

Laser Module

OPERATION MANUAL



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Congratulations on your purchase of a Richmar LaserPrism Cordless. 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 LaserPrism Cordless. 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 LaserPrism Cordless.

In the U.S.A., multiple FDA clearances covering this laser therapy device have been obtained.

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

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

PRODUCT DESCRIPTION

The Richmar LaserPrism Cordless delivers high-quality Low Level Laser Therapy (LLLT) with the convenience of portability. The ergonomic design makes the device functional, easy to use and comfortable to operate.

This device features three near infrared laser diodes and one visible blue LED that deliver LLLT. It has been designed for licensed or certified healthcare professionals and/or their delegated assistants.



Richmar LaserPrism



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

This section of the operating guide describes the available components Richmar's LaserPrism Cordless.

1. 1 Rehab Portable Laser
2. 1 Safety Key
3. 1 Beam Attenuator Cap
4. 1 Battery Recharger: 9VDC
5. 2 Standard Protective Goggles
6. 1 Padded Carrying Case
7. 1 LaserPrism Cordless Operating Guide (this booklet)

Optional and Replacement Components Available for Order:

- Medical Grade Battery Recharger
- Standard Protective Goggles
- Premium Protective Goggles
- Remote Interlock Adaptor

PRECAUTIONS AND WARNINGS

Before connecting the recharger or operating the Richmar LaserPrism Cordless, the operator should become acquainted with the operating procedure, as well as the indications, contraindications, warnings and precautions. On the internet you can find many resource documents for additional information regarding the benefits, limitations and applications of Low Level Laser & Light Therapy.

1. Caution

The Richmar LaserPrism Cordless is classified as a Class IIIb laser. The following recommendations should be adhered to:

- It is recommended that both the patient and operator wear safety glasses to block any infrared energy from eyes during treatment.
- DO NOT point the laser beam directly into human or animal eyes. The lens of the eye does not detect the invisible, coherent 785 nm wavelength beams, potentially resulting in permanent retinal damage.

The following danger label is required by the FDA for Class IIIb laser products and is affixed to this laser based IR therapeutic heating device. The label is located at the lower end of the handle.



Label Location



Danger Label



Radiant Surface

The aperture warning label (above) is located on the device near the radiant surface. It indicates the location of the surface that emits IR laser energy resulting in therapeutic heating, referred to as the active radiant surface, and the direction of the beam of light.

2. Warning

- The Richmar LaserPrism Cordless should be operated by a healthcare professional only
- When the device is not in use, the safety key should be removed or it should be stored in a locked, secure location away from unauthorized users
- Use of controls or adjustments or performance or procedures other than those specified herein may result in hazardous radiation exposure
- Use only as directed



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The Richmar LaserPrism Cordless is a non-invasive, low energy device that emits photons, which are absorbed to produce cellular effects and biological changes. The photons are indicated *“for the temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains, and stiffness, and the relaxation of muscles; for muscle spasms, and minor 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
- Temporarily relieves muscle and soft tissue injury and pain
- Decreases arthritis pain and stiffness
- Relieves muscle spasms

2. Contraindications

The Richmar LaserPrism Cordless **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. If damage has occurred during shipment, notify your area distributor immediately. Check the voltage rating on the decal located on the external recharger for correct voltage. Connect the recharger into an AC outlet. Plug the recharger output connector into the receptacle at the bottom of the MedX Portable Laser unit.

NOTE: It will take approximately 2 hours to fully charge the battery from complete discharge. The battery LED is solid red while the device is charging. When fully charged it will turn green.

A fully charged battery may provide up to 2 hours of continuous treatment time prior to requiring a recharge. The device cannot be used while plugged into the recharger.

To operate the Richmar LaserPrism Cordless, the recharger must be unplugged and the safety key must be inserted. Also, the beam attenuator cap must be removed from the radiant surface.

1. Caution

- **DO NOT** use the device or recharger if it is dropped, cracked or damaged.
- **DO NOT** place the recharger in a location where the cord can be tripped over.

2. Safety Instructions

Disconnect the recharger by pulling the plug (not the cord):

- If the plug or cord frays or is damaged.
- If the device or recharger is exposed to excess moisture or becomes wet
- If the recharger is not going to be used for a long period of time
- Whenever there is a thunderstorm or the potential for power surges

Richmar LaserPrism Cordless

1. ON / OFF

Click this switch to activate the device. Treatment will start after a 1-second delay

2. Service LED

- Solid red indicates the unit needs to be serviced
- Flashing red indicates the battery requires recharging

3. Dosage LED / Active

- Green with 1 short beep indicates 6 Joules
- Blue with 2 short beeps indicates 8 Joules
- Turquoise with 1 long beep indicates 10 Joules

4. Infrared Laser Diode

Near-infrared laser diodes located behind protective lens and guide light (Not shown)

5. Dosage Selection Button

Push this button to cycle the dosage among 6, 8 and 10 Joules, as indicated in item 3 Dosage LED.

