

Bio Compression's IC-1545-DL Multi-Flo DVT Combo



Intermittent Pneumatic Compression Device Operating Instructions



Quality Medical Products Since 1983



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Introduction

Congratulations on the purchase of your Bio Compression Systems model IC-1545-DL Multi-Flo DVT Combo Intermittent Pneumatic Compression pump and garments.

Package Contents

- IC-1545-DL intermittent pneumatic compression pump
- Instructions for use
- Garments

Intended Use

- **Bilateral Calf Application**
 - Intended for prophylaxis of deep vein thrombosis (DVT)
- **Bilateral Foot Application**
 - Intended for prophylaxis of deep vein thrombosis (DVT)
 - Enhancement of venous and arterial circulation
 - Prevention of venous stasis ulcers
 - Assists in healing of cutaneous ulcers
 - Reduction of acute and chronic edema
 - Reduction of compartmental pressures
- **Post-Operative Cold Compression**
 - Intended to help reduce pain and swelling after surgery
 - Enhances faster healing and tissue regeneration required by the body

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
- 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)
- Pulmonary edema
- Severe arteriosclerosis or other ischemic vascular disease
- Any local condition of the extremity that would interfere with its application, including, but not limited to: dermatitis, immediately following vein ligation, gangrene, skin grafts, casts or splints
- Cryo Therapy is not recommended for patients with lymphedema

Device Description and Operating Principle

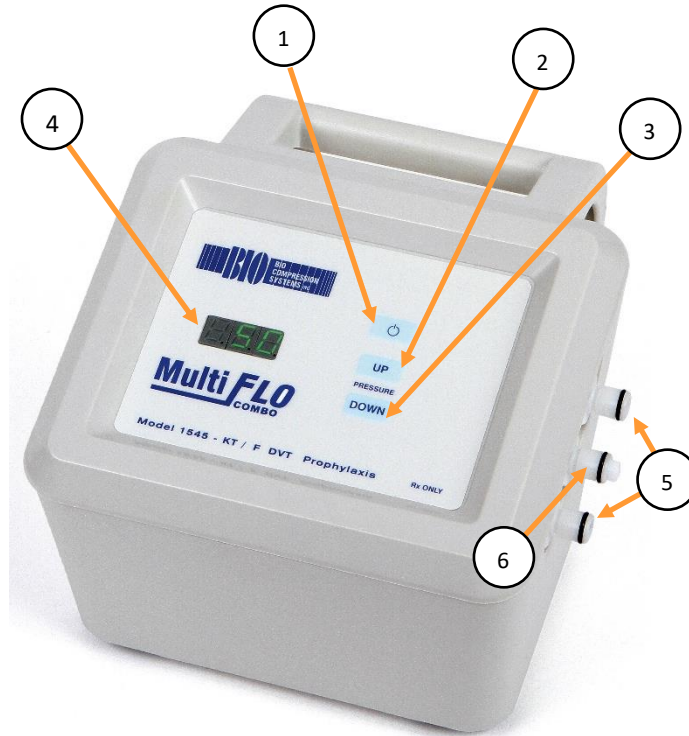
The model IC-1545-DL is an intermittent pneumatic compression device that consists of a compression garment connected to a pneumatic compression pump. The pump's cyclical inflation and deflation of the compression garments stimulates the flow of blood. Pneumatic compression devices are proven to reduce edema, help close up chronic ulcers, and act as a prophylaxis for deep vein thrombosis (DVT).

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.
- Deep vein thrombosis (DVT) prophylaxis should be applied continuously, around the clock at the factory pre-set pressures, dependent upon the application site, unless otherwise ordered by the attending physician. A less aggressive treatment schedule is more commonly prescribed by the physician post discharge in the home setting.

Front Panel and Key Features



Key Functions

1. Power On/Off Button
2. UP Button
3. DOWN Button
4. LED Readout
5. Air Supply Ports
6. Center Port (for post-operative cold compression)

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
- 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
- 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, place in a washing machine or dryer, or attempt to autoclave
- 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
- Place gel insert flat in freezer for 4 hours - do not place directly on metal rack as this could damage inset

Connecting the Garments

- Connect tubing to garment valve by turning clockwise until secure
- Attach Quick-Connect connector at end of tubing to the pump by firmly pushing inwards until it snaps in

Putting the Garments On

- Apply garments and secure using Velcro fasteners

Operating the Device

- Press “Power On/Off” button to turn on
- The device is preset for calf mode at a pressure of 50 mmHg (to change, see below)
- If garment does not properly inflate, alarm will sound – check connection and tubing for obstructions then turn pump off and on

- Upon the completion of treatment or to stop treatment, press “Power On/Off” button to turn off

To select calf mode

- Begin with device turned off
- Press and hold DOWN button and momentarily press power button
- Elapsed time will appear followed by “CAF”
- Release DOWN button
- Pressure will appear (50 mmHg) and device will start running

To select foot mode

- Begin with device turned off
- Press and hold UP button and momentarily press power button
- Elapsed time will appear followed by “FOO”
- Release UP button
- Pressure will appear (120 mmHg) and device will start running

To change pressure

- When display shows “0” during cycle, press and hold UP button until pressure appears
- Adjust using UP or DOWN button
- Press “Power On/Off” button to begin cycle

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, tubing, and calf garment cleaning

- Unplug and wipe down using a damp (not wet) soft cloth with mild antibacterial soap as needed
- Do not use bleach

Foot and cryo 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 |
|-------------|----------------------------------|
| GC1-3035-SH | Cryo Shoulder |
| GC1-3045-A | Cryo Ankle |
| GC1-3045-K | Cryo Knee |
| GI-3045-F | DVT Foot Sleeve (Pair) |
| GID-3045-K | DVT Knee High Calf Sleeve (Pair) |
| GID-3045-T | DVT Calf/Thigh Sleeve (Pair) |

Product Specifications

| | |
|----------------------------|---|
| Models: | IC-1545-DL, IC-1545-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: | 60 ± 10 seconds |
| Inflation: | 15 seconds (calf mode), 6 seconds (foot mode) |
| Deflation: | 45 seconds (calf mode), 54 seconds (foot mode) |
| Pressure Range: | 20-130 mmHg |
| Precision: | 1 mmHg |
| Accuracy: | ± 20% |
| Features: | Compliance/Usage Meter, Low Pressure Alarm |
| 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: | 4.55 lbs. (2.06 kg) |
| Dimensions: | 6.25" x 8" x 8.25" (159 mm x 203 mm x 210 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

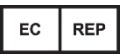











Electromagnetic Emissions













| 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 _{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

| | |
|---|--|
|  | 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 and dripping 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

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

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