# Operator & Service Manual



A.T.S.™ 1200 TOURNIQUET SYSTEM REF 60-1200-101-00



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

#### SCOPE OF WARRANTY

Zimmer, Inc. warrants the Product (*A.T.S.* 1200 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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#### WARRANTY CLAIMS

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 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

# A.T.S. 1200 TOURNIQUET SYSTEM

#### 1.1 SPECIFICATIONS

**Mains Line Voltage Range:** 

 $100-240 \text{ V} \sim (AC)$ , 50/60 Hz. Auto switching

**Line Current:** 

670 mA RMS @ 120 V ~ (AC)

Input Power: 53 W typical Battery Type:

Rechargeable, 12 VDC sealed lead acid,

2.3 A hours

**Battery Discharge Time:** 

Unit will operate on battery power for 45 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 A

**Line Protection:** 

2 time delayed 1.0 A 250 V fuses

# CONTROLS:





Turns the unit on/sets unit to STANDBY.

#### **PRESSURE Button:**



Used in conjunction with the ROTARY knob to adjust the pressure set point. Can also be pressed to verify the set point.

#### **TIME Button:**



Used in conjunction with the ROTARY knob to adjust the time alarm set point. Can also be pressed to verify the set point.

#### **MAIN CUFF INFLATE/DEFLATE Buttons:**



Controls inflation or deflation of the Main cuff. *Orange* LED bar indicates inflation of the main cuff or pressure alarm in the main cuff when flashing in conjunction with the PRESSURE display.

#### **SECOND CUFF INFLATE/DEFLATE Buttons:**



Controls inflation or deflation of the Second cuff. *Orange* LED indicator bar indicates inflation of the second cuff or pressure alarm in the second cuff when flashing in conjunction with the PRESSURE display.

#### **ALARM SILENCE Button:**



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

#### AC MAINS Indicator Light (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 (Orange LED):**

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

#### **Cuff Pressure Range:**

50-475 mm Hg, 5 mm Hg increments

#### **Pressure Accuracy:**

±5 mm Hg (50–475 mm Hg)

#### **Pressure Regulation:**

±6 mm Hg of set point

(10 second average under non-transient conditions without external leaks)

#### **Maximum Pressure:**

475 mm Hg (Normal Operation)

#### **Time Alarm Set Range:**

5–240 minutes; 5 minute increments

#### **Timer Accuracy:**

0.25 % of elapsed time

#### **Internal Diagnostics:**

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

#### SIZE:

Height:

12.50 in. (31.75 cm)

Width:

10.25 in. (26 cm)

Depth:

8.1 in. (20.6 cm) (including clamp and ports)

Weight:

8.0 lbs. (3.63 kg)

#### **DISPLAYS:**

#### PRESSURE Display:

*Red* 14-segment light emitting diodes (LED). Displays pressure setting, sensed cuff pressure, and hardware failure conditions/other messages.

#### TIME Display:

Red 14-segment light emitting diodes (LED)

Displays time alarm set point, elapsed time, and hardware failure conditions/other messages.

#### **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

<sup>\*</sup>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. 1200 Tourniquet System complies with EMC criteria set forth in IEC 601-1-2.

#### 1.2 INTENDED USE

The *A.T.S.* 1200 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<sub>2</sub> 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 PO₂ and pH should be closely monitored.
- ♦ Select the proper cuff size to allow for an overlap of about 3 to 6 in. (7.6 cm − 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 1.5 hours of tourniquet use. Symptoms of tourniquet paralysis are motor paralysis and loss of sense of touch, pressure, and proprioceptive responses.

Intraoperative bleeding may be caused:

- By the slight impeding effect exerted by an unpressurized cuff (and its 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 humerus.

# INSTALLATION AND OPERATING INSTRUCTIONS

# SECTION 2.0 A.T.S. 1200 TOURNIQUET SYSTEM

#### 2.1 INITIAL INSPECTION

Unpack the *A.T.S.* 1200 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 after a 24-hour charge. 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 and 2 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 prior to setting the unit to STANDBY. NOTE: During STANDBY, the power to the A.T.S. 1200 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. ROTARY knob

Changes the value of set time or default time and set pressure or default. 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. MAIN CUFF INFLATE button

Inflation of the Main cuff is initiated by depressing the *red* INFLATE button.

#### 6. MAIN CUFF DEFLATE button

Deflation of the Main cuff is initiated by depressing the *red* 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. SECOND CUFF INFLATE button

Inflation of the Second cuff is initiated by depressing the *blue* INFLATE button.

#### 8. SECOND CUFF DEFLATE button

Deflation of the Second cuff is initiated by depressing the *blue* 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.

#### 9. 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.

#### 10. AC MAINS indicator light

The AC MAINS 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).

#### 11. 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.

#### 12. PRESSURE display

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

#### 13. TIME display

During normal operation with no buttons being pressed, the TIME display will show elapsed inflation time of the first cuff that was inflated in 1-minute increments. At other times, depending on alarm conditions and buttons pressed, this display may communicate other information such as alarm messages, set time, or default set time.

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

#### 14. 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* port and the SECOND CUFF is the *blue* port. The *A.T.S.* 1200 Tourniquet is designed and tested for use with Zimmer single port cuffs. Zimmer does not recommend the use of any cuff other than Zimmer single port cuffs. Do not use dual port cuffs with the *A.T.S.* 1200 Tourniquet.

#### 15. CUFF indicators

The CUFF indicators illuminate steady when stable cuff pressure is sensed in the cuff. The CUFF indicators will also flash during inflation or to indicate an alarm condition in the respective cuff.

