Instructions for use

SMARTmatic PROPHY S19 - 1.011.6740
SMARTmatic PROPHY S19 K - 1.011.6741

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.

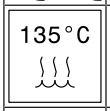
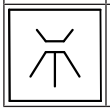
KaVo Repair Service
For repairs, please contact your local dealer or the KaVo Repair Service directly:
+49 (0) 7351 56-1900
service.reparatur@kavo.com

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

Target group

This document is intended for dentists and their assistants. The startup section is also intended for service technicians.

General marks and symbols

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

Hazard levels

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

⚠ DANGER

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

⚠ WARNING

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

⚠ CAUTION

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

NOTICE

In cases which – if not prevented – could lead to material 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 instructions for use, any other type of use is not permitted.

2.1 Infection hazard

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

- Take suitable personal protective measures.
- Follow the instructions for using the components.
- Before the initial startup and after each use, prepare and sterilise the medical device and accessories accordingly.
- Carry out the cleaning and sterilisation as described in the instructions for use. The procedure has been validated by the manufacturer.
- It is essential to ensure the effectiveness of the cleaning and sterilisation in the case of deviation in procedure.
- Prior to disposal, the product and accessories must be appropriately prepared or sterilised.
- In the case of injury to soft tissue, do not continue treatment in the oral cavity with instruments driven by compressed air.
- Use gloves or finger guard whenever you test, insert, and remove the tool.

2.2 Technical condition

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

- Only operate devices or components if they are undamaged on the outside.
- Check that the device is working properly and is in satisfactory condition before each use.
- Have parts with sites of breakage or surface changes checked by the Service.
- If 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

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

- 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 will not be used for a longer period.

High torque of micromotors can lead to severe burn injuries.

- Service micromotors regularly.
- Do no use any damaged motors.

- Do not use motors for unauthorised purposes.

2.3 Accessories and combination with other equipment

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

- Only use accessories that have been approved for combination with the product by the manufacturer.
- Only use accessories that are equipped with standardised interfaces.
- 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 centre released by KaVo.
- Comply with the Instructions for Use of the treatment centre.

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 centre released by KaVo.
- Comply with the Instructions for Use of the treatment centre.

2.4 Qualification of personnel

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

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

The improper use of the device could lead to burns or injuries.

- 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 authorised to do this:

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

Observe all the following items during servicing work:

- Have the service and testing tasks carried out in accordance with the Medical Product Operator Ordinance.
- Following expiry of the warranty, have the tool holding system checked once a year.

- KaVo recommends specifying in-house service intervals where the medical device is brought to a professional shop for cleaning, servicing and a function check. Defined the service interval depending on the frequency of use.

3 Description of the product

SMARTmatic PROPHY S19 (Mat. No. 1.011.6740)

SMARTmatic PROPHY S19 K (Mat. No. 1.011.6741)

3.1 Intended use

Indications for use:

This medical device is
- intended for dental treatment only. All other types of use or modifications of the product are not permitted and can be hazardous. The medical device can be used in combination with a polishing tool to support the periodontal treatment by polishing with a rotating tool.
- A medical device according to relevant national statutory regulations.

Proper use:

According to these provisions, this medical device may only be used for the described application by a properly trained user. You need to comply with the following:
- the applicable health and safety regulations
- the applicable accident prevention regulations
- these Instructions for use

According to these regulations, the user is required to:
- to only use equipment that is operating correctly,
- adhere to the specified intended use
- to protect him or herself, the patient and third parties from hazards, and
- to prevent contamination from the product

3.2 Technical Specifications

Drive speed	max. 20,000 rpm
Speed transmission	8:1
Cooling air flow	5.5 to 9.5 Nl/min

Prophylaxis heads with a Doriot connector can be inserted. Shaft and/or drive shaft in accordance with DIN EN ISO 14457 for:

- metallic and ceramic materials: Ø2.35 0/-0.016mm.
- Plastics: Ø2.35 0/-0.05mm.

Handpiece S19 can be mounted on all INTRAmatic (LUX) motors, and motors with a connection in accordance with ISO 3964 / DIN 13940.
Handpiece S19 K can be attached to the INTRA Motor 181K.

