



LASERSCOPE®

Venus Laser

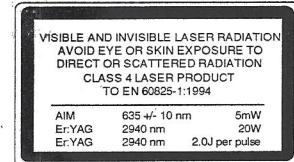
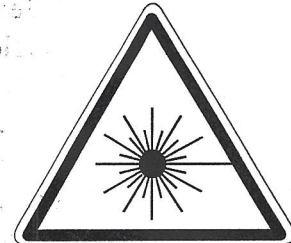
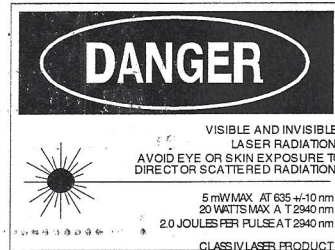
OPERATOR MANUAL
WORLD VERSION

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

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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Rev D

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Section 1: Introduction



Introduction

Manual Overview

This manual contains the safety, installation, and operating requirements for the Laserscope Venus Laser System. It also provides information on delivery devices, eye protection, maintenance, and warranty for this system. Section 9 provides information to medical professionals regarding training and clinical procedures.

Read this manual thoroughly to become familiar with the Venus Laser System before any surgical procedure is attempted. All laser systems should be used and operated only by qualified personnel.

CAUTION

The use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure. U.S. Federal law restricts this device to sale by or on the order of a physician. Laserscope medical lasers and laser delivery systems are intended solely for physicians trained in the use of these instruments.

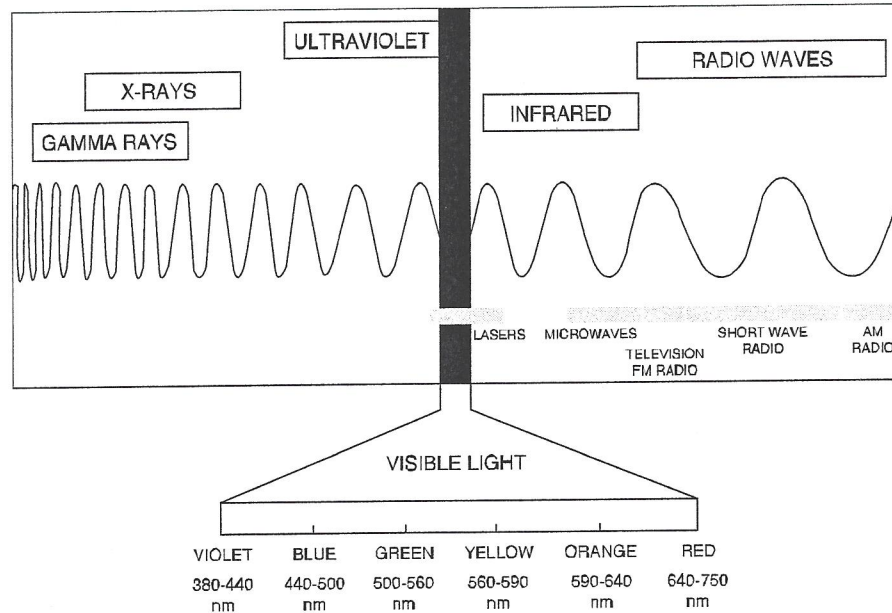


Figure 1.1 Electromagnetic Spectrum.

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.

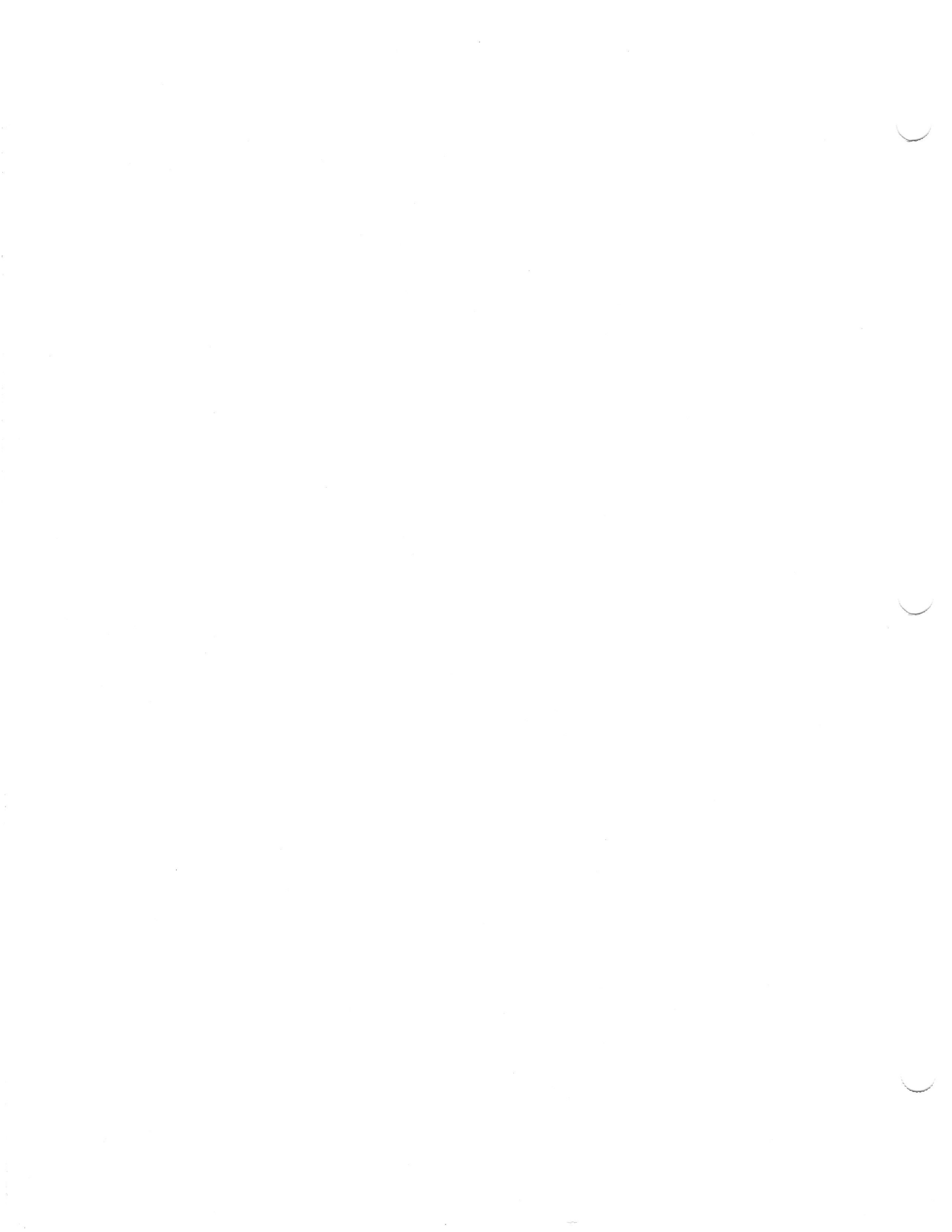
In its simplest form, a laser consists of a lasing medium contained between two mirrors. Electrons in the lasing medium are excited by a strong energy source, such as an arc lamp. These excited electrons emit some of their energy as photons, and return to their normal (ground) state. Most of the light 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 associated acronym, **LASER**.

The light emitted from the lasing medium may be visible, infrared, or ultraviolet, depending upon the medium. Figure 1.1 shows the electromagnetic energy spectrum which covers all wavelengths and frequencies of radiation.

Erbium Lasers

In the Venus laser, the lasing medium is an yttrium aluminum garnet (YAG rod) that has been doped with a small amount of the element erbium (ER). In this system, the electrons of the Erbium atoms are excited by a flashlamp and release photons of a characteristic wavelength. The light energy that is emitted from this source has a wavelength of 2940 nm¹ which is in the infrared portion of the spectrum.

1 nm = Nanometer, or 1×10^{-9} meters



Section 2: Safety



Hazards and Precautions

A laser produces 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

Laser light presents a severe eye hazard and a potential for burns or fire. The AIM beam may be viewed by an unprotected eye. Never view the surgical beam directly or by reflection. Avoid exposure to the laser beam. Take all necessary protective measures in areas where the laser is being used.

Eye Injury

2940 nm light is strongly absorbed by water and biological tissue. This light can cause an accidental corneal burn. 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 where appropriate, for the patient. See the *Eye Protection Information Guide* in this section of the manual for more information regarding eye protection.

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.

Ignition of Flammable Materials

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.

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 plume 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. Figure 2.1 are examples of signs suitable for use with the Venus Laser System.

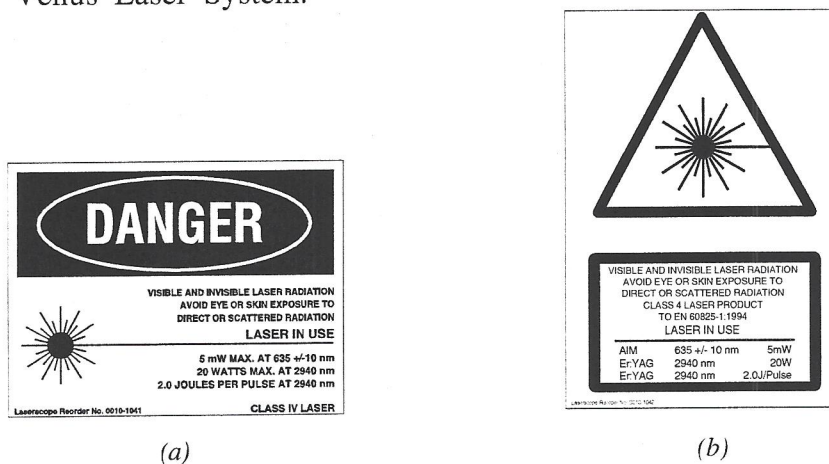


Figure 2.1 Erbium Laser In Use Signs: (a) within the U.S., (b) outside the U.S.

Remote Door 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 door 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, the operator can place the system back in READY and reactivate the surgical beam. The laser cannot be placed in READY unless the interlock is reconnected.

If the use of the remote door interlock is desired, the maintenance personnel at the user's facility can connect it. Access to the laser unit's interlock is made via a socket located on the back panel of the laser.

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;
- Prevent combustion of methane gas by packing the rectum during perineal procedures;
- Review *Anesthesia Considerations* in this section of the manual for specific information regarding endotracheal fires; and
- Review reference Section 6, *Professional Information*, for information regarding specific laser procedures.

IMPORTANT NOTE

All lasers operate with a keyswitch. Keep the laser key in a designated place and allow only trained personnel access to the key.

Eye Protection Information Guide

Introduction

It is the responsibility of the hospital or medical institution where the laser surgery is performed 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.

Laserscope's Erbium Protective Spectacles have been designed to protect operating room personnel from the laser energy produced by the Venus Laser System. The Erbium Protective Spectacles are available for 2940 nm wavelength protection. The lens material in the spectacles have an optical density (O.D.) greater than 4.0. The lenses are clear and cause no noticeable color distortion. For additional information about their use, cleaning, and warranty, consult the applicable product insert or contact the Laserscope Customer Response Center or your local Laserscope distributor.

This guide will address some common questions raised on the issue of laser eye protection. The information contained in this guide is designed to assist you in tailoring a policy to fit the needs of your institution, particularly in relation to the use of the Venus Laser System.

Common Questions about Eye Protection

1. "O.D." is marked on the laser eyewear. What does it mean?

O.D. is an acronym for optical density. It is specific to the spectral wavelength marked on the eyewear and represents the capability of the eyewear to block out laser light. The higher the O.D., the greater the amount of light blocked out. The O.D. marked on the eyewear is sufficient to provide protection for the uses described in the associated product insert.

Eyewear is not interchangeable for different wavelengths. Only eyewear designed for use with 2940 nm should be used when viewing the 2940 nm wavelength.

The O.D. of Laserscope eyewear is verified and tested at Laserscope to ensure adequate protection. For more information about the O.D. of Laserscope's eyewear, consult the product insert shipped with the specific eyewear.

2. Why do goggles fog and what can be done to prevent this from happening?

The fogging of goggles is a common problem experienced by many laser users. The warmth of the wearer, stress of the case, and coolness of the procedure room create ideal conditions for condensation to form on all eyewear, despite manufacturing design. The use of anti-fogging agents before each case should reduce the fogging problem.

