THOR
THE FUTURE OF MEDICINE

LX2.3 Laser & LED Therapy System

Instructions for use

CE
2265

1. Introduction

When used correctly, the THOR LX2.3 treatment system will help tissue repair, reduce inflammation and reduce pain.

Once you understand the photobiological mechanisms and the subsequent physiological effects, the THOR LX2.3 becomes a powerful tool providing great benefit for your patients and your practice.

THOR want you to use it extensively and successfully and for that reason THOR strongly recommend that you attend one of our training courses. These courses are listed on our web site www.thorlaser.com where you can also join our mailing lists for future training dates, product information, conference announcements and medical news. This will help you stay up to date with this fast-developing science and achieve the best possible results.

There are safety issues to be aware of and regulations that differ from one country to another so you should make sure that you are informed about these also. THOR wantsyou to do well so read this manual starting with the safety information, follow instructions, attend our training courses, subscribe to our news, and contact us if you need help via the web, www.thorlaser.com.

James Carroll
CEO

THOR Photomedicine Limited

2. Conventions Used

The following convention and style is used to indicate the importance of the information contained in this manual.

Note: - This is used to indicate additional information that will help in the use and/or understanding of the equipment.

Caution: - This is used to indicate aspects of set-up or operation that should be checked before or during use to ensure compliance with regulations and safe operation of the device. Failure to do so may result in hazardous operation of the device.

WARNING: - This is used to inform the operator of safety aspects that MUST be followed when setting up or using the device.

3. Definitions

The system of unit measurement used follows the SI system of units. The following definitions are used within the manual:

FDA	US Food and Drug Administration
Hz	Hertz (Unit of Frequency)
NIR	Near InfraRed
LED	Light Emitting Diode
LPA	Laser Protection Advisor
LSO	Laser Safety Officer
µA	Microamps
mW	Milliwatt
ME	Medical Equipment
nm	Nanometer (Unit of Wavelength measurement)
nS	Nano Siemens (Unit of Conductance measurement)
RH	Relative Humidity
HF	High Frequency
RF	Radio Frequency
EM	Electromagnetic
W	Watts (Unit of Power)
WEEE	Waste Electrical & Electronic Equipment directive
PBM	Photobiomodulation

4. General Safety

a. The LX2.3 system complies with the international safety standard IEC 60601-1 for medical electrical equipment.
b. The AC mains power cord can be used as a means of isolation from the AC mains supply. Do not position the system so that it is difficult to access this.
c. **WARNING: -** No modification of this equipment is allowed.
d. **WARNING: -** To avoid risk of electric shock, this equipment must only be connected to a AC mains supply with a protective earth/ground.
e. Do not use accessories or procedures other than those specified in these Instruction for Use or as recommended by THOR Photomedicine.
f. THOR Photomedicine approved laser safety eyewear must be worn by the: patient; operator; and any observers, when the laser probes are being used. They are not necessary when the LED probes are used.
g. Do not leave the key in the equipment when it is unattended. Keep the key in a safe place.
h. **WARNING: -** Do not direct laser light into the eye or treat the immediate surrounding area with a laser.
i. A theoretical risk of fire and/or explosion exists when any laser or LED output is used in the presence of flammable materials, solutions or gases (including endogenous gases) or in an oxygen enriched environment.
j. High temperatures produced in normal use of any laser or LED equipment may ignite some materials (e.g. cotton wool when saturated with oxygen) and solvents of adhesives; Ensure any flammable solutions used for cleaning and disinfecting have evaporated before use.
k. Only use the THOR Photomedicine supplied AC mains power cord.
l. Find out if your hospital/clinic has a Laser Protection Advisor (LPA) or Laser Safety Officer (LSO) or equivalent and notify them of the equipment. They may provide you with their own safety guidelines (local rules) to follow.
m. Any serious incident that has occurred in relation to the device needs to be reported to THOR and may need to be reported to your Regulatory Authority.

5. Laser Safety Warning

Some THOR treatment probes are lasers. Follow laser safety instructions when laser probes are used. This is not necessary when LED probes are used.

VISIBLE AND INVISIBLE LASER RADIATION
AVOID EXPOSURE TO BEAM CLASS
3B LASER PRODUCT

THOR approved laser safety eyewear must be worn by the patient & operator when the laser probes are being used. This is not necessary when LED probes are used.

6. Hazards

a. Optical Hazard

Operators should be aware of the potential hazards of lasers, such as eye injury caused by laser irradiation of the eye. Hazard reduction, such as the provision of appropriate safety eyewear, removal or covering of reflective surfaces in the treatment area, adequate signage and removal of the key when not in use is the responsibility of the laser user. This is not necessary when LED probes are used.

b. Heat Hazard

Before treatment starts the operator should ask the patient to report if the treatment probe becomes too hot. If this does occur, then the operator should stop treatment to allow the probe to cool down, another probe can be used in the meantime.

A treatment probe is applied on a point / area for 30 to 60 seconds, multiple applications may be performed during a single treatment session.

The duty cycle for each probe type is shown on its yellow warning label. This gives time limits that ensure the applied part does not exceed 41°C. The maximum on time along with the minimum off time is given. Ensure you adhere to the duty cycle of the treatment probe.

Dark pigmented skin/tissues and tattoos absorb light and may feel hot. See section for further advice.

7. Description

The system consists of a control unit, along with various laser and LED treatment probes, accessories and a Trigger Point Handpiece. These are detailed in section 20. Treatment Probes.

a. The system requires no installation and is ready-to-use out of the box.
b. The system is AC mains powered (100-240V~) on/off with a key switch.
c. There are LED indicators for: power on; probe on; laser ready; and fault.
d. Treatment time and beam modulation frequency are user selectable.
e. There is a red emergency laser stop push-button.
f. Treatment probes and trigger point handpiece are connected on the front panel of the control unit.
g. There are numeric displays of treatment probe power output (mW/W) and measured skin conduction (nS) on the front of the control unit.
h. The probe test window enables measurement of single probe output.
i. A remote interlock can be connected on the back panel of the control unit and can be used to enable/disable the beam output.
j. The weight of the control unit is 3.05 kg, the dimensions are (w) 357 mm X (d) 228 mm X (h) 120 mm.

8. Significant Physical and Performance Characteristics

a. Laser probe accessories emit invisible near infrared (NIR) light (laser class 3B).
b. Laser probe accessories emit visible radiation (laser class 3B).
c. LED probe accessories emit visible red and invisible near infrared (NIR) light.
d. Duration of treatment is selectable between 5 seconds and 5 minutes.

e. Probes are re-usable on multiple patients.

f. Maintenance, performance test and calibration at intervals are required.

g. Requires 100-240V, 50-60Hz AC mains supply voltage

h. All probe accessories have a type BF applied part.

9. Application Specification

a. Intended use

The LX2.3 improves speed of tissue healing, reduces inflammation and reduces pain when applied to the treatment area. The device is intended to be used for medical purposes.

It is indicated for neck pain, back pain, oral mucositis, tendinopathies and joint pain.

b. Intended Patient Population

Age - There are no age limitations or weight range limitations.
Health - Refer to section 14. Contraindications and section 15. Precautions.
Condition - Refer to section 14. Contraindications and section 15. Precautions.

c. Intended Part of the Body to be Applied To

All external and oral parts with the exception of the eye and its surrounding area when using Laser; LED can be applied over the eye and its surrounding area by intended users.

d. Intended User Profile

Physicians
Dentists
Veterinarians
Therapists
Nurses
Technicians

e. Intended Conditions of Use Environment

Indoors. Refer to section 24. Technical Specifications

f. Hygiene requirements

Refer to

- Section 15. Precautions: Hygiene (f)
- Section 12. Operating Instructions: Cleaning of Control Unit and Probes (i); and General Care and Use (k)
- Section 29. Decontamination of Equipment.

g. Location

Indoor only, usually positioned on a desk, table or trolley and in convenient proximity of the patient, given the 2m cable length of the probe accessories.

h. Mobility

The control unit is transportable to other locations by a single individual. It has carrying recesses at opposite ends; its weight is 3.05 kg.

The probe accessories connect to the control unit on a 2m length of highly flexible cable to enable reach to all treatment areas.

i. Operating Principle

The system applies Photobiomodulation (PBM) light. PBM is a laser or LED light therapy that improves tissue repair (skin wounds, muscle, tendon, bone, nerves), reduces inflammation and reduces pain wherever the beam is applied. Treatment sessions typically take 1 - 10 minutes, treatment intervals are two or more times a week and it is usually applied by a physician, therapist, dentist, veterinarian, nurse or technician.

PBM works predominately on a protein in mitochondria (cytochrome c oxidase) to increase ATP and reduce oxidative stress. A cascade of mitochondrial and intracellular downstream effects leads to improved tissue repair and reduced inflammation.

10. Regulations

Most countries regulate medical device safety, efficacy and marketing, and there maybe additional regulations for medical lasers. Search online within your country for medical device regulations or medical laser regulations.

