Instructions for use

MASTERmatic LUX M10 L - 1.009.3570
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1 User instructions

Dear User,

congratulations on purchasing this KaVo quality product. By following the instructions below you will be able to work smoothly, economically and safely.

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Symbols

| ![Symbol] | Refer to the chapter on Safety/Warning symbol |
| ![Info] | Important information for users and service technicians |
| ![Action] | Action request |

### Sterilization parameters

| 1. Sterilizer with pre-vacuum: |
| at least 3 minutes at |
| 135 °C (275 °F) |
| Drying time: 16 min. |
| 2. Sterilizer using the gravity method: |
| at least 10 minutes at |
| 135 °C (275 °F) |
| Drying time: 30 min. |

Suitable for disinfection in a washer disinfector

Target group

This document is intended for dentists and dental assistants. The chapter on commissioning is also intended for service technicians.
2 Safety

2.1 Description of the safety instructions

<table>
<thead>
<tr>
<th>Warning symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

Structure

DANGER

The introduction describes the type and source of the hazard.
This section describes potential consequences of non-compliance.
▶ The optional step includes necessary measures for hazard prevention.

Description of hazard levels

The safety instructions listed here, together with the three hazard levels, help to avoid property damage and injury.

CAUTION

indicates a hazardous situation that can cause damage to property or mild to moderate injuries.

WARNING

indicates a hazardous situation that can lead to serious or fatal injury.

DANGER

indicates a maximal hazard due to a situation that can directly cause serious or fatal injury.

2.2 Safety instructions

WARNING

Hazard from incorrectly processed products.
Contaminated products are associated with an infection risk.
▶ Take suitable personal protective measures.

WARNING

Hazard for dentists and patients.
In the case of damage, irregular running noise, excessive vibration, un-typical warming or when the bur is not held firmly.
▶ Stop working and contact service support.
2 Safety | 2.2 Safety instructions

⚠️ CAUTION
Hazard due to incorrectly stored handpiece.
Injury and infection caused by chucked bur.
Damage to clamping system from dropping the dental instrument.
  ▶ After treatment, place the handpiece properly in the cradle, without the bur.

⚠️ CAUTION
Hazard from use as a light probe.
Do not use the medical device as a light probe since the rotating bur can cause injury.
  ▶ Use an appropriate light probe for additional illumination of the oral cavity or site of preparation.

⚠️ CAUTION
Risks due to lack of control equipment.
Property damage and injury can occur if no control equipment for changing the speed range and the direction of rotation is available.
  ▶ The connected dental treatment center must be equipped with control equipment for changing the speed range and direction of rotation.

⚠️ CAUTION
Premature wear and malfunctioning from improper storage during long periods of non-use.
Reduced product life.
  ▶ The medical device should be cleaned, serviced and stored in a dry location, in accordance with the instructions, before long periods of non-use.

Note
For safety reasons, we recommend checking the tool holder system annually after the warranty period expires.

The following individuals are authorized to repair and service KaVo products:
  • technicians at KaVo branches throughout the world
  • technicians specifically trained by KaVo on the respective product

To ensure proper function, the medical device must be set up in accordance with the processing methods described in the KaVo Instructions for Use, and the care products and care systems described therein must be used. KaVo recommends specifying a service interval at the dental office for a licensed shop to clean, service and check the proper function of the medical device. This service interval depends on the frequency of use and should be adjusted accordingly.

Service may only be performed by KaVo-trained repair shops using original KaVo replacement parts.
3 Description of the product

The MASTERmatic LUX electrical-driven handpieces are dental handpieces in accordance with 21 CFR § 872.4200 (dental handpieces and accessories) for the use by a trained professional in the field of general dentistry.

