USER MANUAL

FloPATCH™

FP120

Ultrasonic Blood Flow Monitor (4 MHz)

FLOSONICS MEDICAL

204-73 Elm St, Unit
Sudbury, Ontario P3C 1R7
Canada

info@flosonicsmedical.com
flosonicsmedical.com

Table of Contents

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 (o/a 1929803 Ontario Corp.)
204-73 Elm Street
Sudbury, Ontario P3C 1R7
Canada

info@flosonicsmedical.com

1.3 FCC Compliance Statement

FCC ID: **2AUWSFP120**

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-FP120**

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.

2. FLOPATCH INTENDED USE/INDICATIONS FOR USE

2.1 Intended Use

The FloPatch (FP120) is intended for the detection and analysis of blood flow in peripheral vasculature. 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 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.

2.5 Contraindications

There are no known contraindications for this device.

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.

The device used with this device is a Type B 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:

Icon	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

Icon	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 and 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 environments. Using the device in an MR 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 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 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, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could occur.
	WARNING! The FloPatch must be inspected before use for any damage to the adhesive. 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 surgical equipment or in a surgical environment. Doing so may create a hazardous situation.

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.

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 7000-0434A**	**Caution**	Important cautionary information, such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	**IEC 60417-5841**	**Defibrillation-Proof Type B Applied Part**	The device meets requirements set for defibrillation-proof Type B 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 7000-3082**	**Manufacturer**	Manufacturer information.
	**ISO 7000-1051**	**Single Use Only**	Intended for single use only and not intended for reuse.

	**ISO 7000-2606**	**Do Not Use if Package is Damaged**	Indicates a medical device that should not be used if the package has been damaged or opened.
	**ISO 7000-0621**	**Fragile, Handle with Care**	It indicates a medical device that can be broken or damaged if not handled carefully.
	**ISO 7000-2609**	**Non-Sterile**	This indicates a medical device that has not been subjected to a sterilization process.
IPX7	**IEC 60529**	**IP Rating**	An IPX7 rating signifies that the labelled device is protected from ingress of water up to a depth of 1m for 30 minutes.

