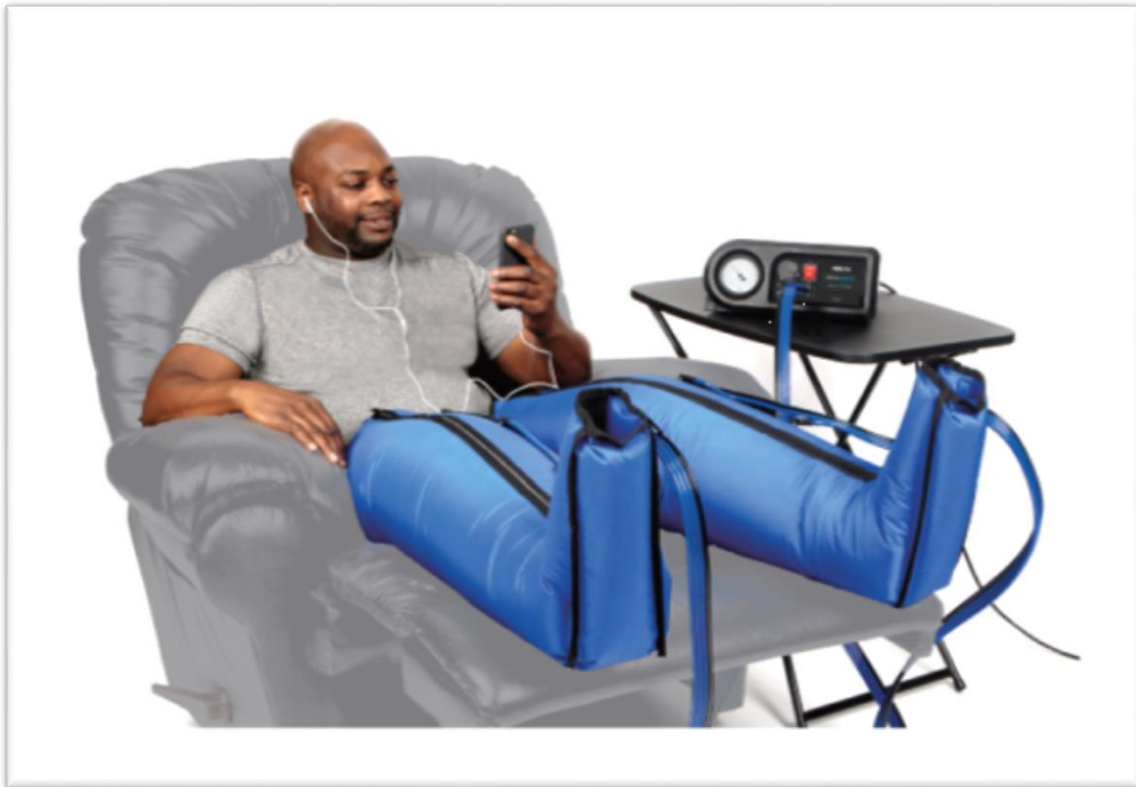


# *Bio Compression's SC-2004-C*



## **SEQUENTIAL CIRCULATOR Operating Instructions**



Quality Medical Products Since 1983



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## Introduction

Congratulations on the purchase of your BioCryo Cold Compression System model SC-2004-C.

### Package Contents

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

### Intended Use

The BioCryo Cold Compression System model SC-2004-C is a gradient, sequential, pneumatic compression device, intended for the primary treatment of tendinitis, hamstring pulls, joint inflammation edema, post-op injuries, soft tissue injuries, acute sprains, bruises and other musculoskeletal injuries. This device is 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)
- Cryo Therapy is not recommended for patients with lymphedema
- Active cancer except for palliative care
- Other indications as identified by the treating physician

