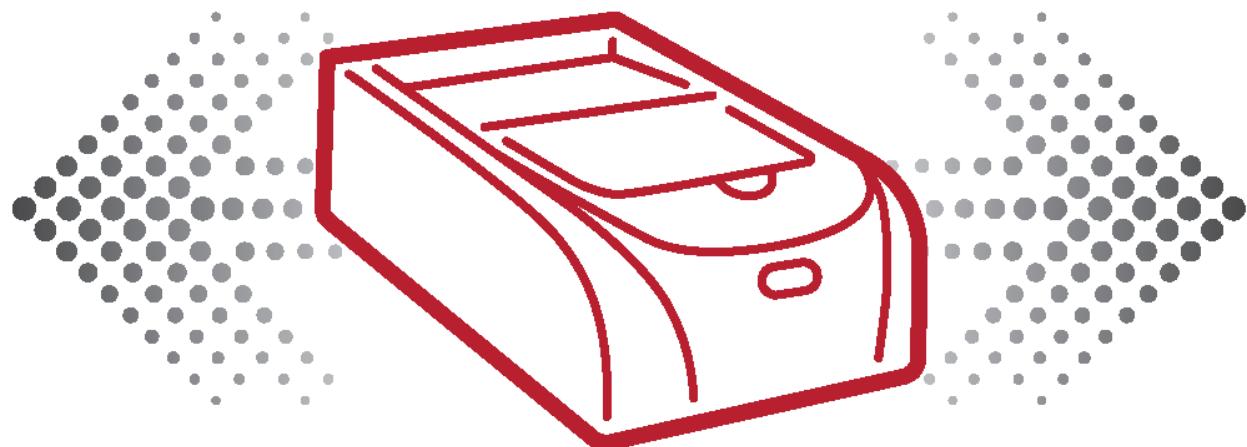


# BioFire® FilmArray® Link Software for the BioFire® FilmArray® 2.0 System



## User Guide



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**BIOFIRE®**  
A BIOMÉRIEUX COMPANY

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# **1. Purpose of the Document**

The purpose of this document is to provide instructions for obtaining, installing or upgrading, and configuring the BioFire® FilmArray® Link Software on a BioFire® FilmArray® 2.0 System. This document also provides instructions for using and troubleshooting the software.

## **2. System Overview**

The BioFire 2.0 System is an automated *in vitro* diagnostic (IVD) device intended for use with FDA-cleared or approved IVD FilmArray panels. The BioFire 2.0 System is intended for use in combination with assay-specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The BioFire® FilmArray® 2.0 Instrument interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The BioFire® FilmArray® Software automatically determines the results and provides a test report.

The BioFire 2.0 System is composed of one to eight BioFire 2.0 Instruments connected to a computer running BioFire Software. The BioFire Software controls the function of each instrument and collects, analyzes, and stores data generated by each instrument.

Refer to the FilmArray® 2.0 Operator's Manual for more information on the system.

## **3. Interface Overview**

As an add-on to the system, the BioFire Link Software provides the BioFire 2.0 System with the capability of interfacing with a data manager (i.e., a laboratory information system or middleware) to transfer test results. There are two supported implementations: 1) a unidirectional, flat-file transfer from the BioFire 2.0 System to a data manager, and 2) a unidirectional transfer of structured text from the BioFire 2.0 System to a data manager.

## **4. Preparation**

Prior to beginning the process of interfacing a BioFire 2.0 System, the following steps must be completed.

1. Review the BioFire® FilmArray® 2.0/Torch Interface Checklist and complete steps 1 and 2 of the checklist.
2. Ensure that no runs are in progress. The software installation and interface setup must NOT be performed while clinical testing is in progress.
3. Remove any pouches from all the instruments and close the instrument lids.

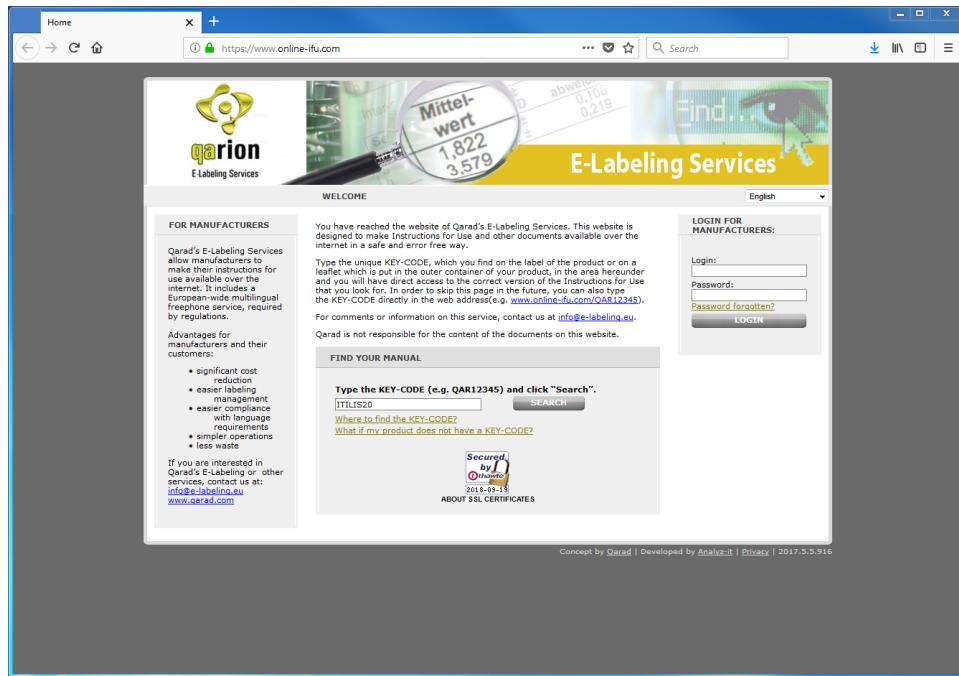
## **5. Obtaining the BioFire Link Software**

The BioFire Link software is available on CD or for download. To order the software on a CD, contact BioFire Diagnostics Technical Support. Refer to the contact information in section 10.

Complete the following instructions to download the software.

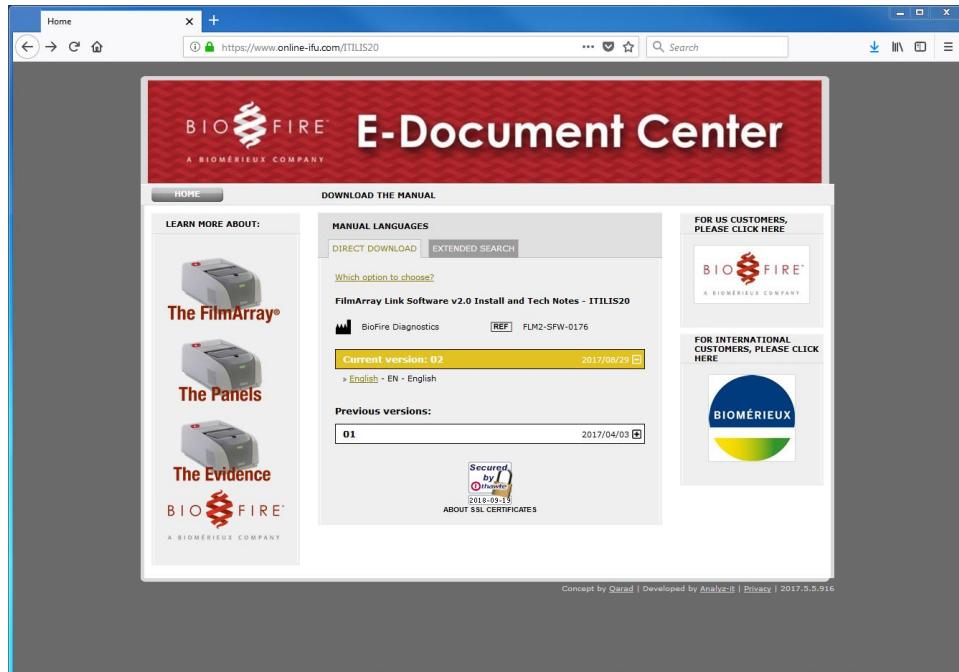
1. Visit the BioFire E-Document Center (<https://www.online-ifu.com/>).

- Enter the KEY-CODE “ITILIS20” and select Search.



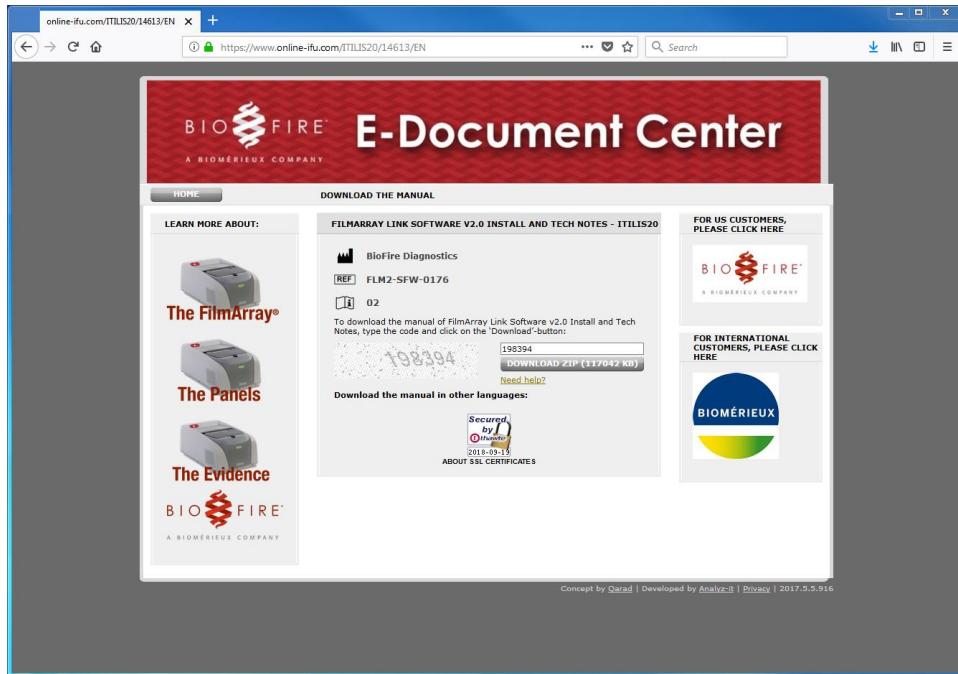
- Ensure that the current version is highlighted in yellow and select English below.

**Note:** The figure is for illustrative purposes and the current version number may change.



4. Enter the code displayed on the screen and select Download Zip.

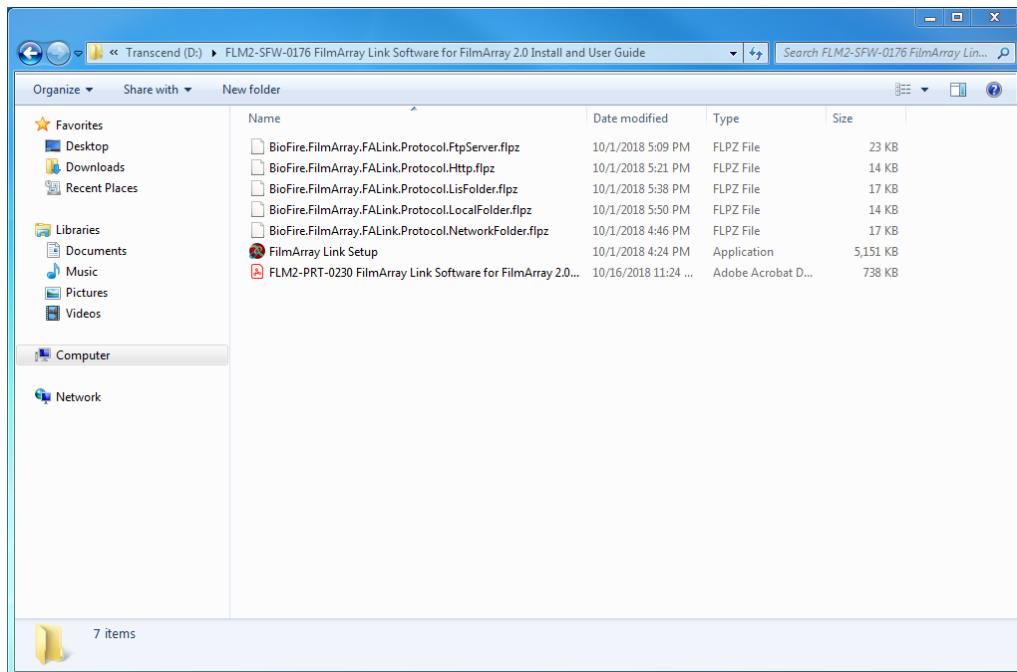
**Note:** A high-speed Internet connection is recommended for downloading the installation file.



5. Save the zipped folder.
6. Unzip the folder and save the contents on a removable drive.

7. Confirm that the following files are saved on the removable drive:

- BioFire.FilmArray.FALink.Protocol.FtpServer.flpz
- BioFire.FilmArray.FALink.Protocol.Http.flpz
- BioFire.FilmArray.FALink.Protocol.LisFolder.flpz
- BioFire.FilmArray.FALink.Protocol.LocalFolder.flpz
- BioFire.FilmArray.FALink.Protocol.NetworkFolder.flpz
- FilmArray Link Setup.exe
- FLM2-PRT-0230 FilmArray Link Software for FilmArray 2.0 User Guide.pdf



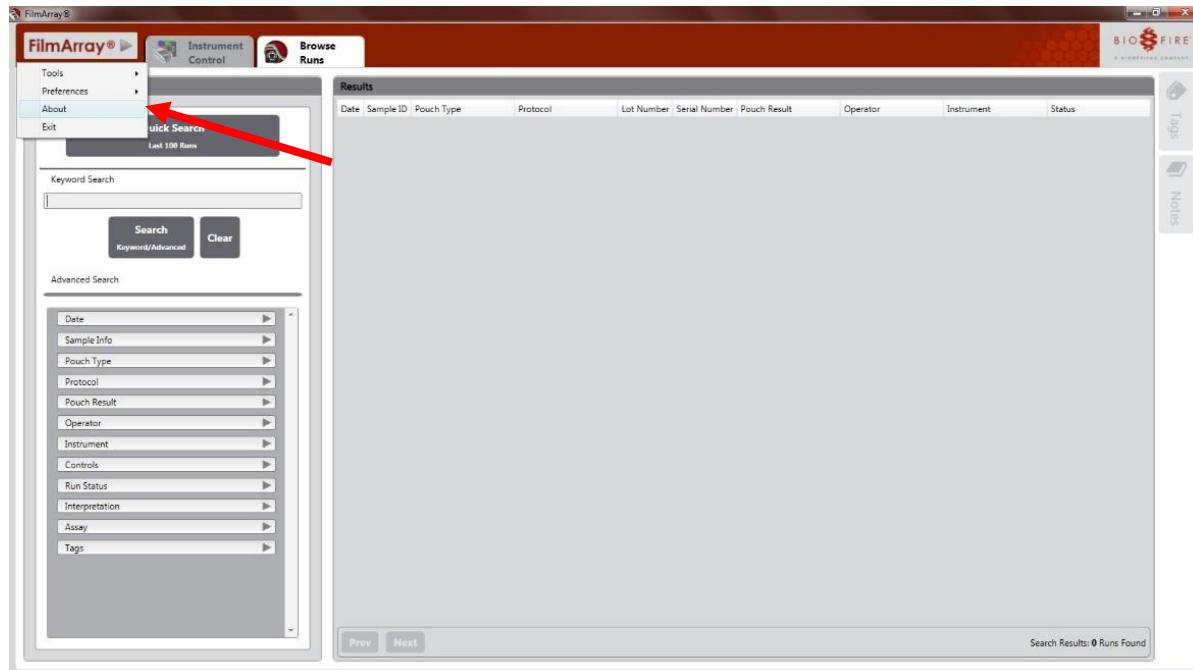
## 6. Installing the BioFire® FilmArray® Link Software

The BioFire Link Software v2.1 and a protocol must be installed in order to interface the BioFire® FilmArray® 2.0 System with a data manager. Sections 4 and 5 of this document must be completed before proceeding.

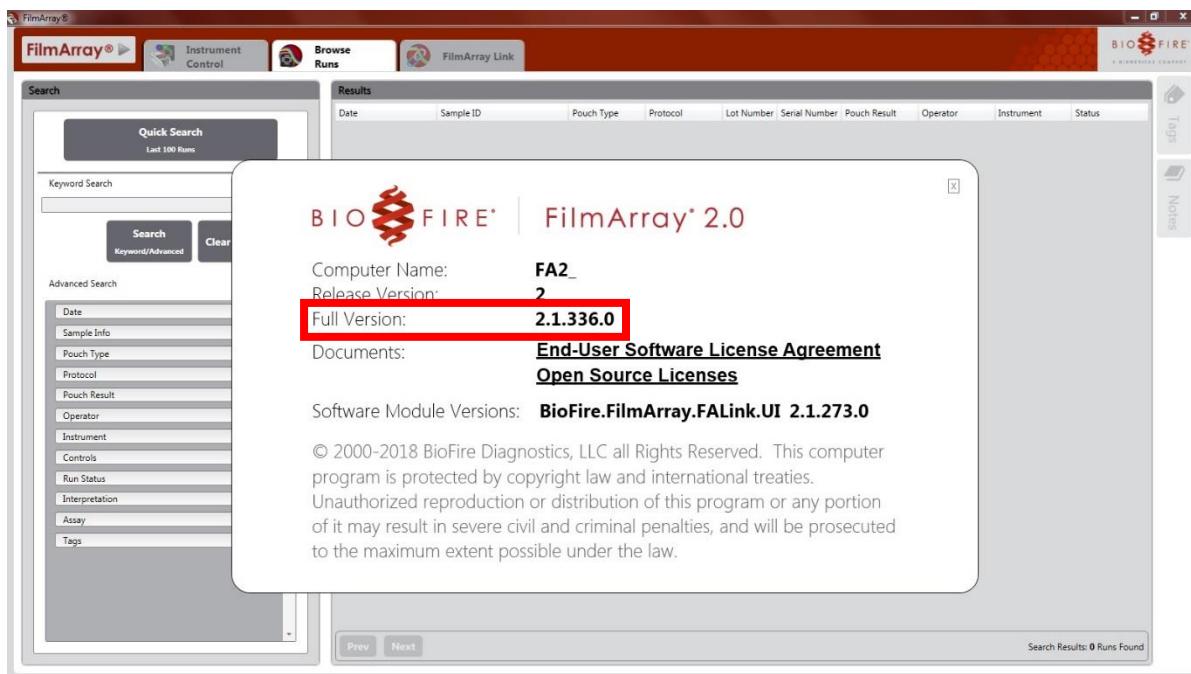
**IMPORTANT:** The BioFire® FilmArray® Software v2.1 must be installed on the BioFire 2.0 System prior to installing the BioFire Link Software v2.1 and a protocol.

### 6.1. Verify the BioFire Software v2.1 is Installed

1. Select **About** from the FilmArray menu.

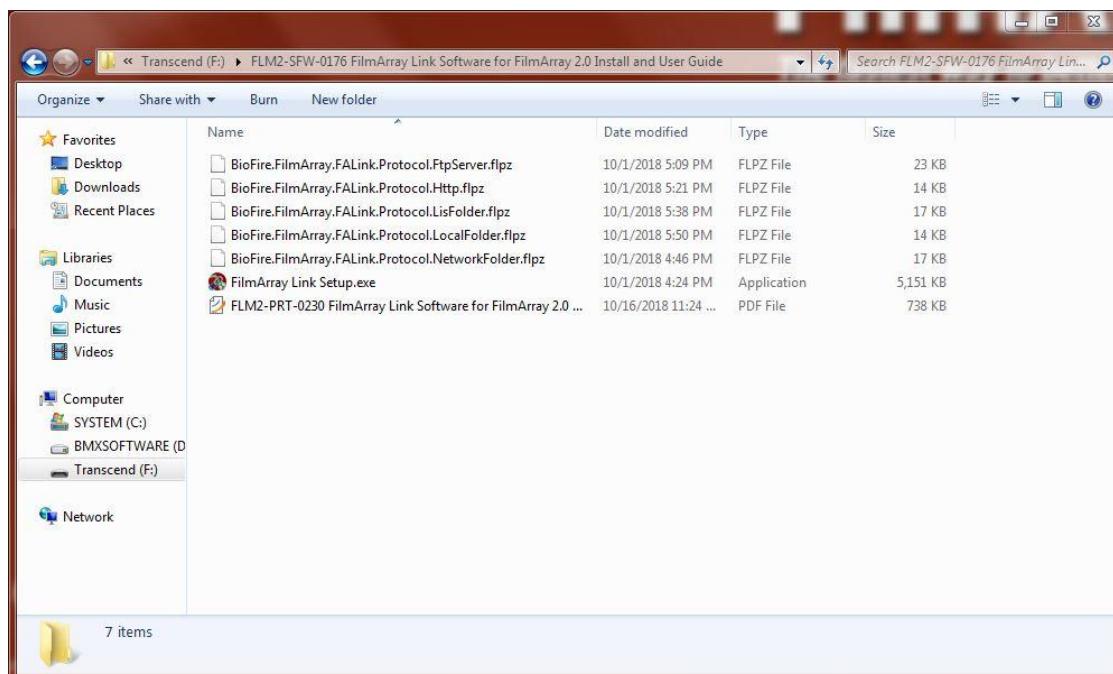


2. Confirm that the full version is 2.1.336.0. If this version is installed, close the dialog and the BioFire® FilmArray® Software application and proceed to section 6.2. If this version is not installed, the BioFire Software must be upgraded before proceeding. Contact BioFire Diagnostics Technical Support for assistance.



## 6.2. Install the BioFire® FilmArray® Link Software v2.1

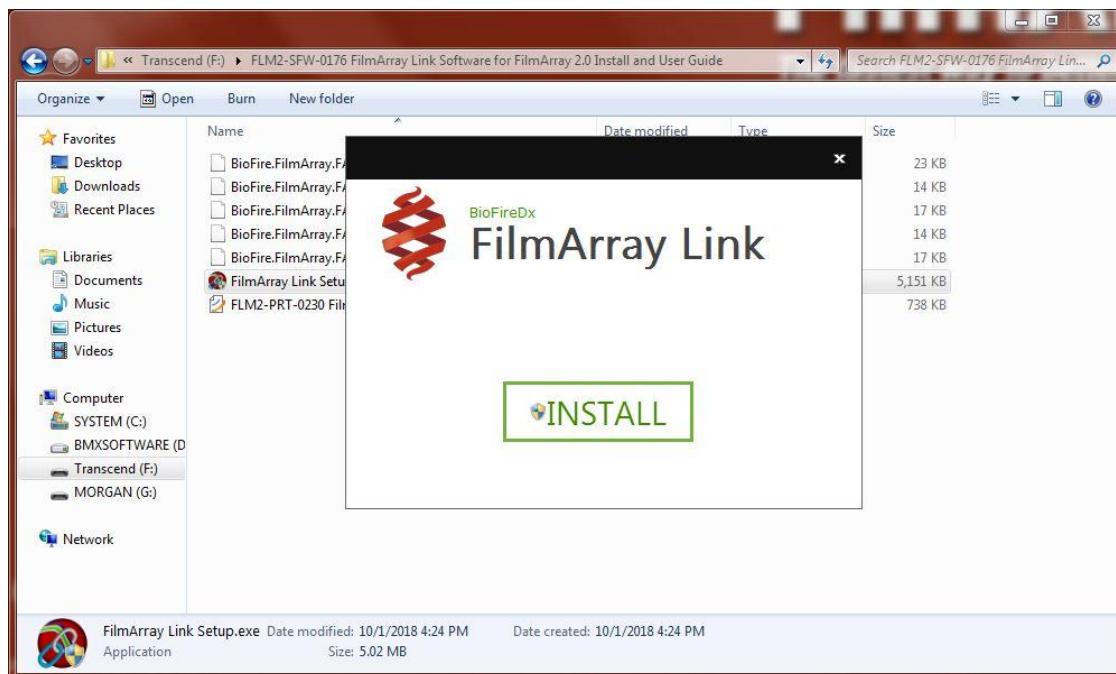
1. Insert the removable drive or CD containing the installation file into the computer.
2. Open Windows Explorer and navigate to the CD/DVD drive or the removable drive.



3. Double-click on the file named **FilmArray Link Setup.exe**. The FilmArray Link installer launches.

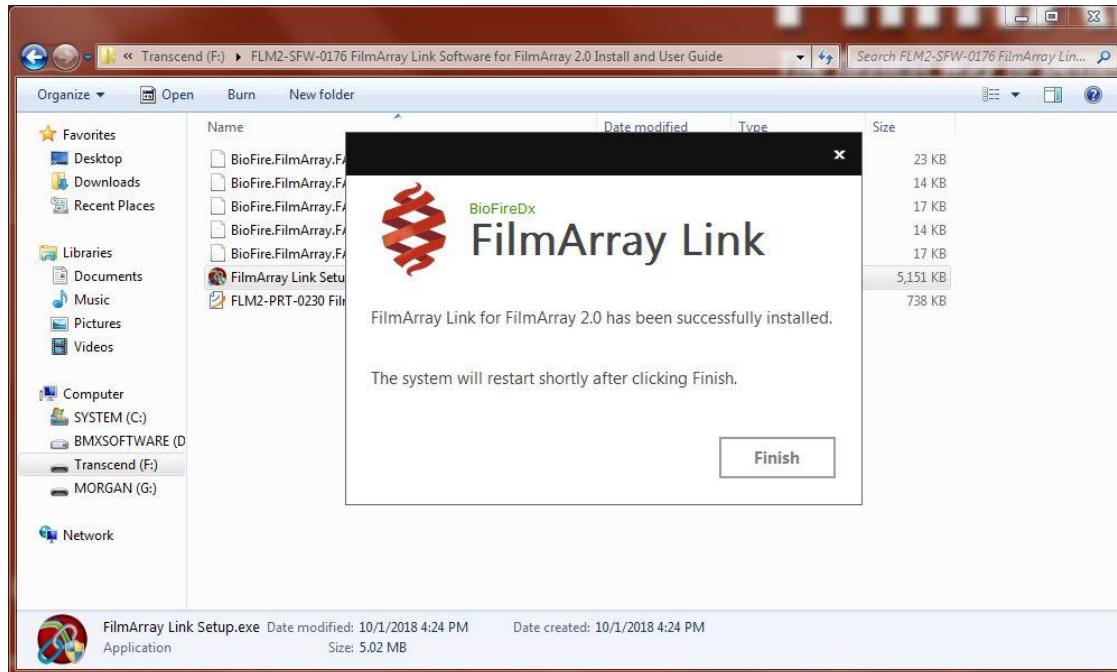
**Note:** A prompt requesting administrative login credentials is displayed. Enter the credentials associated with the LabAdmin user account. Refer to the FilmArray® 2.0 Operator's Manual for more information.

4. Click **Install**. The installer dialog window indicates when the software has been successfully installed.



5. Click Finish. The computer restarts.

**Note:** If using a removable drive, remove it from the computer when prompted.



6. Proceed to section 0.

## 6.3. Install a Protocol

Before proceeding, determine which protocol is required to interface and install it using the instructions provided below. Refer to step 2 in the BioFire® FilmArray® 2.0/Torch Interface Checklist. Sections 4 through 6.2 of this document must be completed before proceeding.

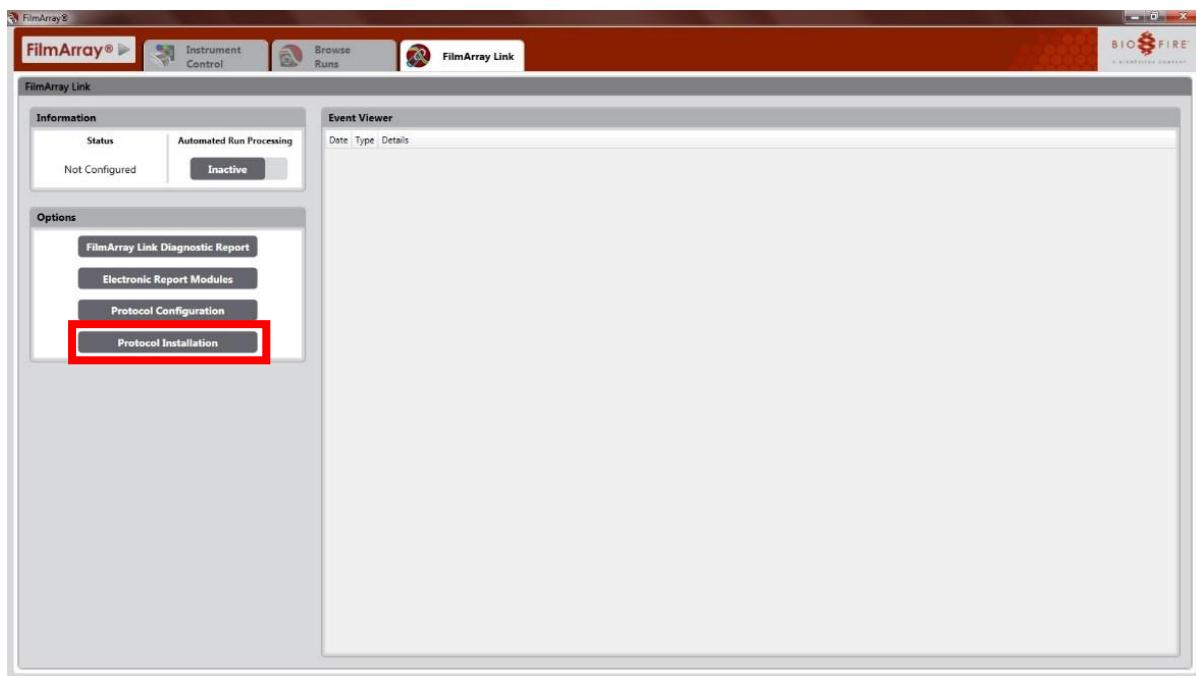
**IMPORTANT: Only one protocol can be installed at a time.** All of the protocols are available on the CD and in the zipped folder downloaded in section 5. If one protocol is installed, it can be replaced with another protocol if necessary.

Complete the following steps to install a protocol.

