Smartepil II
Nd:YAG Laser System
OPERATOR'S MANUAL

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Glossary of Symbols and Abbreviations

The following international symbols and abbreviations may be used on the Smartepil II laser and/or in this manual.

Symbols:

CE	Declaration of Conformity to Medical Device Directive 93/42/EEC CE Mark to Directive 93/465/EEC
	Laser Hazard Warning
	Dangerous Voltage
	Off (power disconnection from mains)
	On (power connection to mains)
	Start (initializes connection to Mains)
	Type B equipment per IEC 601-1
	Footswitch
	Remote Interlock Connector per EN60601-2-22: 1996
	Optical Fiber Applicator per EN60601-2-22: 1996
	Attention

Abbreviations:

°C	Degrees Celsius
A	Amperes
mA	Milliamp
µA	Microamp
AC	Alternating current
cm	Centimeter
mm	Millimeter
nm	Nanometer
CW	Continuous Wave
V	Volts
DVM	Digital Voltmeter
Hz	Hertz
J	Joule
J/cm^2	Joules per square centimeter
W	Watts
kW	Kilowatt
µs	Microsecond
ms	Millisecond
Ω	Ohms
mΩ	Milliohms

Figure 1–Abbreviations and Symbols

About the Laser

The Smartepil II solid state, Nd:YAG laser system emits a wavelength of 1,064 nanometer (nm). This invisible wavelength is highly effective in targeting hair while the surrounding tissue remains unharmed.

About the Manual

The *Smartepil II Operator's Manual* provides the following information about the laser:

- Equipment Safety
- Site Preparation
- Laser Operation
- Clinical Application
- Maintenance
- Customer Support

Although the *Smartepil II Operator's Manual* provides useful information on the use and maintenance of the laser, it is not intended to be a complete guide. Cynosure suggests that healthcare professionals, who plan to use this laser, seek further training in its proper use. The custodian of this laser shall take steps to prevent unauthorized personnel from operating this system.

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

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Potential Hazards

As with any equipment, there are potential hazards. Before using the Smartepil II laser, operators should be aware of potential optical, electrical and combustible hazards.

This section of the manual describes potential hazards and suggests precautions. The section also covers specific safety features designed to minimize the potential hazards.

Optical Hazard

The Smartepil II laser emits an invisible beam of intense energy that can cause serious eye and skin injury with direct or indirect contact. Please adhere to the following precautions to avoid optical damage to laser operators, assisting personnel and patients.

- All persons in the room during treatment must wear protective eyewear, with an optical density (OD) greater than 7.0 at a wavelength of 1,064 nm.
- Never look directly into the handpiece, fiber, or fiber opening, even while wearing protective eyewear.
- Mark treatment rooms with laser warning signs to avoid unnecessary personnel entering during treatment.
- Limit entry to the treatment room to personnel assisting in treatment and trained in the use of the equipment.
- Cover windows and other openings in the treatment room to avoid the inadvertent escape of laser light.
- Direct the activated laser only at the intended area of treatment.
- Place one person in charge of the laser system's controls during the treatment.
- Cover reflective objects, such as jewelry or mirrors, which could deflect the laser beam to an area other than the intended treatment area.
- Put the laser into STANDBY mode when the laser is not in use. When in STANDBY mode, the laser beam cannot be inadvertently activated.
- Ensure that all trained staff assisting in the treatment know how to shut down the laser in the case of an emergency.
- Keep the laser start-up key in a safe place outside of the treatment room when the laser is not in use.

Electrical Hazard

The Smartepil II laser uses extremely high voltage. Do not open the protective panels unless trained and authorized to do so.

Laser-Induced Fire Hazard

When the laser beam contacts an exterior surface, that surface absorbs laser energy. This raises the surface temperature, whether the surface is skin, hair, clothes or any flammable substance. Operators should take the following precautions to prevent a laser-induced fire:

- Use non-flammable substances for uses such as anesthesia, skin preparation, and cleaning or disinfecting instruments.
- Be especially careful with the use of oxygen. Oxygen accelerates both the severity and the extent of a fire.
- Keep a minimum of combustible materials (e.g., alcohol) in the treatment room. If treatment requires the use of gauze, first soak it in water.
- Always keep a small fire extinguisher and water in the treatment room.
- Prevent singeing or burning when treating an area with hair by wetting the area with water or saline before beginning treatment.

Radio Frequency (RF) Interference and Electrostatic Discharge (ESD)

The Smartepil II Laser complies with the EN 60601-1-2(93-12) standard. The system is not affected by electromagnetic noise generated by other devices that conform to the same standard. In addition, the system does not generate electromagnetic noise in compliance with EN 60601-1-2(93-12).

Laser Safety Features

The Smartepil II laser offers several safety features to prevent misuse or unintentional activation of the laser. All personnel who operate the laser or assist in the operation should be familiar with these safety features.

Key Switch

The Key switch controls the electrical activation of the laser system. Only those authorized personnel who have access to the key can start the laser system.

Emergency Stop Switch

The Emergency Stop switch is a dedicated override switch for the immediate emergency shutdown of the laser system.

Stand By Mode

Stand By mode prevents unintentional or accidental activation of the laser. When the laser is in Stand By mode, the system is on but the Nd:YAG laser source is switched off. The operator cannot activate the laser beam until the LASER ON switch is pressed. The system goes into stand by mode in the following cases:

- after the laser system is initially started.
- after calibrating the laser delivery system.
- when the laser has been in Laser On mode for a few minutes without being activated.
- when the Stand By switch is pressed.

Delayed READY Mode

From the Laser On mode, press the Operate switch to enable the foot switch. There is a brief delay between indication of emission and actual emission of the laser beam. This delay, during which the Operate light blinks, provides time for personnel to prepare before the beginning of treatment.

Automatic Shutdown Feature

The Smartepil II laser system includes an automatic shutdown feature. When specific problems occur, the laser automatically switches to a safety state: the laser source is switched off and the foot switch is disabled. A fault menu is immediately displayed on the LCD screen identifying the specific fault(s) and how to proceed. Refer to, "Troubleshooting," starting on page 33 for more information.

Remote Interlock

Cynosure provides a remote interlock that can connect to the door of the laser room. When the remote interlock is activated, the laser automatically shuts down if anyone enters the treatment room.

Audible Tone

Laser emission is indicated by a pulsed tone, for the period of the emission.

Laser Warning Signs

Cynosure supplies laser warning signs with each laser system. We recommend the posting of these signs at all entrances to rooms with an operating laser. Please check the policy of your hospital or clinic.

Device Labels

The Smartepil II laser contains warning labels placed in appropriate locations. All personnel should be familiar with these labels and their meanings. Refer to **Figure 2A** and **2B** for the labels used on this system and their locations.