3. What are some appropriate ways to protect the patient's eyes during laser surgery?

The patient should always be educated about the laser procedure and eye protection requirements prior to the start of the procedure.

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 eyepads, eyeshields, 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.

4. Where can I find additional information about eye safety and protection?

Current literature on laser applications is available in medical libraries.

Additional information on terms, definitions and reference materials may be obtained by reviewing ANSI Z136.1-1988 and ANSI Z136.3-1995, or by contacting:

- Laser Institute of America
12424 Research Parkway, Suite 130
Orlando, FL 32826
- Rockwell Laser Industries
P.O. Box 43010
Cincinnati, OH 45243

Eye Hazards

A laser is concentrated light energy. When focused, it has enough energy to pass through the transparent components of the eye (cornea, lens, aqueous and vitreous humor), and focus on the retina. This light can cause an accidental retinal burn. The degree of burn damage depends on the power of the beam, the focusing lens used, and the duration of the exposure. Eye injury can be avoided with the use of protective eyewear which allows for safe exposure to the laser.

Guidance for the safe use of lasers is given in IEC 825-1. It is also given in two equivalent American National Standards. The first is ANSI Z136.1-1986, *The Safe Use of Lasers*, and covers general use of lasers. The second standard is ANSI Z136.3-1988, *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. Calculations herein are from the ANSI Z136.1-1986 standard.

Maximum Permissible Exposure

IEC 825-1 defines Maximum Permissible Exposure (MPE) in subclause 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 continuous lasers, the MPE is expressed in terms of power density at the eye and is expressed in watts per square centimeter (W/cm^2). The MPE is not as simple as giving one value of the MPE for lasers. The actual MPE depends both on the wavelength of the laser and also the length of the exposure.

Two conditions now have to be considered for the use of a laser and the eye hazards it presents. The first is unintentional exposure, where an unwanted laser beam enters the eye. For MPE calculations, ANSI recommends exposure times of ten seconds.

The other condition that has to be considered is intentional exposure. This occurs when the laser is normally used, and light scattered from the tissue during surgery enters the eye. For MPE calculations, ANSI recommends exposure times of ten minutes (600 seconds). With these assumptions, the MPE values are given in Table 2.1.

Er:YAG Wavelength	Maximum Permissible Exposure	
	Unintentional Viewing (W/cm ²)	Intentional Viewing (W/cm ²)
2940 nm	0.1 (10 sec)	.0837 (600 sec)

Table 2.1 Maximum Permissible Exposure for Intentional and Unintentional Viewing.

These values of the MPE will now be applied to the use of a Venus laser. Consider a laser with 24 watts of average output power at 2940 nm. This is 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 from an object can be hazardous to the eye. We can consider two possible conditions, one where the light from a laser delivery device is aimed directly at the eye, and the other where the diffuse light from a laser is reflected from an object, like a surgical instrument, enters the eye.

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 Venus Laser System. Below is an explanation of the effectivity of protective eyewear.

Optical Density and Attenuation

The amount of protection that eyewear provides is determined by the Optical Density (O.D.) of the eyewear. To define this optical density, first consider a laser beam passing through the lens of the protective eyewear. If the input power is P_{IN} , and after passing through the lens the output power is P_{OUT} , then the attenuation of the eyewear is defined as:

$$\text{Attenuation} = P_{IN} / P_{OUT}$$

The optical density (O.D.) is now defined as:

$$\text{O.D.} = \log_{10} (\text{Attenuation})$$

For example, if the power is reduced by a factor of ten going through the eyewear, then Attenuation = 10 and O.D. = 1. For every factor of ten increase in the attenuation, the O.D. increases by one. Note that the above equation can also be written as:

$$\text{Attenuation} = 10^{\text{O.D.}}$$

With protective eyewear on, the effective power from the laser to damage the eye is reduced by the attenuation. To comply with the ANSI standards the eyewear must attenuate the laser light to a level below the MPE for the worst conceivable case. The worst case scenario for the Venus laser would be to fire the laser directly at the eyewear a point blank range, with the laser set to 24 watts at 10 pps and focused to a 1mm spot for 600 seconds. Although the light is focused to a 1mm diameter spot on the front surface of the eyewear, after traveling the 1 cm distance from the eyewear to the cornea surface the laser beam diameter has increased to a 2 mm diameter spot. The OD requirement for a 2940 nm laser with a pulse duration of 200 microseconds that emits produces 2.4 Joules per pulse at 10 pps can be calculated from the following equation:

$$\text{OD} = -\text{Log} (3.14 \times R^2 \times \text{MPE} / P_{\text{Max}})$$

Where: OD = The OD requirement for the laser protective eyewear.

R = The radius of the smallest spot projected on the cornea (1.0 mm for the Venus).

MPE = The maximum permissible exposure (.1watts/cm² for deliberate viewing of a Venus laser operating at full power for 10 seconds, 8.37 x10⁻² watts/cm² for deliberate viewing of a Venus laser operating at full power for 600 seconds).

P_{Max} = The maximum average power out of the laser (24 watts for the Venus).

When this formula is applied to the Venus laser we find that if the laser were set to its maximum energy per pulse (2.4 joules), at its maximum average power (24 watts), and aimed directly at a persons eye with the smallest possible spot (1mm diameter): eyewear with an OD of 3.88 will provide sufficient protection for 10 seconds and that an OD of 3.96 will provide sufficient protection for 600 seconds. From this we can conclude that laser protective eyewear with an OD of 4.0 is more than sufficient for the most extreme conditions. A higher OD will attenuate more of the light but is not required for surgical applications of the Venus laser.

Anesthesia Considerations

One of the main concerns during oropharyngeal and bronchial procedures is the substantial risk of endotracheal fires. The following sections provide information and safety guidelines which can greatly decrease the risks associated with these procedures. Information is also provided on what to do if such a fire does occur.

Laserscope Anesthesia Recommendations

Laserscope recommends the safety guidelines of US national standard ANSI Z136.3-1995 as follows:

- Use the lowest possible oxygen concentration to support the patient;
- Use the venturi ventilation technique when possible;
- Use intravenous anesthetic agents rather than inhalation techniques;
- Use non-flammable laser-safe endotracheal tubes; and
- Protect the endotracheal tube cuff with wet cottonoids.

Additional Safety Recommendations

In addition to the ANSI recommendations, the following safety recommendations are also advised:

- Use an anesthetic gas mixture incorporating no more than 35% oxygen. (Helium is sometimes used as a gas additive);
- Use sterile water to inflate the endotracheal tube cuff. As an extra precaution, add methylene blue to the water to alert the surgeon if the cuff has been perforated; and
- Use water-soluble lubricant for intubation; glycine and oil-based lubricants tend to hold heat.

Airway Fire Protocol

Always have the following equipment available when oropharyngeal and bronchial laser cases are performed:

- Saline;
- Bronchoscopes, both rigid and flexible;
- Laryngoscopes;
- Endotracheal tubes; and an
- Emergency tracheostomy setup

If there is a fire, immediately:

1. Remove all burning objects from the airway.
2. Maintain patient's airway and ventilate.
3. Immediately shut off the anesthetic gases.
4. Put out any remaining fire.
5. Save and examine the endotracheal tube and other objects.
6. Examine the airway for trauma.
7. Treat burned areas appropriately.

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, Kneeder, 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.

There are many non-U.S. references sources as well.

Safety Features of the Laser System

Safety Regulations

The Venus laser system has all of the safety features required by EN60601-1, EN60601-2-22 and IEC 825-1 including labeling requirements.

The safety features of Laserscope's Venus Laser System are described in the following sections. All required labeling information is also provided in these sections.

System Safety Features

Laserscope's Venus Laser System incorporates the following safety features:

- An automatic circuit breaker shuts the system completely off in the event of an electrical overload.
- The laser provides a procedure room door interlock connection.
- The key can only be removed when the keyswitch is in the OFF position.
- An internal microprocessor continuously monitors the status of the system and displays messages on the control panel screen along with appropriate operator prompts.
- Laser energy cannot be emitted from the system unless a delivery device has been connected.
- A continuous audible tone sounds whenever the laser beam is activated (i.e., control switch is depressed).
- When the system is changed from STANDBY to READY, there is a two-second safety transition period before laser energy can be emitted.

IMPORTANT NOTE

Do not attempt to remove any panel from the laser console. 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

The Venus Laser System meets the following safety classifications:

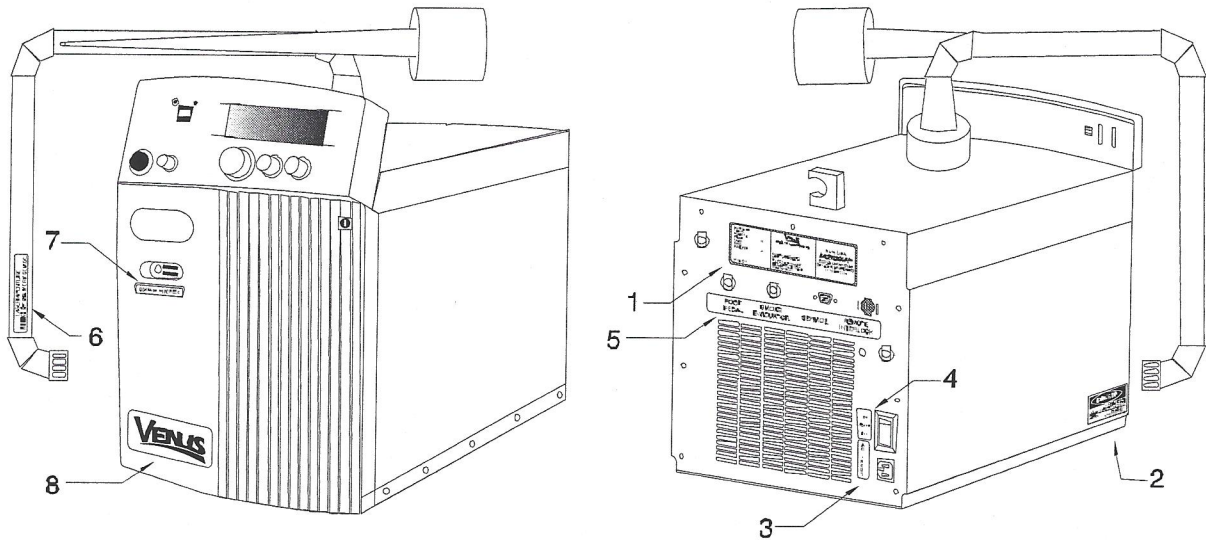
Equipment:	Class 1	IEC 601-1
Working Beam Radiation:	Class 4	IEC 825
AIM Beam Radiation:	Class 3B	IEC 825

The Venus also complies with the requirements for electromagnetic emissions. (EN 55011; class B group 1 and and immunity EN 61000-4-2 through -5).

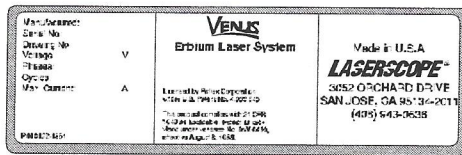
Sound emissions are less than 90 dB (per ANSI S1.4-1983) at a distance of 91 cm.

Labeling

Appropriate information and warning labels and their positions on the Venus Laser System are illustrated in Figure 2.2 on the following page. The actual labels used in these locations are also shown.



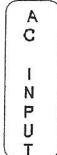
ITEM 1



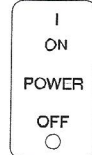
ITEM 2



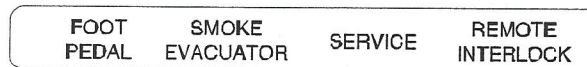
ITEM 3



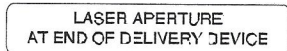
ITEM 4



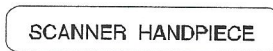
ITEM 5



ITEM 6



ITEM 7



ITEM 8



Figure 2.2a U.S. Product Labeling and Label Locations.

