skylife

color inside

PHOTOTHERAPY SYSTEM

USER MANUAL

neolight

500007-ART Rev T
August 2025

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1. INTRODUCTION

The Skylife Phototherapy System is a portable phototherapy device that delivers a narrow band of high-intensity light via blue light emitting diodes (LEDs) to provide treatment for neonatal unconjugated hyperbilirubinemia. The Skylife system is designed to provide phototherapy treatment from underneath the baby minimizing interference with other ongoing treatments. The Skylife device must be used within a patient bed, such as a bassinet, an open crib, a warming table, or incubator and may be used in either hospital or home settings.

The terms "neonatal" and "neonate" refer to a baby from birth through the first 28 days of life. The Skylife device is intended for use with all neonatal subpopulations.

The system utilizes blue LEDs to achieve intensities from 25 µW/cm^2/nm to >55 µW/cm^2/nm*****, emitting light in a narrow bandwidth between 430-475 nm. This light bandwidth corresponds to the spectral absorption of light by bilirubin and is thus considered to be the most effective for treatment [1,2,3]. The Skylife system utilizes blue LEDs in this range to achieve peak intensities between 25 to 35, 35 to 55, and over 55 µw/cm^2/nm* at low, high, and very high settings.

The Skylife device greatly minimizes the risk of UV exposure typically seen with phototherapy treatment through the use of Blue LEDs, as this light source does not emit significant energy in the ultraviolet (UV) spectrum. However, as with all phototherapy treatment, protective eye masks must be used to protect the baby's eyes from blue light exposure.

Treatment times can range from hours to weeks and should only be performed under the supervision of a licensed practitioner. Treatment exposures may be applied continuously 24 hours a day or as prescribed by the treating physician. The Skylife device may be contraindicated for babies with rapidly rising bilirubin levels. Babies with rapidly rising bilirubin levels must be monitored frequently and may require more intensive therapy.

Read this User Manual carefully before using the device. Please pay careful attention to the Safety Information and Warnings throughout the manual.

Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

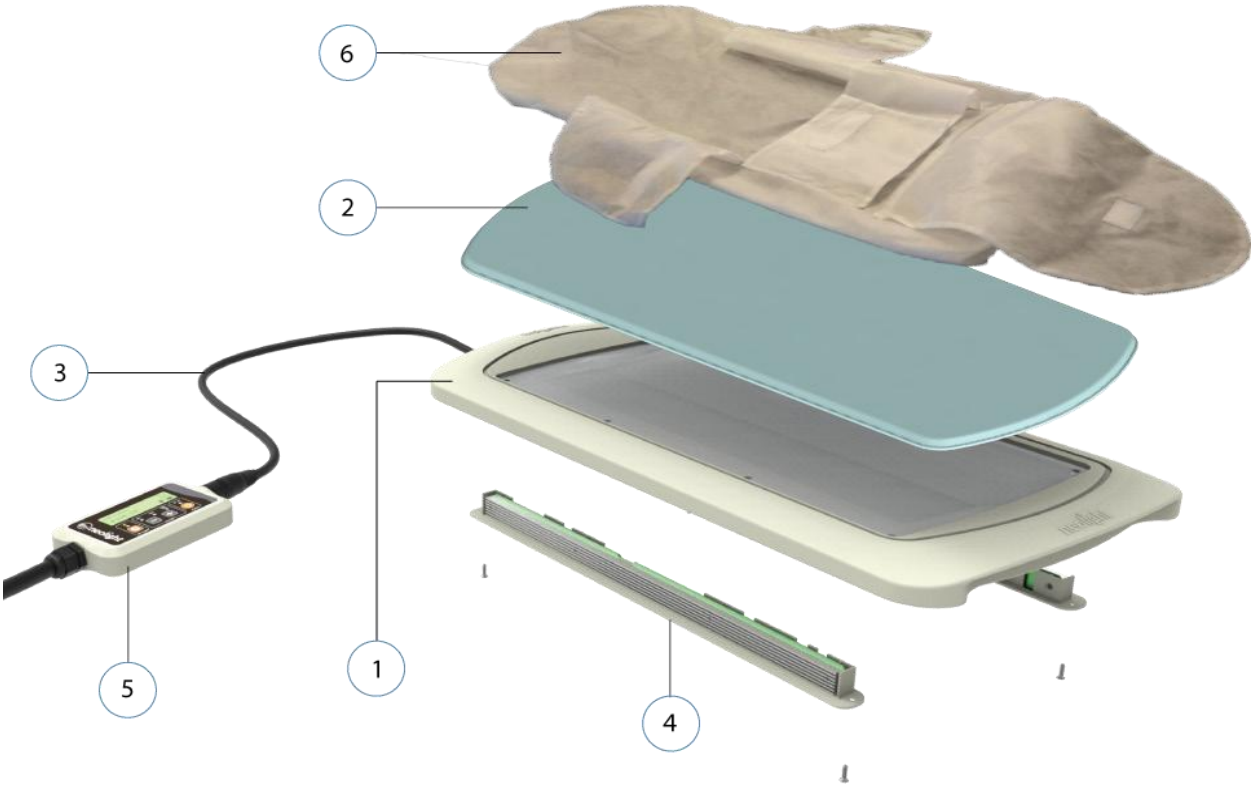
****** *Very High setting provides an average intensity of 56.3 µw/cm^2/nm over the treatment area with peak intensity at 72.4 µw/cm^2/nm*

1. Vreman, Hendrik J., et al. "Light-emitting diodes: a novel light source for phototherapy." Pediatric research 44.5 (1998): 804-809.
2. Lee, Kwang-Sun, and Lawrence M. Gartner. "Spectrophotometric characteristics of bilirubin." Pediatric research 10.9 (1976): 782-788.
3. Dixon, J. M., M. Taniguchi and J. S. Lindsey (2005), "PhotochemCAD 2. A Refined Program with Accompanying Spectral Databases for Photochemical Calculations, Photochem. Photobiol., 81, 212-213.

