stomdevice

Instructions for use

PROPHYflex 4



KAVO
Dental Excellence

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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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All other trademarks are property of their respective owners.

KaVo Original Factory Repair

In the event of a repair, please ship your product to the KaVo Original Factory Repair using www.kavobox.com.



KaVo Technical Service
If you have any questions or complaints, please contact the KaVo Technical Service:
+49 (0) 7351 56-1000
service.instrumente@kavo.com

Target group

This document is intended for dentists and dental office staff. The startup section is also intended for service technicians.

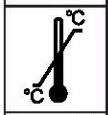
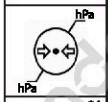
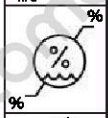
General marks and symbols

	Refer to the chapter on Safety/Warning symbol
	Important information for users and service technicians
▶	Action request
CE	CE mark (European Community). A product bearing this mark meets the requirements of the applicable EC directive.
MD	Medical device, labelling of medical devices
135°C	Can be steam sterilised at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)

Information on the packaging

REF	Material number
SN	Serial number

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	Manufacturer
	Note: Please note accompanying documents
	Follow the electronic instructions for use
	HIBC Code
	CE mark for medical devices
	Medical device, labelling of medical devices
	EAC conformity mark (Eurasian Conformity)
	Transportation and storage conditions (Temperature range)
	Transportation and storage conditions (Air pressure)
	Transportation and storage conditions (Humidity)
	Protect from moisture (Keep dry)
	Protect from impact

Hazard levels

The warning and safety notes in this document must be observed to prevent personal injury and material damage. The warning notes are designated as shown below:



⚠ DANGER

In cases which – if not prevented – directly lead to death or severe injury.



⚠ WARNING

In cases which – if not prevented – can lead to death or severe injury.



⚠ CAUTION

In cases which – if not prevented – can lead to minor or moderate injury.

NOTICE

In cases which – if not prevented – can lead to material damage.

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2 Safety

The instructions for use are a component of the product and must be read carefully prior to use and be accessible at all times.
The device may only be used in accordance with the intended use, any other type of use is not permitted.

2.1 Infection hazard

Patients, users or third parties could be infected by contaminated medical devices.

- Take suitable personal protective measures.
- Follow the instructions for use of the components.
- Before initial startup and after each use, reprocess the product and accessories appropriately.
- Carry out the reprocessing as described in the instructions for use. The procedure has been validated by the manufacturer.
- If you deviate from this procedure, it is essential to make sure that the reprocessing is effective.
- Reprocess the product and accessories appropriately before disposal.
- If there is any injury to soft tissue, do not continue treatment in the oral cavity with compressed air-driven instruments.

2.2 Air embolism and skin emphysema

There is a danger that the insufflation of spray can cause air embolisms and skin emphysema.

- Avoid the insufflation of spray in open wounds.

The improper use of the product might lead to emphysema. Emphysema may arise in extreme individual cases, especially in the presence of pathological gingival pockets (> 3 mm), mucosal lesions, direct skin contact or contact with soft tissue and/or improper handling.

- The powder jet device must be used as briefly as possible.
- The PROPHYflex perio tip may be re-used for up to10 times.
- After the treatment, unscrew the empty powder container and rinse the PROPHYFLEX perio tip with air and water for approx. 10 seconds.
- For safety reasons, the torque wrench should be placed on the perio tip as protection against injuries when the is PROPHYflex in the holder.

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2.3 Technical condition

A damaged device or components could injure patients, users and third parties.

- Only operate devices or components if they are undamaged on the outside.
- Check that the device is working properly and is in satisfactory condition before each use.
- Have parts with sites of breakage or surface changes checked by the Service.
- If you notice any of the following defects on the product or accessories, stop working and have the service personnel carry out repair work.

Observe the following instructions in order to guarantee optimum functioning and prevent material damage:

- The device should be reprocessed and stored in a dry location, according to instructions, if it is not be used for a longer period.

2.4 Accessories and combination with other equipment

Use of un-authorised accessories or un-authorised modifications of the device could lead to injury.

- Only use accessories that have been approved for combination with the product by the manufacturer.
- Only use accessories that are equipped with standardised interfaces.
- Only use consumables that have been approved for combination with the product by the manufacturer.
- Do not make any modifications to the device unless these have been approved by the manufacturer of the product.

2.5 Qualification of personnel

Application of the product by users without the appropriate medical training could injure the patients, the users or third parties.

- Make sure that the user has read and understood the instructions for use.
- Only employ the device if the user has the appropriate medical training.
- Observe national and regional regulations.

2.6 Application

The use of the product might lead to discolouration of the teeth. Following the treatment, the teeth are absolutely clean and all of the dental pellicle (cuticula dentis) is removed. The dental pellicle is restored only some 2 to 3 hours later due to the protein content of saliva. During this time, the teeth are not naturally protected from discolouration.

- Tell your patients not to smoke, drink tea or coffee and not to consume any other discolouring foods for 2 to 3 hours after treatment.

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2.7 Service and repair

Repairs and servicing may only be performed by trained service personnel. The following persons are authorised to do this:

- Service technicians of KaVo branches after the appropriate product training
- Service technicians of KaVo authorised dealers after the appropriate product training

Observe all the following items during servicing work:

- Have the service and testing tasks carried out according to the Medical Device Operator Ordinance.
- KaVo recommends specifying in-house service intervals where the medical device is brought to a professional shop for cleaning, servicing and a function check. Define the service interval depending on the frequency of use.

Cleansers and disinfectants that have not been approved can damage the plastic housing possibly leading to hairline cracks and other damage which can ultimately cause hazards.