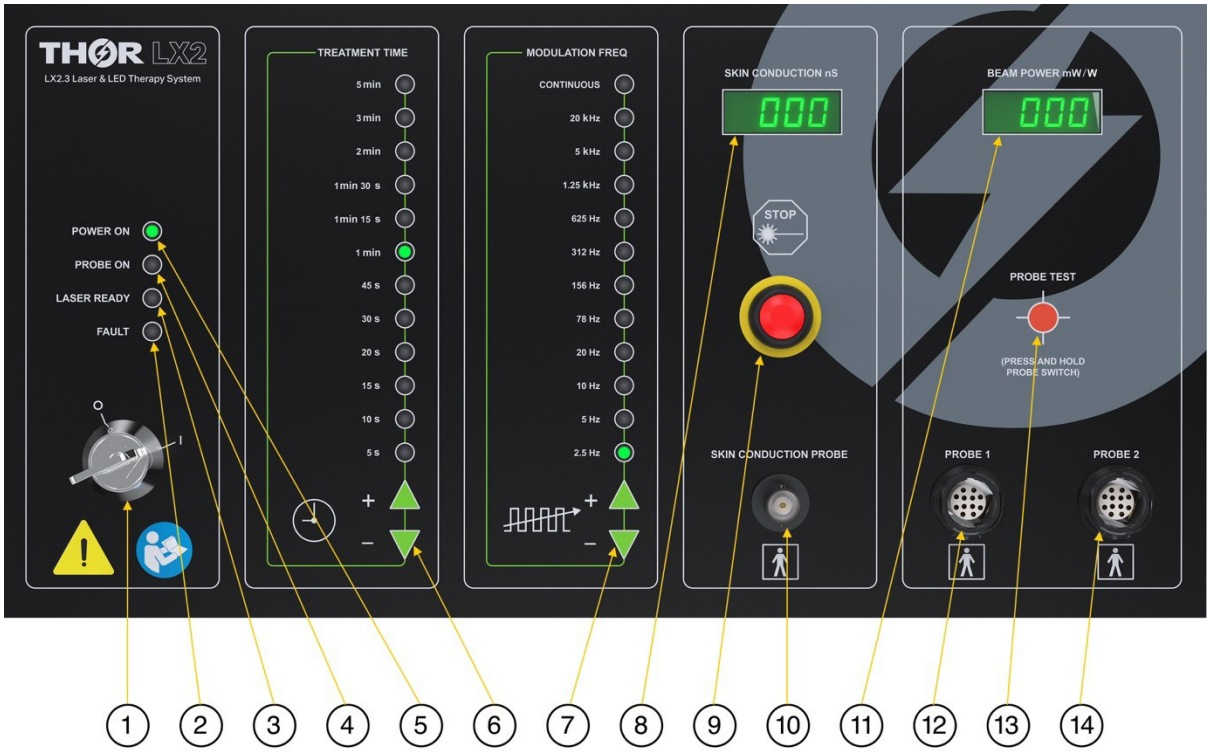
Different countries or regions may have different rules on laser use for different professions. Some require that a medical lasers are registered, fees may need to be paid and a laser safety inspection of your premises may be required. Search online for your country, for example: Medical laser regulations EU.

Some medical boards have regulations regarding which professions can perform a laser procedure. Search online for your profession and state, for example: Medical laser regulations hygienist EU.

Note: Some regulations are for Class 4 lasers only. The THOR lasers are Class 3B and may be exempt from some state or medical board regulations.

LED treatments are usually exempt, so may not be subject to local or medical board regulation.

11. Frequently Used Functions



1. Key On/Off Switch
2. FAULT indicator
3. LASER READY indicator
4. PROBE ON indicator
5. POWER ON indicator
6. TREATMENT TIME
7. MODULATION FREQUENCY
8. Electrical SKIN CONDUCTION to find trigger points
9. Emergency laser stop switch
10. SKIN CONDUCTION handpiece connector
11. Beam power
12. Treatment probe connection PROBE1
13. Laser beam PROBE TEST window
14. Treatment probe connection PROBE2

1. A key-switch on the front panel switches the system on and off. The POWER ON light and a sounder indicate that the control unit is on.
2. Fault Indicator. Section 12. Operating Instructions (h).
3. The LASER READY light and a sounder indicate that a laser treatment probe is ready for use.
4. Probe on Indicator. This light flashes amber whilst a laser or LED probe is in use.
5. Power on indicator. This light is green when the device is powered on.
6. Use the TREATMENT TIME + and – buttons to choose from a range of treatment times. An LED indicator shows which treatment time has been selected.
7. Use the MODULATION FREQ + and – buttons to choose from a range of pulse modulation frequencies. An LED indicator shows which frequency has been selected.
8. Skin Conduction display shows the skin conduction reading in nanoSiemens.
9. The emergency laser stop switch on the front of the control unit, can be depressed to shut down the probes output immediately in the event of an unexpected laser hazard or other emergency.
10. The THOR LX2.3 incorporates a Trigger Point locator which is used to help find myofascial trigger points. Plug the Trigger Point Handpiece into the SKIN CONDUCTION PROBE socket on the front panel; see section 12 Operating Instructions (d) for details

11. To begin treatment, momentarily depress the switch on the treatment probe. The BEAM POWER display shows the power output on the control unit, and a LED on the treatment probe lights up. There is an audible warning when the probe is turned on and off.

12. & **14**. Use PROBE 1 and PROBE 2 sockets on the front panel to connect the LED and laser treatment probes.

- To cancel the treatment at any time, momentarily depress the switch on the probe.
- When the system is switched on, the last-used setting of treatment time and modulation frequency will be automatically restored.

13. The PROBE TEST sensor on the front panel is used to measure the output power of a single point probe via the built-in power meter. See section 12 Operating Instructions (e) for details.

12. Operating Instructions

a. Switching on

Plug the power cord into the AC mains inlet on the THOR LX2.3 control unit and into a suitable electrical AC mains socket.

Caution: - Where the integrity of the PROTECTIVE EARTH CONDUCTOR is in doubt the equipment should not be used.

Caution: - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Turn the key switch clockwise from the “0” to the “I” position. Ensure the control unit displays are illuminated and the “Power On” LED is also illuminated. The LX2.3 control unit will make a few bleeping noises as the circuitry powers up.

b. Treatment

Select the probe to be used and insert it into one of the probe sockets. A list of treatment probes that can be used with the control unit is provided in section 20. Treatment Probe Accessories.

WARNING: - If you are using a laser probe ensure both patient and operator and any observers within 3 m (10ft) are wearing the correct approved laser safety eyewear.

When connecting a laser probe a short warning bleep will be heard for 4 seconds after which the “Laser Ready” warning LED will illuminate.

Note: - During this time it is not possible to switch the laser probe on.

Select the required treatment time using the +/- timer buttons.
Select the desired modulation frequency using the +/- frequency buttons, or if no modulation frequency is required select “Continuous”.

To commence treatment, depress the switch on the probe and release. The probe will then operate for the selected time and then switch off. The LED display on the device automatically shows the power output of the probe while it is on. There is an audible warning when the probe turns on and off.

Note: - On frequency settings of below 20Hz, the display is likely to be unstable due to the low frequency pulsing of the probe, this is normal.

Note: - Adjustment of either the treatment time or frequency is not possible when the probe is switched on.

Note: - The LX2.3 will “Power Up” to the last used settings of treatment time and modulation frequency.

Note: - Treatment probes can be used in contact or a few millimetres away from the tissue surface.

To stop treatment before the set time has elapsed, depress and release the probe switch, the probe will switch off and the timer will reset.

Any treatment probe can be plugged into either probe socket. When two different probes are required to be used during the same treatment session, use both sockets. Only one probe will operate at any one time, they will not work simultaneously. The THOR LX2.3 control unit automatically selects the correct probe when a probe switch is depressed.

c. Using the Treatment Probes with Light Guides – See Section 18.

d. Trigger Point Locator Handpiece / Skin Conduction
(Trigger Point, Acutip laser and Red Spot Laser only)

The THOR LX2.3 incorporates a Trigger Point locator which is used to help find myofascial trigger points. A myofascial trigger point is a hyper-irritable spot, usually within a taut band of skeletal muscle, which is painful on compression and can give rise to characteristic referred pain, motor dysfunction, and autonomic phenomena.

To use this facility, plug the Trigger Point Laser or Acutip laser into a probe socket and plug the Trigger Point Handpiece (hereafter referred to as ‘the handpiece’) into the Skin Conduction Probe socket. Give the Handpiece to the patient to hold, then place the tip of the Trigger Point Laser on the patient’s skin on the body where myofascial trigger points are anticipated. Slowly slide the probe across the skin with firm contact. Look at the digital Skin Conduction display on the control unit and observe the changing numbers and pitch of the audible signal.
The higher the digital reading and audible tone, the more likely you are over a myofascial trigger point. There is no correct number that identifies a myofascial trigger point. The numbers vary widely from one patient to another. Some patients may have normal skin resistance readings of 100 - 500 nS and a trigger point reading of 1,000, others have normal skin resistance reading of 20 - 50 nS and a trigger point reading of 100, or a normal skin resistance reading of 800 - 1,000 nS and a trigger point reading of 1,200.Look for the jump in numbers over the belly of a muscle or muscle insertion point.

When the trigger point has been found, depress the treatment probe switch for treatment of the trigger point. When the probe is switched on, the audible signal switches off.

False readings are possible:

1. If your finger touches the gold tip of the Trigger Point Laser, it will affect the readings
2. If the patients skin is wet with sweat, you will always start with high readings and trigger points may be harder to detect. A cool treatment room will be better for finding trigger points than a hot humid room.
3. If you touch the palms of the hands, plantar surface of the foot, pits of the arms and legs or mucosal tissue (lips, mouth, genitalia) you will always get high readings because these areas are moist due to a high density of sweat glands.

The conductivity of the patient's skin displayed on the control unit Skin Conduction digital display is in units of nS (nanoSiemens). The maximum skin conduction reading (when the two probes are shorted together) is 1850nS. This is set by a resistor in each probe which limits the maximum Skin Conduction (Patient Auxiliary) Current to 10µA to comply with EN60601-1 for a type BF applied part.

To find research on Laser or LED PBM treatments of trigger points search Pubmed.gov for "laser trigger point". For a better understanding of trigger points, search for myofascial trigger points, there are many good books worth reading, and phone apps with physiological maps of common points. To understand the electrical characteristics and diagnostics of myofascial trigger points search for "Surface Electromyography" or "Surface EMG".

e. Laser Probe Output Test

The THOR LX2.3 control unit has a built-in power meter for measuring the output power of the single point laser treatment probes via an automatic calibration feature.

Note: - It is not possible to accurately measure the output of the LED Cluster probes with the built-in power meter.

To measure the treatment probe power output of the Trigger Point, Red Spot or Dental probe with a Light Guide:

Plug in the probe to be tested into a probe socket. Select a treatment time long enough to make the measurement (above 20 seconds) and select the Modulation Frequency "Continuous".

Note: - Measurement below a Pulse Modulation Frequency of 20Hz is not recommended since a stable reading will not be obtained.

Note: - The THOR LX2.3 control unit has special circuitry that maintains the same average power output in continuous and frequency modulated modes.

Depress the switch on the probe but do not release it, keep it depressed. Holding the switch down automatically displays the measured output power as opposed to the pre-set output power.

