Part# FP120-FOT04-010

USER MANUAL

For Use in Canada

FloPATCH™

FP120

Ultrasonic Blood Flow Monitor (4 MHz)

FLOSONICS MEDICAL

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Canada M5V 2Y1

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Phone Number: +1 289-748-3711

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1. NOTICES

1.1 Caution: Federal law restricts this device to sale by or on the order of a physician.

1.2 Manufacturer Contact Information

Flosonics Medical (R/A 1929803 Ontario Corp.)
325 Front St W, Floor 4,
Toronto, Ontario, M5V 2Y1
Canada

info@flosonicsmedical.com

1.3 FCC Compliance Statement

FCC ID: **2AUWSFP120V2**

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.

NOTE: THE GRANTEE IS NOT RESPONSIBLE FOR ANY CHANGES OR MODIFICATIONS NOT EXPRESSLY APPROVED BY THE PARTY RESPONSIBLE FOR COMPLIANCE. SUCH MODIFICATIONS COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT.

NOTE: 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 or more 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.

RF Exposure Information

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

1.4 Industry Canada Compliance

IC: **25612-FP120V2**

This device complies with Industry Canada license-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 ne doit 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.

CAN ICES-3 (B)/NMB-3(B)

RF Exposure Statement:
This equipment complies with ISED RSS-102 radiation exposure limits set forth for an uncontrolled environment.

Cet équipement est conforme avec ISED RSS-102 des limites d'exposition aux rayonnements définies pour un environnement non contrôlé.

1.5 Storage Conditions (Device) (Ambient)

1) Temperature: 10°C to 30°C
2) Humidity: 40% to 60%
3) Pressure: 57-106 kPa

1.6 Battery Life

Cumulative Run Time: at least 90 minutes of active use

2. FLOPATCH FP120 INTENDED USE/INDICATIONS FOR USE

2.1 Intended Use & Indications for Use

The FloPatch FP120 is indicated for use for the non-invasive dynamic assessments of blood flow in peripheral vessels. FloPatch FP120 operates in a single mode, the Continuous Wave (CW) mode, and is not capable of operating in any other mode. The FloPatch FP120 operates by transferring ultrasound energy to the patient's body and then detecting the reflected ultrasound energy. The theory of operation of this device is the Doppler effect.

The device is intended to be used by medical professionals, such as physicians and nurses, in hospitals and professional environments. The device is intended for prescription use on adults only.

2.2 Intended Users

The device is intended to be used by trained medical professionals, such as physicians and nurses.

2.3 Intended Patient Population

Adults (individuals over the age of 18 years).

2.4 Intended Use Environment

Hospitals and professional environments.

3. SAFETY INFORMATION

3.1 Classification

The FloPatch FP120 is classified as a portable, internally powered device. It is a medical device intended for use only by or under the order of trained medical professionals.

This device is a Type BF Defibrillation Proof Applied Part.

Personnel operating this device are responsible for reading and thoroughly understanding all accompanying documents. The device is not intended to be serviced by anyone other than trained personnel from Flosonics Medical.

Statements throughout the accompanying documentation have the following significance:

	Explanation
	WARNING! Indicates the possibility of personal injury to the Operator or Patient.
	CAUTION! Indicates the possibility of damage to the product.

3.2 Warnings

	Explanation
	WARNING! A single device is meant for single use on a single patient only. Attempting to re-use a device can increase risk of cross contamination and cross infection.
	WARNING! The device is an adjunct tool intended to aid in evaluation of cardiovascular health. It is not intended to replace the current standards of care and diagnosis.
	WARNING! The device is not intended to be used in oxygen rich environments, or in the presence of flammable anesthetics.
	WARNING! The device is intended for intact skin only. Do not use the device on or near open wounds.
	WARNING! The device is not intended for MR (Magnetic Resonance) environments. Using the device in an MR (Magnetic Resonance) environment may lead to a hazardous situation.
	WARNING! The device is not provided sterile! The device should not be used in sterile environments.
	WARNING! Use of this device adjacent to or stacked with other equipment should be avoided as it could result in improper operation. If such use is necessary, the device and equipment should be observed to verify that they are operating normally.
	WARNING! Use of accessories, devices and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and result in improper operation.
	WARNING! Portable RF (Radio Frequency) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the FloPatch FP120, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could occur.
	WARNING! The FloPatch FP120 must be inspected before and during use for any damage to the adhesive or enclosure. If any damage is detected, the device must not be used.
	WARNING! The device must not to be used at the same time as HF (High Frequency) surgical equipment or in a surgical environment. Doing so may create a hazardous situation.

	WARNING! Do not use the system for any purposes other than the intended use. Do not use this system with systems that are not expressly recognised as compatible by Flosonics. Operation of this product for unintended purposes may a create a hazardous situation.
	WARNING! Do not use damaged equipment or accessories. Doing so may create a hazardous situation. If damage to the equipment is suspected, contact the manufacturer immediately.
	WARNING! If the FloPatch FP120 hardware is connected to a compatible mobile device that is already connected to other equipment, this could result in previously unidentified RISKS to PATIENTS, OPERATORS or third parties. If such a situation arises, the user should identify, analyze, evaluate and control these RISKS. Flosonics explicitly recommends against connecting equipment other than those part of the FloPatch FP120 system to the compatible mobile device. Doing so may lead to unforeseen hazardous situations. Doing so may create hazards such as the following: - It may compromise the integrity of the wireless connection leading to a degradation in performance of the FloPatch FP120 system. - The use of additional equipment that is part of the FloPatch FP120 system may interfere with the performance of the FloPatch FP120 system. The user must comply with IEC 60601-1:2012-Ed3.1 clause 16 when the additional equipment is used with the FloPatch FP120 system.
	WARNING! The following situations with respect to the compatible mobile device could introduce new RISKS and require additional analysis: - Changes to the compatible mobile device's configuration - Connection of additional items to the compatible mobile device - Disconnecting items from the compatible mobile device - Update of equipment connected to the compatible mobile device - Upgrade of equipment connected to the compatible mobile device
	WARNING! Flosonics Medical explicitly recommends against using additional equipment which is not part of the FloPatch FP120 system. Doing so may create an unforeseen hazardous situation.
	WARNING! The FloPatch FP120 device in not cleared for use in Domestic environments.
	WARNING! Do not use a device that is past its date of expiry. Doing so may create a hazardous situation. Return any such devices to the manufacturer or dispose of such devices in accordance with local regulations.

3.3 Cautions

Icon	Explanation
	CAUTION! Federal law restricts this device to sale by or on the order of a physician.
	CAUTION! Use only manufacturer-provided devices and parts.
	CAUTION! Do not alter the device or provided components.
	CAUTION! Do not attempt to service the device. In the event the device malfunctions, please contact the manufacturer.
	CAUTION! Keep the device dry.

⚠	CAUTION! Do not sterilize the device.
⚠	CAUTION! The use of this device should be avoided in the presence of intentional electromagnetic emitters such as a mobile phone other than the compatible mobile devices specified by Flosonics Medical in Appendix B of this user manual.
⚠	CAUTION! Failure to operate the FloPatch FP120 system in the EMC environment as specified by Flosonics Medical in Appendix C may lead to a degradation in performance of the FloPatch FP120 system.
⚠	CAUTION! Failure of the FloPatch FP120 hardware to connect to a compatible mobile device which has the mobile medical application installed will result in the FloPatch FP120 system not being able to display a waveform and play the Doppler audio. In such situations, the usage of the device must be halted, and the manufacturer must be contacted immediately.
⚠	CAUTION! Do not try to connect the FloPatch FP120 to an incompatible mobile device, the FloPatch FP120 hardware will not be able to connect. If in the rarest of cases a connection is established, the device will not perform as intended and this may create an unknown and unforeseen hazardous situation. In such situations, the usage of the device must be halted, and the manufacturer must be contacted immediately.
⚠	CAUTION! The FloPatch FP120 will not connect to a device whether compatible or incompatible, that has a Bluetooth connection already established with another device. If in the rarest of cases a connection is established, the device will not perform as intended and this may create an unknown and unforeseen hazardous situation. In such situations, the usage of the device must be halted, and the manufacturer must be contacted immediately.
⚠	CAUTION! The user is responsible to configure the system with the institutions security policies.
⚠	CAUTION! Any non-medical grade equipment must be operated at least 1.5 m away from the patient.
⚠	CAUTION! Notifications and alerts from other third-party applications installed on a compatible mobile device may interfere with the use of the FloPatch FP120 system.
⚠	CAUTION! Battery self discharge may cause charge depletion over time. The device must be periodically recharged during factory storage.
⚠	CAUTION! Battery must be recharged just before delivery of the device to the user.
⚠	CAUTION! The FloPatch FP120 system is not intended for fetal use. For pregnant women do not direct the Transducer towards the fetus.

3.4 Symbols

Labelling Presentation	Reference	Title of Symbol	Notes
	ISO 7010-M002	Consult Instructions for Use (IFU)	This indicates that the Instructions for use must be consulted before using this device.
	ISO 15223-1:2021	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or

			operator action in order to avoid undesirable consequences.
	IEC 60417-5334	Defibrillation-Proof Type BF Applied Part	The device meets requirements set for defibrillation-proof Type BF applied part as specified in IEC 60601-1.
	ASTM F2503	MR Unsafe	The device is not intended to be used in an MR environment.
	21 CFR 801.109	Prescription Use Only	The device is intended for prescription use only.
	ISO 15223-1:2021 Reference no. 5.1.1.	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1:2021	Do not re-use	Indicates a medical device that is intended for one single use only. NOTE: Synonyms for “Do not reuse” are “single use” and “use only once”.
	ISO 15223-1:2021	Do not use if package is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	ISO 15223-1:2021	Fragile, Handle with Care	Indicates a medical device that can be broken or damaged if not handled carefully.
	ISO 15223-1:2021	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.
IP67	IEC 60529	IP Rating	An IP67 rating signifies that the labelled device is protected from ingress of water up to a depth of 1m for 30 minutes and protected against the ingress of dust.
	Bluetooth Special Interest Group (SIG)	Bluetooth Symbol	This symbol specifies the use of the Bluetooth technology in this device.
	ISO 15223-1:2021	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.

	ISO 15223-1:2021	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1:2021	Atmospheric pressure limitation	To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.
	Federal Communications Commission	FCC Logo	The FCC logo is used on a product that has been tested, evaluated, and found to be compliant in accordance with the Supplier Declaration of Conformity procedures.
	ISO 15223-1:2021	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
CE 2797	MDR 2017/745, Annex V	CE Marking of Conformity	Indicates that the device complies with applicable directives. 2797 signifies that BSI Netherlands is the notified body assessing conformity
EC REP	ISO 15223-1:2021	Authorized representative in the European Community	Indicates the authorized representative in the European Community / European Union.
MD	MedTech Europe Guidance- Use of Symbols to Indicate Compliance with the MDR ISO 15223-1:2021	Medical Device Symbol	Signifies that the product is a medical device.
	EN 50419:2006	WEEE Symbol	Indicates that the device requires separate collection for WEEE – Waste of electrical and electronic equipment
	ISO 15223-1:2021	Use by date	Indicates the date after which the medical device is not to be used.
SN	ISO 15223-1:2021	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
REF	ISO 15223-1:2021	Catalogue Number	Identifies the Flosonics Medical catalogue number so that the medical device can be identified.

4. FLOPATCH FP120 OVERVIEW

The FloPatch FP120 is a non-invasive blood flow evaluation device to be used in a medical/hospital setting for use by a trained medical professional.

The FloPatch FP120 is a hands-free wearable ultrasound device that is portable and non-invasive. The device consists of a single unit that acquires the signal and processes the signal. The processed signal is transmitted wirelessly to a medical mobile application. The device has one ON/OFF power button and two status indicators. The status indicators indicate the status of the device at any given time, i.e. active, standby, low battery, off, etc. The device operates on a fixed acoustic output level.

The device can be used to detect blood flow in peripheral vasculature. The device uses ultrasound to detect the flow of blood with the help of the Doppler effect.

5. FLOPATCH APPLICATION

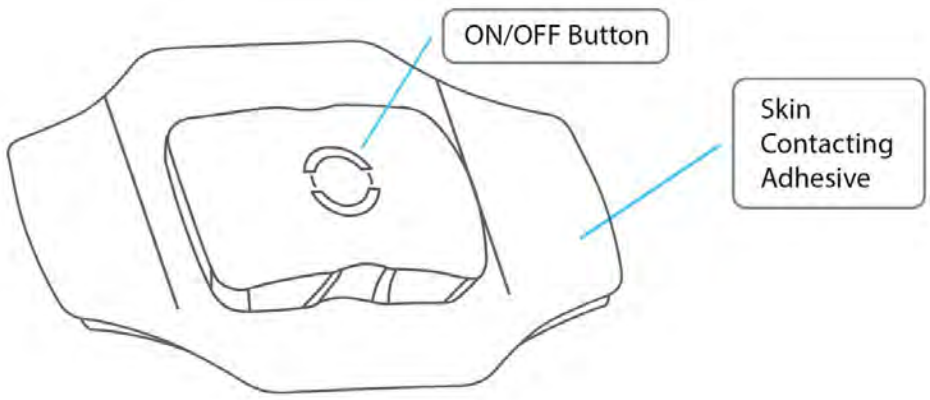
The primary function of the FloPatch is to process and display the Doppler signal received from the FloPatch hardware. The application is not designed for and should not be used for any purpose other than the intended use of the FloPatch system.

The application will be available for download on the Apple Application Store (App Store) and will be installed by Flosonics Medical on the user's compatible mobile devices.

