



POLAR CARE WAVE™

INSTRUCTIONS FOR USE
INSTRUCCIONES DE USO
MODE D'EMPLOI

A large, detailed black and white microscopic image of a snowflake is centered on the page. The snowflake has a complex, six-pointed structure with intricate branching patterns. It is set against a dark background, with a soft, out-of-focus white area at the bottom, suggesting a snowy surface.

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POLAR CARE WAVE™

INSTRUCTIONS FOR USE

CAUTION: United States Federal Law restricts this device to sale by or on the order of a medical professional.

The Polar Care Wave and cold-compression pads are intended for single patient use only, dispensed with a prescription.

For questions or product inquiries, contact **Breg Customer Care** at **1-800-321-0607** or **+1-760-795-5440**.

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INDICATIONS FOR USE

The Polar Care Wave System is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold and compression are indicated. It is intended to be used by or on the order of licensed healthcare professionals in hospitals, outpatient clinics, athletic training settings, or home settings.

CONTRAINDICATIONS









Cold Therapy shall not be used by patients with any of the following conditions:






- History of cold injury, frostbite, or adverse reactions to local cold application
- Patients who are incoherent due to general anesthesia, sedation, or coma
- Application areas with compromised local circulation or potential wound healing problems, including localized compromise due to multiple surgical procedures
- Circulatory syndromes, including Raynaud's disease, Buerger's disease, peripheral vascular disease, vasospastic disorders, sickle cell anemia, and hypercoagulable clotting disorders
- Local tissue infection
- Hand/wrist or feet/ankle surgery with polyneuropathy
- Diabetic Polyneuropathy

Intermittent Pneumatic Compression Therapy shall not be used by patients with any of the following conditions:

- Inflammatory phlebitis in the affected region
- Suspected/observed pre-existing deep vein thrombosis or pulmonary embolism
- Medical situations where increased venous or lymphatic return is undesirable
- Suspected/observed decompensated hypertonia
- Significant arteriosclerosis or other vascular ischemic disease in affected region

SYMBOLS KEY

Label Symbols	Description
	This is the safety alert symbol. It is used to alert of potential personal injury hazards. Obey all safety messages that follow this symbol to avoid possible injury or death.
	Type BF, applied part
	Class II Equipment
	Refer to instructions for use
IP22	Ingress Protection Marking of IP22: Protection against solid foreign objects of 12.5mm and greater and against vertically falling water drops when tilted up to 15°.
	Disposal of product according to local regulations.
	Breg logo
	Lid Lock/Unlock
	Lid to container alignment

Keypad Symbols	Description
	Colder setting
	Cold setting
	Regular compression setting
	Low compression setting
	On/off button

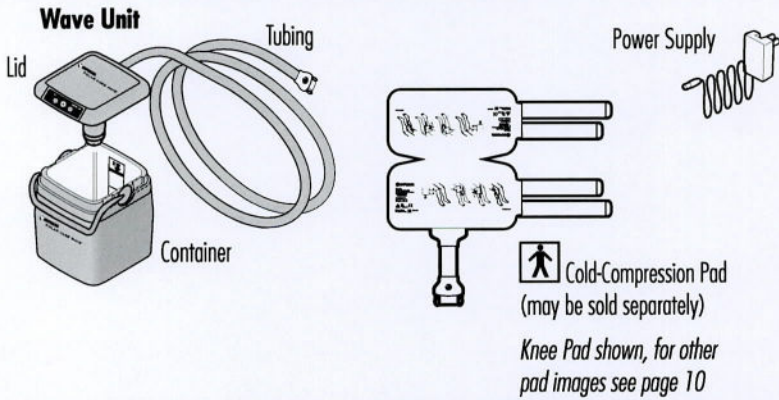
POLAR CARE WAVE DESCRIPTION

The Polar Care Wave is a motorized cold therapy and intermittent compression device. Motorized cold therapy and compression have repeatedly been shown to decrease postoperative pain, swelling, inflammation, and narcotic use following a variety of surgical procedures, such as surgery to the shoulder, knee, and back.

