

BioFire Defense FilmArray® Commercial Laptop Addendum for
BioFire® FilmArray® 2.0
Operator's Manual



The Symbols Glossary is provided on Page 2 of this booklet

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Always maintain the instrument in good working order. If the instrument is used in a manner not specified by BioFire then protection provided by the equipment may be impaired.



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BioFire Defense FilmArray® Commercial Laptop Addendum for BioFire® FilmArray® 2.0 Operator's Manual
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CUSTOMER AND TECHNICAL SUPPORT

Contact Us On the Web

<https://www.BioFireDefense.com>

We strongly encourage users to visit our website for answers to frequently asked questions, updated information, and additional insights into operating the BioFire FilmArray.

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SYMBOLS GLOSSARY

The following symbols can be found on labeling for the BioFire Defense FilmArray Commercial Laptop, the BioFire FilmArray 2.0 Instrument, pouches and throughout accompanying packaging. Use the definitions below as a guideline to interpreting the symbols.
























ISO 15223-1:2016					
Medical devices - Symbols to be used with medical devices labels, labeling and information to be supplied					
5.1.1 	Manufacturer	5.1.2 	Authorized representative in the European Community	5.1.3 	Date of Manufacturer
5.1.4 	Use-By date (YYYY-MM-DD)	5.1.5 	Batch Code (Lot Number)	5.1.6 	Catalog Number
5.1.7 	Serial Number	5.2.8 	Do Not Use if Package Is Damaged	5.3.7 	Temperature Limit
5.4.1 	Biological Risks		5.4.3 	Consult Instructions for Use	
5.4.4 	Caution		5.5.1 	<i>In vitro</i> Diagnostic Medical Device	
IEC 60417					
Graphical Symbols for Use on Equipment					
5007 	On	5008 	Off	5019 	Protective Ground
5032 	Alternating Current		5988 	Computer Network	
Underwriter's Laboratory Listing Mark for Canada and the United States			USB Implementers Forum		
	Underwriter's Laboratory Listing Mark			USB cable	
European Union Directive 98/79/EC of the European Parliament and of the Council on <i>in vitro</i> Diagnostic Medical Device			European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)		
	European Union Conformity			WEEE - Do not throw in trash	
Manufacturer Symbol (BioFire Defense, LLC)					
	NOTE - explains how to operate the instrument more efficiently.				

TABLE OF CONTENTS


Introduction	4
Setup Requirements	4
Components of the BioFire Defense FilmArray Commercial Laptop	5
BioFire Defense FilmArray Commercial Laptop for BioFire FilmArray 2.0 Setup	7
BioFire FilmArray 2.0 Instrument Setup	9
 Connecting Multiple BioFire FilmArray's with the Networking Kit.....	 11
Connecting Multiple BioFire FilmArray's.....	11
External Network Adapter	13

INTRODUCTION

This addendum provides the setup instructions for the BioFire Defense FilmArray Commercial Laptop configuration used with the BioFire FilmArray 2.0 Instrument, and replaces the *FilmArray Computer System Quick Guide* and amends chapters 2 and 4 of the *BioFire FilmArray 2.0 Operator's Manual*.

For IVD testing, use the *BioFire FilmArray 2.0 Operator's Manual IVD_EN* (FLM2-PRT-0002) available by download from <https://www.online-ifu.com/ITI0025> (E-Document Center)


For RUO testing, use the *FilmArray 2.0 Operator's Manual RUO* that is on the CD (FLM2-SCD-0100) that is included with this system.


 **NOTE:** The following sections amend Chapter 2 from the *BioFire FilmArray 2.0 Operator's Manual(s)*.

Setup Requirements

Select a clean, well-ventilated area that is large enough to fit the BioFire FilmArray 2.0 Instrument, laptop computer and peripherals, including the networking kit where applicable.






- The depth of the space required is approximately 20 in. (51 cm).
- The width of the space required is approximately 32 in. (81 cm).
- The height of the space required is approximately 15 in. (38 cm).
- Power Specifications: 100–240VAC, 50-60Hz 1.2A input (grounded outlet)





 **NOTE:** The full system will require one electrical outlet if the laptop is running on battery power, or two electrical outlets if the laptop is running on outlet power (via the power adapter).

