

OPERATING INSTRUCTIONS

SEQUENTIAL CIRCULATORS

MODEL 2004



MODEL 3004



BIO COMPRESSION SYSTEMS, INC.

www.biocompression.com

Phone: 800-888-0908



U.S. BASED MANUFACTURER

Congratulations on the purchase of your
BIO COMPRESSION SYSTEMS
MODEL # SC-2004 /MODEL # SC-3004
SEQUENTIAL CIRCULATOR SYSTEM.

The durable, high quality material used in the manufacturing of this product will ensure you long lasting performance.

On rare incidences when problems occur, you can feel confident that your pump and garment are backed by the best warranty and customer service in the industry!

The Models #SC-2004 and #SC-3004 are manual (not software driven) sequential, pneumatic compression devices intended for either primary or adjunctive treatment of primary or secondary Lymphedema. These devices are also intended for additional or alternative treatment of venous insufficiency and venous stasis ulcers associated with venous insufficiency as well as general treatment for swelling of the extremities. These devices are intended for both home and hospital use. The Model # SC-3004 enables the adjustment of individual gradient pressures where clinical situations deem it necessary to use this feature.

CAUTIONS AND PRECAUTIONS

-  CAUTION: Federal law restricts this device to sale by, or on the order of, a licensed physician.
-  CAUTION: High pressure should be set with caution on patients with peripheral arterial occlusive disease.
-  CAUTION: To prevent the potential for reverse pressure and retrograde flow, do not adjust the gradient pressures without physical supervision.
-  CAUTION: If you experience pain or unusual symptoms during use, discontinue treatment and consult your physician immediately.
-  CAUTION: In the event of a power failure, simply unplug the garment from the pump to release any residual pressure in the garment.
-  CAUTION: The system is not intended for use during sleep.

SYMBOL DEFINITIONS



= “WARNING” Risk of Fire



= “DANGER” Risk of Explosion



= “CAUTION” Risk of Electrical Shock



= “REFER TO DOCUMENTATION BEFORE USING AND SERVICING”



= “TYPE B—APPLIED PART”



= “CLASS II PROTECTION”

CONTRAINDICATIONS

- INFECTIONS IN THE LIMB WITHOUT APPROPRIATE ANTIBIOTIC COVERAGE, INCLUDING CELLULITIS
- THE PRESENCE OF LYMPHANGIOSARCOMA
- DEEP VEIN THROMBOSIS (DVT)
- INFLAMMATORY PHLEBITIS OR EPISODES OF PULMONARY EMBOLISM
- CONGESTIVE HEART FAILURE

GENERAL EQUIPMENT SPECIFICATIONS

Model # SC-2004 - Segmental, Pneumatic Compression Device with Factory Set Gradient Pressures

DIMENSIONS: H X W X D in INCHES 5.5 x 12 x 8

WEIGHT: 8 lbs

PRESSURE RANGE: 0-125mm Hg

ELECTRICAL: 120 VAC, 60 HZ, .5 AMPS

INFLATION: 72 SECONDS

DEFLATION: 18 SECONDS

CYCLE TIME: 18 SECONDS / CHAMBER

Model # SC-3004 - Segmental, Pneumatic Compression Device with Calibrated Gradient Pressures

DIMENSIONS: H X W X D in INCHES 5.5 x 12 x 8

WEIGHT: 8 lbs

PRESSURE RANGE: 0-125mm Hg

ELECTRICAL: 120 VAC, 60 HZ, .5 AMPS

INFLATION: 72 SECONDS

DEFLATION: 18 SECONDS

CYCLE TIME: 18 SECONDS / CHAMBER

(“Electrical Specifications” under separate section)

