Operations and Service Manual

ArtAssist®

THE ARTERIAL ASSIST DEVICE®

Model AA-1000 with EndoShear™ Technology

ACI MEDICAL

L-5.93 Rev. 0

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Operations Manual

Introduction

The ArtAssist® device is the only external pneumatic compression device developed with vascular surgeons for the sole purpose of increasing blood circulation, specifically arterial blood flow. It applies impulse pressure to the foot, ankle, and calf. Single-patient-use cuffs are made of soft durable material designed to last for months of therapy.

Therapy takes place with the patient in a comfortable upright sitting position. Once the cuffs are applied, the patient only needs to turn on the device. All pressure and timing controls are pre-set and hidden from the patient. It is portable and suitable for home, clinic, or hospital use.

The ArtAssist® device is composed of three basic components: an electrically operated controller, tubing sets, and cuffs. The controller is connected to a wall outlet for power using the included power supply and cord. Therapy can be applied to 1 limb or both limbs at the same time. The only control available to the user is an ON-OFF power switch. Pressure and time parameters have been optimized for the population of ischemic patients; but in rare cases, the applied pressure may be altered.

Indications

This device is adjunct therapy for patients with ischemic disease of the lower limbs. It is indicated for improving blood circulation in limbs:

- To help prevent and reduce complications of poor circulation in the legs (lymphedema, edema, and ulcerations associated with venous insufficiency)
- To help prevent and reduce surgical (including orthopedic and musculoskeletal surgery) complications
- To help prevent and reduce complications of immobility (examples included immobility due to swollen joints)
- To help reduce pain, swelling and other clinical complications in legs having poor circulation

Specific indications include:

- When surgery is contraindicated
- While waiting for surgery
- Intermittent claudication
- Rest pain
- Diabetic foot
- Ischemic neuritis
- Arterial ulcers
- Gangrene
- Poor runoff

Contraindications

- During episodes of inflammatory phlebitis or pulmonary embolism
- When deep vein thrombosis is diagnosed or suspected
- When increased venous or lymphatic return is undesirable including presumptive evidence of congestive heart failure
- On limbs with uncontrolled infection
- When pain increases significantly or with worsening skin tissue condition

Warnings

Note: Failure to observe one or more of the following warnings could compromise patient safety or result in ineffective therapy.

Warning or Safety Sign	Consideration of Hazards	
	Possible hazard the warning/safety sign is intended to avoid and likely consequences that could occur if the advice is not followed	**Precautions for Reducing Risk**
 ACI Medical, LLC recommends that all physicians, nurses, technicians, and patients who will be using and operating the ArtAssist AA-1000, review this Operations Manual prior to use. If there are additional questions after reading this manual, contact ACI Medical, LLC.	Improper use of the device might provide no therapy or insufficient therapy	Review this Operations Manual prior to use. If there are additional questions after reading this manual, or you suspect the device may not be operating properly, discontinue its use and contact ACI Medical, LLC.
 Use of the ArtAssist device is restricted to use on a single patient.	A contagious user could possibly infect another user if the device is shared	Prescribed users should not allow others to use their device.
 Use of accessories, power supply, and cables other than those specified or provided by the manufacturer of this equipment could result in improper operation.	The device might malfunction, provide no therapy, or insufficient therapy	Review this Operations Manual prior to use. If there are additional questions after reading this manual, or you suspect the device may not be operating properly, discontinue its use and contact ACI Medical. Use the device only as directed.
 If performance changes are detected during use, stop using the device, remove it from the leg(s), and contact ACI Medical customer service. There is no risk to non-use during period of device return.	A suspect device might provide no therapy or insufficient therapy Improper use of the device might cause discomfort	Review this Operation Manual prior to use. If there are additional questions after reading this manual, contact ACI Medical. Use the device only as directed. If any discomfort is experienced during use, discontinue use immediately and remove the device from the leg(s). Contact ACI Medical.

