CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY
OR ON THE ORDER OF A LICENSED CLINICIAN OR THERAPIST

Operating Guide

Oralase Portable Laser

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www.medxhealth.com

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Foreword

Congratulations on your purchase of a MedX Low Level Laser/Phototherapy device, the **MedX Oralase Portable Laser**.

This Guide is written for the owners and operators of the MedX Oralase Portable Laser. It contains general instructions for operation, warnings, precautionary practices and maintenance. In order to maximize the use, efficiency and life of your device, please read this Guide thoroughly and become familiar with its controls before operating.

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

In Canada, MedX has been licensed by the Medical Devices Bureau of the Therapeutic Products Directorate, Health Canada.

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

Phototherapy is a general term which refers to all light based treatments and includes low level laser and other photonic based devices. It is a safe and effective therapy which uses light energy to decrease or eliminate pain and accelerate tissue healing.

MedX Low Level Laser/Phototherapy systems are 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. Indications for Use are listed further on in this guide.

Product Description

The MedX Oralase Portable Laser delivers high-quality photo-therapy with the convenience of portability. The ergonomic design makes the device easy to use, functional and comfort-able to operate.

The device features one GaAlAs near-infrared laser diode and three visible red guide LEDs that deliver phototherapy.

The MedX Oralase Portable Laser has been designed for licensed or registered healthcare professionals and/or their delegated assistants.

Package Contents

Standard Components

- Oralase Portable Laser (Model LPS200)
- Recharger: $9V_{DC}$
- Fibre Optic Light Guides
  (8mm diameter - one 90mm intra-oral,
  one 25mm extra-oral)
- Safety Key
- Padded Carrying Case
- MedX Quick Reference and Procedures Sheet
- Two pairs of Standard Protective Goggles MPG01
  (one each for patient and clinician)
- Operating Guide (this booklet)
- Dental Patient Brochures (25)

Replacement and Optional Components Available for Order

MPG01	Standard Protective Goggles
MPG02	Premium Protective Goggles (for clinician)
MAB07	Oralase and Fiber Optic Light Guides Cradle
MLC01	MedX Laser Cart
MLG01	Intra-Oral Fibre Optic Light Guide (90mm x 8mm dia.)
MLG02	Fibre Optic Light Guide (10mm x 8mm dia.)
MLG03	Extra-Oral Fibre Optic Light Guide (25mm x 8mm dia.)

Precautions and Warnings

Before connecting the recharger or operating the MedX Oralase Portable Laser, 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 and Phototherapy.

Caution

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

- The patient and operator **MUST ALWAYS** wear Protective goggles (laser safety glasses) to block any infrared energy from eyes during treatment.

- DO NOT point the laser beam directly into human or animal eyes. The human eye does not detect the invisible, coherent near-infrared 808 nm wavelength beam, which could potentially result in permanent retinal damage.

Labels

The following Danger label is required by the FDA for Class IIIb laser products and affixed to the MedX Oralase Portable Laser. 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. Typical power output is calibrated to approximately 250mW after the lens. When fiber optic light guides are inserted there is a further reduction in power. The nominal power at the tip of the 90mm long fiber optic guide is 200mW.

Figure 1 - Danger Label

The following aperture warning label is located on the device near the radiant surface. It indicates the location of the surface that emits near-infrared laser energy referred to as the active radiant surface, and the direction of the beam of light.

Figure 2 -
Laser Aperture Label

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**"

Warning

- The MedX Oralase Portable Laser should be operated by a healthcare professional or trained delegate
- 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

Indications for Use

The MedX Oralase Portable Laser has the following indications for use in Canada:

1. *Increase in microcirculation*
2. *Adjunctive use for relief of temporary pain and stiffness*
3. *Pain and stiffness associated with arthritis*
4. *Muscle relaxation and decrease muscle spasms*

In the US the FDA indications for use are:

> *... for temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness and relaxation of muscles; for muscle spasms, minor pain and stiffness associated with arthritis.*

Research indicates that phototherapy creates a cascade of chemical and biological effects. Further information can be found in books such as 'The Laser Therapy Handbook' authored by J.Tuner and L.Hode and published by Prima Books.