#### 16. **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.

#### 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 to 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.

- 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) A "0\*0\*"/"\*0\*0" sequence appears on the PRESSURE and TIME displays followed by the text "ATS" "1200" on the respective display.
  - b) The unit emits tones when "0\*0\*"/"\*0\*0" and text is displayed.

- The unit will display "SELF" "TEST" for an instant.
   The unit is self-testing specific system hardware and software
- d) "CAL" is displayed in the PRESSURE displays during the calibration check.
- e) "0" is displayed in the PRESSURE and TIME display 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 the PRESSURE button.
  - b) The PRESSURE display should read "\*250" (the default set point) for 2 seconds.
  - knob to change the pressure set point (clockwise to increase, counter-clockwise to decrease). The set pressure can be maintained between 50 mm Hg and 475 mm Hg in increments of 5 mm Hg.
- 4. Test the TIME set point system as follows:
  - a) Press the TIME button.
  - b) The main TIME display should read "\*60" (the default set point) for 2 seconds.
  - c) Within the 2-second time frame, rotate the ROTARY 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 5 minutes.

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

#### 5. Calibration Check

**NOTE:** During the power-up diagnostic self-test described above, the unit will test calibration. Should an out of calibration condition be detected, the unit will display either "CAL" "FAIL", "CALM" "FAIL" or "CAL2" "FAIL" in the PRESSURE and TIME displays. 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 and holding the Main cuff Inflate and Deflate buttons while powering the unit ON. The unit will enter the calibration mode when the Pressure and Time display momentarily displays "CAL" "MODE". After the "CAL" "MODE" is displayed, the unit will display the software revision level. 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 pressure meter, with a minimum range of 0 to 500 mm Hg, to the calibration hose. 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 500 mm Hg of pressure.
- e) Insert the calibration hose connector into the Main Cuff port on the unit (*red* port).

**NOTE:** The unit will be displaying "0" in the Pressure display and alternating "CAL" and "0" in the Time display. During the calibration check, the unit will attempt to deflate any applied pressure if the adjustment point displayed is set to zero. This will result in an inaccurate calibration check. Press the MAIN CUFF INFLATE button once to change the adjustment point to 50 mm Hg in order to close the deflate valve.

- f) Apply 50 mm Hg of pressure to the cuff port. The PRESSURE display should read 50±5 mm Hg when compared to the calibrated meter.
- g) Increase the pressure to 250 mm Hg. The PRESSURE display should read 250±5 mm Hg.
- h) Increase the pressure to 475 mm Hg. The PRESSURE display should read 475±5 mm Hg.
- Remove the calibration hose setup from the unit.
   The PRESSURE display should now read 0 mm Hg.
- j) At this point, use the MAIN CUFF DEFLATE button to back the pressure level down to the point where the Time display is alternating between "CAL" and "0". Then, press the MAIN CUFF INFLATE and the MAIN CUFF DEFLATE buttons simultaneously to exit the Main cuff calibration check and to enter the Second cuff calibration check.
- k) Connect the previously used setup to the Second Cuff port (*blue* port).

**NOTE:** The unit will be displaying "0" in the Pressure display and alternating "CAL" and "0" in the Time display. During the calibration check, the unit will attempt to deflate any applied pressure if the adjustment point displayed is set to zero. This will result in an inaccurate calibration check. Press the SECOND CUFF INFLATE button once to change the adjustment point to 50 mm Hg in order to close the deflate valve.

- Apply 50 mmHg of pressure to the cuff port. The PRESSURE display should read 50±5 mmHg when compared to the calibrated meter.
- m) Increase the pressure to 250 mmHg. The PRESSURE display should read 250±5 mmHg.
- n) Increase the pressure to 475 mmHg. The PRESSURE display should read 475±5 mmHg.

o) Remove the calibration hose from the unit. The PRESSURE display should now read 0 mmHg.

**NOTE:** If any reading is off by more than 5 mm Hg during the calibration check, the unit must be calibrated. See CALIBRATION in MAINTENANCE, Section 3.

p) At this point, use the SECOND CUFF DEFLATE button to back the pressure level down to the point where the Time display is alternating between "CAL" and "0". Exit the calibration check by simply setting the unit to STANDBY.

#### 6. Low Pressure Alarm Check

Connect a cuff and standard length hose to the Main cuff port. Inflate the cuff to 250 mm Hg. Create a leak in the cuff by partially detaching the hose from the unit while a cuff is inflated. Make the leak large enough that the pressure drops more than 15 mm Hg 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 the leak is large enough, the PRESSURE display may show "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 port.

#### 2.5 PRESSURE AND TIME DEFAULTS

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

- 1. Default Pressure
  - a) The Default Pressure is selected by depressing and holding the PRESSURE button for at least 2 seconds. When the default mode is entered, the audible alarm beeps once and a "D" is displayed in the first position on the PRESSURE display.
  - b) The Default Pressure is modified via the ROTARY knob and can be set between 50 and 475 mm Hg in increments of 5 mm Hg.
  - 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 the TIME button for at least 2 seconds.
   When the default mode is entered the audible alarm beeps and a "D" is displayed in the first position on the TIME display.
- b) The Default Time Limit is modified via the ROTARY knob and can be set between 5 and 240 minutes in increments of 5 minutes.
- 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.

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.

#### 2.6 SINGLE CUFF OPERATION

 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 mm Hg or more during power-up, the *A.T.S.* 1200 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 (PRESSURE button pressed).

