TheraTouch® LX2
OPERATION MANUAL

Richmar®

Declaration of Conformity:

Richmar declares that the TheraTouch® LX2 complies with following normative documents:

IEC60601-1, IEC60601-2-22, IEC60825-1

PRECAUTIONARY INSTRUCTIONS

The precautionary instructions found in this section and throughout this manual are indicated by specific symbols. Understanding these symbols and their definitions before operating this equipment. The definition of these symbols are as follows:

DANGER

Possible safety issues that could be imminently hazardous and could result in death or serious injury.

WARNING

Possible safety issues that could cause serious injury and/or equipment damage.

CAUTION

Possible safety issue that could have the potential to cause minor to moderate injury or damage to equipment.

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WARRANTY

The warranty period for this device is three years from the date of purchase.

In case of warranty claim, the date of purchase must be confirmed by the dealer from whom the device was purchased and may require proof by means of receipt or invoice.

Richmar's sole obligation in the case of any warranty claim shall be, at Richmar's option, to replace the Product with a new or factory certified reconditioned Product without charge to the Purchaser or to refund the purchase price of the Product.

NOTE:

1. Repairs under warranty do not extend the warranty period either for the device or the replacement parts.
2. Shelf life is most influenced by several factors: exposure to light and heat, transmission of gases (including humidity), and mechanical stresses, this device is not sterile equipment, materials nor volatilization and degradation, this device has no restricted shelf-life.
3. This device has been evaluated according to IEC 60068-2-14 Tests. Test N: Change of temperature, can affect its safety and effectiveness prior to its first use under the claimed storage conditions described in its labeling.

Circumstances not covered under warranty include, but may not be limited to:

1. All damage which has arisen due to improper treatment, e.g. nonobservance of the manual instructions, warnings, cautions, and installation instructions.
2. All damage which is due to repairs or tampering by any unauthorized personnel or third parties.
3. Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service center.
4. Accessories which are subject to normal wear and tear (Accessories have a one year warranty).
5. Liability for direct or indirect consequential losses caused by the device; even if the damage to the device is accepted as a warranty claim.

FOREWARD

INTENDED USER/OPERATOR

This manual has been written for the owners and operators of the TheraTouch LX2. It contains general instructions on operation, precautionary practices, maintenance and parts information. In order to maximize the use, efficiency and lifespan of your device, please read this manual thoroughly and become familiar with the controls as well as the accessories before operating the device.

This device is designed to only be used by or under the supervision of persons using the medical device in the course of their work and in the framework of a professional healthcare activity, who understand the benefits and limitations of laser therapy. (I.e. “professional users”)

⚠ WARNING

TheraTouch LX2 is Rx ONLY and should only be used under the supervision or by the order of a physician or other licensed healthcare provider.

However, with Richmar's policy of continual improvement, changes to these specifications may be made at any time without obligation or prior notice from Richmar.

PRODUCT LIABILITY

A law on Product Liability has become effective in many countries. This Product Liability law implies, amongst other things, that once a period of 10 years has elapsed after a product has been brought into circulation, the manufacturer can no longer be held responsible for possible shortcomings of the product.

To the maximum extent permitted by applicable law, in no event will Richmar or its suppliers or resellers be liable for any indirect, special, incidental or consequential damages arising from the use of or inability to use the product, including, without limitation, damages for loss of goodwill, work and productivity, computer failure or malfunction, or any and all other commercial damages or losses, even if advised of the possibility thereof, and regardless of the legal or equitable theory (contract, tort or otherwise) upon which the claim is based. In any case, Richmar’s entire liability under any provision of this agreement shall not exceed in the aggregate the sum of the fees paid for this product and fees for support of the product received by Richmar under a separate support agreement (if any), with the exception of death or personal injury caused by the negligence of Richmar to the extent applicable law prohibits the limitation of damages in such cases. Richmar cannot be held liable for any consequence resulting from incorrect information provided by its personnel, or errors incorporated in this manual and / or other accompanying documentation (including commercial documentation)

The opposing party (product’s user or its representative) shall disclaim Richmar from all claims arising from third parties, whatever nature or whatever relationship to the opposing party.

PRODUCT DESCRIPTION

TheraTouch LX2 is a professional low level laser light therapy (LLLT) device to be used in a professional setting. The TheraTouch LX2 comes standard with a 9 diode cluster applicator, touch screen, preset protocols, dosage calculator, and ability to save 99 user protocols.

Low level laser light therapy is capable of producing physiological effects related to regenerative stimulation in chronic pathologies, reduction of acute inflammation of edema, acute and chronic pain, and soft tissue syndromes.

PRECAUTIONARY INSTRUCTIONS

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In this section general Warnings and Cautions are listed, that you should be aware of when using the LX2. Also, see warnings and cautions that are application specific.

⚠ WARNINGS

- **Federal law (USA only) restricts this device to sale by, or on the order of, a physician or licensed practitioner. This device should be used only under the continued supervision of a physician or licensed practitioner.**
- Make certain that the device is electrically grounded by connecting only to a grounded electrical service receptacle conforming to the applicable national and local electrical codes.
- Do not operate the device in an environment of short-wave or micro-wave diathermy.
- The LX2 is not suitable for use in the presence of flammable anesthetics mixture with air, oxygen, or nitrous oxide.
- This device should be kept out of the reach of children.
- Handle applicators with care. Inappropriate handling or misuse of applicators may adversely affect it's characteristics and ability to function properly.
- Dispose of products in accordance with local and national regulations and codes.
- Care must be taken when operating this device adjacent to or stacked with other equipment. Potential electromagnetic or other interference could occur to this or other equipment. Try to minimize this interference by not using other equipment (i.e. cell phones, etc.) in conjunction with it.
- Do not treat through clothing or apply laser on an area of skin that has lotion or ointments applied, or burns may occur.
- Laser head should be cleaned with a disinfectant cleaner between sessions. Do not spray directly on laser head. Spray on cleaning cloth and do not use a chlorine based cleaner.

