

# OPERATING INSTRUCTIONS



## MODEL IC-BAP

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**BIO COMPRESSION SYSTEMS**  
120 West Commercial Avenue  
Moonachie, New Jersey 07074  
Phone: 800-888-0908 Fax: 201-939-4503  
Web site: [www.biocompression.com](http://www.biocompression.com)

**BioArterial Plus**  
**Arterial Blood Flow Enhancement System**

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**Bio Compression Systems, Inc.**  
***BioArterial Plus***  
***Arterial Blood Flow Enhancement System***

**INTRODUCTION**

The **BIOARTERIAL PLUS** is an Intermittent, Sequential, Pneumatic Compression System that sequentially compresses both the foot and calf in patients suffering primarily from diabetic foot ulcers or intermittent claudication (leg pain primarily from decreased arterial circulation).

The **BIOARTERIAL PLUS SYSTEM** is designed to deliver bilateral pressures of 120mmHg (+/- 0.5 sec.) for up to 1 hour, 2 to 3 times per day. The cycle times provide sequential compression to the limbs for 4 second (+/-0.5 sec) followed by a rest period resulting in a total cycle time of 20 seconds (+/-4.0 sec).

**INTENDED USE**

The BioArterial Plus Arterial Blood Flow Enhancement System is intended as an adjunct therapy for patients with ischemic disease of the lower extremities, due to one or more of the following causes:

- Rest or Night Pain
- Ulcers
- Intermittent Claudication
- Ischemia
- Small Vessel Disease
- Graft Failure
- Arteriopathic Wounds
- Angioplasty/Stent Failure
- Minor Amputations

## CONTRAINDICATIONS

- Undesirable venous and lymphatic return (as with congestive heart failure)
- Deep vein thrombosis (suspected or present)
- Inflammatory Phlebitis
- Episodes of pulmonary embolism
- Sepsis in the limb
- Cellulitis without appropriate antibiotic coverage
- Immediately following skin grafts in/around treatment sites
- Pulmonary edema associated with congestive heart failure
- Acute thrombophlebitis

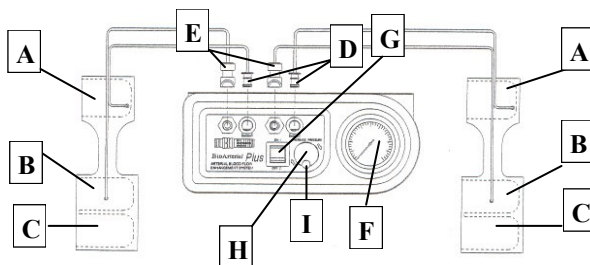
## SYSTEM AND COMPONENTS

The BIOARTERIAL PLUS system is comprised of the Controller/Pump along with a set of bilateral garments with color coded tubing and contrasting style “quick” connectors.

### CONTROLLER/PUMP

- (A) Velcro-type attachment tab (FOOT)
- (B) Velcro-type attachment tab (MID CALF)
- (C) Velcro-type attachment tab (UPPER CALF)
- (D) Tube connector to pump (FOOT)
- (E) Tube connector to pump (CALF)
- (F) Pressure Gauge
- (G) Illuminated ON/OFF Switch
- (H) Pressure Adjustment Knob
- (I) Pressure locking thumb screw

NOTE: For safety purposes, the “locking pressure adjustment knob” (H) & (I) is provided as a tamper-proof method of protection in the presence of children or others who might inadvertently/ unknowingly change pressure settings. Unless otherwise ordered by the attending physician, it is recommended that the pressure be maintained as pre-set at the factory at 120mmHg. Should a pressure change be ordered by the physician, this can be accomplished by slightly turning the locking thumb screw “counter clockwise” freeing up the “pressure adjustment knob” for changing of pressure.



## 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"

## WARNINGS, CAUTIONS AND PRECAUTIONS



Warning: Do not use in the presence of flammable anesthetics



Caution: Federal law restricts this device to sale by, or on the order of a licensed physician.



Caution: Unless otherwise ordered by the physician pressure should not be set any higher than 120mmHg.



Caution: 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, discoloration, welts, or other noticeable changes in the skin), or burning, itching, increased swelling should occur, discontinue use and consult with a physician.



