BIOMÉRIEUX

BioFire® SpotFire™ System

Operator's Manual

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For *in vitro* Diagnostic Use - EN

IVD

UK CA CE

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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.

Intellectual Property

E-Labeling Information

The operator's manual 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
BioFire® SpotFire™ Software	http://www.biofiredx.com/e-labeling/ITISF6528

Customer Technical Support

Customer Technical Support for U.S. Customers	
Reach Us on the Web www.biofiredx.com Reach Us by Email support@biofiredx.com Reach Us by Mail 515 Colorow Drive Salt Lake City, UT 84108 USA	Reach Us by Phone 1-800-735-6544 (Option 5) – Toll Free (801) 736-6354 (Option 5) – United States Reach Us by Fax (801) 588-0507
Customer Technical Support Outside of the U.S.	
Contact the local bioMérieux sales representative or an authorized distributor for technical support.	

1 BioFire® SpotFire™ System

Intended Purpose

Intended Use

The BioFire 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 SpotFire Modules connected to a SpotFire Control Station running SpotFire Software. Each Module can be randomly and independently accessed to run 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.

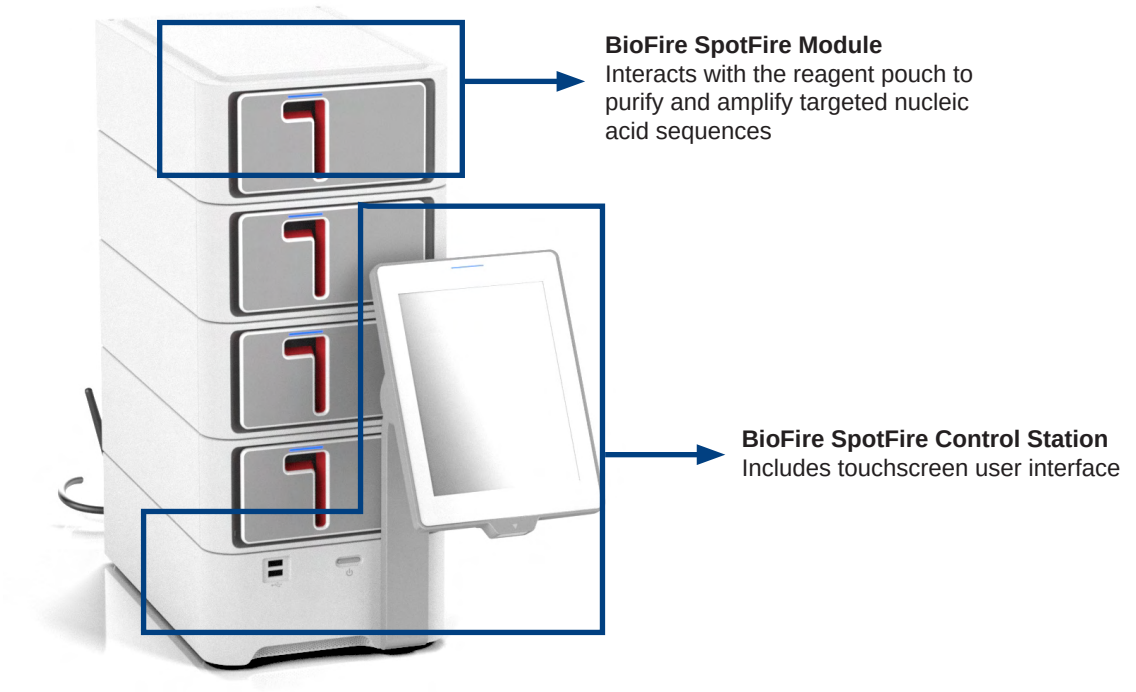
Limitations for Use

- 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 run.
- Use only the supplied cables when connecting any Module to the Control Station.
- Do not use cable extenders to increase cable length.
- 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 re-run a pouch associated with an error, incomplete run, 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 run.
- Do not shut down the SpotFire System while the system is archiving runs.
- 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 flooring and should not be placed directly in a domicile.

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*.



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 Runs

The SpotFire System is used in combination with compatible BioFire Panel pouches to perform tests, also known as “runs,” that detect multiple nucleic acid targets contained in a patient 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 run. Once a pouch has been prepared for testing, on-screen instructions prompt the operator to enter pouch and sample information, insert the pouch into an available Module, and start the run. For more information on starting a run, see Chapter 4, *SpotFire System Operating Instructions*.

Module and Pouch Interaction

Performing a run on the SpotFire System requires a BioFire Panel reagent pouch (a component of the a 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 run 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:

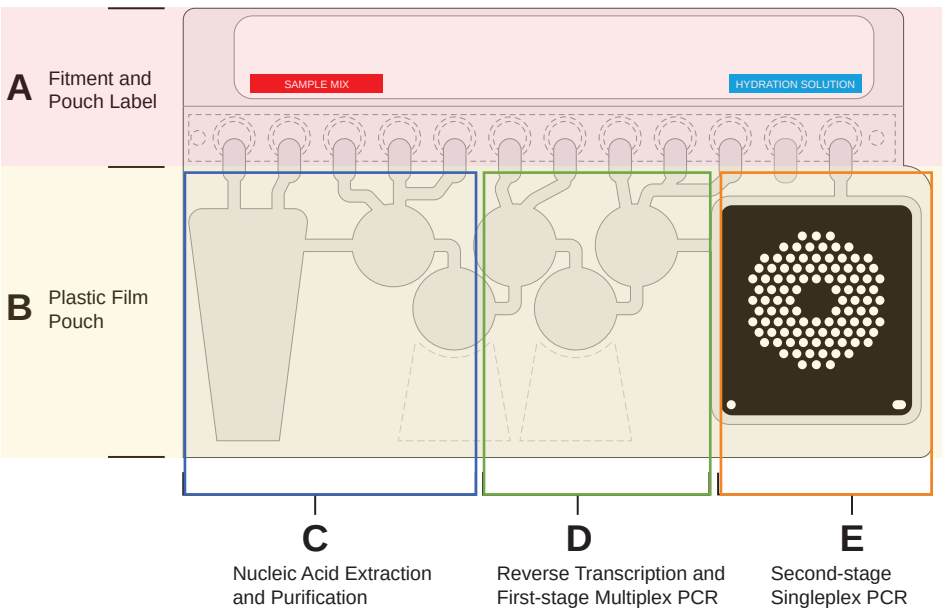
(A) Fitment and Pouch Label: The rigid plastic portion of the pouch is called the fitment. The fitment has reservoirs that contain freeze-dried reagents.

(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 SpotFire Module and chemical processes.

BioFire Panel Software

Each pouch requires pouch-specific panel software to be installed on the 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.

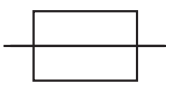
The Module optics system is aligned, focused, and calibrated at the factory. Proper operation and calibration of Module optics is monitored by the Module self-tests and internal pouch controls.

SpotFire Software Overview

The SpotFire Software is integrated in the Control Station and is used to operate the Modules, save runs to the database, and view the results of the runs 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 BioFire SpotFire Modules, the BioFire SpotFire 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)		Batch Code (Lot Number)
	Catalog Number		Serial Number
	Do Not Use if Package Is Damaged		Keep Dry
	Temperature Limit		Biological Risks
	On		Off
	Fuse		Protective Ground

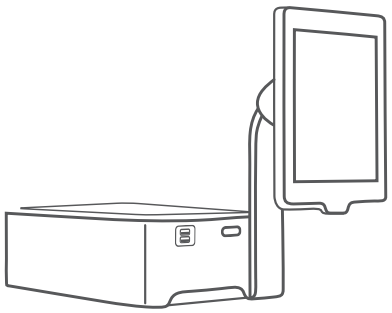
	Underwriter's Laboratory Listing Mark		European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)
	Consult Instructions for Use - Phone		Consult Instructions for Use - Online
	*In vitro* Diagnorstic Medical Device		European Union Conformity
	UKCA - UK Conformity Assessed		Device for Near Patient Testing
	European Union Product Importer		

2 BioFire® SpotFire™ System Components and Setup

SpotFire System Components

Each SpotFire System comes with a SpotFire Control Station, one or more SpotFire Modules, and corresponding accessories.

SpotFire Control Station Box Components



SpotFire Control Station*

Antennas (2)

Pouch Loading Station (2)

Ethernet Cable

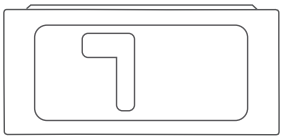
Power Cable**

Operator's Manual

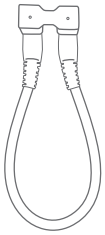
*The Control Station comes pre-loaded with the SpotFire Software.

**One Power Cable included. Power Cable type is dependent on region and may look different from what is pictured.

SpotFire Module Box Components



SpotFire Module



Module Connection Cable

SpotFire Accessory Box Contents

The Accessory Box contents vary based on location.

