Operator & Service Manual



Zimmer A.T.S.® 3000 AUTOMATIC TOURNIQUET SYSTEM REF 60-3000-101-00



LIMITED ONE YEAR WARRANTY (U.S.A.)

SCOPE OF LIMITED WARRANTY

Zimmer, Inc. warrants the Product (*A.T.S.* 3000 Tourniquet System) for one year from date of purchase. During the warranty period, Zimmer 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 this Limited Warranty are the exclusive remedies for breach of warranty. **THIS WARRANTY SHALL NOT APPLY TO ANY PRODUCT WHICH HAS BEEN ALTERED OR MODIFIED IN ANY WAY, OR WHICH HAS BEEN SUBJECTED TO MISUSE OR ABUSE.**

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In no case shall Zimmer, Inc. be liable for any special, incidental, or consequential damages whether based on breach of warranty or other legal theory whether or not such damages are foreseeable. 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:

- Notify Customer Service Department, Zimmer Orthopaedic Surgical Products, at 1-800-348-2759 or contact your local Zimmer representative. Please provide details about the nature of the problem and include the product serial number. Upon receipt of this information, Zimmer will provide a date for service or 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 assure that you receive prompt warranty service for your product.

WARRANTY (OUTSIDE U.S.A.)

Please contact your local Zimmer Representative for warranty information.

Unit Serial Number _____

ENGLISH

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GENERAL INFORMATION SECTION 1.0

ZIMMER A.T.S. 3000 AUTOMATIC TOURNIQUET SYSTEM

1.1 SPECIFICATIONS

Mains Line Voltage Range:

100–240V ~ (AC), 50/60 Hz. Auto switching **Line Current:**

670 mA RMS @ 120V ~ (AC)

Input Power:

53 Watts typical

Battery Type:

Rechargeable, 12 VDC sealed lead acid,

4.0 amp hours

Battery Discharge Time:

Unit will operate on battery power for 240 minutes minimum with a fully charged battery.

Battery Recharge Time:

24 hours

Unit should be plugged in 24 hours before initial use.

Power Cord:

Type SJT, AWG 16, 14 ft. (4.27 m)

Power Plug: Hospital grade, 3 prong straight blade, 15 amp

Line Protection: 2 time delayed 1.0 amp 250 volt fuses

CONTROLS:

ON/STANDBY Button:



Turns the unit ON / sets unit to STANDBY.

Pressure Button: **Pressure**



Used in conjunction with the shuttle knob to adjust the pressure set point. Can also be pressed to verify the set point. The Main Cuff and Second Cuff have separate Pressure buttons. Time Button: Time

Used in conjunction with the shuttle knob to adjust the time alarm set point. Can also be pressed to verify the set point. The Main Cuff and Second Cuff have separate Time buttons.

Cuff Inflate / Deflate Buttons: INFLATE



Controls inflation or deflation of the respective cuff. The Main Cuff and Second Cuff have separate Inflate / Deflate buttons.

Alarm Silence Button:



Allows operator to manually silence <u>most</u> alarms for 30 seconds.

Limb Occlusion Pressure (LOP) Button:



Controls the LOP feature. When the pulse sensor is in place and cuff applied, pressing this button will start the process to measure the patient's LOP and give the user a recommended tourniquet pressure (RTP).

AC Indicator Light Icon (Green LED):



Indicates unit is operating on AC Mains. This is the normal means of operation (battery power is only intended for emergency power loss or patient transport).

Battery Indicator Light Icon (Orange LED):



Indicates unit is operating on backup battery. This indicator always flashes.

Alarm Indicator Light Icon (Red LED):



Visual indicator to show the unit is in an alarm condition.

LOP Heart Indicator Icon (Yellow LED):



Cuff Pressure Range: 50–475 mmHg, 1 mmHg increments

Pressure Accuracy: ±3 mmHg (50–475 mmHg)

Pressure Regulation: ±4 mmHg of set point (10 second average under non-transient conditions without external leaks)

Maximum Pressure: 475 mmHg cuffs

+75 mining cuits

Time Alarm Set Range: 5–240 minutes; 1 minute increments

Timer Accuracy: 0.25% of elapsed time

Internal Diagnostics: Program, memory, watchdog timer, transducer calibration,

improper valve actuation.

SIZE:

Height: 13.0 in. (33.02 cm) Width: 9.5 in. (24.1 cm) Depth: 10.375 in. (26.35 cm) (including clamp and ports) Weight: 16.3 lbs. (7.4 Kg)

DISPLAYS:

The A.T.S. 3000 uses a backlit 1/4 panel LCD.

<u>Pressure Display</u>: Displays pressure setting, sensed cuff pressure, and hardware failure conditions / other messages.

<u>Time Display</u>: Displays time alarm set point, elapsed time, and hardware failure conditions / other messages.

Visual indicator to show the LOP function has been invoked.

UL 60601-1 Classification:

Type of protection against electric shock:	Class I or Internally Powered Equipment*
Degree of protection against electric shock:	Type BF applied part
Classification according to the degree of protection against ingress of water:	IPX0
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.

This device is <u>not</u> suitable for use in the presence of flammable anesthetic or gases.

Emissions/Immunity:

The A.T.S. 3000 Tourniquet System complies with EMC criteria set forth in EN 60601-1-2.

Patents:

* U.S. Patents 5,439,477; 5,556,415; 5,607,447; 5,855,589; 5,911,735; 5,931,853; 6,213,939 B1

1.2 INTENDED USE

The *A.T.S.* 3000 Tourniquet System is intended to be used by qualified medical professionals to temporarily occlude blood flow in a patient's extremities during surgical procedures on those extremities. Tourniquets have been found useful in producing a bloodless operation field in surgical procedures involving the extremities including:

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

WARNING: Do not use tourniquet cuffs to control the distal flow of CO_2 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.

1.3 CONTRAINDICATIONS

The medical literature lists the following as possible contraindications. However, in every case, the final decision whether 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 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

The presence of sickle cell disease is a relative contraindication. (See PRECAUTIONS IN USE.)

A tourniquet should also be avoided in patients who are undergoing secondary or delayed procedures after immobilization.

1.4 PRECAUTIONS IN USE

• 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. Cuffs with inner rubber bladders must be completely enclosed by the outer envelope to preclude ballooning and possible rupture of the bladder. Cleaning and assembly instructions of the cuff manufacturer should be followed carefully.

• 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.

• The tourniquet cuff must be applied in the proper location on the limb, for a "safe" period of time, and within an appropriate pressure range. Never apply a tourniquet over the area of the peroneal nerve or over the knee or ankle. Do not readjust an already inflated cuff by rotating it because this produces shearing forces which may damage the underlying tissue.

• Prolonged ischemia may lead to temporary or permanent damage to tissues, blood vessels, and nerves. Tourniquet paralysis may result from excessive pressure. Insufficient pressure may result in passive congestion of the limb with possible irreversible functional loss. Prolonged tourniquet time can also produce changes in the coagulability of the blood with increased clotting time.

• Inflation should be done rapidly to occlude arteries and veins as near simultaneously as possible.

◆ Careful and complete exsanguination reportedly prolongs pain free tourniquet time and improves the quality of Intravenous Regional Anesthesia, (Bier Block anesthesia). In the presence of infection and painful fractures, after the patient has been in a cast, and in amputations because of 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.

• In case of failure, the tourniquet cuff must be fully deflated and the limb exsanguinated again before reinflation. Reinflation over blood-filled vasculature may lead to intravascular thrombosis.

• Tourniquet users must be familiar with the inflationdeflation sequence when using a dual-cuff tourniquet or two tourniquet cuffs together for IVRA (Bier Block anesthesia), so that the wrong tourniquet will not be released accidentally.

• 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 PO_2 and pH should be closely monitored.

• Select the proper cuff size to allow for an overlap of about 3 to 6 in. (7.6–15 cm). Too much overlap may cause cuff rolling and telescoping, and may lead to 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. As an under padding, a section of stockinette may be used. **The deflated cuff and any underlying bandage or protective sleeve should be completely removed as soon as tourniquet pressure is released. After the cuff has been fully deflated and removed from the patient, the unit can be set to STANDBY.** Even the slightest impedance of venous return may lead to congestion and pooling of blood in the operative field.

• If skin preparations are used preoperatively, they should not be allowed to flow and collect under the cuff where they may cause chemical burns.

◆ 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.

• Whenever IVRA, Bier Block anesthesia, is used, it is recommended that the tourniquet remain inflated for at least 20 minutes from the time of injection.

• WARNING: Cuffs will not deflate in STANDBY mode. Ensure cuffs are fully deflated before setting the unit to STANDBY.

1.5 ADVERSE EFFECTS

A dull aching pain (tourniquet pain) may develop throughout the limb following 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:

- 1. By the slight impeding effect exerted by an unpressurized cuff (and its padding, if used), which prevents venous return at the beginning of the operation.
- 2. By blood remaining in the limb because of insufficient exsanguination.
- 3. By 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.
- 4. By blood entering through the nutrient vessels of the long bones, such as the humerous.

INSTALLATION AND OPERATING INSTRUCTIONS

SECTION 2.0

ZIMMER A.T.S. 3000 AUTOMATIC TOURNIQUET SYSTEM

2.1 INITIAL INSPECTION

Unpack the *A.T.S.* 3000 Tourniquet 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 your Zimmer representative immediately. If the initial inspection results are satisfactory, a functional and calibration check should be performed <u>after a 24-hour charge</u>. The attention label covering the ON/STANDBY button can be removed and discarded after the 24-hour charge.

2.2 CONTROLS, INDICATORS, AND CONNECTORS

Refer to Figure 1 in the back of the manual for the locations of the unit's controls, indicators, and connectors.

1. ON/STANDBY button

Turns the unit ON or sets the unit to STANDBY. This button will not set the unit to STANDBY when the cuff pressure is at a non-zero value. **Ensure both cuffs are fully deflated and have been removed from the patient as well as all underlying bandages or protective sleeve prior to setting the unit to STANDBY.**

NOTE: During STANDBY, the power to the *A.T.S.* 3000 instrument 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.

2. SHUTTLE knob

Changes the value of set time or default time and set pressure or default pressure. Turn knob clockwise to increase the value; turn knob counterclockwise to decrease the value.

3. PRESSURE button

Press to verify or modify set pressure.

4. TIME button

Press to verify or modify set time.

5. INFLATE buttons

Inflation of the respective cuff is initiated by depressing the INFLATE button.

6. DEFLATE buttons

Deflation of the respective cuff is initiated by depressing the DEFLATE button. For greater safety, the DEFLATE button has a delay and, therefore must be held for approximately 2 seconds before the unit will allow a cuff to deflate.

7. ALARM SILENCE button

The ALARM SILENCE button will silence <u>most</u> audible alarms for 30 seconds after the button is pressed. When an alarm sounds because of an internal hardware malfunction, the alarm cannot be silenced.

