Instructions for use

MASTERmatic LUX M10 L - 1.009.3570

KaVo. Dental Excellence.

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CE 0124

Table of contents

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.

Symbols

	Refer to the chapter on Safety/Warning symbol
	Important information for users and service technicians

	Can be steam-sterilised at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
	Thermodisinfectable
	CE-Zeichen (Communauté Européenne). Ein Produkt mit diesem Zeichen entspricht den Anforderungen der anwendbaren EG-Richtlinie.
	Action request

Target group

This document is intended for dentists and their assistants. The section on starting up is also intended for service technicians.

2 Safety

2.1 Description of safety instructions

	Warning symbol

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 levels of danger will help avert property damage and injury.

⚠ CAUTION

CAUTION

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

⚠ WARNING

WARNING

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

⚠ DANGER

DANGER

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

2.2 Safety instructions

⚠ WARNING

Hazard from incorrectly reconditioned products.

An infection hazard exists from contaminated products.

- ▸ Take suitable personal protective measures.

⚠ WARNING

Hazards for the care provider and the patient.

In the case of damage, irregular running noise, excessive vibration, untypical warming or when the cutter or grinder cannot be held.

- Do not use further and notify Service.

⚠ CAUTION

Risk due to incorrectly stored instrument.

Injury and infection caused by chucked cutters or grinders.

Damage to clamping system from dropping the instrument.

- After treatment, place the instrument properly in the cradle, without the cutter or grinder.

⚠ CAUTION

Hazard from use as a light probe.

Do not use the device as a light probe since the rotating cutters or grinders 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.

Hazards can arise if control equipment is not available for changing the speed and the direction of rotation.

- The dental treatment unit connected must have control equipment for changing the speed and direction of rotation.
- A note is to be included in the documents accompanying the dental treatment unit, referring to responsibilities arising from safety, reliability and performance.
- The medical device may only be combined with a treatment centre released by KaVo.

⚠ CAUTION

Premature wear and malfunctioning from improper storage during long periods of nonuse.

Reduced product life.

- The medical device should be cleaned, serviced and stored in a dry location, according to instructions, before long periods of nonuse.

Note

For safety reasons, we recommend that the tool holder system be checked annually after the warranty period expires.

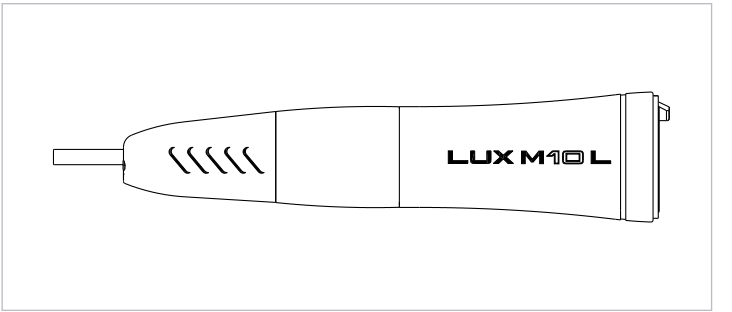
The following individuals are authorized to repair and service KaVo products:

- Technicians at KaVo branches throughout the world
- Technicians specially trained by KaVo

To ensure proper function, the medical device must be set up according to the reprocessing 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 functioning of the medical device. This service interval depends on the frequency of use and should be adjusted accordingly.

Service may only be carried out by KaVo-trained repair shops using original KaVo replacement parts.

3 Product description



MASTERmatic LUX M10 L (**Mat. no. 1.009.3570**)

3.1 Purpose – Intended use

Indications for use:

This medical device is

- intended for dental treatment only. All other types of use or modifications of the product are not permitted and can be hazardous. The medical device is intended for the following applications: Removal of carious material, cavity and crown preparations, removal of fillings, processing of tooth and restoration surfaces.
- A medical device according to relevant national statutory regulations.

Proper use:

According to these regulations, this medical device may only be used for the described application by a knowledgeable user. You need to comply with the following:

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

According to these regulations, the user is required to:

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

3.2 Technical Specifications

Drive speed	max. 40,000 rpm^{-1}
Transmission ratio	1:1
Maximum speed:	max. 40,000 rpm^{-1}
Identification	1 blue ring
Spray water pressure	0.8 to 2.0 bar (12 to 29 psi)
Spray air pressure	1.0 to 2.0 bar (15 to 29 psi)
Spray air quantity	min. 1.5 Nl/min (at 2 bar)
Cooling air flow	5.5 to 9.5 Nl/min

Handpiece cutters or grinders can be used.

