

BIOCOMPRESSION PUMP SC 2008 OC USER MANUAL



Indications for safe use

This product is intended for use by health professionals or patients who are under clinical supervision.



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1. Introduction

Congratulations on the purchase of your Bio Compression Systems SC-2008-OC Sequential Circulator and accompanying garment(s).

The following manual will provide information regarding the technical specifications and use of this device.

INTENDED USE

The Sequential Circulators SC-2008-OC are pneumatic compression devices intended for either primary or adjunctive treatment of primary or secondary lymphoedema and lipoedema. 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. These devices provide sequential (distal to proximal) inflation and deflation cycles of compressed air at pressures. Sequential gradient compression helps to increase blood flow and move excess lymph away from the affected area for clearance from the body.

2. Warnings and Precautions

Warnings:

- The settings navigation guide will provide general information for compression pump usage that may not apply to each individual's circumstances. Consult with your treating therapist regarding specific advice regarding your individual treatment parameter settings of pressure, duration, and treatment frequency.
- Pressure settings should not be changed unless ordered by a clinician. High pressure should be set with caution.
- Caution must be exercised for patients with sensitive, irritated, sunburned, bruised or broken skin, or with skin conditions such as skin cancer, dermatitis, eczema, or psoriasis in/around treatment sites.
- Should changes in skin appearance occur such as blisters, redness, welts, discoloration or other noticeable changes in the skin, or if burning, itching, increased swelling should occur, discontinue use and consult with your therapist or doctor.
- Slip and fall hazard. To avoid the risk of tripping or falling, do not stand or walk while wearing garments.

Precautions:

- This device is not intended for use during SLEEP.
- Do not attempt to modify this device in any way.

Contraindications

Compression is NOT recommended in the following conditions:

- Cellulitis or other infection not treated with antibiotics
- The presence of lymphangiosarcoma
- Known or suspected deep vein thrombosis (DVT)
- Inflammatory phlebitis or episodes of pulmonary embolism
- Uncontrolled/severe cardiac failure
- Active metastatic disease affecting oedematous region
- Thrombophlebitis
- Pulmonary oedema

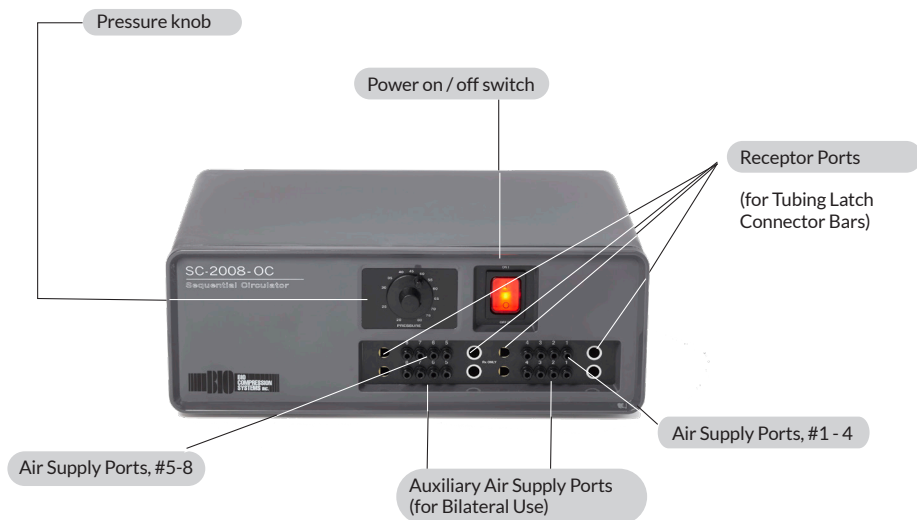
Under Clinical Consultation

Compression pumps may be used with these conditions **under clinical consultation**. Pressure settings may need to be started lower than usual and progressed according to tolerance.

- Acute infection
- An ABPI less than 0.8 or greater than 1.2
- High arterial blood pressure
- Cardiac arrhythmia or cardiac stenosis
- Controlled heart failure
- Artificial material in body e.g. breast implants/tissue expanders
- be guided by comfort levels*
- Lipoedema*
- Acute inflammation*
- Scleroderma*
- Chronic polyarthritis*
- Complex regional pain syndrome*
- Peripheral neuropathy*

* Potential to increase pain or discomfort in some cases

3. Product description - Device



Blocker Bars (uninstalled)

Please note

Your clinician should prescribe suggested settings for your particular condition.

