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REF HTFA-ASY-0102
HTFA-SUB-0103
HTFA-ASY-0104

BioFire® FilmArray® Torch

Operator's Manual

For *In Vitro* Diagnostic Use

BIOFIRE®
BY BIOMÉRIEUX

IVD

UK CA CE

This document is used solely for the purpose of BioFire Torch operation.

Always maintain the BioFire Torch in good working order. If the device 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® Torch Operator's Manual IVD HTFA-PRT-0001-08 June 2023

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® Torch Operator's Manual	http://www.biofiredx.com/e-labeling/ITI0066/
BioFire® FilmArray® Torch Information Quick Guide	http://www.biofiredx.com/e-labeling/ITI0077/
BioFire® FilmArray® Torch Software	http://www.biofiredx.com/e-labeling/ITITORCH64/

Customer and Technical Support

Customer and Technical Support for U.S. Customers

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Customer and Technical Support Outside of the U.S.

Contact the local bioMérieux sales representative or an authorized distributor for Customer 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 BioFire Torch Modules, the System Base, the Duplex(es), the BioFire® FilmArray® 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	5.3.4 	Keep Dry
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		**UK Medical Devices Regulation 2002**			
	Pollution Control - China RoHS	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 BioFire Torch system software. o Additional of Intended Purpose, Intended User, and Use Environment section o The Republic of China standard to GB/T 26572-2011 National Standard of People's Republic of China o Date of Manufacture symbol • 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 Updates to Chapter 9 Cybersecurity to clarify the shared responsibility of medical device security. • Removal of: o Information regarding references to the BioFire Torch information CD.	March 2020
06	• Additions of: o Importer symbol and address o Operator Management section o Melt Curve Viewing section o Map Network Drive section o Weekly Maintenance section o Second barcode to the calibration appendix to accomodate the updated Torch scanner • 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 Browse Run Options menu updated o Minor update to Cybersecurity for LIS connectivity 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	• Additions of: o UKCA Symbol and address • Update of: o China RoHS Symbol o All images of instrument removing branding o Rebranded images to remove BioFire branding o EC updated to EU on EU Rep symbol o IVDD requirement updated to IVDR in symbols glossary o Images of cables updated with new images • 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. o Display dimensions and resolution from Performance Specifications table.	January 2022
08	• Updates to the following: o Torch Module installation steps 8, 9, and 10 moved to be directly after step 5 in chapter 2. o Edits to System Base Shutdown in chapter 8 to power base before powering the modules and installing cable shrouds.	June 2023

CHAPTER 1: BIOFIRE TORCH

BioFire Torch Intended Purpose

Intended Use

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

The BioFire Torch is a modification of BioFire® FilmArray® 2.0 and is composed of one to twelve BioFire Torch Modules connected to a BioFire Torch System Base running BioFire Torch Software. The BioFire Torch System Base houses up to two BioFire Torch Modules. Up to five BioFire Torch Duplex Module enclosures, each capable of housing up to two additional BioFire Torch Modules, may be added on top of the BioFire Torch System Base. Each BioFire Torch Module can be randomly and independently accessed to run a reagent pouch. The BioFire Torch software controls the function of each BioFire Torch Module and collects, analyzes, and stores data generated by each BioFire Torch Module

Intended User and Use Environment.

The BioFire Torch 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 Torch is intended to be used in combination with BioFire® Panels that have been FDA cleared for use on the BioFire Torch.
- For prescription use only.
- Do not remove the BioFire Torch Module(s) front cover during a run.
- Use only the supplied cables when connecting any BioFire Torch Module to the BioFire Torch System Base.
- Do not use cable extenders to increase cable length.
- Do not modify the computer parameters unless you 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 connections.
- Do not remove the default Windows user accounts.
- Do not change screensaver settings on the System Base.
- Do not modify the BioFire Torch Software database or other pre-installed (open source) software.
- Do not adjust system settings (such as date/time) while BioFire Torch Modules are running.
- Do not re-run a pouch associated with an error, incomplete run, or invalid result.
- Only authorized service personnel should perform repairs on the BioFire Torch.

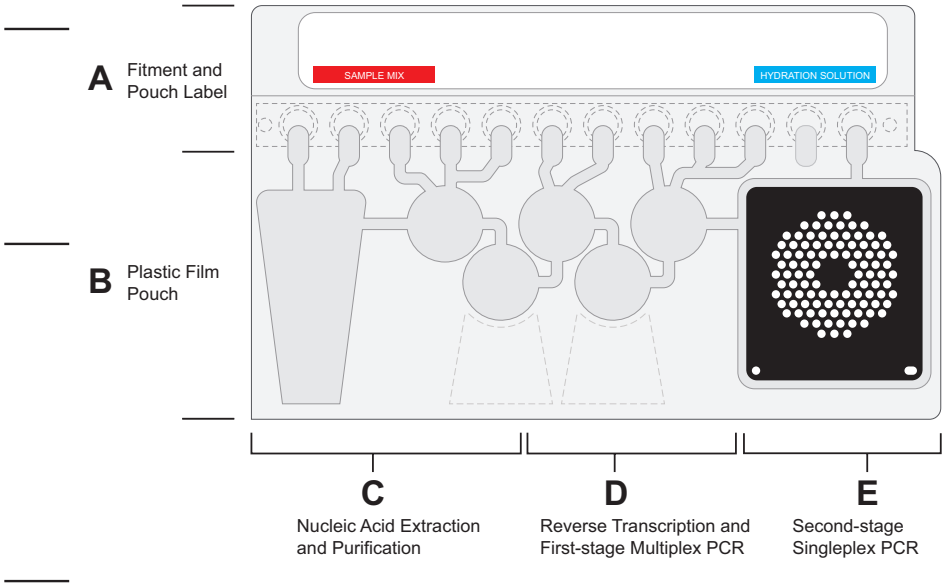
BioFire® Pouch

Each BioFire Pouch is a self-contained, closed-system disposable packet 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 BioFire Torch Module, are where the following chemical processes are performed:

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

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

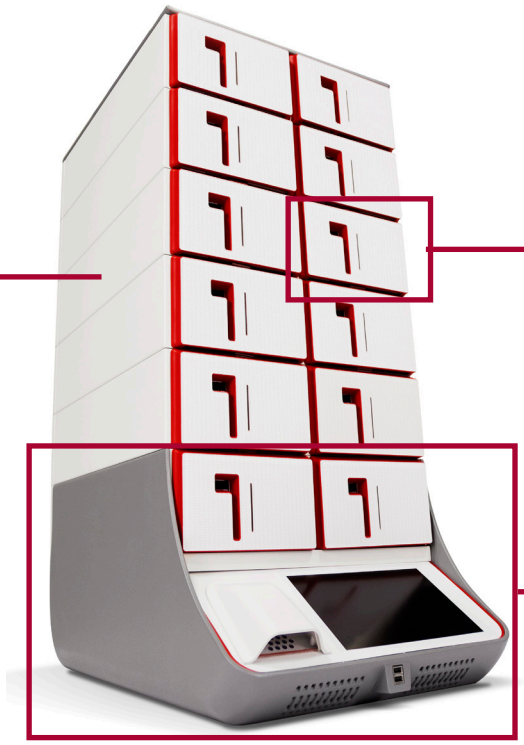
(E) Second-stage singleplex PCR and melting analysis within a multi-well array



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 BioFire Torch Module and chemical processes have been demonstrated.

BioFire Torch

Major components and operations of the BioFire Torch are described below. A full list of components can be found in *Chapter 2* and specific step-by-step operating instructions can be found in *Chapter 5*.



BioFire Torch Duplex
Module enclosure; houses up to two BioFire Torch Modules

BioFire Torch Module
Interacts with the reagent pouch to purify and amplify targeted nucleic acid sequences using nmPCR; includes pouch slot and LED status light

BioFire Torch System Base
Includes barcode scanner, touch screen, and USB ports

BioFire® Pouch Modules

Each reagent pouch requires a pouch-specific software called a pouch module to be installed on the BioFire Torch in order to perform a test. These pouch modules contain definitions, protocols, analysis and reporting for specific BioFire® Reagent Kits. See the *Pouch Modules* section in *Chapter 6* for more information.

BioFire Pouch Preparation

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

BioFire Torch Runs

The BioFire Torch is used in combination with BioFire® Pouches to perform tests, also known as runs, that detect multiple nucleic acid targets contained in clinical specimens. The BioFire Torch interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nmPCR in a closed system.

The BioFire Torch Software includes a detailed workflow that guides the operator on how to perform a run. Once a pouch has been prepared for testing, on-screen instructions prompt the operator to enter pouch and sample information, insert the pouch into an available Torch Module and start the run. For more information on starting a BioFire Torch run, see *Chapter 5.*

BioFire Torch Module 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 BioFire Torch Module controls these functions automatically based on the pouch module run protocol selected for a specific pouch and sample type in the BioFire Torch 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. These reactions take 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 System Base, 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 BioFire Torch Module is aligned, focused, and calibrated at the factory. Proper operation and calibration of BioFire Torch Module optics is monitored by the BioFire Torch Module self-tests and internal pouch controls.

BioFire Torch Software

The BioFire Torch Software manages and controls the operation of each BioFire Torch Module. The software also collects, stores, and analyzes data generated by the BioFire Torch Module. Results of analyses are presented in a test report. A brief overview of major software components are described below. For more detailed information about the features and operation of the BioFire Torch Software, see *Chapter 6, BioFire Torch Software*.

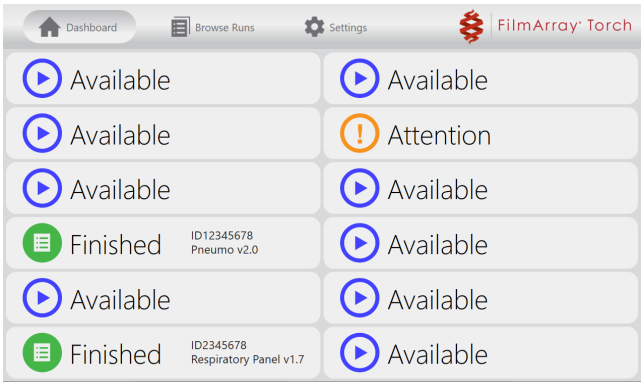
Toolbar

The toolbar always displays at the top of the screen and consists of three options:

- Dashboard
- Browse Runs
- Settings

Dashboard

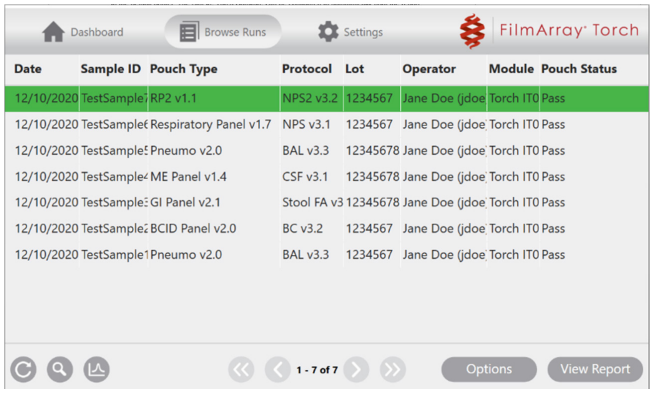
Displays the status of each BioFire Torch Module within the BioFire Torch and guides the operator through the process of operating the Modules.



NOTE: The Dashboard display may be different dependent upon the number of Modules configured.

Browse Runs

Allows operators to search for runs and perform operations on individual runs or on groups of runs.



Settings

Allows users to perform administrative type tasks, such as managing operators (adding and updating), view system logs, etc.

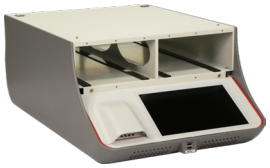
CHAPTER 2: BIOFIRE TORCH COMPONENTS AND SETUP

BioFire Torch Components

Each BioFire Torch comes with a BioFire Torch System Base, one or more BioFire Torch Modules, and accessories. Optional Duplexes are available to house additional Modules (up to 12 total). The BioFire Torch ships in a minimum of two boxes; one System Base box, one to twelve Module boxes (one box per Module), and up to five Duplex boxes (one for every two Modules after the first two Modules).

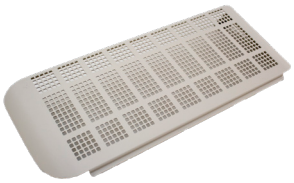
BioFire Torch System Base Box Contents

NOTE: The BioFire Torch System Base comes pre-loaded with the BioFire Torch Software



BioFire Torch System Base

Top Cover



System Base Cable Shroud

Pouch Loading Station

EU Power Cable

US Power Cable

Ethernet Cable

BioFire Torch Module Box Contents

BioFire Torch Module

Module Front Cover

Filter

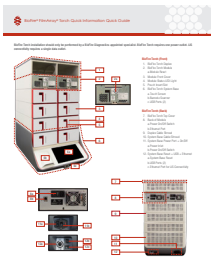
Long Ethernet Cable

Long Power Cable

Spare Filters (2x)

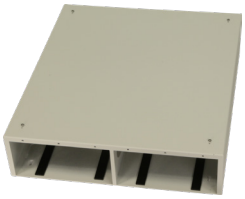
Short Ethernet Cable

Short Power Cable



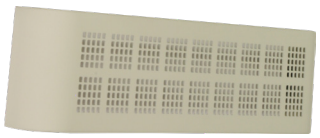
Information Quick Guide

BioFire Duplex Box Contents (Optional)



BioFire Torch Duplex

BioFire® Pouch Loading Station



Duplex Cable Shroud

NOTE: Duplexes ship separately in their own boxes.

Setup Requirements

Select a clean, well-ventilated area that is large enough to fit the BioFire Torch.

- There must be at least 1 inch (2.6 cm) between the rear panels and any other surface (such as the wall) to allow for proper air flow.
- The depth of the bench-top space should be at least 30 in (77 cm).
- The width of the bench-top space should be at least 19 in (49 cm).
- The height of the space required depends on the number of Modules installed:
  - System Base – 11.5 in (30 cm)
  - System Base + 1 Duplex – 16 in (41 cm)
  - System Base + 2 Duplexes – 20.5 in (53 cm)
  - System Base + 3 Duplexes – 25 in (64 cm)
  - System Base + 4 Duplexes – 29.5 in (75 cm)
  - System Base + 5 Duplexes – 34 in (87 cm)

NOTE: One Duplex holds up to two BioFire Torch Modules.

- Minimum Power Specifications:

Configuration	Voltage	Frequency	AC Power at 120V		AC Power at 240V*	
			Active	Apparent	Active	Apparent
Minimum (Single Module)	100-240VAC	50-60Hz	130W	135VA	110W	190VA
Maximum (12 Modules)			850W	935VA	775W	1100VA

*Grounded outlet required

NOTE: BioFire Torch requires one dedicated circuit. A single IEEE 802.1x Ethernet 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 Torch 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 BioFire Torch.

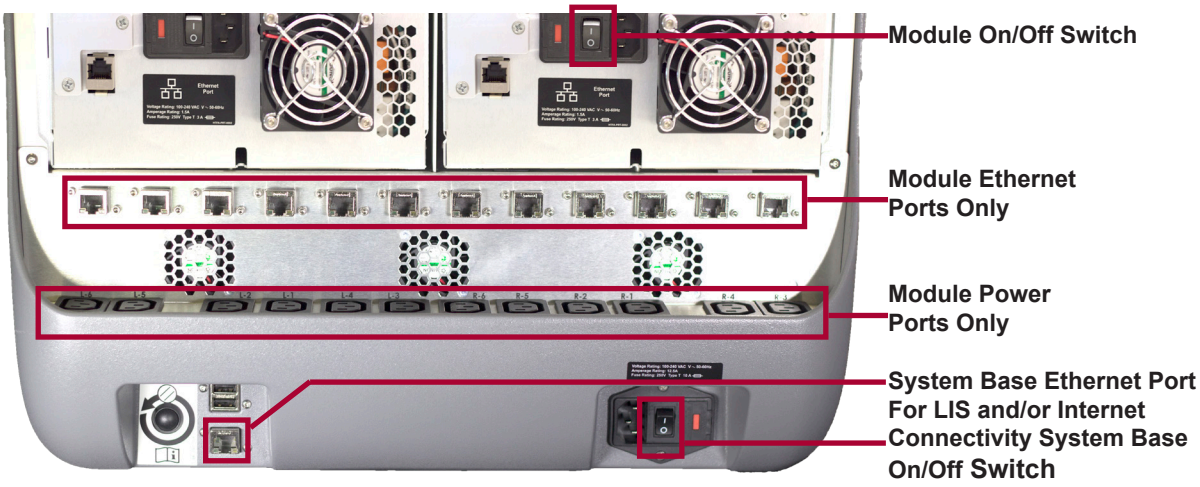
BioFire Torch Installation

⚠CAUTION: BioFire Torch installation should only be performed by a BioFire Diagnostics appointed specialist. A brief description of the installation process is provided below.

