



# TLC-1000 OPERATIONS MANUAL

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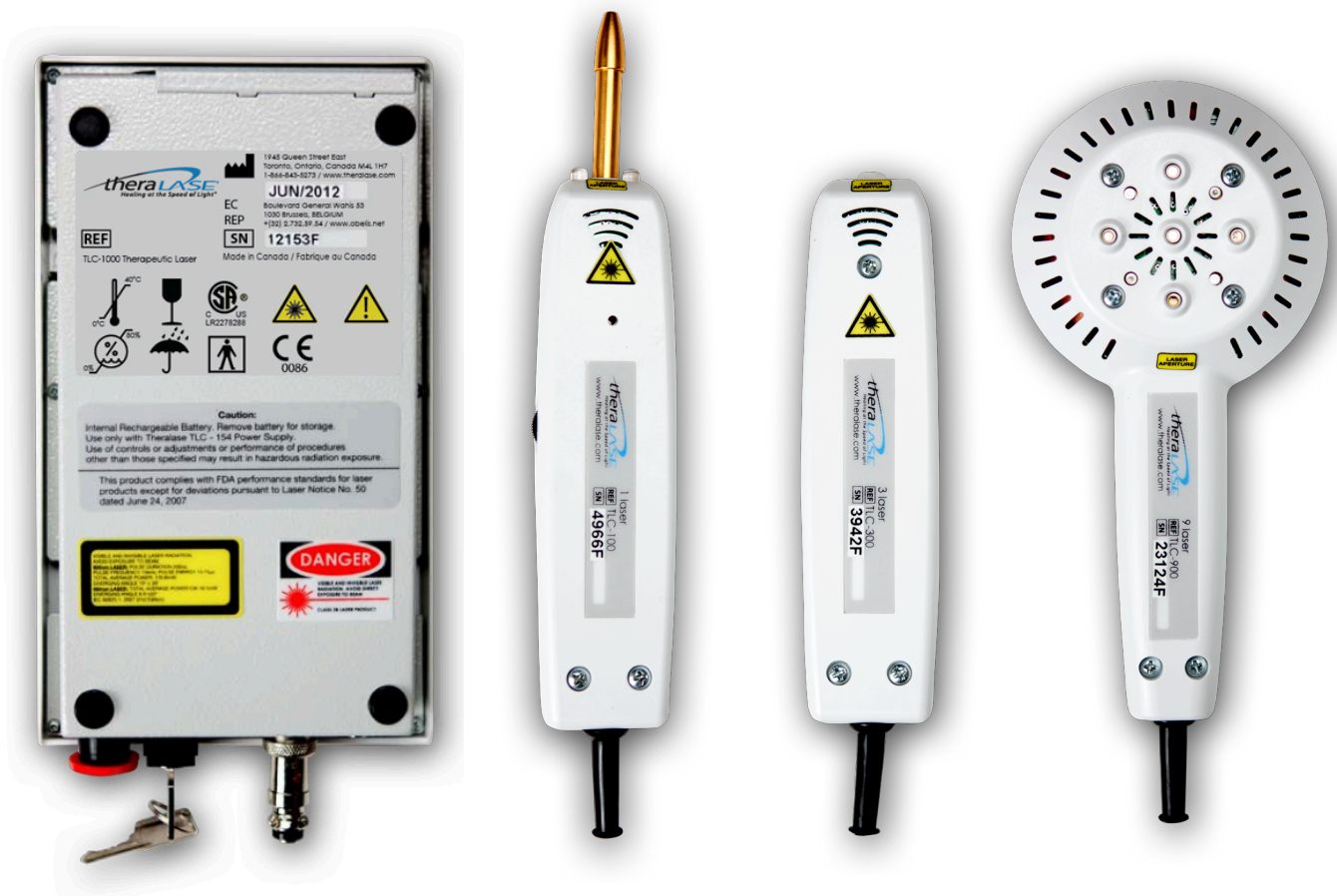
## 1. Safety Information – Please Review Before Using the Theralase System

The Theralase™ TLC-1000 therapeutic laser is a Class 3B medical laser and as such is a potential hazard for direct and indirect viewing of the laser light.

The Theralase™ TLC-1000 system as mentioned earlier is composed of three main components; the TLC-1000 Laser Controller, the Power Supply and the Laser Diode Probes. Safety and safe use of the product are indicated both visually by the use of labels as well as equipment features. These will be detailed below. **IT IS IMPORTANT TO BE WELL AWARE OF ALL THESE SAFETY DETAILS PRIOR TO USING THE EQUIPMENT.**












### Labelling and an Explanation of Symbols

#### *Location of the Labels and Symbols*



**TLC-1000 Laser Controller Labels and Symbols**

The back of the Laser Controller is completely enveloped by a large label which carries safety information.

	<p><b>Canadian Standards Association Symbol (for Canada and US):</b> Certifies that the product bearing this mark meets or surpasses CSA guidelines for Medical Electrical Device Standard IEC 60601-2-22:1995 (2nd Edition)</p>
	<p><b>ATTENTION Consult ACCOMPANYING DOCUMENTS Symbol:</b> Documents accompanying EQUIPMENT or an ACCESSORY and containing all important information for the USER, OPERATOR, installer or assembler of EQUIPMENT, particularly regarding safety.</p>
	<p><b>Class 3B Laser Warning Label Symbol – APERTURE LABEL:</b> Identifies product as a Class 3B laser, which permits human access to laser radiation in excess of the accessible emission limits of Class 1 and Class 2, but which does not permit human access to laser radiation in excess of the accessible emission limits of Class 3B for any emission duration and wavelength.</p>
	<p><b>Type BF Equipment:</b> EQUIPMENT providing a particular degree of protection against electric shock, particularly regarding allowable LEAKAGE CURRENT and reliability of the protective earth connection. Includes an F-TYPE APPLIED PART.</p>
	<p><b>Laser Radiation Warning Label:</b> VISIBLE AND INVISIBLE LASER RADIATION. AVOID EXPOSURE TO BEAM. <b>905nm LASER:</b> PULSE DURATION 200ns; PULSE FREQUENCY 10kHz; PULSE ENERGY 13.75µJ; TOTAL AVERAGE POWER 176.8mW; DIVERGING ANGLE 10°X30°. <b>660nm LASER:</b> TOTAL AVERAGE POWER CW 18.5mW; DIVERGING ANGLE 8.5°X22°. IEC 60825-1: 2007 (2nd Edition)</p>
	<p><b>CE Compliance Symbol</b> Certifies that the product bearing this mark meets or surpasses CE in accordance of the Council Directive MDD 93/42/EEC.</p>
	<p><b>Operation Temperature Range Symbol</b> This equipment shall be operated within 0° to 40° Celsius ambient temperature.</p>
	<p><b>European Authorized Representative</b> Obelis s.a. Corporate Office: Registered address : Bd. Général Wahis 53 Avenue de Tervuren, 34, box 44 B-1030 Brussels, Belgium B-1040 Brussels, Belgium Phone: 32.2.732.59.54 Fax: 32.2.732.60.03</p>
	<p><b>Fragile Symbol</b> Do not drop</p>
	<p><b>Humidity Range Symbol</b> This equipment shall be operated within 0% to 80% humidity</p>
	<p><b>Keep Dry Symbol</b> Keep away from rain and liquids</p>

**Figure 2. Safety Labels and detailed explanations of the symbols**

## Key Equipment Safety Features

### Hardware

In addition to the safety signs placed on each of the elements of the Theralase™ system, key safety features are built into the front panel of the main TLC-1000 Laser Controller as well. These are illustrated below.



**Figure 3. Front panel of TLC-1000 Laser Controller highlighting equipment safety features**

#### Emergency Stop

This button shuts down the entire laser system immediately when pressed.

#### ON/OFF Key Switch

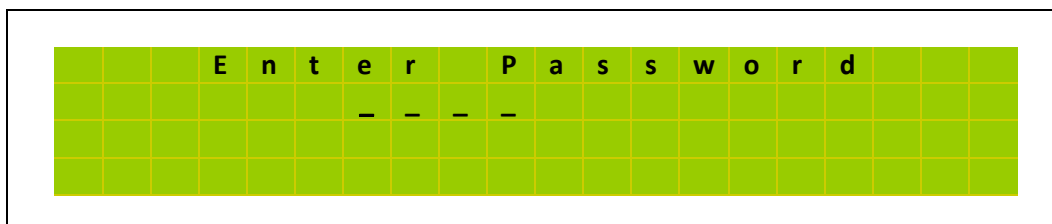
This is the main on / off switch for the laser system. When not in use, the keys can be placed in a safe location to prevent unauthorized use of the equipment.

#### Remote Interlock Connector

The remote interlock connector is a connector that may be connected to a remote connector for disconnecting the mains power once the terminals of the connector are open-circuited.

### Software

Even if the key switch is left in the system and the remote interlock connector is in place, there is yet another security feature in place. The system requires a password to be able to start the Laser Controller software.



This now completes the 3-step security protocol system to prohibit laser use by unauthorized personnel.

## Operational Safety

***Caution: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.***

The Theralase™ TLC-1000 therapeutic laser is a Class 3B medical laser and as such is a potential hazard for direct and indirect viewing of the laser light. As a Class 3B medical laser, the Theralase™ system carries the following warning:

VISIBLE AND INVISIBLE LASER RADIATION.  
AVOID EXPOSURE TO BEAM.  
905nm LASER: PULSE DURATION 200ns;  
PULSE FREQUENCY 10kHz; PULSE ENERGY 13.75µJ;  
TOTAL AVERAGE POWER 176.8mW;  
DIVERGING ANGLE 10°X30°.  
660nm LASER: TOTAL AVERAGE POWER CW POWER 18.5mW;  
DIVERGING ANGLE 8.5°X22°.  
IEC 60825-1: 2007 (2nd Edition)

Consequently users should be well protected with laser safety glasses having a minimum OD of 4 or 5 at 905nm. Suitable eye protection is required when using the TLC-1000 laser system. Use supplied laser safety eyewear (Part #: TLC-901) for patient and for all practitioners involved in the laser treatment. Two sets of laser safety eyewear have been supplied with the Theralase™ TLC-1000 laser system. (1 patient and 1 practitioner pair)

Please note that Theralase™ supplies Laser Safety Eyewear with all of its products and can be contacted directly at 1-866-The-Lase (1-866-843-5273) for additional sets if required. Order (Part #: TLC-901) directly from Theralase™ Inc. for all additional laser eyewear needed. The laser eyewear is for diffuse viewing of laser light only.

The Theralase™ TLC-1000 laser output is athermic. Laser diode package cases may warm up slightly during treatment giving a feeling of warmth to a laser treatment. Under no circumstances should the patient experience a very hot or burning sensation during treatment. If this occurs, discontinue the treatment immediately and contact Theralase™ Inc. for service.

Observe the safeguards as put forward below. The Theralase™ TLC-1000 therapeutic medical laser is a sophisticated medical device and as such should only be handled by experienced medical practitioners suitably trained in its use.

## **Precautions**

- Make sure that the area to be treated is free from any substance that reflects or prevents penetration of the laser beam. It is recommended that areas to be laser treated are cleansed, prior to treatment.
- Operate the laser in a well-illuminated area, as the pupils of the eye are smaller and not as easily damaged.
- Operate the laser in an area free from mirrors or polished metal surfaces to prevent accidental reflections.
- Operate the laser in a segregated area with a sign posted:



Operate the laser probes in direct contact to the tissue being treated and perpendicular to the area of treatment to reduce reflection off the tissue.

Align laser probes to the area to be treated before commencing laser treatment.

Scanning is accomplished by holding the probe perpendicular to the treatment area and in a slow and continuous circular movement covering the area under treatment.

## **Safety Warning:**

- **The TLC-1000 Laser Controller is designed to operate with either, the TLC-100 Single Laser Probe, the TLC-300 Triple Laser Probe or the TLC-900 Multiple Laser Probe only. Only one probe may be connected to the TLC-1000 Controller at any one time.**
- **The Theralase™ TLC-1000 laser and all attachments are not designed to be protected from water intrusion and should never be used wet or in the accompaniment of water. If the laser system becomes wet or immersed in water, thoroughly dry the laser system and allow 48 to 72 hours in a warm environment to fully dry prior to use. If problems persist, contact Theralase™ Inc. for service.**
- **The Theralase™ TLC-1000 laser and all its attachments should not be used in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.**
- **The Theralase™ TLC-1000 laser and all attachments are not suitable for use in the presence of strong electromagnetic field or other electrical interference.**
- **The Theralase™ TLC-1000 laser and all attachments are designed as an integral system and**



**use of parts other than the recognized accessories or parts can degrade the performance of the Theralase™ TLC-1000 laser and may result in hazardous radiation exposure.**

### **Disclaimer Information**

The TLC-1000 therapeutic laser system is a medical device and is sold to healthcare practitioners as a tool for the rehabilitation of their patients. The TLC-1000 therapeutic laser system and attachments are utilized to assist in the alleviation of their patient's symptoms. The TLC-1000 therapeutic laser system is not promoted as a cure for any patient ailments.

The information contained in this manual is for reference only and does not preclude the practitioner from using proper judgement in the rehabilitation of their patients.

It is the practitioner's sole responsibility to decide if laser therapy is indicated for their specific patient's rehabilitation.

The treatment protocols detailed in this manual are for reference only and are not promoted as the only protocol available to the practitioner.

## 2. THERALASE TLC-1000 SERIES PRODUCT INFORMATION

The TLC-1000 therapeutic medical laser and all the accompanying attachments are used in the rehabilitation of muscular skeletal ailments and wound healing. The technology of Low Level Laser Therapy (LLLT) is designed as a non-invasive and non-toxic therapeutic treatment for the safe and effective treatment of:

- acute and chronic pain
- musculoskeletal conditions
- wound healing
- joint restoration

The TLC-100 single laser probe, TLC-300 triple laser probe and the TLC-900 multiple laser probe are used in direct contact with tissue in order to inject photons of light (905 nm invisible laser light and 660 nm visible red light) non-invasively and drug-free into tissue.

### Product Overview and Technical Description

The Theralase™ TLC-1000 series of products is comprised of three main components

- The Laser Controller also referred to as the TLC-1000
- The Power Supply (TLC-154)
- The Output Laser Probe; this could be one of, the TLC-100 (the acupuncture probe), the TLC-300 (the triple probe) or the TLC-900 (the multiple probe).

The TLC-1000 therapeutic laser system is designed to emit 905 nm NIR invisible laser light and 660 nm visible red light. The maximum rated outputs of the TLC-1000 therapeutic laser system are 100 mw average power at 905 nm and 25 mw average power at 660 nm. The TLC-1000 therapeutic laser system is portable and is able to be programmed with specific user defined laser treatment protocols. In order to be portable, the Laser Controller is equipped with an internal rechargeable battery. The following illustrates a Theralase™ TLC-1000 system. As shown, the TLC-900 Multiple Laser Output laser probe has been attached to the controller.