The probe should now be on. Place the tip of the probe lightly (or Light Guide) on the Probe Test window and adjust its position for the maximum reading on the LED display, keeping the switch depressed. The probe tip should be touching the beam test window but take care not to put excessive pressure on the window. Keep the probe at right angles to the front panel and carefully move it to obtain the maximum reading.

Record the maximum reading, then release the probe switch. The display will now revert to showing the pre-set output power of the probe. Switch off the laser.

Neither the measured output power nor the pre-set output power should vary by more than 10% of the stated output power on the probe label. If they do, then your THOR LX2.3 control unit and probes needs a service and you should arrange for your system to be serviced or repaired via the website www.thorlaser.com/service.

Note: - Low readings can also be caused by dirt on the probe lens. Without dismantling the probe, clean the lens regularly to ensure optimum output and effectiveness of treatment. Refer to (i) Cleaning of Control Unit and Probes below.

When measuring Laser Cluster probes, each Laser within the cluster must be tested individually to check its output.

f. Emergency Laser Stop Switch

The emergency laser stop switch on the front of the control unit, can be depressed to shut down the probes output immediately in the event of an unexpected laser hazard or other emergency. It will cause the control unit to go into fault mode. Turn equipment off at the key switch and back on if you want to continue using the equipment. See (h) Fault Conditions.

g. Remote Interlock Connector

The THOR LX2.3 features a “Remote Interlock Connector” that enables a door in the treatment room to be connected to the control unit and to switch the THOR LX2.3 control unit into the “Fault” condition (and therefore stop laser emission) in the event of the door being opened during treatment.

To enable the remote interlock feature, purchase and fit a magnetic contact switch (laser door switch) to the entrance door of the treatment room. It should be wired a “closed circuit” when the door is shut and “open circuit” when the door is open. Wire this switch into a standard (mono 2 pin) quarter inch jack plug and plug this into the back of the THOR LX2.3 control unit.

h. Fault Conditions

There are five conditions which will cause a fault condition to be activated, whereby the FAULT LED illuminates, a fast audible bleep is emitted, and the treatment probes are switched off:

- When the emergency laser stop switch is depressed.
- When the power output of a probe is reduced by more than 10%.
- When the treatment timer fails to operate within 10% of the set time.
- When the remote interlock is activated.
- When a probe is disconnected from the LX2.3 control unit during treatment.

To restore the function of the control unit: turn the key switch to the off position, turn it on again, treatment can then be recommenced.

If the fault condition persists, go to the website https://www.thorlaser.com/service/ and look at the service pages.

i. Cleaning of Control Unit and Probes

The control unit, cables and Treatment probes can be cleaned in situ.

Control Unit
The cleaning and disinfection recommendation for the control unit is PDI Super Sani-Cloth Germicidal disposable wipes or equivalent alternative wipe.

Cables
The cleaning and disinfection recommendation for equipment cables is PDI Super Sani-Cloth Germicidal disposable wipes or equivalent alternative wipe.

Treatment Probes
The cleaning and intermediate disinfection recommendation for all non-critical THOR treatment probes, is PDI Super Sani-Cloth Germicidal disposable wipes or equivalent alternative. Follow the instructions in: i. Hygiene-cleaning and disinfection

If the LED lollipop is used for semi critical applications, high level disinfection is recommended using the Tristel ULT high-level disinfectant foam with dry wipes system. Follow the instructions in: i. Hygiene-cleaning and disinfection

If the LED lollipop or light guide is used for critical applications sterilization is recommended. Follow the instructions in: i. Hygiene-cleaning and disinfection

Note: Other methods may be suitable and effective. Customers may be obligated to work to their own local standards or use alternatives which are deemed acceptable to local protocols.

Step-by-step hygiene guide prior to each use of treatment probes:

With clean ungloved hands: plug in the control unit into the power outlet.

Use key to turn on the control unit and set the chosen treatment time and frequency using the green arrows.

Plug in your chosen treatment probes and apply any transparent barrier sleeve and covers for treatment probes and control unit.

Put on disposable gloves to protect your hands from any possible contaminants and provide treatment.

Step-by-step guide to help you clean the surfaces and treatment probes effectively post treatment:

Remove and dispose of any transparent barrier sleeves and covers on treatment probes and control unit if these have been utilized according to local regulations.

Remove and dispose of dirty gloves according to local regulations.

Apply clean gloves to prevent cross contamination.

Switch off the unit using the key, unplug treatment probes from socket. Remove detachable light guide if dental probes have been used.

Use Super Sani-Cloth Germicidal disposable wipe or equivalent alternative wipe for cleaning and intermediate disinfection.

Gently wipe all contact surfaces of the control unit, treatment probes, light guides and attached cords immediately after each use. Make sure the cloth is moist but not dripping wet, as excessive moisture could damage the material or seep into any electronic components.

Allow the cleaning agent to sit on the surfaces per the wipe manufacturer's recommended length of time to effectively kill pathogens and bacteria.

If treatment probe or light guide, requires higher level of disinfection or sterilization after manual cleaning, follow instructions in: j. Hygiene-cleaning and disinfection

Dispose of gloves and used wipes according to local regulations.

On visual inspection if a treatment probe is still contaminated, repeat the cleaning and disinfection steps above.

Following this cleaning routine after each treatment will help maintain a sanitary environment and reduce the risk of infection or cross-contamination.

Before using treatment probes or light guide again, complete visual inspection for damaged surfaces, discoloration, and contamination.

Do not use damaged treatment probes or light guides.

WARNING: Treatment probes must NOT be autoclaved or immersed in liquids.

j. Hygiene – Cleaning and Disinfection

A single use, transparent biocompatible barrier sleeve can be placed over the NIR Dental and Red Dental treatment probes with a light guide and LED Lollipop treatment probes.
THOR does not provide sleeves or covers and recommends using sleeves for NIR Dental and Red Dental treatment probes with light guides: Ivoclar Vivadent Bluephase Style Sleeves, Mfg Item#:636239 or equivalent alternative.

Sleeves for LED Lollipop: CIV-Flex™ General Purpose Ultrasound Probe Covers 12" Length, Sterile 14 x 30cm (5.5" x 12") flat folded CIV-Flex cover (3D), not made with natural rubber latex, Mfg Item#: 610-1305 or equivalent alternative.

For cleaning and Intermediate level disinfection of non-critical treatment probes and probe plugs, we recommend using Purple Super Sani-Cloth Germicidal disposable wipes as follows:

- Don clean gloves
- Use a Super-Sani wipe to remove gross soil.
- Using a new Super Sani cloth, wipe the probe/probe plug until all visible soil is removed.
- If visible soil remains, use a soft-bristle brush wrapped with a Super-Sani wipe, brush the probe/plug paying special attention to any hard-to-reach areas.
- Additional wipes maybe use as necessary.
- Allow probe to air-dry.

High-Level Disinfection

The LED Lollipop treatment probe can be high-level disinfected using Tristel ULT

- When using a Tristel ULT Foam bottle for the first time, depress the pump four times to prime and prepare for use.
- Don clean gloves.
- Pull one Tristel ULT wipe out of the tub, closing the cap tightly. Use one wipe for each device.
- Lay the Tristel ULT wipe in the palm of your hand and apply four (4) doses of Tristel ULT Foam to the wipe.
- Close your hand around the wipe and wait for 10 seconds without squeezing the wipe.
- Starting with the handle at the cable end of the device, use the wipe to spread the foam with a massaging motion from one end of the probe to the other four (4) times. Ensure all surfaces are covered and the surface is visibly wet (but not dripping wet). Pay particular attention to crevices and indentations, especially the ridges on the handle, the button and area around the gold band where different materials meet.
- After wiping, leave the probe undisturbed on a clean surface to avoid contamination for 2 minutes for high level disinfection – we recommend using a timer for this.
- Discard the used wipe-do not reuse.
- Using a new Tristel ULT wipe and clean gloves, thoroughly remove any foam residue, paying attention to any crevices and indentations, discarding the wipe when all residue is removed.

Sterilisation

The LED Lollipop treatment probe can be sterilised with Hydrogen Peroxide vapour, on the Sterrad manufacturers STANDARD CYCLE;

- ASP Sterrad NX 53% hydrogen peroxide vapour (by weight) using the standard cycle (28minutes).
- ASP Sterrad 100NX 53% hydrogen peroxide vapour (by weight) using the standard cycle (47 minutes).
- APTIMAX tray and sterilisation wrap, were used for processing the lollipop treatment probe for both the Sterrad NX and Sterrad NX100 modes above.

Other cycle parameters may be used if available on an Regulator-approved hydrogen peroxide vapour device.

The light guides may be sterilized in a sterilization pouch, using autoclave steam sterilization: 132°C (270°F), 4 minutes of exposure time and 20-30 minutes drying time.

WARNING: - Treatment probes must not be sterilized in an autoclave or by solution and on no account should any probe be immersed in liquids.

k. General Care and Use

- Clinical hygiene standards and protocols should be applied to prevent cross contamination.
- No parts of the equipment need to be serviced or maintained while in contact with the patient.
- Clean probes as described in (i) Cleaning of Probes above.

WARNING: - Treatment probes must not be sterilised in an autoclave or by solution and on no account should any probe be immersed in liquids.

- Use probes at 90° to, and in contact with skin where possible.
- Protect from mechanical shocks, heating, and water ingress.
- Handle probes gently: do not drop them. A hard knock may reduce probe output.
- With correct care and use, your THOR LX2.3 should work for many years without any trouble. The most vulnerable parts are cables and connectors.

Caution: - Do not remove plugs by pulling on the cables. When packing the probes wind cables loosely and don't overstretch the cables.

13. Documenting Treatment

For each probe used record:

- Probe name
- Locations treated and number of points treated at each location
- Time per application
- Pulse (Hz) (or Continuous)
- Record use of laser safety eyewear

14. Contraindications

a. Direct irradiation of the eyes

Class 3B lasers are potentially harmful to the retina, though retinal damage is unlikely. Laser safety eyewear, with the correct filter for the wavelength and power being used, must be worn by both patient and practitioner and any observers present. We recommend using only the THOR laser safety eyewear supplied with the product.