- 2. Connect a single port cuff to the unit at the Main cuff connector (*red* port).
- 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 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.

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 time limit (inflation) clock. The MAIN CUFF INFLATION indicator will

illuminate to indicate cuff activation. If the unit cannot pressurize the cuff to within 15 mm Hg of the set point in less than 13 seconds, a leak alarm will be sounded. See Section 2.8 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 bar indicator will go out, the PRESSURE display will show the deflation of the cuff, and the time limit (inflation) clock will stop.

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

- 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.* 1200 Tourniquet.
- 9. During normal use, the *A.T.S.* 1200 Tourniquet 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.* 1200 Tourniquet, the unit can be set to STANDBY.

#### 2.7 DUAL CUFF OPERATION

Operation of the unit is identical to Single Cuff operation (see Section 2.6) except for the following points:

- 1. Both single port cuffs are connected at the bottom of the unit (Reminder: Main cuff is the *red* port, Second cuff is the *blue* port).
- The MAIN CUFF and SECOND CUFF indicator lights will illuminate to indicate cuff activation (i.e. if both cuff indicator lights are illuminated then both cuffs are inflated).
- 3. During a pressure alarm a flashing CUFF indicator light warns which cuff(s) to check.
- 4. Deflation of one cuff will not be permitted while the other cuff is inflating.
- 5. 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. The display shows the pressure in the

- inflated cuff so as to allow the operator to view the progress of inflation.
- 6. When both cuffs are inflated, the display indicates an average of the pressures sensed in the two cuffs. If one cuff has a sustained leak or a significant leak (as described in Section 2.9.1) a pressure alarm may be sounded.
- 7. When deflating a cuff with the other cuff remaining inflated, the display shows the pressure in the cuff that remains inflated.
- 8. In order to deflate the final 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).

#### 2.8 BIER BLOCK CUFF OPERATION (IVRA)

Review Sections 2.6 and 2.7, SINGLE CUFF OPERATION and DUAL CUFF OPERATION.

- 1. The following are suggested cuff connections:
  - a) The proximal cuff connected to the *red* Main cuff port using the *white/red* cuff tubing;
  - b) The distal cuff connected to the *blue* Second cuff port 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 final 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.
- 6. For Bier Block procedures follow the cuff inflation/ deflation sequence adapted by your institution or requested by the surgeon.

#### 2.9 ALARM CONDITIONS

There are a number of conditions for which the *A.T.S.* 1200 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 depressing the ALARM SILENCE button. At the end of the silenced period, tones will be reenabled. Depressing the ALARM SILENCE button will cause the alarm tone to be silenced again.

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 line with hemostats and replace the tourniquet unit.

#### 2.9.1 PRESSURE ALARMS

A Pressure alarm will occur when the pressure in a cuff is more than 15 mm Hg 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 mm Hg from the set point, then this type of substantial leak has been detected and all cuffs and pneumatic fittings should be checked for leaks.

**Table 2.1 Alarm Conditions** 

CONDITION	PRESSURE DISPLAY	TIME DISPLAY	APPROPRIATE ACTION/REMARKS
CUFF PRESSURE LOW The pressure in the cuff is 15 mm Hg 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 mm Hg 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> 1200 unit should be replaced.
CUFF SIDE LEAK A leak has been present for at least 7 seconds.	LEAK	normal	A substantial leak has been present for more than 7 seconds. All lines and connections should be checked.
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 mm Hg 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 resetting.
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 <b>fully</b> deflated.
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	BAT LOW PLUG IN	Unit needs to be plugged in.
BATTERY FAILURE Battery voltage is too low to ensure proper operation.	BATT	FAIL	Plug unit in and cycle the ON/STANDBY Button.
CALIBRATION OUT OF SPEC The transducer calibration is out of specification.	CALM or CAL2	FAIL	CALM ( <i>CALIBRATION MAIN</i> ) indicates the main cuff transducer circuitry is out of calibration. CAL2 ( <i>CALIBRATION SECOND</i> ) indicates the second cuff transducer circuitry is out of calibration. Pressure in error by at least 6 mm Hg will cause these failures. Calibrate the unit.
CALIBRATION OUT OF SPEC The 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.	МАТН	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.	VALV	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 Internal diagnostic detected an error.	SYS	FAIL	Cycle the ON/STANDBY Button. If problem persists, service the unit.
OVERPRESSURE The PRESSURE button has detected a pressure higher than the range of the unit.	OVER	PRES	Cycle the ON/STANDBY Button. If problem persists, service the unit. This occurrence could indicate a runaway pump.

## **MAINTENANCE**

## SECTION 3.0

# A.T.S. 1200 TOURNIQUET SYSTEM

#### 3.1 GENERAL MAINTENANCE INFORMATION

While the *A.T.S.* 1200 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. 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 5 screws
- b) Rear 2 large pole clamp screws
- c) 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.

**Table 3.1 Board Plug Designators** 

Component	<b>Board Plug Location</b>
AC Mains	P1
Overpressure Switch	P2
Speaker	Р3
Pneumatic Pump	P5
Valve Harness	P6
Backup Battery	P7
Membrane Panel	P8
Factory Test Port	P9
Main Cuff Port Tube	1117
	U17
Second Cuff Port Tube	U21

To reduce the risk of damage, the tubing should be disconnected at the plastic tee fitting and not 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 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 inset 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) Condition of the power cord-retaining clip.
- d) Tightness of pneumatic fittings.
- e) Condition of internal tubing.
- f) Accumulation of dust or dirt within the unit.
- g) Mating integrity of internal connectors.
- h) Security of the EPROM and safety processor. See Illustration 9 for location.
- i) Integrity of the pump.
- j) Security of circuit board.
- k) 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.