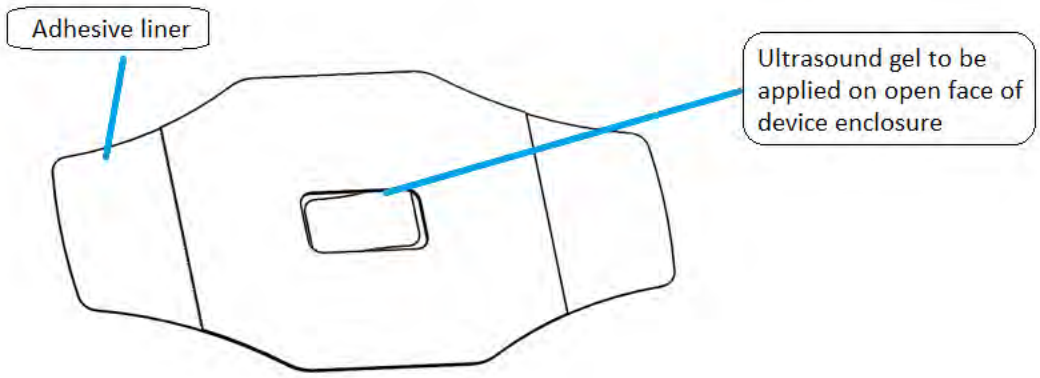
Flosonics Medical staff can be contacted via support@flosonicsmedical.com or phone +1 289-748-3711

5.1 Main Unit Diagram

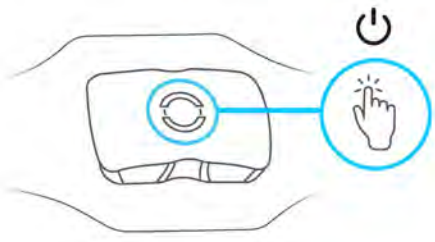
Top View



Angled Bottom View

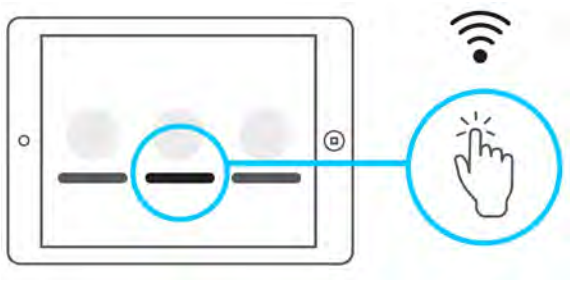


6. BASIC OPERATION



1. Press the power button to turn on the device.

   After initialization, the device LED indicator will pulse to indicate it is ready to connect to the mobile app.



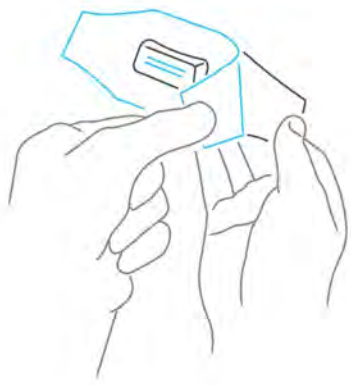
2. Open the mobile app and press Start to open the Active Session screen. A window will appear with a list of devices available to connect.

   Select the desired device. The device LED indicator will initially pulse, and the application will prompt the user to confirm the device ID. Wait until it changes to solid blue to indicate that the device is connected, and data is streaming.

3. If applicable, shave down the target region to remove any excess hair.

4. Apply ultrasound gel on the device directly over the ultrasound transducer in the indicated area.

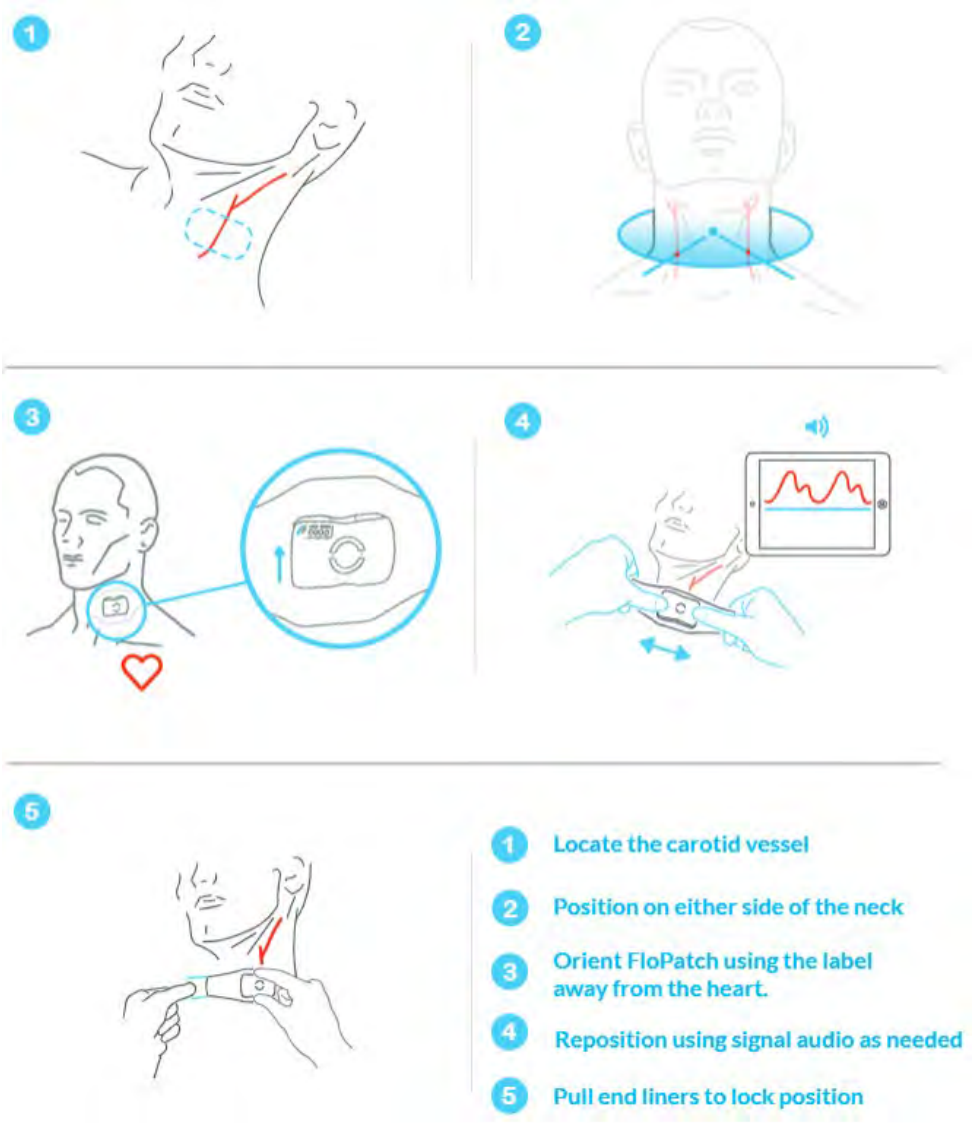
   Auditory feedback should be heard from the mobile app when the gel is applied.



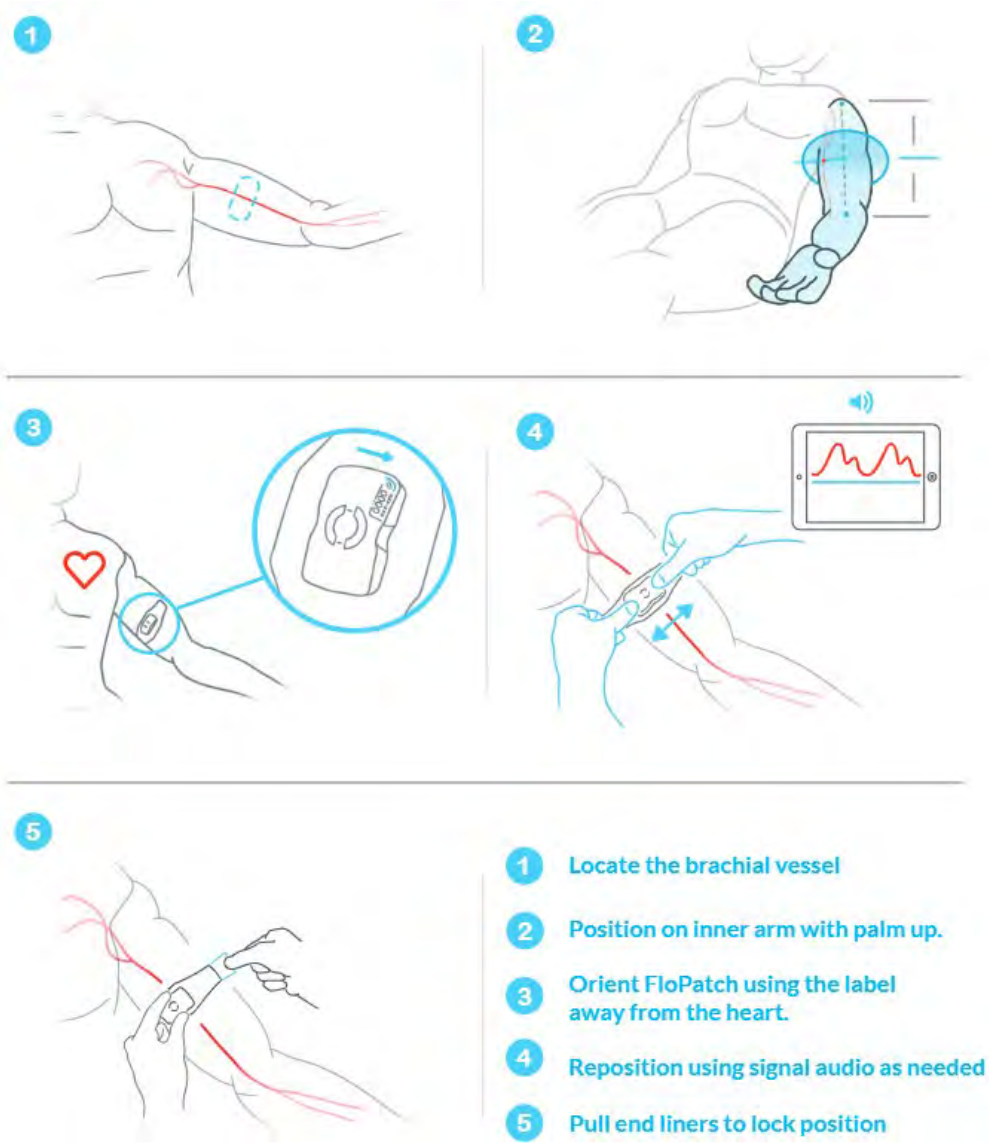
5. Peel the first liner off the back of the adhesive strap and use the end tabs to hold either end of the strap.

6. Locate target vessel and place the FloPatch

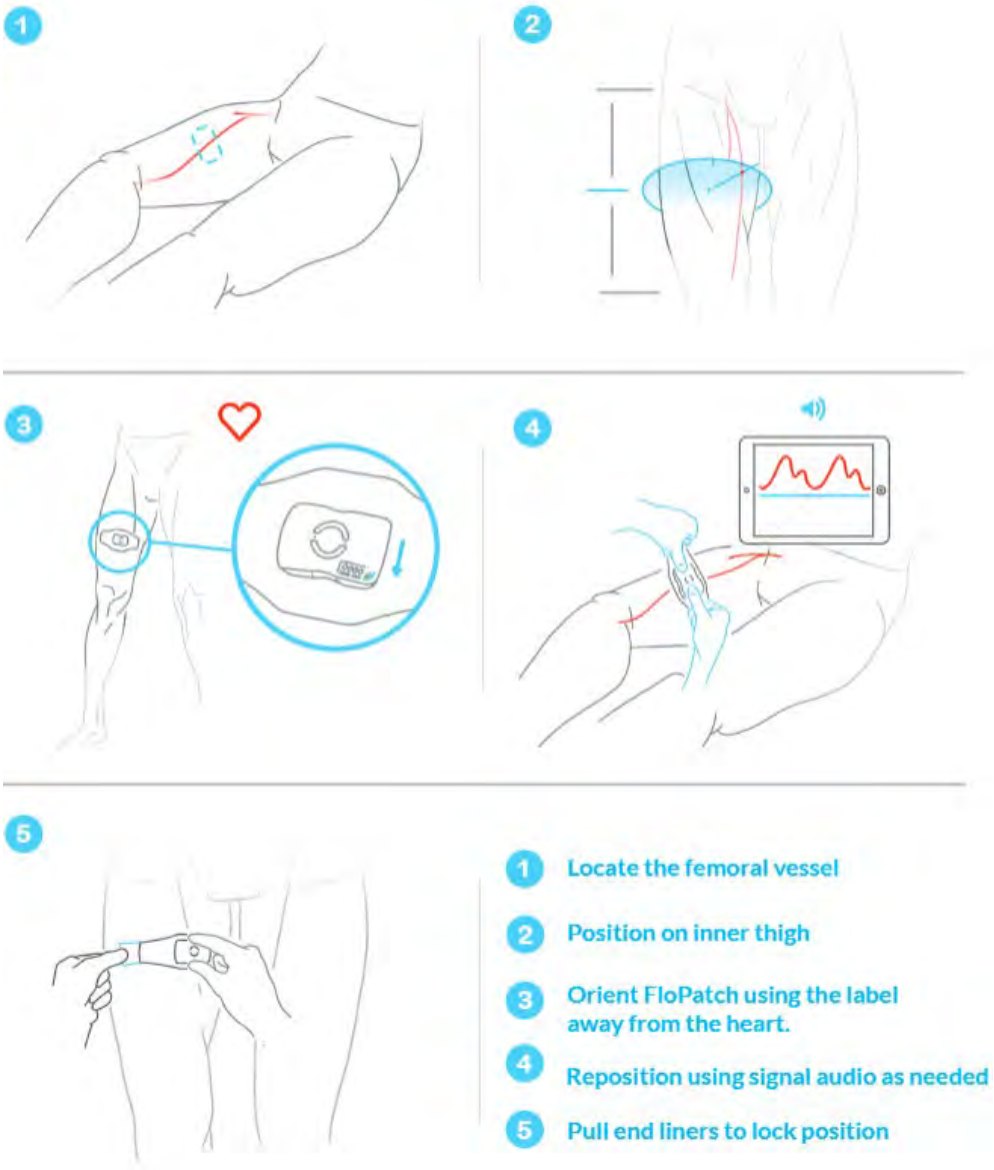
Carotid


1
2
3
4
5
1 Locate the carotid vessel
2 Position on either side of the neck
3 Orient FloPatch using the label away from the heart.
4 Reposition using signal audio as needed
5 Pull end liners to lock position