Laser Safety Eyewear is not necessary when LED probes are used.

b. Pregnancy

Whilst there is no evidence of harm in humans, we recommend not treating over the foetus. However, it may be used elsewhere on the pregnant woman for the treatment of back pain or other indications for use.

c. Cancer

Whilst there is no evidence of harm in humans, we recommend not treating directly over the site of any known primary malignant cancer or secondary metastasis without the oncologist's permission.

EXCEPTION: PBM can be used for palliative care with informed consent and oncologists permission.

PBM is indicated for treatment of oral mucositis and used for treatment of other cancer therapy side effects caused by radiotherapy, chemotherapy or hematopoietic stem cell transplantation. However, the potential for adverse effects on dysplastic and malignant cells has not been definitively resolved so treatment over a primary malignant cancer or secondary metastasis is controversial.

15. Precautions

a. Photosensitivity reactions

Some patients may be taking drugs or natural remedies known to cause photosensitivity reactions. It is unlikely that a combination of PBM laser and / or LED therapy and drug therapy will trigger this as most photosensitivity is caused by UV light, not red or near infrared (NIR).
THOR recommends that "at risk" patients or patients with a history of such reactions be "patch tested". See Section 16. PBM Patch and Tolerance Testing.

b. Photosensitive Epilepsy

Low frequency flashing visible light (<30Hz) can trigger seizures in 5% of patients with photosensitive epilepsy.
Safety eyewear should be used for these patients when using both laser or LED probes. If needed, before initiating the treatment, place the probe on the treatment area and use a towel to cover both the probe and treatment area to prevent the patient from seeing the flashing light.

c. Reactions to treatment

Patients may report sensations, such as localised feelings of warmth, tingling, an increase or decrease in symptoms, within the 24-hour period immediately following PBM. This is a normal transient response. Other sensations that may be experienced in response to PBM are fatigue, nausea or dizziness. In patients with persisting or severe treatment reactions, PBM should be discontinued.

d. Fixators, metal plates, plastics and pacemakers

PBM CAN be safely used over metal implants, plastics and stitches and on patients fitted with a pacemaker.

e. Tattoos, pigmented lesions and tissues

Darkly pigmented skin/tissues and tattoos absorb light. When using Laser probes, absorption may cause localised heating, and subsequent pain or injury of the treated tissue (This does not happen with LED probes)

DARK-PIGMENTED TISSUES: treatment of very dark-pigmented skin with a laser may cause pain as the melanin absorbs the laser energy, and the melanin gets hot. Remove the laser from contact and treat 15mm from the skin surface.

THOR recommends using a laser to conduct a patch-test on very dark-pigmented tissues. See Section 16. PBM patch and tolerance testing.

TATTOOS: treatment over a tattoo with a laser may cause pain as the dye absorbs the laser energy and the dye gets hot. Remove the Laser from contact and treat 15mm from the skin surface.

AROUND THE HAIRLINE: treatment on the neck with laser may cause pain as the melanin in the fine superficial hair follicle absorbs some laser energy. Remove Laser from contact and treat 15mm from surface.

f. Hygiene

The THOR LX2.3 system is intended to be used with commercially available sleeves or barrier film as needed.

Sleeves for NIR Dental and Red Dental treatment probes with light guides: Ivoclar Vivadent Bluephase Style Sleeves, Mfg Item#:636239 or equivalent alternative.

Sleeves for LED Lollipop: CIV-Flex™ General Purpose Ultrasound Probe Covers 12" Length, Sterile 14 x 30cm (5.5" x 12") flat folded CIV-Flex cover (3D), not made with natural rubber latex, or equivalent alternative.

g. Inflammation

Occasionally patients experience a temporary aggravation of symptoms after PBM treatment. Patients should be warned of this prior to treatment..

h. Immune Suppressant Drugs

Patients on medications designed to suppress the immune system (eg: Methotrexate) occasionally experience a mild flare up of symptoms.
If a patient is on immune suppressant medication, then THOR recommend a PBM “tolerance test” is performed prior to commencing treatment. See Section 16. PBM Patch and tolerance testing.

i. Probe warmth

If a treatment probe becomes too warm to hold or for patient comfort, let it cool before re-using. If you have two probes and probe warmth is an issue, try treating alternately with each treatment probe. This allows each probe to cool between treatments. Ensure you keep to the recommended probe duty cycle on the label.

16. PBM Patch and Tolerance Testing

IF YOU CONSIDER A PBM "TOLERANCE TEST" IS NECESSARY:

Treat 2 points only at the recommended minimum treatment time on the appropriate location with each probe intended for use. Monitor response to treatment over 48 hours.

- If no flare up, then proceed with caution and monitor the response.
- If there is a 'flare up', allow this to settle. Retest at half-minimum treatment time and monitor as above. If necessary, repeat with lower treatment times until an acceptable time is reached for each probe.
- PBM can be commenced once an acceptable treatment time has been determined. If the patient does not respond to the lowered treatment time, building up to an "effective dose" can be tried.
- Contact THOR clinical support if needed for further advice: treatment.advice@thorlaser.com

IF YOU CONSIDER A PBM "PATCH TEST" IS NECESSARY:

Treat 1 point only at the recommended minimum treatment time on the appropriate location with each probe intended for use. Monitor immediate response to treatment and over the next 48 hours.

- If no flare up, then proceed with caution and monitor the response.
- If there is a 'flare up', allow this to settle.
- Retest at half-minimum treatment time and monitor as above. If necessary, repeat with shorter treatment times until an acceptable time is reached for each probe.
- PBM can be commenced once an acceptable treatment time has been determined.
- Contact THOR clinical support if needed for further advice: treatment.advice@thorlaser.com

17. Treatment FAQ's

- Anti-coagulants: Patients on anticoagulant medication bruise easily. It is conceivable that heavier pressure using a probe may cause slight bruising after treatment, so apply gently.
- Anti-inflammatories: these are known to impair normal healing processes. Patients taking anti-inflammatories may not respond as quickly to PBM as those who are not.
- "Sensitive" patients: occasionally, patients are "sensitive" / "reactive" to medications, various therapies and treatments. THOR recommend asking patients about this before commencing PBM. If this is a possibility, we recommend a PBM tolerance test is performed prior to commencing treatment. See Section 16. PBM patch and tolerance testing.
- If using a marker pen to identify points for treatment, use light-coloured markers, such as yellow or orange. This is because dark ink will absorb laser light, the ink may get hot which could be painful for the patient (ONLY WHEN USING A LASER).
- PBM CAN be safely used over metal implants, plastics and stitches and on patients fitted with a pacemaker. PBM cannot be used to cut or remove tissue (including ganglion, cyst, lipoma).
- THOR LED Cluster can be used around the eye area.
- PBM does not penetrate though clothing or any opaque material e.g.: Sticking Plaster (Elastoplast, Band-Aid) wound dressing or bandage.

- The use of creams, lotions, oils, gels or other topical materials during treatment with THOR PBM is NOT recommended. Skin should be free of any opaque/ thickly applied topical fluids/ materials prior to treatment. Necessary creams, lotions, oils, gels and other topical materials should be applied after completing treatment.
- The different pulses (Hz) / Continuous deliver the same amount of energy to the patient as long as the same treatment time is used: 'continuous' mode also delivers the same amount of energy when the same treatment time is used.
- PBM cannot be used to cut or remove tissue (including ganglion, cyst, lipoma).

18. Using the dental probes with light guides, the LED Lollipop and barrier sleeves

There are laser treatment probes that come with a non-sterile detachable light guides ("dental laser probes").These are not sterile when delivered, so should be cleaned and disinfected before first use, and then after every use as appropriate.

The light guide should be attached to the dental laser probe prior to connecting the probe socket on the control unit.

Light guides are supplied with a red rubber cap on the tip. Remove the red rubber cap prior to using the treatment probe as light will not penetrate through the cap. Do not replace the red rubber cap once the light guide has been used.

Attach the light guides by connecting the metal base of the light guide to the metal nipple of the treatment probe, gently push until fully seated.

To remove the light guide from the probe body for cleaning purposes and /or when not in use, first unplug the treatment probe from the control unit.

Hold the probe body in one hand, while using your other hand to gently pull the light guide out of the probe metal nipple in a straight-line motion.

Gently push the light guide into the dental laser probe metal nipple in a straight-line motion

Gently pull the light guide out of the dental laser probe metal nipple in a straight-line motion

Remove the light guide from the treatment probe when cleaning / not in use; store securely, making sure it is adequately padded.

Barrier Sleeves

A single use, transparent biocompatible barrier sleeve can be placed over treatment probes for hygiene purposes as needed.

Note: The barrier sleeve may result in up to 10% transmission loss in power output. Increasing treatment time by up to 10% is usually not necessary. Typical treatment times are 30- 60 secs, adding an extra 10 seconds of treatment is optional.
The dental probe or lollipop is typically applied for 30 to 60 seconds, adding an extra 10 seconds of treatment time per application is optional.

Dental Probe and Barrier Sleeve use

The barrier sleeve should be placed over the treatment probe so that it fully covers the light guide and probe handle with a good fit at tip of the light guide.
Ensure there is no major obstruction to the window of the light guide and the treatment probe On/Off button can be pressed with sleeve on.

LED Lollipop and Barrier Sleeve use

The barrier sleeve should be placed over the LED Lollipop, so that it fully covers the probe. Ensure there is no major obstruction to the emission aperture and the treatment probe On/Off button can be pressed with sleeve on.

19. Care for your System FAQs

a. Probe Cables

Probe cables are subject to constant flexing during use. Although they are designed to be robust, they will fail eventually if used and abused enough, just like any component that wears with use. You can extend the life of your probe cables considerably by treating them with respect.

- Do not overstretch them
- Do not pull them at sharp angles to the front panel of the control unit.

Do not pull the connectors out of the LX2.3 control unit by the cable.

- When not in use, coil the cable loosely in a loop, not around the probe handle.

b. Probe Output

Always keep your probe lens clean at all times, even a smear or fingerprint on a probe lens can reduce power by 10 to 20%. Inspect the probes before use to ensure the lens is clean.

