E2 MICROPROBETM

MICROENDOSCOPE SYSTEM

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USA

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WARNING: NO UNAUTHORIZED USE OF LASER. The user of the E2 MicroProbe™ should be thoroughly trained in the applicable procedure. Furthermore, failure to read and thoroughly understand the content of this Operators Manual may result in serious injury to the patient or user. It is essential to follow the instructions contained in this manual which pertain to the E2 MicroProbe™ and accessories used in conjunction with the procedures. Failure to follow these instructions may result in damage to the E2 MicroProbe™ or malfunction of the E2 MicroProbe™.

CAUTION: Endo Optiks restricts the sale of the E2 MicroProbe™ to a physician or on order of a physician.
# Labels

The following labels are affixed to the E2 Microprobe™ system. The title, the part number, and the location on the E2 Microprobe™ are given for each label.

<table>
<thead>
<tr>
<th>Label</th>
<th>Location</th>
</tr>
</thead>
</table>
| Identification | P/N 3840406  
Rear Panel, near the top right corner. |
| Protection Against Electric Shock | P/N L1012  
Incorporated into the Identification label |
| Fuse Replacement Label | P/N 0711111  
Rear Panel, directly below AC receptacle |

Meaning: Type BF equipment

Supply Rating
115/240 Volts, 60/50Hz, 4.0/2.0A
Use 2 Type T6.3A, 250V

Meaning: Dangerous Voltage
P/N L1007  
Incorporated into the Identification label
BEGINNING

LASER APERTURE
P/N L1003C
Front Panel

Caution: Consult Accompanying Documents
P/N L1009
Incorporated into the Identification label

LASER WARNING
P/N L1002C
Top, Front

CONFORMITY & APPLICABLE STANDARDS
P/N L1016
Rear Panel

LASER STOP
P/N L1017
Front Panel

Conforms to European Medical Device Directive 93/42/EC.

P/N L1003
Incorporated into the Identification label
Safety Agency Approvals (MET MARK)

P/N E112374
Rear panel, bottom left, under AC receptacle

Caution: HOT

P/N: L1009A
Front Panel, next to light connector

This symbol has been attached to the equipment or, in the case that this is not possible, on the packaging, instruction literature and/or the guarantee sheet. By using this symbol it states that the device has been marketed after August 13th 2005, and implies that you must separate all of its components when possible, and dispose of them in accordance with local waste disposal legislations.

- Because of the substances present in the equipment, an improper use or disposal of the refuse can cause damage to human health and to the environment.
- With reference to RAEE (Registry of Electrical and Electronic Apparatuses), it is compulsory not dispose of the equipment with normal urban refuse, arrangements should be instigated for separate collection and disposal.
- For more detailed information about recycling of RAEE, please contact your local waste collection body.
- In case of illicit disposal, sanctions will be levied on transgressors.

To achieve proper grounding reliability, a power supply plug must be fully inserted into a receptacle marked "HOSPITAL GRADE"

Hospital Grade Power Cord
P/N: Hospital Grade Labels
Above Power Receptacle On Rear Panel
Precautions

To prevent fire or shock hazard, do not expose the unit to rain or moisture.

Dangerously high voltages are present inside the E2 Microprobe™. Do not open the cabinet. Refer servicing to qualified personnel only.

In the event of a malfunction or when maintenance is necessary, consult:
Endo Optiks
39 Sycamore Ave., Little Silver, NJ, USA.
Tel: 001 732 530 6762, Fax: 001 732 530 5344
Email: info@endooptiks.com

On safety
- Operate the unit on the designated AC voltage only.

- The Fuse Replacement Label indicates operating voltage and is located adjacent to the mains fuse holder in the rear of the cabinet.

- Should any solid object or liquid fall in, unplug the unit and have it checked by qualified personnel before operating it any further.

- To disconnect the AC power cord, pull it out by grasping the plug, never pull the cord itself.

- The outlet shall be installed near the equipment and shall be easily accessible.

Warning
This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the E2 Microprobe or shielding the location.

Endoscopes and Probes
This device is intended to be used in conjunction with Endo Optiks endoscopes and probes ONLY and to assure safety should not be connected or used with any other devices.
Disconnect the endoscope from the system by grasping the connectors only. Do not grasp or bend the endoscope jacketing for this may break the glass fibers that are enclosed within the jacketing.

**CAUTION:** The heat generated by the light source varies and can be hot causing the light connector, on the endoscope, to become hot. To prevent injury to the operator the light intensity should be turned down so the connector can cool before removing it from the system.

**On installation**
- The E2 MicroProbe™ should be used in a Hospital or Clinical setting only. It should be used indoors only under the environmental conditions stated on Page 36 of this document.
- Allow adequate air circulation to prevent internal heat build-up.
- Do not place the unit on surfaces (rugs, blankets, etc.) or near materials (curtains, draperies) that may block the ventilation holes.
- Do not install the unit in a location near heat sources such as radiators or air ducts, or in a place subject to direct sunlight, excessive dust, mechanical vibration or shock.

**On cleaning**
To keep the unit looking brand-new, periodically clean it with a mild detergent solution. Never use strong solvents such as thinner or benzine, or abrasive cleansers since they will damage the cabinet. As a safety precaution, unplug the unit before cleaning it.

**On sterilization before use**

**WARNING** - The endoscopes and probes must be sterilized before use. Please refer to the instructions provided with each device.
SYSTEM OVERVIEW

System

The Endo Optiks E2 MicroProbe™ is the principal component in a new portable laser and endoscopy system. The complete system consists of the therapeutic laser, the endoscope, the monitor and the footswitch. This compact unit creates the opportunity to simultaneously image and photocoagulate the ciliary processes through a corneal incision. It is especially indicated for the safe and effective treatment of glaucoma in combination with cataract surgery. Important vitreo-retinal applications can be realized. It can be used for the contact and non-contact excision, hemostatis, incision and vaporization of soft tissue.

