

450.8000.02 / 2409

1. Scope of delivery

1.1 Package contents LX Master Mirror, Starter Kit Day (REF)



450.6501.10	LX Master Mirror Starter Kit Day consisting of: 1 x 450.0002.10 1 x 450.0036.01 1 x 450.4001.10* 1 x 450.4002.10 1 x 450.7002.01
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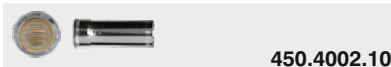
1.2 Components LX Master Mirror (REF)



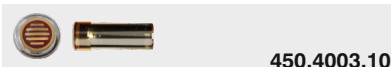
450.0002.10 BeamHub with mirror (Size5) and replacement tool
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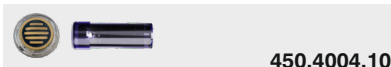
450.4001.10 Charger station with USB-C cable without country-specific power supply*
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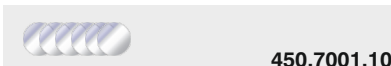
450.4002.10 MicroBeam Day
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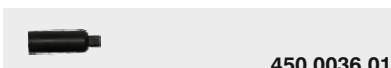
450.4003.10 MicroBeam CureSafe
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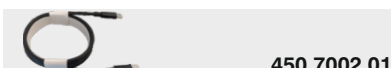
450.4004.10 MicroBeam UV
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450.7001.10 Mirror (Size 5) Set of 6 pcs.
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450.0036.01 Replacement tool
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450.7002.01 USB-C Charger cable USB-C to USB-C - 1m
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 *The power supply is not included in the scope of delivery. Recommended are all commercially available USB-C power supplies.

1.3 Assembling LX Master Mirror (REF)

 For assembling of LX Master Mirror medical device the following individual components are provided in the compatibilityFür das Assembling des Medizinproduktes LX Master Mirror sind folgende einzelne Komponenten in der Vereinbarkeit vorgesehen:

REF	450.0002.10 BeamHub	UDI: 111929426394
	450.4001.10 Charger Station	UDI: 111935132872
	450.4002.10 MicroBeam Day	UDI: 111935133438
	450.4003.10 MicroBeam CureSafe	UDI: 111935135791
	450.4004.10 MicroBeam UV	UDI: 111935134004
	450.7001.10 Mirror (Size 5)	UDI: 111935136357

 The individual components may only be used in combination with the LX Master Mirror medical device. In case of single use, all warranty and liability exclusions are excluded.

Users who use LXMM products and components without CE and MD labels declare that they agree to use a product that is not yet approved and is still in the usability test phase.

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2. Notes

2.1 Warranty / Liability

The warranty and liability for defects are regulated in the General Terms and conditions (GTC) of MIKRONA GROUP AG. The GTC can be downloaded on the homepage of MIKRONA GROUP AG



The operating instructions must be consulted by the user before first use in order to prevent incorrect use and other damage.

Warranty claims are regulated by the General Terms and Conditions. Furthermore, the notes and warnings in the operating instructions must be observed.

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2.2 Conformity assessment



The product LX Master Mirror has been subjected to a conformity assessment procedure in accordance with the Regulation (EU) 2017 / 745 MDR of the European Parliament and of the Council on medical devices and complies with the required essential requirements of this Regulation.

The assessment procedure to which this declaration refers is in accordance with the standards or normative documents EN ISO 9873 /DIN EN 62366-1 / EN 60601-1

The product LX Master Mirror of the company MIKRONA GROUP AG is subject to continuous technical development. Technical changes, which do not correspond to this operating manual, are therefore reserved.

2.3 Classification



MIKRONA GROUP AG declares under its own responsibility that the product LX Master Mirror complies with the regulation (EU) 2017 / 745. Based on the intended use, assessment and analysis with Regulation (EU) 2017 / 745 "Annex VIII Classification Rules", the product LX Master Mirror is classified as a Class 1 medical device.

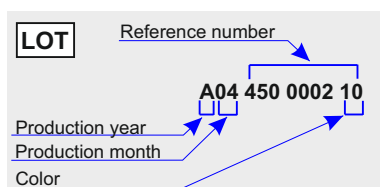
The LX Master Mirror is predominantly a smooth, easy-to-clean corrosion resistant instrument, the cleanliness can easily be visually inspected. The effectiveness of cleaning can be directly assessed simply by inspection. There are no special requirements for cleaning.

The BeamHub with mirror is assigned to the category "semicritical A" without special requirements* for cleaning and disinfection. The classification in "semicritical A" refers to a non-invasively used instrument for general, preventive, restorative and orthodontic measures.

Medical devices in this category must be disinfected.

* Classification according to RKI

2.4 Lotnumber / reference number / UDI



The individual components of the LX Master Mirror are labelled with a lot number. This references the date of manufacture and the article number so that each individual component can be identified and traced.

In case of defects or complaints, always specify the Lot number.

The UDI (Unique Device Identification) product identifier is a unique numerical code for the medical device. It enables the identification of the device and facilitates its traceability. The UDI comprises the following components: the unique device identifier (UDI-DI) and the manufacturing identifier. (see chapter 1.3)

2.5 General notes

The operating instructions is an integral part of the product. It must be available to the user in the vicinity of the product. Observance of the operating instructions is a requirement for the intended use and correct operation of the product. New employees must be instructed properly. The operating instructions must be passed on to successors.



The safety for the user and a trouble-free operation the product is only guaranteed if original parts are used. Furthermore, only the accessories listed in the operating instructions or specifically recommended by MIKRONA GROUP AG may be used. If other accessories are used, MIKRONA GROUP AG cannot guarantee safe operation and function. No warranty claims can be made for such defects.



MIKRONA GROUP AG is responsible for the product with focus to safety, reliability and function only, if readjustments and repairs are carried out by MIKRONA GROUP AG or by an authorized agency of MIKRONA GROUP AG and if the product is used in conformity with the instruction manual.



MIKRONA GROUP AG recommends keeping the original packaging of the Starter Kit and the individual components (see chapter 7).

