

Operator's Manual

for the

LazrPulsr 4X

Low-Level Laser Therapy Device

Home Therapy System

www.lazrpulsr.com

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Warning: It is mandatory that the user read and be familiar with the entire contents of this Operator's Manual for proper and safe utilization of the LazrPulsr 4X. Review and/or familiarity of brochures, sales material or instructional classes are not a substitution for reading and understanding this manual in its entirety.

Introduction

The **LazrPulsr 4X** LLLT unit is for prescription use only by a licensed professional. Federal Law restricts this device to sale to or usage on the order of a physician.

This **Operator's Manual** will guide you through the basic use and maintenance of your **LazrPulsr 4x**. This device has been designed to provide a convenient, versatile, and user-friendly delivery system of pulsed cold laser therapy.

1 Contents

The package should contain:

- 1 **LazrPulsr 4x Mk III Home**
Low-Level Laser Therapy device
- 1 Power Adapter
- 1 Cover for laser beams
- 1 Operator's Manual
- Treatment Guide
- 1 Carrying Case

Additional items may be purchased separately. To order these accessories call 303-696-6532.

2 Overview

The LCD display:

The LCD display has 4 lines, 16 characters each.

Line 1: States the time and battery life

Line 2: States the Name of the program

Line 3: States the Step of the program running

Line 4: States the Program number

Tm:10:00 E+++F
Fatigue Recovery
Step 000
Prog #651

The LazrPulsr 4X Mk III Home unit has 102 possible Therapy program settings as follows.

These are proprietary built in therapy programs that are named and not editable. Programs that are not used will be labeled “Reserved”. The up and down arrows when scrolling through the programs will not land on a reserved program but skip to the next active program.

Programs #001 through #035: These are the 35 therapy programs that we refer to as the **Home Therapy Programs**.

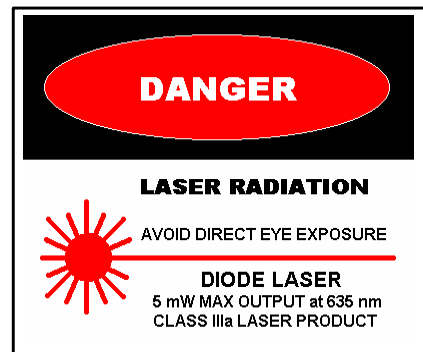
Program #050: Used for FDA Clearance only

Programs #051 through #099: These are 49 different frequency programs that will run for 10 minutes each.

Programs 100 through #116: These programs run the Mk III General Health Procedure.

3 Warnings

The LazrPulsr 4X Mk III Home laser uses 5mW laser diodes with a visible wavelength of 635nm. Collimated Laser radiation can damage vision. Avoid direct or reflected eye exposure.



There are no user serviceable parts inside the device. **Opening the unit will void the warranty.**

The **LazrPulsr 4x** is not waterproof. Exposure to water will cause damage to the device.

4 Indications for use

The **LazrPulsr 4x** was designed for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.

5 User Responsibility

This product will perform in conformity with the description thereof contained in this Operators Manual and accompanying labels and/or inserts, when operated, maintained, and repaired in accordance with the instructions provided.

This product must be checked for excessive wear and/or damage periodically, A defective product should not be used. Parts that are broken, missing, plainly

worn, distorted, or contaminated must be replaced immediately. Should such repair or replacement become necessary, LazrPulsr System recommends that a telephone call or written request be made to either the distributor that sold the product or to LazrPulsr System service department. Current contact information for LazrPulsr System service department can always be found on their website at www.lazrpulsr.com.

This product has no user repairable/serviceable parts and all servicing should be completed by LazrPulsr System service department. **The user of the product shall have the sole responsibility for any malfunction which results from any unauthorized repair or alteration, faulty maintenance or damage.**

6 Charging the Battery

Warning: Use only the power adapter supplied with the laser unit. Use of other power adapters may seriously damage the unit. The power adapter for the *LazrPulsr 4X Mk III Home unit* requires a 9V 500mA negative tip power supply. Use of a positive tip power adapter will destroy the charging circuits inside the laser and will require factory servicing for repair. If power supply cord has removable tip, it must be placed as Neg = Tip. Call our service department for any questions regarding charging the battery of the *LazrPulsr 4X*.

The *LazrPulsr 4x* should be partially charged when it is received from the factory. For optimal use charge this unit for 4 hours when received.

6.1 Plug the power adapter into a standard 110-volt outlet. Plug the charging connector into the bottom of the *LazrPulsr 4x* unit.

