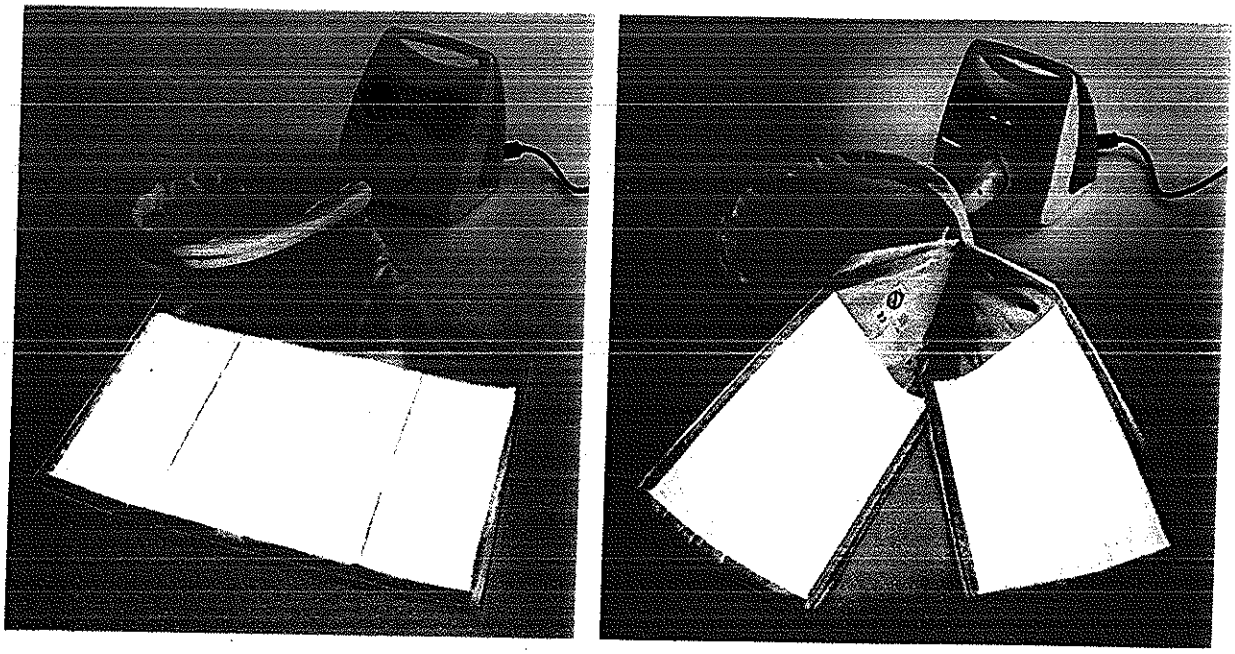
NeoMedLight



BiliCocoon™ System

Phototherapy System
Système de Photothérapie

BiliCocoon™ Nest System
BiliCocoon™ Bag System

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User Responsibility

These Instructions for Use describe the proper setup, use, and maintenance of the BiliCocoon™ phototherapy system[a] - the Device or the System.

The Device is to be used exclusively by a properly trained user and should not be used if it is damaged, contaminated, or if parts are missing. Instead, please contact the supplier immediately. For questions about Device care and maintenance please contact the supplier or authorized staff member of your facility.

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

Any serious incident which occurs in relation to the device should be reported to the manufacturer and the local competent authority of the state in which the user and/or patient is established. You can contact NeoMedLight at the following address: *quality@neomedlight.com*.

According to the US federal law the Device sale is restricted to licensed medical practitioners or clinicians or under their approval.

CE 0459

NeoMedLight declares that the Device complies with the European Directive 93/42/EEC.
The CE mark was obtained and the Device was launched in 2016.

This product is to be handled with care and to be processed separately from consumer waste. Waste of Electrical and Electronic Equipment (WEEE) can pollute the environment and the product is to be disposed of according to its specific Directive 2012/19/EU and following the appropriate paths.

Contact the local authorities or the supplier to determine the proper method of disposal of potentially biohazardous parts and accessories.

[a] The term "System" is not used in this document with the meaning given by the standard EN 60601-1, definition 3.64. It stands for the group of interconnected parts which compose the medical device.

1 PRODUCT DESCRIPTION AND APPLICATION

1.A Description

The BiliCocoon™ System is a phototherapy system designed to treat unconjugated hyperbilirubinemia in the infant. It is a phototherapy device as defined by EN 60601-2-50, which emits light in the absorption spectrum of the bilirubin, from 430 to 490 nm[b], thus reducing the bilirubin concentration in the body of infants.

1.B Intended use of the Device

The BiliCocoonTM Phototherapy System is intended for the treatment of unconjugated hyperbilirubinemia [c]; in the population of neonates and infants under 3 months old and weighing less than 10kg. It can be used in the clinical setting or in the home.

1.C Additional information

- Only for the treatment of unconjugated hyperbilirubinemia, which is responsible for the majority of cases of neonatal jaundice.
- Only with medical prescription
- Only for the duration indicated in the treatment protocol
- Target patient population: neonates and infants [d].
- Over the patient's entire body except for genitals and eyes – eye protection must be worn.
- To be used with a single patient
- To be used in hospital or at home: adapted to different environments for use (in an incubator, on a table, in a cradle, in the arms of a parent or caregiver).
- Not to be used on damaged skin

2 SAFETY INFORMATION

Types of Safety Precautions

Warning

It informs of a danger or a hazard for the infant or the operator.

Important

It mentions the actions required to obtain the expected clinical results.

[b] 96% of light emission is in this wavelength range.

[c] The Device is not designed to treat cholestatic jaundice.

[d] Under 3 months old and weighing less than 10 kg – definition according to EN 60601-2-50. The term "infant" used in this document is used in compliance with this definition according to EN 60601-2-50.

Caution

It indicates a risk of damage to the Device

Prerequisites

The BiliCocoon™ phototherapy system must only be used by clinicians who are qualified and aware of the treatment- and device-associated risks and benefits; or by laypersons who are properly trained and supervised by these clinicians.

Warning

Home Use: see section 6 of these Instructions for Use.

The BiliCocoon™ phototherapy device is not to be used for other medical indications or on different body parts than those recommended. Improper use may lead to an ineffective treatment (i.e. no benefits) or to potential risks to the patient's health (adverse events).

Duration of Session:

Warning

Use the device only for the time prescribed. A use that does not take into account the treatment plan may lead to an ineffective treatment or to potential risks to the patient's health

Warning

No modification of the BiliCocoon™ Phototherapy System is allowed. Do not use any accessories, detachable parts and materials not described in these instructions for use.

The use of a System which has been modified in terms of performances or by replacing its parts disregarding the manufacturer's indications may lead to risks to the patient (e.g. adverse events), the user, other peoples or properties.

Warning

Intensive phototherapy (>30 $\mu W \cdot cm^{-2} \cdot nm^{-1}$) may not be adapted to all infants (e.g. preterm infants with a weight ≤1000 g)

Warning

Blocking the light source or reducing the exposed body surface should be avoided

Contraindications

The BiliCocoon™ phototherapy device must not be used:

Warning

- On patients with congenital porphyria
- On patients with family history of porphyria
- In conjunction with drugs or agents that are photosensitizers
- On patients requiring a sterile environment or equipment and/or who present with skin lesions.

A use that does not take into account these contraindications may lead to an ineffective treatment (i.e. no benefits) or to potential risks to the patient's health (e.g. adverse events).

Eye Protection

Warning

Prolonged exposure to phototherapy light may cause damage to the eyes. The use of the BiliCocoon™ Phototherapy System without suitable protection of the infant's eyes may lead to risks to the infant's health, including retinal damage. Eye protection should be used for other patients who are close to the phototherapy device.

Patient monitoring during the phototherapy treatment

Warning

- **Bilirubin level**: The infant's bilirubin level should be regularly measured during the phototherapy treatment in accordance with the recommendations of the physician in charge.
- **Temperature**: Phototherapy can affect the patient's body temperature. The infant's temperature must be monitored according to the recommendations of the physician who is responsible for the therapy. Because the phototherapy treatment may increase the body temperature, not controlling the infant's temperature may lead to a risk to the patient.

- **Fluid balance**: Phototherapy can affect the patient's fluid balance. Regularly monitor the patient's fluid balance and take appropriate measures to maintain this balance during phototherapy.

Note: The Bilicocoon bag system does not create sweating, however if sweating occurs it can hardly be evacuated which can cause discomfort to the patient. To maximize the patient's comfort in the Bilicocoon bag system we recommend, in case of sweating, to open the device laterally on one or both sides or to leave the patient's arms outside of the device


Warning

Side Effects for Caregivers and People near the Device

Prolonged exposure to the phototherapy device's blue light may cause discomfort to caregivers such as eye irritation, nausea, headaches or dizziness. Caregivers, staff and others who are in close proximity to the Device could be sensitive to blue light and need to protect their eyes.


Warning

Risk of Glare

Do not look at the light source (Pad Connection Port) when the Device is switched ON and the Pad is not connected.

Hot Surface – Risk of burning

When disconnected, the Pad and Light Box connecting surfaces will be hot. There is indeed a risk of burning (see section 5).


Warning

Cutaneous Reactions

Cutaneous eruptions such as erythema may occur in infants treated with phototherapy.


Warning

Skin Color Changes

Blue light may hinder clinical observation by masking skin color changes, such as cyanosis.


