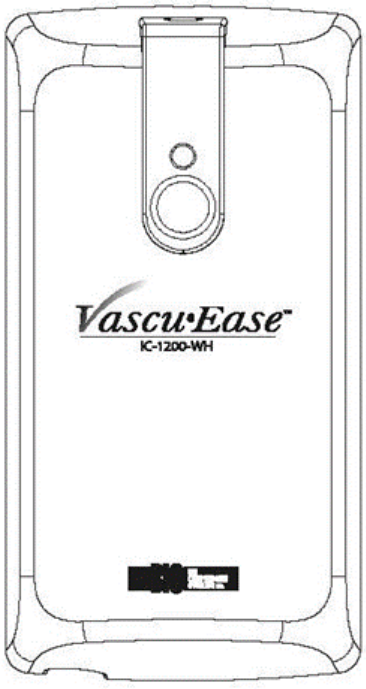
REF IC-1200-WH

BIO COMPRESSION SYSTEMS INC.

Quality Medical Products Since 1983

Vascu·Ease™



Instructions for Use

TÜV SÜD C US CE 0123

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Introduction

Congratulations on the purchase of your Bio Compression Systems model IC-1200-WH VascuEase Portable DVT System.

Package Contents

- IC-1200-WH intermittent pneumatic compression pumps
- Charger
- Instructions for use
- Garments

Intended 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.

Contraindications

Use of this device is contraindicated for patients with any of the following conditions:

- Infections in the limb, including cellulitis, without appropriate antibiotic coverage
- The presence of lymphangiosarcoma
- Suspicion or confirmation of the presence of Deep Vein Thrombosis (DVT)
- Inflammatory phlebitis or episodes of pulmonary embolism
- Congestive Heart Failure (CHF)
- Pulmonary edema
- Severe arteriosclerosis or other ischemic vascular disease
- Any local condition of the extremity that would interfere with its application, including, but not limited to: dermatitis, immediately following vein ligature, gangrene, skin grafts, casts or splints

Device Description and Operating Principle

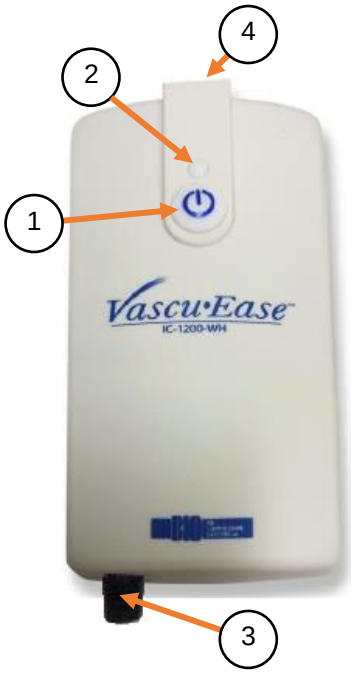
The VascuEase IC-1200-WH is a portable, rechargeable battery-powered, prescription device intended for home or hospital use to help prevent post-operative DVT in patients by stimulating blood flow as an aid in the prevention of DVT. The pump will inflate each leg garment to a preset pressure and deflate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

Guidelines for Treatment

A physician is required to prescribe these settings, but general guidelines are listed below:

- Deep vein thrombosis (DVT) prophylaxis should be applied continuously, around the clock, unless otherwise ordered by the attending physician. A less aggressive treatment schedule is more commonly prescribed by the physician post discharge in the home setting.

Front Panel and Key Features



Key Functions

1. Power On/Off Button
2. LED indicator
3. Pump valve
4. Charger port

Warnings and Precautions

US federal law restricts this device to sale by or on the order of a physician.

