Operator & Service Manual

A.T.S.[™] 2000 TOURNIQUET SYSTEM

REF 60-2000-101-00



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

SCOPE OF WARRANTY

Zimmer, Inc. warrants the Product (*A.T.S.*[™] 2000 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 the 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 the event of a warranty claim within the warranty period please take the following steps:

1. Notify Customer Service Department, Zimmer Orthopaedic Surgical Products at 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_____

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ENGLISH

SECTION 1.0

A.T.S. 2000 TOURNIQUET SYSTEM* GENERAL INFORMATION

*U.S. Patents B1 4,469,099; 4,548,198; 5,556,415; 5,607,447; 5,855,589

1.1 FEATURES

The *A.T.S.* 2000 Tourniquet System is an automatic, microprocessor-based pneumatic tourniquet system. Its features include:

- The ability to independently control and monitor two cuffs in a Bier Block or bilateral procedure.
- Microprocessor control for improved reliability and to help prevent loss of occlusion during Bier Block cuff switching.
- Dual line tubing and dual port cuffs to facilitate monitoring of cuff pressure from one line as well as supplying air to pressurize the cuff via the other.
- A built-in battery charger.
- Precision pressure transducers in conjunction with a microprocessor-based control system.
- Time and pressure defaults that can be customized to fit user preference.
- Built-in inflation time alarm system to alert the operating room staff when the anticipated cuff inflation time has been reached. This system also provides a convenient means to monitor and record total inflation time.
- Large, bright LED displays for easy viewing from a distance.
- High output pump for increased inflation rate.
- Internal reservoir for increased inflation rate.
- Self-testing of alarm tones, displays, system calibration, and certain portions of the hardware and software each time the unit is turned on. In addition, some self-testing occurs continuously during normal operation.
- Multiple audible and visual alarms to alert the user of abnormal conditions: detects pressure not within acceptable limits, time alarm, low battery voltage, hardware failure. For certain types of equipment malfunctions, the unit will also display error messages for certain equipment malfunctions that identify the cause of error, thus reducing fault isolation time.
- Easily accessible Quick Reference Cards containing general use instructions and help codes.
- Alarm silence switch permits silencing of most alarm tones for 30 seconds.
- Adjustable alarm volume (medium to high tone).
- Simple calibration that may be performed without disassembly.
- Modular construction for easy maintenance and repair.
- Portable and designed for tabletop or tourniquet stand mounting.

1.2 SPECIFICATIONS

Line Voltage Range:

90-240 V~, 50/60 Hz, auto switching

Line Current:

670 mA RMS @ 120 V~

Input Power:

53 Watts Typical

AC Indicator Light:

Green LED

Battery Type:

2 Rechargeable, 12 V = sealed lead acid, 2.3 Amp hours

Battery Discharge Time:

Unit will operate on battery power for 60 minutes minimum with fully charged batteries.

Battery Recharge Time:

24 hours (Maximum) 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

Cuff Pressure Range:

50-475 mm Hg

Pressure Accuracy:

±3 mm Hg (50-475 mm Hg)

Pressure Regulation:

±4 mm Hg of set point (10 second average under non-transient conditions without external leaks)

Maximum Pressures:

475 mm Hg cuffs 700 mm Hg reservoir

Time Alarm Set Ranges:

0-240 minutes; 1 minute increments

Timer Accuracy:

0.25% ±1 second

Internal Diagnostics:

Program, memory, watchdog timer, transducer calibration, improper valve actuation.

SIZE:

Height:

12.75 in. (32.4 cm)

Width:

10 in. (25.4 cm)

Depth:

10.5 in. (26.7 cm) (including clamp)

Weight:

19.8 lbs (9 kg)

CONTROLS:

On/Standby Switch:

Applies power to unit / sets unit to **STANDBY**

Pressure Touch-Switches:

Increase or decrease pressure set points.

Time Touch-Switches:

Increase or decrease the time alarm set points.

Cuff Touch-Switches:

Control inflation or deflation of the main cuff and/or second cuff.

Alarm Silence Switch:

Allows operator to manually silence certain alarms for 30 seconds.

DISPLAYS:

Pressure:

Red 14 segment light emitting diodes (LED)

Time:

Red 14 segment light emitting diodes (LED)

AC Indicator Light:

Green LED

UL 60601-1 Classification:

Class I and Internally Powered, Type B, continuous operation. Use ordinary protection against ingression of liquids. Not for use with flammable anesthetic or gases.

The *A.T.S.* 2000 Tourniquet System complies with EMC criteria set forth in IEC 60601-1-2.

1.3 INTENDED USE

The *A.T.S.* 2000 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 of 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 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.

1.4 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 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
- 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.

1.5 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 should 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 IVRA (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 PO₂ and pH should be closely monitored.
- Select the proper cuff size to allow for an overlap of about 3 to 6 inches (7.6 to 15.2 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 bandages 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 Intravenous Regional Anesthesia (IVRA, a Bier Block anesthesia) is used, it is recommended that the tourniquet remain inflated for at least 20 minutes from the time of injection.

1.6 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.
- 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 humerus.

SECTION 2.0

A.T.S. 2000 TOURNIQUET SYSTEM INSTALLATION & OPERATING INSTRUCTIONS

2.1 INITIAL INSPECTION

Unpack the *A.T.S.* 2000 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.

2.2 FUNCTIONAL AND CALIBRATION CHECK

The unit shall produce the results explained in the following steps, exactly as indicated. Failure to do so indicates that the device is not to be used until necessary repairs are made.

- 1. Connect the power plug to the power entry module on the back of the unit, then plug the unit into a source of power compatible with the unit's power rating.
 - a) Observe that the ~ (AC) indicator is on.
 - b) Unit should be connected to A/C power 24 hours before initial use.
- 2. Turn the unit on by pressing the ON/STANDBY (**I/O**) touch-switch and observe the following:
 - a) A series of zeros and asterisks appear on the PRESSURE and TIME displays;
 - b) The unit emits three tones; high, medium, low;
 - c) The word "SELF" appears in the main PRESSURE display and the word "TEST" appears in the main TIME display;
 - d) The word "VER" appears in the second PRES-SURE display and the software version number appears in the second TIME display;
 - e) The Alarm Silence Switch illuminates;
 - f) The word "CAL" appears in both PRESSURE displays;
 - g) The PRESSURE and TIME displays all read zeros.
- 3. Test the PRESSURE set point system as follows:
 - a) Press and hold the main PRESSURE INCREASE
 (+) or DECREASE (-) touch-switch;
 - b) The PRESSURE display reads "*250", the default pressure set point, for approximately 1.5 seconds;
 - c) The main PRESSURE display increases (or decreases) by units of one until reaching a multiple of 5. Then the main PRESSURE display increases (or decreases) by units of 5 to a maximum of 475 (or a minimum of 0), thus altering the pressure set point;
 - d) Releasing the touch-switch causes the sensed pressure of "0" to be displayed;
 - e) Once again, press the main PRESSURE IN-CREASE (or DECREASE) touch-switch; the main PRESSURE display should read the last setting from step c (above);
 - f) Release the main PRESSURE touch-switch;
 - g) Repeat steps **a** through **f** above for the second PRESSURE display functional check.

