



Instructions for Use

venaone™

DVT Compression System



One Touch
Operation



Battery
Operated



Portable



Infection
Control



No Tubes
or Cords



Lightweight

Model No. 08-0030

Precision Medical Products

Customer Support: (800) 604-2487 • info@pmpmed.com • www.pmpmed.com

2217 Plaza Drive, Rocklin, CA 95765

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



Table of Contents

VENAONE OVERVIEW	2
CONTRAINDICATIONS	2
FEATURES AND BENEFITS	3
SYMBOLS	3
SYSTEM CONTENTS	4
BATTERY INDICATORS & CHARGING	5
APPLICATION INSTRUCTIONS	6
PUMP ALARM INDICATORS	7
DEVICE HANDLING	8
CLEANING AND DISINFECTING	8
DISPOSAL	8
USER MAINTENANCE	8-9
STORAGE	9
ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES	10-11
WARNINGS AND CAUTIONS	12
TECHNICAL DATA	13

VENAONE OVERVIEW

Pneumatic compression is a clinically proven modality for reducing the risks associated with deep vein thrombosis (DVT).¹ VenaOne is a tubeless, portable, lightweight and battery-operated DVT compression system designed specifically for the acute-care setting. VenaOne aids in the prevention of DVT by helping to stimulate blood flow in the legs. The pump inflates each leg cuff to a preset pressure of 55 mmHg and deflates once the pressure is reached. Then the cycle repeats. Internal rechargeable batteries allow the VenaOne to be completely portable, thus preventing interruptions in treatment.



INFLATION/DEFLATION CYCLE

When the device is powered on, the audible alarm beeps twice, the LED display illuminates, and the battery icon stays on (refer to the battery indicator section for battery life expectancy).

The devices apply compression to the legs in cycles. During each cycle, the device inflates the cuff to 55 mmHg within 10 seconds, holds the pressure for about 2 seconds, then releases the pressure and rests for about 50 seconds. Then the cycle repeats.

INDICATIONS FOR USE

VenaOne aids in the prevention of DVT, enhances blood circulation, diminishes post-operative pain and swelling, reduces wound healing time, and aids in the treatment and healing of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency, and reduction of edema in the lower limbs.

CONTRAINDICATIONS

The VenaOne Vascular Therapy System 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, thrombophlebitis, 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.

1.Labropoulos N, OH D.S, Golts, E, et al: Improved Venous Return By Elliptical, Sequential and Seamless Air-cellCompression. Loyola University Medical Center, January 2003.

Features and Benefits

Portable

VenaOne's simple design is fully ambulatory.

Easy One-Touch Operation

Controls all functions with just the power button.

Infection Control

The device is designed to help reduce bacterial transfer and subsequent contamination.

No External Tubes or Cords

The tubeless, cordless design helps mitigate tripping hazards and facilitates patient mobility.

Lightweight

Weighs less than one pound.

Battery Operated

~24 hour battery life allows for ease of use and patient compliance.

Compression

Provides asymmetric compression at 55 mmHg.

Symbols



Power Button



Battery Indicator



No Scissors



Power Supply



Manufacturer



Keep Dry



Class II Medical Electrical Equipment



Serial Number



Warning or Caution



Battery Operated



Refer to Instruction Manual



Humidity Range



Atmospheric Pressure Range



Not made with Natural Rubber Latex



Patient Wrap(s) intended for single patient use. Use on more than one patient may cause cross-contamination.



Temperature Range



Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.



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



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



Idle Pulse Between Compression Cycles



Low Pressure Indicator



High Pressure Indicator



Battery Low



System Failure

System Contents



Battery Indicators & Charging



Battery icon:

Remains illuminated at all times during operation.



All 3 Bars Solid Green:

The battery is **100%** charged.



2 Bars Solid Green, 1 Bar Flashing:

The battery is between **31% and 60%** charged. The third bar flashes until fully charged.



One Bar Solid Green, 2 Bars Flashing:

The battery has **30%** charge remaining. The second and third bars flash alternately until the battery reaches 31% charge.



One Bar Flashing Yellow:

The battery will last **30 minutes or less**. Alarm ONE will sound 3 times every 1 minute and "BL" will simultaneously flash on the LED display indicating the battery is nearly depleted. See Page 7 for alarm descriptions.



