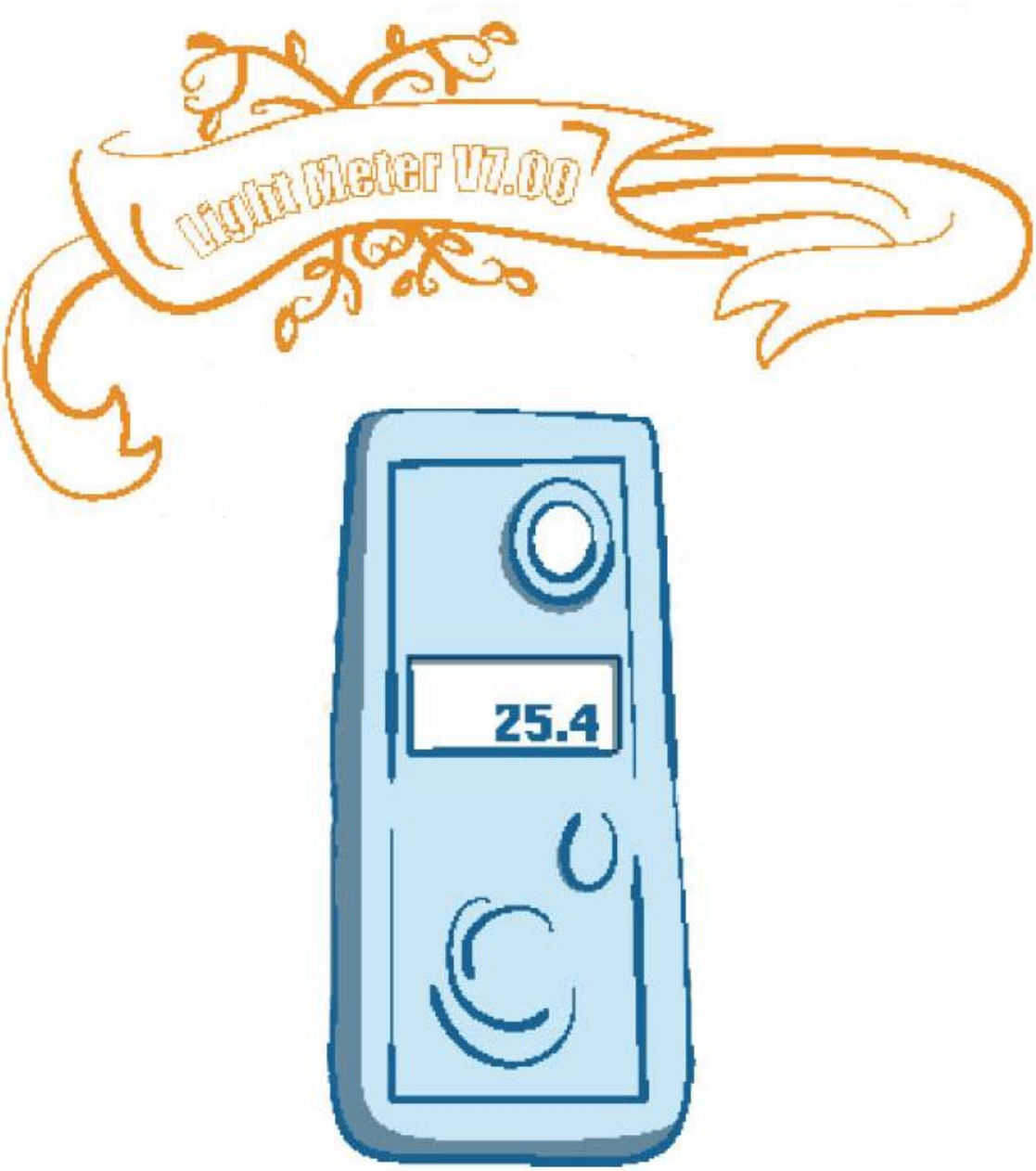


MANUAL

CAUTION

Read and be familiar with this manual before operating or servicing this device. To ensure operator, technician, and patient safety, use only as specified in this manual.

