4meter

MTTS

Model: LM-800

User Manual

CE

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MTTS

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Company Information

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EC REP

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.

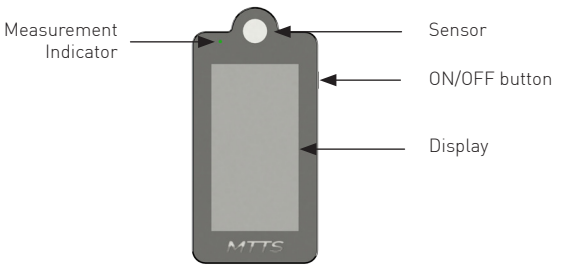
This user manual is intended for health care professionals.

The 4-meter is to be operated by qualified personnel only. This manual, all precautionary information, and specifications should be read before use.

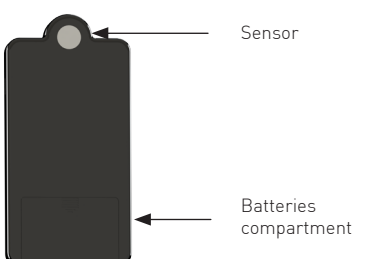
The 4-meter major function is a spectroradiometer for measuring the irradiance (radiant power) of neonatal phototherapy lights and bilibeds.
In additon the device can be connected to the other optional sensors for:
- Oxygen measurement
- Flow measurement
- Pressure measurment

Overview

4-meter is single measurement unit suitable for overhead and bed type phototherapy. It has 2 sensors located on both sides of the unit.

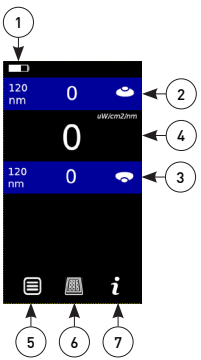


LCD screen is a 'touch type'. Place the finger on the touch panel, do not press hard



Device Description

Display



1	**Battery status**	Battery usage information
2	**Top sensor bar**	Top sensor measurement information including light source, value and estimated bandwidth
3	**Bottom sensor bar**	Bottom sensor measurement information including light source, value and estimated bandwidth
4	**Total measurement bar**	Total measurement value (top + bottom) with the measurement unit Touch this area to hold the measurement values
5	**Menu**	Touch this button to enter Menu screen
6	**Multi-point mode**	Touch this button to enter Multi-point mode screen
7	**Status**	Touch this button to enter Status screen

Device Description

Measuring Irradiance

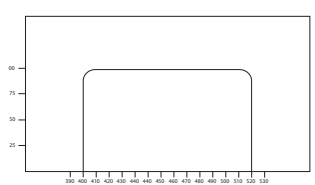
4-meter is a spectroradiometer that measures the therapeutic irradiance (radiant power) of neonatal phototherapy lights. It measures the irradiance of the wavelengths from 400 to 520 nanometers (nm), the blue-green portion of the spectrum, which includes the principal action spectrum of bilirubin. The device accounts for cosine correction allowing more light from different angles.

Units of Measurement

4-meter measures relative irradiance (μW/cm²/nm) and absolute irradiance (μW/cm²).
When referring to the relative irradiance, a nanometer is a measure of wavelength equal to one-billionth of a centimetre. The term "per nanometer" indicates the average irradiance per nanometer across the spectral band being measured, which is 120 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 4-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.

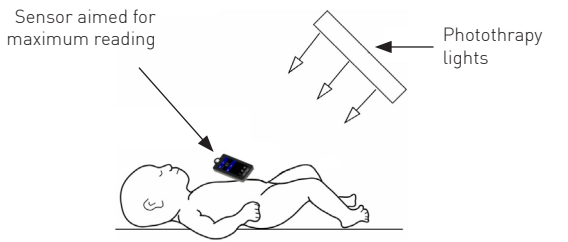
Inspect this device before each use to ensure proper functioning.

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.

Taking Measurements - Overhead Phototherapy

1. Turning the unit ON and OFF
   To turn on: press the ON/OFF button
   To turn off: press and hold ON/OFF button

2. Hold the unit against the infant's body as near to the umbilical as possible and aim it at the centre of the phototherapy light (see figure below).