- b) The main TIME display reads "*60", the default pressure set point, for approximately 1.5 seconds;
- c) The main TIME display increases (or decreases) by units of one until reaching a multiple of 5. Then the main TIME display increases (or decreases) by units of 5 to a maximum of 240 (or a minimum of 0), thus altering the time set point;
- d) Release the touch-switch. This should cause the actual time of "0" to be displayed;
- e) Once again, press the main TIME INCREASE (or DECREASE) touch-switch; the main TIME display should read the last setting from step c (above);
- f) Release the main TIME touch-switch;
- g) Repeat steps **a** through **f** above for the second TIME display functional check.

Notes for steps 3 & 4:

- 1. Anytime an asterisk (*) is displayed in the left display digit, the data being displayed is its set point.
- 2. The default factory set point for pressure is 250 mm Hg.
- 3. The default factory set point for time is 60 minutes.
- 5. Calibration Check

Note: During the power-up diagnostic self-test described above, the unit, which must hold a tolerance of \pm 3 mm Hg, will test calibration. Should an out of calibration condition be detected, the unit will display "AMP" "FAIL" in the PRES-SURE and TIME displays. Even though the unit completes this check during power-up, the following quantitative check is recommended at regular intervals.

- a) Set the unit to STANDBY by pressing and holding the ON/STANDBY (I/O) touch-switch. Note that the unit will not be set to STANDBY immediately. The ON/STANDBY touch-switch has a 2-second delay built in to help prevent accidental turn off.
- b) Wait approximately 10 seconds, then turn the unit back on by pressing the ON/STANDBY (I/O) touchswitch. Press and hold the second PRESSURE (+) and (-) touch-switches until "CUFF" "CAL" is displayed.
- c) Connect a calibrated pressure meter, with a minimum range of 0 to 700 mm Hg, to the Calibration Hose Assembly. See Fig. 1.
- d) Connect a pressure source capable of supplying (at minimum) 700 mm Hg of pressure. See Fig. 1.
- e) Insert the second cuff line with connector into the Second Cuff sense port. See Fig. 1.
- f) Insert the main cuff line with connector into the Main Cuff sense port. See Fig. 1.
- g) Apply 50 mm Hg of pressure to the cuff sense ports. The displays should each read 50 ±3 mm Hg.
- h) Increase the pressure to 250 mm Hg. Again, the displays should each read 250 ±3 mm Hg.
- i) Repeat step h (above) for 475 mm Hg.
- j) Remove the main and second cuff line from the cuff sense ports.
- k) Press and hold the second PRESSURE (+) and (-) touch-switches until "RES" is displayed in the second PRESSURE display. The main PRESSURE display should be reading 0 ±3 mm Hg.
- Insert the main cuff line with connector and second cuff line with connector into the reservoir sense ports. See Fig. 1.

- Mathematical methods in the sense ports. The display should read 250 ±3 mm Hg.
- n) Repeat step m for 475 mm Hg and 700 mm Hg.
- o) Remove pressure as well as the main and second cuff line with connectors from the unit.
- p) Set the unit to STANDBY by pressing and holding the ON/STANDBY (**I/O**) touch-switch.

NOTE: During the calibration check, if any reading is off by more than 3 mm Hg, the unit must be calibrated. See CALIBRATION in MAINTENANCE Section 3.

6. Under Pressure Alarm Check

Create a leak in the main cuff while it is inflated. Make the leak large enough that even though the unit will be attempting to maintain pressure, the pressure still falls more than 15 mm Hg below set point. Observe:

- a) The Main PRESSURE display window indicates low pressure by "LO-P".
- b) The Alarm Silence Switch illuminates.
- c) After approximately 1 second, an audible tone will sound announcing the low pressure condition. This delay is used to preclude nuisance alarms.
- d) Stop the leak and observe that the pressure returns to within limits, the audible tone ends, and the Alarm Silence Switch light extinguishes.

Repeat the above procedures for the second cuff.

2.3 INSTALLATION

The *A.T.S.* 2000 Tourniquet is designed to be mounted on a table top or tourniquet stand (REF 60-4022-001). The adjustment range of the pole clamp on the right side of the unit will accommodate pole diameters of 0.5 to 1.5 inches (1.25 to 3.8 cm). Caution: Do not hang articles on the tourniquet stand which are not related to tourniquet use.

Inspect and ensure that the correct fuse drawer with appropriately rated fuses is present. 100–120 V uses the grey fuse drawer with 1.0 A time delay fuses. 220–240 V uses the black fuse drawer with 500 mA time delay fuses.

Connect the power cord of the unit to a properly polarized and grounded power source whose voltage and frequency characteristics are compatible with those listed on the nameplate of the unit.

The A.T.S. 2000 Tourniquet is now ready for use.

2.3.1 PRESSURE AND TIME DEFAULT SELECTIONS

An operator may want to modify the start up default pressure of 250 mm Hg and the default time of 60 minutes for one or both cuffs.

The following steps will allow a user to customize the default settings for both cuffs.

- 1. Prior to any cuff inflation, set the cuff target pressure and the maximum inflation time to the new desired default values.
- Press the main cuff PRESSURE (+) and (-) touchswitches simultaneously and hold until an audible tone is sounded, indicating that the new default values have been stored. The display should also read "UP" "DATE".

The new pressure and time defaults will be written to nonvolatile storage and will provide the default pressure and

2.3.2 VOLUME SELECTION

An operator may want to change the speaker volume setting from the default value of 2.

The following steps will allow a user to customize the speaker volume default.

- Prior to any cuff inflation, set the speaker volume by pressing and holding the second cuff PRES-SURE (+) and (-) touch-switches simultaneously. Hold until "VOL" is displayed in the second cuff PRESSURE display.
- Adjust the volume to the desired level by pressing the second cuff TIME (+) or (-) touch-switches. The (+) increases volume while the (-) decreases volume. The volume can be set from 1 to 4, with 1 being the lowest volume.
- Exit the volume mode by pressing the second cuff PRESSURE (+) and (-) touch-switches simultaneously. The new speaker volume setting will be written to nonvolatile storage and used as the default setting.

2.4 CONTROLS, INDICATORS, AND CONNECTORS

Refer to Fig. 2 for the locations of the unit's controls, indicators, and connectors. Their primary functions are:

- 1. ON/STANDBY (I/O) touch-switch
 - Turns the unit on or sets the unit to STANDBY. This switch has approximately a 2-second time delay. When setting the unit to STANDBY, this switch must be held in for the 2-second duration. This helps prevent the unit from being accidentally set to STANDBY. This switch will not set the unit to STANDBY when the cuff pressure is at a non-zero value. Ensure cuffs are fully deflated and have been removed from the patient prior to setting the unit to STANDBY. Note: During STANDBY, power to the A.T.S. 2000 instrument and all instrument functions (i.e. inflation, deflation, etc) are off but power continues to supply the battery charging circuitry anytime ~ (AC) power is present.
- 2. PRESSURE SETTING Touch-Switches
 - a) The MAIN CUFF controls, indicators and connectors operate the main cuff. The SECOND CUFF controls, indicators and connectors operate the second cuff. To view the current pressure setting, depress either pressure setting touch-switch (+) or (-). The PRESSURE display will display the pressure setting with an asterisk (*) in the far leftmost digit. The asterisk helps the operator identify that the data displayed is the set point data, not the actual sensed pressure. This is helpful when needing to view the set point data during a procedure.
 - b) To change the pressure setting, depress and hold the increase (+) or decrease (-) touch-switch until the desired setting is reached. The setting will change in 1 mm Hg increments for the first 5 counts or until reaching a multiple of 5, then in increments of 5 until the touch-switch is released or the limits (0 and 475) are reached.

