Instructions for use

SMARTmatic PROPHY S31 - 1.011.6760
SMARTmatic PROPHY S31 K - 1.011.6761
SMARTmatic PROPHY S33 - 1.011.6800

KAVO
Dental Excellence

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CE 0124

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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.

KaVo Repair Service
KaVo Dental Technologies, LLC
11727 Fruehauf Drive
Charlotte, NC 28273 USA
Toll-free Direct Customer Service: 1-888-ASK-KAVO (888-275-5286)
Email: techservice@kavokerr.com
www.kavo.com

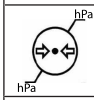
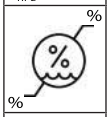
Please direct all questions regarding the product, service and maintenance to the
KaVo Technical Service:
Toll-free: 1-888-ASK-KAVO (888-275-5286)
Email: customerservice@kavokerr.com
Please refer to the serial number of the product in all inquiries!

General marks and symbols

	Refer to the chapter on Safety/Warning symbol
	Important information for users and service technicians
▶	Action request
135 °C 	Sterilization parameters 1. Autoclave with pre-vacuum: at least 3 minutes at 135 °C (275 °F) Drying time: 16 min. 2. Autoclave using the gravity method: at least 10 minutes at 135 °C (275 °F) Drying time: 30 min.
	Suitable for disinfection in a washer disinfector

Information on the package labeling

REF	Catalogue number
SN	Serial number
	Legal Manufacturer

	CE mark according to Medical Devices Directive EC 93/42
	Please note the electronic instructions for use
	Caution: Consult instructions for use
	EAC conformity mark (Eurasian Conformity)
	GOST R certification
	Transportation and storage conditions (Temperature range)
	Transportation and storage conditions (Air pressure)
	Transportation and storage conditions (Humidity range)
	Protect from moisture (Keep dry)
	Fragile, handle with care
	HIBC Code

Hazard levels

The warning and safety notes in this document must be observed to prevent personal injury and property 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 moderate or mild injury.

NOTICE

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

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 can 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, process and sterilize the medical device and accessories appropriately.
- Carry out the cleaning and sterilization 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 ensure the effectiveness of the cleaning and sterilization.
- Prior to disposal, the product and accessories must be appropriately processed and sterilized.
- In the case of injury to soft tissue, do not continue treatment in the oral cavity with instruments driven by compressed air.
- To test, use and remove the tool, use a glove or finger guard.

2.2 Technical condition

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

- Use the device and components only if there is no damage on the outside.
- Check to make sure 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 the following defects occur, stop working and have the service personnel carry out repair work:
  - Malfunctions
  - Damage
  - Irregular running noise
  - Excessive vibration
  - Overheating
  - Tool is not seated firmly in the handpiece

To ensure optimum function and to prevent property damage, please comply with the following instructions:

- Service the medical device with care products and systems regularly as described in the instructions for use.
- The device should be cleaned, serviced and stored in a dry location, according to instructions, if it is not to be used for an extended period of time.

High torque of micromotors can lead to severe burn injuries.

- Service micromotors regularly.

- Do no use any damaged motors.
- Do not use motors for unauthorized purposes.

Note

The head housing is protected against the ingress of polishing paste by special seals.

2.3 Accessories and combination with other equipment

Use of un-authorized accessories on the device or un-authorized modifications to the device can 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 standardized interfaces.
- Do not make any modifications to the device unless these have been approved by the manufacturer of the product.

The lack of control equipment for changing the speed range and the direction of rotation can lead to injury.

- Control facility for changing the speed and the direction of rotation must be present.
- The medical device may only be combined with a treatment center released by KaVo.
- Comply with the Instructions for Use of the treatment center.

2.4 Qualification of personnel

Application of the product by users lacking appropriate medical training can injure the patient, the user or third parties.

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

Improper use of the device can lead to burns or injuries.

- Never touch the handpiece head or handpiece lid to soft tissue!
- After treatment, place the medical device properly in the cradle without the tool.

