Reserved Copyright Policy

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The use of the Micron M7 shall comply with federal, regional and local laws. Excelsius Medical GmbH is not responsible for consequences or damages as a result of using this product other than during commercial use.

Safety and Regulatory Information: The following laser safety and regulations related publications can be obtained in published national standards; we recommend that the owner and operator of the laser should be familiar with the following publications in the message:

- Standard EN 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- Standard EN 62304 Medical device software - Software life-cycle processes.
- Standard EN 62366 Medical devices - Application of usability engineering to medical devices.
- Standard ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes.
- Standard ISO/EN 14971 Medical devices - Application of risk management to medical devices.
- Council Directives concerning Medical Devices MDD 93/42/EEC
Micron M7 Guide

This is a Micron M7 Systems User’s Manual (2017) for operation of main systems / maintenance / surgery operation guide/ outline of system.

How to use this Manual

This manual is divided into seven chapters:

Chapter 1 Outline (for Technician, Surgeon, and User)
This chapter provides a brief overview of the operation process of the Micron M7 and also includes a simplified outline of the main components, it’s location and function.

Chapter 2 Safety Measures (for Technician)
This chapter describes the laser gas and electrical safety considerations

Chapter 3 Software Operation Instructions (for User)
Provides instructions for all categories of surgery software

Chapter 4 System Calibration and Testing (for User)
This chapter provides daily startup calibration instructions and testing procedures to follow before every operation

Chapter 5 Surgery Operation Controls (for Surgeon)
This chapter provides system operations instructions during surgery

Chapter 6 Maintenance (for User)
This chapter provides a table of contents and instructions for maintenance

Chapter 7 Troubleshooting (for Technician)
This chapter provides basic troubleshooting instructions
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Chapter 1. Outline (for Technician, Surgeon & User)

This manual provides Micron M7 Refractive System Information. This chapter includes a brief introduction to the system, operation, and the personnel who operates the system. The personnel has to be certified with the original manufacturer and have a thorough understanding of the operating processes and safety procedures.

- 1.1 Provides a daily operation procedure
- 1.2 Provides system’s basic principle
- 1.3 Provides a general system overview and information about main components and control
- 1.4 Provides Surgery Room Requirements for the System

System maintenance and simple troubleshooting information are available in the following sections:

- Maintenance
- Troubleshooting

***CAUTION***

![CAUTION]

The personnel operating the Micron M7 must be a technician with certification from the original manufacturer and have a thorough understanding of the operating processes and safety procedures.

***WARNING***

![WARNING]

Do not operate in the presence of ignitable gases.

1.1 System Operating Procedure

The procedures listed in this section must be performed every working day.

1. **Turning on the System**  
   - Turn on system power, initiate gas filling (if necessary)
2. **System Calibration**  
   - Calibrate Laser Power  
   - Spot Center Calibration
3. **Testing Prior to Surgery**  
   - Ensure laser spot is centered prior to surgery
4. **Surgery Preparation**  
   - Enter Patient Information  
   - Secure Patient and confirm information
5. **Surgery**  
   - Conducting Excimer Refractive Surgery
6. **Turn off System**
1.2 Principle

1.2.1 Vision System Principles

The Micron M7 corrects refractive errors caused by an inability for light to properly focus on the retina such as myopia, hyperopia, astigmatism, etc. The system utilizes a rapidly scanning UV laser beam to selectively remove (ablate) specific regions of the cornea to reshape it for proper focusing. Figure 1.2.1-1 demonstrates how this type of procedure causes the light to be properly focused.

Figure 1.2.1-2 Description of the optical path of the laser beam

(A) The system’s excimer laser source produces a pulsed laser beam
(B) The system’s laser guidance module transfers and properly positions the pulse of laser beam. The laser beam position is determined by the computer system’s fractal projection of the patient’s inputted parameters.
(C) The downward facing mirror turns the laser beam downwards to the target area (cornea).

Every laser pulse generated has identical characteristics and the pulse duration of each pulse is 4-8ns. The size of ablation per pulse on the cornea is approximately 0.5mm². The depth of the cut is determined by the energy density of the laser. Every layer of the cut is controlled by the system’s computer. The depth of each layer is 0.1 μm and requires an energy density level of 90 ~ 180 mJ/cm².

There are specific areas on the cornea that require ablation to achieve desired corrections. In the “optical area”, there is usually an additional smooth “transition area” located in the tissue between the optical area and the un-ablated area of the cornea. Typical ablation areas are connected layers of tissue. By using a specific or “flat” depth, the laser is able to ablate a limited area layer by layer. Figure 1.2.1-3 (A) depicts ablating the layers of a limited area. The Micron M7 uses a "Diopter-By-Diopter" calculation method cutting a curved “fractal” layer. Every ablated layer has varying depths and the ablation area covers the entire layer. Figure 1.2.1-3 (B).

There are many random factors that are hard to avoid and unable to predict such as gas bubbles, ablation tissue debris, laser energy stability and patient eye movement. Fractal layers use a randomized order for ablation as depicted in 1.2.1-4. By using a randomized order to target ablation depth, we can avoid having random factors consistently appear in one area.

By using a randomized order and a Fractal algorithm to guide the laser, the ablation process can maintain its integrity and continuity even when a pause is necessary. This combination is referred to as “Fractal Projection”.

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Fig. 1.2.1-1 Correcting the curvature of the optical lens changes its refractive index and allows light to be properly focused on the target. (A) The initial lens focal point was short of the target. B) The reshaped lens has a focal point aligned on the target. Similarly, by removing tissue to reshape the cornea, we can adjust the focal point on the retina.

Fig. 1.2.1-2 Overview of Laser Path A) Excimer Refractive Laser System fires a pulse of laser beam (B) Mirrors guide the laser beam into the Mirror Arm (C) The Mirror Arm accurately guides the laser beam to its proper location (D) A downward facing mirror guides the laser beam (E) to the target (Cornea).

Fig. 1.2.1-3 Example of ablating multiple layers: (A) “Flat” limited area of each layer (B) curved “Fractal” utilizes diopter-by-diopter method to ensure every laser covers a complete area of a layer.

Fig. 1.2.1-4 If an ablation area is divided into a 16 block square, each pulse would be guided to one block and the number represents the order it will be ablated (A) Continuous and (B) Randomized.
1.2.2 Excimer Laser Principle

The excimer laser uses concentrated laser light photons to produce the required energy (coherent, amplified) for cornea tissue destruction to tissue destruction (ie bonds between molecules). The Argon Fluoride (ArF) excimer laser refractive surgery system emits an ultraviolet (UV) laser with 193 nm wavelength, and its thermal damage effect on the surrounding tissue is minimal. Although UV is invisible, it can be detected by fluorescence light on the corneal surface as the laser interacts with the tissue.