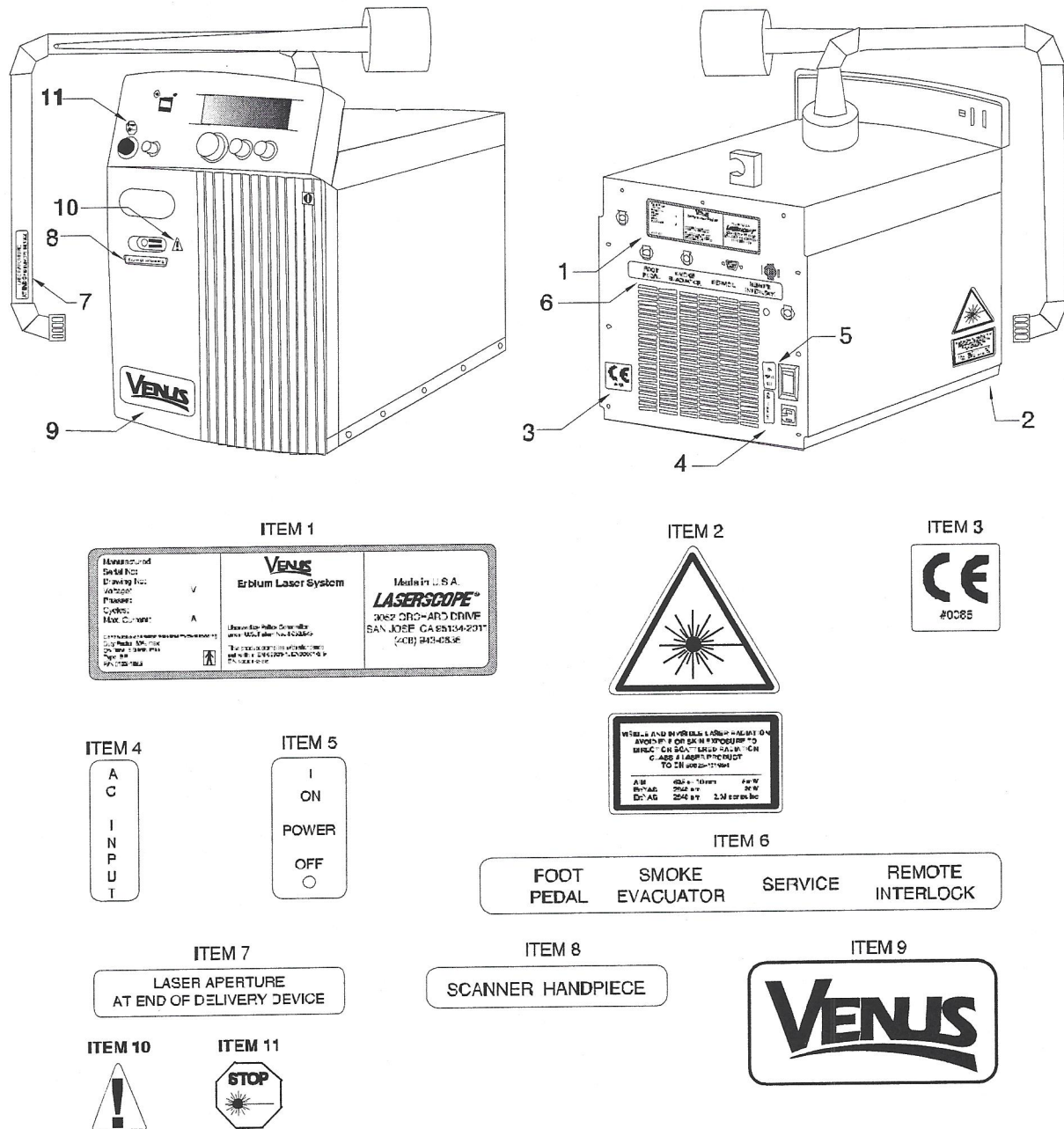


Figure 2.2b International Product Labeling and Label Locations.

Symbols

Symbols that appear on the Venus Laser System are listed and explained in Table 2.2 below.













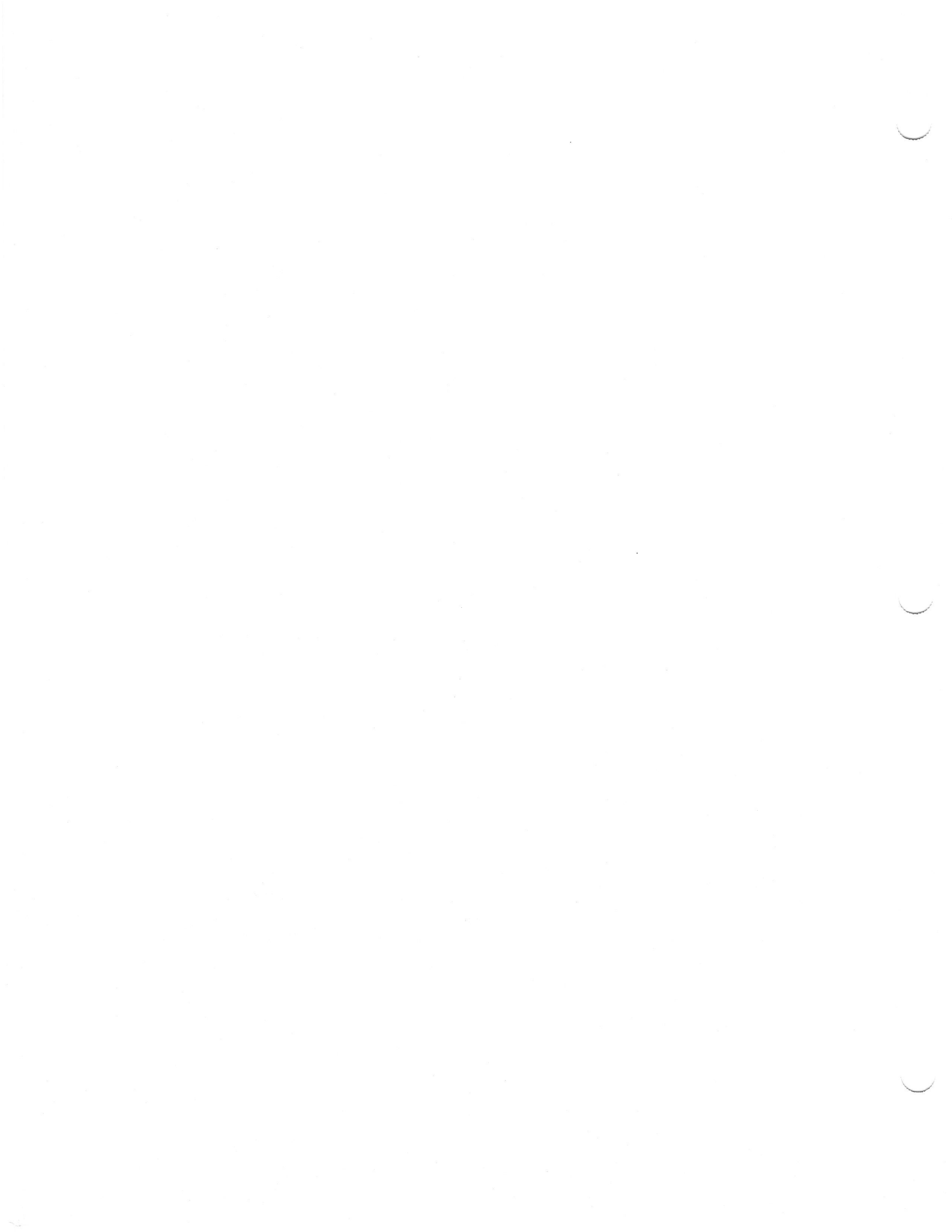
Symbol	Description
	Tone Volume
	Display Brightness
	Laser Radiation (Ready)
	Laser Radiation (Standby)
	See SmartScan Plus Operator's Manual
	System Information (Reset)
	Aim Beam
	Off (power: disconnection from the mains)
	On (power: connection to the mains)
	OFF (Keyswitch)
	ON (Keyswitch)
	Emergency Stop

Table 2.2 Explanation of Symbols

**Section 3:
System Overview,
Installation and Operation**



Overview

The Venus Laser System provides laser energy for use in many surgical and aesthetic procedures. The 2940 nm wavelength is highly absorbed by water. The Erbium wavelength beam is designed for cutting, vaporizing, and coagulating tissue.

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.

Introduction to the System

The entire laser unit and controls are contained in a single console. This console is electrically connected to the facility's power source. The laser energy produced within the unit is delivered to the tissue through an articulated arm and special delivery devices. Figures 3.1 and 3.2 shows the basic system features. Information about specific delivery devices can be found at the end of this section.

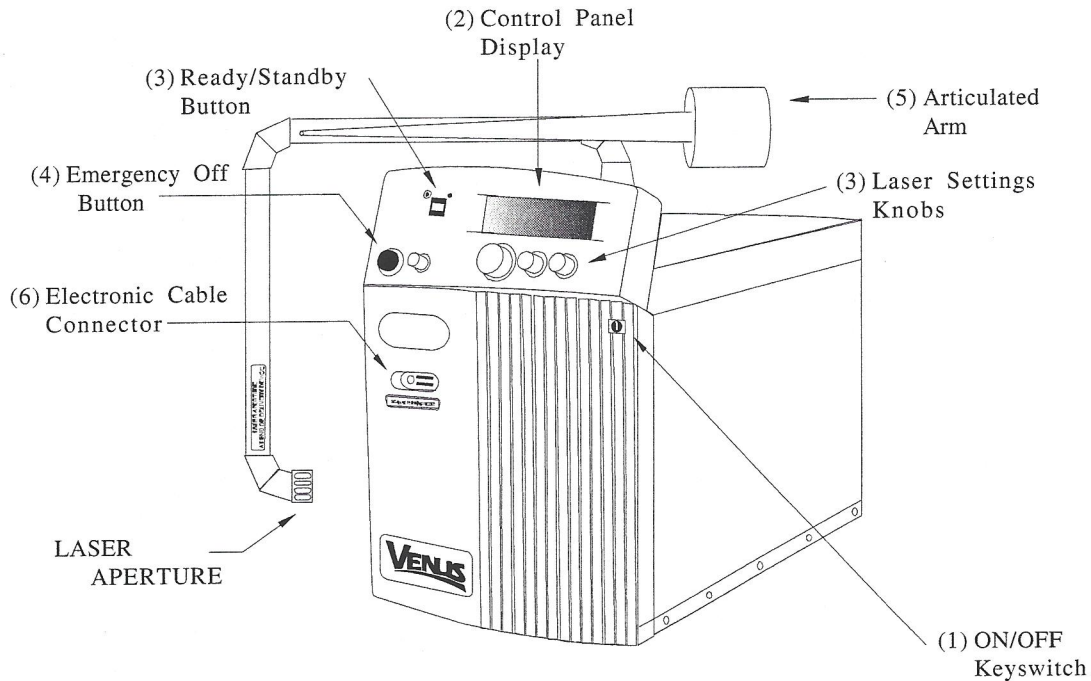


Figure 3.1 Front View of the Venus Laser System.

The following features are shown in Figures 3.1 and 3.2:

- **On/Off Keyswitch (1)**

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.

- **Control Panel Display (2)**

Displays the following operator information:

Laser parameters;

Data on connected devices; and

Information Messages and System Prompts

- **Control Panel Knobs and Buttons (3)**

On the front of the panel, 4 knobs for selection of laser settings, and a READY/STANDBY button for selecting READY or STANDBY. (Fig. 3.1)

On the back of the panel, a System Information button, Tone Volume Control and Display Brightness Control. (Fig. 3.2)

- **Emergency Off Button (4)**

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.

- **Articulated Arm (5)**

The laser aperture and optical connecting port for all delivery devices.

- **Electronic Cable Connector (6)**

Electrical interface for the Scanner delivery device to the laser system.

- **Articulated Arm Retainer (7)**

This clasp holds the articulated arm in place when moving the system or while it's not in use.

