



# Jauni

## wearable phototherapy

### Instruction for Use



**bilihome**

**WARNING** To follow the Instruction for Use is mandatory for the compliant handling of the medical device.



## **1. Jauni Quick Guide**

### **1. Prep**

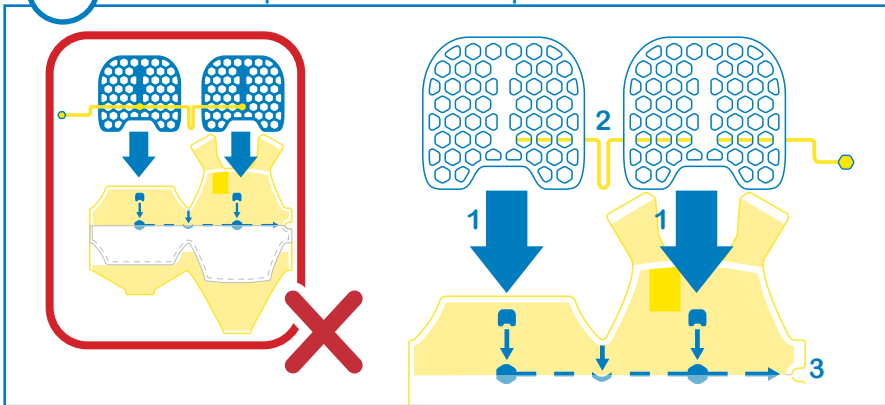
### **2. Use**

### **3. Wrap-up**

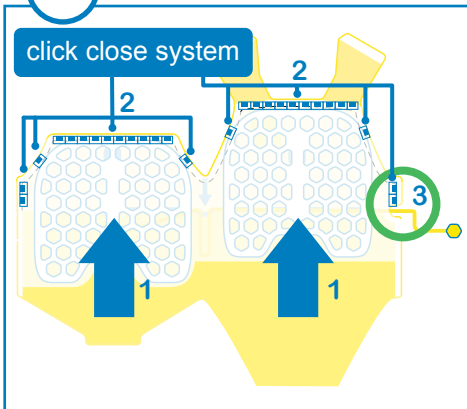
## **2. Instruction for Use**

# 1. Jauni Quick Guide: Prep

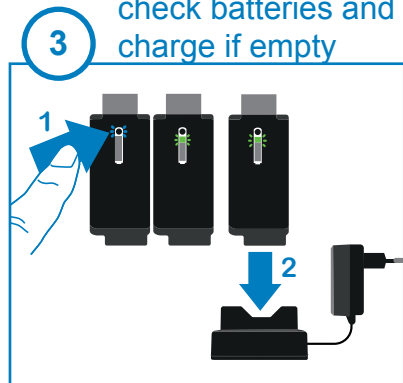
1 insert the pads into the romper



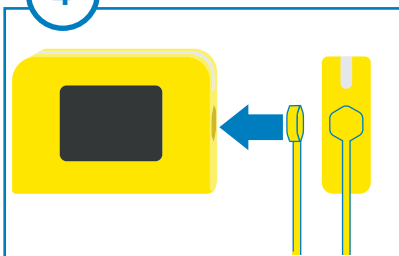
2 close the white fabric



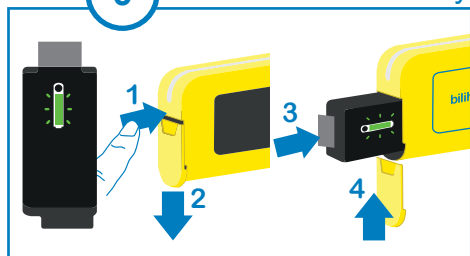
3 check batteries and charge if empty



4 attach the cable to the Yellow Box



5 insert the full battery





To follow this instruction the **Jauni System Kit** and the **Jauni Newborn Kit** is needed. For more information check the Instruction For Use (IFU). The **Jauni Quick Guide** does not replace the IFU.

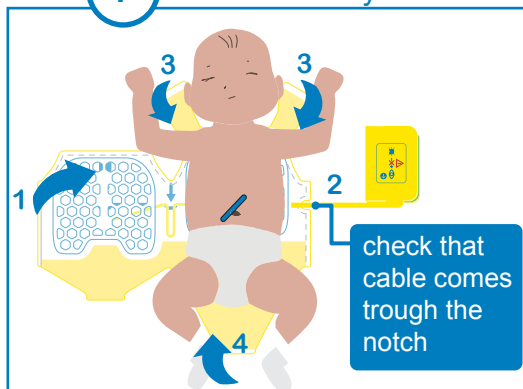
6

caution



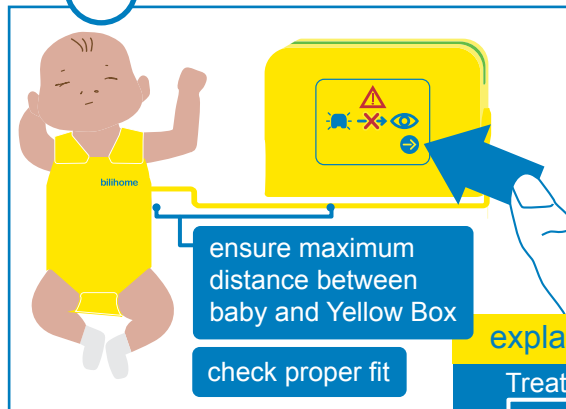
7

dress the baby



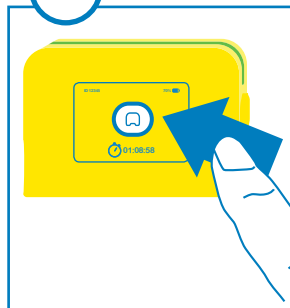
8

turn the light on:  
treatment starts



8a

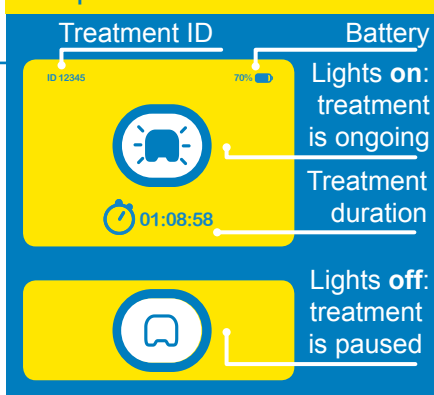
or treatment  
continues



explanation light strip



explanation home screen



## 2. Jauni Quick Guide: Use

### regularly check



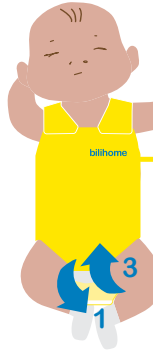
battery status

baby's temperature  
don't overdress!

maximum distance  
between baby and  
the yellow box

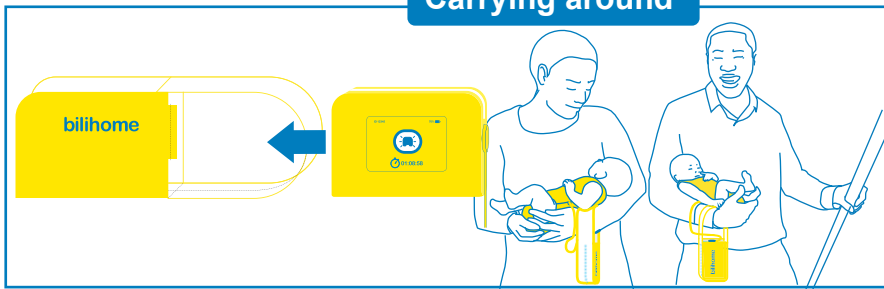
cable connection

### Diaper change during treatment



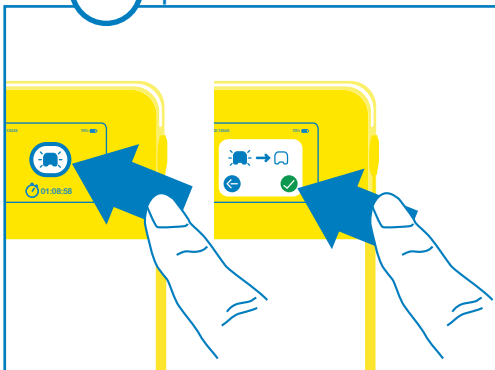
- 1 open the bottom
- 2 change the diaper
- 3 close the bottom

### Carrying around



### Romper change (e.g. bathing)

- 1 pause the treatment

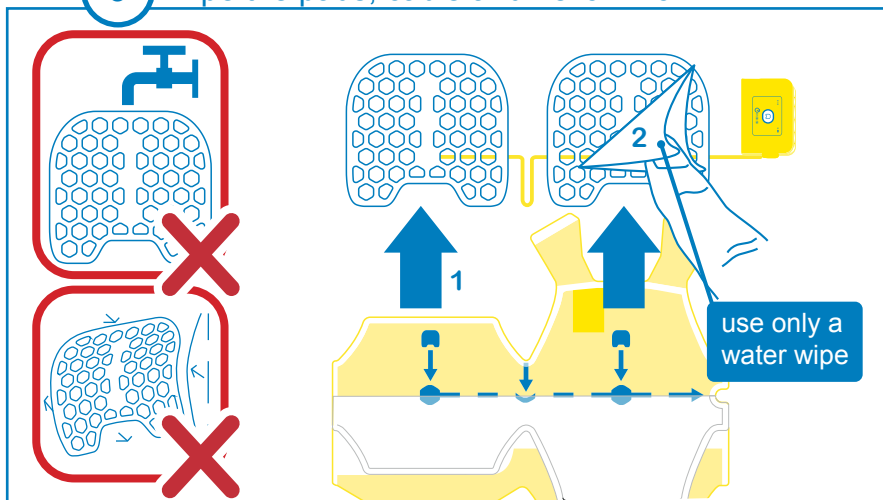


- 2 undress baby

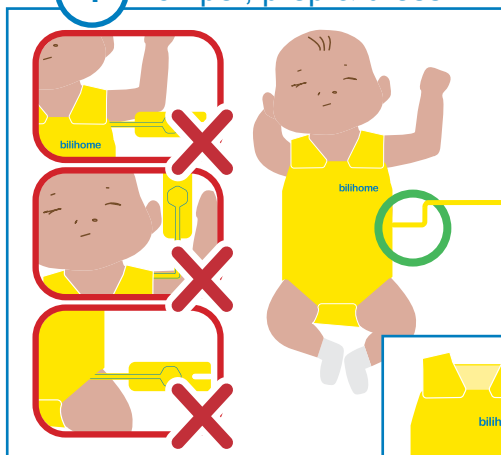


To follow this instruction the **Jauni System Kit** and the **Jauni Newborn Kit** is needed. For more information check the Instruction For Use (IFU). The Jauni Quick Guide does not replace the IFU.

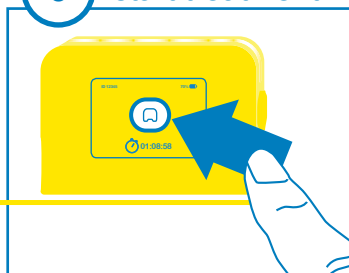
**3** wipe the pads, cable and Yellow Box



**4** unpack a new romper, prep & dress



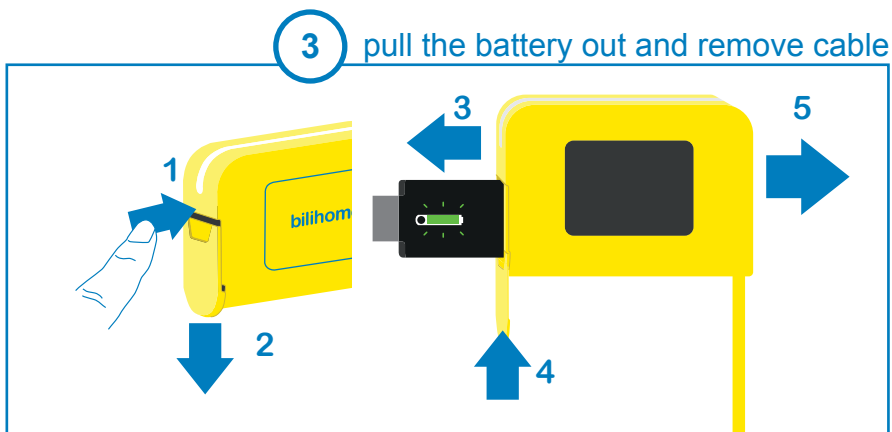
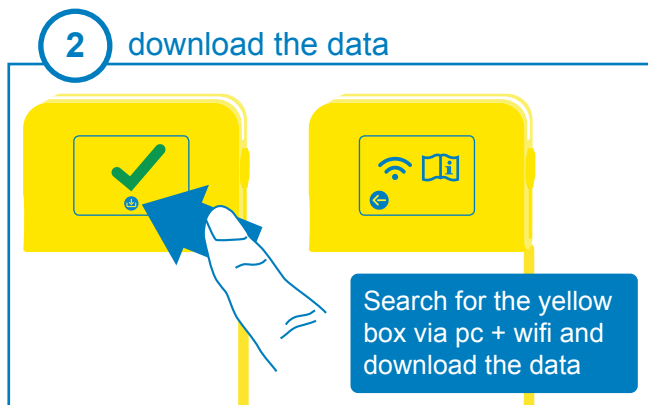
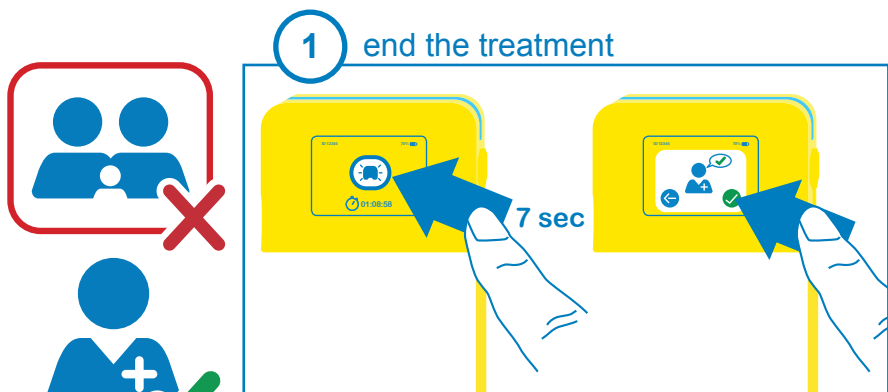
**5** start treatment



**6** wash the romper



### 3. Jauni Quick Guide: Wrap-Up



To follow this instruction the **Jauni System Kit** and the **Jauni Newborn Kit** is needed. For more information check the Instruction For Use (IFU). The Jauni Quick Guide does not replace the IFU.