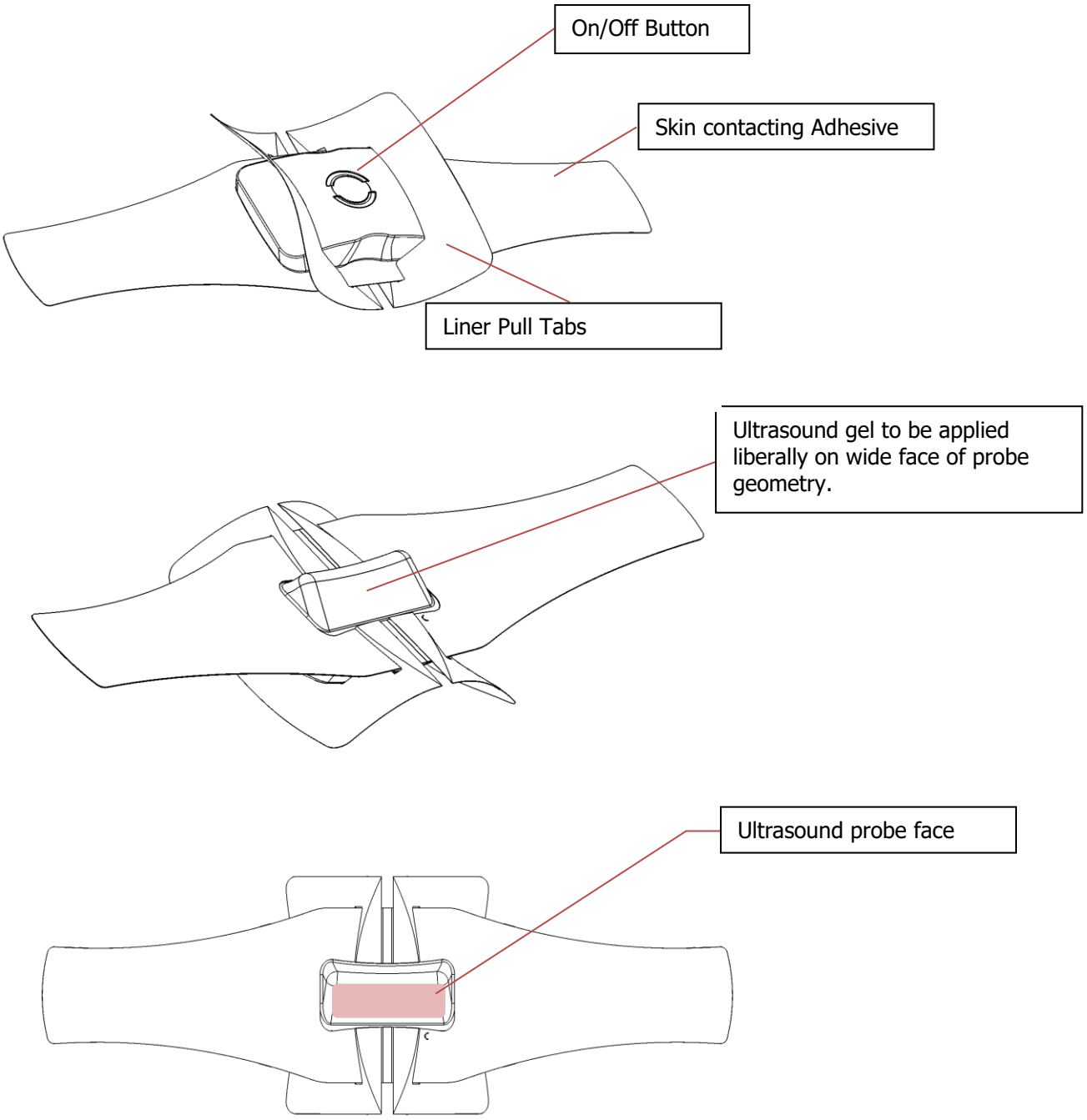
4. FLOPATCH OVERVIEW

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.

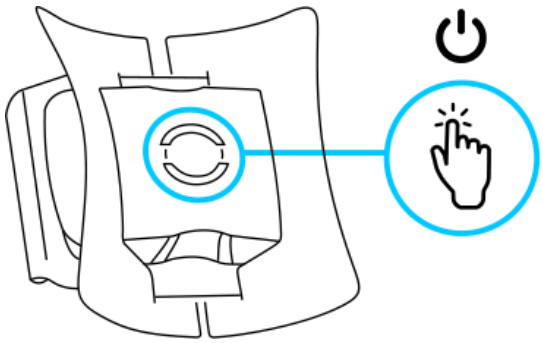
The FloPatch (FP120) is a hands-free wearable ultrasound device that is portable and non-invasive. The device consists of a single unit that acquires the signal and processes the signal. The processed signal is transmitted wirelessly to a medical mobile application. The device has one ON/OFF power button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

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

4.1 Main Unit Diagram

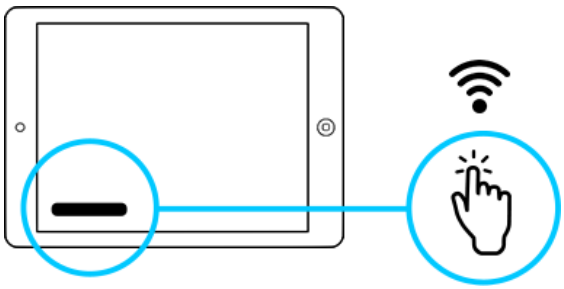


5. BASIC OPERATION



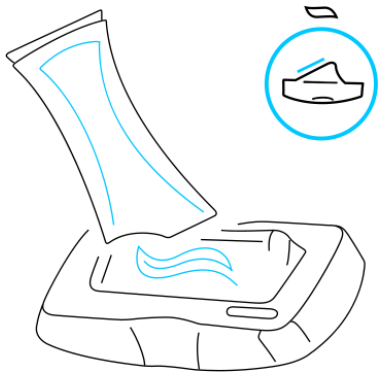
1. Press the power button to initiate the device.

   Upon initiation, the device LED indicator will blink rapidly to indicate it is ready to establish a connection with the mobile app.



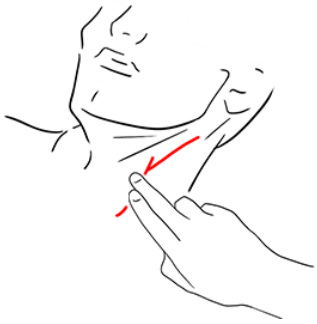
2. Open the mobile app and navigate to the "Assess Bloodflow" screen. Press the button in the bottom left corner to open a list of devices available to connect.

   Select the desired device and wait until the device LED indicator changes to solid blue to indicate a successful connection.

