BIO COMPRESSION SYSTEMS INC.

Quality Medical Products Since 1983

REF SC-2004-C

Instructions For Use
BioCryo Cold Compression System
Model #SC-2004-C
Sequential Circulator

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.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

DESCRIPTION OF SYMBOLS:

	Consult instructions for use
	Refer to Documentation before using and servicing
	CAUTION
	Type B - applied part
	Electrical shock hazard. Disconnect LINE CORD before servicing; refer servicing to qualified service personnel
	Federal (USA) law restricts this device to sale by or on the order of a physician
IPX0	Without protection against ingress of water
	Class II Protection
	Serial Number
	Waste Electrical Goods Recycled
	Authorized Representative in the European Community
	Conforms with the Medical Device Directive (93/42/EEC) and has been subject to the conformity procedures in the council directive
	Manufacturer
	Catalog / Model Number
	Keep Dry

CONTRAINDICATIONS:

Compression is NOT recommended in the following conditions:

- Infections in the limb, including cellulitis without appropriate antibiotic coverage
- The presence of lymphangiosarcoma
- Deep Vein Thrombosis (DVT)
- Inflammatory phlebitis or episodes of pulmonary embolism
- Congestive Heart Failure (CHF)
- Cryo Therapy is not recommended for patients with lymphedema

WARNINGS AND PRECAUTIONS

⚠ Warnings:

- Pressure settings should not be changed unless ordered by a physician. High pressure should be set with caution on patients with peripheral arterial occlusive disease.
- Caution must be exercised for patients with insensitive, 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 a physician.
- 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.
- To prevent the potential for reverse pressure and retrograde flow, do not adjust the gradient pressures without a physician's supervision.

INTRODUCTION

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

DEVICE DESCRIPTION AND OPERATING PRINCIPLE

The BioCryo Cold Compression System Model #SC-2004-C is a state-of-the-art cold therapy pneumatic compression device that safely administers sequential, gradient pneumatic compression and CryoTherapy combined. The BioCryo Cold Compression System Model #SC-2004-C is portable, easy to operate and can treat two extremities simultaneously.

PACKAGE CONTENTS

1 - BioCryo Cold Compression System Model #SC-2004-C Sequential Circulator ("pump")
1 - Instructions for Use (IFU)
2 - Blocker Bars for use during single garment therapy
0 - Garments (Garments provided separately)

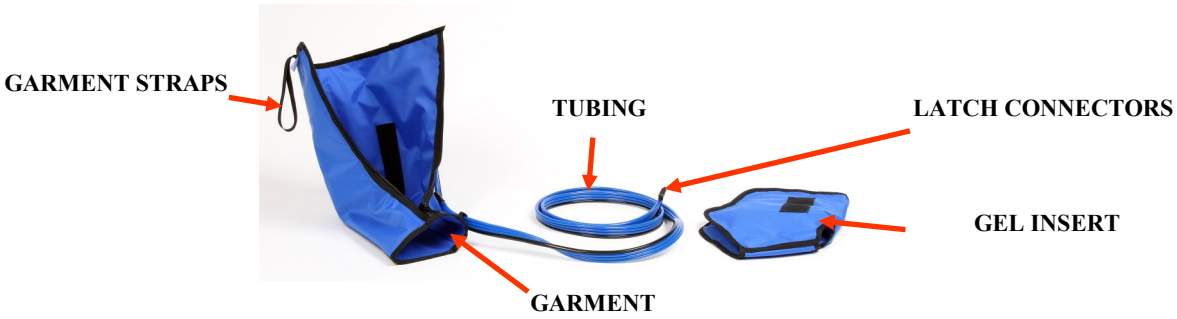
GARMENTS

Caution: Do not share garments with other users.