Contraindications

The MedX Oralase Portable Laser **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 the MedX Oralase Portable Laser

- Over areas injected with steroids or NSAIDS in the past 72 hours
- Over suspicious lesions (potential cancer)
- Over areas with open wounds, unless covered with a clear protective barrier or sterilizing fiber optic light guide between patient uses
- Over the thyroid gland
- Over a pregnant uterus

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 Oralase.

It will take approximately 2 hours to fully charge the battery from complete discharge. The red 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 MedX Oralase Portable Laser functions only when the safety key is inserted.

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

Safety Instructions

Disconnect the recharger by pulling the plug, not the cord:
- If the plug or cord 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

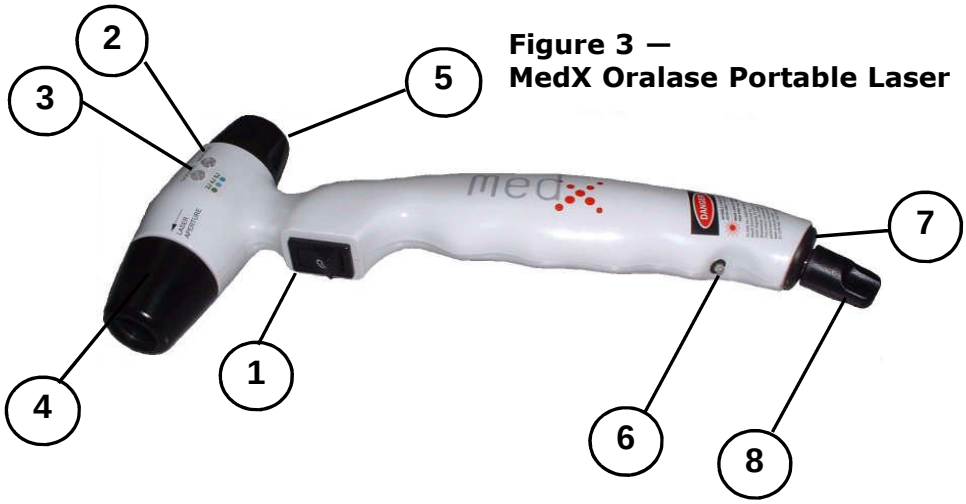

Figure 3 —
MedX Oralase Portable Laser

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**	**Green** with 1 short beep indicates 2 joules **Blue** with 2 short beeps indicates 4 joules **Turquoise** with 1 long beep indicates 8
4	**Infrared Diode**	Near-infrared laser diode located behind protective lens and light guide (Not shown)
5	**Dosage selection button**	Push this button to cycle the dosage among 2,4 and 8 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.

Support Materials

MedX Quick Reference and Procedures Sheet

The easy to use MedX Quick Reference and Procedures Sheet provide rapid access to the information needed for fast, effective treatment of pain, inflammation and tissue repair. The dose, location of treatment and helpful pointers provide guidelines for treating the most common dental indications of use.

MedX Treatment Manual

An outline of highly effective and efficient protocols for the delivery of low level Laser and SLD treatments for many conditions can be found in the MedX Treatment Manual which is available with the MedX Phototherapy System. (Not available with this product)

The MedX Treatment Manual provides detailed treatment parameters including dosage and placement recommendations for the laser and SLD clusters. The introduction provides background information to be considered prior to initiating treatment.

Figure 4 — MedX Treatment Manual

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.

Note: The removable safety key must be inserted into the receptacle located at the bottom of the handle after recharging to enable device operation.

Figure 5 —
Safety key (key shown inserted into receptacle may also be black)

Operating Instructions

The MedX Oralase Portable Laser has been designed for simple operation:

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 a short beep indicates 2 joules, treatment time is 10 seconds.
   Blue LED with two short beeps indicates 4 joules, treatment time is 20 seconds.
   Turquoise LED with a long beep indicates 8 joules, treatment time is 40 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 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.

