ALP[®] 501 PUMP SYSTEM

SERVICE MANUAL

HEALTHCARE SERVICE AND SUPPLY P.O. BOX 1788 TUSTIN, CA 92681 1-714-669-8803

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DESCRIPTION AND OPERATING PRINCIPLE

The Alternating Leg Pressure[®] (ALP[®]) Venous Thromboembolism Prevention System is a noninvasive prophylactic system for reducing the incidence of thromboembolism. The application of external intermittent pneumatic compression has two effects:

- 1. Increases venous blood flow velocity, thereby reducing stasis.
- 2. Enhances fibrinolytic activity to reduce the risk of early clot formation.

The ALP[®] System consists of a pump and a pair of calf or thigh length or foot, single patient use garments. The pump provides intermittent cycles of compressed air, which alternately inflate the single-chambered garments. The compression, when applied properly to the patient, increases venous blood flow velocity and stimulates fibrinolysis.

The pump operates on a 60-second automatically timed cycled consisting of approximately 12 seconds of inflation followed by approximately 48 seconds of deflation.

The ALP[®] 501 System may be used on patients at risk of developing deep vein thrombosis and in conjunction with systemic interventions for the high risk patient.

PRECAUTIONS / COMPLICATIONS

- A. The pump connections should be checked to make sure they are securely locked and that the garment has been properly applied with the tubing <u>at the ankle</u>. Application of the device contrary to this could cause the compression to work against blood flow and cause blood stasis.
- B. If the patient experiences leg pain or tingling numbness, remove garment.
- C. If the calf, leg, or foot compression is discontinued for 30 minutes or longer in a patient considered at risk of developing venous complication, perform a non- invasive evaluation for deep venous thrombosis before resuming compression therapy.

CONTRAINDICATIONS

- A. Pulmonary edema.
- B. Congestive heart failure.
- C. Any ischemic vascular disease such as severe arteriosclerosis.
- D. Phlebitis or any known or suspected deep vein thrombosis.
- E. Any localized condition the placement of the garment would interfere with such as untreated, infected wounds, gangrene, recent skin grafts or dermititis.
- F. The physician should review the patient's medical status and use this device in accordance with his/her best understanding of the patient's needs and current condition.

INSTRUCTIONS FOR USE

The ALP[®] 501 Pump has been tested and found to comply with EMC (Electromagnetic Compatibility). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device
- > Increase the separation between the equipment
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected
- > Consult the manufacturer or field service technician for help

DISPOSAL OF SINGLE USE PRODUCT

Garments (foot, calf, and thigh) used with the Alternating Leg Pressure[®] ALP[®] Venous Thromboembolism Prevention System are disposable. They are constructed of nylon, foam, medical grade PVC, and acetal. Please dispose of these devices in accordance with appropriate local, state or federal requirements.

SYSTEM SET UP

The system is simple to operate:

- 1. Remove the pump and tubing from the carton.
- 2. Plug the pump into an electric socket DO NOT switch the pump on at this time.
- 3. Check that the tubing assembly is inserted into the snap-lock connectors at the side of the pump. Press firmly until a "click" is heard.

GARMENT APPLICATION

INSTRUCTIONS FOR USE:

- A. Plug the pump into an appropriate electrical outlet. AT THIS TIME DO <u>NOT</u> TURN ON THE PUMP.
- B. Remove the garments from the pouch. The garments may be used on either limb.
- C. Follow the printed instructions on and with each garment. For the calf garment, hold the mesh fabric side of the garment against the patient's calf so that the smaller end (tubing end)

rests above the back of the heel and the bladder rests behind the calf. For the thigh garment, make sure the cutout hole rests behind the popliteal fossa. For the foot garment, follow the instructions on the product label and the enclosed pictorial instructions.