One Bar Flashing RED:

The battery will last **5 minutes or less**. Alarm ONE will sound 3 times every 10 seconds and "BL" will flash on the LED display until auto shut down occurs or the device(s) is connected to the power supply. See Page 7 for alarm descriptions.



USING THE AC ADAPTER/BATTERY CHARGER

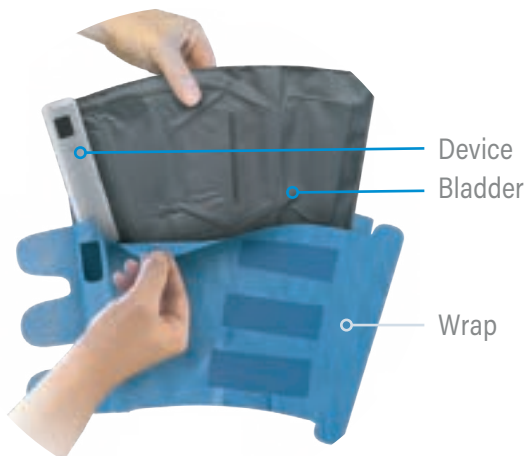
Insert the power supply plug into the port(s) at the bottom end of each device and connect the power supply adapter to the wall socket. The battery indicator icon on the LED Display will illuminate three flashing green bars and provide the current charge status. Once the device is fully charged, all three bars will be solid green. The AC adapter can be connected while the device is in use.

Application Instructions

1

PLACE THE DEVICE IN THE WRAP

The VenaOne Device and Bladder will slide to the bottom of the Wrap (sold separately).



2

SEALING THE WRAP(S)

Once the device is placed inside the wrap, peel off the backing on the adhesive strip. Then simply fold over and press to seal the wrap.



3

CALF WRAP APPLICATION

Apply the wrap around the calf and secure the fabric fasteners to hold it in place. Make sure the wrap is snug, but not too tight. When one or both wraps are secured on the leg(s), the device(s) are ready for operation.



4

TURNING THE DEVICE ON OR OFF

To turn the device on or off, press the power button **3 times**.

USING THE DEVICE

The device will make a quiet “humming” sound when inflating to pressure. This is normal. The wraps inflate once each minute during use.



Pump Alarm Indicators

If the device is turned on after an alarm event, the LED will display the previous alarm.



High Pressure “HP”

In the unlikely event that the device applies higher pressures than normal, a high pressure (HP) alarm will display. If this occurs, power off and restart the system. If the alarm persists, remove the device from service and replace.



Low Pressure “LP”

In the unlikely event that the device applies lower pressures than normal, a low pressure (LP) alarm will display. If this occurs, power off and restart the system. If the alarm persists, remove the device from service and replace.



Battery Low “BL”

When the battery is running low, a BL alarm will display. Replace the battery as needed per the battery indicator. See the Battery Indicator section on page 5 for more information.



System Failure “SF”

If a system failure (SF) occurs, remove the device from service and replace.

TO SILENCE ALARM:

Press and hold POWER BUTTON FOR ONE SECOND, or turn the pump off and restart.

Device Handling

DEVICE DISPOSAL

All contaminated products or accessories should be disposed of appropriately according to hospital policy and state law, taking environmental factors into consideration. When use is completed, or the patient is discharged, remove the device, and discard only the wrap(s).



DO NOT DISPOSE OF THE DEVICE



DISPOSE OF THE WRAP ONLY



DO NOT USE SCISSORS

DO NOT USE ANY SHARP OBJECTS NEAR THE BLADDER.

There is a perforated section at the top of the wrap designed to open the seal easily.

DEVICE CLEANING AND DISINFECTING

NOTE: Inspect the VenaOne device and follow the cleaning and disinfecting procedures prior to each use. The device is intended for multiple patient use.

WARNING: Device must be turned off and disconnected from the wall outlet prior to and during cleaning or disinfecting and for storage between uses. See Storage section for instructions on proper storage.

DO NOT IMMERSE DEVICE IN ANY LIQUID FOR ANY REASON

DO NOT USE ABRASIVE OR VOLATILE CLEANERS.

NEVER REMOVE THE BLADDER FROM THE DEVICE.