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 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.

Sleep mode The device will enter into sleep mode if:

1) After two minutes Standby mode
2) 10 seconds after service LED illuminates
3) Every time the safety key is unplugged

The device can be woken (brought out of sleep mode) 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, then go to Standby mode to previously selected dose.

Step-by-Step Instructions

1. **Intra-oral** applications require positioning the fiber optic light guide in direct contact with soft tissue, unless painful (e.g. apthus ulcer)

   Note: For treatment **over a tooth**, use a water soluble lubricant on the tooth surface, then apply laser.

   Extra-oral treatment **over skin** requires the cleansing/degreasing of the skin with alcohol or soap and water to reduce reflection and refraction. If there are any open areas being treated, cover radiant surface with clear barrier.

2. Position the MedX Oralase fiber optic light guide tip directly onto tissue, at a 90 degree angle perpendicular to the target tissue 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 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, 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 ON SOFT TISSUE, ONLY OVER TOOTH SURFACE.

6. Complete the treatment at each site prior to proceeding to the next site.

7. It is advised to recharge the unit after 120 minutes of treatment time.

User Maintenance

To clean, first turn off the MedX Oralase Portable Laser and unplug the recharger or safety key. Clean the device handle with surface disinfectant. Do not use abrasive cleaners. A surface disinfectant or germicidal wipe (e.g. PDI Sani-Cloth HB) should be used. Fiber optic light guides are autoclaved or disinfected between patients.

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.

Ongoing Maintenance

- The MedX Oralase 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 or an authorized servicing dealer (see *To Obtain Service*, pg. 22)
- The following items should be checked before each use to ensure proper operation of this device:

1. Recharger
   Check to ensure the cord is free of kinks, and not torn or cut, exposing insulation.

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

3. Fiber Optic Light Guides
   Verify that the light guides are transmitting light effectively over their entire surface. A damaged light guide can block a high percentage of the near-infrared radiation used in the treatment.

Equipment Operating Conditions

The device should be operated in the following conditions:

Ambient temperatures	32 to 104F (0° to 40°C)
Relative Humidity	20% - 95% non-condensing
Atmospheric pressure	700 - 1060 hPa

Transport and Storage Conditions

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

Ambient temperatures	-4 to 149F (-20°C to 65°C)
Relative Humidity	20% - 95% non-condensing
Atmospheric pressure	700 - 1060 hPa

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. All MedX Phototherapy products must be serviced by the manufacturer or sent to an authorized servicing dealer for repairs and recalibration. Calibration procedures are NIST certified and available at selected authorized service dealers or the manufacturer's service and repair center.

Device Specifications

The MedX Oralase consists of a hand-held portable laser device and recharger. The device is 23 x 8 x 4 cm and weighs approximately 190 g (not including accessories). The enclosure device is made of ABS plastic, Delrin plastic and the radiant surface is covered with an optical glass lens.

The MedX Oralase Portable Laser contains a laser diode, green, blue and red LEDs, a circuit board, electronic components and labels. The handle contains a momentary ON switch and dosage buttons. The recharger receptacle is located at the base of the handle.

The MedX Oralase Portable Laser contains one 808 nm near-infrared semiconductor laser diode, emitting approximately 200 mW (from the tip of the fiber optic light guide) in continuous treatment mode. The diodes are Gallium-Aluminum-Arsenide (GaAlAs). Once the device is activated, it automatically delivers either 10, 20 or 40 seconds, or respectively 2, 4, or 8 Joules of energy and then turns itself off. The rechargeable battery is capable of delivering over 2 hours of treatment time when fully charged.

The visible red LEDs and near-infrared laser are activated simultaneously. The near-infrared light provides therapeutic energy and the visible red 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.

The MedX Portable Laser operates in a continuous treatment mode.

