

Firefly[®]

phototherapy



User Manual

MD

Infant Phototherapy for Jaundice Treatment

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Firefly

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Company Information



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Introduction

Intended purpose

The Firefly Phototherapy is intended to provide phototherapy to treat infant jaundice when a 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 user manual
- d) Experience (minimum): Qualified medical professional with experience neonatal care

Intended patient population

- Age: Infants
- Weight: < 10kg
- Nationality: Any
- Patient State: patient is not user

Indications

Infant 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).
- The maximum height of the light source is 140 cm.
- The minimum height of the light source is 115 cm.

Clinical Benefit

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

Side effects

All phototherapy methods have possible side effects including: imbalance of thermal environment 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 Firefly, ensuring the device remains at a safe operating temperature.

Device Description

Control Panel



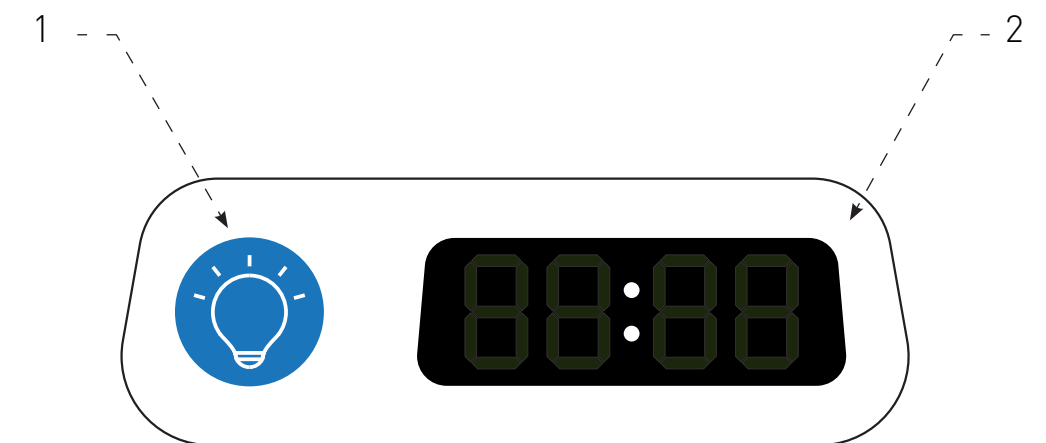
The control panel is located at the front of the Firefly device.
The image above shows the control panel, which consists of:

1. Power button

Turns the device ON and OFF.

2. Display

Shows the 'treatment time', as well as 'total device hours' of Firefly usage.



Safety Information



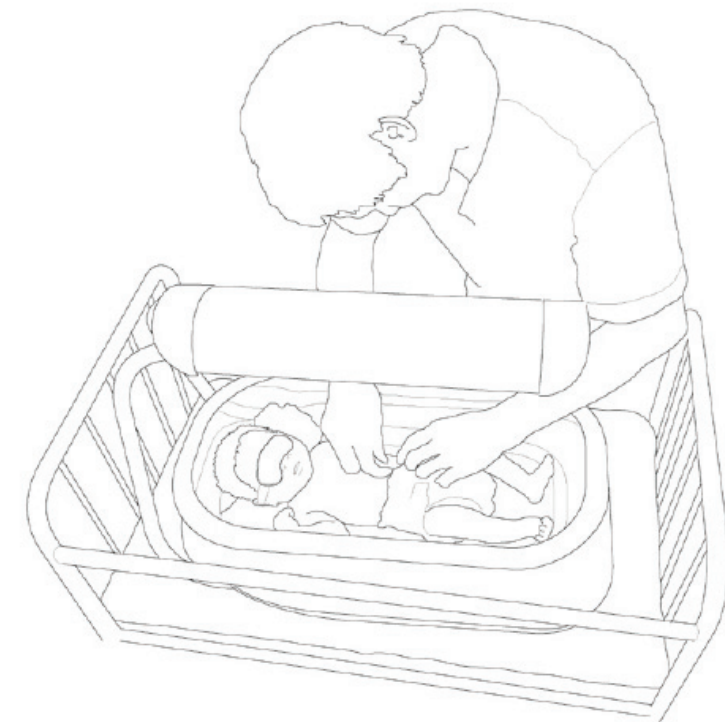
Warnings

- When using Firefly phototherapy the patient should ALWAYS be placed in the bassinet.
- The Firefly 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 patients eye's with a shield or patch whenever the patients eye's can be exposed to the Firefly'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