Caution: Slip and fall hazard. Do not stand or walk while wearing garments

## EQUIPMENT 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  
IPX0

## GARMENT SPECIFICATIONS

### Available Sizing

#### STANDARD (APG-3045-FC S)

FOOT: Fits 8" to 12.5"

MID-CALF: Fits 9.5" to 18"

UPPER CALF: Fits 10.5" to 20.5"

#### WIDE (APGW-3045-FC)

FOOT: Fits 8" to 14.5"

MID-CALF: Fits 11 to 25"

UPPER CALF: Fits 12" to 27.5"

Length Adjusts from 12" to 20.5" on both sleeves.

### TAKING A TREATMENT

- Remove garments from plastic bags with color coded tubing and connectors attached to each garment.
- It is recommended that light bandages, clean hosiery or stockinets be worn under treatment garments.
- Attaching one garment at a time, attach tubing connectors (on ends of tubing) to connectors on face of pump.

***NOTE: Connectors can only be attached in one way due to uniqueness of their design. By pushing in firmly, a "clicking" sound will confirm that proper attachment has been made.***

- After attaching both garments to controller/pump, attach to limbs.

***NOTE: See "System & Components" for tab locations***

- Place heel portion of garment on floor. Place heel of foot snugly into heel portion of garment, depressing foam portion down with arch of foot. (See 1) While pressing down with arch, pull left tab (A) across foot to attach snugly (See 2 & 3)



- Pull up gently on garment, with the two upper tabs detached (See 4)

- Pull upper left tab (C) across leg (just under knee) followed by upper right tab and attach snugly (See 5)

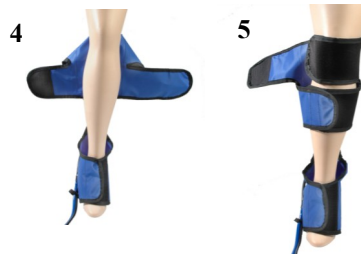


***NOTE: Be sure that black valve on back of garment is centered on the mid to upper calf area.***

Repeat same procedure with mid tab (B)

Repeat same procedure with other garment

- Turn pump to "ON"
- Position and observe gauge to ensure that it reads 120mmHg. If it does not show proper pressure, adjust pressure up (clockwise) or down (counter clockwise) until proper pressure has been attained.



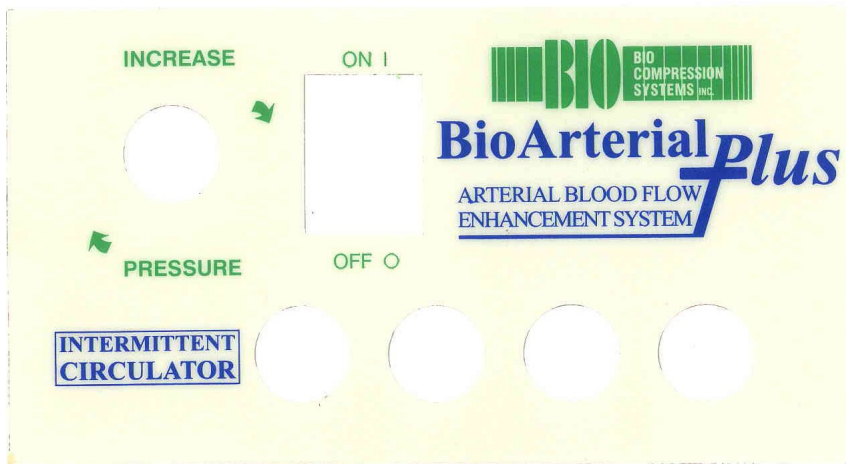
- Begin Treatment

**ON DEVICE LABELING**


**Note: Labeling samples have been reduced to fit manual.**

**FOR MAXIMUM ACCURACY, ALLOW A  
5 MINUTE WARM-UP PERIOD  
BEFORE ADJUSTING PRESSURE**



**BIO COMPRESSION SYSTEMS, INC.**  
Model No.   
Serial No.   
**MOONACHIE, NEW JERSEY**



**ELECTRICAL RATING: 120 VAC, 60 HZ, 0.5A**  
**CARACTERISTIQUES ELECTRIQUES:**  
**120V 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 rechange identiques. Ne retirez pas le Couvercle. Consultez un technicien 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**  
**PIECE APPLIQUEE E-TYPE B**

