

1 Explanation of symbols

	See chapter 2. Safety
	Important information for the user
	Product can be sterilized in a steam sterilizer (Autoclave)
	Can be used in thermal disinfectors
	CE-mark – Confirms that this product fulfills all requirements for medical products
REF	Reference number
SN	Serial number

2 Safety

2.1 Description of danger levels

	CAUTION
	CAUTION is used if a deficiency in adequate care may result in an endangering of the patient, the user or others.
	WARNING
	WARNING is used if improper use may result in serious injuries.

2.2 Safety notes

	WARNING
	Risk of injury for the patient and the operator Concerning damages like irregular running noise, irregular vibrations, an unspecific rise in temperature and/or other defects. → Stop operating immediately and contact our service.
	WARNING
	Risk of infection In case of an injury of the tissue in the oral area, do not proceed to work with air-operated instruments because of a high risk of an infection.

 WARNING	WARNING
	Burns due to an increased heat of the head of the instrument Burns in the oral area may occur due to an increased heat of the head of the instrument.

 CAUTION	CAUTION
	Accelerated deterioration and dysfunctions due to long term non-usage → Before storage, clean, maintain and dry the instrument according to the norm. Store in the original packing, dry and dustproof.

 We recommend an annual check-up and maintenance of the entire spindle system by MK-dent or by personnel authorized by MK-dent.

3 Product description

This manual can be used for the following MK-dent products:

Turbines of the Prime Line series	
Standard head	Small head
HP21KL, HP21WL, HP21SL, HP21NL	HP22KL, HP22WL, HP22SL, HP22NL

Turbines of the Classic Line series	
Standard head	Small head
HC20K/KL, HC21K/KL, HC21W/WL, HC21S/SL, HC21N/NL	HC22K/KL, HC22W/WL, HC22S/SL, HC22N/NL

3.1 Intended purpose

This medical product may only be used in a dental surgery, especially for the following purposes:
Removal of decayed material, preparations of cavities and crowns, removal of fillings.

3.2 Use according to regulations

This product may only be used for the intended purposes, executed by professionally trained personnel.
The indications and warnings in this manual must be considered. This also includes the observing of the processing (see chapter 5 **Processing according to ISO 17664**) and the valid national health and safety regulations. Any other use may result in an endangering of the patient, the operator or others and is strictly prohibited. Before each application, the functionality of the instrument must be tested.

3.3 Technical specifications

	KaVo®-connection	W&H®-connection
Driving pressure (bar)	2.8	3.0 - 3.3
Pressure of spray water (bar)	0.8 - 2.5	0.8 - 2.5
Pressure of spray air (bar)	1.0 - 4.0	1.0 - 4.0
Air consumption (l/min)	40	40
RPM Standard head HC20...	360 000 - 375 000	-
RPM Standard head/Small head HC21.../HC22...	330 000 - 350 000/380 000 - 420 000	330 000 - 350 000/380 000 - 420 000
Recommended press-on force (N)	2 - 3	2 - 3
Spray water consumption (ml/min) according to EN ISO 14457	> 50	> 50
Operating noise dB(A) Standard head/Small head	55/60	55/60

	Sirona®-connection	NSK®-connection
Driving pressure (bar)	2.7	2.8
Pressure of spray water (bar)	0.8 - 2.5	0.8 - 2.5
Pressure of spray air (bar)	1.0 - 4.0	1.0 - 4.0
Air consumption (l/min)	40	40
RPM Standard head/Small head	330 000 - 350 000/380 000 - 420 000	330 000 - 350 000/380 000 - 420 000
Recommended press-on force (N)	2 - 3	2 - 3
Spray water consumption (ml/min) lt. EN ISO 14457	> 50	> 50
Operating noise dB(A) Standard head/Small head	55/60	55/60

 KaVo®, W&H®, Sirona® and NSK® are registered trademarks. MK-dent does not have any economical connection to the companies mentioned above.

3.4 Transport and storage requirements

 CAUTION	CAUTION
	Dysfunction of the instrument while operating after an overcooled storage → Heavily cooled instruments must be warmed to room temperature prior to operating.

For transportation and storage, please consider the following:

Temperature	-20 °C - +70 °C (-4 °F - +158 °F)
Relative humidity	5% - 95%, non-condensing
Air pressure	700 hPa - 1060 hPa (10 psi - 15 psi)

Protect this medical instrument from moisture!