 **CAUTION:** Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional radio frequency sources, etc.), because these may interfere with the operation of the system.

Components of the BioFire Defense FilmArray Commercial Laptop

The following is a detailed list of the items that are included in the BioFire Defense FilmArray Commercial Laptop configuration and available accessory kits:

BioFire Defense FilmArray Commercial Laptop	
*Commercial Laptop Computer with Power Cord Installed with FilmArray software	
*Laptop models may vary	
FilmArray Laptop Accessory Kit (FLM2-ASY-0101)	
BioFire Defense FilmArray Commercial Laptop Addendum for BioFire FilmArray 2.0 Operator's Manual Part No: FLM2-PRT-0030	
Barcode Reader and Stand Part No: SENS-BAR-0003	
Computer Mouse Part No: ASIO-MIS-0001	
BioFire FilmArray 2.0 Operator's Manual For Research Use Only CD Part No: FLM2-SCD-0100	

FilmArray Networking Kit (FLM2-ASY-0100) (Optional, for multiple instruments)	
Switch, 16-port, Gigabit Switch Part No: ELEC-GEN-0254	
Ethernet Cable Part No: ELEC-CAB-0203	
USB Network Adapter Part No: COMP-GEN-0025	
Power Adapter and International Power Clip Kit Part Nos: ELEC-CAB-0204 / ELEC-CAB-0206	

BioFire Defense FilmArray Commercial Laptop for BioFire FilmArray 2.0 Setup

1. Open the cardboard boxes that contain the BioFire FilmArray 2.0 Instrument, FilmArray Commercial Laptop Computer with Power Cord, and the FilmArray Laptop Accessory Kit and/or FilmArray Networking Kit, as applicable.
2. Use the components list in the previous section and the components list for the FilmArray Instrument in chapter 2 of the FilmArray 2.0 Instrument Operator's manual to verify that all of the contents are present.
3. Remove laptop computer, power cord, mouse, and Ethernet cable (FilmArray Instrument) from packaging.



4. Plug the power cord into the laptop and the power plug into a grounded electrical outlet. Plug the mouse into a USB port.



5. Plug the Ethernet cable into the Ethernet port.



NOTE: Be sure that you use the built-in Ethernet port on the laptop to connect to the FilmArray. If you use a USB network adapter to connect to the BioFire FilmArray, you will encounter data loss issues.

NOTE: Be sure to save your boxes and packing material if you plan to repack the BioFire FilmArray system and move it to a new location.

6. Open the laptop by gently lifting up on the screen. Press the **power on** button to start the laptop.



7. Remove the barcode reader and stand from the access and base by removing the wing nut from the threaded screw at the end of the stand.



8. Insert the end of the screw in the opening on the top of the plastic base.



9. From the underside of the plastic base, thread the wing nut. This secures the plastic base to the stand.

NOTE: To prevent the plastic base from cracking, do not tighten the wing nut too tightly.



NOTE: The barcode reader comes with a USB to Ethernet cable that can only be used for the barcode reader and is not to be used in any other connection. Doing so may damage the items that it is connected to. The barcode reader cable has been labeled for use with the barcode reader only.



- Slide the barcode reader into the holding cup of the barcode reader stand.
- Plug the barcode reader cable into one of the unused USB ports.



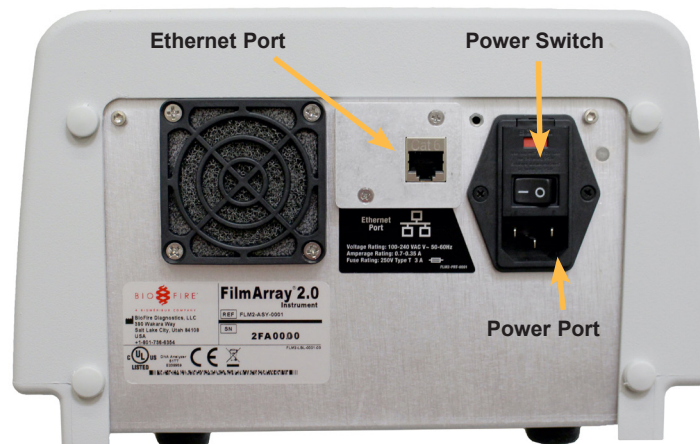
NOTE: Do not remove any USB device before ejecting it. Failing to do so may result in the USB device not operating properly. If the USB device is not operating properly, restart the computer and try again. Never start a computer with a flash drive connected to it.