Product Manufacturer:
Medical Technology Transfer and Services Co Ltd
No 26, Lane 41 An Duong Vuong
Tay Ho, Hanoi
Phone: +84 43 766 6521
Fax: +84 43 766 3844
Web: www.mtts-asia.com

The information in this manual is subject to change without notice.

Contents

Overview

This manual provides the necessary information to maintain and service the MTTS Bili-Light Meter. The operating instructions in this manual are intended for use under the direct supervision of a licensed medical practitioner. The service instructions in this manual are intended for use by qualified technicians.

Conventions

The following conventions are used in this manual.

Table 1 Conventions

Convention	Description
NOTE	Notes provide additional information to clarify a point in the text.
CAUTION	Cautions indicate situations that, if not avoided, could result in minor to moderate injury to the patient or operator, or damage to the equipment
WARNING	Warnings indicate situations that, if not avoided, could result in serious injury or death to the patient or operator.
BUTTON	This character style represents buttons and controls that the user can touch or press.

Symbols

The following symbols are located on the Bili-Light Meter and its packaging.

Table 2 Symbols

Symbol	Description
	Atmospheric pressure
	Battery
	Caution, read instructions
	Humidity, condensing

Symbol	Description
	Shipping
	Storage
	Temperature

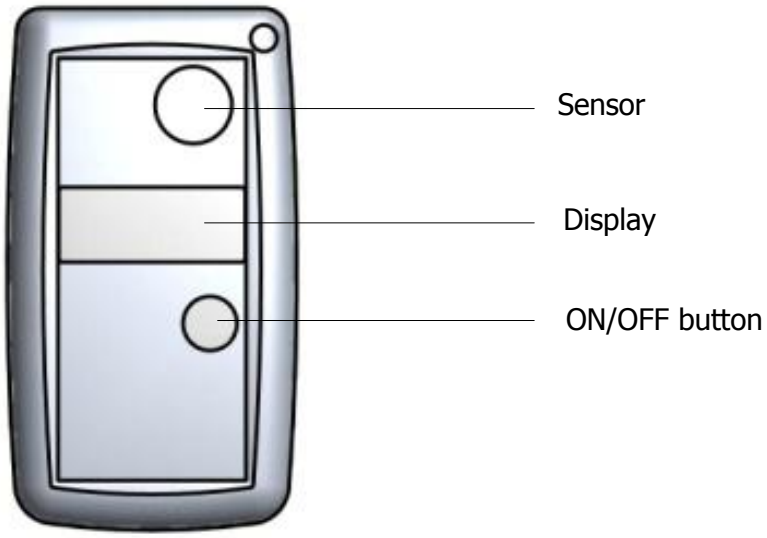
Intended Use

The MTTS Bili-Light Meter Model V6 is a spectroradiometer for measuring the irradiance (radiant power) of neonatal phototherapy lights and bili-beds.

Description

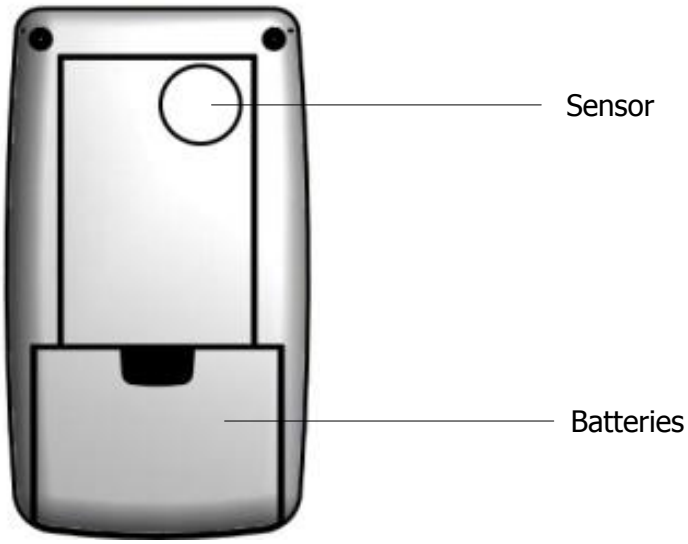
The MTTS Bili-Light Meter is single measurement unit suitable for overhead and bed type phototherapy. It has 2 sensors loc on both sides of the meter.

