PTS ii Personalized Tourniquet System®

Operator & Maintenance Manual

REF 60-1000-101-00

ZIMMER BIOMET

Your progress. Our promise.™

Distributed by:
Zimmer Surgical
200 West Ohio Avenue
Dover, Ohio 44622
(330) 343-8801

ZimmerBiomet.com

Pat.: www.delfimedical.com/patents

WARRANTY

LIMITED TWO-YEAR WARRANTY

SCOPE OF LIMITED WARRANTY

Delfi Medical Innovations Inc. ('Delfi') warrants the components of the PTS ii Personalized Tourniquet System ('product') from date of purchase as follows: PTS ii instrument and accessories (2 years), 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, Zimmer Surgical at (330) 343-8801. Please provide details about the nature of the problem and include the product serial number. Upon receipt of this information, Zimmer Surgical 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 _____

CONTENTS

CONTENTS

GENERAL INFORMATION

1

CAUTION: United States federal law restricts this device to sale by, or on the order of a physician.

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

The Delfi PTS ii Portable Tourniquet System is intended to be used by qualified medical professionals to exert enough pressure on the arterial blood flow in a limb to produce a bloodless operating field. Tourniquets are generally used for operations lasting less than 90 minutes. Tourniquets have been found useful in surgical procedures involving the extremities, such as:

- Reduction of certain fractures
- Kirschner wire removal
- Tumor and cyst excisions
- Knee joint replacements
- Arthroscopy of certain joints
- Replacement of finger joints
- Bone grafts
- Amputations
- Subcutaneous fasciotomy
- Nerve injuries
- Tendon repair
- Total wrist joint replacement

CONTRAINDICATIONS

Refer to the medical literature for possible contra-indications to tourniquet use. A partial list is provided below; however, in every case the final decision to use a tourniquet rests with the attending physician.

- Open fractures of the leg
- Post traumatic lengthy hand reconstruction
- Severe crushing injuries
- Elbow surgery (where there is concomitant excess swelling)
- Severe hypertension
- Skin grafts in which all bleeding points must be readily distinguished
- Compromised vascular circulation, e.g., peripheral artery disease
- Diabetes mellitus
- Secondary or delayed procedures after immobilization

The presence of sickle cell disease is a relative contraindication (see **Precautions in Use** under **Section 1 General Information**).

WARNINGS

Do not use tourniquet cuffs to control the distal flow of CO2 or any other gases used as a distention media. Tourniquet cuffs have not been evaluated for safety or effectiveness in controlling gas flow beyond the surgical site during arthroscopic insufflation procedures. Possible effects of using a tourniquet cuff in this manner include serious subcutaneous emphysema proximal to the cuff.

The tourniquet instrument should only be connected to a tourniquet cuff known to be in operable condition.

GENERAL INFORMATION

1

PRECAUTIONS IN USE

System Handling:

- The tourniquet system must be kept well calibrated and in operable condition. Accessories should be checked regularly for leaks and other defects.
- The tourniquet cuff must never be punctured; therefore, towel clips used near the system must be handled with special care.
- When cleaning, carefully follow the cleaning and assembly instructions for the tourniquet cuff and instrument, refer to **Section 3 Maintenance**.

Patient Considerations:

- 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 anemia. When the tourniquet is used for these patients, the limb should be carefully exsanguinated and the PO2 and pH should be closely monitored.
- Prolonged ischemia may lead to temporary or permanent damage to tissues, blood vessels, and nerves. Prolonged tourniquet time can also produce changes in the coagulability of the blood with increased clotting time. In severe cases, pooling of blood in the edemic limb may cause cardiac arrest and death. Rhabdomyolysis may develop in patients following orthopedic cases where tourniquets have been inflated for extended periods of time (over 90 minutes). Always minimize tourniquet time.
- Tourniquet paralysis may result from excessive pressure. Insufficient pressure may result in passive congestion of the limb with possible irreversible functional loss. Always use the minimum effective tourniquet pressure, as described in the medical literature.

The following clinical conditions have been cited in published medical literature as factors that should be carefully considered before use of a tourniquet during surgical procedures

- Severe atherosclerotic disease and presence of calcified vessels
- Severe brain injury
- Proven or suspected deep vein thrombosis
- Tumor on the surgical site
- Abscess or other limb infections
- Rheumatoid arthritis and other immune disease with vasculitis
- Poor cardiac reserve
- Fragile skin and soft tissue
- Compartment syndrome
- Hemoglobinopathy
- Previous revascularization of the extremity
- Extremities with dialysis access (e.g. arteriovenous grafts, fistulas)
- Acidosis
- Medications (e.g. antihypertensives) and supplements (e.g. creatine)
- History of pain or weakness in muscles or bones in extremities
- Increased intracranial pressure.

Delfi recommends that users regularly review published medical literature for other factors that warrant careful consideration before use of a tourniquet during surgical procedures.

GENERAL INFORMATION

1

User Considerations:

- Careful and complete exsanguination reportedly prolongs pain-free tourniquet time and improves the quality of Intravenous Regional Anesthesia (Bier Block anesthesia). However, partial exsanguination may be desirable in certain cases where residual blood flow will aid in visualization and identification of vascular structures.
- In the presence of infection and painful fractures, after the patient has been in a cast, and in amputations due to malignant tumors, exsanguination before tourniquet application may be done without the use of an elastic bandage by elevating the limb for 3 to 5 minutes.
- Tourniquet users must be familiar with the inflation / deflation sequence when using two tourniquet cuffs and two PTS ii units together for IVRA (Bier Block anesthesia), so that the wrong tourniquet will not be released accidentally, which could cause severe injury to the patient or death.
- Whenever infiltration anesthesia is used, it has been suggested in the medical literature that the tourniquet remain inflated for a minimum of 20 minutes from the time of the injection to ensure that most of the anesthetic agent has been absorbed into the limb tissue. For a procedure requiring only a few minutes, too rapid a release of the anesthetic agent can be prevented by quickly deflating and reinflating the tourniquet several times.
- Do not allow preoperative skin preparations to flow and collect under the cuff where they may cause chemical burns.
- Inflation must be done as rapidly as possible to occlude arteries and veins simultaneously, and to avoid return of blood into the limb. Quick deflation aids preventing engorgement.
- Heat generated by surgical lights or powered instruments is not dissipated in limbs under tourniquet control and tissue may be subject to drying or trauma. Frequent irrigation, special draping and low power surgical lights are recommended to reduce the risk of thermal damage.