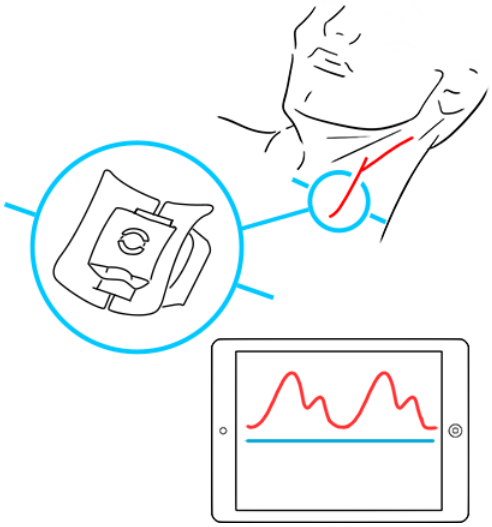


3. Apply ultrasound gel on the device directly over the ultrasound transducer in the indicated area.

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

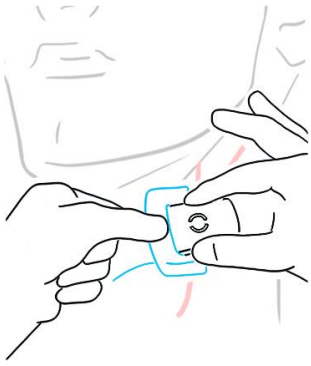


4. Locate the carotid artery in the neck using palpation.



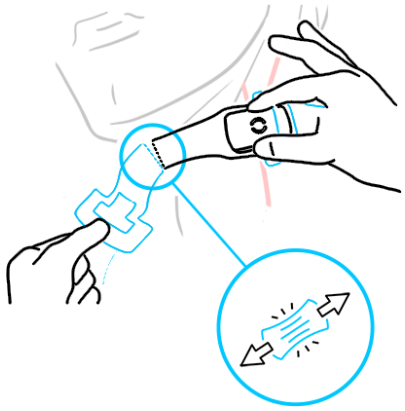
5. Place the FloPatch lengthways across the neck, directly on top of the previously identified carotid artery. Ensure the logos/images are right-side-up.

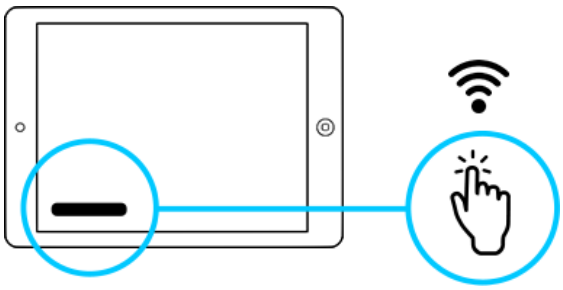
   When the device is placed, the Doppler sound will begin to be heard from the mobile app.

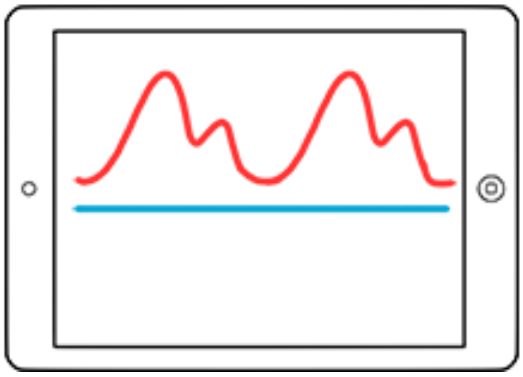


6. Ensure a satisfactory Doppler sound and waveform from the mobile app (i.e. satisfied with the tonal quality, auditory volume, audio stability and waveform performance).

   If satisfied, hold the device in place and remove one liner from the top face of the device, exposing the adhesive onto the skin.







7. Continue to hold the FloPatch securely over the carotid and pull the liner tight to apply tension over the skin. Once applied tightly to the skin, pull sufficiently to rip the liner off the end of the adhesive.

8. Repeat Steps 6-7 for the liner on the opposite side.

9. After securing the FloPatch, the Doppler wave trace can be viewed on the mobile application. Perform any necessary assessments and examine the mobile app for information on patient physiology.

10. Once the assessment is complete, disconnect the FloPatch using the mobile application or by physically pressing the power button on the device for 2 seconds. To disconnect using the mobile application, click on the FloPatch icon on the bottom left of the screen and press the disconnect button on the screen that appears.

    The FloPatch may remain secured to the patient to allow for reassessment.

11. To perform subsequent assessments, repeat Steps 1-2 to reconnect the device to the mobile application.

    Disconnect the device following the assessment by repeating Step 10.

12. After all assessments are completed, or the device battery runs out, press the power button on the device to turn it off if it is still on. Remove the adhesive and the device from the patient's neck. To remove the adhesive, use an alcohol wipe/spray. To remove the adhesive first spray the alcohol on one edge of the adhesive, then slowly start peeling the edge of the adhesive as you spray between the adhesive and the skin such that the alcohol reaches between the adhesive and the skin.