4 Putting into service and operation

 WARNING	WARNING
	Risk of infection for patients and operator due to non-sterile instruments → Before the first and after each further use the instrument and the attachments must be processed and sterilized as defined in chapter 5 Processing according to ISO 17664 .
 WARNING	WARNING
	Risk of infections for others at waste disposal → Before waste disposal, this medical product has to be processed according to instructions and must at least be sterilized.
 CAUTION	CAUTION
	Dysfunctions and/or risk of an infection caused by moist and contaminated compressed air and by contaminated cooling water → This product may only be operated with CE-certified dental units or with others certified by actual national guidelines and with a corresponding supply of water and compressed air according to the valid norms of dental care.

4.1 Preparation for use

4.1.1 Pressure test

Place the testing pressure gauge between the coupler and the instrument to test the following pressures (see chapter 3.3 **Technical specifications**):

- Driving pressure
- Pressure of returning air
- Pressure of spray water
- Pressure of spray air

4.1.2 Testing the quantity of water

 WARNING	WARNING
	Damage to pulpal or teeth A too low quantity of spray water may result in an overheating of the head of the instrument and can lead to corresponding injuries. → Regulate the quantity of the spray water to a minimum of 50 cm ³ /min.

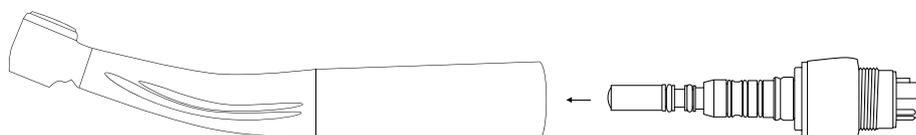
Check the quantity of water with a measuring cup. Check the spray water canals. In case of a too low water supply or a clogged nozzle, clean the nozzle with the enclosed pin. See also chapter 7.1 **Cleaning of the spray nozzle**.

4.2 Operation

i Prior to each working day, all systems with water supply have to be rinsed out for at least 2 minutes, before attaching an instrument. After each treatment another rinsing process has to be performed for 20 to 30 seconds, especially concerning products that rewind/retract.

4.3 Attaching the instrument to the coupler

 WARNING	WARNING
	Dysfunctions due to a decoupling of the instrument while operating An instrument that is not correctly attached to the coupler may loosen while operating. → Prior to each use check if the instrument and the coupler are correctly attached by slightly pulling at the instrument.
 CAUTION	CAUTION
	Damages due to an incorrect coupling If the coupling process is not completely executed, the LED or the halogen light bulb of the coupling may be destroyed or its lifetime may be reduced. → Please check if the instrument and the coupler are completely attached by slightly pulling at the instrument.



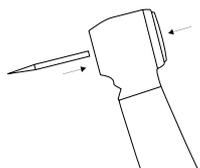
- ☞ Place the instrument exactly on the coupler and firmly push down the instrument until the coupler clicks into place.
- ☞ Check the proper fitting by slightly pulling the instrument in an upward motion.
- ☞ To detach the instrument hold the coupler, while pulling off the instrument in a slightly turning movement.

4.4 Insertion of rotating instruments

 WARNING	WARNING
	Risk of injury for the patient due to a decoupling of the rotating instrument → Check the holding force of the spindle by pulling at the bur after each insertion of burs.
 WARNING	WARNING
	Risk of injury for the patient and possible damages of the instrument Use of other instruments than those mentioned above. → Only use rotating instruments that fulfill the requirements mentioned above. → Consider the manual for the intended use of the rotating instrument.
 WARNING	WARNING
	Risk of injury due to the use of worn out rotating instruments Rotating instruments can fall out while operating and thus injure the patient. → Do not use any rotating instruments with a worn out shaft.
 WARNING	WARNING
	Risk of injury for the user due to rotating instruments Cuts and resulting infections may occur due to incorrect use. → Always use gloves or a finger protection.

 Only use rotating instruments made of steel or carbide metal that fulfill the EN ISO 3823-1 requirements and also the following criteria:

Diameter of the shaft	1.591 to 1.599 mm
Length of the shaft (standard head/small head)	max. 25/21 mm
Full insert length of the shaft (standard head/small head)	min. 12/11 mm
Diameter of the cutter	max. 2 mm

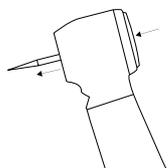


- ☞ Press the push-button of the back cap with your thumb and simultaneously insert the rotating instrument into the spindle as far as it will go.
- ☞ Check the proper fitting by slightly pulling at the bur.