BioFire Torch System Base Setup

⚠CAUTION: Use only the supplied cables when connecting the BioFire Torch Modules to the BioFire Torch System Base. Do not use cable extenders to increase cable length.

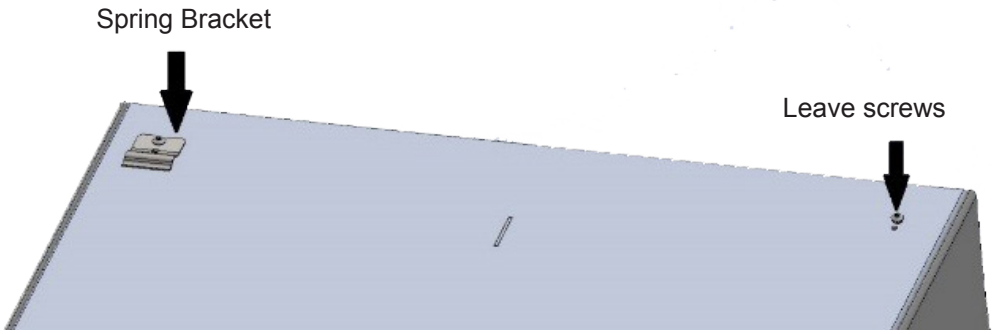
1. Remove all components in the System Base box.
2. Place the System Base in desired location.
3. Plug in power and Ethernet cord from the System Base to the wall.
4. Turn on power to the System Base; then check that the BioFire Torch Software powers on.



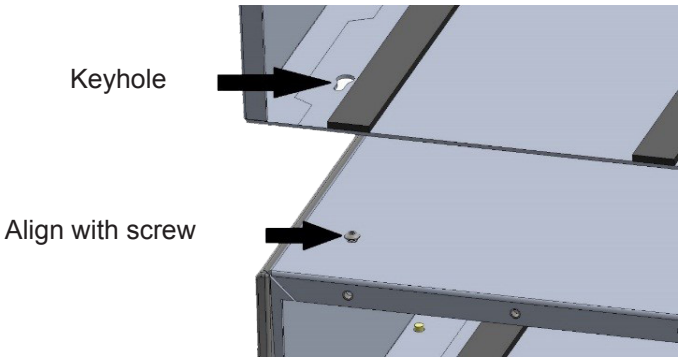
BioFire Torch Duplex Installation

NOTE: BioFire Torch Duplex installation is performed if more than two Modules need to be installed. If not, continue on to the *BioFire Torch Module Installation* section in this chapter.

1. Remove all components from the Duplex box(es).
2. Loosen screw to remove the spring brackets at the rear of the top cover (leave the screw threaded in below).

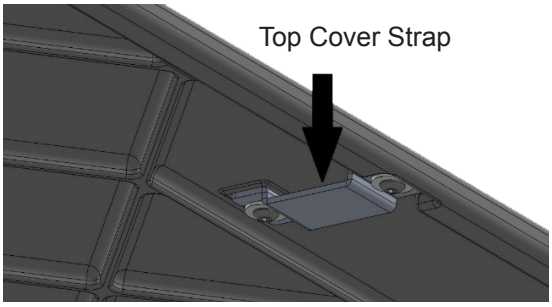


3. Stack a Duplex Module enclosure on top of the System Base/lower Duplex and align the key-holes with the screws in the base/Duplex below.

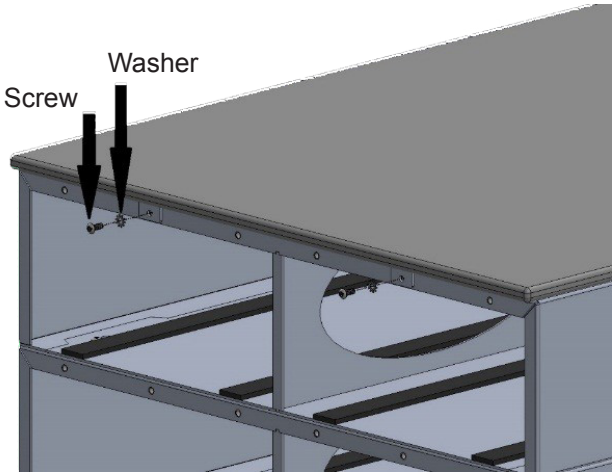


4. Slide the new Duplex back until the front edge is aligned with the Duplex below it; then tighten the fasteners.
5. Repeat steps 3 – 4 until all Duplexes are installed (up to five Duplexes).
6. Reinstall the top cover spring brackets on the top Duplex (at the rear holes) and tighten the screws.

7. Align the top cover straps with the spring brackets; then slide the top cover back until the tabs align with the front of the top Duplex.



8. Fasten with washers and screws.



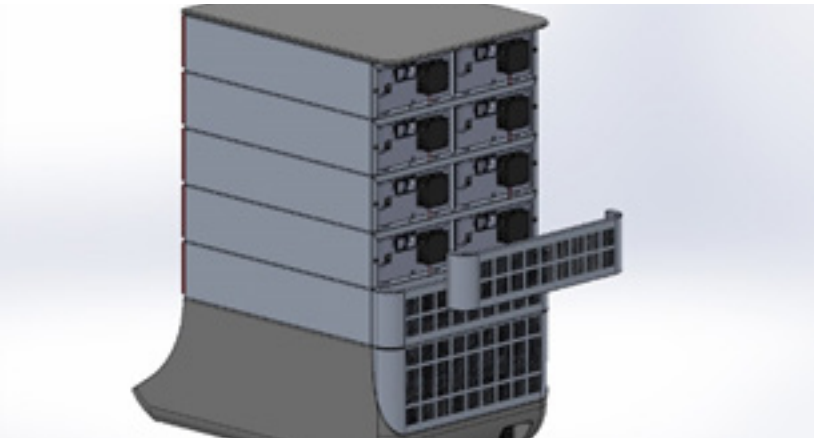
BioFire Torch Module Installation

Unplug the BioFire Torch before beginning.

1. Remove all contents from the Module boxes.
2. If necessary, install all Duplexes (see the *BioFire Torch Duplex Installation* section previously in this chapter for instructions).
3. Loosen the two screws on the front of the preinstalled tabs.
4. Starting at the bottom and working up, install Modules into the front of each Duplex opening and secure each with washers and screws.
5. Using the power and ethernet cables, connect each Module to the back of the System Base. The labels next to the AC power connectors on the System Base will indicate the optimal cable routing order.
6. Ensure the filters are in place on the back of each Module front cover; then attach a front cover to each Module by aligning the mounting posts with the alignment holes in the plastic.
7. Plug the System Base power cord into a power source; then plug the System Base Ethernet

cable into desired Ethernet port.

8. Turn the BioFire Torch on using the power switch on the back of the System Base near the power cord.
9. Turn on power to each Module using the power switch on the back of each Module (see image in the *BioFire Torch System Base Setup* section previously discussed in this chapter for more information).
10. Install cable shrouds over the electrical cables. The shrouds attach by aligning the magnets on the back of each Duplex with the holes in the strikers.



NOTE: To properly turn off, first press the reset button on the back of the System Base until the screen goes black; then turn off the main power switch near the System Base power cord.

BioFire Torch Module Removal

1. Remove the cable shroud from the back of the Module and turn off the Module to be replaced.
2. Disconnect the cables and remove the Module front cover.
3. Unscrew the washers and screws on the front of the Module; then carefully slide the Module out of its Duplex.

NOTE: If installing a replacement Module, install using the steps in the previous section.

Instrument Configuration Application for BioFire Torch

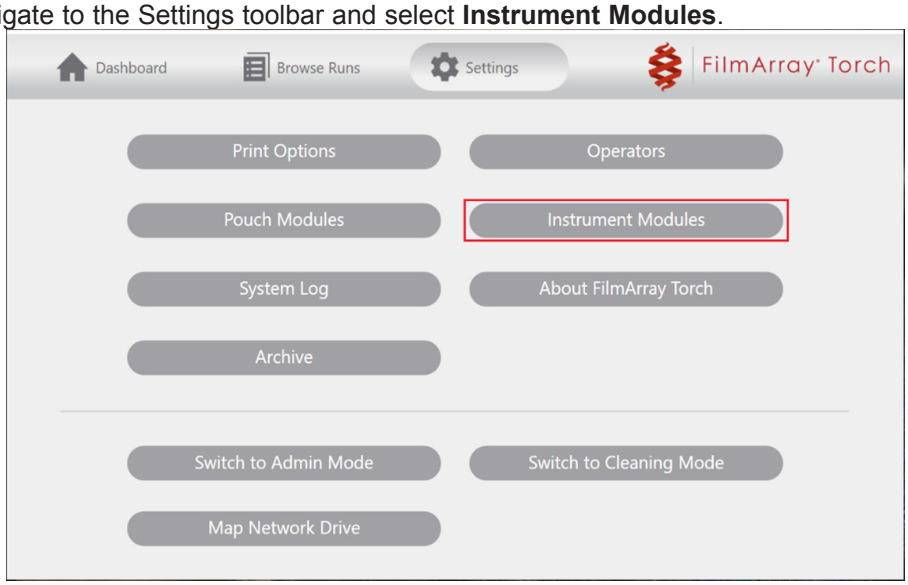
Once connected physically to the System Base, the Instrument Configuration application allows an operator to add or remove Modules to the BioFire Torch Software.

NOTE: A Module must be added to the BioFire Torch before the software can be used to initiate and perform runs.

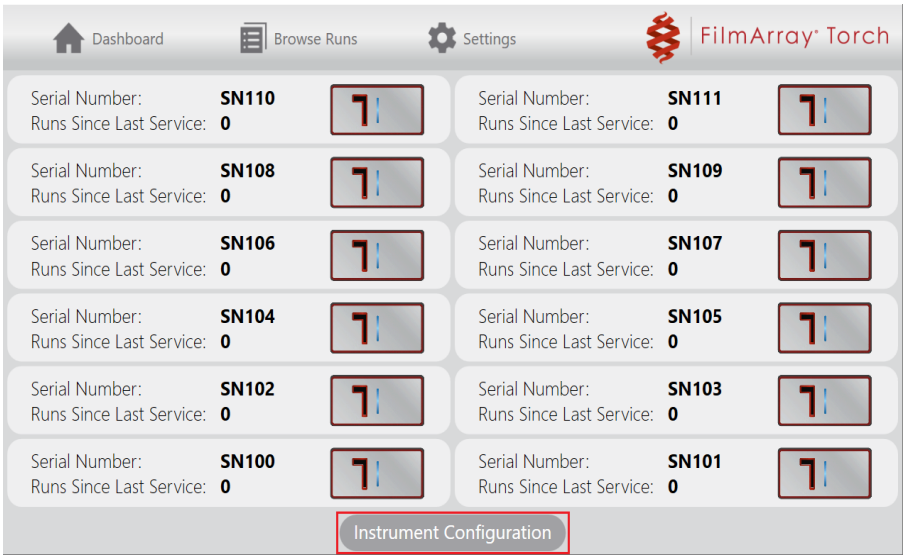
Start Instrument Configuration Application

To access to the application from the BioFire Torch Software:

1. Navigate to the Settings toolbar and select **Instrument Modules**.



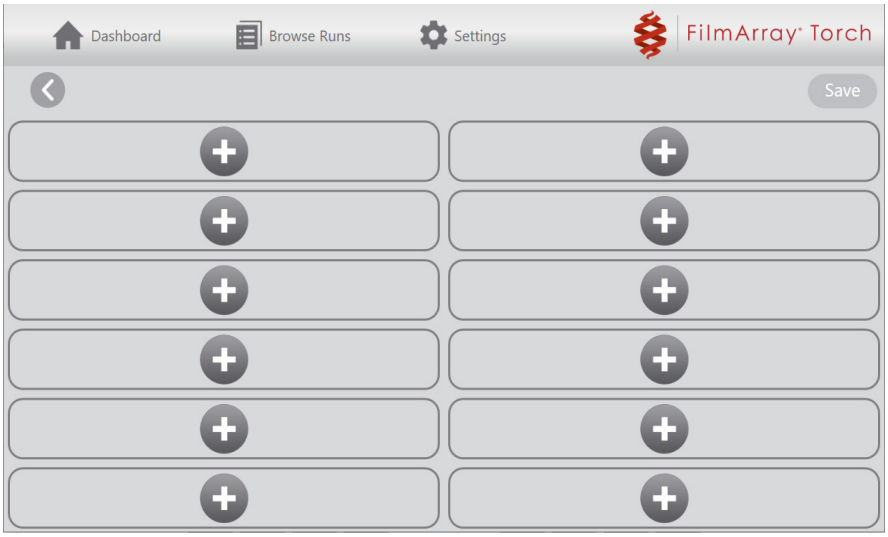
1. Select the **Instrument Configuration** button.



NOTE: BioFire Torch Modules should be configured from the bottom up.

Instrument Configuration Grid

The Instrument Configuration grid is broken into 12 box*es* that represent the physical locations for all 12 potential Modules. Each Module that is currently configured to the BioFire Torch displays within a box. Any boxes that have not had a Module configured to them contain a plus icon .



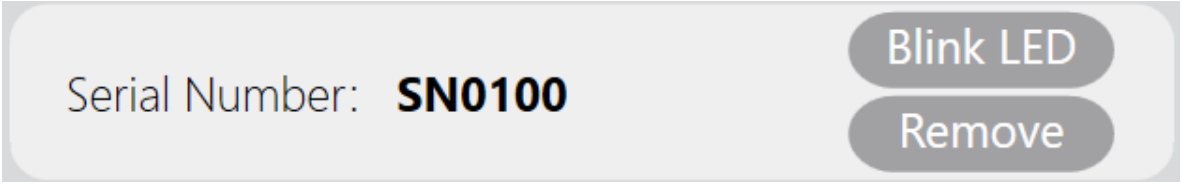
NOTE: Start initial configuration from the bottom and work up. Modules should be configured to correspond with the physical location(s) on the BioFire Torch.

Grid Box

The grid box represents a single location within the BioFire Torch.

Each Module configured to the BioFire Torch displays the following:

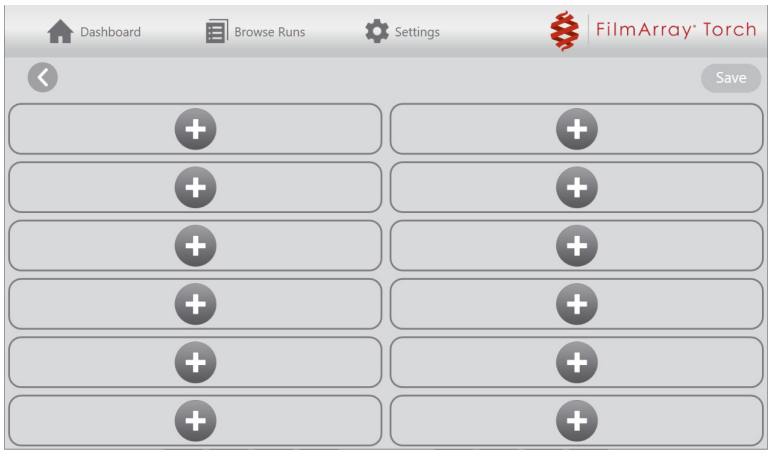
- **Serial Number** displayed as a title
- **Firmware** version
- **Status**
- **Runs Since Last Service**
- **Blink LED** identifies which physical Module is linked to the appropriate location. The Module LED blinks white when the Blink LED option is selected. The Blink LED option is unavailable if the Module is disconnected.
- **Remove** (see the *Remove BioFire Torch Module* section below)



Add BioFire Torch Module

To add a Module to the BioFire Torch software:

1. Select the plus icon for the appropriate location.



The application presents the Detected Modules dialog.

2. Use the scroll bar to locate the applicable Module Serial Number and select **Blink LED**.
3. Use the plus icon to add the appropriate Module.
4. Select **Save** to save all changes made during this operation.

