

Firefly[®]

phototherapy

MTTS



User Manual



Infant Phototherapy for Jaundice Treatment



Firefly

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Contents

Company information	04
Introduction	05
Device description	06
Safety information	08
Setting up the device	11
Using the device	12
Alarm system	13
Battery backup (optional)	15
Examination light	16
Cleaning and disinfection	17
Irradiance measurement	18
Irradiance measurement criteria	19
Disposal	20
Specifications	21
Explanation of symbols	23
Warranty policy	24



Company information



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Introduction

Intended purpose

Firefly Phototherapy is intended to provide phototherapy to treat infant jaundice when phototherapy is required and prescribed by a physician.

Intended users

- a) The device is to be operated by qualified personnel only.
- b) Knowledge (minimum):
 - Understands basic principles of phototherapy
 - Understands the specialized care needed for pre-term and full-term neonates
- c) Language understanding: can read and comprehend the user manual
- d) Experience (minimum): qualified medical professional with experience in neonatal care

Intended patient population

- Age: infants
- Weight: < 10 kg
- Nationality: any
- Patient status: the patient is not user

Indications

Infants with high serum bilirubin or a rapidly rising bilirubin level.

Contraindications

Few contraindications to phototherapy are recognized. These include:

- Neonates with congenital erythropoietic porphyria
- Family history of porphyria
- Concurrent treatment with photosensitising drugs

Limitations

- The effective surface area is 48 cm x 20 cm (960 cm²).

Clinical Benefit

The clinical benefit to the patient is an average 45,6% reduction of total serum bilirubin (TSB) after an average 53-hour treatment based on the clinical evaluation including publicly available data and clinical data collected by the manufacturer.

Side effects

All phototherapy methods have possible side effects including: thermal imbalance and water loss, skin lesions, bronze baby syndrome, disorder of circadian rhythms, patent ductus arteriosus, ocular effects, allergic diseases such as asthma, rhinitis, and conjunctivitis.

NOTE: Any serious incident that has occurred in relation to the device should be reported to MTTS and the competent authority of the Member State in which the user and/or patient is established.

Device description

Overview



1. Top light

Blue light shines onto the top side of the patient.

2. Bassinet

A removable plastic bassinet is used to carry the patient and hold the patient during treatment.

3. Control panel

ON / OFF button and the display, which shows treatment time and total device hours.

4. Lower light

Blue light shines through a window onto the under side of the patient.

5. Heat sink

Heat from the LED light source escapes from below the device, ensuring the device remains at a safe operating temperature.

Device description

Control panel



The control panel is located at the front of the device.

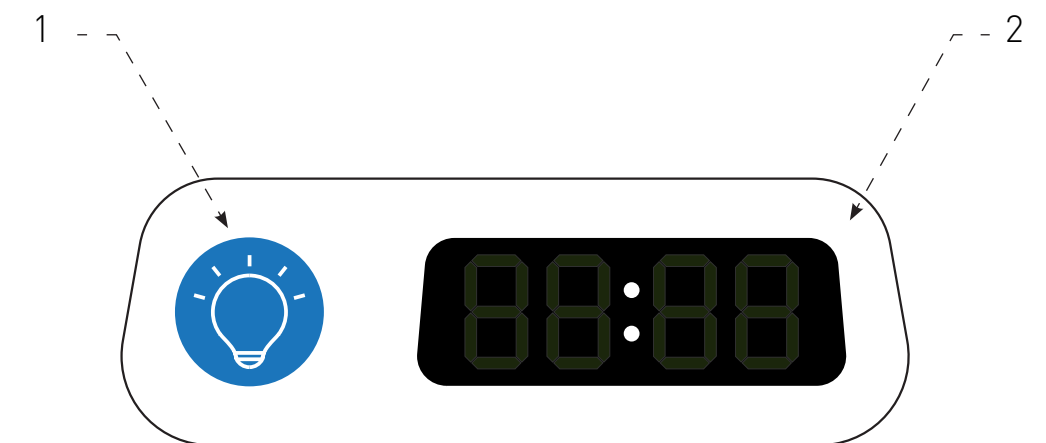
The image above shows the control panel, which consists of:

1. Power button

Turns the device ON/OFF and switches between the blue treatment light and the white examination light.

2. Display

Shows the "treatment time", as well as "total hours of use of the device".



