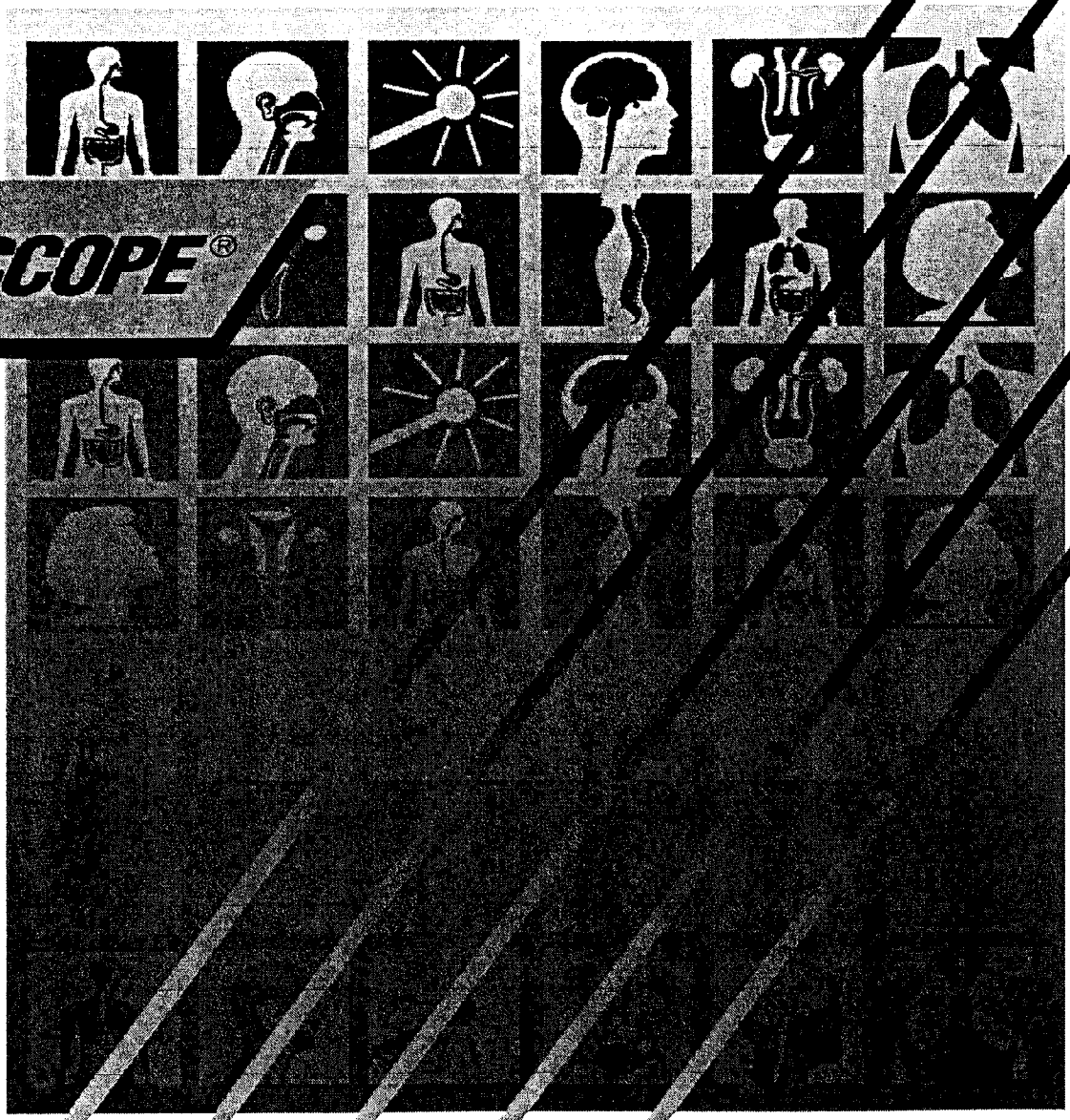
LASERSCOPE®



Lyra *i* Laser System

OPERATOR'S MANUAL

LASERSCOPE®
Corporate Headquarters
3070 Orchard Drive
San Jose, California 95134-2011 U.S.A.
(800) 356-7600 Customer Response Center
(408) 943-0636 Corporate Office
(408) 428-0512 FAX
Web: www.laserscope.com

Laserscope France S.A.
Parc Technologique
18 rue du Bois Chaland
91090 LISSES
France
33/1 60 86 20 49 Office
33/1 60 86 14 88 FAX

Laserscope (U.K.) Ltd.
Raglan House
Llantarnam Park
Cwmbran
Gwent, NP44 3AX
United Kingdom
44/1633-838081 Office
44/1633-838161 FAX

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Section 1: Introduction

Manual Overview

This manual contains the safety, installation, and operating requirements for the Laserscope Lyra *i* Laser System and Lyra *i* Accessories. It also provides information on delivery devices, eye protection, maintenance and warranty for this system. Section 5 provides information to medical professionals regarding clinical procedures.

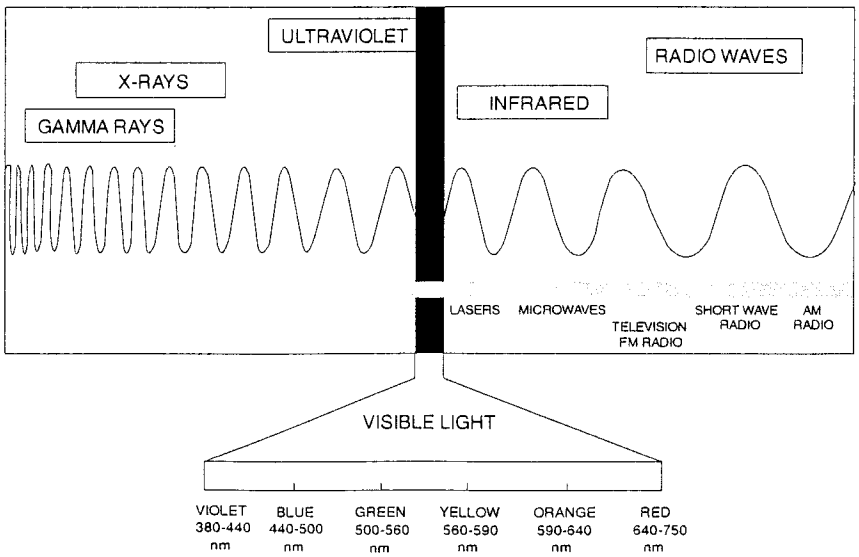
Read this manual thoroughly to become familiar with the Lyra *i* Laser System before any surgical procedure is attempted. Laserscope's laser systems should be used and operated by qualified personnel.

Definition of a Laser

The term Laser is an acronym for 'Light Amplification by Stimulated Emission of Radiation'. In practical terms, a laser produces a narrow beam of monochromatic coherent light. This light is produced when excited electrons release their excess energy in the form of photons.

In its simplest form, a laser consists of a lasing medium contained between two mirrors. Electrons in the lasing medium are excited by a strong energy source, such as an arc lamp. These excited electrons emit some of their energy as photons and return to their normal (ground) state. Most of the light energy that is released from these excited electrons is contained within a special laser cavity and is reflected back and forth between the mirrors. As the light passes by the excited electrons, the emission of more light is further stimulated or amplified. One of the mirrors is semi-transparent and allows some of the light to pass through, creating the laser beam. Hence the expression, 'light amplification by stimulated emission of radiation', and the acronym, LASER.

The light emitted from the lasing medium may be visible, infrared or ultraviolet, depending upon the medium. The following figure shows the electromagnetic energy spectrum, that covers all wavelengths and frequencies of radiation.



Nd:YAG 1064 nm Lasers

In the Nd:YAG laser, the laser medium is an yttrium aluminum garnet (YAG) rod that has been doped with a small amount of the element Neodimium (Nd). In this system, the electrons of the Nd atoms become excited and release photons of a characteristic wavelength. The light energy that is emitted from this source has a wavelength of 1064 nm, which is in infrared portion of the spectrum.

Laser Output Specifications

	Lyra *i*	
Pulse Width	10 – 100*	ms
Pulse Energy	0.89 - 39.3	J
Fluence Range (10mm)	5 – 50	J/cm^2
Fluence Range (1-5mm)	5 – 900*	J/cm^2
Pulse Power	8.9 - 548	W
Average Power	1.8 – 72	W
Pulse Rate	1 – 10**	PPS
Aiming Beam Wavelength	635 +/- 10	nm
Aiming Beam Power	<5	mW

* Range dependent on spot size selected
** Range dependent on pulse energy

Section 2: Safety Section

Hazards and Precautions

The Lyra *i* Laser Systems produce concentrated light energy. It has enough energy to seriously burn tissue and ignite materials. All personnel working with a laser should be aware of these hazards and take the necessary precautions to prevent them. This section describes specific laser hazards and appropriate precautionary measures.

WARNING:

The treatment beam is invisible. Never activate the system treatment beam without eye protection. It presents a severe eye hazard if viewed directly or by reflection. Avoid unintentional skin exposure to the system treatment laser beam. Take all necessary protective measures in areas where the laser is being used.

Eye Injury

Due to it's high pulse energies, the Lyra *i* Laser Systems are classified as a Class IV laser by IEC 825-1 and ANSI. A class IV laser is characterized by the fact that even diffuse reflections off an object can be hazardous to the eye. It is the responsibility of the hospital or medical institution where the laser is used to establish a written policy on eye protection.

