	Source	Event	Description	
2/14/2022 2:22 PM	SFAdmin	Sent Run	Successfully Sent Run to Middleware/LIS	>
2/14/2022 2:22 PM	SFAdmin	Sent Run	Successfully Sent Run to Middleware/LIS	>
2/14/2022 2:18 PM	SFAdmin	Sent Run	Successfully Sent Run to Middleware/LIS	>
2/14/2022 2:17 PM	SFAdmin	Sent Run	Successfully Sent Run to Middleware/LIS	>
2/14/2022 1:51 PM	SFAdmin	Sent Run	Successfully Sent Run to Middleware/LIS	>
2/11/2022 1:41 PM	SFAdmin	Sent Run	Successfully Sent Run to Middleware/LIS	>
2/11/2022 10:26 AM	SFAdmin	Sent Run	Successfully Sent Run to Middleware/LIS	>
1 - 7 of 7				Export

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

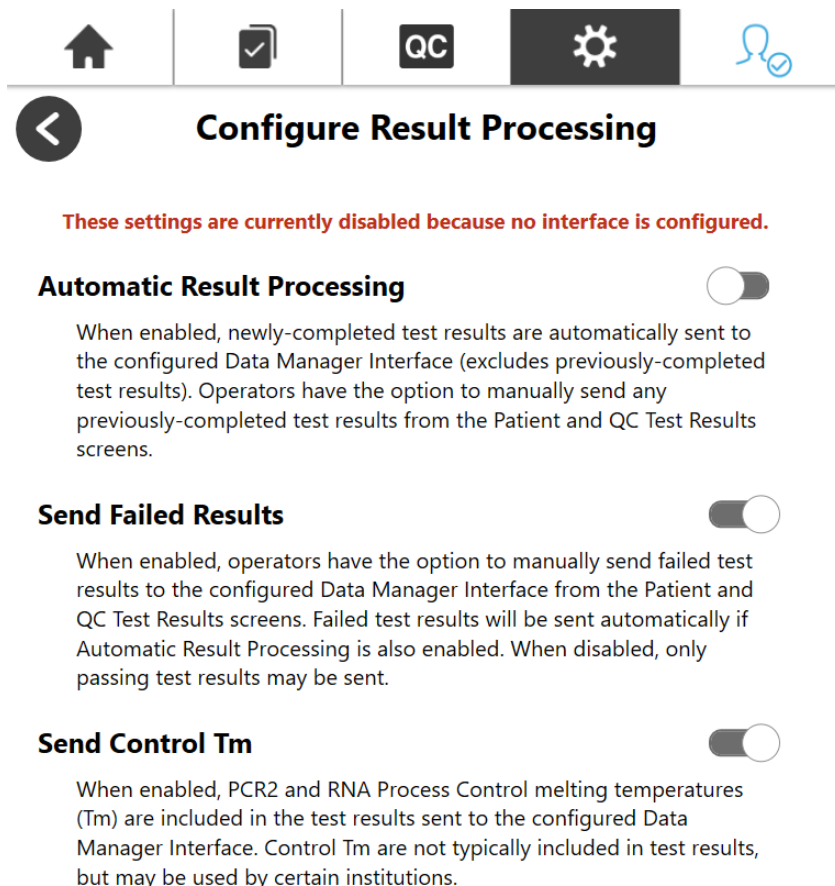
- **Operator ID:** Displays only for manually transmitted test results.
- **Date:** Date and time of transmission.
- **Description:** Indicates whether the transmission succeeded or failed.
- **More Information:** Identifies the Pouch Serial Number and Sample ID associated with the transmitted test result.



4.4. Configure Result Processing Settings



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 can be enabled or disabled using either of the two methods listed below:

1. A SPOTFIRE Administrator selects the corresponding toggle switch directly through the user interface, as shown in the figure below.



Automatic Result Processing

When enabled, newly-completed test results are automatically sent to the configured Data Manager Interface (excludes previously-completed test results). Operators have the option to manually send any previously-completed test results from the Patient and QC Test Results screens.

Send Failed Results

When enabled, operators have the option to manually send failed test results to the configured Data Manager Interface from the Patient and QC Test Results screens. Failed test results will be sent automatically if Automatic Result Processing is also enabled. When disabled, only passing test results may be sent.

