ML7® MICROKERATOME
OPERATIONS MANUAL

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℞ ONLY

CE 2797

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Indications for Use

The ML7® Microkeratome is used to perform lamellar keratoplasty procedures. This procedure is performed by refractive surgeons to create a thin circular corneal cap.

Features and Benefits

The ML7® Microkeratome is a precision-manufactured instrument designed exclusively for use in ophthalmic surgery. The device, when used in the Laser-Assisted In Situ Keratomileusis (LASIK), allows for cutting a precise lamellar flap on the anterior corneal surface through the selection of various Calibrated LASIK Blade (CLB®) models.

Do not attempt to use the ML7® Microkeratome without having an adequate understanding of all its components, functions, controls, and limitations. MED-LOGICS requires all ML7® Microkeratome users to participate in a training session provided by a representative of MED-LOGICS before using the ML7® Microkeratome.

Contact MED-LOGICS at +1(949)582-3891 to schedule a training session.

Console

The ML7® Microkeratome has a designed shelf life of a minimum of 5 years. A pre-surgery setup and functional test are specified within this document and should be performed before the initiation of the surgical procedure. This pre-surgical test ensures the proper console function and familiarizes the surgeon with the controls, display, and attachments of components.

The ML7® Microkeratome is equipped with a battery backup power supply. In the event of a power loss, the battery backup power supply will automatically engage, and the device will function without interruption. It is not recommended that you use the ML7® while on battery backup mode for an extended amount of time. At the end of life, the ML7 will be returned to Med-Logics Inc. for disposal.

The ML7® has a built-in vacuum reservoir for instant vacuum pressure once suction is activated. This reduces the amount of time the Vacuum Ring needs to be placed on the eye.

Vacuum values are easily adjusted which allows the surgeon to utilize the ideal amount of vacuum for each patient.

It also has a quick-connect and disconnect plug and cord for convenience.

Handpiece

ML7® Handpiece is an ergonomic lightweight dual-motor Handpiece with separate motor movement for controlled oscillation and translation.

It has an advanced design to eliminate on-eye assembly and reduce the risk of pre-operative error.

Equipment: (Basic Components)

Catalog Number	Description	Intended use	materials	sterile/ Non-sterile	disposable / reusable	sterilization method	Standards	period of validity
1700ML7	ML7 Microkeratome Console	The ML7 console provides the electrical energy required to power the microkeratome head, the vacuum necessary to achieve fixation of the suction ring, and displays information to the user	The console consists of a metal case that contains the medical grade power supply, the power conversion circuit board, the display circuit board, vacuum system, and the necessary interconnect cabling.	Non-Sterile	reusable	N/A	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	5 years
1400ML7	ML7 Microkeratome Handpiece	The ML7 console provides the electrical energy required to power the microkeratome head, the vacuum necessary to achieve fixation of the suction ring, and displays information to the user	The ML7® Handpiece is an ergonomic lightweight dual-motor Handpiece and consists of medical-grade materials.	Non-Sterile	reusable	N/A	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	5 years
1800ML7	ML7 Microkeratome Footswitch	Primary user input is required to activate the device and to initiate software-controlled device performance.	The Footswitch consists of materials typical in the medical device industry.	Non-Sterile	reusable	N/A	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	5 years
1900ML7	ML7 Microkeratome Stand (Optional)	To hold ML7 Microkeratome console	The Stand consists of materials typical in the medical device industry.	Non-Sterile	reusable	N/A	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	5 years
2000ML7	ML7 Microkeratome Reusable Shipping Case	To ship ML7 Microkeratome	The shipping case consists of polycarbonate, low abrasion polyethylene, and stainless steel.	Non-Sterile	reusable	N/A	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	N/A

UC1101	Ultrasonic Cleaner (110V)	Not a medical device - intended to be used to clean reusable components.	Not a medical device - intended to be used to clean reusable components.	Non-Sterile	reusable	N/A	N/A	N/A
UC2201	Ultrasonic Cleaner (220V)	Not a medical device - intended to be used to clean reusable components.	Not a medical device - intended to be used to clean reusable components.	Non-Sterile	reusable	N/A	N/A	N/A
AD1000	Instrument Dryer	Not a medical device - intended to be used to dry reusable components.	Not a medical device - intended to be used to dry reusable components.	Non-Sterile	reusable	N/A	N/A	N/A
1600PC	Power Cord, Type B (North America)	Not a medical device - intended to be used to plug in the ML7 Microkeratome.	Not a medical device - intended to be used to plug in the ML7 Microkeratome.	Non-Sterile	reusable	N/A	N/A	N/A
	Power Cords for all other countries are available.	Not a medical device - intended to be used to plug in the ML7 Microkeratome	Not a medical device - intended to be used to plug in the ML7 Microkeratome	Non-Sterile	reusable	N/A	N/A	N/A

Components: (Basic Components)

Catalog Number	Description	Intended use	materials	sterile /Non-sterile	disposable/ reusable	sterilization method	reference standards on which they are based	period of validity
1500ML7	Sterilization Tray	The sterilization tray is used to hold components during and after sterilization	The sterilization tray contains a plastic tray, plastic lid, and a rubber insert.	Non-Sterile	reusable	Steam Autoclave	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	N/A
0100ML7	ML7 Head, 100 microns	The microkeratome head precisely holds the disposable keratome blade to provide a precise depth of cut when performing a lamellar keratectomy.	The ML7 heads are manufactured from durable coated, medical-grade stainless steel and assembled utilizing industry-standard processes	Non-Sterile	reusable	Steam Autoclave	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	1 year-requires yearly mainten ance
0130ML7	ML7 Head, 130 microns	The microkeratome head precisely holds the disposable keratome blade to provide a precise depth of cut when performing a lamellar keratectomy.	The ML7 heads are manufactured from durable coated, medical-grade stainless steel and assembled utilizing industry-standard processes	Non-Sterile	reusable	Steam Autoclave	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	1 year-requires yearly mainten ance

1080ML7	Vacuum Ring, 8.0mm	The stainless-steel suction ring provides the interface between the eye and the microkeratome head	The ML7 vacuum rings are manufactured from durable hardened, medical-grade stainless steel and assembled utilizing industry-standard processes	Non-Sterile	reusable	Steam Autoclave	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	1 year-requires yearly maintenance
1085ML7	Vacuum Ring, 8.5mm	The stainless-steel suction ring provides the interface between the eye and the microkeratome head	The ML7 vacuum rings are manufactured from durable hardened, medical-grade stainless steel and assembled utilizing industry-standard processes	Non-Sterile	reusable	Steam Autoclave	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	1 year-requires yearly maintenance
1090ML7	Vacuum Ring, 9.0mm	The stainless-steel suction ring provides the interface between the eye and the microkeratome head	The ML7 vacuum rings are manufactured from durable hardened, medical-grade stainless steel and assembled utilizing industry-standard processes	Non-Sterile	reusable	Steam Autoclave	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	1 year-requires yearly maintenance
1095ML7	Vacuum Ring, 9.5mm	The stainless-steel suction ring provides the interface between the eye and the microkeratome head	The ML7 vacuum rings are manufactured from durable hardened, medical-grade stainless steel and assembled utilizing industry-standard processes	Non-Sterile	reusable	Steam Autoclave	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	1 year-requires yearly maintenance
1100ML7	Vacuum Ring, 10.0mm	The stainless-steel suction ring provides the interface between the eye and the microkeratome head	The ML7 vacuum rings are manufactured from durable hardened, medical-grade stainless steel and assembled utilizing industry-standard processes	Non-Sterile	reusable	Steam Autoclave	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	1 year-requires yearly maintenance
1300ML7	Vacuum Handle	The Vacuum handle provides the vacuum to the ML7 vacuum ring.	The vacuum handle is manufactured from medical grade stainless steel and assembled utilizing industry-standard processes	Non-Sterile	reusable	Steam Autoclave	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	N/A