3. Product description - Device

PACKAGE CONTENTS

- 1 - SC-2008-OC Sequential Circulator ("pump")
 - 1 - User manual
 - 1- General settings navigation guide
 - 1 - Quick set-up guide
 - 2 - Blocker Bars for use during single garment therapy
 - 1 - Power Cord
- Necessary garments ordered

LATCH CONNECTORS

Attach and detach the garment to the pump via the Receptor Ports and Air supply ports depicted in the illustration to the left. A second garment may be attached to the Auxiliary Air Supply Ports for bilateral use. (IMPORTANT: Keep the Blocker bars installed for single garment use).

TUBING

Responsible for delivering air to and from the pump and garment.

COMPRESSION GARMENTS

Garments contain either 8 or 16 chambers, which work in conjunction with the Sequential Circulator to apply controlled, sequential pressure throughout the chambers.

3. Product description - Garments

16 Chamber Pants



8 Chamber Legs



3. Product description - Garments / Accessories

Arm Vest



Optional Accessories

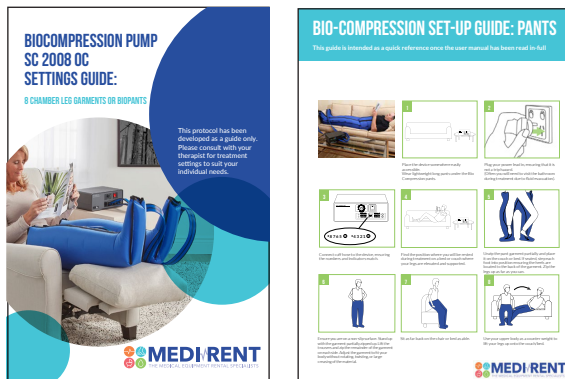


Carry bag

4. Setting up the Pump

Please refer to the Quick Guide and General Settings Guide to set up your pump, apply garments and configure settings.

*PLEASE NOTE: You should be guided by a clinician regarding what settings you should apply for treatment including pressure, cycle time and therapy duration.



Pressure sensor

The pressure sensor monitors and adjusts the garment pressure throughout inflation to ensure filling of the garment approximates the pressure setting on the device.

The function of the sensor enables appropriate filling regardless of the size or style of garment attached to the controller or the limb size within the garment.

It is normal for the garment to feel loose during the first few cycles before the unit fills each chamber to the selected pressure. This may take longer for the arm-vest.

If the system doesn't reach set pressure, then the device will alarm indicating there is a fault with either the garment or the controller. Please see 'Troubleshooting Guide' later in this booklet to determine the cause of the fault and how to rectify it.

5. Safety Information

WEEE Marking





This marking shown on the product or its literature, indicates that it should not be disposed with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this from other types of waste and recycle it responsibly to promote the sustainable reuse of material resources.



Household users should contact Local Council about how and where they can dispose of this item for environmentally safe recycling.

Business users should contact their supplier and check the items and conditions of the purchase contract. This product should not be mixed with other commercial waste for disposal.


Electrical Safety

 <p>prohibited</p>	<ul style="list-style-type: none"> • Only use the supplied AC cord. Inspect the cord and plug for any damage. • To prevent fire or electric shock never plug the device in if any damage is evident. • Stop using the device if you smell electrical burning whilst using the device. In this case, turn off the electric power, pull out plug from outlet, and then inform the service centre. • Grip the plug, not the power cord when inserting or removing the plug from the power outlet. • Never handle device or power connect with wet hands (Electric shocks possible) • Do not bend or twist the power cord.
 <p>caution</p>	<ul style="list-style-type: none"> • To protect device from electrical damage, disconnect it from the power outlet when not in use or during electrical storms.

Regarding Garments

 <p>prohibited</p>	<ul style="list-style-type: none"> • Never apply garments over bare skin, always apply over light clothing or cotton disposable boot liners. (Garment life can be reduced by sweat or cosmetics) • Do not inflate garments with any other device other than the Biocompression Controller. • Never expose garments to oil, benzene, alcohol, hydrocarbons etc. For cleaning refer to the Maintenance and Storage section of this manual.
 <p>caution</p>	<ul style="list-style-type: none"> • Remove jewellery from limbs before use (Damage to garment possible) • Do not expose garments to any heat sources • Do not keep garments near dangerous sharp objects such as needles and scissors

