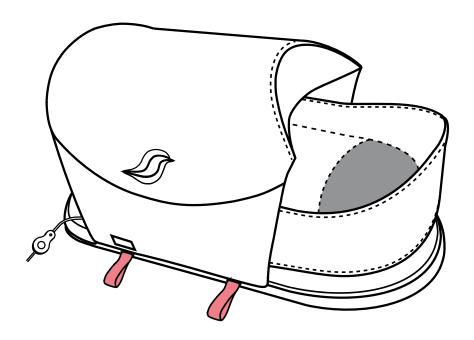
## bili-hut™ Home Use Guide







U.S. federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

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bili-hut™ is a trademark of Little Sparrows Technologies.

Date of Issue:

Doc# BH-IFU-002 Rev D DRAFT, 2020-04-XX

## **Product Responsibility**

The **bili-hut**<sup>™</sup> was designed by Little Sparrows
Technologies. This guide provides information on how to
assemble, operate, disassemble, clean, and store the **bili-hut**<sup>™</sup>. Follow all instructional materials and labels
provided with the **bili-hut**<sup>™</sup>. Check this device regularly
for defects. NEVER use a **bili-hut**<sup>™</sup> or any **bili-hut**<sup>™</sup>
components that appear to be defective.

DO NOT make changes to the **bili-hut**™. DO NOT alter the **bili-hut**™. Changes to the **bili-hut**™ should only be made by a Little Sparrows Technologies representative. Damage to this device due to improper use is solely the responsibility of the user. Little Sparrows Technologies is not responsible for damage from the user making repairs or taking any action not stated in this guide, **bili-hut**™ labels, or other instructional materials prepared by Little Sparrows Technologies.

See **Section 5** for instructions on troubleshooting problems with the **bili-hut**<sup>TM</sup>.

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## **Label Symbols Key**

Symbol	Meaning
$\triangle$	Cautions draw your attention to any hazards that could damage the device or could result in severe but reversible injury to you and/or your baby.
	Warnings describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.
	Single use
	Consult instructions for use
	Eye protection
<b>†</b>	IEC Type BF applied part
	IEC Class II equipment
	Direct current
R <sub>X</sub> Only	CAUTION: Federal law restricts this device to sale by or on the order of a physician.
	Temperature limit
	Manufacturer

#### Section 1: Overview

#### 1.1 Intended Use

The intended use of the **bili-hut™** is for the treatment of neonatal hyperbilirubinemia.

Use the **bili-hut**<sup>™</sup> only as directed by your healthcare provider. Not doing so may result in too much or too little treatment for your baby.

The **bili-hut**<sup>™</sup> is not intended to prevent the onset of jaundice.

#### 1.2 Introduction

## 1.2.1 Purpose of this Guide

The purpose of this guide is to show you how to use the **bili-hut**™ to treat your baby's jaundice. The **bili-hut**™ should only be used by individuals who have read and thoroughly understand this guide.

### 1.2.2 What is Jaundice?

Jaundice is a condition that causes yellow discoloration of the skin, eyes, and mucus membranes. It is caused by increased blood levels of bilirubin. Jaundice is treated with phototherapy.

#### 1.2.3 What is Bilirubin?

Bilirubin is a yellow pigment that occurs naturally in the body as a product of red blood cells, which break down over time. Bilirubin is normally broken down by the liver and passed out of the body through urine and stool.

#### Section 1: Overview

## 1.2.4 What is Phototherapy?

Phototherapy exposes a jaundiced baby's skin to a bright blue LED (Light Emitting Diode) light. The light converts bilirubin in the blood into a form that can naturally pass through the body. Nearly all babies with jaundice can be treated with phototherapy.

#### 1.2.5 What is the bili-hut™?

The **bili-hut**™ is a portable device that uses a curved blue LED light array. It is specially designed to deliver high-intensity phototherapy treatment to more quickly decrease the amount of bilirubin in a baby's body. The **bili-hut**™ is easy to use, clean, and transport.

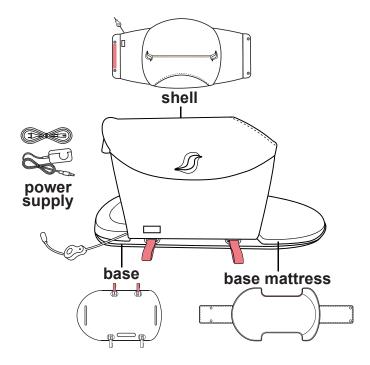
The **bili-hut**™ allows for safe and effective treatment in either the clinical environment or home when used as instructed

## 1.3 Components

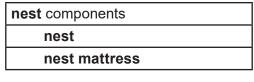
**NOTE:** Only use the components provided by Little Sparrows Technologies shown in this section with the **bili-hut**™.