⚠ CAUTION

- Read, understand and practice the precautionary and operating instructions. Know the limitations and hazards associated with using any laser therapy device. Observe the precautionary and operational stickers placed on the device.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to laser energy.
- Handle the laser applicator with care. Inappropriate handling of the laser applicator may adversely affect its characteristics.
- Inspect the laser applicator for cracks which may affect the laser irradiation before each use.
- Before operating the machine carefully check the correctness of the connections according to the instructions.
- Do not operate the LX2 when connected to any device.
- Do not block the air inlet or outlet in case of reducing cure effect and damaging the product.
- This device should be operated in temperatures between 5°C - 40°C (41°F to 104°F), with a humidity ranging form 10% - 85% non condensing.
- Do not expose the device to direct sunlight, heat radiated from a heat radiator, excessive amounts of dust, moisture, vibrations and mechanical shocks.
- In the case of ingress of liquids, unplug the device from the mains supply and have it checked by an authorized person (see the paragraph on maintenance).
- The radiation from a laser device is dangerous. Always use the appropriate provided protective glasses to avoid exposure to your eyes of the reflected laser beam.
- **Before beginning any treatment both operator and patient must wear the PROTECTIVE GLASSES**
- Before connecting the cable to the mains plug, check that the equipment wasn't damaged during transport. Ensure that the power supply specifications on the mains socket correspond with the information on the label attached to the back of the device.
- The equipment should only be connected to electrical systems that fully comply with regulations.
- Before connecting or disconnecting the power cable from the connecter on the device, make sure it is unplugged from the main socket.
- The power cable has a grounded plug for safety reasons.

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PRECAUTIONARY INSTRUCTIONS

- The applicators should never be directed to areas sensitive to laser radiation, such as the eyes.
- It is important that the operator of the device verify the electrical installation of the device is correct before activating the power supply switch.
- **Laser therapy should not be used over areas with tattoos.**
- **Laser therapy should not be used on dark pigmented skin.**
- **DO NOT** operate this device in an environment where other devices are being used that intentionally radiate electromagnetic energy in an unshielded manner. Portable and mobile RF communication equipment can affect Medical Electrical Equipment.
- **DO NOT** use sharp objects such as a pencil point or ballpoint pen to operate the buttons or touch screen as it may result in equipment damage not covered by the warranty.
- **DO NOT** disassemble, modify or remodel the device or accessories. This could cause the device to malfunction, electrical shock, fire or personal injury.
- To avoid unauthorized use, it will return to the password login after 10 minutes.

INTENDED USE

INTRODUCTION

Laser therapy is based mostly on photochemical and photo-biological effects on cells and tissues. Observations have shown that if the laser light is supplied in the right quantities, you will obtain a stimulation of certain cellular functions, especially in the presence of cells with functional deficiencies. The biological action in using Laser therapy produces a series of effects on the cells in function of a “stimulating” action on mitochondrial functions with a higher production of ATP.

Expect the following effects on tissues treated with TheraTouch LX2 laser therapy:

- Increased local blood circulation
- Acceleration of tissue healing
- Stimulation of the fibroblast cells
- Increase in collagen deposition

TheraTouch LX2 carries out an important therapeutic action for the acceleration of the healing process. Furthermore, it is indicated for the treatment of painful articular, muscle, neurogenic and soft tissue syndromes.

The operator, in fact, should be qualified to be able to use such equipment, and should have passed an adapted training, or should operate under the control of a medical professional adequately qualified to the use of the equipment, in order to guarantee safety conditions to the patient.

INDICATIONS

The following indications can be treated with TheraToch LX2 laser therapy:

- Temporary increase in local blood circulation
- Temporary relief of minor muscle and joint pain and stiffness
- Muscle relaxation
- Temporary relief of muscle spasm
- Temporary relief of arthritis pain

CONTRAINDICATIONS

- **Direct radiation in the eye: Class 3B Lasers are potentially dangerous for the retina. The special safety goggles supplied with the machine must be worn by both patient and the operator.**
- Pregnancy: LLLT should not be administered over the low back, abdomen or pelvic area during pregnancy,
- Neoplasms: you must not use laser on a primary lesion or on pain of unknown etiology. Laser treatment may be granted to relieve pain during the terminal stage of disease, it is recommended that this be performed only with the full consent of the patient.
- Thyroid: the laser should never be used in this area.
- Over areas of hemorrhage.
- Immuno-suppresive therapy: Any patient who has undergone any type of drug therapy related to this ailment.
- Treatments over the sympathetic ganglia, the vagus nerve and region of the heart in patients with heart disease: laser therapy can significantly alter the neural function, and is therefore contraindicated in this regions body patients with heart disease.
- Atopic dermatitis and eczema in the acute phase

INTENDED USE

- Photosensitive patients, or those taking photosensitizing medications
- Recent surgery or cryotherapy areas and inflammation.

PRECAUTIONS AND WARNINGS

- Some patients are more sensitive to laser output (i.e., patients taking medications orally or topically that increase sensitivity to light) and may experience a reaction similar to a heat rash or skin burn.
- Be sure to inspect the treatment area during and following treatment, and discontinue if an adverse reaction does occur.

LASER THERAPY PARAMETER DEFINITIONS

Continuous Mode – The output of the laser light is not interrupted during the treatment time.

Dosage – A measure of the intensity of the laser light energy over the treatment area. The unit of measure are Joules or Joules/cm^2/J/diode.

Energy – Measured in Joules, energy equals the treatment time multiplied by the power. More importantly, Energy Density equals the power output multiplied by the treatment time, and divided by the spot size (cm^2). This gives a more specific measurement of energy delivered.