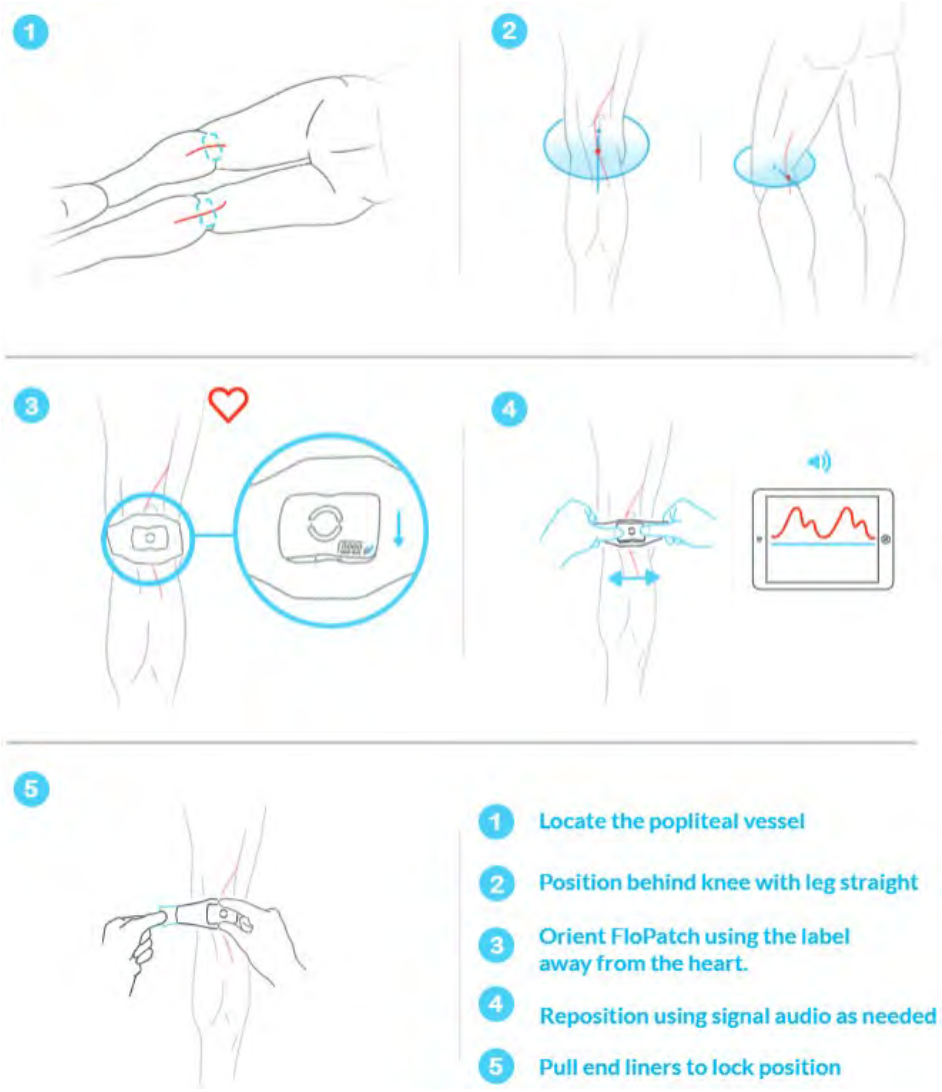
Brachial


1
2
3
4
5
1 Locate the brachial vessel
2 Position on inner arm with palm up.
3 Orient FloPatch using the label away from the heart.
4 Reposition using signal audio as needed
5 Pull end liners to lock position

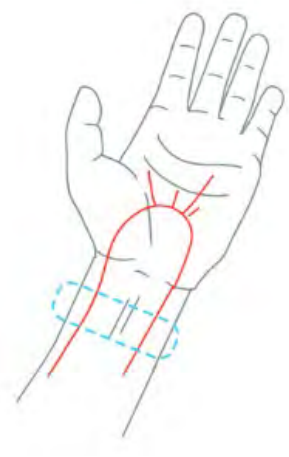
Femoral

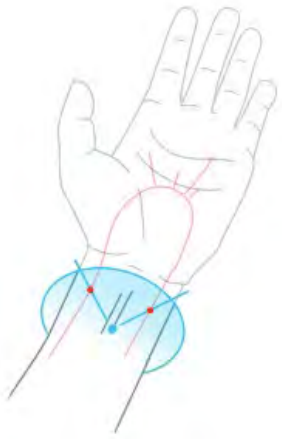

1
2
3
4
5
1 Locate the femoral vessel
2 Position on inner thigh
3 Orient FloPatch using the label away from the heart.
4 Reposition using signal audio as needed
5 Pull end liners to lock position

Popliteal

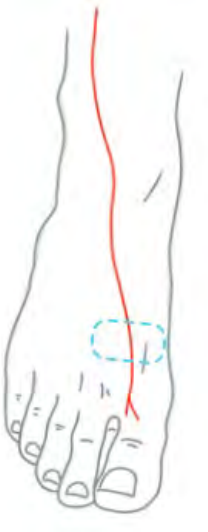

1
2
3
4
5
1 Locate the popliteal vessel
2 Position behind knee with leg straight
3 Orient FloPatch using the label away from the heart.
4 Reposition using signal audio as needed
5 Pull end liners to lock position

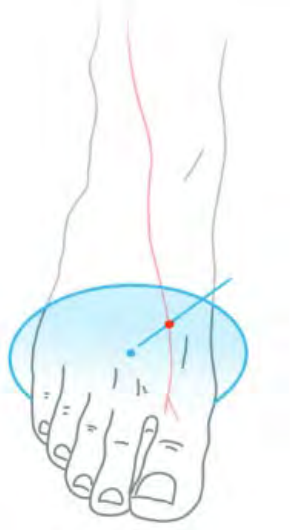
Radial/Ulnar





Dorsalis Pedis

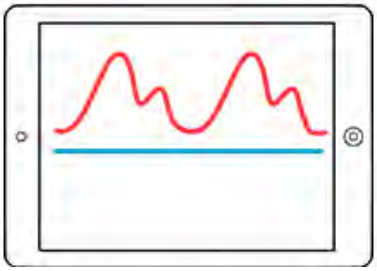




7. Ensure a satisfactory Doppler sound and waveform from the mobile app (i.e. satisfied with the tonal quality, auditory volume, audio stability and waveform performance).

   If satisfied, adhere the exposed adhesive to the skin. Then hold the device in place and remove the end liners one at a time to adhere the entirety of the strap to the skin.

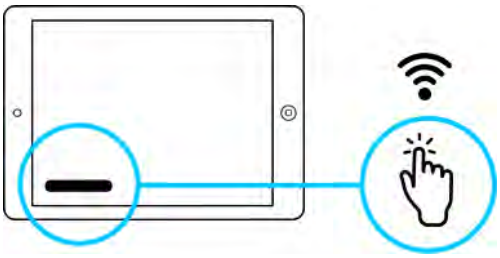
   Additional adhesives may be applied over top of the device. Refer to Section 6.1 for more details.



8. After securing the FloPatch, the Doppler wave trace can be viewed on the FloPatch application. Perform any necessary assessments and examine the mobile app for information on patient physiology.
9. Once the assessment is complete, the FloPatch may remain secured to the patient and will enter into a standby mode to allow for reassessment.

   The standby mode is indicated by a slow pulsing of the LEDs.

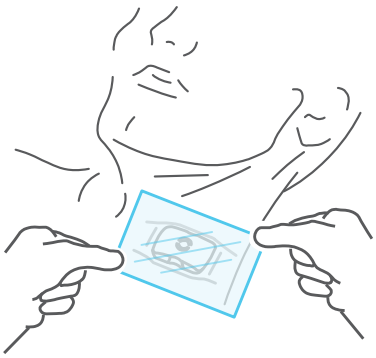
10. To perform subsequent assessments, simply open the Active Session screen and repeat Step 2 to reconnect the device.
11. To switch to another FloPatch or finish using the current FloPatch, manually disconnect the device by pressing the FloPatch Connection Info button in the bottom left corner.



12. After all assessments are completed, or the device battery runs out, press and hold the power button for two seconds to turn off the device. Remove the adhesive and the device from the patient's neck.
    To remove the device for disposal slowly start peeling the edge of the adhesive. If needed, use an alcohol wipe/spray at one edge of the adhesive and then between the adhesive and the skin while peeling.
13. Dispose of the device as required by local regulations for electronics disposal.

⚠	**WARNING!** A single device is meant for single use on a single patient only. Attempting to re-use a device can increase risk of cross contamination and cross infection.

6.1 Additional Adhesives



Additional 3rd party medical grade adhesives may be placed over the device to provide added support. The device will continue to operate normally with the medical grade adhesives overlaid as shown in the image.

Acceptable 3rd party medical grade adhesives are:

- Tegaderm Film
- Opsite Flexifix
- dermaFLEX Film
- Surgical/Medical Tape

7. USER INTERFACE

7.1 Device LEDs

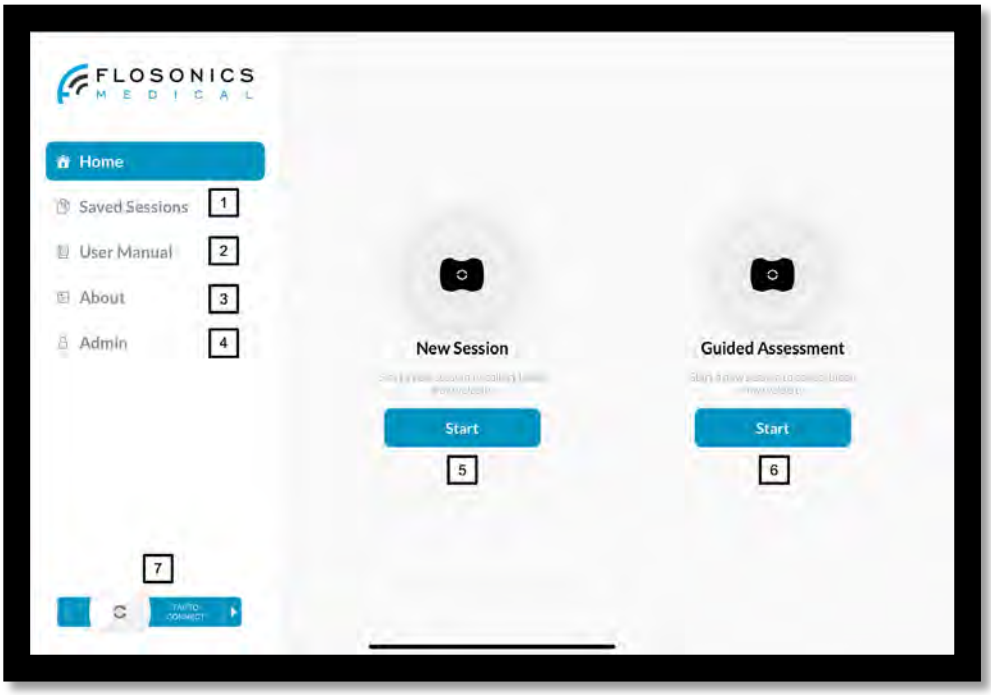
The FloPatch provides the user with information on its current state using LED lights.

LED Color	Battery Status
Blue	Full
Amber	Low

Mode	Device Status	LED Behavior
Initial advertising	FloPatch is actively advertising its availability for a Bluetooth connection.	Fast pulsing light
Connection confirmation	FloPatch reaches this state after a Bluetooth connection is established with an iPad, and the application prompts the operator to confirm device ID.	Fast pulsing light, blue and amber in unison
Initial connection	The FloPatch is connected to the iPad and is ready to stream.	Solid light
Streaming	The FloPatch is connected to the iPad and is actively streaming.	Solid light
Standby	FloPatch has a Bluetooth connection to an iPad but is no longer streaming. or The FloPatch is advertising and is no longer connected to an iPad	Slow pulsing light (i.e., dimly illuminated with one bright pulse every five seconds)

7.2 Main Menu

The main navigation menu for the FloPatch application. It allows the user to access the core functionality of the FloPatch application.



1) Saved Sessions Access previously recorded sessions.

2) User Manual Access this user manual document.

3) About Access application version, FloPatch device label, and user feedback form.

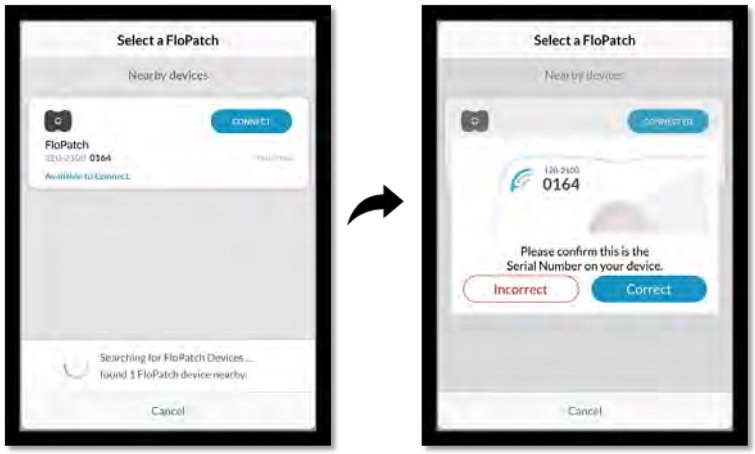
4) Admin Settings Application settings accessible by Flosonics Representatives. This screen is password protected and not available to users.

5) New Session Launches the Active Session screen if a FloPatch is already connected to the iOS device. If no FloPatch is connected, a FloPatch connection screen will appear (see section 7.3). More information about the Active Session screen can be found in section 7.5.

6) Guided Assessment Launches a version of the Active Session screen with an automated assessment workflow that guides the user through data collection and analysis.
If no FloPatch is connected, a FloPatch connection screen will appear (see section 7.3). More information about the Guided Assessment screen can be found in section 7.6.

7) FloPatch Connection Information Users can connect a FloPatch by pressing the FloPatch Connection Info button to open the connection window. The FloPatch Connection Info button will then indicate a device is connected.

7.3 FloPatch Connection Window



The FloPatch Connection window, shown above on the left, appears under the following conditions:

1. One of the Start buttons is selected on the Main Menu and no FloPatch is currently connected.
2. The FloPatch Connection Info button is selected on any screen in the application, and no FloPatch is currently connected.

To connect to a device, press Connect. The window shown above on the right will then appear asking you to verify that you have selected the device with the matching Serial Number. The LED on the selected device will pulse, simultaneously with the display, and the Serial Number can be found on the top of this device as indicated in the image. This will assist in identifying the correct device if multiple devices are discovered nearby.