1. Insert the removable drive or CD into the computer.
2. Start the BioFire® FilmArray® Software application by double-clicking the FilmArray icon on the desktop.

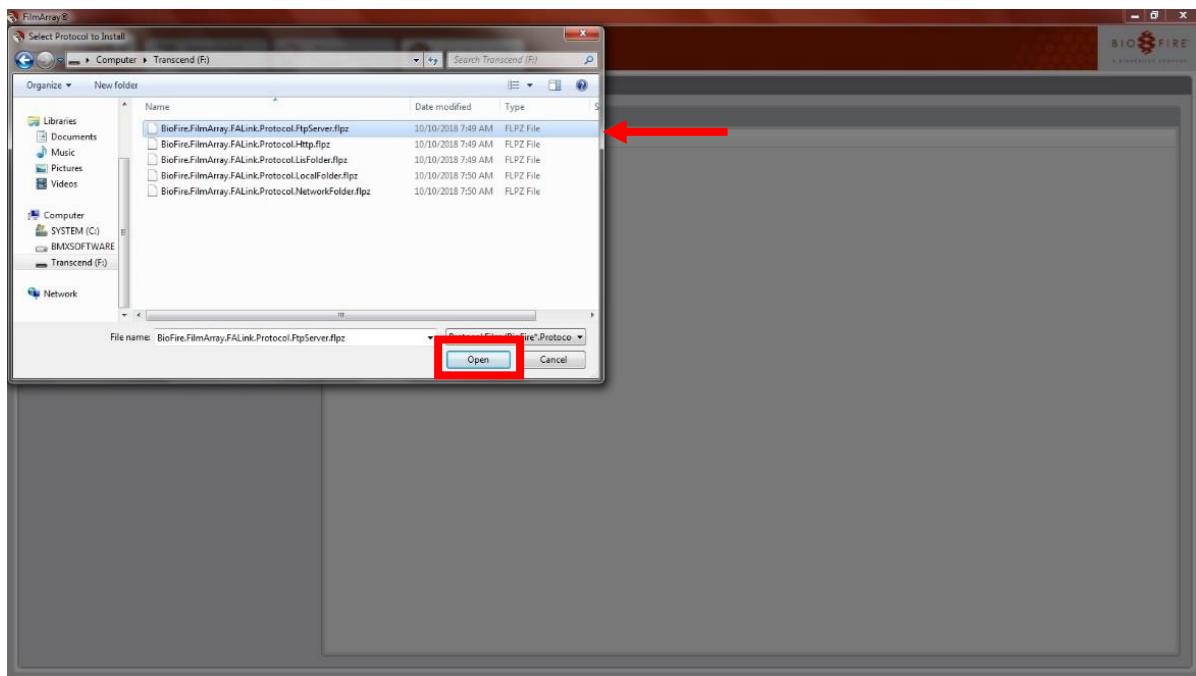


3. From the FilmArray Link tab, select the **Protocol Installation** option.

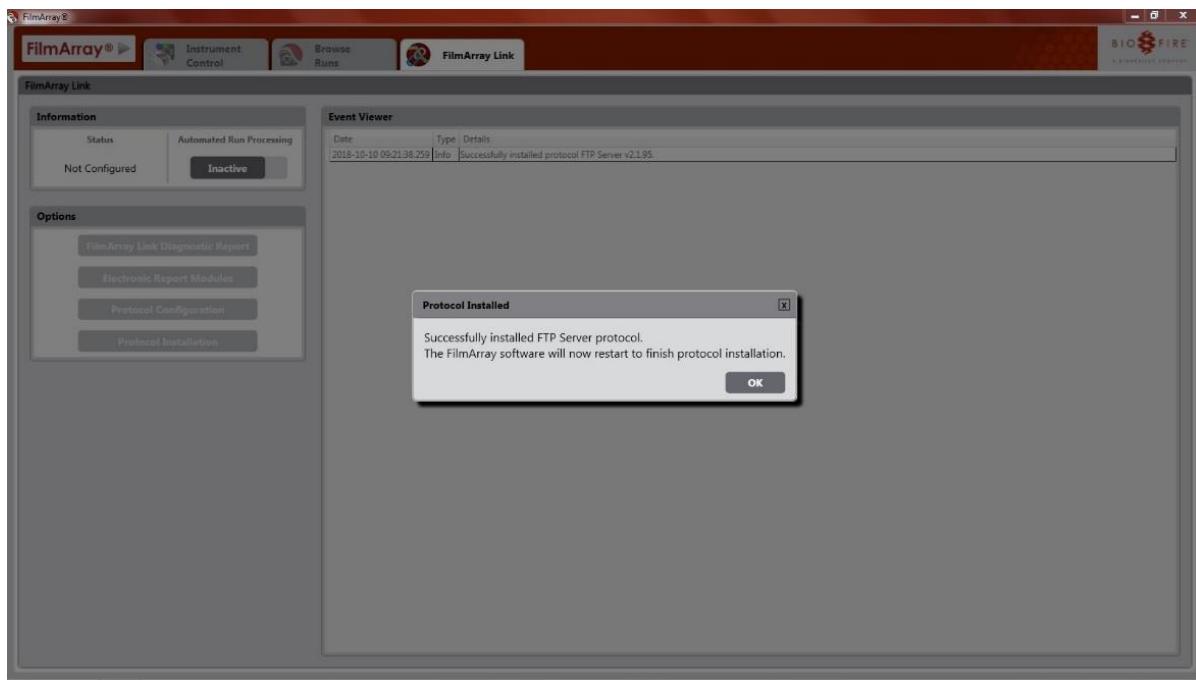


4. In the Select Protocol to Install dialog, navigate to the protocol installation file on the CD or removable drive. Select the file and select **Open**.

**Note:** Each protocol installation file has the name of the protocol in the file name. Ensure that the selected file corresponds with the protocol to be used to establish the interface.



5. Select **OK** to close the Protocol Installed dialog. The BioFire® FilmArray® Software application restarts.



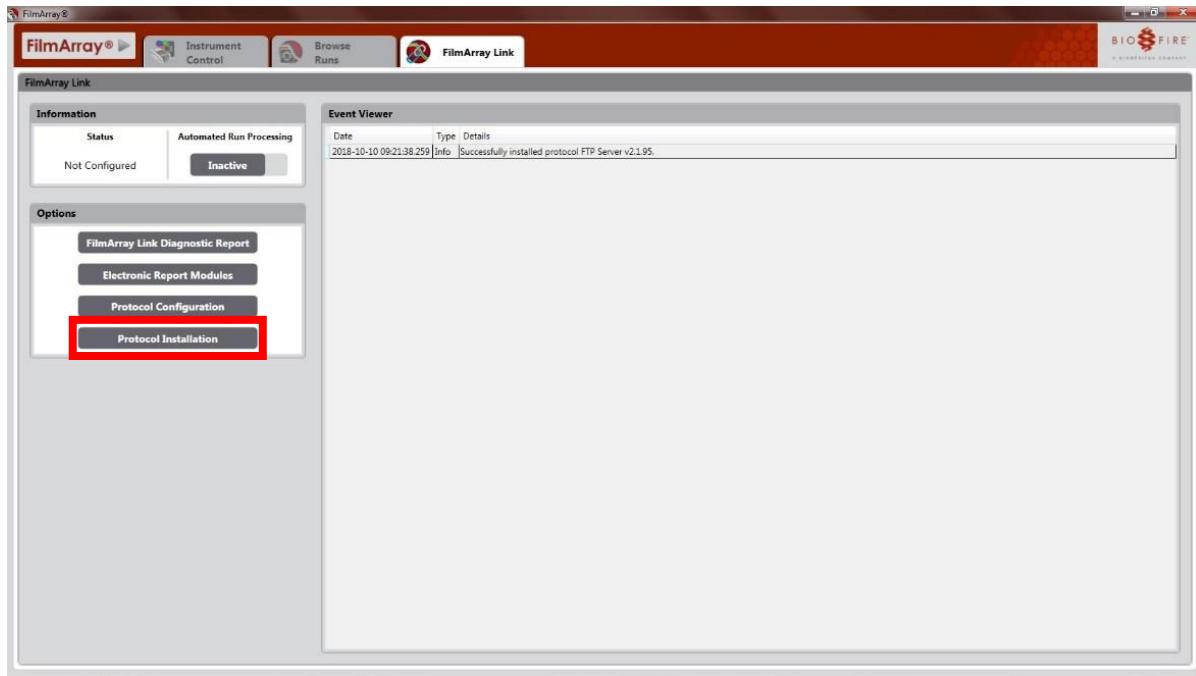
## 6.4. Replace a Protocol

If an installed protocol must be replaced with a different protocol, complete the following instructions.

1. Insert the removable drive or CD into the computer.
2. Start the BioFire Software application by double-clicking the FilmArray icon on the desktop.

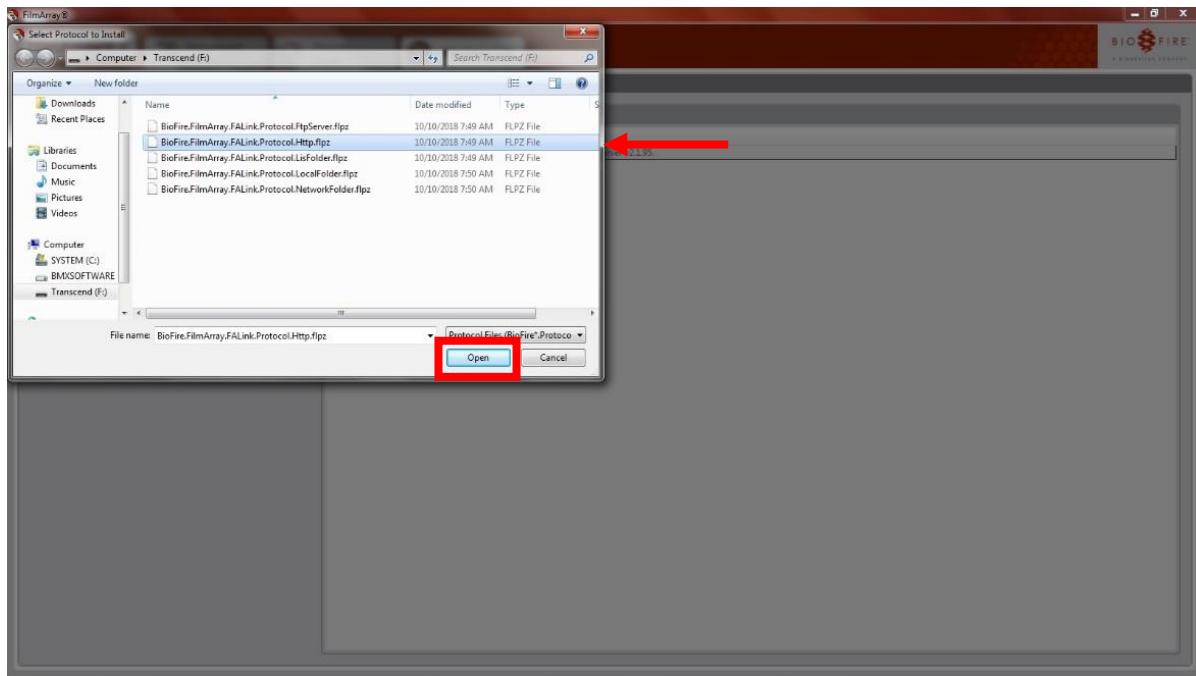


3. From the FilmArray Link tab, select the **Protocol Installation** option.

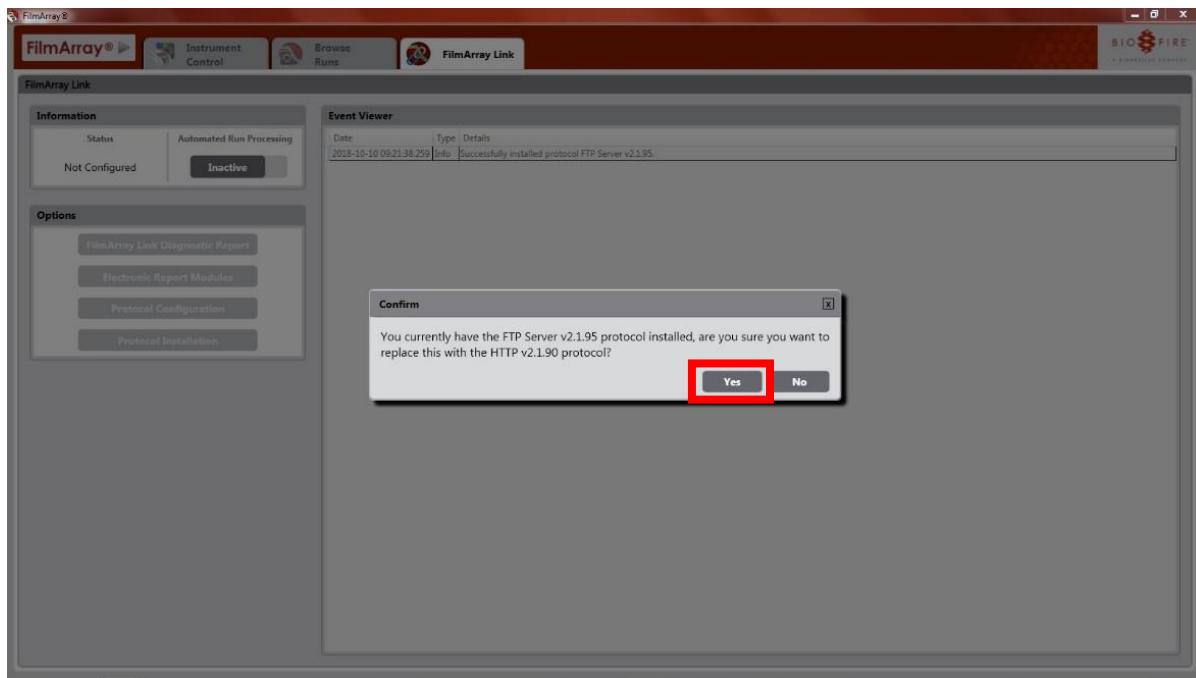


4. In the Select Protocol to Install dialog, navigate to the protocol installation file on the CD or removable drive. Select the file and select **Open**.

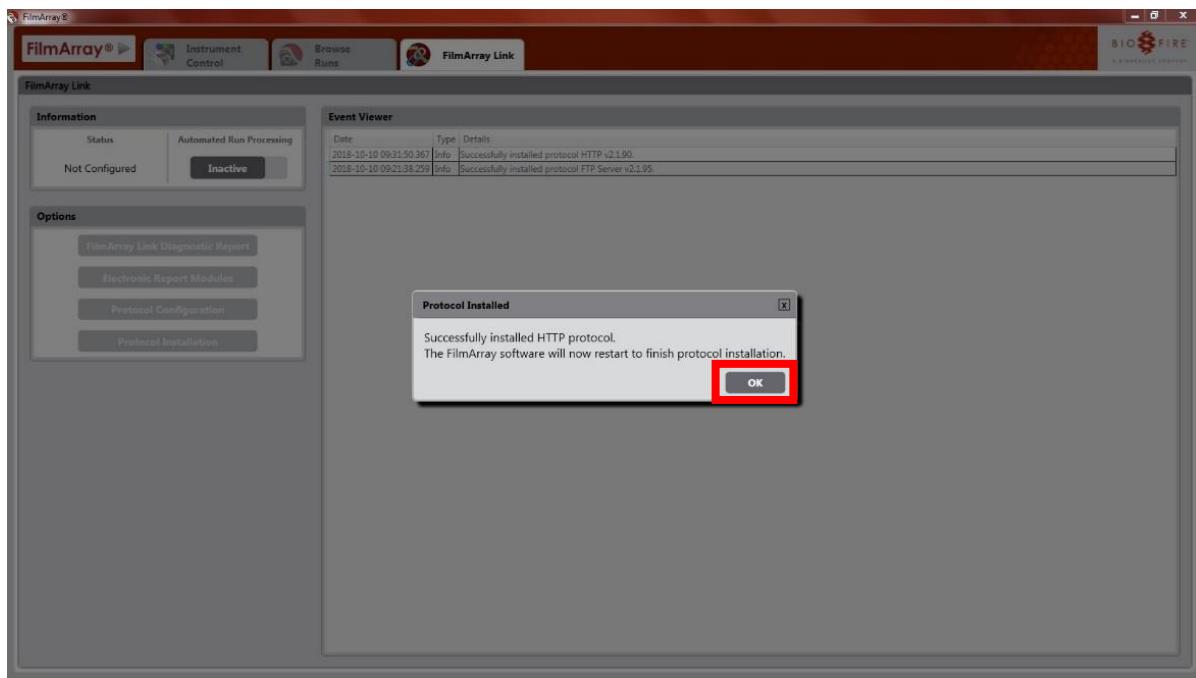
**Note:** Each protocol installation file has the name of the protocol in the file name. Ensure that the selected file corresponds with the protocol to be used to establish the interface.



5. Select **Yes** to confirm that the existing protocol will be replaced with the selected protocol.



6. Select **OK** to close the Protocol Installed dialog. The BioFire® FilmArray® Software application restarts.



## 7. Configuring the BioFire® FilmArray® Link Software

In the BioFire Link software, there are two ways to configure a protocol: 1) a new configuration can be created or 2) a previously exported configuration can be imported.

Based on the protocol that will be used, complete the corresponding instructions in one of the subsections that follow. Only **ONE** of the following subsections must be completed.

**Note:** Only one protocol can be installed at any given time and only one configuration can be active at once.

### 7.1. Configure the FTP Server Protocol

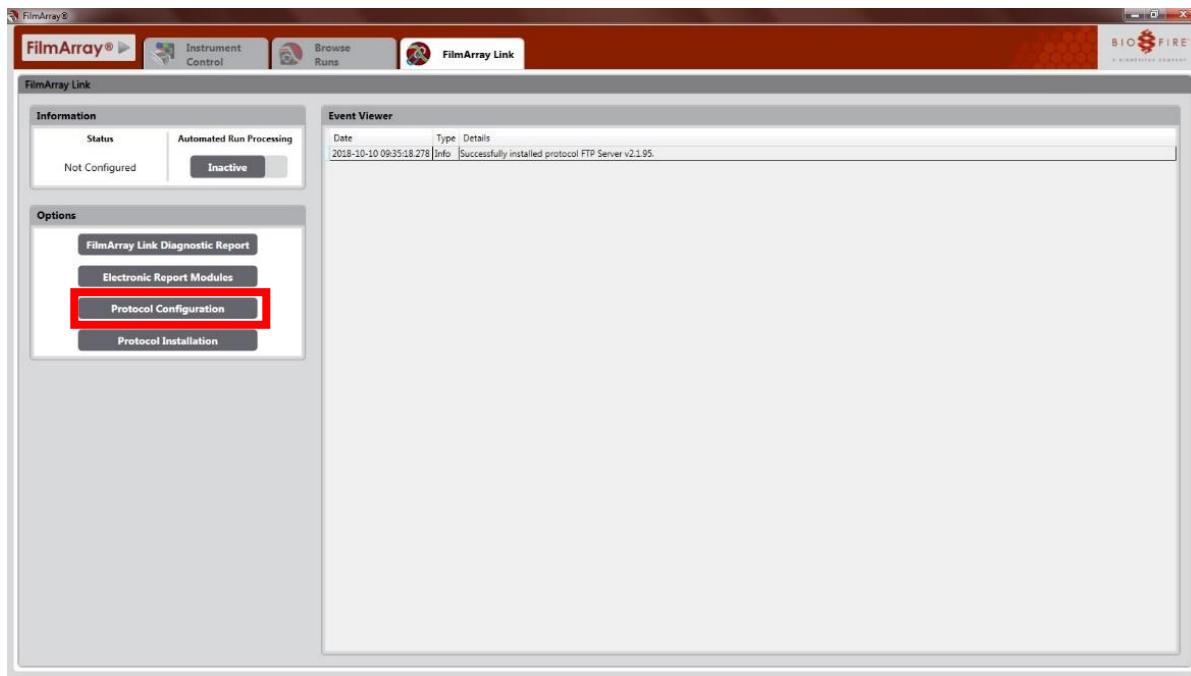
To configure the FTP Server protocol with a new configuration, complete the steps in section 0. Complete the steps in section 0 to configure the FTP Server protocol with an existing configuration from an imported file.

**IMPORTANT:** Before proceeding, ensure the following tasks have been completed:

- Configuring the FTP server on the BioFire® FilmArray® 2.0 System computer requires creating an FTP user account. The FTP user account information will be entered in the data manager's FTP client. Configuration of BioFire® FilmArray® Link requires that the user creates an account name, login, and password. Ensure this information is available.
- Ensure the FilmArray driver has been installed in the data manager.
- Ensure the FTP Server protocol has been installed according to the steps in section 0.

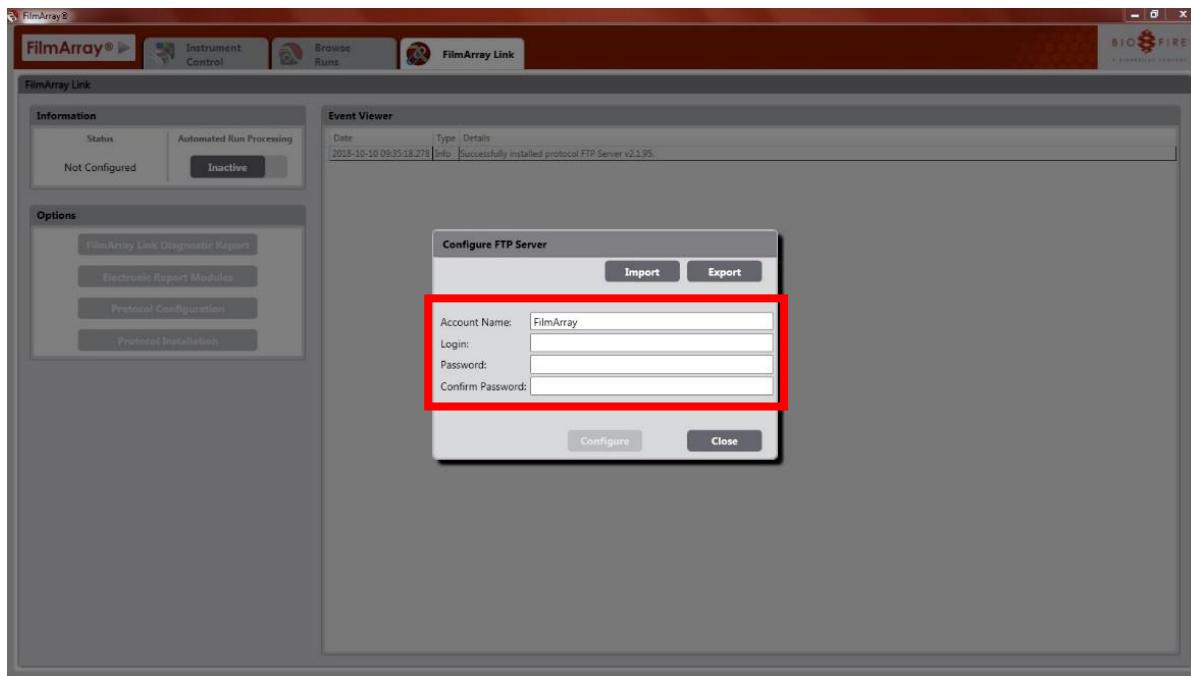
## 7.1.1. Create a New FTP Server Configuration

- From the FilmArray Link tab, select the **Protocol Configuration** option from the Options section.



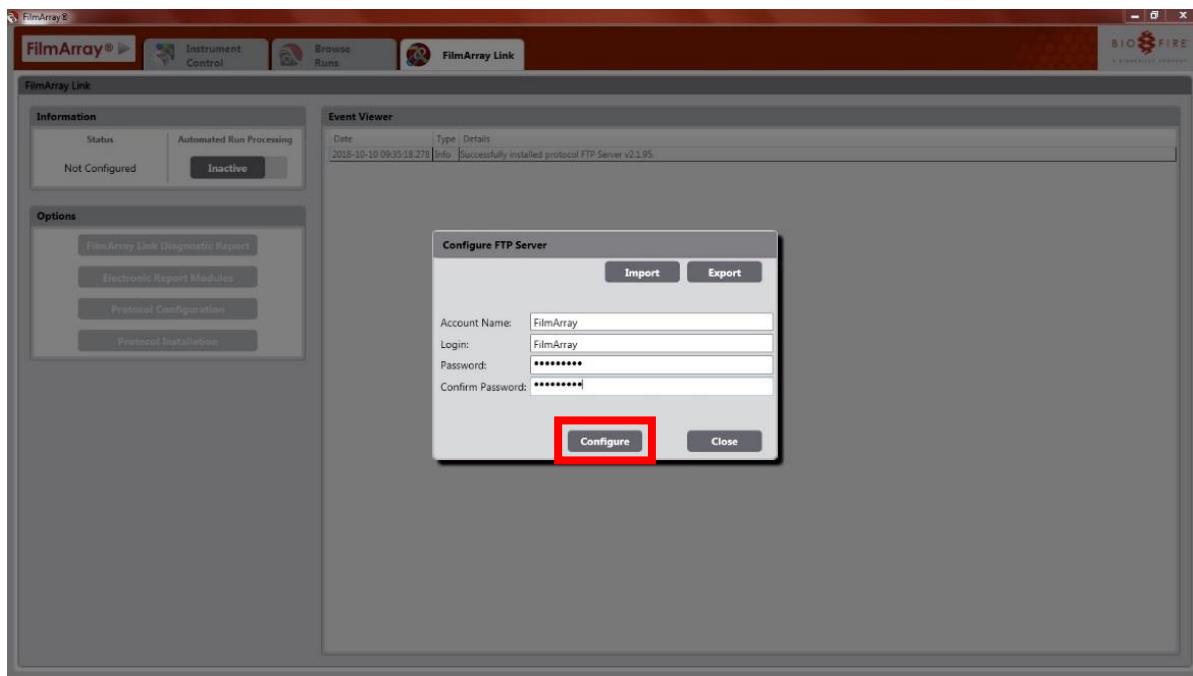
- In the Configure FTP Server dialog, enter the FTP user account credential information.

**Note:** The default account name is “FilmArray” but it can be changed.

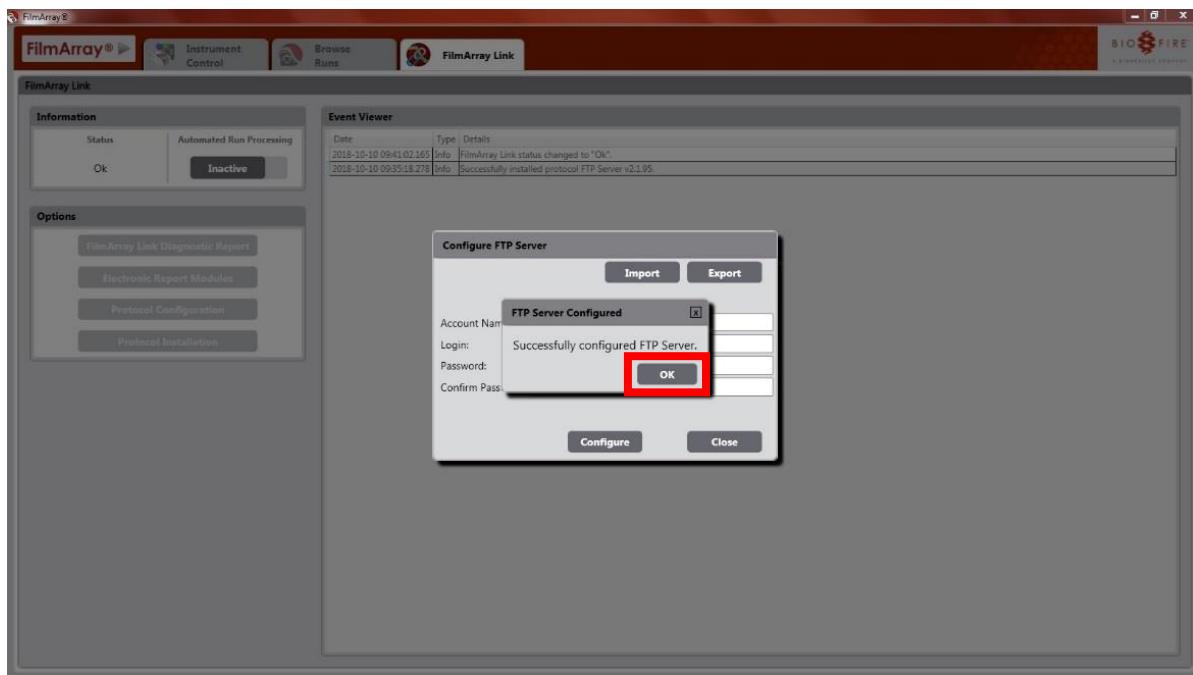


3. Select the **Configure** option. The configuration process begins and a status message dialog is displayed when the configuration is complete.