- The 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 Firefly in a well-lighted 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



Caution

- DO NOT carry the Firefly while the patient is in the device.
- DO NOT place the patient directly on the window of the lower light.
- DO NOT place the Firefly inside an incubator.
- DO NOT use Firefly phototherapy with an MTTS infant warmer, or any other warmer as this will cause damage to the Firefly top light.
- DO NOT disassemble any part of the Firefly phototherapy (excluding the removal of the bassinet).
- DO NOT place the Firefly in direct sunlight.
- DO NOT use the Firefly 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 machine, the Firefly 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 in the presence of potentially combustible gases including oxygen, nitrous oxide or other anaesthetics.

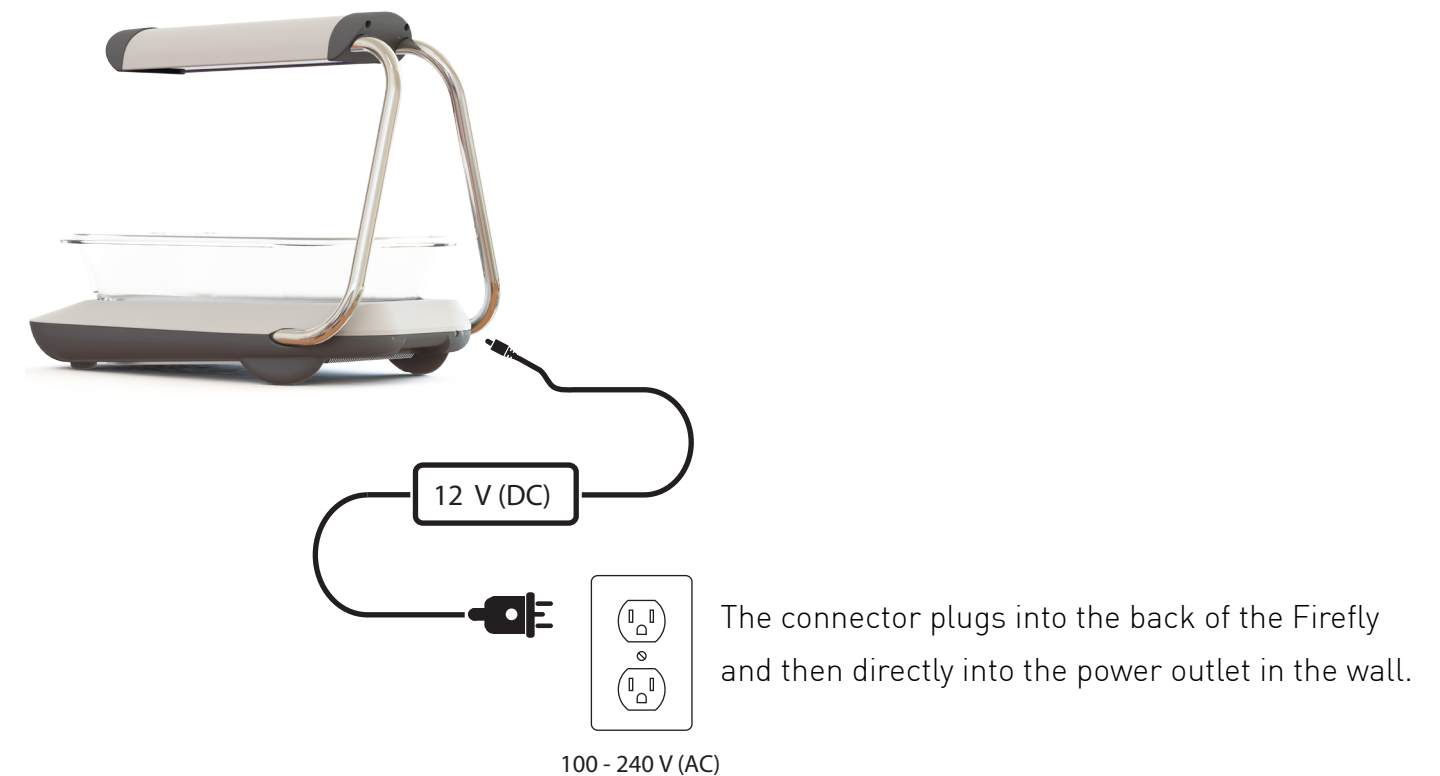
Note: In the event of a power outage, eye coverings should be left on the patient whenever they are inside the Firefly to protect the patient's eyes in case the power returns.

