# Bio Compression's SC-2004-DL/SC-2008-DL



## **SEQUENTIAL CIRCULATOR Operating Instructions**



**Quality Medical Products Since 1983** 



## **Table of Contents**

Introduction	3
Intended Use	3
Device Description and Operating Principle	4
Warnings and Precautions	6
Operating Instructions	8
Accessories	12
Product Specifications	14
Environmental Specifications	15
Symbol Glossary	17
Information for Distributors and Healthcare Providers	18

## Introduction

Congratulations on the purchase of your sequential circulator and garments.

## **Package Contents**

- Sequential Circulator pump
- Power cord
- Instructions for use
- Blocker bar
- Garment(s) possibly packed separately

## **Intended Use**

Sequential Circulators are pneumatic compression devices intended for either primary or adjunctive treatment of lymphedema, peripheral edema, lipedema, venous insufficiency, and venous stasis ulcers. Sequential Circulators are also intended for the prophylaxis of deep vein thrombosis (DVT). Intended for use in a home or healthcare setting.

## **Contraindications**

Compression IS NOT recommended in 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) unless controlled by medication
- Other indications as identified by the treating physician

## **Guidelines for Treatment**

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

- It is ultimately the physician's responsibility to prescribe the setting and it should be written on the prescription upon referral. Every patient is unique and communication with the physician is important when setting the pressure.
- 50 mmHg works well for most patients. However, a different pressure might be prescribed for your personal need and tolerance.

- Presence of fibrotic tissue may require as much as 80 mmHg in order to soften the fibrotic tissue and achieve reduction. Once the tissue is soft, the compression can be readjusted to 50 mmHg.
- Patients with a history of Congestive Heart Failure (CHF), which is controlled with medication, should never be in a flat position while pumping. They should be in a reclined position with elevated legs during treatment. Their treatment regimen duration may be divided into twice a day 30 minutes per treatment.
- Patients with a history of Deep Vein Thrombosis with or without a filter may require less compression. These patients will generally tolerate 40 mmHg. Patients with a filter may need to divide their treatment into twice a day, 30 minutes per treatment. It is suggested that the provider obtain a negative Doppler study from the physician for their records.

## **Device Description and Operating Principle**

Sequential Circulators provide gradient pneumatic compression for the treatment of lymphedema and associated venous disorders. Sequential gradient compression helps to increase blood flow and move excess lymph away from the affected area for clearance from the body. This device can provide sequential (distal to proximal) inflation/deflation cycles of compressed air at prescribed pressures. Pneumatic compression devices are proven to reduce limb swelling associated with lymphedema, help close up chronic ulcers, and act as a prophylaxis for Deep Vein Thrombosis (DVT).

## **Adjustable Pressure**

The pressure of the pump can be adjusted between 10 and 120 mmHg. Pressure can be selected before treatment and adjustments can be made during treatment.

## **Adjustable Cycle Time**

The cycle time is the time it takes the pump to inflate and deflate the garment. The cycle time can be adjusted from 60 to 120 seconds in 15 second intervals.

## **Timed Treatment**

The pump can be run continuously or the treatment time can be set between 10 and 120 minutes in 5 minute increments.

## **Focus Therapy**

Focus Therapy is used to help treat patients at the beginning of their session in an area that requires more attention. Focus therapy doubles the inflation time of two adjacent chambers (SC-2004-DL) or three adjacent chambers (SC-2008-DL) during the first ten minutes of treatment.

## Play/Pause

The "Play/Pause" button gives the patient the option to stop the pump in the middle of a treatment session allowing them to use the bathroom or attend to other needs. Timed treatments will run for the full treatment time even if paused to ensure patient receives appropriate therapy.

## **Treatment Compliance Meter**

The pump records the hours of use.

## **Front Panel**



- LED Indicators
- 2. LED Display
- 3. UP Button
- 4. DOWN Button
- 5. SET Button

- 6. Power On/Off Button
- 7. PLAY/PAUSE Button
- 8. Garment Connector Bar Port
- 9. Auxiliary Connector Bar Port (shown with Blocker Bar)

The SC-2008-DL has two Garment Connector Bar Ports and two Auxiliary Connector Bar Ports as shown below:



## **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
- While sleeping
- 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, or place in a washing machine or dryer
- Do not stand or walk while wearing garments as this can cause a fall
- Always wear clothing, bandages, or stockings underneath garments for hygienic reasons and to avoid irritation
- Never share garments or use someone else's garments single-patient use only
- Avoid folding, pinching, or kinking tubing as this can obstruct air flow
- Do not wrap tubing around limb as this can restrict blood flow
- Do not operate pump on a soft surface, under a blanket or covering, or near a heat source
- Never adjust pump settings unless directed by a physician
- 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 garment(s) and cardboard underneath from box
- Remove garment(s) from plastic bag, unroll, and spread flat
- Lift pump out of box and remove protective end caps save packaging for transport and storage
- Place pump on a flat sturdy surface pump must be close enough for the controls to be reached during use
- Attach power cord and plug into outlet
- Pump is set to run for one hour at 50 mmHg with 90 second cycle time
   to change settings or use Focus Therapy, see below

## To Change Pump Settings or Use Focus Therapy

- Begin with the pump turned off
- Press and hold "SET" button for 5 seconds
- "SEtUP" will appear in LED Display and "Pressure" LED indicator will be lit
- Use UP or DOWN button to adjust pressure and press "SET" button when finished
- "SEt" will appear in LED Display and "Cycle Time" LED indicator will be lit
- Use UP or DOWN button to adjust cycle time and press "SET" button when finished
- "SEt" will appear in LED Display and "Treatment Time" LED indicator will be lit
- Use UP or DOWN button to adjust treatment time to set on continuous mode, press UP button until LED Display shows "COn"
- Press "SET" button when finished "SEt" will appear in LED Display and "Focus Therapy" LED indicator will be lit
- Use UP or DOWN button to select chambers for focus therapy or select "off" to turn off

 Press "SET" button when finished – "SEt" will appear in LED Display and pump will turn off

## **Connecting the Garment(s)**

- Locate the connector bar at the end of garment tubing
- Line up numbers on connector bar with numbers on pump
- Squeeze the sides and insert into pump you will hear a "click" when connected
- (SC-2008-DL only) Locate the second connecter bar and repeat previous steps
- When using two garments, remove blocker bar(s) and repeat previous steps

## **Putting the Garment(s) On**

## **Lower Extremity Garments**

- Leg sleeve: unzip, place leg in and make sure heel is back and down and toes are inside the sleeve, use straps to guide garment on, pull up zipper to secure
- Bio Pants: unzip, place legs in garment and make sure heels are back and down and toes are inside the sleeve, use straps to guide on, pull up zipper on each leg to secure
- Bio Abdominal: unzip, place leg in garment and make sure heel is back and down and toes are inside sleeve, use straps to guide on, secure flaps, pull up zipper on leg to secure

## **Upper Extremity Garments**

- Arm sleeve: slide arm through larger opening, hand should be flat with fingers inside the sleeve
- Arm & Shoulder: slide arm through larger opening, use opposite arm to secure flaps. Hand should be flat and fingers inside the sleeve
- 4-Chamber Vest: place head through hole like a t-shirt and then secure flaps in front
- Elite-8 Bio Vest (left or right): Unzip, slide arm through larger hole, secure flaps, and then zipper in front. Hand should be flat with fingers inside the sleeve.
- Elite-8 Bio Vest (bilateral): Unzip, slide arm through first hole, slide arm through second hole, zipper in front. Hand should be flat with fingers inside the sleeve

## **Operating the Device**

 Sit in a comfortable reclined position with legs elevated within reach of controls

- Press "Power On/Off" button to turn on
- The settings will appear on the LED display and the pump will start
- To pause treatment or change pressure during treatment, see below
- At the end of a timed treatment, your pump will turn off
- To turn off the pump during a treatment, press the "Power On/Off" button "HOld" will show in the LED and then the pump will turn off
- Squeeze sides of connector bar and pull to disconnect garment from pump
- Press garment to remove remaining air until loose enough to remove
- Unzip (if applicable) and remove garment

## **Pausing Treatment**

- To pause treatment, press "Play/Pause" button and "PAUSE" will appear on the LED display
- "HOld" will show in the LED display while the pump returns to its resting position and then "PAUSE" will appear. The garment will then deflate (remove garment using directions above)
- Press "Play/Pause" to resume treatment when using timed treatment, the remaining time will appear on the LED display

## **Changing Pressure During Treatment**

- While the pump is running, press and hold the UP button for 5 seconds until you see the word "HOld" - let go of UP button
- Once the pump returns to its resting position "SEt" and "PrES" will show in LED display, the blue LED will light up under "Pressure" and the current pressure setting will show
- At this point you can adjust the pressure up or down
- When you have reached your desired pressure, hit the "SEt" button, the word "SEt" shows in the LED's and the pump begins to operate again

