

Hot and Cold Portable Therapy System

NOTE: Please read all instructions and warnings before operating this unit

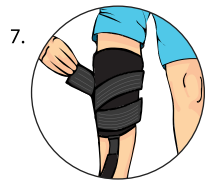
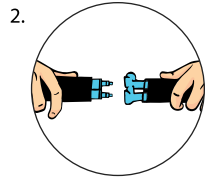
OPERATING INSTRUCTIONS

The CryoHeat can seriously injure skin if used improperly. Follow all instructions to ensure product safety.

DISCUSS TREATMENT WITH YOUR LICENSED HEALTH CARE PRACTITIONER

Provide a complete medical history including any reactions to cold or heat. Ask your practitioner about potential adverse reactions and cold- or heat-induced injuries. Certain conditions make cold- and heat-induced injuries more likely. Use only according to your prescription. Adhere strictly to doctor's instructions regarding use, treatment times, treatment frequency, settings, self-assessment and general best practices regarding your specific condition.

- NEVER OPERATE UNIT WITHOUT WATER.** User must add water to the fill line before turning on the pump. Make sure the power supply is unplugged while adding or emptying water.
- Connect therapy pad to the cooler hose. Couplings will click when they lock together.
- For cold therapy, open the cooler and fill with ice to above the fill line and then add cool tap water to the fill line. For heat therapy, add warm tap water to fill line.
- Plug power supply into a wall outlet (see power supply label for voltage). **NOTE: Always unplug device when refilling with ice or water.**
- Position pad on the target area with the smooth side toward the skin.
- Always use an insulation barrier (such as Webril, Kerlix, cast padding, or elastic bandage) between the CryoHeat therapy pad and skin. **NOTE: Do not let the CryoHeat therapy pad treat exposed skin. If a sterile dressing is required by your doctor, but does not wholly cover the skin under the therapy pad, use an additional barrier.**
- If you are using the universal pad, use the enclosed elastic belt to "mummify" the wrap onto the body part by wrapping the belt around the body part.
- Set your temperature mode to the desired temperature; cold or high heat. Be sure to consult with your physician if you are treating a condition.
- The Control Panel settings on the device are **COLD**, when using with ice and water, and **HOT** when using tap water. When using cold therapy, periodically replenish ice as needed.
- The treatment timer is an analog timer; once adjusted, the timer will set to that time until expired. **DANGER: The C setting is for continuous operation of the device (with no automatic shut-off) and it can be dangerous if not monitored. Please consult your physician for recommended treatment time settings prior to use.**
- User **MUST** empty water from the device after every treatment session. If an adverse reaction occurs, discontinue use and contact your physician immediately.



CAUTIONS AND WARNINGS

DANGER - To reduce the risk of burns, adverse reactions and malfunction, this product must be used in accordance with the following instructions.

Patients first need to be assessed by physicians for contraindications, risk factors, and medical history before using this product. If used improperly, continuous-flow cold therapy could result in serious injury like full thickness skin necrosis. Supervision may be necessary to ensure precautions are followed, especially with young children and the elderly.

- Ensure pads are not wrapped too tight.
- If numbness or burning occurs, discontinue use and consult your prescribing physician.
- Heat can burn or irritate skin. For this reason, it is best not to use it directly against the skin. Note: Minor skin redness is to be expected.
- If the CryoHeat pump is being used on an injury, refrain from using heat for at least 48 hours.
- While in use, keep on a low surface, but away from disturbance by pets or children.
- Monitor patients' skin condition during therapy (every 20 minutes); special care monitoring must be provided for children, patients on prolonged therapy, unconscious or incapacitated patients, diabetics, and those with poor circulation.
- If you notice any adverse reactions, discontinue use immediately and consult your physician.
- Treatment time is highly individual and condition specific. Please consult your physician.

