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WARNINGS:

The BlueFIRE Monitor and BlueFIRE Syringe instructions for use must be completely read and understood prior to use. If performing PTA, the angioplasty balloon manufacturer's instructions for use should be read and followed.

CAUTION: The BlueFIRE Monitor should not be submerged or wet with liquids during use. The BlueFIRE Monitor may be cleaned with a damp cloth and mild detergent between uses.

CAUTION: The BlueFIRE Syringe must be open to atmospheric pressure during zeroing. If the syringe is not open to atmosphere during zeroing, inaccuracy in pressure readings may result.

CAUTION: To ensure Monitor stability, use BlueFIRE mounting accessories only.

CAUTION: The use of accessories, sensors and cables other than those specified may result in increased emission and/or decreased immunity and inaccurate readings of the BlueFIRE Monitor.

CAUTION: Portable and mobile RF communication equipment can affect the BlueFIRE Monitor.

Refer to the provided iPad user manual for instructions on how to connect the BlueFIRE Monitor to Wi-Fi to enable email capability.

INDICATIONS

The Merit Medical BlueFIRE Monitor is for use only with the disposable BlueFIRE Syringe. It may be used to measure the pressure and time of inflation within balloon angioplasty catheters or other interventional devices.

DESCRIPTION

The BlueFIRE Monitor displays pressures created by the BlueFIRE Inflation Syringe. The BlueFIRE Syringe is connected to the Monitor via Bluetooth wireless technology. In addition to displaying pressure parameters in ATM (atmospheres), psi (pounds per square inch), mmHg (millimeters of mercury), or Bar, the BlueFIRE Monitor displays duration of pressurization in minutes and seconds, time elapsed since last pressurization, and indicates when a negative pressure has been reached. The Monitor also stores an activity log of the inflation pressures reached during the procedure, and has the capability to email or print the activity logs.

The BlueFIRE Inflation Syringe is a 30mL disposable device with an integral pressure transducer, threaded plunger assembly with lock/release bar, a flexible high-pressure extension tube, and a three-way stopcock. The BlueFIRE Syringe generates positive and negative pressure over a range of -1 to +40ATM/BAR (-1 to 588 PSI), and sends pressure information to the BlueFIRE Monitor via Bluetooth wireless technology.

COMPONENTS

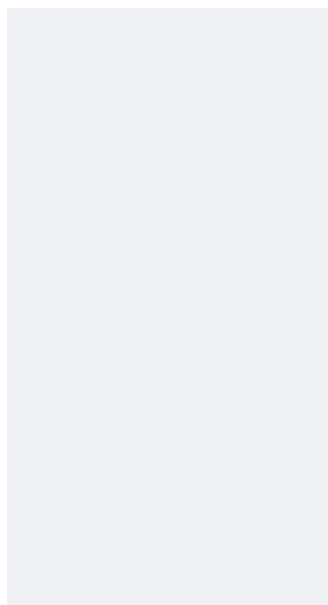
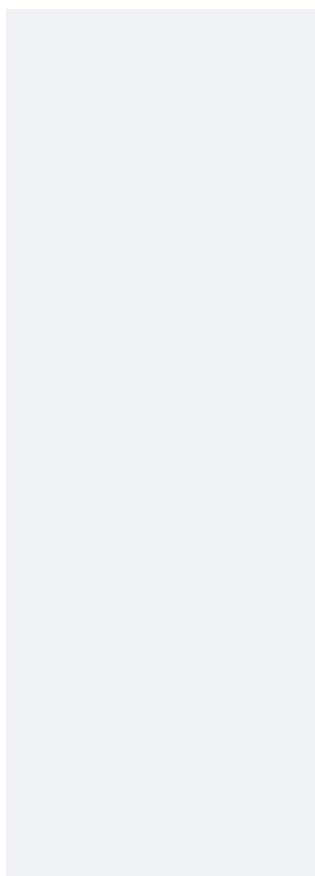


PRINTER

MOUNTING THE BLUEFIRE MONITOR

The BlueFIRE Monitor has two mounting options:

- 1. Pole Mounting:** The BlueFIRE pole mount (part number IN10POLE) may be clamped to any round or square tube from 0.5" to 2". To connect the Monitor to the clamp, loosen the Monitor thumb screw until the socket fits onto the ball on the clamp, position the Monitor, then tighten the thumb screw.
- 2. Table Mounting:** The BlueFIRE table mount (part number IN10TABLE) may be inserted into the edge of a surgical table. To connect the Monitor to the table mount, loosen the Monitor thumb screw until the socket fits onto the ball on the clamp, position the Monitor, then tighten the thumb screw.