The devices are electrical-powered handpieces that are reusable and ergonomically shaped, and provided with a fiber optic light system. The devices can be sterilized by the steam autoclave method. MASTERmatic LUX handpieces equipped with a handpiece connector in accordance with ISO 3964 are connected to a dental unit by means of a tube and the electrical motor and receive the energy for the gear, cooling water and air for conservative dental treatment as well as the light for illumination of the operation area through corresponding output openings. Dental burs in accordance with ISO 1797-1 could be used with the MASTERmatic LUX handpieces. Based on the INTRAmatic connection in accordance with ISO 3964 the MASTERmatic LUX handpieces fits to every electrical dental motor which is in accordance to this standard. MASTERmatic LUX handpieces interact with the patient through a rotating bur with the patient teeth in accordance with the intended use.

3.1 Intended use

Indications for use:

The MASTERmatic LUX handpieces are intended for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, root canal preparations, removal of fillings, processing and finishing tooth preparations, restorations, and for polishing teeth. They are designed for use by a trained professional in the field of general dentistry.

CAUTION

US Federal law restricts this device to sale by or on the order of a healthcare professional / dentist.
For dental use only.
Proper Use:

In accordance with these regulations, this medical device may only be used by a properly trained user and for the application described herein. You need to comply with the following:

- the applicable health and safety regulations
- the applicable accident prevention regulations
- these Instructions for use

In accordance with these regulations, the user is required to:

- only use equipment that is operating properly
- adhere to the specified intended use
- protect himself or herself, the patient and third parties from danger, and
- avoid contamination from the product

3.2 Technical Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drive speed</td>
<td>max. 40,000 rpm</td>
</tr>
<tr>
<td>Transmission ratio</td>
<td>1:1</td>
</tr>
<tr>
<td>Maximum speed</td>
<td>max. 40,000 rpm</td>
</tr>
<tr>
<td>Labeling</td>
<td>1 blue ring</td>
</tr>
<tr>
<td>Spray water pressure</td>
<td>0.8 to 2.0 bar (12 to 29 psi)</td>
</tr>
<tr>
<td>Spray air pressure</td>
<td>1.0 to 2.0 bar (15 to 29 psi)</td>
</tr>
<tr>
<td>Amount of spray air</td>
<td>min. 1.5 Nl/min (at 2 bar)</td>
</tr>
<tr>
<td>Cooling air flow</td>
<td>5.5 to 9.5 Nl/min</td>
</tr>
</tbody>
</table>

Handpiece burs can be inserted.
Short handpiece burs can be inserted after modification.
The handpiece can be mounted on all INTRAmatic (LUX) motors, and motors with a connection in accordance with ISO 3964 / DIN 13940.

3.3 Transportation and storage conditions

⚠️ CAUTION

It is hazardous to start-up the medical device after it has been stored refrigerated. This can cause the medical device to malfunction.

- Prior to start-up, very cold products must be allowed to warm up to a temperature of 20 °C to 25 °C (68 °F to 77 °F).

<table>
<thead>
<tr>
<th>Condition</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>-20 °C to +70 °C (-4 °F to +158 °F)</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>5% RH to 95% RH absence of condensation</td>
</tr>
<tr>
<td>Air pressure</td>
<td>700 hPa to 1060 hPa (10 psi to 15 psi)</td>
</tr>
<tr>
<td>Protect from moisture</td>
<td>(Keep dry)</td>
</tr>
</tbody>
</table>
4 Startup and shut-down

**WARNING**

Hazard from non-sterile products. Infection hazard for dentist and patient.
- Before first use and after each use, process and sterilize the medical device and accessories accordingly.

**WARNING**

Dispose of the product in the appropriate manner. Infection hazard.
- Before disposal, process and sterilize the product and accessories appropriately.

4.1 Checking the water quantity

**WARNING**

Overheating of the tooth due to insufficient amount of cooling water. Thermal damage to the dental pulp.
- Set the water amount for the spray cooling to a minimum of 50 ml/min!

