Operator & Service Manual

A.T.S.[™] 750 TOURNIQUET SYSTEM REF 60-0750-101-00



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

SCOPE OF WARRANTY

Zimmer, Inc. warrants the Product (*A.T.S.* 750 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 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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GENERAL INFORMATION SECTION 1.0 A.T.S. 750 TOURNIQUET SYSTEM

1.1 SPECIFICATIONS

Line Voltage Range: 100-240 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:** Rechargeable, 12 V--- sealed lead acid, 1.2 amp hours **Battery Discharge Time:** Unit will operate on battery power for 30 minutes minimum with fully charged batteries **Battery Recharge Time:** 24 hours Unit should be plugged in 24 hours before initial use. In the event of a deep battery discharge that cannot be recovered in the first 24 hours, a second 24 hour charging period may be required. In this event, the A.T.S. unit should be unplugged for 60 seconds and reconnected to AC power prior to starting the second charging session. **Power Cord:** Type SJT, AWG 16, 14 ft. (4.27 m) **Power Plug:**

Hospital grade, 3 prong straight blade, 15 amp

CONTROLS

On/Standby Switch: Applies power to unit / sets unit to STANDBY Pressure Switch: Press to set pressure set point. Time Switch: Increases or decreases the time alarm set points. Cuff Inflate: Control inflation or deflate of the cuff. Alarm Silence Switch: Allows operator to manually silence certain alarms for 30 seconds. **Line Protection:** 2 time delayed 1.0 amp 250 volt fuses **Cuff Pressure Range:** 50-475 mmHg, 5 mmHg increments **Pressure Accuracy:** ±5 mmHg (50-475 mmHg) **Pressure Regulation:** ±6 mmHg of set point (10 second average under non-transient conditions without external leaks) **Maximum Pressure:** 475 mmHg cuffs **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:** 8 in. (20.3 cm) Width: 7 in. (17.8 cm) Depth: 7.9 in. (20.1 cm)(including clamp and port) Weight: 7.7 lbs (3.5 Kg)

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. 750 Tourniquet System complies with EMC criteria set forth in EN 60601-1-2.

1.2 INTENDED USE

The A.T.S. 750 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 CO₂ or any other gases used as a distention media. Tourniquet cuffs have not been evaluated for safety or effectiveness in controlling gas flow beyond the surgical site during arthroscopic insufflation procedures. Possible effects of using a tourniquet cuff in this manner include serious subcutaneous emphysema proximal to the cuff.

1.3 CONTRAINDICATIONS

The medical literature lists the following as possible ontraindications. 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 - 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 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 IVRA, Bier Block anesthesia, is used, it is recommended that the tourniquet remain inflated for at least 20 minutes from the time of injection.

1.5 ADVERSE EFFECTS

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

Pathophysiologic changes due to pressure, hypoxia, hypercarbia, and acidosis of the tissues occur and become significant after about 1 1/2 hours of tourniquet use. Symptoms of tourniquet paralysis are motor paralysis and loss of sense of touch, pressure, and proprioceptive responses.

- Intraoperative bleeding may be caused: 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. 750 TOURNIQUET SYSTEM

2.1 INITIAL INSPECTION

Unpack the *A.T.S.* 750 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 CONTROLS, INDICATORS, AND CONNECTORS

Refer to Figure 2.1 for the locations of the unit's controls, indicators, and connectors.

1. ON/STANDBY Touch-Switch

Turns the unit on or sets the unit to STANDBY. This switch will not set the unit to STANDBY when the cuff pressure is at a non-zero value. **Ensure the cuff is fully deflated and has been removed from the patient prior to setting the unit to STANDBY.**

Note: During STANDBY, power to the *A.T.S.* 750 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. ROTARY knob

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

3. PRESSURE switch Press to verify or modify set pressure.

4. TIME switch Press to verify or modify set time.

- INFLATE switch Inflation of the cuff is initiated by depressing the INFLATE switch.
- DEFLATE switch Deflation of the cuff is initiated by depressing the DEFLATE switch. For greater safety, the DEFLATE switch has a delay and, therefore, must

be held for approximately 2 seconds before the unit will allow a cuff to deflate.

