



Caution: Federal law restricts this device to sale by or on the order of a licensed clinician therapist

Rehab Portable Laser Operating Guide

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Foreword

Congratulations on your purchase of a **MedX Rehab Portable Laser**. MedX takes pride in its product lines and the service it provides to its customers.

This Guide is written for the owners and operators of the **MedX Rehab Portable Laser**. It contains general instructions for operation, warnings, precautionary practices and maintenance procedures. In order to maximize the use, efficiency and life of your device, please read this Guide thoroughly prior to using the MedX Rehab Portable Laser.

MedX has received international approval for a variety of sports and rehabilitation applications.

MedX Portable Laser is Health Canada licensed under Number: 15556 and Device ID: 245590.

In the USA, MedX has multiple FDA clearances, covering its entire product line.

Low Level Laser and Light Therapy is a safe and effective therapy which uses light energy to decrease or eliminate pain and accelerate tissue healing.

Product Description

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

The device features three near infrared laser diodes and one visible blue LED that deliver LLLT.

The **MedX Portable Infrared Laser** has been designed for licensed or certified healthcare professionals and/or their delegated assistants.



Package Contents

i) Standard Components

- 1 Rehab Portable Laser (model: LCS450)
- 1 Safety Key
- 1 Beam Attenuator Cap
- 1 Battery Recharger: 9V_{DC}
- 2 Standard Protective Goggles
- 1 Padded Carrying Case
- 1 MedX Treatment Guide
- 1 Rehab Portable Laser Operating Guide (this booklet)

ii) Optional Components

MPG01 Standard Protective Goggles
MPG02 Premium Protective Goggles
RIA1 Remote Interlock Adaptor

Precautions and Warnings

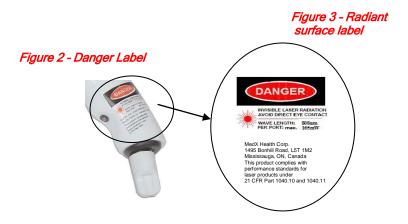
Before connecting the recharger or operating the **MedX Rehab Portable Laser**, the operator should become acquainted with the operating procedure, as well as the indications, contraindications, warnings and precautions. On the internet you can find many resource documents for additional information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

i) Caution

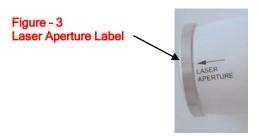
The **MedX Rehab Portable Laser** is classified as a Class IIIb laser. The following recommendations should be adhered to:

- It is recommended that both the patient and operator wear safety glasses to block any infrared energy from eyes during treatment.
- <u>DO NOT</u> point the laser beam directly into human or animal eyes.
 The lens of the eye does not detect the invisible, coherent 808 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.



The following aperture warning label 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.



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"

ii) Warning

- The MedX Rehab Portable Laser 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

Indications and Contraindications

MedX Rehab Portable System is used for the treatment of various medical conditions. The non-invasive, low energy device emits photons, which are absorbed to produce cellular effects and physiological changes. The photons temporarily increase microcirculations, resulting in relief of pain and stiffness, relaxation of muscles, decreased inflammation and edema, as well as accelerated healing of injured tissue. Indications for use are listed further on Page 5.

i) Indications

The MedX Rehab Portable Laser uses laser diodes to deliver IR heat energy for the following FDA cleared indications of use: 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 stiffness associated with arthritis.

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

ii) Contraindications

The MedX Rehab Portable Laser <u>SHOULD NOT</u> 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 MedX Rehab Portable Laser:

- Over areas injected with cortisone in the past 15 days,
- If the patient has been diagnosed and is currently being treated for cancer.
- Over a pregnant uterus.
- Over the thyroid region of the neck,
- Over areas with open wounds, unless covered with a clear protective barrier,
- Where it might deliver direct irradiation to the eye, and
- During the prescription of any photo-sensitive medication such as steroids within 15 days from the last oral intake.

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 MedX Rehab Portable Laser, the recharger must be unplugged and the safety key must be inserted. Also, the beam attenuator cap must be removed from the radiant surface.

i) Caution

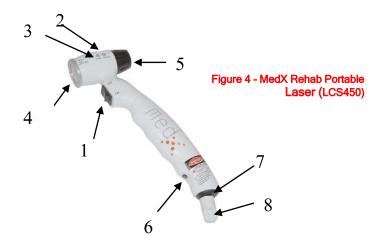
- <u>DO NOT</u> use the device or recharger if it is dropped, cracked or damaged.
- <u>DO NOT</u> place the recharger in a location where the cord can be tripped over.

ii) 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

Device Orientation



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 Diodes	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.

Figure 5 - Safety key (shown inserted into receptacle)



Support Materials

Treatment Guide

An outline of highly effective and efficient protocols for the delivery of SLD and laser treatments for over 65 conditions can be found in the MedX Treatment Guide.

The MedX Treatment Guide provides detailed treatment parameters and placement of the laser. The introduction provides background information to be considered prior to initiating treatment.

Figure 6 - MedX Treatment Guide



Battery Recharging

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 13 seconds.
 - Blue LED with two short beeps indicates 8 Joules, treatment time is 18 seconds.
 - Turquoise LED with a long beep indicates 10 Joules, treatment time is 22 seconds.
- 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.

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.

i) Sleep Mode

The device will enter into Sleep Mode:

- 1. After two minutes Standby mode.
- 2. 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.

Step-by-Step Instructions

- 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.
- Position the MedX Rehab Portable Laser 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 3 hours of treatment time.

