



VENAPRO[™]

Enhancing Life Through Innovation

Instructions for Use

REF 30MI

Vascular Therapy System
(Compressible Limb Sleeve Device)

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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 50 mmHg 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.

User Profile:

The intended users are the patient, caretaker or a family member providing assistance. The user should be able to:

- read and understand the operator's manual, warnings and cautions
- manually place the compression cuff on the body part to be treated
- sense auditory and visual signals

Indications for Use:

The VenaPro Vascular Therapy System 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 (stimulating 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, 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.

WARNINGS

- The VenaPro cuffs are designed for single patient use only.
- Device is to be used only by the patient prescribed, and only for its intended use.
- Operation of this device can be done by the patient.
- 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 VenaPro is a standalone device that uses a DJO AC Adapter and Battery Charger only (see Using the AC Adapter and Battery Charger section) and is not to be used or interconnected to any other device.
- Do not open or remove covers. No user serviceable parts inside. Direct all unit 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.























WARNINGS (continued)

- 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 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.
- Contains no user serviceable parts. Contact your local Customer Service representative.
- 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.

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 5°C (41°F).
- 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 unit to extreme shocks, such as dropping the pump.

SYMBOLS

	Power button and battery indicator	 LOW PRESSURE	Low pressure indicator
	This symbol designates the degree of protection against electrical shock from the wrap as being a type BF applied part		Class II medical electrical equipment
	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 of the VenaPro as replacement parts, may result in increased emissions or decreased immunity of the VenaPro
	CE Mark of conformity with notified body number 0473		Catalogue number
	Refer to Instruction Manual/Booklet		Keep dry
	Temperature range		Humidity range
	Atmospheric pressure range		This end up
	Authorized representative in the European Community		Manufacturer with 4-digit year of manufacture printed underneath
	Warning or Caution		Not made with natural rubber latex
	One touch operation		Integrated cool care releasing technology
	Battery operated		Lightweight

CONTENTS

Each package contains:

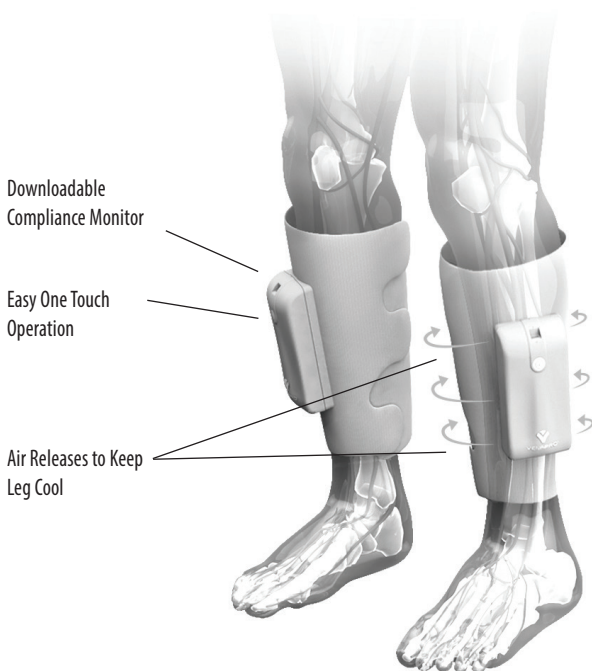
- One right compression cuff
- One left compression cuff
- One AC adapter and battery charger
- One VenaPro operator's manual

The cuff is made of:

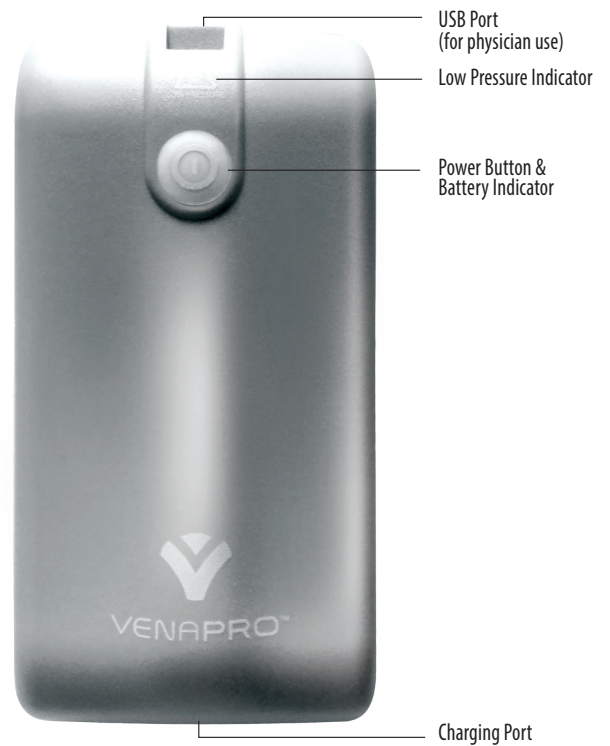
- Polyester 80%
- PU Foam 10%
- PVC 10%

FEATURES AND BENEFITS

- Easy one touch operation
- No restricting air hoses
- Air releases to cool the patients leg
- Soft breathable cuffs
- Battery Operated
- Single Patient Use
- Low Pressure Alarm
- Downloadable Compliance Monitor
- Lightweight
- Compact Design



SYSTEM COMPONENTS



INSTRUCTIONS

SYSTEM OVERVIEW

If necessary, contact your local Customer Service representative for assistance setting up, using or maintaining the device, or to report unexpected operation or events.

1 POWER OFF:

Unit is in “sleep” mode. No visible LED illumination.

2 POWER ON:

Unit powers up with GREEN LED illuminated (flashing GREEN if connected to charger and battery is charging, or YELLOW can be illuminated if battery 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 enter 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.

For 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 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:

1 **STAGE 1 – GREEN:** When the unit power is ON and the battery is charging, the GREEN LED flashes. A steady GREEN LED indicates battery is fully charged (if connected to charger) or has adequate power for portable operation if not connected to charger.

2 **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.

3 **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.

4 **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.

USING THE AC ADAPTER AND BATTERY CHARGER

POWER

1 If the power button illuminates GREEN the units are fully operational.

2 If the devices DO NOT turn ON, or the power button is “YELLOW” or “FLASHING YELLOW” plug in the power cord immediately to the electrical outlet.

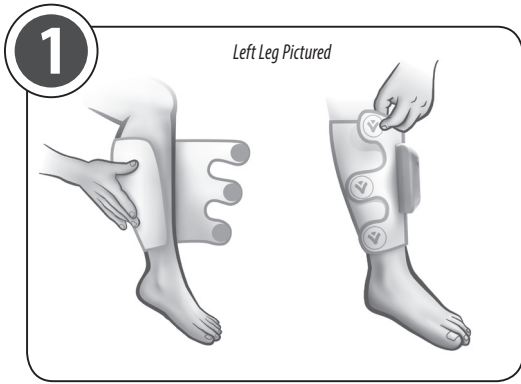
3 If units are plugged in, AND turned ON the power button will either FLASH GREEN (showing the batteries are being charged) or illuminate SOLID GREEN (showing batteries have reached adequate charge for portable operation).

4 When the unit is turned OFF and plugged in the battery is charging and POWER BUTTON FLASHES RED.

5 Once the battery reaches full charge the POWER BUTTON WILL BE RED and REMAIN SOLID.

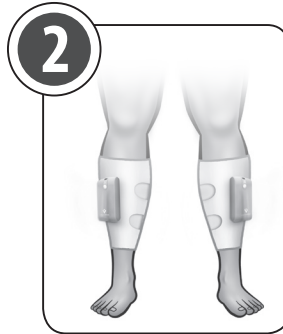


APPLICATION

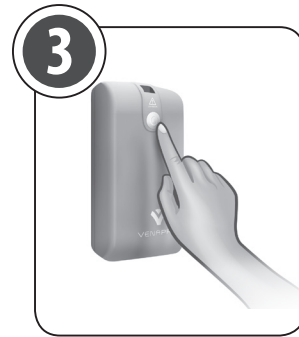


CALF CUFF APPLICATION

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.

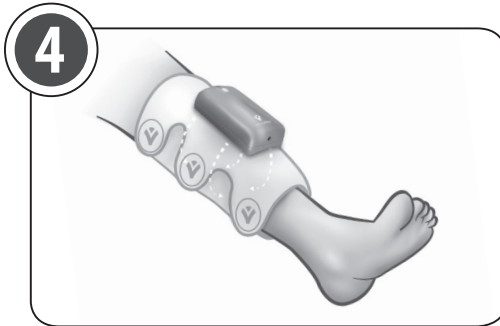


When both wraps are secured on your legs, they should look like the picture above.



TURNING THE DEVICE ON

When the wraps are secured on your legs PRESS and HOLD the WHITE power button for about a second until a single BEEP tone is heard and the light is illuminated on each unit. To turn the unit OFF, PRESS and HOLD the WHITE power button for about a second until a DUAL BEEP tone is heard and the light is no longer illuminated.