Send Control Tm

When enabled, PCR2 and RNA Process Control melting temperatures (Tm) are included in the test results sent to the configured Data Manager Interface. Control Tm are not typically included in test results, but may be used by certain institutions.

2. The Data Manager remotely updates one or more settings via the POCT01-A2 interface. These updates are triggered when the Data Manager sends a SPOTFIRE Device Settings message to the SPOTFIRE System. Refer to section 4.6 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.

4.4.1. Automatic Result Processing

The Automatic Run Processing setting, when enabled, allows future test results to be automatically sent to the Data Manager as patient and QC tests complete on the 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 4.3 for instructions on manually transmitting test results.



Automatic Result Processing



When enabled, newly-completed test results are automatically sent to the configured Data Manager Interface (excludes previously-completed test results). Operators have the option to manually send any previously-completed test results from the Patient and QC Test Results screens.

Send Failed Results



When enabled, operators have the option to manually send failed test results to the configured Data Manager Interface from the Patient and QC Test Results screens. Failed test results will be sent automatically if Automatic Result Processing is also enabled. When disabled, only passing test results may be sent.

Send Control Tm



When enabled, PCR2 and RNA Process Control melting temperatures (Tm) are included in the test results sent to the configured Data Manager Interface. Control Tm are not typically included in test results, but may be used by certain institutions.

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 4.3.3 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 4.2.3 for more information about clearing the interface configuration.

4.4.2. Send Failed Results

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

Automatic Result Processing



When enabled, newly-completed test results are automatically sent to the configured Data Manager Interface (excludes previously-completed test results). Operators have the option to manually send any previously-completed test results from the Patient and QC Test Results screens.

Send Failed Results



When enabled, operators have the option to manually send failed test results to the configured Data Manager Interface from the Patient and QC Test Results screens. Failed test results will be sent automatically if Automatic Result Processing is also enabled. When disabled, only passing test results may be sent.

Send Control T_m



When enabled, PCR2 and RNA Process Control melting temperatures (T_m) are included in the test results sent to the configured Data Manager Interface. Control T_m are not typically included in test results, but may be used by certain institutions.

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.

4.4.3. Send Control Melt Temperatures (T_M)

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



Automatic Result Processing



When enabled, newly-completed test results are automatically sent to the configured Data Manager Interface (excludes previously-completed test results). Operators have the option to manually send any previously-completed test results from the Patient and QC Test Results screens.

Send Failed Results



When enabled, operators have the option to manually send failed test results to the configured Data Manager Interface from the Patient and QC Test Results screens. Failed test results will be sent automatically if Automatic Result Processing is also enabled. When disabled, only passing test results may be sent.

Send Control T_m



When enabled, PCR2 and RNA Process Control melting temperatures (T_m) are included in the test results sent to the configured Data Manager Interface. Control T_m are not typically included in test results, but may be used by certain institutions.

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

Note: Control T_m values are reported for passing test results only. Control T_m values for failed or invalid tests are excluded.

4.5. 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.

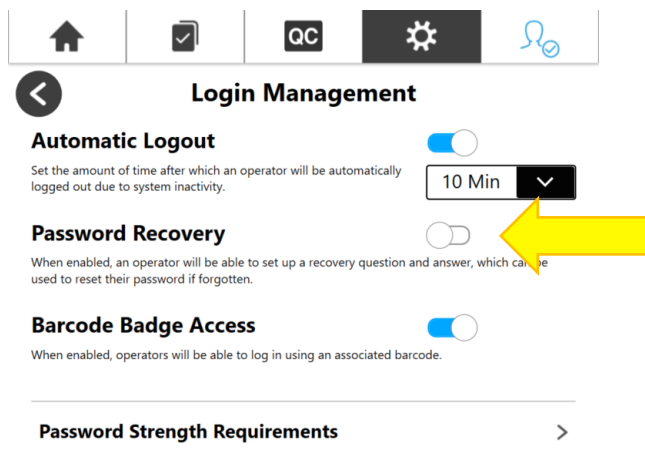
SPOTFIRE maintains Local and Point-of-Care operator information in two separate databases. This allows Administrators to flexibly toggle between the Local and Point-of-Care settings without impacting stored operator account data.