2.5 Service and repair

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

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

Comply with the following items during all servicing work:

- Have the service and testing tasks carried out in accordance with the authorized personal.
- Following expiration of the warranty, have the tool holding system checked once a year.

- Have the medical device evaluated by a professional shop with regard to its cleaning, servicing and functional needs according to an in-house service interval. Define the service interval depending on the frequency of use.

3 Description of the product

SMARTmatic PROPHY S31 (Mat. No. 1.011.6760)

SMARTmatic PROPHY S31 K (Mat. No. 1.011.6761)

SMARTmatic PROPHY S33 (Mat. No. 1.011.6800)

The SMARTmatic electrical-driven handpieces are dental handpieces according to 21 CFR § 872.4200 (dental handpieces and accessories) for the use by a trained professional in the field of general dentistry.
The devices are electrical-powered handpieces that are reusable and ergonomically shaped. The devices can be sterilized by the steam autoclave method. Through the tube and the electrical motor connected to a dental unit, the SMARTmatic handpieces equipped with a handpiece connection according to ISO 3964 receive the energy for the gear, the cooling water and air for cutting treatment. Dental burs and other attachments according to ISO 1797-1 will be used with the SMARTmatic handpieces. Based on the INTRAmatic connection that meets the ISO 3964 the SMARTmatic handpieces fit with any electrical dental motor which is produced in accordance to this standard. The electrical motors carry the energy for the gear, the cooling water and air for cutting treatment from the dental treatment unit to the SMARTmatic handpieces.

3.1 Intended use

Indications for use:

The SMARTmatic handpieces are intended for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, root canal preparations, removal of fillings, processing and finishing tooth preparations, restorations, and for polishing teeth. They are designed for use by a trained professional in the field of general dentistry.

⚠ CAUTION

US Federal law restricts this device to sale by or on the order of a healthcare professional / dentist.
For dental use only.

Proper Use:

In accordance with these regulations, this medical device may only be used by a properly trained user and for the application described herein. You need to comply with the following:

- the applicable health and safety regulations
- the applicable accident prevention regulations
- these Instructions for use

In accordance with these regulations, the user is required to:

- only use equipment that is operating properly
- adhere to the specified intended use
- protect himself or herself, the patient and third parties from danger, and
- avoid contamination from the product

3.2 Technical specifications for S31 and S31 K

Drive speed	max. 20,000 rpm^{-1}
Speed transmission	8:1
Recommended drive speed	max. 500 to 2,500 rpm^{-1}
Cooling air flow	5.5 to 9.5 Nl/min

Note
Operate the product with clockwise rotation.
The support (spindle) for the snap-on polishing attachments can be unscrewed.

The polishing attachments with screw-in for thread types N1-72 UNF and N1-64 UNC or supports with snap-on function in accordance with ISO 13295, type 5 support available in dentistry can be used.

The contra-angle handpiece S31 can be mounted on all INTRAmatic motors and motors fitted with a connector in accordance with ISO 3964.

The contra-angle handpiece S31 K can be mounted on INTRA Motor 181K.

3.3 Technical specifications for the S 33

Drive speed	max. 20,000 rpm^{-1}
Speed transmission	8:1
Recommended drive speed	max. 500 to 2,500 rpm^{-1}

The drive speed is converted into an oscillating motion of approx. 70°.

The snap-on polishing attachments available in dentistry can be attached.

The contra-angle handpiece S33 can be mounted on all INTRAmatic (LUX) motors and motors fitted with a connector in accordance with ISO 3964.

Note
The support (spindle) for the snap-on polishing attachments cannot be unscrewed.

3.4 Transportation and storage conditions

- Do not store in a refrigerated environment.

	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 (Keep dry)

4 Startup and shut-down

⚠ WARNING

Hazard from non-sterile products.

Infection hazard for dentist and patient.

- Prior to initial startup and after each use, process the product and accessories.

⚠ WARNING

Dispose of the product in the appropriate manner.

Infection hazard.

- Process the product and accessories before disposal.

NOTICE

Damage from contaminated and moist cooling air.