13. Dispose of the device as required by local regulations.

⚠	**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. User Interface

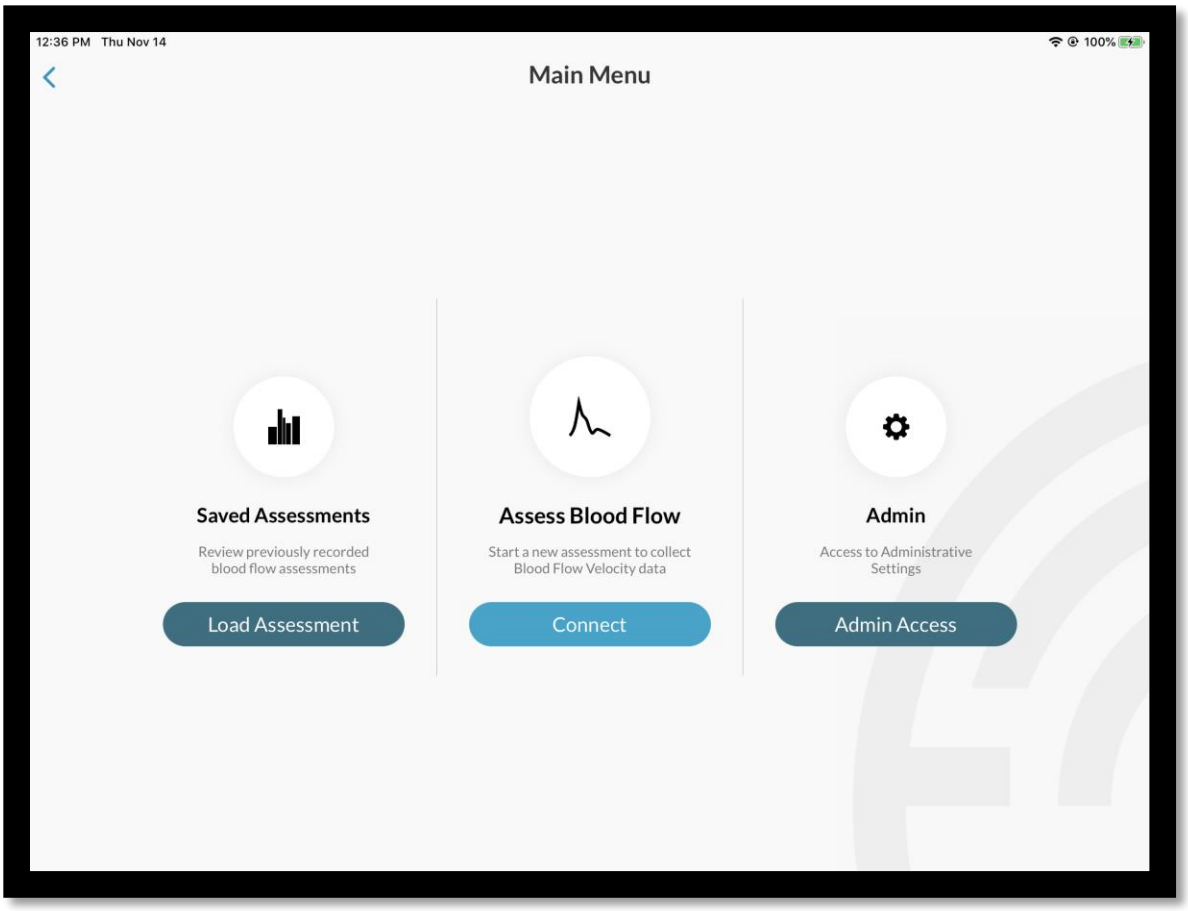
6.1 Welcome Screen

The Welcome Screen is the first window a user can interact with when using the FloPatch iOS application. It will be the first page displayed when the application is opened from being closed. It prompts the user to select one of four options:

1. *Start* navigates the user to the Home Screen of the FloPatch iOS application
2. *Frequently Asked Questions* opens up a list of FAQs' to help answer any questions the user might have
3. *User Manual* opens an electronic version of the FloPatch User Manual
4. *FCC/IC Compliance* opens the FCC/IC Compliance statement

In addition, the Welcome Screen displays the version of the application at the bottom of the screen.

6.2 Home Screen



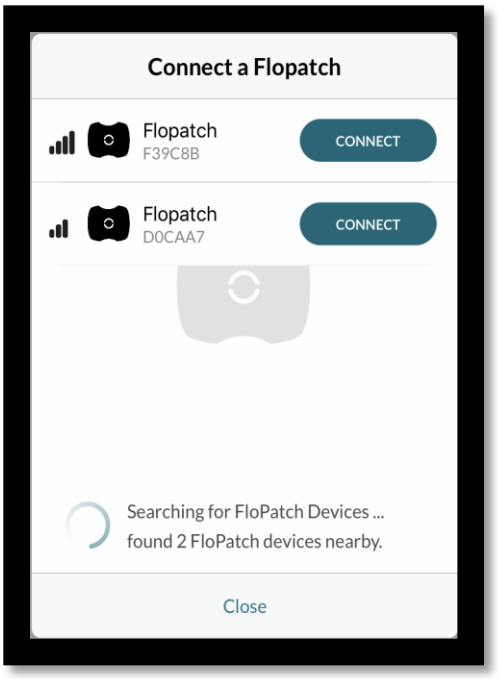
The Home Screen is the main navigation menu for the FloPatch iOS application. It allows the user to access the core functionality of the FloPatch application through its three buttons:

1. *Assess Blood Flow* launches the assess blood flow window if a FloPatch is already connected to the iOS device. If no FloPatch is connected, the FloPatch connection screen will appear (see section 7.3). More information about the Assess Blood Flow window can be found in section 6.4.