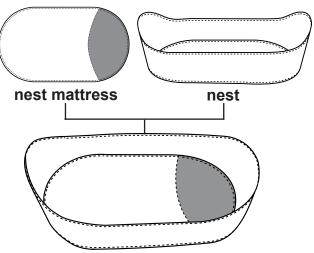
The diagrams on this page and the next page show the location of all **bili-hut**™ components.

assembled hut	
base	
base mattress	
shell	
power supply	



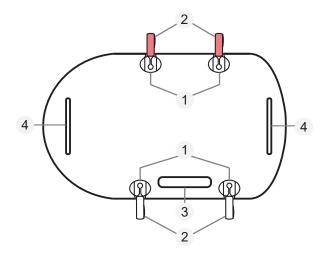
## Section 1: Overview





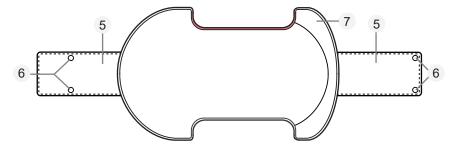
## 1.3.1 base and base mattress

The **base** maintains the structure of the **shell** during treatment.



Feature #	Description
1	Magnetic clasps on the <b>base</b> attach to the <b>shell</b> clasps for assembly.
2	Red and gray straps signal proper assembly of the <b>shell</b> and allow easy disassembly.
3	Handle enables surface-free assembly of the <b>shell</b> .
4	Slots in the <b>base</b> allow easy attachment of the <b>base mattress</b> .

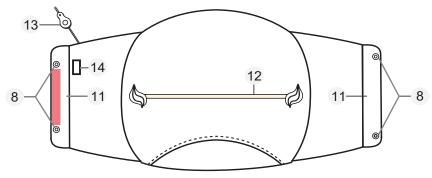
The **base mattress** cushions and aligns the treatment area.



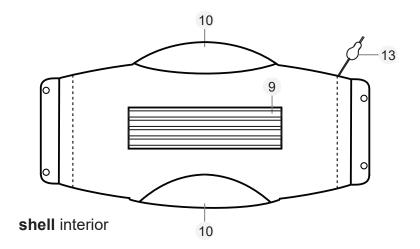
Feature #	Description
5	Straps slide through slots in the <b>base</b> to attach the <b>base</b> to the <b>base mattress</b> .
6	Snaps attach the straps to secure the <b>base</b> to the <b>base mattress</b> .
7	The bumper helps properly align the <b>nest</b> for treatment.

## 1.3.2 **shell**

The **shell** provides high-intensity phototherapy treatment with blue LED treatment lights.



shell exterior

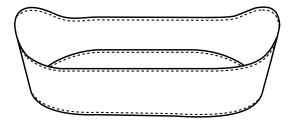


Feature #	Description
8	Magnetic clasps on the <b>shell</b> pair with the <b>base</b> clasps for secure attachment.
9	Blue LED (Light Emitting Diode) treatment lights form the light array to administer high-intensity phototherapy to your baby.
10	Back and front flaps focus light on the treatment area. The flaps also shield the area around the <b>bili-hut™</b> so that you will only see a small amount of blue light.
11	Red and gray tabs indicate proper <b>shell</b> assembly.
12	The yellow indicator light alerts you to an Environment High Temperature Warning. See <b>Section 3.4</b> of this guide for more information. The yellow indicator light is not visible unless the <b>bili-hut</b> ™ is used in a too-hot environment.
13	The power cord connects the <b>assembled hut</b> to a safe <b>power supply</b> . After the <b>power supply</b> is plugged in to a safe and active outlet, the power switch controls whether the <b>bili-hut™</b> is "ON" or "OFF". A small blue indicator light on the power switch illuminates when the power cord is plugged in and the power switch is in the "ON" position.
14	The timer tracks the total use of the blue LED treatment lights in hours. The timer does NOT track individual treatment times.

## 1.3.3 nest (disposable)



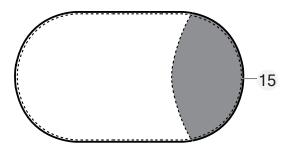
The **nest** properly positions your baby for treatment and improves light array efficacy. The **nest** is disposable for when soiled and between patients. Please see the contact information in **Section 6** of this gude to order additional **nests**.



## 1.3.4 nest mattress (disposable)



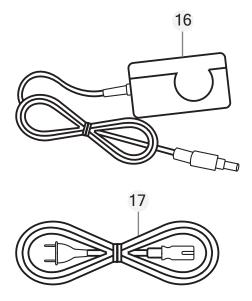
The **nest mattress** provides cushioning for your baby and uses color-blocking to guide placement of your baby. The **nest mattress** is disposable for when soiled and between patients. Please see **Section 6** of this guide to order additional **nest mattresses**.



Feature #	Description
15	The dark section of the <b>nest mattress</b> guides proper placement of your baby within the <b>nest</b> . Specifically, your baby's head and neck are placed entirely within the dark section of the <b>nest mattress</b> .

## 1.3.5 power supply

The medical-grade **power supply** attaches the **bili-hut**™ power cord on the **shell** (see **Feature #13** of **Section 1.3.2**) to a safe and active electrical outlet. The **power supply** is composed of the power brick and AC cord.



Feature #	Description
16	Power brick connects to the <b>bili-hut</b> ™ power cord and the AC cord.
17	AC cord connects the power brick to a safe and active electrical outlet.

## **Section 2: Safety**

#### 2.1 Indications for Use

The **bili-hut**™ provides phototherapy for the treatment of neonatal hyperbilirubinemia, commonly known as neonatal jaundice, during the newborn period in the clinical or home setting.