Warning

Rare Allergic Reactions

Despite the biocompatibility evaluation tests conducted in accordance with the state of the art, rare allergic reactions may nevertheless occur.

Variation of the Ambient Conditions


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 their fluid balance.

Moreover, use of this device outside of the given operating conditions may compromise the product functionality.


Warning

Reflective Foils

Never use reflective foils to increase the effectiveness of phototherapy treatment, it may hazardously increase the body temperature.


Warning

Intravenous drugs and fluids

In order to prevent photochemical modifications, do not store drugs and infusion liquids in the radiation area.


Warning

Combustible gases and flammable solutions

Do not use the BiliCocoon™ phototherapy system in oxygen-rich environments or in the presence of combustible gases, such as nitrous oxide, anesthetics or any other combustible or flammable product.

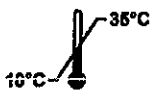

Warning

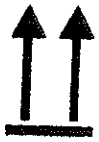
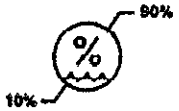
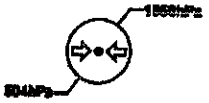
Labels Integrity and Readability

In case labels are degraded, the information addressing the safety of the patient, users, third parties, and properties can be found in this document. Contact the supplier if information concerning the identification of the product or of associated products is not visible anymore.

Make sure that there is no entanglement of the cord or cable at any time.

Warning

Symbol	Description	Symbol	Description
	Manufacturer		CE Marking declaration according to Directive 93/42/EEC
	Consult instructions for use		Caution: law prohibits dispensing without prescription
	Refer to instruction manual/booklet		Date of manufacture
	Protect infants' eyes with opaque eye protection		Catalogue number
	Type BF equipment		Serial number
	The Light Box is a Class II electro-medical device		Pad – Light Box Pairing number
	Waste of electrical and electronic equipment		Direct current
	"ON" (power)		"OFF" (power)
	Operating temperature range		**Hot Surface** – When the Pad is disconnected from the Light Box pay attention to the surfaces of the two elements that are in contact with one another during a therapy session. This symbol is on the product to warn the user about the hot surfaces.
	Do not spray directly over the Connection		Do not bend the fibers at right angles
	LED failure indicator		Device overheating indicator

	Do not store more than four cartons on top of one another		Maintain the carton vertically following the arrows
	Keep dry		Storage humidity range
	QPS certification		Storage astmospheric pressure range
	Fragile, to be handled with care		

Abbreviation	Units and Description	
°C	Degrees Celsius	(Unit of temperature)
kg	Kilograms	(Unit of mass)
$\mu W \cdot cm^{-2} \cdot nm^{-1}$	Microwatt per square centimeter per nanometer	(Unit of spectral irradiance)
λ	Wavelength	(Unit of wavelength)
h	Hour	(Unit of time)
min	Minute	(Unit of time)
nm	Nanometer	(Unit of length)
mm	Millimeter	(Unit of length)
W	Watt	(Unit of power)
Hz	Hertz	(Unit of frequency)
VAC	Alternating current Volt	(Unit of voltage)
VDC	Direct current Volt	(Unit of voltage)
dB(A)	Decibel : Sound level – A weighting	(Unit of acoustic intensity)
hPa	Hectopascal	(Unit of atmospheric pressure)

3 COMPONENTS / SUB-ASSEMBLIES AND USER CONTROLS

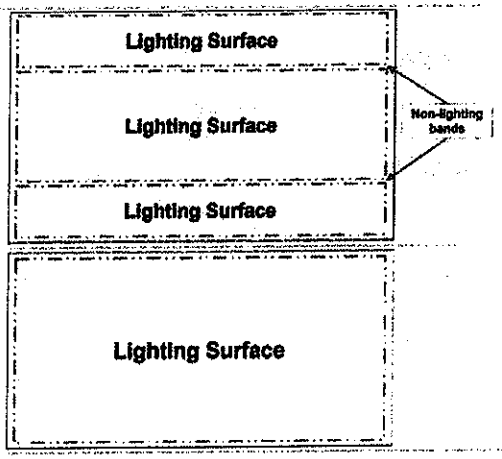
3.A System Description

The BiliCocoon™ phototherapy system is composed of a blue light electronic generator – the Light Box – and of a light-emitting fabric – the Pad – which transmits the blue light to the infant. Light Box and Pad are paired in order to emit light with a peak between 430 and 490 nm and a spectral irradiance of 35 $\mu W \cdot cm^{-2} \cdot nm^{-1}$ (± 15%). The Light Box is connected to the power grid through a specific external power module.

The BiliCocoon™ system is used with the BiliCocoon™ Disposable, a non-woven disposable designed to fit the Pad.

Physical Characteristics

Light Box Dimensions	215 x 198 x 160 mm^3
Light Box Weight	1.4 kg
Nest Pad Dimensions	*Effective light-emitting surface of 40 ± 0.5 cm x 30 cm* Total length 150 ± 4 cm
Bag Pad Dimensions	*2 light-emitting surfaces of 20 ± 0.5 cm x 30 cm* Total length 155 ± 4 cm
Pad Weight	< 1 kg
Optical Fibers Cable	Flexible, opaque Approximate length 100 cm
Protection	Polyurethane enclosure which is translucent on the emitting side and opaque on the non-emitting one
Connection	Plastic
Power Cable	3.5 ± 0.5 m



Technical Features

Mean Spectral Irradiance	**35** µW·cm^{-2}·nm^{-1} ± 15% with disposable[e]. An infant would receive a lower dose if not positioned in contact with the disposable. *The measurement is to be performed with the Ohmeda (GE) BiliBlanket Lightmeter II.*	
Power Supply	Input	Voltage : 100 VAC – 240 VAC Frequency : 50 Hz - 60 Hz AC power plugs compatible with Europe and North America
	Output	Voltage : 12 VDC Current intensity : 7.5 A max Power : 90 W max

[e] This value is measured in direct contact with the disposable. The irradiance value verification should be performed without the disposable as explained in § 4.C

LEDs Characteristics	6 LEDs of 15 W max power and emitting between 400 and 550 nm
Lifetime	The BiliCocoon™ System has an expected lifetime of at least 8000 h, corresponding to approximately 7 years of regular use at ambient temperature.
Sound Level[f]	37 dB(A) at 1 meter

Environmental Conditions

Disregarding the operating and storage conditions may lead to the Device deterioration and failures, therefore creating risks to the patient, the users, third parties or properties.

IP21 protection for the Light Box: protection against the ingress of solid objects larger than 12.5 mm – e.g. a finger won't have access to a hazardous part – and of dripping water – vertically falling drops won't have harmful effects. Although the shell provides protection against liquid ingress, the user must take precautions to avoid the contact of the Device with liquids, which could cause an electrical hazard.

IPX3 protection for the Pad: protection against the ingress of solids of all size and the ingress of direct sprays of water up to 60° from vertical – in these conditions the water ingress won't have harmful effects. Although the enclosure provides protection against liquid and solid ingress, the user must take precautions to prevent the infiltration of fluids, especially in the Connection.

Warning

Do not place the system close to a source of **radiant heat flow** (e.g. radiant warmer). It may impact the proper functioning of the BiliCocoon™ system.

Do not place the system close to a source of moisture like a nebulizer or a steam kettle. The moisture may affect the Light Box proper functioning and safety. **Risk of electric shock.**

Avoid exposure to **environments with excessive dust.** Lint and dust may settle in the Light Box or on the surfaces meant to transfer blue light: the consequence would be an improper functioning of the System and/or the deterioration of its performances.

Operating Conditions

INDOOR use only. The Device is not be used while in motion.

The Pad and the disposable can be placed in the incubator with the infant. The Light Box must be placed outside the incubator.

Temperature range: from 10 to 35°C[g]

Relative humidity range: from 15 to 90%, without condensation

Warning

Atmospheric Pressure range: from 700 to 1060 hPa[h]

Ensure that the air inlets are not covered or obstructed in order to avoid the Light Box overheating.

The power supply to be used is the **MEGMEET MANGO100-12B**. The use of a different power supply may lead to risks to the patient, users, third parties, or properties.

Storage Conditions between uses

INDOOR storage only – do not leave the system exposed to the sun. A prolonged exposure to sun light may lead to the deterioration of the Pad optical fibers and to the system's performances.

Warning

Temperature range: from -25 to 50°C[i]

Relative humidity range: from 10 to 90%, without condensation

Atmospheric Pressure range: from 700 to 1060 hPa

[f] Value of sound pressure.
[g] 50 - 95 °F
[h] Equivalent Altitude : 0 – 3000 m (0 – 9842.52 feet)
[i] -13– 122 °F

Important

The Pad emitting surface should be stored flat, do not ever bend or stretch the emitting surface optical fibers. Do not ever bend the optical fibers at right angles.

The cable must not be coiled more than one and a half turns. A manipulation that does not follow the recommended instructions may damage the optical fibers and affect the Pad lighting performances or lead to a risk to the patient's health.

Transport and Storage Conditions for Packaged Product

Warning

INDOOR storage only.