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.

PUMP ALARMS

What to do if the Pump Alarms

Don't worry, the alarms are there to ensure the units are operating correctly.



BATTERY CRITICAL

If battery voltage drops below a critical level, cycling stops, audible alarm will sound, and UNIT WILL FLASH YELLOW. The Alarm will continue for 30 seconds (unless the unit is powered off) and automatically turn the unit OFF.



LOW PRESSURE OR LEAK

If the ALARM sounds and the BLUE LED is flashing, the pressure is too LOW.

LOW PRESSURE Make sure wrap is attached snugly to the leg. Turn the Unit OFF and then back ON to reset the alarm.

If the unit continues to ALARM after this step, DO NOT try to fix the device. Contact your local Customer Service representative for a replacement unit.

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 and for storage between uses. See Storage section for instructions on proper storage.

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.
- Wipe 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.

USER MAINTENANCE

Contains no serviceable parts. Contact your local Customer Service representative.

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 your local Customer Service representative to receive replacements instructions for any damaged items.

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 your local Customer Service representative for a replacement unit.

STORAGE AND TRANSPORTATION

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

Relative Humidity: 15% to 93%

Atmospheric Pressure: 525mmHg to 795mmHg

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 country 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 your local Customer Service representative.

COMPLIANCE STATEMENTS

ELECTROMAGNETIC COMPATIBILITY (EMC)

The VenaPro has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Caution: Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources, could result in performance disruption of the system. Evidence of disruption may include image degradation or distortion, erratic readings, equipment ceasing to operate, or other incorrect functioning. If this occurs, survey the site of disruption, and take the following actions to eliminate the source(s).

- Turn equipment in the vicinity off and on to isolate disruptive equipment.
- Relocate or reorient interfering equipment.
- Increase distance between interfering equipment and your system.
- Manage use of frequencies close to the system frequencies.
- Remove devices that are highly susceptible to EMI.
- Lower power from internal sources within the facility control (such as paging systems).
- Label devices susceptible to EMI.
- Educate clinical staff to recognize potential EMI-related problems.
- Eliminate or reduce EMI with technical solutions (such as shielding).
- Restrict use of personal communicators (cell phones, computers) in areas with devices susceptible to EMI.
- Share relevant EMI information with others, particularly when evaluating new equipment purchases which may generate EMI.
- Purchase medical devices that comply with IEC 60601-1-2 EMC Standards (3V/meter EMI immunity, limit interference level to 0.0014 V/meter).

ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES - RF EMISSIONS CLASS B

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS		
The VenaPro is intended for use in the electromagnetic environment specified below. The customer or the user of the VenaPro should assure that it is used in such an environment.		
Emissions Tests	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	The VenaPro 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	The VenaPro 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 IEC 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY


The VenaPro is intended for use in the electromagnetic environment specified below. The customer or the user of the VenaPro 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	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV 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 <5% U_T (>95% dip in U_T) for 5 sec	<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 <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the VenaPro requires continued operation during power mains interruptions, it is recommended that the VenaPro be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60Hz) Magnetic Fields IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c mains voltage prior to application of the test level.

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The VenaPro is intended for use in the electromagnetic environment specified below. The customer or the user of the VenaPro 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	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the VenaPro, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	$d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$ 150 KHz to 80 MHz $d = \left[\frac{2,5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{2}{E_1} \right] \sqrt{P}$ 800 MHz to 2,5 GHz 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: <div style="text-align: center;">  </div>

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 the VenaPro is used exceeds the applicable RF compliance level above, the VenaPro should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the VenaPro.

^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 VENAPRO

The VenaPro is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VenaPro can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VenaPro 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	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{2,5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{2}{E_1} \right] \sqrt{P}$
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.

TECHNICAL DATA

MAIN UNIT:

Dimensions: 66 mm X 131 mm (2.6" X 5.2")

Weight: Approx. 0.227 kg (0.5 lb)

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 with the device.

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 DJO for use in hospital settings.

OUTPUT:

Mode of Operation: Continuous

SYSTEM OPERATING ENVIRONMENT:

Temperature: +5°C (41°F) and +40°C (104°F)

Relative Humidity: 15%-93%

Atmospheric Pressure: 525mmHg to 795mmHg

Altitude: below 3000 m

DEFAULT SETTINGS:

Leg Pressure (not adjustable) 50 mmHg

Cycle time: 60 Seconds

TOLERANCES:

Pressure ±5%

BATTERY:

This device is powered by internal Li-ion batteries

BATTERY CHARGE:

Takes approximately 4 hours (from depleted state).

