Instructions for use INTRAmatic contra-angle 14 E - REF 1.003.1108 INTRAmatic contra-angle 20 E - REF 1.003.1107 INTRAmatic Prophy contra-angle 31 E - REF1.003.6976



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## Manufacturer:

Kaltenbach & Voigt GmbH Bismarckring 39 D-88400 Biberach www.kavo.com 

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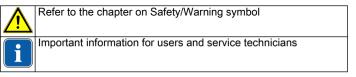
### User instructions

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



	Action request
CE	CE mark (European Community). A product bearing this mark meets the requirements of the applicable EC directive.
135°C ∭	Can be steam-sterilised at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
$[]{\hspace{-0.15cm}/\hspace{-0.15cm}}$	Thermodisinfectable

### Target group

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

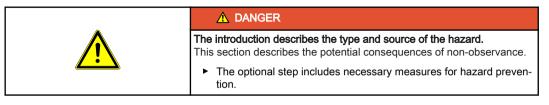
# 2 Safety

2.1.1 Description of safety instructions: Warning symbol



Warning symbol

2.1.2 Description of safety instructions: Structure



Safety

### 2.1.3 Description of safety instructions: Description of danger levels

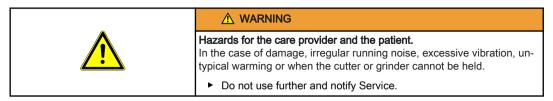
The safety instructions listed here, together with the three levels of danger will help avert property damage and injury.

<b>^</b>	
	CAUTION indicates a hazardous situation that can cause damage to property or mild to moderate injuries.

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

<b>A</b>	
	DANGER indicates a hazardous situation that can directly cause death or serious injury.

## 2.2 Safety instructions



Risk of burn injury from hot handpiece head or hot handpiece lid. Burn injuries in the mouth may be caused if the handpiece overheats.
Never touch soft tissue with the handpiece head or handpiece lid!

$\wedge$	CAUTION	
<u> </u>		

#### 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.

Premature wear and malfunctioning from improper storage during long periods of nonuse. Reduced product life.
<ul> <li>The medical device should be cleaned, serviced and stored in a dry location, according to instructions, before long periods of non- use.</li> </ul>



## Note

The head housing of the **INTRAmatic Prophy contra-angle 31 E** is protected against the permeation of polishing paste by special seals.



### 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. Safety

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

# 3 Product description



### INTRAmatic handpiece 14 E (Mat. no.1.003.1108)



INTRAmatic contra-angle handpiece 20 E (Mat. no.1.003.1107)



INTRAmatic Prophy contra-angle handpiece 31 E (Mat. no.1.003.6976)

# 3.1 Purpose - Proper use

## Purpose:

This medical device is

 intended for dental treatment only. Any other type of use or alteration to the product is impermissible and can be hazardous. The INTRAmatic contra-angles 14 E and 20 E are intended for the following applications: The removal of caries, drilling, removal of fillings, surface processing as well as the polishing and smoothing of tooth and restoration surfaces.

The **INTRAmatic Prophy contra-angle 31 E** can be used in combination with a polishing tool to support the periodontopathy treatment by means of rotating polishing.

• 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 14 E

Drive speed	
identification	1 green ring
Transmission	4 : 1

Note

Operation of product in clockwise rotation.

With press-button chuck.

Short handpiece cutters or grinders can be used.

The contra-angle can be attached to the INTRA Motor 181K.

## 3.3 Technical data 20 E

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



#### Note

Operation of product in clockwise rotation.

With press-button chuck.

Short handpiece cutters or grinders can be used.

The contra-angle can be attached to the INTRA Motor 181K.

# 3.4 Technical data 31 E

Drive speed	max. 10,000 rpm
identification	1 green ring
Transmission	4 : 1



### Note

Operation of product in clockwise rotation.

Rubber cups and polishing brushes can be used.

The contra-angle can be attached to the INTRA Motor 181K.

# 3.5 Transportation and storage conditions

It is hazardous to start up the medical device after it has been stored strongly refrigerated. This can cause the medical device to malfunction.
<ul> <li>Prior to start-up, very cold products must be heated to a tempera- ture of 20°C to 25°C (68°F to 77°F).</li> </ul>

	, C	Temperature: -20°C to +70°C (-4°F to +158°F)
)Ž		Relative humidity: 5% RH to 95% RH absence of condensation

hPa hPa	Air pressure: 700 hPa to 1060 hPa (10 psi to 15 psi)
Ť	Protect from moisture

# 4 Start up and shut down

	A WARNING
	Hazard from nonsterile products. Infection danger to the care provider and patient.
	<ul> <li>Before first use and after each use, prepare and sterilise the medi- cal device if needed.</li> </ul>
	<b>Disposal of the product in the appropriate manner.</b> Prior to disposal, the product must be appropriately prepared or steri-

lised if this is necessary.

# 5 Operation

# 5.1 Attach the medical device

	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.
	<ul> <li>Carefully pull on it before each treatment to ensure that the medical device is securely locked on the motor coupling.</li> </ul>

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.

 Before each treatment, pull on the medical device to check that it is securely seated in the motor coupling.