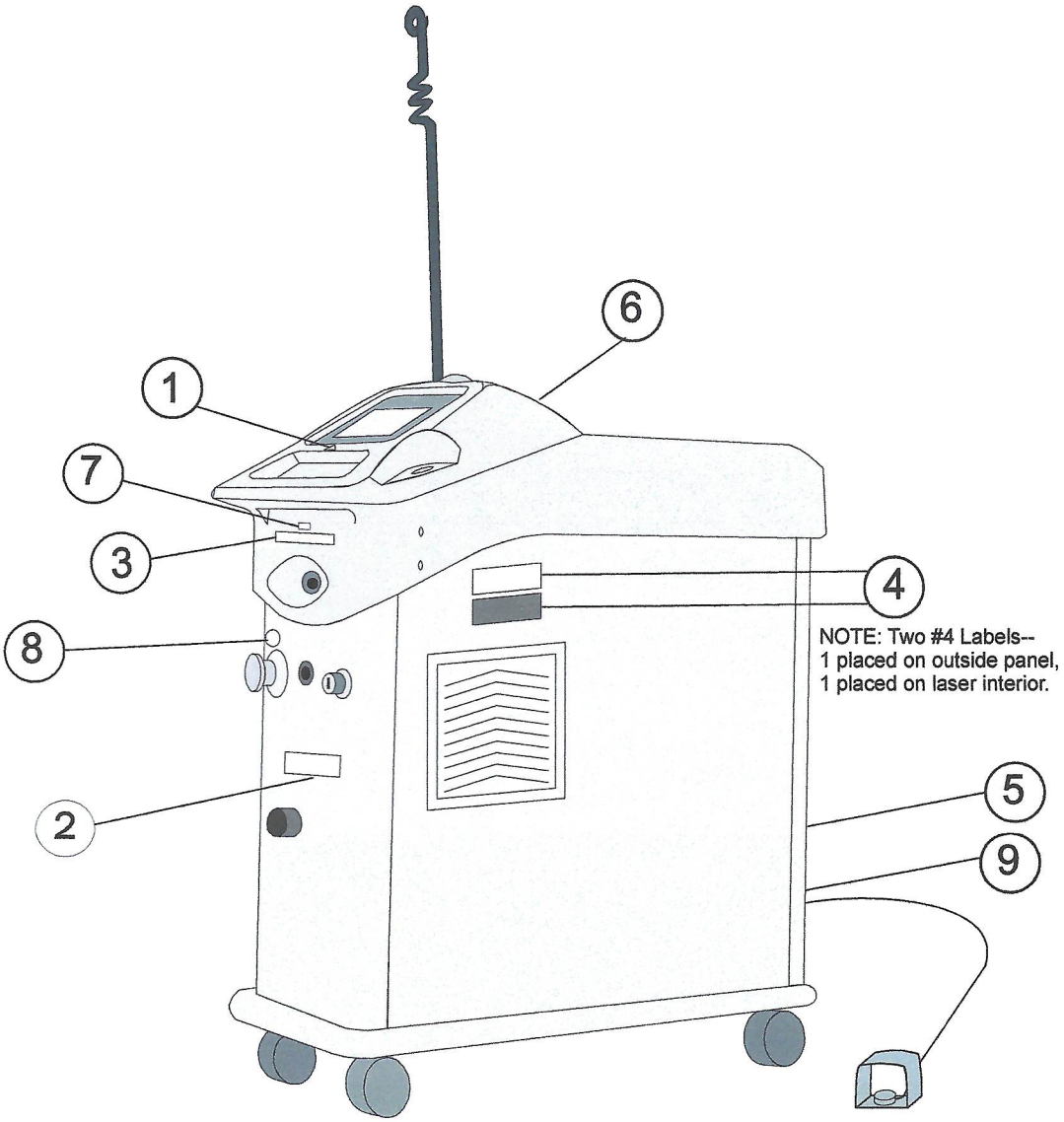

Figure 2A–Labels in Location

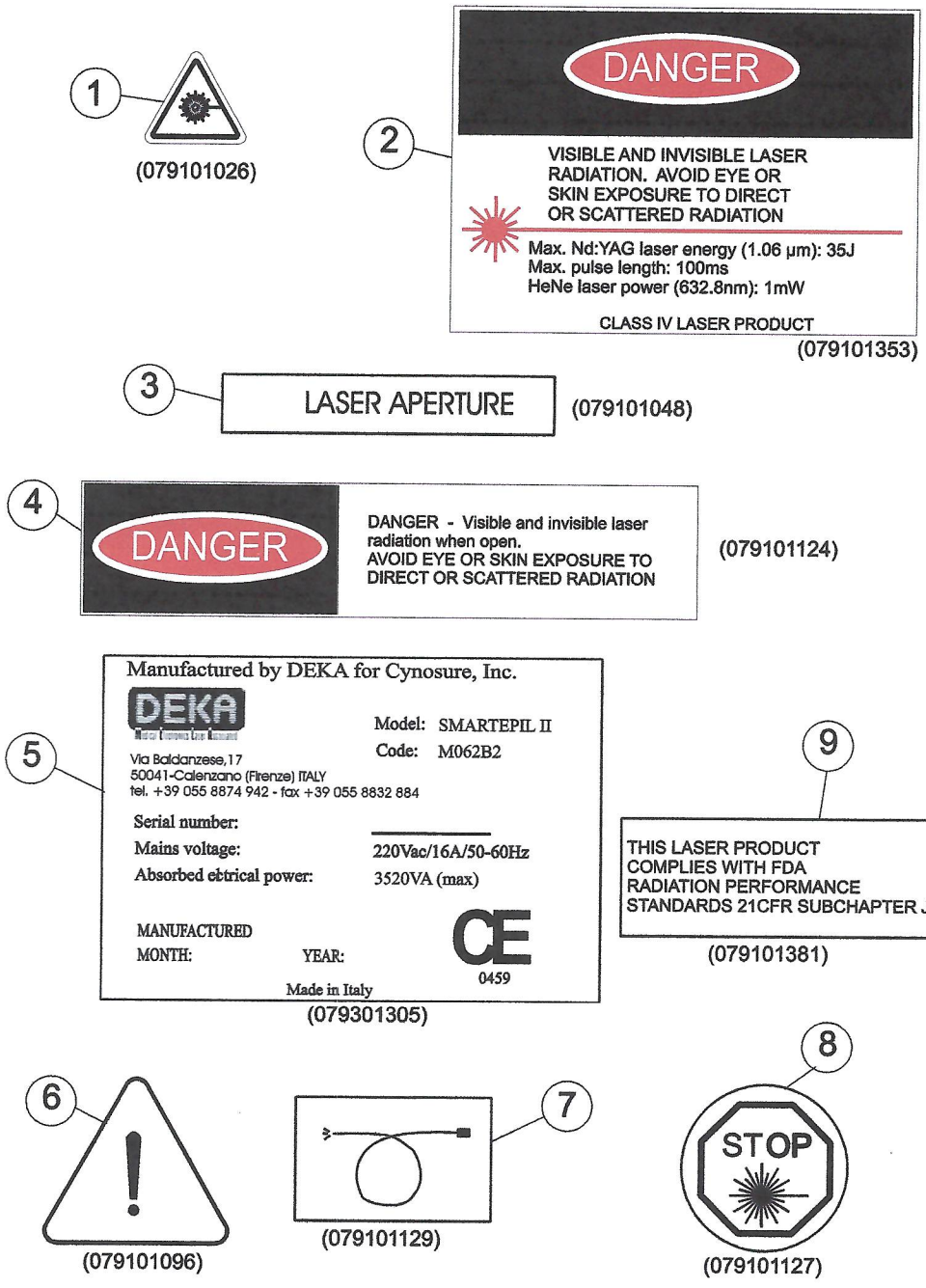

Figure 2B–Labels

When preparing the laser site, operators should consider the spatial, electrical, environmental, transportation and storage requirements of the laser unit.