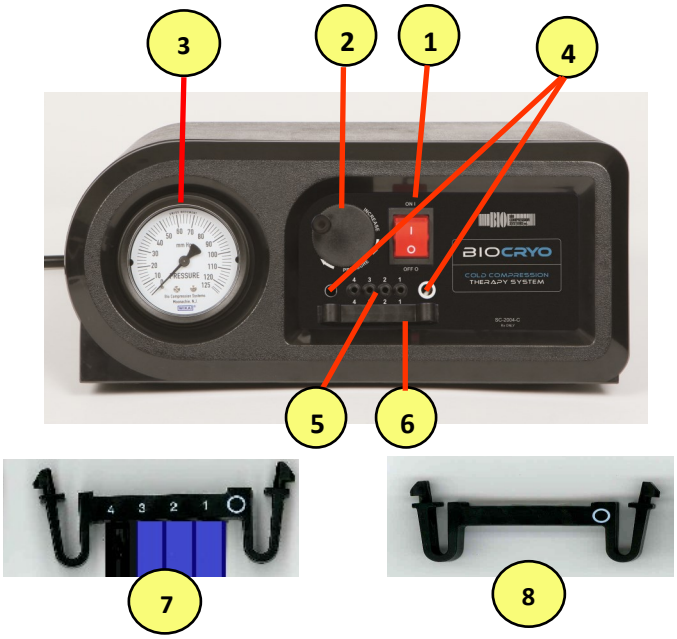
The BioCryo Cold Compression System Model #SC-2004-C garments are available in various configurations, which ensure effective treatment and maximum comfort. The BioCryo Cold Compression System garments delivery a sequential gradient pneumatic compression and Cryo Therapy at the same time. Our cryo garments come with a water-based gel. We also offer cryo -gel inserts that fit into our standard garments. The BioCryo Cold Compression System maintains a constant 40°F skin interface temperature for several hours.

4 Chamber Full Leg Cryo Garment (for use with BioCryo Cold Compression System Model #SC-2004-C)

4 Chamber Ankle Cryo Garment (for use with BioCryo Cold Compression System Model #SC-2004-C)



FRONT PANEL—SC-2004-C



Key Functions

1	Power On/Off Switch
2	Pressure Knob, Locking
3	Pressure Gauge
4	Receptor Ports (for Tubing Latch Connector Bars)
5	Air Supply Ports , #1 - 4
6	Auxiliary Air Supply Ports (for Bilateral Use, shown with Blocker Bars Installed)
7	Tubing Latch Connector Bars (shown on the end of Tubing)
8	Blocker Bars (shown inserted in Auxiliary Air Supply Ports in #7 above)

LATCH CONNECTORS

Attach and detach the garment to the pump via the Receptor Ports (for Tubing Latch Connector Bars), depicted by #4 in the illustration above. 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 GARMENT

Garment with 4 chambers, which works in conjunction with the Sequential Circulator to apply controlled, sequential pressure throughout its chambers.

OPERATING INSTRUCTIONS

Unpacking Equipment

1. Open the shipping box and lift the device up and out of the box.
   (Maintain shipping box for future use. Equipped with a special fold-up handle for ease of use).

2. Remove the protective end caps from the sides of the device.

3. Remove the garment from the plastic bag and unroll the tubing.
   Unfold the garment and spread it flat.

4. Place garment/s or insert/s into the freezer. (Initial freezing time should take 3-4 hours, depending on freezer temperature). It is best to wipe any moisture from the outside of the pack prior to freezing.
   (DO NOT store these items directly on any metal racks as the extreme temperature of the cold metal can damage the pack. These items should be stored flat in the freezer, not folded.)

Preparing for Treatment

5. Place the device on a flat and sturdy surface in close proximity to the patient.

6. Plug the power cord into a safe electrical outlet. A grounded outlet is not required.

7. Remove the garment/s or insert/s from the freezer. If using an insert attach insert to the inside of your garment. As a safety precaution, we advise that a stockinette be worn so the garment does not have direction contact with the skin.

8. After you have your cryo garment set locate the Latch Connectors Bars, numbered 1-4, at the end of the garment tubing.

9. Hold in one hand with numbers facing upward. Squeeze the sides of the Latch Connector Bar and insert receptor ports into the corresponding numbered air supply ports. There shall be an audible 'click' once fully engaged.

10. If two (2) garments are being used simultaneously, remove the Blocker Bars, and attach the Latch Connector Bars to the corresponding numbered auxiliary ports.

Affixing the Compression Garments

Caution: Do not wear garments directly on bare skin. Always wear light clothing, light bandages, clean hosiery or stockinettes underneath garments for hygienic purposes and to prevent skin irritation. Clothing must be free of zippers, buttons and other items that could rub and chafe the skin or damage the compression garment.

11. *Leg Garments* - Carefully unzip the garment fully without separating the zipper at the end. Place foot at bottom end of garment and use garment straps to guide garment onto the leg. Once garment is fully in place, pull zipper up to secure garment around the leg.