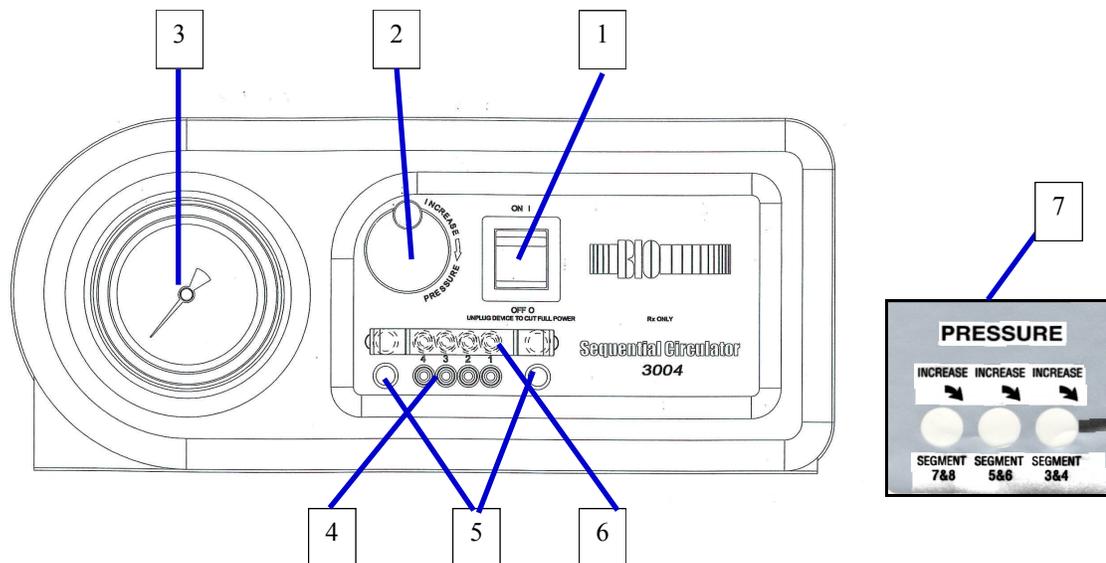
PACKAGING, SHIPPING & STORAGE

The Models # SC-2004 and # SC-3004 are shipped in a specially designed (275 test) corrugated re-usable carton with protective end-caps which envelope each end of the pump, thereby suspending the pump on all four sides within the carton. This packaging design prevents damage to the pump (which would ordinarily be sustained) when the carton is thrown or handled roughly by the carriers.

NOTE: The carton and end-caps should be saved for re-use each time the pump is either transported or shipped. When transporting, for added convenience, the carton is equipped with a fold-up “handle assembly.”

The device should be stored in a secure area, ideally 60 to 80 degrees (F), however, short term storage or shipping with exposure to temperatures of -20°F to $+110^{\circ}\text{F}$ will not harm the unit. To maximize the unit's life, however, time should be allowed for temperature adjustment prior to use, when moving to areas of contrasting temperature. It is also advisable to avoid “extreme” heat ($+110^{\circ}\text{F}$) or cold (-20°F) when long term storage is contemplated.