**Note:** The entries shown in the figure below are for illustrative purposes.

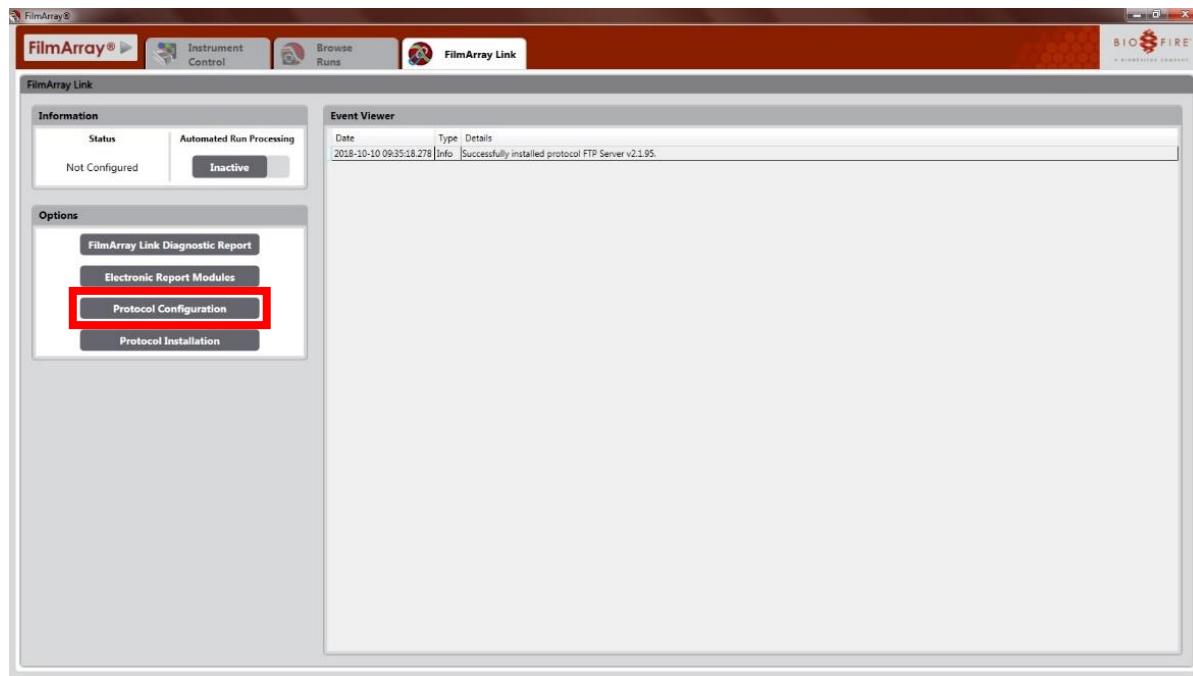


4. Select **OK** to close the status message dialog and the Configure FTP Server dialog.

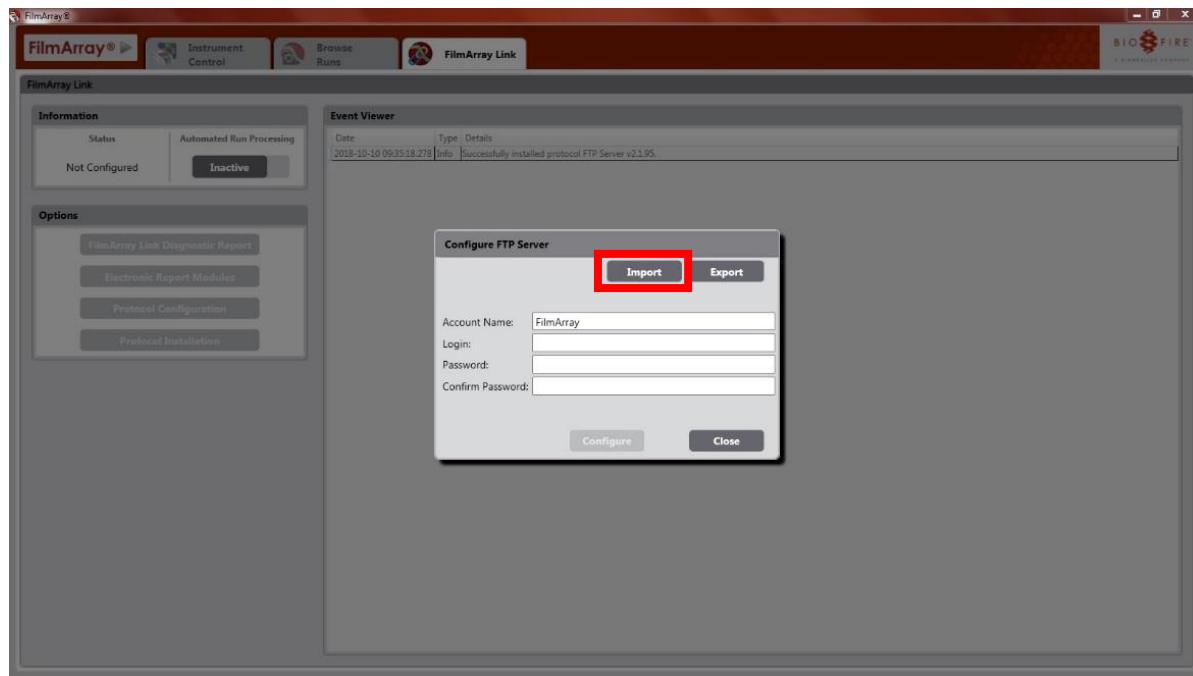


## 7.1.2. Import an FTP Server Configuration

- From the FilmArray Link tab, select the **Protocol Configuration** option from the Options section.



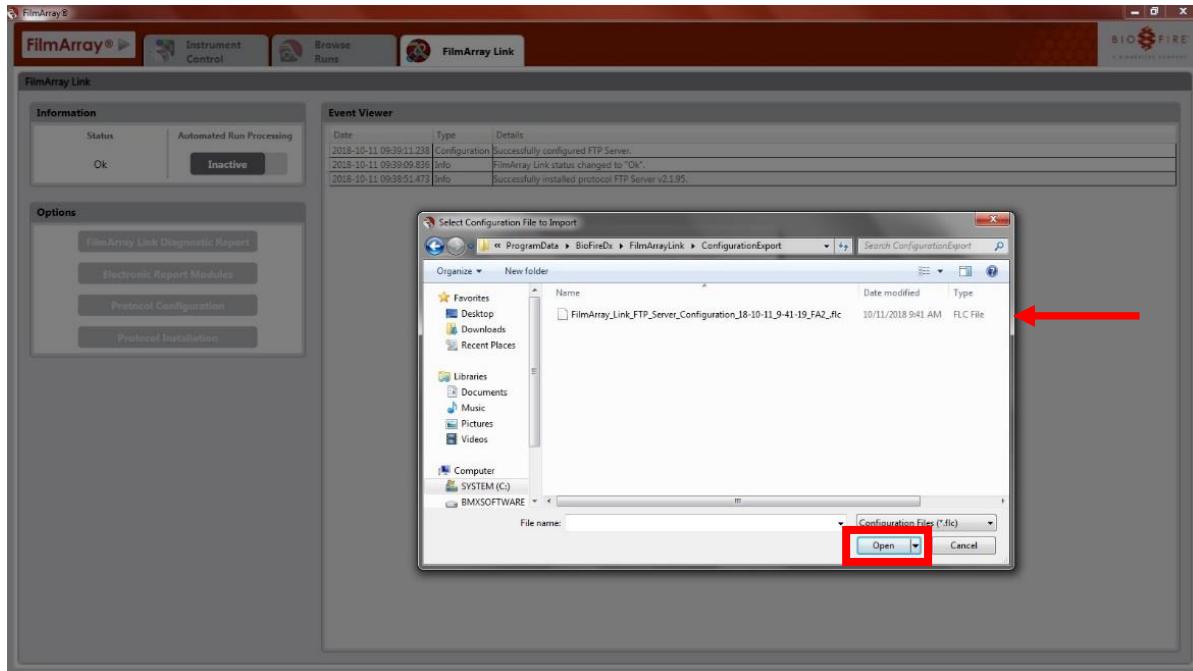
- In the Configure FTP Server dialog, select the **Import** option.



3. In the Select Configuration File to Import dialog, navigate to the configuration file. Select the file and select **Open**. A dialog confirming the import is displayed.

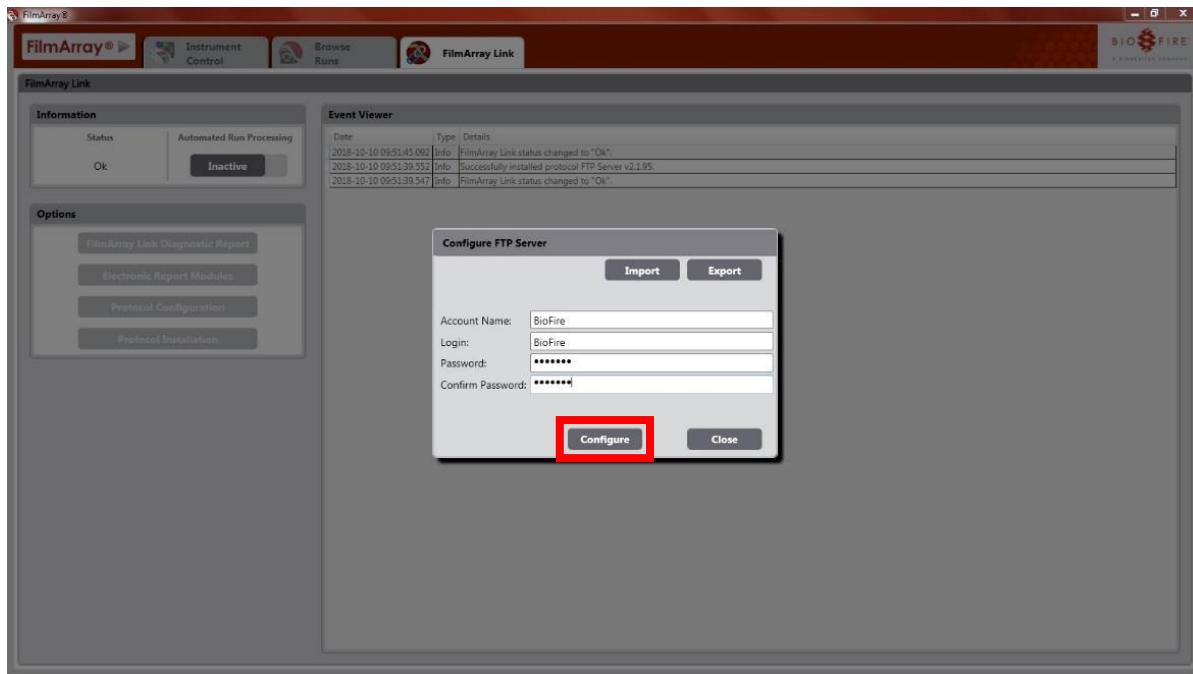
**Note:** If the BioFire® FilmArray® Link Software was upgraded from version 2.0 to version 2.1 and version 2.0 was configured, a configuration file is saved in C:\ProgramData\BioFireDx\FilmArrayLink\ConfigurationExport. The file may also be saved in a location designated in a previous configuration export.

**Note:** If there is text in any of the fields of the Configure FTP Server dialog, a dialog confirming the import is displayed when the **Open** is selected. Select **Yes**.

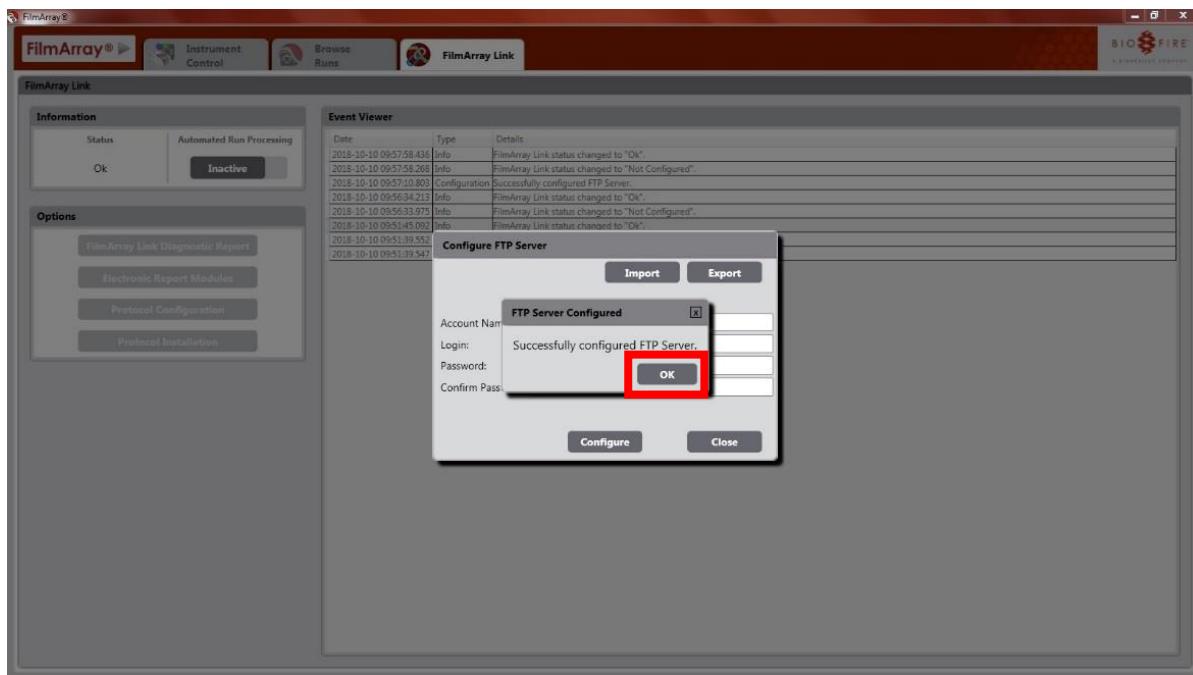


- Enter and confirm the password associated with the FTP user account in the Configure FTP Server dialog. Select the **Configure** option.

**Note:** The entries shown in the figure below are for illustrative purposes.



- Select **OK** to close the status message dialog and the Configure FTP Server dialog.



## 7.2. Configure the HTTP Protocol

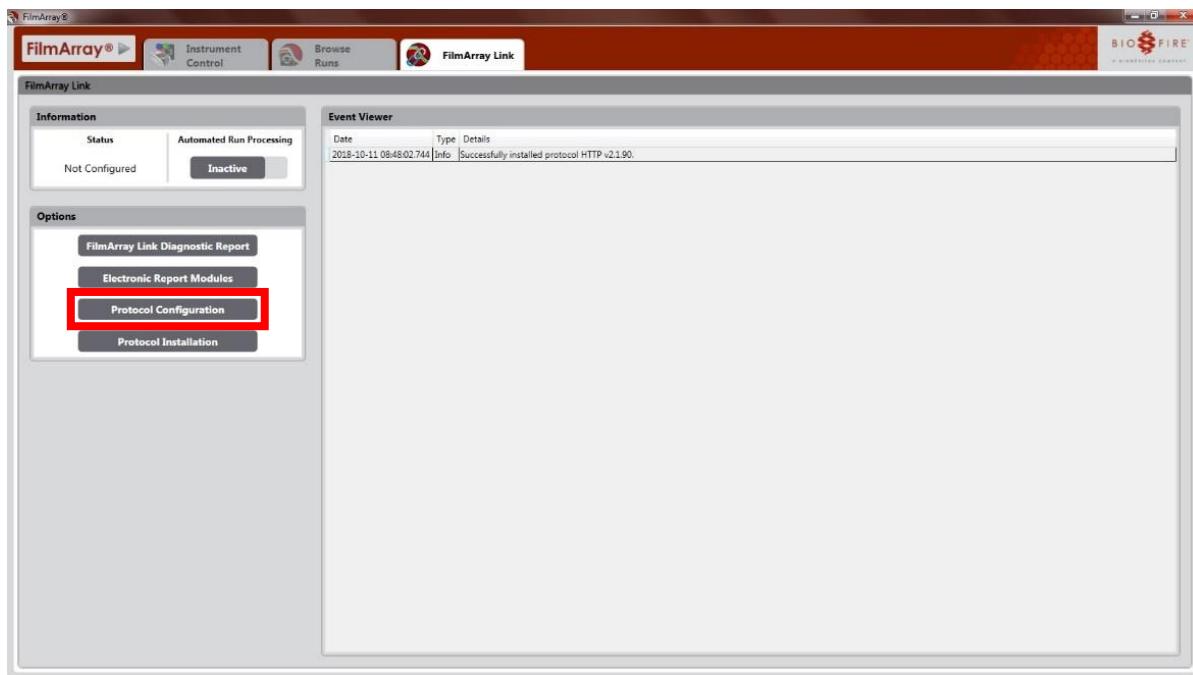
To configure the HTTP protocol with a new configuration, complete the steps in section 7.2.1. Complete the steps in section 7.2.2 to configure the HTTP protocol with an existing configuration from an imported file.

**IMPORTANT:** Before proceeding, ensure the following tasks have been completed.

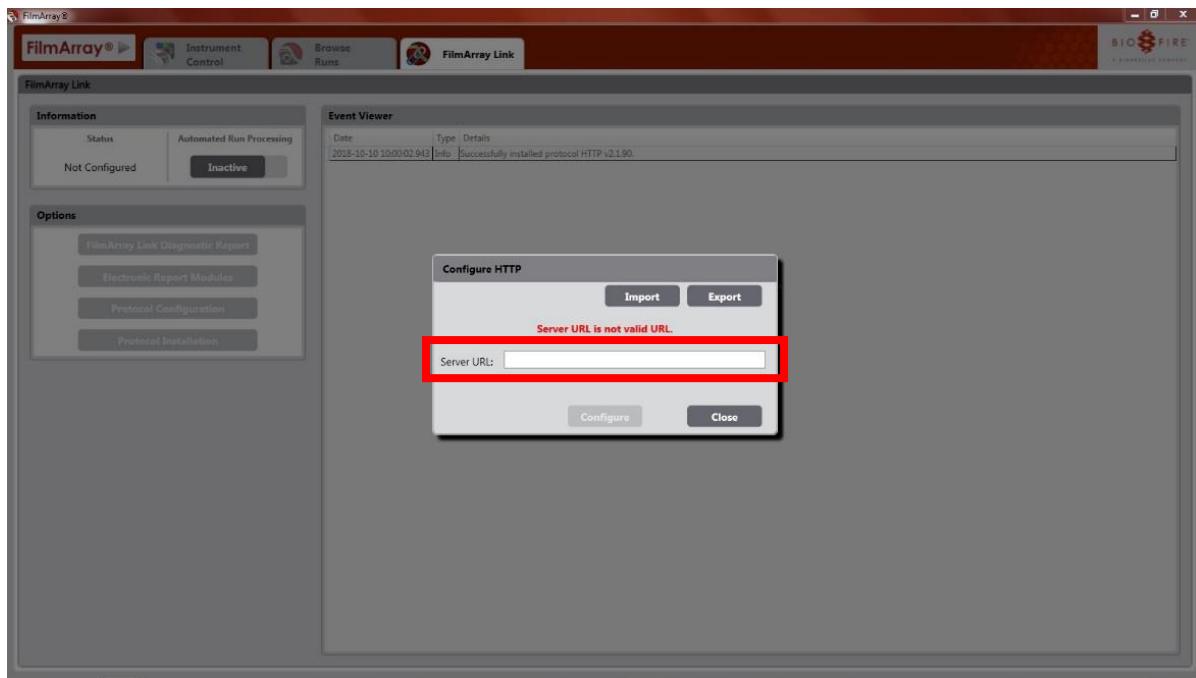
- Obtain the server URL for the data manager and ensure it is active.
- Ensure the FilmArray driver has been installed in the data manager and configured.
- Ensure the HTTP protocol has been installed according to the steps in section 0.

### 7.2.1. Create a New HTTP Configuration

1. From the FilmArray Link tab, select the **Protocol Configuration** option from the Options section.

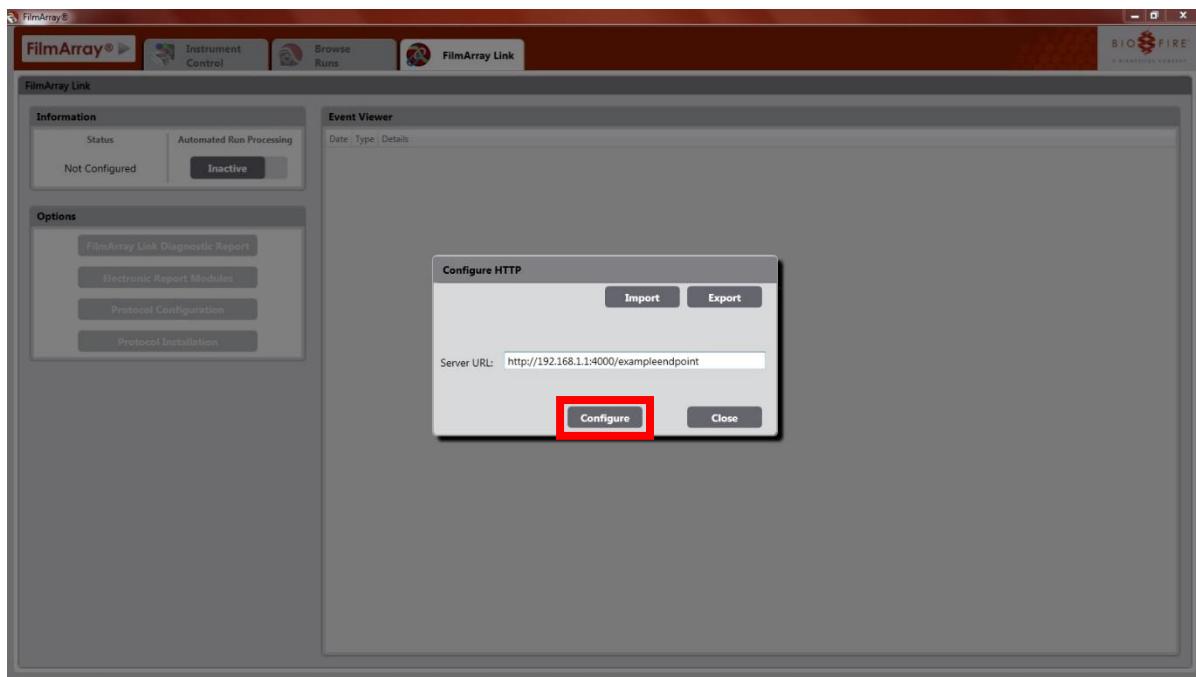


2. In the Configure HTTP dialog, enter the server URL.

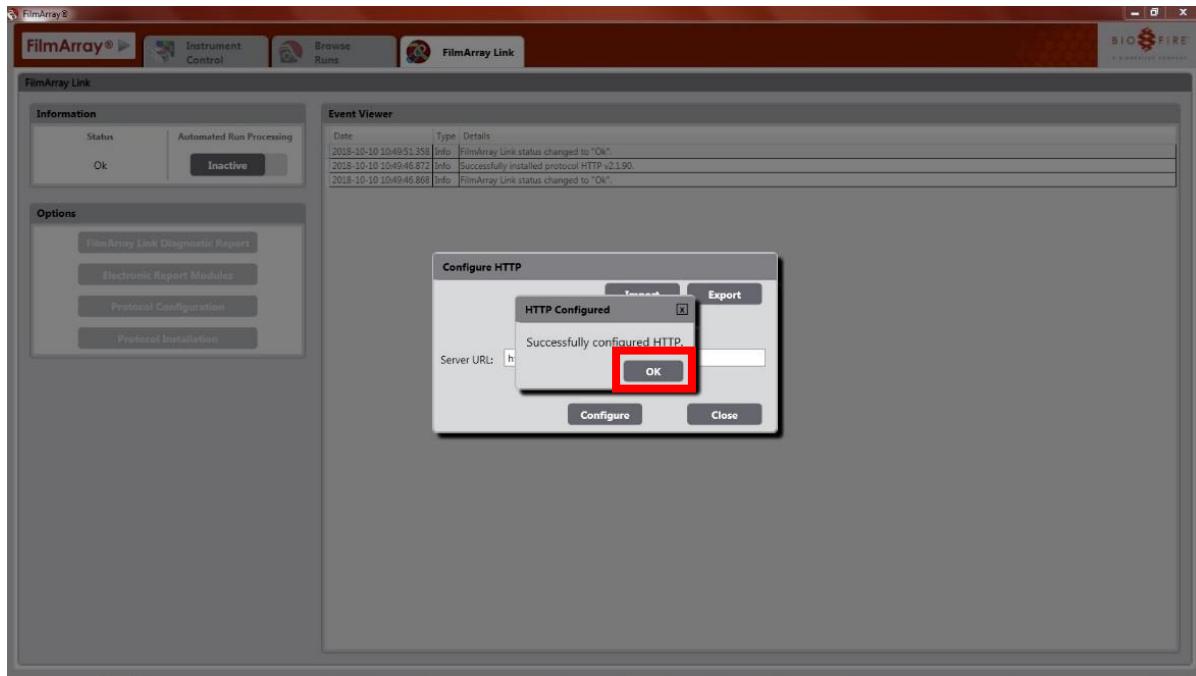


3. Select the **Configure** option. The configuration process begins. A status message dialog is displayed when the configuration is complete.

**Note:** The entry shown in the figure below is for illustrative purposes.

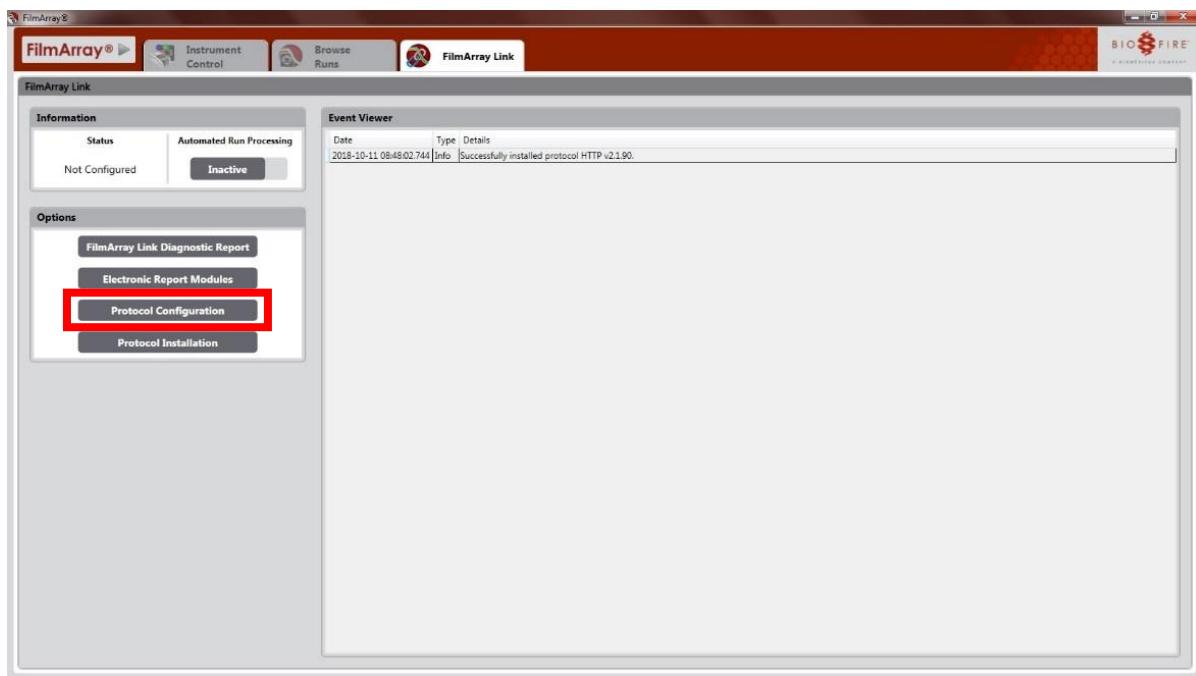


4. Select **OK** to close the status message and the Configure HTTP dialog.

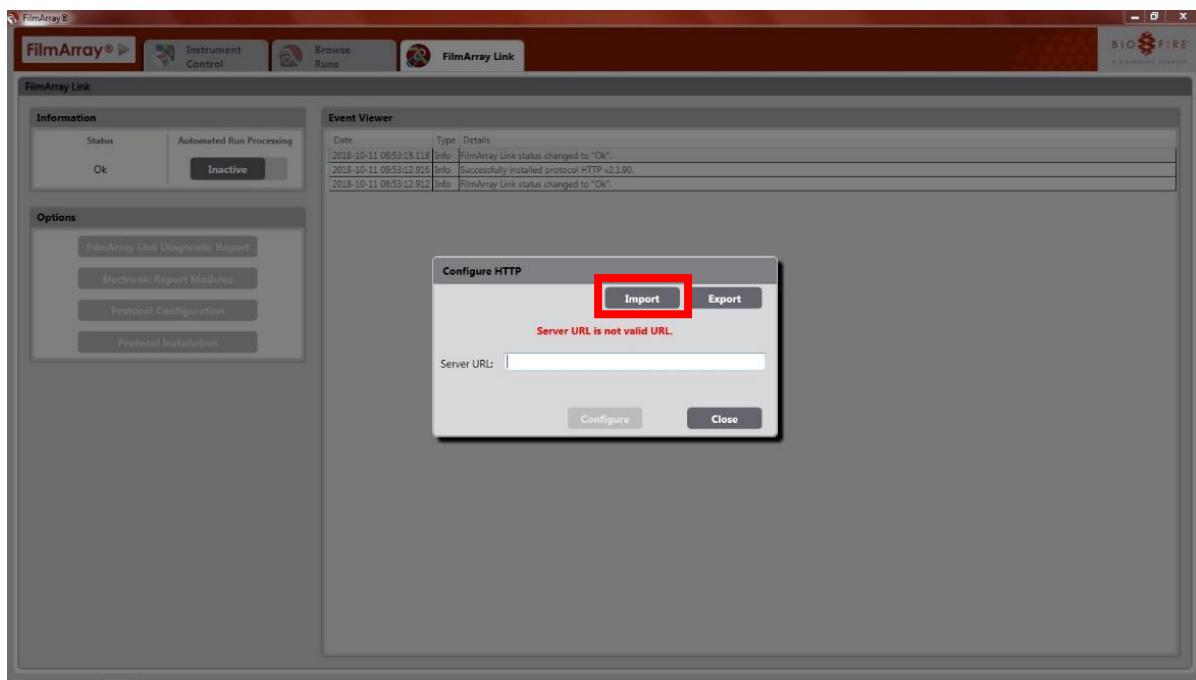


## 7.2.2. Import an HTTP Configuration

1. From the FilmArray Link tab, select the **Protocol Configuration** option from the Options section.



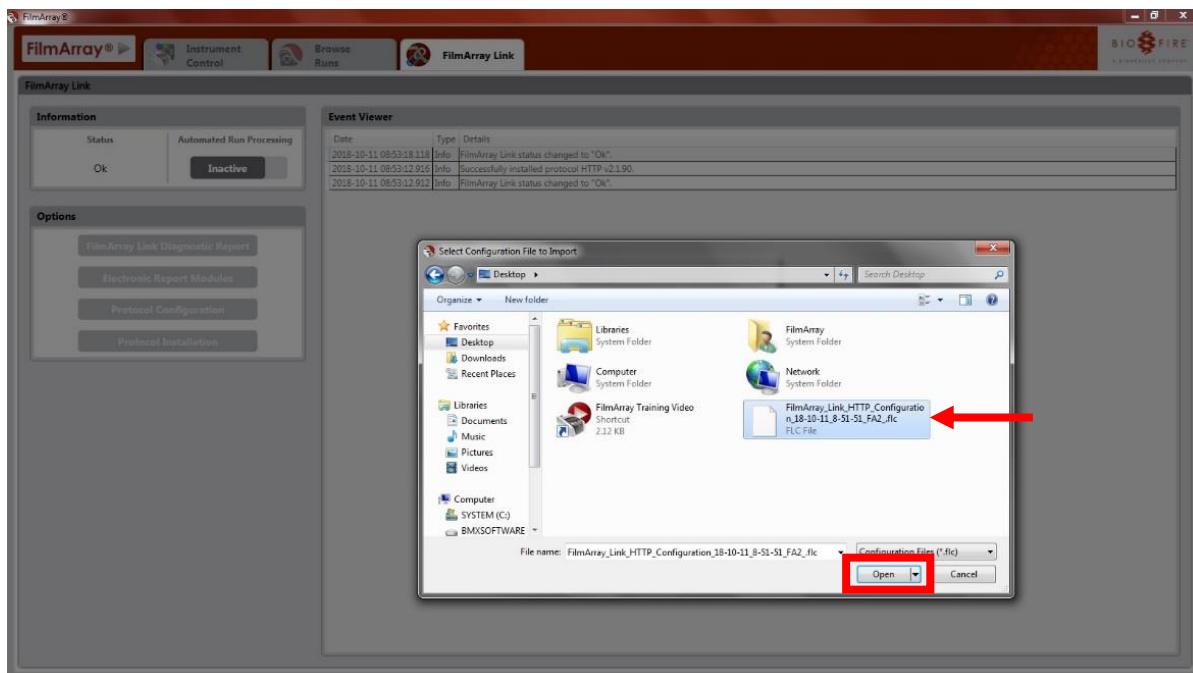
2. In the Configure HTTP dialog, select the **Import** option.