Spatial Requirements

The Smartepil II laser unit has the following dimensions:

Height	92 cm
Width:	40 cm
Depth:	80 cm

Electrical Requirements

Please consider the following electrical requirements before installing the laser unit:

- The AC line power requirements for the Smartepil II laser are:

  220 VAC
  Single Phase
  20 Amps dedicated service
  50-60 Hz

- Power receptacles must be within 10 feet (3 m) of the laser site.
- The power receptacle must be grounded.
- The laser unit cannot share power lines with other heavy power-load equipment. The laser unit should be on a separate power line with a separate circuit breaker.

Environmental Requirements

In order to properly maintain the laser, follow these environmental requirements:

- Keep the air free of corrosive substances, such as salts and acids. These pollutants may damage electrical wiring and optical surfaces.
- Keep dust and hair particles to a minimum. Shave patient's skin in a separate room. Dust and hair particles can cause permanent damage to optical components.
- Keep humidity in the laser room at 20% to 80%, non-condensing.
- Keep the laser room temperature between 10° to 30°C.
- Do not place laser unit near heating vents or other sources of temperature variation.

Storage and Transport Requirements

To maintain the laser system properly during storage and transport, follow these requirements.

- Keep the ambient temperature between 5° and 50°C.
- Keep the laser system in a location where the humidity is between 10% and 90%, non-condensing.
- Minimize shock and vibration.
- Do not drop.
- Store the laser system where the air is free of corrosive substances, such as salts or acids.
- Store the laser system where there is a minimum of dust particles.

This section of the manual gives a general description of the Smartepil II laser and details the system specifications.

Handpieces and Optical Fiber

The Smartepil II laser comes with a set of interchangeable and reusable handpieces, which allow the user to vary the treatment spot size. See **Figure 3** for an overview of the handpiece. From the laser head, the treatment beam and aiming beam are coupled into the optical fiber. The optical fiber delivers the laser and aiming beams to the handpiece and then to the treatment area.

WARNING: There is a potential hazard when inserting, steeply bending, or inadequately tightening the fiber optics. Always follow the recommendations in this manual to avoid damaging the fiber or delivery system and/or harming the patient or user.

"Since the aiming beam passes down the same delivery system as the working beam, it provides a good method of checking the integrity of the delivery system. If the aiming beam is not present at the distal end of the delivery system, its intensity is reduced, or it looks diffused, this is a possible indication of a damaged or not properly working system."

IEC-601-2-22: 1996.

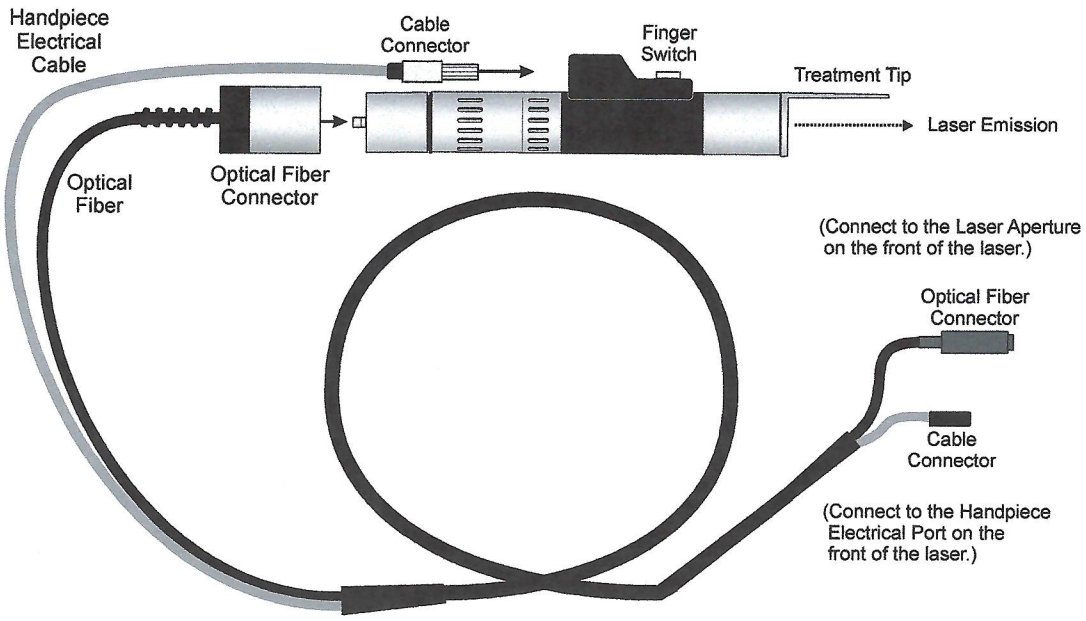

Figure 3–Handpiece

Changing Handpieces

To change handpieces, disconnect the handpiece electrical cable by pulling the cable connector from the handpiece. Then carefully pull the optical fiber connector from the rear of the handpiece. See **Figure 3**. Connect the new handpiece, reversing the steps above. Periodically test the optical fiber and handpiece(s) to confirm the transmission efficiency.

Trigger Switches

When the laser system is in OPERATE mode and the delay has passed, activate the laser beam by pressing one of the following switches:

- The **Finger Switch**, which is an electrical switch on the handpiece, see **Figure 3**.
- The **Foot Switch**, which is an electrical switch intended to be located on the floor and actuated by foot. See **Figure 4**.

HTT Port

The Handpiece Transmission Test (HTT Port) is the aperture in which the operator places the distal end of the handpiece during the Fiber Test. See **Figure 4**.

Major Components

Refer to **Figure 4** to identify the major components of the laser system.