Several articles have been published in the U.S.A. stating the strong OSHA and JCAHO (Joint Commission on Accreditation of Hospital Organizations) position to adhere to ANSI Standards. Refer to ANSI Z136.1-1988 in conjunction with the recommendations of your Laser Safety Officer (LSO) to develop your facility's laser policy.

Eye injury can be avoided with the use of protective eyewear, which allows for safe exposure to the laser. 1064 nm light is absorbed by biological tissue. This light can cause an accidental retinal burn. When focused, the beam can pass through the transparent components of the eye (cornea, lens, and aqueous and vitreous humor), and focus on the retina. The degree of injury to the eye will depend upon the power of the beam, how focused the beam is, and how long the eye is exposed to the beam. Precautions against eye injury must include protective eyewear for the procedure room staff, and when appropriate, for the patient.

Maximum Permissible Exposure

IEC 825-1 defines Maximum Permissible Exposure (MPE) in sub clause 3.5.1. MPE is the level of laser light to which a person may be exposed without hazardous effects or adverse biological changes in the eye or skin. The criteria for MPE for the eye are detailed in clause 13. The equivalent U.S. document is ANSI Z136.1-1986, Section 8. For pulsed lasers, the MPE is expressed in terms of energy density at the cornea and is expressed in Joules per square centimeter (J/cm2). The MPE is not as simple as giving one value of the MPE for lasers. The MPE depends both on the wavelength of the laser, the pulse duration of the laser, the time between laser pulses, and the duration of the laser exposure. The worst case scenario that needs to be considered for the safe use of lasers and the eye hazards it presents is the direct viewing of a laser beam. For MPE calculations, ANSI recommends exposure times of ten seconds.

Nominal Hazard Zone

IEC 825-1 and the ANSI standards define the nominal hazard zone (NHZ) also called the nominal ocular hazard zone (NOHA). This is the space within which the level of the direct, reflected, or scattered light during operation of the laser exceeds the applicable MPE. The distance from the light source to the eye beyond which the light level is below the MPE is defined as the nominal ocular hazard distance (NOHD). Protective eyewear must always be worn when using the Lyra *i* Laser System.

Eye Protection

Laserscope's YAG Protective Spectacles and Goggles have been designed to protect operating room personnel from the laser energy produced by the Lyra *i* Laser System. The lens material in the spectacles have an optical density greater than 5.5. The lenses are clear and cause no noticeable color distortion. For additional information about their use, cleaning and warranty, consult the product insert that accompanies each pair of eyewear or contact the Laserscope Customer Response Center or your local Laserscope distributor.

In addition, the following protective measures should be taken:

- Use moist towels, where appropriate;
- If the patient is awake, use suitable protective eyewear and instruct the patient not to remove the eyewear;
- If the patient is anesthetized, lubricate and tape the patient's eyelids shut;
- Use a combination of moist towels, gauze eye pads, eye shields, and drapes to protect the eyes when the surgical site is on or near the face; and
- Use metal corneal eye shields when the surgical site is around the eyelid.

Burns

Accidental irradiation of tissue other than the target tissue will result in a burn or vaporization, regardless of the wavelength. Surrounding the target area with moist drapes or saline-soaked cottonoids will keep it moist and greatly reduce this hazard. Care and precision in aiming and applying laser energy is of paramount importance.

Reflection of the Beam from Instruments

Care should be taken when aiming the laser beam to prevent reflection of the beam off metallic surgical instruments. New, flat instruments are especially dangerous because they have highly reflective surfaces. The laser light reflected from such instruments is intense and potentially very harmful. Older instruments (less shiny) and those with curved surfaces do not reflect light as intensely. While these instruments usually produce a more diffuse reflection that is less harmful, this reflection can still be damaging.

WARNING:

When using anodized or ebonized instruments during a surgical Procedure, additional care should be taken to prevent burns. These instruments will become extremely hot when they come in contact with a laser beam, and are not able to quickly dissipate heat. When any tissue is touched under these conditions, a burn may result.

Many materials used during a surgical procedure can be ignited by the laser. Use of non-flammable materials is strongly recommended. See *Procedure Room Environment* in this section of the manual for more information regarding flammable materials.

WARNING:
Do not use the laser in the presence of flammable anesthetics.

Vapor/Smoke Plume

There is considerable concern about the biological plume created by electrocautery units, bone saws and lasers. Current medical literature recommends that a smoke evacuator and in-line filter be used to capture this plume. The plume should be regarded as a source of active biological material and a possible carcinogen.

Caution:
Laser plumes may contain viable tissue particulates.

Electrical

Electrical hazards with the laser are the same as with any high-power electrical device. Care should be taken when plugging the unit into the wall outlet. The area must be free of water and your hands must be dry. Always disconnect the laser by grasping the plug and not the power cord. Examine the electrical cord routinely; if signs of wear are noted, contact the Laserscope Customer Response Center or your local Laserscope distributor to have it repaired or replaced.

Procedure Room Environment

This section describes specific safety measures for the procedure room to aid in the safe operation of the laser system.

Laser in Use Signs

The area where the laser is operated should be clearly labeled. Laser in use signs that specify the laser wavelength being used should be posted at all procedure room and procedure site entrances. A set of two Laser in Use Signs is included with your Lyra *i* Laser System.

Remote Interlock

Always limit personnel in the procedure room to those essential to the procedure. To protect intruding personnel from exposure to the laser beam, an optional remote interlock can be connected from the laser system to the procedure room entrance door. Once connected, this interlock will automatically put the laser in STANDBY if the door is opened during a procedure. The laser will remain in STANDBY until the door is closed and the interlock is reconnected. Once reconnection is made, i.e. the door is closed, the operator can place the system back in READY and activate the laser beam.

If the use of the remote interlock is desired, the maintenance personnel at the user's facility can connect it. Access to the laser unit's interlock is made via the socket labeled "Remote Interlock" located on the back panel of the laser. Laserscope recommends that the length of the remote interlock cable used be less than 3 meters

Note:

The remote interlock should be tested prior to each case. This can be done by placing the laser in ready and opening the door to which the remote interlock circuit is connected.

General Safety Recommendations

The following are general safety recommendations for the procedure room:

- Keep drapes and towels moist to prevent them from igniting and burning;
- Use non-flammable prepping solutions;
- Review Professional Information Section, for information regarding specific laser procedures.

Note:

All lasers operate with a key switch. When not is use, remove the key from the laser. Keep the laser key in a designated place and only allow trained personnel access to the key.

Laser Safety Guidance

Guidance for the safe use of lasers is given in IEC 825-1. Guidance is also given in two equivalent American National Standards. The first is ANSI Z136.1-1988, *The Safe Use of Lasers*, and covers general use of lasers. The second standard is ANSI Z136.3-1995, *The Safe Use of Lasers in Health Care Facilities*, and covers specific use of lasers in medical applications. The ANSI Z136.3-1988 standard refers to the general ANSI Z136.1-1986 standard for the actual calculations for eye protection.

Reference Sources

Reference material and additional information regarding laser safety and the prevention of endotracheal fires may be obtained from the following U.S. sources:

- **ANSI Z136.3, The Safe Use of Lasers in Health Care Facilities**, American National Standards Institute (ANSI), 1995.
- **Recommended Practices: Laser Safety in the Practice Setting**, *AORN Journal*, March 1993, Vol. 57 No. 3, Pg. 720-727.
- **Safety Considerations for the Use of Medical Lasers, The Nursing Spectrum of Lasers**, Pfister, Kneedler, Purcell, *Education Design*, 1988, Pg. 70-72.
- **Prevention of Fires and Protection of Non-Target Tissues, Airway Precautions**, *Plan for Success: A Practical Guide for Your Carbon Dioxide Laser Surgery Program*, Lewis, Coherent 1989, Pg. 16-17.
- **Laser Resistant Stainless Steel Endotracheal Tube: Experimental and Clinical Evaluation**, *Lasers in Surgery and Medicine*, Fried, Marvin P., MD, 11:301-306 (1991).

- **Evaluation & Discussion: Issues in Using and Selecting Laser Resistant Endotracheal Tubes (LRETTs) and Wraps,** *ECRI, Health Devices*, July-August 1991, Vol. 20 Nos. 7-8.
- **Diffuse Reflections, Endoscopic Surgery: Is Laser Safety Eyewear Really Needed?,** *Radiant Resources Newsletter*, Winter 1992, Rockwell Laser Industries.

Safety Features of the Lyra *i* Laser Systems

The safety features of the Lyra *i* Laser Systems are described in the following section. All required labeling information is also provided in this section. Laserscope's Lyra *i* Laser Systems incorporate the following safety features:

- A key is required to turn the laser system on and it can only be removed when the keyswitch is in the OFF position;
- A procedure room interlock connection;
- Laser energy cannot be emitted from the system unless a delivery device has been connected;
- A red Emergency Stop button that deactivates the laser system when pressed, regardless of the state it is in, i.e. WARM-UP, STANDBY, READY, ACTIVE;
- A continuous audible tone will sound and a visible emission indicator light will illuminate whenever the laser beam is activated, i.e. the activation switch is depressed;
- There is a two-second safety transition period when the system is changed from STANDBY to READY before laser energy can be emitted;
- An automatic circuit breaker shuts the system completely off in the event of an electrical overload; and
- System operation is continuously controlled and monitored by a microprocessor.

WARNING:

Do not attempt to remove any exterior panel from the laser console. There are hazardous parts within that can deliver a serious electrical shock. Any attempt to remove the panels, unless instructed by authorized Laserscope personnel, will void the manufacturer's warranty.