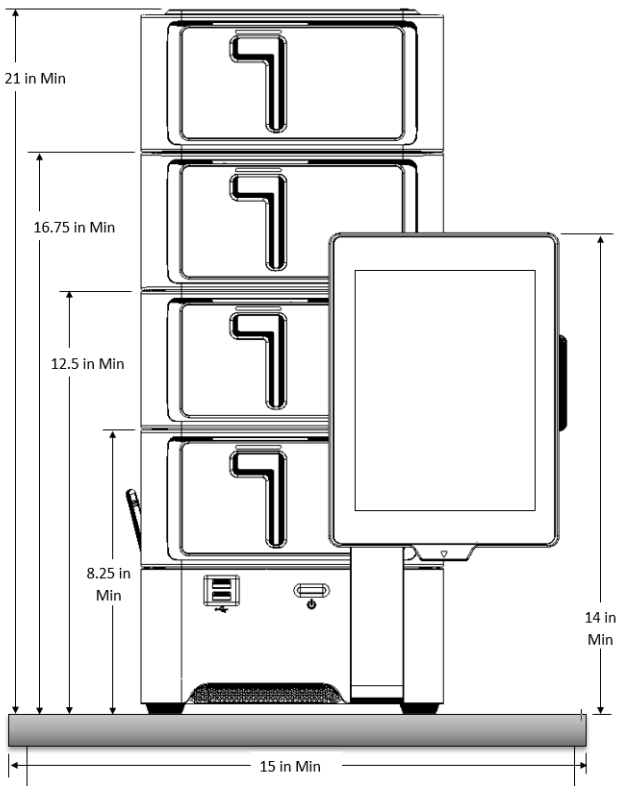
Setup Requirements

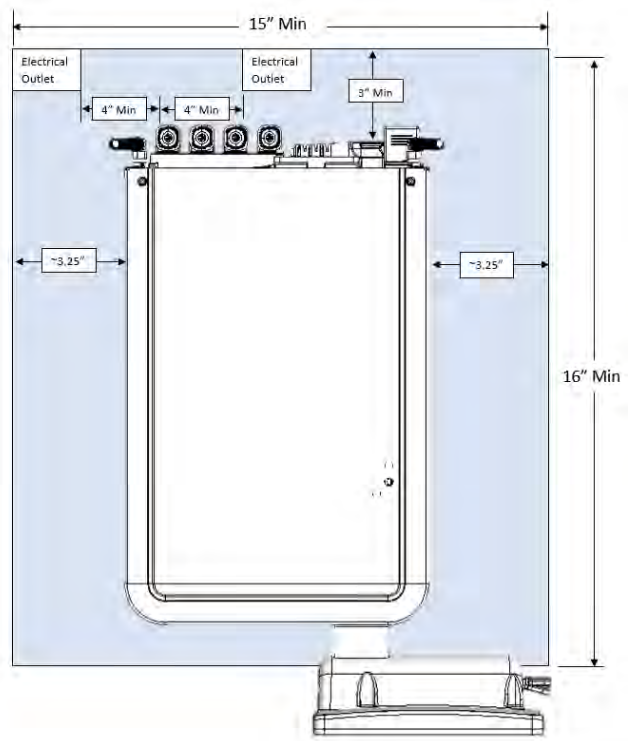
Select a clean, well-ventilated area that is large enough to fit the SpotFire System. The diagrams below show the minimum spaces required for a Control Station with 1-4 Modules to maintain the performance listed in Chapter 3, *Performance Specifications*, allow for sufficient water venting, and provide 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 the performance of this equipment could result. The SpotFire System is intended to produce a result with accuracy according to the claimed test error rates. If this performance is lost or degraded due to electromagnetic disturbances, the user 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 inches) 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)





Note: *The SpotFire System utilizes compressed air for device operation. As air is compressed, moisture is released from the air, which collects inside the SpotFire pneumatic system. For continued operation and reliability, the moisture must be removed from the system. To control the moisture, a small diffusing vent is located on the rear of the Module. This allows the moisture to be vented as a mist. In most cases the venting will not contain any water. However, from time to time a small amount of water may be released during the venting.*

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. If liquid is spilled on the system, wipe it up immediately using decontamination wipes.

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			118 W	192 VA	173 W	216 VA
3 Modules			259 W	264 VA	237 W	277 VA
3 Modules			328 W	333 VA	304 W	341 VA
Grounded outlet required						

The SpotFire System is safe to operate under mains 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.

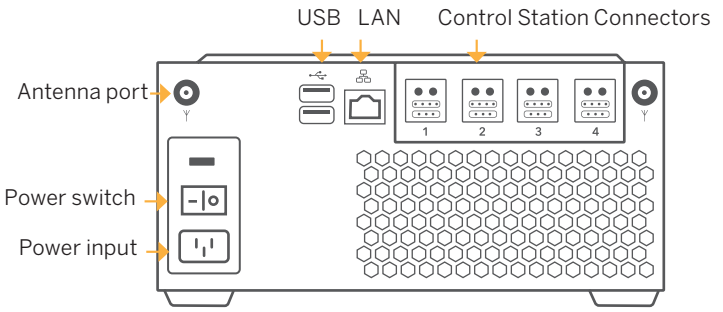
Note: *A single IEEE 802.1x Ethernet is sufficient for optional LIS connectivity and/or allowing BioFire or an authorized distributor to securely connect to the SpotFire System through the internet.*

- 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

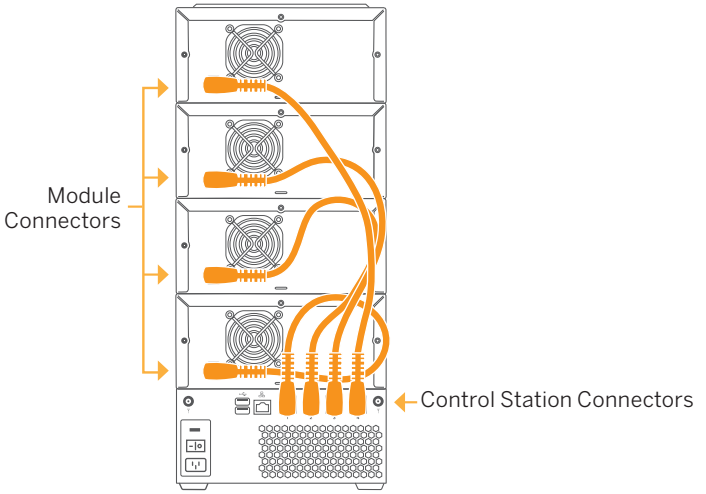
CAUTION: Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation. Do not use cable extenders to increase cable length. Use only 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. There will be tactile feedback when the Module is stacked correctly.



   b.) Repeat for additional Modules.

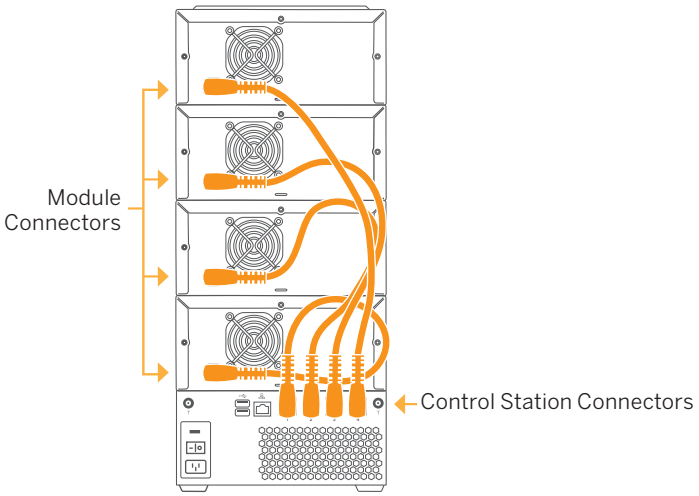
CAUTION: Four is the maximum number of Modules supported. To maintain proper performance, only Modules should be stacked on top of the Control Station. Do not add more than four Modules, and do not place any items on top of the stack (regardless of number of Modules installed).

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 figure TBD 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: *Wi-Fi connectivity is provided for the purpose of connecting the SpotFire System to a local network. If a reliable Wi-Fi 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 System Software powers on.

Note: *See Chapter 6, Precautions when Working with the SpotFire System, for information on decontamination procedures. If disassembly is required for decontamination, re-assemble the SpotFire System per the instructions above.*

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 section *SpotFire System Shutdown or Restart*.
2. Disconnect the Module Connection cable(s) connecting the Module(s) to the Control Station.
3. Because the Modules are stacked on top of one another, all Modules above the one being removed must be removed first. Gently pull 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 System can be set up for use.

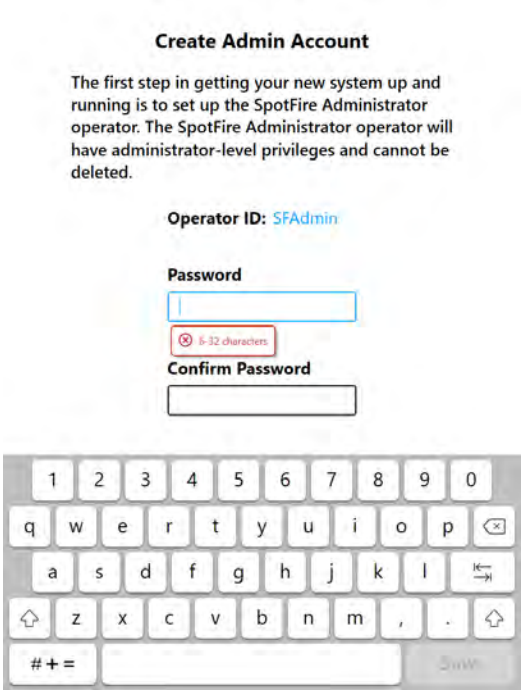
Note: *A Module must be added to the Control Station before the software can be used to initiate and perform runs.*

Initial Setup

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

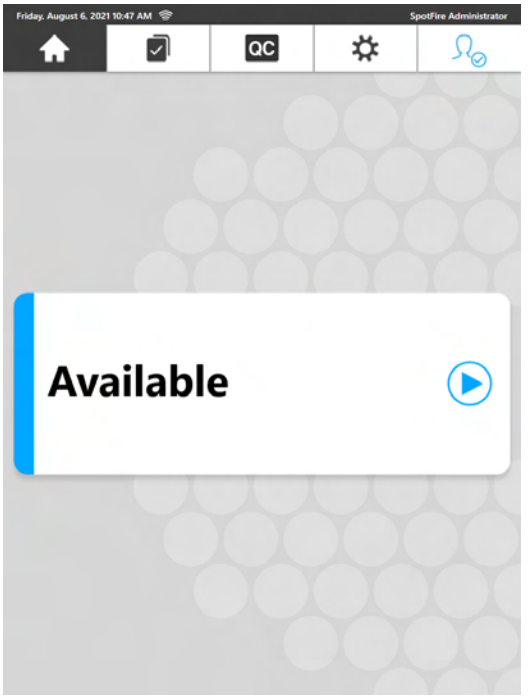
1. Select the **Get Started** button to create the SpotFire Administrator Operator.

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



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

4. The “Initial Setup Complete” screen will appear. Press the **Done** button to continue to the Home Screen logged in as the SpotFire Administrator operator.