12. *Arm Garments* - Slide arm through the internal cavity of the garment.

Powering On the Sequential Circulator

13. For patients using a lower limb sleeve, the patient shall be seated in a reclined position, legs elevated within easy reach of the Sequential Circulator.

14. Press the "Power On/Off" button to turn the pump on.

15. Within several seconds, the pump shall begin producing air pressure. The air pressure may be set in the same position as the previous treatment. Factory default pressure is 50 mmHg in the chamber #1, decreasing incrementally as it moves distally to proximally between zones.

Setting the Air Pressure on the Sequential Circulator

16. Turn Pressure Knob to the prescribed setting.

17. The Pressure Knob determines the pressure in the distal chamber. Once set, the Sequential Circulator shall automatically set the subsequent pressure zones within the garment, by incrementally decreasing each zone as the air pressure moves distally to proximally.

18. Treatment time shall be determined by physician. Adhere to physician's instruction on time allotted for each treatment.

Powering Off the Sequential Circulator

19. Upon completion of treatment, press the "Power On/Off" button to turn off the pump. Please note that when the pump is shut off the light on the On/Off Power button may remain lit until the timer has completed its cycle. Once it has completed it's cycle it will automatically shut-off.
20. Prior to removing the garment, squeeze the sides of the Latch Connector Bars and detach from pump by pulling outward away from pump. This will fully detach the garment from the pump.
21. Repeat removal procedure for any additional garments being used.

⚠ CAUTION*:* In case of power failure, the Sequential Circulator shall automatically power off. The pump does not have a battery backup nor timer memory. Once power is restored, the Sequential Circulator will need to be powered on in order to resume treatment. User must keep apprised of allotted treatment time.

GENERAL GUIDELINES FOR TREATMENT

⚠ Physician must prescribe settings for use with this device. The general guidelines below are for informational purposes only and should not replace settings provided by physician. 60mmHg is an effective setting for many patients. Physician must provide patient's settings.

The presence of fibrotic tissue may require a pressure of 80mmHg in order to soften the fibrotic tissue and achieve reduction. Once tissue softens, compression may be reduced to 60mmHg, if determined by physician

It is suggested that treatment regimens for this device be limited to 20 minutes every two hours or as prescribed by a doctor.

Patients with a history of Congestive Heart Failure (CHF), which is controlled by medication, should never be in a flat position while using the Sequential Circulator. These patients should be in a reclined position with their legs elevated during treatment.

Patients with a history of Deep Vein Thrombosis (DVT), with or without a filter, may require less compression pressure, 40mmHG is generally tolerable but must be prescribed by a physician. It is suggested that the provider obtain a Negative Doppler Study from the physician for their records.

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:

Disconnect garment from device.

2. 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**

3. Cleaning solution should consist of 1/3 cup of laundry detergent per 1 gallon of warm tap water. Use either a large sink or plastic tub able to hold enough solution (depending on size and quantity of garments) to completely submerge the garment leaving the latch connector bars out of the water.

4. Garment should be soaked for 30 minutes with mild agitation every 5 to 10 minutes while keeping it below water surface.

5. Thoroughly rinse garment with warm tap water and allow to air dry.

⚠ • **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.**

6. Harder to remove soil on surface of garment may require additional washing by hand with a clean towel while submerged. Avoid using any abrasive materials such as scrubbing pads or chemicals that could cause damage to the exterior surface of garment.

7. Re-Submerge garment for 30 minutes (with exception of tubing connectors) in solution consisting of 1 cup of bleach per 1 gallon of warm tap water, again agitating garment every 5 to 10 minutes while keeping garment below water surface. Rinse garment thoroughly with warm tap water and allow to air dry. This completes the disinfecting step.

⚠ • **WARNING! DO NOT place garment in washing machine.**

⚠ • **WARNING! DO NOT use the tubing or valves as "handles" for carrying, handing or storing garment.**

TROUBLESHOOTING

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 a uneven or unstable surface	Move to a more stable surface.
	An internal problem	Contact Bio Compression Systems, Inc., for repair.
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 Bio Compression Systems, Inc., for repair.

If the corrective action does not resolve the problem, please call Bio Compression Systems, Inc., at 1-800-888-0908. Serial number is required when calling for service.