#### 3.4 CALIBRATION

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

Calibration of the *A.T.S.* 1200 Tourniquet allows the output signal from the pressure transducer 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 (0 mm Hg, 50 mm Hg, 250 mm Hg, and 475 mm Hg). These four calibration factors are used to correct the signal from the pressure transducers during normal operation. The calibration factors and a checksum are stored in non-volatile memory.

#### **EQUIPMENT REQUIRED:**

*A.T.S.* 1200 calibration hose (supplied). Calibrated 0 to 500 mm Hg pressure meter. Adjustable 0 to 500 mm Hg 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.

#### MAIN CUFF CALIBRATION

The Main cuff transducer is always calibrated first. Below is a step-by-step procedure for calibrating the Main cuff transducer. The procedure continues with the Second cuff. Both cuff transducers should always be calibrated. The calibration will not be complete unless both cuff transducer calibrations are performed.

- To enter the calibration mode, press and hold the MAIN CUFF INFLATE and DEFLATE buttons while powering the unit ON. The unit will enter the calibration mode when the PRESSURE and TIME display momentarily displays "CAL" "MODE". After the "CAL" "MODE" is displayed, the unit will display the software revision level. The software revision level can be recorded for future reference.
- After displaying the software revision level, the unit will display "MAIN" "CUFF" in the PRESSURE and TIME displays respectively. This is to indicate that the unit is now ready to calibrate the Main cuff transducer.
- 3. The unit will now display "0" in the PRESSURE display and alternating "CAL" and "0" in the TIME display. Throughout this procedure, the TIME display will indicate the pressure in which the user is calibrating.
- 4. 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 port). By pressing the PRESSURE button, the unit will calibrate the 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 Cuff port. See Figure 3 for more details.
- 6. 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 display will now be alternating between "CAL" and "50". Apply 50 mm Hg to the unit's Main cuff port. Once the pressure has stabilized, press the PRESSURE button so the unit can calibrate the 50 mm Hg point. The unit will beep to let the user know the set point was taken.
- 7. Once the 50 mm Hg point is calibrated, press the MAIN CUFF INFLATE button to advance the unit to the next pressure level. The unit's TIME display will now be alternating between "CAL" and "250". Apply 250 mm Hg to the unit's Main cuff port. Once the pressure has

- stabilized, press the PRESSURE button so the unit can calibrate the 250 mm Hg point. The unit will beep to let the user know the set point was taken.
- 8. Once the 250 mm Hg point is calibrated, press the MAIN CUFF INFLATE button to advance the unit to the next pressure level. The unit's TIME display will now be alternating between "CAL" and "475". Apply 475 mm Hg to the unit's Main cuff port. Once the pressure has stabilized, press the PRESSURE button so the unit can calibrate the 475 mm Hg point. The unit will beep to let the user know the set point was taken.
- 9. At this point, use the MAIN CUFF DEFLATE button to back the pressure level down to the point where the TIME display is alternating between "CAL" and "0". Then, press the MAIN CUFF INFLATE and the MAIN CUFF DEFLATE buttons simultaneously to exit the Main cuff calibration and to enter the Second cuff calibration.

#### SECOND CUFF CALIBRATION

The Second cuff transducer is always calibrated last. Below is a step-by-step procedure for calibrating the Second cuff transducer. The Second cuff transducer calibration is performed the same way the Main cuff transducer calibration. Following the completion of the Second cuff transducer calibration, be certain to perform the techniques described to save the calibration in non-volatile memory.

- 10. Once the unit enters the Second cuff transducer calibration, the unit will beep and momentarily display "SCND" "CUFF" in the PRESSURE and TIME window respectively. This is to indicate that the unit is now ready to calibrate the Second cuff transducer.
- 11. The unit will now display "0" in the PRESSURE display and alternating "CAL" and "0" in the TIME display. Throughout this procedure, the TIME display will indicate the pressure in which the user is calibrating.
- 12. 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 port). By pressing the PRESSURE button, the unit will calibrate the pressure. The unit will beep to let the user know the set point was taken.
- 13. Connect the calibration hose, calibrated pressure meter and adjustable pressure source to the Second Cuff port. See Figure 3 for more details.
- 14. Once the zero point is calibrated, press the SECOND CUFF INFLATE button to advance the unit to the next pressure level. The unit's TIME display will now be alternating between "CAL" and "50". Apply 50 mm Hg to the unit's Second cuff port. Once the pressure has stabilized, press the PRESSURE button so the unit can calibrate the 50 mm Hg point. The unit will beep to let the user know the set point was taken.

- 15. Once the 50 mm Hg point is calibrated, press the SECOND CUFF INFLATE button to advance the unit to the next pressure level. The unit's TIME display will now be alternating between "CAL" and "250". Apply 250 mm Hg to the unit's Second cuff port. Once the pressure has stabilized, press the PRESSURE button so the unit can calibrate the 250 mm Hg point. The unit will beep to let the user know the set point was taken.
- 16. Once the 250 mm Hg point is calibrated, press the SECOND CUFF INFLATE button to advance the unit to the next pressure level. The unit's TIME display will now be alternating between "CAL" and "475". Apply 475 mm Hg to the unit's Second cuff port. Once the pressure has stabilized, press the PRESSURE button so the unit can calibrate the 475 mm Hg point. The unit will beep to let the user know the set point was taken.
- 17. At this point, use the SECOND CUFF DEFLATE button to back the pressure level down to the point where the TIME display is alternating between "CAL" and "0". Then, press the SECOND CUFF INFLATE and the SECOND CUFF DEFLATE buttons simultaneously to exit the Second cuff calibration. The unit will display "CAL" "DONE" in the PRESSURE and TIME windows respectively. The "CAL" "DONE" message tells the user that the calibration set points that have been calibrated to the unit have now been saved into the non-volatile memory.

