OPERATOR’S MANUAL

for the

ENDO OPTIKS

E4

MICROPROBE™ ENDOSCOPY SYSTEM
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WARNING: The user of the E4 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 E4 MicroProbe™ and accessories used in conjunction with the procedures. Failure to follow these instructions may result in damage to the E4 MicroProbe™ or malfunction of the E4 MicroProbe™.

CAUTION: Endo Optiks restricts the sale of the E4 MicroProbe™ to a physician or on order of a physician.
**Labels**
The following labels are affixed to the E4 Microprobe™ system. The title, the part number, and the location on the E4 Microprobe™ are given for each label.

<table>
<thead>
<tr>
<th>Label</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ENDO OPTIKS, INC.</strong>&lt;br&gt;Little Silver, NJ USA&lt;br&gt;DOM: 18807566363 INT: 17325306762&lt;br&gt;Date of Manufacture: YYYY/MM/DD</td>
<td>Identification</td>
</tr>
<tr>
<td><strong>Model:</strong> E4 MicroProbe™&lt;br&gt;Endoscopy System&lt;br&gt;REF OME 4000&lt;br&gt;SN 4043</td>
<td>P/N 3840425</td>
</tr>
<tr>
<td></td>
<td>Rear Panel</td>
</tr>
<tr>
<td></td>
<td><strong>Meaning:</strong> Type BF equipment</td>
</tr>
<tr>
<td><strong>Protection Against Electric Shock</strong>&lt;br&gt;P/N L1012&lt;br&gt;Rear panel</td>
<td></td>
</tr>
<tr>
<td><strong>Fuse Replacement Label</strong>&lt;br&gt;P/N L1010B&lt;br&gt;Rear Panel</td>
<td></td>
</tr>
<tr>
<td><strong>Fuse Replacement Label</strong>&lt;br&gt;P/N L1011B&lt;br&gt;Rear Panel</td>
<td></td>
</tr>
</tbody>
</table>

**Supply Rating**<br>120 volts, 50/60 Hz, 4 A<br>Use 2 Type T6.3A, 250v.

**Supply Rating**<br>240 volts, 50/60 Hz, 2.0 A<br>Use 2 Type T3.1A, 250v.
Meaning: Dangerous Voltage

P/N L1007

Rear Panel

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

P/N L1003

Rear Panel

Caution: Consult Accompanying Documents

P/N L1009

Rear Panel

Safety Agency Approvals (MET MARK)

P/N E112374

Rear panel, bottom left, under AC receptacle
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, 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.
Precautions

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

Dangerously high voltages are present inside the E4 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
e-mail: info@endooptiks.com

On safety
• Operate the unit on the designated V AC only.

• The Fuse Replacement Label indicates operating voltage and is located adjacent to the mains fuse holder in the rear of the cabinet on the lower right side.

• The Identification Label indicates power consumption and is located on the rear 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 E4 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.
Precautions, cont.

On installation
- The E4 MicroProbe™ should be used in a Hospital or Clinical setting only. It should be used indoors only under the environmental conditions stated in section 7.0 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 endoscope or probe must be sterilized before use. Please refer to the instructions provided with each device.
SYSTEM OVERVIEW

System

The Endo Optiks E4 MicroProbe™ is the principal component in a new portable endoscopy system. The complete system consists of the endoscope, the monitor and the footswitch (optional). This compact unit creates the opportunity to simultaneously image and photocoagulate (when used in combination with a laser) 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 endoscopy cabinet houses a xenon light source and a CCD camera. The camera selection and light intensity are controllable from the front panel. The Rear Panel features connectors to any video monitor, VCR or video printer. A Foot Pedal (optional) 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 an external foot switch (optional).
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.

**Video Display**
The video display can be any high resolution monitor such as the Sony PVM-1953MD 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 NTSC or PAL. There is an S-Video (Y/C Out) and 4 Video Out Connectors. All are BNC connectors (75 ohms terminated).

**Foot Switch (Optional)**
The footswitch is used to vary the illumination intensity of the xenon light source. The footswitch connector is located at the Back Panel (An optional cable allows throughput to control external laser).
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 E4 Microprobe™. The functions and status indicators are:

<table>
<thead>
<tr>
<th>KEY</th>
<th>FUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Illumination – Raise and Lower</td>
</tr>
<tr>
<td>2</td>
<td>Video Adapter (For Camera)</td>
</tr>
<tr>
<td>3</td>
<td>Illumination Input (ACMI)</td>
</tr>
</tbody>
</table>

Front Panel Features
SYSTEM OVERVIEW

Back Panel
The Back Panel contains the Mains Power Inlet, the Fuses, the Foot Switch Connector, the Video Connectors, 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>Voltage Select</td>
</tr>
<tr>
<td>2</td>
<td>Fans</td>
</tr>
<tr>
<td>3</td>
<td>ON/OFF SWITCH</td>
</tr>
<tr>
<td>4</td>
<td>Mains Power Inlet</td>
</tr>
<tr>
<td>5</td>
<td>Video Out</td>
</tr>
<tr>
<td>6</td>
<td>SVHS Super Video Output</td>
</tr>
<tr>
<td>7</td>
<td>Input/Output for optional footswitch</td>
</tr>
<tr>
<td>8</td>
<td>Camera Cable</td>
</tr>
<tr>
<td>9</td>
<td>Camera Cable Input</td>
</tr>
</tbody>
</table>

Back Panel Layout
GETTING READY

Site Preparation

The E4 Microprobe™ system has no special electrical or water requirements.