Handpiece cutters or grinders can be used.

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 strongly refrigerated.

This can cause the medical device to malfunction.

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

	Temperature: -20°C to +70°C (-4°F to +158°F)

	Relative humidity: 5% RH to 95% RH absence of condensation
	Air pressure: 700 hPa to 1060 hPa (10 psi to 15 psi)
	Protect from moisture

4 Start up and shut down

⚠ WARNING

Hazard from non-sterile products.

Infection hazard for care provider and patient.

- Before first use and after each use, prepare and sterilise the medical device and accessories accordingly.

⚠ WARNING

Disposal of the product in the appropriate manner.

Prior to disposal, the product and accessories must be appropriately prepared or sterilised if this is necessary.

4.1 Check the amount of water

⚠ CAUTION

Overheating of the tooth due to insufficient amount of cooling water.

Thermal damage to the dental pulp.

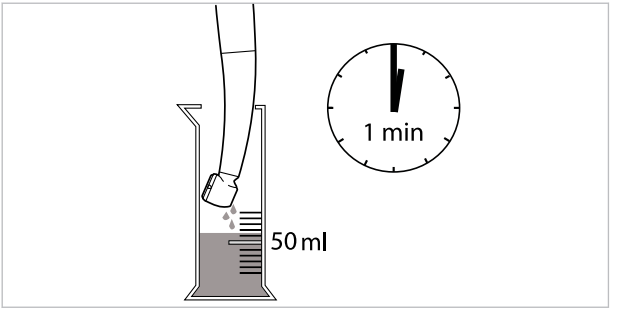
- Adjust the water amount for the spray cooling to a minimum of 50 ml/min!

⚠ CAUTION

Hazard from insufficient 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 necessary.


1 min
50 ml

5 Operation

5.1 Attach the medical device

⚠ WARNING

Release of the medical device during treatment.

A medical device that is not properly locked in place can release from the motor coupling and fall off.

- Carefully pull on it before each treatment to ensure that the medical device is securely locked on the motor coupling.

⚠ CAUTION

Connect to the drive motor.

Handpiece blocked.

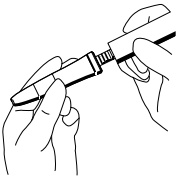
- Only start the handpiece when the chuck is closed.

⚠ CAUTION

Removing and attaching the handpiece while the drive motor is rotating.

Damage to the catch.

- Never attach or remove the handpiece while the device is rotating!



- Lightly spray O-rings on motor coupling with KaVo Spray.
- Attach medical device to the motor coupling and turn it until you hear the latch snap into place.
- Pull on the medical device to make sure that it is securely affixed to the coupling.

5.2 Remove the medical device

- Unlock the medical device from the motor coupling by twisting it slightly and then pulling it along its axis.

5.3 Insert the handpiece or contra-angle handpiece drill bit.

Note

Only use handpiece or contra-angle handpiece drills that correspond to 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

with a drill bit stop:

- Shaft clamping length: at least 12 mm
- Overall length: max. 22 mm

without a drill bit stop:

- Shaft clamping length: at least 30 mm
- Overall length: max. 44.5 mm

⚠ WARNING

Use of unauthorised cutters or grinders.

Injury to the patient or damage to the medical device.

- Observe the instructions for use and use the cutter or grinder properly.
- Only use cutters or grinders that do not deviate from the specified data.

⚠ CAUTION

Injury from using worn drill bits or burs.

Drill bits or burs could fall out during treatment and injure the patient.

- Never use drill bits or burs with worn shafts.

⚠ CAUTION

Injury hazard from cutters or grinders.

Infections or cuts.

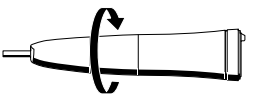
- Wear gloves or fingerstalls.

⚠ CAUTION

Hazard from defective chucking system.

The cutter or grinder could fall out and cause injury.

- Pull on the cutter or grinder to check that the chucking system is okay and the cutter or grinder is securely held. When checking, inserting and removing, use gloves or a fingerstall to prevent an injury or infection.