 **CONFORMS TO CONFORM A**  
US UL Std 60601-1  
9801681 CSA C22.2 No. 601.1

## **GENERAL EQUIPMENT SPECIFICATIONS**

DIMENSIONS: H x W x D (inches) 5 x 12 x 8

WEIGHT: 7.5 Pounds  
COMPRESSION TIME: 4 Seconds (+/-0.5 Sec)  
NON-COMPRESSION TIME: 16 Seconds (+/- 3.0 Sec)  
DELAY BETWEEN FOOT & CALF: 1 Second (+/-0.5 Sec)  
CYCLE: 20 Seconds/3 Cycles per Minute

### CONTROLLER/PUMP ENCLOSURE

The pump enclosure is constructed of "Polylac" which is a trademark of General Electric.

UL FLAME RATING: Under File# E47016, the UL test method of UL 94@23C resulted in a flammability rating of (2.3VO).

NOTE: Additional testing and certification of molding parameters pending via Intertek

## **ENVIRONMENTAL SPECIFICATIONS**

*For transport and storage:*

*Ambient temperature: -20°F - +110°F (-29°C - +44°C)*

*Relative humidity: 30% - 75%*

*Atmospheric pressure: 700hPa to 1060hPa*

*For operation:*

*Ambient temperature: +50°F - +100°F (+10°C - +40°C)*

*Relative humidity: 30% - 75%*

*Atmospheric pressure 700hPa to 1060hPa*

## **ELECTROMAGNETIC COMPATIBILITY (EMC)**

The BioArterial Pump System has been evaluated to international standard EN60601-1-2:2001, Medical Electrical Equipment-Part 1-2:

General Requirements for Safety –Collateral Standard Electromagnetic Compatibility –Requirements and Tests:

- A. The Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided here with in the accompanying documents.
- B. Portable and mobile RF communication can affect the Medical Electrical Equipment.

Table 201 – Guidance and Manufacturer’s Declaration – Emissions  
All Equipment and Systems

Guidance and Manufacturer’s Declaration - Emissions		
The BioArterial Plus is intended for use in the electromagnetic environment specified below. The customer or user of the BioArterial Plus should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The BioArterial Plus uses RF energy only for its internal function. 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	
Harmonics IEC 61000-3-2	N/A	The BioArterial Plus is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Flicker IEC 61000-3-3	N/A	

Table 202 – Guidance and Manufacturer’s Declaration – Immunity

Guidance and Manufacturer’s Declaration – Immunity			
The BioArterial Plus is intended for use in the electromagnetic environment specified below. The customer or user of the BioArterial Plus should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/ Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle  60% Dip for 5 Cycles  30% Dip for 25 Cycles  >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle  60% Dip for 5 Cycles  30% Dip for 25 Cycles  >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BioArterial Plus requires continued operation during power mains interruptions, it is recommended that the BioArterial Plus be powered from an uninterruptible power supply or battery.
Power Frequency 60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Table 204 – Guidance and Manufacturer’s Declaration – Immunity  
**Equipment and Systems that are NOT Life-supporting**

Guidance and Manufacturer’s Declaration – Immunity			
The 1545-KT is intended for use in the electromagnetic environment specified below. The customer or user of the 1545-KT should ensure 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 150 kHz to 80 MHz	(V1)Vrms	Portable and mobile communications equipment should be separated from the 1545-KT by no less than the distances calculated/listed below:  $D=(3.5/V1)(\text{Sqrt } P)$  $D=(3.5/E1)(\text{Sqrt } P)$ 80 to 800 MHz  $D=(7/E1)(\text{Sqrt } P)$ 800 MHz to 2.5 GHz  where P is the max power in watts and D is the recommended separation distance in meters.  Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).  Interference may occur in the vicinity of equipment containing a transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	(E1)V/m	

Table 206 – Recommended Separation Distances between portable and mobile RF Communications equipment and the 1545-KT

**Equipment and Systems that are NOT Life-supporting**

Recommended Separations Distances for the Compression Pump			
The 1545-KT is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the 1545-KT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the 1545-KT as recommended below, according to the maximum output power of the communications equipment.			