2. *Saved Assessments* launches the Saved Assessments Screen. The previous 10 assessments taken from the currently connected FloPatch are saved and can be accessed through this window. More information about this screen can be found in section 6.5.

3. *Admin* is password protected and not accessible to the user.

6.3 FloPatch Connection Screen



The FloPatch Connection screen appears under the following conditions:

1. The *Assess Blood Flow* button is selected on the Home Screen and no FloPatch is currently connected

2. A FloPatch is manually disconnected from the Assess Blood Flow screen and *connect* is selected

The FloPatch connections screen allows you to connect a FloPatch by selecting *connect*. If multiple FloPatch's are discovered, they can be differentiated by a unique ID found under the word FloPatch, and a Bluetooth signal strength indicator found on left side of the connection window. The application will only allow for one FloPatch to be connected at a time.

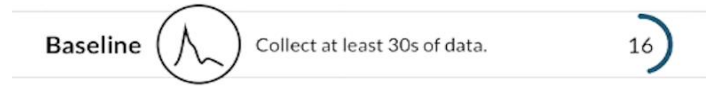
6.4 Assess Blood Flow Screen

The Assess Blood Flow 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 iOS application and has several parts. In the above image, the parts of the screen are labeled 1-14, and information about each component can be found below:

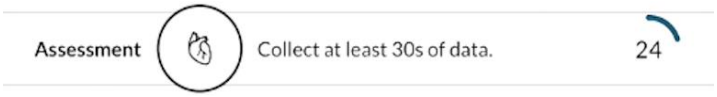
1. The *Return Button* returns the iOS application back to the Home Screen of the iOS application.

2. The *Heart Rate Display* shows the current beats-per-minute (BPM) of the patient wearing the FloPatch application. The BPM is calculated using the incoming Doppler waveforms.

3. The *Assessment State* label displays the current state the Assess Blood Flow Screen is in. There are 3 possible states:
   a. *Baseline*



   b. *Assessment*



   c. *Analysis*

The following table displays the workflow of changing assessment states:

State	Triggered by Button	Minimum Duration of State	Ended by Button
Baseline	7a	30 seconds	7b
Assessment	7b	30 seconds	7c
Analysis	-	No time limit	-

When the Assess Blood Flow screen first opens, the only selectable button is 7a, *Collect Baseline*. When in the baseline or assessment state, the user must wait a minimum of 30 seconds before being able to select the button to continue to the following state.

4. The *Waveform Display Scale* allows the user to increase or decrease the scale of the x-axis (time) on the waveform display

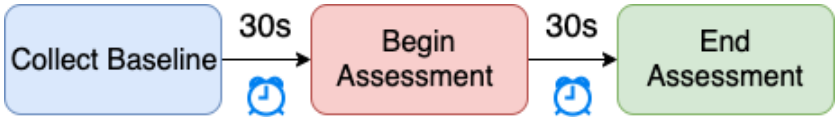
5. The *Waveform Display* covers the upper half of the screen and is a large plot where the incoming information from the FloPatch is graphed in real time. The waveform streams from the left side of the screen to the right with a scrolling axis. The waveform itself is displayed in red when in FWD mode and blue when in REV mode.

6. The *Restart* button clears all information in the waveform display (5) and the characteristics display (9) and restarts the streaming from the FloPatch.

7. The *Assessment State* button group controls the assessment state (3) of the iOS application. There are three buttons in the assessment state button group:

   7a. Collect Baseline
   7b. Begin Assessment
   7c. End Assessment

   The assessment state buttons must be selected in a sequential manner, with Collect Baseline being the only button initially selectable. Once selected, a minimum of 30 seconds of baseline must be collected before you can select Begin Assessment. Similarly, a minimum of 30 seconds of assessment must be collected before end assessment can be selected.



   Initially selecting Collect Baseline displays the pre and post assessment sliders in the characteristics display.

8. The *Save* button saves the waveform and characteristics so they can be loaded from the Saved Assessments window (see section 6.5).

9. The *Characteristics Display* sits below the waveform display on the lower half of the screen. This area displays the calculated metric as bars, with one bar corresponding to one heartbeat. The Characteristics display allows the user to toggle between Max Total VTI and Corrected Flow Time using the left and right arrow buttons.

