Instructions for use
INTRAmatic handpiece 10 E - REF 1.003.6977

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.

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.
	Can be steam-sterilised at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
	Thermodisinfectable

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 the potential consequences of non-observance.

- ▶ 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 cause death or serious injury.

⚠ DANGER

DANGER
indicates a hazardous situation that can directly cause death or serious injury.

2.2 Safety instructions

⚠ 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

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 non-use.

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

INTRAmatic handpiece 10 E (**Mat. no. 1.003.6977**)

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 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. 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 Specifications

Drive speed	max. 40,000 rpm
identification	1 blue ring
Transmission	1 : 1
Maximum speed	max. 40,000 rpm

Handpiece cutters or grinders can be used.
Short handpiece cutters or grinders can be used after conversion.

The handpiece can be attached to the INTRA Motor 181K.

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 nonsterile products.
Infection danger to the care provider and patient.

- ▶ Before first use and after each use, prepare and sterilise the medical device if needed.

⚠ WARNING

Disposal of the product in the appropriate manner.
Prior to disposal, the product must be appropriately prepared or sterilised if this is necessary.

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

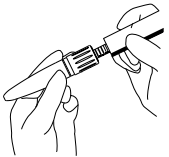
Connect to the drive motor.
Handpiece blocked.

- 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!



- Place the medical device on the motor coupling and lock it into place.

- Pull on it to make sure that the medical device 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 drill bits that correspond to ISO 1797-1, are made of steel or hard metal, and meet the following criteria:
- Shaft diameter: 2.334 to 2.35 mm

with bit stop:
- Shaft clamping length: 12 mm
- Shaft clamping length: max. 22 mm

without bit stop:
- Shaft clamping length: min. 30 mm
- Shaft clamping 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

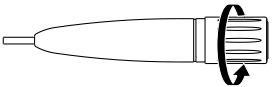
Injury hazard from cutters or grinders.
Infections or cuts.

- 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.



- Hold the grip sleeve, rotate the sleev all the way in the direction of the arrow, and insert the handpiece cutter or grinder into the chuck.
- Hold the grip sleeve, and turn the sleeve into the 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.

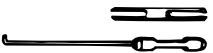
- Do not touch the cutter or grinder when it is rotating!
- Remove the cutter/grinder from the contra-angle handpiece after treatment to avoid injury and infection when putting it away.

- After the cutter or grinder has stopped rotating, turn the grip sleeve in the direction of the arrow to the stop.
- Turn the grip sleeve into the 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 accompanying drill bit stop into the chuck.
- Press the contra-angle handpiece drill bit against the stop, close the clamping ring and make sure that the bit is firmly seated.

- Use the accompanying hook to remove the bit stop.

6 Preparation methods according to ISO 17664

6.1 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 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.

6.2 Cleaning

⚠ CAUTION

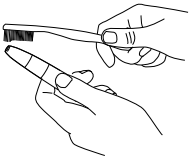
Malfunctions from cleaning in the ultrasonic unit.
Defects in the product.

- ▶ Only clean manually or in a thermodisinfector.

6.2.1 Cleaning: 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.

6.2.2 Cleaning: 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, and then lubricate immediately with care agents from the KaVo care system.

6.2.3 Cleaning: 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.

6.2.4 Cleaning: 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, and then lubricate immediately with care agents from the KaVo care system.

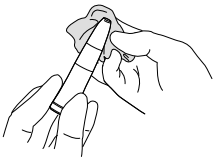
6.3 Disinfection

⚠ CAUTION

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

- Only disinfect in a thermodisinfector or manually.

6.3.1 Disinfection: Manual disinfection - external



KaVo recommends the following products based on material compatibility. The microbiological efficacy must be ensured by the disinfectant manufacturer.

- Mikrozid AF Liquid made by Schülke & Mayr
- 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.

6.3.2 Disinfection: 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.

6.3.3 Disinfection: 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, and then lubricate immediately with care agents from the KaVo care system.

6.4 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.

6.5 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.

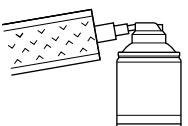
- Perform proper care regularly!

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.

6.5.1 Care products and systems - Servicing: Care with KaVo Spray

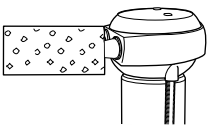
KaVo recommends servicing the product after each time it is used, i.e. after each automatic cleaning and before each sterilisation.



- Remove cutter or grinder.
- Cover the product with the CLEANpac bag.

- Place the product on the cannula and press the spray button for one second.

6.5.2 Care products and systems - Servicing: Care with the KaVo SPRAYrotor

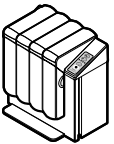


KaVo recommends servicing the product after each time it is used, i.e. after each automatic cleaning and before each sterilisation.

- 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**

6.5.3 Care products and systems - Servicing: Servicing with KaVo QUATTROcare PLUS



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

See also: Instructions for use **KaVo QUATTROcare PLUS**

6.6 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 weld the medical device in the sterilised item packaging (such as KaVo STERIclave bags **Mat. no. 0.411.9912**)!

6.7 Sterilisation

Sterilisation in a steam steriliser (autoclave) in accordance with EN 13060 / ISO 17665-1 (z. B. KaVo STERIclave B 2200 / 2200 P)

⚠ 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 ℃ (280.4 °F).

(Depending on the available autoclave,) select a suitable procedure from the following sterilisation processes:

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

6.8 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.

7 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
Drill stop	0.524.0892
Hook	0.410.1963

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

Material summary	Mat. no.
KaVo Spray 2112 A	0.411.9640
ROTAspray 2 2142 A	0.411.7520
QUATTROcare plus Spray 2140 P	1.005.4525
STERIclave bags	0.411.9912

8 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 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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