Cabinet

The compact laser and endoscopy cabinet houses a xenon light source, a therapeutic laser and a CCD camera. The laser output, pulse width, light and aiming beam intensity are controllable from the Front Panel. The parameters are displayed on Front Panel digital displays and lighted status indicators. For safety there is an emergency shutoff button. The Rear Panel features connectors to any video monitor, VCR or video printer. A Foot Pedal enables hands-free operation.

Light Source

The xenon light source is used to provide light to the endoscope. The intensity of light can be adjusted from the Front Panel, or with the foot switch.

CAUTION: The heat generated by the light source varies and can be hot causing the light connector, on the endoscope, to become hot. To prevent injury to the operator the light intensity should be turned down so the connector can cool before removing it from the system.
SYSTEM OVERVIEW

CCD Camera
The CCD camera is used to process the image obtained by the fiberoptic endoscope and display it on the video display. There is a Video Camera BNC connector Input and Outputs located at the Back Panel. The Video Camera Cable Output can be plugged into the Video Camera Cable Input or a remote Video Camera Cable Input can be used.

Digital Displays and Indicators
The Display consists of four Light Emitting Diodes and four Lighted Indicators. They are as follows:

<table>
<thead>
<tr>
<th>FUNCTION</th>
<th>DISPLAY TYPE</th>
<th>Key*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laser Power</td>
<td>Digital</td>
<td>1</td>
</tr>
<tr>
<td>Laser Active</td>
<td>Lighted</td>
<td>2</td>
</tr>
<tr>
<td>Laser Duration</td>
<td>Digital</td>
<td>3</td>
</tr>
<tr>
<td>Laser Standby</td>
<td>Lighted</td>
<td>4</td>
</tr>
<tr>
<td>Laser Enable</td>
<td>Lighted</td>
<td>5</td>
</tr>
<tr>
<td>Laser Aiming Power</td>
<td>Digital</td>
<td>6</td>
</tr>
<tr>
<td>Laser Cool Down</td>
<td>Lighted</td>
<td>7</td>
</tr>
<tr>
<td>Laser Shot Counter</td>
<td>Digital</td>
<td>8</td>
</tr>
</tbody>
</table>

* Please refer to the Diagram labeled Front Panel on Page 8.

Video Display
The video display can be any high resolution monitor such as the Sony LMD-1530MD and is used for displaying the endoscopic image. The video outputs are located at the Back Panel and can be utilized for recording the endoscopic image onto any video recording format such as the U.S. standard NTSC or the European standard PAL. There is an S-Video (Y/C Out) and 4 Video Out Connectors). All are BNC connectors (75 ohms terminated).

Foot Switch
The footswitch is used to activate the laser. Some footswitch models can also be used to vary the illumination intensity of the xenon light source. The footswitch connector is located at the Back Panel.
**SYSTEM OVERVIEW**

**Front Panel**
The Front Panel contains the color coded switches, digital displays and indicators used to control the functioning and show the status of the E2 Microprobe™. The functions and status indicators are:

<table>
<thead>
<tr>
<th>KEY</th>
<th>COLOR</th>
<th>FUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>Laser Power Digital Display</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>Laser Active Lighted Indicator</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>Laser Duration Digital Display</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>Laser Standby Lighted Indicator</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>Laser Enable Lighted Indicator</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td>Laser Aiming Power Digital Display Counter</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td>Laser Cool Down Lighted Indicator</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td>Laser Shot Counter Digital Display</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td>Laser Output Connector</td>
</tr>
<tr>
<td>10</td>
<td>Yellow</td>
<td>Laser Power Up and Down Switch</td>
</tr>
<tr>
<td>11</td>
<td>Blue</td>
<td>Laser Duration Up and Down Switch</td>
</tr>
<tr>
<td>12</td>
<td>Green</td>
<td>Laser Enable Switch</td>
</tr>
<tr>
<td>13</td>
<td>Red</td>
<td>Aiming Beam Intensity Up and Down Switch</td>
</tr>
<tr>
<td>14</td>
<td>White</td>
<td>Illumination Intensity Up and Down Switch</td>
</tr>
<tr>
<td>15</td>
<td></td>
<td>Xenon Lamp Out</td>
</tr>
<tr>
<td>16</td>
<td></td>
<td>Counter Reset</td>
</tr>
<tr>
<td>17</td>
<td>Red</td>
<td>STOP (Big Red Button)</td>
</tr>
<tr>
<td>18</td>
<td></td>
<td>Camera</td>
</tr>
</tbody>
</table>

**Front Panel Features**
SYSTEM OVERVIEW

Back Panel
The Back Panel contains the On -- Off Key Switch, the Mains Power Inlet, the Fuses, the Foot Switch Connector, the Video Connectors, the Remote Interlock and the Remote Communications Port. The locations are:

<table>
<thead>
<tr>
<th>KEY</th>
<th>FUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Video Camera Cable (located under the cabinet foot)</td>
</tr>
<tr>
<td>2</td>
<td>Video Camera Cable Input</td>
</tr>
<tr>
<td>3</td>
<td>S-Video (Y/C Out)</td>
</tr>
<tr>
<td>4</td>
<td>Foot Switch</td>
</tr>
<tr>
<td>5</td>
<td>Remote Interlock</td>
</tr>
<tr>
<td>6</td>
<td>Laser On -- Off Key Switch</td>
</tr>
<tr>
<td>7</td>
<td>RS-232 Remote Communications Port</td>
</tr>
<tr>
<td>8</td>
<td>ON/OFF Switch and Mains Power Inlet and Fuses</td>
</tr>
<tr>
<td>9</td>
<td>Video Out</td>
</tr>
<tr>
<td>10</td>
<td>Video Out</td>
</tr>
<tr>
<td>11</td>
<td>Fuse for Lamp Power Supply</td>
</tr>
<tr>
<td>12</td>
<td>Video Out</td>
</tr>
<tr>
<td>13</td>
<td>Video Out</td>
</tr>
</tbody>
</table>

Back Panel Layout
SYSTEM OVERVIEW

Diode Laser and Principal of Operation
Diode lasers are small semiconductor devices consisting of a sandwich of gallium-aluminum arsenate crystalline materials and end mirrors. The electrons of the crystal are raised to an excited energy state by an electrical current. When the electrons return to their original energy state, photons are emitted. In the laser cavity, these emitted photons are trapped between the cladding layers and the end mirrors. When a photon passes close to an excited electron, the electron will be stimulated to emit another photon that is identical in wavelength and phase to the first. This amplification process continues, increasing the number of active photons as the photon light beam is reflected back and forth between the cavity mirrors. One of these mirrors releases a percentage of the energy hitting its surface resulting in the infrared laser light.