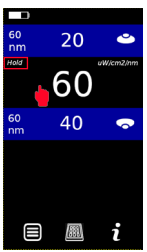


- For reproducible measurements, always hold the sensor on the same place on the infant's body.

- 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.

3. Read irradiance measurement from the display. Adjust the aim of 4-meter sensor to obtain the maximum reading.

4. The values can be 'frozen' on the display. Touch the total measurement area to stop the measurement and hold the values.



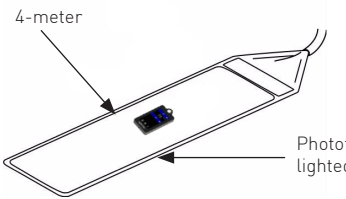
If more than one phototherapy light is being used on the infant, take separate measurements for each light and chart each reading.

The measurement indicator is flashing during the sensors' operations. When the 'hold the values' function is active, the indicator stays red.

Taking Measurements - Bili-Bed Phototherapy

1. Turning the unit ON and OFF
   To turn on: press the ON/OFF button
   To turn off: press and hold ON/OFF button

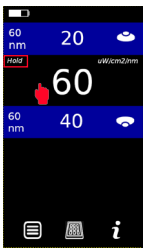
2. Place 4-meter in the middle of the lighted side of the pad or mattress (see figure below). Any disposable covers should be on the pad or mattress.



3. Read irradiance measurement from the display. Adjust the aim of 4-meter to obtain the maximum reading.

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

5. The values can be 'frozen' on the display. Touch the total measurement area to stop the measurement and hold the values.

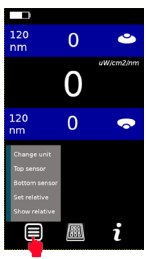


If a Bili-Bed is being used at the same time as an overhead phototherapy light 4-meter displays combined value of both devices.

The measurement indicator is flashing during the sensors' operations. When the 'hold the values' function is active, the indicator stays red.

Additional options

4-meter offers a selection of choices for different types of measurements.



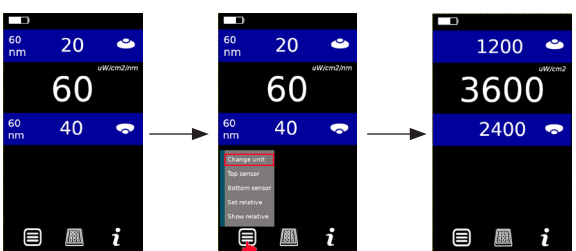
Change unit	Changes units between relative irradiance (μW/cm²/nm) and absolute irradiance (μW/cm²)
Top sensor	Activates / deactivates the top sensor. When the Top sensor is deactivated, the top sensor bar is gray.
Bottom sensor	Activates / deactivates the bottom sensor. When the bottom sensor is deactivated, the Bottom sensor bar is gray.
Set relative	Sets the current measurement as reference values
Show relative	Shows / hides the relative ratio of current measurement to the previously set reference value

Operation

Bandwidth estimator and units of measurement

4-meter measures the bandwidth of 400-520 nm. As opposed to the traditional fluorescent light sources, LED based phototherapies are narrow-banded. The aim of 4-meter is to estimate light source bandwidth to get meaningful average values.
Given the complexity of the light measurement 4-meter offers the user the choice of 2 measurement units:
- μW/cm²/nm for relative irradiance measurement and
- μW/cm² for absolute irradiance measurement

In the example below:
- the estimated bandwidth of the light source is 60 nm
- the top relative irradiance measured is 20 μW/cm²/nm
- the bottom relative irradiance measured is 40 μW/cm²/nm
- the total relative irradiance measured is 60 μW/cm²/nm
- the total absolute irradiance measured is 3,600 μW/cm²