7. ALARM SILENCE switch

The ALARM SILENCE switch will silence most audible alarms for 30 seconds after the switch is depressed. When an alarm sounds because of an internal circuit malfunction, the alarm cannot be silenced.

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

- AC INDICATOR light The AC INDICATOR light indicates that the unit is plugged in and is being powered by alternating current.
- 9. PRESSURE display

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

10. TIME display

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

11. CUFF connector

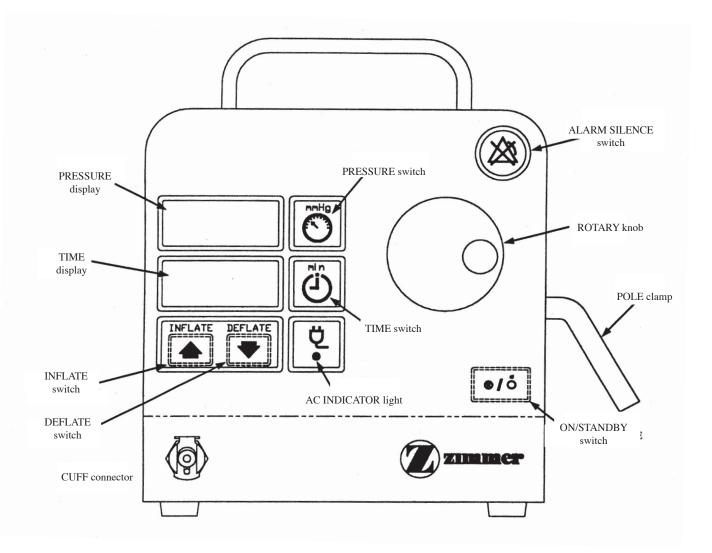
The CUFF connector is the port used to connect the unit to cuff hose.

12. 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 which are not related to tourniquet use.

FIGURE 2.1 Controls, Indicators, & Connectors



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 grey fuse drawer with 1.0 A time delay fuses. The 220-240 V unit uses the black fuse drawer with 1.0 A time delay fuses. The power cord should be plugged into the power entry module on the back of the unit. The unit should be plugged into $V\sim$ power for 24 hours before initial use.

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 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 V~ indicator light turns on.
- 2. Turn the unit ON by pressing the ON/STANDBY switch and observe the following:
 - a) A 0*0*/*0*0 sequence appears on the PRESSURE and TIME displays.
 - b) The unit emits a tone when *0*0 is displayed.
 - c) "CAL" is displayed in the PRESSURE displays during the calibration check.
 - d) "0" is displayed in the PRESSURE and TIME display after the startup routing is complete.
- 3. Test the PRESSURE set point system as follows:
 - a) Press the PRESSURE switch.
 - b) The PRESSURE display should read "* 250," the default set point, for 2 seconds.
 - c) Within the 2 second time frame, rotate the ROTARY DIAL to change the pressure set point (clockwise to increase, counter-clockwise to decrease). The set pressure can be maintained between 50 mmHg and 475 mmHg in increments of 5 mmHg.
- 4. Test the TIME set point system as follows:
 - a) Press the TIME switch.
 - 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 DIAL 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 (*) is displayed in the left display digit, the data being displayed is its set point. Set pressure and time will revert to default pressure and time when the unit is turned off.

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 "CAL" "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) Simultaneously press the PRESSURE and TIME during power-up until "VCAL" appears in the TIME display.
- b) Connect a calibrated pressure gauge, with a minimum range of 0 to 500 mmHg, to the calibration hose.
- c) Connect a pressure source capable of supplying 500 mmHg of pressure.
- d) Insert the calibration hose connector into the cuff port on the unit.
- Apply 50 mmHg of pressure to the cuff port. The PRESSURE display should each read 50±5 mmHg.
- f) Increase the pressure to 250 mmHg. The PRESSURE display should read 250±5 mmHg.
- g) Increase the pressure to 475 mmHg. The PRESSURE display should read 475 ±5 mmHg.
- h) 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 mmHg during the calibration check, the unit must be calibrated. See CALIBRATION in MAINTENANCE, Section 3.