NOTE: The alarm messages will continue to flash on the displays until the alarm condition is corrected.

8. AC INDICATOR light

The AC INDICATOR light indicates that the unit is plugged in and is being powered by AC Mains. This is the normal means of operation (battery power is only intended for emergency power loss or patient transport).

9. BATTERY INDICATOR light

The BATTERY INDICATOR light indicates that the unit is operating on backup battery. The light will flash continuously while the unit is running on battery backup power.

10. PRESSURE displays (independent)

During normal operation with no buttons being pressed, the independent PRESSURE display areas will show the monitored cuff(s) pressure. At other times, depending on alarm conditions and buttons pressed, the display may communicate other information such as alarm messages, set pressure, or default set pressure.

11. TIME displays (independent)

During normal operation with no buttons being pressed, the independent TIME display area will show elapsed inflation time of each cuff. At other times, depending on alarm conditions and buttons pressed, the display may communicate other information such as alarm messages, set time, or default set time.

A.T.S. 3000 TOURNIQUET SYSTEM

NOTE: The elapsed inflation time can be "zeroed" at any point in the procedure by pressing the TIME and PRESSURE buttons for the respective cuff simultaneously.

12. CUFF connector ports

The CUFF connectors are the ports used to connect the unit to the cuff hoses. Please note that the Main Cuff is the RED ports and the Second Cuff is the BLUE ports. The *A.T.S.* 3000 is designed and tested for use with Zimmer dual port cuffs. Zimmer does not recommend the use of any cuff other than Zimmer dual port cuffs. Do not use single port cuffs with the *A.T.S.* 3000.

13. POLE clamp

The POLE clamp is used to mount the unit on an I.V. pole.

NOTE: Do not hang articles on the tourniquet pole that are not related to tourniquet use. For stability reasons, do not use an I.V. pole with a base less than 27.27 inches (70 cm) in diameter.

14. Hose hangers

The *A.T.S.* 3000 is equipped with hose hangers that pull out of the unit's handle. The cuff hoses can be temporarily hung on the hangers for transport or when disconnecting from the cuff.

NOTE: Do not hang articles on the tourniquet's hose hangers that may cause the tourniquet to become unstable. Cuff hoses or the LOP sensor should be the only item to utilize the hose hangers.

2.3 INITIAL SETUP

Inspect to ensure the correct fuse drawer with the appropriately rated fuses is present. The 100–120 V unit uses the gray fuse drawer with 1.0 A time delay fuses. The 220–240 V unit uses the black fuse drawer with 1.0 A time delay fuses. The power cord should be plugged into the power entry module on the back of the unit. **The unit should be plugged into** ~ (AC) **power** (Mains) for 24 hours **before initial use. During shipping and storage, the unit's battery could become weak. Always charge 24 hours before any initial use including any calibration checking procedures, initial checks, tests and any institutional performed biomedical evaluations.**

2.4 FUNCTIONAL AND CALIBRATION CHECK

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.

- 1. Connect the power plug of the unit to a properly polarized and grounded power source with voltage and frequency characteristics compatible with the specifications listed in Section 1.1.
- Observe that the green AC Mains indicator light turns on.
- 2. Turn the unit ON by pressing the ON/STANDBY button and observe the following:
- a) "Zimmer" along with the circle "Z" appears on the LCD display.
- b) The unit displays "SELF TEST" below the "Zimmer" name. The unit is self-testing specific system hardware and software.
- c) Emits tones while "SELF TEST" is displayed.
- d) The front panel "Alarm", "LOP", and "Battery" indicators flash on and off while "SELF TEST" is displayed.
- e) "CAL" is displayed in the PRESSURE display areas during the calibration check.
- f) "0" is displayed in the PRESSURE and TIME display areas after the startup routing is complete. If a number other than zero is displayed in the PRESSURE display, the unit should be calibrated.
- 3. Test the PRESSURE set point system as follows:
- a) Press either PRESSURE button.
- b) The PRESSURE display should read "*250" (the factory default set point) for approximately 2 seconds.
- c) Within the 2 second time frame, rotate the SHUTTLE KNOB to change the pressure set point (clockwise to increase, counter-clockwise to decrease). The set pressure can be maintained between 50 mmHg and 475 mmHg in increments of 1 mmHg.
- d) Repeat step 3 for the other PRESSURE set point.
- 4. Test the TIME set point system as follows:
- a) Press either TIME button.
- b) The main TIME display should read "* 60" (the factory default set point) for 2 seconds.
- c) Within the 2 second time frame, rotate the SHUTTLE KNOB to change the time set point (clockwise to increase, counter-clockwise to decrease). The set time can be maintained between 5 and 240 minutes in increments of 1 minute.
- d) Repeat step 4 for the other TIME set point.

NOTE: Anytime an asterisk (*) appears in the left most display digit, the data being displayed is the set point. Set pressure and time will revert back to the default pressure and time settings when the unit is set to STANDBY.

5. Calibration Check

NOTE: During the power-up diagnostic self-test described above, the unit will test the calibration. Should an out of calibration condition be detected, the unit will display either "CAL" "FAIL", "CAL M" "FAIL" or "CAL 2" "FAIL" in the PRESSURE and TIME display areas. Even though the unit performs this check at every power-up, the following quantitative check is recommended at regular intervals.

- a) Verify the unit is in the STANDBY mode.
- b) Enter the calibration mode by pressing then releasing the ON/STANDBY button then immediately depress and hold in the Main Cuff INFLATE and Main Cuff DEFLATE buttons during power on self test. The unit will enter calibration mode after momentarily displaying "ZIMMER" "SELF TEST". When "CALIBRATION" is momentarily displayed, release the Main Cuff INFLATE and Main Cuff DEFLATE buttons. The unit will also display the software revision level in the lower left corner. The software revision level can be recorded for future reference.

NOTE: The calibration is only being checked in this section. For complete calibration, see Maintenance Section 3.0.

- c) Connect a calibrated 0 to 700 mmHg pressure meter (minimum requirement) to the calibration hose assembly. The calibrated meter will be used as the pressure standard (See Figure 3 in the back of the manual).
- d) Connect a pressure source capable of supplying 0 to 700 mmHg of pressure, minimum.
- e) Insert one end of the calibration hose assembly connector into the Main Cuff sense port on the unit (*red* port). The sense port is the second port over from the left side of the unit.
- f) Insert the other end of the calibration hose assembly connector into the Second Cuff sense port on the unit (*blue* port). The sense port is the fourth port over from the left side of the unit.

NOTE: The unit will be displaying "0" where the cuff pressures are normally displayed and alternating "CAL" and "0" where the cuff times are normally displayed.

- g) Increase the pressure in the calibration hose assembly to 50 mmHg. Both PRESSURE displays should read 50±5 mmHg when compared to the calibrated meter.
- h) Increase the pressure to 250 mmHg. Both PRESSURE displays should read 250±5 mmHg.
- i) Increase the pressure to 475 mmHg. Both PRESSURE displays should read 475±5 mmHg.

- j) Decrease the pressure to 0 mmHg and remove the calibration hose assembly from the unit. The PRESSURE displays should return to 0 mmHg.
- Press and hold in the Main Cuff INFLATE and Main Cuff DEFLATE buttons to advance to the reservoir calibration check.

NOTE: At this point the reservoir pressure, if pressurized, will be exhausted through the source ports and the Main Cuff PRESSURE display should go to "0" while the Main Cuff TIME display should continue to display "CAL" "0" as described earlier.

- Insert one end of the calibration hose assembly connector into the Main Cuff <u>source</u> port on the unit (*red* port). The source port is the first port from the left side of the unit.
- m) Insert the other end of the calibration hose assembly connector into the Second Cuff <u>source</u> port on the unit (*blue* port). The source port is the third port over from the left side of the unit.
- n) Increase the pressure in the calibration hose assembly to 250 mmHg. The display should read 250±5 mmHg.
- o) Increase the pressure to 475 mmHg. The display should read 475±5 mmHg.
- p) Increase the pressure to 700 mmHg. The display should read 700±5 mmHg.

NOTE: If any reading is off by more than ± 5 mmHg, the entire unit must be recalibrated by following the calibration procedure as outlined in Maintenance Section 3.0.

- q) To complete this procedure, turn the unit OFF by holding in the ON\STANDBY button until the unit is set to STANDBY.
- r) Calibration check is complete.
- 6. Low Pressure Alarm Check Turn the unit ON by pressing the ON/STANDBY button. Connect a cuff and standard length hose set to the Main Cuff ports. Inflate the cuff to 250 mmHg. Create a leak in the cuff by partially detaching the hose (either port) from the unit while a cuff is inflated. Make the leak large enough that the pressure drops more than 15 mmHg below set point. Observe:
- a) A 1.5 second delay is instituted to reduce nuisance alarms.
- b) The PRESSURE display flashes between "LO-P" and the monitored pressure (if a substantial leak has been present for more than 9 seconds, the PRESSURE display will show "CUFF" "LEAK").
- c) An audible tone will sound and the red alarm indicator will illuminate announcing the alarm condition.

d) Stop the leak and observe the monitored pressure returns to regulated state, the audible tone stops, the red alarm indicator turns off, and the alarm message is no longer displayed.

Repeat this procedure with the Second Cuff ports.

2.5 PRESSURE AND TIME DEFAULTS

To modify the default pressure or time limits for either cuff, follow the following steps.

- 1. Default Pressure
 - a) The Default Pressure is selected by depressing and holding either PRESSURE button for 2 seconds.
 When the default mode is entered, the audible alarm beeps once and a "D" is displayed in the first position on the selected cuff PRESSURE display.
 - b) The Default Pressure is modified via the SHUTTLE KNOB and can be set between 50 and 475 mmHg in increments of 1 mmHg.
 - c) After the correct value is selected, it is saved by momentarily depressing the PRESSURE button or it will be saved automatically in 3 seconds.
 - d) The new default value will be displayed for 1.5 seconds and the audible alarm will beep once signifying a new default value has been stored.
 - e) The new default pressure will be stored and remains the default every time the machine is turned on.
- 2. Default Time Limit
 - a) The Default Time Limit is selected by pressing and holding either TIME button for 2 seconds. When the default mode is entered the audible alarm beeps and a "D" is displayed in the first position on the selected cuff TIME display.
 - b) The Default Time Limit is modified via the SHUTTLE KNOB and can be set between 5 and 240 minutes in increments of 1 minute.
 - c) After the correct value is selected, it is saved by momentarily depressing the TIME button or it will be saved automatically in 3 seconds.
 - d) The new default value will be displayed for 1.5 seconds and the audible alarm will beep once signifying a new default value has been stored.
 - e) The new time limit default will be stored and remains the default every time the machine is turned ON.

NOTE: The elapsed inflation time can be "zeroed" at any point in the procedure by pressing the TIME and PRESSURE buttons simultaneously for each respective cuff time.