CONTROLS AND INDICATORS



- 1) LIGHTED “ON / OFF” PUMP SWITCH
- 2) PRESSURE ADJUSTMENT KNOB, LOCKING

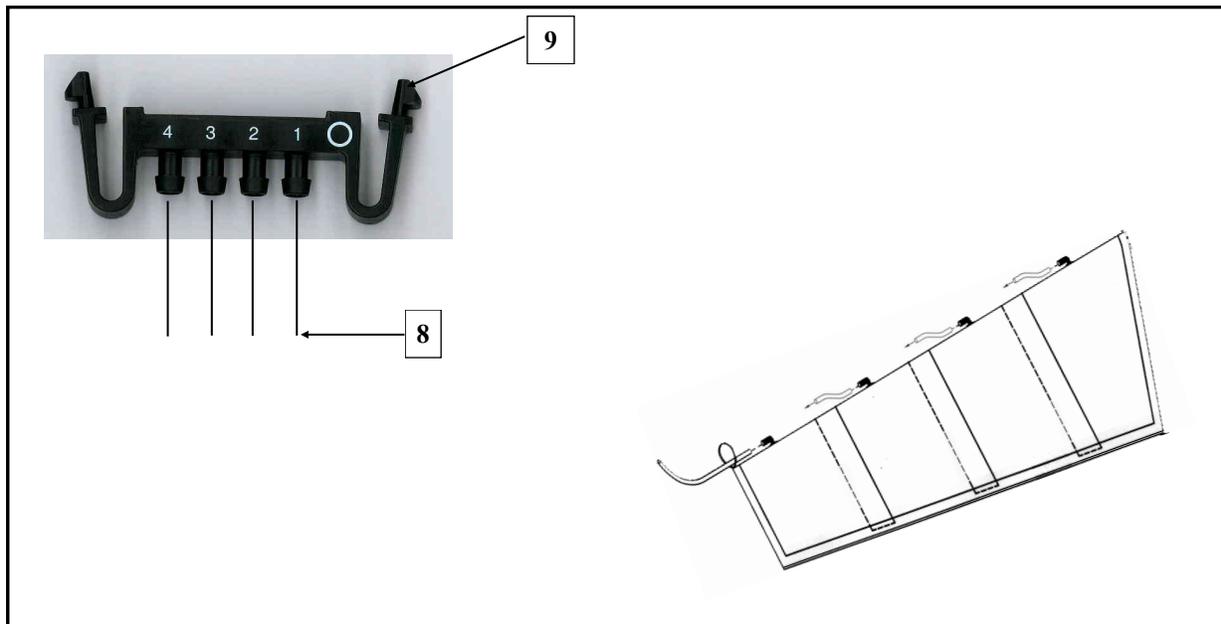
To prevent against involuntary changes in the pressure setting due to inadvertent movement of the Pressure Adjustment Knob, a new “locking” Pressure Adjustment Knob has been implemented on all model pumps to provide for safer, more effective therapy. After the pressure has been set, simply by turning the smaller “inner locking knob” clockwise to tighten, the pressure adjustment knob will now remain secure in place. Turning the “inner knob” counter-clockwise will enable the “pressure adjustment knob” to again turn free without resistance.

CAUTION: Care must be taken not to “OVER-TIGHTEN” the inner locking knob as only minimal force is required to lock pressure setting in place.

NOTE: Changing the inner knob to a 1/2” x 8/32” ALLEN HEAD SET SCREW will upgrade this feature to tamper

- 3) PRESSURE GAUGE (mmHg)
- 4) AIR SUPPLY PORTS
- 5) RECEPTOR PORTS FOR LATCH CONNECTOR BAR
- 6) “CAPPED” AIR SUPPLY PORTS FOR LATCH CONNECTOR BLOCKER BAR
(For Use with Secondary Garment)
- 7) ADJUSTABLE GRADIENT PRESSURE
“OVERRIDE”(Model # SC-3004 Only)
Located on underside of pump

UPPER EXTREMITY GARMENT WITH TUBING PLUG/CONNECTOR



8) TUBING PLUG/S

9) LATCH CONNECTOR BAR

ADJUSTABLE GRADIENT PRESSURE

NOTE: When a pressure adjustment is made to any Individual chamber, one must be conscious of the overall Gradients across all chambers so as not to create reverse Gradients.

ELECTRICAL SPECIFICATIONS

The Models SC-2004 and SC-3004, Sequential Circulator's electrical pumps and components are "double insulated" and thus do not require a "protective ground." As a result, the pumps are equipped with an 18 gauge, 2-wire, 10 ft. power cord, secured through the pump casing with a "Heyco" strain relief bushing.

Affixed to the rear exterior of the pump is a 3"x 3" Foil Label containing the "Electrical Specifications" printed in contrasting black type. These specifications are printed in both English and French and contain the following:

ELECTRICAL RATING: 120 VAC, 60Hz, 0.5 A

CARACTERISTIQUES ELECTRIQUES: 120 V c.a., 60 Hz, 0, 5 A

When servicing, use only identical replacement parts. Do not remove cover. Refer to qualified service personnel.

Lors des reparations, utilisez, exclusivement des pieces de re change identiques. No retirez pas le couvercle. Consultez un tech niciaen qualifie.