## 2.2 Contraindications

Contraindications are conditions when the **bili-hut™** should not be used because the risks outweigh the benefits of using it.

There are no known contraindications for the **bili-hut**™ in the home use setting.

#### 2.3 Recommendations

Little Sparrows Technologies recommends that the **bili-hut**™ be used for patients with a birthweight of more than 2500 grams (5.5 pounds) and with a gestational age of greater than or equal to 35 weeks. However, the prescribing clinician defines the need for phototherapy with each patient.

Use the **bili-hut™** in these environments:

- recommended room temperature: select a location where the room temperature can be maintained between 70°F and 76°F (21.1° C and 24.4°C) for your baby's comfort and safety during treatment
- humidity range: 10 to 90% rH non-condensing

## 2.4 General Warnings

Warnings describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. General warnings are listed in this section. Specific warnings are listed with the relevant device use instructions.

## 2.4.1 Electrical Warnings



Only use the **power supply** supplied by Little Sparrows Technologies. Using non-standard electrical parts may result in undertreatment or electrical shock of your baby.



Only plug the **bili-hut**™ into a properly grounded electrical outlet. Plugging the **bili-hut**™ into an unsafe outlet could result in malfunction of the device or injury to your baby.

## 2.4.2 Environmental Warnings



DO NOT operate the **bili-hut**™ if any of the below are present:

- nitrous oxide
- · an oxygen-rich environment
- · a flammable anesthetic mixture of gases
- · flammable cleaning agents

Doing so could result in danger to you and/or your baby.

## 2.4.2 Environmental Warnings (continued)

<u> </u>	NEVER lay anything on top of the assembled <b>bili-hut™</b> or any of its components. Doing so could result in damage to the structure of the <b>bili-hut™</b> and/or injury to your baby.
Ţ	DO NOT block the front and rear openings of the <b>bili-hut</b> ™ during treatment. Doing so could result in over-heating of both your baby and the device as well as suffocation of your baby.
<u></u>	DO NOT use or store the <b>bili-hut</b> ™ in direct sunlight. Doing so could damage the device or result in over-heating of your baby.
$\wedge$	NEVER stack the assembled <b>bili-hut</b> ™ on top of



NEVER stack the assembled **bili-hut™** on top of other equipment. Doing so could result in damage to the device. During treatment, this could result in injury to your baby.



DO NOT transport the **bili-hut**™ with a baby inside. The **bili-hut**™ is not a "transporting" device. Doing so could result in injury to the baby.

## 2.4.3 Warnings About Your Baby



DO tend to other medical needs of your baby as needed. Determine safe sleeping positions for your baby with your healthcare provider if these needs require special attention.



NEVER carry the **nest** or **assembled hut** with your baby inside of it. Doing so could lead to injury of your baby.



DO NOT treat your baby in the **bili-hut**™ if he or she has other medical conditions that require additional medical equipment. No medical equipment should be placed in the **bili-hut**™.



Your baby's water balance may be altered by phototherapy treatment. A baby will typically have a wet diaper about every three hours if he or she is well hydrated. Wet diapers should be changed so that you can keep track of fluid output. Changing wet diapers also prevents your baby from becoming too cold during treatment.



Note that the reflective interior of the **bili-hut™ shell** is designed to increase patient exposure to the blue treatment lights; however, in certain environments, it may result in increased patient body temperatures. Regularly check on your baby and monitor your baby's body temperature to prevent over-heating.

#### 2.5 General Cautions

Cautions draw your attention to any hazards that could damage the device or could result in severe but reversible injury to you and/or your baby. General cautions are listed in this section. Specific cautions are listed with the relevant device use instructions.

#### 2.5.1 Electrical Cautions



Disconnect the **bili-hut**™ from the **power supply** when the device is not in use and before cleaning.



DO NOT move the **bili-hut™** by pulling on the power cord. This could result in damage to the device.

## 2.5.2 Cautions About Your Baby



Use and assemble this device only in the way described in this guide and only for the intended use as specified in **Sections 1.1**, **3.1**, and **3.2**. Using the **bili-hut**™ for other purposes may be harmful to you and/or your baby.

### 2.5.3 User Cautions



The **bili-hut**<sup>™</sup> flaps shield the area around it from the blue treatment lights so that only a small amount of blue light will be seen by you. However, some people are very sensitive to blue light and may experience discomfort such as eye irritation, nausea, or headache. If you or anyone else experiences this type of discomfort while near the **bili-hut**<sup>™</sup>, discomfort will likely be resolved by wearing yellow goggles.



Use only the instructions supplied with the **bili-hut**™. Use of an unauthorized guide or other unauthorized instructional materials may lead to misuse and undesirable results.



This guide is not a substitute for healthcare professional guidance.

## Section 3: Using the bili-hut™

## 3.1 Assembling and Setting-up the bili-hut™

Complete the following six (6) steps to assemble and set-up the **bili-hut**™.

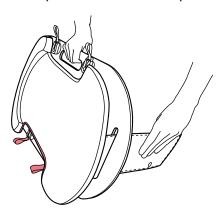
### Unpacking:

1 Remove all components from their packaging.

**NOTE:** The **nest** may require a short time to assume its shape after unpacking. Gently push the **nest** to shape if needed.