NOTE: If the "CAL" "DONE" 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 SECOND CUFF INFLATE and DEFLATE buttons and verifying the "CAL" "DONE" message.

If the pressure settings were adjusted incorrectly on the Main or Second cuff and an attempt is made to have the unit calibrate the incorrect value that is off by more than 15 mm Hg, a "CAL" "FAIL" alarm will be generated. Service or calibration to the user's pressure meter or pressure source is recommended.

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

- 18. The unit remains in calibration mode until it is set to STANDBY.
- 19. The stored calibration factors are retrieved from the non-volatile 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.
- 20. 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.

#### 3.5 LEAK TESTING

The *A.T.S.* 1200 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. 1200 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 port (red) of A.T.S. 1200 Tourniquet System. Adjust the Main cuff set point to 475 mm Hg. 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 2.6 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 mm Hg 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 port.

# 3.6 BATTERY VOLTAGE AND BATTERY SERVICE

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

Battery Voltage Check
 Be sure the unit is unplugged. Measure the battery
 voltage. The battery voltage should not be lower than
 12 V while the unit is unplugged and set to STANDBY.

If, after 1 minute, the voltage reads less than 12 V, the integrity of the battery should be suspect and should be replaced.

#### 2. Battery Service

The 12 V 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.* 1200 Tourniquet System be replaced annually. As a reminder, the *A.T.S.* 1200 System should be plugged in 24 hours before initial use.

#### 3.7 UNSCHEDULED MAINTENANCE

The *A.T.S.* 1200 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 Table 2.1.

Another mode of failure that may occur is when an audible alarm occurs that cannot be silenced by the ALARM SILENCE button. The valve and pump will be disabled which seals off the cuff 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 unit should be serviced if this occurs.

The calibration error message "CAL" "FAIL", "CALM" "FAIL" or "CAL2" "FAIL" may be due to defective circuitry or may simply indicate the need for calibration.

#### 3.8 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.

#### 3.9 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. Main cuff or Second cuff will not inflate.	<ul> <li>a) Membrane Panel not properly plugged into P8.</li> <li>b) Tubing inside unit may be pinched or improperly connected.</li> <li>c) Deflate valve is stuck open.</li> <li>d) Pump not properly plugged into P5.</li> <li>e) Pump's electrical harness damaged.</li> <li>f) INFLATE button not working.</li> <li>g) Valve's electrical harness damaged (P6).</li> <li>h) Defective valve driver circuitry.</li> </ul>
2. Main cuff or Second cuff will not deflate.	<ul> <li>a) Membrane Panel not properly plugged into P8.</li> <li>b) DEFLATE button not pressed long enough (at least 2 seconds).</li> <li>c) Deflate valve is stuck shut.</li> <li>d) DEFLATE button not working.</li> <li>e) Valve's electrical harness damaged (P6).</li> <li>f) Defective valve driver circuitry.</li> </ul>
3. No green AC MAINS indicator light.	<ul> <li>a) Unit not plugged into wall outlet.</li> <li>b) No Power at wall outlet.</li> <li>c) Mains AC harness not properly plugged into P1.</li> <li>d) Blown fuse(s).</li> <li>e) Membrane Panel not properly plugged into P8.</li> <li>f) Defective AC MAINS indicator.</li> <li>g) Defective AC MAINS indicator circuitry.</li> </ul>
4. No flashing <i>orange</i> BATTERY indicator light.	<ul><li>a) Unit running on AC.</li><li>b) Membrane Panel not properly plugged into P8.</li><li>c) Defective BATTERY indicator.</li><li>d) Defective BATTERY indicator circuitry.</li></ul>
5. ALARM SILENCE button not working.	<ul><li>a) Membrane panel not properly plugged into P8.</li><li>b) Non-silenceable alarm (System Failure).</li><li>c) ALARM SILENCE button defective.</li><li>d) Defective alarm silence circuitry.</li></ul>
6. ALARM indicator light not working.	<ul><li>a) Membrane panel not properly plugged into P8.</li><li>b) Defective ALARM indicator.</li><li>c) Defective ALARM indicator circuitry.</li></ul>
7. No cuff pressure reading.	<ul><li>a) Transducer amplifier not working.</li><li>b) Internal tubing kinked.</li><li>c) Transducer tubing on incorrect transducer.</li></ul>
8. Pump will not stop running.	<ul><li>a) Leak in internal hose or connector.</li><li>b) Internal tubing kinked.</li><li>c) Transducer(s) not working.</li><li>d) Transducer tubing on incorrect transducer.</li></ul>
9. BATTERY FAIL alarm/message.	<ul><li>a) Blown battery fuse (board mounted F1).</li><li>b) Broken Battery wire harness.</li><li>c) Dead or depleted battery.</li></ul>