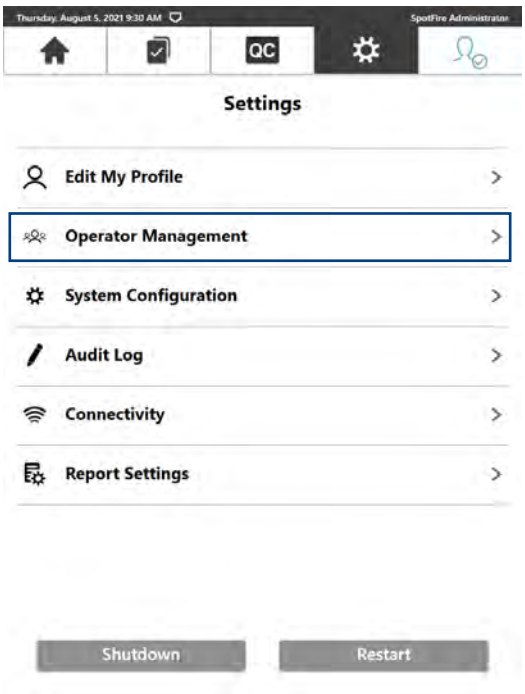


Create Operators

The SpotFire Administrator operator and other operators with administrator privileges can create additional operators using the following steps:

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

2. Select **Operator Management**.

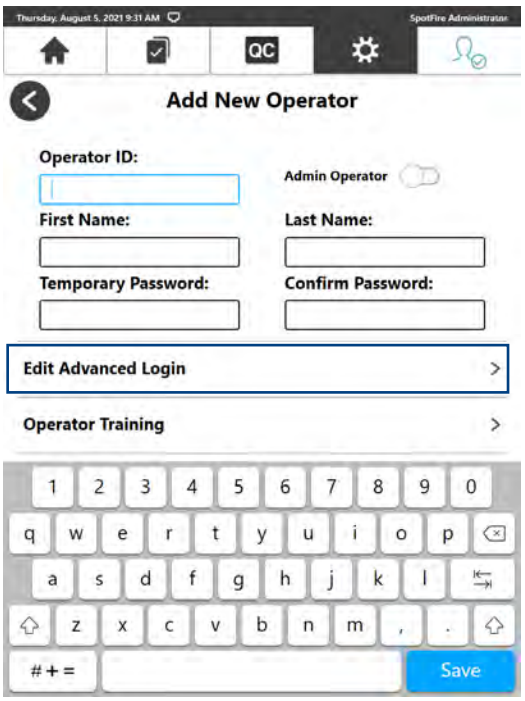


3. Select **Operator List**.

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. To set up arcode access for the Operator, select **Edit Advanced Login**.

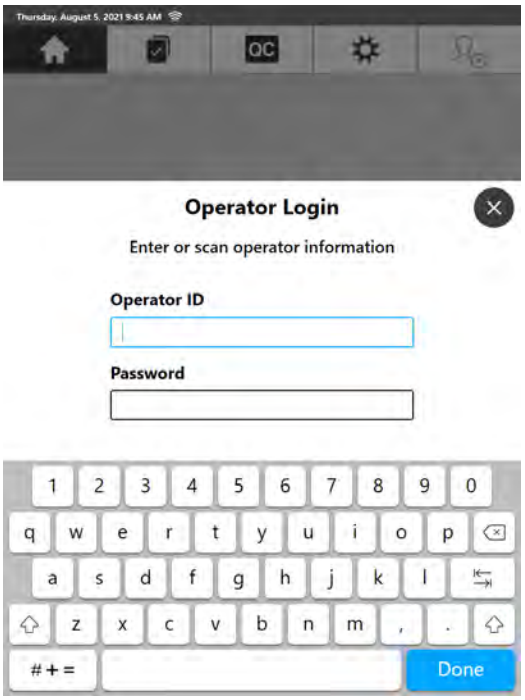


Note: *An operator with administrator privileges must first enable the barcode badge access setting within the login management screen.*

7. Press the **Setup** button.
8. Follow the prompts to add the barcode.
9. Once finished, press the back button.
10. Press **Save** to complete.

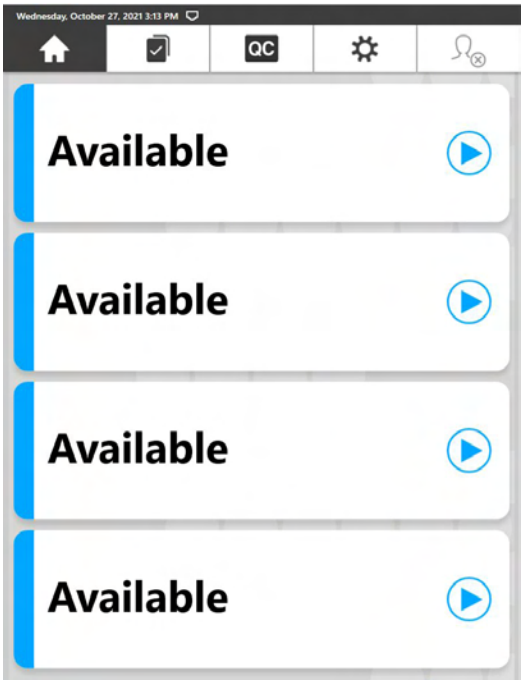
Operator Login

To log in to the SpotFire System, click anywhere in the software. Enter the Operator ID and Password, and press **Done**.



Home Screen

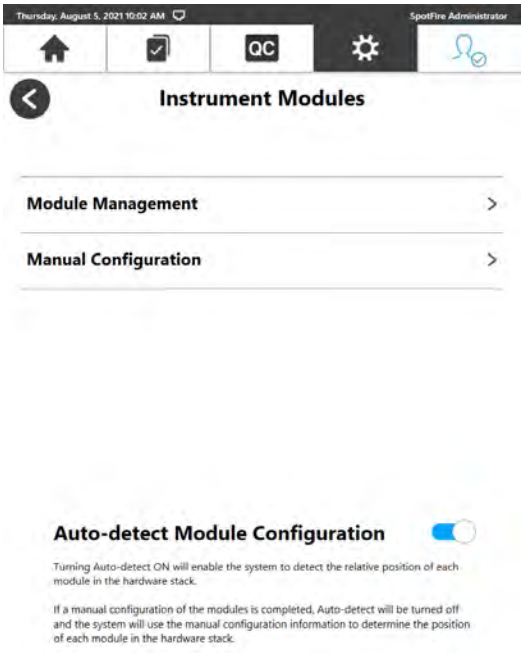
The Home Screen is split into four boxes that represent the physical locations for all installed Modules. Each Module that is currently configured to the SpotFire System displays within a box and shows the status of the Module.



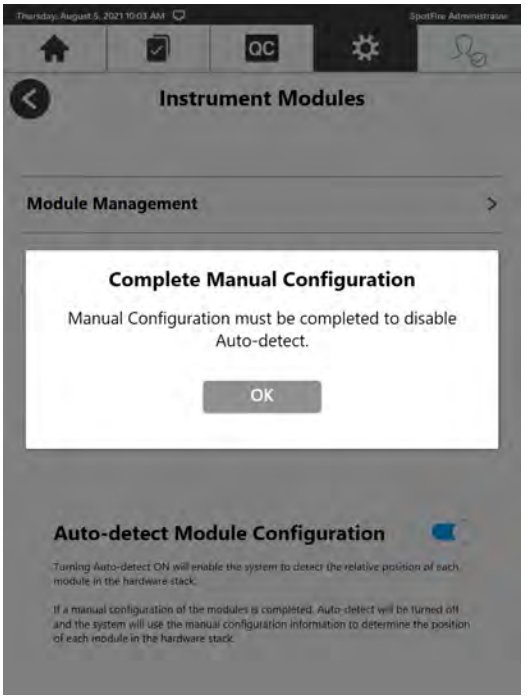
The System will automatically detect the relative position of each Module in the hardware stack. However, if desired, the Modules can be configured manually, as shown below.

Module Manual Configuration

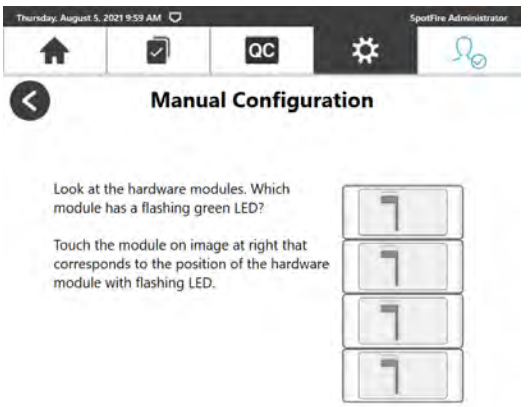
1. Navigate to the Settings tab. Select **System Configuration** > **Instrument Modules**. At the bottom of the screen, there is a toggle to turn off the Auto-detect function.