2.8 Protective equipment

PROPHYflex Powder and other powders can be aspirated or get into the eyes of the user or patient during treatment.

- Both patient and user have to wear protective goggles during the treatment.
- KaVo recommends the use of dust extraction equipment and mouth protection during the treatment with PROPHYflex.

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3 Product description



PROPHYflex 4 Wave (**Mat. no. 3.002.8000**)
PROPHYflex 4 Lime (**Mat. no. 3.002.8200**)
PROPHYflex 4 Flamingo (**Mat. no. 3.002.8800**)
PROPHYflex 4 S Wave (**Mat. no. 3.004.5900**)
PROPHYflex 4 S Lime (**Mat. no. 3.004.5930**)
PROPHYflex 4 S Flamingo (**Mat. no. 3.004.5950**)

The three power levels are as follows:

- Highest Level: Suitable for supragingival treatment and offers full cleaning power.
- Medium Level: Suitable for sub- and supragingival treatment and enables gentle cleaning at a reduced powder quantity.
- Lowest Level: Helps rinsing the powder off the tooth and blowing the powder from the system after the treatment.

During supragingival treatments (e.g. stain removal), the device does not contact the patient but is placed at a distance of 3 – 5 mm from the area to be cleaned. During subgingival treatments (biofilm removal) with the perio tip, the tip is inserted up to 5 mm deep into the pocket and is angled towards the tooth. The components of the PROPHYflex 4, including the powder container, need to be completely reprocessed after each use.

3.1 Purpose – Intended use

Indications for use:

This medical device is

- intended for dental treatment only. All other types of use of or modifications to the product are not permitted and can be hazardous. The medical device is intended for the following applications: Removal of discoloration

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and bacterial plaque, orthodontics, cleaning prior to fissure sealing, prosthetics, conservative and aesthetic dentistry. Please refer also to the Instructions for Use.

- A medical device according to relevant national statutory regulations.

Proper use:

According to these regulations, this product may only be used for the described application by a properly trained 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
- to protect him or herself, the patient and third parties from hazards
- to prevent contamination from the product

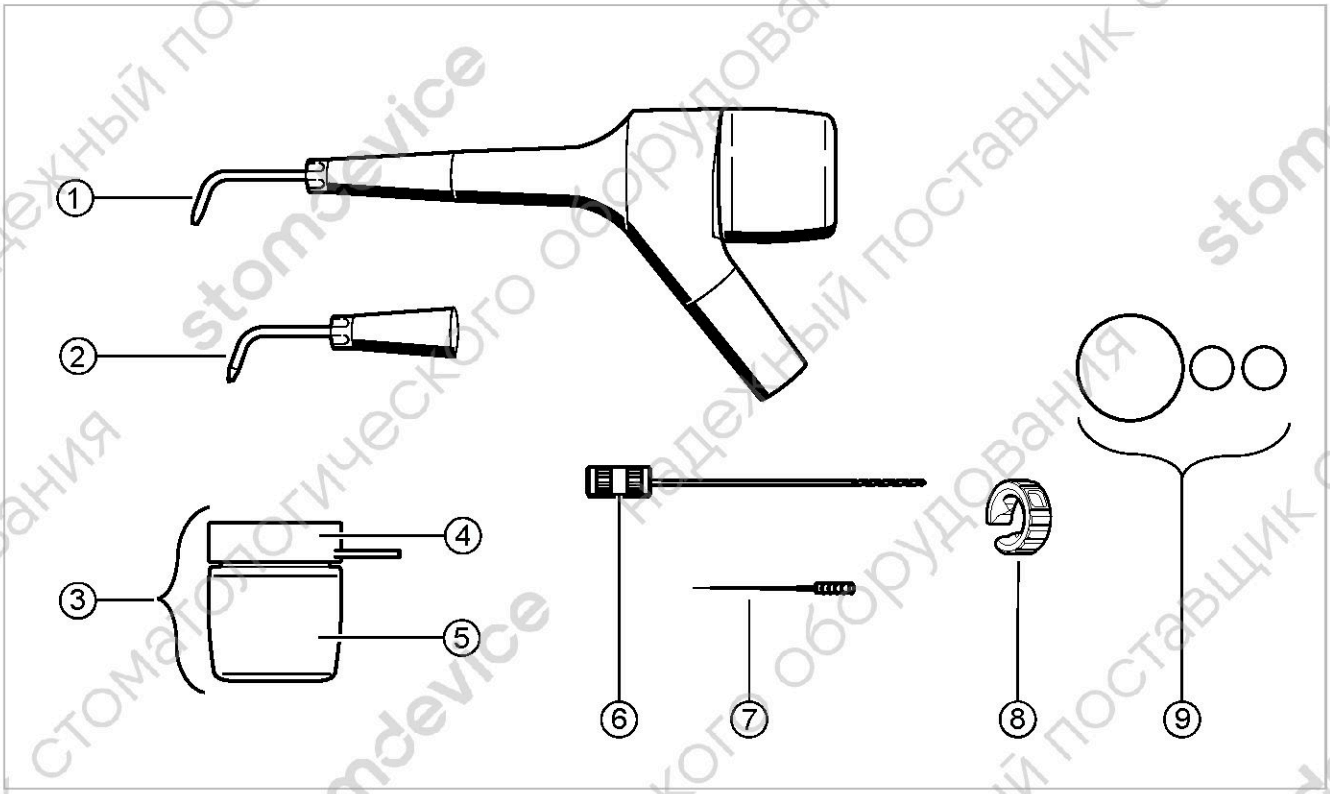
3.2 Technical data

Drive pressure	3.2 - 5 bar (46 - 73 psi)
Air consumption	8-13 Nl/min
Water pressure	1.0 - 2.5 bar (15 - 36 psi)
Spray water flow	approx. 35 - 80 cm^3
Spray air pressure	1.0 - 2.5 bar (15 - 36 psi)

Attachable to all MULTIflex (LUX) / MULTIflex LED couplings.