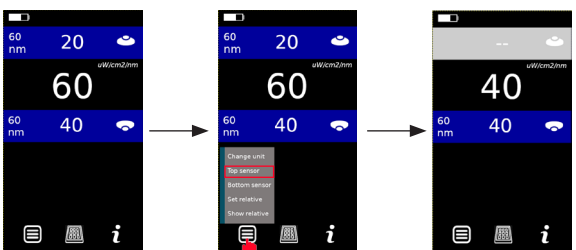


Activating/deactivating sensors

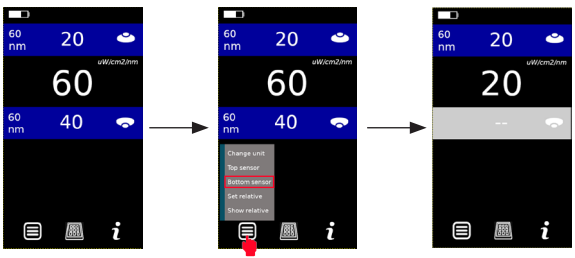
4-meter measures the irradiance using 2 sensors:
- top for overhead phototherapy units
- bottom for bed-type phototherapy units
- top and bottom - for double sided phototherapy units

> Both sensors (top and bottom) are active when the device is turned on.

To disable the top sensor and use only the bottom sensor touch the menu icon and select 'Top sensor' from the list.



To disable the bottom sensor and use only the top sensor touch the menu icon and select 'Bottom sensor' from the list.



Relative measurement

Relative measurement can be used to determine/verify treatment size of a phototherapy device.
The example below explains the process for a single sided photo therapy device.

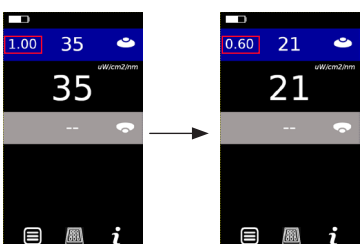
1. Select: Menu - 'Bottom sensor' to disable the bottom sensor (see above)

2. Place 4-meter unit under a phototherapy device in centre position.

3. Select: Menu - 'Set relative' to set the current measurement as reference value

4. Select: Menu - 'Show relative' to show the ratio between current measurement and reference value.
The ratio is shown on the left side of the top sensor bar ('1.00').

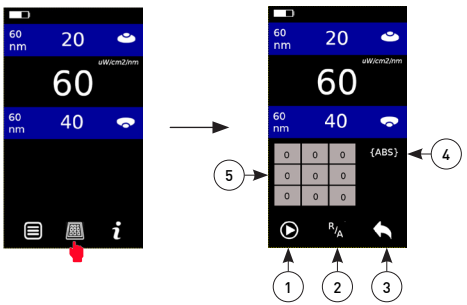
5. Move 4-meter unit away from centre position, the irradiance should decrease. This will also be indicated by a decreasing ratio.



In this example 4-meter unit was moved away from centre to a position where irradiance is 60% of the centre (reference) irradiance point.

Multi-point mode

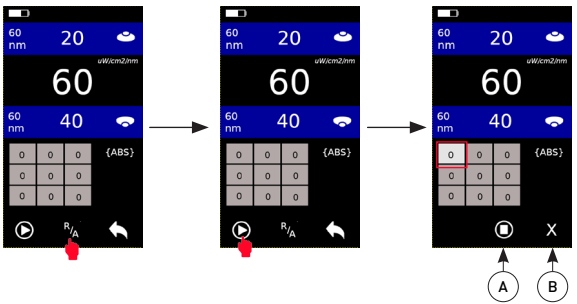
Multi-point mode supports irradiance measurement of up to 9 location points.
Select: 'Multi-point mode' on the main display



1	**Start**	Activates the multi-point measurement process
2	**Relative/Absolute**	Changes between absolute and relative view of multi-point measurement data.
3	**Exit**	Exits multi-point measurement
4	**Relative/Absolute indicator**	Indicates absolute {ABS} and relative {REL} view
5	**Measurement matrix**	3 x 3 measuring points field

1. Select relative or absolute measurement units.

2. Touch 'Start' button to begin the multi-point measurement
The matrix button of the first position will be highlighted.