1350ML7	Wrench, Helical Drive	The helical drive wrench is a tool used to tighten the helical screw on the vacuum ring.	The wrench, helical drive is manufactured from medical grade stainless steel and assembled utilizing industry-standard processes	Non-Sterile	reusable	Steam Autoclave	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	N/A
2100ML7	Titanium Eye Marker	The eye marker is used to mark the positioning on the eye.	The eye marker is made of titanium.	Non-Sterile	reusable	Steam Autoclave	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	N/A
BRO1	Small Cleaning Instrument Brush	Not a medical device - intended to be used to clean reusable components.	The cleaning instrument brush is made of nylon, Aluminum, PS.	Non-Sterile	reusable	N/A	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	N/A
BR02	Medium Cleaning Instrument Brush	Not a medical device - intended to be used to clean reusable components.	The cleaning instrument brush is made of nylon, Aluminum, PS.	Non-Sterile	reusable	N/A	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	N/A
BRO3	Large Cleaning Instrument Brush	Not a medical device - intended to be used to clean reusable components.	The cleaning instrument brush is made of nylon, Aluminum, PS.	Non-Sterile	reusable	N/A	IEC 60601-1, IEC 60601-2, Medical Device Directive 93/42/EEC, ISO 14971	N/A

Disposables:(Additional Components)

Catalog Number	Description	Intended use	materials	sterile /Non-sterile	disposable/ reusable	sterilization method	reference standards on which they are based	period of validity
ML7100	ML7 Microkeratome Calibrated LASIK Blade (CLB)	The ML7000 Series Blades are designed to perform lamellar keratoplasty procedures	The microkeratome blades are manufactured from medical grade stainless steel and assembled utilizing industry-standard processes	sterile	disposable	Ethylene Oxide	ISO 13485:2003, EN ISO 11135-1:2007, ISO 10993, IEC 60601-1, Medical Device Directive 93/42/EEC, ISO 14971	5 years from the date of manufacture
ML8060VS	Disposable, Single-Use Sterile Vacuum Tubing	The ML8000 Series Sterile Pressure Tubing sets are designed to be used in conjunction with a Keratome.	The ML8060VS tubing consists of PVC, nylon, polypropylene, cycrolate GS90, and acrylic copolymer membrane cast nonwoven nylon support.	sterile	disposable	Ethylene Oxide	ISO 3485:2003, EN ISO 11135-1:2007, ISO 10993, IEC 60601-1, Medical Device Directive 93/42/EEC, ISO 14971	5 years from the date of manufacture

Head
A durable coated, stainless steel, calibrated Head with tight tolerances allows for interchangeability between components.

Vacuum Ring
The Vacuum Rings are made from durable hardened, stainless steel with a unique patented four-slit vacuum ring design to equally distribute vacuum and avoid pseudo suction. Elevated linear rails act as a lid retainer preventing interference during the cutting process.

Essential Performance of ML7 Equipment
The Essential Performance of the ML7 Microkeratome System includes the ability to apply vacuum (at least 375mmHg) to the eye to fixate the handpiece assembly during operation, the oscillation of the Lasik blade at approximately 10,500 oscillations per minute (+/- 3%), and the transition of the Lasik blade across the cornea at approximately 3.5mm per second (+/- 10%). An error code will alert the user if these essential performance criteria are not met during operation. For more information, see Troubleshooting Section.

Component List
The ML7® Microkeratome is a precision instrument designed for performing lamellar corneal resections. Never modify any ML7® device or its components. MED-LOGICS, Inc. is not responsible for any patient injury or damage to the ML7® caused by unapproved device modification. No parts of the ML7® Microkeratome should be serviced or maintained while in use with the patient. All servicing should take place at a MED-LOGICS, Inc. approved service provider or the MED-LOGICS, Inc. office.

The system includes the following listed equipment, components, and disposables. Sample pictures of each basic component are included. Four sample pictures are available for the additional equipment as noted below.

Basic Components

ML7® Console

Handpiece

Head

Vacuum Ring

Vacuum Ring Handle

Power Cord

Sterilization Tray

Footswitch

Additional Equipment

Calibrated LASIK Blade (CLB®) and Shuttle

Vacuum Tubing Part #ML8060VS

Microkeratome Stand

(Footswitch sold separately)

Microkeratome Carrying Case

Care and Maintenance

Proper care and maintenance of the ML7® is required to assure the optimal operation of the system and the removal of all bioburdens, biofilms, or contaminants. The ML7® Head, Vacuum Ring, and Vacuum Ring Handle must be cleaned thoroughly after each use.

MED-LOGICS suggests the use of a cleaning solution designed specifically for a microkeratome or equivalent when cleaning the Heads, Vacuum Rings, and Vacuum Ring Handle. All parts must be thoroughly rinsed with distilled or filtered water after each step in the cleaning process. Completely dry all parts to ensure the components do not corrode over time. It is recommended that when the Heads, Vacuum Rings, and Vacuum Handle are not being used, they are stored in the sterilization tray for protection.

Ultrasonic Cleaning

The Head and Vacuum Rings contain several small and difficult-to-reach surfaces or cavities, and it is mandatory to ultrasonically clean the Heads, Vacuum Rings, and the Vacuum Ring Handle for 10 minutes at the end of the surgery day before being thoroughly dried. It is also highly recommended that the components are ultrasonically cleaned for 3 minutes between patients. (*Refer to Cleaning Process Section for additional information)*

Drying

Place the clean instruments and components on a lint-free disposable instrument pad or a dry towel. Completely dry all the components using an air duster. It is critically important to completely dry all components at the end of the surgical schedule to ensure components don’t corrode over time.

Head

Using a soft-bristled brush, clean all surfaces thoroughly with a microkeratome cleaning solution, including the blade holder cavity after each use. Rinse with distilled or filtered water. Ultrasonically clean as indicated above. Before storage, completely dry with lint-free instrument wipes or air duster. When finished cleaning, place the components in the Sterilization Tray for storage. (*Refer to Cleaning Process Section for additional information)*

Vacuum Ring

Using a soft-bristled brush, clean all surfaces thoroughly with a microkeratome cleaning solution. Rinse with distilled or filtered water. Ultrasonic clean as indicated above. Before storage, completely dry with lint-free instrument wipes or air duster. When finished cleaning, place the Vacuum Ring back into the Sterilization Tray for storage. (*Refer to Cleaning Process Section for additional information)*

Vacuum Ring Handle

Using a soft-bristled brush, clean all surfaces thoroughly. Check the vacuum passage for blockage and force air and/or cleaning solution as necessary to clean. Rinse with

distilled or filtered water and dry completely. (*Refer to Cleaning Process Section for additional information)*

Handpiece
Carefully wipe the outside of the motorized Handpiece with a lint-free cloth moistened with a small amount of isopropyl alcohol and clean the motor shaft with a dry soft-bristled brush or a PVA eye spear containing isopropyl alcohol while holding the handpiece with the drive pinpointing downward. **Never immerse the motorized Handpiece in any type of fluid**. Do not use any form of sterilization for the Handpiece as this can cause damage to the motors. Do not attempt to lubricate the motors. If the Handpiece is damaged, call MED-LOGICS for service at +1(949)582-3891. (*Refer to Cleaning Process Section for additional information)*

ML7® Console
A damp cloth may be used to clean the outside of the ML7® Console. Do not immerse the ML7® Console in any fluid. Avoid drawing fluid through the Vacuum Tubing and into the diaphragm pump located in the ML7® Console. Never immerse the Vacuum Ring or Vacuum Tubing in fluid while attached to the console and the vacuum pump is running.

Sterilization Tray
This component can be rinsed with distilled or filtered water before sterilization. It should then be sterilized using a steam autoclave or a gas sterilized (EtO) process. Do not sterilize using a dry heat sterilizer.

Blade
The CLB® is a single-use item. Care should be taken when handling and installing the blade so as not to damage the cutting edge. The CLB® blade is inserted into the Head directly from the Blade Shuttle.

Vacuum Tubing
The Vacuum Tubing set for the ML7® system is a single-use item. Carefully inspect the Vacuum Tubing set to make sure there are no kinks in the tubing or visible damage before use. The large connector is attached to the vacuum receptacle on the ML7® Console and the smaller connector is attached to the Vacuum Ring Handle.

WARNING: There is a risk of electrical shock if the ML7® Microkeratome is exposed to or immersed in fluid. Do not operate if the console is wet or exposed to fluids. Call MED-LOGICS, Inc. at +1(949)582-3891 for service.