### Assembling the base:

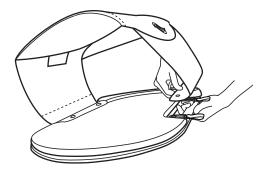
2 If not already attached, pull the **base mattress** straps through the slots in the **base**. The red trim on the **base** mattress should face up and align with the side of the **base** with red straps. Secure the snaps.



#### Assembling the hut:

3 Align the red-striped **shell** tab with the matching red straps on the **base**. Attach the magnetic clasps. The clasps will "click" and mechanically lock when in place.

Holding the base by the handle, align the solid gray tab of the shell with the matching gray straps on the base. Attach the magnetic clasps. The clasps will "click" and mechanically lock when in place.



**NOTE:** Check for secure attachment by gently tugging upward on the **shell**. Look to see if all four clasps are still in place. If any of the four clasps are not in place, reference troubleshooting item #8 in **Section 5** of this guide.

#### WARNING



DO NOT place the **bili-hut**™ near a:

- space heater
- radiator or heating vent
- other device that gives off heat or has a hot surface

Also DO NOT place the bili-hut™ in:

- direct sunlight
- extremely high room temperatures Doing so could damage the device, lead to your baby becoming over-heated or cause burns or other injury of your baby, and/or lead to the Environment High Temperature Warning turning on.

#### **WARNING**



DO NOT place the **bili-hut**™ near cooling sources such as:

- fans
- air conditioners or other devices that are cold or cool the air

Also DO NOT place the **bili-hut™** in extremely low room temperatures. Doing so could lead to your baby becoming too cold. The Environment High Temperature Warning is NOT caused by cooling sources or low room temperatures.

## WARNING



DO NOT place the **bili-hut™** on an uneven surface or a surface smaller than 2 x 4 feet (0.6 m x 1.2 m) without barriers. Doing so could result in injury to your baby.

### WARNING



DO NOT place the **bili-hut**™ near a source of liquid that could spill into or onto the device. Doing so could result in damage to the device and/or electrical shock of you and/or your baby.

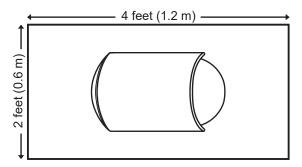
## CAUTION



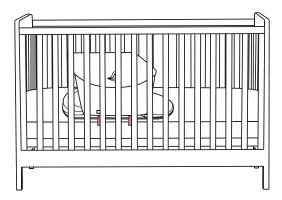
DO NOT place or store the **bili-hut™** on or near an abrasive surface. Doing so could damage the device and/or its components.

#### Placement of the assembled hut:

Place the **assembled hut** on a smooth, sturdy, even surface, such as a table measuring at least 2 x 4 feet (0.6 m x 1.2 m).



Alternatively, the **bili-hut**™ can be used in a crib.



## Assembling the power supply:

6 To assemble the **power supply**, connect the AC cord to the power brick.

## 3.2 Operating the bili-hut™

**NOTE:** Before starting treatment, complete the following steps:

- **1.** Completely read and understand this guide.
- 2. Read the bili-hut™ Home Record Sheet Instructions.

NOTE: Fill out the top section of the bili-hut™ Home Record Sheet.

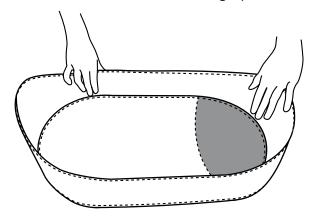
WARNING	DO NOT put any creams or lotions on your baby's skin before or during treatment. Doing so could change the effectiveness of the phototherapy, resulting in less treatment for your baby than desired.
CAUTION	DO NOT place items in the <b>assembled hut</b> or <b>nest</b> that could alter or lift your baby's position. Keeping your baby flat on the <b>nest mattress</b> provides the best possible treatment for your baby and prevents suffocation or over-heating of your baby.

**NOTE:** Blue light can hinder clinical observations by masking skin color changes, such as cyanosis.

Cyanosis occurs when a person has poor circulation or is not receiving enough oxygen, resulting in blue discoloration of the person's skin.

Once the **assembled hut** is set up according to the instructions in **Section 3.1** and placed in an appropriate location, follow the next six (6) steps.

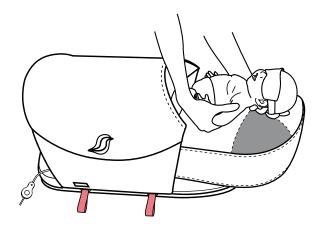
1 Place the **nest mattress** in the **nest** so that the dark section of the **nest mattress** is facing up.



2 Place the **nest** partially into the head-end of the **assembled hut**. The dark section of the **nest mattress** should stick out of the **assembled hut**.

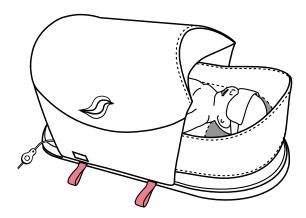
### Section 3: Using the bili-hut™

Undress your baby except for a diaper. Place eye protection over your baby's eyes. Then, place your diapered baby in the **nest** on his or her back. Your baby's head and neck should lie entirely within the dark section of the **nest mattress**.

