

AQUA-RELIEF

Model ARS-2000D

Hot and cold portable therapy system

Note: please read all instructions and warnings before operating this unit

OPERATING INSTRUCTIONS

The ARS 2000 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. Ask your practitioner about potential adverse reactions and cold-induced injuries. Certain conditions make cold-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.

1. Connect therapy pad (or booties if provided) to the cooler hose. Couplings will click when they lock together.
2. Make sure the power supply is unplugged while adding water;
3. For cold therapy, open the cooler and fill with ice to above the fill line and then fill with water to the fill line; for heat therapy, add warm tap water to fill line. NEVER OPERATE UNIT WITHOUT WATER. User must fill water to the fill line before turning on the pump.
4. Plug power supply into the wall outlet. (See power supply label for voltage.) **NOTE: Always unplug unit when refilling with ice and water.**
5. Position pad on the target therapy area with the smooth side toward the skin or slip on the booties.
6. If booties are included with your system, always use with the diabetic socks provided; the socks provide buffering and comfort to the area. Place feet into the booties and secure Velcro strap. Always use an insulation barrier (such as Webriil, Kerlix, cast padding, or elastic bandage) between the ARS therapy pad and skin. **NOTE: Do not let the ARS 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 insulation barrier.**
7. If you are using the universal or back pad, use the enclosed elastic belt to comfortably hold the wrap in place. Do not over-tighten the elastic belt.
8. Set your temperature mode to the desired temperature; cold, low heat or high heat. Be sure to consult your physician if you are treating a condition.
9. The Control Panel settings on the unit are **Cold**, when using with ice and water, and **Hot** when using tap water. When using cold therapy, periodically replenish ice as needed.
10. The Treatment Timer is located opposite the Control Panel. Consult your physician for recommended treatment time settings, however, automatic shot-off is at 60 minutes.
11. User **MUST** empty water from the unit after every treatment session.

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 their 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.

1. Ensure pads are not wrapped too tight.
2. If numbness or burning occurs, discontinue use and consult your prescribing physician.
3. 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.
4. If the ARS pump is being used on an injury; refrain from using heat for at least 48 hours.
5. While in use, keep on a low surface, but away from disturbance by pets or children.

CONTRAINDICATIONS

- » History of cold injury, frostbite, or adverse reactions to cold application
- » History of heat injury or adverse reactions to heat
- » 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
- » 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 bedsores
- » 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 effect circulation, such as poor nutritional habits, using tobacco, caffeine abuse, and alcohol abuse
- » Medications that negatively impact mental capacity
- » Diabetes
- » 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 ARS 2000. 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
- » Frequent skin checks and follow up examinations

WATER DAMAGE AND LEAKS » **WATER SPILLAGE CAN HAPPEN DURING USE. THEREFORE, PLEASE SET THE ARS-2000 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 ARS 2000 holds and pumps water, the electrical connections at the power outlet and from the power cord to the ARS 2000 unit are not waterproof and must be kept dry. 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 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 PMT.

- » **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 places with flammable vapors or gasses, high oxygen concentrations 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 | WARRANTY

The ARS 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 circulate through your unit for 10 minutes then drain and rerun 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 going to be 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 your warm tap water. Either let it cycle with the heater on - or replenish the reservoir with hotter tap water.

WARRANTY: A one year 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 like model. The warranty policy only applies to the device and does not include the pad or accessories supplied with the unit. The pad is covered under a 30-day warranty. Units used as commercial rentals can void the warranty.

Prescription labeling: Federal law restricts this device to sale or use by or on the order of a practitioner so licensed by the state.

ARS-2000 IMPORTANT SAFETY INSTRUCTIONS READ AND FOLLOW ALL INSTRUCTIONS DO NOT DESTROY

MUST READ Before Using ARS System • DO NOT SIT, STAND OR LAY ON PADS

Please consult physician before using this device

⚠ WARNING

The ARS-2000 can be cold enough to seriously injure the skin.

Follow these Operating Instructions, the must-read safety instructions and all accompanying documentation.

WATER DAMAGE and LEAKS • WATER SPILLAGE CAN HAPPEN DURING USE.

THEREFORE, PLEASE SET THE ARS-2000 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.

To REDUCE THE RISK OF BURNS, ELECTRICAL SHOCK AND FIRE, THIS PRODUCT MUST BE USED IN ACCORDANCE WITH THE FOLLOWING INSTRUCTIONS.

Cautions and warnings: to reduce the risk of burns, adverse reactions, and malfunction, this product must be used in accordance with instructions.

Contraindications

- SAFETY FOR THE ARS FOR USE DURING PREGNANCY HAS NOT BEEN ESTABLISHED.
- CAUTION SHOULD BE USED FOR PATIENTS WITH SUSPECTED OR DIAGNOSED HEART PROBLEMS.
- CAUTION SHOULD BE USED FOR PATIENTS WITH SUSPECTED OR DIAGNOSED EPILEPSY.