- 6. Low Pressure Alarm Check
 - 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 falls more than 15 mmHg below set point. Observe:
 - a) A 1.5 second delay is insituted to proclude nuisance alarms.
 - b) The PRESSURE display flashes between "LO-P" and the monitored pressure.
 - c) An audible tone will sound announcing the alarm condition.
 - d) Stop the leak and observe the monitored pressure returns to regulated state, the audible tone stops, and the alarm message is no longer displayed.

2.5 PRESSURE AND TIME DEFAULTS

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

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

2.6 CUFF OPERATION

1. Press the ON/STANDBY switch 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 the cuff is pressurized to 50 mmHg or more during power-up, the *A.T.S.* 750 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 switch depressed).

- 2. Connect a single port cuff to the unit at the cuff connector.
- 3. The default settings for cuff pressure and time limit are retrieved from the nonvolatile storage during power up.

For each patient, tourniquet pressure 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 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 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 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 about 60 degrees, and steady pressure should be applied to the incision with sterile dressings.

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.

5. The cuff is inflated by pressing the INFLATE switch. The unit will pressurize the cuff to the set pressure and start the time limit (inflation) clock. If the unit cannot pressurize the cuff to within 15 mmHg 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.

At the end of the procedure, deflate the cuff by pressing the DEFLATE switch for 2 seconds. 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 switches simultaneously.

6. Remove the tourniquet cuff and any underlying bandages immediately following final deflation. The time of tourniquet cuff removal should be noted, and the circulation of the limb should be checked.

2.7 DUAL CUFF OPERATION

A Dual Control Valve (DCV), 60-0750-401-00, is available for purchase and use with the *A.T.S.* 750 System. This accessory must be used to perform bilateral and Bier Block/I.V.R.A. procedures using the *A.T.S.* 750 System.

To operate the Dual Control Valve refer to the operating instructions that accompany the Dual Control Valve accessory.

For Bier Block procedures, follow the cuff inflation/ deflation sequence adopted by your institution or requested by the surgeon.

2.8 ALARM CONDITIONS

There are a number of conditions for which the A.T.S. 750 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 very likely that the valve 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 switch. At the end of the silenced period, tones will be reenabled. Depressing the Alarm Silence switch will cause the alarm tone to be silenced again.

To minimize nuisance pressure 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 switch. Since this removes power from the internal instrument circuitry and all instrument functions, commands to the valve 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.

Table 2.1 Alarm Conditions

CONDITION	PRESSURE DISPLAY	TIME DIS- PLAY	APPROPRIATE ACTION/REMARKS
CUFF PRESSURE LOW The pressure in the cuff is 15 mmHg below set point	LO-P	normal	This condition is generally caused by a leak in the system, or a hose occlusion. All lines and connections should be checked.
CUFF PRESSURE HIGH The pressure in the cuff is 15 mmHg above set point	HI-P	normal	Normally caused by transient conditions such as patient movement, controller overshoot, or hose occlusion. This condition, for an extended period, would indicate a harware failure and the <i>A.T.S.</i> 750 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.
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. On the advice of the surgeon, time should be set to new value.
CUFF INFLATED ON POWER UP Cuff pressurized to 50 mmHg or greater at power up	CUFF	INFL	The system assumes that a procedure is in progress and adopts the sensed pressure as the new set point. The operator should immediately check the set value to determine if it needs reset.
CUFF NOT DEFLATED Pressure in deflated cuff is a non-zero value.	normal	CUFF NOT DEFL	Check for kinks in hose. If alarm persists, disconnect hose from cuff. If attempting to set the unit to STANDBY, ensure that cuff is fully deflated.
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 Switch.
CALIBRATION OUT OF SPEC The transducer calibration is out of specification	CAL	FAIL	Calibrate the unit.
AMPLIFIER FAILURE Amplifier is out of range	AMP	FAIL	Cycle the ON/STANDBY Switch. If problem persists, service the unit.
MATH FAILURE Result of math operation was out of range	MATH	FAIL	Cycle the ON/STANDBY Switch. If problem persists, service the unit.
ROM FAILURE Microprocessor failed a ROM memory check	ROM	FAIL	Cycle the ON/STANDBY Switch. If problem persists, service the unit.
RAM FAILURE Microprocessor failed a RAM memory check	RAM	FAIL	Cycle the ON/STANDBY Switch. If problem persists, service the unit.
VALVE FAILURE Improper valve combination occurred	VALV	FAIL	Cycle the ON/STANDBY Switch. If problem persists, service the unit.
WATCHDOG FAILURE Windowing watchdog system detected a malfunction	WDT	FAIL	Cycle the ON/STANDBY Switch. If problem persists, service the unit.
SYSTEM FAILURE Internal diagnostics detected an error	SYS	FAIL	Cycle the ON/STANDBY Switch. If problem persists, service the unit.
OVERPRESSURE The pressure switch has detected a pressure higher than the range of the unit	OVER	PRES	Cycle the ON/STANDBY Switch. If problem persists, service the unit. This occurrence could indicate a runaway pump.