Contaminated and moist cooling air can cause malfunctions.

- Make sure that the supplied cooling air is dry, clean and free of contamination in accordance with ISO 7494-2.

NOTICE

Damage to the contra-angle handpiece caused by spray air and spray water.

Property damage

- Un-select spray air and spray water on the supply unit before startup!

5 Operation

5.1 Attaching the medical device

⚠ WARNING

Detachment of the medical device during treatment.

A medical device that is not properly locked in place can become disconnected from the motor coupling and fall off.

- Carefully pull on the medical device before each treatment to make sure that it is securely locked onto the motor coupling.

NOTICE

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

Damage to the driver.

- Never attach or remove the contra-angle handpiece while the drive motor is rotating.

NOTICE

Pressing the foot switch while attaching or detaching the medical device.

Property damage to the medical device.

- Do not connect or remove the medical device while pressing the foot switch.

- Lightly spray O-rings on motor coupling with KaVo Spray.

- Attach the medical device to the motor coupling and lock it into place.

- Pull on the medical device to make sure that it is securely affixed to the coupling.

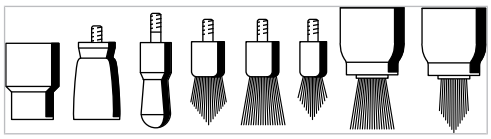
5.2 Removing the medical device

- Unlock the medical device from the motor coupling by twisting it slightly and then pulling it along its axis.

5.3 Inserting the prophy cups or polishing brushes

Note

Only use prophy cups or polishing brushes in accordance with ISO 13295 for support (spindle) type 5.



⚠ WARNING

Use of non-approved inserts.

Injury to the patient or damage to the medical device.

- Comply with the instructions for use and the intended use of the insert.

⚠ CAUTION

Injury from using worn inserts.

Insert can fall out during treatment and harm the patient.

- Never use inserts with a worn thread.

⚠ CAUTION

Risk of injury from the insert.

Infections or cuts.

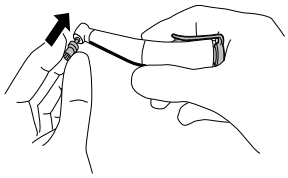
- Wear gloves or finger guards.

⚠ CAUTION

Risk of burn injury from hot handpiece head.

If prophylaxis cups touch the handpiece head, the head may heat up due to friction. Burn injuries in the mouth may be caused if the handpiece overheats.

- Do not use prophylaxis cups that touch against the handpiece head.



- Block the catch pin of the contra-angle handpiece with the enclosed holder.

- Screw or push the insert into/onto the head
- Remove the holder.
- Make sure that the insert is firmly seated.

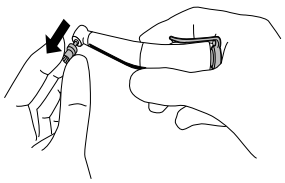
5.4 Removing prophy cups or polishing brushes

⚠ WARNING

Hazard from rotating insert.

Lacerations.

- Do not touch rotating insert!
- Remove the insert from the contra-angle handpiece after treatment to avoid injury and infection during storage.



- Block the catch pin of the contra-angle handpiece with the enclosed holder.

- Unscrew and/or take off the insert from the head.

6 Checking for malfunctions and troubleshooting

⚠ CAUTION

Missing or damaged O-rings.

Malfunctions and premature failure.

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

⚠ CAUTION

Product heats up.

Burn injury or product damage due to over-heating.

- Do not continue working if the product heats up irregularly.

- The medical device overheats while working:
  Service the medical device.
- When the speed drops or is uneven:
  Service the medical device.
- Missing O-ring on the motor coupling:
  Replace O-ring.

See also:

Instructions for use of motor

6.1 Troubleshooting

6.1.1 Replacing the O-rings

⚠ CAUTION

Hazard due to improper servicing of the O-rings.

Malfunctions or complete failure of the medical device.

- Do not use Vaseline or other grease or oil.

Note

The O-rings on the coupling may only be lubricated with a cotton ball wetted with KaVo Spray.