Figure 4. TLC-1000 System and ease of setup

**TLC-154 Power Supply:**

Input Voltage / Current	100 - 240 VAC / 1.5 A, 50 to 60 Hz, 1 phase
Output Voltage / Current	+ 24 VDC / 2.7 A
Maximum Watts:	65 W
Safety Class	I

**TLC-1000 Optical Power Output:**

Each near infra-red (NIR) laser:

wavelength	905 nanometer (nm) +/- 10 nm
average power	0 to 100 mW (variable)
peak power	50.0 W (50,000 mW)
repetition rate	10.0 kHz (10,000 Hz)
beam divergence	10° x 30° (50% intensity)
pulse duration	200 nanoseconds
total number of NIR lasers	5

Total NIR laser power 0 – 500 mW

Each visible laser:

wavelength	660 nm +/- 10nm
beam divergence	8.5° x 22° (50% intensity)
average Power	25 mW (fixed)
total number of visible lasers	4

Total visible laser power 100 mW

**Compliances:**

North America	CAN/CSA C22.2 601.1-M90 (IEC601-1 2nd Ed. 1990), CAN/CSA C22.2 601.1S1-94, CAN/CSA C22.2 601.1B-98, CAN/CSA C22.2 No.60601-1-22-01 UL 60601-1 (1st Ed), IEC 60601-2-22-01
EMC/EMI	IEC 60601-1-2:2007 (Ed. 3.0)
Laser Safety	IEC-60825-1:2007 (2nd Ed.)
Global Quality Management	ISO-13485

**Equipment Classifications:**

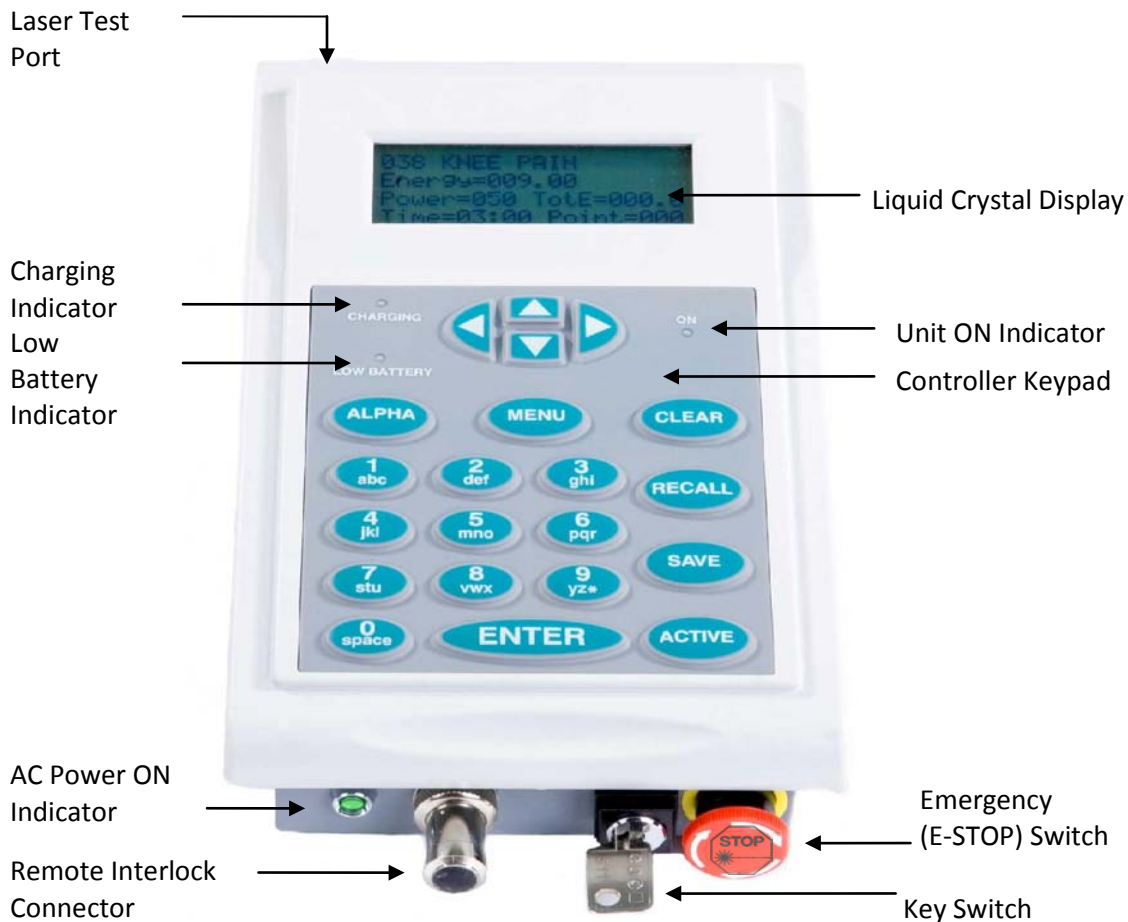
Laser Class	Class 3B medical laser
Risk Class	2G medical equipment
Electrical Shock Protection	BF
Water Protection	IPX0 (not water-tight)
EMC Class	A (commercial use)

**Physical Characteristics:**

Dimensions	23.3 cm x 13.4 cm x 8.8 cm
Weight	1.5 kg

**The Laser Controller (TLC-1000)**

The Theralase™ TLC-1000 laser controller is shown below. The Controller consists of a steel base with a fire retardant ABS plastic top. It has a soft touch rubber keypad and a 4 line backlight Liquid Crystal Display (LCD).



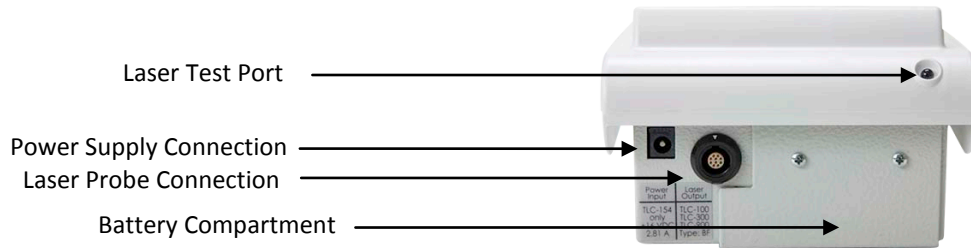
**Figure 5. The TLC-1000 Controller**

The Theralase™ TLC-1000 laser and all attachments are rated as Class 2G medical equipment, type BF and are equipped with Class 3B lasers.

Details regarding the safe use of the TLC-1000 controller and its accompanying accessories are detailed in section 2 and operation of the unit in sections 3 and 4.

The front of the unit has an emergency STOP button (red button with white arrows), a key switch for switching the unit off and being able to lock the unit from unauthorized use, an interlock switch and a green ON LED. A further detail of these items as well as their operation is detailed in section 2.

The TLC-1000 has a couple of detachable parts associated with it. These include the power supply and the laser diode probes.



**Figure 6. Controller's rear panel**

The following are the detachable parts for the TLC-1000:

- Power Supply:** TLC-154 Power Supply (+24 VDC, 2.7 A)
- Laser Probe:** TLC-100 Single Laser Probe, TLC-300 Triple Laser Probe and TLC-900 Multiple Laser Probe

**WARNING: PLEASE DISCONNECT POWER SUPPLY BEFORE SERVICING**

**The Power Supply (TLC-154) and Rechargeable Battery**

The TLC-154 is a universal power supply – the input voltage range is 100VAC to 240VAC, 50 to 60Hz, meaning that it can be safely used anywhere in the world. The TLC-154 power supply is able to power the TLC-1000 laser controller with or without a TLC-1001 built-in battery in place.



**Figure 7. TLC-154 Power Supply and associated Line Cord**

With the *proper* cord set the TLC-154 can be plugged in anywhere in the world. The cord set (TLC-155) supplied with your Theralase™ TLC-154 power supply is a hospital grade 115 to 120 VAC, 50 to 60 Hz approved cord set. This is built to a North American standard and was chosen to work in Canada and the United States.

Some of the key features of the TLC-154 Power Supply include

100-240 VAC Universal Input	Meets Safety Agency Requirements
In Case IEC320	Complies with EMC/EMI Regulations
Single Output up to 65 Watts	CE Compliant
Outputs Regulated with Low Ripple	Impact Resistant Polycarbonate Enclosure

The Nickel Metal Hydride (NiMH) batteries that are included in the Controller are medical grade, and rated in charge / discharge cycles (as are all other rechargeable batteries). This means that the more times you charge them (even partially), then their life expectancy is reduced.

These NiMH batteries can be charged / discharged approximately 300 times before they need to be replaced. Therefore, if they are discharged daily and recharged in the evening, they will last approximately 1 year and then need to be replaced.

In order to increase the lifespan of the battery to 2 to 3 years, a “smart” charging circuit has been included which will only allow the batteries to be recharged, if they are almost fully discharged, thus saving battery life by not allowing partial charging cycles.

The operating life of the battery is approximately 3 hours when driving a multiple probe at full power (100 mW). (5 times longer or 15 hours for the triple probe or single probe with controller). The red “Low Battery” light will illuminate when there is approximately 15 minutes of battery life left.

If you plug in the external power supply (after the red “Low Battery” light has come on) and switch on the Controller, the yellow “Charging” light will illuminate. The Controller will need to be plugged in for at least 6 hours to fully charge the battery (overnight, with key switch on). It is best to leave the controller plugged in for at least 6 hours to fully charge the battery. The yellow “Charging” light will extinguish when the battery is fully charged.

If you plug in the external power supply and the red “Low Battery” light has not come on, the yellow “Charging” light will not illuminate and the controller will need to be plugged in for approximately 100 hours to fully charge the battery (4 days). This is due to the fact that the battery will only be charged at a “trickle” charge rate.

**ATTENTION: The Controller must be switched on in order to charge the built-in battery pack.**

If you wish to know how much battery life is remaining, disconnect the external power supply (as this will give a false battery life reading), go to 05 Options on the menu and look for 12 Check Battery. (96% to 100% is fully charged – 3 hours of battery life left, 12% would be less than ½ hour of battery life).

If you leave the controller plugged in most days and need it only occasionally to treat patients on battery power, then you can simply plug it back in to the external power supply after the patient treatment and the trickle charge will recharge what little battery power they used.

If you use the controller on battery power constantly, it is best to continue to use it on battery power until the red “Low Battery” light comes on and then to leave the controller plugged in for at least 6 hours (overnight, with key switch on) to fully charge the battery. The yellow “Charging” light will extinguish when the battery is fully charged.

**CAUTION:**

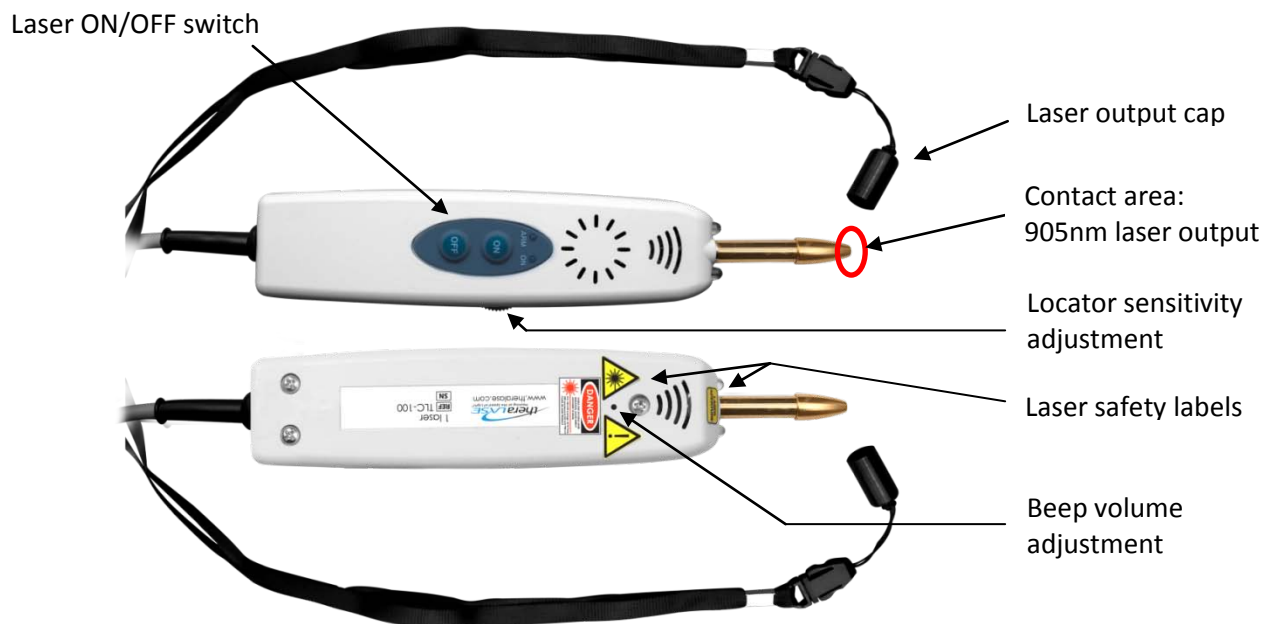
- Use only the TLC-154 power supply (+24 VDC, 2.7 A) to power the TLC-1000 laser controller. This is the only power supply approved to be used with the TLC-1000 laser controller.
- Outside of North America, the proper international cord set must be specified and purchased from Theralase™ Inc. or purchased separately for the country of preference.

**Laser Output Probes**

The TLC-1000 Laser Controller is designed to operate with **ONE** of the TLC-100 Single Laser Probe, the TLC-300 Triple Laser Probe or the TLC-900 Multiple Laser Probe.

***The Single Laser Probe (TLC-100)***

The Theralase TLC-100 single laser probe is illustrated below. It is hand held and ergonomic and comes with a flexible retractable cord which is attached to the back of the Laser Controller.



**Figure 8. Front and back view of the Single Laser Probe**

The output of the TLC-100 Single probe laser consists of:

- one (1) 905 nanometer (nm), invisible, near infrared (NIR), 0 to 100 mW average power laser diode.

The output of the probe, the laser, is a very fine beam and is invisible. Output can be tracked by using the sensor located at the top left hand corner of the Laser Controller. Please refer to Section 5 on Maintenance and Service and how to track the output power of the laser diodes.

**Locator Sensitivity Adjustment:**

Located on the side of the TLC-100 laser probe is a sensitivity thumbwheel which can be adjusted to assist in the location of acupuncture points. To utilize this feature the patient is required to wear the grounding wrist strap. For more information on the wrist strap, see the accessories section following this section. Please also note that the sensitivity of the system is patient dependent and so has to be set individually for each patient.

To calibrate the probe for a particular patient, first rotate the wheel all the way down (or to one end). The practitioner then places the laser probe tip on a **known** acupuncture point and adjusts the sensitivity of the probe until the laser probe just begins to “beep”. Next, alternate between this known acupuncture point and tissue areas void of known acupuncture points to set the sensitivity of the patient. Once properly set up, the laser probe should “beep” when an acupuncture point is detected versus tissue with no known acupuncture points.

**Beep Volume Adjustment:**

The TLC-100 has a volume adjustment control in order to be able to raise or lower the sound of the beep when used to locate acupuncture points. This is especially useful when trying to locate points along the ear, when some patients may be more tolerant of the beep level than others.

In order to be able to vary the loudness of the beep, you need to have a small flat screwdriver. The location of the volume control is illustrated in the above picture. Place the flat end of the screwdriver into the open slot and turn the screw a fraction clockwise (to raise the volume) or counter clockwise to lower the volume. Adjust until patient is comfortable with the beep level.