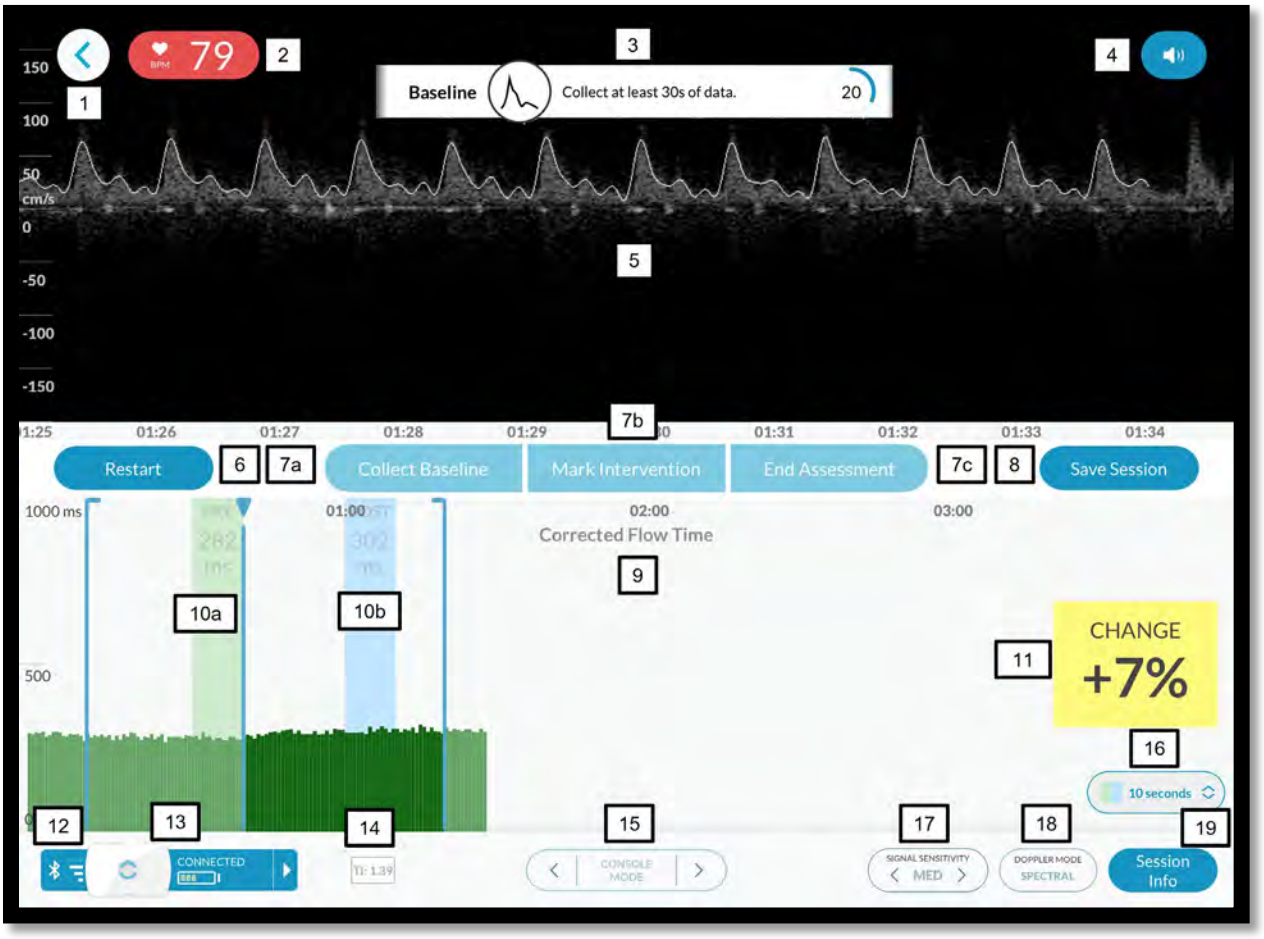
The application will only allow for one FloPatch to be connected at a time.

If you attempt to connect to a FloPatch in a low battery state, the notification message below is displayed. In this case, the FloPatch battery is unlikely to last the duration of an assessment. If you choose to continue, the FloPatch may power off during an assessment without additional warning. If more assessments are required, it might be more appropriate to replace the existing FloPatch with a new one.

7.4 FloPatch Info and Disconnect Window

The FloPatch Info window can be accessed by pressing the FloPatch Connection Info button in the bottom left corner of the app (on the Main Menu or Active Session screen) when a device is connected.
The *Disconnect FloPatch* button on this screen manually disconnects a connected FloPatch when pressed.

7.5 Active Session Screen



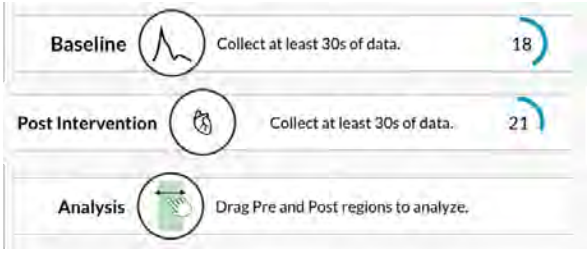
The Active Session screen is where the Doppler information taken from the FloPatch is displayed graphically to the user. This screen is the core functional part of the FloPatch application and has several features. In the above image, the parts of the screen are labeled 1-19, and information about each component can be found below:

1) Return Button — Returns to the Main Menu.

2) Heart Rate Display — Displays the current heart rate of the patient wearing the FloPatch in beats per minute (BPM). (BPM is calculated using the incoming Doppler waveforms).

3) Assessment Stage

Displays the current stage in the assessment workflow. This workflow consists of 3 stages:



The user can navigate in succession through these 3 stages using the Assessment Stage buttons.

It's recommended that the user collect a minimum of 30 seconds of data in the Baseline and Post Intervention stages and a timer is provided for reference.

4) Volume

Press the speaker button to adjust the volume of the Doppler audio.

5) Waveform Display

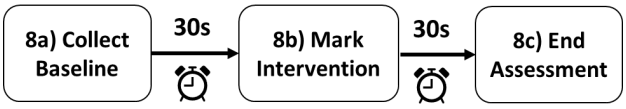
Covers the upper half of the screen and displays the maximum velocity trace over the spectrogram, as measured by the FloPatch, in real-time. The device waveform streams from the right side of the screen to the left with a scrolling axis.

6) Restart

Clears all information in the Waveform Display and the Metrics Console and restarts the data stream from the FloPatch.

7) Assessment Stage Buttons

Controls the assessment stage. The 3 buttons must be selected in a sequential manner as shown below. It's recommended that a minimum of 30 seconds of data be collected in the Baseline and Post Intervention stages.



Markers are placed in the Metrics Console at the point in time that Collect Baseline, Mark Intervention, and End Assessment are selected. The metric bars generated during the post intervention stage will also be shaded a darker color.

8) Save Session

Stops the recording, opens the Session Review screen, and saves the current session data for review from the Saved Sessions screen.

9) Metrics Console

Covers the lower half of the screen and displays the calculated metric as bars, with one bar corresponding to one heartbeat. The user can toggle between different metrics using the Console Mode button.

Metric bars representing heartbeats recorded while in the post intervention stage will be shaded a darker color to easily identify when an assessment was completed.

10) Pre and Post Intervention Sliders

Green (pre-intervention) and blue (post-intervention) sliding bars appear after selecting the Collect Baseline button for the metrics Max Total VTI and Corrected Flow Time. The user may slide the bars over the desired metric bars to compare the percentage change between the two sections of the session.

11) Comparison Result

Calculated values are displayed which represent the comparison between the metrics collected during the Pre and Post Intervention Sliders. The yellow box can be tapped to toggle between the following values:

1) **Percent Change**
   The percent increase or decrease of the mean post-intervention data relative to the mean pre-intervention (baseline) data.

2) **Change**
   The increase or decrease of the mean post-intervention data relative to the mean pre-intervention (baseline) data**.**

3) **Variability** (only metric for Peak Systolic Velocity)
   Peak Systolic Velocity is a time-varying metric that depends on changes in respiratory rate, hence, it is continuously updated and doesn't depend on comparisons of two sections of data. The current Peak Systolic Velocity Variability will be displayed on the right most side in an orange box, as shown below. The current Peak Systolic Velocity Variability will continue to update until Mark Intervention is pressed. After Mark Intervention is pressed the value will stop updating and be labeled Baseline PSV Variability.

12) Wireless Connection Performance Indicator

The Bluetooth icon flashes red when data has not been successfully transferred between the FloPatch and FloPatch application to warn the user of a decrease in signal quality.

See Section 8 Wireless Connection Performance for additional information.

The Bluetooth connection strength is displayed to the right of the Bluetooth icon as a value from 1 to 4 bars.

13) FloPatch Connection Information

Displays the connection status of the connected FloPatch. This includes the battery level, which is displayed graphically as a battery with green charge units. The battery graphic turns red in a low battery state, when the FloPatch battery is unlikely to last for another assessment.

Selecting the button opens the FloPatch Information and Disconnect Window.

14) Thermal Index

The Bone Thermal Index (TIB) is displayed here. See Appendix D for additional information on Ultrasound Intensity and Safety.

15) Console Mode

Allows the user to view definitions of each metric and change the displayed metric in the Metrics Console area between:

1) Corrected Flow Time
2) Max Total VTI
3) Peak Systolic Velocity

16) Pre and Post Intervention Window Size

Allows the user to toggle between different window sizes of 10 seconds, 20 seconds, or 30 seconds in length. The change calculations will automatically update based on all the data highlighted in these windows.

By using these variable window sizes, users can ensure they are highlighting only the highest quality data available throughout a session.

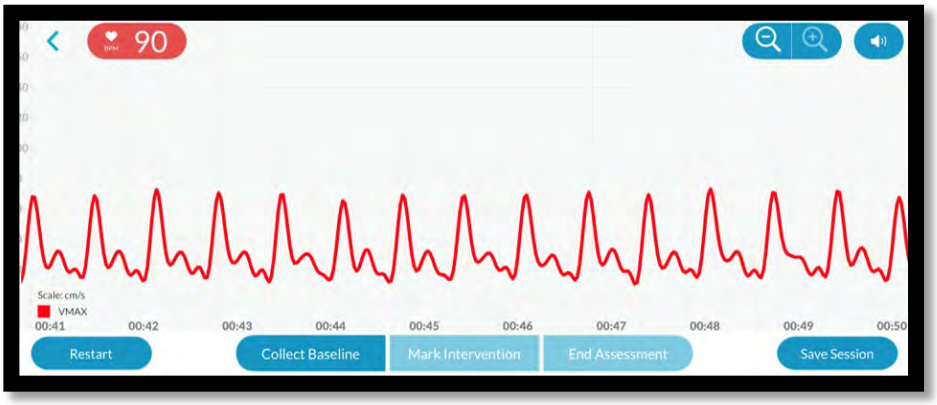
17) Signal Sensitivity

Allows the user to increase the signal sensitivity to improve signal quality, when they are having difficulty locating a high-quality Doppler signal on a patient. The default sensitivity setting is “Medium,” and the user may decrease this to “Low” or increase this to “High”.

18) Doppler Mode

Provides the user with an additional waveform display and allows them to toggle between:

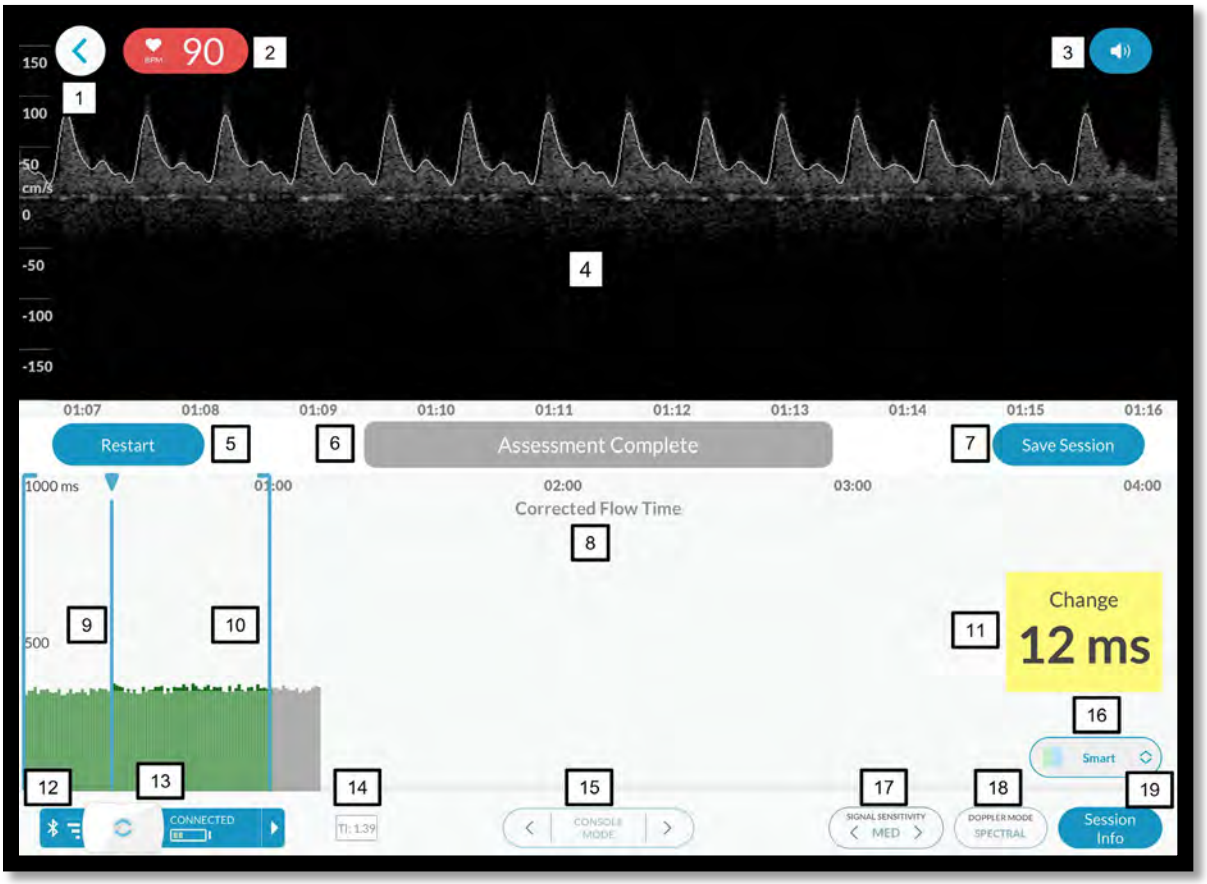
1) Spectrogram (raw Doppler waveform with the trace)
2) Forward Trace
   The forward trace includes buttons to allow the user to increase or decrease the scale of the x-axis (time) on the waveform display. The user may also grab and drag the display to scroll back in time to view the entire trace.



19) Session Info

Allows the user to enter a session ID, session notes, and specify the intervention that was completed for a particular session. This information is saved and available for review in the Saved Sessions screen (Section 7.7).