Application and Use:

- Select the proper cuff size to allow for the overlap recommended by the manufacturer. Too much or too little overlap may cause cuff rolling and telescoping, unexpected release of the cuff from the limb, inability to maintain a bloodless field at normal pressures, and/or undesired pressure distribution on the limb.
- The skin under the tourniquet cuff must be protected from mechanical injury by smooth, wrinkle free application of the cuff. If the tourniquet cuff is applied over any material that may shed loose fibers (such as Webril) the fibers may become embedded in the contact closures and reduce their effectiveness. Follow the cuff manufacturer's recommendations for limb protection material under the cuff. 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.
- Do not use an elastic bandage for exsanguination in cases where this will cause bacteria, exotoxins, or malignant cells to spread to the general circulation, or where it could dislodge thromboemboli that may have formed in the vessels.
- Observe the cuff during inflation and periodically while inflated to ensure the cuff is not migrating on the patient's limb.
- In case of incomplete or improper inflation, the tourniquet cuff must be fully deflated and the limb exsanguinated again before cuff reinflation. Reinflation over blood-filled vasculature may lead to intravascular thrombosis.
- If the tourniquet cuff migrates on the limb during surgery, apply a pressure dressing to the wound and exsanguinate the limb by elevation. Deflate and reapply the cuff. Reinflate the cuff and observe for migration. If migration persists, replace the cuff.
- Whenever the tourniquet cuff pressure is released, the wound should be protected from blood surging back by applying pressure dressings and, if necessary, elevating the limb. Transient pain upon tourniquet 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.
- Completely remove the delated cuff, matching Limb Protection Sleeve or any underlying padding immediately following final cuff deflation. Even the slightest impedance of venous return may lead to congestion and pooling of blood in the operative field. After the cuff has been fully deflated and removed from the patient, the unit can be set to STANDBY.

ADVERSE EFFECTS

A dull aching pain (tourniquet pain) may develop throughout the limb following use. Stiffness, weakness, reactive hyperemia, & skin discolouration may also occur to some degree in all patients after tourniquet use.

Pathophysiologic changes due to pressure, hypoxia, hypercarbia, and acidosis of the tissues occur and become significant after about 1 1/2 hours of tourniquet use.

Symptoms of tourniquet paralysis are motor paralysis and loss of sense of touch, pressure, and proprioceptive responses.

Intraoperative bleeding may be caused by:

- The slight impeding effect exerted by an unpressurized cuff (and its limb protection material or padding, if used), which prevents venous return at the beginning of the operation,
- Blood remaining in the limb because of insufficient exsanguination,
- Inadequate tourniquet pressure (between systolic and diastolic blood pressure of the patient), or slow inflation and deflation, all of which allow arterial blood to enter while preventing venous return,
- Blood entering through the nutrient vessels of the long bones, such as the femur or humerus.

Some other adverse effects of tourniquet use identified in the published medical literature include:

- Cardiovascular, respiratory, cerebral circulatory, and hematological effects related to the metabolic changes that result from ischemia caused by the pneumatic tourniquet applied to the extremity during surgery.
- Temperature changes
- Prolonged postoperative swelling of the affected limb
- Arterial injury
- Skin injuries (e.g. blistering, bruising, necrosis)
- Compartment syndrome
- Deep Vein Thrombosis
- Rhabdomyolysis
- Skin chemical burns caused by solutions used for operative preparation passed underneath the tourniquet cuff and remaining there during inflation
- Tissue or muscle injury may occur due to ischemia and local pressure
- Reperfusion injury may occur to the limb and produce systemic effects if the tourniquet inflation is prolonged
- Hematoma

Delfi recommends that users regularly review published medical literature for other adverse effects that warrant careful consideration before use of a tourniquet during surgical procedures.

SPECIFICATIONS

AC Power Adapter	Use only supplied AC adapter / power cord assembly, Zimmer Surgical (REF 60-1000-213-00)
~ AC Power Mains Line Voltage Range	100-240 ~ (AC), 50/60 Hz. Auto switching

GENERAL INFORMATION

Line Current	175 mA RMS @ 120V ~ (AC) typical, Zimmer Surgical (REF 60-1000-213-00)
Input Power	100 watts maximum, Zimmer Surgical (REF 60-1000-213-00)
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	12V nickel-metal-hydride (NiMh) internally protected pack, 2200 milliamp hours. Use only Zimmer Surgical (REF 60-1000-210-00) battery pack
Battery Discharge Time	10.0 hours (typical)
Battery Recharge Time	5.0 hours (typical)
Cuff Pressure Range	20 – 600 mmHg, 1 mmHg increments
Cuff Pressure Accuracy	± 2 mmHg
Pressure Regulation	± 6 mmHg of set-point (10-second average under non-transient conditions without external leaks
Inflation Timer Set-point Range	5-240 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

Tourniquet Cuff Connection	Tourniquet cuffs with single port male 1/8 inch flow Positive Locking Connector
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)
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

EN 60601-1 CLASSIFICATION

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

Type of protection against electric shock	Class I or Internally Powered Equipment*
Degree of protection against electric shock	Type B applied part
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 ii* complies with EMC criteria set forth in EN 60601-1-2. 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

2

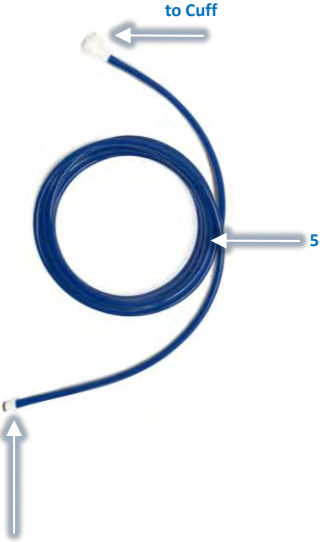
INITIAL INSPECTION

Unpack the *PTS ii* 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 Zimmer Surgical 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.

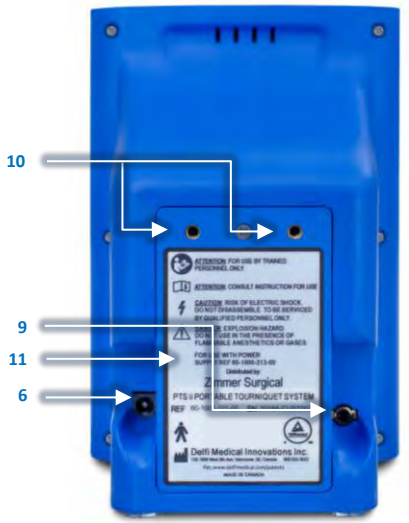
FEATURES

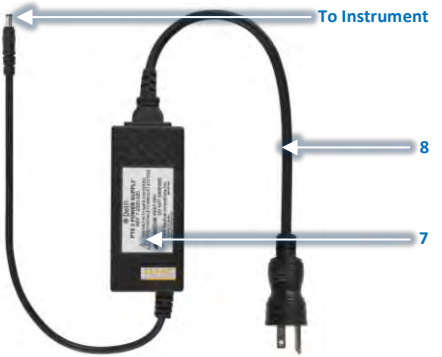
The *PTS ii* has a variety of features, as described below:

FRONT



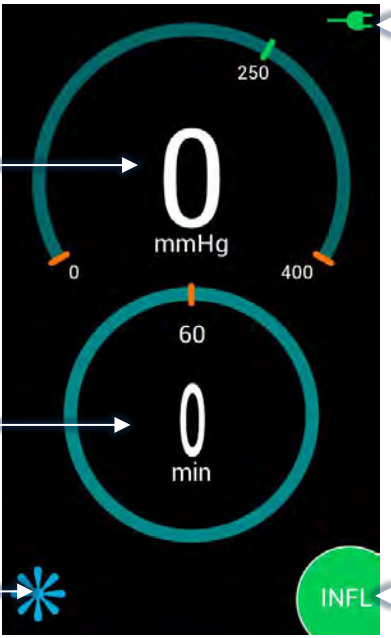
BACK


10
9
11
6
Zimmer Surgical
Delfi Medical Innovations Inc.