Caution:

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

Safety Standards and Classifications

Laserscope's Lyra *i* Laser Systems and accessories comply with the U.S. Federal Regulations and the performance standards 21CFR1040.10 and 1040.11 for medical laser systems. Additionally the device is classified as a IIb device defined by the Medical Device Directive (93/42/EEC) for CE marking.

The Lyra *i* Laser Systems and accessories have been manufactured and tested to meet the requirements of the following standards: ISO 9001; EN 46001; IEC 601-1; IEC 825; MDD, 21CFR 820 and ISTA-2A.

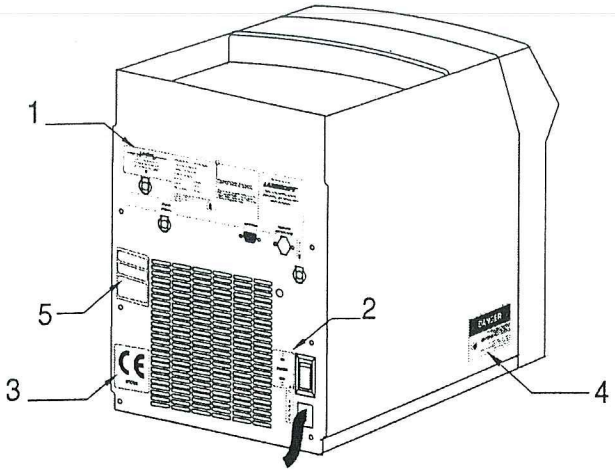
The Lyra *i* Laser Systems meet the following safety classifications:

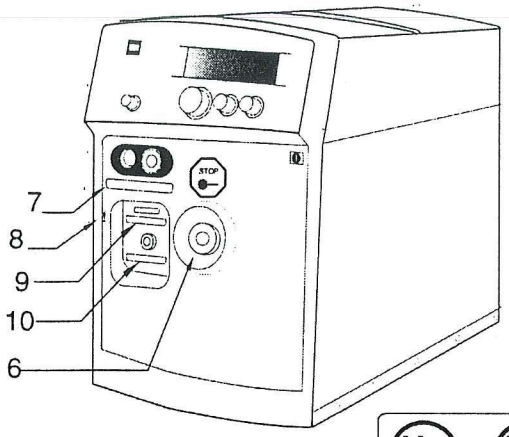
Equipment:	Class 1	IEC 601-1
Working Beam Radiation:	Class IV	IEC 825; 21CFR1040
Aim Beam Radiation:	Class 3B	IEC 825; 21CFR1040

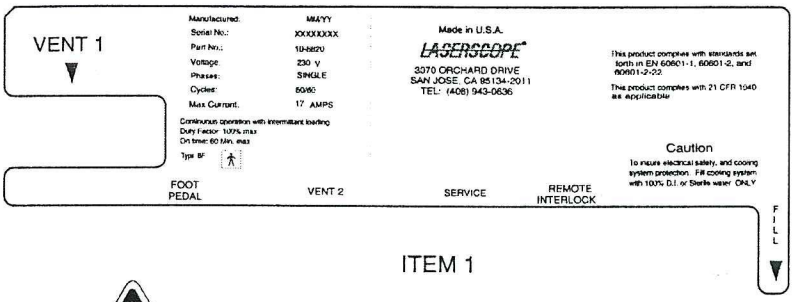
Sound emissions are less than 90 dBA at a distance of 5 feet (152 cm) per ANSI S1.4-1983.

Labeling

The Lyra *i* Laser Systems are labeled to provide the user with both general and critical safety information. The user should review the following figures and familiarize themselves and their staff with the label locations and meanings prior to using the laser. The labels and their positions on the Lyra *i* Laser Systems are illustrated in the diagram on the following page.







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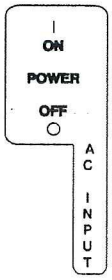

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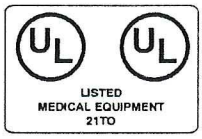
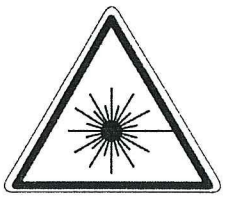
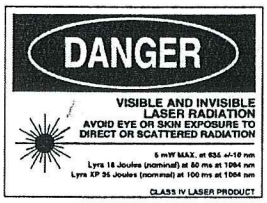


ITEM 3
USA

ITEM 3
International



ITEM 4
International



ITEM 4
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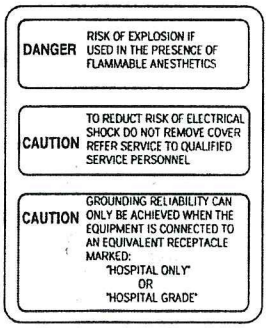

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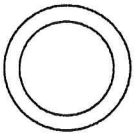

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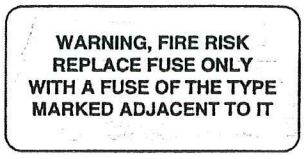
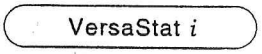


ITEM 11*

ITEM 12*



ITEM 10

ITEM 13**

*Items 11 and 12 are under the laser top cover.
**Item 13 is on the foot pedal.

Labeling on the Lyra *i* Laser System

Symbol	Description
	Aim Beam
	Display Brigtness
	Emergency Stop
	Attention Consult Accompanying Documents
	Laser Active
	Laser Standby
	Laser Keyswitch On
	Laser Keyswitch Off
	Reset/System Information
	Tone Volume
	Type BF Equipment

Explanation of the symbols used on the Lyra *i* Laser System

Section 3: System Installation

System Installation and Site Requirements

This section provides general guidelines for the installation of the Lyra *i* Laser System. This laser system has specific installation and operating requirements. It is the customer's responsibility to fulfill these requirements prior to the installation of the system. Failure to do so can result in intermittent operation and even damage to the laser system. Read the following information carefully.

Responsibility of Laserscope

Laserscope considers itself responsible for effects on safety, reliability and performance of its products only if extensions, readjustments, modifications or repairs are carried out by persons authorized by Laserscope, the electrical installation of the relevant room complies with the appropriate requirements, and the product is used in accordance with the applicable instructions for use.

Shipment

The Lyra *i* Laser Systems are shipped in a specially designed box. When shipment is received, inspect the container for damage. If there is exterior damage, notify the freight shipping company immediately. DO NOT UNPACK THE SYSTEM. After notifying the freight company, call Laserscope or your local Laserscope distributor.

Installation

The laser and chiller are shipped without coolant. Equipment and instructions to properly fill both the laser and chiller with coolant are included. Please follow the instructions carefully to ensure the coolant is added properly, failure to do so could result in damage or malfunction. Laserscope offers a complimentary installation service where a Laserscope representative will fill and set up the laser and chiller.

Space Requirements

The laser unit's dimensions are: Height - 24 inches (61 cm), Width - 12 inches (31 cm), Length - 23 inches (59 cm). These space requirements are for the laser only. The total system weight is approximately 73 pounds (33 kg). Adding the cart brings the overall height to approximately 38 inches (97 cm), the width to 16 inches (41 cm) and the length to 30 inches (77 cm). The cart weighs approximately 25 pounds (12 kg.)

Power connections must be within a radius of 6 feet (1.8 meters) from where the laser console will be positioned in the procedure room. The laser console, in turn, must be able to be positioned not more than 3 feet (.9 meters) from the centerline of the treatment area.

The back of the Lyra *i* Laser System must be positioned a minimum of 1 foot (.3 meters) from the wall to provide adequate ventilation for the laser's cooling system.

Power Requirements

In the US, the Lyra *i* Laser System requires a minimum dedicated 208VAC / 20A / 60Hz electrical service with a thermo-magnetic "motor start" circuit breaker. The optimal US electrical service is a dedicated 230-240VAC / 20A / 60HZ electrical service using a 10KVA isolation transformer. High quality large conductors are recommended (10 gauge wire for lengths over 50

feet). Do not connect the electrical service through an electrical panel that is heavily loaded or near its maximum capacity.

Outside the US, the Lyra *i* Laser System requires a minimum dedicated 200-240V / 20A / 50 or 60 Hz electrical service with a thermo-magnetic "motor start" circuit breaker. High quality large conductors are recommended (10 gauge wire for lengths over 50 feet). Do not connect the electrical service through an electrical panel that is heavily loaded or near its maximum capacity.

Environmental Requirements

The Lyra *i* Laser System has the following environmental temperature range requirements:

Operation:	55 – 85° F (13 – 29° C)
Storage:	40 - 120°F (5 - 50°C)

Note:
The laser system continuously monitors its temperature and will reduce the pulse rate or stop lasing if the system operation temperature limit is reached. The system may be susceptible to overheating when a continuous exposure of greater than 60 minutes is performed in a 55-85°F (13-29°C) room.

Electromagnetic Compatibility

This equipment has been tested and found to comply with the limits for medical devices to the IEC 601-1-2:1994. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

Section 4: Instructions for Use

System Overview

This section describes the settings and button functions on the control panel and describes step-by-step instructions on how to operate the system. The Lyra *i* Laser System features are detailed in the following section. If more information is needed, contact the Laserscope Customer Response Center or your local Laserscope distributor.

