Instructions for use
GENTLEmini LUX 5000 B - 1.002.3300



Always be on the safe side.

KaVo. Dental Excellence.

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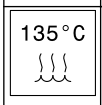
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1 User instructions

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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	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 mark (European Community). A product bearing this mark meets the requirements of the applicable EC directive.
▶	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 **Hazards for the care provider and the patient.** In the case of damage, irregular running noise, excessive vibration, un-typical warming or when the cutter or grinder cannot be held. ▸ Do not use further and notify Service.



⚠ WARNING

Hazard from contraindication.
If the soft tissue in the oral cavity is injured, the compressed air may enable septic substances to enter the tissue.

- ▸ Treatment must be discontinued with instruments operated by compressed air when soft tissue is damaged in the oral cavity.



⚠ CAUTION

Burning hazard from hot instrument head or hot instruments cover.
If the instrument overheats, burns may arise in the oral area.

- ▸ Never contact soft tissue with the instrument head or instrument cover.



⚠ 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

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, serv-

ice 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



GENTLEmini LUX 5000 B (**Mat. no. 1.002.3300**)

3.1 Purpose – Intended use

Purpose:

This medical device is
- Only intended for dental treatment. Any other type of use or alteration to the product is impermissible and can be hazardous. The medical device is intended for the following uses: Removal of carious material, cavities and crown preparations, removal of fillings, processing of tooth, restoration surfaces and surgical procedure.
- 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. The following must be observed:
- the applicable health and safety regulations
- the applicable accident prevention regulations
- these instructions for use

According to these regulations, it is the responsibility of the user to:
- only use equipment that is operating correctly,
- use the equipment for the proper purpose,
- protect him or herself, the patient and third parties from danger, and
- avoid contamination from the product.

3.2 Technical data

Minimum pressure	2.1 bar (30 psi)
Drive pressure	2.1 to 4.2 bar (30 - 60 psi)
Recommended	> 2.8 bar (40 psi)
Air consumption	49 to 51 Nl/min.
Idle speed	380,000 to 450,000 min^{-1} (rpm)
Recommended operating pressure	2 to 3 N (0.45 - 0.68 lbs)

Can be attached to all MULTIflex (LUX) / MULTIflex LED couplings.

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.



⚠ CAUTION

Damage from contaminated and moist cooling air.
Contaminated and moist cooling air can cause malfunctions.

- Make sure that the supply of cooling air is dry, clean, and uncontaminated according to EN ISO 7494-2.

4.1 Mounting the MULTIflex (LUX) / MULTIflex LED coupling



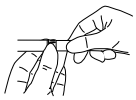
⚠ WARNING

Release of the medical device during treatment.
A medical device that is not properly locked in place can release from the MULTIflex (LUX) / MULTIflex LED coupling during treatment.

- Before each use, check if the medical device is securely locked onto the MULTIflex (LUX) / MULTIflex LED coupling by pulling on it.



- Screw the **MULTIflex (LUX) / MULTIflex LED coupling** onto the turbine hose and tighten with the wrench.



- Rotate the spray ring on the **MULTIflex (LUX) / MULTIflex LED coupling** in order to regulate the fraction of water.

4.2 Check the amount of water



⚠ CAUTION

Overheating of the tooth due to insufficient amount of cooling water.
Insufficient spray water can cause the medical device to overheat and damage the pulp and tooth.

- ▸ Adjust the water amount for the spray cooling to a minimum of 50 cm^3/min (3.1 $inch^3$).
- ▸ Check spray water channels and if necessary clean spray nozzles with the nozzle needle (**Mat. no. 0.410.0921**).
- ▸ Check water filter and replace, if necessary.

4.3 Check the pressure



⚠ CAUTION

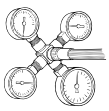
Compressed air connection on devices.
Contaminated and humid compressed air leads to premature wear and tear.

- ▸ Ensure that the cooling air is dry, clean and uncontaminated in accordance with EN ISO 7494-2.

A minimum drive pressure of 2.1 to 4.2 bar (30 to 60 psi) is required to operate the medical device.

A higher drive pressure will be reduced automatically by the medical device.

The air consumption is 49 to 51 Nl/min.



- ▸ Insert the test manometer (**Mat. no. 0.411.8731**) between the hose and the **MULTIflex LUX coupling** and check the following pressures:

  - Drive air: 2.1 to 4.2 bar (30 to 60 psi) (recommended: 2.8 bar (40 psi))
  - Return air: < 0.5 bar (7 psi)
  - Water: 0.8 to 2.0 bar (11 - 29 psi)
  - Spray air: 1.0 to 2.5 bar (14 - 36 psi)

4.4 Check O-rings



⚠ CAUTION

Missing or damaged O-rings.
Malfunctions and premature failure.

