Bio Compression's SC-3008-DL

SEQUENTIAL CIRCULATOR

Operating Instructions

BIO COMPRESSION SYSTEMS INC.

Quality Medical Products Since 1983

TÜV SÜD C US CE 0123

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Introduction

Congratulations on your purchase of your sequential circulator and garments.

Package Contents

• Sequential Circulator pump
• Power cord
• Instructions for use
• Blocker bars (2)
• Garment(s) possibly - packed separately

Intended Use

Sequential Circulators are pneumatic compression devices intended for either primary or adjunctive treatment of primary or secondary lymphedema. The devices are also intended for additional or alternate treatment of venous insufficiency and chronic venous stasis ulcers associated with venous insufficiency as well as general treatment for swelling of the extremities. The devices are intended for both home and hospital use.

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)
• Active cancer except for palliative care
• Other indications as identified by the treating physician

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.

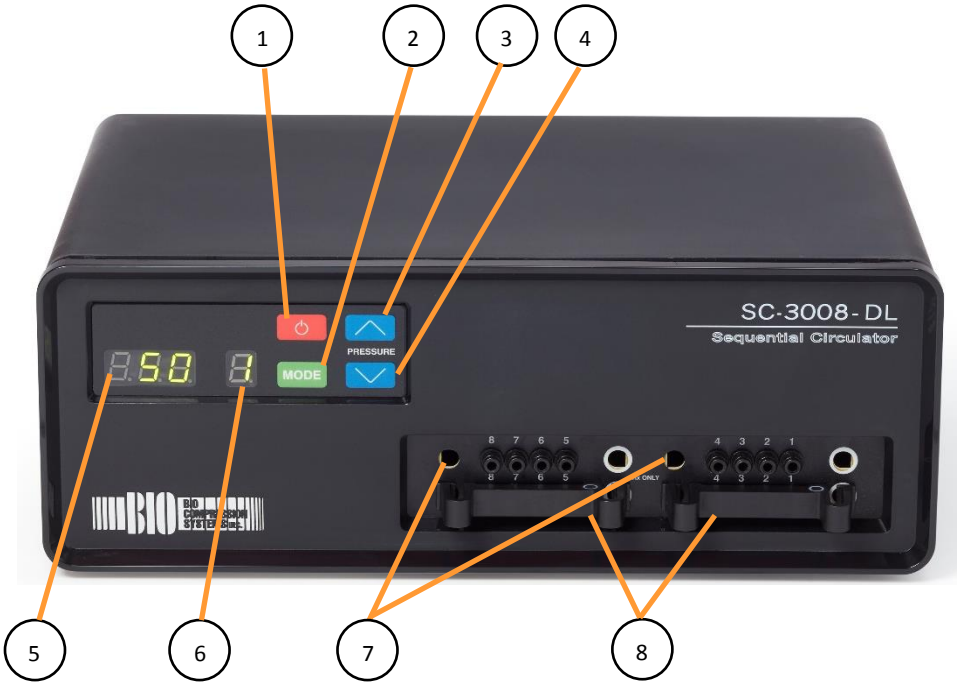
Pneumatic compression devices are proven to reduce limb swelling associated with lymphedema, help close up chronic ulcers, and act as a prophylaxis for Deep Vein Thrombosis (DVT).

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.

Front Panel and Key Features



Key Functions

1. Power On/Off Button
2. MODE Button
3. UP Button
4. DOWN Button
5. LED Readout
6. Chamber Number LED
7. Garment Connector Bar Ports
8. Auxiliary Connector Bar Ports (shown with Blocker Bars)

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
• 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
• Remove garment(s) from plastic bag, unroll, and spread flat

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
• 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

• 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 “Power On/Off” button to turn on
• Hours of use will appear for 5 seconds followed by the mode
• The device will start at a pressure of 50 mmHg for a duration of 1-hour (to change, see below)
• Upon the completion of treatment or to stop treatment, press “Power On/Off” button to turn off
• Wait until light goes out
• 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

To change mode

• Begin with device turned off
• Press “Power On/Off” button

• Within 5 seconds, press and hold MODE button
• Mode will appear (“1Hr” for timed operation, “COn” for continuous, or “PrE” for pre-therapy)
• Press MODE button to change between modes
• While mode says “1Hr” use UP or DOWN button to adjust treatment time
• While mode says “Pre” use UP or DOWN button to turn on or off (“1” for on, “0” for off)
• Press “Power On/Off” button to begin cycle

To change pressure

• Begin with device turned off
• Press “Power On/Off” button
• Within 5 seconds, press and hold UP and DOWN buttons
• Pressure and chamber number will appear
• Use UP or DOWN button to adjust pressure and use MODE button to change chamber number
• Press “Power On/Off” button to begin cycle

Reading the Usage Meter

When the pump is turned on, hours of use will appear for 5 seconds. The letter in the Chamber Number LED represents the first digit – A is 0, B is 1, C is 2, D is 3, E is 4, and F is 5. The remaining digits appear in the LED Readout. For example, if the Chamber Number LED is D and the LED Readout is 013 that represents 3013 hours of use.