Setting up the Device

Box content

- Firefly unit
- External power supply
- Eye Patches (optional)

Plug in and power up



Caution

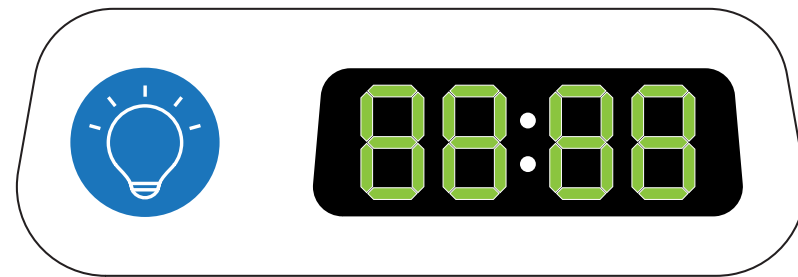
- Only use the cable and connector that is provided by MTTS.
- The Firefly should only be used with the power outlets that have a protective earth (ground) pin.

Using the Device

Plug in the Firefly.

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

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



Turn on the Firefly.

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

This will be displayed for 3 seconds.

This example shows 17 500 hours



The blue phototherapy lights will now start to shine.

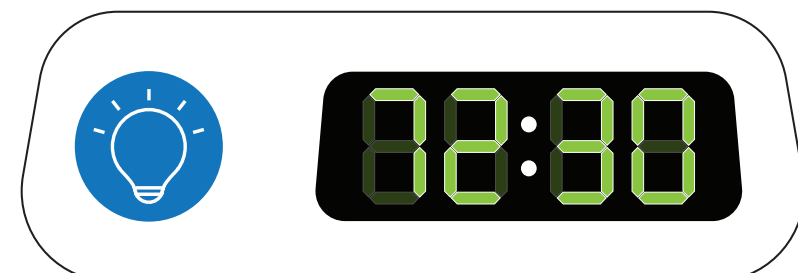
The display will start counting the “treatment time”.

This example shows 1 minute



The phototherapy treatment will continue until the doctor decides therapy is no longer necessary and the device can be switched OFF.