The inside of the excimer laser source is a cavity that includes a lasing medium, a mixture of Argon (Ar) and Fluorine (F) (and Neon (Ne) as filler). When exposed to high-voltage discharge energy, the thin Argon and Fluorine gas combine to form a halide gas, referred to as "excited state molecules" or "excimer laser" gas. These excimer molecules (ArF) have a short life cycle (approximately a ns). As ArF naturally returns to its ground state, it releases photons with wavelength of 193 nm. Some of the photons will interact with other excited molecules causing it to return a ground state and release additional photons. The interacting photons triggering more photons in the same way is known as "coherent". The photon utilizes mirrors at both ends of the laser cavity (referred to as the window of the laser) for reflection and moves back and forth within the "lasing medium" between the front and back mirrors (Fig. 1.2.2-1). During every pass, the released photons trigger more photon release and amplify the radiation light beam. The released photon's wavelength are all in phase. One of the mirrors of the laser cavity allows a portion of the light beam to leave the laser cavity. As a pulse is released, the next wave of radiation beam is being generated and the process is repeated. Thus, LASER stands for "light amplification by stimulated emission of radiation". The gas in the laser cavity can be continuously stimulated by consistent release of high-voltage discharge energy.

Fig. 1.2.2-1 Same phase photons (like wavy lines) are reflected back and forth from the mirrors at the end of the laser cavity and a few photons are released from the front mirror of the laser cavity to form a laser beam.
1.3 System Description and Control

1.3.1 System Specifications

- Laser Type: Green Diode Laser, 532±5 nm, <1mW class 2
- Laser Type: Red Diode Laser, 652±5 nm, <1mW class 2
- Laser Type: ArF Excimer Laser, 193±5 nm, <3W class 4
- Laser model: Multiple Mode
- Radiation Flux: 90~180mJ/cm² at the cornea
- Pulse Energy: <1mJ at the cornea
- Repetition Rate: 600Hz ±5%
- Spot Size: 1mm²(1.2mm x 0.9mm)±10%(foot print)
  0.5mm² (0.75mm x 0.65mm)±10%(effective size)
- Ablation Method: Random Scanning, Fractal Projection
- Pulse Width: 4~8 ns
- Cooling: Air Cooled
- Ablation Area: 3~8mm ±10%(optical)
- Input Voltage: 230V 50/60HZ ±10%
- Input Current: 7A (max)
- Length * Width * Height (mm): 1980 * 830 * 1720
- Weight: 380 KG
- Correction Range:
  
  Myopia: -0.25D ~ -12D
  Hyperopia: +0.25D ~ +6.0D
  Astigmatism: -6.0D ~ +6.0D

1.3.2 System Measurements

Below are the basic measurements of the Micron M7. The displayed numbers are in mm.
1.3.3 System Description
Micron M7 is composed of the following critical components:

(Right Side View)

(Left Side View)
Light Guidance (Laser source / DOM / Mirror Arm / Handpiece)

Optical path (1): When the system fires the excimer laser but the footswitch is not depressed, the shutter prevents the laser from exiting the system. A power sensor measures the readiness of the laser energy.

Optical path (2): When the system fires the excimer laser with the footswitch depressed, it raises the shutter and allows the laser to be delivered to the eye.

Optical path (3): When the fixation and focus function is selected on the touch screen, the microscope will send a green/red diode laser to eye.

Gas System: The excimer refractive laser system uses Argon Fluoride (ArF) for lasing and needs to be replaced periodically. The gas management system pumps old gas from the system and replace it with new pressurized ArF. The system also requires another cylinder of buffer gas (Helium (He) or Argon (Ar)) during system operation to protect the tube between the valves and the laser cavity. The Halogen filters can buffer harmful Fluorine gas to prevent harm to the laser and people.
1.3.4 Control

♦ External Control Panel (Fig. 1.3.4-1)

(1) Touch Monitor: The monitor is at the front of the system and displays data. The monitor is touch screen and utilizes arrows on screen ([←] [→] [↑] [↓]) to select and edit. Press [Enter] to accept inputted parameters and [Esc] to leave the menu. Press [Icon] to start/close the function.

(2) Keyboard: utilizes arrows on keyboard ([←] [→] [↑] [↓]) to select and edit. Press [Enter] to accept inputted parameters and [Esc] to leave the menu.

(3) Joystick: Use joystick to operate stepper and servomotors on the X / Y / Z-axis, and also control the microscope and hand piece.

(4) Emergency Stop Button: Press the button during an emergency, and the laser shutter /Step/Servo motors will automatically cut off all power and lock the system interface. Turn the button clockwise to reactivate the system.

(5) Footswitch: The footswitch is located at the bottom in the front of the system. Depressing the footswitch will open the shutter door and send a signal to the computer to allow the laser to fire.
♦ Exterior Control Panel (Fig. 1.3.4-2)

(1) **POWER INPUT**: Where the main power chord is connected
(2) **MAIN SWITCH**: The main power On/Off switch (primary)
(3) **LASER KEY SWITCH**: Controls the On/Off of the laser power (secondary)
(4) **INTERLOCK**: Laser safety switch. When interlock is unattached, the laser will not fire even when in the “On” status.
1.4 Surgery Requirements

1.4.1 Facility Requirements
Minimum Floor Pressure Support: 3000N/㎡
Exhaust Fan: Run every five minutes in room
Temperature: 19-25°C
Humidity: 40-50% (Ideal: 45% ± 5% )
Air Conditioner Filter Tube: HEPA model (Replace at least twice/year)

- Avoid using paint and sealant (especially resin glue) in operation room if possible. Use two weeks before installation of machine if unavoidable.
- The operation room requires a small air regulation and cleaning unit.
- The flooring of the operation room should use an odorless material or else it can absorb laser power/beam. Carpets are unsuitable because it easily collects dust.
- The operation room should have a “dust-free” design. Recommend the ceiling, wall and flooring all use moisture-resistant material. Tile is ideal to prevent dust buildup.
- Air Conditioning (if needed) has to be an independent unit.
- The excimer refractive laser system should be in its own operation room designed specifically for its use.
- The operation room requires sufficient air circulation. Moisture, cleaning solution, dehumidifier gas and disinfecting machines all affect the stability of the laser.
- Keep operating room temperature between 19 to 25°C. Keep the operating room free of dust, smoke, fumes or oil.
- The humidity in the operating room cannot exceed 50%. Humidity can damage the electrical system and lenses.
- The humidity in the operating room needs to be stable. Cannot change by more than 10% in a short amount of time.

CAUTION
The above mentioned issues can be lead to a reduction of short-wavelength laser and lead to a reduction of laser beam energy that weakens the corneal surgery effect.

1.4.2 Power Requirements
Electricity Requirement: 230V 50/60HZ ±10%, 7A
Power Consumption: 1600W
Independent Uninterrupted Power Supply (UPS): Recommend 3.5 KW system power, and 15A system current

CAUTION
The system should always use a 230V ±10% outlet; power should not be shared with other equipment
Chapter 2. Safety Measures (for Technician)

For safety reasons, only personnel who have been instructed on the Micron M7 should operate the system. The system utilizes laser, pressurized gas and high voltage electricity, and it is imperative that all safety measures are thoroughly understood and followed. This chapter focuses on safety measures for the laser, gas and electricity. Caution notices are placed appropriately throughout the manual. This chapter is for technicians who are certified from the original manufacturer and have a thorough understanding of the operating processes and safety procedures.