Safety information



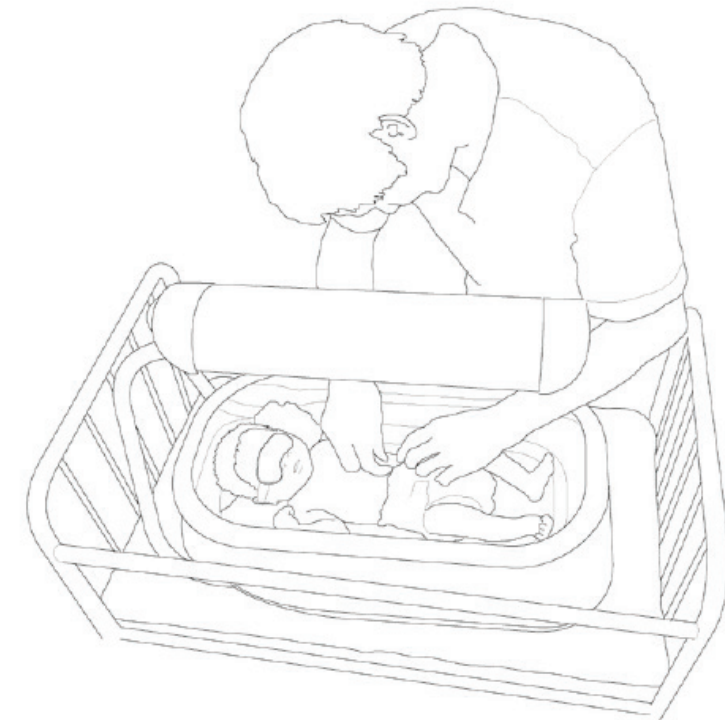
Warnings

- When using Firefly Phototherapy the patient should ALWAYS be placed in the bassinet.
- Firefly Phototherapy has been designed so that the bassinet is removable. The patient should be placed in the bassinet then the bassinet into the device to ensure patient comfort and safety.
- Always cover the patient's eyes with a shield or patch whenever they can be exposed to the device's light. Periodically, you may want to ensure that the baby's eyes are protected and infection free.
- Patient's bilirubin values should be measured regularly while undergoing phototherapy treatment.
- To accurately assess the baby's skin colour turn off the light when checking the baby's condition.
- Regularly monitor the patient's temperature and fluid status.



Safety information

- Firefly Phototherapy should be used only by appropriately trained personnel and under the direction of qualified medical personnel familiar with currently known risks and benefits of infant phototherapy equipment use.
- Patients adjacent to the infant phototherapy equipment may need to be protected with protective shields or eye protection.
- The operator may experience some effects during prolonged exposure to the area irradiated by the infant phototherapy equipment.*
- Blue light can hinder clinical observations by masking skin colour changes, such as cyanosis.
- An infant's water balance may be influenced by phototherapy. Regular feeding times may need to occur more often in order to prevent dehydration.
- Varying the ambient conditions (ambient temperature and/or different radiation sources) may negatively affect the patient. Refer to your hospital phototherapy policy and procedure regarding appropriate ambient conditions.
- Bilirubin photoisomers may be toxic.



*Sensitive individuals may experience headache, nausea or mild vertigo if he/she stays too long in the illuminated area. Using the device in a well-lit area or wearing glasses with yellow lenses can alleviate potential effects. Guard Dog Bones glasses (p/n 413BB) are recommended and are available online at www.safetyglasses.com

Safety information

NOTE

- DO NOT carry Firefly Phototherapy while the patient is in the device.
- DO NOT place the patient directly on the window of the lower light.
- DO NOT place Firefly Phototherapy inside an incubator.
- DO NOT use Firefly Phototherapy with an MTTS infant warmer, or any other warmer as this will cause damage to the top light of the device.
- DO NOT disassemble any part of Firefly Phototherapy (excluding the removal of the bassinet).
- DO NOT place Firefly Phototherapy in direct sunlight.
- DO NOT use Firefly Phototherapy if it appears that any part of the device is not functioning properly or if any parts appear damaged. Contact MTTS.
- In case of any malfunction, DO NOT attempt to service this device. Firefly Phototherapy should only be serviced by a qualified MTTS technician.
- Due to photo effects, drugs and infusion liquids should not be stored in the radiation area.
- Do not use the device in the presence of potentially combustible gases including oxygen, nitrous oxide or other anaesthetics.