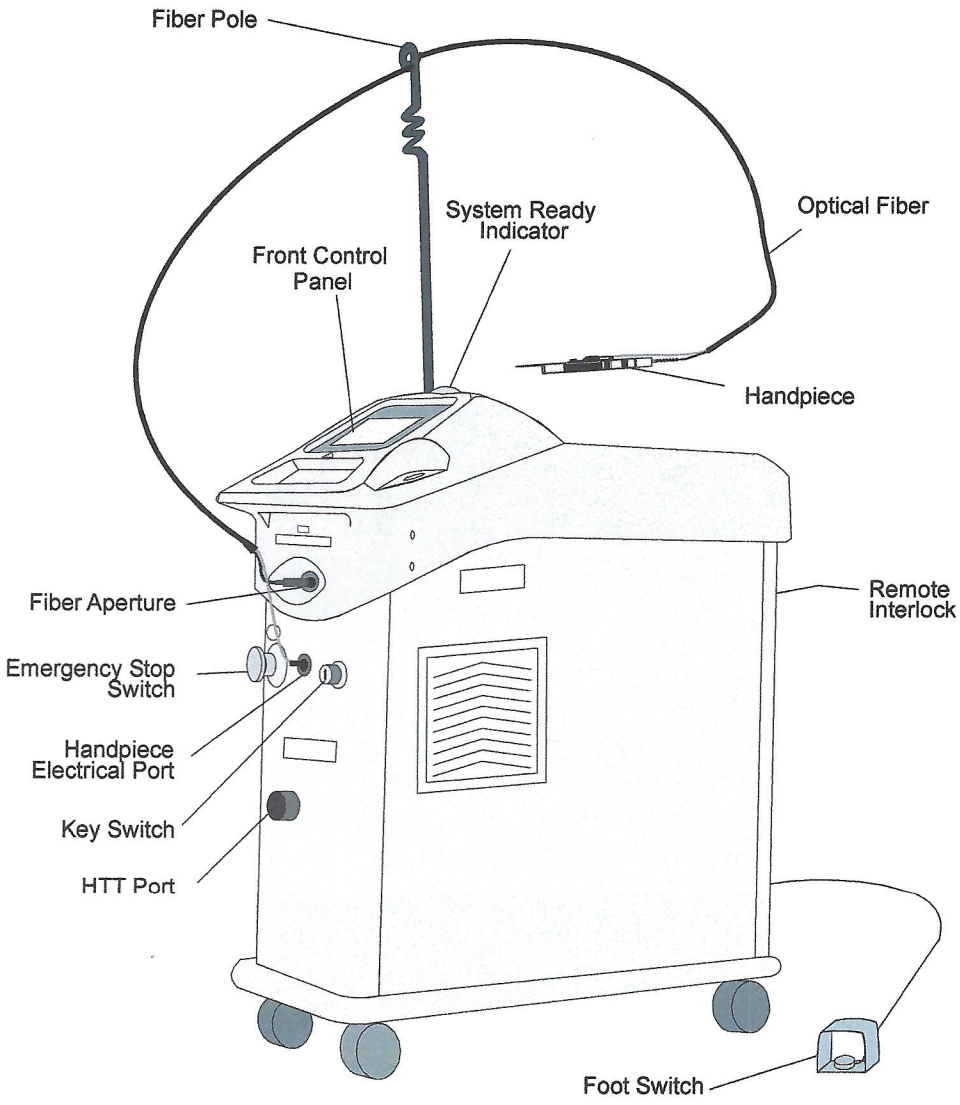

Figure 4–Major Components

System Power Controls

The System Power Controls include the keyswitch and the red Emergency STOP switch. They are located on the front of the system below the control panel, see **Figure 4.**

Key Switch

The Key Switch turns the system on. There are two positions on the switch: ON and OFF. To start the laser, insert the key and turn the key to the ON position. To turn the system off, turn the key to the OFF position and remove the key.

Emergency Stop Switch

The Emergency STOP Switch is used for emergency situations when the operator needs to shut down the system immediately. To shut the system off immediately, push the switch in. To reset the Emergency Stop switch, twist and pull the switch out.

Control Panel

The control panel, detailed in **Figure 5**, contains switches and displays for operating and monitoring the laser. It is essential that the uses understand and use these controls properly.

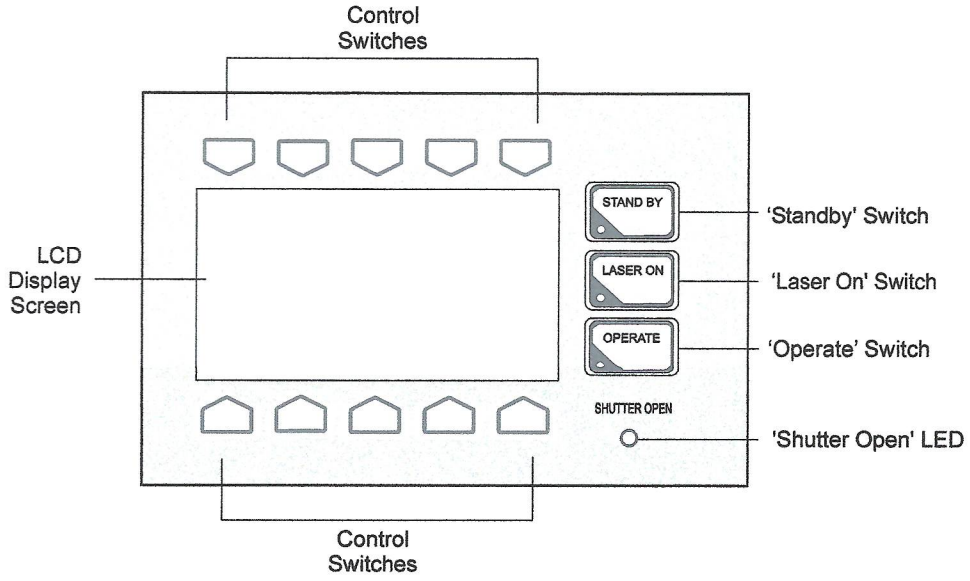

Figure 5–Control Panel

'Stand By' Switch

The STAND BY switch places the system in Stand By mode (indicated by a green light near the switch). When in Stand By mode, the laser is switched off and cannot produce a beam.

'Laser On' Switch

The LASER ON switch powers the laser (indicated by a red light near the switch).

'Operate' Switch

The OPERATE switch enables the foot switch or finger switch after a brief delay (the red light near the OPERATE switch flashes during the delay). When the system is in Operate mode, the red light, as well as the System Ready Indicator, see Figure 3, are illuminated indicating that the laser is operational. Activate the laser beam with the foot switch or finger switch.

NOTE: The first time the Operate switch is pressed after the system is in Laser On mode, or after the fluence setting has been changed, the system goes into 'calibration' mode. See "Laser Start-Up," on page 24 for further detail.

'Shutter Open' LED

The 'Shutter Open' LED, when lit, indicates that the shutter is open and the laser energy is being emitted.

Display Screen and Selection Controls

The LCD display screen and control switches provide user interface and control, as well as displaying information on the current system status. Refer to **Figure 6**, and the following detailed descriptions of the display screen functions.