If a return delivery becomes necessary during the warranty period, MIKRONA GROUP AG will not accept any liability for damage during transport that occurred due to defective packaging!

2.6 General safety notes

The product has been developed and constructed by MIKRONA GROUP AG in such a way that hazards are almost impossible if the product is used in accordance with its intended use. Nevertheless, we see ourselves obliged to describe the following safety measures, so that a residual danger can be excluded.



Mikrona products are built in conformity with the relevant safety regulations and fulfill the legal requirements. The EMC protection requirements have been tested and are fulfilled.



When operating the product, the laws and regulations applicable at the place of use must be observed! It is not allowed to modify or change the device. For reasons of product safety, the device may only be equipped with adaptable original accessories from MIKRONA GROUP AG. The user carries the risk if unapproved accessories is used.



Components which have an effect on the safety of the device must be replaced with original parts. In the interest of safe use and application of the device the operator and user is responsible for compliance with the rules and regulations.

MIKRONA GROUP AG cannot assume any warranty or liability for converted or modified devices.

The user must check the functional safety and the proper condition of the device before use.

2.7 Labeling of warning and hazard information

For correct, hazard-free and professional use of the device, it is necessary to know and follow the relevant safety regulations and instructions. It is essential that you observe the warnings and notes listed here. Important information concerning the safety of persons and of the device is marked in the operating instructions with the following designations and symbols:



The symbol «Attention» is used to indicate information and texts which, if not followed, may pose a risk to the device or its user. This information or instructions and prohibitions serve to prevent personal injury or extensive damage to property.



The symbol «Instruction manual» refers to information in the product-specific operating instructions.



The electrical safety mark 'Type B' indicates a medical device where the leakage current does not exceed the values required by the standard and is not suitable for direct application to the heart.



The symbol «Special note» symbol is used to indicate notes and texts that require special attention and which, if observed, can lead to improvements in the operating process.



The symbol «Dangerous electrical voltage» is used to indicate instructions and texts that represent a danger to the life and health of the user or other persons.



The symbol «Note» is used for notes and texts that are particularly important and must be observed, or which may cause malfunctions in the operating process if not observed.



The symbol «Fragile» is used to indicate a medical device with a fragile package contents.



The symbol «Sterilization» indicates a medical device that can be steam sterilized (autoclave) at the specified temperature.



The symbol «Cleaning, disinfection» indicates a medical device that is suitable for reprocessing in a washer-disinfector (WD).



The symbol «Wipe disinfection» indicates a medical device that is only suitable for wipe disinfection.



The symbol «Keep dry» indicates a medical device that must be protected from moisture. must be protected from humidity.



The symbol «no direct sunlight» indicates a medical device that must be protected from direct sunlight.



The symbol «Humidity Limitation» indicates a medical device to which the medical device can be safely exposed.



The symbol «Temperature limits» indicates a medical device to which the medical device can be safely exposed.



The symbol «Packaging damaged» indicates a medical device that should not be used if the packaging is damaged.



The symbol «Air pressure limitation» indicates a medical device to which to which the medical device can be safely exposed.



The symbol «Manufacturer» indicates the manufacturer of the medical device.



The symbol «Date of manufacture» indicates the date on which the medical device was manufactured.



The symbol «Authorized representative in the European Union» indicates the authorized representative in the European Community/European Union.



The symbol «catalog number» indicates the manufacturer's catalog number so that the medical device can be identified. the medical device can be identified.



The symbol «Lot number» is used to display the manufacturer's Lot number so that a specific medical device can be identified and traced back.



The symbol «medical device» indicates that the item in question is a medical device.



The symbol «unique device identification» indicates information about a unique product identification (UDI).



The symbol «Non Steril» indicates a medical device that has not been subjected to a sterilization process.



The symbol «Protective gloves» indicates that protective gloves must be used to protect user.



The symbol «Recyclable packaging materials» indicates a medical device that uses recyclable materials.



The symbol «Disposal» indicates a medical device that must not be disposed in the normal household waste or the normal waste disposal system.

2.8 Notes of instruction manual

Read the Instruction and maintenance manual before using the device. Be sure to observe all safety instructions.



This instruction manual contains important information in use the device. It helps to avoid dangers and to reduce repair costs and breakdown time. This increases the reliability of operation and extends the service life.

2.9 Warranty policy

MIKRONA GROUP AG grants the user a warranty that covers all functional, material and production defects.

The warranty period is 12 months (1 year) from the date of invoice. It begins with the shipment of the deliveries ex works or with the possibly agreed acceptance of the deliveries and services.

In the case of authorized complaints, MIKRONA GROUP AG or its authorized representative will repair or replace the product free of charge. Excluded are other claims of any kind, in particular claims for damages and their consequences resulting from the following:

- abnormal use
- incorrect use
- Ignoring the instruction manual
- unusual chemical, electrical or electrolytic influences
- Deep discharge of the MicroBeam



The warranty does not apply if the damage and its resulting damage is due to improper interventions or modifications to the product by unauthorized third parties. Warranty claims can only be made if a copy of the invoice or delivery bill is submitted with the product. The following information must be visible on it:

- the date of sale
- the lot number

2.10 Technical customer support

Technical support for the device is provided by Mikrona. If you have any questions, please contact:



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3. Product information

3.1 Intended use



The product is designed exclusively for professional use in general dentistry, including restorative treatments, prophylaxis and orthodontics.

The LX Master Mirror is an intraoral mouth mirror, hand-held dental instrument for intraoral examination. The product includes the BeamHub (mirror with integrated light guide), a MicroBeam light module and the Charger.


The product is in use with a MicroBeam *Day* for integrated high power LED, a MicroBeam *CureSafe* for antipolymerization, a MicroBeam *UV* for detection of fluorescent composite materials and a high resolution Rhodium mirror.

With the LX Master Mirror, the examination can be performed independently of an additional light. Due to the integrated light, there is no need to change the hand to switch to an additional light, therefore the examination can be performed faster, more concentrated, safer and more ergonomically. The MicroBeam module must be charged with the charger included in the system kit.