2. INTENDED USE

The Skylife system is intended for the treatment of neonatal unconjugated hyperbilirubinemia. It is designed to provide phototherapy treatment from underneath the baby. The Skylife unit must be used within a patient bed, such as a bassinet, an open crib, a warming table or an incubator. The system can be used in a clinical setting or in the home.

3. SYSTEM COMPONENTS



No.	Part Name	Description
1.	Light Bed	Top part of main device that emits blue light
2.	GelMat	Protective cushion attached to the top of the bed
3.	Light Bed Cable	Connects device to Skylife controller
4.	Light Modules	Modules hold the light source inside the Light Bed
5.	Controller	Allows user to operate/control the device
6.	CloudCover / CloudCover Plus	Disposable cover and containment that ensures hygienic use for baby and protection for Skylife

4. EXPLANATION OF SYMBOLS

The following symbols are used in this user manual, on the device packaging, on the device and accessory labeling.

Symbol	Description
	Reference number; part number
	Lot number
	Serial number
	Manufacturing date
	Legal Manufacturer name and address
	Follow instructions for use
	Prescription only (USA)
	Product contains electrical and electronic equipment. User should not discard this product along with other household waste; it must be collected and treated separately
	Minimum and maximum operating and storage temperature range
	Minimum and maximum storage humidity range
	Minimum and maximum operating atmospheric pressure range

Symbol	Description
	Type BF applied parts
	Warning: indicates a hazardous situation that, if not avoided, could result in death or serious injury.
	Caution: indicates a hazardous situation that, if not avoided, could result in minor / moderate injury & could damage equipment
	Non Sterile
	Refer to the User Manual
	Keep the device away from sunlight
	Keep the device dry
IP23	Protected electrical shock from touch by hands greater than 12 millimeters. Protected from water spray less than 60 degrees from vertical
	Baby Eye Protection Required
	Single use only. Do not reuse
	Hazard of severe electric shock or burn
	Double insulated

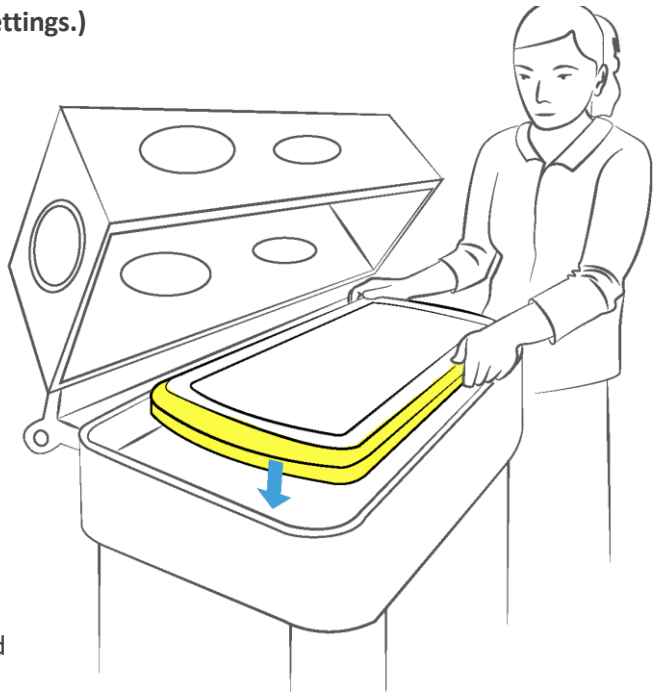
4.1 WARNINGS & PRECAUTIONS

1. Use the Skylife Phototherapy System only for its intended use as described in this manual.
2. Never operate the system if it has a damaged plug, damaged or frayed power cord or wires. Do not insert anything into the end of the plug.
3. Always connect the device to a properly grounded outlet. Do not use an extension cord.
4. Always use the Skylife system in a crib, bassinet, incubator, or warmer where walls protect the baby from injury. These environments must have a stable base that does not rock or tip, as in the case of a rocking cradle.
5. Avoid using the device adjacent to or stacked on other equipment (except for incubators, warmers, bassinets, or crib) as it could result in improper operation.
6. Do not use the device in the presence of flammable substances such as anesthetics, cleaning agents and gases that support combustion.
7. Do not disassemble the Skylife device unless you are a certified technician.
8. Do not use items such as blankets to cover the device.
9. Do not place the device where it can fall or be pulled into a tub, sink, or other liquid source.
10. Keep the Skylife controller in a location that is inaccessible to the baby.
11. Keep the Skylife controller and cords in a location away from toddlers, children and pets.
12. The Skylife Light Bed and GelMat must be used only with the CloudCover / CloudCover Plus provided. Any other type of cover may cause a reduction in light intensity.
13. Baby eye protection is required prior to turning on the Skylife unit.
14. If the user should experience discomfort from exposure to blue LED light, eye protection is recommended (yellow lenses) while operating the unit.
15. Baby should be wearing only a diaper and not otherwise wrapped or clothed during treatment.
16. Ensure the baby is secured during treatment.
17. Ensure that device cords and any other equipment cords are outside treatment area and do not pose an entanglement, strangulation, or tripping hazard.
18. Do not operate the Skylife unit at temperatures above 37°C (98.6°F). Keep the device away from heated surfaces, heaters, and other heat sources (like fireplaces or warming blankets).
19. Do not use the device while bathing or feeding the baby.
20. During phototherapy, the baby's water balance may become disturbed. Before and during treatment, make sure the baby is properly hydrated and that his or her body temperature is maintained.
21. During phototherapy, monitor baby's bilirubin levels according to your practitioner's recommendations.
22. The Skylife device should be turned off prior to evaluating baby's skin color, as lighting will affect visual color evaluation. Parents should contact their medical practitioner if needed.
23. Turn off and unplug the unit during device service.
24. If the Light Bed is exposed to liquid (falling into water or fluid is spilled on the device), immediately unplug the unit from the power source prior to taking any other action. Discontinue use of the device immediately.
25. Store the device in dry location away from direct sunlight. Avoid exposure to dust, lint or other particulates.
26. Do not place heavy objects on the Light Bed. This can damage the panel and may affect light output.
27. Do not place sharp objects on any element of the device as it may cause damage.
28. Do not drop the device. If the system is dropped, contact your hospital technician or the manufacturer for further information prior to resuming use of the Skylife unit.
29. Ensure that the device is inaccessible to children or pets when not in use.
30. Handle GelMat with care. Do not stretch, twist, fold, or remove the GelMat.
31. Keep sharp objects away from GelMat.
32. Use dry cloth wipes only on the cloudy area of the Light Bed. Do not clean the Light Bed top surface with liquids.
33. Due to photo effects, drugs should not be stored in treatment area.
34. Not for use with babies greater than 10kg (22 lbs.).
35. Do not use the Skylife system without GelMat and CloudCover, or place baby directly on the Light Bed.
36. Always ensure to firmly secure the neonate's arms, legs, and body using CloudCover Plus.