7.6 Guided Assessment Screen



The Guided Session screen is also where the Doppler information taken from the FloPatch is displayed graphically to the user but differs from the Active Session Screen. This screen is the core functional part of the FloPatch application and has several features. In the above image, the parts of the screen are labeled 1-19, and information about each component can be found below:

1) Return Button — Returns to the Main Menu.

2) Heart Rate Display — Displays the current heart rate of the patient wearing the FloPatch in beats per minute (BPM). (BPM is calculated using the incoming Doppler waveforms).

3) Volume — Press the speaker button to adjust the volume of the Doppler audio.

4) Waveform Display — Covers the upper half of the screen and displays the maximum velocity trace over the spectrogram, as measured by the FloPatch, in real-time. The device waveform streams from the right side of the screen to the left with a scrolling axis.

5) Restart — Clears all information in the Waveform Display and the Metrics Console and restarts the data stream from the FloPatch.

6) Workflow Status

The Guided Assessment will guide the user through the following 7 steps, which will be indicated by the Workflow Status bar. A loading bar will be displayed while collecting data to indicate how much data needs to be recorded before moving to the next stage in the workflow. A button animation periodically reminds the user that sufficient data has been collected if they would like to move to the next stage.

1) Acquiring Signal (loading bar displayed)
2) Begin Assessment (button displayed)
3) Collecting Baseline (loading bar displayed)
4) Mark Intervention (button displayed)
5) Assessing Intervention (loading bar displayed)
6) End Assessment

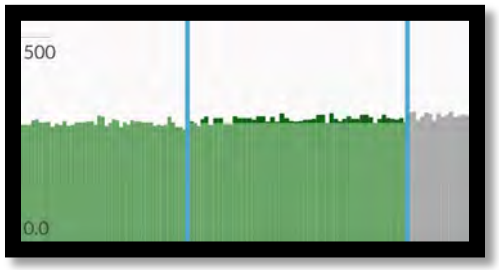
7) Save Session

Stops the recording, opens the Session Review screen, and saves the current session data for review from the Saved Sessions screen.

8) Metrics Console

Covers the lower half of the screen and displays the calculated metric as bars, with one bar corresponding to one heartbeat. The user can toggle between different metrics using the Console Mode button.

During the assessment, metric bars calculated after the intervention will be shaded darker where there is an increase above the mean value of the baseline metrics. This helps to visually identify when there has been a change in blood flow.



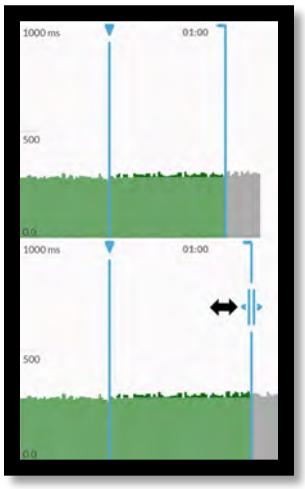
9) Intervention Marker

Marks the point in time at which the intervention was started after collecting baseline data. If this marker is placed before or after the intervention began, the intervention marker may be moved after the assessment is complete by dragging it with your finger. There must be enough data in the baseline and post-intervention regions to make a calculation, so you will not be able to drag the markers to make the regions too short.

10) End Assessment Marker

Marks the point in time at which the assessment was completed. Data will continue to be collected after this point in time until the session is ended, or until one minute elapses, at which point the session will end and save automatically.

If additional data is collected, the assessment marker may be moved by dragging it with your finger to include additional metrics in the comparison calculations.



11) Comparison Result

Calculated values are displayed which represent the comparison between the metrics collected during baseline and the metrics collected after the intervention. The yellow box displays the increase or decrease of the mean post-intervention data relative to the mean pre-intervention (baseline) data.

12) Wireless Connection Performance Indicator

The Bluetooth icon flashes red when data has not been successfully transferred between the FloPatch and FloPatch application to warn the user of a decrease in signal quality.

See Section 8 Wireless Connection Performance for additional information.

The Bluetooth connection strength is displayed to the right of the Bluetooth icon as a value from 1 to 4 bars.

13) FloPatch Connection Information

Displays the connection status of the connected FloPatch. This includes the battery level, which is displayed graphically as a battery with green charge units. The battery graphic turns red in a low battery state, when the FloPatch battery is unlikely to last for another assessment.

Selecting the button opens the FloPatch Information and Disconnect Window.

14) Thermal Index

The Bone Tissue Thermal Index (TIB) is displayed here. See Appendix D for additional information on Ultrasound Intensity and Safety.

15) Console Mode

Allows the user to view definitions of each metric and change the displayed metric in the Metrics Console area between:

1) Corrected Flow Time
2) Max Total VTI

16) Manual / Smart Data Selection

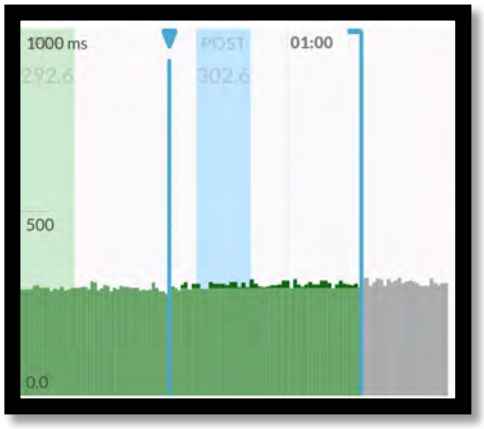
Allows the user to toggle between the following two modes for analyzing the data:

1) Smart Selection

Smart Selection provides the user with automated data analysis by selecting statistically relevant sections of the data collected in the baseline and post-intervention stages of the assessment.
This is the default method and requires no user input.

2) Manual Selection

Manual Selection provides the user the ability to directly highlight sections using 10 second sliding windows of the pre-intervention and post-intervention data to compare.



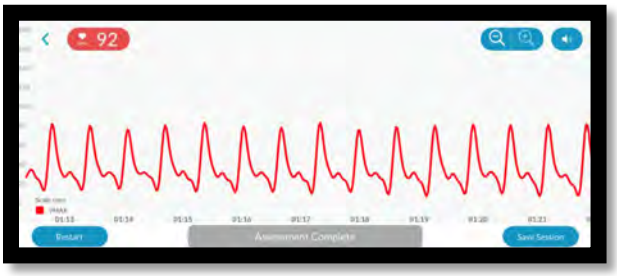
17) Signal Sensitivity

Allows the user to increase the signal sensitivity to improve signal quality, when they are having difficulty locating a high-quality Doppler signal on a patient. The default sensitivity setting is “Medium,” and the user may decrease this to “Low” or increase this to “High”.

18) Doppler Mode

Provides the user with an additional waveform display and allows them to toggle between:

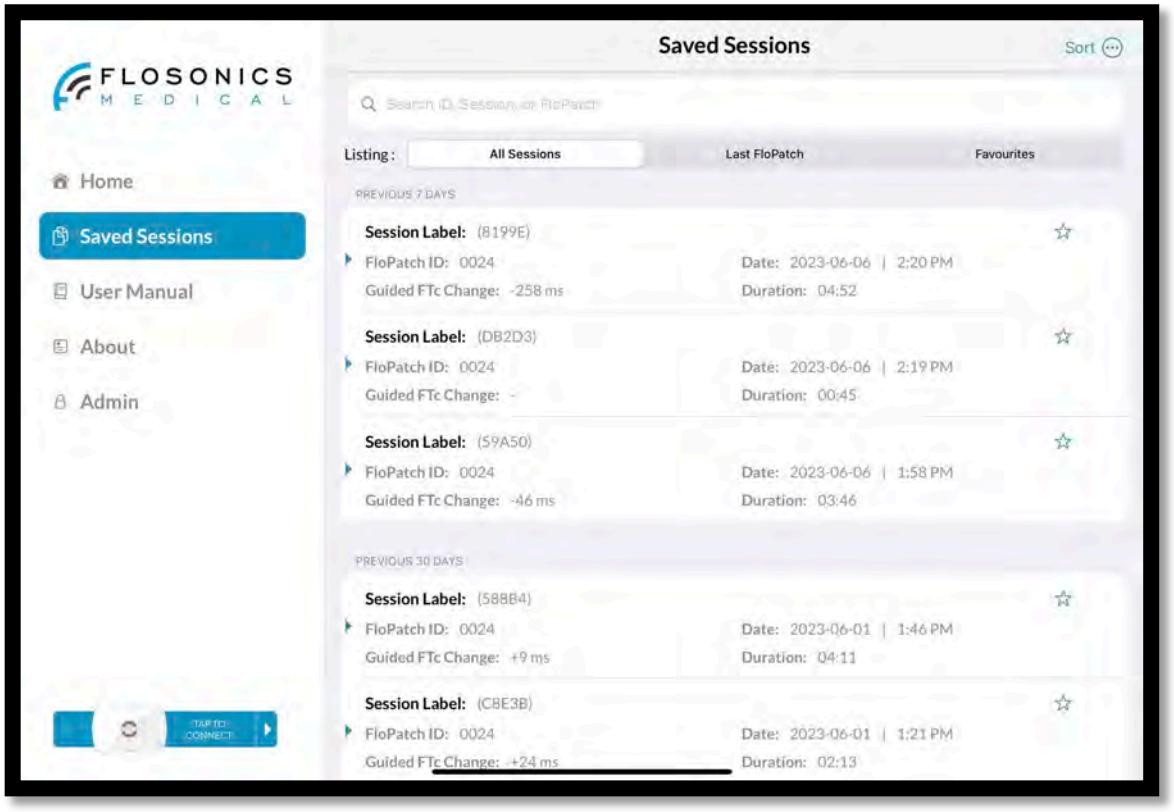
1) Spectrogram (raw Doppler waveform with the trace)
2) Forward Trace
   The forward trace includes buttons to allow the user to increase or decrease the scale of the x-axis (time) on the waveform display. The user may also grab and drag the display to scroll back in time to view the entire trace.



19) Session Info

Allows the user to enter a session ID, session notes, and specify the intervention that was completed for a particular session. This information is saved and available for review in the Saved Sessions screen (Section 7.7).

7.7 Saved Sessions Screen



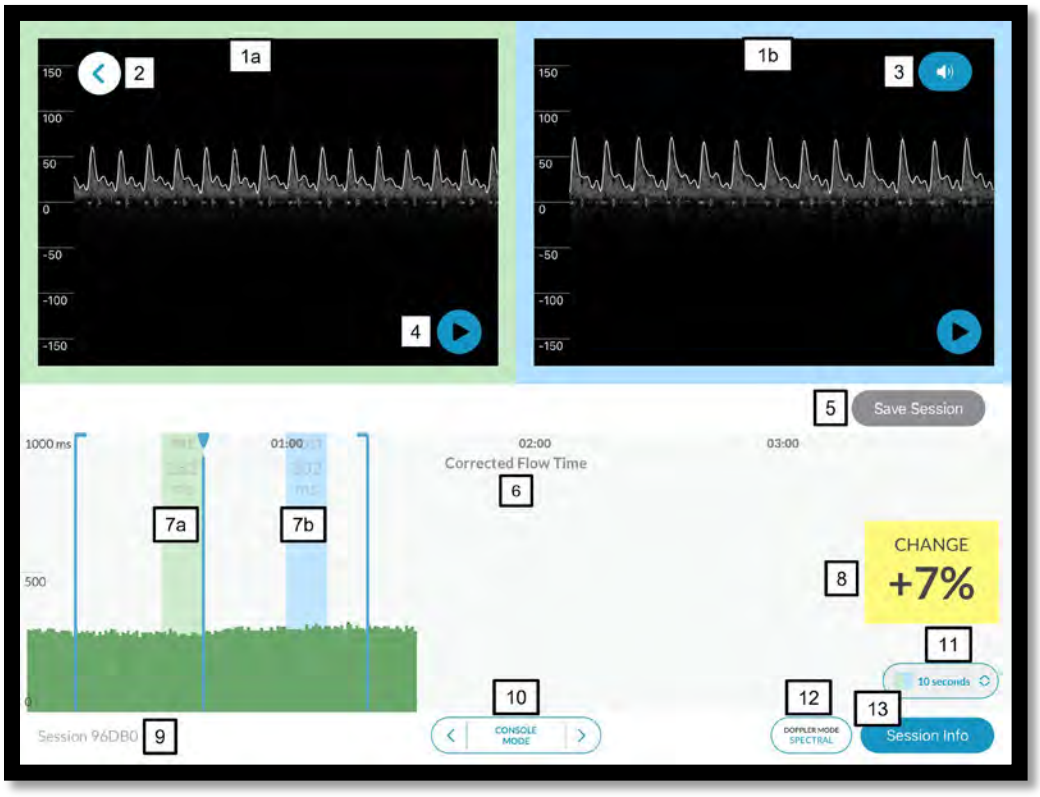
The Saved Sessions screen allows the user to load previously recorded data into a session review screen. The individual sessions can be identified by:

1. The session ID
2. The last four digits of the FloPatch ID
3. The duration of the session
4. The date and time of the recording
5. The change in FTc if it's a Guided session

From this view, the user may edit or review the Session Label, assessment maneuver/intervention, and assessment notes. The user may add or remove sessions from the "Favourites" list by tapping the blue star icon. A session may also be deleted by the user. If deleted, the session ***cannot*** be recovered.

The search bar at the top of the view allows the suer to search and filter the session list by Session ID or FloPatch ID. The filter bar allows the user to filter sessions by the current or last connected FloPatch, or by favorites.

7.7.1 Session Review Screen for an Active Session

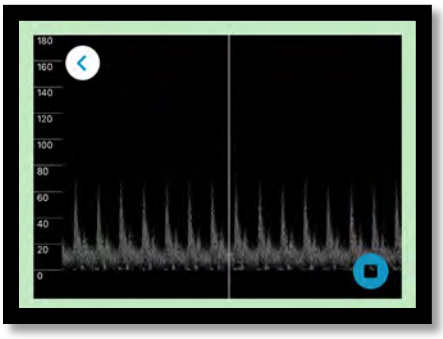


1) Pre and Post Waveform Displays — The top half of the screen shows the waveform of the selected pre (1a) and post (1b) regions.

2) Return to Saved Sessions — Returns the user to the Saved Session page to select a new Saved Session or return to the Main Menu.

3) Volume — Press the speaker button to adjust the volume of the Doppler audio.

4) Audio replay — Press the play button to hear the doppler audio of the displayed waveform. A line will scroll across the screen to indicate where in the waveform the audio is from.



5) Save Session — Save any changes made to the session data.