MAINTENANCE SECTION 3.0

A.T.S. 750 TOURNIQUET SYSTEM

3.1 GENERAL MAINTENANCE INFORMATION

While the *A.T.S.* 750 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.

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 all eight screws, four on each side of the unit.

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 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.

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 six months. Inspection points are:

- a) Obvious internal or external damage.
- b) Condition of the power cord.
- c) Condition of internal tubing.
- d) Accumulation of dust or dirt within the unit.
- e) Mating integrity of internal connectors.
- f) Security of the EPROM and safety processor. See Figure 3.1 for location.
- g) Integrity of the pump.
- 3. Functional and Calibration Checks It is recommended that the functional and calibration checks described in Section 2.4 be 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.* 750 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 transducer is recorded at each of four set points. These four calibration factors are used to correct the signal from the pressure transducer during normal operation. The calibration factors and a checksum are stored in non-volatile memory.

To enter the Calibration Mode, simultaneously press and hold the inflate and the deflate switches during power up.

EQUIPMENT REQUIRED:

A.T.S. 750 calibration hose. Calibrated 0 to 500 mmHg pressure gauge. Adjustable 0 to 500 mmHg 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.

- 1. Connect the calibration hose, pressure gauge and adjustable pressure source.
- 2. Enter the calibration mode by pressing and holding the inflate and deflate switches during power-up.
- 3. The message "CUFF" "CAL" is displayed by the TIME and PRESSURE DISPLAYS. During the Calibration process, the message "CAL" and the calibration set point are alternately displayed on the TIME display.
- 4. Calibration measurements are made at each of four set points, 0 mmHg, 50 mmHg, 250 mmHg, and 475 mmHg. The initially selected point is 0 mmHg. Set points are selected by the INFLATE and DEFLATE switches; pressing the INFLATE switch selects the next higher set point, pressing the DEFLATE switch selects the next lower set point. The Deflate Valve is open when the 0 mmHg set point is selected and closed for all other set point measurements.
- 5. For each of the four set points the pressure source is adjusted to the set point value. When the correct pressure is applied, the PRESSURE switch is pressed and a measurement is made. The audible

alarm will beep once to signal that the measurement is complete.

- 6. If the pressure signal from the internal transducer requires more than 15 mmHg correction to equal the applied pressure, a "CAL" "FAIL" alarm is generated. Service to the unit is recommended if this occurs.
- 7. When all four set point measurements are complete, the values are stored in non-volatile memory by pressing the INFLATE and DEFLATE switches simultaneously. At this point the audible alarm will beep once and the message "CAL" "DONE" will appear in the displays.
- 8. The unit remains in calibration mode until it is powered down.
 9. The stored calibration factors are retrieved from
- 9. 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 powered down. Re-calibration is required if this occurs.
- 10. It is recommend that you check your 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. 750 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.* 750 Tourniquet per Section 2.4, connect a 24 in. (61 cm) (or larger) cuff which is known to be leak free to the *A.T.S.* 750 Tourniquet System. Adjust the cuff set point to 475 mm Hg. Ensure that all external connections are tight. Inflate the 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 the cuff. 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 and the alarm message "CUFF" "NOT" "DEFL" will be displayed. The alarm cannot be silenced by the alarm silence touch-switch.

