Treatment Period	Awake/ Asleep	Frequency / Duration	Temp	Inspect Skin Every
Day:	Awake			
Through				
Day:	Asleep			
Day:	Awake			
Through				
Day:	Asleep			
Day:	Awake			
Through				
Day:	Asleep			

POLAR CARE® 500

AW-1.90028 REV B

PRODUCT INSERT

INFORMATION FOR PATIENTS & MEDICAL PROFESSIONALS

USAGE TIPS

1. Use cubed or chunked ice for optimal performance.
2. To make sure the pump can work effectively, keep the unit at the same height as the pad or no more than two feet below. A Polar Care Hanger is available upon request if needed to hang the unit at the proper height.
3. To drain the pad between uses, hold it upright with the hose pointed toward the ground. Depress the two black plungers and allow the water to drain out of the pad.
4. You may disconnect the Polar Pad from the unit without removing the pad from the affected area by depressing the tabs on the hose coupling and gently pulling the hoses apart. The Polar Pad and unit will seal itself and will not leak. Note: Some dripping during release is normal.

CLEANING, MAINTENANCE, & SERVICE

After use, drain and dry pump with a soft cloth. Warm water and mild detergent may be used occasionally to clean the pump and tubes. There are no serviceable parts. Contact BREG Customer Service if replacement parts are needed.

DISPOSAL

Dispose of product according to local regulations.

ELECTRICAL SAFETY

Like all electrical products, you must follow precautions to avoid electrocution, fire, burns, or other injuries. Supervise children and invalids near this product to ensure that these precautions are followed.

Keep electrical connections dry

Even though the Polar Care unit is designed to hold and pump water, the electrical connections at the power outlet and from the power cord to the Polar Care unit are not waterproof and must be kept dry.

- Do not handle the transformer 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.).
- Do not use outdoors.

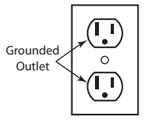
If the electrical connections fall into water, do not touch any wet part of the product. Unplug only at dry electrical connections.

Avoid flammables and oxidizers

Do not use in places with flammable vapors or gasses (for example, flammable anesthetics), high oxygen concentrations or other oxidizers (for example, Nitrous Oxide).

Use a grounded outlet

Connect this product to a properly grounded outlet only.



Protect the power cord and transformer

- Keep the cord and transformer away from heated surfaces.
- Set up and use this equipment in a low traffic location away from children and pets.

Never operate this product if it has a damaged cord, transformer or plug. If the cord, transformer or plug is damaged, unplug and contact BREG Customer Service.

Start the product

Use only the transformer provided with the Polar Care 500®, BREG P/N 6.00230 in order to meet the requirements of UL 60601-1. With dry hands, plug the transformer into an electrical outlet. Insert the opposite end of the plug into the electrical housing receptacle located on the temperature regulator.

Unplug to stop the product when not in use

Unplugging the Polar Care unit turns it off. Always unplug immediately after use. Never leave it plugged in while unattended.

Electromagnetic Interference

This Polar Care unit may cause electromagnetic or other interference with other electrical devices. To check whether the Polar Care unit is interfering with another device, unplug the Polar Care unit. If this corrects the problem, move the Polar Care unit or other device, or use an outlet on a different circuit.

TROUBLESHOOTING GUIDE

Pump not running
Water not flowing to the pad
Temperature reading above 55° F

1. Check that the transformer is properly plugged into the unit and the wall outlet.
2. Ensure ice and water are filled to the indicated level.
3. Check that there are no kinks in the pad.
4. Confirm the pump is completely submerged in the water.
5. Gently pull on the blue tube to make sure the tube/pad junction is straight.
6. To help dislodge possible debris in the line, reverse the flow in the pad by disconnecting the coupling and rotating one end by 180°.
7. Remove the pad and fill it while pad is lying flat; then reapply to the patient.
8. Confirm that the unit is at the same height as the pad or no more than two feet below.
9. Check that the pad couplings are securely attached to the unit.

Leaks

Note: Some condensation on the lines, controller, and pads is unavoidable, especially in warmer climates.

1. If a leak exists (not condensation on the lines) disconnect the pad couplings. Make sure the release clips on the couplings are depressed before reconnecting the pad to the pump hose; then confirm both sides of the coupling are properly clicked in.
2. If a leak is detected in the pad, stop using it and call BREG customer service.

Excessive Noise

1. Check that the pump is completely submerged in the ice water.
2. Confirm that the pump is not resting against the sides or the bottom of the unit. Use the included bowtie clip to prevent this.

Broken Bowtie Clip

If the bowtie clip inside the Polar Care breaks, call BREG customer service for a free replacement. You can still operate the unit by fully submersing the pump in the unit.

WARRANTY

BREG, Inc. warrants that this product is free from defects in workmanship, materials, and fitness for use for 180 days from initial purchase under normal use for which it was intended if it has been properly used under direct supervision of a licensed health care practitioner. BREG, Inc.'s obligation under this warranty is limited to the replacement or repair of any defective part or parts of this product. All express 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, express or implied, is given and no affirmation of or by seller, by words or action, will constitute a warranty.