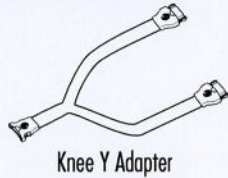
The Polar Care Wave unit consists of a container, tubing, lid with pumps, power supply, and a cold-compression pad. The cold-compression pad is applied to the patient's injured area which delivers cold and intermittent compression therapy. The unit delivers cold therapy by circulating water from the container through the tubing into the cold-compression pad. The compression therapy is delivered by the unit's air pump, which inflates and deflates air into the cold-compression pad providing gentle squeezing of the pad around the affected area. The cold and compression therapies can be used in conjunction with each other or independently of each other, if preferred or prescribed by a licensed healthcare professional. Breg offers a family of cold-compression pads to meet treatment needs (see page 10 for the full cold-compression pad options).

The Polar Care Wave can be used and operated by a patient or caretaker in a home or clinical setting.

These items are included:



Accessories (sold separately):



⚠ WARNINGS

⚠ WARNING

The Polar Care Wave can be cold enough to cause serious injury, including full skin necrosis. Follow and carefully read the instructions for use and the cold-compression pad fitting instructions (printed on each cold-compression pad) prior to use.

WARNINGS

General Warnings

Cognitive risk factors	<p>Patients with any of the following cognitive risk factors should only use Polar Care Wave under direct supervision of a medical professional or caretaker. If patient has any of the cognitive risk factors below, medical professional or caretaker should provide skin checks:</p> <ul style="list-style-type: none">• Young children and elderly• Cognitive disabilities• Communication barriers• Use of medications that have a negative effect upon mental capacity• Visually impaired
Discuss treatment with your licensed healthcare professional	<p>Ask your healthcare professional about potential adverse reactions and cold-induced injuries. Certain medical conditions make cold-induced injury more likely.</p>
Use only as prescribed	<p>Do not use this device if you did not receive or do not understand the instructions. Use only according to your healthcare professional's instructions regarding the frequency and duration of cold and compression application and length of breaks between uses, how and when to inspect the skin, and total length of treatment.</p> <p>Federal law restricts this device to sale by or on the order of a healthcare professional. The Polar Care Wave and cold-compression pads are intended for single patient use only, dispensed with a prescription.</p>
Inspect skin regularly	<p>Inspect the skin under the cold-compression pad (by lifting the edge) as prescribed, typically every 1 to 2 hours. Do not use the Polar Care Wave unit if skins checks are inhibited by a barrier.</p> <p>Stop using and contact your healthcare professional immediately if you experience any adverse reactions, such as: increased pain, burning, increased swelling, itching, blisters, increased redness, discoloration, welts, other changes in skin appearance, or any other reaction identified by your healthcare professional.</p>

Warnings continued through page 7.

⚠ WARNINGS

General Warnings	
General safety	<ul style="list-style-type: none"> • Keep tubing and cords away from the neck to avoid risk of strangulation. • If a leak or a steady stream of water is flowing from any part of the unit, tubing or pad, discontinue use and contact Breg Customer Care. Excess moisture could result in a slip hazard or unwanted moisture at an injury site. • Do not modify, service, or perform unspecified maintenance on this equipment or accessories. Only use parts and accessories designed for the Polar Care Wave. • Set up and use this equipment in a location away from unsupervised children and pets. • Do not operate the unit in a heavy dust/lint environment, excessive dust/lint may cause clogging. Do not leave the unit in direct sunlight, UV light may damage or discolor the unit.
Cold-compression pad	<ul style="list-style-type: none"> • Regularly check the therapy area. • Patients should take caution in applying cold-compression pads over open sores and abrasions. At a minimum, these areas should be cleaned and bandaged. • Do not wrap the cold-compression pads as to restrict blood flow or fluid flow within the cold-compression pad. • Do not apply any casting or restrictive devices over the cold-compression pad and tubing set as this may prevent proper operation and restrict skin checks.