### Device Description and Operating Principle

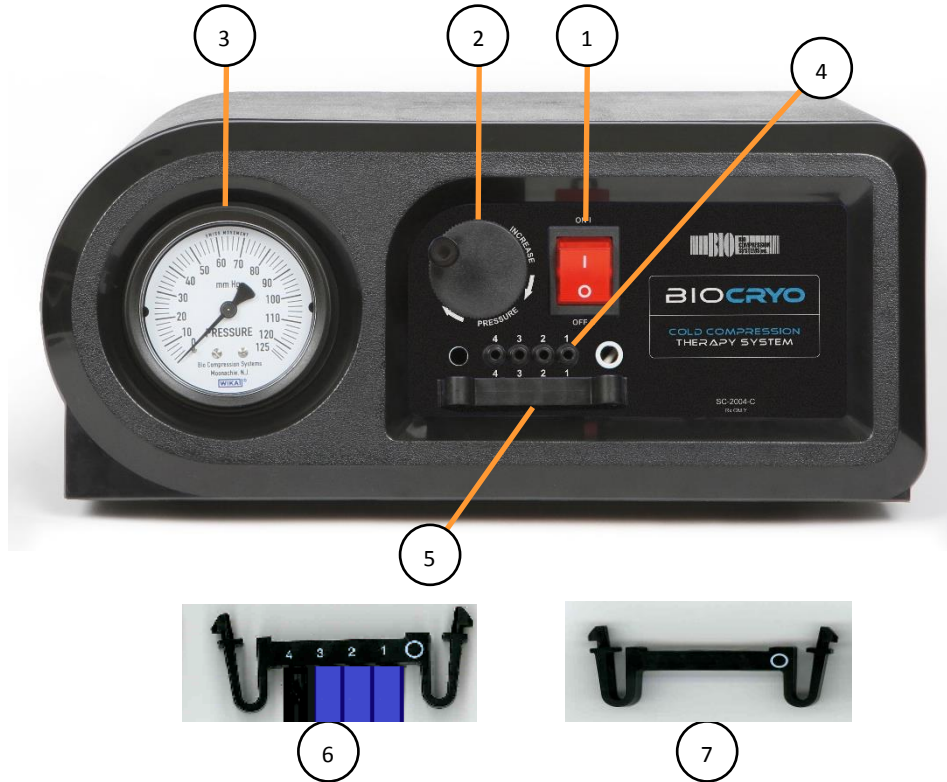
The BioCryo Cold Compression System model SC-2004-OC Sequential Circulator provides gradient pneumatic compression and cold therapy at the same time. Sequential gradient compression helps to increase blood flow to the affected area. Pneumatic compression devices are proven to reduce limb swelling. Garments come with a water-based gel insert that maintain a constant temperature of 40° F (4° C).

## 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. Pressure Knob
3. Pressure Gauge
4. Garment Connector Bar Ports
5. Auxiliary Air Supply Port (shown with Blocker Bar)
6. Garment Connector Bar
7. Blocker Bar (uninstalled)

## 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
- Cold therapy products for more than 20 minutes every two hours
- 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
- Peripheral arterial occlusive disease
- Circulatory problems or problems in sensing heat or cold

## **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
- Plug power cord into outlet
- Remove garment(s) from plastic bag, unroll, and spread flat
- Place gel insert flat in freezer for 4 hours - do not place directly on metal rack as this could damage inset

### 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
- 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
- Set pressure by turning knob
- Press “Power On/Off” button to turn on
- Run for treatment time determined by physician
- 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

## **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
- Do not store cold therapy garments on metal freezer racks

### **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
CI-3035-B	Cryo Insert - Back
CI-3035-E	Cryo Insert - Elbow
CI-3035-H-W	Cryo Insert - Hand/Wrist
CI-3035-SH	Cryo Insert - Shoulder
CI-3045-A	Cryo Insert - Ankle
CI-3045-K	Cryo Insert - Knee
CP-L	BioCryo Gel Insert - Large
CP-M	BioCryo Gel Insert - Medium
CP-S	BioCryo Gel Insert - Small
GC-3035-B	BioCryo Back
GC-3035-EC	BioCryo Elbow
GC-3035-H-W	BioCryo Hand/Wrist
GC-3035-SH-C	BioCryo Isolated Shoulder
GC-3045-A	BioCryo Ankle
GC-3045-KC	BioCryo Knee

## Product Specifications

Models: SC-2004-C, SC-2004-C-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:  $90 \pm 10$  seconds (inflation 72 seconds - 18 seconds/garment chamber, deflation 18 seconds)

Pressure Range: 0-120 mmHg

Precision: 2 mmHg

Accuracy:  $\pm 20\%$

Warranty: Pump 3 years, garment 1 year

Expected Service Life: 5 years

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

Weight: 8 lbs. (3.62 kg)

Dimensions: 5.5" x 12" x 8" (140 mm x 305 mm x 203 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 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, 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 <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% U <sub>T</sub> 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; no protection from 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

## 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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