- D. First wrap the flap without the velcro hook material SNUGLY around the patient's leg. Then SNUGLY wrap the other flap with the velcro hook to the garment, making certain the bladder rests behind the calf. If the thigh garment is used, additionally, the cut hole rests behind the popliteal fossa.
- E. Repeat the above procedure for other leg (or foot). IT IS IMPORTANT THAT BOTH GARMENTS BE APPLIED SNUGLY TO THE LEGS OR FEET. Note: If only one garment is to be used, simply leave the unused air outlet on the pump free (no tubing attached)
- F. Air tubing is required to connect the garment to the pump and is sold separately. Use the tubing from Healthcare Service and Supply for this purpose (ALP[®] 25 series). Attach the garments to the air tubing using the white snap lock connectors. Each tubing has a male end connector at one end and a female end connector at the other. The female end (large white connector) will fit to the male end (small white connector) that is on the garment. Make certain that a "click" sound is heard to insure a solid connection.
- G. Attach the other end(s) of the air tubing (male end) to the large white female connector(s) on the pump. Make certain that a click is heard with each snap lock connection. If you need to disconnect the tubing, press the silver colored tab on the large white (female) connector and pull apart.
- H. Adjust the pump pressure to a pressure setting of 40 mm Hg unless otherwise specified / ordered by a physician.
- I. Press the on/off switch to turn the pump on.

NOTE: Air tubing hose is <u>REUSUABLE</u>. <u>DO NOT DISCARD</u> the air tubing hose with the disposable garments.

PUMPOPERATION

ALP[®] 501 PUMP OPERATING INSTRUCTIONS

- 1. Plug the ALP[®] pump into a suitable 110 VAC electrical outlet. **DO NOT TURN THE PUMP ON AT THIS TIME.**
- 2. Adjust the pressure regulator dial to a pressure setting of 40 mm Hg unless otherwise ordered by a physician.
- 3. Connect the tubing set to the two outlets on the pump ensuring that a click is heard from the snap lock connectors.

FOR ONE GARMENT USE: If a leg is involved in the surgical procedure and only one garment is to be used, simple leave the unused air outlet free.

- 4. Remove the two calf (or thigh or foot, if indicated) garments from the sealed bag. They may be used on either limb.
- 5. Follow the instructions printed on each garment. For the calf garment, hold the mesh fabric side of the garment against the patient's calf so that the smaller end (tubing end) rest above the back of the heel and the bladder rests behind the calf. For the thigh garment, make sure the cutout hole rests behind the popliteal fossa. For the foot garment, follow the instructions on the product label and pictorial instructions.
- 6. First wrap the flap without the velcro hook material **SNUGLY** around the patient's leg. Then **SNUGLY** wrap the other flap with the velcro hook to secure the garment, making certain the bladder rests behind the calf. If the thigh garment is used, additionally, the hole cutout rests behind the popliteal fossa.
- 7. Repeat for the other leg or foot. IT IS IMPORTANT THAT BOTH GARMENTS BE APPLIED SNUGLY TO THE LEGS OR FEET.
- 8. Connect the snaplock connection tubing to the garments by pushing them firmly together until they click. (To remove them, press the button on the female end of connector while simultaneously pulling on the male end).
- 9. Turn the pump on. The ON / OFF switch should be illuminated.
- 10. If the patient is ambulatory, turn the pump off and disconnect the tubing from the garments. The patient may ambulate with only the calf and thigh garments in place. Once the patient returns to the chair or bed, connect the tubing to the garments and turn the pump on.

OPERATION CHECKLIST

- 1. After a short delay (maximum of 30 seconds), one of the garments will rapidly inflate. The other will inflate 30 seconds later.
- 2. Check that the garments alternately inflate and deflate (12 seconds inflation/48 seconds deflation).
- 3. If the audible / visual pressure alarm activates, refer to the Trouble Shooting section provided with the pump or return the unit to Healthcare Service and Supply. The garments should inflate within 1 minute of starting the pump. The garments will alternately inflate, each garment inflating within 30 seconds of the other. If this does not occur, make certain the pump is plugged into a viable 110 VAC outlet and the **ON / OFF** switch is turned **ON**.

