

Laser Prism Pro-1100

OPERATION MANUAL



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Congratulations on your purchase of a Laser Prism Pro-1100 Console. 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 Laser Prism Pro-1100 Console. 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 Laser Prism Pro-1100 Console.

The Laser Prism Pro-1100 Console controls and powers both SLD clusters for larger area treatment; and handheld laser devices for various clinical applications.

MedX has received international approval for these devices as a means of laser and light therapies.

In the U.S.A., MedX has multiple FDA clearances, covering its entire product line.

In Canada, MedX has 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 Laser Prism Pro-1100 Console (see page 3 for package contents) 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 designated assistants.

The Laser Prism Pro-1100 Console powers the convenient, high-quality handheld laser therapy device and two SLD Cluster accessories.

The MedX Handheld Laser accessory is a Low Level Laser Therapy (LLLT) device for deeper tissue conditions. This accessory features three near-infrared laser diodes for therapeutic applications and a visible LED guide light.

The MedX SLD Cluster accessory offers SLD light therapy for broader applications. This accessory can be strapped to the body for "handsfree", unattended treatment.



Laser Prism Pro-1100 Console



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

1. Standard Components

- 1 Laser Prism Pro-1100 Console with Removeable Key
- 1 Handheld Laser
- 1 Laser Holding Bracket
- 2 SLD Clusters with Flexstrap
- 1 Cluster Holding Container

• 1 Power Supply

- 2 Standard Protective Goggles (one each for patient and Clinician)

2. Optional and Replacement Components Available for Order:

- Rehab Handheld Laser
- SLD Cluster

PRECAUTIONS AND WARNINGS

Before using the Laser Prism Pro-1100 Console, the operator should become acquainted with the operating procedures, 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 LLLT and SLD therapy.

1. Caution

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

- **DO NOT** point the laser beam directly into human or animal eyes. The lens of the eye does not detect the invisible, coherent near-infrared 785 nm wavelength beam potentially resulting in retinal damage.
- Both the patient and operator must always wear Protective Goggles (laser safety glasses) to block any near-infrared energy from the eyes during treatment.
- 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 danger labels are required by the FDA for Class IIIb laser products and affixed to all MedX Lasers. The label warns users of the near-infrared laser radiation emitted by the device. The label is located at the lower end of the handle.



Label Location



Danger Label

3. Warning

- MedX accessories should be operated by a healthcare professional or trained healthcare delegate.
- When the Laser Prism Pro-1100 Console is not in use, remove the key to prevent unauthorized operation.
- Use of controls or adjustments or performance or procedures other than those specified herein may result in hazardous radiation exposure.
- Patients and operator must wear the specified safety goggles, when the Handheld Laser accessory is being used.
- Use only as directed.
- Avoid excessive use.



Radiant Surface Label



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The Laser Prism Pro-1100 Console is used for the treatment of various medical conditions. The non-invasive, low energy devices 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

Laser Prism Pro-1100 Console is FDA cleared, and Health Canada Licensed. MedX products are produced in an ISO 13485: 2003 certified manufacturing and testing facility. The Laser Prism Pro-1100 Console is cleared for the following indication of use:

“to increase local microcirculation resulting in 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.”

2. Contraindications

Avoid using MedX laser devices on the following areas:

- 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
- Where it might deliver direct irradiation to the eye
- 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




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INITIAL SETUP INSTRUCTIONS

After unpacking, make sure all items are present and undamaged. Connect the power cord to the AC adaptor, and then plug the power cord into an AC outlet. Ensure the adaptor is connected to the power port in the rear of the console, marked POWER. Remove protective coverings from the radiant surface of each accessory. Plug accessories into ports at the front of the Console, starting with Port 1. (left port on front)

Please Note: Arrow or Red mark on the connector must be on top. DO NOT rotate connector while inserting into the port or damage may occur.

The MedX Handheld Laser accessory must be plugged **ONLY** into Port 1 in order to operate.

- Caution 

1. Place unit in a location where the power cord cannot be tripped over or pulled

out during treatment.

2. Use the system only if it is properly grounded.
3. 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.

Each kit includes a holding bracket for the Handheld Laser accessory and a container for the SLD accessories. These can be mounted on the sides of the Console as shown on the enclosed assembly diagram at the discretion of the user.



Laser Prism Pro-1100 Console

The Laser Prism Pro-1100 Console is turned ON and OFF by using the removable key in the keyhole on the back panel. Also on the back panel is the POWER port.