Figure 1 MTTS Bili-Light Meter front



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

Figure 2 MTTS Bili-Light Meter back



Measuring Irradiance

The Bili-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.

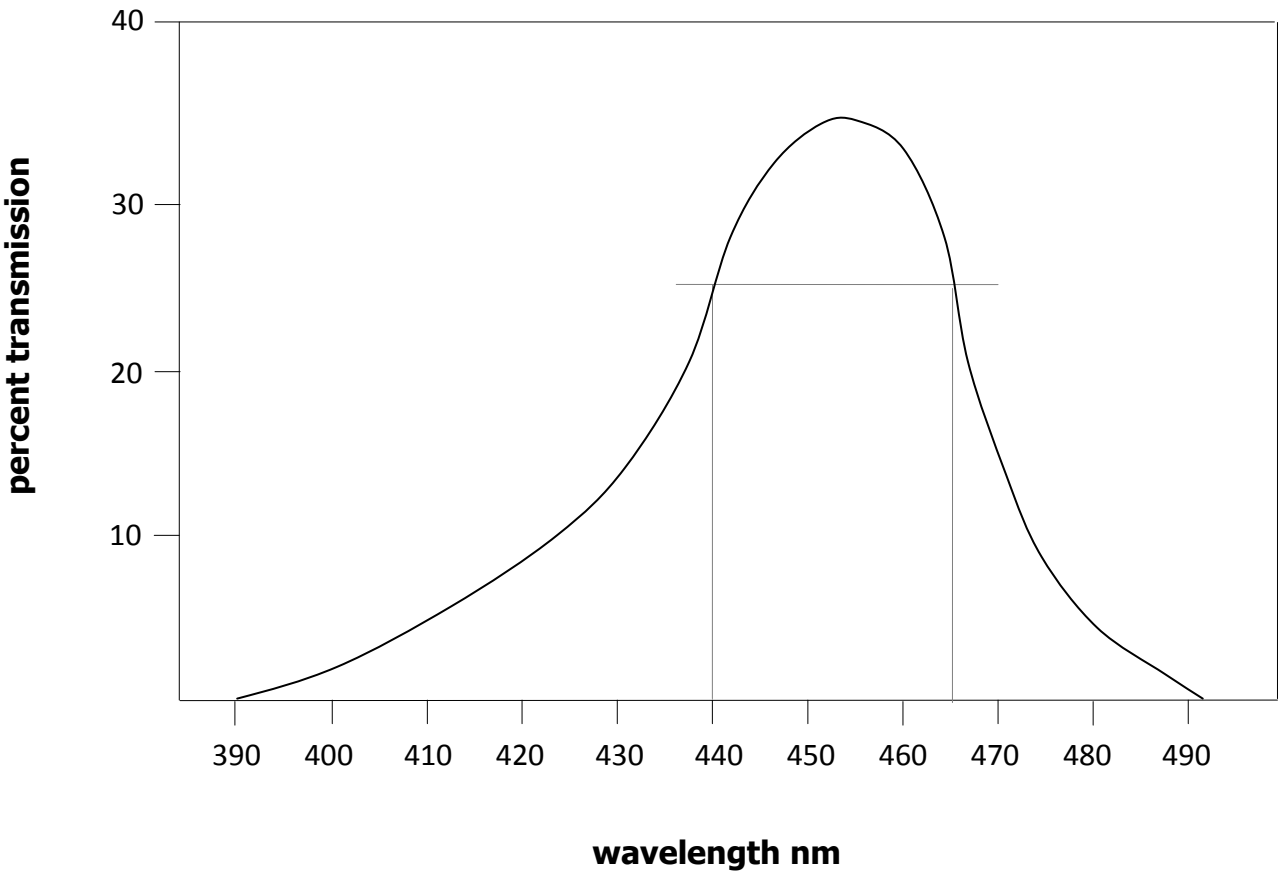
Units of Measurement

The Bili-Meter measures irradiance in units of microwatts per square centimeter per nanometer ($\mu W/cm^2/nm$). 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

Figure 3 represents the nominal response characteristics of the Bili-Meter, which matches the action spectrum of bilirubin as closely as possible.