Cleaning Process

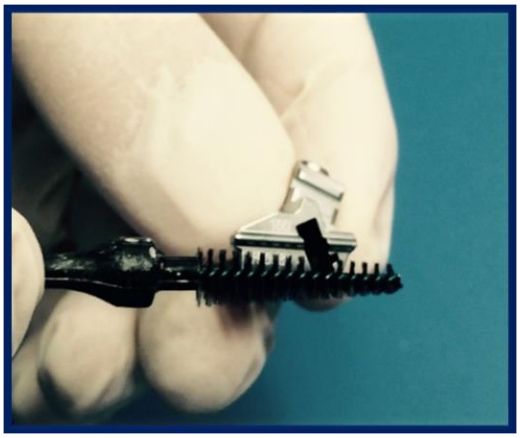
Thorough cleaning of the ML7® components after each use is of critical importance to assure proper and reliable performance. The cleaning instructions below should be implemented without deviation.

The ML7® components are made with very tight tolerances, which is required for achieving accurate LASIK flaps. If the components are not properly cleaned after each use, performance can be diminished. Cleaning the components with the brushes and ultrasonic cleaner that are made available with the ML7® make the cleaning process efficient and effective. It is also important to thoroughly dry the components at the end of the surgical schedule each day. It is not recommended to autoclave the components before placing them in storage because that can lead to corrosion.

Disinfect Components
Take the microkeratome head assembly and instruments into the cleaning area and transfer them into a clean, properly rinsed container filled with diluted Universal™ Concentrated Surgical Instrument Cleaner and Lubricant. To allow the cleaning solution to work properly, the instruments should be completely submerged for a minimum of 2 minutes.

Meticulously clean the vacuum handle threads using a soft-bristled brush and diluted Universal™ Concentrated Surgical Instrument Cleaner and Lubricant. Check the handle for blockage by using a disposable syringe to force clean/distilled/filtered water to remove any cellular debris or contaminants. Rinse the handle for at least 1 minute. The 0-ring is considered permanent and should not be removed.

Thoroughly brush the entire metal head with a focus on the linear bearings (rails) of the head using a soft-bristled brush and diluted Universal™ Concentrated Surgical Instrument Cleaner and Lubricant. Brushes must be replaced when they show wear.



Clean the blade holder cavity (the area that the microkeratome blade is inserted and removed) between cases thoroughly using a soft-bristled brush and diluted Universal™ Concentrated Surgical Instrument Cleaner and Lubricant.

Clean the blade exit cavity between cases thoroughly using a soft-bristled brush and diluted Universal™ Concentrated Surgical Instrument Cleaner and Lubricant.

Clean the linear bearing (rail) on the vacuum ring thoroughly using a soft-bristled and diluted Universal™ Concentrated Surgical Instrument Cleaner and Lubricant. Also, check the suction ring ports for blockage by using a disposable syringe to force clean/distilled/filtered water through the cavities to remove any cellular debris or contaminants. Rinse the lumens of the suction ring for at least 1 minute.

Rinse Components

The components are required to undergo ultrasonic cleaning using an Ultrasonic Cleaner with a **Plastic Basket** (similar to the one shown) to avoid potential damage to the delicate metal components. Metal baskets can damage critical surfaces of the components. Use warm (80° F or warmer), clean, distilled/filtered water in the ultrasonic bath for 8 minutes between patients and at the end of the surgical schedule to remove materials from small and difficult-to-reach surfaces and cavities.

Transfer the cleaned instruments into the first rinse container (a clean container filled with warm (80° F or warmer), clean/distilled/filtered water that has not been used). Using a second, unused cleaning brush, clean all surfaces of the microkeratome components.

Transfer the cleaned instruments into a second rinse container (a clean container filled with warm (80° F or warmer), clean/distilled/filtered water that has not been used). Copiously rinse all microkeratome components for a minimum of 1 minute. NOTE: It is always acceptable to use a third rinse cycle to repeat this step to ensure the best results.

Properly Dry Components
Place the clean instruments and components on a lint-free disposable instrument pad or a dry towel.
Completely dry all instruments. It is suggested to use an instrument dryer at the end of everyday.
Not completely drying heads and vacuum rings will lead to corrosion.

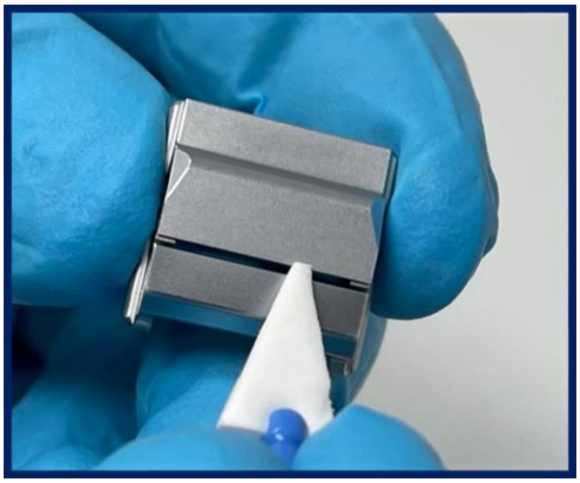
NOTE: **It is critically important to COMPLETELY DRY ALL COMPONENTS at the end of the surgical schedule to ensure components don't corrode over time.**

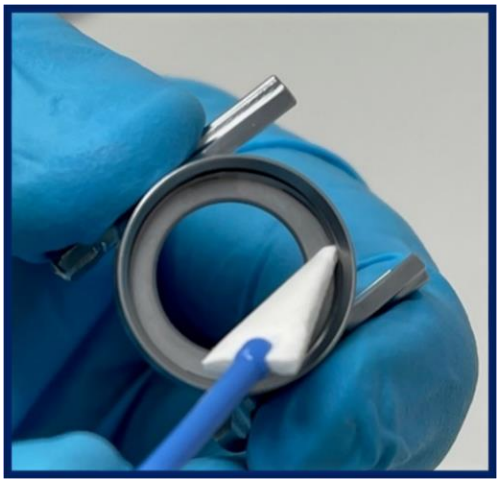
Another option is to dry the outer surface of the head using a lint-free material.

The vacuum ring outer surface can be quickly dried by using the same lint-free material.

The inner cavities of the head must be thoroughly dried and a PVA eye spear is a good option. It is important to insert the eye spear into the blade cavity from both sides.

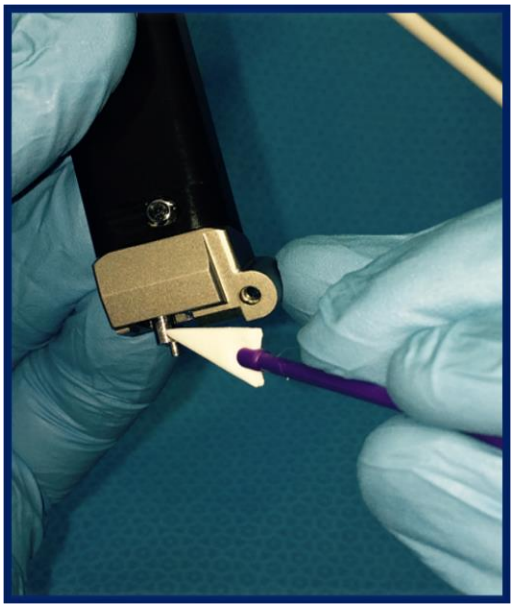
The applanation cavity could also have moisture that requires removal with the PVA eye spear.





The vacuum slits inside the vacuum ring will contain moisture that must be removed. The eye spear can be placed inside each vacuum slit to absorb the fluid.

Using a PVA eye spear dampened with alcohol to remove any debris from the handpiece drive pin. It is important to keep the handpiece drive pin in a downward position to prevent any fluid from entering the handpiece.



Proper Storage
Place all instruments and components into their protective tray to store them for future use. It is recommended to autoclave the components the day of use and avoid autoclaving them before placing them in storage to avoid corrosion. If a high-temperature dry heat sterilizer is to be used, the plastic sterilization tray should not be used during that process.