2.6 LIMB OCCLUSION PRESSURE (LOP) DETERMINATION

NOTE: Limb Occlusion Pressure (LOP) determination is not intended for use in pediatric procedures.

The patient's limb occlusion pressure is the lowest pressure required to stop the flow of blood in the extremity. The *A.T.S.* 3000 has the ability to estimate the patient's limb occlusion pressure based on their physiological characteristics. The *A.T.S.* 3000 will also take into account anticipated changes in blood pressure during the procedure by adding an additional pressure margin to the LOP measurement at the end of the LOP determination. This additional pressure margin added to the LOP measurement is referred to as the *Recommended Tourniquet Pressure* or RTP. The RTP is calculated using the LOP with the following:

LOP 90–130 mmHg \rightarrow LOP + 50 mmHg = RTP

LOP 131–190 mmHg \rightarrow LOP + 75 mmHg = RTP

LOP 191–300 mmHg \rightarrow LOP + 100 mmHg = RTP

The RTP can be accepted or rejected based on the physician's discretion. The RTP value is presented at the end of the LOP determination.

When deciding to accept the RTP value or not the physician may take into account other factors such as the patient's blood pressure, anesthetic technique to be used, expected procedure duration, cuff location, cuff type, cuff width, snugness of cuff application and surgical procedure to be performed. The physician may also choose to use an alternative method such as the Doppler stethoscope to manually determine the patient's LOP, or to confirm the LOP determined by the *A.T.S.* 3000. The accuracy of the automatic determination of LOP can be verified manually, by employing a Doppler stethoscope and carefully following the published technique for manual LOP determination.

The *A.T.S.* 3000 will suggest the RTP as the lowest pressure for the extremity to ensure the field will remain clear even during changes in blood pressure. However large changes in the patient's blood pressure during surgery may result in reduced visibility in the field. The pressure may need to be adjusted slightly to improve visual quality. The RTP may be overridden at any time simply by changing the pressure set point.

It should be noted that certain physiologic conditions in some patients may prevent the *A.T.S.* 3000 from making a determination of LOP, in which case the instrument will display an appropriate message and will terminate the attempt to measure LOP. In that event, the physician's judgment should be used to set tourniquet pressure in the absence of LOP and RTP values.

The determination of LOP is intended as additional, supplementary information for the physician responsible for selecting the tourniquet pressure to be employed for a specific patient and procedure. The physician's best judgment should always be paramount in the selection of tourniquet pressure.

NOTE: The pulse sensor appears very similar to other sensors used for pulse measurements. It should be noted, the *A.T.S.* 3000's pulse sensor does not measure oxygen saturation nor can it be modified to do so. The *A.T.S.* 3000 uses a custom sensor. Non Zimmer sensors will not work with the *A.T.S.* 3000. Use of a non Zimmer sensor could damage the *A.T.S.* 3000 or cause unpredictable operation. Never use any sensor other than approved Zimmer pulse sensors.

2.6.1 Single Bladder Cuff LOP Measuring

NOTE: LOP determination temporarily inflates then deflates the tourniquet cuff automatically to obtain the patient's LOP.

a) Press the ON/STANDBY button to turn the unit ON. The unit will execute a self-check diagnostic test as described in Section 2.4 of this manual. Successful completion of the self-check indicates the unit is ready for use.

CAUTION: If a connected cuff is pressurized to 50 mmHg or more during power-up, the *A.T.S.* 3000 Tourniquet will declare it an abnormal start-up sequence. It will assume that a surgical procedure is in process, and will adopt the pressure sensed in the cuff as the **new set point.** It will automatically go into the regulate mode on the cuff. To alert the operator of this condition, the unit will sound a tone and display a "CUFF" "INFL" alarm. The operator should immediately check the pressure set point and readjust to the proper set point if necessary. The alarm will be cleared as soon as the set point is examined, (press the correct pressure button).

b) Connect a dual port cuff to the unit at the Main Cuff or Second Cuff port connectors. The Main Cuff and Second Cuff both have the ability to perform the LOP function. **NOTE:** If the LOP determination is performed on the Main Cuff, all readings and recommendations are for the Main Cuff only. If the LOP determination is performed on the Second Cuff, all readings and recommendations are for the Second Cuff only.

- c) Connect the LOP pulse sensor to the LOP socket in the front of the *A.T.S.* 3000.
- d) Prepare the patient in accordance with your established procedures and cuff manufacturer's instructions. The precautions of Section 1 and 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. In certain cases of fore-foot surgery, the tourniquet cuff can be applied around the calf or to the area proximal to the malleoli. The valve port and hose connections should be placed so that the hose will not be kinked when the limb is positioned for surgery.
- e) Attach the LOP pulse sensor to the patient's index finger or second toe on which the tourniquet cuff has been applied.

NOTE: The LOP Pulse Sensor is applied to a finger or toe on the operative limb.

- f) Ensure the sensor is fully engaged to achieve the best possible and most accurate reading.
- g) With the cuff and sensor applied to the patient, press the corresponding LOP icon to start the LOP determination. The *A.T.S.* 3000 will begin to inflate the cuff incrementally while continuously analyzing the patient's pulse. If the sensor or cuff were not properly installed, the unit will display alarm messages. The meanings to the alarm messages are found in Table 2.2.
- h) The LOP determination will last approximately 30 seconds depending on the quality of pulse sensed.
- At the end of the LOP determination, the A.T.S. 3000 will beep and display the LOP and RTP pressures in the lower display area for that cuff. The unit will automatically display the RTP in the cuff pressure display area preceeded by a "*".

NOTE: The RTP is the summation of the pressure margin and the LOP which ensures the field visibility remains clear during the procedure.

j) To accept the RTP and return to normal operation press the corresponding PRESSURE button. To reject the

RTP value and enter a user defined pressure value, turn the SHUTTLE KNOB and follow the procedure in Section 2.4.3.c.

k) To retry the LOP procedure, repeat section 2.6 steps f thru i.

NOTE: The *A.T.S.* 3000 will not automatically inflate the cuff at the end of the LOP determinations. It is the user's responsibility to accept or reject the RTP.

- 1) If the RTP is acceptable and no other adjustments are required, pressing the respective INFLATE button will inflate the cuff to the RTP.
- m) In the event the quality of visibility is reduced by an increase in patient blood pressure, the tourniquet pressure can be increased manually. To increase the tourniquet pressure manually, momentarily press the corresponding PRESSURE button and rotate the SHUTTLE KNOB clockwise to increase the pressure set point.
- n) After the LOP has been measured and the unit has offered an RTP, the unit is ready to be used. However, the user need not perform a LOP measurement to use the tourniquet system.

NOTE: The LOP is only used to obtain patient LOP prior to tourniquet use. Once the patient LOP measurement is complete, remove the LOP sensor from the patient and store.

2.6.2 Dual Bladder Cuff LOP Measuring

NOTE: LOP determination temporarily inflates then deflates the tourniquet cuff automatically to obtain the patient's LOP.

LOP measurement for a dual bladder cuff is identical to a single bladder cuff except for the following points:

- 1. A dual bladder dual port cuff is connected to the unit (Reminder: Main Cuff is the *Red* ports, Second Cuff is the *Blue* ports).
- 2. At the end of the LOP determination using the first bladder, press the corresponding PRESSURE button to accept the RTP for that cuff.
- 3. Initiate an LOP determination using the second bladder by pressing the corresponding LOP button.
- 4. At the end of the LOP determination using the second bladder, the RTP will appear in the corresponding pressure display area preceded by a "*".
- 5. Compare the RTP currently being displayed with the RTP that was accepted in step 2 above.

NOTE: The RTP accepted in step 2 above is now the pressure set point for that cuff. To verify the RTP, momentarily press the corresponding PRESSURE button. During this activity the RTP in step 4 will temporarily be "cleared" from the display but will return following a 3-second delay.

- 6. If the RTP from the first LOP determination is higher than the second RTP, turn the SHUTTLE KNOB and follow the procedure in Section 2.4.3.c to adjust the second RTP to equal the first RTP.
- If the RTP from the first LOP determination is lower than the second RTP, press the corresponding PRESSURE button to accept the RTP from the second LOP determination. Next, follow the procedure in Section 2.4.3.c to adjust the first RTP to equal the second RTP.

2.7 SINGLE CUFF OPERATION

1. Press the ON/STANDBY button to turn the unit ON. The unit will execute a self-check diagnostic test as described in Section 2.4 of this manual. Successful completion of the self-check indicates the unit is ready for use.

CAUTION: If a connected cuff is pressurized to 50 mmHg or more during power-up, the *A.T.S.* 3000 Tourniquet will declare it an abnormal start-up sequence. It will assume that a surgical procedure is in process, and will adopt the pressure sensed in the cuff as the **new set point.** It will automatically go into the regulate mode on the cuff. To alert the operator of this condition, the unit will sound a tone and display a "CUFF" "INFL" alarm. The operator should immediately check the pressure set point and readjust to the proper set point if necessary. The alarm will be cleared as soon as the cuff set point is examined, (press the correct PRESSURE button).

- 2. Connect a dual port cuff to the unit at the Main Cuff connectors (red ports).
- 3. The default settings for cuff pressure and time limit are retrieved from the nonvolatile memory during power up. For each patient, tourniquet pressure required to occlude blood flow to the operative site should be set to the minimum effective pressure. The minimum effective pressure should be determined by factors such as: whether the cuff is to be applied to an upper or lower limb; whether the limb is normal, hypertrophied, or obese; the patient's preoperative systolic pressure; and the maximum anticipated rise in systolic pressure during the procedure. The *A.T.S.* 3000 has the unique ability to estimate the minimum effective pressure or LOP. Refer back to Section 2.6 for using the LOP measuring feature.

4. Prepare the patient in accordance with your established procedures and cuff manufacturer's instructions. The precautions of Section 1 and 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. In certain cases of fore-foot surgery, the tourniquet cuff can be applied around the calf or to the area proximal to the malleoli. For emergency surgery of the hand, a sufficiently small tourniquet can be fitted around the wrist.

Apply a leak-free tourniquet cuff smoothly without wrinkles. The valve port and hose connections should be placed so that the hose will not be kinked when the limb is positioned for surgery. The viability of the skin and deeper tissues should be established prior to exsanguination of the limb and tourniquet inflation. Exsanguinate the limb by elevating it for a minimum of 2 minutes and wrapping it, distal to proximal, using an Esmarch, Martin, or elastic bandage. The bandage should come up approximately to 1 in. (2.5 cm) from the edge of the tourniquet cuff. The elastic bandage is removed following inflation of the cuff. If regional anesthesia is being used, the anesthetic agent or nerve block is then administered. The tourniquet time depends greatly on the patient's anatomy, age, and absence of vascular disease. The surgeon will determine:

- 1) When the tourniquet is to be inflated;
- 2) What pressure is applied;
- 3) How long the tourniquet is applied;
- 4) Whether to allow for intermittent aeration of tissue by deflating the cuff for 10 to 15 minutes;
- 5) To what point in the operation the tourniquet should be released.