PRODUCT SPECIFICATIONS

Symbols used on the Polar Care 500

Symbol	Description
⚠	This is the safety alert symbol. It is used to alert you to potential personal injury hazards. Obey all safety messages that follow this symbol to avoid possible injury or death.
	Type B, applied part.

Physical and Electrical Specifications

Electrical Specifications:		
Input	120 VAC 60Hz 28 Watts	
Environmental Requirements:		
Temperature:		
Operating	50°F to 100°F	(10°C to 40°C)
Transport & Storage	-40°F to 158°F	(-40°C to 70°C)
Humidity:		
Operating	30 – 75% R.H.	
Transport & Storage	10 – 100% R.H., non-condensing	
Atmospheric Pressure:	700 hPa to 1060 hPa	
Standards Compliance:	Designed to conform to applicable requirements of: UL 60601-1, CSA C22.2 / No. 601.1	
Electrical Classifications:	Class II, Continuous Operation. Not suitable with flammable anesthetics.	

Product #:	02020
Weight:	5 lb. (2.3 kg) Empty, 21 lb. (9.5 kg) Filled
Average Operating Range:	≥45°F (≥7.2°C)
Plug:	2.5 mm CTR. PIN POSITIVE
Thermometer Accuracy:	+/- 2°F (1.1°C)
Power:	12 VDC 800 mA

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AW-1.90028 REV B

POLAR CARE 500
PRODUCT INSERT

INFORMATION FOR MEDICAL PROFESSIONALS

⚠ WARNING

The Polar Care 500 can be cold enough to seriously injure skin. Follow this information, the Operating Instructions (on the Polar Care 500 lid), and the Polar Pad Fitting Instructions (provided with each Polar Pad).

INDICATIONS FOR USE

The extended use of continuous-flow cold therapy modalities, such as the Polar Care 500, have been shown to have many beneficial effects following surgery. Continuous-flow cold therapy has 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. For a bibliography of extended use continuous-flow cold therapy studies, contact BREG, Inc. at 760-599-3000.

GUIDELINES FOR USE

1. Screen Patients for Contraindications and Risk Factors

Before prescribing cold therapy, always consider the patient's medical history, particularly any contraindications or risk factors. If not appropriately prescribed, continuous-flow cold therapy can result in serious cold-induced injury, including full thickness skin necrosis.

CONTRAINDICATIONS
Patients with any contraindications should not use Polar Care

- History of cold injury, frostbite, or adverse reactions to local cold application.
- Patients that 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.

RISK FACTORS for Cold-Induced Injury

- Pathologic sensitivity to cold.
- Behaviors that negatively effect circulation, including poor nutritional status,smoking and tobacco use, excessive caffeine use, and excessive alcohol use.
- Patients with cold application area desensitization due to local anesthesia or regional nerve blocks.
- Medications that have a negative effect on peripheral vascular circulation, including beta adrenergic blockers and local epinephrine use (such as in local anesthetics).
- Medications that have a negative effect upon mental capacity.
- Excessive moisture at the application site due to excessive bleeding, sweating, or condensation.
- Diabetes.
- Hand/wrist or feet/ankle surgery.
- Cognitive disabilities.
- Communication barriers.
- Young children and the elderly.

If the risk of cold-induced injury outweighs the benefits of cold therapy, do **not** prescribe the Polar Care 500. If you prescribe this product to patients with risk factors, consider taking special measures to control the risk, such as:

- Recommending more frequent skin checks.
- Requiring more frequent follow-up examinations.
- Prescribing higher temperatures or using a thicker insulation barrier between the pad and skin.
- Prescribing shorter durations of application, less frequent application, or eliminating nighttime application.

2. Apply Insulation Barrier and Polar Pad

Always use an insulation barrier (such as BREG Polar Dressing, Webril, Kerlix, cast padding, elastic bandage) between the Polar Pad and skin. **Do not let any part of the Pad touch skin.** If a sterile dressing has been applied to the treatment site that does not completely cover the skin under the pad, use an additional insulation barrier. The Pad alone is too cold to be applied directly to the skin.

Use only BREG Polar Pads. Other pads may be colder, increasing the risk of skin injury.

Do not cover the Polar Pad with dressing, wrapping, bracing, or casting that prevents the patient from checking the skin under the Pad.

3. Provide Prescription and Instructions

The Polar Care 500 is classified by the FDA as a Class II medical device that must be prescribed by a physician or licensed healthcare practitioner. A proper prescription for use must include:

- Operating temperature range;
- Frequency and duration of use (and breaks if applicable);
- Frequency and instruction on skin inspections;
- Treatment Period.

Use the Physician Prescription Form on the other side of this document. This document should be given to the patient (or caregiver) upon discharge or transfer from the recovery room.

Common operating temperatures for patients without risk factors for extended use (longer than 20 minutes) is 45° to 55°F (7.2° to 12.8°C). Never prescribe temperatures below 45°F for longer than 20 minutes per application. This can result in cold-related injuries, including full thickness skin necrosis.