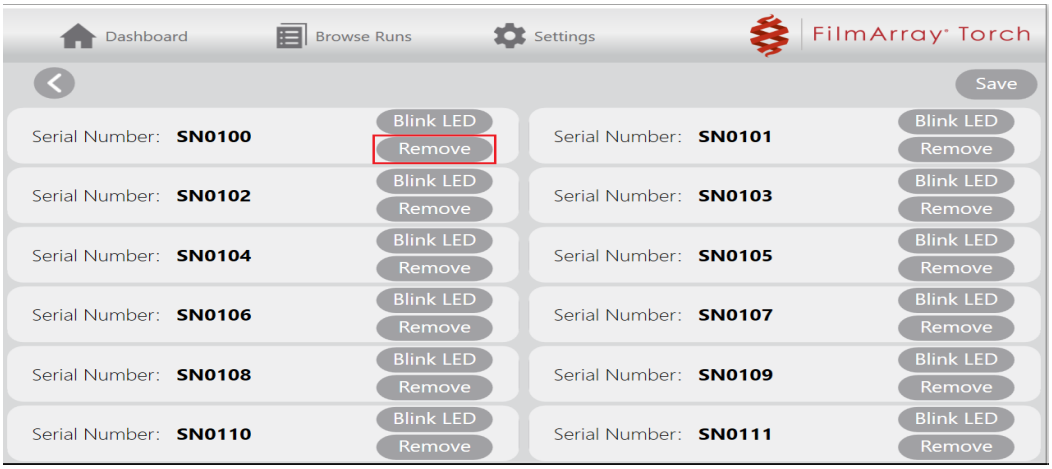
Remove BioFire Torch Module

To remove a Module from the BioFire Torch Software:

1. Identify the location configured to Module and check that its status is **Idle**.

NOTE: There is no warning presented for removal of a BioFire Torch Module that is currently in a running status.

2. Select **Remove** on the applicable location.

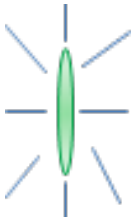
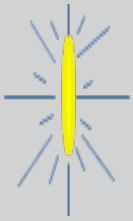


3. Select the **Save** option to save all changes made during this operation.

BioFire Torch Module Status

The front of each BioFire Torch Module is equipped with an LED light that shows the specific status of that Module.

LED	Color	Status	Meaning
	White	Solid	Module initializing.
	Yellow	Solid	Warning - e.g., Module not connected.
	Blue	Solid	Module idle and available to run a pouch.

LED	Color	Status	Meaning
	Blue	Blink	Module waiting for operator to insert a pouch.
	Green	Fast Blink	Pouch inserted and seated, but pouch run not started.
	Green	Solid	Pouch run in progress.
	Green	Slow Blink	Run complete – remove pouch.
	Yellow	Blink	Warning – Operator action required – e.g., unknown insertion, double insertion, pouch jam. Follow on-screen instructions.
	Purple	Blink	Error. Operator intervention or maintenance required. Module must be reset. Remove the front cover of the affected Module and reset the Module, or power off then power on the Module.
	Red	Solid	Error. Operator intervention or maintenance required. Module must be reset. Remove the front cover of the affected Module and reset the Module, or power off then power on the Module.

Connecting a Printer to BioFire Torch

The BioFire Torch can be configured to print to any printer compatible with a Windows 10 operating system.

Add or Update Printer

1. Navigate to the **Settings** toolbar.
2. Select **Switch to Admin Mode**. A warning message informs the operator that switching to Admin Mode will close the application and log off.
3. Select **Yes** to confirm the switch.
4. Enter the appropriate user name and password to log in. The standard Windows desktop layout will display.
5. Navigate to the Control Panel to manipulate printer details for the BioFire Torch.
6. Reset the System Base when printer maintenance is complete. The BioFire Torch Software will automatically load.

CHAPTER 3: PRINCIPLES OF OPERATION

The BioFire® System is an automated *in vitro* diagnostic (IVD) system that utilizes nmPCR and high-resolution melting analysis to detect and identify multiple nucleic acid targets from clinical specimens. The user of the BioFire Torch loads the sample into a reagent pouch, places the pouch into the BioFire Torch Module, and starts the run. The BioFire Torch Module interacts with the reagent pouch to extract nucleic acids from the sample and to amplify 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 BioFire® FilmArray® Software in a test report.

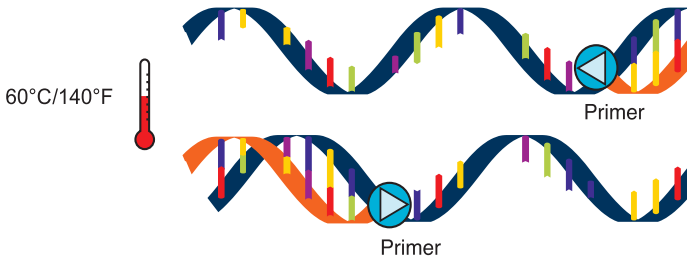
PCR Basics

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 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).

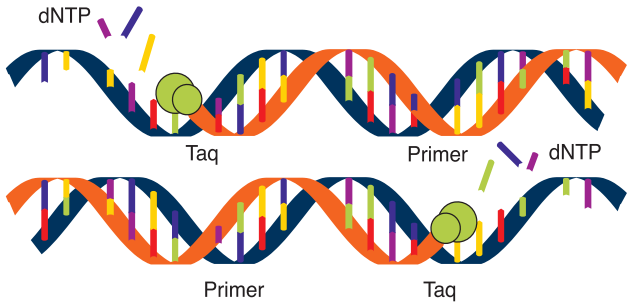
There are 3 steps to a PCR cycle:

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

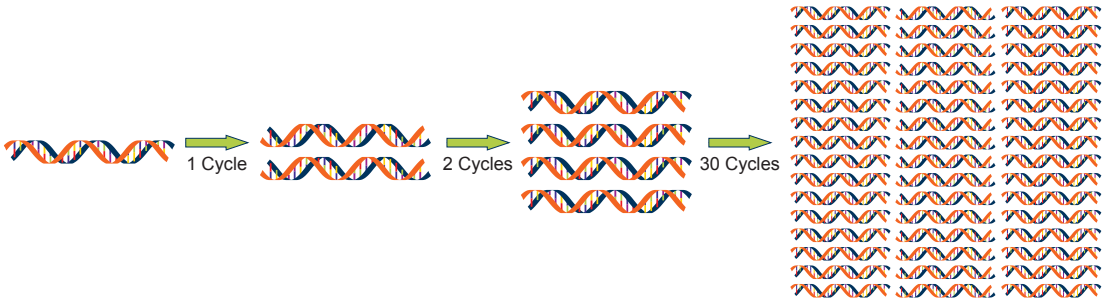
Step 2: Primer annealing - The sample is cooled to about 60°C, allowing the primers to bind or "anneal" to the target DNA strands at a specific site.



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

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).

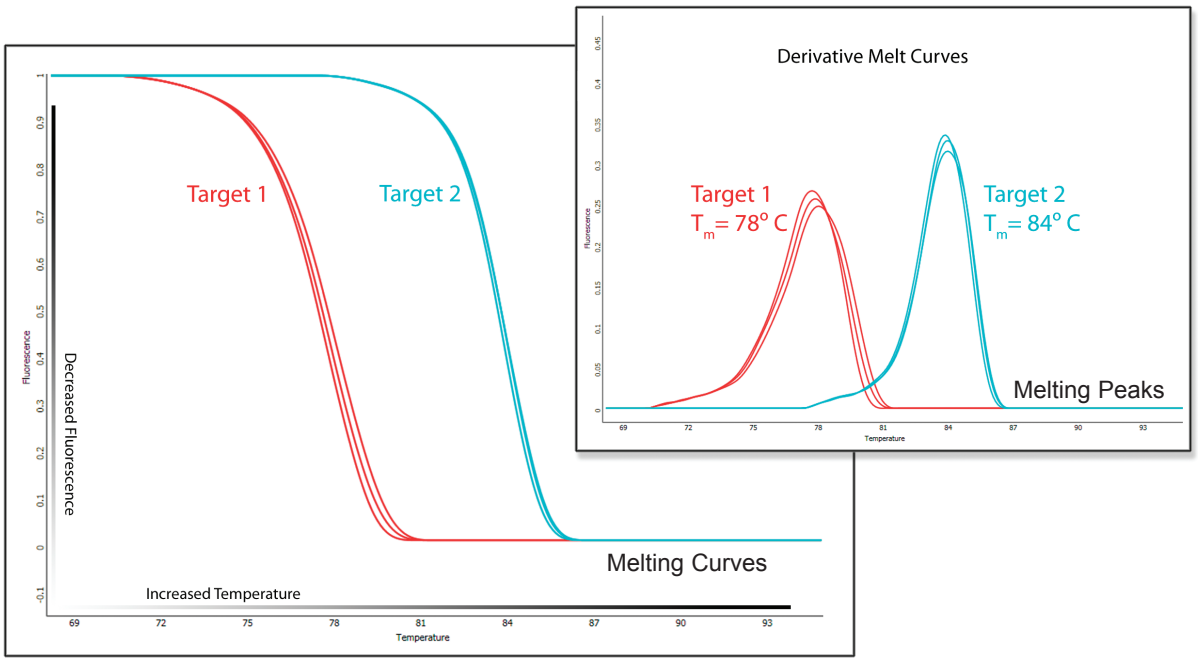
High-Resolution Melting Analysis

BioFire® System 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 BioFire Torch Module. As the temperature is increased and the copies of double-stranded DNA melt, the LCGreen Plus dye is released and a reduction in fluorescence is detected.

The 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 will melt 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 BioFire Torch Module 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® System 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 Torch System Specifications

<table>
<tr><td>Sample Description</td><td>• One sample capacity per BioFire Torch Module (with up to 12 samples per BioFire Torch)</td></tr>
<tr><td>Run Time</td><td>• Sample run time about one hour</td></tr>
<tr><td>User Interface</td><td>• System Base with touch screen and barcode scanner</td></tr>
<tr><td>Data Output</td><td>• Automatic analysis with end-of-run result reports</td></tr>
<tr><td>Fluorescence Acquisition</td><td>• Single color optics module: 475nm excitation, 545nm emission, and sensor imaging</td></tr>
<tr><td>Temperature Control</td><td>• Operating temperature 15°C to 30°C
• Peltier devices:
  • Ambient to 100°C
  • Ramp rate from 0.1–0.5°C /sec on melt</td></tr>
<tr><td>Operations Specification</td><td>• 15°C to 30°C @ 20 to 80% relative humidity (non-condensing)
• -16m to 3048m
• Indoor use only</td></tr>
<tr><td>Shipping Specifications</td><td>• -30°C to 38°C @ 5 to 85% relative humidity (non-condensing)
• -16m to 10,600m</td></tr>
<tr><td>Power Requirements</td><td>
<table>
<tr><th rowspan="2">Qty. of Modules</th><th rowspan="2">Voltage</th><th rowspan="2">Frequency</th><th colspan="2">AC Power at 120V</th><th colspan="2">AC Power at 240V</th></tr>
<tr><th>Active</th><th>Apparent</th><th>Active</th><th>Apparent</th></tr>
<tr><td>Minimum (Single Module)</td><td rowspan="2">100-240VAC</td><td rowspan="2">50-60Hz</td><td>130W</td><td>135VA</td><td>110W</td><td>190VA</td></tr>
<tr><td>Maximum (12 Modules)</td><td>850W</td><td>935VA</td><td>775W</td><td>1100VA</td></tr>
</table>
</td></tr>
<tr><td>Fuse</td><td>• 250V 3.15A Type T (Modules)
• 250V 10A Type T (System Base)</td></tr>
</table>

Dimensions and Weight	• 18 x 29 x 11.5 in (45.8 x 73.66 x 29.21 cm) (W x D x H; System Base only)
	  • 4.5 in (11.43 cm) (H; Modules only)
	  • 34 in (86.36 cm) max height (12 Modules)
	• Weight: Approximately 268 lbs (121.6 kg) maximum:
	  • System Base – 36 lbs (16.3 kg)
	  • Modules – 15 lbs (6.8 kg) each
	  • Duplex (Module enclosure) – 6.5 lbs (2.95 kg) each

EMC Requirements	• The BioFire Torch complies with the emission and immunity requirements in IEC 61326: Electrical equipment for measurement, control, and laboratory use - EMC requirements - Part 1: General requirements.
Safety Requirements	• The BioFire Torch complies with IEC 61010-2-101: Safety requirements for electrical equipment for measurement, control and laboratory use Part 2-101: Particular requirements for *in vitro* diagnostic (IVD) medical equipment.
CPU	• Intel®
Storage and Memory	• 512 GB hard drive or greater • 16 GB RAM or greater
Interfaces and Peripherals	System Base • 12+1 Ethernet network interfaces • 4 USB connections or more
	Module • One Ethernet network interface
Display	• LCD • Capacitive touch screen interface
Operating System	• Microsoft® Windows® OS as released with the BioFire® System
Cybersecurity	• See *Chapter 9, BioFire Torch Cybersecurity*

CHAPTER 5: BIOFIRE TORCH OPERATING INSTRUCTIONS

NOTE: BioFire® 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 Torch involves three main steps:

1. Adding a patient sample to the BioFire Pouch.
2. Performing a run within a BioFire Torch Module.
3. Viewing and/or printing a report.

BioFire® FilmArray® Reagent Kits

BioFire Reagent Kits include BioFire Pouches and all components required to run tests on the BioFire Torch. Components will 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 Batch Code

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.

BioFire Torch Test Procedure

General Precautions

BIOLOGICAL RISKS: When working with the BioFire Torch and clinical specimens, personnel may come into contact with contaminants or with 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 biological safety cabinet or hood, or behind a protective shield. Once a 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:

- Sample collection, pouch loading, and BioFire Torch operation should each be performed in separate locations or work areas.
- 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).
- Prepare and load only one pouch at a time.
- 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 a BioFire Torch Module will be available and operational before unwrapping any pouches for loading.

Initiate 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 BioFire Torch Software includes a detailed workflow that guides the operator on how to perform a run.

Once a pouch has been prepared for testing, follow the on-screen instructions to enter pouch and sample information. Insert the pouch into an available BioFire Torch Module and start the run.

The operator cannot start a run until one BioFire Torch Module has been added to the BioFire Torch Software. Please see the *Instrument Configuration* section in *Chapter 2* for more information about adding a BioFire Torch Module. In addition, the appropriate pouch module must be installed on the BioFire Torch in order to start a run (see the *Pouch Module* section in *Chapter 6*).

Initiate a BioFire Torch run by Manual Initiation or Scan Initiation.

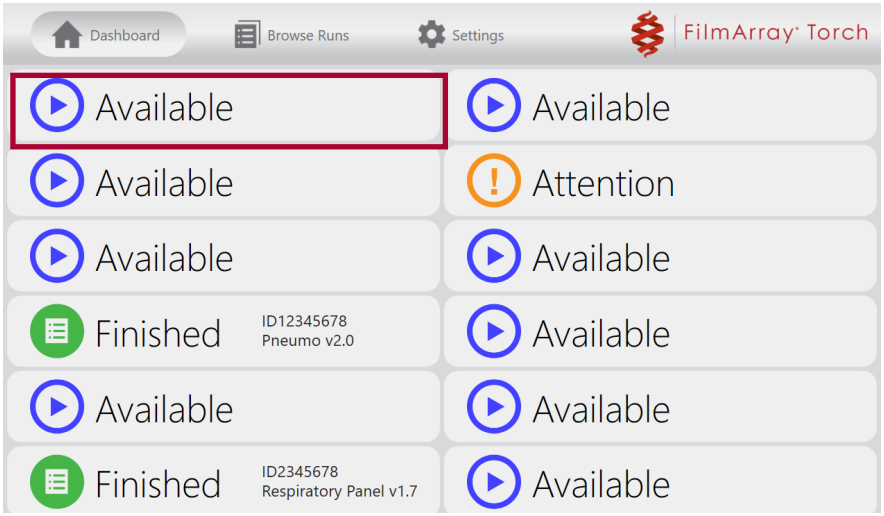
Manual Initiation

The operator selects a specific BioFire Torch Module from the Dashboard using the touch screen. To initiate a run manually:

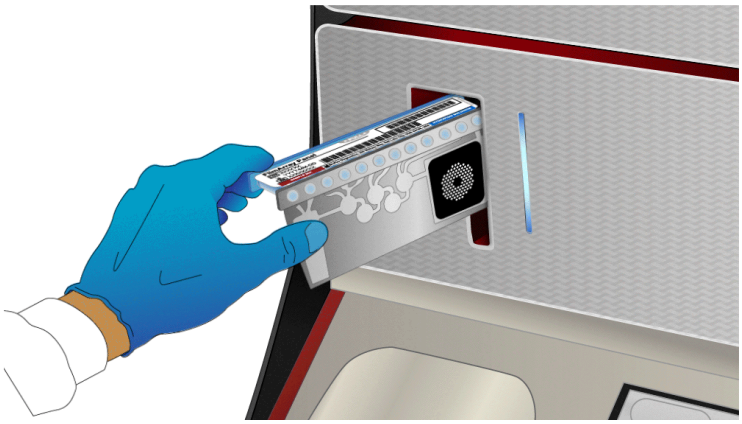
1. Select an **Available** Module on the Dashboard and scan the pouch barcode on the fitment label. Then scan or manually enter the Sample ID.

