BIOMÉRIEUX

BIOFIRE® SPOTFIRE®
System

Operator's Manual

For *in vitro* Diagnostic Use - EN

IVD

UK CA CE

Table of Contents

General Information

This document is used solely for the purpose of SPOTFIRE System operation.

Always maintain the System in good working order. If the System 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.

Intellectual Property

E-Labeling Information

The operator's manual and other relevant items for this product can be accessed online at the links below.

BIOFIRE® SPOTFIRE® Operator's Manual	http://www.biofiredx.com/e-labeling/ITI0127
BIOFIRE® SPOTFIRE® Instrument Setup Quick Guide	http://www.biofiredx.com/e-labeling/ITI0149

Customer Technical Support

Customer Technical Support for U.S. Customers	

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Reach Us by Email
   BioFireSupport@biomerieux.com
 	
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	   +1-801-582-0636
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	   +1-801-588-0507

Customer Technical Support Outside of the U.S.	
Contact the local bioMérieux sales representative or an authorized distributor for technical support.	

NOTE FOR CUSTOMERS WITHIN THE EUROPEAN UNION (EU): Any serious incident that has occurred in relation to the device must be reported to BioFire Diagnostics, LLC or a local bioMérieux sales representative and the competent authority of the Member State in which the user and/or the patient is established.

1 SPOTFIRE System

Intended Purpose

Intended Use

The SPOTFIRE System is an automated *in vitro* diagnostic (IVD) device intended for use with compatible BIOFIRE® IVD Panels to detect multiple nucleic acid targets contained in patient specimens. The SPOTFIRE System interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex polymerase chain reaction (nmPCR) in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The software automatically determines the results and provides a test report.

The SPOTFIRE System is composed of one to four BIOFIRE® SPOTFIRE® Modules connected to a BIOFIRE® SPOTFIRE® Control Station running BIOFIRE® SPOTFIRE® Software. Each Module can be randomly and independently accessed to test a reagent pouch. The software controls the function of each Module and collects, analyzes, and stores data generated by each Module.

Intended User and Use Environment

The SPOTFIRE System is intended for use by medical and/or laboratory professionals in professional healthcare facilities, such as physician offices, clinics, long-term care facilities, laboratories, and hospitals.

Limitations for Use

- For prescription use only.

- The SPOTFIRE System is intended to be used in combination with BIOFIRE IVD Panels that are compatible for use on the SPOTFIRE System.

- The SPOTFIRE System is not intended to be used outdoors or with mobile applications.

- Do not remove the Module front cover during a test.

- Use only the supplied cables when connecting any Module to the Control Station.

- Do not use cable extenders to increase cable length.

  - The use of a surge protection device is permitted.

- Do not modify the computer parameters unless authorized to do so. For example:

  - 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 remove the default Windows® user accounts.

  - Do not modify the SPOTFIRE System database or other pre-installed software.

- Do not re-test a pouch associated with an error, incomplete test, or invalid result.

- Only authorized service personnel should perform service or repairs on the SPOTFIRE System.

- Do not move the Control Station or Modules while the system is running.

- Do not change the settings on the SPOTFIRE System during a test.

- Do not shut down the SPOTFIRE System while the system is archiving tests.

- Do not use near active high frequency surgical equipment, the shielded room of an MRI system, or other locations where electromagnetic disturbances are high.

- Do not place the SPOTFIRE System in an area with synthetic materials that may cause damaging electrostatic discharge such as carpet, as this may cause erroneous results.

SPOTFIRE System Overview

The SPOTFIRE System is composed of a Control Station (pre-loaded with SPOTFIRE Software) and up to four Modules. The system is used in combination with specific BIOFIRE® Panels (described in the section above) and panel-specific software. A full list of SPOTFIRE System components is included in Chapter 2, *SPOTFIRE Components and Setup*, and specific step-by-step operating instructions can be found in Chapter 5, *SPOTFIRE Software*.

Module
Interacts with the reagent pouch to purify and amplify targeted nucleic acid sequences

Control Station
Includes touchscreen user interface
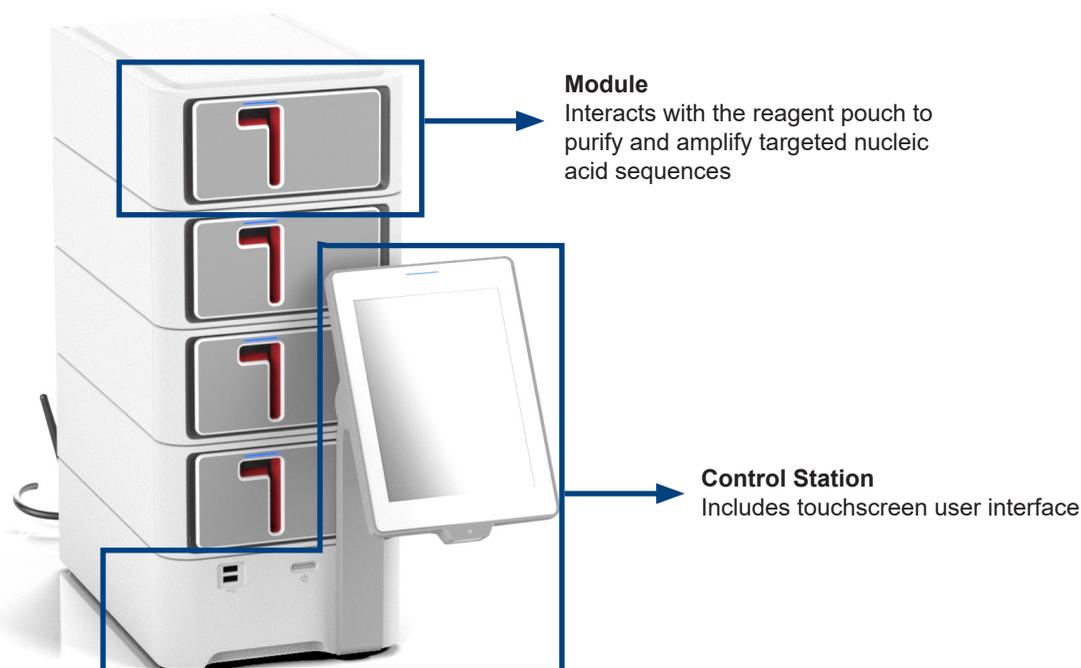
BIOFIRE Panel Pouch Preparation

Refer to the Procedure section of the appropriate BIOFIRE Panel Instructions for Use for step-by-step instructions for sample and pouch preparation.

SPOTFIRE System Tests

The SPOTFIRE System is used in combination with compatible BIOFIRE Panel pouches to perform tests that detect multiple nucleic acid targets contained in a sample. The SPOTFIRE System interacts with the pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR in a closed system.

The SPOTFIRE Software includes a detailed workflow that guides the operator through a test. 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 Module, and start the test. For more information on starting a test, see Chapter 4, *SPOTFIRE System Operating Instructions*.

Module and Pouch Interaction

Performing a test on the SPOTFIRE System requires a BIOFIRE Panel reagent pouch (a component of the BIOFIRE Panel reagent kit). Each pouch is a self-contained, closed-system disposable pouch that contains chemistry that enables nucleic acid from a patient sample to be isolated, amplified, and detected.

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

The pouch is composed of the following:

(A) Fitment and Pouch Label: The rigid plastic portion of the pouch is called the fitment. The fitment has reservoirs that contain freeze-dried reagents.

(B) Plastic Film Pouch: The flexible plastic film portion of the pouch is divided into distinct areas (blisters). These blisters are where the following chemical processes are performed:

(C) Nucleic Acid Extraction and Purification: Nucleic acids from a patient sample are extracted and purified by mechanical lysis (bead beating) and magnetic bead technology.

(D) Reverse Transcription and First-stage Multiplex PCR: The nucleic acids are amplified in first-stage multiplex PCR (including reverse transcription of target RNAs when appropriate).

(E) Second-stage Singleplex PCR: The nucleic acids are further amplified in second-stage singleplex PCR. The nucleic acids are then identified through melting analysis within the multi-well array.
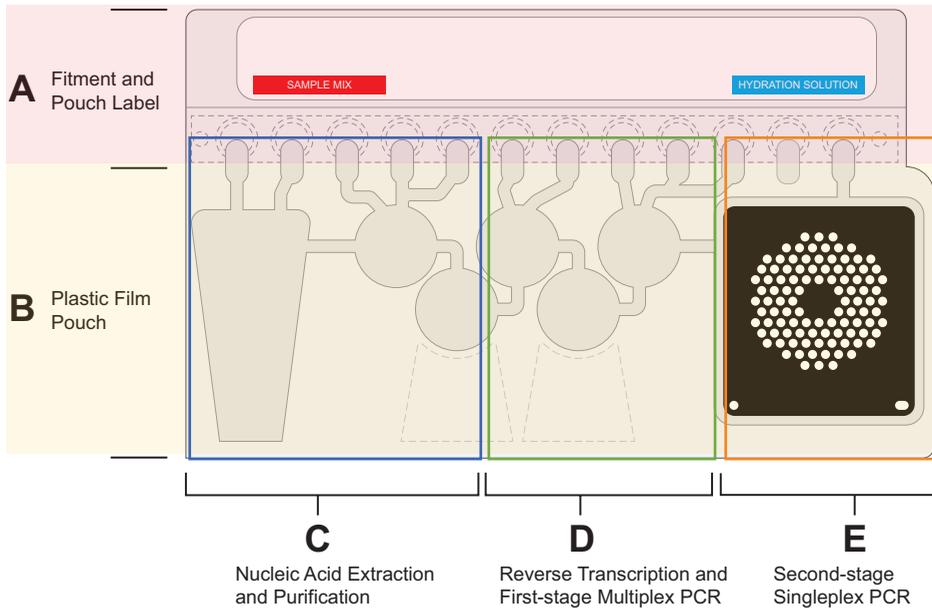
Each BIOFIRE Panel pouch contains an internal process control. The control material is lysed and its nucleic acids are extracted along with the nucleic acids of the patient sample. When the internal control is positive, it indicates proper operation of the Module and chemical processes.

BIOFIRE Panel Software

Each pouch requires pouch-specific panel software to be installed on the SPOTFIRE System in order to perform a test. The panel software contains definitions, protocols, analysis, and reporting for specific BIOFIRE Panels.

Optics and Imaging

The SPOTFIRE System uses DNA melting curve analysis to identify specific PCR products. The SPOTFIRE System captures images of DNA melting curves by slowly increasing the temperature of the PCR array and using a camera to capture the fluorescent signal emitted by LCGreen® Plus dye. These images are processed automatically by the Control Station, and the data is analyzed to determine if the control passed and which targets were detected.

The Module optics system is aligned, focused, and calibrated at the factory. Proper operation and calibration of Module optics is monitored by the Module self-tests and internal pouch controls.

SPOTFIRE Software Overview

The SPOTFIRE Software is integrated in the Control Station and is used to operate the Module(s), save tests to the database, and view the results of the tests via the computer touch screen. The software user interface component guides the operator through the various workflows to deliver a result. For more detailed information about the features and operation of the SPOTFIRE Software, see Chapter 5, *SPOTFIRE Software*.

Symbols Glossary

The following symbols may be located on the Module(s), the Control Station, associated BIOFIRE Panel reagent kits, or throughout this manual. Use the definitions below to interpret the symbols.

	Manufacturer		Date of Manufacture
	Use By (YYYY-MM-DD)	LOT	Batch Code (Lot Number)
SN	Serial Number		Do Not Use if Package Is Damaged
	Keep Dry		Temperature Limit
	Biological Risks		On
	Off		Fuse
	Protective Ground	∼	Alternating current
	Caution, risk of electric shock		USB Cable
	Antenna		Computer Network
c(UL)us LISTED	Underwriter's Laboratory Listing Mark		European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) - Do not throw in trash
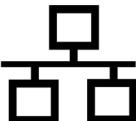
	Consult Instructions for Use	**EC** | **REP**	Authorized representative in the European Community
IVD	*In vitro* Diagnostic Medical Device	CE	European Union Conformity
UKCA	UKCA - UK Conformity Assessed	EU	European Union Product Importer
⚠	Caution	**UDI**	Unique Device Identifier
	Giteki Mark		

2   SPOTFIRE System Components and Setup

SPOTFIRE System Components

Each SPOTFIRE System comes with a Control Station, one or more Modules, and corresponding accessories (accessories may vary by region).

Control Station Box Components
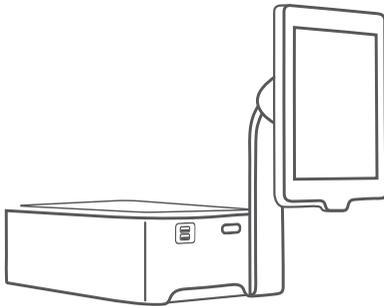
Control Station*

Antennas (2)
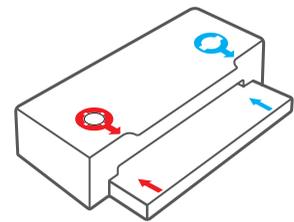
Pouch Loading Station (2)
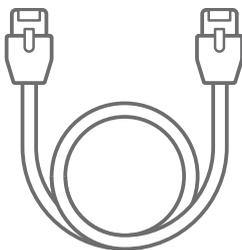
Ethernet Cable
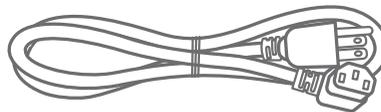
Power Cord†

*The SPOTFIRE Software comes pre-installed on the Control Station.

