VenaPulse®

HANDS-FREE AUGMENTATION DEVICE

for venous evaluations

Model VP-25
Operations and Service Manual

ACI MEDICAL

L-5.94 Rev. 0

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Operations Manual

Introduction

The VenaPulse® Model VP-25 is a hands-free augmentation device that rapidly inflates and deflates pneumatic tourniquet cuffs with approximately 300 millisecond rise and fall times. It generates static, tourniquet pressures to limbs of patients. It is indicated for use in imaging of peripheral blood vessels in the lower extremities for patients with suspected vascular disease for diagnostic purposes and preoperative information. It's useful during imaging studies for identifying venous valvular incompetence. It is intended to be used only by trained medical personnel who maintain constant control of the tourniquet during its uses.

This device is also 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. Inflation and deflation are controlled either with a foot switch or with a manual switch. Applied pressure can be adjusted (in increments of 5mmHg) between 30 and 200mmHg. The applied pressure tolerance is +/- 10mmHg of the set pressure.

Indications

When used with duplex ultrasonic imaging the device is useful for:

- Distal augmentations
- Vein Mapping
- Locating suitable distal vessel for bypass
- Quantification of venous flow
- Reflux measurements of specific venous valves

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
- Amputations
- Tendon repair
- Bone grafts
- Total wrist joint replacement
- Replacement of joints in the fingers
- Knee joint replacements
- Replantations

Contraindications

Do Not Use This Device on Patients with:

- Acute deep vein thrombosis
- Thrombophlebitis
- Hot, swollen, and tender leg

Warnings

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

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 VenaPulse VP-25, 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 not provide desired pressures	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 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	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 patient, and contact ACI Medical customer service.	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 patient. Contact ACI Medical.

Do not autoclave, use automated cleaning methods, or immerse the VenaPulse 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 patient. 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.	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 patient. Contact ACI Medical.
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.

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 VenaPulse Model VP-25.*

- Never use unattended.
- Remove tourniquet cuff if leaving the patient for any period of time.
- The VenaPulse device can generate very high pressures (above systolic blood pressure).
- There is no known potential electromagnetic or other inference between the VenaPulse device and other devices.

List of Symbols and Abbreviations

Symbol	Meaning
	Manufacturer
	Date of manufacture
	Serial number of the device
	VenaPulse model VP-25 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

