ENGLISH

Delfi

Personalized Tourniquet Systems

PTS for Blood Flow Restriction System

Operator & Maintenance Manual

REF 9-2200-200BFR

delfimedical.com/ifu

Pat.:www.delfimedical.com/patents

WARRANTY

LIMITED TWO-YEAR WARRANTY (North America only)

SCOPE OF LIMITED WARRANTY

Delfi Medical Innovations Inc. ('Delfi') warrants the components of the PTS Personalized Tourniquet System for Blood Flow Restriction ('product') from date of purchase as follows: PTS for BFR instrument and accessories (2 years), Easi-Fit for BFR Reusable Cuffs (6 months), and rechargeable battery (90 days). During the warranty period, Delfi will repair or replace, at its option, any product which is defective in materials or workmanship or which fails to meet the published specification for that model. This Limited Warranty is made only to the original purchaser of the product and is non-transferable. The remedies described in the Limited Warranty are the exclusive remedies for breach of warranty. THIS WARRANTY SHALL NOT APPLY TO ANY PRODUCT WHICH HAS BEEN ALTERED, MODIFIED, DISASSEMBLED OR SERVICED BY ANYONE OTHER THAN DELFI STAFF IN ANY WAY, OR WHICH HAS BEEN SUBJECTED TO MISUSE OR ABUSE.

DISCLAIMER OF IMPLIED WARRANTIES

The foregoing Express Limited Warranty is given in lieu of any and all other express or implied warranties. DELFI MAKES NO OTHER WARRANTIES INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

LIMITATION OF REMEDIES

In no case shall Delfi Medical Innovations Inc. be liable for any special incidental or consequential damages whether based on breach of warranty or other legal theory. Some states do not allow limitations on warranties or on remedies for breach in certain transactions. In such states, the limits in this paragraph and the preceding paragraph do not apply.

WARRANTY CLAIMS

In the event of a warranty claim within the warranty period please take the following steps:

1. Notify Customer Service Department, Delfi Medical Innovations Inc. at 800-933-3022 or email info@delfimedical.com. Please provide details about the nature of the problem and include the product serial number. Upon receipt of this information, Delfi will provide a date for service and a return shipping authorization.

2. Upon receipt of the shipping authorization, forward the equipment, freight prepaid, to the location specified in the shipping authorization.

Your compliance with these steps will help ensure that you receive prompt warranty service for your product.

WARRANTY (Outside North America)

SCOPE OF WARRANTY

Please contact Delfi for warranty information at info@delfimedical.com.

Unit Serial Number _____

AC Power Supply Serial Number _____

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GENERAL INFORMATION

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CAUTION: United States Federal law restricts this device to sale by or on the order of a physician or physician's designated licensed healthcare practitioner

NOTES: Use this tourniquet system according to the policies in your practice setting. The following information on intended use, precautions, contraindications, and adverse effects are offered as a guide to assist in this process

INTENDED USE

This device is intended to be used only with a Delfi BFR Tourniquet Cuff by a physician or physician's designated licensed healthcare practitioner to preoperatively and/or postoperatively exert enough pressure on the arterial blood flow in a patient's extremity to reduce or totally occlude blood flow into the limb.

INDICATIONS FOR USE

This device is indicated for use on patients for whom a physician or physician's designated licensed healthcare practitioner has indicated preoperatively and/or postoperatively blood flow restricted therapy.

The target treatment group shall be drawn from those patients who require or may require perioperative procedures to affect the structure or function of limbs and/or to treat or mitigate diseases associated with limb anatomy or physiology. A physician or physician's designated licensed healthcare practitioner may indicate treatment with the Delfi PTS for BFR for patients who may be unable to withstand the stresses of high load therapies (e.g. persons recovering from injury, persons with chronic health conditions, or persons suffering from other musculoskeletal conditions).

NOTES: Physician or physician's designated licensed healthcare practitioner include but not limited to: physiotherapists and surgeons, physiotherapy clinics, sports teams with resident physiotherapists/athletic trainers/physicians.

CONTRAINDICATIONS

Delfi recommends that users regularly review published medical literature for factors that warrant careful consideration before prescribing blood flow restriction techniques. The current list of contraindications has been developed through current research on blood flow restriction therapy, as well as through the well-established risks for tourniquet use in surgery which are also contraindicated for use in blood flow restriction. The listed contraindications are:

Cardiovascular disease:

- Unstable and/or severe hypertension
- Compromised vascular circulation (e.g. peripheral vascular disease)
- Hypercoagulable states (blood clotting disorders)
- Varicose veins in the indicated limb for BFR intervention
- Atherosclerotic vessels causing poor blood circulation
- IV drug use in the indicated limb for BFR intervention

Musculoskeletal injury:

- Recent muscle trauma or crush injuries
- Postsurgical excess swelling
- Open fractures
- Skin graft in which all bleeding points must readily be distinguished
- Secondary or delayed procedures after immobilization
- Post-traumatic lengthy hand reconstruction

- Direct peripheral nerve injury

Other factors:

- Uncontrolled diabetes mellitus
- Sickle cell disease or trait (relative contraindication, see **Precautions in Use** under **Section 1 General Information**)

WARNINGS

This device is not indicated for use on patients during surgery.

Caution should be exercised when prescribing BFR therapy for patients with compromised cardiac function including silent myocardial ischemia or left ventricular dysfunction.

If serious adverse effects are seen while performing BFR therapy, the intervention should be stopped. The physician or physician's designated practitioner shall use their discretion throughout use of the BFR therapy to identify any serious adverse effects which may require the patient to stop the therapy. Such serious adverse effects include but are not limited to excessive limb swelling or signs of nerve injury.

This product is subject to wear and deteriorates with use. It is essential to inspect this device before each use. Refer to **Utilization** under **Section 3 BFR Cuff Utilization**. If the cuff fails to pass inspection, it is no longer usable and must be discarded. Use of a damaged cuff could result in one or more of the following events: loss of cuff pressure; release of the cuff from around the patient's limb; movement of the cuff on the patient's limb; excessive leakage of the cuff pressure; or pinching of tissue under the cuff.

The cuff should only be connected to a tourniquet instrument known to be in an operable condition. Refer to **Section 4 Maintenance** for information on testing and maintenance.

The Matching Limb Protection Sleeves (MLPS) single patient multiple-use is intended for use on a single patient only. Do not reuse sleeve on another patient.

The Matching Limb Protection Sleeves (MLPS) single -use disposable is intended for single use only. Do not reuse sleeve.

PRECAUTIONS IN USE

Delfi recommends that users regularly review published medical literature for factors that warrant careful consideration before performing blood flow restricted techniques. The following clinical conditions have been cited in publications as factors that should be carefully considered before performing blood flow restricted therapy and/or for which there is not sufficient clinical evidence to be a listed contraindication:

Cardiovascular conditions:

- Coronary heart disease
- Existing or at increased risk for venous thromboembolism
- At increased risk of hemorrhagic stroke
- At increased risk of exercise induced rhabdomyolysis
- At increased risk of atrial fibrillation or heart failure
- Prior use of medications known to increase blood clotting risk
- Induration/Marfan syndrome
- Vascular endothelia dysfunction
- Prior Hemophilia
- Cardiopulmonary conditions
- Silent myocardial ischemia

- Left ventricular dysfunction

Musculoskeletal conditions:

- Existing compartment syndrome
- Open soft tissue injuries
- Extremity infections

Patient considerations:

- Pediatric patients
- History of smoking
- Pregnancy
- Dehydration
- History of cancer

System Handling:

- The tourniquet system must be well calibrated and in operable condition. Accessories should be checked regularly for leaks and other defects.
- The tourniquet cuff must never be punctured; therefore, any sharp objects which may be used near the system must be handled with care.
- When cleaning, carefully follow the cleaning and assembly instructions for the tourniquet cuff and instrument.

Patient Considerations:

- Prolonged ischemia may lead to temporary or permanent damage to tissues, blood vessels, and nerves. Tourniquet paralysis may result from either excessive or insufficient pressure. Prolonged tourniquet time can also produce changes in the coagulability of the blood with an increase in clotting time.
- When using a tourniquet on patients with sickle-cell disease or trait, severe post-use pain may result in the applied limb which may be caused by sickling of cells. Test for hemoglobin type and level before using a tourniquet on patients with sickle cell disease or trait. When the tourniquet is used for these patients, closely monitor the patient's PO2 and pH since sickling is dependent on oxygen tension and pH.

Application and Use:

- Select the proper cuff size to allow for the overlap recommended by Delfi Medical Innovations Inc. Refer to the Cuff Size guide under Section 3 BFR Cuff Utilization. Too much or too little overlap may cause cuff rolling and telescoping, unexpected release of the cuff from the limb, and/or undesired pressure distribution on the limb.
- The skin under the tourniquet cuff may be protected from mechanical injury by smooth, wrinkle free application of the cuff Follow the Delfi's recommendation for limb protection material under the cuff; refer to the Application guide under Section 3 BFR Cuff Utilization. In general, a limb protection sleeve designed specifically for the cuff provides the best protection.
- The tourniquet cuff must be applied in the proper location on the limb. Tourniquet pressure and the time the tourniquet is inflated on the limb should both be minimized. There is additional potential risk to superficial nerves in unprotected areas; never apply a tourniquet over an area where major nerves may be directly compressed against bone (e.g. peroneal nerve near the proximal head of the fibula). Never apply a tourniquet over the joints of the limb. Do not readjust an already inflated cuff by rotating it because this produces shearing forces which may damage the underlying tissue.
- Limb Occlusion Pressure (LOP) is defined in the medical literature as the minimum pressure required to stop the flow of arterial blood into the limb distal to the tourniquet cuff, at a specific time in a specific tourniquet cuff applied to a specific patient's limb at a specific location. For each patient, the tourniquet pressure should be set to a percentage of the LOP as recommended by the supervising physician or physician's designated licensed health care

practitioner.

- Observe the cuff during inflation and periodically while inflated to ensure the cuff is not migrating on the limb. If the tourniquet cuff migrates on the limb during use, deflate and reapply the cuff. Inflate the cuff and observe for migration. If migration persists, replace the cuff.
- In case of incomplete or improper inflation, the tourniquet cuff must be fully deflated before cuff reinflation.
- The deflated cuff and any underlying limb protection material should be completely removed as soon as tourniquet pressure is released and the prescribed blood flow restriction therapy protocol is complete.

ADVERSE EFFECTS

Possible adverse effects which may occur from performing blood flow restriction techniques using a pneumatic tourniquet include bruising at the site of the cuff, numbness, cold feeling, venous thrombus, fainting/dizziness, delayed onset muscle soreness, increased perceived exertion/pain/discomfort, stiffness, weakness, skin discoloration, exercise-induced rhabdomyolysis. Symptoms of tourniquet paralysis are motor paralysis and loss of sense of touch, pressure, and proprioceptive responses.

SPECIFICATIONS

AC Power Adapter	Use only supplied AC adapter / power cord assembly, Delfi (REF 7-2200-020)
~ AC Power Mains Line Voltage Range	100-240 ~ (AC), 50/60 Hz. Auto switching
Line Current	175 mA RMS @ 120V ~ (AC) typical, Delfi (REF 7-2200-020)
Input Power	100 watts maximum (REF 7-2200-020)
AC Power Plug (North America)	Hospital grade, 3 prong straight blade, 15 amp
Power Cord	Medical grade NEMA 5-15P, type SJT, AWG 18, 2.45 m (8 ft) or international equivalent
Battery Type	15.2V Lithium-ion internally protected 3000 mAh pack. Use only Delfi (REF 7-2200-046) battery pack
Battery Discharge Time	10.0 hours (typical)
Battery Recharge Time	3.0 hours (typical)
Limb Occlusion Pressure Measurement Range	90 – 300 mmHg
Personalized Tourniquet Pressure Calculation Range	30% - 140% of LOP, User Adjustable
Cuff Pressure Range	20 – 350 mmHg, 1 mmHg increments
Cuff Pressure Accuracy	± 2 mmHg

GENERAL INFORMATION

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Pressure Regulation	± 6 mmHg of set-point (10-second average under non-transient conditions without external leaks
Inflation Timer Set-point Range	1-30 minutes, 1-minute increments
Lockout Timer Set-point Range	1-10 minutes, 1-minute increments
Timer Accuracy	0.1% of elapsed time
Inflation Rate	34-inch cuff applied to a 30-inch thigh inflates to 350 mmHg in less than 5 seconds
Deflation Rate	34-inch cuff applied to a 30-inch thigh deflates to less than 10 mmHg in less than 10 seconds
Internal Diagnostics	Program, memory, watchdog timer, transducer calibration, improper valve actuation
Display	Color 480x800 LCD Backlit
Status Indicator	Blue – Charging Red Constant – Technical alarm Red Flashing – High priority alarm Yellow Flashing – Medium priority alarm Yellow Constant – Low priority alarm
Controls	640 mm x 1080 mm touch screen and **ON/STANDBY** button located on the front panel
Size	**Height**: 180 mm (7.0 in) **Width**: 120 mm (4.7 in) **Depth**: 110 mm (4.3 in) **Weight:** 1.263 kg (44.5 oz)
Indicated Tourniquet Cuffs for Use (provided with system unless indicated)	PTS BFR Easi-Fit 18” Tourniquet Cuff (RED) PTS BFR Easi-Fit 24” Tourniquet Cuff (GREEN) PTS BFR Easi-Fit 34” Tourniquet Cuff (BLUE) PTS BFR Easi-Fit 44” Tourniquet Cuff (BROWN) Order separately
Indicated Matching Limb Protection Sleeves (MLPS) for Use, Single Patient Multiple Use (provided with system unless indicated)	MLPS – for PTS BFR Easi-Fit 18” reusable cuff (RED) MLPS – for PTS BFR Easi-Fit 24” reusable cuff (GREEN) MLPS – for PTS BFR Easi-Fit 34” reusable cuff (BLUE) MLPS – for PTS BFR Easi-Fit 44” reusable cuff (BROWN) Order separately

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Indicated Matching Limb Protection Sleeves (MLPS) for Use, Single Use Disposable (Optional accessory, Order separately**)**	MLPS - for PTS BFR Easi-Fit 18" reusable cuff (RED) MLPS - for PTS BFR Easi-Fit 24" reusable cuff (GREEN) MLPS - for PTS BFR Easi-Fit 34" reusable cuff (BLUE) MLPS - for PTS BFR Easi-Fit 44" reusable cuff (BROWN)
PTS Roll Stand (Optional)	**Height**: 127.6 cm (50.25 in) **Pole Diameter**: 3.175 cm (1.25 in) **Base Diameter**: 55.88 cm (22 in)
Environmental Conditions	**Operating temperature:** 10 °C to 40 °C (50 °F to 104 °F) **Storage temperature:** 20 °C to 40 °C (-4 °F to 104 °F) **Relative humidity:** Max 80 % non-condensing

GENERAL DEVICE FUNCTION

The Personalized Tourniquet System for Blood Flow Restriction (*PTS for BFR*) and Accessories provide temporary reduction of arterial blood flow for a predetermined length of time. The system is designed to assist a trained and licensed physician or physician's designated healthcare practitioner in the treatment for the structure and function of a patient's limb(s) by reducing blood flow to a patient's extremities combined with or without muscle activation, to stimulate biological processes which reduce muscular atrophy and increase muscle strength.

The Delfi *PTS for BFR* has the capability of determining a patient's Personalized Tourniquet Pressure (PTP) as a percentage of the patient's Limb Occlusion Pressure (LOP) by automatically measuring LOP. The *PTS for BFR* maintains the cuff pressure at the pressure set-point for the time period(s) required for a BFR therapy session.

The Delfi *PTS for BFR* has the capability of measuring the patient's Limb Occlusion Pressure (LOP) and recommend a Personalized Tourniquet Pressure (PTP) based on the LOP for use during a BFR therapy session.