Laser Radiation Emission Indicators

There are certain signals that indicate the INFRARED laser diode is active. The first indicator is the corresponding DOSAGE LED(s), which are illuminated upon activation for the selected number of joules. The second indicator is the illumination of the red 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 pushed, as treatment begins. There is also a single beep emitted every 5 seconds which indicates the delivery of 1 joule of energy. This Beep per Joule feature can be disabled. (See Operating Instructions on page 12)

Power Measurement Safety Control

The laser diode includes a photodiode detector that monitors the optical power from the infrared laser diode. The laser output is regulated within the nominal 20% tolerance of the 200 mW laser diode at the tip of the long fibre optic light guide.

If the photodiodes indicate that the optical output power has exceeded the tolerance, the laser deactivates and the red SERVICE LED illuminates; the laser power is continuously monitored while it is active.

NOTE: The laser diode is calibrated to approximately 250mW of power. Some energy is lost internally by the lens, heatsink enclosure and fiber optic light guide. The effective output power at the treatment site is reduced to 200mW for the 90mm long fiber optic light guide. Using the shorter fiber optic light guide will have a slightly lower loss. Always use a fiber optic light guide when using the MedX Oralase Portable Laser to maintain safe operating conditions.

Battery

The MedX Oralase Portable Laser holds an internal $3.6V_{DC}$ Li-Ion battery pack providing up to 2 hours of treatment time before requiring a recharge.

Recharger

The recharger is CSA and UL 1950 approved. It has an input of $100\text{-}120V_{AC}$ 50/60Hz, and $9V_{DC}$ 1.3A output. It connects to a 2.1 mm recharger receptacle on the MedX Oralase.

A Universal Medical Grade Recharger is available as an optional accessory. Contact MedX Technical Service if required.

Technical Specifications

MedX Oralase Portable Laser (Model LPS200)

Category	Description
Laser Diodes	GaAlAs
Laser Equipment Safety Classification	Class IIIb
FDA Regulatory Classification	Class II
Nominal Laser Wavelength	808 nm (near-infrared)
Guide Light	633 nm (visible red)
Duty Cycle	100% (Continuous mode)
Typical Optical Output Power at tip of light guide	200 mW +/- 20%
Max. Optical Output at lens.	250 mW +/- 20% (without light guide)
Output	Continuous: 2 Joules - 10 seconds 4 Joules - 20 seconds 8 Joules - 40 seconds
Laser Power Monitoring	Automatic, continuous
Max Beam Divergence	17 x 40 degrees (prior to lens) Collimated output)
Spot size	10 mm^2 +/- 20%
Safety Interlock	Yes (Remote Safety Interlock Optional)
NOHD (Nominal Ocular Hazard Distance)	2.6 meters (worst case) 33 cm (typical)
Battery	3.6V_{DC} Li-Ion, 1500 mAh capacity
Dimensions	~ 23 cm x 8 cm x 4 cm
Weight	~ 190 g (not including accessories)

Recharger

Category	Specification
Input	100~120V_{AC} 50/60 Hz, 0.3A max.
Output	9V_{DC} 1.3A max.
Safety Approval	UL/UL_C Listed, CSA 22.2

Standard Protective Goggles

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

Warranty

MedX Electronics Inc. ("Company") warrants that the MedX Oralase Portable Laser (“Product”) is free of defects in material and workmanship. This warranty shall remain in effect for one (1) year, on the Oralase (Laser device) from the date of original consumer purchase of this Product and extends to any owner of the Product during the warranty period. The internal rechargeable battery warranty is limited to 12 months from the date of manufacture as marked on the handle of the Oralase. 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 center 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 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 MedX Technical Service for clarification.

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

Some states or provinces 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.
   3350 Ridgeway Drive, Unit 3
   Mississauga, ON Canada
   L5L 5Z9

   Phone: **905.826.0766**
   Toll free: **1-888-363-3112**
   Fax: **905-826-0086**
   Email: **service@medXhealth.com**
   Web: **www.medXhealth.com**

2. Contact MedX Technical Service to obtain a Return Material 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.

Your local representative is:

Manufacturer
MedX Electronics Inc.
3350 Ridgeway Drive, Unit #3
Mississauga, ON
L5L 5Z9
905.826.0766
1.888.363.3112
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