

LX2 Laser & LED Therapy System

Instructions For Use



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22.0 RMA Checklist

Prior to the inspection, Servicing, Repair or Return of Medical & Laboratory Equipment

To:-

RMA #	Date
Model # and Serial #:-	Company Name Telephone #

Exposure to Hazards

Has this equipment/item been exposed internally or externally to hazardous materials as indicated below?

Blood, body fluids, respired gases pathological samples **YES/NO** If Yes provide details:

Other biohazards **YES/NO** If Yes provide details:

Chemicals or substances hazardous to health **YES/NO** If Yes provide details:

Other hazards **YES/NO** If Yes provide details:

Cleaning/decontamination method

Have the items been cleaned prior to shipping to THOR Photomedicine **YES/NO** If Yes provide details:

If No then wipe all surfaces with an alcohol wipe. Gloves should be worn for this task

Cleaned By: Date:

Preparation for Shipping

Has the probes been unplugged and the key removed from the key-switch
Yes/No

I Declare that I have taken all reasonable steps to ensure the accuracy of the above information, in accordance with HSG(93)26.

Authorised signature:-	Unit:-
Name (printed):-	Dept:-
Position:-	Tel no:-
Date:-	

20.0 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. The exception to this is the oral attachment of the Dental probe which can be autoclaved in accordance with local procedures.

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

For NHS hospitals in the United Kingdom see the NHS leaflet HSG(93)26 for further information. In addition the form "Declaration of Contamination Status HSG(93)26 Annex" should be supplied with all returned equipment, a copy of which is included over the page. This is a requirement of the Health & Safety at work Act 1974.

THOR Photomedicine Limited and its service centres, reserve the right to refuse to service or repair any equipment supplied without a completed HSG(93)26 form or any equipment that is seriously contaminated.

21.0 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.

1. Introduction



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

Once you understand the photobiological mechanisms and the subsequent physiological effects, this THOR Laser and LED treatment system 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 want you to do well so read this manual starting with the *safety procedure*, 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. General Safety

1. The LX2m system has been designed and approved to comply with regulatory safety standards:
 EN60601-1:1990/A13:1996 and IEC 60601-1:1998/A22:1995
 UL60601-1:2003 and CAN/CSA C22.2 No 601.1-M90
 IEC 60601-2-22: 1995/1996
 BS EN 60825-1:2007
 BS EN 62471:2008
2. Do not open or attempt to modify this equipment. Failure to comply may result in electric shock or hazardous exposure to laser radiation.
3. Do not use accessories or procedures other than those specified in this Instruction For Use manual or recommended by THOR Photomedicine.
4. THOR Photomedicine approved laser safety spectacles 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).
5. Do not leave the key in the equipment when it is unattended. Keep the key in a safe place.
6. Do not treat the eye or surrounding area with a laser light. LED light is not a risk but we suggest the patient keeps their eye closed because it is unpleasantly bright.
7. Do not direct Laser light into the eyes.
8. Only use the THOR Photomedicine supplied mains power lead.
9. Only connect the LX2 unit to an earthed (grounded) mains power supply.
10. Find out if your organisation has a LPA or LSO or some equivalent and notify them of the equipment. They should be able to provide you with their own safety guidelines (local rules) for you to follow.

Symptom	Action
No measured probe output	<p>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.</p> <p>Clean the lens as per section 8 of the Operating Instructions.</p> <p>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.</p> <p>If the LED on the probe does not light, check that the probe plug is screwed into the socket on the unit. If the fault persists then send the unit and the probe back for repair via the website www.thorlaser.com/service</p>
Unit blows fuses	<p>Replace the fuse. If the fault persists then return the unit for servicing via the website www.thorlaser.com/service</p>
Unit goes into fault mode	<p>Are any of the fault conditions in section 7 of the Operating Instruction valid?</p> <p>If not then return the unit and probes for servicing via the website www.thorlaser.com/service</p>
Probe gets too hot	<p>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.</p> <p>Allow the probe to cool before resuming treatment. See Probe Temperature under Reliability section for further information</p>

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

19.0 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	Is the LX2 plugged into the mains? Is the mains supply switched on? Is the LX2 unit switched on? Check/replace the fuse in the mains plug Check/replace the fuse on the rear of the unit Check the mains supply voltage If none of the above correct the fault and return the unit for servicing with the mains lead via the website www.thorlaser.com/service
Probe operation intermittent	Ensure that the probe collar is fully screwed into the probe socket on the unit If you have more than one probe, does the fault occur with both probes? If yes, clean the probe socket with compressed air or an electrical cleaner. If the fault persists then return the 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 as per section 8 of the Operating Instructions Is the indicated power correct? If yes then return the 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 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