Caution:

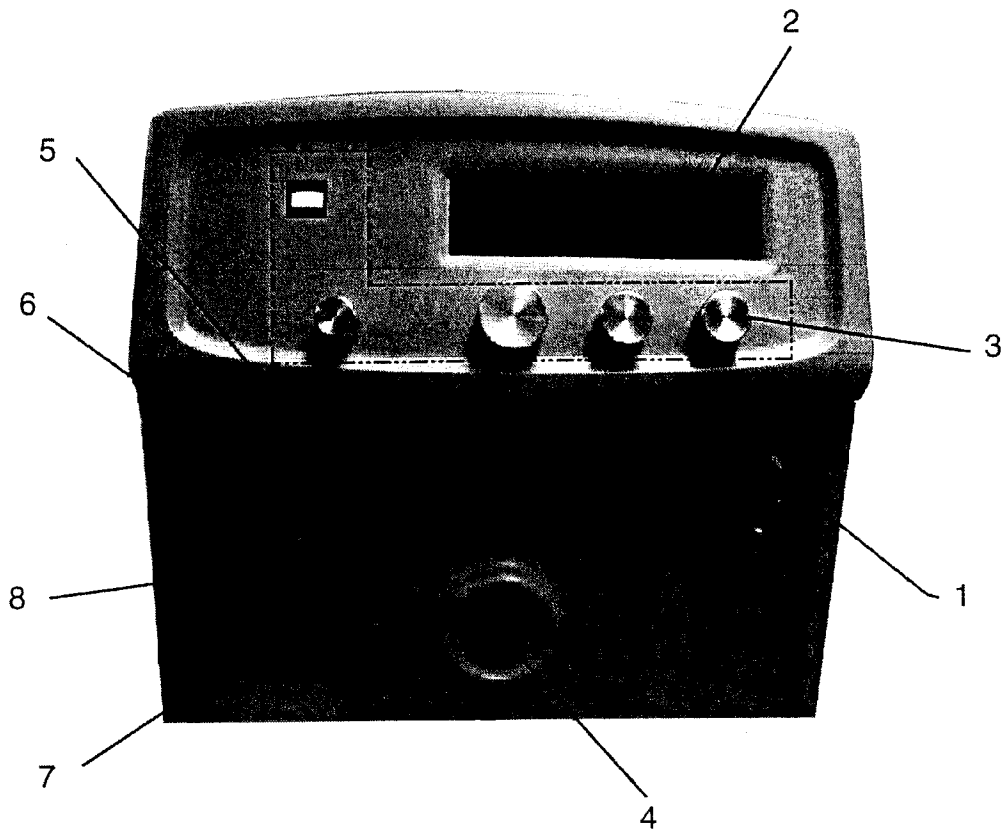
Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Fiber Optic Delivery

The Lyra *i* Laser System has one laser aperture for all delivery devices located on the front of the laser console. This aperture is designed to accommodate Laserscope SmartConnector™ delivery devices only.

Device Recognition

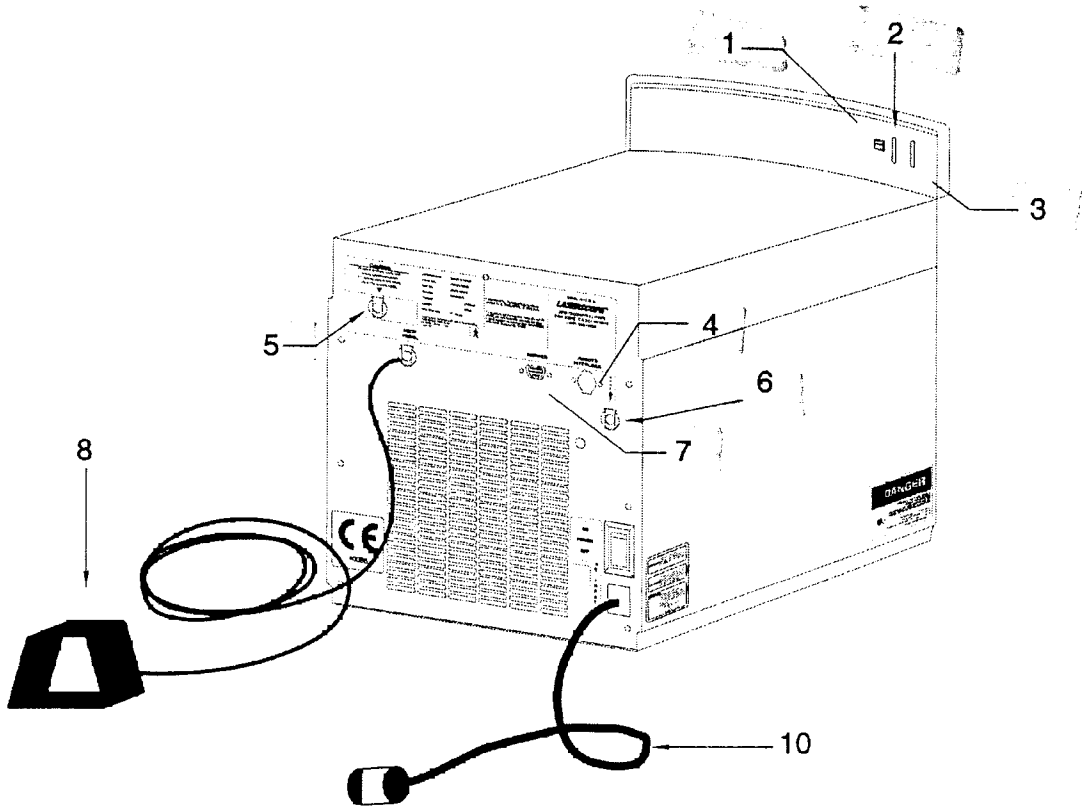
The Lyra *i* Laser System recognizes the specific delivery device connected via the SmartConnector. The laser automatically shows the applicable treatment parameters for the specific device on the control panel display.



Front View of the Lyra *i* Laser System

User Interface, Front Panel

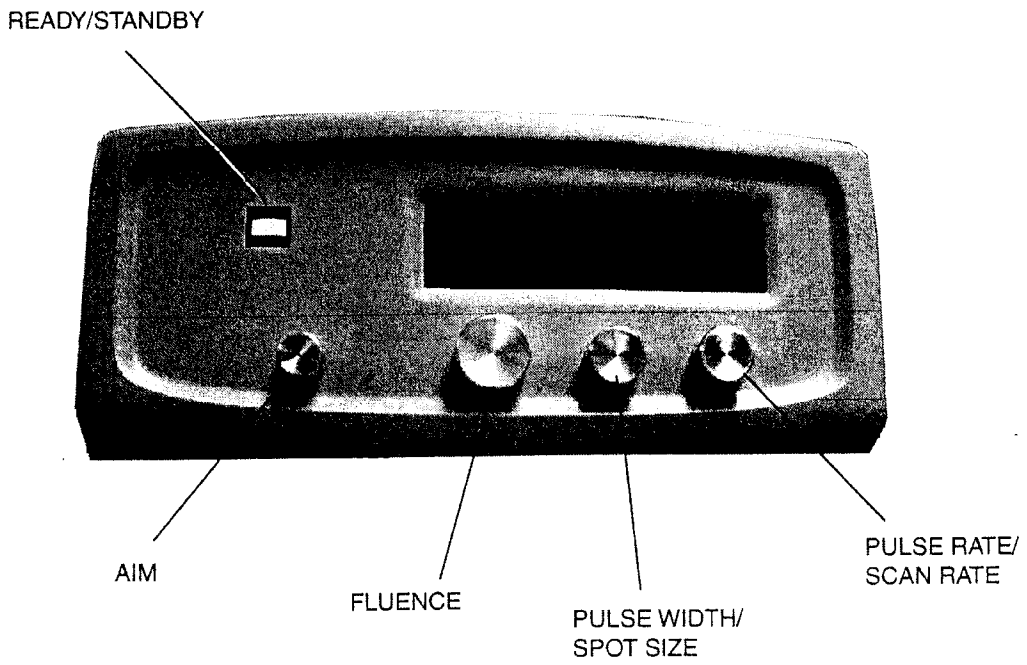
1. On/Off Keyswitch: Turns the laser system on and off. The key should always be kept in a safe place and should never be left in the laser keyswitch when the laser is not in use;
2. Control Panel Display: Displays the following operator information; Laser parameters; Data on connected devices; and Information Messages and System Prompts;
3. Control Panel Knobs and Buttons: On the front of the panel, 4 knobs for selection of laser settings and a READY/STANDBY button for selecting READY or STANDBY.
4. Emergency Shut Off Button: When button is pressed, it disables the laser and places the system in a holding status. To continue to use the laser system it must be restarted;
5. Deliver Device/Fiber Optic Port: Delivery devices are connected to the laser system via this port, which only accepts Laserscope devices featuring the SmartConnector;
6. Calibration Port: Delivery devices are calibrated via this port;
7. VersaStat *i* Electronic Cable Connector: Electrical interface for the VersaStat *i* delivery device to the laser system;
8. SmartScan Plus Electronic Cable Connector: Electrical interface for the scanner delivery device to the laser system.



Rear View of the Lyra *i* Laser System Without the Tray

User Interface, Rear

1. System Information Button: Pressing this button activates the System Information Menu;
2. Audible Tone Volume Control: Sliding this switch changes the volume of the audible tone emitted when the laser beam is activated. The volume level will momentarily sound while being adjusted to give the user audible feedback;
3. Display Brightness Control: Sliding this switch changes the brightness of the display;
4. Remote Interlock Socket: Allows a door interlock circuit to be connect to the laser;
5. Coolant Breather Port: Air is purged from the coolant system via this port;
6. Coolant Fill Port: The laser system coolant reservoir is filled through this port;
7. Service Port: Connection to Chiller. Also allows authorized access to service screen and diagnostics;
8. Foot Pedal and hose: The foot switch is the default activation switch for most delivery devices and it is connected to the laser console via a hose;
9. Circuit Breaker: Automatically trips in the event of a power overload, shutting off power to both the laser and the control electronics;
10. Power Cord: Connects laser console to wall electrical outlet.