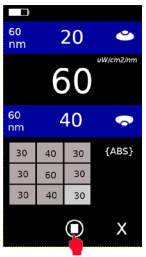
A	**Stop button**	Stops the process and exits to the main menu
B	**Clear button**	Clears the data and starts the process over

3. Touch the highlighted area to assign its measurement value.

4. Assign the values to the remaining measurement points.

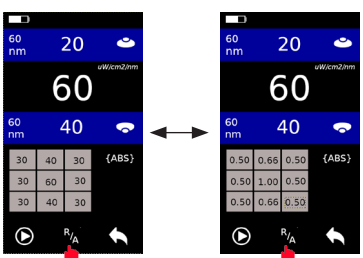
The process can be completed at any time. It's not necessary to assign values to all 9 measurement points.

5. Touch 'Stop button' to complete the process



6. The multi-point matrix displays absolute values of collected data

7. Touch 'Relative/Absolute' button to switch between relative and absolute values of the collected multi-point data points.



4-meter calculates relative values in the reference to the highest value measured. The remaining values are calculated as the ratio of the highest value.

Alarm System

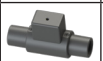
1. Low battery - Battery power is low
   replace the battery (see page 28)
2. System failure - contact the authorized representative
3. Out of measurement - the light irradiance is outside the
   measurement range of the device

Optional sensors

4-meter unit can be connected to the other optional sensors for:
- Oxygen measurement
- Flow measurement
- Pressure measurment

In each mode, a primary and secondary value is displayed. The primary value is the parameter to be observed, the secondary value is the raw value of the sensor.

List of supported accessories:

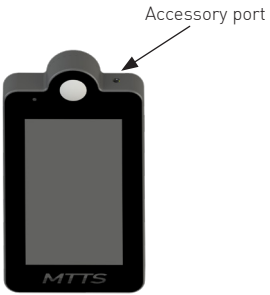
Name		Order code	Specification	Calibration recommendation
Oxygen analyzer		LM-800-020	Range: 0 .. 100% O_2 Accuracy: ±3% O_2 Resolution: 0.1% O_2	Not required Lifetime: 18-24 months
Flow meter		LM-800-030	Range: -160 .. 160 l/min Accuracy: ±2.5% Resolution: 0.1 l/min	Every 2 years
Manometer		LM-800-040	Range: 0 .. 100cm H_2O Accuracy: ±1% Resolution: 0.1cm H_2O	Not required

ONLY use accessories and cable supplied by MTTS. Using non-compliant cable or accessory may cause damage to the device.

All sensors are intended for equipment maintenance only, NOT to be used on a patient.

Optional sensors

Accessory port



Manometer can be connected directly to the device.
Oxygen analyzer and flow meter are connected to the device via an accompanied cable.
The device will automatically recognize the plugged accessory and change the display to appropriate mode to show measurement.

Multiple sensors can be connected at the same time using a port extender supplied by MTTS.

Optional sensors

Oxygen analyzer

Don't use the sensor with a humidifier

Replace sensor if output is below 9mV

Don't calibrate the sensor in rooms where oxygen is used

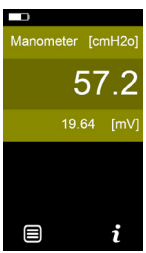
Step 1 – plug-in oxygen sensor; oxygen analyzer mode is activated
Step 2 – select CalFiO_2 in Menu to calibrate sensor against ambient
Step 3 – oxygen concentration is displayed (%)

If the secondary value is below 9mV at ambient O_2 concentration of 20.8%, the O_2 sensor need to be replaced

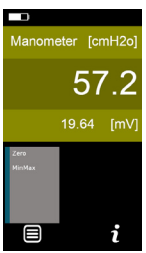
Optional sensors

Manometer

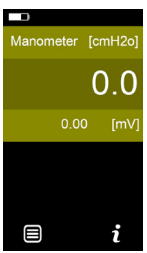
- Do not use the sensor with a humidifier
- Max pressure allowed: 100 cmH_2O (1.4 PSI)
- The sensor's barb connector fits a standard 6mm tube
- Leaks can affect measurement