Sterilization Protocol

The following matrix indicates which sterilization or sanitization methods are safe and acceptable for each ML7® Microkeratome component. The ML7® components indicated below must be sterilized or cleaned before each use. High-level disinfectant will cause undesirable resistance if not thoroughly rinsed. It is recommended to rinse components twice before each sterilization cycle. Alcohol does not constitute a sterilization procedure and will damage plastic and acrylic parts.

Component	Autoclave[a]	Alcohol[b]
Instrument Tray	Yes	No
Vacuum Ring/Handle	Yes	No
Head	Yes	No
Handpiece[c]	No	Wipe Only
Motor Power Cord	No	Wipe Only

The ML7® components should be sterilized in an autoclave (moist heat sterilizer) at **134º** C, at least 27psi for 18 minutes.
Do not attempt to sterilize the motorized Handpiece as this will damage the motors inside the handpiece.

NOTE: Leaving the vacuum rings, handle and heads in the sterilizer overnight may cause corrosion due to residual moisture. It is recommended that the vacuum rings, handle and heads are sterilized on the day of use.

Initial Installation

Caution: Do not attempt to use the ML7® without having an adequate understanding of all its components, functions, controls, and limitations.

1. Place the ML7® Console on a firm and level surface. Insert the female end of the main Power Cord firmly into the female receptacle located on the rear panel of the ML7® Console. Plug the male end of the cord into a properly grounded electrical outlet.

2. Firmly attach the Footswitch to the ML7® Console by inserting the connector into the receptacle located on the rear panel of the ML7® Console marked with a Footswitch symbol. Rotate the knurled locking ring in a clockwise manner to secure the connector to the Console.

3. The “I/O” main power switch located on the rear panel of the ML7® Console provides power to the unit and activates charging of the internal battery. The battery needs to be charged for at least 24 hours before use to ensure the device has sufficient power to complete a procedure in the event of an AC power failure. The “I/O” power switch on the rear of the panel must remain in the “I” or ON positions and the device plugged into an AC outlet at all times to ensure the device stays charged. If the switch is in the “O” or OFF position, the Console will run on battery power until the internal backup battery is exhausted. At this point, the Console will display a “bAT” error message on the front panel display to alert the user that the backup battery has been depleted.

4. The Console is capable of full operation without having a fully charged backup battery if the Console is plugged into a wall outlet and the main power switch is in the “ON” position. However, if the Console is used without a fully charged backup battery, the Console may cease to function in the event of an AC power failure.

5. Note: The internal battery should be tested annually.

Surgical Setup

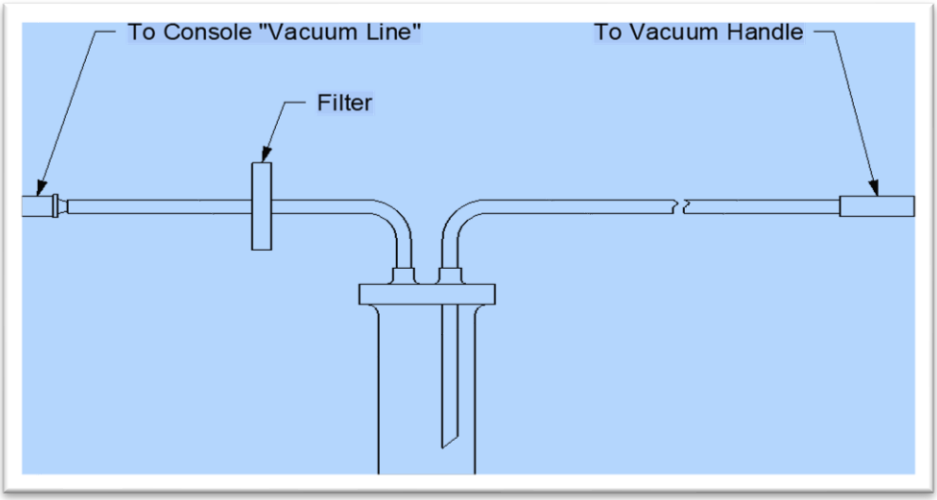
1. The Handpiece cord should be connected to the ML7® Console at the connector identified by the handpiece symbol.

2. Install the Vacuum Tubing to the ML7® Console by inserting the collection bottle end of the Vacuum Tubing set to the receptacle symbol "⍒", located on the lower-left area of the ML7® Console front panel. *(figure 1)*

   <u>WARNING:</u> The Vacuum Tubing is a single-use item and must be changed regularly. Repeated use can cause the tubing filter to become degraded and prevent the Console from applying adequate vacuum to fixate the cornea and may result in a damaged cornea.

3. The white luer taper fitting of the Vacuum Tubing is then attached to the Vacuum Ring Handle. *(figure 1)*

Figure 1

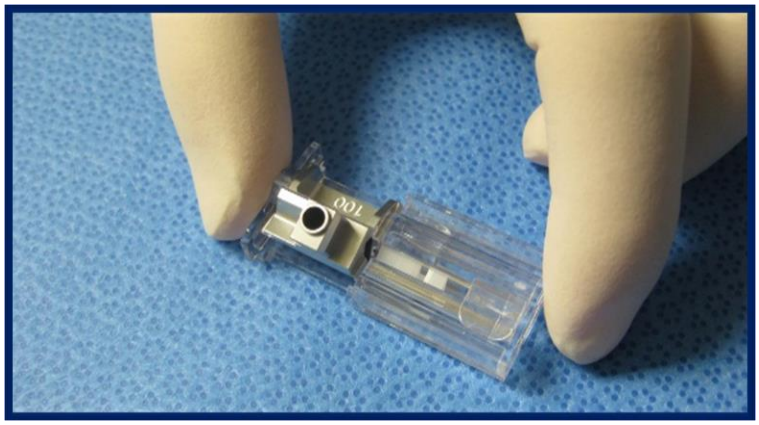


4. Turn both On/Off power switches to the "I" position on the front and rear panel of the ML7® Console.

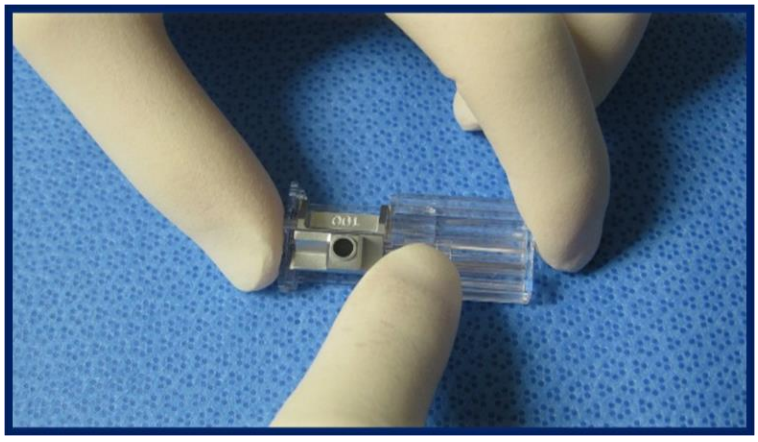
5. There are two vacuum readouts on the front panel display; "PRESET" and "ACTUAL". The system has a default preset value of 635 mm/Hg and can be adjusted up or down based on surgeon preferences.

   Caution: If the established vacuum drops below 385 mm/Hg for any reason, the "VACUUM LOSS INDICATOR" light will activate. If the "VACUUM LOSS INDICATOR" light is activated, the user should check the unit for a loss of vacuum before resuming the operation.