This example shows 72 hours 30 minutes

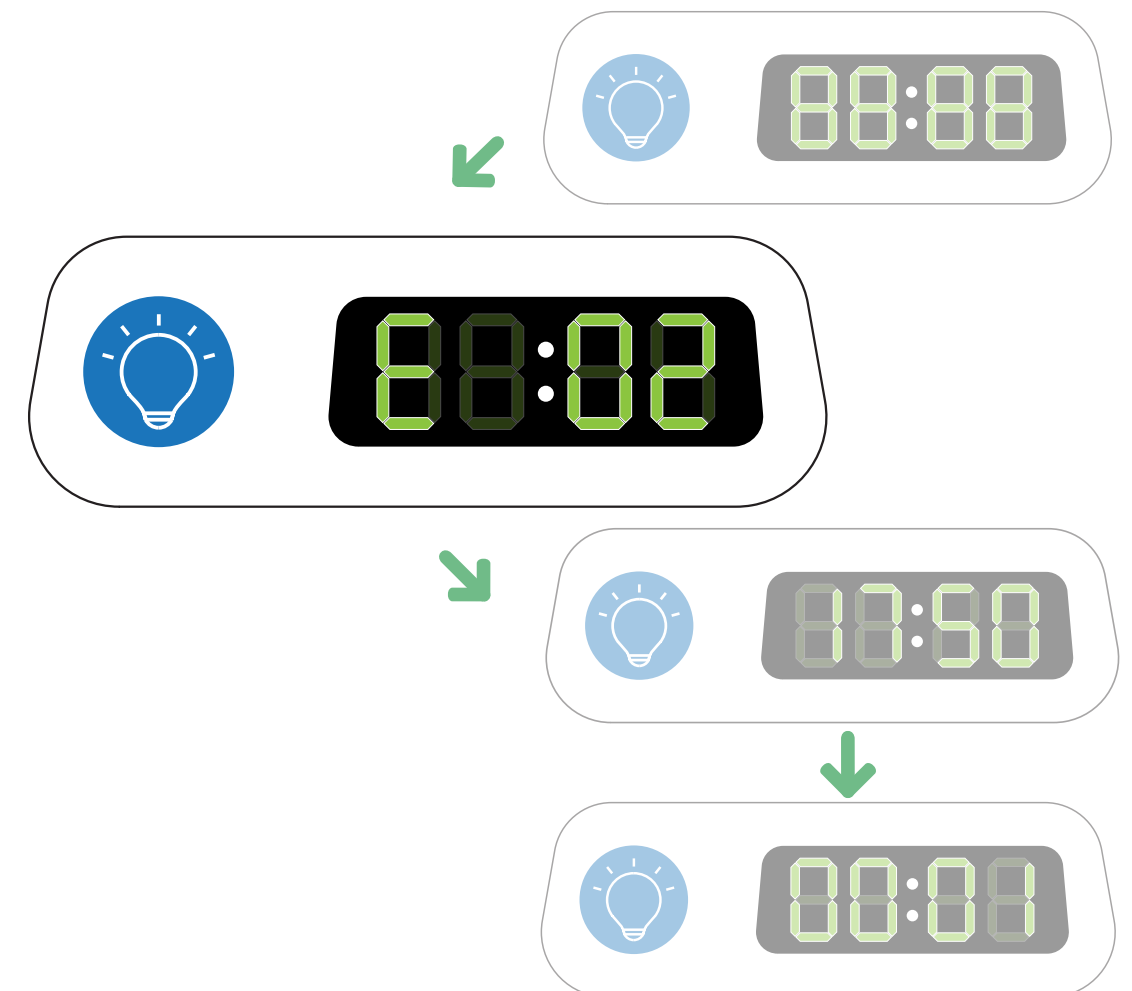


Alarm System

Error messages: In the case that the Firefly has a minor error then 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 Firefly is switched on.

The Firefly 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.

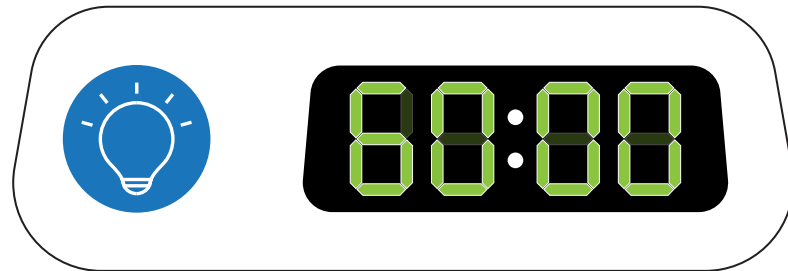


The image above shows when exactly in the ‘start-up’ process the error message will be displayed.

General warning: In the rare occurrence that the Firefly experiences a more serious error which results in the blue lights to “turn-off”, then 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 Firefly will automatically turn back on and resume therapy, if not please contact MTTs and report the error code to MTTs.