#### 4 cleaning and disinfecting

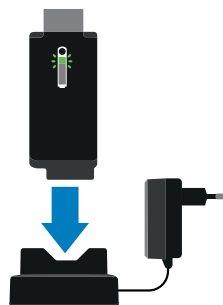


#### 5 dispose the rompers

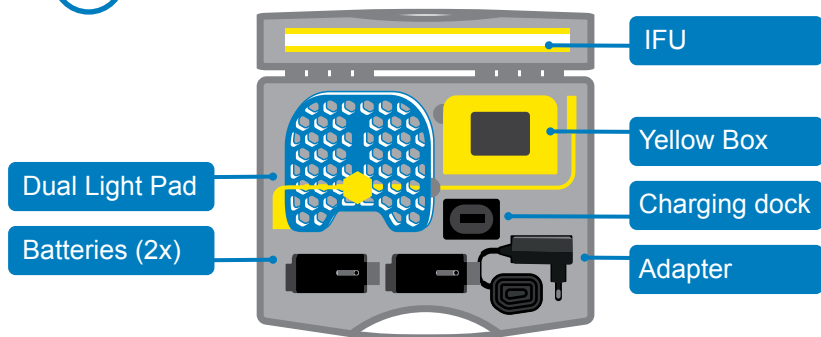


The Newborn Kit is for single patient use. Do not use the garments from a dedicated newborn patient kit for different newborn patients.

#### 6 charge both batteries



#### 7 store the cleaned components in the transport case



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# **1. Information about this document “Instruction for Use”**

## **1.1 Introduction**

The instruction for use is part of the Jauni system which is referred to as ‘Jauni device’ throughout this Instruction for Use. Read this Instruction for Use carefully and familiarize yourself with all the components, the functionality of the user interface and the accessories before using the wearable phototherapy device Jauni from Bilihome B.V.. This medical device is only available via healthcare professionals. To achieve optimal treatment success, you must use the device according to the prescribed treatment plan by a certified healthcare professional and according to the Instruction for Use of Jauni.

Pictures and illustrations may differ from the actual product received based on the ordered configuration and country-specific designs.

The meaning of the word “accessories” relates to accessories according to the definition of IEC 60601-1, for consumables, and supporting parts.

## **1.2 Copyrights and Trademarks**

All copyrights are reserved for Bilihome B.V., including the right to make changes in specifications and features shown herein.

Bilihome and Jauni are registered trademarks of Bilihome B.V.. Other company and product names in this document mentioned may be trademarks of the companies with which they are associated.

## **2. Application**

### **2.1 Device description**

Jauni from Bilihome B.V. is a wearable phototherapy device. It is a medical device class IIa, designed according to EN ISO 60601-2-50. It emits blue LED light in the bandwidth of 430 to 490 nm and helps to break down the bilirubin, the root cause of newborn jaundice and subsequently hyperbilirubinemia. Rechargeable batteries power the device. Jauni should always be used following the safety procedures and operating instructions included in this Instruction for Use and for the purpose for which it is designed.

### **2.2 Intended use indications**

According to the EN ISO 60601-2-50, Jauni, the Bilihome B.V. wearable phototherapy system is intended for the treatment of unconjugated hyperbilirubinemia by phototherapeutic radiation.

The Jauni Newborn Kit is meant to be used together with the Jauni System Kit specifically to directly assist the medical functionality of the Jauni Wearable Phototherapy in terms of its intended purpose. The Jauni Newborn kit is intended to fixate the phototherapy light close to the skin, in the population of infants up to 3 months old (postnatal age) and weighing less than 10kg (22 lb.) with intact skin, while allowing the handling of the newborn.

### **2.3 Intended use environment**

The device can be used in hospital nurseries, neonatal, or pediatric intensive care units of all levels or newborn-friendly outpatient facilities. As well as in the nursery at home the supervision of a certified healthcare professional.

## 2.4 Contra indications

It is also not indicated for the following patients:

- Patients with congenital erythropoietic porphyria or other photosensitizing disorders.
- Patients with conjugated hyperbilirubinemia.
- Patients with the indication of exchange transfusion.
- Patients under photosensitive medication.
- Patients with skin conditions, categorize as unsuitable for an on-skin treatment by a healthcare professional.
- Patients with cholestatic jaundice.
- Patients with fever.

## 2.5 Possible adverse effects

Literature shows that phototherapy is related to possible adverse effects including, but not limited to the following:

- Apnea
- Bronze baby syndrome
- Diarrhea
- Hyperpigmentation-reddening
- Patent ductus arteriosus
- Riboflavin-calcium and other deficiencies
- Skin blistering, irritation, and thrombocytopenia
- Hyper- and hypothermia

Watch closely for signs of the above mentioned conditions during treatment. This information should be conveyed to non-medical caregivers by trained healthcare professionals.

## 2.6 Intended users

The intended users of Jauni are trained certified health professionals and trained non-medical caregivers, supervised by a certified health professional on the options to apply this medical device use and according to the intended use and the instructions for use. Trained and certified health professionals are predominantly neonatologists, pediatricians, neonatal and pediatric nurses and midwives. Non-medical caregivers are predominantly parents and maternity carers.

The certified health professional should check if the non-medical caregiver is capable to use the medical device use, understands the intended use and the instructions for use.

The intended users shall only perform the following tasks:

<b>Jauni System (Bilihome Wearable Phototherapy)</b>	<b>Intended users/operators (USER)</b>	
	<b>Trained certified healthcare professional (HEALTHCARE PROFESSIONAL)</b>	<b>Supervised non- medical caregivers (CAREGIVERS)</b>
Preparation and initiation of phototherapy	X	
Operation after initiation of phototherapy	X	X
Ending the treatment of phototherapy (wrap-up)	X	
Reprocessing and storing of the device	X	
Service (maintenance and repair)	Bilihome B.V.	

## 2.7 User Responsibility

Phototherapy is a medical intervention for newborns as described in the intended use and should be prescribed by a certified healthcare professional. The Instructions for Use (IFU) describe the proper preparation, initiation, operation, ending, reprocessing and service (maintenance and repair) of the wearable phototherapy Jauni System Kit and its accessories. The entire Jauni system and accessories shall only be used by the intended user and shall not be used if damaged, contaminated, or if parts are missing. For questions about device repair and maintenance, see chapter 9.4.

The intended user is solely responsible for the risks to the newborn patient. Clinicians, third parties, or properties are responsible for treatment with inadequate performances due to abusive or improper use, inadequate maintenance, reparation, or modifications made by unauthorized individuals.

### Recommendations for certified health professionals



**WARNING:** The medical staff is in charge of the user training regarding the verification of the patient and of the system proper functioning, and regarding all other operations related to the use of the Jauni. The user must be trained before the first use of the Jauni about its setup and use and become aware of the device-associated risks. Clinicians remains in charge of the verification (e.g. irradiance) and of the cleaning of the Jauni.

### Recommendations for the non-medical caregiver



**WARNING:** The user must follow the recommendations and instructions contained in the Instruction for Use – concerning the Jauni – and provided by certified health professional. In case of malfunctioning the non-medical caregiver must stop the Jauni and contact the certified healthcare professional.

### 3. Safety-related information



**WARNING:** Jauni should be used only by appropriately trained persons and under the direction of qualified medical personnel familiar with currently known risks and benefits of newborn infant phototherapy use.



**WARNING:** Do not leave the patient with Jauni unattended with untrained persons.



**WARNING:** Variations of the ambient conditions (room temperature and humidity, sun exposure, nearby devices) may unfavorably affect the patient's health, including their temperature or water balance. The use of this device outside of the specified operating conditions may compromise the functionality of the device.



**WARNING:** Although the LED light source does not produce any infrared radiation, the water balance for some newborn patients may be disturbed.



**WARNING:** The newborn patient and the intended users do not come in contact with direct harmful light. For the inconvenience during some handling during the preparation, it is advised to avoid looking directly at the blue light of the therapy pads.



**WARNING:** The newborn patient's bilirubin values shall be measured regularly.



**WARNING:** There is no possibility to place reflective foil between the patient and the light source since the light source is directly on the patient's body.



**WARNING:** The blue light can hinder clinical observations by masking skin colour changes, such as cyanosis.



**WARNING:** To prevent photochemical modifications, do not store drugs and infusion liquids in the radiation area.



**WARNING:** Keep the device dry.



**WARNING:** Do not modify the Jauni.



**WARNING:** The operator shall never touch the exposed contacts of the Yellow Box connector while touching the newborn patient.



**WARNING:** If the device is non operational or non functional, follow the steps in the trouble-shooting chapter.



**WARNING:** Always check for completeness of Jauni before handing it over to parens(s)/caregiver(s).

### 3.1 Explanation of symbols



### 3.1.1 General symbols in the Instruction for Use

**WARNING:** May result in death or serious injury for the patient or the operator.



**CAUTION:** May result in moderate or minor injury for the patient or the operator.



**NOTE:** May result in property damage.



Manufacturing location



Medical device



Serial number, includes the manufacturing date -YYMMDD-



Lot number



Indicates a reference number



CE certified product

0297

Notified Body, who has certified the product

Limited dust ingress protection / Protected against vertically falling drops of water

IP21

Protected against solid objects over 12mm/Protected against direct sprays of water up to 60 degrees from the vertical

IP23

TYPE B Applied part acc IEC 60601



Refer to the Instruction for Use



The temperature limits for save operation is 15°C-30°C



Only for trained healthcare professionals





















Not for (supervised) non-medical caregivers (e.g. parent)



### 3.1.2 Symbols on the Yellow Box screen

Treatment ID, which can be documented in the

Symbol	Description
ID 12345	electronic patient record, if desired
	One or two Light Pads contain an error or is missing.
	Battery contains an error.
	Yellow Box contains an error.
	Dual Light Pad is on. Blue light is emitted.
	Dual Light Pad is paused. No blue light is emitted.
	Continue in the menu button
	Go back in the menu button
	Trained healthcare professional
	OK/confirm button
	Battery low indication
	Actions required to check the device operation
	Dual Light Pad reached its maximum internal temperature and switched off
	Cable connected to the Yellow Box
	Human eye
	One or two Light Pads have a failure or are not connected.
	The effective treatment time in hh:mm:ss
01:08:58	
	Download treatment data after finalizing the phototherapy.
	Consult the Instruction for Use for further information.

### 3.1.3 Symbols on the romper



Single patient use



Machine washing temperature



No dry cleaning



No tumble drying



No ironing



No chemical washing

50% Cotton |  
50% Lyocell

Fabrics composition

### 3.1.4 Symbols on adapter



Dispose of this product according to local regulations



Power adapter is for indoor use only



Power adapter is a Class II device

### 3.1.5 Symbols on battery



Recycling symbol, to follow the local recycling regulations



Germany, GS



Taiwan, Recycling Symbol



China, RoHS



China, RoHS



United Kingdom, UKCA



Morocco, CMIM



For Canada & USA: Please call 1-800-822-8837 for information on how to recycle this battery



UN Transportation Test



Canada and USA, UL



China, CQC



EAC symbol



Australia and New Zealand, RCM



Japan, PSE



India, BIS



Korea, KC



Taiwan, BSMI



Russia, GOST-R

### 3.1.6 Symbols on packaging



Recycling symbol LDPE



Recycled and recyclable symbol

## 3.2 Safety Instructions

### 3.2.1 Cable Management

The cable connects the Dual Light Pad to the Yellow Box. The length minimizes the chance of strangling. Follow the instructions in chapter 5.4 for correct cable management. To prevent damage to the cable, follow these guidelines:

- Do not allow the cable to be crushed or bent at a sharp angle.
- Do not place anything on the cable.

If the cable is damaged, it must be repaired. See chapter 9.

### 3.2.2 Device compatibility safety



**WARNING:** The device has been tested for the maximum touchable temperature of 40 degree according ISO 60601-2-50. The Jauni wearable phototherapy is not indicated for use inside a warming therapy device or an heating blanket when the operational conditions are outside the specification of the Jauni system.



**WARNING:** If the trained healthcare professional can not ensure an air temperature range from 15°C to 30°C and the mattress temperature is less than 36.5 °C., do not use it in combination with warming therapy device or heated blanket/ mattress.

### 3.2.3 Safety instructions for accessories

Use only accessories recommended by Bilihome B.V..

### 3.2.4 Electrical safety

Jauni is a medical device which complies with safety measurements concerning EMC (Electromagnetic Compatibility) and must be installed and made ready for use according to the EMC information in this Instruction for Use. Radio frequencies may influence the device. For electrical safety, use only Jauni supplied power charging dock and adapter.

### 3.2.5 Explosion and fire protection

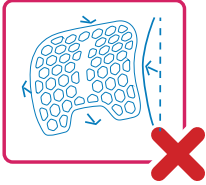
Do not use parts or accessories in environments with a risk of explosion or fire.

### 3.2.6 Risks of interference

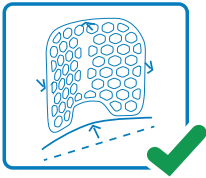
The cable and the romper contain small magnets which can interfere with other medical devices.