The product is for the following group of users:

- Dentist
- Children's dentist
- Orthodontic
- Oral surgeons
- Dentalhygienic
- Dental trade

3.2 Intended operating conditions

 The intended EM environment (according to IEC 60601-1-2) is that of a professional medical facility. It is just as appropriate for use in home healthcare settings as it is in medical facilities. This medical device has no critical functions and therefore has no essential performance characteristics. However, in the unlikely event of a disturbance affecting the device's performance, the operator may notice a temporary reduction in light output or battery charging efficiency. This should not affect basic safety, and the device will return to normal operation once the disturbance has ceased.



Operating conditions: 10°C to 35°C (50°F to 95°F)

Relative humidity: 30% to 60%


Air pressure limitation: 650hPa to 1060hPa


3.3 Safety requirements for use

According to IEC 60601-1 :2006 + A1 :2013 /Annex, electrified devices can only be used safely in a medical environment in which potentially explosive or flammable mixtures of anaesthetic agents with air, oxygen and nitrogen monoxide are administered to the patient if the following conditions are met:


-  - The MicroBeam is not used at the same time as the anaesthetic is administered to the patient. Anaesthetic to the patient.
-  - The distance between the MicroBeam, the Charger and the anaesthesia breathing circuit is more than 25cm. In addition, it is recommended that the MicroBeam and Charger are not stacked or positioned in close proximity to other medical electrical equipment, to avoid potential electromagnetic interference or mechanical hazards.

3.4 Electrical safety

 According to the IEC 60601-1 standard (General safety of medical electrical equipment), the device is to be categorised as class 1 type B. The associated terminology is defined in sections 3.13 and 3.132 of the same standard. The following requirements specified in IEC 60601-1 must be complied with:

- Protection against electric shock and Leakage currents
- Protection against excessive temperatures and other safety hazards
-  - Type B applied parts are not suitable for use on the heart


3.5 Electromagnetic safety


 Electromagnetic compatibility in accordance with IEC 60601-1-2 and manufacturer's declaration with regard to electromagnetic compatibility. The following accessories and cables are tested and validated for use with the LXMM to ensure compliance with EMC requirements: USB Cable, Charger Station, MicroBeam, BeamHub and Mirror. Other USB-C cables and accessories can impair the EMC performance or magnetic interference can also be caused by other electromedical devices. This medical device is neither life-sustaining nor patient-coupled. It is suitable for operation in areas of domestic healthcare as well as in facilities used for medical purposes, except in rooms/areas in which high intensity EM disturbances occur.


The user must ensure that the medical device is set up and operated in such an environment or in accordance with the manufacturer's specifications. This medical device does not use HF energy and is unlikely to interfere with other nearby electronic devices.

However, portable RF communication devices, such as mobile phones, should not be used closer than 30 cm (12 inches) to the LXMM or its cables, as they may affect the performance. No special precautions are required to maintain the basic safety and essential performance characteristics of this medical device.






3.6 HF communication devices

 The medical device is not intended for use in the vicinity of HF surgical devices. Portable HF communications equipment (including accessories such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the medical device. Non-compliance can lead to a reduction in the performance characteristics of the medical device.

 Mikrona Group AG guarantees the conformity of the appliance with the EMC directives only if original Mikrona Group AG accessories and spare parts are used. The use of accessories and spare parts that are not approved by Mikrona Group AG can lead to increased emission of electromagnetic interference or to reduced resistance to electromagnetic interference. If non-original accessories are used, the user is fully responsible and liable in connection with any harm or destruction done to users and patients as well as to other devices and real estates.









 If use in the manner described is nevertheless necessary, the medical device and the other devices should be observed to ensure that they are working properly.

3.7 Not intended use



-  The device and the accessories are for dental use. The LX Master Mirror should only be used by trained specialists. Any other use or use beyond this is considered improper. MIKRONA GROUP AG is not responsible for any damage resulting therefrom.
-  The maximum time of application the LX Master Mirror in the oral situation should not be more than 60 min.
-  The product is intended for temporary use. The product must not be used in case of existing injuries in the oral cavity or during surgical procedures in the oral cavity.
-  The LED light output of the MicroBeam Day and MicroBeam UV is in a range that can lead to premature polymerization of composite materials. To minimize premature polymerization, use the MicroBeam CureSafe module, which filters out the polymerizing light components.
-  The single components may only be used in combination with the LX Master Mirror medical device. In case of single use, all warranty and liability exclusions are excluded.

3.8 Safety notes

If there are any indications that a risk could arise for the user due to partial wear or a technical fault in the device, the product must be checked immediately by an authorized customer service or by MIKRONA GROUP AG or the fault must be repaired and fixed immediately and may no longer be used.

-  The product is not delivered sterile and has not been placed under any sterilization procedure. Before first use in the oral situation, the BeamHub must be sterilized in the steam sterilization (autoclave) (see Chapter 6).
-  Do not look directly at an illuminated MicroBeam module. This may cause visual irritation.
-  Do not dip the MicroBeam module and the charger into liquids (irreparable damage).
-  Do not clean the MicroBeam module and the charger in the WD/thermo washer disinfectant (irreparable damage).
-  Do not autoclave the MicroBeam module and the charger. (irreparable damage).
-  Do not cool the BeamHub quickly after steam sterilization (autoclave). The mirror may be damaged.
-  Steam sterilization (autoclave) must be carried out before exchanging and replacing the mirror.
-  The generally valid safety procedures, in particular the wearing of personal protective equipment (gloves, glasses, etc.), must be observed by medical personnel who use and maintain contaminated or potentially contaminated medical products.