†One Power Cable included. Power Cord type is dependent on region and may look different than the pictured cable.

Module Box Components
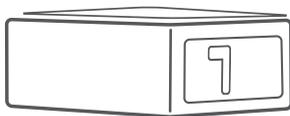
Module
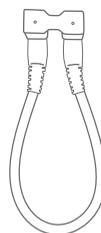
Module Connection Cable

Setup Requirements

Select a clean, well-ventilated area large enough to fit the SPOTFIRE System. The diagrams below show the minimum spaces required for a Control Station with one to four Modules to maintain the performance listed in Chapter 3, *Performance Specifications*, allow for sufficient venting, and provide access to the AC power switch.

CAUTION: Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional radio frequency sources); degradation of device performance could result. The SPOTFIRE System is intended to perform according to the claimed test error rates. If performance is lost or degraded due to electromagnetic disturbances, the operator may see increased test error rates (i.e., increase of false positive, false negative, or no result errors).

The SPOTFIRE System should not be used any closer than 30 cm. (12 in.) to any of the following:
- Portable RF communications equipment (including cellular phones and peripherals such as antenna cables and external antennas)
- Other sources of strong RF radiation (including RFID readers and wireless charging devices)
- The SPOTFIRE System should not be used any closer than 7.62 cm. (3 in.) from the wall.

Refer to the Limitations for Use for additional sources of electromagnetic disturbance that should be avoided.
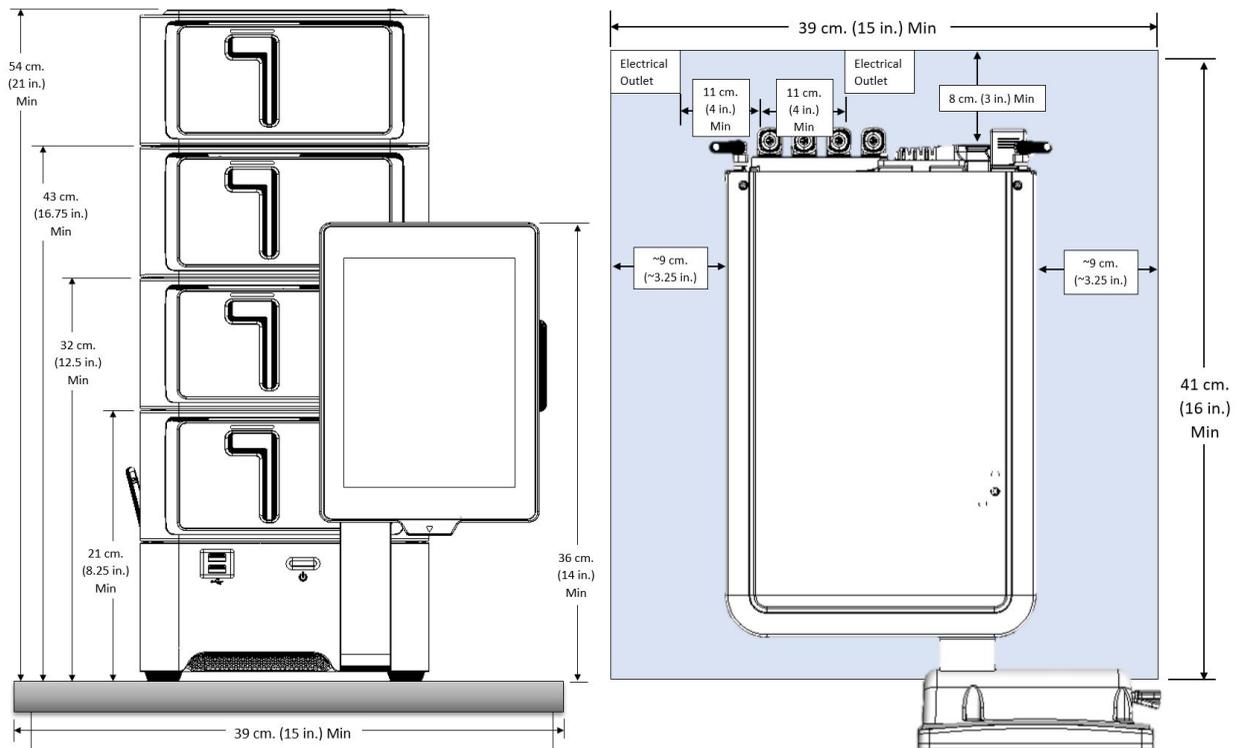
Note: *The SPOTFIRE System utilizes compressed air for device operation. As air is compressed, moisture is released from the air and may collect inside the SPOTFIRE's pneumatic system. A small diffusing vent is located on the rear of the Module, allowing the Module to release any accumulated moisture.*

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

CAUTION: Any liquid spilled on the system may result in the system malfunctioning.

Minimum Power Specifications:

Configuration	Voltage	Frequency	AC Power at 100 VAC		AC Power at 240 VAC	
			Active	**Apparent**	**Active**	**Apparent**
1 Module	100-240 VAC	50-60 Hz	117 W	121 VA	101 W	148 VA
2 Modules			188 W	192 VA	173 W	216 VA
3 Modules			259 W	264 VA	237 W	277 VA
4 Modules			328 W	333 VA	304 W	341 VA
Grounded outlet required						

The SPOTFIRE System is safe to operate under main supply voltage fluctuations up to ±10% of the nominal voltage.

The SPOTFIRE System should be connected to an outlet with a circuit breaker having an interrupt rating ≥1500A. If unsure whether the circuit breaker meets this requirement, check with a licensed electrician.

• AC Power Cord: Only use the power cord that has been provided by the manufacturer. Using a non-approved cord may result in a risk of fire or improper operation of the SPOTFIRE System.

• Surge Protection: A surge protection device is recommended in locations that are prone to frequent voltage surges or unstable power distribution systems.

• Power Interruption: In locations that experience frequent power interruptions, it is recommended that the SPOTFIRE System is connected to an Uninterruptable Power Supply (UPS).

• Internet Connectivity: The SPOTFIRE System is a standalone device that does not require internet connectivity to function. However, the SPOTFIRE System does support internet connectivity.

Note: *A single IEEE 802.1x Ethernet is sufficient for optional bidirectional connectivity with a data manager and/or allowing BioFire Diagnostics or an authorized distributor to securely connect to the SPOTFIRE System through the internet.*

• Electromagnetic Environment: The SPOTFIRE System complies with the emission and immunity requirements in IEC 60601-1-2 and IEC/EN 61326-2-6. The electromagnetic environment should be evaluated prior to operating the device.

SPOTFIRE System Installation

> ⚠️ **CAUTION:** Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation. Do not use cable extenders to increase cable length. Use only supplied antennas. Do not connect to coaxial cable or substitute antenna.

1. Remove all components from the Control Station box.

2. Place the Control Station in desired location (see Setup Requirements section above).

3. Attach one antenna to each antenna port. Rotate each antenna outward 45°.

4. Ensure power switch is turned off, then plug power cord into Control Station. Wait to plug power cord into an electrical outlet until setup is complete.
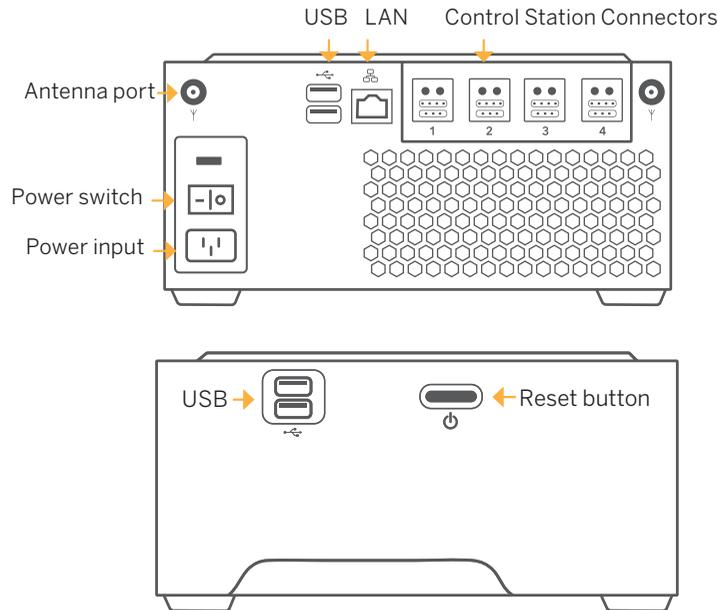
5. Remove all contents from the Module box(es).

6. Remove the shipping guard from the pouch slot.

7. Install Module(s).

    a.) Stack the first Module on top of the Control Station, fitting the guide pins into the wells on the Control Station or Module below. The operator will feel tactile feedback (i.e., the Module will click into place) when the Module is stacked correctly.
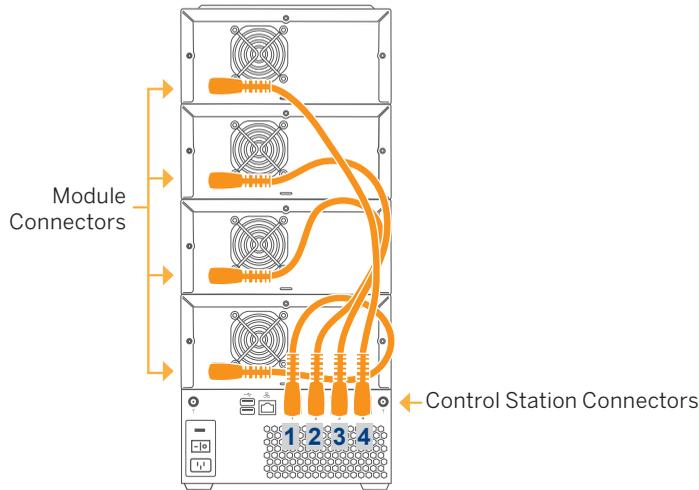
b.) Repeat for additional Modules.

⚠️ **CAUTION:** Four is the maximum number of Modules supported. To maintain proper performance, only Modules should be stacked on top of the Control Station. Do not add more than four Modules, and do not place any items on top of the stack (regardless of number of Modules installed).

Use of this equipment adjacent to other equipment could result in improper operation. Use of this equipment stacked with other equipment could result in improper operation or a tipping hazard. Refer to the Setup Requirements section above for required clearances.

8. Connect each Module to the back of the Control Station with included Module Connection Cable.

   a.) The Control Station Connectors are labeled 1-4.

   b.) It is best practice to connect the Modules in the arrangement shown below. The Module stacked directly on top of the Control Station is plugged into the #1 Control Station Connector, the second Module is plugged into #2, etc.
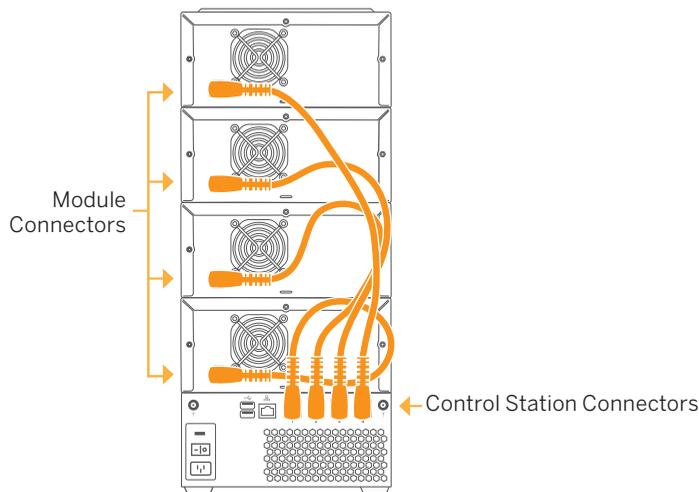
9. If using a hard-wired connection, plug the Ethernet cable from the Control Station into an Ethernet port.

Note: *WiFi connectivity is provided for the purpose of connecting the SPOTFIRE System to a local network. If a reliable WiFi connection cannot be established, the wired Ethernet port should be used to provide the connection.*

10. Plug the Control Station power cord into a properly grounded outlet complying with local electrical code.

11. Turn the SPOTFIRE System on using the main power switch on the back of the Control Station. Check that the SPOTFIRE Software powers on.

Note: *Should assistance be needed with installation, a BioFire Diagnostics-appointed specialist can be requested.*

SPOTFIRE Module Removal

1. Shut down the SPOTFIRE System as described in the *SPOTFIRE System Shutdown or Restart* section.

2. Disconnect the Module Connection cable(s) connecting the Module(s) to the Control Station.

3. Gently lift the top Module upward, making sure the guide pins disengage from the wells. Repeat until the desired Module has been removed.

Note: *If installing a replacement Module, install using the steps in the previous sections.*

SPOTFIRE System Setup

Once all Modules have been physically connected to the Control Station, the SPOTFIRE System can be set up for use.

Note: A Module must be connected to the Control Station before the software can be used to initiate and perform tests.

