

Bio Compression's

SC-4004-DL/SC-4008-DL



SEQUENTIAL CIRCULATOR

Operating Instructions



Quality Medical Products Since 1983



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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. 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-4004-DL) or three adjacent chambers (SC-4008-DL) during the first ten minutes of treatment.

Pre-Therapy

Pre-Therapy is only available in the SC-4008-DL. It is a setting that allows a patient to inflate chambers 6, 7, and 8 for ten minutes prior to running a full cycle of chambers 1 through 8.

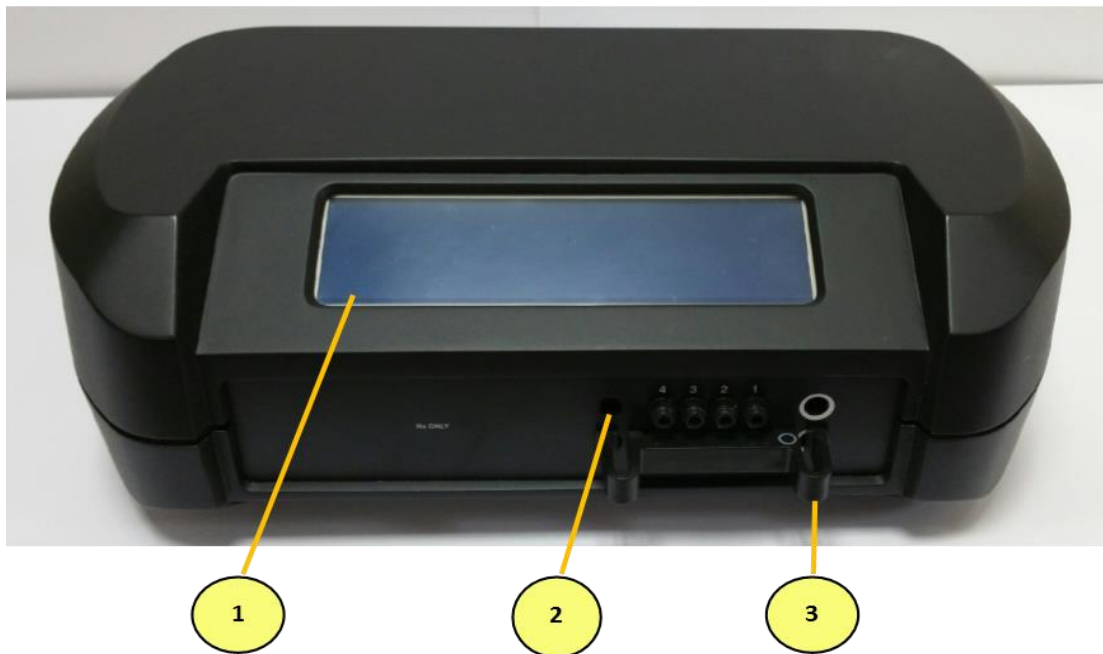
Pause Feature

The 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



1. Touch Screen LCD Display
2. Garment Connector Bar Port
3. Auxiliary Connector Bar Port (shown with Blocker Bar)

The SC-4008-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 60 second cycle time
- to change settings, see below

To Change Pump Settings

- Begin with the pump turned off
- Press the Touch Screen LCD Display (1) to wake up your device
- When the home screen lights up, press and hold the lower right corner of the Touch Screen LCD Display (1) for 3 seconds until you see the main setup screen
- You can review the pump's current Pressure, Cycle Time, and Treatment Time settings on this main screen – if the current settings are acceptable, hit "Done"
- To adjust the settings, press "Setup" in the lower right corner
- The first screen that appears is the Pressure settings screen
- Press "Up" and "Down" to adjust the pressure, beginning with Chamber 1, and press "Chamber" to move to the next chamber
- Repeat the previous steps to set each chamber – please note that you cannot set the pressure in the next chamber higher than the previous chamber
- When all chambers have been set, press "Next"
- You are now on the Cycle Time screen – press "Up" and "Down" to adjust the cycle time and press "Next" when finished
- You are now on the Treatment Time screen – press "Up" and "Down" to adjust the treatment time
- To set on continuous mode, press "Up" one more time after reaching "120" and the word "Continuous" will appear – press "Next" when finished
- You are now on the Focus Therapy screen – press "Up" and "Down" to select chambers for focus therapy or "Off" to turn off
- At this point the SC-4008-DL will switch to the Pre-Therapy screen