1. Power Port
2. Removable Key



1. **START** This key will START treatment, following a 3 second delay. An audible beep indicates the unit has been activated.
2. **MENU** This key will prompt the next selection option.
3. **ENTER** key confirms the setting selection during Manual Setup.
4. **PAUSE/CLEAR** During parameter selection, this key returns the screen to previous display. After treatment starts, this key will PAUSE the treatment and treatment timer. A second push of the key will CLEAR the setting and return it to the previous screen.
5. **ARROWS** Use these keys to scroll up and down options on the screen.
6. **NUMERIC KEYS** Numeric Keys are used to select dosage, treatment mode, and conditions.
7. **ACCESSORY PORTS** The Laser Prism Pro-1100 Console includes three ports for accessories. The Console firmware allows the three ports to be programmed and used simultaneously. This system verifies that the accessories are operational. A warning message indicates if the accessory is unplugged or fails. Always plug the Handheld Laser accessory into Port 1.
8. **LCD** Liquid Crystal Display



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MedX Handheld Laser

- 1. START/PAUSE** A click of this switch will activate the accessory (after the START key has first been pushed on the Laser Prism Pro-1100 Console). Treatment will start immediately, in conjunction with the illumination of the Active LED.

A second click of this switch while the accessory is active will PAUSE treatment. To resume treatment from PAUSE, reactivate the accessory by clicking this switch.

- 2. SERVICE LED** Continuous illumination of this red LED indicates that service is required. Contact your MedX distributor for further instructions.
- 3. ACTIVE LED** Continuous illumination of this green LED indicates that the accessory is active.
- 4. GUIDE LED** Visible LED to indicate treatment area center.
- 5. LASER DIODES** Three infrared laser diodes.
- 6. BEAM ATTENUATOR** Laser cap to be utilized to cover the radiant surface when the device is not in use.



MedX SLD Cluster / 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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The Laser Prism Pro-1100 Console has been designed for ease-of-use. Set up the equipment. Plug the accessories into the ports located on the front of the Console, with the red mark or arrow facing up. The MedX Handheld Laser accessory must be plugged into Port 1. If a MedX Handheld Laser accessory is not being used, the other accessories must be plugged into the ports in sequence (i.e. Port 1, Port 2, Port 3), otherwise, the following warning message will be displayed on the LCD.

WARNING: Move Laser Handheld Accessory To Port 1

1. Connect the power cord to the AC adaptor, plug the power cord into an AC outlet, and connect the AC adaptor to the Laser Prism Pro-1100 Console.
 2. Remove protective covering (beam attenuator for MedX Laser), from the radiant surface of accessory. Wipe radiant surface with damp cloth, followed by germicide to ensure surface is clean.
 3. Turn on the Laser Prism Pro-1100 Console by inserting the key and turning to the ON position. The following statement will appear on the liquid crystal display screen. (version number may vary). After a 5 second delay the screen will display the first prompt.
4. Place the radiant surface of the accessories directly on skin in appropriate positions for treatment. If necessary, use the flexstraps to hold accessories in place for the duration of treatment. (If there are open areas on the skin, cover accessory or open area with clear plastic barrier prior to use.)
5. The Console will automatically detect which accessories are plugged in. If using a MedX Handheld Laser accessory, plug ONLY into Port 1.

The MedX SLD accessory can be plugged into any port.

Select Accessory Ports to be Use
1:Port 1 ◆ 2:Ports 1,2 ◆ 3:Ports 1,2,3

6. After 1, 2 or 3 is entered, the next prompt screen will be displayed:

Push Category Number or Scroll ▲ or ▼
Push "enter" for Default (Manual Setup)

If the category number is known, enter the Console setting code. Then press the start key.

If using the preprogrammed codes in the Console and category number *is not known*, use the arrow keys to scroll through the category list.

- 0 – Manual Setup
- 1 – Muscle/Joint Category
[12J* continuous]
- 2 – Muscle/Joint Deep Category
[16J* continuous]
- 3 – Nerve Category
[16J* Pulsed Low]
- 4 – Wound Superficial Category
[4J* continuous]
- 5 – Wound Deep Category
[6J* continuous]

Only the category on display can be selected. Once category is displayed, press the corresponding number. This will bring up selected settings - push "Start" to begin the treatment.

7. If "0" is selected for manual setup, the display will change to:

Select Dosage (max 20J) and push "enter"
0-- manual J* [*Laser: J SLD : J/cm²]

8. After entering desired dosage the display will change to:

Push 0-Continuous or 1, 2, 3 Pulsing
06- manual 6J*

The third digit indicates continuous or pulsed laser and light therapy treatment. There are 4 options:

- 0 – Continuous
- 1 – Low (8 pulses/second)
- 2 – Medium (146 pulses/second)
- 3 – High (1000 pulses/second)

Pulsing outputs have an 80% ON duty cycle. Treatment times are 25% longer than continuous mode.