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.

NOTE: If the barcode scanner is not available or the barcode is unreadable, manually enter the lot number and serial number printed on the pouch label.



2. Insert the pouch into the selected BioFire Torch Module. The Module's LED will blink blue. Ensure that the pouch fitment label is lying flat on top of the pouch and not folded over. As the pouch is inserted, the Module will grab onto the pouch and pull it into the chamber.



CAUTION: Do not insert sharp objects to remove a jammed pouch. In the event of a jammed pouch, contact BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor for Customer Support.

Scan Initiation

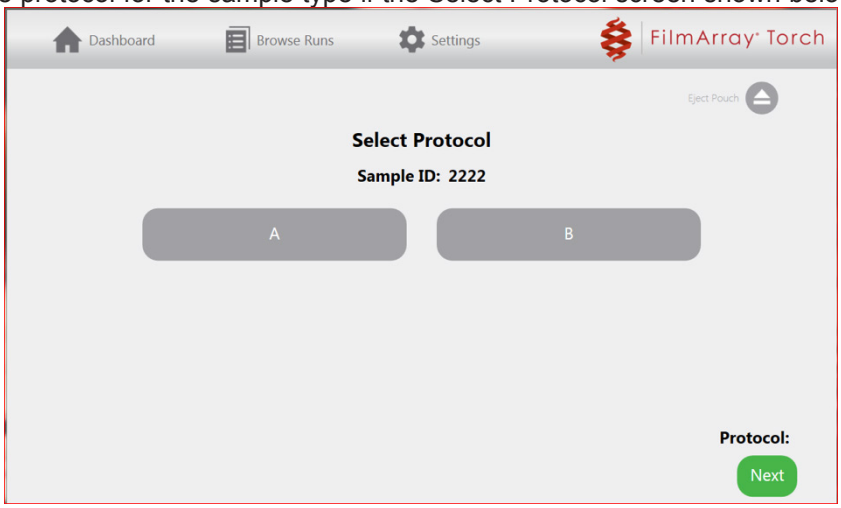
The operator scans the fitment label on the pouch while the Dashboard is displayed on the touch screen. To initiate a run by scanning:

1. Scan the pouch barcode on the fitment label. Then scan or manually enter the Sample ID.
2. Insert the pouch into any available BioFire Torch Module. The LED for all available modules will blink blue. Ensure that the pouch fitment label is lying flat on top of the pouch and not folded over. As the pouch is inserted, the Module will grab onto the pouch and pull it into the chamber.

Start Run

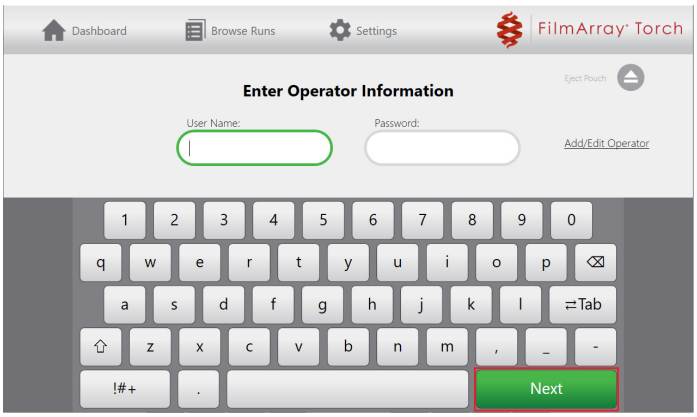
After the pouch is correctly inserted into the BioFire Torch Module, the LED will blink green to indicate that the pouch has been seated but the run has not yet started. To continue the run after Manual or Scan Initiation:

1. Select the protocol for the sample type if the Select Protocol screen shown below is displayed.



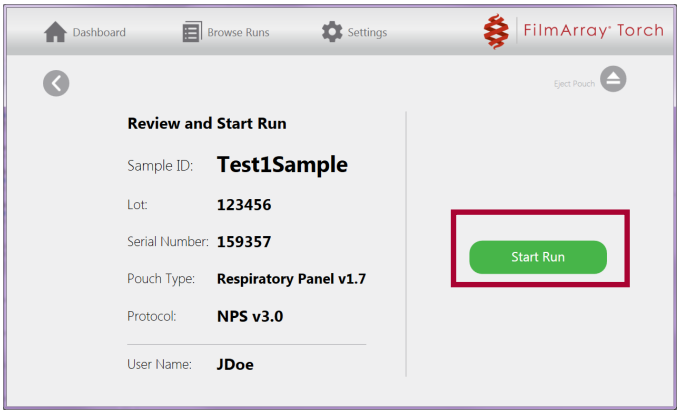
2. Enter operator username and password, then select **Next**.

NOTE: The Next key will only become available when a correct username and password is entered. See the *Create New Operator(s)* section in *Chapter 6* for more information on how to create a new operator's username and password.

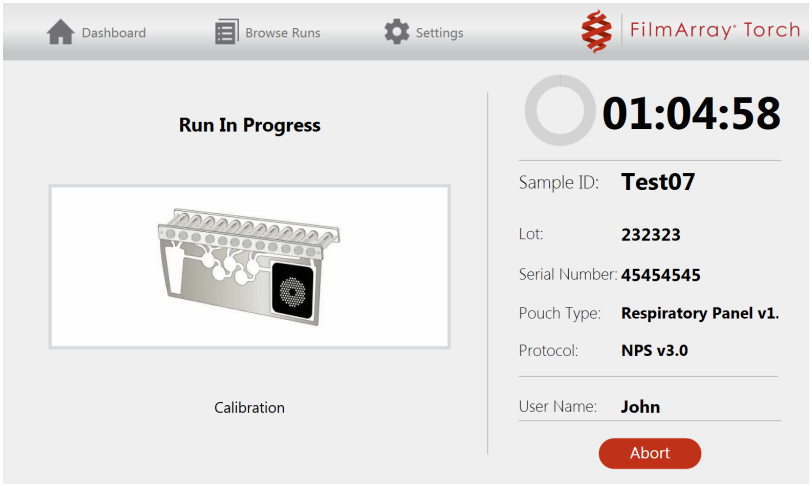


NOTE: The font color of the username and password is red until the user name is recognized by the BioFire Torch Software.

3. Review run information on the screen and if correct, select **Start Run.**



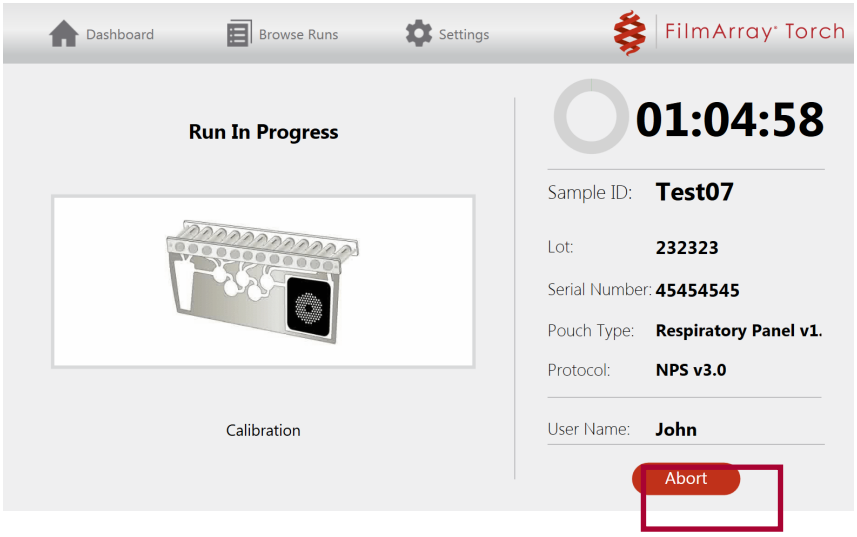
Once the run has been started, the selected Module's LED will turn solid green to indicate that the run is in progress. The display also changes to the Run In Progress screen and shows the steps that the Module is currently performing and the approximate remaining run time. The operator may navigate to the Dashboard to perform other tasks.



Abort Run

If a run needs to be stopped before it is finished, select the applicable BioFire Torch Module from the Dashboard. The Run In Progress screen will display the current run information; select **Abort**. Any data that has been generated for the aborted run will not be available for analysis. An aborted run cannot be restarted and the pouch must not be re-run.

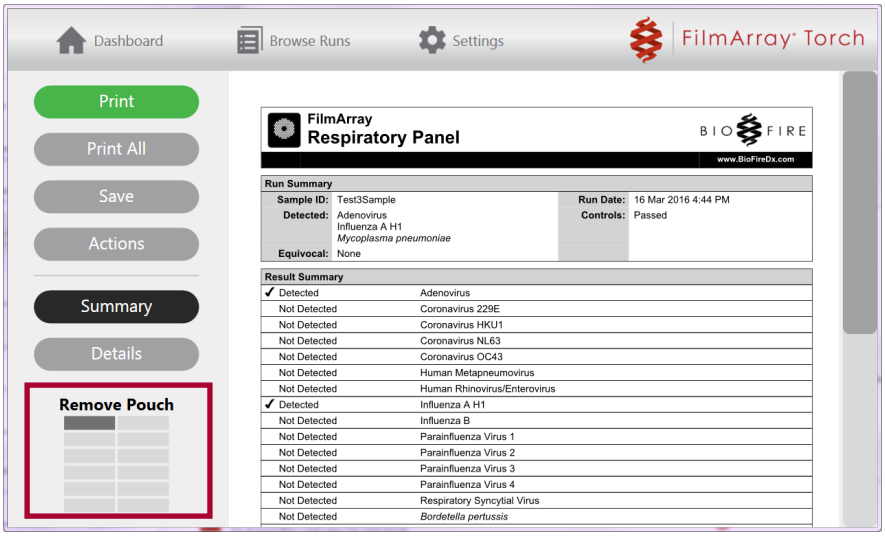
NOTE: Aborting a run may take up to five minutes to complete.



Finish Run

At the end of the run, the Dashboard changes the status of the Module to Finished and the pouch is partially ejected. To finish a run:

1. Select the **Finished** Module on the Dashboard to view the report.



2. Remove the pouch from the Module as shown in the diagram in the lower-left corner of the display. The Module LED is solid blue indicating that the Module is ready for a new run

NOTE: Once the pouch has been removed, the report can only be viewed through the Browse Runs feature.

View Report

When a run is finished, the report can be viewed on the:

- Run In Progress screen — the run report displays once the run is complete.
- Dashboard screen — a report icon appears and the status changes to Finished. Selecting the Module box displays the run report. Once the pouch is removed from the BioFire Torch Module, the status changes to Available.
- Browse Runs screen - the run reports are accessible from the table.

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

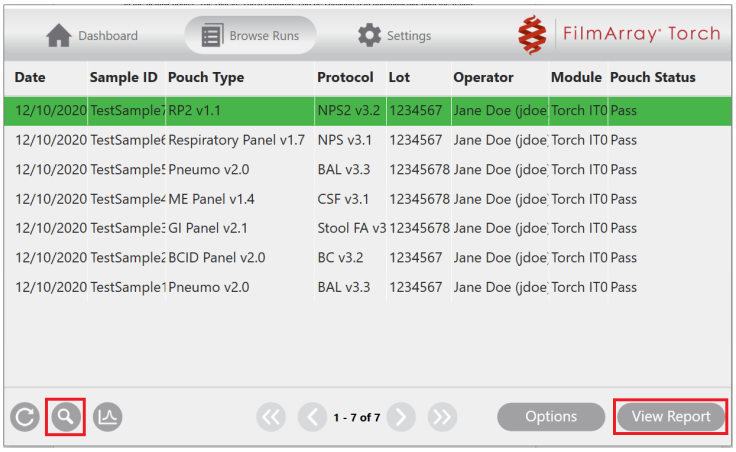
Print Report

If you have connected your BioFire Torch to a local network of printer, reports will always be printed to the default printer. The BioFire Torch Software can be configured to automatically print the report at the end of the run (see the *Print Options* section within *Settings* in *Chapter 6, BioFire Torch Software*).

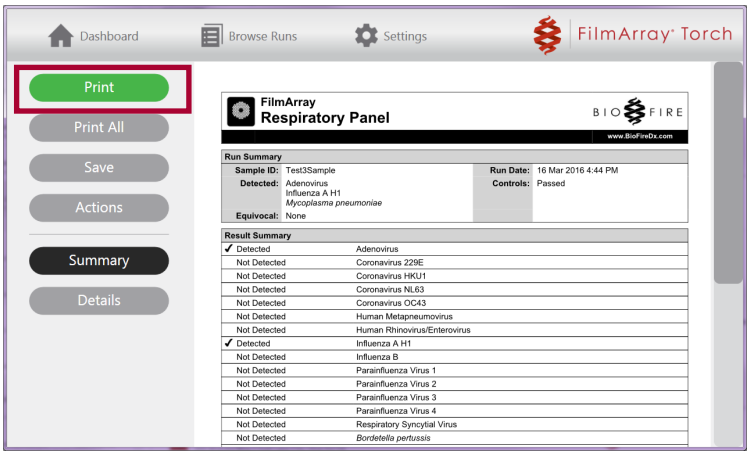
To print a report from a previous BioFire® Pouch run:

1. Select **Browse Runs** in the top menu on the touch screen.
2. Select one desired run from the table.
3. Select **View Report** to open the report page.

NOTE: If no runs or multiple runs are selected, the View Report option is disabled.

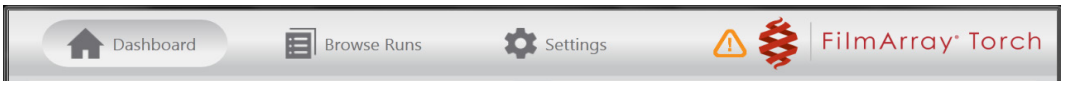


4. Select **Print.**



Error Messages

If errors occur, see *Chapter 8, Preventative Maintenance and Troubleshooting*, for more information on viewing and handling error messages.



NOTE: A yellow triangle or message box will appear when an error occurs.

CHAPTER 6: BIOFIRE® FILMARRAY® TORCH SOFTWARE

This chapter explains how to use the BioFire Torch Software and manage the database. The BioFire Torch Software automatically starts when the BioFire Torch is powered on – no login is required.

BioFire Torch Toolbar

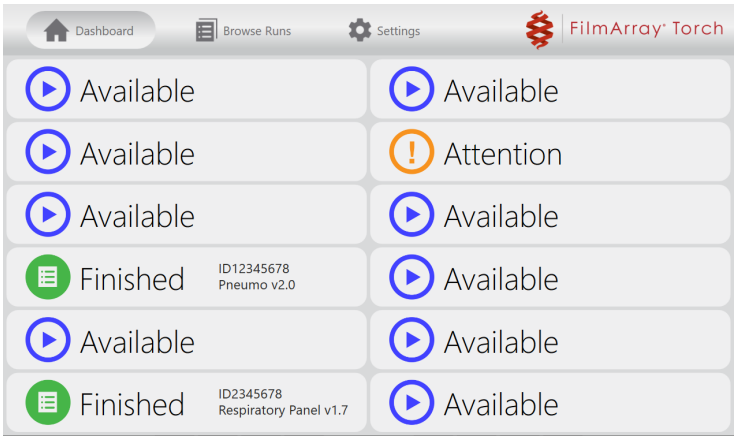
The table below lists the features available in the BioFire Torch toolbar:

BioFire Torch Toolbar	Description
Dashboard	The Dashboard allows the operator to do the following: • View the status of each BioFire Torch Module in the system on a display that can be seen from a distance. • View the status of all runs that are in progress, along with the Sample ID, Pouch Type, and time remaining until completion. • Start a run by using the Start Run Workflow.
Browse Runs	Browse Runs allows the operator to review Run Results for runs performed on all BioFire Torch Modules within the BioFire Torch. The Browse Runs feature displays all the runs and allows access to the following actions: • View Report – This option is inactive until a specific report is selected. • Options – Allows access to additional features. • Run Table – Allows the operator to perform the following actions: a. View and sort runs in the database. b. Filter the database by run criteria. c. Page through the runs using the paging navigation at the bottom of the screen.
Settings	Settings allows the operator to perform basic configuration and management of the BioFire Torch. See the Settings section for details.