**WARNING**

Hazard from insufficient amount of spray water. Insufficient spray water can cause the medical device to overheat and damage the tooth.
- Check the spray water channels and clean the spray nozzles with the nozzle needle Mat. no. 0.410.0921, if needed.
5 Operation

5.1 Attaching the medical device

⚠️ WARNING
Detachment of the medical device during treatment.
A medical device that is not properly locked in place can become disconnected from the motor coupling and fall off.
▶ Carefully pull on the medical device before each treatment to make sure that it is securely locked onto the motor coupling.

⚠️ CAUTION
Connection to the drive motor.
Handpiece jams.
▶ Operate the handpiece only with the chuck being closed.

⚠️ CAUTION
Removing and attaching the handpiece while the drive motor is rotating.
Damage to the driver.
▶ Never attach or remove the handpiece while the drive motor is rotating!
▶ Lightly spray O-rings on motor coupling with KaVo Spray.
▶ Attach the medical device to the motor coupling and turn it until the latch audibly snaps into place.
▶ Pull on the medical device to make sure that it is securely affixed to the coupling.

5.2 Removing the medical device

▶ Unlock the handpiece from the motor coupling by twisting it slightly and then pulling it along its axis.

5.3 Inserting a straight or contra-angle bur

Note
Only use handpiece burs or contra-angle handpiece burs that are in conformance with ISO 1797-1, type 1 and type 2, are made of steel or hard metal and meet the following criteria:
- Shaft diameter: 2.334 to 2.350 mm
- Shaft clamping length:
  - min. 12 mm
  - max. 22 mm
- without a drill bit stop:
  - Shaft clamping length:
    - min. 30 mm
    - max. 44.5 mm
5.4 Removing a straight or contra-angle bur

**WARNING**

Use of unauthorized burs.
Injury to the patient or damage to the medical device.
- Comply with the instructions for use and the intended use of the bur.
- Only use burs that do not deviate from the specified data.

**CAUTION**

Injury from using worn burs.
Burs could fall out during treatment and injure the patient.
- Never use burs with worn shafts.

**CAUTION**

Danger of injury from bur.
Infections or cuts.
- Wear gloves or finger guards.

**CAUTION**

Hazard from defective chucking system.
The bur could fall out and cause injury.
- Pull on the bur to make sure that the chucking system works properly and that the bur is held securely. Wear gloves or finger guards when you check, insert or remove the insert to prevent injury and infection.
- Rotate the clamping ring sleeve in the direction of the arrow to the stop and insert the handpiece bur or diamond in the chuck.
- Turn the clamping ring back into its initial position.
- Check to make sure that the bur is securely attached by pulling on it.

**WARNING**

Hazard from rotating bur.
Lacerations and damage to the chuck system.
- Do not touch the bur while it is rotating!
- Remove the bur from the handpiece after treatment to avoid injury and infection when putting it away.
- After the bur has come to a standstill, turn the clamping ring in the direction of the arrow to the stop and remove the bur.
- Turn the clamping ring back into its initial position.

**5.5 Modification for contra-angle burs**

**WARNING**

Hazard from non-sterile products.
Infection hazard for dentist and patient.
- Process and sterilize the medical device properly before the next use.

**Note**

Using contra-angle burs, the handpiece must be converted.
- Open the handpiece chuck.
5 Operation | 5.5 Modification for contra-angle burs

- Insert the enclosed bur stop in the chuck.
- Press the contra-angle bur onto the bur stop, close the clamping ring and make sure that it is firmly seated.
- Use the enclosed hook to remove the bur stop.
6 Checking for malfunctions and troubleshooting

6.1 Check for malfunctions

⚠️ CAUTION

Missing or damaged O-rings.
Malfunctions and premature failure.
▶ Make sure that all O-rings are present on the coupling and are undamaged.

⚠️ WARNING

Product heats up.
Burn injury or product damage due to over-heating.
▶ Do not continue working if the product heats up irregularly.

▶ The medical device overheats while idling:
  Check the amount of cooling air.
▶ The medical device overheats while working:
  Service the medical device.
▶ When the speed drops or is uneven:
  Service the medical device.
▶ Missing O-ring on the motor coupling:
  Replace O-ring.

