

Otter Newborn Warmer: Executive Summary

Design that Matters and MTTs Co., Ltd.

I. Overview

The Otter Newborn Warmer is a conductive warming device specifically designed to address the challenges of preventing and treating neonatal hypothermia in low-resource settings. Developed by Design that Matters (DtM), an American 501(c)3 nonprofit, and MTTs Co., Ltd., a medical device manufacturer based in Vietnam, Otter represents a redesign of the newborn conductive warmer based on an eight-year interactive product development process involving field research, subject matter expert interviews and design reviews in Africa and Southeast Asia.

Regulatory Status: Otter has successfully passed EU MDR 2017/745 conformity assessment conducted October 30-31, 2025 by Notified Body 3EC International a.s. (NB2265). The EU Quality Management System Certificate will be issued in late December 2025, following closure of audit non-conformities pertaining to another certified MTTs product.

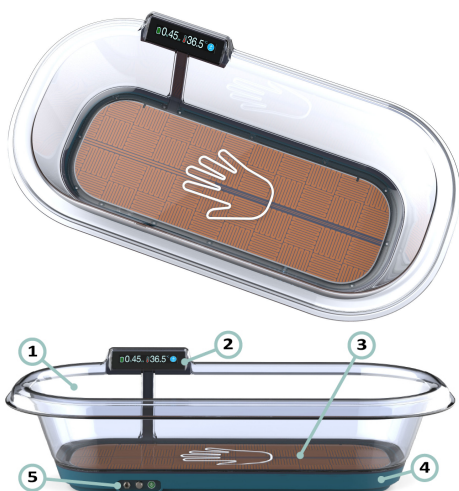


Fig. 1. Otter Newborn Warmer: (1) Seamless, shatterproof polycarbonate bassinet (2) Touch-screen user interface display (3) Heating element, attached under bassinet (4) Lower housing for electronics, batteries (5) Power connector, skin temperature probe connector and power button

II. The Context-Appropriate Design Challenge

Medical devices designed for high-income countries often prove unsuitable for hospitals in low and middle-income countries. International standards for medical devices assume ideal clinical conditions—including reliable infrastructure, resources and staff capabilities—that are uncommon in low-resource settings, particularly in public care facilities.

Neonatal hypothermia is defined as the thermal state in which a newborn’s body temperature drops below 36.5°C.

TABLE I
Otter Value Proposition

Feature	Conventional Warmers	Otter
Infection Control	Fabric/vinyl with seams	Seamless surface, quick wipe-clean
Power Reliability	Requires continuous mains power	2+ hours battery backup
Consumables	Water/gel mattresses, biocides, fabric covers	None required
Transport	Stationary or requires external power	Hand-portable with continuous warming (3.6 kg device weight)
User Error Risk	Removable mattress enables burns from direct heating element contact	Integrated design prevents element access
Purchase Price	USD\$1,932 USD	USD\$985

Hypothermia is recognized as a comorbidity factor to the three main direct causes of neonatal death: severe infection (36% of all neonatal deaths), preterm birth (29%), and asphyxia (23%) [1]. Studies have found that the odds of a newborn patient dying increased by 28% per degree decrease in admission temperature below 35°C [2].

Despite thermoregulation guidelines and recommendations, hypothermia remains prevalent in all clinical settings [3]. A high prevalence of hypothermia is reported from countries with the highest burden of neonatal mortality, even in warmer tropical environments [4].

III. Critical Innovation: Seamless Polycarbonate Bassinet Eliminates Infection Risk and User Error

Otter replaces the conventional water or gel mattress with a heated polycarbonate bassinet, addressing the two most significant failure modes of traditional conductive warmers:

Infection Prevention and Control: Nosocomial or hospital-acquired infections are one of the leading causes of mortality and morbidity in neonatal intensive care units [5]. A 2009 study found that despite national guidelines requiring frequent and thorough cleaning and disinfection of newborn health equipment, bacteria were isolated from 35% of incubators in a Cairo newborn unit [6].

Compared to a soft mattress, a seamless firm surface is easier to properly clean and disinfect between patients. The Otter bassinet has a smooth internal surface with no fabric, seams or gaps, and can be quickly disinfected with standard hospital cleaning products.

Prevention of "Latent Errors": "Latent errors" are defined as errors "waiting to happen", or conditions that make user-errors more likely [7]. For a device with a removable gel or water mattress, the surface of the heating element must reach 45°C or higher to provide a mattress surface

temperature of 37°C. Despite warnings in user manuals, it is possible for users to remove the mattress and place the newborn directly on the too-hot heating element. Eliminating the removable mattress from Otter eliminates this type of latent error.

Field Validation: In the ongoing implementation study at Kapiri District Hospital in Zambia (March 2025-present), families naturally line the bassinet with their own blankets for comfort. Clinical staff monitor patient temperature and adjust the device set temperature by 1-1.5°C as needed to account for blanket insulation.

IV. Critical Innovation: Integrated Battery System Maintains Warming During Power Failures and Patient Transport

Otter's internal battery provides uninterrupted warming for more than two hours at 15°C ambient. The device automatically switches to internal backup battery when disconnected from mains electricity. The user interface displays an estimate of battery life remaining.