Dashboard

The Dashboard option is always accessible from the toolbar. To access the Dashboard from any screen, select the **Dashboard** option on the toolbar. The BioFire Torch Dashboard allows the operator to interact with several BioFire Torch Modules from one System Base. Each BioFire Torch Module is represented by a box displayed on the touch screen. Until at least one Module has been added to the BioFire Torch Software, the Dashboard will be blank. The number of boxes on the Dashboard mirrors the number of Modules that are configured.

Any BioFire Torch Module box on the Dashboard can be selected to display additional details about the BioFire Torch Module status.



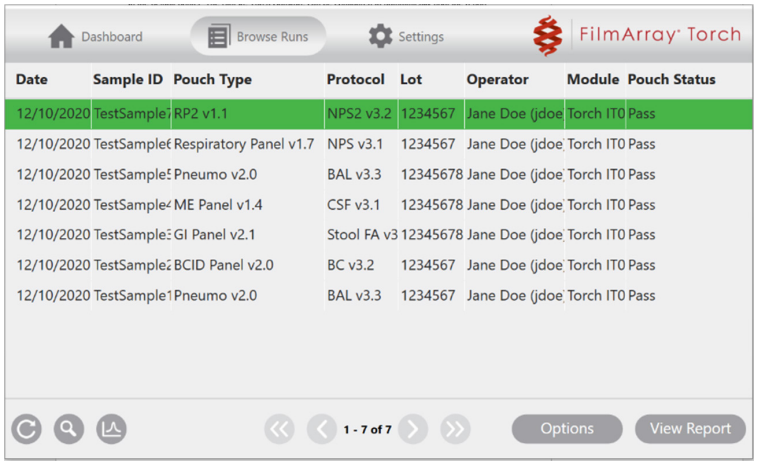
The details for each BioFire Torch Module include the following:

Status Icon	Status	Description
Available	Available	The Module is available for a new run. The operator can initiate a new run (Manual Initiation of workflow)
01:04:43 test27sample GI Panel v2.1	Run In Progress	Module is performing a run and displays the Time Remaining
Overtime test27sample GI Panel v2.1	Overtime	Module is performing a run and has gone over the expected run time for the pouch and displays Overtime
Finished test21sample Respiratory Panel v1.7	Finished	Run has finished, pouch is ejected, run report is ready for viewing
Attention	Attention	Module has lost connection with the software as a result of one of the following: • Module is initializing or is not connected • There is an unknown pouch in the Module
Attention	Attention	The Module needs to be reset Module has an error on it as a result of one of the following: • Pouch jam • Stalled • Module error

Browse Runs

The Browse Runs option is always accessible from the toolbar. To access Browse Runs from any screen, select the **Browse Runs** option on the toolbar. When a run is completed on a Module, the software generates a report with the results of the run. Upon initial entry into the Browse Runs screen, all the runs within the database are displayed.

The runs are presented as a table that lists the date of the run, the Sample ID, and other information about the run. Selecting an individual run enables the View Report option, which can be selected to display the run report. For more information on viewing a report, see *Chapter 5, BioFire Torch Operating Instructions.*



View Report Menu

The table below lists the features available on the View Report menu:

Menu Item	Description
Print	Prints the run report. See *Chapter 5, BioFire Torch Operating Instructions* for more information about printing a report.
Save	Opens a dialog that enables the operator to save the run report to a chosen location.
Actions	Allows for the following actions to be performed for the selected report: 1. **Edit Sample ID**: If a mistake was made during run setup when entering the Sample ID, the operator can make the necessary corrections. A history is recorded of all changes and will be added to the run report. 2. **Show Run Details**: Allows the operator to view system details, messages and errors associated with a run. 3. **Export Data Bundle**: If an error associated with a run occurs, a Customer Support representative may request that the operator creates a data bundle for that run and send it to BioFire Diagnostics. For more information on creating a data bundle, see the *Data Bundle* section in *Chapter 8*.

Save Report

Run reports can be saved as a PDF file for future use. To save reports as PDF file:

1. Select **Save** on the View Report page.
2. Choose location and filename; then select **Save**. If multiple drives are available, select a destination device.
3. After save completion, select **OK** to close the dialog.

Edit Sample ID

To change the Sample ID:

1. Select **Actions** in the View Report page; then select **Edit Sample ID**.

   The operator is presented with a table that lists any previous change history.

2. Update the current Sample ID; then enter Username and Password.

   The save option is not enabled until the operator has entered their Username and Password. This tracks the changes to a specific user and meets the electronic signature and records requirements required in laboratories.

3. Select **Save**.

   After saving the changes, the report reflects the new Sample ID and displays the Change History.

Show Run Details

To see details of the run:

1. Select **Actions** on the View Report page; then select **Show Run Details** from the menu.

   The operator is presented with a list of the system details, messages, and errors associated with that run.

Export Data Bundle

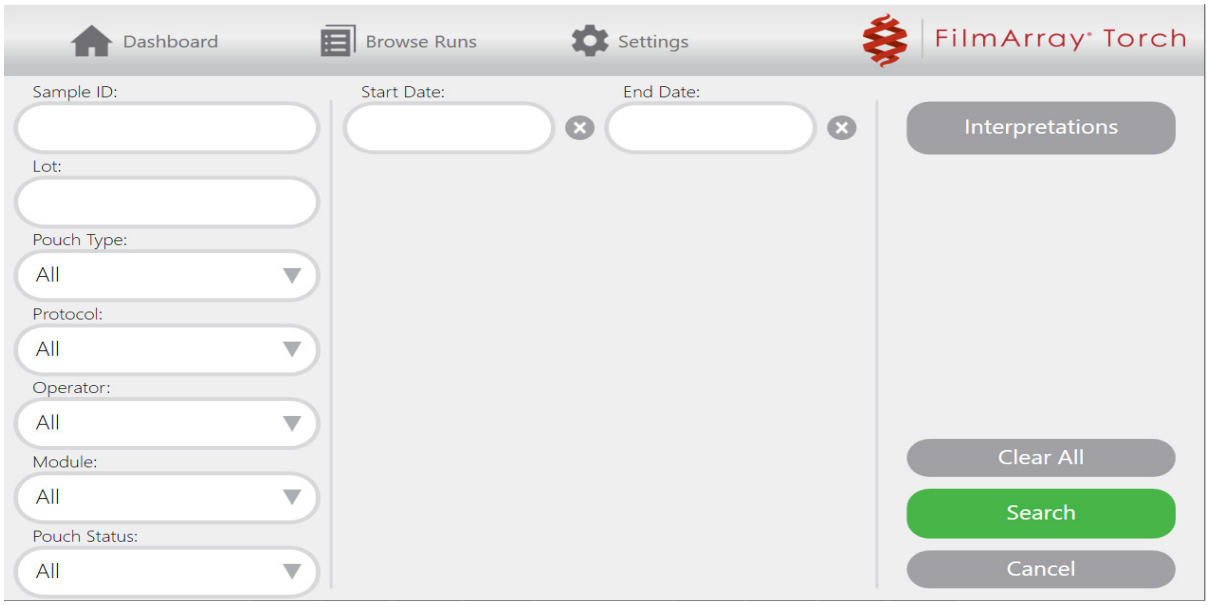
For more information on exporting a Data Bundle, see the *Data Bundle* section in *Chapter 8.*

Search Run Data

Search

The search icon on the Browse Runs page contains multiple search criteria the operator can use to locate desired runs. The following table describes the search criteria options:

Criteria	How to Search
Date	Select the date or date range of interest.
Sample ID	Enter the Sample ID of interest.
Pouch Type	Select the panel of interest.
Operator	Select the operator of interest.
Module	Select the Module serial number of interest.
Pouch Status	Select the pouch outcome of interest: Pass, Fail or Invalid, Completed, Incomplete, Aborted, Instrument Error, or Software Error.
Interpretations	Search by specific organism detected.



To clear Search Criteria and view all of the runs saved in the database, select **Clear All** on the search screen or the **X** on the search results page.

To retain the search criteria and update the search results to include recent runs, select **Refresh**.

Melt Curve Viewing

Melt Curve Viewer

The melt curve icon on the Browse Runs page becomes available when a run is selected. This icon will open up the Melt Curve Viewer showing the PCR melt curves for the selected run. The Melt Curve Viewer 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.

Heading

The heading on the melt curve viewer screen will show the run information.

The header will also display several icons. Each icon will have a specific function aiding in the viewing of the melt curves for that run.

Icon	Description	Number in Figure Above
	The report icon will display the report for the selected run.	1
	The expand icon will display the melt curve on the entire screen.	2
	Reduce Expand is visible on the Expanded melt curve screen. It will take the customer to the normal melt curve view.	3
	The reset zoom icon will re-center the melt curve and zoom to normal.	4
	The zoom in icon will increase the melt curve size on the screen	5
	The zoom out icon will reduce the melt curve size on the screen.	6

Tabs

The melt curve viewer will have the following tabs available. Control Tab, Interpretation Tab and a Bin Interpretation Tab.

Feature	Description	Number in Figure Above
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.	1
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 for an organism: 1. The Operator will select an assay from the Interpretation tab. The title for that assay will be displayed above the melt curve graph. 2. The operator can view all the pathogen assays available or deselect those they do not wish to see. 3. The Tm will be available when only one pathogen assay is selected.	2
Bin Interpretation tab	The Bin Interpretation tab will only display under the Interpretation window for semi-quantitative panels. All positive assay results are selectable and will be displayed below the Melt Peaks Chart. 1. The Operator will select an assay from the Interpretation tab. The title for that assay will be displayed above the melt curve graph. 2. The operator can view all the pathogen assays available or deselect those they do not wish to see. 3. The Tm will be available when only one pathogen assay is selected **NOTE: Melt curves will not be shown for negative assays.**	N/A


Dashboard
Browse Runs
Settings
FilmArray Torch
Sample ID: TestSample1
Pouch Type: Pneumo v2.0
Serial Number: 1234567
Lot Number: 1234567
Control
Interpretation
Bin Interpretation
QSM
QSM
RNA Process Control
Fluorescence
Temperature
Tm: 84.91
Tm: 85.03
Tm: 85.03
QSM
POS


Dashboard
Browse Runs
Settings
FilmArray Torch
Sample ID: TestSample1
Pouch Type: Pneumo v2.0
Serial Number: 1234567
Lot Number: 1234567
Control
Interpretation
Bin Interpretation
Adenovirus
Adenovirus
Chlamydia pneumoniae
Coronavirus
CTX-M
Human Metapneumovirus
Human Rhinovirus/Enterovirus
IMP
Influenza A
Influenza B
KPC
Fluorescence
Temperature
Adenovirus7
POS
Adenovirus3
POS
Adenovirus2
POS

Browse Runs Options Menu

The Browse Runs options menu presents a list of actions the operator can use on BioFire Torch runs. The following table describes the available Browse Runs options:

Menu Item	Description
Export Anonymous Runs	Works like the Export Runs option, but removes Sample ID in the run file and replaces it with 'Anonymous'.
Export Runs	Enables the operator to write runs to a file while leaving the original runs in the database.
Import Runs	Enables the operator to import runs from a separate database into the database on the BioFire® System Base being used.
Save Reports	Enables the operator to save a report to a pdf.
Print Reports	Enables the operator to print the report.
View Control Results	Enables viewing and exporting of control results.

To access the Browse Runs options menu, select **Options** to bring up the Options menu.

Export Anonymous Runs

Anonymous run files are saved with extension .adb. If a copy of run files must be sent to an external site, this option protects patient confidentiality. To prevent operators from overwriting a run file with an anonymous run file, these files cannot be imported back into the database

To export anonymous runs to a file:

1. Select **Browse Runs** from the toolbar to display a list of runs in the database. Runs can be searched and filtered by selecting the search icon . See the *Search Run Data* section in this chapter for more information.
2. Select **Options** to view the Options menu; then select **Export Anonymous Runs**.
3. Select one or more desired runs on the Browse Runs page; then select **OK.**
4. Select a location and filename for the .adb file within the Specify Filename dialog. If multiple drives are available,select the destination.
5. Select **Save** to start the export process. The message **Exporting Runs...** appears during the exporting process.

NOTE: The operator can cancel the export process before it completes by selecting Cancel on the export process dialog. Any runs that were exported before selecting Cancel will be saved to the chosen location.

6. After export completion, a **Successfully Exported [n] Runs to File** message appears. Select **OK** to close the export process dialog.

Export Runs

When exporting runs, database files are saved with the extension .db. To export runs to a file:

1. Select **Browse Runs** from the toolbar to display a list of runs in the database. Runs can be searched and filtered by selecting the search icon . See the *Search Run Data* section in this chapter for more information.
2. Select **Options** to view the Options menu; then select **Export Runs**.
3. Select one or more desired runs on the Browse Runs page; then select **OK**.
4. Select a location and filename for the .db file within the Specify Filename dialog. If multiple drives are available, select the destination.
5. Select **Save** to start the export process. The message **Exporting Runs...** appears during the exporting process.

NOTE: The operator can cancel the export process before it completes by selecting Cancel on the export process dialog. Any runs that were exported before selecting Cancel will be saved to the chosen location.

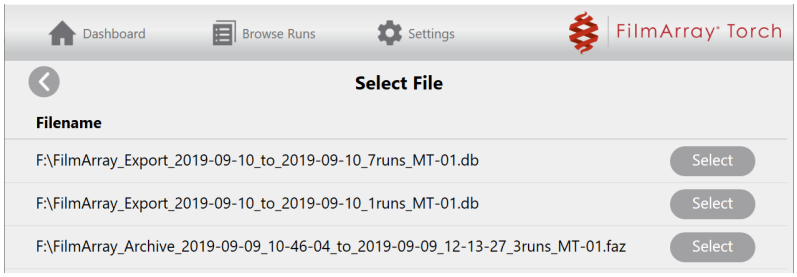
6. After export completion, a **Successfully Exported [n] Runs to File** message appears. Select **OK** to close the export process dialog.

Import Runs

When importing runs, database files with the extension .db are added.

This process can also be used to restore any archived files with the extension .faz. Prior to restoring archived runs, verify that there is sufficient room in the database. If the database is approaching 5,000 runs, see the *Archive Runs* section in this chapter for more information.

1. To import runs from a file: On the Browse Runs page, select **Options** to display the Options menu; then select **Import Runs**.



2. Select the runs needing to be imported (or restored) to start the import process.

NOTE: The operator can stop the import process before it completes by selecting Stop. Any runs that were imported before selecting Stop will be saved in the database.

3. After import completion, select **OK** to close the dialog. It is now safe to remove the drive(s) from the front of the System Base.

Save Reports

Refer to the Save Report section in this chapter for how to save a report.

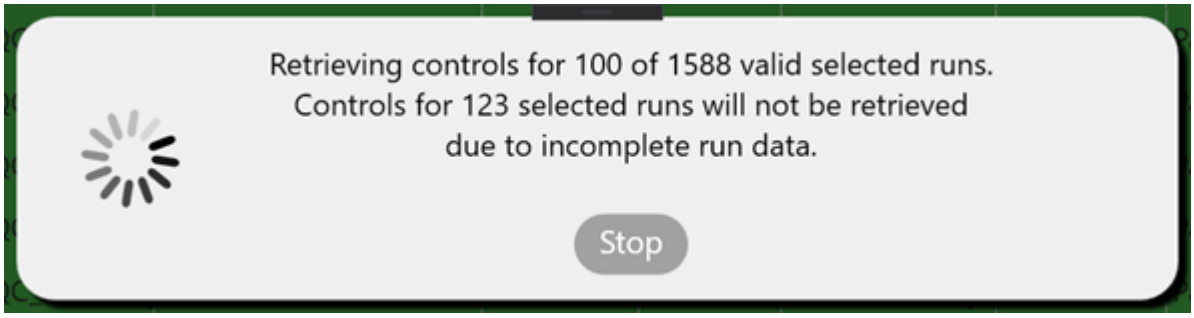
Print Reports

Refer to the Print Options section in this chapter for how to print a report.