 Do not autoclave, use automated cleaning methods, or immerse the ArtAssist device in liquid as damage may occur.  Do not operate in wet areas or with wet hands, feet, etc.  Avoid spilling any liquids onto the device. This can cause possible damage to the unit.	A damaged device might operate in such a way as to cause discomfort	Review this Operation Manual prior to use. If there are additional questions after reading this manual, contact ACI Medical. Use the device only as directed. If any discomfort is experienced during use, discontinue use immediately and remove the device from the leg(s). Contact ACI Medical. If exposed to liquids, turn off the unit and dry the unit thoroughly. Test the device off-limb to evaluate for proper operation before reapplying to the limb for use.
 Keep the device dry and away from heaters, steam, children, and pets.	The unit might become damaged and provide no therapy or insufficient therapy Improper use of the device might cause discomfort	Review this Operation Manual prior to use. If there are additional questions after reading this manual, contact ACI Medical. Use the device only as directed. If any discomfort is experienced during use, discontinue use immediately and remove the device from the leg(s). Contact ACI Medical. After therapy, be sure to put it in a safe place and out of reach of children.
 Risk of electric shock. Disconnect power supply and cord before opening or servicing this device	User, technician, or servicer may expose themselves to an electric shock	Disconnect power supply and cord before opening or servicing this device
 For grounding reliability, plug only into a three-pronged grounded outlet. When used in a health care facility, use only with an outlet labeled “Hospital Grade”.	In event of surge, grounding wire redirects voltage.	Plug device only into a three-pronged grounded outlet.
 Risk of explosion. Do not use this device in the presence of flammable anesthetics or other flammable gases.	User may expose themselves to dangerous explosion	Do not use this device in the presence of flammable anesthetics or other flammable gases.
 Cuffs must be removed before walking or the patient may slip and fall.	Patient slip or fall and acquire an injury	Remove cuffs before standing up or walking.
 Apply the cuffs over bandages and clean white cotton socks	Avoid getting bodily fluids on the device cuffs	Apply cuffs over bandages and clean, tall socks.

Cautions

Note: *Caution statements are used to highlight information relating to special care that should be exercised to ensure the safe and effective use of the ArtAssist®, Model AA-1000.*

- Federal (U.S.A.) law restricts this device to sale by, or on, the order of a physician.
- The device is intended to be used in a home, clinic, hospital, or similar environment.
- The device is intended to be used by patients that may be instructed for proper use by their medical professional.
- Do not allow the device to be used by others for whom the device is not prescribed.

- Proper use of the device is to be monitored by the patient and physician, and not by ACI.
- If rented, return the device and accessories to ACI Medical or the provider of the device promptly after physician orders discontinuation of its use.
- There is no known potential electromagnetic or other inference between the ArtAssist® device and other devices.
- For cleaning the device, it is recommended cleaning the exterior case, cuffs, and tubing with a damp (**NOT WET**) cloth of mild soap and water or alcohol. Allow device to dry before reusing.

List of Symbols and Abbreviations

Symbol	Meaning
	Manufacturer
	Date of manufacture
	In the United States of America, federal law restricts this device to sale by or on the order of a physician, physical therapist, occupational therapist, or equivalent healthcare professional.
	Serial number of the device
	ArtAssist model AA-1000 is a Type B applied part (per IEC 60601-1)
	Refer to the Instructions for Use
	General Warning
	Keep dry
	This product contains electronic components and must be disposed of in accordance with local laws or regulations that apply.
	Represents compliance to North American product safety standards through independent testing and certification by Intertek Group PLC

Physical Description

ArtAssist®

Power Requirements: 24VDC, 60W MAX

Maximum Operating Temperature: 85º F degrees = 29.4ºC

Dimensions: 10 ⅛" wide, 8 ¼" high, 8 ⅜" deep = 25.7 x 21 x 21.3 cm

Weight: 13 pounds = 5.9 Kg

Power Supply

ACI Medical's AC/DC External Class I Power Supply has a standard IEC320-C14 AC inlet with an input voltage range of 80VAC to 264VAC. The 24VDC output connects to the ArtAssist® unit via its DC plug (tuning fork style 2.1x5.5x11mm). **Only use the provided ACI Medical Power Supply to power the ArtAssist®**. A six foot long, hospital grade power cord with a female plug will be supplied with the power supply.

