EN

REF FLM2-ASY-0001

BioFire® FilmArray® 2.0

Operator's Manual

For *In Vitro* Diagnostic Use

BIOFIRE® BY BIOMÉRIEUX

IVD

UK CA CE

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

A printed version of this manual is available upon request.

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BioFire® FilmArray® 2.0 Operator's Manual IVD FLM2-PRT-0002-08 August 2022

E-Labeling

The manual for this product can be accessed online at www.biofiredx.com/e-labeling/KEY-CODE. The product KEY-CODE is provided on the outer box label at the end of the URL. The KEY-CODE for this operator's manual is also listed below. Additionally, a paper copy is available upon request by contacting customer service via phone, fax, e-mail, or regular mail.

BioFire® FilmArray® 2.0 Operator's Manual	http://www.biofiredx.com/e-labeling/ITI0025/
BioFire® FilmArray® 2.0 System Quick Guide	http://www.biofiredx.com/e-labeling/ITI0079/
BioFire® FilmArray® 2.0 Instrument Quick Guide	http://www.biofiredx.com/e-labeling/ITI0028/
BioFire® FilmArray® 2.0 Software	http://www.biofiredx.com/e-labeling/ITIFA20312/

Customer and Technical Support

Customer Technical Support for U.S. Customers

Reach Us on the Web
www.biofiredx.com

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1-800-735-6544 –Toll Free
801-736-6354 – United States

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801-588-0507

Customer Technical Support Outside of the U.S.

Contact the local bioMérieux sales representative or an authorized distributor for technical support.

NOTE FOR CUSTOMERS WITHIN THE EUROPEAN UNION (EU): Any serious incident that has occurred in relation to the 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.

Symbols Glossary

The following symbols can be found on the instrument, on pouches, or throughout this manual. Use the definitions below as a guideline to interpreting the symbols.

ISO 15223-1 Medical devices - Symbols to be used with medical devices labels, labeling and information to be supplied					
5.1.1 	Manufacturer	5.1.2 EC REP	Authorized representative in the European Community	5.1.3 	Date of Manufacture
5.1.4 	Use By (YYYY-MM-DD)	5.1.5 LOT	Batch Code (Lot Number)	5.1.6 REF	Catalog Number
5.1.7 SN	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 IVD	*In vitro* Diagnostic Medical Device	5.7.10. UDI	Unique Device Identifier		
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**			
c UL us LISTED	Underwriter's Laboratory Listing Mark		USB Cable		
European In Vitro Diagnostic Regulation (IVDR 2017/746)		**European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)**			
CE	European Union Conformity		WEEE - Do not throw in trash		
GB/T 26572-2011 National Standard of People's Republic of China		**Eurasian Conformity Mark of the Custom Union Member State**			
50	Pollution Control - China RoHS	EAC	Eurasian Conformity Mark		
UK Medical Devices Regulation 2002					
UK CA	UKCA - UK Conformity Assessed				
Manufacture Symbols (BioFire Diagnostics, LLC)					
www	Consult Instructions for Use - Online	Tel.	Consult Instructions for Use - Phone		NOTE - explains how to operate the instrument more efficiently
EU	European Union Product Importer				

Abbreviation of Terms

A	amp (ampere)
cm	centimeters
DNA	deoxyribonucleic acid
dNTP	deoxyribonucleotide triphosphate
kg	kilograms
Hz	hertz
in	inches
IVD	*in vitro* diagnostic
lbs	pounds
m	meters
nmPCR	nested multiplex PCR
PCR	polymerase chain reaction
PPE	personal protective equipment
RNA	ribonucleic acid
rt	reverse transcription
Taq	enzyme from *Thermus aquaticus*
Tm	melting temperature
VAC	volt, alternating current

TABLE OF CONTENTS

Revision History

Revision History		
Rev	**Description of Change**	**Effective**
01-04	Previous releases	February 2015 - November 2018
05	• Addition of: o Revision History table. o Electronic download link for obtaining FA 2.0 system software. o Additional of Intended Purpose, Intended User, and Use Environment section • Updates, including: o Updates to Global branding. o Minor updates to add clarification and correct typographical errors. o Minor updates to images where necessary to support Windows 10 OS adoption o Electronic labeling links updated from http://www.online-ifu.com/[keycode] to http://www.biofiredx.com/e-labeling/[keycode]. o Update to the Republic of China standard to GB/T 26572-2011 National Standard of People's Republic of China o Updates to Chapter 9 Cybersecurity to clarify the shared responsibility of medical device security. • Removal of: o Information regarding references to the FA 2.0 system printer, information CD, and software CD. o Specification regarding 8X DVD+/-RW or better and dedicated video card	November 2019
06	• Addition of: o Importer symbol and address o Operator Management section • Updates, including: o Minor updates for typographical errors o Updated notes for LIS connectivity o Images for software update o Error Bundle changes to Data Bundle o Minor update to Cybersecurity for LIS connectivity o Update Printer Cover to Computer Stand o Updated chapter 9 to remove PHI section o Updated PHI note in chapter 5 to be generic for sensitive information and not PHI specific.	March 2021

Revision History		
07	• Addition of: o UKCA Symbol and address • Update of: o China RoHS Symbol o Pouch Loading Station image o EC updated to EU on EU Rep symbol o IVDD requirement updated to IVDR in symbols glossary • Removal of the following sentence o The purchase of this product includes a limited, non-transferable license under U.S. Patent No. 5,871,908, owned by Evotec Biosystems GmbH and licensed to Roche Diagnostics GmbH.	January 2022
08	• Removal of: o Pictures of keyboard, computer, barcode scanner, mouse, ethernet cable, and ethernet switch in chapter 2. • Update of: o Verbiage for connecting components to computer o Dimensions and weight in chapter 4 table updated with new weights	August 2022

CHAPTER 1: BIOFIRE® FILMARRAY® SYSTEM

Intended Use

The BioFire FilmArray 2.0 (BioFire 2.0) System is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved IVD BioFire® 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 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 software automatically determines the results and provides a test report.

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

Intended User and Use Environment

The BioFire 2.0 System is intended for use by trained medical and laboratory professionals in a laboratory setting or under the supervision of a trained laboratory professional.

Limitations of Use

- The BioFire 2.0 is intended to be used in combination with BioFire® Panels that have been FDA cleared for use on the BioFire 2.0.
- For prescription use only.
- Use only the supplied cables when connecting the instrument to the computer.
- Do not use cable extenders to increase cable length.
- Do not modify the computer parameters unless authorized to do so. For example:
    - Do not change screensaver settings on the computer.
    - Do not download or install any software other than software provided or recommended by BioFire Diagnostics.
    - Do not change language settings on the computer.
    - Do not enable wireless network connection.
- Do not run other software programs when running the software.
- Do not modify the software or configuration settings.
- Do not adjust system settings (such as date/time) while instruments are running.
- Do not re-run a pouch associated with an error, incomplete run, or invalid result.
- Only authorized service personnel should perform service or repairs on the system.
- Do not move instruments or reconfigure the instrument dashboard while instruments are running.

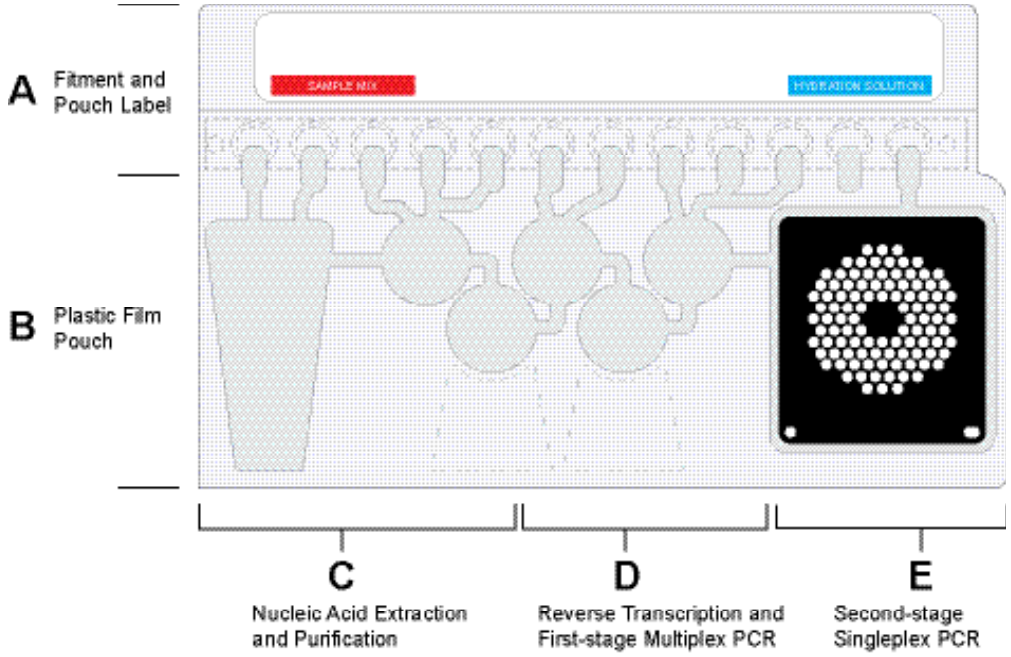
BioFire® FilmArray® Pouch

Each BioFire Pouch is a self-contained, closed system disposable that houses all the chemistry required to isolate, amplify, and detect nucleic acid from a sample. The reservoirs in the rigid plastic component, or fitment, of the pouch (A) contain freeze-dried reagents. The flexible plastic film portion of the pouch (B) is divided into discrete segments (blisters) which, via interactions with actuators and sensors in the instrument, are where the following chemical processes are performed:

(C) Extraction and purification of nucleic acids from a raw sample using mechanical lysis (bead-beating) and magnetic-bead technology

(D) First-stage multiplex PCR (including reverse transcription of target RNAs)

(E) Second-stage singleplex PCR and melting analysis within a multi-well array



Each pouch contains at least one internal process control. Control material is lysed and the nucleic acids of the control material are extracted along with that of the organisms contained in the sample. When the internal control is positive, proper operation of the instrument and chemical processes have been demonstrated.

BioFire® FilmArray® Instrument

The components and operations of the instrument and accessories are described below. Specific step-by-step operating instructions can be found in Chapter 5 and in the instruction booklet for each BioFire® FilmArray® Reagent Kit.

Instrument and Pouch Interaction

After the run is started, a series of plungers, pneumatic actuators, and hard seals work together to move and mix liquid reagents between the blisters of the pouch. The instrument automatically controls these functions based on the run protocol selected for a specific pouch and sample type in the software.

Mechanical Lysis

The first step in processing a sample is to break the outer membrane of the target cells or organisms contained in the sample using a device called a bead-beater. A sensor detects the speed and operation of the bead-beater motor and aborts the run if the bead-beater is not working properly.

Nucleic Acid Extraction

Following bead-beating, the nucleic acids contained in the sample are purified by magnetic bead technology. A retractable magnet is used to capture or release the magnetic beads during washes.

Thermal Control

The purified nucleic acids are mixed with PCR reagents, which amplify all of the targets identified by the pouch as well as the control material. A Peltier device drives the thermocycling (heating and cooling of the solution) of the reverse transcription and/or first-stage PCR reactions. A second Peltier device controls thermocycling for second-stage PCR and DNA melting. This reaction takes place in the array located in the final pouch blister. The thermocycling conditions are controlled by the run protocol associated with each specific reagent pouch and sample type.

Optics and Imaging

To identify targets from positive PCR reactions, DNA-melting curve analysis is performed. The fluorescence emitted by the LCGreen® Plus dye is imaged by a camera. DNA-melting curves are captured by slowly increasing the temperature of the PCR array and capturing the fluorescent signal. These images are processed automatically by the computer, and the data is analyzed to determine if the control reactions passed and which targets were detected in the sample.

The optics system contained in the instrument is aligned, focused, and calibrated at the factory. Proper operation and calibration of instrument optics are monitored by the instrument self-tests and pouch control reactions.

BioFire® FilmArray® Software

The software provided with the system controls the operation of the instrument. The software also collects, stores, and analyzes data generated by the instrument. The results of the analyses are presented in a test report. Detailed information about the features and operation of the software is provided in Chapter 6.

CHAPTER 2: BIOFIRE 2.0 SETUP

Setup Requirements

Select a clean, well-ventilated area for the BioFire 2.0 System that is large enough to fit the instrument(s), instrument rack(s), computer stand, computer, and Ethernet switch.

- The depth of the bench-top space should be at least 24 in (61 cm).
- The width of the counter space required depends on the number of instrument rack(s) being set up:
  - 1 Rack – 36 in (91 cm)
  - 2 Racks – 48 in (122 cm)
  - 3 Racks – 60 in (155 cm)
  - 4 Racks – 72 in (185 cm)
- The height of the space required is at least 36 in (91 cm).
- Power Specifications: 100–240VAC, 50-60Hz 1.2A input (grounded outlet)

NOTE: A full eight-instrument setup requires 12 electrical/power outlets.

NOTE: One instrument rack can hold one or two instruments. A rack is optional if using a single instrument.

NOTE: A single IEEE 802.1x Ethernet port is sufficient for optional LIS connectivity and/or for allowing BioFire or an authorized distributor to securely connect to the BioFire System through the internet.

The BioFire 2.0 System complies with the emission and immunity requirements in IEC 61326. It is advisable to evaluate the electromagnetic environment prior to operating the device.

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

Components of the BioFire 2.0 System

Each BioFire 2.0 System comes with an instrument, accessories, computer system, and an instrument rack (optional). The system ships with three or four boxes: two computer system boxes, the instrument box, and the instrument rack box if ordered. Materials provided in each box include:

BioFire 2.0 Computer System

Computer

Computer Power Cord

Monitor

Monitor Power Cord

Mouse

Keyboard

Ethernet Cable

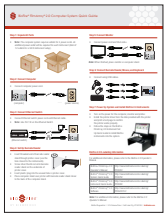
VGA Cable

Barcode Reader

Barcode Reader Stand

Ethernet Switch

DVI Cable



BioFire 2.0 Computer System Quick Guide (Paper copy)

Computer Stand

NOTE: An extra DVI cable and USB cable are included with the monitor. These cables are not needed and may be discarded.

NOTE: The computer comes preloaded with the BioFire Software and training video.

BioFire 2.0 Instrument

BioFire Instrument

BioFire Instrument Power Cord

Ethernet Cable

BioFire® FilmArray® Pouch Loading Station

BioFire 2.0 Instrument Setup Quick Guide

Instrument Rack

Instrument Rack

Rack Clip

NOTE: The instrument rack is optional and is shipped separately in its own box. The instrument rack also includes a clip to attach to an additional rack (if applicable).

BioFire 2.0 System Setup

CAUTION: Use only the supplied cables when connecting the instrument to the computer. Do not use cable extenders to increase cable length.

BioFire 2.0 Computer System Setup

1. Open both computer system boxes, remove all components, and BioFire® FilmArray® Computer System Quick Guide. The quick guide provides abbreviated setup instructions.
2. Place the computer vertically toward the back of the workbench and plug in the computer power cord.

3. Place the Ethernet switch vertically near the back and plug in the power cord for the switch.
4. Connect the barcode scanner, keyboard, and mouse to the USB ports on the computer. Plug the ethernet cable from the computer into port 16 on the ethernet switch.
5. Mount the barcode reader stand onto the computer stand. Place the monitor, keyboard and mouse on top of the computer stand. Plug the monitor into the VGA monitor port on the computer.
6. Plug the power cords for the computer, monitor, and Ethernet switch into a grounded power source.
7. Turn on power to the computer, and monitor.

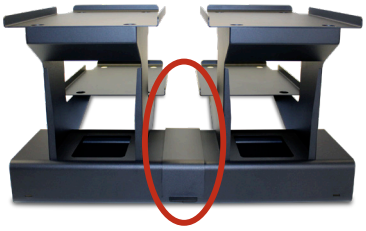
NOTE: The computer is equipped with additional USB ports that can be used for connecting flash drives and other USB devices. The required drivers for these USB devices can be installed on the computer.

CAUTION: Do not install any software other than the software on this computer unless required by peripheral devices as described above.

CAUTION: 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 2.0 Instrument Setup

1. Unpack the instrument rack (optional) and place it on a flat, sturdy surface. When using more than one rack, lock together adjoining racks using the rack clip.



2. Unpack the instrument and place on the instrument rack or on a flat, sturdy surface.

NOTE: If placing the instrument on an instrument rack, fill the bottom position first.

3. Connect the instrument Ethernet cable and instrument power cord to the back of the instrument as shown.

Ethernet cable

Power cable

4. Plug the instrument power cord into a power source. Plug the instrument Ethernet cable into the Ethernet switch.

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

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

6. Launch the BioFire 2.0 training video by clicking on the training icon found on the desktop. See Chapter 6, *BioFire Software,* for detailed information on instrument configuration.

NOTE: The 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 computer can be shut down and restarted as needed.

BioFire 2.0 Instrument Status

The light on the front of the instrument shows the status of the instrument. The light around the button indicates the status of the chamber.

Instrument Status Light	
Off	No Power
Yellow Blinking	Locate Instrument
On	Instrument Ready
Green Blinking	Instrument Running
Red Blinking	Instrument Error
Purple Blinking	Instrument Error (Requires restart)
White	Initializing
Yellow Solid	No Network Connection

Chamber Status Light	
Off	Chamber Locked or Instrument Off
On	Chamber Ready
Blinking	Run Complete/ Remove Pouch

CHAPTER 3: PRINCIPLES OF OPERATION

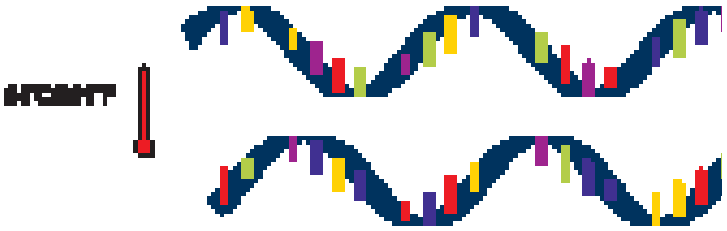
BioFire 2.0 is an automated *in vitro* diagnostic (IVD) system that utilizes nested multiplex PCR (nmPCR) and high-resolution melting analysis to detect and identify multiple nucleic acid targets from clinical specimens. The user of the BioFire 2.0 System loads the sample into a reagent pouch, places the pouch into the instrument, and then starts the run. The instrument interacts with the reagent pouch to extract nucleic acids from the sample and amplifies pathogen-specific DNA sequences that are targeted by the assays. The resulting PCR products are evaluated using DNA-melting analysis and the results are automatically determined and presented by the software in a test report.