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, the following preliminary actions should be performed:

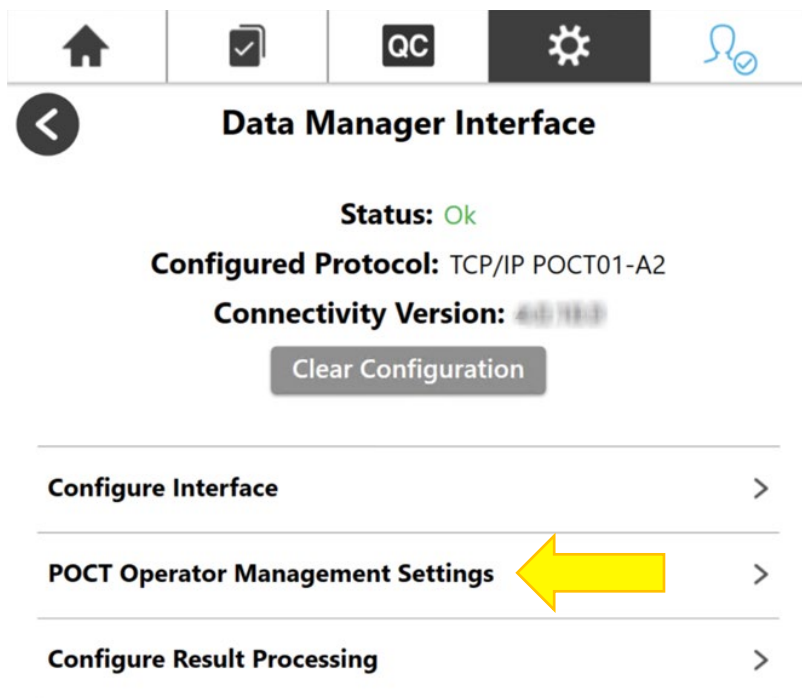
1. Verify that your institution's Data Manager is configured to support SPOTFIRE operators via the POCT01-A2 interface.
2. Disable the **Password Recovery** setting, as described below:
 - a. Login into SPOTFIRE as an administrator.
 - b. Navigate to Settings → Operator Management → Login Management.
 - c. If enabled, tap the **Password Recovery** toggle to disable.



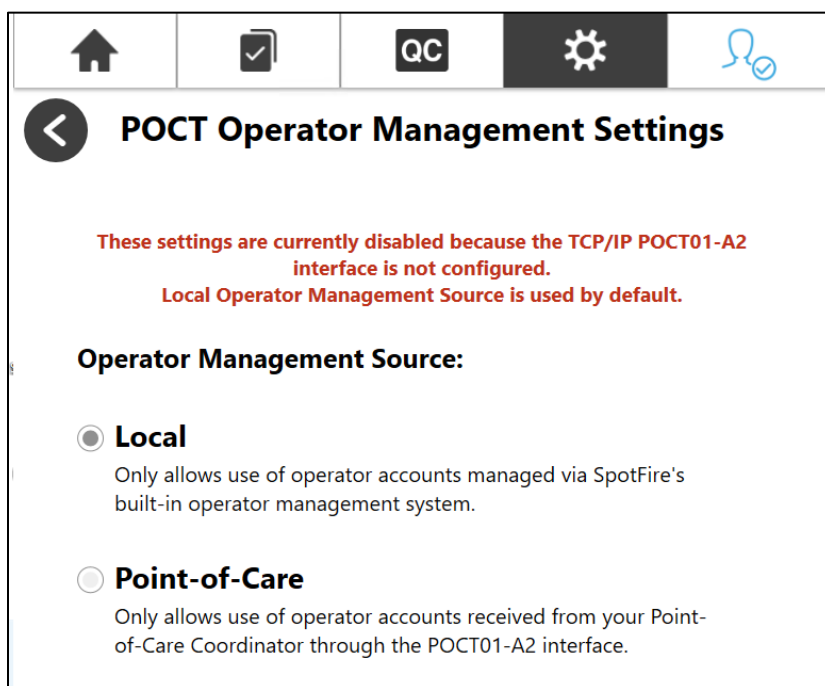
Refer to BFR0001-1641: *BIOFIRE® SPOTFIRE® System Operator's Manual* for more information on the **Password Recovery** setting.

