

Instructions for use

INTRAmatic contra-angle 80 E - 1.004.6401



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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Symbols

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

	Action request
	CE mark (Communauté Européenne). 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

2.1.1 Description of safety instructions: Warning symbol



Warning symbol

2.1.2 Description of safety instructions: 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.

2.1.3 Description of safety instructions: Description of danger 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, un-typical warming or when the cutter or grinder cannot be held.

- ▶ Do not use further and notify Service.

**⚠ 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.

**⚠ CAUTION**

Injury or damage due to wear.

Irregular running noise, significant vibration, overheating, imbalance or insufficient grip.

- ▶ Stop work and seek service support.

**⚠ CAUTION**

Risk of burn injury from hot handpiece head or hot handpiece lid.
Burn injuries in the mouth may be caused if the instrument overheats.

- ▶ Never touch soft tissue with the handpiece head or handpiece lid!

**⚠ CAUTION**

Risk due to incorrectly stored instrument.
Damage to clamping system from dropping the instrument.

- ▶ After treatment, place the instrument properly in the cradle without the tool.

**⚠ CAUTION**

Instructions for the safe use of handpieces with electronic micromotors. Electronic micromotors generate much more energy than conventional pneumatic turbines and motors. Given the higher torque and speed, handpieces that are poorly serviced, damaged or used improperly can overheat which can seriously burn the patient.

- ▶ Never contact soft tissue with the instrument head.

**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

The following guidelines must be observed to ensure safe use of the electrically driven handpieces:

- The service instructions for handpieces must be precisely followed when using KAVO spray or QUATTROcare care systems.
- Before each use, the handpiece must be checked for external damage.
- Before each use, perform a test run with the handpiece, and watch for atypical heating and unusual noise and vibration.
- Immediately stop using handpieces that act unusual.
- Never press the pushbutton during operation. This also includes lifting the cheek or tongue!

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 80 E, Mat. no. 1.004.6401

3.1 Purpose – Proper 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, the user is required 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

Drive speed	max. 40,000 rpm
Speed transmission	1:1
ID	1 blue ring
Pushbutton chuck	1.6 dia.
Milling cutters or grinders	ISO 1797-1 type 3

The contra-angle handpiece can be attached to INTRA motors 181K and 181KB in accordance with ISO 3964.

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

 A circular icon representing a pressure gauge. It features a central dot with two horizontal arrows pointing outwards. The label 'hPa' is positioned at the top right and bottom left of the circle, with thin lines connecting them to the gauge's perimeter.	Air pressure: 700 hPa to 1060 hPa (10 psi to 15 psi)
 A simple icon of an open umbrella with several raindrops falling from its canopy.	Protect from moisture.

4 First use



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.



4.1 Check the coolant media supply

Note

External coolant should be supplied to prevent overheating.

**⚠ CAUTION**

Overheating of the tooth due to lack of cooling water.

Thermal damage to the dental pulp.

- ▶ Adjust the water amount for the spray cooling to a minimum of 50 cm³/min

5 Operation



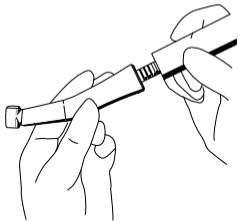
CAUTION

Removing and attaching the contra-angle handpiece while the device is rotating.

Damage to the drive.

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

5.1 Attaching the medical device



- ▶ Place the medical device on the (LUX) motor coupling and lock it into place.

- ▶ Before each treatment, pull on the medical device to see if it is securely seated in the motor coupling.

5.2 Removing the medical device

- ▶ Unlock the contra-angle handpiece from the motor coupling and remove it, or pull it off by twisting it slightly.

5.3 Inserting the milling cutters or diamond grinders



Note

Only use carbide cutters or diamond grinders that comply with 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. 25 mm
- Shaft clamping length: min. 11 mm
- Blade diameter: max. 2 mm

**⚠ WARNING****Use of unauthorised tools.**

Injury to the patient or damage to the medical device.

- ▶ Observe manufacturer instructions and use the tool properly.
- ▶ Only use tools that do not deviate from the specified data.

**⚠ CAUTION****Injury from using worn tools.**

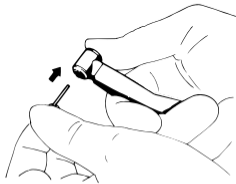
Tools can fall out during treatment and harm the patient.

- ▶ Never use tools with worn shafts.
- ▶ Follow the instructions for use of the tool.

**⚠ CAUTION**

Injury hazard from tools.
Infections or cuts.

- ▶ Wear gloves or fingerstalls.



- ▶ Press the push button firmly with your thumb and simultaneously insert the milling or grinding tool until it contacts the stop.
- ▶ Check that the cutter or grinder is securely attached by pulling on it.

5.4 Removing the milling tool or diamond grinder



CAUTION

Hazard from rotating tools.
Laceration.