3.9 Waste management


-  The created waste is to be recycled or disposed of in a process that is safe for people and the environment, in compliance with the applicable national regulations. Beam Hub and accessories must be decontaminated before recycling (see chapter 6).
-  The LX Master Mirror product and its components must be recycled. Electrical or electronic devices may contain substances hazardous to health and the environment. The user has to return the equipment to his dealer or has directly to contact a facility authorized dealer for equipment of this type (European Directive 2012/19/EU). The mirror can be disposed of with the clinic waste. Dispose of the used MicroBeam modules (batteries) in the collection boxes provided in shops or at municipal collection points. (Document SI.230601.31)

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4. Starting up

4.1 Shipping and packing for transport

 For shipping the LX Master Mirror, the MicroBeam module must be removed from the BeamHub and safely stored and transported in the original packaging (see chapter 7).

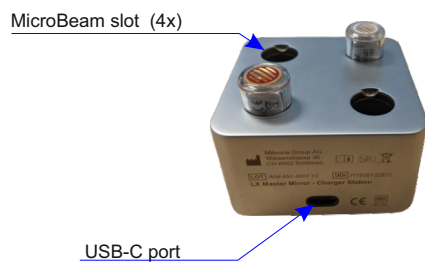
 Do not ship MicroBeam modules with cracked, deformed or damaged housings.


4.2 Initial use

 The product is not delivered sterile, clean dry and sterilize the BeamHub before first use (see chapter 6).

Follow their country-specific guidelines, standards and specifications for cleaning, disinfection and sterilization.

4.3 Electrical connection



 The charger must be installed and used at a safe distance from sources of moisture and heat.


Please position the device with a minimum distance to the patient of 1.5 m on a stable, horizontal surface.


The charger is equipped with a standard USB-C port. The USB-C to USB-C charger cable (1m) is included in the scope of delivery.

The power supply unit is not included in the scope of delivery. All commercially available power supplies (chargers) are usable for power supply.


4.4 MicroBeam charging




 Before using the MicroBeam the first time, charge it completely. The MicroBeam must be fully charged in the charger before it is used for the first time, otherwise it cannot be set into operation.

 To do this, insert the MicroBeam module into the Charger and position/rotate the MicroBeam until it clicks into place and is held by the magnet.

The red signal LED lights up to indicate that the charging process is started. After the charging capacity has reached approx. 80%, the red signal LED is switched off and the white signal LED lights up. When the white signal LED lights off, the charging process is finished.


 Indication Signal LED during the charging process:


0- approx.80%	charged:	signal LED red	= ON
approx. 80-100%	charged:	signal LED white	= ON
100%	charged:	signal LED	= OFF

 When the BeamHub is not in use, it is recommended to leave the MicroBeam module in the charger for storage to ensure the longest possible runtime of the MicroBeam module.


Fully discharged MicroBeam modules require approximately one hour for full recharge.

With a charged MicroBeam module, the LX Master Mirror can be used continuously for approx. 120 min.

 As normal with all battery-powered devices, the battery capacity will slowly be reduced with aging which will reduce the operating times. Replacement of the MicroBeam module is then at the disposal of the user.

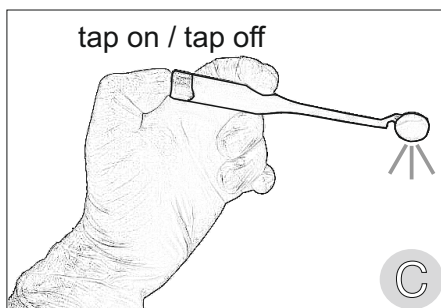
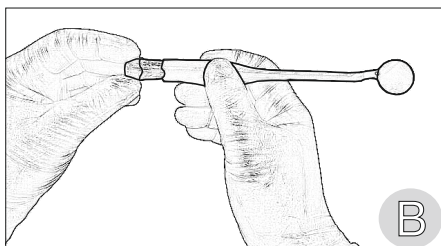
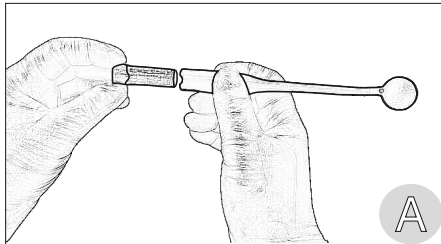
 These MicroBeam modules may only be charged with the charger provided for this device.

The MicroBeam module has IP 40 protection and cannot be opened.

 Please note that the MicroBeam module can discharge if it is not used for a long time.

5. Operation

5.1 Insert MicroBeam in BeamHub



The product is not delivered sterile. Clean, dry and sterilise the BeamHub before first use. (see chapter 6)



Wear single-use gloves according to DIN EN 455 in the correct size during treatment.

- protect yourself and others from the risk of transmitting pathogens
- protection against infection during treatment
- protection of surfaces from contamination

Procedure:



The MicroBeam must be fully charged in the charger before it is used for the first time, otherwise it cannot be set into operation.

A) Insert the MicroBeam module into the BeamHub without applying pressure. Due to the chosen design between the MicroBeam module and the BeamHub it can be easily inserted and positioned.

B) The MicroBeam module is automatically held in position by the chosen design. Preventing it from falling out on its own is thus prevented.

With a slight pull on the MicroBeam it can be removed out.

C) By pressing the button on the MicroBeam module the power LED light can be switched on. Switching on is confirmed by the white signal LED flashing for a short time.

The power LED is switched on in two stages.
First approx. 6% and then 100% of the power.

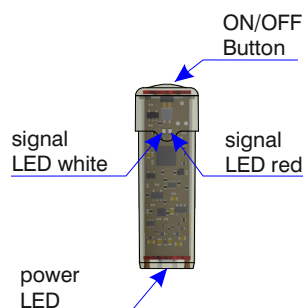
Press the button on the MicroBeam button to switch off the power LED light. Switching off is indicated by the white signal LED flashing for a short time.

Automatic switch-off of the power LED after 5 minutes in standby mode, the power LED switches off automatically and must be switched on again manually.



The stem of this BeamHub is not suitable for bending !

5.2 LED status MicroBeam modul



The MicroBeam module is equipped with a motion sensor which puts the MicroBeam into an energy-saving mode when not in use. Waking up from battery saving mode is confirmed by the red signal LED!