Cold Therapy Warnings	
Cold risk	If the risk of cold-induced injury outweighs the benefits of cold therapy, do not prescribe Polar Care Wave.
Clinical risk factors	<p>If the patient has any of the following clinical risk factors, use of Polar Care Wave may result in serious cold-induced injury, including full thickness skin necrosis:</p> <ul style="list-style-type: none"> • Pathologic sensitivity to cold • Behaviors that negatively affect circulation, including poor nutritional status, smoking and tobacco use, excessive caffeine use, and excessive alcohol use • Cold application area desensitization due to local anesthesia or regional nerve blocks • Diabetes • Hand/wrist or feet/ankle surgery • Taking medications that have a negative effect on peripheral vascular circulation, including beta adrenergic blockers and local epinephrine use (such as in local anesthetics)

Warnings continued on next page.

▲ WARNINGS

Cold risk mitigation	If you prescribe this product to patients with risk factors, consider taking special measures to control the risk, such as: <ul style="list-style-type: none">• Recommending more frequent skin checks. If patient has cognitive risk factors, healthcare professional or caretaker should provide skin checks• Requiring more frequent follow-up examinations• Adding an insulation barrier between the pad and skin• Prescribing shorter durations of application, less frequent application, or eliminating nighttime application• Prescribe the warmer temperature setting (smaller snowflake/"cold" setting)
Application site	Excessive moisture at the application site due to excessive bleeding, sweating, or condensation may increase the risk of serious cold-induced injury, including full thickness skin necrosis.

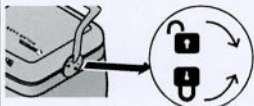
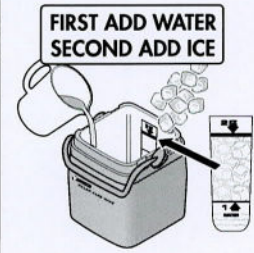

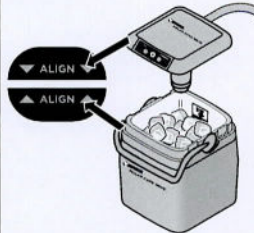
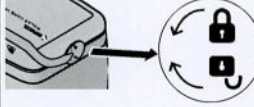
WARNINGS / CAUTIONS

Compression Therapy Warnings	
Compression risk	If the risk of injury outweighs the benefits of compression therapy, do not prescribe Polar Care Wave.
Clinical risk factors	Patients with any of the following compression risk factors should consult with a healthcare professional prior to use: <ul style="list-style-type: none">• Neuropathies or tissue viability problems (i.e. diabetes, arterial or venous insufficiencies.)• Patients positioned in the supine lithotomy position for extended lengths• Poor circulation
Compression risk mitigation	If uncomfortable, lower the compression level to the "low" compression setting or turn off compression and contact your healthcare professional.

CAUTIONS

- Do not walk with tubing connected to the cold compression pads. It is a trip hazard.
- If the unit is damaged or cracked, discontinue use and contact Breg Customer Care.
- Do not use hot water in this unit. It may be unsafe or damage the unit since it has not been designed or tested with use of hot water.
- Do not use any other fluids besides water or recommended cleaning agents on page 13 with the Polar Care Wave. Doing so will damage the unit.
- Do not run cold therapy without water. Using cold therapy without water can cause permanent damage to the water pump.

OPERATING INSTRUCTIONS

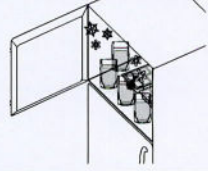
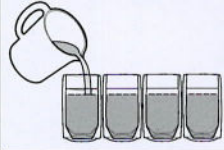
Setup with Water and Ice:		
1	Set up and operate unit on a flat surface so the unit does not tip over.	
2	<p>Unlock handle by rotating handle to the front of the unit.</p> <p>Remove lid and fill container with water to indicated water fill line.</p>	
3	<p>Fill to lines on label inside container. Use cubed ice for optimal performance.</p> <p>Only use ice and water or four (4) Breg Ice Bags and water with this unit (see page 9 for Setup with Breg Ice Bag Accessories).</p> <p>CAUTION: Do not overfill the unit with ice and water. Appropriate levels are indicated by the ice/water label in the container. Overfilling the unit can cause water to spill out or prevent the lid from closing properly.</p>	
4	<p>Place lid on container using align stickers.</p> 	
5	<p>Lock by rotating the handle to the upright or back position according to image on handle.</p>	
6	<p>Every 6-8 hours or as needed, pour out enough water to return water level to original water fill line and re-fill ice to ice line.</p>	

Continue to Power Supply instructions on page 9.