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

REF	Description
A8-3045-L	8-Chamber Adjustable Leg Sleeve - Large
A8-3045-M	8-Chamber Adjustable Leg Sleeve - Medium
A8-3045-S	8-Chamber Adjustable Leg Sleeve - Small
G8-3035-L	8-Chamber Arm Sleeve - Large
G8-3035-M	8-Chamber Arm Sleeve - Medium
G8-3035-S	8-Chamber Arm Sleeve - Small
G8-3035-SH-L-L	8-Chamber Arm & Shoulder Sleeve - Large, Left
G8-3035-SH-L-R	8-Chamber Arm & Shoulder Sleeve - Large, Right
G8-3035-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-S-L	8-Chamber Arm & Shoulder Sleeve - Small, Left
G8-3035-SH-S-R	8-Chamber Arm & Shoulder Sleeve - Small, Right
G8-3045-L	8-Chamber Leg Sleeve - Large
G8-3045-M	8-Chamber Leg Sleeve - Medium
G8-3045-S	8-Chamber Leg Sleeve - Small
GBA-3045-L-2	Bio Pants - Large
GBA-3045-L-L	Bio Abdominal - Large, Left Leg
GBA-3045-L-R	Bio Abdominal - Large, Right Leg
GBA-3045-M-2	Bio Pants - Medium
GBA-3045-M-L	Bio Abdominal - Medium, Left Leg
GBA-3045-M-R	Bio Abdominal - Medium, Right Leg
GBA-3045-S-2	Bio Pants - Small
GBA-3045-S-L	Bio Abdominal - Small, Left Leg
GBA-3045-S-R	Bio Abdominal - Small, Right Leg
GN8-3045-L	8-Chamber Narrow Leg Sleeve - Large
GN8-3045-M	8-Chamber Narrow Leg Sleeve - Medium
GN8-3045-S	8-Chamber Narrow Leg Sleeve - Small
GV-3000-8C	8-Chamber Vest
GV-3010-L-2	Elite 8 Vest with Bilateral Arms - Large
GV-3010-L-L	Elite 8 Bio Vest - Large, Left
GV-3010-L-R	Elite 8 Bio Vest - Large, Right
GV-3010-M-2	Elite 8 Vest with Bilateral Arms - Medium
GV-3010-M-L	Elite 8 Bio Vest - Medium, Left
GV-3010-M-R	Elite 8 Bio Vest - Medium, Right
GV-3010-S-2	Elite 8 Vest with Bilateral Arms - Small
GV-3010-S-L	Elite 8 Bio Vest - Small, Left
GV-3010-S-R	Elite 8 Bio Vest - Small, Right
GW8-3045-L	8-Chamber Wide Leg Sleeve - Large
GW8-3045-M	8-Chamber Wide Leg Sleeve - Medium
GW8-3045-S	8-Chamber Wide Leg Sleeve - Small
GWA8-3045-L	8-Chamber Wide Adjustable Leg Sleeve - Large
GWA8-3045-M	8-Chamber Wide Adjustable Leg Sleeve - Medium
GWA8-3045-S	8-Chamber Wide Adjustable Leg Sleeve - Small
GXW8-3045	8-Chamber Extra Wide Leg Sleeve
GXWA8-3045	8-Chamber Extra Wide Adjustable Leg Sleeve

Product Specifications

Models: SC-3008-DL, SC-3008-DL-230
Electrical Rating: 120 VAC, 60 Hz, 0.5 A or 230 VAC, 50 Hz, 0.5 A
Electrical Classification: Class II
Type Applied Part: Type BF
Ingress Protection: IP20
Mains Isolation: Unplug
Mode of Operation: Continuous
Essential Performance: The pump's cyclical inflation and deflation of the garment(s)
Cycle Time: 60 ± 10 seconds (inflation 54 seconds - 6.5 seconds/garment chamber, deflation 6 seconds)
Pressure Range: 0-120 mmHg
Precision: 1 mmHg
Accuracy: ± 20%
Features: Compliance/Usage Meter, Individual Pressure Adjustment in Each Chamber
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: 5.9 lbs. (2.68 kg)
Dimensions: 4.5" x 11.75" x 7.75" (114 mm x 298 mm x 197 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 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°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	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
IEC 61000-4-2 Electrostatic Discharge Immunity	±8kV contact, ±2, 4, 8kV 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

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
IP20	Ingress protection (against solids up to 12.5 mm; no protection from water)

	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 and hold the MODE, UP, and DOWN buttons for 5 seconds.
• LED Readout will light up.
• Release the buttons and then press the MODE button.

Contact Information

Manufacturer

Bio Compression Systems, Inc.
120 West Commercial Avenue
Moonachie, NJ 07074, USA
Phone: +1-201-939-0716
Toll-Free Phone (US): 800-888-0908
E-mail: biosystems@biocompression.com
Website: www.biocompression.com

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

Authorized European Representative

Emergo Europe
Prinsessegracht 20
2514 AP, The Hague
The Netherlands

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