In many operating rooms, it is customary to prominently note the time of inflation, and to warn the surgeon after a certain time has elapsed. This will allow the surgeon to assess the need for further tourniquet time.

There is a general agreement that, for reasonably healthy adults, 2 hours should not be exceeded without releasing the tourniquet to allow the underlying tissue to breathe. During this time, the limb should be elevated to about 60 degrees, and steady pressure should be applied to the incision with sterile dressings.

5. The cuff is inflated by pressing the red Main Cuff INFLATE button. The unit will pressurize the Main

Cuff to the set pressure and start the elapsed inflation time alarm clock. The Main Cuff inflation information will be displayed on the LCD screen. If the unit cannot pressurize the cuff to within 15 mmHg of the set point in less than 30 seconds, a leak alarm will be sounded. See Section 2.12 for information about possible alarm conditions. Once the cuff is inflated, the time display will track elapsed inflation time.

6. At the end of the procedure, deflate the cuff by pressing the Main Cuff DEFLATE button for minimum of 2 seconds. The Main Cuff PRESSURE display will show the deflation of the cuff and the elapsed inflation time alarm clock will stop.

NOTE: The elapsed inflation time can be "zeroed" at any point by pressing the TIME and PRESSURE buttons simultaneously.

- 7. Remove the tourniquet cuff and any underlying bandages or protective sleeve immediately following final deflation. The time of tourniquet cuff removal should be noted, and the circulation of the limb should be checked.
- 8. After the cuff has been removed, disconnect the cuff from the *A.T.S.* 3000.
- 9. During normal use, the *A.T.S.* 3000 should not be set to STANDBY if pressure is present in either cuff. Once the cuff has been properly deflated, removed from the patient, and disconnected from the *A.T.S.* 3000, the unit can be set to STANDBY.

2.8 DUAL CUFF OPERATION

Operation of the unit is identical to Single Cuff operation (see Section 2.7) except for the following points:

- Two dual port cuffs are connected to the unit (Reminder: Main Cuff is the *Red* ports, Second Cuff is the *Blue* ports).
- 2. The Main and Second LCD screen section will display inflation information and begin timing the cuff inflation.
- 3. Deflation of one cuff will not be permitted while the other cuff is inflating.
- 4. When inflating a second cuff with the other cuff already inflated, the unit will continuously check the original cuff to ensure that the pressure is within allowable limits. The unit will stop its inflation and maintain the original cuff to within 10 mmHg of the set point before returning to the inflating cuff. This ensures that at least one cuff maintains occlusion at all times. If there is a significant leak in the original cuff, this feature could cause the inflation rate of the subsequent cuff to be longer and perhaps even cause the 30-second inflation alarm to sound.

- 5. When both cuffs are inflated, the LCD screen displays independent information for each cuff. That is, the PRESSURE and TIME displays are independently operated and controlled for each cuff.
- 6. In order to deflate the <u>final</u> cuff, a sequence must be followed to prevent accidental deflation:
 - a) Press and hold the DEFLATE button on the cuff to be deflated;
 - b) When the "CUFF" "DEFL" alarm is active, release the DEFLATE button;
 - c) Within 5 seconds of the alarm discontinuing, press the DEFLATE button once again;
 - d) The cuff will deflate. This safety feature is particularly useful when using the unit for Bier Block Cuff Operation, (IVRA).

2.9 BIER BLOCK CUFF OPERATION (IVRA)

Review Sections 2.7 and 2.8, SINGLE CUFF OPERATION and DUAL CUFF OPERATION.

- 1. The following are suggested cuff connections:
 - a. The proximal cuff connected to the Red Main Cuff ports using the white/red cuff tubing;
 - b. The distal cuff connected to the Blue Second Cuff ports using the white/blue cuff tubing.
- 2. Follow the cuff inflation sequence adopted by your institution or requested by the surgeon.
- 3. Deflation of a cuff is not possible while the other is inflating.
- 4. When requested, the first can be deflated simply by pressing and holding the DEFLATE button for a minimum of 2 seconds.
- 5. In order to deflate the <u>final</u> cuff, a sequence must be followed to prevent accidental deflation:
 - a) Press and hold the DEFLATE button on the cuff to be deflated;
 - b) When the "CUFF" "DEFL" alarm is active, release the DEFLATE button;
 - c) Within 5 seconds of the alarm discontinuing, press the DEFLATE button once again;
 - d) The cuff will deflate.
- For Bier Block procedures follow the cuff inflation/ deflation sequence adopted by your institution or requested by the surgeon.

2.10 SPEAKER VOLUME SETTING

An operator may want to change the speaker volume setting from the default. The following steps will allow a user to customize the speaker volume default setting.

1. Press the ON/STANDBY button to turn the unit ON. The unit will execute a self-check diagnostic test as described in Section 2.4.

- 2. Press and hold both the Main Cuff TIME and Main Cuff PRESSURE buttons for approximately 3 seconds.
- 3. When the volume selection screen appears, the user can adjust the volume up or down by turning the SHUTTLE KNOB. Clockwise rotation increases volume while a counterclockwise rotation decreases volume. With every increment or decrement the speaker will sound to give the user feedback of the volume level setting selected. After 5 seconds of inactivity the system will accept the volume setting as displayed and return the display back to its normal mode of operation.
- 4. The user can accept the volume setting by pressing the Main Cuff PRESSURE button which stores the setting and returns the display to its normal mode. Or, wait approximately 5 seconds as noted above to allow the system to accept the new volume setting.

2.11 CONTRAST DISPLAY SETTING

An operator may want to change the display contrast setting from the default. The following steps will allow a user to customize the display contrast default setting.

- 1. Press the ON/STANDBY button to turn the unit ON. The unit will execute a self-check diagnostic test as described in Section 2.4.
- 2. Press and hold both the Second Cuff TIME and Second Cuff PRESSURE buttons for approximately 3 seconds.
- 3. When the contrast control setting selection screen appears, the user can adjust the display contrast by turning the SHUTTLE KNOB. Clockwise rotation increases display contrast while a counterclockwise rotation decreases display contrast. With every increment or decrement the display will show the new contrast setting selected. After approximately 5 seconds of inactivity the system will accept the contrast control setting as displayed and return the display back to its normal mode of operation.
- 4. The user can accept the new setting by pressing the Second Cuff PRESSURE button which stores the setting and returns the display to its normal mode. Or, wait approximately 5 seconds as noted above to allow the system to accept the setting.

2.12 ALARM CONDITIONS

There are a number of conditions for which the *A.T.S.* 3000 Tourniquet will produce a visual and/or audible alarm. Those conditions, indications, and appropriate actions are shown in Table 2.1. 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. In addition to the conditions shown in Table 2.1, it is conceivable that a malfunction could occur for which the indications are unintelligible and unpredictable. In this

situation, it is likely that the valves will be disabled causing the system to hold cuff pressure. It is also likely that a tone will sound under these conditions. Most audible alarm tones may be silenced for 30 seconds by pressing the ALARM SILENCE button. The tone will be reenabled at the end of the silenced period. Pressing the ALARM SILENCE button will cause the alarm tone to be silenced again. The A.T.S. 3000 Tourniquet will also provide Error Code information for critical alarms as shown in Table 2.3. To minimize nuisance alarms (i.e. "HI-P", "LO-P") that can be caused by vigorous movement of the patient's limbs, a 1.5-second delay has been designed into the alarm actuation. Under certain conditions, such as when a FAIL indication appears in the TIME display or the information that appears in the TIME and PRESSURE displays is unintelligible, the operator should conclude that a hardware failure has occurred, rendering the unit unusable. The appropriate action is to 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. This

will cause the cuff to hold pressure (in the absence of leaks). Clamp the cuff lines with hemostats and replace the tourniquet unit.

2.12.1 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, or a 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 continuously present for more than 9 seconds. 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.

CONDITION	PRESSURE DISPLAY	TIME DISPLAY	APPROPRIATE ACTION/REMARKS
CUFF PRESSURE LOW The pressure in the cuff is 15 mmHg below set point	LO-P	normal	This condition is generally caused by a leak in the system, or a hose occlusion. All lines and connections should be checked.
CUFF PRESSURE HIGH The pressure in the cuff is 15 mmHg above set point	HI-P	normal	Normally caused by transient conditions such as patient movement, controller overshoot, or hose occlusion. This condition, for an extended period, would indicate a hardware failure and the <i>A.T.S.</i> 3000 unit should be replaced.
CUFF SIDE LEAK A leak has been present for at least 9 seconds.	CUFF LEAK	normal	A substantial leak has been present for more the 9 seconds. All lines and connections should be checked.
RESERVOIR LEAK A leak is present between the pump and valves	RES LEAK	normal	Do not use the unit. Service the unit.
INFLATION TIME IN EXCESS OF SETTING The cuff has been inflated beyond the set time limit	normal	TIME UP	Surgeon should be warned of time up condition. Only on the direction of the surgeon, time should be set to new value.
CUFF INFLATION ON POWER UP Cuff pressurized to 50 mmHg or greater at power up	CUFF	INFL	The system assumes that a procedure is in progress and adopts the sensed pressure as the new set point. The operator should immediately check the set value to determine if it needs reset.
CUFF NOT DEFLATED Pressure in deflated cuff is a non- zero value	normal	CUFF NOT DEFL	Check for kinks in hose. If alarm persists, disconnect hose from cuff. If attempting to set the unit to STANDBY, ensure that cuff is fully deflated.

Table 2.1 Alarm Condition

Table 2.1 Alarm Condition Continued

CONDITION	PRESSURE DISPLAY	TIME DISPLAY	APPROPRIATE ACTION/REMARKS
LINE OCCLUSION An occlusion is present in the cuff tubing	LINE OCCL	normal	Check for hose kinks or other defects.
LOW BATTERY VOLTAGE Low battery voltage	normal	BATT LOW PLUG IN	Plug unit in. If the unit is not plugged in, a battery failure condition will occur and the unit will shut down in a fail safe mode closing all valves. While running with a Low Battery Voltage Alarm Condition other alarm conditions can not be guaranteed.
CHECK CUFF An increase in cuff pressure has not been sensed within 1 second after depressing the inflate key	СНК	CUFF	Check to see that a cuff and hose assembly is connected to the proper ports on the unit.
BATTERY FAILURE Battery voltage is too low to ensure proper operation	BATTEI	RY FAIL	Plug unit in and cycle the ON/STANDBY Button.
CALIBRATION OUT OF SPEC The transducer calibration is out of specification	CAL M or CAL 2 FAIL		CAL M (<i>CALIBRATION MAIN</i>) or CAL 2 (<i>CALIBRATION SECOND</i>) indicates a cuff transducer circuitry is out of calibration. Pressure in error by at least 6 mmHg will cause these failures. Calibrate the unit.
CALIBRATION OUT OF SPEC A transducer calibration is out of specification	CAL FAIL		Indicates general calibration fail. Calibrate the unit.
AMPLIFIER FAILURE Amplifier is out of range	AMP FAIL		Cycle the ON/STANDBY Button. If problem persists, service the unit.
MATH FAILURE Result of math operation was out of range	MATH FAIL		Cycle the ON/STANDBY Button. If problem persists, service the unit.
ROM FAILURE Microprocessor failed a ROM memory check	ROM FAIL		Cycle the ON/STANDBY Button. If problem persists, service the unit.
RAM FAILURE Microprocessor failed a RAM memory check	RAM FAIL		Cycle the ON/STANDBY Button. If problem persists, service the unit.
VALVE FAILURE Improper valve combination occurred	VALVE FAIL		Cycle the ON/STANDBY Button. If problem persists, service the unit.
WATCHDOG FAILURE Windowing watchdog system detected a malfunction	WDT FAIL		Cycle the ON/STANDBY Button. If problem persists, service the unit.
SYSTEM FAILURE	SYSTEM FAIL		Cycle the ON/STANDBY Button. If problem persists, service the unit.