The charging status of the MicroBeam is indicated by the signal LED. When the red signal LED lights up, charging in the charger is recommended.

Signal LED MicroBeam remaining operating time when light is switched on:

approx. 11 min to approx. 120 min operating time: signal LED = OFF
0 min to approx. 10 min operating time: signal LED red = ON



We recommend charging the MicroBeam in the charger for <10 min (signal LED = red) and not discharging the MicroBeam completely.



As normal with all battery-powered devices, the battery capacity and light intensity will slowly be reduced with aging the MicroBeam which reduces the operating and usage times. Replacement of the MicroBeam module is then at the disposal of the user.

5.3 MicroBeam Day



The light of the MicroBeam LED can be evaluated with two parameters:

The LED light performance of the MicroBeam Day is in a wavelength range that can lead to premature polymerisation of composite materials.

When using the MicroBeam Day, there may be can happen undesired premature activation of the photopolymerisation. The MicoBeam Day has a CRI of 95 (colour rendering index) and a colour temperature of 5700°K, which corresponds approximately to natural daylight.



Do not look directly at a MicroBeam Day module that is switched on. This may cause visual complaints.

5.4 MicroBeam CureSafe



The LED light output of the MicroBeam CureSafe is in a wavelength range that prevents premature polymerisation of composite materials.

The MicoBeam CureSafe operates in a wavelength range of 615 nm.



Do not look directly at a MicroBeam CureSafe module that is switched on. This may cause visual complaints.

5.5 MicroBeam UV



Adhesives are sometimes mixed with fluorescent materials to make them visible under ultraviolet (UV) light ("black light"). Their wave spectrum is outside the visual range.

The wavelength of the MicroBeam UV is approx. 385 nm.

The LED light intensity of the MicroBeam UV is in a wavelength range that helps users. Adhesives can be visualised with help of inserted fluorescent particles and supports a complete and safe removal of adhesive particles.

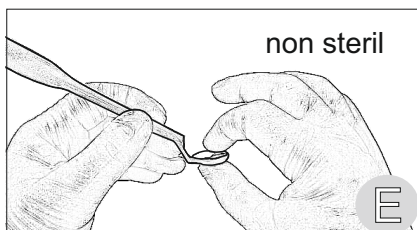
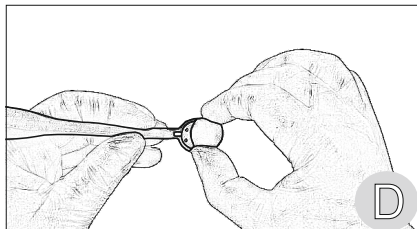
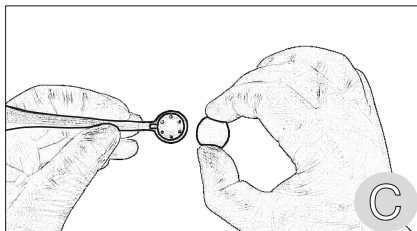
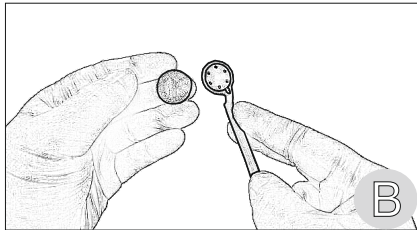
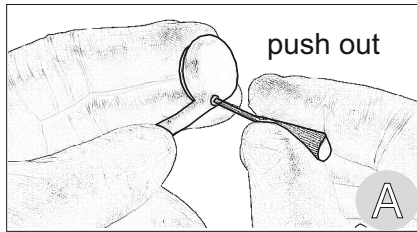



The MicroBeam UV has been tested for photobiological safety in accordance with EN 62471 and approved for the intended use.





Do not look directly at a MicroBeam UV module that is switched on. This may cause visual complaints.


5.6 Mirror replace




 Caution, pressures and forces can damage the glass. Handling and especially cleaning must be carried out with appropriate care. Avoid incrustations by soaking the instrument in a disinfectant solution after treatment.

 Do not clean in an ultrasonic!
The rhodium coating has the effect of a non-stick coating. Rhodium is acid-proof. In combination with the non-stick effect, limescale residues can be removed with a cellulose cloth dipped in commercially available descaler.


 The mirror is mounted on a metal carrier, the mirror is inserted into the BeamHub so that the reflective surface is on the outside and the metal carrier is in direct contact with the inserted magnets.


 Wear single-use gloves according to DIN EN 455 in the correct size during treatment.
- protect yourself and others from the risk of transmitting pathogens
- protection against infection
- protection of surfaces from contamination

 Steam sterilisation must be carried out before exchanging and replacing the mirror.

Procedure:

- A) Eject the defective/ damaged mirror from the rear side using the ejector tool.
- B) Dispose of the defective/ damaged mirror (see chapter 3.4)
- C) Insert the new mirror into the BeamHub. The back of the mirror is labelled and easy to identify.
- D) The mirror is in the BeamHub automatically held in position by the inbuilt magnets and hold automatically in position, which prevents the mirror from falling out.

 E) The mirror must be checked for correct fit and position in the BeamHub.

 After replacing the mirror, the BeamHub must be cleaned and sterilised before next use (see chapter 6)

6. Reprocessing

6.1 General information

Disinfection means placing the instruments in a condition where there is no risk of infection. This can be done manually, in a wet-chemical dipping process with final thermal disinfection in a steam steriliser or by machine in a thermal cleaning and disinfection process (washer-disinfector/thermal disinfector).

Proceed reconditioning only in the rooms/areas specified for this operation. Follow the hygiene-effective procedures according to country-specific regulations.

Use a neutral agent to clean the BeamHub before sterilisation.

Do not dip or soak the BeamHub in antiseptic acid.

Do not dip the BeamHub in a physiological liquid (NaCl) until cleaning and do not use saline solutions to keep it humid.



The BeamHub is approved for cleaning in a washer-disinfector/thermal disinfector. If you reprocess with a washer-disinfector, make sure that the decalcification is correctly adjusted (staining).