6.2 Allow the unit to charge approximately two hours. There are no external light indicators displaying the charging cycle. The battery indicator at the upper right corner of the LCD display will have 3 stars when the unit is fully charged and can be viewed by activating the LCD at any time during the charging cycle. The unit will routinely recharge in about 3 to 4 hours.

6.3 To maintain optimal battery life of the *LazrPulsr 4x*, recharge the battery regularly. You can not over charge the battery so placing the laser on the charger overnight at least 2 to 3 times a week is recommended regardless of use.

7 Quick Start Instructions

7.1 If the unit will not respond, unlock the laser following the instructions in Section 8.1.

7.2 To activate the laser, press the **Laser On/Off** key or the **Time** key one time. The laser will activate the current program.

7.3 To momentarily activate the laser press the **Laser Pulse** key and the laser will activate the current program for as long as you hold the button down.

7.4 To change programs press the **Select** key and scroll through the programs with the arrow buttons or enter the program # with the number buttons. Press the **Select** key again and the current program is ready to use.

8 Functions of the LazrPulsr 4x

There are 4 modes that the **LazrPulsr 4x** can be placed in. These are as follows:

8.1 Locked Mode

This is a secure mode where the unit will only respond to the Unlock Sequence.

To lock the unit, press and hold the **Laser On/Off** key for 5 seconds.

To unlock the laser press the following 3 keys in this order.

- 1.– **Laser On/Off** key
2. - **Select** key
3. - **Laser Pulse** key

The laser will enter the Powered On mode and the LCD display is active.

8.2 Sleep Mode

The unit is unlocked but the LCD display is not active. The unit will automatically go into sleep mode after being left dormant for 5 minutes. This saves power when the unit is not in use. There are only three keys that are active in this mode, they are:

Laser Pulse key – The unit will power on and the currently displayed program will run as long as you hold the key.

Laser On/Off key – The unit will power on and the currently displayed program will begin running until you press the **Laser On/Off** key again.

Light key – The unit will enter the Powered On and the LCD will be active, no laser function will occur. The information screen on the LCD will be active for a few seconds prior to entering the powered on mode.

8.3 Powered On Mode

The LCD Display is always active in the Powered On mode. Only 7 keys are active in the powered on mode. These are as follows:

Laser Pulse key – The laser will run the currently displayed program as long as you keep the key depressed.

Laser On/Off key – The laser will run the currently displayed program until it is completed or until you press the **Laser On/Off** key a second time.

Time key – The laser will run the currently displayed program in the **Time Function** for the duration of the preset time. The Time Function allows you to pause the program at any time by pressing the **Laser Pulse** key. Pressing the **Laser Pulse** key again will continue the program where it left off. During programs that require you to change locations on the body the laser will automatically pause for you to change location. Pressing the Laser Pulse key again will continue the program. If the laser is left in the pause state for over 5 minutes the laser will move to the **Sleep Mode**. If you press the **Laser Pulse** key at this time it will return to running the program where it left off.

Select key – The unit will enter the Edit mode.

Number 1 key – The unit will immediately move to the Sleep mode and the LCD will deactivate.

Number 2 key – The unit will display the System information screen.

Number 4 key – The unit will display the Sound Configuration Screen. Turn the Sound On or Off with the **Laser Pulse** Button and then press the #4 key again to return to the Powered on Mode.

8.4 Edit Mode

In **Edit** mode you can change programs. To enter the **Edit** mode press the **Select** key from the **Powered On** mode. To exit the **Edit mode** and save your changes, press the **Select** key again. To exit and cancel your changes press the **Cancel** key.

9 Activating the LazrPulsr 4x

For maximum flexibility, there are three methods of illuminating the lasers: The **Laser Pulse** key, **Laser On/Off** key or the **Time** key. There are a variety of pre-set treatment programs to choose from.

9.1 Preset Treatment Programs

The *LazrPulsr 4x Mk III Home unit* comes with 102 proprietary treatment programs that have been preset at the factory. These programs cover a variety of causes for pain of the neck and shoulders. These programs will begin at Program #001. These programs are for symptomatic relief of common health conditions and not to be used as a treatment for any disease process. **Program #000 will produce a continuous wave or no frequency, and is not recommended for therapy. Prolonged use of this program may damage the unit.**

The unit should be Partially charged and locked when you receive it. First follow the unlock instructions on page 7 and then the following sections for operation.

9.2 Laser Pulse key

Press and hold the **Laser Pulse** key to activate the current program displayed as long as the **Laser Pulse** key is held down or until the program is complete.