PCR Basics

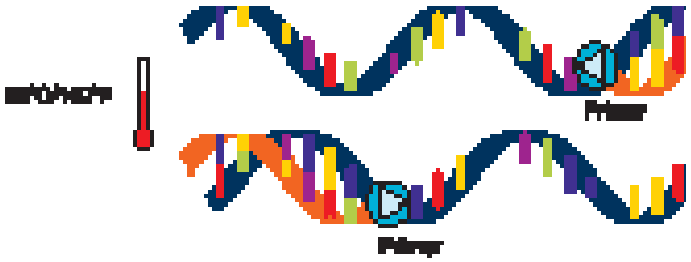
Polymerase chain reaction (PCR) is the process of making billions of copies of DNA. Copies are made by melting the DNA into separate strands and using each strand as a template for the generation of a new strand. To identify specific pathogens using PCR, primers (short pieces of a specific DNA sequence) are included in the PCR reaction to target unique segments of the pathogen genome. If the organism of interest has an RNA genome, a process called reverse transcription (rt) is performed prior to PCR in order to convert the RNA template into a DNA template (rt-PCR).

There are 3 steps to a PCR cycle:

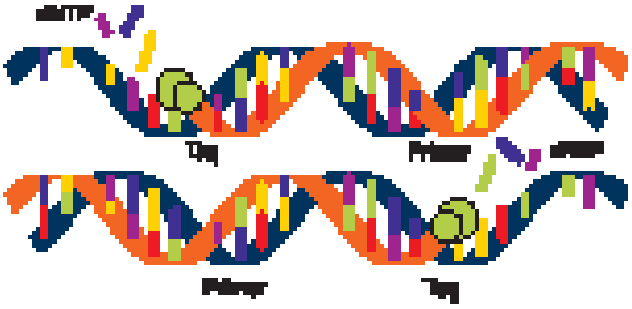
Step 1: Denaturation - The sample is heated to about 94°C to denature or 'melt' the double-stranded target DNA into single strands.



Step 2: Primer annealing - The sample is cooled to about 60°C, allowing the primers to bind or "anneal" to the target DNA strands at a specific site.



Step 3: Primer extension - an enzyme (Taq DNA polymerase) binds to the DNA/primer complex and makes a copy of the original double-stranded DNA by adding nucleotides (dNTPs A, G, T or C) that are complementary to the nucleotide sequence of the target DNA.



At the end of a cycle, each piece of double-stranded target DNA has been duplicated. The new DNA copies act as templates in the next cycles, so after 30 cycles, as many as 1 billion copies of a single piece of DNA can be produced. With this duplication process, it becomes possible to detect DNA or RNA from even a low concentration of pathogens in the original sample.

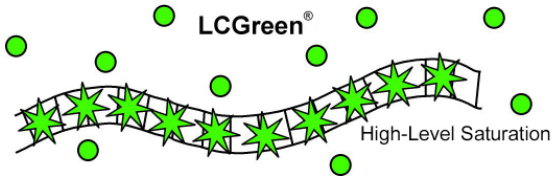
Nested Multiplex PCR

Nested multiplex PCR (nmPCR) uses two stages of PCR. During the first-stage PCR, multiple "outer primers" are used to perform multiplex PCR on the target templates present in the sample.

Second-stage PCR is performed in a singleplex format to further amplify the DNA copies generated during the first-stage PCR. The "inner primers" used in second-stage PCR are made up of sequences "nested" within the first-stage PCR product(s).

High Resolution Melting Analysis

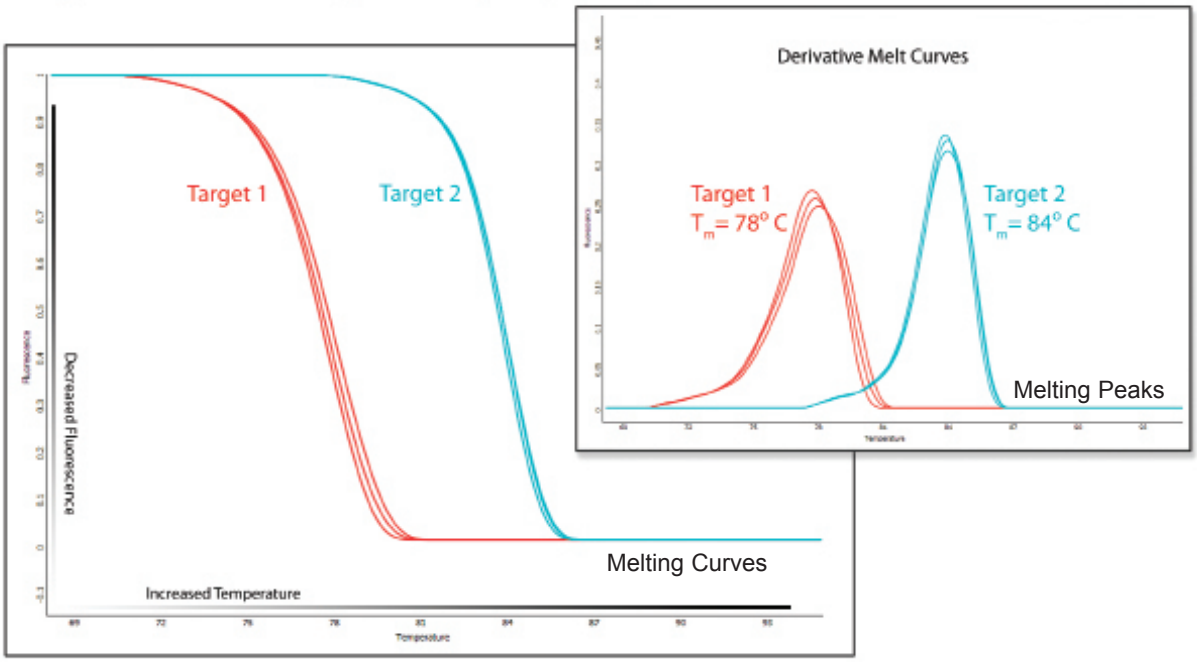
BioFire PCR reactions contain the DNA binding dye LCGreen® Plus. LCGreen Plus is incorporated into the copies of DNA as they are made during each PCR cycle. When bound to double-stranded DNA, the dye fluoresces and the fluorescence is detected by the instrument. As the temperature is increased and the copies of the double-stranded DNA melt, the LCGreen Plus dye is released and a reduction in fluorescence is detected.



Copies of double-stranded DNA generated during PCR (called PCR products or amplicon) will have unique sequences based on the template that was amplified. Amplicon length and sequence determines the temperature at which the double-stranded DNA melts apart, which is known as the melting temperature (Tm) of the amplicon. PCR products made from different targets will have different sequences and, therefore, different Tms.

After the last cycle of PCR, the instrument gradually raises the temperature of the reaction from approximately 60°C to 94°C. As the temperature reaches the Tm of an amplicon, the amplicon denatures and fluorescence drops, releasing LCGreen Plus. This produces a melting curve, seen in the graph below, which shows the rapid decline in fluorescence. A melting peak with a specific Tm is generated for each amplicon by plotting the negative derivative of the melting curve.

Melting Curves for two Different Targets with Unique Amplicon Sequences



The BioFire 2.0 uses melting curve analysis to identify pathogen-specific PCR product. Since the sequence and Tm of an amplicon from a specific target is known and consistent, pathogen-specific PCR product can be identified as being copied from that target. Non-specific PCR products with different Tms are excluded.

CHAPTER 4: PERFORMANCE SPECIFICATIONS

BioFire 2.0 System Specifications

Sample Description	• One sample capacity per instrument
Run Time	• Sample run time about one hour
User Interface	• Computer and (optional) barcode reader
Data Output	• Automatic analysis with end-of-run interpretive reports
Fluorescence Acquisition	• Single-color optics module: 475nm excitation, 545nm emission, and sensor imaging

Temperature Control	• Operating temperature 15°C to 30°C
	• Peltier devices:
	  • Ambient to 100°C
	  • Ramp rate from 0.1–0.5°C /sec on melt

Operations Specification	• 15°C to 30°C @ 20 to 80% humidity (non-condensing) • -16m to 3048m • Indoor use only
Shipping Specifications	• -30°C to 70°C @ 5 to 95% humidity (non-condensing) • -16m to 10,600m
Power Requirements	• 100-240VAC 50-60Hz 1.2A input
Fuse	• 250V 3A Type T

Dimensions and Weight	• 10 x 15.5 x 6.5 in (25.4 x 39.3 x 16.5 cm) (W x D x H; instrument only)
	• Weight*: Approximately 80.2 lbs (36.4 kg):
	  • Instrument – 16 lbs (7.3 kg)
	  • Rack – 16 lbs (7.3 kg)
	  • Computer & Peripherals – 48.2 lbs (21.9 kg)
	  • Computer – 16 lbs (7.3 kg)
	  • Monitor – 13.6 lbs (6.2 kg)
	  • Computer Stand, Keyboard, Mouse, Barcode Scanner – 15 lbs (6.8 kg)
	  • Ethernet Switch – 3.6 lb (1.6 kg)
	* Base system with instrument, computer, and one rack

EMC Requirements	• The BioFire 2.0 system complies with the emission and immunity requirements in IEC 61326

CPU	• Intel®
Storage and Memory	• 500 GB Hard Drive or greater • 4 GB RAM or greater
Interfaces and Peripherals	Computer • 2 Ethernet network interfaces • 4 USB connections or more • VGA connection
	Ethernet Switch • 16 Ethernet network interfaces
	Instrument • One Ethernet network interface
Display	• 20 in (51 cm) • VGA (analog) • 1600 x 900 resolution or equivalent
Operating System	• Microsoft® Windows® OS as released with the BioFire 2.0 System
Cybersecurity	• See Chapter 9, Cybersecurity

CHAPTER 5: BIOFIRE 2.0 OPERATING INSTRUCTIONS

NOTE: Additional instruction on how to operate the BioFire 2.0 is provided in the BioFire 2.0 training video found on the computer.

NOTE: Pouch preparation may vary depending on the pouch type used. Please consult the instruction booklet for each BioFire® Reagent Kit for specific preparation steps.

Using the BioFire 2.0 System involves three main steps:

1. Adding a patient sample to the BioFire® Pouch.
2. Loading the BioFire Pouch into the instrument and performing a run.
3. Viewing and/or printing a report.

BioFire 2.0 Reagent Kits

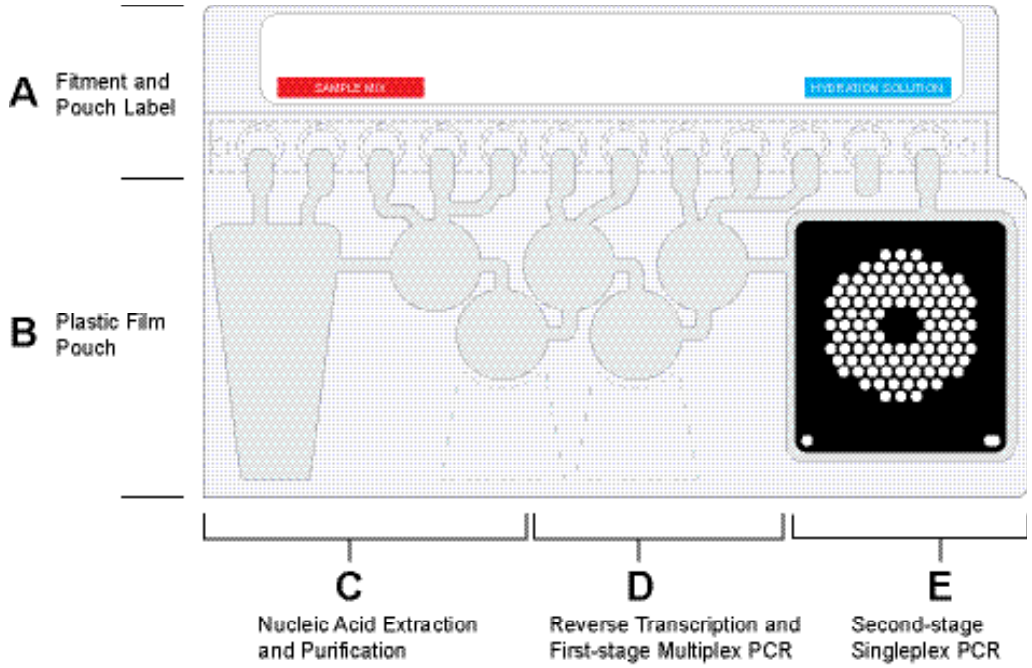
Each kit includes BioFire Pouches and all components required to run tests on the instrument. Components vary based on the type of BioFire Reagent Kit. Refer to the instruction booklet or quick guide for specific preparation and testing procedures.

CAUTION: Do not attempt to use components from one reagent kit to prepare a different pouch type. Components are pouch specific.

Each BioFire Pouch is labeled with:

LOT Lot Number Expiry Date SN Serial Number

This information is both human-readable and contained in the barcode. The pouch also includes a space to write the Sample ID or affix a Sample ID barcode.



Test Procedure

General Precautions

BIOLOGICAL RISKS: When working with the BioFire 2.0 System, personnel may come in contact with contaminants or potentially infectious material. Appropriate biohazard guidelines for working with potentially infectious samples should be followed. Refer to the *Safety Precautions* section of the appropriate BioFire® Reagent Kit instruction booklet for additional safety information.

It is recommended that the handling of potentially infectious samples be performed in a biologicalsafety cabinet or hood, or behind a protective shield. Once patient sample has been added to the BioFire® Pouch, move the pouch to a separate area to perform the test.

One of the most important guidelines for a test using PCR is to avoid contamination. Some important rules to follow are:

1. Sample collection, pouch loading, and instrument operation should each be performed in separate locations or work areas.
2. Do not leave a work area or return to a previous work area without first completing decontamination procedures (i.e., washing the area and changing protective clothing and gloves).
3. Prepare and load only one pouch at a time.
4. Always dispose of used pouches, or pouches that have come in contact with a sample, in a biohazard waste container. Change gloves after handling a used pouch.

BioFire Pouches are stored under vacuum in individually-wrapped canisters. To preserve the integrity of the pouch vacuum for proper operation, be sure that an instrument is available and operational before unwrapping any pouches for loading.

Start BioFire 2.0 Run

Refer to the *Procedure* section of the appropriate BioFire® Reagent Kit instruction booklet for step by step instructions for sample and pouch preparation.

The software includes a step-by-step tutorial that 1) walks the operator through placing the BioFire® Pouch into the instrument and 2) demonstrates how to perform a run.

Follow the on-screen instructions located in the Next Step box to perform the run.

1. Open the software (if not already open) by double-clicking on the software desktop icon.
2. Ensure that the instrument is properly configured. Refer to Chapter 6, *BioFire Software*, for more information about the instrument configuration process.
3. Open the instrument lid (if not already open).
4. Load the pouch into the instrument.

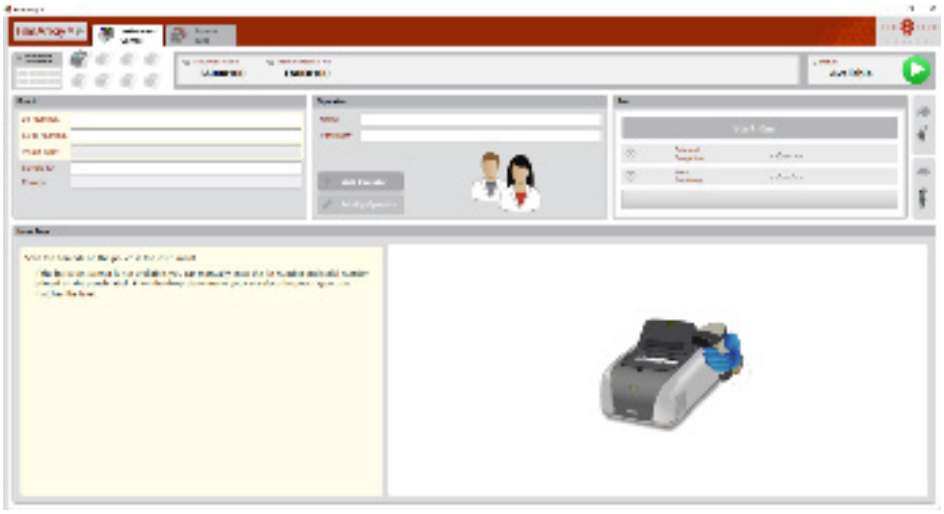
   Position the pouch with the black array on the right side and the film portion of the pouch entering the instrument first. The pouch locks into place when it is properly inserted.

   Ensure that the red and blue labels on the pouch align with the red and blue arrows on the instrument as shown in the figure above. If inserted correctly, the barcode label is visible on the top of the BioFire Pouch. There is an audible click when the pouch is securely in place.

   If the pouch is not completely in place, the instrument and software will not continue to the next step.

NOTE: The instrument lid must be opened completely. If the pouch cannot be easily inserted into the pouch chamber of the instrument, gently push the instrument lid back completely and try again.

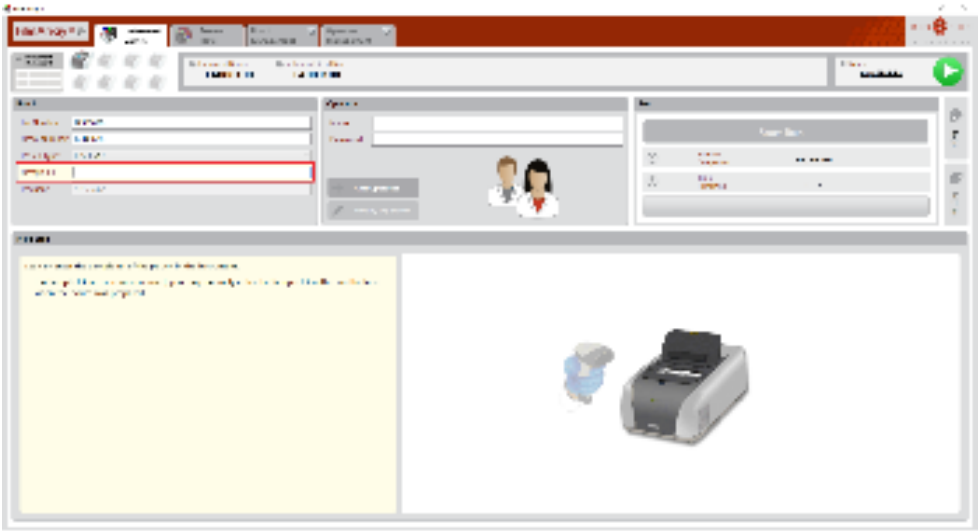
5. Scan the barcode on the BioFire Pouch label using the barcode scanner provided. If the barcode scanner is not available, manually enter the lot number and serial number printed on the pouch label. Use the drop-down menu to select the pouch type that matches the label. Be sure that all barcode labels are as smooth and flat as possible. Hold the scanner about 10 centimeters from the barcode. Center the aiming beam on the barcode to scan.
   Pouch information and protocols are preprogrammed in the rectangular barcode located on the BioFire® Pouch. The first three fields of the FilmArray pouch section of the screen (Lot Number, Serial Number, and Pouch Type) will be filled in by scanning the barcode.



NOTE: Keep the lens of the barcode reader free of dust and scratches.