TO CLEAN:

The device can be cleaned with a soft cloth dampened with soapy water or a mild detergent. To sanitize the device, apply cleaning agents with a soft cloth, moistened with 70% isopropyl alcohol. Avoid excessive spraying, especially in the areas of the connection ports on the top and bottom of the device. If any liquid enters the ports, then internal component damage may occur.

The VenaOne DVT compression system cannot be effectively sterilized by liquid immersion, autoclaving, or ETO sterilization, as irreparable damage to the system will occur.

To ensure the device is completely dry prior to use, leave the device powered off and disconnected from the wall outlet for 30 minutes after cleaning or disinfecting.

USER MAINTENANCE:

The device contains no serviceable parts. For more information, contact your local sales representative.

Inspect the device 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 housing, torn cuff(s) or bladder(s), etc. Refer to the image of VenaOne for the description of all components.

Do not attempt to connect to a battery charger if any damage is noticed. Avoid subjecting the devices 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 device or cuffs.

Replacement devices will be made available to you by your local sales representative.

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

This device is not protected against water.

STORAGE AND TRANSPORTATION

 Store in a dry location between -25C (-13F) and +70C (158F).

 Relative Humidity: 15% to 90%

 Atmospheric Pressure: 525mmHg to 795mmHg

Do not store items in direct sunlight.

DEVICE DISPOSAL

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

LATEX INFORMATION

 All components of the VenaOne Vascular Therapy System are latex-free. All VenaOne wraps are latex-free and may be placed directly against the skin or over a light compression dressing.

LITHIUM-ION BATTERY MAINTENANCE GUIDELINES

OVERVIEW

Do not leave batteries unused for extended periods of time because Lithium-Ion batteries continue to slowly discharge (self-discharge) when not in use or while in storage. The typical estimated life of a Lithium-Ion battery is about two to three years or 300 to 500 charge cycles, whichever occurs first. One charge cycle is a period of use from fully charged to fully discharged and fully recharged again. For batteries that do not run through complete charge cycles, there is a two to three-year life expectancy. Rechargeable Lithium-Ion batteries have a limited life and will gradually lose their capacity to hold a charge. This loss of capacity (aging) is irreversible. As the battery loses capacity, the length of time it will power the product (run time) decreases.

BATTERY MAINTENANCE

Unused batteries should be charged every 3 to 6 months to extend useful life.

CHARGING

Always follow the charging instructions provided in your Instructions for Use (IFU). See battery charging accessories and instructions on page 5.

EMC GUIDANCE

-  **Warning:** Don't use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
-  **Warning:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
-  **Warning:** Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
-  **Warning:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 in (30 cm) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

TECHNICAL DESCRIPTION

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the expected service life.
2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS			
VenaOne is intended for use in the electromagnetic environment specified below. The customer or the user of VenaOne should assure that it is used in such an environment.			
EMISSIONS TEST	Compliance	ELECTROMAGNETIC ENVIRONMENT GUIDANCE	
RF Emissions CISPR 11	Group 1	VenaOne uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF Emissions CISPR 11	Class B	VenaOne is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	
Harmonic Emissions IEC 61000-3-2	Class A		
Voltage Fluctuations Flicker Emissions IEC 61000-3-3	Complies		

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
VenaOne is intended for use in the electromagnetic environment specified below. The customer or the user of VenaOne should assure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Electrostatic Discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input output /lines	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV air common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U _T (>95% dip in U _T) for 0,5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles 70% U _T (30% dip in U _T) for 25 cycles	<5% U _T (>95% dip in U _T) for 0,5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles 70% U _T (30% dip in U _T) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of VenaOne requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterrupted power supply or a battery.
Power Frequency (50/60Hz) Magnetic Fields IEC 61000-4-8	<u>3 A/m</u>	<u>3 A/m</u>	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
VenaOne is intended for use in the electromagnetic environment specified below. The customer or the user of VenaOne should assure that it is used in such an environment.			
Immunity Test	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the VenaOne including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Radiated RF IEC 61000-4-6	3V/m 80 MHz to 2,5 GHz	3V/m	$d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$ 150 KHz to 80 MHz $d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which VenaOne is used exceeds the applicable RF compliance level above, VenaOne should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating VenaOne.			
^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V /m.			
RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE VENAONE			
VenaOne is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of VenaOne can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and VenaOne as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter w	Separation distance according to frequency of transmitter m		
	150 KHz to 80 MHz $d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