Utilities

**Electrical:** The E4 Microprobe™ can be configured to operate from a power source in the range of either 115 volts AC or 230 volts AC, 50/60 Hz, 400 watts maximum. A standard grounded AC outlet is sufficient. Verify that the voltage indicated on the label 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 E4 Microprobe or shielding the location.
CLEANING AND STERILIZATION

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

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.
WARNING
The E4 MicroProbe™ system is intended solely for use by physicians trained in ophthalmic endoscopy.

Indication For Use
The ophthalmic endoscope is indicated for evaluation of internal ocular structures.

OPERATION

Set Up and Operation
The E4 MicroProbe™ system must be set up and operated with care. The endoscopic probe is a fragile component and great care should be used when handling it.

Endoscopes and Probes
Before each use, the device should be thoroughly inspected in order to detect any irregularity or abnormality. If these are noted, the device should not to 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 mandatory 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 E4 MicroProbe™. A clear view should be obtained.
OPERATION

Eye Insertion and Videography

Insertion: The E4 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 E4 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.
OPERATION

**E4 MicroProbe™ Preliminaries**

- Ensure the E4 MicroProbe™ is connected to the mains.
- Ensure the Footswitch (if applicable) is properly connected.
  (see Connection Points diagram on page 9)

**Connecting a Microendoscope or Probe**

- Ensure the Endoscope or probe is connected to the Front Panel.
  1. Attach the Video Connector to the Video Adapter on the Front Panel (Page 8 – Number 2).
  2. Attach the ACMI Light Connector to the Light Source on the Front Panel (Page 8– Number 3).

**Connecting a Glass Rod Endoscope**

1. Attach camera cable to camera input on Rear Panel (Page 9 – Number 9)
2. Attach ACMI connector to the light source on the Front Panel (Page 8 – Number 3)

The E4 MicroProbe™ is now ready for Turn-on.

**Adjusting the Image**

1. Adjust the Light Source push buttons to obtain a satisfactory video image.
   Bring the target video image into clear focus by rotating the star wheel on the Video Adapter (for Microendoscopes) or the focus wheel on the camera cable (for Glass Rod Endoscopes) while viewing the target through the endoscope.
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 can be found on the insert provided with each device.

Replacement: The endoscope may be reused until the optical component or the laser delivery component prove to be inadequate, as previously described. If either of these two variables prove to be inadequate, the endoscope should be discarded and a new one employed.
MAINTENANCE AND TROUBLESHOOTING

E4 MicroProbe Maintenance

The ONLY user replaceable maintenance items are the mains fuses. They are located on the Back Panel of the E4 Microprobe™. The mains fuse holders are in the lower left hand corner.

For 120 volts
Supply Rating
120 Volts, 50/60~, 4A
Use 2 type T6.3A, 250V
Schurter P/N FSM 034.2521
(2 Amp)

or equivalent

For 240 volts
Supply Rating
240 Volts, 50/60~, 2.0A
Use 2 type T3.1A, 250V
Schurter P/N FSM 034.2519 (3.15 Amp)

or equivalent

Troubleshooting

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

## E4 MicroProbe™ 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>Main Power Circuit Breaker Is In The Off Position</td>
<td>Turn The Main Power Circuit Breaker To The On Position</td>
</tr>
<tr>
<td></td>
<td>Building Power Turned Off</td>
<td>Turn On Building Power</td>
</tr>
<tr>
<td>Blurry Video Image.</td>
<td>Video Adapter Out of Focus</td>
<td>Adjust Video Adapter Focus</td>
</tr>
<tr>
<td></td>
<td>Video Adapter Lens Needs Cleaning</td>
<td>Clean Video Adapter Lens</td>
</tr>
<tr>
<td></td>
<td>Endoscope Video Connector Needs Cleaning</td>
<td>Clean 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>No White Light or Intensity Not Adjustable</td>
<td>White Light Source</td>
<td>Call Endo Optiks Service</td>
</tr>
</tbody>
</table>
**MAINTENANCE AND TROUBLESHOOTING**

**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>E4 MicroProbe Video Coupler</td>
<td>OME 300Z</td>
</tr>
<tr>
<td>Foot Switch</td>
<td>MicroProbe Foot Switch</td>
<td>SW001</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 3,048m (-1000 to 10,000ft)
- Shipping, non-operating: -305 to 15,240m (-1000 to 50,000ft)

Voltage requirements

- Voltage: 120 AC or 240 AC

Power consumption (typical)

- Watts: 214 W

Light Source

175 Watt Xenon Light
- Visible Output: 2,200 Lumins
- Radiant Output: 25 Watts

Expected lifetime of the light source is 3,200 hours (This could be equivalent to up to 6 years of usage. Calculations are based on 10 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.
BIBLIOGRAPHY- ENDOSCOPY


75. Sheilds S., Chen P. Sequential or simultaneous cyclophotocoagulation and glaucoma drainage implant for refractory glaucoma. J Glaucoma 2002: 11:203-208
82. Faude F., Wiedemann P. Vitreoretinal endoscope for the assessment of the peripheral retina and the ciliary body after large retinectomies in severe anterior retina and the ciliary body after large retinectomies in severe anterior PVR. Int. Ophthalmol. 2004 Jan;25(1):53-6.


91. 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


Front Control Panel

- Turn Power ON
- TV monitor should be ON
- Select camera number ONE on front panel.

Endoscope or Probe

- Connect Probe Ends to Front Panel (save caps)
  - Light – Right
  - Video Connection – Camera

- Increase Illumination - only part way up
- Focus Image - ring around video adapter on panel

- Clean probe tip during surgery if image becomes blurred - instr. wipe or weck
- Clean probe tip with concentrated alcohol then rinse before machine is disconnected. Check image clarity before machine turnoff.

Glass Rod Endoscope

- Attach camera cable to camera input number 9 on Rear Panel.
- Attach ACMI connector to the light source on the Front Panel.