## 5.2 Remove the medical device

- Remove the medical device from the motor coupling in an axial direction.
- 5.3 Inserting the milling tool or diamond grinder into the E 14 / E 20



#### Note

Only use carbide cutters or diamond burs that correspond to ISO 1797-1 type 1, are made of steel or tungsten carbide and meet the following criteria:

- shaft diameter: 2.334 to 2.35 mm

- overall length: max. 22 mm

A WARNING
<ul> <li>Use of unauthorised cutters or grinders.</li> <li>Injury to the patient or damage to the medical device.</li> <li>Observe the instructions for use and use the cutter or grinder properly.</li> <li>Only use cutters or grinders that do not deviate from the specified data.</li> </ul>

Injury from using worn drill bits or burs. Drill bits or burs could fall out during treatment and injure the patient.
<ul> <li>Never use drill bits or burs with worn shafts.</li> </ul>

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		CAUTIO	N		

**Injury hazard from cutters or grinders.** Infections or cuts.

► Wear gloves or fingerstalls.

<ul> <li>Hazard from defective chucking system.</li> <li>The cutter or grinder could fall out and cause injury.</li> <li>▶ 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.</li> </ul>



Insert the cutter or grinder into the segment of the head drive by twisting the tool slightly, and push to the stop.

Check that the tool is seated by pulling on it.

# 5.4 Removing the milling tool or diamond grinder from E 14 / E 20





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

## 5.5 Inserting the prophy cup or polishing brush into the E 31

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Note

Only use rubber calyces and polishing brushes that are conformant with DIN EN ISO 13295.

	Use of impermissible inserts. Injury to the patient or damage to the medical device.
	<ul> <li>Observe the instructions for use, and use the insert properly.</li> </ul>

	Danger of injury from insert. Infections or cuts.
	<ul> <li>Wear gloves or fingerstalls.</li> </ul>

	Hazard to patients A loosened insert can lead to injury.
	<ul> <li>Check that the insert is firmly attached to the head by pulling on it.</li> </ul>

Block drive with holder..





Push or screw the insert onto/into the head.

- Remove the holder.
- Check that the insert is firmly seated.

# 5.6 Removing prophy cups or polishing brushes from the E 31

Hazard from rotating insert. Lacerations.
<ul> <li>Do not touch rotating insert!</li> <li>Remove the insert from the contra-angle handpiece after treatment to avoid injury and infection during storage.</li> </ul>

• After movement has stopped, unscrew or remove the insert.

# 6 Reprocessing methods according to ISO 17664

# 6.1 Preparation at the site of use

	Hazard from nonsterile products. There is a risk of infection from contaminated medical devices.
	<ul> <li>Take suitable personal protective measures.</li> </ul>

- 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

Malfunctions from cleaning in the ultrasonic unit. Defects in the product.
<ul> <li>Only clean manually or in a thermodisinfector.</li> </ul>

6.2.1 Cleaning: Manual external cleaning

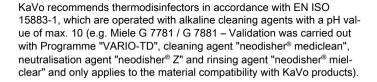
Accessories required:

- Tap water 30 °C ± 5 °C (86 °F ± 10 °F)
- Brush, e.g. medium-hard toothbrush



Brush off under flowing tap water.

#### 6.2.2 Cleaning: Automated external cleaning



- 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

Malfunctioning from using a disinfectant bath or disinfectant containing chlorine. Defects in the product.
<ul> <li>Only disinfect in a thermodisinfector or manually.</li> </ul>

#### 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 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 dis-

infection 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

Sharp cutters or grinders in the medical device. Risk of injury from sharp or pointed cutters or grinders.
<ul> <li>Remove cutter or grinder.</li> </ul>

<b>Premature wear and malfunctions from improper servicing and care.</b> Reduced product life.
Perform proper care regularly!

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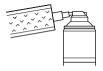


#### Note

Take the prophy cup or polishing brush out of the **INTRAmatic Prophy contra-angle 31 E** for conditioning.

#### 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.

Removing the milling tool, grinder or insert.

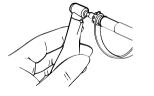
- Cover the product with the Cleanpac bag.
- Plug the product onto the cannula, and press the spray button for one second.

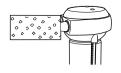
## Servicing the chuck for 14 E / 20 E

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 2104 / 2104A

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 the cutter or grinder.
- Servicing the product.



# Servicing the chuck for 14 E / 20 E

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 speci-► fied

See also: Servicing with KaVo QUATTROcare 2104 / 2104A

# 6.5.4 Care products and systems - Servicing: 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.

Servicing the product in QUATTROcare PLUS. ٠

See also: Instructions for use KaVo QUATTROcare PLUS



#### Servicing the chuck for 14 E / 20 E

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

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



# Switch on the chuck service mode.

Note

No handpieces may be on the treatment coupling at the start of and during the chuck service mode.

Close the front flap and press the chuck service button 0 for at least three seconds until the spray canister control LED 0 flashes three times consecutively. The QUATTROcare is now in chuck service mode.



 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

**Completing the chuck service mode.** Option 1: Equipping the **QUATTROcare** with handpieces and closing the front panel. Option 2: after three minutes without a service procedure, the device

switches automatically to normal service mode.

See also: Care with 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 guality 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.

# 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)



Ń	
	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  $^\circ C$  (280.4  $^\circ F).$ 

(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.
Holder (31 E)	1.004.0596
Instrument stand 2151	0.411.9501
Cleanpac 10 units	0.411.9691
Cellulose pad 100 units	0.411.9862

Material summary	Mat. no.
Adaptor INTRAmatic (CLEANspray	1.007.1776
and DRYspray)	
KaVo CLEANspray 2110 P	1.007.0579
KaVo DRYspray 2117 P	1.007.0580
KaVo Spray 2112 A	0.411.9640

Material summary	Mat. no.
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 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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