2.1 Laser Safety

2.1.1 Excimer Laser
This system utilizes a 193nm wavelength ArF excimer laser, and the maximum laser power output can reach one watt. This type of UV radiation is not visible and can cause permanent bodily harm if used improperly. Please read and understand all safety measures prior to use.

Avoid exposing the eyes and skin to the laser beam of this system. The invisible UV laser will harm the eyes and skin. Also, avoid directly gazing at the laser beam.

No Harm Distance (NOHD) : 150mm (*) (*) : Refers to the distance at which the radiation strength is equal to the maximum Cornea (MZB) surgery allowable parameters.

- Avoid exposure to reflected laser beam as it is also harmful. For the safety of everyone in the room, wear reflective and optical equipment when operating the laser.
- Ensure that all personnel in the surgery room are wearing safety goggles that can safely protect from UV radiation (OD>10).
- Follow all regulations of the local government. Each nation has their own appointed regulating agency and specific rules.
Safety features: Includes safety shutter and foot pedal switches, etc., in order to avoid unnecessary laser firing.

Safety Labels: safety labels affixed in accordance with government regulations on the system (Figure 2.1.1-1). Do not remove the label.

**WARNING**
Safety labels can help avoid laser leakage when operating the system. Please do not remove the labels.

(Figure 2.1.1-1)
Position 1
(Indicates danger when DOM is open)

DANGER – CLASS 4 INVISIBLE LASER RADIATION WHEN OPEN AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION

Position 2
(Indicates the emergency stop button)

STOP

Position 3
(Indicates laser outlet)

DANGER
LASER APERTURE

Position 4
(Indicates laser radiation when safety locks opened)

DANGER LASER RADIATION WHEN SAFETY LOCKS OPENED AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION.

Position 5
(Indicates laser specifications and applicable standard)

DANGER - INVISIBLE LASER RADIATION AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION CLASS 4 LASER PRODUCT

EXCIMER LASER
Wavelength: 193nm
Pulse Duration: 4 - 8ns
Maximum power: <3W

ALIGNMENT LASER
Wavelength: 532nm / 652nm
Maximum power: <1mW


Position 6
(Indicates company and product information)

Excelsius Medical GmbH
Magirus-Deutz-Str. 14
89077 Ulm, Germany

PRODUCT: Excimer Refractive Laser
MODEL: Micron M7

Input Rating
230V-50/60Hz 7A

SN

CE 2460

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2.1.2 Positioning the Laser

When using the diode laser during surgery, properly place the patient so his/her eye can focus on the light spot to avoid excessive eye movement. The diode laser emits wavelength with axis positioning between 630nm-670nm on the visible spectrum and working distance horizontal positioning at 532 nm on the visible spectrum. The maximum optical power is 1 mW.

2.2 Gas Safety

The excimer refractive laser system uses Argon Fluoride (ArF) as the lasing medium and uses the inert gas (Helium or Argon) as buffer gas. Although the density of the Argon is very low, it still has corrosive and toxic qualities. Please follow all safety procedures and regulations.

a). Confirm gas composition: check the mixture and ratio of the gas. Incorrect composition will damage the system. Do not remove manufacturer-provided labels for identifying gas composition. Note: The ArF gas (UN Number 1956) and buffer He gas (UN Number 1046) are both level 2.2.

b). Leakage Testing: Use a suitable gas leakage testing device such as the SWAGELOK produced “Snoop” leakage test solution. Please refer to chapter 5 for more details.

c). Fixed Cylinders: Even the best regulators can break due to cracked valves or corrosion. We strongly recommend storing the ArF gas cylinders in a secured exhaust tank to minimized unnecessary movement.

d). Use Suitable Pressure Regulator: Use suitable pressure regulator for all gas cylinders. Use the Monel alloy pressure regulator for the ArF gas.

e). Valve Damage Reporting: Do not attempt to fix valve damage or change valves. Contact the manufacturer for repairs or replacement.

f). Set the adjustment knob to zero (0) for unused gas and turn off gas cylinder valve even if the cylinder is still connected to the system. This prevents potential valve damage when reopening the cylinder.

g). Use halogen filters in the exhaust pipe: Use of halogen filter can prevent vacuum pump damage.

h). Avoid exposing the laser cavity and gas pipe to air: Exposure will damage the cavity’s passivation and the moisture will combine with the halogen and halide salt residue to
cause serious corrosive effects. When removing the front and back mirrors of the cavity (for cleaning), use a rubber plug to prevent air from entering the cavity and maintain slightly greater pressured (~1.2 bar) inert gas.

i). When separating pipelines, seal the laser’s inlet and outlet valves. This prevents moisture from entering through the valve to cause corrosion in the cavity.

j). Ensure protective masks are readily available. The mask should have a filter and easily accessible in the workspace. Properly maintain and inspect the mask.

2.3 Electrical Safety

- The laser power supply can generate a high 1.2KV. Please use appropriate caution labels.

- Affix high voltage signs in high voltage areas. (high voltage)
- Confirm the laser is properly grounded. The grounding terminal should have proper symbols for identification. (grounded)

- Use only the manual’s indicated voltage. 230V
- Check the cords and wires for damage; worn wires can cause sparks or electric shock.

---

CAUTION

When the emergency stop button is pressed, it will automatically cut power to the laser and prevent laser beams from emitting. The button will be locked in the “in/closed” position. Turning the button clockwise will unlock the button and reactivate the power.
2.4 EMS certification and declaration

Declaration of Conformity

The following products is herewith confirmed to comply with the requirements set out in the Council Directive on the Approximation of the laws of the Member States relating to Electromagnetic Compatibility Directive (93/42/EEC). The listed standard as below were applied:

The following Equipment:

Product: Excimer Refractive Laser
Trade Name: EXCELSIUS
Model Number: Micron M7
Company Name: Exccelsius Medical Co., Ltd

This product is herewith confirmed to comply with the requirements set out in the Council Directive on the Approximation of the laws of the Member States relating to Electromagnetic Compatibility Directive (93/42/EEC). For the evaluation regarding EMC, the following standards were applied:

Emission:
EN 55011: 2009+A1: 2010, Group 1, Class A: Emission standard
EN 61000-3-2: 2014: Limits for harmonic current emission
EN 61000-3-3: 2013: Limitation of voltage fluctuation and flicker in low-voltage supply system

Immunity:

The following importer/manufacturer is responsible for this declaration:

Company Name: Exccelsius Medical Co., Ltd
Company Address: 6F., No. 20, Chuangye Rd. Xinyi Dist., Taipei City, Taiwan
Telephone: +886-6-285-5850
Facsimile: +886-6-285-5811

Person is responsible for marking this declaration:

ChengHao Huang
Name (Full Name)

2016
Date

[Signature]

[Signature]

General Manager
Position/Title

Legal Signature
Statement of Conformity

Issued Date: Sep. 05, 2016
Report No.: 1680140R-ITCEP14V00

This is to certify that the following designated product

Product: Excimer Refractive Laser
Trade name: EXCELSIUS

Model Number: Micron M7
Company Name: Excelsius Medical Co., Ltd

This product, which has been issued the test report listed as above in QuieTek Laboratory, is based on a single evaluation of one sample and confirmed to comply with the requirements of the following EMC standard.