## **To See Treatment Compliance Meter (Hours of Use)**

- Begin with the device turned off
- Press and hold the "Play/Pause" button for 5 seconds
- "C" will appear followed by the hours of use since the last reset
- Information will be displayed until "Play/Pause" is hit again

## To Check Pressure Setting While Pump is Running

• Hold the Down button until the pressure setting and the letter "P" show

## To Reset Your Device to Factory Settings and Clear Compliance Meter

 Press and hold the Up, Down, and Set buttons together for 5 seconds until the compliance meter hours show on the LED Display. Let go of the buttons and then hit the "SET" button. You will see "CLr" in the LED Display and the LED will shut off.

## **Cleaning**

The pump, garment, and tubing can be wiped down using a damp (not wet) soft cloth while unplugged – if more thorough pump cleaning or garment disinfection is desired, use the following directions.

## **Pump and Tubing Cleaning**

- Unplug and wipe down using a damp (not wet) soft cloth with mild antibacterial soap as needed
- Do not use bleach

## **Garment Disinfection**

- Disconnect from pump and open to expose all sides
- Prepare a solution of 1/3 cup of laundry detergent per 1 gallon of warm water (20 mL laundry detergent per 1 L water) in a sink or container large enough to hold the garment
- Place garment in solution but do not submerge or place connectors in water as this will damage the device
- Soak for 30 minutes with mild agitation every 5-10 minutes hard to remove soil may require hand washing using a soft clean cloth while garment is in solution
- Rinse with warm water and allow to air dry
- Repeat previous steps using a solution of 1 cup of bleach per 1 gallon of warm water (60 mL bleach per 1 L warm water)

## **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. Check to see if the pump is plugged in
- 2. Unplug and examine power cord for damaged if damaged, contact Bio Compression Systems
- 3. 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. Check garment hose for damage, kinks, or twists
- 3. Check garment for damage
- 4. Contact Bio Compression Systems

### Pressure seems low:

- 1. Check garment connection to pump
- 2. Check garment hose for damage, kinks, or twists
- 3. Check garment for damage
- 4. Contact Bio Compression Systems

## Device is loud or making strange noises:

- 1. Make sure pump is on a stable surface
- 2. Assure stable surface is free and clear of any loose object
- 3. Contact Bio Compression Systems

## **Accessories (SC-2004-DL)**

REF	Description
GS-3035-S	4-Chamber Arm Sleeve - Small
GS-3035-M	4-Chamber Arm Sleeve - Medium
GS-3035-L	4-Chamber Arm Sleeve - Large
GS-3035-SH-S-L	4-Chamber Arm & Shoulder Sleeve - Small, Left
GS-3035-SH-S-R	4-Chamber Arm & Shoulder Sleeve - Small, Right
GS-3035-SH-M-L	4-Chamber Arm & Shoulder Sleeve - Medium, Left
GS-3035-SH-M-R	4-Chamber Arm & Shoulder Sleeve - Medium, Right
GS-3035-SH-L-L	4-Chamber Arm & Shoulder Sleeve - Large, Left
GS-3035-SH-L-R	4-Chamber Arm & Shoulder Sleeve - Large, Right
GV-3000	4-Chamber Vest
GS-3045-H	4-Chamber Leg Sleeve - Half
GS-3045-S	4-Chamber Leg Sleeve - Small
GS-3045-M	4-Chamber Leg Sleeve - Medium
GS-3045-L	4-Chamber Leg Sleeve - Large
GN-3045-S	4-Chamber Narrow Leg Sleeve - Small
GN-3045-M	4-Chamber Narrow Leg Sleeve - Medium
GN-3045-L	4-Chamber Narrow Leg Sleeve - Large
GW-3045-H	4-Chamber Wide Leg Sleeve - Half

REF	Description
GW-3045-S	4-Chamber Wide Leg Sleeve - Small
GW-3045-M	4-Chamber Wide Leg Sleeve - Medium
GW-3045-L	4-Chamber Wide Leg Sleeve - Large
GXW-3045	4-Chamber Extra Wide Leg Sleeve
GA-3045-H	4-Chamber Adjustable Leg Sleeve - Half
GA-3045-S	4-Chamber Adjustable Leg Sleeve - Small
GA-3045-M	4-Chamber Adjustable Leg Sleeve - Medium
GA-3045-L	4-Chamber Adjustable Leg Sleeve - Large
GWA-3045-H	4-Chamber Wide Adjustable Leg Sleeve - Half
GWA-3045-S	4-Chamber Wide Adjustable Leg Sleeve - Small
GWA-3045-M	4-Chamber Wide Adjustable Leg Sleeve - Medium
GWA-3045-L	4-Chamber Wide Adjustable Leg Sleeve - Large
GXWA-3045	4-Chamber Extra Wide Adjustable Leg Sleeve