Frequency – Determines the number of laser pulses delivered per second during a pulsed treatment and is measured in Hz. Depending on the frequency selected, this will determine the amount of pauses between laser pulses.

Power - A rate in which energy is produced. For LLLT, it is measured in Milliwatts or Watts. Higher power levels result in reduced treatment times and deeper penetration.

Power Density - The average power per unit area of the beam size. It is determined by dividing the power level of the laster by the area of the beam. The beam is fixed and smaller areas will produce a higher power density because the light is concentrated over a smaller area.

Pulsed Mode - Decreases the overall power level proportional to the frequency selected.

Beam Area (spot size) – Area of the laser beam when it leaves the face of the lens.

Measurements –

- Joules per laser diode
- Joules
- Joules per cm^2

Duty Cycle – Fixed in pulse mode at 90%

PACKAGE CONTENTS

STANDARD ACCESSORIES

DESCRIPTION	QTY
Interlock	1
Laser Protective Glasses	2
User Manual	1
AC Power Cord	1
Cluster Applicator, 9 Diode Laser LED (850nm)	1

OPTIONAL ACCESSORIES

DESCRIPTION	QTY
Cart	1
Single Applicator, 650nm	1

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INSTALLATION

- Remove the LX2 device and any additional items ordered from the carton and inspect for damage that may have occurred during shipment.
- Place the device on a desk or Therapy Cart. Ensure that there is sufficient air flow below the device (do not place the device on a table-cover).

CONNECTION TO POWER SUPPLY

- The power entry module can be found on the back of the device and consists of a three-pole socket for the cable set and the main switch.
- Connect the power cord to the back of the laser device, that consists of a 3-prong plug. Do not use a 3-to-2 prong adapter or any other non-grounded means of attaching to a wall outlet.
- Attach the female end of the included power cord tot he male power connector. Plug the male end of the power cord to a grounded wall outlet that is rated a 100-240 Volt AC 50/60Hz. The power supply must match the voltage requirements listed on the serial number label on the bottom of your device. Do not connect the TheraTouch LX2 to a power supply rated differently than described above.
- Attach the blue interlock connector to the back of the device by lining up the placement, push on completely and then turn to the right to lock into place. If this is not connected, the laser device will not produce any output and produce an error code of 714 until it is connected.

⚠ WARNING

The TheraTouch LX2 may emit radio interference. Avoid operating other electrical devices adjacent to and simultaneously with the TheraTouch LX2 Laser Light device.

⚠ CAUTION

Do not place the device in a location where the power cord could be tripped over or pulled out during treatment.

⚠ CAUTION

Do not attempt to use the device if it is not properly grounded. Make certain that the device is electrically grounded by connecting it only to a grounded electrical service receptacle conformable with the applicable national and local electrical codes regarding medical environments.

- Set power line switch on
- Power LED indicator is lit blue indicating that the device is connected to the mains supply.
- The device will initialize and perform a self test. This may take a while.
- At the end of the self test the device enters the password interface and is ready for use.

DISCONNECTION FROM MAINS SUPPLY

- Turn off the device with push button.
- Set power line switch off to stop charging and to disconnect the device from the mains supply.

APPLICATION INFORMATION

BEFORE TREATMENT

- Check the patient for contraindications.
- Before applying laser therapy, it is necessary to prepare the patients skin to allow the laser light to reach the target tissue better and to reduce skin irritation, by doing the following:

1. Clean the area where the head of the laser will be positioned with soap and water or alcohol.
2. Make sure to dry the area well before starting laser application.

Both operator and patient must wear the PROTECTIVE GLASSES.

DURING TREATMENT

- Frequently ask to ensure patients are not experiencing undesired effects from treatment. If necessary the treatment will have to be adapted. The amplitude can be reduced or the continuous mode can be changed to pulsed mode or vice versa.
- Do not look directly into the laser or remove protective glasses prior to treatment ending.

AFTER TREATMENT

- Ensure the laser output has stopped before removing the protective glasses from the patient and treating clinician.
- Observe the treatment area to ensure no undesired effects have occurred.
- Tell the patient to inform the clinician should they have any adverse reactions.

TREATMENT TIPS

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CONTACT

For most effective results, the applicator should be in contact with the patient's skin and may require multiple applications around the treatment area.

APPLICATOR SELECTION

For very small treatment areas, treat with the single diode applicator. For areas that are sensitive, use the single applicator first, then use the cluster applicator.

PRE & POST TREATMENT

Cold: If treating with cold therapy as part of the treatment regimen, apply cold therapy prior to laser treatment as it reduces the energy that is removed from the area and slows the flow of red blood cells.

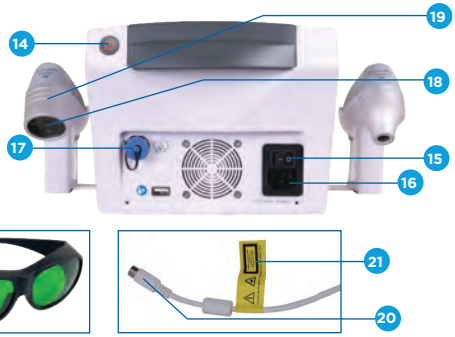
HOT

If treating with hot therapy as part of the treatment regimen, apply heat after laser treatment as it increases the energy and can be removed from the area by speeding up the flow of red blood cells.