EN 55011: 2009+A1: 2010
EN 61000-3-2: 2014
EN 61000-3-3: 2013

IEC 61000-4-2 Ed. 2.0: 2008
IEC 61000-4-3 Ed. 3.2: 2010
IEC 61000-4-4 Ed. 3.0: 2012
IEC 61000-4-5 Ed. 3.0: 2014
IEC 61000-4-6 Ed. 4.0: 2013
IEC 61000-4-8 Ed. 2.0: 2009
IEC 61000-4-11 Ed. 2.0: 2004

TEST LABORATORY

Arthur Liu / Deputy Manager

QuieTek Corporation
No.75-2, 3 Lin, Weng-Yeh Valley, Yang-Haeng Tsuen, Chuang-Lin Shiang, Hsin-Chu 307 Taiwan, R.O.C.
TEL: +886-3-592-8858 FAX: +886-3-592-8859 Email: service@quitek.com http://www.quitek.com
Test Report Certification

Issued Date: 2016/09/05
Report No.: 1660140R-ITCEP14V00

Product Name: Excimer Refractive Laser
Applicant: Excelsius Medical Co., Ltd
Address: 4F, No.20, Chuangye Rd. (Tainan Science Park), Xinshi Dist, Tainan City 74144, Taiwan (R.O.C)
Manufacturer: Excelsius Medical Co., Ltd
Model No.: Micron M7
EUT Voltage: AC 230V, 50-60Hz
Trade Name: EXCELSIUS
Applicable Standard:
- EN 55011: 2009+A1: 2010, Group 1, Class A
- EN 61000-3-2: 2014
- EN 61000-3-3: 2013

Test Result: Compiled
Performed Location: Hsinchu EMC Laboratory
No. 75-2, 3rd Lin, Wangye Keng, Yongxing Tsuen, Qionglin Shiang, Hsinchu County 307, Taiwan
TEL:+886-3-592-8858 / FAX:+886-3-562-8859

Documented By:

Demi Chang / Senior Engineering Adm. Specialist

Reviewed By:

Winston Wen / Senior Engineer

Approved By:

Arthur Liu / Deputy Manager

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Laboratory Information

We, QuieTek Corporation, are an independent EMC and safety consultancy that was established the whole facility in our laboratories. The test facility has been accredited/accepted (audited or listed) by the following related bodies in compliance with ISO 17025, EN 45001 and specified testing scopes:

<table>
<thead>
<tr>
<th>Country</th>
<th>Certification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taiwan R.O.C.</td>
<td>BSMI, NCC, TAF</td>
</tr>
<tr>
<td>Germany</td>
<td>TUV Rheinland</td>
</tr>
<tr>
<td>USA</td>
<td>FCC</td>
</tr>
<tr>
<td>Japan</td>
<td>VCCI</td>
</tr>
</tbody>
</table>

The related certificate for our laboratories about the test site and management system can be downloaded from QuieTek Corporation’s Web Site:


The address and introduction of QuieTek Corporation’s laboratories can be found in our Web site:


If you have any comments, Please don’t hesitate to contact us. Our contact information is as below:

HsinChu Testing Laboratory:
No.75-2, 3rd Lin, Wangye Kang, Yonghoing Tsuen, Qionglin Shiang, Hsinchu County 307, Taiwan
TEL: +886-3-692-8658 / FAX: +886-3-692-8699  E-Mail: service@quietek.com

LinKou Testing Laboratory:
No. 5, Ruei-Shu Valley, Ruei-Ping Tsuen, Lin-Kou Shiang, Taipei, Taiwan
TEL: 886-2-8601-3768 / FAX: 886-2-8601-3769  E-Mail: service@quietek.com
Chapter 3 Software Control Interface (For User)

This chapter is for the personnel who operates the system, and this chapter provides an introduction of the software interface. The personnel who operates the system has to be certified by the original manufacturer and have a thorough understanding of the operating processes and safety procedures.

3.1 Software Version
After starting the Micron M7, the user can find the current Windows software version (Fig.3.1-1) in the upper right and DOS software version in the middle (Fig.3.1-2) of the user interface.

(Fig.3.1-1)

(Fig 3.1-2)
3.2 Software Structure
3.3 Software Control

![Software Initial Screen](image)

**3.3.1 Starting Laser**
1. Select “Laser control” to enter into Laser control window.
2. Select “Laser Ready” to start the laser mode.

3.3.2 Position Initial
1. Select “Position Initial” to initial the operation position.
2. Select "Yes" to start the initialization.

3.3.3 OD/OS positioning
1. Select OD/OS and press "Yes" to move to OD/OS.

(choice OD screen)
2. Rotate the joystick right/left (Display: up/down) to calibrate the laser spot center.
3. Select “Move to Eye” and press “Yes” to position the applicator.

4. Rotate the joystick right (up)/left (down) to adjust the applicator into laser-ready position.

(Laser locked)  (Laser permitted)
3.3.4 Entering System Menu
1. Select “Enter” to enter into System Menu. (Fig. 3.3.4-1)

3.3.5 Calibration

1. Calibrate OD
Select [1.Calibration] (Fig. 3.3.4-1), Press "Enter" to enter into OD/OS Calibration Menu, select [1.OD] (Fig. 3.3.5-1).
1.1 Calibrate Center
Select [1.Calibrate Center] (Fig. 3.3.5-2) to enter. Ensure the interface shows “Use all arrow keys to calibrate” (Fig. 3.3.2-3). Depress the footswitch. Use direction button to calibrate the laser beam spot into the red circle area on CCD Display (Fig. 3.3.2-4). Select “ESC” to leave this window.
1.2 Measure Diameters

Select [2.Measure Diameters] (Fig. 3.3.5-5) to enter (Fig. 3.3.5-6). Select [1.Ablate Testing Pattern] in this menu and press “Enter”. Ensure the interface shows “Ablating testing pattern. Type ESC to quit”. Depress the footswitch (inner diameter 8.5mm; outer diameter 9.1mm) (Fig. 3.3.5-7).

If the treatment parameter does not match the specification, insert the parameter [2.Diameter On X(mm)], [3.Diameter On Y(mm)] and [4.Axis Angle(Degree)] (Fig.3.3.5-8). Select [5.Calibrate Beam Menu] or “ESC” to return to Calibration Menu.
1.3 Calibration Menu
Select [3.Calibration Menu] (Fig. 3.3.5-9) to return to Calibration Menu.