Alarm System

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



After turning ON the Firefly the display will show the “total device hours”
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 LED's have reached the recommended life span.
This message will appear for 5 seconds after the device is switched on following total number of hours displayed for 3 seconds. After that E04 and total number of hours will alternate 1 second each.



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 life span 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 the Firefly should be replaced.

Battery backup (optional)

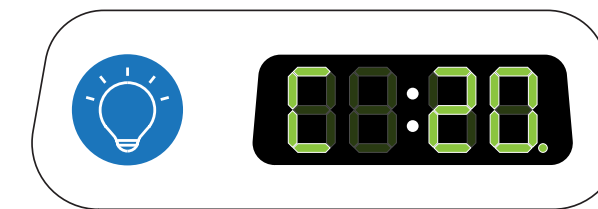
Battery Backup

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

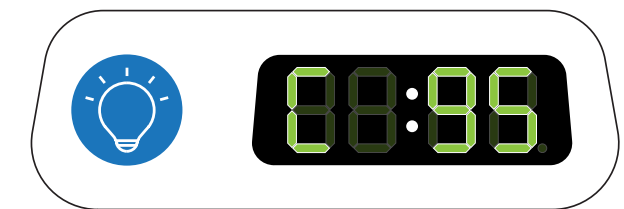
To check the battery charge level press (do not hold) ‘power button’.

‘C:XXX’ = charge (c) percentage (xxx)

The dot after the last digit indicates charging (connected to AC power source)



This example shows battery charge level
20% and charging

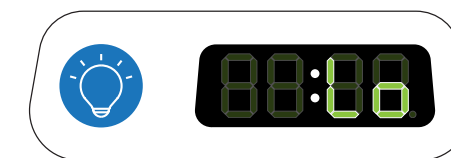


This example shows battery charge level
95% and not charging

When battery charge level goes down to zero (C: 0), visual and audio alarm goes off. The message displayed is:



Treatment time: 3 sec



‘Low’: 1 sec



‘Battery’: 1 sec

The alarm continues for 50 second and there is no action, the devices powers off.
If during the duration of the alarm ‘power button’ is pressed, the alarm is muted and the device enters the **E-mode**.

Battery backup (optional)

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 50 second low battery alarm.



Caution

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

Cleaning and disinfection

- The Firefly bassinet should be disinfected, before and after the treatment of each patient. In the case that a patient undergoes treatment for more than one week then be sure to disinfect the bassinet 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.



When cleaning the device disconnect the power cord.



Caution

- 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 Firefly in the following way.

Measurement instructions:

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

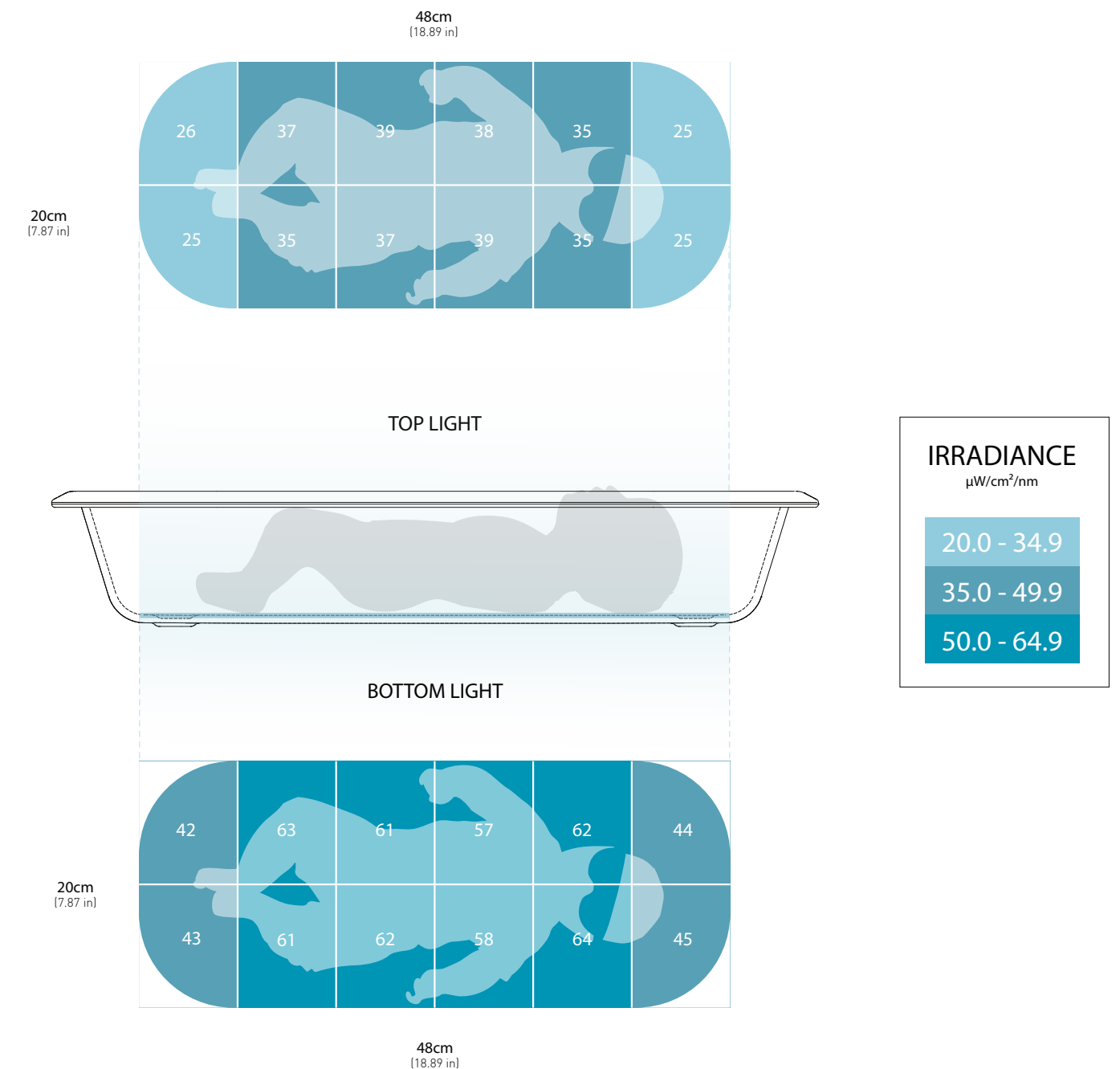
A stabilization time of 2 hours of continuous operation is required for accurate measuring of the irradiance.

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 lights will decay 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.



Specifications

Performance Specifications

Illumination source		High-power blue LEDs, 1-1.25W standard operating
Peak wavelength		440 - 460 nm
Lamp duration		60,000 hours
Total spectral irradiance	top light	40.0 μW/cm2/nm
	bottom light	66.0 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		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
	top light	51.6 cm x 12.5 cm x 6.3 cm
	bottom light	64.7 cm x 38 cm x 10cm
Total unit mass		13 kg

Electrical Specifications

Power characteristics	60W, 100-240VAC, 47/63Hz
Off-the-shelf external power supply	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
	Over voltage / over current protection

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

Standards for Reference

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

	This statement is a warning. Not following this statement could result in injury to the patient or operator, or damage to the device.		Authorized Representative in the European Community
	Caution: Hazard with a low level of risk, which, if not avoided, could result in minor or moderate injury.		Device manufacturer.
	CE Marking with Notified Body Number.		Date of manufacture.
	Consult instructions for use or consult the electronic instructions for use		Country of manufacture
	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 Firefly top light.
	Catalogue number		Power supply polarity.
	Serial number.		12 Volts, Direct Current, 5 Ampere
	Website where a user can obtain additional information on the medical product		Temperature limit
			Humidity limitation
			Atmospheric pressure limitation

Warranty Policy

General Terms	<p>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.</p>
<p>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.</p> <p>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)</p>	

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 gas 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 MTT 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 Center:
+84 43 766 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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