### 3.2.7 Mechanical safety

All parts of Jauni cope with mechanical stress during normal use. To prevent damage to parts of Jauni, follow these guidelines:



Do not place anything on one or multiple parts of Jauni.  
Do not bend the Dual Light Pads more than 15 degrees.



### 3.2.8 Device failure

If the device fails, carefully read this Instruction for Use. If the failure is not present in this Instruction for Use, stop the treatment and contact Bilihome B.V. (contact information in chapter 9, service).

## 3.3 Serious incident

Any serious incident that has occurred concerning the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or newborn patient and/or caregiver is established. Contact [regulatory@bilihome.org](mailto:regulatory@bilihome.org) immediately.

## 4. Jauni Device

### 4.1 Jauni device configuration

The Jauni device is a wearable phototherapy. It is a combination of the following items:

- Jauni System Kit (1x)
- Accessory: Jauni Newborn Kit



**CAUTION:** To ensure the safety and performance of the Jauni System Kit, you must only use the dedicated accessories, described in this Instruction for Use.



**CAUTION:** One Newborn Kit is dedicated to one specific newborn patient with single-patient use accessories.



**CAUTION:** The device and its accessories shall be stored in the transport case when not in use.

#### 4.1.1 Packaging

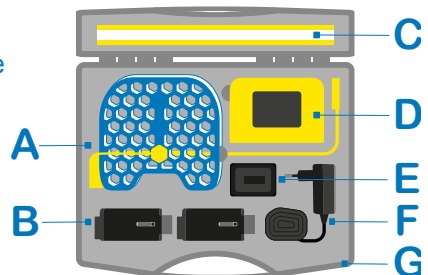
See chapter 9 if the Jauni System Kit package is damaged or exposed to environmental conditions outside of those specified for storage.

If the delivery package of the Jauni Newborn Kit is damaged, unintentionally opened before use of a specific newborn patient, or exposed to environmental conditions outside of those specified, do not use it in clinical use.

#### 4.1.2 Jauni System Kit

The Jauni System Kit consists of:

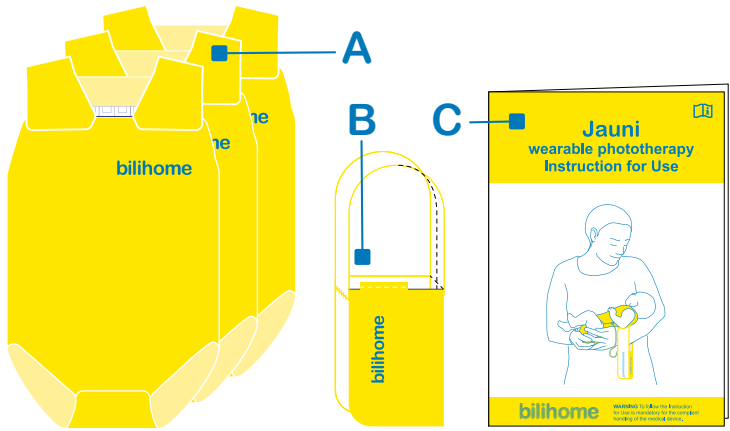
- A. Dual Light Pad connected with cable
- B. Battery (2x)
- C. Jauni Instruction for Use (IFU) - country specific
- D. Yellow Box
- E. Battery charger
- F. Battery adapter (country specific)
- G. Jauni Transport Case



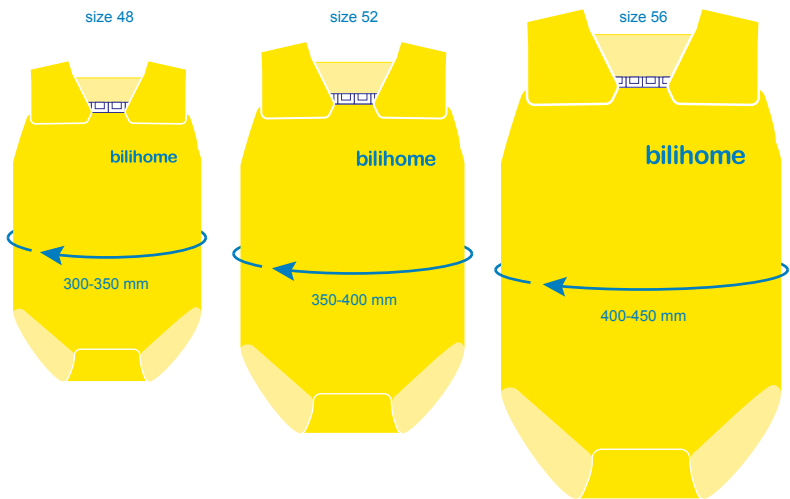
### 4.1.3 Accessory: Jauni Newborn Kit

The Jauni Newborn Kit consists of:

- A. a selection of Jauni rompers
- B. Yellow Box Bag (1x)
- C. Instruction for Use



The Jauni Newborn Kit comes in three sizes available:





## 4.2 Description of Jauni Subcomponents

### 4.2.1 Dual Light Pad with cable

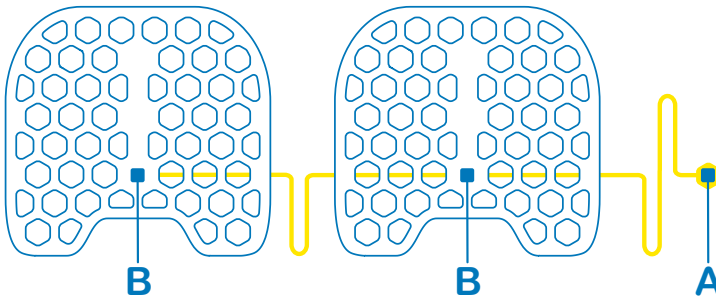


**CAUTION:** Risk to damage or malfunction the Dual Light Pad, do not fold, stretch or over-bend the Dual Light Pad, other than following the natural body contour of the newborn (approx. 15 degrees).

To apply phototherapy, two (2) reusable silicone light pads, part of the Dual Light Pad, emit light towards the newborn. The Dual Light Pad is placed between the yellow fabric and the translucent inner lining of the romper. One Light Pad illuminates the chest and the other one the back of the newborn. The Dual Light Pad follows the contour of the newborn and bend therefore slightly. The Light Pads connect with a fixed yellow cable. The cable ends with a magnet plug to connect to the Yellow Box.

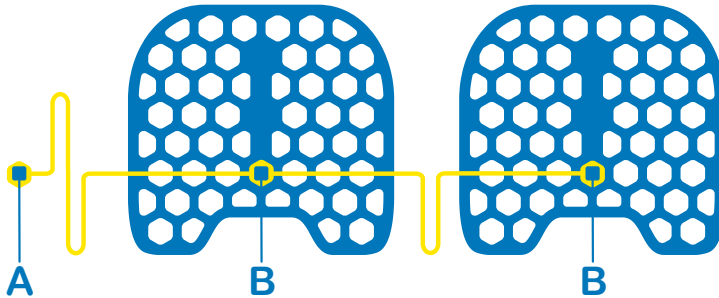
Skin-facing side (translucent) of the Dual Light Pad:

- Visible blue-light LEDs are modeled in the silicon structure.



Upper side (non-translucent, blue) of the Dual Light Pad:

- Faces away from the newborn's body when used in therapy.



- A. The magnet connector attaches/detaches the Yellow Box which connects with the power supply and the touch screen.
- B. Connectors (2x) are permanently fixed to the Dual Light Pad.

#### 4.2.2 Yellow Box

The Yellow Box is solely battery driven and never connects to the main supply.



**CAUTION:** Always have a charged battery to avoid the risk of delayed or unintentional interruption of the therapy.

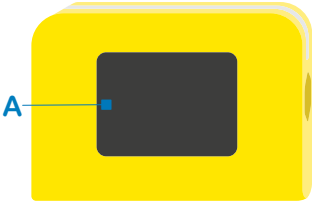


**CAUTION:** Do not cover the light strip of the Yellow Box to ensure visibility of the device status.

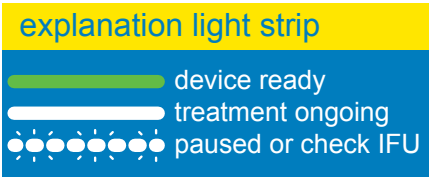
The Yellow Box is the operational unit of the Jauni system, to supply the necessary battery power and control the device during therapy. A touch screen and light strip provide information on the current operational status.

The Yellow Box includes:

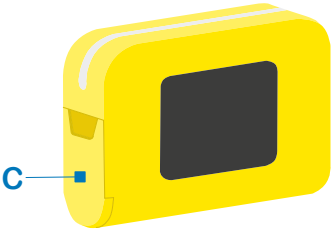
**A.** Touch screen as the user interface (UI).



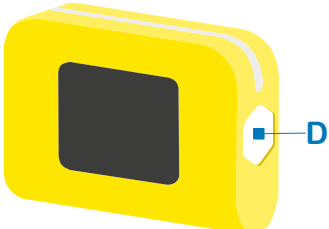
**B.** Light strip, visible from three sides.



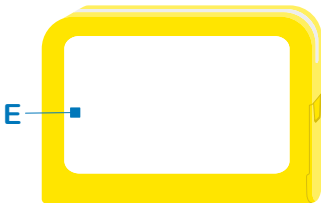
**C.** Removable battery lid.



**D.** Connection point for the hexagon magnetic cable.



**E.** UDI-DI-PN label.



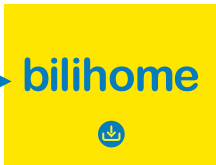
4.2.3 Screen User Interface on Yellow Box

Here the User interface flow on the screen. After 30 seconds of inactivity the screen will turn off. By touching the screen it will turn on again.

Action: Battery is inserted:  
screen of the Yellow Box  
starts up.



Screen 1  
see chapter 5.6



Screen 2  
see chapter 5.6

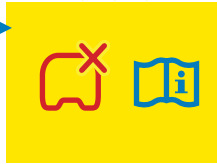


Screen 3  
see chapter 5.6



Screen 4  
see chapter 5.6

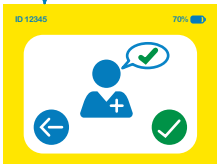
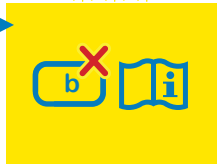
Dual Light  
Pad error  
see chapter  
trouble shoot-  
ing 12.1.1



Battery error  
see chapter  
12.1.1



Yellow Box  
error  
see chapter  
12.1.1



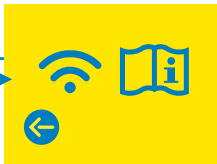
Screen 9  
see chapter 7.1



Screen 10  
see chapter 7.1



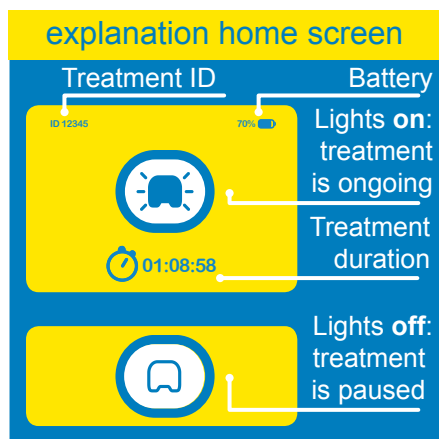
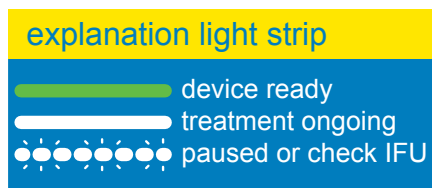
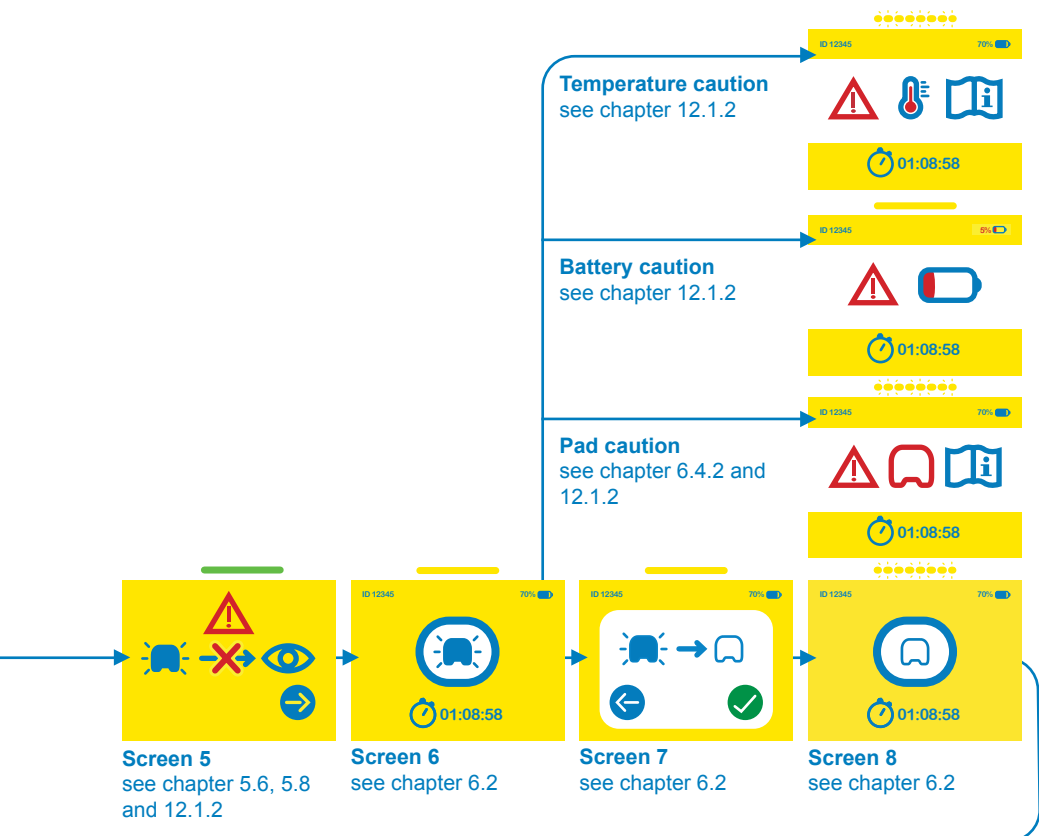
Screen 11  
see chapter 7.1



Screen 12  
see chapter 7.1

FOR PROFESIONAL USE ONLY

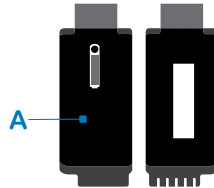




#### 4.2.4 Battery and charging dock

A set of batteries are the sole power source of the Jauni device and need to be charged alternating to ensure continuous therapy.