The frequency of the diode laser employed in this system is 810nm. This laser is intended only for the use of physicians who are trained in operation of laser photocoagulators. Training in the therapeutic use of lasers is available in medical courses and seminars offered throughout the world.
GETTING READY

Site Preparation

The E2 Microprobe™ system has no special electrical or water requirements. Standard wall voltage can be utilized and no special cooling is required because a solid state diode laser is used.

Utilities

**Electrical:** The E2 Microprobe™ can be configured to operate from a power source in the range of either 115 volts AC or 240 volts AC, 60/50Hz, 400 watts maximum. A standard grounded AC outlet is sufficient. Verify that the voltage indicated on the fuse holder, below the A/C receptacle, at the back of the laser console matches the actual line voltage before the instrument is plugged in.

**Warning**

This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the E2 Microprobe or shielding the location.

**Laser Safety**

**WARNING** - Never look directly into the laser aperture (output port) or fiberoptic when power is applied. Severe eye damage could occur.

As a precaution against accidental exposure to the output beam or its reflection, all persons in the vicinity during operation of the photocoagulator must wear laser safety glasses. The only exception is the surgeon if he or she is looking through a delivery system which is protected by an internal laser filter. Never look directly into the laser beam or its reflection, even with the laser safety glasses in place. The laser safety glasses must give protection at 810NM.

**Note:** The Endo Optiks diode laser safety glasses have been tested and are compliant with EN60207-EN60208 standards. The wavelength and Optical Density (O.D.) are clearly indicated on the laser safety glasses. Safety glasses that are obtained from any vendor other than Endo Optiks should be compliant with these standards.

GETTING READY
**Reflection Hazard**

Smooth objects will reflect a diode laser beam. Reflection hazards can exist beyond the laser beam aperture. Regardless of the surface, reflection is a potential hazard when the laser strikes a nonabsorbent surface such as a metallic instrument. There are two types of reflections which can occur: Specular and diffuse.

**Specular reflections:** Specular reflection occurs when the size of the surface irregularities is less than the wavelength of the incident radiation. In this instance the laser beam reflects at the same angle as the angle of incidence. The danger occurs when a concentrated beam of laser light could accidentally strike unintended tissue or the eyes causing significant thermal damage.

**Diffuse reflections:** Diffuse reflection occurs when surface irregularities are randomly oriented and are much greater than the wavelength of the incident light. In this instance the reflected laser beam is disorganized and scatters in many directions though a laser light may still strike an unintended target surface. But the power density will be reduced to a degree that will cause minimal, if any, thermal effect.

**Tissue Protection**

**WARNING** - Never place your hand or other objects in the pathway of the laser beam. Severe burns could occur.

**Explosion Hazard**

**WARNING** - Never operate the laser in the presence of flammable anesthetics. An explosion and fire could occur.

Do not use the laser in the presence of flammables or explosives such as volatile anesthetics, alcohol, certain surgical preparation solutions and other such substances.

The E2 MicroProbe™ should be kept in the Standby mode whenever the system is not actually in use during treatment of a patient. The Standby mode is to prevent accidental laser discharge if the Foot Pedal is inadvertently depressed

**CAUTION:** Laser plume may contain viable tissue particulates; however the endoscope is fired in a closed environment in both the anterior and posterior segments of the eye so the plume does not escape into the atmosphere. There are no possible hazards associated with the laser plume.
GETTING READY

Exposure Protection From the Aiming Beam Laser

CAUTION: The maximum safe power that can be visualized indefinitely by the retina is 0.39 microwatts (Class 1). The diode laser that produces the red aiming beam is a Class 3A laser, producing up to 1,500 microwatts. Direct visualization of Class 3A laser radiation by a patient during treatment has not been shown to be safe. To protect the patient from possible retinal damage use the lowest practical aiming beam intensity during treatment. The diode laser produces a red diode aiming beam with power variable from barely visible to 1.5 milliwatts maximum. The safe (Class 1) exposure duration limit at maximum power level of 1.5 milliwatts is 0.047 seconds.

Safe Viewing Times

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Safe under conditions of operation.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Eye protection by aversion response (blink).</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Minimum safe viewing time.</td>
<td>Aiming Laser</td>
</tr>
<tr>
<td>4</td>
<td>Use requires extreme caution.</td>
<td>Treatment Laser</td>
</tr>
</tbody>
</table>

Safety Features

Key Lock Switch: The laser can be turned on only with the proper key to close the master switch. The key cannot be removed in the On position and the laser will operate only when the key is in place. When the Key Switch is rotated to the On position, power is available to the instrument.

Enable Function: Even when the E2 MicroProbe™ is activated by turning the key on, the Foot Pedal will not fire the laser. The laser cannot be fired unless the ENABLE control is pressed on. This control takes the laser out of the STANDBY mode and allows laser firing by footswitch activation. This safety feature requires a deliberate second action by the Operator of the laser prior to its being fired.
GETTING READY

**Protective Housing:** The diode laser has a protective housing which prevents unattended human access to laser radiation above safe limits. The user shall not perform maintenance or service operations inside the protective covers. This housing is to be opened only by an Endo Optiks Service Representatives or an Endo Optiks certified technician.