3. TIME SETTING Touch-Switches

- a) To view the current time setting, depress either time setting touch-switch (+) or (-). The TIME display will display the time setting with an asterisk in the far left digit. The asterisk helps the operator identify that the data being displayed is the set point data, not the actual elapsed time. This is helpful when viewing the setpoint data during a procedure.
- b) To change the time setting, depress and hold the increase (+) or decrease (-) touch-switch until the desired setting is reached. The setting will change in 1 minute increments for the first 5 counts or until reaching a multiple of 5, then in increments of 5 until the touch-switch is released, or the limits (0 and 240) are reached.
- c) The accumulated inflation time may be reset to zero by depressing the TIME increase (+) and decrease (-) touch-switches simultaneously for 2-seconds. This enables the unit to be used for multiple procedures at the same pressure setting without setting the unit to STANDBY (and thus erasing the selected pressure set point if other than the default is used.)

4. INFLATE/DEFLATE Touch-Switches

Inflation or deflation of the cuff(s) is accomplished by depressing the appropriate touch-switch. For greater safety, the deflate touch-switch has a delay and, therefore, must be held for 1.5 seconds before the unit will allow a cuff to deflate.

Note: It is not possible to deflate one cuff while the other cuff is inflating.

5. ALARM SILENCE SWITCH

This push-button switch will light when any of a number of alarm conditions exist. The audible tone associated with most of these alarms may be silenced for 30 seconds by depressing this switch. The push-button will remain lighted until the alarm condition is corrected. Note: In general, when an alarm sounds because of an internal circuit malfunction, the tone cannot be silenced by this switch.

6. PRESSURE DISPLAYS

During normal operation with no touch-switches being depressed, the displays will show the pressure sensed in the cuff(s) over the range of 0 to 475 mm Hg. At other times, depending on alarm conditions and touchswitches, these displays may communicate other information such as alarm messages or pressure set point. The pressure set point may be viewed on the displays when the PRESSURE SETTING touch-switches are operated in accordance with point 2 above.

7. TIME DISPLAYS

During normal operation, with no touch-switches being depressed, the displays will show the inflation time of the cuff(s) in 1-minute increments, up to a maximum of 240 minutes. At other times, depending on alarm conditions and touch-switches, these displays may communicate other information such as alarm messages or time set point. The time set point may be viewed on the displays when the TIME SETTING touch-switches are operated in accordance with point 3 above. If the inflation time has exceeded the time alarm setting, the display will flash between inflation time and "TIME" "UP" message.

8. AC INDICATOR LIGHT

Identifies that the unit is plugged into an ~ (AC) power source. The unit is operating on battery if this light is not illuminated.

9. QUICK REFERENCE CARDS

Pull-out cards that contain general use instructions and help codes.

10. CUFF CONNECTORS

Ports to connect hoses to cuff(s).

11. POLE CLAMP

Adjustable clamp to mount the unit on a tourniquet stand.

2.5 SINGLE CUFF OPERATION

- 1. Connect the power cord to an electrical power source that is compatible with the ratings listed on the nameplate of the unit.
- 2. Connect a dual port cuff to the unit at the main cuff connectors.
- 3. Press the ON/STANDBY touch-switch to turn the unit on. The unit will execute a self-check diagnostic test as described in Section 2.2 of this manual. Successful completion of the self-check indicates the unit is ready for use.

CAUTION: If either cuff is pressurized to 50 mm Hg or more during power-up, the *A.T.S.* 2000 Tourniquet will declare it an abnormal start-up sequence. It will assume that a surgical procedure is in process, and will adopt pressures sensed in each cuff as the <u>new set point</u>. It will automatically go into the regulate mode on the cuff(s) which had the excess pressure. To alert the operator of this condition, the unit will sound a high pitch tone and illuminate the Alarm Silence Switch Light. 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.

- 4. The default settings for cuff pressure and time are retrieved from the nonvolatile storage during power up. These values may be changed prior to cuff inflation by following Section 2.4 step 2b. For each patient, tourniquet pressure should be set to 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.
- 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 forefoot 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 limb is then prepared and draped 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. to what pressure; 3. for how long; 4. whether to allow for intermittent aeration of tissues by deflating the cuff for 10 to 15 minutes; 5. at 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, about 1 1/2 hours is safe and 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 about 60 degrees, and steady pressure should be applied to the incision with sterile dressing. Under optimum conditions, the tourniquet cuff can be kept inflated until the final compression dressings are in place. Postoperative swelling is then kept to a minimum.

- 6. The cuff is inflated by pressing the MAIN CUFF INFLATE touch-switch. The unit will pressurize the main cuff to the preset pressure and start the inflation clock. If the unit cannot pressurize the cuff to within 15 mm Hg of the set point in less then 30 seconds, a pressure alarm will be sounded. See Section 2.8 for information about possible alarm conditions.
- At the end of the procedure, deflate the cuff by pressing the MAIN CUFF DEFLATE touch-switch. The PRESSURE display will show the deflation of the cuff, and the inflation clock will stop. Record the elapsed time if desired.
- 8. Remove the tourniquet cuff and any underlying bandages immediately following final deflation. The time of tourniquet cuff removal should be noted, and circulation of the limb should be checked.
- 9. The time clock display(s) may be reset to zero without turning the unit off. This would enable the unit to be used for multiple procedures without turning the unit off (and thus erasing the selected pressure set point if other than the default is used). see Section 2.4 step 3c.

10. Set the unit to STANDBY by pressing and holding the ON/STANDBY touch-switch. This switch has approximately a 2-second delay before allowing the unit to be set to STANDBY. You must hold the switch in for the 2-seconds before the unit will be set to STANDBY.

2.6 DUAL CUFF OPERATION

Operation of the unit is identical to single cuff operation (see Section 2.5) except for the following points:

- 1. Both dual port cuffs are connected at the bottom of the unit.
- 2. Deflation of one cuff will not be permitted while the other is inflating.
- 3. 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 mm Hg 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.
- 4. At the end of the procedure one cuff, either the MAIN or SECOND CUFF, may be deflated by pressing the appropriate deflate touch-switch without the Bier Block Safety Lock Out feature interrupting. When attempting to deflate the other cuff, an alarm code "CUFF" "DEFL" will appear. Release the deflate touch-switch and within 5 seconds of the alarm discontinuing, press the deflate touch-switch again. Immediately upon cuff deflation, the cuff should be removed from the patient. After the cuff has been fully deflated and removed from the patient, the unit can be set to STANDBY.

2.7 BIER BLOCK CUFF OPERATION, (IVRA)

Review Sections 2.5 and 2.6, SINGLE CUFF OPERATION and DUAL CUFF OPERATION.