To Instrument
8
7


12

MAIN SCREEN – DEFLATED



Power Status Indicator

PRESSURE Button / Indicator

TIME Button / Indicator

SETTINGS Button

INFLATE Button

MAIN SCREEN – INFLATED

Power Status
Indicator

PRESSURE
Button / Indicator

TIME
Button / Indicator

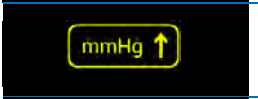
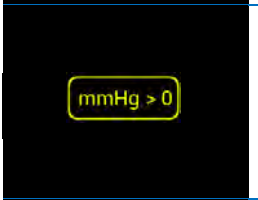
DEFLATE
Button / Slider

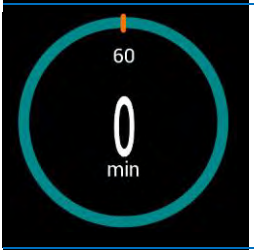
	Feature	What it does
1	**Touch Screen GUI**	Touchscreen based graphical user interface (GUI) for interacting with and controlling most of the *PTS ii*'s functions
2	**Status Indicator**	Indicates the status of the *PTS ii* Blue – Charging Red Constant – Technical alarm Red Flashing – High priority alarm 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 limb protection material 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 ii* 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 ii hose assembly (see below) leading to cuffs with female Positive Locking Connectors plugs in to the *PTS ii* at the hose connector. The hose connector makes an audible 'click' when properly connected
5	**Hose Assembly**	A PTS ii hose assembly is supplied with each *PTS ii*. The male connector on the hose plugs into the female Positive Locking Connector on the *PTS ii* (see above). The other end of the hose has a female Positive Locking Connector that plugs into cuffs with female Positive Locking Connectors. The *PTS ii* is designed, tested, and recommended for use with single port cuffs having Positive Locking Connectors only. Use with supplied PTS ii hose assembly only. An adapter is available for connecting the PTS ii unit to calibration equipment. To engage the Positive Locking Connector, fully depress and then release the 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 locking button. Carefully separate the connector while holding the metal locking button. Excessive force is not required. To prevent O-

	Feature	What it does
		ring damage the metal locking button must always be in the open position before connectors are engaged or disengaged
6	**Power Receptacle**	The power receptacle is located on the left of the battery compartment from a rear view of the *PTS ii*. The *PTS ii* 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 ii*. It is a sealed unit designed specifically for the *PTS ii*. Contact Zimmer Surgical 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 ii* (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 ii* 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 ii*. 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 ii* to a pole mounting bracket (REF 60-1000-211-00). Use only Zimmer Surgical (REF 60-1000-211-00) bracket.
11	**Battery Compartment**	Compartment that holds the *PTS ii* battery
12	**Pole Mount Bracket**	Used to secure the *PTS ii* to a mobile IV pole (REF 60-1000-211-00)

TOUCHSCREEN BUTTONS AND ICONS

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

Button/Indicator	Title	Description
	**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 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 colored bars
	**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

Button/Indicator	Title	Description
	**PRESSURE Button / Indicator**	Indicates the current cuff pressure in the center of the **PRESSURE** indicator The scale of the **PRESSURE** indicator is indicated by the orange lower scale and upper scale markers The pressure set-point is indicated by the green marker **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**	Indicates the inflation time in the center of the **TIME** indicator Touch to adjust the inflation time set-point **NOTE:** When cuff is inflated, inflation time will count up. When inflation time reaches the inflation time set-point, the Time Up alarm will be triggered
	**INFLATE Button**	Touch to inflate cuff
	**SETTINGS Button**	Touch to access the Leak Test and System Defaults Menu buttons
	**LEAK TEST Button**	Touch to conduct leak test
	**SYSTEM DEFAULTS Button**	Touch to view and adjust system defaults settings

Button/Indicator	Title	Description
	**DEFLATE Button / Slider**	Touch and slide the **DEFLATE** button to the left side of the **DEFLATE** slider and hold for ~1 second to deflate cuff
	**STOP Button**	Touch to stop 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
	**SCROLL RIGHT Button**	Touch to scroll right. Only used in Calibration Mode
	**SCROLL LEFT Button**	Touch to scroll left. Only used in Calibration Mode

OPERATING INSTRUCTIONS

2

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 Zimmer Surgical (REF 60-1000-213-00) AC power supply and cord assembly supplied with your *PTS ii*. 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 ii*, 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

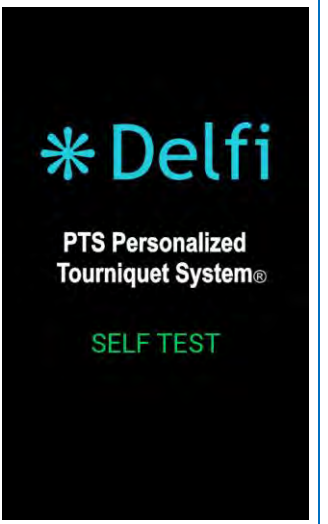
WARNING: Use only a Zimmer Surgical (REF 60-1000-210-00) NiMh battery pack with your *PTS ii.* Do not use any other battery pack. Use of an improper battery pack may cause irregular operation that could be hazardous to the patient and/or user, and may permanently damage the *PTS ii*, voiding the warranty

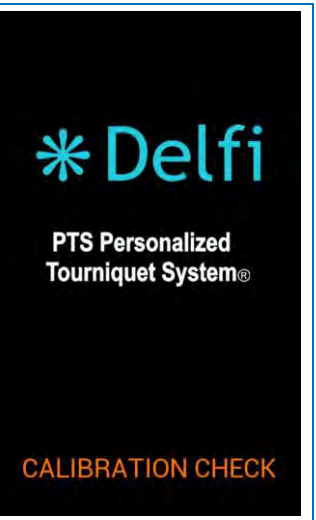
TESTS AND CHECKS

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 3 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 ii*, 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, PTS Personalized Tourniquet System are displayed • "SELF TEST" will displayed followed by "CALIBRATION CHECK"	