**Protective Jacketing:** The laser fiber inside the endoscope is protected by jacketing. In the event that the laser fiber breaks, the jacket protects the user from laser radiation emission.

**Viewing Optics:** When employing the laser endoscope in the Video mode, direct viewing of the laser and ocular tissues is not an issue, because the laser energy cannot be emitted through the video display.

**Room Door Interlock:** The E2 MicroProbe™ will be switched into standby mode when the treatment room door is opened during use.

**System Labels:** Appropriate warning labels have been mounted in specified locations on the instrument to indicate conditions under which the user could be subjected to laser radiation.

**STOP:** Depressing the STOP (the Big Red Button) will immediately disable the laser and reset all the treatment parameters to zero. The E2 MicroProbe™ will be in the stand-by mode with the power on.

**WARNING**

It is not intended that the user perform any maintenance or service operations inside the protective housing of the diode laser. All internal adjustments, cleaning, maintenance, and servicing shall be performed only by an Endo Optiks Service Representative or an Endo Optiks certified technician.

**CAUTION**

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

Cleaning the Laser Console
To clean the external surface of the Laser Console, wipe using a cloth dampened with a noncaustic cleaning solution such as soap and water, isopropyl alcohol or a "hospital grade" disinfectant. Do not spray or put cleaning agents directly on the system. Dry with a clean, dry cloth or allow to air dry.

Cleaning the Laser Connector
Before connecting an endoscope to the system, clean the tip of the Laser Connector with alcohol and lens cleaning tissue. Moisten the lens tissue with alcohol and gently wipe it once across the tip of the Laser Connector.

Cleaning the Video Adapter
Before connecting an endoscope to the system, clean the tip of the Video Connector with alcohol and lens cleaning tissue. Moisten the lens tissue with alcohol and gently wipe it once across the tip of the Laser Connector. This will prolong the life of the endoscope and maximize image quality.

Clean the Video Adapter with a lens cleaning tissue. Do not use alcohol for this may harm the laser filter that is built into the Video Adapter.

Endoscope and Probe Cleaning and Sterilization
These devices are delivered non-sterile and are designed to be reusable in accordance with the constraints described in the information supplied. The Endoscope should be sterilized before each use. If the endoscope is sterilized but not cleaned after each use, you will almost certainly destroy the tip of the endoscope the next time you fire the laser.

FULL INSTRUCTIONS FOR CLEANING AND STERILIZATION ARE PROVIDED WITH EACH ENDOSCOPE OR PROBE.
CLINICAL APPLICATIONS

WARNING
The MicroProbe™ system is intended solely for use by physicians trained in the operation of laser photocoagulators.

Indication For Use
The ophthalmic laser endoscope is indicated for the Endo intraoperative photocoagulation of the ciliary processes in the treatment of glaucoma, proliferative retinopathies, retinal detachment, focal treatment of retina or choroidal disorders, and for evaluation of the internal ocular structures in patients with dense opacifications of the anterior segment which do allow a posterior view.

Glaucoma
This instrument is indicated for the treatment of glaucoma in patients who have failed with conventional topical and systemic medications, or previous laser photocoagulation, or trabeculectomy and other filtering procedures, or cyclocryotherapy or other cyclodestructive procedures.

The endophotocoagulation of ciliary processes under direct endoscopic view is highly controllable, i.e. titratable, and has been demonstrated to be effective in the treatment of glaucoma.

Vitreoretinal Surgery
The endoscopically controlled endophotocoagulation that is possible with the ophthalmic laser endoscope is also useful for endophotocoagulation:

- During vitreous surgery to produce chorioretinal scar around retinal breaks or retinotomy sites
  - To perform intraoperative panretinal photocoagulation (PRP) in proliferative retinopathies
  - To perform intraoperative retinal photocoagulation on a scleral buckle
  - To perform intraoperative photocoagulation around focal neovascularization
CLINICAL APPLICATIONS

Contraindications

CAUTION: It is NOT advisable to use the E2 Microprobe if the following contraindications are present.

USE CONTRAINDICATED IN:

- An albino eye

WARNING
The diode laser and endoscopic photocoagulation are intended solely for use by physicians trained in the operation of photocoagulators.

WARNING
Excessive number or short pulse durations may result in choroidal hemorrhage.

WARNING
Excessive laser power settings may result in retinal holes and retinal hemorrhages.

WARNING
Photocoagulation of ciliary processes may result in anterior or posterior segment hemorrhage, uveitis or hypotony. A diode laser has an effect on tissue similar to that of the krypton laser. The longer wavelengths of krypton and diode lasers relative to argon lasers may result in the following situations:

- An increased uptake by the choroid which may cause
  a. Increased patient discomfort
  b. Increased choroidal edema
  c. Increased choroidal hemorrhage
  d. Reduced accommodation

- Poor uptake by hemoglobin in management and treatment of retinal capillary aneurysms, retinal arteriolar macroaneurysms and retinal capillary hemangioma.
- Poor uptake in a hypopigmented eye.
OPERATION

Set Up and Operation

The E2 MicroProbe™ system must be set up and operated with care. The endoscopic laser probe is a fragile component and great care should be used when handling it.

Endoscopes and Probes
Before each use, the endoscope or probe should be thoroughly inspected in order to detect any irregularity or abnormality. If these are noted, the endoscope or probe should not be used and a new one should be employed.

Inspection of the Optical System
The endoscope allows two functions. The first is optical viewing and the second is delivery of therapeutic laser energy. Both of these functions can be determined prior to insertion into the eye. It is essential that the viability of the fiberoptic pathways be demonstrated prior to use and this may be done in a rather simple manner.

To check the integrity of the optical viewing system, direct the distal end of the endoscope to a point of reference, such as the focus ring at the video adapter for the image fiberguide on the Front Panel of the E2 MicroProbe™. A clear view should be obtained.