5. SKYLIFE OPERATING INSTRUCTIONS

(Steps 1 - 6 are applicable in both home and hospital settings.)

5.1 SETTING UP THE SYSTEM

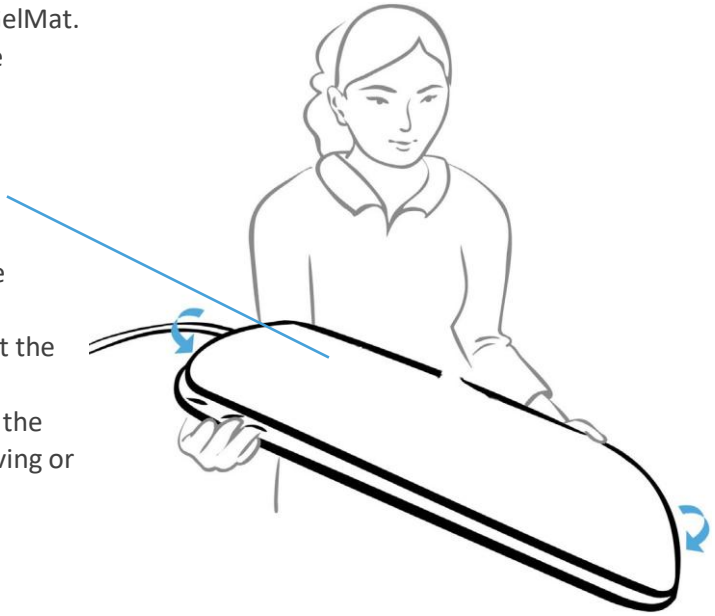


1. Place the Skylife device in a location with walls (e.g. bassinet, warmer, crib, or incubator).

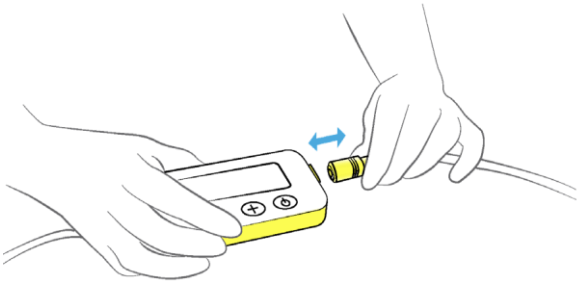
⚠ **Caution:** Do not allow items such as blankets to cover the outside edges of the device.

2. Visually inspect Light Bed and GelMat for damage or wear. If GelMat becomes damaged, torn, or develops a yellowish discoloration, refer to section 6.2, steps #1 - 4 for replacement information. A home user should contact the system provider for replacement.

3. Place the CloudCover on the device over the GelMat. Secure the CloudCover to the device using the corner pockets like a fitted bed sheet.

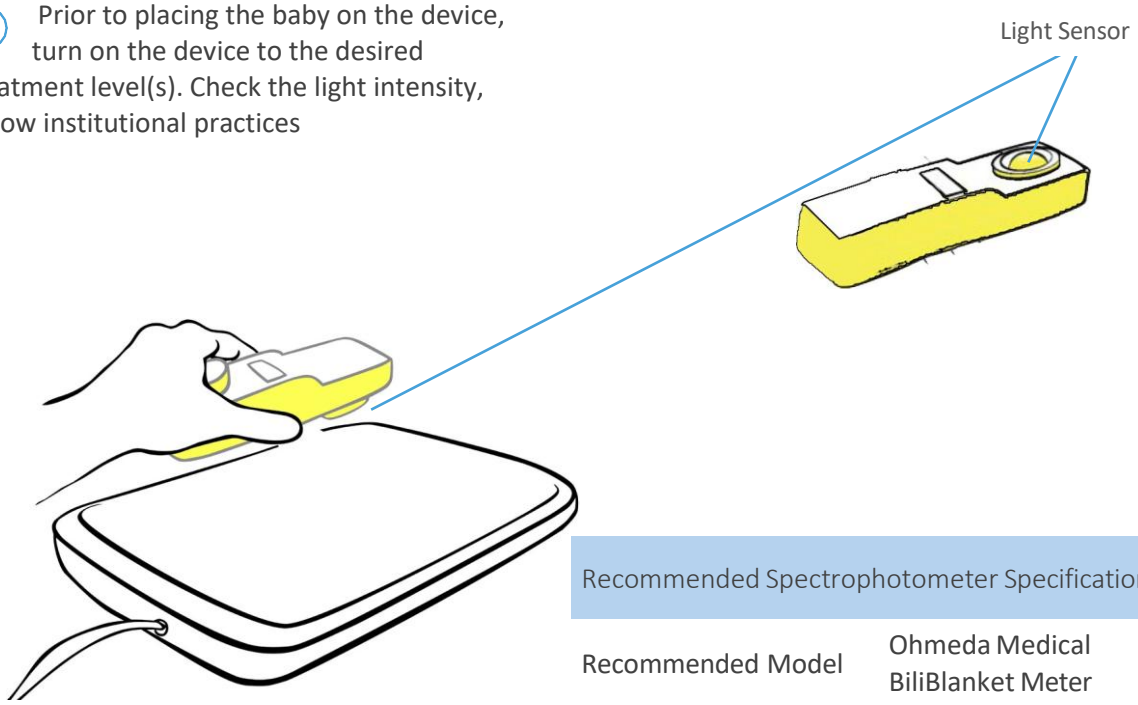


4. Attach the Controller and Power Supply to the device and place the Controller outside the enclosing walls of the treatment area. Ensure that the cord does not pose a hazard to the baby. Plug the Power Supply into the wall outlet. Keep controller connected unless moving or storing device.