Initial Setup

When an operator turns on the SPOTFIRE System for the first time, the following screen will appear:

1. Select the **Get Started** button to create the SpotFire Administrator operator.

2. Create password and select **Save**.

Create Admin Account

The first step in getting your new system up and running is to set up the SpotFire Administrator operator. The SpotFire Administrator operator will have administrator-level privileges and cannot be deleted.

Operator ID: SFAdmin

Password

⊗ 6-32 characters

Confirm Password

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

| q | w | e | r | t | y | u | i | o | p | ⌫ |

| a | s | d | f | g | h | j | k | l | ⇤ |

| ⇧ | z | x | c | v | b | n | m | , | . | ⇧ |

| # + = | | Save |

3. Set the Time Zone, Time, and Date. Press **Save** to continue.

4. The "Initial Setup Complete" screen will appear. Press the **Done** button which will restart the Control Station. You will be prompted to log in after the restart.

Initial Setup Complete

Congratulations, you have completed the initial setup!

Select the "Done" button at the bottom of this screen to restart the control station. You will be prompted to log in after the restart.

Done

Create Operators

Once the SpotFire Administrator operator is created in the step above, please create at least one more Administrator operator using the following steps:

1. Log into the System, if necessary, and navigate to the Settings tab.

2. Select **Operator Management**.
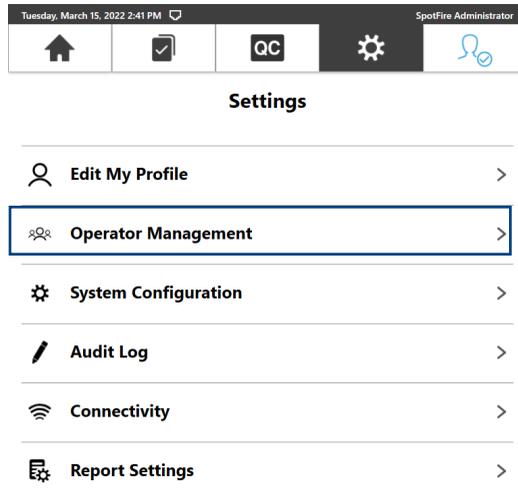
3. Select **Operator List**.

4. Select the **Add Operator** button.

5. Assign an Operator ID, and select the Admin Operator toggle if applicable. Enter the Operator's details, including First and Last Name. Assign a temporary password.

6. Press **Save** to complete.

Operator Login

To log in to the SPOTFIRE System, tap anywhere in the software. Enter the Operator ID and Password and press **Done**.
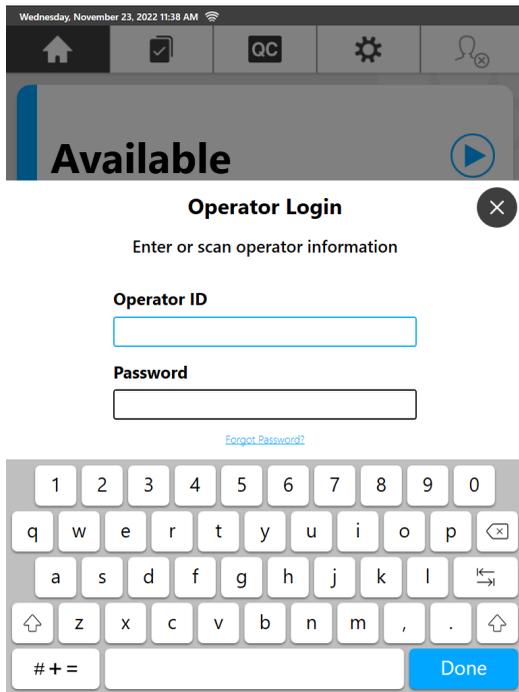
Home Screen

The Home Screen is split into boxes that represent the physical locations for all installed Modules. Each Module that is currently configured to the SPOTFIRE System displays within a box and shows the status of the Module. The SPOTFIRE System will automatically detect the relative position of each Module in the hardware stack.
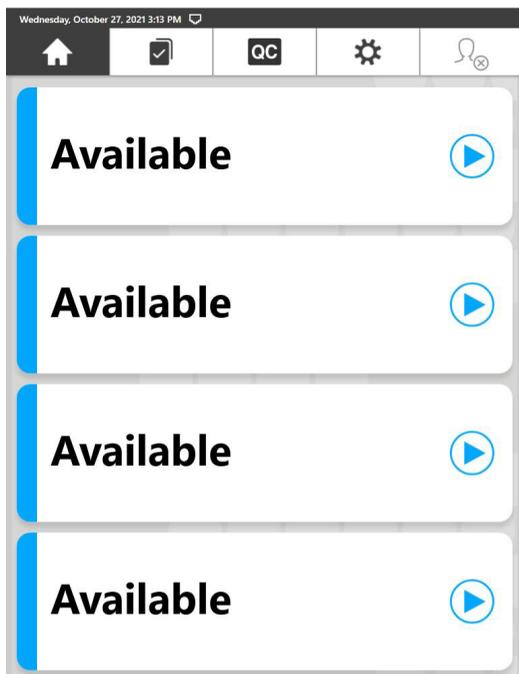
SPOTFIRE Module Status

The front of each Module is equipped with an LED light that shows the specific status of that Module.
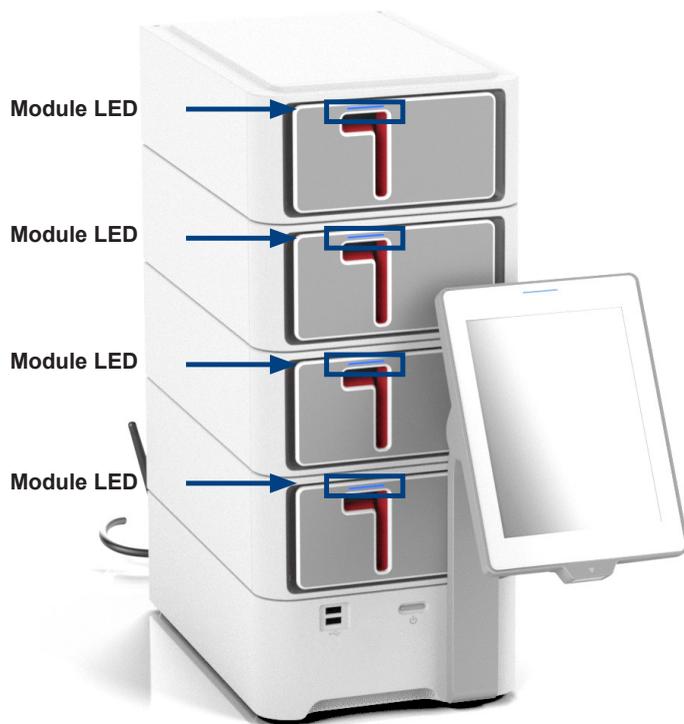
LED Color	Status	Meaning(s)
White	Solid	Module initializing
		Module restarting
		Firmware upgrade in progress
		Module Diagnostic Self Tests in progress
Blue	Solid	Module idle and available to test a pouch
	Blink	Module waiting for operator to insert a pouch
Green	Solid	Pouch test in progress
	Blink	Test complete – waiting for operator to remove pouch
Amber	Solid	Module error, follow on-screen instructions
	Blink	Waiting for operator action for: • Pouch insertion errors (unknown pouch, double insertion, pouch jam) • Other Module errors

SPOTFIRE System Shutdown or Restart

1. Login to the SPOTFIRE System.

2. Select the Access Control icon in the navigational header.

3. Press the **Shutdown** or **Restart** button, as desired.
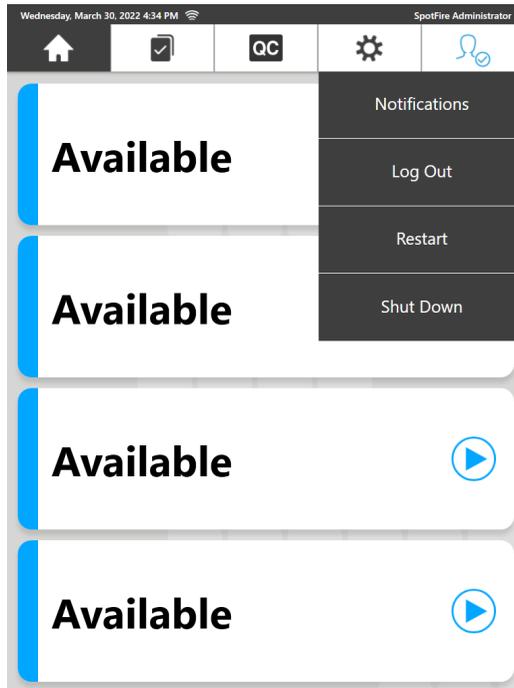
4. If shutting down, turn off the main power switch on the back of the Control Station **after** the Control Station has been powered off.

Note: *Shutting down the SPOTFIRE System without using the software will result in an improper shutdown detected dialog being shown the next time the system is powered on. We recommend the system to be shut down through the software.*

Note: *It is recommended to restart the Control Station on a weekly basis.*

3   SPOTFIRE Performance Specifications

SPOTFIRE System Specifications

Sample Description	One pouch capacity per Module (with a maximum of 4 Modules per SPOTFIRE System)
Test Time	Refer to the appropriate BIOFIRE Panel Instructions for Use (IFU)
Maximum Noise Level	< 85 dB at 1 m from SPOTFIRE System
User Interface	Control Station with touch screen and barcode scanner
Fluorescence Acquisition	Single color optics Module: 420 nm–470 nm excitation, 520 nm–570 nm emission, and sensor imaging
Temperature Control	Peltier devices: • PCR temperature range 40°C–105°C • PCR melt rate from 0.1°C–2°C /sec
Operating Specifications	• 15°C–30°C @ 15–80% relative humidity (non-condensing) • -50 ft (-15 m) to 10,000 ft (3,048 m) operating altitude • Indoor, stationary use only
Shipping/Storage Specifications	• -8°C–38°C @ 5–85% relative humidity (non-condensing)

Power Requirements

Configuration	Voltage	Frequency	AC Power at 100 VAC		AC Power at 240 VAC	
			Active	Apparent	Active	Apparent
1 Module	100-240 VAC	50-60 Hz	117 W	121 VA	101 W	148 VA
2 Modules			188 W	192 VA	173 W	216 VA
3 Modules			259 W	264 VA	237 W	277 VA
4 Modules			328 W	333 VA	304 W	341 VA
Grounded outlet required						

Overvoltage	Category II
Fuse	(2) 250V 10A Type T (Control Station) 5x20 mm Ceramic Cartridge Fuses
Dimensions and Weight	Dimensions: • Control Station Only (W x D x H): 8.52 x 12.77 x 3.82 in (21.64 x 32.43 x 9.70 cm) • Modules Only (H): 4.13 in (10.49 cm) • Max Height (4 modules): 21.0 in (54 cm) Weight: • Maximum Total Weight: Approximately 74 lbs. (33.6 kg) • Control Station: 18 lbs. (8.2 kg) • Modules: 14 lbs. (6.4 kg) each
CPU	• Intel® Atom x7-E3950
Storage and Memory	• 250 GB or greater solid-state hard drive • 8 GB RAM

Interfaces and Peripherals	Control Station • 4 internal IEEE 802.3 compliant 10/100/1000 Ethernet connections (to connect Modules only) • 1 external IEEE 802.3 compliant 10/100/1000 Ethernet connection (RJ-45) • Dual band IEEE 802.11n and 802.11ac (WiFi) compliant network connection (2.4 GHz and 5 GHz ISM Bands) • 4 USB 2.0 compliant Type A connections Display • 8.4 in diagonal (21.3 cm) • 1280 x 768 resolution or greater • Touch screen interface
	Control Station Power Entry Module • Current rating: 10 A • Voltage rating: 100 to 240 VAC • NEMA 5-15R receptacle (straight) • Dual fuse cartridge
	Module • One IEEE 802.3 compliant 10/100/1000 Ethernet connection
	Module Connection Cable • 10 pin RA connector • 17.17 ±0.39 in. (436 ±10mm) length
	CAUTION: Compliance to EMC standards may be affected if the following cables or accessories are replaced with non-approved cables or accessories: • Power Cable: Only use the Power Cable supplied with the SPOTFIRE System. Contact Customer Technical Support for a replacement. • Wireless Antenna: Only use antennas supplied with the SPOTFIRE System. Contact Customer Technical Support for a replacement.
Pollution Degree	Pollution Degree II
Operating System	Microsoft® Windows® OS as released with the SPOTFIRE System
Cybersecurity	See *Chapter 8, Cybersecurity FDA Statement*

WiFi Specifications

General Specifications

	2.4 GHz Band	5 GHz Band
Supported Standards	802.11b, 802.11g, 802.11n	802.11a, 802.11n, 802.11ac
Transfer Rate	802.11b: 11.0 / 5.5 / 2.0 / 1.0 Mbps 802.11g: 54.0 / 48.0 / 36.0 / 24.0 / 18.0 / 12.0 / 9.0 / 6.0 Mbps 802.11n: up to 300.0 Mbps	802.11a: 54.0 / 48.0 / 36.0 / 24.0 / 18.0 / 12.0 / 9.0 / 6.0 Mbps 802.11n: up to 300.0 Mbps 802.11ac: up to 866.7 Mbps