Table 2.2 LOP Alarm Condition

CONDITION	PRESSURE DISPLAY	TIME DISPLAY	APPROPRIATE ACTION/REMARKS
No LOP pulse sensor detected during LOP	Message displayed at bottom of display area. "CONNECT LOP SENSOR"		Plug LOP pulse sensor in. Reattach LOP pulse sensor and retry. Replace LOP pulse sensor with known good working sensor and retry. If problem persists, service the unit.
LOP pulse sensor not properly secured to patient	normal	CHECK SENSOR	Check LOP pulse sensor and retry. Replace LOP pulse sensor with known good working sensor and retry. If problem persists, service the unit.
	normal	LOW SIGNAL	Check LOP pulse sensor and retry. Replace LOP pulse sensor with known good working sensor and retry. If problem persists, service the unit.
	normal	NOISY SIGNAL	Check LOP pulse sensor and retry. Replace LOP pulse sensor with known good working sensor and retry. If problem persists, service the unit.
	normal	TIME OUT	Check LOP pulse sensor and retry. Replace LOP pulse sensor with known good working sensor and retry. If problem persists, service the unit.
Cuff is leaking or not connected to unit or connected to incorrect port during LOP function	normal	CUFF INFL	Check cuff for leaks and retry. Connect cuff to correct port and retry. Connect cuff to unit and retry. If problem persists, service the unit.
Patient LOP is too high for LOP measurement	normal	HIGH LOP	Check LOP pulse sensor and retry. Replace LOP pulse sensor with known good working sensor and retry. Do not use the LOP function, follow normal tourniquet procedures.
LOP pulse sensor attached to incorrect limb	normal	CHECK SENSOR	Attach LOP pulse sensor to correct limb and retry. Replace LOP pulse sensor with known good working sensor and retry. If problem persists, service the unit.
LOP procedure stopped	normal	STOP	A front panel button may have been pressed while in the LOP function. Wait for the message to clear and retry. If problem persists, service the unit.

NOTE: ¹ Some Error Codes are followed by a four-digit numeric code. This code represents detailed information related to the failure. Contact the manufacturer for information concerning those specific codes.

Table 2.3 Error Codes	information related to the failure	e. Contact the manufacturer for information concerning those specific codes.
ERROR CODE	CRITICAL FAILURE	EXPLANATION/APPROPRIATE ACTIONS
E001 XXXX ¹	SYSTEM FAIL	A timing error was detected during self-test. Cycle the ON/ STANDBY button. If problem persists, note error code and contact manufacturer.
E002 XXXX ¹	SYSTEM FAIL	A Safety Monitor signal error was detected. Cycle the ON/STANDBY button. If problem persists, note error code and contact manufacturer.
E003	SYSTEM FAIL	A pneumatic system error was detected during self-test. Cycle the ON/STANDBY button. If problem persists, note error code and contact manufacturer.
E004	WDT FAIL	A Safety Monitor timing error was detected. Cycle the ON/ STANDBY button. If problem persists, note error code and contact manufacturer.
E005	VALVE FAIL	The Safety Monitor detected an illegal valve state. Cycle the ON/ STANDBY button. If problem persists, note error code and contact manufacturer.
E006	SYSTEM FAIL	A Safety Monitor detection error was detected. Cycle the ON/ STANDBY button. If problem persists, note error code and contact manufacturer.

Table 2.3 Error Codes Continued

ERROR CODE	CRITICAL FAILURE	EXPLANATION/APPROPRIATE ACTIONS
E007	MATH FAIL	A processor error was detected. Cycle the ON/STANDBY button. If problem persists, note error code and contact manufacturer.
E008	SYSTEM FAIL	The processor received an unknown interrupt. Cycle the ON/STANDBY button. If problem persists, note error code and contact manufacturer.
E010	ROM FAIL	A non-volatile memory value was detected during power-up. Cycle the ON/STANDBY button. If problem persists, note error code and contact manufacturer.
E011	ROM FAIL	ROM check error detected a self-test. Cycle the ON/STANDBY button. If problem persists, note error code and contact manufacturer.
E012	RAM FAIL	A microprocessor RAM error was detected during self-test. Cycle the ON/STANDBY button. If problem persists, note error code and contact manufacturer.
E013	BATTERY FAIL	Battery voltage below minimum threshold. Plug unit in and cycle the ON/STANDBY button. If problem persists, note error code and contact manufacturer.
E014	BATTERY FAIL	A battery charging circuit failure was detected at power-up. Verify a battery is connected and cycle the ON/STANDBY button. If problem persists, note error code and contact manufacturer.
E015	CAL FAIL	Incorrect zero pressure calibration point was detected. Calibrate unit. If problem persists, note error code and contact manufacturer.
E016	CAL FAIL	Incorrect calibration point was detected. Calibrate unit. If problem persists, note error code and contact manufacturer.
E017	CAL FAIL	Calibration error was detected. Calibrate unit. If problem persists, note error code and contact manufacturer.
E018	CAL M FAIL	Main cuff transducer calibration error was detected. Calibrate unit. If problem persists, note error code and contact manufacturer.
E019	CAL 2 FAIL	Second cuff transducer calibration error was detected. Calibrate unit. If problem persists, note error code and contact manufacturer.
E020 XXXX ¹	SYSTEM FAIL	A software exception error was detected. Cycle the ON/STANDBY button. If problem persists, note error code and contact manufacturer.
E021 XXXX ¹	AMP FAIL	A transducer reference voltage is out of range. Calibrate unit. If problem persists, note error code and contact manufacturer.
E022 XXXX ¹	AMP FAIL	Reservoir transducer is out of range. Calibrate unit. If problem persists, note error code and contact manufacturer.
E023 XXXX ¹	AMP FAIL	The Main cuff transducer is out of range. Calibrate unit. If problem persists, note error code and contact manufacturer.
E024 XXXX ¹	AMP FAIL	The Second cuff transducer is out of range. Calibrate unit. If problem persists, note error code and contact manufacturer.
E025 XXXX ¹	AMP FAIL	A voltage level is out of range. Cycle the ON/STANDBY button. If problem persists, note error code and contact manufacturer.
E026 XXXX ¹	AMP FAIL	A voltage level is out of range. Cycle the ON/STANDBY button. If problem persists, note error code and contact manufacturer.
E027 XXXX ¹	SYSTEM FAIL	A speaker or alarm tone generation circuitry failure was detected. Verify that the speaker is connected and cycle the ON/STANDBY button. If problem persists, note error code and contact manufacturer.

MAINTENANCE SECTION 3.0 ZIMMER A.T.S. 3000 AUTOMATIC TOURNIQUET SYSTEM

3.1 GENERAL MAINTENANCE INFORMATION

While the *A.T.S.* 3000 Tourniquet has been designed and manufactured to high industry standards, it is recommended that regular inspection and calibration be performed to ensure continual safe and effective operation. This section contains information to assist in the effort as well as serve as a guide to expediting unscheduled maintenance.

3.2 ACCESS TO PARTS

CAUTION: Be sure that the unit is set to STANDBY and the power plug is unplugged before disassembly. **To remove mains power from unit, disconnect power cord from wall or rear of unit.** Many of the parts on the control board are static sensitive. Take precaution when servicing the board.

To gain access to all internal parts, remove:

- a) Rear 4 (#6) nuts
- b) Rear 2 large pole clamp screws
- c) Rear 2 carrying handle screws
- d) Bottom 4 foot pad screws

See illustration 4 through 8 in the back of the manual.

When opening, take care not to damage any of the wire harnesses or pneumatic tubing. The control board is attached to the front housing therefore the harnesses and tubing will need to be disconnected for full disassembly. Follow the table below to reassemble.

Component	Board Plug ID
Alarm Silence	P1
AC Mains	P2
LCD Panel Display	P5
Valve Harness Second	P6
Valve Harness Main	P7
Membrane Panel	P8
LOP Harness	P9
Backup Battery	P10
ON/STANDBY	P11
Factory Test Port	P12
Speaker	P13
Pneumatic Pump	P14

Table 3.1 Board Plug Designators

To reduce the risk of damage, tubing should not be disconnected at the transducer.

NOTE: Failure to plug the electrical or pneumatic components into the correct associated receptacle can result in damage to the control board.

When reassembling the unit, be extremely careful not to pinch any wiring or tubing.

3.3 LIMB OCCLUSION PRESSURE (LOP) SENSOR CLEANING AND DISINFECTING

Clean or disinfect the sensor before attaching to a new patient.

1. Cleaning

Unplug the LOP sensor from the *A.T.S.* 3000 Tourniquet before cleaning. Clean the sensor and patient contact surfaces with a soft cloth moistened in water or a mild soap solution.

2. Disinfecting

Unplug the LOP sensor from the *A.T.S.* 3000 Tourniquet before disinfecting. Disinfect the sensor by wiping the sensor and patient contact surfaces with disinfecting solution. Isopropyl alcohol is recommended as a disinfecting solution. If another commercially available disinfectant is used, follow the manufacturer's recommendation for use.

3.4 PERIODIC MAINTENANCE

Test and inspect as per this section at minimum every six months.

1. Cleaning

The exterior of the unit may be cleaned with a cloth that has been dampened (not dripping) with a mild detergent. The interior of the unit may be vacuumed or blown out as required. The exterior of the cuff hose may be cleaned using a mild detergent solution or alcohol. The interior of the cuff hoses should not be cleaned. Tourniquet cuffs should be cleaned in accordance with their cuff package insert instructions.

2. Inspection

The unit should be inspected at regular intervals. It is recommended that a qualified technician perform a visual inspection at least once every six months. Inspection points are:

- a) Obvious internal or external damage.
- b) Condition of the power cord.
- c) Tightness of pneumatic fittings.

- d) Condition of internal tubing.
- e) Accumulation of dust or dirt within the unit.
- f) Mating integrity of internal connectors.
- g) Integrity of the pump.
- h) Security of circuit board.
- i) Security of the membrane panel.
- 3. Functional and Calibration Checks

It is recommended that the functional and calibration checks described in Section 2.4 are performed at least once every three months.