1



2



3

Step 1 – plug-in pressure sensor; manometer mode is activated
Step 2 – pressure sensors can have an offset; press menu button to select "Zero" function.
Step 3 – device is ready to measure

To monitor pressure flucations, select Min/Max function from the menu

Optional sensors

Flow meter

- Do not use the sensor with a humidifier
- Ambient air flow and tube turbulence can affect measure-ment
- Connect the sensor to a straight 22mm diameter tube to avoid turbulence. To measure lower diameters connect 20 cm extention tube first (22mm diameter)

1

2

3

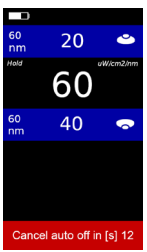
Step 1 – plug-in flow sensor; flowmeter mode is activated
Step 2 – flow sensors can have an offset; press menu button to select "Zero" function.
Step 3 – device is ready to measure

To monitor flow flucations, select Min/Max function from the menu

Optional sensors

Turning off

The device will turn off automatically after 3 minutes of no action.



To keep using the device and cancel the auto turn off sequence, select the option that appears 15 seconds in advance at the bottom of the screen. The auto turn off notification will appear again after 5 minutes.

Cleaning

Required items:

Clean Cloth

Mild Detergent

To clean the 4-meter:

1. Confirm that the device 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 4-meter.

Only qualified technicians should maintain or service this device.

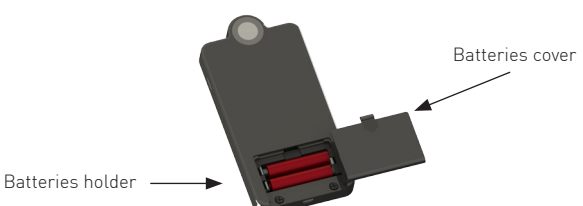
Read and be familiar with this instruction manual before using this device.

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 x AAA/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



Calibrating 4-meter

Each 4-meter unit is 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 4-meter should be recalibrated every **24 months** to a radiometric (irradiance) standard. Because certain calibration factors are stored in the device memory, the unit must be recalibrated at MTTS. The date of the last calibration is labelled on the Calibration Certificate.

The 4-meters under warranty are recalibrated at no cost. Others are recalibrated at nominal cost. For information on returning the device, see below.

Service and Repair

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

Customer attempts to service 4-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 more information on returning address and shipping details

- 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

Performance Specifications

Control Settings		
LIGHT SENSOR		
Spectral response		400–520 nm
Measuring range	single side	0.0 – 150.0 µW/cm²/nm
	double side	0.0 – 300.0 µW/cm²/nm
Resolution		0.1 µW/cm²/nm
Cosine characteristics		±2% @ 30 degree angle
		±7% @ 60 degree angle
		±25% @ 80 degree angle
Accuracy		+/- 3%
OXYGEN SENSOR - FIO_2		0-100%
PRESSURE SENSOR		0-100cm H_2O
FLOW SENSOR		0-160 lpm, bi-directional
Displays		
Characteristics		Touch LCD
Features		auto-zeroing, self-check, auto-off after 1 min, results 'freeze'
Indicators		low battery, system failure, out of measurement

Physical Specifications

Dimensions (HxWxD)	148 x 73 x 17 mm
Total unit mass	200 g

Electrical Specifications

Battery	2 x AAA 1.5V alkaline batt, non-recharg.
Operational Duration	Up to 120h

Environmental Specifications

Operating	Ambient temperature 10°C to 40°C
	Humidity: 30% to 90% RH non condensing
	Atmospheric Pressure: 70-106kPa
Transport and storage	Ambient temperature 0°C to 50°C
	Humidity: 5% to 90% RH non condensing
	Atmospheric Pressure: 70-106kPa
Exclusions	None

Specifications

Standards for Reference

ISO 13485:2016
IEC 61010-1:2010
IEC 61326-1:2012
ROHS III

Explanation of Symbols

Explanation of Symbols

Refer to User Manual before operating this device.

Do not disassemble 4-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

CE Marking

Name and address of European Authorized Representative

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 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 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 reminder 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 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 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 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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