BeamHub is suitable for sterilisation in a steam sterilisation (autoclave). (134°C / 273.2°F). no rapid cooling after steam sterilisation (autoclave)



The BeamHub is not for cleaning with ultrasonic! (irreparable damages).



The MicroBeam has to be removed before cleaning and sterilisation.

6.2 Machined preparation and cleaning BeamHub



As a general rule, the following rules are valid for all cleaning work: Never use abrasive sponges, abrasive cleaners or scrubbing agents. Use cleaning agents with a pH value of 8 to 11 that is not corrosive and does not contain chlorine, acetone and or aldehydes.



Clean and disinfect the BeamHub with the mirror within a maximum of 30 minutes after each treatment. By following this procedure, any saliva residue will be eliminated. Additionally drying of residues (protein fixation) is prevented.



The MicroBeam module must be removed before (IP40). Hold the BeamHub by the shaft under water at a temperature of 15°C up to 38°C (59°F-100°F) and wash it off. The tap water must have a ph value between 7-11°dH / 13-19° fH and have a chlorine content of less than 100mg/l. If the tap water does not fulfill these requirements, demineralized water must be used instead.



The BeamHub, without the MicroBeam module inserted can be placed in an instrument tray until machine reprocessing in the thermo washer disinfector starts and can be temporarily stored covered with a cleaning and disinfecting solution. The application time of at least 5 minutes begins after the last medical device has been inserted.



The BeamHub with mirror cannot be cleaned in an ultrasonic bath for pre-cleaning.



The BeamHub with mirror can be alkaline-cleaned for pre-cleaning in an WD/thermo-disinfector and thermally cleaned and disinfected at 90°C (194°F). The MicroBeam module must be removed (irreparable damage). Remove instruments from the instrument tray immediately before machine reprocessing and rinse thoroughly under running drinking water. (mind. 15 Sek.). To prevent foaming in the wash chamber of the washer-disinfector, no residues of the detergent and disinfectant should be transferred. To prevent excessive coagulation proteins, the instrument should be reprocessed in the thermal disinfector no later than 6 hours after use.



Generally, gentle, aldehyde-free products with good material compatibility should be used for instrument disinfection. The following products are considered suitable and approved for the product, taking into account the dosage:

ID 212, 2%, Contact time of 5 min. as per AAH* Dürr Dental, DE-Bietigheim
ID 213, 2%, Contact time of 5 min. as per AAH* Dürr Dental, DE-Bietigheim

*Association for Applied Hygiene

6.3 Machined cleaning in the washer-disinfector

Processing should preferably be done by machine in accordance with the RKI recommendation.

Facilities:



1. Thermal Disinfector (washer), e.g. from Miele with Vario-program. It must reach an Ao value of at least 3000.
2. Neodisher® Mediclean Dental I from the Dr. Weigert company
3. Neodisher® Z from the Dr. Weigert company
4. Suitable instrument rack or sieve tray



Also follow the instructions for use at all times for the products and devices to be used. Observe standards EN ISO 15883-1 and EN ISO 15883-2



Information from EN ISO 17664-1, 6.7.2.1: If your Thermal Disinfector is compliant with the ISO 15883 standards, you may use the programs recommended by the manufacturer and do not have to follow our below validated processing procedure.



Procedure, validated:

1. Take the instruments out of the disinfection bath and rinse thoroughly under running potable water immediately before the automated processing (at least 10 seconds). No residues from the cleaning /disinfection agent should be transferred to the Disinfector.
2. Place the instruments in a suitable instrument rack or sieve tray.
3. Place the instrument rack/sieve tray in the Thermal Disinfector so that the spray jet comes into direct contact with the instruments.
4. Start the Vario program including thermal disinfection. Thermal disinfection is carried out with an Ao value of at least 3000.

5. Program:

- 1 min. pre-washing with cold water
- Emptying
- 3 min. pre-washing with cold water
- Emptying
- 10 min. washing at 55°C (131°F) with neodisher® MediClean Dental alkaline cleaning agent
- Emptying
- 3 min. neutralization with warm tap water (>40°C)(>59°F) and 0,1% neodisher® Z neutralizer, Dr. Weigert, Hamburg
- Emptying
- 2 min. intermediate flushing with warm tap water (>40°C)(>59°F)
- Emptying
- Thermal disinfection with demineralized water Water, at 92°C, (197°F) for at least 5 Min.
- Automatic drying, around 30 Min. around 60°C (>140°F)

6. Remove the instruments at the end of the program cycle and dry them with compressed air according to the RKI recommendation. With instrument racks/sieve trays, pay special attention to the drying of hard-to-reach areas.



7. Check for intactness and cleanliness with a suitable magnifying glass. An 8 x magnification is usually enough for a visual check. If there is still residual contamination after the automatic processing, cleaning and disinfection should be repeated until all visible traces of contamination have been eliminated.



Make sure the decalcification is correctly adjusted, otherwise white water spots and deposits will be left on the mirror surface. Only put completely dry instruments in the sterilizer in order to prevent limescale deposits and/or water spots.



Please observe the instructions for use of the equipment used and those of the manufacturer(s) and ensure that the maximum load of the devices is observed

Please observe the legal provisions for the processing of medicinal products applicable in your country. Observe the national regulations for disposal



All cleaning and reprocessing must also be carried out before first use. The product is not shipped sterile.



Information from EN ISO 17664-1: Biocompatibility may be impaired if rinsing agents are used.

6.4 Sterilization BeamHub



Use a steam steriliser, in accordance with EN ISO 17665 moist heat. The quality of sterilisation depends crucially on the cleanliness of the instrument. Only sterilise clean instruments. To improve the effect of sterilisation, make sure that the BeamHub is completely dry before and after sterilisation to avoid chalky deposits and/or water stains, for example.



Steam sterilisation with effective and validated process. Use standardized packaging material (EN ISO 11607-1) designed for this purpose. The packaging must be large enough so that no stress is placed on the seal. Sterile barrier systems must be checked for integrity prior to use.