1.4. System Menu :
Select [3.System Menu] (Fig.3.3.5-10) or “ESC” to return to System Menu.
3.3.6 Tests

1. Film test
Select [2.Tests] (Fig. 3.3.6-1). Press “Enter” to enter into Tests Menu. Select [1.Film Test] (Fig. 3.3.6-2) to open the Film testing interface (Fig 3.3.6-3). Depress the footswitch to start the Film Test.

(Fig. 3.3.6-1)

(Fig. 3.3.6-2)
2. Reading Energy
Select [2. Reading Energy] (Fig. 3.3.6-4) to display the energy measurement window (Fig. 3.3.6-5), the system activates the laser beam through its internal DOM’s energy stable system and monitors the readings. The laser will maintain an excited state for approx. one minute to stabilize the laser output energy level.
When the energy reserve is between 50%~100%, the display will show that it is sufficient to proceed with surgery.

When the energy reserve is between 25%~50%, the display will show yellow indicating that there is enough for approx. six operations.

When the energy reserve is between 0%~25%, the display will show red indicating not suitable for surgery. Replace the ArF.
3. Set tracking Value
Select [3. Set Tracking Value] (Fig. 3.3.6-6) to enter (Fig. 3.3.3-7) and adjust the tracking value for the day. Can set to +/- 5 from previous day’s tracking value.

If the display is still yellow or red after replacing the ArF, please contact the engineer responsible.
4. System Menu:
Select [5. System Menu] (Fig. 3.3.6-8) to return to System Menu.

The Tracking value (Fig. 3.3.6-7) has to be between 160 or 190. If not, please contact the responsible engineer.
3.3.7 Operation
Select [3. Operation] (Fig. 3.3.7-1), press “Enter” to enter into the Operation Window (Fig. 3.3.7-2). Enter the Patient Information and the Patient Treatment Parameter.

Operation Window Guide: (Fig. 3.3.7-2)
(1) Patient Information
   a. Patient ID: Open the keyboard and press [Shift+I] to display window to input patient ID
   b. Patient Name: Press [Shift+N] to display window to input patient name
      OD and OS must be capitalized when entered
(2) Patient Treatment Parameter:
   a. Sph. Correction(12mm): Myopia, hyperopia value (+6.0D ~ -12D)
b. Cyl. Correction(12mm): Astigmatism value (+6.0D ~ -6.0D)
c. Sph. Optical zone(mm): Myopia correction zone (2.0mm~9.0mm)
d. Sph. Trans. Zone(mm): Myopia transition zone (3.0mm~10.0mm)
e. Cyl. Optical zone(mm): Astigmatism correction zone (2.0mm~8.0mm)
f. Cyl. Trans. Zone(mm): Astigmatism transition zone (4.0mm~10.0mm)

(3) Surgery ablation surface curvature display
(4) Fixation: green laser beam spot centering, red circle focusing, eye tracking mode
(5) Provides surgery ablation depth, laser pulse and surgery time info
(6) Surgery ablation depth distribution simulation
(7) CCD Display: dynamic eye tracking
(8) Keyboard: program operating
(9) Direction button: program operating
(10) Enter

3.3.8 Presbyopia

Select [4.presbyopia] (Fig. 3.3.8-1) to enter Presbyopia surgery window (Fig. 3.3.8-2). Enter the patient’s personal information and surgery parameters.
Presbyopia Window Guide: (Fig. 3.3.8-2)
Same as Operation screen functions (refer to 3.3.7-2)
(1) and (2) are new surgery treatment parameters. (Fig. 3.3.8-3) (Fig. 3.3.8-4)

(1) Presbyopia (12mm): Presbyopia value (+1.0D ~ +5.0D)

(Fig. 3.3.8-3)
(2) Pupil size (mm): Pupil size (3.5mm~5.0mm)

3.3.9 Enhancement- Biased Treatment (not yet available)

3.3.10 Advanced- For use with special equipment (not yet available)

3.3.11 PTK Operation
1. PTK Operation 1

Select PTK Operation [7.PTK Operation] (Fig. 3.3.8-1) and select PTK Operation 1 (Fig. 3.3.11-2) to bring up operation window (Fig. 3.3.11-3). Enter the patient’s personal information and surgery parameters.
PTK Operation 1 Window Guide: (Fig. 3.3.11-3)

1. Ablation Depth (um)
2. Optical Zone Size (mm)
3. Transition Zone Size (mm)

2. PTK Operation 2 (Appropriate for straight ahead view Presbyopia)
   Select PTK Operation 2 (Fig. 3.3.11-4) to bring up operation window (Fig. 3.3.8-5).
   Enter the patient’s personal information and surgery parameters.
PTK Operation 2 Window Guide:

(1). Ablation Depth (um)  
(2). Outer Optical Zone Size (mm)  
(3). Outer Transition Zone Size (mm)  
(4). Inner Optical Zone Size (mm)  
(5). Inner Transition Zone Size (mm)

3.3.12 Exit Surgery Software

Select [8.System Menu] press Enter or ESC to leave surgery software interface.
Chapter 4. System Calibration and Testing (For User)

The Micron M7 must be calibrated and inspected regularly as instructed to preserve product quality and safety standards. The section explains why, how and when to perform these functions. The following is an overview of calibration and testing instructions. The personnel who operates the system calibration and testing has to be certified by the original manufacturer and have a thorough understanding of the operating processes and safety procedures.

4.1 Starting the System

This section details how to start the Micron M7 system and how to display basic laser beam calibration.

4.1.1 Initial Inspection

Room Temperature: 19~25℃
Room Humidity: 40~50% (Humidity must be stable)
Front control panel: Footswitch is installed (Fig. 4.1.1-1).
Back control panel: Power cable, key and interlock are installed (Fig. 4.1.1-2).
4.1.2 Supply System Power
(a) Turn the MAIN SWITCH to “On” (Fig. 4.1.2-1), then turn the LASER KEY SWITCH to “On” (Fig. 4.1.2-2).

1). Position Screen: Ensure position screen is on

2). Screen Function: Ensure the screen is function

3). Positioning distance and center: Turn on the fixation light and focus light. Adjust the height of microscope’s Z axis and ensure the fixation and focus are overlapping on the film.

4). Microscope: Ensure magnification and the image through the eye piece is clearly displayed.
4.1.3 Inspect and Stabilize Laser Power

(a) Select [2.Test] (Fig. 4.1.3-1)

(b) Select [2. Reading Energy] (Fig. 4.1.3-2) to activate laser beam and monitor its internal DOM energy stability system. The laser will maintain an excited state for approx. one minute as the laser stabilizes output energy level.

(c) Ensure the laser energy value can reach preset tracking value (Fig. 4.1.3-3)
When the energy reserve is in green, the display will show that it is sufficient to proceed with surgery.

When the energy reserve is in yellow, the display will show yellow indicating that there is enough for approx. six operations.

When the energy reserve is in red, the display will show red indicating not suitable for surgery. Replace the ArF.
4.1.4 Initiating Gas Refill Procedure

(a) Press the double-circle-symbol next to “Micron M7” in the upper right of windows interface to start the origin Laser Program.