Electrical Medical Equipment

- To avoid the risk of electric shock, burns, fire, injury, or improper treatment, read the entire instruction manual before operating this device
- Use of accessories or a power cord not specified or provided by Bio Compression Systems could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation
- Portable RF communications equipment (including cell phones and peripherals such as antenna cables and external antennas) should be used no closer than 12" (30 cm) to any part of the device including the power cord - otherwise, degradation of the performance of this equipment could result
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation

Do Not Use

- For any contraindicated condition
- If the pump, accessories, or power cord are damaged or have been immersed in water
- With any accessories or power cord not specified or provided by Bio Compression Systems
- In the presence of flammable anesthetics or in an oxygen rich environment
- In an MRI environment
- Near water, in a wet environment, or where aerosols are being sprayed
- For any use not described in this manual

Ask A Doctor Before Use If You Have

- Insensitive, irritated, injured skin, or skin conditions in/around treatment sites

When Using This Product

- Examine the device, accessories, and power cord for damage before using or cleaning
- Handle garments with care - do not fold or crease, use near a heat source, handle with sharp objects, clean with abrasive materials, place in a washing machine or dryer, or attempt to autoclave
- Never share garments or use someone else’s garments - single-patient use only
- Do not carry or suspend the device using tubing, valves, or the power cord as handles

- Do not submerge the device or allow liquids to enter the device
- Never attempt to open, repair, or modify the device - no modification of this equipment is allowed

Stop Use And Ask A Doctor If

- Changes in skin appearance occur such as color changes, blisters, welts, or increased swelling
- You feel burning, itching, increased pain, numbness, or tingling

In the event the pump stops working (e.g., power failure), release pressure by disconnecting the garment.

Any serious incident that has occurred in relation to the device must be reported to Bio Compression Systems. In the European Union (EU), incidents should also be reported to the competent authority of the Member State in which the user and / or patient is established.

Keep out of reach of children and pets.

Operating Instructions

The patient is the intended user and can safely use all functions.

Preparing the Device for Use

- Remove garments and cardboard underneath from box
- Lift re-shipper box out of outer box and open
- Remove pumps and charger – save packaging for transport and storage
- Connect charger to pumps and plug into outlet
- Indicator light will be a steady yellow until pump is fully charged – a depleted battery can take up to 4 hours to charge
- Assure pumps are fully charged before first use
- Assure pumps are fully charged before first use

Connecting the Garments

- Firmly insert pump valve into garment input tube
- Attach pump to garment using Velcro on back

Putting the Garments On

- Snugly wrap sleeve marked “L” around left calf and sleeve marked “R” around right calf – secure using Velcro fasteners
- Ensure air chamber is positioned at back of calf

Operating the Device

- Press “Power On/Off” button to turn on
- Indicator light will flash green – if it simultaneously flashes yellow, the battery is low and must be charged
- Pump will inflate garment and hold for 15 seconds every minute until turned off with power button
- If sleeve does not properly inflate in 3 minutes, pump will stop operating and alarm will sound until power button is pressed or battery dies
- Should battery become low, an alarm will sound for 1 second each minute and indicator will turn yellow
- Upon completion of treatment, press “Power On/Off” button to turn pump off
- Charge pumps for next use
- Upon the completion of treatment or to stop treatment, press “Power On/Off” button to turn off

Reading the Usage Meter

Begin with device turned off. Press and hold the “Power On/Off” button for 10 seconds until you hear a short beep. Release button and you will hear a long beep. The pump will then emit a series of short beeps to indicate the hours of use. For example, if the pump emits 3 short beeps followed by 5 short beeps, that indicates 35 hours of use. When complete, you will hear another long beep.

Cleaning

The pumps and garments can be wiped down using a damp (not wet) soft cloth while unplugged – if pump disinfection is desired, use the following directions.