The Control Panel

Control Panel Knob/Button Functions

Laser parameters are selected and the system status is changed by using the 4 knobs and 1 button on the front of the Control Panel and the 2 slide controls and 1 button on the rear of the Control Panel.

Ready/Standby Button

The Ready/Standby button toggles the system between STANDBY and READY status. There is a required two-second transition period between STANDBY and READY. In STANDBY, the laser is warmed up and operating, but neither the aiming beam nor the working beam can be emitted. All of the parameters for treatment should be set while the system is in STANDBY, but they can be adjusted in READY as well. In READY, laser energy can be emitted when the foot switch is depressed. By pressing the Ready/Standby button while in READY, the system will revert back to STANDBY. There are two small LED's positioned above this button: a green READY light is illuminated when in READY; and a yellow light is illuminated when the foot switch is activated and during calibration. The laser automatically returns to STANDBY whenever one of the following occurs: the Ready/Standby button is pressed when the system is in READY; two minutes pass after the system has been placed in READY and the control switch has not yet been depressed; and/or the remote interlock is activated.

Aiming Beam Knob

The Aiming Beam Knob controls the aiming beam brightness. When the aim beam is adjusted a graphic depicting the percentage of maximum brightness temporarily appears along the top of the display. The graphic disappears after 2-3 seconds.

Fluence Knob

The Fluence Knob controls the treatment fluence level. If for any reason the laser cannot attain the fluence setting desired, it will establish the highest attainable fluence.

Pulse Width/Spot Size Knob

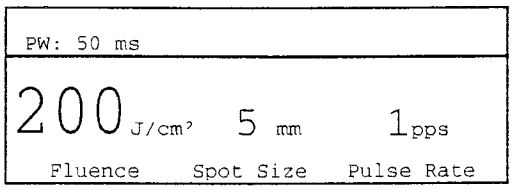
The Pulse Width/Spot Size knob is a multi-purpose control. With all non VersaStat *i* handpieces the knob controls pulse width when on the main screen. With the VersaStat *i* handpiece, the knob controls the spot size on the main screen and controls the pulse width on the System Information Menu. The System Information Menu can be accessed by pressing the System Information Button on the back left hand side of the control panel.

Pulse Rate/Scan Shape Knob

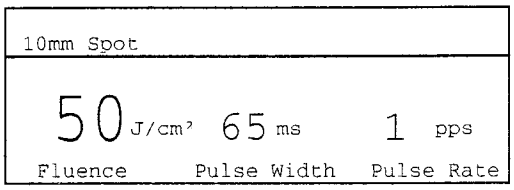
The Pulse Rate/Scan Size and Shape knob is a multi-purpose control. When all non SmartScan Plus devices are connected the knob controls the pulse rate when on the Main screen. With the SmartScan Plus is connected the knob control the scan size and shape on the main screen.

Main Screen

The Control Panel Display is a back lit LCD display. All user information is accessible via the display screen.



VersaStat *i* (sample)

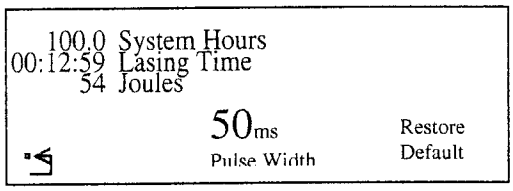


10 mm VersaStat (sample)

System Information Menu

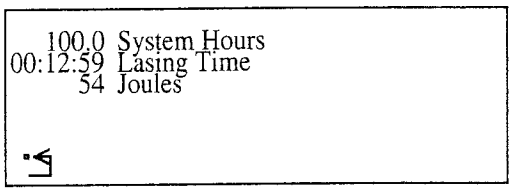
The Lyra *i* Laser System has a System Information Menu, which displays stored information such as the total lasing energy and the system hours. This menu is accessed by pressing the System Information Button located on the back of the control panel. The total lasing energy (Joules) and total lasing time are cumulative and this information will be retained even when a device is disconnected during a procedure. The operator can zero the total energy and lasing time by turning the Fluence Knob (under the reset icon) the display can be recalled by turning the Fluence Knob again. The total joules and lasing time will also reset to zero when the system is turned off. The system hours display cannot be reset except by a Laserscope Service representative. The display can be returned to the initial screen by pressing the button a second time or it will return automatically after 20 seconds.

When the VersaStat *i* handpiece is used with the laser, the System Information Menu looks like this:



The pulse width can be adjusted via the Pulse Width/Spot Size Knob (center knob).

When the VersaStat handpieces (discrete 1.5mm, 3mm, 5mm, 10mm) are used with the laser, the System Information Menu looks like this:



System Start-up

The following procedure is recommended for system start-up:

Connecting the LASER to the Electrical Service

1. Place the "Laser In Use" signs in plain view on each door to the procedure room.
2. Confirm that the system circuit breaker on the back of the laser is in the OFF position to prevent a power surge to the system;
3. Plug the system into a grounded outlet;
4. Turn the system circuit breaker to the ON position by flipping the switch up until it clicks;

Connecting the CHILLER to the Electrical Service

1. Confirm that the ON/OFF switch on the back of the chiller is in the OFF position to prevent a power surge to the system;
2. Plug the system into a grounded outlet;

Connecting the CHILLER to the LASER

1. Connect one end of the chiller interface cable to the service port on the chiller and the other end to the service port on the laser.

Note:
If this is the first time the laser and/or chiller is being turned on, please make sure the cooling systems are full. Refer to the Fill Kit product insert for specific instructions.

WARNING:
To fill or top off the Lyra *i* Laser System use de-ionized water only, use of any other type or mixture of coolant will result in damage to the system.

WARNING:
To fill or top off the Cart/Chiller use de-ionized (or distilled) water.

Note:
Never block the cooling system vents on the front or rear of the unit.

Note:
Calibration is not allowed after handpiece is chilled.

Turning the LASER On

1. Turn the keyswitch ON. A system warm-up message will appear on the display until the laser has warmed up (approximately 2 minutes);
2. Connect a Laserscope delivery device;
3. Calibrate all devices intended for use before the cooling tips have chilled.

Turning the CHILLER On

1. Flip the ON/OFF switch located on the back panel of the chiller to the ON position by flipping it up in until it clicks.
2. Push the green ON/OFF switch located on the front panel of the chiller to the illuminated ON position.
3. Check the water level through the viewing slot in the back panel to make sure the reservoir is at least 3/4 full.
4. Wait approximately 20 minutes for the chiller to reach optimal temperature. During this time, the laser will display the message, "Chiller not ready. Please wait or press STANDBY to continue." As the chiller approaches the optimal temperature, the laser will beep twice. Observe the temperature indicator dot at the tip of the handpiece. Blue indicates the device is chilled and ready for use. White indicates the device is NOT ready for use.

General System Use

1. The aiming beam is activated when the system is placed in READY, and the working beam is activated when the system is in READY and the foot switch is depressed;
2. Parameters may be adjusted in discrete increments by turning the appropriate knob. An audible tone will sound when maximum and minimum levels are reached.

WARNING:
All personnel viewing the laser procedure, including the patient, should follow the Eye Protection Policy of the facility. Specific laser eye protection is required for each type of laser. Check the labeling of protective eyewear to ensure that it protects against the 1064 nm wavelength of light being emitted by the laser. Refer to the Safety section for more information about eye protection.

Delivery Devices

Several delivery devices are available to deliver laser energy to the operative site, which are described below. All of the devices are connected to the Lyra *i* Laser System via the Laserscope SmartConnector delivery device port.

- VersaStat *i*
- VersaStat 10mm
- VersaStat 1.5mm, 3mm & 5mm
- SmartScan Plus

WARNING:
Do not use non-Laserscope delivery devices. Use of non-Laserscope delivery devices or fiber adapters may lead to laser damage, device damage and/or user and/or patient harm.

VersaStat *i*

The VersaStat *i* handpiece is a non-sterile laser delivery device designed for precise spot delivery of Nd:YAG laser energy. The handpiece is ideal for vascular applications, allowing the spot size to be properly matched to the vessel size, thus improving patient comfort and clinical effectiveness. Refer to the VersaStat *i* Product Insert for detailed instruction for use of the device, including cleaning.

WARNING:
Do not sterilize the VersaStat *i* or the calibration inserts.

Set Up and Calibration

With the laser turned off, insert the VersaStat *i* electrical connector into the receptacle on the front of the laser. Then insert the SmartConnector on the proximal end of the fiber into the delivery device port of the laser and turn it ¼ turn clockwise. Turn the laser on, the laser will complete its warm-up (approximately 2 minutes) and then it will indicate the option for calibration. By choosing to bypass calibration, the system will automatically select a default calibration value. If calibration is desired, perform the following steps:

1. Do NOT calibrate with a cold cooling tip/window, calibrate the handpiece when the cooling tip/window is at room temperature. If an attempt is made to calibrate a chilled handpiece, the laser will use a default calibration;
2. Attach the VersaStat *i* calibration insert to the output tip of the device;
3. Insert the distal end of the device into the calibration port and hold it in place until the system indicates successful calibration;
4. Remove the device from the calibration port and remove the calibration insert, device calibration below 80% will limit the maximum fluence settings.