**Acupuncture Protocol:**

In the TLC-1000 Laser Controller, a specific acupuncture protocol – Protocol #57 has been set up and can be employed when using this probe.

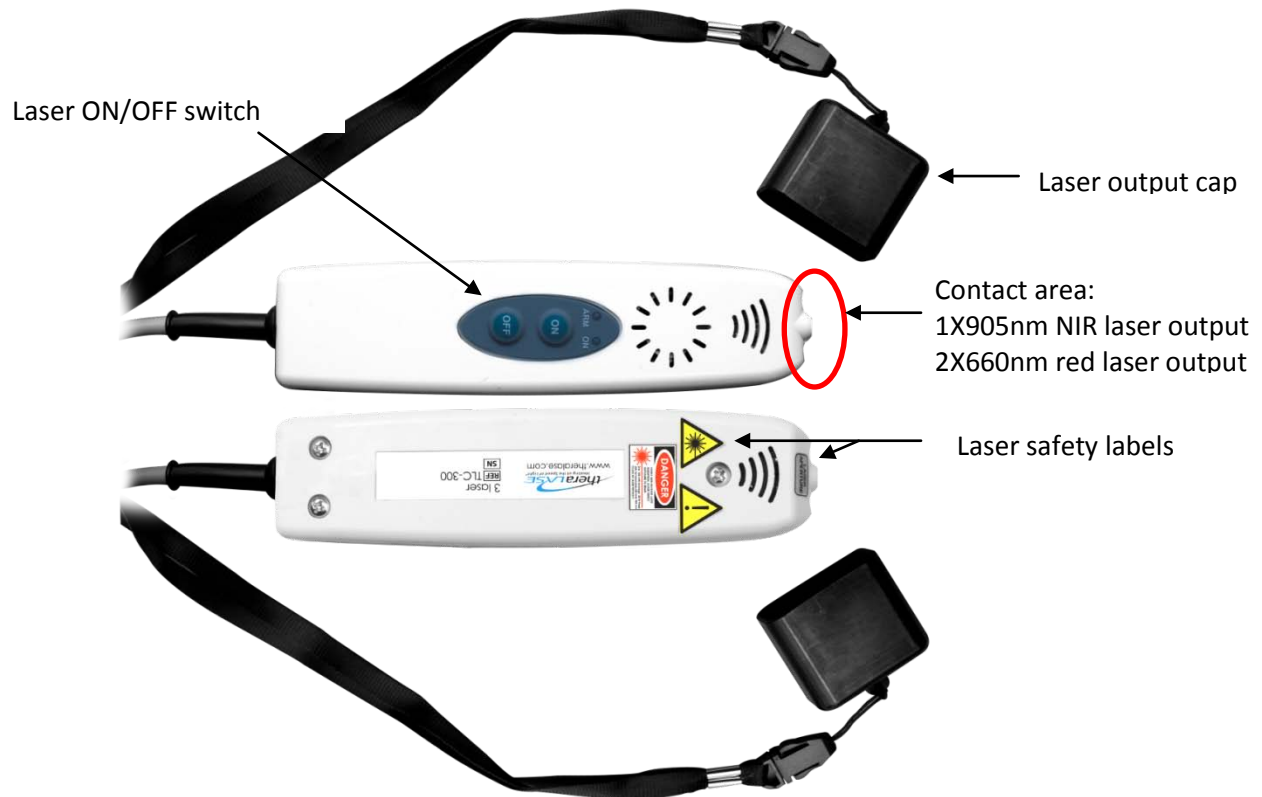
**CAUTION:**

- ***Please be careful when handling the gold tip of the TLC-100 probe. Although it is firmly locked into place, either dropping the probe on the tip or exerting too much force when applying it, can cause the tip to fracture and thus reduce the efficacy of the laser output.***
- ***Sensitivity of the laser probe acupuncture finder may need to be adjusted in different regions of the body. Sensitivity of the laser probe acupuncture finder will vary between patient, moisture content of the skin and humidity present in the treatment room.***
- ***Never point a laser device towards a person’s eyes under any circumstances.***



**The Triple Laser Probe (TLC-300)**

The Theralase TLC-300 Triple Laser Probe is highlighted below. Much like the single probe, it is also hand held and ergonomic and comes with a flexible retractable cord which is attached to the back of the Laser Controller. It is used in direct contact with tissue.



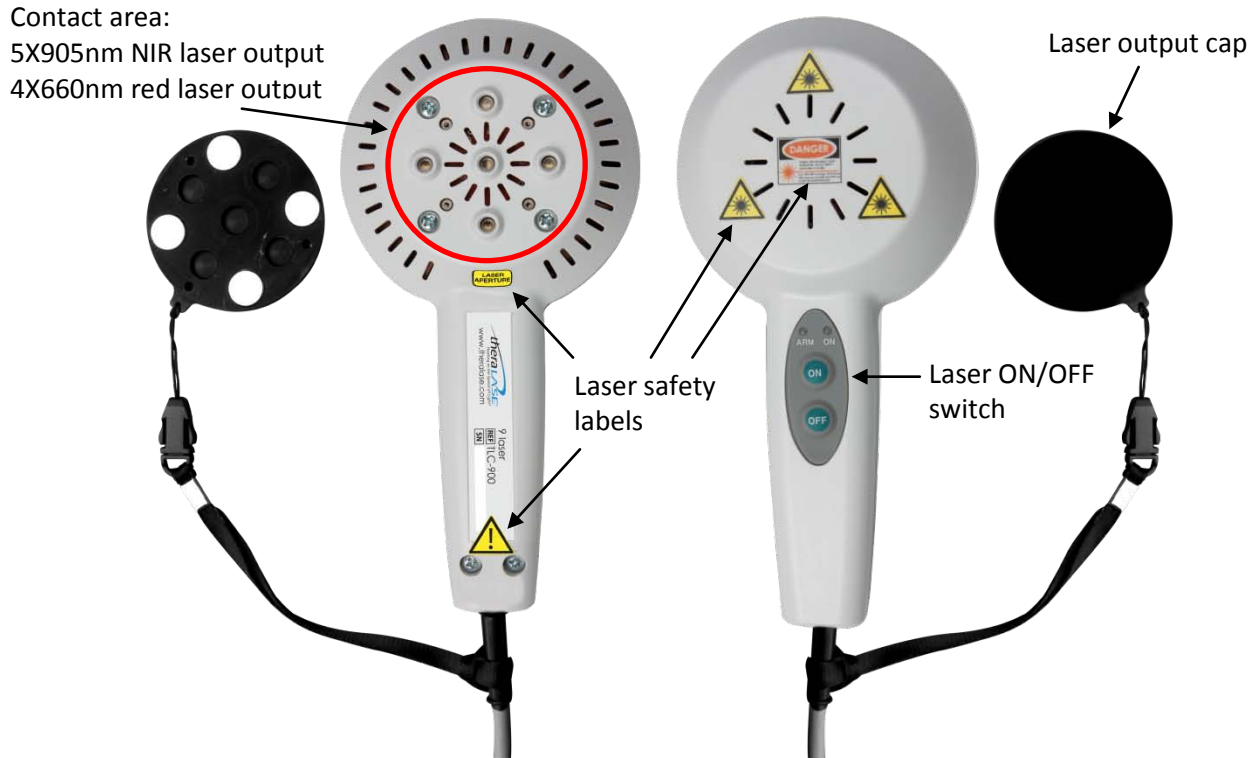
**Figure 9. Front and back view of the TLC-300 Triple Laser Probe**

The output of the TLC-300 Triple Probe Laser consists of:

- one (1) 905 nanometer (nm), invisible, near infrared (NIR), 0 to 100 mW average power laser diode;
- two (2) 660 nm, visible, red, 25 mW average power laser diodes.

***The Multiple Laser Probe (TLC-900)***

The Theralase TLC-900 Multiple Laser Probe is shown below. An additional feature of the multiple probe is the built-in fan that keeps the probe cool during use. This also means that the probe has to be used in such a manner to encourage free air flow around it. This would discourage placing the probe under gowns, towelings or clothing if it is not absolutely necessary.



**Figure 10. Front and back view of the multiple probe**

The output of the TLC-900 multiple laser probe consists of:

- five (5) 905 nm, invisible, Near Infrared (NIR), 0 to 100 mW average power laser diodes
- four (4) 660 nm, visible, red, 25 mW average power laser diodes

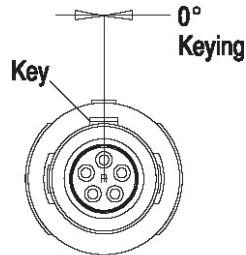
**CAUTION**

**Laser Output Cap is attached to the Probe by some very strong magnets. Be careful and do not put your fingers between the cap and the probe.**

## Connecting/Disconnecting the Laser Diode Probes and the TLC-1000

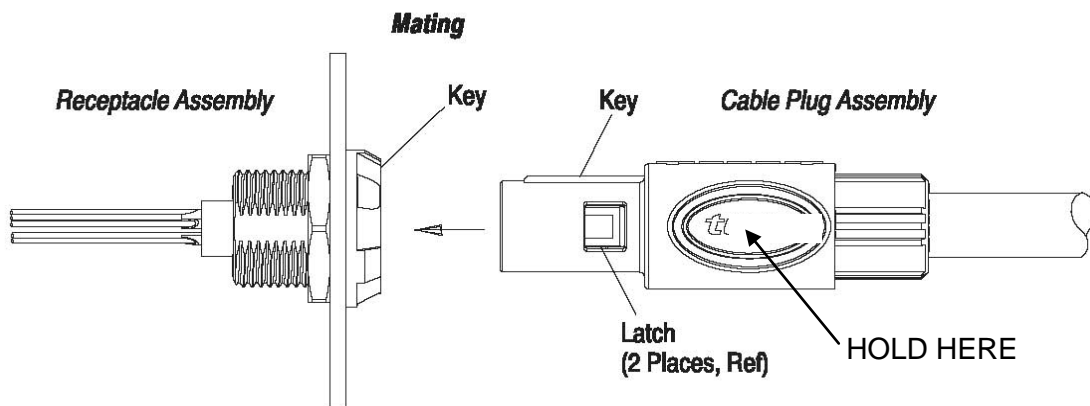
All the Laser Diode probes feature a very simple medical grade push-pull latch connector. This consists of a cable plug assembly on the probe end and a panel-mount receptacle assembly on the controller.

Assurance of proper mating is provided by keying. The key(s) of the cable plug assembly must align with the key of the receptacle assembly.



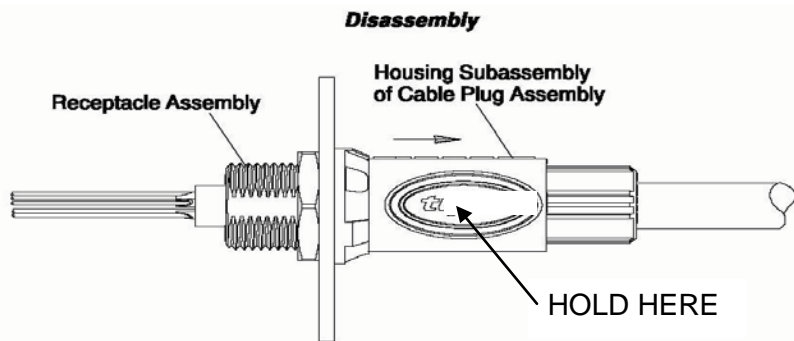
**Figure 11. Panel Mount Receptacle Assembly illustrating the key**

The cable plug assembly must be properly aligned with the receptacle assembly, and then inserted until the latches engage the receptacle assembly. There should be no need to force the connector into the receptacle. To ensure proper mating, there must be an audible “click”. Refer to Figure 12.



**Figure 12. Mating the Connectors – Cable Plug Assembly Key is aligned with Receptacle key**

The connectors must be unmated by gently pulling the housing subassembly away from the receptacle assembly – see Figure 13. PLEASE hold the main body and DO NOT pull the cable.



**Figure 13: Un-mating the connected assembly**

## Accessories

Accompanying the TLC-1000 system, in addition to the above main items, will be two sets of laser safety goggles and in some instances the locator cord and wrist strap.

### **Safety Eyewear:**

Two sets of laser safety goggles (part #: TLC-901) are supplied by Theralase as standard accessories. This laser safety goggle is provided for viewing of diffused laser light only because it can not attenuate the direct laser output to the eye-safe level, even though it offers the convenience of letting the user to see everything in the treatment room.

Another type of metallic laser safety eyewear, the i-Shield (part #: TLC-902), can be ordered from Theralase™ Inc. The i-Shield eyewear has a much higher light-blocking capability. However, it does not allow the user to see the surrounding environment. It is highly recommended that both the practitioner and the patient wear laser safety eyewear during laser therapy treatment.



**Figure 14. Theralase supplied Laser Safety Eyeweares**

Optical Density (OD) is the scientific term to describe a material's ability to block light of a certain wavelength. It is a logarithmic formula, where the higher the O.D. value, the better the material blocks light. For example, an O.D. of 1 means the material will allow 10% of the light through at a particular wavelength.

- An O.D. of 2 allows 1% of the light through
- An O.D. of 3 allows 0.1% of the light through
- An O.D. of 4 allows 0.01% of the light through
- An O.D. of 5 allows 0.001% of the light through
- An O.D. of 7 allows 0.00001% of the light through

Optical Density Ratings of the Theralase approved laser safety goggles TLC-901 are as follows:

- 1) 190-400 nm (ultraviolet range): 5+ O.D.
- 2) 660-670 nm (visible red): 2+ O.D.
- 3) 800-915 nm (near infrared): 3+ O.D.

Optical Density Ratings of the Theralase approved laser safety goggles TLC-902 are as follows:

190-10600 nm: 7+ O.D.

Theralase™ uses two wavelengths of diodes; specifically, 660 nm (25 mW average power) and 905 nm (100 mW average power) laser diodes.

Therefore, using the Theralase™ approved laser glasses may result in the following levels of light being transmitted to the eye (assuming of course that the laser diode is directly in contact with the laser glasses and pointed at the eyes on the individual's face):

For TLC-901 laser safety goggle,

- 1) 660 nm (visible red):  $25 \text{ mW} \times 1\% = 0.25 \text{ mW}$  (barely visible)
- 2) 905 nm (near infrared):  $100 \text{ mW} \times 0.1\% = 0.1 \text{ mW}$  (not visible and **NOT** eye safe)

For TLC-902 i-shield,

- 1) 660 nm (visible red):  $25 \text{ mW} \times 0.00001\% = 2.5 \text{ nW}$  (invisible)
- 2) 905 nm (near infrared):  $100 \text{ mW} \times 0.00001\% = 10 \text{ nW}$  (not visible and **NOT** eye safe)

**Caution:**

- *Use only Theralase™ Inc. supplied laser safety eyewear or laser safety eyewear that meets or surpasses the above noted optical densities at the above-specified wavelengths*
- **NEVER POINT A LASER TOWARDS A PERSON'S EYES UNDER ANY CIRCUMSTANCES**

***AcuPoint Locator and Patient Grounding Strap (TLC-156):***

AcuPoint locator and accompanying cord set with patient grounding strap is provided with the Single Probe (TLC-100). With this system the interlock connector is attached to a cord. As can be seen from the picture below, the cord is plugged in, much the same way that you would the remote interlock connector by itself.