Tubing sets

Each PVC tubing set is four feet (122cm) long (¼"ID, ½"OD = .64 x 1.3 cm). There are white pneumatic connectors on one end that attach to the ArtAssist® and barb fittings on the other end that attach to the cuffs.

Compressions cuffs

Cuffs are for single patient use only. They are mostly "one size fits all" and can be used on either leg. Smaller cuffs are available if needed.

Outside surface – Hook-compatible loop with pockets containing two air bladders: one for the foot and ankle regions; another for the calf region.

Inside surface – Napp nylon tricot non-woven cloth.

Do not machine wash cuffs. Wipe with a moist cloth only.

Instructions

An Instructions for Use (IFU) brochure is supplied with all devices.

Set Up, Proper Operation, and Use

View the Instructions for Use brochure to set up the device and use.

- Unpack items and save all packing materials and paperwork. You may need these to return the device to ACI Medical or your provider.
- Set the controller by a chair for use in therapy. Make sure the power switch is in the OFF position. Be careful not to obstruct the fan's air inlet, located on the side of the device.
- Plug the power cord into a wall outlet and into the female receptacle of the external, desktop power supply. Plug the power supply's output plug into the ArtAssist's® power jack connector. Do not use an extension cord or a "cheater" adapter that eliminates the effect of the ground pin on the outlet plug. In health care facilities, used only AC outlets labeled "Hospital Grade".
- Plug the tubing sets' white, plastic connectors into the upper side of the ArtAssist® (make sure you hear a click).
- Connect the other end of the tubing set into the cuff. Plug the barb fittings labeled "Foot" into the Foot Cuff (Black) and the "Calf" fittings into the Calf Cuff (Red).

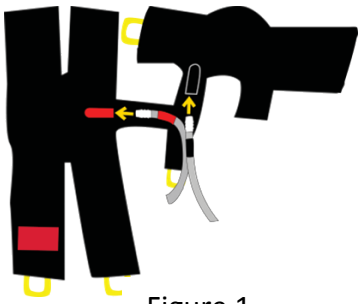


Figure 1

Note: Make sure tubing is secure by inserting past the first couple of barbs.

Figure 2

- Apply the cuff over a clean sock, with bandages left in place. Place the cuff open on the floor with the Velcro®-like hook tape facing up and the hose fittings facing down (Figure 3). Center your foot over the cuff (Figure 4). Bring the side strap over the top of the foot and attach snugly (Figure 5). Bring the back heel strap around the ankle and attach it (Figure 6). Center the remaining cuff behind your calf (Figure 7). Attach the upper and lower straps snugly around the front of the leg with Velcro®-like hook tape (Figure 8).

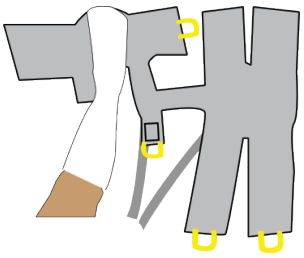


Figure 3

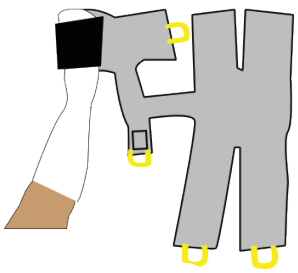


Figure 4

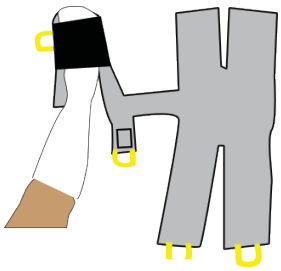
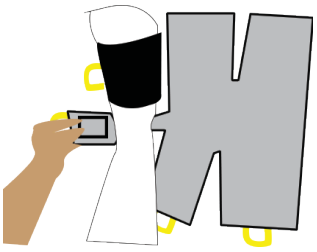