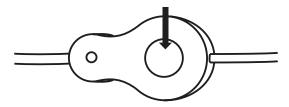


WARNING	DO NOT operate the <b>bili-hut</b> ™ before protecting your baby's eyes using eye protection. Treatment without eye protection could damage your baby's vision.
WARNING	Only place a single diapered baby in the <b>bili-hut</b> ™. Placing any other objects in the <b>bili-hut</b> ™ could result in suffocation of your baby, over-heating, or other injury. It could also damage the <b>bili-hut</b> ™.
WARNING	NEVER place your baby in the <b>assembled hut</b> without the <b>nest</b> . Only use the <b>bili-hut™</b> with the <b>nest</b> . Use of the <b>bili-hut™</b> without the <b>nest</b> could lead to injury or undertreatment of your baby.

Gently slide the nest into the bili-hut™ until the nest touches the bumper at the foot-end of the base mattress. Ensure that the shell front flap is pushed down and inward and the shell back flap is pulled down and outward toward the foot-end of the assembled hut.



- Plug the pronged end of the **power supply** into a safe and active electrical outlet. Plug the other end of the **power supply** into the barrel connector of the **bili-hut™** power cord. Route the **power supply** and cord in such a way as to not interfere with the operation of the **bili-hut™**.
- Press the power switch on the power cord to turn on the blue treatment lights. Check to make sure the blue treatment lights are on.



NOTE: Complete the bili-hut™ Home Record Sheet for steps completed so far (ex. start of treatment).

## 3.3 Removing Your Baby from the bili-hut™

## WARNING



Phototherapy may alter your baby's body temperature. Therefore, check the following every 2 to 4 hours:

- your baby's body temperature
- your baby's diaper
- ensure your baby's head and neck lie entirely within the dark section of the nest mattress
- ensure the Environment High Temperature Warning's yellow indicator light is NOT on

## CAUTION

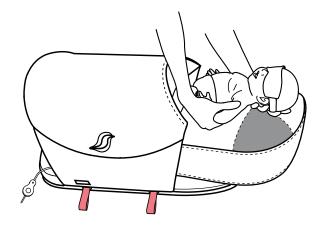


Phototherapy treatment should only be interrupted when needed for:

- feeding
- diaper changes
- · medical needs
- end of treatment
- an Environment High Temperature Warning
- other necessary interruptions

Complete the following two (2) steps to remove your baby from the **bili-hut**™. Return your baby to the **bili-hut**™ as soon as possible after an interruption.

Turn off the blue treatment lights before removing your baby from the bili-hut™. To turn off the blue treatment lights, press the power switch on the power cord. <sup>2</sup> Gently slide the **nest** out of the **assembled hut**. Carefully lift your baby out of the **nest** and place your baby in a safe location. Remove your baby's eye protection.



NOTE: Record any treatment interruptions using the bili-hut™ Home Record Sheet.

To resume treatment, follow the instructions starting at **Step 3** of **Section 3.2** of this guide.

WARNING



Avoid interrupting treatment unless necessary. Resume therapy as soon as possible after the interruption. If treatment is interrupted for a long period or is interrupted too frequently, it could reduce the effectiveness of the treatment.

# 3.4 Actions for an Environment High Temperature Warning

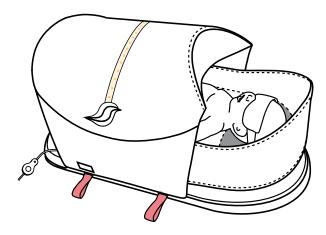
The Environment High Temperature Warning automatically turns on when the environment temperature surrounding the **bili-hut™** is too high. During the Environment High Temperature Warning, the blue treatment lights turn off and a yellow indicator light turns on.

The Environment High Temperature Warning may occur if the **bili-hut**™ is used near:

- radiators
- · heating vents
- space heaters
- · other heat sources

OR if the bili-hut™ is used in:

- direct sunlight
- extremely high room temperatures



When the environment temperature lowers to a safe range, the yellow indicator light will turn off. At that time, the blue treatment lights will automatically turn back on.

Follow the flowchart instructions starting at the top of the next page when the Environment High Temperature Warning occurs. This warning is visible when the yellow indicator light turns on and the blue treatment lights turn off.

**NOTE:** Record interruptions to treatment on the **bili-hut**™ **Home Record Sheet** when the Environment High Temperature Warning occurs.

Environment High Temperature Warning turns on.

#### **REMOVE YOUR BABY:**

- 1. DO NOT turn off the bili-hut™.
- 2. Gently slide the nest out of the assembled hut.
- **3.** Carefully lift your baby out of the **nest** and place in a safe location. Remove your baby's eye protection.

#### TROUBLESHOOT:

#### First:

 Turn off and/or move any heat sources such as radiators, heating vents, or space heaters. Relocate the bili-hut™ away from heat sources if necessary.

In addition, you can:

- Ensure the bili-hut™ is not in direct sunlight.
- Lower the ambient temperature of the room.
- Move the bili-hut<sup>™</sup> to a cooler, safe location.

Wait for the blue treatment lights to turn back on. This may take a few minutes. The **bili-hut™** must be left on during this time to see when the Environment High Temperature Warning automatically turns off.

