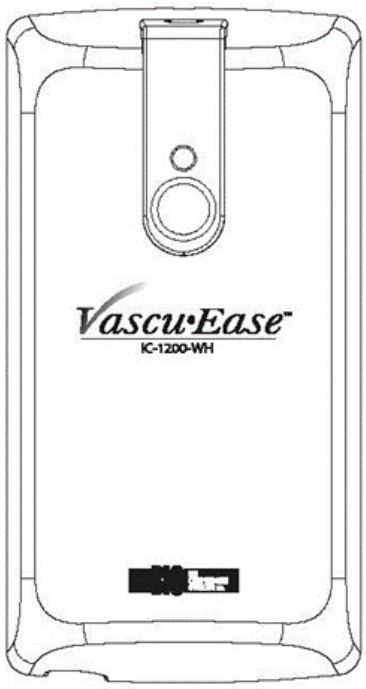
REF IC-1200-WH

BIO COMPRESSION SYSTEMS INC.

Quality Medical Products Since 1983

Vascu·Ease™

Instructions For Use



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INDICATIONS FOR USE:

VascuEase is a prescription device intended for the prophylaxis of Deep Vein Thrombosis (DVT), stimulating venous and arterial circulation, aiding in prevention of venous stasis ulcers, aiding in the healing of cutaneous ulcers, reducing acute/ chronic edema and compartmental pressures. For use in home or hospital setting.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION:

The VascuEase IC-1200-WH is a portable, rechargeable battery-powered, prescription device intended for home or hospital use to help prevent post-operative DVT in patients by stimulating blood flow as an aid in the prevention of DVT.

The pump will inflate each leg garment to a preset pressure and deflate after a period of time. The cycle continues until the unit is turned off. Internal rechargeable batteries allow the VascuEase to be completely portable, allowing for continued treatment without interruptions.

Instructions are provided for the patient to attach the garments and perform therapy at home after a physician has prescribed treatment and the patient has had orientation and been educated on proper use of the device.

DESCRIPTION OF SYMBOLS:


Manufacturer


The use of accessories, power supplies and cables other than those specified, with the exception of components sold by Bio Compression Systems, may result in increased emissions or decreased immunity of the VascuEase.


Class II Equipment


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


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

DESCRIPTION OF SYMBOLS: - continued from previous page


Follow the Instructions for Use.


Caution, consult accompanying documents.


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


Keep Dry.

WARNINGS AND PRECAUTIONS:

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 Bio Compression Systems Customer Service at 800-888-0908.

- VascuEase garments 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.
- 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 garments.
- Do not open or remove covers. No user serviceable parts inside. Direct all service inquiries to Bio Compression Systems Customer Service.
- If pulsations or throbbing occur, the garment may be wrapped too tightly. Loosen immediately.
- Stop using the device if swelling occurs and consult a Physician.

WARNINGS AND PRECAUTIONS: - continued from previous page

- Device is to be used only by the patient prescribed and only for its intended use.
- Ensure the device is turned off and unplugged from the wall outlet prior to and while cleaning and 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.
- Do not subject the device to extreme shocks, such as dropping the device.
- Do not place the device or any garments in an autoclave.
- Operation of this device can be done by the patient.
- This device should not be altered or modified.

CONTRAINDICATIONS:

Use of this device is contraindicated for conditions of the extremity that would interfere with its application, such as, but not limited to:

- Dermatitis
- Immediately following vein ligature
- Gangrene
- Skin grafts
- Casts or splints
- Severe arteriosclerosis or other ischemic vascular diseases
- Pulmonary edema
- Congestive heart failure
- Suspicion or confirmed presence of existing DVT
- Infections of the limb, including cellulitis without appropriate antibiotic coverage for a minimum of 72 hours prior to treatment
- Presence of lymphangiosarcoma
- Inflammatory phlebitis or episodes of pulmonary embolism

CLEANING:

Note: Inspect the VascuEase device and follow the cleaning procedures prior to each use.

Warning: Device must be turned off and unplugged from the wall outlet prior to and during cleaning.

Warning: Do not immerse device in any liquid for any reason. Do not use abrasive or volatile cleaners. Do not place garments in dryer.