9.3 On/Off key

Press the **Laser On/Off** key to run the displayed program. The therapy program will continue operating the entire program until completed pausing only for a few seconds when the laser needs to change position. Pressing the **Laser On/Off** key while the program is running will stop the program and the unit will return to **Powered On** mode.

9.4 Time key

Press the **Time** key to run the currently displayed program. The laser will automatically pause between steps that require the laser to change position. Pressing the Laser Pulse key again will continue the program. To pause the **Timed program**, press the **Laser Pulse** key. To continue the timed program function, press the **Laser Pulse** key again. To end the timed program function press the **Cancel** key or let the time expire. The **Laser Pulse** key will continue the program even if the laser has entered the **Sleep** mode while paused.

9.5 Changing the Treatment Programs

From the **Powered On** mode press the **Select** key. The unit will enter the **Edit** mode with the program number underlined. Use the up/down arrows to scroll through the programs or use the keypad to select the desired program. When the desired program number is displayed, press the **Select** key again and the unit will return to the **Powered On** mode ready to operate the new program.

10 To activate a therapy program

10.1 Defined

The Therapy Group Function operates an entire therapy program as they are outlined in the Treatment Guide utilizing multiple proprietary frequency settings in the laser. These Groups are located in programs beginning at #001.

These can be utilized in the following ways.

10.2 Activated with the Laser On/Off key

If you activate a Therapy program with the Laser On/Off key, the entire therapy session will run beginning with the first frequency program which will operate for the preprogrammed length of time. If the laser needs to change position for the next step, then, it will pause for 4 seconds and automatically begin the next frequency program and continue until finished.

If the laser does not require a change in body position it will continue without pausing through the next step or steps until the laser requires changing location.

10.3 Activated with the Time key

When you activate a Therapy program with the Time key, the laser will automatically pause between each step where the laser requires a change in position. The display will show the number of the next Step to be performed for the operator to know where to place the laser on the patient. The Steps will match the steps in the Treatment Guide for each given therapy program. To continue running the program, press the Laser Pulse key and the laser will continue the next step. This will continue until the program is completed.

You may also pause the laser at any time if needed by pressing the Laser Pulse key. Pressing the Laser Pulse key again will continue the program where it left off. If you do not reactivate the laser while in the paused state within 5 minutes the laser will enter the Sleep Mode. From the sleep mode, the Laser Pulse key will still continue the program from where it left off.

11 Mechanical Operation

The **LazrPulsr 4x Home** therapy laser is a safe and effective tool for clinical use

in pain therapy. However, when using the laser it should be considered that it is a Class IIIa laser device which is regulated by the United States Food and Drug Administration.

This requires the user to exercise certain patient and operator precautions.

Neither the operator nor the patient should ever look directly into the beam or a reflection of the beam. Approved safety glasses are not necessary.

Step 1: Position the patient so that the area of the body to be illuminated is exposed. Do not illuminate through jewelry or metallic material.

Step 2: Remove the laser beam cover. Press the **Light** key on the **LazrPulsr 4x Home** unit to activate the Display.

Step 3: Decide if the treatment mode should be continuous or pulsed, i.e.; one of the preprogrammed memory settings set by the operator or the factory.

Step 4: Keep the laser head between two to eight inches from the patient's body and keep the laser head directed at the area to be illuminated.

Step 5: Activate the laser by pressing the **Laser On/Off** key, the **Laser Pulse key**, or the **Time** key. The visible light gives the operator an exact location of where the therapy is being applied.

Step 6: Scan the area to be treated for the given treatment duration and deactivate the laser beams prior to removing the laser from the treatment area.

Step 7: Return the laser to the case and replace the laser beam cover. If the unit will be left unattended, press the **Laser On/Off** key for 5 seconds to lock the laser to prevent any unauthorized use.

12 Clinical Operation

The **LazrPulsr 4x** is intended to be administered externally for adjunctive use in providing temporary relief of minor neck and shoulder pain. The following protocols have been developed specifically to address musculoskeletal discomfort. It is intended for use by experienced healthcare professionals.

Use the steps in Section 11: Mechanical Operation to apply the **LazrPulsr 4x** device appropriately to the areas of therapy described in the following steps.

These steps are preprogrammed into therapy program #550 of the **LazrPulsr 4X Mk III Home** therapy unit.

Step 1: Set the frequency to 300 Hertz and apply the laser to the sagittal suture for one minute.