User Maintenance

To clean, first turn Off the MedX Rehab Portable Laser 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.

i) Ongoing Maintenance

- The MedX Rehab Portable Laser should be checked regularly to determine that it functions normally.
- When the rechargeable battery requires replacement, the device must be returned to MedX Health (see Service Contact Information, page 20)
- The following items should be checked before each use to ensure proper operation of this device:
 - > Battery Recharger

Check to ensure the cord is free of kinks, and not frayed, torn or cut, exposing wire.

MedX Rehab Portable Laser

Check the radiant surface to ensure it is intact, as well as free of foreign material, grease and cream.

ii) Equipment Operating Conditions

The device should be operated in the following conditions:

Ambient temperatures 0 ° to 40 ° C (32 ° to 104 ° F)
Relative Humidity 20% - 95% non-condensing

Atmospheric pressure 700 - 1060 hPa

iii) Transport and Storage Conditions

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

Ambient temperatures -20° to 65° C (-4° to 149° F)
Relative Humidity 20% to 95% non-condensing

Atmospheric pressure 700 - 1060 hPa

iv) 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 MedX Rehab Portable Laser consists of a hand-held laser device and recharger. The device is $23 \times 8 \times 4$ 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 MedX Portable Laser contains three 808 nm near infrared semiconductor laser diodes, each emitting approximately 150 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 3 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.

i) Frequency

The MedX Portable Laser operates on continuous treatment mode.

ii) 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 guidelight, 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.

iii) 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 450 mW 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.

iv) 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 offsite.

v) 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 MedX Rehab Portable Laser handle to render the device operational.

vi) Remote Interlock Adaptor (Optional)

A Remote Interlock Adaptor is offered as an optional accessory with the MedX Rehab Portable Laser. Its purpose is to terminate laser emission when a door or other portal is opened into a room where laser treatment is being provided.

To use the Remote Interlock feature, remove the Safety Key from the device. Insert the Remote Interlock Adaptor into the receptacle at the base of the handle. If a specified portal is opened while the device is active, the MedX Rehab Portable Laser is immediately deactivated.

vii) Battery

The MedX Rehab Portable Laser holds an internal 3.6 $V_{\rm DC}$, Li-lon battery pack with negligible memory effect providing over 3 hours of treatment time.

viii) Battery Recharger

The MedX Rehab Portable Laser is not designed for use during recharging.

The recharger is medical grade power supply. It has an input of 100-240 $V_{AC},\,50/60\,Hz,$ and $9\,V_{DC},\,1.66A$ output. It connects to a 2.1 mm Recharger Receptacle on the MedX Rehab Portable Laser

Technical Specifications

i) MedX Portable Laser (LCS450)

Category	Description	
Laser Diodes	GaAlAs	
Laser Equipment Safety Classification	Class IIIb	
Regulatory Classification	Class III - Medical Device (Canada) Class II - Medical Device (US)	
Nominal Laser Wavelength	808nm (near infrared)	
Guide Light	470nm (visible blue)	
Duty Cycle	100% (Continuous mode)	
Total Optical Output Power	450mW +/- 10% at 808 nm	
Max. Optical Output Power	165mW per port	
Output	Continuous: 6 Joules - 13 seconds 8 Joules - 18 seconds 10 Joules - 22 seconds	
Laser Power Monitoring	Continuous with automatic shutdown if optical power is + 10%; -20%	
Max Beam Divergence	17°x8° typical (15°x6° minimum)	
Treatment Area at Skin Spot Size	0.026cm ² for 3 spots 0.00881cm ² per spot	
Remote Safety Interlock	Optional	
Beam Attenuator	Yes	
Safety Interlock	Yes	
NOHD (Nominal Ocular Hazard Distance)	193 mm (typical) 226 mm (maximum)	
Battery	3.6V _{DC} Li-lon, 1500mAh capacity	
Dimensions	~23cm x 8cm x 4cm	
Weight	~113g (not including accessories)	

ii) Battery Recharger

Category	Specification	
Туре	Wall mount	
Input	100~240V _{AC} , 50/60 Hz, 0.7A~0.4A	
Output	9V _{DC} , 1.66 A max	
Safety Approval	UL/UL _C Listed	

iii) Standard Protective Goggles

Category	Specification	
OD (Optical Density)	OD1.5 + at 380 - 1800nm	

Warranty

MedX Health Corp. ("Company") warrants that the MedX Rehab Portable Laser ("Product") is free of defects in material and workmanship. This warranty shall remain in effect for three (3) 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 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 MedX Health Corp. 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 MedX Health Corp., by the original owner within 15 business days of purchase.

This Warranty Does Not Cover

- Replacement parts or labour furnished by anyone other than the Company, the dealer or an authorized Company service agent.
- 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.

Service Contact Information

MedX 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 MedX or the authorized service agent under this warranty, the owner must do or abide by the following (see Warranty Card for details):

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

> MedX Health Corp. 1495 Bonhill Road, Unit 1 Mississauga, ON L5T 1M2 Canada

Phone: 905-670-4428

Toll Free: 1-888-363-3112 (USA/Canada only)

Fax: 905-670-4749

Email: service@medxhealth.com Web: www.medxhealth.com

- Contact MedX Technical Service to obtain a Return Materials Authorization (RMA) number.
- The product must be returned (freight prepared) to MedX 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.

MedX 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.

Revisions

Table A.1. Revisions			
Revision Description	Date		
First draft released	Jan.14, 2016		
Added Revisions Table Updated warranty period Updated Contraindication section	May 15, 2017		
	Revision Description First draft released Added Revisions Table Updated warranty period		

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