3. Safety Warnings

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



VISIBLE AND INVISIBLE LASER RADIATION
AVOID EXPOSURE TO THE BEAM
CLASS 3B LASER IS POTENTIALLY HAZARDOUS TO THE EYE

WEAR LASER SAFETY SPECTACLES
THOR APPROVED LASER SAFETY SPECTACLES
MUST BE WORN BY THE PATIENT & OPERATOR
WHEN THE LASER PROBES ARE BEING USED

*READ THIS MANUAL FOR SAFE AND EFFICIENT USE
BEFORE USING THE THOR TREATMENT SYSTEM*

4. Hazards

Optical Hazard

Laser operators should be aware of the potential hazards of Lasers, such as optical injury caused by unintended 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, and adequate signage and removal of the key when not in use is the responsibility of the Laser user. Not necessary for THOR LED probes.

Heat Hazard

Before treatment starts the operator should ask the patient to report if the heat from the treatment probe becomes too hot. If this does occur then the operator should then split the longer treatment times and separate them by rest periods to allow the probe to cool down. Typical single area use times are between 30 seconds and 1 minute. See section 8 *precautions* for advice on skin types.

Probe type	Maximum* continuous treatment time in minutes
19 LED cluster probe 370mW	20
69 LED cluster probe 1390mW	10
104 LED cluster probe 2000mW	10
660nm 30mW Laser probe Dental tip	30
660nm 200mW Laser probe Dental tip	7
810nm 200mW Laser probe	15
810nm 200mW Laser probe Dental tip	15
810nm 1W Cluster Laser probe	10
810nm 2W Cluster Laser probe	6

* - This is the time the probe takes to reach 40°C when in continuous use or with very brief breaks in use (less than a minute) when the starting ambient temperature is 20°C.

18.0 Electrical Testing

It is a United Kingdom legal requirement of the Health and Safety at Work Act, that all electrical appliances be periodically checked for electrical safety. In the case of medical equipment, this should consist of electrical safety tests in accordance with 60601-1. THOR strongly recommend that these tests are carried out at least every 12 months.

Unless the equipment is serviced 12 months from the date of purchase, the extended warranty will be invalid (see warranty terms and conditions). If the equipment is used heavily this should be done every 6 months. In addition the equipment should be tested for correct optical output and calibrated, in order 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 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. Do not attempt to dismantle the equipment without first disconnecting from the 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 all Laser Diodes are easily susceptible to damage from static or high voltage sources. All THOR Laser probes have static filters built into them to help prevent damage. Additionally the THOR LX2 unit grounds both Laser drive pins when the probe is not on. Therefore THOR recommended that high voltage tests are only performed on probes when they are plugged into the LX2 and with the probe switched off.

17.0 Maintenance and Servicing

THOR units and probes are generally very reliable, but like all professional equipment, they are subject to wear and tear and require routine preventative maintenance. If you return your equipment for annual servicing to an approved THOR service centre, it will be tested for correct output and electrical safety. THOR also look for worn items and replace them before they cause a reliability issue. Annual servicing will greatly improve the reliability of your equipment, as opposed to just using it every day until it goes wrong. Think of servicing your Laser equipment as you would your car, it requires annual electrical safety testing and calibration to ensure it meets regulatory requirements and is functioning correctly, and preventative maintenance of cables and probes (oil and filter change). Servicing intervals will depend on your use (mileage). If you use a non approved THOR engineer for your servicing, the chances are that he will only be testing for electrical safety and correct output and not doing any preventative maintenance. To book your system for a service go to the website www.thorlaser.com/service and follow on onscreen instructions.

The most common failures are with probe cables and low output due to dirty or damaged probe lens.

Probe Cables

The probe cables take a lot of current and are subject to constant flexing during use. Although they are designed to be as robust as possible 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 over stretch them
- Do not pull them at sharp angles to the front panel of the unit.
- Do not pull the connectors out of the LX2 unit by the cable.

If your cables are starting to look worn and used, return your unit and probes for service via the website www.thorlaser.com/service when it is convenient and get the probe cables changed to prevent failure, rather than waiting for a failure at an inopportune moment.