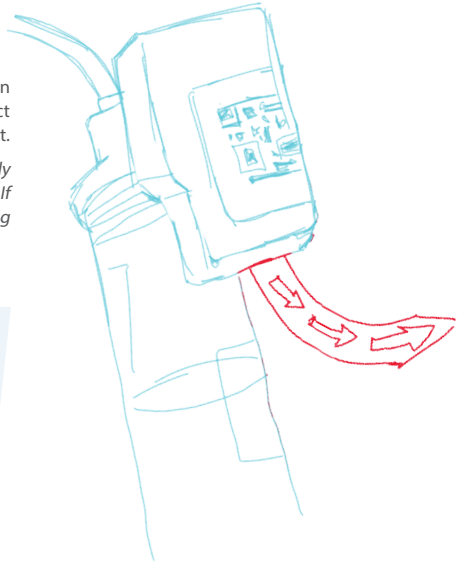
CONNECTING A SYRINGE

NOTE: Refer to the BlueFIRE Syringe “Instructions for Use” for the correct preparation of the syringe before connecting it to the Monitor.

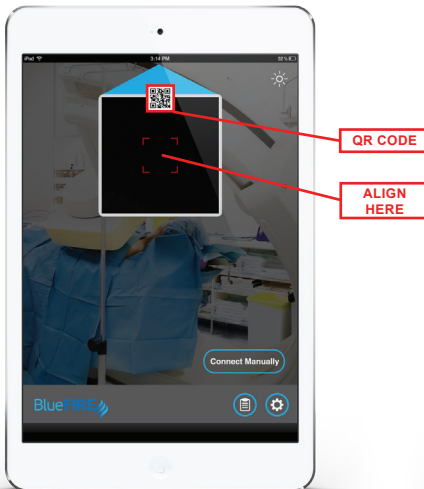
1. Pull the orange tab from the BlueFIRE Syringe.
2. To connect the Syringe, you can either scan the QR code on the Syringe or press “Connect Manually” and select the Syringe from the list.

Note: To scan, hold the Syringe QR code steady and aligned within the red box on the screen. If it does not immediately scan, try slowly rotating the Syringe QR code within the red box.

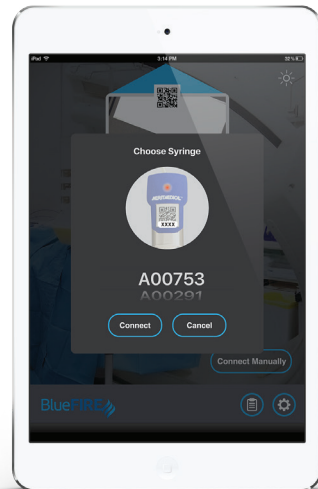
CAUTION: The syringe must be open to atmospheric pressure during connection or accurate zeroing of the pressure transducer is not assured and inaccuracy may result.



SCAN CONNECT



MANUAL CONNECT









MENU FUNCTIONS

Note: Menu Functions are not available while inflation is in progress (while there is positive pressure displayed).

Activity Log:

Access the activity log by pressing the clipboard icon . This allows the user to review data associated with all syringes in the log memory. Syringe IDs in the activity log are displayed on the left side of the screen. Select the desired syringe for review by pressing the syringe ID. The BlueFIRE app will display all events associated with that syringe on the right side of the log. Swipe up/down to review all data.

- Press the trash can icon  to delete the selected syringe from the log memory.
- Press the email icon  to email the data.
- Press the print icon  to print the data.
- Press the **X** in the upper right corner to return to the previous screen.



OPERATING THE BLUEFIRE MONITOR WITH A BLUEFIRE SYRINGE:


After connecting the BlueFIRE Syringe, the display will show the current pressure **1** and a time **2**. As the pressure exceeds 0.7 ATM (10 psi), the timer will reset and begin timing the inflation. Upon completion of an inflation, the timer will reset to zero and the duration since the last pressurization will be displayed. The last pressurization maximum value and pressurization duration are displayed in the lower right corner **3**. Values are also stored to the activity log within the BlueFIRE app (see above).