Make certain all snap lock connectors are securely locked in.

The pressure alarm, which is audible and visual, will function under situations of low pressure, continued pressure, when a garment fails to inflate or deflate, and a malfunctioning pump.

When there is a problem with one garment, there will be an intermittent audible and visual alarm. The alarm will function only during that garment cycle. Items that need to be checked include pump and garment connection, bladder leaks, kinked tubing and confirmation of the proper garment application.

PRESSURE ADJUSTMENT

The pressure control is on the front of the pump and ranges from 40-60 mm Hg. The pressure exerted by the garments on the foot can be adjusted by turning this knob. Turning the knob clockwise increases the pressure; counter clockwise decreases the pressure. The recommended pressure setting is 40 mm Hg.

PREVENTIVE MAINTENANCE

There is no preventive maintenance required on the ALP® 501 pump. Follow the operation checklist for conformance and the cleaning information for cleaning and disinfection.

REPLACEMENT OF INTERCHANGEABLE AND/OR DETACHABLE PARTS

A. TUBING REPLACEMENT

Press the silver tab on the white female connector on the exit port at the pump site to release the tubing from its connection. To replace tubing, press the male connector of the tubing into the female connector at the pump site.

Push until a "click" is heard. Nylon cable ties should be used to secure the pump tubing to the pump to prevent inadvertent disposal.

B. FUSE REPLACEMENT

If the system fails to operate when plugged in and switched on, the fuse on the underside of the pump should be checked. To do this, disconnect the pump from the main power supply and remove the fuse holder cap using a suitable flat blade screwdriver.

Important

To protect against fire hazard, replace blown fuse with identical type and rating -500 mAmp, 250 V AC fast acting, low breaking capacity. If the fuse blows again, refer the pump for service.

TROUBLESHOOTING

The ALP[®] 501 pump is fitted with an audible and visual alarm. When a problem occurs, the audible alarm sounds and the red light illuminates.

Alarm Fault Intermittent beep and red light. Low pressure or continued pressure.

Corrective Action

Ensure all tubing is connected at the pump and garments and the tubing is not kinked. Try the pump again. If this result is unsuccessful, turn off the pump and disconnect the garments.

Refer pump to the service department and obtain new pump.

TRANSPORT AND STORAGE

The following are the permissible environmental conditions for the transport and storage of the Alternating Leg Pressure[®] (ALP[®]) Venous Thromboembolism Prevention System pump and garments:

- 1. Ambient temperature range of -40°C to +70°C
- 2. Relative humidity range of 10% to 100%, including condensation
- 3. Atmospheric pressure range of 500 hPa to 1060 hPa.

CLEANING/ DISINFECTION

The exterior casing of the ALP[®] 501 pump is made of ABS plastic and should be cleaned using a soft, damp cloth with a mild detergent. Hypocarbonate and phenolic based cleaning solutions should NEVER be used since they cause this and other plastics to deteriorate. The pump may be disinfected using a dilute hyperchlorite solution (1000ppm).

SERVICE AND MAINTENANCE

For service or maintenance, please contact: Healthcare Service and Supply Tustin, CA 92681 U.S.A. 1-714-669-8803 Pump Model Number: Size: Weight: Pressure Range:

Cycle Time:

Indicators:

Rated Voltage: Rated Frequency: Rated Input Power: Rated Current: Fuses:

Certification/Listing

Protection Category

Mode of Operation

Flammable Reactivity

Degree of protection against ingress of water

ALP[®] 501

5.5 X 12.5 X 5.5 inches

7.9 lbs.

40-60 mm Hg

Inflation 12 seconds (approx.) Deflation 48 seconds (approx.)

Audible beep and visual red LED light alarm activated with continued or low pressure.