**Figure 15. Wrist strap and connection to the TLC-1000 Laser Controller**

The AcuPoint Locator / patient grounding strap is placed on the patient's wrist and is part of a system used to assist in locating acupuncture points. See the section above on the TLC-100 Single probe for additional information on how to use the acupuncture system.

**Caution:**

- *Keep the Theralase acupuncture system away from other devices that may emit radiation or high frequency signals. The wrist strap and cord could behave like an antenna picking up these extraneous signals and disrupting the accuracy of locating acupuncture points on the body.*

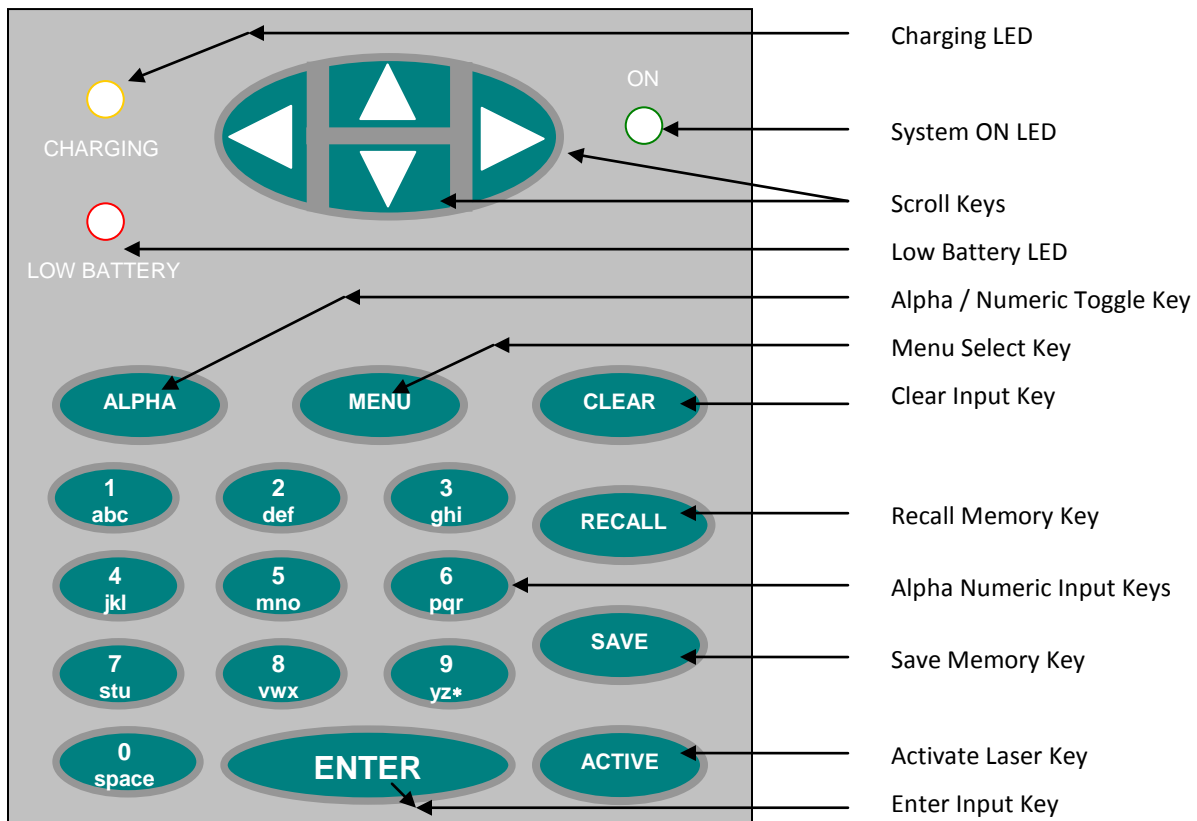


**Hard case for TLC-1000 system (part number: TLC-1200)**

### 3. Start-Up Information

#### The Basics

*The TLC-1000 Main Keypad*



**Figure 16. A detailed look at the Main Controller Keypad**

#### 1) Charging LED

Indicates that the battery is in charge mode when illuminated. The charging LED will illuminate only when the DC power adapter is plugged into the unit. The charging LED will shut off when the battery has been fully charged. The TLC-1000 incorporates a “smart” power supply that will recharge the battery only when required, thus preserving battery life.

#### 2) Low Battery LED

Indicates that the system’s internal battery is low and is in need of recharging via the DC power adapter. This warning light turns on shortly after CHECK BATTERY reads 0%. Once this indicator is activated, it will not turn off until the battery has been fully charged.

#### 3) ALPHA key

After the memory save key is pressed; this key can be used to toggle between numbers (0-9) and alphabetic characters (A-Z). Pressing the ALPHA key once and then pressing the “1” key will display an “a”, pressing twice a “b”, and three times

a “c”. After a one second delay, the cursor will automatically advance to the next character position.

- 4) **MENU key** Press this key to return to the main menu.
- 5) **Alphanumeric keys** These keys are used to input data into the laser system memory, either in the form of numerics (i.e.: 1, 2, 3, et cetera) or in the case of pressing the ALPHA key, alphabetic characters (i.e.: a, b, c, et cetera).
- 6) **Scroll keys** Scroll keys are used to scroll up, scroll down, scroll left or scroll right on the LCD display.
- 7) **ON LED** On LED illuminates when the main system power is on.
- 8) **CLEAR key** CLEAR key will clear or zero a variable on the LCD display. This key may also be used to return to the main menu if so desired.
- 9) **RECALL key** RECALL key initializes the memory recall feature of the TLC-1000 allowing access to programs stored in memory.
- 10) **SAVE key** SAVE key initializes the memory save feature allowing treatment protocols to be saved to memory.
- 11) **ACTIVE key** ACTIVE key provides power to the laser probe and prepares the laser for treatment.

**Caution: The flashing cursor must be in the lower right hand corner of the LCD screen in order to allow use of the ACTIVE key.**

After the ACTIVE key is pressed, ARM LED on the laser probe is on, and the cooling fan on Triple Probe and Multi Probe should be running. If the fan is not running, switch off the laser system immediately and send the unit for repair.

**Warning: Operating Triple Probe / Multi Probe without cooling fan running will damage the laser permanently!**

- 12) **ENTER key** Press this key to enter any data input on the LCD screen and / or to execute a program. This key can be used to go to the top of a file if the cursor remains at the bottom of the screen, for more information see Custom Setup mode.

*The TLC-1000 Front Panel*



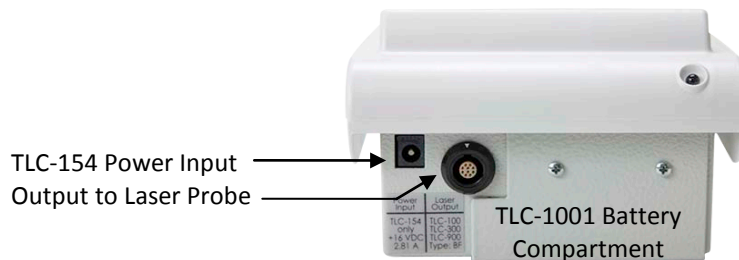
**Figure 17. Vertical front panel facing the user**

- 13) **AC Power ON LED** This green LED comes on when the Power Supply (TLC-154) is plugged into the unit.



- 14) Remote Interlock** This is the remote interlock connector capable of disconnecting the TLC-1000 controller from main power when not present. To remove, turn the knurled knob counter-clockwise until loose and pull the remote interlock connector straight out. Main power is now disabled and no action will restore it until the remote interlock connector is replaced. To replace, insert straight into the matching receptacle and turn the knurled ring clockwise until finger tight.
- 15) Emergency Stop** This button shuts down the entire laser system immediately when pressed.  
**Caution: Depress the Red Emergency Stop Button to disable the power and immediately disable the laser system. Operation may be resumed by rotating the Red Emergency Stop Button 1/4 of a turn to the right and allowing it to “pop out” again.**
- 16) Key Switch** This is the main on / off switch for the laser system. When the key is turned to the left, the system is off. When the key is turned ¼ turn to the right, the system is on.

**TLC-1000 Rear Panel:**



**Figure 18. Key elements of the rear panel**

- 17) Power Input** Input for black DC adapter cord. When the DC adapter is connected the laser system may be operated directly from an AC wall outlet and / or used to re-charge its internal battery.  
**Caution: Use only the TLC-154 power supply for the Theralase™ system.**
- 18) Laser Output** Universal laser output for connection to TLC-100 single probe, TLC-300 triple probe or TLC-900 multiple probe laser (High Density 10 pin medical grade connector)
- 19) Laser Test Port** The laser probe is placed inside this port to detect the real time output of the laser beam (displayed in milliwatts).  
**Note:** The laser test port only works on the 905nm laser diodes  
**Caution: Alignment of the laser diode to the internal photo detector is achieved by rotating and rocking the laser diode above the photo detector cavity. Keep**

the laser probe snug to this port for an accurate reading of the laser output. The highest value achievable is the true value.

## 20) Battery Door

Two screws secure the battery door, which houses the internal battery, which is a Nickel Metal Hydride Panasonic medical grade battery (Part Number: NIMH Battery).

**Note:** The section on maintenance and service details how this battery can be replaced by the user.

### Laser Diode Probe Keypad:

NOTE: All the laser diode probe models have the same probe keypad.

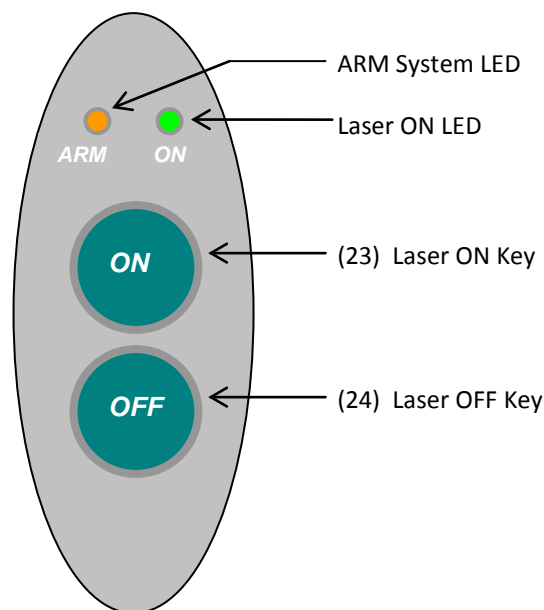


Figure 19. Laser Diode Probe Keypad

## 21) ARM LED

This LED is illuminated when the laser system is ready to commence treatments.

**Note:** It may only be illuminated by pressing the **ACTIVE** key, when the LCD display shows a valid treatment protocol and the flashing cursor is located in the bottom right hand of the LCD display.

## 22) ON LED

This LED is illuminated only when the laser beam is on and is activated by pressing the ON key.

**Note:** There must be a two (2) second time delay between pressing the **ACTIVE** key and the **ON** key. Pressing the **OFF** key will pause laser operation until re-commenced with the **ON** key. After completion of a treatment, the **ON** key can be used to repeat the treatment. **ARM** LED must be illuminated to commence laser operation.

## 23) Laser ON key

Pressing this key will commence laser operation.

24) Laser OFF key

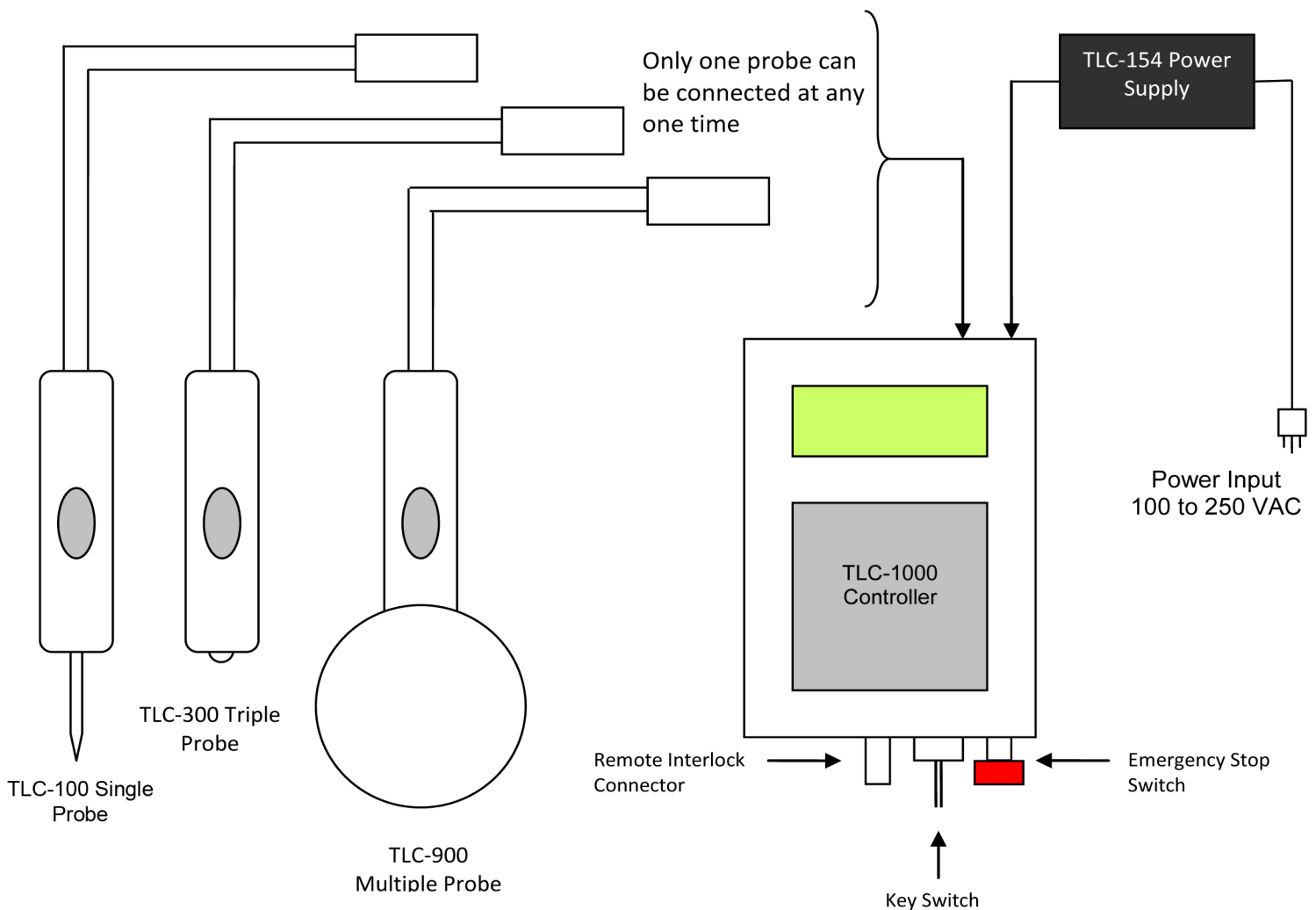
Pressing this key will stop the laser operation.

**Caution:** The laser operation is only temporarily halted when the OFF key is pressed as long as the ARM LED is still illuminated. To prevent accidental laser operation, press the MENU key or the CLEAR key to de-activate the laser system. The system is successfully disarmed if the ARM LED is not illuminated.