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3.3 Scope of delivery



The set consists of:

No./ Item no.	Description	Mat. No.
1 x ①	PROPHYflex 4 with: Long gripping sleeve Cannula Powder container	 3.003.0520 3.003.1138 3.002.8136
1 x ②	Short gripping sleeve Power cannula	3.003.2607 3.005.0077
1 x ③	Powder container ⑤ Rubber cover supra ④	3.002.8136 3.004.4708
1 x ⑥	Cleaning bur	3.004.9870
1 x ⑦	Nozzle needle	0.573.6052
1 x ⑧	Wrench for cannula	3.004.6351
1 x ⑨	O-rings for powder container and coupling interface to the gripping sleeve	can be ordered individually **See also:** 8 Consumables, Page 32

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3.4 Optional accessories

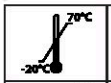
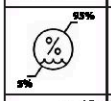
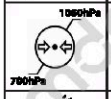
PROPHYflex 4 Perio Kit (**Mat. no. 1.011.9403**)
Accessories for PROPHYflex for subgingival bio-film removal and cleaning of implant surfaces, crowns and bridges

Refill PROPHYflex perio tip (**Mat. no. 1.010.0287**)
Kit for refilling the PROPHYflex 4 Perio Kit (1.010.0287)

3.5 Transportation and storage conditions

NOTICE

Startup after refrigerated storage.
Malfunction.
- Prior to startup, strongly refrigerated products must be allowed to warm up 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 85% RH absence of condensation
	Air pressure: 700 hPa to 1060 hPa (10 psi to 15 psi)
	Protect from moisture

3.5.1 Currently valid packaging regulations

Note
Only valid for the Federal Republic of Germany.

Dispose of and recycle the packaging appropriately in accordance with current packaging law, employing waste management or recycling companies. Comply with the comprehensive return system. KaVo has had its packaging licensed for this purpose. Please comply with the regional public waste-disposal system.

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4 Start up and shut down

⚠ WARNING

Hazard from non-sterile products.

Infection hazard to the dentist and patient.

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

⚠ WARNING

Dispose of the product in appropriate manner.

Infection hazard.

- Before disposal, reprocess and sterilise the product and accessories appropriately.

NOTICE

Damage from soiled 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 Installing the MULTIflex coupling

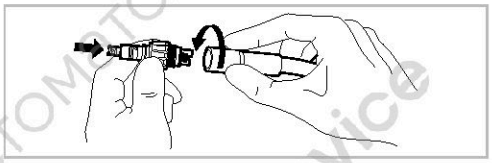
⚠ WARNING

Detachment of the medical device during treatment.

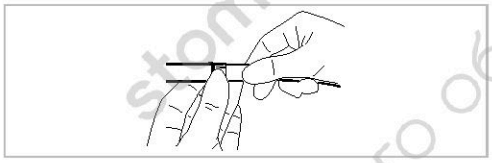
A medical device that is not properly locked can release from the MULTIflex coupling during treatment.

- Before each use, check if the medical device is securely locked onto the MULTIflex coupling.

- Screw the MULTIflex coupling onto the turbine hose.



- Open the water supply all the way using the spray ring on the MULTIflex coupling.



4.2 Check the O-rings (MULTIflex)

NOTICE

Missing or damaged O-rings.

Malfunction and premature failure.

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

Number of available O-rings: 5

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5 Operation

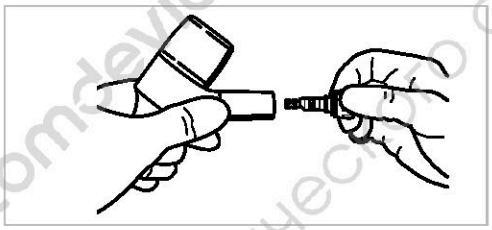
Note
At the beginning of each workday, the water-conducting systems should be rinsed for at least 2 minutes (without transmission handpieces being attached) and if there is a risk of contamination from reflux or back suction, the system may also need to be rinsed for 20 to 30 seconds after each patient.

5.1 Attaching the medical device

⚠ WARNING

Detachment of the medical device during treatment.
A medical device that is not properly locked can release from the MULTIflex coupling during treatment.
- Before each use, check if the medical device is securely locked onto the MULTIflex coupling.

- 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.



- Check if the medical device is securely seated on the coupling by pulling on it.

5.2 Remove the medical device

- Grasping the coupling, twist the medical device slightly and pull it off.

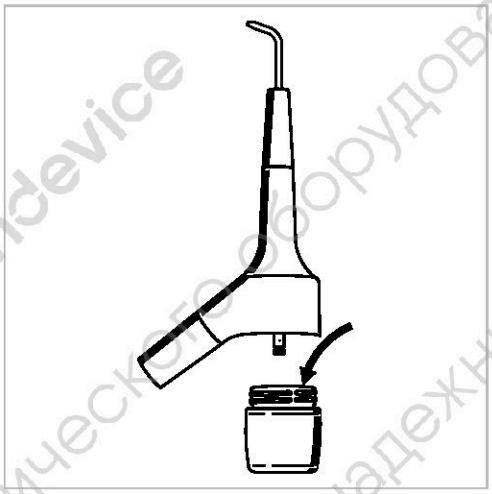
5.3 Filling the powder container

⚠ CAUTION

Open powder container.
Infection hazard from contaminated powder.
- Only use original KaVo powder.
- Reprocess and refill the powder container before each patient.
- Comply with the safety data sheets for KaVo powders.
- Safety data sheets are available for inspection at www.kavo.com, "Safety data sheets".