**A.** Batteries (2x), interchangeable, with a charging indicator.

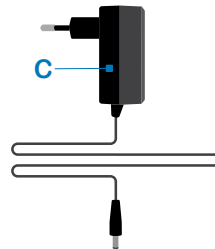


**B.** Charging dock

- One battery shall be charged while using Jauni.



**C.** Power plug, connect to the charging dock.



#### 4.2.5 Jauni romper

The Jauni Romper of the Jauni Newborn Kit is an applied part B of the Jauni System Kit. It is exclusively developed for wearable phototherapy. It consists of two layers with unique features:

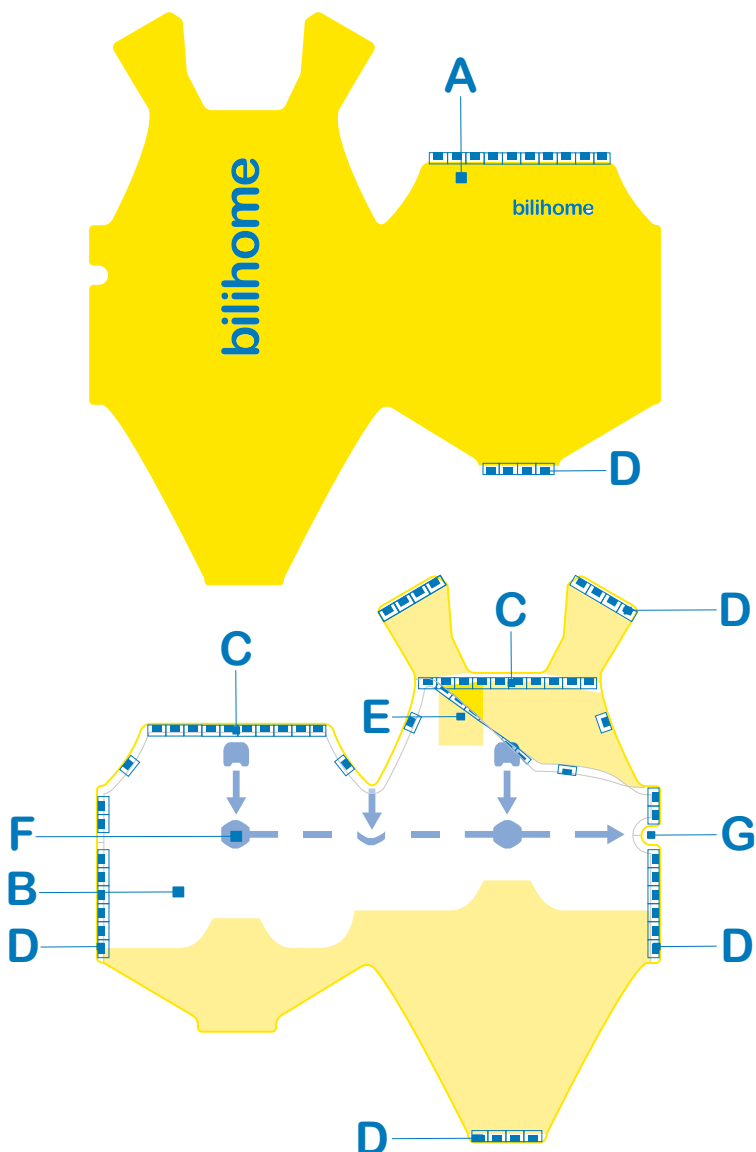
- A.** Yellow outer layer, made from cotton, blocks the blue light to a minimum.
- B.** White inner pocket layer, a breathable, translucent, skin-friendly, soft, lyocell. The Dual Light Pad is inserted between the inner pocket to transmit the light onto the skin.
- C.** Inner Click Close system opens and closes the pocket for the Dual Light Pad and holds it in place.
- D.** Outer Click Close system opens and closes the romper on the shoulders, neckline, and diaper area.
- E.** Label, provides washing and manufacturing instructions
- F.** Position instructions indicate the correct placement of Dual Light Pad inside the romper and the correct cable direction to sideways exit notch.
- G.** Sideways exit notch, fixes the cable in the right position.



**WARNING:** Choking resulting from a child swallowing a magnet that has become detached from the romper.

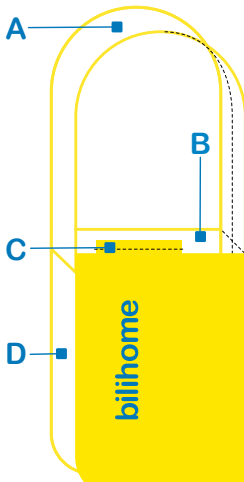


**CAUTION:** Do not use the romper if the newborn is allergic to cotton or viscose.



### 4.2.6 Yellow Box Bag

The Yellow Box Bag is part of the Jauni Newborn Kit and is exclusively developed for the Jauni wearable light therapy. The Yellow Box is inserted in the Yellow Box Bag for hands-free handling of the newborn, e.g., baby carrying and still being able to see the operation status from the light strip of the Yellow Box.



The Yellow Box Bag consists of:

- A.** Handle, to sling around the arm.
- B.** Opening, place the Yellow Box with the connector on top.
- C.** Label, provides washing and manufacturing instructions
- D.** White-translucent side to enable light from the light strip shining through.





## 5. Jauni preparation

The Jauni device may be checked for spectral irradiance with the specified radiometer in the service chapter before the initial use and the use with each patient.

### 5.1 Insert the Dual Light Pad into the romper



**CAUTION:** Do not use the device when the visual check shows signs of physical damage or loose parts.



**CAUTION:** Before placing the newborn on the romper, check the romper surface for folds in the fabrics to avoid unintended pressure points.



**CAUTION:** Never use the Dual Light Pad without the romper.

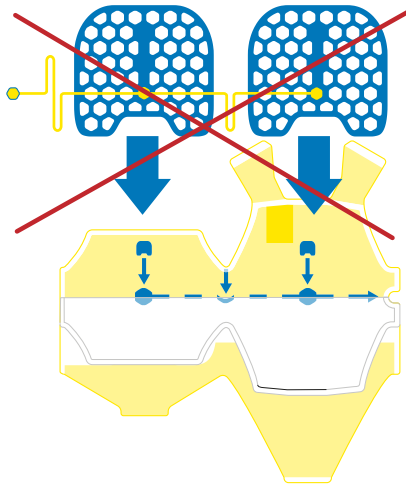


**CAUTION:** Put the Dual Light Pad with the transparent side towards the newborn.

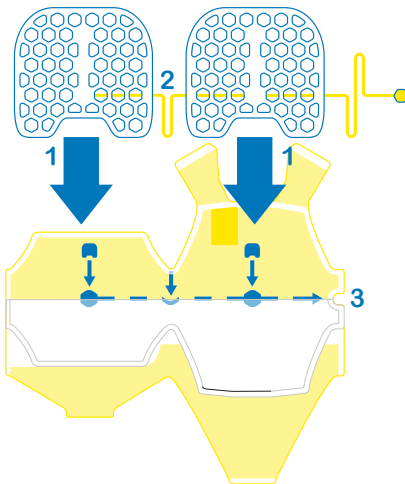
- Open the Jauni System Kit and check completeness (see chapter 4.1).
- Check all items for signs of visible and physical loose parts and/or damage by looking at all sides. If you find any items with visible and physical loose parts and/or damage during the check, do not use the device.

Start the assembly of the Jauny System Kit and Jauni Newborn Kit by putting the Dual Light Pad into the romper:

1. Open the romper at the shoulders, side, and diaper area so the inner (white) layer faces up.
2. Lay the romper flat on a flat surface (e.g., the changing table).
3. Fold the inner white layer open by opening the Click Close system to reveal the pockets for the Dual Light Pad.
4. Take the Dual Light Pad and place it onto the romper, the transparent silicone side facing up and the side with the cable coming out facing down.

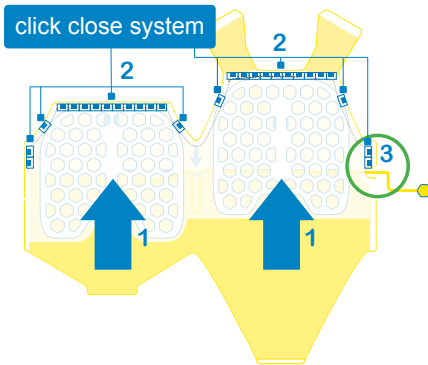


**CAUTION:** The incorrect way of putting the Dual Light Pad into the romper.



1. Insert the Dual Light Pad, transparent silicon side facing up, in the white fabric pocket.
  - The white pocket follows the contour of the Light Pad.
2. The cable between the Light Pads should be tucked in between the Light Pads inside the romper.
3. The cable leaving the Light Pads should leave the romper at the designated notch on the right side of the romper, under the armhole.
  - Follow the blue markings inside the romper

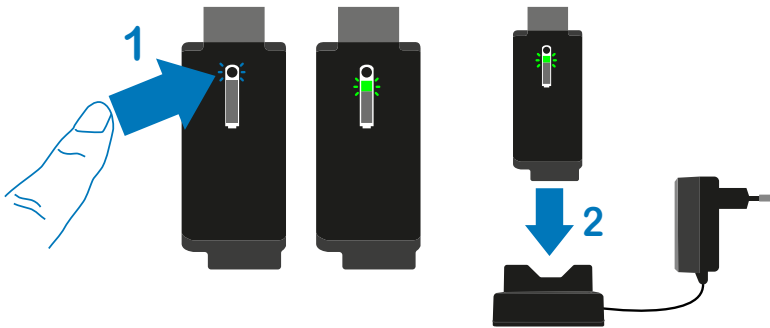
## 5.2 Close the romper pockets



Lay down the romper on a flat surface as shown in the image.

1. Close the pockets by pulling up the white layer.
2. Close the Romper by letting the Click Close system snap together.
3. Make sure the cable going away from the Dual Light Pad exits the romper at the designated notch at the side of the romper.

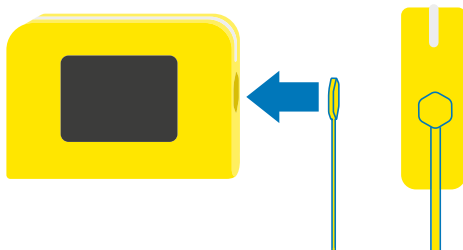
## 5.3 Check status and charge empty batteries



1. Check the status of the batteries by pressing the small black button next to the battery icon on the batteries.
  - One battery should be charged for at least 75% (three out of four lights on the battery). This battery should be used when starting up the Yellow Box as described below.
  - If neither of the batteries is charged for at least 75%, use the fullest one – this will result in a shorter treatment time so a battery change should be performed sooner.
2. Put the other battery in the charging station and charge it until the battery needs to be changed. If the light in the battery icon is blinking the battery is charging.

## 5.4 Attach the Yellow Box to the cable

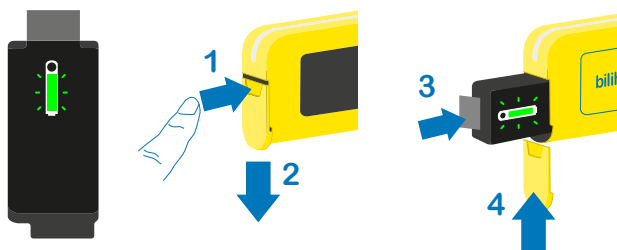
Attach the cable from the Dual Light Pad to the Yellow Box. Point the cable downwards when holding the Yellow Box with the light strip facing up.



## 5.5 Insert the charged battery



**CAUTION:** Do not put the Dual Light Pad onto the newborn while the Yellow Box performs a self-test.



1. Insert the battery by slightly pressing the notch on the left side of the Yellow Box.
2. Slide the battery lid down: this reveals the battery chamber.
3. Insert the battery with the flap facing outwards and the battery icon facing you.
4. Slide the battery lid back until you feel a click.

## 5.6 Ready to start



**CAUTION:** Never look into the light. Never let the light shine into the newborn's eyes.

After the battery is inserted, the system performs a self-test automatically. The Dual Light Pad will flash shortly during the self-test.

Several screens will appear. For a few seconds the software version appears in the upper left corner. Note that the self-test automatically starts and only takes seconds. You might not have noticed all the screens, but you should see the final screen:



If the self-test finalizes successfully, the screen with the symbol “do not look directly in the light” will stay.



- Before initiating the treatment, dress the newborn with the Jauni romper. Make sure the size of the romper is fitting the newborn: the romper should be fitted snug around the body.
- If the self-test indicates an error, see chapter troubleshoot.