**Set-Up Procedure:**

Before setting up the system, please take a moment to fill out the checklist on the last page of the previous section. This is not only for your records but also quickly familiarizes you to all the parts of the system.

Set the TLC-1000 therapeutic laser on a steady surface and ensure the key switch is in the “off” position. Set-up the TLC-1000 therapeutic laser system as shown in the diagram below and read the following set of instructions **BEFORE** setting up the system.



**Figure 20. Outline of how the TLC-1000 system comes together**

1. Unpack the contents of the case and identify each of the pieces as outlined in the figure above.

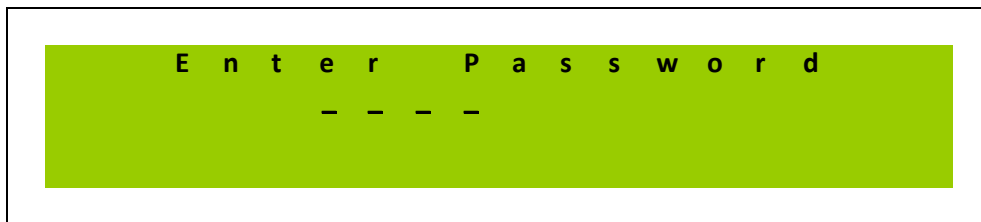
2. Connect the 120 VAC hospital grade line cord into the TLC-154 power supply (or approved Hospital Grade cord set for country of use) and then connect the TLC-154 power supply into the power input located at the rear of the laser system.

**NOTE:** On first power up, it is advisable to let the system charge overnight (or for at least 6 hours) to ensure that the battery pack is fully charged. It would be a good idea to connect the laser diode probe to the controller at this time.

3. Connect the Laser Diode Probe to the Controller by inserting the medical grade push-pull connector to mate with the receptacle in the panel. Detailed instructions on how to connect the laser diode probe to the controller is given in section 3.

**NOTE:** It would be advisable to connect the laser diode probe to the controller PRIOR to switching the controller ON.

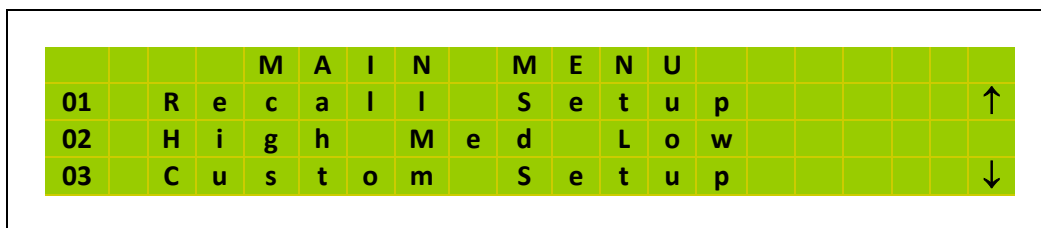
4. Start the controller by
  - a. Turning the E-STOP switch a quarter turn clockwise to release it
  - b. Inserting the remote interlock connector into it's receptacle on the front panel and screwing it firmly into place
  - c. Turning the Keyswitch a full 90° to the right
5. At this point the Controller should come on and the display should light up. The following screen should become visible within a couple of seconds.



6. Enter the initial security password "1234". The Controller should display a Main Menu Screen. At this time you could scroll through the menus and familiarize yourself with the menu and command system within the controller.
7. It is highly recommended that you put your safety glasses on at this time.

**NOTE:** Please make sure that the Laser Probe is pointed down or into the palm of the healthcare practitioner to avoid focusing the laser light into or in the direction of the practitioner's or patient's eyes.

8. Once the Controller is up and running you should be at the Main Menu Screen – which should look like the following.



**NOTE:** You have to scroll down the menu items to see the complete list.

9. Scroll down the list till you get to Item 5 or **OPTIONS** – select this item by pressing on the **ENTER** key on the keypad.

10. Scroll down the **OPTIONS** Menu to Item 11 – **TEST LASER**. Select this item again by pressing the **ENTER** key on the keypad.

				O	P	T	I	O	N	S					
09		V	i	e	w		U	s	a	g	e				↑
10		R	e	s	e	t		L		H	o	u	r	s	
11		T	e	s	t		L	a	s	e	r				↓

11. Press the **ACTIVE** key on the main keypad to Arm the Laser Probe. On the Laser Probe keypad there are two LEDs; one yellow and the other green. When the probe is activated the **ARM** LED will come on – indicating that the laser probe is now ready to be used. Please note at this time the probe is NOT emitting a laser – it is simply ready.
12. Switch the Laser on by pressing the **ON** switch on the Laser Probe keypad. For the probes with visible (660nm) laser diodes a visible red light will be seen. For the 905nm laser diodes, no light will be visible and the best way to tell if your laser is operational is to place it over the built in sensor on the top left hand corner of the Laser Controller.
13. At this time you should see a corresponding reading come up on the screen as shown below. This would be a good indication that the Laser is on and your system is now operational.

				T	E	S	T		L	A	S	E	R		
S	e	t		P	o	w	e	r	=	1	0	0	m	W	
A	c	t	u	a	l		P	w	r	=	1	0	2	m	W

**NOTE:** **Set Power** is the output power of the laser; **Actual Pwr** is measured value – tolerance of this reading is ±20%.

14. To switch the laser off, press the **OFF** key on the Laser Probe keypad. If for some reason this does not work, the laser can also be switched off by hitting any of the large Oval keys on the Main Controller Keypad. If uncertain you can always switch the system OFF by turning the Keyswitch to the OFF position.
15. For more advanced operation of the system please see Section 3 once you have completed this section.

## Stop Procedure

After the treatment has been completed, the laser may be turned off by either of the following means:

- 1) Press the **OFF** key on the laser probe to stop the laser output and allow the user to re-commence laser operation, by pressing the **ON** key.
- 2) Press the **MENU** or **CLEAR** key to stop laser operation and return the user to the Main Menu.

- 3) Press the **Red Emergency Stop Button** to stop laser operation and disable the main power to the laser system. Laser operation may only be re-commenced by turning the E-STOP switch a quarter turn clockwise to release it .
- 4) Turn the on / off power key switch to the left  $\frac{1}{4}$  turn to stop laser operation and to disable the main power to the laser system.

The key switch or remote interlock connector may now be removed if desired to disable the laser system from unauthorized operation.

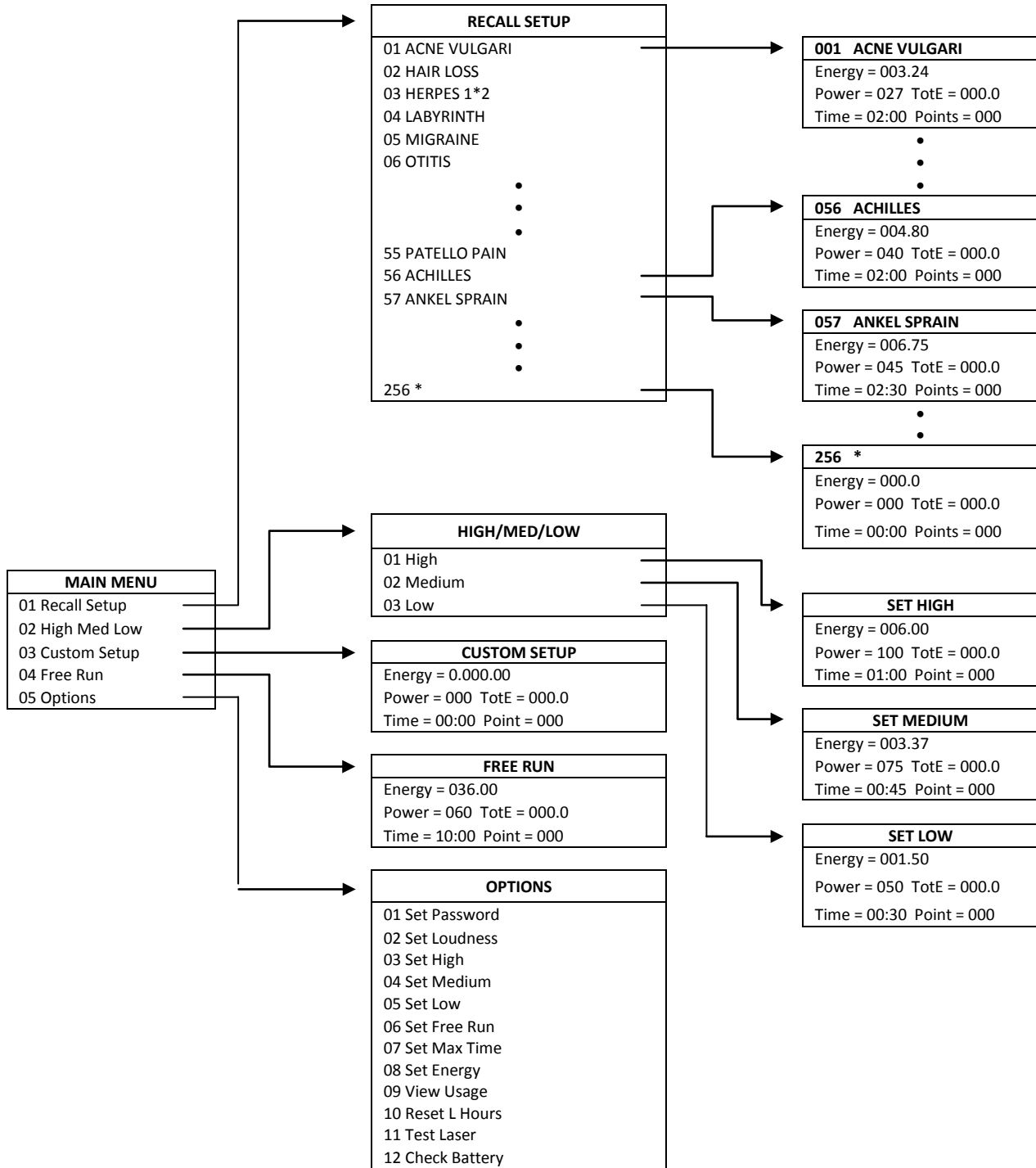
**Note:**

When the laser is emitting during a treatment, pressing any key on the main controller will discontinue laser output and place the laser system in a deactivated mode of operation. (See diagram on page 27)

Even if the key switch is left in the system and the remote interlock connector is in place, the security password must be known to enable laser operation; thereby, providing a 3 step security protocol to prohibit laser use by unauthorised personnel.

**Overview of the Menu**

The following is a map of the menu system. The TLC-1000 Controller menu system is extremely simple and very user friendly and this illustration can be used as a quick guide to where everything is located.



**Figure 21. Map of the TLC-1000 menu system**

### Laser Energy Dose Calculation

905 nm diode laser:

Peak power            50 W  
 Pulse duration        200 ns  
 Repetition rate       10 kHz

Average power        = Peak power X Pulse duration X Repetition rate  
 = 50.0 W x 200 x 10<sup>-9</sup> s x 10,000 Hz  
 = 0.1 W or 100 mW

660 nm diode laser:

Average power        25 mW

Thus, for each type of laser,

$$\text{Energy emitted (J)} = \text{Average power (W)} \times \text{Treatment time (s)} \times \text{Number of lasers} \quad (3-1)$$

and

$$\text{Treatment time (s)} = \frac{\text{Energy emitted (J)}}{\text{Average power (W)} \times \text{Number of lasers}} \quad (3-2)$$

In TLC-1000 system, the average power of the 905 nm lasers can be adjusted by user in the range of 0 to 100mW, while the power of the 660 nm lasers is fixed at 25 mW.

The following table shows the **energy dose (J)** for a *single* laser at different power settings and different treatment times:

		Power (mW)										
		100	90	80	70	60	50	40	30	25	20	10
Time (s)	1	0.1	0.09	0.08	0.07	0.06	0.05	0.04	0.03	0.025	0.02	0.01
	10	1.0	0.9	0.8	0.7	0.6	0.5	0.4	0.3	0.25	0.2	0.1
	20	2.0	1.8	1.6	1.4	1.2	1.0	0.8	0.6	0.5	0.4	0.2
	30	3.0	2.7	2.4	2.1	1.8	1.5	1.2	0.9	0.75	0.6	0.3
	40	4.0	3.6	3.2	2.8	2.4	2.0	1.6	1.2	1.0	0.8	0.4
	50	5.0	4.5	4.0	3.5	3.0	2.5	2.0	1.5	1.25	1.0	0.5
	60	6.0	5.4	4.8	4.2	3.6	3.0	2.4	1.8	1.5	1.2	0.6
	120	12.0	10.8	9.6	8.4	7.2	6.0	4.8	3.6	3.0	2.4	1.2
	180	18.0	16.2	14.4	12.6	10.8	9.0	7.2	5.4	4.5	3.6	1.8
	240	24.0	21.6	19.2	16.8	14.4	12.0	9.6	7.2	6.0	4.8	2.4
	300	30.0	27.0	24.0	21.0	18.0	15.0	12.0	9.0	7.5	6.0	3.0
600	60.0	54.0	48.0	42.0	36.0	30.0	24.0	18.0	15.0	12.0	6.0	



For example, when a Multiple Laser Probe is set at 80mW (905nm) and the treatment time is 1 minute, the total energy does is:

$$5 \times 4.8J + 4 \times 1.5J = 30J$$

## Transport

Remove the key from the main power switch and store in a safe location. Disassemble the laser system, carefully packing all components and taking special care with the laser probe assembly. In packing and unpacking the apparatus, be careful not to twist or kink the probe cable too sharply to prevent damage to the probe cable assembly. Ensure proper storage of the laser heads to avoid laser diode damage. If you damage your laser diodes, please notify Theralase™ Inc. immediately for service / replacement. The laser system should be kept within 0 to 40°C and 0 to 80% humidity during transport.

## Audible Tone

When the apparatus is in operating mode, an audible tone will be heard for every correct or incorrect input to the laser system. A correct response is indicated by an audible “click” and an incorrect response is indicated by a loud “beep”. The laser system will “beep” at the end of a treatment, for audible confirmation of the completion of the treatment. Volume of the audible tone is adjustable through the Options menu.

## 4. Advanced Operation

After following the Starting Procedure, the Main Menu appears allowing you to select from a set of options. The TLC-1000 has a user friendly menu system and by using the SCROLL and **ENTER** keys on the front keypad you can navigate through the entire menu. A quick reference map of the menu is outlined in the previous section.

### The Main Menu

				M	A	I	N		M	E	N	U							
01		R	e	c	a	l	l		S	e	t	u	p						↑
02		H	i	g	h		M	e	d		L	o	w						
03		C	u	s	t	o	m		S	e	t	u	p						↓

**Note:** You have to scroll down the menu items to see the complete list.

The main menu consists of five items as outlined below. Using the scroll keys, you can pick one of the items

- |                           |   |
|---------------------------|---|
| <b>01 Recall Setup</b>    | which allows selection of these pre-set treatment protocols |
| <b>02 High Medium Low</b> | which allows selection of these pre-set treatment protocols |
| <b>03 Custom Setup</b>    | allows custom programming of a specific treatment protocol  |
| <b>04 Free Run</b>        | allows the laser to run freely while incrementing time      |
| <b>05 Options</b>         | allows setting of the laser system preference options       |

Press **ENTER** to select. Alternatively, any of the above can be selected by simply keying in the number of the option (i.e.: pressing 02 selects the High/Medium/Low screen).

