MTTS Ligth Meter





User Manual

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Introduction



WARNING - a warning statement refers to the conditions when the possibility of injury to the patient or user exists if a procedure is not followed correctly.



NOTE - a note statement provides additional information intended to clarify points, procedures or instructions.



This user manual is intended for health care professionals.

The Light Meter is to be operated by qualified personnel only. This manual, all precautionary information, and specifications should be read before use.

The MTTS Light Meter is a spectroradiometer for measuring the irradiance (radiant power) of neonatal phototherapy lights and bili-beds.

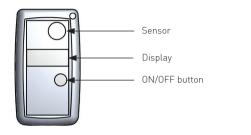




Device Description

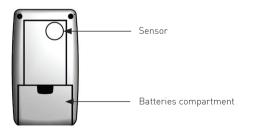
Device Description

The MTTS Light Meter is single measurement unit suitable for overhead and bed type phototherapy. It has 2 sensors loc on both sides of the meter.



i

 ON/OFF button is the 'touch type'. Place the finger on the touch panel, do not press hard



Device Description

Measuring Irradiance

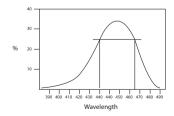
The MTTS Light Meter is a spectroradiometer that measures the therapeutic irradiance (radiant power) of neonatal phototherapy lights. It measures the irradiance of the wavelengths from 440 to 465 nanometers (nm), the blue-green portion of the spectrum, which includes the principal action spectrum of bilirubin.

Units of Measurement

The MTTS Light Meter measures irradiance in units of microwatts per square centimeter per nanometer (μ W/cm2/nm). A nanometer is a measure of wavelength equal to one-billionth of a centimeter. The term "per nanometer" indicates the average irradiance per nanometer across the spectral band being measured, which is 50 nm wide. This makes it possible to compare average irradiance across spectral bands of different widths.

Instrument Response Characteristics

The figure below represents the nominal response characteristics of the MTTS Light Meter, which matches the action spectrum of bilirubin as closely as possible.







Warnings



Explosion hazard. Do not use this device in the presence of flammables (e.g., oxygen, nitrous oxide, anesthetics).



Read and be familiar with this instruction manual before using this device.



Only use this device under the direct supervision of a licensed medical practitioner.

Inspect this device before each use to ensure proper functioning.



The hospital/facility is responsible for ensuring that all personnel who operate or maintain this device are trained in its operation and safe use, and for maintaining training records of attendance and evidence of understanding.

Operation

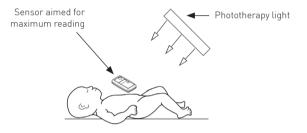
Taking Measurements - Overhead Phototherapy

1. Turn the MTTS Light Meter on.



 ON/OFF button is the 'touch type'. Place the finger on the touch panel, do not press hard

2. Hold the MTTS Light Meter against the infant's body as near to the umbilical as possible and aim the Light Meter at the center of the phototherapy light (see figure below).



- For reproducible measurements, always hold the sensor on the same place on the infant's body.

- Changes in the distance or angle of the light to the patient will change the irradiance the patient receives, requiring new measurements to be taken.





Operation

3. Read irradiance measurement from the display. Adjust the aim of the MTTS Light Meter sensor to obtain the maximum reading.

4. Press on/off button to turn MTTS Light Meter off. MTTS Light Meter automatically shuts off after 1 minute to preserve battery life.



If more than one phototherapy light is being used on the infant, take separate measurements for each light and chart each reading.

Operation

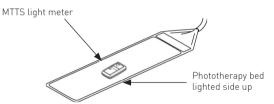
Taking Measurements - Bili-Bed Phototherapy

1. Turn the MTTS Light Meter on.



 $\mathsf{ON/OFF}$ button is the 'touch type'. Place the finger on the touch panel, do not press hard

2. Place the MTTS Light Meter in the middle of the lighted side of the pad or mattress (see figure below). Any disposable covers should be on the pad or mattress.