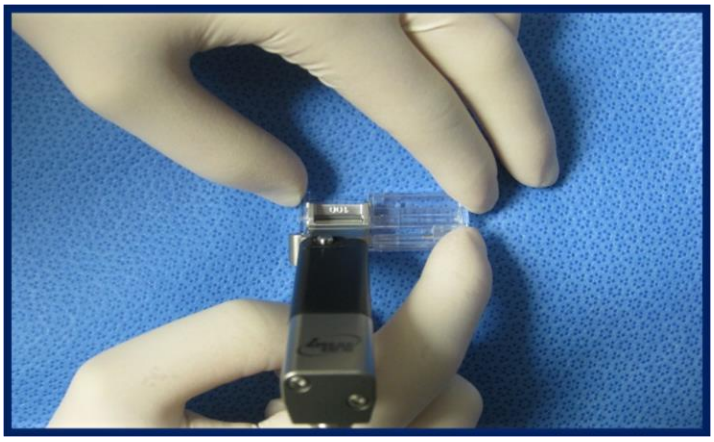
6. Select the appropriate type of CLB® needed for the procedure. To install the CLB® into the Head, place the CLB® Shuttle on a flat surface and slide the Shuttle drawer to an open position. Insert the calibrated Head (100 or 130-micron options) into the CLB® Shuttle drawer and close the drawer against the Head. Hold the CLB® Shuttle with your thumb and forefinger at opposing ends of the shuttle.



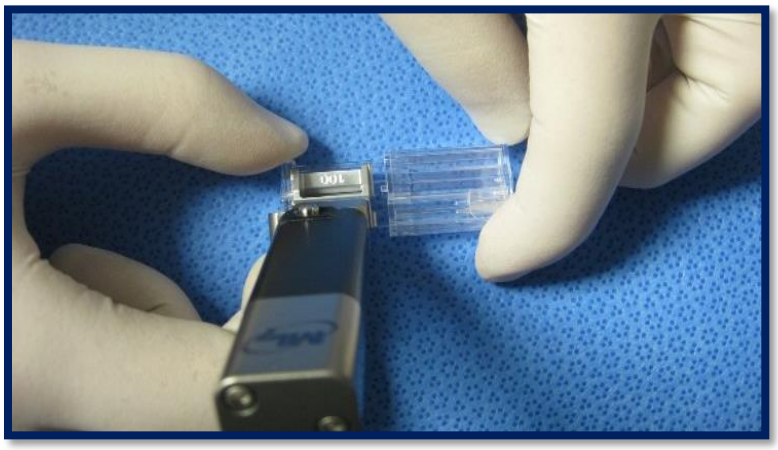
7. Slide the tab towards the calibrated Head to insert the CLB® into the Head to the proper position.



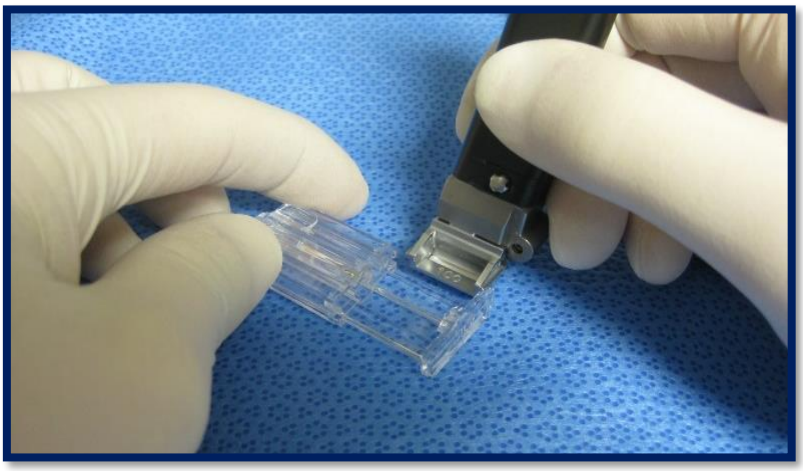
8. The Handpiece is then connected to the Head with the quick connect system.



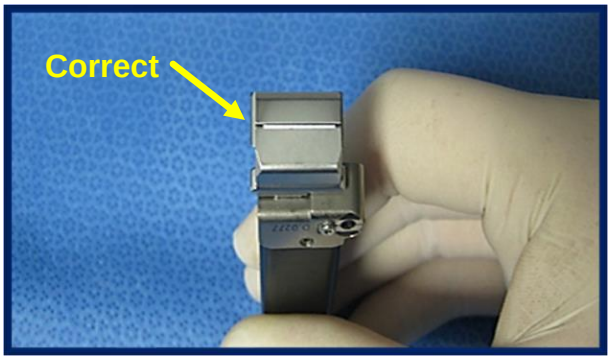
9. The blade slide or tab is then retracted into the blade Shuttle.

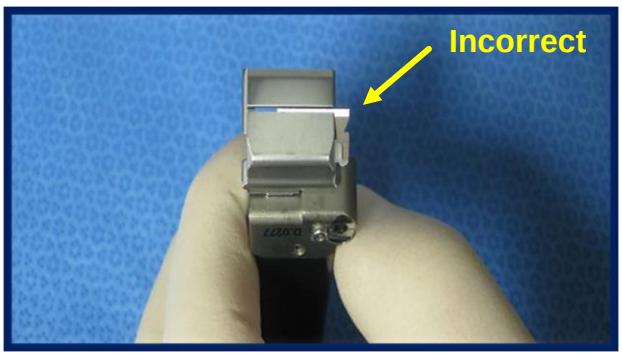


10. The drawer is then opened to allow the removal of the assembled calibrated Head and Handpiece from the CLB® Shuttle.



11. Check the operation of the blade in the Head by rotating the Handpiece as shown in the two photos (as shown below) and activate the “FORWARD” foot pedal. If the blade oscillates, the blade has been installed correctly. If the blade does not oscillate, the blade may not have been installed correctly.



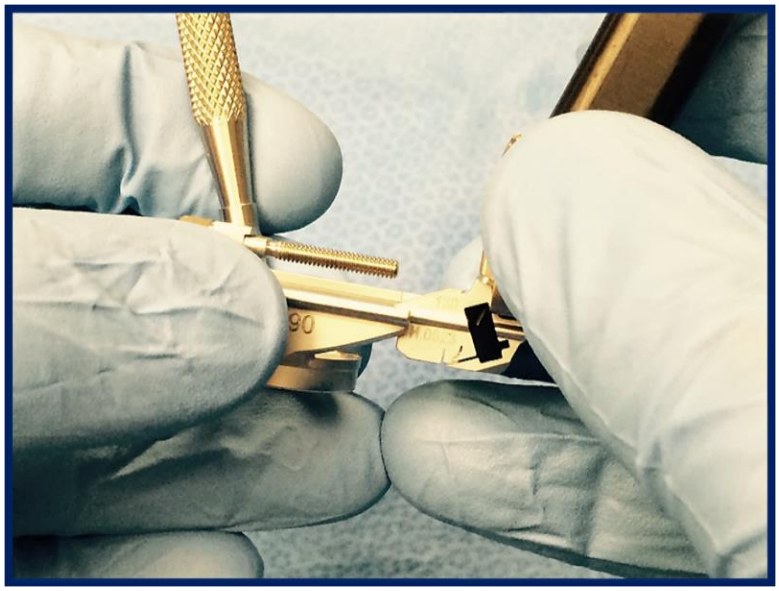


12. If the Blade does not oscillate, correction can often be made by simply disconnecting the Handpiece from the Head while holding the Head with fingers placed on each side of the Head to prevent the Blade from falling out of the Head. The Handpiece can then be reattached to the Head while continuing to hold the Head on each side.

13. Using the ML7® Vacuum Nomogram, select the recommended vacuum ring size.

14. Screw the Vacuum Ring Handle onto the Vacuum Ring.

15. Assemble the Head and Handpiece to the Vacuum Ring by lowering the calibrated Head linear rails between the side rails of the Vacuum Ring and pushing it forward to match the helical screw to the helical drive cavity of the motorized Handpiece.



16. The “FORWARD” foot pedal located on the Footswitch is then pressed to position the calibrated Head to the desired location on the Vacuum Ring. The “REVERSE” pedal can be used to adjust the location of the Head on the Vacuum Ring.