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- Unscrew the powder container anticlockwise.



- Before filling the powder container, shake the powder in the refilling bag well.
- Fill the powder container up to the marking.

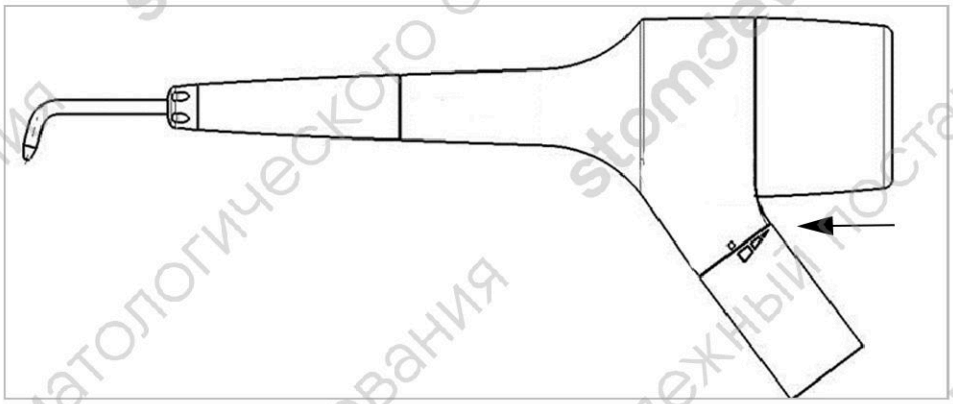


- Keep the powder container closed by the rubber cover until the powder is used on the patient.
- Remove the rubber cover before use.
- To screw-on the powder container and to tighten it keep the container upright and turn to the right.

5.4 Adjusting the powder volume

The powder quantity can be controlled at 3 levels using the adjusting ring:

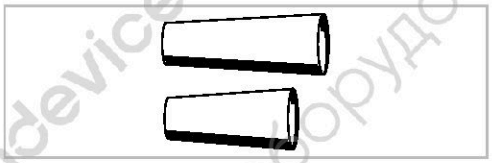
- The highest level is suitable for supragingival treatment and offers full cleaning power
- The medium level is suitable for sub- and supragingival treatment and enables gentle cleaning at a reduced powder quantity
- The lowest level helps rinsing the powder off the tooth and blowing the powder from the system after the treatment; it is nearly free of powder



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5.5 Mounting the gripping sleeve

The gripping sleeve is available in two different lengths.



- Long gripping sleeve: 3.003.0520
- Short gripping sleeve: 3.003.2607

▸ Mount the ergonomically fitting gripping sleeve on the instrument without tilting it.

5.6 Screwing-in the cannula / Power cannula

⚠ CAUTION

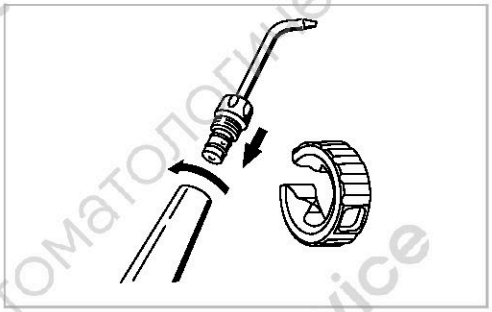
Cannula falls off during the treatment.

Detachment of the cannula is a hazard for patient and user.

Visual inspection after each time the cannula is inserted with the wrench for the cannula.

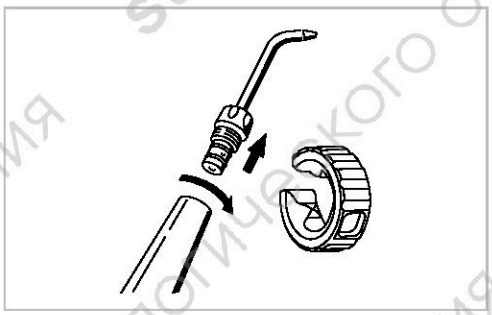
Before commencing the treatment, check that there is no gap between the cannula and the gripping sleeve.

▸ Insert the cannula in the gripping sleeve with the wrench for the cannula and screw it in clockwise while holding on to the gripping sleeve.



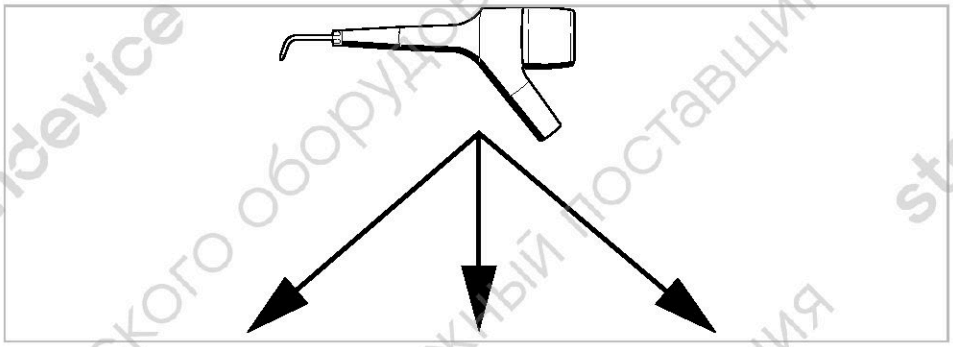
5.7 Unscrewing the cannula / Power cannula

▸ Unscrew the cannula in counterclockwise direction using the wrench for the cannula.