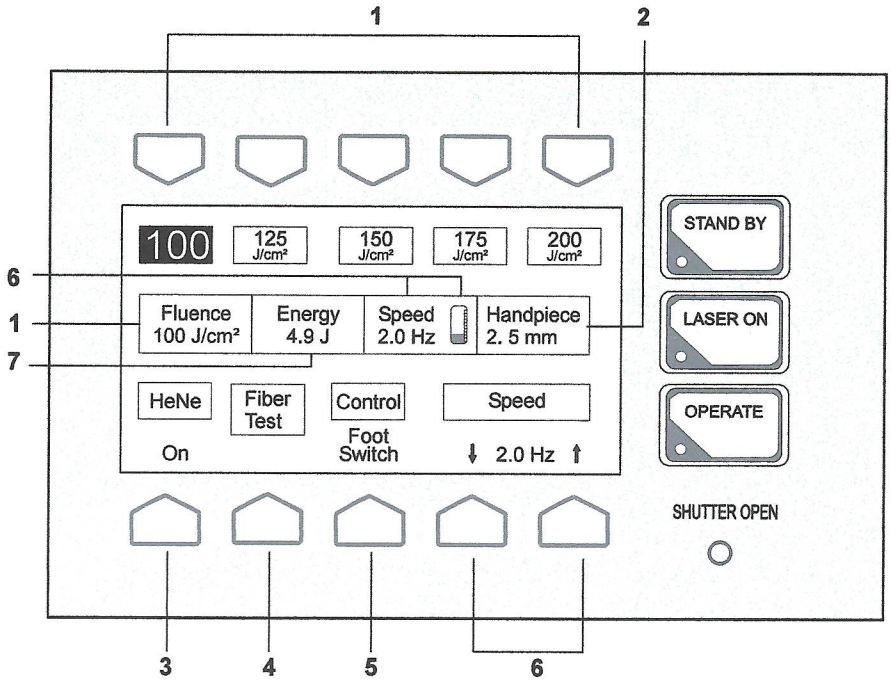

Figure 6–Control Panel

1–'Fluence' Switches

The Fluence switches select one of five fluences displayed. The fluences that are displayed depend on the spot size of the current handpiece as detected by the system. The selected fluence is displayed in large, reverse contrast characters. Available fluences range from 25 J/cm^2 to 200 J/cm^2 depending on spot size.

Current fluence is also displayed in the center row of the display.

2–'Handpiece' Display

The spot size for the current handpiece as detected by the system is displayed in the center row of the display.

3–'HeNe' Switch

The HeNe switch turns the aiming beam on and off.

4–'Fiber Test' Switch/Pulse Counter Display

The Fiber Test switch is used to check the transmission efficiency of the optical fiber and handpiece. See, "Appendix B Fiber Test," on page 43 for details on how to perform this test.

The switch is also used to access and display a pulse counter that displays the total pulses. To access and display the Pulse Counter, press the STAND BY switch. Now press and hold down the Fiber Test switch. The message, "First set OPERATE ON state," is briefly displayed, and then the pulse count. Release the switch and the system returns to stand by mode.

5–'Control' Switch

The Control switch selects which device (foot switch or handpiece finger switch) controls laser emissions. The currently selected device is displayed. To change the selection, press the switch.

6–'Speed' Switches

The 'Speed' switches increases or decreases and displays frequency of laser emission from 0.5 Hz to 6.0 Hz in 0.5 Hz increments, as well as single pulse.

The current speed setting, as well as the percentage of available frequency, shown as a bar graph are also displayed in the center row of the display.

7–'Energy' Display

The current energy is calculated by the system based on the current spot size and fluence settings, and then displayed in the center row in Joules.

System Specifications

Type:	Flashlamp-excited, solid state, Nd:YAG
Wavelength:	1,064 nm
Method of Optical Output:	Quartz optical fiber and handpiece lens
Output Mode:	Multimode
Maximum Delivered Fluence:	200 J/cm2 for 2.5 mm spot size 90 J/cm2 for 5 mm spot size 90 J/cm2 for 7 mm spot size 45 J/cm2 for 10 mm spot size
Pulse Characteristics:	
Duration (max.)	100 ms
Repetition Rates	1.0 to 6.0 Hz for 2.5 and 5 mm spot size 1.0 to 3.3 Hz for 7 mm spot size 1.0 to 2.0 Hz for 10 mm spot size
Protective Safety Eyewear Required:	> 7.0 OD at 1,064 nm
Nominal Ocular Hazard Distance (NOHD):	131 meters
Cooling Method:	Water, internally circulated with heat exchanger to air
Aiming Beam	
Laser Type:	HeNe (CW)
Wavelength:	632.8 nm
Max. Delivered Output Power:	1 mW
Electrical Power:	220 VAC, 3520 VAmax.
Electrical Service Requirements:	20 Amps dedicated outlet 50/60 Hz Single phase

Handpiece Characteristics:

Handpiece Type	*Color*	*Spot Size*	*Divergence (full angle)*
2.5 mm	Red	2.5 mm ± 0.5 mm	80 mrad
5 mm	Black	5 mm ± 0.5 mm	40 mrad
7 mm	Gray	7 mm ± 0.5 mm	50 mrad
10 mm	Blue	10 mm ± 0.5 mm	15 mrad

This section of the manual explains how to prepare, start, use and turn off the laser.

Laser Setup

Prior to starting the laser, care must be taken to prepare the laser properly. The following steps should be performed and checked

1. The Remote Interlock, a safety option that connects the laser to the entry door into the treatment area, must be connected to either the remote interlock system connector or the connector provided with the unit. The connector is plugged into the socket located on the rear of the laser and labeled INTERLOCK.
2. The Foot Switch allows laser emission by means of the user's foot. Plug the connector at the end of the foot switch cable into the socket on the rear of the laser labeled FOOT SWITCH. Place the foot switch on the floor near the treatment area.
3. The fiber pole supports the optical fiber. The pole can be located on either side of the laser for convenience. To install the pole, slide the large end of the pole into either of the holes above, and to either side of the control panel.

   NOTE: Refer to **Figures 3** and **4** while performing the following step of this section.
4. Install the optical fiber assembly. Carefully pass the proximal end of the optical fiber assembly through the loop at the top of the pole. Remove the black cap and connect the proximal Optical Fiber Connector to the Laser Aperture on the front of the laser. Connect the Cable Connector to the Handpiece Electrical Port located on the front of the laser. Properly connect the distal end of the optical fiber assembly to the handpiece as shown in **Figure 3**.
5. Plug the system into electrical service. Check the thermomagnetic circuit breaker switch located on the lower rear of the unit. The switch must be to the left (next to I).

Laser Start-Up

Follow the procedure below to start the laser.