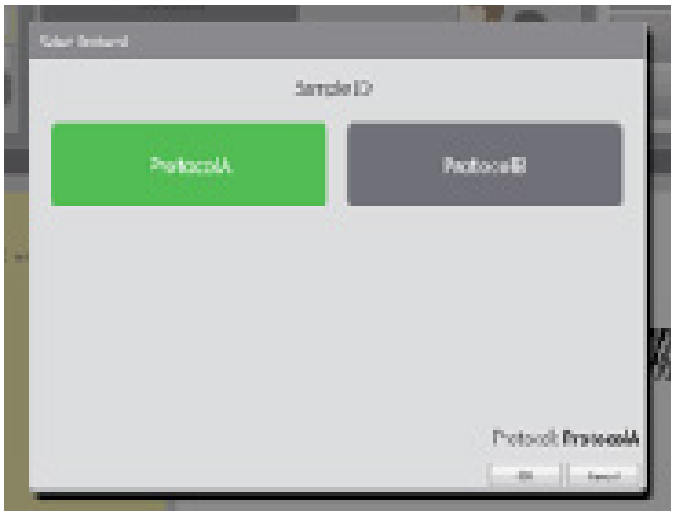
NOTE: A pouch must be placed in the instrument prior to being scanned. A warning message displays if the scanned pouch is not in the instrument stating: "The lid needs to be open and a pouch loaded in order to scan."

6. Scan the Sample ID. If a Sample ID barcode was not used, manually enter the Sample ID written on the label when the pouch was prepared.



NOTE: When manually entering a Sample ID, please use sequentially generated recycled accession numbers. Do not enter patient names, addresses, demographic information, financial information, medical record numbers, Social Security numbers, or any other unique identifying numbers, characteristic, or code in the Sample ID field.

7. Once the pouch type has been entered, the appropriate sample protocol(s) automatically displays.



Select the appropriate protocol based on the panel and/or sample type, then select OK.

CAUTION: The correct sample type must be selected. If not, the incorrect protocol may be loaded and cause incorrect report results.

8. Enter the operator name and password in the Name and Password fields. Use the Add Operator button to create a new account if needed.

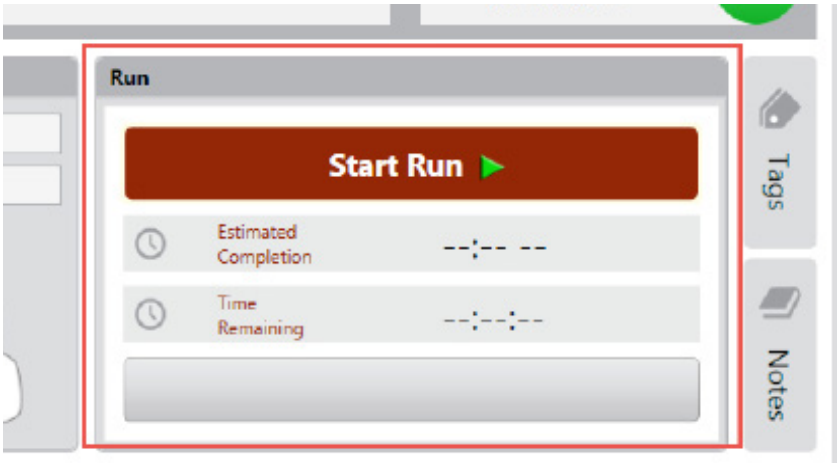
NOTE: The font color of the name and password is red until the user name is recognized by the software.

NOTE: See Chapter 6, *BioFire Software*, for more information on creating a user name and password and adding or deleting operators.

9. Close the lid on the instrument.

CAUTION: Use caution when closing the lid to avoid pinching fingers.

10. Click the Start Run button on the software screen. The software starts the run on the selected instrument



A checklist of steps is displayed in the Next Step section of the main Instrument Control screen. As the instrument proceeds through each step, a checkmark appears by the step. The approximate remaining run time is displayed in the Run box.

Once a run has started, then the user can navigate to the Instrument Dashboard and perform tasks on other instruments.

If it is necessary to stop a run before it is finished, select Abort Run. When a run is aborted, any data that has been generated for that run will not be available for analysis. An aborted run cannot be restarted or rerun.

If communication is lost during a run, the run continues and the data uploads when communication is re-established.

CAUTION: Do not adjust system settings, including date/time, during a run. Do not change instrument or dashboard configuration during a run.

NOTE: The software has an option for an audible alert sound upon run completion. See Chapter 6, *BioFire Software*, for more information on selecting this option.

11. At the end of the run, remove the pouch from the instrument.

    The flashing blue light indicates that the test is complete. The lid on the instrument may be opened and the pouch removed. Removing the pouch clears all the fields on the screen and prepares the instrument for another test.

View and/or Print Report

When a run is finished:

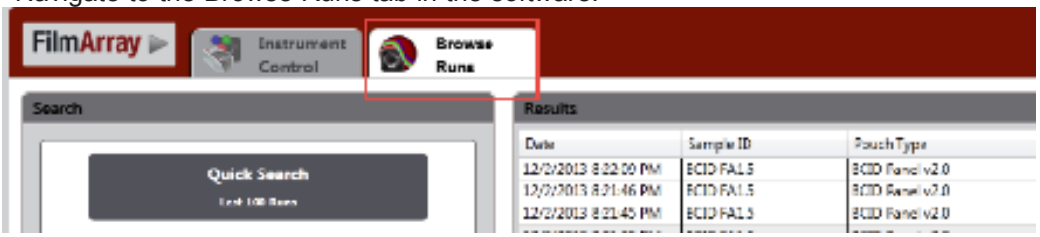
- On the Instrument Control screen, the View Report tab opens automatically at the completion of a run to display the report.
- On the Instrument Dashboard, after a run completes, a report icon appears in the top right corner of the Instrument Dashboard box for the instrument. Click anywhere in that box to view the report.

The software can be configured to automatically print the report at the end of the run (see below). At any time when viewing a report, the operator can select the Print button to print the report or select the Save button to save the report as a PDF file.

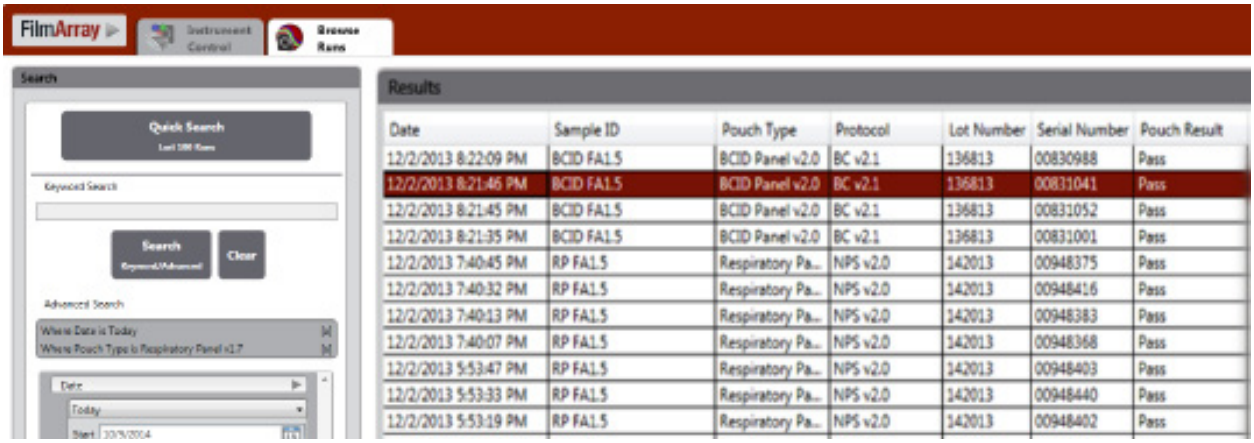
Refer to the instruction booklet for the appropriate BioFire® Reagent Kit for more details about the information provided in the report.

To view or print a report from a previous BioFire® Pouch run stored in the database:

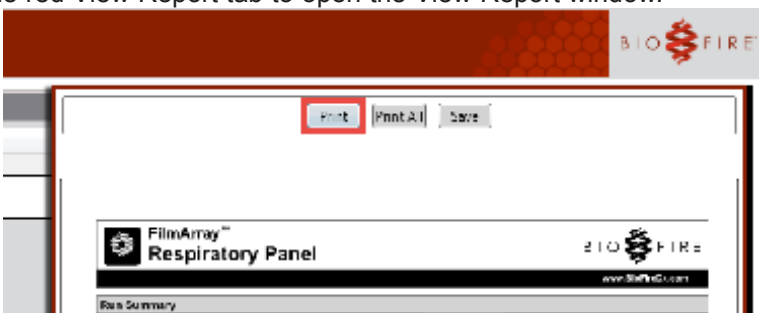
1. Navigate to the Browse Runs tab in the software.



2. Use the Quick Search, Keyword Search, or Advanced Search options to locate runs in the database.
3. Select the desired run from the Results table by clicking and highlighting the appropriate table row.



4. Click on the red View Report tab to open the View Report window.

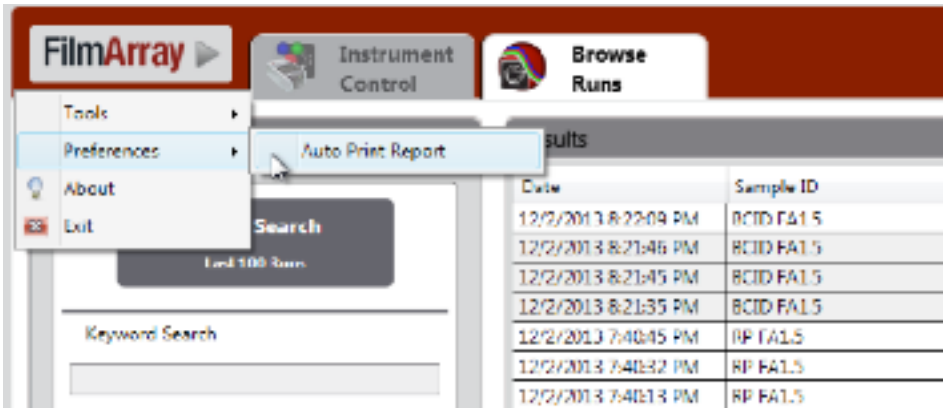


5. To print the report, click the Print button at the top of the View Report window.

   The report for a run or runs can also be printed by right-clicking the applicable runs in the Browse Runs table and selecting Print Reports from the Browse Runs context menu:

To configure the software to automatically print the report at the end of each run:

1. Highlight the Preferences option in the software menu.



2. Click on Auto Print Report to enable the automatic printing of the report.
3. Navigate to Devices and Printers in the Windows Start menu. Set the default printer by right-clicking on the icon for the desired device and checking the Set as default printer option. A green check mark is displayed on the icon for the selected device.
4. The software prints the report to the default printer.
5. After completion of the next run, the report automatically prints.

Error Messages

Errors in the BioFire 2.0 System may originate in the instrument, in the software, or in communication between the two. Any run that receives an error message should be repeated with a new pouch. See Chapter 8, *Preventative Maintenance and Troubleshooting*, for more information on viewing and handling error messages.

CHAPTER 6: BIOFIRE® SOFTWARE

Introduction

The software comes preinstalled on the BioFire 2.0 computer. It communicates with the instrument(s), and is used to enter pouch and sample information, start a run, analyze data, and provide a report with all test results. This chapter explains how to use the software, set up the Instrument Dashboard, and manage the database.

BioFire Software

The BioFire computer is preconfigured with the software. No password is required when logging on. To open the software, turn the computer on and double-click the software icon  found on the desktop.

BioFire Software Menu

To access the software menu, click the FilmArray button, located in the top left-hand corner of the window.

The table below lists all the features available in the FilmArray menu.

FilmArray Software Menu	Description
Tools	**Pouch Management:** Enables the operator to view existing and install new pouch modules. For more information see the *Pouch Management* section in this chapter. **Operator Management:** Enables the operator to add, modify, delete, import or export operators. For more information see the Operator Management section in this chapter. **Instrument Configuration**: Enables the operator to add instruments to the BioFire 2.0 System. For more information see the *FilmArray Instrument Configuration* section in this chapter. **System Log**: Provides details about error messages. For more information see the *Software Troubleshooting* section in Chapter 8.
Preferences	**Auto Print Report**: Enables the operator to set reports to auto print. For more information see the V*iew and/or Print Report* section in Chapter 5.
About	Provides the software version, end-user license and build information.
Exit	Exits the software.

Pouch Management

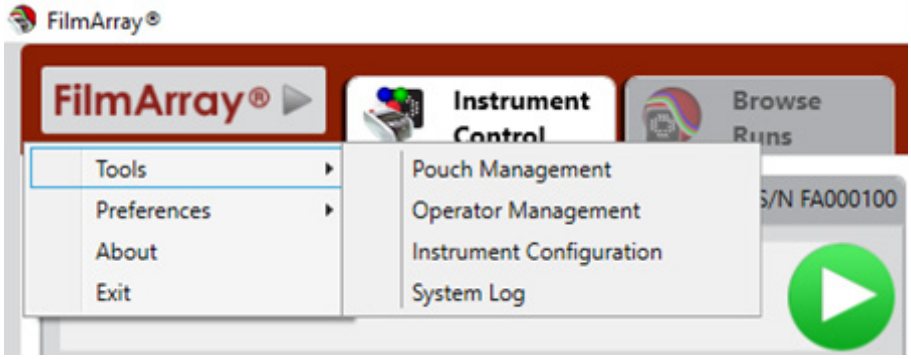
The Pouch Management feature enables the operator to see which pouch modules are currently installed and available for use. This feature also enables the operator to install new pouch modules. These pouch modules contain definitions, instrument protocols, analysis and reporting for specific BioFire® Reagent Kits.

Pouch Module Installation

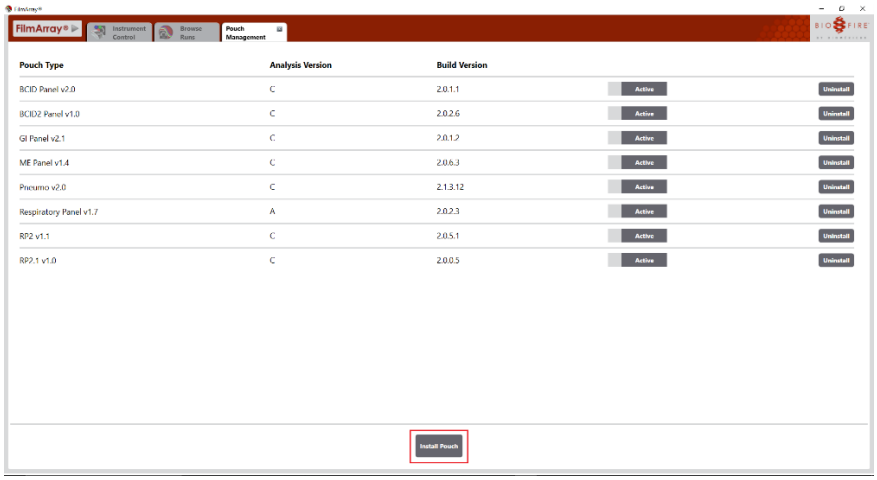
When new pouch modules are received from BioFire Diagnostics, Pouch Manager must be used to add these to the list of available pouches.

The operator can access the Pouch Manager via the software menu. To add a new pouch to the system:

1. Select Tools > Pouch Management to open the Pouch Manager.

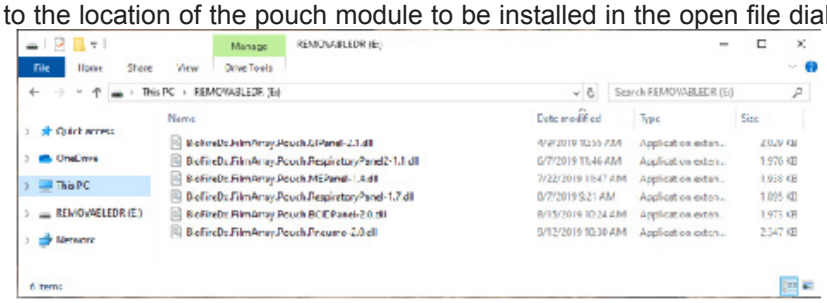


2. Click Install New Pouch to add a new pouch to the system.

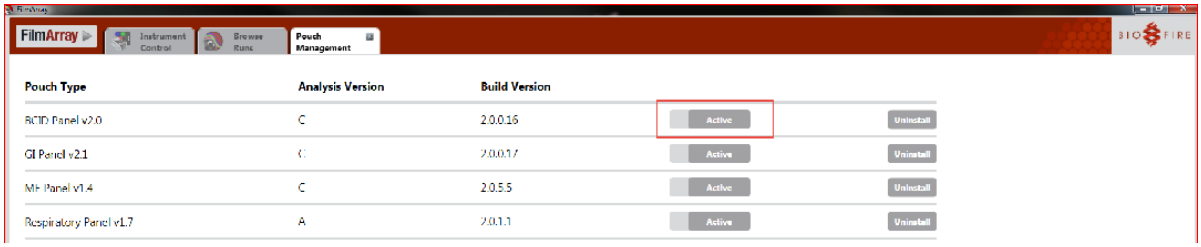


NOTE: The list of available pouch types may differ from the picture above.

3. Navigate to the location of the pouch module to be installed in the open file dialog box.



4. Select the pouch module to be installed, then select Open.
   The pouch module will display and slide bar will be in the Active position.



NOTE: To inactivate a pouch module, select the Active slide bar and slide it to Inactive. To uninstall a pouch module, select Uninstall and follow the on-screen prompts to complete uninstallation.

Operator Management

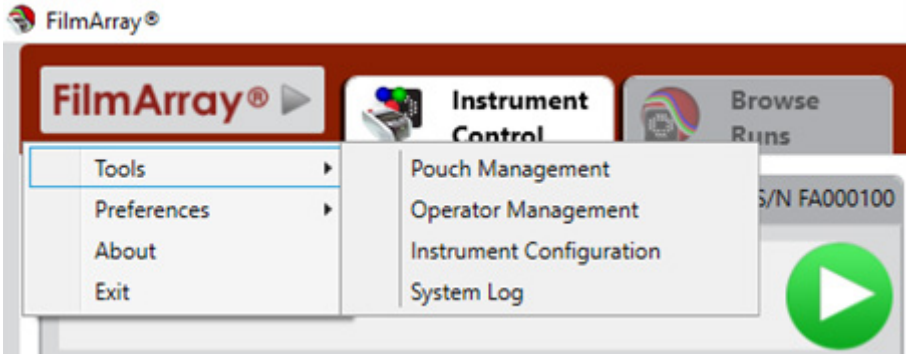
The Operator Management feature enables the operator to see what operators are currently listed in the system. This feature also enables the operator to add new operators, modify existing operators, and delete existing operators. This feature will also import new operators or export existing operators.