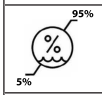
3.3 Transportation and storage conditions

NOTICE

Startup after refrigerated storage.

Malfunction.

- Prior to startup, very cold products must be heated up to a temperature of 20 °C to 25 °C (68 °F to 77 °F).

	Temperature: -20°C to +70°C (-4°F to +158°F)
	Relative humidity: 5% RH to 95% RH absence of condensation
	Air pressure: 700 hPa to 1060 hPa (10 psi to 15 psi)
	Protect from moisture

4 Startup and shut down

⚠ WARNING

Hazard from non-sterile products.

Infection hazard for care provider and patient.

- Before first use and after each use, sterilise the medical device.

⚠ WARNING

Dispose of the product in appropriate manner.

Infection hazard.

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

NOTICE

Damage from soiled and moist cooling air.

Contaminated and moist cooling air can cause malfunctions.

- Make sure that the supply of cooling air is dry, clean, and uncontaminated according to EN ISO 7494-2.

NOTICE

Damage to the 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

⚠ CAUTION

Detachment of the medical device during treatment.

Injury or property damage

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

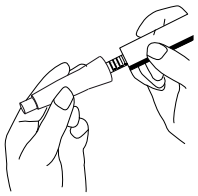
- Carefully pull on the medical device before each treatment to ensure that it is securely locked onto the motor coupling.

NOTICE

Removing and attaching the handpiece while the drive motor is rotating.

Damage to the driver.

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



- Lightly spray O-rings on motor coupling with KaVo Spray.
- Attach the handpiece to the motor coupling until it locks into place.
- Before each treatment, pull on the medical device to make sure that the handpiece is securely seated on the motor coupling.

5.2 Removing the medical device

- Unlock the handpiece from the motor coupling in axial direction and remove it, or pull it off by twisting it slightly.

5.3 Attach the prophylaxis head

Note

All prophylaxis heads with a Doriot connection can be attached.

The clamping system is designed for drive shafts working in accordance with DIN EN ISO 14457 for metallic and ceramic materials: Ø2.35 0/-0.016mm and plastic materials: Ø2.35 0/-0.05mm.

⚠ WARNING

Use of unauthorised prophylaxis heads.

Injury to the patient or damage to the medical device.

- Comply with the instructions for use and the intended use of the tools.
- Only use prophylaxis heads that do not deviate from the specified data.

⚠ WARNING

Damaged prophylaxis head.

Injuries.

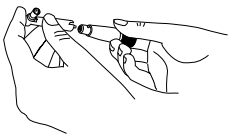
- Check the prophylaxis head for damage before each use.
- See the manufacturer's instructions for use.

NOTICE

Rotating prophylaxis head.

Damage to the chucking system.

- Never attach or remove the prophylaxis head while the device is rotating!



- Attach the prophylaxis head on the handpiece proceeding in axial direction to the limit stop.

- Before the start of treatment, check if the seat is secure by pulling on the head.

5.4 Removing the prophylaxis head

- Remove the prophylaxis head axially from the handpiece.

⚠ CAUTION

Hazard due to incorrectly stored instrument.

Injury and infection from clamped prophylaxis head.

- After each treatment, place the instrument properly in the cradle without the prophylaxis head.

6 Checking for malfunctions and troubleshooting

6.1 Checking for malfunctions

⚠ CAUTION

Missing or damaged O-rings.

Malfunction and premature failure.

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

⚠ CAUTION

Heating of the product.

Burns or product damage from overheating.

- Do not use the product if it is irregularly heated.

- The medical device is too hot while working:
  Service the medical device.
- When the speed drops or is uneven:
  Service the medical device.
- An O-ring is missing on the motor coupling:
  Replace O-ring.

See also:

Instructions for use of motor

6.2 Troubleshooting

6.2.1 Replacing the O-rings

⚠ CAUTION

Hazard from improper care of the O-rings.

Functional problem 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 Reprocessing 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.

- ▸ Remove all residual cement, composite or blood immediately.
- ▸ Reprocess the medical device as soon as possible after treatment.
- ▸ Remove the prophylaxis head from the medical device
- ▸ The medical device must be dry when transported to reprocessing.
- ▸ Do not place in solutions or similar substance.