1. Insert the key into the key switch and turn it to ON. The system will immediately respond.
2. Verify during start-up that all indicator lights flash and that the LCD screen lights up.
3. The unit will run a self test, and then switch to the user menu. If no faults are detected, then the following default settings are displayed:

Laser Source:	Off (Stand By Mode)
Foot Switch:	Disabled
Aiming Beam:	On
Handpiece Spot Size:	Automatically Detected (Verify that it matches the handpiece.)
Frequency:	Single Pulse
Fluence:	Minimum Setting

   If a fault is detected during the self test, see, "Troubleshooting" starting on page 33.
4. Perform the 'Fiber Test' weekly, or if there is any evidence the laser delivery system may not be functioning correctly. See, "Appendix B" on page 43 for details on performing this test.
5. Select the desired parameters: fluence, frequency, control device, etc.
6. Press the Laser On switch. The red indicator light next to the switch blinks during the laser power-up process. The light remains illuminated if the laser is powered. A fault message is displayed if the laser is not powered.

   NOTE: The laser automatically calibrates the laser output to the fluence selected in the following situations: 1) the first time the Operate switch is pressed after the Laser On procedure is successfully completed, or 2) when a new fluence value is selected while the system is in the Operate mode.

   If the calibration is successful, the system enables the foot switch or finger switch. If the user needs to stop the laser during calibration, press the Stand By or Operate switch to suspend the procedure.

   If the calibration fails a fault is displayed. See "LOWener/HIGHener" faults in the Troubleshooting section, page 35 for more information.
7. Laser start-up is complete, proceed to the next section.

Laser Use

WARNING: Always wear the protective eyewear supplied with your laser system! Failure to wear protective eyewear can result in serious eye injury.

1. Attach a clean, disinfected treatment tip to the distal end of the handpiece. Push the end of the tip with the spring into the end of the handpiece as far as it will go. See **Figure 3** for a detailed view of the handpiece components.
2. Hold the handpiece perpendicular to the treatment surface. Using the treatment tip as a distance guide, touch the end of the tip to the skin.
3. Press the Operate switch and wait for the indicator light to illuminate.
4. Use the finger switch or foot switch to emit laser energy. Avoid multiple pulses at the same spot and minimize the overlap of adjacent treatment spots.
5. When treatment is complete or when laser emission is not needed, press the stand by switch to secure the laser in a safe condition. Place the handpiece in the Handpiece Rest provided with the unit.

Laser Shutdown

To shut down the laser, press the Stand By switch, turn the key to the Off position and remove the key.

In an emergency situation, push in the Emergency Stop switch.

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This section of the manual discusses the clinical application of the Smartepil II laser in general terms. The section covers training requirements, indications, contraindications, possible adverse effects, patient selection and treatment recommendations.

Laser Operator Training Requirements

This manual is not intended to be a complete guide to the use of the Smartepil II laser. Cynosure recommends that all qualified personnel who operate the laser system first seek training that includes, but is not limited to, the following aspects of laser operation:

- Basic Laser Physics
- Laser Safety
- Tissue Interaction
- Laser Operating Procedures
- Laser Set-Up Procedures
- Potential Hazards
- Hands-on Experience

Indications

The Smartepil II laser system is indicated for hair removal and vascular lesion treatment.

Contraindications

Therapy using the Smartepil II laser is contraindicated for those patients who:

- are hypersensitive to light in the near-infrared wavelength region,
- take medication that is known to increase sensitivity to sunlight,
- take anticoagulants,
- have seizure disorders triggered by light,
- are pregnant,
- have a personal history of skin cancer.

Adverse Effects

Adverse effects such as scarring, hypopigmentation or hyperpigmentation may result from the use of excessive energy levels.

Pretreatment Recommendations

At the time of the initial visit, the physician should determine the suitability of the laser treatment, inform patients about the treatment, and take photographs of the treatment area.

Determining Suitability

In determining suitability, physicians should consider the following factors for each individual case:

- Patient's age.
- Location to be treated.
- Patient's skin type.
- Family history of the patient.
- Current medications.
- Reason patient is seeking treatment.
- Patient's expectations.

Patient Information

After determining suitability, the physician should inform the patient of the following:

- The expected outcome of the treatment vs. other possible outcomes.
- The probable number of treatments needed to achieve the desired outcome.
- Possible side effects resulting from laser treatment.

Photographs

It is helpful to have photographs of the pretreated lesions in order to precisely assess the success and progression of the treatment.

Treatment Recommendations

The operator should be able to determine the appropriate energy level of the laser, number of treatment sessions, size of treatment area at each session, and when no further treatment is warranted. At the time of the treatment, the laser operator should also take precautions to prevent fire. See, "Laser-Induced Fire Hazard" on page 8.

Prior to commencing the treatment, test spots should be performed to determine the appropriate fluence level to use for the skin type. A slight perifollicular erythema is the recommended end point to use. If a uniform erythema occurs throughout the beam area, the fluence setting used is probably too high.

Minimizing Adverse Effects

Adverse effects such as erythema, blistering, burns and scarring may be reduced by coolant gel. Prior to treatment, apply cooled, clear gel to freshly prepared, clean areas. An ice water bag may also be used pretreament and posttreatment. Alternatively, cold air may also be used to cool the treatment area before and after laser treatment. A cooling adapter that attaches to the laser handpiece and to a cold air supply (SmartCool) may also be used. In this case, the treatment tip is replaced with the cooling handpiece attachment.

Setting Energy Level

Depending on the patient's skin type, different energy levels are needed. For skin type IV, Cynosure recommends that physicians test each lesion on a low energy level of 20 J/cm^2 and then increase the level as needed.

Number and Length of Treatment Sessions

The number and length of treatment sessions depends on the size of the treatment area, the success rate of the treatment and the patient's tolerance of the treatment.

Determining End of Treatment

The physician should determine the end of the treatment by the complete success of the treatment, non-compliance on the part of the patient or adverse effects of the treatment.

Posttreatment Recommendations

After each treatment session, physicians should advise their patients on the proper care of the treated area.

- Wash the treatment area gently with soap and water. Do not soak.
- Do not shave the treated area if crusting is evident.
- Avoid all exposure to the sun between treatments. If exposure is unavoidable, use a sunblock with an SPF of at least 15 on the uncovered, treated area.
- Avoid contact sports or any other activity that could cause bruising of the treated area.

This section of the manual provides basic maintenance practices and information, a troubleshooting chart and a list of laser accessories.

Annual Service

The maintenance steps detailed below are to be performed at least once a year. These procedures should only be performed by qualified authorized service personnel who:

- are familiar with the operation of the Cynosure lasers,
- are familiar with the operation of the calibration standard,
- are well-versed in the general methods and techniques of laser energy measurements,
- have read and thoroughly understood these procedures.

Service Tasks

1. Replace the cooling circuit filters. Check for leaks and check the coolant level.
2. Clean, inspect and repair laser and laser delivery optics including the optical fiber.
3. Inspect and calibrate the internal power meter. See, "Appendix A," on page 41 for more information.
4. Inspect the flashlamps and the laser source.
5. Check all electrical insulation.
6. Check all shutters and the foot switch.

Routine Maintenance

There are routine maintenance items that the operator should take note of. These items are non-technical in nature. The environment and frequency of use the system is exposed to will influence the necessary and regularity of maintenance.

