

FilmArray® Link ME Panel v1.4 Electronic Report Module

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FilmArray Link Overview

The FilmArray Link Software and FilmArray Link Meningitis/Encephalitis (ME) Panel v1.4 Electronic Report Module (referred to as the ME Panel Electronic Report Module throughout this document) facilitate the transfer of ME Panel v1.4 test results from a FilmArray system to a laboratory information system (LIS).

The software functions as follows:

- The FilmArray Link Software retrieves ME Panel v1.4 test result data from a configured FilmArray database.
- The data is sent to the ME Panel Electronic Report Module, where the data is formatted into an XML file (an electronic report).
- The FilmArray Link Software then sends the electronic report to the bioMérieux Communication Interface (BCI) Link software.
- BCI Link transfers the electronic report to the LIS.

NOTE: The ME Panel Electronic Report Module is compatible with the FilmArray Link Software v2.0 (FilmArray 2.0 system) and the FilmArray Link Software v3.0 (FilmArray Torch system). “FilmArray Link Software” and “FilmArray system” are used throughout this document to refer to both versions of the software and system.

Purpose of the Document

The purpose of this document is to provide instructions for installing the ME Panel Electronic Report Module on a FilmArray system. This document also describes how ME Panel v1.4 test results are reported. The reporting information can be used to map the ME Panel v1.4 test results from an electronic report to an LIS.

Installing the ME Panel Electronic Report Module

The FilmArray Link Software must be installed on the FilmArray system before installing the ME Panel Electronic Report Module. The ME Panel Electronic Report Module will only process ME Panel v1.4 test results.

Before installing:

1. Download the software or order the software from BioFire Diagnostics (provided on a CD and a USB drive).
 - To download the software, visit the BioFire E-Document Center (<https://www.online-ifu.com/>). The KEY-CODE is ITILIS14.

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

NOTE: Save the installation file to the root directory on a removable drive.

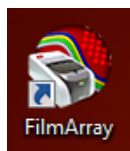
- To order the software on CD and USB drive, contact BioFire Diagnostics Customer Support. Refer to the contact information at the end of this document.

2. Refer to the appropriate instructions below to install the software on a FilmArray 2.0 or a FilmArray Torch system.

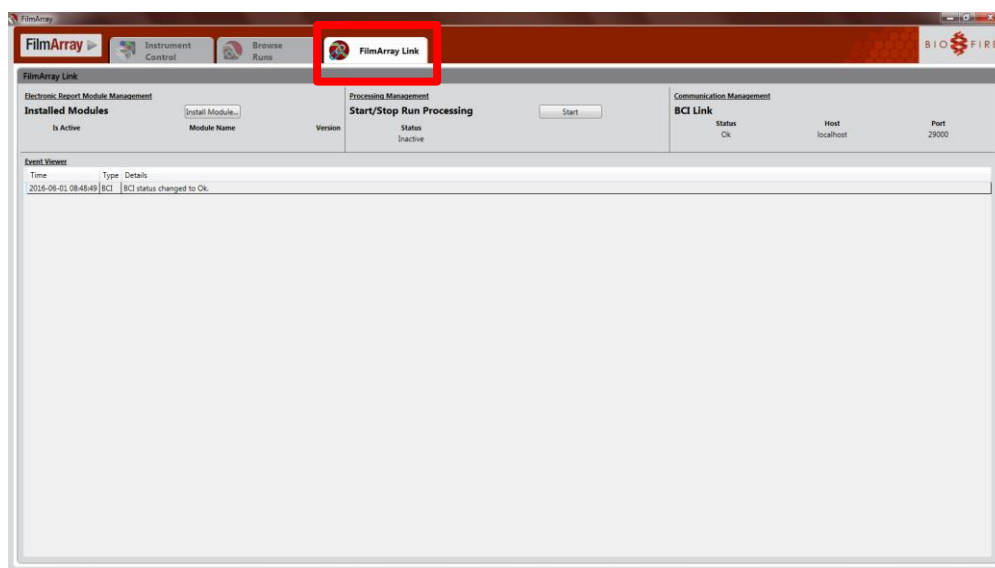
FilmArray 2.0 System

To install the ME Panel Electronic Report Module on a FilmArray 2.0 system computer:

1. Insert the CD or the removable drive containing the installation file into the computer.
2. Launch the FilmArray Software v2.0 from the shortcut on the desktop.