7.2 Cleaning

NOTICE

Never reprocess this medical device in an ultrasonic device.

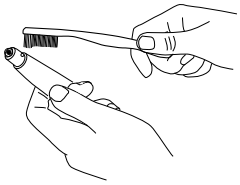
Malfunction and material damage.

- ▸ 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 off under flowing tap water.

7.2.2 Automated external cleaning

KaVo recommends washer disinfectors in compliance with EN ISO 15883-1 that are operated with alkaline cleaning agents.

The validations were conducted with the VARIO-TD program, the cleaning agent neodisher® MediClean and the neutralisation agent neodisher® Z.

- ▸ The program settings and cleansers and disinfectants that must be used can be found in the instructions for use of the thermodisinfector.
- ▸ In order to prevent negative effects on the KaVo medical device, make sure that the interior and the exterior of the medical device are dry after completion of the cycle, and then grease it immediately with servicing agents from the KaVo care system.

7.2.3 Manual internal cleaning

Validated internal cleaning (removal of residual protein) can be accomplished with KaVo CLEANspray and 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 cleanser act 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.

7.2.4 Automated internal cleaning

KaVo recommends washer disinfectors in compliance with EN ISO 15883-1 that are operated with alkaline cleaning agents.
The validations were conducted with the VARIO-TD program, the cleaning agent neodisher® MediClean and the neutralisation agent neodisher® Z.

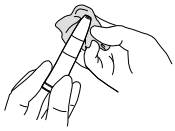
- For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector.
- In order to prevent negative effects on the KaVo medical device, make sure that the interior and the exterior of the medical device are dry after completion of the cycle, and then grease it immediately with servicing agents from the KaVo care system.

7.3 Disinfection

⚠ WARNING
Incomplete disinfection.
Infection hazard.
- Principally, KaVo recommends carrying out an final disinfection of the unpackaged item to guarantee the complete disinfection.

NOTICE
Using the disinfectant bath or chlorine-containing disinfectants.
Malfunction and material 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 compatibility of the materials.
The microbiological efficacy must be ensured by the disinfectant manufacturer and proven by an expert opinion.

- Mikrozid AF made by Schülke & Mayr (liquid or cloths)
- FD 322 made by Dürr

Consumables required:
- Cloths for wiping the medical device.

▸ Spray the disinfectant on a cloth, then wipe down the medical device and allow the disinfectant to act according to the instructions of the disinfectant manufacturer.

Note
Follow the instructions for use of the disinfectant.

7.3.2 Manual internal disinfection

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).

▸ Blow off with compressed air until no water drops are visible.
▸ Immediately after internal disinfection, lubricate the KaVo medical device with care agents from the KaVo care system.

7.3.3 Automated external and internal disinfection

KaVo recommends washer disinfectors in compliance with EN ISO 15883-1 that are operated with alkaline cleaning agents.
The validations were conducted with the VARIO-TD program, the cleaning agent neodisher® MediClean and the neutralisation agent neodisher® Z.

▸ For programme 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 negative effects on the KaVo medical device, make sure that the interior and the exterior of the medical device are dry after completion of the cycle, and then grease it immediately with servicing agents from the KaVo care system.

7.4 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 usually part of the cleaning programme of the washer disinfector.

▸ Follow the instructions for use of the thermodisinfector.

7.5 Care products and systems - Servicing

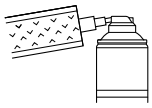
NOTICE

Improper service and care.
Premature wear and reduced product service life.
▸ Service regularly with suitable agents.

Note
KaVo guarantees the proper function of KaVo products only if the care products listed as accessories are used, since these were tested for proper use on our products.

7.5.1 Servicing with KaVo Spray

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

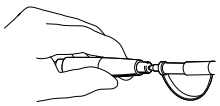


- Remove the tool.

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

Servicing the chucking system

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

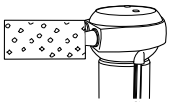


- Remove the tool, place the spray nipple tip in the opening and spray.

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

7.5.2 Servicing with KaVo SPRAYrotor

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



- Place the product on the appropriate coupling on the KaVo SPRAYrotor and cover it with the Cleanpac bag.
- Service the product.