A variety of extended use continuous-flow cold therapy protocols are reported in the literature. Treatment protocols vary based upon specific patient conditions and health history, physician experience with continuous-flow cold therapy application, and medical judgment. See the Sample Cold Therapy Protocols to the right.

Tell patients how to inspect skin under the Polar Pad without compromising the sterile site and how often to do so.
Instruct patients to stop using the Polar Care 500 and contact you immediately if they experience **any** adverse reactions such as: increased pain, burning, increased swelling, itching, blisters, increased redness, discoloration, welts, or other changes in skin appearance.

Review all product information with your patient.
Review the Information for Patients and Medical Professionals in this document, the Operating Instructions on the unit, and the Polar Pad Fitting Instructions.

SAMPLE COLD THERAPY PROTOCOLS

The following protocols are examples of appropriate post-operative extended (>20 minute application) continuous-flow cold therapy for patients with no risk factors. This is not a comprehensive list of treatment possibilities. Treatment protocols for extended continuous-flow cold therapy may vary based upon specific patient conditions and health history, physician experience with cold therapy, and medical judgment.

While protocols may vary, the temperature for extended use should not be below 45˚ F.

The Polar Care 500 has a cold application time up to 11 hours. Accordingly, the unit does not need to be refilled through the night.

Sample Protocol 1

Treatment Period	Frequency / Duration	Temp.	Skin Inspection
Day 1-3	***While awake:*** Continuous	45˚ - 55˚ F	Inspect skin under pad every 1-2 hours
	While asleep: Continuous	45˚ - 55˚ F	Upon waking
Day 4-10	***While awake:*** Cyclic: 1 hour on and 1 hour off	45˚ - 55˚ F	Periodically inspect the skin under pad
	While asleep: Continuous	45˚ - 55˚ F	Upon waking
Day 11 and beyond	***While awake:*** As needed for pain control: Continuous for 1 hour intervals; not to exceed 12 hours/day	45˚ - 55˚ F	Periodically inspect the skin under pad
	While asleep: Continuous	45˚ - 55˚ F	Upon waking

The duration of a cyclic application may vary depending upon the patient. If the patient does not experience pain relief, the physician may increase the duration of application. As the application duration is increased, the frequency of the skin inspections should increase.

Sample Protocol 2

Treatment Period	Frequency / Duration	Temp.	Skin Inspection
Day 1-3	***While awake:*** Continuous	45˚ - 55˚ F	Inspect skin under pad every 1-2 hours
Day 4 to suture removal (day 7-14)	***While awake:*** As needed for pain control: Continuous for 1 hour intervals; not to exceed 12 hours/day	45˚ - 55˚ F	Periodically inspect the skin under pad

Sample Protocol 3

Treatment Period	Frequency / Duration	Temp.	Skin Inspection
Day 1-30	***While awake:*** Cyclic: 1 hour on and 1 hour off	45˚ - 55˚ F	Periodically inspect the skin under pad
	While asleep: Continuous	45˚ - 55˚ F	Upon waking
Day 30 and beyond	As needed for pain control: Continuous for 1 hour intervals; not to exceed 12 hours/day	45˚ - 55˚ F	Periodically inspect the skin under pad

PATIENT DISCHARGE PROTOCOL

Follow this protocol prior to discharging the patient from facility care to home use.

1. **Patient Screen.** Screen the patient for any contraindications and/or associated risk factors. If the patient has any contraindications, do not dispense the Polar Care 500 to the patient. If the patient has any associated risk factors, consult with the licensed healthcare practitioner to determine the appropriateness of application of the Polar Care 500 to that patient.
2. **Instructions For Use.** Instruct the patient on how to properly use the Polar Care 500. Review the Operating Instructions affixed to the unit with each patient.
3. **Prescription.** Instruct the patient regarding the licensed healthcare practitioner's prescribed protocol (temperature, frequency and duration of use, and, if applicable, breaks), frequency and instruction on skin inspections, and treatment period.
4. **Potential For Injury.** Inform the patient that improper use can result in serious skin injury, including necrosis. Emphasize the importance of following the prescribed protocol, proper pad application, and skin inspection.
5. **Proper Pad Application.** Instruct the patient that an insulation barrier must be between the Polar Pad and skin during use. No part of the Polar Pad should touch the skin for any period of time.
6. **Skin Inspection.** Instruct the patient to inspect the skin receiving cold treatment per the practitioner's instructions, typically every 1 to 2 hours. If dressing, wrapping, bracing, or casting over the Polar Pad prevents the ability of the patient to regularly perform skin checks under the pad, do **not** dispense the Polar Care 500 to the patient.
7. **Discontinue.** Instruct the patient to stop using the Polar Care 500 and contact their licensed health care practitioner immediately if they experience **any** adverse reactions such as: increased pain, burning, increased swelling, itching, blisters, increased redness, discoloration, welts, or other changes in skin appearance.
8. **Documentation.** Give the patient this document with the Polar Care 500 Physician Prescription form filled out.