WARNING: REPLACE FUSE WHERE MARKED

AVERTISSEMENT: REMETTRE LE FUSIBLE A L'ENDROIT INDIQUE

Fuse rated 3 Amps Time Delay, 250 VAC

Fusible de 3 A a retardement, 250 V c.a.

Continuous Operation with Intermittent Loading

TYPE B—APPLIED PART CLASS II

Pie'ce Applique'e—Type B CLASSE II

ETL 9801681

CONFORMS TO

CONFROM A

Authorized service personnel, in addition to possessing proper tools and testing equipment have access to electrical schematics, calibration criteria and an inventory of identical replacement parts

CLASSIFICATION

1. Class of protection against electrical shock.
CLASS II EQUIPMENT
2. The degree of protection against electric shock.
APPLIED PART—TYPE B
3. Mode.
CONTINUOUS OPERATION WITH INTERMITTENT
LOADING
4. According degree of protection against ingress of water..
IPXO

FUSE REPLACEMENT

Occasionally power surges, etc. or normal age can result in a blown outer safety fuse located in the rear of pump, adjacent to the power cord.

The safety fuse may be replaced by the user or caregiver, provided it is replaced with an identical type (T3AL 250V).

Prior to removal of fuse, disconnect power cord from socket. While pushing inward on fuse cap, turn counter clockwise to release cap and remove fuse. After placing new fuse in cap slot, push cap and fuse inward and turn clockwise to lock in place.

NOTE: The outer safety fuse is the only item serviceable by some one other than a Bio Compression Systems technician at the factory. Bio Compression Systems technicians have been trained specifically for the manufacturing and repair of all Bio Compression Systems products.

NOTE: Having little or no “electromagnetic” or “radio frequency” signal sensitivity type components, these devices neither generate nor are they affected by any of this type of interference. Further, their accuracy remains consistent in the presence of such devices emitting this type of interference.

PUMP ENCLOSURE

The pump enclosures are constructed of “Cyclac” which is a trademark of General Electric.

UL FLAME RATING: Under file #E47016, The UL Test method of UL 94, @ 23°C, resulted in a Flammability Rating of (2.3 VO)

UNPACKING EQUIPMENT

SEQUENTIAL CIRCULATOR

By laying carton on its side, slide pump out with protective end caps still attached. After removing pump from carton, protective end caps may be detached by gently pulling off each side.

NOTE: Be sure to SAVE carton and end caps for future transporting or shipping. When transporting, the carton is equipped with “fold-up” handles for easy carrying.

SLEEVE/GARMENT

Remove sleeve from package and unroll tubing section which is permanently attached to garment with tubing plug attached to the end.

OPERATING INSTRUCTIONS

Having familiarized yourself with the controls and features of this equipment, you are now ready to begin your treatment according to your physician’s prescribed course of therapy.

1. Make sure that your circulator is plugged into a safe, properly secured, 110 V, AC outlet.
2. Place unit on a sturdy table or other type surface close to where you will be sitting. The unit has non-slip-rubberized feet on the bottom, however placing paper or other items underneath may defeat that purpose, causing unit to slide off of surface.
3. Press PUMP SWITCH (#1) up to “ON” position and let pump run for approximately five minutes. After 5 minutes, place finger over Air Supply Port Number One. At first, only partially cover port until you feel it start to release air. Then, quickly occlude the port and adjust the PRESSURE ADJUSTMENT KNOB (#2) until the PRESSURE GAUGE (#3) reaches the desired setting.

NOTE: You may have to repeat this procedure several times, since you can only set the pressure on port number one which is the highest pressure of the four chambers.

4. Take the Latch Connector Bar (#9) which is located at the end of the tubing on your sleeve. Holding in one hand with numbers facing up, squeeze ends together to line up (1 to 1) & (4 to 4) to Air Supply Ports (#4) then push onto ports. You should hear a click when fully engaged.
5. If you are USING TWO GARMENTS, remove cap from AUXILIARY AIR SUPPLY PORTS (#6) and follow steps outlined in (#4).

NOTE: If NOT using two garments, the CAP (#6) MUST REMAIN COVERING AUXILIARY AIR SUPPLY PORTS (#6).