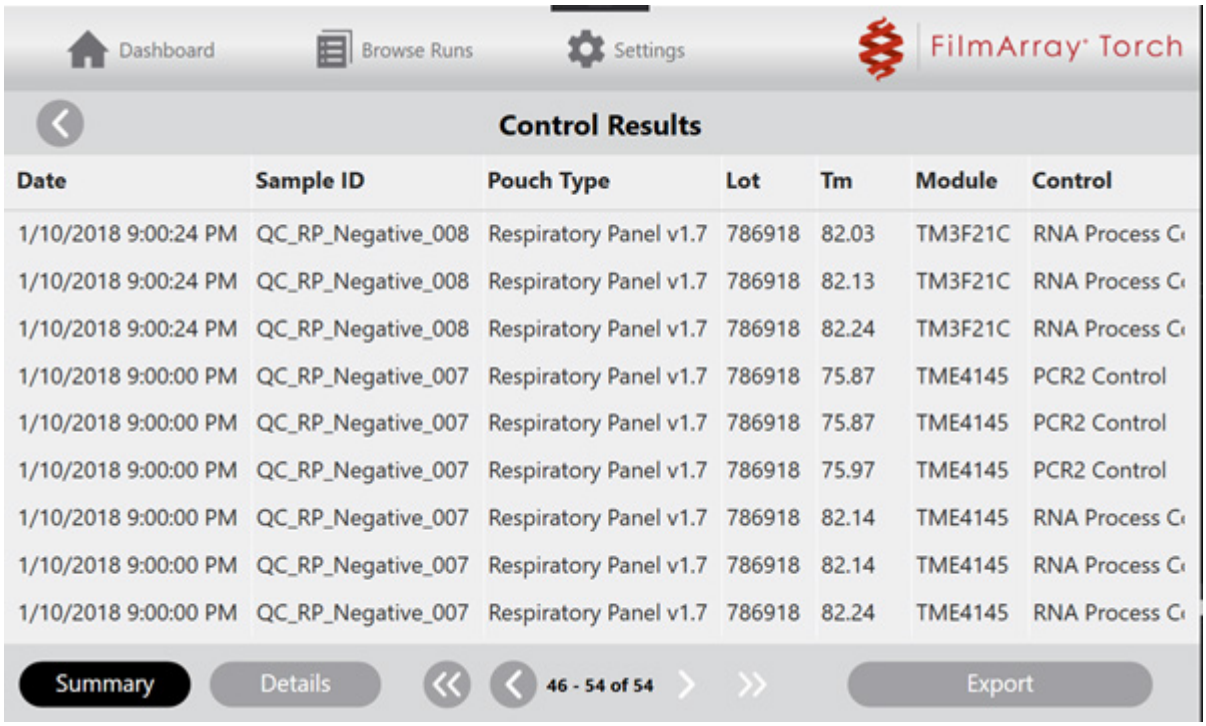
View Control Results

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 or to a network drive and imported into a different application, such as Microsoft Excel.

Once the runs are selected the operator will see a message indicating the control results are being retrieved. Incomplete runs will not have control results to be gathered and will not be retrieved.



The operator will be taken to the Control Results summary page. The summary page will display the Date, Sample ID, Pouch Type, Lot, Tm, module and the Control.



Date	Sample ID	Pouch Type	Lot	Tm	Module	Control
1/10/2018 9:00:24 PM	QC_RP_Negative_008	Respiratory Panel v1.7	786918	82.03	TM3F21C	RNA Process C
1/10/2018 9:00:24 PM	QC_RP_Negative_008	Respiratory Panel v1.7	786918	82.13	TM3F21C	RNA Process C
1/10/2018 9:00:24 PM	QC_RP_Negative_008	Respiratory Panel v1.7	786918	82.24	TM3F21C	RNA Process C
1/10/2018 9:00:00 PM	QC_RP_Negative_007	Respiratory Panel v1.7	786918	75.87	TME4145	PCR2 Control
1/10/2018 9:00:00 PM	QC_RP_Negative_007	Respiratory Panel v1.7	786918	75.87	TME4145	PCR2 Control
1/10/2018 9:00:00 PM	QC_RP_Negative_007	Respiratory Panel v1.7	786918	75.97	TME4145	PCR2 Control
1/10/2018 9:00:00 PM	QC_RP_Negative_007	Respiratory Panel v1.7	786918	82.14	TME4145	RNA Process C
1/10/2018 9:00:00 PM	QC_RP_Negative_007	Respiratory Panel v1.7	786918	82.14	TME4145	RNA Process C
1/10/2018 9:00:00 PM	QC_RP_Negative_007	Respiratory Panel v1.7	786918	82.24	TME4145	RNA Process C

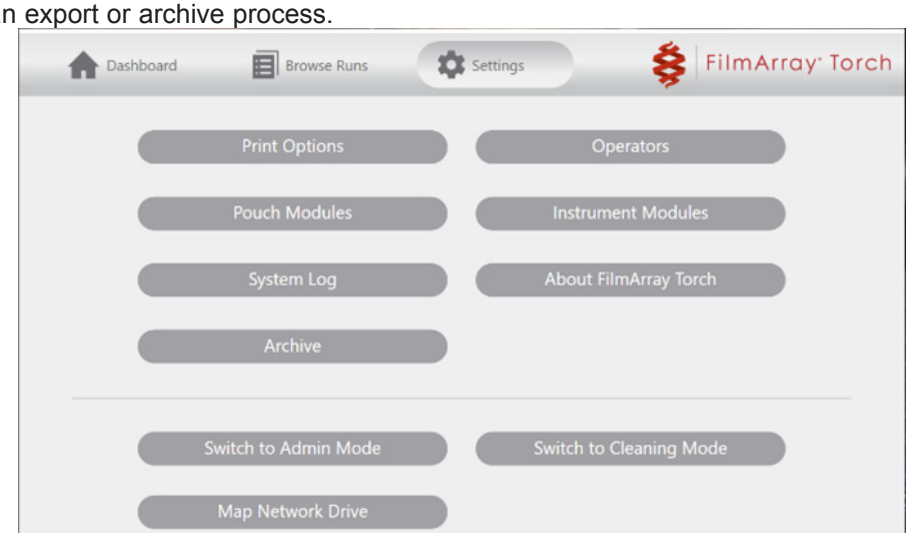
To see an expanded view of the control results the operator will select the Details button. The information on this screen will contain the following: Date, Sample ID, Pouch Type, Protocol, Lot, Serial, Tm, Operator, Module (Instrument), Pouch Status, Pouch Result, Control, Control Result, Assay and Melt Call. This is also the data that will be included in the .csv file for export.

Settings

The Settings option is always accessible from the toolbar. To access Settings, select the **Settings** option on the toolbar. The Settings option allows users to perform the following administrative type tasks:

- **Print Options** - Allows the operator to set or change a default printer as well as the option to have reports automatically printed.
- **Operators** - Displays all of the operators currently recognized in the software and allows for addition and modification of operators within the system.
- **Pouch Modules** - Displays all of the currently installed pouch modules within the software and allows for installation of new pouch modules, modification of their status (active/inactive), and removal.
- **Instrument Modules** - Displays high-level information for all of the Modules connected to BioFire Torch.
- **Archive** - Allows operators to archive old runs off BioFire Torch to a removable drive.
- **System Log** - Allows access to system logs for all Modules.
- **About FilmArray** - Displays details about BioFire Torch installation.
- **Switch to Admin Mode** - Allows an administrator to log out of the BioFire Torch Software and access the Windows OS to perform administrative tasks (such as software/firmware updates and printer maintenance).

- **Switch to Cleaning Mode** - Allows an operator to temporarily freeze the touch screen so the surface can be cleaned without activating any actions (see *Chapter 8, Preventative Maintenance and Troubleshooting*).
- **Map Network Drive** - Allows an operator to map to a network drive to be used when saving data in an export or archive process.



Print Options

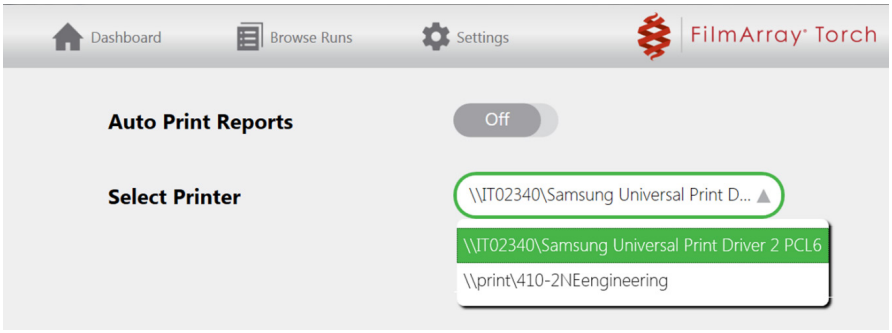
Any printer that has been configured to BioFire Torch can be selected as the default.

To set a default printer:

1. Select the **Select Printer** drop down box to display all printers configured to the System Base. The current default printer is highlighted green.
2. Select the applicable printer to set it as the default.

   The software updates the default printer and displays the new default within the Select Printer display box.

   To Auto Print Reports after a run, toggle the Auto Print Reports setting to On or Off.



Operators

An operator username and password are required to run a pouch on BioFire Torch.

The BioFire Torch Software prompts the operator to enter these credentials after a pouch has been inserted into an available Module and pouch information has been captured.

The Operators feature displays all current operators on BioFire Torch. This feature allows for the addition, modification, and/or deletion of operators. This feature will also allow for the importing of operators from another FilmArray database onto the Torch System. Operators can also be exported. The Export Operator 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 FilmArray Software on a different computer or Torch Base. The exported operator files are saved with the extension .fau.

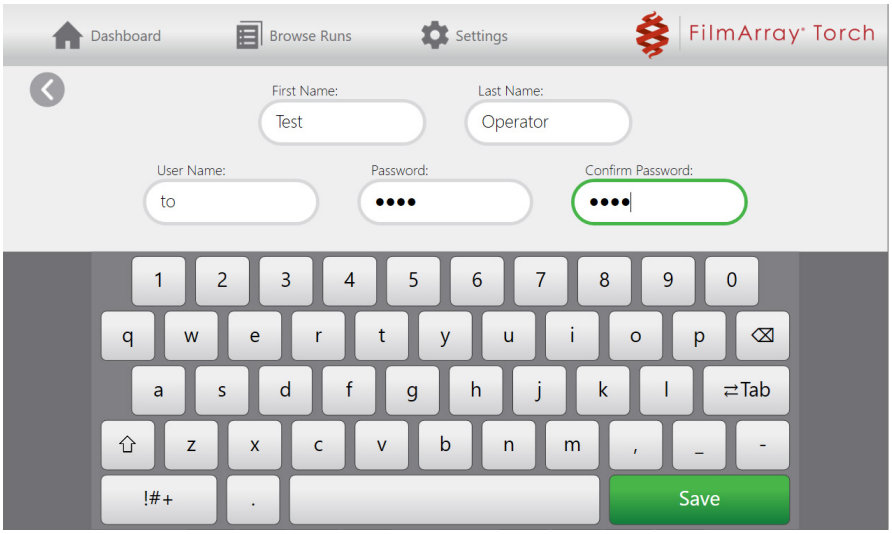
Create New Operator(s)

New operators are created in two ways:

- Within the Settings toolbar Operators menu option within the Settings toolbar.
- Before starting a run during the Enter Operator Information step.

Operators menu options:

1. Select the **Settings** options from the toolbar; then select **Operators**.
2. Select **Add Operator** at the bottom of the screen when the list of current operators display.
3. Enter the new operator's information in the following fields:
   - **First Name**
   - **Last Name**
   - **Username**
   - **Password**
   - **Save**

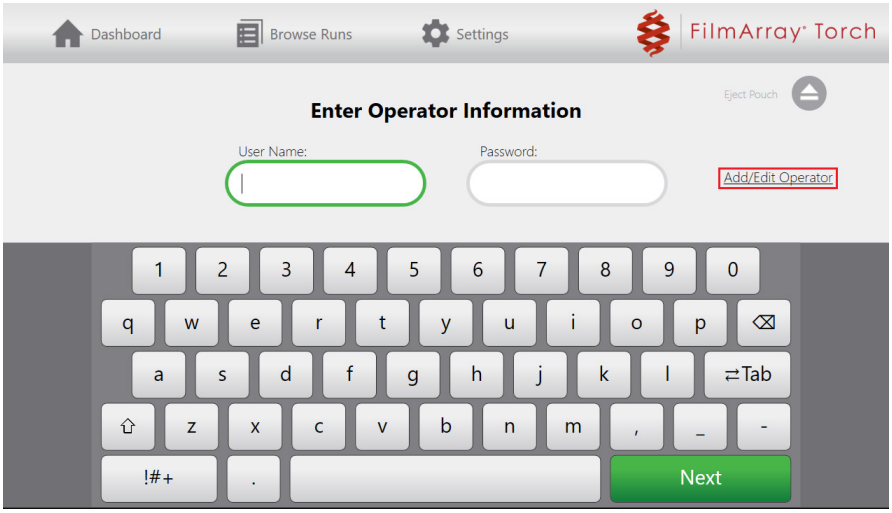


NOTE: The Confirm field will always display the password dots in red until the Password and Confirm fields match.

4. Select **Save** when complete.

Enter Operator Information step:

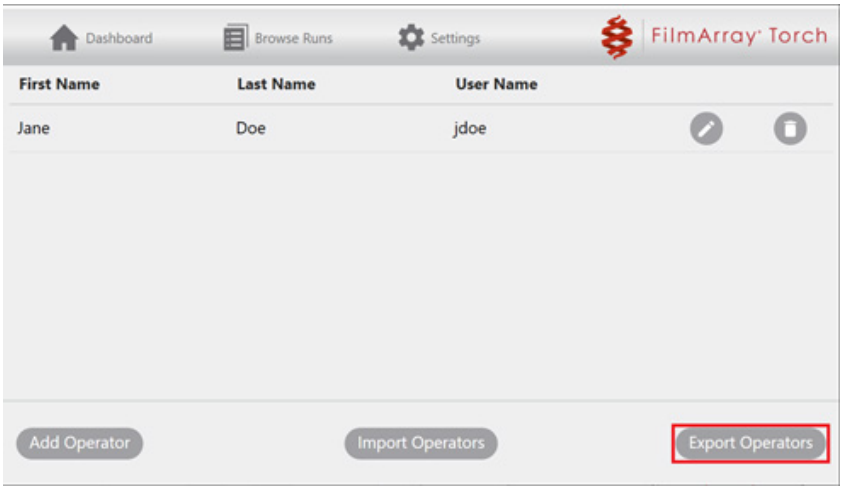
1. Select **Add/Edit Operator**.
2. Follow steps 3 and 4 in the previous instructions, *Create New Operator(s).*



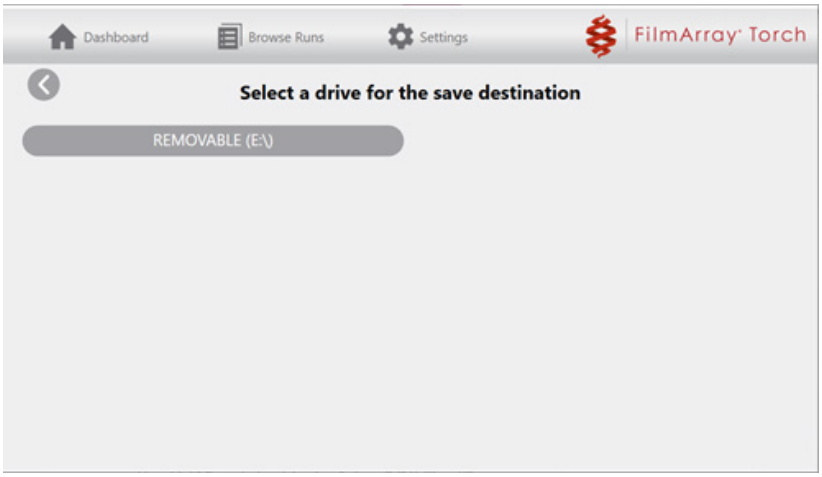
Export Operator(s)

1. Select the **Settings** options from the toolbar; then select **Operators**.

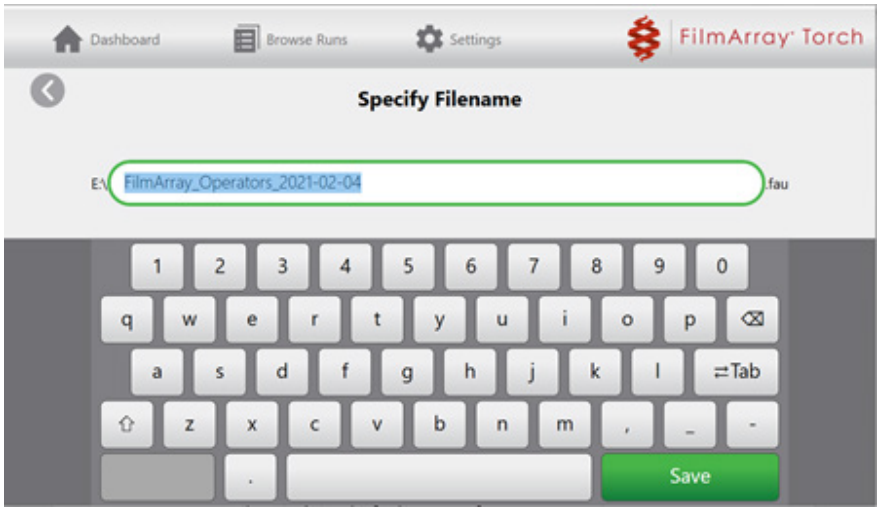
2. Select **Export Operators** at the bottom of the screen when the list of current operators display.