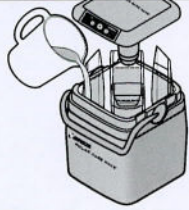
OPERATING INSTRUCTIONS

OPERATING INSTRUCTIONS

Setup with Breg Ice Bag Accessories and Water:	
1	Remove four (4) empty Breg Ice Bags from the packaging. Only use Breg Ice Bags that come with the Polar Care Wave.
2	Fill the four (4) Breg Ice Bags with water to fill line. Do not over fill.
3	Freeze Breg Ice Bags in freezer. Dry Breg Ice Bag exterior before placing in freezer.
4	Set up and operate unit on a flat surface so the unit does not tip over.
5	Unlock handle by rotating handle to the front of the unit. Remove lid and add water to fill line in container.
6	Place all four (4) Breg Ice Bags into the corners of the container as shown. Only use ice and water or four (4) Breg Ice Bags and water with this unit.
7	Replace lid and lock by rotating the handle to the upright or back position.
8	Replace four (4) melted Breg Ice Bags with four (4) frozen Breg Ice Bags every 4-5 hours or as needed. While using the Breg Ice Bags, cubed ice may also be added to the container up to the ice fill line to optimize the colder setting.

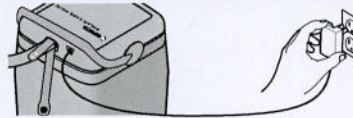


**FIRST ADD WATER
SECOND ADD ICE BAGS**



Power Supply:

1	Plug power supply into the wall and other end of cord into lid.
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OPERATING INSTRUCTIONS

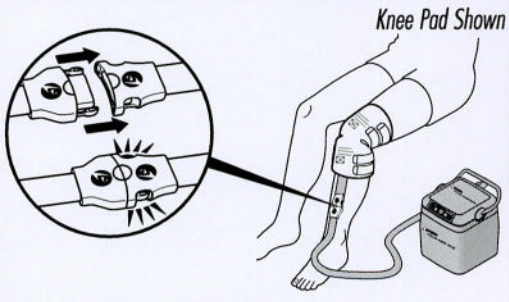
Pad Application:
(Make sure Breg logo and pad instructions are facing out, away from the injury site)

<p>Standard / Large Knee Pad</p>	
<p>Hip Pad</p>	
<p>Shoulder Pad</p>	
<p>Back Pad</p>	
<p>Foot / Ankle Pad</p>	
<p>Universal Pad (use for knee or shoulder)</p>	

OPERATING INSTRUCTIONS

Connecting and Disconnecting Pad to Unit:

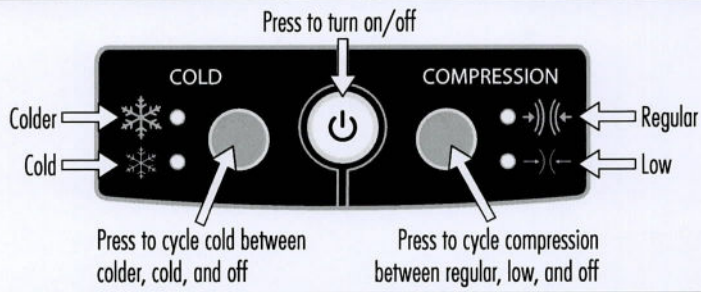
- 1 Line up the Breg logos on the tubing and pad connectors.
- 2 Squeeze down gently on the blue clips.
- 3 Push connectors together until they make a "click" sound.



- 4 Disconnect the cold-compression pad from the unit by pressing the blue clips and gently pulling the connectors apart.
- 4 The Breg Polar Care cold-compression pad may be disconnected from the unit while it's running and connectors will seal, preventing water from flowing out of tubing. **Note:** Some dripping during release is normal.