☞ Check the holding force of the spindle at least weekly by using the measurement tool RT1020 or another device according to ISO 8325. The holding force of the spindle must not be less than 2.5 kg. At a holding force of less than 3 kg, we recommend to replace the cartridge.

4.5 Removal of rotating instruments

 WARNING	WARNING
	Risk of injury due to rotating instruments Cuts and damages in the spindle system may occur. → Never touch the rotating instrument. → Do not press the push button of the back cap while operating. → Remove the rotating instrument after each operation to prevent any kind of injuries and infections during storage.



- ☞ After the rotating instrument has stopped moving, press the push button of the back cap with your thumb while simultaneously pulling out the rotating instrument.

5 Processing according to ISO 17664

5.1 Processing at the location of use

 WARNING	WARNING
	Risk of infection due to non-sterile instruments. → Always wear gloves.

- ☞ Process the instrument within one hour after each treatment in order to prevent piling.
- ☞ Immediately remove any debris of cement, blood or composite.
- ☞ Ensure a dry transport of the instrument to the place of processing.
- ☞ Do not put the instrument in any kind of solution.

5.2 Cleaning

 WARNING	WARNING
	Dysfunctions due to cleanings in an ultrasonic bath → Only clean the instrument as described below.

5.2.1 Manual pre-cleaning

 CAUTION	CAUTION
	Risk of infection due to multiple uses of dental brushes → To prevent cross infections always use a new dental brush for each instrument.

 CAUTION	CAUTION
	Insufficient cleaning of the surface and the water- and air pipes → In order to ensure a successful cleaning a thorough manual pre-cleaning, even with the small brush, must be done.

Tools:

- Drinkable water 30 °C ± 5 °C (86 °F ± 10 °F)
- Brush or soft tooth brush
- Dental brush
- 50 ml syringe without cannula

- ☞ To pre-clean the instrument place it under running water and carefully brush debris completely off the surface by using one of the tools mentioned above.
- ☞ To pre-clean the spindle, please insert the enclosed dental brush in the spindle opening. Carefully loosen and remove any residue and debris by circular motions with the brush.
- ☞ Repeat the process several times and each time clean the dental brush with water.
- ☞ To pre-clean the water- and air pipes place the syringe at the lower end of the handpiece and rinse the cavities at least 5 times.

5.2.2 Cleaning the visible end of the glass rod of dental turbines with light

 CAUTION	CAUTION
	Risk of scratches due to careless treatment Defects of the glass rod result in a lower light quality. → Clean the glass rod with great care.

- ☞ Clean the visible part of the glass rod with warm water and a soft cloth.
- ☞ Dry with air or with a new soft cloth.
- ☞ Pre-check the glass rod before each use. In case of a damage of the glass rod do not operate and contact your dealer or the MK-dent's repair service immediately.

5.3 Disinfection

 CAUTION	CAUTION
	The use of disinfecting baths and/or of chlorinated disinfectants may lead to defects and dysfunctions of the instrument. → Only clean and disinfect the instrument in a thermal disinfectant.

5.3.1 Manual disinfection of the surface

Only use disinfectants whose microbiological effectiveness is ensured by the manufacturer (e.g. VAH/DGHM-regis-tration and CE-mark). Concerning the material compatibility, only disinfectants free of aldehyde and based on alcohol may be used.

- ☞ Apply the disinfectant to a cloth and wipe the instrument clean.
- ☞ Consider the reacting time that is set by the manufacturer of the disinfectant.
- ☞ Follow the manual for the disinfectant.

5.3.2 Mechanical cleaning and disinfection of the interior and the exterior

 MK-dent recommends thermal disinfectors that fulfill the EN ISO 15883-1 requirements and are approved by the manufacturer for the straight- and contra angle, as well as for high speed handpieces. The cleaning should be carried out at a minimum of 55°C (131°F) and for at least 5 minutes, the disinfection at a minimum of 90°C (194°F) and for at least 5 minutes (for an A0-value > 3,000). For the cleaning a mild alkaline cleaning agent with a pH of 9 to 11 is recommended, like e.g. Neodisher® MediClean Forte. For the validation of the process see chapter 6.2 **Validation of the processing.**

- ☞ For the internal cleaning the adaptors specified by the manufacturer must be used.
- ☞ Repeat the process, if visible contaminations still exist after the treatment in a thermal disinfectant.
- ☞ Before use the instrument must be dry and free of residues.
- ☞ To prevent any kind of impairments of the instrument, make sure after every cycle that the instrument is dry on the inside and the outside.
- ☞ Directly afterwards use the MK-dent Premium Service Oil to lubricate the instrument.