(Steps 5 - 6 are applicable in a hospital setting only, including technical references on this page.)

5 Prior to placing the baby on the device, turn on the device to the desired treatment level(s). Check the light intensity, follow institutional practices



6 Measurements should be taken on the surface of the GelMat. The CloudCover must be on the device when taking readings and be sure to focus the light sensor towards the GelMat.

The device has been calibrated to deliver the following light Intensity levels	
Low	30 ± 5 µW/cm²/nm
High	45 ± 10 µW/cm²/nm
Very High	>55 µW/cm²/nm*

Recommended Spectrophotometer Specifications	
Recommended Model	Ohmeda Medical BiliBlanket Meter
Spectral Response	400-520 nm
Center Wavelength	450 nm
Bandwidth	60 nm
Light Acceptance Angle Cosine Characteristics	±2% @ 30° angle ±7% @ 60° angle ±25% @ 80° angle
Receptor Type	Silicon Photocell
Measuring Function	Spectral Irradiance µW•cm^{-2}•nm^{-1}
Accuracy	Within ± 3% of reading ±1 digit in the last position

⚠ **Caution:** If device does not meet the desired intensity range for treatment, replace GelMat and repeat setup. If device still fails to meet the required levels contact Customer Service.

⚠ **Warning:** Varying ambient lighting (including exposure to sunlight and other photoradiation sources) and varying temperature conditions may affect patient response to treatment, monitor patient closely.

⚠ **Caution:** Avert eyes from blue lights in the phototherapy light to prevent effects such as eye irritation, headache, and nausea.

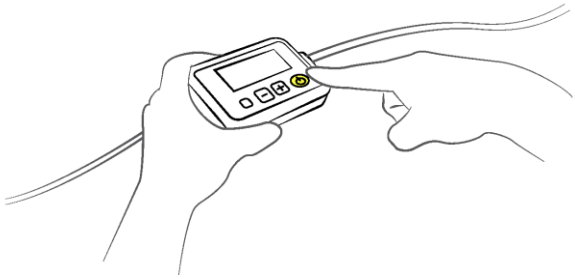
** Very High setting provides an average intensity of 56.3 µw/cm²/nm over the treatment area with peak intensity at 72.4 µw/cm²/nm.*

5.2 PREPARING BABY FOR PHOTOTHERAPY

① Before starting treatment, always shield the baby's eyes with a protective eye mask designed for use during phototherapy. During phototherapy treatment, regularly remove the coverings according to hospital policy to assess the baby's eyes for signs of irritation or infection. Important! Eye Protection: Do not look directly into the blue light for a prolonged period of time.

② Position the baby on the CloudCover. Ensure that only the CloudCover is directly under the baby. Do not use blankets, swaddles, bumpers, etc. to cover the device.

IMPORTANT: During treatment, always ensure to completely secure the neonate using CloudCover Plus