- 1. The following are suggested cuff connections:
 - a. The proximal cuff connected to the red outlined MAIN CUFF connectors, using the white/red cuff tubing;
 - b. The distal cuff connected to the blue outlined SECOND CUFF connectors, 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. At the end of the procedure one cuff, either the MAIN or SECOND CUFF, may be deflated by pressing the appropriate deflate touch-switch without the Bier Block Safety Lock Out feature interrupting. When attempting to deflate the other cuff, an alarm code "CUFF" "DEFL" will appear. Release the deflate touch-switch and within 5 seconds of the alarm discontinuing, press the deflate touch-switch again. Immediately upon cuff deflation, the cuff should be removed from the patient. After the cuff has been fully deflated and removed from the patient, the unit can be set to STANDBY.

2.8 ALARM CONDITIONS

There are a number of conditions for which the *A.T.S.* 2000 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. It is very likely that the valves will be disabled causing the system to hold cuff pressure. It is also likely that a high pitched tone will sound under these conditions.

Most audible alarm tones may be silenced for 30 seconds by depressing the Alarm Silence switch. The light in the Alarm Silence switch will normally remain lit until the condition that created the alarm has been corrected. At the end of the silenced period, tones will be re-enabled. Depressing the Alarm Silence switch will cause the alarm tone to be silenced again.

It is possible for more than one alarm condition to be present. In that event, the unit will announce the alarm conditions in sequence. The operator should identify the causes of the alarms and act on the condition that presents the most significant risk to the patient first. Note that the Alarm Silence switch will silence the audible tones associated with multiple alarm conditions in the same manner that it does for single alarm conditions.

To minimize nuisance pressure alarms that can be caused by vigorous movement of the patient's limbs, a 1.5 second delay has been designed into the tone generator. The Alarm Silence light will still turn on during the 1.5 second period.

Under certain conditions, such as when a FAIL indication appears in the TIME display or the information that appears in the TIME and PRESSURE display 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 and holding the ON/STANDBY touch-switch until the unit is set to STANDBY. Since this removes power from the internal instrument circuitry and all instrument functions, commands to the valves and pump will cease. This should cause the cuff to hold pressure (in the absence of leaks). Clamp the cuff lines with hemostats and replace the tourniquet. FAIL conditions can only be reset by setting the unit to STANDBY. In the event that a FAIL shutdown was caused by transient condition, it may be possible to resume normal operation by setting the unit to STANDBY then back on again. Please read the special CAUTION note in Section 2.5

2.8.1 PRESSURE ALARMS

A pressure alarm "LO-P" will occur when the pressure in a cuff is more than 15 mm Hg from the pressure set point. A cuff can have a leak that is substantial but which the unit can compensate for by continual pumping and maintain cuff pressure within the 15 mm Hg set point window. This type of leak could be due to a pin hole in a cuff bladder, or loose pneumatic/hose fitting(s). This type of leak could progress into a total failure of a cuff if not corrected. The operator is alerted to a substantial leak by "LEAK" in the cuff pressure display. Should a "LEAK" be detected, all connections must

be checked for leaks and fixed and/or replaced.

Table 2.1 Alarm Conditions

CONDITION	AUDIBLE			ALARM SILENCE	
CUFF PRESSURE LOW: 15 mm Hg or more below desired set point	STEADY HIGH PITCH	LO-P	DISPLAT	LIGHT	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: 15 mm Hg or more above desired set point	STEADY HIGH PITCH	HI-P		LIT	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> 2000 should be replaced.
CUFF SIDE LEAK: A sustained leak exists that may affect the cuff pressure.	STEADY HIGH PITCH	LEAK		LIT	A substantial leak has been present for more than 9 seconds.
RESERVOIR LEAK: An internal leak exists that may affect the reservoir pressure.	STEADY HIGH PITCH	RES LEAK		LIT	A substantial leak has been detected which may indicate a leak has occurred between the manifold and pump/reservoir.
INFLATION TIME IN EXCESS OF SETTING	STEADY HIGH PITCH		TIME UP	LIT	Surgeon should be warned of time up condition. On the advice of the surgeon, time should be set to a new value.
LOW BATTERY VOLTAGE	STEADY HIGH PITCH		BAT LOW PLUG IN	LIT	Unit needs to be connected to A/C (~) power.
CUFF PRESSURIZED DURING POWER UP: This will occur if, for example, the unit is turned off and back on without deflating the cuff.	STEADY HIGH PITCH	CUFF	INFL	LIT	If a cuff pressure is 50 mm Hg or greater at the time that the ON/STANDBY touch- switch is set to ON, the system assumes that a procedure is in progress. It adopts the sensed pressure of the cuff(s) as the new cuff set point and sounds the alarm to notify the operator that it has done so. The operator should immediately check the pressure set point to see if it needs to be reset to a different value.
CUFF NOT DEFLATED	STEADY HIGH PITCH		CUFF NOT DEFL	LIT	Pressure in the deflated cuff is a non-zero value. Check for kinks in hose(s). If alarm persists, disconnect hose(s) from cuff. If attempting to set the unit to STANDBY, ensure that cuff is fully deflated and has been removed from the patient.

NOTE: In addition to the conditions shown, it is conceivable that a malfunction could occur for which the indicators are unintelligible or unpredictable. It is very likely that the valves will be disabled causing the system to hold cuff pressure. It is also likely that a high pitched tone will be sounded under these conditions. The operator should conclude that a hardware failure has occurred rendering the unit unusable. The appropriate action in such an event is to turn the unit off by pressing and holding the ON/STANDBY touch-switch until the unit turns off. Another tourniquet system should be brought in and cuff hoses must be clamped off prior to changing units.

Table 2.2 Hardware Malfunction Codes

PRESSURE DISPLAY	TIME DISPLAY	AUDIBLE TONE	ALARM SILENCE LIGHT	MEANING OF INDICATIONS
АМР	FAIL	STEADY HIGH PITCH	LIT	AMPLIFIER OUT OF RANGE.
BAT LOW	PLUG IN	STEADY HIGH PITCH	LIT	BATTERY VOLTAGE TOO LOW TO ENSURE RELIABLE OPERATION.
BAT	FAIL	STEADY HIGH PITCH	LIT	BATTERY DEFECTIVE OR TOO LOW TO USE.
CALM	FAIL	STEADY HIGH PITCH	LIT	MAIN CUFF OUT OF CALIBRATION OR "CAL" VALVE MALFUNCTION.
CAL2	FAIL	STEADY HIGH PITCH	LIT	SECOND CUFF OUT OF CALIBRATION OR "CAL" VALVE MALFUNCTION.
CALR	FAIL	STEADY HIGH PITCH	LIT	RESERVOIR OUT OF CALIBRATION OR "CAL" VALVE MALFUNCTION.
MATH	FAIL	STEADY HIGH PITCH	LIT	RESULT OF A MATH OPERATION WAS OUT OF RANGE.
ROM	FAIL	STEADY HIGH PITCH	LIT	MICROPROCESSOR FAILED A "ROM" MEMORY CHECK.
RAM	FAIL	STEADY HIGH PITCH	LIT	MICROPROCESSOR FAILED A "RAM" MEMORY CHECK.
VALV	FAIL	STEADY HIGH PITCH	LIT	AN IMPROPER VALVE COMBINATION OCCURRED.
WDT	FAIL	STEADY HIGH PITCH	LIT	WINDOWING WATCHDOG SYSTEM DETECTED A MALFUNCTION.