Country-Specific Specifications

United States

	2.4 GHz Band	5 GHz Band
Output Power	213.21 mW	207.999 mW for 5180 ~ 5240 MHz 206.26 mW for 5260 ~ 5320 MHz 207.629 mW for 5500 ~ 5720 MHz 208.731 mW for 5745 ~ 5825 MHz
Operating Frequencies	2412 ~ 2462 MHz	5180 ~ 5240 MHz 5260 ~ 5320 MHz 5500 ~ 5720 MHz 5745 ~ 5825 MHz
Channels	1-11 (HT20), 3-9 (HT40)	5180 ~ 5240 MHz 36, 40, 44, 48 (VHT20) 38, 46 (VHT40) 42 (VHT80) 5260 ~ 5320 MHz 52, 56, 60, 64 (VHT20) 54, 62 (VHT40) 58 (VHT80) 5500 ~ 5720 MHz 100, 104, 108, 112, 116, 120, 124, 128, 132, 136, 140, 144 (VHT 20) 102, 110, 118, 126, 134, 142 (VHT40) 106, 122, 138 (VHT80) 5745 ~ 5825 MHz 149, 153, 157, 161, 165 (VHT 20) 151, 159 (VHT40) 155

Canada

	2.4 GHz Band	5 GHz Band
Output Power	213.21 mW	69.2 mW for 5180 ~ 5240 MHz 83.791 mW for 5260 ~ 5320 MHz 207.629 mW for 5500 ~ 5720 MHz 208.731 mW for 5745 ~ 5825 MHz
Operating Frequencies	2412 ~ 2462 MHz	5180 ~ 5240 MHz 5260 ~ 5320 MHz 5500 ~ 5720 MHz 5745 ~ 5825 MHz

Channels	1-11 (HT20), 3-9 (HT40)	5180 ~ 5240 MHz 36, 40, 44, 48 (VHT20) 38, 46 (VHT40) 42 (VHT80) 5260 ~ 5320 MHz 52, 56, 60, 64 (VHT20) 54, 62 (VHT40) 58 (VHT80) 5500 ~ 5720 MHz 100, 104, 108, 112, 116, 132, 136, 140, 144 (VHT 20) 102, 110, 134, 142 (VHT40) 106, 138 (VHT80) 5745 ~ 5825 MHz 149, 153, 157, 161, 165 (VHT 20) 151, 159 (VHT40) 155

European Union, Hong Kong

	2.4 GHz Band	**5 GHz Band**
EIRP Power	19.70 dBm	22.44 dBm for 5180 ~ 5250 MHz 19.70 dBm for 5250 ~ 5320 MHz 19.74 dBm for 5500 ~ 5700 MHz
Operating Frequencies	2412 ~ 2472 MHz	5180 ~ 5250 MHz 5250 ~ 5320 MHz 5500 ~ 5700 MHz
Channels	1-13 (HT20), 3-11 (HT40)	5180 ~ 5320 MHz 36, 40, 44, 48, 52, 56, 60, 64 (VHT20) 38, 46, 54, 62 (VHT40) 42, 58 (VHT80) 5500 ~ 5700 MHz 100, 104, 108, 112, 116, 120, 124, 128, 132, 136, 140 (VHT 20) 102, 110, 118, 126, 134 (VHT40) 106, 122 (VHT80)

Japan

	2.4 GHz Band	5 GHz Band
Radiated RF Output Power Density	16.147 mW/MHz for 802.11b 16.273 mW/MHz for 802.11g 16.145 mW/MHz for 802.11n (HT20) 8.028 mW/MHz for 802.11n (HT40)	9.848 mW/MHz for 802.11a W52 4.89 mW/MHz for 802.11a W53 23.187 mW/MHz for 802.11a W56 9.452 mW/MHz for 802.11ac (VHT20) W52 4.789 mW/MHz for 802.11ac (VHT20) W53 22.842 mW/MHz for 802.11ac (VHT20) W56 4.942 mW/MHz for 802.11ac (VHT40) W52 2.342 mW/MHz for 802.11ac (VHT40) W53 11.337 mW/MHz for 802.11ac (VHT40) W56 2.386 mW/MHz for 802.11ac (VHT80) W52 1.142 mW/MHz for 802.11ac (VHT80) W53 5.523 mW/MHz for 802.11ac (VHT80) W56
Operating Frequencies	2412 ~ 2472 MHz	5180 ~ 5320 MHz 5500 ~ 5700 MHz
Channels	1-13 (HT20), 3-11 (HT40)	5180 ~ 5320 MHz 36, 40, 44, 48, 52, 56, 60, 64 (HT20 and VHT20) 5500 ~ 5700 MHz 100, 104, 108, 112, 116, 120, 124, 128, 132, 136, 140 (HT20 and VHT20) 102, 110, 118, 126, 134 (VHT40) 106, 122 (VHT80)

Chile

	2.4 GHz Band	5 GHz Band
Output Power	202.552 mW	206.545 mW for 5180 ~ 5240 MHz 202.453 mW for 5260 ~ 5320 MHz 199.216 mW for 5500 ~ 5720 MHz 198.421 mW for 5745 ~ 5825 MHz
Operating Frequencies	2412 ~ 2462 MHz	5180 ~ 5240 MHz 5260 ~ 5320 MHz 5500 ~ 5720 MHz 5745 ~ 5825 MHz
Channels	1-13 (HT20), 3-11 (HT40)	5180 ~ 5240 MHz 36, 38, 40, 42, 44, 46, 48 (VHT20) 34, 38, 46 (VHT40) 42 (VHT80) 5260 ~ 5320 MHz 52, 54, 56, 58, 60, 62, 64 (VHT20) 54, 62 (VHT40) 58 (VHT80) 5500 ~ 5720 MHz 100, 102, 104, 106, 108, 110, 112, 114, 116, 118, 120, 122, 124, 126, 128, 132, 134, 136, 138, 140, 142, 144 (VHT20) 102, 110, 118, 126, 134, 142 (VHT40) 106, 122, 138 (VHT80) 5745 ~ 5825 MHz 149, 151, 153, 155, 157, 159, 161, 163, 165 (VHT20) 151, 159 (VHT40) 155 (VHT80)

SPOTFIRE System Regulatory Compliance

Safety Requirements	The SPOTFIRE System complies with the applicable requirements of: • IEC 61010-1:2017, Safety requirements for electrical equipment for measurement, control, and laboratory use-Part 1: General requirements • IEC 61010-2-010:2019, Particular requirements for laboratory equipment for the heating of materials • IEC 61010-2-101:2018, Particular requirements for in vitro diagnostic (IVD) medical equipment
Hazardous Substances and Chemical Substances	The SPOTFIRE System complies with the requirements of: • EC 1907/2006 • 2011/65/EU

SPOTFIRE System Electromagnetic Compatibility (EMC)

Standard or Regulation	Description	Test Level
IEC 60601-1-2:2014 (Edition 4.0)	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance –Collateral Standard: Electromagnetic disturbances – Requirements and tests	Home Healthcare Environment, Class B emissions
IEC 61326-1:2012 (Edition 2.0)	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	Class B emissions
IEC 61326-2-6:2012 (Edition 2.0)	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment	Class B emissions
EN 61326-1:2013 (Edition 2.0)	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	Class B emissions
EN 61326-2-6:2013 (Edition 2.0)	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment	Class B emissions
ETSI EN 301 893 V2.1.1 (2017-05)	5 GHz RLAN; Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU	N/A
ETSI EN 300 328 V2.2.2 (2019-07)	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonized Standard for access to radio spectrum	N/A
EN 62311:2008	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz to 300 GHz)	N/A
KDB 447498 D01	RF Exposure procedures and equipment authorization policies for mobile and portable	FCC Part 2 (Section 2.1091)
IEEE C95.3-2002	IEEE Recommended Practice for Measurements and Computations of Radio Frequency Electromagnetic Fields With Respect to Human Exposure to Such Fields, 100 kHz-300 GHz	FCC Part 2 (Section 2.1091)

Manufacturer's Declaration – Electromagnetic Emissions	
Emissions Test	**Compliance**
RF Emissions EN 55011:2015+A1:2016 (CISPR11)	Group 1 Class B
RF Emissions ANSI C63.4:2014	Class B
AC Conducted Emissions EN 55011:2015+A1:2016 (CISPR11)	Group 1 Class B
Wire Network Port Conducted Emissions EN 55032 (CISPR 32)	Class B
Harmonic Distortion IEC 61000-3-2	Compliant
Voltage Fluctuations and Flicker IEC 61000-3-3	Compliant

Manufacturer's Declaration – Electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2 Compliance Level**	**EN/IEC 61326-2-6 Compliance Level**
Electrostatic Discharge IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air (Home Healthcare Environment)	± 2 kV, ± 4 kV contact ± 2 kV, ± 4 kV, ± 8 kV air
Radiated RF EM Fields IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz (Home Healthcare Environment)	3 V/m (80 MHz to 1 GHz) 3 V/m (1,4 GHz to 2 GHz) 1 V/m (2,0 GHz to 2,7 GHz)
Proximity Fields from RF Wireless Communications Equipment IEC 61000-4-3	Compliant	N/A
Electrical Fast Transients / Bursts (Input AC Power) IEC 61000-4-4	± 2 kV	1 kV
Electrical Fast Transients / Bursts (USB, Ethernet Ports) IEC 61000-4-4	± 1 kV	0.5 kV
Electrical Fast Transients / Bursts (USB, Ethernet Ports) IEC 61000-4-4	± 1 kV	0.5 kV
Surges Line-to-Line (Input AC Power) IEC 61000-4-5	± 0.5 kV, ± 1 kV	1 kV
Surges Line-to-Ground (Input AC Power) IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV	2 kV
Conducted Disturbances Induced by RF Fields (Input AC Power, USB, Ethernet Ports) IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	3 V 150 kHz to 80 MHz

Manufacturer's Declaration – Electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2 Compliance Level**	**EN/IEC 61326-2-6 Compliance Level**
Rated Power Frequency Magnetic Fields IEC 61000-4-8	30 A/m	30 A/m
Voltage Dips IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % during 1 cycle 40 % during 5/6 cycles 70 % during 25/30 cycles
Voltage Interruptions IEC 61000-4-11	0 % UT; 250/300 cycles	Less than 5 % during 250/300 cycles
RFID Immunity AIM 7351731	Compliant	

FCC Warning

Any changes or modifications not expressly approved by the party responsible for compliance could void the operator's authority to operate the equipment.

FCC Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC Compliance

1. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the operator is encouraged to try to correct the interference by one of the following measures:

   • Reorient or relocate the receiving antenna.

   • Increase the separation between the equipment and receiver.

   • Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

   • Consult the dealer or an experienced radio/TV technician for help.

2. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

3. This device meets all the other requirements specified in Part 15E, Section 15.407 of the FCC Rules.

4. Radiation Exposure Statement:
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 cm between the radiator and your body.

Industry Canada Statement

This device complies with ISED's licence-exempt RSSs. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Le présent appareil est conforme aux CNR d' ISED applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) le dispositif ne doit pas produire de brouillage préjudiciable, et (2) ce dispositif doit accepter tout brouillage reçu, y compris un brouillage susceptible de provoquer un fonctionnement indésirable.

Caution:

(i) the device for operation in the band 5150-5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems;

(ii) for devices with detachable antenna(s), the maximum antenna gain permitted for devices in the bands 5250-5350 MHz and 5470-5725 MHz shall be such that the equipment still complies with the e.i.r.p. limit;

(iii) for devices with detachable antenna(s), the maximum antenna gain permitted for devices in the band 5725-5850 MHz shall be such that the equipment still complies with the e.i.r.p. limits as appropriate;

(iv) where applicable, antenna type(s), antenna models(s), and worst-case tilt angle(s) necessary to remain compliant with the e.i.r.p. elevation mask requirement set forth in section 6.2.2.3 shall be clearly indicated.

Avertissement:

Le guide d'utilisation des dispositifs pour réseaux locaux doit inclure des instructions précises sur les restrictions susmentionnées, notamment :

(i) les dispositifs fonctionnant dans la bande 5150-5250 MHz sont réservés uniquement pour une utilisation à l'intérieur afin de réduire les risques de brouillage préjudiciable aux systèmes de satellites mobiles utilisant les mêmes canaux;

(ii) pour les dispositifs munis d'antennes amovibles, le gain maximal d'antenne permis pour les dispositifs utilisant les bandes de 5 250 à 5 350 MHz et de 5 470 à 5 725 MHz doit être conforme à la limite de la p.i.r.e;

(iii) pour les dispositifs munis d'antennes amovibles, le gain maximal d'antenne permis (pour les dispositifs utilisant la bande de 5 725 à 5 850 MHz) doit être conforme à la limite de la p.i.r.e. spécifiée, selon le cas;

(iv) lorsqu'il y a lieu, les types d'antennes (s'il y en a plusieurs), les numéros de modèle de l'antenne et les pires angles d'inclinaison nécessaires pour rester conforme à l'exigence de la p.i.r.e. applicable au masque d'élévation, énoncée à la section 6.2.2.3, doivent être clairement indiqués

Radiation Exposure Statement:

This equipment complies with ISED radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with greater than 20cm between the radiator & your body.

Déclaration d'exposition aux radiations:

Cet équipement est conforme aux limites d'exposition aux rayonnements ISED établies pour un environnement non contrôlé. Cet équipement doit être installé et utilisé à plus de 20 cm entre le radiateur et votre corps.

