

Medivance Arctic Sun® Energy Transfer Pad™ Temperature Management System Instructions for Use



Directions for use

1. Arctic Sun Energy Transfer Pads are only for use with an Arctic Sun Control Module. See Operators Manual for detailed Instructions on system use.
2. Select the proper number, size and style pad for the patient size and clinical indication. However, the rate of temperature change and potentially the final achievable temperature is affected by pad surface area, patient size, pad placement and water temperature range. Best system performance will be achieved by using the maximum number and largest size pads.
3. For patient comfort, the pads may be prewarmed using Water Temperature Control Mode (manual) prior to application.
4. Place the pads on healthy, clean skin only. Remove any creams or lotions from patient's skin before pad application. Remove the release liner from each pad and apply to the appropriate area. The pads may be overlapped or folded adhesive-to-adhesive to achieve proper placement. The pads may be removed and reapplied if necessary. The pad surface must be contacting the skin for optimal energy transfer efficiency.
5. Attach the pad's line connectors to the patient line manifolds. Begin circulating water through the pads using either Patient Temperature Control Mode (automatic) or Water Temperature Control Mode (manual). If the pads fail to prime or a significant continuous air leak is observed in the pad return line, check connections, then if needed replace the leaking pad.
6. Once all the pads are primed, assure the flow rate displayed on the control panel is appropriate for the number of pads connected.

The minimum flow rates are:

Number of Pads	2	3	4	5
Flow Rate, lpm	1.3	1.8	2.3	2.8

7. When finished, purge water from pads. Slowly remove pads from the patient and discard.

Indications

The Arctic Sun® Temperature Management System is intended for monitoring and controlling patient temperature within a range of 33°C and 37°C (91.4°F and 98.6°C).

The indications include any condition where patient temperature control within a range from mild hypothermia to normothermia is required. This includes, but not limited to, medical, surgical, febrile, accidental hypothermia or heat stroke patients.

Contraindications

There are no known contraindications for the use of a thermoregulatory system.

Do not place Arctic Sun Energy Transfer Pads on skin that has signs of ulcerations, burns, hives or rash.

While there are no known allergies to hydrogel materials, caution should be exercised with any patient with a history of skin allergies or sensitivities. Some pad styles include medical grade adhesive edge

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tapes to minimize the chance of solutions pooling between the pad and skin. Do not apply the adhesive tape to patients with a history of sensitivity to adhesive tape.

The pads do not contain latex.

Cautions

Federal law restricts this device to sale by or on the order of a physician.

This product is to be used by or under the supervision of trained, qualified medical personnel.

The clinician is responsible for determining the appropriateness of use of this device and the user-settable parameters, including water temperature, for each patient. Due to underlying medical or physiological conditions, some patients are more susceptible to skin damage from pressure and heat or cold. Patients at risk include those with poor tissue perfusion or poor skin integrity due to diabetes, peripheral vascular disease, poor nutritional status or steroid or high dose vasopressor therapy. If accessible, examine the patient's skin under the Energy Transfer Pads often; especially those patients at higher risk of skin injury.

Skin injury may occur as a cumulative result of pressure, time and temperature. Do not place bean bags or other firm positioning devices under the Energy Transfer Pads. Do not place any positioning devices under the Pad manifolds or patient lines.

Do not allow antibacterial agents to pool underneath the Energy Transfer Pads. Excess antibacterial agents can absorb into the pad adhesive and cause chemical burns and loss of pad adhesion.

Do not place an Energy Transfer Pads directly over an electrosurgical grounding pad. The combination of heat sources may result in skin burns.

Carefully remove Energy Transfer Pads from the patient's skin at the completion of use. Aggressive removal of the pad or edge tape adhesive from the patient's skin may result in skin tears.

The Energy Transfer Pads are non-sterile for single patient use only. Do not place pads in the sterile field. If used in a sterile environment, pads should be placed according to the physician's directions, either prior to the sterile preparation or sterile draping.

Do not reprocess or sterilize.

Use Pads immediately after opening. Do not store pads in opened pouch.

Do not allow circulating water to contaminate the field when lines are disconnected.

The Energy Transfer Pads should not be punctured with sharp objects. Punctures will result in air entering the fluid pathway and may reduce performance.

If warranted, use pressure relieving or pressure reducing devices under the patient to protect from skin injury.

The Energy Transfer Pads are only for use with an Arctic Sun Control Module.

The Energy Transfer Pads must be changed after 72 hours of use.



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