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5.8 Instructions for use for PROPHYflex Powder, PROPHYpearls, PROPHYflex Perio Powder



PROPHYflex powder	PROPHYpearls	PROPHYflex Perio powder
When: ▪ Conservative and aesthetic dentistry ▪ Cleaning of tooth surfaces ▪ Removal of stains and plaque ▪ Orthodontics and prosthetics (pre- and after-treatment of adhesive surfaces)	When: ▪ Conservative and aesthetic dentistry ▪ Cleaning of tooth surfaces ▪ Removal of stains and plaque ▪ Orthodontics and prosthetics (pre- and after-treatment of adhesive surfaces)	When: ▪ Subgingival treatment ▪ Removal of periodontal biofilm ▪ For follow-up treatment after the initial use in periodontal therapy ▪ Preservation of dental implants (including titanium polish)

PROPHYflex powder	PROPHYpearls	PROPHYflex Perio powder
from pink to white working	from pink to white working	any direction of work
water-soluble	slightly water-soluble	water-soluble

NOTICE

Do not run the instrument with RONDOflex powder.
Defects on the PROPHYflex.

See also:

- Instructions for use PROPHYflex Powder, PROPHYpearls, PROPHYflex Perio Powder

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6 Troubleshooting

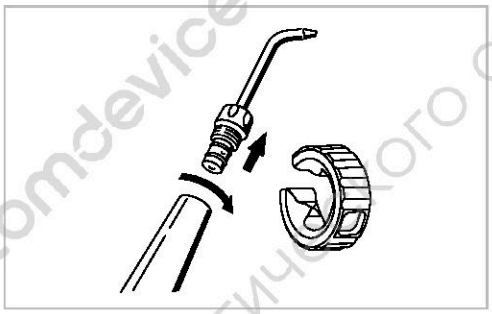
Preventive measures

- After each treatment and before each sterilisation, unscrew the powder container in an anticlockwise direction and replace it with a clean powder container.
- Mount the PROPHYflex on the MULTIflex coupling and blow through the air and water channels.
- Switch the water off and blow through the air and water channels again.

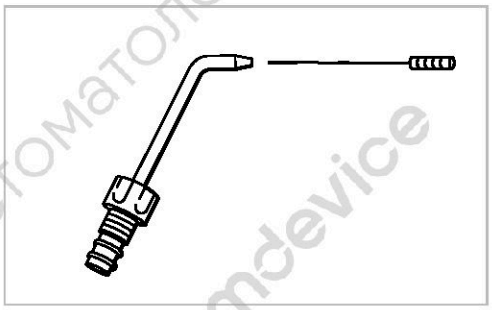
6.1 Cleaning a clogged cannula / Power cannula

Note
After using a needle pin or cleaning burr, the instrument must be reprocessed before further use. Nozzle pin and cleaning burr cannot be reprocessed.

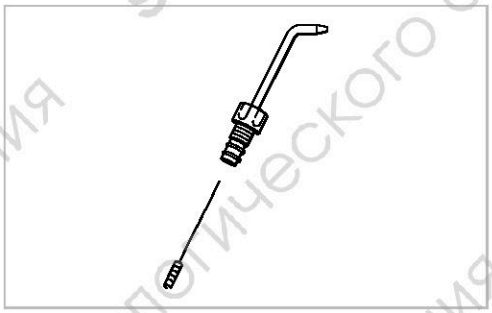
- Unscrew the cannula in anticlockwise direction using the wrench.



- Slide the nozzle needle into the cannula from the front while rotating it.



- Then slide the nozzle needle into the cannula from the back while rotating it.



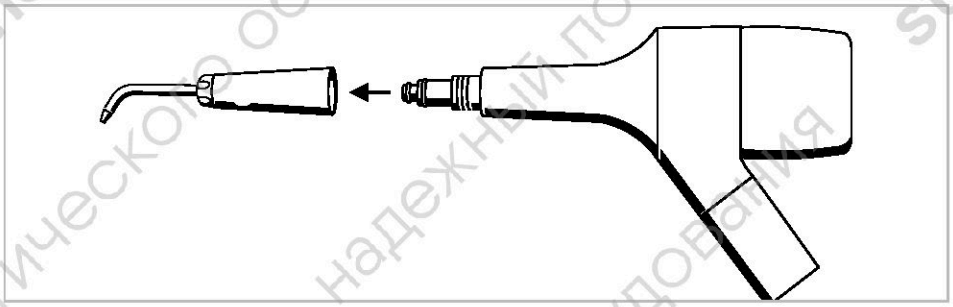
- Then remove the nozzle needle, and blow out the cannula with compressed air.

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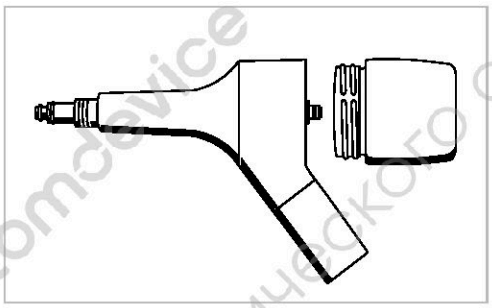
6.2 Cleaning a clogged main body

Note
After using a needle pin or cleaning burr, the instrument must be reprocessed before further use. Nozzle pin and cleaning burr cannot be reprocessed.

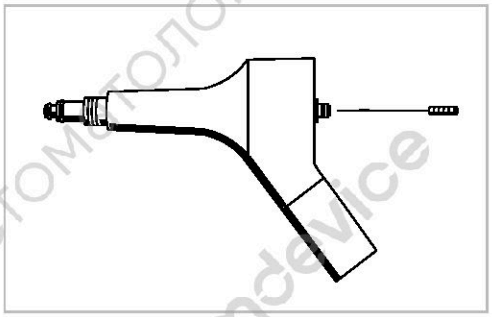
- Pulling off the grip sleeve with cannula.