4 SPOTFIRE System Operating Instructions

Using the SPOTFIRE System involves three main steps:

1. Adding a sample to the BIOFIRE Panel pouch.

2. Loading the pouch into a Module and performing a test.

3. Viewing and/or printing a report.

BIOFIRE Panel Reagent Kits

BIOFIRE Panel reagent kits include reagent pouches and all components required to run tests on the SPOTFIRE System. Refer to the appropriate BIOFIRE Panel Instructions for Use or Quick Guide for specific preparation and testing procedures.

Each BIOFIRE Panel pouch is labeled with:

| LOT | Batch Code | ⧗ Expiration Date | SN | Serial Number |

This information is also contained in the barcode. In addition, the pouch includes a space to write the Sample ID or affix a Sample ID barcode.

SPOTFIRE System Test Procedure

General Precautions

BIOLOGICAL RISKS
When working with the SPOTFIRE System and patient samples, personnel may come into contact with contaminants or potentially infectious material. Appropriate biohazard guidelines for working with potentially infectious samples should be followed. Refer to the *Safety Precautions* section of the appropriate BIOFIRE Panel instructions for use for additional safety information

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

• Perform sample collection, pouch loading, and SPOTFIRE System operation 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 contacted a sample, in a biohazard waste container. Change gloves after handling a used pouch.

BIOFIRE Panel pouches are stored under vacuum in individually wrapped canisters. To preserve the integrity of the pouch vacuum for proper operation, ensure that a Module will be available and operational before unwrapping any pouches for loading.

Start Test

The SPOTFIRE Software includes a detailed workflow that guides the operator through performing a test.

Once a pouch has been prepared for testing, select a Module with an available status and follow the on-screen instructions to enter pouch and sample information.

1. Select an available Module on the Home Screen and login if necessary.
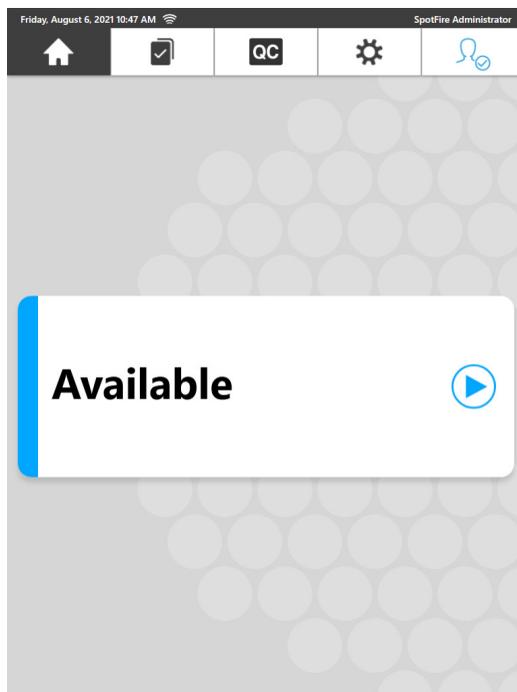
2. Scan pouch barcode.

Note: *If the barcode is unreadable, select the Enter Manually button to enter the lot, serial number, expiration date, and pouch type printed on the pouch label.*

3. Scan or enter the sample ID.

Note: *When manually entering a Sample ID, use sequentially generated recycled accession numbers to ensure that no Protected Health Information ("PHI"), as defined by the Health Insurance and Portability and Accountability Act ("HIPAA"), is requested, required, displayed, transmitted, or maintained on the device. Do not enter patient names, addresses, demographic information, financial information, medical record numbers, Social Security numbers, or any other unique identifying number, characteristic, or code in the Sample ID field.*

4. If applicable, select the appropriate sample type.

5. Review the patient test information, then insert the pouch.

The selected Module's front panel LED will blink blue, indicating it is ready to accept a pouch. As the pouch is inserted, the Module will pull it into the chamber and automatically start the test. Once the test has been started, the selected Module's front panel LED will turn solid green to indicate that the test is in progress. The screen will then change to the Home Screen and show the appropriate Module status.
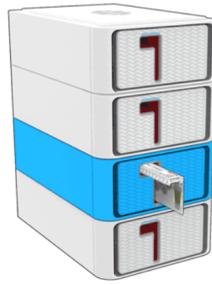
CAUTION: Do not insert sharp objects to remove a jammed pouch. In the event of a jammed pouch, contact BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor for Customer Technical Support.

Abort Test

If a test needs to be stopped before it is finished, select the applicable Module from the Home Screen. The Test In Progress screen will display the current test information. Select **Abort**. Any data that has been generated for the aborted test will not be available for analysis.

Note: *An aborted test cannot be restarted, and the pouch must not be re-tested.*
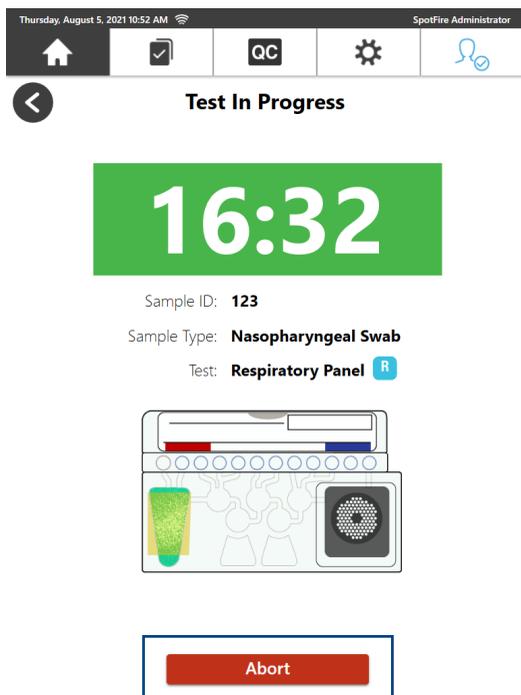
Finish Test and View Report

At the end of the test, the Module status on the Home screen changes to Complete and the pouch is partially ejected.

Results can be viewed both before and after a pouch is removed from the Module. To view results before a pouch is removed, select the appropriate Module on the Home screen to view the test information.
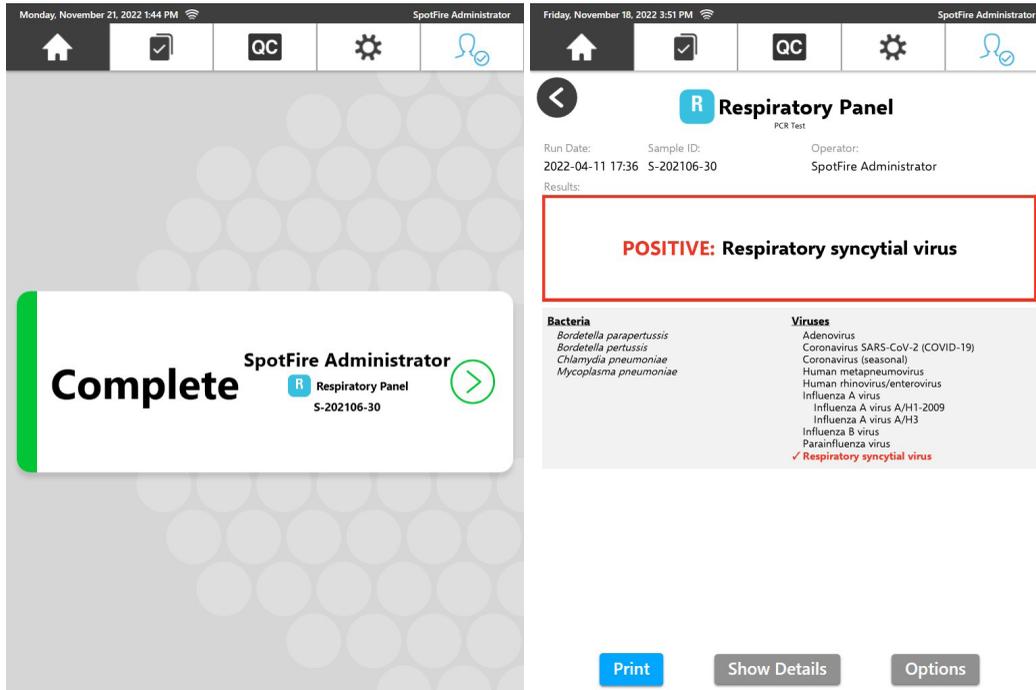
To finish the test:

1. Remove the pouch from the Module.

   Once the pouch is removed, the Module LED will turn solid blue, indicating that the Module is ready for a new test.

Note: Once the pouch has been removed, the report can only be viewed through the Patient Test Results screen.

View Report After Pouch Removal

After the pouch has been removed, the report can only be viewed on the Patient Test Results screen ☑, which displays a list of patient test results.

Refer to the appropriate BIOFIRE Panel Instructions for Use of the appropriate BIOFIRE Panel reagent kit for more details about the information provided in the report.

Print Report

To print a report from a previous pouch test:

1. View the desired report.

2. Select the **Print** button.

3. Select the print type (either Color or Grayscale).

Note: See Chapter 5, SPOTFIRE Software, for instructions on printer setup..

Error Messages

If errors occur, refer to Chapter 7, *Preventative Maintenance and Troubleshooting*, for more information on viewing and handling error messages.

5 SPOTFIRE Software

This chapter explains how to use the SPOTFIRE Software and manage the database. The SPOTFIRE Software automatically starts when the SPOTFIRE System is powered on.

SPOTFIRE System Toolbar

The toolbar is always visible at the top of the screen and consists of five tabs:

- Home 🏠

- Patient Test Results ☑

- Quality Control **QC**

- Settings ⚙

- Access Control

These tabs are described in the following sections.

Home Tab

The Home icon 🏠 is always visible on the toolbar. To navigate to Home from another screen, select the Home icon.

From Home, an operator can:

- View the status of each connected Module in the system.

  Operators can interact with connected Modules from the Control Station. Each Module is represented by a box displayed on the screen. Any Module on the Home tab can be selected to display additional details about the Module status.

- View the status of all tests that are in progress.

  Operators can view the status of all tests that are in progress, along with the Operator, Sample ID, panel type, and time remaining until completion.

- Start a patient test.

  Tests are started by selecting an available Module on the Home tab. If no operator is logged into the SPOTFIRE System, an operator login dialog will appear. Authorized operators can enter a valid operator ID and password to log in to the SPOTFIRE System.
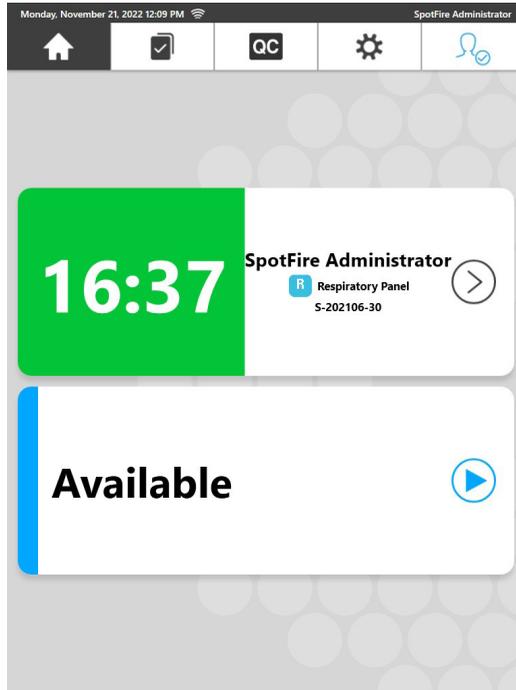
Note: *The Home screen may look different from the image above depending on the number and status of configured Modules.*

Potential Module statuses include the following:

Status Icon	Status	Description
Initializing	Initializing	The Module is performing power on self-tests.
Available	Available	The Module is available to perform a task.
16:37 SpotFire Administrator Respiratory Panel S-202106-30	Test In Progress	The Module is performing a test and displays the estimated time remaining.
Finalizing SpotFire Administrator Respiratory Panel 112233	Finalizing	The Module is finalizing a test.

Status Icon	Status	Description
Running SpotFire Administrator Instrument Module Diagnostic Self Test	Running	The Module is running diagnostic self-tests.
Updating, Please Wait	Updating	The Module is updating.
Complete SpotFire Administrator R Respiratory Panel S-202106-2	Complete	The Module has successfully completed a test, the pouch has been ejected, and the test report is ready for viewing or the Module has completed diagnostic self-tests.
Attention (!)	Attention	An error has occurred and operator action is required. Examples of errors that cause this status include the following: • Pouch jam • There is an unknown pouch in the Module • The Module has lost connection with the software • Module Error • The test ended in an error
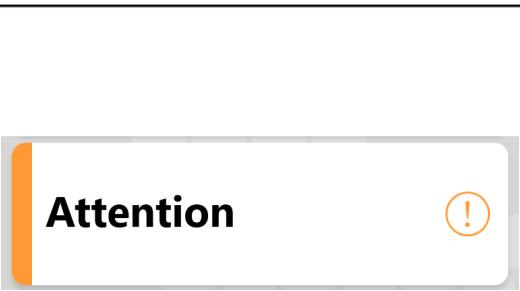
Patient Test Results Tab

The Patient Test Results icon ⬚ is always visible on the toolbar. To navigate to Patient Test Results from another screen, select the Patient Test Results icon.