Functional Test

It is strongly recommended that before each procedure a function test is performed. The steps below outline the process for a functional test.

a. Pressing the “VACUUM I/O” button on the Footswitch and occluding the end of the vacuum tubing will test the vacuum system.

b. Once the “ACTUAL” vacuum level reaches the “PRESET” level and is stable, there will be two audible beeps indicating that the device is ready for operation. Press the “FORWARD” pedal to start the Head and Handpiece across the Vacuum Ring. Once the Head travels across the Vacuum Ring and makes contact with the stop on the helical screw, it will automatically start traveling back to its original starting location unless you remove your foot from the “FORWARD” pedal early. If this happens, the user needs to find the “REVERSE” pedal to continue the reverse movement.
IMPORTANT: Only one pedal should be pressed at a time.

c. Press the “REVERSE” foot pedal to fully retract the Head and remove it from the Vacuum Ring. The forward and reverse travel of the Head across the Vacuum Ring must be completely smooth. If binding or resistance is encountered, do not attempt a surgical procedure. Repeat the cleaning process and functional test. If resistance is still encountered, call MED-LOGICS at +1(949)582-3891 for service.

d. If all functional tests in this section have been completed and passed, the ML7® Microkeratome is ready for use in a surgical procedure.

Surgical Procedure

If the functional testing was completed without any problems (passed), then the surgical procedure may proceed.

a. Ensure all steps in the Setup Procedure are complete, including the last two steps where the Head and Vacuum Ring are assembled and engaged.

b. Before placing the vacuum ring on the patient’s eye, check the Handpiece and Vacuum Ring to ensure they are assembled correctly and that the helical screw is properly engaged.

c. Next, check the location of the Head on the Vacuum Ring making sure the Head is not too far forward allowing the blade edge to come in contact with the cornea prematurely. If the Head is out of place, simply use the “FORWARD/REVERSE” pedals to deliver it to the correct starting position.

d. Using the ML7® Eye Marker find the cornea centration center (not pupil) of the eye and mark the cornea according to the direction for the intended cut.

e. Using the marks created in the previous step, place the assembled vacuum ring on the patient's eye and orient the markings on the Vacuum Ring with the marks on the cornea. Once the Vacuum Ring is positioned correctly, activate suction by pressing the "VACUUM I/O" button to affix the ring to the patient's cornea. **Wait for the ML7® Console to beep twice to indicate that adequate suction has been reached.** Verify the suction or intraocular pressure with a tonometer. Caution: The Handpiece will not travel across the Vacuum Ring until the "PRESET" vacuum level has reached 385mm/Hg. The vacuum level must maintain at least 385mm/Hg or an "error code E7" will appear on the "PRESET" vacuum display and the forward movement of the Handpiece will immediately stop and back up 2mm. The reverse movement will always work.

f. Deliver one or two drops of refrigerated/chilled proparacaine 0.5% or equivalent, to the exposed cornea surface.

g. Activate the Handpiece by pressing the "FORWARD" foot pedal and holding continuous pressure until the Handpiece automatically returns to the original starting position.

h. Once the Handpiece has arrived at its starting position, release the "FORWARD" foot pedal and then release suction by pressing the "VACUUM I/O" button on the Footswitch once, to release the Vacuum Ring from the patient's cornea.

i. Repeat Steps "a-f", if performing surgery on the same patient's other eye.

Troubleshooting

This section focuses on troubleshooting various situations that can be encountered when using the ML7® Microkeratome. The ML7® will alert the user to certain performance issues using error codes that will be illuminated on the front panel of the console where the "PRESET" Vacuum is located.

The following is a list of error codes but note: These codes may not be inclusive. Contact MED-LOGICS for any questions.

ERROR	DESCRIPTION
E1	Program memory failure
E2	Footswitch failure
E3	Critical RAM failure
E4	Communications failure
E5	Vacuum error
E6	Blade motor failure
E7	Vacuum leak
bAT	Low battery voltage

Functional Scenarios

Although it is impossible to depict every troubleshooting scenario, MED-LOGICS has included the following list of common scenarios and proposed solutions. Should there

be a scenario not listed, contact the nearest authorized representative or MED-LOGICS for assistance in resolving the problem.

Head

Advancement of the Head is not smooth: Check the helical screw for damage or debris that might be interfering with the advancement of the Head. If the helical screw is damaged, a replacement Vacuum Ring should be used. If debris is located on the helical screw, a soft-bristled brush should be used to remove the debris.

The blade is not moving freely: The plastic blade holder may be restricted within the cavity of the Head because of residue cleaning solution or BSS. Remove the blade and thoroughly clean the blade cavity on the Head with a soft-bristled brush using the microkeratome cleaning solution. Completely rinse the components with distilled or filtered water and dry them before sterilizing. Review Section Pre-Surgical Set-Up step (Page 14-17) in the manual to determine if the Blade Shuttle instructions were followed.

The blade falls out of the head after attaching the head to the Handpiece: Remove the head from the Handpiece and depress the drive pin on the handpiece. The Handpiece drive pin has a spring inside it and if the drive pin doesn't spring back after depressing it, then the Handpiece needs to be returned to MED-LOGICS for cleaning and service. Don't try dipping the Handpiece in any fluid because it could cause more damage to the Handpiece.

The Head will not connect to the Handpiece: Check the Head and the Handpiece for debris that might be preventing the quick connect from engaging the two components. If no debris is discovered, replace components to discover which is malfunctioning. Check the orientation of the blade in the Head to determine if the Handpiece drive pin is properly seated in the drive pin cavity of the white plastic blade holder.

Vacuum Ring

The Head is stuck on Vacuum Ring: Remove the helical screw from the Vacuum Ring by unscrewing the nut located at the end of the helical screw. A wrench is supplied as an accessory for this purpose.

Vacuum Ring doesn't have adequate suction at the eye even though the "ACTUAL" vacuum display is higher than 385 mm/Hg of vacuum: First, remove the Vacuum Ring from the Vacuum Ring Handle.

Activate the vacuum and if the amount of vacuum on the "ACTUAL" readout decreases, then there may be a blockage in the Vacuum Ring. If the vacuum level remains the same, remove the Vacuum Ring Handle from the tubing to determine if the amount of vacuum decreases.

If this does not clear the component, then place the Vacuum Ring and/or Vacuum Ring Handle in an ultrasonic cleaner for a minimum of 3 minutes.

If the blockage remains, contact MED-LOGICS or an authorized representative to schedule a service.

Handpiece

Motor shaft will not rotate: If the motor shaft, which drives the blade, does not rotate when the "FORWARD" foot pedal is depressed, check to determine that the unit is turned on. Also, confirm that the Footswitch and Handpiece cord are properly connected to the ML7® Console. Replace the Handpiece if necessary.

The Handpiece won't move across the vacuum ring when pressing the "FORWARD" foot pedal: Check to make sure the Handpiece and Vacuum Ring are properly assembled. If so, then try to advance the Handpiece by pushing it across the Vacuum Ring. If you can do this, the Handpiece needs to be sent back to MED-LOGICS or your distributor for service. If you can't advance the Handpiece across the Vacuum Ring then try reassembling the components again contact MED-LOGICS or a distributor for additional support.

The Handpiece will not attach to the ML7® Head: If the Handpiece will not attach to the Head, test the quick connect to determine if it is operational. If the quick-connect is not allowing the Handpiece to be connected to the Head, a replacement Handpiece or Head should be used.

NEVER IMMERSE THE MOTORIZED HANDPIECE IN FLUID. BE CAREFUL NOT TO DROP THE HANDPIECE. DO NOT AUTOCLAVE OR STERILIZE THE HANDPIECE OR HANDPIECE CABLE.

ML7® Console

The vacuum display on the front panel does not illuminate: Make sure the main power switch located on the front panel is on "I". Confirm that the Power Cord is properly attached to the back panel of the ML7® Console and that it is plugged into a functioning, grounded outlet of the appropriate voltage. If the vacuum display remains off, service may be required. Contact MED-LOGICS at +1(949)582-3891 for service.

Vacuum pump does not start: If the vacuum pump does not start when the black "VACUUM I/O" button on the Footswitch is pressed, confirm that the unit is plugged in, that the Vacuum displays are illuminated, and that the Footswitch cord is properly attached to the rear of the ML7® Console. If the vacuum pump still will not start, the Footswitch may be malfunctioning, or the pump may be damaged. Call MED-LOGICS at +1(949)582-3891 for service.

"bAT" error appears: Make sure that the main power switch located at the rear of the Console next to the power inlet is on "I". Confirm that the Power Cord is properly attached to the back panel of the ML7® Console and that it is plugged into a functioning, grounded outlet of the appropriate voltage. If the "bAT" error persists, service may be required. Contact MED-LOGICS at +1(949)582-3891 for service.