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz	Separation (m) 80 to 800MHz	Separation (m) 800MHz to 2.5GHz
	$D=(3.5/V1)(\text{Sqrt } P)$	$D=(3.5/E1)(\text{Sqrt } P)$	$D=(7/E1)(\text{Sqrt } P)$
0.01	.12	.12	.23
0.1	.37	.37	.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

## **ELECTRICAL SPECIFICATIONS**

The BioArterial Plus Controller/Pump and interior components are “double insulated” and thus, do not require a “protective ground.” Therefore, the system is equipped with an 18 gauge, 2-wire, 10ft. Power cord, secured through the pump casing with a Heyco strain Relief bushing as well as an additional “hold-down” clamp for added safety.

Affixed to the rear exterior of the controller/pump is a 3”x 3” silver foil label containing the “Electrical Specifications” printed in contrasting black type. The specifications are printed in both English and French and contain the following...

ELECTRICAL RATING: 120 VAC, 60Hz, 0.5A  
*CARACTERISTIQUES ELECTRIQUES 120 Vc.a, 60Hz, 0.5A*

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 FUSILE A  
L'ENDROIT INDIQUE*  
Fuse rated 3 Amps Time Delay, 250 VAC  
*Fusible de 3A a retardement, 250 V c.a.*  
Continuous Operation with Intermittent Loading

TYPE B—APPLIED PART CLASS 11  
*PIECE APPLIQUE'E—TYPE B CLASSE II*

ETL  
CONFORMS TO: UL Std. 60601-1  
*CONFROM A: UL Std. 60601-1*

NOTE: In addition to possessing proper tools and testing equipment, authorized service personnel have access to all electrical schematics, calibration instrumentation and criteria and an inventory of authorized replacement parts.

## **FUSE REPLACEMENT**

There are a total of two fuses in the BioArterial Plus System, an “inner fuse” and an “outer safety fuse.” Of these two, the “outer safety fuse” is the only item serviceable by someone other than a Bio Compression Systems technician who has been specifically trained in the manufacturing and repair of all Bio Compression Systems products. The outer fuse is located in the rear of the controller, adjacent to the power cord outlet. The outer safety fuse may be replaced by either the user or the caregiver provided it is done so with an identical make and model ... (3.0 Amp FSL).

Prior to removing outer fuse, disconnect power cord from the wall socket or other source. While pushing inward on the fuse cap, turn counter clockwise to release the cap and fuse. After replacing with a new fuse inside of cap, push cap and fuse inwards while turning clockwise to lock back in place.

## **PACKAGING, SHIPPING, STORAGE AND HANDLING**

The BioArterial Plus System is shipped in a specially designed (275 test) Corrugated re-usable type carton with foam cushioned 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 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° F, however, short term storage or shipping with exposure to temperatures of -20° to 110°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 temperatures. It is also advisable to avoid “extreme” heat (+110°F) or cold (-20° F) when long term storage is contemplated.

When unpacking pump, turn carton on its side and slowly slide pump out with protective foam end-caps still attached. After removing pump from carton, end-caps should be removed and retained along with carton for future use.

When transporting as opposed to shipping, note that the carton is equipped with special fold-up handles for ease in carrying.

## **CLEANING INSTRUCTIONS**

### Exterior Case Cleaning Instructions:

Clean the exterior case and tubing with a damp (not wet) cloth using a mild soap and water solution once per month or as needed. Do not allow liquids to enter the equipment, an electrical hazard may be presented. Always allow the unit to dry before re-using.