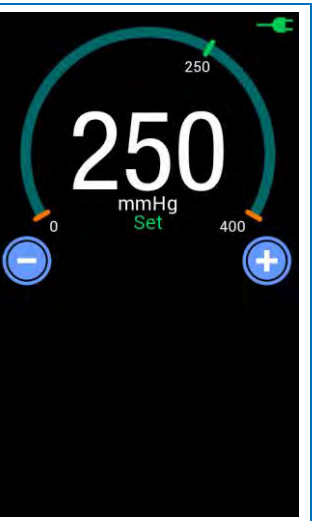


After the startup routine is completed, the Main Screen appears

- "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 3 Maintenance**
- The default pressure set-point is indicated by the green marker on the **PRESSURE** indicator

MANUAL TESTS AND CHECKS

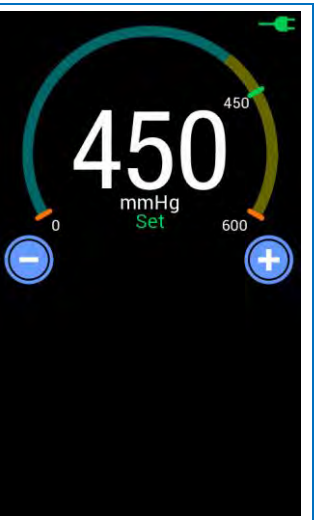
These manual tests and checks verify certain System Functions and include Pressure and Time set-point tests and Calibration and Low-Pressure Alarm checks.

1	**Pressure Set-Point Adjustment Test:** • Enter the pressure adjustment mode by touching the **PRESSURE** button • The **PRESSURE** indicator should read "250" (the factory default set-point) • Touch the **DECREMENT** button to decrease or the **INCREMENT** button to increase the pressure set-point **NOTE:** If the **INCREMENT** or **DECREMENT** button is touched, the set-point will change by 1 mmHg. If the button is held, the set-point will change by 5 mmHg. **NOTE:** The pressure set-point can be maintained between 20 mmHg and 400 mmHg while in the "normal pressure range". The pressure set-point can be maintained up to 600 mmHg while in the "extended pressure range". See below.	
2	**Extended Pressure Set-Point Adjustment Test:** • Attempt to increase the pressure set-point to above 400 mmHg. A confirmation message "SET ABOVE 400 MMHG?" will appear. • Touch the **CONFIRM** button to enter extended pressure range (up to 600 mmHg) **NOTE:** Touching the **CANCEL** button to remain in the normal pressure range (up to 400 mmHg)	

- Touch the **DECREMENT** button to decrease the pressure set-point to 250 mmHg

NOTE: If the pressure set-point is below 400, the instrument will automatically return to the normal pressure range (up to 400 mmHg)

- Touch the **PRESSURE** button, or wait approximately 10 seconds to return to the Main Screen



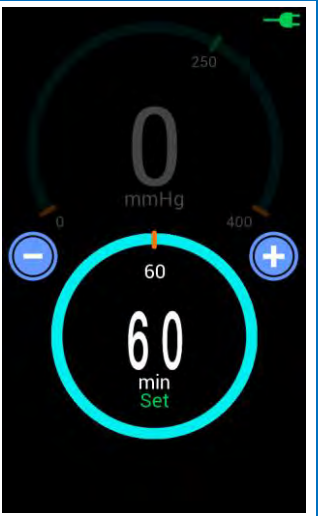
3 **Time Set-Point Adjustment Test:**

- Enter the time adjustment mode by touching the **TIME** button
- The **TIME** indicator should read “60” (the factory default set-point)
- Touch the **DECREMENT** button to decrease or the **INCREMENT** button to increase the time set-point

NOTE: If the **INCREMENT** or **DECREMENT** button is touched, the set-point will change by 1 min. If the button is held, the set-point will change by 5 min.

NOTE: The time set-point can be adjusted between 5 min and 240 min

- Touch the **TIME** button, or wait approximately 10 seconds to return to the Main Screen

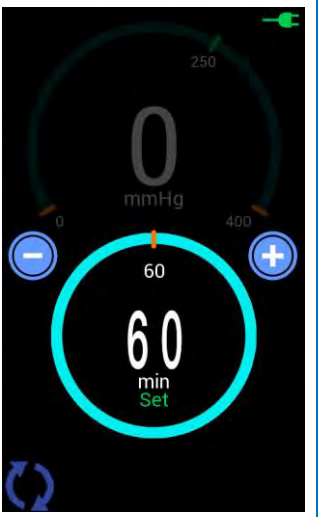


4 **Low Pressure Alarm Test:**

- Connect the PTS ii hose assembly and a cuff to the *PTS ii*
- 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 ii* 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:
  1. The **LOW-PRESSURE WARNING** indicator appears above the displayed pressure
  2. The displayed pressure is yellow
  3. The **WARNING** indicator appears
  4. 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

5 **Reset Inflation Time:**

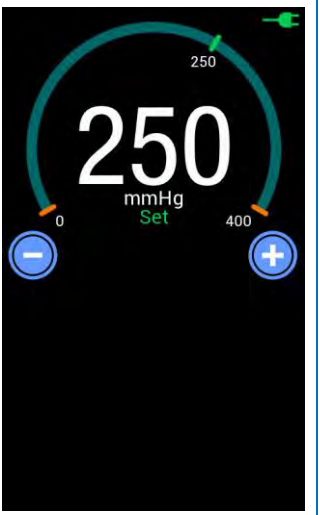
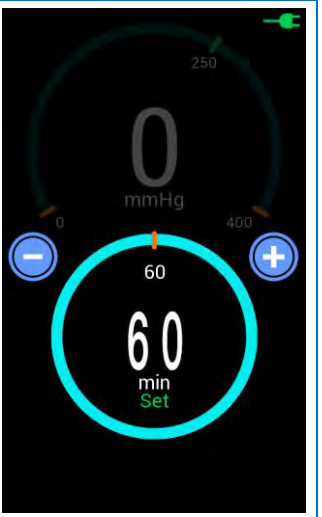
- Enter the time adjustment mode by touching the **TIME** button
- Touch the **RESET** button



	• Touch the **CONFIRM** button to reset the inflation time **NOTE**: Touching the **CANCEL** button to keep the existing inflation time	