LOP is the lowest pressure required for a specific cuff to stop the flow of blood in the extremity of a specific patient at a specific time and location. It is personalized to the patient and accounts for patient's physiology, limb characteristics, cuff properties and cuff application. PTP is a personalized pressure that is a percentage of the LOP. The percentage of LOP used for PTP depends on the BFR therapy prescribed by the physician or physician's designated licensed healthcare practitioner.

There are two types of BFR therapy: standard "BFR", and "Cyclic BFR".

Standard BFR therapy involves restricting arterial blood flow into an extremity of a patient while the patient performs low-intensity movements (aerobic or resistive). BFR rehabilitation may involve the patient performing exercise repetitions for a number of repetition sets (sets) for strength gain, or may involve the patient performing walking or cycling exercise for a longer duration for increasing the patient's endurance. Owens Recovery Science (ORS), a leader in BFR rehabilitation, recommends strength protocols with 30 reps, 15 reps, 15 reps, and 15 reps (REPs) with 30 seconds rest periods in between (Rest Time). Typically, strength protocols require 6-8 minutes and endurance protocols require 15-20 minutes of inflated time (Inflation Time). ORS recommends setting PTP to 50% or 80% of LOP when performing BFR rehabilitation on an upper limb or lower limb, respectively.

Cyclic BFR (C-BFR) therapy involves the cyclical application of arterial restriction or occlusion, and reperfusion of a patient's extremity. PTP, duration at which the cuff is inflated (Inflated Time) and deflated (Deflated Time), and the

number of inflation cycles (Inflation Cycles) may be adjusted based on the prescription of the physician or physician's designated licensed healthcare practitioner. During C-BFR, the patient may perform low-intensity exercise or may remain inactive.

Delfi *PTS for BFR* provides twelve selectable BFR protocols for BFR or C-BFR therapies. Six of these protocols are based on ORS recommendations with restricted adjustment capabilities. The remaining six protocols are fully customizable within the instrument's limits.

EN 60601-1 CLASSIFICATION

Note: This device is not suitable for use in the presence of flammable anesthetic or gases.

Medical Equipment with respect to electrical shock, fire and mechanical hazards, in accordance with CAN/CSA – C22.2 No. 60601:14, ANSI/AAMI ES60601-1:2005, and EN 60601-1:2006 all with A1:2013, A12:2014, and A2:2021. Medical Equipment with respect to electromagnetic compatibility in accordance with ANSI/AAMI/IEC 60601-1-2:2014 and EN 60601-1-2:2015 all with A1:2021.

Type of protection against electric shock	Class I or Internally Powered Equipment*
 **Degree of protection against electric shock**	Type B applied part
IPX0 Classification according to the degree of Protection against ingress of water	IPX0 (Ordinary equipment)
Mode of operation	Continuous operation

*When the unit is operating on backup battery, the type of protection against electric shock changes to internally powered equipment

EMISSIONS/IMMUNITY

The Delfi *PTS for BFR* complies with EMC criteria set forth in ANSI/AAMI/IEC 60601-1-2:2014 and EN 60601-1-2:2015, all with A1:2021. The user of this device should be aware that precautions should be taken in regards to EMC. The device should be installed and used according to the EMC information provided in the instructions for use. See **Electromagnetic Compatibility** under **Section 2 Operating Instructions**.

Cable	Maximum length
~ AC Power Mains power cord	2.45 m (8 ft)

WARNING: use of an ~ AC Power Mains power cord with a length other than those specified may result in increased emissions and decreased immunity

OPERATING INSTRUCTIONS

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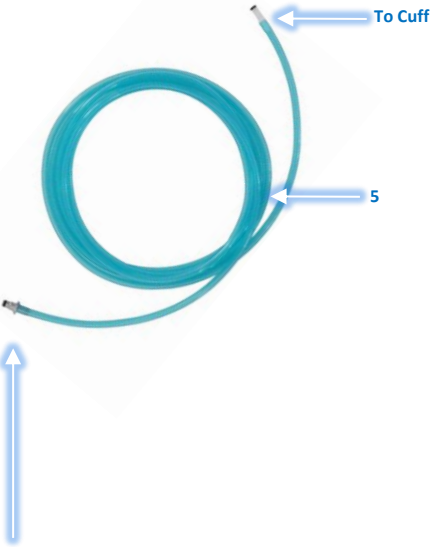
INITIAL INSPECTION

Unpack the *PTS for BFR* upon receipt and inspect the unit for any obvious damage that may have occurred during shipment. We recommend that this inspection be performed by a qualified biomedical engineer or other person thoroughly familiar with electronic medical devices. If the unit is damaged, notify the carrier and Delfi immediately. If the initial inspection results are satisfactory, a functional and calibration check should be performed **after a 5-hour charge**. The attention label covering the pressure/time display window may be removed and discarded after the initial 5-hour charge.

FEATURES

The *PTS for BFR* has a variety of features, as described below:

FRONT



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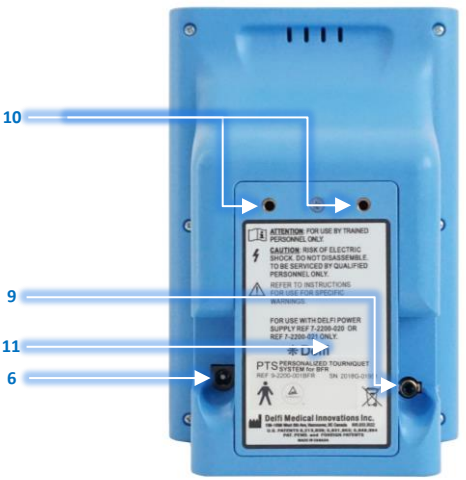
10
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ATTENTION: FOR USE BY TRAINED PERSONNEL ONLY
CAUTION: RISK OF ELECTRIC SHOCK. DO NOT DISASSEMBLE. TO BE SERVICED BY QUALIFIED PERSONNEL ONLY
REFER TO INSTRUCTIONS FOR USE FOR SPECIFIC WARNINGS
FOR USE WITH DELFI POWER SUPPLY REF 7-2200-020 OR REF 7-2200-021 ONLY.
PTS PERSONALIZED TOURNIQUET SYSTEM
Delfi Medical Innovations Inc.


To Instrument
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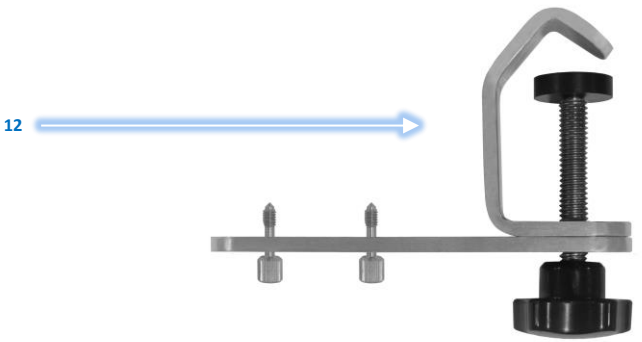
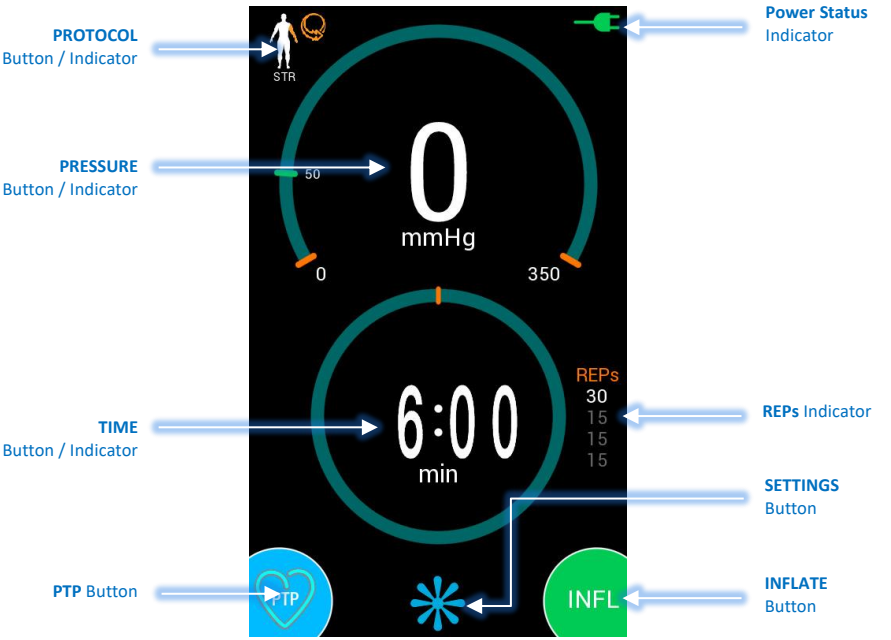

12

MAIN SCREEN – DEFLATED & PTP NOT DETERMINED



MAIN SCREEN – INFLATED & PTP DETERMINED

PROTOCOL Button / Indicator

PRESSURE Button / Indicator

TIME Button / Indicator

DEFLATE Button

Power Status Indicator

PTP Indicator

LOP Indicator

REST TIME Indicator

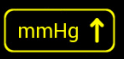
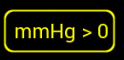
REPs Indicator

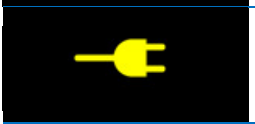
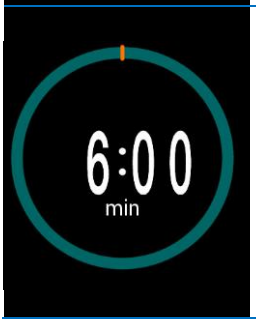
	Feature	What it does
1	**Touch Screen GUI**	Touchscreen based graphical user interface (GUI) for interacting with and controlling most of the *PTS for BFR*'s functions
2	**Status Indicator**	Indicates the status of the *PTS for BFR* Blue – Charging Red Constant – Technical alarm Red Flashing – High priority alarm Yellow Flashing – Medium priority alarm Yellow Constant – Low priority alarm
3	**ON/STANDBY Button**	Turns the unit ON or sets the unit to STANDBY (powered off) **CAUTION**: Ensure cuff is fully deflated and has been removed from the patient as well as the Matching Limb Protection Sleeve (MLPS) prior to setting the unit to STANDBY **NOTE:** This button will not set the unit to STANDBY when the cuff pressure is at a non-zero value **NOTE:** During STANDBY, the power to the *PTS for BFR* and all instrument functions (i.e. inflation, deflation, etc.) are OFF but power continues to supply the battery charging circuitry anytime ~ AC Power Mains is present
4	**Hose Connector**	The PTS for BFR hose assembly (see below) leading to the Delfi Easi-Fit BFR Tourniquet Cuff plugs in to the *PTS for BFR* at the hose connector. The hose connector makes an audible 'click' when properly connected
5	**Hose Assembly**	A PTS for BFR hose assembly is supplied with each *PTS for BFR*. The male metal connector on the hose plugs into the female metal Positive Locking Connector on the *PTS for BFR* (see above). The other end of the hose has a male quick-connect connector that plugs into a female quick-connect connector on the Easi-Fit BFR Cuff. The *PTS for BFR* is designed, tested, and for use with only with Delfi Easi-Fit BFR Tourniquet Cuffs having female quick-connect connectors. Use the supplied PTS for BFR hose assembly only To engage the Positive Locking Connector on the *PTS for BFR*, fully depress and then release the metal locking button. Carefully slide the connectors together. An audible 'click' can be heard when the connectors are properly connected and locked. To disengage, fully depress and hold the metal locking button. Carefully separate the connector while holding the metal locking button. Excessive force is not required. To prevent O-ring damage the metal locking button

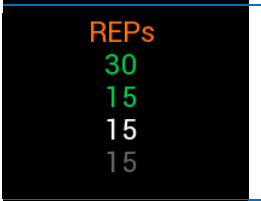
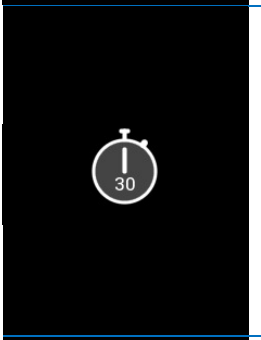
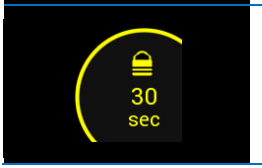
	Feature	What it does
		must always be in the open position before connectors are engaged or disengaged To engage the quick-connect connector to the Easi-Fit BFR cuff carefully slide the connectors together. An audible 'click' can be heard when properly connected and locked. To disengage carefully separate the connectors by pulling them apart. Excessive force is not required
6	**Power Receptacle**	The power receptacle is located on the left of the battery compartment from a rear view of the *PTS for BFR*. The *PTS for BFR* is designed for use with the supplied AC power supply (see below) only; do not use any other type of connection to AC power
7	**~ AC Power Supply**	An AC power supply adapter is supplied with every *PTS for BFR*. It is a sealed unit designed specifically for the *PTS for BFR*. Contact Delfi if your power supply needs service or replacement. Plug the connector on the AC power supply cord into the AC power receptacle on the *PTS for BFR* (see above) and plug the AC power cord into a power outlet (see below) whenever using the unit where AC power is easily accessible To isolate the *PTS for BFR* from external AC power disconnect the AC power supply adapter from the power outlet
8	**~ AC Power Cord**	An AC power cord with a hospital grade plug is supplied with every *PTS for BFR*. Plug the socket end of the cord into the AC power supply and the plug end into an easily accessible AC power outlet
9	**Information Port**	The information port is used for servicing purposes only
10	**Pole Mount Bracket Attachment Points**	Used to secure the *PTS for BFR* to a Delfi PTS Roll Stand (REF 9-2200-550). Use only Delfi (REF 9-2200-008) bracket
11	**Battery Compartment**	Compartment that holds the *PTS for BFR* battery
12	**Pole Mount Bracket**	Used to secure the *PTS for BFR* to a Delfi PTS Roll Stand (REF 9-2200-550)

TOUCHSCREEN BUTTONS AND ICONS

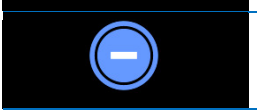
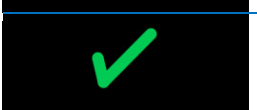
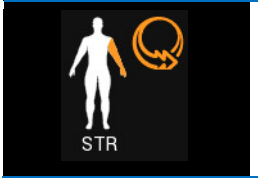
Various colored buttons and icons are used in the *PTS for BFR* and described below.