BioFire FilmArray 2.0 Instrument Setup


- Remove the BioFire FilmArray 2.0 Instrument from the packaging.
- Plug the power cord into the back of the instrument and into a grounded electrical outlet.
- Plug the other end of the Ethernet cable into the back of the instrument.

NOTE: If you are using the BioFire Defense FilmArray Networking Kit to connect multiple instruments to the laptop, follow the setup instructions found in this Addendum.

- Turn on the power switch located on the back of the instrument.



BioFire Defense FilmArray Commercial Laptop Specifications

 **NOTE:** The following section amends Chapter 4 from the *BioFire® FilmArray® 2.0 Operator's Manual(s)*.


Dimensions and Weight	Laptop Dimensions
	12.7 x 8.5 x 0.8 in (32.2 x 21.6 x 2.0 cm) (W x D x H)
	BioFire FilmArray Instrument – 16 lbs (7.3 kg)
	Laptop – Approximate 3.5 lbs (1.6 kg)
	Mouse and Barcode Reader – 2.8 lbs (1.2 kg)
	Laptop models varies by configuration.

BioFire FilmArray 2.0 Reference Materials

Follow these steps to access BioFire FilmArray 2.0 Reference Materials.

For the *FilmArray® 2.0 Operator's Manual RUO (FLM2-SCD-0100)*

1. Obtain an external CD drive (not included with the BioFire FilmArray system) and connect it to the laptop. Additional software may need to be loaded onto the laptop for the external CD drive to work. Consult the external CD drive documents for set-up instructions.
2. Insert the BioFire FilmArray Information CD into the CD Drive and push the tray back into the computer.
3. The Auto play screen opens. Double-click on the “**Open to view files**” link to view the information files listed below.

 **NOTE:** If the Auto play screen does not open, click the “Windows” icon on the left side of the taskbar. Click “Computer”, and then double-click on the CD icon (drive D:) to view the files.

For the *BioFire FilmArray 2.0 Operator's Manual IVD_EN (FLM2-PRT-0002)*

1. Visit <https://www.online-ifu.com/ITI0025> (E-Document Center) and follow the instructions to download the IVD operator's manual.

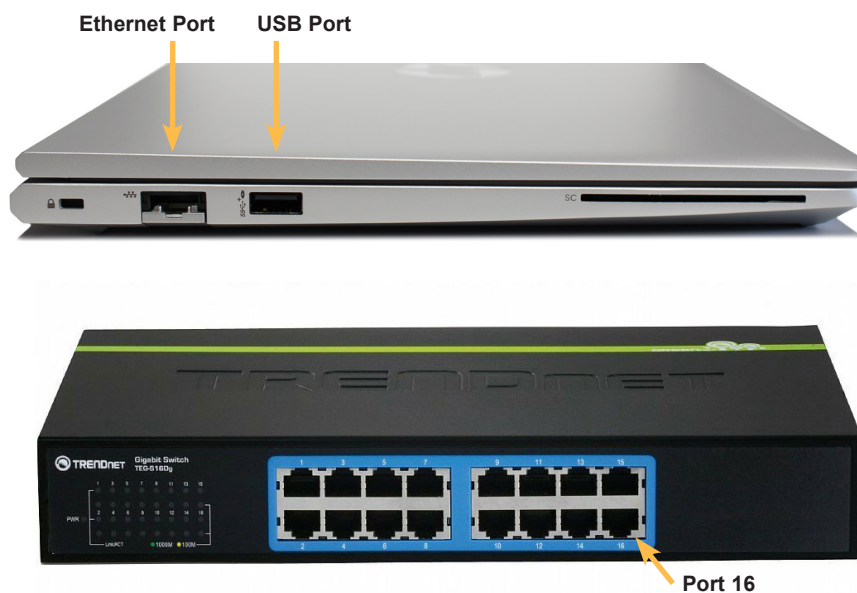
CONNECTING MULTIPLE BIOFIRE FILMARRAY'S WITH THE NETWORKING KIT

The FilmArray software allows users to connect multiple instruments to one FilmArray Commercial Laptop. To do this, you will need to purchase the optional FilmArray Networking Kit, which comes with a validated 16-port network switch and a USB network adapter for external networking capabilities.