6.2 Troubleshooting

6.2.1 Replacing the O-rings

⚠️ CAUTION

Hazard due to improper servicing of the O-rings.
Malfunctions or complete failure of the medical device.
▶ Do not use Vaseline or other grease or oil.

Note

The O-rings on the coupling may only be lubricated with a cotton ball wetted with KaVo Spray.

▶ Press the O-ring between your fingers to form a loop.
▶ Push the O-ring to the front, and remove it.
▶ Insert new O-rings into the grooves.

6.2.2 Cleaning the spray nozzle

⚠️ WARNING

Hazard from non-sterile products.
Infection hazard for dentist and patient.
▶ Process and sterilize the medical device properly before the next use.
6.2 Troubleshooting

**WARNING**

Hazard from insufficient amount of spray water.
Overheating of the medical device and damage to the tooth.

- Check the spray water channels and clean the spray nozzles with the nozzle needle Mat. no. 0.410.0921, if needed.
- Check the water filter and exchange, if needed.

- Use the nozzle needle (Mat. no. 0.410.0921) to free the water passage in the spray nozzles.
7 Processing steps in accordance with ISO 17664

7.1 Preparations at the site of use

**WARNING**

Hazard from non-sterile products.
There is a risk of infection from contaminated medical devices.

- Take suitable personal protective measures.
- Remove all residual cement, composite or blood immediately.
- Process the medical device as soon as possible after treatment.
- Remove the bur from the medical device.
- The medical device must be dry when transported to processing.
- Do not immerse in solutions or the like.

7.2 Cleaning

**CAUTION**

Malfunctions from cleaning in the ultrasonic unit.
Defects on the product.

- Only clean manually or in a washer disinfector!

7.2.1 Manual external cleaning

Accessories required:

- Tap water 30 °C ± 5 °C (86 °F ± 10 °F)
- Brush, e.g. medium-hard toothbrush

- Brush under flowing tap water.

7.2.2 Automated external cleaning

KaVo recommends washer disinfectors in compliance with ISO 15883-1, which are operated using alkaline cleaning agents.

- For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the washer disinfector.
- In order to prevent negative effects on the KaVo medical device, make sure that the interior and the exterior of the medical device are dry after completion of the cycle, and then lubricate it immediately with care products from the KaVo care system.

7.2.3 Manual internal cleaning

Not applicable.
This product is suitable for automated cleaning only.
7.2.4 Automated internal cleaning

KaVo recommends washer disinfectors in compliance with ISO 15883-1, which are operated using alkaline cleaning agents.

▶ For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the washer disinfecter.

▶ In order to prevent negative effects on the KaVo medical device, make sure that the interior and the exterior of the medical device are dry after completion of the cycle, and then lubricate it immediately with care products from the KaVo care system.

7.3 Disinfection

**WARNING**
Incomplete disinfection.
Infection hazard
▶ Principally, KaVo recommends carrying out a final disinfection of the unpackaged item in the sterilizer unit if complete disinfection cannot be guaranteed without this measure.

**CAUTION**
Malfunctioning from using a disinfectant bath or chlorine-containing disinfectant.
Defects on the product.
▶ Only disinfect in a washer disinfecter or unpacked in the autoclave or manually!

CAUTION
Malfunctioning from using a disinfectant bath or chlorine-containing disinfectant.
Defects on the product.
▶ Do not use an ultrasonic bath.

CAUTION
Never use alkaline or chlorine-containing disinfectants.
Saline solution corrodes metal parts.
▶ Immediately remove all residue.

7.3.1 Manual external disinfection

KaVo recommends the following products based on material compatibility. The microbiological efficacy must be ensured by the disinfectant manufacturer and proven by an expert opinion.

▪ CaviCide made by Metrex

Consumables required:
▪ Cloths for wiping the medical device.

▶ Spray the disinfectant on a cloth, then wipe down the medical device and allow the disinfectant to act in accordance with the instructions of the disinfectant manufacturer.