Probe Output

Low probe output is another common fault. This is nearly always caused by a dirty probe lens. If the contamination is bad enough, the excessive localised heating can damage the Laser diode. Keep your probe lens clean at all times, even a smear or finger print on a probe lens can reduce power by 10 to 20%. It is also not uncommon for probes to be dropped, which often breaks or cracks the probe lens. Inspect probes before use to ensure lens are clean and free from damage.


Probe Temperature

Use common sense with Laser probe temperature. If a Laser probe becomes too hot to hold, let it cool down before re-using it. Some THOR probes produce high powers, the higher the probe output the higher the power dissipation. 810nm 450mW and 2W cluster probes get hot quite quickly in use. These probes are designed for applications where short treatments are required. If you want to treat for long periods you are better off with lower powered probes. If you have two probes and probe temperature is a problem, try treating alternately with each probe rather than just using one probe for 30 minutes then another. This will allow each probe to cool between treatments and keep your probes (and your patient) healthier.

5. Electromagnetic Compatibility (EMC)

Guidance and manufacturer's declaration – electromagnetic emissions		
The THOR LX2 is intended for use in the electromagnetic environment specified below. The customer or the user of the THOR LX2 should assure that it is used in such an environment		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The LX2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	The LX2 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.

Guidance and manufacturer's declaration – electromagnetic immunity			
The THOR LX2 is intended for use in the electromagnetic environment specified below. The customer or the user of the THOR LX2 should assure that it is used in such an environment			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-2	±2 kV for power supply lines±1 kV for input / output lines	±2 kV for power supply lines±1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kV differential mode±2 kV common mode	±1 kV differential mode±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC61000-4-11	<5% U _T (>95% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles	<5% U _T (>95% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the LX2 requires continued operation during mains power interruptions, it is recommended that the LX2 be powered from an uninterruptible power supply.
	<5% U _T (>95% dip in U _T) for 5 seconds	Not applicable	If the user of the LX2 requires continued operation during mains interruptions, it is recommended that the LX2 be powered from an uninterruptible power supply.
Power frequency (50/60Hz) Magnetic field IEC61000-4-8	3 A/M	3 A/M	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Note U _T is the a.c. mains voltage prior to the application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
The THOR LX2 is intended for use in the electromagnetic environment specified below. The customer or the user of the THOR LX2 should assure that it is used in such an environment			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
			Portable and mobile RF communications equipment should be no closer to any part of the LX2. Including cables, than the recommended distances calculated from the equation applicable to the frequency of the transmitter Recommended separation distance
Conductive RF IEC61000-4-6	3Vrms 150kHz to 80MHz	3Vrms	$d=1.2\sqrt{P}$
Radiated RF IEC61000-4-3	3V/m 80MHz to 2,5GHz	3V/m	$d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.5GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1 At 80MHz and 800MHz the higher frequency range applies. Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitted, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment in the location due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LX2 is used exceeds the applicable RF compliance level above, the LX2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the LX2.			
^b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.			

Recommended separation distances between portable and mobile communication equipment and the THOR LX2			
The THOR LX2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the THOR LX2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the THOR LX2 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz $d=1.2\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitter rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer. Note 1. At 80MHz and 800MHz the higher frequency range applies. Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

16.0 Specification - Safety Spectacles



It is now a legal requirement in Europe that Laser safety goggles 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 goggles are dual wavelength and can be used with 660nm and 810nm laser probes. They are suitable even if the operator wears prescription glasses, as they fit over spectacles.

NOIR ML3

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

If you are in doubt that the safety spectacles 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

15.0 Technical Specifications - LX2m

Mains Voltage	110 to 240 V 50 to 60 Hz
Current Consumption	150 mA (Full Load at 240V) 300 mA (Full Load at 120V)
Power Consumption	30 VA at 115 V
Mains Fuse	T2AH 250 V
Power Supply Classification	Class 2
Insulation	Type B
Mode of Operation	Continuous
Timer Settings	5 secs, 10 secs, 15 secs, 20 secs, 30 secs, 45 secs, 1 min, 1 min 15 secs, 1 min 30 secs, 2 mins, 3 mins, 5 mins
Timer Accuracy	±10%
Frequency Outputs	2.5 Hz, 5 Hz, 10 Hz, 20 Hz, 78 Hz, 156 Hz, 312 Hz, 625 Hz, 1.25 kHz, 5 kHz, 20 kHz and continuous
Duty Cycle	88%
Laser Ready Delay	4 seconds
Automatic Shutdown for	10% probe power reduction Failure of primary timer Remote interlock activation Operation of Laser Stop switch
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 Temperature	+10°C to +40°C
Transport and Storage Temperature Range	+10°C to +40°C
Humidity	30% to 75% RH (Non condensing)
Dimensions	355(w) x 230(d) x 123(h) mm
Weight	3 Kg

6. Intended and Indications For Use

The LX2 Laser and LED Therapy System improves speed and quality of tissue healing, reduces inflammation and reduces pain when applied to the treatment area.