A.T.S. 2000 TOURNIQUET SYSTEM MAINTENANCE

3.1 GENERAL MAINTENANCE INFORMATION

While the *A.T.S.* 2000 Tourniquet has been designed and manufactured to high industry standards, it is recommended that periodic inspection and calibration be performed to ensure continual safe and effective operation. This section contains information to assist in that effort as well as serve as a guide to expediting unscheduled maintenance.

This unit is organized into easily accessible modular assemblies for ease of service. The major subassemblies of the unit are shown in Fig. 3 through 10.

3.2 GENERAL THEORY OF OPERATION

Refer to Block Diagram (Fig. 3).

The *A.T.S.* 2000 Tourniquet is a microprocessor controlled automatic tourniquet. The microprocessor takes inputs from various switches, the A/D converter, and memory, then uses this information to generate commands to the outputs (valves, pump, displays, alarm circuitry) to regulate cuff pressure. The pump and the eight valves control the inflation, deflation, and regulation of the tourniquet cuff(s).

The main and second cuffs are connected to the pump via a reservoir and manifold. There are eight valves mounted to the manifold to control the inflation, regulation, and deflation, four valves for each cuff. The cuff valves are further divided as slow and fast inflate, as well as slow and fast deflate valves. When a cuff is inflating, the fast inflate valve opens to pressurize the cuff quickly. When the cuff is deflating, the fast deflate valve opens to remove pressure quickly. The slow inflate and slow deflate valves are used to regulate the pressure during cuff regulation. Please note that block diagram Fig. 3 shows all valves in their off (no power) condition. In the event of a power failure or if the unit enters a failure mode, power to the valves will be removed and all of the valves will close which will prevent internal leaks.

The three pressure transducers, main cuff, second cuff, and reservoir, are connected to the A/D converter via high precision amplification circuitry. The digitized pressure signals are used by the microprocessor to regulate the pressure in the cuff(s) as well as in the reservoir. The condition of the pump, transducers reference, +15 volts, and safety monitor voltages are periodically checked for proper voltage levels. The battery condition is checked during power up for proper connection, i.e., broken wire or blown battery fuse. The unit can alarm when the battery voltage becomes low during a loss of AC (~) power or during patient transport.

The Windowing Watch Dog Circuit (Safety Processor) is a hardware circuit that monitors the timing signal generated by the microprocessor as well as valve states and system modes. Should any abnormality exist, indicating a problem with either the microprocessor, software, or valves, the safety processor will remove power to all eight valves. This means the valves will all close, flag the microprocessor of the error and turn the alarm light and speaker on. If the microprocessor is able, a message will be displayed indicating the failure. **CAUTION:** BE SURE THAT THE UNIT IS SET TO STAND-BY AND THE POWER PLUG IS UNPLUGGED BEFORE DISASSEMBLY.

CAUTION: MANY OF THE PARTS ON THE CPU AND POWER SUPPLY PRINTED BOARDS ARE STATIC SEN-SITIVE. TAKE APPROPRIATE PRECAUTIONS WHEN SERVICING THESE BOARDS.

To gain access to all internal parts, first remove the four rubber feet from the bottom of the unit. Remove the I.V. pole clamp knob, and the 2 screws from the top back of the unit, and then slide the back cover away from the front. See Fig. 4–7.

To access the power supply and CPU boards, remove the 3 screws from the bottom of the chassis, just behind the battery compartment, along with the 2 screws from the front top chassis. By removing these 5 screws, the chassis will be divided into two halves for clear and easy access. See Fig. 8–10.

3.4 PERIODIC MAINTENANCE

Test and inspect as per this section at least every 6 months.

3.4.1 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 hoses may be cleaned using a mild detergent solution or with alcohol. The interior of the cuff hoses should not be cleaned. Tourniquet cuffs should be cleaned in accordance with their cuff package insert instructions.

3.4.2 INSPECTION

The unit should be inspected at regular intervals. It is recommended that a visual inspection be performed by a qualified technician at least every 6 months. Inspection points are:

- Obvious internal or external damage;
- Condition of the power cord;
- Condition of hoses (both internal and external cuff connection hoses);
- Accumulation of dust or dirt within the unit;
- Mating integrity of internal connectors;
- Integrity of battery fuse mounted on the CPU printed circuit board;
- Security of the EPROM (U15) and safety processor (U10). See Fig. 11 for location;
- Integrity of the pump filters;
- Tightness of the pump mount.

3.4.3 FUNCTIONAL AND CALIBRATION CHECKS

It is recommended that the functional and calibration checks described in Section 2.2 be performed at least once a quarter.

3.3 ACCESS TO PARTS

3.4.4 CALIBRATION

CALIBRATION SHOULD BE PERFORMED EVERY 6 MONTHS, OR AFTER ANY UNSCHEDULED MAINTE-NANCE.

Calibration of the *A.T.S.* 2000 Tourniquet consists of a series of set-points from which the microprocessor can calculate the correct pressure readings by linearizing the pressure from the set-point voltages. These set-points are made by pressurizing the individual transducers to a predetermined pressure then allowing the microprocessor to read the voltages at those pressures (set-points). The set-point voltages are stored in nonvolatile memory and used whenever pressure is calculated.

The unit software contains an instruction set for the Calibration Mode that is independent of the normal operating software. To enter the Calibration Mode, turn the unit on, then press and hold the Second Pressure Increase (+) and Decrease (-) touch-switches until "CUFF" "CAL" is displayed.

EQUIPMENT REQUIRED:

- A. Calibration connecting hose
- B. Calibrated mm Hg pressure meter
- C. Adjustable pressure source, 0 to 700 mm Hg

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.

- Connect the calibration connecting hose, pressure gauge and adjustable pressure source as shown in Fig. 1.
- 2. Turn the unit on and enter the Calibration Mode.
- 3. Set the zero point in the main cuff by pressing the Main Cuff "INFLATE" and "DEFLATE" touch-switches at the same time. A tone will be heard letting you know that the zero point has been entered.
- 4. Set the zero point in the second cuff by pressing the Second Cuff "INFLATE" and "DEFLATE" touch-switches at the same time. A tone will be heard letting you know that the zero point has been entered.

NOTE: Steps 3 and 4 must be performed with the Calibration Connecting Hose disconnected from both Cuff Sense Ports.

- 5. Adjust the main cuff set point by pressing the Main Cuff Time (+) touch-switch once. The Main Cuff Time display should be showing 50.
- 6. Adjust the second cuff set point by pressing the Second Cuff Time (+) touch-switch once. The Second Cuff Time display should be showing 50.
- 7. Insert the main cuff line with connector into the Main Cuff Sense Port. See Fig. 1.
- 8. Insert the second cuff line with connector into the Second Cuff Sense Port. See Fig. 1.
- 9. Apply 50 mm Hg of pressure to the input ports.
- 10. Set the 50 mm Hg point in the main cuff by pressing the main cuff "INFLATE" and "DEFLATE" touch-switches at the same time. A tone will be heard letting you know that the 50 mm Hg has been entered.
- 11. Set the 50 mm Hg point in the second cuff by pressing the second cuff "INFLATE" and "DEFLATE" touchswitches at the same time.
- 12. Repeat steps 5–11 for set points of 250 and 475.

