Infant radiant warmer

Country of origin | India

Health problem addressed.

In under-resourced settings, hypothermia at birth is one of the most important risk factors for newborn morbidity and mortality. 99% of newborns that die globally are in such settings. It is vital to keep newborns warm and help them achieve thermoregulation in order to prevent and minimize morbidities and mortalities due to hypothermia.

Product description.

The device consists of a biocompatible bed on which to place the infant, and an overhead heater that delivers radiant heat. A skin temperature probe monitors infant temperature. Heat output can be controlled manually or through baby mode (feedback mode) for thermoregulation. Visual and audio alarms are present for safety. An APGAR timer helps to efficiently take APGAR scores post-delivery.



Developer's claims of products benefits.

Current radiant warmers have heaters typically made from quartz or ceramic. These heaters tend to breakdown faster as well as take a much longer time to heat up - up to 13 minutes in some cases. Each additional minute of cold stress can lead to increased morbidity for an infant. This device gives better clinical results because it provides uniform heating across the bed as well as a much faster warmup time (4 minutes only) that reduces the time to warm a hypothermic infant. Furthermore, the lower power consumption and long life of the heating element (Calrod heater) lead to considerable cost savings.

Suitability for low-resource settings _

The device uses less power at startup and during operation compared to other radiant warmers. It is designed for infection control (e.g. non-stitch biocompatible mattress for no infections in stitches plus no need for a mattress cover). It has a faster warmup time for high volume environments with little pre-warming. Over 1500 warmers have been deployed in lowresource settings.

The device has been designed, developed and manufactured in India based on extensive customer input in India and similar countries. It has been adopted in Tier 2 and 3 towns in India, as well throughout the country of Myanmar by the Ministry of Health. Testing of the device includes protocols that try to simulate low-resource setting issues such as voltage fluctuations, high humidity etc.

Operating steps _

The device is usually pre-warmed in manual mode for at least four minutes. The infant is then placed on the bed mattress and the skin temperature probe is attached. The operator then switches to baby mode (feedback) and enters the desired baby temperature. The APGAR timer and observation light can be switched on as needed.

Regulatory status _

It conforms with the requirements of Medical Devices Directive 93/42/EEC - BSI CE 0086 mark. It is also certified ISO 13485. It has US FDA 510K clearance (K121625), and it is ROHS compliant.

Use and maintenance _

User: Physician, nurse, midwife

Training: Initial training by manufacturer, and operator manual Maintenance: Annually by technician, engineer, or manufacturer

Environment of use.

Settings: Rural, urban settings, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

Requirements: Continuous power supply (100-240V). Can withstand some fluctuations in voltage and occassional spikes, but stable power supply is strongly recommended. General cleaning supplies to disinfect after every infant are needed.

Product specifications.

Dimensions (mm): 1120 x 655 x 1800 (minimum height), can be ordered at different settings from factory

Weight (kg): 72

Consumables: Reflector patches to cover the sensor are recommended in order to provide an accurate reading

Life time: 7 years

Shelf life: 2 years (6 months without any operation) Retail Price (USD): 3000, with considerable variation between countries

List price (USD): 3500

Other features: Software use, mobile, capital equipment

Year of commercialization: 2009

Currently sold in: 115 countries. Emerging market countries include Albania, Algeria, Brazil, Bulgaria, Cambodia, Chile, Domnican Republic, Egypt, Gabon, India, Indonesia, Iraq, Jordan, Kazakhstan, Kenya, Lebanon, Macedonia, Nigeria, Palestinian Territory, Philippines, Syria, South Africa, Vietnam.

ess of any technology for a particular purpose. All the informati provided by the developers. WHO will not be held to endorse to recommend any technology in the contract