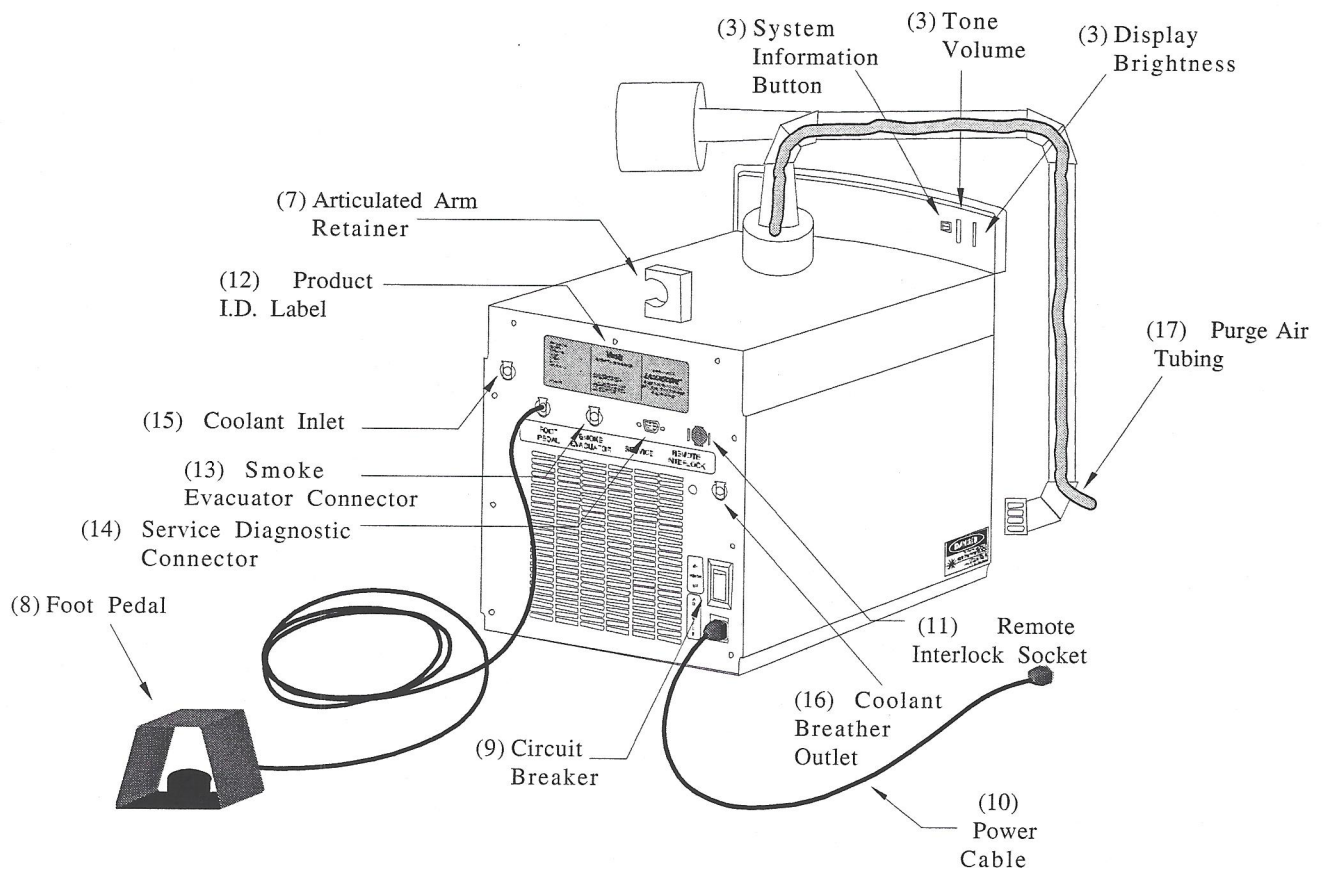


Figure 3.2 Rear View of the Venus Laser System.

- **Foot Pedal and Cable (8)**

The foot pedal is the control switch for most delivery devices.

- **Circuit Breaker (9)**

Automatically trips in the event of a power overload, shutting off power to both the laser and the control electronics.

- **Power Cable (10)**

3 meter removable cable connecting laser to wall electrical outlet.

- **Remote Interlock Socket (11)**

Will disable the laser if the circuit is opened during lasing. Laserscope recommends that the remote interlock cable used be less than 3 meters.

- **Product Identification Label (12)**

Contains serial number and electrical information about the laser system.

- **Smoke Evacuator Connector (13)**

When a smoke evacuator is connected the laser foot pedal will activate the smoke evacuator.

- **Service Diagnostics Connector (14)**

When a service key is connected the laser service screens are enabled.

- **Coolant Inlet (15)**

The laser system coolant reservoir is filled through this port.

- **Coolant Breather Port (16)**

Air is purged from the coolant system via this port.

- **Purge Air Tubing (17)**

When connected to a device this provides positive air pressure (flow) to purge the plume away from the devices optics.

System Features

The Venus Laser System has been designed with the following features. Detailed information on each of these features is provided in the following sections. If more information is needed, contact the Laserscope Customer Response Center or your local Laserscope distributor.

Articulated Arm

The Venus Laser System has one laser aperture for all delivery devices located at the distal end of the articulated arm. The articulated arm contains specially designed optical components that precisely reflect the laser beam down its length to the aperture. This aperture has been designed to accommodate:

- The CBH-2™ Handpiece with 1, 3, 5 and 7 mm lens calls; and
- The SmartScan Plus™ scanning device.

These devices are described at the end of this section.

Scanner Recognition

The Venus Laser System is designed to recognize a SmartScan Plus when it is attached to the laser. The laser automatically shows on the Control Panel Display, the treatment parameters and the scanning parameters. The operator only sees those settings and parameters that are appropriate to the SmartScan Plus.

System Information Display

The total lasing energy, total exposure pulses and system hours are recorded in the System Information Display. The System Information Display is accessed by pressing the System Information button located on the back of the Control Panel. The total lasing energy and total exposure pulses are cumulative, and this information is retained even when a device is disconnected during a procedure. The display can be returned to the initial screen by pressing the button a second time or it will return automatically after 20 seconds.

The operator can zero the lasing energy and exposure pulses by turning the Spot Size/Scan Size knob on the front of the Control Panel. The display can be recalled by turning the knob again. The lasing energy and exposure pulses will also change to zero when the system is turned off. The system hours display cannot be reset except by a Laserscope Service representative.

Purge Air System

The Venus Laser System has an internal purge air system that provides positive air pressure (flow) to delivery devices via the tubing on the articulated arm. This feature prevents particulates like those contained in the smoke plume from damaging the optics in the delivery devices.

Cart (optional)

An optional cart is available with the Venus Laser System. The wheeled cart provides a platform for the laser when counter space is limited, easier mobility, a drawer for storage of accessories. Laserscope recommends using the Aura/Venus Laser Cart ONLY. The cart is designed to support the laser and passes all "tip" tests when used properly.

WARNING

THE SUPPLIED FASTENERS MUST BE USED IF USING THE VENUS LASER CART. The laser is designed to be fastened to the cart with two fasteners included with the cart. Refer to the Laser Cart Product Insert for specific instructions.

Smoke Evacuation (optional)

An optional smoke evacuator is available with the Venus Laser System Cart. The smoke evacuator has a main power switch and utilizes a pneumatic (non-electrical) switch for activation. The laser system and smoke evacuator can be coupled together utilizing the same footswitch, so the smoke evacuator operates only when laser energy is delivered (the laser in READY and the footswitch pressed).

System Installation and Laser Requirements

This section provides a general guideline for the installation of the Venus 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.

Shipment

The Venus Laser System will be shipped in three specially designed boxes. When shipment is received, inspect the exterior container for damage. If there is exterior damage, notify the freight shipping company immediately. **DO NOT UNBOX THE SYSTEM.** After notifying the freight company, call Laserscope or your local Laserscope distributor.

Installation

The Venus Laser System requires a Laserscope Service Representative for installation. The laser is shipped without coolant. It is Laserscope's responsibility to unbox the laser and install it following a specific installation procedure.

Space Requirements

The laser unit's dimensions are: **Height** - 24 inches (61 cm), **Width** - 12 inches (31 cm), **Length** - 23 inches (58 cm). The total system **Weight** is 75 pounds (34 kg). These space requirements are for the laser only. Adding the cart brings the overall height to 50 inches (127 cm), the width to 16 inches (42 cm) and the length to 30 inches (80 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 center line of the treatment area.

Power Requirements

The maximum power consumption of the Venus Laser System at nominal voltage is shown in Table 3.1.

<u>Venus Laser</u>
2.0 Joule/Pulse System 115V/15 A 60 Hz
2.0 Joule/Pulse System 230V/10 A 50/60 Hz

If laser is to be used on a non-dedicated line, for example, both laser and smoke evacuator on same circuit, then the following requirements apply.

<u>Model</u>	<u>Maximum Additional Circuit Load</u>	<u>Maximum Total Power/ Service Requirements</u>
2.0 Joule System	5 A	20 A at 115 V
2.0 Joule System	5 A	15 A at 230 V

Table 3.1 Maximum Power Consumption

The Venus Laser System can function when the voltage of the service line is in the range nominal +/- 10% (207-253 V) under load.

Environmental Requirements

The Venus Laser System has the following environmental requirements for operation and storage:

Temperature Range (ambient):

- Operation: 10 - 40½C (55½ - 104½F).

NOTE:

The maximum pulsed exposure time is 3 minutes. At 40½C (104½F), worst case, the maximum duty cycle is 50%, i.e. 3 minute ON/3 minutes OFF. The duty cycle increases linearly to 100% at 20½C (68½F) and below. The laser system continuously monitors its temperature and will default to Standby mode if the system operation temperature limit is exceeded.

- Storage: 5½ - 50½ C (40½ - 120½ F).

Humidity:

- 5% - 90% non-condensing

Shock and Vibration:

- Crated: 39 N.
- Uncrated: 9.75 N.

Electromagnetic Compatibility:

- In conformance with IEC 601-1-2, radiated and conducted emissions of the Venus are below the levels required by EN55011. Immunity to malfunction (due to spark discharges, AC line voltage disturbances, and high radiation emissions from other equipment) is greater than required by the IEC 801-x family of standards.

Laser Output Specifications

The laser output specifications for the Venus Laser System are listed in Table 3.2 below.

	Venus Laser System
Laser Wavelength	2940 nanometers (infrared)
Laser Type	Pulsed Er:YAG
Maximum Energy	2 joules
Pulse Width	200-300 μ sec.
Maximum Rep. Rate	20 pulses per second
Divergence (typical)	2 degrees +/- 0.5%
Aim Beam Wavelength	635 +/- 10 nanometers (Red)
Max. Aim Beam Power	< 5 milliwatts

Table 3.2 Laser Output Specifications

System Operation

This section describes the settings and button functions on the Control Panel and describes step-by-step instructions on how to operate the system.

CAUTION:

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

Control Panel Settings and Knob/Button Functions

Laser parameters are selected and the system status is changed by using the 4 knobs and 2 buttons on the front of the Control Panel and the 2 slide controls and 1 button on the rear of the Control Panel. 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 control switch is depressed. The control switch is either the footswitch or, in the case of the Scanner, the treatment control button on the device.

Laser parameters are displayed on the Control Panel display. Parameters may be adjusted in discrete increments by turning the appropriate knob. An audible tone will sound when maximum and minimum levels are reached.

System Display Controls

The following controls are located on the back of the Control Panel.

- System Information Button;
- Tone Volume Control; and
- Display Brightness Control.

Laser Beam Controls

The following controls are located on the front of the Control Panel, (except the control switch):

- Ready/Standby Button;
- Energy Knob;
- Pulse Rate/Scan Shape;
- Spot Size/Scan Size;
- Aiming Beam Knob;
- Emergency Off Button;
- Display; and a
- Control Switch (footswitch or handswitch)

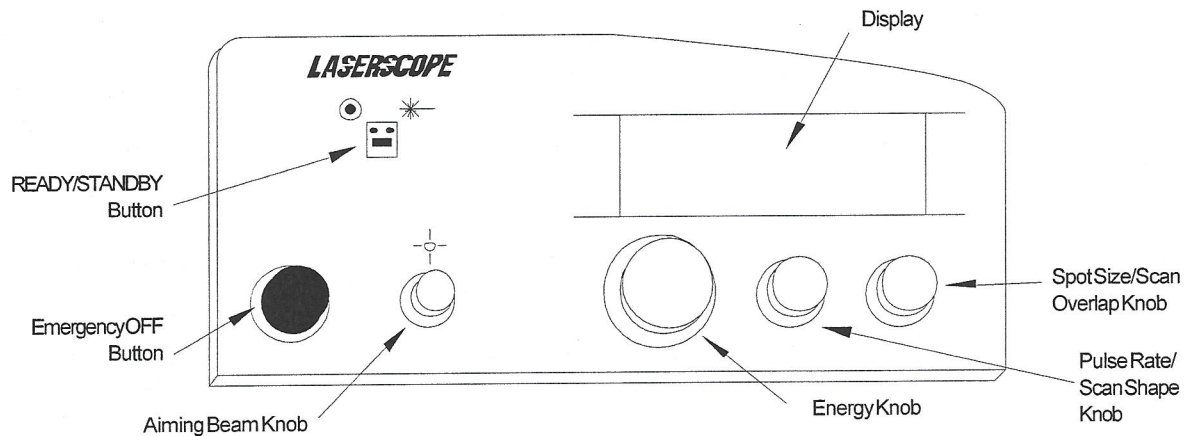


Figure 3.3 Control Panel of Venus Laser System.