3. Read irradiance measurement from the display. Adjust the aim of the Light Meter sensor to obtain the maximum reading.

4. Take two additional readings at different places on the pad, then average all three readings.

5. Press on/off button to turn the Light Meter off. The Light Meter automatically shuts off after 1 minute to preserve battery life.



If a Bili-Bed is being used at the same time as an overhead phototherapy light the Light Meter displays combined value of both units.



Alarm System

LOW BAT - Battery power is low; replace the battery (see page 10).

Cleaning

Required items:



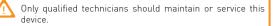
To clean the Light Meter:

1. Confirm that the Light Meter is off. If it is on, press $\ensuremath{\mathsf{POWER}}$ to turn it off.

2. Dampen the cloth with either the mild soap-and-water solution or detergent, then wipe down all exterior surfaces of the Light Meter.



Maintenance and Service





Read and be familiar with this instruction manual before using this device.

The printed circuit boards (PCBs) contain static sensitive parts. Always use appropriate electrostatic discharge protection, such as an electrical-grounding wrist strap, when working with internal components.

Replacing the Batteries

Required items:

2 x AA/LR6/1.5V alkaline, non-rechargeable batteries

To replace the battery:

1. Remove the back cover

2. Insert the new 1.5-volt batteries into the battery holder



Maintenance and Service

Calibrating the Light Meter

The MTTS Light Meter was factory calibrated to a radiometric standard in accordance to the National Institute of Standards and Technology (NIST). The Calibration Certificate is enclosed with this the device.

To assure continued accurate measurement of irradiance, the MTTS Light Meter should be recalibrated every **36 months** to a radiometric (irradiance) standard. Because certain calibration factors are stored in the Light Meter memory, the Light Meter must be recalibrated at MTTS. The date of the last calibration is labeled on the Calibration Certificate.

Both the readout and sensor should be returned for calibration. The Light Meters under warranty are recalibrated at no cost. Others are recalibrated at nominal cost. For information on returning the Light Meter, see below.

Service and Repair

The MTTS Light Meter has no customer serviceable parts, and must be returned to MTTS for all repairs and parts replacement. After any service, the Light Meter must be recalibrated radiometrically to assure accurate measurement of irradiance.



Customer attempts to service the Light Meter will invalidate the warranty and may result in irreparable damage

Maintenance and Service

Returning for Service

When sending equipment for service:

- Contact MTTS Technical Service for a Return Merchandise Authorization (RMA) number and the location where the equipment should be sent.

- Clean the device, securely package it, and include the RMA number on the outside of the box.

- In the Asia, ship the equipment to: Medical Technology Transfer and Services (MTTS) Ltd No 26 Lane 41 An Duong Vuong Tay Ho, Hanoi

Specifications

Specifications

Performance Specifications

Control Settings	
Wavelength spectrum	440–465 nm
Measuring range	0.0 – 150.0 μW/cm²/nm
Accuracy	+/- 2%

Displays

Characteristics Features Indicators

Liquid-crystal display (LCD) 4 digits, indicator, automatic off after 1 min low battery

Physical Specifications

Dimensions (HxWxD)	12.5cm x 7.0cm x 2.4cm
Total unit mass	225 g

Electrical Specifications

Battery Operational Duration	2 x 1.5V alkaline battery, non-rechargeable Up to 120h
Environmental Specifications	
Operating	Ambient temperature 0°C to 40°C

operating	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	None

Exclusions





Specifications

Standards for Reference

ISO 13485:2016 IEC 61010-1:2010 - General safety IEC 61326-1:2012 - EMC

Explanation of Symbols

Explanation of Symbols



Refer to User Manual before operating this device.



Do not disassemble Light Meter unless you are an MTTS trained technician or have been instructed to by qualified personnel.



Keep out of direct sunlight.



This device should be disposed of separately from normal household waste so that components can be recycled.



Device manufacturer.



Date of manufacture.