3. In the Select Configuration File to Import dialog, navigate to the configuration file. Select the file and select **Open**.

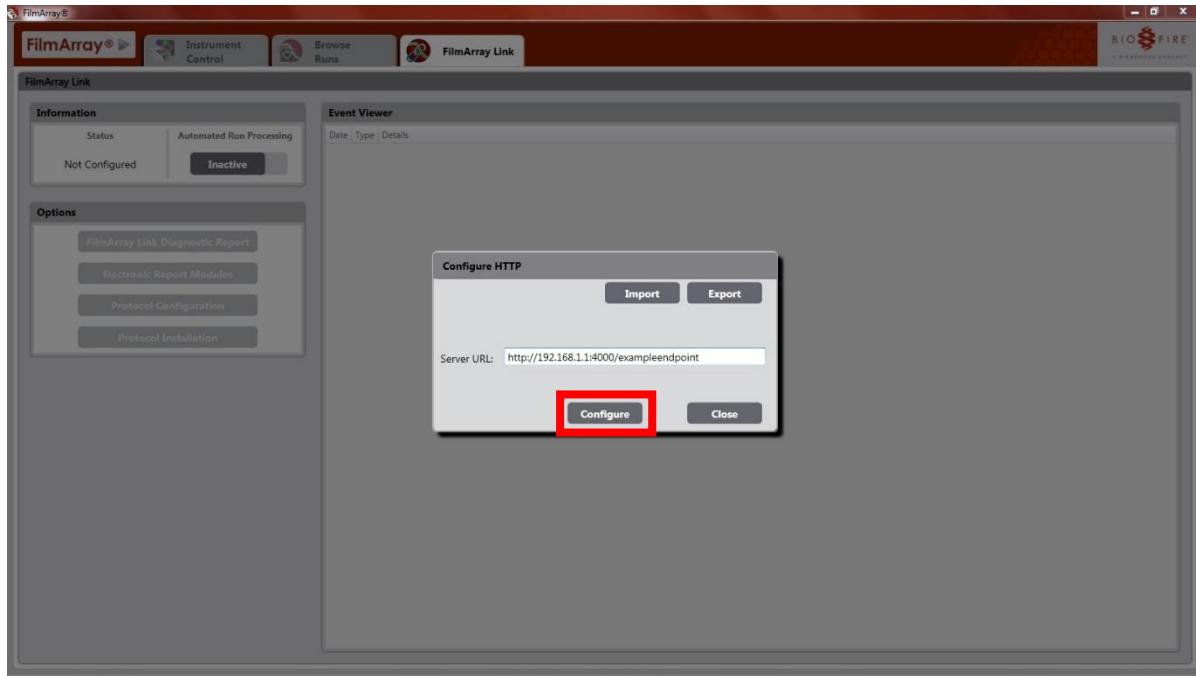
**Note:** If the BioFire® FilmArray® Link Software was upgraded from version 2.0 to version 2.1 and version 2.0 was configured, a configuration file is saved in C:\ProgramData\BioFireDx\FilmArrayLink\ConfigurationExport. The file may also be saved in a location designated in a previous configuration export.

**Note:** If there is text in the field of the Configure HTTP dialog, a dialog confirming the import is displayed when the **Open** is selected. Select **Yes**.

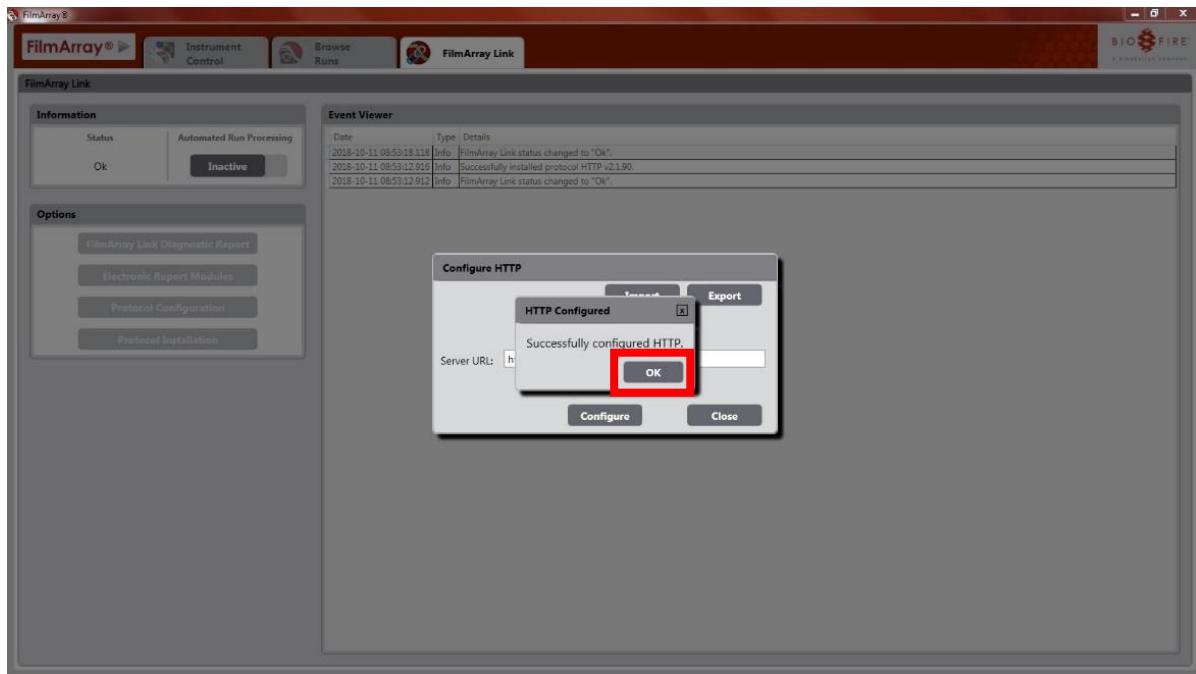


4. Select the **Configure** option.

**Note:** The entry shown in the figure below is for illustrative purposes.



5. Select **OK** to close the status message dialog and the Configure HTTP dialog.



## 7.3. Configure the Local Folder Protocol

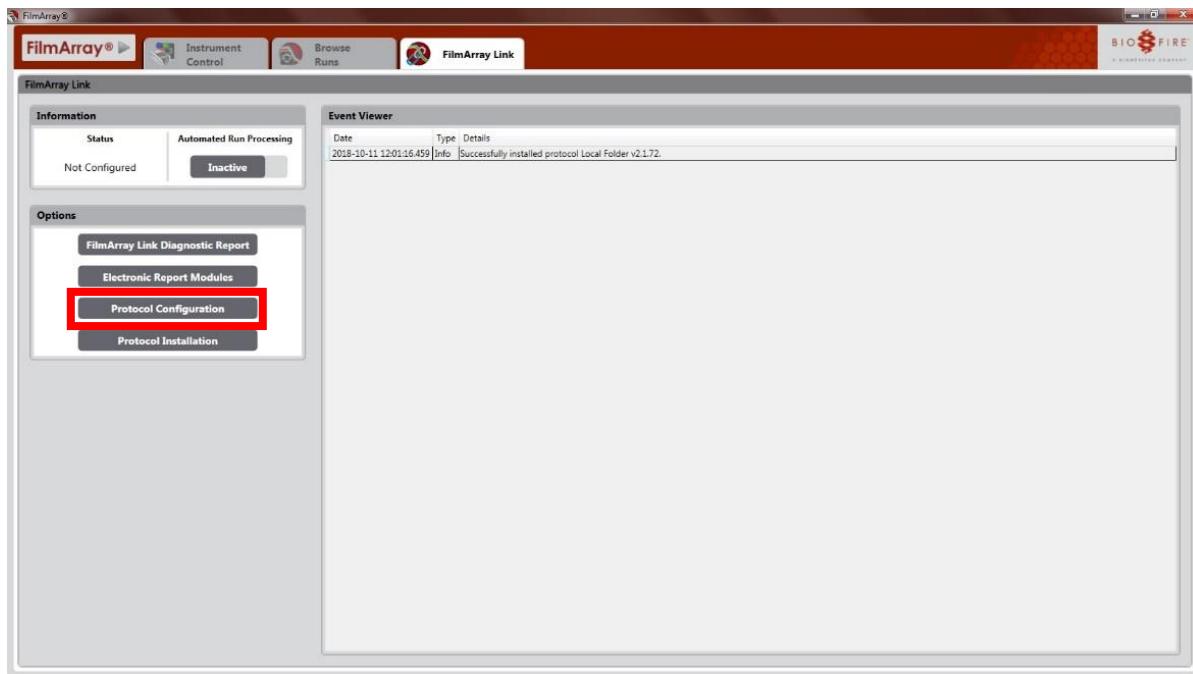
To configure the Local Folder protocol with a new configuration, complete the steps in section 7.3.1. Complete the steps in section 7.3.2 to configure the Local Folder protocol with an existing configuration from an imported file.

**IMPORTANT:** Before proceeding, ensure the following tasks have been completed.

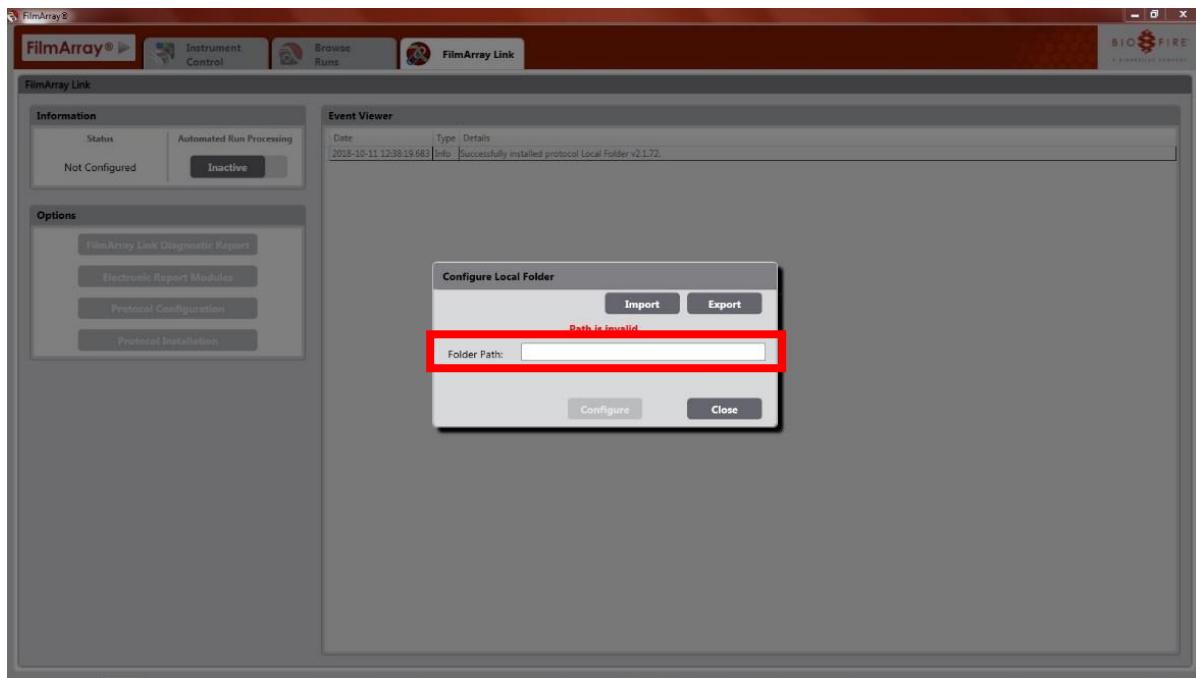
- Designate the folder path on the BioFire® FilmArray® 2.0 System computer to which the XML files will be sent.
- Ensure the FilmArray driver has been installed in the data manager. The driver must also be configured to access the XML files in the designated folder path.
- Ensure the Local Folder protocol has been installed according to the steps in section 0.

### 7.3.1. Create a New Local Folder Configuration

1. From the FilmArray Link tab, select the **Protocol Configuration** option from the Options section.

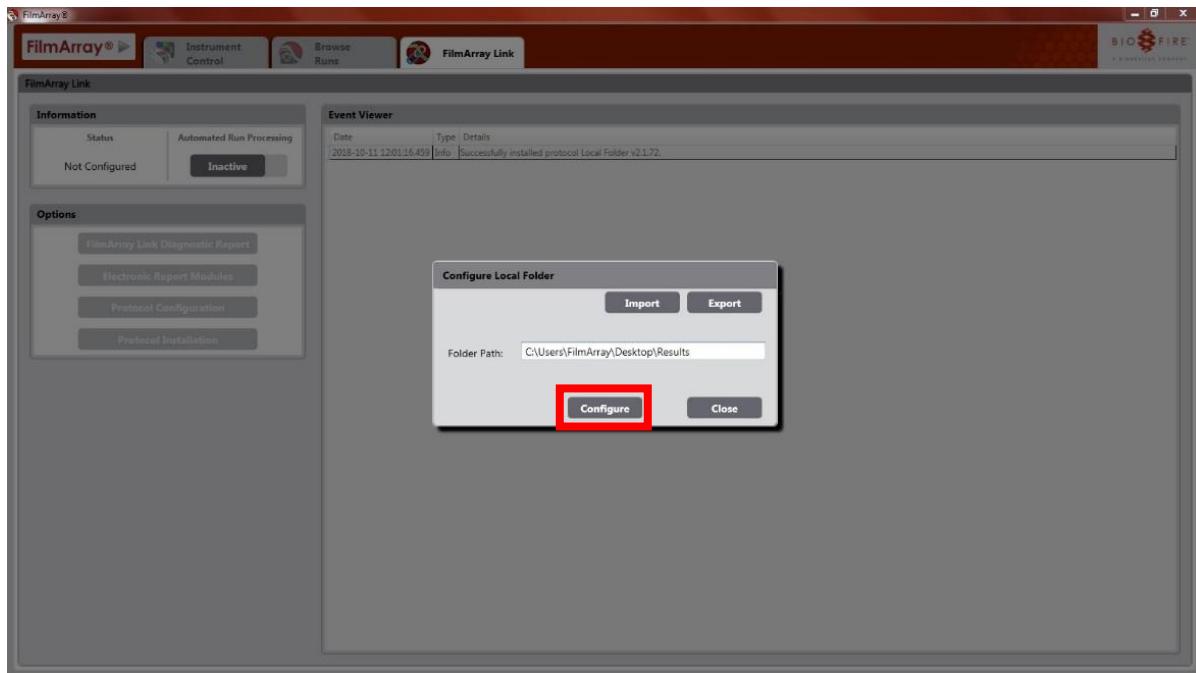


2. In the Configure Local Folder dialog, enter the local folder path.

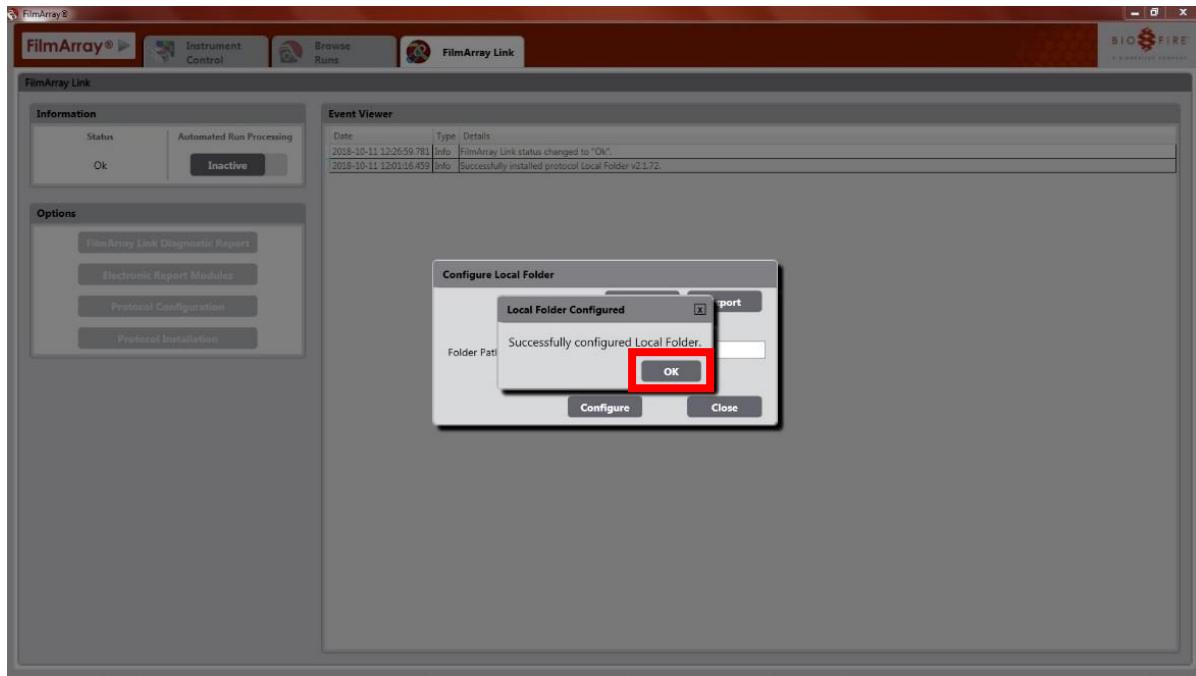


3. Select the **Configure** option. The configuration process begins and a status message dialog is displayed when the configuration is complete.

**Note:** The entry shown in the figure below is for illustrative purposes.

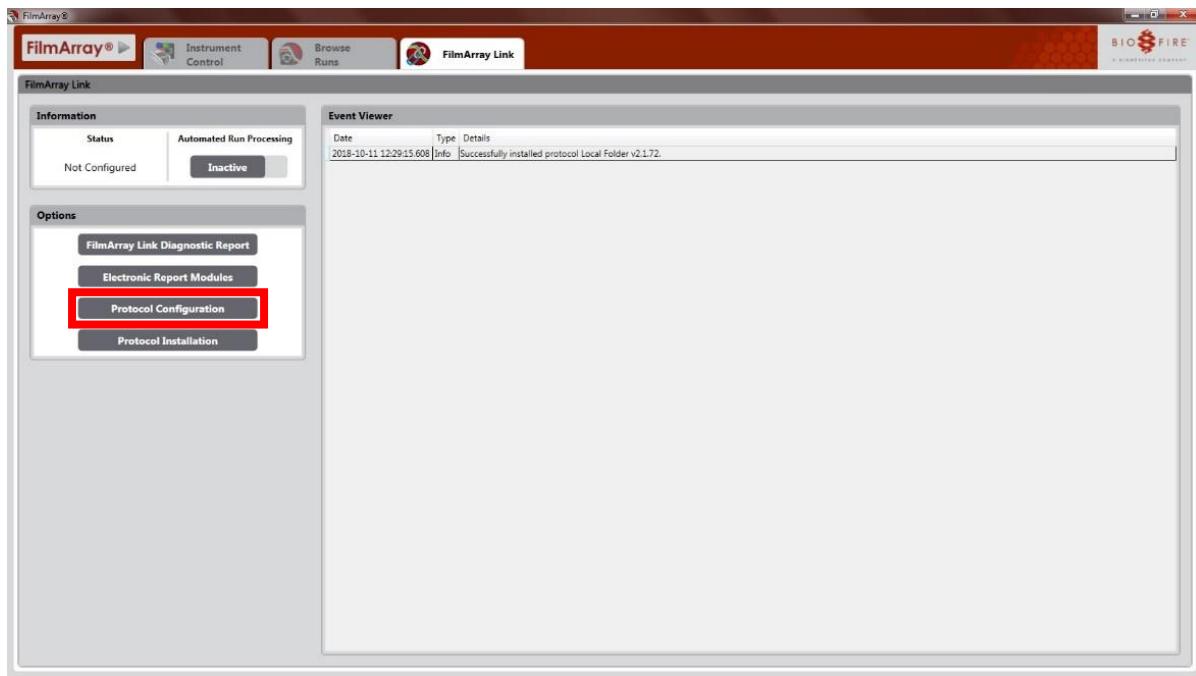


4. Select **OK** to close the status message and the Configure Local Folder dialog.

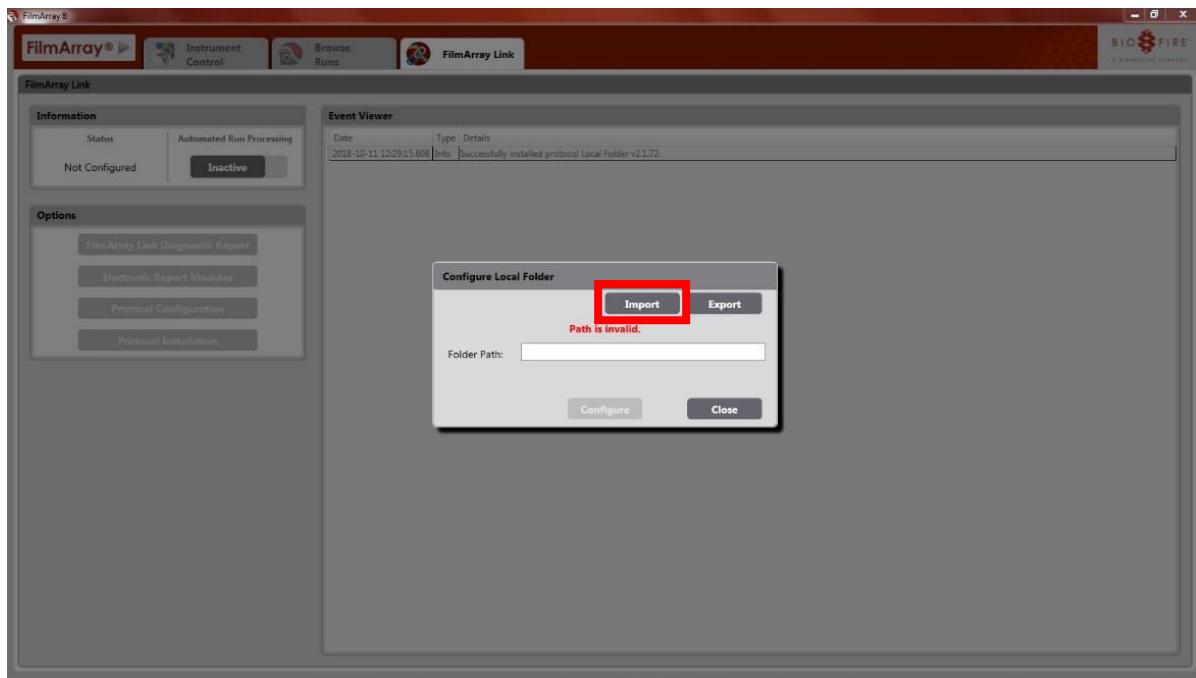


### 7.3.2. Import a Local Folder Configuration

1. From the FilmArray Link tab, select the **Protocol Configuration** option from the Options section.



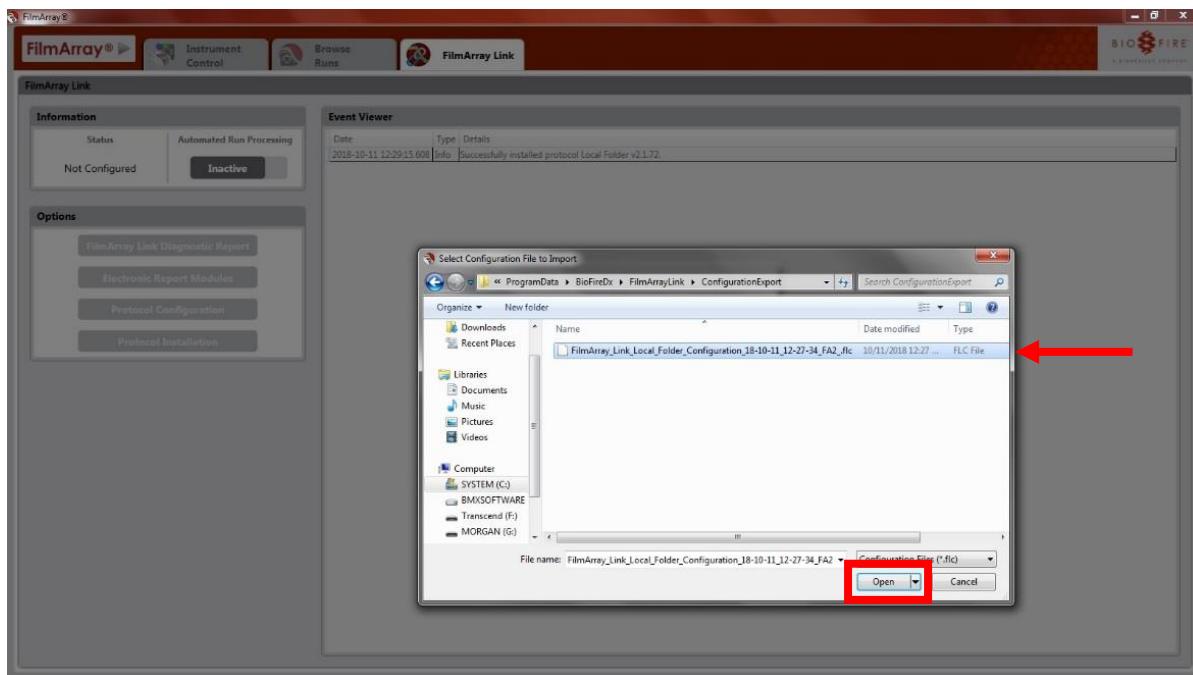
2. In the Configure Local Folder dialog, select the **Import** option.



3. In the Select Configuration File to Import dialog, navigate to the configuration file. Select the file and select **Open**.

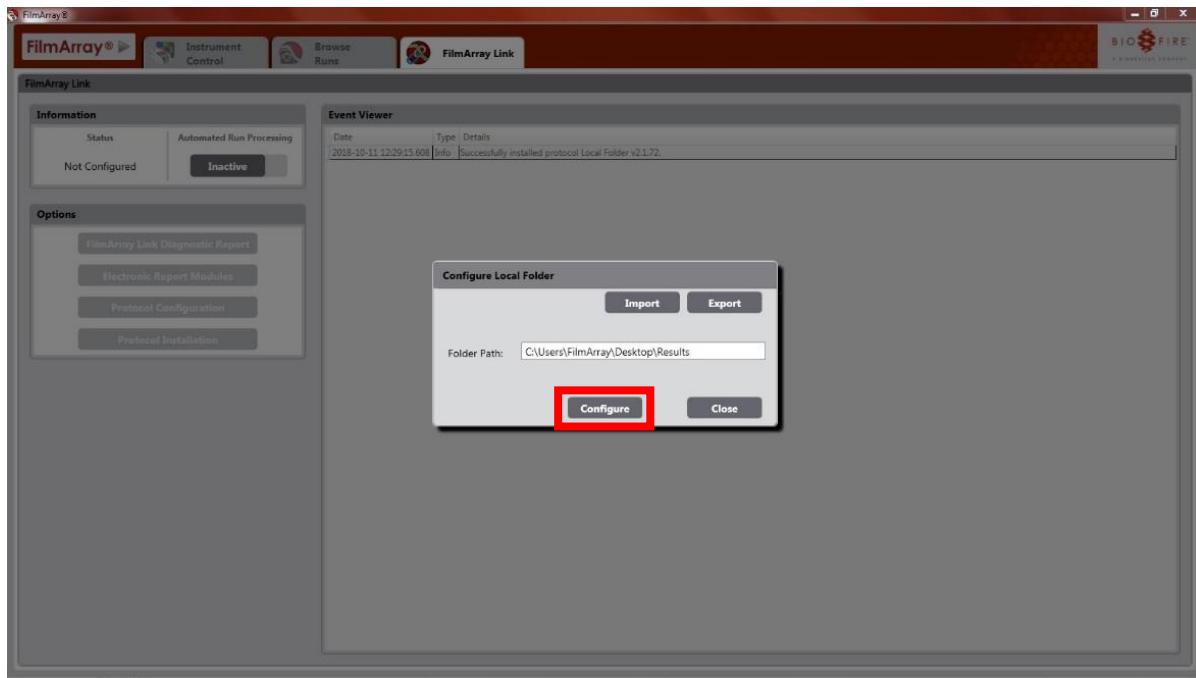
**Note:** If the BioFire® FilmArray® Link Software was upgraded from version 2.0 to version 2.1 and version 2.0 was configured, a configuration file is saved in C:\ProgramData\BioFireDx\FilmArrayLink\ConfigurationExport. The file may also be saved in a location designated in a previous configuration export.

**Note:** If there is text in the field of the Configure Local Folder dialog, a dialog confirming the import is displayed when the **Open** is selected. Select **Yes**.

