

# Portable, high-intensity neonatal LED phototherapy\*

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

## Commercial information

**List price (USD):** 2500

**Year of commercialization:** 2020

**Number of units distributed:** 250

**Currently marketed in:** Indonesia, Kuwait, Mongolia, Malaysia, United Arab Emirates and United States of America

**Model:** bili-hut global™

## Product description

Ultraportable, high intensity LED phototherapy for the treatment of neonatal hyperbilirubinemia (jaundice)

## Product details

**Accessories:** phototherapy swaddling garment (optional); bassinet cart adapter (“perch”)

**Consumables:** both reusable or disposable positioning “nest” options for infant are available

**Warranty duration:** 3 years

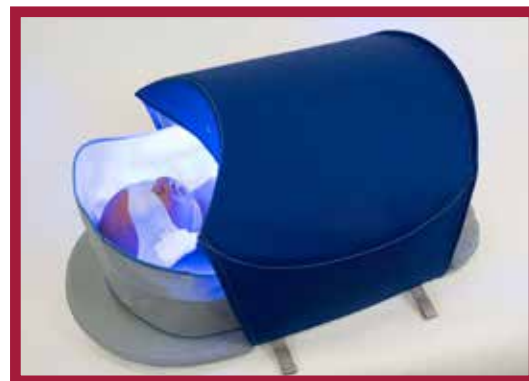
**Lifetime:** 5 years

**Energy requirements:** 90-264 VAC 50/60 Hz

**Facility requirements:** Approved for hospital use. It may be set up at mother’s side on a table, cart, trolley or crib.

**Contact:** Donna Brezinski, MD | **Phone:** +1 78 172 52460 | **Web:** <https://rb.gy/g10r9c>

\* Information reported by manufacturer, October 2023



2024

Inclusion in the Compendium does not constitute a warranty by WHO of the fitness of any technology or product for a particular purpose, as no rigorous review for safety, efficacy, quality, applicability or cost acceptability was conducted by WHO. WHO will not be held to endorse nor to recommend any technology or product included in the Compendium. WHO disclaims any and all liability whatsoever for any damage of any kind that may arise in connection with the procurement, distribution and/or use of any such technology or product.

## WHO assessment\*\*

### Clinical



Clinical



Recommended

Neonatal hyperbilirubinemia is a common occurrence in neonates, as the immature liver is unable to adequately metabolize bilirubin. High serum levels of bilirubin lead to its deposition in the skin, mucosae, and sclerae, thus manifesting as jaundice. Bilirubin may also be deposited in the central nervous system, predominantly in the basal ganglia. If left untreated, this may lead to severe neurological impairment and death.

The standard of care for this condition is phototherapy which breaks down circulating bilirubin into molecules that can be excreted without hepatic metabolism. As the newborn’s liver matures, it can adequately metabolize and excrete bilirubin and the phototherapy can be discontinued.

Despite being standard of care, the effective application of phototherapy in low-resource settings has been hindered by the medical devices used. Issues with size, transportability, robustness, and energy consumption have led to limited access to treatment across the globe. This technology attempts to overcome these limitations, greatly increasing treatment coverage while maintaining the standard for the adequate care of this condition.

## Comparison with WHO technical specifications

Cannot be verified.

The user manual provided is well detailed and it reports accurately the technical details. A technical brochure would give a better view of technical details but it is not strictly necessary in this case since the provided technical documents are complete. UNICEF has technical specifications available for a “Mobile LED phototherapy unit AC powered”, but this is not a cot-shaped device but a mobile lamp. At the time of report creation, WHO phototherapy / hyperbilirubinemia / jaundice lamps or unit technical specifications were not available to compare the specific requirements of this type of technology.

## 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 with caution</b>


















**Pre-market:** This product is a Class IIa medical device and has obtained market approval in UAE, Indonesia, Kuwait, Mongolia, Malaysia, and the USA. Based on the certification and standards for the performance of this device, the documentation submitted is adequate to demonstrate the product is safe and effective.

**Post-market:** The manufacturer submitted partial post-market surveillance and vigilance documentation. According to the submission, there have been no recalls or adverse events since the release of Bili Hut. Nevertheless, it is considered good regulatory practice to establish the PM system before introducing the product to the market.

**Quality management system (QMS):** The manufacturer has submitted a valid ISO13485:2016 which is valid until 15 July 2025. Based on the certification and standards for performance, the product is safe and effective.

**Security:** The manufacturer did not submit the risk management documentation, which is crucial to ensure safety and performance of the device.

## 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 device stands out due to its innovative design, featuring a curved, flexible canopy equipped with LED lights. This design provides multidirectional illumination, covering approximately 50% more skin area than standard of care (SoC) devices. It boasts a simple, collapsible structure, weighing under 4 kg and having a compact size, making it easy to store and transport in a carrying case. This portability allows it to be conveniently set up next to the mother in a hospital. Its semi-enclosed design helps to minimize heat loss, often removing the need for an incubator during treatment for most infants, and prevents light leakage into the surrounding area.

The device is safe, not posing any additional risks compared to SoC devices, and adheres to all relevant safety standards. The innovator manages risks in line with ISO 14971:2019 and upholds quality management according to ISO 13485. This technology has been utilized in various clinical settings worldwide for over three years without any reported adverse events.

It has proven to be highly reliable and effective, even under challenging conditions, with treatment times typically less than two days for nearly all patients, surpassing other SoC devices. This makes it particularly advantageous for low-resource areas where jaundice is more prevalent.

Technology readiness level **9**

Technology evidence assessment **Recommended**

## Health technology management



**Durability**

Health-care delivery platform



**Ease of Use**

The bili-hut is a specialized neonatal phototherapy device designed to provide 180° light coverage in a portable, lightweight package with an enclosed design to prevent patient heat loss. However, this enclosure design may obstruct constant patient visibility necessary for nursing staff in hospitals. Though this may be less of an issue in one-on-one home care, the device's 2500 USD cost significantly restricts its accessibility in both health-care facilities and for home use in low-resource settings (LRS); home use is impractical unless health facilities are sufficiently organized and supported to offer such devices on a borrowed term for home treatment.



**Ease of maintenance**



**Environmental conditions**



**Affordability**



**Local access to technical support**



**Ease of cleaning**



**Infrastructure requirements**

A notable concern is the device's recommended room temperature range of 70°F to 76°F (21.1°-24.4°C), which is quite narrow and more suited to controlled home settings. This temperature requirement is challenging to maintain in many areas where neonatal jaundice demands are the highest due to varying climate and infrastructural constraints. While the bili-hut is innovative and effective in treating jaundice and significant effort has been dedicated to testing usability and durability, its practicality in LRS hospital and home contexts is limited.

## Intellectual property and local production



**Technology transferability**

**Intellectual property:** It is patent-protected. To use this technology, authorization from the patent owner or the assignee is required.



**Open source/access**

**Local production:** Product design is advantageous for moderate to high-volume manufacturing. Moderate cost reduction can be achieved through local manufacturing. Local production is promising only for regions or markets with consistent, high annual product demand.



**Local production**

## WHO guidance

- 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>