OPERATING INSTRUCTIONS

THERATOUCH® LX2, FRONT

THERATOUCH® LX2, REAR



1. Power Indicator LED
2. Touch Screen Display
3. Emergency Laser Stop Button
4. Shortcut: Manual Operation
5. Shortcut: Clinical Protocols
6. Shortcut: Favorites
7. Central Controller Indicator LED
8. Central Controller Dial
9. Applicator "A" Connection Port
10. Applicator "B" Connection Port
11. Laser Applicator (Device comes with one)
12. LED Output Indicator
13. Laser Protective Glasses (2)
14. Power Button
15. AC Power Switch
16. Power Connection
17. Interlock Connector
18. Laser Aperture
19. Applicator Head
20. Applicator Connector
21. Applicator Rating Label

⚠ CAUTION

Connection of accessories other than the ones specified by the manufacturer can adversely affect the safety of the patient and correct functioning of the equipment, and is therefore not permitted. For combined applications only use NU-TEK type B equipment. The very low leakage current of this type of equipment ensures absolute safe therapy.

⚠ CAUTION

The laser applicator is a precision instrument. Great care has been taken during the development and in production to obtain the best possible beam characteristics. Rough treatment can adversely affect these characteristics, and must therefore be avoided.

To protect the device against being used by unauthorized personnel, the password login will pop up on the screen if the device is idle for 10 mins.

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OPERATING INSTRUCTIONS

SHORTCUT BUTTONS

ICON	NAME	DETAILS
	Stop	Press this button to stop treatment immediately.
	Clinical Protocols	Press this button to go directly to the clinical protocols when device is in standby.
	Favorites	Press this button to enter stored favorites when device is in standby.
	Manual Operation	Press this button to enter the manual treatment screen when device is in standby.

NAVIGATION

Below is a list of software symbols you will notice throughout the device. Please make yourself familiar with each symbol and its definition before operating the TheraTouch® LX2.

SOFTWARE SYMBOLS

ICON	NAME	DETAILS
	Back	Return to previous screen.
	Home	Return to Home screen.
	Stop	Stop Treatment
	Favorite	Store favorite protocols/treatments
	Start	Start power output
	Pause	Pauses power output
	Delete	Delete Favorite
	Save	Save favorites protocol
	Info	Description of Clinical Protocol
	A Indicator	Detects applicator plugged into A port

DEVICE USER INTERFACE

SOFTWARE SYMBOLS (CONTINUED)

ICON	NAME	DETAILS
	B Indicator	Detects applicator plugged into B port
	Wavelength/ Power	Active Laser Applicator State Indication
	Frequency Setting	Frequency Indication (only in pulsed mode)
	Start Button	Press to activate applicator for treatment (does not start treatment)
	Treatment Time	Treatment Time Indication
	Dosage Setting	Dosage Measurements include Joules, J/cm2 and J/diode
	Dosage Display	Displays Dosage option (4 measurements available)

SYSTEM STARTUP

STARTUP SCREEN

- Once power supply is connected, turn the On/Off Switch on the back of the devices to the On position.
- The Home Screen will appear in approximately 2 seconds.

LOGIN SCREEN

- To use the device you must first login using your password. The initial password is 12345678. You have the ability to change it after you log in for the first time by going into the maintenance screen (See page 15 for this option).
- To protect the device against being used by unauthorized personnel, the password login will pop up on the screen if the device is idle for 10 mins.

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DEVICE USER INTERFACE

CLINICAL PROTOCOLS

HOME SCREEN

The Home Screen includes the following functions:

- Clinical Protocols
- Favorites
- Manual Operation
- System Settings

Press Clinical Protocols

CLINICAL PROTOCOLS SCREEN

For Treatment Information, such as specific parameters for each clinical indication, press i on the left side of the desired protocol.

Note: To go directly to the Treatment Screen, press the desired protocol button Pain & Inflammation - Chronic

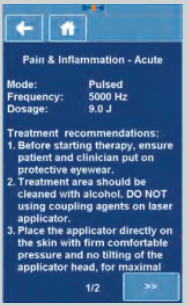
TREATMENT INFORMATION SCREEN

This screen shows the parameters of treatment and treatment recommendations.

Touch >> to advance to proceeding treatment recommendations, as well as the treatment screen.

Note: To return to the Clinical Protocols Screen, touch ←.

Then press the desired clinical protocol to advance to the Treatment Screen.



TREATMENT SCREEN

To change a parameter, touch the corresponding button and adjust accordingly with the Central Controller Dial.

DEVICE USER INTERFACE

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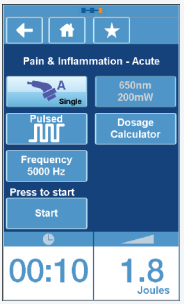
CLINICAL PROTOCOLS CONTINUED

Applicator Selection

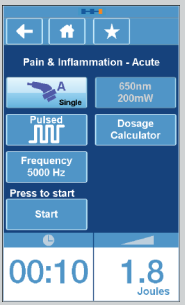
- Press and rotate the central controller dial to change from either a Single or Cluster applicator.*
- If using an LX2 with both applicators, the device will recognize which applicator is plugged into each Connection Port. Applicator A is on the left of the device and Applicator B is on the right.
- To ensure the correct applicator displayed is being used for treatment, press and the applicator indicator will turn orange to indicate it is ready for treatment.

Note: The output cannot be changed when treatment is active and both applicators cannot work simultaneously.



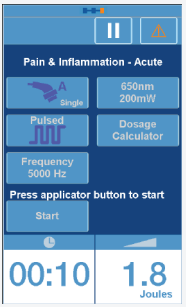
Treatment Ready

- Once the parameters are set, press the start button to activate the applicator and the indicator will turn orange.
- If you do not have the blue interlock connector connected to the back of the device, the system will show error 714. Simply plug the connector into the back and proceed with the below directions.
- If the treatment time equals zero, you cannot press the Start button. A treatment time must be populated based on the energy density.



Start Treatment

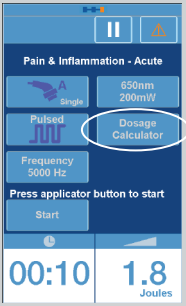
- Place firm, comfortable pressure on the treatment site with no tilting of applicator head, for maximal energy.
- Press the orange button on the applicator to begin energy output. The orange button will change to blue when energy output has begun. The Treatment Time will begin counting down.
- During treatment the laser output can be stopped by pressing or .



