

Fisher & Paykel **HEALTHCARE**

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510(k) Summary of Safety and Effectiveness Information

Model Number / Name: **IW910 Servo-Control Mobile Infant Warmer**
IW920 Manual-Control Mobile Infant Warmer
Classification Name: Warmer, Infant Radiant - 80 FMT
General Hospital Devices, 21 CFR §880.5130 (Class III)
Predicate Device: Ohmeda, Ohio Infant Warmer System, Model 3000, K921766

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The Fisher & Paykel Healthcare IW910 Servo-Control and IW920 Manual-Control Mobile Infant Warmers consist of a heater assembly, controller unit, and mounting pole and base sections.

The heater assembly includes a single rod infrared heating element housed inside a parabolic reflector. An observation lamp is mounted at the back of the heater unit. The thermoplastic enclosure is of similar cross-sectional shape to the reflector and is approx. 125mm high × 197mm wide × 625mm deep. It can be rotated to either side of the warmer, clear of the infant bed. A metal grill on the underside of the heater assembly prevents contact with the element.

The heater assembly is mounted on top of the controller unit. The transformer and Power PCB are mounted to the aluminum extrusion back section. The Control PCB is mounted on the inside of the thermoplastic front panel. This panel contains the control buttons, displays, main power switch and temperature sensor socket.

Controls consist of buttons to select operating modes, timer functions and lamp operation. A control knob selects temperature or power level. LED displays include indicators for operating mode, alarms, timer, lamp and heater power, and 3-digit displays for temperature and timer readings.

The main label is located on the controller unit rear panel, with the power inlet socket mounted in the underside. Dimensions of the controller are approx. 329mm high × 193mm wide × 104mm deep.

The controller section is supported by a single pole mounting system, with two sections of stainless steel tubing of 25mm and 32mm diameters. The upper pole section fits inside the lower to provide a height adjustment function. The tubes are secured to prevent inadvertent separation, and a polypropylene collet is used to fix the assembly at the required height. An internal spring provides support for the weight of the heater and controller assemblies. A height indication scale is etched into the upper and lower pole sections to enable correct heater-to-mattress distance to be set.

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The lower pole section is mounted into a steel stabilizer weight attached to the five-arm thermoplastic base unit. The radius of the base is approximately 315mm. The base is supported by five 50mm casters used to position the unit. All the casters include a foot-operated brake lever.

In Baby mode, the IW910 provides stable control of the baby's skin temperature by automatically adjusting the heater power to compensate for varying metabolic and environmental conditions. In Manual mode, both the IW910 and IW920 provide user-adjustable heater power. In Prewarm mode the IW910 and IW920 maintain power at a constant level of 25% ready for use.

A double thermistor sensor probe measures the baby's skin temperature, and audible and visual alarms alert the user to high or low temperature situations, equipment fault, power failure and periodic reminders to reassess the baby's clinical condition, depending on the control mode being used. Various independent safety features are included to control maximum output and avoid thermal injury to the infant.

The intended use of Infant Radiant Warmers is to provide thermal support for newborn babies in the first few weeks of life. This may include in the delivery room in the period immediately after birth, and in the neonatal intensive care unit for critically ill babies which may require frequent intervention from hospital personnel.

New-born babies (including low birth-weight or premature infants) and critically ill babies may have a reduced self-thermoregulation capacity. Body heat can be lost through the mechanisms of conduction, convection, radiation and evaporation. Low quantities of internal energy and insulating fat, and a high surface area-to-mass ratio can also be contributing factors. In these cases, or when thermal support is required or desirable, radiant heat may be provided to prevent the various clinical consequences of excessive heat loss.

Infant Radiant Warmers contain an infrared heating element intended to be placed over an infant in a pediatric hospital bed, to maintain an infant's body temperature by means of controlled radiant heat. Heat energy is absorbed through an infant's skin, increasing local blood flow which transfers heat to the rest of the body by blood convection and tissue conduction.

Situations which necessitate unobstructed access to an infant, including during resuscitation or surgical procedures, may indicate the need for a radiant heat source instead of equivalent support devices such as infant incubators.

The object of providing controlled radiant heat is to stabilize the infant's temperature at the level where metabolic rate is at a minimum. At this state the infant's internal energy sources are used primarily for growth and healing, and not trying to keep warm or cool.

The technological characteristics of the IW910 and IW920 Mobile Infant Warmers are equivalent to those of the predicate device.

The free-standing configuration, location of heater and controller sections, and mounting on lockable casters to enable positioning are equivalent. Both feature a single-bar radiant heating element with a parabolic metal reflector design. Heater output is regulated by microprocessor-controlled circuitry. The modes of operation, alarm configurations and user controls are very similar between the devices. Both

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devices use self-monitoring software and hardware options to ensure device faults are detected and do not result in hazardous states. The power used and irradiance levels achieved on a mattress surface by the two devices are very similar in quantity.

Improvements in safety and effectiveness include the use of a dual-thermistor skin temperature sensor, the comparison of readings from which allows the equipment to detect any variation in the sensor performance, and ensure accurate temperature measurement. The temperature controlling system and software used to regulate this allow for very accurate and stable control of an infant's skin temperature, hence providing optimal environmental clinical conditions.

Performance testing for the IW910 and IW920 has been carried out in the areas of functional verification, temperature control, irradiance distribution patterns and clinical verifications.

This testing demonstrates the safety, uniform distribution, accuracy and absolute accuracy of temperatures achieved on an infant bed, and the qualitative nature of the irradiance distribution pattern on the mattress, including irradiance in specific regions of the infra-red spectrum. Clinical verification studies demonstrated the ability of the warmers to warm up babies to a stable desired set temperature level accurately in a short period of time, and the ability to control the set temperature very accurately for a stable situation. The proposed devices meet specific aspects of performance required by the standard for Infant Radiant Warmers, IEC 601-2-21, including:

- temperatures achieved on the mattress surface for different materials.
- temperature distribution and variance across the mattress surface.
- accuracy of temperature control in the servo-controlled mode.
- absolute accuracy of temperature measurement against an external comparison.
- maximum irradiance levels for overall IR and near IR spectrum regions.

The product testing carried out for the IW910 and IW920 Mobile Infant Warmers indicate that they meet their design and performance functional requirements. Clinical verification studies demonstrate the successful use of the warmers and their ability to provide accurate and stable warming of infants. The proposed devices also meet the requirements of the international standard for Infant Radiant Warmers, IEC 601-2-21.

signed:



Chris Mander
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date:

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