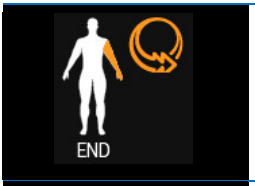
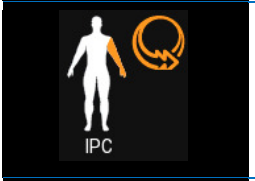
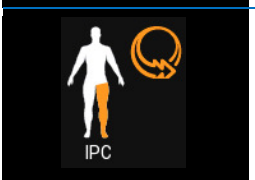
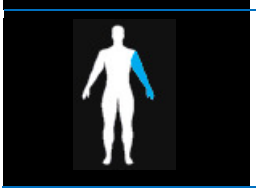
Button/Indicator	Title	Description
	**PROTOCOL Button / Indicator**	Indicates the protocol currently being used The selected protocol establishes the protocol parameters when the cuff gets inflated. Protocol parameters include BFR or C-BFR mode, PTP, REPs, pressure and time set-points Touch to change protocol **NOTE:** If a pressure or battery low alarm is present, the **PROTOCOL** indicator will be replaced by the **Warning** indicator
	**Warning Indicator**	Indicates a warning condition or system failure
	**Alarm Paused Indicator**	Indicates an alarm is paused
	**High Pressure Warning Indicator**	Indicates a high-pressure warning (cuff pressure is more than 15 mmHg greater than the pressure set-point)
	**Low Pressure / Cuff Leak Warning Indicator**	Indicates a low-pressure warning (cuff pressure is more than 15 mmHg lower than the pressure set-point) OR Indicates a cuff leak warning (unit has to continuously pump to maintain pressure for more than 7-seconds, even if the unit is maintaining the cuff pressure within 15 mmHg of the pressure set-point)
	**Cuff Not Deflated Warning Indicator**	Indicates a cuff-not-deflated warning (user attempts to set the unit to STANDBY when the cuff pressure is at a non-zero value) OR Indicates a cuff-not-deflated warning (unit is

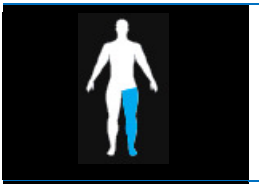
Button/Indicator	Title	Description
		deflated but sees cuff pressure at a non-zero value)
	**~ AC Power Status Indicator**	Indicates that the unit is operating on ~ AC Power and charging the battery
	**Battery Status Indicator**	Indicates that the unit is operating on battery. Battery charge level is indicated by the filled green color and percentage shown below the indicator
	**Low Battery Indicator (critically low charge level)**	Indicates that the unit is operating on battery, currently at critically low charge level. The unit should be plugged into ~ AC Power Mains immediately
	**PRESSURE Button / Indicator**	Indicates the current cuff pressure in the center of the **PRESSURE** indicator The scale of the **PRESSURE i**ndicator is indicated by the orange lower scale and upper scale markers The pressure set-point is indicated by the green marker **NOTE:** If PTP has been set, **LOP** and **PTP** indicators will be indicated on the **PRESSURE** indicator by green and red markers, respectively **NOTE:** If a pressure alarm is present, a pressure alarm indicator will be displayed above the current pressure, and the current pressure will be displayed in yellow Touch to adjust pressure set-point
	**TIME Button / Indicator (BFR)**	Indicates the remaining inflation time in the center of the **TIME i**ndicator Touch to adjust the inflation time set-point **NOTE:** When cuff is inflated, touch and hold to adjust the inflation time set-point **NOTE:** When cuff is inflated, inflation time will count down. When inflation time reaches 0, the unit will automatically deflate **NOTE:** When cuff is inflated, **TIME i**ndicator will

Button/Indicator	Title	Description
		contain an inactive **REST TIME** indicator **NOTE:** When a C-BFR protocol is being followed, the **TIME** indicator will display the C-BFR version
	**TIME** **Button / Indicator (C-BFR)**	Indicates the remaining C-BFR time in the middle of the **TIME** indicator **NOTE:** When cuff is inflated, C-BFR time will count down inside the **TIME** indicator. When C-BFR time reaches 0, the unit will automatically deflate **NOTE:** Cyan sections indicate proportional duration of the total C-BFR time in which the cuff will be inflated. Magenta sections indicate proportionally the duration of the total C-BFR time in which the cuff will be deflated
	**REPs Indicator**	Indicates the number of repetitions sets, the number of repetitions in each set, and the protocol progress. Protocol progress is advanced through the activation of the **REST TIME** indicator **NOTE:** The current set is displayed in white. Completed sets are displayed in green
	**REST TIME** **Button / Indicator**	Indicates the remaining rest time **NOTE:** The inactive **REST TIME** indicator is visible when the remaining inflation time is greater than rest time set-point Touch to activate the **REST TIME** indicator **NOTE:** When **REST TIME** button is touched, it will become active, **REST TIME** indicator will count down inside the **TIME** indicator, and the **REPs** indicator will be updated. When **REST TIME** indicator reaches 0, it will return to its inactive state
	**LOCKOUT TIME Indicator**	Indicates the unit is in Lockout mode The cuff cannot be inflated while in Lockout mode **NOTE:** When the cuff is deflated after 1 minute has elapsed, or when the **TIME** indicator reaches 0, the unit will automatically deflate and enter Lockout

Button/Indicator	Title	Description
		mode
	**PTP Button**	Touch to initiate an LOP measurement, and set the PTP
	**INFLATE Button**	Touch to inflate cuff **NOTE:** If PTP has not been determined, the **PTP Not Determined** indicator will appear briefly. A subsequent touch of the **INFLATE** button will inflate the cuff to the pressure set-point
	**SETTINGS Button**	Touch to access the Stats Menu, Protocols Menu, Leak Test, and System Defaults Menu buttons
	**STATS Button**	Touch to view protocol parameters associated with the last five protocols used
	**PROTOCOLS Button**	Touch to select protocol and adjust protocol parameters
	**LEAK TEST Button**	Touch to conduct leak test
	**SYSTEM DEFAULTS Button**	Touch to view and adjust system defaults settings **NOTE:** System defaults may be restored to factory settings using the “reset to factory defaults” button
	**PTP Indicator**	Indicates Personalized Tourniquet Pressure
	**LOP Indicator**	Indicates Limb Occlusion Pressure

Button/Indicator	Title	Description
	**PTP Not Determined Indicator**	Indicates PTP has not been determined and reminds user to measure LOP and set PTP
	**DEFLATE Button**	Touch to deflate cuff
	**STOP Button**	Touch to stop LOP measurement process, C-BFR protocol, or leak test
	**INCREMENT Button**	Touch to increment selected parameter
	**DECREMENT Button**	Touch to decrement selected parameter
	**CONFIRM Button**	Touch to approve, save and exit specific functions
	**CANCEL Button**	Touch to exit specific functions without saving
	**BACK Button**	Touch to go back
	**RETRY / RESET Button**	Touch to retry, or reset specific functions
	**ORS Upper Limb (STR) Protocol Indicator**	ORS upper limb strength protocol

Button/Indicator	Title	Description
	**ORS Upper Limb (END) Protocol Indicator**	ORS upper limb endurance protocol
	**ORS Upper Limb (IPC) Protocol Indicator**	ORS upper limb ischemic pre-conditioning protocol
	**ORS Lower Limb (STR) Protocol Indicator**	ORS lower limb strength protocol
	**ORS Lower Limb (END) Protocol Indicator**	ORS lower limb endurance protocol
	**ORS Lower Limb (IPC) Protocol Indicator**	ORS lower limb ischemic pre-conditioning protocol
	**Custom Upper Limb Protocol Indicator**	Custom upper limb protocol

Button/Indicator	Title	Description
	**Custom Lower Limb Protocol Indicator**	Custom lower limb protocol
	**SCROLL RIGHT Button**	Touch to scroll right. Only used in Calibration Mode
	**SCROLL LEFT Button**	Touch to scroll left. Only used in Calibration Mode

INITIAL SETUP

During shipping and storage, the unit's battery could lose charge. Prior to initial use, the unit must be plugged into AC power using the AC power supply and cord assembly until the battery is fully charged. This initial charge should take no more than 5 hours. The battery must be fully charged before initial use, including any calibration checking procedures, initial checks, or tests performed by biomedical engineering at your facility.

WARNING: Use only a Delfi (REF 7-2200-020) AC power supply and cord assembly supplied with your *PTS for BFR*. Do not use any other AC power supply or cord. Use of an improper power supply may cause irregular operation that could be hazardous to the patient and/or user, and may permanently damage the *PTS for BFR*, voiding the warranty

CAUTION: Avoid exposing the AC power supply to liquids. Do not immerse in fluid. Do not allow the AC power supply to lie on the floor where pooling of liquids may occur. Clean with a damp cloth (alcohol or mild detergent wipe) only. The AC power supply is resistant to occasional splashing or dripping of fluids but is not fluid-tight. If immersed in or exposed to excessive amounts of liquids, the AC power supply may fail and may pose an electrical shock hazard

WARNING: Use only a Delfi (REF 7-2200-046) Lithium-ion battery pack with your *PTS for BFR*. Do not use any other battery pack. Use of an improper battery pack may cause irregular operation that could be hazardous to the patient and/or user, and may permanently damage the *PTS for BFR*, voiding the warranty

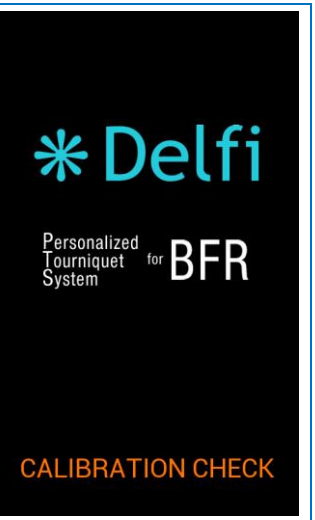
TESTS AND CHECKS

The unit shall produce the results explained in the following steps exactly as indicated. Failure to do so indicates that a problem may exist and the device is not to be used until necessary repair or calibration has been made. Refer to **Alarm Conditions** under **Section 2 Operating Instructions** or **Section 4 Maintenance** as appropriate.

AUTOMATIC DIAGNOSTIC AND CALIBRATION CHECKS

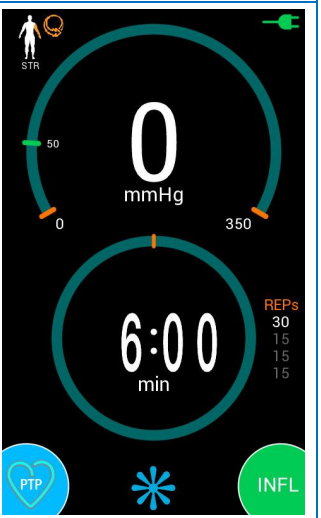
These automatic checks verify certain System Functions through diagnostics and calibration to system standards.

1	Connect the power supply to the *PTS for BFR*, then connect the AC power plug to a compatible grounded power source. Refer to **Specifications** under **Section 1 General Information**. Observe that the **Status** indicator light turns on and displays blue	
2	Power up the unit by pressing the **ON/STANDBY** button and observe the following: • A welcome audio tune is sounded. A rotating Delfi logo and the product name, Personalized Tourniquet System for BFR are displayed • "SELF TEST" will displayed followed by "CALIBRATION CHECK"	



After the startup routine is completed, the Main Screen appears

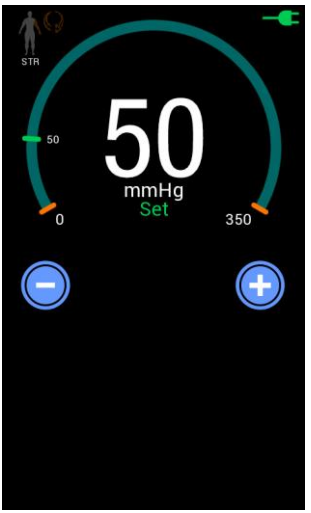
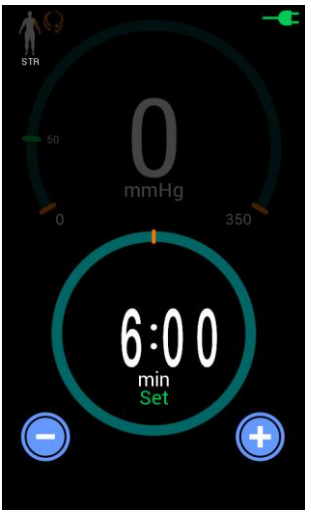
- "0 mmHg" is indicated in the **PRESSURE** indicator
- If a number other than zero is indicated in the **PRESSURE** indicator, the unit should be calibrated by a qualified technician. Refer to **Calibration** under **Section 4 Maintenance**
- The default pressure set-point is indicated by the green marker on the **PRESSURE** indicator
- If the default protocol is in BFR mode:
  - The default time set-point is displayed in the **TIME** indicator
  - The default reps and sets are displayed in the **REPs** indicator
- If the default protocol is in C-BFR mode:
  - The default total C-BFR time is displayed in the **TIME** indicator

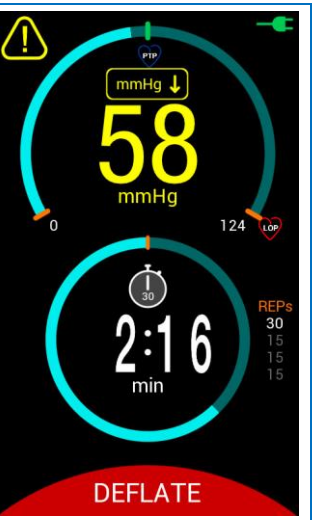


NOTE: the default protocol may be changed as desired in the System Defaults Menu

MANUAL TESTS AND CHECKS

These manual tests and checks verify certain System Functions and include Pressure and Time set-point tests and Calibration and Low-Pressure Alarm checks.

1	**Pressure Set-Point Adjustment Test:** • Enter the pressure adjustment mode by touching the **PRESSURE** button • The **PRESSURE** indicator should read “50” (the factory default set-point) • Touch the **DECREMENT** button to decrease or the **INCREMENT** button to increase the pressure set-point **NOTE**: The pressure set-point can be maintained between 20 mmHg and 350 mmHg in increments of 1 mmHg **NOTE**: If the **INCREMENT** or **DECREMENT** button is held, the increments will change by 5 mmHg • Touch the **PRESSURE** button, or wait approximately 10 seconds to return to the Main Screen	
2	**Time Set-Point Adjustment Test:** • Enter the time adjustment mode by touching the **TIME** button • The **TIME** indicator should read “6” (the factory default set-point) • Touch the **DECREMENT** button to decrease or the **INCREMENT** button to increase the time set-point **NOTE**: The time set-point cannot be accessed if the selected protocol is in C-BFR mode. The time set-point can be adjusted in the Protocols Menu **NOTE**: The time set-point can be adjusted between 1 min and 30 min in increments of 1 min • Touch the **TIME** button, or wait approximately 10 seconds to return to the Main Screen	

3	**Low Pressure Alarm Test:**
	• Connect the PTS for BFR hose assembly and a cuff to the *PTS for BFR*
	• Adjust the pressure set-point to 200 mmHg
	• Touch the **INFLATE** button to inflate the cuff
	• Create a leak by partially detaching the hose from the unit while the cuff is inflated
	• Make the leak large enough that the pressure drops more than 15 mmHg below set-point. The pump in the *PTS for BFR* will start as the unit tries to maintain the set pressure
	• After the cuff pressure has been more than 15 mmHg below the set-point constantly for more than 1 second, confirm that:
	  ○ The **LOW-PRESSURE WARNING** indicator appears above the displayed pressure
	  ○ The displayed pressure is yellow
	  ○ The **WARNING** indicator replaces the **PROTOCOL** indicator
	  ○ An audio tone will sound and the **STATUS** indicator flashes red announcing the alarm condition
	• Press anywhere on the display to silence the alarm tone. Confirm that the alarm tone restarts after 30 seconds
	• Stop the leak and observe the displayed pressure returns to regulated state, and the display returns to the Main Screen
		

OPERATION

1 Physician or Physician's Designated Licensed Healthcare Practitioner's Decision:

Physician or physician's designated licensed healthcare practitioner's discretion will be used to determine the following:

- Which protocol should be used for the patient

  A suitable protocol should be selected and adjusted depending on the patient's physiology and needs. Each protocol contains parameters that control the BFR therapy session, including:

  - Whether the BFR therapy session is Cyclic or not

BFR Protocol Parameters	C-BFR Protocol Parameters
• Percentage of Limb Occlusion Pressure (LOP) as Personalized Tourniquet Pressure (PTP)	• Percentage of Limb Occlusion Pressure (LOP) as Personalized Tourniquet Pressure (PTP)
• Total time allowed for each cuff inflation	• Number of C-BFR cycles
• Rest time between repetition sets	• Duration of each C-BFR inflation
• REPs (number of reps and sets)	• Duration of each C-BFR deflation

- What pressure to apply

  Refer to **Manual Tests and Checks** under **Section 2 Operating Instructions** for how to set target pressure set-point. For each BFR therapy session, the patient's Personalized Tourniquet Pressure (PTP) should be determined by measuring the patient's Limb Occlusion Pressure (LOP). Tourniquet pressure should be set to the PTP, with consideration to the protocol being used for the BFR therapy session

- When to inflate the tourniquet cuff
- How long to apply the tourniquet cuff
  Refer to **Manual Tests and Checks** under **Section 2 Operating Instructions** for how to set the time set-point. The time set-point should be set with consideration to the protocol being used for the BFR therapy session

