Distributed by DJO GLOBAL™

VENAPRO™

Enhancing Life Through Innovation

Manufactured For:

INNOVAMED HEALTH™

Vascular Therapy System

(Compressible Limb Sleeve Device)

Customer Service

Toll Free: 877-475-7050
Email: Info@InnovaMedHealth.com
Web: www.InnovaMedHealth.com

1299 West 75 North, Centerville, UT 85014

Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner

USER MAINTENANCE

Contains no serviceable parts. Contact InnovaMed Health Customer Service at 877-475-7050

Inspect the unit and all components for any damage that may have occurred during shipping or general handling prior to each use (for example, frayed or cut charging cord, cracked plastic housings, torn cuffs, etc). Refer to image of VenaPro for description of all components.

Do not attempt to connect the wall supply if any damage is noticed.

Avoid subjecting the units to shocks, such as dropping the pumps.

Do not handle the leg cuffs with any sharp objects. If a bladder is punctured or you notice a leak, do not attempt to repair the unit or cuffs. Replacement units are available through customer service.

Avoid folding or creasing the bladder during use and transportation of the units.

Battery is not replaceable, replacement units are available through customer service.

Contact InnovaMed Health to receive replacements instructions for any damaged items.

STORAGE

Store in a dry location between +10°C (50°F) and +40°C (104°F).

Do not expose to heat exceeding 65°C (149°F).

Do not store items in direct sunlight.

DISPOSAL

This unit is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Consult local county requirements for proper disposal instructions.

Pump control units contain rechargeable batteries. Do not discard the pump unit in regular waste. Bring the unit to your local recycle center or contact InnovaMed Health.

The use of accessories, power supplies and cables other than those specified, with the exception of components sold by the manufacturer of the VenaPro as replacement parts, may result in increased emissions or decreased immunity of the VenaPro.

Class II medical electrical equipment

This unit is a electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Consult local county requirements for proper disposal instructions.

This symbol designates the degree of protection against electrical shock from the wrap as being a type B applied part.

Follow the instructions for use.

This device is not protected against water. Equipment is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide. The rechargeable batteries supplied in this unit are not field replaceable. If you have any issues please contact 877-475-7050 for a replacement unit.

PURPOSE OF THIS DEVICE

The purpose of the VenaPro is to aid in the prevention of Deep Vein Thrombosis (DVT) by helping to stimulate blood flow in the legs. This is accomplished by an electronically controlled pump delivering a set amount of air to the leg cuffs that, in turn, compress the calf or calves to aid blood flow out of the lower extremities.

The pump will inflate each leg cuff to a preset pressure of 50mmhg and deflate once the pressure is reached. The cycles are repeated on each unit until the power is turned off. Internal rechargeable batteries allow the VenaPro to be completely portable, thus preventing interruptions in treatment.

Indications for Use:

The Vena Pro Vascular Therapy System, model VP-3111, is intended to be an easy to use portable system, prescribed by a physician, for use in the home or clinical setting to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions).

This device can be used to:

Aid in the prevention of DVT

Enhance blood circulation

Diminish post-operative pain and swelling

Reduce wound healing time

Aid in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs

As prophylaxis for Deep Vein Thrombosis (DVT) by persons expecting to be stationary for long periods of time

CONTRAINDICATIONS

The VenaPro MUST NOT be used to treat the following conditions:

Persons with suspected, active or untreated: deep vein thrombosis, ischemic vascular disease, severe arteriosclerosis, pulmonary edema, severe congestive heart failure, thrombphlebitis, or an active infection.

On the legs where cuffs would interfere with the following conditions: vein ligation, gangrene, dermatitis, open wounds, a recent skin graft, massive edema or extreme deformity of the leg.

On any neuropathy.

On extremities that are insensitive to pain.

Where increased venous or lymphatic return is undesirable.

TECHNICAL DATA

Specifications:

Main Unit:

Dimensions: 2.6" X 5.2" (66 mm X 131 mm)
Weight: Approx. 0.5 lb (0.227 kg)
Mode of Operation: Cyclic
Source of Power: 7.4 volt Li-ion battery pack (made up of 2 – 3.7 volt cells)

CAUTION: Charge batteries using only the power source provided by InnovaMed health.

POWER SUPPLY:

Class II, input: 100 - 240 Vac, 50 - 60 Hz, output: 10 Vdc @ 1.1 Amp)
Use only UL/60601-1 approved power supplies from InnovaMed Health for use in hospital settings.