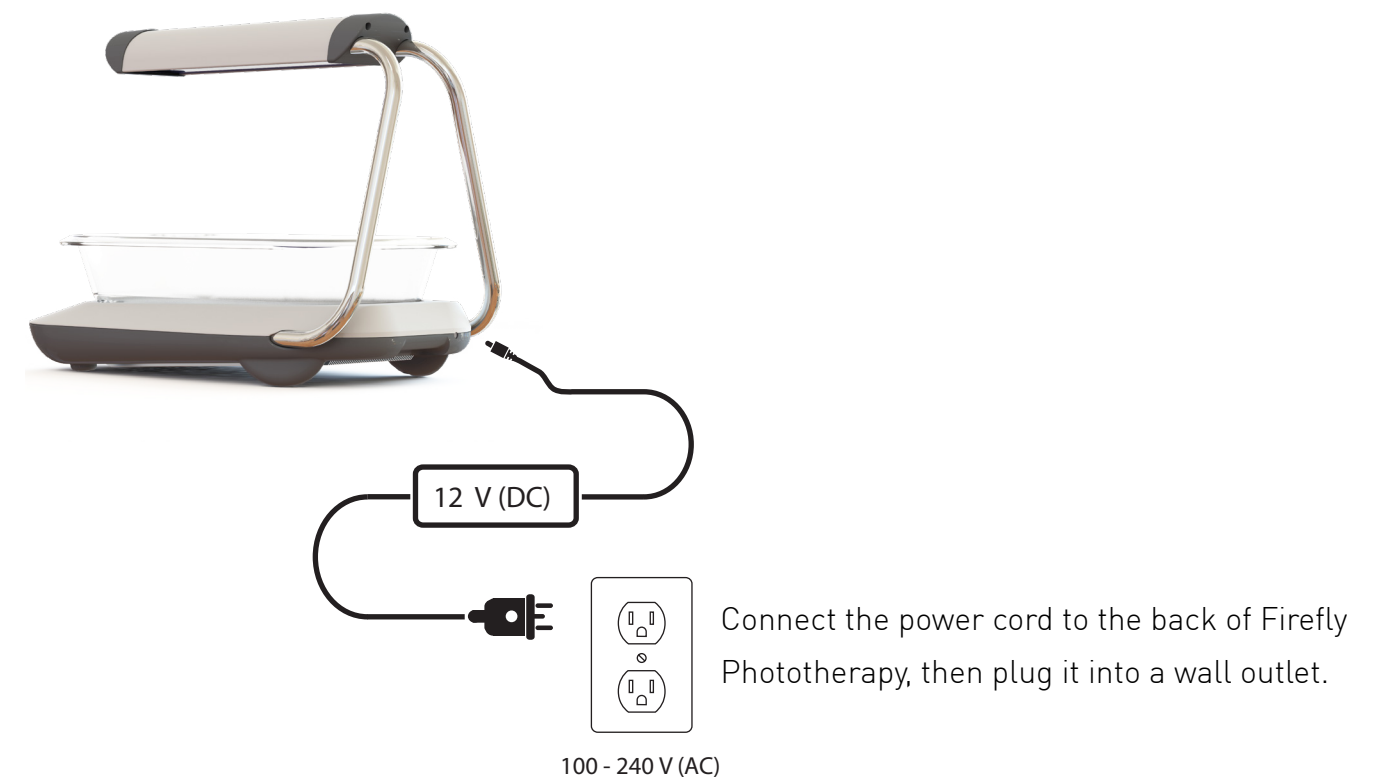
Note: In the event of a power outage, eye protection should be left on the patient whenever they are inside Firefly Phototherapy to protect the patient's eyes in case the power returns.

Setting up the device

The content of the box

- Firefly Phototherapy unit
- External power supply
- Bassinet

Plug in and power up



NOTE

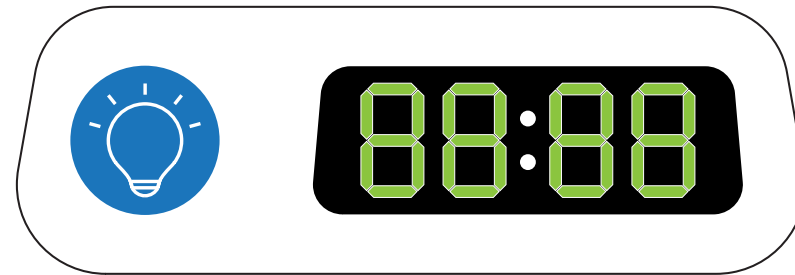
- Use only the cable and connector provided by MTTS.
- The device should only be used with the power outlets that have a protective earth (ground) pin.

Using the device

Plug in the device.

The device recognises the connection by illuminating every LED on the Control Panel display.

This is displayed for just a few moments before returning to a blank screen.



Turn on the device.

The display shows the “total hours of use of the device”.

The “total hours of use of the device” is a multiple of 10 of what is actually displayed.

This information is displayed for 3 seconds.

In this example, the device has been used for 17,500 hours.



The blue phototherapy lights start to illuminate.

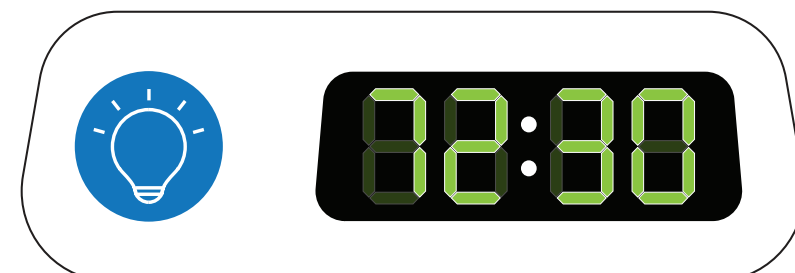
The display starts counting the “treatment time”.

In this example, the device has been operating for 1 minute.



Once the treatment is concluded, the device can be turned off by pressing the Power button.

In this example, the device has been used for 72 hours 30 minutes.



Alarm system

Error messages: If Firefly Phototherapy has a minor error, the error number will be displayed on the control panel.

If such an error occurs, this message will appear for 5 seconds after the device is connected to the power supply but before the device is switched on.

Firefly Phototherapy is still safe to operate, however, please contact MTTs and quote the error number and device serial number. This error number will help the MTTs technical team identify and solve the problem.