If a probe is dropped, inspect the probe to ensure the lens is free from damage.

c. Probe Temperature

If a treatment probe becomes too hot to hold or for patient comfort, let it cool before re-using. Ensure you are following duty cycles described on the labels (See section 22 Equipment Labels). If your treatment plan requires the use of two or more different probes and probe warmth is an issue, try treating alternately with each treatment probe. This allows each probe to cool between treatments.

20. Treatment Probe Accessories

The following probes are available with your LX2.3 Control unit (Product Code S1022):

Product code	Short Name	Technical Description	Laser Classification & LED Emissions
S2090	NIR Acutip Laser	810 nm/200 mW Infra-red single laser. Acupuncture tip. Intensity: $1/e^2$ power density = 1.97 W/cm^2 Distribution: $1/e^2$ spot size = 0.260 cm^2 NOHD: 0.64 m (continuous exposure) MPE: 1.31 mW/cm2 (continuous exposure) Beam divergence: 60°	Laser Class 3B
S2091	NIR Dental Laser	810 nm/200 mW Infra-red single laser. Dental light guide. Intensity: $1/e^2$ = 1.97 W/cm² Distribution: $1/e^2$ spot size area = 0.088 cm² NOHD: 0.64 m (continuous exposure) MPE: 1.31 mW/cm² (continuous exposure) Beam divergence: 32°	Laser Class 3B
S2092	Trigger Point Laser	810 nm/200 mW Infra-red single laser. Standard tip Intensity: $1/e^2$ = 4.75 W/cm² Distribution: $1/e^2$ spot size area = 0.0364 cm² NOHD: 0.64 m (continuous exposure) MPE: 1.31 mW/cm² (continuous exposure) Beam divergence: 10° x 54° (elliptical)	Laser Class 3B

S2040	Red Acutip Laser	660 nm/30 mW Visible red single laser. Acupuncture tip Intensity: 1/e² power density 0.245 W/cm² Distribution: 1/e² spot size = 0.260 cm² NOHD: 0.09 m (continuous exposure) MPE: 3.54 mW/cm² (continuous exposure) Beam divergence: 60°	Laser Class 3B
S2042	Red Spot Laser	660 nm/30 mW Visible red single laser. Standard tip Intensity: 1/e² power density 0.46 W/cm² Distribution: 1/e² spot size = 0.05640 cm² NOHD: 0.09 m (continuous exposure) MPE: 3.54 mW/cm² (continuous exposure) Beam divergence: 32°	Laser Class 3B
S2173	Red Dental Laser	660 nm/75 mW Visible red single laser. Dental light guide. Intensity: 1/e² = 0.245 W/cm² Distribution: 1/e² spot size area = 0.260cm² NOHD: 0.35 m (continuous exposure) MPE: 3.54 mW/cm² (continuous exposure) Beam divergence: 32°	Laser Class 3B
S2160	Laser Cluster	810 nm/1000 mW Infra-red laser cluster Intensity: 1/e² = 5.96 W/cm² Distribution: 1/e² spot size area = 0.029 cm² NOHD: 1.15 m (continuous exposure) MPE: 1.31 mW/cm² (continuous exposure) Beam divergence: 10° x 54° (5 elliptical beams)	Laser Class 3B
S2195	Giant Laser Cluster probe	810 nm /16 W Infra-red laser cluster Intensity: 1/e² = 5.96 W/cm² Distribution: 1/e² spot size area = 0.029 cm² NOHD: 2.3 m (continuous exposure) MPE: 1.31 mW/cm² (continuous exposure) Beam divergence: 8° x 28° (80 elliptical beams)	Laser Class 3B
S2140	Large LED Cluster	LED Cluster. 850 nm & 660 nm / 2000 mW 104 diodes Maximum intensity: 47.3mW/cm² Mean intensity: 45.0mW/cm² +/-5% Distribution: circular active area (45.3cm²)	LED Exempt Group
S2110	Medium LED Cluster	LED Cluster. 850nm & 660nm / 1390mW 69 diodes Maximum intensity: 46.9 mW/cm² Mean intensity: 44.6 mW/cm² +/-5% Distribution: circular active area (31.2cm²)	LED Exempt Group
S2131	Small LED Cluster	LED Cluster. 850 nm & 660 nm/370 mW 19 diodes Maximum intensity: 42.7 mW/cm² Mean intensity: 40.6 mW/cm² +/-5% Distribution: circular active area (9.2 cm²)	LED Exempt Group

S2197	LED Lollipop	LED Cluster. 850 nm & 660 nm/2800 mW 23 LEDs at 850 nm; 18 LEDs at 660 nm Average power density: 50 mW/cm²±10% Active area: 56 cm²	LED Exempt Group
S2030	Trigger Point Handpiece	Skin Conductance Probe.	N/A

Fig. 1 Single laser, standard tip

Fig. 2 Single laser, dental light-guide

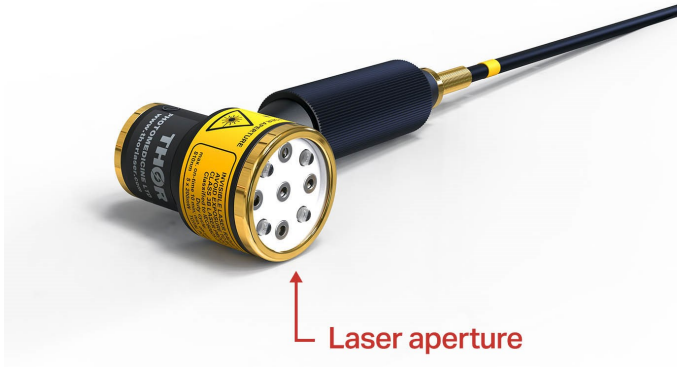


Fig. 3 Laser cluster

Note: - Figures 1, 2, and 3, above, show the variation in location of the laser aperture.

Fig. 4 LED Cluster probe

Note: - Figure 4, above, shows an LED cluster probe (S2140) where the emission aperture is the glass window shown. The other LED cluster probes (S2110 and S2131) have identical emission aperture locations.

Fig. 5 LED Cluster (Lollipop) probe

Note: - Figure 5, shows the LED Lollipop probe (S2197) where the emission aperture is the transparent tip shown.

Laser Safety Eyewear for your LX2.3 System

Laser Safety Eyewear: Two pairs of Laser Safety Eyewear are provided with each THOR LX2.3 Laser and LED Therapy system and should be worn by patient and operator when using any of the Laser probes. See Section 25 for specification of laser safety eyewear.

Other

A single use, transparent biocompatible barrier sleeve can be placed over the NIR Dental and Red Dental treatment probes with a light guide and LED Lollipop. THOR does not provide sleeves or covers and recommends using:

Sleeves for NIR Dental and Red Dental treatment probes with light guides: Ivoclar Vivadent Bluephase Style Sleeves, Mfg Item#:636239 or equivalent alternative.

Sleeves for LED Lollipop: CIV-Flex™ General Purpose Ultrasound Probe Covers 12" Length, Sterile 14 x 30cm (5.5" x 12") flat folded CIV-Flex cover (3D), not made with natural rubber latex, Mfg Item#: 610-1305 or equivalent alternative.

21. Symbols

The symbols on the unit have the following meaning:

Power on
(Control Unit)

Power off
(Control Unit)

Warning
(Control Unit)

Follow instructions for use
(Control Unit & probes)

Treatment time
(Control Unit)

Pulse repetition frequency
(Control Unit)

Decrease
(Control Unit)

Increase
(Control Unit)

Emergency laser stop
(Control Unit)

Type BF applied part
(Control Unit)

Test target for laser
(Control Unit)

Remote interlock connector
(Control Unit)

Careful disposal
(Control Unit)

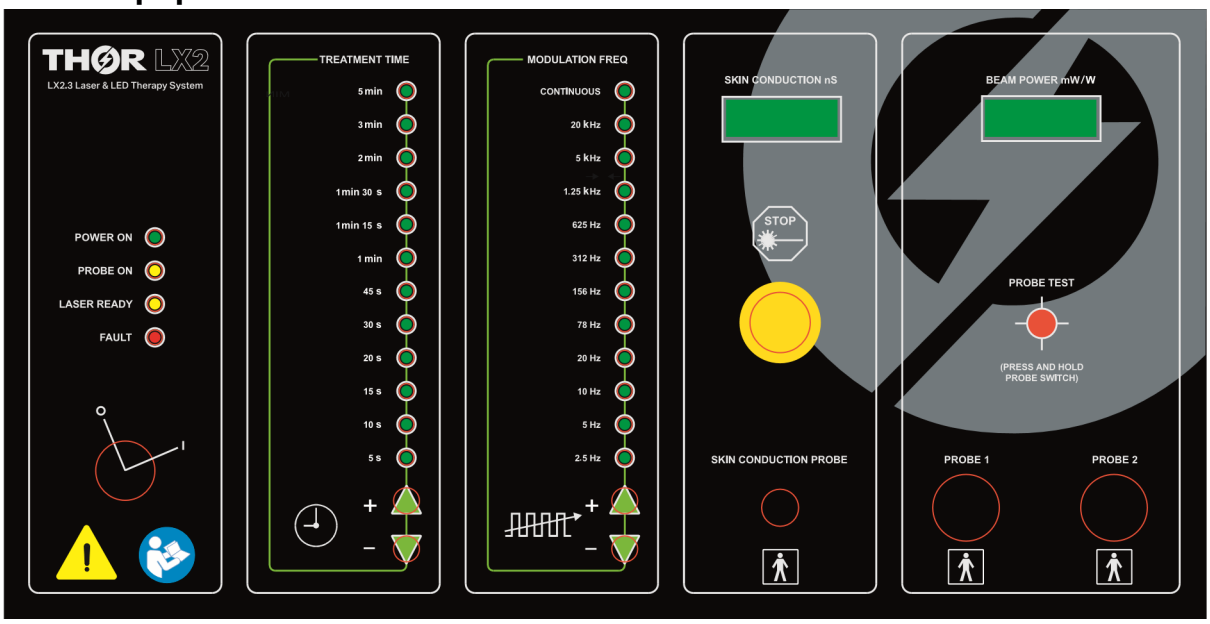
Date of manufacture &
Manufacturer
(Control Unit)

Warning, laser beam
(Control Unit & probes)

