User Manual







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Introduction – The LaserTouchOne™ (OTC)

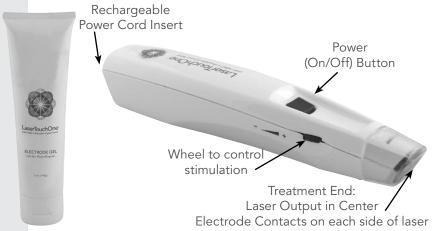
The LaserTouchOne™(OTC) (referred to further as simply LTO) is a rechargeable hand-held pain therapy device. It has a single diode laser for delivery of low level laser therapy, referred to by some as a 'cold laser' or LLLT. The single laser source is extremely low power (< 1mW) and in the Class IIa regulatory classification for laser lights. It operates at the 670 nm wavelength. The second therapy delivered by the device is a micro-current electrical stimulation, similar to devices that are referred to as transcutaneous electrical nerve stimulators (TENS), but at a much lower level. The device contains a rechargeable lithium ion battery.

The combined therapies are activated with an on/off power button, which when pressed is set for a 2-minute cycle. Depending on the severity of pain, you can treat a single area with 4 to 5 treatment cycles (8 to 10 minutes), up to 5 times each day. The electrical stimulation and the laser light therapies are activated at the same time by pushing the on/off switch. The pulse width (e.g. intensity) of the electrical stimulation is variable and is controlled by you, the user. This is described in the Treatment Steps on pages 6 and 7. It is recommended that the intensity of the electrical stimulation be kept very low, so that you barely feel it. The combination of low level laser and micro-current electrical stimulation will facilitate pain relief. This combination of therapies has been shown to be effective at very low levels of stimulation, so setting the electrical stimulation dial to a higher intensity is not necessary.

It is important that the cause of your pain be identified before you start treating it with any device, including the LTO.

Device Features and Controls

The following photograph shows the LTO device and the electroconductive gel used for treatment. The steps for using the device follow on page 6. If this is your first use, be sure the device is fully charged prior to use.



Product Contents

The shipping box should contain the following device components:

- LaserTouchOne[™] treatment unit
- Power cord for recharging the battery
- Tube of electroconductive gel
- Warranty card
- User Manual
- Instructional DVD

Inspect contents to ensure there is no obvious damage to the LTO treatment device or the gel tube.

Safety

Laser Safety – Caution: Do not stare into the visible light. Laser light is emitted from this device. **Avoid extreme exposure.** Do not point the device at anyone's eyes.

Electrical Safety – Use care when plugging the power cord into the wall outlet for recharging the LTO device. See the picture below for the power charging unit which is provided with the device. It is UL certified as safe for use with this device.

Instructions For Use:

Charging the Unit

The device will need to be fully charged for at least 5 hours prior to the first use. Plug the AC recharging power cord into the unit and then into the wall socket (if possible, a power surge protector, or power strip, is recommended). The unit will not operate unless the battery is charged. When the device is not in use, do not store the device plugged into the charger unless it needs to be charged. Do not use the device while it is plugged in. Recharge the device at least once every 3-4 weeks for 5 hours if you are using it daily. Charge the device once every two months if you are only using it occasionally. Do not let the LTO completely lose its battery charge.

This is the charging unit which is supplied with your device. Do not attempt to use another power recharger – it may fail to recharge or can damage your device.

Holding the Device

Generally, the LTO device is best held as you would a pen, with the index finger on top to operate the power (on/off) button. This allows the middle finger (right hand) or thumb (left hand) to manipulate the electrical stimulation (e-stim) wheel (or dial) to control the pulse width (intensity). However, you



may find it is more comfortable to hold in another position.

Treatment Steps:

Step 1: Adjust the E-Stim Wheel

Turn the dial (e-stim wheel) on the side of the device completely toward the minus (-) sign (as shown by the arrow).



Step 2: Apply Gel

Apply a small amount of gel to the area you wish to treat.



Step 3: Turn on the LaserTouchOne™

Push the on/off button on the LTO once.

Step 4: Apply the LaserTouchOne™

Use a paint-stroke or circular motion to treat the painful area. Adjust the dial toward the positive (+) sign until you feel a slight tingle. Remove your finger from the dial leaving it at that setting.



NOTES REGARDING SETTING THE ELECTRICAL STIMULATION INTENSITY:

- If you have limited or no skin sensitivity in the area you plan to treat, test the intensity of the stimulation on a sensitive area (such as between your thumb and first finger, or on top of your hand) before starting treatment. This will ensure that you do not turn the setting too high.
- Effective treatment can be achieved with only a slight tingle sensation of the micro-current electrical stimulation. Be sure to treat the area of immediate pain and also surrounding areas that may also be affected by the immediate area of pain.

Step 5: Continue For Up To Five Treatment Sessions Per Day

Continue moving the unit in a paint-stroke or circular motion in the desired area until the LTO and red light turn off after 2 minutes. You can continue your treatment by pressing the

power button again. If you desire to stop the unit at any point, simply push the power button to turn it off.

It is recommended that you start with four to five 2-minute cycles for a particular area of pain, and repeat this up to five times throughout the day. You can do this for each area of pain you wish to treat. Be sure to treat above and below the area of pain as well, as the pain may originate in the areas surrounding where it is felt.

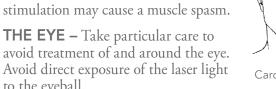


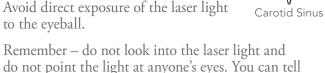
Usually, treatment with the LTO requires little or no pressure to the area being treated. However, in areas with a lot of muscle or fat, a more firm application may be necessary, although the pressure applied should not be painful.