Figure 5



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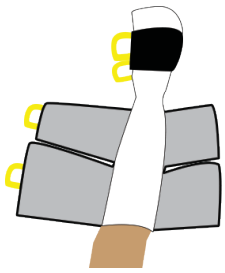

Figure 7

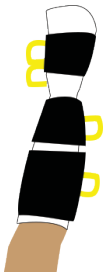

Figure 8

Velcro® is a registered trademark of Velcro Corp.

- Sit with feet on the floor and then turn the power switch ON to begin therapy. Turn OFF the switch to end therapy or wait for the hourglass icon to appear (signaling therapy timeout). Turn OFF power to clear the visual indicators.
- It is recommended to use this device at least 2-4 hours a day, for 1-hour intervals or as instructed by your doctor. Ideally: 60 minutes in the morning, 60 minutes in the afternoon, and 60 minutes before bedtime. For those who work or are unable to work around the ideal schedule, 1-2 hours in the morning and 1-2 hours at night may be adequate. Consult your doctor and follow the prescribed schedule.

Device Return Packaging Instructions

Upon termination of your prescription by your doctor, return the device, the power supply, power cord, and tubing to ACI Medical or your provider by using the same shipping materials that it came in. Do not return used cuffs.

1. Carefully pack the controller with its top handle facing up and curved front panel matching the curved part of the front panel to the bottom packing foam. Put the top packaging foam over the top of the controller again, matching the curved part of the front panel to the packing foam.
2. Place the tubing, power supply, and power cord into the empty spaces between the foam and the box.
3. Use the tape provided to seal the box. Remove any old labels on the box and place the return shipping label provided on the top of the box (Figure 9).
4. Contact the provider or ACI Medical to arrange a pickup.

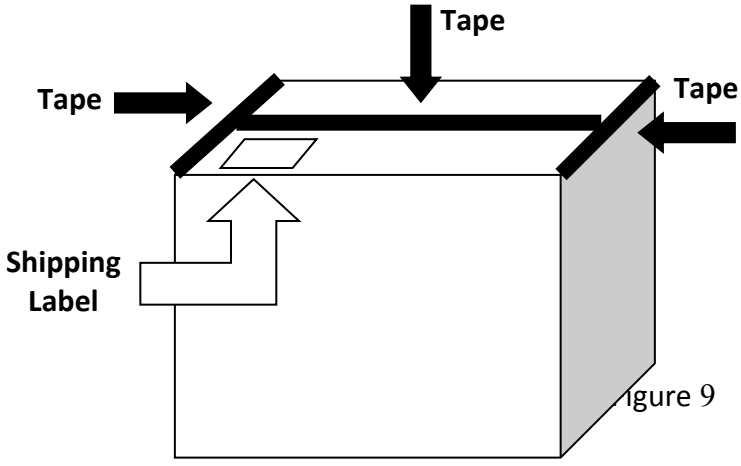

Figure 9

ArtAssist® LED Indicators

Startup LED Diagnostic: When the ArtAssist® is powered ON, it will briefly illuminate all its LEDs.

Figure 10

Therapy Countdown: While applying therapy, the display will show the number of minutes left before the device reaches its therapy timeout.

Figure 11

Timeout: The Hourglass Icon will illuminate when the device has reached its therapy timeout.

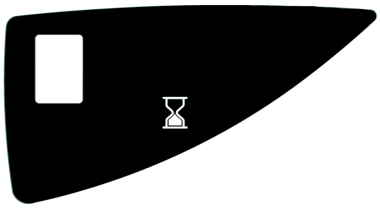

Figure 12

Repair Mode: The display will show an orange repair symbol and an Error Code if there is a fault with the unit. Consult the Service Manual or contact ACI Medical for assistance if this symbol appears.