1. Clean the outer surface of the device and garments, using a soft cloth moistened with soapy water or 70% isopropyl alcohol.
2. Leave the device OFF and unplugged from wall outlet for at least 30 minutes after cleaning or disinfecting to ensure the device is completely dry before using.

INSTRUCTIONS FOR USE (IC-1200-WH):

1. Remove the VascuEase pumps, garments and power supply from the packaging. Inspect the device and all components for any damage that may have occurred during shipping or general handling prior to each use.

   WARNING: Do not attempt to plug in the power adapter if any damage is noticed.

   WARNING: Use only the charger provided by Bio Compression Systems. Use of the wrong charger can cause excessive heat, damage to the charging circuit and shorten the life of the battery.

2. Connect a pump to each garment by firmly inserting the valve from the pump into the air input tube on the garment. Then adhere the Velcro backing on the pump onto the garment at the side of your leg.

3. Insert the provided power supply plug into the port at the top of the device. Connect the power supply adapter to the wall outlet. A solid yellow LED indicator will illuminate until the device is charged. **Please assure product is fully charged before first use.**

4. A full charge of a depleted battery will take approximately 4 hours. The device may be used while charging. The solid yellow LED indicator will remain illuminated until a full charge is complete. Once fully charged the LED indicator will extinguish.

INSTRUCTIONS FOR USE (IC-1200-WH): - continued from previous page

5. Begin treatment by wrapping a calf garment snugly around each calf, ensuring Velcro holds the garments in place. Assure that air chamber is positioned at the back of your calf.

   Note: The provided garments are side specific and therefore marked accordingly with either a "L" or "R". Please be sure to apply the proper garment on each leg.

6. Press the white power button on each pump to turn on the devices. A GREEN LED indicator will flash. (If YELLOW LED indicator flashes simultaneously, battery is low and requires immediate charging).

   Note: The yellow LED indicator will remain illuminated during charging. This will go off once device is fully charged.

7. The pump will inflate the garments to 50 mmHg + - 10 mmHg and hold for approximately 15 seconds.

8. The pumps will allow the garment to deflate and will then be without pressure for 45 seconds.

9. This cycle will continue until the power button is pressed again and the pump is turned off.

10. Peel apart the Velcro on the garments to remove from calves

ALARMS:

Battery Low – If the battery becomes low, an audible alarm will sound for one second each minute and the LED Indicator on the pump will turn YELLOW.

Low Pressure/Leak – If the sleeve does not inflate to 30 mmHg for 3 consecutive cycles, an ALARM will sound and the pump will shut off. The ALARM will continue until the power button is pressed or the battery dies. If this occurs, make sure the garment is attached snuggly to leg. Turn the device OFF and then turn it back ON. If the ALARM continues, DO NOT try to fix the device. Please call Bio Compression Systems Customer Service at 800-888-0908.

COMPLIANCE METER:

The VascuEase has a built in audible Compliance Meter to monitor hours of use.

To check the number of hours on VascuEase:

1) With the pump powered off, press and hold the Power Button for 10 seconds until you hear one short beep.
2) Release your finger from the Power Button and listen for a long beep. This indicates that the compliance reading is about to be delivered. Each group of short beeps will indicate an hour total on the VascuEase so 3 short beeps followed by another series of 5 beeps would indicate 35 hours of use. When the reading is complete, another long beep will sound and the pump will be ready to use.

To clear the Compliance Meter:

In order to reset the compliance meter, with the pump powered off, press and hold the Power Button for 30 seconds. You will hear a series of beeps along the way but at 30 seconds, 4 quick beeps will sound and the LED will flash green. Release the Power Button and the VascuEase is now reset.

USER MAINTENANCE:

The VascuEase Intermittent Compression Pump contains no user serviceable parts. Contact Bio Compression Systems Customer Service for assistance.

Avoid subjecting the device to shocks, such as dropping.

Do not handle the garments with any sharp objects. If a garment is punctured or you notice a leak, do not attempt to repair the garments.

Note: Avoid folding or creasing the garment during use and while transporting.

Replacements for damaged pumps or garments are available through Bio Compression Systems Customer Service.

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).