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

Number of available O-rings: 5

5 Operation

Note

At the beginning of each workday, the water-conducting systems should be rinsed for at least 2 min. without the instrument being attached; if there is a risk of contamination from reflux or back suction, the system must be rinsed for 20-30 seconds.

5.1 Mount the medical device

⚠ WARNING

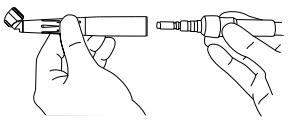
Release of the medical device during treatment.
A medical device that is not properly locked in place can release from the MULTIflex (LUX) / MULTIflex LED coupling during treatment.

- Before each use, check if the medical device is securely locked onto the MULTIflex (LUX) / MULTIflex LED coupling by pulling on it.

⚠ CAUTION

Damage from inaccurate coupling.
Inaccurate coupling (especially during the afterglow period) can destroy the high-pressure lamp or the LED of a MULTIflex (LUX) / MULTIflex LED coupling or reduce its service life.

- Check the seat of the turbine on the coupling by pulling on it.



- Mount the medical device accurately on the **MULTIflex (LUX) / MULTIflex LED coupling** and push it backward until the coupling audibly locks in the medical device.
- Pull on it to make sure that the medical device is securely affixed to the coupling.

5.2 Remove the medical device

- Hold the coupling tight, and pull the medical device off while twisting slightly.

5.3 Insert the milling cutters or diamond grinders

Note

Only use carbide cutters or diamond grinders that correspond to DIN EN ISO 1797-1 type 3, are made of steel or hard metal and meet the following criteria:
- Shaft diameter: 1.59 to 1.60 mm
- Overall length: max. 19 mm
- Shaft clamping length: at least 9 mm
- Blade diameter: max. 2 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

Danger of injury from cutters or grinders.
Infections or cuts.

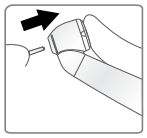
- Wear gloves or fingerstalls.



⚠ CAUTION

Hazard from defective chucking system.
The tool can fall out and cause injury.

- Pull on the tool to check if the chucking system is functioning properly and that the tool is firmly clamped. Wear gloves or a thimble to check, insert, or remove the bits to prevent injury and infection.



- Forcefully press the push button with your thumb and simultaneously insert the cutter or grinder all the way.
- Check that the cutter or grinder is seated by pulling on it.

5.4 Removing the milling tool or diamond grinder



⚠ WARNING

Do not press the pushbutton while the cutter or grinder is rotating.
If you press the pushbutton when the cutter or grinder is rotating, it can damage the chucking system and cause injury.

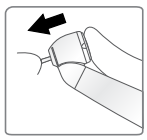
- Never touch soft tissue with the head or tip since it may be hot and cause a burn.
- After treatment is over, remove the cutter or grinder from the contra-angle handpiece since injury and infection may result from putting it away when the cutter or grinder are inserted.



⚠ CAUTION

Danger from rotating tools.
Lacerations.

- Do not unintentionally contact rotating tools.



- After the cutter or grinder has stopped rotating, press the press-button with your thumb and simultaneously pull out the drill bit or bur.

6 Troubleshooting

6.1 Changing the O-rings on the coupling of the supply hose



⚠ 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.

- 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 Cleaning the spray nozzle.



⚠ CAUTION

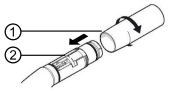
Hazard from insufficient spray water.
Overheating of the medical device and damage to the tooth.

- 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.

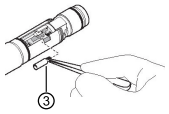


- Clean the water passage in the spray nozzles by using the nozzle needle (**Mat. no. 0.410.0921**).

6.3 Change the water filter



- Unscrew the sleeve ① anticlockwise from the insert ② and pull off.
- Pull back the insert ② slightly.



- Use tweezers to remove the water filter ③ from the insert ②.
- Insert a new water filter.
- Pull back the insert ② slightly.
- Place the sleeve ① on the insert ②, and screw it tight clockwise.

7 Reconditioning methods according to ISO 17664

7.1 Preparation 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 without delay.
- ▸ Recondition 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 reconditioning.
- ▸ Do not place it in a solution or similar.

7.2 Cleaning



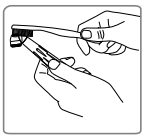
⚠ CAUTION

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

- ▸ Only clean manually or in a thermodisinfector.

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 off under flowing tap water.

7.2.2 Automated external cleaning



KaVo recommends thermodisinfectors in accordance with EN ISO 15883-1, which are operated with alkaline cleaning agents with a pH value of max. 10 (e.g. Miele G 7781/G 7881 – Validation was carried out with Programme "VARIO-TD", cleaning agent "neodisher® mediclean", neutralisation agent "neodisher® Z" and rinsing agent "neodisher® mielclear" and only applies to the material compatibility with KaVo products).

- ▸ For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector (complying with max. pH value of 10).