▶ Comply with the instructions for use of the disinfectant.
7.3.2 Manual internal disinfection

Not applicable.
This product is suitable for automated disinfection only.

7.3.3 Automated external and internal disinfection

KaVo recommends washer disinfectors in compliance with ISO 15883-1, which are operated using alkaline cleaning agents.

- For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the washer disinfector.
- In order to prevent negative effects on the KaVo medical device, make sure that the interior and the exterior of the medical device are dry after completion of the cycle, and then lubricate it immediately with care products from the KaVo care system.

7.4 Drying

Manual drying

- Clean the outside and inside with compressed air until no drops of water are visible.

Automated drying

The drying procedure is usually part of the cleaning program of the washer disinfector.

- Please comply with the instructions for use of the washer disinfector.

7.5 Care products and systems - Servicing

**WARNING**

Sharp bur in the medical device.
Risk of injury from sharp and/or pointed bur.

- Remove bur.

**CAUTION**

Premature wear and malfunctions from improper servicing and care.
Reduced product life.

- Service regularly with suitable agents!

**Note**

KaVo only guarantees that its products will function properly if the care products listed as accessories are used, since these products have been tested for proper use on our products.

7.5.1 Servicing with KaVo Spray

KaVo recommends servicing the product as part of the processing after each use, i.e. after each cleaning, disinfection, and before each sterilization.
7 Processing steps in accordance with ISO 17664 | 7.5 Care products and systems - Servicing

- Remove the bur.
- Cover the product with the Cleanpac bag.
- Plug the product onto the cannula, and press the spray button for one second.

Servicing the chuck

KaVo recommends cleaning and servicing the chuck system once a week.

- Remove the bur, place the spray nozzle in the opening and spray.
- Carry out the servicing in accordance with the instructions in the section, "Servicing with KaVo Spray".

7.5.2 Servicing with KaVo QUATTROcare 2104 / 2104A

Note

QUATTROcare 2104 / 2104 A is no longer included in the current delivery program.
Follow-up product:
- QUATTROcare PLUS 2124 A

Servicing and cleaning device with expansion pressure for internal cleaning of inorganic residues and optimum servicing.

KaVo recommends servicing the product as part of the processing after each use, i.e. after each cleaning, disinfection, and before each sterilization.

- Remove the bur.
- Service the product.

See also:
- Instructions for use KaVo QUATTROcare 2104 / 2104A / 2124A

Servicing the chuck

KaVo recommends cleaning and servicing the chuck system once a week.

See also:
- Instructions for use KaVo QUATTROcare 2104 / 2104A / 2124A
- Remove the bur, place the spray nozzle in the opening and spray.
- Subsequently treat with the specified care products and systems.

See also:
- Servicing with KaVo QUATTROcare 2104 / 2104A
7.5.3 Servicing with KaVo QUATTROcare PLUS 2124 A

Servicing and cleaning device with expansion pressure for internal cleaning of inorganic residues and optimum servicing.

- Remove the bur.
- Service the product in the QUATTROcare PLUS.

See also:
- Instructions for use KaVo QUATTROcare PLUS

Servicing the chuck

KaVo recommends cleaning and servicing the chuck system once a week using the chuck servicing program integrated in the device.

See also:
- Instructions for use KaVo QUATTROcare PLUS

Note
Handpieces must be taken off the service couplings before the chuck service can be started and run.

- Remove the service coupling for the chuck from the side hatch of the QUATTROcare PLUS and attach it to coupling service station four, on the far right. A MULTI-flex adaptor must be mounted there.
- Press the handpiece together with the guide bush of the chuck to be serviced against the tip of the service coupling.
- Press the button marked with the chuck service symbol.

Note
Close the chuck service mode.
Option 1: Place the dental handpieces in the QUATTROcare PLUS 2124 A, close the front door and start the service procedure.
Option 2: After three minutes with no service procedure running, the device automatically switches back to normal service mode.