Dosage Calculator Options

To choose which dosage measurement preferred, press the Dosage Calculator Button. There are several options to choose from:

- Joules only
- J/cm² only
- J/diode
- All above options in one (Joules, J/cm² and J/diode)



*Device comes with cluster (single applicator is optional)

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DEVICE USER INTERFACE

SAVING FAVORITES

You may only save Favorites prior to beginning a treatment, or after a treatment has ended

TREATMENT SCREEN

- To begin saving a Favorite from the Treatment Screen, press ★.

SAVE FAVORITE SCREEN

- Enter the name of your Favorite, using the keyboard.

Note: Per HIPPA Guidelines, you should not store favorites under a patient's name. We recommend saving under a general treatment description or the patient's chart number.

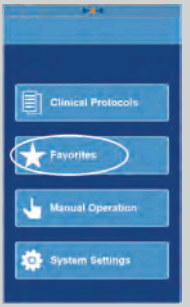
- Press ☑ to save the name chosen, under favorites.

Note: Once saved, you can view saved Favorites, and recall them to be used in future treatments.

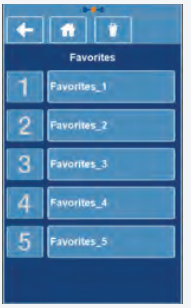
DELETING FAVORITES

HOME SCREEN

Press **Favorites**.



FAVORITES SCREEN



- Press 🗑.
- With the 🗑 icon highlighted, you may select any Favorite you would like to delete. You will be asked to confirm the deletion of any Favorite you select; press Yes to confirm deletion.

Note: Once deleted, a Favorite can no longer be recalled. A deleted Favorite cannot be undone.

DEVICE USER INTERFACE

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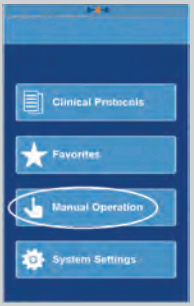
MANUAL OPERATION

Manual Operation allows the user to select customizable parameters specific to the patient.

HOME SCREEN

- Press Manual Operation to navigate directly to the Treatment Screen.



TREATMENT SCREEN

To change a specific parameter, press the button on the screen and use the central controller dial to adjust to desired setting.

Applicator Selection

- Press and rotate the central controller dial to change from either a Single or Cluster applicator.*
- If using an LX2 with both applicators, the device will recognize which applicator is plugged into each Connection Port. Applicator A is on the left of the device and Applicator B is on the right.
- To ensure the correct applicator displayed is also being used for treatment, press and the applicator indicator will turn orange to get ready for treatment.

Note: The output cannot be changed when treatment is active and both applicators cannot work simultaneously.

Output Mode Selection

- Press to choose between Continuous or Pulsed. If choosing Pulsed Mode, an adjustable Frequency parameter will display. Press and use the central controller dial for desired parameter. (Not available in Continuous Mode)

Note: Output Mode cannot be changed when treatment is active. Both applicators CANNOT work simultaneously.

*Device comes with cluster (single applicator is optional)

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DEVICE USER INTERFACE

MANUAL OPERATION CONTINUED

Dosage Selection

- Touch the energy density area to highlight it orange. Then adjust the density by rotating the Central Controller Dial.
- The energy density selected, will change the treatment time automatically. You cannot increase the treatment time without the device also changing the energy density level.
- For a longer treatment time of the selected energy density, it is recommended to apply multiple applications of the desired dosage, at several points. For maximum effectiveness, a minimum of 20 secs of treatment time is recommended for the treatment area.

Treatment Ready

- Once the parameters are set, press the start button to activate the applicator and the indicator will turn orange.
- If you do not have the blue interlock connector connected to the back of the device, the system will show error 714. Simply plug the connector into the back and proceed with the below directions.
- If the treatment time equals zero, you cannot press the Start button. A treatment time must be populated based on the energy density.

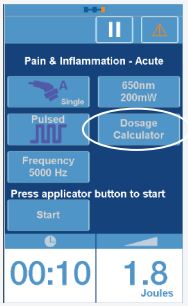
Start Treatment

- Place firm, comfortable pressure on the treatment site with no tilting of applicator head, for maximal energy.
- Press the orange button on the applicator to begin energy output. The orange button will change to blue when energy output has begun. The Treatment Time will begin counting down.
- During treatment the laser output can be stopped by pressing ⏸ or ⛔.

Dosage Calculator Options

To choose which dosage measurement preferred, press the Dosage Calculator Button. There are several options to choose from:

- Joules only
- J/cm^2 only
- J/diode
- All above options in one (Joules, J/cm^2 and J/diode)



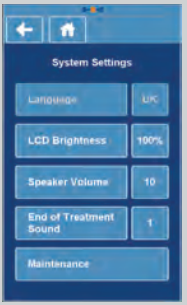
DEVICE USER INTERFACE

SYSTEM SETTINGS

System Settings

In this screen you can personalize some features on the device such as:

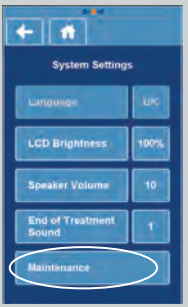
- Language
- LCD Brightness
- Speaker Volume
- End of Treatment Sound



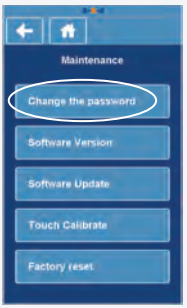
CHANGING THE PASSWORD

System Settings

- From the System Settings Menu, select Maintenance.



- Press "Change the Password."