## Accessories (SC-2008-DL)

REF	Description
G8-3035-S	8-Chamber Arm Sleeve - Small
G8-3035-M	8-Chamber Arm Sleeve - Medium
G8-3035-L	8-Chamber Arm Sleeve - Large
G8-3035-SH-S-L	8-Chamber Arm & Shoulder Sleeve - Small, Left
G8-3035-SH-S-R	8-Chamber Arm & Shoulder Sleeve - Small, Eert
G8-3035-SH-M-L	8-Chamber Arm & Shoulder Sleeve - Small, Night
G8-3035-SH-M-R	8-Chamber Arm & Shoulder Sleeve - Medium, Eent
G8-3035-SH-L-L	8-Chamber Arm & Shoulder Sleeve - Medium, Right
G8-3035-SH-L-R	8-Chamber Arm & Shoulder Sleeve - Large, Left  8-Chamber Arm & Shoulder Sleeve - Large, Right
G8-3045-S	8-Chamber Leg Sleeve - Small
G8-3045-M	8-Chamber Leg Sleeve - Small 8-Chamber Leg Sleeve - Medium
G8-3045-W	
	8-Chamber Leg Sleeve - Large
GN8-3045-S	8-Chamber Narrow Leg Sleeve - Small
GN8-3045-M	8-Chamber Narrow Leg Sleeve - Medium
GN8-3045-L	8-Chamber Narrow Leg Sleeve - Large
GW8-3045-S	8-Chamber Wide Leg Sleeve - Small
GW8-3045-M	8-Chamber Wide Leg Sleeve - Medium
GW8-3045-L	8-Chamber Wide Leg Sleeve - Large
GXW8-3045	8-Chamber Extra Wide Leg Sleeve
A8-3045-S	8-Chamber Adjustable Leg Sleeve - Small
A8-3045-M	8-Chamber Adjustable Leg Sleeve - Medium
A8-3045-L	8-Chamber Adjustable Leg Sleeve - Large
GWA8-3045-S	8-Chamber Wide Adjustable Leg Sleeve - Small
GWA8-3045-M	8-Chamber Wide Adjustable Leg Sleeve - Medium
GWA8-3045-L	8-Chamber Wide Adjustable Leg Sleeve - Large
GXWA8-3045	8-Chamber Extra Wide Adjustable Leg Sleeve
GBA-3045-S-2	Bio Pants - Small
GBA-3045-M-2	Bio Pants - Medium
GBA-3045-L-2	Bio Pants - Large
GBA-3045-S-L	Bio Abdominal - Small, Left Leg
GBA-3045-S-R	Bio Abdominal - Small, Right Leg
GBA-3045-M-L	Bio Abdominal - Medium, Left Leg
GBA-3045-M-R	Bio Abdominal - Medium, Right Leg
GBA-3045-L-L	Bio Abdominal - Large, Left Leg
GBA-3045-L-R	Bio Abdominal - Large, Right Leg
GV-3010-S-L	Elite 8 Bio Vest - Small, Left
GV-3010-S-R	Elite 8 Bio Vest - Small, Right
GV-3010-M-L	Elite 8 Bio Vest - Medium, Left
GV-3010-M-R	Elite 8 Bio Vest - Medium, Right
GV-3010-L-L	Elite 8 Bio Vest - Large, Left

REF	Description
GV-3010-L-R	Elite 8 Bio Vest - Large, Right
GV-3010-S-2	Elite 8 Vest with Bilateral Arms - Small
GV-3010-M-2	Elite 8 Vest with Bilateral Arms - Medium
GV-3010-L-2	Elite 8 Vest with Bilateral Arms - Large

## **Product Specifications**

Models: SC-2004-DL, SC-2008-DL

Power Supply Rating: 120-240V, 50/60 Hz

Rated Input: 12VDC, 3A

Electrical Classification: Class II

Applied Part: Type BF Ingress Protection: IP21 Mains Isolation: Unplug

Mode of Operation: Continuous

Essential Performance: The pump's cyclical inflation and deflation of the

garment(s)