Following is a brief description of the function of each of the system display controls located on the back of the control panel. See Figure 3.2:

System Information Button

The System Information Button is located on the back of the Control Panel. When pressed, total joules delivered, exposure pulses and cumulative exposure pulses will appear on the display. The total joules and exposure pulses can be reset to zero by turning the knob farthest to the right (the Spot Size/Scan Overlap Knob) while in this screen. The display can be returned to the initial screen by pressing the button a second time. The total joules and exposure pulses will automatically reset to zero when the system is turned off.

Tone Volume Control

A tone sounds throughout the laser activation period and stops when the treatment switch is released or the treatment cycle is ended. The Tone Volume can be adjusted with the slide control on the back of the Control Panel. The tone level will momentarily sound while being adjusted to give the user audible feedback.

Display Brightness Control

The display is a backlit LCD. The Display Brightness can be adjusted with the slide control on the back of the Control Panel.

Following is a brief description of the function of each of the Laser Beam Controls:

Ready/Standby Button

The Ready/Standby button toggles the system between STANDBY and READY status. A Green READY light is illuminated when in READY. A Yellow light is illuminated when the control switch is activated. In STANDBY, the laser is warmed up and operating, but neither the aiming beam nor the surgical working beam can be emitted. All of the parameters for treatment should be adjusted while the system is in STANDBY.

The aiming beam can also be adjusted in READY. When the desired parameters have been selected, pressing the Ready/Standby button will put the system into READY status. There is a required two-second safety transition period between

STANDBY and READY. Once in READY, laser energy can be emitted when the treatment switch is depressed. By pressing the Ready/Standby button while in READY, the system will revert back to STANDBY.

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.

Energy Knob

The Energy Knob controls the energy or fluence level before treatment. If for any reason the laser cannot attain the energy setting desired it will reduce the pulse rate before reducing the energy level.

Pulse Rate/Scan Shape Knob

The Pulse Rate/Scan Shape knob is a multi-purpose control. When a fixed spot handpiece is attached the knob controls the pulse rate over a range of 3 to 20 pulses per second and single shot. Square, rectangle, triangle, circle, hexagon, parallelogram, line, semi-circle and doughnut scan shapes are available. For detailed information on the scan shapes see the Scanner manual.

Spot Size/Scan Overlap Knob

The Spot Size/Scan Overlap knob is a multi-purpose control. When a handpiece is attached, the knob is used to identify the spot size of the lens cell to the laser allowing it to calculate the fluence. When the Scanner (optional) is connected, the Scan Size knob controls the size of the scan shape from small (S) to extra large (XL). For detailed information on the scan sizes see the Scanner manual.

Aiming Beam Knob

The Aiming Beam Knob controls the Aiming Beam brightness. When the aim beam is adjusted a graphic will temporarily appear along the top of the display indicating the aim level. The display will disappear after 2-3 seconds.

Control Switch

When the system is in Ready mode, the Control Switch allows laser energy to be emitted when pressed. A pneumatic (non-electrical) foot pedal functions as the control switch unless the optional Scanner is attached. When the optional Scanner is attached the laser will default to a hand activated treatment switch located on the handpiece.

Emergency Off Button

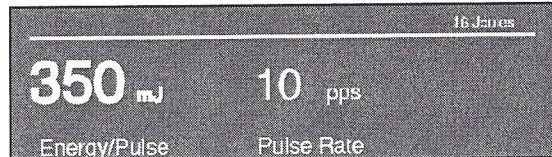
The Emergency Shut Off button on the left-hand side of the Control panel shuts the laser system off immediately. The key must be turned off and back on to reactivate the laser.. This button can be pressed at anytime to stop the laser working beam from being emitted. Pressing the Emergency Shut Off button does not actually shut off the system. It deactivates the laser and places it in a holding status. To restart, turn the key OFF and On again.

Display

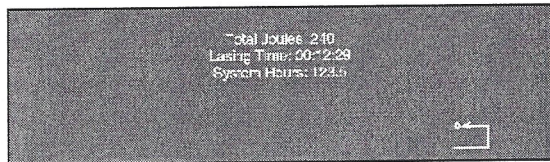
The Control Panel Display is an adjustable brightness backlit LED. All user information is accessible via the display screens. Figure 3.4 contains examples of the display screens



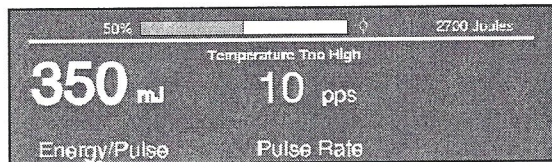
Warmup Screen



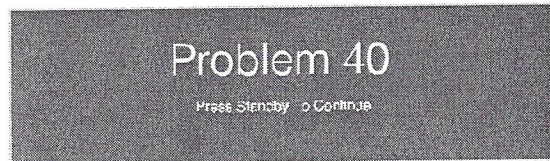
Standby Screen



System Information Screen



Aim Level and Temperature Warning



Problem Screen

Figure 3.4 Venus Laser System Control Panel Displays

System Start-up

The following procedure is recommended for system start-up:

Connecting the System

1. Confirm that the system circuit breaker is in the OFF position to prevent a power surge to the system.
2. Find the power cord for the system. Plug one end into the power connector on the rear panel of the system, and the other end into a grounded outlet.
3. Turn the system circuit breaker to the ON position, pushing the top of the rocker switch in until it clicks.

NOTE

Never block the front or rear cooling system vents.

Turning the System On

1. Turn the Keyswitch ON. A System Warmup message will appear on the display until the laser has warmed up (approximately 2 minutes).

WARNING

All personnel viewing the laser procedure, including the patient, should follow the Eye Protection Policy of the facility.

WARNING

Specific laser eye protection is required for each type of laser. Check the labeling of protective eyewear to ensure that it protects against the 2940 nm wavelength of light being emitted by the laser. See Section 2, Safety, for more information about eye protection.

Delivery Devices

Several delivery devices are available to deliver laser energy to the operative site. These devices are described below. All of the devices are connected to the Venus Laser System via the articulated arm. The devices described in this section include:

- The CBH-2 handpiece; and
- The SmartScan Plus.

General information about each device and its particular capabilities are summarized in this section. More detailed information is contained in the respective delivery device product insert.

WARNING DO NOT USE non-Laserscope delivery devices. Use of non-Laserscope delivery devices or fiber adapters may lead to laser, device and/or user and/or patient harm.

CBH-2™ Handpiece

The CBH-2 handpiece is a non-sterile laser delivery device designed for precise spot delivery of Erbium:YAG laser energy. The handpiece features interchangeable lens cells that produce spot sizes of 3, 5 and 7 millimeters.

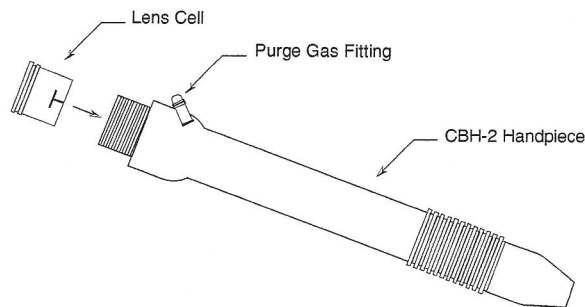


Figure 3.5 CBH-2 Handpiece with Lens Cell

Prior to use, ensure the optic in the lens cell is clean and is properly secured in place.

If the handpiece lens becomes dirty from smoke or debris, it should be cleaned to prevent degrading the beam quality or destroying the parts.

To clean the lens cell, remove the handpiece from the articulated arm. Remove the lens cell from the proximal end of the handpiece. Use a cotton-tipped applicator lightly wetted with absolute alcohol to wipe away particles and remove film debris from the lens. Use each cotton-tipped applicator for one pass, dragging it across the surface. Repeat with as many applicators as necessary to clean the surface. DO NOT rub with excessive force. The optical coating is very delicate and is easily damaged.

The handpiece is provided non-sterile. Laserscope recommends the handpiece be disinfected according to hospital protocol, then sterilized by autoclave before each use according to the following parameters:

<i>Method</i>	<i>Temperature</i>	<i>Time (wrapped)</i>
<i>Pre-vacuum</i>	<i>270½ - 275½ F</i>	<i>4 minutes</i>

WARNING

DO NOT STERILIZE THE LENS CELLS. THE TEMPERATURE AND MOISTURE MAY DAMAGE THE LENS.

Reinsert the lens cell into the CBH-2 handpiece using sterile gloves. Reattach the air purge hose onto the handpiece, taking care not to contaminate the handpiece.

The SmartScan Plus™

The SmartScan Plus is a microprocessor-controlled delivery system that is fitted with a sterilizable Scanner Focal Distance Guide Tip (SFDGT). The scanner delivers homogeneous patterns utilizing the laser beam. Single spot, circle, rectangle, hexagon, parallelogram, square, triangle and line scan shapes in various sizes are available. For detailed information on the scanner features see the SmartScan Plus Operator's Manual.

The scanner is not designed to be used in a sterile environment. To clean the scanner, use a soft cloth lightly dampened with water, or a mild soap solution. Stains may be removed using a mild ammonia-based cleaner. Do not use abrasives or solvents, since they may damage the paint or the control panel.

The SFDGT is provided non-sterile. Laserscope recommends the SFDGT be disinfected according to hospital protocol, then sterilized by autoclave according to the following parameters:

<i>Method</i>	<i>Temperature</i>	<i>Time (wrapped)</i>
<i>Pre-vacuum</i>	<i>270½ - 275½ F</i>	<i>4 minutes</i>

Reattach the SFDGT to the scanner using sterile gloves.

WARNING

DO NOT STERILIZE THE SCANNER HANDPIECE. THE TEMPERATURE AND MOISTURE MAY DAMAGE THE MIRRORS OF THIS DEVICE.

To connect any Venus Laser System delivery device gently thread it onto the articulated arm and turn it clockwise until handtight.

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).

Information Messages

An Information Message will appear on the main display without affecting normal operation. Information Messages inform the operator that a minor irregularity exists, like the system temperature has risen above normal operating range.

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;
- Not In Ready;
- Remote Interlock Open;
- Temperature Too High; and
- Warmup.

Service Prompts

A Service Prompt will appear and replace the main display. Detailed information regarding Service Prompts can be found in the Venus Laser System Service Manual. 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 Failure
20-29:	Lamp Failure
40-59:	Power Measurement Failure
60-69:	Shutter Failure
70-79:	Control Board Failure
80-89:	Low Voltage Power Supply Failure
100-119:	Scanner Failure

Turning the System Off

1. Turn the Keyswitch to the OFF position and remove the key. Switch the circuit breaker to the OFF position.
2. Place the articulated arm in its holder.