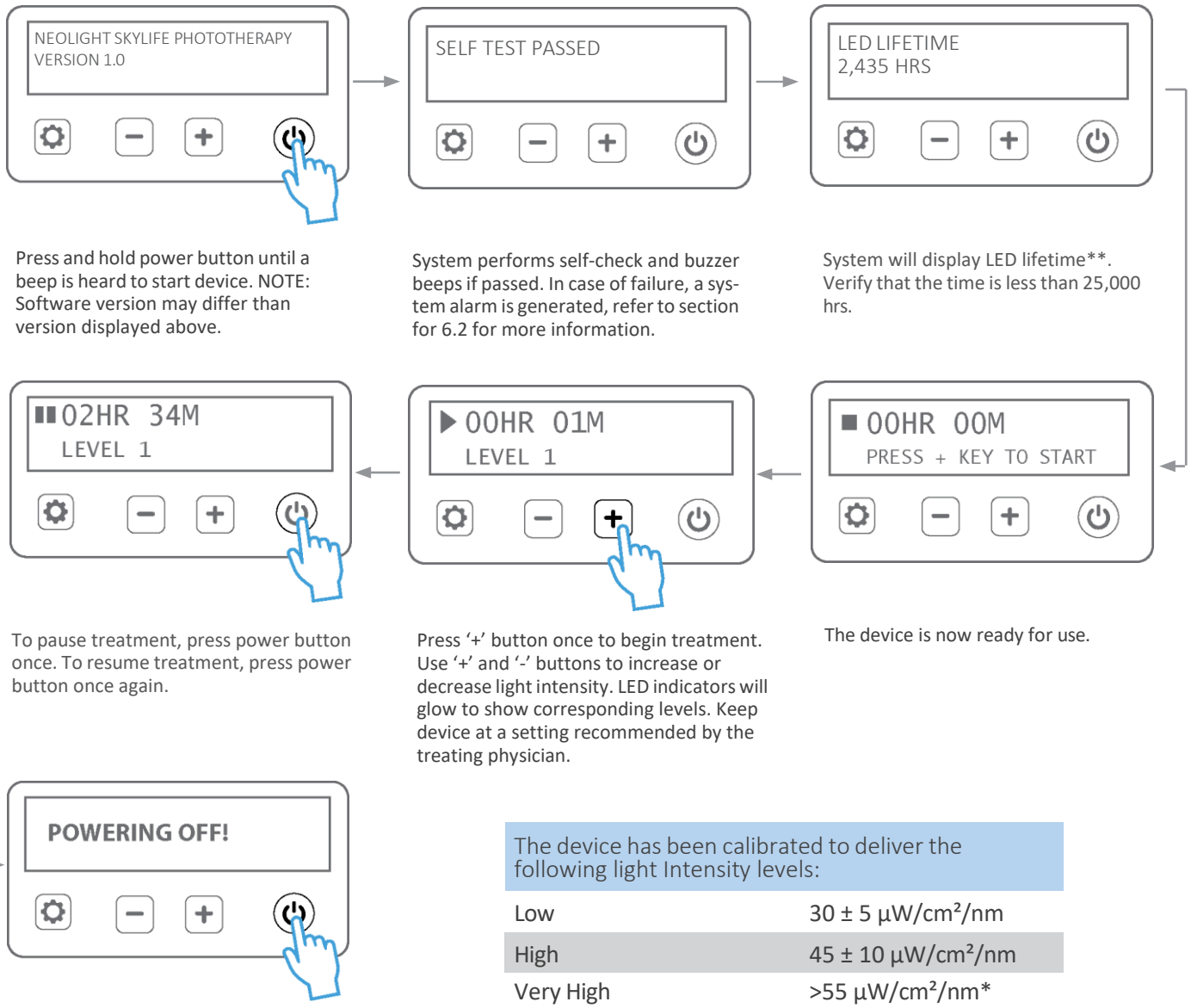


③ To power on the device, press and hold the power button on the controller until you hear a beep and the lights come on.

5.3 ADMINISTERING PHOTOTHERAPY TREATMENT

Once baby is secure, turn on the device and use the controller to administer therapy. Follow the steps below and set light intensity level as directed by physician to achieve desired results*.

Normal use cycle:



Press and hold power button until a beep is heard to start device. NOTE: Software version may differ than version displayed above.

System performs self-check and buzzer beeps if passed. In case of failure, a system alarm is generated, refer to section for 6.2 for more information.

System will display LED lifetime**. Verify that the time is less than 25,000 hrs.

The device is now ready for use.

Press '+' button once to begin treatment. Use '+' and '-' buttons to increase or decrease light intensity. LED indicators will glow to show corresponding levels. Keep device at a setting recommended by the treating physician.

To pause treatment, press power button once. To resume treatment, press power button once again.

Press hold the power button for a longer duration to power OFF the device.

The device has been calibrated to deliver the following light Intensity levels:	
Low	30 ± 5 µW/cm²/nm
High	45 ± 10 µW/cm²/nm
Very High	>55 µW/cm²/nm*

** Actual display may vary based on software revisions.*
*** LED lifetime refers to the number of hours the LED modules have been used to date.*

High Temperature Alarm Condition:

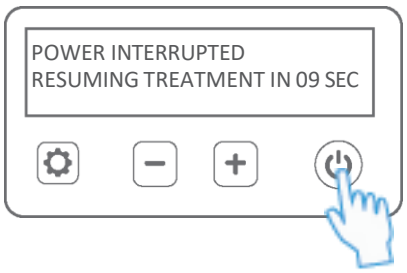
If the system temperature increases beyond a certain threshold, the High Temperature Alarm will sound and LED indicators on the controller will flash. Press any button **except power button** to mute the alarm. Check if the air vents on the underside of the device are blocked, remove any items that may be blocking air vents. Resume treatment.

If high temperature condition persists, power OFF the device and remove the baby from the Skylife device. Contact treating physician, technician, or manufacturer.

System Failure Condition:

If any part of the device fails to perform as expected, a "System Failure' alarm will sound, LED indicators on controller will flash and the device will shut OFF automatically. Restart the device to see if it works. If the device shows the same error message or fails to power on, contact treating physician, hospital technician, or manufacturer.

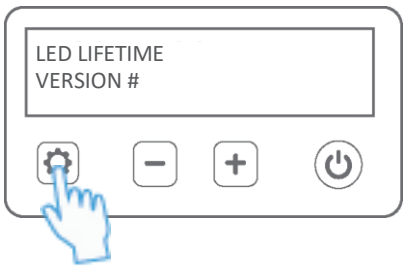
Accidental Power Disconnection:



If the power cable is accidentally unplugged from the wall socket, plug in the power cable back into the socket. The system will display a count down prior to automatically continuing treatment. To pause treatment, press the power button . To discontinue treatment, press and hold the power button.

⚠ **Caution**: The system will automatically restart treatment within 10 seconds of power application.

Settings:



Press Settings button to view the system settings. The Settings will display following information:

- LED Lifetime**
- Version Number

Only a certified technician may change these settings

IMPORTANT! User Safety: Sensitive individuals may experience headache, nausea or mild vertigo in case of prolonged exposure to illuminated surface. Using the Skylife device in a well-lit area or wearing glasses with yellow lenses can alleviate potential effects.

Monitor the baby during treatment.

IMPORTANT! Baby Monitoring: Regular monitoring during treatment is recommended. Use the following guidelines:

- Measure the baby's bilirubin level periodically during treatment per institutional procedures or treating physician's instructions.
- Turn off the treatment when checking the baby's condition and assessing skin color.
- Follow standard procedures for monitoring the baby's temperature and vital signs.
- Verify that the baby's eyes are protected and free of infection per institutional procedures or treating physician's instructions.

When treatment is completed, unplug the power supply and remove the device from the therapy area. Follow proper cleaning procedures according to your institutions guidelines before storing the device.

5.4 ROUTINE MAINTENANCE

PRIOR TO TREATMENT

1. Ensure the unit is unplugged from the Power Supply.
2. Inspect the GelMat for signs of wear or damage. Replace worn or damaged GelMat prior to treatment.
3. Place new CloudCover (Plus) on device.