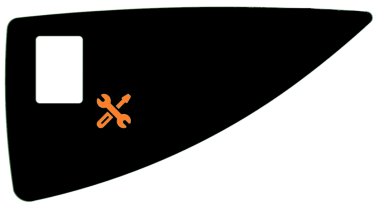

Figure 13

Repair Leak Mode: The display will show an orange repair symbol and E06 or E07 if there is a leak. Consult the Service Manual or contact ACI Medical for assistance if these symbols appear.

Operation Mode

The ArtAssist® has a single operation mode. When powered ON, the device goes through a pressure cycle where the Foot and Calf Air Bladders inflate to 120mmHg. This pressure is held for 3 seconds before the bladders are deflated to 10mmHg. That pressure is held for 20 seconds before the next inflation cycle begins. This cycle continues until the power switch is turned OFF or when the device reaches the therapy timeout. The first 5 minutes of inflation is a staggered, EndoShear™ inflation. This staggered inflation occurs while the device is adjusting its adaptive valve timing. After the first 5 minutes, the device will apply rapid, single inflation. The ArtAssist® bladder pressure as a function of time is shown below.

Pressure vs. Time Characteristic

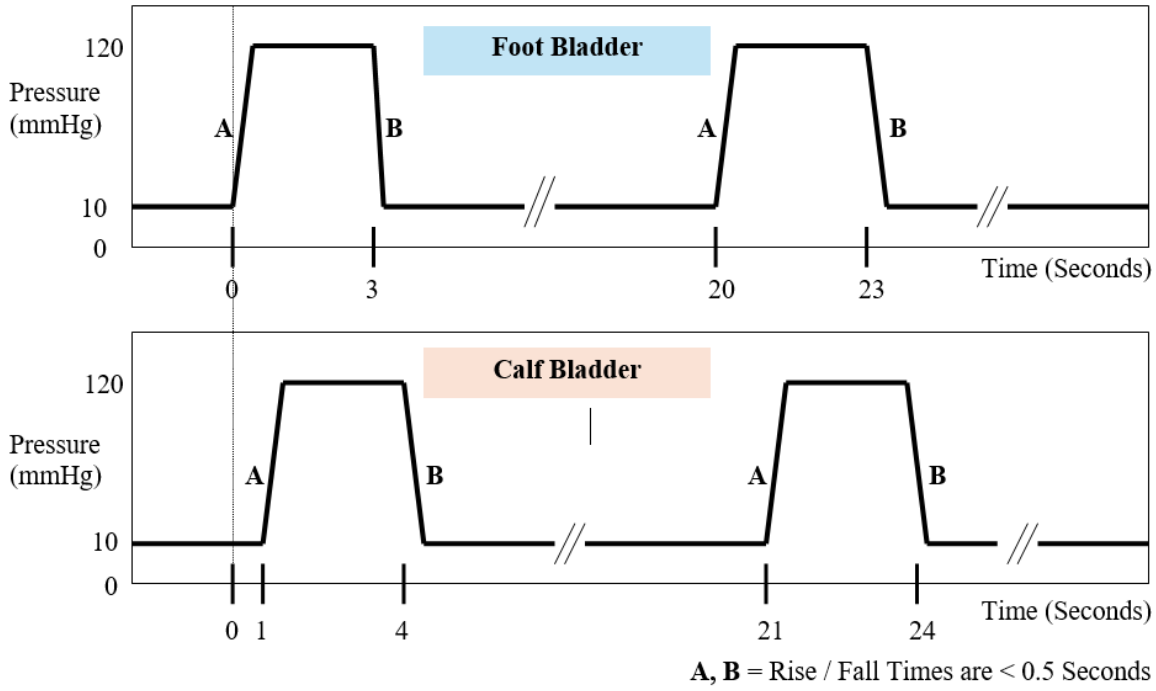

Figure 14

Pneumatic Block Diagram

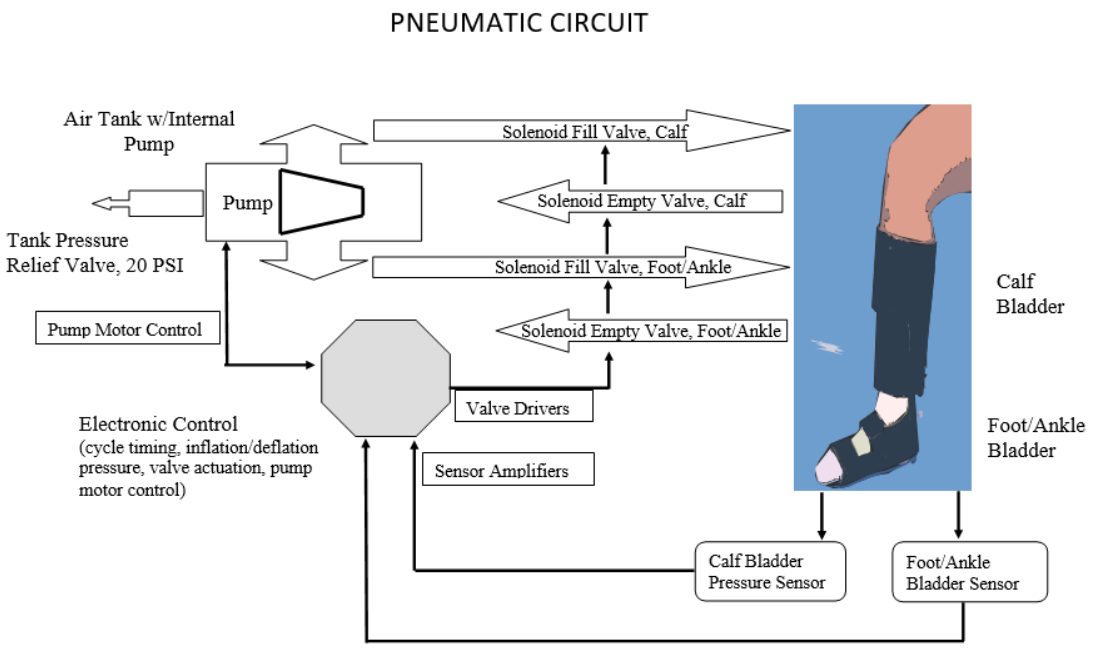

Figure 15

Classification and Standards

The ArtAssist® model AA-1000 meets the electrical safety requirements of:

- IEC/EN 60601-1, 1st Edition
- IEC/EN 60601-1-2, 3rd Edition

Safety Features

- The medical grade power supply (2xMOPP) has short circuit, overload, over-voltage, and over-temperature protections.
- The device is safety fused for excessive current consumption by the ArtAssist®.
- Audio and visual indicators will appear if there are any problems with over-pressure, under-pressure, air leaks, the power supply, or the pump/motor.
- A cooling fan is installed for temperature stability.
- In a problem condition, power is removed from the pump and solenoid valves, which exhausts pressure from all cuffs. The cooling fan remains on.
- If the unit loses power, all cuffs exhaust.

How the Device is Supplied

The ArtAssist® device model AA-1000 is supplied non-sterile.

Disposal

For disposing of the device owned by the user (**NOT RENTAL DEVICES**), the user must contact its local authorities to determine the proper method of disposal of potentially biohazardous materials such as the wrap component.

Warranty

ACI has exercised reasonable care in the manufacture of this device. All ACI devices are guaranteed to be free of functional defects in workmanship and materials when used normally for their intended use. Any ACI device proving to be defective will be replaced upon return of the defective device to ACI. Replacement or repair of the device at ACI sole discretion shall be the sole remedy for any device determined to be defective. Any type of misuse in accordance with this instruction manual or the directions of a patient's professional medical advisor or abuse of any nature will render the warranty void.