3.5 CALIBRATION

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

Calibration of the *A.T.S.* 3000 Tourniquet 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 for cuffs (0 mmHg, 50 mmHg, 250 mmHg, and 475 mmHg) and 4 set points for the reservoir (0 mmHg, 250 mmHg, 475 mmHg, and 700 mmHg). These calibration points are used to correct the signal from the pressure transducers during normal operation. The calibration points and a checksum are stored in non-volatile memory.

EQUIPMENT REQUIRED:

A.T.S. 3000 calibration hose (supplied). Calibrated 0 to 700 mmHg pressure meter (minimum requirement). Adjustable 0 to 700 mmHg pressure source (minimum required pressure source).

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.

CUFF AND RESERVOIR CALIBRATION

Below is a step-by-step procedure for calibrating both cuff transducers as well as the reservoir transducer. The calibration procedure will not be complete until both cuff transducers are calibrated as well as the reservoir transducer.

 To enter the calibration mode, press and hold the Main Cuff INFLATE and Main Cuff DEFLATE buttons while powering the unit ON. When the unit displays "CALIBRATION" release the Main Cuff INFLATE and Main Cuff DEFLATE buttons. Calibration mode is indicated by alternating "CAL" and "0" in the TIME display windows and indicates the unit is now ready to be calibrated.

- 2. The unit will display "0" in the PRESSURE displays and alternating "CAL" and "0" in the TIME displays. Throughout this procedure, the TIME display(s) will indicate the pressure in which the user is calibrating.
- 3. For zero, allow the port to be open to atmospheric pressure so the unit can sense the zero point (i.e. when setting the zero point, nothing should be connected to the cuff ports). Press the Main PRESSURE button, the unit will calibrate the zero pressure. The unit will beep to let the user know the set point was taken.
- 4. Connect the calibration hose, calibrated pressure meter and adjustable pressure source to the Main and Second Cuff sense ports. See Figure 3 for more details.
 - a. The Main Cuff sense port is the second port over from the left side of the unit.
 - b. The Second Cuff sense port is the fourth port over from the left side of the unit.
- 5. Once the zero point is calibrated, press the Main Cuff INFLATE button to advance the unit to the next pressure level. The unit's TIME displays will now be alternating between "CAL" and "50". Apply 50 mmHg of pressure. Once the pressure has stabilized, press the Main Cuff PRESSURE button so the unit can calibrate the 50 mmHg point. The unit will beep to let the user know the set point was taken.
- 6. Once the 50 mmHg point is calibrated, press the Main Cuff INFLATE button to advance the unit to the next pressure level. The unit's TIME displays will now be alternating between "CAL" and "250". Increase the pressure to 250 mmHg. Once the pressure has stabilized, press the Main Cuff PRESSURE button so the unit can calibrate the 250 mmHg point. The unit will beep to let the user know the set point was taken.
- 7. Once the 250 mmHg point is calibrated, press the Main Cuff INFLATE button to advance the unit to the next pressure level. The unit's TIME displays will now be alternating between "CAL" and "475". Increase the pressure to 475 mmHg. Once the pressure has stabilized, press the Main Cuff PRESSURE button so the unit can calibrate the 475 mmHg point. The unit will beep to let the user know the set point was taken.
- 8. After the 475 mmHg set point has been taken, press the Main Cuff INFLATE and Main Cuff DEFLATE buttons to advance to the reservoir transducer calibration step. When in the reservoir calibration process the Second Cuff display area goes blank and the Main Cuff display area switches to "RESERVIOR". Calibration mode is indicated by alternating "CAL" and "0" in the lower display area and indicates the unit is now ready to calibrate the reservoir transducer.

NOTE: At this point the reservoir pressure, if pressurized, will be exhausted through the source ports and the lower portion of the display should continue to display "CAL" "0" as described earlier.

- 9. For zero, allow the port to exhaust to atmospheric pressure so the unit can sense the zero point (i.e. when setting the zero point nothing should be connected to any cuff port). Press the Main Cuff PRESSURE button, the unit will calibrate the reservoir zero pressure, the unit will beep to let the user know the set point was taken.
- Connect the calibration hose, calibrated pressure meter and adjustable pressure source to the Main and Second Cuff <u>source</u> ports. See Figure 3 for more details.
 - a. The Main Cuff (*red port*) **source** port on the unit is the first port from the left side of the unit.
 - b. The Second Cuff (*blue port*) **source** port on the unit is the third port over from the left side of the unit.
- 11. Press the Main Cuff INFLATE button to advance the unit to the next reservoir pressure level. The display will now be alternating between "CAL" and "250". Apply 250 mmHg of pressure. Once the pressure has stabilized, press the Main Cuff PRESSURE button so the unit can calibrate the 250 mmHg point. The unit will beep to let the user know the set point was taken.
- 12. Once the 250 mmHg point is calibrated, press the Main Cuff INFLATE button to advance the unit to the next reservoir pressure level. The display will now be alternating between "CAL" and "475". Apply 475 mmHg of pressure. Once the pressure has stabilized, press the Main Cuff PRESSURE button so the unit can calibrate the 475 mmHg point. The unit will beep to let the user know the set point was taken.
- 13. Press the Main Cuff INFLATE button to advance the unit to the next reservoir pressure level. The display will now be alternating between "CAL" and "700". Apply 700 mmHg of pressure. Once the pressure has stabilized, press the Main Cuff PRESSURE button so the unit can calibrate the 700 mmHg point. The unit will beep to let the user know the set point was taken.
- 14. At this point, press the Main Cuff INFLATE and Main Cuff DEFLATE buttons. The unit will display "CALIBRATION" "COMPLETE". The message tells the user the calibration set points have been calibrated to the unit and have now been saved into the non-volatile memory.

NOTE: If the "CALIBRATION" "COMPLETE" message is not displayed, the calibration is incomplete and the adjustments will not be saved. Be certain to end the calibration session by simultaneously pressing the Main Cuff INLFATE and Main Cuff DEFLATE buttons and verify the "CALIBRATION" "COMPLETE" message is displayed.

If any pressure setting is off by more than 15 mmHg or adjusted incorrectly, a "CAL" "FAIL" alarm will be generated and service or calibration to the user's pressure meter or pressure source is recommended.

If the pressure signal from the internal transducer requires more than a 15 mmHg correction to equal the applied pressure, a "CAL" "FAIL" alarm will also be generated. Service to the unit is recommended.

- 15. The unit remains in calibration mode until it is set to STANDBY.
- 16. The stored calibration factors are retrieved from the nonvolatile memory during the power-up sequence. If the checksum is invalid, a "CAL" "FAIL" alarm is generated in the displays. The alarm will persist until the unit is set to STANDBY. Re-calibration is required if this occurs.
- 17. It is recommended to check the calibration by following the steps in Section 2.4 Step 5 "Calibration Check" before using this unit on a patient.

3.6 LEAK TESTING

The A.T.S. 3000 Tourniquet is capable of keeping a cuff with a substantial leak inflated. Naturally it is desirable to keep plumbing leaks to an absolute minimum. For this reason, a check for significant leakage is recommended at regular intervals as well as following any service procedure. After verifying the operation of the A.T.S. 3000 Tourniquet per Section 2.4, connect a 24 in. (61 cm) (or larger) cuff which is known to be leak free to the Main cuff ports (Red) of A.T.S. 3000 Tourniquet System. Adjust the Main Cuff set point to 475 mmHg. Ensure that all external connections are tight. Inflate the Main Cuff and allow the pressure to stabilize. At this point, the unit must be set to STANDBY. Under normal use, the unit cannot be set to STANDBY with a non-zero pressure value displayed in either cuff. However for leak testing purposes, a bypass feature has been incorporated. Press the ON/STANDBY button until the alarm message "CUFF" "NOT" "DEFL" appears. Release the ON/STANDBY button and within 5 seconds of the alarm discontinuing, press and hold the ON/STANDBY button again. The button must be held in for an additional 10 seconds before the unit will be set to STANDBY.

NOTE: During the 10 seconds, the alarm message will be displayed, the alarm will continue to sound and the ALARM SILENCE button will not silence the alarm.

Once the unit is set to STANDBY, wait for approximately 10 minutes and turn the unit back on. Operation will resume under cuff inflated start-up conditions (See Section 2.7 Part 1 for explanation). Cancel the alarm using the ALARM SILENCE button. Display the set point by activating the PRESSURE button and view the current (new) pressure set point. The set point is always displayed with an asterisk in the far left position. The current set point for the cuff should be at least 400 mmHg or more. Values less than this indicate an unacceptable leak rate and the source of the leak should be traced and corrected. The first connection to check should be the connections of the cuff. Different cuffs and/or cuff hoses may be tried to determine if the leak is internal or external of the unit.

Repeat the test for the Second cuff ports.

3.7 BATTERY VOLTAGE AND BATTERY SERVICE

NOTE: This section assumes that the unit has been charged for at least 24 hours. The unit's bottom battery compartment must be removed to measure battery voltage. See Section 3.2 "Access to Parts" and be sure to follow cautionary statements.

1. Battery Voltage Check

Be sure the unit is unplugged. Measure the battery voltage. The battery voltage should not be lower than 12 volts while the unit is unplugged and set to STANDBY. If, after 1 minute, the voltage reads less than 12 volts, the integrity of the battery should be suspect and should be replaced.

2. Battery Service

The 12-volt sealed lead acid battery is charged using lead acid charging technology. The charging circuit is active anytime the unit is plugged into an acceptable AC Mains outlet. The charger automatically sequences through several charge states based on the battery voltage and charging current conditions. Based on a charger test, the best charge mode is selected. No maintenance is required of the battery charging circuit. The life of the battery depends on the type of service and the storage method. Battery replacement will need to be more frequent with continued cycles of deep discharge and/or storage in a high temperature environment. Infrequent short-term use of the battery and storage in a room temperature environment will result in maximum life. It is recommended that the battery in the *A.T.S.* 3000 Tourniquet System be replaced annually. As a reminder, the *A.T.S.* 3000 System should be plugged in 24 hours before initial use.

NOTICE – BATTERY DISPOSAL

THE BATTERY IS OF A LEAD ACID TYPE. BATTERY MUST BE RECYCLED OR DISPOSED OF PROPERLY.

3.8 UNSCHEDULED MAINTENANCE

The *A.T.S.* 3000 Tourniquet is designed with several specific self-test features to assist in fault isolation. These features are designed to show messages in the Pressure and Time displays. The meanings of these messages are delineated in Tables 2.1, 2.2 and 2.3.