The aiming beam provides a good method of checking delivery of the therapeutic laser energy since it passes down the same delivery system as the therapeutic laser beam. If the aiming beam spot 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 delivery system.
**OPERATION**

**Eye Insertion and Videography**
Insertion: The E2 MicroProbe™ endoscope may be inserted in the eye through the pars plana through a standard vitrectomy incision or may be inserted through a limbal incision that has had previous or concurrent surgery.

Observation: Observation of the intraocular structures occurs by viewing of the high resolution video monitor. The internal structures of the eye from the posterior aspect of the iris, ciliary body, pars plana, peripheral retina and more posterior retina may be imaged.

Videography: Video outputs are included in the E2 MicroProbe™ system. Simply attach a video recorder to these outputs, insert a video tape and depress the PLAY & RECORD buttons simultaneously. The video image will be recorded. **Digital video recording devices can also be utilized.**

**Eye Endophotocoagulation**
Endophotocoagulation of the ciliary processes, pars plana, peripheral retina and more posterior retina is possible through this instrument.

**Front Panel Features**
The following controls and indicators are located on the Front Panel:

**Emergency Off (STOP Button)**
Depressing the Emergency Off (Big Red Button) de-energizes the lasers. All laser parameters are then reset to zero. The power supply remains on. The switch does **NOT** de-energize the entire unit. It is not intended as a normal shutdown control.

**Standby**
The E2 MicroProbe™ is in the Standby mode when first turned on. The Foot Pedal is disabled and therefore no laser treatment beam is possible. The aiming beam, however, is available. The Standby lighted status indicator will illuminate to indicate that the system is in the Standby mode.
OPERATION

WARNING

Except during the actual treatment, the system should always be in the Standby mode. Maintaining the system in the Standby mode prevents accidental exposure if the Foot Pedal is inadvertently depressed.

Enable

Key # 12, page 8

The E2 MicroProbe™ is put in the Enable mode by pressing the Enable switch. In Enable mode, the Foot Pedal is activated: depressing the footswitch will deliver the treatment beam to the target. The Enable indicator will illuminate to alert the operator that the system is in the Enable mode.

Aiming Beam Push Button

Key # 13, page 8

The Aiming Beam up and down push buttons are used for controlling the aiming beam intensity. Press the up button for higher intensity and the down button for lower intensity.

Laser Power Push Button

Key # 10, page 8

The Laser Power up and down push buttons are used for selecting laser output power. Press the up button for higher power and the down button for lower power. The power changes in 10 milliwatt increments.
OPERATION

Laser Duration Push Buttons
Key # 11, page 8

The Laser Duration push buttons are used for selecting laser exposure time. Exposure time is the amount of time the laser produced a treatment beam and is measured in seconds. Preset exposure times range from 0.05 to 2.0 seconds; and, continuous wave is noted as “Con”. Press the Laser Duration up button to increase the exposure time; press the Laser Duration down button to decrease the exposure time. When the time indicated on the setting has elapsed, the treatment beam stops even if the Footpedal is still depressed (unless a continuous laser exposure has been selected).

Laser Output Power Control

The initial laser output power is permanently recorded by the E2 Microprobe™. If the subsequent laser output power varies by 20% or more, the Laser Output Power Meter will start blinking.

Counter Display
Key # 8, page 8

The Counter display indicates the number of exposures delivered to the target tissue since the last reset.

Counter Reset Push Button
Key # 16, page 8

Press the Reset button on the front control panel to zero the counter display.
OPERATION

E2 MicroProbe™ Preliminaries

- Ensure the E2 MicroProbe™ is connected to the mains.
- Ensure the Footswitch is properly connected.
  (See Connection Points diagram on page 1-1, Topic 1.1 System)
- Ensure the Laser Endoscope is connected to the Front Panel.
  1. Attach the Laser Connector to the Laser Aperture receptacle on the Front Panel. Screw the connector on.
  2. Attach the Video Connector to the Video Adapter on the Front Panel.
  3. Attach the ACMI Light Connector to the Light Source on the Front Panel.

The E2 MicroProbe™ is now ready for Turn-on.

WARNING

To prevent explosion and fire do not operate the laser in the presence of flammables or explosives such as volatile anesthetics, alcohol or other such substances. Do not look into the Laser Output at any time. Severe eye damage could occur.

E2 MicroProbe™ System Turn-on

1. Turn the mains power switch “On”. A system Self-Test begins.
2. The audible Pre-Laser Firing (PLF) Warning Alarm will remain ON for approximately 10 seconds.
3. After the PLF Warning Alarm ceases, the system will go into the Standby mode.
4. The STANDBY light on the display panel illuminates after the PLF Warning Alarm and the COOLDOWN light go off (if it illuminates).

The E2 MicroProbe™ is now ready for Setting of the Treatment Beam.
OPERATION

E2 MicroProbe™ Setting of the Treatment Beam

To set the treatment beam:

1. Insert the key in the Key Switch and turn to the "On" position.
2. Depress the Laser Power push button until the desired laser power appears in the Laser Power display. The lowest practical setting should always be used.
3. Depress the Laser Duration push button until the desired exposure time appears in the Laser Duration display.
4. Press the Enable push button and the green LED status indicator will light. The 810 NM laser will not fire until the Foot Pedal is used.

SAFETY PRECAUTION

The LASER DURATION and the LASER POWER must be set to get an aiming beam.

Before Firing the Laser

1. Adjust the Light Source push buttons to obtain a satisfactory video image. If the Light Source is set too high, the aiming beam will appear diminished.
2. Bring the target video image into clear focus by rotating the star wheel on the Video Adapter while viewing the target through the endoscope.
3. Place the tip of the endoscope near a white paper. Press the Aiming Beam Intensity push button up and verify that the red aiming beam intensity increases on the paper and the monitor. An audible modulating tone indicates an aiming beam firing.
OPERATION

Firing the Laser

1. Target the tissue to be treated with the aiming beam. The lowest practical setting should always be used.

CAUTION
The maximum safe power that can be visualized indefinitely by the retina is 0.39 microwatts (Class 1). The diode laser that produces the aiming beam is a Class 3a laser. Direct visualization of Class 3a laser radiation by a patient during treatment has not been shown to be safe. To protect the patient from possible retinal damage, use the lowest practical aiming beam intensity during treatment. Start at zero and go up to the minimum amount that is practical. Endo Optiks recommends an aiming beam setting of 40.