Safety for Body

 <p>caution</p>	<ul style="list-style-type: none"> • Always supervise children when near the device. Serious injuries could be sustained if the unit is used inappropriately. • Do not apply air hose to nose, mouth or ears (Injuries possible) • Seek medical approval when in use by individuals with heart conditions - pacemaker, heart transplant, uncontrolled heart failure etc • Never apply garments to bare skin, always use while wearing thin clothes or liners. Zip the garment the entire way closed to avoid damage to the skin during application. • Stop using the device if you feel any abnormal condition during use and consult your doctor or therapist. • Use the device under the supervision and guidance of your health professional.
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6. Troubleshooting

Stop the device during operation




* Stop the operation of the device and seek medical advice if the following occurs:

1. Difficulty breathing or dizziness
2. Pain in any body part during compression that continues even when the treatment has stopped
3. Temporary body paralysis

Recommendation

* Seek advice from your health professional with regard to setup and progression of pressure, mode, and speed treatment parameters to ensure effective and safe use with consideration of your specific medical history and presenting condition.

Use and Maintenance

 prohibited	<ul style="list-style-type: none"> • Use the device indoors between 0-40°C • Do not use or keep the device near heating equipment or direct sunlight (Defects and flammable accidents possible)
 warning	<ul style="list-style-type: none"> • Do not use the device in high humidity (Bathroom and sauna etc). (Flammable accidents, electric shocks possible)
 caution	<ul style="list-style-type: none"> • Keep the device upright. (Defects or malfunctions possible)

Symptom	Possible Cause	Corrective Action
The device is not working.	No electricity	Check the electrical wall outlet to be sure that the pump is plugged into the outlet correctly. Check the circuit breaker to be sure there is power to the outlet.
	Power cord	Unplug the power cord and look for any damage or defects.
One garment inflates but the second one does not.	The second garment is not receiving air.	Check the garment hoses for adequate connection to the device, kinks, punctures, twists and /or folds.
The device is making strange and/or loud noises.	Device is on an uneven or unstable surface.	Move to a more stable surface.
	An internal problem	Contact Medi-Rent for repair or replacement.
Regardless of the pressure setting the garments are applying a very low pressure.	Defective garment	Check the garment for adequate connection to the device, leaks, kinks, punctures, twists and /or folds.
	An internal problem	Contact Medi-Rent for repair or replacement.

7. Maintenance and Storage

Exterior Pump Case Cleaning instructions:

1. Clean the exterior case and tubing with a damp (not wet) cloth using mild soap and water solution once per month.

WARNING!

- Only an authorized technician may open the pump
- Before cleaning, unplug power cord from electrical outlet

Garment cleaning/disinfecting instructions:

2. Disconnect garment from device.
3. Open garment to expose all sides either by separating Velcro type hook and loop or by unzipping (depending on type of garment).

WARNING!

- Do not allow liquids to enter pump, as this can present an electrical hazard
 - Always allow the pump to dry before using
 - Do not use bleach on the pump
4. Wipe the garments thoroughly with a ph neutral cleaner or Clinell wipes. Solutions with alcohol should be avoided.

WARNING!

- Never allow the Latch Connectors to be submerged into the water. If water enters the inside of the garment, damage may occur to the device.
- DO NOT place garment in washing machine.
- WARNING! DO NOT use the tubing or valves as “handles” for carrying, handing or storing garment.

The unit contains no user serviceable parts and should only be serviced by a competent electrical technician or returned to Medi-Rent Pty Ltd or your local authorised dealer.

All Biocompression products should be serviced regularly by Medi-Rent Pty Ltd or an authorised dealer in order to comply with warranty conditions.

NB. Before returning equipment to Medi-Rent Pty Ltd for service, be sure that it has been properly cleaned and disinfected in accordance with local health service guidelines.

8. Specifications

General Equipment Specifications

Dimensions	11.43 H x 29.86 W x 19.69 D cm	Weight	2.5kg
Inflation/Deflation	44/5.5 Seconds	Cycle Time	5.5 Secs / chamber
Electrical	120 VAC, 60 Hz, 0.5 A (USA) 230 VAC,	Applied Part	Type B
Protection against Electrical Shock	CLASS II (USA) CLASS IIa (EU)	Operation Mode	Continuous Operation

Environmental Conditions


For Operation	
Ambient temperature:	+10°C - +44°C
Relative humidity:	30% - 75%
Atmospheric pressure:	700hPa to 1060hPa

For Transport and Storage	
Ambient temperature:	+10°C - +44°C
Relative humidity:	30% - 75%
Atmospheric pressure:	700hPa to 1060hPa

Electrical Specifications/Equipment Classification

The Sequential Circulator SC-2008-OC interior components are “double insulated” and do not require a “protective ground.” The devices are equipped with 18 gauge, 2-wire, 10' Power Cords, secured through the pump casings with a Heyco strain relief brushing, as well as, an additional “hold-down” clamp for added safety.