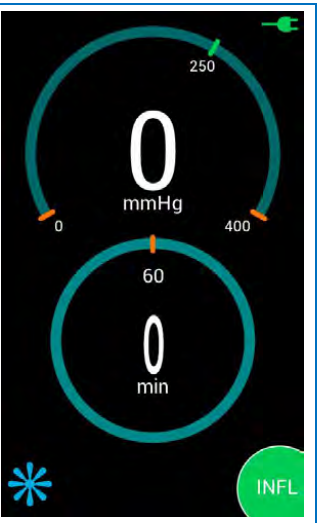
OPERATION

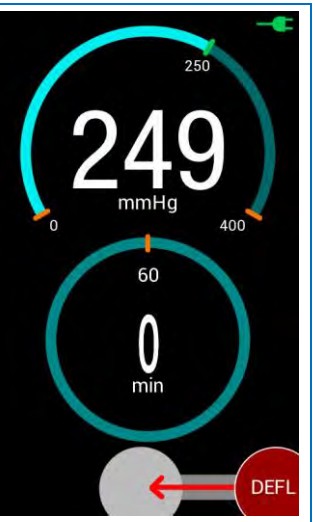
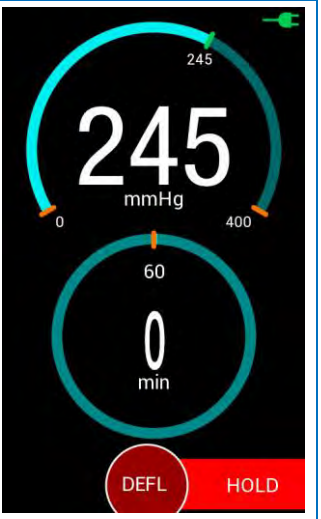
1	**Physician's Decision**: Physician's discretion will be used to determine the following: • What pressure set-point to use • How long to apply the tourniquet cuff • When to inflate the tourniquet cuff
2	**Patient Preparation**: Prepare the patient in accordance with your established procedures and manufacturer's cuff utilization instructions. Ensure that the chosen tourniquet cuff's specified maximum pressure is greater than the pressure set point to use. 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
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 ii hose assembly and a tourniquet cuff with Positive Locking connector to the unit at

	the hose connector	
	WARNING: Do not allow foreign objects from entering the *PTS ii,* the hose assembly, or the cuff. This could damage/affect the performance of the PTS ii system	
4	**Selecting a Pressure Set-Point**: • Enter the pressure adjustment mode by touching the **PRESSURE** button • Touch the **DECREMENT** button to decrease or the **INCREMENT** button to increase the pressure set-point	
	NOTE: If the **INCREMENT** or **DECREMENT** button is touched, the set-point will change by 1 mmHg. If the button is held, the set-point will change by 5 mmHg.	
	• Refer to **Manual Tests and Checks** under **Section 2 Operating Instructions** on how to increase the pressure set-point above 400 mmHg • Touch the **PRESSURE** button, or wait approximately 10 seconds to return to the Main Screen	
5	**Selecting a Time Set-Point:** • Enter the time adjustment mode by touching the **TIME** button • The **TIME** indicator should read “60” (the factory default set-point) • Touch the **DECREMENT** button to decrease or the **INCREMENT** button to increase the time set-point	
	NOTE: If the **INCREMENT** or **DECREMENT** button is touched, the set-point will change by 1 min. If the button is held, the set-point will change by 5 min.	
	NOTE: The time set-point can be adjusted between 5 min and 240 min in increments of 1 min	
	• Touch the **TIME** button, or wait approximately 10 seconds to return to the Main Screen	

6 **Inflating the Cuff:**

- When instructed by the physician, touch the **INFLATE** button to inflate the cuff to the pressure set-point (top image)
- The **DEFLATE** button and slider will appear after the **INFLATE** button is touched (bottom image).



7	**Deflating the Cuff:** • When instructed by the physician, deflate the cuff as follows: 1. Touch and hold the **DEFLATE** button	
	NOTE: An animation of a red arrow pointing towards a grey circle at the left of the **DEFLATE** slider will appear while the **DEFLATE** button is pressed	
	2. Drag the **DEFLATE** button to the left of the **DEFLATE** slider	
	NOTE: Once the **DEFLATE** button is overlapping the grey circle, a "HOLD" message will be visible on the **DEFLATE** slider. If the **DEFLATE** button is held for ~1 second while the "HOLD" message is visible, the instrument will deflate the cuff	
	3. Hold the **DEFLATE** button for ~1 second	

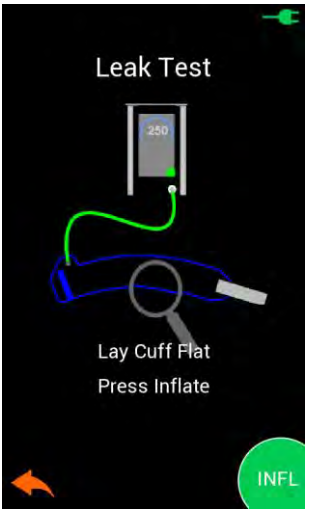
SETTINGS

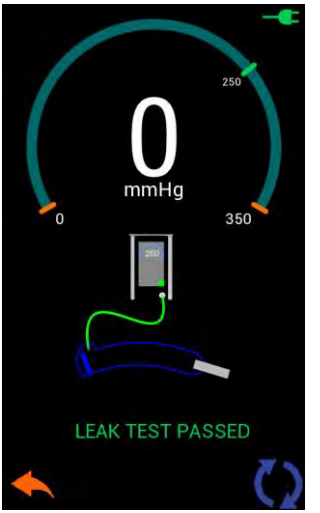
Settings options include performing a leak test, and modifying system defaults. To access the Settings Menu, touch the **SETTINGS** button from the Main Screen.

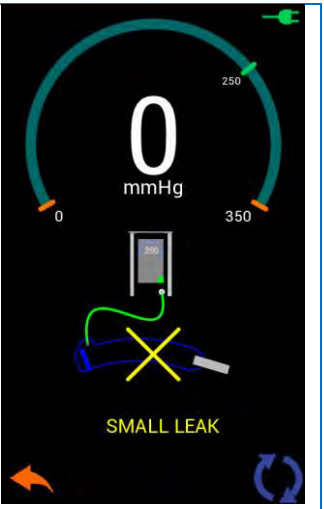
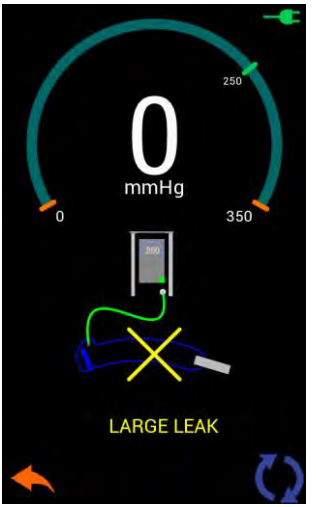
NOTE: Settings Menu is not accessible while the cuff is inflated

LEAK TEST

The *PTS ii* 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:

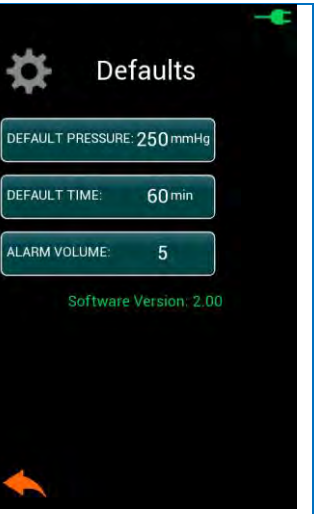
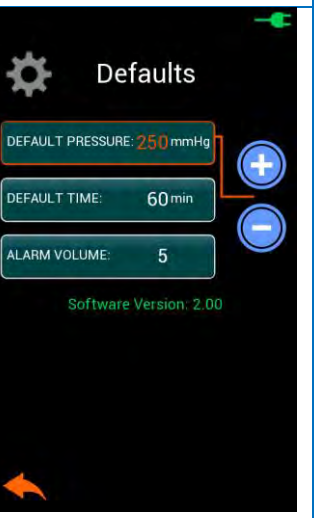
1	**Setting Up for a Leak Test:** • Touch the **LEAK TEST** button from the Settings Menu to access the leak test • Connect a cuff and hose to the *PTS ii*. Keep the cuff open and flat • Touch the **BACK** button to exit the leak test and return to the Main Screen as necessary	

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 ii* internal pneumatics. Repeat the test with a variety of different cuffs and hose assemblies. If the unit continues to fail, the leak is internal, and the *PTS ii* 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 ii* internal pneumatics. Repeat the test with a variety of different cuffs and hose assemblies. If the unit continues to fail, the leak is internal, and the *PTS ii* 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 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	
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 ii* 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.	

ALARM AND WARNING CONDITIONS

There are a number of conditions for which the *PTS ii* 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 and warning 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.

The alarm and warning conditions, indications, and appropriate actions are shown in the **ALARM AND WARNING CONDITIONS** table under **Section 2 Operating Instructions**. The *PTS ii* 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.

STATUS INDICATOR 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.

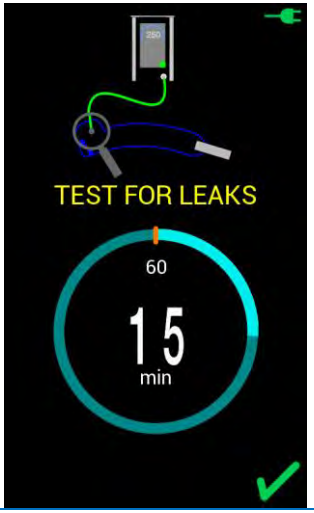
VISUAL AND AUDITORY ALARM PRIORITY

STATUS Indicator Light	Auditory Priority Tone	Auditory Pulse Pattern	Comments
Constant Red	Technical	1 tone pulse per burst	Indicates technical failure.
Flashing Red	High	10 tone pulses per burst	Indicates immediate operator response is required. Fastest auditory indicator tone pulse speed.
Flashing Yellow	Medium	3 tone pulses per burst	Indicates prompt operator response is required. Baseline auditory indicator tone pulse speed.
Constant Yellow	Low	2 tone pulses per burst	Indicates operator awareness is required. The auditory indicator tone pulse is slower than either Medium, High, or Technical priority.

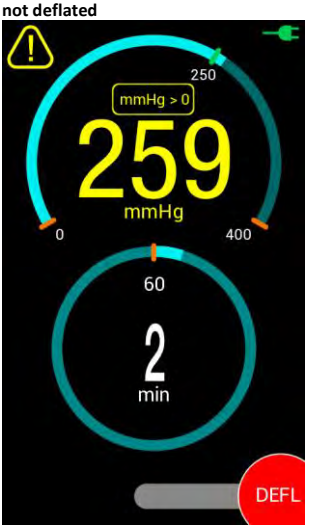
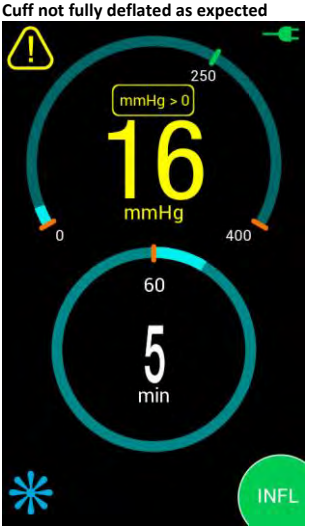
ALARM AND WARNING CONDITION, AND ERROR CODE TABLES

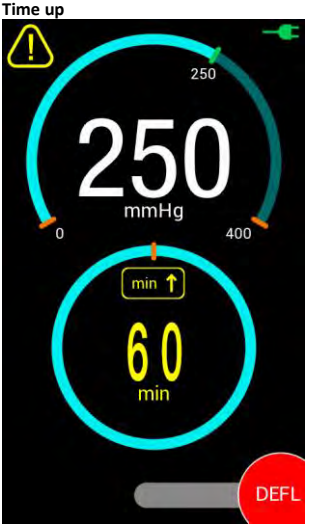
Alarm Conditions are accompanied by a warning message and sometimes Error Codes along with a **Status** Indicator Light and audible Priority Tone as detailed in the **ALARM AND WARNING CONDITIONS** table below. Error Codes are detailed in the **ERROR CODES** table below.

ALARM AND WARNING CONDITIONS

Conditions	Status Indicator Light	Auditory Priority Tone	Remarks and Appropriate Actions
Test for Leaks 	-	-	• This warning is only given when the cuff is deflated • If during the time that a cuff is inflated, the PTS ii detects minor leakage from the cuff, hose, or connectors, this warning is given. • Touch the **OK** button to clear the warning message • Inspect the cuff, hose, and connectors for damage. Perform a leak test (Refer to **Leak Test** under **Section 2 Operating Instructions**)
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 ii* 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
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 ii* may require servicing • Alarm will stop automatically whenever the unit can regulate the cuff to within 15 mmHg of the pressure set-point
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 • Connections, hose, and cuff should be checked and the leak repaired, OR • Reduce pressure set-point until unit can maintain pressure, OR • Deflate the cuff (Refer to Section 7 of **Operation** under **Section 2 Operating Instructions**) • If this condition persists without apparent cause, the *PTS ii* may require servicing

Conditions	Status Indicator Light	Auditory Priority Tone	Remarks and Appropriate Actions
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 • Deflate the cuff (Refer to Section 7 of **Operation** under **Section 2 Operating Instructions**), then press **ON/STANDBY** button to set the unit to STANDBY
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

Conditions	Status Indicator Light	Auditory Priority Tone	Remarks and Appropriate Actions
Time up 	Flashing Yellow	Medium	• The unit's elapsed timer, which advances when the cuff is inflated, has reached the time set-point and caused the time alarm to activate • The physician should be warned of the time up condition. Only on the direction of the physician, should the time set-point be set to a new value • Touch the **TIME** indicator and increase the time set-point, OR • Deflate the cuff (Refer to Section 7 of **Operation** under **Section 2 Operating Instructions**)
Battery is low 	Constant Yellow	Low	• The battery voltage has dropped to a level 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 Voltage Alarm Condition other alarm conditions cannot be guaranteed

Conditions	Status Indicator Light	Auditory Priority Tone	Remarks and Appropriate Actions
Battery fail 	Constant Red	Technical	• The battery voltage has dropped below the threshold of safe operation and 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 3 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 ii* requires calibration service. Refer to **Calibration** under **Section 3 Maintenance**

Conditions	Status Indicator Light	Auditory Priority Tone	Remarks and Appropriate Actions
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 Zimmer Surgical

*In the 'safe state' mode, the pneumatic valve is closed to maintain cuff pressure.