10. The *Pre and Post Assessment* (10a and 10b) sliders appear once selecting the Collect Baseline button. The user may slide the pre-assessment and post-assessment bars with their finger and compare the percent change between two areas. When the percent change between two sections

of data is calculated, it is displayed on the right most side of the characteristics display in a yellow box (10c).

11. The *FloPatch Connection Information* displays the connection status information for the FloPatch to the user. This includes the battery level, which is displayed graphically as a battery with green charge units. Additionally, the Bluetooth connection strength is displayed on the left side of this component, as a value from 1 to 4. Selecting this button opens a pop-up containing the ID and device information for the connected FloPatch, as well as an option to disconnect the current FloPatch.

12. The *Select Metric* buttons allow the users to change the displayed metric in the characteristics display area. The user may select one of the two metrics:

    a. Max Total VTI
    b. Corrected Flow Time

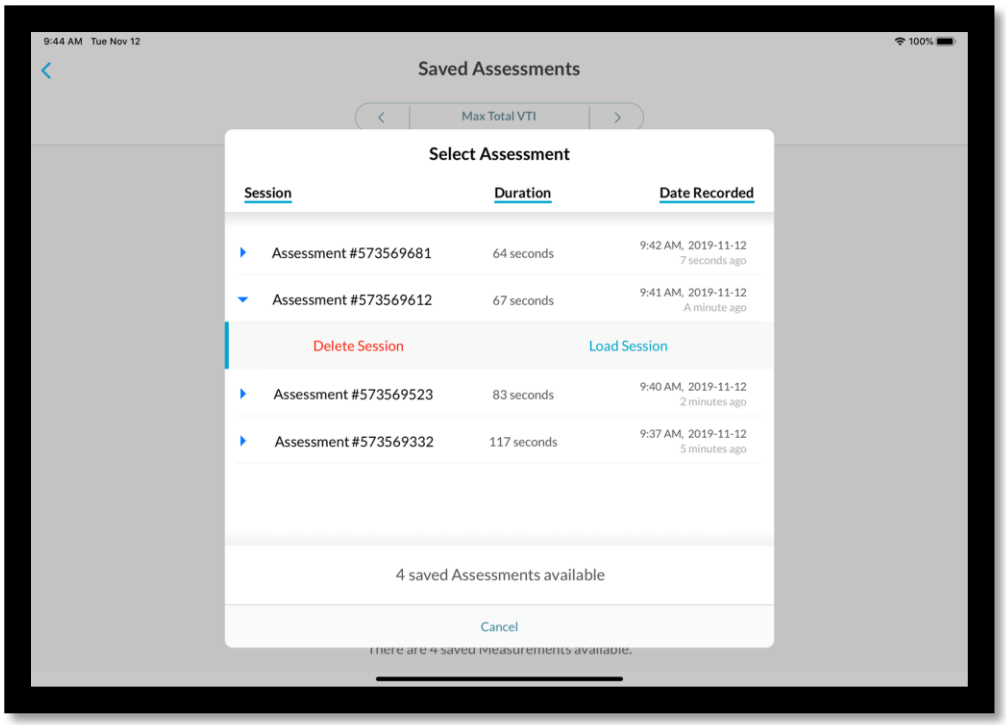
13. The *Flow Direction* button changes the direction of the displayed flow. There are two flow options:

    a. Forward (denoted as a red waveform)
    b. Reverse (denoted as a blue waveform)

An example of reverse mode is shown below:

14. The *Volume* button toggles the Doppler shift audio on and off from the iOS device

6.5 Saved Assessments Screen

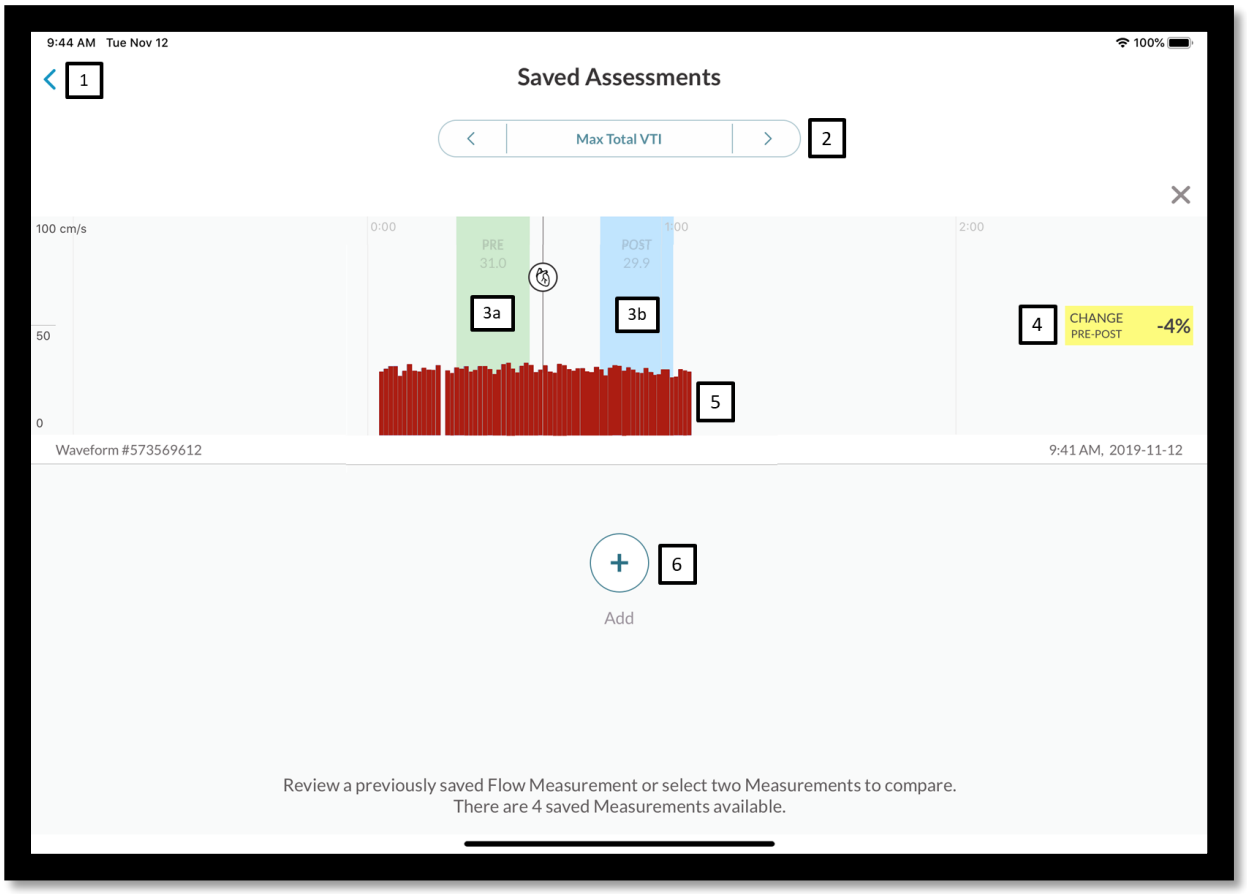


The Saved Assessments Screen allows the user to load previous assessments taken from the Assess Blood Flow screen. The individual assessments can be identified by three features:

1. The unique assessment ID
2. The duration of the assessment
3. The date and time of the recording

A session may be deleted or loaded by the user. If deleted, the session ***cannot*** be recovered.

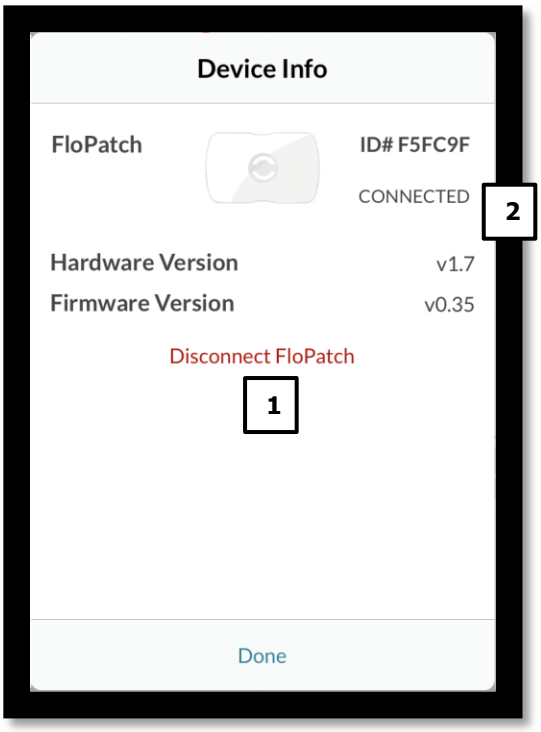
If a session is loaded, the application will display the previously collected characteristic data from the assessment in question. The image below demonstrates what a saved assessment looks like:



The Saved Assessments window has a few features to note:

1. The *Return* button returns you to the main Saved Assessments window
2. The *Select Metric* arrows allow you to toggle between Max Total VTI and Corrected Flow Time
3. The *Pre and Post Assessment Sliders* (3a and 3b) allow you to calculate the percent change between areas in the saved assessment
4. The *Percent Change Area* displays the percentage change between the pre and post assessment sliders
5. The *Characteristics Display* displays a bar representing each beat for the selected metric
6. The *Add* button allows for an additional assessment to be loaded alongside the first, so two assessments can be compared at the same time.

6.6 Disconnect Screen



The disconnect screen appears when a FloPatch device is connected to the mobile medical application and the 

button is pressed on the Assess Blood Flow Screen.