Maintenance

Fuses

If the power cord is connected and the ML7® Console power switch is turned “ON”, and there is no display on the console the fuse may need to be replaced. To replace the fuses inside the Console, the following procedure is required:

1. Turn off “O’’ both front & back power switch on the Console.
2. Unplug the power cord from the wall outlet.
3. Remove the fuse cover using a flathead screwdriver.
4. Pull out the fuse carrier.
5. Replace both fuses with the following:
6. 2A/250V 5X20mm Fast Acting Fuse
7. If the fuses fail again, contact the authorized MED-LOGICS distributor/representative or contact MED-LOGICS directly.
8. Re-attach the fuse carrier in the reverse order of step 5.

Verify the fuses following the procedures below:

1. Plug the Power Cord into the ML7® Console inlet and then to the wall outlet.

2. Turn on both power switches to “I” on the ML7® Console and verify that the front panel display illuminates.

3. Attach the inlet cover in the reverse order of step 3 from above.

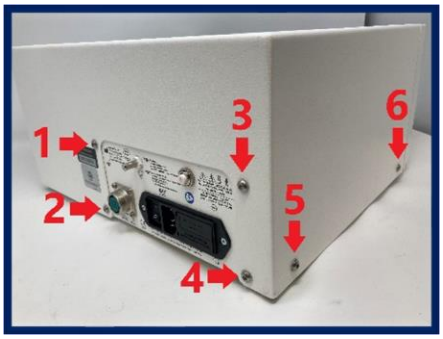
Battery

The ML7 is equipped with a battery backup power supply. In the event of a power loss, the battery backup power supply will automatically engage, and the device will function without interruption. It is not recommended that you use the ML7 while on battery backup mode for an extended period of time. The battery backup is for emergency power supply.
It is recommended that the battery inside the ML7® Console be tested at least once a year and be replaced every three years by a qualified MED-LOGICS representative or MED-LOGICS directly.

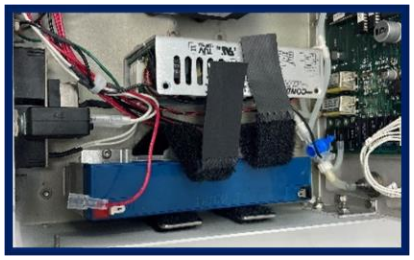
Battery Replacement

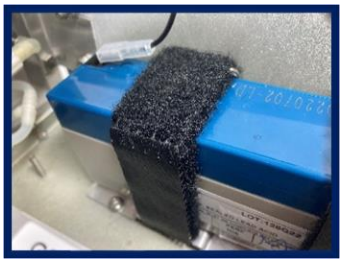
The ML7 Console will still function when supplied with external AC power even if the internal battery is faulty. The battery should be replaced to maintain the ML7 Console's emergency backup power functionality. A qualified technician should follow the procedure below to replace an ML7 battery using only a PowerSonic PS-1220 12 Volt 2.5 Ah rechargeable SLA battery.

1. Use an anti-static wristband and gloves to avoid damaging any sensitive electronics.
2. Unplug the ML7 console. Place both switches, front and back, to the off (O) position.
3. Remove the 8 cover screws with a T15 Security Torx driver bit.

4. Pull the cover straight upwards to remove it from the console.
5. Disconnect both battery cables by gently pulling them off the terminals.
6. Unstrap the two Velcro ties and remove the battery.
7. Place the new battery between the metal tabs with the black (-) terminal towards the front of the console.
8. Tightly strap the Velcro ties and verify that the battery is securely held in place.



9. Reattach the two battery cables by gently pressing the connectors all the way onto the terminals. The red cable should connect to the red (+) terminal, and the black cable should connect to the black (-) terminal.
10. Power on the console to ensure no BAT error is present. MED-LOGICS recommends fully charging the backup battery before using the console in surgery. The battery will charge as long as the console is plugged in to AC power and the rear switch is in the on position (I).

Warranty

MED-LOGICS warrants that the ML7® Microkeratome will conform to the manufacturer's version for the published specifications for the ML7® Microkeratome in all material respects and shall be free from defects in material or workmanship for a

period of twelve (12) months from documented receipt date. Repaired parts by MED-LOGICS have a ninety-day warranty.

The exclusive remedy for any breach of the Warranty shall be at MED-LOGICS option, the repair or replacement of the non-conforming equipment or part thereof which is returned to MED-LOGICS. An authorization number must be obtained by calling MED-LOGICS Customer Service at +1(949)582-3891 and must accompany equipment returned for any reason. Please print the authorization number on the outside of the shipping box.

MED-LOGICS shall pay only for shipping expenses for equipment repaired under Warranty. For equipment returned for repair, which is not under warranty, the standard repair charges of MED-LOGICS shall apply.

This Warranty does not apply to normal wear and tear, or to defects, malfunctions, or failures that result from the abuse, neglect, improper installation or maintenance, alteration, modification, accident or misuse of the equipment, excessive exposure to fluid, or the user not following directions provided in the Operator's Manual. Also, if the device shows evidence of blade reuse, MED-LOGICS has the right to revoke or void the Warranty.

THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NO WARRANTY IS GIVEN THAT THE EQUIPMENT IS DELIVERED FREE OF THE RIGHTFUL CLAIM OF ANY THIRD PARTY FOR PATENT INFRINGEMENT, AND THE LIKE.

The warranty set forth above may not be extended, expanded, or otherwise modified by any MED-LOGICS agent or employee, and MED-LOGICS does not assume any liability or make any warranty except as stated above.

MED-LOGICS shall not be liable for, and specifically disclaims responsibility for any incidental consequential or exemplary loss, damage, or expenses, directly or indirectly arising from the use of the ML7® Microkeratome even if MED-LOGICS has been advised of the possibility of such loss, damage or expense.

For optimum performance, it is the operator's responsibility to schedule preventive maintenance of the MED-LOGICS ML7® Microkeratome and its accessories. It is strongly recommended that the system be returned to Med-Logics for annual inspection and/or service. Contact MED-LOGICS to schedule an inspection and/or service.

Specifications

Vacuum Ring	
Ring options	Five vacuum ring options 8.0mm diameter fenestration 8.5mm diameter fenestration 9.0mm diameter fenestration 9.5mm diameter fenestration 10.0mm diameter fenestration
Material	Proprietary Hardened Stainless Steel
Handpiece	
Forward speed	3.5mm/sec. (3.15mm/sec – 4.00mm/sec)
Reverse speed	3.5mm/sec. (3.15mm/sec – 4.00mm/sec)
Oscillation rate	10,500 oscillations per minute +/- 3%
Head	
Material	Proprietary Hardened Stainless Steel
Two-flap Thickness options	100 microns 130 microns
Blade	
Material	Stainless Steel
Sterilization Method	EtO
Options	Six Options PLANO Minus 10 (microns) Minus 20 (microns) Minus 30 (microns) Plus 10 (microns) Plus 20 (microns)
Console	
Material	Steel
Vacuum Accuracy	+/- 10mmHg
Footswitch	Waterproof
Structure	Note: Metal parts corrode if left wet for extended periods of time.
Vacuum Tubing	
Material	PVC
Length	212mm
Power Source	
Voltage/Frequency	100-240VAC, 50/60Hz
Fuses	40W 2A 250V FA x2

Surgical Cart

Height	34”
Tray Dimensions	19.4” X 16”
Tray Weight Limit	10lbs

Environmental Conditions

In Transportation & In Storage	Temperature: +32°F to +89°F (0°C to +32°C) Humidity: 0 to 90% (non-condensation) Air Pressure: 650 to 1070 hPa
In Use	Temperature: +59°F to +77°F (+15°C to +25°C) Humidity: 0 to 70% (non-condensation)

EMC Statement

Important information regarding Electromagnetic Compatibility (EMC)
With the increased number of electronic devices such as PC’s and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation.

Medical devices should also not interfere with other devices.
In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC 60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

The ML7® Microkeratome conforms to this IEC60601-1-2:2015 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed.