REPAIR SERVICE INFORMATION

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

Toll Free	800-888-0908.
Phone/OUS	201-939-0716

⚠ 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.

WARRANTY INFORMATION

You can feel confident that your product is backed by the best warranty in the industry, covering any and all malfunctions (including parts and labor) 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: _____

Local Representative/Dealer: _____

Phone Number: _____

DISPOSAL OF DEVICE 

Medical equipment and devices should be disposed of in proper containers that meet Environmental Protection Agency standards. Check with your local, regional and national laws and regulations for specific requirements.

4 CHAMBER GARMENT SPECIFICATIONS - (for use with SC-2004-C)

PRODUCT	APPLICATION	SIZE	SIDE
GC-3035-S	Arm	Small	
GC-3035-M	Arm	Medium	
GC-3035-L	Arm	Large	
GC-3035-SH	Arm & Shoulder	One Size	
GC-3035-EC	Elbow	One Size	
GC-3035-H-W	Hand/Wrist	One Size	
GC-3035-B	Back	One Size	
GC-3045-A	Ankle	One Size	
GC-3045-S	Full Leg	Small	
GC-3045-M	Full Leg	Medium	
GC-3045-L	Full Leg	Large	
GC-3045-KC	Knee	One Size	
CP-S	Cryo-Patch	Small	
CP-M	Cryo-Patch	Medium	
CP-L	Cryo-Patch	Large	

GENERAL EQUIPMENT SPECIFICATIONS

DIMENSIONS:	5.5” (H) x 12” (W) x 8” (D)
WEIGHT:	8 lbs.
INFLATION:	72 Seconds
DEFLATION:	18 Seconds
CYCLE TIME:	18 Seconds / Chambers
ELECTRICAL:	120 VAC, 50 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
PROTECTION MODE AGAINST WATER:	IPX0

ENVIRONMENTAL CONDITIONS

FOR OPERATION	
AMBIENT TEMPERATURE:	+50°F - +110°F (+10°C -+40°C)
RELATIVE HUMIDITY:	30% - 75%
ATMOSPHERIC PRESSURE:	700hPa to 1060hPa

FOR TRANSPORT AND STORAGE	
ATMOSPHERIC PRESSURE:	-20°F - + 110°F (10°C- +40°C)
RELATIVE HUMIDITY:	30% - 75%
ATMOSPHERIC PRESSURE:	700hPa - 1060hPa

ELECTRICAL SPECIFICATIONS/EQUIPMENT CLASSIFICATION

The BioCryo Cold Compression System, 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: IXP0

Guidance and Manufacturer's Declaration — Electromagnetic Immunity

The SC-2004-C are intended for use in the electromagnetic environment specified below. The customer or the user of the SC-2004-C 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 Radiated RF IEC 1000-4-3	3 Vrms 15 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the model SC-2004-C, 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:

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-C is used exceeds the applicable RF compliance level above, the model SC-2004-C 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-C.

[b] Over the frequency range 150 kHZ to 80 MHz, field strengths should be less than 3 V/m.

Model SC-2004-C Electromagnetic Emissions—Manufacturer's Declaration

The SC-2004-C is intended for use in the electromagnetic environment specified below. The customer or the user of the SC-2004-C 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-C 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 model SC-2004-C 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	

Recommended separation distances between portable and mobile RF communications equipment and the SC-2004-C

The SC-2004-C are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer of user of the SC-2004-C can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SC-2004-C 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 m**		
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**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-C are intended for use in the electromagnetic environment specified below. The customer or the user of the SC-2004-C 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, and6 kV contact ± 2, 4 and 8 kV air	± 2, 4, and6 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-C requires continued operation during mains power interruptions, it is recommended that the model SC-2004-C 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.

See Other Quality Sequential Circulators and Compression Garments

- **Sequential Circulator Model SC-2004, SC-2004-FC & SC-2004-OC**
- **Sequential Circulator Model SC-3004, SC-3004-FC & SC-3004-DL**
- **Sequential Circulator Model SC-3008-T & SC-3008-DL**
- **Sequential Circulator Model SC-2008 & SC-2008-OC**
- **Multi-Flo DVT Combo Prophylaxis System**
- **Bio Arterial Plus (Arterial Blood Flow Enhancement System)**
- **Compression Garments**
  (Including Custom Garments with the fastest turn around in the industry!)

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