## 5.7 Dress the newborn



**WARNING:** Do not use Jauni if the newborn has a fever. Contact a healthcare professional immediately.



**WARNING:** Ensure the newborn is wearing the correct romper size: the romper should be fitting snugly around the body.

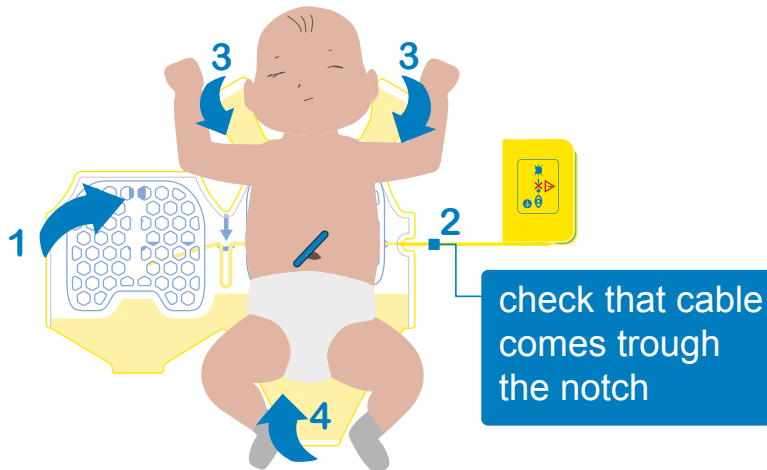


**CAUTION:** The Jauni romper is the main garment for the newborn during phototherapy. In case the child will be covered, use no more than one additional thin layer, e.g. a thin, non-padded layer of cotton, max. 200 g/m<sup>2</sup>.



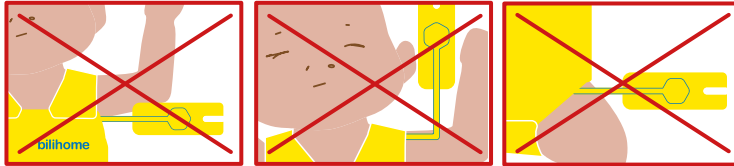
**CAUTION:** Do not guide the cable through a trouser leg, armhole, or neckline of the garment. This could cause the cable to get tangled around one of the newborn's limbs.

Properly dressing the newborn with the romper is very important to allow the correct position of the Dual Light Pad. Ensure the romper is fitted properly around the body of newborn.

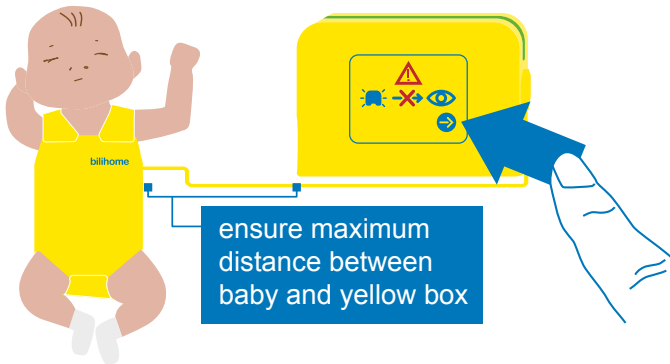


Place the newborn onto the right side of the open romper.

1. Fold the left side over the newborn's chest.
2. Make sure the cable connecting the Yellow Box and the Dual Light Pad leaves the romper through the designated notch.
3. Close the shoulder straps.
4. Close the diaper strap.



## 5.8 Turn the light on: treatment starts



- Once the newborn is dressed in the romper, you can continue from the light caution screen. The light will turn on and the treatment starts.
- Place the Yellow Box as far as possible from the newborn, to make sure the newborn cannot get tangled in the cable.
- Place the Yellow Box with the LED strip visible to you.



## 6. Jauni use during therapy

The numbering in this chapter follows the Jauni Quick Use Guide.



**CAUTION:** Regularly check the battery status.



**CAUTION:** Regularly check whether the distance between the newborn and the Yellow Box is the maximum distance the cable allows.



**CAUTION:** Regularly check whether the cable is connected to the Yellow Box



**CAUTION:** Don't drop the Yellow Box.



**CAUTION:** Regularly check the newborn's skin for wounds or irritations. Prolonged exposure with the Jauni device could result in skin irritation.



**CAUTION:** Regularly check rectally if the newborn's temperature won't exceed 37,5 °C. Avoid over-dressing.

### 6.1 Diaper change during treatment



**CAUTION:** The duration and any pausing of the light therapy must follow the instruction of the supervising medical specialist. Not following the instructions can lead to unintended undertreating of the newborn.

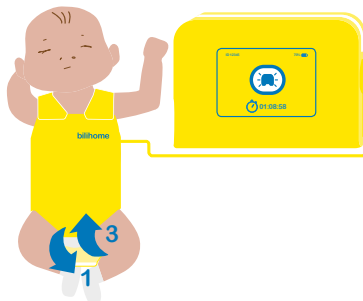


**CAUTION:** Always check the proper fit of the romper, closures, and cable position.

The diaper change can be done without disconnecting or pausing the Yellow Box. Do not undress the newborn but only open the lower closure:

The Dual Light Pad stays on.

1. Open the bottom.
2. Clean the newborn and change the diaper.
3. Close the bottom with the Click Close system.



## 6.2 Changing a Romper



**CAUTION:** The duration and any pausing of the light therapy must follow the instruction of the supervising medical specialist. Not following the instructions can lead to unintended undertreating of the newborn.

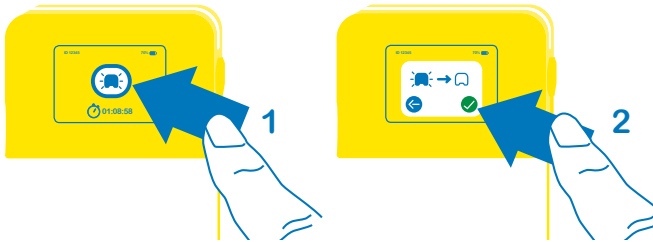


**CAUTION:** When opening the Jauni garment during the therapy, make sure that you switch off the blue light to avoid light leakage directly to the newborn's eyes.



**CAUTION:** Regularly check the newborn's skin for wounds or irritations.

In some situations, for example, when undressing the newborn for a daily routine, the Dual Light Pad may need to be turned off temporarily to protect the caregiver's and the newborn's eyes from the light. This is done on the screen of the Yellow Box:



1. Press the button in the middle of the screen.
2. Confirm that you want to turn off the Dual Light Pad temporarily.
  - The time indicator is blinking, indicating the treatment has temporarily stopped.



Always turn the Dual Light Pad back on when the newborn is dressed in the romper.



Undress the newborn:

1. Open the bottom of the romper.
2. Open the shoulder straps.
3. Open the side.

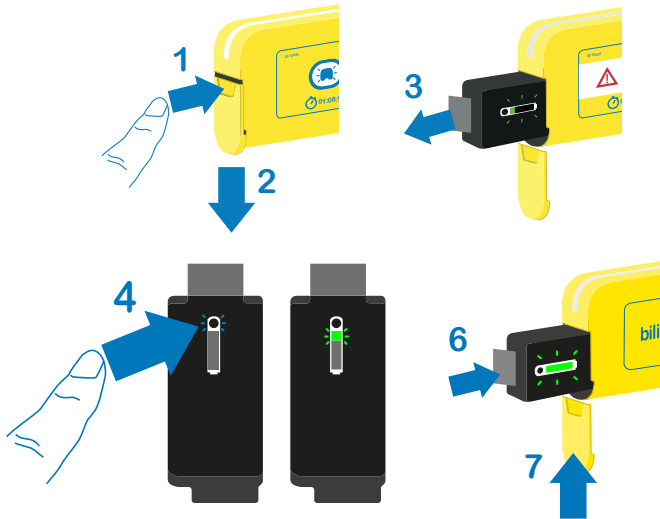
When changing the newborn's romper:

- If needed, clean the Dual Light Pad, cable, and Yellow Box by following the instructions in chapters 6.4.2 and 6.4.3.
- Unpack a new romper, prep, and dress.
- Press the switch in the middle of the screen of the Yellow Box. The Dual Light Pad turns back on immediately: the home screen shows the switch on again and the timer is running.
- Wash the worn romper by following the washing instructions, see chapter 6.4.1.

### 6.3 Changing battery

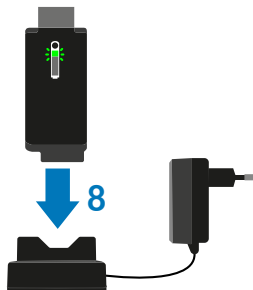


**CAUTION:** Make sure there is always one battery charging in the charging cradle, so that when the battery needs to be changed there is always a full battery available.



To change the battery:

1. Push down on the battery lid.
  2. Slide it open.
  3. Grab the black label, pull the battery out, and put it aside for now.
  4. Take the charged battery out of the charging dock.
  5. Double-check the battery status.
  6. Slide the charged battery in the Yellow Box until you feel a click.
  7. Slide the battery lid back onto the Yellow Box until you feel it click in place.
- Wait until the Yellow Box is ready to start again.
  - Check if the battery status updates. If so, you've successfully swapped the batteries.



8. After changing the batteries, always put the empty battery in the charger to ensure you have a charged battery when you need one.

## 6.4 Washing and Cleaning Instructions

### 6.4.1 Romper washing



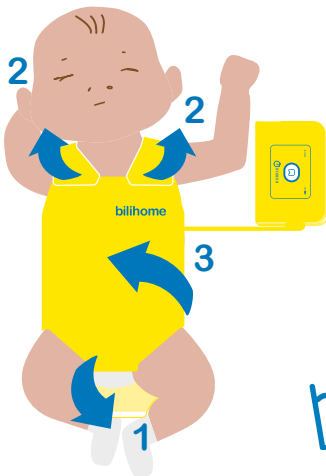
**CAUTION:** Before and after washing, check the romper for loose parts in the Click Close system. Dispose of the garment, when the Click Close system is damaged or loose parts are identified.



**CAUTION:** Do not bleach, chemical clean, tumble dry or iron the therapy-specific garment, to avoid skin irritation and extreme shrinking of the garment



**CAUTION:** The Newborn Kit is for single patient use. Do not use the garments from a dedicated Newborn Kit for different newborns.



1. Undress the newborn.
2. Check the garment for damaged and lose parts on the Click Close system.
3. Close the Click Close system, use a wash bag and wash the romper in the washing machine at 40°C in a regular program.
4. Hang the garment open on the washing line until completely dried.
5. Check the garment again for any damage and lose parts from the Click Close system.
6. Store back in the Newborn Kit of the dedicated newborn, ready to reuse for this particular newborn.

### 6.4.2 Yellow Box



**CAUTION:** In case of visible cracks or damages, do not use the device anymore and contact the provider.



**CAUTION:** Do not reprocess the Yellow Box during the therapy.

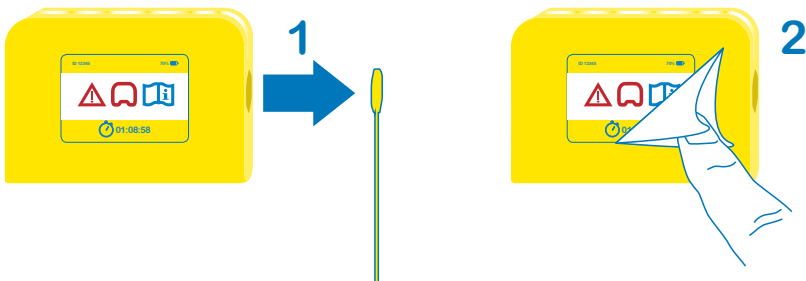


**CAUTION:** Do not wet clean the connector inside the cable or Yellow Box.



**CAUTION:** If needed, clean the surfaces of the Yellow Box during the phototherapy session only with water wipes without perfume if necessary.

1. Disconnect the Yellow Box from the cable.
  - The Yellow Box will give a white blinking error message as long as the Yellow Box is disconnected from the Dual Light Pad.



2. Take a water wipe and gently clean the surface of the Yellow Box on all sides.
3. Do not wet wipe the inner side of the cable socket.
4. Wait until the Yellow Box is dry again to connect the cable.
  - The white blinking error message will disappear. If this is not the case, consult chapter 2.3.
5. Place the Yellow Box furthest away from the newborn so that the light indicator is visible from 2-meter distance and so the newborn will not be able to get tangled in the cable.

### 6.4.3 Dual Light Pad and cable



**CAUTION:** Remove the cable from the Yellow Box before cleaning the cable.



**CAUTION:** To clean the cable, use water wipes without perfume to wipe the surface of the cable.



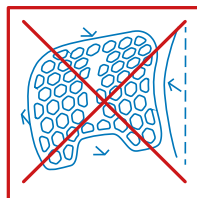
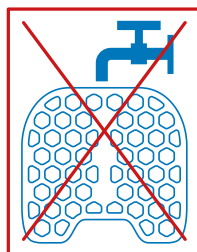
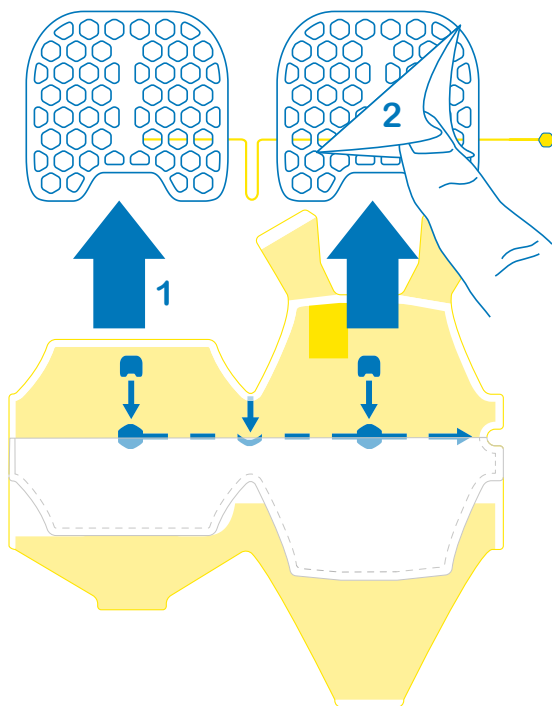
**CAUTION:** Do not clean the cable socket or insides.