Create New Operator(s)

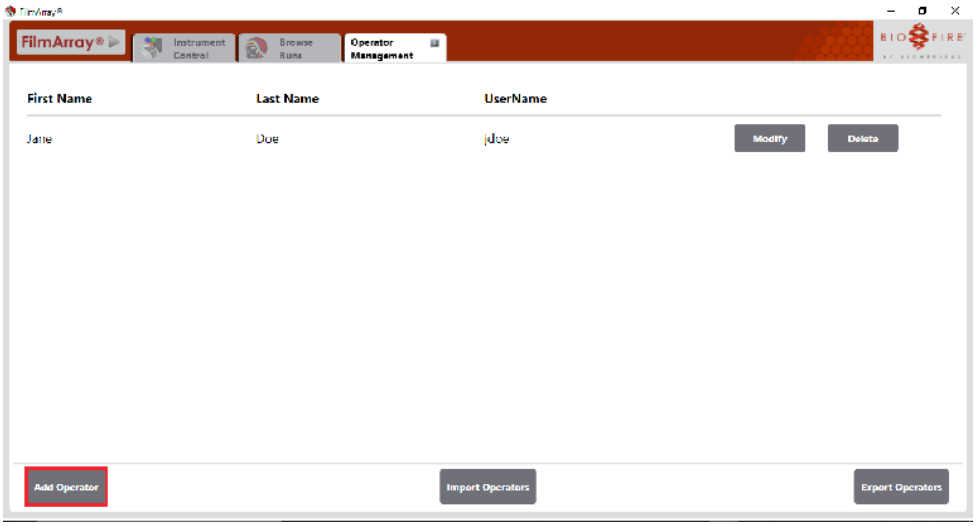
An operator name and password are required to run a pouch on the instrument. The Operator Management view will allow the creation of new operators.

To create a new operator:

1. Select Tools > Operator Management to open the Operator Management View

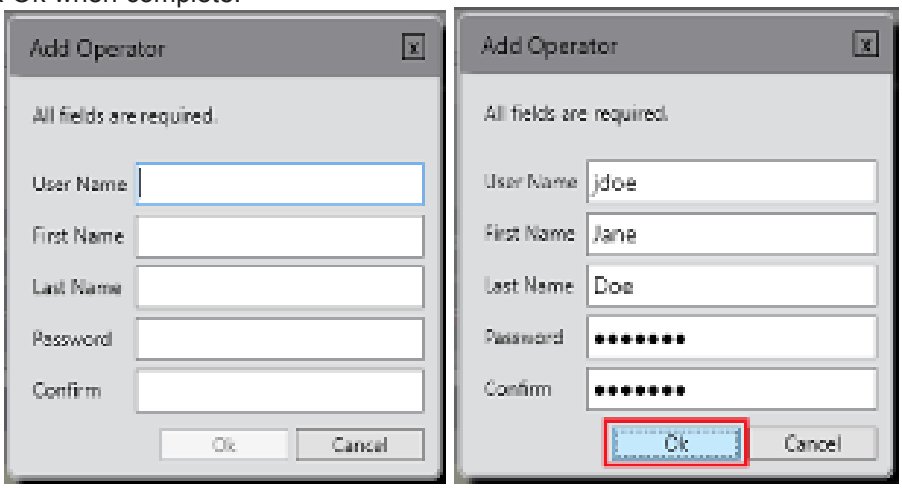


2. In the Operator Management view, click the Add Operator button.



3. When the Add Operator dialog box displays, enter a User Name, the First name and Last Name of the operator, and a password in both the Password and Confirm fields.

4. Click Ok when complete.

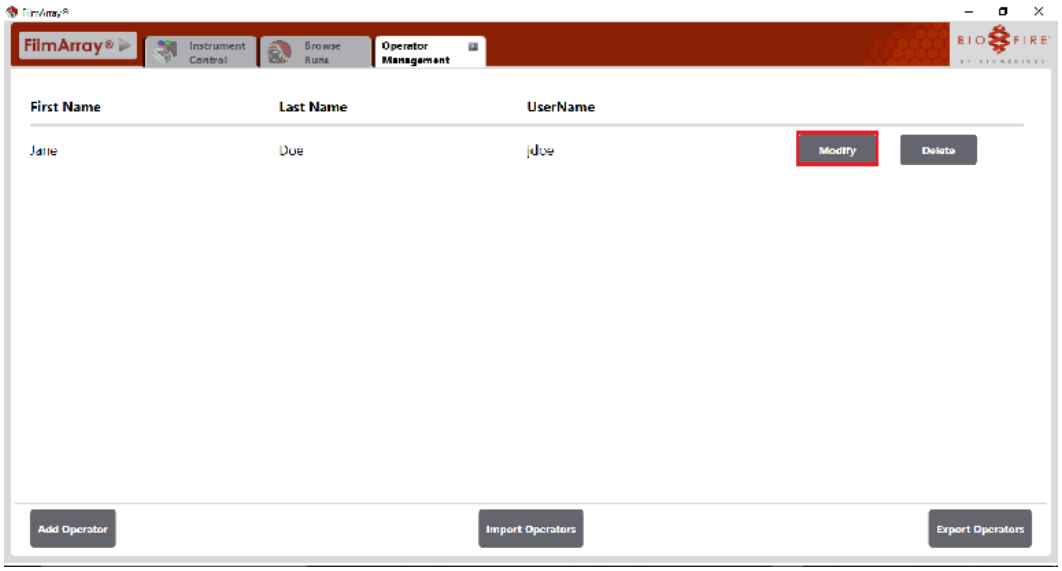


NOTE: The Confirm field displays the password dots in red until the Password and the Confirm fields match.

Modify Operator(s)

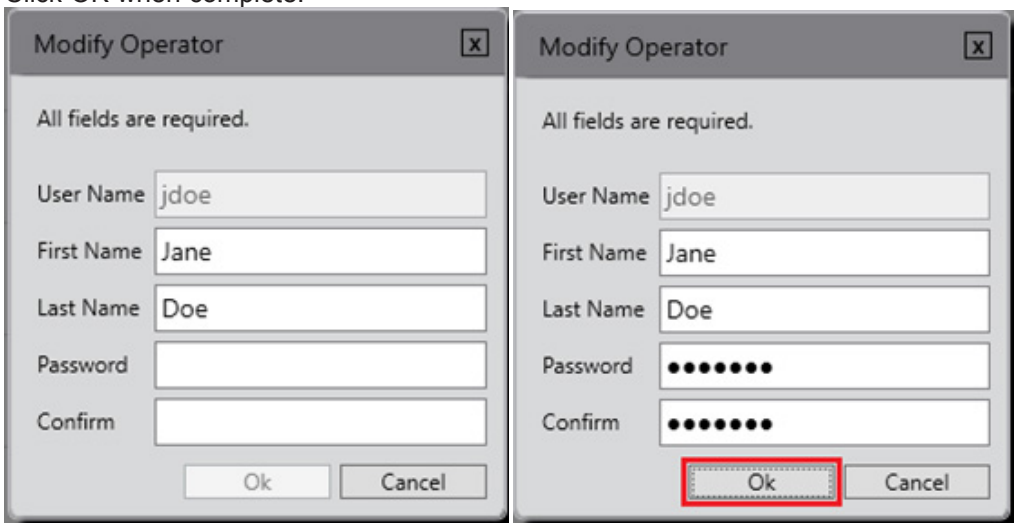
The Operator Management view will display all operators added to the system. The Operator Management view will allow the modification of existing operators.

1. In the Operator Management view, click the Modify button.



2. When the Modify Operator dialog box displays, enter a User Name, the First Name and Last Name of the operator, and a password in both the Password and Confirm fields.

3. Click OK when complete.



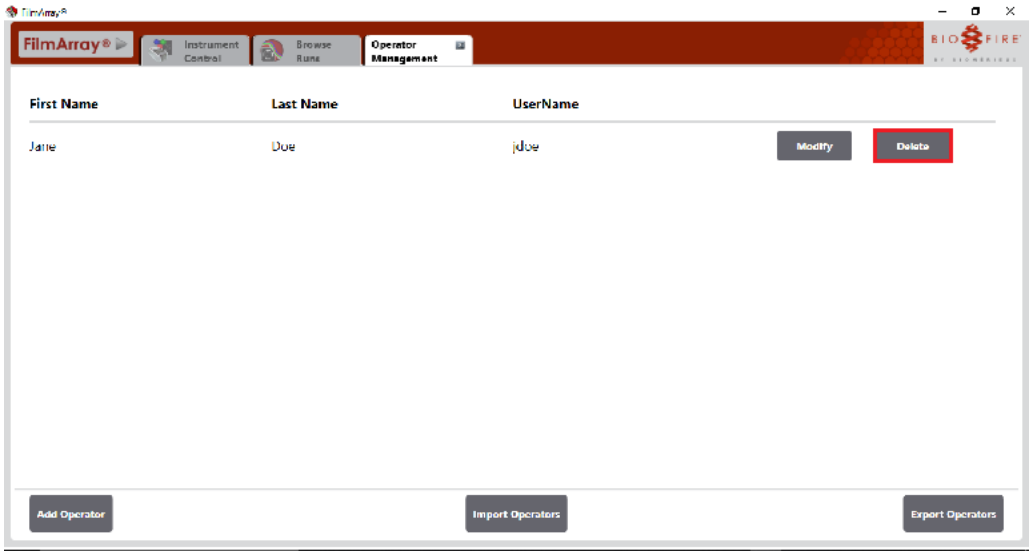
NOTE: The Confirm field displays the password dots in red until the Password and Confirm fields match.

Delete Operator(s)

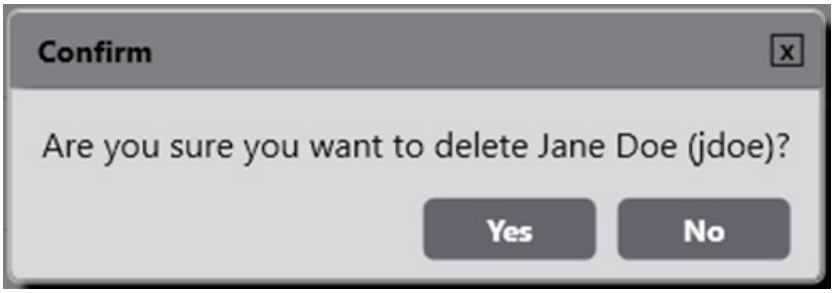
The Operator Management view will display all operators added to the system. The Operator Management view will allow the deletion of existing operators.

To delete an existing operator:

1. In the Operator Management view, click the Delete Button.



2. A Confirm dialog will display the operator selected for deletion and ask if the operator is sure they want to delete the selected user.



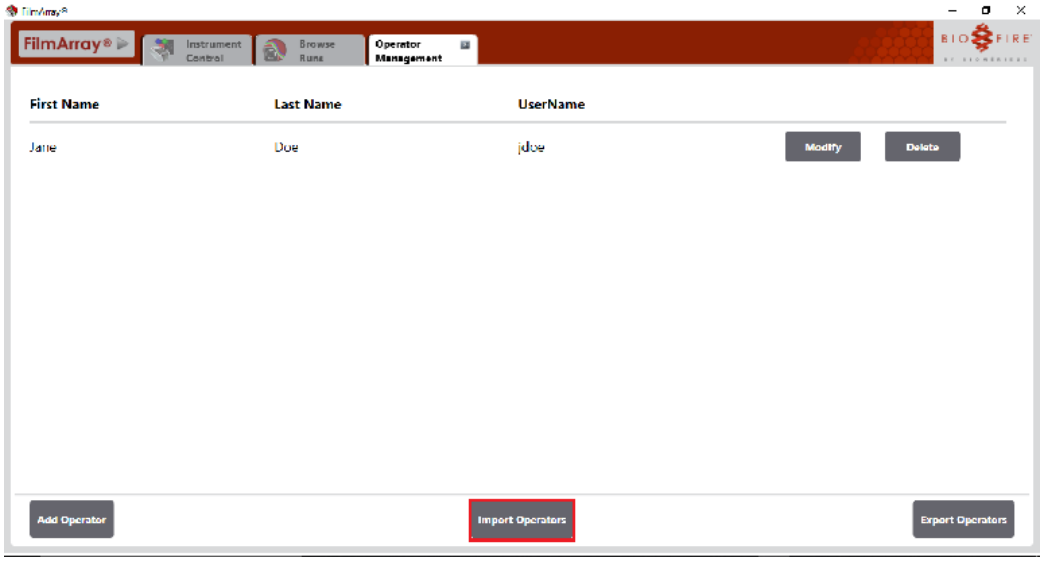
3. Click **Yes** if you want to delete the listed operator.

Import Operator(s)

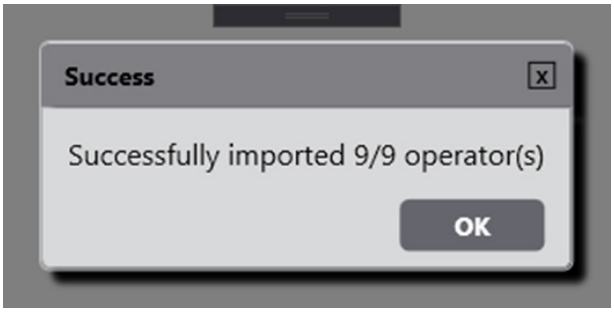
This feature enables the operator to import operators from another FilmArray database onto the computer being used.

To import Operators from a file:

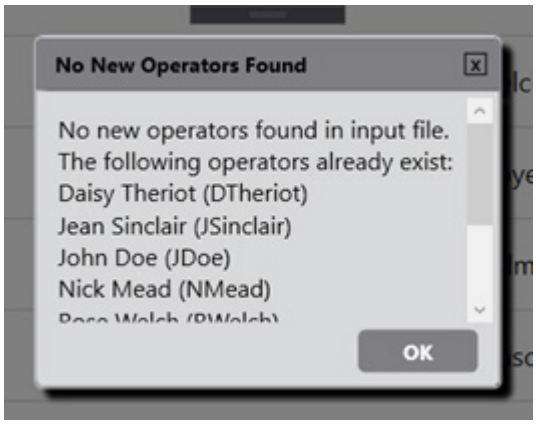
1. In the Operator Management view select the Import Operators button.



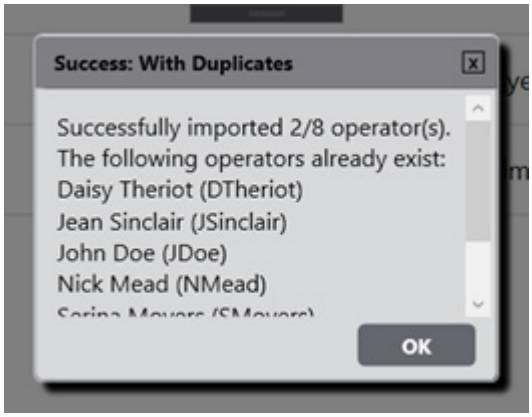
2. Navigate to the desired .fau file(s) location and then click Open to start the import process.
3. Upon completion of the import the Success dialog will display how many operators were imported.



NOTE: The import process will also provide messages when no operators were imported due to duplicates.



NOTE: The import process will also provide messages a partial import occurred due to duplicates.

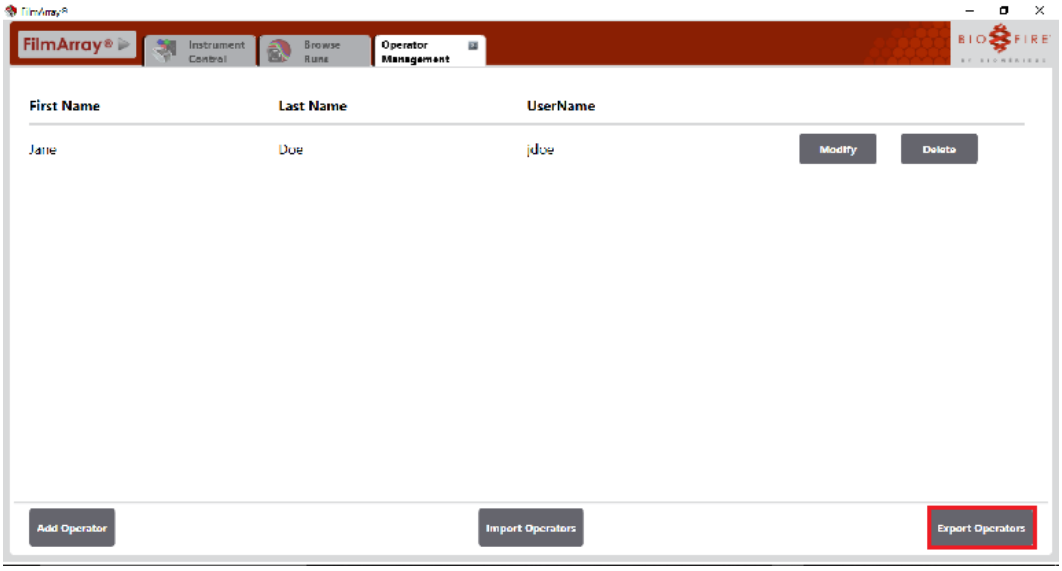


Export Operator(s)

The Export Operator to File option is used to save a copy of one or more operators while leaving the operators in the database. The copy of the operator files can then be imported into the software on a different computer. The exported operator files are saved with the extension .fau.

To export Operators to a file:

1. In the Operator Management view select the Export Operators button.



2. The Create/Select Export File dialog will display. Navigate to the desired location, select a name for the .fau file, and then click Save to start the export process.

Instrument Configuration

The Instrument Configuration window enables the operator to add one to eight instruments to a BioFire 2.0 System and configure them.

NOTE: An instrument must be added to the BioFire 2.0 System before the software can be used to set up and perform runs on that instrument, save runs to the FilmArray database, or view the results.

The figure below shows where each of the following features is located in the Instrument Configuration window.

1. Add an instrument to the system.
2. Rename the instrument.
3. Assign an end-of-run sound that alerts the operator when a run has finished.
4. Verify the correct instrument has been selected before configuration changes are made by clicking the Blink LED button.
5. Remove the instrument from the system.

Add Instruments to System

An instrument can only be added in Instrument Configuration if that instrument is on and connected.

1. If the instrument is not yet connected to the system, connect all cables as indicated in Chapter 2, *BioFire 2.0 Setup*

2. Turn the instrument on. The instrument will connect within 10 seconds.

NOTE: If the instrument is not connecting, see the *Hardware Troubleshooting* section in Chapter 8.

3. Select Tools > Instrument Configuration from the software menu. The Instrument Configuration window opens.
4. Click the Add button from the Instrument Configuration window. The Detected Instruments window opens as shown to the right.
5. Click the Blink LED button to verify the correct instrument is selected.
6. Click the Add button. The Detected Instruments window closes automatically after an instrument is selected. The instrument's icon is now shown in the Instrument Configuration window.
7. Click Save. The Instrument Configuration window will close.

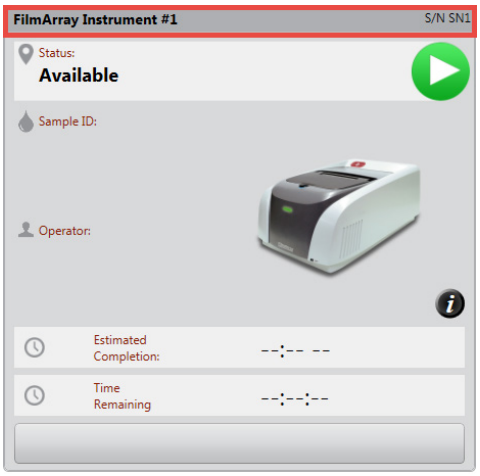
Rename Instrument

The operator can change the name of an instrument when first added in the Instrument Configuration window or any time thereafter.