Laser Systems and Accessories

Venus Laser System

Venus Laser, 115V	10-1210
Venus Laser, 115V with SmartScan Plus	10-1211
Venus Laser, 230V	10-1220
Venus Laser, 230V with SmartScan Plus	10-1221
Venus Laser, German, 230V	10-1240
Venus Laser, German, 230V with SmartScan Plus	10-1241
Venus Laser, Spanish, 230V	10-1250
Venus Laser, Spanish, 230V with SmartScan Plus	10-1251
Venus Laser, Spanish, 115V	10-1252
Venus Laser, Spanish, 115V with SmartScan Plus	10-1253
Venus Laser, French, 230V	10-1270
Venus Laser, French, 230V with SmartScan Plus	10-1271
Venus Laser, French, 115V	10-1272
Venus Laser, French, 115V with SmartScan Plus	10-1273
Aura/Venus Cart	10-8310

Scanning Devices and Accessories

SmartScan Plus	10-1300
SmartScan Plus Focal Distance Guide Tip	10-1310
SmartScan Plus Window Cell	10-1320
SmartScan Plus Operator's Manual	10-1330

Focusing Handpieces and Accessories

CBH-2 Handpiece	10-1060
-----------------------	---------

1 mm Lens Cell	10-1071
3 mm Lens Cell	10-1072
5 mm Lens Cell	10-1073
7 mm Lens Cell	10-1074

Protective Eyewear and Miscellaneous Accessories

Erbium Protective Spectacles	10-1020
Laser in Use Signs, Erbium, U.S. (set of 2)	10-1041
Laser in Use Signs, Erbium, English (set of 2)	10-1042
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Section 4:
Routine Maintenance and Calibration

Maintenance

Introduction

The Venus 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 circuit diagrams, components part lists, descriptions, calibration instructions, or other information to the appropriately qualified technical personnel to repair the parts of the product that are designated as repairable.

WARNING

This system requires technical maintenance after 6 months of usage. Failure to complete this maintenance can cause a safety hazard.

Care of the Outside Surfaces

The operator should periodically wipe the outside surfaces of the laser 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.

Calibration

Introduction

This section outlines routine calibration procedures recommended by Laserscope. The procedures described must be performed every 6 months by a Laserscope trained service representative. The procedures described in this section should not be confused with the delivery device calibration procedures described in Section 4.

Technical information including but not limited to circuit diagrams and component lists are available from the Laserscope Customer Service Department upon written request.

Flashlamp

The flashlamp should be changed every 6 months or 500 hours which ever comes first. Refer to the Service Manual for specific instructions.

Calibrating the Internal Detector

The Internal Detector must be calibrated every 6 months by a Laserscope trained service technician using the procedure described in this section. If it is determined that the laser is out of calibration, following this procedure will allow you to match the laser output to an external laser energy meter, but it will not likely fix the cause of the calibration drift.

WARNING

Laserscope believes that it is vital that a properly trained Service Representative perform this calibration and that he/she understands the complex electronic systems involved.

WARNING

Always use proper eye protection designed for 2940 nm wavelength while performing calibration procedures.

Equipment Required

The following equipment is needed to perform the calibration procedure:

1. Laser Energy Meter; calibrated and traceable to a national standards laboratory and capable of measuring laser light at 2940 nm, up to 2.5 joules;
2. Laserscope Smart Driver;
3. Potentiometer Adjustment Tool;
4. Service Key; and
5. Protective Eyewear for 2940 nm.

Test for Accuracy

Before performing the calibration procedure, conduct the following test to determine the equipment's accuracy. The results of this test may indicate that no calibration is necessary.

1. Turn the laser ON.
2. Aim the delivery device into the head of the laser energy meter. Set the laser to maximum energy (2.0J). Place the laser in READY mode and step on the foot pedal. Read and record the energy shown on the laser energy meter.

NOTE

Always wear eye protection for 2940 nm laser light.

3. If the displayed energy is not within 20% of than the energy meter reading, the laser is out of adjustment and needs to be calibrated. This procedure must

only be done by a trained service representative. The Calibration Procedure is described in the next section.

4. If the energy meter reading is within 20% of than the energy meter reading, the laser is properly calibrated. No more action is required at this time.

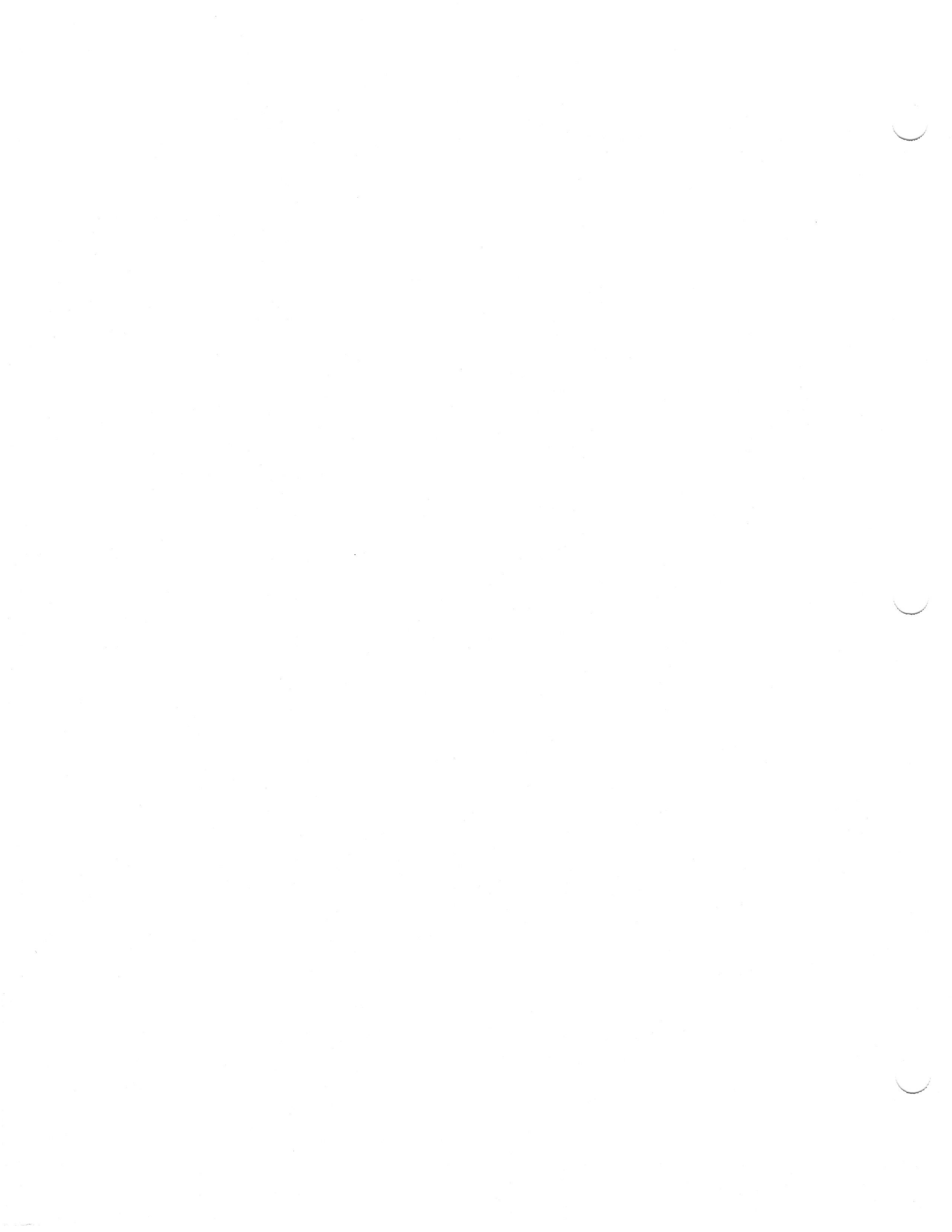
CAUTION

Laserscope strongly recommends that you only *verify* the calibration accuracy with an external laser energy meter and that you call Laserscope Customer Service to perform the actual calibration should the system appear to require it.

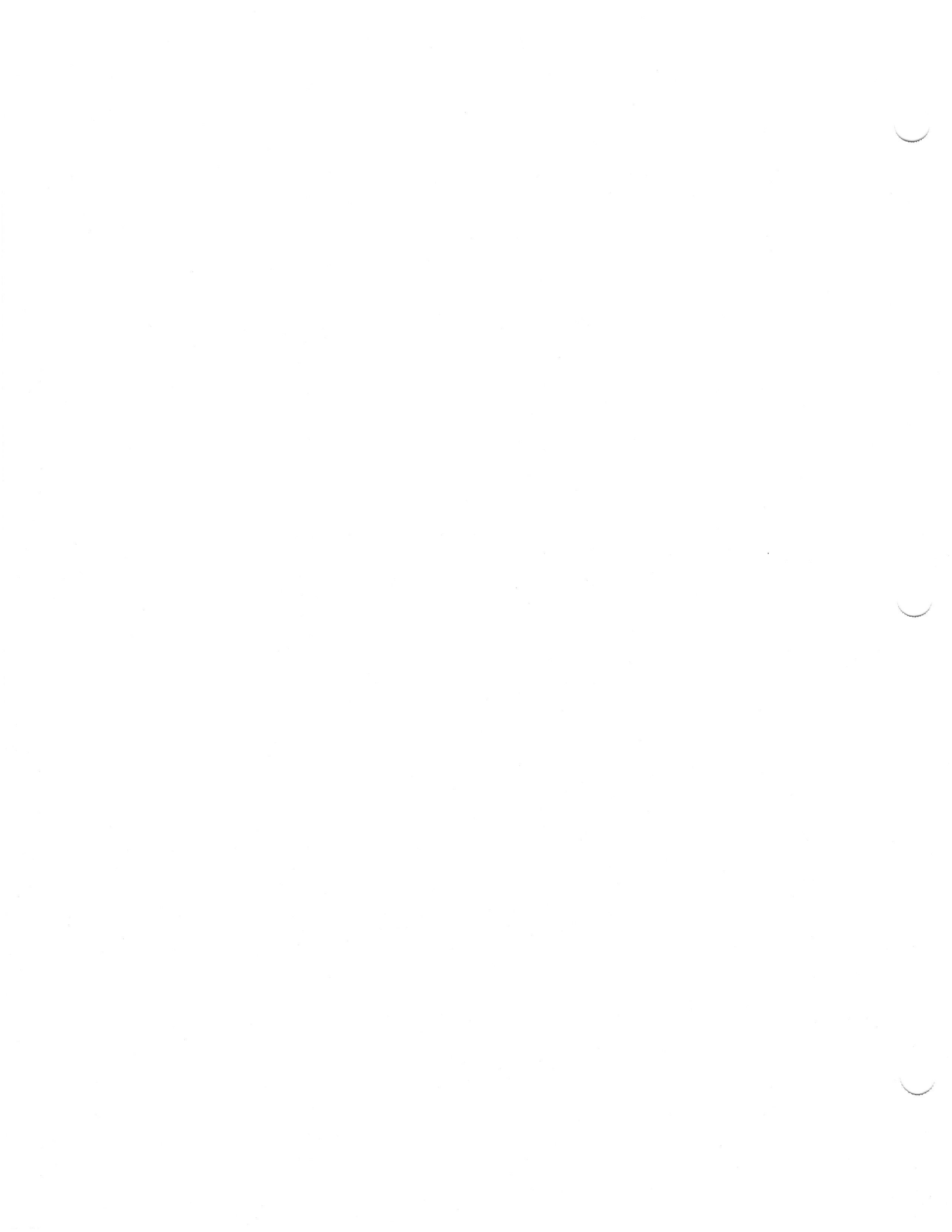
Calibration Procedure

If the test for accuracy indicates that calibration is necessary, a qualified service representative should be contacted to perform the procedure. The calibration procedure can be performed as follows:

1. Remove the top cover of the laser.
2. Connect the Service Key to the RS232 port on the rear panel of the laser.
3. Turn the laser ON.
4. After system warmup is complete, access the main service screen by pressing Ready/Standby button and the System Information button simultaneously.
5. Select the "System Calibration" service screen.
6. Follow the instructions on the screen for calibration.
7. Return to Applications screen by pressing the Ready/Standby button and the System Information button simultaneously.
8. Turn the laser off, disconnect the Service Key from the RS232 port on the rear panel of the laser.
9. Perform the Test for Accuracy (from the previous section).
10. Replace the top cover of the laser.



Section 5:
Warranty Policy and Product Returns



Product Warranty

Warranty Policy

Laserscope warrants its products against defects in materials and workmanship for the periods specified. 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. The duration of the warranty period and the extent of the warranty vary from product to product. Every Laserscope product is assigned a warranty code which defines the nature of the warranty provided for the particular product.

If Laserscope receives notice of such defects during the warranty period, Laserscope shall, at its option, either repair or replace equipment or components which prove to be defective. Equipment or components replaced under the Warranty Policy may be refurbished or new equipment substituted instead at Laserscope's option.