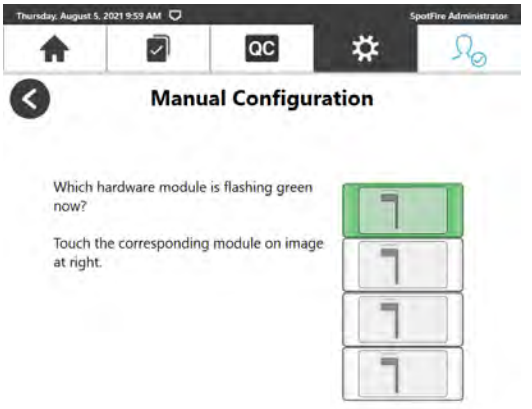


2. If the Auto-detect Module Configuration toggle is turned off, the following dialog will appear:

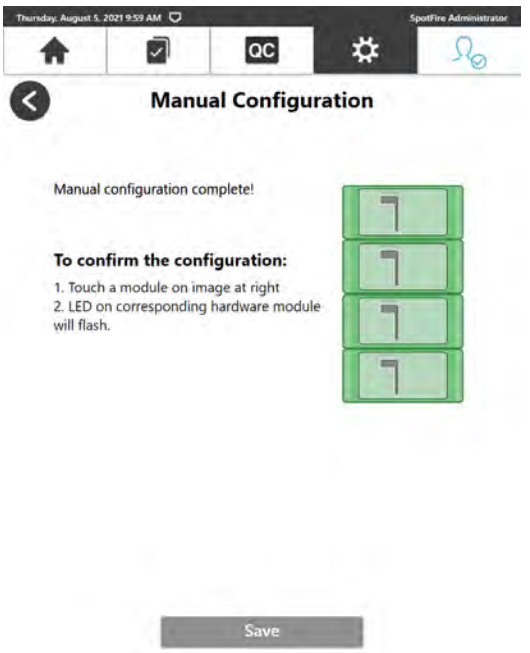


3. To complete the Manual Configuration, select the **Manual Configuration** button and follow the on-screen prompts.

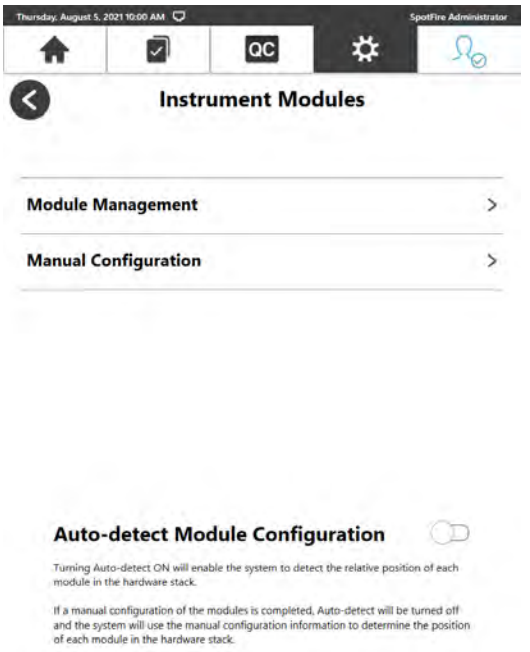




4. Press Save when complete.

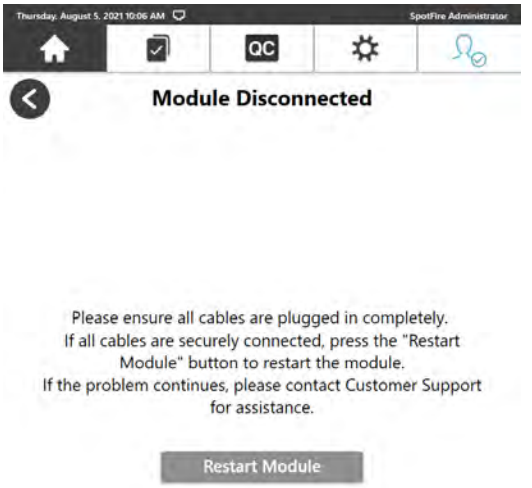


5. After pressing the **Save** button, the Auto-detect Module Configuration toggle is turned off.



a.) The Auto-detect Module Configuration can then be toggled on at any time and the system will again auto-detect the relative position of each Module in the hardware stack.

b.) If a Module becomes disconnected, the software will display a Module Disconnected screen.



Printer Setup

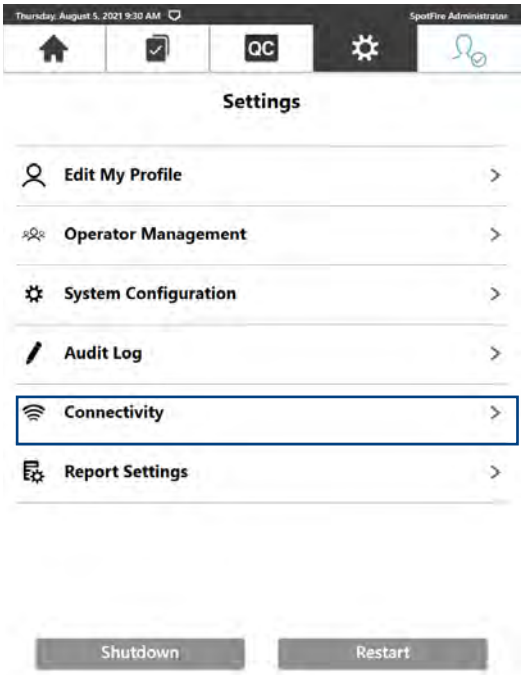
The SpotFire System can be configured to print to any printer compatible with a Windows 10 operating system. Printer Settings are covered in Chapter 5, *SpotFire Software*.

Wifi

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

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

2. Select the **Connectivity** button.



3. Select the **Wireless** button.
4. Select a wireless network to join.

5. Enter credentials for the network.

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

SpotFire Module Status

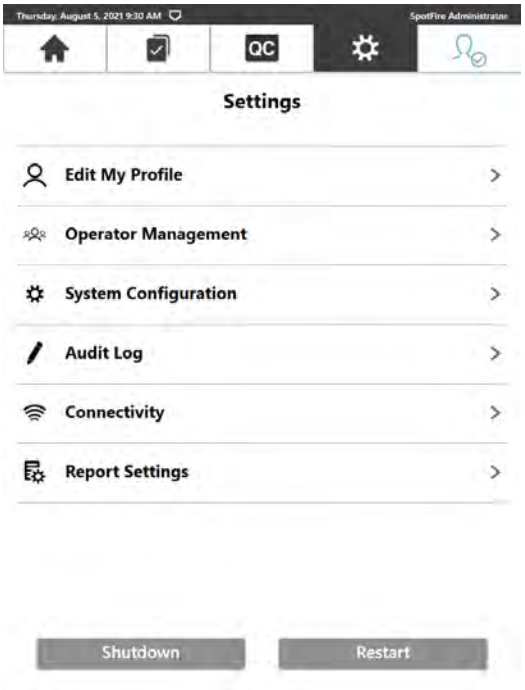
The front of each Module is equipped with an LED light that shows the specific status of that Module.

LED Color	Status	Meaning(s)
White	Solid	Module initializing
White	Solid	Module restarting
White	Solid	Firmware upgrade in progress
White	Solid	Module Diagnostic Self Tests in progress
Blue	Solid	Module idle and available to run a pouch
Blue	Blink	Module waiting for operator to insert a pouch
Green	Solid	Pouch run in progress
Green	Blink	Run complete – waiting for user to remove pouch
Amber	Solid	Module error, follow on-screen instructions

LED Color	Status	Meaning(s)
Amber	Blink	Waiting for user 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 Settings 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.
5. To shut down the SpotFire System without using the software, first press and hold the reset button on the front of the Control Station until the screen goes black; then turn off the main power switch on the back of the Control Station.

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

3 BioFire® SpotFire™ System Components and Setup

SpotFire System Specifications

<table>
<tr><td>Sample Description</td><td>One pouch capacity per SpotFire Module (with a maximum of 4 Modules per SpotFire system)</td></tr>
<tr><td>Run Time</td><td>Refer to the appropriate BioFire reagent panel Instructions for Use (IFU)</td></tr>
<tr><td>Data Output</td><td>Control Station with touch screen and barcode scanner</td></tr>
<tr><td>Fluorescence Acquisition</td><td>Single color optics Module: 420nm–470nm excitation, 520nm–570nm emission, and sensor imaging</td></tr>
<tr><td>Temperature Control</td><td>Peltier devices:
• PCR temperature range 40°C–105°C
• PCR melt rate from 0.1–2°C /sec</td></tr>
<tr><td>Operations Specification</td><td>• 15°C - 30°C @ 15 - 80% relative humidity (non-condensing)
• -50 ft (-16m) to 0,000 ft (3,658m) operating altitude
• Indoor use only</td></tr>
<tr><td>Shipping Specifications</td><td>• -30°C - 38°C @ 5 - 85% relative humidity (non-condensing)</td></tr>
<tr><td>Power Requirements</td><td>
<table>
<tr><th rowspan="2">Configuration</th><th rowspan="2">Voltage</th><th rowspan="2">Frequency</th><th colspan="2">AC Power at 100 VAC</th><th colspan="2">AC Power at 240 VAC</th></tr>
<tr><th>Active</th><th>Apparent</th><th>Active</th><th>Apparent</th></tr>
<tr><td>1 Module</td><td rowspan="4">100-240 VAC</td><td rowspan="4">50-60 Hz</td><td>117 W</td><td>121 VA</td><td>101 W</td><td>148 VA</td></tr>
<tr><td>2 Modules</td><td>118 W</td><td>192 VA</td><td>173 W</td><td>216 VA</td></tr>
<tr><td>3 Modules</td><td>259 W</td><td>264 VA</td><td>237 W</td><td>277 VA</td></tr>
<tr><td>3 Modules</td><td>328 W</td><td>333 VA</td><td>304 W</td><td>341 VA</td></tr>
<tr><td colspan="7">Grounded outlet required</td></tr>
</table>
</td></tr>
<tr><td>Overvoltage</td><td>Category II</td></tr>
<tr><td>Fuse</td><td>(2) 250V 10A Type T (Control Station) 5x20 mm Ceramic Cartridge Fuses</td></tr>
<tr><td>Dimensions and Weight</td><td>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</td></tr>
<tr><td>CPU</td><td>• Intel® Atom x7-E3950</td></tr>
<tr><td>Storage and Memory</td><td>• 250 GB or greater solid state hard drive
• 8 GB RAM</td></tr>
</table>

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 (Wi-Fi) compliant network connection (2.4 GHz and 5 GHz ISM Bands) • 4 USB 2.0 compliant Type A connections Display • WXGA LCD • 8.4” diagonal (21.3 cm) • 1280 x 768 resolution • Capacitive 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 BioFire SpotFire System
Cybersecurity	• See *Chapter 8, Cybersecurity FDA Statement*

WiFi Specifications

	2.4 GHz Band	5 GHz Band
Supported standards	802.11b, 802.11g, 802.11n	802.11a, 802.11n, 802.11ac
Output power (US)	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
Output power (Canada)	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
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

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

Manufacturer's Declaration – Electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2 Compliance Level**	**EN/IEC 61326-2-6 Compliance Level**
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
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 cycle	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 user'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.

Industry Canada Statement

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions:

(1) this device may not cause interference, and

(2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes

(1) l'appareil nedoit pas produire de brouillage, et

(2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

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 user 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 minimum distance 20cm between the radiator & your body.

4 SpotFire System Operating Instructions

Note: *BioFire® Panel pouch preparation may vary depending on the pouch type used. Please consult the Instructions for Use of the appropriate BioFire® Panel kit for specific preparation steps.*

Using the SpotFire System involves three main steps:

1. Adding a patient sample to the BioFire Panel pouch.
2. Loading the BioFire Panel pouch into a Module and performing a run.
3. Viewing and/or printing a report.

BioFire Panel Reagent Kits

BioFire Panel reagent kits include BioFire Panel pouches and all components required to run tests on the SpotFire System. Components will vary based on the type of BioFire Panel. Refer to the Instructions for Use or Quick Guide for specific preparation and testing procedures.

Each BioFire Panel pouch is labeled with:

Batch Code


Expiration Date

Serial Number

This information is also contained in the barcode. In addition, tThe pouch also 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 Ssample collection, pouch loading, and SpotFire System operation should each be performed in separate locations or work areas.
- Do not leave a work area or return to a previous work area without first completing decontamination procedures (i.e., washing the area and changing protective clothing and gloves).
- Prepare and load only one pouch at a time.
- Always dispose of used pouches, or pouches that have contacted sample, in a biohazard waste container. Change gloves after handling a used pouch.