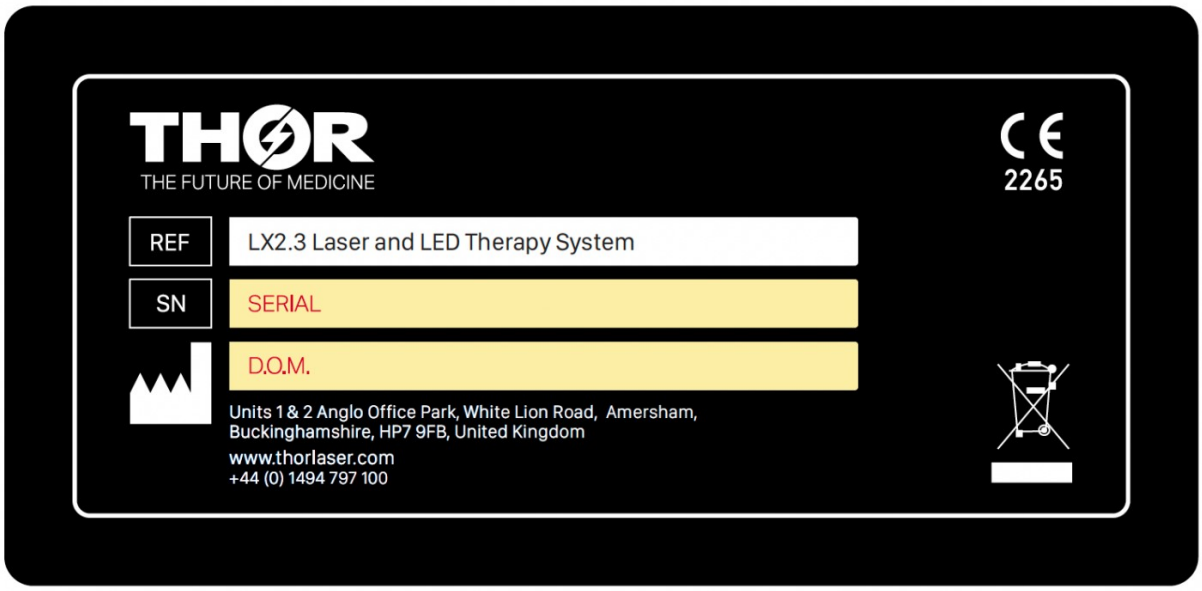
Serial number
(Control Unit)

Catalogue number
(Control Unit)

22. Equipment Labels



Front panel (Control Unit)



Back panel (Control Unit)

Back panel (Control Unit)

EU REPRESENTATIVE

Mr I Clinch

EC REP

THOR Photomedicine EU Limited
North Point Business Park, Unit 3D North Point House
New Mallow Rd, Cork, T23 AT2P, Ireland

Phone: +35 31 592 4057
Email: QARA@thorlaser.com
Company number: 682663

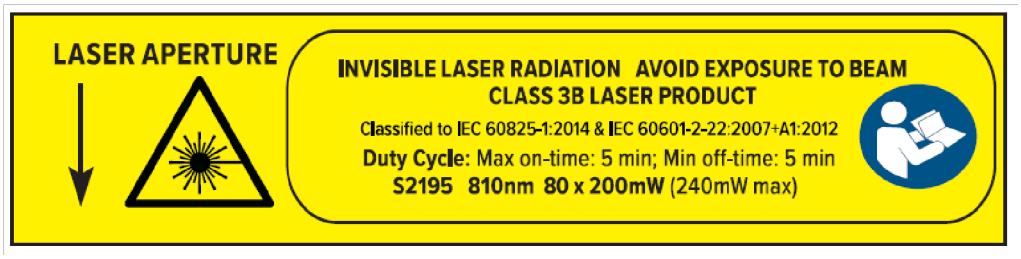
On/off switch (Probes)

NIR (810 nm, 200 mW) Laser Probe: Trigger Point Laser (S2092), NIR Dental Laser (S2091)

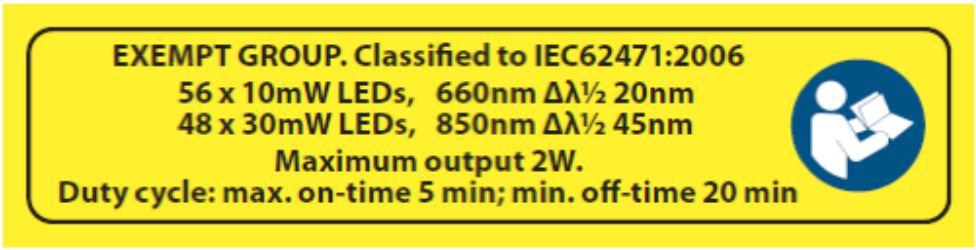
Visible Red (660 nm, 30 mW) Laser Probe: Red Spot Laser (S2042)

Visible Red (660 nm, 75 mW) Laser Probe: Red Dental Laser (S2173)

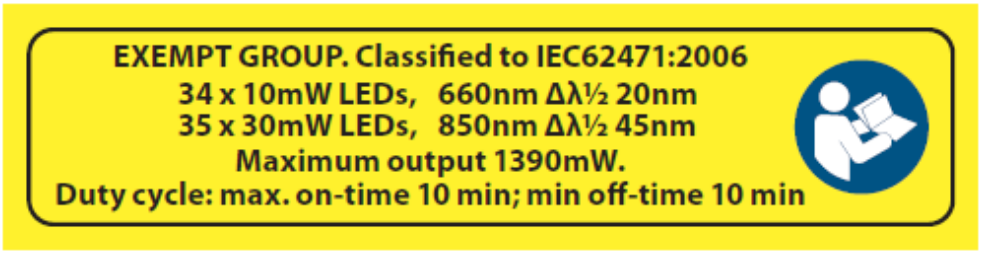
NIR (810 nm, 5 x 200 mW) Laser Cluster Probe: Laser Cluster (S2160)



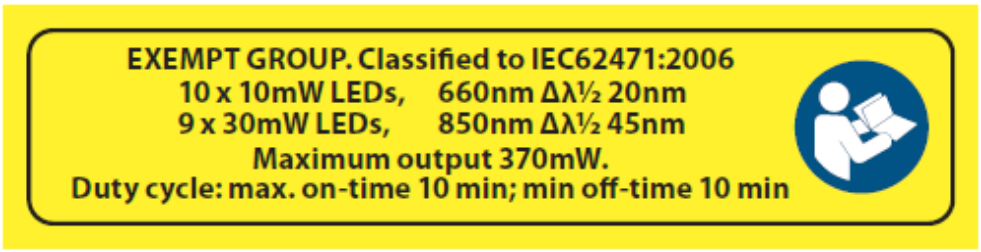
NIR (810 nm, 80 x 200 mW) Laser Cluster Probe: Giant Laser Cluster (S2195)



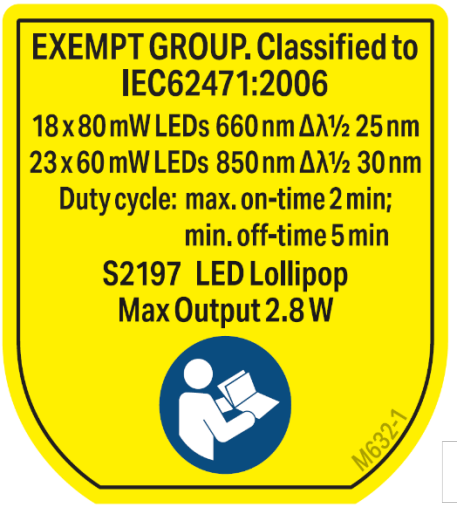
104 LED (660 nm and 850 nm) Cluster Probe: Large LED Cluster (S2140)



69 LED (660 nm and 850 nm) Cluster Probe: Medium LED Cluster (S2110)



19 LED (660 nm and 850 nm) Cluster Probe: Small LED Cluster (S2131)



LED (660 nm and 850 nm) Cluster Probe: LED Lollipop (S2197)

23. Troubleshooting Guide

The following information is provided as a guide for the operator to help diagnose possible faults that can be cured or corrected by the operator. This information can also help diagnose which part of your THOR system is faulty, to ensure the correct part is returned for repair.

Symptom	Action
No power to LX2.3	Is the LX2.3 plugged into the AC mains supply? Is the AC mains supply switched on? Is the LX2.3 control unit switched on? Check/replace fuse in the AC mains plug. Check/replace fuse(s) on the rear of the control unit. Check the AC mains supply voltage. If none of the above correct the fault, return the control unit for servicing, with the AC mains lead, via the website www.thorlaser.com/service
Probe operation intermittent	Ensure that the probe plug is correctly mating with the probe socket on the control unit. If you have more than one probe, does the fault occur with both probes? If yes, clean the probe socket and plug with compressed air or an electrical cleaner. If the fault persists, then return the control unit and probes for servicing via the website www.thorlaser.com/service. If the fault lies with just one probe, then return the faulty probe for servicing via the website www.thorlaser.com/service.
Measured probe power is low	Is the lens dirty? if so clean according to (i) Cleaning of the control unit and probes in section 12. Operating Instructions. Is the indicated power correct? If yes, then return the control unit and the probe for servicing via the website www.thorlaser.com/service. If not, see next section below.
Indicated power is low	Are all of the probes indicating low power? If yes, then return the control unit and probes for servicing via the website www.thorlaser.com/service. If not, just return the probes for servicing via the website www.thorlaser.com/service

No measured probe output	Check the lens for cracks and other signs of physical damage. If lens is damaged return the probe for servicing via the website www.thorlaser.com/service. Clean the lens according to (i) Cleaning of probes in section 12. Operating Instructions. Does the amber LED of the probe light when the probe is switched on? If yes and there is still no probe output, return the probe for servicing via the website www.thorlaser.com/service. If the LED on the probe does not light, check that the probe plug is correctly mated with the probe socket on the control unit. If the fault persists, then send the control unit and the probe back for repair via the website www.thorlaser.com/service
Unit blows fuses	Replace the fuse. If the fault persists, then return the control unit for servicing via the website www.thorlaser.com/service
Unit goes into fault mode	Are any of the fault conditions in (h) Fault Conditions of section 12. Operating Instructions valid? If not, then return the control unit and probes for servicing via the website www.thorlaser.com/service
Probe gets too hot	Ensure the lens on the front of the probe is not broken or damaged. If so, return the probe for servicing via the website www.thorlaser.com/service. Allow the probe to cool before resuming treatment. Refer to section 19. Care for your System FAQs c. Probe Temperature, and section 26. Maintenance and Servicing for further information.