ERROR CODES

Error Code	Problem	Possible Causes and Corrective Actions
E0000 to E0008 **E0012 to E0014** **E0026 to E0027**	Internal electronics failures	› The unit detected a failure related to the internal electronics › Physically separate ESU, ESU pencil and ESU cable from the *PTS ii* and PTS ii power adapter (E0004) › 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 Zimmer Surgical
E0016 to E0019	Calibration failures	› The unit detected a failure related to calibration › Calibrate the unit. Refer to **Calibration** under **Section 3 Maintenance** › If problem persists, note error code and the accompanied numeric code (if any) and contact Zimmer Surgical
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 3 Maintenance** › If problem persists, note error code and the accompanied numeric code (if any) and contact Zimmer Surgical

Error Code	Problem	Possible Causes and Corrective Actions
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 Zimmer Surgical

ELECTROMAGNETIC COMPATIBILITY (EMC) GUIDANCE TABLES

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

EMC GUIDANCE AND DECLARATION - EM EMISSIONS

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The PTS ii Personalized Tourniquet System is intended for use in the electromagnetic environment specified below. The user of the *PTS ii* should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guidance**
RF emissions CISPIR 11	Group 1	The system's RF emissions are very low, therefore, are not likely to cause interference in nearby electronic equipment.
RF emissions CISPIR 11	Class A	The *PTS ii* is suitable for use in all establishments other than those directly connected to the public low voltage power supply network that 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 ii Personalized Tourniquet System is intended for use in the electromagnetic environment specified below. The customer or the user of the *PTS ii* 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	± 6 kV contact ± 8 kV air	±6 kV Contact Discharge, VCP, HCP ±8 kV Air Discharge	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	±2 kV on AC Mains ±1 kV on I/O Ports	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, ±2kV CM Line-Gnd ±0.5 kV, ±1 kV, DM Line-Line NA on I/O Ports	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	<5 % *UT* (>95 % dip in *UT*) for 0,5 cycle 40 % *UT* (60 % dip in *UT*) for 5 cycles 70 % *UT* (30 % dip in *UT*) for 25 cycles <5 % *UT* (>95 % dip in *UT*) for 5 s	>95%, 5 periods (100ms) 30%, 25 periods (500ms) 60%, 50 periods (1 sec) >95%, 250 periods (5 sec)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *PTS ii* requires continued operation during power mains interruptions, it is recommended that the *PTS ii* 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/60Hz 3 orthogonal orientations	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: *UT* is the a.c. mains voltage prior to application of the test level.			

EMC GUIDANCE AND DECLARATION - EM EMISSIONS/RF

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The PTS ii Personalized Tourniquet System is intended for use in the electromagnetic environment specified below. The customer or the user of the *PTS ii* 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3Vrms 3V/m,	Portable and mobile RF communications equipment should be used no closer to any part of the *PTS ii*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 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: 
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 ii Personalized Tourniquet System is used exceeds the applicable RF compliance level above, the PTS ii Personalized Tourniquet System 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 ii Personalized Tourniquet System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [*V*1] V/m.

EMC GUIDANCE AND DECLARATION – IMMUNITY/SEPARATION DISTANCES

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

The PTS ii Personalized Tourniquet System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *PTS ii* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *PTS ii* 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.

MAINTENANCE

3

GENERAL MAINTENANCE INFORMATION

While the *PTS ii* 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 ii*. The *PTS ii* is not designed to be disassembled and serviced by anyone other than Zimmer Surgical staff. Disassembly and attempted service by anyone other than Zimmer Surgical 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 ii* can only be serviced at the factory by Zimmer Surgical staff. Please contact Zimmer Surgical if you have problems with your *PTS ii* 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.

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

CAUTION: Do not attempt to clean or flush out the interior of the PTS ii hose assembly. Do not allow fluids or debris to enter the hose connectors on the *PTS ii* or the PTS ii 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 ii*
- Secure connection and locking of the hose connectors on the *PTS ii* to the PTS ii hose assembly
- Kinks or damage in the PTS ii 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

3

CALIBRATION

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

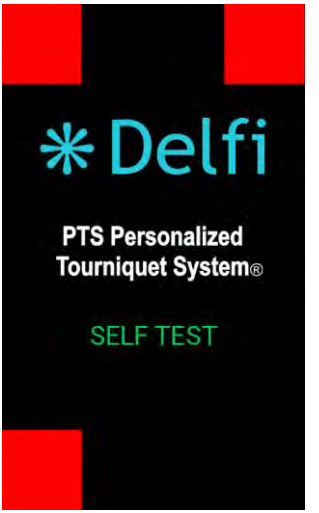
Calibration of the *PTS ii* allows the output signal from the pressure transducers to be compared against a calibrated pressure source. The difference between the known pressure and the pressure measured by the transducers is recorded at each of four set-points, and these four calibration factors are 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: An adapter is available for connecting the PTS ii unit to calibration equipment.

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 ii,* 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 ii* 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.

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 cuff transducers. If the calibration is suspected of being out of specification, complete the calibration per **Calibration** under **Section 3 Maintenance**. This section will allow the cuff transducers to be checked without changing or modifying the saved calibration.

1	**Setting Up the Calibration Check:** • Connect the PTS ii hose assembly to the *PTS ii*, then connect the hose to 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: An adapter is available for connecting the PTS ii unit to calibration equipment.
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 ii* 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, the unit must be calibrated. Refer to **Calibration** under **Section 3 Maintenance** for instructions on calibration

3	**Calibration Check (250 mmHg, 400 mmHg, and 600 mmHg):** • Repeat the previous step for 250 mmHg, 400 mmHg, and 600 mmHg
	NOTE: If any stabilized pressure reading is off by more than 5 mmHg during the calibration check, the unit must be calibrated. Refer to **Calibration** under **Section 3 Maintenance** for instructions on calibration
4	**Calibration Check (0 mmHg):** • Touch the **DEFLATE** button to deflate the unit. Disconnect the hose from the *PTS ii*. 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 3 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 ii* 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 ii* internal pneumatics. Repeat the test with a variety of different cuffs and hose assemblies. If this condition persists, the leak is internal, and the *PTS ii* will require servicing

BATTERY TESTING AND REPLACEMENT

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

A new battery pack is designed to run the *PTS ii* without AC power for up to 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. **For best battery performance when operating the unit primarily on battery, allow the battery to discharge to a low level before recharging.** Battery replacement will need to be more frequent with continued cycles of deep discharge and/or storage at high temperatures. Infrequent short-term use of the battery and storage at room temperature or lower will result in maximum life.

