

Laser Module

OPERATION MANUAL



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Congratulations on your purchase of a Richmar Laser Module. Richmar takes pride in its product lines and the Service it provides to its customers. This upgrade may include both the LaserPrism low level laser and Light Cluster Probe, or only one of these.

This Guide is written for the owners and operators of the Richmar Laser Module Upgrade Kit. It contains general instructions for operation, warnings, precautionary practices and maintenance procedures. In order to maximize the use, efficiency and life of your product, please read this Guide thoroughly prior to using the Richmar Laser Module Upgrade Kit.

In the U.S.A., multiple FDA clearances covering the laser and light therapy devices have been obtained.

In Canada, the laser and light devices have been licensed by the Medical Devices Bureau of the Therapeutic Products Directorate, Health Canada.

Laser and Light Therapy (phototherapy) is a safe and effective therapy which uses light energy to decrease or eliminate pain.

PRODUCT DESCRIPTION

The Richmar Laser Module has been developed to offer product flexibility and choice. The components have been designed for ease of use by licensed healthcare professionals and/or their delegated assistants.

The convenient, high-quality laser and light therapy devices are seamlessly integrated into Richmar EVO devices. These devices include both a low level laser therapy device and light therapy (SLD) accessories.

The Richmar LaserPrism device is a handheld low level laser therapy device for deeper tissue conditions. This accessory features three near-infrared laser diodes for therapeutic applications and a visible LED guide light for attended therapy.

The Richmar Light Cluster Probe offers SLD (superluminous diode) light therapy for broader applications. This device can be strapped into position for "hands-free", unattended treatment.



Richmar LaserPrism



Richmar Light Cluster Probe



Visible and Invisible laser radiation.
Avoid direct exposure to beam.
Class IIIb laser product.

CONTENTS

This section of the operating guide describes the different configurations of the Richmar Laser Module upgrade kit and available components.

1. 1 LaserPrism (REF 500-031)
2. 1 Light Cluster Probe (REF 600-123)
3. 2 Keys
4. 2 Pair of Safety Goggles

5. 1 Operating Guide

Optional and Replacement Components Available for Order:

- LaserPrism Device (REF 500-031)
- Light Cluster Probe (REF 600-123)
- Standard Protective Goggles (REF 600-207)

PRECAUTIONS AND WARNINGS

Before using the Richmar Laser Module, the operator should become acquainted with the operating procedures, as well as the indications, contraindications, warnings and precautions. Consult other resources for additional information regarding the benefits, limitations and application of low level laser therapy and SLD therapy.

1. Caution

The Richmar Laser is a Class IIIb laser. Therefore, the following recommendations should be adhered to:

- Both the patient and operator must wear the provided protective goggles to block any near-infrared energy from “entering” the eyes during treatment. (Not required for light cluster probe.)
- DO NOT point the laser beam directly into human or animal eyes. The eye does not detect the invisible, coherent near-infrared 785 nm wavelength beam, which could potentially result in retinal damage.
- A visible guide LED is active when the laser is operating to provide a direct indication at the radiant (treatment) surface.

2. Labels

The following label is located on the Richmar Laser for safety precaution purposes.



Label Location



Danger Label



Radiant Surface

Additionally, the following statement is printed on the product “This product complies with performance standards for laser products, under 21 CFR 1040.10 and 1040.11”

Clinician operators should always take caution to NOT place the Richmar SLD devices directly over the eyes of a patient while it is actively in operation. These are bright sources of visible and infrared light and comparable to staring into a household incandescent lamp or heat source.

3. Warning

- Richmar devices should be operated by a trained healthcare professional or delegated trained assistant.
- Use of controls or adjustments or performance or procedures other than those specified herein may result in hazardous radiation exposure.
- Patients and operator should wear the specified safety goggles, when the laser device is being used.
- Use only as directed
- Avoid excessive use



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The Richmar Laser Module along with Richmar LaserPrism and/or Light Cluster Probe are non-invasive, low energy devices that emit photons, which are absorbed to produce cellular effects and biological changes. The photons temporarily increase microcirculation, resulting in temporary relief of pain and stiffness, relaxation of muscles, decrease of muscle spasms and decreased pain and stiffness associated with arthritis. The dosage and frequency of treatment needs to be adjusted to produce the desired effects.