Temperature range: from -25 to 50°C [j]

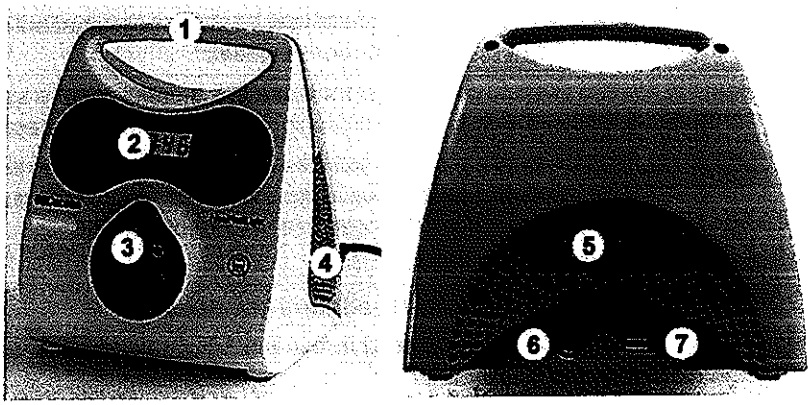
Relative humidity range: from 10 to 90%, without condensation

Atmospheric Pressure range: from 504 to 1060 hPa[k]

3.B Light Box Features

The BiliCocoon™ Light Box is an electronic device incorporating LEDs and emits between 430 and 490 nm. This emission range corresponds to the absorption spectrum of bilirubin, with this light leading to bilirubine conversion and elimination without the liver intervention.

The Light Box includes an ergonomic handle which allows an intuitive grasp.

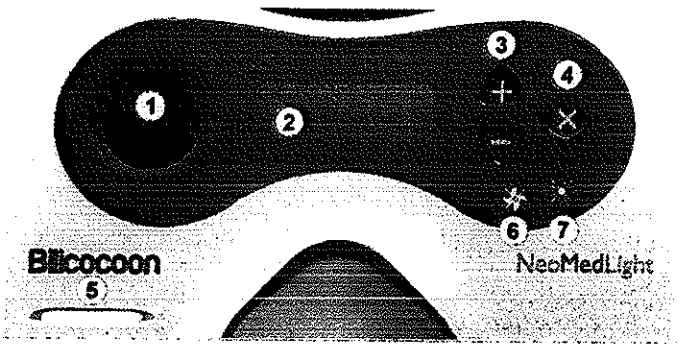


1	Ergonomic **handle**	
2	**Front panel** with display and user controls	
3	**Connection** Port with the lenses which transfer the blue light to the Pad optical fibers	
4	Side **ventilation (air inlets): DO NOT OBSTRUCT**	
5	Back **ventilation (air inlets)** with dust filter (inside): **DO NOT OBSTRUCT**	
6	**Power** socket (to be connected to the external power module)	
7	**USB Port**	**NOT OPERATIONAL, DO NOT USE. The symbol "CAUTION" is close to the USB port to recall not to use this port.**

Controls

Controls can be used while the user is wearing medical gloves.

[j] -13 – 122 °F
[k] Equivalent Altitude : 0 – 5500 m (0 - 18044,62 feet)

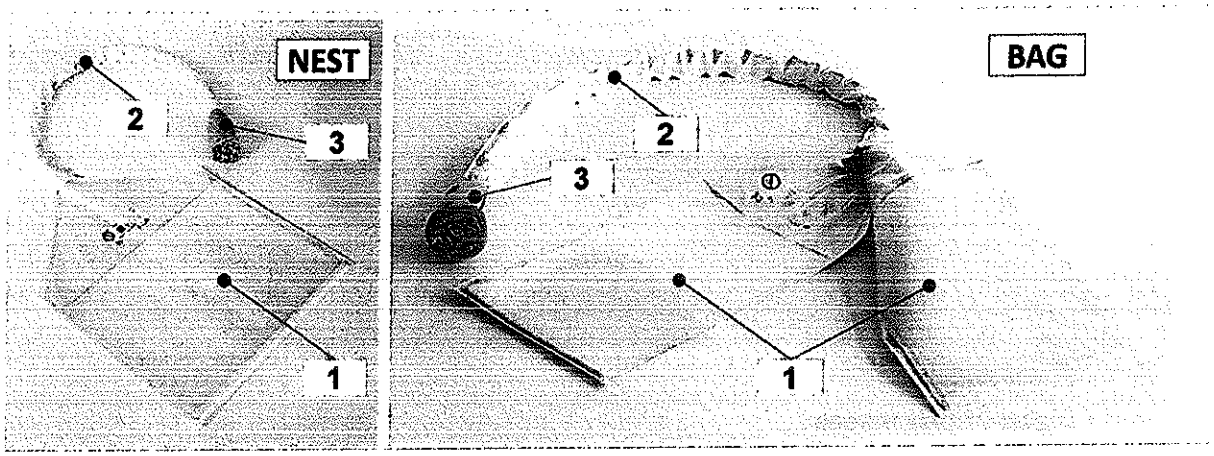


1	Power **switch**
2	**Digital Display Screen:** - Session Time (format: HH:MM, where HH stands for the hours and MM for the minutes): it's the time remaining before the session's end. The colon between HH and MM flashes during an ongoing phototherapy session. - Total Time (format: HHHH, which stands for the hours): it's the total time of use of the Device. The user can obtain this information by pressing the RESET button for 10 seconds from the system startup. **This timer should not, under any circumstance, be used to evaluate the phototherapy treatment duration.**
3	**+ and — controls:** to set session time. The session time can be set between 00:10 (= 10 min) and 99:50 (= 99 h and 50 min). The minimum session time increment or decrement is 10 min.
4	**RESET** button to reset session time. The user can verify that the light indicators properly light up by pressing this button for 10 seconds from the system startup.
5	**Operation indicator: blue light strip** - Continuous light: Therapy session running - Flashing light: Therapy session is configured but Pad is disconnected or not properly connected. - Light Off: A therapy session is neither ongoing nor configured.
6	**Overheating indicator** - Continuous light: Fan failure - Flashing light: Light Box overheating during treatment
7	**LED failure indicator** - Continuous light: Failure of one or more LEDs

For more information on these failures, please refer to section 5.E "Failures and possible resolutions".

3.C Pad Technical Features

The Pad is a woven fabric made of textile and optical fibers covered with a polyurethane enclosure. The Pad Connection enables the transfer of blue light between the Pad and the Light Box.



1. Lighting Surface	1. Lighting Surfaces
2. Cable	2. Cable
3. Connection	3. Connection

3.D Technical Features of the Disposable

Important **Never use the BiliCocoon™ system without the BiliCocoon™ Disposable**

The BiliCocoon™ Disposable is a single-use, **single-patient** device, which ensures the system cleanliness during a phototherapy treatment. (See the BiliCocoon™ Disposable Instructions for Use)

The BiliCocoon™ Bag Disposable is designed to be used with the BiliCocoon™ Bag Pad.

The BiliCocoon™ Nest Disposable is designed to be used with the BiliCocoon™ Nest Pad.

4 INSTALLATION AND USE

Important **Beforehand, read this manual, paying particular attention to its warnings.**

Warning

The phototherapy system may increase the patient's body temperature when it's used in combination with a thermotherapy system (e.g. infant incubators, infant transport incubators, infant radiant warmers, devices supplying heat via blankets, pads or mattresses). In this case the user should measure the infant's body temperature directly (i.e. on the skin's surface) and use the baby controlled mode of these devices, otherwise the set air temperature of the incubator or the heater output of the radiant warmer or heated mattress has to be adjusted according to the body temperature measurements.

Place the Light Box outside of these systems.

4.A Light Box Positioning

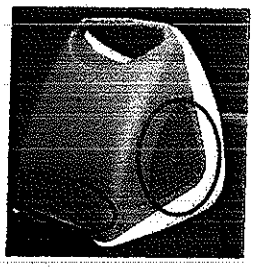
The BiliCocoon™ should only be used according to the described operating conditions *(see section 3.B Light Box Features).*

If the Light Box was stored under environmental conditions outside of the operating condition range, place the Device in the proper operating conditions for at least 1 hour before using it and let its temperature stabilize.

1. **Verification**
   - Verify that the Light Box is not damaged
   - Check before each use that the power cord and the power supply do not show any abnormality.

Warning **Risk of Electric Shock**
Disregarding the verification instructions may inhibit the detection of a system malfunction or failure and lead to risks to the patient's health or to the user.

2. **Positioning:**
   - Place the Light Box on a flat, stable surface
   - Take care not to block the side (left as in the picture and right) and rear air inlets.
   - Make sure not to position the Device or the external power supply so that the power cord would be difficult to unplug in case of emergency.
   - Do not use adjacent to or stacked with other equipment.
   - Consider not to place the infant too close (< 30 cm[1]) to the Light Box.