1. From the software menu, select Tools > Instrument Configuration. The Instrument Configuration window opens.
2. Click in the field next to Name and enter the desired name.

3. Click the Save button at the bottom left of the window.

4. The Instrument Dashboard displays the new name for that instrument.

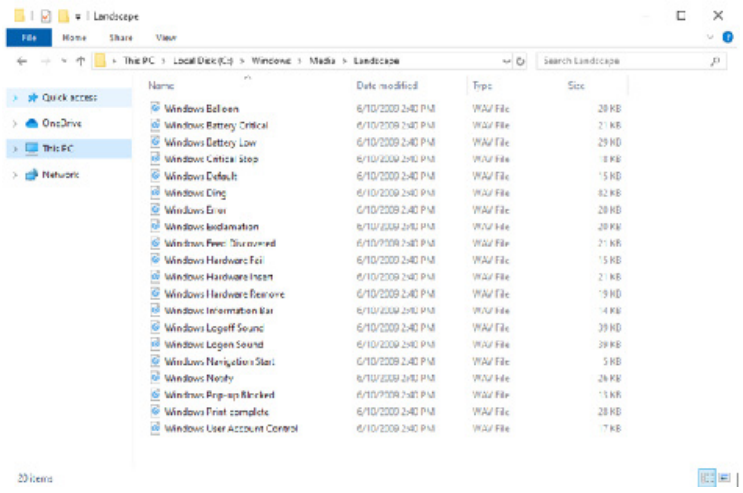


Assign End-of-Run Sound

Each instrument in the BioFire 2.0 System can be assigned a sound to alert the operator when a run has ended. The operator can assign or change an end-of-run sound on any instrument when the instrument is first added in the Instrument Configuration window or any time thereafter. The end-of-run sound may also be muted.

1. From the software menu, select Tools > Instrument Configuration. The Instrument Configuration window then opens.
2. In the End-of-Run Sound field for an instrument that has been added to the system, note the sound file name ending in ".wav".

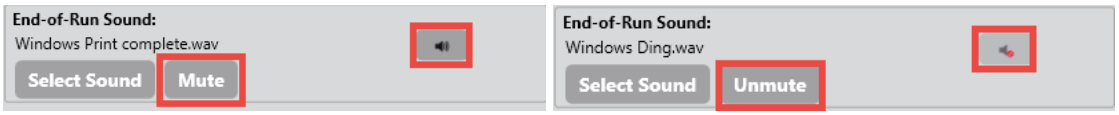
3. To change the sound file, click the Select Sound button. A window opens with a list of options for an end-of-run sound.



4. Choose a sound file and click Open.

5. The selected sound file then displays in the End-of-Run Sound field.

6. To mute an alert at the end of a run, click the Mute button. The button will now be labeled "Unmute." In addition, the speaker symbol located to the right of the Mute button will have a crossed-out red circle next to it.

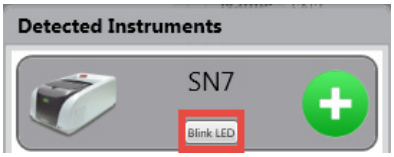


7. To unmute the end-of-run sound, click on the Unmute button. The speaker symbol will now have a sound wave symbol next to it.

8. Click the Save button at the bottom left of the window.

Blink LED

When adding an instrument in the Instrument Configuration window, the Blink LED button in the Detected Instruments window can be used to verify that the correct instrument is being added to the system. Clicking the Blink LED button for the selected instrument makes the status light flash on that instrument.



The operator can arrange the Instrument Configuration window and dashboard to match the physical placement of the instrument in the rack. The Blink LED button for each instrument displayed in the Instrument Configuration window can assist with instrument placement. It can also verify that the correct instrument has been selected before any configuration changes are made to that instrument in the software.

Remove Instrument from Instrument Configuration

Each instrument can be removed from the Instrument Configuration by using the following steps:

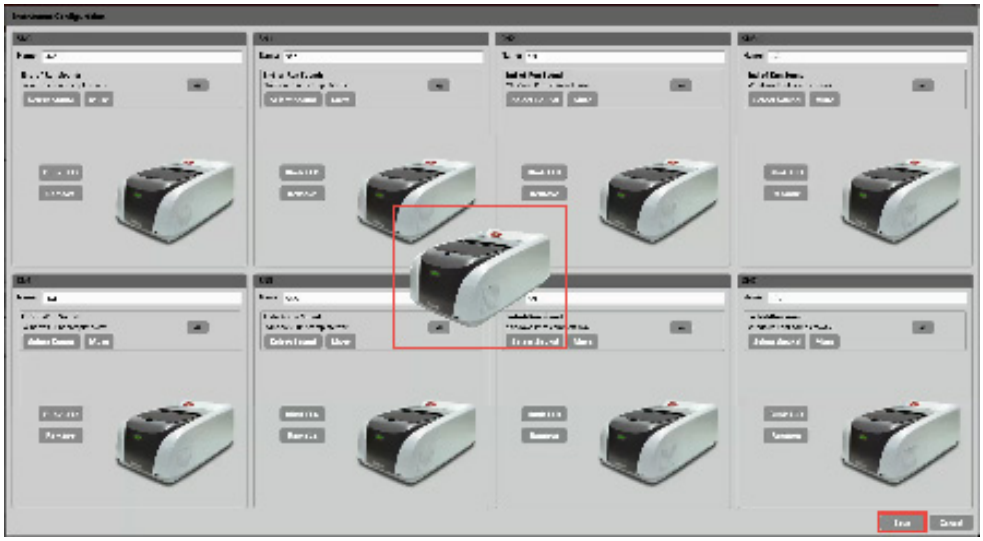
1. From the FilmArray software menu, select Tools > Instrument Configuration. The Instrument Configuration window opens.
2. Find the instrument to remove. Click on the Remove button located next to that instrument. The instrument then disappears from the screen, and a green plus sign will appear in its place.

3. Click the Save button at the bottom left of the window when finished.

Rearrange Instruments in Instrument Configuration

The operator can rearrange the Instrument Configuration and Instrument Dashboard to match to the physical placement of the instrument(s) in the rack.

1. From the software menu, select Tools > Instrument Configuration. The Instrument Configuration window opens.
2. Use the Blink LED button to verify the instrument in the software corresponds to the correct instrument. For more information see the *Blink LED* section in this chapter.
3. To move an instrument that is displayed in the Instrument Configuration window, click anywhere within the box for that instrument and drag it to the new position. The cursor appears as an icon of the instrument when moving instrument positions.



4. Click the Save button at the bottom left of the window when finished.

Instrument Dashboard

The operator will not have access to the Instrument Dashboard until at least one instrument has been added to the software. Once the instrument has been added, the Instrument Dashboard displays automatically. Please see the *Instrument Configuration* section in this chapter for more information about adding a instrument.

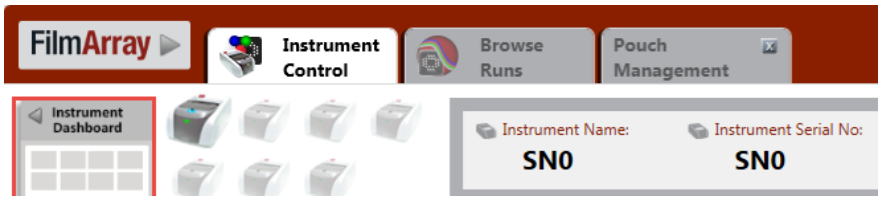
The Instrument Dashboard can display instrument details for one to eight instruments. The details include the following:

1. Instrument name
2. Instrument serial number
3. Instrument status
   - Available
   - Error
   - Disconnected
   - Finished
   - Run stage in progress, showing each stage of the run as it takes place

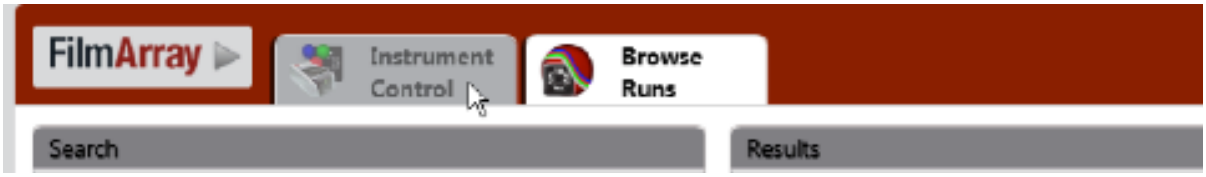
4. Instrument status icon
5. Sample ID
6. Operator name
7. Estimated Completion field shows the end time of the current run
8. Time Remaining field
9. The Instrument Information button, which provides additional details about the instrument and its current status

The figure below shows where each feature is located on the Instrument Dashboard. Information for each instrument is displayed in its own box. The Instrument Control tab appears highlighted when the Instrument Dashboard displays. For information about the Instrument Control tab, please see the *Instrument Control* section in this chapter.

To access the Instrument Dashboard from the main Instrument Control screen, click the Instrument Dashboard button, located in the upper left-hand side of the screen as shown below.



To return to the Instrument Dashboard from the Browse Runs tab, click the Instrument Control tab as shown below.



NOTE: After clicking the Instrument Control tab, either the Instrument Dashboard or the main Instrument Control displays, depending on which feature was last displayed in that tab.

Instrument Control

The main Instrument Control screen helps the operator to set up and perform runs on an instrument, save runs to the FilmArray database, and view the results of runs.

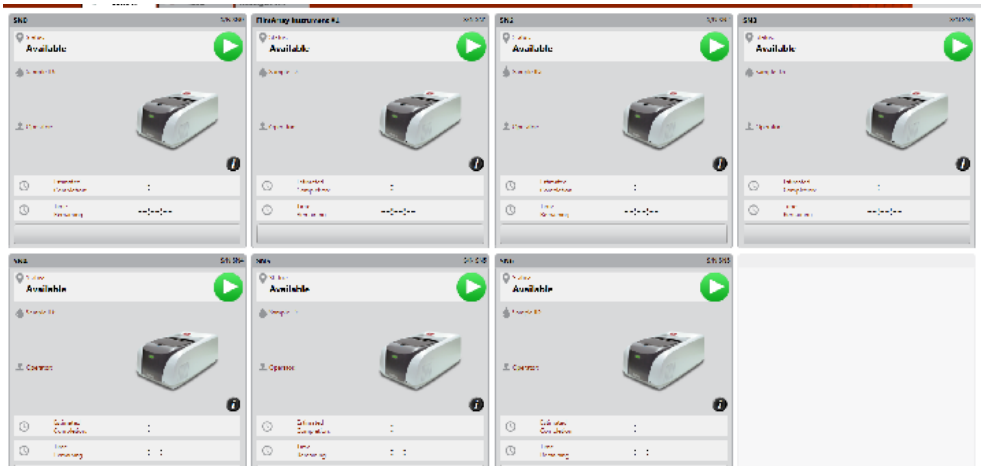
The following table describes each feature and the figure below where each feature is located on the main Instrument Control screen.

Feature	Description	Number in Figure Below
Instrument Dashboard button	Click this button to access the Instrument Dashboard.	1
Instrument icons	There is an instrument icon for each instrument in the BioFire 2.0 System. Click any icon to access Instrument Control for that instrument.	2
Instrument name and serial number	These details are provided for the instrument that is currently selected.	3
Instrument Status	Instrument Control displays the current status of the selected instrument: Disconnected, Available, Running, Finished, or Error.	4
Pouch box	This box contains fields for information to be entered about the pouch, including Lot Number, Serial Number, Pouch Type, Sample ID, and Protocol.	5
Operator box	This box contains the User Name and Password fields to verify the operator of the run. Operator credentials can also be added or modified.	6
Run box	This box contains the Start Run button for a run and displays the estimated completion time for and time remaining in the current run.	7
Next Step box	This box uses text, graphics, and animation to guide the operator through loading a pouch and performing a run.	8

Start Run in Instrument Control

The operator cannot access Instrument Control until at least one instrument in the BioFire 2.0 System has been added to the software using the Instrument Configuration window. Please see the *Instrument Configuration* section in this chapter for more information about adding a instrument.

Once an instrument has been added, the Instrument Control tab appears, and the Instrument Dashboard is displayed



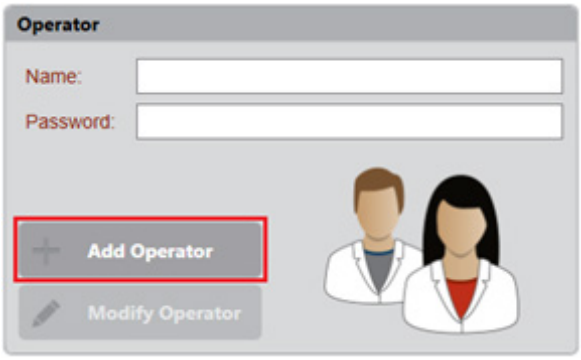
1. Click anywhere in the dashboard box for an instrument that has been configured and the main Instrument Control screen for that instrument will be displayed.
2. Refer to the Next Step box of the main Instrument Control window for step-by-step instructions on how to insert a pouch, to populate the fields correctly in the Pouch and Operator boxes, and to start a run.

Create New Operator(s)

An operator name and password are required to run a pouch on the instrument. The software prompts the operator to enter these credentials after the pouch has been inserted into the instrument and the pouch information has been scanned.

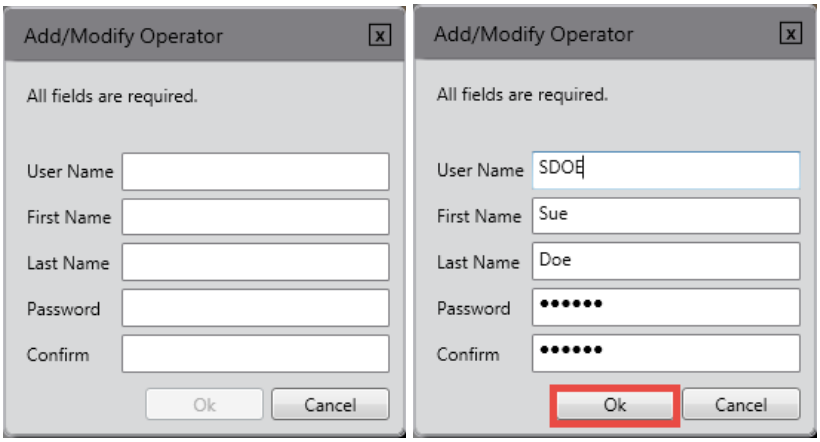
To create a new operator:

1. In the Operator box of the main Instrument Control screen, click the Add Operator button.



2. When the Add/Modify Operator dialog box displays, enter a User Name, the First Name and Last Name of the operator, and a password in both the Password and Confirm fields.

3. Click Ok when complete.

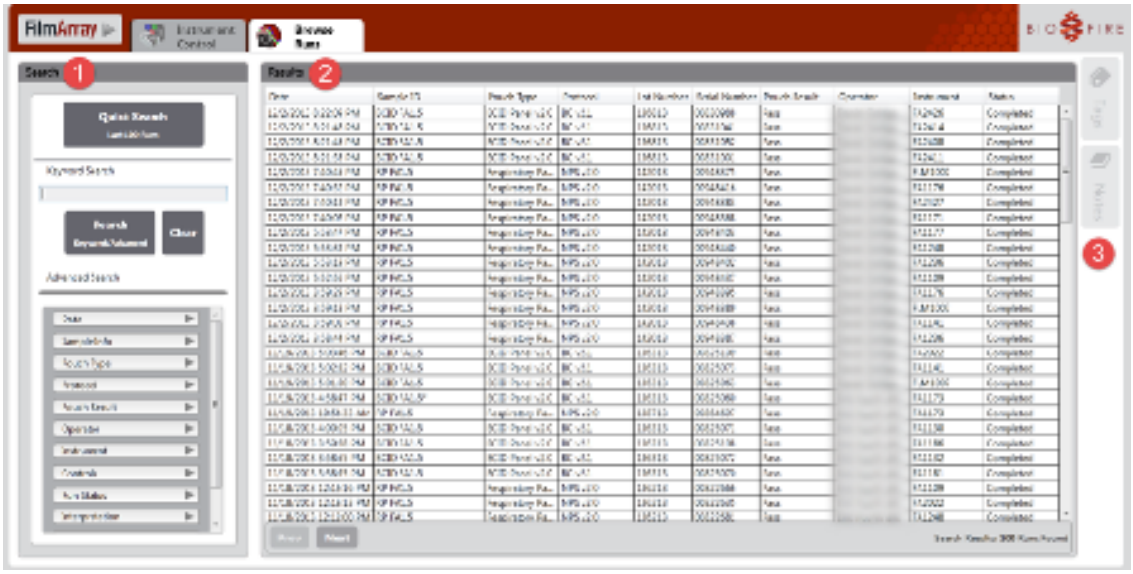


NOTE: The Confirm field displays the password dots in red until the Password and Confirm fields match.

Browse Runs

Browse Runs displays information for all runs stored in the database according to search criteria. It contains the following:

Feature	Description	Number in Figure Below
Search	Searches for runs using a variety of methods.	1
Results	Displays the runs that meet the search criteria.	2
Notes and Tags tabs	Adds notes or tags to a run.	3



Search and View Run Data

The Browse Runs tab displays in the upper left-hand corner of the window. Select this tab to search and view run data.

Quick Search

To quickly search for recent runs, click the Quick Search button located in the Search box. The Results box displays the 100 most recent runs stored in the FilmArray database.

A search can also be performed using a keyword. Type the keyword into the Keyword Search field (beneath the Quick Search button) and click Search. The Results section displays a list of runs that meet the search criteria.

Advanced Search

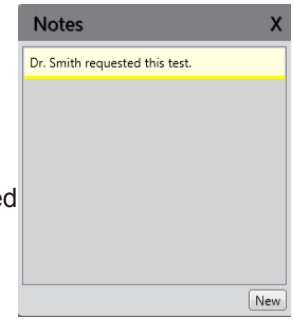
The Advanced Search has multiple menus the operator can use to select search criteria. Selecting multiple search criteria helps to narrow the search for the desired run. The following table describes the search criteria that can be used to locate a desired run.

Criteria	Description
Date	Search by a date range for the desired run(s).
Sample Info	Search by pouch lot number, serial number, or sample ID.
Pouch Type	Place a check mark next to the specific panel of interest.
Protocol	Place a check mark next to the protocol of interest.
Pouch Result	Place a check mark next to the pouch outcome of interest: Pass, Fail or Invalid.
Operator	Place a check mark next to the operator of interest.
Instrument	Place a check mark next to the instrument of interest.
Controls	Search by results of specific controls.
Run Status	Search by run status: Completed, Incomplete, Aborted, Instrument Error, or Software Error.
Interpretation	Search by the specific organism detected.
Assay	Search by the specific assay detected.
Tags	Search by tags designed to organize groups of data.

Viewing All Runs

To view all runs saved in the database, remove all Advanced Search selections and click the Search button. The total number of runs saved in the database is displayed at the bottom of the Results table.