1. Indications of Use

Research indicates that therapeutic heat creates a cascade of chemical and biological effects, which result in the following benefits:

- Increases microcirculation
- Elevates tissue healing
- Temporarily relieves muscle and soft tissue injury and pain
- Decreases arthritis pain and stiffness
- Relieves muscle spasms

2. Contraindications

The Richmar LaserPrism **SHOULD NOT** be used under the following conditions:

- Where analgesia may mask progressive pathology, and where the practitioner would normally avoid the use of any other analgesia in order to retain the beneficial aspects of pain.
- Where it might deliver direct irradiation to the human or animal eye.

AVOID using Richmar Laser and Light Therapy devices:

- Over areas injected with steroids in the past 72 hours
- Over suspicious lesions (potential cancer)
- Over a pregnant uterus
- Over the thyroid region of the neck
- Over areas with open wounds, unless covered with a clear protective barrier



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INITIAL SETUP INSTRUCTIONS

After unpacking, make sure all items are present and undamaged. Remove protective coverings from the radiant surface of each device. Plug devices into related ports on the Console.

1. Console Device Ports

The Richmar Laser Module has two ports which can be used for either a combination of a laser and SLD devices or laser only. These devices can be plugged into either port.

2. Caution

- Place unit in a location where the power cord cannot be tripped over or pulled out during treatment.

- Use the system only if it is properly grounded.
- Prior to use, the following items should be checked to ensure proper operation:
 - a. Power cord, plug and AC power supply:** Check to ensure the cord is free of kinks, and not frayed, torn or cut, exposing insulation.
 - b. Therapy accessories:** Check to ensure the cables are flexible, free of kinks, not frayed and that the insulation is intact. Check the radiant surfaces to ensure they are free of foreign materials, grease or cream.

DEVICE PLUG IN AND OUT INSTRUCTIONS

To plug in: line up top with arrows and push in until it clicks

To remove: slide back outer sleeve to unlock



Richmar LaserPrism

1. ON / OFF

Click this switch to Start/Stop the treatment.

2. Service LED

Solid red indicates the unit needs to be serviced. Try to retrigger, if Service LED is still on, contact your distributor.

3. Dosage LED / Active

- Slow flashing Green with 1 short beep indicates 8 joules
- Slow flashing Blue with 2 short beeps indicates 14 joules
- Fast flashing Turquoise with 1 long beep indicates 18

4. Infrared Laser Diode

Three near-infrared laser diodes.

5. Dosage Selection Button

Push this button to cycle the dosage among 8, 14 and 18 joules, as indicated in Item 3 Dosage LED.

6. Beam Attenuator

Laser cap to be utilized to cover the radiant surface when the device is not in use.



Light Cluster Probe

1. Visible Diodes

There are 9 visible, red diodes. These form the visible red "X".

2. Infrared Laser Diodes

There are 52 infrared diodes. These infrared diodes are not visible to the human eye. If the red "X" is ON, then the infrared diodes are also active. Using a digital camera, it is possible to take a picture and see the active diodes.



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Both the Richmar LaserPrism and Light Cluster Probe are controlled by the laser module; therefore the following combinations can be used:

- Simultaneously plug both the Laser and Light devices into the Laser Module - OR
- Only the Laser device plugged into the Laser Module

Note: The SLD light device will not function without the laser device.

Note: The safety key must be on to operate the devices. The safety key location may vary.



Key

1. Plug device(s) into Richmar console, Laser device only or combination Laser and SLD cluster devices (see page 3).

2. Dose Selection

Push the Dosage button to select the dosage for both the laser and SLD devices. The dose selection will cycle through 8, 14 and 18 joules. When you push the Dosage button the Dosage LED will change color and sound indicating dose selection.

Note: Dose selection is made for both the laser and SLD light cluster (if plugged in simultaneously).

- Slow flashing Green LED with short beep indicates 8 joules, treatment time is 40 seconds.
- Slow flashing Blue LED with two short beeps indicates 14 joules, treatment time is 70 seconds.
- Fast flashing Turquoise LED with a long beep indicates 18 joules, treatment time is 90 seconds.

3. Device Control

- Clicking "ON/OFF" Switch of the laser will control the laser alone, both the laser and SLD light cluster or the SLD light cluster alone.
- LaserPrism - Single click to start or stop
- SLD Cluster - Double-click to start or stop (similar to double clicking a mouse)
- Stops both - Single longer (2 second) click to stop both devices

4. Once the ON/OFF switch has been triggered to activate the device, the Dosage LED will remain the color selected in Step 2. There will be a 1-second delay before treatment is initiated. Initiation is indicated by a single beep, the device beeps every 5 seconds. (Beep per Joule feature).