After 10 minutes, 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 touch-switch. Display the set point by activating the PRESSURE touch-switch 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.

3.6 BATTERY VOLTAGE AND BATTERY SERVICE

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

1. Battery Voltage Check

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

2. Battery Service

The 12-volt sealed lead acid battery is charged using lead acid charging technology. The charging circuit is active anytime the unit is plugged into an acceptable V~ 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 batteries in the *A.T.S.* 750 System be replaced annually. The *A.T.S.* 750 System should be plugged in 24 hours before initial use.

3.7 UNSCHEDULED MAINTENANCE

The *A.T.S.* 750 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 switch. 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.

3.8 TROUBLESHOOTING GUIDE

To aid in unscheduled maintenance, Table 3.1 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 the control board are shown in Table 3.2. 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.

3.9 EXPECTED TEST POINT READINGS

To expedite unscheduled maintenance, Table 3.2, Expected Test Point Readings, has been incorporated into this manual. This table, as well as Table 3.1, 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.

Table 3.1 Troubleshooting

SYMPTOM	POSSIBLE CAUSES
1. Cuff will not inflate.	 a) Control Panel not properly plugged into P2. b) Tubing inside unit may be pinched or improperly connected. c) Valve is stuck open. d) Pump not properly plugged into P5. e) INFLATE switch not working.
2. Cuff will not deflate.	 a) Control Panel not properly plugged into P2. b) Deflate switch not depressed long enough (at least 2 seconds). c) Valve is stuck shut. d) DEFLATE switch not working.
3. No V~ Indicator light.	 a) Unit not plugged into wall outlet. b) No Power at wall outlet. c) Blown fuse(s). d) Control Panel not properly plugged into P2.
4. Alarm Silence switch not working.	a) Control Panel not properly plugged into P2.b) Non-silenceable alarm (System Failure).c) Alarm Silence Switch not working.
5. No cuff pressure reading.	a) Transducer amplifier not working.b) Internal tubing kinked.
6. Pump will not stop running.	a) Leak in internal hose or connector.b) Internal tubing kinked.c) Transducer not working.
7. Battery Fail alarm/message.	a) Blown Fuse.b) Broken Battery wire harness.c) Dead or depleted batteries.
8. Unit does not turn on.	a) Control Panel not properly plugged into P2.b) ON/STANDBY switch not working.c) Blown Fuse(s).