**CAUTION:** Do not bend the Dual Light Pad.



**CAUTION:** Do not hold the Dual Light Pad underwater or under the tab.



use only a  
water wipe

1. Disconnect the Yellow Box from the cable.
  - The Yellow Box will give an error message because it has been disconnected from the box. The error can be ignored during the cleaning process. Take the Dual Light Pad out of the romper completely.
2. Check for damages or scratches.
3. Do not put the Dual Light Pad under water or under the tap.
4. Do not bend the Dual Light Pad while cleaning. It is advised to put the Dual Light Pad onto a flat surface, clean one side and then turn the Dual Light Pad over to clean the other side. Hard to reach spots, like the back of the cable, may be reached through the holes of the Dual Light Pad, instead of bending the Dual Light Pad or the cable.
5. Wipe the Dual Light Pad and cable using water wipes.
6. If one of the holes of the Dual Light Pad needs cleaning, cover your finger with the wet wipe and put your finger through the hole.
7. When the Dual Light Pad has dried, put them back into the romper and close the romper.
8. Connect the Yellow Box to the pads. The error message should disappear. If this is not the case, consult chapter 2.3.

#### 6.4.4 Yellow Box Bag

1. Wash the Yellow Box Bag in the washing machine at 40°C in a regular program.
2. Hang the bag on the washing line until completely dried.





## 6.5 Carrying, soothing, and feeding during therapy



**CAUTION:** Make sure the cable does not come loose from the Yellow Box when picking up the newborn.



**CAUTION:** Limit the IR and UV exposure, by placing the newborn in a room with an average room temperature and without putting the newborn in the direct sun near a window.



**CAUTION:** Ensure that the light strip from the Yellow Box is visible through the translucent white fabric of the Yellow Box Bag.



**CAUTION:** Check the sling of the Yellow Box Bag for damage.



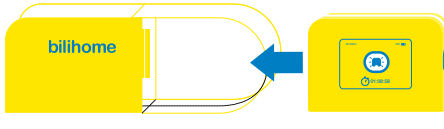
**CAUTION:** To avoid dropping the Yellow Box while carrying the newborn, always insert the Yellow Box into the Yellow Box Bag and put the Yellow Box Bag around your arm.



**CAUTION:** Carefully pick up the newborn with both hands, making sure the Yellow Box Bag including the box does not hit the newborn.

## 6.6 Baby carrying

1. Take the Yellow Box Bag out of the Newborn Kit for the dedicated newborn.
2. Identify the white semi-transparent strip on the Yellow Box Bag.
3. Slide the Yellow Box in the Yellow Box Bag with the cable connection facing up and the LED strip to the white semi-transparent strip of the Yellow Box Bag.
4. To use both hands optimally for newborn carrying, hang the Yellow Box Bag around the arm with which you will support the newborn while walking around.
5. Carefully pick up the newborn and make sure the Yellow Box Bag with the Yellow Box does not hit the newborn.
6. Check if the cable did not come loose from the Yellow Box.
7. You're now free to walk around with the newborn.



Put the Yellow Box into the Yellow Box Bag.



Holding the newborn and Yellow Box.



Holding the newborn, Yellow Box, and climbing stairs.

## 6.7 Soothing

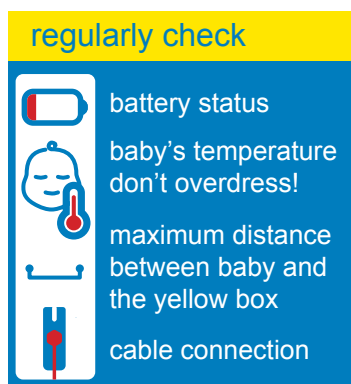
Read the carrying instructions to make sure the Yellow Box is held correctly while carrying the newborn. Make sure the cable does not tangle around any of the limbs. Soothing, like shushing or patting the newborn's back, may be done as would in a normal situation.

## 6.8 Feeding

As with soothing, read the carrying instructions to make sure the Yellow Box is held correctly while carrying the newborn. Make sure the cable is not tangled around any of the limbs. When sitting down, make sure to keep checking the cable and whether it's attached to the Yellow Box. Other than this, feeding can be done as normal.

## 6.9 Regularly checks

During the treatment, regulatory check the battery status, the baby's temperature, the maximum distance between the baby and the yellow box and if the cable is still connected to the Yellow Box.



## 7. Jauni Wrap-up

### 7.1 Ending the Therapy

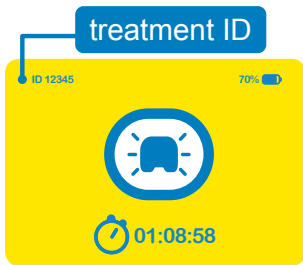


**CAUTION:** Ending the phototherapy session requires medical assessment and thus can only be decided by the medical specialist responsible for the newborn.



**CAUTION:** Do not re-use or interchange the Jauni romper between newborns or from an open newborn Kit to avoid cross-contamination

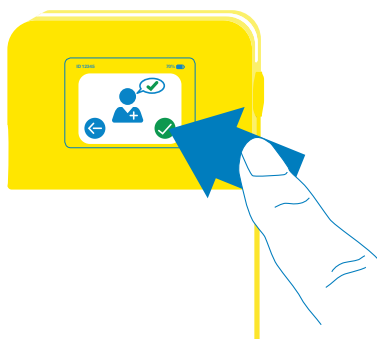
Once the healthcare professional has decided to end the therapy, the light system shall be turned off and the newborn redressed with non-therapy garment:



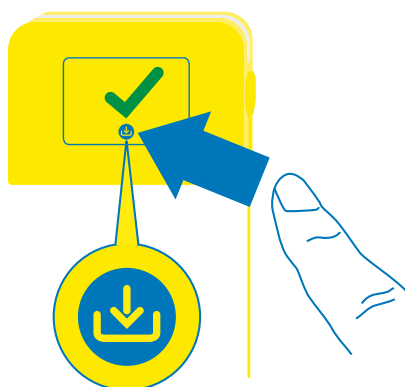
1. Write down the ID of the therapy session to document in the EPR (electronic patient record).



2. Press and hold the Pad icon on the screen of the Yellow Box for 7 (seven) seconds.



3. Press the confirm symbol on the pop-up message that the healthcare professional has been consulted for ending the therapy.



- The Dual Light Pad and the light strip on the Yellow Box turn off and on the screen appears the download icon.
- For downloading the data log see chapter 7.3.



4. Take off the therapy-specific garment and dress the newborn in personal garments

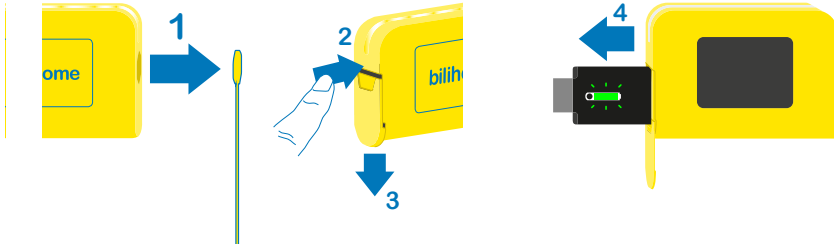


**CAUTION:** Dispose the garments with the parents or send the garment(s) to Bilihome B.V..

## 7.2 Remove the cable and battery



**CAUTION:** Following the ending of the therapy (section 7.1) removing the battery stops the treatment for this specific newborn and to continuous therapy, a new treatment ID will be generated.



1. Remove the cable connecting the Yellow Box to the Dual Light Pad.
2. Open the battery lid by pressing down on the notch.
3. Slide down the lid to reveal the battery chamber.
4. Slide out the battery by pulling the black label on the battery.

## 7.3 Download of device data log (optional)



**CAUTION:** Downloading device data is only for professional use to avoid misinterpretation.



**CAUTION:** keep a minimal distance of 20 cm from the patient when the wifi is used.

- To respect the General Data Protection Regulation (GDPR), the data transfer from the Yellow Box to the wifi is encrypted.
- A data download is optional and can only be done after finalizing the newborn's treatment (section 7.1).
- The data log does not collect or store personal data. Therefore, if downloaded, the healthcare professional needs to manually write the treatment ID of the device see chapter 7.1.

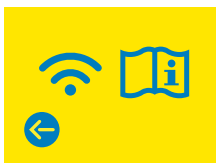
The touch screen allows the professional to download the device data of the last finalized phototherapy session. The therapy session can be identified with the ID number (see also chapter 7.1). Each ID should represent a full treatment from initiation to the finalization of the therapy.

Downloading data is optional via the Yellow Box, which enables a WIFI access point. The following events are logged:

- irradiation level
- events during phototherapy (low battery, failures, on/off, paused, etc.)
- treatment time
- operational time (for treatment adherence)



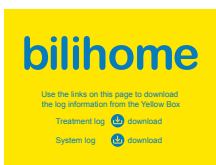
1. Confirm the download intention by pressing the green arrow.



2. Look for the Wi-Fi access point “JauniXXXX” (in which XXXX represents the first digits of the treatment-id as shown on the display) on the computer or smart-phone and connect by using the following password: “BilihomeYYYY” (in which YYYY represents the lasts for digits of the treatment-id as shown on the display). For example: treatment-id 123456789 results in access point name “Jauni1234” and password “Bilihome6789”.



3. Once connected, the healthcare professional can access the Yellow Box by means of the browser on <http://192.168.4.1>



4. Download the device data log via the link “Treatment log: Download” on the page. The link “System log: Download” is for service purposes.

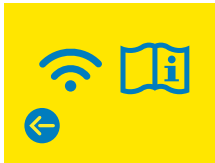
```

@treatment_log (00) - Notepad
file edit format view help
2000-01-01 07:44:24 Treatment "1734895924" created
2000-01-01 07:44:30 Battery level: 40%
2000-01-01 07:44:30 Pad ID: 4108a30505172033342
2000-01-01 07:44:30 Pad Pw: 1.R.R.899
2000-01-01 07:44:30 Pad ID: 1008a30505172033342
2000-01-01 07:44:30 Pad Pw: 1.R.R.899
2000-01-01 21:11:17 Battery level: 300%
2000-01-01 21:11:18 Treatment started, cause: pads disconnected
2000-01-02 09:15:12 Battery level: 300%
2000-01-02 09:15:12 Treatment started
2000-01-02 09:15:14 Pad ID: 4108a30505172033342
2000-01-02 09:15:14 Pad Pw: 1.R.R.899
2000-01-02 09:15:14 Pad ID: 1008a30505172033342
2000-01-02 09:15:14 Pad Pw: 1.R.R.899
2000-01-02 09:15:14 Treatment finished, cause: stopped by user
2000-01-02 09:15:17 Total duration: 00:00:18

```

5. The Yellow Box presents the user with a webpage from which the treatment log of the last treatment ID (e.g. '1734895924') can be downloaded.

- The treatment log of one ID consists of all events, which happened during the application of phototherapy.
- The time stamp uses the relative time, starting January 1st 2000, 00:00h.
- Treatment\_log shows the number of treatments performed with this specific device.



6. To leave the “download log” press the “back button”.





## 8. Reprocessing



The Jauni System Kit shall be reprocessed for the initial use and reused with the next newborn according to the reprocessing instruction in this document. The reprocessing includes wipe-cleaning and -disinfection.



**CAUTION:** Follow the Instruction for Use. Insufficient cleaning or non-compliance with the cleaning process causes a risk of contamination or damage to the device.



**CAUTION:** Do not reprocess the Jauni System Kit during phototherapy.



**CAUTION:** Do not re-use the romper for another patient to avoid the risk of cross-contamination



**CAUTION:** The reprocessing shall only be done by a trained healthcare professional.



**CAUTION:** Do not use flammable disinfectant to clean the device.



**CAUTION:** Do only use the recommended cleaning agent in chapter 8.



**CAUTION:** Do not spray, rinse, or immerse the Jauni System Kit in water or a cleaning agent. Risk due to penetrating liquid. Penetration liquid may damage or malfunction the device.



**CAUTION:** Do not machine clean with thermal disinfection, steam and gas sterilization and/or other special reprocessing measures.



**CAUTION:** Do not use harsh cleaning agents or methods that can damage the device: e.g., harsh cleaning solutions, scouring pads and abrasives. Only use non-aggressive cleaning agents.

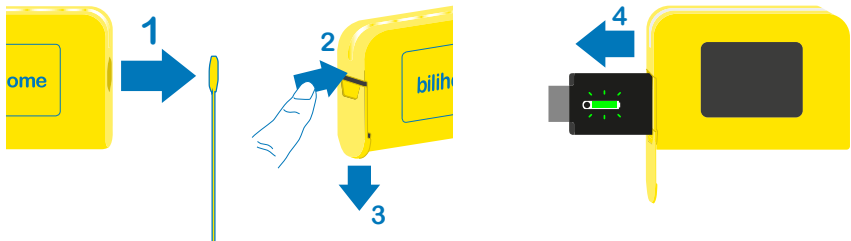


**CAUTION:** Do not use the Jauni System Kit in case the visual check shows surfaces damages e.g. visible cracks on the Yellow Box, the Dual Light Pad, or the cable.

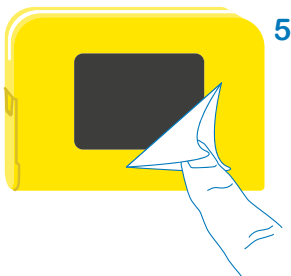
## 8.1 Yellow Box



**CAUTION:** Risk of damage and malfunction of the device, when cleaning the inner pins on the magnet connector with a cleaning agent based on  $H_2O$ .



1. Remove the cable connecting the Yellow Box to the Dual Light Pad.
2. Open the battery lid by pressing down on the notch.
3. Slide down the lid to reveal the battery chamber.
4. Slide out the battery by pulling the black flap on the battery.



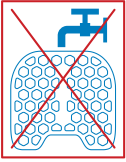
The Yellow Box is now ready to be cleaned:

5. Use recommended disinfectant wipes (chapter 8.4) and wipe all surfaces, including the touch screen and the battery lid.