Once the treatment is complete, the device will immediately emit three beeps. The DOSAGE LED will blink the color selected. To initiate the same dosage, click the ON/OFF switch.

Dose selection will return to original setting of 8 joules (green) if the laser is unplugged or the console is turned off or unplugged.

Treatment can be interrupted at any point by clicking ON/OFF switch.

5. Beep per Joule:

This option can be turned OFF or ON by holding down the Dosage Selection button for 5 seconds. After releasing the Dosage button a single beep will acknowledge the 'beep per joule' is OFF. To turn this feature ON again, hold the Dosage button for longer than 5 seconds. Two beeps will acknowledge the 'beep per joule' feature is active again.

6. Configure Mode

This Mode is used to adjust volume of beeps or to stop beeps. To initiate the Configure Mode, complete the following steps.

- a. First unplug the laser and SLD devices from the console.
- b. Simultaneously hold down the ON/OFF switch and the Dosage button on the Laser device with one hand and with the other hand, plug laser device into the console.
- c. The primary function of the configure mode is to change the volume of the beeps or stop the beeps. As well, the version numbers for the equipment can be determined. For further information contact the Richmar Service Department.
- d. To Exit Configure Mode unplug the laser device from the console.



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7. Volume Control:

While in Configure Mode, hold the Dosage button down for 5 seconds or longer. There are four volume settings. Repeat to move to the next volume setting:

- Low: One (1) beep (factory setting)
- Medium: Two (2) beeps
- High volume: Three (3) beeps
- Off: Silence (no beeps at all)

8. Delivery of Energy (Joules)

- Laser delivers 1 joule every 5 seconds
- SLD Cluster delivers 1 joule/cm² every 45 seconds



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STEP-BY-STEP INSTRUCTIONS

1. Cleanse and degrease skin with alcohol or soap and water to reduce reflection and refraction. Cover treatment head with a clear barrier for asepsis if skin over the treatment area is open.
2. Plug in the Laser and SLD devices into the ports on the Richmar console.
3. Insert the safety key into keyhole and turn on. (Page 10)
4. Remove the clear protective barrier from the radiant surface of the SLD device. Place radiant surface of the SLD device directly on appropriate area of the skin for treatment. Use strap to secure into position.
5. Remove the red protective cap (beam attenuator) from the Laser device. Position the Laser device directly onto skin applying gentle pressure, at a 90 degree angle perpendicular to the target tissue.
6. Click the "ON/OFF" switch once for the Laser device and double click for the SLD device. There is a 1-second delay prior to the device activating. While the laser is ON, the Dosage LED is illuminated with the color related to the dose selected. To deliver the desired dosage of energy and optimize penetration, the laser should be held firmly in one position for the entire treatment.

7. The Laser and SLD devices are programmed to shut off after the selected number of Joules has been delivered.

(Laser = 5 sec/joule, SLD = 45 sec/joule/cm²).

- Unless volume control has been turned off, there are three short beeps after treatment has been delivered. The Dosage LED will continue to blink the selected dosage color while the unit is ON. If same treatment dose is required, re-click the ON/OFF switch for the corresponding Laser and SLD devices.
8. While treatment is being provided, maintain the device in one position without moving it. **NO MEDIUM OR GEL IS REQUIRED**



WARNING
Patient and operator should wear safety goggles when laser device is to be used.

Between uses, wipe radiant surface of laser and light devices with a clean, damp cloth with a hospital grade germicide. Follow germicide manufacturer directions. Do not use highly concentrated germicide mixtures. Dilute according to directions of the germicide manufacturer, or damage may result. DO NOT spray cleaner directly onto radiant surface.

1. Ongoing Maintenance

- The Richmar Laser and Light Kit devices should be checked regularly to determine that all controls function normally.
- Inspect radiant surfaces before each use to ensure cleanliness.
- Inspect associated connectors before each use.
- The Richmar Laser Module should be operated in temperatures between 32°F and 104°F (0°C to 40°C), with relative humidity ranging from 20% to 95% non-condensing. Store or transport from -4°F to 149°F (-20°C to 65°C).

2. Technical Maintenance

NO attempt should be made to disassemble the unit. Only authorized personnel should complete maintenance and repairs. The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.

To maintain full compliance with The United States Code of Federal Regulations Title 21 (21 CFR, part 1040.10 and 1040.11), the device should be tested annually. It is recommended all Richmar products be serviced by the manufacturer or sent to an authorized servicing dealer for repairs and recalibration. Calibration procedures are NIST traceable and available at selected authorized service dealers or the manufacturer's service and repair center. Recalibration is also recommended after the replacement or repair of any major component.