- 13. Remove source pressure then disconnect the calibration connecting hose from both sense ports.
- 14. Return the set points to zero by pressing the time (–) touch-switch 3 times for each cuff.
- 15. Press the second cuff pressure (+) and (-) touchswitches at the same time to move into reservoir calibration. The second pressure display should be showing "RES".
- 16. Set the zero point in the reservoir by pressing the main cuff "INFLATE" and "DEFLATE" touch-switches at the same time. A tone will be heard letting you know that the zero point has been entered.
- 17. Adjust the reservoir set point by pressing the main cuff time (+) touch-switch once. The main cuff time display should be showing 250.
- Insert the main cuff line with connector into the Main Cuff Reservoir sense port. The Main Cuff Reservoir sense port is the leftmost port on the main cuff. See Fig. 1.
- Insert the second cuff line with connector into the Second Cuff Reservoir sense port. The Second Cuff Reservoir sense port is the leftmost port on the second cuff. See Fig. 1.
- 20. Apply 250 mm Hg of pressure to the reservoir sense ports.
- 21. Set the 250 mm Hg set point in the reservoir by pressing the main cuff "INFLATE" and "DEFLATE" touchswitches at the same time. A tone will be heard letting you know that the 250 mm Hg point has been entered.
- 22. Repeat steps 20 and 21 for 475 and 700 mm Hg pressure set points.
- 23. Remove source pressure then disconnect the calibration connecting hose from both sense ports.
- 24. Return the reservoir set point to zero by pressing the Main Cuff Time (–) touch-switch 3 times.
- 25. Press the Second Cuff Pressure (+) and (–) touchswitches at the same time. The Main and Second Pressure displays should be showing "CAL" "DONE".

NOTE: THE "CAL" "DONE" MUST BE DISPLAYED BE-FORE TURNING THE UNIT OFF. THE NEW SET POINTS WILL NOT BE SAVED IF POWER IS REMOVED BEFORE "CAL" "DONE" IS DISPLAYED.

- 26. Set unit to STANDBY at the ON/STANDBY (I/O) touchswitch. Remember, this switch has approximately a 2-second delay before allowing the unit to be set to STANDBY, so you must hold the touch-switch in.
- 27. Restart the unit. We recommend that you check your calibration by following the steps in Section 2.2 step 5 "Calibration Check".

3.4.5 LEAK TESTING

The A.T.S. 2000 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. 2000 Tourniquet per Section 2.2, connect two 24 in. (61 cm) (or larger) cuffs which are known to be leak free to the A.T.S. 2000 Tourniquet System. Adjust both cuff set points to 475 mm Hg. Ensure that all external connections are tight. Inflate the main and second cuffs 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 the cuff(s). However for leak testing purposes, a bypass feature has been incorporated. Press the ON/STANDBY touch-switch until the alarm message "CUFF" "NOT" "DEFL" appears. Release the ON/STANDBY touch-switch and within 5 seconds of the alarm discontinuing, press and hold the ON/STANDBY switch again. The switch must be held in for an additional 10 seconds before the unit will be set to STANDBY.

NOTE: During the 10 seconds, the alarm will continue to sound a high pitch tone, the alarm silence lamp will be lit and the alarm message "CUFF" "NOT" "DEFL" will be displayed. The alarm cannot be silenced by the alarm silence switch.

After 10 minutes, turn the unit back on. Operation will resume under cuff inflated start-up conditions (see section 2.5 part 3 for explanation). Cancel the alarm using the ALARM SILENCE push-button. Display both main and second pressure points be activating either PRESSURE touchswitch 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 either cuff should be at least 400 mm Hg or more. Values less than this should be traced and corrected. The first connection to check should be the connections of the cuffs. Different cuffs and/or cuff hoses may be tried to determine if the leak is internal or external of the unit.

3.4.6 BATTERY VOLTAGE AND BATTERY SERVICE

NOTE: This section assumes that the unit has been plugged in and the battery charging for at least 24 hours. The rear case must be removed to measure battery voltage. See Section 3.3 ACCESS TO PARTS and be sure to follow cautionary statements.

A. Battery Voltage Check

Be sure the unit is unplugged. Attach a volt meter to the battery plug (P6 on the CPU board). The battery voltage should not be lower than 24 volts while in this off state. If, after 1 minute, the voltage reads less than 24 volts, the integrity of the batteries should be suspect and they should be replaced.

B. Battery Service

The two 12-volt sealed lead acid batteries are charged using the latest lead acid charging technology. The charging circuit is active anytime the unit is plugged into an acceptable

AC (~) outlet and the batteries are installed. 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 batteries 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 batteries and storage in a room-temperature environment will result in maximum life. It is recommended that the batteries in the *A.T.S.* 2000 be replaced annually. **The** *A.T.S.* **2000 should be connected to** ~ **power 24 hours before initial use.** The *A.T.S.* 2000 Tourniquet is designed with several specific self-test features to assist in fault isolation. These features are designed to show a message in PRESSURE and TIME displays. The meaning of these messages are delineated in Tables 2.1 and 2.2.

Another mode of failure that might occur is where the high pitched tone occurs that cannot be silenced by the ALARM SILENCE push-button. The valves and pump will be disabled, which seals off the cuff(s) to prevent pressure loss. The displays may show random characters. Should this occur, the Watch Dog 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. This failure mode, and all others giving a "FAIL" message, might be cleared by cycling the ON/STANDBY touch-switch.

The calibration error message (CALM, CAL2 or CALR) may be due to faulty circuitry or may simply indicate the need for calibration. The Watch Dog Timer (WDT) error message may be due to a faulty Watch Dog Timer circuit or improper microprocessor timing.

3.6 EXPECTED TEST POINT READINGS

To expedite unscheduled maintenance, Table 3.1, 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.

3.7 TROUBLESHOOTING 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.

Expected readings on both the CPU and power supply boards are shown in Table 3.1. All measurements are to be made at room temperature with the cuffs disconnected, and the unit <u>connected to AC (\sim) power</u>. All voltage measurements are with respect to ground and are to be made with the unit on.

3.5 UNSCHEDULED MAINTENANCE

Table 3.1 Expected Test Point Readings

Power Supply Board	Normal Reading	Tolerance	Conditions/Comments
TP1	V Common	+/-50 mV	Bulk Supply Common
TP2	+27 V	+/-2 V	Main $$ supply for entire system