Figure 3.1 Control Board and Test Points

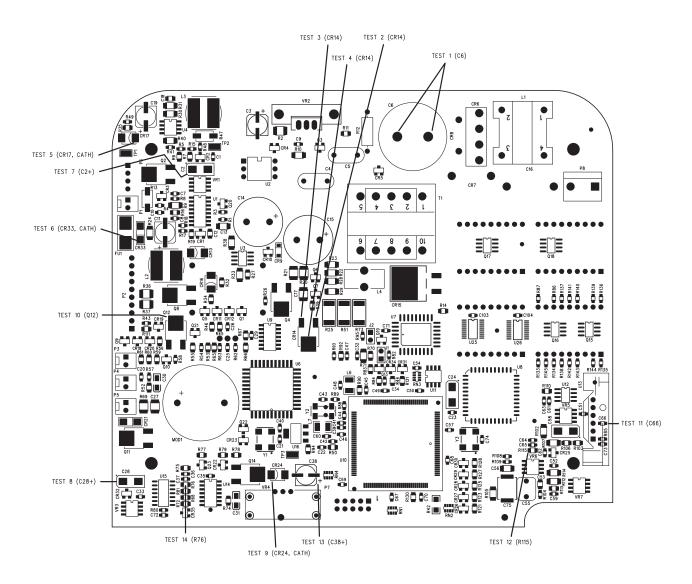


Table 3.2 Expected Test Point Readings

Test	Board Location	Nominal-Reading	Tolerance	Conditions/Comments
Test 1	Between + and - of C6	168 V= @ 120 V~ 310 V= @ 220 V~ 338 V= @ 240 V~	+/- 10%	This is the V~ rectified line voltage. The following calculation must be used to determine cor- rect expected V reading. (V~ line voltage)*1.414) -1.4 = V reading
Test 2 (VBULK)	CR14	15.0 V	+/- 0.5 V	Main V supply for entire system without V~ power.
Test 3	CR14	12.0 V		Battery supply to system without V~ power.
Test 4 (VRAW)	CR14	12 - 15 V		Main V supply for entire system. Same as Test 2 with V~ power. Same as Test 3 without V~ power.
Test 5	CATH. CR17	26.4 V	+/- 1.5 V	V supply for battery charging circuit.
Test 6	CATH. CR33	12.0 V	+/- 1 V	Battery supply after 3 Amp fuse.
Test 7	+ C2	5.0 V 	+/- 0.25 V	Charger circuit - 5 volt supply.
Test 8 (+VUS)	+ C28	5.0 V 	+/- 0.25 V	5 volt V uninterrupted supply.
Test 9 (+ Va)	CATH. CR24	12 - 15 V		Main V supply while unit is "ON"
Test 10	Q12	12 - 15 V 		Pneumatics: Supply to valve and pump circuits.
Test 11	C66	5.0 V 	+/- 100 mV	Supply voltage for analog/transducer circuits.
Test 12	R115	4.096 V 	+/- 100 mV	Reference voltage for analog circuits.
Test 13	+ C38	5.0 V 	+/- 0.25 V	5 volt supply for digital circuits.
Test 14	R76	5.0 V 	+/- 0.25 V	5 volt logic - Always 5 volts as long as ON/STANDBY switch is not pushed in.

NOTE: USE P4-2 (GND) AS VOLTAGE REFERENCE FOR TESTS 2 THRU 14.

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

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:

Zimmer Orthopaedic Surgical Products MAIL: 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)

			1
Zimmer		Zimmer	
Replacement		Replacement	
Part Number	Description	Part Number	Description
0600-1304883	1 A Fuse, 5 x 20 mm	60-1729-001-00	A.T.S. 750 Digital Encoder
0600-1304888	Case Ground Wire	60-2260-001-00	A.T.S. 750 Pole Clamp Assembly
0600-1501263	Calibration Hose	60-3000-001-00	A.T.S. Cal & Regulator Kit
0600-2001370	Plumbing Assembly	61-7308-000-00	PLC O-Rings Kit, 25 each
60-0750-000-01	Control Board	62-1137-001-00	Fuse Drawer, 1/4 in. x 1-1/4 in.
60-0750-000-02	Battery	62-1138-001-00	Fuse Drawer, 5 x 20 mm
60-0750-000-03	Membrane Control Panel	62-1167-001-00	Power Entry Ground Wire
60-0750-000-04	12 Volt Pump	62-1179-001-00	1 Amp Time Delay 1-1/4 in. Glass
60-0750-000-05	Case Base		fuse
60-0750-000-06	Case Lid	62-1184-001-00	Power Cord
60-0750-000-08	Battery Bracket	62-1340-001-00	Valve Muffler
60-0750-000-09	Deflate Valve	62-1714-001-00	Rotary Knob
60-0750-000-10	Power Entry Module	62-1725-101-00	Manual
60-0750-000-11	Mains Wire Harness	62-1726-001-00	Overpressure Switch
60-0750-000-12	Battery Harness	62-2671-001-00	A.T.S. Female Pneumatic Coupling
60-0750-000-13	Overpressure Switch Harness	62-2879-001-00	Male PLC
60-0938-003-00	A.T.S. Stand 5-Wheel Caster Kit	62-2879-002-00	Female PLC

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

3.11 STORAGE

The A.T.S. 750 Tourniquet System has an operating range of 50°F to 100°F (10°C to 38°C).