OPERATING INSTRUCTIONS

Keypad Key:



Operating the Unit:

- 1 Press the on/off button to turn the unit on. It will illuminate.
Upon initial start-up, the unit will default to colder and regular settings for cold and compression therapy, respectively.
If the unit was previously in use, it will default to the last settings selected when the unit was turned off.
 - 2 Press the cold button to cycle between colder, cold, and off.
 - 3 Press the compression button to cycle between regular, low, and off.
 - 4 Press the on/off button to turn the unit off. All lights will turn off.
- Cold and compression therapies may be used at the same time or independently.
 - If the on/off button continuously flashes, refer to troubleshooting guide on page 16.
 - If the on/off button is on and both therapies are off for more than 15 minutes, the unit will automatically shut off.
 - Some condensation on the tube and pad is possible, especially in warmer climates.

CLEANING

▲ WARNING: Do not apply cold-compression pad to patient during the cleaning procedure. Exposure to cleaning agent may cause injury.

CAUTION: Do not apply a direct stream of any liquid onto the unit's lid, submerge the unit, or allow any liquid to pool on the top of the lid. The unit's lid contains all of the unit's electronics.

Clean as necessary or if soiled or debris is present in the unit. If using well water, more frequent cleanings may be required.

Polar Care Wave – Exterior Surfaces

(container, lid, tubing, cold-compression pad, and y-adapter)

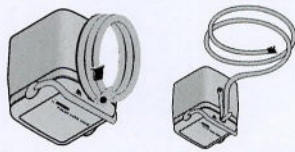
Cleaning agents for home setting:	<ul style="list-style-type: none">• Mild soap• Water
Cleaning agents for clinical setting:	<ul style="list-style-type: none">• Use only mild soap and water on cold-compression pad• PDI sani cloth wipes• Quaternary ammonium
Procedure:	<ul style="list-style-type: none">• Follow the manufacturer's instructions and precautions for the cleaning agent you select.• Use selected cleaner and a soft cloth to wipe surfaces of container, lid, tubing, connectors, and cold-compression pad.• Wipe dry.

Polar Care Wave – Internal Components

(pump system, internal tubing, inside of cold-compression pad, and y-adapter)

Cleaning agents:	<ul style="list-style-type: none">• Bleach• Water
Procedure:	<ul style="list-style-type: none">• Connect pad to unit.• Fill the unit with cold tap water to the ice line and add 1/2 teaspoon of bleach.• Do not add ice.• Run the cold therapy for at least 10 minutes.• Roll the pad while still connected and squeeze the water back into the container.• Disconnect the pad, pour the water out of the unit, and wipe dry.

Storing the Unit:	
1	Remove water from the cold-compression pad by rolling the pad up while still connected and squeezing the water back into the unit. Disconnect cold-compression pad.
2	Pour out water from unit and wipe dry.
3	Coil tubing as shown and secure using straps.
4	Do not store with water. Refer to page 18 for environmental storage requirements.



PRODUCT PART NUMBERS

Product #	Description
100577-000	Polar Care Wave
100578-000	PC Wave Combo Cold Compression Knee
100579-000	PC Wave Combo Cold Compression Shoulder
100580-000	PC Wave Combo Cold Compression Universal
C00003	Breg Cold Compression Pad, Knee L
C00004	Breg Cold Compression Pad, Shoulder
C00005	Breg Cold Compression Pad, Foot/Ankle
C00013	Breg Cold Compression Pad, Hip
C00016	Breg Cold Compression Pad, Universal
C00017	Breg Cold Compression Pad, Knee
C00020	Breg Cold Compression Pad, Back
C00015	Breg Carrying Bag
100581-000	PC Wave Knee Y Adapter
100582-000	Breg Ice Bags
100584-000	PC Wave Replacement Power Supply
100585-000	PC Wave Int'l Adapter Kit Type I Adapter — Australia Type M Adapter — South Africa & United Arab Emirates Type N Adapter — Latin America

PRODUCT PART #S / WARRANTY

WARRANTY

Breg, Inc. warrants that this product is free from defects in workmanship and materials, and fit for use for 180 days from initial purchase under normal use for which it was intended.