Note:
When calibration is complete attach the VersaStat *i* cooling lines and/or turn on the chiller and allow time for the handpiece tip/window to reach a suitable temperature, observe the temperature indication dot and use only when the dot is blue. Then set the laser parameters to the desired levels and proceed by placing the laser in READY mode.

WARNING:
Only connect or disconnect the VersaStat *i* electrical cable when the laser is turned OFF.

Note:

When changing the Spot Size parameter the Fluence and Pulse Width setting are adjusted to provide an approximately equivalent clinical setting at the new spot size. As the Spot Size is increased the Fluence decreases and the Pulse Width increases. As the Spot Size is decreased the Fluence increases and the Pulse Width decreases.

VersaStat *i* Parameter Range

The table depicts a sampling of maximum fluence settings for various spot size and pulse duration settings with the VersaStat *i*. The max repetition rate (not shown in the table) will decrease as pulse durations and fluence settings are increased. Device calibration below 80% will limit the maximum fluence settings.

		Pulse Duration									
		10 ms	20 ms	30 ms	40 ms	50 ms	60 ms	70 ms	80 ms	90 ms	100 ms
Spot Size	1 mm	680J/cm^2	900J/cm^2	900J/cm^2	900J/cm^2	900J/cm^2	900J/cm^2	900J/cm^2	900J/cm^2	900J/cm^2	900J/cm^2
	2 mm	170J/cm^2	340J/cm^2	520J/cm^2	680J/cm^2	860J/cm^2	900J/cm^2	900J/cm^2	900J/cm^2	900J/cm^2	900J/cm^2
	3 mm	75J/cm^2	155J/cm^2	230J/cm^2	310J/cm^2	380J/cm^2	460J/cm^2	540J/cm^2	560J/cm^2	560J/cm^2	560J/cm^2
	4 mm	N/A	N/A	130J/cm^2	170J/cm^2	215J/cm^2	260J/cm^2	300J/cm^2	310J/cm^2	310J/cm^2	310J/cm^2
	5 mm	N/A	N/A	80J/cm^2	110J/cm^2	135J/cm^2	165J/cm^2	195J/cm^2	200J/cm^2	200J/cm^2	200J/cm^2

Minimum Fluence: 55J/cm^2 for ≤3mm
5 J/cm^2 for >3mm

Max Rep Rate: 1-10Hz; depending on pulse duration and fluence settings

VersaStat 10mm

The 10mm VersaStat handpiece is a non-sterile laser delivery device designed for large spot delivery of Nd:YAG laser energy. The handpiece is designed for optimal and safe hair removal and subablative skin resurfacing. Refer to the 10mm VersaStat Product Insert for detailed use of the devices, including cleaning.

WARNING:
Do not sterilize the VersaStat 10mm or the calibration inserts.

Set Up and Calibration

To connect the 10mm VersaStat handpiece to the laser insert the SmartConnector on the proximal end of the fiber into the delivery device port of the laser and turn it ¼ turn clockwise. The laser display will indicate the option for calibration. By choosing to bypass calibration the system will automatically select a default calibration value. If calibration is desired, perform the following steps:

1. Do NOT calibrate with a cold cooling tip/window, calibrate the handpiece when the cooling tip/window is at room temperature. If an attempt is made to calibrate a chilled handpiece, the laser will use a default calibration.
2. Attach the VersaStat 10mm calibration insert to the output tip of the device
3. Insert the distal end of the device into the calibration port and hold it in place until the system indicates successful calibration
4. Remove the device from the calibration port and remove the calibration insert; device calibration below 80% will limit the maximum fluence settings.

Note:
When calibration is complete attach the VersaStat 10mm cooling lines and/or turn on the chiller and allow time for the handpiece tip/window to reach a suitable temperature, observe the temperature indication dot and use only when the dot is blue. Then set the laser parameters to the desired levels and proceed by placing the laser in READY mode.

VersaStat 10mm Parameter Range

The table depicts a sampling of maximum fluence settings for the 10mm VersaStat at various pulse width settings. The max repetition rate (not shown in the table) will decrease as pulse durations and fluence settings are increased. Device calibration below 80% will limit the maximum fluence settings.

	Pulse Duration									
	22 ms	30 ms	40 ms	50 ms	60ms	65 ms	70 ms	80 ms	90 ms	100 ms
10 mm Spot Size	8J/cm^2	24J/cm^2	32J/cm^2	40J/cm^2	48J/cm^2	50J/cm^2	50J/cm^2	50J/cm^2	50J/cm^2	50J/cm^2

Minimum Fluence: 5 J/cm^2

Max Rep Rate: 1-10Hz; depending on pulse duration and fluence settings

	100 ms
	900J/cm^2
	500J/cm^2
	200J/cm^2

SmartScan Plus™

The SmartScan Plus scanning device is a microprocessor-controlled delivery system designed to deliver homogeneous treatment patterns. The scanning device is used in conjunction with an active cooling feature. The cooling system consists of a chiller that circulates cold water through hoses to the scanner chilling tip. The chilled water circulates through the chilling tip providing continuous cooling to the sapphire window. The scanner is not designed to be used in a sterile environment. Refer to the SmartScan Plus Product Insert for detailed use of the device, including cleaning.

WARNING:
Do not sterilize the SmartScan Plus, cooling tip or the calibration inserts.

Set Up and Calibration

With the laser turned off laser insert the SmartScan electrical connector into the receptacle on the front of the laser. Then insert the SmartConnector on the proximal end of the fiber into the delivery device port of the laser and turn it ¼ turn clockwise. Turn the laser on, the laser will complete its warm-up (approximately 2 minutes) and then it will indicate the option for calibration. By choosing to bypass calibration the system will automatically default to an 87% calibration value. If calibration is desired, perform the following steps:

1. Do NOT calibrate with a cold cooling tip/window, calibrate the handpiece when the cooling tip/window is at room temperature. If an attempt is made to calibrate a chilled handpiece, the laser will use a default calibration;
2. Attach the SmartScan Plus calibration insert to the cooling tip;
3. Insert the distal end of the device into the calibration port with the button pad facing upward. Release the scanner and let it rest freely during calibration;
4. Remove the device from the calibration port and remove the calibration insert, device calibration below 80% will limit the maximum fluence settings.

Note:
When calibration is complete attach the SmartScan Plus cooling lines and/or turn on the chiller and allow time for the cooling tip/window to reach a suitable temperature. Then set the laser parameters to the desired levels and proceed by placing the laser in READY mode.

WARNING:
Only connect or disconnect the SmartScan Plus electrical cable when the laser is turned OFF.

Handswitch Option

When using the SmartScan Plus the switch used to activate the laser can be either the footswitch or the SmartScan Plus handswitch. The user can select the desired switch via the System Information Menu. The factory default setting is the footswitch, however once changed by the user the last selected switch setting will be stored in laser memory and used the next time the SmartScan Plus is used.

The selection for footswitch or handswitch can be made in the System Information Menu. Press the System Information Button on the back left hand side of the control panel to access the System Information Menu. Rotate the center knob, directly under the word "Active", either FOOT or HAND will be displayed as the knob is rotated. Once the selection is made press the System Information Button again (or wait 20 seconds) to return to the main screen.

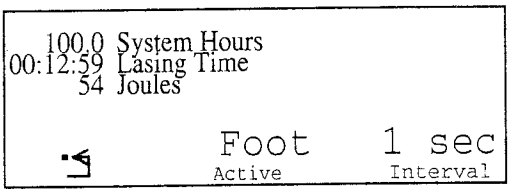
Interval Between Patterns

The SmartScan Plus has an adjustable interval (delay) time between the end of one pattern and the start of the next pattern, when the foot/hand switch is continuously depressed. Upon completion of a pattern this interval allows time to move the scanner to the next area for treatment without having to release the foot/hand switch.

The Interval setting can be made in the System Information Menu. Press the System Information Button on the back left hand side of the control panel to access the System Information Menu. Rotate the right knob, directly under the word "Interval", to select the desired delay time. Once the selection is made press the System Information Button again (or wait 20 seconds) to return to the main screen.

System Information Menu: With SmartScan Plus

When the SmartScan Plus scanner is used with the laser the System Information Menu looks like this:



1(800)356-7600

SmartScan Plus Parameter Range

The table depicts a sampling of maximum fluence settings for various pulse duration settings with the SmartScan Plus. The max repetition rate (not shown in the table) will decrease as pulse durations and fluence settings are increased. Device calibration below 80% will limit the maximum fluence settings.

	Pulse Duration							
	30 ms	40 ms	50 ms	60 ms	70 ms	80 ms	90 ms	100 ms
5 mm Spot Size	90J/cm^2	120J/cm^2	150J/cm^2	185J/cm^2	200J/cm^2	200J/cm^2	200J/cm^2	200J/cm^2

Minimum Fluence: 5 J/cm^2
Max Rep Rate: 1-10Hz; depending on pulse duration and fluence settings

Turning the System Off

1. Turn the key switch to the OFF position and remove the key;
2. Turn the chiller switch to the OFF position;
3. Inspect and clean the delivery device;
4. Switch the circuit breaker to the OFF position.

Maintenance

The Lyra *i* Laser System has been designed to provide trouble-free operation with minimal maintenance. This section provides information on the routine maintenance and care required for this laser system.

The laser, cooling system, and control electronics are enclosed in a tamper-resistant console. The laser system does not contain any user serviceable components. Operator maintenance is limited to cleaning the outside surface of the laser. A Laserscope trained technician is required for internal maintenance.