Pump disinfection

- Unplug and turn off
- Wipe down using a damp (not wet) soft cloth with mild antibacterial soap antibacterial soap
- Air dry or pat dry using a soft cloth
- Wipe down using cotton balls moistened with 70% isopropyl alcohol
- Air dry for 30 minutes

Storing and Transporting

- Keep and reuse packaging for transporting the device
- Store in a dry location away from a source of heat and free of pests

Servicing and Repairs

- Contact Bio Compression Systems for servicing – there are no user serviceable parts
- Tampering, modifying, or dismantling this device in any way voids the warranty
- When contacting Bio Compression Systems, please have your model number and serial number ready

Troubleshooting

Pump does not turn on:
1. Examine charger for damaged - if damaged, contact Bio Compression Systems
2. Plug in to see if pump is charging (solid yellow LED)
3. If not charging, check circuit breaker to make sure outlet has power
4. Contact Bio Compression Systems

Garment does not deflate:
1. Check garment connection to pump
2. Contact Bio Compression Systems

Low pressure alarm:
1. Make sure garment is snug
2. Check garment connection to pump
3. Check garment for damage
4. Contact Bio Compression Systems

Pump does not charge:
1. Examine charger for damaged - if damaged, contact Bio Compression Systems
2. Plug in to check for solid yellow LED
3. If LED does not illuminate, check circuit breaker to make sure outlet has power
4. If LED does not illuminate or battery does not charge after 4 hours, contact Bio Compression Systems

Accessories

REF	Description
GID-1000-PR	VascuEase DVT Garments

Product Specifications

Models: IC-1200-WH
Electrical Input Rating: 120-240 VAC, 50-60 Hz, 0.7 A (max)
Electrical Classification: Class II
Type Applied Part: Type BF
Ingress Protection: IP22
Battery: 3.7 V Li-ion battery
Charge Time: 4 hours
Mains Isolation: Battery powered
Mode of Operation: Continuous
Essential Performance: The pump's cyclical inflation and deflation of the garment(s)
Cycle Time: 60 ± 10 seconds (inflation 15 seconds, deflation 45 seconds)
Pressure: 50 mmHg
Accuracy: ± 20%
Features: Compliance/Usage Meter, Low Pressure Alarm, Low Battery Alarm
Warranty: Pump 6 months
Expected Service Life: 5 years
Software Safety Class: A
Regulatory Classification: AU IIa, CA 2, BR II, EU IIa, US 2
Weight: 0.5 lbs. (0.28 kg)
Dimensions: 5.1" x 2.7" x 1.6" (130 mm x 69 mm x 41 mm)

Environmental Specifications

Consumables and Natural Resources Used During Care and Use

- Electrical energy for operation
- 1 drop of mild antibacterial soap and 2-3 cotton balls moistened with 70% isopropyl alcohol - only as needed
- 70 mL laundry detergent and 250 mL bleach per 7.6 liters water for garment cleaning - only as needed

Emissions During Normal Use

- Compressed air
- Minimal acoustic energy - nearly silent
- Minimal electromagnetic emissions - see manufacturer's declaration and related information below

Instructions for Minimizing Environmental Impact

- Do not clean garment soiled - this minimizes the consumables used
- Reuse packaging for storing and transporting device

Operation Environment

- Intended for use in a healthcare or home environment
- Not intended of use in the presence of flammable anesthetics, an oxygen rich environment, or an MRI environment
- Altitude up to 6561 feet (2000 m)
- Temperature 50-104° F (10-40° C)
- Humidity 30-75% RH
- Atmospheric pressure 700-1060 hPa

Transportation and Storage Environment

- Temperature 50-104° F (29-44° C)
- Humidity 30-75% RH
- Atmospheric pressure 700-1060 hPa

End of Life Management

- There are no components which contain stored electrical energy after the device has been shut off
- Does not contain hazardous substances requiring special handling and treatment

- Dispose of the battery in accordance with the local regulations for lithium battery disposal - batteries should never be thrown away or incinerated
- Dispose of in an environmentally responsible manner in accordance with regional requirements
- Contact Bio Compression Systems if you have questions or concerns regarding disassembly and disposal

Manufacturer's EMC Declaration

Electromagnetic Emissions

The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should assure that it is used in such an environment.