Breg, Inc.'s obligation under this warranty is limited to the replacement or repair of any defective part or parts of this product. All expressed or implied warranties, including the warranty of merchantability and fitness for a particular purpose, are limited to the actual warranty period set forth above. No other warranty, expressed or implied, is given and no affirmation of or by seller, by words or action, will constitute a warranty.

TROUBLESHOOTING GUIDE

Problem	Possible Solutions
On/off button flashing notification	<ul style="list-style-type: none"> • Restart the Unit <ul style="list-style-type: none"> ○ Turn unit off by either pressing the on/off button or by disconnecting and reconnecting power supply from the unit or from the wall. ○ Press on/off button to turn unit back on. ○ Press cold or compression therapy buttons (if required) to start desired therapies. • If compression therapy does not function after pressing compression button (cold-compression pad doesn't appear to be inflating or compression therapy setting light is not on), see Compression Therapy troubleshooting sections on page 17. • If cold therapy does not function after pressing cold button, see Cold Therapy troubleshooting section on page 17.
On/off button isn't responding	<ul style="list-style-type: none"> • Confirm power outlet is working and power supply is fully inserted in the outlet. • Confirm that power supply plug is fully inserted into the unit lid. • Confirm the correct Polar Care Wave power supply is connected (see page 18).
Condensation	<ul style="list-style-type: none"> • Wrap material loosely over pad and tubing to minimize air exposure. • Protect the wound site by using a sterile dressing with waterproof barrier. Acceptable barriers include Webril™, Kerlix™, cast padding and elastic bandage. <p>Note: Some condensation on the tube and pad is possible, especially in warmer climates. Place a cloth layer under the container to protect items under the unit.</p>
Unit is leaking from blue connectors	<ul style="list-style-type: none"> • Disconnect blue tabs on the cold-compression pad connector. • Check that the Breg logos on the blue connectors are lined up correctly and reconnect.

If the problem continues, please contact Breg Customer Care at 1-800-321-0607 or +1-760-795-5440 for assistance.

TROUBLESHOOTING GUIDE

Problem	Possible Solutions
<p>Cold therapy: water not flowing to pad or pad not cold</p>	<ul style="list-style-type: none"> • Confirm on/off button is illuminated and a cold therapy "colder" or "cold" setting light is on to indicate that cold therapy is functioning. • Check that blue connectors between cold-compression pad and tubing are fully engaged with Breg logos lined up. Disconnect blue connectors and reconnect if needed. • Allow 10 minutes for cold-compression pad temperature to stabilize. • Confirm unit has both ice and water to appropriate levels. • While using the Breg Ice Bags, cubed ice may also be added to the container up to the ice fill line to optimize the colder setting. • Elevating the unit to the same or higher elevation than the cold-compression pad may increase water flow to the cold-compression pad. • Check that tubing and cold-compression pad are not kinked. • Remove cold-compression pad and lay it flat. Allow cold-compression pad to fill with water and then reapply.
<p>Compression therapy: pad not compressing or filling with air</p>	<p>Note: During compression therapy operation, it is normal for the compression to inflate and deflate continuously. The duration of each inflation-deflation cycle is approximately 1 to 2 minutes.</p> <ul style="list-style-type: none"> • Confirm on/off button is illuminated and a compression therapy "regular" or "low" setting light is on to indicate that compression therapy is functioning. • Check that blue connectors between cold-compression pad and tubing are fully engaged with Breg logos lined up. Disconnect blue connectors and reconnect if needed. • Tighten cold-compression pad. • Check that tubing and cold-compression pad are not kinked. • Remove cold-compression pad and lay it flat. Check if the cold-compression pad is inflating with air and then reapply.
<p>Compression therapy: pad not deflating properly</p>	<ul style="list-style-type: none"> • Check that blue connectors between cold-compression pad and tubing are fully engaged with Breg logos lined up. • Disconnect blue connectors, deflate pad by rolling to remove air, and reconnecting blue connectors if needed.

If the problem continues, please contact Breg Customer Care at 1-800-321-0607 or +1-760-795-5440 for assistance.