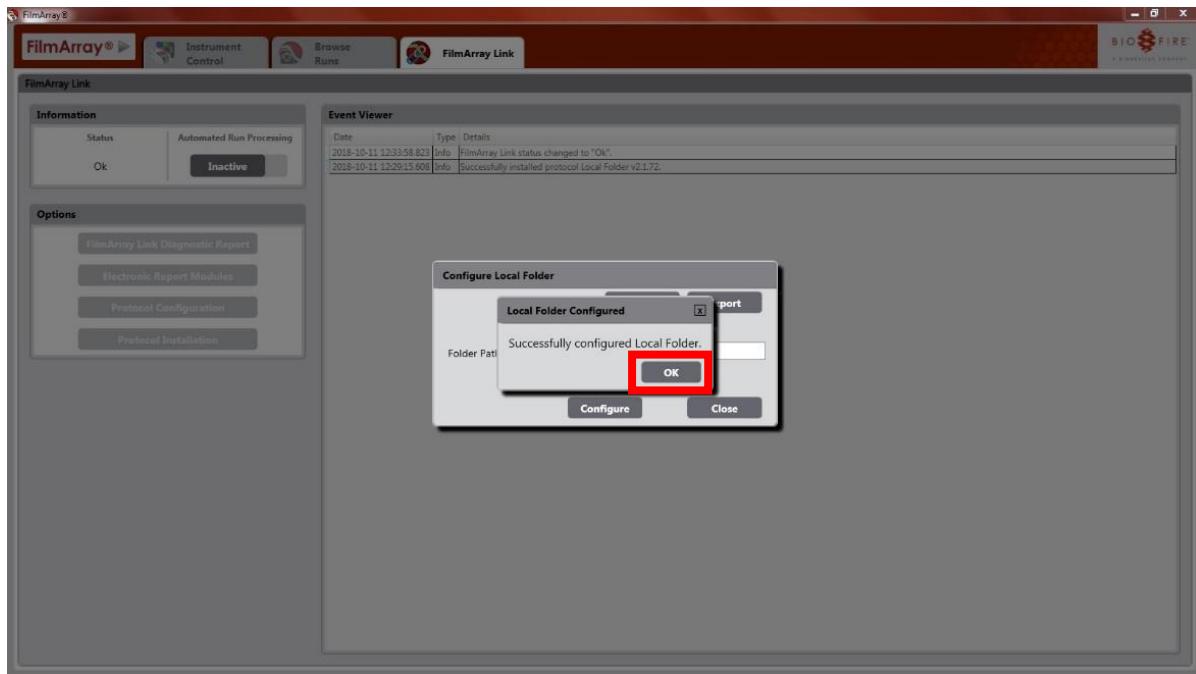


4. Select the **Configure** option.

**Note:** The entry shown in the figure below is for illustrative purposes.



5. Select **OK** to close the status message dialog and the Configure Local Folder dialog.



## 7.4. Configure the LIS Shared Folder Protocol

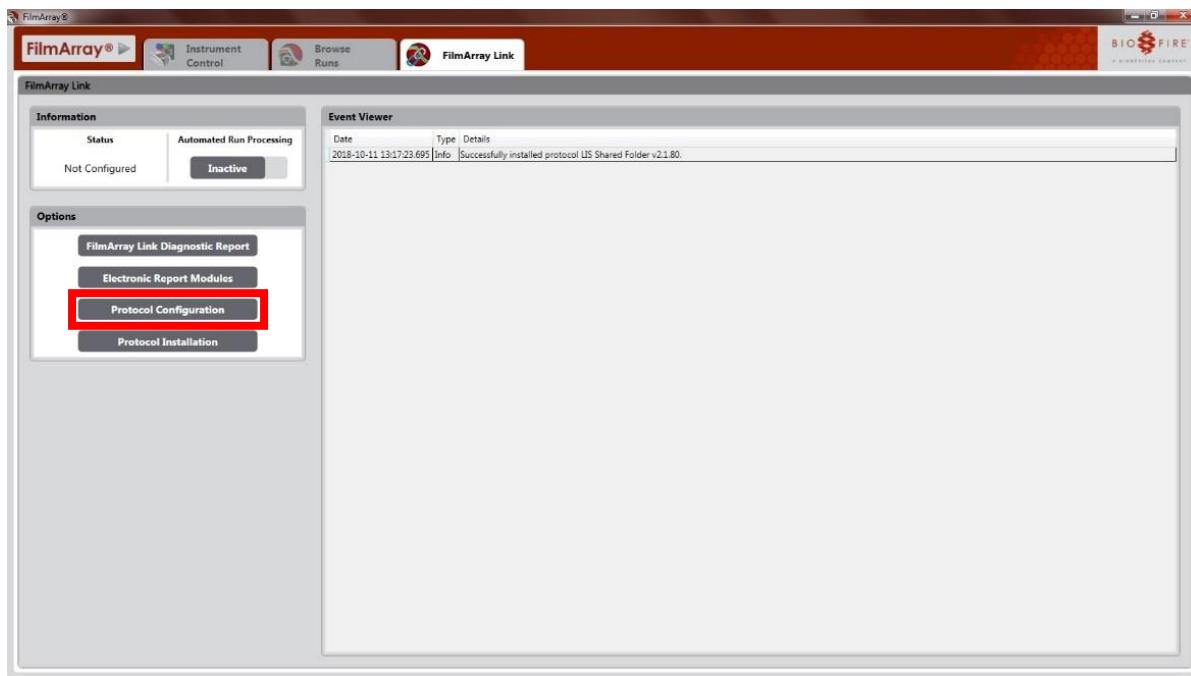
To configure the LIS Shared Folder protocol with a new configuration, complete the steps in section 7.4.1. Complete the steps in section 7.4.2 to configure the LIS Shared Folder protocol with an existing configuration from an imported file.

**IMPORTANT:** Before proceeding, ensure the following tasks have been completed.

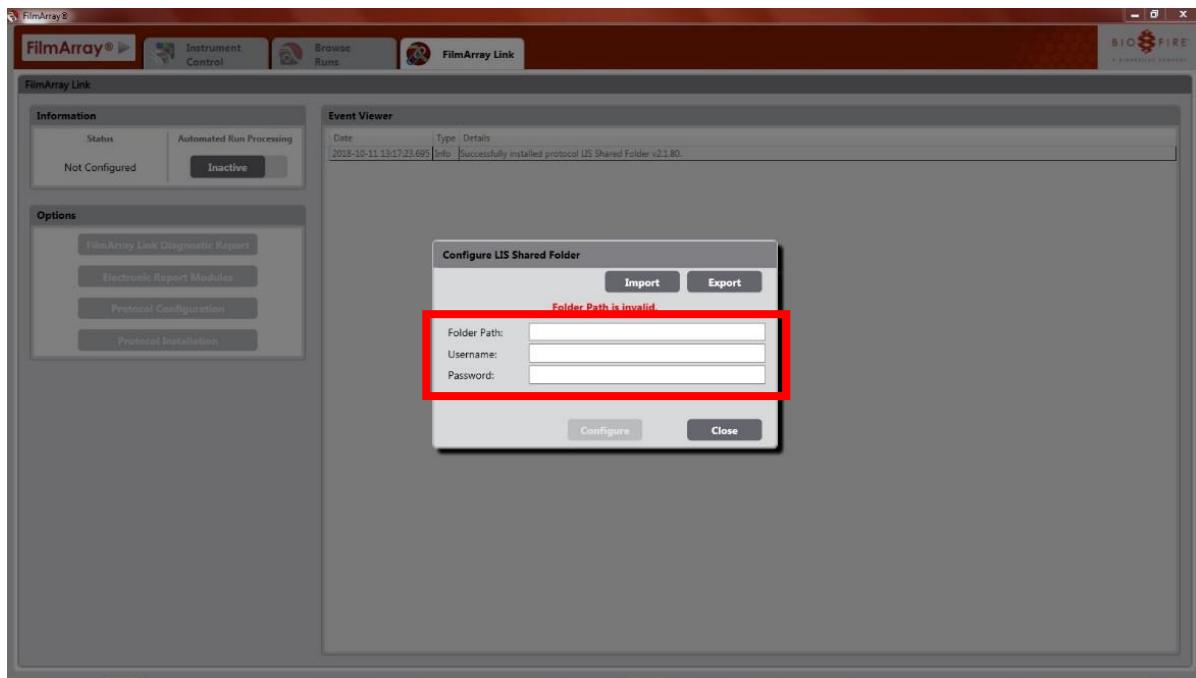
- Designate the LIS folder path to which the XML files will be sent.
- Ensure that credentials for a user account with read and write access to the LIS shared folder path and the domain name are available.
- Ensure the FilmArray driver has been installed in the data manager. The driver must also be configured to access the XML files in the designated folder path.
- Ensure the LIS Shared Folder protocol has been installed according to the steps in section 0.

### 7.4.1. Create a New LIS Shared Folder Configuration

1. From the FilmArray Link tab, select the **Protocol Configuration** option from the Options section.

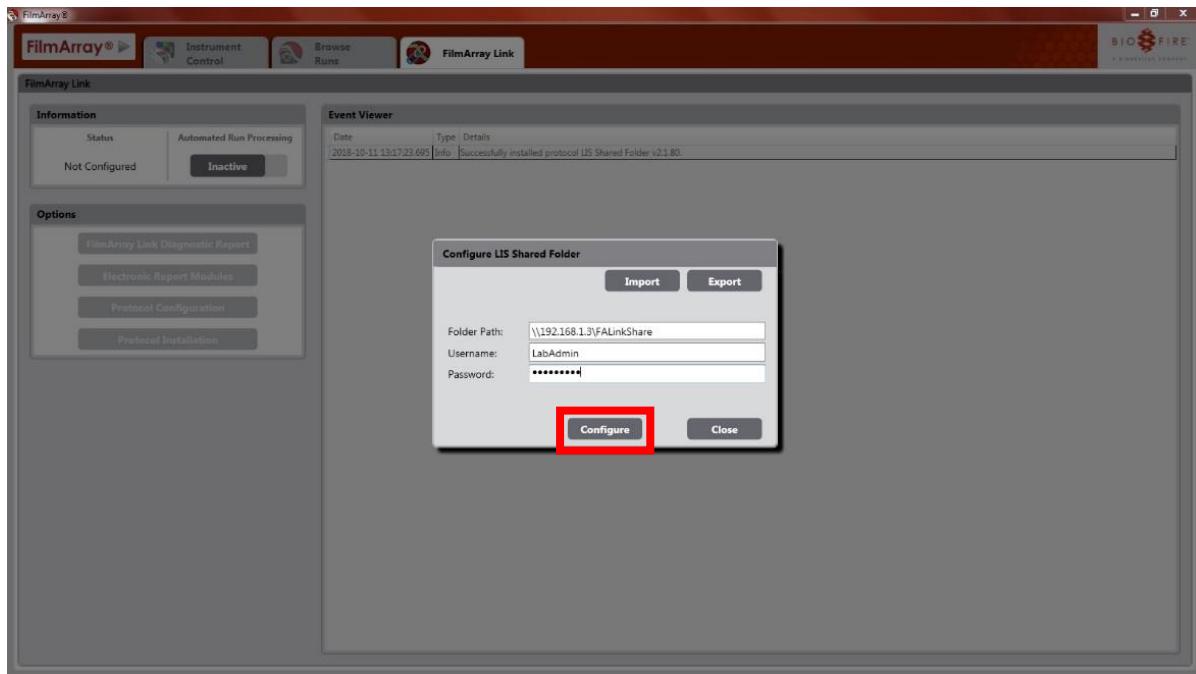


2. In the Configure LIS Shared Folder dialog, enter the LIS shared folder information.

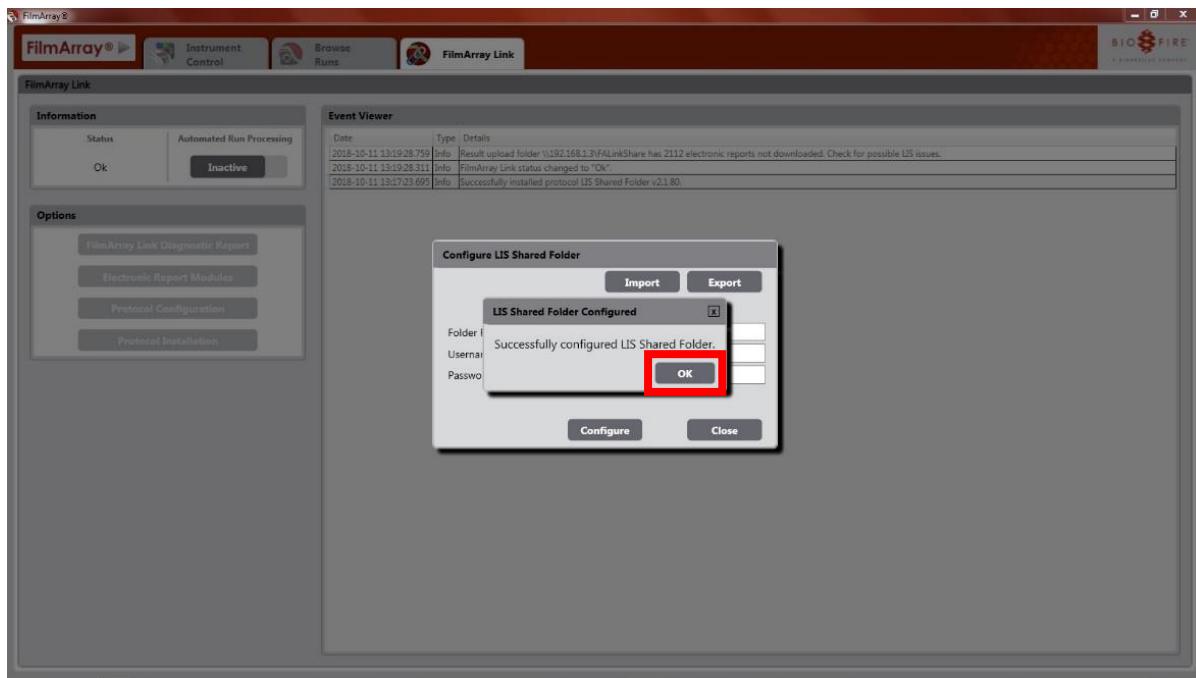


3. Select the **Configure** option.

**Note:** The entries shown in the figure below are for illustrative purposes.

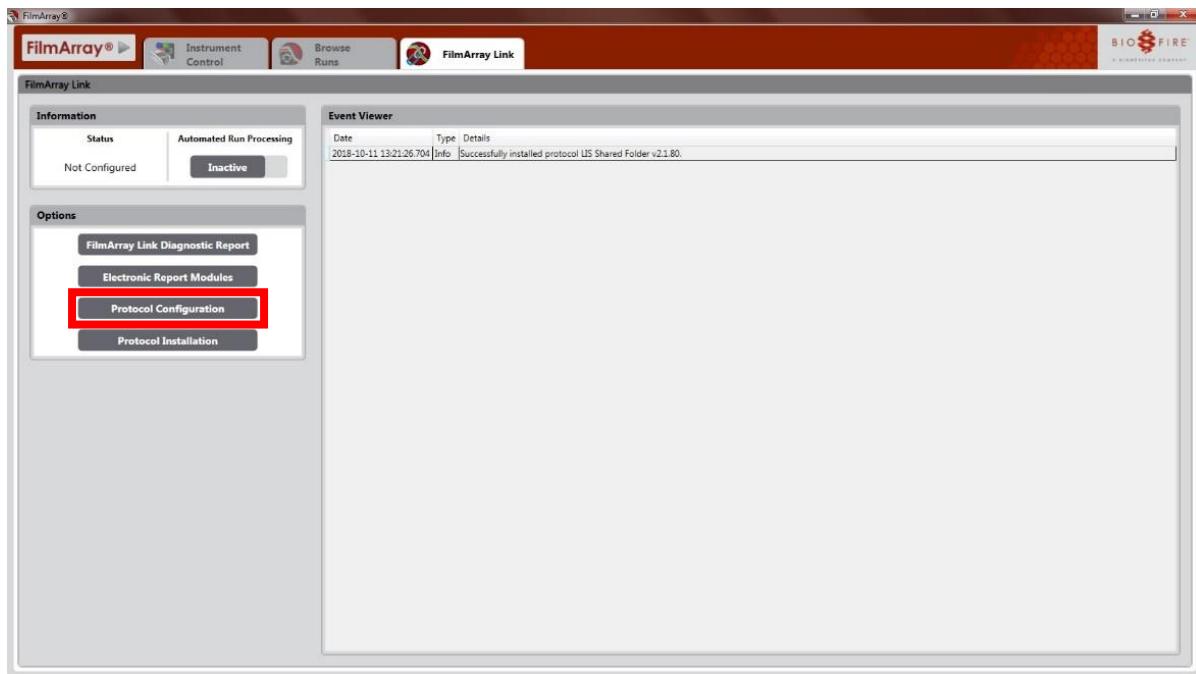


4. Select **OK** to close the status message dialog and the Configure LIS Shared Folder dialog.

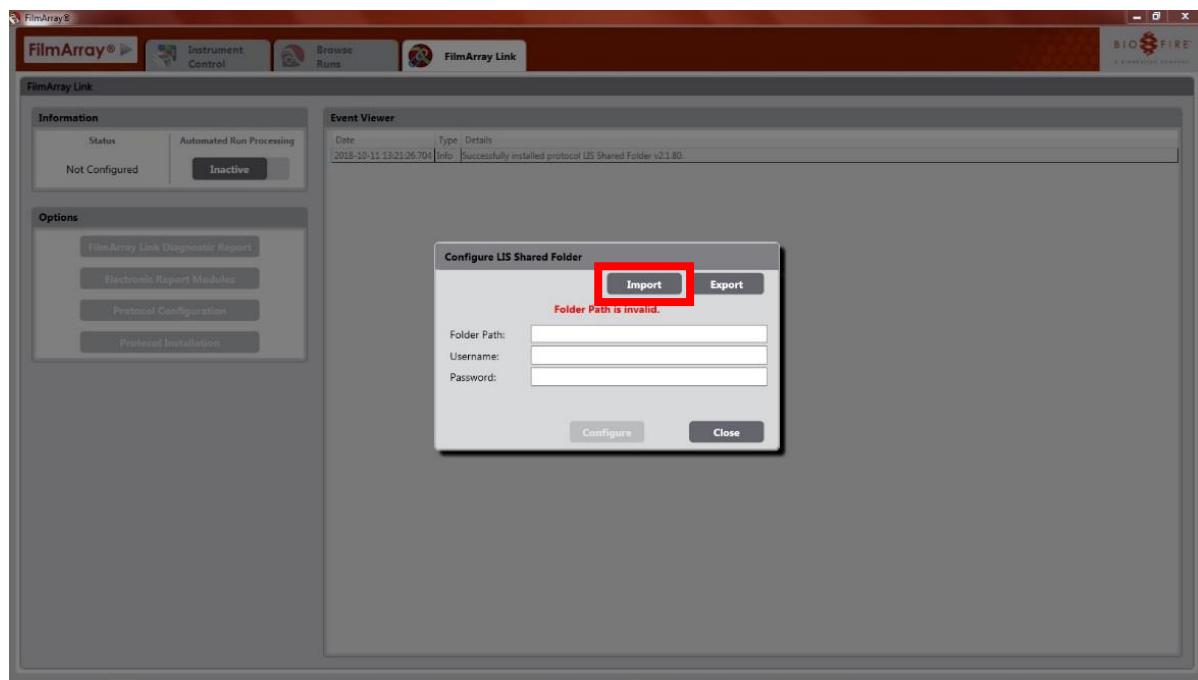


## 7.4.2. Import an LIS Shared Folder Configuration

1. From the FilmArray Link tab, select the **Protocol Configuration** option from the Options section.



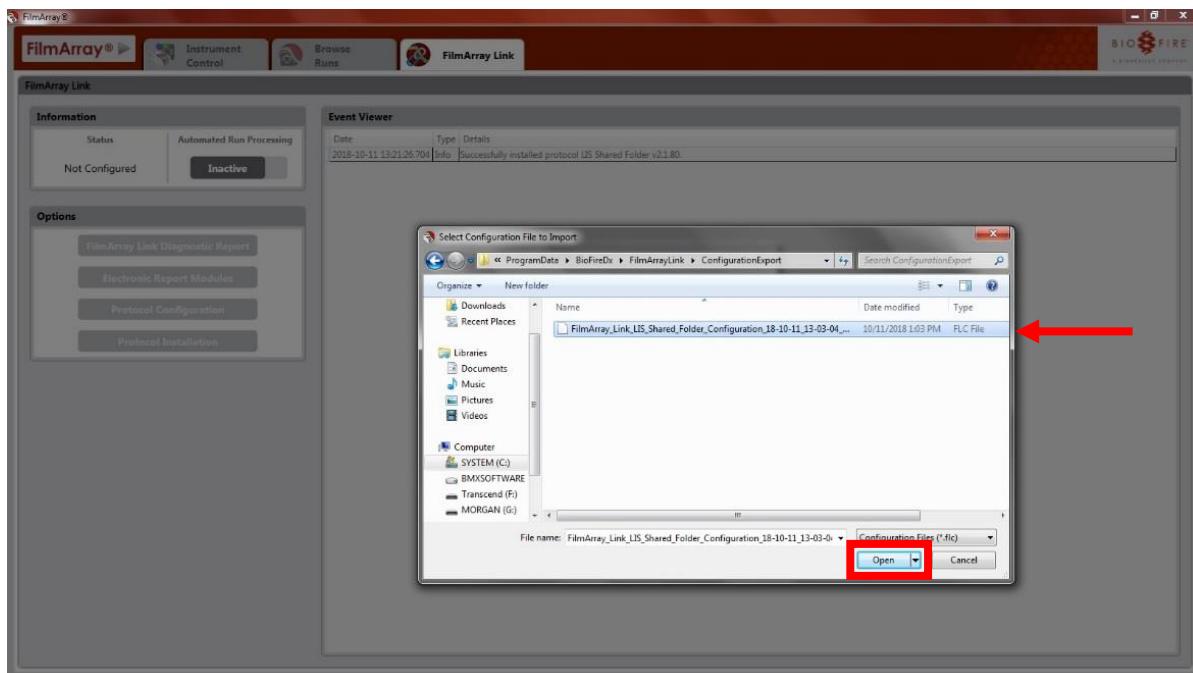
2. In the Configure LIS Shared Folder dialog, select the **Import** option.



3. In the Select Configuration File to Import dialog, navigate to the configuration file. Select the file and select **Open**.

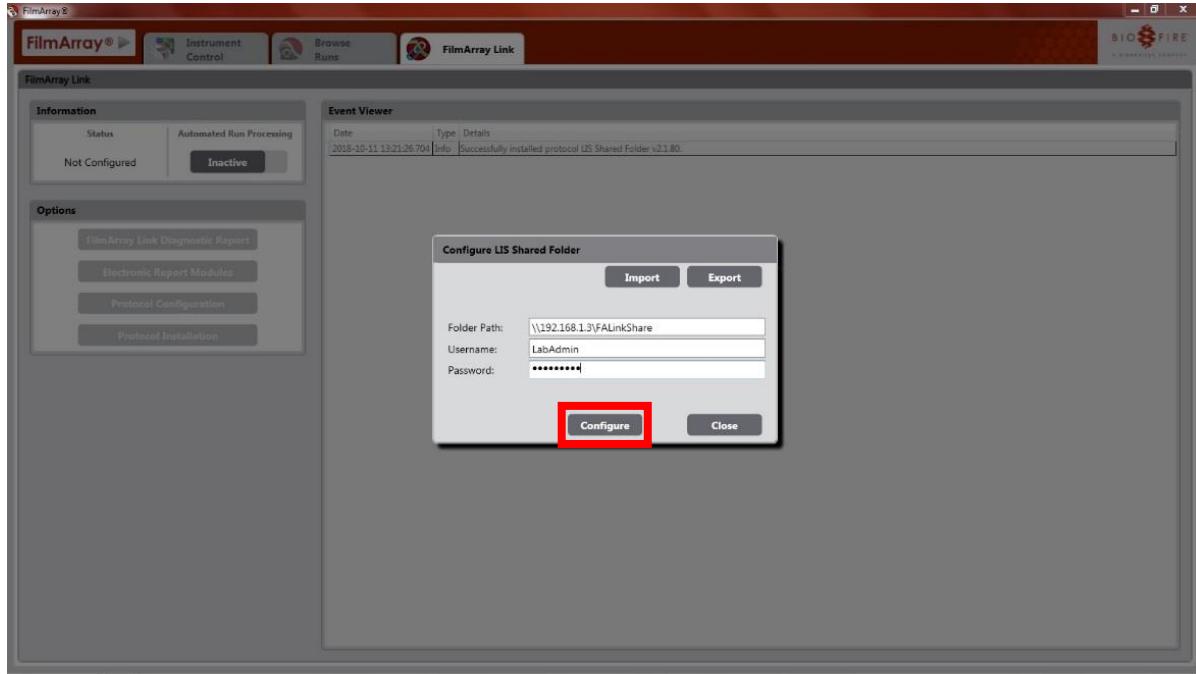
**Note:** If the BioFire® FilmArray® Link Software was upgraded from version 2.0 to version 2.1 and version 2.0 was configured, a configuration file is saved in C:\ProgramData\BioFireDx\FilmArrayLink\ConfigurationExport. The file may also be saved in a location designated in a previous configuration export.

**Note:** If there is text in any of the fields of the Configure LIS Shared Folder dialog, a dialog confirming the import is displayed when the **Open** is selected. Select **Yes**.

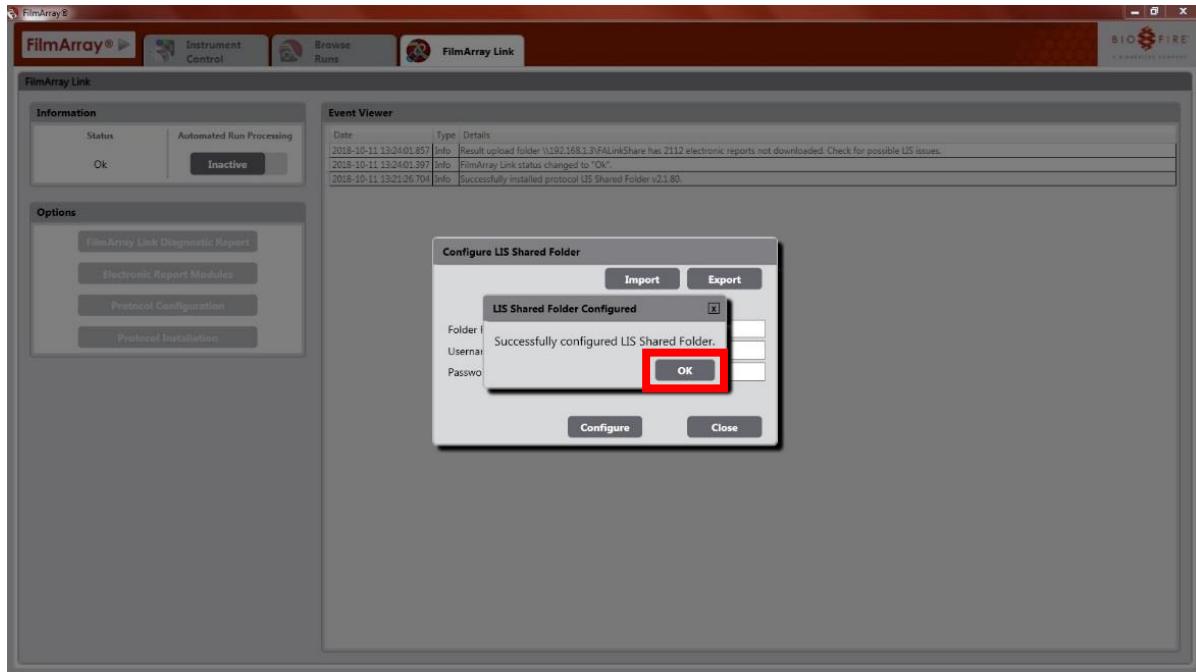


4. Enter the password and select the **Configure** option.

**Note:** The entries shown in the figure below are for illustrative purposes.



5. Select **OK** to close the status message dialog and the Configure LIS Shared Folder dialog.



## 7.5. Configure the Network Shared Folder Protocol

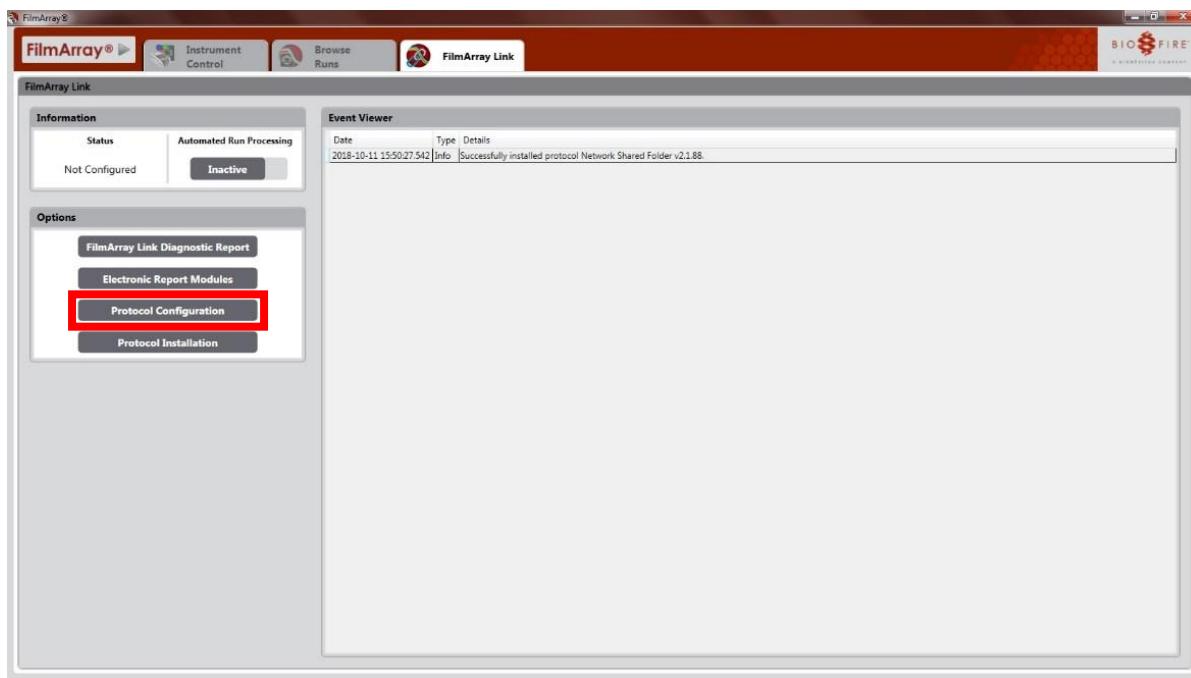
To configure the Network Shared Folder protocol with a new configuration, complete the steps in section 7.5.1. Complete the steps in section 7.5.2 to configure the Network Shared Folder protocol with an existing configuration from an imported file.