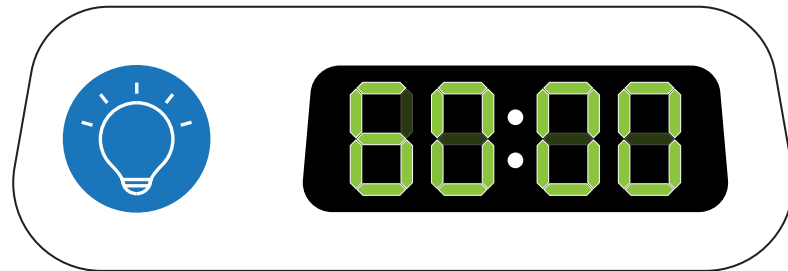


The image above shows when exactly in the ‘start-up’ process the error message will be displayed.

General warning: In the rare occurrence when Firefly Phototherapy experiences a more serious error that causes the blue lights to turn off, immediately remove the patient from the device, as they will not be receiving any phototherapy. An error code will be shown on the display panel, this error will most likely correct itself and the device will automatically turn back on and resume therapy. Otherwise please contact MTTs and report the error code.

Alarm system

LEDs lifetime warning: The blue LEDs in Firefly Phototherapy are rated to provide effective treatment for 60,000 hours.



After turning ON the device the display will show the “total hours of use of the device” This particular example shows 60,000 hours.



At 60,000 hours and anytime after 60,000 hours E04 code will be displayed. This indicates that the LEDs have reached the recommended service life. This message will appear for 5 seconds after the device is switched on after the total device hours have been displayed for 3 seconds. After that, E04 and the total device hours will alternate every second.



The blue phototherapy lights will turn ON and the treatment will start as normal. The display will show the “treatment time” again.

Note: the estimated 60,000-hour service life is equal to a full 7 years of non-stop use. After this period of time the LED phototherapy lights will continue to function, however, treatment will be significantly less effective and Firefly Phototherapy should be replaced.

Battery backup (optional)

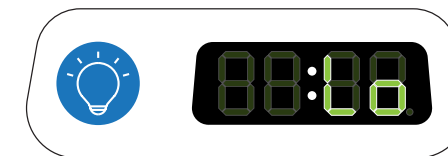
Battery backup

The battery backup allows the device to operate for 2 hours without AC power supply. The backup activates automatically as soon as the AC power supply is off.

When the battery charge level reaches zero, the visual alarm (blinking top light) goes off. The message displayed is:



Treatment time: 1 sec



‘Low’: 0.5 sec



‘Battery’: 0.5 sec

If no action is taken during the 120-second alarm, the device powers off. If during the alarm ‘power button’ is pressed, the alarm is deactivated and the device enters the **E-mode**.

E-mode - extended battery operation

E-mode allows using the battery for extended period of time (additional 2 hours). During that time the battery is discharged further. To activate the ‘E-mode’ press ‘power button’ during the 120-second low battery alarm.