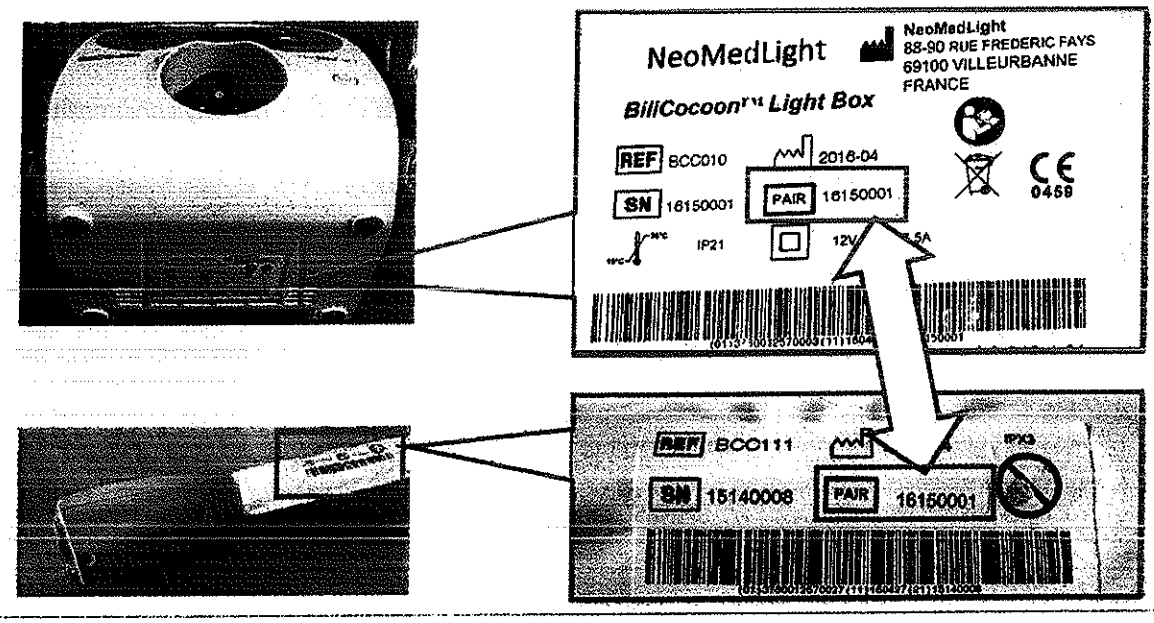
Warning If adjacent or stacked use is necessary, the Light Box should be observed to verify normal operation in the configuration in which it will be used.

3. **Connection of the Power Supply to the Light Box**
   - Connect the Power Supply in the power socket

4.B Pad Setup

1. **Verification and Cleaning**
   - Make sure the Pad enclosure does not present sharp edges which may injure the infant.
   - Make sure the Connection is not broken
   - Clean the Pad before and after each use (see Chapter 5.C Pad Cleaning)
   - Check the number to the right of the "PAIR" symbol on both the Pad and on the Light Box labels: these numbers must match.

[1] ≈ 11.8 inches



Warning

If the following defects are detected, discontinue use of the Pad:

- Cracks or holes in the polyurethane enclosure
- Cracked or broken Connection
- Presence of sharp edges

Warning

Do not cut or scratch the Pad

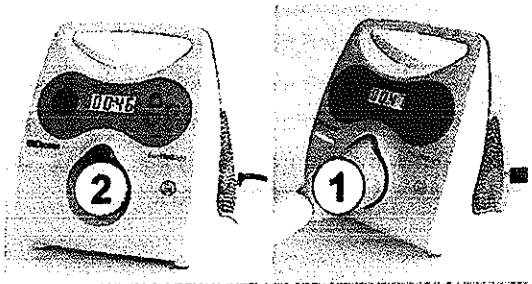
Take care to avoid dropping or handling the Device in a way that may cause the Connection to deform.

2. **Positioning**

- Place the Pad on a flat, stable surface

3. **Connection of the Pad with the Light Box**

- Connect the Pad with the Light Box by inserting the Pad Connection (1) into the Connection Port (2).
- Make sure the Pad and the Light Box are well connected.
- Make sure the cable and the light-emitting area are not bent or stretched.



Warning

Use or manipulation of the Pad outside of these recommendations may damage the optical fibers and affect the Pad lighting performances or lead to a risk to the patient's health.

4.C Verification of the Irradiance Value

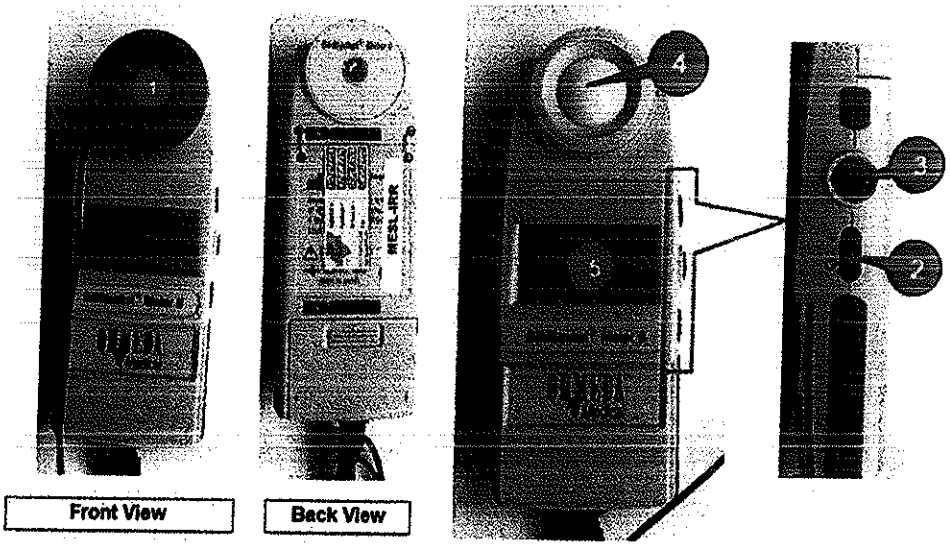
Warning

Prior to insertion of the Pad in the disposable, measure the irradiance value on the Pad lighting surface.

If this step is neglected, there is a risk of under-exposure – leading to an ineffective treatment – or a risk of over-exposure.

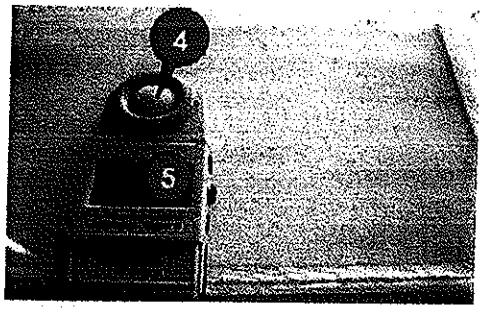
Recommended Radiometer: BiliBlanket Lightmeter II from Ohmeda (General Electrics). *For more information on how to use the radiometer refer to its instructions for use.*

The blue light emission is stable from the session start: irradiance measurements can be taken as soon as the phototherapy session is active.



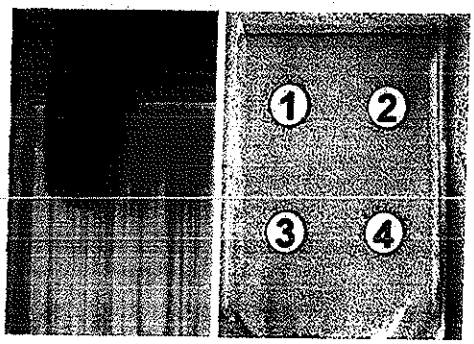
1. Remove the Receptor Cap (1)
2. Switch On the Radiometer using the ON/OFF switch (2) on the side of the device as in the picture. Check that the Hold-Run (3) is released (i.e. the display reading is not frozen). In case the display is frozen push the Hold-Run to release it.

3. Measure the blue light from the environment while the Device is turned off. Place the radiometer with the Light receptor dome (4) oriented upward as in the picture on the right. The displayed value should be lower than **1 µW·cm^{-2}·nm^{-1}.**



4. Connect the Pad to the Light Box, switch the Device on and launch a test session. The Pad now emits blue light. See section 4.E.

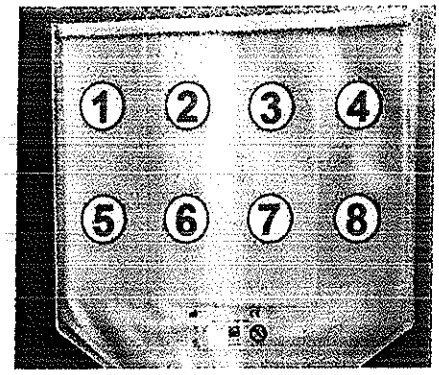
5. To make a measurement place the light receptor dome (4) in contact with the surface as in the picture – in this position the user looks at the back of the radiometer.
6. Place the light receptor dome on the measurement point n° 1 as in the picture
7. Leave the light receptor dome in this position for few seconds.



8. Press the Hold-Run (3) which freezes the measurement displayed on the screen.
9. Turn the radiometer, read and note the value displayed on the screen (5).
10. Push the Hold-Run (3) again to unfreeze the displayed measure.
11. Repeat steps 5 to 10 for the 7 other measuring points as shown in the pictures.

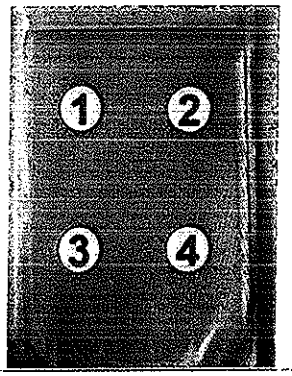
For the Nest Pad

Consider the 8 measuring points as identified below



For the Bag Pad

Consider the 4 measuring points on each small Pad as identified below (8 measuring points totally)



12. Calculate the mean value over the eight measures. This value should be in the range defined in the table below.

Average spectral irradiance (I - µW·cm^{-2}·nm^{-1}) over the eight points	Conclusion
38 < I < 43[m]	Optimal Irradiance[n]
I < 38 or I > 43	Out of specification – refer to Section 5.F "Maintenance Operations"

Important Refer to section 5.E in case the irradiance value is outside of the defined range and inform the manufacturer.