If the blue treatment lights remain off for >1 hour and you completed all possible troubleshooting items as listed above, call Little Sparrows Technologies using the contact information in Section 6.

The yellow indicator light turns off and the blue treatment lights turn back on.

#### **RESUME TREATMENT:**

Place eye protection over your baby's eyes. Place your baby in the **nest** and gently slide the **nest** into the **assembled hut** until the **nest** touches the bumper at the foot-end of the **base mattress**.

## 3.5 Disassembly

WARNING

DO NOT disassemble the **bili-hut™** while your baby is inside. Doing so could lead to injury of your baby.

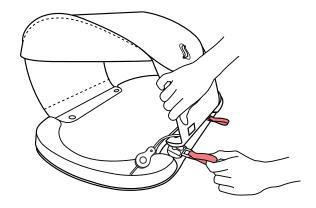
NOTE: Record the end of treatment on the bili-hut™ Home Record Sheet.

Disassemble the **bili-hut**™ using the following seven (7) steps when treatment is complete.

- 1 Follow the instructions to remove your baby from the **bili-hut™** in **Section 3.3**.
- 2 Unplug the bili-hut™ from the electrical outlet and disconnect the power supply from the bili-hut™ power cord.
- 3 Completely remove the **nest** from the **assembled hut**.
- 4 Dispose of the **nest** and **nest mattress** in your trash bin.

**NOTE:** Please see the contact information in **Section 6** of this guide to reorder **disposable nest packages**.

<sup>5</sup> Pull the red straps outward from the **assembled hut** to release the magnetic clasps. Repeat this step with the gray straps on the other side of the **shell** to release the **shell** from the **base**.



6 Clean the **shell**, **base**, and **base mattress** according to the instructions in **Section 4.1** of this guide.



DO NOT store the **bili-hut**™ near open water such as a tub or sink where it could fall in. Doing so could damage the device and/or its components.

Return the bili-hut™ components using the information provided to you by the medical personnel who provided you with the bili-hut™.

#### **Section 4: Maintenance**

WARNING
$\wedge$

DO NOT perform service or maintenance on the **bili-hut**™ or any of its components during use. Doing so could result in injury or electric shock to you or your baby.

## 4.1 Cleaning

WARNING	DO NOT use flammable cleaning agents when cleaning the device.  DO NOT use cleaning agents containing ethanol or hydrogen peroxide, abrasive cleaning agents, or abrasive cleaning tools to clean the <b>bili-hut</b> ™ because these may damage the device.  Only use the cleaning agents and tools specified in <b>Section 4.1</b> to clean the <b>bili-hut</b> ™.
WARNING	DO NOT use a soiled <b>bili-hut</b> ™. Failure to complete the cleaning described in <b>Section 4.1</b> could lead to undertreatment, skin irritation, and/or infection of your baby.
CAUTION	Disconnect the <b>bili-hut™</b> from the <b>power supply</b> when the device is not in use and before cleaning.
CAUTION	DO NOT immerse any <b>bili-hut</b> ™ components in liquid such as water or cleaning solutions. DO NOT spray water, cleaning agents, or any other liquid directly on the <b>bili-hut</b> ™. DO NOT clean the <b>bili-hut</b> ™ using an oversaturated wipe/cloth. Any of these actions may damage the efficiency and integrity of the device.

#### Acceptable cleaning methods:

Use a cleaning agent with one of the following active ingredients:

- quaternary ammonium OR
- bleach

DO NOT use cleaning agents containing ethanol or hydrogen peroxide, abrasive cleaning agents, or abrasive cleaning tools to clean the **bili-hut**™ because these may damage the device.

Follow the instructions provided by the manufacturer of the cleaning agent including any instructions which recommend wiping the device with water before/after cleaning.

Clean the **bili-hut™** components as outlined in this section by using a wipe/cloth that has been:

- sprayed with cleaning agent OR
- dampened with cleaning agent OR
- pre-dampened with cleaning agent by the manufacturer

#### When to clean the bili-hut™:

If any component(s) become soiled during use, stop treatment using the instructions in **Section 3.3**. Replace a soiled disposable **nest** or **nest mattress** with a new **nest** or **nest mattress**. If a reusable portion of the **bili-hut™** (**shell**, **base mattress**, **or base**) also becomes soiled during use, clean the soiled component(s) using the following instructions, and then resume treatment.

Dispose of the **nest** and **nest mattress** at the end of treatment.

DO NOT resume treatment or pack up the device into its carrier until all components are clean and dry.

## 4.1.1 Cleaning the shell

Clean the interior of the **shell** by wiping down the light array and reflective material. Allow to air dry.

If dirtied, wipe down the exterior of the **shell**. DO NOT use excess cleaning agent. Allow to air dry.

## 4.1.2 Cleaning the base and base mattress

To clean the **base mattress**, undo the snaps and remove from the **base**. Wipe down the **base** and **base mattress**. Allow to air dry.

Once dry, reattach the base and base mattress.

## 4.2 Disposal

Dispose of the **nest** and **nest mattress** when soiled and at the end of treatment.

To dispose of a soiled **nest** or **nest mattress**, place the item in your trash bin.