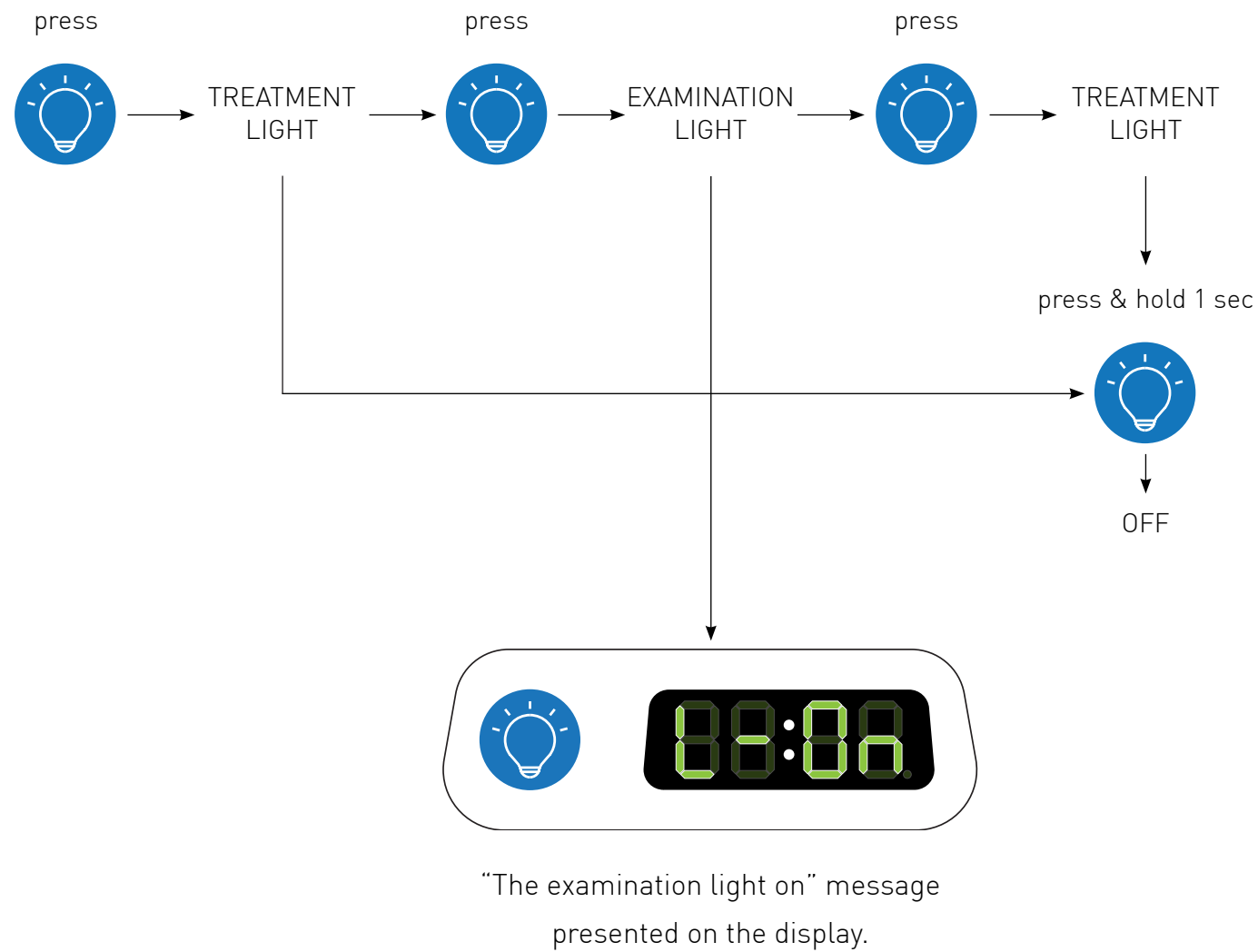
NOTE

- To protect the batteries and prolong their lifetime **E-mode** should be used only in emergency situations.

Examination light

Examination light

To activate the white examination light use the power button following the sequence:



Cleaning and disinfection

- The device bassinet should be disinfected, before and after the treatment of each patient. If a patient undergoes treatment for more than one week, disinfect the bassinet at least once a week.
- If visibly soiled, clean the affected parts with soap and water using a soft cloth. Then wipe with a wet cloth and dry with a soft cloth. For difficult areas use a standard soft-bristled brush.
- To loosen heavy, dried-on soil, you may first need to saturate the spot with water.
- **Only disinfect the bassinet** with a solution containing at least 70% alcohol.
- Apply the disinfectant with a clean cloth or soft sponge. Wait for the device to dry after cleaning or disinfecting before use.

NOTE

- When cleaning the device disconnect the power cord.
- DO NOT use alcohol to disinfect any other part of the device.
- DO NOT immerse any part of the device in water or alcohol.



Irradiance measurement

Note: to ensure that the device is functioning properly, regularly monitor the device in the following way.

Measurement instructions:

To test the irradiance of Firefly Phototherapy measure using a lightmeter specifically designed to measure wavelengths for phototherapy, preferably a double sided such as MTTS LM-800.

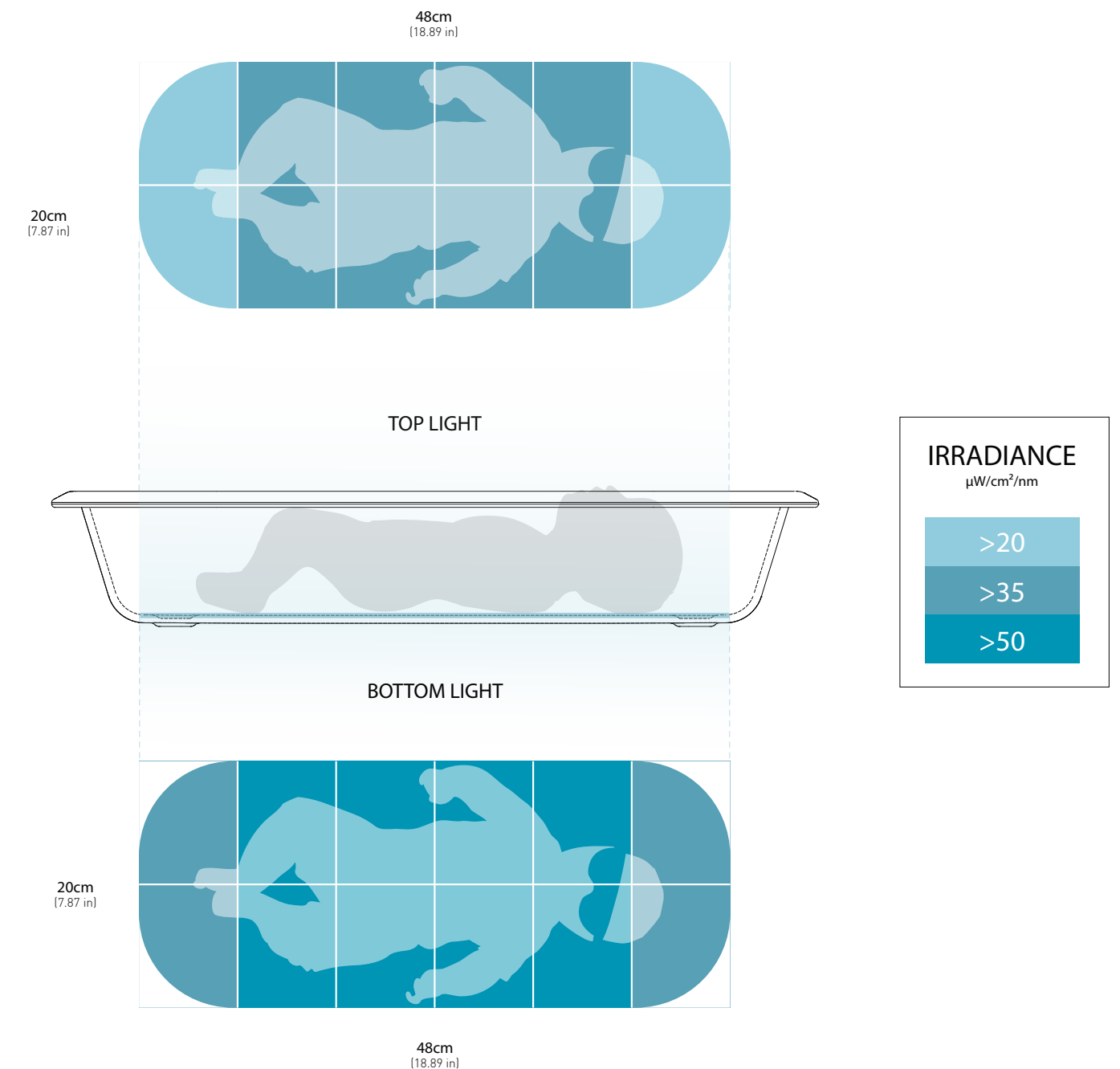
A stabilization time of 2 hours of continuous operation is required for accurate measuring of the irradiance.