**IMPORTANT:** Before proceeding, ensure the following tasks have been completed.

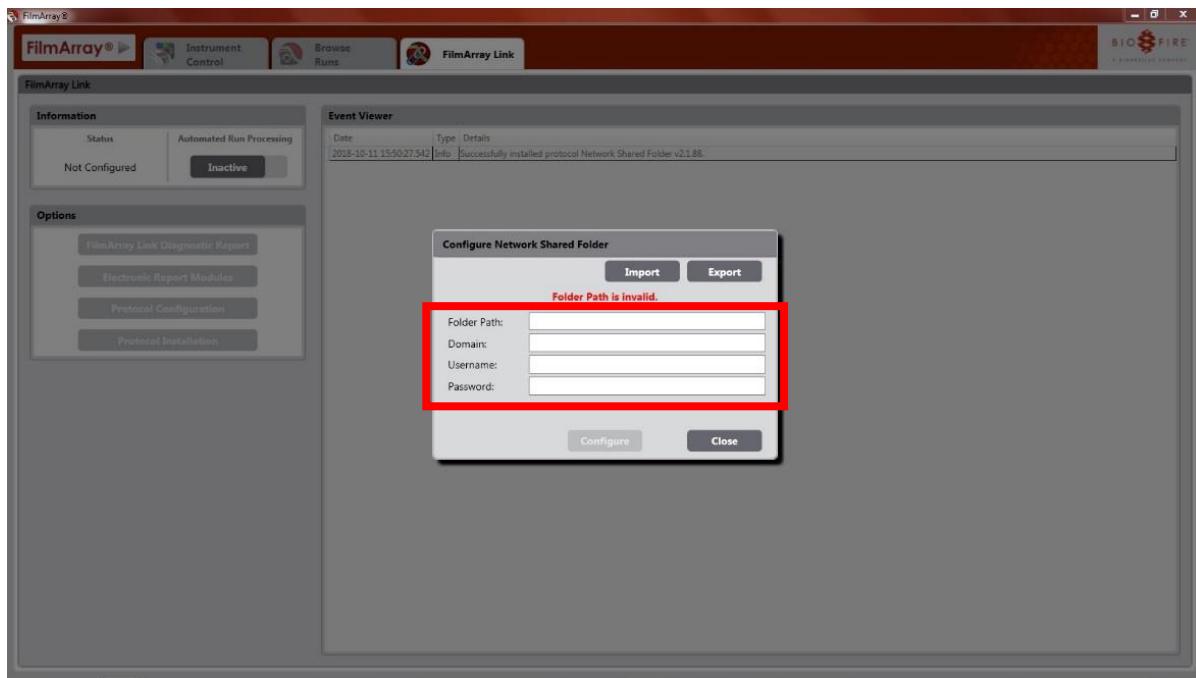
- Designate the network folder path to which the XML files will be sent.
- Network domain name and user account credentials with read and write access to the network shared folder path are required. Ensure that these credentials and the domain name are available.
- Ensure the FilmArray driver has been installed in the data manager. The driver must also be configured to access the XML files in the designated folder path.
- Ensure the Network Shared Folder protocol has been installed according to the steps in section 0.

### 7.5.1. Create a New Network Shared Folder Configuration

1. From the FilmArray Link tab, select the **Protocol Configuration** option from the Options section.

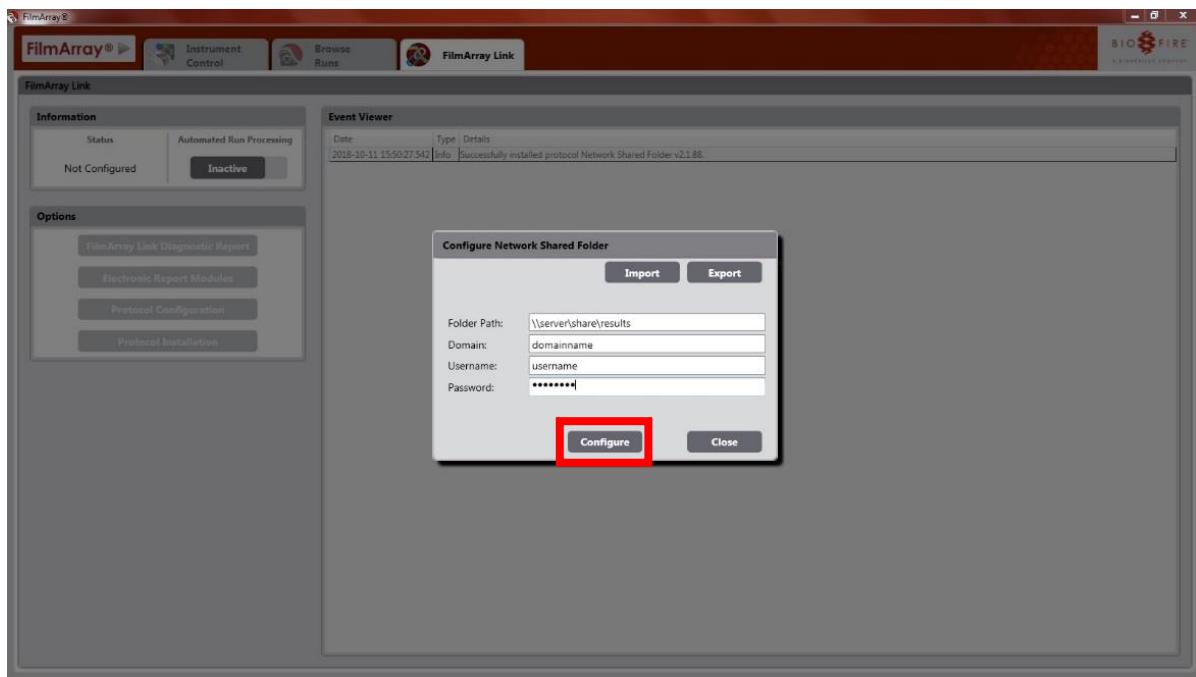


2. In the Configure Network Shared Folder dialog, enter the network shared folder information.

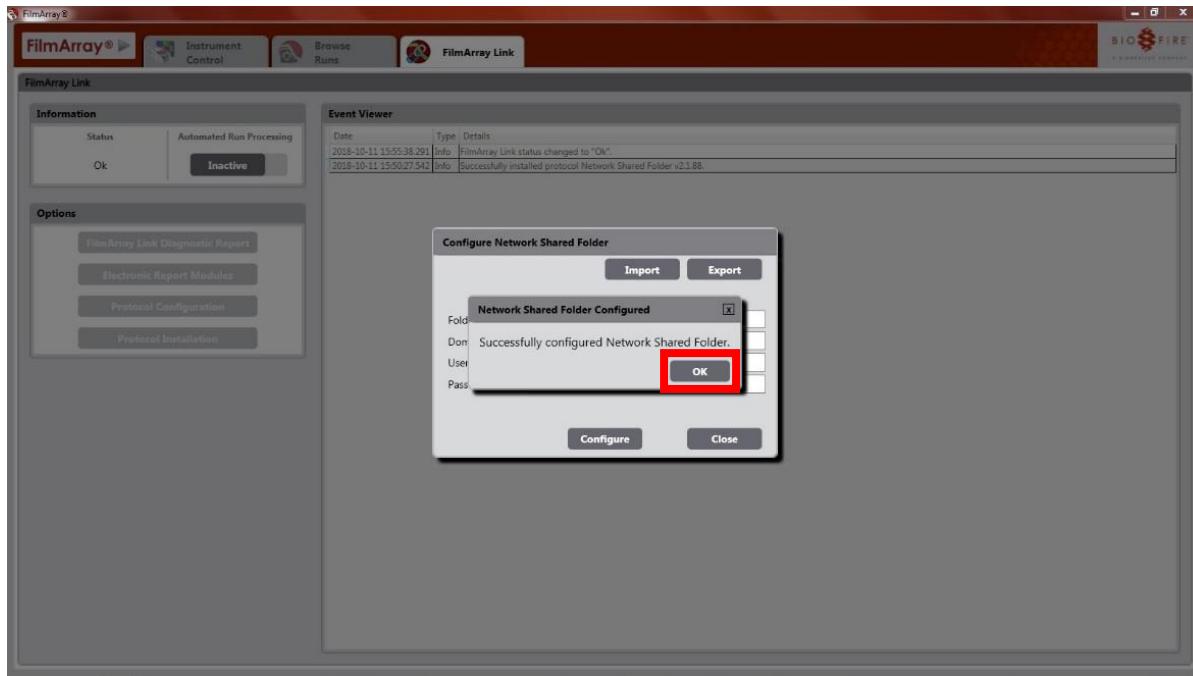


3. Select the **Configure** option. The configuration process begins and a status message dialog is displayed when the configuration is complete.

**Note:** The entries shown in the figure below are for illustrative purposes.

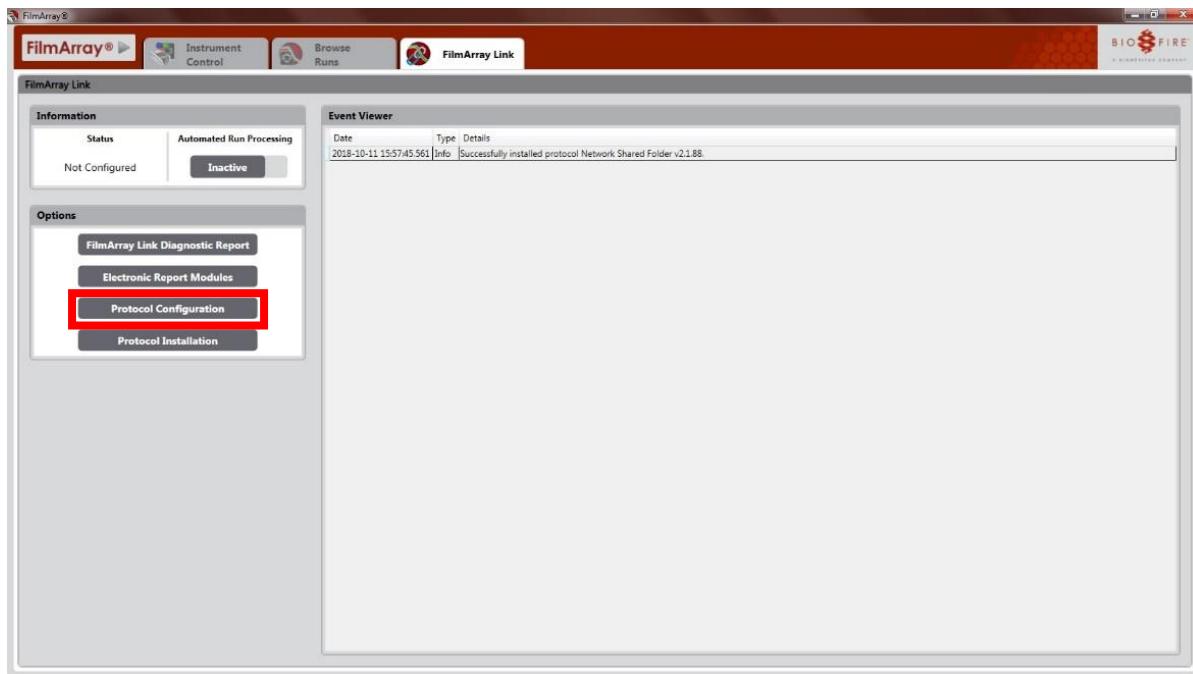


4. Select **OK** to close the status message dialog and the Configure Network Shared Folder dialog.

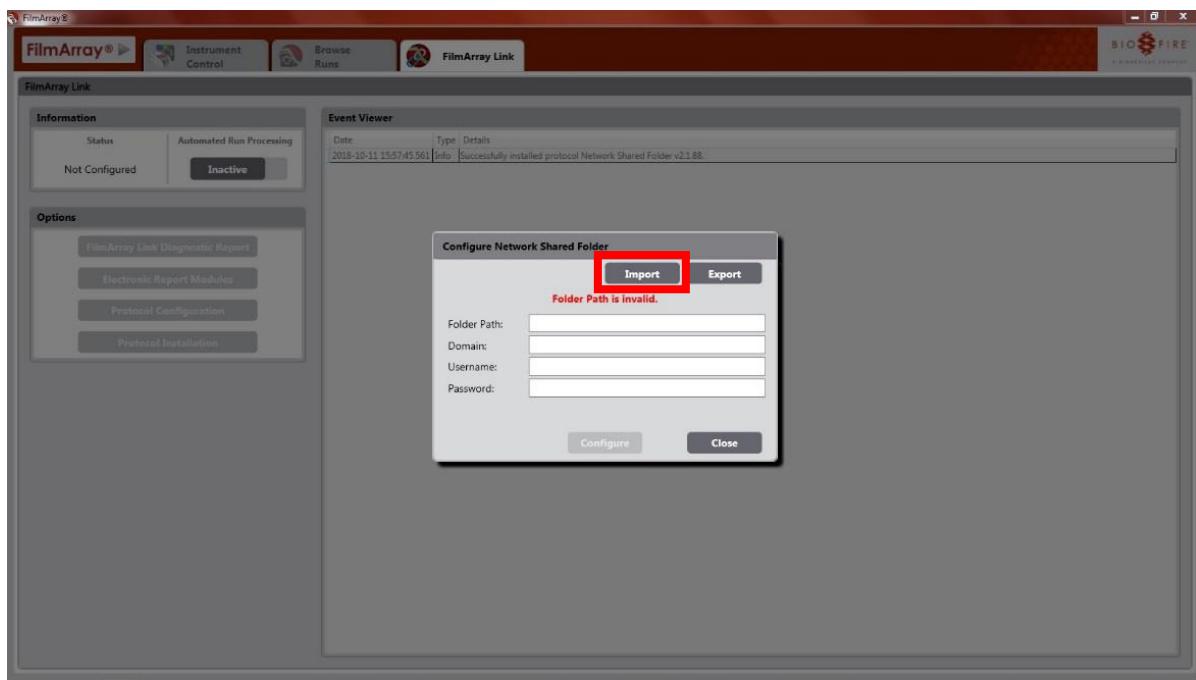


## 7.5.2. Import a Network Shared Folder Configuration

1. From the FilmArray Link tab, select the **Protocol Configuration** option from the Options section.



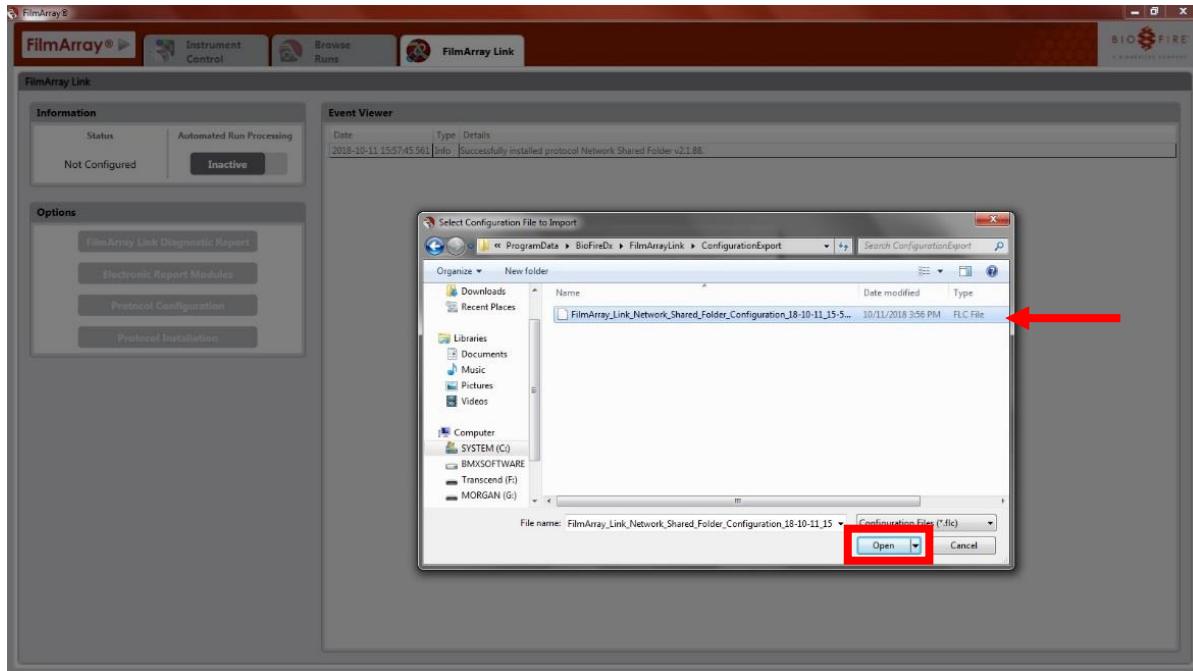
2. In the Configure Network Shared Folder dialog, select the **Import** option.



3. In the Select Configuration File to Import dialog, navigate to the configuration file. Select the file and select **Open**.

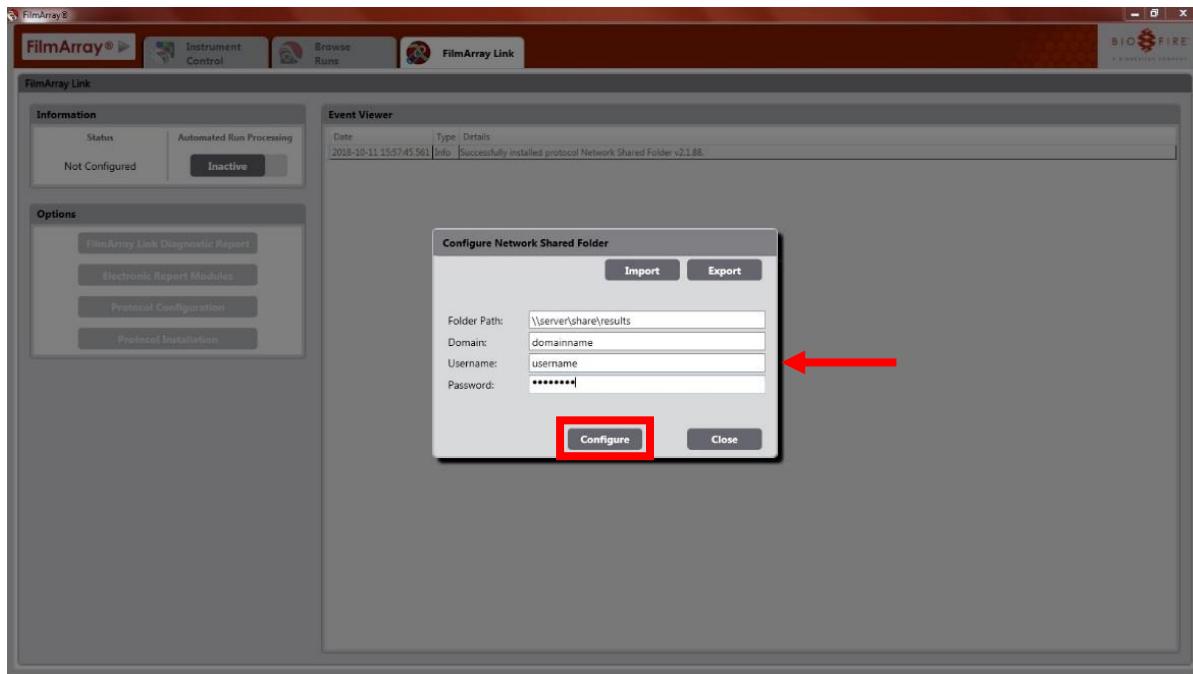
**Note:** If the BioFire® FilmArray® Link Software was upgraded from version 2.0 to version 2.1 and version 2.0 was configured, a configuration file is saved in C:\ProgramData\BioFireDx\FilmArrayLink\ConfigurationExport. The file may also be saved in a location designated in a previous configuration export.

**Note:** If there is text in any of the fields of the Configure Network Shared Folder dialog, a dialog confirming the import is displayed when the **Open** is selected. Select **Yes**.

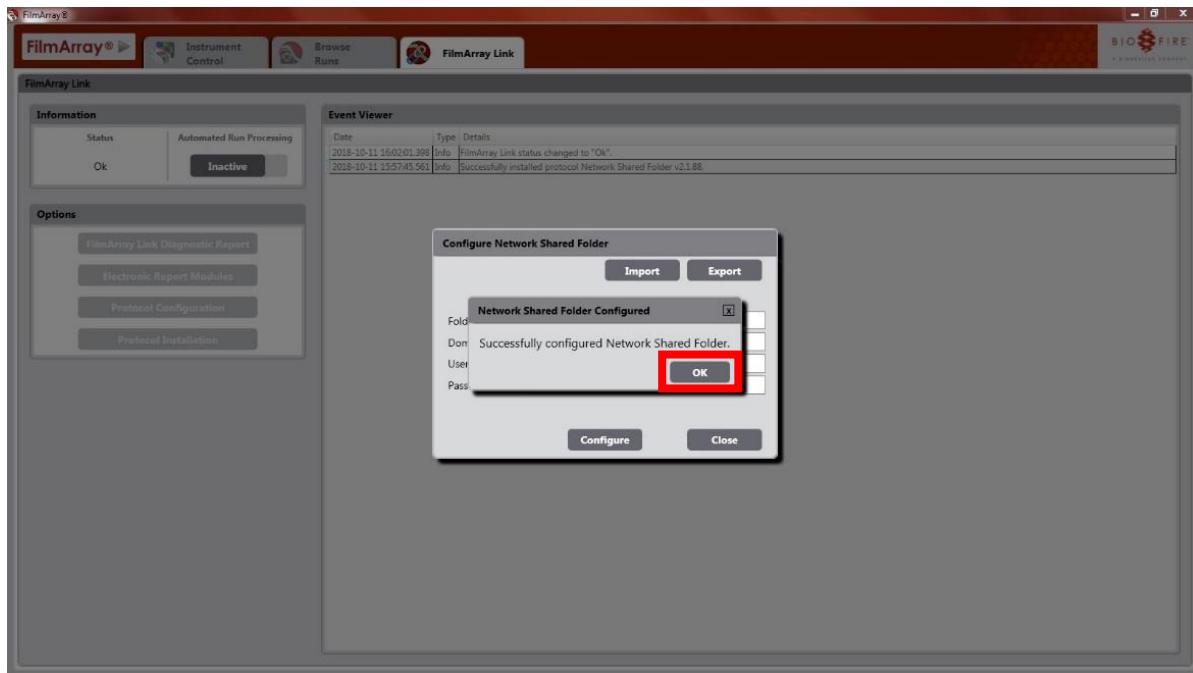


4. Enter the password associated with the user that has read and write access to the shared folder and select the **Configure** option.

**Note:** The entries shown in the figure below are for illustrative purposes.



5. Select **OK** to close the status message dialog and the Configure Network Shared Folder dialog.

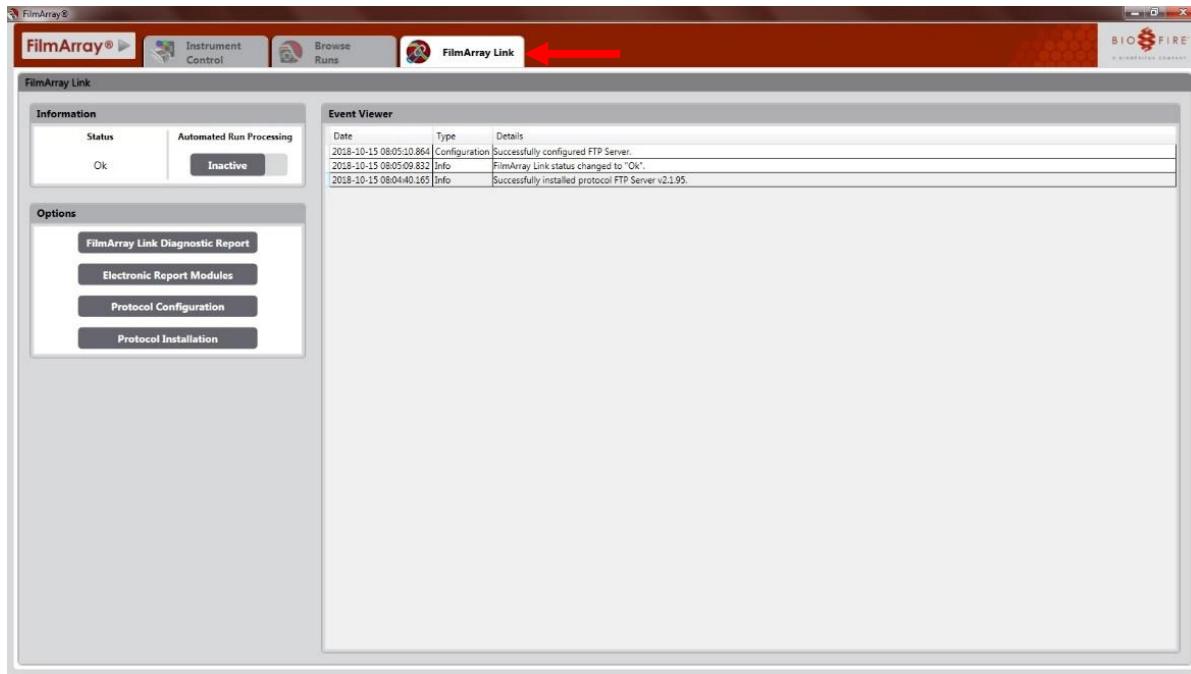


## 8. Using the BioFire® FilmArray® Link Software

This section describes how to use the BioFire Link software. The BioFire Link software can be accessed from the FilmArray Link tab in the BioFire® FilmArray® Software v2.1 user interface. From the FilmArray Link tab, operators can:

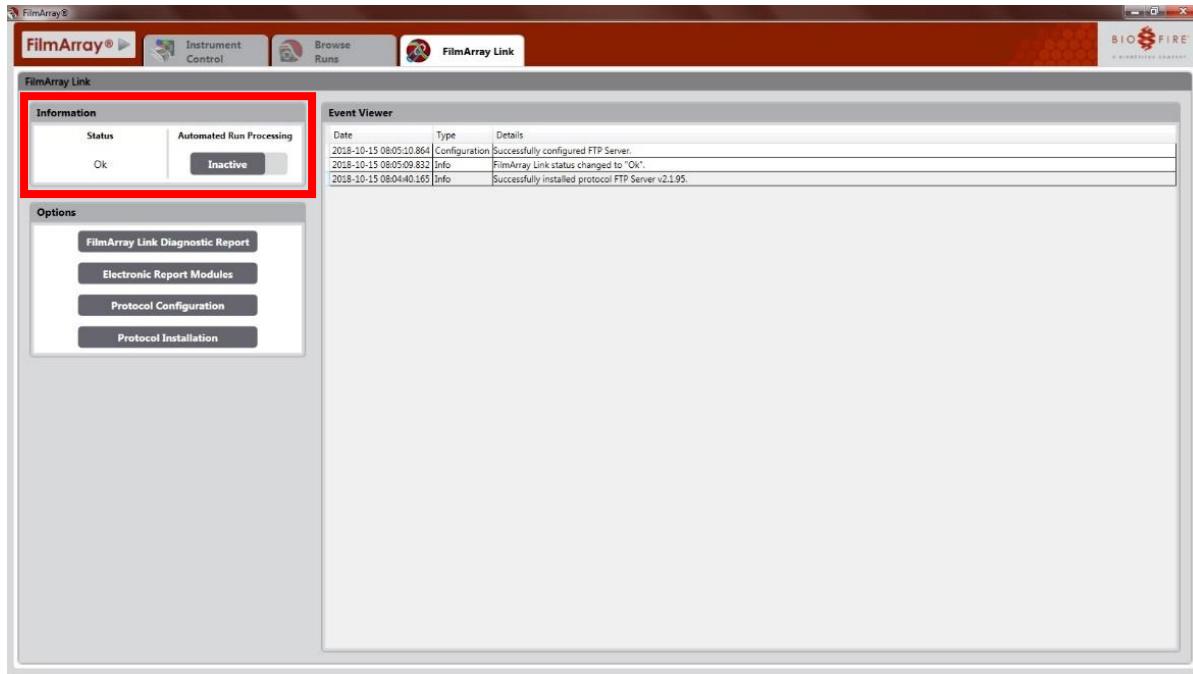
- View the status of the BioFire Link software.
- Enable and disable automated run processing.
- View events related to BioFire Link software.
- Access other features of the BioFire Link software, including electronic report modules, protocols and protocol configuration, and the FilmArray Link Diagnostic Report.

**Note:** The interface between the BioFire® FilmArray® 2.0 System and the data manager must be set up before test results can be sent. Refer to sections 7 and 0 in this document and the BioFire® FilmArray® 2.0/Torch Interface Checklist.



## 8.1. View the Status of BioFire® FilmArray® Link

The Information section of the FilmArray Link tab displays the status of the BioFire® FilmArray® Link software.



The status of the BioFire Link software is either Ok, Not Configured, or Error. The following table provides a description of each status.

Status	Description
Ok	The BioFire Link software is configured and the connection with the data manager is established.
Not Configured	The BioFire Link software is not configured and there is no connection with the data manager. Refer to section 7 of this document for more information.
Error	The BioFire Link software has detected a connection error which interrupts communication between the software and the data manager. Refer to section 9 of this document for more information.

## 8.2. Send Runs to a Data Manager

The BioFire® FilmArray® Link software allows runs to be sent to a data manager automatically or manually. The following sections provide instructions for activating and deactivating automated run processing, as well as for manually sending test results.