From the Patient Test Results screen, an operator can:

- Review results for patient tests performed on all Modules connected to the Control Station.

  When a test is completed on a Module, the software generates a report with the results of the test. Upon initial entry into the Patient Test Results screen, all the tests within the database are displayed in a table that lists the date of the test, the operator who performed the test, and other information about the test. Selecting an individual test will display the report.

- View, sort, and search tests in the database.

- Perform actions on patient test results including printing reports, editing Sample IDs, exporting to PDFs, and creating data bundles.
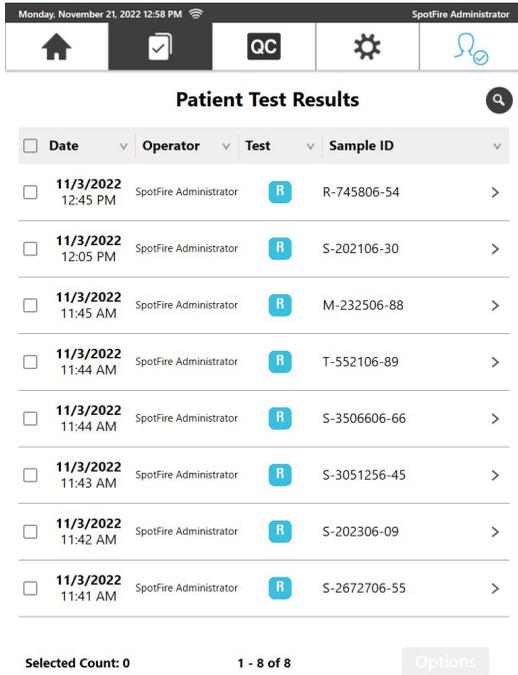
View Report

When an operator selects a test to view the on-screen report, the following features are available:

Menu Item	Description
Print	Prints the test report. See Chapter 4, *SPOTFIRE System Operating Instructions*, for more information about printing a report.
Show Details	Displays additional test information.
Options	Allows operator to select the following options: • Edit Sample ID • Export to PDF • Create Data Bundle • Transmit Results
Options > Edit Sample ID	If a mistake was made during test setup when entering the Sample ID, the operator can make the necessary corrections, then select **Save**. ***Note:*** *If the Sample ID has any previous changes, a table will display information about the previous edit(s).* After saving the changes, the report reflects the new Sample ID.

Menu Item	Description
Options > Export to PDF	Allows the operator to save the test report as a PDF to a selected drive. After selecting **Export to PDF**, the operator chooses the location and filename for the PDF, then selects **Save**. If multiple drives are available, the operator selects a destination device. After the PDF has saved, the operator selects **OK** to close the dialog. *Note: If the file already exists on the save destination, the operator will see a dialog that asks if they want to overwrite it. Selecting **Yes** will overwrite the file. Selecting **No** will close the dialog and display the on-screen report.*
Options > Create Data Bundle	If an error associated with a test occurs, a Customer Technical Support representative may request that the operator create and send a data bundle. For more information on creating a data bundle, see the *Data Bundle* section in Chapter 7, *Preventative Maintenance and Troubleshooting*.
Options > Transmit Results	Allows the operator to electronically send the report to a connected Data Manager. Requires configuration of the Data Manager Interface (refer to BFR0001-6608 *BIOFIRE SPOTFIRE System Connectivity User Guide* for additional information.)

Search Patient Test Results

Patient test results can be searched by Sample ID, Pouch Lot, Pouch Type, Sample Type, Operator, Module, Test Status, and Date.

To search patient test results, perform the following steps:

1. If applicable, navigate to the Patient Test Results screen.

2. Select the Search icon 🔍.

3. Enter desired search criteria.

4. Select **Search**.

To clear search criteria and view all patient tests saved in the database, select **Clear All** or the back arrow.

Exporting Tests

The Export Tests feature enables the operator to write tests to a file while leaving the original tests in the database. The operator will also have an option to remove the Sample ID in the test file and replace it with 'Anonymous'. If a copy of test files must be sent to an external site, this option protects patient confidentiality. To prevent operators from overwriting a test file with an anonymous test file, anonymous files cannot be imported back into the database..
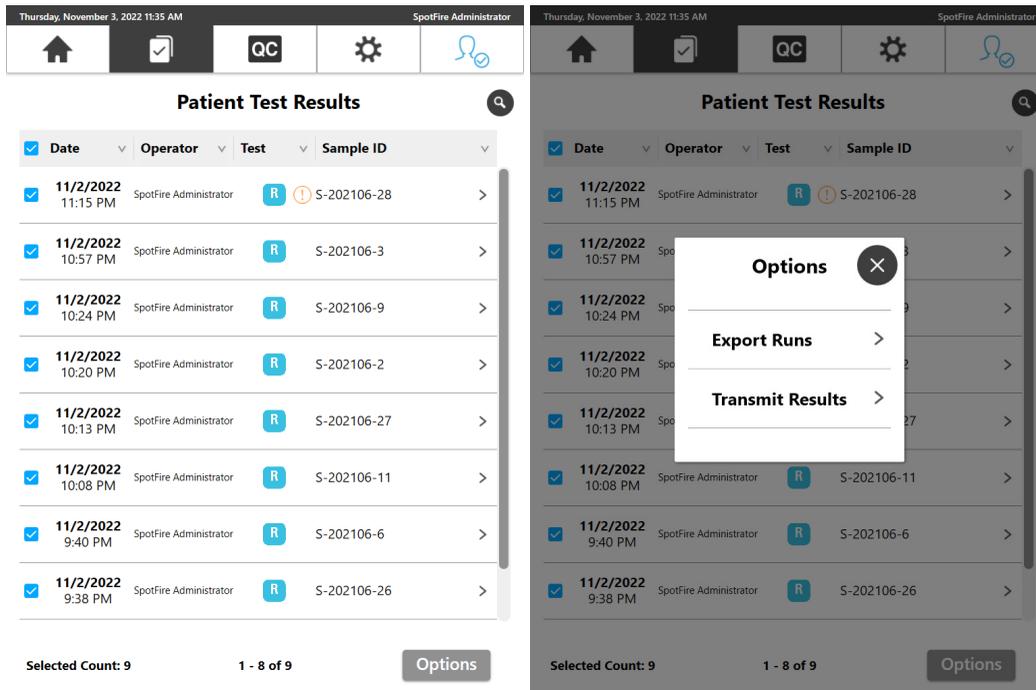
To export tets stored in the SPOTFIRE System database:

1. Log into the system, if necessary.

2. Navigate to the patient test results or QC test results screen.

3. Select the tests to export.

4. Select the **Options** button.

5. Select **Export Tests**.

6. Select either **Yes** or **No** when the Clear Sample ID prompt appears.

7. Select the drive for the tests to be exported.

8. Select the confirmation button to initiate the export.

Note: *The operator can cancel the export process before it finishes by selecting **Cancel** on the export process dialog. Any tests that were exported before selecting **Cancel** will be saved to the chosen location.*

Importing Tests

Tests that have been previously exported from the SPOTFIRE database may be imported back into the database. In addition, operators may import tests from a separate Control Station's database into the database on the Control Station being used.

To import tests:

1. Navigate to Settings Tab > System Configuration > About SpotFire.

2. Connect a drive containing SPOTFIRE tests files.

3. Select the **Restore System** button.

4. Select the available test files to import.

5. Select **Restore Data** button
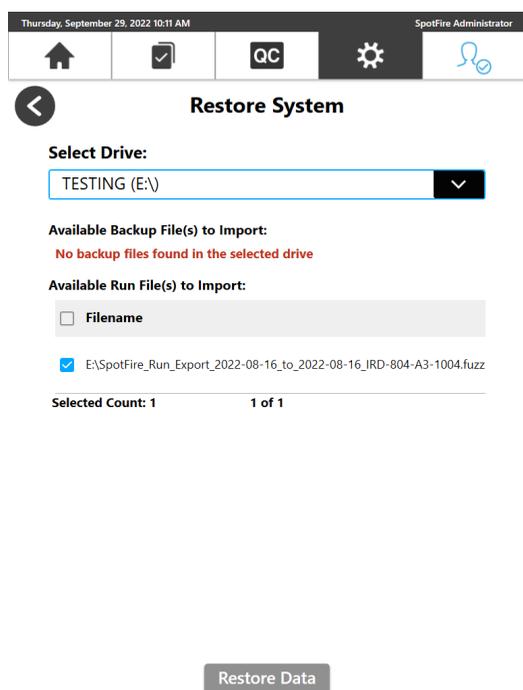
Quality Control Tab

The Quality Control option is always visible on the toolbar. To navigate to Quality Control from another screen, select the QC icon .

From the QC screen, an operator can:

- Start a Negative QC or Positive QC test.

- Review QC Test Results for quality control tests performed on all Modules connected to the Control Station.

    The QC Test Results option displays all quality control test tests, allows operators to view and sort tests in the database, filter the database by test criteria, and export tests or transmit results.

- Enable initial lot lockout (if an operator with Administrator privileges is logged in).

Negative and Positive QC Tests

1. To run a negative QC test, select the **Negative QC** button. To run a positive test, select the **Positive QC** button. Choose an available Module and scan pouch barcode.

2. Scan the QC material barcode or manually enter the QC Material Type (choose Negative if performing a negative run or Positive if performing a positive run), lot, vendor name, expiration date, and QC compatibility.
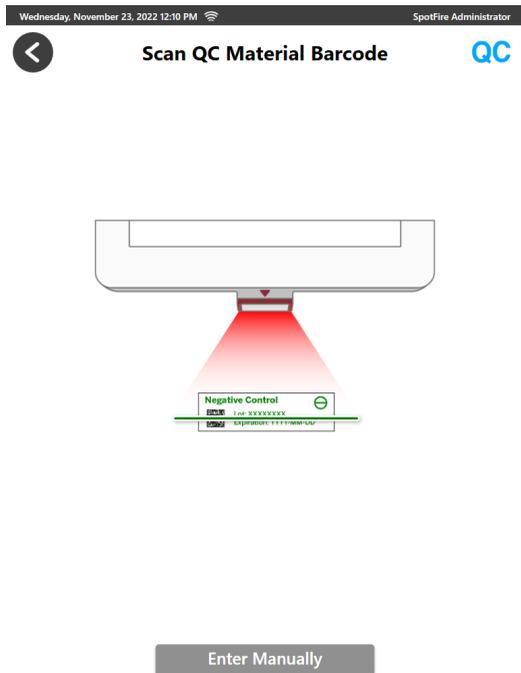
3. Review the QC test information, then insert the pouch.

   The selected Module's front panel LED will blink blue, indicating it is ready to accept a pouch. As the pouch is inserted, the Module will grab onto the pouch and pull it into the chamber. Once the pouch is inserted into the correct Module, the run will automatically start. Once the run has been started, the selected Module's front panel LED will turn solid green to indicate that the run is in progress. The appropriate Module status will also be displayed on the Home screen.

4. At the end of the test, the Module status on the Home screen changes to Complete and the pouch is partially ejected.

To view results and finish a test:

1. On the Home screen, select the Module that completed a test to view the test information.

2. Remove the pouch from the Module.
   Once the pouch is removed, the Module LED will turn solid blue, indicating that the Module is ready for a new test.

Note: *Once the pouch has been removed, the report can only be viewed through the QC Test Results feature as described below.*

To view QC Test Results after the pouch has been removed:

1. Select the QC icon from the toolbar.

2. Select QC Test Results.
   The QC tests are presented as a table that lists the date of the test, the pouch lot used, and other information about the test. Selecting an individual test will display the tests report.

Lot Lockout

Admin operators can enable a lot lockout feature. The initial lot lockout feature prevents/restricts a pouch lot from being used for patient tests until passing positive and negative QC tests have occurred for that lot.
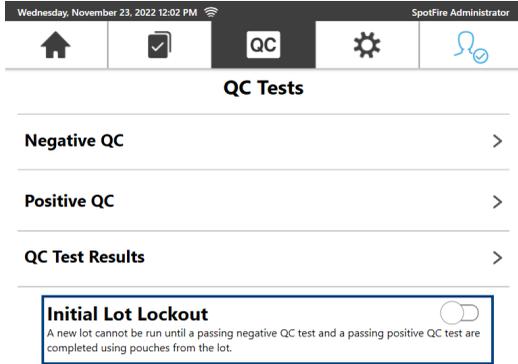
Settings Tab

The Settings icon ⚙ is always visible on the toolbar. To navigate to Settings from another screen, select the Settings icon.