Measure each of the sections of the bassinet seen in the adjacent picture. Compare the measurements to the expected values assuming some decay over time.

Irradiance measurement criteria

The light output will decrease gradually over time, reaching approximately 70% of their original irradiance at 60,000 hours.

Note that the irradiance should be measured when the device has reached 60,000 hours. After 60,000 hours the device should be replaced with a new one.



Disposal

1. This medical device is classified as electrical and electronic equipment (EEE) as per 2012/19/EU
2. The presence of hazardous substances in EEE poses serious environmental risks (soil contamination, water pollution, air pollution, biodiversity loss, resource depletion) and health risks (toxic exposure, neurological damage, cancer risk, respiratory issues, reproductive health issues).
3. Users have a vital role in the lifecycle of electronic products. By taking proactive steps in re-use, recycling, and recovery, they can significantly reduce the environmental impact of waste electrical and electronic equipment (WEEE) and contribute to a more sustainable future.

NOTE

- Do not dispose of WEEE as unsorted municipal waste and collect such WEEE separately.
- Return the medical device considered to be WEEE to the nearest collection point when it's ready for disposal. The collection points near you can be found here: <https://weee-directory.com/>

Specifications

Performance Specifications

Illumination source		High-power blue LEDs, 1-1.25W standard operating	
Peak wavelength		465 - 485 nm	
Lamp duration		60,000 hours	
Peak irradiance	top light	>37 µW/cm2/nm	
	bottom light	>57 µW/cm2/nm	
Effective surface area	top light	48 cm x 20 cm	
	bottom light	48 cm x 20 cm	
Relative local distribution	top light	0.63 (IEC Compliant >0.4)	
	bottom light	0.64 (IEC Compliant >0.4)	
Time totalizer		Treatment time and total device hours	
Measured with		an MTTs LM-800	

Physical Specifications

Key features		No moving parts	
		Enclosed designed toward NEMA Type 5	
Dimensions (LxWxD)	overall	66 cm x 38 cm x 49.5 cm	26in x 4.9in x 19.5in
	top light	51.6 cm x 12.5 cm x 6.3 cm	0.3in x 4.9in x 2.5in
	bottom light	64.7 cm x 38 cm x 10cm	25.5in x 15in x 3.9in
Total unit mass		13 kg	28.7lbs

Electrical Specifications

Power characteristics		60W, 100-240VAC, 47/63Hz	
Off-the-shelf internal power supply		Part No. Sinpro MPU60A-105	
		International medical safety approvals	
		(ANSI/AAMI/EN 60601-1, UL/TUV)	
		Class I construction is standard (ground required)	
		100k hours MTBF	
		Energy Star Efficiency Level V compliant	
		RoHS 3 compliant	
		Overvoltage/overcurrent protection	
		Continuous service	
Power Cords (length: 3m)		North America	(part 50-07302-01)
		C.E.	(part 50-07305-01)
		U.K.	(part 50-09273-01)

Specifications

Environmental Specifications

Operating	Ambient temperature +10°C to +35°C Humidity: 0% to 90% RH non condensing Atmospheric pressure: 70-106kPa
Transport and storage	Ambient temperature 0°C to +50°C Humidity: 0% to 90% RH non condensing Atmospheric pressure: 70-106kPa
Exclusions	Not for use inside an incubator and or any radiant warmer

Referenced standards

EN 60601-1:2006 + A1:2013: Medical electrical equipment – Part 1 General requirements for basic safety and essential performance

EN 60601-1-2:2015: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

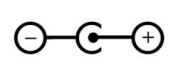
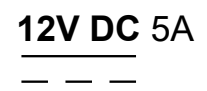
EN 60601-2-50: 2009: Medical electrical equipment – Part 2-50: particular requirements for the basic safety and essential performance of infant phototherapy equipment