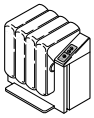
See also:
- Instructions for use KaVo SPRAYrotor

7.5.3 Servicing with KaVo QUATTROcare

Note

QUATTROcare 2104 / 2104 A is no longer included in the current delivery programme.
Follow-up product:
- QUATTROcare PLUS 2124 A

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



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

- Remove the dental bur or diamond grinder.
- Service the product.

See also:
- Instructions for use KaVo QUATTROcare 2104 / 2104A

Servicing the chuck

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

See also:
- Instructions for use KaVo QUATTROcare 2104 / 2104A

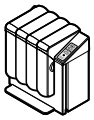
- Remove the cutter or grinder, place the spray nipple tip in the opening and spray.
- Subsequently treat with the specified care products and systems.

See also:
- Servicing with KaVo QUATTROcare

7.5.4 Servicing with KaVo QUATTROcare PLUS

Servicing and cleaning device with expansion pressure for the interior cleaning of inorganic residues and optimum care.

(no validated cleaning of the interior in accordance with German RKI requirements) KaVo recommends servicing the product as part of the reprocessing after each use, i.e. after each cleaning, disinfection, and before each sterilisation.



- Remove the dental bur or diamond grinder.
- Service the product in the QUATTROcare PLUS.

See also:
Instructions for use KaVo QUATTROcare PLUS

Servicing the chuck

KaVo recommends cleaning and servicing the chuck system once a week using the collet servicing program integrated in the device.

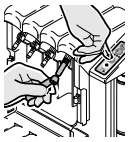
See also:
Instructions for use KaVo QUATTROcare PLUS

Note
Handpieces must be taken off the service couplings before the chuck service can be started and performed.

- Close the front door and press the chuck service button for at least three seconds until the spray canister control LED flashes three times consecutively.

⇨ The device is in chuck service mode.

- Remove the service coupling of the chuck from the side hatch of the QUATTROcare PLUS and attach it to coupling service point four, on the far right. A MULTIflex adaptor 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.
- Press the button marked with the chuck service symbol.

Note
Close the chuck service mode.
Option 1: Place the dental handpieces in the QUATTROcare PLUS 2124 A, close the front door and start theservice procedure.
Option 2: After three minutes with no service procedure running, the device automatically switches back to normal service mode.

See also:
Servicing with KaVo QUATTROcare PLUS

7.6 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!

- ▸ Seal the medical device individually in the sterilised item packaging.

7.7 Sterilisation

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

NOTICE

Improper service and care.

Premature wear and reduced product service life.

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

NOTICE

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 °C (280.4 °F).

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

- Autoclave with three times pre-vacuum:
  - at least 3 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
- Steriliser using the gravity method:
  - at least 10 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
- ▸ Use according to the manufacturer's Instructions for Use.

7.8 Storage

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

Note

Comply with the expiry date of the sterilised 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
Spray head INTRA (KaVo Spray)	0.411.9911
INTRA service coupling	1.009.6143

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
Adapter INTRAmatic (CLEANspray and DRYspray)	1.007.1776
KaVo CLEANspray 2110 P	1.007.0579
KaVo DRYspray 2117 P	1.007.0580

9 Terms and conditions of warranty

The following warranty conditions apply to this KaVo medical device:

KaVo provides the end customer with a warranty of proper function and guarantees zero defects in respect of material and processing for a period of 12 months from the date of the invoice, subject to the following conditions:
In case of justified complaints, KaVo will honour its warranty with a free replacement or repair. Other claims of any nature whatsoever, in particular with respect to compensation, are excluded. In the event of default, gross negligence or intent, this shall only apply in the absence of mandatory legal regulations to the contrary.
KaVo shall not be liable for defects and their consequences that have arisen or may arise from natural wear, improper handling, cleaning or maintenance, non-compliance with operating, maintenance or connection instructions, calcination or corrosion, contaminated air or water supplies or chemical or electrical factors deemed abnormal or impermissible in accordance with KaVo's instructions for use or other manufacturer's instructions. The warranty granted does not usually extend to lamps, optical fibres 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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