### 01 Recall Setup

Recalling a Memory Stored Treatment Protocol – Specific Conditions

By choosing **01 Recall Setup** at the Main Menu prompt, the memory stored treatment protocols are displayed allowing selection of a pre-set treatment protocol.

		R	E	C	A	L	L		S	E	T	U	P						
001		A	C	N	E		V	U	L	G	A	R	I						↑
002		H	A	I	R		L	O	S	S									
003		H	E	R	P	E	S												↓

Scroll to one of the pre-sets and press **ENTER** to select that treatment protocol.

**Note:**

The TLC-1000 comes with 162 pre-programmed treatment protocols. Each of these protocols is for a specific condition. In addition the controller is capable of storing up to 94 additional protocols **defined by the user** so that a number of treatment scenarios possibly even specific to individual patients can be set up. For example if treatment protocol **038 TENNIS/GOLF'S ELBOW** is selected this is the screen that will now come up:

0	3	8		T	E	N	N	I	S		E	L	B	O	W				
E	n	e	r	g	y	=	0	0	9	.	0	0							
P	o	w	e	r	=	0	6	0		T	o	t	E	=	0	0	0	.	0
T	i	m	e	=	0	2	:	3	0		P	o	i	n	t	=	0	0	0

Press the **ACTIVATE** key and then the **ON** key on the laser diode probe to commence laser operation.

As mentioned earlier, these are pre-programmed protocols, meaning they are programmed at the factory. These are the protocols developed for these specific conditions and are a baseline model. Based upon experience and practical results there may or may not be minor variations that one has to accommodate in the protocols to accommodate a wider variety of patient characteristics, such as, age, sex, obesity, pigmentation, etc. For a detailed listing of these pre-programmed protocols see Appendix D.

### **Setting up a Custom Treatment Protocol by Changing a Preprogrammed Treatment Protocol**

The following procedure enables modifications or adjustments to be made to both preprogrammed protocols. It is a good idea to skip down two pages to the Custom Setup section prior to reading these instructions. For the purposes of this example treatment protocol **031 FROZEN SHOULDER** has been used.

1. Go to the Main Menu or press the **MENU** button to return to this screen.
2. Go to **01 Recall Setup** and press **ENTER**.
3. Press arrow key down to desired protocol and press **ENTER**. If you know the protocol 3 digit identifier, you could enter this numeric identifier to go directly to the treatment protocol record.
4. The selected protocol screen now shows on the LCD display, with the blinking cursor positioned at POINTS=000 (bottom right hand corner).

0	3	1		F	R	O	Z	E	N		S	H							
E	n	e	r	g	y	=	0	1	1	.	7	0							
P	o	w	e	r	=	0	6	5		T	o	T	E	=	0	0	0	.	0
T	i	m	e	=	0	3	:	0	0		P	o	i	n	t	=	0	0	0

5. Press **ENTER**. The blinking cursor will now be positioned at the top of the LCD screen at **Energy = 011.70**.
6. Press **CLEAR** to clear the Energy values.
7. Use the down arrow key to scroll to the Power variable and enter the power desired in milliwatts (i.e.: for 75 milliwatts, press 075).

0	3	1		F	R	O	Z	E	N		S	H							
E	n	e	r	g	y	=	0	0	0	.	0	0							
P	o	w	e	r	=	0	7	5		T	o	t	E	=	0	0	0	.	0
T	i	m	e	=	0	3	:	0	0		P	o	i	n	t	=	0	0	0

8. The blinking cursor will now automatically advance to the Time variable once the three digits of the power variable number have been entered. Enter the desired time in minutes and seconds (i.e.: 03:00 equals 3 minutes 0 seconds). Once all four digits of the time variable have been entered, the blinking cursor will automatically advance to the top of the LCD screen to the **Energy** variable.

0	3	1		F	R	O	Z	E	N		S	H							
E	n	e	r	g	y	=	0	0	0	.	0	0							
P	o	w	e	r	=	0	7	5		T	o	t	E	=	0	0	0	.	0
T	i	m	e	=	0	5	:	3	0		P	o	i	n	t	=	0	0	0

9. Press **ENTER**. The system will now calculate the required Energy (in joules) and then display this value. The blinking cursor will then move to the bottom right hand corner of the screen.

0	3	1		F	R	O	Z	E	N		S	H							
E	n	e	r	g	y	=	0	2	4	.	7	5							
P	o	w	e	r	=	0	7	5		T	o	t	E	=	0	0	0	.	0
T	i	m	e	=	0	5	:	3	0		P	o	i	n	t	=	0	0	0

10. The blinking cursor should be at the bottom right hand corner of the screen before you can activate the probe. If it is, press the **ACTIVE** key to illuminate the **ARM** LED on the laser diode probe. Press the **ON** switch on the laser probe to commence laser operation. The treatment protocol is now in operation; however, it has not been saved to memory.

11. If desired, after treatment is completed - press the **SAVE** key to go to the **SAVE SETUP** screen.

		S	A	V	E	S	E	T	U	P									
001		A	C	N	E	V	U	L	G	A	R	I							↑
002		H	A	I	R	L	O	S	S										
003		H	E	R	P	E	S	1	*	2									↓

The blinking cursor will now be located at the first entry on the list. The list comprises both pre-programmed protocols as well as any user specific protocols that have been programmed and saved.



## 02 High Medium Low

Recalling a Memory Stored Treatment Protocol – Generic Conditions

By choosing **02 High Medium Low** at the Main Menu prompt, the generic treatment protocols will be displayed.

				H	I	G	H	/	M	E	D	/	L	O	W				
01		H	i	g	h														
02		M	e	d	i	u	m												
03		L	o	w															

You may now select either, **01 High**, **02 Medium** or **03 Low**. Selecting one of these will display their respective treatment protocols – the **02 Medium** protocol is shown below.

		S	E	T		M	E	D	I	U	M								
E	n	e	r	g	y	=	0	0	3	.	3	7							
P	o	w	e	r	=	0	7	5		T	o	t	E	=	0	0	0	.	0
T	i	m	e	=	0	0	:	4	5		P	o	i	n	t	=	0	0	0

Press the **ACTIVE** key and then the **ON** key on the laser diode probe to commence laser operation.

### *Changing the Generic Conditions*

The Power or the Time variables of the generic treatment can only be changed through the **OPTIONS** menu. Scroll down the MAIN MENU until you come to the **OPTIONS** sub menu. More details about how to change these variables are listed under **03 SET HIGH**, **04 SET MEDIUM** and **05 SET LOW** in the **OPTIONS** sub menu.

### 03 Custom Setup

Setting up a Custom Treatment Protocol

Choosing **03 Custom Setup** allows programming of a specific treatment protocol. This can be for one time use or can be saved and reused. It can be treatment specific or you can save it explicitly with a particular patient's name for easy reference and recall at a later time.

Please keep in mind that the TLC-1000 comes with 162 pre-programmed treatment protocols and has space to be able to save an additional 94 protocols.

When you press **03 Custom Setup** the following screen will come into view

		S	E	T		C	U	S	T	O	M								
E	n	e	r	g	y	=	0	0	0	.	0	0							
P	o	w	e	r	=	0	0	0		T	o	t	E	=	0	0	0	.	0
T	i	m	e	=	0	0	:	0	0		P	o	i	n	t	=	0	0	0

All of the variables should be zeroed out – a blank protocol screen and a blinking cursor should be positioned on the first row at **000.00**.

1. To set the required power - Press the arrow down key once and with the blinking cursor now at **Power=000**, enter the required mW (i.e.: 060 represents 60 mW). Once completed the blinking cursor will automatically jump to the Time variable.
2. To set required time, with the blinking cursor now at **Time=00:00**, enter the required time (i.e. 02:30 represents 2 minutes 30 seconds). Please enter all four digits.
3. The blinking cursor will now return to the top of the LCD screen at **Energy=000.00**

		S	E	T		C	U	S	T	O	M								
E	n	e	r	g	y	=	0	0	0	.	0	0							
P	o	w	e	r	=	0	6	0		T	o	t	E	=	0	0	0	.	0
T	i	m	e	=	0	2	:	3	0		P	o	i	n	t	=	0	0	0

4. After the blinking cursor moves to the top row, press **ENTER**. The laser controller system will automatically calculate the joules of energy. The blinking cursor will now jump to the bottom right hand corner of the screen indicating that it is done with the calculations.
5. At this point, press **SAVE** and the following screen will appear. The blinking cursor will now be located at the first entry on the list. The list comprises both pre-programmed protocols as well as any user specific protocols that have been programmed and saved.

		S	A	V	E		S	E	T	U	P								
001		A	C	N	E		V	U	L	G	A	R	I						↑
002		H	A	I	R		L	O	S	S									
003		H	E	R	P	E	S		1	*	2								↓





It is good practice to keep a written record of all new protocols. In the Clinical section of this manual, details of the pre-programmed protocols are outlined. In addition there is a blank “template” protocol. You may want to make a few copies of this and use it to record your new protocols.

#### 04 Free Run

Manual or Continuous Run of the Laser

Choosing **04 Free Run** displays the **Free Run** screen which allows continuous laser operation after the **ACTIVE** key and the **ON** key on the laser probe are pressed. The following are the default parameters.

		S	E	T		F	R	E	E											
E	n	e	r	g	y	=	0	3	6	.	0	0								
P	o	w	e	r		=	0	6	0		T	o	t	E	=	0	0	0	.	0
T	i	m	e		=	1	0	:	0	0		P	o	i	n	t	=	0	0	0

The default parameters cannot be changed at this screen but only through the **OPTIONS** menu. As such it will be necessary to skip forward to the relevant sections in the **OPTIONS** menu (which follows further down) to be able to make these changes. There are two variables that can be changed, the Power and the Treatment Time.

- Select **06 Set Free Run** in order to set the power level of your Free-Run pre-set. Enter the power level desired.

			S	E	T		F	R	E	E			R	U	N					
			P	o	w	e	r		=	0	6	0								
			P	u	l	s	e		=	0										

The blinking cursor will be at the Power setting. Change this to whatever value that you want. When you are done the screen will default back to the **OPTIONS** sub menu listing. At this time if you go back to the **MAIN MENU** and access **04 FREE RUN** and check the settings, you should see that the power settings will have changed to the ones you had made in the **SET FREE RUN** screen.

**Note:** Enter 075 for 75 milliwatts, 047 for 47 milliwatts, et cetera.

Select **07 Set Max Time** in order to set the maximum time the TLC-1000 laser system is allowed to operate per treatment location prior to stopping. Enter time in minutes and then seconds.

			S	E	T		M	A	X		T	I	M	E						
M	a	x		T	i	m	e		=	1	0	:	0	0						

The blinking cursor will be at the timer setting. Change this to whatever value that you want. When you are done the screen will default back to the **OPTIONS** sub menu listing. At this time if you go back to the **MAIN MENU** and access **04 FREE RUN** and check the settings, you should see that the timer settings will have changed to the ones you had made in the **SET MAX TIME** screen.

**Note:** 02:25 would be equal to 2 minutes, 25 seconds.

## 05 Options

Change of settings

From the Main Menu, select **05 Options** and press **ENTER**. The Options menu is now shown on the LCD display.

### 1. Set Security Password

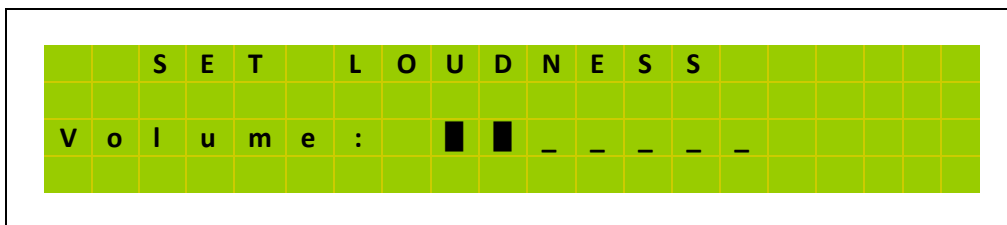
Select **01 Set Password** to modify your system user password. Follow the system prompts, key in the new password. The system will ask you to verify your new password. Input the new password again for verification.

#### Caution:

- Once you enter this screen you will not be allowed to go back until the password is changed. You may reuse the same password if you find yourself in this predicament but do not wish to change the password.
- Set your password to a 4 digit sequence you will remember, once the password has been changed access will be denied if you forget your password.

### 2. Changing the Audible Tone of the System

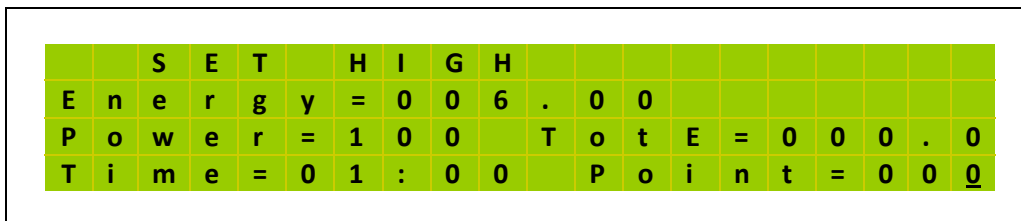
Select **02 Set Loudness** to change the volume of the system's audible tone.



Use the left scroll and right scroll keys to adjust the volume to the desired level and press **ENTER**.

### 3. Changing the Generic Protocol Setting – High

Select **03 Set High** to set the High pre-set of the laser system.



1. Press **Enter** to move the cursor to the top of the screen. Use the **CLEAR** key to clear the contents of the ENERGY variable
2. Next, scroll down to the power variable and set the desired power level followed by the desired time. Please note that for power entry is in mW (i.e.: 060 represents 60 mW) and for time it is in seconds (i.e.: 0230 represents 2 minutes 30 seconds). Please enter all four digits.
3. Press **ENTER** to display the Energy or Energy Density of the treatment protocol.
4. Press **SAVE**, to store your selection. The word **SAVED** will be displayed when data is properly stored.

**4. Changing the Generic Protocol Setting – Medium**

Select **04 Set Medium** to set the Medium pre-set of the laser system.

		S	E	T		M	E	D	I	U	M								
E	n	e	r	g	y	=	0	0	3	.	3	7							
P	o	w	e	r	=	0	7	5		T	o	t	E	=	0	0	0	.	0
T	i	m	e	=	0	0	:	4	5		P	o	i	n	t	=	0	0	<u>0</u>

The procedure is identical to the one above for setting HIGH. Make the changes as required and SAVE the setting.

**5. Changing the Generic Protocol Setting – Low**

Select **05 Set Low** to set the Low pre-set of the laser system.

		S	E	T		L	O	W											
E	n	e	r	g	y	=	0	0	1	.	5	0							
P	o	w	e	r	=	0	5	0		T	o	t	E	=	0	0	0	.	0
T	i	m	e	=	0	0	:	3	0		P	o	i	n	t	=	0	0	<u>0</u>

The procedure is identical to the one above for setting HIGH. Make the changes as required and SAVE the setting.