CONTRAINDICATIONS

- History of cold injury, frostbite, or adverse reactions to cold application
- History of heat injury or adverse reactions to heat
- Application areas with compromised local circulation
- Potential wound healing problems, including those from multiple surgical procedures; do not apply heat to areas that are susceptible to developing bed sores
- Circulatory syndromes such as 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 w/ polyneuropathy

RISK FACTORS FOR COLD-INDUCED INJURY

- Pathological sensitivity to cold
- Young children and the elderly
- Behaviors that negatively affect circulation, such as poor nutritional habits, using tobacco, caffeine abuse, and alcohol abuse
- Medications that negatively impact mental capacity
- Diabetics
- Application area desensitization due to local anesthesia or regional nerve blocks
- Medications that have a negative effect on peripheral vascular circulation: beta adrenergic blockers and localized epinephrine
- Excessive moisture at the application site
- Hand/wrist or feet/ankle surgery
- Communication barriers

If the risk of cold-induced injury is greater than the benefit of cold therapy, do not prescribe the CryoHeat. When prescribing to patients with risk factors:

- Use higher temperatures or a thicker insulation barrier on the skin
- Shorter treatment times, less frequent application, or eliminating nighttime application

WATER DAMAGE AND LEAKS

WATER SPILLAGE CAN HAPPEN DURING USE. THEREFORE, PLEASE SET THE CRYOHEAT ON A SURFACE THAT CAN TOLERATE SPILLS OR WATER ABSORPTION. DO NOT USE ON WOOD THAT CAN WARP, FINE CARPET, MATERIAL THAT WILL BLEED COLOR, ETC. HOWEVER, IF YOUR PRODUCT LEAKS OR HAS ANY OTHER MECHANICAL DEFECT, DISCONTINUE USE AND CONTACT YOUR PROVIDER IMMEDIATELY.

ELECTRICAL PRECAUTIONS

Keep connections dry. The CryoHeat holds and pumps water, the electrical connections at the power outlet and from the power cord to the CryoHeat device are not waterproof and must be kept dry. Always keep the device in a location 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 wet part of the product. Unplug only at dry electrical connections.

Do not operate - or unplug immediately - if transformer, plug, or cord is damaged. To resolve damaged parts, unplug and contact Zynex Medical.

- CONNECT TO A PROPERLY GROUNDED OUTLET ONLY.**
- DO NOT HANDLE THE TRANSFORMER OR ELECTRICAL CORD WITH WET HANDS.**
- UNPLUG TO STOP THE PRODUCT WHEN NOT IN USE.**
- Unplug immediately after use. Never leave unattended when plugged in.
- USE INDOORS ONLY**
- FLAMMABILITY:** Do not use in locations with flammable vapors or gases, high oxygen concentration or other oxidizers. Risk of explosion if used in the presence of flammable anesthetic. Keep the cord and transformer away from heated surfaces.

CARE AND MAINTENANCE

The CryoHeat therapy pump can run on tap water. Distilled water will help keep the unit running cleaner than tap water, but it is not necessary to its operation. To clean your device, fill unit to fill line and then add a quarter cup of bleach or rubbing alcohol to circulate through the device for 10 minutes. Then drain and refill with tap water, and then drain again. This should be performed once every 6-12 months.

When using the large therapy boot (after turning the unit on), add water to the fill line, as the large boot consumes more water. It is optimal to empty the water out of the hose and therapy pad. However, all water does not need to be removed from the therapy pad (it is difficult to do so). If you do not empty the water out of your hose, upon your next use, you will have cold water mixing with warm tap water. Either let it cycle with the heater on - or replenish the reservoir with hotter tap water.

WARRANTY

WARRANTY: A six month manufacturer's warranty is given to all water therapy systems. This warranty is for replacement of like items only. The warranty does not cover items out of production. If the item is no longer in stock, then we will upgrade to a similar model. The warranty policy only applies to the device and does not include the therapy pad or accessories supplies with the unit. The therapy pad is covered under a 30-day warranty. Devices used as commercial rentals can void the warranty.