Notes and Tags



Information can be added to a run using notes or tags. Notes can be viewed on a run-by-run basis. Runs with the same or multiple tags can be retrieved using the Advanced Search options (see previous section).

Notes Tab

The Notes tab is located on the right-hand side of the screen. This tab is used for longer notations about a selected run. To enter a notation:

1. Select a run in the Browse Runs tab.
2. Click on the Notes tab on the right side of the window.
3. Click on the New button to display the Notes dialog box.
4. Enter the note and click Save. This note will now be associated with the selected run and cannot be edited or removed. The notes are only visible in the Browse Runs tab. These do not appear on a report.

Tags Tab

Tags are short notations that identify a particular event or situation with a run. This feature can be used to identify a specific group of related runs. To create custom tags:

1. Select one or more runs in the Browse Runs tab.
2. Click on the Tags tab on the right side of the window.
3. The Unselected section lists all tags that are currently in the database. The Selected section lists all tags that are currently selected for the run(s) that are highlighted.
4. In the field at the top of the Tags window, enter in the text for the new (or desired) tag. The new tag will be added to the list of tags under Unselected. Place a check mark next to the tag in the Unselected section to assign the tag to the run. The tag appears in the Selected section and are visible in the Browse Runs tab. These do not appear on a report.
5. To remove the tag from a run, remove the check mark next to the tag in the Selected section.

NOTE: If the tag is removed and is no longer applied to any runs in the database, it will be removed from the database and will no longer be displayed as an option in the Unselected section of the Tags tab.

Browse Runs Context Menu

The Browse Runs context menu presents a list of actions the operator can take on runs. These actions are presented in the table that follows.

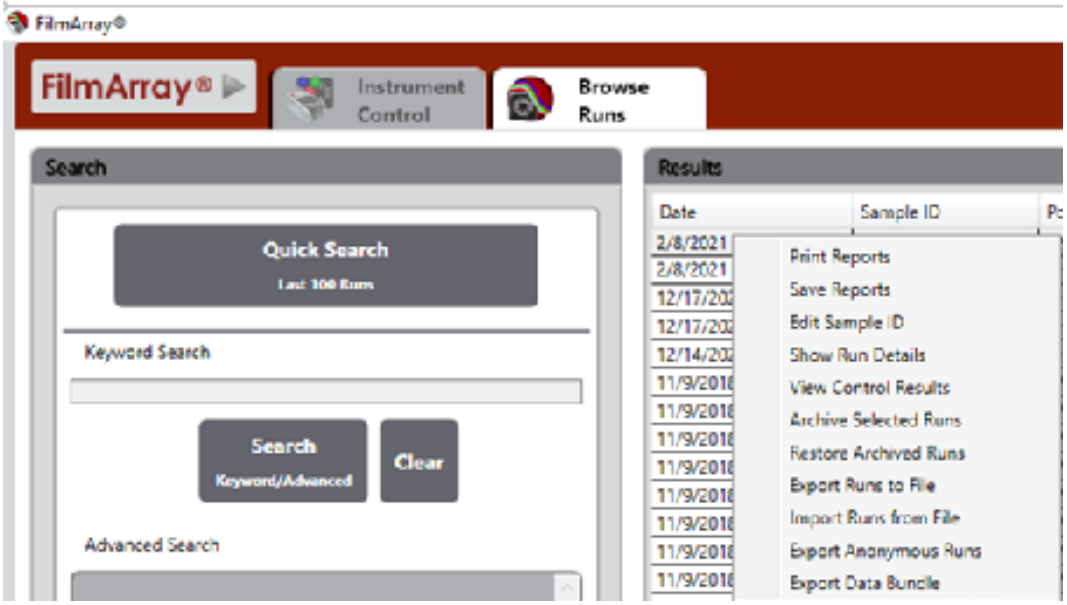
Menu Item	Description
Print Reports	Use this feature to print a report(s) of the results associated with the applicable run.

Menu Item	Description
Save Reports	Selecting this option opens a Windows file navigator dialog that enables the operator to save the entire report(s) to the chosen location.
Edit Sample ID	If a mistake occurs when entering the sample ID during run setup, this feature enables the operator to make the necessary corrections. A history is recorded of all changes. This Change History helps laboratories meet electronic signature and records requirements.
Show Run Details	With this feature the operator can view system details, messages, and errors associated with a particular run.
View Control Results	This feature allows the operator to view control data for runs. The data in the table can be exported into a .csv file to external media and imported into a different application, such as Microsoft Excel.
Archive Selected Runs	The FilmArray database reliably stores up to 8,000 runs. Should this number be exceeded, this feature can be used to remove run files from the database and store the data in a separate location. For more information on archiving runs, see the *Database Management* section in this chapter.
Restore Archived Runs	With this feature the operator can restore runs to the database that were previously removed from the database and stored in a separate location. For more information on restoring archived runs, see the *Database Management* section in this chapter.
Export Runs to File	This feature enables the operator to write runs to a file while leaving the original runs in the FilmArray database. The copied runs can then be imported into the software on a different computer. For more information on exporting runs to a file, see the *Database Management* section in this chapter.
Import Runs from File	This feature enables the operator to import FilmArray runs from another FilmArray database into the database on the computer being used. For more information on importing runs from a file, see the *Database Management* section in this chapter.
Export Anonymous Runs	This feature works like the Export Runs to File option, but also replaces the Sample ID in the run files with the text "Anonymous." If a copy of the database files must be sent to an external site, then this option should be used to protect patient confidentiality. For example, this option is appropriate if a run error occurs and a technical support representative requests that a copy of the run file be sent to BioFire Diagnostics for investigation. For more information on exporting anonymous runs, see the *Database Management* section in this chapter.

Menu Item	Description
Export Data Bundle	If an error occurs that is associated with a run, a technical support representative may request that the operator create a data bundle for that run and send it to BioFire Diagnostics. The data bundle is designed to assist in troubleshooting errors associated with a run. It packages files related to the state of the user's system, instrument, and software, including System Log data. For more information on creating a data bundle, see the *Data Bundle* section in Chapter 8.

Follow these steps to access items in the Browse Runs context menu:

1. In the Browse Runs tab, highlight one or more desired runs.
2. Right-click the highlighted runs to open the Browse Runs context menu.



NOTE: The operator can select the options Edit Sample ID and Export Data Bundle only if a single run has been selected. All other options apply to both single and multiple runs.

3. Select the appropriate menu item and follow the directions in the dialog box or tab that opens.

NOTE: Import Runs from File and Restore Archived Runs are the only menu items that are independent of the selected runs: The operator can click on a run or runs to access these options, but the particular run(s) selected are immaterial.

Any tables accessed using the menu can be sorted by clicking on the column headers. The column width can be resized by dragging the column header boundaries to the desired size.

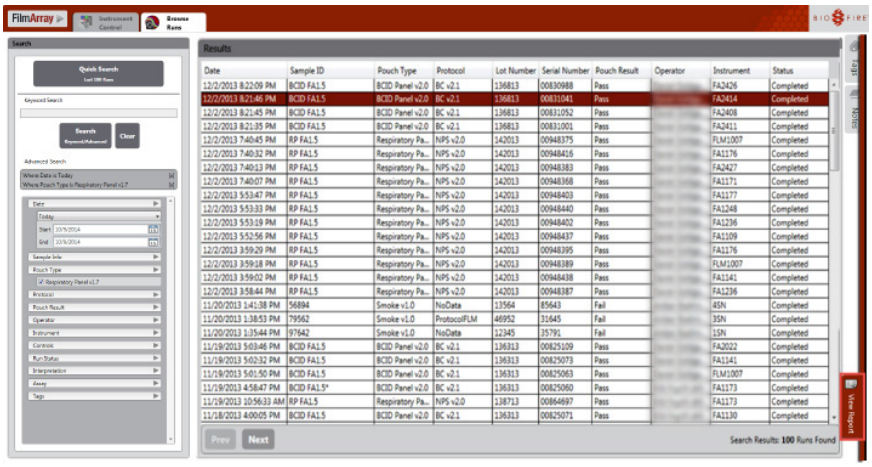
View Report Tab

When the instrument completes a run, the software generates a report with the run results.

The operator can view the report using the View Report tab that is displayed at the end of the run. If the operator is on the main Instrument Control screen for that instrument when the run ends, this tab automatically displays the report over the Instrument Control screen.

If the operator is not on that screen when the report ends, it is possible to return to the main Instrument Control screen for that instrument and click the View Report tab to access the report.

The View Report tab is also displayed whenever a run is highlighted in the Results table in Browse Runs.



NOTE: The View Report tab is not an option when more than one run is highlighted in the Results table. It is only visible when a single run is selected.

The report can be saved locally as a PDF or printed.

To print reports use either of the following:

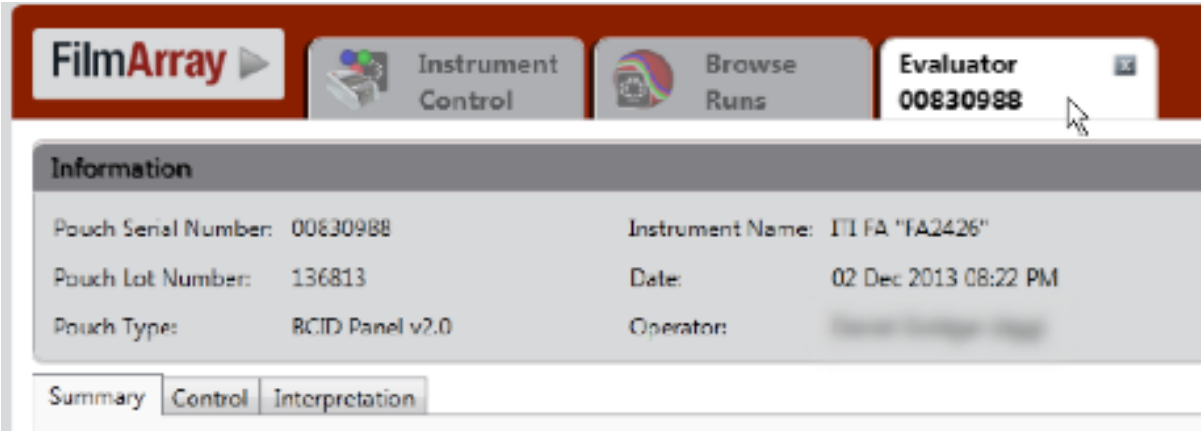
- Print a single report—use the Print Reports option in the Browse Runs context menu. For more information, see the *Browse Runs Context Menu* section in this chapter. A report can also be printed from the View Report tab.
- Set all reports to auto print—use the Auto Print Report option in the software menu. Select Preferences > Auto Print Report.

To close the report, click the View Report tab.

Evaluator

The Evaluator enables the operator to view melting curve analysis results for each control and pathogen assay in a run. It is only used to evaluate the test results and cannot be used to operate the instrument or perform a run.

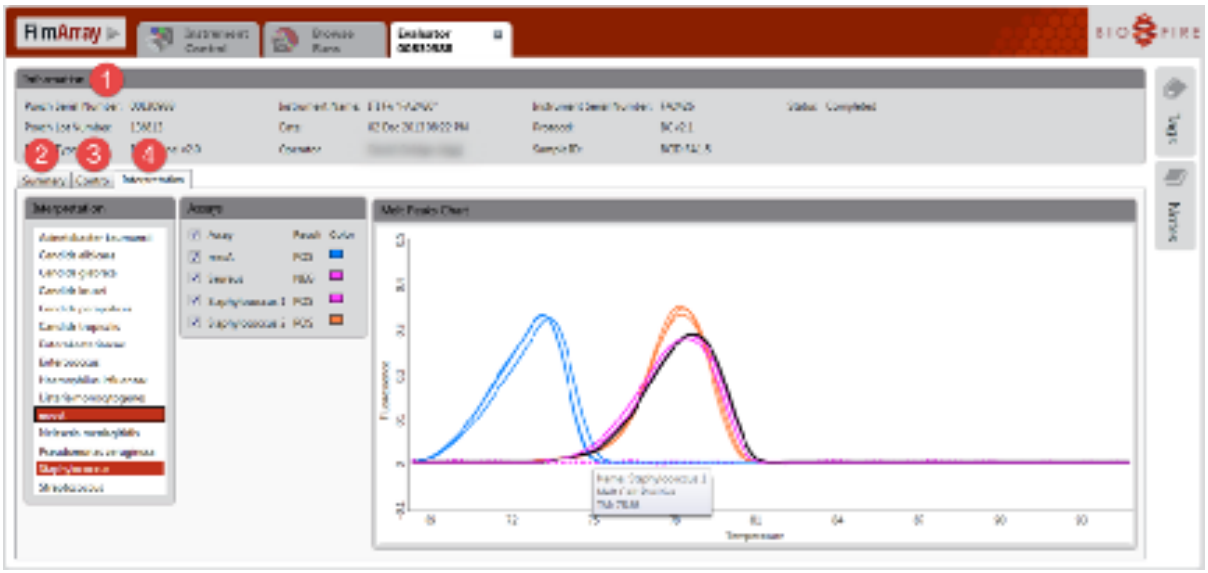
The Evaluator is accessed from the Browse Runs tab. When an individual run has been selected and opened from Browse Runs, a new, run-specific tab appears and is identified by the Pouch Serial Number.



Multiple run-specific windows can be open at the same time. Each window contains the features listed in the table below. The table also shows where each feature is located on the screen.

Feature	Description	Number in Figure Below
Information bar	This section of the screen summarizes information about the run in the following fields: Pouch Serial Number, Pouch Lot Number, Pouch Type, Instrument Name, Date, Operator, Protocol, Sample ID, and Status.	1
Summary tab	This tab shows the pouch status, the organisms that were positive in the run, and whether the controls passed or failed. If there is a positive interpretation or a failed control, the operator can double-click on the text to display the curves.	2
Control tab	This tab shows each control used in the run and whether it passed. To view melt curve data for a control, select the control name from the list in the Control section. The selected control's curve will be displayed in the graph, and information regarding the control will display in the Assays box.	3

Feature	Description	Number in Figure Below
Interpretation tab	To view information and the curves for each interpretation, click on the individual organism. The Interpretation tab displays each of the organisms tested in the BioFire® Pouch. To view melt curve data in the Melt Peaks Chart box for an organism: 1. Select the organism interpretation from the list in the Interpretation tab. The selected curves will be displayed in the Melt Peaks Chart box, and information for the assays used for the interpretation will be displayed in the Assays box. 2. Additional information about the individual curve is displayed in the Tool Tip when the cursor is placed on top of the curve.	4



View Melting Curve Analysis Results

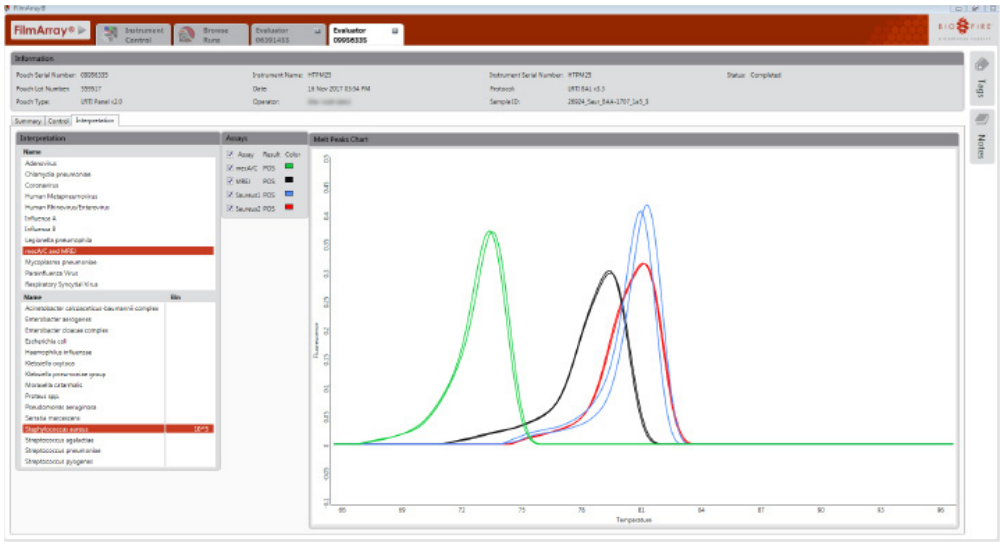
To access run-specific Evaluator tabs: In the Browse Runs tab, double-click the desired run in the Results table. The tab for that run will open.

For information on using the Summary, Control and Interpretation tabs associated with the Evaluator, see the *Evaluator* section in this chapter.

Interpretations with Bins

The Interpretations with Bins tab will only display under the Interpretation window for semi-quantitative panels.

All positive assay results are selectable and will be displayed in the Melt Peaks Chart box.



NOTE: Melt curves will not be shown for negative assays.

Database Management

A local database on the computer stores all of the run data generated by the BioFire 2.0 System. The runs saved in the FilmArray database are listed in the Results table in the Browse Runs tab. For more information on the function and use of the Browse Runs tab, see the *Browse Runs* section in this chapter.

The database reliably stores up to 8,000 runs. If this number is approached, use the Archive Selected Runs feature in the Browse Runs context menu to remove run files from the database and store the data in a separate location. Information follows on archiving runs.

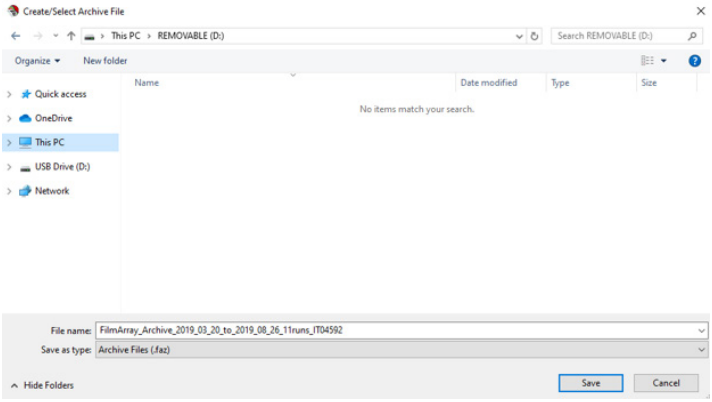
When the number of runs in the database nears capacity, the following Database Capacity Warning message is displayed, "The FilmArray database is nearing capacity. Please use the Archive Selected Runs option to remove runs from the database and store them according to your data retention policy. Please Contact FilmArray Customer Support if you require assistance." This prompts the operator to archive runs from the database.

NOTE: All files that are archived or exported cannot be imported/restored to a FilmArray computer that has a previous software version.

Archive Runs

To archive runs stored in the FilmArray database:

1. In the Browse Runs tab, highlight one or more desired runs. Use the Quick Search, Keyword Search or Advanced Search options to search for particular runs to archive. For more information, see the *Search and View Run Data* section in this chapter.
2. Right-click the highlighted runs to open the Browse Runs context menu.
3. Select the menu item Archive Selected Runs. The Create/Select Archive File dialog is displayed.