Step 2: Modify the frequency to 900 Hertz. Starting in the cerebral region at the top of the left ear. Move to the left cervical anterior and posterior muscles then work down into the left shoulder and torso anterior and posterior muscles. Apply this therapy for two minutes.

Step 3: Repeat the therapy of Step 2 for the right cervical shoulder and torso area.

Step 4: With the frequency still set to 900 Hertz, apply the laser to the right shoulder as the shoulder is rotated. Apply light to the anterior shoulder muscles with the patient's arm bent at the elbow.

Step 5: With the frequency still set at 900 Hertz, apply the laser to the posterior muscles of the right shoulder. Adduct the arm as the laser is being applied for one minute.

Step 6: With the frequency still set at 900 Hertz, apply the laser to the right cervical muscle and trapezius muscle while rotating the spine to the left. Begin in the neutral position and rotate while the laser is applied for one minute.

Step 7: With the frequency still set at 900 Hertz, apply the laser to the right sternocleidomastoid and scalenus muscles as the neck is moved through the passive range of motion.

Step 8: Repeat steps 4 through 7 for the left side of the body.

13 Troubleshooting

Why will the laser not work?

The laser may be locked, follow instructions in 8.1 of this manual to unlock the laser.

Laser may require charging. Plug the laser into the supplied power adapter for several minutes and try again. The laser will not operate immediately when plugged in if the battery is low. The battery will need to charge for 5 to 10 minutes before the laser will activate.

The laser may be on a program that is reserved. Move to another program.

A key may be stuck down. Check to make sure there is not a key that is wedged or stuck in the down position. This will confuse the internal computer and lock all functions.

If the above fail to correct the problem, call Customer Service at 303 696-6532.

14 Service

The **LazrPulsr 4x** can be cleaned using a damp cloth and/or mild cleanser. Do not use an aerosol cleaner as the moisture may damage the electrical components. Harsh chemicals or oils will dull the finish on the acrylic face plate and make it difficult to read the LCD.

The case of the LazrPulsr 4X Home unit is painted with a high quality automotive paint. It should last many years but will scratch and chip with rough use.

Never submerge the **LazrPulsr 4x** into water. If it is accidentally submerged into water call Customer Service before attempting to turn it on.

If the end cap that covers the laser diodes becomes contaminated or soiled from contact with wounds, etc., remove the cap for sanitizing or replace the cap with a new one. Caps can be ordered from LazrPulsr System at 303 696 6532.

LazrPulsr System recommends factory servicing or refurbishing every 1 to 3 years or as needed based on the amount of use. To arrange for refurbishing please contact Customer Service in Colorado - 303-696-6532, or use the contact page of our website www.lazrpulsr.com for current contact information.

15 Specifications

Power Supply

Li-Polymer Rechargeable Battery 1.8 Amp Hours

Up to 8 hours of continuous operation (with both lasers active).

Rapid recharge system, less than 4 hours.

Unit uses a 9V, 500ma with **negative tip** Wall Transformer as the recharge source.

Display

LCD Display

Battery Level Indicator

Current Program Indicator

Count-Down Timer

Memory

Non-volatile storage for programs

Safety

Pressing the Laser On/Off key for 5 seconds places unit in the Lock Mode where it can only be operated through the use of a unlock key sequence.

Laser Operational Parameters:

2 individually pulsed 635nm Class IIIa Lasers

Laser Light <5mW of Optical Energy

FDA cleared operational Pulse – Continuous to 5 KHz

Research operational pulse - Continuous to >120 MHz

Weight of unit: about 7oz.

16 Limited Warranty

LazrPulsr System warrants that, for 2 years from date of purchase, it will repair or replace this product if found to be defective in materials or workmanship. Damage to case or electronic components from dropping are not covered under warranty. Opening the case will void warranty. Please contact LazrPulsr System Customer Service at 1-303-696-6532, or use the contact page of our site at www.lazrpulsr.com for current contact information, for a return authorization and return the product postage paid to 1276 S. Chambers Rd. Aurora, CO 80017 for prompt repair or replacement with the current equivalent product free of charge .

This repair or replacement is LazrPulsr System's sole obligation under this warranty. LazrPulsr System will not be responsible for any incidental or consequential damages or for any loss arising in connection with the use or inability to use this product.

Some states do not allow the exclusion or limitation of incidental or consequential damages. So the above limitation or exclusion may not apply to you. This warranty excludes defects of damage due to misuse, abuse or neglect. This warranty gives you specific legal rights. You may also have other rights which vary from state to state.

Specifications and features are subject to change without notice. Product may vary from that shown.

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