Serial Number

⊖ ⊖ ⊖ Power supply polarity



- 12 Volt, Direct Current, 5 Ampere
- CE 2265 CI

CE Marking with Notified Body Number

EC REP Name and address of European Authorized Representative





Warranty Policy

General Terms

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

MITS MAKES NO OTHER EXPRESS WARRANTY OR CONDITION WHETHER WRITTEN OR ORAL AND MITS. EXPRESSLY DISCLAIMS ALL WARRANTIES AND CON-DITIONS NOT STATED IN THIS LIMITED WARRANTY TO THE EXTENT ALLOWED BY LOCAL LAW OF JURIS-DICTIONS 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 PARTICU-LAR PURPOSE IS LIMITED TO THE DURATION OF THE EXPRESS WARRANTY SET FORTH ABOVE. SOME COUN-TRIES 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 MODIEV 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 MTS 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 MTS authorized service provider can provide you with details. MTS will not alter form, fit, or function of this MTS product to make it operate in a country for which it was never intended to function for legal or regulatory reasons. MTS is not responsible for any tariffs or duites 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 or 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

products required within the Limited Warrany Period. Unless otherwise stated, and to the extent permitted by local aw, new MTTS product may be manufactured using new materials and used materials equivalent to new in performance and reliability. MTTS products 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 warkmanship for ninety (90] days or, for the reminder of Limited Warranty Period 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 deflect in materials or workmanship during the Limited Warranty Period. All component parts removed under this Limited Warranty becoment parts removed under this Limited Warranty becoment parts removed under this Limited WTTS at its ole discretion, may elect to provide you with (al a replacement unit selected by MTTS that is the same or equivalent to your MTTS product in performance or lb) to give you a refund of your purchase price or lease payments (liess interests) instead of a replacement. This is your exclusive remedy for deflective 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 narameters stated in the user documentation shinned. with the product; (c) by software, interfacing, parts or supplies not supplier 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 MITS PRODUCT FAILS TO WORK AS WARRANT-ED ABOVE, THE MAXIMUM LIABILITY OF MITS UNDER THIS LIMITED WARRANTY IS EXPRESSIV LIMITED TO THE LESSER OF THE PRICE YOU HAVE PAID FOR THE PRODUCT OR THE COSTS OF REPAIR OR REPLACE-MENT OF ANY HARDWARE COMPONENTS THAT MAL-FUNCTION IN CONDITIONS OF NORMAL USE.

EXCEPT AS INDICATED ABOVE, IN NO EVENT WILL MITS BE LIABLE FOR ANY DAMAGES CAUSED BY THE PRODUCT OR THE FAILURE OF THE PRODUCT TO PER-FORM, INCLUDING ANY LOST PROFITS OR SAVINGS OR SPECIAL, INCLUDING ANY LOST PROFITS OR SAVINGS OR TITS IN ON LIABLE FOR ANY CLIM MADE BY A THIRD PARTY OR MADE BY YOU FOR A THIRD PARTY.

THIS LIMITATION OF LUABILITY APPLIES WHETHER DAMAGES ARE SOUGHT, OR CLAIM MADE, UNDER THIS LIMITED WARRANTY OR AS A TORT CLAIM IINCLUD-ING NEGLIGENCE AND STRICT PRODUCT LUABILITY, CONTRACT CLAIM, OR ANY OTHER CLAIM. THIS LIMITA-TION LUBILITY CANNOT BE WAIVED OR AMENDED BY ANY PERSON. THIS LIMITATION OF LUBILITY WILL BE EFFECTIVE EVEN IF YOU HAVE ADVISED MTS 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

Contacting MTTS

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 lissues 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 LO-CATION TO THE MTTS AUTHORIZED SERVICE POINT. 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 pro-
- vider please have the following information available:
- Product serial number and model name
- Applicable error messages
 Detailed questions





MEDICAL TECHNOLOGY TRANSFER AND SERVICES Co., LTD House No. 26, Alley 41, An Duong Vuong Street, Tay Ho District, Hanoi City, Vietnam

> Tel: +84 24 3766 6521 Fax: +84 24 3718 8050 Email: assistance@mtts-asia.com www.mtts-asia.com





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