STORAGE: - continued from previous page

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

DISPOSAL: 

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

TECHNICAL DATA/SPECIFICATIONS:

MAIN UNIT:

Dimensions:	2.7” x 5.10” (69mm x 130mm)
Weight:	Approx 0.5 lbs (0.277 kg)
Mode of Operation:	Cyclic
Source of Power:	3.7 volt Li-ion battery pack (made up of 1 - 3.7 volt cell)

CAUTION: Charge batteries using only the power source provided by Bio Compression Systems.

POWER SUPPLY: Class II, input: 100-240 Vac, 50-60 Hz, output: 5 Vac @ 3 Amp
Use only UL/60601-1 approved power supplied from Bio Compression Systems for use in hospital settings.

Output:
Mode of Operation: Continuous

Tolerances:
Pressure 20%

Default Settings:
Leg Pressure (not adjustable) 50 mmHg
Cycle Time: 60 Seconds

System Operating Environment:
Temperature: +10°C (50°F) to +40°C (104°F)
Humidity: 30%-75%

Battery Charge:
Takes approximately 4 hours from depleted state

Electromagnetic Compatibility Information

- The use of the VascuEase IC-1200-WH requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying table.
- Portable and mobile RF communications equipment can affect the normal functioning of the VascuEase IC-1200WH.

Electromagnetic Compatibility Information: - continued from previous page

Technical Description

1. Warning: The use of accessories, transducers and cables other than those specified and sold by Bio Compression Systems as replacement parts for internal components may result in increased emissions or decreased immunity of the VascuEase IC-1200-WH device.
2. Warning: The VascuEase IC-1200-WH should not be used adjacent to or stacked with other equipment.

<table>
<tr><th colspan="3">Guidance and Manufacturer's Declaration - Electromagnetic Emissions</th></tr>
<tr><td colspan="3">The VascuEase IC-1200-WH is intended for use in the electromagnetic environment specified below. The customer or the user of the VascuEase IC-1200 -WH should ensure that it is used in such an environment.</td></tr>
<tr><th>Emissions</th><th>Compliance</th><th>Electromagnetic Environment — Guidance</th></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Group 1</td><td>The VascuEase IC-1200-WH uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The VascuEase IC-1200-WH is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies building used for domestic purposes.</td></tr>
<tr><td>Harmonic Emissions

IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage Fluctuations / Flicker Emissions

IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
The VascuEase IC-1200-WH are intended for use in the electromagnetic environment specified below. The customer or the user of the VascuEase IC-1200-WH 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	± 8kV Contact ± 2, 4 and 15kV Air Discharge	± 8kV Contact ± 2, 4, 8, 15kV Air Discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic fast transient IEC 61000-4-4	± 2 kV (Power), ± 1 kV (Signal), 100 Hz Repetition Frequency	± 2kV (Power), ± 1kV (Siginal), 100 Hz Repetition Frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge immunity IEC 61000-4-5	± 0.5kV, 1, 2kV Line-PE, ± 0.5, 1kV Line-Line	± 0.5kV, 1, 2kV Line-PE, ±0.5, 1kV Line-Line	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	0% U_T/0.5 cycles 0% U_T/1.0 cycles 70% U_T/25/30 cycles	0% U_T/0.5 Cycles 0% U_T/1.0 Cycles 70% U_T /25/30 cycles	Mains power quality should be that of a typical commercial or hospital or hospital environment. If a dips or an interruption of mains power occurs, the current of the VascuEase IC-1200-WH may be dropped off from normal level, it may be necessary to use uninterruptible power supply or a battery.
Power frequency Magnetic Field Immunity IEC 61000-4-8	30A/m, 50 or 60Hz	90A/m, 50 or 60Hz	Power frequency magnetic fields should be at the levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF Immunity IEC 61000-4-6	3V: 150kHz, 6V in Amature Radio & ISM Bands, 80% AM at 1kHz	3V: 150kHz, 6V in Amature Radio & ISM Bands, 80% AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the VascuEase IC-1200-WH device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF Field Immunity IEC 61000-4-3	80MHz - 2.7GHz: 10V/m, 80% AM at 1kHz	80MHz - 2.7GHz: 10V/m, 80% AM at 1kHz	
Proximity Fields From RF Wireless Communications Equipment IEC 61000-4-3	IEC 60601-1-1-2, Section 8.10, Table 9	IEC 60601-1-2, Section 8.10, Table 9	

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