9. Once treatment mode is selected, the display will change to:

Push "start" to Begin, "clear" to Cancel
Manual 6J* Pulsed Low

- If changes are required, press the PAUSE/CLEAR key to return to the previous prompt display. Each time the PAUSE/CLEAR key is pressed, the screen will return to the previous display until reaching the beginning of the program.
10. Push the START key. There is a 3 second timer countdown, and then a single beep indicates that treatment has been initiated. Treatment timer will start counting down. However, when using the MedX Handheld Laser accessory, the momentary switch (marked START/PAUSE) on Handheld Laser accessory must also be pressed to initiate treatment.

When using the MedX Handheld Laser accessory, a LED marked ACTIVE will signal that treatment has started. When using the MedX SLD Cluster accessory, the console will signal that treatment has started and the visible red LEDs will light to form an "X" on the treatment face of the accessory.

During treatment, maintain pressure on the accessory by firmly holding it in a stable position, or strapping the accessory (SLD only) in position. No medium or gel is required.

During the last 10 seconds of treatment, the Console will beep every 2 seconds and then emit 3 quick beeps to indicate treatment is complete.

11. Once treatment is complete the following message will be displayed:

Treatment Complete.
Press "menu" to Exit or Retrigger Port 1

Remove accessories from patient and turn the ON/OFF key to OFF position. Remove the key if the Laser Prism Pro-1100 Console is not in use or unattended.

12. A Remote Interlock Adaptor is available as an optional accessory. If in use, when the terminals of the interlock are open-circuited, the laser radiation will be terminated, and the following warning message will be displayed on the LCD:

WARNING: Output Remote Shutoff
Push Any Key To Continue

The remote interlock adaptor would be placed in Port 3.



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USER MAINTENANCE



To clean the Laser Prism Pro-1100 Console, first turn off system, unplug power cord and wipe Console 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 accessories 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 Laser Prism Pro-1100 Console 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.

2. Equipment Operating Conditions:

This device should be operating in the following conditions:

- Ambient Temperature: 32°F and 104°F (0°C to 40°C)

- Relative Humidity 20% to 95% non-condensing

- Store or Transport -4°F to 149°F (-20°C to 65°C).

3. 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.

The Laser Prism Pro-1100 Console should be tested annually to verify functional condition. It is recommended that all MedX LLLT products be serviced by the manufacturer or send to an authorized servicing dealer for repairs or recalibration. Recalibration is also recommended after the *replacement or repair of any major component.*

TECHNICAL SPECIFICATIONS

Laser Prism Pro-1100 Console

Ports	1 output for Laser or SLD light therapy accessory 2 outputs for SLD accessory only or R.I.A. Port 3
Duty Cycle & Frequency Setting	100% (continuous mode) or 80% for 3 pulsing modes: 1 (low) — 8 Pulses/second 2 (medium) — 146 Pulses/second 3 (high) — 1000 Pulses/second
Main Power	EN60601 medical grade approved switching power supply AC Input: 100-240VAC, 50/60Hz, 1.5A – 0.8A DC Output: 12VDC, 4.58A, 60 W Max
Port Output	12 VDC, 0.5 A per port maximum
Timer Accuracy	+/- 1 second

Please Note: Technical Specifications may vary from current description due to changes in approved vendor product availability or other circumstances. Please contact the MedX Technical Support Department if you have questions.



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MedX Handheld Laser Accessory

Light Source	3 near infrared laser diodes (GaAlAs)
Laser Equipment Safety Classification	Class IIIb
Regulatory Classification	Class II - Medical Device (US) Class III - Medical Device (Canada)
Nominal Laser Wavelength	785 nm (near infrared)
Guide Light Wavelength	470 nm (visible blue)
Duty Cycle	100% (continuous mode) 80% (3 pulsing modes)
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).

MedX SLD Cluster Accessory

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) 80% (3 pulsing modes)
Pulse Mode	8, 146 or 1000 pulses/second
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
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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MedX Electronics Inc. ("Company") warrants that the Laser Prism Pro-1100 Console ("Product") is free of defects in material and workmanship. This warranty shall remain in effect for two (2) years, on the console and accessories (Laser and SLD) 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 Electronics Inc. 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 Electronics Inc., 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.

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):

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

MedX Electronics Inc.
220 Superior Boulevard
Mississauga, ON Canada
L5T 2L2

Phone: (905) 670-4428

Toll Free: 1 (888) 363-3112 (US/Can only)

Fax: (905) 670-4749

Email: service@medxhealth.com

Web: www.medxhealth.com

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

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