Precautions

- SENSITIVE SKIN PATIENTS OR PATIENTS WITH COMPROMISED CIRCULATORY DISORDERS MUST CONSULT THEIR PHYSICIAN IN ALL SITUATIONS.
- THERE IS ABSOLUTE DANGER IN USING ARS IN CONJUNCTION WITH EXTERNAL ANALGESICS. PLACING METHYL SALICYLATE, CAMPHOR, OR MENTHOL-CONTAINING EXTERNAL ANALGESICS ON THE PAINFUL AREA INCREASES SUPERFICIAL BLOOD FLOW. IF A HEATING PRODUCT IS SUBSEQUENTLY PLACED ON THE MEDICATED AREA, THE HEAT DELIVERED TO THE SITE CANNOT BE REDISTRIBUTED VIA BLOOD FLOW. THIS INCREASES THE RISK OF BURNS.

Warnings

- IF YOU ARE PREGNANT, PLEASE CONSULT YOUR PHYSICIAN BEFORE USING
- PLEASE CONSULT YOUR PHYSICIAN BEFORE USING
- IF YOU HAVE SENSITIVE SKIN, OR SKIN INSENSITIVITY, PLEASE CONSULT YOUR PHYSICIAN
- ARS SHOULD BE KEPT OUT OF THE REACH OF INFANTS AND CHILDREN
- DO NOT USE WHILE SLEEPING
- THIS PRODUCT IS NOT TO BE USED BY AN INVALID, UNCONSCIOUS PERSON OR PERSON WITH LOW BLOOD CIRCULATION UNLESS ATTENDED
- DO NOT LEAVE UNATTENDED WHILE TURNED ON
- DISCONTINUE USE IF YOU EXPERIENCE IF RASH OR DISCOMFORT PERSISTS
- CHECK SKIN UNDERNEATH THERAPY WRAP PERIODICALLY THROUGHOUT A TREATMENT SESSION
- ARS SHOULD NOT BE APPLIED OVER CANCEROUS LESIONS, WOUNDS, INFECTED AREAS OR OPEN SORES
- BURNS CAN OCCUR REGARDLESS OF CONTROL SETTING. CHECK SKIN UNDER PAD FREQUENTLY
- NEVER UNPLUG BY PULLING ON THE CONNECTING CORDS
- TURN OFF WHEN NOT IN USE
- AFTER APPLYING PAD RUN UNIT FOR 15 MINUTES AND CHECK FOR ANY DISCOMFORT. IF YOU FEEL THAT THE TEMPERATURE IS TOO HOT – PLEASE DISCONTINUE USE AND CONTACT YOUR SUPPLIER
- DO NOT TOUCH ANY OF THE COMPONENTS INSIDE YOUR RESERVOIR WHILE THE SYSTEM IS PLUGGED IN
- PATIENT SHOULD USE EXTREME CAUTION WHEN USING UNIT FOR LONG PERIODS OF TIME AND SHOULD MONITOR SKIN UNDERNEATH PAD EVERY 20 MINUTES. IT IS RECOMMENDED TO TAKE REST TIME FROM TREATMENTS – ESPECIALLY TREATMENTS EXCEEDING 60 MINUTES

PHYSICIAN INSTRUCTIONS for PRESCRIPTION of this ITEM:

PLEASE READ THE FOLLOWING AND PROVIDE THIS FORM TO YOUR LICENSED HEALTH CARE PROFESSIONAL

Provide Prescription and Instructions

The ARS-2000 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

Treatment protocols vary based upon specific patient conditions and health history, physician experience with continuous-flow cold therapy application, and medical judgment. Tell patients how to inspect skin of the treatment site without compromising the sterility, and how often to do so. Instruct patients to stop using the ARS-2000 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 all ancillary instructions.

PATIENT DISCHARGE PROTOCOL: Follow this protocol prior to discharging the patient from facility care to home use

1. Screening. Screen the patient for any contraindications and/or associated risk factors. If the patient has any contraindications, do not prescribe the ARS-2000 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 ARS-2000.

2. 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.

3. 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.

4. Instructions. Instruct the patient on how to properly use the ARS-2000. Review the Operating Instructions with each patient.

5. Proper Therapy Pad Application. Instruct the patient that an insulation barrier must be between the Therapy Pad and skin during use. No part of the Therapy 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 20 minutes. If dressing, wrapping, bracing, or casting over the Therapy prevents the ability of the patient to regularly perform skin checks under the pad, do not dispense the ARS-2000 to the patient.

7. Discontinue. Instruct the patient to stop using the ARS-2000 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.

Apply Insulation Barrier & Therapy Pad

Always use an insulation barrier (such as Webril, Kerlix, cast padding, or elastic bandage) between the ARS therapy pad and skin. Do not let any ARS 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 insulation barrier.

Skin Inspection

Inspect the skin of the treatment areas as prescribed (every 20 minutes). Do not use the ARS-2000 if dressing, wrapping, bracing, or casting over prevents skin checks. Stop using and contact your practitioner 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 practitioner*