

## Infant warmer\*

Country of origin	Viet Nam
Primary use	Treatment/resuscitation/palliative care/surgery
Category	Medical device (including in vitro diagnostics)

### Commercial information

**List price (USD):** 1900

**Year of commercialization:** 2018

**Number of units distributed:** 785

**Currently marketed in:** Benin, Burkina Faso, Sierra Leone, Ghana, Gambia, Indonesia, Iraq, Jamaica, Kenya, Cambodia, Lao People's Democratic Republic, Myanmar, Mozambique, Malawi, Malaysia, Namibia, Niger, Nigeria, Nepal, Philippines, Singapore, Togo, Thailand, Timor-Leste, United Republic of Tanzania, Uganda, Viet Nam, Zambia and Zimbabwe

**Model:** Wallaby

### Product description

The Wallaby Warmer is designed to provide a controlled source of warmth to babies in the first weeks of life. The warmers can provide complete care for the newborn baby from the delivery through to the critically ill baby in neonatal intensive care.

### Product details

**Accessories:** none

**Consumables:** none

**Warranty duration:** 2 years

**Lifetime:** 7 years

**Energy requirements:** 100-240VAC, 47-63Hz

**Facility requirements:** None

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**\* Information reported by manufacturer, October 2023**



## WHO assessment\*\*

### Clinical



Clinical



Recommended

Hypothermia is a cause of neonatal morbidity and mortality. Neonates are at high risk for hypothermia due to an increased surface-to-mass ratio as well as immature thermoregulation. Preterm neonates are at increased risk, making adequate thermal care essential to their initial resuscitation and care.

This technology provides a comprehensive answer to the problem of thermal care. Radiant heat is delivered by the overhead heating element, and the neonate is placed on an insulated mattress that minimizes heat loss. Skin temperature is monitored through a standard skin sensor and a remote temperature sensor as a backup. The device allows for automated control of energy output to optimize power usage, and the electronic display has several timers to assist in resuscitation. The device allows integration of other equipment used during resuscitation and serves as an X-ray bed.

# Comparison with WHO technical specifications

Compliant (some requirements to be clarified).

The manufacturer provides a link to the available technical documentation. WHO has a technical specification document available (last modification applied in 2014) for infant warmers that can be used to compare the technical requirements of the proposed technology to assess their compliance.

Based on the technical data analyzed and compared, the technology can be considered compliant with the available WHO technical specifications, with the exception of the following minor requirements, which, while not strictly determinant for the compliance assessment result of the technical specifications, may be brought to the manufacturer's attention for clarification:

- The device can be operated by both a timer and skin temperature regulation;
- Table tilting capabilities for Trendelenburg and inverse Trendelenburg positions;
- Height-adjustable equipment and a height range are available.

## Regulatory

 <b>Pre-market assessment</b>	 <b>Proceed</b>
 <b>Post-market assessment</b>	 <b>Proceed with caution</b>
 <b>Quality system assessment</b>	 <b>Proceed</b>
 <b>Security</b>	 <b>Proceed</b>












**Pre-market:** This product is a Class IIb medical device. The manufacturer has provided validation reports: IEC60601-1 and IEC60601-1-2. The software validation report IEC62304 and the IEC 60601-2-21:2009 specific safety requirements for the infant warmer test report are not available. A biocompatibility test based on ISO10993 has been provided. A clinical evaluation has been conducted, but a full report is not available.

**Post-market:** The manufacturer submitted post-market studies, ongoing post-market reports, and records of customer complaints. All regulatory approvals, including market authorizations, are not supported by documents; however, the Malaysian MDA website states that the product has been registered. The field safety corrective action plan and recall procedure documentation were not submitted.

**Quality management system (QMS):** The manufacturer has submitted an ISO13485:2016 certificate valid until 13 December 2023. Based on the certification and standards for performance, the product is safe and effective.