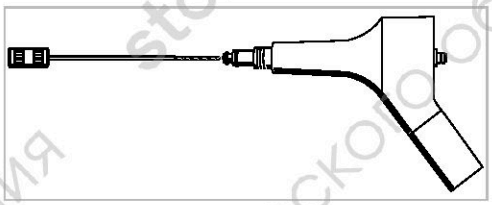
- Unscrew the powder container anticlockwise.



- Push the nozzle needle through the aperture of the nozzle.



- Use the cleaning drill to clean or remove obstructions from the media tube.

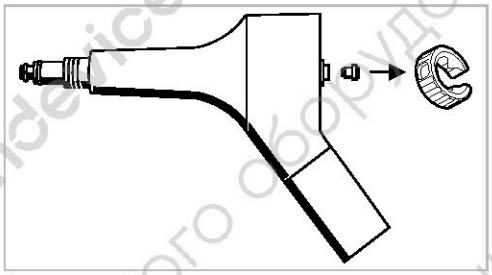


- Then blow through with compressed air.

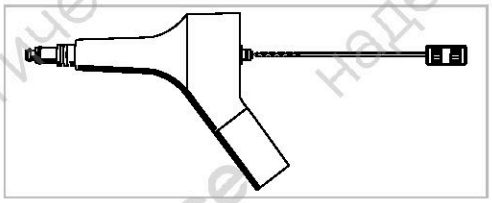
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If the clogging persists:

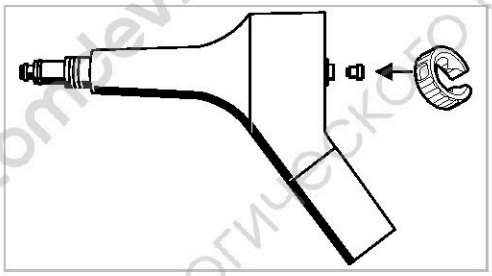
- Use the wrench for cannula to unscrew the nozzle by placing the lateral recess of the wrench on the nozzle and unscrewing the nozzle.



- Use the cleaning drill to clean or remove obstructions from the media tube from the front and the back.



- Tighten the nozzle carefully and with gentle force with the wrench again.

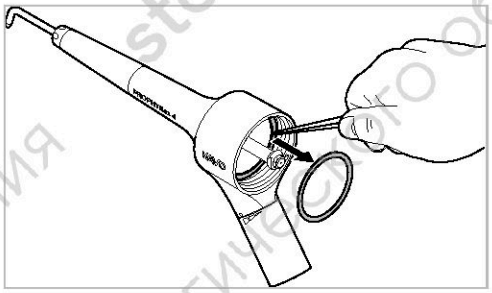


- Blow compressed air through.

6.3 Replacing the O-ring for powder container

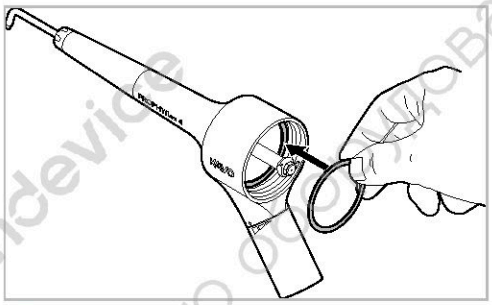
If there is any air leakage on the powder container or visible damage on the O-ring, replace the O-ring.
A spare O-ring is included in the scope of delivery.

- Remove the powder container by rotating it in counterclockwise direction.
- Remove the O-ring with a probe or tweezers.



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- Carefully push the spare O-ring into the recess using your fingers.



⇨ Do not damage the spare O-ring when you do this.

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7 Reprocessing steps in accordance with ISO 17664

Note
The components of the PROPHYflex 4, including the powder container, need to be completely reprocessed after each use.

7.1 Preparation at the site of use

⚠ WARNING

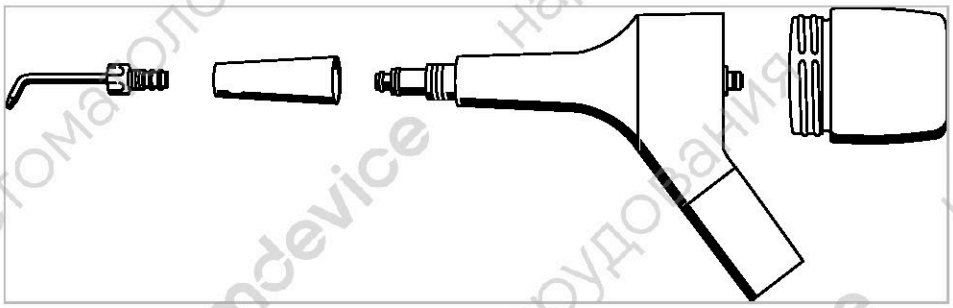
Hazard from contaminated products.
Contaminated products are associated with an infection hazard.
- Take suitable personal protective measures.

- Reprocess the medical device as soon as possible after treatment.
- The medical device must be dry when transported to reprocessing.
- To minimise the risk of infection during reprocessing, always wear protective gloves.
- Remove all residual cement, composite or blood immediately.
- Do not place in solutions or similar substance.

7.2 Disassembly

⚠ WARNING

Incomplete reprocessing.
Infection hazard.
- To ensure complete reprocessing of all parts, the medical device needs to be disassembled before reprocessing.



- Unscrew the powder container.
- Pull the gripping sleeve off.
- Remove the cannula from the gripping sleeve.
- Set the powder regulation to the highest level.