WARRANTY

DJO, LLC will replace VenaPro units for material or workmanship defects for up to 60 days or 500 hours.

CUSTOMER CARE CONTACT INFORMATION

AUSTRALIA

DJO Australia
PO Box 6057,
Frenchs Forest DC,
NSW 2086
Australia
Tel: +1300 66 77 30
Fax: +1300 66 77 40
Email: customerservice.au@djoglobal.com

BENELUX

DJO Benelux
Welvaartstraat 8
2200 Herrentals
Belgium
Tel: +32 (0) 14 24 80 90
Email: benelux.orders@DJOglobal.com

CANADA

DJO Canada
6485 Kennedy Road
Mississauga
Ontario
L5T 2W4
Canada
Tel: +11866 866 5031
Fax: +11866 866 5032
Email: canada.orders@DJOglobal.com

CHINA

DJO China
A312 SOHO ZhongShan Plaza
1055 W. ZhongShan Road
Shanghai, 200051
China
Tel: +8621 6031 9989
Fax: +8621 6031 9709
Email: information_china@DJOglobal.com

DENMARK, FINLAND, NORWAY & SWEDEN

DJO Nordic AB
Murmansgatan 126
21225 Malmo
Sweden
Tel: Sweden: 040 39 40 00
Tel: Norway: 8006 1052
Tel: Finland: 0800 114 582
Tel: Denmark: +46 40 39 40 00
Email: info.nordic@DJOglobal.com

FRANCE

DJO France S.A.S.
Centre Européen de Fret
64990 Mouguerre
France
Tel: +33 (0)5 59 52 86 90
Fax: +33 (0)5 59 52 86 91
Email: sce.cial@DJOglobal.com

GERMANY, AUSTRIA & SWITZERLAND

DJO Germany GmbH
Merzhauser Str. 112
D-79100 Freiburg
Germany
Tel: +49 761 4566 251
Fax: +49 761 4566 55251
Email: infoservice@djoglobal.com

INDIA

DJO Global India
Regus RMZ Milenia Business Park 2
Campus 4B, 6th Floor, No 143, Dr.MGR Road
Perungudi
Chennai-600 096
India
Tel: +91 44 66915127
Email: customercare.india@DJOglobal.com

ITALY

DJO Italia Srl
Via Leonardo Da Vinci 97
Trezzano Sul Naviglio
20090 Milano
Italy
Tel: +39 02 484 63386
Fax: +39 02 484 09217
Email: vendite@djoglobal.com

SOUTH AFRICA

DJO South Africa (Pty) Ltd
Unit 1, Brackengate Business Park
5 on London
Brackenfell, 7560
Cape Town
South Africa
Tel: +27 21 706 16 88
Email: info.southafrica@djoglobal.com

SPAIN

DJO Ibérica
Carretera de Cornellá, 144 1º 4ª
Esplugues de Llobregat
08950 Barcelona
Spain
Tel: +34 93 480 32 02
Fax: +34 93 473 36 67
Email: es.info@DJOglobal.com

UK & IRELAND

DJO UK Ltd
1a Guildford Business Park
Guildford
Surrey
GU2 8XG
UK
Tel: +44 (0)1483 459 659
Fax: +44(0)1483 459 470
Email: ukorders@DJOglobal.com

UNITED STATES

DJO Global Inc.
1430 Decision Street
Vista
CA 92081-8553
U.S.A.
Tel: +1 800 336 6569
Fax: +1 800 936 6569

DJO EXPORT

ASIA-PACIFIC

DJO Asia-Pacific Limited
Unit 1905, 19/F, Tower II
Grand Central Plaza
138 Shatin Rural Committee Road
Shatin
Hong Kong
Tel: +852 3105 2237
Fax: +852 3105 1444
Email: info.asia-bs@djoglobal.com

EUROPE, MIDDLE EAST & AFRICA

DJO Benelux
Welvaartstraat 8
2200 Herrentals
Belgium
Tel: +32 (0) 14248350
Fax: + 32 (0) 14248358
Email: info.emea@djoglobal.com

LATIN AMERICA

DJO Global Inc.
1430 Decision Street
Vista
CA 92081-8553
U.S.A.
Tel: +1 800 336 6569
Fax: +1 800 936 6569
Email: info.latam@DJOglobal.com

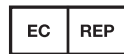


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DJO, LLC
1430 Decision Street
Vista, CA 92081-8533, USA



MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

DJOglobal.com

