



Arctic Sun™ Analytics

Subscription Service



Indications for use

The Arctic Sun™ Temperature Management System is a thermal regulating system, indicated for monitoring and controlling patient temperature in adult and pediatric patients of all ages.

Contraindications

- There are no known contraindications for the use of a non-invasive thermoregulatory system.
- Do not place ArcticGel™ pads on skin that has signs of ulcerations, burns, hives or rash.
- Do not remove the fabric release liner of the Neonatal ArcticGel™ pad and expose the hydrogel.
- Do not place ArcticGel™ pads on immature (non-keratinized) skin or premature babies.
- While there are no known allergies to hydrogel materials, caution should be exercised with any patient with a history of skin allergies or sensitivities.

Warnings

- When using the Arctic Sun™ Temperature Management System, note that all other thermal conductive systems, in use while warming or cooling with this device may interfere with patient temperature control.
- The Arctic Sun™ Temperature Management System is not intended for use in the operating room environment.
- Medivance supplies temperature simulators (fixed value resistors) for testing, training and demonstration purposes. Never use this device, or other method, to circumvent the normal patient temperature feedback control when the system is connected to the patient. Doing so exposes the patient to the hazards associated with severe hypo- or hyper-thermia.

Cautions

- 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 edema, diabetes, peripheral vascular disease, poor nutritional status, steroid use or high dose vasopressor therapy. Examine the patient's skin under the ArcticGel™ pads.
- Skin injury may occur as a cumulative result of pressure, time and temperature.
- Carefully remove ArcticGel™ pads from the patient's skin at the completion of use. Aggressive removal or removal of cold pads from the patient's skin may result in skin tears.
- The rate of temperature change and potentially the final achievable patient temperature is affected by many factors. Treatment application, monitoring and results are the responsibility of the attending physician. If the patient does not reach target temperature in a reasonable time or the patient is not able to be maintained at the target temperature, the skin may be exposed to low or high water temperatures for an extended period of time which may increase the risk for skin injury.

Please consult package insert for more detailed safety information and instructions for use.

Federal Law (USA) restricts this device to sale by or on the order of a physician.

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