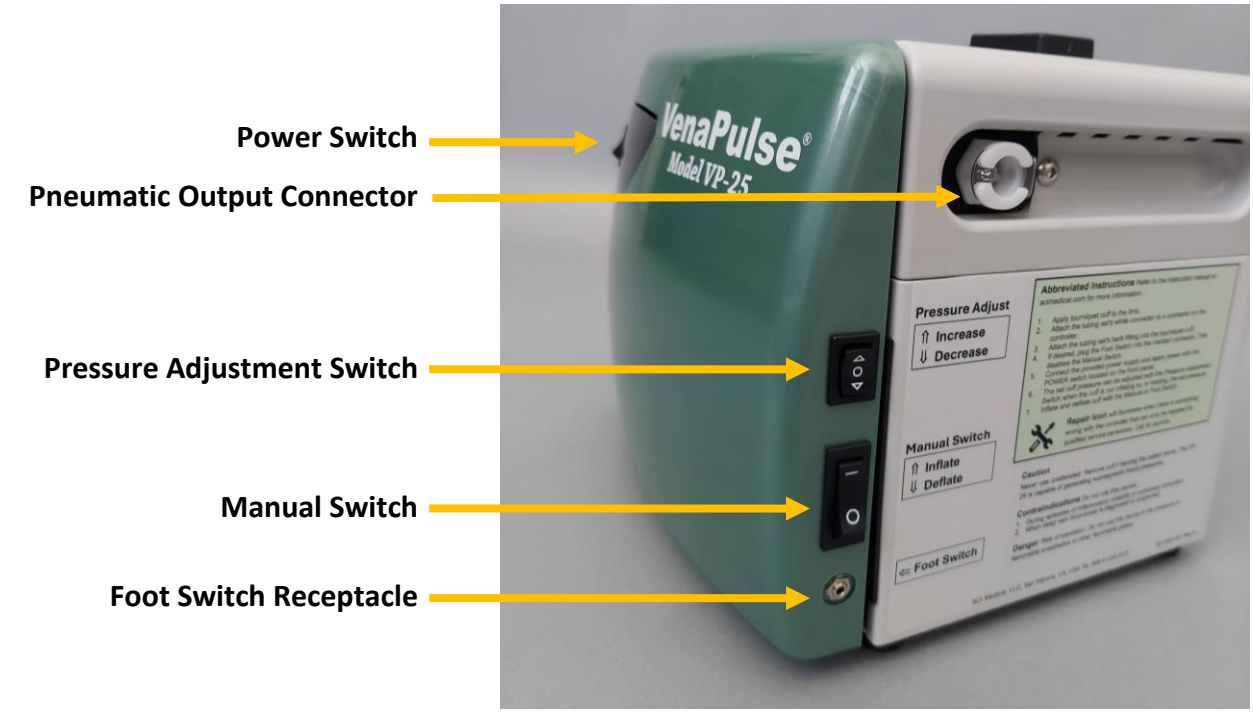


Figure 1

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

Components

Figure 2

1. **Power Supply**
2. **Power Cord**
3. **Controller**
4. **Tourniquet Leg Cuff (Blue)**
5. **Tourniquet Foot Cuff (Black)**
6. **Foot Switch**
7. **Tubing**

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 VenaPulse device unit via its DC plug (tuning fork style 2.1x5.5x11mm). **Only use the provided ACI Medical Power Supply to power the VenaPulse device**. A six foot long, hospital grade power cord is supplied with the power supply.

Tubing Sets and Connectors

Each PVC tubing set is five feet (152.4cm) long (¼"ID, ½"OD = .64 x 1.3cm). There is a white pneumatic connector on one end that attaches to the VenaPulse device and a barb fitting on the other end that attaches to the cuff.

Tourniquet Cuffs

SC 10D – 10cm wide cuff, re-useable. Foot and calf configurations are also available. Do not machine wash cuffs.

Instructions for Use (IFU)

Installation

- Plug the Power Supply into the back of the Controller (1). Attach the Power Supply and Power Cord together (2). Plug the Power Cord into a grounded wall outlet (3). 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”.

Figure 3

- Plug the tubing set’s white, plastic connector into the upper side of the VenaPulse device (make sure you hear a click).

- Connect the other end of the tubing set into the tourniquet cuff.

Operation

- Apply the tourniquet cuff snugly to the limb. Snug (not tight) application ensures rapid pressure rise times. Up to two cuffs can be applied which will inflate and deflate simultaneously.

- If desired, plug the foot switch into the connector on side of front panel (below the manual switch). **This disables the manual switch.**

- Turn the VP-25 on using the power switch on the front panel. The display will illuminate all its LED diagnostics when powered on.

- After illuminating the LED diagnostics, the display will show the set pressure for 5 seconds and the “mmHg” text will be flashing. Adjust the tourniquet cuff inflation

pressure from 30 - 200mmHg using the pressure adjustment switch. Recommended inflation pressures to aid in ultrasonic imaging is 80 to 120mmHg.

- If the unit is at bias pressure (10mmHg), the user can adjust the set pressure using the pressure adjustment switch. The Pressure Adjustment Mode is identifiable by the display showing the set pressure and flashing the "mmHg" text. **The unit will not allow pressure adjustment when inflating, deflating, or holding target pressure.**

- Depress the manual or foot switch to inflate the tourniquet cuff to target pressure and release the manual or foot switch to deflate the tourniquet cuff to bias pressure (~10mmHg). The user will not be able to start the next inflation until the unit has achieved bias pressure first.

- "LO mmHg" will appear on the screen prior to first inflation, during deflation, and when the tourniquet cuff is at bias pressure.

- The target pressure and a solid "mmHg" will appear when the tourniquet cuff is inflating to and holding target pressure.

- To disconnect the tubing connector from the mating connector on the VP-25, depress the latch and pull on the connector's fitting (avoid pulling just on the tubing).

Manual Inflation Mode

- In Manual Inflation Mode, the VenaPulse device will inflate and hold target pressure for as long as the user has the manual switch set to ON (or, if the foot switch is connected and the foot switch is depressed).

- Switching the manual switch to OFF (or releasing the foot switch), will deflate the cuff to bias pressure.

- The user will know the unit is set to Manual Inflation Mode if three dashed segments appear on the display during startup (right after flashing all of its LED diagnostics) and by the absence of the Hourglass icon.