Figure 3 Nominal response of the Bili-Light Meter



Operation

WARNING

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

CAUTION

- 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.

NOTE

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.

Taking Measurements

Overhead phototherapy:

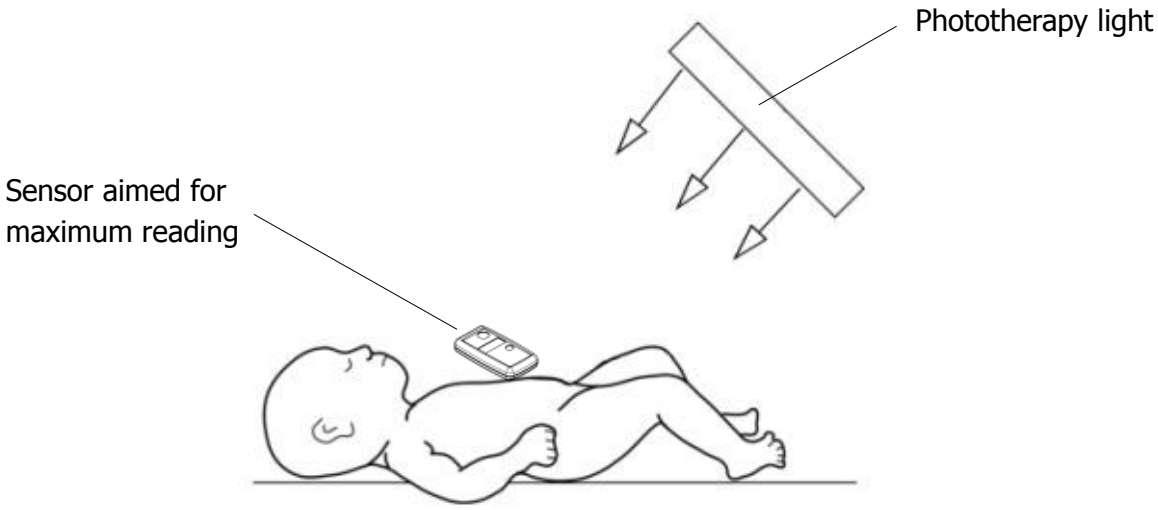
1. Turn Bili-Light Meter on.

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

2. Hold Bili-Light Meter against the infant's body as near to the umbilical as possible and aim Bili-Light Meter at the center of the phototherapy light (see Figure 4).

   - 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.

Figure 4 Measuring overhead light



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

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

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

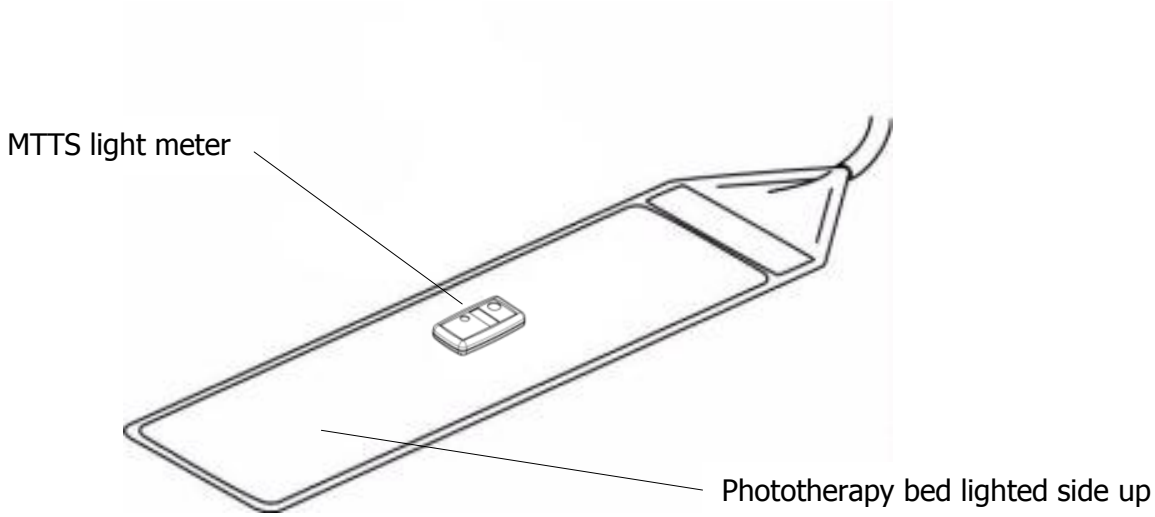
Bili-Bed phototherapy:

1. Turn Bili-Light Meter on.

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

2. Place Bili-Light Meter in the middle of the lighted side of the pad or mattress (see Figure 8). Any disposable covers should be on the pad or mattress.