- Rotate the clamping ring all the way in the direction of the arrow, and insert the handpiece cutter or grinder into the chuck.

- Turn the clamping ring back into its initial position.

- Check that the cutter or grinder is seated by pulling on it.

5.4 Remove the handpiece or contra-angle handpiece drill bit

⚠ WARNING

Hazard from rotating cutter or grinder.

Lacerations and damage to the chucking system.

- Do not touch the cutter or grinder when it is rotating!
- Remove the cutter/grinder from the contra-angle handpiece after treatment to avoid injury and infection when putting it away.

- After the cutter or grinder has stopped rotating, turn the clamping ring in the direction of the arrow to the stop.

- Turn the clamping ring back into its initial position.

5.5 Conversion for contra-angle handpiece drill bit

Note

The handpiece must be converted to use contra-angle handpiece drill bits.

- Open the handpiece chuck.
- Insert the enclosed drill stop in the chuck.
- Press the contra-angle drill bit onto the stop, close the clamping ring, and check for firm seating.

- To remove the drill bit stop, use the accompanying hook.

6 Troubleshooting

6.1 Check for malfunctions

⚠ CAUTION

Missing or damaged O-rings.

Malfunctions and premature failure.

- Make sure that all O-rings are on the coupling and undamaged.

⚠ CAUTION

Heating of the product.

Burns or product damage from overheating.

- Do not use the product if it is irregularly heated.

- The medical device is too hot while idling:

  Check the amount of cooling air.

- The medical device is too hot while working:

  Caring for the medical device.

- When the speed drops or is uneven:

  Caring for the medical device.

- An O-ring is missing on the motor coupling:

  Replace O-ring.

6.2 Troubleshooting

6.2.1 Replacing the O-rings

⚠ CAUTION

Hazard from improper care of the O-rings.

Malfunctions or complete failure of the medical device.

- ▸ Do not use Vaseline or other grease or oil.

Note

The O-ring on the coupling may only be lubricated with a cotton ball wet with KAVO spray.

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

6.2.2 Cleaning the spray nozzle

⚠ CAUTION

Hazard from insufficient 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 necessary.
- Check the water filter and exchange if necessary.

- Use the nozzle needle (**Mat. no. 0.410.0921**) to free the water passage in the spray nozzles.

7 Reprocessing steps in accordance with ISO 17664

7.1 Preparations at the site of use

⚠ WARNING

Hazard from nonsterile products.

There is a risk of infection from contaminated medical devices.

- ▸ Take suitable personal protective measures.

- ▸ Remove all residual cement, composite or blood immediately.
- ▸ Reprocess the medical device as soon as possible after treatment.
- ▸ Remove the cutter or grinder from the medical device.

- The medical device must be dry when transported for reprocessing.
- Do not place it in solutions or the like.

7.2 Cleaning

⚠ CAUTION

Malfunctions from cleaning in the ultrasonic unit.

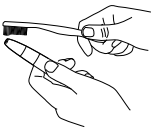
Defects in the device.

- Only clean manually or in a thermodisinfector!

7.2.1 Manual cleaning - external

Accessories required:

- Tap water 30 °C ± 5 °C (86 °F ± 10 °F)



- Brush, e.g. medium-hard toothbrush

▸ Brush off under flowing tap water.

7.2.2 Automated external cleaning

KaVo recommends washer disinfectors in compliance with EN 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 thermodisinfector.

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

7.2.3 Manual cleaning - internal

Validated interior cleaning (residual protein removal) can only be accomplished with KaVo CLEANspray and KaVo DRYspray.

- Cover the medical device with the KaVo CLEANpac bag, and place it on the corresponding care adapter. Press the spray button three times for 2 seconds each time. Remove the medical device from the spray attachment and let the cleaner work for one minute.

- Afterwards, rinse for 3-5 seconds with KaVo DRYspray.

See also:

KaVo CLEANspray / KaVo DRYspray Instructions for Use

Note

KaVo CLEANspray and KaVo DRYspray for manual interior cleaning are only available in the following countries:

Germany, Austria, Switzerland, Italy, Spain, Portugal, France, Luxembourg, Belgium, Netherlands, United Kingdom, Denmark, Sweden, Finland and Norway.

In other countries interior cleaning can only be carried out with thermodisinfectors in accordance with EN ISO 15883-1.