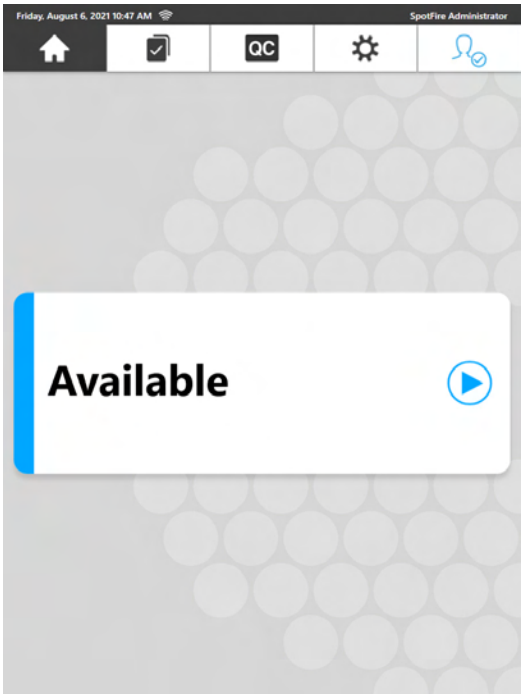
BioFire Panel pouches are stored under vacuum in individually wrapped canisters. To preserve the integrity of the pouch vacuum for proper operation, ensure that a Module will be available and operational before unwrapping any pouches for loading.

Start Run

The SpotFire Software includes a detailed workflow that guides the operator through performing a patient 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.



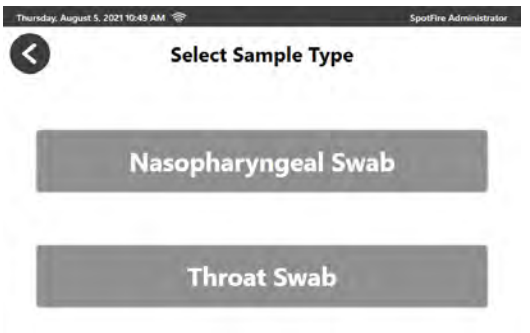
2. An operator can scan or manually enter pouch information.

Note: *If the barcode scanner is not available or the barcode is unreadable, manually enter the lot, serial number, expiration date, and pouch type printed on the pouch label*

3. Scan or enter the sample ID.

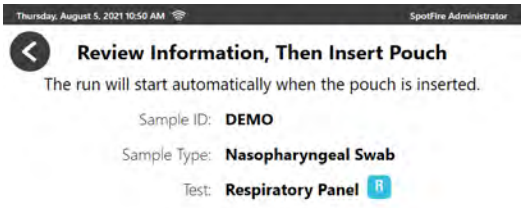
Note: *When manually entering a Sample ID, use sequentially generated recycled accession numbers to ensure that no Protected Health Information ("PHI"), as defined by the Health Insurance and Portability and Accountability Act ("HIPAA"), is requested, required, displayed, transmitted, or maintained on 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. Select the appropriate sample type, if applicable.



5. The operator can review the patient test information before inserting 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 screen will then change to the Home Screen and show the appropriate Module status.

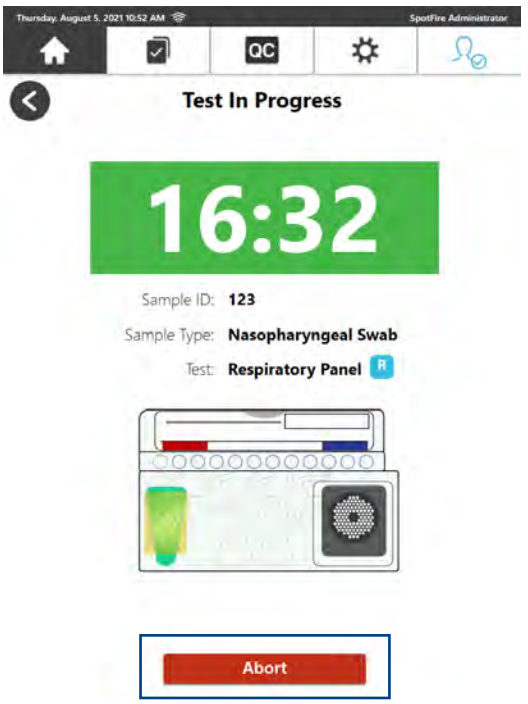


CAUTION: Do not insert sharp objects to remove a jammed pouch. In the event of a jammed pouch, contact BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor for Customer Technical Support.

Abort Run

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

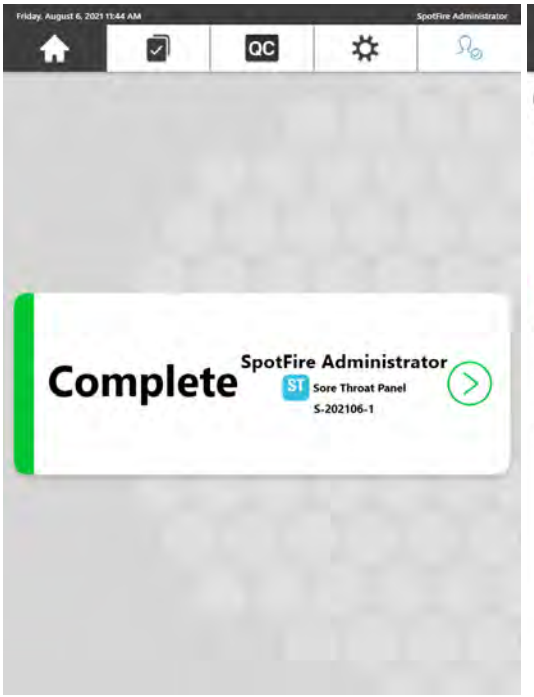
Note: An aborted run cannot be restarted, and the pouch must not be re-run.



Finish Run and View Report

At the end of the run, the home screen displays the Module's new status (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 run information.



To finisht the run:

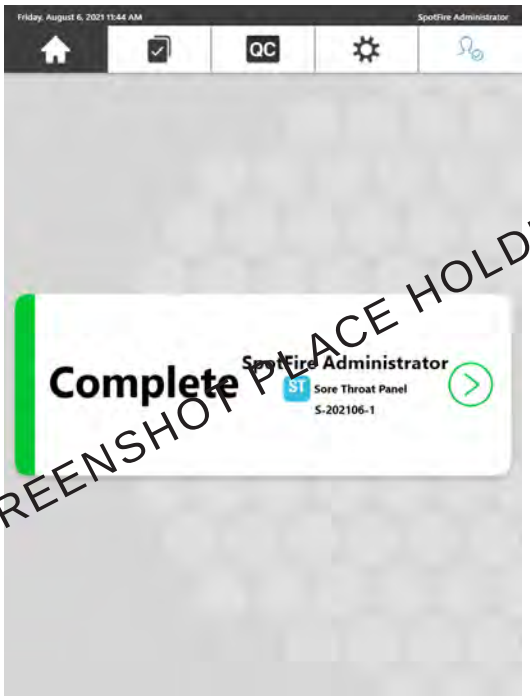
1. Remove the pouch from the Module.

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

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

View Report

After the pouch has been removedWhen a run is finished, the report can be viewed on the Patient Test Results screen. Run reports are accessible from the list.



SCREENSHOT PLACE HOLDER

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 run:

1. View the desired report
2. Select the **Print** button
3. Select the print type (either Color or Grayscale).

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 System Software and manage the database. The SpotFire System Software automatically starts when the SpotFire System is powered on.

SpotFire System Toolbar

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

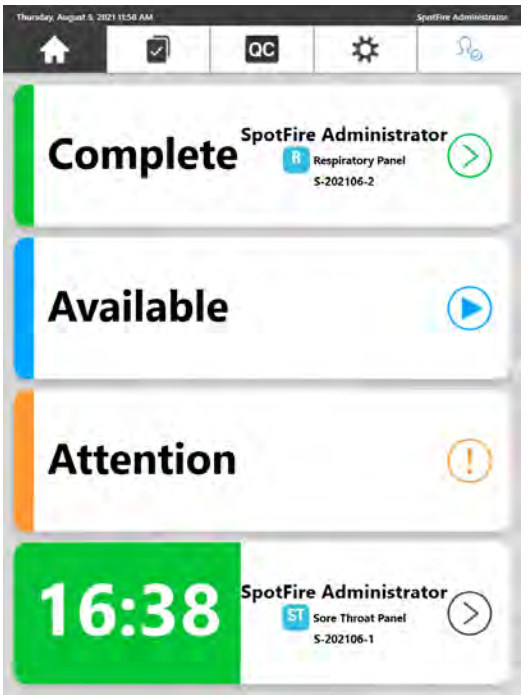
- Home Screen
- Patient Test Results
- Quality Control
- Settings
- Access Control

These five options are described below.

Home Screen

Allows the operator to do the following:

- View the status of each connected Module in the system on a display that can be seen from a distance.
- View the status of all runs that are in progress, along with the Operator who started the test, Sample ID, panel, and time remaining until completion.
- Start a patient test by using the Start Patient Test Workflow.