6) Metric Console

Covers the lower half of the screen and displays the calculated metric as bars, with one bar corresponding to one heartbeat. The user can toggle between different metrics using the Console Mode button.

Metric bars representing heartbeats recorded while in the post intervention stage will be shaded a darker color to easily identify when an assessment was completed.

7) Pre and Post Intervention Sliders

Green (pre-intervention) and blue (post-intervention) sliding bars appear if an assessment was completed in the saved session for the metrics Max Total VTI and Corrected Flow Time. The user may slide the bars over the desired metric bars to compare the percentage change between the two sections of the session.

8) Comparison Result

Calculated values are displayed which represent the comparison between the metrics collected during the Pre and Post Intervention Sliders. The yellow box can be tapped to toggle between the following values:

1) **Percent Change**
   The percent increase or decrease of the mean post-intervention data relative to the mean pre-intervention (baseline) data.

2) **Change**
   The increase or decrease of the mean post-intervention data relative to the mean pre-intervention (baseline) data.

3) **Variability** (only metric for Peak Systolic Velocity)
   Peak Systolic Velocity is a time-varying metric that depends on changes in respiratory rate, hence, it is continuously updated and doesn't depend on comparisons of two sections of data. The Baseline Peak Systolic Velocity Variability is the variability of the data prior to the Intervention Marker.

9) Session ID

Displays the Session ID of the Session being reviewed.

10) Console Mode

Allows the user to view definitions of each metric and change the displayed metric in the Metrics Console area between:

1) Corrected Flow Time
2) Max Total VTI
3) Peak Systolic Velocity

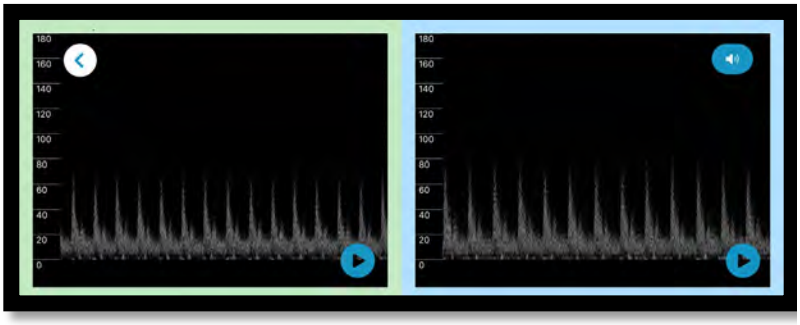
11) Pre and Post Intervention Window Size

Allows the user to toggle between different window sizes of 10 seconds, 20 seconds, or 30 seconds in length. The percentage change calculation will automatically update based on all the data highlighted in these windows.

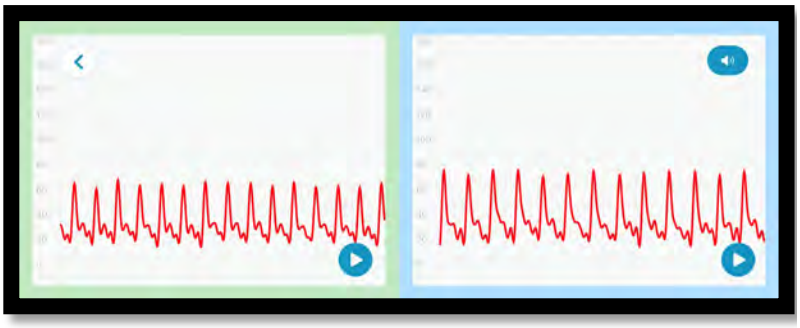
12) Doppler Mode

Provides the user with an additional waveform display and allows them to toggle between:

1) Spectrogram (raw Doppler waveform with the trace)
2) Forward Spectrogram (raw Doppler forward waveform)



3) Forward Trace

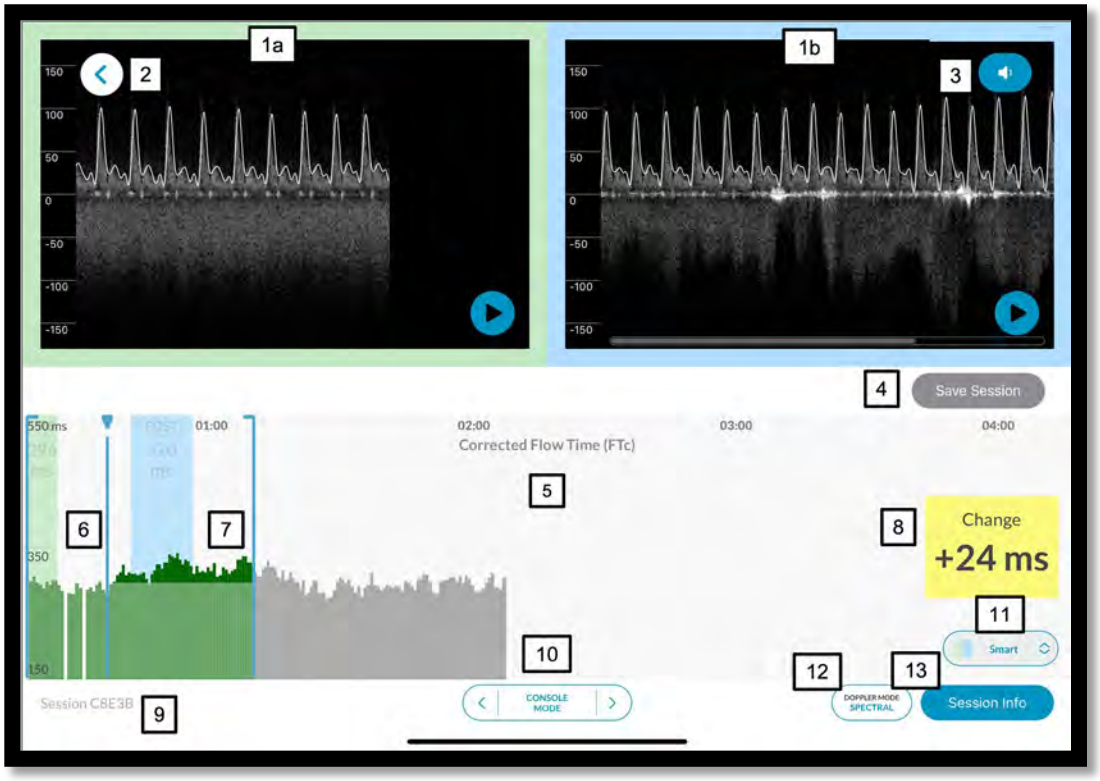


13) Session Info

The following information can be entered and reviewed for each session:

- User specified session ID
- Assessment maneuver/intervention
- Assessment notes

7.7.2 Session Review Screen for a Guided Session



1) Pre and Post Waveform Displays — The top half of the screen shows the waveform of the selected pre (1a) and post (1b) regions.

2) Return to Saved Sessions — Returns the user to the Saved Session page to select a new Saved Session or return to the Main Menu.

3) Volume — Press the speaker button to adjust the volume of the Doppler audio.

4) Save Session — Save any changes made to the session data.

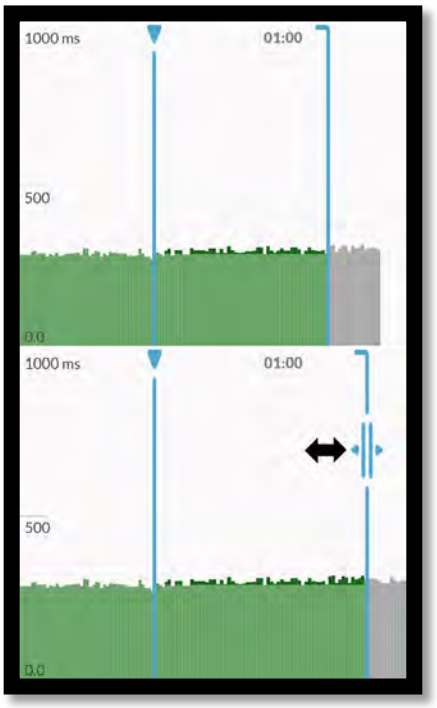
5) Metric Console — Covers the lower half of the screen and displays the calculated metric as bars, with one bar corresponding to one heartbeat. The user can toggle between different metrics using the Console Mode button.

6) Intervention Marker — Marks the point in time at which the intervention was started after collecting baseline data. If this marker is placed before or after the intervention began, the intervention marker may be moved after the assessment is complete by dragging it with your finger. There must be enough data in the baseline and post-intervention regions to make a calculation, so you will not be able to drag the markers to make the regions too short.

7) End Assessment Marker

Marks the point in time at which the assessment was completed. Data will continue to be collected after this point in time until the session is ended, or until one minute elapses, at which point the session will end and save automatically.

If additional data is collected, the assessment marker may be moved by dragging it with your finger to include additional metrics in the comparison calculations.



8) Comparison Result

Calculated values are displayed which represent the comparison between the metrics collected during baseline and the metrics collected after the intervention. The yellow box displays the increase or decrease of the mean post-intervention data relative to the mean pre-intervention (baseline) data.

9) Session ID

Displays the Session ID of the Session being reviewed

10) Console Mode

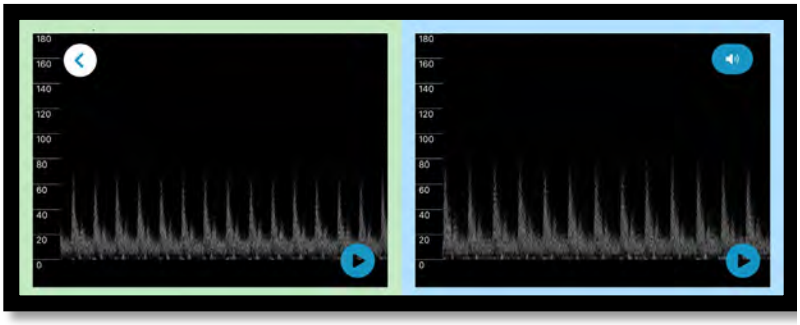
Allows the user to view definitions of each metric and change the displayed metric in the Metrics Console area between:
1) Corrected Flow Time
2) Max Total VTI

11) Smart or Manual Windows

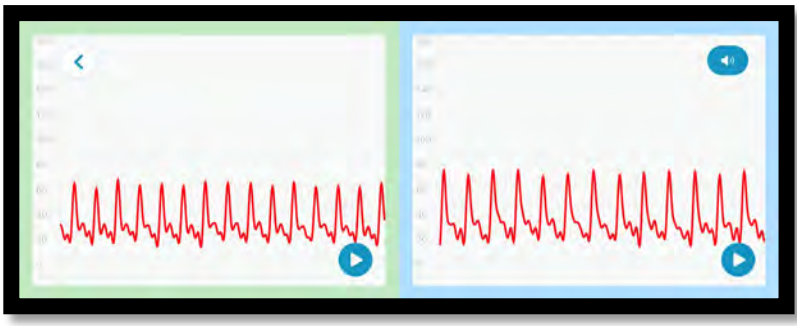
Allows the user to toggle between Smart or Manual windows. When Manual windows are toggled on, the user will be able to manually select the data being used for calculations.

12) Doppler Mode Provides the user with an additional waveform display and allows them to toggle between:

1) Spectrogram (raw Doppler waveform with the trace)
2) Forward Spectrogram (raw Doppler forward waveform)



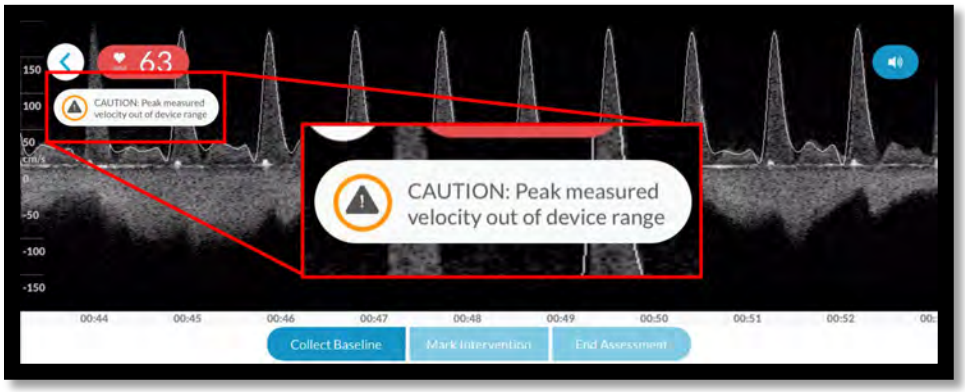
3) Forward Trace



13) Session Info The following information can be entered and reviewed for each session:

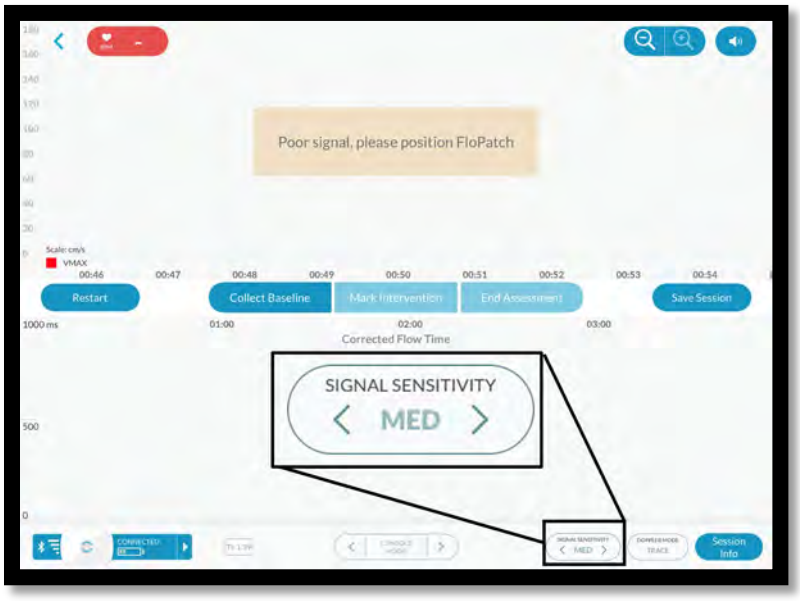
- User specified session ID
- Assessment maneuver/intervention
- Assessment notes

7.8 Peak Velocity Alert



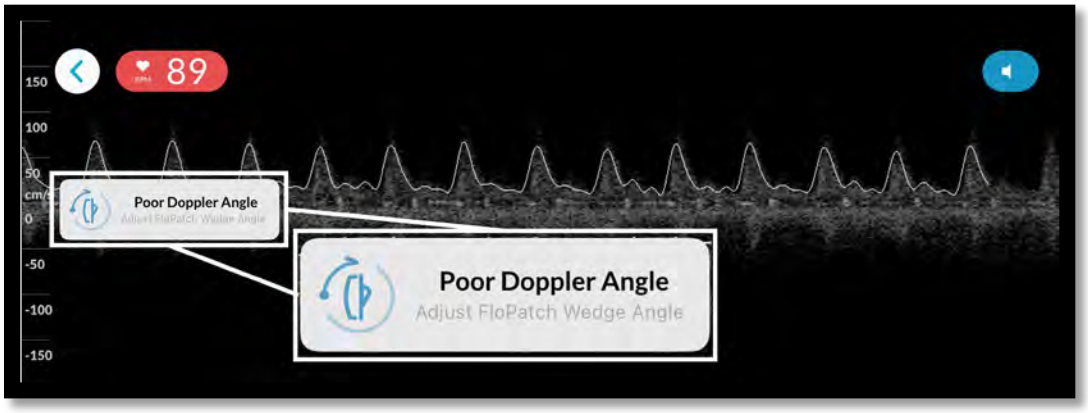
The *Peak Velocity Alert* is displayed when peak measured blood velocity is outside of the device's maximum velocity range.