Caution: Do not use damp wipes or liquids of any kind on the light emitting area as this may damage the device. Do not soak or spray water on the device.

DURING TREATMENT

Replace the CloudCover every 24 hours at a minimum. Should CloudCover become soiled for any reason:

1. Turn off the device and unplug the power cord from outlet.
2. Remove and discard CloudCover following institution practice.
3. Visually inspect GelMat and Light Bed for soil or liquid. Clean as required per institutional practices or as instructed below.
4. Allow the system to fully dry before continuing treatment.

CLEANING

The Skylife system consists of four (4) components: Light Bed with Controller, GelMat (mattress), CloudCover (disposable mattress cover), and the Power Supply. Only three of the four components are designed to be reused, the Light Bed, GelMat, and Power Supply. The CloudCover is disposable/single use only.

CloudCover & GelMat

The CloudCover protects the GelMat (mattress), and Light Bed from contamination during use. In the event that bodily fluids soak through the CloudCover to the GelMat, the GelMat may require cleaning. Do not remove GelMat during cleaning.

Cleaning and Disinfection Procedure

1. Unplug the device. Always turn off and disconnect the device from the power outlet during cleaning.
2. Remove CloudCover from device and discard. Make sure to replace CloudCover between patients, whenever soiled, or every 24 hrs, whichever occurs first.
3. Using recommended, pre-moistened disinfection wipes (such as Super Sani Cloth®), remove all visible contamination from the GelMat and verify under normal lighting. Do not remove GelMat during cleaning.
4. After all visible contamination has been removed, use disinfection wipes to thoroughly wet the exposed surfaces of the GelMat and exposed edges of the Light Bed.
5. Ensure that the surface remains visibly wet for 3 minutes at room temperature (68°F/20°C), or as specified by product instructions. Use additional wipes as needed to maintain a visibly wet surface.
6. Allow the surface to dry.
7. Follow this by using a clean damp cloth moistened only with clean water to rinse the same exposed surfaces. Repeat this at least 2 more times with a clean damp cloth or until any remaining chemical residues are removed.
8. If the device is determined not to be visibly clean after these steps, repeat the cleaning process or do not use the device.

Professional and Home Usage

For healthcare and home use, make sure to use the disposable CloudCover according to the directions above. The Skylife device is to be cleaned using standard cleaning cloths (such as Super Sani Cloth®) prior to use. You may clean the non-body contact areas such as the Light Bed, GelMat, controller, and power supply of the Skylife™ system using standard cleaning wipes (such as Super Sani Cloth®).

If the unit is cleaned in a healthcare setting, make sure to refer to the institutional cleaning procedures and requirements for cleaning the non-body contact areas such as the Light Bed, GelMat, controller, and power supply.

Caution: In either healthcare or home use setting, do not allow liquids to seep into the Light Bed housing. Do not use strong acidic and alkaline solutions, & do not autoclave or gas sterilize the Skylife. As mentioned above, always turn off the device and disconnect it from the power outlet during cleaning before reuse.

6. CUSTOMER SERVICE & MAINTENANCE

6.1 CUSTOMER SERVICE

Please contact Customer Service if you need assistance setting up, using, or maintaining your Skylife unit(s) or to report any unexpected operation or events. NeoLight Customer Service can be reached at **support@theneolight.com or (480) 626-0304.**

When returning any products, please include your name, address, phone number, and Return Material Authorization (RMA) number provided by Customer Service.

All product returns should be mailed to:
NeoLight LLC.
Attn: RMA # _____
1475 N. Scottsdale Rd. Suite 110, Scottsdale AZ 85257

6.2 REPAIR & MAINTENANCE

- Please contact NeoLight Customer Service in case of any damage or failure of the Skylife system.
- Do not attempt to repair any part of your Skylife unit(s). Never dismantle the system due to risk of electric shock. NeoLight LLC declines all responsibilities for any damages or consequences resulting from unauthorized attempts to open, modify/ repair the device.
- The following components must be replaced as directed for proper function of Skylife:

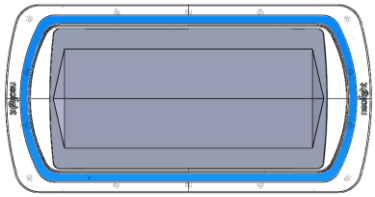
Part Name	Part Number	Recommended Replacement Time
LED Light Modules (pair)	SKY-LIM	25,000 hours of use as indicated on the controller
GelMat (Pack of 1)	SKY-GEL	Every 1,500 hours of treatment, or 6 calendar months, or if Light Intensity becomes reduced below calibrated levels, whichever occurs first.
CloudCover (Pack of 5)	CC-5	24 hours of use or if soiled
CloudCover (Single Unit)	CC-1	24 hours of use or if soiled
CloudCover Plus (Pack of 25)	CCP-25	24 hours of use or if soiled
CloudCover Plus (Pack of 5)	CCP-5	24 hours of use or if soiled
CloudCover Plus (Single Unit)	CCP-1	24 hours of use or if soiled
Eye Protection Micro	EP1M-5	Per Patient or if soiled
Eye Protection Preme	EP1P-5	Per Patient or if soiled
Eye Protection Newborn	EP1N-5	Per Patient or if soiled

- Follow appropriate steps in response to system alarms. Always contact the treating physician in the event that treatment with the Skylife device must be discontinued.
- The light intensity output of the Skylife device is calibrated at NeoLight prior to shipment. For home use, follow instructions provided by care provider regarding light intensity measurements. For hospital use, it is recommended to follow institutional practices or check light intensity prior to use with each patient.

⚠ **Improper Operation**: Use of accessories, cables and replacement parts other than those supplied by Neolight can increase electromagnetic emissions and decrease electromagnetic immunity resulting in improper system operation. Follow instructions supplied with parts to replace them.