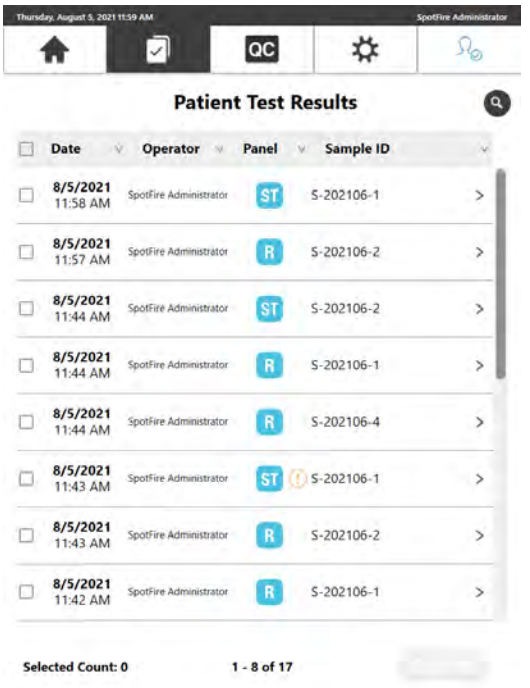


Note: *The home screen display may be different depending on the number of configured Modules.*

Patient Test Results

Allows the operator to review results for patient tests performed on all Modules connected to the Control Station. The Patient Test results screen displays all patient test runs and allows access to the following actions:

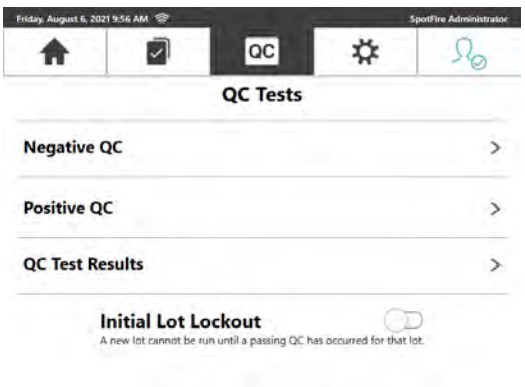
- Patient Test Results Table – Allows the operator to perform the following actions:
  a. View and sort runs in the database.
  b. Filter the database by run criteria.
  c. Page through the runs using the scrolling feature.
- Options – Allows access to additional features.



Quality Control

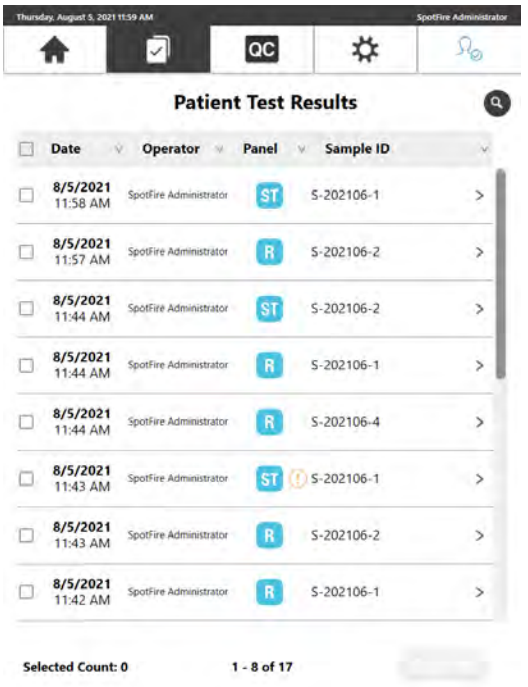
Allows operator to do the following:

- Start a positive or negative quality control test by following the Quality Control Test Workflow.
- Review results for quality control tests performed on all Modules connected to the Control Station.
- The Quality Control Test results screen displays all quality control test runs and allows access to the following actions:
  - View Report – This option is inactive until a specific report is selected.
  - Options – Allows access to additional features.
  - QC Test Results Table – Allows the operator to perform the followingactions:
    a. View and sort runs in the database.
    b. Filter the database by run criteria.
    c. Page through the runs using the scrolling feature.



Settings

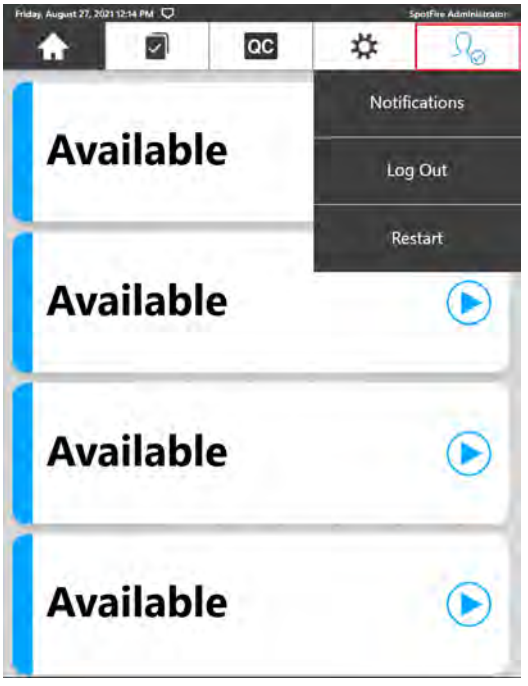
Allows the operator to perform basic configuration and management of the SpotFire. See the Settings section for details.



Note: *The options on the Settings Screen will be different when a standard user is logged in. The screenshot above shows the Settings Screen when an Administrator is logged in.*

Access Control

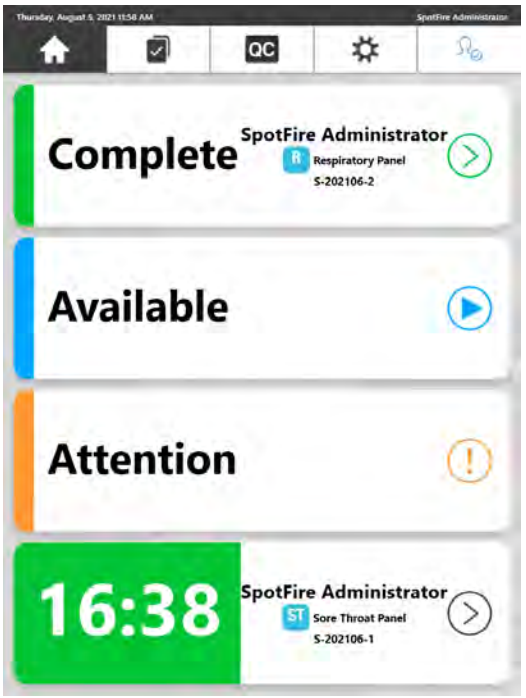
Allows operators to review notifications, restart the Control Station, and log out of the SpotFire system.



Home Screen

The Home Screen option is always accessible from the toolbar. To access the Home Screen from any screen, select the Home Screen option on the toolbar. The SpotFire Home Screen allows the operator to interact with connected Modules from one Control Station. Each Module is represented by a box displayed on the touch screen. Until at least one Module has been connected to the Control Station, the Home Screen will be blank. The number of boxes on the Home Screen mirrors the number of Modules that are configured. Any Module box on the home screen can be selected to display additional details about the Module status.

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.



Details for each Module include the following:

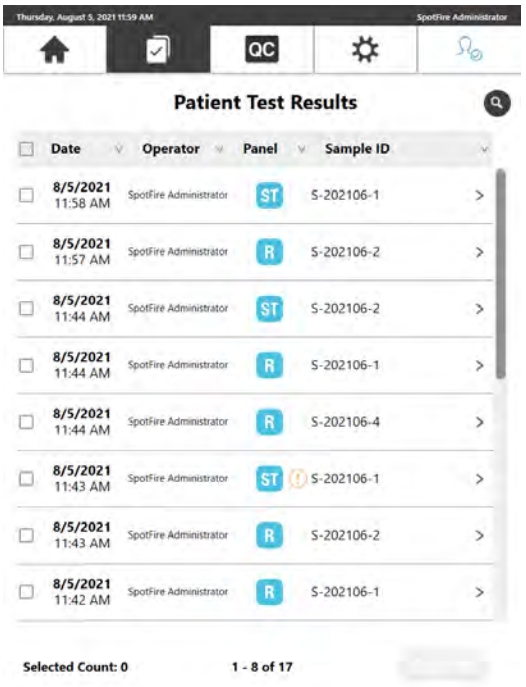
Staus Icon	Status	Descriptoin
	Initializing	The Module is performing power on self-tests.
	Available	The Module is available for to perform a task.
	Run In Progress	The Module is performing a run and displays the estimated time remaining.

	Finalizing	The Module is finalizing a run.
	Running	The Module is running diagnostic self tests.
	Complete	The Module has successfully completed a run, the pouch is ejected and the run report is ready for viewing or the Module has completed diagnostic self-tests
	Updating	The Module is updating.
	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 run ended in an error

Patient Test Results

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

The runs are presented as a table that lists the date of the run, the Operator who performed the run, and other information about the run. Selecting an individual run will display the run report.



View Report

The table below lists the features available when viewing a patient test report:

Menu Item	Description
Print	Prints the run report. See Chapter 4, SpotFire System Operating Instructions for more information about printing a report.
Show Details	Displays additional information associated with that run.
Options	Allows for the following actions to be performed for the selected report: 1. Edit Sample ID: If a mistake was made during run setup when entering the Sample ID, the operator can make the necessary corrections. A history is recorded of all changes. 2. Export to PDF: Allows the operator to save the run report as a PDF to a selected drive. 3. Create Data Bundle: If an error associated with a run occurs, a Customer Technical Support representative may request that the operator creates a data bundle for that run and send it to BioFire Diagnostics. For more information on creating a data bundle, see the *Data Bundle* section in Appendix A.

Print: For more information on printing, see Chapter 4, SpotFire System Operating Instructions.

Show Details: To see details of the run:

1. Select the run to view the on-screen report
2. Select Show Details

The operator is presented with additional information associated with that run.

Edit Sample ID: To change the Sample ID:

1. Select the run to view the on-screen report.
2. Select the options button; then select Edit Sample ID.
3. The Edit Sample ID screen is displayed.

Note: *If the Sample ID has any previous changes a table will display information about the previous edit(s).*

4. Update the current Sample ID; then select Save.

After saving the changes, the report reflects the new Sample ID.

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

1. Select the run to view the on-screen report
2. Select the Options button; then select Export to PDF.

3. Choose location and filename; then select Save. If multiple drives are available, select a destination device.

4. After save completion, select 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.*

Create Data Bundle: For more information on creating a data bundle, see the Data Bundle section in Appendix A.

Searth Patient Test Data

The Search icon on the Patient Test Results screen contains multiple search criteria an operator can use to locate desired runs. The following table describes the search criteria options:

Criteria	How to Search
Sample ID	Enter the Sample ID of interest.
Pouch Lot	Enter the Pouch Lot of interest.
Pouch Type	Select the panel of interest.
Sample Type	Select the Sample Type of interest.
Operator	Select the operator of interest.
Module	Select the Module serial number of interest.
Test Status	Select the test status of interest.
Date	Select the date or date range of interest.

To clear Search Criteria and view all patient tests saved in the database, select the Clear All or back button on the search screen.