EN 60601-1-6:2010: Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

Biocompatibility tests

- Skin sensitization as per ISO: 10993-Part 10
- Cytotoxicity direct contact as per ISO 10993-Part 5
- Primary skin irritation as per ISO:10993-Part 10

Explanation of symbols

	WARNING. Not following this statement could result in injury to the patient or the operator, or damage the device.		Authorized Representative in the European Union
	Consult instructions for use or the electronic instructions for use (ISO 15223-1)		Device manufacturer.
	Consult instructions for use or the electronic instructions for use (EN 60601-1)		Date of manufacture (YYYY-MM)
	This device contains electronic parts. Do not dispose of it with normal waste. Dispose of it according to local guidelines for disposal of electronics. Dispose according to the WEEE directive in the European Union.		Keep out of direct sunlight.
	Medical device		Liquid ingress protection - level 3 (spraying water).
	Unique device identifier		An eye patch should always be placed on the patient before commencing treatment.
	Model number		DO NOT use Firefly Phototherapy with an MTTS infant warmer, or any other warmer as this will cause damage to the device's top light.
	Serial number.		Power supply polarity.
	Website where a user can obtain additional information on the medical product		12 Volts, Direct Current, 5 Ampere
			Temperature limit
			Humidity limitation
			Atmospheric pressure limitation

Warranty policy

General Terms

This MTTS Limited Warranty gives you, the customer, express limited warranty rights from MTTS, the manufacturer for the duration specified on the Warranty Card. Please refer to the MTTS Website for an extensive description of your limited warranty entitlements. In addition, you may also have other legal rights under applicable law or special written agreement with MTTS.

MTTS MAKES NO OTHER EXPRESS WARRANTY OR CONDITION WHETHER WRITTEN OR ORAL AND MTTS EXPRESSLY DISCLAIMS ALL WARRANTIES AND CONDITIONS NOT STATED IN THIS LIMITED WARRANTY. TO THE EXTENT ALLOWED BY LOCAL LAW OF JURISDICTIONS OUTSIDE VIETNAM, MTTS DISCLAIMS ALL IMPLIED WARRANTIES OR CONDITIONS, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. FOR ALL TRANSACTIONS OCCURRING IN VIETNAM ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY, SATISFACTORY QUALITY, OR FITNESS FOR A PARTICULAR PURPOSE IS LIMITED TO THE DURATION OF THE EXPRESS WARRANTY SET FORTH ABOVE. SOME COUNTRIES DO NOT ALLOW A LIMITATION ON HOW LONG AN IMPLIED WARRANTY LASTS OR THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES FOR CONSUMER PRODUCTS. IN SUCH COUNTRIES, SOME EXCLUSIONS OR LIMITATIONS OF THIS LIMITED WARRANTY MAY NOT APPLY TO YOU. FOR CONSUMER TRANSACTION, THE LIMITED WARRANTY TERMS CONTAINED IN THIS STATEMENT, EXCEPT TO THE EXTENT LAWFULLY PERMITTED, DO NOT EXCLUDE, RESTRICT, OR MODIFY BUT ARE IN ADDITION TO THE MANDATORY STATUTORY RIGHTS APPLICABLE TO THE SALE OF THIS PRODUCT TO YOU.

This Limited Warranty is applicable in all countries and may be enforced in any country or region where MTTS or its authorized service providers offer warranty service for the same product model number (subject to the terms and conditions set forth in this Limited Warranty)

Under this Limited Warranty, products purchased in one country or region may be transferred to another country or region where MTTS or its authorized service providers offer warranty service for the same product model number. Warranty terms, service availability, and service response times may vary from country or region to country or region. Standard warranty service response time is subject to change due to local parts availability. If so, your MTTS authorized service provider can provide you with details. MTTS will not alter form, fit, or function of this MTTS product to make it operate in a country for which it was never intended to function for legal or regulatory reasons. MTTS is not responsible for any tariffs or duties that may be incurred in transferring the products.

MTTS guarantees that the product that you have purchased or leased from MTTS is free from defects in materials or workmanship under normal use during Limited Warranty Period. The Limited Warranty Period starts on the date of purchase or lease from MTTS, or from the date MTTS completes installation. Your dated sales or delivery receipt, showing the date of purchase of the product, is your proof of the purchase or lease date. You may be required to provide proof of purchase or lease as a condition of receiving warranty service. You are entitled to hardware warranty service according to the terms and conditions of this document if a repair to your MTTS product is required within the Limited Warranty Period.

Unless otherwise stated, and to the extent permitted by local law, new MTTS product may be manufactured using new materials and used materials equivalent to new in performance and reliability. MTTS may repair or replace MTTS products (a) with new or previously used products or parts equivalent to new in performance and reliability, or (b) with equivalent products to an original product that has been discontinued. Replacement parts are warranted to be free from defects in material or workmanship for ninety (90) days or, for the remainder of Limited Warranty Period of the MTTS product they are replacing or in which they are installed, whichever is longer.