120V ~

60 Hz

14 Watts

.15 Amps

500 mA, 250 V AC, Fast Acting/ Low Breaking Capacity

CSA File 219885 Complies with (C22.2 No 601.1-M90 and UL Std No. 2601-1)

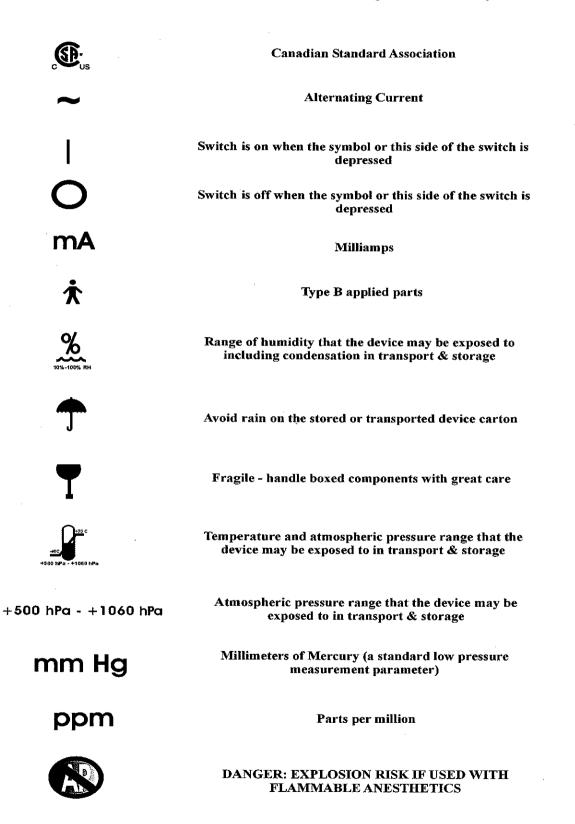
Type B Applied Parts Class I Equipment

Continuous

Equipment NOT suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide

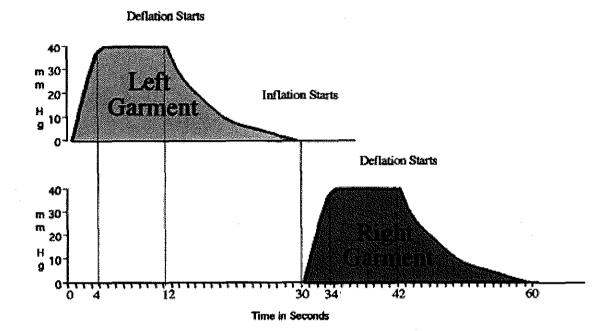
IPXO

Definitions of Symbols and Warning Statement/ Symbols



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Pressure / Time Cycle ALP[®] 501 Pump



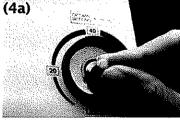
ALP[®] 501 Pump Calibration Instructions

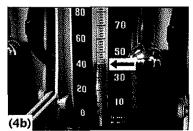
- 1. Plug the ALP® 501 Pump into a suitable 110 VAC electrical outlet. (1a) Hook the outlet ports (or outlet tubing) to a mercury sphygmomanometer. (1b, 1c) (if a male adapter is needed to convert/adapt your sphygmomanometer call the above number and we will gladly send you what you need to adapt it.)
- 2. Turn the pump on (2a). Make sure the blue dial (knob) is set to 40mmHg. (2b)
- If sphygmomanometer is not 40mmHg (+/-5mmHg), loosen set screw underneath knob. (3a) (A screwdriver can be inserted through calibration hole in the protective Delrin™ "U" at the front of the pump. (3b)) Remove blue knob.
- (3a)

(1a)

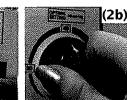
- 4. On the inflation cycle (12 second pressure pulse each port per minute) set the brass screw by screwing clockwise to increase or counter-clockwise to decrease to 40mmHg (+/- 5). (4a, 4b) Place blue knob back on the post, applying a little pressure with the thumb to depress wave washers enough to have tension on the knob. Tighten knob set screw.
- 5. Allow the pump to inflate again on the sphygmomanometer to make sure you have calibrated the pump correctly.