Output:

Mode of Operation: Continuous

SYSTEM OPERATING ENVIRONMENT:

Temperature: +10 Degrees C (50 Degrees F) to +40 degrees C (104 degrees F)
Humidity: 30%-75%

DEFAULT SETTINGS:

Leg Pressure (not adjustable) 50mmhg
Cycle time: 60 Seconds

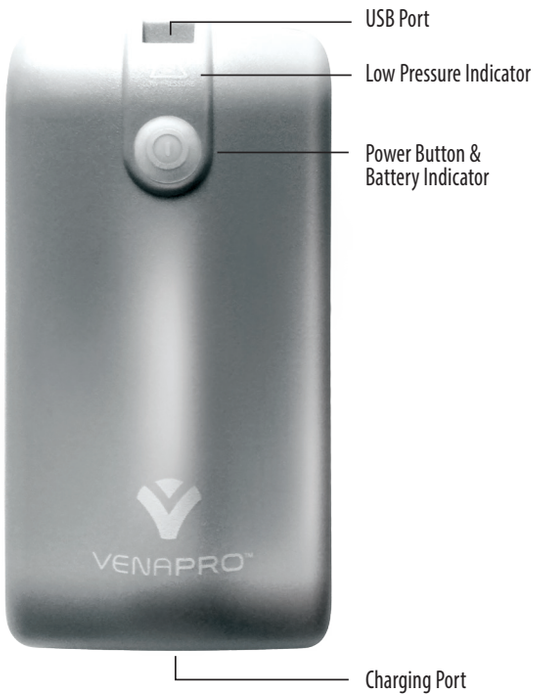
TOLERANCES:

Pressure ± 5%

BATTERY CHARGE:

Takes approximately 6 hours (from depleted state).

SYSTEM COMPONENTS



INSTRUCTIONAL

POWER OFF:
Unit is in "sleep" mode. No visible LED illumination.

POWER ON:
Unit powers up with GREEN LED illuminated (YELLOW can be illuminated if battery voltage is LOW). After a 5 second delay, the pumps will allow inflation of the attached wrap to a pre-determined pressure of 50 mmHg. Once the pressure reaches the proper level, the pump will turn OFF for a 50 second "rest" period, and the cuff deflates through the vent port to cool the leg or legs. After the "rest" period, the wrap is again inflated, and so on every 50 seconds.

By Prescribing Physician Only:
Unit use time (amount of time the unit is powered ON) is monitored and stored by the MPU (Microprocessor Unit) and can be downloaded into Excel via the USB interconnecting to an interface module.

BATTERY INDICATOR:

In order to properly indicate the state of the battery and charger, there are THREE stages of the BATTERY INDICATOR as follows:

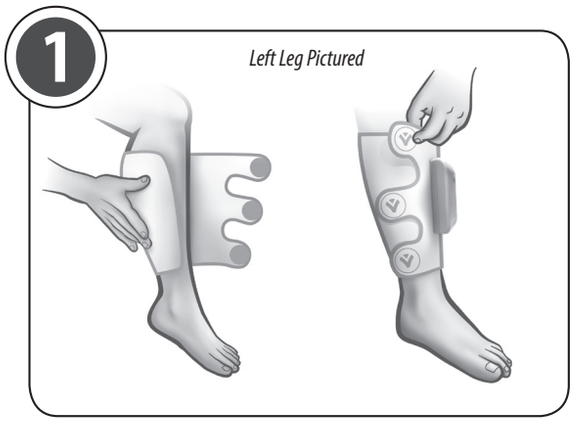
STAGE 1 – GREEN: When unit power is ON and fully operational.

STAGE 2 – YELLOW: The yellow LOW BATTERY INDICATOR will REMAIN ILLUMINATED during the pumping time and rest period. At this stage the battery charger MUST be connected immediately to avoid any interruption in the treatment sessions.

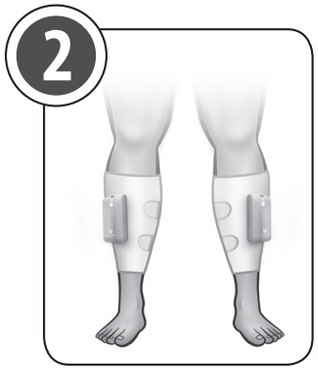
FLASHING YELLOW: If the battery voltage drops below a critical level at any time, while unit is ON, flashing yellow and audible alarm beeps for 30 seconds. Unless unit is turned off OR connected to charger within that 30 seconds, unit WILL AUTOMATICALLY power OFF.

STAGE 3 – RED: When the unit is turned OFF and the battery is charging, the RED LED FLASHES. Once the battery reaches full charge, the RED LED REMAINS SOLID.

QUICK START

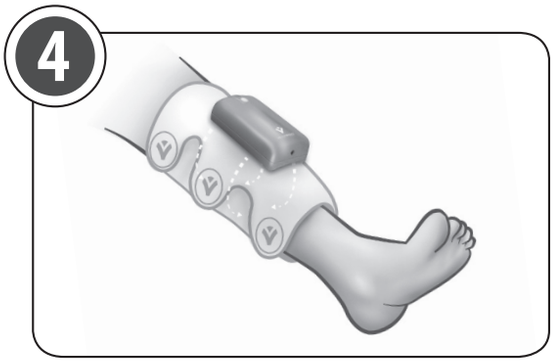


CALF CUFF APPLICATION
Wrap the cuff around the calf and secure the Velcro to hold it in place. Make sure the wrap is snug, but not too tight.



When both wraps are secured on your legs, they should look like the picture above.

TURNING THE DEVICE ON
When the wraps are secured on your legs PRESS and HOLD the WHITE power button for about a second until the light is illuminated on each unit.