Connecting Multiple BioFire FilmArray's

1. Remove the network switch from the packaging.

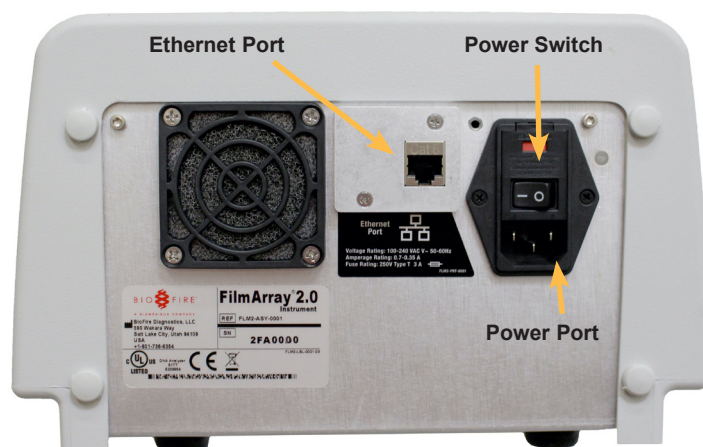
Setup the laptop computer as described in the previous sections. Plug the Ethernet cable that came with the FilmArray Networking Kit into the laptop and then into **Port 16** on the network switch.



2. Plug the network switch into a grounded power supply.

NOTE: A power adapter and International Power Clip Kit have been provided with the FilmArray Networking Kit (ELEC-CAB-0204 / ELEC-CAB-0206). Use the appropriate power adapter and power clip combination necessary for your location when powering the network switch. See manufacturer's instructions for more information on how to properly use the power adapter and International Power Clip Kit.

3. Set up the BioFire FilmArray 2.0 Instrument as described in the previous sections.
4. Connect the instrument Ethernet cable and instrument power cord to the back of the instrument as shown.



5. Plug the instrument power cord into a grounded power source. Plug the instrument Ethernet cable into the network switch.



NOTE: Use Port 1 for instrument 1, Port 2 for instrument 2, and so on.

6. Turn the instrument **ON** using the power switch on the back of the instrument near the power cord.

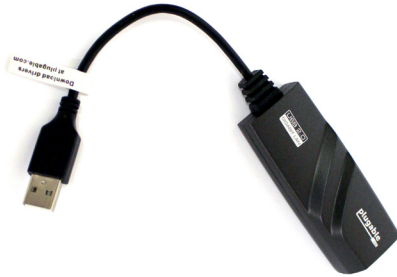
NOTE: The BioFire FilmArray 2.0 Instrument does not require routine shutdown but can be turned OFF using the power switch on the back of the instrument near the power cord. The laptop can be shut down and restarted as needed.

External Network Adapter

If you need to connect the laptop to an external network, use the validated USB network adapter that is included in the optional FilmArray Networking Kit.

NOTE: Do not connect the external network to the Network switch; this will expose the instruments to outside network activity that may result in data loss and vulnerability. Be sure to use the validated USB network adapter when connecting to an external network.

1. Locate the USB network adapter that was included in the FilmArray Networking Kit.



2. Power on the laptop and allow it to boot up properly.
3. Plug the USB network adapter into an available USB port on the laptop. The drivers for the adapter have been preloaded onto the laptop and do not require any additional software.
4. Plug one end of a standard Ethernet network cable into the USB network adapter and the other end into your desired network.



5. The network properties on the laptop may need to be configured to work correctly on your desired network.

NOTE: Do not remove any USB device before ejecting it. Failing to do so may result in the USB device not operating properly. If the USB device is not operating properly, restart the computer and try again. Never start a computer with a flash drive connected to it.



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