The use of accessories and cables other than those specified by MED-LOGICS, Inc., with the exception of cables sold by MED-LOGICS, Inc. as replacement parts for internal components, may result in increased emission or decreased immunity of the device.

Warning: The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.

Refer to further guidance below regarding the EMC environment in which the device should be used.

Guidance and manufacturer's declaration – electromagnetic emissions		
The ML7® Microkeratome is intended for use in the electromagnetic environment specified below. The customer or the user of the ML7® Microkeratome should ensure that it is used in such an environment. NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF Emissions CISPR 11	Group 1	The ML7® Microkeratome uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class A	The ML7® Microkeratome is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **WARNING:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the ML7® Microkeratome or shielding the location.
Harmonic Emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The ML7® Microkeratome is intended for use in the electromagnetic environment specified below. The customer or the user of the ML7® Microkeratome should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IED 61000-4-4	±2kV Mains ±1kV I/O's	±2kV Mains ±1kV I/O's	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95% Dip for 0.5 Cycle >95% Dip for 1 Cycle 30% Dip for 25/30 Cycles >95% Dip for 250/300 Cycles	>95% Dip for 0.5 Cycle >95% Dip for 1 Cycle 30% Dip for 25/30 Cycles >95% Dip for 250/300 Cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ML7® Microkeratome requires continued operation during power mains interruptions, it is recommended that the ML7® Microkeratome be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The ML7® Microkeratome is intended for use in the electromagnetic environment specified below. The customer or the user of the ML7® Microkeratome should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 V 0.15 MHz-80 MHz 6 V[1)] in ISM between 0.15 MHz and 80 MHz[2)] 80 % AM at 1 kHz	3 V 0.15 MHz-80 MHz 6 V[1)] in ISM between 0.15 MHz – 80 MHz	PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT
1) r.m.s. before modulation is applied. 2) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The ML7®Microkeratome is intended for use in the electromagnetic environment specified below. The customer or user of the ML7®Microkeratome should ensure that it is used in such an environment.

Test Frequency	Band[1]	Service[1]	Modulation[2]	Maximum Power	Distance	Immunity Test Level
MHz	MHz			W	Meters	(V/m)
385	380-390	TETRA 400	Pulse modulation [2] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [3] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation [2] 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [2] 18 Hz	2	0.3	28
1720 1845 1970	1700-1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [2] 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [2] 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11a/n	Pulse modulation [2] 217 Hz	0.2	0.3	9

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[1] For some services, only the uplink frequencies are included.

[2] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[3] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Recommended separation distances between portable and mobile RF communications equipment and the ML7® Microkeratome

The ML7® Microkeratome is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ML7® Microkeratome can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ML7® Microkeratome as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of the transmitter In watts(W)	**Separation distance according to frequency of transmitter** in meters (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

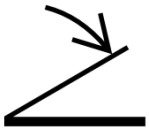
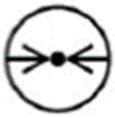
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

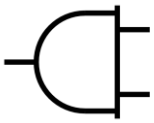
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Label Definitions

CONSOLE LABELS

	Catalog or Re-Order Number
	Risk of electric shock.
	Caution
	Equipotential Ground
	Fuse rating
	OFF switch position
	ON switch position
	Console is classified as a type B system
	Manufacturer
	Authorized representative in the European Community

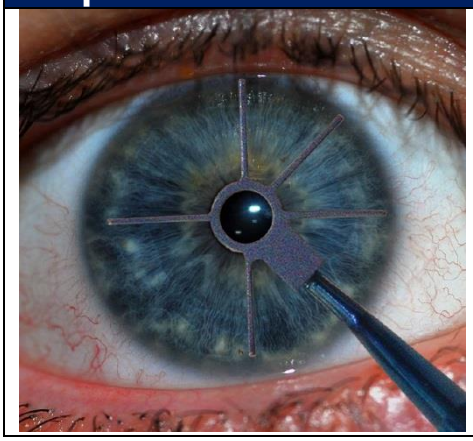
UK REP	Authorized representative in the United Kingdom
	Footswitch connection location
	Footswitch connection location
	Handpiece connection location
	Vacuum connection location
℞ ONLY	CAUTION: Federal (U.S.) law restricts this device to sale by, or on the order of, a physician
CE 2797	CE mark and Identification number of Notified Body. The product meets the essential requirements of the Medical Device Directive (93/42/EEC)
	Date and country of Manufacture
	Pressure Sensing
MD	Medical Device
	Eject

	Power Connection Point
	Unique Device Identifier

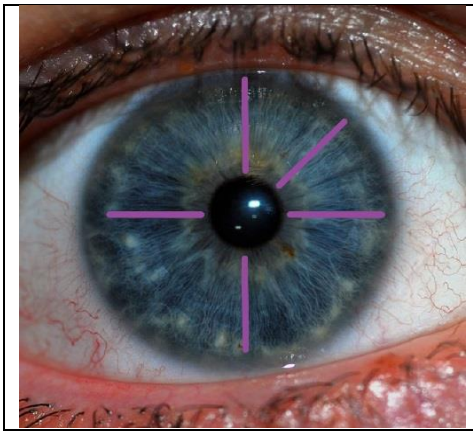
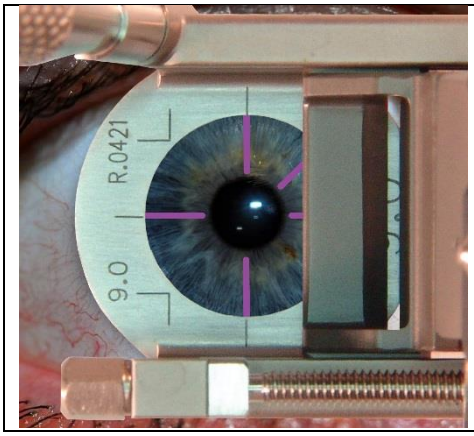
DISPOSABLE LABELS	
	Catalog or Re-Order Number
	Caution
	Do not re-use
	Date and country of Manufacture
	Use-by
	Lot number
	Manufacturer
	Authorized representative in the European Community

UK REP	Authorized representative in the United Kingdom
STERILE EO	Sterilization using ethylene oxide
℞ ONLY	CAUTIION: Federal (U.S.) law restricts this device to sale by, or on the order of, a physician
CE 2797	CE mark and Identification number of Notified Body. The product meets the essential requirements of the Medical Device Directive (93/42/EEC)
MD	Medical Device
UDI	Unique Device Identifier

Flap Centration



- Select Nasal, Superior, or Temporal hinge.
- Center the circle of the marker over the pupillary axis of the eye.
- Orient cornea marker lines based on the preferred placement of the hinge.

	• Confirm marks to be centrally located over the pupil. • The image shows the proper orientation for Nasal hinge placement.
	• Position the assembled ring on the cornea by matching cornea markings with lines on the vacuum ring deck. • Activate vacuum and confirm cornea markings remain aligned before creating the flap.

Vacuum Ring Nomogram

Selecting a Vacuum Ring

1. Determine the Steepest K reading and Corneal Diameter for each eye.

2. Using the chart below, locate the Steepest K reading and Corneal Diameter (White to White) to locate the recommended ring size.

3. In the case of a patient being on the margin of a category, the smaller vacuum ring size should be considered.

CHART

Corneal Steepest K	Corneal Diameter (mm)	Vacuum Ring (mm)
≤40	10.0 – 12.0	9.0
	12.0 – 13.5	9.5
41	10.0 – 12.0	9.0
	12.0 – 13.5	9.5
42	10.0 – 12.0	8.5
	12.0 – 13.5	9.0
43	10.0 – 12.0	8.5
	12.0 – 13.5	9.0
44	10.0 – 12.0	8.5
	12.0 – 13.5	9.0
45	10.0 – 12.0	8.5
	12.0 – 13.5	9.0
46	10.0 – 12.0	8.5
	12.0 – 13.5	9.0
47	10.0 – 12.0	8.0
	12.0 – 13.5	8.5
48	10.0 – 13.5	8.0

Patents

US 6,663,644, US 7,645,291, US 6,358,260
US 6,183,488, US 8,070,764, US 9,125,731