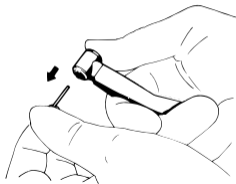
- ▶ Do not carelessly contact rotating tools.



CAUTION

Actuation of the pushbutton chuck while the tool is rotating.
Injury.
Damage to the chucking system.

- ▶ Do not press the pushbutton while the tool is rotating!



- ▶ After the tool has stopped rotating, forcefully press the pushbutton with your thumb and simultaneously remove the tool.



 **DANGER**

Hazard from defective checking 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.

6 Setup methods according to DIN EN ISO 17664

6.1 Preparation at the site of use



WARNING

Hazard from non-sterile products.

There is a risk of infection from contaminated medical devices.

- ▶ Observe 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 an ultrasonic unit.

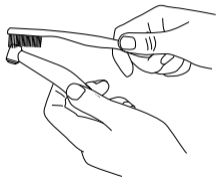
Defects in the product.

- ▶ Only clean manually or in a thermodisinfector.

6.2.1 Cleaning: Manual cleaning - external

Accessories required:

- Tap water $30\text{ °C} \pm 5\text{ °C}$ ($86\text{ °F} \pm 10\text{ °F}$)
- 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 that are operated with alkaline cleaning agents at a pH of max. 10 (e.g. Miele G 7781 / G 7881 – validation was performed with the "VARIO-TD" programme, "neodisher® mediclean" cleaning agent, "neodisher® Z" neutralisation agent, and "neodisher® mielclear" rinsing agent and extends only to the compatibility of materials with respect to KaVo products).

- ▶ For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfectant (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 cleaning - internal

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, only automated interior cleaning with thermodisinfectors in accordance with ISO 15883-1.



6.2.4 Cleaning: Automated internal cleaning

KaVo recommends thermodisinfectors in accordance with EN ISO 15883 that are operated with alkaline cleaning agents at a pH of max. 10 (e.g. Miele G 7781 / G 7881 – validation was performed with the "VARIO-TD" programme, "neodisher® mediclean" cleaning agent, "neodisher® Z" neutralisation agent, and "neodisher® mielclear" rinsing agent and extends only to the compatibility of materials with respect to KaVo products).

- ▶ For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfectant (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



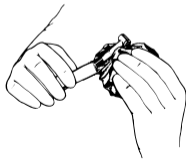
CAUTION

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.

- Microcide AF from Schülke&Mayr (liquid or cloths)
- FD 322 from Dürr

- CaviCide from Metrex

Tools required:

- Cloths for wiping down 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.

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).

- ▶ 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 that are operated with alkaline cleaning agents at a pH of max. 10 (e.g. Miele G 7781 / G 7881 – validation was performed with the ""VARIO-TD"" programme, "neodisher® mediclean" cleaning agent, "neodisher® Z" neutralisation agent, and "neodisher® mielclear" rinsing agent and extends only to the compatibility of materials with respect to KaVo products).

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

Machine drying

The drying procedure is normally part of the cleaning program of the thermodisinfectors.

- ▶ Follow the instructions for use of the thermodisinfectors.

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.



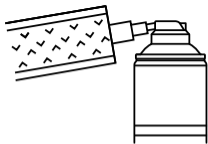
CAUTION

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.

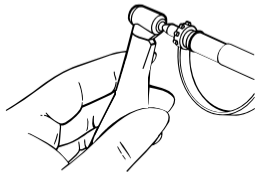
6.5.1 Care products and systems - Servicing: Care with KaVo Spray

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.

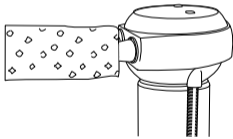
Servicing of the clamping chuck

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



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

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



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

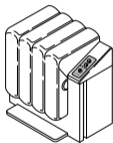
KaVo recommends servicing the product after each time it is used, i.e. after each automatic cleaning and before each sterilisation.

- ▶ 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

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



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.
- ▶ Service the product.

Chuck care

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

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



- ▶ 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: Care with KaVo QUATTROcare

6.6 Packaging



Note

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

The quality and use of the sterilised product 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 STERlclave bags **Mat. no. 0.411.9912**)!

6.7 Sterilisation

**Sterilisation in a steam steriliser (autoclave) in accordance with EN 13060/
ISO 17665-1 (e.g. KaVo STERlclave 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!

135 °C



The KaVo medical device has a maximum temperature resistance up to 138 °C (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

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

- ▶ 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
Cellulose pad 100 units	0.411.9862
Cleanpac 10 units	0.411.9691

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

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

KaVo cannot be held liable for defects and their consequences that have arisen or may arise from 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 ac-

cordance with KaVo's instructions for use or other manufacturer's instructions.

No liability is assumed when defects or their consequences are derived from manipulations or changes to the product by the customer or a third party.

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



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