

VenaPulse®

HANDS-FREE AUGMENTATION DEVICE
for venous evaluations

Model VP-25

Operations and Service Manual



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DESCRIPTION

VenaPulse® Model VP-25 generates a static, tourniquet pressures to limbs of patients that are undergoing vascular testing. The tourniquet pressure is reached very rapidly and the tourniquet cuff is deflated very rapidly with approximately 300 millisecond rise and fall times. Inflation and deflation are controlled with a foot switch or with a manual switch. The pressure is regulated between 0 and 240mmHg.

Indications For Use:

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

Contraindications: Do Not Use This Device On Patients With:

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

PRECAUTIONS

Never use unattended. Remove cuff if leaving the patient for any period of time. The VenaPulse® device can generate very high pressures above systolic blood pressure.

PHYSICAL DESCRIPTION

VenaPulse® Model VP-25



Figure 1

Size: 10" wide, 12" high, 7 ¾ deep. The top handle adds 1 ¼ in height.

Weight: 23 pounds, controller only.

Connectors: Black double lumen connectors. Patent pending.

Tubing: 5 feet long with barb fitting on one end and the patented black double lumen connector on the other end.

Tourniquet Cuff: SC 10D – 10cm wide cuff, re-useable. Foot & calf configurations upon request.

<u>Operating voltage</u>	<u>Model Number</u>	<u>Max. Current</u>
115 V, 60 Hz	VP-25	0.4 Amps
220 V, 50 Hz	VP-25e	0.2 Amps
100 V, 60 Hz	VP-250n	0.5 Amps

Indicators – Located on the front panel's black bezel, just right of the power switch.

REPAIR will light when the pressure exceeds 250mmHg (+20, -10) or when there is something wrong with the controller that can only be repaired by qualified service personnel. Reduce the pressure and recycle the power. If the REPAIR light persists, call for service.

INSTRUCTIONS FOR USE

Installation (Refer to Figure 1)

Connect the power cord to the power receptacle on the side of the VP-25 case (below the instruction label) and into a hospital grade power outlet.

Connect the foot switch to the side receptacle of the VP-25 case if its use is desired. Connecting the foot switch will deactivate the manual inflate/deflate switch located above the foot switch receptacle.

Operation

1. Apply the tourniquet cuff snugly to the limb. Snug (not tight) application ensures rapid pressure rise times.
2. Attach the tubing set's black connector to mating connector on the VP-25.
3. The barb fitting is then connected to the tourniquet cuff on the patient. Two cuffs can be simultaneously inflated when connected to either side of the VP-25.
4. If desired, plug foot switch into connector on side of front panel, below the manual switch. This disables the Manual switch. Depress the foot switch to inflate the cuff and release the foot switch to deflate the cuff. Place the Manual switch in the Deflate position when the foot switch is not connected. This prevents air from possibly escaping if the cuff is not yet connected.
5. Turn the VP-25 on using the power switch on the front panel. It will illuminate when power is on. REPAIR light will briefly illuminate to show that the alarm light is functional.
6. Inflate cuff with Manual or Foot switch and set desired pressure from 0-240mmHg as displayed on the front panel digital display by using the regulator knob. This may also be done with the tubing set disconnected from the controller. *SET GAUGE PRESSURE:* Turn the knob clockwise to increase pressure and counter clockwise to decrease pressure.

The cuffs will rapidly reach at least 70mmHg when cycled no quicker than 15 seconds between inflations. More frequent inflation cycles or higher pressure settings may result in inflation rates slower than 300 millisecond rise times.

SAFETY FEATURES

There are safety alarms to ensure safe operation.

An alarm will sound and the cuffs will deflate if:

- Cuff pressure exceeds 250mmHg (+20, -30) for more than one second. An enunciator on the front panel will indicate REPAIR.
- The internal compressor overheats. An enunciator on the front panel will indicate REPAIR.
- The voltage supply to the internal solenoid valve fails. An enunciator on the front panel will indicate REPAIR.

Upon opening the front panel, by a qualified repair technician only, the reason for failure can be determined by the LED's on the main circuit board.

- If the red LED is lit, it is due to an overpressure condition (over 250mmHg [+20, -10] for more than one second).
- If the green LED labeled Vv is OFF, then the 12-volt power supply to the solenoid valve is faulty.
- If the green LED is on and the red LED is off, then the compressor has overheated.

MAINTENANCE

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

Suggested Cleaning Procedure for Hospital Use

1. Clean the VenaPulse® device monthly.
2. 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.
3. Clean all visible soiling.
4. If blood or body fluids are present on the device, follow the 2 step cleaning process recommended by OSHA.
 - a) Apply an EPA registered tuberculocidal disinfectant. Remove and clean all visible soil.
 - b) Wipe down with 1:100 sodium hypochlorite solution.
5. Remove gloves and wash hands thoroughly.
6. Allow the device to dry before reusing.

To be performed by a qualified technician only. The pressure delivered to the cuffs should be checked annually by connecting a calibrated pressure gauge (available from ACI Medical) to any one of the controller's pneumatic outlet connectors. Pressure accuracy of 5mmHg is adequate. Replace the pressure gauge if found to be inaccurate.

Check for overpressure alarm operation by increasing the gauge pressure slowly from 240mmHg to 270mmHg. Alarm should activate within that pressure range.

If alarm fails to properly activate:

Slowly apply 270mmHg to pressure sensor (PS1) while measuring voltage at test point 5 (TP5). It should reach 10.0V or greater prior to alarm mode entry and:

1. Pin 14 of op amp U7 should be a logic 0 (0 to .3V).
2. "D" input to D-flip flop U6, pin 9 should be logic 1 (11.2 to 12V).
3. Clock input to U6, pin 11 should be logic 1.
4. The output of U6, pin 13 should be logic 1.
5. The red LED (D3) should be lit.
6. The rest of the circuit is straight forward to troubleshoot.

To set the alarm pressure threshold, apply 250mmHg to PS1 and adjust R30 for $10.00 \pm .05V$ at TP5. Recycle the power and test the circuit for proper operation.

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 for damage and replace as necessary.

Clean the fan filter annually or every 8,000 hours, whichever is sooner.