## 8.2 Dual Light Pad



**CAUTION:** Do not reprocess the light elements during a treatment to avoid skin irritation.



**CAUTION:** To avoid stains and cross contamination, clean and wipe disinfect the Dual Light Pad according to the instruction for use of the supplier by the cleaning agent.

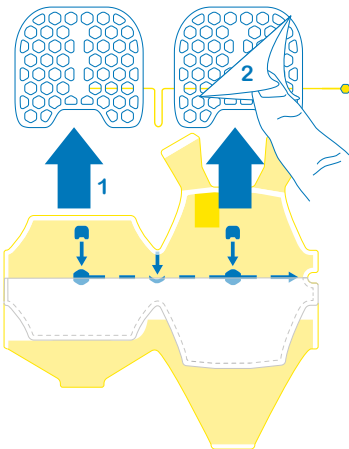


**CAUTION:** Do not immerse the Dual Light Pad in liquid and do not over-bend the pad and cable, to avoid any performance and safety hazards.

**CAUTION:** Risk of damage to the device, do not bend the Dual Light Pad to avoid cracks around the connection area of the Dual Light Pad and the connector.



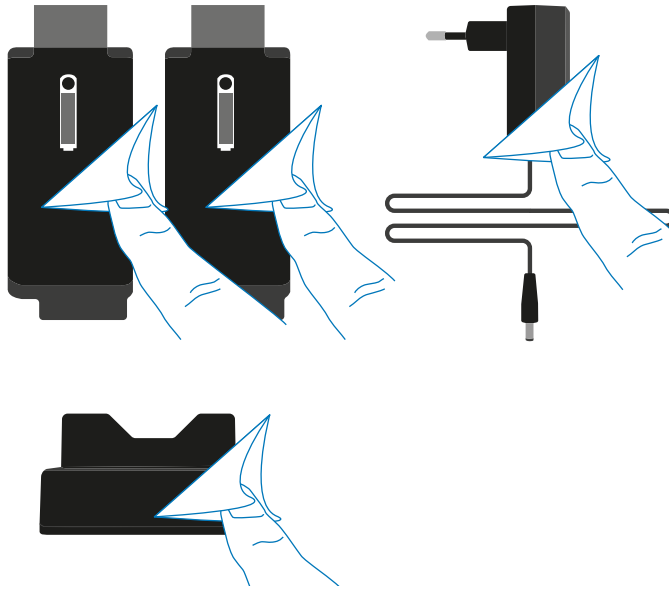
**CAUTION:** Risk of damage and malfunction of the device, when cleaning the inner pins on the magnet connector of the cable with a cleaning agent based on  $H_2O$ .



1. Remove the Dual Light Pad from the romper pockets and place them on a flat surface.
2. Use a recommended disinfectant wipe for removing the debris on the Dual Light Pad. For disinfecting take a single disinfectant wipe and wet the surface thoroughly, ensuring contact with the entire surface:

- Both sides of both pads
- Inside hexagonal cavities
- Along the cable
- Let it dry and do not rinse it afterwards
- Check for visible wet spots

### 8.3 Battery, charging dock, and adapter



Clean the batteries, the charging dock, and the adapter with wet wipes.

### 8.4 Cleaning agent recommendation

The reprocessing starts only after the wearable phototherapy has ended and has been removed from the newborn.

Cleaning and disinfection of the Jauni System Kit shall be done according to the reprocessing procedure in chapter 8.

The following reprocessing procedures suggest good material compatibility and effectiveness when following the instruction of the manufacturer of the cleaning agent:

#### **Cleaning procedure:**

surface wipe disinfection

#### **Cleaning agent:**

Incidin™ OxyWipe (sporicidal ready-to-use surface cleaning and disinfection. acc. Directive 93 / 42 / EEC: for medical devices (classification IIb)

#### **Concentration per 100g:**

1.0g hydrogen peroxide

**Manufacturer:**

Ecolab Europe (head quarter)  
Richtistrasse 7, 8304 Wallisellen  
Switzerland tel: +41(0)44 877 2001

**Cleaning procedure:**

Cleaner and disinfectant of medical device surfaces / Professional use / products are ready-to-use with no dilution.

**Cleaning agent:**

CaviWipes™ / METREX

**Supplier:**

Kerr Italia S.r.l.  
Via Passanti 174, Scafati (SA) 84018  
Italy tel: +39 081 850 3511

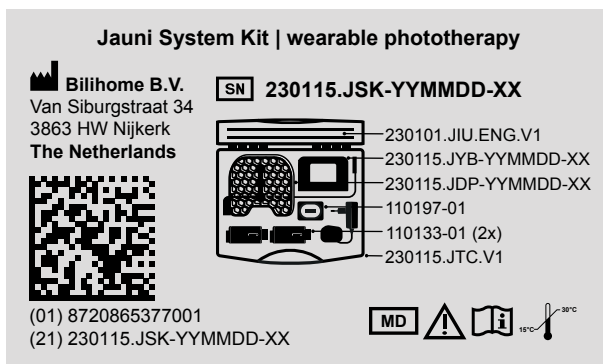
## 8.5 Storage after reprocessing



**CAUTION:** Risk of under-performance of the device due to depleted batteries during storage.

1. Store the other battery separated from the Yellow Box.
2. To have a functional battery for the next patient, charge both batteries before storing in the Jauni Transport Case.
3. Check the product for visible damage and replace it if necessary.
4. Place all components of the Jauni System Kit in its Jauni Transport Case for storage.

**NOTE:** Place only all items, which are listed on the label of the Jauni Transport Case, into that dedicated case.





## 9. Service

### 9.1 Inspection: Light performance test

The specified irradiance level of the Jauni System kit should only be checked with the Gossen spectrometer MAVOSPEC Base or a manufacturer validated and recommended radiometer in combination with Jauni Dome for the specified output range. The measurement is a one step measurement and the expected range is specific with each dome and comes with the necessary instruction.

One Pad at a time should be placed on the plateau. Put the dome on the plateau, make sure no cable or part of the pad gets trapped between the edges of the plateau and the dome. Place the meter on top of the dome in the designated shape. The irradiance should be measured with the radiometer as stated in the Instruction for Use of the spectrometer or radiometer.

Contact Bilihome B.V. in case the Dual Light Pad is outside the range.

### 9.2 Recycling

The Jauni Newborn Kit shall be recycled as general garment waste or as refereed to on the packaging, if not reused by the specific newborn patient, who has ended the phototherapy. The romper can also be sent back to Bilihome for recycling.

The Jauni System Kit should be sent back to Bilihome for disposal. The Waste Electrical and Electronic Equipment Directive (WEEE Directive) is a European Community Directive, numbered 2012/19/EU, concerned with waste electrical and electronic equipment (WEEE). Together with the RoHS Directive 2011/65/EU, it became European Law in February 2003. Therefore, the Jauni System kit should be sent back to Bilihome for recycling or recycled according the WEEE Directive locally.

Contact Bilihome B.V.



## 9.3 Inspection: Jauni System Kit

Visually inspect all parts of the Jauni System Kit before and after every use. In case of damage do not use the Jauni System Kit and contact the Bilihome representation for maintenance and repair options.

## 9.4 Maintenance and repair Jauni System Kit

The device is maintenance free for 3 years. Bilihome offers repair and replacement options.

In case, the self-test was not performed correctly, or the Instruction for Use directed you to this service chapter, do not use the Jauni System Kit and contact the Bilihome representation for repair or replacement options.

For fast identification of the troubled Jauni System Kit, provide always:

1. SN no. of the Jauni Transport Case and
2. SN no. of the defective component

The SN numbers are on the label of the component:

- A)** backside of the Yellow Box
- B)** on the Dual Light Pad
- C)** on the battery, charger and adapter

## 9.5 Accessories and spare parts

Request a quote

Jauni Newborn Kit Size 48 \_\_\_\_\_ pcs

Jauni Newborn Kit Size 52 \_\_\_\_\_ pcs

Jauni Newborn Kit Size 56 \_\_\_\_\_ pcs

Jauni Dome - on request \_\_\_\_\_ pcs

Battery (spare part) \_\_\_\_\_ pcs

EU Charger & Adapter \_\_\_\_\_ pcs

## 9.6 Warranty

This product is sold by Bilihome B.V. with a repair warranty that covers labor and parts through the Bilihome service center.

The Dual Light Pad and the Yellow Box have a 12-month warranty, if not overruled by country-specific laws for warranty in the Netherlands.

The Bilihome offers product warranty only through the Bilihome service center (field service is not available).

## 9.7 Contact information

Bilihome B.V.  
Van Siburgstraat 34  
3863 HW Nijkerk  
The Netherlands

[service@bilihome.org](mailto:service@bilihome.org)

[www.bilihome.org](http://www.bilihome.org)

## 10. Technical information

If not specified otherwise or shown as a range,  $\pm 10\%$  tolerance on values are applied.

### 10.1 Device classification

Type of protection against electric shock MOOP / MOPP	Class IIa
Software classification	Class A
Dual Light Pad (excluding the Yellow Box Connector)	IP23
Yellow Box	IP21
Mode of operation	Continuous
Protection against flammable anesthetics	Not applicable
Classification in accordance with MDR 2017/745 - EU Medical Device Regulation Jauni System Kit Jauni Newborn Kit (accessory)	IIa I
UMDNS code/GMDN code ("Blanket/pad infant phototherapy unit")	13-037 / 33791
EMDN code (Paediatric Phototherapy Equipment)	Z12080401
EMDN code (Neonatal and Paediatric Phototherapy Equipment - Accessories not included in other classes)	V028099
Regulatory compliance following MDR 2017/745 - EU Medical Device Regulation: ISO 13485:2016; ISO 14971:2019; IEC 60601-2-50:2020; IEC 60601-1:2005 + A1:2012 + A2:2020; IEC 60601-1-2:2014 + A12020; IEC 60601-1-8:2006 + A1:2012 + A2:2020; IEC 60601-1-11: 2015/AMD1:2020;	
Regulatory compliance following MDR 2017/745 - EU Medical Device Regulation	IEC 62304:2006 + A1:2015; IEC 62366-1: 2015 + A1:2020; ISO 10993-1:2018; ISO 15223-1:2016; ISO 20417:2021

## 10.2 Physical and performance attributes

Jauni System Kit in Transport Case Jauni Newborn Kit: 3 rompers, 1 Yellow Box Bag	1500g 340x286x74mm <300g
Expected service life of Jauni System Kit	3 years
Service lifetime (extended maintenance)	8 years or as long as spare parts are available
Noise level	<10 dB

### 10.2.1 Dual Light Pad and connected cable

Length (one Pad)	140mm
Width (one Pad)	150mm
Height min. / max. (one Pad)	5mm - 8mm
Weight (Dual Light Pad and connected cable)	146g
Total cable length	550mm
Expected minimum period of use of LED lights	30.000 hours
Power consumption	2x 270 mW (23mA / 11.65V)
Placement and orientation towards the patient	Only in combination with the Jauni Newborn Kit as accessory
Eye protection	Not applicable: Jauni Romper avoids exposure to the eyes

### 10.2.2 Yellow Box

Length	78mm
Width; approx.	101mm
Height; approx.	28mm
Weight; without / with battery approx.	130g / 250g

Connection points	Magnet connector for Dual Light Pad
Touch screen	2,7 inch color touch screen
Touch screen information	Treatment ID / battery status / time elapse of treatment
Touch screen operator function (after treatment initiation)	Confirm pause / pause / un-pause
Power supply	Battery powered
Power consumption	23mA / 11.65V / 270mW
Operational status	Visual from at least 4m distance from 3 sides
Wi-Fi Frequency	2.4 GHz
Wi-Fi Operating channels	12, 13 & 14
Wi-Fi Mode	802.11 B/g/n
Wi-Fi Output power	17dBm mode B 13dBm mode g 12dBm mode n

### 10.2.3 Battery

Length	85mm
Width	42mm
Height	22mm
Weight	120g
Life expectancy	Up to 80% of initial capacity after 800 cycles
Power type	Li-Ion, rechargeable
Nominal voltage	7.2 V
Nominal capacity	2900 mAh
Replaceable	Interchangeable

Charging time	approx 3 hours
Operation time	approx 4 - 6 hours

#### 10.2.4 Battery charging dock

Length	56mm
Width	40mm
Height	31mm
Weight	34g

#### 10.2.5 Power adapter

<b>For electrical safety of the Jauni system, use only Bilihome supplied power adapters.</b>	
Length	59mm
Width	41mm
Height	64mm
Weight	82g
Power input	100-240V~, 50/60Hz 0.3A

#### 10.2.6 Romper size 48

Length	253mm
Width	144mm
Height	5mm
Weight	56g
Material	50% cotton   50% lycocell
Washable	Max. 10 times at 40°C

#### 10.2.7 Romper size 52

Length	309mm
Width	176mm
Height	5mm
Weight	70g

Material	50% cotton   50% lycocell
Washable	Max. 10 times at 40°C

### 10.2.8 Romper size 56

Length	387mm
Width	220mm
Height	5mm
Weight	83g
Material	50% cotton   50% lycocell
Washable	Max. 10 times at 40°C

### 10.2.9 Yellow Box Bag

Length	173mm
Width	72mm
Height	31mm
Weight	19g
Material	50% cotton   50% TPU
Washable	Max. 10 times at 40°C

## 10.3 Environmental requirements

Operating temperature	15°C to 30°C
Operating relative humidity (R.H.) non-condensing, not requiring a water vapour partial pressure greater than 50 hPa	10% to 90%
Operating atmospheric pressure	700 hPa to 1060 hPa
Maximum altitude at which the device is usable	2000m
Storage and transport temperature	- 40°C to +70°C
Storage and transport Relative humidity (R.H.)	10% to 100%
Storage and transport atmospheric pressure	500 hPa to 1060 hPa

## 10.4 Pre-aging and Stabilization time

The Jauni Wearable Phototherapy does not require a pre-aging time or a stabilization period. It is ready for use immediately after it is turned on.

