Bio Compression's
IC-BAP-DL Bio Arterial Plus

Arterial Blood Flow Enhancement System

Operating Instructions

BIO COMPRESSION SYSTEMS INC.

Quality Medical Products Since 1983

TÜV SÜD C US CE 0123

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Introduction

Congratulations on the purchase of your Bio Compression Systems model IC-BAP-DL Bio Arterial Plus Arterial Blood Flow Enhancement System and garments.

Package Contents

- IC-BAP-DL Bio Arterial Plus pump
- Instructions for use
- Garments

Intended Use

Pneumatic compression devices are intended to prevent pooling in a limb by periodically inflating a sleeve around the limb. Pneumatic compression devices are intended to simulate the kneading and stroking of tissues with the hands by use of an inflatable sleeve.

Not intended for use by children. Pregnant women should ask a doctor before use.

Indications for Use

The Bio Arterial 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: amputations (minor), angioplasty/stent failure, arteriopathic wounds, graft failure, intermittent claudication, ischemia, night pain, rest pain, small vessel disease, ulcers

Contraindications

Use of this device is contraindicated for patients with any of the following conditions:

- Infections in the limb, including cellulitis, without appropriate antibiotic coverage
- Suspicion or confirmation of the presence of Deep Vein Thrombosis (DVT)
- Inflammatory phlebitis or episodes of pulmonary embolism
- Congestive Heart Failure (CHF)
- Undesirable venous and lymphatic return
- Sepsis in the limb or limbs

- Immediately following skin grafts in or around treatment sites
- Pulmonary edema
- Acute thrombophlebitis

Device Description and Operating Principle

The Bio Arterial Plus is an intermittent 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 device consists of a compression garment connected to a pneumatic compression pump. Pressure to the foot and calf is delivered via the pump's cyclical inflation and deflation of the garment. The movement of the garment compresses the blood vessels in the foot and calf, expelling blood from the leg, overcoming blood stasis and circulation.

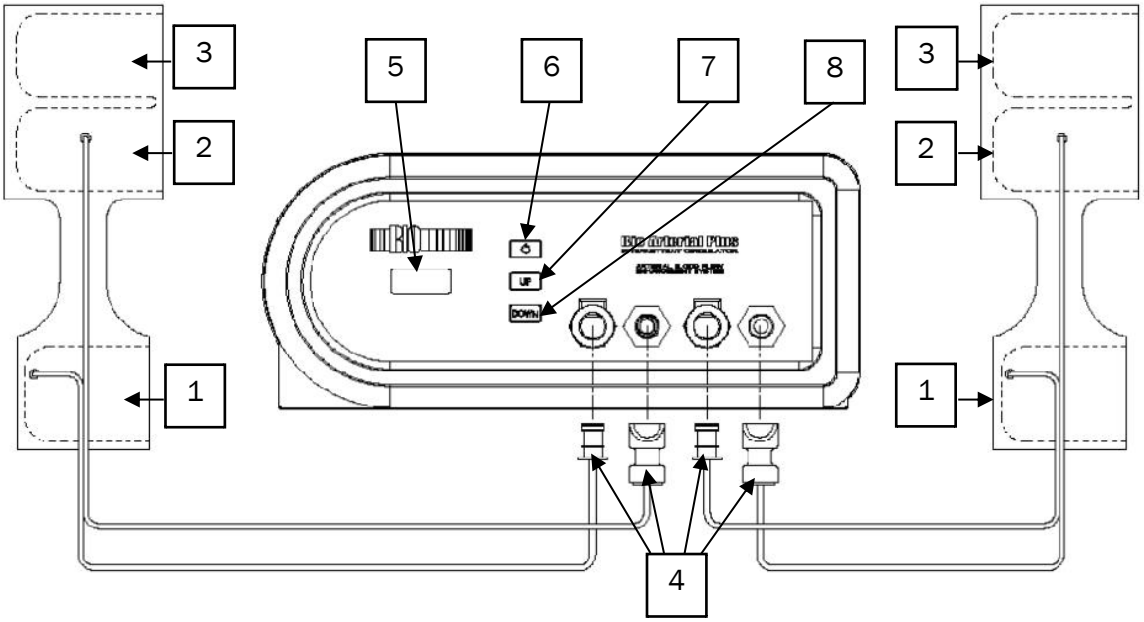
Pneumatic compression devices are proven to reduce pain and help close up chronic ulcers.