Another mode of failure that may occur is when an audible alarm occurs that cannot be silenced by the ALARM SILENCE button. The valves and pump will be disabled which seals off the cuff to prevent pressure loss. The displays may show random characters. Should this occur, the watchdog timer circuit of the safety processor has detected a problem. The microprocessor may not be executing reliable instructions and is not able to display the correct failure message. The unit should be serviced if this occurs. The calibration error message "CAL" "FAIL", "CAL M" "FAIL" or "CAL 2" "FAIL" may be due to defective circuitry or may simply indicate the need for calibration.

3.9 TROUBLE SHOOTING GUIDE

To aid in unscheduled maintenance, Table 3.2 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.

3.10 EXPECTED TEST POINT READINGS

To expedite unscheduled maintenance, Table 3.3, Expected Test Point Readings, has been incorporated into this manual. This table, as well as Table 3.2, Troubleshooting, should give a qualified technician a good starting point from which to locate and repair most problems that could occur during the life of the unit. Unless noted, all measurements are to be made at room temperature with the cuffs disconnected, and the unit **plugged in.** All voltage measurements are with respect to ground and are to be made with the unit ON.

Table 3.2 Troubleshooting

SYMPTOM	POSSIBLE CAUSES
1. <u>Main Cuff</u> or <u>Second Cuff</u> will not inflate.	 a) Membrane Panel not properly plugged into P8. b) Tubing inside unit may be pinched or improperly connected. c) Deflate valve is stuck open. d) Pump not properly plugged into P14. e) Pump's electrical harness damaged. f) INFLATE button not working. g) Valve's electrical harness damaged. h) Defective valve driver circuitry.
2. <u>Main Cuff</u> or <u>Second Cuff</u> will not deflate.	 a) Membrane Panel not properly plugged into P8. b) DEFLATE button not pressed long enough (at least 2 seconds). c) Deflate valve is stuck shut. d) DEFLATE button not working. e) Valve's electrical harness damaged. f) Defective valve driver circuitry.
3. No green AC Indicator light.	 a) Unit not plugged into wall outlet. b) No Power at wall outlet. c) Mains AC harness not properly plugged into P2. d) Blown fuse(s). e) Membrane Panel not properly plugged into P8. f) Defective AC indicator. g) Defective AC indicator circuitry.
4. No flashing orange Battery Indicator light.	a) Unit running on AC.b) Membrane Panel not properly plugged into P8.c) Defective battery indicator.d) Defective battery indicator circuitry.
5. ALARM SILENCE button not working.	 a) ALARM SILENCE button not properly plugged into P1. b) Non-silenceable alarm (System Failure). c) ALARM SILENCE button defective. d) Defective alarm silence circuitry.
6. Alarm indicator light not working.	a) Membrane panel not properly plugged into P8.b) Defective alarm indicator.c) Defective alarm indicator circuitry.

Table 3.2 Troubleshooting

SYMPTOM	POSSIBLE CAUSES
7. No cuff pressure reading.	a) Transducer amplifier not working.b) Internal tubing kinked.c) Transducer tubing on incorrect transducer.
8. Pump will not stop running.	 a) Leak in internal hose or connector. b) Internal tubing kinked. c) Transducer(s) not working. d) Transducer tubing on incorrect transducer.
9. Battery Fail alarm/message.	a) Blown battery fuse (board mounted F1).b) Broken battery wire harness.c) Dead or depleted battery.
10. Backup battery not charging.	 a) Blown battery fuse (board mounted F1). b) Battery not properly plugged into P10. c) Unit not plugged into wall outlet (verify the green AC indicator is illuminated). d) Mains AC harness not properly plugged into P2 (verify the green AC indicator is illuminated). e) Unit was not permitted to charge for at least 24 hours. f) Defective battery. g) Defective battery charging circuitry.
11. AMP FAIL alarm.	a) Transducer(s) amplifier out of range.b) Battery fully depleted or defective.c) Extremely high pressure exerted on transducers.
12. Unit cannot be set to STANDBY.	 a) ON/STANDBY Membrane not properly plugged into P11. b) Pressure sensed in the Main or Second Cuff (unit will alarm "CUFF" "NOT" "DEFL"). c) ON/STANDBY not fully pressed. d) ON/STANDBY button defective.
13. Unit does not turn ON.	 a) Membrane panel not properly plugged into P8. b) ON/STANDBY button defective. c) Blown Fuse(s). d) Unit not plugged in and battery fully depleted.

Board Location	Nominal-Reading	Tolerance	Description / Comments
TP1	5.0 Vdc 0.0 Vdc	<u>+</u> 0.2	5 Volt DC supply for battery charge circuit 0 Vdc while on battery operation
TP2	26.9 Vdc	±1.5	Battery DC bulk charging voltage 12 Vdc nominal while on battery operation Voltage will vary while on battery operation and condition of battery
TP3	N/A	N/A	Not used for any measurement (high voltage DC common only)
TP4	DC Common	<u>+</u> 50 mV	DC common supply
TP5	5.0 Vdc	<u>+</u> 0.2	5 Volt DC switch mode supply
TP6	13.6 Vdc	<u>+</u> 1.0	Nominal system voltage Voltage will vary while on battery operation and condition of battery
TP7	14.0 Vdc	<u>+</u> 1.0	Bulk system voltage 0 Vdc while on battery operation
TP8	N/A	N/A	Development programmable pins only
TP9	N/A	N/A	Development programmable pins only
TP10	5.0 Vdc	<u>+</u> 0.2	Nominal voltage under normal use Voltage goes to 0 Vdc under system reset condition
TP11	4.1 Vdc	<u>+</u> 0.2	On / Standby switch logic
TP12	5.0 Vdc	<u>+</u> 0.3	5 Volt DC regulator supply
TP13	Removed	Removed	Not used
TP14	5 Vdc	5 Vdc	Transducer reference voltage supply
TP15	Removed	Removed	Not used
TP16	13.6 Vdc		Nominal system voltage Voltage will vary while on battery operation and condition of battery
TP17	4.095 Vdc	<u>+</u> 50mV	Precision reference voltage supply

Table 3.3 Expected Test point Readings

NOTE: USE TP4 (DC COMMON) AS THE VOLTAGE REFERENCE FOR ALL MEASURE-MENTS LISTED ABOVE.

CAUTION: HIGH VOLTAGE ELECTRICAL HAZARD. HIGH VOLTAGE WILL BE PRES-ENT ON THE POWER INPUT MODULE AND CONTROL BOARD. ALL SERVICE WORK MUST BE COMPLETED BY QUALIFIED TECHNICIANS.

Note: If the unit is locked in a failure, not all test voltages will be valid. Above voltages are listed for normal readings because failure readings will likely be unpredictable.

3.11 REPLACEMENT PARTS

The following is a list of field replacement parts that can be ordered from Zimmer. To obtain part or additional information regarding your unit, write or phone:

MAIL:	Zimmer Orthopaedic Surgical Products	
	200 West Ohio Avenue	
	Dover, Ohio 44622 U.S.A.	
<u>PHONE</u> :	1-330-343-8801 or 1-800-830-0970	

You can also contact your Zimmer distributor. To ensure prompt service, please include the following information with your order:

Model Number		
Serial Number		
Description of Part		
Part Number (if known)		
Quantity Desired		
Shipping Address		
Shipping Means (if any)		

We strongly recommend that all repairs be done by Zimmer staff.

Parts marked with an "*" are commonly used maintenance and/or preventative maintenance parts.

Table 3.4 Parts List

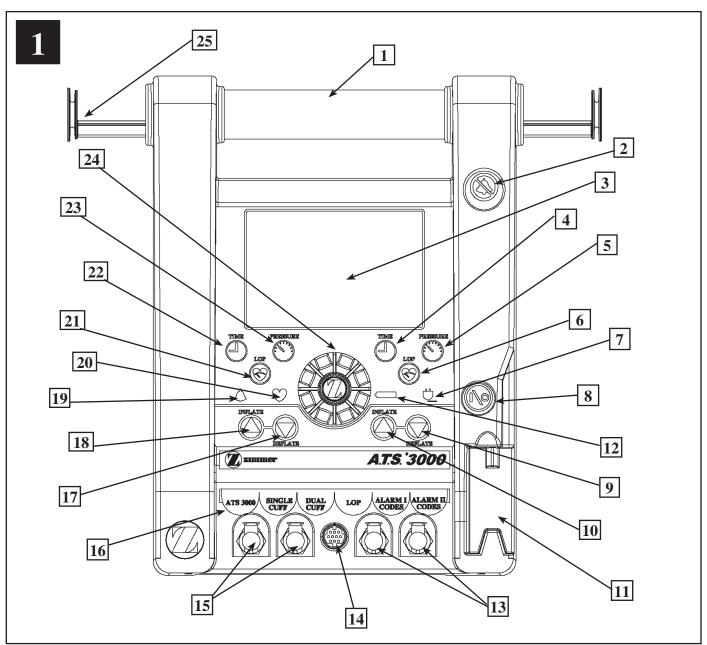
Replacement Part	Description	
Number	Description	
0600-1304883	1A Time Delay Fuse 5 x 20 mm *	
60-2000-110-00	Calibration Hose Assembly *	
60-2360-001-00	Pole Clamp Knob	
60-3000-105-00	05-00 LOP Sensor Kit *	
60-3000-700-00	LCD Panel Kit	
60-3000-701-00	Control Board Kit	
60-3000-702-00	Battery Kit *	
60-3000-703-00	Pump Kit	
60-3000-704-00	Slow Valve Kit	
60-3000-705-00	Fast Valve Kit	
60-3000-706-00	Front Case Kit	
60-3000-707-00	Rear Case Kit	
60-3000-708-00	Hose Hanger Kit	
60-3000-710-00	Battery Harness Kit	
60-3000-711-00	Pole Clamp Kit	
60-3000-712-00	Membrane Panel	
60-3000-713-00	On/Standby Switch Membrane	

Replacement Part	Description
Number	
60-3000-714-00	Alarm Silence Switch Membrane
60-3000-715-00	LOP Bulk Head Wiring Harness
60-3000-716-00	Shuttle Knob
61-2100-002-00	Cord/Pole Clamp Cover
62-1112-001-00	Valve Muffler
62-1137-001-00	Fuse Drawer, 1/4 in. x 1-1/4 in.
62-1138-001-00	Fuse Drawer, 5 x 20 mm
62-1167-001-00	Power Entry Ground Wire
62-1179-001-00	1A Time Delay Fuse, 1-1/4 in. *
62-1193-001-00	Power Entry Module
62-2100-019-00	Battery Bracket Base
62-2100-020-00	Battery Bracket
62-2100-096-00	Operator & Service Manual
62-2671-001-00	Pneumatic Coupling Female
62-8000-010-00	Power Cord *
62-8000-018-00	Mains Wire Harness

3.12 STORAGE

The *A.T.S.* 3000 Tourniquet System has an operating range of 50° F to 100° F (10° C to 38° C). The following are environmental conditions for transportation and storage:

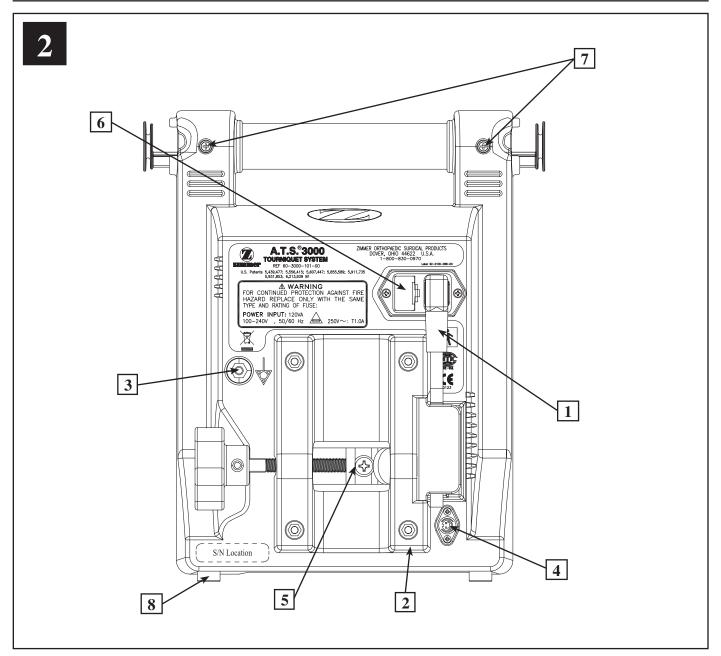
- A. Ambient temperature range......1°F to 149°F (-17°C to 65°C).
- B. Relative humidity range10% to 80%



FRONT CASE VIEW

- 1. Carrying Handle
- 2. Alarm Silence Button
- 3. Display Window
- 4. Second Cuff Time Button
- 5. Second Cuff Pressure Button
- 6. Second Cuff LOP Button
- 7. Green AC MAINS Indicator
- 8. ON/STANDBY Button
- 9. Second Cuff Deflate Button
- **10. Second Cuff Inflate Button**
- **11. LOP Sensor Holder**
- 12. Orange Backup Battery Indicator
- 13. Second Cuff Ports

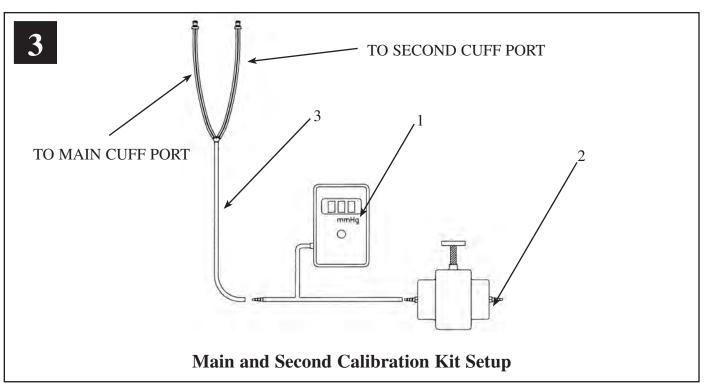
- 14. LOP Port Socket
- 15. Main Cuff Ports
- **16. Quick Reference Cards**
- 17. Main Cuff Deflate Button
- 18. Main Cuff Inflate Button
- **19. Red Alarm Indicator**
- 20. Yellow LOP Indicator
- 21. Main Cuff LOP Button
- 22. Main Cuff Time Button
- 23. Main Cuff Pressure Button
- 24. Shuttle Knob
- 25. Pull Out Hose Hanger One on each side of unit



REAR CASE VIEW

- 1. Power Cord
- 2. Power Cord & Clamp Cover
- 3. Potential Equalization Conductor Stud
- 4. Factory Test Port

- 5. Pole Clamp
- 6. Mains Fuse Block
- 7. Rear Case and Handle Screws
- 8. Bottom Feet Case Screws



- 1. Calibrated Pressure Meter with a minimum range of 0 to 700 mmHg.
- 2. Pressure Regulator / Source adjustable from 0 to 700 mmHg minimum.
- 3. Calibration Hose Kit Included with Unit.



Removing the Battery – Easiest if unit is mounted to stand.

1) Remove two (2) screws from bottom plate.



Removing the Battery Continued

 Carefully slide the bottom battery plate to the left and away from front of unit. Battery will drop out.
 Caution: battery is heavy



Removing the Battery Continued

- 3) Disconnect battery at the cord plug connection.
- 4) Replace battery by removing battery clamp.
- 5) Make note of wire color to battery polarity.
- 6) Reverse the process to reassemble.



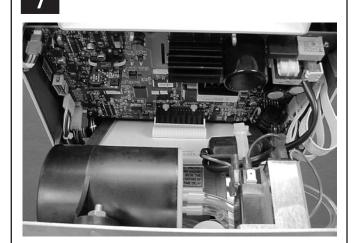


Removing the Rear Power Cord Clamp Cover1) Remove the 4 #6 nuts holding the Rear Clamp Cover.



Removing the Rear Clamp

1) Remove the two (2) pole clamp screws from the rear.



Disconnecting wiring from control board.

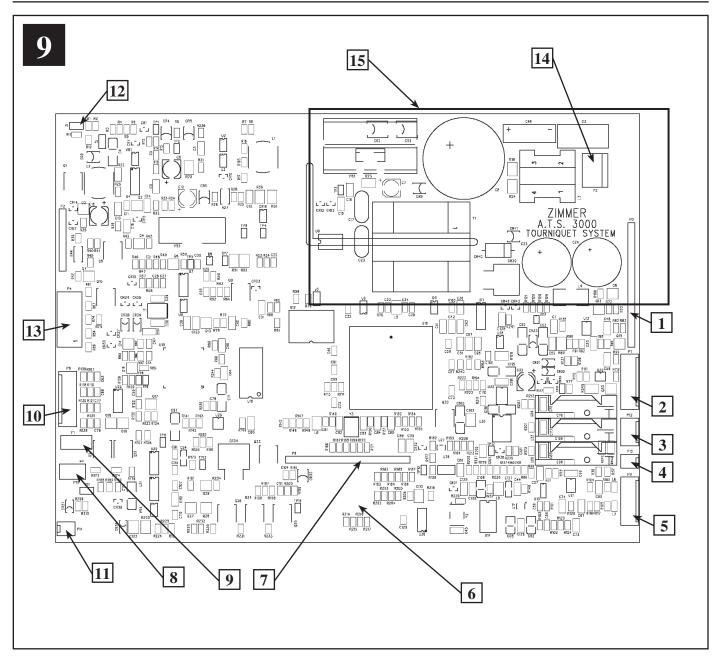
- 1) Use caution when disconnecting wiring from printed circuit board headers.
- Mark wires before disconnecting and see Section 3.2 Table 3.1 for proper re-connect of Board Plug Designators.



Rear case separation

- 1) All components are easily accessed when the rear case is removed.
- 2) Remove the Pole Clamp Cover and Pole Clamp before proceeding. See illustrations 5 and 6.
- 3) Remove the power cord from the back of the unit.
- 4) Remove the two screws from the rear bottom feet.
- 5) Remove the rear handle screws, one on each side of the handle.
- 6) Slide the rear cover away from the front cover.
- 7) Remove mufflers from inside of rear case.
- 8) Reverse the process to reassemble.

Be extremely careful not to pinch any wiring or tubing when reassembling!



Control Board Layout

- 1. LCD Panel Header (P5)
- 2. Main Cuff Valve Header (P7)
- 3. Factory Test Port Header (P12)
- 4. Speaker Header (P13)
- 5. LOP Sensor Socket Header (P9)
- 6. Shuttle Knob Retaining Washer/Screw (not shown)
- 7. Front Membrane Header (P8)
- 8. Batttery Header (P10)

9. Battery Fuse (F1)
10. Second Cuff Valve Header (P6)
11. On / Standby Header (P12)
12. Alarm Silence Header (P1)
13. Not Used - Development Ports Only (P4)
14. AC Power Input Header (P2)
15. Power Supply Area

3.13 Warnings, Cautions, and Symbol Definitions



Type BF equipment



Declaration that a product meets the EMC regulations per marking requirements.



Protective earth ground



This product contains a Lead Acid Battery that must be recycled.



Potential Equalization Conductor



Do not dispose of battery in trash.



Electrical hazard dangerous voltage



Alternating current (AC)





Direct Current (DC)

Year of manufacture



Replace fuse as marked



Refer to instruction manual



Conformity Marking of the Council of the European Community (TUV Product Services, Munich, Germany)

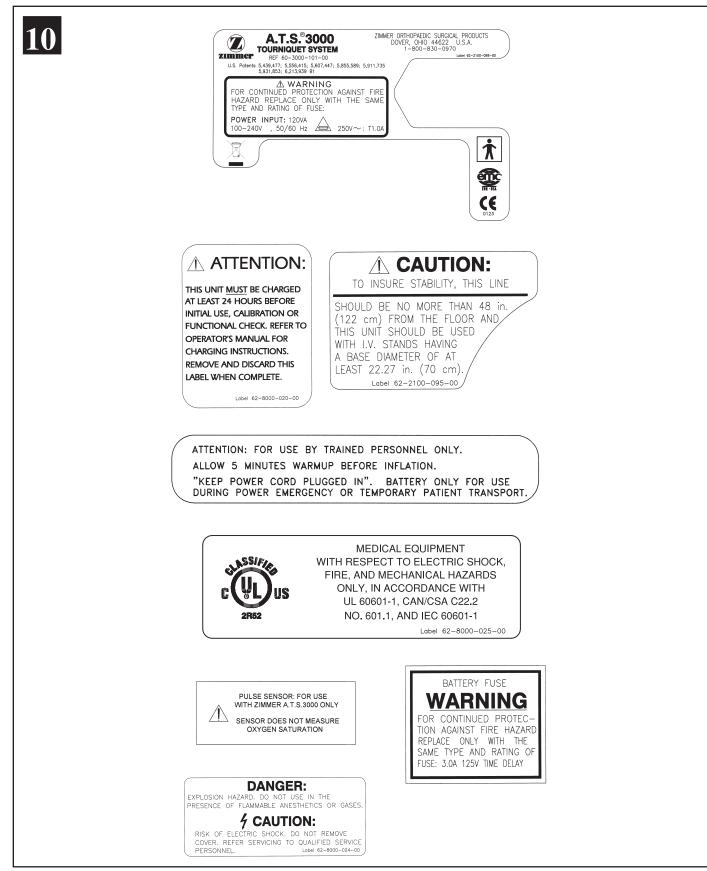


UL / C-UL Classification mark Medical Equipment with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601-1, CAN/CSA C22.2 No. 601.1, and IEC 60601-1



This product contains electrical or electronic materials. The presence of these materials may, if not disposed of properly, have potential adverse affects on the environment. Presence of this label on the product means it must not be disposed of in normal household waste and must be disposed of separately. To find out how to properly dispose of this product, please contact your local Zimmer Representative.

Labels





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