## 10.5 Declaration of Compliance

### 10.5 Declaration of Compliance

The Jauni device complies with the applicable requirements of:

- Regulation (EU) 2017/45 on medical devices.
- IEC 60601-1:2005 + A1:2012 + A2:2020.
- IEC 60601-1-2:2014 + A1:2020, class B proximity magnetic field not considered.
- IEC 60601-2-50:2020
- EN 62471:2008.
- IEC 60601-1-11: 2015/ AMD1:2020.
- IEC 62304:2006 + A1:2015.
- IEC 62366-1: 2015 + A1:2020.
- EN 62311:2020
- European Radio Equipment Directive (RED) 2014/53/EU
- Radio Equipment Regulations 2017 of the United Kingdom.
- EN 300 328 v2.2.2.
- EN 301- 489-1 V2.2.3, class B proximity magnetic field not considered.
- EN 301 489-17 V3.2.4, class B proximity magnetic field not considered.

For specific purposes, detailed information on the Declaration of Conformity can be requested at Bilihome. To contact Bilihome see section 9.3 Contact information.



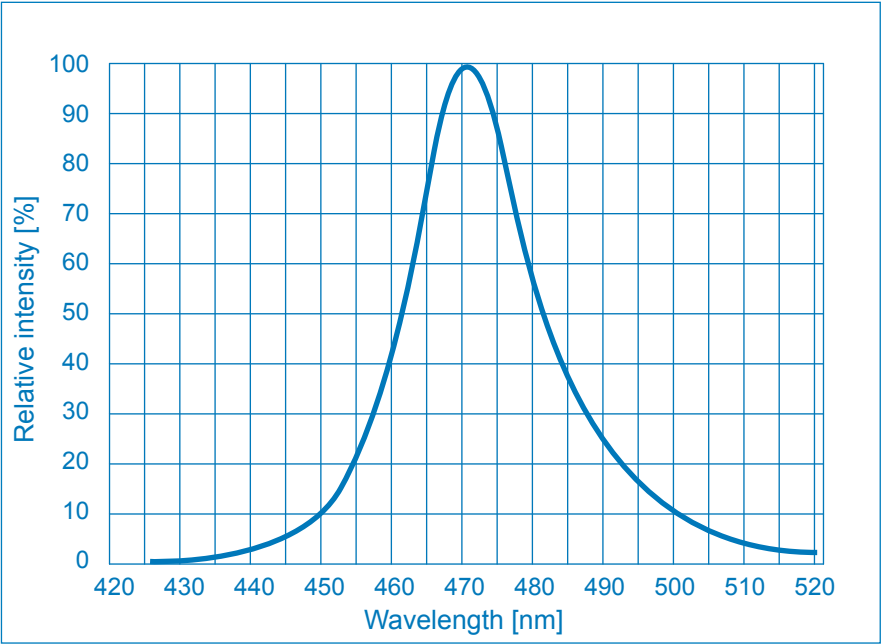
# 11. Light performance characteristics

## 11.1 Irradiance

Peak wavelength	470nm
Spectral bandwidth	21nm (460-481nm)
Spectral irradiance $E_{\lambda \text{ mean}}$ (460-481nm) (50% bandwidth) $E_{\lambda \text{ mean}}$ (460-490nm)	30 $\mu\text{W}/\text{cm}^2/\text{nm}$ 25 $\mu\text{W}/\text{cm}^2/\text{nm}$
Distance Dual Light Pad and skin surface	constantly <5mm

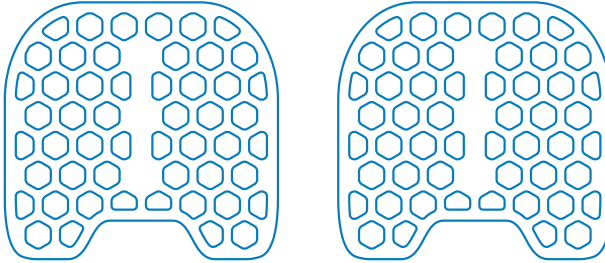
The optical efficiency of the Jauni Romper fabric is at least 80%.

## 11.2 Spectral irradiance distribution graph



### 11.3 Distribution of irradiance

This measurement refers to one pad of the of the Dual Light Pad.

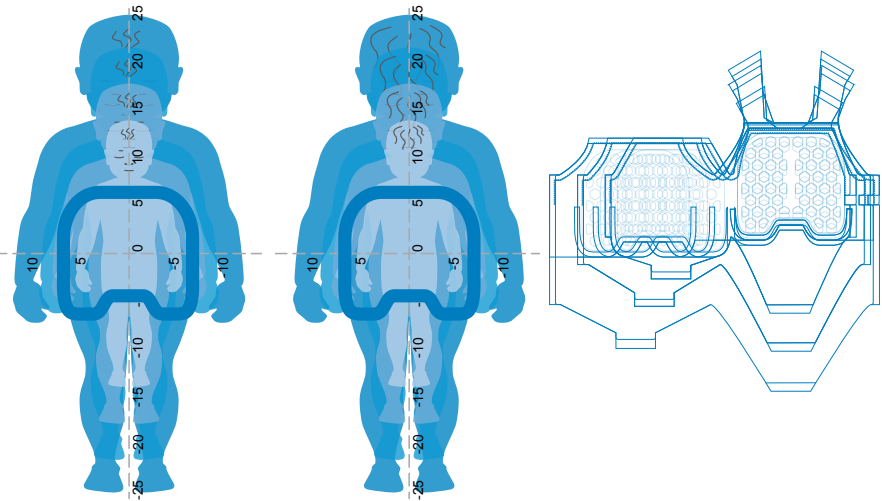


The total irradiance for bilirubin E<sub>bi</sub> (400-550nm) is on average 1,0 mW/cm<sup>2</sup> with a ratio of  $E_{bi\ min}/E_{bi\ max}$  of 70%. The total irradiance does not influence the distance nor the effective irradiated area of the treated newborn.

# 11.4 Effective irradiated area

The Dual Light Pad is placed on the chest and the back of the newborn patient. And follow the contour of the newborns body line inside the fitting of the romper. The skin of the newborn patient is therefore uniformly illuminated by each pad. The distance between the Dual Light Pad and the effective irradiated area is therefore 0 cm and is not adjustable.

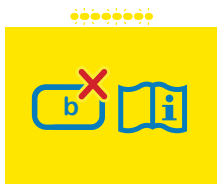
Effective irradiated area	1 pads x 175cm <sup>2</sup> = 350cm <sup>2</sup>
Body surface area (irradiance footprint)	350 cm <sup>2</sup>



## 12. Troubleshoot

### 12.1 Yellow Box screens

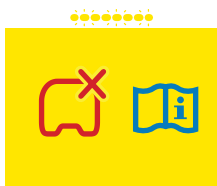
#### 12.1.1 Error screens during Self-test



##### YELLOW BOX ERROR SCREEN

During self-test an error of the Yellow Box was found.

1. Remove the battery and make a visual check of the Yellow Box and battery for damages and
2. Insert the battery again to activate a restart and continue the treatment preparation.
3. Write down the new ID from the screen.
4. In case the screen will still appear, stop using the Jauni System Kit and refer to the service chapter.



##### DUAL LIGHT PAD ERROR SCREEN

During self-test an error of the Dual Light Pad was found.

1. Check that the magnetic connector of the Dual Light Pad is connected to the Yellow Box.
2. Check that the cable of the Dual Light Pad is not broken or damaged.
3. After checking point 1. and 2. remove and insert the battery again to activate a restart and continue the treatment preparation.
4. Write down the new ID from the screen.
5. In case the screen will still appear, stop using the device and refer to the service chapter.



## BATTERY ERROR SCREEN

During self-test an error of the battery was found.

1. Remove and check that the battery is charged and not damaged.
2. Check, if the first and replacement battery are charged, sufficiently.
3. After checking point 1. and 2. Insert the battery again to activate a restart and continue the treatment preparation.
4. If the same error occurs with the first battery, use the second battery
5. In case the same error occurs again on the screen, stop using the faulty battery check the service chapter.

### 12.1.2 Caution screens preparation and treatment

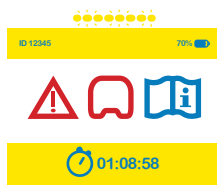


## DIRECT LIGHT CAUTION SCREEN

**CAUTION:** Never look directly into the light! Never let the light shine into the newborn's eyes.

this screen occurs:

- a) at the end of the self-test
- b) in case of re-boot self-test

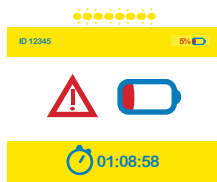


## DUAL LIGHT PAD CAUTION SCREEN

**CAUTION:** To avoid inadequate treatment, stop using the Jauni System Kit, when the Dual Light Pad is not functioning.

The Dual Light Pad is not functioning.

1. Check that the magnetic connector of the Dual Light Pad is connected to the Yellow Box and go to 3.
2. Check that the cable of the Dual Light Pad is not broken or damaged and go to 3.
3. After checking point 1. and 2. remove and insert the battery again to activate a restart and continue the treatment preparation.
4. Write down the new ID from the screen.
5. In case the screen will still appear, stop using the device and refer to the service chapter.



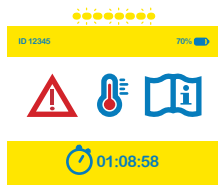
## BATTERY CAUTION SCREEN

**CAUTION:** To avoid inadequate treatment, exchange and re-charge intermittently the two available batteries of the Jauni system.

**CAUTION:** To avoid inadequate treatment, check the charging battery from time to time, to know the status

The screen indicates a low battery charge:

1. Replace the empty battery with the charged battery
2. Charge the empty battery in the doc charger, connected to the main supply via the Jauni adapter. (see also Quick Guide: Prep)



## TEMPERATURE CAUTION SCREEN

**CAUTION:** Avoid to look direct light on the Dual Light Pad during cooling down and dressing

**CAUTION:** Check frequently the body temperature of the newborn for fever or overheating and dress the newborn accordingly

**CAUTION:** Avoid inadequate treatment time due long pausing

For safety reasons, the touchable temperature of the Dual Light Pads is limited. When this screen occurs, the Dual Light Pad temperature has reached the upper limit:

- The Dual Light Pad switches off to pause the treatment
- The light strip on the Yellow Box blinks white.
- The timer stops to count the treatment time.

To cool down the Dual Light Pad:

1. remove it from the newborn
2. Wait a short while, until the light switches automatically on again
3. Pause the Jauni device and dress the newborn again
4. Start the treatment again

## 12.2 Jauni System Kit components

This trouble shoot chapter refers to the components of the Jauni System Kit: Yellow Box, Dual Light Pad, and Battery.

### **The battery does not charge.**

1. Check, if the battery is correctly placed and pushed into the doc charger
2. Check, if the doc charger is correctly connected to the adapter
3. Check, if the power adapter is correctly connected to a power outlet.
4. In case the battery is still not charging, after checking 1., 2. and 3., check the Service chapter for spare part options.

### **The Yellow Box does not turn on.**

1. Check, that the battery is charged and slide it in, until you feel a click.
2. When the Yellow Box still does not switch on, use the exchange battery and do the same as in the 1.
3. When after 20 seconds the Yellow Box still does not switch on, check the service chapter for repair options.

### **The Dual Light Pad does not turn on or off.**

1. Check, that the magnet connector is correctly placed on the Yellow Box connection point
2. Check the message on the screen of the yellow box and follow the instruction (see also chapter 12.1 Yellow Box screens)
3. In case, the Dual Light Pad still does not work, check the service chapter for repair options.

### **The battery cavity of the Yellow Box can not be closed with the Yellow Lid.**

1. Pull out the battery and slide it in again.
2. Check, that the flexible flap is facing upwards, (to pull the battery out later)
3. Push down the battery, until you feel a click.

### **The Yellow Cable between the pads of the Dual Light Pad is broken or damaged.**

Do not use the Jauni system for treatment and check the service chapter for repair options.



## 13. Frequently asked questions

### 13.1 General

#### **Is it dangerous to pause the treatment?**

Discuss and follow your newborn's care and treatment plan with your responsible health care professional.

### 13.2 Dual light pad

#### **Can I turn off the Dual Light Pad?**

There is a pause button, to interrupt the light therapy for a short while. Consult your responsible healthcare professional first on the treatment schedule for your child. Only trained medical professionals are allowed to turn-off the unit, to ensure, the treatment is ongoing as intended.

#### **Does the Dual Light Pad get too warm?**

The Jauni device is designed according to the Phototherapy safety and performance standards, which limits a maximum touchable temperature to 40 degree Celsius. However, this is only valid, if the use is in the specification of the operation condition specified. It is advised to check the infant's temperature on fever and over-or underdressing.

### 13.3 Romper

#### **Can I carry the baby with the romper on?**

Consult your responsible healthcare professional for advice. The Jauni device is designed for natural newborn care. The special romper and miniaturized Yellow Box inside the Yellow Box bag allows a safe carrying of the newborn with both your hands free for your newborn.

### 13.4 Yellow Box

#### **Where is the on / off switch?**

There is no ON/OFF switch. The Yellow Box starts immediately, when a full battery is put in.

**Is the light strip on the side of the Yellow Box dangerous?**

The light on the Yellow Box is a different light as in the Dual Light Pad for the light therapy. This is visible light, however, as with every light source, it is not recommended to stare for long in a bright light source.

**13.5 Battery****How long does the battery last before I need to change it?**

When the Jauni System Kit is used without interruption, the battery should last between 4 to 6 hours. This may vary, for example depending on the environmental factors.

**How long does charging a battery takes?**

The charging time is around 3 hours. This may vary, for example depending on the environmental factors.

**Is there a limit, how often I can charge the batteries?**

During the treatment, there is no limit, how often you can charge the battery. The battery should be re-charged, when the battery indicator switches on the of the Yellow Box indicates a low battery.

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Jauni System Kit and Jauni Newborn Kit  
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