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. 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. The buyer agrees to make the equipment available to Laserscope during normal business hours.

Limitation of Warranty

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

- Improper or inadequate maintenance by the buyer;
- 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; and/or
- Use of delivery devices or accessories not manufactured by Laserscope or approved for use with the Laserscope systems.

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.

Warranty Codes

Table 5.1 summarizes the warranty codes assigned to Laserscope products, and lists the warranty period for each code.

WarrantyCode	WarrantyPeriod	CommencementDate
12	12Months	Installation
6	6Months	Shipment
3	3Months	Shipment
1	1Procedure	Shipment
0	None	NA

Table 5.1 Warranty Codes for Laserscope Products.

NOTE

All warranty periods are expressed in months or number of procedures.

Product Warranties

Table 5.2 summarizes the product warranties and the products to which they apply.

NOTE

The products listed under Warranty Code 1 in Table 5.2 are examples only. This list is not all inclusive.

WarrantyCode	Products Covered	Notes
12 Parts & Labor for 12 Months from Installation	-Laser Systems -Scanners -Smoke Evacuators	--
3 Parts & Labor for 3 Months from Shipment	-CBH-2 Handpiece -CBH-2 Lens Cells -Protective Spectacles	Replacement parts will be warranted for the remaining amount of the 90-day warranty or 30 days, whichever is longest.
0 No Warranty Provided	-Manuals and Literature -Products Not Listed	--

Table 5.2 Product Warranties.

In addition to the above warranties, service visits will warranty Parts & Labor for 30 days from completion of the billable service repair or shipment of part(s).

Product Returns

Overview of Laserscope's Return/Repair Policy:

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. 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.

Sterile/Non-Sterile Surgical Instruments

In order to protect the customer and Laserscope, all non-disposable surgical instruments must be cleaned and sterilized, and returned in a sealed peel pack with a sterilization indicator. Any instruments not sterilized will be returned, and the customer will be charged for the exchanged product. If a non-disposable surgical instrument 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 30 days. A 20% restocking fee will be charged for unused/unopened returned products.

Unused/Unopened Disposable Accessories:

Sterile disposable products can only be returned if the seal on the original package is not broken. If the seal on the outer box is broken, sterile disposable products

can not be returned. A 20% restocking fee will be charge for unused/unopened disposable accessories. Items must be returned within 30 days of order.

Return Material Authorization

If you return a failed item that is under warranty, Laserscope will credit your account 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).
8. Your "replacement" Purchase Order Number.

Shipping Procedures:

1. As a courtesy, you will be sent a mailing label in the package containing the replacement item(s). Please use this mailing label and return the damaged or failed item(s) to Laserscope in that same package.
2. Ship the package, postage pre-paid. Insure the package for its appropriate value (as indicated on the original purchase order), as Laserscope will not be financially responsible for the loss of any item being returned.

NOTE:

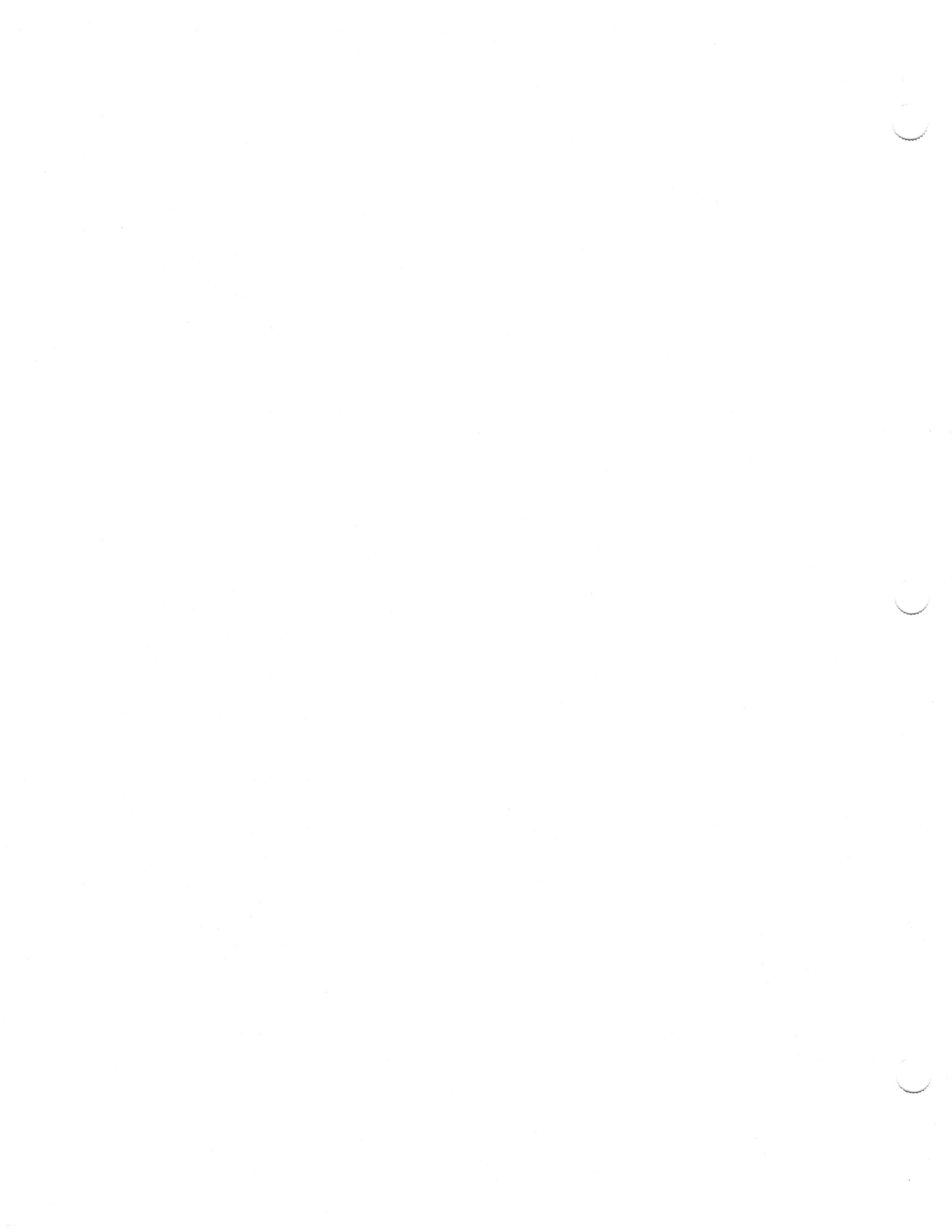
If a damaged item is not received by Laserscope within 10 days of shipment of the replacement item, the customer will be invoiced for the list price of the replacement item.

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.



Section 6:
Professional Information



Introduction

This section provides information on the use of Laserscope's Venus Laser System in clinical applications. Information is provided by specialty and 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 laser system should be used only by surgeons and staff who have been appropriately trained and who are thoroughly familiar with the instructions and safety precautions provided in this manual. A review of the published literature is strongly encouraged and recommended.

This manual is intended for operators of the Venus Laser System. The Venus is available in several different configurations, therefore, not all specialties or procedures presented in this section may be applicable to your particular configuration. Laserscope's Venus Laser System is designed as a multi-specialty system.

Training

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.

- Review of the following information:
- Published literature;
- General laser physics, biology and treatment techniques for each specific disease entity;
- Treatment techniques for other surgical modalities in several specialties; and
- Familiarization with treatment parameters using all laser types, such as Argon, Er:YAG, Ho:YAG, Tunable 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. If outside the United States contact your local Laserscope distributor for more details.
- Preceptorships should be made as frequently as possible with other surgeons 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
John Wiley & Sons, Inc.
Subscription Department
7th Floor
605 Third Avenue
New York, NY 10158
Membership Information: (715) 845-9283.

Nursing Education and Training

Nursing education and training should include a review of the following information:

- 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 other laser types, such as Argon, Er:YAG, Ho:YAG, Tunable Dye, CO₂, KTP and Nd:YAG;
- Attendance at medical meetings dealing with the use of the laser; and
- Attendance at seminars and hands-on workshops on laser therapy in a specific specialty. Laserscope maintains a listing of instructional courses in a broad range of medical specialties. Within the United States, contact the Customer Response Center at (800) 356-7600 for more details. If outside the United States contact your local Laserscope distributor for more details.

Warnings and Risks

General Warnings and Precautions for the Venus Erbium Laser System

The physician or surgeon should become fully acquainted with the unique surgical and therapeutic effects produced with the 2940 nm laser wavelength before using Laserscope's Venus 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 Venus Laser System is a surgical device that should be used only by physicians or surgeons who have been trained in laser surgery through courses, preceptorships, and under the guidance of other physicians or surgeons knowledgeable in laser use. No claim is made that the laser will cure any medical condition.
- BEFORE operating the laser system, surgeons and all staff operating the laser should carefully read Section 2, *Safety*, of this manual.
- Surgeons using Laserscope's Venus Laser System must understand the laser's unique properties prior to using the device.
- Prior to turning the laser system on, operating room personnel and the patient should be wearing protective eyewear suitable for Erbium laser energy.
- 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, nerves and veins.
- Begin laser treatment at the lowest energy setting, until fully familiar with the tissue effects of the applicable wavelength.
- Flash fires can occur. Refer to Section 2, *Safety*, for more information. A basin of water should be available in case a fire occurs.
- Laserscope has no clinical information or experience concerning the use of Laserscope's Venus Laser System on pregnant women or nursing mothers.
- Patients who experience discomfort during laser treatment may require analgesics.
- Alterations in surgical approach or technique may be required to accommodate laser use.
- The surgeon should schedule follow-up visits in the same manner as for any patient undergoing such surgery with other modalities.
- Tissue interaction - Compared to a continuous wave laser, Erbium:YAG laser procedures on soft tissue may be slower to perform.
- The footswitch is the ultimate control which releases the Er:YAG beam. The responsible laser surgeon should under no circumstances delegate control of the footswitch to another person.
- Prior to use, inspect the footswitch, cable and connector for signs of damage, e.g. loose connections, crushed or broken cable, etc. If any damage is found, **DO NOT USE THE LASER SYSTEM**. Contact the Laserscope Customer Response Center or your local Laserscope distributor.
- Wear only shoes that guarantee that you feel the release point of the footswitch (pressure point) when switching on and off.
- Position the footswitch so that inadvertent activation is ruled out. Do not allow the laser system's footswitch to be used near footswitches which belong to other equipment.

- Ensure that the possibility of accidental activation by, for example, heavy objects, or by levers or other items projecting into the room, is eliminated.
- A smoke evacuator and in-line filter should be used to capture the smoke plume that results from laser procedures. The plume should be regarded as a source of active biological material and a possible carcinogen.

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; and
- Infection.

Thermal (Acute) Complications and Risks:

- Induced hemorrhage;
- Ulceration;
- Perforation;
- Edema;
- Pain;
- Fever;
- Leukocytosis; and
- Chills.

Thermal (Chronic) Complications and Risks:

- Delay in healing;
- Perforation;
- Stricture;
- Delayed hemorrhage; and
- Sepsis.

NOTE Refer to individual specialty sections for application-specific complications and risks. Also see Section 2, *Safety*.

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 performed by 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; and
- Where laser therapy is not considered the treatment of choice.

Clinical Specialties

This section provides information on the use of Laserscope's Venus Laser System in clinical specialties. Information is provided by specialty and 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 to the United States only. Regulations may be different in other nations. Information regarding U.S. regulations is provided for example only.

FDA Regulations Regarding Clearance for Clinical Specialties

The United States Federal Food, Drug and Cosmetic (FDC) Act provides two basic review procedures for new medical devices prior to marketing. Certain devices may qualify for a Section 510(k) Pre-Market Notification, a procedure under which the manufacturer gives the FDA notification of its intention to commence marketing its device. The manufacturer must, among other things, establish that the device to be marketed is "substantially equivalent" to another legally marketed device. In some cases, this may require the submission of clinical data demonstrating that the device is as safe and effective as the legally marketed device. Marketing may commence when the FDA issues a written order finding "substantial equivalence." FDA regulations specifically provide that a finding of substantial equivalence "does not in any way denote official approval of the device."