The *PTS ii* 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 ii* must be ON with no AC power connected. When ON under battery power, the **BATTERY STATUS** indicator appears. When the colored bar completely fills the **BATTERY STATUS** indicator, the battery has a full charge. Reducing length of the bar and the change in color from green to orange to yellow to red progressively indicate decreasing battery capacity and the need for recharging.

MAINTENANCE

3

NOTE: It is recommended that the battery in the *PTS ii* be tested as described below every 3 months and replaced annually. Even when the *PTS ii* 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 ii*. The **BATTERY STATUS** indicator should be completely filled with 5 green bars
2	• Connect the *PTS ii* to a tourniquet cuff and inflate to 350 mmHg
3	• If only one red segment shows after 1 hour, 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 ii* 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 ii* 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 ii* (directly above the label) and remove the battery cover
- Unplug the battery by pulling the battery wires straight up from the battery compartment and remove the old battery pack. This will disconnect the battery connector from the four-pin plug inside the *PTS ii*. **Recycle or dispose of the old battery pack in accordance with local regulations and procedures**
- Install the new battery pack supplied by Zimmer Surgical by aligning the keyed plug and pushing the connector onto the four-pin plug inside the *PTS ii*. Push the connector all the way down until it stops. The top of the connector will be about flush with the battery compartment surface. The connector cannot be installed the wrong way; if it will not slide easily all the way down, rotate it one-half turn and try again

- **WARNING:** Use only Zimmer Surgical NiMh battery packs (REF 60-1000-210-00). 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 ii*, voiding the warranty

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

MAINTENANCE

3

INTERNAL HARDWARE SERVICING

The *PTS ii* 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 Zimmer Surgical for service advice.

CAUTION: Do not attempt to disassemble or open the enclosure of your *PTS ii*. The *PTS ii* is not designed to be disassembled and serviced by anyone other than Zimmer Surgical staff. Disassembly and attempted service by anyone other than Zimmer Surgical 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 ii* can only be serviced at the factory by Zimmer Surgical staff. Please contact Zimmer Surgical if you have problems with your *PTS ii* 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 "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 Zimmer Surgical
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 Zimmer Surgical
Cuff does not deflate	**DEFLATE** slide not engage	Engage the **DEFLATE** slider. Refer to **Operation Step 7** under **Section 2 Operating Instructions**
	Hose kinked or blocked	Unkink hose or disconnect cuff from hose. Ensure complete cuff deflation to clear CUFF NOT

Malfunction	Possible Causes	Corrective Actions
	Internal hardware failure	DEFLATED alarms Contact Zimmer Surgical
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 ii*	Ensure connector is fully engaged
	Incorrect AC power supply assembly	Ensure AC power adapter is the one supplied with the *PTS ii*
	AC power supply not working	Contact Zimmer Surgical
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 Zimmer Surgical
STATUS indicator does not illuminate during alarm conditions	**STATUS** indicator not working	Confirm that **STATUS** indicator illuminates during self-check upon power-up. Contact Zimmer Surgical
No cuff pressure and/or tourniquet time reading	Faulty pressure/time display	Confirm that all segments of the display illuminate during self-check upon power-up
	Internal hardware failure	Contact Zimmer Surgical
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 3 Maintenance**
	Internal hardware failure	Disconnect *PTS ii* from cuff to deflate cuff if required. Contact Zimmer Surgical
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 3 Maintenance**

Malfunction	Possible Causes	Corrective Actions
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 3 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 Zimmer Surgical. Unit can be powered OFF by unplugging the AC power and removing the battery pack. Refer to **Battery Testing and Replacement** under **Section 3 Maintenance**

ADDITIONAL POWER CORDS

Description	Unit	Zimmer Surgical Part Number
Power Cord, JIS 8303 (for PTS ii)	1/ea	60-1000-214-00
Power Cord, GB 20991 (for PTS ii)	1/ea	60-1000-215-00
Power Cord, BS 546 (for PTS ii)	1/ea	60-1000-216-00
Power Cord, AS NZS 3112 (for PTS ii)	1/ea	60-1000-217-00
Power Cord, BS 1363 (for PTS ii)	1/ea	60-1000-218-00
Power Cord, CEE 7 (for PTS ii)	1/ea	60-1000-219-00
Power Cord, Malaysia (for PTS ii)	1/ea	60-1000-225-00

CONTACT INFORMATION

For sales and servicing inquiries, contact your Zimmer Surgical distributor or Zimmer Surgical:

Mail	Telephone	Website
Zimmer Surgical 200 West Ohio Avenue Dover OH USA 44622	330.343.8801	www.ZimmerBiomet.com

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

WARNINGS, CAUTIONS & SYMBOLOGY

4

WARNINGS, CAUTIONS & SYMBOLOGY

Below are graphical warning, caution and other symbols indicated on the *PTS ii* and within this manual:

Graphic	Description
	Type B Medical Equipment
	Refer to instruction manual / booklet
	Consult instructions for use
	Federal law (USA) restricts this device to sale by or on the order of a physician
	Signifies a general warning
	Caution
	Indicates hazards arising from dangerous voltages
	Keep Dry
	Indicates suitability for alternating current only
	Indicates suitability for direct current only

WARNINGS, CAUTIONS & SYMBOLOGY

4

Graphic	Description
	Indicates manufacturer and is accompanied by the name and address of the manufacturer
	cTUVus: Medical Equipment with respect to electrical shock, fire and mechanical hazards and electromagnetic compatibility only. In accordance with CAN/CSA – C22.2 No. 60601:14, ANSI/AAMI ES60601-1:2005 and A2 (R)2012 and A1. QAI Laboratories: Medical Equipment with respect to electromagnetic compatibility only. In accordance with ANSI/AAMI/IEC 6060-1-2:2014.
	Indicates catalog, reorder or reference number
	Indicates equipment serial number
	Indicates medical device
	Indicates unique device identifier

Distributed by:

Zimmer Surgical

200 West Ohio Avenue

Dover, Ohio 44622

(330) 343-8801

ZimmerBiomet.com

Printed in Canada
4-2200-025Z Rev 5 2022-08-22