Areas to Avoid

Parts of the head, face and front of the neck:

CAROTID SINUS – The location of the carotid sinus is illustrated in this drawing. Care should be taken to avoid the carotid sinus, as the electrical stimulation may cause a muscle spasm.





do not point the light at anyone's eyes. You can tell that the device is on by seeing the light from the side through the plastic tip.

Indications for Use

The LaserTouchOne™ device combines a low level laser and micro-current electrical stimulation. This combination of low level light and electrical stimulation provides symptomatic relief of chronic, intractable pain, and is indicated for adjunctive treatment of post-surgical and post-traumatic acute pain and for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.

Contraindications

This device is contraindicated in patients with cardiac pacemakers, implanted defibrillators or other implanted devices.

Warnings

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- Because the device contains a laser, do not shine it directly into your eyes or look directly at the laser light. Do not point the LTO device at your or another person's eyes.
- The safety of TENS devices on pregnant women has not been established.
- The device should be applied only to normal, intact clean skin. Note that the device may be applied to bruised skin, although care should be taken to reduce any pressure. Avoid use over open wounds or swollen, infected or inflamed areas or skin eruptions.
- Avoid use of the LTO device along the eye area, or on the front or sides of the neck at the carotid artery (shown at left).
- Avoid use of the LTO device over, or in the area of, cancerous lesions.
- The device should not be used during the following activities:
 - bathing or showering
 - sleeping
 - driving or operating machinery



Do not look into the laser light and do not point the light at anyone's eyes.

Precautions

- If you have a suspected or diagnosed heart condition (such as irregular heart beat, cardiac arryhthmia) or epilepsy, you should consult with your physician before using the LTO device to treat any pain condition.
- The long-term effects of prolonged exposure to non-thermal laser and electrical stimulation are unknown.
- Electrical stimulation (TENS) is not known to be effective in treating pain of central origin, including headache.
- TENS devices are not a substitute for pain medications and other pain management therapies.
- Since the effects of stimulation of the brain are unknown, avoid use across the head.
- TENS devices have no curative value.
- TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism. This is particularly important in the use following surgical procedures.
- Keep the device out of the reach of children
- Some patients may experience skin irritation or hypersensitivity to the electrical stimulation or the electrical conductive medium (gel).
- Care should be taken by patients whose skin in areas lack normal sensation.

Care and Maintenance

Like any electronic product, the LTO requires proper care and handling. The following is recommended:

- Do not disassemble the device. Do not try to remove the clear cover at tip of unit.
- Do not drop the device or handle it roughly.
- Do not immerse the device in water or any liquid.
- Use the gel sparingly only a small amount is needed on the skin.
- After each treatment, wipe the treatment end of the device clean of any gel with a slightly damp cloth.
- If using the device on more than one person, carefully decontaminate the treatment end, including the stainless steel electrodes with a moist alcohol wipe.



Warranty

The LaserTouchOne[™] carries a 1-year warranty. If your device should malfunction due to defective materials and/or workmanship, it is fully guaranteed for one year from the date of purchase, providing:

- the enclosed warranty card is mailed to Laser Health Technologies within 10 days of purchase;
- the LTO is returned for servicing to Laser Health Technologies;
- the LTO is not misused, altered, or serviced by any person or entity other than Laser Health Technologies;
- the electroconductive gel provided with the product is the only type of gel to be used with the LTO device;
- the LTO is used according to these instructions and in the manner intended.

Use of a different recharging unit or a different type of electroconductive gel will void the 1-year warranty.

Service

If servicing is needed for your LTO, please call 1-877-751-7665 for the shipping address to send the LaserTouchOne and the charger.

Include the following information with your unit: name, address for return, phone number, and a brief description of the issue.

Laser Health Technologies will contact you with an estimate of cost to complete any repairs, if not under warranty, and arrange for payment.

More Questions?

Call or e-mail Laser Health Technologies for any additional information at 877-751-7665 or info@lasertouchone.com.





View instructional videos at www.LaserTouchOne.com.

LaserTouchOne™ Specifications

Laser		
LASER Type	Laser Diode	
Wavelength	670nm +/- l0nm	
Power	1.2mW	
Transcutaneous Electrical Nerve Stimulation		
Waveform, shape	Pulsed, rectangular	
Maximum output voltage	15V @ 500 ohm load 150V @ 10K ohm load	
Maximum output current	30 mA peak at 500 ohm load	
Pulse width	6 – 80 μsec	
Frequency	45 Hz+/- 10%	
Pulse period	22 mS	
Maximum current density	0.23 mA/cm2 average @ 500 ohms	
Maximum power density	0.0034 W/cm2 average @ 500 ohms	
Maximum charge per pulse	36 μJ @ 500 ohms or 2.4 μC @ 500 ohms	
Power		
Rechargeable Battery	Lithium Ion	

Glossary

ADJUNCTIVE TREATMENT – Treatment used together with the primary treatment. Its purpose is to assist the primary treatment.

CARDIAC ARRHYTHMIA – An abnormal rate of muscle contractions in the heart.

CONTRAINDICATIONS – To make (a treatment or procedure) inadvisable.

DIODE – An electrical device with two active terminals, an anode and a cathode, through which current passes more easily in one direction.

ELECTROCONDUCTIVE – Having the property or capability of conducting electricity.

FDA – Food and Drug Administration.

INTRACTABLE PAIN – Pain that is hard to treat, relieve, difficult to solve, alleviate, or cure.

LLLT – Low Level Laser Therapy, often referred to as Cold Laser.

OTC – Available without a prescription, "Over The Counter."

TENS – Transcutaneous electrical nerve stimulators.



Laser Health Technologies

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