EXCEPT AS PROVIDED IN THE SPECIFIC WARRANTIES SET OUT HEREIN, ALL DEVICES ARE PROVIDED ON AN "AS IS" BASIS. NEITHER ACI, NOR ANY OF ITS AFFILIATES, EMPLOYEES, OFFICERS, DIRECTORS, AGENTS, OR LICENSORS WARRANTS THAT THE DEVICES SOLD BY ACI, INCLUDING THE ARTASSIST DEVICE WILL BE DEFECT FREE, NOR DO THEY WARRANT THAT CERTAIN RESULTS MAY BE OBTAINED BY THE USE OF ANY DEVICE IN CONNECTION WITH THE DELIVERY OF PROFESSIONAL MEDICAL SERVICES BECAUSE, WITHOUT LIMITATION, STORAGE AND HANDLING OF THIS DEVICE BY THE USER, AS WELL AS OTHER FACTORS RELATING TO THE USER DIAGNOSIS, TREATMENT, SURGICAL THERAPY, AND OTHER MATTERS ARE BEYOND THE CONTROL OF ACI. ACI AND ITS AFFILIATES, EMPLOYEES, OFFICERS, DIRECTORS, AGENTS, AND LICENSORS MAKE NO WARRANTY, GUARANTEE, OR REPRESENTATION, EITHER EXPRESS OR IMPLIED, REGARDING THE MERCHANTABILITY, TITLE, OR FITNESS FOR A PARTICULAR PURPOSE OF THE ACI DEVICES INCLUDING THE ARTASSIST DEVICE.

NOTWITHSTANDING ANY TERM OR PROVISION CONTAINED HEREIN, IN NO EVENT SHALL ACI, BE LIABLE TO ANY PURCHASER OR USER OF THE DEVICES SOLD BY ACI, OR TO ANY OTHER PERSON OR ENTITY, FOR ANY INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL, EXEMPLARY, OR PUNITIVE DAMAGES, OR OTHER SIMILAR TYPE OF DAMAGES, ARISING OUT OF OR IN ANY WAY RELATED TO THE PURCHASE, USE OR PERFORMANCE OF THE ART ASSIST DEVICE OR ACI'S ALLEGED BREACH OF ANY WARRANTY OR AGREEMENT, REGARDLESS OF WHETHER ACI, KNEW OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES IN ADVANCE.

Returned Goods Policy

Purchased products must be returned in unopened packages, with manufacturer's seals intact to be accepted for replacement or credit and to avoid a restocking charge, unless returned due to a complaint of product defect or mislabeling.

Determination of a product defect or mislabeling will be made by ACI, and the determination will be final.

Limitations of Liability

ACI assumes no liability if the device is misused, and ACI neither assumes, nor authorizes any other person to assume for it, any other or additional LIABILITY or RESPONSIBILITY in connection with the sale or use of any ACI device.

UNDER NO CIRCUMSTANCES WHATSOEVER SHALL ACI BE LIABLE TO ANY PURCHASER, USER, OR ANY OTHER PERSON OR ENTITY FOR DAMAGES OF ANY KIND ARISING OUT OF OR IN ANY WAY RELATED TO THIS SALE OF AN ACI DEVICE OR THE PERFORMANCE THEREOF OR ACI'S ALLEGED BREACH OF ANY ALLEGED OBLIGATION IN ANY AMOUNT OF MONEY WHICH SHALL EXCEED THE AMOUNT PAID BY THE PURCHASER TO ACI, FOR THE ACI DEVICE.