Important The use of a BiliCocoon™ system with a mean irradiance value exceeding the defined range upper limit, may deteriorate the Pad's optical fibers.

4.D Setup of the Disposable and Positioning of the Infant

Warning

For any information on the Disposable and its use, please refer to the last version of the Instructions for Use of the BiliCocoon™ Disposable.

The BiliCocoon™ Disposable is not intended to be used with a phototherapy treatment system other than the BiliCocoon™.

The BiliCocoon™ Disposable is a **single use, single-patient** medical device. It should be used respecting the usual hygiene precautions. There is indeed a cross-contamination risk if the Disposable is used for more than one patient.

Warning

Never place the infant directly on the Pad. Always use the Disposable specifically designed for the BiliCocoon™.

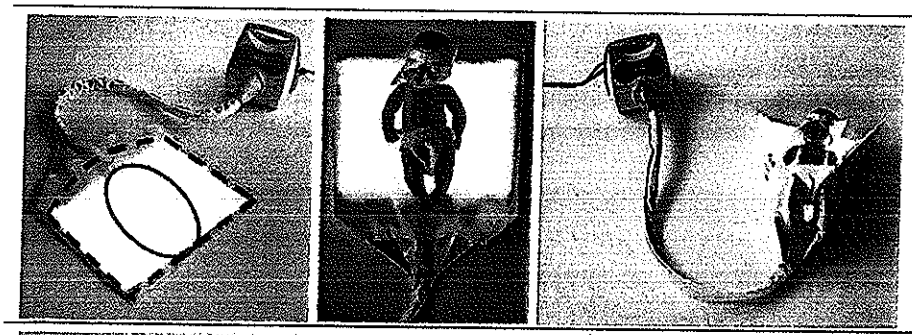
The Disposable is not designed for re-use and should not be cleaned, disinfected, or placed in contact with the cleaning products used to clean the BiliCocoon™ Pad.

Not using the disposable or having the cleaning products in contact with the infant may lead to allergic reactions for the patient.

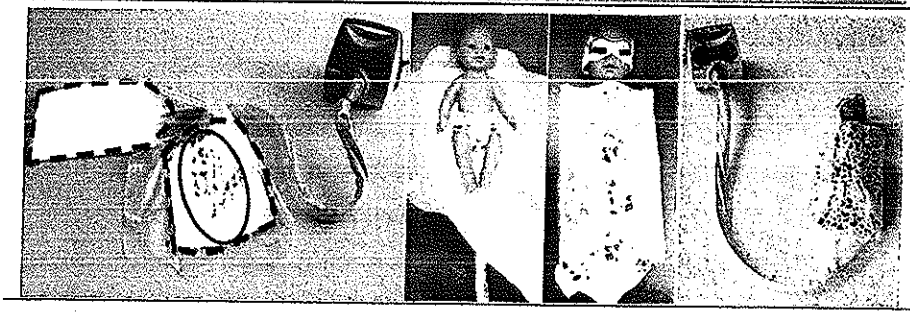
[m] The user should refer to the radiometer instructions for use and take into account its accuracy (±3%).

[n] Defined according to: "*Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation*", Pediatrics 2004; 114:1 297-316; doi:10.1542/peds.114.1.297, prepared by the AMERICAN ACADEMY OF PEDIATRICS.

Warning	Infants should wear a diaper during a phototherapy session.
Warning	Do not place the infant too close (< 30 cm[o]) to the Light Box.
Warning	Check that the packaging of the BiliCocoon™ Disposable is not damaged: The use of a device whose cleanliness is intended as a main feature and controlled thereof, but whose packaging is damaged, may lead to a risk to patient's health.
Warning	Ensure that the Pad is clean and dry. The BiliCocoon™ Disposable should not come into contact with the cleaning and disinfectant agents used to clean the Pad.
Important	Select the Disposable according to the type of Pad **(Nest Disposable or Bag Disposable)** and install the Disposable **according to the Disposable Instructions for Use.**
Important	We recommend not to use the Bag System for babies weighing less than 2500g
Warning	Ensure that the Pad is inserted right to the end of the BiliCocoon™ Disposable pocket and that the Disposable pocket hasn't been damaged by this insertion.
Warning	Place the infant on the Disposable with the baby's legs towards the Pad cable. Never place the infant's head close to the Pad cable. This positioning may otherwise lead to a risk of strangulation for the patient.
Important	Ensure that the maximum of the skin surface area will be in contact with the light-emitting area.
Warning	Once the infant has been properly installed protect the infant's eyes with **suitable eye protection.**



The infant in the BiliCocoon™ Nest System: the Nest Pad is inserted in the Nest Disposable; the infant is then placed on the disposable in the zone[p] defined by the red line as in the picture.



The infant in the BiliCocoon™ Bag System: the Bag Pad is inserted in the Bag Disposable; the infant is then placed on one of the internal faces of the disposable in the zone[q] defined by the red line as

[o] ≈ 11.8 inches

[p] The zone defined by the dashed black line represents the part of the Device the infant is in contact with. Please refer to the Instructions for Use of the BiliCocoon™ Disposable for more details.

[q] The zone defined by the dashed black line represents the part of the Device the infant is in contact with. Please refer to the Instructions for Use of the BiliCocoon™ Disposable for more details.

in the picture; the other surface is folded on the infant's chest.

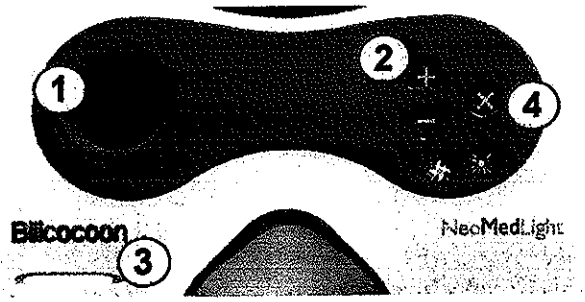
XXX

4.E Performing a Treatment

Precautions

Warning	Before beginning the treatment check the installation and the Light Box / Pad connection. **When the Device is switched ON but the Pad is not connected, do not look at the Pad Connection port.**
Warning	During the session or at its end, the temperature of the Connection surface which is in contact with the Light Box can be high. There is a risk of burning – see section 5. Take care in handling the Device.
Warning	Keep the Light Box steady with one hand when disconnecting the Pad through its Connection. Pulling the Connection without keeping the Light Box may lead the Light Box to fall, be damaged and harm users and other people.

Setting a Session



1. Turn ON the Light Box using the ON/OFF black switch (1)
2. Set the session time (HH:MM) using the + and – controls (2). If a session was previously set refer to the following section.
3. The session automatically begins in 5 seconds with the Device emitting blue light through the disposable. Check that the Pad and the Light Box are well connected: the Blue line feature light (3) should be continuous. In case the light flashes or is off, refer to the table "Failures and possible resolutions".
4. When the session starts all the controls become inactive. To reactivate them, switch OFF and ON the Device.
5. The session will stop automatically when the session time will be 00:00.

Resetting a Session or Changing the Settings of a Session

1. Switch OFF (1)
2. Switch ON (1)
3. To set the session time to zero press the RESET (4) button within 5 seconds from the switch ON
4. Set the session time (HH:MM) using the + and – controls (2) within 5 seconds after powering up.

Interrupting a Session

1. Switch OFF (1) to interrupt the session.
2. Switch ON (1) to restart a session: The system displays the last session time.

Stopping the System

1. Switch OFF (1)
2. Unplug the power supply from the power socket
3. Unplug the Pad from the Connection Port
4. Clean the Pad and the Light box according to the specific instructions (See Section 5.C)

In case of power failure, the Device keeps the session time recorded.
The phototherapy system can be disconnected from the power grid by unplugging the specified power supply.

5 CARE AND MAINTENANCE

Warning

There is a risk of contamination or damage to the Device in case of insufficient cleaning and / or non-compliance with the cleaning instructions.

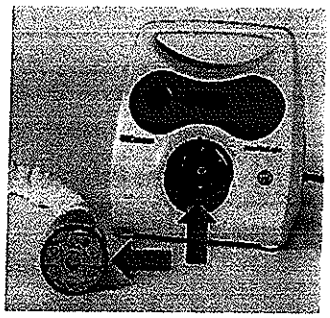
No care or maintenance while the BiliCocoon™ system is being used with a patient.

All care and maintenance operations must be performed when the system is disconnected from the power grid.

Risk of burning

When the Pad is disconnected from the Light Box, pay attention to the surfaces of these two elements which are in contact with each other during a therapy session. These surfaces may be hot. The dedicated warning symbol is placed close to these surfaces. There is a risk of burning for people touching these surfaces for a prolonged period and in the 5 min immediately after the Connection withdrawal.

Wait **5 min** after disconnecting before initiating any care or maintenance operation on the hot surfaces.



5.A List of Authorized Cleaning Agents and Disinfectants

The efficiency of cleaning and disinfection of the system has been demonstrated and validated with an EPA-registered cleaning and disinfectant product, specifically with CaviWipes™ from METREX.

To clean and disinfect the product, use an EPA-registered hospital disinfectant, such as CaviWipes™.