Note:

Laserscope will make available on request information to appropriately qualified technical personnel to repair the parts of the product that are designated as repairable.

WARNING:

The Lyra *i* Laser System requires technical maintenance every 500 hours or every 6 months, which ever comes first. Failure to complete this maintenance can cause a safety hazard or a degradation in system performance.

Calibration of the Laser System

Laserscope recommends that the system be calibrated every 500 hours or every 6 months, which ever comes first.

Care of the Outside Surfaces

The operator should periodically wipe the outside surfaces of the laser and/or chiller with a cloth dampened with a mild antiseptic solution. Stubborn marks can be removed with a cleaning cloth dampened with a weak solution of water and mild detergent or a cleaning agent.

When cleaning the laser, follow these instructions:

- NEVER use harsh or abrasive cleansers, especially on the Control Panel Display. Damage to the finish will result.
- NEVER pour water or any other liquid over the console. If any liquid is spilled on the console and it is thought that some may have gone inside, TURN THE UNIT OFF and call the Laserscope Customer Response Center or your local Laserscope distributor.

System Monitoring

Whenever the system detects a problem, a message will appear on the screen. Depending upon the severity of the problem, the system will either maintain status (Information Messages) or require a solution before reactivating (System Prompts and Service Prompts).

System Prompts

A System Prompt will appear and replace the main display. System Prompts require that corrective action be taken. The System Prompts are as follows:

• Emergency Off	Emergency off has been activated, system will restart after pressing the READY/STANDBY button
• Attach Device	Insert device's SmartConnector into the device port
• Device Port Overheat	Allow system to sit in STANDBY mode for several minutes to cool device port, call for service if problem persists
• Calibration Error	Attempt to recalibrate, try an alternative device if possible, call for service if problem persist
• Device Not Recognized	Defective device or device not intended for use
• Not In Ready	Release the footswitch and place the system in READY mode
• Remote Interlock Open	Ensure the door interlock circuit is closed
• Temperature Too High	Allow system to sit in STANDBY mode for several minutes to cool down, make sure the front and rear cooling vents are unobstructed, call for service if problem persists
• Warm-up	Wait for the warm-up to complete (approximately 2 minutes)
• Service Recommended	Contact Laserscope to arrange a standard preventive maintenance service. (US: 800 356-7600)
• Water Low	Add deionized or distilled water to the laser per the Water Fill Kit Product Insert instructions.
• Chiller Not Ready Please Wait or Press Standby to Continue	Chiller temperature is too warm. Wait for chiller to cool down or press STANDBY to allow handpiece calibration.

• Check Handpiece Temperature Press Standby to Continue	Reminder to check the handpiece temperature on the operator's skin to ensure that the handpiece is cool.
• Handpiece is Chilled Using Default Calibration	Handpiece is chilled and cannot be calibrated. The laser will use a default calibration. Calibrate handpiece only when at room temperature.
• Check Chiller	Chiller has one of the following problems: 1. No water flow. Check power cord, ON/OFF Switch, water level, and handpiece water connections. 2. No connection between laser and chiller. Check Chiller Interface Cable connection.
• **CAUTION!** Cooling Required Continue With Alternate Or No Cooling? YES NO	Allows user to bypass chiller monitoring and continue to use the laser without chiller monitoring. Screen is accessed by pressing the System Information Button on the rear of the display while the Check Chiller message is displayed. CAUTION! Cooling is required when using this laser.

Service Prompts

A Service Prompt will appear and replace the main display. If the problem persists the operator should note the problem number and contact Laserscope Customer Service or your local Laserscope distributor.

Problem	Description
10-19:	Coolant System Problem
20-29:	Lamp Problem
30-39	Detector Problem
40-59:	Power Measurement Problem
60-69:	Shutter Problem
70-79:	Control Board Problem
80-89:	Low Voltage Power Supply Problem
90-99	Unassigned block
100-119:	Scanner Problem
130-139	VersaStat *i* Problem

Laser Models and Accessories

Part Number	Description
0010-8820	Lyra *i*, USA, 208V/20A
0010-8880	Lyra *i*, with SmartScan Plus, USA, 208V/20A
0010-8890	Lyra *i*, English 208V/20A
0010-8900	Lyra *i*, with SmartScan Plus, English, 208V/20A
0010-8910	Lyra *i*, German, 208V/20A
0010-8920	Lyra *i*, with SmartScan Plus, German, 208V/20A
0010-8930	Lyra *i*, Spanish 208V/20A
0010-8940	Lyra *i*, with SmartScan Plus, Spanish, 208V/20A
0010-8950	Lyra *i*, French, 208V/20A
0010-8960	Lyra *i*, with SmartScan Plus, French, 208V/20A
0010-8970	Lyra *i*, Japan 208V/20A
0010-8980	Lyra *i*, with SmartScan Plus, Japan, 208V/20A
0010-8590	Cart/Chiller 115V
0010-8591	Cart/Chiller 230V
0010-8860	VersaStat *i*
0010-8810	VersaStat *i*, Calibration Insert
0010-8620	VersaStat, 10mm
0010-8640	VersaStat 10mm, Calibration Insert
0010-8600	Coolspot, Recirculating
0010-8611	VersaStatRC, 1.5mm
0010-8612	VersaStatRC, 3mm
0010-8613	VersaStatRC, 5mm
0010-1550	SmartScan Plus, Lyra
0010-1590	Calibration Insert, SmartScan Plus
0010-1580	Window Cell, SmartScan Plus, Lyra
0010-6102	Fiber, SmartScan Plus, Lyra
0010-9120	Lyra *i* Operator's Manual
0010-1020	Protective Glasses, IR Lasers
0010-1030	Protective Goggles, IR Lasers
0010-0693	Laser in Use Signs, Lyra, USA

Section 5: Professional Information

Healthcare Professionals Education and Training

Standards of training for surgeons have been established by the American Society for Lasers in Medicine and Surgery (ASLMS). These standards include the following:

- Published literature
- General laser physics, biology and treatment techniques for each specific disease entity
- Treatment techniques for other surgical modalities in several specialties
- Familiarization with treatment parameters using all laser types, such as Argon, Ho:YAG, Tune-able Dye, CO2, KTP and Nd:YAG.
- Attendance at medical meetings dealing with the use of the laser.
- Attendance at seminars and hands-on workshops on laser therapy in a specific specialty. (Laserscope maintains a listing of instructional courses and preceptorship sites in a broad range of medical specialties. Within the United States, contact the Customer Response Center at (800) 356-7600 for more details.)
- Preceptorships should be made as frequently as possible with other doctors who are performing laser therapy. These usually allow in-depth discussions of all aspects of laser treatment, along with the possibility of observing or participating in actual cases.

For further information about ASLMS, write:

Lasers in Medicine and Surgery
605 Third Avenue
New York, NY 10158
Membership Information: (715) 845-9283

General Warnings and Precautions for the Laser System

The surgeon should become fully acquainted with the unique surgical effects produced with the 1064 nm laser wavelength before using the Lyra *i* Laser System clinically. These effects include coagulation, depth of penetration, and cutting intensity.

Caution should be used with surgical power and timing duration until the surgeon is completely familiar with the biological interactions of the laser energy on various types of tissue. Unless otherwise stated in the specific application section, the surgeon should begin at the lowest power and use short duration exposures. The surgeon should note the surgical effect and adjust the settings until the desired surgical effect is obtained.

The following warnings and precautions are applicable for each surgical specialty contained in this manual. For specific application warnings and precautions, see the section specific to a given surgical specialty.

- The Lyra *i* Laser System is a surgical device that should be used only by doctor who have been trained in laser surgery through courses, preceptorships, and under the guidance of other doctors knowledgeable in laser use. No claim is made that the laser will cure any medical condition.

- BEFORE operating the laser system, doctors and all staff operating the laser should carefully read the Safety Section of this manual.
- Prior to turning the laser system on, operating room personnel and the patient should be wearing protective eyewear suitable for Nd:YAG laser energy.
- Doctors using Laserscope's Lyra *i* Laser System must understand the laser's unique properties prior to using the device.
- When used in either a contact or non-contact application, the Nd:YAG wavelength penetrates biological tissues to significantly different levels than does other wavelengths.
- Careful assessment of the target and surrounding tissue should be made, and appropriate power and pulse duration should always be used.
- Tissue perforation can result if excessive laser energy is applied. This can occur through the use of excessive laser power or the application of power for excessive periods of time, particularly in diseased tissue.
- Aim and use the laser only on tissues that are in full view.
- Extra caution should be used when lasing tissue close to known arteries, eyes and nerves.
- Begin laser treatment at the lowest power, with short duration exposures until fully familiar with the tissue effects of the applicable wavelength.
- Flash fires can occur. Refer to the Safety Section for more information. A basin of water should be available in case a fire.
- Laserscope has no clinical information or experience concerning the use of Lyra *i* Laser System on pregnant women or nursing mothers.
- Patients who experience discomfort during laser treatment may require a topical anesthetic.
- As with conventional non-laser surgical procedures, there is no guarantee that treatment with the Lyra *i* Laser System will entirely eliminate the diseased entity. Repeated treatment or alternative therapies may subsequently be required.
- The laser may not be effective for coagulation in massive hemorrhage situations. The surgeon must be prepared to control hemorrhages with strident alternative non-laser techniques, such as ligature or electrocautery.
- Alterations in surgical approach or technique may be required to accommodate laser use.
- The doctor should schedule follow-up visits in the same manner as for any patient undergoing such surgery with other modalities.
- Care must be taken to protect endotracheal tubes from laser radiation. Ignition or perforation of endotracheal tubes by the laser beam could result in serious or fatal patient complications.