PRODUCT SPECIFICATIONS

Electrical Specifications (Also see Electromagnetic Immunity Test Table on page 19)

Unit Rated: 12VDC, 1A		
Power supply is specified as part of ME Equipment		
Manufacturer: HDP	Model: HDP12-MD12010C	Output: 12VDC, max. 1.0A
Back up supply: FRIWO	Model: FW8000M/12	Output: 12VDC, max. 1.0A
Rated Input: 100-240VAC, 50-60Hz		
Standards Compliance:	Designed to conform to applicable requirements of: EN 60601-1, Edition 3.1 and 60601-1-2, 4th Edition	
Electrical Classifications:	Class II, Continuous Operation. Not suitable with flammable anesthetics. Group 1, Class B.	

Physical Specifications

Weight:	5 lbs (2.3 kg) Empty, 16 lbs (7.3 kg) Filled
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Environmental Requirements

Transport & Storage:	-25°C to 5°C, and 5°C to 35°C at a relative humidity of 10% to 90%, non-condensing; >35°C to 70°C at a water vapor pressure up to 50 hPa
Operating:	5°C to 40°C (41°F to 104°F) 15-90% RH non-condensing, 700 hPa to 1060 hPa Indoor use only up to 2000m altitude There is no warm up time required from when the Wave is stored at the minimum storage temperature and when the product is used.

Performance Specifications

Expected Service Life:	1 year from date of first use (unit and accessories).
Average operating temperature of a Polar Care Wave cold-compression pad:	≥45°F at the colder setting ≥50°F at the cold setting
Average peak compression pressure of the cold-compression pad:	50 mmHg at the regular setting 25 mmHg at the low setting

PRODUCT SPECIFICATIONS

Electromagnetic Immunity Test Table

Immunity Test	Basic EMC Standard	IEC 60601 Test Level (Home Healthcare)
Electrostatic discharge (ESD)	IEC 61000-4-2	+/- 8 kV contact +/- 2kV, +/-4kV, +/-8 kV, +/- 15kV air
Radiated RF EM fields	IEC 61000-4-3	10V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Reference IEC 60601-1-2 table 9
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50Hz or 60Hz
Electrical fast transients/bursts	IEC 61000-4-4	+/- 2 kV for power supply lines 100 kHz repetition frequency
Surge	IEC 61000-4-5	+/- 0.5 kV, +/- 1 kV line-to-line +/- 0.5 kV, +/- 1 kV, +/- 2 kV line-to-ground
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V 0.15MHz - 80 MHz 6V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage dips	IEC 61000-4-11	0% UT 0.5 cycle At 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% UT: 1 cycle 70% UT: 25/30 cycles Single phase: at 0 degrees
Voltage interruptions	IEC 61000-4-11	0% UT: 250/300 cycles
<i>Note: UT is the mains voltage prior to application of the test level</i>		

⚠ ELECTRICAL SAFETY

Flammables	<ul style="list-style-type: none">• When using or cleaning the Polar Care Wave, avoid flammables and oxidizers. Do not use in places with flammable vapors or gases (e.g., flammable anesthetics), high oxygen concentrations, or other oxidizers (e.g., nitrous oxide).
Keep electrical components dry and free of debris	<ul style="list-style-type: none">• Even though the Polar Care unit is designed to hold and pump water, the electrical components of the unit and power supply must be kept dry.• Do not handle the power supply or electrical cord with wet hands.• Always keep the unit in a place where the connections will not fall into water (e.g., a tub, sink, etc.).• If the electrical connections fall into water, do not touch any part of the product.• Unplug only at dry electrical connections.
Power supply	<ul style="list-style-type: none">• Use only the power supply provided with the Breg Polar Care Wave unit. Model number is listed in Electrical Specification section on page 18.• Keep the cord and power supply away from heated surfaces.• Never operate this product if it has a damaged cord, power supply, or plug, which could result in electric shock.• If the cord, power supply, or plug is damaged, unplug and contact Breg Customer Care.
Electromagnetic interference and emissions	<ul style="list-style-type: none">• This Polar Care Wave unit may cause electromagnetic or other interference with other electrical devices. Avoid using the Polar Care Wave unit adjacent to or stacked on other equipment because it could result in improper operation of the unit or the other equipment.• Portable RF communications equipment should be used no closer than 12 inches (30 cm) to any part of the Polar Care Wave unit, doing so may result in product performance degradation.• Using accessories or a power supply other than those provided could result in increased electromagnetic emissions or decreased electromagnetic immunity of the unit and can result in unit malfunction.