(b) Select “Laser Ready” to stop the Laser Emission mode.

(c) Select “Standby” to set the Laser on standby mode.

(d) Cancel the option “External trigger”.

(e) Select “Gas” to enter into Gas Intensity Menu.

If the display is still red after replacing the ArF, please contact the engineer responsible.
(f) Open ArF gas bottle valve.

(g) Select “Start gas exchange program” to start the gas exchange procedure.

(h) After gas exchange, close ArF gas bottle valve.

(i) Select “Shot” to return to Main Menu.

(j) Select “External trigger”.

(k) Select “Laser Ready”.

(l) Select “Laser Emission”.

Before initiating gas refill, confirm Premix capacity. If the gas cylinder pressure is lower than 50 Bar, purchase new gas cylinders from local distributors. Replace gas cylinders when pressure is below 20 Bars.
4.2 Laser Spot Center Calibration

4.2.1 Calibrating OD Center: [Refer to 3.3.5 Calibrate OD]

(a) Select “OD” and Press “Yes” to operate.
(b) Calibrate Laser Spot Center.
(c) Select “Move to Eye” and press “Yes” to operate.
(d) The applicator moves to Standby-Position.
(f) Select [1. OD] and press “Enter”.
(g) Select [1. Calibrate Center] and press “Enter”.
(h) After “Use all arrow keys to calibrate Type ESC to quit” dialog box pops up (Fig. 4.2.1-1), depress the footswitch to start Laser Emission. Laser beam emit on Test Film. Use direction button to calibrate the laser beam spot into the red circle area on CCD display (Fig. 4.2.1-2)

(i) After centering, release the footswitch and press 「ESC」 to return to previous menu.
4.2.2 Testing the Spot Diameter

(a) In the Spot calibration menu select [2. Measure Diameters] (Fig. 4.2.2-1).

(b) Select [1. Ablate Testing Pattern] (Fig. 4.2.2-2), and adjust the information display. (Fig. 4.2.2-3)

(c) Depress the footswitch and the laser beam will cut out a test diameter spot (Inner diameter 8.5mm Outer diameter 9.1mm) (Fig. 4.2.2-4).

(d) Use calipers or a ruler to measure the x and y dimensions of the diameter to ensure it passes testing

(e) If the X or Y dimensions are not suitable, select [Diameter on X] or [Diameter on Y].
on Y], and move the arrows (left or right) to adjust the diameter value. Repeat B-D until the inner and outer diameter match the required value. (Inner diameter 8.5mm Outer diameter 9.1mm)

(f) If the axis angle of the diameter needs adjustment, select [4. Axis Angle (Degree)](Fig. 4.2.2-5), and adjust using the arrows (left or right)

![Image](Fig. 4.2.2-5)

(g) After completing diameter testing, select [5. Calibrate Beam Menu] or press ESC to return to previous menu.
4.3 Executing Film Testing

4.3.1 Film Position Test
Touch the screen and open the fixation and focus function, adjust the height of the Z axis. Ensure the fixation and focus overlap on the film.

4.3.2 Film Test

(a) Select [2. Test] (Fig. 4.3.2-1)

(b) In the submenu select [1. Film Test] (Fig. 4.3.2-2)

(c) When the testing interface appears, press Enter (fig. 4.3.2-3) and a “Start” notification will display. Depress the footswitch and excite the surgery spot. Continue to depress the footswitch and observe through CCD until the film breaks (Fig. 4.3.2-4). Now the observation notification will display a percentage. Make sure the results are 95-100% matching the specifications.
(d) Continue to depress the footswitch until testing is complete. Press [ESC] to return to the testing menu.

If three of the five film tests do not pass (95-100%), please follow section [4.3.3] to adjust tracking value.

4.3.3 Adjusting the Tracking Value

(a) Observe the film (Fig. 4.3.3-1), A (no penetration) B (penetrated)
If the film is penetrated before the test display value reaches 95%, lower the tracking value. -1 should be the minimum adjustment value. If the testing is complete and the film is still not penetrated, raise the tracking value by a minimum of +1.

Current surgery parameters can be adjusted to within +/- 5 of previous surgery parameters. If it exceeds that amount please contact the engineer responsible.

(b) Select [3.Set Tracking Value](Fig. 4.3.3-2), and follow step (a) to increase/decrease surgery tracking value (Fig. 4.3.3-3).

(c) Using the CCD to observe, replace the film and repeat film testing.

(d) Repeat (a) to (c) until the tracking value penetrates the film at 95-100% (Need to achieve this 3/5 times).

(e) Press [Esc] to return to main menu after tracking value is set.
Chapter 5 Surgery Operation Controls (For Surgeon)

This section provides details for controls during operation. This manual only provides operation system information. For surgery indication, surgical procedure, patient’s criteria, monograms, surgery recommended parameters…etc., please follow Annex C, LASIK PROTOCOL. The personnel who operate the system has to be certified by the original manufacturer and have a thorough understanding of the operating processes and safety procedures.

WARNING
Before conducting any operations, the surgeon must attend Micron M7 training to familiarize with safety and controls.

Diverse operations’ parameters of patients are given to the surgeon to set up the machine parameter. The suggested ranges are as follows:

Treatment Range:
Correcting refractive errors (Myopia/Hyperopia/Astigmatism/Presbyopia), and each symptom’s treatment range as below.

Correction Range:
Myopia: -0.25D ~ -12D
Hyperopia: +0.25D ~ +6.0D
Astigmatism: -6.0D ~ +6.0D
Presbyopia: +1.0D ~ +5.0D
**Treatment Plan:**

Excelsius Medical provides the treatment parameters as follows:

The optical zones for myopia and hypermetropia have zones of transition defined to smooth the changes of curvature in the cornea. In the following table the proportions and maximums and minimums recommended for each type of ametropia are defined.

<table>
<thead>
<tr>
<th></th>
<th>Optical zones</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Maximum</td>
</tr>
<tr>
<td>Myopia</td>
<td>9.0 mm</td>
</tr>
<tr>
<td>Hypermetropia</td>
<td>8.0 mm</td>
</tr>
</tbody>
</table>

**Recommended monogram of treatment area:**

<table>
<thead>
<tr>
<th>Ametropia (Diopters)</th>
<th>Optical Zone (mm)</th>
<th>Transition Zone (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>From -12.00D to -9.25D</td>
<td>6.0</td>
<td>7.0</td>
</tr>
<tr>
<td>From -9.00D to -6.25D</td>
<td>6.3</td>
<td>7.3</td>
</tr>
<tr>
<td>From -6.00D to -3.25D</td>
<td>6.6</td>
<td>7.6</td>
</tr>
<tr>
<td>From -3.00D to -0.25D</td>
<td>7.0</td>
<td>8.0</td>
</tr>
<tr>
<td>From +0.25D to +3.00D</td>
<td>7.0</td>
<td>9.0</td>
</tr>
<tr>
<td>From +3.25D to +6.00D</td>
<td>6.6</td>
<td>8.6</td>
</tr>
</tbody>
</table>

**Optical zone more frequent**

<table>
<thead>
<tr>
<th></th>
<th>Maximum</th>
<th>Minimum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myopia and astigmatism</td>
<td>6.2   7.5   6.2   8.4</td>
<td>5.5   6.5   5.5   7.5</td>
</tr>
<tr>
<td>Hypermetropia and astigmatism</td>
<td>6.2   8.4   6.2   8.4</td>
<td>______________________</td>
</tr>
</tbody>
</table>

Greater depth ablation

Reflections and aberrations, and more tendency to the regression in the case of hypermetropias.