**Note:** When the BioFire Link software is initially installed, automated run processing is inactive.

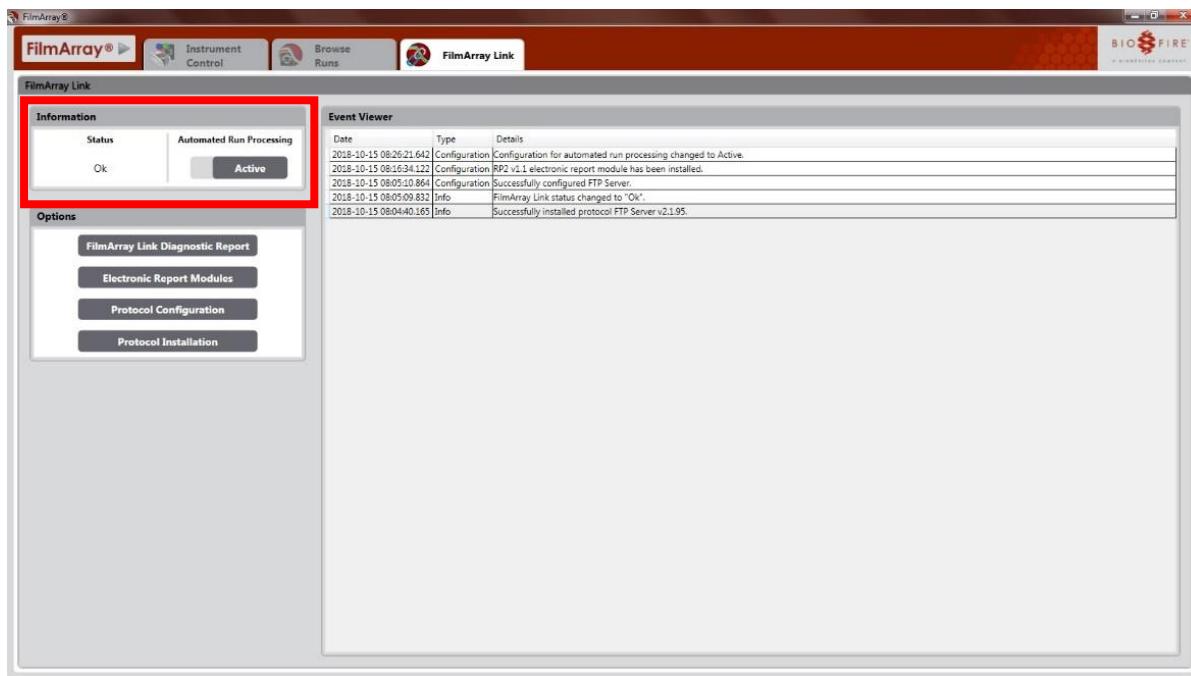
**Note:** The BioFire Link software will only send runs with a pouch result of Pass and a status of Completed.

### 8.2.1. Start Automated Run Processing

From the Information section of the FilmArray Link tab, toggle the **Inactive** slider for Automated Run Processing to **Active**.

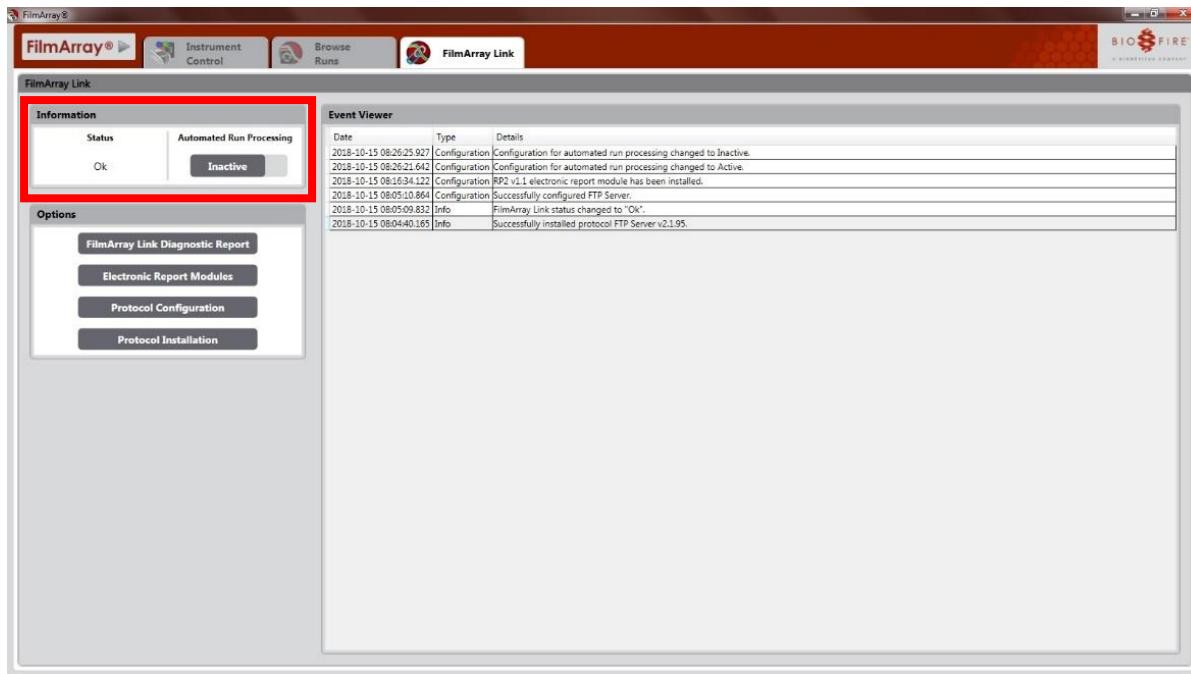
When automated run processing is enabled, newly completed runs and runs completed within the last two hours of enabling automated run processing will be formatted as XML files and the files will be sent to the data manager within two minutes.

Runs completed more than two hours prior to enabling automated run processing must be manually processed. Runs can be manually processed when automated run processing is active.



## 8.2.2. Stop Automated Run Processing

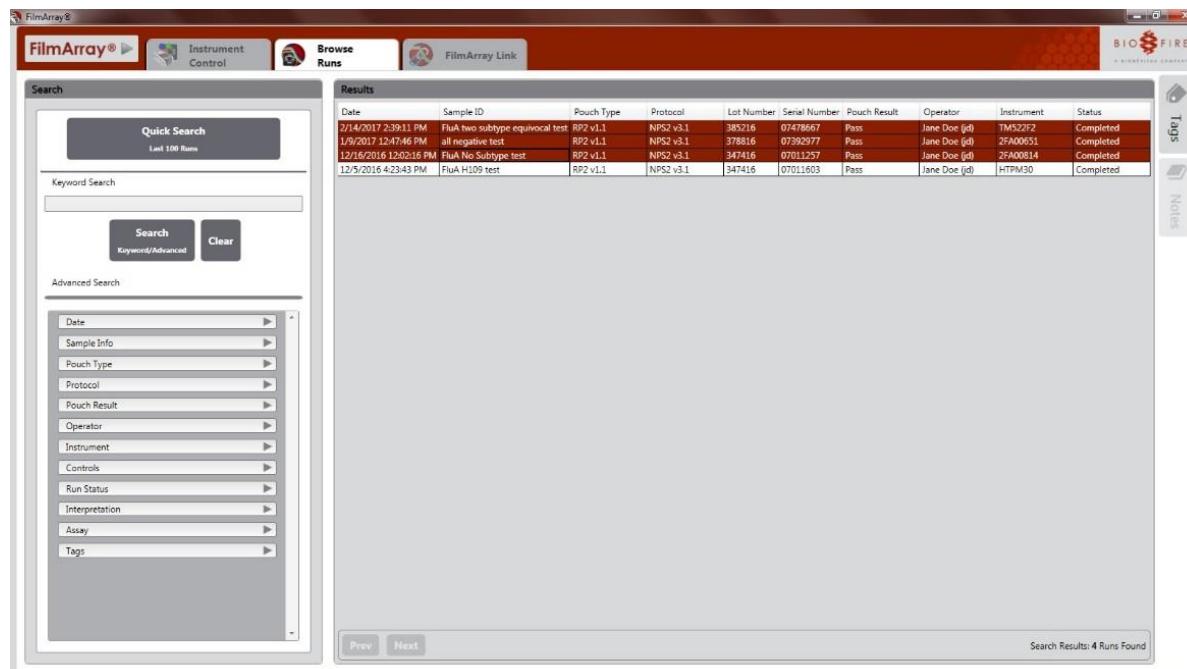
From the Information section of the FilmArray Link tab, toggle the **Active** slider for Automated Run Processing to **Inactive**.



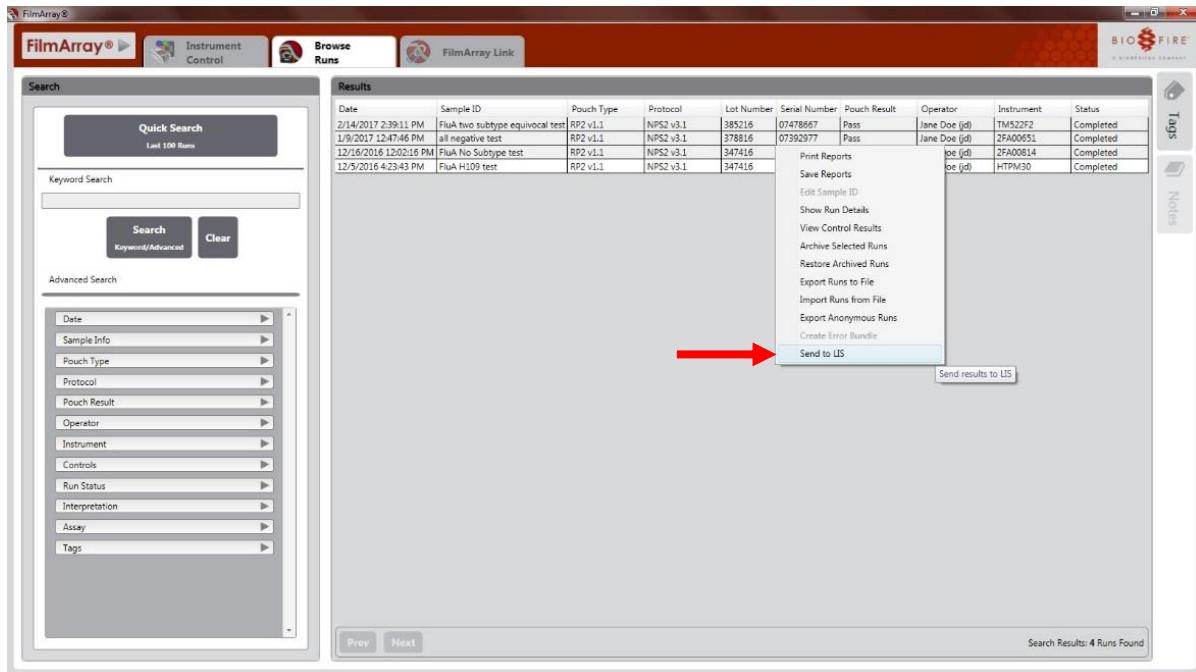
## 8.2.3. Start Manual Run Processing

Complete the following steps to manually send one or more FilmArray runs.

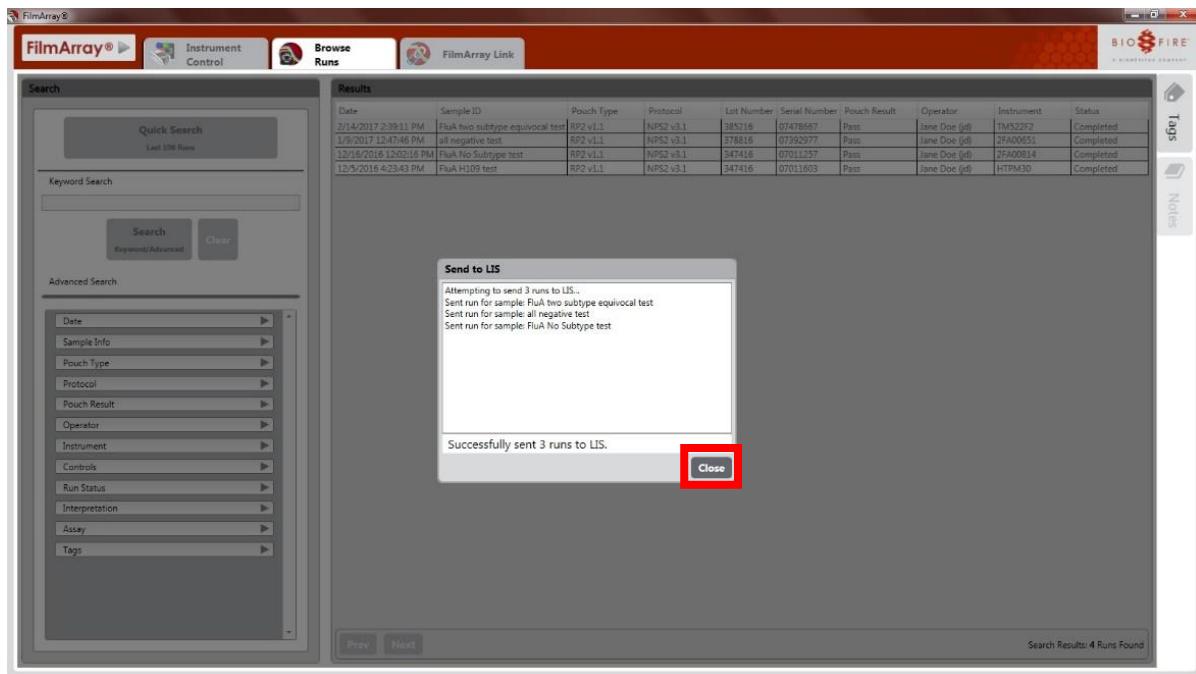
1. From the Browse Runs tab, select one or more runs to be sent to the data manager.



2. Right-click on the run(s) to activate the context menu and select the **Send to LIS** option.



3. When the runs have been sent, select **Close** to close the dialog.



## 8.2.4. Stop Manual Run Processing

Complete the following steps to stop manual run processing.

1. From the Browse Runs tab, select one or more runs to be sent to the data manager.
2. Right-click on the run to activate the context menu and select the **Send to LIS** option.
3. When the processing is in progress, a status message is displayed in a dialog with a Cancel option. Select **Cancel** to stop run processing.
4. Manual run processing is cancelled. Select **Close** to close the dialog.

## 8.3. View BioFire® FilmArray® Link Events

The Event Viewer section of the FilmArray Link tab displays messages associated with events in the BioFire® FilmArray® Link software. Messages are shown for the following types of events:

- Transfer of a FilmArray run to the data manager (e.g., successful and failed transfers)
- Changes in the BioFire Link status
- Installation of a protocol
- Installation of an electronic report module
- Changes to the protocol configuration
- Changes to the software settings
- Generation of a FilmArray Link Diagnostic Report

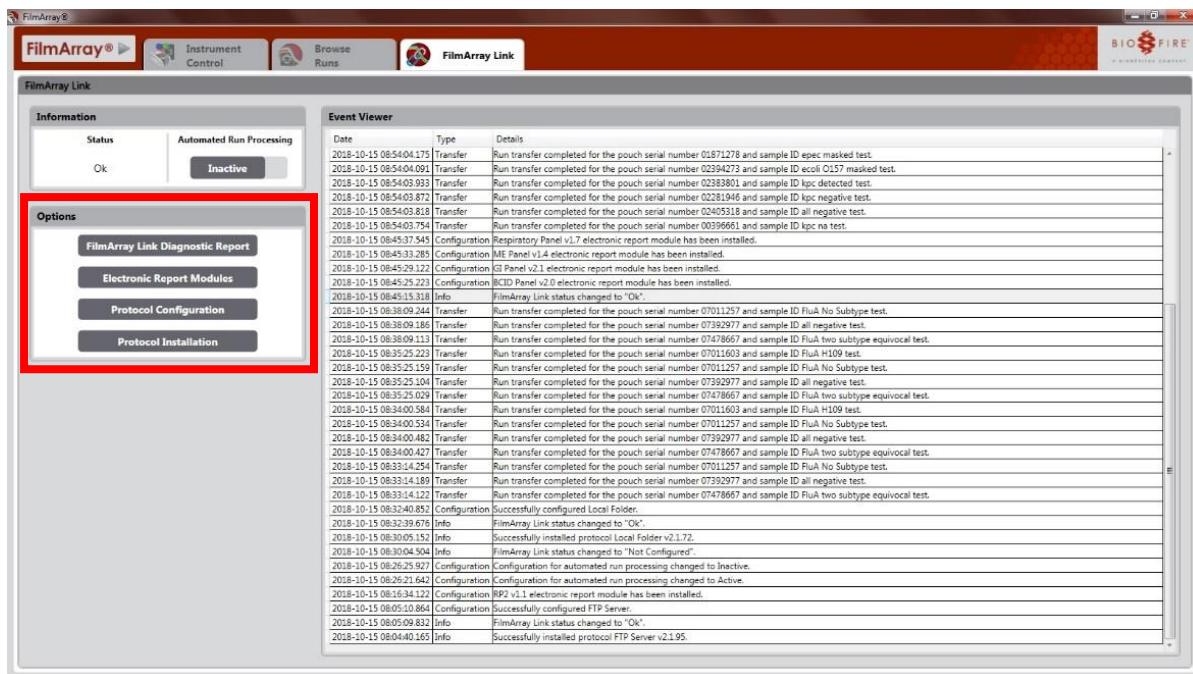
Events are presented in a scrollable table that lists the date of the event, the type of event, and the message details. They can be sorted by date and type.

The screenshot shows the BioFire FilmArray Link software interface. At the top, there is a navigation bar with tabs for 'Instrument Control', 'Browse Runs', and 'FilmArray Link'. The 'FilmArray Link' tab is active. On the left, there is a sidebar with sections for 'Information' (Status: Ok, Automated Run Processing: Inactive) and 'Options' (FilmArray Link Diagnostic Report, Electronic Report Modules, Protocol Configuration, Protocol Installation). The main area is titled 'Event Viewer' and contains a table of log entries. A red box highlights the 'Event Viewer' table. The table has columns for Date, Type, and Details. Some entries include timestamps like '2018-10-15 08:54:04.091' and '2018-10-15 08:54:04.091'. The details column describes various events such as 'Run transfer completed for the pouch serial number 02994273 and sample ID ec01 O157 masked test.' and 'ME Panel V1.4 electronic report module has been installed.'

Date	Type	Details
2018-10-15 08:54:04.175	Transfer	Run transfer completed for the pouch serial number 01871278 and sample ID epec masked test.
2018-10-15 08:54:04.091	Transfer	Run transfer completed for the pouch serial number 02994273 and sample ID ec01 O157 masked test.
2018-10-15 08:54:05.933	Transfer	Run transfer completed for the pouch serial number 02936801 and sample ID kpc detected test.
2018-10-15 08:54:05.872	Transfer	Run transfer completed for the pouch serial number 02831946 and sample ID kpc negative test.
2018-10-15 08:54:05.818	Transfer	Run transfer completed for the pouch serial number 02495318 and sample ID all negative test.
2018-10-15 08:54:05.759	Transfer	Run transfer completed for the pouch serial number 00396661 and sample ID kpc no test.
2018-10-15 08:45:37.545	Configuration	Respository Panel v1.7 electronic report module has been installed.
2018-10-15 08:45:31.285	Configuration	ME Panel V1.4 electronic report module has been installed.
2018-10-15 08:45:29.122	Configuration	GI Panel v2.1 electronic report module has been installed.
2018-10-15 08:45:29.222	Configuration	ICD Panel v2.0 electronic report module has been installed.
2018-10-15 08:45:15.538	Info	FilmArray Link status changed to "OK".
2018-10-15 08:38:09.244	Transfer	Run transfer completed for the pouch serial number 07011257 and sample ID FluA No Subtype test.
2018-10-15 08:38:09.186	Transfer	Run transfer completed for the pouch serial number 07392977 and sample ID all negative test.
2018-10-15 08:38:09.113	Transfer	Run transfer completed for the pouch serial number 07478667 and sample ID FluA two subtype equivocal test.
2018-10-15 08:35:25.223	Transfer	Run transfer completed for the pouch serial number 07011603 and sample ID FluA H109 test.
2018-10-15 08:35:25.159	Transfer	Run transfer completed for the pouch serial number 07011257 and sample ID FluA No Subtype test.
2018-10-15 08:35:25.104	Transfer	Run transfer completed for the pouch serial number 07392977 and sample ID all negative test.
2018-10-15 08:35:25.029	Transfer	Run transfer completed for the pouch serial number 07478667 and sample ID FluA two subtype equivocal test.
2018-10-15 08:34:00.584	Transfer	Run transfer completed for the pouch serial number 07011603 and sample ID FluA H109 test.
2018-10-15 08:34:00.554	Transfer	Run transfer completed for the pouch serial number 07011257 and sample ID FluA No Subtype test.
2018-10-15 08:34:00.486	Transfer	Run transfer completed for the pouch serial number 07392977 and sample ID all negative test.
2018-10-15 08:34:00.427	Transfer	Run transfer completed for the pouch serial number 07478667 and sample ID FluA two subtype equivocal test.
2018-10-15 08:33:14.294	Transfer	Run transfer completed for the pouch serial number 07011257 and sample ID FluA No Subtype test.
2018-10-15 08:33:14.189	Transfer	Run transfer completed for the pouch serial number 07392977 and sample ID all negative test.
2018-10-15 08:33:14.122	Transfer	Run transfer completed for the pouch serial number 07478667 and sample ID FluA two subtype equivocal test.
2018-10-15 08:32:30.852	Configuration	Successfully configured Local Folder.
2018-10-15 08:32:30.674	Info	FilmArray Link status changed to "OK".
2018-10-15 08:30:05.152	Info	Successfully installed protocol Local Folder v2.1.72.
2018-10-15 08:30:04.503	Info	FilmArray Link status changed to "Not Configured".
2018-10-15 08:26:55.927	Configuration	Configuration for automated run processing changed to Inactive.
2018-10-15 08:26:21.642	Configuration	Configuration for automated run processing changed to Active.
2018-10-15 08:16:34.122	Configuration	RP2 v1.1 electronic report module has been installed.
2018-10-15 08:05:10.864	Configuration	Successfully configured FTP Server.
2018-10-15 08:05:09.832	Info	FilmArray Link status changed to "OK".
2018-10-15 08:04:40.165	Info	Successfully installed protocol FTP Server v2.1.95.

## 8.4. Access Additional Features of the BioFire® FilmArray® Link Software

The Options section of the FilmArray Link tab provides the operator with a menu that lists other features of the software. The features are described in the table below.

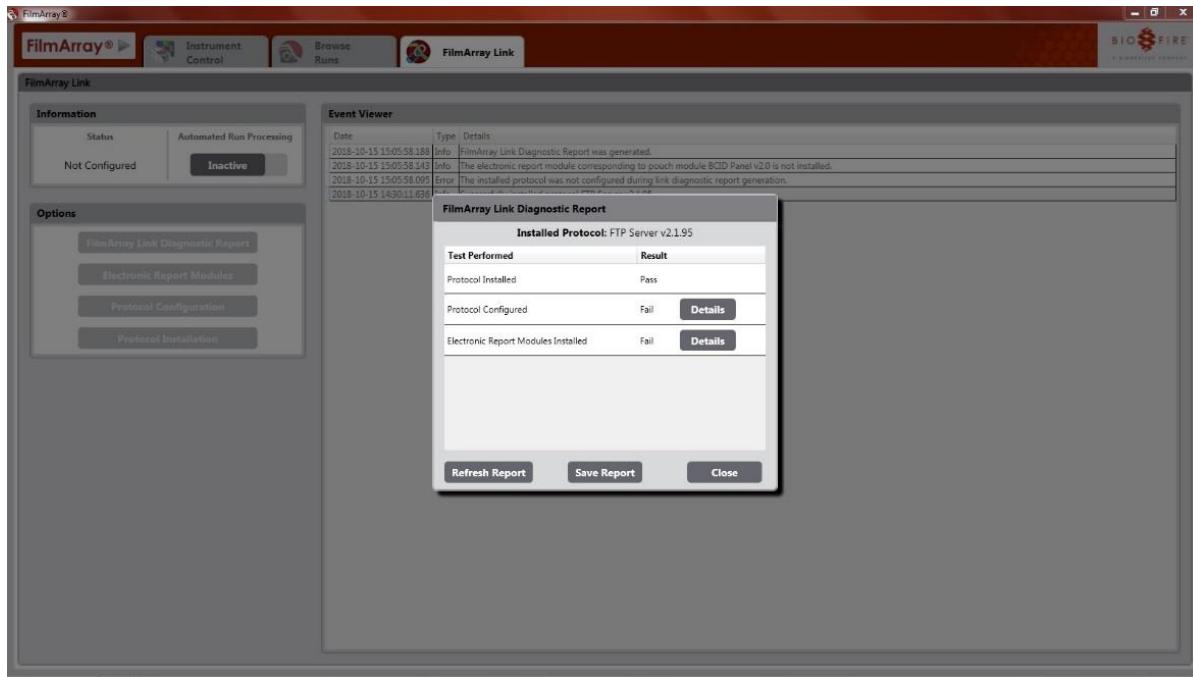


Menu Item	Purpose
FilmArray Link Diagnostic Report	Enables the operator to access a report to assist with troubleshooting the BioFire Link software and the network connection with the data manager.
Electronic Report Modules	Enables the operator to install and manage electronic report modules.
Protocol Configuration	Enables the operator to configure an installed protocol.
Protocol Installation	Enables the operator to install a protocol.

## 8.4.1. FilmArray Link Diagnostic Report

The FilmArray Link Diagnostic Report is designed to assist the user with troubleshooting the BioFire® FilmArray® Link software and potential issues with the network connection and the interface. The information provided in the report will vary depending on if a protocol is installed and on which protocol is installed.

Selecting the **FilmArray Link Diagnostic Report** option will generate and display a report. When generating the report, the BioFire Link software performs tests to determine if there are any issues with the BioFire Link software, network connection, or the interface. The results of the tests are shown in the report when it is generated. If a test failed, more information is provided by selecting the **Details** option associated with the test.



Once a report is generated, the operator can refresh the report by selecting the **Refresh Report** option.

A report can also be saved by selecting the **Save Report** option. It can then be sent to BioFire Diagnostics Technical Support to assist with troubleshooting.

Refer to section 9 for instructions about how to use the report to assist with troubleshooting.

Select the **Close** option to return to the FilmArray Link tab.

## 8.4.2. Electronic Report Modules

The Electronic Report Modules feature, accessed by selecting the **Electronic Report Modules** option from the Options section, allows the user to install and uninstall electronic report modules.

A panel-specific electronic report module must be installed to process and send test results for a corresponding panel to a data manager.

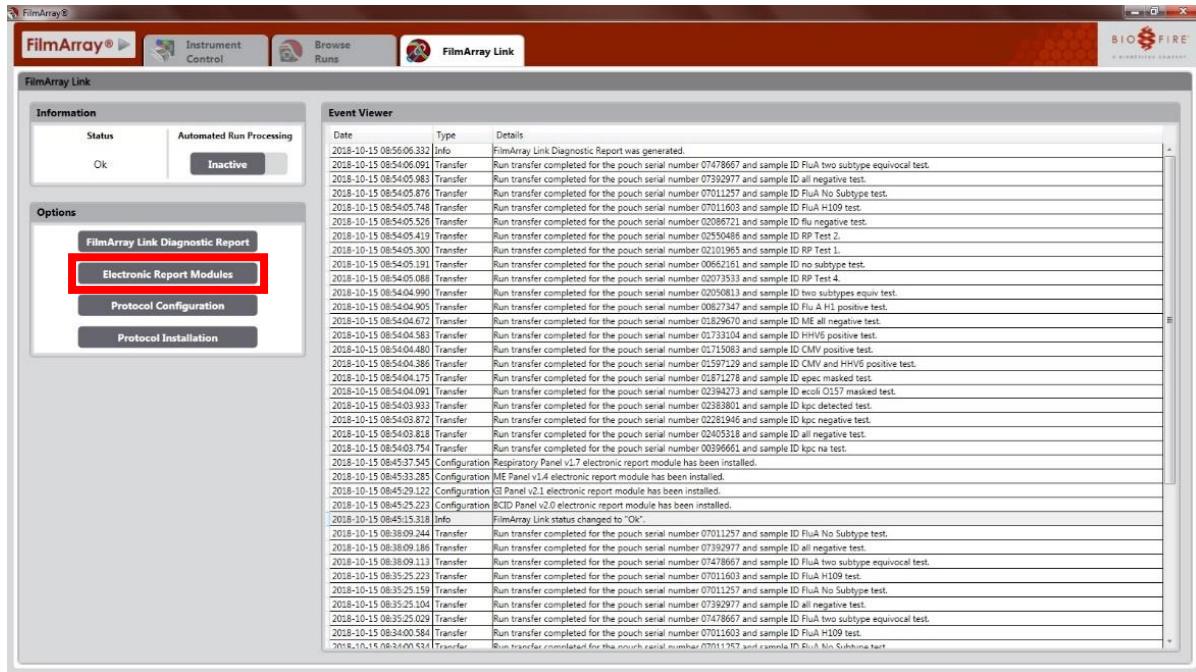
### 8.4.2.1. Install an Electronic Report Module

Refer to the panel-specific electronic report module technical note for installation instructions.