- Press the O-ring between your fingers to form a loop.
- Push the O-ring to the front, and remove it.
- Insert new O-rings into the grooves.

7 Processing steps in accordance with ISO 17664

7.1 Preparations at the site of use

⚠ WARNING

Hazard from non-sterile products.

There is a risk of infection from contaminated medical devices.

- ▸ Take suitable personal protective measures.

- ▸ Take screw-in and/or snap-on polishing attachments off the contra-angle handpiece.
- ▸ Remove all residual cement, composite or blood immediately.
- ▸ Process the medical device as soon as possible after treatment.
- ▸ The medical device must be dry when transported to processing.
- ▸ Do not immerse in solutions or the like.

7.2 Cleaning

NOTICE

Never process this medical device in an ultrasonic device.

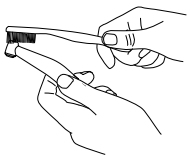
Functional damage and property damage.

- ▸ Clean manually or in a washer disinfector only.

7.2.1 Manual external cleaning

Accessories required:

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



- ▸ Brush under flowing tap water.

7.2.2 Automated external cleaning

KaVo recommends washer disinfectors in compliance with ISO 15883-1, which are operated using alkaline cleaning agents.

- ▸ The program settings and cleansers and disinfectants that must be used can be found in the instructions for use of the thermodisinfector.
- ▸ Directly after automated cleaning/disinfection, treat the medical device with the care products and systems supplied by KaVo.

7.2.3 Manual internal cleaning

The interior of this product is not to be cleaned manually.

7.2.4 Automated internal cleaning

KaVo recommends washer disinfectors in compliance with ISO 15883-1, which are operated using alkaline cleaning agents.

- For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the washer disinfector.
- In order to prevent damage to the medical device due to residual fluid, make sure that the inside and outside of the device is dry after the end of the cycle. Remove any residual liquids from the interior and exterior of the medical device using compressed air.
- Immediately after drying, lubricate the medical device with care agents from the KaVo care system.

The drying procedure is usually part of the cleaning program of the washer disinfector.

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

7.3 Disinfection

⚠ WARNING

Incomplete disinfection.
Infection hazard
- Principally, KaVo recommends carrying out a final disinfection of the unpackaged item in the sterilizer unit if complete disinfection cannot be guaranteed without this measure.

NOTICE

Using the disinfectant bath or chlorine-containing disinfectants.
Functional damage and property damage.
- Do not disinfect the device in the disinfection bath or with chlorine-containing disinfectants.

7.3.1 Manual external disinfection

KaVo recommends the following products based on material compatibility. The microbiological efficacy must be ensured by the disinfectant manufacturer and proven by an expert opinion.

- 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 in accordance with the instructions of the disinfectant manufacturer.
- Comply with the instructions for use of the disinfectant.

7.3.2 Manual internal disinfection

Not applicable.

This product is suitable for automated disinfection only.

7.3.3 Automated external and internal disinfection

KaVo recommends washer disinfectors in compliance with ISO 15883-1, which are operated using alkaline cleaning agents.

- For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the washer disinfector.
- In order to prevent damage to the medical device due to residual fluid, make sure that the inside and outside of the device is dry after the end of the cycle. Remove any residual liquids from the interior and exterior of the medical device using compressed air.
- Immediately after drying, lubricate the medical device with care agents from the KaVo care system.

The drying procedure is usually part of the cleaning program of the washer disinfector.

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

7.4 Drying

Manual drying

- Clean the outside and inside with compressed air until no drops of water are visible.

Automated drying

The drying procedure is usually part of the cleaning program of the washer disinfector.

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

7.5 Care products and systems - Servicing

NOTICE

Improper service and care.
Premature wear and reduced product service life.

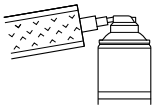
- Perform proper service regularly.

Note
Remove the insert for servicing.

Note
KaVo only guarantees that its products will function properly if the care products listed as accessories are used, since these products have been tested for proper use on our products.

