

Operator's Manual

for the

LazrPulsr 4X

Low-Level Laser Therapy Device

Mk III Personal

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 Personal**
Low-Level Laser Therapy device
- 1 Power Adapter
- 1 Cover for laser beams
- 1 Operator's Manual
- 1 Treatment Guide, Part A & B
- 1 Quick Start Operator Guide
- 1 Carrying Case

Additional items may be purchased separately. To order these accessories visit us online at www.lazrpulsr.com or 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 Personal has 999 possible program settings.

Frequency Programs

#001 thru #199, #280 thru #299 & #800 thru #899:

These are preset frequency programs that are named and not editable. Currently we are only utilizing programs #001 through #199. The remainder are reserved for later use. The up and down arrows when scrolling through the programs will

not land on empty programs but skip to the next active program.

User defined Programs #200 through #279:

These are available for the user to enter and save their own frequency programs.

Therapy Programs

#500 thru #699, #710 thru #799 & #900 thru #999:

These are preset Therapy Group programs. These programs will run a series of the frequency programs automatically. Therapy Programs greater than #699 are reserved for future use.

Programs #700 through #709

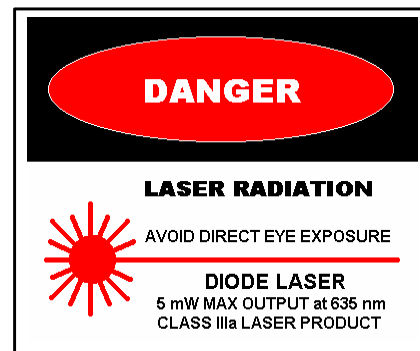
These are user-defined Therapy Group programs that can be saved and recalled.

3 Warnings

The LazrPulsr 4X uses 5mW laser diodes with a light wavelength of 635-nm. 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: The LazrPulsr 4X therapy unit contains very high-tech computer chips that are very sensitive to power surges. Always utilize a quality surge protection outlet for charging. 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* requires a 9V 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 finish charging the unit 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 or into the back of the charging cradle, optional, and place the laser in the cradle.

6.2 Allow the unit to charge approximately four 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 completely recharge in four hours.

6.3 To maintain optimal battery life of the *LazrPulsr 4x*, recharge the battery regularly. You can not over charge the battery so charging the battery 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 one time. The laser will activate the current program for a period of 5 minutes and turn off automatically.

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.

7.5 To enter program frequencies of your choice press the **Select** key and move to a desired program, #200 through #279. Then press the **Laser Pulse** button to underline one of the laser entries. Using the Up/Down arrow keys move to the laser you wish to edit. Using the number buttons, enter the desired frequency. Using the arrow keys move to any other laser beams you wish to program and enter the frequency. When finished entering frequencies, press the **Select** key and the current program is saved and ready to operate.

8 Functions of the LazrPulsr 4x

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

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 2 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 run for 6 minutes or 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 10 seconds prior to entering the powered on mode.

8.3 Powered On Mode

The LCD Display is always active, the lasers are always off and nothing is underlined on the display 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 or until the 6 minute timer expires.

Laser On/Off key – The laser will run the currently displayed frequency program for 6 minutes or until you press the **Laser On/Off** key a second time. If there is a therapy program displayed it will run the entire program or until you press the **Laser On/Off** key again.

Time key – The laser will run the currently displayed program for the duration of the preset time using the timed therapy function.

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 information screen as long as the #2 key is depressed.

Number 4 key – The unit will enter the Sound Configuration.

8.4 Edit Mode

In Edit mode you can change programs, edit existing user defined programs and set the timer. Lasers will not illuminate while in the Edit mode. Almost all of the keys are active in the Edit mode.

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 or you may set your own by following the instructions in Section 10.

9.1 Preset Treatment Programs

The **LazrPulsr 4x** comes with a potential of 999 preset and user defined treatment programs. You may run any of the active programs following the instructions below. These programs are for research and field studies only and not cleared for use by the FDA. **Program #000 will produce a continuous wave or no frequency, and is not recommended for therapy.**

The unit should be Partially charged and locked when you receive it. First follow the unlock instructions in Section 8.1 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 for up to a maximum of 6 minutes. Upon release of the **Laser Pulse** key or after a duration of 6 minutes, the unit will stop illumination and return to the Powered On mode.

9.3 Laser On/Off key

Press the **Laser On/Off** key to run the displayed Frequency program for a period of 6 minutes. Pressing the **Laser On/Off** key while the program is running will stop the program and the unit will return to Powered On mode. If the displayed program is a Therapy Program pressing the **Laser On/Off** key will run the entire Therapy program or until you press the **Laser On/Off** key again.

9.4 Time key

Press the **Time** key to run the currently displayed program for the specified period of time set on the timer utilizing the **timed function**. The LazrPulsr unit will turn on and the timer will begin decrementing to 00:00. When the duration of the timer has elapsed the lasers will turn off and unit will return to the Powered On mode.

The **timed function** has several qualities specific to this function.

1. You may pause the program in the timed function by pressing the “**Laser**

Pulse” key at any time for up to 5 minutes. Pressing the **“Laser Pulse”** key again will continue the program from where it left off.