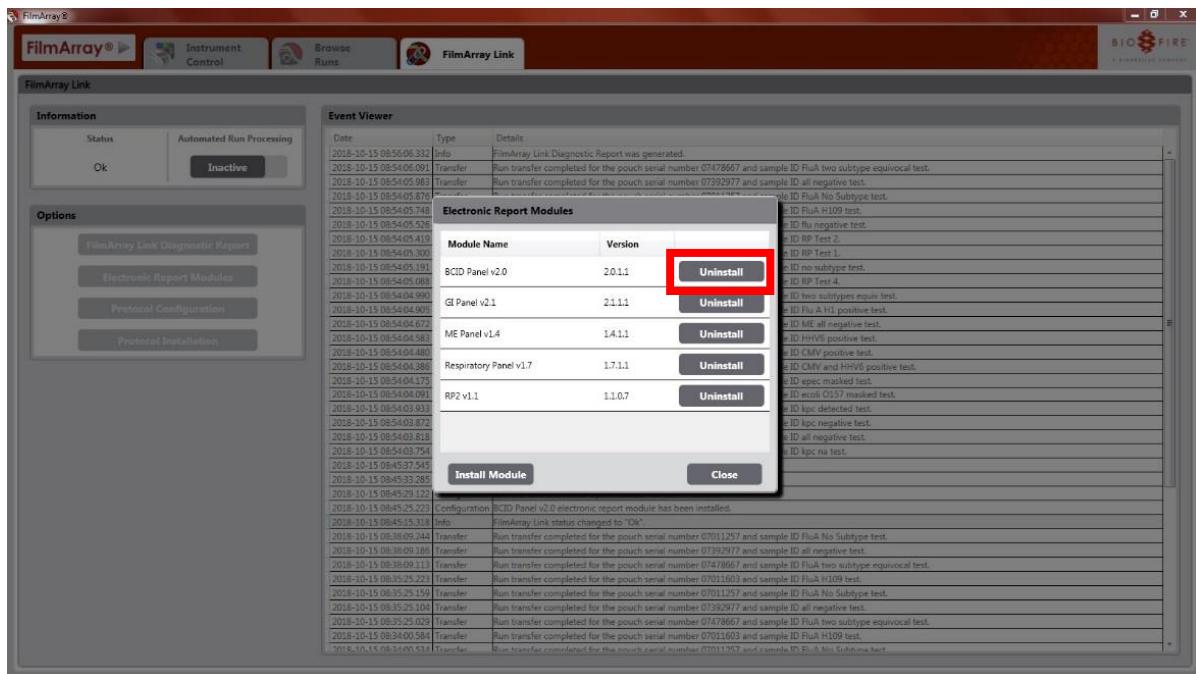
## 8.4.2.2. Uninstall an Electronic Report Module

Complete the following steps to uninstall an electronic report module.

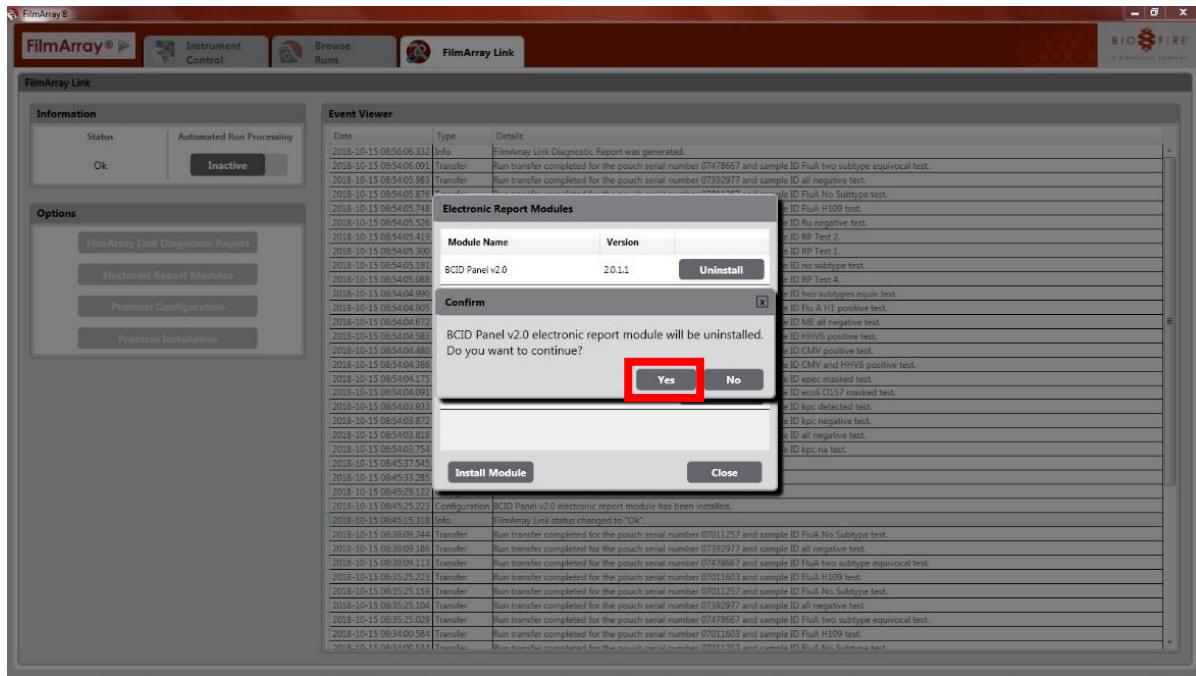
1. Select the **Electronic Report Modules** option from the Options section of the FilmArray Link tab.



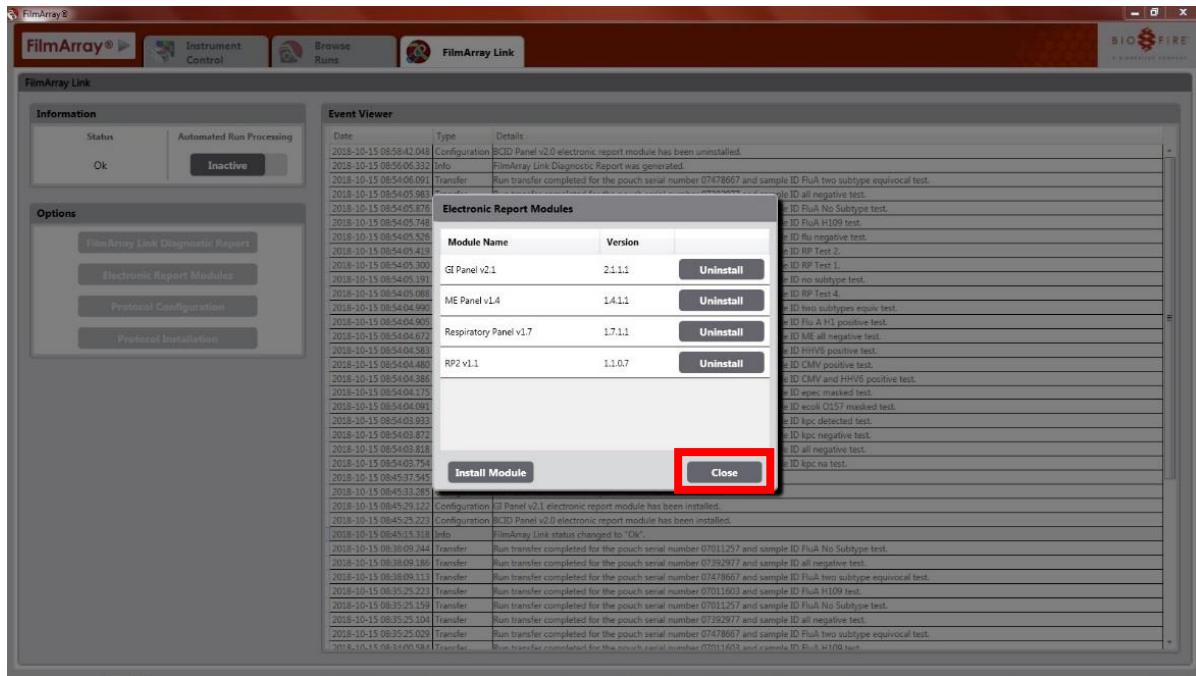
2. Select the **Uninstall** option associated with the electronic report module to be uninstalled.



3. Select **Yes** to confirm that the electronic report module will be uninstalled.



4. Select **Close** to close the Electronic Report Modules dialog.



## 8.4.3. Protocol Configuration

The Protocol Configuration feature allows the user to configure an installed protocol. Refer to section 5 of this document for more information.

### 8.4.3.1. Import a Configuration

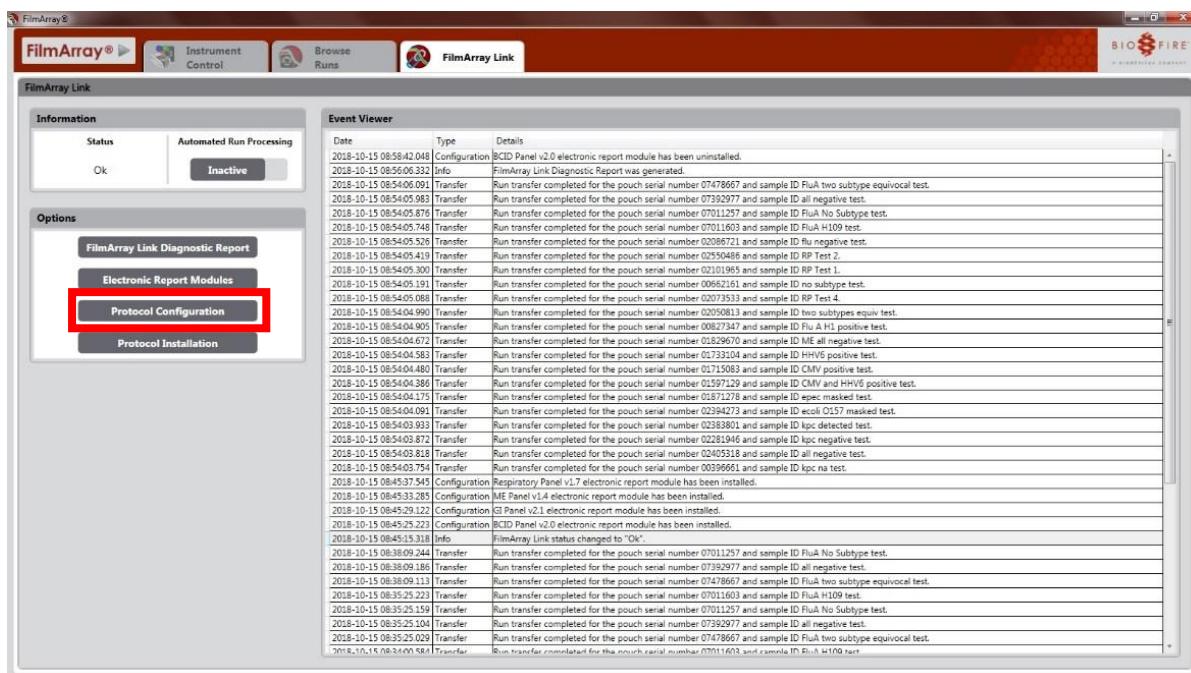
The Import feature allows the user to import a protocol configuration that was used to configure a BioFire® FilmArray® LIS interface previously. Refer to section 5 of this document for more information.

### 8.4.3.2. Export a Configuration

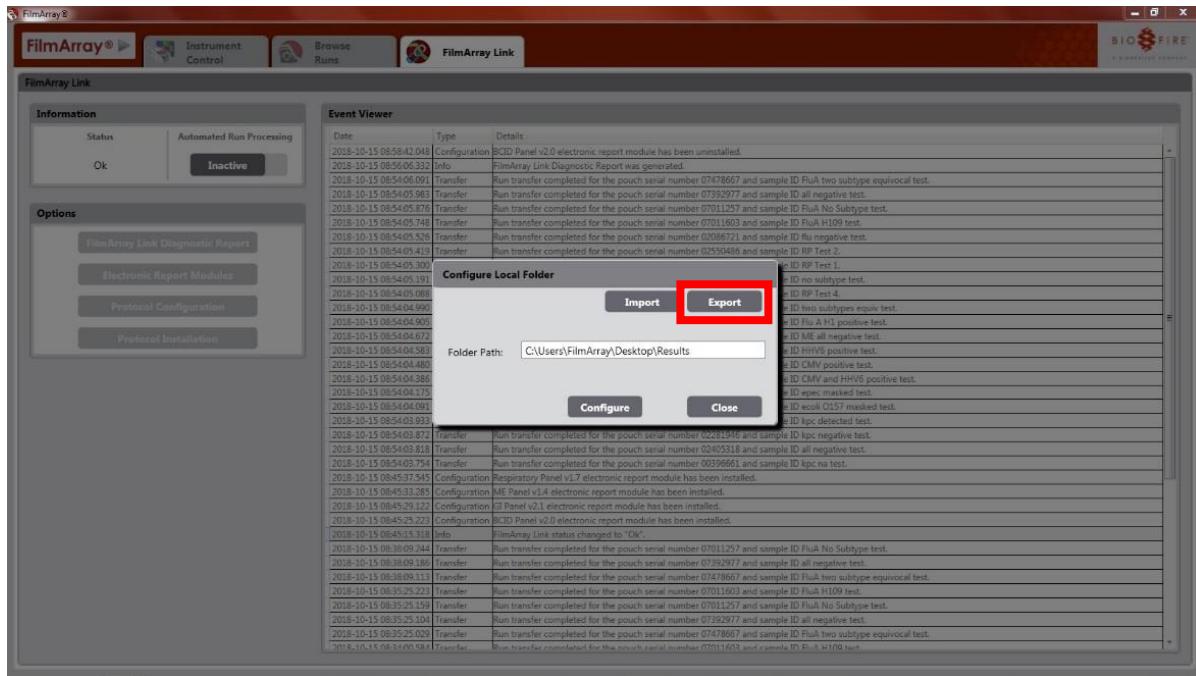
The Export feature allows the user to export a protocol configuration. Complete the following steps to export a configuration.

**Note:** The following steps describe how to export a local folder protocol configuration but they can be completed for any FilmArray Link protocol. If a configuration requires a password, the password will not be included as part of the exported configuration.

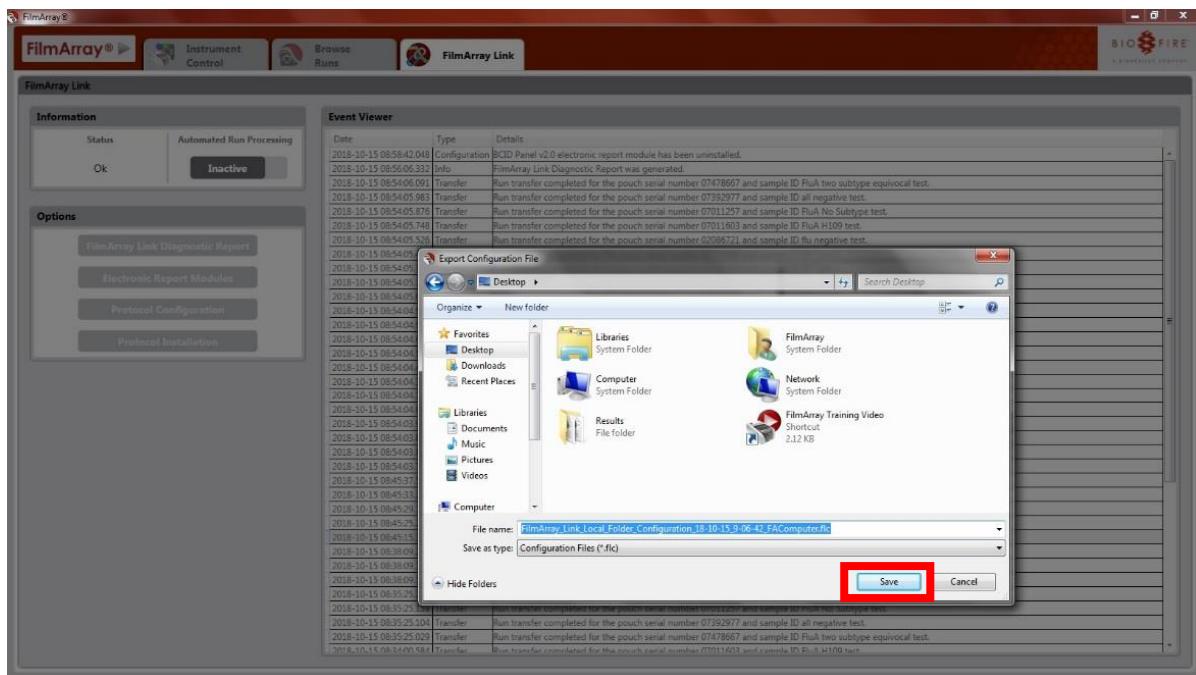
1. Select the **Protocol Configuration** option from the Options section of the FilmArray Link tab.



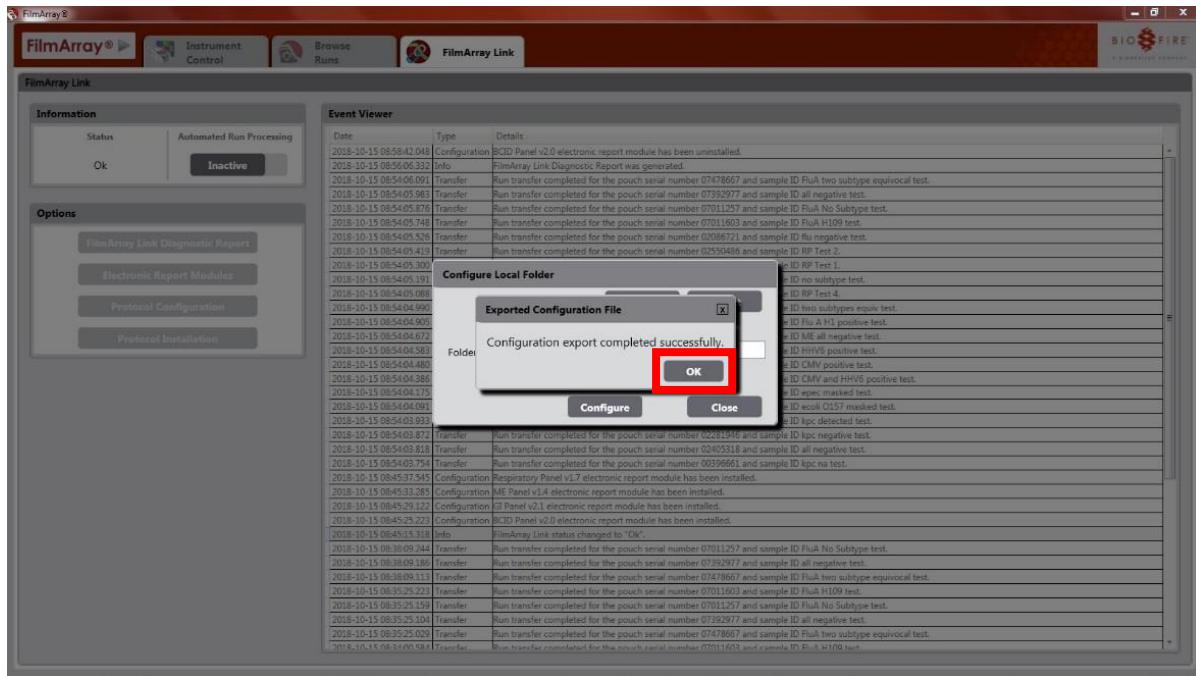
2. In the Configure Local Folder dialog, select the **Export** option.



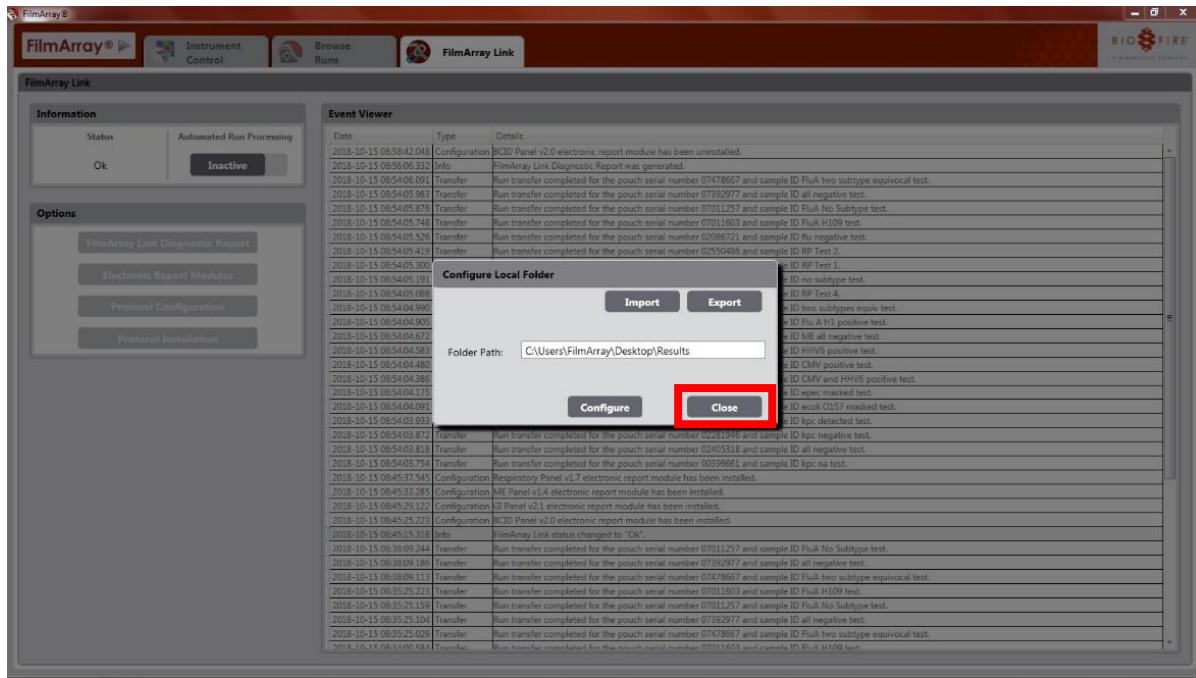
3. From the Export Configuration File dialog, navigate to the location to which the configuration should be saved and click **Save**.



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



5. Click **Close** to close the Configure Local Folder dialog.



## 8.4.4. Protocol Installation

The Protocol Installation feature allows the user to install a protocol. Refer to section 0 of this document for more information.

## 9. Troubleshooting

If there are any issues with the BioFire® FilmArray® Link software or the interface between the BioFire® FilmArray® 2.0 System and the data manager, refer to FilmArray Link Diagnostic Report. The report can be accessed from the Options section of the FilmArray Link tab. Refer to section 8.4.1 for more information.

The following table describes the tests the BioFire Link software performs and displays on the FilmArray Link Diagnostic Report. It also provides troubleshooting steps that can be used to resolve the issue.

Test	Description	Action
Protocol Installed	Tests that a protocol is installed.	If the test failed, a protocol must be installed. Complete the steps in section 0. If the issue persists, save the report and contact BioFire Diagnostics Technical Support.
Protocol Configured	Tests that the installed protocol is configured.	If the test failed: <ol style="list-style-type: none"><li>1. Ensure that a protocol is installed. If a protocol is not installed, complete the steps in section 0.</li><li>2. Configure the installed protocol according to the instructions provided in section 7.</li><li>3. If the configuration fails and the issue persists, save the report and contact BioFire Diagnostics Technical Support.</li></ol>
Electronic Report Modules Installed	Tests that for every pouch module installed, the corresponding electronic report module is installed.	If the test failed: <ol style="list-style-type: none"><li>1. From the FilmArray Link Diagnostic Report dialog, select the <b>Details</b> option associated with the test.</li><li>2. Install the electronic report module(s) referenced in the message. Refer to section 8.4.2.</li><li>3. If the issue persists, save the report and contact BioFire Diagnostics Technical Support.</li></ol> <p><b>Note:</b> This test may fail because certain IVD BioFire® FilmArray® Panels are not in use. All pouch modules are delivered pre-installed on the computer but electronic report modules must be manually installed. If an electronic report module has not been installed because a BioFire IVD Panel is not in use, the test will fail but the software is functioning as expected.</p>
Electronic Reports Not Downloaded	Tests that there are no files older than one hour in the FTP server folder, LIS shared folder, local folder, or the network shared folder.	If the test failed: <ol style="list-style-type: none"><li>1. Contact LIS Support personnel to verify that the data manager is running and downloading reports from the configured location.</li><li>2. If the issue persists, save the report and contact BioFire Diagnostics Technical Support.</li></ol>

Test	Description	Action
FTP Service Running (FTP Server Protocol only)	Tests that the FTP server service is running.	<p>If the test failed:</p> <ol style="list-style-type: none"> <li>1. Restart the BioFire® FilmArray® 2.0 System Computer.</li> <li>2. Regenerate the report. If the issue persists, proceed to the next step.</li> <li>3. Reconfigure the FTP Server Protocol using the credentials previously used to configure the software. Refer to the instructions in section 7.1.</li> <li>4. Regenerate the report.</li> <li>5. If the issue persists, save the report and contact BioFire Diagnostics Technical Support.</li> </ol>
FTP Site Configured (FTP Server Protocol only)	Tests that the FTP server site has been created.	<p>If the test failed:</p> <ol style="list-style-type: none"> <li>1. Reconfigure the FTP Server Protocol using the credentials previously used to configure the software. Refer to the instructions in section 7.1.</li> <li>2. Regenerate the report.</li> <li>3. If the issue persists, save the report and contact BioFire Diagnostics Technical Support.</li> </ol>
FTP User Configured (FTP Server Protocol only)	Tests that the FTP user has been created.	<p>If the test failed:</p> <ol style="list-style-type: none"> <li>1. Reconfigure the FTP Server Protocol using the credentials previously used to configure the software. Refer to the instructions in section 7.1.</li> <li>2. Regenerate the report.</li> <li>3. If the issue persists, save the report and contact BioFire Diagnostics Technical Support.</li> </ol>
FTP File Downloaded (FTP Server Protocol only)	Tests that files can be downloaded from the FTP server.	<p>If the test failed:</p> <ol style="list-style-type: none"> <li>1. Restart the BioFire 2.0 System Computer.</li> <li>2. Regenerate the report. If the issue persists, proceed to the next step.</li> <li>3. Reconfigure the FTP Server Protocol using the credentials previously used to configure the software. Refer to the instructions in section 7.1.</li> <li>4. Regenerate the report.</li> <li>5. If the issue persists, save the report and contact BioFire Diagnostics Technical Support.</li> </ol>

Test	Description	Action
HTTP Server Responding (HTTP only)	Tests that the HTTP server is responding.	<p>If the test failed:</p> <ol style="list-style-type: none"> <li>1. Verify that the BioFire® FilmArray® System is connected to the network via Ethernet cable.</li> <li>2. Regenerate the report.</li> <li>3. If the test failed again, contact LIS Support personnel to verify that the data manager HTTP server is running and accepting POST requests.</li> <li>4. If the issue persists, save the report and contact BioFire Diagnostics Technical Support.</li> </ol>
LIS Host Available (LIS Shared Folder Protocol only)	Tests that the LIS shared folder host is present.	<p>If the test failed:</p> <ol style="list-style-type: none"> <li>1. Verify that the BioFire System is connected to the network via Ethernet cable.</li> <li>2. Regenerate the report.</li> <li>3. If the issue persists, reconfigure the LIS Shared Folder Protocol using the credentials previously used to configure the software. Refer to the instructions in section 7.4.</li> <li>4. Regenerate the report.</li> <li>5. If the issue persists, save the report and contact BioFire Diagnostics Technical Support.</li> </ol>
Credential Mapped to LIS Shared Folder (LIS Shared Folder Protocol only)	Tests that the credentials with read and write access to the shared folder are saved on the BioFire® FilmArray® 2.0 System.	<p>If the test failed:</p> <ol style="list-style-type: none"> <li>1. Reconfigure the LIS Shared Folder Protocol using the credentials previously used to configure the software. Refer to the instructions in section 7.4.</li> <li>2. Regenerate the report.</li> <li>3. If the issue persists, save the report and contact BioFire Diagnostics Technical Support.</li> </ol>
LIS Shared Folder Permissions Valid (LIS Shared Folder Protocol only)	Tests that the BioFire® FilmArray® Link software has read and write access to the LIS shared folder.	<p>If the test failed:</p> <ol style="list-style-type: none"> <li>1. Verify that the BioFire System is connected to the network via Ethernet cable.</li> <li>2. With assistance from LIS Support personnel, verify that the shared folder has read and write access for the provided credentials.</li> <li>3. Regenerate the report.</li> <li>4. If the issue persists, reconfigure the LIS Shared Folder Protocol using the credentials previously used to configure the software. Refer to the instructions in 7.4.</li> <li>5. Regenerate the report.</li> <li>6. If the issue persists, save the report and contact BioFire Diagnostics Technical Support.</li> </ol>

Test	Description	Action
Local Folder Permissions Valid (Local Folder Protocol only)	Tests that the BioFire® FilmArray® Link software has read and write access to the folder.	<p>If the test failed:</p> <ol style="list-style-type: none"> <li>With assistance from LIS Support personnel, verify that the local folder has read and write access for the FilmArray user account.</li> <li>Regenerate the report.</li> <li>If the issue persists, save the report and contact BioFire Diagnostics Technical Support.</li> </ol>
Network Shared Folder Host Available (Network Shared Folder Protocol only)	Tests that the network shared folder host is present.	<p>If the test failed:</p> <ol style="list-style-type: none"> <li>Verify that the BioFire® FilmArray® System is connected to the network via Ethernet cable.</li> <li>Regenerate the report.</li> <li>If the issue persists, reconfigure the Network Shared Folder Protocol using the credentials previously used to configure the software. Refer to the instructions in section 7.5.</li> <li>Regenerate the report.</li> <li>If the issue persists, save the report and contact BioFire Diagnostics Technical Support.</li> </ol>
Credential Mapped to Network Shared Folder (Network Shared Folder Protocol only)	Tests that the credentials with read and write access to the shared folder are saved on the BioFire® FilmArray® 2.0 System.	<p>If the test failed:</p> <ol style="list-style-type: none"> <li>Reconfigure the Network Shared Folder Protocol using the credentials previously used to configure the software. Refer to the instructions in section 7.5.</li> <li>Regenerate the report.</li> <li>If the issue persists, save the report and contact BioFire Diagnostics Technical Support.</li> </ol>
Network Shared Folder Permissions Valid (Network Shared Folder Protocol only)	Tests that the BioFire Link software has read and write access to the network shared folder.	<p>If the test failed:</p> <ol style="list-style-type: none"> <li>Verify that the BioFire System is connected to the network via Ethernet cable.</li> <li>With assistance from LIS Support personnel, verify that the shared folder has read and write access for the provided credentials.</li> <li>Regenerate the report.</li> <li>If the issue persists, reconfigure the Network Shared Folder Protocol using the credentials previously used to configure the software. Refer to the instructions in section 7.5.</li> <li>Regenerate the report.</li> <li>If the issue persists, save the report and contact BioFire Diagnostics Technical Support.</li> </ol>

## 10. Technical Support Contact Information

BioFire is dedicated to providing the best customer support available. If you have any questions or concerns about this process, please contact the FilmArray Technical Support team for assistance.

### **BioFire Technical Support**

Email: [support@biofiredx.com](mailto:support@biofiredx.com)

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