It is indicated for:

Neck pain
Oral mucositis
Tendinopathies
Chronic Joint Disorders

7. Contra-Indications

Direct Irradiation of the Eyes

Class 3b Lasers are potentially harmful to the retina, though retinal damage is unlikely. Laser safety goggles, with the correct filter for the wavelength and power being used, must be worn by both patient and practitioner. Not necessary for THOR LED probes.

Pregnancy

Laser is contra-indicated for use over the pregnant uterus, however it may be used with caution on the pregnant woman as an adjunct to the other modalities being used for the treatment of back pain or other complaints.

Carcinoma

Do not use the Laser over any known primary or secondary lesions. Laser treatment may be given for pain relief during the terminal stages of the illness. THOR recommend this be done only with the informed consent of both patient and consultant involved.

Thyroid

Laser should not be used over the thyroid gland.

Haemorrhage

It is conceivable that Laser-mediated vasodilatation may worsen the haemorrhage.

Immune Suppressant Drugs

Laser Therapy is contra-indicated for patients on these drugs.

Treatment over Sympathetic Ganglia, the Vagus Nerves and Cardiac Region in Patients with heart Disease

Laser Therapy may significantly alter neural function, and is therefore contra-indicated over these regions in patients with heart disease.

8. Precautions

Steroid Injections

Patients may suffer an exacerbation of symptoms after Laser therapy in conjunction with a recent steroid injection. For this reason Laser should not be used within 2-3 weeks of a recent steroid injection on or near the same site. After 2-3 weeks, you may then use the Laser. THOR recommend one or two treatment points only at the minimum recommended dosage for that probe.

Photosensitivity Reactions

Some patients may be taking drugs or natural remedies known to cause photosensitivity reactions. It is unlikely that a combination of Laser and drug will trigger a response. However THOR suggest that "at risk" patients or patients with a history of such reactions be "patch tested" for the minimum recommended treatment time for that probe, and each probe expected to be used on that patient.

Anti Coagulants

It is possible that probe pressure may cause slight bruising after treatment.

Anti-Inflammatories

Patients taking anti-inflammatories for acute soft tissue injuries may not respond as quickly to Laser therapy as those who are not. Ideally, THOR would suggest a combination of ice and Laser therapy without the use of an anti-inflammatory.

N.S.A.I.D. and Steroidal A.I.

Patients using topical or systemic steroids or N.S.A.I.D's for pain or skin conditions may experience a mild "flare up" of their symptoms. If such a reaction occurs, Laser therapy should be stopped. The reaction should be allowed to settle. Laser treatment can then be recommenced at minimum or half-minimum treatment times. If necessary building up to an "effective dose" if the patient does not respond to the lowered treatment times. For patients with persisting treatment reactions, Laser therapy should be discontinued.

Epilepsy

Take care when using Laser therapy, especially with pulsed or modulated emissions, for these patients, particularly when treating around the head and neck. If practical, cover the area being treated with a towel draped over the probe.

Reactions to Treatment

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

Pins, Metal Plates, Plastics and Pacemakers

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

14.0 Probe Accessories

The following probes are available with your unit:

Product code	Description	Laser/ LED & *Classification
S1091	810nm/200mW Infra red single laser. Dental light guide.	Laser Class 3B
S1092	810nm/200mW Infra red single laser. Standard tip.	Laser Class 3B
S1061	remove -660nm/200mW Visible red single laser. Dental tip.	Laser Class 3B
S1041	660nm/30mW Visible red single laser. Dental light guide.	Laser Class 3B
S1042	660nm/30mW Visible red single laser. Standard tip.	Laser Class 3B
S1173	660nm/75mW Visible red single laser. Dental tip.	Laser Class 3B
S1120	810nm/2000mW Infra red laser cluster.	Laser Class 3B
S1160	810nm/1000mW Infra red laser cluster.	Laser Class 3B
S1140	LED Cluster. 2000mW 104 diodes.	LED Class 2M
S1110	LED Cluster. 1390mW 69 diodes.	LED Class 2M
S1131	LED Cluster. 370mW 19 diodes.	LED Class 2M
S1030	Skin Conductance Probe.	N/A

* In Canada all probes are classified under IEC 60825-1

10. General Care and Use

The probes should be cleaned as described in section 8 - Cleaning of Probes.