2 Patient Preparation:

Prepare the patient in accordance with your established procedures and Delfi's cuff utilization instructions. Use only the patient-size appropriate PTS BFR Easi-Fit Tourniquet Cuff and the Matching Limb Protection Sleeve for the selected PTS BFR Easi-Fit Tourniquet Cuff with the PTS for BFR instrument. The **Precautions In Use** detailed under **Section 1 General Information**, as well as the following, are offered as a guide to assist in this process

- In most cases, a tourniquet cuff should be applied to the widest part of the limb to allow as much tissue as possible to lie between the cuff and any nerves or vascular structures susceptible to damage
- The optimum positions are the upper arm and the proximal third of the thigh

Refer to **Section 3 BFR Cuff Utilization** for more information on cuff selection and cuff application

3 Turning the Unit ON:

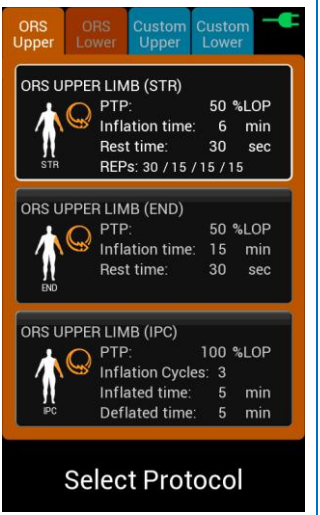
- Press the **ON/STANDBY** button to turn on the unit. Refer to **Automatic Diagnostic and Calibration Checks** under **Section 2 Operating Instructions**
- Successful completion of the self-check and calibration check indicates that the unit is ready for use

- Connect the PTS for BFR hose assembly and a Delfi Easi-Fit BFR cuff to the unit at the hose connector

WARNING: Do not allow foreign objects from entering the *PTS for BFR,* the hose assembly, or the cuff. This could damage/affect the performance of the PTS for BFR system

4 **Selecting a Protocol**:

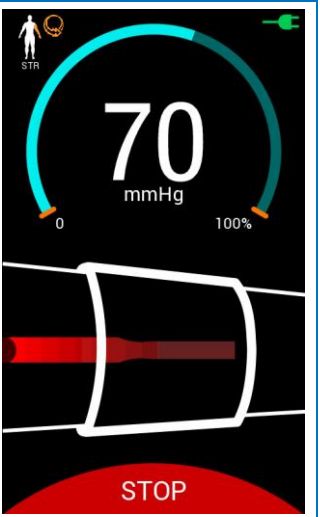
- Touch the **PROTOCOL** button to view 4 tabs of protocols
- Touch to navigate between tabs
- Touch to select a suitable protocol
- Refer to **Protocols Menu** under **Section 2 Operating Instructions** for information on adjusting protocol parameters



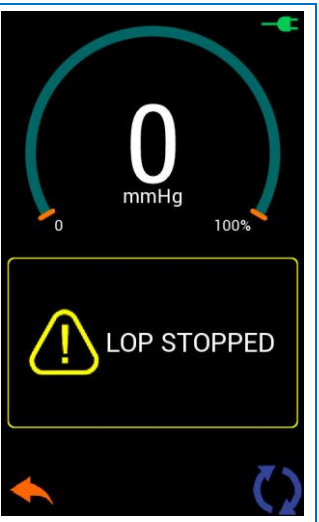
5 **Determining a PTP:**

- Touch the **PTP** button to initiate a LOP measurement
- During the LOP measurement, the following will be visible:
  - Cuff pressure will be indicated inside a 0% - 100% progress gauge
  - LOP measurement animation
  - **STOP** button for stopping the LOP measurement
- Refer to **Personalized Tourniquet Pressure (PTP)** under **Section 2 Operating Instructions** for more information

NOTE: For accurate LOP measurements, the cuff should be snugly applied and the patient should remain still and refrain from talking during the LOP measurement. Any excessive movement, tensing, or coughing by the patient during the LOP measurement may affect the completion or accuracy of the measurement



- If the **STOP** button is touched, or an LOP measurement alarm is triggered, the unit will deflate the cuff, display a warning message, and allow the user to return to the Main Screen or to restart the LOP measurement
- To return to Main Screen, touch the **BACK** button
- To restart a LOP measurement, touch the **RETRY** button
- Refer to **Alarm Conditions** under **Section 2 Operating Instructions**



- Once the LOP measurement has completed, the unit will display the LOP and the selected protocol's parameters
- To change the selected protocol, press the **PROTOCOL** button
- To adjust the protocol parameter, touch appropriate parameter button then use the **INCREMENT** and **DECREMENT** buttons
- Once all parameters are set, touch the **CONFIRM** button to accept the PTP

NOTE: To reject the PTP, touch the **CANCEL** button, then touch the **CONFIRM** button when prompted to "reject LOP"

6a **BFR Therapy session:**

NOTE: For C-BFR therapy session procedures, go to step 6b

- Touch the **INFLATE** button to begin a BFR therapy session
- While the cuff is inflated, the **TIME** indicator will count down the inflation time and display the exercise time period in cyan
- While the cuff is inflated, the **REST TIME** button will be visible inside the **TIME** indicator

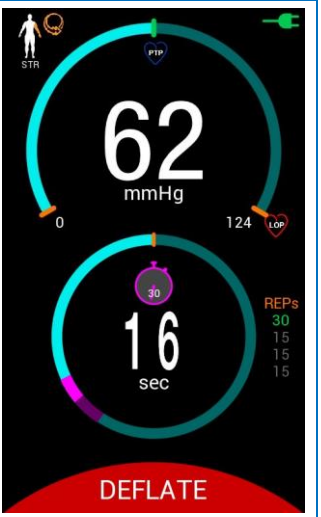
NOTE: The **REST TIME** button will disappear if the remaining inflation time is less than the rest time

NOTE: To adjust the pressure set-point, touch the **PRESSURE** button. To adjust the time set-point, touch and hold the **TIME** button

NOTE: To view the % of LOP the PTP is set to, touch the **PRESSURE** button

- Touch the **DEFLATE** button to deflate the cuff as necessary

- Once the patient has completed the first repetition set, touch the **TIME** button to activate the **REST TIME** indicator and update the **REPs** indicator



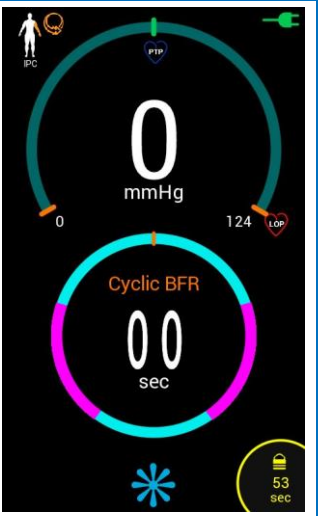
NOTE: The **REPS** indicator displays the number of repetition sets and number of repetitions in each set for the selected protocol. Values shown as: White – current set; Green – completed set(s); Gray – uncompleted set(s)

- While the **REST TIME** indicator is activated, the **TIME** indicator will count down and display the rest time period in magenta
- When the **TIME** indicator counts to 0, the **REPs** indicator will update, and an audio tone will sound to notify the patient to start the next set of exercise
- Repeat the above until all exercise sets in the selected protocol are completed

	• Touch the **DEFLATE** button to deflate the cuff after all exercise sets are completed • The unit will enter Lockout mode • While the unit is in Lockout mode, the unit will prevent cuff inflation and the **LOCKOUT TIME** indicator will count down the lockout time	
6b	**C-BFR Therapy Session:** **NOTE:** For BFR therapy session procedures, go to step 6a • Touch the **INFLATE** button to begin a C-BFR therapy session • While the cuff is inflated, the **TIME** indicator will count down the total C-BFR time • The **TIME** indicator will display the inflated and deflated time periods in cyan and magenta, respectively **NOTE:** To adjust the pressure set-point, touch the **PRESSURE** button • Touch the **STOP** button to deflate cuff as necessary	

- After each inflated time period, the unit will automatically deflate and begin the deflated time period
- The unit will repeat the inflation and deflation cycle until all inflation cycles as defined by the selected protocol have been completed

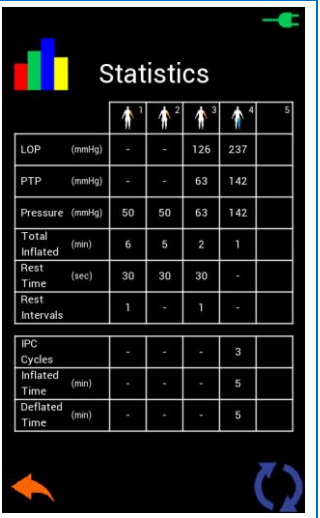
- Once the **TIME** indicator counts down to 0, the unit automatically deflates and enter Lockout mode
- While the unit is in Lockout mode, the unit will prevent cuff inflation and the **LOCKOUT TIME** indicator will count down the lockout time



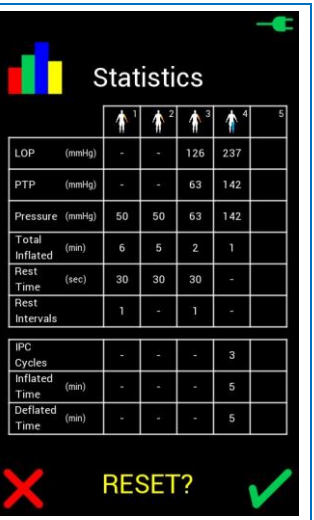
7 **Viewing Stats:**

- On the Main Screen, touch the **SETTINGS** button to open up the Settings Menu.

- Touch the **STATS** button to enter the Stats Menu
- The Stats Menu displays protocol parameters associated with the last five protocols used
- To return to the Main Screen, touch the **BACK** button



- To reset the Stats, touch the **RESET** button followed by the **CONFIRM** button when prompted. Refer to **Stats Menu** under **Section 2 Operating Instructions** for more information



SETTINGS

Settings options include viewing the stats, adjusting the protocols, performing a leak test, and modifying system defaults. To access the Settings Menu, touch the **SETTINGS** button from the Main Screen. Refer to step 7 in **Operation** under **Section 2 Operating Instructions**.

NOTE: Settings Menu is not accessible while the cuff is inflated

STATS MENU

The Stats Menu displays protocol parameters associates with the last five protocols used. If the parameter was not measured or used, a '-' marker will be visible in the parameter box. Refer to step 7 in **Operation** under **Section 2 Operating Instructions** for information on how to access and reset the Stats Menu.

PROTOCOLS MENU

The Protocols Menu contain twelve selectable protocols. Six of these protocols are based on ORS recommendations with restricted adjustment capabilities. The remaining six protocols are fully customizable within the instrument's limits. Refer to **General Device Function** under **Section 1 General Information** for more information on protocols. Refer to step 3 in **Operation** under **Section 2 Operating Instructions** on how to select a protocol for use.

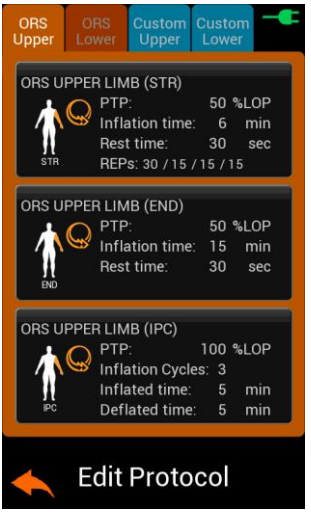
Various parameters and abbreviations are used in the Protocols Menu and described below:

Parameter/Abbreviation	Description
ORS	Owens Recovery Science Indicates the protocol has parameters as recommended by ORS. ORS protocols have restricted adjustment limits
STR	Strength As recommended by ORS, strengthening protocols are used to achieve muscle fatigue and/or significant muscle metabolites with a high volume of slow/controlled repetitions
END	Endurance As recommended by ORS, endurance protocols are used to provide a potent stimulus for hypertrophy, muscular endurance, and VO2 adaptation while working at low intensity.
IPC	Ischemic Pre-Conditioning As recommended by ORS, Ischemic Pre-Conditioning protocols are used to potentially benefit patients who are unable to perform exercise while under tourniquet or can be used as a recovery strategy from High-Intensity Work

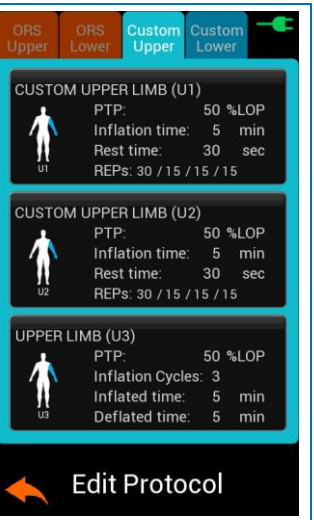
PTP	Personalized Tourniquet Pressure Refer to **Personalized Tourniquet Pressure (PTP)** under **Section 2 Operating Instructions**
LOP	Limb Occlusion Pressure Refer to **Personalized Tourniquet Pressure (PTP)** under **Section 2 Operating Instructions**
Inflation Time	Maximum duration in which the cuff is inflated during a BFR therapy session Inflation time will count down once the cuff is inflated. Once inflation time reaches 0, the unit will automatically deflate the cuff **NOTE:** The Inflation Time parameter is only applicable for BFR protocols
Rest Time	The rest time period between each repetition set during a BFR therapy session Rest time will count down when it is activated. When rest time reaches 0, an audio tone will sound to indicate the patient should continue with the next repetition set. Refer to step 6a in **Operation** under **Section 2 Operating Instructions** for more information. **NOTE:** The Rest Time parameter is only applicable for BFR protocols
REPs	Number of repetition sets and number of repetitions in each set during a BFR therapy session. Refer to step 6a in **Operation** under **Section 2 Operating Instructions** for more information **NOTE:** The REPs parameter is only applicable for BFR protocols
Inflation Cycles	The number of automatic inflation and deflation cycles during a C-BFR therapy session. Refer to step 6b in **Operation** under **Section 2 Operating Instructions** for more information **NOTE:** The Inflation Cycles parameter is only applicable for C-BFR protocols
Inflated Time	The duration in which the cuff is inflated during each inflation and deflation cycle in a C-BFR therapy session. Refer to step 6b in **Operation** under **Section 2 Operating Instructions** for more information **NOTE:** The Inflated Time parameter is only applicable for C-BFR protocols
Deflated Time	The duration in which the cuff is deflated during each inflation and deflation cycle in a C-BFR therapy session. Refer to step 6b in **Operation** under **Section 2 Operating Instructions** for more information **NOTE:** The Deflated Time parameter is only applicable for C-BFR protocols

Cyclic BFR Toggle Switch	A toggle switch to switch the selected protocol from a BFR protocol to a C-BFR protocol (or vice versa)
	NOTE: The Cyclic BFR Toggle Switch is only available on two fully-customizable protocols
Protocol Name	Protocol name may have up to 30 characters. Abbreviated Name can be added by enclosing up to 6 characters inside parentheses ( )
	NOTE: The Protocol Name can only be modified on fully-customizable protocols
Protocol Description	Protocol description may have up to 96 characters
	NOTE: The Protocol Description can only be modified on fully-customizable protocols

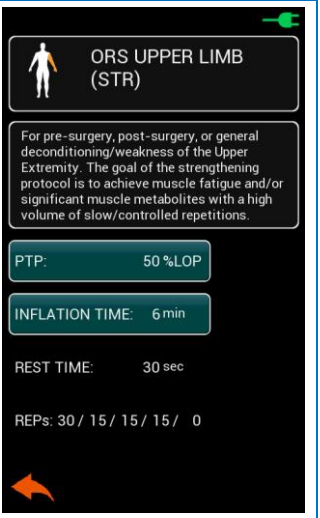
To view and edit a protocol, follow the instructions below:

1	**Viewing a Protocol's Parameters:** • Touch the **PROTOCOLS** button from the Settings Menu to access the protocols • Touch the **BACK** button to return to the Main Screen as necessary	