2. Depress the Foot Switch to deliver the treatment beam to the tissue.

SAFETY PRECAUTION
The endoscope must be connected to get an aiming beam and to fire the laser.

NOTE
Early release of the Foot Switch will terminate the treatment beam before the indicated exposure time has elapsed. This will alter the therapeutic effect. To ensure that the treatment beam has exposed for the proper duration, hold the Foot Switch down until the selected exposure time has expired. The treatment beam exposure can be halted by releasing the Foot Switch before the end of the selected exposure time.

3. If surgery is interrupted, select the Standby mode with the Enable push button as indicated by the Enable status indicator.

WARNING
Do not leave the laser unattended when it is on. Except during actual treatment, the system must always be in the Standby mode. Maintaining the system in the Standby mode prevents accidental laser exposure if the Foot Switch is inadvertently depressed.
OPERATION

Setting Single Exposure Time

To deliver a single exposure to the target tissue:

1. Using the Laser Duration push button, adjust the exposure time to the desired setting. The selected exposure time will appear in the Laser Duration display.
2. Select the Enable mode with the Enable push button as indicated by the Enable status indicator. Each depression of the Foot Switch will deliver only one exposure at the selected exposure time. The yellow display will count down the exposure time.

Between Patient Treatments and System Turn Off

When treatment is complete or is to be interrupted:

1. Depress the Enable push button and place the system in the Standby mode.
2. If several patients are to be treated, always return all Front Panel controls to their minimum settings. Disinfection and sterilization procedures are necessary and required between each surgical operation. The E2 Microprobe™ should be de-energized for cleaning.
3. When all treatments are concluded, turn the Key switch to the “O” (off) position. Remove the key to prevent unauthorized use of the laser system.
MAINTENANCE AND TROUBLESHOOTING

Endoscope Maintenance

Handling: The endoscope fiberoptic cable can be damaged or fractured if mistreated. Be careful not to step on, kink, tightly coil, pull the fiber, or catch it on any equipment. Do not clamp the fiber with a hemostat. Such stress can damage the fiber which may result in accidental laser exposure to the operating personnel or the patient. Undue physical stresses should not be applied to this instrument as it will shorten its useful life. The endoscope should be inspected monthly for physical damage to ensure that the endoscope is within the compliant criteria stated within the manual.

Sterilization: Sterilization methods for the endoscopes and probes are described in the inserts provided with each device.

Replacement: The endoscope may be reused until the optical component or the laser delivery component proves to be inadequate, as previously described. If either of these two variables proves to be inadequate, the endoscope should be discarded (dispose of in accordance with medical waste procedures) and a new one employed.

Laser Maintenance

LASER EMERGENCY TURN OFF

To de-energize the laser system in an emergency situation: Depress the STOP push button.

Introduction: The E2 MicroProbe™ system has been designed to give lifelong, trouble-free service. Service can be obtained by shipping the unit to our facility for system performance and laser safety checks.

User Maintenance for the Laser: There are no maintenance procedures to be performed by the user to ensure the intended performance of the laser.
MAINTENANCE AND TROUBLESHOOTING

**Laser Power Calibration:** This system is calibrated by the manufacturer and cannot be calibrated by the user. Opening the enclosure will void the warranty on this product. The power output reading at the tip of the microendoscope is calibrated to be ± 20% of the power setting. If the laser power reading is more or less than 20% of the power setting the laser power display will flash and Endo Optiks should be called to schedule servicing.

**NOTE:** Insufficient laser power could be a result of debris on the tip of the microendoscope. Particular care should be employed at all times to ensure that the tip is clean and free of tissue or any other debris. Reduced laser power could also be caused by degradation of the laser fiber in the microendoscope and a new microendoscope should be employed.

**WARNING**

LASER SERVICE is to be done ONLY by Endo Optiks service engineers. Possession of service instructions or tools does not authorize repair or modification of this instrument.

**WARNING**

As a precaution against accidental exposure to a laser output beam or its reflection, anyone servicing the E2 Microprobe™ should wear specially tinted laser safety glasses.

**WARNING**

If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
E2 MicroProbe Maintenance

The ONLY user replaceable maintenance items are the mains fuses. They are located on the Back Panel of the E2 Microprobe™. The mains fuse holders are in the lower left hand corner.

<table>
<thead>
<tr>
<th>For 120 volts</th>
<th>For 240 volts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Supply Rating</strong></td>
<td><strong>Supply Rating</strong></td>
</tr>
<tr>
<td>120 Volts, 50/60~, 4A</td>
<td>240 Volts, 50/60~, 2.0A</td>
</tr>
<tr>
<td>Use 2 type T6.3A, 250V</td>
<td>Use 2 type T3.1A, 250V</td>
</tr>
<tr>
<td>Schurter P/N FSM 034.2521 (2 Amp) or equivalent</td>
<td>Schurter P/N FSM 034.2519 (3.15 Amp) or equivalent</td>
</tr>
</tbody>
</table>

Troubleshooting

The treatment laser has been subjected to rigorous mechanical and environmental tests. In the unlikely event that the laser fails to operate properly, the Troubleshooting Guide will help you locate and correct the malfunction. Should a major malfunction occur a service representative must be contacted.