Surgical Complications and Risks

The same complications and risks that exist for conventional or traditional surgery exist for laser surgery. These include, but are not limited to, the following:

Non-Thermal Complications and Risks:

- Perforation
- Aspiration
- Induced hemorrhage
- Allergic reaction to medication
- Hypertension
- Arrhythmia

- Pain
- Gas over-distension
- Pneumothorax
- Infection

Thermal (Acute) Complications and Risks:

- Induced hemorrhage
- Ulceration
- Perforation
- Edema
- Erythema
- Pain
- Discoloration
- Scarring
- Fever
- Leukocytosis
- Chills

Thermal (Chronic) Complications and Risks:

- Delay in healing
- Perforation
- Stricture
- Discoloration
- Scarring
- Delayed hemorrhage
- Sepsis
- Embolism

Contraindications for Laser Surgery

The laser system should only be used in conditions where its use is appropriate and of proven efficacy. Clinical applications should be under the direct supervision of a qualified surgeon. The use of the laser is contraindicated for patients:

- Whose general medical condition contraindicates surgical intervention
- Where appropriate anesthesia is contraindicated by patient history
- Where tissue (especially tumors) has calcified
- Where laser therapy is not considered the treatment of choice

Clinical Specialty

This section provides information on the use of the Lyra *i* Laser System clinical specialty. Information includes procedural recommendations along with specific indications and contraindications. The information provided in this section is not intended to be all-inclusive and is not intended to replace surgeon training or experience. The regulatory information provided is applicable only in the United States.

Clinical Specialty Cleared for Laser Surgery

Laserscope has secured clearance to market the Lyra *i* Laser System for the specific clinical application listed herein. This application has been reviewed by the FDA through the 510(k) process and has been determined to be substantially equivalent to previously cleared products. As mentioned previously, the determination of substantial equivalence by the FDA does not denote official approval of the device but it does allow Laserscope to market the Lyra *i* Laser System for the application mentioned hereafter.

Nd:YAG Dermatology Indications:

- Photocoagulation of pigmented and vascular lesions to reduce lesion size.
- For the removal and lightening of unwanted hair in Fitzpatrick Skin Types I to VI.
- Intended to effect stable long-term, or permanent hair reduction in skin types I - VI through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as a long-term stable reduction in the number of hairs re-growing after a treatment regimen.
- For the removal of unwanted body hair that causes the condition known as Pseudofolliculitis barbae (PFB)(Razor Bumps) in Fitzpatrick Skin Types I to VI.
- Vessel coagulation for the treatment of leg veins.

Note:

Treatment with Nd:YAG laser energy results in deep penetrating tissue interaction. Lesion color may be affected by this procedure.

Specific Warnings and Precautions:

- It is essential that the surgeon and attending staff be trained in all aspects of this procedure. No surgeon should use these laser products for Dermatology applications without first obtaining detailed instructions in laser use.
- Refer to General Warnings and Precautions for the Lyra *i* Laser System for additional information.
- If the area to be treated would be inaccessible if the patient wore laser protective eyewear, use laser corneal protectors. For further information, see the *Safety* Section of this manual.
- Not all lesions respond positively to laser treatment. Therefore, it is advisable to "test patch" patients and evaluate the results prior to proceeding to treatment.
- Dark-skinned patients must be carefully evaluated by the surgeon for their risk of discoloration, scarring, keloid formation, and/or indentation versus the treatment-to-benefit ratio.
- Lesions that have been previously treated with lasers or chemicals should be retreated with caution and with the lowest energy possible in order to avoid damage to previously treated skin.
- Treatment should be done in a "dot" type fashion in areas where the skin is thin, such as the temple or the scalp.
- Use the lowest energy possible to achieve treatment effect.

- Due to concerns about scarring, special caution should be used when treating the pediatric population with the Nd:YAG wavelength.

Specific Complications and Risks:

- Incomplete removal or recurrence of lesion
- Scarring (hypertrophic or non-hypertrophic)
- Burns (superficial to full thickness)
- Excessive tissue destruction
- Ulceration
- Hypopigmentation/Hyperpigmentation
- Induced hemorrhage
- Edema
- Pain
- Long-term effects of this procedure are not known to date. However, based on current results, long-term complications are not expected.
- Failure of the procedure. A) Although clinical studies have shown efficacy in treating vascular lesions, it is possible that there may be regeneration of some ectatic vessels. Should this happen, further laser treatment may be necessary. B) Although clinical studies have shown efficacy in hair removal, additional laser treatments may be necessary to achieve the desired effect.

Section 6: Warranty Policy and Product Returns

Warranty Policy

Laserscope warrants the Lyra *i* Laser System and its delivery devices against defects in materials and workmanship for one year. The warranty period begins on the date of installation where installation is included in the purchase price and on the date of shipment where installation is not included in the purchase price.

If Laserscope receives notice of such defects during the warranty period, Laserscope shall, at its option, either repair or replace equipment or components that prove to be defective. Laserscope retains the option to replace equipment/components under warranty with new or refurbished equipment/components.

Warranty service is performed either on site or at a Laserscope facility, at Laserscope's option. When warranty services are provided on site, the work will be performed at the buyer's facility at no charge. When warranty services are provided at Laserscope, products must be returned to a Laserscope service facility designated by Laserscope. Products may only be returned with the prior approval of Laserscope. Such approval must be evidenced by a valid Return Material Authorization (RMA) number issued by Laserscope headquarters personnel or your local Laserscope distributor. The buyer shall pre-pay shipping charges (and shall pay all duties and taxes) for products returned to Laserscope. Laserscope shall pay for return of products to the buyer. The buyer agrees to make the equipment available to Laserscope during normal business hours. When warranty work is performed at the buyer's facility, such work shall be performed during normal business hours. If the buyer requests work to be performed outside of normal business hours, then the buyer shall pay reasonable charges for the incremental cost of such work.

Limitation of Warranty

The foregoing warranty shall be voided where, in Laserscope's judgment, there has been:

- Improper or inadequate maintenance by the user;
- Unauthorized modification or misuse;
- Operation outside of the environment specification for the product;
- Improper site preparation and maintenance, including, but not limited to, improper electrical utilities;
- Use of delivery devices or accessories not manufactured by Laserscope or approved for use with the Laserscope system.

THE WARRANTY SET FORTH ABOVE IS EXCLUSIVE AND NO OTHER WARRANTY, WHETHER WRITTEN OR ORAL, IS EXPRESSED OR IMPLIED. LASERSCOPE SPECIFICALLY DISCLAIMS THE IMPLIED WARRANTIES OR MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. THE REMEDIES PROVIDED HEREIN ARE THE BUYER'S SOLE AND EXCLUSIVE REMEDIES. IN NO EVENT SHALL LASERSCOPE BE LIABLE FOR DIRECT, INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES

(INCLUDING LOSS OF PROFITS), WHETHER BASED ON CONTRACT, TORT, OR ANY OTHER LEGAL THEORY.

Product Returns

Generally, any Laserscope product that fails during its warranty period because of defects in materials or workmanship—NOT MISUSE—may be returned by the customer to Laserscope for replacement or repair at Laserscope's discretion. Additionally, certain accessories that fail after the warranty period has expired may be returned for repair. After warranty, the customer may be responsible for repair costs. All returns are handled by the Laserscope Customer Response Center or your local Laserscope distributor. Within the United States, you can reach someone at the Customer Response Center by calling (800) 356-7600 Monday through Friday, 8:00 a.m. to 4:30 p.m. Pacific Standard Time. Outside of the United States, contact your local Laserscope distributor.

Handpiece/Scanner

In order to protect the customer and Laserscope, all handpieces/scanners must be cleaned prior to return. If a handpiece or scanner has not been used, and is in its original plastic bag (unopened), it may be returned non-sterile. The Laserscope Customer Response Center will give the customer an additional code to add to the RMA number to verify that this is acceptable. Items must be returned within 15 days. A 20% restocking fee will be charged for unused/unopened returned products.

Return Material Authorization

If you return a failed item that is under warranty, Laserscope will credit your account, repair, or replace the item only if you obtain a Return Material Authorization (RMA) number from Laserscope's Customer Response Center.

Obtaining a Return Material Authorization (RMA) Number:

When you call the Customer Response Center to obtain an RMA number, you will be asked to provide the following information:

1. Your facility: Customer name, address and contact person.
2. Your Laserscope Customer Number.
3. Your Laserscope Sales Order Number.
4. Your original Purchase Order Number.
5. Catalog Number of item to be returned.
6. Serial or Lot Number of item to be returned.
7. Reason for return (including error codes, if available).

NOTE:

If a damaged item is not received by Laserscope within 10 days of shipment of the replacement item, the customer will be invoiced for the list price of the replacement item.

Replacement Items Out of Stock or Not Timely Delivered:

If, as a result of unforeseen events, Laserscope does not have the appropriate replacement item in stock or the replacement item is not timely delivered, Laserscope assumes no responsibility for monetary loss or damage resulting to the customer/end-user.

Determining if Credit is Due:

Within 15 days of receipt of a returned item, Laserscope will evaluate and test the returned item to determine if credit is due the customer. Laserscope warrants products only for defects in materials and workmanship and only for a specific period, so it is possible that returned items may not be credited to a customer's account.