- Touch to navigate between tabs



- Touch a protocol to view its parameters

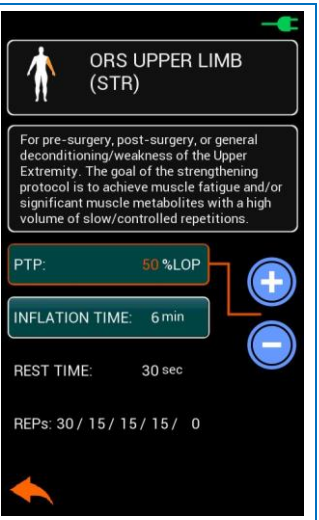


2a **Modifying a Protocol's Parameters (ORS):**

- Touch an ORS protocol from the Protocols Menu
- To modify a parameter, touch an adjustable parameter button and use the **INCREMENT** and **DECREMENT** buttons

NOTE: For ORS protocols, some parameters cannot be modified and other parameters have restricted adjustment limits. To modify all parameters, select a protocol from the six fully-customizable protocols. Refer to Step 2b for information on modifying a fully-customizable protocol's parameters

- Touch the **BACK** button to return to the Main Screen as necessary



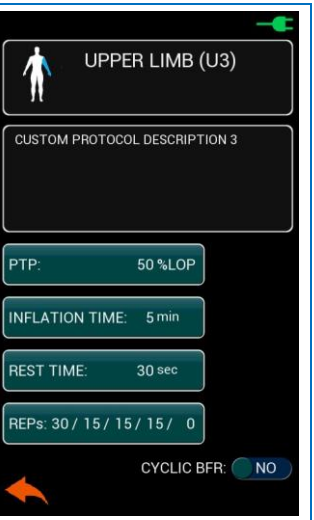
2b **Modifying a Protocol's Parameters (Fully-Customizable):**

- Touch a fully-customizable protocol from the Protocols Menu
- To modify a parameter, touch an adjustable parameter button and use the **INCREMENT** and **DECREMENT** buttons

NOTE: Touch the REPs parameter to step through the adjustment of the number of reps in each repetition set

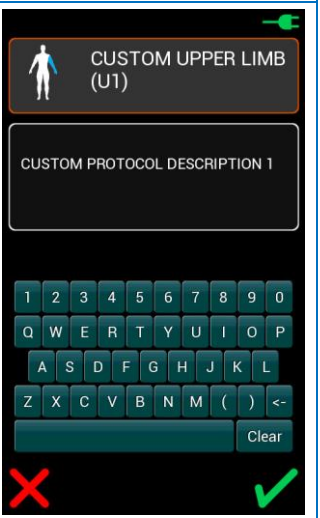
- Touch the **BACK** button to return to the Main Screen as necessary

NOTE: Two fully-customizable protocols can be switched between a BFR protocol and a C-BFR protocol by touching the Cyclic BFR Toggle Switch. The parameters applicable will change based on the type of protocol (BFR or C-BFR)



- Touch the Protocol Name or Protocol Description boxes then use the keyboard to modify the protocol name or description

NOTE: Each fully-customizable protocol can have up to 6 characters displayed underneath its icon. This is the protocol's abbreviated name. The abbreviated name is created by using up to 6 characters enclosed in parentheses. In the figure to the right, the abbreviated name is "U1" and is displayed underneath its icon as shown in the second figure of step 1



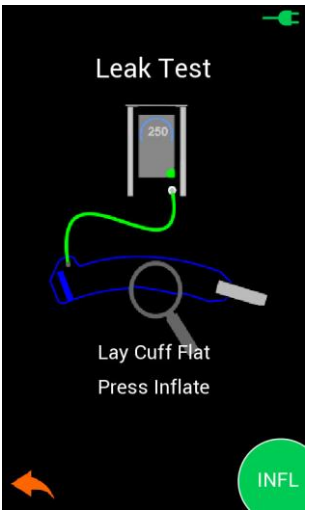
- To accept changes, touch the **CONFIRM** button
- To decline changes, touch the **CANCEL** button

LEAK TEST

The *PTS for BFR* includes an automatic test feature to check for leakage from an attached cuff, hose and connectors. To perform a leak test, follow the instructions below:

1 Setting Up for a Leak Test:

- Touch the **LEAK TEST** button from the Settings Menu to access the leak test
- Connect a cuff and hose to the *PTS for BFR*. Keep the cuff open and flat
- Touch the **BACK** button to exit the leak test and return to the Main Screen as necessary

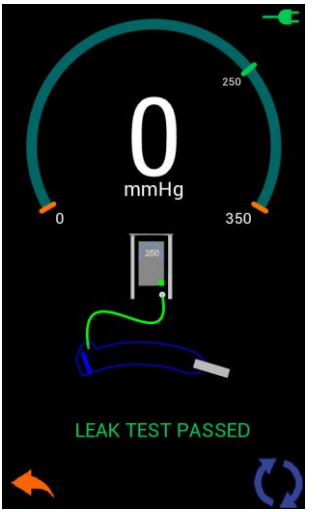
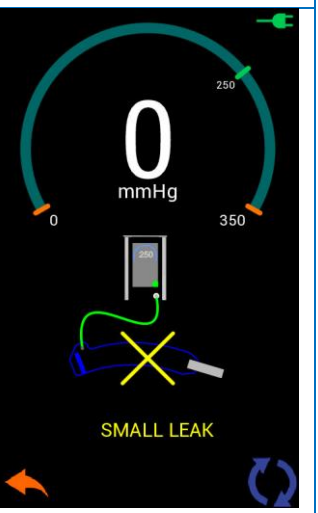


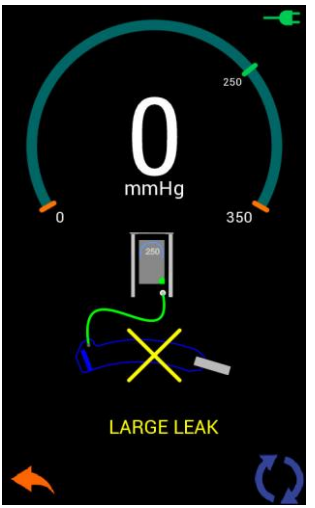
2 Initiating a Leak Test:

- Press the **INFLATE** button to initiate a leak test
- During a leak test, the cuff will inflate to approximately 250 mmHg and a 30 second leak test will commence. At the end of the test, the cuff will automatically deflate and the test result will be displayed

WARNING: Do not start a leak test (press the **INFLATE** button) if the cuff is applied to a patient

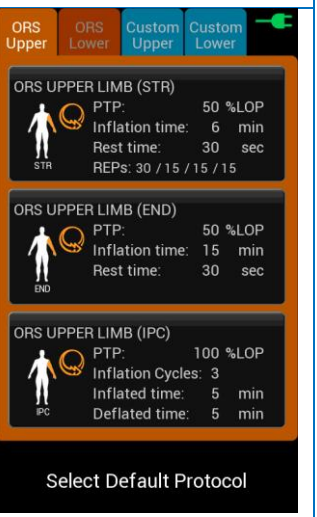
- To stop the leak test, touch the **STOP** button

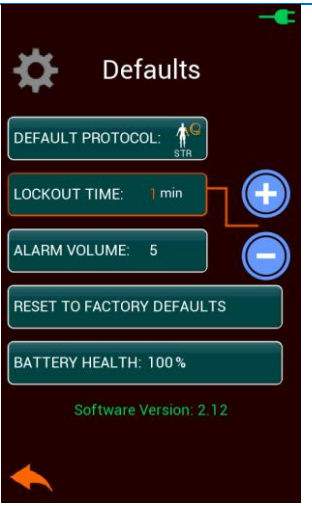
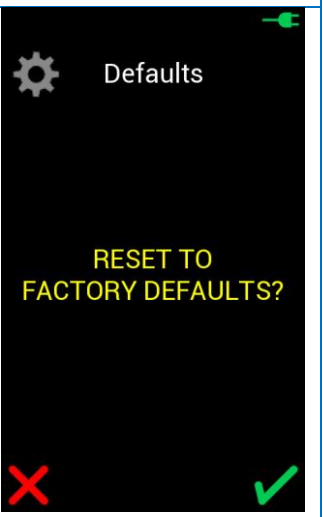
3a	**Leak Test Results (Passed):** • If the leak test has passed, a “LEAK TEST PASSED” notification will be visible • To initiate a new leak test, touch the **RETRY** button • Touch the **BACK** button to exit the leak test and return to the Main Screen as necessary	
3b	**Leak Test Results (Small Leak):** • If the leak test has failed due to a small leak, a “SMALL LEAK” notification will be visible • To initiate a new leak test, touch the **RETRY** button • Touch the **BACK** button to exit the leak test and return to the Main Screen as necessary **NOTE:** This indicates that there is a leak in either the test cuff, hose, connection points or in the *PTS for BFR* internal pneumatics. Repeat the test with a variety of different Easi-Fit BFR cuffs and hose assemblies. If the unit continues to fail, the leak is internal, and the *PTS for BFR* must be serviced	

3c	**Leak Test Results (Large Leak):** • If the leak test has failed due to a large leak, a "LARGE LEAK" notification will be visible • To initiate a new leak test, touch the **RETRY** button • Touch the **BACK** button to exit the leak test and return to the Main Screen as necessary	
	NOTE: This indicates that there is a leak in either the test cuff, hose, connection points or in the *PTS for BFR* internal pneumatics. Repeat the test with a variety of different Easi-Fit BFR cuffs and hose assemblies. If the unit continues to fail, the leak is internal, and the *PTS for BFR* must be serviced	

SYSTEM DEFAULTS MENU

The System Defaults Menu allows user to set the default protocol, default lockout time, alarm volume, and restore instrument to factory defaults. It also shows battery health information and the unit's software version. The default settings will be selected when the instrument is powered ON.

1	**Accessing the System Defaults Menu:** • Touch the **DEFAULTS** button from the Settings Menu to access the System Defaults Menu • Touch the **BACK** button to return to the Main Screen as necessary	
2a	**Selecting a Default Protocol:** • Touch the "DEFAULT PROTOCOL" button • Navigate between the tabs then touch to select a protocol as the Default Protocol	

2b	**Adjusting Default Parameters:** • From the System Defaults Menu, touch an adjustable parameter button then use the **INCREMENT** and **DECREMENT** buttons to modify the selected default parameter • The volume can be changed to accommodate different environmental conditions so that the audio alarm can be reliably detected without being too intrusive in most situations. The *PTS for BFR* has nine volume levels ranging from approximately 65 dB to a minimum of 75 dB when measured at 1 meter from the center of the touch screen.	
2c	**Resetting Unit to Factory Defaults:** • From the System Defaults Menu, touch the "RESET TO FACTORY DEFAULTS" button • Touch the **CONFIRM** button to reset unit to factory defaults • To return to System Defaults Menu, touch the **CANCEL** button	

PERSONALIZED TOURNIQUET PRESSURE (PTP)

The Delfi *PTS for BFR* has the capability of determining a patient's Personalized Tourniquet Pressure (PTP) as a percentage of the patient's Limb Occlusion Pressure (LOP) by automatically measuring LOP. The PTP percentage should be set as directed by a physician or physician's designated licensed healthcare professional. For standard BFR the percentage can be set between 40%-80% of the LOP and should be selected based on the indicated limb for therapy, type of therapy to be performed, and patient comfort. Cyclic BFR is intended to be performed at full occlusion, thus the PTP is set between 100%-140% of the LOP. *PTS for BFR* maintains the cuff pressure at the pressure set-point for the time period(s) required for a BFR or C-BFR therapy session.

Limb Occlusion Pressure (LOP) is defined in the medical literature as the minimum pressure required to stop the flow of arterial blood into the limb distal to the tourniquet cuff, at a specific time in a specific tourniquet cuff applied to a specific patient's limb at a specific location. The LOP is used to calculate a Personalized Tourniquet Pressure (PTP), and the PTP is the patient specific tourniquet pressure used to restrict blood flow into the limb.

ALARM CONDITIONS

There are a number of conditions for which the *PTS for BFR* will produce a visual and audible alarm. The appropriate actions indicated are based on the most probable causes and should only be used as a guide. Other causes of alarm conditions may indicate a need for other actions.

Most audible alarm tones (non-technical failures) may be silenced for 30 seconds by touching anywhere on the touchscreen display. The tone will be re-enabled at the end of the silenced period. Touching anywhere on the touchscreen display will cause the alarm tone to be silenced again.

To minimize nuisance alarms that can be caused by range-of-motion movement of the patient's limbs, a 3-seconds delay has been designed into the alarm actuation.

The alarm conditions, indications, and appropriate actions are shown in the **ALARM CONDITIONS** table under **Section 2 Operating Instructions**. The *PTS for BFR* will also provide Error Code information for technical failure alarms.

Under certain conditions, such as "SYSTEM FAILURE DETECTED" appears or the information that appears on the screen is unintelligible, the operator should conclude that a technical failure has occurred, rendering the unit unusable. In this situation, it is likely that the unit has put itself in the 'safe state' mode, in which the pneumatic pump is disabled and the pneumatic valve is open to deflate the cuff. The appropriate action is to immediately disconnect the cuff and set the unit to STANDBY by pressing the **ON/ STANDBY** button. **Since this removes power from the internal instrument circuitry, all instrument functions, commands to the valves and pump will cease.**

NOTE: Non-technical alarm conditions will terminate automatically when the alarm condition that was generating the alarm signal is corrected

PRESSURE ALARMS

A pressure alarm will occur when the pressure in a cuff is more than 15 mmHg from the pressure set-point. It is also possible for a cuff to have a leak that is substantial but which the unit can compensate for by continual pumping. This type of leak could be due to a:

- Pin hole in a cuff bladder
- Defective o-ring
- Loose pneumatic fitting

This type of leak could progress into a total failure of a cuff to hold pressure. To alert the operator that a substantial leak is present, a pressure alarm is declared when this type of leak is detected. If a pressure alarm occurs, and the displayed pressure is not more than 15 mmHg from the set-point, then this type of substantial leak has been detected and all cuffs and pneumatic fittings should be checked for leaks.

ALARM/WARNING COLORS AND AUDIBLE TONES

During the course of operation when an alarm is triggered, the **Warning** indicator will become visible, an audio tone is sounded, and the **Status** indicator will display a flashing or constant red or yellow light. For a technical failure, it will also display warning messages and may be accompanied by Error Codes.

Note: The volume for non-technical alarms can be adjusted in the settings between a sound level of 1 to a sound level of 10. Alarm volume cannot be fully silenced. Audio alarm can only be temporarily paused for 30 seconds through interaction with the touchscreen display. Setting the volume to a low sound level may impede operator recognition of alarm conditions.

VISUAL AND AUDITORY ALARM PRIORITY

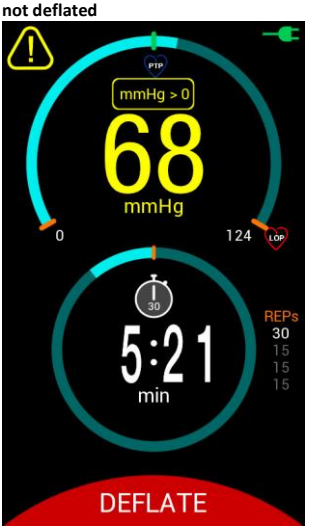
STATUS Indicator Light	Auditory Priority Tone	Auditory Pulse Pattern	Comments
Constant Red	Technical	1 tone pulse per burst	Indicates technical failure.
Flashing Red	High	5 tone pulses per burst	Indicates immediate operator response is required. Fastest auditory indicator tone pulse at less than half the duration of Medium priority.
Flashing Yellow	Medium	5 tone pulses per burst	Indicates prompt operator response is required. Baseline auditory indicator tone pulse speed.
Constant Yellow	Low	3 tone pulses per burst.	Indicates operator awareness is required. The auditory indicator tone pulse is slower than either Medium, High, or Technical priority.

ALARM CONDITION AND ERROR CODE TABLES

Alarm Conditions are accompanied by a warning message and sometimes Error Codes along with a **Status** Indicator Light and audible Priority Tone as detailed in the **ALARM CONDITIONS** table below. LOP related alarms are grouped at the end of the table. Error Codes are detailed in the **ERROR CODES** table below.