- 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 internal cleaning

Can only be done with KaVo CLEANspray or 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 thermodisinfectors in accordance with EN ISO 15883-1, which are operated with alkaline cleaning agents with a pH value of max. 10 (e.g. Miele G 7781/G 7881 – Validation was carried out with Programme "VARIO-TD", cleaning agent "neodisher® mediclean", neutralisation agent "neodisher® Z" and rinsing agent "neodisher® mielclear" and only applies to the material compatibility with KaVo products).

- For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector (complying with max. pH value of 10).

- 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.

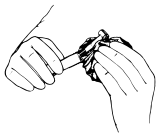
7.3 Disinfection

⚠ CAUTION

Malfunctioning from using a disinfectant bath or disinfectant containing chlorine.
Defects in the product.

- Only disinfect in a thermodisinfector or manually.

7.3.1 Manual external disinfection



KaVo recommends the following products based on material compatibility.

- 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 thoroughly wipe down the medical device and leave the disinfectant to soak in according to the instructions from 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).

- ▸ Follow the instructions for use of the disinfectant.

- ▸ 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 thermodisinfectors in accordance with EN ISO 15883-1, which are operated with alkaline cleaning agents with a pH value of max. 10 (e.g. Miele G 7781/G 7881 – Validation was carried out with Programme "VARIO-TD", cleaning agent "neodisher® mediclean", neutralisation agent "neodisher® Z" and rinsing agent "neodisher® mielclear" and only applies to the material compatibility with KaVo products).

- ▸ For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector (complying with max. pH value of 10).

- ▸ 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 normally 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 or pointed cutters or grinders.

- Remove cutter or grinder.



⚠ CAUTION

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

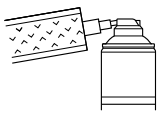
- Perform proper care regularly!



Note

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

7.5.1 Servicing with KaVo Spray

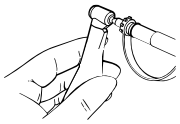


KaVo recommends servicing the product after each time it is used, i.e. after each automatic cleaning and before each sterilisation.

- Remove cutter or grinder and close chuck.
- Cover the product with the Cleanpac bag.
- Place the product on the cannula, and press the spray button for one second.

Servicing the clamping chuck

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

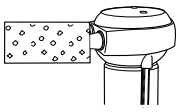


- Remove the cutter or grinder, place the spray nipple tip in the opening and spray.

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

7.5.2 Care of the KaVo SPRAYrotor

KaVo recommends servicing the product after each time it is used, i.e. after each automatic cleaning and before each sterilisation.

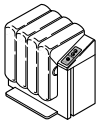


- Place the product on the appropriate coupling of the **KaVo SPRAYrotor** and cover it with a CLEANpac bag.
- Service the product.

See also: Instructions for use **KaVo SPRAYrotor**

7.5.3 Servicing with KaVo QUATTROcare 2104 / 2104A

Cleaning and care unit with expansion pressure for effective cleaning and care.



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.

Servicing the clamping chuck

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

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

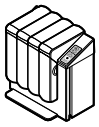


- Remove the cutter or grinder, place the spray nipple tip in the opening and spray.

- Subsequently treat with the care products and care systems specified.

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

7.5.4 Servicing with KaVo QUATTROcare PLUS



KaVo recommends servicing the product after each time it is used, i.e. after each automatic cleaning and before each sterilisation.

- Remove the cutter or grinder.
- Servicing the product in QUATTROcare PLUS.

See also: Instructions for Use **KaVo QUATTROcare PLUS 2124 A**

Servicing of the clamping chuck

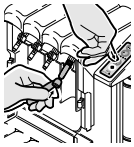
KaVo recommends cleaning and servicing the chuck system once a week.

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 adapter 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 chuck.
- Press the button showing 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: Care with KaVo QUATTROcare PLUS

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 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

- Reprocessed products should be stored protected from dust with minimum exposure to germs in a dry, dark and cool space.

- Comply with the expiry date of the sterilised items.

8 Tools

Available from dental suppliers.

Material summary	Mat. no.
Instrument stand 2151	0.411.9501
Cleanpac 10 units	0.411.9691
Spare turbine with wrench	1.006.5535
Spare turbine without wrench	1.006.4564
Insert for turbines	0.411.9902
Water filter with nipple	1.000.4823
Nozzle pin	0.410.0921
MULTIflex spray head (nozzle)	0.411.9921
Service coupling QUATTROcare MULTIflex	0.411.7991

Material summary	Mat. no.
Adaptor INTRAmatic (CLEANspray and DRYspray)	1.007.1776
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 the date of the 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 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, light conductors made of glass and glass fibres, glassware, rubber parts, and the colourfastness of plastic parts.
All liability is 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 authorised by KaVo.
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 or note of delivery. The dealer, purchase date, type, and serial number must be clearly evident from this document.

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