To organise your equipment to be serviced or repair go to the THOR website, www.thorlaser.com/service and complete the online instructions.

24. Technical Specifications

Mains supply:	100-240 V~ 50-60 Hz
Mains supply current:	1.5-0.9 A
Means of supply mains isolation:	The mains AC power cord on the rear panel.
Mains fuses:	T2AH250V
ME equipment:	Class IIb
Applied part:	Type BF
Mode of Operation:	Non-continuous
Treatment times:	5s; 10s; 15s; 20s; 30s; 45s; 1min; 1min 15s; 1min 30s; 2min; 3min; and 5min.
Modulation frequencies:	2.5 Hz; 5 Hz; 10 Hz; 20 Hz; 78 Hz; 156 Hz; 312 Hz; 625 Hz; 1.25 kHz; 5 kHz; 20 kHz; continuous.
Modulation duty cycle:	88%
Laser Ready Delay:	4 s
Skin Conduction Range:	0 to 1851 nS
Skin Conduction Accuracy	5%
Maximum skin conduction current:	10 µA
Power Meter Accuracy:	10% at stated wavelengths
Power Meter Range:	0.1 mW to 1999 mW (Auto- ranging)
Auto calibration at:	660 nm and 810 nm
Operating locations:	Indoor use only
Operating temperature:	+10°C to +25°C
Transport & storage temperature:	-20°C to +50°C
Humidity:	30% to 75% RH (non-condensing)
Dimensions:	(w) 357 mm x (d) 228 mm x (h) 120 mm
Weight:	3.05 kg

25. Specification Laser Safety Eyewear

It is a legal requirement in Europe that Laser safety eyewear must carry the CE mark under the “Personal Protective Equipment” Directive and be type tested and labelled to EN207. In the USA the ANSI standard applies. THOR laser safety eyewear are dual wavelength and can be used with 660 nm and 810 nm laser probes. They are suitable even if the operator wears prescription glasses, as the laser safety eyewear fits over spectacles.

630-660 DIR LB3
>660-670 DIR LB2
780-920 DIR LB2
800-915 DIR LB3

If you are in doubt that the laser safety eyewear are correct for your equipment, then contact THOR Photomedicine Limited or your designated safety officer. Further information on safety can be found on the THOR website www.thorlaser.com/safety.

26. Maintenance and Servicing

WARNING: - The laser probes are a class 3B laser product which output potentially hazardous visible and invisible radiation. Therefore, avoid exposure to the beam and wear THOR approved laser safety eyewear when the laser probes are being used.
This is not necessary when LED probes are used.

Caution: - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

The THOR LX2.3 system will operate safely and will perform its intended purpose within its stated warranty period of 2 years and conditional warranty period of 6 years.
The system has an expected life of 7 years, minimum, with full THOR product support.
Many THOR units serve customers 15+ years and beyond.

a. **User Maintenance**

Clean THOR products routinely according to the approved methods and with approved materials 12.h. Cleaning of Control Unit and Probes
Check routinely for signs of physical wear and tear of the lens/window, cable and plug, listen for unusual sounds. If visual signs of wear and tear, the probe is getting hot or unusual sounds occur contact your THOR representative or THOR Customer Services at www.thorlaser.com/contact
Check periodically Laser Probe Output: check probe output as per section 12.d. Laser Probe Output Test
Note:- It is not possible to accurately measure the output of LED Cluster probes with the built-in power meter. Calibration is completed during bi-annual servicing.

If in doubt, contact THOR Customer Service, who will provide remote support or suggest service or repair options. www.thorlaser.com/contact

b. **Servicing and Repairs**

To keep your THOR LX2.3 product in warranty, follow the recommended 2-year service intervals. THOR LX2.3 system doesn't contain user serviceable parts outside what is described in this manual. See Section 23. Troubleshooting Guide
To organise your equipment to be serviced or repair go to the THOR website, www.thorlaser.com/service and complete the online instructions.

The THOR approved service centre will test for optimal performance and electrical safety to IEC 60601-1 standards
THOR products are carefully calibrated to provide precise and optimal light output, which needs to be verified periodically. During service, the system is tested on special, calibrated instruments for LED and laser power, performance of other components is also checked to ensure equipment is operating to original, proprietary specifications.
If a failure or potential of failure is detected, the issue is addressed in warranty, or repair recommendations are made outside warranty.
The service and test regime is designed to provide long-term, reliable performance and optimal treatment.
Non-THOR approved servicing will not test to original specifications, may not use original parts and will void warranty.

Note:- Equipment that is heavily used may wear and tear faster, requiring additional servicing intervals to ensure best performance.

To organise your equipment to be serviced or repaired go to the THOR website, www.thorlaser.com/service and complete the online instructions.

27. Electrical Testing

Electrical safety testing should be performed by THOR-authorised service representatives in accordance with IEC 60601-1. THOR strongly recommend that these tests be carried out at least every two years.

Unless the equipment is serviced two years from the date of purchase, the conditional warranty will be invalid (see warranty terms and conditions). If the equipment is used heavily this should be done every year. In addition, the equipment should be tested for correct optical output and calibrated to ensure effective treatment. Electrical safety tests and calibration can be carried out by THOR service personnel. For further information, go to the website, www.thorlaser.com/service and examine the service pages.

No user maintenance is to be carried out. Please refer all technical servicing to THOR via the website www.thorlaser.com/service.

Caution: - There are high voltages present inside the THOR LX2.3. Do not attempt to dismantle the equipment without first disconnecting from the AC mains supply.

When performing electrical safety tests on this unit using a 'Rigel' safety tester, or similar high voltage test device, please be aware that laser diodes are susceptible to damage from high voltages. Therefore, THOR recommend that high voltage tests are only performed on probes when they are plugged into the LX2.3 and switched off.

28. Electromagnetic Compatibility (EMC)

Environments

The LX2.3 system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. However, in hospitals, it should not be used near active HF surgical equipment and in the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Essential Performance

The light intensity range is detailed in section 19. Probe Accessories. The treatment time can be set by the user at a number of levels up to 5 minutes. The light output can be set by the user as continuous or with a selected modulation frequency.

Note that, as a result of EM disturbances: the light output may be changed or lost; and/or the set treatment time may change; and/or the set modulation frequency may change.

WARNING: - The LX2.3 system should not be used adjacent to or stacked with other equipment. However, if adjacent or stacked use is necessary, the LX2.3 system should be observed to verify normal operation in the configuration in which it will be used.

WARNING: - The use of probe accessories other than those listed in section 19 of this IFU may result in increased emissions or decreased immunity of the LX2.3 system.

WARNING: - Portable RF communications equipment (including peripherals such as antennae cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the LX2.3 system including cables specified by THOR. Otherwise, degradation of the performance of this equipment could result.

Emissions Compliance

EN60601-1-2: 2015	**Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – Requirements and tests for Home Healthcare Environment (worst case)**	
Reference Standard	**Class/limit**	**Comments/deviations from the standard**
Conducted RF emission EN55011:2010 Referenced in Table 2 (Page 26)	Class B	Applies – PASS Test applies at any one voltage and any one frequency (Table 1)
Radiated RF emission (Enclosure) EN55011:2010 Referenced in Table 2 (Page 26)	Class B	Applies – PASS Test applies at any one voltage and any one frequency (Table 1) Tested within a 3m SAC, emissions limits adjusted by +10dB from 10m limits
Harmonic Distortion EN61000-3-2+A1:2009+A2:2009 Referenced in Table 2 (Page 26) and section 7.2.1	A	Applies – Mode 1 PASS
Voltage Fluctuations and Flicker EN61000-3-3: 2013 Referenced in Table 2 (Page 26) and section 7.2.2	Plt Pst Dmax	Applies – Mode 1 PASS

Immunity Compliance

EN60601-1-2:2015	**Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – Requirements and tests for Home Healthcare Environment (worst case)**	
Enclosure Port (Table 4 – Page 34)		
Reference Standard	**Level**	**Comments/deviations from the standard**

Electrostatic Discharge EN61000-4-2: 2009 Referenced in Table 4 (Page 34)	±2, 4, 8, 15kV air ±2, 4, 6, 8kV contact	**Applies – Mode 1 PASS** Ten +ve and -ve discharges each at 10 points plus 4 vertical and 1 horizontal coupling plane points. If the EUT requires significantly more than 10 discharge points, testing time will inevitably increase. Test performed at any one voltage and any one frequency (c.f. Table 1 of EN60601-12:2015).
Radiated RF EM fields EN61000-4-3: 2006+A1:2008+ IS1:2009+A2: 2010 Referenced in Table 4 (Page 34)	10V/m 80-2700MHz	**Applies – Mode 1 PASS** Swept frequency testing to be performed on 4 faces of the EUT. Frequency range: swept 1% steps Modulation: 1kHz 80% AM Dwell time:3 seconds Test performed at any one voltage and any one frequency (c.f. Table 1 of EN60601-12:2015).
Reference Standard	**Level**	**Comments/deviations from the standard**
Proximity fields from RF wireless communications equipment EN61000-4-3: 2006+A1:2008+ IS1:2009+A2: 2010 Referenced in Table 9 (Page 40)	As detailed below and in section 8.10 of standard.	**Applies – Mode 1 PASS** Test performed at any one voltage and any one frequency (c.f. Table 1 of EN60601-12:2015).
RATED power frequency magnetic fields EN 61000-4-8:2010 Referenced in Table 4 (Page 34)	30A/m	**Applies – Mode 1 = PASS** Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry. Test performed at any one voltage. Either 50 Hz or 60 Hz. During the test, the frequency of the generated magnetic field and the line frequency of the ME EQUIPMENT or ME SYSTEM shall be the same c.f. Table 1 of EN60601-1-2:2015).
Input a.c. power Port (Table 5 – Page 35)		
Electrical Fast Transients / Bursts EN61000-4-4:2012 Referenced in Table 5 (Page 35)	±2kV 100kHz repetition frequency	**Applies – Mode 1 = PASS** Test performed at any one voltage and any one frequency (c.f. Table 1 of EN60601-12:2015).