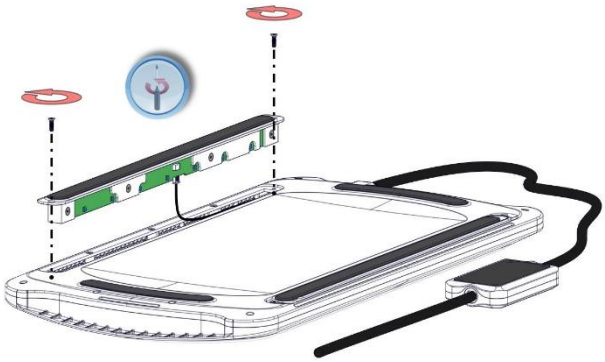
GelMat

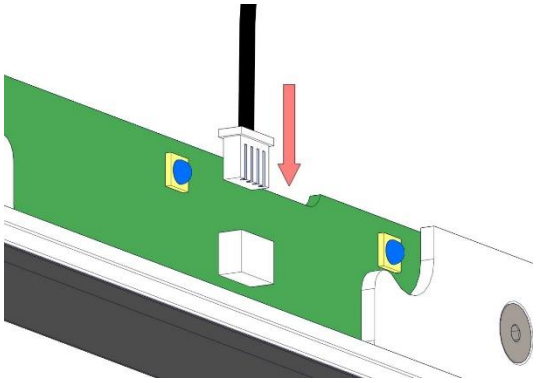
1. GelMat should be replaced if damage has been observed or if it becomes discolored.
2. GelMat should only be replaced by a biomed technician or other medical professional.
   If a new GelMat is needed, contact NeoLight Customer Service at (480) 626-0304
3. If installing a new GelMat, remove protective liners from the adhesive strips on the back of the GelMat.
4. Place GelMat on the Light Bed in the center of the device.



Light Module

1. Light Module should be replaced after 25000 hours of use.
2. Light Module should be replaced by a biomed technician or other medical professional.
3. To begin replacing the Light module, Position the Light Bed upside down. Locate and unscrew the two screws (6-32 x ½" Flat head machine screws) adjacent to the straight rubber feet, which secure the light modules as shown in the image
4. Gently lift the old Light Module from the Light Bed and rest the modules on the Light Bed.
   Note: Do not strain the connecting wires.
5. Carefully remove the Light Module data port by pulling the connector.
   Note: Always pull from the connector, not the wires, to prevent damage.
6. Align the new Light Module's data port with the connector and push firmly to secure the connection.
7. Gently place the Light module back into the Light Bed. Tighten the screws to 40 in-oz by using a calibrated torque screwdriver.
8. Repeat steps 3 to 7 for the other module to complete the installation.

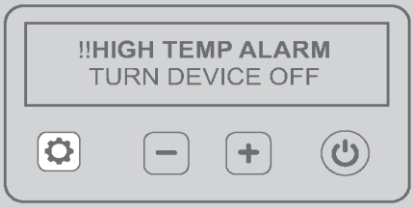
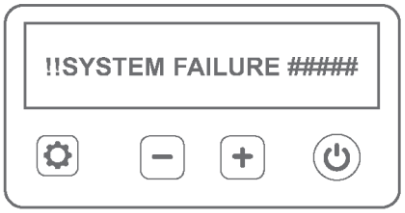




NOTE Technical Documentation

On request, NeoLight will provide those circuit diagrams, itemized parts listings, descriptions, and other items of available documentation to suitably qualified user personnel duly authorized by NeoLight for their use in repairing those components of the instrument that have been designated by their respective manufacturers as repairable.

Supply of such technical documentation relating to the equipment shall not be construed as constituting NeoLight's authorization of user's personnel, regardless of their levels of technical training, to open or repair the instrument. Explicitly exempted here are those maintenance and repair operations described in this manual.

Displayed Warnings & Alarms	Action
	Press any button on the keypad to acknowledge the warning. Verify that the vents are not blocked or covered, remove any obstructions. Treatment may continue unless alarm repeats. If alarm repeats, discontinue treatment and contact NeoLight Customer Service. Consult with treating physician for further treatment options.
	Press Power button to turn off device and suspend treatment for a minimum of 20 minutes to allow device to cool. Verify that the vents are not blocked or covered, remove any obstructions. Treatment may continue unless alarm repeats. If alarm repeats, discontinue treatment and contact NeoLight Customer Service. Consult with treating physician for further treatment options.
	Contact NeoLight Customer Service for troubleshooting.

6.3 CALIBRATION

The Skylife device has been calibrated to Z540 STANDARD TRACEABLE CALIBRATION. No calibration is required by the user.

6.4 LABELING STANDARDS

Skylife device labels have been designed to ISO 15223-1.

6.5 OPERATING CONDITIONS

The Skylife system should be operated in temperatures between 50°F and 98.6°F (10°C and 37°C), atmospheric pressures between 50 and 106 kPa (7.25psi to 15.37psi), and relative humidity between 15% and 90% RH.

6.6 TRANSPORTATION AND STORAGE

The Skylife device should be transported and stored in temperatures between -13°F and 122°F (-25°C and 50°C), atmospheric pressures between 50 and 106 kPa (7.25psi to 15.37psi) and relative humidity between 10% and 93% RH.

6.7 EXPECTED SERVICE LIFE AND DISPOSAL

The Skylife device is warranted to perform as expected for 3 years of normal use.

The Skylife device is a piece of electronic equipment and may include substances that can damage the environment. DO NOT dispose of the device in municipal waste. Please deliver the device to a suitable collection point for recycling of electronic equipment in accordance with local regulations.

6.8 WARRANTY

NeoLight, LLC ("NeoLight") warrants to the initial Purchaser ("Purchaser") that each Covered Component of each new Product, as such terms are defined below, purchased hereunder will be free from defects in workmanship and materials for the applicable period of indicated below (each, a "Warranty Period") from the date of the Product's initial shipment to Purchaser.

Three years for the Skylife Phototherapy System (the "Product") including all components of the Product, excluding the Disposable Parts (collectively with the Light Modules, the "Covered Components").