CPU Board	Normal Reading	Tolerance	Conditions/Comments
TP1	+27 V	+/-2 V	Main supply for entire system
TP2	+26 V	+/-2 V	V_ON voltage. Energized when unit is ON.
TP3	+26 V	+/-2 V	24 V $\overline{}$ nominal if ~ (AC) present.
TP4	0.0 V +26 V	+/-50 mV +/-2 V	0.0 V = when unit is ON. 26 V when unit is OFF.
TP6	6 V	+/-2 V	~ (AC) signal if speaker is sounding.
TP8	5 V	+/-0.5 V	5 V $\overline{}$ supply for battery charging logic.
TP9	V Common	+/-50 mV	= Bulk Supply Common.
TP10	5 V 26 V	+/-0.5 V +/-2 V	5 V = when pneumatics are NOT enabled. 26 V = when pneumatics ARE enabled.
TP11	5 V	+/-0.5 V	5 V Supply
TP12	5 V 0 V	+/-0.5 V +/-50 mV	5 V Nominal. 0 V when depressing ON/STANDBY switch on membrane panel.
TP13	V Common	+/-50 mV	$\overline{}$ Bulk Supply Common.
TP14	4.5 V 0 V	+/-1 V +/-50 mV	0 V if Safety Circuit is enabled and alarm condition exists.
TP15	4.5 V	+/-1 V	At power up, this TP will be held low until approximately 0.2 seconds after TP11 reaches 5 V Ensures microprocessor has reset properly.
TP16	32.768 kHz		Square wave.
TP17	4.5 V	+/-1 V	0 V indicates problem with valve(s) or valve driver circuit.
TP20	V Common	+/-50 mV	Bulk Supply Common.
TP22	12 V	+/-1 V	12 V \equiv = = = for audio amplifier.
TP23	4.1 V	+/-0.1 V	4.1 V Transducer reference voltage.
TP24	5 V	+/-0.5 V	5 V \equiv A to D supply voltage
TP27	V Common	+/-50 mV	Bulk Supply Common.
TP30	V Common	+/-50 mV	Bulk Supply Common.
TP31	5 V	+/-0.5 V	5 V $\overline{}$ for ON/STANDBY switch logic.

Table 3.2 Troubleshooting

To aid in unscheduled maintenance, the following list 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, this list in conjunction with the attached schematics will be of assistance in isolating the most common problems. Expected reading on the CPU and Power Supply boards are shown in Table 3.1. The 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 unless otherwise noted.

CAUTION: HIGH VOLTAGE ELECTRICAL HAZARD. HIGH VOLTAGE WILL BE PRESENT ON THE POWER INPUT MODULE AND POWER SUPPLY BOARD.

ALL SERVICE WORK MUST BE DONE BY QUALIFIED TECHNICIANS.

SYMPTOM	POSSIBLE CAUSES	CHECK TEST POINTS
1. Cuff(s) will not inflate.	a) Touch-Switch Panel connector not	
	properly plugged into P9.	
	b) Tubing inside unit may be pinched or	
	improperly connected.	
	c) Valve(s) stuck.	
	d) Pump not properly plugged into P10.	
2. Cuff(s) will not deflate.	a) Touch-Switch Panel connector not	
	properly plugged into P9.	
	b) Deflate touch-switch not depressed long	
	enougn.	
	c) valve(s) stuck.	
	a) Denation on one cuit will not be	
	Deflate touch-switch must be depressed	
	within 5 seconds after "CLIEF" "NOT"	
	"DEFL" message appears	
3 No ~ Indicator light.	a) Unit not plugged into wall outlet.	
Unit still runs.	b) No power at wall outlet.	
	c) Bulk Supply harness	
	loose/disconnected at P2 or P3.	
	d) Blown Fuses(s).	
4. Alarm Silence Switch not	a) Connector not properly plugged into P1.	
working.	b) Broken wire.	
	c) Non-silenceable alarm (hardware failure).	
	d) Faulty switch.	
5. Safety Circuit Failure.	a) 32 kHz clock not working correctly.	TP16 (CPU Board)
No sound from speaker.	a) No output from audio amp U1.	TP6 (CPU Board)
	b) No output from CPU.	
	c) Faulty 12 volt supply.	TP22 (CPU Board)
7. Alarm Light does not turn on.	a) Alarm lamp burned out.	
	I c) Broken wire.	

SYMPTOM	POSSIBLE CAUSES	CHECK TEST POINTS
 Unit turns on and gives tones but no displays are present. 	a) Faulty 5 V display voltage (+V)	TP11 (Power Supply Board)
9. "AMP" "FAIL" at start up.	 a) Faulty 15 V supply. b) Faulty A to D supply voltage. c) Transducers reference voltage. d) Too high main supply. 	TP25 (CPU Board) TP24; 4.1 V TP21; 0.25 V CPU Board) TP23; 4.1 V CPU Board) TP23; 4.1 V CPU Board) TP23; 4.1 V TP2 (Power Supply Board)
10. No Main Cuff pressure	a) Transducer amplifier not working.	*TP26; Voltage will vary with pressure. 0.25 to 4 V (CPU Board)
11. No Second Cuff pressure reading.	a) Transducer amplifier not working.	TP28; Voltage will vary with pressure. 0.25 to 4 V
12. Pump does not stop running.	a) Internal leak in hose or hose fittings.b) Leak in valve manifold.c) Transducer not working.	*TP29; Voltage will vary with pressure. 0.25 to 4 V (CPU Board)
13. Valve fail alarm / message.	a) Faulty valve driver. b) No power to valves.	TP17 (CPU Board) TP10 (CPU Board)
 14. Battery fail alarm / message. Other unexplained error codes: "AMP" "FAIL" "CAL" "FAIL" "WDT" FAIL" "BAT" "FAIL" 	 a) Blown battery fuse. b) Broken battery wire. c) Dead or depleted batteries. d) Connect unit to ~ (AC) power to allow batteries to charge. 	
15. Unit does not turn on.	a) ON/STANDBY touch-switch not working.	TP12 (CPU Board)
	c) No power control.	TP2 (Power Supply Board)
16. Low Battery Alarm, (allow 24 hours for batteries to fully charge.)	 a) Plug unit in to allow batteries to charge. b) No charging voltage. c) No 5 V charging logic voltage. 	TP7 (CPU Board) TP8 (CPU Board)

*NOTE: TEST POINT MEASUREMENTS TP21,23,26,28, AND 29 MUST BE MEASURED WITH RESPECT TO ANALOG GROUND (TP27). FAILURE TO DO SO WILL RESULT IN ERRONEOUS READINGS

3.8 REPLACEMENT PARTS

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

- MAIL: Zimmer Orthopaedic Surgical Products 200 West Ohio Avenue Dover, Ohio 44622 U.S.A.
- PHONE: 330-343-8801 or 800-321-5533

You can also contact your local 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 properly trained staff.

Zimmer Replacement Part Number	Description
62-1109-001-00	Valve Manifold, without valves
62-1112-001-00	Pump Muffler, without tubing
60-2000-000-03	Pump, without tubing
62-1117-001-00	3/16 in. (.5 cm) Y-Connector
62-1119-001-00	Reservoir, 20 cubic in. (328 cm ³)
60-2000-000-06	Valve, 24 V Clippard: slow inflate/deflate
60-2000-000-07	Valve, 24 V Burkert: fast inflate/deflate
60-2000-000-08	Fuse, 500 mA 5 x 20 mm
62-1129-001-00	Contol Panel, 13 touch-switch
62-1131-001-00	Alarm Silence Switch without lamp
62-1132-001-00	Alarm Silence Lamp
62-1133-001-00	Alarm Silence Lens, red Bulk Power Supply
62-1134-001-00	Feet, without screws
60-2000-000-14	Power Supply
60-2000-000-15	CPU Board
62-1137-001-00	Fuse Drawer, 1/4 in. x 1 1/4 in. (.6 x 3.2 cm)
62-1138-001-00	Fuse Drawer, 5 x 20 mm
62-1160-001-00	Molex 8-pin connector