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.

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 the probe output.

With correct care and use the equipment should work for many years without any trouble. The most vulnerable parts are the cables and connectors.

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

Tattoos, Pigmented Lesions and Tissues

Dark pigments, such as tattoos, marker-pen inks, melanin, and other natural or man-made pigments, may absorb light at the wavelengths used in Laser medicine. Where probes with high power densities are in use, the absorption of Laser energy by these pigments may cause localised heating, and subsequent discomfort or injury, of the irradiated tissue. THOR recommend conducting patch-tests on darker-pigmented tissues. When identifying points for treatment it is advisable to use lighter-coloured markers, such as yellow or orange. Treatment around sensitive areas with dense hair follicle distribution, such as the hairline, top lip, and so on, may cause discomfort for individuals with darker-coloured hair.

Hygiene

General clinical hygiene standards and protocols apply.

9.0 Regulations

Regulations differ from one country to the next and in the USA the regulations can differ between states. In addition regulations can differ between professions also.

There are regulations for manufacturers regarding safety and efficacy claims. Some countries have a formal application and approval process. (USA the FDA, UK the MHRA, Canada - Health Canada and Australia has TGA).

In some countries there are regulations for users. These usually determine which professions can operate a medical laser and what is considered a safe environment. These may not affect the use of LED treatment probes.

The THOR web site has some useful links that may help you understand the regulations in your country. www.thorlaser.com/regulations

REFERENCE SOURCES AND MATERIALS

THOR refer users to the website, www.thorlaser.com for additional information which may assist in the safe and effective application of Laser medicine and phototherapy. There are many training courses around the world, scientific conferences, scientific and professional associations, web pages and books giving instruction on Laser therapy, all available via our web page www.thorlaser.com

10.0 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.

11.0 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 SI Unit of Frequency
IR	Infra-Red
LED	Light Emitting Diode
LPA	Laser Protection Advisor
LSO	Laser Safety Officer
mA	Milliamperes (x10 ⁻³ A) Unit of measure of Current
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
nm	Nanometer (x10 ⁻⁹ m) Unit of measure of wavelength
nS	NanoSiemens (x10 ⁻⁹ S) Unit of measure of conductance
RH	Relative Humidity
RoHS	Restrictions of the Use of certain Hazardous Substances in electrical and electronic equipment regulations 2008
TGA	Therapeutic Goods Administration
W	Watts, SI unit of Power
WEEE	Waste Electrical & Electronic Equipment directive

6. Remote Interlock Connector

The THOR LX2 features a "Remote Interlock Connector" that enables a door in the treatment room to be connected to the unit and to switch the THOR LX2 unit into the "Fault" condition (and therefore stop the Laser emission) in the event of the door being opened during treatment in order to comply with EN60601-2-22.

To enable the remote interlock connector fit a magnetic contact switch to the entrance door of the treatment room that is "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 unit.

7. Fault Conditions

The THOR LX2 unit will shut down in the event of certain fault conditions as defined in EN60601-2-22.

Fault Conditions are as follows:-

- The "Laser Stop" switch has been depressed.
- The power output of the probe has dropped by more than 10%, due to either a fault with the THOR LX2 or the probe.
- The Primary Timer has failed to operate within 10% of its set time and the Watchdog timer has shut the unit down to prevent a treatment overdose.
- The "Remote Interlock Connector" has been operated.
- A probe has been removed from a socket during treatment.

When a "Fault" condition occurs the "Fault" LED will be illuminated and a fast audible warning beep will be heard and all probe outputs are switched off.

NOTE:- It is not possible to operate the unit in this condition.

To "reset" the THOR LX2, turn the key switch off and then back on. Repeat the treatment again.

If the fault condition persists go to the website www.thorlaser.com and look at the Service pages.

8. Cleaning of Probes

The lenses of the probes should be kept clear of impurities at all times so that the optical path of light remains unobstructed. The probes should be cleaned using a chlorhexidine wipe or similar cloth soaked in surgical spirit.