**Security:** The manufacturer submitted the risk analysis, risk management plan, risk control, post-production information, and protection against excessive temperature, and other hazard reports. The risk management report demonstrates that risk management activities carried out during the development and manufacturing of wallaby warmers are compliant with EN ISO 14971:2012. The introduction of this technology does not pose a biosecurity risk. The software validation report based on IEC62304 was provided to demonstrate the product is safe, effective, and cybersecure.

## Health technology assessment

Indicators	Evidence assessment	Innovation
 <b>Medical</b>		
 <b>Safety</b>		
 <b>Economy</b>		
 <b>Organizational</b>		
 <b>Legal</b>		
 <b>Social</b>		
 <b>Ethical</b>		
 <b>Green environment</b>		

The product features a lower price and power consumption, though being as effective as the SoC products. It is CE certified, and the innovator has submitted a comprehensive suite of validation reports, affirming compliance with all essential standards for general safety and electromagnetic compatibility, alongside a software validation report ensuring the product's cybersecurity integrity. Notably, the report specific to the safety requirements for infant warmer tests, as stipulated by IEC 60601-2-21, is absent.

Furthermore, the innovator has conducted and presented a biocompatibility test, ensuring the product's biological safety and holds an ISO 13485:2016 certification, and the risk management, as documented in the related report, aligns with the EN ISO 14971:2012 standard. Collectively, the provided documents support the product's safety and reliability for clinical use. The device cost is listed as 1900 USD, so the device may be considered cost-effective. The Innovator's statement that the delivery costs are lower due to compact packing allowing savings on transportation fees is fully supported by the packaging validation report, which also proves the reliability of packaging design and materials, thus providing reliable protection to the device during storage and transportation to any location. The product does not use consumables and features cheap and widely available spare parts as stated by the innovator, which makes it particularly suitable for low-resource settings.

Technology readiness level **9**

Technology evidence assessment **Recommend with caution**

## Health technology management



	Durability
	Ease of Use
	Ease of maintenance
	Environmental conditions
	Affordability
	Local access to technical support
	Ease of cleaning
	Infrastructure requirements






### Health-care delivery platform



The MTTs Wallaby provides safe and automatic control of patient temperature, incorporates smart problem detection, and features an intuitive control panel with a clear LCD display for enhanced functionality and clinical performance. The device's energy efficiency and comprehensive safety alarms are tailored for global accessibility and cost-effectiveness, including low initial costs. A significant advantage for low resource settings is the ease of accessing internal components for repair and maintenance, coupled with the affordability and availability of spare parts. This design consideration facilitates timely and efficient servicing. However, the Warmer's touchscreen interface, while designed for straightforward navigation, may pose challenges in environments with limited digital literacy or under adverse environmental conditions. Additional considerations include the need for a reliable power supply and the importance of adequate staff training.

## Intellectual property and local production

	Technology transferability
	Open source/ access
	Local production



**Intellectual property:** The embedded software is proprietary. A clearance is required to use this technology.

**Local production:** Current regional volumes are low, manufacturing and technology are already in an optimal cost environment, and the final product is in the form of a semi-knocked-down kit. However, generating advantages through local production can be challenging.

## WHO guidance

- Thermal Control of the Newborn: a practical guide. (2017). [https://iris.who.int/bitstream/handle/10665/63986/WHO\\_RHT\\_MSM\\_97.2.pdf?sequence=1](https://iris.who.int/bitstream/handle/10665/63986/WHO_RHT_MSM_97.2.pdf?sequence=1)
- WHO recommendations on newborn health: guidelines approved by the WHO Guidelines Review Committee. (2017). <https://iris.who.int/bitstream/handle/10665/259269/WHO-MCA-17.07-eng.pdf?sequence=1>
- WHO recommendations for care of the preterm or low birth weight infant. (2022). <https://iris.who.int/bitstream/handle/10665/363697/9789240058262-eng.pdf?sequence=1>