3. Select the drive destination to save the file.



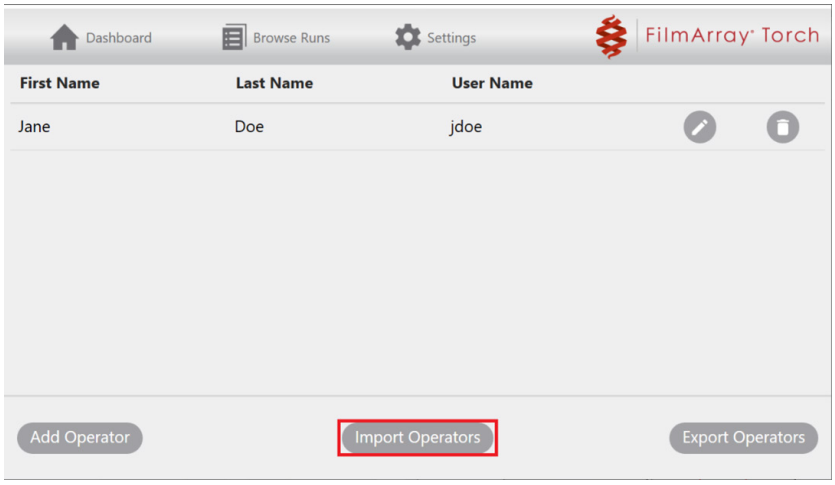
4. Select **Save**.



Import Operator(s)

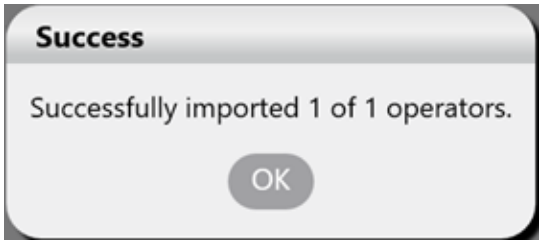
1. Select the **Settings** options from the toolbar; then select **Operators**.

2. Select **Import Operators** at the bottom of the screen when the list of current operators display.



3. Select the filename to import.

4. The system will indicate if the import was successful, select **OK**.



Pouch Modules

This feature enables the operator to install, and inactivate/uninstall pouch modules. These pouch modules contain definitions, protocols, analysis, and reporting for specific BioFire® Reagent Kits.

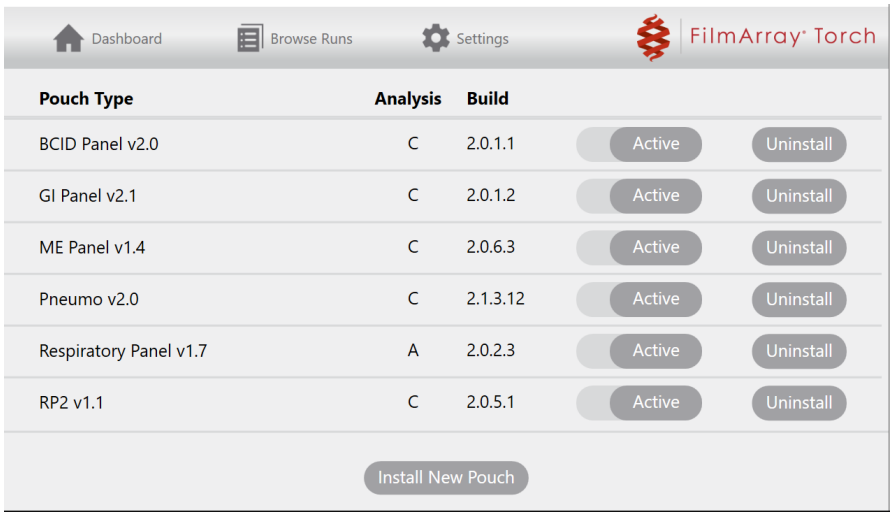
Install Pouch Modules

When new pouch modules are received from BioFire Diagnostics, the Pouch Modules option must be used on the BioFire Torch. For information on receiving new pouch modules, contact Customer Support (see *page i*).

To install a new pouch module:

1. Insert removable drive containing the pouch module software. One or more removable drives, (e.g. USB flash drives and external hard drives), can be connected to the USB ports on the System Base.
2. Navigate to the Settings menu from the toolbar.
3. Select **Pouch Modules**.

   All pouch modules currently installed display as Active.



4. Select **Install New Pouch** The software searches the root level of all connected removable drives and displays any detected pouch modules.

5. Select **Install** next to the desired pouch module. The new pouch module then displays with an Active status in the list of installed pouch modules to indicate that it is ready for use.

Inactivate/Uninstall Pouch Module

To inactivate a pouch module:

- Toggle the **Active** slider next to the pouch name to **Inactive**.

To uninstall a pouch module:

- Select **Uninstall** next to the pouch module name.

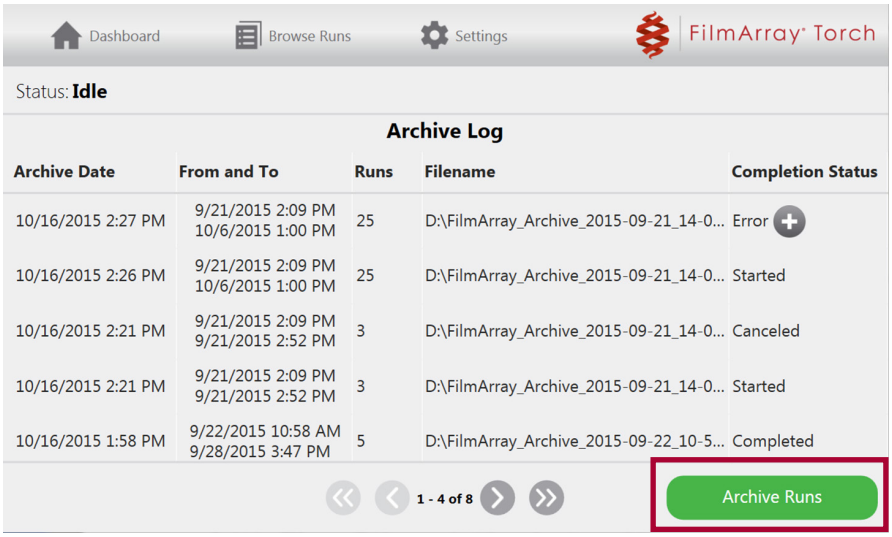
  When a pouch module in uninstalled, it is no longer available for selection when starting a run. To re-activate an uninstalled pouch module, it must be installed again.

Archive Runs

To archive runs stored in the BioFire Torch database:

1. Navigate to the Settings menu from the toolbar.
2. Select **Archive**.

   The Archive Log will display the current status of archives and a log of all previous archiving tasks.



3. Select **Archive Runs** to display a calendar.
4. Select a date parameter on the calendar. This parameter means that all runs on or before that date will be archived.

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.

5. Select **Next** to choose the location and filename for the archived runs. If multiple drives are connected to the USB ports on the System Base, select a destination device.

NOTE: By default, runs are saved to a file with the extension .faz. Filenames default to a name containing the date parameter and the name of the System Base being used.

NOTE: After selecting the file name, a message displays indicating that the selected runs will be deleted from the database.

6. Select **Yes** to launch the archiving process. The date and time of the start will be recorded in the Archive Log.

NOTE: The archive process executes in the background and the status of the archive is seen in the status message on the Archive Log page. The operator may navigate to the Dashboard to perform other tasks.

NOTE: The software verifies that all runs have been saved to the file, and then deletes each run from the database one at a time.

NOTE: When the archiving is complete, the date and time of the completion is logged and the archiving Status is set to Idle.

Abort Archive Process

It is safe to abort the archive process while runs are being saved. To abort:

- Select the **Cancel** status message; then select **Confirm**.

  The status message changes to Canceling Archive. The archive stalls and all runs remain in the database.

  When archive cancellation is complete, the date and time of the completion is recorded in the Archive Log and the archiving Status is set to Idle.

NOTE: It is not safe to abort the archiving process 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 System Base or switch to Admin Mode during the archiving process. Wait until the process is complete before shutting down the System Base 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 database by using Import Runs (see the *Import Runs* section in this chapter for more information).

Switch to Admin Mode

Logging into Admin Mode requires an administrative password. The BioFire Torch is pre-configured 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 LabAdmin user account.

Admin Mode tasks are specific to the Windows application; these include:

- Installing printers
- Updating software and applying security patches.

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

To access the main Windows application:

- Select **Settings** from the toolbar; then select **Switch to Admin Mode**.

This logs the user out of the BioFire Torch Software and allows for the admin user to log into Windows. Once logged in as the admin user, the normal Windows desktop is displayed with limited access to Windows tools and the Instrument Configuration application.

Printer Configuration

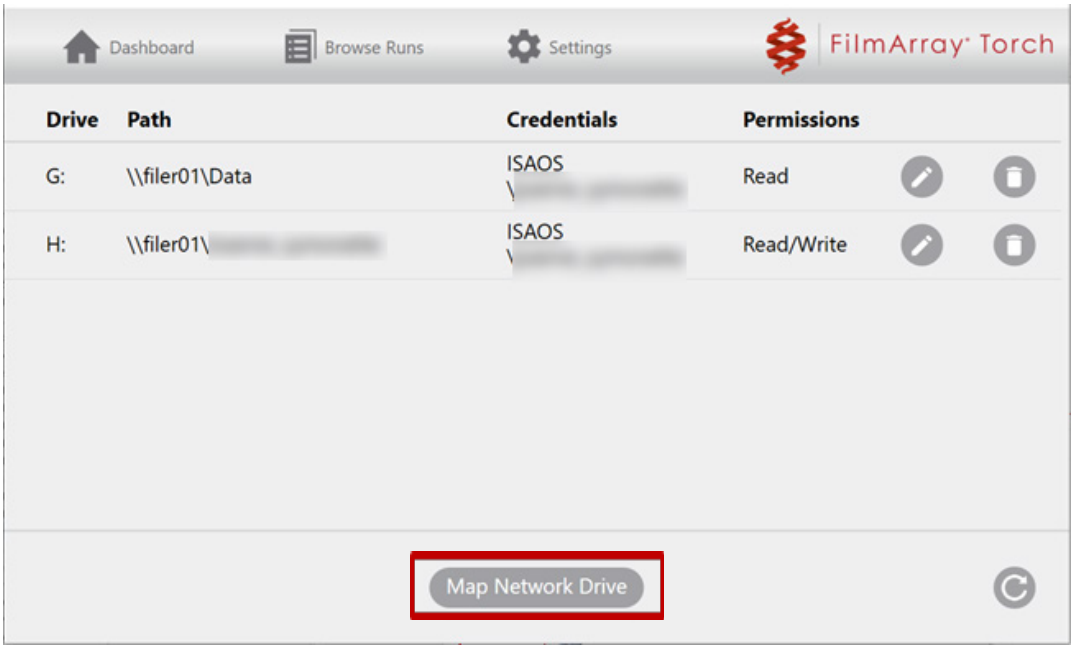
Adding and configuring printers to the BioFire Torch is done through Admin Mode using the standard Windows features.

Map Network Drive

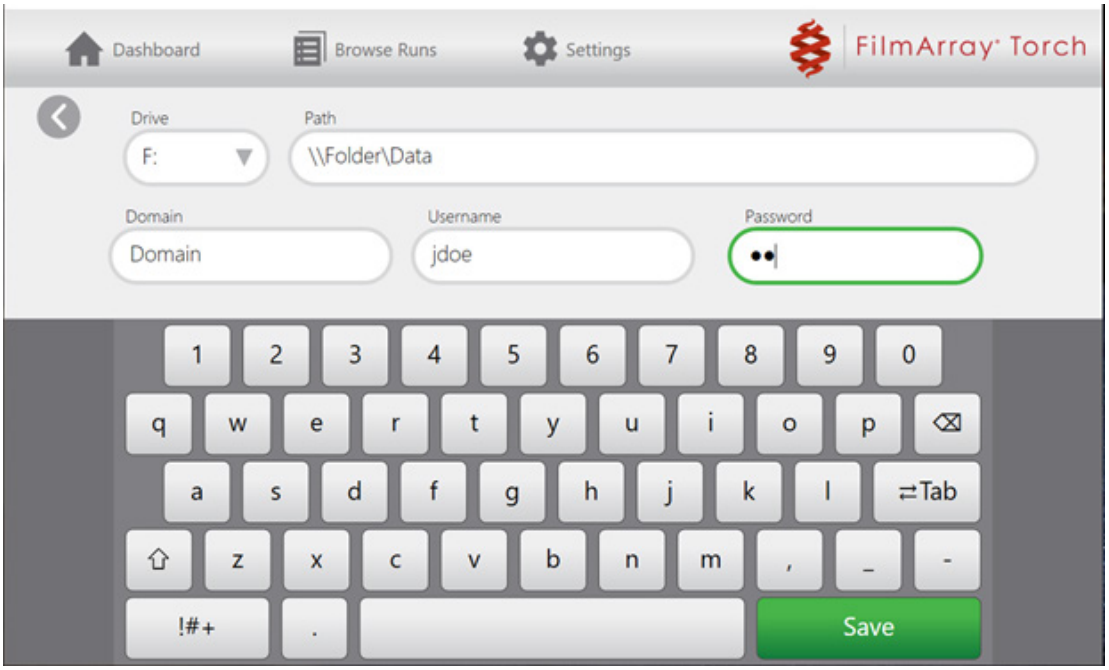
To map a network drive:

1. Select **Map Network Drive** option on the Settings menu.

2. Select Map Network Drive

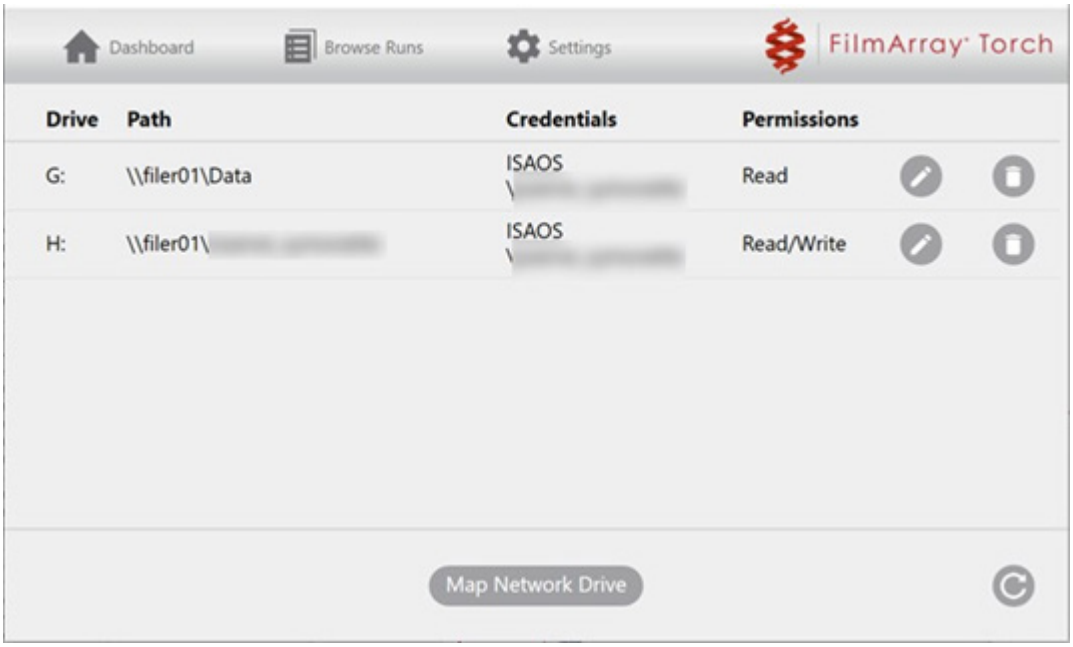


3. Fill out the Network Drive information.



4. Select **Save**.

After the network drive has been successfully connected, the Map Network Drive view will list all of the drives that have been mapped. The drive letter, network path, credentials for the folder and the folder permissions will be displayed for each Mapped Network Drive.



- To edit an established Network Drive select the edit button. 

- To remove a Network Drive select the delete button. 
- To refresh the Network Drive connection select. 