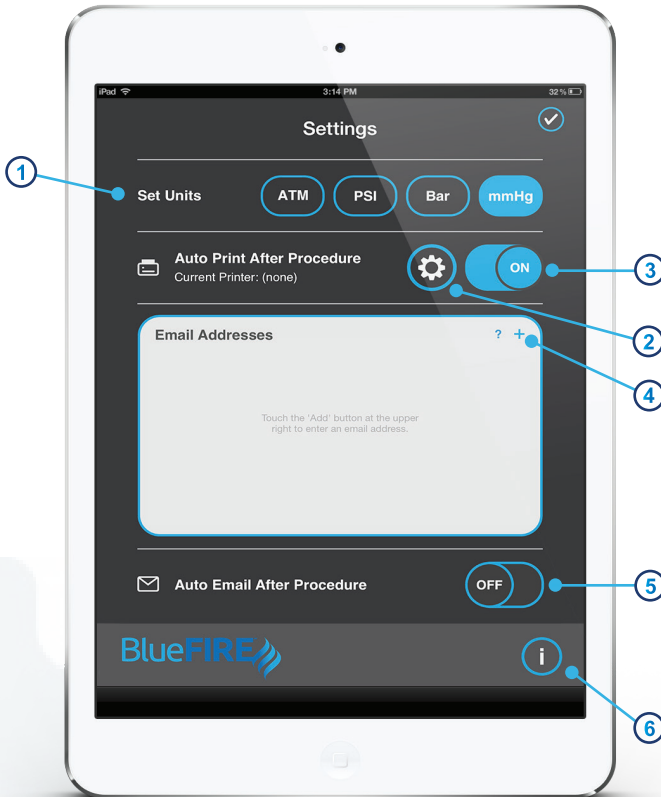
When monitoring is complete, disconnect the BlueFIRE Syringe by pressing the “Disconnect” button.

CLEANING:

The BlueFIRE Monitor is not required to be sterile. It should be cleaned regularly to prevent the build-up of contrast, saline and other contaminants with a cloth dampened with water, isopropyl alcohol or mild detergent. Do not spray the Monitor directly with the cleaning solution.

SETTINGS:

Access settings by pressing this icon 



- ① Set Units allows the user to change the current pressure display units. To set units, press the desired unit of pressure measurement (ATM, PSI, BAR, mmHg).
- ② Press this icon to set up a Bluetooth printer. Refer to the Star Micronics website to access the printer manual.
- ③ Swipe this slider to toggle auto-printing after the procedure. With this function activated, the inflation data will automatically print to a Bluetooth printer after the procedure.
- ④ Press the + symbol to add email addresses to the address list. These email addresses will be added to the "To" field of the email. Swipe to the left to delete entries from the address list.
- ⑤ Swipe this slider to toggle auto-emailing after the procedure. With this function activated, the inflation data will automatically be sent to the address list after the procedure.
- ⑥ Press this icon to view information on the BlueFIRE app and syringe.

Note: The Bluetooth printer must be set up.



SPECIFICATIONS:

Calibration	Preset
Transducer Zero	Automatic at connection of syringe
Operating Temperature Range	10°C – 35°C (50°F – 95°F)
Storage Temperature Range	-25°C – 60°C (-11°F – 140°F) packaged
Relative Humidity	30%-70% Non-condensing
Power	100-240V 50-60Hz 0.45A
System Accuracy	±3.0% of full scale range

FCC 15.21 STATEMENT:

This device complies with Part 15 of the FCC rules. Its operation is subject to the following two conditions:

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by Merit Medical Systems, Inc. would void the user's authority to operate this produce.

FCC 15.105 STATEMENT:

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

BLUEFIRE PART NUMBERS

Part Number	Description
IN10START	BlueFIRE Starter Kit, includes Monitor, Syringe, printer, pole mount, table mount, and cables.
IN10140	BlueFIRE Syringe
IN10XXX	BlueFIRE Syringe with MAP kit XXX
IN10XXX	BlueFIRE Syringe with MAP kit XXX
IN10XXX	BlueFIRE Syringe with MAP kit XXX
IN10XXX	BlueFIRE Syringe with MAP kit XXX
IN10PAD	BlueFIRE Monitor (includes cables)
IN10CABLE	BlueFIRE Cables
IN10POLE	BlueFIRE Pole Mount
IN10TABLE	BlueFIRE Table Mount
IN10PRINT	BlueFIRE Printer



End of English Manual



