

Operating Instruction
INTRAmatic Prophy Handpiece 19 E -
1.004.6403



KaVo. Dental Excellence.

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



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User instructions

Dear user,
KaVo hopes that you enjoy your new high-quality product. Following the instructions below will allow you to work smoothly, economically and safely.

Symbols

	See the section Safety/Warning Symbol
	Important information for users and technicians
	Disinfectable with heat

 135°C 	Steam sterilisable up to 135°C
	CE mark (Communauté Européenne). A product with this mark meets the requirements of the relevant EC directive, i.e. the applicable standards in Europe.
	Action request

Target group

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

Warranty provisions

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 data of invoice, subject to the following conditions:

In case of justified complaints, KaVo will honour its warranty with a repair or free replacement. 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 are or may be due to natural wear, improper handling, cleaning or maintenance, non-compliance with operating 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 specifications. The warranty does not

usually cover lamps, light conductors made of glass and glass fibres, glassware, rubber parts and the colourfastness of plastic parts.

No liability is assumed when defects or their consequences arise 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, unit number or type and serial number must be clearly visible on this document.

Description of safety instructions: Warning symbol

Warning symbol



Description of safety instructions: Structure

The introduction describes the type and source of the hazard.

This section describes the potential consequences of non-observance.

- ▶ The optional step contains necessary measures for avoiding hazards.

Description of safety instructions: Description of hazardous steps

The safety instructions cited herein with the three levels of danger will help avert property damage and injury.

**CAUTION****CAUTION**

indicates a hazardous situation that can lead to property damage or minor to moderate injury.

**WARNING****WARNING**

indicates a hazardous situation that can lead to serious injury or death.

**DANGER**

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

Purpose – Proper use

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 use: Processing of tooth and restoration surfaces.
- A medical device according to relevant national statutory regulations.

According to these provisions, 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.
- to protect himself, the patient and third parties from danger.
- to avoid contamination from the product.



Safety instructions

Hazard from defective tool holding system.

A defective tool holding system can substantially endanger the patient and user.

- ▶ For safety reasons, we recommend that the tool holder system be checked before each use after the warranty period expires.

Premature wear and malfunction due to improper storage or longer periods of nonuse.

Reduced product life.

- ▶ The medical device should be cleaned, serviced and placed in a dry stored location according to instructions before long periods of non-use.



CAUTION



WARNING

Injury or damage due to wear.

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

- ▶ Stop work and seek service support.

Hazard to care provider and patient

Stop working in case of damage, irregular noise during operation, excessive vibration, atypical heating or when the tool cannot be firmly held.

- ▶ The instrument must be cleaned, serviced and stored dry if it has not been used for a long period.

The following individuals are authorised to repair and service KaVo products:

- The technicians of KaVo branches throughout the world
- Special technicians especially trained by KaVo

**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.

To ensure proper function, the medical device must be handled in accordance with the setup procedure in the KaVo instructions for use, and the care products and systems listed there 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 should take into account the frequency of use.

Service may only be provided by repair shops that have undergone training by KaVo and that use original KaVo replacement parts.

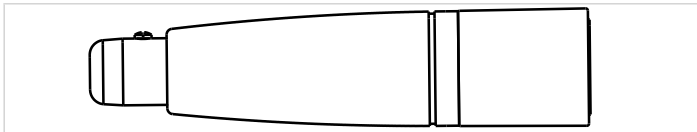


Risk due to incorrectly stored instrument.

Damage to clamping system from dropping the instrument.

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

Product description



INTRAmatic Prophy handpiece 19 E, Mat. no. 1.004.6403

Technical data

Drive speed	max. 40,000 rpm
Transmission ratio	7,4:1
ID	1 green ring

Prophylaxis heads with a Doriot connection can be used. Shaft according to DIN EN ISO 1797 part 1 and part 2 for shaft diameters of 2.300 – 2.350 mm.

The handpiece can be mounted on all INTRAmatic Lux motors, and motors with a connection in accordance with ISO 3964 / DIN 13940.







Transportation and storage conditions

Starting up the medical device can be hazardous after it has been stored in an excessively cold location.

The medical device can malfunction.

- ▶ Products that are very cold must be warmed to 20°C to 25°C before use.

	Temperature: -50 °C to 80°C
	Relative humidity: Non-condensing
	Air pressure: 700 hPa to 1060 hPa
	Protect from moisture.



WARNING



CAUTION

First use

Hazard from nonsterile products.

Infection danger to the care provider and patient.

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

May only be operated without spray air and spray water.

Damage to the handpiece.

- ▶ Select spray air and water on the supply unit before startup.