Disposal

This product contains electrical components and can not be discarded in standard waste. Dispose of product according to local regulations.



DISCHARGE REMINDERS FOR HEALTHCARE PROFESSIONALS

Follow these reminders prior to discharging the patient from facility care to home use.

1. **Patient Screen.** Screen the patient for any contraindications and/or applicable warnings. If the patient has any contraindications (see Contraindications), do not dispense Breg's Polar Care Wave to the patient. If any of the warnings apply to the patient (see Warnings), determine the appropriateness of application of Breg's Polar Care to that patient.
2. **Instructions For Use.** Instruct the patient on how to properly use Breg's Polar Care Wave. Review the Operating Instructions in this document and affixed to the unit with each patient.
3. **Prescription.** Instruct the patient regarding the healthcare professional's prescribed protocol: frequency, compression level, temperature level and duration of use, length of breaks between uses, how and when to inspect the skin, and total length of treatment. A protocol template is included in this document (see page 22) to fill in and provide to the patient. The duration of application, temperature and compression level may vary depending upon the patient. If the patient does not experience pain relief, the physician may increase the duration of application and/or adjust temperature and compression levels. As the application duration is increased, the frequency of the skin inspections should increase (see Warnings). Instruct the patient to take breaks by turning off the unit for a specified period of time.
4. **Potential For Injury.** Inform the patient that improper use can result in serious skin injury, including full thickness skin necrosis. Emphasize the importance of following the prescribed protocol, proper pad application, and skin inspection.
5. **Proper Pad Application.** Instruct the patient to use only the Breg Polar Care Wave cold-compression pad designed for the body part being treated; other pads may not connect or may be colder, increasing the risk of serious cold-induced injury, including full thickness skin necrosis. Do not use the Polar Care Wave unit if skin checks are inhibited by a barrier.
6. **Skin Inspection.** Instruct the patient to inspect the skin receiving treatment per the practitioner's instructions, typically every 1 to 2 hours. Do not use the Polar Care Wave unit if skin checks are inhibited by a barrier.
7. **Discontinue.** Instruct the patient to stop using Breg Polar Care Wave and contact his/her healthcare professional immediately if he/she experiences any adverse reactions, such as: increased pain, burning, increased swelling, itching, blisters, increased redness, discoloration, welts, or other changes in skin appearance.
8. **Documentation.** Provide the patient a prescription for the duration of the total treatment period, the frequency and duration of individual treatment sessions, and the frequency of skin inspections.

Cold Compression Protocol*

Treatment Period	Cold Frequency/Duration	Compression Frequency/Duration	Skin Inspection Frequency
Week 1			
Weeks 2-4			
Week 4+			

*To be completed by a licensed healthcare professional.

Discuss treatment with your licensed healthcare professional

Ask your healthcare professional about potential adverse reactions and cold-induced injuries. Certain medical conditions make cold-induced injury more likely.

Use only as prescribed

Do not use this device if you did not receive or do not understand the instructions. Use only according to your healthcare professional's instructions regarding the frequency and duration of cold and compression application and length of breaks between uses, how and when to inspect the skin, and total length of treatment.

Federal law restricts this device to sale by or on the order of a healthcare professional. The Polar Care Wave and cold-compression pads are intended for single patient use only, dispensed with a prescription.

Inspect skin regularly

Stop using and contact your healthcare professional immediately if you experience any adverse reactions, such as: increased pain, burning, increased swelling, itching, blisters, increased redness, discoloration, welts, other changes in skin appearance, or any other reaction identified by your healthcare professional.

Inspect the skin under the cold-compression pad (by lifting the edge) as prescribed, typically every 1 to 2 hours. Do not use the Polar Care Wave unit if skin checks are inhibited by a barrier.

Contact information

Breg Customer Care 1-800-321-0607 or +1-760-795-5440.