ALARM CONDITIONS

Conditions	Status Indicator Light	Auditory Priority Tone	Remarks and Appropriate Actions
High Pressure 	Flashing Red	High	• The unit has detected high pressure in the cuff. High pressure is defined as pressure that is +15 mmHg above the pressure set-point continuously for more than 1 second • Normally caused by transient conditions such as patient movement, regulator overshoot, or hose occlusion. • Check lines and connections. If this condition persists without apparent cause, the *PTS for BFR* may require servicing • Alarm will stop automatically whenever the unit can regulate the cuff to within 15 mmHg of the pressure set-point
Low Pressure 	Flashing Red	High	• The unit has detected low pressure in the cuff. Low pressure is defined as pressure that is +15 mmHg below the pressure set-point continuously for more than 1 second • Check lines and connections. If this condition persists without apparent cause, the *PTS for BFR* may require servicing • Alarm will stop automatically whenever the unit can regulate the cuff to within 15 mmHg of the pressure set-point

Conditions	Status Indicator Light	Auditory Priority Tone	Remarks and Appropriate Actions
Cuff or hose is leaking 	Flashing Red	High	• The unit has detected a large leak in the cuff, hose or connectors which is defined as the cuff failing to reach the pressure set-point in a reasonable time, or the pump running excessively while regulating the pressure and the pressure set-point is not being adjusted • Check lines and connections. If this condition persists without apparent cause, the *PTS for BFR* may require servicing
Power switch was activated with cuff not deflated 	Flashing Yellow	Medium	• Cuff pressure greater than zero when **ON/STANDBY** button pressed. The system assumes that a procedure is in progress and prevents activation of STANDBY mode • Touch **DEFLATE** button to deflate cuff, then press **ON/STANDBY** button to set the unit to STANDBY

Conditions	Status Indicator Light	Auditory Priority Tone	Remarks and Appropriate Actions
Cuff not fully deflated as expected 	Flashing Red	High	• The unit has detected pressure in the cuff greater than 5 mmHg, 25 seconds after the cuff has been deflated • Disconnect hose from cuff to exhaust pressure
Battery is low 	Constant Yellow	Low	• The battery state of charge has dropped to 10% or lower indicating that the unit should be plugged into AC power for continued use, and to charge the battery • Plug unit in. If the unit is not plugged in, a battery failure condition will occur and the unit will shut down in a 'safe state' mode* opening all valves, OR • Press **ON/STANDBY** button to shut unit down **WARNING**: While running with a Low Battery Alarm Condition other alarm conditions cannot be guaranteed

Battery fail 	Constant Red	Technical	• The battery state of charge has dropped to 4% or lower and the unit has shut down in a 'safe state' mode*, OR • Press **ON/STANDBY** button to shut unit down. When cuff deflation is required, disconnect hose from cuff. Ensure that the battery is connected properly. Plug in AC power to attempt to recharge the battery. Service or replace the battery pack. Refer to **Battery Testing and Replacement** under **Section 4 Maintenance**
Calibration failure 	Constant Red	Technical	• The unit has detected that the calibration in the pressure transducer is invalid. The unit has shut down in a 'safe state' mode* • Disconnect the hose and press the **ON/STANDBY** button twice to restart the unit • If this problem persists, the PTS for BFR requires calibration service. Refer to **Calibration** under **Section 4 Maintenance**

System error (ex – Error 24)

Constant Red

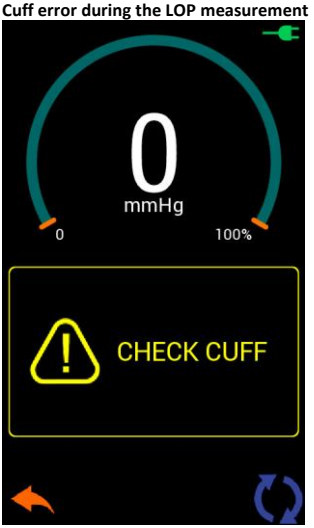
Technical

- The unit has detected an internal error and has shut down in a 'safe state' mode*
- Press **ON/STANDBY** twice to shut down and restart the unit
- When cuff deflation is required, disconnect hose to cuff
- Refer to **ERROR CODES** table below for more information

NOTE: Some Error Codes are accompanied by a second numeric code at the bottom right of the display. This code represents detailed information related to the failure

- If problem persists, note error code and the accompanied numeric code (if any) and contact Delfi

Cuff error during the LOP measurement

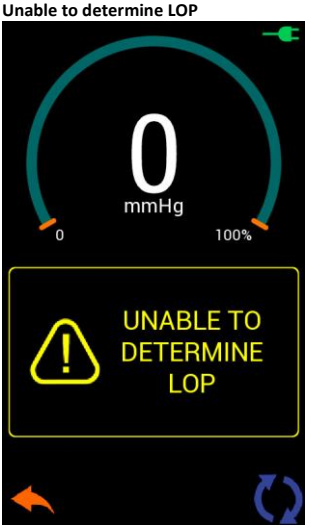


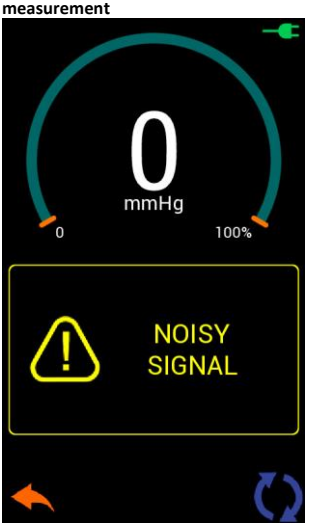
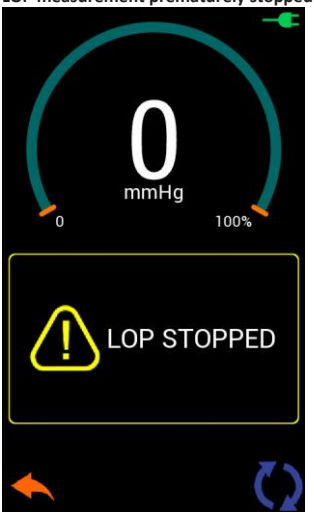
Constant Yellow

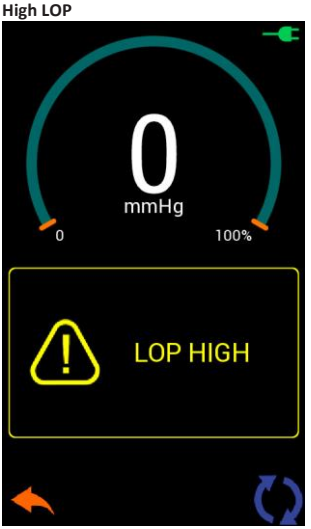
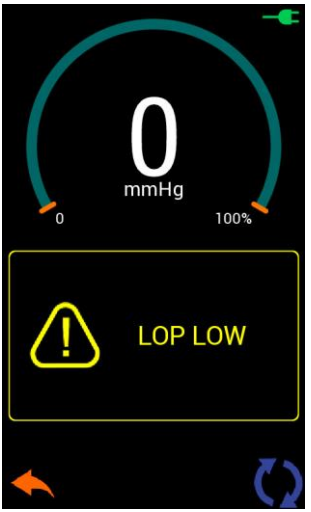
Low

- The unit does not detect an increase in cuff pressure during the LOP measurement process and cannot determine the PTP
- Check the hose connection between the cuff and the instrument to ensure proper connection
- Perform a Leak Test to determine if there is a leak in the cuff. Refer to **Leak Testing** under **Section 4 Maintenance**

NOTE: If there is a leak, replace the cuff with another Easi-Fit BFR Cuff and hose assembly. If this condition persists, the *PTS for BFR* may require servicing

Unable to determine LOP 	Constant Yellow	Low	• Due to noisy or aberrant signals the unit cannot measure the LOP • Reapply the cuff snugly • Keep the limb and cuff still during the LOP measurement • Ensure the patient remain quiet and still **Note:** If the error persists after applying these troubleshooting steps and attempting another LOP measurement, set the tourniquet pressure to a standard pressure as directed by a physician or physician's designated licensed healthcare professional
No signal measured during the LOP measurement 	Constant Yellow	Low	• The unit has not been able to detect a pressure signal during the measurement of LOP and cannot determine the PTP • Check the hose connection between the cuff and the instrument to ensure proper connection • Reapply the cuff snugly • Keep the limb and cuff still during the LOP measurement • Ensure the patient remain quiet and still **Note:** If the error persists after applying these troubleshooting steps and attempting another LOP measurement, set the tourniquet pressure to a standard pressure as directed by a physician or physician's designated licensed healthcare professional

Noisy signal measured during the LOP measurement 	Constant Yellow	Low	• The unit has detected noise in the pressure signal during the measurement of LOP and cannot determine the PTP • Check the hose connection between the cuff and the instrument to ensure proper connection • Reapply the cuff snugly. • Keep the limb and cuff still during the LOP measurement • Ensure the patient remain quiet and still **Note:** If the error persists after applying these troubleshooting steps and attempting another LOP measurement, set the tourniquet pressure to a standard pressure as directed by a physician or physician's designated licensed healthcare professional
LOP measurement prematurely stopped 	Constant Yellow	Low	• The **STOP** button was touched causing the LOP measurement to terminate • Press the **BACK** button to exit or **RETRY** button to start a new LOP measurement again.

High LOP 	Constant Yellow	Low	• The unit has detected that the LOP is higher than the maximum allowable inflation pressure. The unit cannot determine the PTP • Reapply the cuff snugly • Keep the limb and cuff still during the LOP measurement • Ensure the patient is quiet and still **Note:** If the error persists after applying these troubleshooting steps and attempting another LOP measurement, set the tourniquet pressure to a standard pressure as directed by a physician or physician's designated licensed healthcare professional
Low LOP 	Constant Yellow	Low	• The unit has detected that the LOP is lower than the minimum measurable LOP of the instrument. The unit cannot determine the PTP • Reapply the tourniquet cuff snugly • Keep the limb and cuff still during the LOP measurement • Ensure the patient is quiet and still **Note:** If the error persists after applying these troubleshooting steps and attempting another LOP measurement, set the tourniquet pressure to a standard pressure as directed by a physician or physician's designated licensed healthcare professional

*In the 'safe state' mode, the pneumatic valve is opened to deflate the cuff. Refer to **Alarm Conditions** under **Section 2 Operating Instructions** for more information.

ERROR CODES

Error Code	Problem	Possible Causes and Corrective Actions
E0000 to E0008 **E0012 to E0014** **E0026 to E0027** **E0031**	Internal electronics failures	• The unit detected a failure related to the internal electronics • Restart the unit by pressing the **ON/STANDBY** button twice. • If problem persists, note error code and the accompanied numeric code (if any) and contact Delfi
E0016 to E0019	Calibration failures	• The unit detected a failure related to calibration • Calibrate the unit. Refer to **Calibration** under **Section 4 Maintenance** • If problem persists, note error code and the accompanied numeric code (if any) and contact Delfi
E0009 **E0021 to E0023** **E0024 to E0025**	Pressure failures	• The unit detected a pressure failure • Pressure failures may be caused by incorrect or drifted pressure calibration, or by exceeding a safety pressure limit during use (E0024) • Calibrate the unit. Refer to **Calibration** under **Section 4 Maintenance** • If problem persists, note error code and the accompanied numeric code (if any) and contact Delfi
E0029	Alarm system failures	• One or more components of the audiovisual alarm system has failed • Note error code and the accompanied numeric code (if any) and contact Delfi

ELECTROMAGNETIC COMPATIBILITY (EMC) GUIDANCE TABLES

The following tables provide guidance on needs and installation of the *PTS for BFR* regarding electromagnetic compatibility.

EMC GUIDANCE AND DECLARATION – EM EMISSIONS

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The PTS Personalized Tourniquet System for BFR is intended for use in the electromagnetic environment specified below. The user of the *PTS for BFR* should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guidance**
RF emissions CISPR 11	Group 1	The system's RF emissions are very low, therefore, are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The *PTS for BFR* is suitable for use in locations in residential environments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

EMC GUIDANCE AND DECLARATION – EM IMMUNITY/DISTURBANCES

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The PTS Personalized Tourniquet System for BFR is intended for use in the electromagnetic environment specified below. The customer or the user of the *PTS for BFR* should ensure 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 for Contact ±2, ±4, ±8, ±15 kV for Air	±8 kV for Contact ±2, ±4, ±8, ±15 kV for 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 @ 100kHz for power supply lines ± 1 kV @ 100 kHz for input/output lines	± 2 kV @ 100 kHz for power supply lines ± 1 kV @ 100 kHz for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 0.5 kV, ± 1 kV line-to-line ± 0.5 kV, ± 1 kV, ±2 kV line-to-earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0%, 0.5 Cycle, 0°, 45°, 90°, 35°,180°, 225°, 270°, 315° 0%, 1 Cycle, 0° 40%, 5 Cycle, 0° 70%, 25/30 Cycle, 0°, 10 periods @ 50 Hz or 12 periods at 60 Hz	0% during 0.5 Cycle, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% during 1 Cycle 70% during 25 Cycles 0% during 250 Cycles (Interruption)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *PTS for BFR* requires continued operation during power mains interruptions, it is recommended that the *PTS for BFR* be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3A/m @ 50Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

EMC GUIDANCE AND DECLARATION – EM EMISSIONS/RF

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The PTS Personalized Tourniquet System for BFR is intended for use in the electromagnetic environment specified below. The customer or the user of the *PTS for BFR* should ensure 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 in ISM Bands between 150 kHz to 80 MHz	3 Vrms & 6 Vrms in ISM Bands, 150 kHz. – 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the *PTS for BFR*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 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] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	3 V/m, 80 MHz to 2.7 GHz @ 10 sec. dwell time	
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 PTS Personalized Tourniquet System for BFR is used exceeds the applicable RF compliance level above, the PTS Personalized Tourniquet System for BFR should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PTS Personalized Tourniquet System for BFR.

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

EMC GUIDANCE AND DECLARATION – IMMUNITY/SEPARATION DISTANCES

Recommended separation distances between portable and mobile RF communications equipment and the PTS Personalized Tourniquet System for BFR

The PTS Personalized Tourniquet System for BFR is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *PTS for BFR* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *PTS for BFR* 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		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
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 meters (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.

BFR CUFF UTILIZATION

3

PRODUCT DESCRIPTION

Delfi Easi-Fit BFR Tourniquet Cuffs are specifically designed for use with the *PTS for BFR*, featuring quick-connect connectors and patented LOP sensor technology. Easi-Fit BFR cuffs are equipped with a unique stabilizer strap / application handle and are color coded for size identification. The cuff is inflated by connecting it to the *PTS for BFR*, via a PTS for BFR hose assembly. Easi-Fit BFR cuffs are reusable, latex-free, and available in a selection of sizes and styles to accommodate a wide range of limb shapes and sizes.

Each Easi-Fit BFR cuff includes a Matching Limb Protection Sleeve (MLPS) to help protect a patient's limb from possible wrinkling, pinching and shearing of the skin and soft tissues of the limb. MLPS apply a low pressure that is less than a snuggly wrapped cuff, within the range of the limb circumference sizes recommended for the matching cuff. (See Utilization instructions below).

UTILIZATION

SLEEVE USE AND INSPECTION

If a single patient is using the single patient multiple-use MLPS multiple times, then inspect the MLPS before each use by that patient

- Are there any tears in the fabric?
- Is there a loss of elasticity resulting in a loose fit on the limb?
- Is the sleeve contaminated or stained?

If any of the above conditions are present, the sleeve is no longer usable and must be discarded

The Matching Limb Protection Sleeves (MLPS) single -use disposable is intended for single use only. Do not reuse sleeve.

CUFF INSPECTION BEFORE USE

This product is subject to wear and deteriorates with use. It is essential to inspect the cuff before each use. The following is a list of items to check.