Otter weighs 3.6 kg. The total carry weight with an average-sized newborn is 5.6 kg—less than half the recommended 13 kg safe-carry weight limit for small adults [8]. For those facilities that are able to use wheeled trolleys, Otter also fits inside a standard hospital bassinet.

Addressing Electricity Insecurity: One study found that only 34% of public hospitals in surveyed sub-Saharan African countries had reliable electricity access [9]. Another more recent study found that over 50,000 health care facilities in sub-Saharan Africa lacked any electricity supply [10].

Our field research found that even facilities with generators experience long daily interruptions of mains electricity. During a 2022 visit to Murtala Muhammad Speciality Hospital in Kano, Nigeria—one of the largest public secondary hospitals in the country—staff explained they experienced long daily interruptions of mains electricity, and that the onsite generator was available only infrequently.

Clinical Need During Transport: During our research, clinical staff identified three stages in the newborn treatment journey with higher incidence of hypothermia: transport to and within facilities, during newborn assessment in triage, and during hospital stay in the newborn unit [11]. One peer-reviewed study in Nepal with newborns under continuous thermal monitoring found a significant drop in core temperature during the process of transferring the infant to the postnatal ward, which prolonged the time taken for the infant's core temperature to recover to 36°C [12].

V. Critical Innovation: Durable, Integrated Construction Eliminates Common Failure Modes

Many conventional conductive warmers connect the mattress to the control unit via cable. This connection point is prone to damage from rough handling, and difficult to

repair in low-resource settings. Otter's control interface is integrated into the bassinet housing, eliminating this common vulnerability.

Design for Durability: The heating element and temperature sensors are located inside a water-resistant housing attached to the underside of the polycarbonate bassinet. This polyamide resistive heating element is pressed against the bassinet, conducting heat through the polycarbonate to the inner surface. This configuration makes it impossible for user-error to lead to direct contact between the newborn and the heating element, and protects the heating element and sensors from damage due to rough handling. Unlike flexible heating elements in conventional warmers that can fail if folded or creased too sharply, Otter's protected element withstands the rigors of delivery, storage, and use in challenging environments.

Eliminating Consumables: Conventional warmers impose "ownership costs" that are many multiples of the initial purchase price [13]. Hidden expenses include:

- Water or gel mattresses that are vulnerable to punctures and seam failures
- Biocide additives to prevent algae growth in water mattresses that are difficult to source in low-resource settings
- Fabric covers that deteriorate rapidly when hand-washed (many facilities lacking washing machines)

Otter is expected to operate for years without consumables or replacement parts. The device functions safely in high ambient temperatures and resists malfunction due to humidity, dust and insects.

Affordability: Despite these durability features and meeting CE Mark medical device certification standards, Otter's purchase price of USD\$985 is significantly less than the indicative price of USD\$1,932 for conductive warmers in the UNICEF Supply Catalog [14].

VI. Clinical Performance and Evidence Base

Temperature Performance: From cold start at 15°C ambient, the bassinet inner surface reaches 37°C in less than twenty minutes. Otter prevents newborn hypothermia in ambient temperatures from 15-40°C.

Regulatory Compliance: Otter meets IEC 60601-1 (Medical Electrical Equipment - General requirements for basic safety and essential performance) and IEC 80601-2-35 (Performance Requirements of heating devices using blankets, pads or mattresses and intended for heating in medical use) specifications.

VII. Implementation Experience

Zambia Implementation Study: Five Otter devices have been in continuous operation at Kapiri District Hospital since May 2025, treating newborns including extremely low birthweight infants (as small as 840g). The device has

also been used to successfully maintain normothermia in low-birthweight (under 1,200g) during in-hospital transfer from the surgical theater to the newborn unit, which requires transporting the newborn outdoors between buildings. The ongoing study evaluates device performance, user acceptance, and integration with existing protocols under real-world conditions including frequent power outages (documented incidents of 7-11 hours), high patient volume, and limited biomedical support.

VIII. Conclusion

Otter represents a purpose-built solution for low-resource settings rather than an adaptation of high-resource designs. By eliminating consumables, preventing common user errors, and providing power-independent operation, Otter addresses the primary failure modes that render conventional warmers unsuitable for contexts where they're most needed. The device demonstrates that appropriate technology means thoughtful design matching operational realities while maintaining clinical effectiveness and modern medical device standards.

IX. Disclaimer

The opinions and feedback on the Otter Newborn Warmer referenced in this document were provided by individuals at Médecins Sans Frontières, Murtala Muhammad Speciality Hospital in Kano, Nigeria and Kapiri District Hospital in Zambia, solely for informational purposes. This information is not intended to represent, and should not be construed as, an endorsement, official statement, or approval of the Otter Warmer by Médecins Sans Frontières, Murtala Muhammad Speciality Hospital or by Kapiri District Hospital. The views shared are those of the contributing individuals and do not necessarily reflect the official position or policy of Médecins Sans Frontières, Murtala Muhammad Speciality Hospital or of Kapiri District Hospital.

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Fig. 2. Otter Newborn Conductive Warmer at Kapiri District Hospital in Zambia, demonstrating facilitation of kangaroo mother care (KMC) by providing accessible warming during breaks in skin-to-skin care.



Fig. 3. During a mains power outage, a newborn unit nurse at Kapiri District Hospital in Zambia transfers a vulnerable low-birthweight newborn from a disabled radiant warmer to the battery-powered Otter warmer.