- Class of protection against electrical shock: CLASS II EQUIPMENT
- The degree of protection against electric shock: APPLIED PART-TYPE B
- Mode: CONTINUOUS OPERATION WITH INTERMITTENT LOADING
- According degree of protection against ingress of water: IXPO

Guidance and Manufacturer's Declaration — Electromagnetic Immunity			
The SC-2004-OC/SC-2004FC-OC/SC-2008-OC are intended for use in the electromagnetic environment specified below. The customer or the user of the SC-2004-OC/SC-2004FC-OC/ C-2008-OC should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Conducted RF IEC 61000-4-6	3 Vrms 15 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the model SC-2004-OC/SC-2004FC-OC/SC-2008-OC, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 1000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply to all situations. Electromagnetic propagations is affected by absorption and reflections from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model SC-2004-OC/SC-2004FC-OC/SC-2008-OC is used exceeds the applicable RF compliance level above, the model SC-2004-OC/SC-2004FC-OC/SC-2008-OC should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the model SC-2004-OC/SC-2004FC-OC/SC-2008-OC.			
^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Model SC-2004-OC/SC-2004FC-OC/SC-2008-OC Electromagnetic Emissions—Manufacturer's Declaration		
The SC-2004-OC/SC-2004FC-OC/SC-2008-OC are intended for use in the electromagnetic environment specified below. The customer or the user of the SC-2004-OC/SC-2004FC-OC/SC-2008-OC should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment—guidance
RF emissions CISPR 11	Group 1	The model SC-2004-OC/SC-2004FC-OC/SC-2008-OC 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. The model SC-2004-OC/SC-2004FC-OC/SC-2008-OC 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	

Recommended separation distances between portable and mobile RF communications equipment and the SC-2004-OC/SC-2004FC-OC/SC-2008-OC			
The SC-2004-OC/SC-2004FC-OC/SC-2008-OC are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the SC-2004-OC/SC-2004FC-OC/SC-2008-OC can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SC-2004-OC/SC-2004FC-OC/SC-2008-OC as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	$d = 1.2\sqrt{P}$ 150 kHz to 80 MHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz	$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: At 80 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
The SC-2004-OC/SC-2004FC-OC/SC-2008-OC are intended for use in the electromagnetic environment specified below. The customer or the user of the SC-2004-OC/SC-2004FC-OC/SC-2008-OC 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	± 2, 4, and 6 kV contact ± 2, 4 and 8 kV air	± 2, 4, and 6 kV contact ± 2, 4 and 8 kV air	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 / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV Not applicable	Mains power quality should be that of a typical home use location.
Surge IEC 61000-4-5	± 0.5 and 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 0.5 and 1 kV differential mode Not applicable, no ground wire	Mains power quality should be that of a typical home use location.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0.5 cycles 40 % U_T (60% dip in U_T) for 6 cycles 70 % U_T (30% dip in U_T) for 30 cycles <5 % U_T (>95% dip in U_T) for 5 s	<5 % U_T (>95% dip in U_T) for 0.5 cycles 40 % U_T (60% dip in U_T) for 6 cycles 70 % U_T (30% dip in U_T) for 30 cycles <5 % U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical home use location. If the user of the model SC-2004-OC/SC-2004FC-OC/SC-2008-OC requires continued operation during mains power interruptions, it is recommended that the model SC-2004-OC/SC-2004FC-OC/SC-2008-OC be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic fields should be at the levels found in a typical home use location.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

9. Repair Service and Warranty

Repair Service Information

Technical Support—please call for all service repairs. Model and Serial numbers are required for all service inquiries.

Phone AU: 1300 726 666

International call to AU: 612 9700 1744

Phone NZ: 09 972 3068

Warranty Information

CAUTION: Tampering with or dismantling the Sequential Circulator in any way shall void the warranty on the device.

Warranty repairs or adjustments shall be performed in a timely manner with minimal inconvenience. For this reason, it is important that you obtain a “Return Material Authorization” Number (RMA #) when calling Customer Service.

You can feel confident that your product is backed by the best warranty in the industry, covering any and all malfunctions (including parts and labour) resulting from component and/or manufacturing defects.

Compression Pump = 3 years from date of purchase / invoice

Sleeves/Garments = 1 year from date of purchase / invoice

Serial Number: _____

Date Purchased: _____



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