7.3 Pre-cleaning

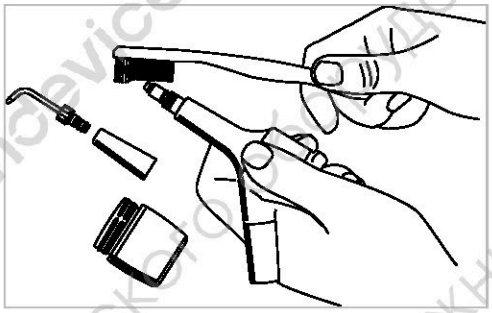
NOTICE

Never reprocess this medical device in an ultrasonic device.
Malfunction and material damage.
- Clean it in a washer disinfector only.

Accessories required:
- Tap water 30 °C ± 2 °C (86 °F ± 4 °F)

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- Brush, e.g. medium-hard toothbrush
- ▸ Disassemble the instrument completely.
- ▸ Brush off all individual parts under running tap water.



7.4 Manual Reprocessing

NOTICE

Never reprocess this medical device in an ultrasonic device.
Malfunction and material damage.
- ▸ Clean it in a washer disinfector only.

7.4.1 Manual external cleaning

The PROPHYflex 4 is not designed for manual external cleaning. For effective reprocessing, the inside of the device must be subjected to automated cleaning in a cleaning and disinfection unit in accordance with ISO 15883-1.

7.4.2 Manual internal cleaning

Manual internal cleaning of the PROPHYflex 4 is not applicable. For effective reprocessing, the inside of the device must be subjected to automated cleaning in a cleaning and disinfection unit in accordance with ISO 15883-1.

7.4.3 Manual external disinfection

The PROPHYflex 4 is not designed for manual external disinfection. For effective reprocessing, the inside of the device must be subjected to automated cleaning in a cleaning and disinfection unit in accordance with ISO 15883-1.
- ▸ Manual external disinfection is permissible only as an occupational safety measure (personal protection measure).

NOTICE

Never disinfect the handpiece with chloride-containing products.
Malfunction and material damage.
- ▸ Only disinfect in the washer disinfector.

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.

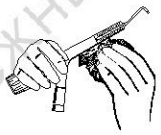
Approved disinfectants:
- Mikrozid AF made by Schülke & Mayr (liquid or cloths)

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- FD 322 made by Dürr
- 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 according to the instructions of the disinfectant manufacturer.
- ▸ Follow the instructions for use of the disinfectant.

7.4.4 Manual internal disinfection

Manual internal disinfection of the PROPHYflex 4 is not applicable. For effective reprocessing, the inside of the device must be subjected to automated cleaning in a cleaning and disinfection unit in accordance with ISO 15883-1.

7.4.5 Manual drying

Manual drying of the PROPHYflex 4 is not applicable. For effective reprocessing, the inside of the device must be subjected to automated cleaning in a cleaning and disinfection unit in accordance with ISO 15883-1.

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7.5 Automated reprocessing



⚠ WARNING

Incomplete disinfection.

Infection hazard.

- Only use disinfection procedures that are verified to be bactericidal, fungicidal and virucidal.
- If the disinfectants used do not meet these requirements, the process must be concluded by disinfection of the unit(s) without packaging using a steam steriliser.

NOTICE

Never disinfect the handpiece with chloride-containing products.

Malfunction and material damage.

- Only disinfect in the washer disinfector.

NOTICE

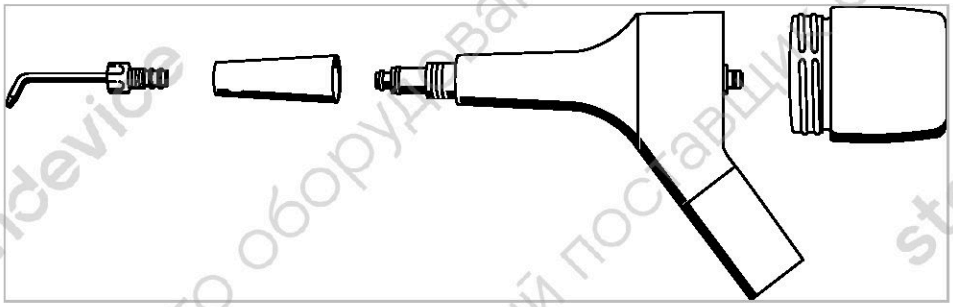
Never reprocess this medical device in an ultrasonic device.

Malfunction and material damage.

- Clean it in a washer disinfector only.

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7.5.1 Overview of the automated reprocessing options



	Pre-cleaning	Automated external cleaning	Automated internal cleaning	Automated internal and external disinfection	Sterilisation
Main body	✓	✓	✓	✓	✓
Gripping sleeve	✓	✓	✓	✓	✓
Cannula / Power cannula / Adapter + Perio Tip	✓	✓	✓	✓	✓
Gripping sleeve and cannula / Power cannula / Adapter + Perio Tip	✓	✓	✓	✓	✓
Powder container	✓	✓	not usable	✓	✓
Cover for powder container	✓	✓	not usable	✓	✓
Wrench for cannulas	✓	✓	not usable	✓	✓

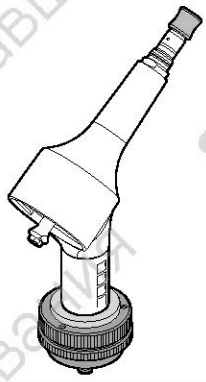
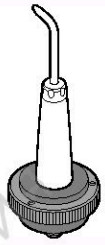
✓ possible

Note
Adapters are needed for automated cleaning.
Order adapter separately.