9. Use of Probes on Broken Skin & Wounds

This device is not intended for use on broken skin and wounds.

To measure a single probe power output proceed as follows:-

4. Laser and LED Single Probe Output Test (continued)

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.

NOTE:- Measurement below 20Hz is not recommended since a stable reading will not be obtained.

The recommended Modulation Frequency setting for Probe Power Measurements is "Continuous."

NOTE:- The THOR LX2 Laser 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 on the Probe Test window and adjust its position for the maximum reading on the LED display, taking care to keep 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 back to showing the pre-set output power of the probe.

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 unit and probes are in need of 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 lens of the probe. Without dismantling the probe, clean the probe lens regularly to ensure optimum output and effectiveness of the treatment given.

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

5. Laser Stop Switch

The "Laser Stop" switch on the front of the unit, can be depressed to shut down the THOR LX2 immediately in the event of an unexpected Laser hazard or other emergency.

NOTE:- Depressing the "Laser Stop" switch will switch off power to the probes immediately. (See section 7 below).

NOTE:- Due to the nature of the internal circuitry in the THOR LX2, the "Laser Stop" switch will not activate the fault condition for the first 4 seconds that the probe is on.

12.0 Symbols

The symbols on the unit have the following meaning:



Power On



Power Off



Follow Instructions for Use



Treatment Time



Modulation Frequency



Decrease



Increase



Laser Stop



Type B applied part



Test target for Laser



Careful Disposal



Remote Interlock Connector

13.0 Operating Instructions

1. Switching On

Plug the IEC lead into the mains inlet on the THOR LX2 and into a suitable electrical mains socket.

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

Turn the key switch clockwise from the "0" to the "1" position. Ensure the unit displays are illuminated and the "Mains On" LED is also illuminated. The LX2 unit will make a few bleeping noises as the circuitry powers up.

2. Treatment

Select the probe to be used and insert it into one of the probe sockets. Screw the collar of the probe connector into the socket until finger tight. A full list of probes that can be used with the unit is provided in the accessory section.

Caution:- the probe collar must be screwed into the socket in order to comply with EMC Legislation.

WARNING:- If you are using a Laser probe ensure both patient and operator are wearing the correct approved Laser safety spectacles

When connecting a Laser probe a short warning bleep will be heard for 4 seconds and the "Laser Ready" warning LED will be illuminated.

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

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 will automatically show the power output of the probe while it is on. There is an audible warning when the probe turns on and off.

NOTE:- The control unit is limited to a maximum single use time of 5 minutes which does not allow the probes to rise above 40°C. The typical single area treatment time is between 30 seconds and 1 minute. See Hazards section for probe maximum recommended use times.

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

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

NOTE:- The LX2 will "Power Up" to the last used settings of time and frequency

2. Treatment (continued)

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

When two different probes are required to be used during the same treatment session, use both sockets. Two treatment probes cannot be used simultaneously but the THOR LX2 unit automatically selects the correct probe when the appropriate probe switch is depressed.

3. Skin Conduction

The THOR LX2 incorporates a skin conduction measurement facility. This is used to find nerve endings, which respond particularly well to laser treatment. To use this facility connect any single probe to either probe socket.

Attach the Hand Probe to the unit and place it in the patient's hand and then place the single probe on the patient's skin. The conduction of the patient's skin will be displayed in unites of nS (nano Siemens). The higher the reading the higher the conduction. An audible warning is also given, which increases in frequency with conduction. This enables the point of best conduction to be found without looking at the display. Readings will tend to be much higher in the summer when temperatures are higher and the patient's skin is moist with perspiration.

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.

When the nerve ending or trigger point has been found the laser probe switch can be depressed for treatment.

NOTE:-When the probe is switched on the audible skin conduction indication will be switched off. Be careful not to touch the laser probe tip with your fingers whilst making a skin conduction measurement on the patient as this will lead to false readings.

4. Laser and LED Single Probe Output Test

The THOR LX2 has a built in power meter for measuring the output power of both single LED and single LASER probes. This power meter has an automatic calibration feature that enables it to measure probes at the following different wavelengths:- 660nm and 810nm as well as compensation for different power densities.

NOTE:- The 660nm LED probe can be measured however it will read approximately 10% low.

NOTE:- It is not possible to accurately measure the output of LED cluster probes.