6. Charger Status LED

This LED near the recharge receptacle indicates the charger status. Solid red indicates charging, while solid green indicates that charging is complete

7. Receptacle

Battery recharger receptacle. Also safety key or remote interlock receptacle

8. Safety Key

This key must be inserted into receptacle in order to operate the device.

- Note: The removable Safety Key must be inserted into the receptacle located at the bottom of the handle to render the device operational.

9. Beam Attenuator

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



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When the battery voltage level is low, the Service LED located at the top of the device will flash red. This indicates the battery requires recharging. If the Service LED begins to flash during treatment, there is sufficient battery power to complete the ongoing treatment. Once the treatment is complete, it is recommended that the unit be recharged. If it continues to be used until all power is depleted, the Service LED will no longer be illuminated.

When the battery is completely discharged, it takes approximately 2 hours to completely recharge. The red LED charger status (at the bottom of the handle) will be on while charging. When the green LED illuminates, the battery is fully recharged. This time will vary depending on the state of battery usage.

OPERATING INSTRUCTIONS

1. Insert the safety key into the receptacle
2. Push the Dosage button to select the dosage. When you push the Dosage button the Dosage LED will change color:
 - Green LED with short beep indicates 6 Joules, treatment time is 30 seconds.
 - Blue LED with two short beeps indicates 8 Joules, treatment time is 40 seconds.
 - Turquoise LED with a long beep indicates 10 Joules, treatment time is 50 seconds.
3. Click the ON / OFF switch and release it to activate the device. The Dosage LED will remain the color you 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 for two minutes (Standby mode) and then turn off, indicating the device has entered Sleep mode. While the Dosage LED is blinking and in the Sleep mode, the last selected dose is retained.

The next treatment with the same dosage can be initiated by clicking the ON / OFF switch during the two minutes standby time period.

Treatment can be interrupted at any point by clicking the ON / OFF switch or by removing the safety key.

4. Beep per Joule

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

5. Sleep Mode

The device will enter into Sleep Mode:

- After two minutes Standby mode.
- 10 seconds after Service LED illuminates.
- Every time the Safety Key is unplugged.

The device can be reawakened by clicking the ON / OFF switch or by pushing the Dosage Selection Button. The device will sequentially turn on the green, blue and red LED, and then go to Standby mode.



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STEP-BY-STEP INSTRUCTIONS

1. Cleanse and degrease skin with alcohol to reduce reflection and refraction. Cover treatment head with a clear wrap barrier for asepsis if treatment area above the target muscle or joint tissue below is open.
2. Position the Richmar LaserPrism Cordless radiant surface directly onto skin, at a 90 degree angle (perpendicular) to the skin surface while applying gentle pressure.
3. Click the "ON / OFF" switch and release it. 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 in one position for the entire treatment set.
4. The unit is programmed to shut off after the selected number of Joules has been delivered. For 2 minutes, the Dosage LED will blink the selected dosage color. If another treatment set is required, click the ON / OFF switch; this will start the selected dose treatment.
5. While treatment is being provided, maintain the device in one position without moving it. No medium or gel is required.
6. Complete treatment for each location prior to proceeding to next site.
7. It is advised to recharge the unit after 4 hours of treatment time.



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USER MAINTENANCE

To clean, first turn Off the Richmar LaserPrism Cordless and unplug the Battery Recharger or Safety Key. Clean the radiant surface with a damp cloth. Do not use abrasive cleaners. A small amount of mild household detergent may be used, if desired.

Between uses, wipe radiant surface of accessory with a clean, slightly damp cloth and 12% Isopropyl alcohol or 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.

It is recommended that the manufacturer or authorized distributor complete an annual equipment calibration. This will ensure that laser output is within specified limits and all components are functioning properly.

1. Ongoing Maintenance

- The Richmar LaserPrism Cordless should be checked regularly to determine that it functions normally.
- When the rechargeable battery requires replacement, the device must be returned to Richmar (see Service Contact Information, page 9)

- The following items should be checked before each use to ensure proper operation of this device:
 - a. **Battery Recharger**
Check to ensure the cord is free of kinks, and not frayed, torn or cut, exposing wire.
 - b. **Richmar LaserPrism Cordless**
Check the radiant surface to ensure it is intact, as well as free of foreign material, grease and cream.

2. Equipment Operating Conditions

The device should be operated in the following conditions:

Ambient temperatures:
32 °F to 104 °F (0 °C to 40 °C)

Relative Humidity:
20% - 95% non-condensing

Atmospheric pressure:
700 - 1060 hPa

3. Transport and Storage Conditions

The device should be transported and stored in the following conditions:

Ambient temperatures:
-4 °F to 149 °F (-20 °C to 65 °C)

Relative Humidity:
20% to 95% non-condensing

Atmospheric pressure:
700 - 1060 hPa

4. Technical Maintenance

NO attempt should be made to disassemble the device. 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 MedX 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.