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Healthcare Service & Supply Phone (800) 669-3521

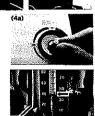
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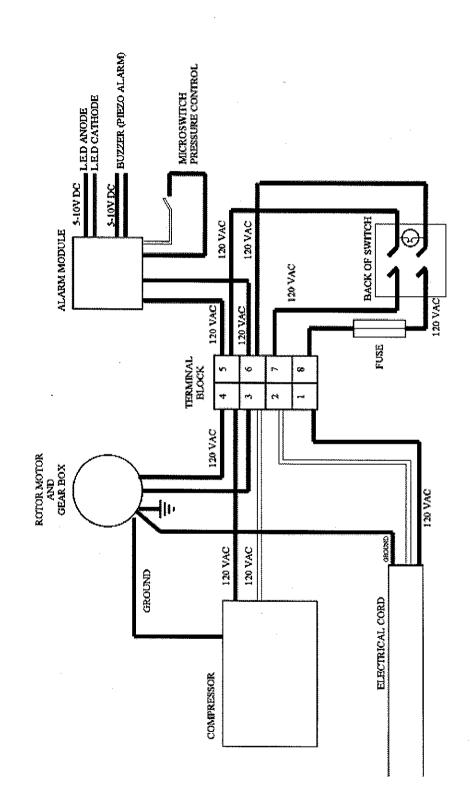
Inspection Checklist for ALP® 501 Alternating Leg Pressure (ALP®) Pump and Tubing

 Inspect pump connecting tubing for areas of damage which include but are not limited to the following:
Cuts, abrasions or kinks that would hinder the delivery of air to the garment.
Damaged connectors (male or female) on tubing set or pump site that would necessitate repair or replacement. The male connector with the visible o-ring when inserted into the female connector will snap when fully seated. The silver tab on the female connector will release the male when depressed and pulled apart.

- II. Follow operating instructions as listed on the top of the pump or as described in the Service/Operations Manual. Finish by observing the operation checklist to make certain all normal operation parameters are in order.
- III. Disconnect one tubing at the garment site and run the pump to make sure the pump will alarm under situations of low pressure. With one tubing disconnected the pump should alarm within one minute. Reconnect the tubing. The alarm should reset within one minute. Deviations from these observations require the pump to be sent in for service.
- IV. Calibrate the pump as per the following instructions:
 - Plug the ALP® 501 Pump into a suitable 110 VAC electrical outlet. (1a) Hook the outlet ports (or outlet tubing) to a mercury sphygmomanometer. (1b, 1c) (If a male adapter is needed to convert/adapt your sphygmomanometer call the above number and we will gladly send you what you need to adapt it.)
 - 2. Turn the pump on (2a). Make sure the blue dial (knob) is set to 40mmHg. (2b)
 - If sphygmomanometer is not 40mmHg (+/- 5mmHg), loosen set screw underneath knob. (3a) (A screwdriver can be inserted through calibration hole in the protective Delrin[™] "D" at the front of the pump. (3b)) Remove blue knob.
 - 4. On the inflation cycle (12 second pressure pulse each port per minute) set the brass screw by screwing clockwise to increase or counter-clockwise to decrease to 40mmHg (+/- 5). (4a, 4b) Place blue knob back on the post, applying a little pressure with the thumb to depress wave washers enough to have tension on the knob. Tighten knob set screw.
 - 5. Allow the pump to inflate again on the sphygmomanometer to make sure you have calibrated the pump correctly.
- V. Inspect the case for cracks, dents, bent bed hooks, cut or frayed electrical cord, bent or missing plug prongs, broken or bent switches, LED's, control knob, or broken handles. Inspect the bottom of the pump for missing feet. Any damage should be reported to HSS at 800-669-3521. For technical support the pump may be sent along with a written communication describing the nature of the problem to:

Currie Medical Specialties, Inc. 730 East Los Angeles Avenue Monrovia, CA 91016 Attn: Customer Service ALP Technical Support





ALP& 501 Pump Electrical Schematic Rev. N/C Drawing 501-1

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