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: POCT Operator Management Settings are disabled if no POCT01-A2 interface is currently configured, as shown in the figure below.



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

POCT Operator Management Settings

Operator Management Source:

☐ **Local**
Only allows use of operator accounts managed via SpotFire's built-in operator management system.

☒ **Point-of-Care** ←
Only allows use of operator accounts received from your Point-of-Care Coordinator through the POCT01-A2 interface.

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

3. Select **OK** on the Auto-Logout Notice to confirm (not applicable if logged in as “SFAdmin”).

Operator Management Source:

☐ **Local**

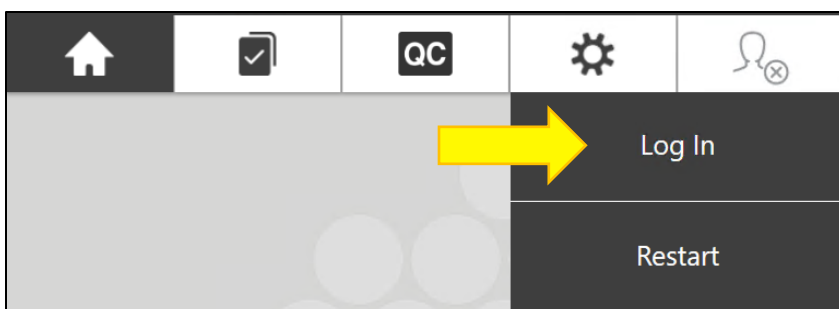
Auto-Logout Notice

Changing this setting will automatically log you out.
Please confirm to continue.

OK **Cancel**

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

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



5. 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.

4.5.1. 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.

<input type="checkbox"/>	Name	Training Expiration	Admin Operator
<input type="checkbox"/>	Jane Doe	12/30/2022	<input checked="" type="checkbox"/>
<input type="checkbox"/>	John Doe	12/30/2022	<input type="checkbox"/>
<input type="checkbox"/>	SpotFire Administrator		<input checked="" type="checkbox"/>

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

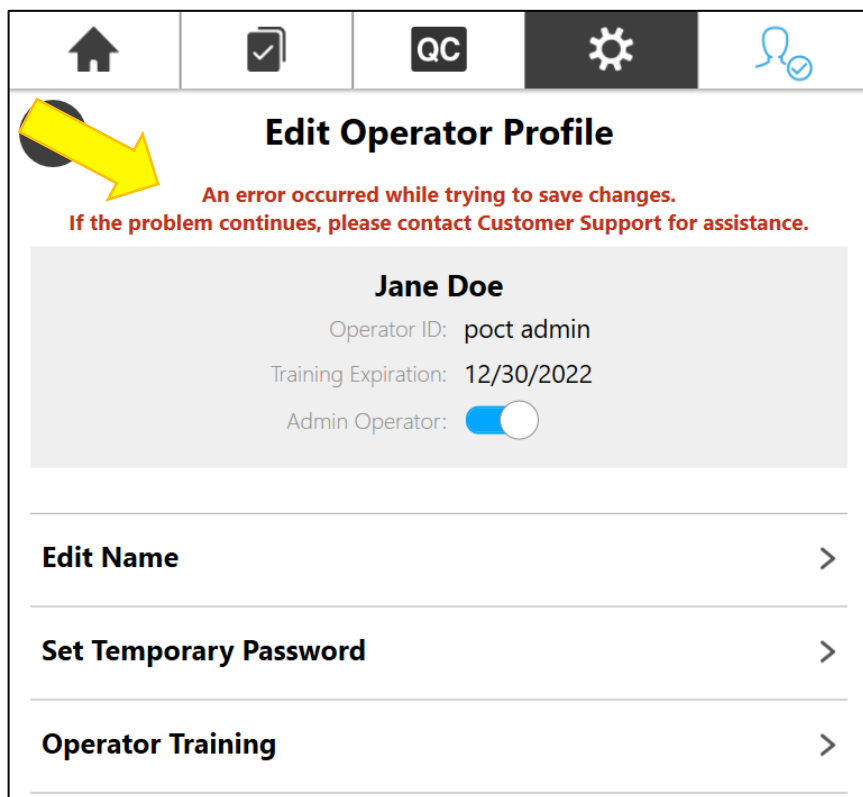
Note: The SPOTFIRE Administrator ("SFAdmin") is a locally managed account that remains permanently active and cannot be modified or removed by the Data Manager via the POCT01-A2 interface.