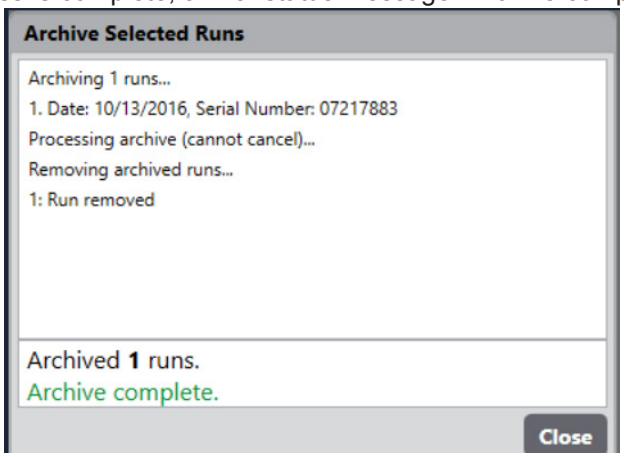
4. Navigate to the desired location, select a name for the file, and then click Save. As the figure illustrates, the selected runs are saved by default to a file with the extension .faz and with a name containing the first and last dates for the set of runs being archived as well as the name of the computer being used to perform the archive.
5. The software prompts the operator to verify removal of the selected runs from the database. Click Yes to continue, or No to cancel the archive process.
6. The software verifies that all runs have been saved to the file, and then deletes each run from the database one at a time. A progress dialog will display during the archive.

NOTE: It is recommended that runs be archived in batches of no more than 500.

Archiving 500 runs will take approximately one hour to complete.

NOTE: It is recommended that runs be archived monthly.

7. When the process is complete, a final status message "Archive complete" is displayed.

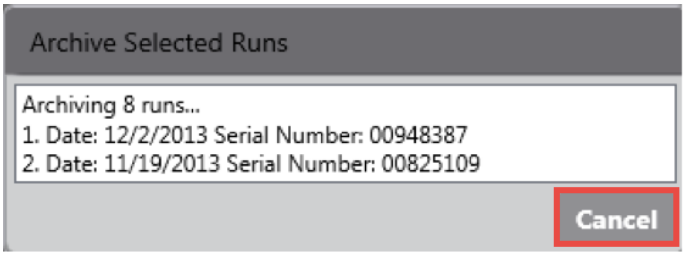


8. Click Close to close the dialog box.
9. The .faz file can be transferred from the computer using a portable media device and stored according to institutional data retention policies.

Abort Archive Process

It is safe to abort the archive process during the first step, while the runs are being saved. The Archive Selected Runs dialog displays the message "Archiving <n> runs …" and lists each run as it is saved individually to the file. To abort the process during this time:

1. Click the dialog's Cancel button.



2. The dialog will display the following message, "User cancelled. No archive created."
3. Close the dialog and all the runs will still be in the database.

NOTE: It is not safe to abort the archiving process during the second step, while runs are being removed from the database. During this time, the software will not allow the operator to cancel the process.

CAUTION: Do not attempt to shut down the computer during the archiving process. Wait until the process is complete before shutting down the computer or performing other tasks.

Restore Runs

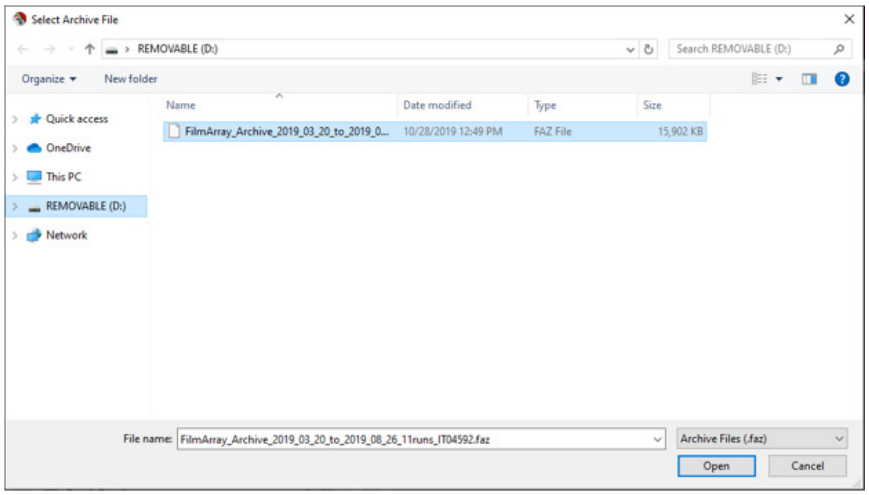
If a run file must be accessed after it has been removed from the database, the runs stored in the .faz file can be restored to the FilmArray database by using the Restore Archived Runs option in the Browse Runs context menu.

Prior to restoring runs to the database, verify that there is sufficient room in the FilmArray database for the runs. If approaching 8,000 runs in the database, remove some of the runs by using the Archive Selected Runs menu option. See the Archive Runs section in this chapter for more information.

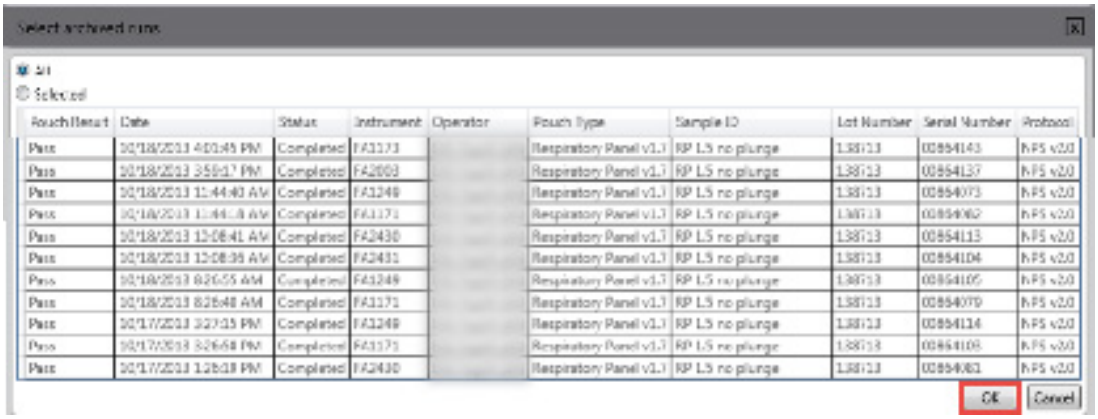
To restore archived runs to the database:

1. In the Browse Runs tab, highlight a run, right-click the highlighted run to open the Browse Runs context menu, and then select the menu item Restore Archived Runs. The Select Archive File dialog is displayed.

NOTE: Restore Archived Runs is one of two Browse Runs context menu options that are independent of the selected runs: The operator can click on a run or runs to access this option, but the particular run(s) selected are immaterial.



2. Navigate to the desired .faz file(s) and click Open.
3. The Select archived runs dialog is displayed. Select the files to restore by clicking All or selecting files individually.



4. Click OK to start the restore process. A progress dialog will display during the restore. When the process is complete, a final status message will be displayed.

NOTE: The operator can cancel the restore process before it completes by clicking the Cancel button in the bottom-right corner of the dialog. Any runs that were restored to the database before clicking Cancel will remain in the database, but any runs not yet restored are not processed.

5. Whether the operator allows the process to complete or clicks Cancel, it is necessary to click the Close button, when it appears, to close the dialog.

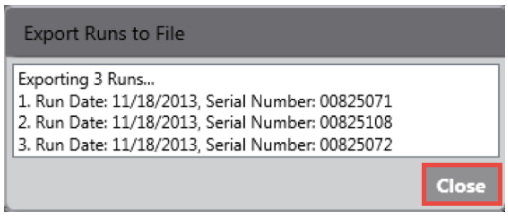
Export Runs

The Export Runs to File option is used to save a copy of one or more database run files while leaving the run files in the database. The copy of the database files can then be imported into the software on a different computer. The exported database files are saved with the extension .db. To export runs to a file:

1. In the Browse Runs tab, highlight one or more desired runs. Use the Quick Search, Keyword Search, or Advanced Search options to search for particular runs to archive. (For more information, see the *Search and View Run Data* section in this chapter.)
2. Right-click the highlighted runs to open the Browse Runs context menu.
3. Select the menu item Export Runs to File. The Create/Select Export File dialog will display. Navigate to the desired location, select a name for the .db file, and then click Save to start the export process.
4. During the export process, the Export Runs to File dialog will display the run date and the serial number of the runs being exported.

NOTE: The operator can cancel the export process before it completes by clicking the Cancel button in the bottom-right corner of the dialog. Any runs that were exported before clicking Cancel will be saved to the chosen location, but any runs not yet exported are not processed.

5. Whether the operator allows the process to complete or clicks Cancel, it is necessary to click the Close button, when it appears, to close the dialog.



Import Runs

This feature enables the operator to import runs from another FilmArray database onto the computer being used.

To import runs from a file:

1. In the Browse Runs tab, right-click a highlighted run to open the Browse Runs context menu, and then select menu item Import Runs from File. The Select Database dialog will display.

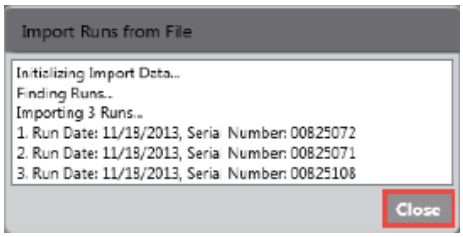
NOTE: Import Runs from File is one of two Browse Runs context menu options that are independent of the selected runs: The operator can click on a run or runs to access this option, but the particular run(s) selected are immaterial.

2. Navigate to the desired .db file(s) location and then click Open to start the import process.

3. During the import process, the Import Runs from File dialog will display the run date and the serial number of the runs being imported.

NOTE: The operator can cancel the import process before it completes by clicking the Cancel button in the bottom-right corner of the dialog. Any runs that were imported before clicking Cancel will remain in the database, but any runs not yet imported are not processed.

4. Whether the operator allows the process to complete or clicks Cancel, it is necessary to click the Close button, when it appears, to close the dialog.



Export Anonymous Runs

The Export Anonymous Runs option works like the Export Runs to File, but also replaces the Sample ID in the run files with the text "Anonymous". If a copy of the database files must be sent to an external site—for example, if a run error occurs, and a technical support representative requests that a copy of the run file be sent to BioFire Diagnostics for investigation—this option should be used to protect patient confidentiality. The exported, anonymized database files are saved with extension .adb.

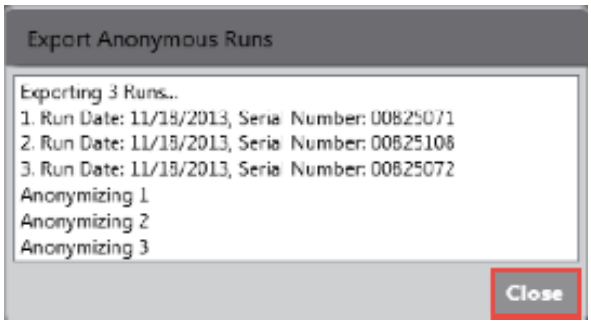
NOTE: To prevent operators from overwriting a run file with an anonymized run file, the anonymized database files cannot be imported back into the software.

To export anonymous runs to a file:

1. In the Browse Runs tab, highlight one or more desired runs. Use the Quick Search, Keyword Search, or Advanced Search options to search for particular runs to archive. For more information, see the *Search and View Run Data* section in this chapter.
2. Right-click the highlighted runs to open the Browse Runs context menu.
3. Select the menu item Export Anonymous Runs. The Create/Select Export File dialog is displayed.
4. Navigate to the desired location, select a name for the .adb file, and then click Save to start the export process.
5. During the export process, the Export Anonymous Runs dialog displays the run date and the serial number of the runs being exported.

NOTE: The operator can cancel the export process before it completes by clicking the Cancel button in the bottom-right corner of the dialog. Any runs that were exported before clicking Cancel will be saved to the chosen location, but any runs not yet exported are not processed.

6. Whether the operator allows the process to complete or clicks Cancel, it is necessary to click the Close button, when it appears, to close the dialog.



System Administrator Tasks (Windows)

System Administrator tasks are specific to the Windows application. Please see Microsoft help for instructions on adding and deleting printers and changing the date and time. For further assistance, please contact technical support (see page i).

NOTE: Do not perform administrative tasks on the computer—including setting the computer's date/time—while a run is in progress on the instrument.

Performing administrative tasks requires an admin password. The BioFire 2.0 is preconfigured with an administrative user account. The Windows user name is "LabAdmin" and the default password is "Lab_Admin". It is recommended that local IT personnel change the default password for the LabAdmin user account. Do not delete or modify the groups associated with the Lab Admin user account.

CHAPTER 7: PRECAUTIONS WHEN WORKING WITH THE BIOFIRE 2.0 SYSTEM

Laboratory Safety and Biohazards

General Safety Precautions

Please note that while the BioFire® Pouches and the instruments are not themselves biohazardous, it is good laboratory practice to handle all waste materials as potentially biohazardous material.

a. Follow all safety instructions printed on, or attached to, the instrument.

b. Observe all general safety precautions that apply to electrical instruments.

c. Never touch switches or power cords with wet hands.

d. Do not open the housing of the instrument or computer.

CAUTION: Use caution when closing the instrument lid to avoid pinching fingers.

NOTE: Only authorized service personnel should perform service or repairs required for this unit.

Laboratory Precautions

Handle all samples and waste materials as if they were capable of transmitting infectious agents. Refer to Biosafety in Microbiological and Biomedical Laboratories (Centers for Disease Control and Prevention and National Institutes of Health; available online or other appropriate Biosafety procedures.

Observe safety guidelines found in the Clinical and Laboratory Standards Institute (CLSI) Protection of Laboratory Workers from Occupationally Acquired Infections, Approved Guideline M29 or other appropriate safety guidelines.

Wear personal protective equipment (PPE) and disposable powder-free gloves while handling reagents or samples and change gloves often. Wash hands thoroughly after performing a run.

Refer to the instruction booklet for assay-specific safety precautions.

CAUTION: Use caution when removing pouches from the instrument; a tear in the pouch could contaminate the instrument and the surrounding area. Carefully dispose of pouches in a biohazard waste container.

General PCR Precautions

One of the most important guidelines when performing PCR is to avoid contamination. Some important rules to follow are:

a. Perform sample collection, pouch preparation, and running the instrument in separate locations.

b. Load the pouch with sample behind a protective shield (or in a biological safety cabinet or hood whenever possible).

c. Do not leave a laboratory area without first completing decontamination procedures (i.e., washing and changing protective clothing and gloves).

Decontamination and Cleaning Procedures

The decontamination and cleaning procedures listed are intended to limit spread of contaminants as a result of a broken or leaked pouch. Decontamination is necessary to prevent false-positive results in subsequent runs.

If a pouch leaks or breaks, change gloves and other potentially contaminated personal protective equipment (PPE). Change gloves often during the decontamination process, especially during the first steps of decontamination and before touching any clean surface. All PPE should be disposed of after decontamination.

CAUTION: It is important that contamination from leaking and/or punctured pouches be contained and cleaned immediately. Pouches that break after PCR can contain large quantities of contaminants. This material, although noninfectious, is easily spread by normal human activity. Consequently, very small (molecular) quantities can be amplified by PCR in future runs, which can then be identified as positive by the instrument. Treat all broken pouches as capable of contaminating the work area.

BIOLOGICAL RISKS: If the pouch contains potentially-infectious material, the risk of biohazard contamination exists in addition to sample contamination.

Cleaning Materials

This list provides items that are necessary to have in a laboratory to keep contamination to a minimum.

- 10% bleach solution in a squeeze or spray bottle (1 part bleach to 9 parts water)
- Distilled water in a squeeze or spray bottle
- DNAZap™ or equivalent DNA degrading system
- Paper towels
- Bleach wipes

BioFire® Pouch Loading Station Decontamination

Routine cleaning of the Pouch Loading Station requires a 10% bleach wipe followed by two water wipes before each new pouch is loaded.

In the event of a sample spill or pouch leak, perform the following decontamination procedures.

1. Put on clean PPE, such as a lab coat and gloves.
2. Fill a sink or bin with water and add bleach to create a 10% bleach solution.
3. Submerge the Pouch Loading Station until completely covered with bleach solution. Soak for 15 minutes.
4. Remove the Pouch Loading Station from sink or bin. Replace bleach solution with distilled water.
5. Rinse the Pouch Loading Station by completely submerging in distilled water two additional times.

Contact BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor to obtain a replacement Pouch Loading Station, if necessary.

Decontamination Related to Pouch Leakage

If a pouch leaks, take the following precautions to avoid contamination:

1. Put on clean PPE, such as a lab coat and gloves.
2. Ensure no one uses the instrument or potentially-contaminated areas until the decontamination is complete.
3. Decontaminate the instrument and work area and dispose of the pouch using the following steps:
    a. Dispose of potentially-contaminated gloves and put on clean gloves.
    b. Dispose of the potentially-contaminated lab coat and put on a clean lab coat.
    c. Discard leaking pouch in a biohazard container.
    d. Change gloves.
    e. Clean the instrument and affected work areas following the guidelines below.

CAUTION: Use only 10% bleach solution, distilled water, and/or DNAZap to decontaminate the instrument and Pouch Loading Station.

Instrument Decontamination

Pouch Loading Chamber Decontamination

1. Put on clean PPE, such as a lab coat and gloves.
2. Remove pouch from the instrument and discard in biohazard waste container.

3. Wet a paper towel with 10% bleach (one part bleach to nine parts water) and wipe the inner chamber and under the lid. Change gloves.
4. Repeat Step 3 twice with fresh paper towels for a total of three bleach wipes.
5. Wet a paper towel with distilled water and wipe the inner chamber.
6. Repeat Step 5 with fresh gloves and paper towel.

Instrument Exterior Decontamination

1. Put on clean PPE, such as a lab coat and gloves.
2. Wet a paper towel with the 10% bleach solution and wipe all exterior surfaces of the instrument, including the bottom and the bench top where the instrument had contact. Change gloves.
3. Repeat Step 2 twice with fresh paper towels and clean gloves, for a total of three bleach wipes.
4. Change gloves, then wet a new paper towel with distilled water and wipe the surfaces of the inner chamber, including under the lid, and the entire exterior of the instrument, including the bottom and the benchtop where the instrument had contact.
5. Repeat Step 4, with fresh gloves and paper towel.

Decontamination of Bench Tops and Other Areas

1. Put on clean PPE, such as a lab coat and gloves.
2. Spray the 10% bleach solution on the area that may have been contaminated. Let it stand for at least three minutes to allow the bleach solution to react with any contaminants on the surface.
3. Wipe the area with a clean paper towel. Change gloves.
4. Repeat Steps 2 and 3 twice, for a total of three wipes.
5. Change gloves. Spray the area with distilled water.
6. Wipe the area dry with a new paper towel. Change gloves.
7. Spray the area with DNAZap or an equivalent product. Follow the product's instructions for correct use. Change gloves.
8. Rinse the area by spraying it with distilled water and wiping it dry.