See also:
8 Accessories, Page 32

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7.5.2 Preparation for automated internal and external cleaning as well as internal and external disinfection

Miele Series G 7881/7891		
Main body	Requisite material: Cleaning cover PROPHYflex 4 (3.004.6658) Reprocessing with Miele AUF Adapter	
Gripping sleeve	Requisite material: Cleaning in Miele sieve basket	
Cannula / Power cannula / Adapter + Perio Tip	Requisite material: Cleaning adapter PROPHYflex 4 long (3.004.6640) Reprocessing with Miele AUF Adapter	
Gripping sleeve and cannula / Power cannula / Adapter + Perio Tip	Reprocessing with Miele AUF Adapter	
Powder container	Requisite material: Reprocessing in Miele sieve basket	
Cover for powder container	Requisite material: Reprocessing in Miele sieve basket	
Wrench for cannulas	Requisite material: Reprocessing in Miele sieve basket	

7.5.3 Automated internal and external cleaning and internal and external disinfection

KaVo recommends washer disinfectors according to EN ISO 15883-1, which are operated using alkaline cleaning agents having a maximum pH value of 11. The validation was performed in a Miele washer disinfector using the "VARIO-TD" program, the "neodisher mediclean forte" cleaning agent, the "neodisher Z" neutraliser, and the "neodisher mielclear" rinsing agent.

- For programme settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector.

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For tests on the disinfection the following parameters will be applied:

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7.5.4 Automated drying

The drying procedure is normally part of the cleaning programme of the washer disinfector.

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

- In order to prevent impairment of the KaVo medical device, make sure that the inside and outside of the device is dry after the end of the cycle.

7.6 Care products and systems - Servicing

NOTICE

Improper care.
Malfunction or property damage.
- Do not service the medical device with oil or maintenance spray.

7.7 Packaging

Note
The sterile goods package must be large enough for the product so that the packaging is not stretched.
The quality and use of the packaging of the items to be sterilised must satisfy the applicable standards and be appropriate for the sterilisation process!

- The medical device must be packed before sterilisation.

7.8 Sterilisation

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

NOTICE

Contact corrosion due to moisture.
Damage to product.
- Immediately remove the product from the steam steriliser after the sterilisation cycle.

Note
Prior to attaching the powder container, all powder-conducting parts and air channels must be absolutely dry. Screw together the powder container and handpiece only while the parts are cold.



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

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Select a suitable process from the following sterilisation processes (depending on the available steriliser):

- Steriliser with triple pre-vacuum:
  - at least 3 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
- Steriliser using the gravity method:
  - at least 10 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F) or alternatively
  - at least 60 minutes at 121 °C -1 °C / +4 °C (250 °F -1.6 °F / +7.4 °F)

▸ Use according to the manufacturer's Instructions for Use.

7.9 Storage

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

Note
Comply with the expiry date of the sterilised items.

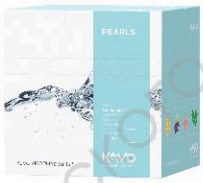
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8 Auxiliary equipment

Available from dental suppliers.

Cannula		**Mat. no. 3.003.1138**
Power cannula		**Mat. no. 3.005.0077**
Powder container		**Mat. no. 3.002.8136**
Rubber cover supragingival		**Mat. no. 3.004.4708**
Rubber cover subgingival		**Mat. no. 3.004.4709**
Cleaning bur		**Mat. no. 3.004.9870**
Nozzle needle		**Mat. no. 0.573.6052**
Nozzle		**Mat. no. 3.004.2324**
Long gripping sleeve		**Mat. no. 3.003.0520**
Short gripping sleeve		**Mat. no. 3.003.2607**
Cleaning adapter PROPHYflex 4 long		**Mat. no. 3.004.6640**
Cleaning cover PROPHYflex 4		**Mat. no. 3.004.6658**
Cleaning adapter PROPHYflex 4		**Mat. no. 3.004.8509**
Cleaning adapter PROPHYflex 4 S		**Mat. no. 3.004.8523**
PROPHYflex 4 Perio Kit	Accessories for PROPHYflex for subgingival bio-film removal and cleaning of implant surfaces, crowns and bridges	**Mat. no. 1.011.9403**
Refill PROPHYflex perio tip (	Kit for refilling the PROPHYflex 4 Perio Kit (1.011.9403)	**Mat. no. 1.011.9403**

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O-ring for powder container		**Mat. no. 3.003.0608**
O-ring for coupling interface to gripping sleeve, rear		**Mat. no. 1.004.2776**
O-ring for coupling interface to gripping sleeve, front and cannula		**Mat. no. 0.200.6084**
PROPHYflex Powder orange, Pack of 80 sticks PROPHYflex Powder, berry, Pack of 80 sticks PROPHYflex Powder, cherry, Pack of 80 sticks PROPHYflex Powder, mint, Pack of 80 sticks		**Mat. no. 1.007.0014** **Mat. no. 1.007.0015** **Mat. no. 1.007.0016** **Mat. no. 1.007.0017**
PROPHYpearls neutral, Pack of 80 sticks		**Mat. no. 1.010.1826**
PROPHYpearls mint, Pack of 80 sticks PROPHYpearls peach, Pack of 80 sticks PROPHYpearls orange, Pack of 80 sticks PROPHYpearls black currant, Pack of 80 sticks		**Mat. no. 1.010.1828** **Mat. no. 1.010.1829** **Mat. no. 1.010.1830** **Mat. no. 1.010.1831**
PROPHYpearls neutral, 4 bottles containing 250g each		**Mat. no. 1.010.1798**
PROPHYflex Perio powder 4 bottles containing 100g each		**Mat. no. 1.009.3732**

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9 Terms and conditions of warranty

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 12 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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