- Enter the new password you want.
- Passwords must be between 2 and 8 digits in length.
- To erase an incorrect entry and start again, press the "reset" button to clear all the numbers and reenter.
- Once you have the password, press enter.
- It will prompt you to re-enter the password a second time.
- Enter the password again for confirmation.

CHANGING THE PASSWORD CONTINUED

- If the passwords match, the system will display it was successful.

- If they do not match, an error code 708 will show that the passwords were inconsistent and you will have to reenter again.

EMERGENCY SHUTOFF

The output of the TheraTouch® LX2 can be ended immediately in the following ways:

- Pressing .
- Pressing .
- Pressing .
- Turn off power switch on the rear of the device.

FOR FACTORY RESET

- Press System Settings
- Press Maintenance
- Press Factory Reset
- Input Password to confirm
- Once confirmed, the device will take you back to the start up screen. This is the confirmation that the device is back to the factory's original settings.

Please Note: Once you perform a factory reset, it will delete any favorites stored in your device and this operation cannot be reversed.

MAINTENANCE

CLEANING & DISINFECTING

When cleaning the device, keep in mind the following:

- Press the Power On/Off button so that the device is off.
- Unplug the power plug from the power outlet before cleaning or disinfecting the device.
- After each patient use, clean the accessories using a soft, clean cloth dampened with water and a mild antibacterial detergent. Avoid the use of abrasive materials and cleaning solvents.
- Wait until the device is completely dry before operating it again.

Cleaning Display Panel

- Use a soft and dry cotton cloth or micro fiber tissue to clean the panel. To remove fingerprints or grease, use a non-abrasive glass cleaning agent.

⚠ CAUTION

Do not spray the cleaning agent directly on the glass panel.

⚠ CAUTION

Do not use cleaning agents that contain strong alkalies, lye, acid, detergents with fluoride or detergents with ammonia.

Cleaning Laser Applicator

To prevent corrosion, clean and dry the contact surface immediately after use. We further recommend cleaning the applicator and cable daily, using lukewarm water. Check the applicator and cable regularly for damage.

It is recommended to clean the applicator before and after each patient. If using a cloth with any disinfectant, ensure that it does not contain corrosive ingredients as they may damage the applicator.

⚠ DANGER

- Under no circumstances may liquid penetrate the openings on the device (i.e. the connection ports of the cables or interlock connection). Therefore, do not use cleaning or disinfectant sprays directly on any part of the device. Spray cleaning solution on a soft cloth and clean AROUND any openings of the device.
- The device and associated accessories may not be sterilized using steam or gas.
- Never clean the device with abrasives, disinfectants, or solvents that could scratch the housing or LCD or otherwise damage the device.

SAFETY INSPECTIONS

The following safety inspections must be performed on this device. This must be done by persons who, based on training, knowledge or practical experience, are capable of conducting the inspections correctly and independently.

Visual Inspection (Daily)

When performing daily inspections of the device, pay particular attention the following areas of potential damage:

⚠ WARNING

Service personnel must wear protective goggles while inspecting the laser device.

- Deformation of unit housing
- Power cable damage
- Laser Applicator connection sockets damage
- Laser Applicator cable damage

Function Test (Daily)

- When performing daily inspections of the device, pay particular attention the following areas of potential damage:
- Correct function of indicators
- Display of operating modes
- Patient Interrupt Button

NOTE: It is the responsibility of the health care facility to verify that the device complies with the facility, local, and national Earth Leakage limits.

WARNING MESSAGES, ERROR MESSAGES

Software Error Code

When the apparatus is turned on, it will first execute a self test. When an error is detected, both during the self test and during normal operation, a pop-up screen will appear on the display. When the error is displayed, all outputs will be disabled. When this situation occurs, remove all cables and switch the apparatus off and switch it on again. When the error re-appears, stop using the device and contact your supplier.

Laser Applicator Error

If the Laser Applicator has reported an error:

- Disconnect the applicator from the device
- After 10 minutes, reconnect the applicator
- If the error persists, discontinue use of the device and contact your supplier.

TECHNICAL MAINTENANCE

If technical maintenance is required, please call your supplier or the manufacturer for troubleshooting. If the problem cannot be resolved over the phone, please do not attempt to repair, open, or calibrate the device unless you have been trained and authorized by the manufacturers specifications.

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to energy.

CALIBRATION

It is recommended to calibrate the laser source every 1 year. The device

should be sent to the factory or a Trained Technician for this procedure.

Measuring equipment specification:

Optical power meter

- Wavelength Range: include 600nm~900nm
- Measuring range: include 10mW~500mW
- Resolution: <5%

The brief calibration procedure is as follows.

1. Choose a enclosed, secure room and put the calibrate device and optical power meter on a steady position. Put on the laser protective glasses.
2. Set the optical power meter correctly (Such as wavelength, measuring range etc.).
3. Insert the applicator which is needed to be calibrated, and place it in calibration tooling. Turn on the laser device. Using administrator password to enter System Settings – Maintenance – Power Calibration, and select the corresponding calibration power button. Then pressing the button of applicator, and adjust the output power by using the central controller, until the display value of optical power meter is consistent with the set value.
4. Click the "Save" button after power adjustment. The interface will shows that the calibration data has been saved successfully and the power calibration process has been completed correctly.

⚠ WARNING

This device operates with high voltages. No attempt should be made to disassemble the device.

Maintenance and repair should be carried out by authorized personnel only. The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.

All other technical maintenance is restricted to authorized Richmar maintenance personnel.

END OF LIFE

The LX2 contains materials that can be recycled and/or are noxious to the environment. Specialized companies can dismantle the device and sort out these materials. When you dispose of the device, find out about local regulations concerning waste management.