Zimmer Replacement Part Number	Description
62-1162-001-00	Battery Jumper
62-1163-001-00	Battery Harness
62-1164-001-00	Power Entry Harness
62-1165-001-00	Power Entry Jumper, Blue
62-1166-001-00	Power Entry Jumper, Brown
62-1167-001-00	Power Entry Harness Ground
62-1168-001-00	Alarm Silence Harness
62-1169-001-00	Speaker Harness
62-1175-001-00	8 Ohm Speaker
62-1179-001-00	1 Amp Time Delay 1 1/4 in. (3.2 cm) Glass fuse
62-1180-001-00	Pump Gasket
60-4000-821-00	Crimp Terminal for Molex Connector
62-1389-001-00	Molex 2-pin Connector
62-2360-001-00	Pole Clamp Knob
60-7000-027-00	12 V, 2.3 Amp Hour Battery
	Power Entry Module
62-1184-001-00	Gray Power Cord
62-1192-001-00	Harness

REF	Description
60-2000-102	A.T.S. 2000 Tourniquet System (with A.T.S. Cylindrical Cuffs) with Hoses
60-2000-103	A.T.S. 2000 Tourniquet System (with A.T.S. Cylindrical Cuffs) with Hoses, Tourniquet Stand and Basket
60-2000-104	A.T.S. Tourniquet System (without Cuffs) with Hoses, Tourniquet Stand and Basket
60-4022-001	Tourniquet Stand (includes Base and Pole)
60-1908-001	Tourniquet Accessory Basket
	A.T.S. Cylindrical Cuffs, Dual Ports, Single Bladder:
60-7500-001	8 in. (20 cm) x 3.125 in. (7.0 cm)
60-7500-002	12 in. (30 cm) x 4.125 in. (10.5 cm)
60-7500-003	18 in. (46 cm) x 4.125 in. (10.5 cm)
60-7500-004	24 in. (61 cm) x 4.125 in. (10.5 cm)
60-7500-005	30 in. (76 cm) x 4.125 in. (10.5 cm)
60-7500-006	34 in. (86 cm) x 4.125 in. (10.5 cm)
60-7500-007	42 in. (107 cm) x 4.125 in. (10.5 cm)
	A.T.S. Contour Cuff, Dual Port, Single Bladder:
60-7500-008	42 in. (107 cm) x 4.81 in. (12.2 cm)
	A.T.S. Cylindrical Cuffs, Dual Port, Dual Bladder:
60-7555-001	12 in. (30 cm) x 5.5 in. (14.0 cm)
60-7555-002	18 in. (46 cm) x 5.5 in. (14.0 cm)
60-7555-003	24 in. (61 cm) x 5.5 in. (14.0 cm)
	<i>Zimmer</i> Sterile Disposable Tourniquet Cuffs with Positive Locking Connectors, Dual Port, Single Bladder (sterile packed in a box of 10 with attached sterile tubing on each cuff):
60-7070-101	8 in. (20 cm) x 2.75 in. (7.0 cm)
60-7070-102	12 in. (30 cm) x 3.5 in. (7.6 cm)
60-7070-103	18 in. (46 cm) x 4 in. (10.2 cm)
60-7070-104	24 in. (61 cm) x 4 in. (10.2 cm)
60-7070-105	30 in. (76 cm) x 4 in. (10.2 cm)
60-7070-106	34 in. (86 cm) x 4 in. (10.2 cm)
60-7070-107	42 in. (107 cm) x 4 in.(10.2 cm)

REF	Description
	<i>Zimmer</i> Sterile Disposable Tourniquet Cuffs with Positive Locking Connectors, Dual Port, Dual Bladder (sterile packed in a box of 10 with attached sterile tubing on each cuff):
60-7080-101	12 in. (30 cm) x 5.5 in. (14.0 cm)
60-7080-102	18 in. (46 cm) x 5.5 in. (14.0 cm)
60-7080-103	24 in. (61 cm) x 5.5 in. (14.0 cm)
	<i>Zimmer</i> Sterile Disposable Esmarch Bandages (sterile packed in boxes of 20):
60-2694-001	3 in. (8 cm) x 9 feet (3 m)
60-2694-002	4 in. (10 cm) x 9 feet (3 m)
60-2694-003	6 in. (15 cm) x 9 feet (3 m)
60-2694-004	3 in. (8 cm) x 12 feet (4 m)
60-2694-005	4 in. (10 cm) x 12 feet (4 m)
60-2694-006	6 in. (15 cm) x 12 feet (4 m)
	A.T.S. Low Pressure Cuffs, Dual Port, Single Bladder:
60-7400-001	Cylindrical Arm Cuff
60-7400-002	Contour Arm Cuff
60-7400-003	Contour Thigh Cuff
60-7400-004	Lower Leg Cuff
	A.T.S. Low Pressure Cuff, Dual Port, Dual Bladder:
60-7400-010	Cylindrical Arm IVRA Cuff
60-7400-011	Contour Arm IVRA Cuff
60-4017-001	A.T.S. Dual Hose, Blue/White
60-4018-001	A.T.S. Dual Hose, Red/White

3.9 STORAGE

The *A.T.S.* 2000 Tourniquet System has an operating temperature range of 50° F to 100° F (10° C to 38° C).

The following are environmental conditions for transportation and storage:

- A. Ambient temperature range1°F to 149°F (-17°C to 65°C)
- C. Atmospheric pressure range 500 hPA to 1060 hPA



Main and Second Calibration Setup Assembly

- A. Reservoir Sense Ports
- B. Main Cuff Sense Port
- C. Second Cuff Sense Port
- **D.** Calibration Hose Assembly
- E. Calibrated mmHg Pressure Meter minimum range of 0 to 700 mmHg
 F. Pressure Regulator 0 to 700 mmHg minimum
- G. Pressure Source, minimum of 700 mmHg

2



Controls, Indicators & Connectors

- A. ON/STANDBY (I/O) Touch-Switch
- **B.** PRESSURE SETTING Touch-Switches
- C. TIME SETTING Touch-Switches
- D. INFLATE/DEFLATE Touch-Switches
- E. ALARM SILENCE Switch
- F. PRESSURE Displays
- G. TIME Displays
- H. AC Indicator Light
- I. Quick Reference Cards
- J. Cuff Connectors
- $\textbf{K.} \ \textbf{Pole} \ \textbf{Clamp}$





Removing Chassis from Rear Case 1. Remove Pole Clamp knob

- Removing Chassis from Rear Case 2. Remove Rear Cover Screws

5

7



Removing Chassis from Rear Case 3. Remove 4 Feet and Screws



Removing Chassis from Rear Case 4. Slide Front and Rear Covers Apart

4





Separating Chassis

3. Access to all components



CPU Board



Power Supply Board

Warnings,	Cautions,	and	Symbol	Definitions
(See Fig. 1	7.)			

∪ | | Power "OFF" for a part of equipment

Power "ON" connected to the mains

Type B equipment



Alternating Current



Protective earth ground



Direct Current



Refer to instruction manual



Electrical Hazard



Year of manufacture



Replace fuse as marked

Conformity Marking of the Council of the European Community (TÜV Product Service, Munich, Germany)



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

SYMBOL DEFINITION:

LATEX FREE This product does not contain natural rubber latex.







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Revised: 02-05 © 1996, 2005 Zimmer Orthopaedic Surgical Products Printed in U.S.A. 62-2000-101-00