Warning

Do not use products containing:

- Caustic or abrasive cleaners
- Powerful cleaning solutions (acidic or alkaline solutions)
- Iodine-based solutions
- Products based on phenolic compounds, which can lead to increased bilirubin levels in infants

Warning

Never immerse any component of the phototherapy system in a liquid and never spray cleaning and disinfectant agents directly on the surface of the Device.

5.B Light Box Cleaning

Important The Light Box must be cleaned after each use.

Warning Do not autoclave or gas sterilize the Light Box

1. Wait 5 min after turning OFF the Light Box before start cleaning.
2. Unplug the power cord of the Light Box from the power socket before cleaning **(risk of electric shock)**

Warning

3. Moisten a soft, clean cloth **with a mild cleaning agent (refer to the list of allowed products in § 5.A.)**. Clean the outside of the Light Box and the power cord with the cloth. Be careful not to let the cleaning agent infiltrate into the Light Box.
4. Moisten another soft, clean cloth with water. Wipe the outside of the Light Box with it taking care to remove any cleaning agent residue.

Take care when cleaning the Connection Port to avoid damaging the optical lenses.

Warning

5. Perform a visual inspection of the LightBox to assure that it is clean. Otherwise repeat the previous instructions until there is no more soil observed.
6. Before use, make sure the Light Box is completely dry.

5.C Pad Cleaning & Dinsinfection

Warning The Pad must be cleaned and disinfected before and after each use and between each patient.

Caution

Do not expose the Pad to sunlight or ultraviolet light
Do not autoclave or gas sterilize the Pad
Do not bleach
Do not tumble dry
Do not iron
Do not dry clean

Warning

Cleaning

1. Make sure the Pad is disconnected from the Light Box before cleaning
2. Under running tap water at room temperature (+15°C/25°C), wipe the device unilaterally using a soft, lint-free cloth for a minimum of 1 minute
3. Wipe the device unilaterally using one moisten soft, clean cloth with a suitable cleaning agent, or use a pre-saturated wipe with a suitable cleaning agent to ensure complete removal of all gross debris. Repeated use of the product may be required to ensure that the surface is free of visible soil.

Caution

4. Use a second moistened clean cloth with a suitable cleaning agent, or pre-saturated wipe adapted to medical device cleaning (refer to the list of allowed cleaning agents). Wipe the device unilaterally to thoroughly wet the surface. Give special attention to hard to reach areas and dirtiest parts of the device.

   Repeted use of the product may be required to ensure that the surface remains visibly wet for a minimum of 2 minutes at room temperature (+15°C/25°C). Take care when cleaning the Pad connection to avoid damaging the optical fiber

5. Perform a visual inspection. If needed repeat the previous instruction until there is no more soil observed.

Disinfection

6. Use one moistened clean cloth with a suitable disinfectant agent, or pre-saturated wipe adapted to medical device cleaning (refer to the list of allowed disinfectant agent). Wipe the device from the plug, to the pad to thoroughly wet the surface. Give special attention to hard to reach areas of the device. Repeated use of the product may be required to ensure that the surface remains visibly wet for a minimum of 3 minutes at room temperature (+15°C/+25°C). Take care when cleaning the Pad connection to avoid damaging the optical fibers.

Warning

7. Moisten another clean soft cloth with water and wipe the Pad taking care to remove the disinfectant residues.
8. Allow the device to air dry thoroughly
9. Before use, make sure the Pad is completely dry.

5.D No Cleaning for the Disposable

Caution

The BiliCocoon™ Disposable is a SINGLE USE component, it is not designed to be reused, disinfected or cleaned.

5.E Failures and Possible Resolutions

Event	Causes	Actions
Operation indicator (blue light strip) – **off**	No therapy session is configured	
Operation indicator (blue light strip) – **flashing**	The Pad is disconnected or not properly connected. Even if a session has been configured, it's not active.	Check that the Pad is properly connected to the Light Box. Reconnect the Pad if necessary. The operation indicator will turn a continuous blue to indicate that the session is active. If the blue indicator light continues to flash, contact the technical support.
LED failure indicator – continuous light 	Session configured but one or more LEDs has failed The session has stopped and cannot be restarted.	Contact technical support.
Overheating indicator – continuous light 	Fan failure The session has stopped	Contact technical support. Switch the Light Box OFF and ON If the fan failure indicator light is on, put the Device out of service. If the fan failure indicator does not light up and the session does not restart after 5 seconds: • Turn OFF the Light Box and wait 15 min before switching it ON again.

		• If the session does not restart after 5 seconds, put the Device out of service.
Overheating indicator – flashing light 	Overheating The session is stopped.	Verify that the ambient temperature does not exceed the maximum operating temperature (35°C[1]). In case of high ambient temperature, move the system to an environment with a temperature below 35°C and let the temperature stabilize for 20 min. Verify that the air inlets are not blocked. If the air inlets are not blocked: - Contact the technical service - Switch OFF and ON the Light Box - If the session does not restart after 5 seconds, turn OFF the Light Box and wait 15 min before switching it ON again. - If the session does not restart after 5 seconds, depending on the urgency of the treatment replace the phototherapy system with one that works. If the air inlets are blocked: - Remove anything that is obstructing the air inlets - Switch the Light Box OFF and ON - If the session does not restart after 5 seconds, switch OFF the Light Box and wait for 15 min before switching it ON again. - If the session does not restart after 5 seconds, depending on the urgency of the treatment replace the phototherapy system with one that works. - In that case contact the technical support
The RESET or the session time setting buttons do not work	Defective Light Box	Do not use the Device. Put the Device out of service. Contact the technical support.
The Pad is cracked or damaged	Defective Pad	Do not use the Pad or the Light Box the Pad is paired with Contact the technical support.
The Connection is cracked or damaged	Defective Connection	Do not use the Pad or the Light Box the Pad is paired with Contact the technical support.
The Connection does not fit or does not properly connect with the Light Box	Defective Light Box or defective Connection	Do not use the Device. Put the Device out of service. Contact the technical support.
The Light Box shell is cracked or damaged	Defective Light Box	

[1] ≈ 95°F

5.F Maintenance Operations

⚠ Warning	**DO NOT ATTEMPT TO REPLACE** the LEDs at their end of life, neither by identical LEDs nor by a different component. CONTACT YOUR SUPPLIER.
Important	If the irradiance value is out of the specified range it should be reset: contact the authorized technical staff of the hospital or the supplier
⚠ Caution	The dust filter may only be changed by authorized technical staff of the hospital or of the supplier - Following the communication of "overheating". - During the annual preventive maintenance.
⚠ Caution	The fuse may only be changed by authorized technical staff of the hospital or of the supplier - Following a system failure event. - During the annual preventive maintenance.
⚠ Warning	Failure to perform the required preventive maintenance (i.e. periodic verifications of the system) by the authorized technical staff of the supplier may cause: - System's failures - Settings drifts - Malfunctions which could create risks to the patient, the user, third parties or properties.
Important	The following risks may occur in the event the user does not perform preventive maintenance (i.e. cleaning) as recommended or at an insufficient rate: - Device deterioration - Non-optimal operation of the Device
⚠ Warning	The failure to perform the required corrective maintenance by authorized technical staff of the hospital or the supplier, may cause failures or malfunctions that may in turn create risks to the patient, user, third parties or properties.

6 HOME USE

RECOMMENDATIONS FOR CLINICIANS

⚠ Warning	The medical staff is in charge of the home 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 BiliCocoon™ System. The user must be trained before the first use of the System 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 Device.

RECOMMENDATIONS FOR THE HOME USER

⚠ Warning	The home user must follow the recommendations and instructions contained in the instructions for use – concerning the System and the disposable – and provided by clinicians. In case of Device malfunctioning the home user must stop the Device and contact the clinicians.

For the description and the instructions for use of the BiliCocoon™ Phototherapy System refer to sections 3 and 4. For the description and setup of the BiliCocoon™ Disposable refer to section 4 of this document and to the specific instructions for use.

Check that the medical staff has provided:

- A phototherapy system which was verified and cleaned
- Eye protection, which is required to prevent lesions for the patient's eyes
- Instructions for Use for the Device and for the Disposable
- The instructions concerning the infant surveillance
- Spare Disposables
- The medical staff's contact details

Observe the operating and storage conditions as described in section 3.

Variations of the ambient conditions (room temperature and humidity, sun exposure, nearby devices) may unfavorably affect the patients' health, including their temperature or their fluid balance.

Use and store the system INDOOR exclusively. The Device is not be used while in motion.

Warning

Do not place the system close to a **heat source.**

Do not place the system close to a source of moisture like a nebulizer or a steam kettle.

Avoid exposure to **environments with excessive dust.**

Ensure that the air inlets are not covered or obstructed in order to avoid the Light Box overheating.

Keep the system out of reach of children and animals. Children and animals (domestic, insects...) may be responsible of the deterioration of the system, of its performances, and of its safety.

Warning

Duration of Session:

Use the device only for the time prescribed. A use that does not take into account the treatment plan may lead to an ineffective treatment or to potential risks to the patient's health.

Infants should wear a diaper during a phototherapy session.

Never place the infant directly on the Pad. Always use the Disposable specifically designed for the BiliCocoon™.

Warning

Place the infant on the Disposable with the baby's legs towards the Pad cable. Never place the infant's head close to the Pad cable. This positioning may otherwise lead to a risk of strangulation for the patient.

Ensure that a maximum of the skin surface will be in contact with the light-emitting area.