7.9 Signal Strength Indicator



The *Signal Strength Indicator* is displayed when the signal quality is too poor to produce a maximum velocity trace. When this is the case, the trace will no longer be displayed. The user can adjust the position of the FloPatch device to improve the signal quality. The user can also adjust the Signal Sensitivity setting, which is in the bottom right corner.

7.10 Doppler Angle Indicator

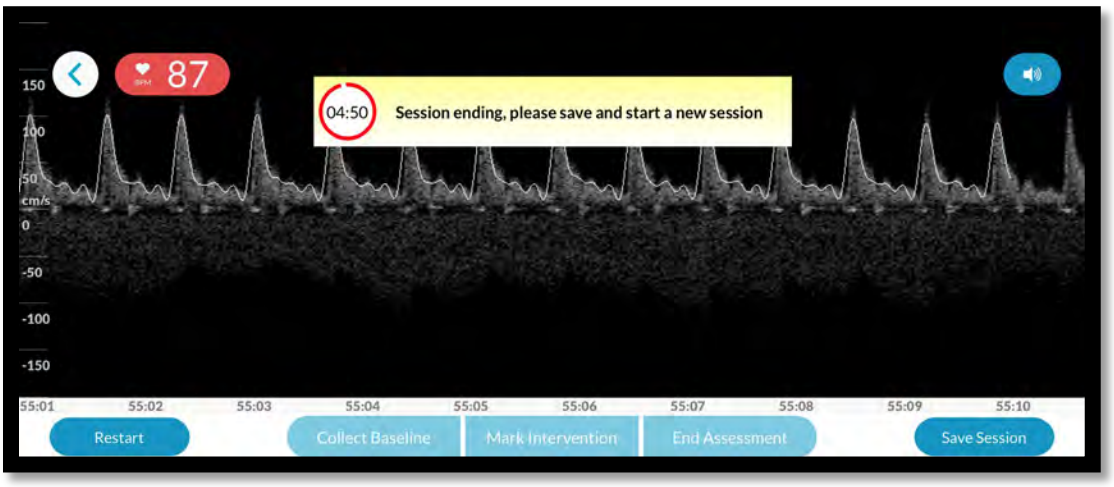


The *Doppler Angle Indicator* is displayed when the FloPatch wedge angle relative to the blood vessel is not optimal for signal detection. When this is the case, the trace will continue to be displayed but it is recommended the FloPatch wedge angle be adjusted for best performance.

7.11 Low Battery Indicators

When the connected FloPatch is in a low battery state, the FloPatch LED turns from Blue to Amber, and the battery icon in the FloPatch Connection Information indicator turns red. In this case, the FloPatch battery is unlikely to last the duration of an assessment. If you choose to continue, the FloPatch may power off during an assessment without additional warning. If more assessments are required, it might be more appropriate to replace the existing FloPatch with a new one.

7.12 Session Length Limit



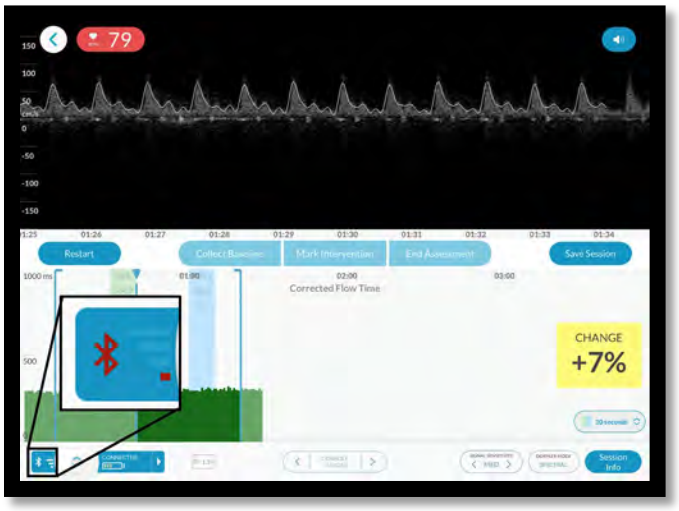
Sessions are limited to 60 minutes. Five minutes prior to the 60-minute limit, a timer will start counting down and the user will be reminded save. When 60 minutes is reached the session will stop and save. The user can start a new session immediately after, but this should be done following the ALARA principle (see Section D.2 for information on Ultrasound Safety and the ALARA principle).

8. WIRELESS CONNECTION PERFORMANCE

An indicator, as shown below, is displayed to provide information on the quality of the wireless connection and data transfer between the FloPatch device and the FloPatch application.

The Bluetooth symbol remains white in color during normal use and flashes red when data is not transferred successfully. This indicates to the user that there has been a momentary loss in signal quality.

Data transfer performance and signal quality can be improved by moving the iOS device closer to the FloPatch device.



9. Cyber-Security

FloPatch FP120 uses a Bluetooth Low Energy wireless communication protocol to transmit physiological signal data from the sensor to a monitoring apparatus. All wireless devices are exposed to some risk of cyber-attack. If the user suspects that the sensor's data stream is compromised, they can confirm signal fidelity by performing auditory Doppler shift test and mechanical tap test as outlined below. If the data integrity suspected to be compromised based on the results of these tests, the user should not rely on the FloPatch FP120 data analysis.

Flosonics has identified three potential cyber-attack points in our systems architecture and the resulting risk:

1. **System-on-Chip Vulnerabilities**: FP120 chipset (Manufacturer Name: Nordic Semiconductor, Manufacturer Part Number: NRF52832-QFAA-R) (Bluetooth 5.0; SDK v15.3 and soft device API S132 v6.1.1) is not vulnerable to Sweyn Tooth family of vulnerabilities. Nordic Semiconductor has not officially issued a statement, but their representative has clarified this issue through a service ticket on their developer support website. (https://devzone.nordicsemi.com/f/nordic-q-a/57990/is-the-sweyntooth-vulnerabilities-addressed-in-nrf-products).

   As devices are stored in a power down mode with no BLE broadcasting, these types of attacks would need to occur while the device was in use; and it would likely compromise the unit functionality rather than harm the device. If data fidelity was ever questioned – the clinician can perform the sensor tap test (see below) to obtain instantaneous audible and visual feedback from the device.

2. **Compromised BLE data stream**: This vulnerability is unlikely, as it is very unlikely that an adversary could adequately simulate physiologic Doppler shift data in real-time, in such a way that the data could be interpreted by the FloPatch FP120 software, and if interpreted by the software, and be mistaken for physiologically relevant data by the clinical end user. In the unlikely event that the BLE data stream was thought to be compromised, the clinician could perform the sensor-tap test to verify the fidelity of the data through instantaneous audible and visual feedback from the device.

3. **Compromised FloPatch FP120 software**: There is a possibility that the FloPatch FP120 software could be subject to attack which renders false or compromised information to the end user. To mitigate this risk, the monitoring device is provided to the end-user in a Guided Access Mode which does not enable loading of any unauthorized software. Flosonics believes it is very unlikely that malicious software could be loaded onto the monitor to cause compromised data display. While the auditory and sensor tap test will confirm the fidelity of the information, the end user would likely not be able to assess the validity of false data if it were being displayed.

Cyber-Security Device Checks
Auditory Doppler Shift Test **Description**: The auditory Doppler shift test is intended to give the user a qualitative indication of the signal integrity. **Protocol:** 1) Ensure the FloPatch FP120 is connected to the iOS device running FloPatch FP120 application. 2) Ensure the volume setting audible (i.e., not on mute). 3) Once the sensor has been acoustically coupled over the target vessel the user can listen to the changing systolic and diastolic signal which are characteristic of Doppler shift. 4) The user can also palpate the target vessel (e.g., carotid artery) to confirm the physical sensation of the pulse corresponds to the audible signal. **Expected Result:** The user will expect to hear characteristic systolic/diastolic Doppler shift which is consistent with the palpation of the target artery. If the Doppler shift and the pulsatile nature of the palpation do not align, it is an indication that the data stream may be compromised. The end user should not rely on FloPatch FP120 if the data stream is suspected to be compromised.
Auditory Sensor Tap Test **Description:** The sensor tap test is an easy technique which allow the user to impart a high-amplitude Doppler-shift which is mechanical (rather than physiological) in nature. **Protocol:** 1) Ensure the FloPatch FP120 is connected to the iOS device running FloPatch FP120 application. 2) Ensure the volume setting audible (i.e., not on mute). 3) Once the sensor has been acoustically coupled over the target vessel (or when the transducer is gel loaded) the user can tap-and-listen for a large amplitude mechanical Doppler shift. **Expected Result:** The user will expect to instantaneously hear a loud and scratchy Doppler shift which is consistent with the user tapping on the sensor. If the mechanical Doppler shift does not coincide with user tapping action, it is an indication that the data stream may be compromised. The end user should not rely on FloPatch FP120 if the data stream is suspected to be compromised.

10. TROUBLESHOOTING

Issue	Solution
Device is damaged	Contact the manufacturer or return the device to manufacturer and stop all usage of the device.
Low Battery	Contact your Flosonics Representative to return used product to Flosonics. If product is not returned, dispose of product based on local regulations for electronics and biohazardous disposal, as applicable.
No Doppler sound from the device	1) Ensure that the wireless connection has been established. If the device status LEDs are flashing, this would mean that the device is either not connected or in a low power state. 2) Using the wireless performance indicator described in Section 8, ensure that there is adequate signal strength and no loss of data transferred between the device and the FloPatch FP120 application. 3) Ensure that there is adequate ultrasound gel on the device. 4) Ensure that the device is placed sufficiently close to the carotid artery on the neck. 5) Ensure that the device is oriented correctly. 6) Ensure the volume is turned up in the FloPatch FP120 application
No FloPatch FP120 devices detected in the connection screen	Ensure FloPatch FP120 device is powered on and in range of the iPad.

If any of the above solutions do not resolve the issue, please contact the manufacturer.

11. MAINTENANCE

The device or the main unit do not require any calibration. Ensure the device has no visible damage before using it. If any damage is evident, stop all usage of the device and contact the manufacturer.
Do not reuse devices. They are intended for a single use on a single subject only.
Neither the device, nor the main unit are intended for sterilization, disinfection, or cleaning.

12. SERVICING

The device is not intended to be serviced by the user. If the device malfunctions, please contact the manufacturer or return the device to manufacturer.

13. RETURN OR DISPOSAL

Contact your Flosonics Representative to return used product to Flosonics. If product is not returned, dispose of product based on local regulations for electronics and biohazardous disposal, as applicable.

14. SOFTWARE UPDATES

If an update for the FloPatch application is available, the updated FloPatch application will be automatically installed. Connection to Wi-Fi is required for this to occur.

The firmware for the FloPatch hardware cannot be updated by the user. It can only be updated by Flosonics or an authorised representative of Flosonics.

Appendix A – Product Specifications

Product Name	FloPatch FP120
Model Number	FP120
Standards Compliance	IEC 60601-1 IEC 60601-2-37 IEC 60601-1-2
Battery Specification	Lithium Polymer (IEC 62133)
Classification	ME Classification (IEC 60601-1): Internally Powered Equipment
Applied Part	Type BF
Degree of Protection Against Harmful Ingress of Fluids	IP67
Degree of Safety in Presence of Flammable Anaesthetics	Equipment not suitable for use in presence of flammable gases
Environmental	Operating Conditions (Ambient) 1) Temperature: 10°C to 30°C 2) Humidity: 30% to 85% 3) Pressure: 57-106 kPa Storage Conditions (Device) (Ambient) 1) Temperature: 10°C to 30°C 2) Humidity: 40% to 60% 3) Pressure: 57-106 kPa

Ultrasound Specifications

Frequency	4 MHz central

For ultrasound safety information, please refer to Appendix C.

Wireless Specifications

Frequency	2.40 – 2.48 GHz
Modulation	GFSK
EIRP	1.6 dBm
ERP	1.6 – 2.15 = -0.55 dBm

Clinical Measurement Accuracy

Velocity Range	10cm/s – 170cm/s (with a mean relative error <1.5%) **WARNING: The above value is a mean across the velocity range.**

Appendix B – Compatible Mobile Devices & Wireless Information

Compatible Mobile Devices

iPad Air (4th generation) (2020):	A2316
iPad Air (5th generation) (2022):	A2588
iPad Mini (6th generation) (2021):	A2567
iPad Pro (12.9" 5th generation) (2021):	A2378, A2461, A2379
iPadOS Version :	iPadOS 16.5+

Wireless Information

- The FloPatch uses Bluetooth Low Energy 5 (BLE 5 or BT5) for wireless data transmission to a compatible mobile device.
- The FloPatch uses a proprietary data format which will not transmit physiological data to any device that does not have the FloPatch application installed. The FloPatch application can only connect to legitimate FloPatch hardware. Legitimate FloPatch hardware refers to FloPatch hardware that has a unique Bluetooth Service Identifier.
- Please refer to Section 3.3 regarding specific cautions about the use of the FloPatch hardware and FloPatch application in ways other than those recommended by Flosonics.

Appendix C – EMC Information

C.1 Electromagnetic Emissions

NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). The device complies with CISPR 11 Class B but should only be used in environments identified in Section 2.4 of this user manual.