If the product does not qualify for the 510(k) procedure, the manufacturer must file a Pre-Market Approval application (PMA) based on testing intended to demonstrate that the product is both safe and effective. This historically has required more extensive pre-clinical and clinical testing than the 510(k) procedure and involves a significantly longer FDA review process. The FDA prohibits manufacturers who receive approval for their products through the PMA process from citing such approval in advertising or labeling.

An Investigational Device Exemption (IDE) allows a manufacturer to ship its investigational device to clinical sites in order to collect data involving human subjects. The data can then be used to support either a 510(k) or PMA submission. The IDE contains an "Investigational Plan." The Investigational Plan for a PMA is typically more complex

than that required for a 510(k), requiring more clinical trials and a longer duration of follow-up. Before a clinical trial can be initiated at a study site, the FDA requires that an Institutional Review Board (IRB) approve the study. The IRB's primary interest is in protecting the rights of human subjects.

Laserscope's Venus Laser System is cleared for the uses included in this manual. If you choose to use the Venus Laser System for indications not included herein, you will be subject to 21 CFR Part 812, the Food and Drug Administration's Investigational Device Exemption (IDE) regulations.

For information regarding the regulatory status of indications other than those listed in this manual, contact Laserscope's Regulatory Affairs Department at (800) 356-7600.

Clinical Specialties Cleared for Laser Surgery

Laserscope has secured clearance to market the Venus Laser System in the U.S. for the specific clinical applications listed in Tables 6.1. These applications have been reviewed by the FDA through the 510(k) process and have 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 Venus Laser System for these applications.

Erbium Applications
Cosmetic/Dermatology/Plastic Surgery
General Surgery
Genitourinary
Gynecology
Oral/Maxillofacial
Otorhinolaryngology/Head and Neck (ENT)
Ophthalmology
Podiatry

Table 6.1 Clinical Specialties Cleared for the 2940nm Wavelength.

Erbium Applications

This section provides information on the use of 2940 wavelength (erbium) in clinical specialties. Information is provided by specialty and includes procedural recommendations along with specific indications and contraindications. The information provided in this section is not intended to be all-inclusive nor is it intended to replace surgeon training or experience.

Erbium Applications Cosmetic/Dermatology/Plastic Surgery

Indications:

The Laserscope Venus Laser System is intended for the surgical incision/excision, vaporization, ablation and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

Indications include epidermal nevi, telangiectasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision (including acne scars), microplaning of scars, debulking benign tumors and cysts, skin resurfacing, tissue sculpting, superficial skin lesions, performing diagnostic biopsies and benign pigmented lesions..

Procedural Recommendations:

- **Technique:** The laser energy must be administered via a handpiece or the Scanner delivery device. Directions for use of these delivery devices should be followed.
- **Laser Settings:** Beginning at the low end of the available energy range, combined with short duration exposures, the surgeon should note the treatment effect and increase power, energy density (fluence), or exposure duration until the desired treatment effect is observed.
- **Follow-up:** The surgeon should schedule follow-up visits in the same manner as for any patient undergoing such treatment via non-laser or other laser means.

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 Cosmetic/Dermatology/Plastic Surgery applications without first obtaining detailed instructions in laser use.

Erbium Applications Cosmetic/Dermatology/Plastic Surgery

Specific Warnings and Precautions (cont.):

- Refer to *General Warnings and Precautions for the Erbium 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 Section 2, *Safety*.
- Not all lesions respond positively to laser therapy. 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 scarring, keloid formation, and/or indentation versus the treatment-to-benefit ratio.
- Lesions that have been 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.
- The Erbium wavelength is highly absorbed by the water in the skin.

WARNING

Patients under the age of 15 years or those with a history of wound healing problems (i.e., Keloid scar formation) should be carefully evaluated before laser treatment due to the high incidence of scar formation in these populations.

Erbium Applications Cosmetic/Dermatology/Plastic Surgery

Specific Complications and Risks:

- Refer to *Surgical Complications and Risks* for general information.
- Potential complications from laser treatment of cutaneous lesions include:
 - Hypopigmentation/Hyperpigmentation;
 - Scarring (Hypertrophic or Non-Hypertrophic);
 - Texture change;
 - Indentation;
 - Keloid formation; and
 - Incomplete removal or recurrence of lesion.

Specific Contraindications:

- Refer to *Contraindications for Laser Surgery* for general information.
- None known specific to Cosmetic/Dermatology/Plastic Surgery use at this time.

Erbium Applications General Surgery

Indications:

The Laserscope Venus Laser System is intended for the surgical incision/excision, vaporization ablation and coagulation of soft tissue during any general surgery application where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue ablation and/or vessel coagulation may be indicated. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

Specific Warnings and Precautions:

For all procedures

- **It is essential that the surgeon and attending staff be trained in all aspects of these procedures.**
- Refer to *General Warnings and Precautions for the Erbium Laser System* for additional information.
- Alterations in surgical approach or technique may be necessary to accommodate laser use.

Specific Complications and Risks:

- Refer to *Surgical Complications and Risks* for general information.
- Thermal damage at site of incision.

Specific Contraindications:

- Refer to *Contraindications for Laser Surgery* for general information.
- None known specific to General Surgery at this time.

Erbium Applications Genitourinary

Indications:

The Laserscope Venus Laser System is intended for the surgical incision/excision, vaporization, ablation and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

Indications include lesions of the external genitalia, urethra and anus, penis, scrotum and urethra (includes condyloma acuminata, giant perineal condyloma and verrucous carcinoma), vulvar lesions, polyps and familial polyps of the colon.

Specific Warnings and Precautions:

- It is essential that the surgeon and attending staff be trained in all aspects of these procedures. No surgeon should use these laser products for Genitourinary surgical procedures without first obtaining detailed instructions in laser use.
- Refer to *General Warnings and Precautions for the Erbium Laser System* for additional information.
- The risk of combustion, perforation, and laser-induced hemorrhage, all of which could cause serious or fatal complications, must be fully explained to the patient.
- Extra precautions should be taken when radiation therapy and laser therapy are to be used concurrently, including more stringent post-operative monitoring. Clinical studies have shown that patients who have undergone radiation therapy present a greater risk of perforation or tissue erosion.
- Use of lower power levels and shorter exposure times are required in order to prevent thermal damage to underlying structures (e.g., to thin-walled structures such as the bladder).

Erbium Applications Genitourinary

Specific Complications and Risks:

- Refer to *Surgical Complications and Risks* for general information.
- **Fever and Leukocytosis:** Immediately after laser therapy, the patient may experience fever and leukocytosis which are commonly associated with tissue destruction. These generally resolve without treatment. Cultures are indicated to exclude the possibility of infection.
- **Bleeding:** Patients may experience bleeding at the site of the laser therapy or from erosion of a tumor during or after laser therapy. Post-treatment hematocrits are recommended to identify the potential complication.
- **Sepsis:** Laser-ablated tissue may become infected after therapy. If a question of sepsis exists, a culture should be taken and other appropriate evaluations made.
- **Perforation:** Perforation can occur as a result of excessive exposure to laser radiation. Perforation can also occur from tumor erosion. To clinically diagnose perforations, patients must be monitored post-operatively through physical signs, hematocrits, and radiography.

Specific Contraindications:

- Refer to *Contraindications for Laser Surgery* for general information.
- The Erbium wavelength is contraindicated for destruction of urinary stones.

Erbium Applications Gynecology

Indications:

The Laserscope Venus Laser System is intended for the surgical incision/excision, ablation, vaporization and coagulation of vulvar, vaginal and endocervical tissues. All soft tissue is included, such as, skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

Indications include, cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts and condyloma.

Specific Warnings and Precautions:

- **It is essential that the surgeon and attending staff be trained in all aspects of these procedures. No surgeon should use these laser products for Gynecologic procedures without first obtaining detailed instructions in laser use.**
- Refer to *General Warnings and Precautions for the Erbium Laser System*.
- As with “conventional” non-laser surgical procedures, there is no guarantee that treatment with the Laserscope Venus Laser System will entirely eliminate the disease entity. Repeat treatment or alternative therapies may be subsequently required.
- Treatment of intraepithelial neoplasia may necessitate continuous follow-up and multiple treatments to effectively manage the condition.

Specific Complications and Risks:

- Refer to *Surgical Complications and Risks* for general information.
- None known specific to this application at this time.

Erbium Applications Gynecology

Specific Contraindications:

- Refer to *Contraindications for Laser Surgery* for general information.
- These procedures may be contraindicated for women who are pregnant, or have suspected pregnancy, and for whom open abdominal surgery would not be appropriate.

Erbium Applications Oral and Maxillofacial

Indications:

The Laserscope Venus Laser System is intended for the surgical incision/excision, ablation, vaporization and coagulation of soft tissue from the oral and maxillofacial area. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

Indications include benign oral tumors, oral and glossal lesions and gingivectomy.

Specific Warnings and Precautions:

- **It is essential that the surgeon and attending staff be trained in all aspects of these procedures. No surgeon should use these laser products for Oral and Maxillofacial surgical procedures without first obtaining detailed instructions in laser use.**
- Refer to *General Warnings and Precautions for the Erbium Laser System* and *Warnings and Precautions* for additional information.

Specific Complications and Risks:

- Refer to *Surgical Complications and Risks* for general information.
- None known specific to **Oral and Maxillofacial** use at this time.

Specific Contraindications:

- Refer to *Contraindications for Laser Surgery* for general information.
- None known specific to **Oral and Maxillofacial** use at this time.

Erbium Applications Otorhinolaryngology /Head and Neck (ENT)

Indications:

The Laserscope Venus Laser System is intended for the surgical incision/excision, ablation, vaporization and coagulation of soft tissue from the ear, nose or throat area. All soft tissue is included, such as, skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

Indications include, ear, nose and throat lesions, polyps, cysts, hyperkeratosis; excision of carcinogenic tissue and oral leukoplakia.

Specific Warnings and Precautions:

- It is essential that the surgeon and attending staff be trained in all aspects of these procedures. No surgeon should use these laser products for Head and Neck/Otorhinolaryngology surgical procedures without first obtaining detailed instructions in laser use.
- Refer to *General Warnings and Precautions for the Erbium Laser System* and *Warnings and Precautions* for additional information.

Specific Complications and Risks:

- Refer to *Surgical Complications and Risks* for general information.
- None known specific to ENT use at this time.

Specific Contraindications:

- Refer to *Contraindications for Laser Surgery* for general information.
- None known specific to ENT use at this time.

Erbium Applications

Ophthalmology

Indications:

The Laserscope Venus Laser System is intended for the surgical incision/excision, ablation, vaporization and coagulation of soft tissues surrounding the eye and orbit and anterior capsulotomy.

Procedural Recommendations:

- **Laser Settings:** Beginning with low energy and a low pulse rate, the surgeon should note the surgical effect and increase the energy and pulse rate until the desired surgical effect is obtained.

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 Ophthalmological surgical procedures without first obtaining detailed instructions in laser use.**
- Refer to *General Warnings and Precautions for the Erbium Laser System* for additional information.
- Proper eye protection for 2940 nm light must be utilized. Follow the Eye Protection Policy at your facility.

Specific Complications and Risks:

- Refer to *Surgical Complications and Risks* for general information.
- None known specific to Ophthalmology use at this time.

Erbium Applications Ophthalmology

Specific Contraindications:

- Refer to *Contraindications for Laser Surgery* for general information.
- None known specific to Ophthalmology use at this time.

Erbium Applications

Podiatry

Indications:

The Laserscope Venus Laser System is intended for the surgical incision/excision, ablation, vaporization and coagulation of soft tissue during podiatry procedures. All soft tissue is included, such as, skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

Indications include, warts, plantar verrucae, large mosaic verrucae, and matrixectomy.

Specific Warnings and Precautions:

- It is essential that the surgeon and attending staff be trained in all aspects of these procedures. No surgeon should use these laser products for Podiatric surgical procedures without first obtaining detailed instructions in laser use.
- Refer to *General Warnings and Precautions for the Erbium Laser System* and *Warnings and Precautions* for additional information.

Specific Complications and Risks:

- Refer to *Surgical Complications and Risks* for general information.
- None known specific to Podiatry use at this time.

Specific Contraindications:

- Refer to *Contraindications for Laser Surgery* for general information.
- None known specific to Podiatry use at this time.