Please see the contact information in **Section 6** of this guide to order additional **disposable nest packages**.

For questions regarding the disposal of any other of the **bili-hut**™'s components, contact Little Sparrows Technologies. For contact information, see **Section 6** of this guide.

## **Section 5: Troubleshooting**

The following are a list of problems that may occur while using the **bili-hut**™.

DO NOT attempt to service the **bili-hut™** or its components beyond the instructions given in the following troubleshooting scenarios. If these steps below do not solve the problem, contact a Little Sparrows Technologies representative for assistance using the contact information in **Section 6**.

#	Problem	Action
1	The Environment High Temperature Warning remains on after following the troubleshooting instructions in Section 3.4.	Contact Little Sparrows Technologies for assistance.
2	Your baby is too cold.	<ol> <li>Remove your baby from the bili-hut™ and warm your baby, ideally using skin-to-skin care.</li> <li>If possible, adjust the ambient temperature of the room or move the bili-hut™ to a warmer area.</li> <li>NEVER place the bili-hut™ near a space heater or other heat-emitting device.</li> </ol>
3	Your baby is too warm.	<ol> <li>If the Environment High Temperature Warning is on, refer to Section 3.4.</li> <li>Otherwise, remove your baby and take his or her body temperature again. Notify your baby's healthcare provider if you have concerns that your baby has a fever.</li> </ol>

# Section 5: Troubleshooting

#	Problem	Action
4	Liquid is spilled in or on the <b>bili-hut</b> ™.	<ol> <li>If in use, immediately press the power switch to turn off the bili-hut™. Then unplug the power supply from the electrical outlet. Remove your baby according to the instructions in Section 3.3.</li> <li>Dry the bili-hut™ and replace any wet nest or nest mattress.</li> <li>If the bili-hut™ turns back on and operates normally, resume treatment. If not, DO NOT use. Contact Little Sparrows Technologies for assistance.</li> </ol>
5	The <b>bili-hut</b> ™ is not turning on or the light array is not emitting light.	<ol> <li>Check to see if the Environment High Temperature Warning is on. If it is on, follow the instructions in Section 3.4.</li> <li>Ensure the power supply is properly assembled (AC cord is fully plugged in to the power brick). Ensure the power supply is properly connected to a safe and active outlet and the bili-hut™ power cord.</li> <li>Ensure the power switch on the power cord is in the "ON" position.</li> <li>If the issue continues, DO NOT use. Contact Little Sparrows Technologies for assistance.</li> </ol>
6	Power cord or <b>power</b> <b>supply</b> appears frayed or is deteriorating.	DO NOT use. Contact Little Sparrows Technologies for assistance.

#	Problem	Action
7	The <b>bili-hut</b> ™ appears distorted or deformed when compared to the pictures of the device in this guide.	DO NOT use. Contact Little Sparrows Technologies for assistance.
8	One or more magnetic clasps on the <b>shell</b> is not clicking into place on the <b>base</b> or becomes undone after attachment.	Remove any debris from the magnetic clasps on the <b>base</b> and re-attach the magnetic clasp. The clasp will "click" and mechanically lock when in place. Check for secure attachment by gently tugging upward on the <b>shell</b> .
9	Blue LED treatment lights flicker or substantially increase/ decrease in brightness.	<ol> <li>Ensure only the power supply supplied by Little Sparrows         Technologies for use with the bili-hut™ is used.</li> <li>Ensure the power supply is properly assembled (AC cord is fully plugged in to the power brick). Ensure the power supply is properly connected to a safe and active outlet and the bili-hut™ power cord.</li> <li>Ensure that nothing is pressing on the power switch.</li> <li>If the issue continues, DO NOT use. Contact Little Sparrows         Technologies for assistance.</li> </ol>

**IMPORTANT:** If troubleshooting reveals a health problem with your baby rather than an issue with the **bili-hut™**, call 911 for emergency assistance or your healthcare provider for non-emergency situations.

#### Section 6: Contact and Reorder Information

Contact a Little Sparrows Technologies representative if:

- taking the troubleshooting steps listed in Section 5 does not resolve the associated problem
- more information is needed for operation or repair of the device
- · you have any other comments or questions
- you need to reorder disposable nest packages

disposable nest package component # 0133AFD Box of 1 nest (disposable) and 1 nest mattress (disposable)

To contact Little Sparrows Technologies:

Phone: (781) 725-2460

Email: info@littlesparrowstech.com

Mailing address:

Little Sparrows Technologies 288 Walnut St, suite 300 Newton, MA 02460

Website: www.littlesparrowstech.com

Twitter: @TechSparrows

Facebook: Little Sparrows Technologies

Copies of this guide and other instructional materials to be available electronically via the Little Sparrows Technologies website.

Translated instructional materials to be available electronically via the Little Sparrows Technologies website.