Cynosure suggests that operators periodically clean and disinfect the exterior of the laser system, the handpiece and the optical fiber. Take care not to contaminate any optical surface in the process. Clean and disinfect the laser with the system turned off.

Cleaning and Disinfecting Equipment

Clean exterior parts of the equipment with mild soap and water.

When necessary, disinfect the exterior parts of the equipment with a hospital-grade disinfectant.

Use a soft cloth for both cleaning and disinfecting.

Be careful not to contaminate the optics with soap or disinfectant when cleaning or disinfecting.

Cleaning and Disinfecting the Laser Delivery System

1. Remove the optical fiber and cable from the handpiece and clean the exterior of the handpiece using a soft cloth with mild soap and water. Remove all visible debris. Be careful not to saturate the finger switch or coat the optics with soap and debris. Take care not to contaminate any optical surface while cleaning.

2. Remove the treatment tip from the handpiece by pulling the tip out of the end of the handpiece body. Immerse the treatment tip in a disinfectant following the disinfectant manufacturer's instructions.

Cleaning the Air Filter

Periodically remove and vacuum the air filter located on the rear of the system.

Troubleshooting

The Smartepil II Laser provides a fault management feature that constantly monitors critical systems and displays any detected problems. If any of the following faults are detected, the laser will automatically go into Stand By mode. Once the fault is cleared, press any key to reset the fault display and exit the alarms menu. The possible faults and the appropriate action to take are detailed below.

ALARMS DETECTED		
INTERLOCK	FLOW	SIMMER
TEMPERATURE	EEPROM	SERVICE
SHUTTER IC	FIBER	LOWener.
SHUTTER EC	SW-PRG	HIGHener.
SCAN		
Press any key to reset.		

Descriptions of Faults

Temperature

This fault is displayed if the temperature of the laser source gets too high. **NOTE:** Do not turn off the system. Wait approximately 2 minutes to allow the cooling fluid to reduce the temperature, then press any key to reset the fault display. Call Technical Service if this fault persists.

Interlock

This fault is displayed if the Remote Interlock system detects an open circuit. If the Interlock feature is attached to an external interlock device, check that the door is closed, that the external interlock device is functioning and that the cable from the external interlock device is properly attached to the socket on the rear of the laser labeled INTERLOCK. Press any key to reset this fault display. If the fault does not clear or if an external interlock device is not used, check that the Interlock connector (provided with the laser accessories) is properly attached to the socket labeled INTERLOCK. Press any key to reset the fault display. Call Technical Service if this fault persists.

Shutter IC/Shutter EC

This fault is displayed if the shutters' detected position is not the same as the shutters' expected position. Press any key to reset the fault display. Call Technical Service if this fault persists.

Flow

This fault is displayed if poor flow in the cooling circuit is detected. Press any key to reset the fault display. Call Technical Service if this fault persists.

Simmer

This fault is displayed if the laser source is in Laser On mode but is not switched on. Press any key to reset the fault display. Press the Laser On switch. Call Technical Service if this fault persists.

Service

This fault is displayed if, after pressing the Laser On switch, the laser source fails to switch on. Press any key to reset the fault display. Press the Laser On switch. Call Technical Service if this fault persists.

Fiber

This fault is displayed if the optical fiber is not detected. Attach the fiber or check the connection. Press any key to reset the fault display. Call Technical Service if this fault persists.

High Power/Low Power

If the laser source fails to achieve the energy level selected, either of these faults will be displayed. Press any key to reset the fault display. Press the Laser On key. Call Technical Service if this fault persists.

EEPROM

This fault is displayed if an internal memory component does not work properly. This fault can be detected during system start-up or when the energy test is complete. Press any key to reset the fault display. Call Technical Service if this fault persists.

LOWener/HIGHener

This fault is displayed if the detected energy during self-calibration does not match the energy selected by the user. As indicated, measured energy is LOWER or HIGHER than expected.

Should the calibration cycle find the laser output high, a 'HIGHener' fault message appears. Press any key to reset the fault display and repeat.. The system will not allow laser emission if the laser output is too high. Call Technical Service if this fault persists.

Should the calibration cycle find the laser output low, the system asks the user if they wish to continue, and the system will try to calibrate at a frequency lower than the maximum frequency available for the selected fluence. If the user answers no, the 'LOWener.' fault message appears and the system switches to Stand By. If the user answers yes, the calibration cycle is repeated at a lower frequency. If the calibration is successful, the system will switch to the Operate mode and limit the frequency selection available. Should the calibration fail, the screen will display the low energy message and offer the user a choice to continue again. If calibration fails after a second attempt, the 'LOWener.' fault message is displayed and the system switches to Stand By. Call Technical Service if this fault persists.

Press any key to reset the fault display. Press the Laser On switch. Call Technical Service if this fault persists.

SW-PRG

This fault is displayed if corrupted data are found while the laser system is on. Press any key to reset the fault display. Call Technical Services if this fault persists.

SCAN

This fault is displayed if the optional scanner is connected to the system and a fault associated with the scanner system is detected. See the *Hi-Scan Operator's Manual* for details and to correct the problem.

System Warning

If the system displays the ENERGY value in reverse contrast, the supply voltage may not be correct. In this case, the performance of the system may be affected. Press any key to reset the fault display. Call Technical Service if this fault persists.

Troubleshooting Chart

The summary chart below shows faults that can be easily identified and solved by the operator:

Fault	Possible Solution
The system will not turn on.	Check the electrical cable connection and that the source voltage/current values match the system specifications. Check that the circuit breaker switch and the Emergency OFF Switch are correctly positioned. See, "Laser Setup," page 23. Check that the Key Switch is in the ON position. See, "Laser Start-Up," page 24.
No response when the foot switch is pressed.	Make sure the system is in the OPERATE mode. Make sure the CONTROL switch is set to "footswitch". See, "Laser Setup," page 23. Make sure the footswitch is connected to the system. See, "Laser Setup," page 23.
No response when finger switch is pressed.	Make sure the system is in the OPERATE mode. Make sure CONTROL switch is set to "finger switch". See, "Laser Setup," page 23. Make sure that the fiber assembly is properly connected to both the laser and the handpiece. See, "Laser Setup," page 23.
Poor laser emission or no laser emission from the handpiece.	Turn off the system and make sure the fiber is properly connected. See, "Laser Setup," page 23. Perform a fiber test, see page 43.
The fiber test results in a "defective" message.	Make sure the fiber is properly connected to the system and to the handpiece. See, "Laser Setup," page 23. If the fiber is properly connected, the fault may be due to fiber damage. A heavily damaged fiber optic causes strong attenuation of the red HeNe aiming spot. Replace the fiber. The fault may be caused by dirty or damaged internal lenses in the handpiece. Replace the handpiece.

If any problems occur that are not stated in the troubleshooting chart or the suggested solutions do not work, call the Cynosure Service Department at (978) 256-4200 or (888) 692-2966.