THE LIMITATIONS ON LIABILITY SET FORTH ABOVE SHALL APPLY TO ALL CAUSES OF ACTION, INCLUDING, WITHOUT LIMITATION, BREACH OF CONTRACT, BREACH OF WARRANTY, STRICT LIABILITY, NEGLIGENT MISREPRESENTATION AND OTHER TORTS, AND LIABILITY BASED UPON THE PROVISIONS OF ANY OTHER ALLEGED AGREEMENT AND ANY NATIONAL, STATE, OR LOCAL LAW OR ORDINANCE. THE LIMITATIONS ON LIABILITY REPRESENT A FUNDAMENTAL TERM OF SALE AND USE OF ANY ACI DEVICE, AND ACI, WOULD NOT HAVE SOLD ANY DEVICE WITHOUT THEIR INCLUSION.

NO ACTION, REGARDLESS OF FORM, ARISING OUT OF THE PURCHASE OR USE OF ANY ACI DEVICE MAY BE BROUGHT BY ANY PURCHASER OR USER AGAINST ACI, MORE THAN ONE YEAR AFTER THE CAUSE OF ACTION HAS ARISEN.

Service Manual

Troubleshooting

If the device is not operating:

- Check if the power cord is plugged into both the power supply and the wall outlet.
- Check to see if the power supply is plugged into the device.
- Check to see if the power supply's green LED is illuminated.

If alert indicators appear in the black lens:

- Immediately stop use.
- The audio indicator will sound with a visual indicator appearing.
    - **Hourglass Icon** indicates the device has been continuously in use for one hour. Cycle the ArtAssist® power (flip the power switch OFF and then back ON again) to reset the one-hour timer and to continue use of the device. Do this as prescribed.
    - **Repair Icon** with an Error Code indicates that there is a problem in the system.
    - **Repair Icon with E06 or E07** Error Code indicates an under-pressure condition, most likely due to an air leak. Check for leaks in the cuffs, tubing, and connectors. The pump may be malfunctioning or there may be a leak elsewhere in the system. It takes at least 5 minutes for a leak condition to trigger the alarm. A leak is considered significant if the cuff pressure is not able to exceed 100mmHg.
- Contact ACI Medical for instructions.

If the cuff pressure feels weak:

- Listen for air leaks in the cuff and tubing.
- If there is a leak in the cuff or the tubing, contact ACI Medical or your supplier.
- Check for kinked tubing that prevents airflow to the cuff.

Error Codes

Error Code	Fault	Error Code	Fault
E01	Motor Controller	E08	Foot Sensor Calibration Fail
E02	Supply Voltage	E09	Calf Sensor Calibration Fail
E03	EEPROM	E10	Unresponsive Foot or VenaPulse Sensor
E04	Foot or VenaPulse Over-Pressure	E11	Unresponsive Calf Sensor
E05	Calf Over-Pressure	E12	Shorted Foot Sensor Output
E06	ArtAssist Foot Leak	E13	Shorted Calf Sensor Output
E07	ArtAssist Calf Leak	CAL	Sensor Re-Calibration Complete (Power-Reset Required)

ACI Medical will provide assistance if the device is malfunctioning, but no guarantees are made as to the effectiveness of the device on a given patient. Proper use of the device is to be monitored by the patient and physician, not by ACI. If the device seems to be ineffective or causing problems, the patient must consult with their physician. If the problem is not resolved and the cause cannot be determined, do not use or attempt to repair it. Instead, contact ACI Medical for technical service.

Warning

Do not disassemble the ArtAssist AA-1000. Refer all servicing to qualified service personnel at ACI Medical, LLC. No modification of the ArtAssist device is allowed.

CONTACT INFORMATION

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L-5.93 (DOC-808) Ver. 0

Approved By:

(CO-79) D4 Release to Production

Description

Releasing documents necessary to ship AD4 devices to customers. Any reference to ECO#1513 is due to the ECO being started under our legacy QMS and is being completed in our current QMS.

Justification

The documents being released are those that are ready and necessary to ship D4 devices to customers.

Assigned To:	Initiated By:	Priority:	Impact:
Michael Arkans	Michael Arkans	Medium	Major

Version History:

Author	Effective Date	CO#	Ver.	Status
Michael Arkans	April 9, 2025 1:43 PM PDT	CO-79	0	Published