- Press “On” to turn pre-therapy on and “Off” to turn off
- You can now review your settings on the screen. Hit “Done” if your new settings are correct, hit “Setup” if you want to make changes and follow directions above

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-4008-DL only) Locate the second connector bar and repeat previous steps
- When using two garments, remove blocker bar(s) and repeat previous steps

Putting the Garment(s) On

- Leg sleeve: unzip, place foot in and use straps to guide garment on, pull up zipper to secure
- Arm sleeve: slide arm through larger opening

Operating the Device

- Sit in a comfortable reclined position with legs elevated within reach of controls
- Press the Touch Screen LCD Display (1) – to wake up your device - the pressure, cycle time, and treatment time appear at the top of the screen
- Press “Start” to begin treatment. If you do not press “Start” within 1 minute, your device will go back into sleep mode.
- At the end of a timed treatment, your pump will turn off
- To turn off the pump during a treatment, press “Stop” – “Please Wait” will appear while the pump returns to its resting position
- Once the pump has returned to its resting position, the sleeve will deflate and the LCD 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 “Pause” – “Please Wait” will appear while the pump returns to its resting position

- Once the pump has returned to its resting position, the sleeve will deflate and “Paused, Press to Continue” will appear (remove garment using directions above)
- Press “Press to Continue” to resume treatment

Changing pressure during treatment

- To change pressure during treatment, press and hold the lower right corner of the Touch Screen LCD Display (1) for 5 seconds – “Please Wait” will appear while the pump returns to its resting position
- Once the pump has returned to its resting position, the sleeve will deflate and “Change Pressure Setting” will appear – press “Up” and “Down” to change pressure and “Chamber” to select the next chamber
- Press “Set” when finished and the pump begins to operate again

To See Treatment Compliance Meter (Hours of Use)

- Wake up your device and wait for the “Start” screen to appear
- Press and hold the bottom center of the Touch Screen LCD (1) for 3 seconds until hours of use information appears
- Hours of use will appear for 5 seconds
- To reset the device to Factory Defaults, while the compliance meter is showing press and hold the bottom right corner of the LCD. A message will ask if you want to “Reset to Factory Defaults” – press “No” to return to the “Start” screen and “Yes” to reset.

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-4004-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
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-4008-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, Right
G8-3035-SH-M-L	8-Chamber Arm & Shoulder Sleeve - Medium, Left
G8-3035-SH-M-R	8-Chamber Arm & Shoulder Sleeve - Medium, Right
G8-3035-SH-L-L	8-Chamber Arm & Shoulder Sleeve - Large, Left
G8-3035-SH-L-R	8-Chamber Arm & Shoulder Sleeve - Large, Right
G8-3045-S	8-Chamber Leg Sleeve - Small
G8-3045-M	8-Chamber Leg Sleeve - Medium
G8-3045-L	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
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-4004-DL, SC-4008-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: $\pm 20\%$

Features: Adjustable Cycle Time, Compliance/Usage Meter, Individual Pressure Adjustment in Each Chamber, Focus Therapy, Pause, Pre-Therapy, 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-4004-DL) 3.5 lbs. (1.59 kg)

Weight (SC-4008-DL): 3.85 lbs. (1.75 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 minimized the consumables used
- Reused 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 700-1060hPa

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 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.
RF emissions CISPR 11	Class B	
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
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 _{RMS} in whole range, 6V _{RMS} 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 _T per 0.5 cycles, 0% U _T per 1.0 cycle, 70% U _T per 25/30 cycles
IEC 61000-4-11 Voltage Interruptions	0% U _T per 250/300 cycles

Symbol Glossary

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

	Manufacturer
	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
	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 providing the device to a new patient. To reset the pump, refer to the directions under “To See Treatment Compliance Meter (Hours of Use)” in the Operating Instructions section.

Authorized European Representative

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