3 Second Hold Inflation Mode

- In 3 Second Hold Inflation Mode, the VenaPulse device will start inflation when the manual switch is set to ON (or, if the foot switch is connected, when the foot switch is depressed). The device will inflate to and hold target pressure for 3 seconds and then deflate to bias pressure. During this 3 second period, the unit will ignore any changes in switch position.

- If using the manual switch, the user must switch it back to the OFF position and then back to ON before starting the next inflation. This feature ensures a single 3 second hold inflation and not a continuous series of 3 second inflations if the side switch is left in the ON position.

- If using the foot switch, the user must release the foot switch and depress again for another inflation.

- The user will know the unit is set to 3 Second Hold Inflation Mode if “3 SEC” text and the Hourglass icon appear on the display during startup (right after flashing all its LED diagnostics). The Hourglass icon will remain illuminated as a visual cue to the user that the device is in 3 Second Hold Inflation Mode instead of Manual Inflation Mode.

Changing the Inflation Mode

ACI Medical will pre-set the Inflation Mode to the customer’s preference prior to shipping. However, following the steps below, the Inflation Mode can be changed at any time by the technician:

- Turn OFF the unit and remove the foot switch if it is connected. Flip the manual switch up to the ON position.
- Turn the unit ON.
- Quickly press and hold the UP arrow on the Pressure Adjustment Switch. Continue to hold the three-position switch UP until you see flashing LEDs.
- Flashing dashes on the seven-segment display represent Manual Inflation. Flashing “3” and the Hourglass Icon represent a 3 Second Hold Inflation. Use the pressure adjustment switch (up or down) to go back and forth between the modes.
- Once the inflation mode you wish to use is flashing on the display, flip the Inflation Switch to the OFF position to lock in that mode. The unit will now be ready for use in the inflation mode selected.
- If there is an Hourglass icon on the display, the device is in 3 Second Hold Inflation Mode. If there is not an Hourglass icon, the device is in Manual Inflation Mode.
- Power OFF the device and repeat these steps if you wish to change the Inflation Mode again. You cannot change the Inflation Mode after startup/while the device is running.

VenaPulse LED Indicators

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

Figure 4

Manual Inflation Mode Indicator During Startup: In Manual Inflation Mode, three dashed segments will appear on the display during startup (after the LED Diagnostics).

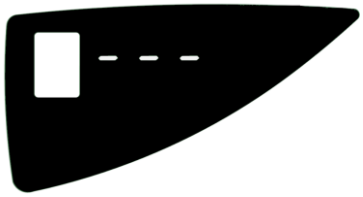
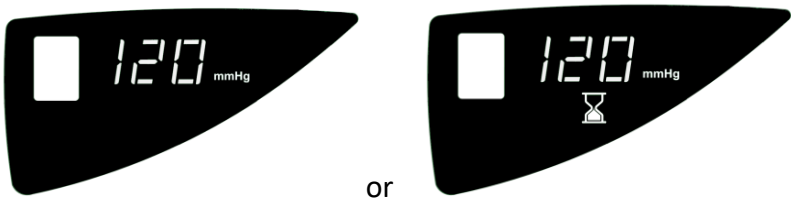


Figure 5

3 Second Hold Inflation Mode Indicator During Startup: In 3 Second Hold Inflation Mode, "3 SEC" text and the Hourglass icon appear on the display during startup (after LED Diagnostics).

Figure 6

Target Pressure: The target pressure and a solid "mmHg" will appear when the cuff is inflating to and holding the target pressure.



or

Figure 7

Bias Pressure: “LO mmHg” will appear on the screen prior to first inflation, during deflation, and when the tourniquet cuff is at bias pressure.

or

Figure 8

Pressure Adjustment Mode: The Pressure Adjustment Mode is identifiable by the display showing the set pressure and flashing the “mmHg” text.

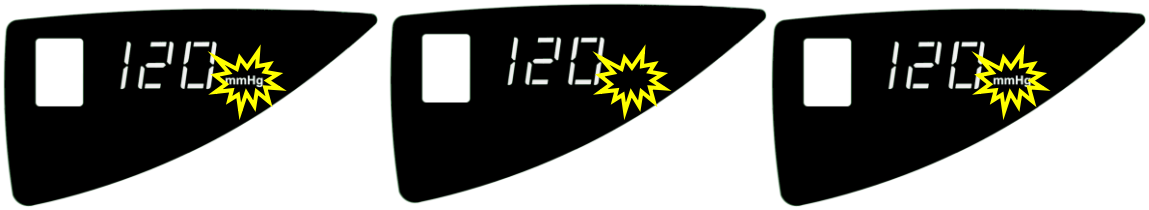


Figure 9

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.