10. Backup battery not charging.	<ul> <li>a) Blown battery fuse (board mounted F1).</li> <li>b) Battery not properly plugged into P7</li> <li>c) Unit not plugged into wall outlet (verify that the <i>green</i> AC MAINS indicator is illuminated).</li> <li>d) Mains AC harness not properly plugged into P1 (verify that the <i>green</i> AC MAINS indicator is illuminated).</li> <li>e) Unit was not permitted to charge for at least 24 hours.</li> <li>f) Defective battery.</li> <li>g) Defective battery charging circuitry.</li> </ul>
11. AMP FAIL alarm.	<ul><li>a) Transducer(s) amplifier out of range.</li><li>b) Battery fully depleted or defective.</li><li>c) Extremely high pressure exerted on transducers.</li></ul>
12. Unit cannot be set to STANDBY.	<ul> <li>a) Membrane panel not properly plugged into P8.</li> <li>b) Pressure sensed in the Main or Second cuff (unit will be alarming "CUFF" "NOT" "DEFL").</li> <li>c) ON/STANDBY not fully pressed.</li> <li>d) ON/STANDBY button defective.</li> </ul>
13. Unit does not turn on.	<ul><li>a) Membrane panel not properly plugged into P8.</li><li>b) ON/STANDBY button defective.</li><li>c) Blown Fuse(s).</li><li>d) Unit not plugged in and battery fully depleted.</li></ul>

**Table 3.3 Expected Test Point Readings** 

Board Location	Nominal-Reading	Tolerance	Description/Comments
TP1	0 VDC	N/A	GND – Digital ground
TP2	14 VDC	±1 VDC	Main DC supply voltage
TP3	AC Line Voltage	N/A	AC power supply common
TP4	0 VDC	N/A	Digital ground
TP5	0 VDC	N/A	Digital ground
TP6	14 VDC	±1 VDC	Main DC supply voltage
TP7	4.4 VDC	±0.5 VDC	Audio amp output resting voltage
TP8	11 to 14 VDC 0 VDC	±1.0 VDC N/A	Power ON/STANDBY – unit ON Power ON/STANDBY – unit STANDBY
TP9	5 VDC	±0.5 VDC	Digital 5 V power
TP10	0 VDC	N/A	Analog ground
TP11	5 VDC	±0.5 VDC	Supply voltage for U12 and U8
TP12	4.096 VDC	±0.1 VDC	Transducer(s) reference voltage
TP13	5 VDC	±0.5 VDC	Transducer(s) voltage supply
TP14	12 to 14 VDC	1.0 VDC	Battery/AC supply output
TP15	5 VDC	±0.5 VDC	Reset – U14 or U7
TP16	11 to 14 VDC	±1.0 VDC	Pneumatics control ON/OFF
TP17	32.768 kHz	N/A	Oscillator square wave
TP18	N/A	N/A	Factory use only
TP19	0 VDC	N/A	Digital ground
TP20	N/A	N/A	Factory use only
TP21	26.4 to 27.5 VDC	±1.0 VDC	Boost supply for battery charger
TP22	5 VDC	±0.5 VDC	Supply voltage for battery charger
TP23	5 VDC 0 VDC	±0.5 VDC N/A	ON/STANDBY switch = OPEN ON/STANDBY switch = CLOSED
TP24	4 to 5 VDC 0 VDC	±0.5 VDC	Power ON control signal to Q10 = ON Power ON control signal to Q10 = STANDBY
TP25	0 VDC	N/A	Digital ground

NOTE: USE TP1 (GND – DIGITAL GROUND) AS VOLTAGE REFERENCE FOR ALL DIGITAL MEASUREMENTS AND TP10 (ANALOG GROUND) FOR ALL ANALOG MEASUREMENTS.



CAUTION: HIGH VOLTAGE ELECTRICAL HAZARD. HIGH VOLTAGE WILL BE PRESENT 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. For instance if the unit is experiencing valve trouble, the pneumatic voltage will not be the normal reading but rather a post failure reading which could be erratic. Above voltages are listed for normal readings because failure readings will likely be unpredictable.

#### 3.10 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: 1-330-343-8801 or 1-800-830-0970

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 Zimmer staff.

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

**Table 3.4 Parts List** 

Zimmer	Description
Replacement	Description
Part Number	
0600-1304883	1 A Fuga 5 x 20 mm*
	1 A Fuse, 5 x 20 mm*
0600-1501263	Calibration Hose*
0600-2002018	Plumbing Assembly
60-0938-003-00	A.T.S. Stand 5-Wheel Caster Kit
60-2360-001-00	A.T.S. Pole Clamp Knob w/Screw
60-3000-001-00	A.T.S. Cal & Regulator Kit
60-7000-027-00	Backup Battery
60-8000-013-00	A.T.S. 1200 Rear Housing w/5 Labels
60-8000-014-00	A.T.S. 1200 Feet and Case Screws
60-8000-020-00	A.T.S. 1200 Digital Encoder
60-8000-026-00	A.T.S. 1200 Pole Clamp Assy
60-8000-102-00	A.T.S. 1200 P.C.B. Calibrated & Tested
60-8000-112-00	A.T.S. 1200 Front Housing
61-7308-000-00	PLC O-Rings Kit, 25 each
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	1 A Time Delay 1-1/4 in. Glass Fuse*
62-1193-001-00	Power Entry Module