Emissions Class and Group Compliance

The FloPatch FP120 is intended for use in the electromagnetic environment specified below. The customer or the user of the FloPatch FP120 should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Emissions – Guidance**
RF Emissions CISPR 11	Group 1	The FloPatch FP120 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The FloPatch FP120 is suitable for use only in the environments identified in Section 2.4: **Warning:** This equipment/system is intended for use by trained medical professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the FloPatch FP120 or shielding the location.
Harmonic Emissions IEC 610000-3-2	Not Applicable	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Not Applicable	

C.2 Electromagnetic Immunity

The FloPatch FP120 is intended for use in the electromagnetic environment specified below. The customer or the user of the FloPatch FP120 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV Contact ±15 kV Air	±8 kV Contact ±15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines	Not Applicable	Not Applicable
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line & ±0.5 kV, ±1 kV, ±2 kV line to ground 0% U_T (100% dip in U_T) for 0,5 cycle	Not Applicable	Not Applicable

Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 1 cycle(s) 70% U_T (30% dip in U_T) for 30 cycles 0% U_T (100% dip in U_T) for 5 sec	Not Applicable	Not Applicable
Power Frequency Magnetic Field (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

The FloPatch FP120 is intended for use in the electromagnetic environment specified below. The customer or the user of the FloPatch FP120 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM bands inside 150 kHz to 80 MHz	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the FloPatch FP120 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz RF communication equipment inside 80 MHz to 6 GHz	3 V/m 80 MHz to 2,7 GHz RF communication equipment inside 80 MHz to 6 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d Is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the FloPatch FP120 is used exceeds the applicable RF compliance level above, the FloPatch FP120 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the FloPatch FP120

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

C.3 Device immunity to proximal RF emitters

The FloPatch FP120 has been tested to and complies with requirements for Enclosure Port Immunity to RF Wireless Communication Equipment laid out in IEC 60601-1-2:2014, Table 9. The device was subjected to a field strength of 3 V/m (80% AM) for frequency range of 80MHz – 2.7GHz. The device was subsequently tested for “spot frequencies” as specified in the table (in accordance with Table 9 of IEC 60601-1-2:2014 below:

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1,720	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1,845						
1,970						
2,450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5,240	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5,500						
5,785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

C.4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the FloPatch FP120

The FloPatch FP120 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FloPatch FP120 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FloPatch FP120 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1	At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.		
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

C.5 EMC Note

If the FloPatch FP120 system is operated within the EMC environment described in Appendix C the device will maintain essential performance and provide the following within specifications:

1. Doppler Audio and Waveforms Display
2. Calculated Metrics
3. Acoustic output

Operations in environments other than those specified in Appendix C may lead to a degradation in performance which would manifest as a “stuttering waveform” and “stuttering audio.” It will be obvious to the user when this occurs.

Appendix D – Ultrasound Intensity and Safety

D.1 Ultrasound in Medicine

The use of diagnostic ultrasound has proved to be a valuable tool in medical practice. Given its known benefits for non-invasive investigations and medical diagnosis the question of clinical safety with regards to ultrasound intensity arises. There is no easy answer to the question of safety surrounding the use of diagnostic ultrasound equipment. Application of the As Low As Reasonably Achievable (ALARA) principle serves as a rule-of-thumb that will help you to get reasonable results with the lowest possible ultrasonic output.

The American Institute of Ultrasound in Medicine (AIUM) states that given its track record of over 25 years of use and no confirmed biological effects on patients or instrument operators, the benefits of the prudent use of diagnostic ultrasound clearly outweigh any risks.

D.2 Ultrasound Safety and the ALARA Principle

Ultrasound waves dissipate energy in the form of heat and can, therefore, cause tissue warming. It is important to know how to control and limit patient exposure. Major governing bodies in ultrasound have issued statements to the effect that there are no known adverse effects from the use of diagnostic ultrasound, however, exposure levels should always be limited to 'As Low As Reasonably Achievable' (the ALARA principle).

D.2.1 AIUM Recommended Maximum Scanning Times for Displayed Thermal Index Values

The American Institute of Ultrasound in Medicine (AIUM) provides recommended maximum times for the duration of an ultrasound exposure at a given setting of thermal index. These recommendations are intended to provide reasonable assurance that an ultrasound examination can be conducted without risk of producing an adverse effect due to a thermal mechanism under any scanning conditions. The following values are the recommended dwell time and TI ranges for adult peripheral vasculature.

TI Range	Max Dwell Time (minutes)
TI > 6.0	Not recommended
5.0 < TI ≤ 6.0	< 0.25 (15 s)
4.0 < TI ≤ 5.0	< 1
3.0 < TI ≤ 4.0	< 4
2.5 < TI ≤ 3.0	< 15
2.0 < TI ≤ 2.5	< 60
1.5 < TI ≤ 2.0	< 120
TI ≤ 1.5	No time limit

The FloPatch FP120 has a TIB average of 0.69 with an upper bound of 1.21. Per the TI value, there is no time limit to the max dwell time. When the device is not in an active session, the FloPatch FP120 is not transmitting and there is no impact to the dwell time. See Section D.3.6 and D.3.7 for more information on the acoustic output of the FloPatch FP120.

D.3 Explanation of MI/TI

D.3.1 Mechanical Index (MI)

Scientific evidence suggests that mechanical or nonthermal bioeffects, such as cavitation, are threshold phenomena, occurring only when a certain level of output is exceeded. The phenomena is determined by acoustic pressure, spectrum, focus, transmission mode, and factors such as states and properties of tissue and boundary. The threshold level varies depending on the tissue. The potential for mechanical effects is

thought to increase as the peak-rarefaction pressure increases but to decrease as the ultrasound frequency increases. Although no confirmed adverse effects on patients and mammals caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported, the threshold for cavitation is still undetermined.

The AIUM and NEMA (The Association of Electrical Equipment and Medical Imaging Manufacturers) formulate mechanical index (MI) in order to indicate the potential for mechanical effects. The MI is defined as the ratio of the peak-rarefaction acoustic pressure (should be calculated by tissue acoustic attenuation coefficient 0.3 dB/cm/MHz to acoustic frequency) to the square root of acoustic frequency.

D.3.2 TI (Thermal Index)

TI is an estimate of the increase in temperature that occurs in the region of the ultrasound scan. It is defined as the ratio of the total acoustic power to the acoustic power required to raise the tissue temperature by 1°C (1.8 °F).

There are 3 kinds of TI:

1. TIS (Soft Tissue Thermal Index): It provides an estimate of potential temperature rise in soft or similar tissues.
2. TIB (Bone Thermal Index): It provides an estimate of potential temperature rise when the ultrasound beam passes through soft tissue and the focal region is in the immediate vicinity of bone.
3. TIC (Thermal Index for cranial applications): It provides an estimate of potential temperature rise in the cranial bones or superficial bones.

D.3.3 Measurement Uncertainties

The devices used in the measurement (hydrophone, oscilloscope) have systematic errors associated with their use, either by calibration uncertainty or design limitations. These are noted below and were not associated with statistical analysis; they are therefore Type B uncertainties. There are other systematic sources of essential random error (such as temperature) as well as uncertainties estimated from measurement of the device in question (spatial averaging and non-linear distortion). The influence of these factors has been derived from uncertainties assigned by reference materials or sources (as noted), and therefore these are also Type B uncertainties. Efforts have been made to reduce the Type B uncertainties as much as possible through proper calibration, procedures, etc.

Several individual samples of the device under test were evaluated. The statistical analysis of these data produces the Type A measurement uncertainty estimation.

Whether the sources of the uncertainties in the measurement are random or systematic, or more formally, Type A or Type B, they may be combined into an overall assessment of measurement uncertainty. The analysis of the Type B uncertainties below should be combined with the statistically derived Type A measurements on a root sum squared basis.

1. Voltage (σV , oscilloscope): ±2.4%

   The two contributing sources were the stated DC gain accuracy and digitization error of the digital oscilloscope.

2. Hydrophone Pressure Sensitivity (σML): ±3.6%

   The principal source of this uncertainty is the stated uncertainty of the hydrophone calibration at a representative center frequency, shown in Appendix B. Additional variance is introduced by the stated temperature range of the water bath (±0.9%, combined in a root sum squared manner).

3. Acoustic Impedance (σZ): ±0.8%

Variance is introduced by the stated temperature range of the water bath.

4. Spatial averaging (σSA): ±4.1%
5. Derating (σDer): ±0.6%

   The contributing factor is error in the mechanical positioning of the hydrophone. The estimate is worst case by assuming a high frequency probe.

6. Power factor (PF) (σPF): ±1.7%

   The contributing factor is error in the mechanical positioning of the hydrophone.

7. Spatial-peak depth (σzsp): ±1.2%

   If the exact spatial peak depth is missed due to the step size the PII and related values will be systematically incorrect. To account for this an estimate was calculated from the spatial variability for worst-case historical values.

8. Non-linear Distortion (σNLD) ±1.2%

   The uncertainty of the intensity and (rarefactional) pressure are estimated from *Corbett, S. S. The influence of nonlinear fields on miniature hydrophone calibrations using the planar scanning technique. IEEE transactions on ultrasonics, ferroelectrics, and frequency control 35, 162-167 (1998)*, and subsequent discussion with FDA personnel.

   The uncertainty for temperature rise measurement derived from 53hermos coupler method is 0.5 °C.

D.3.4 Prudent Use Statement

Although no confirmed bioeffects on patients caused by exposure from present diagnostic ultrasound equipment have ever been reported, the potential exists that such bioeffects may be identified in the future. Therefore, the ultrasound should be used prudently by appropriately trained health care providers. The use of ultrasound for non-medical purposes should be avoided. When in use, scan times should be limited to the duration needed to obtain the necessary diagnostic information.

D.3.5 References for Acoustic Output Safety

1. Medical Ultrasound Safety, Third Edition, published by AIUM in 2014
2. Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Devices; Document issued in February 2023 by the FDA
3. IEC 60601-2-37, Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment. Edition 2.1 published in 2015.
   The FloPatch FP120 is a Track 3 device based on the FDA Guidance “Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Devices.”

D.3.6 Summary of Global Max Values

NOTE: The Mechanical Index and Thermal Indices is 1.0 or less for all device settings (there is only a single setting in the device which cannot be altered by the user).

These values have been averaged over 10 probes.

Quantity (x)	K	$\bar{x}$	σ_x	L_1 upper bound	γ_x	L_2 upper bound
MI	2.06	3.09E-02	6.32E-03	4.40E-02	6.60E-03	4.46E-02
Ispta, α	2.06	53.58	17.42	89.55	18.63	92.04
TIS	2.06	0.42	0.17	0.78	0.18	0.80
TIB	2.06	0.69	0.24	1.18	0.25	1.21
TIC	2.06	0.63	0.26	1.17	0.27	1.20

D.3.7 IEC 60601-2-37, Ed 2.1 Reporting Table

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			3.09E-02	0.42		0.69		0.63
Index component value				0.30	0.42	0.30	0.60	
Acoustic Parameters	pr, α at zMI	(MPa)	6.20E-02					
	P	(mW)		31.66		31.66		31.66
	P1×1	(mW)		15.51		15.51		
	zs	(cm)			1.31			
	zb	(cm)					1.30	
	zMI	(cm)	0.45					
	zpii, α	(cm)	1.31					
	fawf	(MHz)	4.02	4.02		4.02		4.02
Other Information	prr	(Hz)	N/A					
	srr	(Hz)	N/A					
	npps		1					
	Ipa, α at zpii,α	(W/cm^2)	N/A					
	Ispta,α at zpii,α or zsii,α	(mW/cm^2)	53.58					
	Ispta at zpii or zsii	(mW/cm^2)	77.28					
	pr at zpii	(MPa)	4.93E-02					
Operating control conditions	CW							

NOTE 1	Only one operating condition per index.
NOTE 2	Data should be entered for "at surface" and "below surface" both in the columns related to TIS or TIB.
NOTE 3	Information need not be provided regarding TIC for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.
NOTE 4	If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5	If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.
NOTE 6	Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.
NOTE 7	The depths zpii and zpii,α apply to NON-SCANNING MODES, while the depths zsii and zsii,α apply to SCANNING MODES.

List of symbols

Symbol	Term
MI	Mechanical index
TIS	Soft tissue thermal index
TIB	Bone thermal index
TIC	Cranial-bone thermal index
$P_{r,\alpha}$	Attenuated peak-rarefactional acoustic pressure
f_{awf}	Acoustic working frequency
P	Output power
z_b	Depth for bone thermal index
z_s	Depth for soft-tissue thermal index
z_{MI}	Depth for mechanical index
prr	Pulse repetition rate
$I_{pa,\alpha}$	Attenuated pulse-average intensity
I_{spta}	Spatial-peak temporal-average intensity
srr	Scan repetition rate
p_r	Peak acoustic pressure
n_{pps}	Number of pulses per ultrasonic scan line
z	Distance between a hydrophone and an ultrasonic device

Appendix E – Clinical Information

Definitions

Corrected Flow Time: The corrected flow time is the defined as the duration of systole corrected for heart rate. The FP120 software uses **Wodey's formula***.

***Hossein-Nejad, H., Banaie, M., Davarani, S. and Mohammadinejad, P., 2017. Assessment of corrected flow time in carotid artery via point-of-care ultrasonography: Reference values and the influential factors. *Journal of Critical Care*, 40, pp.46-51.**

Velocity Time Integral: The velocity time integral (VTI) is defined as the area under the velocity trace for one cardiac cycle. VTI units are in centimeters (cm). An alternative name for VTI is stroke distance, or the distance a given blood cell travels through the vessel in per cardiac cycle.

Peak Systolic Velocity: The peak systolic velocity is defined as the maximal velocity value of the Doppler waveform. The units are in centimeters per second (cm/s).

Clinical Assessments

FloPatch FP120 may be used for functional hemodynamic monitoring (FHM); FHM is characterized by measuring a patient's response - such as the Doppler pulse - to a defined stress applied to the cardiovascular system. The purpose of functional monitoring is to describe a patient's pre-load reserve; the passive leg raise maneuver is a well-defined and accepted cardiovascular stress employed for FHM in the intensive care unit (Monnet, Marik, Teboul, 2016).

Session Screen

The session screen allows the clinician to easily calculate a patient's cardiovascular response during functional hemodynamic monitoring (FHM). For example, before an intervention/cardiovascular stress such as a passive leg raise (i.e. baseline) metrics are obtained, calculated and then compared to the 'post-intervention' period. The clinician selects regions of interest during the monitoring episode, and the sampling boxes (green / blue) display percentage change between the selected regions.