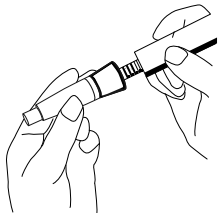
Operation

Pulling off and mounting the contra-angle piece during rotation.

Damage to the catch.

- ▶ Never mount or remove the contra-angle piece during rotation!

Mount the contra-angle handpiece



- ▶ Shove the contra-angle handpiece on the motor coupling until it locks into place.
- ▶ Before each treatment, pull on the contra-angle handpiece to see if it is securely seated in the motor coupling.

Removing the contra-angle handpiece

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

Attach the prophylaxis head



Note

Prophylaxis heads with a Doriot connection can be attached. The chucking system is designed for drive shafts that are in accordance with DIN EN ISO 1797 part 1 and part 2 for shaft diameters of 2.3 to 2.35 mm.



CAUTION

Use of impermissible prophylaxis heads.

Injury to the patient or damage to the medical device.

- ▶ Observe manufacturer instructions and use the device properly.
- ▶ Only use prophylaxis heads that do not deviate from the indicated data.



CAUTION

Removing and attaching the prophylaxis head while the device is rotating.

Damage to the chucking system.

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

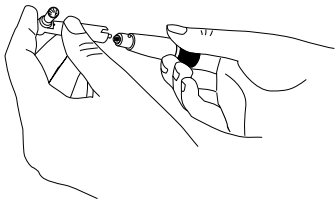


CAUTION

Damaged prophylaxis head.

Injuries.

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



- ▶ Mount the prophylaxis head axially all the way on the handpiece.

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

Removing the prophylaxis head

- ▶ Remove the prophylaxis head axially from the handpiece.



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.



Preparation at the site of use

Hazard from nonsterile products.

An infection hazard exists from contaminated medical devices.

- ▶ Observe suitable personal protective measures.

- ▶ Remove residual cement, composite or blood at the site of use.
- ▶ The medical device must be dry when transporting it to be prepared. Do not place it in a solution or the like.
- ▶ The medical device should be prepared as close to the treatment time as possible.
- ▶ Remove the prophylaxis head from the medical device.



Cleaning

Malfunctions from cleaning in the ultrasonic unit.

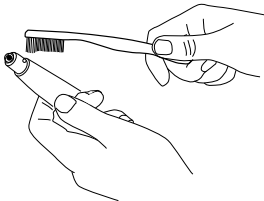
Defects to the product.

- ▶ Only clean manually or in the thermodesinfector!

Cleaning: Manually cleaning the outside

Necessary accessories:

- Tap water $30^{\circ}\text{C} \pm 5^{\circ}\text{C}$ or a 60 to 70% alcohol solution
- Brush such as a medium-hard toothbrush



- ▶ Brush off under flowing tap water, or clean with a 60-70% alcohol solution.

Cleaning: Manually cleaning the interior

To effectively set up, the inside of the machine must be cleaned automatically in a cleaning and disinfection unit in accordance with ISO 15883-1. (The interior of this product is not to be cleaned manually).

Cleaning: Mechanically cleaning the exterior and interior

KaVo recommends thermodesinfektors in accordance with DIN EN ISO 15883 such as the Miele G 7781/ G 7881.

(Validation was performed with the program "VARIO-TD", the cleaner "neodisher® mediclean", the neutraliser "neodisher® Z" and rinse "neodisher® mielclear").

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



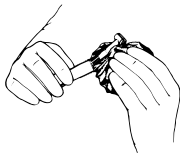
Disinfection

Malfunctions from using a disinfectant bath or chlorine-containing disinfectant.

Defects to the product.

- ▶ Only clean manually or in the thermodesinfector!

Disinfection: Manually disinfecting the exterior

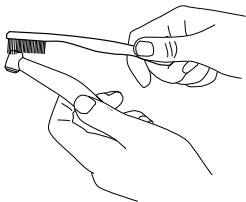


KaVo recommends the following products based on material compatibility. The microbiological efficacy must be ensured by the disinfectant manufacturer.

- ▶ Microcide AF by Schülke&Mayr (liquid or cloths)
- ▶ FD 322 by Dürr
- ▶ CaviCide by Metrex

Required tools:

Cloths for wiping off the medical device.



Spray the disinfectant on a cloth then wipe the medical device and let it work according to the disinfectant manufacturer.

Note

Observe the instruction for use for the disinfectant.

Disinfection: Manual disinfection of the interior

To effectively set up, the inside of the machine must be cleaned automatically in a cleaning and disinfection unit in accordance with ISO 15883-1. (The interior of this product is not to be disinfected manually).