Before proceeding to the Troubleshooting Guide, check the following items:

1. Electrical Power.
   - Verify that the main electrical power on the wall is on.

   - Verify that the circuit breaker is in the On Position.
## MAINTENANCE AND TROUBLESHOOTING

### E2 Troubleshooting Guide

<table>
<thead>
<tr>
<th>DIFFICULTY</th>
<th>PROBABLE CAUSE</th>
<th>SUGGESTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>System Does Not Turn On</td>
<td>Laser Fuse Is Blown</td>
<td>Replace Fuse</td>
</tr>
<tr>
<td></td>
<td>Main Power Circuit Breaker Is In The Off Position</td>
<td>Reset The Main Power Circuit Breaker To The On Position</td>
</tr>
<tr>
<td>Inadequate Aiming Beam</td>
<td>Aiming Beam On Low Setting</td>
<td>Increase Aiming Beam Setting</td>
</tr>
<tr>
<td>No Aiming Beam</td>
<td>Laser Duration and Power Not Set</td>
<td>Laser Duration and Power Must Be Set Before the Aiming Beam Can Be Enabled</td>
</tr>
<tr>
<td></td>
<td>Endoscope Not Connected Properly</td>
<td>Check Connection of Endoscope</td>
</tr>
<tr>
<td></td>
<td>Emergency Stop is Depressed</td>
<td>Release Emergency Stop Button</td>
</tr>
<tr>
<td>No Laser Treatment Beam</td>
<td>Laser Enable Mode Not Selected</td>
<td>Depress Enable Push Button</td>
</tr>
<tr>
<td>No Laser Treatment Beam or White Light or Video</td>
<td>Delivery System Not Properly Plugged In</td>
<td>Check Endoscope Connections</td>
</tr>
<tr>
<td>Inadequate Laser Treatment Power</td>
<td>Low Level Of Laser Transmission</td>
<td>Use New Endoscope</td>
</tr>
<tr>
<td></td>
<td>Internal Problem</td>
<td>Call Endo Optiks Service</td>
</tr>
<tr>
<td>Blurry Video Image</td>
<td>Video Adapter Out of Focus Tissue on Endoscope Tip</td>
<td>Adjust Video Adapter Focus</td>
</tr>
<tr>
<td></td>
<td>Video Connector Not Seated In Adapter Or O-Ring Missing</td>
<td>Clean Endoscope With Merocel Wipe</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Check Connector Seating And O-Ring</td>
</tr>
<tr>
<td>Black spot(s) on Image</td>
<td>Dirty Video Adapter Lens</td>
<td>Clean Video Adapter Lens</td>
</tr>
<tr>
<td></td>
<td>Dirty Endoscope Video Connector</td>
<td>Carefully Clean Center of Endoscope Video Connector</td>
</tr>
<tr>
<td>No Video Image</td>
<td>Monitor is turned Off</td>
<td>Turn Monitor On</td>
</tr>
<tr>
<td></td>
<td>Video Cables Not Properly Connected.</td>
<td>Check For Proper Cable Attachment.</td>
</tr>
<tr>
<td></td>
<td>Signal Not Selected</td>
<td>Depress A or B on Monitor</td>
</tr>
<tr>
<td>Cool Down Light Stays On</td>
<td>Check For Proper Airflow Under Console</td>
<td>Turn Off Unit, Clear Obstruction and Allow Unit to Cool. Restart Unit.</td>
</tr>
<tr>
<td></td>
<td>Emergency Stop Switch Pressed In Key Is Not In “1” Position</td>
<td>Turn Emergency Stop Switch Clockwise ¼ Turn</td>
</tr>
<tr>
<td></td>
<td>Endoscope Is Not Connected Software Malfunction</td>
<td>Turn Key To “1” Position</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Connect Endoscope To System</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Turn Off Unit. Disconnect and Reconnect Endoscope. Restart Unit.</td>
</tr>
</tbody>
</table>
### MAINTENANCE AND TROUBLESHOOTING

#### E2 Troubleshooting Guide (cont.)

<table>
<thead>
<tr>
<th>DIFFICULTY</th>
<th>PROBABLE CAUSE</th>
<th>SUGGESTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>777 Showing on Laser Power Display</td>
<td>Not Enough Amperage Available From Power Source</td>
<td>Plug Unit Into a Non-overloaded Outlet</td>
</tr>
<tr>
<td></td>
<td>Front Panel Button Sticking</td>
<td>Press Each Button To Verify It Clicks Twice</td>
</tr>
<tr>
<td></td>
<td>Footswitch Has An Electrical Short</td>
<td>Footswitch Needs to Be Rewired – Call Endo Optiks Service</td>
</tr>
<tr>
<td>No White Light or Intensity Not Adjustable</td>
<td>Footswitch Inadvertently Depressed.</td>
<td>Reposition Foot</td>
</tr>
<tr>
<td></td>
<td>White Light Source Malfunction</td>
<td>Call Endo Optiks Service</td>
</tr>
<tr>
<td>Laser Power Indicator Flashes “FFF” Or Goes Out When Laser Is Fired</td>
<td>Footswitch Cable Is Twisted Where It Enters The Footswitch</td>
<td>Call Endo Optiks Service</td>
</tr>
<tr>
<td></td>
<td>Internal Switch In Footswitch is Defective</td>
<td>Call Endo Optiks Service</td>
</tr>
</tbody>
</table>

### Operator Replaceable Parts

The following list of spare parts is available from Endo Optiks or Endo Optiks distributors.

<table>
<thead>
<tr>
<th>Part Name</th>
<th>Description</th>
<th>Part Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Video Coupler</td>
<td>E2 MicroProbe Video Coupler</td>
<td>OME 300Z – 10k Scopes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OME 300ZMG – 10k Scopes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OME 170Z – 17k Scopes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OME 170ZMG – 17k Scopes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OME 600ZMG – 6k Scopes</td>
</tr>
<tr>
<td>Foot Switch</td>
<td>MicroProbe Foot Switch</td>
<td>SW001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SW002</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SW003</td>
</tr>
</tbody>
</table>
TECHNICAL SPECIFICATIONS

Temperature

Celsius (C) and Fahrenheit (F)

• Operating temperature  + 5° to 55° C (41° to 131° F)
• Storage (6 months)  -30° to 50° C (-22° to 122° F)
• Transient (72 hours)  -40° to 65° C (-40° to 149° F)