WARNINGS

- The VenaOne wraps are designed for single patient use only.
- The device is to be used only by the patient prescribed, and only for its intended use.
- To avoid tripping or falling, do not walk with cuffs on your legs while the device is charging.
- Keep this device out of the reach of children and away from household pets and pests.
- The VenaOne is a standalone device that uses a VenaOne AC Adapter and Battery Charger only (see Using the AC Adapter and Battery Charger section). It is not to be used or interconnected to any other device.
- Do not open or remove covers. No user-serviceable parts inside. Direct all device issues to your local Customer Service representative.
- If you experience pain, swelling, sensation changes, or any unusual reactions (including allergic reactions to the materials used in this device) while using this device, stop using this device and consult your medical professional immediately.
- If pulsations or throbbing occur, the cuff may be wrapped too tightly. Loosen Immediately.
- The device is designed to comply with electromagnetic safety standards. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with 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. Harmful interference to other devices can be determined by turning this equipment on and off. Try to correct the interference using one or more of the following:
 - Reorient or relocate the receiving device
 - Increase the separation between the equipment
 - Consult your local customer service representative for help
- Care must be taken when operating this equipment around other equipment to avoid reciprocal interference. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with this device.
- Ensure the pump control device is turned off and unplugged from the wall outlet prior to and while cleaning or disinfecting.
- Do not place any items in an autoclave.
- No Service is to be attempted while the device is in use.
- This device is NOT to be altered or modified.
- Contains no user serviceable parts. Contact your local Customer Service representative.

CAUTIONS

- Medical Electrical Equipment needs special precautions regarding EMC. Portable and mobile RF communication equipment can be affected by other medical electrical devices. If you believe interference is occurring, please consult Electromagnetic Compatibility (EMC) section.
- 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.
- Cuffs used in combination with warming devices may cause skin irritation. Regularly check for patient discomfort, compliance, and skin irritation.
- Allow cuffs to warm to room temperature if exposed to temperatures below 5C (41F).
- Do not immerse in any liquid for any reason.
- Do not operate device in a wet environment.
- Equipment should be used in a lint-free and dust-free environment.
- Do not subject the device to extreme shocks, such as dropping the pump.
- Do not disassemble, crush, or puncture a battery.
- Do not short the external contacts on a battery.
- Do not dispose of a battery in fire or water.
- Do not expose a battery to temperatures above 60 °C (140 °F).
- Keep the battery away from children.
- Avoid exposing the battery to excessive shock or vibration.
- Do not use a damaged battery.
- If a battery pack has leaking fluids, do not touch any fluids.
- Properly dispose of a leaking battery pack.
- In case of eye contact with fluid, do not rub eyes. Immediately flush eyes thoroughly with water for at least 15 minutes, lifting upper and lower lids, until no evidence of the fluid remains. Seek medical attention



Precision Medical Products

Customer Support: (800) 604-2487 • info@pmpmed.com • www.pmpmed.com
2217 Plaza Drive, Rocklin, CA 95765

TECHNICAL DATA

MAIN DEVICE:

Dimensions: 190 mm X 44 mm X 36.3mm (7.5" X 1.7" X 2.5")
Weight: Approx. 0.276.7 kg (0.61 lb)
Mode of Operation: Cyclic
Source of Power: 3.7V 3600mA Lithium-Ion Battery

CAUTION:

Charge batteries using only the power source provided with the device.

POWER SUPPLY:



Class II, input: 100 - 240 Vac, 50 - 60 Hz, output: 12 Vdc @ 2 Amp
Use only 60601-1 approved power supplies from VenaOne for use in hospital settings.

OUTPUT:

Mode of Operation: Continuous

SYSTEM OPERATING ENVIRONMENT:



Temperature: +10C (50F) and +40C (104F)



Relative Humidity: 15%-93%



Atmospheric Pressure: 525mmHg to 795mmHg

DEFAULT SETTINGS:

Leg Pressure (not adjustable) 55 mmHg
Cycle time: 60 Seconds

TOLERANCES:

Pressure 10%

BATTERY:

This device is powered by internal Li-ion batteries

BATTERY CHARGE:

Takes approximately 4 hours (from depleted state).