<b>†</b>	IEC Type BF applied part
	CE
	EN
	IEC Class II equipment
	FDA Class II
	Direct Current

Component	PN or REF
base	0106C
base mattress	0109H
carrier	NA
disposable nest package	0133AFD
power supply	0116CPS
power switch	NA
shell	0102D

## 7.1 Electrical

Power Consumption	20 Watts
LED Module Estimated Life	Up to 50,000 hours
Size of Light Source	16 x 6 inches (40.6 x 15.2 cm)
bili-hut™ Fuses	3.0A 32Vdc and 2.5A 40Vdc on DC input
Power Supply Fuses	2.0A 250Vac on Line and 2.0A 250Vac on Neutral
Degree of Protection Against Electrical Shock	2x MOPP
Cable Length	10 inches (25.4 cm)
Power Supply: Input	90-264VAC, 50/60Hz, 1.2A, Class II
Power Supply: Output	12VDC, 3.4A

## 7.2 shell

Dimensions (flat)	34 x 17 inches (86.5 x 43 cm)
Materials	Nylon, thermoplastic polyurethane (TPU), mylar, polycarbonate, foam
	Up to 3 years of continuous use if used with care and within the ranges recommended in this document

## 7.3 **base**

Dimensions	24.5 x 14 inches (62 x 35.5 cm)
Materials	High-density polyethylene, nylon, aluminum, rubber, steel
Service Life	Up to 3 years of continuous use if used with care and within the ranges recommended in this document

#### 7.4 base mattress

Dimensions	24.5 x 14 inches (62 x 35.5 cm)
Materials	Vinyl, foam, nylon, metal, polyester, cotton
Service Life	Up to 1 year of continuous use if used with care and within the ranges recommended in this document

# 7.5 disposable nest package

Dimensions	(assembled)**
Materials	Polypropylene, foam
	Single use disposable <b>nest</b> and <b>nest mattress</b>

# 7.6 **bili-hut™** (assembled)

Dimensions	25 x 16 x 12 inches (63.5 x 40.5 x 30.5 cm)
Weight	8 lbs (3.5 kg)**
Estimated Device Lifetime	Up to 3 years of continuous use if used with care and within the ranges recommended in this document
Maximum Noise Level	0.5 dB
Treatment Distance	8.7 inches (22 cm)**
Effective Surface Treatment Area	170 square inches (1097 square cm)**

#### 7.7 Environmental

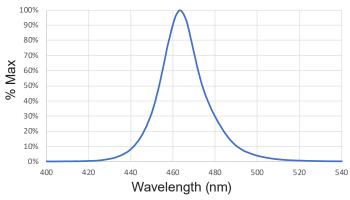
Storage Temperature	-40°F to +158°F (-40°C to +70°C)
Storage Humidity	10 to 90% rH non-condensing
Storage Altitude	10,000 feet (3000 m) maximum
Operating Temperature* (range over which the bili-hut™ meets all performance specifications)	41°F—104°F (5°C—40°C)
Operating Humidity	10 to 90% rH non-condensing
Operating Altitude	10,000 feet (3000 m) maximum
Operating Electromagnetic Environment	Not to be used around high- intensity EM disturbances (e.g. HF equipment, near a shielded room of an MRI system).
Internal Temperature of the <b>bili-hut™</b> that triggers the Environment High Temperature Warning	≤109.4°F (≤43°C) (in accordance with IEC 60601-2-50)
Ingress Protection	IP23 protects against solid objects over 12 mm and sprays of water from any angle up to 60° from the vertical

<sup>\*</sup>NOTE: The recommended room temperature range for treatment with the bili-hut™ is 70°F—76°F (21.1°C—24.4°C). For more information on recommendations for safe treatment, see **Section 2.3** of this guide. Phototherapy with the bili-hut™ may alter your baby's body temperature.

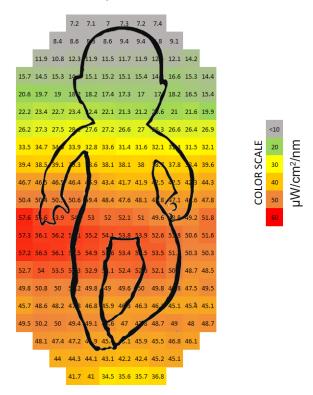
#### 7.8 Effects

# 7.8.1 Wavelength





## 7.8.2 Irradiance Map\*\*

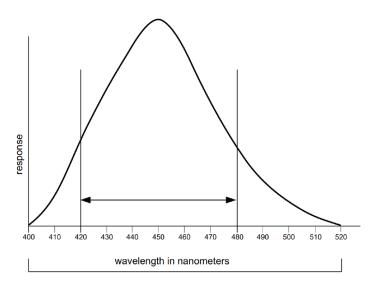


Measured at a distance of 22 cm\*\* from the blue LED treatment lights

Total Treatment Area	228 in <sup>2</sup> (1470 cm <sup>2</sup> )**
Effective Treatment Area	170 in <sup>2</sup> (1097 cm <sup>2</sup> )**
E <sub>bi max</sub>	57.6 μW/cm²/nm**
40% E <sub>bi max</sub>	23.0 μW/cm²/nm**
Effective Area Average	45.1 μW/cm²/nm**

# 7.8.3 Spectral Sensitivity of the Irradiance Measurement Device

The following graph shows the nominal response characteristics of the GE BiliBlanket Light Meter II, which corresponds to the peak absorption spectrum of bilirubin. The irradiance of every **bili-hut™** device is measured with the BiliBlanket Light Meter II at the manufacturer prior to shipment.



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