Surges EN61000-4-5:2006 Referenced in Table 5 (Page 35)	±0.5 and 1kV line to line ±0.5, 1 and 2kV line to earth	**Applies – Mode 1 = PASS** ME EQUIPMENT and ME SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only at ± 2 kV line(s) to earth and ± 1 kV line(s) to line(s). Test performed at any one voltage and any one frequency (c.f. Table 1 of EN60601-12:2015).

Conducted disturbances induced by RF fields EN 61000-4-6: 2014 Referenced in Table 5 (Page 35)	3Vrms 0.15-80MHz 6Vrms in ISM and amateurs radio bands between 0.15MHz and 80MHz. The ISM (industrial, scientific and medical) bands between 0.15MHz and 80MHz are 765MHz to 6.795MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz. The amateur radio bands between 0,15MHz and 80MHz are 1,8MHz to 2,0MHz, 3,5MHz to 4,0MHz, 5,3MHz to 5,4MHz, 7MHz to 7,3MHz, 10,1MHz to 10,15MHz, 14MHz to 14,2MHz, 18,07MHz to 18,17MHz, 21,0MHz to 21,4MHz, 24,89MHz to 24,99MHz, 28,0MHz to 29,7MHz and 50,0MHz to 54,0MHz.	**Applies – Mode 1 = PASS** Frequency range: swept 1% steps Modulation: 1kHz 80% AM Dwell time:3 seconds Test performed at any one voltage and any one frequency (c.f. Table 1 of EN60601-12:2015).
Reference Standard	**Level**	**Comments/deviations from the standard**
Voltage Dips and Interrupts EN 61000-4-11:2004 Referenced in Table 5 (Page 35)	0 % U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycle	**Applies – Mode 1 = PASS** For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the minimum and maximum RATED input voltage U_T.
Input DC Power Port (Table 6 – Page 37)		
Electrical Fast Transients / Bursts EN61000-4-4:2012 Referenced in Table 6 (Page 37)	±2kV 100kHz repetition frequency	**Not Applicable** The test is applicable to all d.c. power PORTS intended to be connected permanently to cables longer than 3 m. Direct coupling shall be used.
Surges EN61000-4-5:2006 Referenced in Table 6 (Page 37)	±0.5 and ±1kV line to line ±0.5, 1 and 2kV line to earth	**Not Applicable** The test is applicable to all d.c. power PORTS intended to be connected permanently to cables longer than 3 m. Direct coupling shall be used. Test performed at any one voltage and any one frequency (c.f. Table 1 of EN60601-12:2015).

Conducted disturbances induced by RF fields EN 61000-4-6: 2014 Referenced in Table 6 (Page 37)	3Vrms 0.15-80MHz 6Vrms in ISM and amateurs radio bands between 0.15MHz and 80MHz. The ISM (industrial, scientific and medical) bands between 0.15MHz and 80MHz are 765MHz to 6.795MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz. The amateur radio bands between 0,15MHz and 80MHz are 1,8MHz to 2,0MHz, 3,5MHz to 4,0MHz, 5,3MHz to 5,4MHz, 7MHz to 7,3MHz, 10,1 MHz to 10,15 MHz, 14MHz to 14,2MHz, 18,07MHz to 18,17MHz, 21,0MHz to 21,4MHz, 24,89MHz to 24,99MHz, 28,0MHz to 29,7MHz and 50,0MHz to 54,0MHz.	**Not Applicable** Frequency range: swept 1% steps Modulation: 1kHz 80% AM Dwell time:3 seconds Test performed at any one voltage and any one frequency (c.f. Table 1 of EN60601-12:2015).
Electrical Transient conduction along supply lines ISO7637-2	As specified in ISO7637-2	**Not Applicable**
Patient coupling port (Table 7 – Page 38)		
Reference Standard	**Level**	**Comments/deviations from the standard**
Electrostatic Discharge EN61000-4-2: 2009 Referenced in Table 7 (Page 38)	±2, 4, 8, 15kV air ±2, 4, 6, 8kV contact	**Applies – Mode 1 = PASS** Ten +ve and -ve discharges each at 10 points plus 4 vertical and 1 horizontal coupling plane points. If the EUT requires significantly more than 10 discharge points, testing time will inevitably increase. Test performed at any one voltage and any one frequency (c.f. Table 1 of EN60601-12:2015).

Conducted disturbances induced by RF fields EN 61000-4-6: 2014 Referenced in Table 7 (Page 38)	3Vrms 0.15-80MHz 6Vrms in ISM and amateurs radio bands between 0.15MHz and 80MHz. The ISM (industrial, scientific and medical) bands between 0.15MHz and 80MHz are 765MHz to 6.795MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz. The amateur radio bands between 0,15MHz and 80MHz are 1,8MHz to 2,0MHz, 3,5MHz to 4,0MHz, 5,3MHz to 5,4MHz, 7MHz to 7,3MHz, 10,1MHz to 10,15MHz, 14MHz to 14,2MHz, 18,07MHz to 18,17MHz, 21,0MHz to 21,4MHz, 24,89MHz to 24,99MHz, 28,0MHz to 29,7MHz and 50,0MHz to 54,0MHz.	**Applies – Mode 1 = PASS** Frequency range: swept 1% steps Modulation: 1kHz 80% AM Dwell time:3 seconds PATIENT-COUPLED cables shall be tested using a current clamp unless a current clamp is not suitable. In cases where a current clamp is not suitable, an EM clamp shall be used. Test performed at any one voltage and any one frequency (c.f. Table 1 of EN60601-12:2015).
Signal input/output parts Port (Table 8 – Page 39)		
Electrostatic Discharge EN61000-4-2: 2009 Referenced in Table 8 (Page 39)	±2, 4, 8, 15kV air ±2, 4, 6, 8kV contact	**Not Applicable** Ten +ve and -ve discharges each at 10 points plus 4 vertical and 1 horizontal coupling plane points. If the EUT requires significantly more than 10 discharge points, testing time will inevitably increase. Test performed at any one voltage and any one frequency (c.f. Table 1 of EN60601-12:2015).
Electrical Fast Transients / Bursts EN61000-4-4:2012 Referenced in Table 8 (Page 39)	±1kV 100kHz repetition frequency	**Not Applicable** SIP/SOPS whose maximum cable length is less than 3 m in length are excluded. Capacitive coupling shall be used.
Surges EN61000-4-5:2006 Referenced in Table 8 (Page 39)	±0.5 and ±1kV line to line ±0.5, 1 and 2kV line to earth	**Not Applicable** This test applies only to output lines intended to connect directly to outdoor cables. Test performed at any one voltage and any one frequency (c.f. Table 1 of EN60601-12:2015).

Reference Standard	Level	Comments/deviations from the standard
Conducted disturbances induced by RF fields EN 61000-4-6: 2014 Referenced in Table 8 (Page 39)	3Vrms 0.15-80MHz 6Vrms in ISM and amateurs radio bands between 0.15MHz and 80MHz. The ISM (industrial, scientific and medical) bands between 0.15MHz and 80MHz are 765MHz to 6.795MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz. The amateur radio bands between 0,15MHz and 80MHz are 1,8MHz to 2,0MHz, 3,5MHz to 4,0MHz, 5,3MHz to 5,4MHz, 7MHz to 7,3MHz, 10,1MHz to 10,15MHz, 14MHz to 14,2MHz, 18,07MHz to 18,17MHz, 21,0MHz to 21,4MHz, 24,89MHz to 24,99MHz, 28,0MHz to 29,7MHz and 50,0MHz to 54,0MHz.	**Not Applicable** Frequency range: swept 1% steps Modulation: 1kHz 80% AM Dwell time:3 seconds SIP/SOPS whose maximum cable length is less than 3 m in length are excluded. Test performed at any one voltage and any one frequency

29. Decontamination of Equipment

If this equipment has been exposed to bodily fluids, blood, respired gases, pathological samples or used in the treatment of HIV or Hepatitis viruses, IT MUST BE DECONTAMINATED BEFORE BEING RETURNED FOR REPAIR OR SERVICING.

WARNING: - The probes must not be sterilised in an autoclave or by solution and on no account should any probe be immersed in liquids. If in doubt, please visit the website www.thorlaser.com/service.

The exception to this is the dental light guide attachment of the dental probe which can be autoclaved in accordance with local procedures.

If decontamination is not possible, equipment must not be dispatched without prior agreement from THOR Photomedicine Limited or its service centre.

The form “Declaration of Contamination Status” is supplied by THOR and is to be completed and returned with any returned equipment.

THOR Photomedicine Limited and its service centres, reserve the right to refuse to service or repair any equipment supplied without a completed Declaration of Contamination Status form or any equipment that is seriously contaminated.

30. Correct Disposal of This Product (WEEE)

This marking on the product and literature indicates that the product and its accessories should not be disposed of with other commercial or household waste at the end of their working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate these items from other types of waste and recycle them responsibly to promote the sustainable reuse of material resources.

Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can take these items for environmentally safe recycling.

Business users should contact their supplier and check the terms and conditions of the purchase contract. This product and its accessories should not be mixed with other commercial wastes for disposal.

31. Disclaimer

Neither THOR Photomedicine Limited, its officers, employees or agents, nor the author of this manual, hold that the application of laser medicine and phototherapy will achieve any or all of the benefits referred to or implied in this text or in any other materials prepared or supplied by THOR. There may be other dangers or consequences associated with the use of laser medicine and phototherapy, known or otherwise, which are not referred to in this manual.

Whilst THOR has taken all possible care in the design and manufacture of this laser unit, no responsibility can be taken by THOR for the way in which it is used. The user operates the laser unit at their own risk.

THOR will not accept any liability for any injury or damages resulting directly or indirectly from the use of the laser unit and any associated equipment, or the information contained in this manual or any other materials or advice provided by THOR to the purchaser or any officer, employee, or agent of the purchaser.

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