- Is there any physical damage (rips, tears, holes, etc.) to the cuff?
- Is the quick-connect connector bent, broken or worn?
- Are the fasteners and straps torn or is any of the strap stitching broken?
- Are the hook and loop fasteners of the application handle worn or damaged?
- After cleaning, is more than 25% of the hook material embedded with fibers that cannot be removed, thus reducing the effectiveness of the contact closure?
- Perform a test for leakage from the cuff, hose and connectors (Refer to Leak Test, Section 2.14). Are there any leaks in the cuff or connectors?
- Is there any other physical change or damage to the cuff which would compromise the cuff's ability to maintain the pressure to which it is inflated?

If any of the above conditions are present, the cuff is no longer usable and must be discarded. Refer to **Warnings** under **Section 1 General Information** for a description of the possible consequences of using a damaged cuff.

BFR CUFF UTILIZATION

3

CUFF SIZE

Prior to cuff application, measure the circumference of the patient's limb at the point where the center of the cuff will be. Each style of Easi-Fit BFR cuff is designed to accommodate a range of limb circumferences. The following table shows the Recommended Limb Circumference Range for each cuff size.

Cuff	Recommended Limb Circumference Rage
PTS BFR Easi-Fit 18" Tourniquet Cuff (RED)	27.9 to 40.6 cm (11 to 16 in)
PTS BFR Easi-Fit 24" Tourniquet Cuff (GREEN)	38.1 to 55.9 cm (15 to 22 in)
PTS BFR Easi-Fit 34" Tourniquet Cuff (BLUE)	53.3 to 76.2 cm (21 to 30 in)
PTS BFR Easi-Fit 44" Tourniquet Cuff (BROWN)	73.7 to 101.6 cm (29 to 40 in)

APPLICATION

In most cases, a cuff should be applied at the widest part of the limb to allow as much tissue as possible to lie between the cuff and any nerves or vascular structures susceptible to damage.

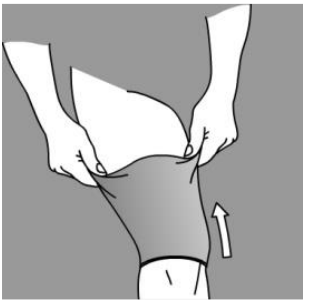
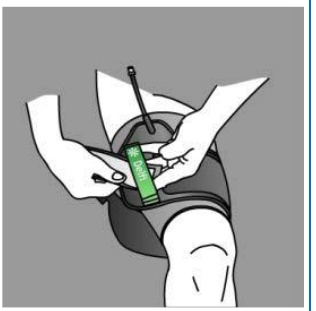
The optimum positions are the upper arm and the proximal third of the thigh. Safe cuff positioning at the calf has been reported in the medical literature. The cuff should be placed so as to avoid being compressed by other equipment or devices, and to avoid the hose being kinked during use.

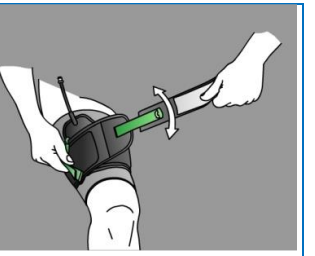
Loose fibers in the hook material must be removed prior to cuff application since these fibers will reduce their effectiveness. If more than 25% of the hook is embedded with fibers that cannot be removed, the cuff is no longer usable and must be discarded.

All Delfi Easi-Fit BFR Tourniquet Cuffs are intended for use in conjunction with a Delfi Matching Limb Protection Sleeve (MLPS). Delfi strongly recommends the application of a MLPS to the limb beneath the cuff prior to the application of an Easi-Fit BFR cuff. Matching Limb Protection Sleeves are available in sizes that are matched to the recommended limb circumference range of each Easi-Fit BFR cuff and will help protect the limb of the patient from soft tissue injuries without impairing cuff performance.

To apply cuff, follow the instructions below:

1	**Selecting the Correct Cuff and Matching Limb Protection Sleeve:** • Measure the circumference of the patient's limb at the point where the center of the cuff will be • Refer to the **Cuff Size** under **Section 3 BFR Cuff Utilization** to select a cuff of the correct size • Select the correct MLPS by confirming the color of the MLPS matches the color of the trim on the cuff

2	**MLPS Application:** • Apply the Matching Limb Protection Sleeve on the limb without wrinkles in the fabric	
3	**Cuff Application:** • Place a leak-free cuff on the limb and position the hose connection so that the hose will not be kinked during use	
	• Apply the cuff snugly by sliding the pivoting hook strap under the stabilizer strap / application handle	
	Note: A cuff that is applied too loosely will reduce the effectiveness of the selected pressure. Confirm that the patient's limb circumference is within the range of the selected Easi-Fit BFR cuff. Refer to **Cuff Size** under **Section 3 BFR Cuff Utilization**	



- Secure the cuff to the limb by using the hook fastener on the underside of the cuff, and the pivoting hook strap. All hook materials must be pressed firmly against the loop material on the cuff surface

- Connect the cuff to the tourniquet instrument using a PTS for BFR hose assembly. Note that the hose has a quick-connect connector on one end to match the cuff port and a metal male connector on the other end to match the *PTS for BFR*. Refer to **Section 2 Operating Instructions** for information on the proper use of the *PTS for BFR* and Easi-Fit BFR cuffs and accessories

PRESSURE SETTING

For each patient, the tourniquet pressure should be set to a percentage of the "Limb Occlusion Pressure" as recommended by the supervising physician or physician's designated licensed health care practitioner. Refer to **Operation** under **Section 2 Operating Instructions**. Limb Occlusion Pressure (LOP) is defined in the medical literature as the minimum pressure required to stop the flow of arterial blood into the limb distal to the tourniquet cuff, at a specific time in a specific tourniquet cuff applied to a specific patient's limb at a specific location.

For more information on determining the Limb Occlusion Pressure, a list of references in the medical literature can be obtained from Delfi Medical Innovations Inc. upon request.

To prevent damage to the Delfi Easi-Fit BFR Tourniquet Cuffs, do not inflate these cuffs to a pressure greater than 350 mmHg.

BFR CUFF UTILIZATION

3

INFLATION TIME

Appropriate tourniquet inflation time depends on the blood flow restriction protocol prescribed by the physician or physician's designated licensed health care practitioner. The *PTS for BFR* limits the maximum settable inflation time to 30 minutes.

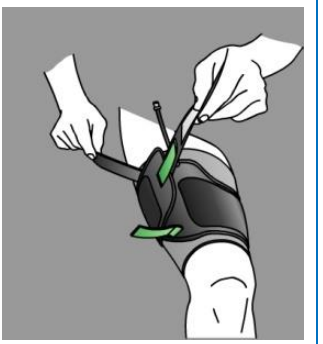
BFR CUFF UTILIZATION

3

REMOVAL

Transient pain upon tourniquet cuff pressure release can be lessened by elevation of the limb. If full color does not return within 3 to 4 minutes after release, the limb should be placed in a position slightly below body level.

To remove cuff, follow the instructions below:

1	**Cuff Removal:** • Remove the Easi-Fit BFR cuff from the limb by first opening the stabilizer strap / application handle and disengaging the hook fastener strap	
2	**MLPS Removal:** • Slide the Matching Limb Protection Sleeve off the limb	
	NOTE: To prevent venous congestion, the Matching Limb Protection Sleeve should also be removed from the limb immediately following final deflation of the cuff and the circulation of the limb should be checked. The time of tourniquet application and removal should be noted along with the tourniquet pressure(s) used	

CLEANING

Easi-Fit BFR cuffs may be cleaned in lukewarm water and an alkaline detergent and rinsed thoroughly. A soft hand brush may be used to remove encrusted material. Cuffs may also be wiped with isopropyl alcohol. Easi-Fit BFR cuffs should not be immersed. Presence of fluid in the bladder may damage the tourniquet instrument.

Cleaned cuffs should be allowed to drip dry at room temperature. If loose fibers are present in the contact closure strap, the fibers may be removed using a non-metallic brush or comb using a side to side manner.

Cuffs must not be autoclaved and are not intended for sterilization.

Single patient multiple-use Matching Limb Protection Sleeves (MLPS) are not intended to be cleaned. If the single patient multiple-use MLPS becomes contaminated or stained it must be discarded. The single-use disposable MLPS must be discarded after initial use even if it is not contaminated or stained.

STORAGE

Cuff storage: Store the Easi-Fit BFR cuffs in a clean, dry area. Do not store the cuff wet. Store the cuffs lying flat or in a loose roll.

BFR CUFF UTILIZATION

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Single patient multiple-use MLPS storage: After use, store the single patient multiple-use sleeve in a clean, dry area. Do not store the sleeve wet. Store the sleeve lying flat or in a loose roll.

Single-use disposable MLPS storage: Store in a clean, dry area.

MAINTENANCE

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GENERAL MAINTENANCE INFORMATION

While the *PTS for BFR* has been designed and manufactured to high industry standards, it is recommended that periodic inspection, testing, and calibration ('maintenance') be performed as described in this section to ensure continual safe and effective operation. This section also serves as a guide to troubleshooting and expediting unscheduled maintenance. The maintenance intervals listed below are provided as a guideline; refer also to the policies in your practice setting for general tourniquet maintenance procedures and intervals.

CAUTION: Do not attempt to disassemble or open the enclosure of your *PTS for BFR*. The *PTS for BFR* is not designed to be disassembled and serviced by anyone other than Delfi staff. Disassembly and attempted service by anyone other than Delfi staff poses a risk of electric shock, damage to the unit, and injury to the patient and will void all warranties. Internal parts in the *PTS for BFR* can only be serviced at the factory by Delfi staff. Please contact Delfi if you have problems with your *PTS for BFR* that cannot be resolved by following the maintenance and troubleshooting procedures described below

PERIODIC MAINTENANCE

Cleaning

The exterior of the unit may be cleaned with a cloth that has been dampened (not dripping) with a mild detergent. The exterior of the cuff hose may be cleaned using a mild detergent solution with a neutral PH or isopropyl alcohol. Easi-Fit BFR cuffs should be cleaned in accordance with Delfi's instructions. Refer to **Cleaning** under **Section 3 BFR Cuff Utilization**.

WARNING: Do not allow foreign objects from entering the *PTS for BFR,* the hose assembly, or the cuff. This could damage/affect the performance of the PTS for BFR system

CAUTION: Do not attempt to clean or flush out the interior of the PTS for BFR hose assembly. Do not allow fluids or debris to enter the hose connectors on the *PTS for BFR* or the PTS for BFR hose assembly

CAUTION: Avoid exposing the AC power supply to liquids. Do not immerse in fluid. Do not allow the AC power supply to lie on the floor where pooling of liquids may occur. Clean by damp cloth (alcohol or mild detergent wipe) only. The AC power supply is resistant to occasional splashing or dripping of fluids but is not fluid-tight. If immersed in or exposed to excessive amounts of liquids, the AC power supply may fail and may pose an electrical shock hazard

External Inspection

The unit should be externally inspected as follows at least once every three months:

- Obvious external damage
- Missing or illegible labels and warnings
- Kinks or damage in the power cord
- Secure connection and locking of the power cord plug to the receptacle on the *PTS for BFR*
- Secure connection and locking of the hose connectors on the *PTS for BFR* to the PTS for BFR hose assembly
- Kinks or damage in the PTS for BFR hose assembly

Functional and Calibration Checks

It is recommended that the functional and calibration checks described in the **Tests and Checks** under **Section 2 Operating Instructions** are performed at least once every three months.

MAINTENANCE

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CALIBRATION

Calibration should be performed every twelve months, or after any unscheduled maintenance.

Calibration of the *PTS for BFR* allows the output signal from the pressure transducers to be compared against a calibrated pressure source. The difference between the known pressure and the pressure measured by the transducers is recorded at each of four set-points, and these four calibration factors are used to correct the signal from the pressure transducers during normal operation. The calibration factors are stored in memory.

Required Equipment:

- Calibrated 0 to 650 mmHg pressure gauge.
- Adjustable 0 to 650 mmHg pressure source.
- Suitable pneumatic hoses and connectors.

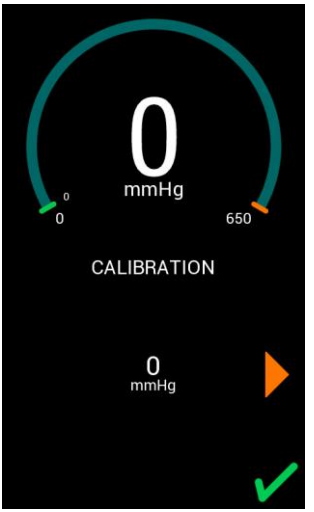
Note: A calibration hose set Delfi (REF 9-2200-611) can be purchased from Delfi to connect the *PTS for BFR* to a pressure source and a reference pressure gauge

CAUTION: The following steps must be taken in the exact order to calibrate the unit. Failure to do so may result in incorrect pressure readings while the unit is in operation

1	**Enter Calibration Mode:** • Touch the **ON/STANDBY** button to turn the unit ON, then touch and hold three hidden buttons during the welcome screen • The locations of the three hidden keys are indicated by the three red rectangles in the figure to the right	

2 **Calibrating Zero Pressure:**

- Once start-up sequence completes, the unit will enter the Calibration mode and display "0 mmHg" under a **PRESSURE** indicator
- With the hose connector on the *PTS for BFR,* open to atmosphere, touch the **CONFIRM** button to indicate zero reference pressure is applied. The unit will adjust the transducer output corresponding to zero pressure. The unit will then sound a tone and the "0 mmHg" will turn green to indicate that the reference pressure was taken



3 **Calibrating 100 mmHg:**

- Once the zero point is calibrated, press the **SCROLL RIGHT** button to advance the unit to the next pressure level. The display will now show "100 mmHg"
- Connect the *PTS for BFR* to the pressure source and a reference pressure gauge
- Apply a calibrated reference pressure of 100 ± 1 mmHg to the cuff port
- Once the pressure has stabilized, press the **CONFIRM** button to indicate the reference pressure is applied. The unit will adjust the transducer output corresponding to 100 mmHg. The unit will then sound a tone and the "100 mmHg" will turn green to indicate that the 100 mmHg reference pressure was taken

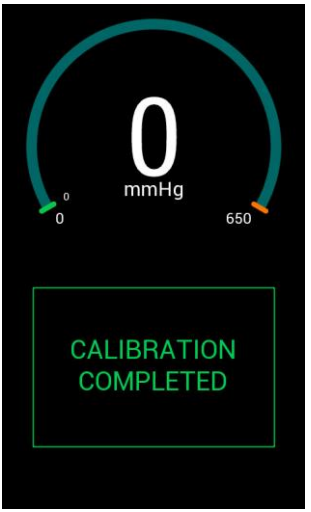
Note: If the reference pressure is more than 15 mmHg difference from the sensed pressure, the unit will sound an alarm tone and will not accept the pressure applied. If this happens, try to adjust it to a correct pressure

4 **Calibrating 300 mmHg and 600 mmHg:**

- Repeat the preceding step for reference pressures of 300 ± 1 mmHg and 600 ± 1 mmHg

Note: At any time, touch the **SCROLL LEFT** or **SCROLL RIGHT** buttons to switch between pressure levels for calibration

Note: The unit will not allow calibration points to be missed. For calibration purposes the device must be able to inflate above the maximum desirable set pressure. The device may only be set for use to a maximum pressure of 350 mmHg.

5	**Completing Calibration:** • Once all calibration points are obtained (0 mmHg, 100 mmHg, 300 mmHg, and 600 mmHg), a **BACK** button will appear • Touch the **BACK** button to complete calibration • The unit will display a "CALIBRATION COMPLETED" message • Press the **ON/STANDBY** button to set the unit to STANDBY	

CALIBRATION CHECK

Below is a step-by-step procedure for checking the calibration for the pressure transducers. If the calibration is suspected of being out of specification, complete the calibration per **Calibration** under **Section 4 Maintenance**. This section will allow the pressure transducers to be checked without changing or modifying the saved calibration.