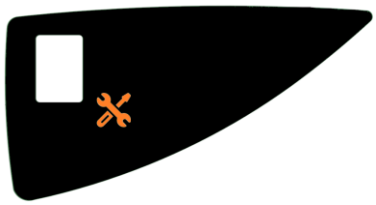


Figure 10

Pressure vs. Time Characteristic (Manual Inflation)

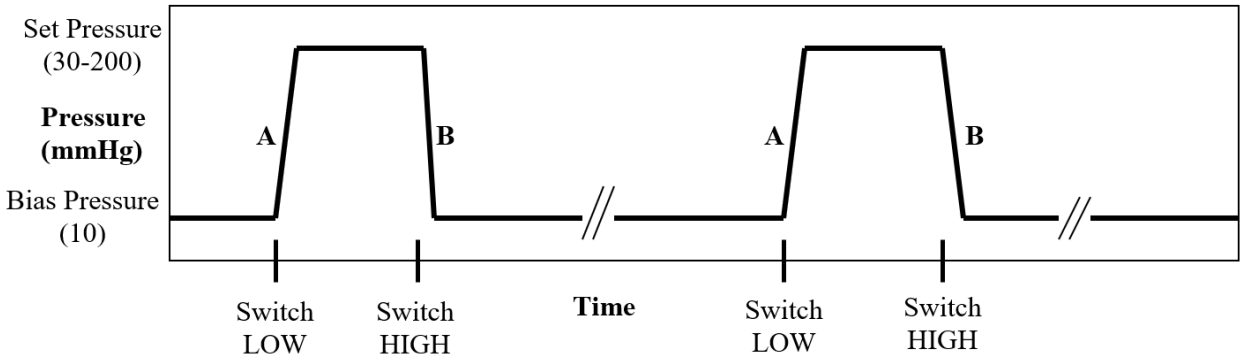


Figure 11

Classification and Standards

The VenaPulse model VP-25 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 VenaPulse device
- Audio and visual indicators will appear if there are any problems with over-pressure, 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 VenaPulse device model VP-25 is supplied non-sterile.

Disposal

For disposing of the device, 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 VENAPULSE 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 VENAPULSE DEVICE.

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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 indicator appears in the black lens:

- Immediately stop use.
- The audio indicator will sound, the Repair Icon will illuminate, and an Error Code will be visible on the display.
- Contact ACI Medical for instructions.

If the cuff pressure feels weak:

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

Maintenance

The VenaPulse device requires little maintenance, but it is recommended that hospitals maintain the unit as required by hospital safety regulations.

Inspect the connectors and tubing sets at least annually for integrity and proper sealing. Be sure to check the tubing for possible kinking. Also, inspect the power cord and power supply for damage and replace as necessary.

Suggested Cleaning Procedure for Hospital Use:

- Clean the VenaPulse device monthly.

- Wipe all areas of the device using a cloth and an EPA registered hospital-grade disinfectant following the manufacturer's Material Safety Data Sheet. It is recommended that hospital gloves be used to prevent the possible spread of infections.
- Clean all visible soiling.
- If blood or body fluids are present on the device, follow the 2-step cleaning process recommended by OSHA.
- Apply an EPA registered tuberculocidal disinfectant. Remove and clean all visible soil.
- Wipe down with 1:100 sodium hypochlorite solution.
- Remove gloves and wash hands thoroughly.
- Allow the device to dry before reusing.

Service and Repair

The VenaPulse device has no user-serviceable parts. If malfunction is suspected, call ACI Medical for servicing.

Error Codes

Error Code	Fault	Error Code	Fault
E01	Motor Controller	E08 or E09	Pressure Sensor Calibration Fail
E02	Supply Voltage	E10 or E11	Unresponsive Pressure Sensor
E03	EEPROM	E12 or E13	Shorted Pressure Sensor Output
E04	VenaPulse Over-Pressure	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.

Warning
Do not disassemble the VenaPulse VP-25. Refer all servicing to qualified service personnel at ACI Medical, LLC. No modification of the VenaPulse device is allowed.

CONTACT INFORMATION

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