1. The *Disconnect FloPatch* button when pressed, disconnects a connected FloPatch FP120 device.
2. Hardware and Firmware information of the connected FloPatch FP120 device is displayed on the disconnect screen.

7. TROUBLESHOOTING THE FLOPATCH

Issue	Solution
Device is damaged	Contact the manufacturer or return the device to manufacturer and stop all usage of the device
Low Battery	Dispose of the device based on local regulations for electronics disposal.
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 the battery is low 2) Ensure that there is adequate ultrasound gel on the device. 3) Ensure that the device is placed sufficiently close to the carotid artery on the neck.

	4) Ensure that the device is oriented correctly.

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

8. 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.

9. 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.

Appendix A – Product Specifications

Product Name FloPatch FP120

Model Number FP120

Standards Compliance IEC 60601-1, IEC 60601-2-37 and IEC 60601-1-2.

Battery Specifications Lithium Polymer, IEC 62133

Classification ME Classification (IEC 60601-1): Internally Powered Equipment

Applied Part Type B

Degree of Protection Against Harmful Ingress of Fluid
IPx7

Degree of Safety in Presence of Flammable Anaesthetics
Equipment not suitable for use in presence of flammable gases.

Environmental

Operating Conditions
1) Temperature: 10°C to 30°C
2) Humidity: 30% to 85%

Storage Conditions (Device)
1) Temperature: 10°C to 30°C
2) Humidity: 40% to 60%

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.

Appendix B – Compatible Mobile Devices

iPad Pro Models: A1980, A1876

iPad Air Gen 3 Models: A2152

iOS Version: iOS 12+

Appendix C – EMC Information

9.1 Electromagnetic Emissions

NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If used in a residential environment (for which CISPR 11 Class B is normally required) this equipment may not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

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 in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **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	

9.2 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	N/A	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]

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.

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.

9.3 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.

9.4 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

9.5 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, including investigation of the human fetus, 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.

9.6 Ultrasound Safety and the ALARA Principle

Ultrasound waves dissipate energy in the form of heat and can therefore cause tissue warming. Although this effect is extremely low with Doppler, 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).

9.7 Explanation of MI/TI

9.7.1 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 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).

9.7.2 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 rause 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 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.

9.7.3 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 statisti- cal analysis; they are therefore Type B uncertainties. There are other systematic sources of essentially random error (such as temperature) as well as uncertainties estimated from measurement of the device in question (spatial aver- aging 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 produce 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): ±2.9%

   The two contributing sources were the stated DC gain accuracy and digitization error of the digital oscillo- scope. As the reported values are derived from a cross-calibrated hydrophone, this value was increased (along with σzsp)
2. Hydrophone Pressure Sensitivity (σML): ±3.6%

   The principal source of this uncertainty is the stated uncertainty of the hydrophone calibration at a representa- tive 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): ±0.0%

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): ±1.4%

   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. As the reported values are derived from a cross-calibrated hydrophone, this value was increased (along with σV)
8. Non-linear Distortion (σNLD) ±1.2%

   The uncertainty of the intensity and (rarefactional) pressure are estimated from [8], and subsequent discussion with FDA personnel.
   The uncertainty for temperature rise measurement derived from thermo coupler method is 0.6 °C.

9.7.4 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. High levels of acoustic output and long exposure time should be avoided while acquiring necessary clinical information.

9.7.5 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 on: September 9, 2008 by the FDA
3. Draft Document: Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Devices; Document issued on: October 2, 2017 by the FDA
4. 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.

9.7.6 Summary of Global Max Values

NOTE: Thermal Indices and the Mechanical Index are 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 3 probes.

Quantity (x)	K	$\bar{x}$	σ_x	L_1 upper bound	γ_x	L_2 upper bound
MI	4.26	0.0111	0.00146	0.0173	0.00156	0.0178
$I_{spta, \alpha}$	4.26	15.8	3.83	32.1	4.12	33.3
TIS	4.26	0.297	0.0209	0.386	0.0359	0.45
TIB	4.26	0.323	0.0408	0.497	0.0517	0.543
TIC	4.26	0.48	0.0301	0.608	0.056	0.718

9.7.7 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			1.11E-02	0.30		0.32		0.48
Index component value				0.30	0.27	0.30	0.32	
Acoustic Parameters	pr, α at zMI	(MPa)	2.23E-02					
	P	(mW)		29.63		29.63		29.63
	P1×1	(mW)		15.42		15.42		
	zs	(cm)			2.70			
	zb	(cm)					2.50	
	zMI	(cm)	2.70					
	zpii, α	(cm)	2.70					

	fawf	(MHz)	4.03	4.03		4.03		4.03
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)	15.78					
	Ispta at zpii or zsii	(mW/cm^2)	33.07					
	pr at zpii	(MPa)	3.24E-02					
Operating control conditions	CW-mode							

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 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