Perform a dynamic air displacement cycle and then steam sterilise at 134°C (273.2°F) for 5 minutes. In countries where sterilisation of prions (proteins of cellular origin) is required, sterilise at 134°C (237.2°F) for 18 minutes. Drying time: minimum 10 minutes



The following parameters are recommended for the sterilisation cycle: The maximum temperature in the sterilisation chamber does not exceed 137°C (278.6°F), i.e. the nominal temperature of the autoclave is limited to 134°C (273.2°F), 135°C (275°F) or 135.5°C (275.9°F) taking into consideration the inaccuracy regarding the temperature in a steriliser.

The maximum interval time at the maximum temperature of 137°C (278.6°F) complies with national regulations for moist heat sterilisation and does not exceed 30 minutes.

The absolute pressure in the sterilisation chamber of the autoclave is between 0.07bar and 3.17bar (1psia to 46psia).

The temperature change is not faster than 15°C/min (59.°F/min) when increasing and 35°C/min (-31.°F/min) when decreasing the temperature.

The pressure change is not faster than 0.45bar/min (6.6psia/min) when increasing and 1.7bar/min (-25psia/min) when lowering the pressure. No chemical or physical reagents are added to the physical reagents are added to the steam.

Work exclusively with dynamic air displacement, pre-vacuum method or fractionated vacuum method.

Documented release of the medical device for use and contamination-protected storage.



The BeamHub, including the mirror, fulfils the requirements of EN ISO 9873:2019 during reconditioning without any signs of visible damage.

6.5 Cleaning and disinfection MicroBeam



MicroBeam Day



MicroBeam CureSafe



MicroBeam UV

The MicroBeam is made of plastic and easy to clean. Clean soiled parts with a soft multi-purpose cloth (e.g. ZVG cellulose) or with a cloth.



Avoid rubbing with a dirty cloth. Do not use abrasive sponges, scouring agents or abrasive cleaning agents. Do not use products or cleaning agents containing solvents (e.g. nitro thinners, synthetic resin thinners). The MicroBeam can may be irreparably damaged.

Do not dip or soak the MicroBeam module in liquids or in antiseptic acid, do not immerse the MicroBeam module in a physiological liquid (NaCl) until cleaning, and do not use saline solutions to keep it wet.



The MicroBeam module is not for cleaning with ultrasonic.



The MicroBeam module is not for use in a washer-disinfector/thermo washer-disinfector.



The MicroBeam module is not for use in steam sterilisation (autoclave).



Generally, mild surface disinfectants should be used for disinfection, without additions of alcohols or aldehydes. The following products are suitable and approved for the product:

FD 322, undiluted 1min. as per AAH*

Dürr Dental, DE-Bietigheim

FD 366, undiluted 1min. as per AAH*

Dürr Dental, DE-Bietigheim

*Association for Applied Hygiene

6.6 Cleaning and disinfection Charger Station



Disconnect the charger from the power supply by pulling the plug.



When cleaning the Charger, make sure that no liquid flows into the inside of the device, as this can produce irreparable damages.

The charger is made of metal and easy to clean. Clean contaminated parts with a soft multi-purpose cloth (e.g. ZVG cellulose) or clean with a tissue, if necessary, moisten the cloth by adding warm water and a household detergent.

Avoid rubbing with a dirty cloth. Do not use abrasive sponges, scouring agents or abrasive cleaning agents. Do not use products or cleaning agents containing solvents (e.g. nitro thinners, synthetic resin thinners). The Charger can may be irreparably damaged.



Do not dip or soak the Charger in antiseptic acid, do not immerse the Charger in a physiological liquid (NaCl) until cleaning, and do not use saline solutions to keep it wet.



The Charger is not for cleaning with ultrasonic.



The Charger is not for use in a washer-disinfector/thermo washer-disinfector.



The Charger is not for use in steam sterilisation (autoclave).



Generally, mild surface disinfectants should be used for disinfection, without additions of alcohols or aldehydes. The following products are suitable and approved for the product:

FD 322, undiluted 1min. as per AAH*

Dürr Dental, DE-Bietigheim

FD 366, undiluted 1min. as per AAH*

Dürr Dental, DE-Bietigheim

*Association for Applied Hygiene

6.7 Cleaning and disinfection USB-C charger cable and replacement tool



Disconnect the USB-C cable from the charger and the power supply by pulling the plug.



When cleaning, make sure that no liquid enters into the USB-C connector, as this can lead to irreparable damage.

Clean any dirty parts with a soft multi-purpose cloth (e.g. ZVG cellulose) or cloth, if necessary moisten the cloth with warm water and a household cleaning agent.

Do not use abrasive sponges, scouring agents or abrasive cleaning agents. Do not use any products or cleaning agents containing solvents (e.g. nitro or synthetic resin thinners, etc.).



Do not dip or soak the USB-C Charger cable in liquids.



USB-C charger cable and replacement tool are not suitable for ultrasonic cleaning.



USB-C Charger cable and Replacement tool are not designed for cleaning and reprocessing in a washer-disinfector/thermal disinfector.



USB-C Charger cable and Replacement tool are not designed for reprocessing in steam sterilisation (autoclave).



Generally, mild surface disinfectants should be used for disinfection, without additions of alcohols or aldehydes. The following products are suitable and approved for the product:

FD 322, undiluted 1min. as per AAH*

Dürr Dental, DE-Bietigheim

FD 366, undiluted 1min. as per AAH*

Dürr Dental, DE-Bietigheim

*Association for Applied Hygiene

6.8 Replacing the mirror



The glass mirror is subject to a certain amount of wear and tear. As scratched mirrors can affect the image, we recommend checking the mirror regularly and replacing it if necessary. (Refer to 5.6)







Steam sterilisation must be carried out before exchanging and replacing the mirror.