6. Unzip sleeve gently down to bottom stop (zipper will not separate). Place garment onto arm or leg and re-zip up to top of garment.
7. Press PUMP SWITCH (#1) up to “ON” position. Allow two to three complete inflation / resting cycles before the garment reaches its pre-set therapeutic chamber pressures.
8. As each chamber of the garment inflates, the PRESSURE GAUGE (#3) will dip down momentarily then return to the actual chamber pressure. This will continue each time a chamber becomes pressurized.

SETTING THE PRESSURE

The physician is required to prescribe these settings, but general guidelines are listed below:

60mmHG is the general rule of thumb for most patients. However, other circumstances may require adjustments to the compression used.

Presence of fibrotic tissue may require as much as 80mmHG in order to break up the fibrotic tissue and achieve reduction. Once the tissue is soft, the compression can be readjusted to 60mmHG.

Patients with a history of Congestive Heart Failure, 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.

SETTING THE PRESSURE (CONTINUED)

Patients with a history of Deep Vein Thrombosis with or without a filter may require less compression. These patients will generally tolerate 40mmHG. These 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.

All compression settings should be discussed with the physician. It is ultimately his/her 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 pressures.

MODEL #3004 ONLY

ADJUSTING GRADIENT PRESSURES

- Model #SC-3004 Sequential Circulators provide total Calibrated Gradient Pressure.
- All gradients have been carefully calibrated at the factory resulting in the highest pressure in chamber #1 graduated down to the lowest in chamber #4.
- The main PRESSURE ADJUSTMENT KNOB (#2) sets the pressure for section one (lowest section of the sleeve. As it is adjusted, it will also raise or lower proportion, the remaining sections.
- In the unlikely event you would wish to change the gradient settings calibrated at the factory, it is possible to do so by using the “over-ride” adjustments (#7) on the underside of the pump.
- We describe earlier how the Pressure Gauge responds to filling pressures with a brief “dip” before raising back up to the actual pre-set pressure.

GARMENT SPECIFICATIONS

TUBING:

The garment tubing is produced in pleural form consisting of two groups of 4 Tubes bonded together and color coded with 3 tubes in blue and 1 tube in black. This color coding prevents attachment of both tubing bundles to the pump is reverse order. The tubing is 80A durometer PVC with each tube measuring .281 x .187 with a Tolerance of +/- .005.”

END OF TREATMENT

When your treatment time is completed, press the PUMP SWITCH (#1) down to the “OFF” position.

As noted earlier, although the pump shuts off, the switch may remain lighted until the timer completes its cycle, at which time it will automatically shut off. Unplugging the power cord at this point will cut total power to device

Once the light has shut off, it is also safe should you desire, to remove the garment.

1. Squeeze Latch Connector Bar (#9) outward to remove garment from pump.
2. First gently bend your arm or leg (depending where garment is located) to partially release some air from chambers.
3. Continue to assist the evacuation of air from garment, working downward from top to bottom.
4. Once the garment feels loose enough, you can unzip the garment all the way down to bottom-stop and remove.

OVERRIDING PRE-SET GRADIENT PRESSURES

1. A small screw driver is the only tool needed to adjust the gradient pressures.
2. If you turn the pump on its side, you will notice underneath, three screw ports labeled #4, #3, and #2, each having a directional arrow indicating the way in which the pressure is increased.
3. It only takes a very small turn of the screw to adjust since you are adjusting (mmHg) as reflected on the gauge.
4. With the pump on its side and running, place your finger over the number air supply port you wish to adjust.
5. When you feel the air coming out of the specific port, using your finger, occlude the port and while observing the Pressure Gauge, gently and gradually adjust the screw valve to the desired setting.

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 Pumps = 3 years from date of purchase / invoice

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

NOTES: _____

Serial Number: _____

Date Purchased: _____

Local Representative/Dealer: _____

REPAIR SERVICE

1-800-888-0908

BIO COMPRESSION SYSTEMS, INC.

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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 or as needed.



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 the 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.

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