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 Data Manager administrator to ensure that operator accounts are being

transmitted to the SPOTFIRE System. Additionally, refer to section 5 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: Operator information cannot be modified using the SPOTFIRE Software while the **Operator Management Source** is set to Point-of-Care. Attempting to add, delete, or modify operator data locally on the SPOTFIRE System will result in an error, as shown in the figure below.



4.6. 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 login 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 4.3.1 for additional information).
- **Send Failed Results:** When enabled, failed test results may be transmitted to the Data Manager (refer to section 4.3.2 for additional information).
- **Send Control T_M:** When enabled, internal process control melting temperatures are included in transmitted test results (refer to section 4.3.3 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.

4.6.1. Updates to System Date and Time

The POCT01-A2 interface also allows the connected Data Manager to update system data 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.

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

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

5. Troubleshooting

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
Cannot import interface configuration settings	<ol style="list-style-type: none"> 1. Verify that the interface configuration file (.sfcc) exists in the root directory of an available removable (e.g. USB) or mapped network drive. 2. Verify the contents of the .sfcc file are well formed (refer to example shown below): <pre> { "Host": "172.24.16.43", "Port": 3000, "ConfigurationType": "PoctConfiguration" }</pre>
Cannot export interface configuration settings	<ol style="list-style-type: none"> 1. Verify that valid Host and Port values are entered on the Configure Interface screen. 2. Verify that a removable (e.g., USB) or mapped network drive is available. 3. Check the target drive/folder properties to ensure that Write access is allowed.
POCT01-A2 connection cannot be established	<ol style="list-style-type: none"> 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.
Data Manager Interface Status displays "Error"	<ol style="list-style-type: none"> 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. Clear the current interface configuration (refer to section 4.2.3). 4. Re-configure the interface (refer to sections 3.2.2 or 4.2.2).
Missing/incomplete Operator List	<ol style="list-style-type: none"> 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: <i>BIOFIRE® SPOTFIRE® System Operator's Manual</i>.

Issue	Troubleshooting Steps
Unable to automatically transmit completed test results to Data Manager	<ol style="list-style-type: none"> 1. Verify your institution's Data Manager is currently online and operational. 2. Verify the Automatic Result Processing setting is enabled on the Configure Result Processing screen (refer to section 4.3.1). 3. If attempting to automatically transmit failed test results, verify the Send Failed Results setting is enabled on the Configure Result Processing screen (refer to section 4.3.2). 4. Verify the RunTrackerService is running on the Windows OS. For more information about accessing the Windows OS on SPOTFIRE, refer to BFR0001-1641: <i>BIOFIRE® SPOTFIRE® System Operator's Manual</i>.
Unable to manually transmit completed test results to Data Manager	<ol style="list-style-type: none"> 1. Verify your institution's Data Manager is currently online and operational. 2. If attempting to manually transmit a failed test result, verify the Send Failed Results setting is enabled on the Configure Result Processing screen (refer to section 4.3.2). 3. Verify the RunTrackerService is running on the Windows OS. For more information about accessing the Windows OS on SPOTFIRE, refer to BFR0001-1641: <i>BIOFIRE® SPOTFIRE® System Operator's Manual</i>.
Data Manager Interface is not available in Connectivity menu	<ol style="list-style-type: none"> 1. Verify your operator profile has Administrator permissions. For more information about operator permissions in SPOTFIRE, refer to BFR0001-1641: <i>BIOFIRE® SPOTFIRE® System Operator's Manual</i>.
Cannot update Configure Result Processing settings	<ol style="list-style-type: none"> 1. Verify that the Data Manager Interface is currently configured (refer to section 4.1). 2. Configure the Data Manager interface, if needed (refer to sections 3.2.2 or 4.2.2).

5.1. 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.

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

6. 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 Technical Support for assistance.

BIOFIRE Technical Support

Email: biofiresupport@biomerieux.com

Phone: +1-801-736-6354, select Option 5

For customer technical support outside the United States, contact the local bioMérieux sales representative or an authorized distributor.

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



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