DEVICE SPECIFICATIONS

The Richmar LaserPrism Cordless consists of a hand-held laser device and recharger. The device is 23 x 8 x 4 cm and weighs approximately 113 g (not including accessories). The enclosure is made of ABS plastic and the radiant surface is covered with a polycarbonate window.

The Richmar LaserPrism Cordless contains three 785 nm near infrared semiconductor laser diodes, each emitting approximately 66 mW in continuous treatment mode. The diodes are gallium-aluminum-arsenide (GaAlAs). Once the device is activated, it automatically delivers the selected dosage of energy (a treatment set), goes into Standby mode for two minutes, and then turns itself Off. The rechargeable battery is capable of delivering over 4 hours of treatment time.

The near infrared light provides therapeutic heating. The visible blue light has two purposes; first, as a guide-light to assist directing therapy to the desired location, and second, to indicate that the accessory is On. Both wavelengths of light are activated simultaneously and cannot be used separately.

1. Frequency

The Richmar LaserPrism Cordless operates on continuous treatment mode.

2. Laser Radiation Emission Indicators

There are certain signals that indicate the IR laser diodes are active. The first indicator is the Dosage LED, which is illuminated upon activation. The second indicator is the illumination of the blue guide-light, which emits light from the radiant surface. The third indicator is an audible beep, which occurs one second after the ON switch is clicked, as treatment begins. Also, there is an optional single beep emitted each time 1 joule of energy is delivered.

3. Power Measurement Safety Control

Each laser diode includes a photodiode detector that monitors the optical power from the infrared laser diode. The laser output is monitored within the nominal 20% tolerance for total 200mW laser power.

If the photodiodes indicate that the optical output power has exceeded the optical tolerance (+/- 20%), the laser deactivates and the red Service LED illuminates; the laser power is continuously monitored while it is active.

DEVICE SPECIFICATIONS



4. Beam Attenuator Cap

The beam attenuator is a plastic cap capable of attenuating infrared emission from the radiant surface for prevention of accidental emissions. The cap is also used to protect the radiant surface when it is taken off-site.

5. Safety Key

Laser safety regulations require that there be a Safety Key for use as a safety measure. The Safety Key must be inserted into the Recharger Receptacle at the base of the Richmar LaserPrism Cordless handle to render the device operational.

6. Battery

The Richmar LaserPrism Cordless holds an internal 3.6 VDC, Li-Ion battery pack with negligible memory effect providing over 4 hours of treatment time.

7. Battery Recharger

The Richmar LaserPrism Cordless is not designed for use during recharging.

The recharger is CSA and UL 1950 approved. It has an input of 100-240VAC, 50/60Hz, and 9VDC, 0.67A output. It connects to a 2.1 mm Recharger Receptacle on the Richmar LaserPrism Cordless.

A Universal Medical Grade Battery Recharger is available as an optional accessory.

TECHNICAL SPECIFICATIONS

Richmar LaserPrism Cordless

Laser Diodes	GaAIAs
Laser Equipment Safety Classification	Class 3B 111b
Regulatory Classification	Class III - Medical Device (Canada) Class II - Medical Device (US)
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)	200mW +/- 10% at 785 nm
Max Optical Output Power (per Diode at Continuous Mode)	80mW
Output	Continuous; 6 Joules - 30 seconds 8 Joules - 40 seconds 10 Joules - 50 seconds
Laser Power Monitoring	Automatic, continuous
Max Beam Divergence	10 x 20 degrees
Treatment Area at Skin Spot Size	0.026cm ² for 3 spots
NOHD (Nominal Ocular Hazard Distance)	188 mm (NOHD is calculated for the worst case condition. Normal operating conditions are 66mW per diode)
Battery	3.6VDC Li-Ion, 1500mAh capacity



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Battery Charger

Type	Wall Mount
Input	100 - 240VAC, 50/60 Hz, 0.3A max
Output	9VDC, 0.67 A max
Safety Approval	UL/ULC Listed

WARRANTY

Richmar (“Company”) warrants that the Richmar LaserPrism Cordless (“Product”) is free of defects in material and workman-ship. This warranty shall remain in effect for two (2) years, from the date of original purchase of this Product and extended to any owner of the Product during the warranty period. If this Product fails to function during the warranty period because of a defect in material or workman-ship, 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 centre or dealer. 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 labour 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 the 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 a 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.

4. The rechargeable battery warrant is limited by the original supplier to 12 months from the date of manufacture. Contact Richmar Technical Service for clarification.
5. 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

6. Contact Richmar Technical Service to obtain a Return Materials Authorization (RMA) number.
7. 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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