Humidity

• Operating  5% to 90% noncondensing
• Storage  5% to 95% noncondensing

Altitude

• Meters (m) and feet (ft.)
  • Operating  -305 to 3,048 m (-1000 to 10,000 ft.)
  • Shipping, non-operating  -305 to 15,240 m (-1000 to 50,000 ft)

Voltage requirements

• Voltage  120 AC or 240 AC

Power consumption (typical)

• Watts  408 W
TECHNICAL SPECIFICATIONS

Light Source
175 Watt Xenon Light
  • Visible Output 2,200 Lumens
  • Radiant Output 25 Watts

300 Watt Xenon Light
  • Visible Output 5,000 Lumens
  • Radiant Output 50 Watts

Expected lifetime of the light source is 1,000 hours until the light reaches half of its initial output. (This could be equivalent to up to 6 years of usage. Calculations are based on 3.25 hours of use per week.) The failure of the light source is expected to be the deciding factor of the service life of the equipment.

CAUTION: The heat generated by the light source varies and can be hot causing the light connector, on the endoscope, to become hot. To prevent injury to the operator the light intensity should be turned down so the connector can cool before removing it from the system.

Treatment Laser
  • Semiconductor GaAlAs Laser Diode, 810 ± 25 Nanometers,
  • Waveform can be continuous or intermittent
  • 1.2 Watts Output
  • Class IV Laser
  • Nominal Ocular Hazard Distance - 0.6 Meters

Aiming Beam Laser
  • Visible Laser Diode, 640 ± 30 Nanometers,
  • 1.5 Milliwatt Output
  • Class IIIa Laser

Operational Mode
  • Continuous Wave

Laser Source Power
  • Less than 5 watts
TECHNICAL SPECIFICATIONS

Endoscope
• Beam Divergence - 40°
• Laser Delivery System - 200 μm fiberoptic terminating in a 0.89 mm diameter distal end SS tube with a laser fiber, video fiber and light fiber inside.
• Fiberoptic Connector - SMA 905 with the Endo Optiks Optical Safety Interlock to prevent firing the laser without the Endoscope connected.
• Nominal Ocular Hazard Distance - 0.6 Meters

Console Cooling
• Forced air
86. Faude F., Wiedemann P. Vitreoretinal endoscope for the assessment of the peripheral retina and the ciliary body after large retinectomies in sever anterior retina and the ciliary body after large retinectomies in severe anterior PVR. Int. Ophthalmol. 2004 Jan;25(1):53-6.


95. Faude F, Weidemann P. Vitreoretinal endoscope for the assessment of the peripheral retina and ciliary body after large retinectomies in severe anterior PVR. International Ophthalmology 2004; 25:53-56


131. Francis, Kawji, Vo, et al. Endoscopic Cyclophotocoagulation (ECP) in the Management of Uncontrolled Glaucoma with prior aqueous tube shunt. J. Glaucoma 2010; 00-000-000


HERE ARE SOME SUGGESTIONS REGARDING ECP CASE SELECTION AND EXTENT OF TREATMENT!

<table>
<thead>
<tr>
<th>Lens Status</th>
<th>Range</th>
<th>Difficulty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combined with Phaco</td>
<td>180°</td>
<td>Good for learning</td>
</tr>
<tr>
<td>With medically controlled glaucoma pre-operatively</td>
<td></td>
<td></td>
</tr>
<tr>
<td>With uncontrolled glaucoma</td>
<td>270° - 360°</td>
<td>Good for learning</td>
</tr>
<tr>
<td>Posterior chamber pseudophakia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Open-angle glaucoma</td>
<td>270° - 360°</td>
<td>Good for learning</td>
</tr>
<tr>
<td>Non-vascularized angle closure</td>
<td>270° - 360°</td>
<td>Good for learning</td>
</tr>
<tr>
<td>Anterior chamber pseudophakia</td>
<td>270° - 360°</td>
<td>Can be difficult</td>
</tr>
<tr>
<td>Aphakic open or closed angle glaucoma</td>
<td>270° - 360°</td>
<td>Can be difficult</td>
</tr>
<tr>
<td>Phakic open or closed angle glaucoma</td>
<td>270° - 360°</td>
<td>Should have some prior experience</td>
</tr>
<tr>
<td>Neovascular glaucoma</td>
<td>180° first</td>
<td>May need additional 90° - 180° lens status determines difficulty</td>
</tr>
</tbody>
</table>

LENSES STATUS DETERMINES DIFFICULTY
QUICK SET UP GUIDE

Color Video Monitor
⇒ Turn monitor ON by depressing power button lower right

Back of E2 Unit
⇒ Start with Laser Key in the OFF Position (O) top center
⇒ Turn Power ON (1) above power cord
⇒ Laser Key to ON Position (1)

E2 Front Control Panel
⇒ Connect Three Probe Ends to Front Panel (save caps)
  Laser· Screw on · top right
  Light· Plug in · lower center
  Video Connection· Firm Plug in · lower right
⇒ Laser Power (yellow) · set to .25 watts
⇒ Laser Duration (blue) · set to Continuous
⇒ Increase Illumination (white) · only partially
⇒ Focus Image · knurled ring around video connection.
⇒ Press Enable Button (green) · indicator light comes on
⇒ Increase Aiming Beam (red) · red light in field

• When the surgeon is ready to use microendoscope, light and aiming beam may need to be adjusted.
• Laser power may be adjusted intraoperatively while pedal is not depressed.
• Red emergency stop button must be in the out (off) position for laser to operate.
• ONLY sodium hyaluronate viscoelastics may be instilled when laser is to be applied.
• If image becomes blurred during surgery, clean probe tip with Merocel ® Instrument Wipe or Spear.
• Before disconnecting microendoscope, clean probe tip with concentrated alcohol and then rinse. Check image clarity before turning off unit.

CAUTION: The heat generated by the light source varies and can be hot causing the light connector, on the endoscope, to become hot. To prevent injury to the operator the light intensity should be turned down so the connector can cool before removing it from the system.