Disinfection: Mechanically disinfecting the exterior and interior

KaVo recommends thermodesinfektors in accordance with DIN EN ISO 15883 such as the Miele G 7781/ G 7881.

(Validation was performed with the program "VARIO-TD", the cleaner "neodisher® mediclean", the neutraliser "neodisher® Z" and rinse "neodisher® mielclear").

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

Drying

Manual drying

- ▶ Blow off the outside and inside the compressed air until no water drops are visible.

Machine drying

The drying procedure is normally part of the disinfection program of the thermodisinfector.



Note

Please follow the instructions for use of the thermodisinfector (compressed air quality - see the Warning under "Start-up").



Care products and systems – Servicing

Premature wear and malfunction from improper service and care.

Shortened product service life.

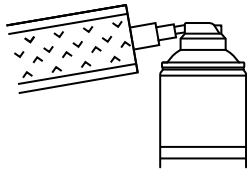
- ▶ Regularly service the device properly!

Note

KaVo only guarantees that its products will function properly when care products are used that are listed by KaVo in the accessories since they were tested for proper use on KaVo products.

Care products and systems – Servicing: Care with KAVOspray

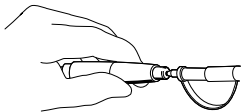
KaVo recommends servicing the project twice daily (at noon and in the evening after hours), after each time the machine is cleaned, and before each sterilisation.



- ▶ Removing the tool.
- ▶ Cover the product with the Cleanpac bag.
- ▶ Place the product on the cannula, and press the spray button for one second.

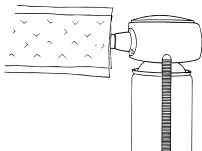
Chuck care with KAVOspray

KaVo recommends cleaning and servicing the chucking system once weekly.



- ▶ Remove tool, place the spray nipple tip in the opening and spray.
- ▶ Subsequently treat with the care products and systems listed below.

Care products and systems – Servicing: Care of the KaVo SPRAYrotor



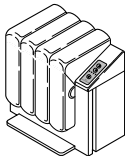
KaVo recommends servicing the project twice daily (at noon and in the evening after hours), after each time the machine is cleaned, and before each sterilisation.

- ▶ Place the product on the appropriate coupling on the **KaVo SPRAYrotor** , and cover the product with the Cleanpac bag.
- ▶ Servicing the product.

See also: Instructions for use **KaVo SPRAYrotor**.

Care products and systems – Servicing: Care with KaVo QUATTROcare

Cleaning and care unit with expansion pressure for thorough cleaning and care



KaVo recommends servicing the project twice daily (at noon and in the evening after hours), after each time the machine is cleaned, and before each sterilisation.

- ▶ Removing the tool.

- ▶ Servicing the product.

KaVo QUATTROcare plus spray can

KaVo recommends cleaning and servicing the chucking system once weekly.

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



- ▶ Remove tool, place the spray nipple tip in the opening and spray.
- ▶ Subsequently treat with the care products and systems listed below.

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 packaging of the items to be sterilised must satisfy the applicable standards and be appropriate for sterilising.

- ▶ Individually weld the medical device in the sterilised item packaging (such as KaVo STERlclave bags **Mat. no. 0.411.9912**)!

Sterilisation

Sterilisation in a steriliser in compliance with DIN EN 13060



Premature wear and malfunctions from improperly care and service shortens the service life of the product.

Shortened product life.

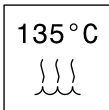
- ▶ The medical device must be serviced with KaVo care products before each sterilisation cycle.



Contact corrosion from moisture.

Damage to the product.

- ▶ Immediately remove the product from the steam steriliser after the sterilisation cycle!



The medical device has a max. temperature resistance of 138°C.

KaVo recommends for example

- STERlclave B 2200/ 2200P by KaVo
- Citomat/ K-series by Getinge

Autoclave three times with an initial vacuum for at least 4 minutes at 134°C ± 1

Autoclave using the gravitation method for at least 10 minutes at 134°C ± 1

Autoclave using the gravitation method for at least 60 minutes at 121°C ± 1

Follow the manufacturer's instructions for use.

Storage

Prepared products should be stored protected germ-free from dust in a dry, dark and cool room.



Note

Observe the expiration date of the sterilised item.

Accessories

Accessories obtainable from dental and medical suppliers.

Material summary	Mat. no.
Instrument stand 2151	0.411.9501
Cellulose pad 100 units	0.411.9862
Cleanpac 10 units	0.411.9691
KAVO Spray 2112 A	0.411.9640
ROTAspray 2142 A	0.411.7520
QUATTROcare plus Spray 2140 P	1.005.4525



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