**6. Setting the Power Level of the Free Run Generic Protocol**

Select **06 Set Free Run** in order to set the power level of your Free-Run pre-set. Enter the power level desired.

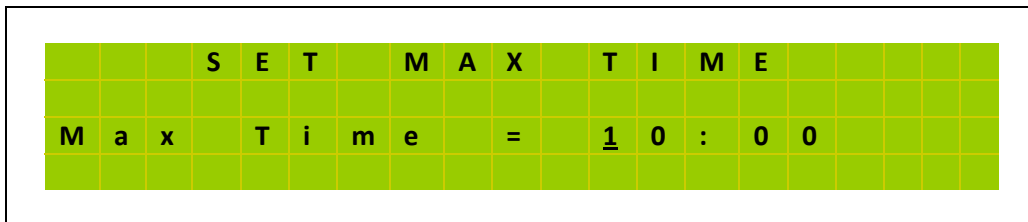
		S	E	T		F	R	E	E		R	U	N						
		P	o	w	e	r	=	<u>0</u>	6	0									
		P	u	l	s	e	=	0											

The blinking cursor will be at the **Power** setting. Change this to whatever value that you want. When you are done the screen will default back to the **OPTIONS** sub menu listing. At this time if you go back to the MAIN MENU and access **04 FREE RUN** and check the settings, you should see that the power settings will have changed to the ones you had made in the SET FREE RUN screen.

**Note:** Enter 075 for 75 milliwatts, 047 for 47 milliwatts, et cetera.

### 7. Setting the Maximum Time of Treatment per Location

Select **07 Set Max Time** in order to set the maximum time the TLC-1000 laser system is allowed to operate per treatment location prior to stopping. Enter time in minutes and then seconds

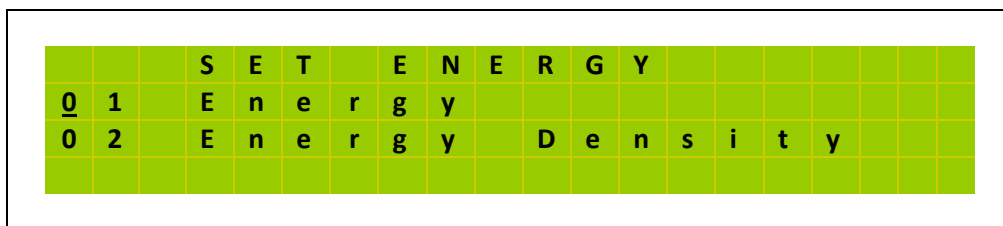


The blinking cursor will be at the timer setting. Change this to whatever value that you want. When you are done the screen will default back to the **OPTIONS** sub menu listing. At this time if you go back to the MAIN MENU and access **04 FREE RUN** and check the settings, you should see that the timer settings will have changed to the ones you had made in the **SET MAX TIME** screen.

**Note:** 02:25 would be equal to 2 minutes, 25 seconds.

### 8. Change Energy Display

Select **08 Set Energy** to modify the LCD display and choose between displayed Energy or displayed Energy Density. Use the scroll keys to select either **01 Energy** or **02 Energy Density**. Press **ENTER** to input your selection.



Next time you enter your treatment protocol screen you will notice the changed setting for Energy/Energy Density.

**9. View Laser and System Usage Hours**

Select **09 View Usage** to view the Laser Hours and Total Hours of laser usage. Laser Hours is an indication of the use of the laser system since this value was last zeroed. (This is useful for determining the amount of usage of the laser system per healthcare practitioner).

Total Hours represents the total hours of usage that the lasers have been used over their lifetime or since new replacement. (This is useful for determining remaining laser diode life expectancy).

			V	I	E	W		U	S	A	G	E							
L	a	s	e	r		H	r	s	=	0	0	0	0	.	3	0			
T	o	t	a	l		H	r	s	=	0	1	0	0	.	0	0			

**10. Resetting Laser Hour Usage**

Select **10 Reset L Hours** to reset the Laser Hours to zero.

**Note:**

- Total Hours are not able to be zeroed by the healthcare practitioner.

**11. Testing the Laser Diode Probe**

Select **11 Test Laser** to test the laser.

- 1) Press the **ACTIVATE** key on the main keypad to Arm the Laser Probe. On the Laser Probe keypad there are two LEDs; one yellow and the other green. When the probe is activated the **ARM** LED will come on – indicating that the laser probe is now ready to be used. Please note at this time the probe is NOT emitting a laser – it is simply ready.
- 2) Switch the Laser on by depressing the **ON** switch on the Laser Probe keypad. For the probes with visible (660nm) laser diodes a visible red light will be seen. For the 905nm laser diodes, no light will be visible and the best way to tell if your laser is operational is to place it over the built in sensor on the top left hand corner of the Laser Controller.
- 3) At this time you should see a corresponding reading come up on the screen as shown below. This would be a good indication that the Laser is on and your system is now operational.

				T	E	S	T		L	A	S	E	R						
S	e	t		P	o	w	e	r	=	1	0	0	m	W					
A	c	t	u	a	l		P	w	r	=	1	0	2	m	W				

**Note:** Set Power is the output power of the laser; actual power is measured value – tolerance of this reading is  $\pm 20\%$

- 4) Record the value of the actual power of the laser diode on the map created earlier. Repeat for all the laser diodes of the probe under test and record all the values. Please note that the sensor only works for the 905nm laser diode output.
- 5) To switch the laser off, depress the **OFF** key on the Laser Probe keypad. If for some reason this does not work, the laser can also be switched off by hitting any of the large Oval keys on the Main Controller Keypad. If uncertain you can always switch the system OFF by turning the key switch to the OFF position.

**Caution:**

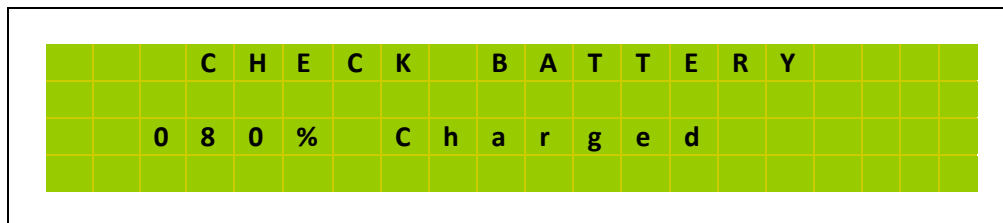
Place laser safety eyewear on for this procedure.

**Note:**

- Rotation of the laser diode and keeping it perpendicular relative to the photo detector must be achieved in order to obtain the maximum output possible. This is the true laser output.
- Laser diodes should be calibrated when they are displaying  $\pm 20\%$  of their rated output.
- Laser diodes should be replaced when they are displaying  $\pm 50\%$  of their rated output.

**12. Checking the Charge Level of the Battery**

Select **12 Check Battery** to determine the battery life remaining. This is merely a display screen and the value shown will indicate the level of charge available in the battery, very much like the fuel gauge in an automobile.



Due to the drain characteristics of this medical battery 100% is at or near full charge, while 0-5% is almost fully discharged.

When the battery is close to being fully discharged the red **LOW BATTERY** LED on the front panel will come ON. This indicates that the unit should be plugged in to the AC Mains for the battery to be recharged. When plugged in to the wall the **CHARGING** LED will now come on to indicate that the battery is now being recharged.

**Note:**

- When the unit is plugged in, but has not reached the **LOW BATTERY** level, it will recharge automatically. For example, say the battery is at 53% and the unit is now plugged in to the AC Mains, the battery will begin to recharge. In this condition the **CHARGING** LED will NOT come on –

charging is accomplished in the background. If unsure, let the unit charge for a few minutes and if everything is working to order, you will see that the charging value will go up.

- When completely discharged, the unit will need to be plugged in to the AC Mains for between 4 to 6 hours for the battery to be completely charged again. Hence, probably a good idea to do it at the end of the work day.
- If the unit is used off the battery, it is advisable to plug the system in to the AC Mains at the end of the day. The unit will then recharge itself completely and be ready for use at the beginning of the next work day.



## 5. Maintenance and Service

This section deals with maintenance and serviceability of the Theralase™ system by the end user. If further detailed service of your laser system is required, contact Theralase Inc directly for assistance. Detailed contact information is supplied at the end of this section.

### Inspection and Cleaning

#### *Weekly*

Follow the stop procedure in the basic operation section of this manual. Remove the key from the main controller. Disconnect the laser probe and power input to the main controller. Carefully clean the TLC-100 Single Laser Probe, the TLC-300 Triple Laser Probe and/or the TLC-900 Multiple Laser Probe with isopropyl alcohol swabs being careful not to immerse the laser probe heads. Rotate the swab in the laser aperture carefully to avoid damaging the laser diode.

#### *Monthly*

Follow the stop procedure in the basic operation section of this manual. Remove the key from the main controller. Disconnect the laser probe and power input to the main controller. Inspect the laser diodes for cracks or chips in the glass. A visible chip in the glass, a crack in the glass or a missing glass mandates replacement of the laser diode. Contact Theralase immediately for replacement of the defective / damaged laser diode.

**Check the optical output of each laser diode according to the procedure below to ensure laser diode optical output at least once per month.**

### Preventive Maintenance Schedule

In addition to performing the monthly inspection for physical problems associated with the diodes, it is also important to check the efficacy of each of the laser diode outputs. Laser diodes typically wear or drop in average power as the total usage hours of the system increases. The real time laser power indicator is used as a reference for when the laser diodes should be calibrated / replaced.

#### **Note:**

The TLC-1000 therapeutic laser system may only be calibrated by Theralase Inc. or trained personnel equipped with the proper service equipment. Laser diode recalibration is highly recommended when the average power output of the laser diode under test is +/-20% of its nominal rated value. The manufacturer mandates laser diode replacement when the average power output of the laser diode is +/- 50% of its nominal rated value. (i.e.: 100mw laser diode should be replaced if it reads 50mw or less)

### How to check the output power of the laser diodes in the probes

Please make sure the Laser Probe that you want to test is plugged in to the Laser Controller. Switch the system ON if it is not already running. Key in your password and the Main Menu screen should come up. If the system is already ON, navigate back to the Main Menu screen – if uncertain press on the MENU key a couple of times and when the screen stops changing you should be back to the root menu – also known as the Main Menu. Prior to starting the test, identify the laser diodes on the probe and record the location and the type of diodes (660nm or 905nm) – a simple map if you will. Follow the procedure below to test the laser diodes.

1. Once the Controller is up and running you should be at the Main Menu Screen – which should look like the following.

				M	A	I	N	M	E	N	U				
01	R	e	c	a	i	l	S	e	t	u	p				↑
02	H	i	g	h	M	e	d	L	o	w					
03	C	u	s	t	o	m	S	e	t	u	p				↓

**Note:** You have to scroll down the menu items to see the complete list.

2. Scroll down the list till you get to Item 5 or **OPTIONS** – select this item by pressing on the **ENTER** key on the keypad.
3. Scroll down the **OPTIONS** Menu to Item **11 – TEST LASER**. Select this item again by depressing the **ENTER** key on the keypad.

				O	P	T	I	O	N	S					
09	V	i	e	w	U	s	a	g	e						↑
10	R	e	s	e	t	L	H	o	u	r	s				
<u>11</u>	T	e	s	t	L	a	s	e	r						↓

4. Press the **ACTIVATE** key on the main keypad to Arm the Laser Probe. On the Laser Probe keypad there are two LEDs; one yellow and the other green. When the probe is activated the **ARM** LED will come on – indicating that the laser probe is now ready to be used. Please note at this time the probe is NOT emitting a laser – it is simply ready.
5. Switch the Laser on by depressing the **ON** switch on the Laser Probe keypad. For the probes with visible (660nm) laser diodes a visible red light will be seen. For the 905nm laser diodes, no light will be visible and the best way to tell if your laser is operational is to place it over the built in sensor on the top left hand corner of the Laser Controller.
6. At this time you should see a corresponding reading come up on the screen as shown below. This would be a good indication that the Laser is on and your system is now operational.

				T	E	S	T	L	A	S	E	R			
S	e	t	P	o	w	e	r	=	1	0	0	m	W		
A	c	t	u	a	l	P	w	r	=	1	0	2	m	W	

**Note:** **Set Power** is the output power of the laser; **Actual Pwr** is measured value – tolerance of this reading is  $\pm 20\%$ .

7. Record the value of the actual power of the laser diode on the map created earlier. Repeat for all the laser diodes of the probe under test and record all the values. Please note that the sensor only works for the 905nm laser diode output.
8. To switch the laser off, depress the **OFF** key on the Laser Probe keypad. If for some reason this does not work, the laser can also be switched off by hitting any of the large Oval keys on the Main Controller Keypad. If uncertain you can always switch the system OFF by turning the key switch to the OFF position.

**Caution:**

***Calibration must only be performed by Theralase™ Inc. or by trained personnel possessing the proper knowledge and test equipment. Contact Theralase™ Inc., if after testing, it is deemed that recalibration of the laser diodes is required.***

### **Calibration of the Real-Time Near Infrared (NIR) Detector**

Calibration of the real-time NIR detector is not a process that can be easily performed in the field. Although it is a matter of simply adjusting a “screw-type” item (resistor) inside the unit, it does mean having to take the unit apart to get to it.

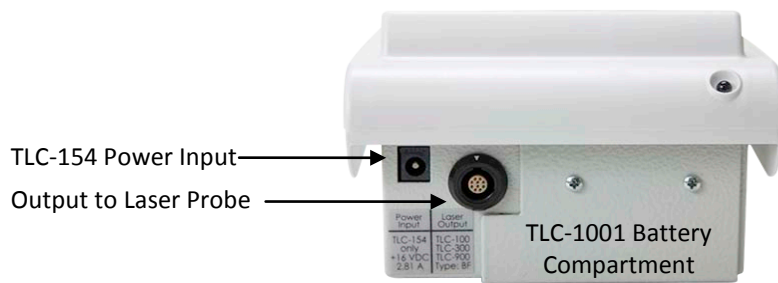
The NIR detector is used to determine the output value of the diodes. Thus it is difficult to say if the NIR detector requires calibration or whether the diodes require calibration or replacement. In any event, if such a situation does arise, it is recommended to call Theralase Customer Support for detailed instructions on how to deal with this condition.

### **Service of Laser Diodes**

The TLC-1000 therapeutic medical laser system contains no user serviceable parts, except for laser diodes and switches. If laser diodes are no longer able to be calibrated and / or exhibit greater than + / - 50% variation from nominal output power, contact the factory for replacement laser diodes.

### **Servicing the Battery**

As mentioned earlier, the Theralase™ TLC-1000 is equipped with an internal battery. The battery is a Nickel Metal Hydride, Panasonic medical grade battery (Part Number: TLC-165). This battery must be ordered directly from Theralase™ Inc.



**Figure 22. Location of the battery compartment for the TLC-1000**

All rechargeable batteries have a limited lifespan. If the battery is used a lot, over the course of a couple of years it will hold less and less charge. There will come a point when the battery will hold insufficient charge to be expected to reliably complete a treatment. When the battery has little or no charge in it, the unit will indicate this situation by lighting up the **Low Battery** LED (red colour) on the front panel of the Laser Controller. Further charging will not eliminate this condition. At this time the user has three options

- I. The Laser Controller and associated Probes will work completely normally with the AC Power cord plugged in to the Controller. That is, the unit is no longer portable. In fact, this would be the preferred method of use if it is unnecessary to move the TLC-1000 Laser Controller.
- II. Contact Theralase customer service and arrange to have your unit sent in to have the battery upgraded to a new one.
- III. Alternatively, you could call Theralase customer service and request to have a Nickel Metal Hydride Panasonic medical grade battery (Part Number: TLC-165) sent to you. If so, follow the procedure below to change the battery in your system.