The following are environmental conditions for transportation and storage:

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

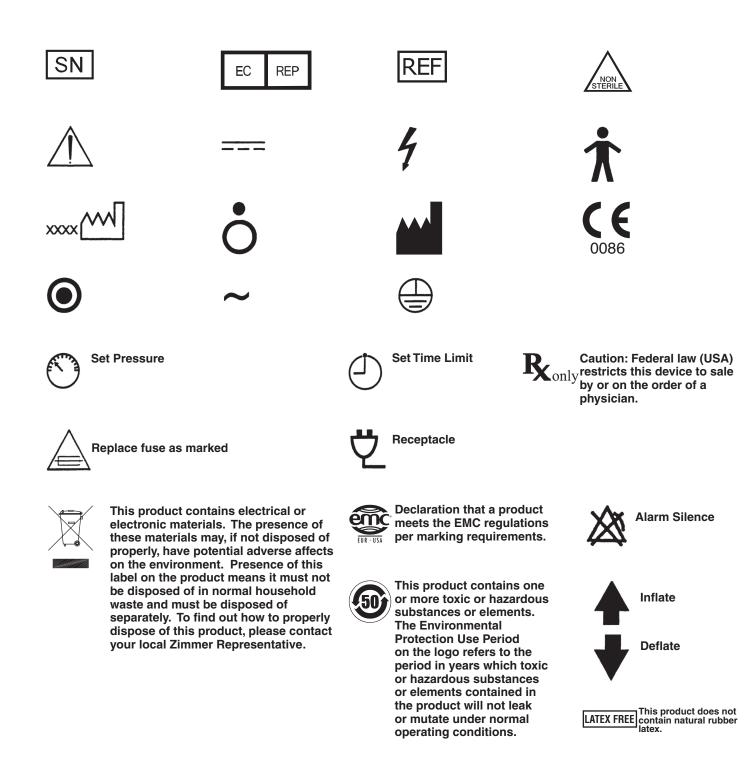
A.T.S.[®] 750 ZIMMER ORTHOPAEDIC DANGER: **TOURNIQUET SYSTEM** SURGICAL PRODUCTS EXPLOSION HAZARD REF 60-0750-101-00 DOVER, OHIO 44622 U.S.A. DO NOT USE IN PRESENCE zimmer 1-800-830-0970 OF FLAMMABLE ANESTHETICS U.S. Patents 5,607,447; 5,681,339; 5,935,146; 6,213,939 B1 6 589 268 OR GASES. ATTENTION: FOR USE BY TRAINED PERSONNEL ONLY. 7 CAUTION ALLOW 5 MINUTES WARMUP BEFORE INFLATION. KEEP POWER CORD PLUGGED IN. BATTERY ONLY FOR USE DURING POWER RISK OF ELECTRIC SHOCK EMERGENCY OR TEMPORARY PATIENT TRANSPORT. DO NOT REMOVE COVER. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL TO INSURE STABILITY, THIS LINE 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 SHOULD BE NO MORE THAN 48 in. (122 cm) FROM THE EU RECYCLING Awarning INFORMATION: FLOOR AND THIS UNIT FOR CONTINUED PROTECTION AGAINST www.weee.zimmer.eu FIRE HAZARD REPLACE ONLY WITH THE SHOULD BE USED WITH SAME TYPE AND RATING OF FUSE: I.V. STANDS HAVING A BASE emc 50 Τ POWER INPUT: 120VA DIAMETER OF AT LEAST 250V~:T1.0A 100-240V~, 50/60 Hz LABEL 62-1723-000-00 REV. 12-09 27.73 in. (70 cm). WARNING FOR CONTINUED PROTEC TION AGAINST FIRE HAZARD WARNING: A.T.S. [®] WILL NOT DEFLATE CUFF IN "STANDBY" MODE. REPLACE ONLY WITH THE SAME TYPE AND RATING OF SSIFIE UL Classification Mark Medical Equipment With Respect to Electric FUSE: 3.0A 125V TIME DELAY

Shock, Fire, and Mechanical Hazards Only, In Accordance with UL

60601-1, CAN/CSA C22.2 No. 601.1, and IEC 60601-1

US

3.12 Warnings, Cautions, and Symbology





Revised: 12-09 ©1997, 2009 Zimmer Orthopaedic Surgical Products, Inc. Printed in U.S.A. 62172510100 ENG



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