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.
- Typical treatment is for a duration of up to 1 hour, 2 to 3 times daily

Front Panel and Key Features



Key Functions

1. Garment foot tabs
2. Garment middle tabs
3. Garment upper tabs
4. Connectors
5. Digital display
6. Power On/Off button
7. UP button
8. DOWN button

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
- 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

Ask A Doctor Before Use If You Are

- Pregnant

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 garments 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 garments from plastic bag, unroll, and spread flat

Connecting the Garments

- Locate the connector at the end of garment tubing
- Attach connector to the pump by firmly pushing inwards – you will hear a “click” when connected

Putting the Garments On

- Place heel portion of garment on floor and place heel in
- While pressing down on foam with arch, snuggly close by pulling left tab across followed by right tab
- Pull up gently and snuggly close upper tabs just under the knee
- Ensure valve on back is centered
- Snuggly close middle tabs

Operating the Device

- Press “Power On/Off” button to turn on
- Current setting will briefly appear (“1Hr” for 1-hour operation or “CON” for continuous)
- Current pressure will briefly appear
- The device will start (in some cases, a 20 second countdown will appear while internal valve re-orientates)
- Upon the completion of treatment or to stop treatment, press “Power On/Off” button to turn off

To change mode

- Begin with device turned off
- Press and hold DOWN button and momentarily press power button
- Release DOWN button after mode changes
- Device will start running

To change pressure

- Begin with device turned off
- Press and hold UP and DOWN buttons and momentarily press “Power On/Off” button
- When display shows “---”, pressure can be adjusted using UP or DOWN button
- Startup will begin in 10 seconds or after pressing “Power On/Off” button

Reading the Usage Meter

- Begin with device turned off
- Press and hold UP button and momentarily press power button
- A letter representing the first digit will appear in the Digital Display – A is 0, B is 1, C is 2, D is 3, E is 4, and F is 5
- Release DOWN button after letter appears
- The remaining three digits will be displayed
- Device will start running

For example, if the Digital Display shows “D” followed by 013, that represents 3013 hours of use.

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

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
APG-3045-FC	Arterial Foot and Calf Sleeve - Standard
APGN-3045-FC	Arterial Foot and Calf Sleeve - Narrow
APGW-3045-FC	Arterial Foot and Calf Sleeve - Wide

Product Specifications

Models:	IC-BAP-DL, IC-BAP-DL-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:	IP21
Mains Isolation:	Unplug
Mode of Operation:	Continuous
Essential Performance:	The pump's cyclical inflation and deflation of the garment(s)
Cycle Time:	20 ± 4 seconds (compression 5 seconds, non-compression 15 seconds, 1 second delay between foot and calf)
Pressure Range:	10-150 mmHg
Precision:	1 mmHg
Accuracy:	± 20%
Features:	Compliance/Usage Meter
Warranty:	Pump 3 years, garment 1 year
Expected Service Life:	5 years
Software Safety Class:	A
Regulatory Classification:	AU IIa, CA 2, BR II, EU IIa, US 2
Weight:	7.5 lbs. (3.4 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 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 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.
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, $3V_{RMS}$ in whole range, $6V_{RMS}$ 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_T per 0.5 cycles, 0% U_T per 1.0 cycle, 70% U_T per 25/30 cycles
IEC 61000-4-11 Voltage Interruptions	0% U_T per 250/300 cycles

Symbol Glossary

EC REP	Authorized Representative in the European Community
	Atmospheric pressure limitation
LOT	Batch code (lot number)
REF	Catalog number
	Caution
	Class II equipment (protection against electric shock)
	Complies with the Waste Electrical and Electronic Equipment Directive (WEEE Directive)
CE 0123	Complies the European Medical Device Regulation
	Date of manufacture
	Fragile, handle with care
	Humidity limitations
IP21	Ingress protection (against solids up to 12.5 mm and dripping water)

	Manufacturer
MD	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
SN	Serial number
	Temperature Limit
	This way up
	TÜV SÜD Certification Mark (safety tested and production monitored)
	Type BF Applied Part
	Warning: Electricity

Information for Distributors and Healthcare Providers

Resetting the Pump

The pump remembers user settings and therefore it is important to reset the pump to its original factory settings when placing the device on a new patient. To reset the usage meter and return the pump to factory settings:

- Begin with pump running
- Press and hold the DOWN button then press and hold the POWER button - both buttons must be held down together for five seconds
- Digital Display will show “rES” - release buttons
- “rES’ will be displayed for three seconds then usage meter will be reset.

Cleaning the Pump

The device does not have microbiological requirements or specifications. Pneumatic compression pumps are non-contacting reusable device, and pneumatic compression garments/sleeves are single patient use devices.

Use a US EPA registered low-level disinfectant or low-level disinfectant wipe on the pump in accordance with the US CDC’s *Guideline for Disinfection and Sterilization in Healthcare Facilities* or local requirements. Do not use excessive liquid to enter the pump where the garment(s) or power cord connect. Follow all directions for the disinfectant.

Grounding Plug Not Required

This double insulated device does not require a three-wire power cord and a three-pin grounding type plug for use in the patient care vicinity of a hospital or other healthcare facility (see NFPA 99).

Contact Information

Manufacturer

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Website: www.biocompression.com

When contacting us, please have your model number and serial number ready.

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