Laser Accessories

The Smartepil II comes with the following accessories. All items are also sold separately. Please reference the part number when calling Cynosure or your distributor.

Description	*Part Number*	*Quantity*
Safety Goggles, 1,064 nm	809-5000-005	1
Safety Spectacles, 1,064 nm	809-5000-004	1
Patient Eye Shield	100-0222-000	1
Remote Interlock Connector	100-1586-000	1
Red Handpiece, 2.5mm	100-1574-000	1
Handpiece, 4 mm (optional)	100-1623-000	1
Black Handpiece, 5mm	100-1576-000	1
Gray Handpiece, 7mm	100-1578-000	1
Blue Handpiece, 10mm	100-1580-000	1
Laser System Cover	163-4264-020	1
Optical Fiber Assembly, 600µm	100-1581-000	1
System key (for Key Switch)	200-0006-000	2
Window Holder Key	130-4872-300	2
Warning Label, Door	215-7403-000	2
Footswitch assembly	712-0000-054	1
Operator's Manual	850-0040-000	1
Fiber Pole	130-5269-000	2

Warranty

Cynosure, Inc., warrants to the original purchaser of any new merchandise, that the merchandise is free from defects in material and workmanship under normal use and service for a period of one (1) year from the date of purchase.

The obligation of Cynosure, Inc., under this warranty is limited, in its exclusive option, to repair or replace parts and materials, which prove to be defective.

The happening of any of the following events will serve to void the warranty:

1. Defects due to negligence, alteration, modification by anyone other than factory authorized personnel.
2. Abuse or misuse by purchaser.
3. Attempted or actual dismantling, disassembling, service or repair not specifically authorized by Cynosure, Inc.

All merchandise should be inspected for obvious damage upon arrival. If merchandise has been damaged in transit, the Cynosure Service Department must be notified within 72 hours.

All claims for nonconforming or defective product must be made in writing within 10 days after delivery to the purchaser, and any claims not made within that period shall be deemed waived and released.

IN NO EVENT SHALL CYNOSURE BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES DUE TO ANY CAUSE WHATSOEVER. No suit or action shall be brought against Cynosure more than one year after the related cause of action has accrued.

THE FOREGOING CONSTITUTES OUR SOLE LIABILITY AND THE PURCHASER'S SOLE REMEDY WITH RESPECT TO PRODUCTS SOLD BY US. EXCEPT AS THUS PROVIDED, WE DISCLAIM ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Installation

Cynosure or its authorized personnel installs the Smartepil II Laser, gives a demonstration of operation and provides a basic training service for each new customer.

Customer Service

Cynosure's Customer Service Policy includes the following support for customers:

- On-site repair of equipment
- On-site customer training of use and maintenance
- Telephone troubleshooting. Call the Cynosure Service Department at (978) 256-4200 or (888) 692-2966, or FAX (978) 256-4888.

Appendix A Internal Energy Meter Calibration

WARNING: The following procedure should be done only by trained personnel. When the enclosure is removed, hazardous voltages and/or laser light levels are exposed.

Schedule for Calibration

Cynosure calibrates the laser's internal energy meter and control circuits at the factory prior to shipment. The laser's energy meter and controls should be recalibrated annually by Cynosure authorized service personnel. Call your local Cynosure representative to arrange for recalibration.

This procedure should *only be performed by qualified authorized personnel who:*

- are familiar with the operation of the Smartepil laser,
- are familiar with the operation of the calibration standard,
- are well versed in the general methods and techniques of laser energy measurements, and have read and thoroughly understood this procedure.

NOTE: The accuracy of the calibration depends completely upon the measurement of laser power using a separate instrument as an independent calibration standard. If the independent calibration standard is not accurate, or is not used correctly, then the built-in laser energy meter will also be inaccurate after calibration.

Required Equipment

- An accurate, NIST-traceable laser energy meter for use as a calibration standard. The power meter used in this procedure must be capable of measuring a maximum of 50 joules at 1,064 nm. Its sensor element or input attenuator must withstand, without damage, the range of fluence and power per unit area typical of this laser.
- A screwdriver for removing the laser side panels and top cover.
- A trim potentiometer screwdriver for adjusting.
- A digital voltmeter with chip-on probe leads.

Procedure

The Internal Energy Meter is used by the system to perform the calibration procedure. The calibration procedure includes the transmission efficiency of the optical fiber and handpiece.

1. Enter the service menu.
2. Check the optical fiber and laser source alignment and efficiency using the 'Fiber Test'.
3. Select the following values:
   - 7mm (handpiece)
   - 2.5 Hz (frequency)
   - 17.3 J (energy)
4. Position the external service energy meter head 10 to 15 cm from the handpiece aperture.
5. Close the EC shutter.
6. Switch on the Nd:YAG source and press the foot switch for 7 seconds. Read and record the measured value and release the foot switch.
7. Open the EC shutter. Repeat step 6.
8. If the two measurements differ more than 5%, adjust the RV2 trim (gain) on the CPU board. Turn clockwise to decrease the displayed value from the internal meter or counter clockwise to increase the displayed value.
9. Repeat steps 5 through 8 until the internal and external service meters measurements are within 5%.
10. Now adjust RV1 trim (dumping) on the CPU board until the internal meter energy reading stabilizes within 4 to 5 seconds without overshoot. Turn clockwise to speed up the read rate or counter clockwise to slow down the read rate.
11. Now repeat steps 5 through 8 to confirm that the internal and external meters agree within 5%. If not, repeat steps 5 through 10.
12. Once test is complete, seal the trims.

The Fiber Test is used to check the transmission efficiency of the laser delivery system (the optical fiber and handpiece). If the measured transmission efficiency drops below 80%, the system displays DEFECTIVE DELIVERY SYSTEM. Check the fiber and handpiece for physical damage. Also, check the spot size and shape. To stop the Fiber Test, release the finger switch (or foot switch if active) or press any other switch.

Follow the Fiber Test procedure below:

1. Remove the treatment tip from the distal end of the handpiece.
2. Press the Laser On switch and then the Operate switch. Once the system is ready, press the Fiber Test switch.
3. The screen will prompt the user step by step. The message 'Energy Meter not ready' may be displayed at the beginning of the procedure, wait a few seconds and the message will clear.

   CAUTION: The handpiece must be supported throughout the remainder of this procedure or it may fall from the port and become damaged.
4. Insert the handpiece into the HTT Port as prompted. Press and hold down the finger switch (or foot switch if active) until prompted to stop.
5. During the procedure, the test will abort for the following reasons:
   - If the finger switch is released,
   - If the handpiece is withdrawn from port,
   - If the energy meter is not working properly,
   - If any switch, other than the finger switch, is pressed.
6. Once the test is complete, release the finger switch and remove the handpiece from the port as prompted.
7. If the laser delivery system passes the test, press any key to reset the display as prompted. If the laser delivery system fails the test, the screen displays the measured efficiency and determines that the system is defective.

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