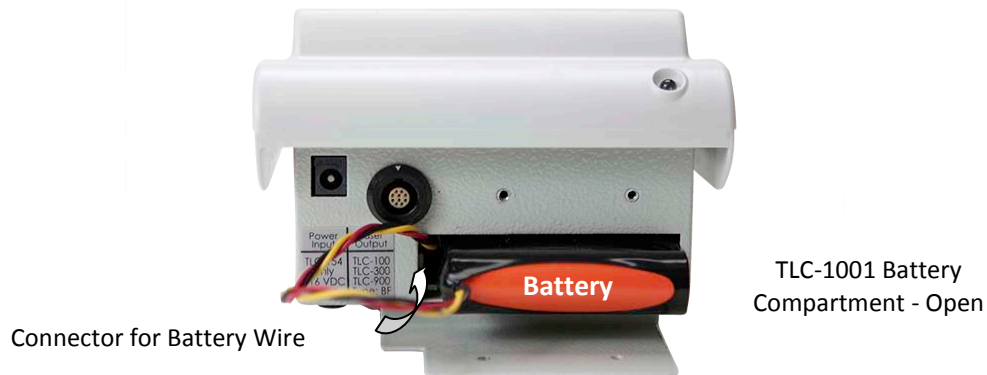
It is recommended that in order to increase battery life, once a month, allow the laser system to run on battery power only until battery discharges (i.e.: **Low Battery** Warning – red LED). Reconnect the power supply and allow battery to fully charge again. (i.e.: **Charging** – Yellow LED on and then it turns off when fully charged)

### ***Replacing the Battery in the TLC-1000 Laser Controller***

**Battery Removal:** (Tools required: ¼” slot screwdriver, Philips #1 screwdriver)

1. At the rear of the Theralase™ TLC-1000 laser controller is a small metal door secured by two Philips screws.
2. Remove these 2 screws to remove the battery door.
3. Remove the black foam used as a shock absorber for the battery.

4. Use a ¼" slot screwdriver to unclip the battery clip from the circuit board.
5. The battery is now able to slide out for replacement or service.



**Figure 23. Dis-engaging the battery**

**Battery Installation:** (Tools required: ¼" slot screwdriver, Philips #1 screwdriver)

1. Slide new battery into slot with terminals exposed closest to the battery clip.
2. Install battery clip on circuit board.
3. Install black foam shock absorber.
4. Install battery door and secure with two (2) Philips screws.

**Caution:**

- *If the equipment is not in use, do not store the Theralase<sup>™</sup> TLC-1000 laser controller with the battery in place. Remove the battery from the laser system and store separately in a cool dry location.*
- *If the battery needs replacement replace with a Nickel Metal Hydride Panasonic medical grade battery (Part Number: NIMH Battery) and safely dispose of the used battery. Risk of fire and or explosion may result if the battery is not disposed of safely and properly. Contact your local authorities in regards to the procedures for safe battery disposal.*
- *Never use a battery that has been breached or exhibits signs of leaking or corrosion. Contact Theralase Inc. immediately for replacement.*

**Product Warranty**

The TLC-1000 Therapeutic Laser System is warranted for one full year commencing from the date of delivery. This warranty includes all parts and labour used in the repair of the TLC-1000 laser system for the term of one (1) year.

Laser diodes are exempted from this warranty, as laser diodes are wear items and are expected to deteriorate in power output during usage.

Laser diodes that have been cracked by misuse or have been worn due to operation will be replaced only at the owner's cost. Laser diodes are considered wear parts and as such are not warranted. This warranty is considered null and void if the laser system has been opened, misused, physically damaged or in any other way physically tampered with.

### **Theralase Customer Service Contact Information**

Please note the following contact info for Theralase Customer service. When sending your unit in, it would be advisable to make a copy of your checklist (see Section 2) and attach this to your package. Describe the issue that your therapeutic laser system is experiencing and the customer service department will instruct you on the recommended service / replacement parts for your equipment.

**Toll Free Phone:** 1-800-THE-LASE (1-800-843-5273)

**Alternative Phone:** 416-699-5273

**Fax:** 416-669-5850

**Email:** [service@theralase.com](mailto:service@theralase.com)

**Internet:** [www.theralase.com](http://www.theralase.com)

**Address:** 1945 Queen Street East  
Toronto, Ontario  
M4L 1H7

## 6. Laser Exposure Level Calculations

### MPE's for skin and cornea

According to IEC 60825-1: 2007 standard, at 905nm, the maximum permissible exposure (MPE) of the skin to laser radiation for 10 to  $3 \times 10^4$  seconds is:

$$\text{MPE (905nm)}_{\text{skin}} = 2000 C_4 [\text{W/m}^2]$$

$$\text{where } C_4 = 10^{0.002(\lambda-700)} = 10^{0.002(905-700)} = 10^{0.41} = 2.57,$$

$$\text{So } \text{MPE (905nm)}_{\text{skin}} = 2000 \times 2.57 [\text{W/m}^2] = 5140 [\text{W/m}^2] = 514 [\text{mW/cm}^2] \quad (6-1)$$

And for 660nm red laser,

$$\text{MPE (660nm)}_{\text{skin}} = 2000 [\text{W/m}^2] = 200 [\text{mW/cm}^2] \quad (6-2)$$

Similarly, for exposure to the cornea of the eye,

$$\text{MPE (905nm)}_{\text{cornea}} = 10 C_4 C_7 [\text{W/m}^2]$$

$$\text{where } C_4 = 10^{0.002(\lambda-700)} = 10^{0.002(905-700)} = 10^{0.41} = 2.57, \text{ and } C_7 = 1,$$

$$\text{So } \text{MPE (905nm)}_{\text{cornea}} = 10 \times 2.57 \times 1 [\text{W/m}^2] = 25.7 [\text{W/m}^2] = 2.57 [\text{mW/cm}^2] \quad (6-3)$$

$$\text{and } \text{MPE (660nm)}_{\text{cornea}} = 10 [\text{W/m}^2] = 1 [\text{mW/cm}^2] \quad (6-4)$$

The TLC-1000 laser system has been tested at CSA International's testing facility in Toronto, Canada, in June, 2010. For the Multi Laser Probe, a 7mm pin hole was placed at 100mm distance, and average power was measured at this distance for both 905nm and 660nm at the 'single fault condition':

$$P_{10\text{cm}905} = 176.8\text{mW} \quad (6-5)$$

$$P_{10\text{cm}660} = 18.5\text{mW} \quad (6-6)$$

Since the Multi Laser Probe can be used in direct contact with patient skin, skin irradiance for both 905nm and 660nm are calculated in this configuration:

The total area of illumination is:

$$\pi (4.5\text{cm}/2)^2 = 15.9\text{cm}^2$$

Skin irradiance:

$$L(905\text{nm})_{\text{skin}} = 5 \times 100\text{mW} / 15.9\text{cm}^2 = 31.45\text{mW/cm}^2 \quad (6-7)$$

$$L(660nm)_{skin} = 4 \times 25mW / 15.9cm^2 = 6.3mW/cm^2 \quad (6-8)$$

Comparing (6-1), (6-2) and (6-7), (6-8), because  $L(905nm)_{skin} < MPE(905nm)_{skin}$  and  $L(660nm)_{skin} < MPE(660nm)_{skin}$ , we conclude that the optical power densities of 905nm and 660nm lasers emitted from TLC-1000 are less than the MPE values permitted according to IEC 60825-1:2007 standard.

### NOHD Calculation

The nominal ocular hazard distance (NOHD) is the distance from the laser output aperture at which the beam irradiance ( $mW/cm^2$ ) equals to the corneal MPE (section 3.62, page 35, IEC 60825-1:2007 standard).

For 905nm laser diode, the total diverging angle is  $10^\circ \times 30^\circ$  at 50% peak intensity. Since the laser diodes are mounted at different orientation angles, it is reasonable to use the average value of  $20^\circ$  as total diverging angle for calculation purpose.

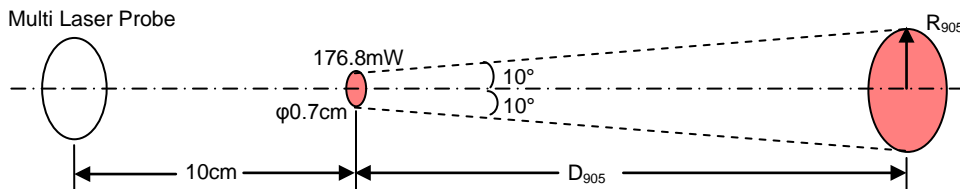


Figure 24. 905nm laser NOHD calculation

Now we treat the 7mm diameter spot as the light source. After distance of  $D_{905}$ , beam spot becomes  $2R_{905}$  and power density (irradiance) becomes  $2.57mW/cm^2$  ( $MPE(905)_{cornea}$ ).

$$R_{905} = D_{905} \tan 10^\circ$$

$$176.8mW / \pi R_{905}^2 = 2.57mW/cm^2$$

therefore,

$$R_{905} = [176.8 / (\pi \cdot 2.57)]^{1/2} = 4.68cm$$

$$D_{905} = R_{905} / \tan 10^\circ = 4.68cm / 0.176 = 26.59cm$$

and

$$NOHD_{905} = 10cm + D_{905} = 36.59cm \quad (6-9)$$

For 660nm laser diodes, the total diverging angle is  $8.5^\circ \times 22^\circ$  at 50% peak intensity and therefore the average total diverging angle is  $15.25^\circ$ .



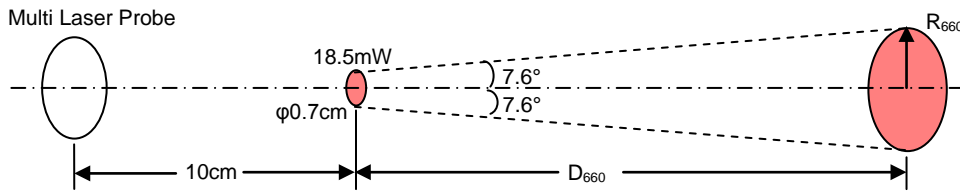


Figure 25. 660nm laser NOHD calculation

$$18.5\text{mW}/\pi R_{660}^2 = 1\text{mW}/\text{cm}^2 \text{ (MPE(660))}_{\text{cornea}}$$

therefore,

$$R_{660} = [18.5/(\pi \cdot 1)]^{1/2} = 2.43\text{cm}$$

$$D_{660} = R_{660}/\tan 7.6^\circ = 2.43\text{cm}/0.133 = 18.27\text{cm}$$

and

$$\text{NOHD}_{660} = 10\text{cm} + D_{660} = 28.27\text{cm} \tag{6-10}$$

Considering both equation (6-9) and (6-10), we conclude that it is safe to the eye as long as the TLC-1000 laser is firing at 36.59cm away. **However, it is strongly recommended that one should never point the laser beam directly to the eye.**

## 7. Electro Magnetic Compatibility Information

In accordance with clause # 5.2.x of EN 60601-1-2.

### Interconnecting Cables

Cable NO.	Type	Length	Connected From	Connected To	Special Accessories (ferrites, etc.)
1	Power Cord	2.37M	Power Supply	Power Outlet	None

**Warning:** The use of Power Cord other than the one provided by Theralase Inc. for the TLC-1000 may result increased EMISSIONS or decreased IMMUNITY of the TLC-1000 system.

**Warning:** The TLC-1000 should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the TLC-1000 should be observed to verify normal operation in the configuration in which it will be used.

Guidance and THERALASE INC's declaration- ELECTROMAGNETIC EMISSIONS		
The TLC-1000 is intended for use in the electromagnetic environment specified below. The customer or the user of the TLC-1000 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The TLC-1000 uses RF energy only as a bi-product of its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronics equipment.
RF emissions CISPR 11	Class B	The TLC-1000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.


Guidance and THERALASE INC's declaration- electromagnetic IMMUNITY			
The TLC-1000 is intended for use in the electromagnetic environment specified below. The customer or the user of the TLC-1000 should assure that it is used in such an environment.			
IMMUNITY test	IEC60601 Test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) IEC 61000-4-2	±6KV contact ±8KV air	±6KV contact <b>Criteria A Level 3</b> ±8KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2KV for power supply lines ±1KV for input/output lines	±2KV for power supply lines <b>Criteria A Level 3</b> ±1KV for input/output lines	Mains power quality should be that of typical commercial or hospital environment.
Surge IEC 61000-4-5	±1KV line(s) to line(s) ±2KV line(s) to earth	±1KV line(s) to line(s) Differential mode <b>Criteria A Level 2</b> Common mode ±2KV line(s) to earth	Mains power quality should be that of typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines  IEC 61000-4-11	$<5\% U_T$ (>95% dip in $U_T$ ) for 0,5 cycles  $40\% U_T$ (60% dip in $U_T$ ) For 5 cycles  $70\% U_T$ (30% dip in $U_T$ ) For 25 cycles  $<5\% U_T$ (>95% dip in $U_T$ ) For 5 s	$<5\% U_T$ (>95% dip in $U_T$ ) for 0,5 cycles  $40\% U_T$ (60% dip in $U_T$ ) For 5 cycles  $70\% U_T$ (30% dip in $U_T$ ) For 25 cycles  $<5\% U_T$ (>95% dip in $U_T$ ) For 5 s	Mains power quality should be that of typical commercial or hospital environment. If the user of the TLC1000 requires continued operation during power mains interruptions, it is recommended that the TLC1000 be powered from the battery (with the system) or from an uninterruptible power supply.
Power frequency (50/60 Hz) Magnetic field  IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE  $U_T$  is the a.c. mains voltage prior to application of the test level.

### Guidance and THERALASE INC's declaration- electromagnetic IMMUNITY

The TLC-1000 is intended for use in the electromagnetic environment specified below. The customer or the user of the TLC-1000 should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 Test LEVEL	Compliance level	Electromagnetic environment-guidance
Conducted RF  IEC 61000-4-6  Radiated RF IEC 61000-4-6	3 Vrms  150 kHz to 80 MHz  3 V/m 80 MHz to 2.5 GHz	$[V1]V$ 3V  $[E1]V/m$ 3V	Portable and mobile RF communications equipment should be used no closer to any part of the TLC1000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. <b>Recommended separation distance</b> $d = \left[ \frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[ \frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[ \frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in meters(m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range,<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following Symbol.</p> 

**NOTE 1:** At 80 MHz and 800 MHz, the higher frequency range applies.  
**NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio(cellular, cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the TLC-1000 is used exceeds the applicable RF compliance level above, the TLC1000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the TLC1000.

<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than  $[V_1]V/m$ .

**Recommended separation distances between portable and mobile RF communications equipment and the TLC-1000**

The TLC-1000 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TLC-1000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TLC-1000 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter  W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 M kHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters(m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**Note 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.