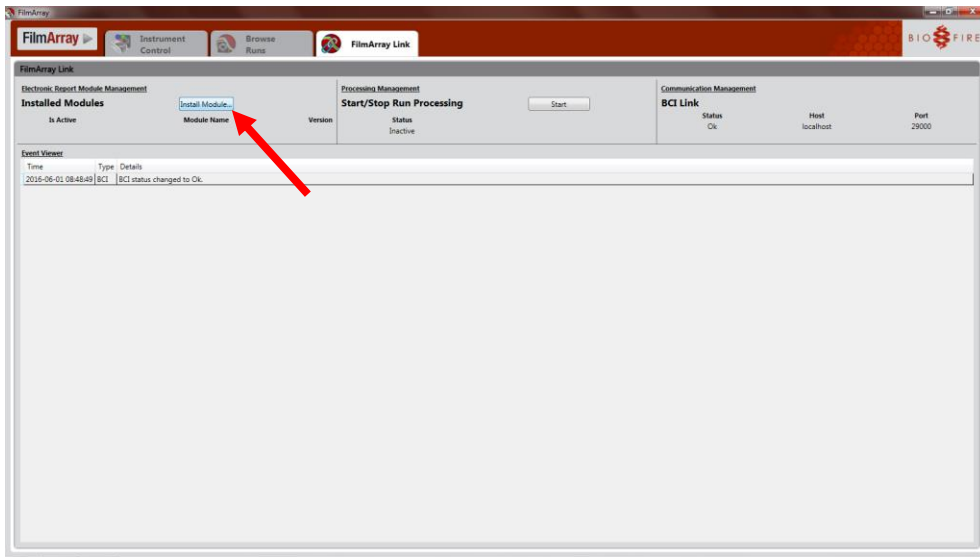


3. Click on the FilmArray Link tab.

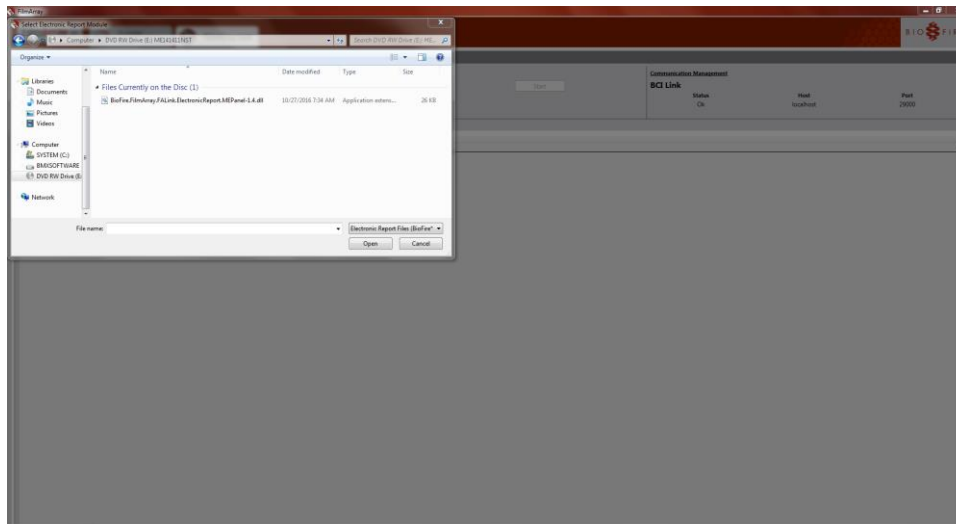


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- Click the Install Module... button in the Electronic Report Module Management section of the tab.