The GelMat, the CloudCover or CloudCover Plus, or other expendable or disposable parts of the Product are the "Disposable Parts."

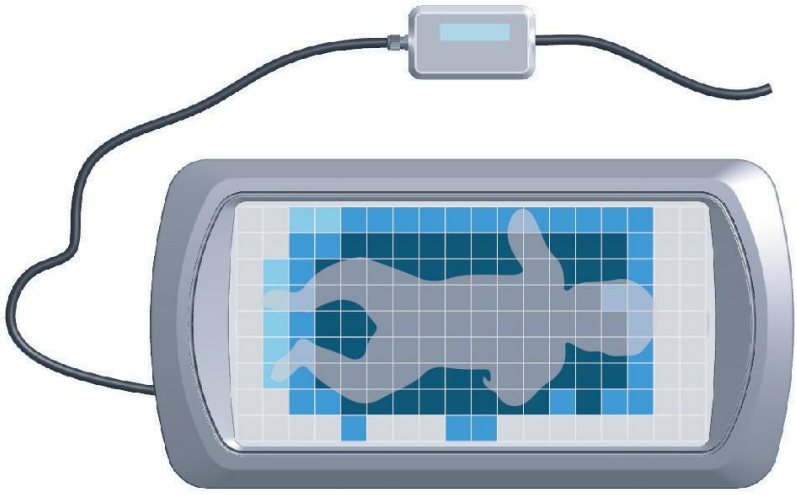
7. TECHNICAL SPECIFICATIONS

7.1 ELECTRICAL

AC Power	100-240 VAC, 50-60 Hz, 1.0A/115V- 0.5A/230V
Type of Protection Against Electrical Shock	Class II Equipment
Degree of Protection Against Electrical Shock	Type BF Applied Part
Degree of Protection Against Ingress of Water	IP23
Mode of Operation	Continuous

7.2 LIGHT DISTRIBUTION

**Actual results may vary*



Light Intensity distribution map on Bed (with GelMat and CloudCover). Maximum intensity in the center.

The ratio of minimum to maximum measured intensity across the effective surface area is >0.4 (avg. 0.79).

(The CloudCover attenuates an average of 10.0 µW/cm²/nm.)

7.3 PHYSICAL

Physical Specifications	
Device Dimensions	23.94” L x 12.25” W x 1.91” H (60.81 x 31.12 x 4.85 cm)
Device Weight	<11lbs (5 kg)
Patient Area	21.41” L x 10.24” W (54.38 x 26 cm)
Effective Surface Area	119in^2 (769 cm^2)
Light Distribution Ratio (min to max)	>0.4 (avg. 0.79)
Controller Dimensions	4.75” L x 2.75” W x 0.89” H (12.07 x 7 x 2.26 cm)
Controller Weight	<0.5lbs (0.23 kg)
Length of device cord to controller	20” (50.8 cm)
Length of connecting cord between controller and power adapter	53” (134.62 cm)
Length of power cord from adapter to plug	66.5” (168.91 cm)
Storage and Transportation Conditions	
Temperature	-25°C to +50°C (-13°F to 122°F)
Relative Humidity	10%-93% RH Non-condensing
Operating Conditions	
Temperature	10°C to 37°C (50°F to 98.6°F)
Relative Humidity	15%-90% RH Non-condensing

*Specifications subject to change without notice.

7.4 COMPLIANCE DECLARATION

IEC 60601-1: 2005, 3rd Edition ANSI/AAMI ES60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2: 2014, 4th Edition	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC 60601-1-6: 2010, 3rd Edition	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability
IEC 60601-1-11: 2015	Medical electrical equipment - Part 1-11: Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment used in the home healthcare environment
IEC 60601-2-50: 2012, 2nd Edition	Medical electrical equipment - Part 2-50: Particular requirements for the safety of infant phototherapy equipment
IEC 60601-1-8: 2006	Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62304: 2006	Medical device software — Software life cycle processes

7.5 STABILIZATION TIME

The Skylife Phototherapy System does not require a pre-aging time. It is ready for use immediately after it is turned on the initial time.

The Skylife Phototherapy System does not require a stabilization period. It is ready for use immediately after it is powered ON.

7.6 GUIDANCE & MANUFACTURER'S DECLARATION

Electromagnetic Compatibility (EMC)

The Skylife system is suitable for the electromagnetic environment of typical homes, commercial or hospital settings. During the immunity testing described below the Skylife device continued to deliver treatment at a wavelength of 430-475 nm at an intensity between 25 to 72 µW/cm^2/nm.

Warning

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Skylife device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The Skylife unit should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation. If operation is not normal, the Skylife device or the other equipment should be relocated.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Electromagnetic Emissions		
Skylife™ is intended for use in the electromagnetic environment specified below. The customer or the user of Skylife™ should assure that it is used in such an environment.		
Emission Tests	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	Skylife™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Skylife™ is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity		
Skylife™ is intended for use in the electromagnetic environment specified below. The customer or the user of Skylife™ should assure that it is used in such an environment.		
Immunity Test	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± 15kV air	The relative humidity should be at least 5 %
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines	Mains power quality should be that of a typical home commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode	Mains power quality should be that of a typical home commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% .5 Periods 0% 1 Period 70% 25 Periods 0% 5 sec	Mains power quality should be that of a typical home commercial or hospital environment. If the user of Skylife™ requires continued operation during power mains interruptions, it is recommended that Skylife™ is powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	Power frequency magnetic fields from common appliances in the home are not expected to affect the device. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Keep Skylife™ away from sources of high levels of power line magnetic fields (in excess of 30 A/m) to reduce the likelihood of interference."
NOTE: U_T is the A/C. mains voltage prior to application of the test level.		
Skylife™ is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 6 Vrms in ISM and amateur radio bands	Skylife™ is suitable for the electromagnetic environment of typical homes, commercial or hospital settings.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	

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