7.2.4 Automated internal cleaning

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

- For programme 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 medical device, make sure that the interior and the exterior of the medical device are dry after completion of the cycle, and then grease it immediately with servicing agents from the KaVo care system.

7.3 Disinfection

⚠ WARNING

Hazard due to incomplete disinfection.

Principally, KaVo recommends carrying out an final disinfection of the unpackaged item if complete disinfection cannot be guaranteed without this measure.

⚠ CAUTION

Malfunctioning from using a disinfectant bath or chlorine-containing disinfectant.

Defects in the device.

- Only disinfect in a washer disinfector or, in unpacked condition, in the autoclave or manually!

⚠ CAUTION

Malfunctioning from using the disinfectant bath or chlorine-containing disinfectants.

Defects in the device.

- Do not use an ultrasonic bath.

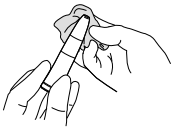
⚠ CAUTION

Never use alkaline or chlorine-containing disinfectants.

The saline solution corrodes the metal parts.

- Immediately remove all residue.

7.3.1 Manual disinfection - external



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

- Mikrozid AF made by Schülke & Mayr (liquid or cloths)
- FD 322 made by Dürr
- CaviCide made by Metrex

Consumables required:

- Cloths for wiping off the medical device.

- Spray the disinfectant on a cloth, then wipe down the medical device and allow the disinfectant to act according to the instructions of the disinfectant manufacturer.

- Follow the instructions for use of the disinfectant.

7.3.2 Manual disinfection - internal

The efficacy of manual internal disinfection must be demonstrated by the manufacturer of the disinfection agent. With KaVo products, use only disinfection agents that have been released by KaVo, with respect to the compatibility of materials

(e.g. WL-cid / made by ALPRO).

- Blow off with compressed air until no water drops are visible.

- Immediately after internal disinfection, lubricate the KaVo medical device immediately with care agents from the KaVo care system.

7.3.3 Machine disinfection - external and internal

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

- For programme 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 medical device, make sure that the interior and the exterior of the medical device are dry after completion of the cycle, and then grease it immediately with servicing agents from the KaVo care system.

7.4 Drying

Manual Drying

- Blow off the outside and inside with compressed air until water drops are no longer visible.

Automatic Drying

The drying procedure is usually a part of the cleaning program of the thermodisinfector.

- Follow the instructions for use of the thermodisinfector.

7.5 Care products and systems - Servicing

⚠ WARNING

Sharp cutters or grinders in the medical device.

Risk of injury from sharp and/or pointed cutters or grinders.

- ▸ Remove cutter or grinder.

⚠ CAUTION

Premature wear and malfunctions from improper servicing and care.

Reduced product life.

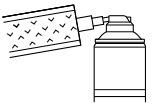
- ▸ Perform proper care regularly!

Note

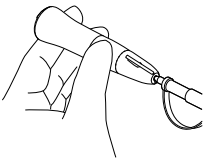
KaVo only guarantees that its products will function properly when the care products are used that are listed as accessories since they were tested for proper use on our products.

7.5.1 Care with KaVo Spray

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



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

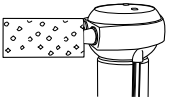


Servicing of the clamping chuck

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

- Remove the cutter or grinder, place the spray nipple tip in the opening and spray.

- Carry out the servicing according to the instructions in the section, "Care with KaVo Spray".



7.5.2 Care with the KaVo SPRAYrotor

- Place the product on the appropriate coupling on the KaVo SPRAYrotor and cover it with the Cleanpac bag.

- Servicing the product.

See also:

Instructions for use KaVo SPRAYrotor

7.5.3 Servicing with KaVo QUATTROcare 2104 / 2104A

Note

QUATTROcare 2104 / 2104 A is no longer included in the current delivery programme.

Follow-up products:

- QUATTROcare PLUS 2124 A
- QUATTROcare CLEAN 2140 A

Servicing and cleaning device with expansion pressure for the interior cleaning of inorganic residues and optimum care.

(no validated cleaning of the interior in accordance with German RKI requirements)

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

- ▸ Remove the cutter or grinder.
- ▸ Servicing the product.

See also:

Instructions for use KaVo QUATTROcare 2104 / 2104A

Servicing of the clamping chuck

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

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

- Remove the cutter or grinder, place the spray nipple tip in the opening and spray.