- 2.If you pause the program longer than 5 minutes it will move to the Sleep Mode. If this occurs you can activate the laser with the same three keys described in section 8.2, however if you reactivate the laser using the Laser Pulse key it will return to the same point in the program as where you paused it. The other two keys will reactivate the laser to the On Mode.
- 3.While operating a Therapy Program that has multiple steps, The laser will automatically pause itself between steps that require you to change location of the laser giving the operator time to move the laser to the next location. Pressing the Laser Pulse key will cause the laser to continue with the next step. While the laser is paused the display will state the next step to be run. On steps that do not require a change in position of the laser it will not pause but automatically continue with the next step in the program.
- 4.To begin running a Therapy Program on any step desired, begin running a program with the Time key. Immediately press the Laser Pulse key to pause the program. Press the up or down arrows to scroll through the steps of the program. When the desired step is displayed press the Laser Pulse key to begin running the program from that step.
- 5.To exit the timed function prior to finishing the therapy program press the Cancel key and the laser will return to the On Mode.

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 Programs 001 through 999. As you scroll past or enter a program number the frequencies of that program or the description of the preset programs will be displayed. When the desired program number is displayed, press the **Select** key again and the unit will return to the Powered On mode with the new program.

10 Programming Your LazrPulsr 4x

In addition to the preset programs described in Section 9.1 there are additional spaces for defining custom frequency programs, #200 thru #279. Each program consists of up to 4 individual frequencies, one for each laser diode. To enter the Edit mode the unit must first be in the Powered On mode.

10.1 Editing user defined Freq Programs

To edit a program:

- Press the **Select** key.
- Use the **up/down** arrow keys to move to the correct program number or type in the program number using the number keys. (# 200 - #279)
- Press the **Laser Pulse** button to underline one of the two laser frequencies to edit.
- Use the **up/down** arrow keys to select the next laser diode you wish to set.
- Use the number keys to enter pulse frequency in pulses/second (Hz).
- Repeat the past 2 steps to set the frequencies for the second laser diode.
- Press the **Select** key again to save the frequency values entered. When the frequencies are saved the unit will automatically:
 - ⇒ Return to the Powered On mode with the new program setting.
 - ⇒ If you decide at any time to cancel the Edit function, press the **Cancel** key and the unit will return to the Powered On mode and not save any of the edited information.

To edit frequencies that have already been set, simply use the steps above to overwrite the previous settings.

10.2 Editing the Timer

The **LazrPulsr 4x** has a timer that can be set to limit the duration of a treatment for the frequency program. Therapy programs have the time preset and can not be altered. When the timer is set and a program is activated the program will run for the duration set on the timer. To set the timer:

- Press the **Select** key to enter the Edit mode.
- Press **Time** key. The timer section of the display will be underlined.
- Set the time by:
 - ⇒ Entering numbers with the number pad. **OR**
 - ⇒ Incrementing or decrementing minutes using right and left arrow keys and incrementing and decrementing seconds using the up and down arrow keys.

- Press the **Select** key again to save the changes and return to Powered On mode.
- Press the **Cancel** key to exit without saving any changes.

10.3 To program the User Defined Therapy Programs

Move to the desired user defined Group beginning at #700. While the program number is underlined press the Laser pulse key. On the LCD, line #2 will display the step # and line #3 will display the program selected for this step. You may select any of the active built in programs or any user defined frequency programs #001 thru #279. Make sure all programs entered are active and contain frequencies, otherwise the laser will be inactive for the duration of that program.

Next, press the up arrow. This will display a line to enter the amount of time you wish to run this program. You may enter up to 99 minutes and 99 seconds.

Then press the up arrow again. This will display the amount of time for the laser to wait between this frequency program before beginning the next, 4 to 5 seconds is usually adequate.

Repeat this process for each program (Step) you wish to use in this therapy procedure. When finished, press the Select key again and the Group Program will be saved in this program number. This Group will operate the same as the Preprogrammed Group Function in Section 11.

If you wish to change any component of the Group program simply move to the area you wish to change and overwrite the information and press Select again to save changes.

11 Preprogrammed Therapy Group Functions

11.1 Defined

The Therapy Group Function operates an entire therapy program as they are outlined in the Treatment Guide utilizing any of the other frequency programs, #001 through #199. It is made up of three components, the frequency program to be utilized, how long it will run and how long it will pause before starting the next program. These Therapy Groups are numbered in the laser to match the Therapy Card programs found in the treatment guide. These numbers are located in the upper right corner of each therapy card and they will match the therapy program displayed on the card. These programs begin at #500.

These can be operated as described in section 10.

12 Mechanical Operation

The **LazrPulsr 4x** 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 and approved safety glasses are optional.

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** to activate the LCD.

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.

13 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.

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.

14 Troubleshooting

The number I entered in is not the number displayed.

Some frequencies may not be displayed as input. Example: If you program in 600.3 Hz you may receive a display figure of 600.2999. This is not an error, it is producing the closest .3 Hz as possible.

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 any program from #200 through #279 that allow the user to enter their own frequencies and they are blank. If the frequency lines are blank, the program will run, the time will count down but the lasers will not activate. Move to another program or enter frequencies into 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 processor and lock all functions.

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

15 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.

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.

16 Specifications

Power Supply

Li-Polymer Rechargeable Battery 1.8 Amp Hours

Up to 6 hours of continuous operation (with all lasers active).

Rapid recharge system, less than 4 hours.

Charging Cradle as a storage stand.

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

Individual Laser Settings

Memory

Non-volatile storage for programs

Up to 1000 programs can be stored for up to 10 years

Timer settings can be stored up to 10 years.

Safety

Pressing and holding down the Laser Pulse Key for 5 seconds places the unit in the Lock Mode where it can only be operated through the use of the 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.

17 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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