In Settings, an operator can perform the following administrative tasks based on their administrative privileges:

Menu Item	All Operators	Admin Operators Only
Edit My Profile – Edit operator's own profile information.	X	
Operator Management – Configure automatic logout, password recovery, password strength, advanced login options, and the operator list.		X
System Configuration – View and update configuration settings.		
Speaker Volume – Allows the operator to control the volume of the Control Station speakers.	X	
Display Brightness – Allows the operator to control the brightness of the touch screen.	X	
Date and Time – Set the time zone, time, and date settings.		X
Panel Management – View and activate/inactivate all installed pouch types.		X

Menu Item	All Operators	Admin Operators Only
Archive – Removes test data off SPOTFIRE System to a removable or mapped drive.		X
About SpotFire – Displays details about SPOTFIRE System installation and allows operators to create system data bundles or switch to the Windows OS.	X	
Audit Log – View a log of system and operator actions.	X	
Connectivity – Connect to a network via an ethernet connection or wireless connection, configure printer settings, map network drives, and configure bi-directional connectivity with a Data Manager.	X	
Report Settings – Customize report information and auto print settings.	X	
Modules – Manage Module configuration, view connected Module information, reset Module power, and run self diagnostics.	X	

Monday, September 19, 2022 4:19 PM   Standard Operator

🏠   🗹   QC   ⚙   👤

Settings

👤   **Edit My Profile**   >

⚙   **System Configuration**   >

✎   **Audit Log**   >

📶   **Connectivity**   >

Monday, September 19, 2022 4:18 PM   SpotFire Administrator

🏠   🗹   QC   ⚙   👤

Settings

👤   **Edit My Profile**   >

👥   **Operator Management**   >

⚙   **System Configuration**   >

✎   **Audit Log**   >

📶   **Connectivity**   >

📑   **Report Settings**   >
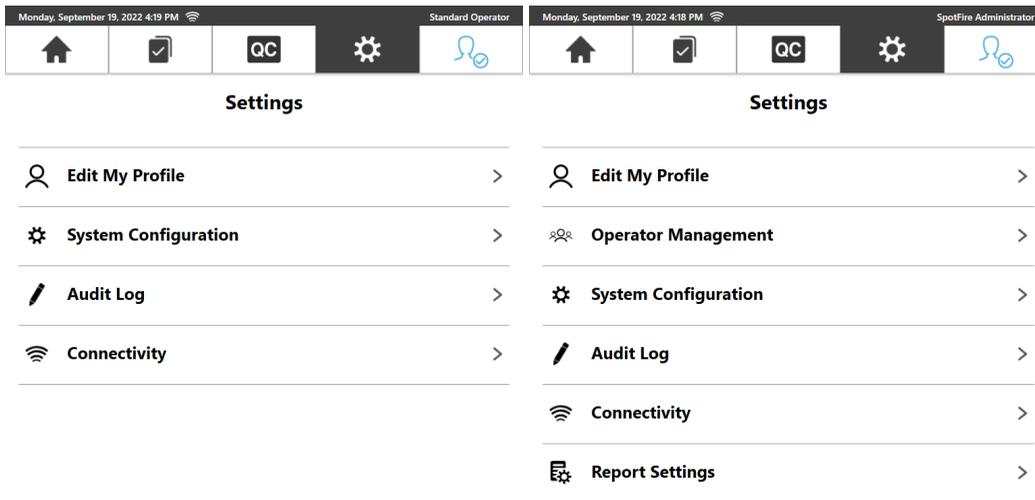
Note: *The options on the Settings tab will be different when a standard operator is logged in rather than an Administrator (screenshot above-right shows an Administrator logged in).*

Admin Mode

The **Switch to Windows OS** button within the About SPOTFIRE screen allows operators to log out of the SPOTFIRE Software and access the Windows Operating System to perform administrative tasks (e.g., printer maintenance).

Print Options

Any printer that has been configured to SPOTFIRE System can be selected as the default.

To set a default printer:

1. to Settings Tab > Connectivity > Printer.

2. The Select Default Printer dropdown box will display all printers configured to the SPOTFIRE System.

3. Select the applicable printer to set it as the default.

4. Optionally, the **Test Print** button can be selected to ensure the default printer is successfully connected.

To Auto Print Reports after a test:

1. Navigate to the Report Settings screen.

2. Select the **Auto Print** button.

3. Configure the desired Auto Print settings.

4. Select the **Save** button.

WiFi

The SPOTFIRE System is a standalone device that does not require network connectivity to function. However, the SPOTFIRE System does support network connectivity. To connect to a wireless network, an operator can follow the instructions below.

1. Navigate to the Settings tab.

2. Select the **Connectivity** button.
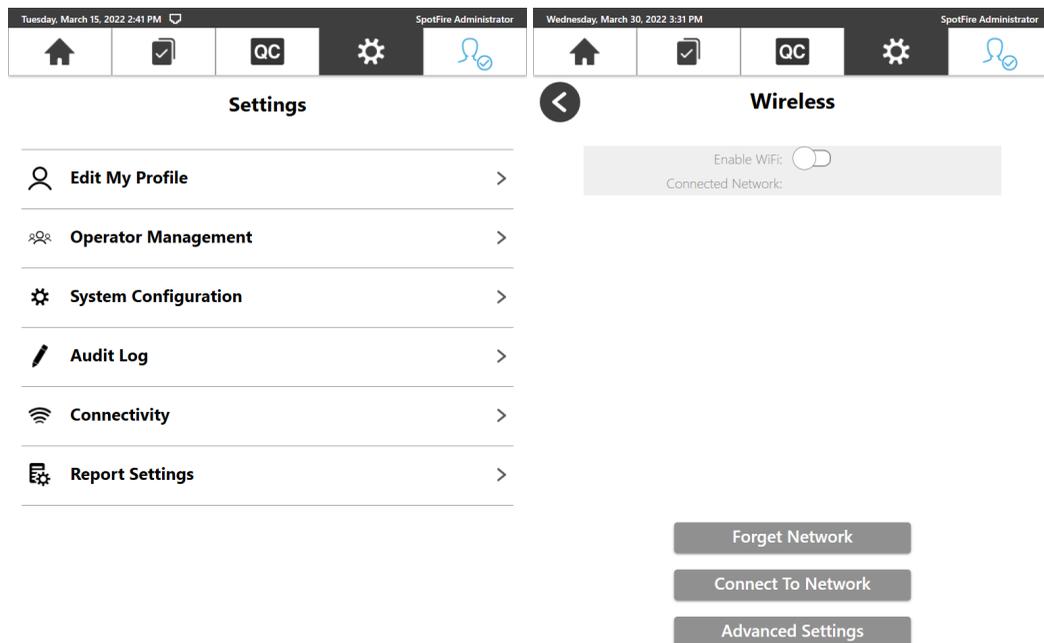
3. Select the **Wireless** button.

4. Select the **Connect To Network** button.

5. Manually enter the Network Name and Password. Select the **Connect** button.

6. If the System is able to connect to the network, the software will display a Connected dialog.

Archive

When tests are archived, the software verifies that all tests have been saved to the file, and then deletes each test from the database one at a time.

To archive tests stored in the SPOTFIRE System database:

1. If necessary, log into the system as an administrative operator.
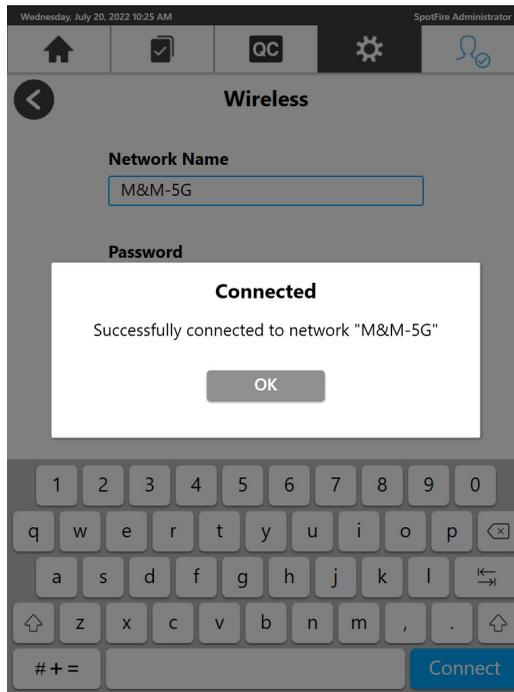
2. Navigate to the Settings tab.

3. Select **System Configuration**.

4. Select **Archive**.

The archive settings can be modified to auto archive, modify which tests should be archived based on tests older than a specified time frame, and select if patient results and/or QC test results should be included in the archive.

Refer to *Chapter 7* for archive recommendations.

Note: *A database administrator is not required for the SPOTFIRE System.*

Note: *It is recommended to perform monthly archives.*

Access Control Tab

The Access Control icon ♐ is always visible on the toolbar. If an operator is logged in, clicking the Access Control icon allows operators to view notifications, log out, restart, and shut down. When no operator is logged in, the access control menu displays Log In, Restart, and Shut Down. Please reference section 2-17 for proper shutdown procedure.

Database Management

A local database on the Control Station stores all test data generated by the SPOTFIRE System. The runs saved in the database are listed within Patient Test Results and QC Test Results. For more information on the function and use of the Patient Test Results, see the Patient Test Results section in this chapter. For more information on the function and use of the QC Test Results, see the Quality Control section in this chapter

Note: *Information about recommended archiving intervals is contained in Chapter 7, Preventative Maintenance and Troubleshooting.*

Data Manager Interface

Optional bi-directional connectivity can be configured using the Data Manager Interface (available from the Settings tab > Connectivity) . For assistance please refer to the SPOTFIRE System Connectivity User Guide (BFR0001-6608) or contact Customer Technical Support.

6   Precautions When Working with the SPOTFIRE System

Laboratory Precautions

Handle all samples and waste materials as if they could transmit infectious agents.

Observe safety guidelines such as those outlined in:

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

- Biosafety in Microbiological and Biomedical Laboratories (Centers for Disease Control and Prevention and National Institutes of Health) or other appropriate biosafety procedures.

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 test.

Refer to the BIOFIRE Panel reagent kit instructions for use for assay-specific safety precautions.

> ⚠ **CAUTION:** A tear or leak in the pouch could contaminate the Module and the surrounding area. Since tears and leaks are not always obvious, used pouches should always be handled with appropriate PPE, removed from the instrument, and discarded immediately in a biohazard waste container.

> ⚠ **CAUTION:** Do not attempt to lift or carry the SPOTFIRE System while Modules are installed. Remove all Modules prior to lifting or carrying the Control Station and always lift from the bottom.

General PCR Precautions

It is critical to avoid contamination when performing PCR. Some important rules to follow are:

- Perform sample collection, pouch preparation, and SPOTFIRE System tests in separate locations.

- Load the pouch while wearing appropriate PPE (e.g., gloves, a standard surgical mask, face shield, or equivalent), and avoid touching one's face while preparing specimens and/or performing the test procedure.

- Laboratory area decontamination/cleaning procedures should be performed daily (i.e., cleaning the Pouch Loading Station and loading area). PPE should be changed after cleaning.

Decontamination and Cleaning Procedures

The decontamination and cleaning procedures are intended to limit the spread of contaminants due to broken or leaked pouches. Decontamination is necessary to prevent false-positive results in subsequent tests.

If a pouch leak or breakage occurs, change gloves and other potentially contaminated 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 essential that contamination from leaking and/or punctured pouches be contained and cleaned immediately. Pouches that break after PCR can contaminate future pouch tests. 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 tests, which can then be identified as a false positive by the BIOFIRE Panel.

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

> ⚠ **CAUTION:** Bleach should never be added to any components of the BIOFIRE Panel reagent kit, sample, or sample waste. BIOFIRE Panel Sample Buffer will form hazardous compounds and fumes when mixed with bleach or other disinfectants. A water wipe before disinfecting with bleach is essential when Sample Buffer or sample is spilled or leaked or suspected to be present.

Cleaning Materials

This list provides items that are necessary for 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

Pouch Loading Station Decontamination

Routine daily cleaning of the BIOFIRE® FILMARRAY® Pouch Loading Station includes a 10% bleach wipe, followed by a water wipe.

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. Rinse the Pouch Loading Station by filling a sink or bin with water and submerging the Pouch Loading Station.

3. Remove Pouch Loading Station from sink or bin. Replace water with a 10% bleach solution.

4. Soak the Pouch Loading Station by submerging the Pouch Loading Station until completely covered with bleach solution. Soak for 15 minutes.

5. Remove Pouch Loading Station from sink or bin. Replace bleach solution with distilled water.

6. Rinse the Pouch Loading Station by completely submerging in distilled water two additional times.

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

Decontamination Related to Pouch Leakage

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

1. Put on clean PPE, such as a lab coat and gloves.

2. Ensure no one uses the Module or potentially contaminated areas until the decontamination is complete.

3. Decontaminate the 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 System Decontamination.

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

SPOTFIRE System 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 water and wipe all exterior surfaces of the SPOTFIRE System, including the bottom. Wipe the surface where the Module had contact with contaminants from a broken or leaked pouch.

5. Wet paper towel with the 10% bleach solution and wipe all exterior surfaces of the SPOTFIRE System. 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.

⚠ **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.

6. Repeat Step 5 twice with fresh paper towels for a total of three bleach wipes.

7. Change gloves, then wet a new paper towel with distilled water and wipe all exterior surfaces of the SPOTFIRE System. Dispose of paper towel in biohazard waste. Change gloves.

8. Repeat Step 7 with a new paper towel.

Decontamination of Bench Tops and Other Areas

1. Put on clean PPE, such as a lab coat and gloves.

2. Wet a paper towel with water and wipe area that may have been contaminated.

3. Wet a paper towel with 10% bleach solution and wipe 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.

4. Change gloves.

5. Repeat Steps 3 and 4 twice, for a total of three bleach wipes.

6. Change gloves. Spray the area with distilled water.

7. Wipe the area dry with a new paper towel. Change gloves.

8. Clean with a nucleic acid degrading solution like DNAZap™ or an equivalent product. Follow the product's instructions for correct use. Change gloves.