Database Management

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

The database stores up to 12,000 runs reliably. A warning appears when 5,000 runs are reached to encourage frequent archiving of data. For more information on archiving runs, see the *Archive Runs* section in this chapter.

NOTE: A database administrator is not required for the BioFire Torch System.

CHAPTER 7: PRECAUTIONS WHEN WORKING WITH THE BIOFIRE® SYSTEM

Laboratory Safety and Biohazards

General Safety Precautions

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

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

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

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

CAUTION: Before powering on the BioFire Torch System Base, ensure the On/Off Switches on all connected Modules are in the "off" position.

CAUTION: Do not attempt to lift or carry the BioFire Torch while Modules are installed. Remove all Modules prior to lifting or carrying the BioFire Torch System Base and always lift from the bottom.

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 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 BioFire® Reagent Kit instruction booklets for assay-specific safety precautions.

CAUTION: A tear in the pouch could contaminate the Module 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 BioFire Torch 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 leak or breakage occurs, 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 contaminate future pouch runs. This material, although noninfectious, is easily spread by normal human activity. Treat all broken pouches as capable of contaminating the work area. Very small (molecular) quantities can be amplified by PCR in future runs, which can then be identified as a false positive by the BioFire Torch.

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 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® FilmArray® Pouch Loading Station Decontamination

Routine cleaning of the BioFire Pouch Loading Station includes 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 lab coat and gloves.
2. Fill a sink or bin with water and add bleach to create a 10% bleach solution.
3. Submerge the BioFire Pouch Loading Station until completely covered with bleach solution. Soak for 15 minutes.
4. Remove BioFire Pouch Loading Station from sink or bin. Replace bleach solution with distilled water.
5. Rinse the BioFire 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 BioFire 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 BioFire Torch Module or potentially contaminated areas until the decontamination is complete.
3. Decontaminate the BioFire Torch Module and work area and dispose of the pouch using the following steps:
    a. Dispose of leaking pouch in a biohazard container.
    b. Dispose of potentially contaminated gloves and put on clean gloves.
    c. Dispose of the potentially contaminated lab coat.
    d. Put on clean PPE, such as a lab coat and gloves.
    e. Clean the Module and affected work areas following the guidelines below in Module Decontamination.

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

BioFire Torch Module Decontamination

1. Put on clean PPE, such as a lab coat and gloves.
2. Remove pouch from Module and dispose in biohazard waste container.
3. Dispose of potentially contaminated gloves and lab coat and put on clean gloves and lab coat.
4. Wet a paper towel with the 10% bleach solution and wipe all exterior surfaces of the BioFire Torch, including the bottom and the bench top where the BioFire Torch Module had contact. Let it stand for at least 3 minutes to allow the bleach solution to react with any contaminants. Discard paper towel in biohazard waste. Change gloves.

NOTE: When cleaning the touch screen, put the BioFire Torch into Cleaning Mode. The Cleaning Mode allows 30 seconds for the touch screen to be cleaned. Access this feature from the Settings toolbar (see *Chapter 8, Preventative Maintenance and Troubleshooting* for more information).

CAUTION: The interior of the pouch slot and Module(s) should not be cleaned. Do not spray or insert any cleaning materials into the Module.

5. Repeat Step 4 twice with fresh paper towels for a total of three bleach wipes.
6. Change gloves, then wet a new paper towel with distilled water and wipe the all exterior surfaces of the BioFire Torch. Dispose of paper towel in biohazard waste. Change gloves.
7. Repeat Step 6 with a new paper towel.
8. Remove Module front cover. Repeat Steps 3 through 7 for inner front cover surfaces and pouch slots.

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 BioFire Torch Module

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 Module 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 performing basic maintenance and troubleshooting for the BioFire Torch.

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.

In the event that an individual Module or the entire BioFire Torch is taken out of service, follow the *BioFire Torch Return Procedure* in *Appendix A*.

General Maintenance

There is weekly general maintenance needed for the BioFire Torch software and periodic cleaning steps listed below:

1. Wipe down all outside surfaces of the BioFire Torch 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.

NOTE: Do not remove the Module front cover and clean underneath it, except in the case of a contamination event.

2. Periodically check and clean the BioFire Torch Module's air filters for any build up and debris. Air filters can also be swapped out with the spare filters included with the BioFire Torch Module box (see *Chapter 2, BioFire Torch Setup*).

3. When cleaning the touch screen of the BioFire Torch, it is recommended that the BioFire Torch software be put into cleaning mode in order to avoid any accidental selections.

   This can be done by navigating to the Settings toolbar and selecting the **Switch to Cleaning Mode** option. After selecting a confirmation for this action, the screen will display a timer for 30 seconds that will temporarily freeze the screen and allow for cleaning of the surface.

Software Weekly Maintenance

It is recommended to reset the base on a weekly basis. If the System Base has not been reset for 15 days a warning message will be displayed reminding the operator to reset the System Base. This message will disappear when the operator hits the OK button but will reappear the next day until a reset has occurred. Press the reset button on the back of the System Base to reset.

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.

System Base Shutdown

If the system needs to be powered down for any reason, follow these steps:

1. Press the reset button on the back of the System Base.
2. Wait for the screen to go black, then switch off the power using the System Base On/Off Switch.
3. Remove the cable shrouds from the back of each Module and switch off the power to each Module using the Module On/Off Switch.

System Base Startup

If the system needs to be powered up, follow these steps:

CAUTION: Before powering on the BioFire Torch System Base, ensure the On/Off Switches on all connected Modules are in the "off" position.

1. Using the System Base On/Off Switch, press the "on" position. This will start the software automatically.
2. Once the software is displayed on the touch screen, switch on the power to each Module using the Module On/Off Switch .
3. Re-install the cable shrouds over the electrical cables.

Troubleshooting

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 BioFire Torch Module are not functioning properly	Retest sample in a new pouch.
		If controls continue to fail contact Customer Support.
Inadequate volume in Hydration Solution or Sample Buffer vials/ampoules	Evaporation or leakage	Discard vials/ampoules and obtain new ones.

Warning Messages

Warning Messages may originate in a BioFire Torch Module, in the software, or in communication between the two. These messages and the suggested actions are reported in the table that follows.

Warning Message	Possible Solution
The pouch has already been run - a pouch can only be used once.	Dispose of any pouch that has already been run in a BioFire Torch Module.
An attempt to leave the workflow has been made. If a pouch has been inserted the pouch will be ejected and Run Setup will have to be restarted. Do you wish to continue?	Select **Yes** to end the workflow. If a pouch has been inserted, it will eject from the Module. The ejected pouch may be used to begin another workflow.

Warning Message	Possible Solution
FilmArray Torch database has more than 5,000 runs on it. Please use the Archive feature within Settings to remove runs from the database and store them according to your data retention policy. Please contact FilmArray Customer Support if you require assistance.	Use the Archive Runs feature in the Settings tab to remove run files from the database. Contact Customer Support if the problem persists.
Auto Print Error. There is an error auto printing reports. See the System Log for details of affected runs.	The BioFire Torch Software could not find the default printer. Ensure printer is properly connected. Use Print Options on the Settings toolbar to select a new default printer or Admin Mode to add a new default printer. For more information see *Chapter 6*.
Printer Error. The report could not be printed	
System restart warning message. When instruments have not been reset a System Warning message will display the following: The FilmArray Torch Base has not been restarted for <n> days. Please restart the base soon.	Hit OK to close down the message. Reset the System Base.

Hardware Troubleshooting

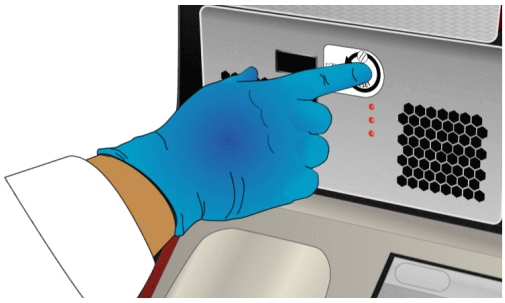
The table below lists potential symptoms and possible solutions for troubleshooting hardware issues with the BioFire Torch. If the issue(s) persists after applying the recommended solutions, contact Customer Support for further assistance (see page i).

Symptom	Possible Solution
BioFire Torch Module status lights are not on	• Turn Module on • Check power cord • Try different outlet • If problem persists, contact Customer Support
BioFire Torch Module status light is red	• Reset system using the reset button located on the rear of the System Base • Check and reconnect cables • If problem persists, contact Customer Support
BioFire Torch Module status light is blinking purple	• Remove and discard the pouch • Remove the front cover of the affected Module and reset the Module • If problem persists, contact Customer Support
Software will not connect to BioFire Torch Module	• Check cable connections • Turn off system and disconnect all cables • Reconnect all cables and turn system on • If problem persists, contact Customer Support
Pouch is not recognized when inserted into or removed from BioFire Torch Module	• Remove the front cover of the affected Module and reset the Module • If problem persists, contact Customer Support

Symptom	Possible Solution
Pouch is not recognized when inserted into BioFire Torch Module, due to jam	• Follow the software's on-screen instructions for recovery • If problem persists, contact Customer Support
Pouch is ejected immediately after insertion	• Remove the front cover of the affected Module and reset the Module • Check and reconnect cables • If problem persists, contact Customer Support
Pouch is difficult to insert into BioFire Torch Module	• Remove the front cover of the affected Module and reset the Module • If problem persists, contact Customer Support
Pouch does not eject from Module after run	• Remove the front cover of the affected Module and reset the Module • If problem persists, contact Customer Support
Software on the System Base crashes	• Reset the System Base using the reset button on the back of the System Base • If problem persists, contact Customer Support
Barcode will not scan	• Manually input the pouch serial number and lot number

Module Reset

If a Module needs to be reset, remove the magnetic front cover; then press and hold the Reset button until the light turns off.



Error Messages

Errors in the BioFire Torch may originate in a Module, 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.

The BioFire Torch 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.

If communication is lost between the Module and System Base during a run, the run will continue and data will be uploaded when communication is re-established.

Error Message	Possible Solution
Remove the magnetic front cover from the Module and press the Reset button. A white light on the Module indicates initialization which may take up to 2 minutes. If the problem persists, contact FilmArray Customer Support for assistance.	Follow the error message as directed. Contact Customer Support if the problem persists.
The FilmArray Torch 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. The message should be accompanied by a fast blinking green light on the Module. The light indicates that the pouch can be removed. Removing the pouch sets the Module into an Available state. Contact Customer Support if the problem persists.
Data Recovered. Data has been recovered from a FilmArray Torch Module that could not be processed. Please see the System Log for details. Please contact Customer Support for assistance.	Follow the error message as directed. Contact Customer Support if the problem persists.
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.	
The software for the scanned pouch is not installed or is inactive. Please install or activate the required pouch module.	Verify that the correct pouch module is installed and the correct barcode has been scanned for the pouch.
When the drive could not be mapped due to an incorrect domain user name and password the Map Network Drive Error dialog is displayed: Credentials could not be validated. Please verify path and credentials are valid.	Verify path and credentials and re-enter the information
When the drive could not be mapped dur to an incorrect server name or main directory is invalid, the following dialog is displayed: Unable to map to the specified network path as one or more directories in the path do not exist. Please verify the network path is valid.	Find a valid directory and re-enter the path and credentials

Error Message	Possible Solution
When the drive could not be mapped a Map Network Drive Error will display: Unable to map to the specified network path. Please verify that your firewall allows shared folder access.	Verify the firewall allows access and re-enter the information.
When a network path cannot be mapped the Map Network Drive Error is displayed: The Network Drive is already mapped with different credentials. Remove the following mapped network drive(s) before adding new credentials: <Drives to remove>.	Use a network drive that had not been mapped with different credentials. Update the existing drive.
When a network path cannot be mapped the Confirm is displayed: The target server is already mapped using different credentials. Do you want to replace the existing credentials?	Use a network drive that had not been mapped with different credentials. Update the existing drive.

Diagnostic Errors

Diagnostic errors are used by Customer Support representatives to troubleshoot BioFire Torch problems. See the *System Log* section in this chapter for details on accessing diagnostic error information.

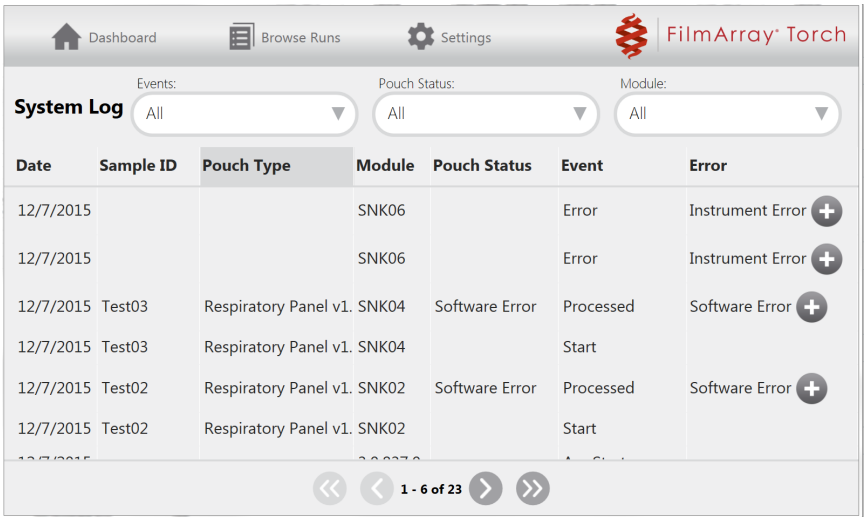
The table that follows lists potential error messages and possible solutions. If the error(s) persists after applying the recommended solutions, contact Customer Support for further assistance. Before contacting Customer Support, write down all error messages, the serial numbers of the System Base, affected Module(s), and pouch lot numbers. Customer Support will use this information to identify and resolve the error(s).

Error Message	Possible Solution
1012 Pouch Not Present	• Remove the magnetic front cover and press and hold the Reset button until the light turns off. • A white light on the Module indicates initialization which may take up to 2 minutes. • If the problem continues, please contact Customer Support for assistance.
1014 Failed to Find Run Data	
1015 Failed to Read Run Data	
2003 Thermoboard is not present	
2004 Valve board is not present	
3001 Valve Board Response Timeout	
3002 Valve Board Malformed Response	• Remove the magnetic front cover and press and hold the Reset button until the light turns off. • A white light on the Module indicates initialization which may take up to 2 minutes. • If the problem continues, please contact Customer Support for assistance.
3003 Valve Board Command Error Response	
3004 Thermocycler Board Response Timeout	
3005 Thermocycler Board Malformed Response	
3006 Thermocycler Board Command Error Response	
4001 Pressurization failed	
7001 Camera Initialization Error	
7003 Failed Excitation Check	

Error Reporting Tools

System Log

The error messages may refer to the System Log for details depending on the error and is accessed via the Settings option. When the System Log is opened, the following is displayed. Select the plus icon  to view additional information regarding the error.



Data Bundle

A Customer Support representative may request the operator to create and provide a data bundle to assist in troubleshooting.

To create a data bundle:

1. Select the **Browse Runs** option from the toolbar.
2. Select the desired run.
3. Select **View Report** to open the report page; then select **Actions**.

4. Select **Export Data Bundle** menu item. A dialog displays the drive path(s) and file name(s).
5. Navigate to a file location to save the zipped error bundle.
6. Select **Save**.
7. When the error bundle is complete, a message will indicate that the error bundle has been created.
8. Email this file to the Customer Support representative to diagnose errors.

CHAPTER 9: BIOFIRE TORCH CYBERSECURITY

The BioFire Torch System 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 Torch System 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 Torch 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 Torch. Prior to delivery, BioFire Diagnostics verifies that the computer is free of malicious software.

The BioFire Torch 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 account 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.

Introduction of malicious software to the BioFire Torch may result in loss of functionality and/or compromised data. In an effort to maintain integrity of the BioFire Torch:

- 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 by or recommended by BioFire Diagnostics.

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

APPENDIX A: BIOFIRE SUPPORT INFORMATION

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

BioFire Torch Module Return Procedure

If returning a BioFire Torch Module from within the United States, visit the Return Forms and Decontamination Procedures webpage:

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

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

Disposal Recommendation

Components of the BioFire Torch such as the BioFire Torch Module, the BioFire Torch System Base, 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 old product, please contact local city office or waste disposal service; or BioFire Diagnostics Customer Support Department, a local bioMérieux sales representative, or an authorized distributor.

BioFire Ordering Instructions

Customers inside the United States should contact BioFire Diagnostics to order any BioFire® System 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 scanner is not functioning, calibrate it by scanning the barcodes shown below to program the barcode scanner.

1. 

2. 

BIOFIRE®

BY BIOMÉRIEUX

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