- Subsequently treat with the specified care products and systems.

See also:
- Servicing with KaVo QUATTROcare 2104 / 2104A

7.5.4 Servicing with KaVo QUATTROcare PLUS 2124 A

Servicing and cleaning device with expansion pressure for the interior cleaning of inorganic residues and optimum care.

(no validated cleaning of the interior in accordance with German RKI requirements)

- Remove the cutter or grinder.

- Servicing the product in the QUATTROcare PLUS.

See also:

Instructions for Use KaVo QUATTROcare PLUS 2124 A

Servicing the clamping chuck

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

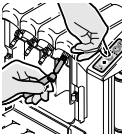
See also:

Instructions for Use KaVo QUATTROcare PLUS 2124 A

Note

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

- Remove the service coupling chuck from the side hatch of the QUATTROcare PLUS and attach it to coupling service point four, on the far right. A MULTIflex 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 theservice procedure.

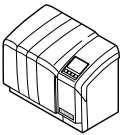
Option 2: After three minutes with no service procedure running, the device automatically switches back to normal service mode.

See also:

Servicing with KaVo QUATTROcare PLUS

7.5.5 Servicing with KaVo QUATTROcare CLEAN 2140 A

Programme-controlled cleaning and servicing device for perfect servicing of handpieces and turbines.



- Remove the cutter or grinder.

- Servicing the product in QUATTROcare CLEAN.

See also:
Instructions for use KaVo QUATTROcare CLEAN 2140 A

Servicing the clamping chuck

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

See also:

Instructions for use KaVo QUATTROcare CLEAN 2140 A

7.6 Packaging

Note

The sterilisation bag must be large enough for the handpiece so that the bag is not stretched.

The quality and use of the sterilisation packaging must satisfy applicable standards and be suitable for the sterilisation procedure!

- Individually seal the medical device in the sterilised item packaging.

7.7 Sterilisation

Sterilisation in a steam steriliser (autoclave) in accordance with EN 13060 / ISO 17665-1

⚠ CAUTION

Premature wear and malfunctions from improper servicing and care.

Reduced product life.

- ▸ Before each sterilisation cycle, service the medical device with KaVo care products.

⚠ CAUTION

Contact corrosion due to moisture.

Damage to product.

- ▸ Immediately remove the product from the steam steriliser after the sterilisation 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 sterilisation processes:

- Autoclave with three times pre-vacuum:
  - at least 3 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)

- Autoclave using the gravity method:
  - at least 10 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
- ▸ Use according to the manufacturer's Instructions for Use.

7.8 Storage

Prepared products must be stored, protected from germs (as far as possible) and dust, in a dry, dark, cool room.

Note

Comply with the expiry date of the sterilised items.

8 Tools and consumables

Available from dental suppliers.

Material summary	Mat. No.
Instrument stand 2151	0.411.9501
Cleanpac 10 units	0.411.9691
Cellulose pad 100 units	0.411.9862
Nozzle pin	0.410.0921
Spray hose, sterilisable	0.065.5188
Drill stop	0.524.0892
Hook	0.410.1963
Spray head INTRA (KaVo Spray)	0.411.9911

Material summary	Mat. no.
KaVo CLEANspray 2110 P	1.007.0579
KaVo DRYspray 2117 P	1.007.0580
KaVo Spray 2112 A	0.411.9640
ROTAspray 2 2142 A	0.411.7520
QUATTROcare plus Spray 2140 P	1.005.4525

9 Warranty terms and conditions

The following warranty conditions 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 data of invoice, subject to the following conditions:

In case of justified complaints, KaVo will honour its warranty with a free replacement or repair. 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 cannot be held liable for defects and their consequences that have arisen or may arise from to 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 accord-

ance with KaVo's instructions for use or other manufacturer's instructions. The warranty does not usually cover lamps, light conductors made of glass and glass fibres, glassware, rubber parts and the colourfastness of plastic parts.

Defects or their consequences that can be attributed to interventions on or changes made to the product by the customer or a third party not authorised by KaVo are excluded from the warranty.

Service warranty claims will only be accepted if the product is submitted along with proof of purchase in the form of a copy of the invoice/delivery note. The dealer, purchase date, unit number or type and serial number must be clearly visible on this document.

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