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Richmar LaserPrism

| | |
|---|--|
| Light Source | 3 near infrared laser diodes (GaAlAs) |
| Laser Equipment Safety Classification | Class 3B I11b |
| FDA Regulatory Classification | Class II |
| Nominal Laser Wavelength | 785 nm (near infrared) |
| Guide Light Wavelength | 470 nm (visible blue) |
| Duty Cycle | 100% (continuous mode) |
| Total Optical Output Power (Continuous Mode) | 200 mW \pm 10% |
| Max Optical Output Power (per Diode at Continuous Mode) | 80 mW |
| Energy Delivered | 1 Joule per 5 seconds |
| Treatment Area at Skin | 0.026 cm ² from 3 laser spots |
| Spot Size | 0.00881 cm ² single laser spot |
| Power Monitoring | Continuous with automatic shutdown if optical power is \pm 30% |
| Beam Divergence | 17°x8° typical (15°x6° minimum) |
| Nominal Ocular Hazard Distance (NOHD) | 188 mm (NOHD is calculated for the worst case 80 mW condition. Normal operating conditions are typically 67 mW per diode, which reduces the NOHD). |

Light Cluster Probe

| | |
|--|---|
| Light Source | 52 near infrared diodes 9 visible red diodes |
| FDA Regulatory Classification | Class II |
| Treatment Wavelength | 870 nm (near infrared) |
| Guide Light Wavelength | 633 nm (visible red) |
| Duty Cycle | 100% (continuous mode) |
| Total Optical Output Power (Continuous Mode) | 500 mW \pm 20% |
| Irradiance | 22.2 mW/cm ² \pm 20% |
| Treatment Area at Skin | 22.48 cm ² |
| Spot Size | 0.00881 cm ² single laser spot |
| Treatment Time | 1.0 Joules/cm ² in 45 seconds |
| Beam Divergence | 17°x8° typical (15°x6° minimum) |
| Nominal Ocular Hazard Distance (NOHD) | Not applicable for these diodes. (Avoid direct exposure to eyes. 188 mm or greater is recommended.) |



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Richmar (“Company”) warrants that the Richmar Laser and Light Kit (“Product”) is free of defects in material and workmanship. This warranty shall remain in effect for one (1) year on the accessories (Laser and SLD) from the date of original consumer purchase of this Product. It is extended to any owner of the Product during the warranty period. Extended warranties may be available. If this Product fails to function during the warranty period because of a defect in material or workmanship, the Company at its discretion will repair or replace this Product without charge. The Company or dealer will ship the Product to the customer as quickly as possible.

All repairs must be performed by Richmar or an authorized service center. Any modifications or repairs performed by unauthorized centers or groups will void this warranty. To participate in warranty coverage, this Product’s warranty registration card (included with Product) must be filled out and returned to Richmar by the original owner within 15 business days of purchase.

This Warranty Does Not Cover:

1. Replacement parts or labor furnished by anyone other than the Company, the dealer or an authorized Company service agent.
2. Defects or damage caused by labor furnished by someone other than Company, the dealer or an authorized Company service agent.
3. Any malfunction or failure in the Product while it is in the possession of the owner during the warranty period if the malfunction or failure is not caused by defect in material or workmanship, or if the malfunction or failure is caused by unreasonable use, including the failure to provide reasonable and necessary maintenance.

Richmar Shall Not Be Liable for Incidental or Consequential Damages to Property or Business

Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply.

TO OBTAIN SERVICE from Richmar or the authorized service agent under this warranty, the owner must do or abide by the following:

1. A written claim must be made within the warranty period to Richmar or the selling dealer. If claim is made to Richmar, a written claim should be sent to:

Richmar
4120 South Creek Road
Chattanooga, Tennessee
37406 USA

Phone: (423) 648-7730

Toll Free: (888) 549-4945

Fax: (423) 648-7735

Email: technicalsupport@richmarweb.com

Web: www.richmarweb.com

2. Contact Richmar Technical Service to obtain a Return Materials Authorization (RMA) number.
3. The product must be returned (freight prepaid) to Richmar or the authorized service agent by the owner and clearly marked with the RMA number.

This warranty grants the owner specific legal rights. The owner may have other rights, which vary from state to state or other jurisdictions. Richmar does not authorize any person or representative to create for it any other obligation or liability in connection with the sale of the Product. Any representation or agreement not contained in the warranty shall be void and of no effect.

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Richmar is an ISO 13485 Certified Company.

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