Protect the infant's eyes with a **suitable eye protection.**

Do not place the infant too close (< 30 cm) to the Light Box.

Warning

Eye Protection

Prolonged exposure to phototherapy light can cause damage to the eyes. The use of the BiliCocoon™ Phototherapy System without a suitable protection of the infant's eyes may lead to risks to the infant's health, including retinal damage.

Warning

Side Effects for Caregivers and People near the Device

The prolonged exposure to the phototherapy device blue light may cause discomfort to caregivers such as eye irritation, nausea, headaches or dizziness. Caregivers, parents and people who stay close to the Device could be sensitive to blue light and need to protect their eyes.

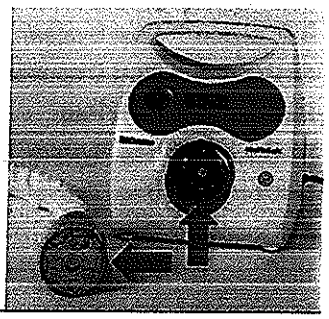
Warning

Risk of Glare

Do not look to the Pad Connection Port when the Device is switched ON and the Pad is not connected.

Risk of Burning

When the Connection is disconnected from the Light Box, pay attention to the surfaces of these two elements which are in contact with each other during a therapy session. These surfaces may be hot. The dedicated warning symbol is placed close to these surfaces. There is a risk of burning for people touching these surfaces for a prolonged period and in the 5 min immediately after the Connection withdrawal.



Refer to section 5.E of these Instructions for Use in case of malfunctioning.

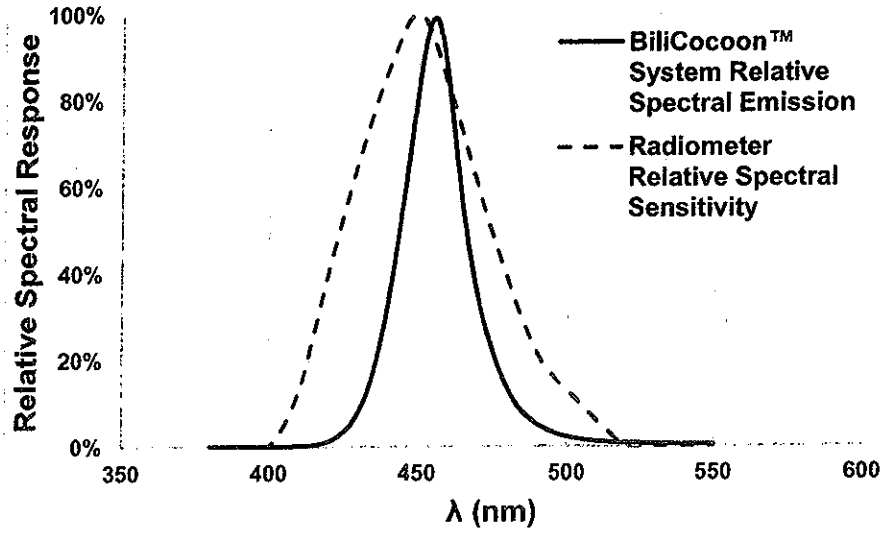
7 PRODUCT CATALOG NUMBERS

BiliCocoon™ Light Box	BCC010
BiliCocoon™ Nest System: BiliCocoon™ Light Box & Nest Pad	BCC101
BiliCocoon™ Nest Disposable (x50)	BCC12150
BiliCocoon™ Nest Pad	BCC111
BiliCocoon™ Bag System: BiliCocoon™ Light Box & Bag Pad	BCC201
BiliCocoon™ Bag Disposable (x50)	BCC22150
BiliCocoon™ Bag Pad	BCC211
BiliCocoon™ Fixation System	BCC301

8 TECHNICAL REFERENCES

8.A BiliCoon™ System Spectral Emission

The following figure shows the System's relative spectral emission (continuous line) and the radiometer[s] relative spectral sensitivity (dashed line). Total mean irradiance for bilirubin for the System with Disposable: 2,1 $mW \cdot cm^{-2} \pm 15\%$.



8.B Standards and regulations

EN 60601-1, EN 60601-1-2, EN 60601-2-50, EN ISO 15223-1
Directive DEEE 2012/19/CE, Directive 93/42/EEC, Directive RoHS 2011/65/EU, REACH Regulation 1907/2006

[s] BiliBlanket Lightmeter II from Ohmeda (General Electrics) according to the Manufacturer's recommendation.

9 WARRANTY

The Light Box and the Pad are covered by a 1-year warranty.

ANNEX A: Service Manual

A.1 Purpose

This Service Manual describes the maintenance operations to be performed on the BiliCocoon™ Phototherapy System exclusively by the authorized technical staff of the hospital or the supplier.

Applicable part number: BiliCocoon™ Light Box – BCC010

List of Interchangeable or Detachable Parts (excluding Pad and disposable):

Part	*Part Number*
Power Supply	MEGMEET MANGO100-12B
Power Cord	EU : Qualtek 360007-01 UK : Cabcon UKA03.H02.C07.0200.B US : Schurter 6010.5274 AU/NZ : IEC-C7 2m AC-Cord Blk 2-Pin Plug to Iec320-C7 - K3762
Service Kit	BCC010-SK10 • **Fuse** : SCHURTER 0001.1013 (8A/250V/FAST/Breaking Capacity : H (1500A) and size: 5x20mm) • **Dust Filter** : SANYO DENKI 109-1001F20

A.2 Maintenance Operations

The following sections detail the preventive and corrective maintenance operations to be carried out. No other operation is authorized on the Device.

A.2.1 Failures and Corrective Operations

Warning The failure to perform the required corrective maintenance by authorized technical staff of the hospital or of the supplier, may cause failures or malfunctions which may in turn cause risks to the patient, user, third parties or properties.

Warning **DO NOT ATTEMPT TO REPLACE** the LEDs at their end of life, neither by identical LEDs nor by a different component. CONTACT YOUR SUPPLIER.

The following table lists the failures that may occur and the actions to be undertaken. If the problem persists after performing the maintenance operation, contact the supplier.

Observation		Failure	Actions
LED failure indicator – continuous light		**LED failure**	Contact the supplier

Overheating indicator – continuous light		**Fan failure**	Contact the supplier
Overheating indicator – flashing light (Occurring while operating within the specified environmental conditions)		**Overheating – the dust filter may be damaged or dirty**	Verify that the problem persists after running the therapy at the operating conditions specified in the Instructions For Use and with the air inlets/outlets not blocked. If it does persist replace the dust filter as described in Section A.4.
Irradiance out of specification		**Un-calibrated Device**	Calibrate the system as described in Section A.3
Light Box not working when plugged to power supply and turned ON		**The fuse may have blown**	Replace the fuse as described in Section A.5
Any other indication of malfunction or damage		**Any other failure**	Contact the supplier.

A.2.2 Annual Preventive Maintenance


Warning

The failure to perform the required preventive maintenance by the authorized technical staff of the supplier – periodic verifications of the system – may cause:

- System's failures
- Settings drifts
- Malfunctions

which may lead to risks to the patient, the user, third parties or properties.

Dust filter is to be replaced (Section A.4) once per year during preventive maintenance.

A.3 Calibration


Warning

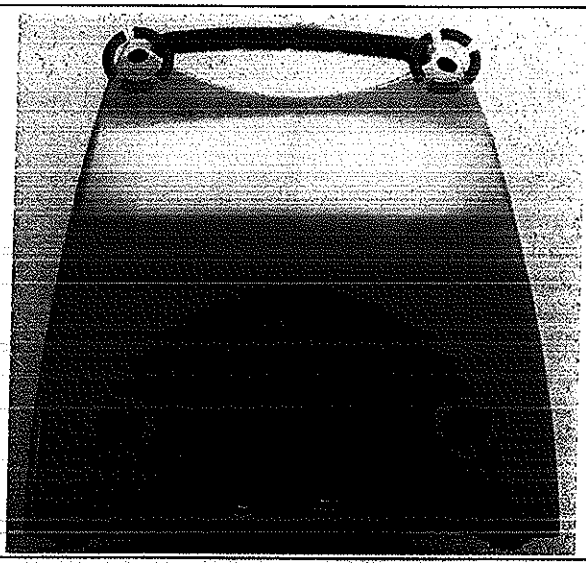
Before starting the operation ensure that the external **power supply is not plugged to the Light Box.**

This operation should **only be performed by the authorized technical staff** of the hospital or the supplier.