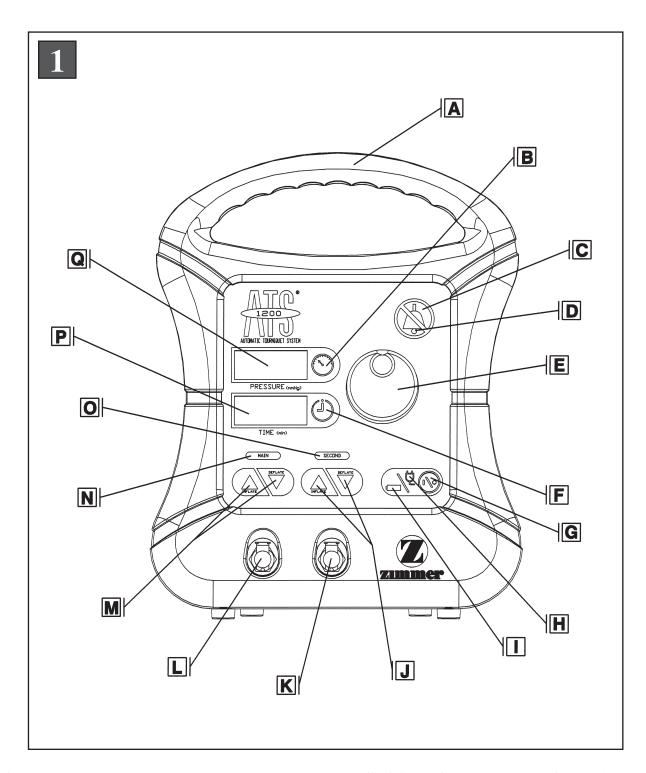
Zimmer	Description
Replacement	r
Part Number	
62-1340-001-00	Valve Muffler
62-1711-001-00	12 V Pump
62-1714-001-00	ROTARY Knob
62-1726-001-00	Overpressure Switch
62-2671-001-00	A.T.S. Female Pneumatic Coupling
62-2879-001-00	Male PLC
62-2879-002-00	Female PLC
62-8000-001-00	Pneumatic Manifold
62-8000-004-00	Battery Bracket
62-8000-005-00	Membrane Panel
62-8000-006-00	Clippard Valve (yellow)
62-8000-007-00	Burkert Valve (black)
62-8000-008-00	Overpressure Switch Harness
62-8000-009-00	Battery Harness
62-8000-010-00	Power Cord*
62-8000-015-00	Operator's and Service Manual
62-8000-018-00	Mains Wire Harness
62-8000-019-00	Cord Retaining Clip*

#### 3.11 STORAGE

The A.T.S. 1200 Tourniquet System has an operating range of 50 °F to 100 °F (10 °C to 38 °C).

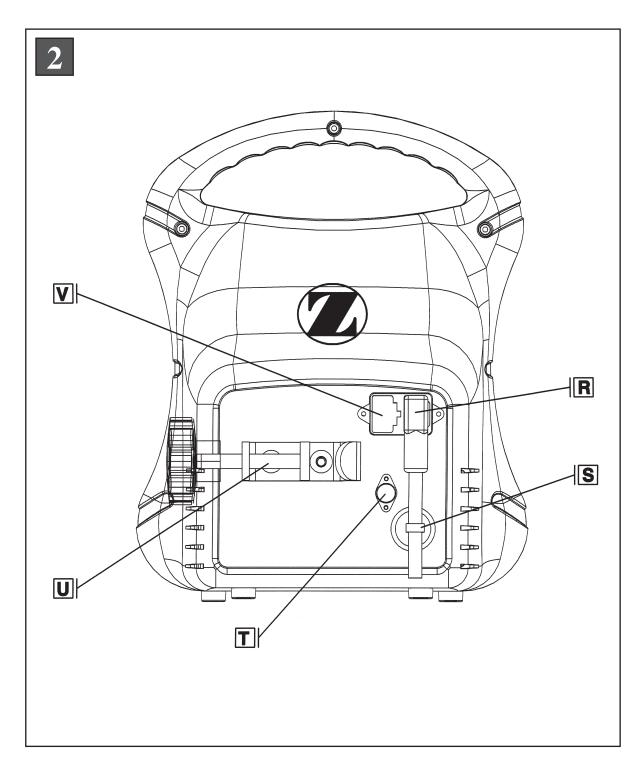
The following are environmental conditions for transportation and storage:

- A. Ambient temperature range  $1 \,^{\circ}$ F to  $149 \,^{\circ}$ F ( $-17 \,^{\circ}$ C to  $65 \,^{\circ}$ C)

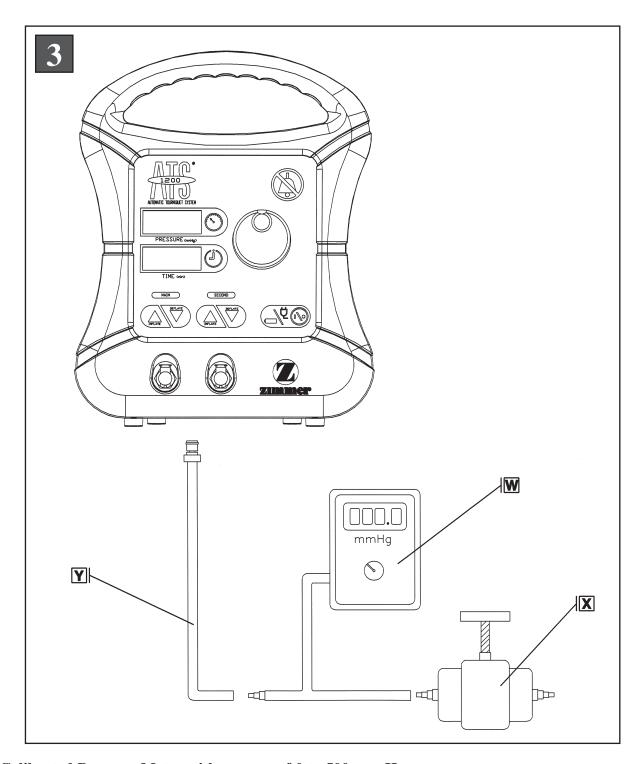


- A) Carrying Handle
- **B) PRESSURE ADJUST Activation Buttons**
- **C) ALARM SILENCE Button**
- D) Red ALARM Indicator
- E) TIME/PRESSURE Adjustment Knob
- F) TIME ADJUST Activation Button
- **G) ON/STANDBY Button**
- H) Green AC MAINS Indicator
- I) Orange BACKUP BATTERY Indicator

