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510(k) Summary of Safety & Effectiveness

SAFETY

This 510(k) Summary of Safety & Effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The device is a Class II device, System Thermal Regulating 74 DWG, Patient Warming System called the Bair Hugger® Total Temperature Management® System - Model 505 Warming Unit. The predicate device is the Bair Hugger® Patient Warming System, Model 500 Warming Unit. The following summarizes safety issues related to skin surface warming devices and the measures to prevent these problems.

1. Summary of Safety:

A. **Injuries to tissue:** Cutaneous burns. Thermal injury is determined by a combination of temperature and time. Patients with ischemic limbs or extremely poor perfusion are especially susceptible to thermal injuries.

Prevention: The Bair Hugger® Series 500's Maximum Heat Output (setting III at 43°C) does not provide temperatures high enough to cause burns to tissue when used as directed. Performance testing demonstrated that by the time the air leaves the Bair Hugger Temperature Management Units, flows through the hose and is circulated through the inflatable Blanket placed over the patient, temperatures have dropped from 43°C to 41°C. These temperatures are well within the range of safety[1,2].

Over-temperature condition: Bair Hugger Temperature Management Units temperature-out-of-range detection system is an independent, mechanical, using thermostats to detect over temperature conditions. The system triggers audible and visual alarms and shuts the heating elements down when over-temperature conditions are detected.

Labeling: Labels affixed to each Bair Hugger Blanket at the inlet port *and* packaged with each Bair Hugger Blanket read as follows:
"Contraindications: 1. Do not apply heat to lower extremities during aortic cross-clamping. Thermal injury to ischemic limbs may occur.
2. Do not leave patients with poor perfusion unmonitored durihg prolonged warming therapy sessions."

B. **Hyperthermia:** Warming treatment continued past the point of the patient reaching normothermia may eventually produce hyperthermia[3].

Prevention: Instructions packaged with each Bair Hugger® Blanket instruct the user to "Monitor the patient's temperature at least every 10-20 minutes."

C. Other Safety Concerns:

1. **Contamination.** Airborne contamination from air blown intraoperatively across the surgical wound may result in airborne contamination.

   Prevention of airborne contamination: All Bair Hugger® Blankets designed for use in the operating room feature a tape barrier which prevent air from migrating toward the surgical site. Additionally, air is filtered through a 0.2 micron filter. Two studies have concluded that the Bair Hugger® 500 Series Units (that have the same air output specifications and the same filter density as the Model 505) do not increase the incidence of microbial or wound contamination[4,5]. ✓

2. **Summary of Effectiveness.** Performance data show that the Model 505 Patient Warming System delivers air temperatures in the warming mode within the same specifications as the Bair Hugger® Model 500 Patient Warming System, using the same Bair Hugger® Blankets.

Bibliography on which the above summary is based:

1. Moritz AR, Henriques FC. The Relative Importance of the Time and Surface Temperature in the Causation of Cutaneous Burns. Am J Path 23:695-720, 1947.
2. Stoll AM, Green LC. Relationship Between Pain and Tissue Damage Due to Thermal Radiation. J Apply Phys 14:373-382, 1959.
3. Genauer, MB. Postoperative Heat Stroke. Anesthesiology 7:302-309, 1946.
4. Hall, A. Bair Hugger® Warmer Does Not Increase Microbial Contamination in the Operating Room. Abstract presented at the Post Graduate Assembly, New York Society of Anesthesiologists, New York, NY, December 1991.
5. Zink, RS. Convective Warming Therapy Does Not Increase the Risk of Wound Contamination in the Operating Room. Anesthesiology 77:A1093, 1992 & Anesth Analg, 1993:76;50-3.

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