### Garment Cleaning Instructions:

- 1) Disconnect tubing 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).
- 3) Use either a large sink or plastic tub able to hold enough solution (depending on size and quantity of garments) to completely submerge garment/s under water including tubing, with the exception of connectors at end of tubing. Solution should consist of 1/3 cup of Tide or equivalent detergent per 1 gallon of warm tap water.
- 4) **NOTE: IT IS EXTREMELY IMPORTANT THAT CONNECTORS AT END OF TUBING BE KEPT OUT OF WATER AT ALL TIMES TO AVOID WATER FROM ENTERING INTERIOR PORTION OF GARMENT/S.**
- 5) Garment/s should be soaked for 1/2 hour with mild agitation of garment every 5 to 10 minutes while keeping it below surface of water.
- 6) **NOTE: Occasionally, hard to remove soiling on surface of garment may require additional washing by hand with a clean towel while submerged.**
- 7) **NOTE: In all cases, avoid using any abrasive type materials such as scrubbing pads or chemicals that might cause damage to the exterior surface of garment.**
- 8) Thoroughly rinse garment with warm tap water.
- 9) Re-submerge garment in solution consisting of 1 cup of Clorox bleach per gallon of warm tap water for 1/2 hour, again agitating garment every 5 to 10 minutes while keeping garment/s below surface (with the exception of tubing connector/s).
- 10) Rinse garment/s thoroughly and allow to air dry.
- 11) **DO NOT place garment in washing machine or submerge in water unprotected from water entering interior portion of garment where ultimate damage to pump can occur.**
- 12) **DO NOT use the tubing or valves as "handles" for carrying, hanging or storing garment/s.**
- 13) **In cases when it is necessary for a garment to be returned to the factory for repair or evaluation, it is essential that garment/s are thoroughly cleaned and disinfected before returning.**

## **PRODUCT CARE AND PREVENTIVE MAINTENANCE/INSPECTION**

### Product Care Instructions:

- Do not subject the unit to extreme temperatures, humidity, direct sunlight, etc. Store the unit in a clean, dry location when not in use. Such treatment may result in equipment malfunction, shortened equipment lifespan or damaged parts.
- Do not subject the unit to excessive force and shock (such as dropping the unit on the floor).
- With the exception of fuse replacement, do not disassemble the unit or tamper with its internal components. Doing so will terminate the unit's warranty and may cause damage. The unit contains no user-serviceable parts.

### Preventive Maintenance/Inspection:

- Should your unit fail to operate, check to make sure that the prongs on the power cord plug are making good contact in the outlet.
- Should your garments fail to inflate properly, check the garments for leaks, check the hoses for splits or kinks, and check the connectors and tubing sets for integrity and leaks.

- At least annually, check the power cord for damage and frays.
- At least annually, check the garments, connectors and tubing sets for integrity and leaks, proper sealing, and for kinks in the hoses.
- At least annually, check the general integrity of the exterior case, gauge and components.
- Using a soft hair brush, occasionally brush velcro to remove lint or other debris that may gather on the surface.

Contact Bio Compression Systems for repair or replacement as necessary.

### **REPAIR SERVICE AND DISPOSAL**

With the exception of the garments and tubing sets all components of the Arterial Plus are returnable for repair or replacement at Bio Compression Systems’ facility. Garments and tubing sets are not repairable, and should be properly disposed of if damaged.

#### **Replacement Parts:**

The items below are available from Bio Compression systems or your local sales representative. Please be sure to use the Bio Compression Systems’ Part No. for the item when placing an order:

#### **Table 3: BioArterial Plus Replacement Parts**

<b>Part No.</b>	<b>Description</b>
<b>APG-3045-FC</b>	<b>Garment Set</b>

**NOTE:** Outer safety fuse should be replaced with a 3 Amp, 250V, Type T, 5mm x 20mm

#### **Repair Service:**

Prior to shipping the product back to the factory for repair, Customer Service must be contacted by calling 800-888-0908 to obtain a Return Authorization Number.

Repairs CAN NOT be performed or tracked without an assigned “RA” number.

Be sure to have the product’s serial number available when calling. The serial number is located on the rear of the pump, printed on a rectangular foil type label.

#### **Disposal:**

This product may contain components that are not suitable for direct landfill disposal. If the unit is no longer required for future use, protect the environment by disposing of it in accordance with local regulations (i.e., at designated collection point for proper electronic recycling and disposal). Contact Bio Compression Systems for additional details concerning the specific configuration of your product, and which may affect proper disposal.

Alternately, you may contact Bio Compression Systems for return and we will dispose of the unit in accordance with the Department of Environmental Protection rules and regulations. Please follow the repair service instructions (above) for returning your unit.

### **WARRANTY INFORMATION**

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

**Controller/Pump = 3 Years from Date of Purchase**

**Garments = 6 Months from the Date of Purchase**

**Thank you for choosing  
Bio Compression Systems...  
Serving Patients for over 20 Years!**

**[www.biocompression.com](http://www.biocompression.com)**



**ART-D ISSUED 01-26-09  
REV.B 02-09-11**