See also:
- Servicing with KaVo QUATTROcare PLUS

7.6 Packaging

Note
The sterilization bag must be large enough for the handpiece to fit without stretching the bag.
The quality and use of the sterilization packaging must comply with applicable standards and be suitable for the sterilization procedure!
- Seal each medical device individually in a sterilization item package.
7.7 Sterilization

Sterilization in a steam sterilizer (autoclave) in accordance with ISO 17665-1

⚠️ CAUTION
Premature wear and malfunctions from improper servicing and care.
Reduced product life.
▶ Before each sterilization cycle, service the medical device with KaVo care products.

⚠️ CAUTION
Contact corrosion due to moisture.
Damage to the product.
▶ Remove the product from the steam sterilizer immediately after the sterilization cycle!

The KaVo medical device has a maximum temperature resistance of up to 138 °C (280.4 °F).

Select a suitable procedure (depending on the available autoclave) from the following sterilization processes:
- Sterilizer with pre-vacuum:
  - at least 3 minutes at 135°C (275 °F)
  - Drying time: 16 min.
- Sterilizer using the gravity method:
  - at least 10 minutes at 135°C (275 °F)
  - Drying time: 30 min.
▶ Use in accordance with the manufacturer's Instructions for Use.

7.8 Storage

Processed products must be stored, protected from bacteria, to the extent possible, and dust, in a dry, dark, cool room.

Note
Comply with the expiration date of the sterilized items.
8 Tools and consumables

Available from dental suppliers.

<table>
<thead>
<tr>
<th>Material summary</th>
<th>Mat. No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instrument stand 2151</td>
<td>0.411.9501</td>
</tr>
<tr>
<td>Cleanpac 10 units</td>
<td>0.411.9691</td>
</tr>
<tr>
<td>Cellulose pad 100 units</td>
<td>0.411.9862</td>
</tr>
<tr>
<td>Nozzle needle</td>
<td>0.410.0921</td>
</tr>
<tr>
<td>Spray hose, sterilizable</td>
<td>0.065.5188</td>
</tr>
<tr>
<td>Bur stop</td>
<td>0.524.0892</td>
</tr>
<tr>
<td>Hook</td>
<td>0.410.1963</td>
</tr>
<tr>
<td>Spray head INTRA (KaVo Spray)</td>
<td>0.411.9911</td>
</tr>
</tbody>
</table>

USA only

<table>
<thead>
<tr>
<th>Material summary</th>
<th>Mat. No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>KaVo Spray USA and Canada 2113 A</td>
<td>0.411.9660</td>
</tr>
<tr>
<td>QUATTROcare plus Spray USA and Canada 2141 P</td>
<td>1.005.4524</td>
</tr>
</tbody>
</table>
9 Terms and conditions of warranty

The following Terms and conditions of warranty apply to this KaVo medical device:

KaVo provides the end customer with a warranty of proper function and guarantees zero defects in respect of material and processing for a period of 24 months from the date of the invoice, subject to the following conditions:

In case of justified complaints, KaVo will honor its warranty with a free repair or replacement, as needed. Other claims of any nature whatsoever, in particular with respect to compensation, are excluded. In the event of default, gross negligence or intent, this shall only apply in the absence of mandatory legal regulations to the contrary.

KaVo shall not be liable for defects and their consequences that have arisen or may arise from natural wear, improper handling, cleaning or maintenance, non-compliance with operating, maintenance or connection instructions, calcination or corrosion, contaminated air or water supplies or chemical or electrical factors deemed abnormal or impermissible in accordance with KaVo’s instructions for use or other manufacturer’s instructions. The warranty granted does not usually extend to lamps, optical fibers made of glass and glass fibers, glassware, rubber parts, and the colorfastness of plastic parts.

All liability shall be excluded if defects or their consequences originate from manipulations or changes to the product made by the customer or a third party that is not authorized by KaVo.

Warranty claims shall be accepted only if the product is submitted along with proof of purchase in the form of a copy of the invoice or note of delivery. The dealer, purchase date, unit number or type and serial number must be clearly evident from this document.