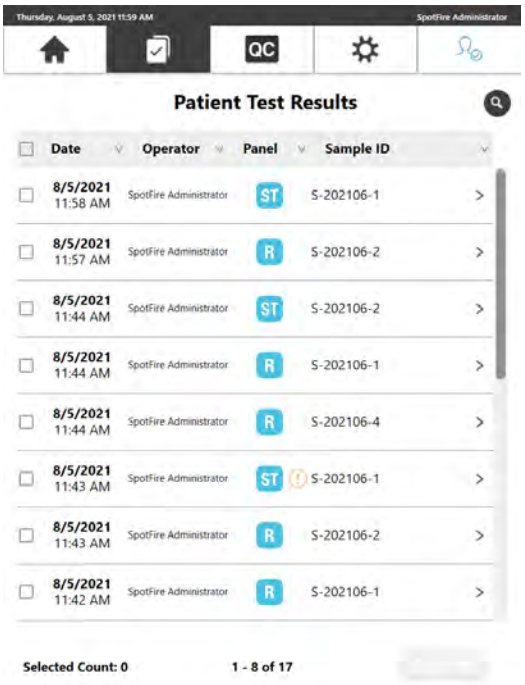
To perform the search based on entered search criteria and update the patient tests results screen, select Search.

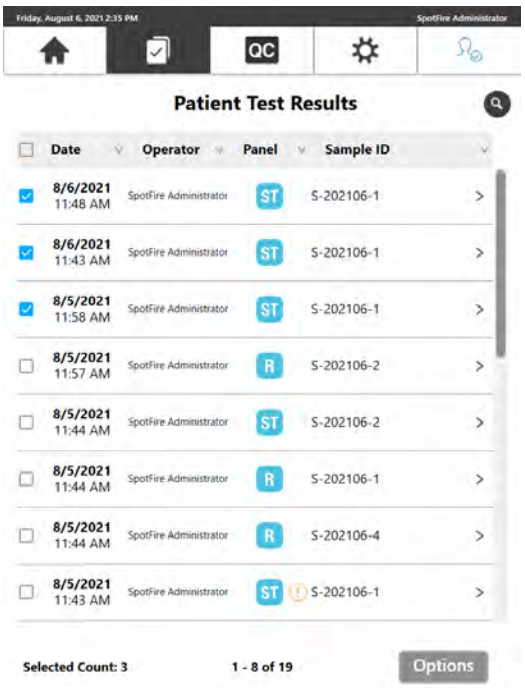
Patient Test Results Options Menu

The Patient Test Results options menu presents a list of actions the operator can use on SpotFire System runs. The following table describes the available Patient Test Results options:

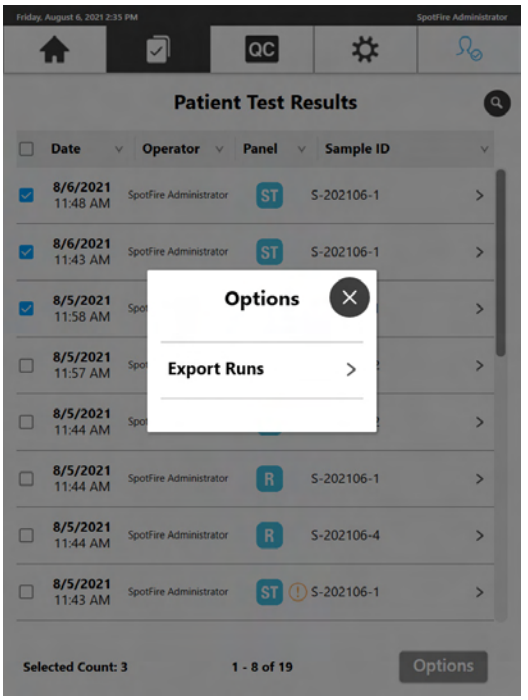
Menu Item	Description
Export Runs	Enables the operator to write runs to a file while leaving the original runs in the database. The operator will also have an option to remove the Sample ID in the run file and replace it with ‘Anonymous’.

To access the Patient Test Results options, select one or more runs to enable the Options button.





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



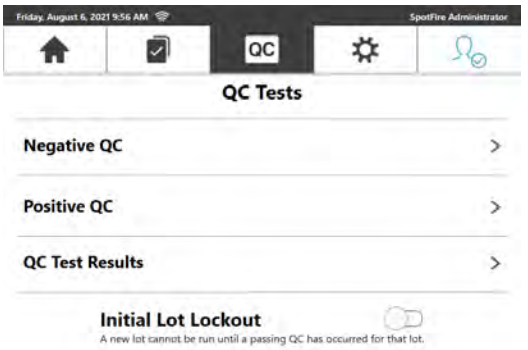
Note: *The operator can cancel the export process before it finishes by selecting Cancel on the export process dialog. Any runs that were exported before selecting Cancel will be saved to the chosen location.*

Importing Runs

Runs that have been previously exported from the SpotFire database may be imported back into the database. In addition, operators may import runs from a separate database into the database on the Control Station being used.

Quality Control

The Quality Control option is always accessible from the toolbar. To access Quality Control from any screen, select the Quality Control option on the toolbar. The Quality Control screen allows operators to start Positive and Negative QC tests as well as view previously run QC test results. Additionally, if an operator with Administrator privileges is logged in, the initial lot lockout can be enabled. The initial lot lockout will prevent a pouch from a new lot from being used for patient tests until a passing QC run has occurred for that lot.



Negative and Positive QC Runs

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. Either scan the Pouch Barcode or manually enter the Lot, Serial Number, Expiration Date, and Pouch Type.

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. The operator can review the QC test information before inserting 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 display also changes to the Home Screen and shows the appropriate Module status.

4. At the end of the run, the Home Screen changes the status of the Module and the pouch is partially ejected.

To finish a run:

1. Select the Module that completed a run on the Home Screen to view the run information.
2. Remove the pouch from the Module. The Module LED is solid blue indicating that the Module is ready for a new run.

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

To view QC Test Results:

1. Select the Quality Control option from the toolbar.
2. Select QC Test Results, the QC runs are presented as a table that lists the date of the run, the pouch lot used, and other information about the run. Selecting an individual run will display the run report.

Settings

The Settings option is always accessible from the toolbar. To access Settings, select the Settings option on the toolbar. The Settings Option allows operators to perform the following administrative tasks based on their administrative privileges:

All Operators can perform the following tasks:

- Edit My Profile – Allows the operator who is currently logged in to edit their own profile information.
- System Configuration – Allows the operator to view and update configuration settings.
  - Speaker Volume – Allows the operator to control the volume of the Control Station speakers.
  - Display Brightness – Allows the operator to control the brightness of the touch screen.
  - Modules – Allows the operator to manage Module configuration, view connected Module information, reset Module power, and run self diagnostics.
- Audit Log – Allows the operator to view a log of system and operator actions.
- Connectivity – Allows the operator to connect to a network via an ethernet connection or wireless connection, configure printer settings, and map network drives.
- Shutdown – Allows the operator to shut down the Control Station and connected Modules.
- Restart – Allows the operator to restart the Control Station without impacting connected Modules.
- The following tasks are accessible if an operator with administrative privileges is logged in:
- Operator Management – Allows an admin operator to configure automatic logout, password recovery, password strength, advanced login options, and the operator list.
- System Configuration – Allows the operator to view and update configuration settings.
  - Date and Time – Allows an admin operator to set the time zone, time, and date settings.
  - Panel Management – Allows an admin operator to view and activate/inactivate all installed pouch types.
  - Archive – Allows an admin operator to archive old runs off SpotFire System to a removable or mapped drive.

- About SpotFire – Displays details about SpotFire System installation and allows operators to create system data bundles or switch to the Windows OS.

- Report Settings – Allows an admin operator to customize report information and auto print settings.

Admin Mode

The Switch to Windows OS button within the About SpotFire screen allows operators to log out of the SpotFire System Software and access the Windows Operating System to perform administrative tasks (such as 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. Navigate to the Printers screen
2. The Select Default Printer drop down 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 run:

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

Database Management

A local database on the Control Station stores all run 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: *A database administrator is not required for the SpotFire System System.*

Archive

To archive runs stored in the SpotFire System database:

1. Log into the system as an administrative operator, if necessary, and navigate to the Settings tab.
2. Select System Configuration
3. Select Archive

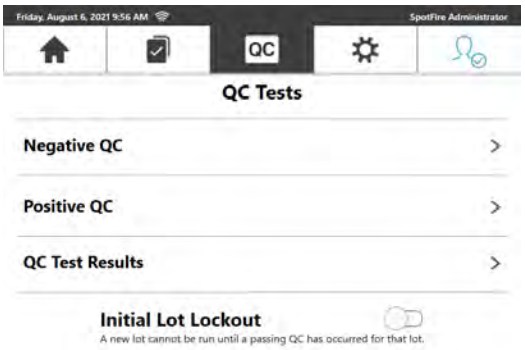
Export

To export runs 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 runs to export.
4. Select the options button.
5. Select Export Runs.
6. Select either Yes or No when the Clear Sample ID prompt appears.
7. Select the drive for the runs to be exported.
8. Select the confirmation button to initiate the export.

Lockout Statement

Admin operators can enable a lot lockout feature. The initial lot lockout will prevent a pouch from a new lot from being used for patient tests until a passing QC run has occurred for that lot.



Bi-Directional Connectivity

Optional bi-directional connectivity can be configured using the software. For assistance please refer to the SpotFire System Connectivity User Guide (BFR0001-#####) or contact Customer Technical Support.

Access Control

If the operator selects the operator icon, they will have the option to view notifications, restart, or log out.

6 Precautions When Working With the SpotFire System

Laboratory Precautions

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

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

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

Refer to the BioFire® 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. Carefully dispose of pouches 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

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

- Perform sample collection, pouch preparation, and running the SpotFire in separate locations.
- Load the pouch with wearing appropriate personal protective equipment (PPE) (e.g., 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, and protective clothing and gloves should be changed after).

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 runs.

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

CAUTION: It is essential that contamination from leaking and/or punctured pouches be contained and cleaned immediately. Pouches that break after PCR can contaminate future pouch runs. This material, although noninfectious, is easily spread by normal human activity. Treat all broken pouches as capable of contaminating the work area. Very small (molecular) quantities can be amplified by PCR in future runs, which can then be identified as a false positive by the BioFire 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, patient 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

SpotFire® Pouch Loading Station Decontamination

Routine daily cleaning of the 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. Fill a sink or bin with water and submerge the SpotFire Pouch Loading Station.
3. Fill a sink or bin with water and add bleach to create a 10% bleach solution.
4. Submerge the SpotFire Pouch Loading Station until completely covered with bleach solution. Soak for 15 minutes.
5. Remove SpotFire Pouch Loading Station from sink or bin. Replace bleach solution with distilled water.
6. Rinse the SpotFire 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 Module Decontamination.