Check Function of Decontaminated Instrument

1. Test a negative sample by preparing a pouch according to instructions in Chapter 5, using water as the sample. Use distilled, sterile or molecular grade water for this test.
2. If the run is successful and all results are negative, continue using the instrument as normal.
3. If unexpected positive results are obtained, or the run fails, please contact BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor for further instructions.

CHAPTER 8: PREVENTATIVE MAINTENANCE AND TROUBLESHOOTING

Introduction

This chapter provides step-by-step instructions for operators for performing basic maintenance and troubleshooting for the instrument.

The tasks performed in this chapter are the only tasks that should be performed by the operator. Do not attempt to perform any additional maintenance without the guidance and direction of a specialist from BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor.

NOTE: Instruments should not be disposed of as waste for any reason.

In the event that an instrument is taken out of service, it should be returned following the *Instrument Return Procedure* in Appendix A.

CAUTION: Before performing maintenance on the BioFire 2.0, put on appropriate PPE, turn off the power to the instrument, and unplug the Ethernet and power cables.

General Maintenance

There is no general maintenance needed for the instrument other than the periodic cleaning steps listed below:

1. Wipe down the surface of the instrument, including the inner chamber, with a cloth or paper towel and a freshly prepared 10% bleach solution (one part bleach to nine parts water), followed by a water wipe.
2. Use a lens cloth and lens cleaner to clean the lens of the barcode reader.
3. The BioFire® Pouch Loading Station should be wiped down between runs and decontaminated daily or whenever a pouch leak occurs (see *Decontamination and Cleaning Procedures* in Chapter 7).

Software Weekly Maintenance

It is recommended to shut down and restart the computer on a weekly basis. Prior to shutting down the computer, close the software by selecting Exit from the software menu or clicking the Close button in the upper right-hand corner of the window.

It is recommended to perform monthly archives. Archives run in the background and do not limit the ability to perform runs while in progress.

NOTE: A database warning message will appear when archives are not performed regularly. See Error Messages.

Error Reporting Tools

The instrument performs self-diagnostics with every run. Malfunctions are reported as errors to the operator with instructions on how to correct them. Record any error messages to assist in troubleshooting. Questions should be directed to BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor.

Troubleshooting

Hardware Troubleshooting

The table below lists potential symptoms and possible solutions for troubleshooting hardware issues with the BioFire 2.0 System. If the issue(s) persists after applying the recommended solutions, contact technical support for further assistance (see page i).

Make note all error messages, as well as the instrument serial number, and any necessary pouch lot numbers before contacting technical support. Technical support personnel will use this information to identify and resolve the issue(s).

Symptom	Possible Solution
Instrument status lights are not on	• Turn instrument on • Check power cord • Try different outlet • If problem persists, contact technical support
Instrument status light is blinking red	• Turn instrument off • Check and reconnect cables • Turn instrument on • If problem persists, contact technical support
Instrument status light is blinking purple	• Remove and discard the pouch • Turn instrument off and back on • If problem persists, contact technical support

Symptom	Possible Solution
Software will not connect to instrument	• Verify instrument is on • Check cable connections • Turn off instrument and disconnect all cables • Reconnect all cables and turn instrument on • Shut down and restart computer • If problem persists, contact technical support
Pouch not recognized when inserted into or removed from instrument	• Turn instrument off and back on • Shut down and restart computer • If problem persists, contact technical support
Instrument lid close/open position not recognized by software	• Turn instrument off • Check and reconnect cables • Turn instrument on • If problem persists, contact technical support
Pouch is difficult to insert into instrument	• Push instrument lid all the way back • If problem persists, contact technical support
Pouch is difficult to remove from instrument after run	• Push instrument lid all the way back • Turn instrument off and gently try removing pouch • If problem persists, contact technical support
Instrument lid remains unlocked during run	• Firmly press the lid down • If problem persists, contact technical support
Instrument lid remains locked after a run has ended	• Firmly press the lid down then try re-opening • Power instrument off and try re-opening lid • If problem persists, contact technical support
Pouch does not remain firmly in place after insertion	• Contact technical support
Instrument will not run	• Verify that the pouch has been inserted into the instrument correctly • Verify that all required information has been entered into the software and click Start Run • If problem persists, contact technical support

Barcode Reader

The barcode reader is included with the BioFire 2.0 System as an accessory. It is pre-programmed to read the pouch barcodes. Pouch information may be entered manually in the event the barcode scanner is not working.

If the issue persists after applying the recommended solution shown in the table below, contact technical support for further assistance (see page i).

Symptom	Possible Solution
Barcode will not scan	• Place the cursor in the Lot Number field of the Pouch box and try scanning • Clean the barcode reader screen • Check that the barcode reader is plugged in. If it still does not scan, see Appendix C: *Barcode Calibration* • Manually input the pouch serial number and lot number

Diagnostic Errors

Diagnostic errors are used mainly by technical support representatives to troubleshoot instrument problems. Diagnostic errors can be found in the System Log. See the *System Log* section in this chapter for details on accessing this information.

The table below lists potential error messages and possible solutions. If the error(s) persists after applying the recommended solutions, contact technical support for further assistance (see page i).

Take note all error messages and numbers, as well as the instrument serial number, and any necessary pouch lot numbers before contacting technical support. Technical support personnel will use this information to identify and resolve the error(s).

Error Message	Possible Solution
1011 Lid not Closed	• Turn instrument off and back on • If problem persists, contact technical support
1012 Pouch Not Present	
1013 Failed To Store Run Data	
1014 Failed to Find Run Data	
1015 Failed to Read Run Data	
1016 Failed to Erase Run Data	
1034 ImageInterface command failure	
2003 Thermoboard is not present in the instrument	
2004 Valve board is not present in the instrument	
3001 Valve Board Response Timeout	
3002 Valve Board Malformed Response	
3003 Valve Board Command Error Response	• Turn instrument off and back on • If problem persists, contact technical support
3004 Thermocycler Board Response Timeout	
3005 Thermocycler Board Malformed Response	
3006 Thermocycler Board Command Error Response	
4001 Pressurization failed	
6001 Seal Seq Failed	
6002 Seal Bar Command Error Response	
7001 Camera Initialization Error	
7002 Failed To Find Mask	
7003 Failed Excitation Check	

Software Troubleshooting

Error Messages

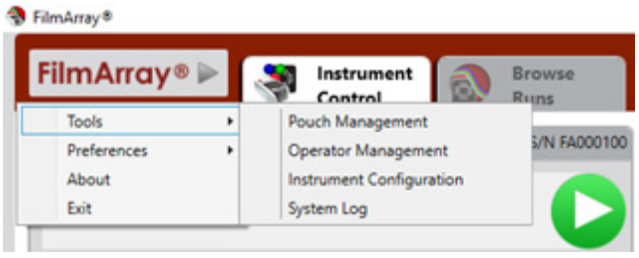
Errors in the BioFire 2.0 System may originate in the instrument, in the software, or in communication between the two. In each case, the software reports a clear message with instructions that the operator can follow to resolve the issue. These messages and the suggested actions are reported in the table that follows.

Error Message	Possible Solution
Pouch serial number has already been used.	Verify the correct pouch has been loaded into the instrument. Discard any pouch that has already been run in an instrument.
The lid needs to be open and a pouch loaded in order to scan.	Open the lid and scan the pouch that is loaded in the instrument.
The module for the scanned pouch is not installed. Please install the module.	Verify the correct pouch module is installed and the correct barcode has been scanned for the pouch.
Too many instruments with Lids Open and Pouches Inserted. Please remove the pouches or close the lids of all FilmArray instruments indicated.	Remove the pouch(s) or close the instrument lid(s) indicated in the Next Step box of the main Instrument Configuration window.
The Run Setup window is in progress. To exit Run Setup, remove the pouch. NOTE: All entered data will be lost.	Remove the pouch to exit Run Setup, or complete the run before attempting other actions using the software.
The FilmArray database is nearing capacity. Please use the Archive Selected Runs option to remove runs from the database and store them according to your data retention policy. Please contact FilmArray Customer Support if you require assistance.	The FilmArray database stores up to 8,000 runs reliably. Should this number be approached, use the Archive Selected Runs feature in the Browse Runs context menu to remove run files from the database and store the data in a separate location. Contact Technical Support if the problem persists.
The FilmArray instrument is in an error state. Power down the instrument, wait 10 seconds, power it back on and try again. Please see the System Log for details. If the problem persists, contact FilmArray Customer Support for assistance.	Follow the error message as directed. Contact technical support if the problem persists.
The FilmArray instrument encountered an error during the run. The test results are invalid. Please see the System Log for details. If the problem persists, contact FilmArray Customer Support for assistance.	Discard the pouch and follow the error message as directed. This message should be accompanied by a flashing blue light on the instrument. This light indicates that the test is complete and the lid on the instrument can now be opened and the pouch removed. Removing the pouch clears all the fields on the screen and prepares the instrument for another test. Contact technical support if the problem persists.

Error Message	Possible Solution
The FilmArray instrument <SerialNumber> encountered an unexpected error. Please see the System Log for details. If the problem persists, contact FilmArray Customer Support for assistance.	Follow the error message as directed. Contact technical support if the problem persists.
The FilmArray software encountered an unexpected error. Please see the System Log for details. If the problem persists, contact FilmArray Customer Support for assistance.	
Run data was retrieved but cannot be analyzed because the <pouch type> pouch module was not installed in the software. For assistance, please contact FilmArray Customer Support.	
Data not associated with a test has been recovered from the FilmArray instrument <SerialNumber>. Please see the System Log for details. For assistance, contact FilmArray Customer Support.	
System restart warning message. When instruments have not been reset a System Warning message will display the following: The FilmArray computer has not been restarted for <n> days. Please restart the computer soon.	Hit OK to close down the message. Restart the computer.

System Log

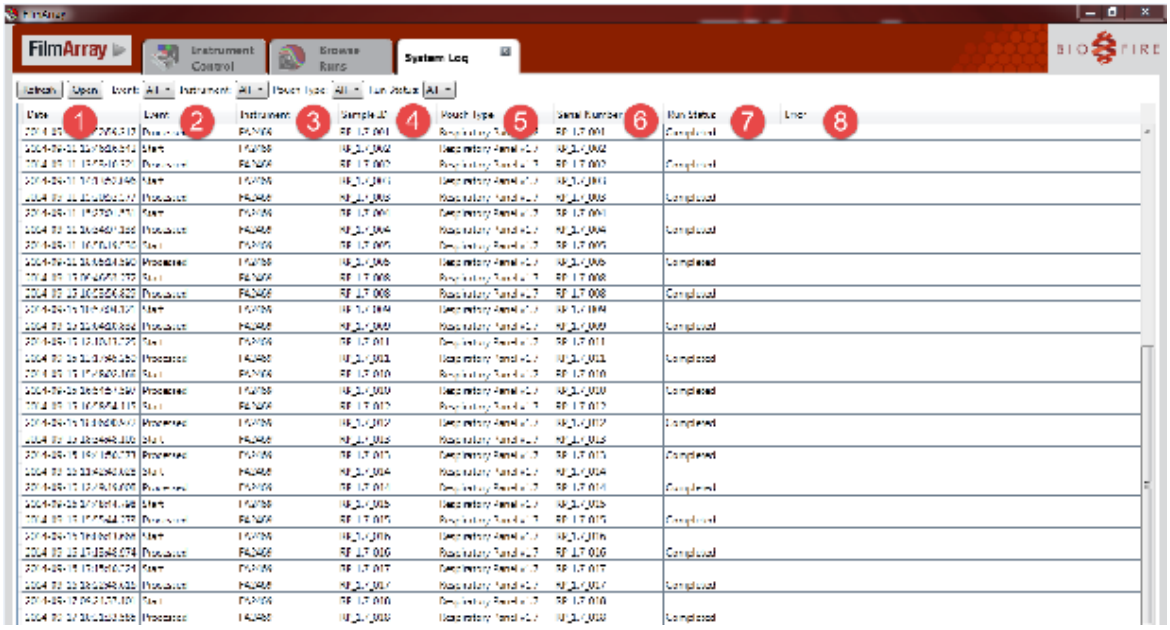
Depending on the error, the software may refer to the System Log for details about the errors. The System Log is accessed via the software menu, as shown below.



When the System Log is opened, a table is presented that displays the following information as shown in the figure below.

1. Date the log was created

2. Type of log event (run start, run processed, or in this case, error)
3. Instrument serial number
4. Sample ID
5. Pouch type
6. Pouch serial number
7. Run status
8. Error encountered



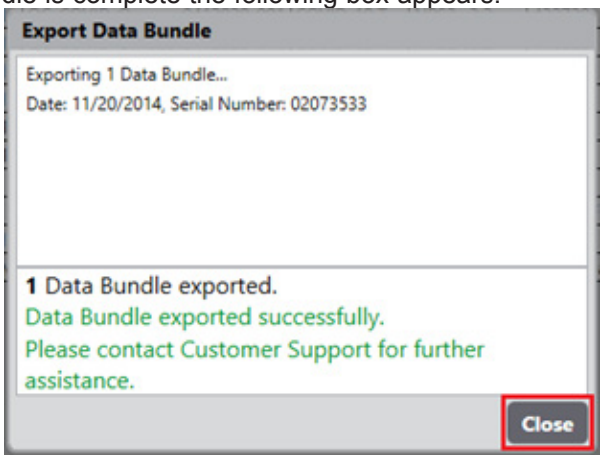
The System Log file has a maximum allowable size. When that size is reached, the System Log file is automatically saved, and a new one is started. To view older System Log files that have been saved, click the Open button and choose the desired System Log file from the list.

Data Bundle

If an error occurs that is associated with a run, a technical support representative may request the operator to create and provide a data bundle for that run. The data bundle is designed to assist in troubleshooting errors associated with a run. It packages files related to the status of the system, instrument, and software; including System Log data.

To create a data bundle:

1. Highlight the desired run in the Browse Runs tab.
2. Right-click the highlighted run to open the Browse Runs context menu.
3. Select the menu item Create Data Bundle. The Browse for Folder window opens.
4. Select an existing folder to store the zipped file in, or create a new one. The software saves the file to the desired folder.
5. When the data bundle is complete the following box appears.



Pouch Troubleshooting

For problems encountered while using a BioFire® Pouch, see the possible solutions below. If pouch leakage occurs, refer to Chapter 7 for proper decontamination procedures.

Problem	Possible Error Cause	Solution
Pouch packaging is not sealed tightly around pouch canister	Loss of vacuum in pouch packaging	Attempt to hydrate. If pouch hydration is successful, continue the run. Otherwise, discard the pouch and use a new pouch to test the sample.
Pouch does not automatically draw Hydration Solution or sample mix into pouch when loading	Loss of vacuum in pouch	Discard the pouch and use a new pouch to test the sample.
Failed controls	Hydration Solution not added or drawn into pouch	Retest sample in a new pouch.
	Sample mix not added or drawn into pouch	Retest sample in a new pouch.
	Pouch and/or instrument are not functioning properly	Retest sample in a new pouch.
		If controls continue to fail contact technical support.
Inadequate volume in Hydration Solution or Sample Buffer vials/ampoules	Evaporation or leakage	Discard vials/ampoules and obtain new ones.

CHAPTER 9: BIOFIRE SYSTEM CYBERSECURITY

The BioFire 2.0 may be run as a standalone device or in a networked environment. Networking is restricted to approved configurations such as sending test results from the BioFire 2.0 to a laboratory information system (LIS) or allowing BioFire or an authorized distributor to securely connect to the BioFire System through the internet.

The BioFire 2.0 has been developed and configured to incorporate cybersecurity controls. Cybersecurity controls are applied to the computer operating system, which is delivered pre-configured on the BioFire 2.0. Prior to delivery, BioFire Diagnostics verifies that the computer is free of malicious software.

The BioFire 2.0 is operated using a Windows operating system user account that does not have administrative privileges. Configuration changes require administrative privileges using an administrative Windows user pre-configured on the computer. Only modify the software configuration parameters you are authorized to modify and which are described in the user documentation.

Medical device security is a shared responsibility among stakeholders, including health care facilities, patients, health care providers, and manufacturers of medical devices. It is your responsibility to secure your network and ensure this protection is appropriate and maintained. It is recommended to use all appropriate means to protect your network from virus intrusion, unauthorized use, alteration, manipulation, and disclosure.

The introduction of malicious software to the BioFire 2.0 may result in loss of functionality and/or compromised data. In an effort to maintain integrity of the BioFire 2.0 System:

- Do not use personal computer media (e.g., CDs, DVDs, USB devices).
- Use computer media that have been scanned and are free of malicious software.
- Use caution when transferring computer media between computers.
- Do not download or install any software other than software provided or recommended by BioFire Diagnostics.

For additional information about supported network configurations and cybersecurity risk management (including patch management, antivirus software installation, software updates), please contact BioFire Diagnostics Customer Technical Support.

APPENDIX A: BIOFIRE 2.0 SUPPORT INFORMATION

Instrument problems may be reported by contacting BioFire Diagnostics Customer Support, the local bioMérieux sales representative, or an authorized distributor.

Instrument Return Procedure

If returning an instrument from within the United States, visit the Return Forms and Decontamination Procedures webpage:

- http://www.biofiredx.com/support/return-forms/

If returning an instrument from outside the United States, contact the local bioMérieux sales representative or an authorized distributor for detailed instructions.

Disposal Recommendation

Components of the BioFire 2.0 such as the BioFire 2.0 instrument, the computer, monitor, keyboard, etc. which are marked with the crossed-out wheeled bin symbol are covered by the European Directive 2012/19/EU.

These items must be disposed of via designated collection facilities appointed by government or local authorities.

For more information about disposal of your old product, please contact your city office or waste disposal service; or BioFire Diagnostics Customer Support Department, a local bioMérieux sales representative, or an authorized distributor.

Ordering Instructions

Customers inside the United States should contact BioFire Diagnostics to order any BioFire 2.0 equipment, accessories, and/or supplies.

BioFire Diagnostics accepts purchase orders and credit cards (Visa®, MasterCard®, and American Express®) as methods of payment.

Orders can be made via:

- E-mail: salesorders@biofiredx.com
- Fax: 801-588-0507
- Phone: 800-735-6544 or 801-736-6354
  - Payment is by credit card only for phone orders.

If ordering from outside the United States, contact the local bioMérieux sales representative or an authorized distributor for detailed instructions.

Warranty Information

Product warranty information is available online at:

- http://www.biofiredx.com/support/

For warranty information for customers outside the United States, contact the local bioMérieux sales representative or an authorized distributor.

APPENDIX B: BARCODE CALIBRATION

If the barcode reader is not functioning, calibrate it by following the steps below:

1. Plug in the barcode reader and wait for the start-up sound.
2. Scan the barcodes sequentially to program the barcode reader. The reader sounds as codes are scanned.
3. If a code is skipped during calibration, begin with the first code and scan all codes again sequentially (the first code resets previous entries).

a.

Set All Defaults

b.

Low Volume

c.

Erase All Rules

d.

Begin New Rule

e.

Send Control [

f.

Send All Data That Remains

g.

Send Control]

h.

Save Rule

i.

Quit Entering Rules

For additional information regarding our products and applications, please contact BioFire Diagnostics Customer Support Department, local bioMérieux sales representative or an authorized distributor.