USING THE DEVICE
Don't be startled. The device will make a "humming" sound when inflating and squeezing your leg. **THIS IS NORMAL.** The wraps will inflate once a minute. IF you FEEL air releasing around the legs, this is normal. This is a function of the device to keep your legs cool.

WARNINGS AND PRECAUTIONS

- The VenaPro cuffs are designed for single patient use only.
- Medical Electrical Equipment needs special precautions regarding EMC. Portable and mobile RF Communications Equipment can be affected by other Medical Electrical Devices.
- Cuffs used in combination with warming devices may cause skin irritation. Regulary check for patent discomfort, compliance, and skin irritation.
- To prevent extremity compartment syndrome, special attention should be given to patients who are positioned in the supine lithotomy position for extended lengths of time. This includes patients with or without cuffs.
- Do not open or remove covers. No user serviceable parts inside. Direct all unit issues to InnovaMed Health.
- If pulsations or throbbing occur, the cuff may be wrapped too tightly. Loosen Immediately.
- Stop using device if swelling occurs; consult a Physician.
- Device is to be used only by the patient prescribed, and only for its intended use.
- Ensure the pump control unit is turned off and unplugged from the wall outlet prior to and while cleaning or disinfecting.
- Equipment should not be used in the presence of any flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- Do not immerse in any liquid for any reason.
- Do not operate device in a wet environment.
- Allow cuffs to warm to room temperature if exposed to temperatures below 5^{0}C or (41^{0}F).
- Do not subject the unit to extreme shocks, such as dropping the pump.
- Contains no user serviceable parts. Contact InnovaMed health Customer Service.
- Do not place any items in an autoclave.
- Operation of this device can be done by the patient.
- No Service is to be attempted while the device is in use.
- This device is NOT to be altered or modified.

USING THE AC ADAPTER / BATTERY CHARGER

UNIT POWERED OFF

Insert the supplied power supply plug by into the port at the bottom end of the unit and connect the power supply adapter to the wall socket. The RED "Charging" indicator on the unit will illuminate or flash, depending on the state of charge.

A full charge of a depleted battery should take about 6 hours. When the unit is turned off and plugged in the battery is charging, the power button will flash red. Once the battery reaches full charge the power button will be red and remain solid.

UNIT POWERED ON

For extended operation periods, or to charge the battery during treatment sessions, the AC adapter CAN be connected while the device is in use. The UNIT LED will illuminate GREEN and they will be charging simultaneously. Whenever the unit is powered ON and charger connected, LED indicator will always show GREEN.

CHARGING THE BATTERY: USE ONLY THE CHARGER PROVIDED BY INNOVAMED HEATLH. Use of the wrong charger can cause excessive heat, damage to the charging circuit and shorten the life of the battery.

ALARMS:

"Battery Critical" – If battery voltage drops below critical level, cycling stops, audible alarm will sound, and UNIT WILL FLASH YELLOW. Alarm will continue for 30 seconds (unless unit is powered OFF) and automatically turn the unit OFF. Plug in power supply immediately.

"Low Pressure or Leak" – When activated, if pressure limit is NOT reached within 30 seconds after pump is energized, cycling stops, ALARM sounds and BLUE "low pressure" LED flashes. Alarm will continue for 30 seconds (unless unit is powered OFF) and automatically turn the unit power OFF. Make sure wrap is attached snugly leg. Turn the unit OFF, and then turn the unit back ON. If the unit continues to alarm after this step, DO NOT try to fix the device. Call customer service for a replacement unit at 877-475-7050.

ALARM RESET:

To reset an alarm condition after the "operation inhibit" stage is reached, the unit must be turned OFF. If not manually turned OFF within 30 seconds of such an alarm condition occurring, unit automatically turns itself OFF. Once the unit is turned back on the alarm is RESET.

OPTIONS:

By Prescribing Physician Only:

At the top edge of the pump/controller unit is access to a mini USB port. This is NOT to be directly connected to a computer. In order to download use data, a data expander interface must be purchased from InnovaMed Health.

An additional function available thru the USB port is to add a remote control module for ON/OFF operation from a handheld transmitter. These modules aid in controlling the system for patients unable to access the device operations.

CLEANING AND DISINFECTING

NOTE: Inspect the VenaPro unit and follow the cleaning and disinfecting procedures prior to each use.

WARNING: Device must be turned off and disconnected from the wall outlet prior to and during cleaning or disinfecting.

DO NOT IMMERSE UNIT IN ANY LIQUID FOR ANY REASON

- Clean the outer surface of the pump unit using a soft cloth, moistened with soapy water or 70% isopropyl alcohol.
- Do not use abrasive or volatile cleaners.
- Do not place cuffs in dryer.
- NEVER remove the unit from the cuff.
- Hand wash the exterior of the cuffs using a soft cloth, moistened with soapy water or 70% isopropyl alcohol and let air dry.
- To ensure the unit IS completely dry prior to use, leave unit in the OFF condition and disconnected from the wall outlet for 30 minutes after cleaning or disinfecting.