SPECIFICATIONS

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THERATOUCH LX2

Power Supply	100-240V AC 50/60Hz
Maximum absorbed power	60W
Programmable treatment time	Up to 4 minutes
Mode of operation	Continuous or pulsed
Emission frequency	1Hz-10000Hz
Pulsed mode	90%
Output channels	2
LCD back-lit display	Graphic 480 X 800 pixels TOUCH SCREEN
Protocols in memory	10
Number of protocols that can be saved in the user memory	100
Laser classification	3B
Remote interlock connector	1
Key control	Passwords
Command of execution of the treatment	Button
Class of isolation / parts applied according to the rule EN 60601-1	Class I, B-type
Dimensions (Width * Height * Depth)	197*240*285 mm
Sound	Speaker

SINGLE DIODE APPLICATOR (DQLLLT-SA)

Diode Specifications	650nm +/- 30nm
Maximum Power	200mW±20%
Beam Divergence	19° x 34°
Nominal Optical Hazard Distance (NOHD)	40cm

MULTIPLE DIODE APPLICATOR (DQLLLT-CA)

Diode Specifications	**9 Diode Cluster Laser 1040 mW** Four 650 ±30 nm (10 mW) LED Five 850 ±30 nm (200mW) Laser
Maximum Power	1040mW±20%
Beam Divergence	12° x 30°
Nominal Optical Hazard Distance (NOHD)	60cm

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SPECIFICATIONS

LASER APPLICATOR SPECIFICATIONS

Below is an example parameter description when calculating the dosage for both the single and cluster applicators available for the TheraTouch LX2 Low Level Laser Therapy (LLLT) device. For both applicators, the standard deviation in measured quantities at the time of manufacturing is +/-20%.

The TheraTouch LX2 software includes a feature which could require a cooling off period for the applicator in between treatments. This cooling off period is affected by several factors such as environmental temperature/humidity, output power used, real time temperature of applicator after use, etc. The desired environmental temperature is between 68 - 77° F (20-25° C). Should you receive a cooling off message displayed on the screen, please waiting between 2-4 mins before starting the next treatment.

LASER APPLICATOR SPECIFICATIONS

Applicator	Output Power (mW)	Spot Size (cm^2)	Mode	Power Density (W/cm^2 per diode)	Energy Density (J/cm^2 per diode)	Energy (Joules Total Energy & LED)	Joules (All laser diodes only)	J/diode (excludes LED)	Diode Specification
Cluster	200 (Laser) 40 (LED) 1040 (Total)	0.1041	Continuous	1.9	38.4	20.8	20	4	Four 650 nm (10mW) LED Five 850 nm (200mW) Laser
Single	200 (Laser)	0.1607	Continuous	1.2	24.9	4	4	N/A	650 nm 200mW Laser

CONDITIONS OF USE

Temperature Environment	5°C - 40°C
Relative Humidity	10% - 85%
Atmospheric Pressure	700 - 1060hPa

STORAGE / TRANSPORT CONDITIONS

Temperature Environment	-20°C - 55°C
Relative Humidity	10%-93%
Atmospheric Pressure	700-1060hPa

PROTOCOL PARAMETERS

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TREATMENT RECOMMENDATIONS

1. Before starting therapy, ensure patient and clinician put on protective eyewear.
2. Treatment area should be cleaned with alcohol. DO NOT using coupling agents on laser applicator.
3. Place the applicator directly on the skin with firm comfortable pressure and no tilting of the applicator head, for maximal energy.
4. Each session requires multiple applications of the recommended dosage for affected tissue. Target the tissue at several points for a minimum of 20 secs TOTAL.
5. DO NOT perform laser over tattoos. Dark pigmented skin may affect light absorptions and may require therapy adjustment.

CLUSTER APPLICATOR - PARAMETERS

Protocol	Mode	Frequency	Joules (all laser diodes or total laser energy)	Joules (J) Total Energy Laser & LED	J/cm² (per diode)	J/diode
Pain & Inflammation Acute	Pulsed	5000Hz	9.0 J	9.4 J	17.3 J/cm²	1.8 J/diode
Pain & Inflammation Chronic	Continuous	N/A	23 J	23.9 J	44.19 J/cm²	4.6 J/diode
Musculoskeletal Soft Tissue Injury Acute	Pulsed	105Hz	9.0 J	9.4 J	17.3 J/cm²	1.8 J/diode
Musculoskeletal Soft Tissue Injury Chronic	Continuous	N/A	20 J	20.8 J	38.42 J/cm²	4 J/diode
Increase in Microcirculation Acute	Continuous	N/A	5 J	5.2 J	9.6 J/cm²	1 J/diode
Increase in Microcirculation Chronic	Continuous	N/A	10 J	10.4 J	19.21 J/cm²	2 J/diode
Myofascial Trigger Point Acute	Pulsed	105Hz	9.0 J	9.4 J	17.3 J/cm²	1.8 J/diode
Myofascial Trigger Point Chronic	Continuous	N/A	20 J	20.8 J	38.42 J/cm²	4 J/diode
Muscle Spasm Relief Acute	Pulsed	105Hz	9.0 J	9.4 J	17.3 J/cm²	1.8 J/diode
Muscle Spasm Relief Chronic	Continuous	N/A	20 J	20.8 J	38.42 J/cm²	4 J/diode

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PROTOCOL PARAMETERS

TREATMENT RECOMMENDATIONS

1. Before starting therapy, ensure patient and clinician put on protective eyewear.
2. Treatment area should be cleaned with alcohol. DO NOT using coupling agents on laser applicator.
3. Place the applicator directly on the skin with firm comfortable pressure and no tilting of the applicator head, for maximal energy.
4. Each session requires multiple applications of the recommended dosage for affected tissue. Target the tissue at several points for a minimum of 20 secs TOTAL.
5. DO NOT perform laser over tattoos. Dark pigmented skin may affect light absorption and may require therapy adjustment.