1	**Setting Up the Calibration Check:** • Connect the *PTS for BFR* to a cuff and a reference pressure gauge known to be accurate (e.g. manometer or calibrated gauge) • Touch the **ON/STANDBY** button to turn the unit ON
	Note: A calibration hose set Delfi (REF 9-2200-611) can be purchased from Delfi to connect the *PTS for BFR* to a cuff and a reference pressure gauge
2	**Calibration Check (100 mmHg):** • Enter the pressure adjustment mode by touching the **PRESSURE** indicator • Set the pressure set-point to 100 mmHg. **Refer to Step 1 of Manual Tests and Checks for more information** • Touch the **INFLATE** button • Allow the pressure to stabilize. The pressure reading on the *PTS for BFR* and the reference pressure gauge should be within 5 mmHg of each other, and within 5 mmHg of the pressure-set point of 100
	NOTE: If any stabilized pressure reading is off by more than 5 mmHg during the calibration check or the pressure display does not return to zero, the unit must be calibrated. Refer to **Calibration** under **Section 4**

	Maintenance for instructions on calibration
3	**Calibration Check (250 mmHg and 350 mmHg):** • Repeat the previous step for 250 mmHg and 350 mmHg
	NOTE: If any stabilized pressure reading is off by more than 5 mmHg during the calibration check or the pressure display does not return to zero, the unit must be calibrated. Refer to **Calibration** under **Section 4 Maintenance** for instructions on calibration
4	**Calibration Check (0 mmHg):** • Touch the **DEFLATE** button to deflate the unit. Disconnect the hose from the *PTS for BFR*. The pressure reading should decrease to 0 mmHg
	NOTE: If any stabilized pressure reading is off by more than 5 mmHg during the calibration check or the pressure display does not return to zero, the unit must be calibrated. Refer to **Calibration** under **Section 4 Maintenance** for instructions on calibration

LEAK TESTING

Leak testing should be performed at least once every twelve months, or if leak alarms occur without an obvious cuff or hose leak. The *PTS for BFR* is capable of maintaining cuff pressure even with a substantial leak in the system; however, any leak may become worse and lead to loss of pressure during a procedure, so it is important to find and correct leaks as soon as possible.

To conduct a leak test, follow instructions in **Leak Test** under **Section 2 Operating Instructions**.

NOTE: If "SMALL LEAK" or "LARGE LEAK" are displayed there is a significant leak in either the test cuff or hose or in the *PTS for BFR* internal pneumatics. Repeat the test with a variety of different Easi-Fit BFR cuffs and hose assemblies. If this condition persists, the leak is internal, and the *PTS for BFR* will require servicing

BATTERY TESTING AND REPLACEMENT

CAUTION: Risk of electric shock. Set the *PTS for BFR* to STANDBY and disconnect AC power before opening the battery compartment

A new battery pack is designed to run the *PTS for BFR* without AC power for about 10 hours of typical use on a full charge; however, this charge life will vary greatly depending on the conditions of use. The life and performance of the battery pack also depend on the conditions of use and storage. Storage at room temperature or lower will result in maximum life.

The *PTS for BFR* features automatic battery charging and monitoring functions and attempts to charge the battery whenever the unit is connected to AC power, both in ON and STANDBY modes. No maintenance is required of the battery charging circuit. To check the charge level in the battery, the *PTS for BFR* must be ON with no AC power connected. When ON under battery power, the **BATTERY STATUS** indicator appears. The **BATTERY STATUS** indicator and percentage shown below indicate the battery charge level. The **BATTERY STATUS** indicator will change color from green to yellow to red, to indicate decreased battery charge and the need for recharging.

MAINTENANCE

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NOTE: It is recommended that the battery in the *PTS for BFR* be tested as described below every 3 months and replaced when Battery Health is below 50%. Even when the *PTS for BFR* is used on AC power, the battery pack must be in good condition to provide backup power in the event of the AC power being disconnected

BATTERY TESTING

To determine if the battery pack needs replacement, charge it for at least 5 hours and then test as follows:

1	• Remove the AC power supply and power up the *PTS for BFR*. The **BATTERY STATUS** indicator should be completely filled green and percentage charge level should indicate 100%
2	• Connect the *PTS for BFR* to an Easi-Fit BFR cuff
3	• Select the third protocol in the Custom Lower Limb tab
4	• Set the protocol to C-BFR mode with Inflation Cycles to 5, Inflated Time to 6 minutes, and Deflated Time to 1 min
5	• Set the pressure set-point to 325 mmHg and touch the **INFLATE** button
6	• Touch the **INFLATE** button to run a second then a third C-BFR protocol after the completion of the previous C-BFR protocol
7	• If the "LOW BATTERY" alarm is activated during the 3 C-BFR protocols, replace the battery pack
8	• Touch the **DEFAULTS** button from the Settings Menu to check the Battery Health. If the Battery Health is below 50%, replace the battery pack

If battery runtime is much shorter than previously experienced, consider replacing the battery pack.

NOTE: The battery pack must also be replaced if a "BATTERY FAILURE" alarm condition occurs (Refer to **Alarm Conditions** under **Section 2 Operating Instructions**) that cannot be corrected by plugging the *PTS for BFR* into AC power or by confirming that the battery pack is securely connected. You may also wish to replace the battery pack if you regularly use your *PTS for BFR* on battery power and have LOW BATTERY alarm conditions occurring soon after a full charge

BATTERY PACK REPLACEMENT

Follow the procedures below to replace the battery pack:

- Remove the single battery cover screw from the back of the *PTS for BFR* (directly above the label) and remove the battery cover
- Using the pull tab, remove the battery pack from the battery compartment. **Recycle or dispose of the old battery pack in accordance with local regulations and procedures for Lithium-ion batteries**
- Hold new battery pack supplied by Delfi by the pull tab, ensure the 5-pin female battery connector is at the bottom and facing the male connector pins in the battery compartment. Align new battery pack with the battery compartment and push it in. Secure the new battery in place by putting the battery cover on. If the battery pack

cannot be pushed all the way in or the battery cover does not fit flush against the case, the battery is installed incorrectly. Remove the battery, ensure the connectors are properly aligned, and re-install the battery.

- **WARNING:** Use only Delfi Lithium-ion battery packs (REF 7-2200-046). Do not use any other batteries. Use of improper batteries may cause irregular operation that could be hazardous to the patient and/or user and may permanently damage the *PTS for BFR*, voiding the warranty

- **WARNING:** When a new battery pack is installed, the *PTS for BFR* must be plugged in to AC power for at least 5 hours to fully charge the new battery before use

- **WARNING:** DO NOT modify, disassemble, puncture, cut or crush, the battery pack. A damaged battery pack may overheat and catch fire.
- **WARNING:** NEVER dispose of the battery in a fire or incinerator, as the battery may catch fire and explode


Li-ion

NOTICE: BATTERY PACK DISPOSAL: The battery is of a Lithium-Ion type. When the battery reaches the end of its useful life, the battery should be disposed of by a qualified recycler or hazardous materials handler. Do not mix this battery with the solid waste stream. Contact your local recycler or hazardous materials handler for recycling or disposal information.

INTERNAL HARDWARE SERVICING

The *PTS for BFR* is designed with self-test and self-monitoring features to warn of failures. Refer to **Alarm Conditions** under **Section 2 Operating Instructions**. Although very unlikely, modes of failure may also occur that cause erratic operation and/or illegible displays and may or may not trigger alarms. If the maintenance, calibration, and troubleshooting procedures do not restore normal operation, contact Delfi for service advice.

CAUTION: Do not attempt to disassemble or open the enclosure of your *PTS for BFR*. The *PTS for BFR* is not designed to be disassembled and serviced by anyone other than Delfi staff. Disassembly and attempted service by anyone other than Delfi staff poses a risk of electric shock, damage to the unit, and injury to the patient and will void all warranties. Internal parts in the *PTS for BFR* can only be serviced at the factory by Delfi staff. Please contact Delfi if you have problems with your *PTS for BFR* that cannot be resolved by following the maintenance and troubleshooting procedures described above

TROUBLE SHOOTING GUIDE

To aid in unscheduled maintenance, the **TROUBLESHOOTING** table below delineates a number of possible malfunctions that could occur with the unit. The most likely causes are shown for each symptom. While it is not practical to enumerate every conceivable malfunction and all possible causes, the table will assist in isolating the most common problems.

TROUBLESHOOTING

Malfunction	Possible Causes	Corrective Actions
Unit does not turn ON (with no AC power connected)	Battery pack not charged	Plug in to AC power and allow battery to charge. Attempt to turn unit ON with AC power. Refer to

Malfunction	Possible Causes	Corrective Actions
		"BATTERY FAILURE" alarm below
	Battery pack disconnected	Remove battery cover and ensure battery pack is securely plugged in
Unit does not turn ON (with AC power connected)	Internal hardware failure. Defective AC adapter/cord assembly	Contact Delfi
Cuff does not inflate	**INFLATE** button not touched	Touch the **INFLATE** button
	Hose kinked or blocked	Unkink hose or disconnect cuff from hose.
	Internal hardware failure	Contact Delfi
Cuff does not deflate	**DEFLATE** button not touched	Touch the **DEFLATE** button
	Hose kinked or blocked	Unkink hose or disconnect cuff from hose. Ensure complete cuff deflation to clear CUFF NOT DEFLATED alarms
	Internal hardware failure	Contact Delfi
AC POWER STATUS indicator does not appear when unit is ON and is plugged in to AC power	AC power supply assembly not plugged in to suitable wall outlet	Ensure wall socket is working and of the correct voltage, and that the plug is all the way in
	AC power supply assembly not plugged in to *PTS for BFR*	Ensure connector is fully engaged
	Incorrect AC power supply assembly	Ensure AC power adapter is the one supplied with the *PTS for BFR*
	AC power supply not working	Contact Delfi
STATUS indicator does not illuminate blue when unit is on STANDBY and is plugged in to AC power	**STATUS** indicator not working	Confirm that **STATUS** indicator illuminates during self-check upon power-up. Contact Delfi
STATUS indicator does not illuminate during alarm conditions	**STATUS** indicator not working	Confirm that **STATUS** indicator illuminates during self-check upon power-up. Contact Delfi
No cuff pressure and/or tourniquet time reading	Faulty pressure/time display	Confirm that all segments of the display illuminate during self-check

Malfunction	Possible Causes	Corrective Actions
	Internal hardware failure	upon power-up Contact Delfi
Pump runs continuously	External leak (cuff or hose)	Correct leak to clear leak alarm
	Internal leak	Test for leaks. Refer to **Leak Testing** under **Section 4 Maintenance**
	Internal hardware failure	Disconnect *PTS for BFR* from cuff to deflate cuff if required. Contact Delfi
BATTERY FAILURE alarm	Fully discharged battery	Connect to AC power and allow battery to recharge for 5 hours
	Battery pack disconnected	Remove battery cover and ensure battery pack is securely plugged in
	Faulty or dead battery pack	Replace battery pack. Refer to **Battery Testing and Replacement** under **Section 4 Maintenance**
Battery does not charge when unit is plugged in to AC power	Faulty or dead battery pack	Replace battery pack. Refer to **Battery Testing and Replacement** under **Section 4 Maintenance**
Unit does not turn OFF (cannot be set to STANDBY)	Pressure in cuff	Deflate cuff and ensure it deflates fully (disconnect hose if required) to clear CUFF NOT DEFLATED alarm
	Internal hardware failure	Contact Delfi. Unit can be powered OFF by unplugging the AC power and removing the battery pack. Refer to **Battery Testing and Replacement** under **Section 4 Maintenance**

MAINTENANCE

4

REPLACEMENT PARTS

BFR CUFFS

Description	Unit	Part Number
PTS BFR Easi-Fit 18” Tourniquet Cuff, reusable, (4.5” x 18”- RED)	1/ ea	9-7550-018
PTS BFR Easi-Fit 24” Tourniquet Cuff, reusable, (4.5” x 24” – GREEN)	1/ ea	9-7550-024
PTS BFR Easi-Fit 34” Tourniquet Cuff, reusable, (4.5” x 34” – BLUE)	1/ ea	9-7550-034
PTS BFR Easi-Fit 44” Tourniquet Cuff, reusable, (4.5” x 44” – BROWN)	1/ ea	9-7550-044

MATCHING LIMB PROTECTION SLEEVES (MLPS) SINGLE PATIENT MULTIPLE-USE

Description	Unit	Part Number
MLPS Single Patient Multiple-Use (RED) for PTS BFR Easi-Fit 18” reusable cuff	10 / box	9-7950-018
MLPS Single Patient Multiple-Use (GREEN) for PTS BFR Easi-Fit 24” reusable cuff	10 / box	9-7950-024
MLPS Single Patient Multiple-Use (BLUE) for PTS BFR Easi-Fit 34” reusable cuff	10 / box	9-7950-034
MLPS Single Patient Multiple-Use (BROWN) for PTS BFR Easi-Fit 44” reusable cuff	5 / box	9-7950-044

MATCHING LIMB PROTECTION SLEEVES (MLPS) DISPOSABLE SINGLE -USE

Description	Unit	Part Number
MLPS Disposable Single-Use (RED) for PTS BFR Easi-Fit 18” reusable cuff	25 / box	9-7960-018
MLPS Disposable Single-Use (GREEN) for PTS BFR Easi-Fit 24” reusable cuff	25 / box	9-7960-024
MLPS Disposable Single-Use (BLUE) for PTS BFR Easi-Fit 34” reusable cuff	25 / box	9-7960-034
MLPS Disposable Single-Use (BROWN) for PTS BFR Easi-Fit 44” reusable cuff	12 / box	9-7960-044

ACCESSORIES

Description	Unit	Part Number
PTS Roll Stand and Basket	1/ ea	9-2200-550
PTS Portable Basket with Pole Clamp, Blue	1/ea	9-2200-501
JuiceBlok AC Power Bank, Lithium-Ion, 150 Wh	1/ea	9-2200-600
Power Supply, *PTS for BFR*	1/ea	9-2200-020

Battery (Lithium-ion), *PTS for BFR*	1/ea	9-2200-046
Mount Bracket, Single, *PTS for BFR*	1/ea	9-2200-008
Mount Bracket, Twin, *PTS for BFR*	1/ea	9-2200-009
Single Hose, *PTS for BFR* – 11ft (w/ metal male connector)	1/ea	9-2200-025
Calibration Hose Set, *PTS for BFR* (w/ metal male connector)	1/ea	9-2200-611
PTS Transport Case (BLACK) – for twin system and cuffs, with foam insert	1/ ea	9-2200-410
PTS Transport Bag (BLACK) – includes padded instrument case & cuff set pouch	1/ea	9-2200-300
Instrument Case – grey, padded	1/ea	9-2200-301
Cuff Set Pouch – grey, padded	1/ea	9-2200-302

CONTACT INFORMATION

For sales and servicing inquiries, contact your Delfi distributor or Delfi:

Mail	Telephone	Website
Delfi Medical Innovations Inc. 106 – 1099 West 8th Avenue Vancouver BC Canada V6H 1C3	1.800.933.3022 (US & Canada) +1.604.742.0600 (Global)	www.delfimedical.com

NOTE: We strongly recommend that all repairs be done by Delfi or authorized personnel

PRODUCT REPORTING

Notify Customer Service Department, Delfi Medical Innovations Inc, at 1-800-933-3022 or info@delfimedical.com, or contact your local representative. Please provide details about the nature of the problem and include the product serial number or lot number. Upon receipt of this information, Delfi will provide assistance for resolution or a return shipping authorization.

The user and/or patient should report any suspected serious incident related to the device by informing Delfi Medical Innovations Inc, and your local representative. If in the European Union, also inform the competent authority of the member state in which the serious incident has occurred.

DISPOSAL

To dispose of the device or its accessories, follow appropriate national or local laws, regulations, and procedures.

WARNINGS, CAUTIONS & SYMBOLOGY

5

WARNINGS, CAUTIONS & SYMBOLOGY

IFUs and Symbol Glossary
delfimedical.com/ifu













Li-ion

Personalized Tourniquet Systems

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