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

SpotFire Module Decontamination

1. Put on clean PPE, such as a lab coat and gloves.
2. Remove pouch from Module and dispose in biohazard waste container.
3. Dispose of potentially contaminated gloves and lab coat and put on clean gloves and lab coat.
4. Wet a paper towel with water and wipe all exterior surfaces of the SpotFire System, including the bottom. Wipe the surface where the SpotFire Module had contact.
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 the 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. Wipe the area with a clean paper towel. Change gloves.
5. Repeat Steps 2 and 3 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. Spray the area with 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 wiping it dry.

Check Function of Decontaminated Module

1. Perform a negative QC test according to instructions in *Chapter 5, SpotFire Software*.
2. If the run is successful and all results are negative, continue using the Module as normal.
3. If unexpected positive results are obtained, or the run fails, please contact BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor for further instructions.

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 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. Wipe down all exterior surfaces of the SpotFire System with a lint-free cloth or paper towel and a freshly prepared 10% bleach solution (one part bleach to nine parts water), followed by a water wipe.
2. Periodically check and clean the Module's air filters for any build up and debris. When cleaning the touch screen of the SpotFire, it is recommended that the user log out of the SpotFire software in order to avoid any accidental selections.
3. 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%)
4. 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.*

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, for proper decontamination procedures.

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

Warning Messages

Warning Messages may originate in a 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.	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).

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 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 run 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 run. Please ensure at least one Module is in the available state.	Ensure a Module is connected to the Control Station.

Hardware Troubleshooting

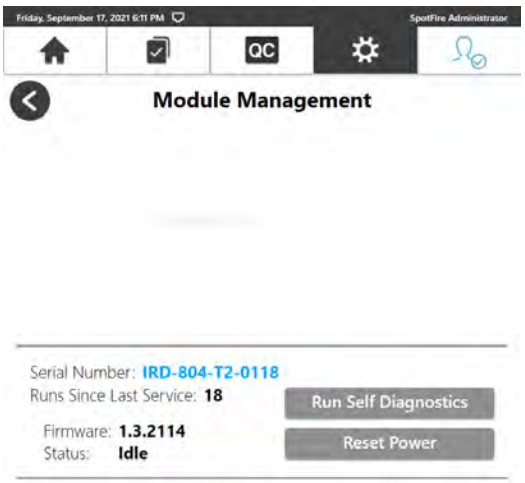
The table below lists potential symptoms and possible solutions for troubleshooting hardware issues with the SpotFire System. If the issue(s) persists after applying the recommended solutions, contact Customer Technical Support for further assistance (see page i).

Symptom	Possible Solution
Module status lights are not on	• Turn Module on • Check power cord • Try different outlet • If problem persists, contact Customer Technical Support
Module status light is blinking amber	• Reset Module using software • Check that cables are seated (do not unplug) • If problem persists, follow on-screen instructions.
Software will not connect to Module	• Make sure all cables are fully seated • 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 SpotFire Module, due to jam	• Reset Module using software • If problem persists, contact Customer Technical Support
Pouch is ejected immediately after insertion	• Reset Module using software • If problem persists, contact Customer Technical Support
Pouch is difficult to insert into SpotFire Module, or will not load into SpotFire Module	• Reset Module using software • If problem persists, contact Customer Technical Support

Pouch does not eject from Module after run	• 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 or damaged, and that no debris is obscuring it • Manually input the pouch serial number and lot number

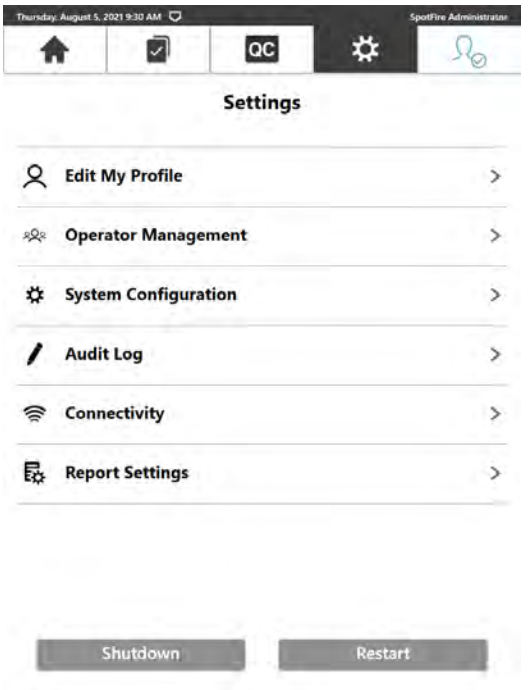
Module Reset

Navigate to the Settings tab. Select System Configuration > Instrument Modules > Module Management. Press **Reset Power** for the Module that needs to be reset.



Control Station Reset

If the Control Station needs to be reset, press and hold the Reset button for a minimum of three seconds. The Control Station will restart.



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. These messages and the suggested actions are reported in the table that follows.

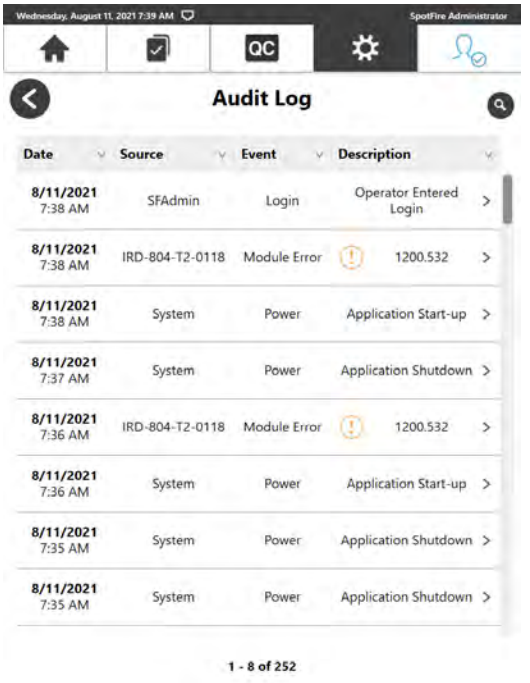
The SpotFire System performs self-diagnostics each time power is applied. Malfunctions are reported as errors to the operator. Record any error messages to assist in troubleshooting. Questions should be directed to BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor.

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

Error Reporting Tools

Audit Log

The error messages may refer to the Audit Log for details depending on the error. The Audit Log is accessed via Settings. When the Audit Log is opened, the table will be populated with system and operator events:

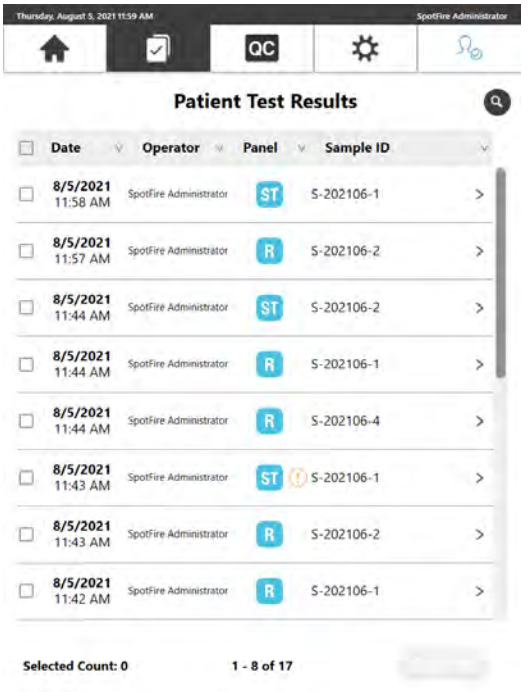


Data Bundle

If an error occurs during a pouch run, 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 run to view the on-screen report.
4. Click the Options button.
5. Select 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.

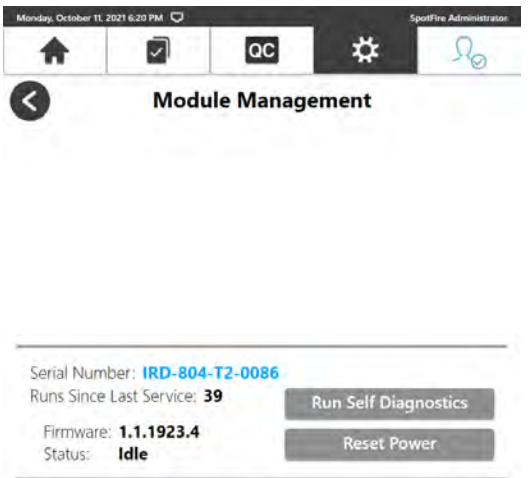
Email this file to the Customer Technical Support representative to diagnose errors.

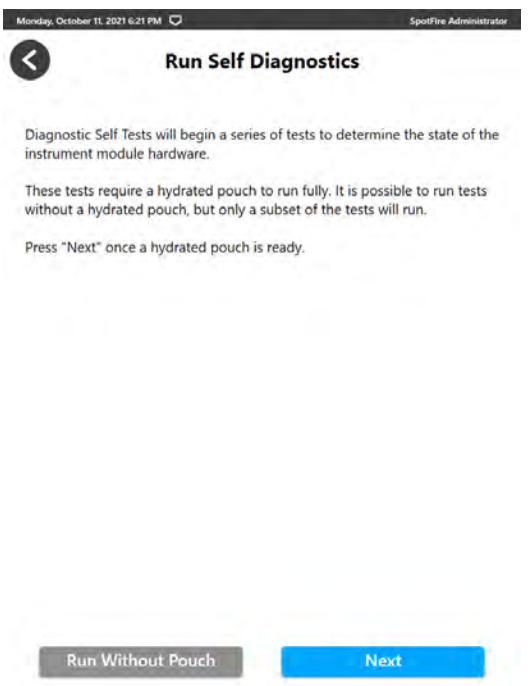
Diagnostic Self Tests

The Diagnostic Self Test function can be used to check the heath 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 run 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 Run 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, please 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 Support Information

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

SpotFire 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 SpotFire 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:

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

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

Warranty Information

Product warranty information is available online at:

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

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

Revision History

Revision History		
Rev	**Description of Change**	**Effective**
01	Initial Release	

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