SINGLE APPLICATOR - PARAMETERS

Protocol	Mode	Frequency	Joules	Energy Density (J/cm^2)	Power Density (W/cm^2 per diode)
Pain & Inflammation Acute	Pulsed	5000Hz	1.8 J	11.2 J/cm^2	1.1
Pain & Inflammation Chronic	Continuous	N/A	4.6 J	28.62 J/cm^2	1.2
Musculoskeletal Soft Tissue Injury Acute	Pulsed	105Hz	1.8 J	11.2 J/cm^2	1.1
Musculoskeletal Soft Tissue Injury Chronic	Continuous	N/A	4 J	24.89 J/cm^2	1.2
Increase in Microcirculation Acute	Continuous	N/A	1 J	6.2227 J/cm^2	1.2
Increase in Microcirculation Chronic	Continuous	N/A	2 J	12.445 J/cm^2	1.2
Myofascial Trigger Point Acute	Pulsed	105Hz	1.8 J	11.2 J/cm^2	1.1
Myofascial Trigger Point Chronic	Continuous	N/A	4 J	24.89 J/cm^2	1.2
Muscle Spasm Relief Acute	Pulsed	105Hz	1.8 J	11.2 J/cm^2	1.1
Muscle Spasm Relief Chronic	Continuous	N/A	4 J	24.89 J/cm^2	1.2

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SPECIFICATIONS

SAFETY AND PERFORMANCE STANDARDS

IEC 60601-1 : General requirements for the safety of electrical medical systems, including Annex 1, national differences for Australia, Canada and the United States.

Safety class according to IEC 60601-1: Class I type B 

IEC 60601-2-22 : Particular requirements for the safety of laser therapy equipment.

IEC 60825-1 : Safety of laser products : Equipment classification and requirements

EMC DETAILS

With the increased number of electronic devices such as PC's and mobile(cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation

Medical devices should also not interfere with other devices. In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Medical devices manufactured by MANUFACTURER conform to this IEC60601-1-2 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified by MANUFACTURER, with the exception of cables sold by MANUFACTURER as replacement parts for internal components, may result in increased emission or decreased immunity of the device.
- The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- Refer to EMC table guidance regarding the EMC environment in which the device should be used.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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APPENDIX A - EMC TABLES

TABLE 1: GUIDELINES AND MANUFACTURER'S DECLARATION ELECTROMAGNETIC INTERFERENCE

TheraTouch LX2 is intended for operation in an electromagnetic environment as indicated below. The customer or user of the LX2 device should ensure that it is operated in such an environment.

Emissions tests	Conformity	Electromagnetic environment guideline
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 CISPR11	Class A	The LX2 device is suitable for use in all installations including those in a residential environment and those which are directly connected to the public mains network which also supplies buildings which are used for residential purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Conforms	

The device should not be used when placed immediately next to or stacked on top of other devices. If operation is necessary when immediately next to or stacked on top of other devices, the device should be monitored to ensure it is operating as intended in this arrangement.

APPENDIX A - EMC TABLES

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TABLE 2: GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

Guidance and manufacturer's declaration — electromagnetic immunity			
The LX2 device is intended for use in the electromagnetic environment specified below. The customer or the user of the LX2 device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 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 input lines IEC 61000-4-11	<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 5 seconds)	<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 5 seconds)	Mains power quality should be that of a typical commercial or hospital environment. If the use of the LX2 device requires continued operation during mains power interruptions, it is recommended to install a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 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 main power voltage prior to application of the test level.			

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APPENDIX A - EMC TABLES

TABLE 3: GUIDANCE AND MANUFACTURER'S DECLARATION ELECTROMAGNETIC IMMUNITY

Guidance and- manufacturer's declaration. Electromagnetic immunity			
The LX2 device is intended for use in. the electromagneticenvironment specified below. The customer or the user of the LX2 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF disturbance variables according to IEC 61000-4-6	3 V 0.15 MHz to 80 MHz	3 V 0.15 MHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the LX2 device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d= 1.2 P ,150 KHz to 80 MHz d= 1.2 P , 80MHz to 800MHz d= 2.3 P , 800MHz to 2.7GHz 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 meters (m)[b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site 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:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	
NOTE 1 At 80 MHz ends 800 MHz. 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 transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically withaccuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LX2 device is used exceeds the applicable RF compliance level above, 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 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

APPENDIX A - EMC TABLES

TABLE 4: RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND LX2

Recommended separation distances between portable and mobile RF communications equipment and the LX2 device

The LX2 device device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LX2 device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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 transmitterm**		
	150 kHz to 80 MHz d= 1.2√P	80 MHz to 800MHz d= 1.2√P	800 MHz to 2.7GHz d= 2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters 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 rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz. the separation distance for 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.

GLOSSARY OF SYMBOLS

GLOSSARY OF GENERAL SYMBOLS

ICON	DETAILS
	Electrical devices are recyclable material and should not be disposed of with household waste after their useful life! Help us to protect the environment and save resources and take this device to the appropriate collection points. Please contact the organization which is responsible for waste disposal in your area if you have questions.
	Type B Applied Part
	Refer to instruction manual
	Please refer to instruction manual because of the higher levels of output
	**EMERGENCY LASER STOP.** To stop the laser output immediately in case of emergency.
	Date of manufacture
	The name and the address of the manufacturer
	Remote interlock connector
	Transportation and storage temperature from -20°C to 55°C
	Transportation and storage humidity limits from 10% to ~93%
	Transportation and storage atmospheric pressure limits from 700hPa to 1060hPa

GLOSSARY OF WARNING SYMBOLS

ICON	DETAILS
	Warning: The values of laser light energy used during therapy exceed safe values and proper precautions listed in this manual need to be taken.
	Warning: the values of supply voltage exceed safe values need to be taken.
	Warning: Avoid exposure to beam and indicated the classification of the device.