Figure 5 Measuring Bili-Bed light



3. Read irradiance measurement from the display. Adjust the aim of the Bili-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 Bili-Light Meter off. Bili-Light Meter automatically shuts off after 1 minute to preserve battery life.

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

Messages

The following message may show on the display of the readout:

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

Cleaning

Required items:

- Soft cloth
- Mild cleaning detergent or mild soap-and-water solution

To clean the Bili-Light Meter:

1. Confirm that the Bili-Light Meter is off. If it is on, press 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 Bili-Light Meter.

Maintenance and Service

CAUTION

- Only qualified technicians should maintain or service this device.
- 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 AA/LR6/1.5V alkaline, non-rechargeable batteries

To replace the battery:

1. Remove the back cover

NOTE An instruction label on the inside of the back cover illustrates how to remove and insert the battery.

Figure 6 Replacing batteries

2. Insert the new 1.5-volt batteries into the battery holder (see Figure 6).

Calibrating the Bili-Meter

The Bili-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 manual.

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

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

Service and Repair

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

Customer attempts to service the Bili-Meter will invalidate the warranty and may result in irreparable damage.

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

Contacting MTTS

To obtain service support or order additional products, contact:
Medical Technology Transfer and Services (MTTS) Ltd
Customer Service Department
Phone: +84 43 766 6521
Fax: +84 43 766 3844
Email: assistance@mtts-asia.com

Specifications

Clinical	Wavelength spectrum		440–465 nm
	Measuring range		0.0 – 150.0 µW/cm²/nm
	Accuracy		+/- 2%
Display	Characteristics		Liquid-crystal display (LCD)
	Features		4 digits, indicator, automatic off after 1 min
	Indicators		low battery
Environmental Ratings	Temperature	Operation	-10°C to 40°C
		Storage	-20°C to 45°C
	Atmospheric pressure	Operation	600 – 1,300 hPA
		Storage	300 – 1,500 hPA
	Humidity	Operation	10 – 95% Relative Humidity (rH)
		Storage	5 – 95% Relative Humidity (rH)
	Altitude	Operation	Up to 3,000 m
		Storage	n/a
	Durability	Water resistance	Splash – proof, IP-54
		Dust resistance	Dust – proof, IP-54
		Drop/shock resistance	1m onto hard surface, meets or exceeds IEC 68-2-32
Service	Calibration	Required	Every 2 years from the delivery date; return to MTTS for calibration
	Parts	no customer serviceable parts	return to MTTS for service
Miscellaneous	Standards		FDA Class 1, Health Canada Class 2
	Electrical Safety		UL 61010-B-1, Ordinary Equipment (IPXØ), Indoor Use Only
	Electromagnetic Compatibility		IEC 61326
	Dimensions		12.5cm x 7.0cm x 2.4cm
	Environmental Safety		Pollution Degree 2
	Weight		225 g
	Batteries		2 x 1.5V alkaline battery, non-rechargeable
	Operational Duration		Up to 120h
Ordering Information		**Item Order Number**	
	Light meter	BLM-1000	Main unit
	Light meter	Firefly-1020	Accessory to Firefly Phototherapy
	Light meter	PT3-1030	Accessory to V3000 Phototherapy

Calibration Certificate

This device has been calibrated to radiometric standards in accordance to the National Institute of Standards and Technology (NIST).

Radiometric calibration of this device can be only performed at a laboratory with appropriate lamp standards. Return the device to the factory or an authorized service center every 36 months for recalibration.

Device Light Meter Model V7.00

Serial Number _____

Calibration Details

Calibration Date _____

Recalibration Recommended: _____

Calibration Technician: _____