- J) SECOND CUFF INFLATE/DEFLATE Buttons
- **K) Second Cuff Port**
- L) Main Cuff Port
- M) MAIN CUFF INFLATE/DEFLATE Buttons
- N) MAIN CUFF INFLATION Indicator
- O) SECOND CUFF INFLATION Indicator
- P) TIME Window (displayed in minutes)
- Q) PRESSURE Window (displayed in mm Hg)



- R) Power Cord
- S) Cord Retaining Clip
- T) Factory Test Port
- U) Pole Clamp
- V) Mains Fuse Block



- W) Calibrated Pressure Meter with a range of 0 to 500 mm Hg
- X) Pressure Regulator/Source adjustable from 0 to 500 mm Hg
- Y) Calibration Hose Included with Unit





#### Opening the front case

1) Remove 3 screws on top, 2 at side and 2 feet on bottom.





#### Removing the front case

1) Carefully slide the front off the rear.





#### Disconnecting the wiring

1) Use caution when disconnecting the wiring. Mark the wires before disconnecting or see Section 3.2 for proper re-connect.





#### Removing the rear case

1) Remove 2 pole clamp screws on rear and 2 feet on bottom.

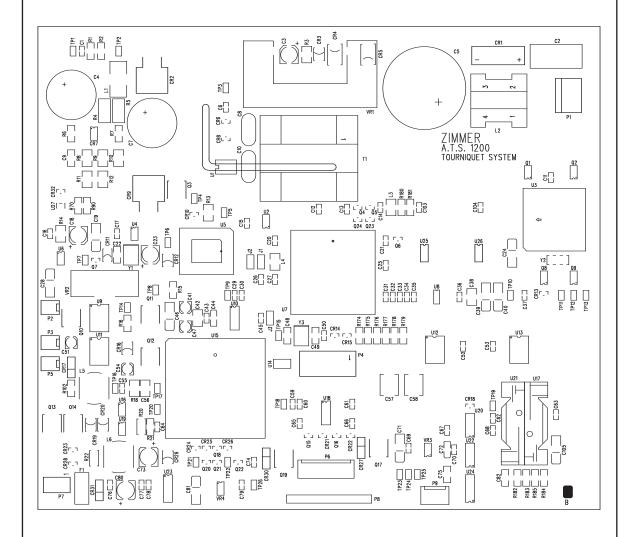


## **Rear Case separation**

1) All components are easily accessed when the rear case is removed. Reverse the process to reassemble.

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





Control Board Layout

#### 3.12 WARNINGS, CAUTIONS, AND SYMBOL DEFINITIONS

(See Illustration 10)



Type BF equipment



Alternating Current (AC)



Protective earth ground



Direct Current (DC)



Refer to instruction manual



Electrical hazard dangerous voltage



xxxx M

Year of manufacture



Replace fuse as marked



Conformity Marking of the Council of the European Community (TÜV 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.



REF 60-1200-101-00









Label 62-8000-016-00



ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS DOVER, OHIO 44622 U.S.A. 1-800-830-0970 U.S. Patents 5,556,415; 5,607,447; 5,681,339; 5,855,589; 5,935,146; 6,213,939 B1

#### **MARNING**

FOR CONTINUED PROTECTION AGAINST FIRE HAZARD REPLACE ONLY WITH THE SAME TYPE AND RATING OF FUSE:

**POWER INPUT:** 120VA 100-240V $\sim$ , 50/60 Hz



250V∼: T1.0A



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

Label 62-8000-025-00

ATTENTION: FOR USE BY TRAINED PERSONNEL ONLY.

ALLOW 5 MINUTES WARMUP BEFORE INFLATION.

"KEEP POWER CORD PLUGGED IN". BATTERY ONLY FOR USE DURING POWER EMERGENCY OR TEMPORARY PATIENT TRANSPORT.

# **ATTENTION**:

THIS UNIT MUST BE CHARGED AT LEAST 24 HOURS BEFORE INITIAL USE, CALIBRATION OR FUNCTIONAL CHECK. REFER TO OPERATOR'S MANUAL FOR CHARGING INSTRUCTIONS. REMOVE AND DISCARD THIS LABEL WHEN COMPLETE.

Label 62-8000-020-00

## **⚠** CAUTION:

TO INSURE STABILITY, THIS LINE

SHOULD BE NO MORE THAN 48 in. (122 cm) FROM THE FLOOR AND THIS UNIT SHOULD BE USED WITH I.V. STANDS HAVING A BASE DIAMETER OF AT LEAST 27.27 in. (70 cm).

#### DANGER:

EXPLOSION HAZARD. DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS OR GASES.

## CAUTION:

RISK OF ELECTRIC SHOCK. DO NOT REMOVE
COVER. REFER SERVICING TO QUALIFIED SERVICE
PERSONNEI
Label 62-8000-024

# BATTERY FUSE WARNING

FOR CONTINUED PROTECTION AGAINST FIRE HAZARD REPLACE ONLY WITH THE SAME TYPE AND RATING OF FUSE: 3.0A 125V TIME DELAY





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