7.5.1 Servicing with KaVo Spray

KaVo recommends servicing the product as part of the processing after each use, i.e. after each cleaning, disinfection, and before each sterilization.



- Take screw-in and/or snap-on polishing attachments off the contra-angle handpiece.
- Cover the product with the Cleanpac bag.
- Plug the product onto the cannula, and press the spray button for one second.

7.5.2 Servicing with KaVo QUATTROcare

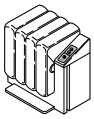
Note

QUATTROcare 2104 / 2104 A is no longer included in the current delivery program.

Follow-up product:

- QUATTROcare PLUS 2124 A

Servicing and cleaning device with expansion pressure for internal cleaning of inorganic residues and optimum servicing.
(no validated internal cleaning in accordance with German RKI requirements)



KaVo recommends servicing the product as part of the processing after each use, i.e. after each cleaning, disinfection, and before each sterilization.

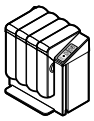
- Take screw-in and/or snap-on polishing attachments off the contra-angle handpiece.
- Service the product.

See also:

Instructions for use KaVo QUATTROcare 2104 / 2104A

7.5.3 Servicing with KaVo QUATTROcare PLUS

Servicing and cleaning device with expansion pressure for internal cleaning of inorganic residues and optimum servicing.
(no validated internal cleaning in accordance with German RKI requirements)
KaVo recommends servicing the product as part of the processing after each use, i.e. after each cleaning, disinfection, and before each sterilization.



- Take screw-in and/or snap-on polishing attachments off the contra-angle handpiece.
- Service the product in the QUATTROcare PLUS.

See also:

Instructions for use KaVo QUATTROcare PLUS

7.6 Packaging

Note

The sterilization bag must be large enough for the handpiece to fit without stretching the bag.

The quality and use of the sterilization packaging must comply with applicable standards and be suitable for the sterilization procedure!

- ▸ Seal each medical device individually in a sterilization item package.

7.7 Sterilization

Sterilization in a steam sterilizer (autoclave) in accordance with ISO 17665-1

NOTICE

Improper service and care.

Premature wear and reduced product service life.

- ▸ Before each sterilization cycle, service the medical device with KaVo care products.

NOTICE

Contact corrosion due to moisture.

Damage to the product.

- ▸ Remove the product from the steam sterilization immediately after the sterilization cycle.

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

Select a suitable procedure (depending on the available autoclave) from the following sterilization processes:

- ▪ Sterilizer with triple pre-vacuum:
  - at least 3 minutes at 135°C (275 °F)
- – Drying time: 16 min.
- ▪ Sterilizer using the gravity method:
  - at least 10 minutes at 135°C (275 °F)
- – Drying time: 30 min.
- ▸ Use in accordance with the manufacturer's Instructions for Use.

7.8 Storage

Processed products must be stored, protected from bacteria, to the extent possible, and dust, in a dry, dark, cool room.

Note

Comply with the expiration date of the sterilized items.

8 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
Holder	1.004.0596
Spray head INTRA (KaVo Spray)	0.411.9911
INTRA service coupling	1.009.6143
Spindle	0.549.0602

Material summary	Mat. No.
Adapter INTRAmatic (CLEANspray and DRYspray)	1.007.1776
KaVo CLEANspray 2110 P	1.007.0579
KaVo DRYspray 2117 P	1.007.0580
KaVo Spray 2112 A	0.411.9640
ROTAspray 2 2142 A	0.411.7520
QUATTROcare plus Spray 2140 P	1.005.4525

Material summary	Mat. No.
KaVo Spray USA and Canada 2113 A	0.411.9660
QUATTROcare plus Spray USA and Canada 2141 P	1.005.4524

9 Terms and conditions of warranty

The following Terms and conditions of warranty 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 honor its warranty with a free repair or replacement, as needed. 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, noncompliance 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, optical fibers made of glass and glass fibers, glassware, rubber parts, and the colorfastness of plastic parts.
All liability shall be 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 authorized by KaVo.
Warranty claims shall be accepted only 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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