Emissions	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device 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.
RF emissions CISPR 11	Class B	The device 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.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic Immunity

Immunity Test	Immunity Test Level	Compliance Level
IEC 61000-4-2 Electrostatic Discharge Immunity	±8kV Contact, ±2, 4, 8, 15kV Air Discharge	±8kV Contact, ±2, 4, 8, 15kV Air Discharge
IEC 61000-4-3 Radiated RF Field Immunity	80MHz – 2.7GHz: 10V/m, 80% AM at 1kHz	80MHz – 2.7GHz: 10V/m, 80% AM at 1kHz
IEC 61000-4-3 Proximity Fields from RF Wireless Communications Equipment	IEC 60601-1-2, Section 8.10, Table 9	IEC 60601-1-2, Section 8.10, Table 9
IEC 61000-4-4 Electrical Fast Transients	±2kV (Power), ±1kV (Signal), 100kHz Repetition Frequency	±2kV (Power), ±1kV (Signal), 100kHz Repetition Frequency
IEC 61000-4-5 Surge Immunity	±0.5, 1, 2kV Line-PE, ±0.5, 1kV Line-Line	±0.5, 1, 2kV Line-PE, ±0.5, 1kV Line-Line
IEC 61000-4-6 Conducted RF Immunity	3V: 150kHz - 80MHz, 6V in Amateur Radio & ISM Bands, 80% AM at 1kHz	3V: 150kHz - 80MHz, 6V in Amateur Radio & ISM Bands, 80% AM at 1kHz
IEC 61000-4-8 Magnetic Field Immunity	30A/m, 50 or 60Hz	90A/m, 50 or 60Hz
IEC 61000-4-11 Voltage Dips	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
IEC 61000-4-11 Voltage Interruptions	0% U_T / 250/300 Cycles	0% U_T / 250/300 Cycles

Symbol Glossary

EC REP	Authorized Representative in the European Community
	Atmospheric pressure limitation
LOT	Batch code (lot number)
REF	Catalog number
	Caution
	Class II equipment (protection against electric shock)
	Complies with the Waste Electrical and Electronic Equipment Directive (WEEE Directive)
CE 0123	Complies the European Medical Device Regulation
	Date of manufacture
	Fragile, handle with care
	Humidity limitations
IP22	Ingress protection (protection against solids up to 12.5 mm and dripping water when tilted up to 15°)

	Manufacturer
MD	Medical Device
	Keep dry
	Power on/off (stand-by)
	Refer to instruction manual/ booklet
	Restricted to sale by or on the order of a physician
SN	Serial number
	Temperature Limit
	This way up
	TÜV SÜD Certification Mark (safety tested and production monitored)
	Type BF Applied Part
	Warning: Electricity

Information for Distributors and Healthcare Providers

Resetting the Pump

The pump remembers user settings and therefore it is important to reset the pump to its original factory settings when placing the device on a new patient. To reset the usage meter and return the pump to factory settings:

- Begin with pump turned off
- Press and hold the power button for 30 seconds
- You will hear a series of beeps then at 30 seconds you will hear 4 quick beeps the LED will flash green
- Release the power button

Cleaning the Pump

The device does not have microbiological requirements or specifications. Pneumatic compression pumps are non-contacting reusable devices, and pneumatic compression garments/sleeves are single patient use devices.

Use an US EPA registered low-level disinfectant or low-level disinfectant wipe on the pump in accordance with the US CDC's *Guideline for Disinfection and Sterilization in Healthcare Facilities* or local requirements. Ensure the charger port cover connected to the pump is inserted. Do not use excessive liquid and do not allow liquid to enter the pump valve where the garment connects. Follow all directions for the disinfectant.

Contact Information

Manufacturer

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Website: www.biocompression.com

When contacting us, please have your model number and serial number ready.

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