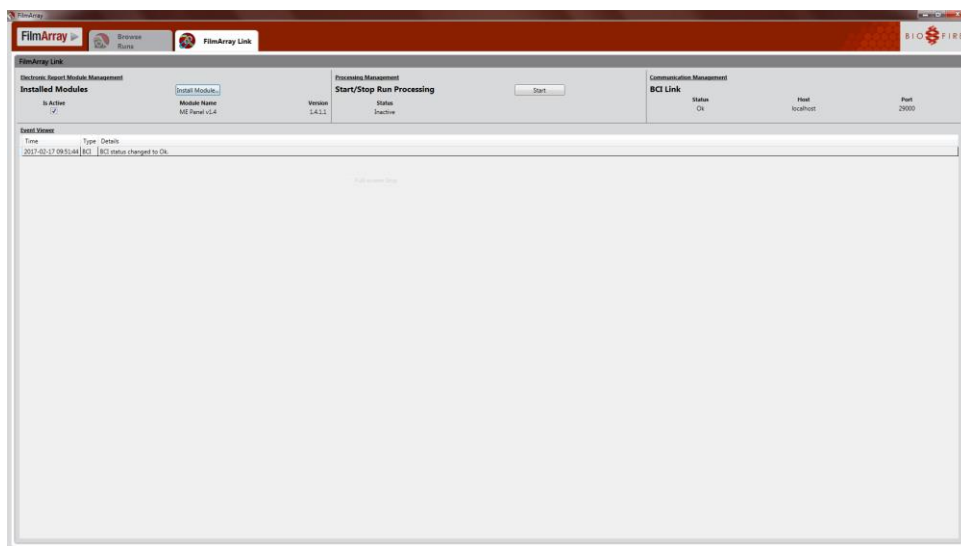


- Navigate to the installation file and double-click on the file **BioFire.FilmArray.FALink.ElectronicReport.MEPanel-1.4.dll**.



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- When the software has been successfully installed, the module name and version are displayed in the Electronic Report Module Management section of the FilmArray Link tab and the corresponding Is Active box is checked.



- Remove the CD or the removable drive from the computer.

FilmArray Torch System

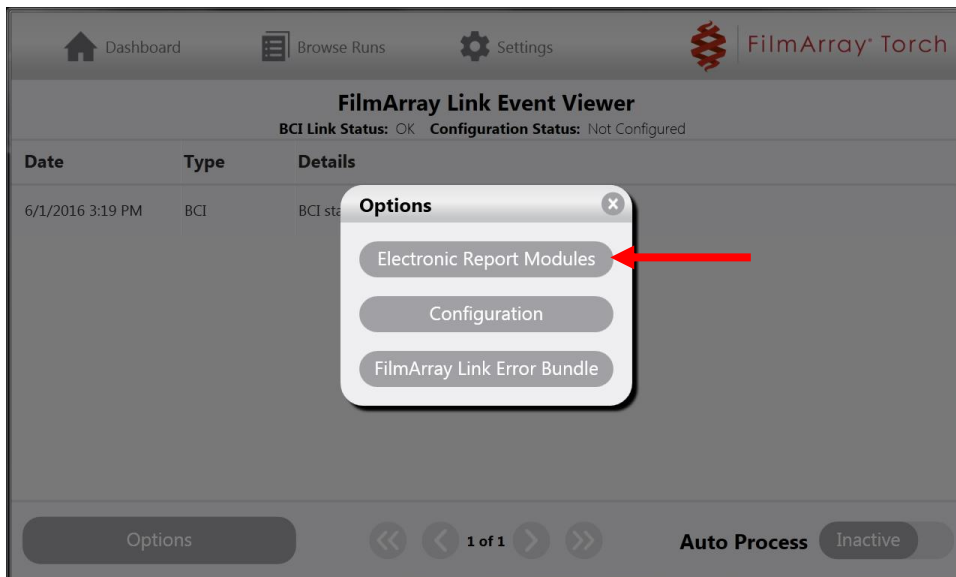
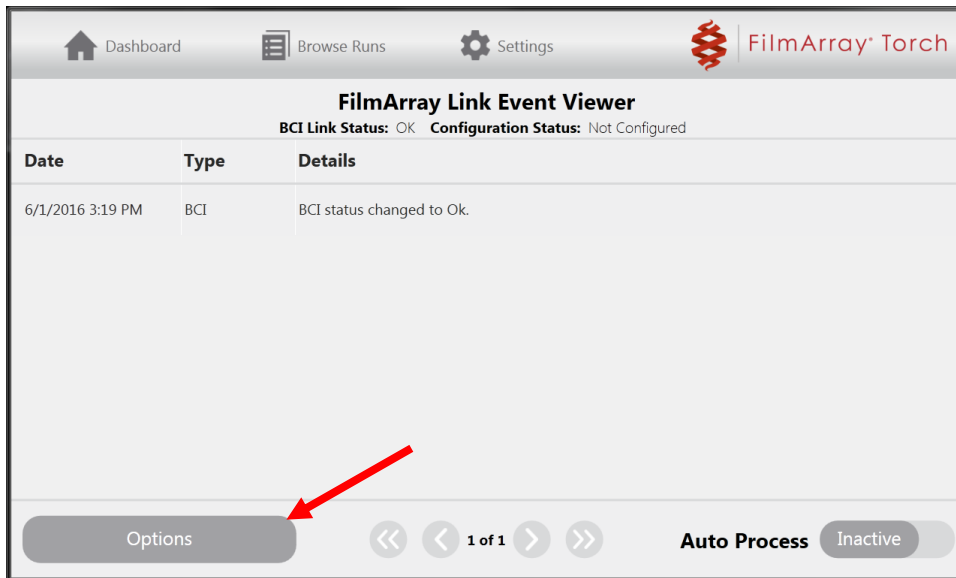
To install the ME Panel Electronic Report Module on a FilmArray Torch system base:

- Insert the removable drive containing the installation file into the system base.
- Select the **FilmArray Link** option on the Settings screen.



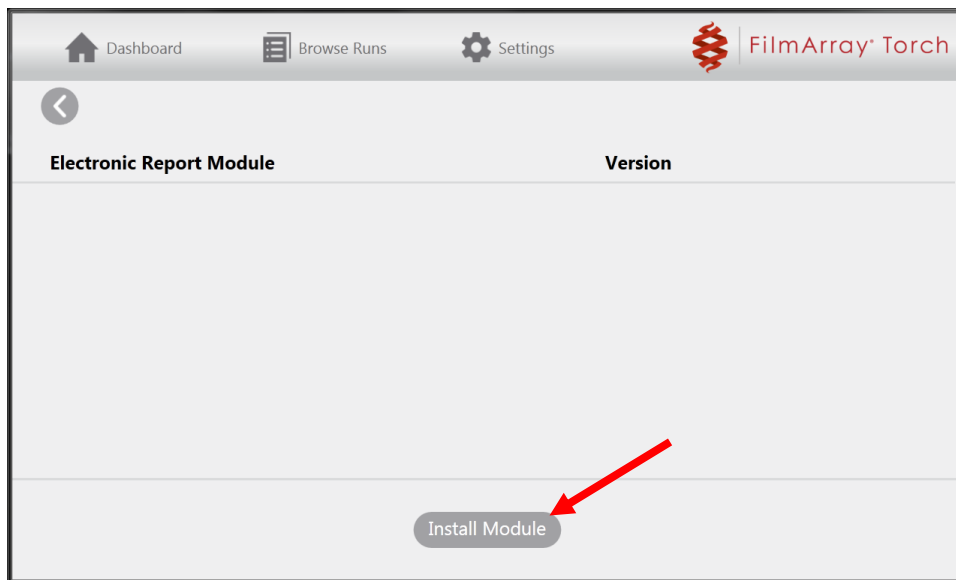
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3. Select **Options** on the FilmArray Link screen and then select the **Electronic Report Modules** option.



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4. Select the **Install Module** option on the Electronic Report Modules screen.