Warranty policy

MTTS will, at its sole discretion, repair or replace any components or product that manifests a defect in materials or workmanship during the Limited Warranty Period. All component parts removed under this Limited Warranty become the property of MTTS. In the unlikely event that your MTTS product has recurring failures, MTTS at its sole discretion, may elect to provide you with (a) a replacement unit selected by MTTS that is the same or equivalent to your MTTS product in performance or (b) to give you a refund of your purchase price or lease payments (less interests) instead of a replacement. This is your exclusive remedy for defective products.

Exclusions

MTTS DOES NOT WARRANT THAT THE OPERATION OF THIS PRODUCT WILL BE UNINTERRUPTED OR ERROR-FREE. MTTS IS NOT RESPONSIBLE FOR DAMAGE THAT OCCURS AS RESULT OF YOUR FAILURE TO FOLLOW THE INSTRUCTIONS INTENDED FOR THE PRODUCT.

This Limited Warranty does not apply to expendable or consumable parts and does not extend to any product from which the serial number has been removed or that has been damaged or rendered defective (a) as a result of accident, misuse, abuse, contamination, improper or inadequate maintenance or calibration (if required) or other external causes; (b) by operation outside the usage parameters stated in the user documentation shipped with the product; (c) by software, interfacing, parts or supplies not supplied by MTTS; (d) improper site preparation or maintenance; (e) virus infection; (f) loss or damage in transit ; or (g) by modification or service by anyone other than (i) MTTS personnel, (ii) an MTTS authorized service provider, or (iii) your own installation of end-user replaceable MTTS or MTTS approved parts if available for your MTTS product in the servicing country or region.

Limitation of Liability

IF YOUR MTTS PRODUCT FAILS TO WORK AS WARRANTED ABOVE, THE MAXIMUM LIABILITY OF MTTS UNDER THIS LIMITED WARRANTY IS EXPRESSLY LIMITED TO THE LESSER OF THE PRICE YOU HAVE PAID FOR THE PRODUCT OR THE COSTS OF REPAIR OR REPLACEMENT OF ANY HARDWARE COMPONENTS THAT MALFUNCTION IN CONDITIONS OF NORMAL USE.

EXCEPT AS INDICATED ABOVE, IN NO EVENT WILL MTTS BE LIABLE FOR ANY DAMAGES CAUSED BY THE PRODUCT OR THE FAILURE OF THE PRODUCT TO PERFORM, INCLUDING ANY LOST PROFITS OR SAVINGS OR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES. MTTS IS NOT LIABLE FOR ANY CLAIM MADE BY A THIRD PARTY OR MADE BY YOU FOR A THIRD PARTY.

THIS LIMITATION OF LIABILITY APPLIES WHETHER DAMAGES ARE SOUGHT, OR CLAIM MADE, UNDER THIS LIMITED WARRANTY OR AS A TORT CLAIM (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), A CONTRACT CLAIM, OR ANY OTHER CLAIM. THIS LIMITATION LIABILITY CANNOT BE WAIVED OR AMENDED BY ANY PERSON. THIS LIMITATION OF LIABILITY WILL BE EFFECTIVE EVEN IF YOU HAVE ADVISED MTTS OF THE POSSIBILITY OF ANY SUCH DAMAGES. THIS LIMITATION OF LIABILITY, HOWEVER, WILL NOT APPLY TO CLAIMS FOR PERSONAL INJURY.

THIS LIMITED WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS. YOU MAY ALSO HAVE OTHER RIGHTS THAT MAY VARY FROM COUNTRY TO COUNTRY. YOU ARE ADVISED TO CONSULT APPLICABLE COUNTRY LAWS FOR A FULL DETERMINATION OF YOUR RIGHTS.

Warranty Policy

Limited Warranty Period

The Limited Warranty Period for this MTTS product is a specified, fixed period commencing of the date of purchase and specified on the Warranty Card. The date on your sales receipt is the date of purchase unless MTTS or your reseller informs you otherwise in writing.

Customer Responsibilities

In order to avoid the risk of charges for issues not covered by your limited warranty (issues that are not due to defects in materials and workmanship on MTTS product), you will be asked to assist MTTS as follows:

- Verify configurations, load most recent firmware, install software patches, run MTTS diagnostics and utilities;
- Implement temporary procedures or workarounds provided by MTTS while MTTS works on permanent solution;
- Cooperate with MTTS in attempting to resolve the problem using online chat, email, or telephone. This may involve performing routine diagnostic procedures, installing additional software updates or patches;
- Perform additional tasks as defined within each type of warranty service provided by MTTS and any other actions that MTTS may reasonably request in order to best perform the warranty support

CUSTOMER IS RESPONSIBLE FOR DELIVERING THE PRODUCT (AND ALL COSTS INVOLVED) FROM HIS LOCATION TO THE MTTS AUTHORIZED SERVICE POINT.

Contacting MTTS

If your MTTS product fails during the Limited Warranty Period and the suggestions in the product documentation do not solve the problem, you can receive support by doing one of the following:

- Locate and contact your nearest MTTS service provider via MTTS website:
<http://www.mtts-asia.com/support/>
- Call the Technical Support Centre:
+84 24 3766 6521

Before calling MTTS or an MTTS authorized service provider please have the following information available:

- Product serial number and model name
- Applicable error messages
- Detailed questions





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