**Recommended monogram of treatment diopter:**

In order to prevent regression after surgery, we recommend the parameters which apply to different ametropia as follows:

**Myopia**

Case 1: -2.00+0.50x90
Recommended transcription: -2.50+0.50 x90
Case 2: -6.00+0.75x180
Recommended transcription: -6.50+0.75x180

**Hyperopia**

Case 1: +3.00+0.25x90
Recommended transcription: +3.50+0.25x90

Case 2: +5.00+0.50x180
Recommended transcription: +5.50+0.50x180

**Presbyopia**

Case 1 (Age:58 years old): OD -4.00+0.75x165
Recommended transcription: -4.00+0.75x165  Add:+2.50D  Pupil Size:3.7

Case 2 (Age:54yrs old): OS +2.00+0.75x175 Recommended transcription: +2.00+0.75x175 Add:+2.00D  Pupil Size:3.2

The system must be calibrated and tested according to [Chapter 4] prior to surgery.

- Initiating System
- Calibrating System
- Testing prior to Operation

### 5.1 Preparation for Surgery

#### 5.1.1 Initial Inspections:
- Ensure all recording documents are ready (inspection protocols, forms, and instructions)
- Ensure all surgical instruments and drugs are available
- Ensure patient preparation is complete
- Complete [Chapter 4] Calibration and testing

#### 5.1.2 Secure Patient

(a) Guide the patient to surgery bed
(b) Select OD/OS and press “Yes” to operate Auto Tracking procedure
(c) Touch the screen and open the fixation and focus function, adjust microscope to ensure patient’s cornea can be clearly observed through microscope.

Set Microscope to 1X magnification for operation on cornea

(d) Select “Move to Eye” and press “Yes” to start the applicator
(e) Install the eye ring to applicator.

![WARNING]

Each eye piece has to be autoclaved, high temperature sterilized before use. Each eye piece is limited to its patient only; it can’t be used on second patient.

(f) Select “Auto Tracking” and press “Yes” to start. If the first time failed, press “Auto Tracking” again.
(g) Use the joystick to adjust the applicator, that the eye ring contacts the eye directly.

5.2 Operation Control

5.2.1 Operation Menu

**When conducting common refractive surgery select** [3.Operation] (Fig. 5.2.1-1). Select [4.Presbyopia] for Presbyopia (Fig. 5.2.1-2).

![menu](image1)

(Fig. 5.2.1-1) common refractive surgery

![menu](image2)

(Fig. 5.2.1-2) Presbyopia

5.2.2 Confirming or changing surgery parameters: [Refer to 3.3.4]

(a) Ensure the patient info and values in the display are correct. To change, use the arrows (Fig. 5.2.2-1). Press [Enter] after confirming.

**CAUTION**

We recommend that doctors perform surgery, should wear sterile latex gloves in order to avoid patient cross-infection.
(b) Ensure all information entered match what is required for surgery. (Fig. 5.2.2-2)

(c) After confirming all information displayed, press ENTER for next screen to prepare for surgery.

5.2.3 Automatic Surgery Energy Level Adjustment
Prior to surgery, the system will automatically adjust the laser energy level to the preset value. The status window will display the reserve energy level (red arrow)(Fig. 5.2.3-1). After detection is complete, operator needs to press ENTER to confirm, and depress the footswitch to begin surgery.

WARNING

Post-surgery stroma thickness should be kept above 250µm
5.2.4 Surgery

(a) Ensure eye tracking is on eyetrack, and check through CCD to see if it tracks the center of the pupil (Fig. 5.2.4-1). Adjust the distance of the Z-axis of the hand piece. The eye piece will make gentle contact with the patient's cornea.

When the eye piece contacts the cornea, a green light indicates all parameters are met while a red light signals an error.
(b) Depress the footswitch to activate laser beam spot. Surgery progress % will be displayed in the status window. Every 10% complete will be accompanied with a “beep” sound. Surgery completion will be accompanied by a long “beep” sound. This way, the surgeon is aware of surgery progress even if using microscope.

Pause: Releasing the footswitch will pause surgery. Depressing the footswitch will continue surgery.

Stop: For emergencies, press the red emergency stop button located on the front of the system.

(c) After surgery is complete, the screen will ask whether to print surgery data. Press “Y” to print and “N” or ESC to cancel.

(d) Press [Esc] to return to main menu.

5.3 Post-Surgery/Preparing to Repeat

5.3.1 Post-Surgery Inspection
(a) Follow standard medical post-surgery inspection procedures
(b) Ensure all reports are prepared (See protocol, forms and instructions).

5.3.2 Preparing surgery for next patient
(a) Conduct required cleaning
(b) Prior to conducting next surgery, calibrate laser spot center [4.2] and carry out film testing [4.4].

5.4 System Shutdown
This section describes how to shut down Micron M7 at the end of the work day.

1. System Shutdown:
   Turn Laser Switch to OFF (Fig. 5.4-1), then turn main switch to off (Fig. 5.4-2).
2. **Final Inspection:**

   (a) All materials should be stored in appropriate environment.
   (b) Ensure the Premix cylinder is closed.
   (c) Shut off all other devices.
Chapter 6  Maintenance (for User)

This chapter provides Micron M7 maintenance details. Improper maintenance can lower system effectiveness or even damage the system. The following are key maintenance areas: The personnel who operate the system has to be certified by the original manufacturer and have a thorough understanding of the operating processes and safety procedures.