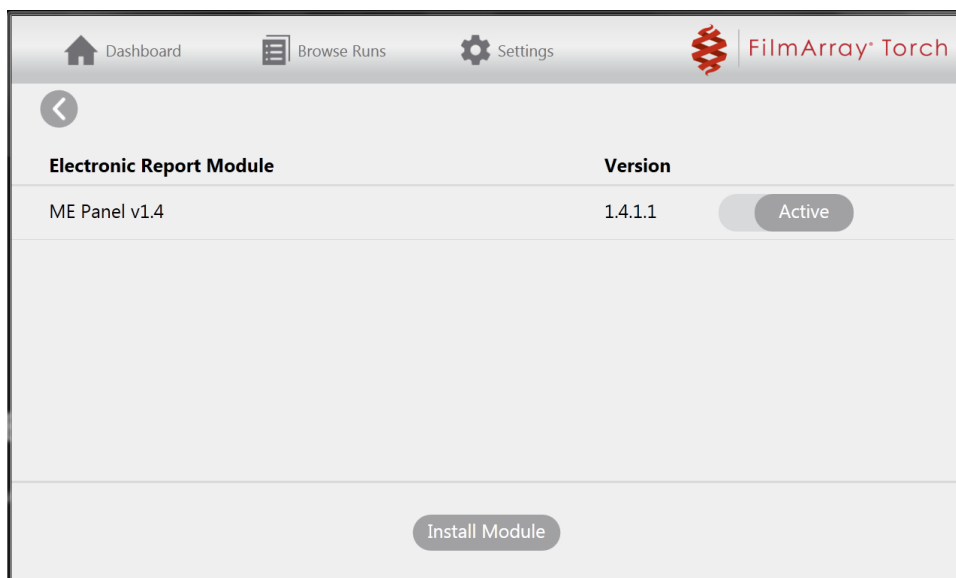
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5. Select the **Install** option associated with the ME Panel v1.4 Electronic Report Module (version 1.4.1.1).

NOTE: The software will only display installation files available in the root directory of the connected removable drive.

A list of installed modules will be displayed once the installation is complete.

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6. Remove the removable drive from the system base.

Reporting the FilmArray ME Panel Targets and Results in the Electronic Report

The ME Panel Electronic Report Module formats ME Panel v1.4 test results into electronic reports. Each electronic report contains information from a single FilmArray test. The report includes the names of the targets on ME Panel v1.4, as well as the corresponding target codes and test results.

Table 1 shows the reported names, result codes, and all possible results for each ME Panel v1.4 target.

Table 1. ME Panel Test Result Reporting

Reported Name	Result Code	Possible Result
Cryptococcus neoformans/gattii	PCR_CRYPTO_NEO_GAT	Detected, Not Detected
Cytomegalovirus	PCR_CMV	Detected, Not Detected
Enterovirus	PCR_ENTEROV	Detected, Not Detected
Escherichia coli K1	PCR_ESCCOL_K1	Detected, Not Detected
Haemophilus influenzae	PCR_HAEINF	Detected, Not Detected
Herpes simplex virus 1	PCR_HSV_1	Detected, Not Detected
Herpes simplex virus 2	PCR_HSV_2	Detected, Not Detected
Human herpesvirus 6	PCR_H_HV_6	Detected, Not Detected
Human parechovirus	PCR_H_PEV	Detected, Not Detected
Listeria monocytogenes	PCR_LISMOC	Detected, Not Detected
Neisseria meningitidis	PCR_NEIMEN	Detected, Not Detected
Streptococcus agalactiae	PCR_STRAGA	Detected, Not Detected
Streptococcus pneumoniae	PCR_STRPNE	Detected, Not Detected
Varicella zoster virus	PCR_VZV	Detected, Not Detected
<p>Notes:</p> <p>All the ME Panel targets listed above are always reported in the Electronic Report, regardless of the result.</p> <p>The following are the result codes in the Electronic Report for the possible test results:</p> <ul style="list-style-type: none">Detected (DETECT)Not Detected (NOT_DETECT)		

The ME Panel Electronic Report Module also returns the annotations that are displayed on the FilmArray PDF reports. These annotations are returned as comments in the electronic reports. Table 2 includes the comments that are associated with the ME Panel v1.4.

Table 2. ME Panel Annotations

Comment	Reporting Conditions
WARNING: The FilmArray ME Panel does not distinguish between latent and active CMV and HHV-6 infections. Detection of these viruses may indicate primary infection, secondary reactivation, or the presence of latent virus. Results should always be interpreted in conjunction with other clinical, laboratory, and epidemiological information.	The comment is included in the XML file if Cytomegalovirus is Detected or Human herpesvirus 6 is Detected. Otherwise, the comment is not included in the XML file.

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Technical Support Contact Information

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

BioFire Technical Support

Email: support@biofiredx.com

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

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