9. Rinse the area by spraying it with distilled water and wipe it dry.

Check Function of Decontaminated Module

•   Perform a negative QC test according to instructions in Quality Control Tab (5-8).

•   If the test is successful and all results are negative, continue using the Module as normal.

•   If unexpected positive results are obtained or the test fails, please contact BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor for further instructions.

7   Preventative Maintenance and Troubleshooting

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

The tasks performed in this chapter are the only maintenance 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 SPOTFIRE System is taken out of service, follow the SPOTFIRE Return Procedure in Appendix A.

General Maintenance

No general maintenance is needed for the SPOTFIRE System other than the periodic cleaning steps listed below:

1. When cleaning the touch screen of the SPOTFIRE System, it is recommended that the operator log out of the SPOTFIRE Software in order to avoid accidental selections. The following can be used to clean the Control Station touch screen:

   - CaviWipes (Metrex)

   - Super Sani-Cloth wipes (PDI)

   - Bleach wipes (sodium hypochlorite 0.55%)

   - Ammonia (10%)

   - Isopropanol (99%)

2. Periodically check the touch screen's display angle adjustment paddle to ensure it is functioning properly and the screen angle is still adjustable. If the paddle is not functioning properly, contact Customer Technical Support.

Control Station Shutdown

It is not necessary to shut down the Control Station upon completing work for the day. If facility policy requires regular shutdown, select the shutdown function through the software.

Note: It is recommended to restart the Control Station on a weekly basis.

Periodic Data Archival

It is recommended to perform monthly archives. Archives test in the background and do not limit the ability to perform tests while in progress. See Chapter 5 *SPOTFIRE Software* for more information on archiving data.

Troubleshooting

Pouch Troubleshooting

For problems encountered while using a BIOFIRE Panel pouch, see the possible solutions below. If pouch leakage occurs, refer to Chapter 6, *Precautions When Working with the SPOTFIRE System*, 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 test. Otherwise, discard 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 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 Module are not functioning properly	Retest sample in a new pouch.
		If controls continue to fail, contact Customer Technical Support.
Inadequate volume in Hydration Solution vial or Sample Buffer ampoule.	Evaporation or leakage	Discard vials/ampoules and obtain new ones.

Warning Messages

Warning Messages may originate in a 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
Cannot use temporary password as new password.	Ensure the new password is different from the temporary password.
Cannot remove Admin status for the SpotFire Administrator account.	Do not attempt to remove Admin status—the SpotFire Administrator account must be an Administrative account.
No panels are currently active. Please contact an administrator to activate the required panel.	An admin operator can navigate to the Panel Management screen within System Configuration and activate the applicable panel(s).
A pouch barcode with an inactive panel has been scanned. Please contact an administrator to activate the required panel.	An admin operator can navigate to the Panel Management screen within System Configuration and activate the applicable panel(s).

Warning Message	Possible Solution
The pouch is expired.	Dispose of any pouch that has expired and use a non-expired pouch.
The pouch lot is locked out. A passing QC test must be performed to unlock this lot.	An operator must complete a passing positive and negative QC test using the lot before it can be used for patient tests.
The QC material is expired.	Dispose of any QC reagent material that has expired and use a non-expired QC reagent material.
Cannot open Module management. No Modules were detected.	Ensure a Module is connected to the Control Station.
Cannot test manual Module configuration. No modules were detected.	Ensure a Module is connected to the Control Station.
Manual configuration must be restarted due to a Module disconnection.	Ensure a Module is connected to the Control Station.
No Modules are available to start a QC test. Please ensure at least one Module is in the available state.	Ensure at least one Module is connected to the Control Station and in an available state.

Hardware Troubleshooting

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

Symptom	Possible Solution(s)
Module status lights are not on.	• If user interface is available, restart the SPOTFIRE System through the software. • Ensure all cable connections are secure. • Ensure the Control Station power switch is in the on position. • Try different power outlet if the user interface is not available. • If problem persists, contact Customer Technical Support.
Module status light is blinking amber.	• Reset Module using software. • Check that cables are plugged in (do not unplug). • If problem persists, follow on-screen instructions.
Software will not connect to Module.	• Ensure all cables are plugged in and then restart through the software. • Turn off system and disconnect all cables. 　◦ Ensure pins in cable connections are not missing or bent. 　◦ Reconnect all cables and turn system on. • If problem persists, contact Customer Technical Support.
Pouch not recognized when inserted into or removed from Module.	• Reset Module using software. • If problem persists, contact Customer Technical Support.
Pouch not recognized when inserted into Module, due to a pouch jam.	• Reset Module using software. • If problem persists, contact Customer Technical Support.

Symptom	Possible Solution(s)
Pouch is ejected immediately after insertion.	• Reset Module using software. • If problem persists, contact Customer Technical Support.
Pouch is difficult to insert into Module, or will not load into Module.	• Reset Module using software. • If problem persists, contact Customer Technical Support.
Pouch does not eject from Module after test.	• Reset Module using software. • If problem persists, contact Customer Technical Support.
Software on the Control Station becomes unresponsive.	• Reset the Control Station using the reset button on the front. • If the reset button does not fix the problem, turn the power switch off and then back on. • If problem persists, contact Customer Technical Support.
Barcode will not scan.	• Ensure that the barcode is not wrinkled, damaged, or obscured by debris. • Manually input the pouch serial number and lot number.

SPOTFIRE SYSTEM Reset

See Chapter 2 *SPOTFIRE System Components and Setup* for instructions on resetting the SPOTFIRE System.
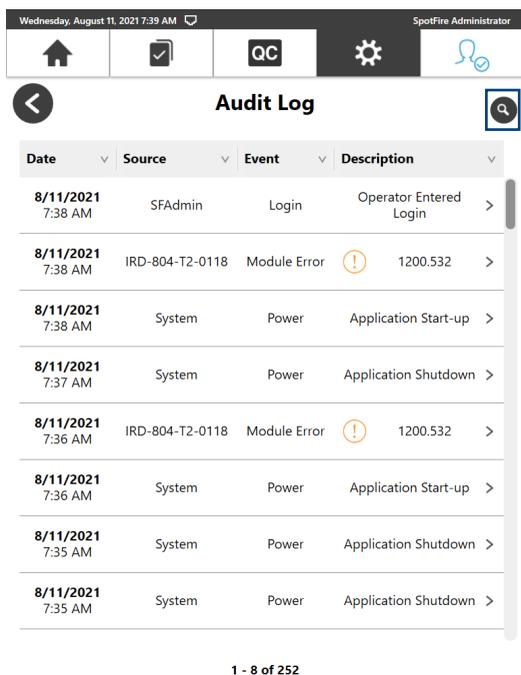
Error Messages

Errors in the SPOTFIRE System may originate in a Module, in the software, or in communication between the two and may result in the loss of a pouch. In each case, the software reports a clear message with instructions that the operator can follow to resolve the issue.

The SPOTFIRE System performs self-diagnostics when the instrument modules are powered on. Malfunctions are reported as errors to the operator. Record any error messages to assist in troubleshooting. Questions should be directed to BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor.

Error Reporting Tools

Audit Log

When the Audit Log is opened, the table will be populated with system and operator events. To search the Audit Log, select the search icon in the upper right hand corner.

Data Bundle

If an error occurs during a pouch test, the error is stored in a data bundle. A Customer Technical Support representative may request the operator to create and provide a data bundle to assist in troubleshooting.

To create a data bundle:

1. Insert a removable drive into a USB port located on the front of the Control Station.

2. Navigate to the Patient Tests Results or QC Test Results view.

3. Select the desired test to view the on-screen report.

4. Click the **Options** button.

5. Select the **Create Data Bundle** menu item. A screen displays the drive path and file name.

6. Click the confirmation button on the keyboard.

7. When the data bundle is complete, a message will indicate that the data bundle has been created.

8. Remove the removable drive.

This file can then be emailed to a Customer Technical Support representative to diagnose errors.
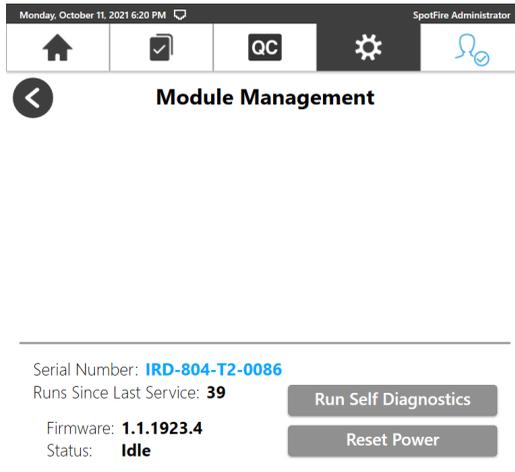
Diagnostic Self Tests

The Diagnostic Self Test function can be used to check the health of the Module. A Customer Technical Support representative may request the operator to perform a diagnostic self test and provide a data bundle to assist in troubleshooting.

To run a Diagnostic Self Test:

1. Navigate to Module Management screen within **Settings** > **System Configuration** > **Instrument Modules** > **Module Management**.

2. Select **Run Self Diagnostics**

a. The Diagnostic Self Tests require a hydrated pouch to test fully. It is possible to run tests without a pouch, but only a subset of the tests will run.

3. Select the **Next** button to run the tests using a hydrated pouch.

4. If running the tests without a pouch, select **Test Without Pouch**.

a. Select **Start** to begin the Diagnostic Self Tests.

5. The operator will be able to review the results during the tests:
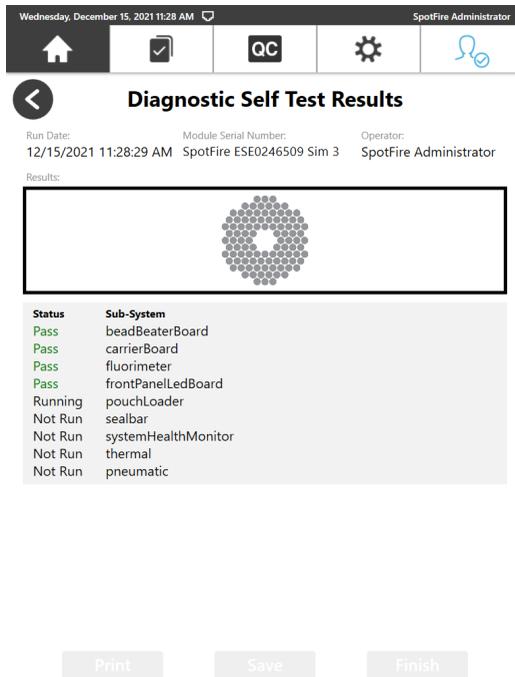
6. The operator can save and/or print the results.

8   Cybersecurity

The SPOTFIRE System may be run as a standalone device or in a networked environment. The SPOTFIRE System 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 SPOTFIRE System. Prior to delivery, BioFire Diagnostics verifies that the computer is free of malicious software.

The SPOTFIRE System 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 SPOTFIRE System may result in loss of functionality and/or compromised data. In an effort to maintain integrity of the SPOTFIRE System:

- Do not use personal computer media (e.g., CDs, DVDs, USB devices).

- Use computer media that have been scanned and are free of malicious software.

- Use caution when transferring computer media between computers.

- Do not download or install any software other than software provided 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.

Factory Reset

The Factory Reset feature can be used to restore the SPOTFIRE System to original settings.

Note: This feature will remove all data (e.g., test results, operator IDs, etc.) from the SPOTFIRE System. This data cannot be restored after the feature has been used.

Protected Health Information

When manually entering a Sample ID, use sequentially generated recycled accession numbers to ensure that no Protected Health Information ("PHI"), as defined by the Health Insurance and Portability and Accountability Act ("HIPAA"), is requested, required, displayed, transmitted, or maintained on the device. Do not enter patient names, addresses, demographic information, financial information, medical record numbers, Social Security numbers, or any other unique identifying numbers, characteristics, or codes in the Sample ID field.

A   Appendix - SPOTFIRE System Support Information

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

Module Return Procedure

If returning a Module from within the United States, visit the Return Forms and Decontamination Procedures webpage: http://www.biofiredx.com/support/return-forms/

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

Procedure

Components of the SPOTFIRE System, such as the Module(s), Control Station, 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 Technical Support Department, a local bioMérieux sales representative, or an authorized distributor.

SPOTFIRE System Ordering Instructions

Customers inside the United States should contact BioFire Diagnostics to order any SPOTFIRE 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:

- Email: 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.
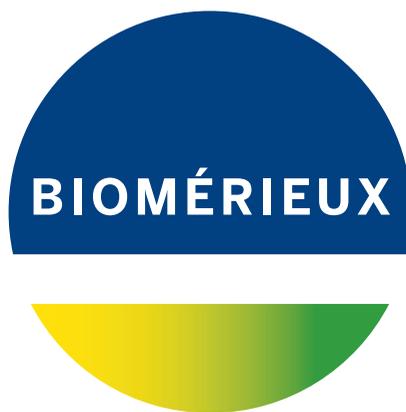
Warranty Information

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.

Revision History

Revision History		
Rev	**Description of Change**	**Revision Date**
01	Initial Release	January 2023

BIOMÉRIEUX