- Gas (ArF, He) system maintenance
- DOM lens maintenance
- Module maintenance
- Laser maintenance

**Note:**
Before proceeding with any procedures, please review related preventative safety measures.

### Table 6-1 Maintenance Schedule

<table>
<thead>
<tr>
<th>Topic</th>
<th>Measures</th>
<th>Maintenance Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gas:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Premix Gas</td>
<td>Fill Laser Cavity</td>
<td>At least every two weeks or as needed</td>
</tr>
<tr>
<td></td>
<td>Change Cylinders</td>
<td>When pressure is below 20 bar</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Change Cylinders</td>
<td>(Suggest notifying engineer when below 50 bar)</td>
</tr>
<tr>
<td>Buffer Gas</td>
<td>Change Cylinders</td>
<td>As applicable</td>
</tr>
<tr>
<td>Gas Pipeline</td>
<td>Test for Leaks</td>
<td>Notify engineer if detect smell</td>
</tr>
<tr>
<td>Halogen Filter</td>
<td>Replace</td>
<td>Notify engineer every three ArF cylinder changes</td>
</tr>
<tr>
<td><strong>Optical Lenses:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DOM Lens</td>
<td>Inspect/Clean</td>
<td>Notify engineer after six months or as needed</td>
</tr>
<tr>
<td></td>
<td>Replace</td>
<td>Notify engineer after twelve months or as needed</td>
</tr>
<tr>
<td>Laser Lens (front)</td>
<td>Inspect</td>
<td>Notify engineer after three months or as needed</td>
</tr>
<tr>
<td></td>
<td>Replace</td>
<td>Notify engineer after six months or as needed</td>
</tr>
<tr>
<td>Laser Lens (back)</td>
<td>Inspect</td>
<td>Notify engineer after six months or as needed</td>
</tr>
<tr>
<td></td>
<td>Replace</td>
<td>Notify engineer after 12-18 months or as needed</td>
</tr>
<tr>
<td><strong>Laser:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diode Laser</td>
<td>Replace</td>
<td>Notify engineer when depleted</td>
</tr>
<tr>
<td>Excimer Laser</td>
<td>Replace</td>
<td>Notify engineer when depleted</td>
</tr>
</tbody>
</table>

**Note:**
Use soft cloth with 75% EtOH when cleaning outside of system. Don’t use potentially corrosive cleaning agents.
Chapter 7  Troubleshooting (for Technician)
This chapter provides basic troubleshooting information. If proposed measures fail to solve the problem, please contact responsible engineer. The personnel who operate the system has to be certified by the original manufacturer and have a thorough understanding of the operating processes and safety procedures.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Probable Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Startup:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Turning key-switch doesn't start the system</td>
<td>No power</td>
<td>1. Check power output is normal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Main system power is plugged</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Main switch is turned to “ON”</td>
</tr>
<tr>
<td></td>
<td>Electrical specifications do not match</td>
<td>Make sure the power voltage is AC 230V , 50 /60 Hz outlet</td>
</tr>
<tr>
<td></td>
<td>Broken fuse</td>
<td>Replace fuse. Refer to appendix A for fuse specifications.</td>
</tr>
<tr>
<td><strong>Laser Energy:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reserve laser energy level is low</td>
<td>Laser output energy is low</td>
<td>If reserve laser energy level is still low after refilling gas.</td>
</tr>
<tr>
<td></td>
<td>(1) Low thyatron voltage</td>
<td>(Notify engineer)</td>
</tr>
<tr>
<td></td>
<td>(2) Dirty cavity lens</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(3) Cavity lens change</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(4) Poor gas quality</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(5) Cavity pollution</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(DOM) lens is dirty, misaligned or damaged causing system laser output energy to be low</td>
<td>Clean, align or replace the DOM lens. (Notify engineer).</td>
</tr>
<tr>
<td>Reserve laser energy level is quickly depleting</td>
<td>(1) Poor gas quality</td>
<td>If reserve laser energy level is still quickly depleting after refilling gas. (Notify Engineer)</td>
</tr>
<tr>
<td></td>
<td>(2) Cavity Pollution</td>
<td></td>
</tr>
<tr>
<td>Tracking value lower than 160 or higher than 190</td>
<td>DOM lens is damaged</td>
<td>Check the lens for damaged or poor light path; if necessary, replace the lens or re-adjust the optical path. (Notify Engineer)</td>
</tr>
<tr>
<td><strong>Laser Beam:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laser spot changes shape</td>
<td>Cavity lens misaligned</td>
<td>Adjust Gauss Lens (Notify Engineer)</td>
</tr>
<tr>
<td></td>
<td>DOM lens misaligned or Damaged</td>
<td>Adjust or replace DOM lens (Notify Engineer)</td>
</tr>
<tr>
<td>Problem</td>
<td>Probable Cause</td>
<td>Solution</td>
</tr>
<tr>
<td>--------------------------</td>
<td>---------------------------------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td>Laser spot doesn't move properly</td>
<td>Scanning motor loss of Function</td>
<td>Replace scanning motor (Notify Engineer)</td>
</tr>
<tr>
<td></td>
<td>Scanning driving board is damaged</td>
<td>Replace scanning driving board (Notify Engineer)</td>
</tr>
<tr>
<td>Fixation red dot not active</td>
<td>Diode depleted</td>
<td>Replace (Notify Engineer)</td>
</tr>
<tr>
<td>Illumination light not active</td>
<td>LED depleted</td>
<td>Replace (Notify Engineer)</td>
</tr>
<tr>
<td>Focus green line not active</td>
<td>Diode depleted</td>
<td>Replace (Notify Engineer)</td>
</tr>
</tbody>
</table>

**Safety Features:**

<table>
<thead>
<tr>
<th>Laser Beam doesn't activate when footswitch is depressed</th>
<th>Emergency stop button is pressed</th>
<th>Rotate to loosen emergency stop button</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTERLOCK not connected</td>
<td>Click the icon [Move to eye], let Laser Hp to be moved to correct position</td>
<td></td>
</tr>
<tr>
<td>Laser HP is not yet moving to eye contact position</td>
<td>Connect INTERLOCK</td>
<td></td>
</tr>
<tr>
<td>Eyetracker malfunctioning</td>
<td>Click the icon [CCD] to improve the camera light exposure, then click icon [Auto Eyetracking] one time. (If the Eyetracker is still isn’t working, please click [Eyetracker Off] and [Joystick manual control] mode to move joystick to set CCD green light on eye center manually).</td>
<td></td>
</tr>
</tbody>
</table>

| Shutter doesn't raise when footswitch is depressed      | Shutter motor damaged           | Replace (Notify Engineer)               |
|                                                        | CPM module damaged              |                                        |

| Step/Servo motors not moving                           | Emergency stop button is pressed | Rotate to loosen emergency stop button |

<p>| Step/Servo motors can't correct operation              | [Initial Position] not executing | Restart main power and click [Initial Position] again. (Notify Engineer) |</p>
<table>
<thead>
<tr>
<th>Problem</th>
<th>Probable Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery software not responsive</td>
<td>DOS system crash</td>
<td>Restart computer</td>
</tr>
<tr>
<td>Touch monitor not Responsive</td>
<td>WIN system crash</td>
<td>Restart computer</td>
</tr>
</tbody>
</table>

**Manufacturer:**
Excelsius Medical GmbH
Address: Magirus-Deutz-Str.14, 89077, Ulm, Germany
Appendix A

Fuse Specification:

<table>
<thead>
<tr>
<th>Fuse Description</th>
<th>System Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 Amp 250V 5x20 mm Slow-Blow Fuse</td>
<td>Transformer Module</td>
</tr>
</tbody>
</table>

Appendix B

Equipment Use Record Form:

<table>
<thead>
<tr>
<th>Micron M7 Excimer Laser Refractive System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
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</tbody>
</table>

Person Using Equipment Should Fill Out Form