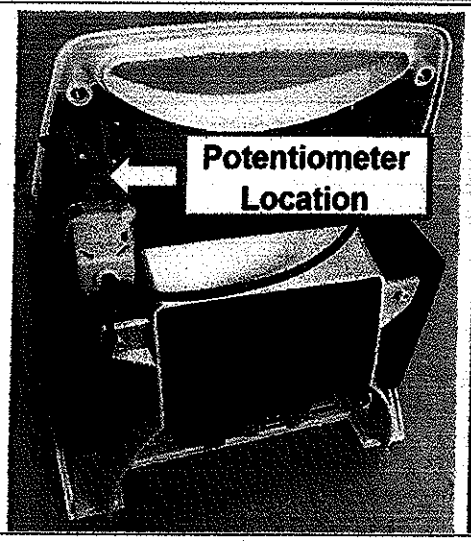
Calibration Procedure:

1. **Check the irradiance before recalibrating the system (see the procedure in the Instructions for Use) verifying if the irradiance value is in the calibration range: 39 – 42 $\mu W \cdot cm^{-2} \cdot nm^{-1}$. (Note that this range is not the same that is to be checked by the user). Continue with the calibration procedure only if the irradiance is out of the calibration range.**

2. **Remove the 4 screws (part numbers: H10, CBLX, M3x10, ISO 14583, Inox 2) with a Torx adapted screwdriver and then the back cover of the Light Box. The figure on the right shows the location of the screws:**



3. **Locate the calibration potentiometer, shown in the pictures on the right:**



4. **Use a small screwdriver to adjust the irradiance to the calibration range, using the following indications:**
   a. **Rotation sense: Clockwise to increase, counterclockwise to reduce.**
   b. **Number of turns: 1 turn represents approximately 4 - 5 $\mu W \cdot cm^{-2} \cdot nm^{-1}$.**
5. **Close the enclosure, plug the power supply and the Pad and measure again the irradiance.**
6. **Repeat the procedure if the measurement is still out of the calibration range.**

A.4 Dust Filter Replacement

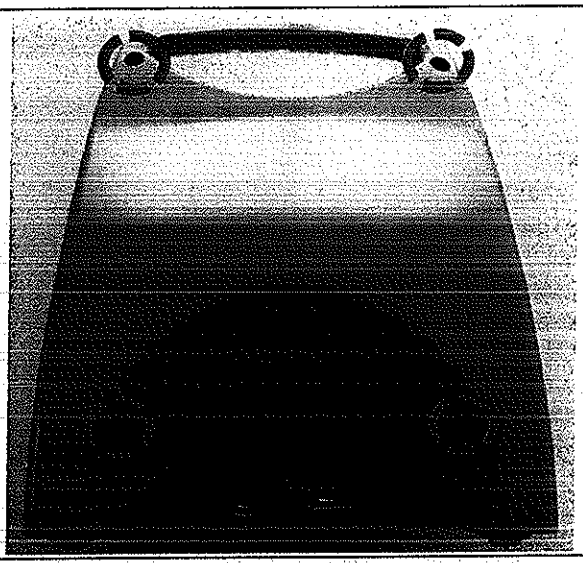
Warning

Before starting the operation assure that the external **power supply is not plugged to the Light Box.**

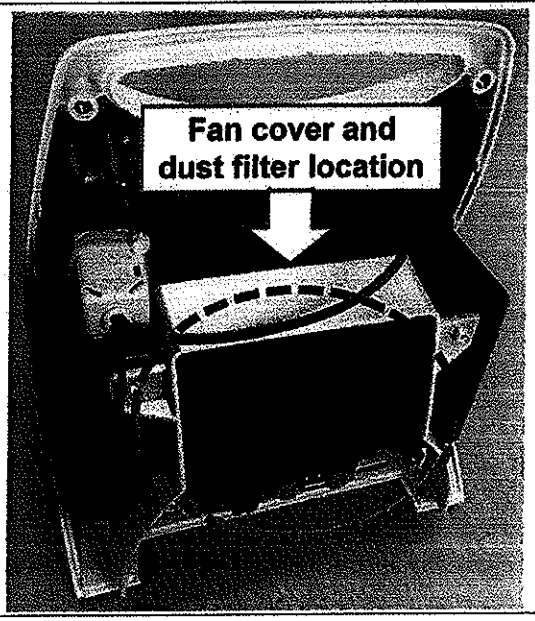
This operation should **only be performed by the authorized technical staff** of the hospital or the supplier.

Replacement Procedure:

1. **Remove the 4 screws (part numbers: H10, CBLX, M3x10, ISO 14583, Inox 2) with a Torx adapted screwdriver and then the back cover of the Light Box. The figure on the right shows the location of the screws:**



2. **Locate the dust filter and its cover, shown in the pictures on the right:**



3. **Remove the cover, to do so a small flat screwdriver might be used to push through the holes situated next to the screw holes. Note that the screws that hold the Fan do not have to be removed in order to replace the filter.**
4. **Replace the filter behind the cover with a new one. Use only the part number "SANYO DENKI 109-1001F20", which is provided in the service kit. Do not clean and/or reuse the old filter.**
5. **Place the cover over the new filter by applying a small pressure.**
6. **Verify the irradiance of the system before using it**

A.5 Fuse Replacement

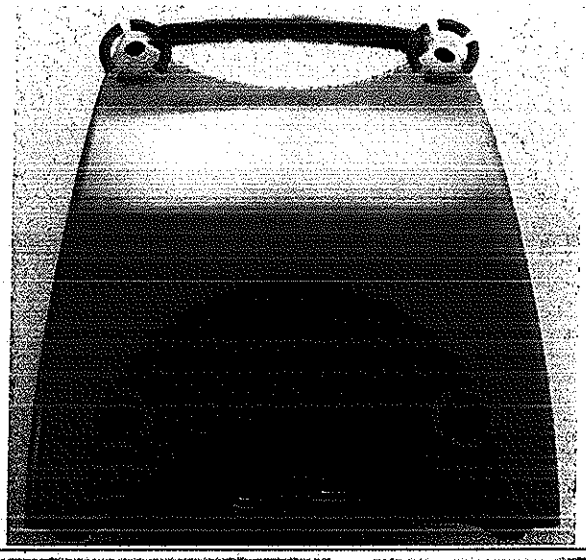
Warning

Before starting the operation assure that the external **power supply is not plugged to the Light Box.**

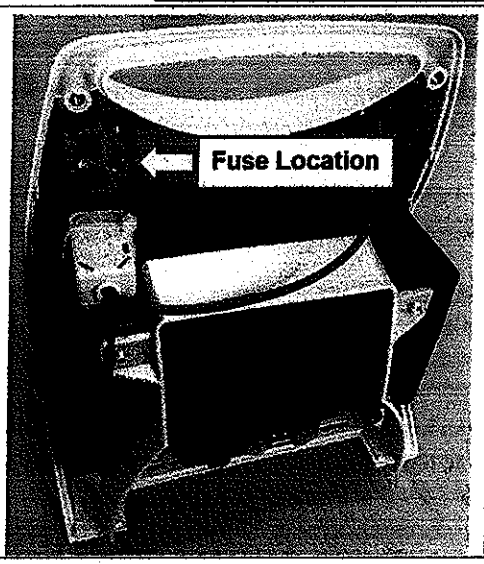
This operation should **only be performed by the authorized technical staff** of the hospital or the supplier.

Replacement Procedure:

1. **Remove the 4 screws (part numbers: H10, CBLX, M3x10, ISO 14583, Inox 2) with a Torx adapted screwdriver and then the back cover of the Light Box. The figure on the right shows the location of the screws:**



2. **Locate the Fuse, shown in the pictures on the right:**



3. **Remove the fuse while taking care not to damage the electronic components nearby.**
4. **Replace the fuse with a new one. Use only the part number "SCHURTER 0001.1013", which is provided in the service kit. Do not use any other type of fuse.**
5. **Verify the irradiance of the system before using it**

NeoMedLight
88-90 rue Frédéric Faÿs 69100 VILLEURBANNE, FRANCE

Octobre 2017

Responsabilité de l'utilisateur

Ce manuel d'utilisation décrit les opérations d'installation, d'utilisation et de maintenance du système[1] de photothérapie BiliCocoon™ - aussi nommé le Dispositif ou le Système.

Le Dispositif ne doit être utilisé que par un utilisateur formé de façon opportune et ne doit pas être utilisé s'il est endommagé, contaminé, ou si des parties sont manquantes. Dans ce cas contacter immédiatement le fournisseur. Pour l'entretien et la maintenance du Dispositif, il convient de se référer au fournisseur ou au personnel habilité de l'hôpital.

L'utilisateur sera considéré comme seul responsable des risques encourus par le patient, le personnel soignant, les tiers ou les biens, ou si les performances étaient amenées à être différentes de celles attendue provoqués par un emploi abusif, inadapté, un mauvais entretien, une réparation inadéquate ou des modifications apportées par quiconque non habilité à intervenir sur le Dispositif.

Tout incident grave survenant en lien avec le dispositif doit faire l'objet d'une notification au fabricant ainsi qu'à l'autorité compétente locale de l'Etat dans lequel l'utilisateur et/ou le patient est établi. *Vous pouvez contacter NeoMedLight à l'adresse suivante : quality@neomedlight.com.*

Selon la loi fédérale des Etats-Unis la vente du Dispositif est permise exclusivement aux professionnels autorisés ou suite à leur demande.

CE 0459

NeoMedLight déclare que ce produit satisfait aux exigences de la Directive 93/42/CEE.
Année d'apposition du marquage CE et de mise sur le marché du Dispositif : 2016.

Ce produit doit être manipulé avec attention et ne doit pas être mis au rebut avec les déchets ménagers. Les déchets d'équipements électriques et électroniques (DEEE) peuvent polluer l'environnement et on doit s'en débarrasser conformément à la Directive 2012/19/UE et aux circuits appropriés.

Contacter les autorités locales ou le fabricant pour déterminer la méthode adéquate de mise au rebut des parties et des accessoires potentiellement dangereux pour l'environnement.

[1] Le terme « Système » n'est pas utilisé dans ce document avec le même sens défini par la norme EN 60601-1, définition 3.64. Il représente l'ensemble des composants qui sont reliés à former le dispositif médical.