7. Packing and transport

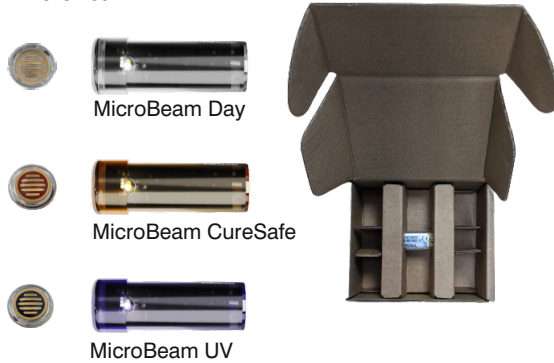
7.1 Storage, packaging and transport BeamHub




	Temperature limit	-20°C bis 55°C (-28.8°F bis 131°F)
	Relative humidity	10% bis 80%
	Air pressure limit	650hPa bis 1060hPa
	Keep away from humidity	





The BeamHub has to be stored in a dry condition in a sterilisation bag. The temperature must not exceed 55°C (131°F). If the BeamHub is not used for 7 days or more after sterilisation, remove the BeamHub from the sterilisation pouch and store it in the original packaging. If the BeamHub is not stored in a sterilisation pouch or the pouch is no longer sterile, clean, dry and sterilise the BeamHub before use.


7.2 Storage, packaging and transport MicroBeam



 If the MicroBeam is not used for a longer period (> 3 months), it can fall into a critical state due to the deep discharge. The MicroBeam loses charge cycles or can no longer be charged at all. A deep discharge can damage the MicroBeam or make it unusable.





If the MicroBeam module is not stored in the BeamHub, disinfect the MicroBeam before using.

	Temperature limit	-20°C bis 55°C (-28.8°F bis 131°F)
	Relative humidity	10% bis 80%
	Air pressure limit	650hPa bis 1060hPa
	Keep away from humidity	

 Please note that the MicroBeam module can discharge if it is not used for a long time (see Chapter 5.2).

7.3 Storage, packaging and transport Charger







	Temperature limit	-20°C bis 55°C (-28.8°F bis 131°F)
	Relative humidity	10% bis 80%
	Air pressure limit	650hPa bis 1060hPa
	Keep away from humidity	

The Charger has to be stored in a dry condition. The temperature must not exceed 55°C (131°F). If the charger is not to be used for a longer period of time, it must be stored in the original packaging. Before use, clean, dry and disinfect the charger.

7.4 Storage, packaging and transport Mirror



	Temperature limit	-20°C bis 55°C (-28.8°F bis 131°F)
	Relative humidity	10% bis 80%
	Air pressure limit	650hPa bis 1060hPa
	Keep away from humidity	

The mirror has to be stored in a dry condition. The temperature must not exceed 55°C (131°F). If the mirror is not to be used for a longer period of time, it must be stored in the original packaging. Before use, clean, dry and disinfect the mirror.

8. Troubleshooting

If a malfunction is detected, do not continue to use the product..
(See chapter 3.3)

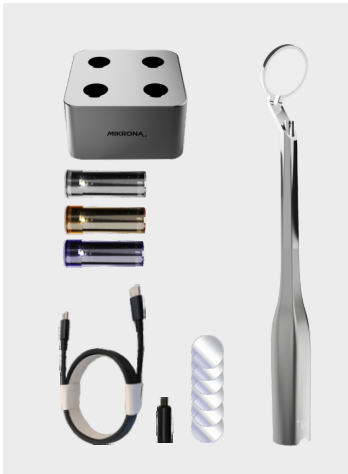
Do not use the product again until the fault has been solved.
(See chapter 2.6)

If faults cannot be localised with the help of this troubleshooting, technical customer service must be contacted.
(See chapter 2.10)

8.1 Error	Reason	Troubleshooting
MicroBeam cannot be switched on	Charge status too low	Fully charge the MicroBeam in the charger before using it for the first time
MicroBeam will not be loaded	Power supply or Charger (USB C) not plugged	Plug in power adapter or charger
MicroBeam will not be loaded	Fuse in the charger responds	Check power supply unit

8.2 LED signal codes	Reason	Troubleshooting
MicroBeam in Charger LED permanently red	Charge status 0% up to approx. 80%	Leave the MicroBeam in the charger
MicroBeam in Charger LED permanently white	Charge status approx. 80% up to 100%	Leave the MicroBeam in the charger
MicroBeam in BeamHub LED permanently red	Charge status low	Charging the MicroBeam in the charger

9. Technical data



1. Manufacturer	MIKRONA GROUP AG CH-8952 Schlieren
2. Distribution	Specialised trade
3. Product name	LX Master Mirror
4. Color	Stainless stell
5. Material BeamHub	polished, stainless steel 316
6. Dimension BeamHub	L x W x H: 172mm x 23mm x 16mm
7. Weight BeamHub with MicroBeam	net: 60gr.
8. Dimension Charger Station	L x W x H: 69mm x 69mm x 43mm
9. Weight Charger Station	net: 366gr.
10. Dimension MicroBeam	L x W x H: 47 x 16 x 16mm
11. Weight MicroBeam	net:10gr.
12. Charging time MicroBeam	approx. 60min
13. MicroBeam protection class	IP40
14. MicroBeam Capacity and performance	170mAh / 3.7V / 629mWh
15. Mirror size	Size 5 (approx. 22mm)
16. Mirror material	Rhodium
17. Mirror shape	Planmirror
18. Mirror head angle	30°
19. Charger station protection class	IP20
20. Charger station charger port	USB-C
21. MicroBeam «Day»	Colour temperature 5700°K
22. Illumination time MicroBeam «Day»	approx. 120min
23. MicroBeam «CureSafe»	Light wavelength 615 nm
24. Illumination time MicroBeam «CureSafe»	approx. 120min
25. MicroBeam «UV»	Light wavelength 385 nm
26. Illumination time MicroBeam «UV»	apporox. 120min
27. MicroBeam Energy accumulator	rechargeable Lithium-Polymer (Li-Po) Akku
28. Power devices for charger*	USB-C port

* Not included in the system and scope of delivery, all standard power devices can be used.

