

**Bair Hugger® Therapy**

## Indications for Use & Warnings

### Bair Hugger Blankets

#### **INDICATIONS**

The Bair Hugger Temperature Management system is intended to prevent and treat hypothermia. In addition, the temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The temperature management system can be used with adult and pediatric patients.

#### **CONTRAINDICATIONS**

Do not apply heat to lower extremities during aortic cross-clamping. Thermal injury may occur if heat is applied to ischemic limbs.

#### **WARNINGS**

1. Do not leave patients with poor perfusion unmonitored during prolonged warming therapy sessions. Thermal injury may result.
2. Do not use this blanket with any device other than a Bair Hugger unit. Do not use Bair Hugger 200 series warming units in operating rooms. Thermal injury may result.
3. Do not treat patients with the Bair Hugger hose alone. Thermal injury may result. Always attach the hose to a Bair Hugger blanket before providing therapy.
4. Do not place the non-perforated side of the blanket on the patient. Thermal injury may result. Always place the perforated side (that is, with small holes) towards the patient.
5. Do not continue temperature management therapy if the over-temp indicator light illuminates and the alarm sounds. Thermal injury may result. Unplug the unit, and contact a qualified service technician.
6. Do not use a forced-air warming device over transdermal medications; increased drug delivery, patient injury, or death may occur.
7. Do not allow the patient to lie on the warming unit hose or allow the hose to directly contact the patient's skin during patient warming; thermal injury may result.
8. Do not use a Bair Hugger blanket to transfer or move the patient, injury may result.
9. Do not use any fluid administration device other than the 241® blood/fluid warming set with Bair Hugger warming units. Thermal injury or device damage may result.

#### **CAUTIONS**

1. Except for specific blanket models, Bair Hugger blankets are not sterile and are intended for single patient use ONLY. Placing a sheet between the Bair Hugger blanket and the patient does not prevent contamination of the product.
2. Do not leave pediatric patients unattended during therapy.

3. This product is classified as Class I Normal Flammability as defined by the Consumer Products Safety Commission's flammable fabric regulation, 16 CFR 1610. However, follow standard safety protocols when using high intensity heat sources.
4. Monitor the patient's temperature and cutaneous response of patients who are incapable of reacting, communicating and/or who are without a sense of feeling every 10-20 minutes or according to institutional protocol and monitor the patient's vital signs regularly. Adjust air temperature or discontinue therapy when the therapeutic goal is reached or if vital sign instability occurs. Notify physician of vital sign instability immediately.

## Bair Hugger Temperature Management Units

### INDICATIONS

The Bair Hugger Temperature Management system is intended to prevent and treat hypothermia. In addition, the temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The temperature management system can be used with adult and pediatric patients.

### CONTRAINDICATIONS

Do not apply heat to lower extremities during aortic cross-clamping. Thermal injury may occur if heat is applied to ischemic limbs.

### WARNINGS

1. Do not leave patients with poor perfusion unmonitored during prolonged warming therapy sessions. Thermal injury may result.
2. The Bair Hugger temperature management unit has been designed to operate safely ONLY with Arizant Healthcare® disposable components. Use with other products may cause thermal injury. (To the full extent permitted by law, the manufacturer and/or importer declines all responsibility for thermal injury resulting from the unit being used in conjunction with non-Arizant Healthcare products.)
3. Do not warm patients with the temperature management unit hose alone. Thermal injury may result. Always connect the hose to a Bair Hugger blanket or Bair Paws gown before providing therapy.
4. Do not place the non-perforated side of the blanket on the patient. Thermal injury may result. Always place the perforated side (that is, with small holes) towards the patient.
5. Do not continue temperature management therapy if the over-temp indicator light illuminates and the alarm sounds. Thermal injury may result. Unplug the unit, and contact a qualified service technician.
6. Do not continue 241 blood/fluid warming therapy if the over-temp indicator light illuminates and the alarm sounds. Immediately stop fluid flow, and discard the blood/fluid warming set. Unplug the temperature management unit, and contact a qualified service technician.
7. Do not use a forced-air warming device over transdermal medication. Increased drug delivery and patient injury or death may occur.

8. Do not allow the patient to lie on the warming unit hose or allow the hose to directly contact the patient's skin during patient warming; thermal injury may result.
9. Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
10. Reusable blankets made from woven fabric, or blankets without discrete, visible holes, can cause the safety system of this unit to fail, which may result in serious thermal injury. This warming unit has been designed to operate safety ONLY with Bair Hugger® blankets and Bair Paws® gowns.

## CAUTIONS

1. Except for specific blanket models, Bair Hugger blankets are not sterile and are all intended for single patient use ONLY. Placing a sheet between the Bair Hugger blanket and the patient does not prevent contamination of this product.
2. Monitor the patient's temperature and cutaneous response of patients who are incapable of reacting, communicating and/or who are without a sense of feeling response every 10-20 minutes or according to institutional protocol and monitor the patient's vital signs regularly. Adjust air temperature or discontinue therapy when the therapeutic goal is reached or if vital sign instability occurs. Notify physician of vital sign instability immediately.
3. Do not leave pediatric patients unattended during therapy.
4. Do not initiate temperature management therapy unless the temperature management unit is safely placed on a hard surface or securely mounted. Otherwise, injury may result.
5. To prevent tipping, clamp the Temperature Management Unit to an IV pole at a height that provides stability. We recommend clamping the unit no higher than 44" (112cm) on an IV pole with a minimum 28" (71 cm) diameter wheelbase. Failure to do so may result in IV pole tipping, catheter site trauma, and patient injury.
6. Electrical shock hazard. Do not disassemble the temperature management unit unless you are a qualified service technician. There are electrically live parts with in the unit when it is connected to a power source, even when the unit is in Standby mode.

## NOTICES

1. The Bair Hugger temperature management unit meets medical electronic interference requirements. If radio frequency interference with other equipment should occur, connect the unit to a different power source.
2. Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare professional.
3. To reliably ground this BH warming unit, only connect to receptacles marked "Hospital Only" or "Hospital Grade."