Cycle Time: 60-120 seconds in 15 second increments

Treatment Time: Continuous or 10-120 minutes in 5 minute increments

Pressure Range: 10-120 mmHg

Precision: 1 mmHg Accuracy: ± 20%

Features: Adjustable Cycle Time, Compliance/Usage Meter, Focus

Therapy, Play/Pause, Timed Treatment Warranty: Pump 3 years, garment 1 year

Expected Service Life: 5 years

Software Safety Class: A

Regulatory Classification: AU IIa, CA 2, BR II, EU IIa, US 2

Weight: (SC-2004-DL) 3.3 lbs. (1.5 kg) Weight: (SC-2008-DL) 3.65 lbs. (1.66 kg)

Dimensions: 4.5" x 12" x 7.34" (114 mm x 304 mm x 186 mm)

## **Environmental Specifications**

## **Consumables and Natural Resources Used During Care and Use**

- Electrical energy for operation
- 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**

- Unplug the pump after charging unplugging electronic devices when they are not being used saves electricity
- Unplug the pump when not in use unplugging electronic devices when they are not being used saves electricity
- Do not clean garment soiled this minimizes the consumables use
- 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°F 100°F (10°C 38°C)
- Humidity 30-75% RH
- Atmospheric pressure 700-1060 hPa

## **Transportation and Storage Environment**

- Temperature -20°F 110°F (-29°C 43°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 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**

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	
Harmonic emissions IEC 61000-3-2	Not applicable	network that supplies building used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

## **Electromagnetic Immunity**

Immunity Test	Immunity Test Level
IEC 61000-4-2 Electrostatic Discharge Immunity	±8kV contact, ±2, 4, 8, 16kV air discharge
IEC 61000-4-3 Radiated RF Field Immunity	80MHz – 2.7GHz, 10V/m, AM 80% at 1kHz
IEC 61000-4-3 Proximity Fields from RF Wireless Communications Equipment	IEC 60601-1-2, Section 8.10, Table 9
IEC 61000-4-4 Electrical Fast Transients	±2kV/100kHz power, ±1kV/100kHz signal
IEC 61000-4-5 Surge Immunity	±0.5, 1kV line to line, ±0.5, 1, 2kV line to ground
IEC 61000-4-6 Conducted RF Immunity	150kHz - 80MHz, 3V <sub>RMS</sub> in whole range, 6V <sub>RMS</sub> in amateur radio and ISM, AM 80% at 1kHz
IEC 61000-4-8 Magnetic Field Immunity	30A/m, 50 or 60Hz
IEC 61000-4-11 Voltage Dips	0% U <sub>T</sub> per 0.5 cycles, 0% U <sub>T</sub> per 1.0 cycle, 70% U <sub>T</sub> per 25/30 cycles
IEC 61000-4-11 Voltage Interruptions	0% U₁ per 250/300 cycles

## **Symbol Glossary**

EC REP	Authorized Representative in the European Community
<b>\$•</b> \$	Atmospheric pressure limitation
LOT	Batch code (lot number)
REF	Catalog number
	Caution
	Class II equipment (protection against electric shock)
Z	Complies with the Waste Electrical and Electronic Equipment Directive (WEEE Directive)
<b>CE</b> 0123	Complies the European Medical Device Regulation
$\sim$	Date of manufacture
	Fragile, handle with care
<u></u>	Humidity limitations
IP21	Ingress protection (against solids up to 12.5 mm and dripping water)

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

## Information for Distributors and Healthcare Providers

## **Compliance Meter**

To see hours of use since last reset, refer to "To See Treatment Compliance Meter (Hours of Use)" in the Operating Instructions section.

To see pump total hours of use, press "Play/Pause" for 10 seconds while viewing hours since last reset - "t" will appear followed by the total hours of use.

## **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 treatment compliance meter and return the pump to factory settings:

- Begin with the device turned off and plugged in
- Press and hold the UP, DOWN, and SET buttons simultaneously for 5 seconds until the LED display lights up and shows the compliance meter
- Release the buttons
- Press "SET" button. LED display will show "CLr" and then turn off

## **Cleaning the Pump**

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

Use a 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. Do not use excessive liquid to enter the pump where the garment(s) or power cord connect. Follow all directions for the disinfectant.

## **Grounding Plug Not Required**

This double insulated device does not require a three-wire power cord and a three-pin grounding type plug for use in the patient care vicinity of a hospital or other healthcare facility (see NFPA 99).