5.4 Process of drying

5.4.1 Manual drying

- ☞ Blow on the instrument with compressed air from the inside and the outside until no visible drops are left.

5.4.2 Mechanical drying

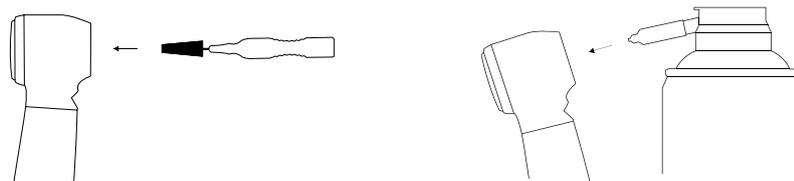
The drying process normally is part of the cleaning process of your thermal disinfectant. Please follow the instructions for your thermal disinfectant.

☞ In case of moisture remaining on the instrument after the cleaning process, blow with compressed air until completely dry.

5.5 Maintenance with the MK-dent Premium Service Oil LU1011

5.5.1 Cleaning and maintaining the spindle

Before each sterilization, please follow these steps in the declared order.



☞ Please insert the enclosed dental brush into the spindle and carefully remove any kind of debris or residue by circular movements with the brush. Repeat this process several times and clean the brush with water.

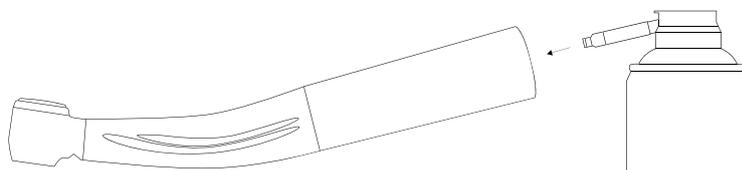
☞ Place the enclosed lubrication tool LT1014 on the MK-dent Premium Service Oil can and spray for approximately 2 seconds.



If very unclean, repeat this process several times.

5.5.2 Lubrication of the canal for drive air

MK-dent recommends lubricating and maintaining the instrument after each mechanical cleaning and before each sterilization process.



☞ For the maintenance of the cartridge screw the lubrication tool (included in the consignment) onto the lubrication can.

☞ Insert the lubrication tool into the lower end of the instrument and spray into the canal of the driving air for approximately 2 seconds.

☞ Connect the instrument to your treatment unit and let it run for 15 to 20 seconds, so that the surplus lubricant can escape from the instrument.

6 Sterilization



The sterilization bag has to be big enough for the instrument so that the instrument fits without stretching the bag. Concerning quality and application, the bag has to fulfill all the valid norms and has to be suitable for the sterilization process.

☞ Shrink-wrap each instrument individually into a sterilization bag.

6.1 Sterilization with a steam sterilizer (Autoclave) according to EN 13060/ISO 17665-1

 CAUTION	<p>CAUTION</p> <p>Damages due to inappropriate maintenance or service may result in dysfunctions and/or deterioration.</p> <p>Reduced lifetime of the product → Lubricate the instrument with the MK-dent Premium Service Oil before each sterilization.</p>
 CAUTION	<p>CAUTION</p> <p>Contact corrosion caused by moisture</p> <p>Damages of the product → After sterilization, immediately remove the instrument from the autoclave.</p>



This medical product has a temperature resistance of up to max. 135 °C (275 °F).

Only apply the following sterilization process:

- Autoclave with a triple pre-vacuum (recommended): minimum of 5 minutes at a minimum of 134°C (273°F)

☞ Pay close attention to the manufacturer's instruction.

6.2 Validation of the processing



The validation of the cleaning and of the disinfection was carried out with the device Miele® G 7835 in the programme Vario TD with the cleanser Neodisher® MediClean Forte.

Adjustment:

- Pre-rinsing for 1 minute

- Cleaning at 55°C (131°F) for 5 minutes with a dosage of 0.5% Neodisher® MediClean Forte

- Neutralization
- Washing down
- Disinfection at 90°C (194°F) for 5 minutes

The sterilization was validated with the device Tuttnauer® EHS 3870 in a fractional pre-vacuum process at 134°C (273°F) for 5 minutes. Please note, that the reprocessing procedure performed in your dental office must be validated also.

i For more information on the entire preparation process download our MK-dent Processing Guide for High- & Low Speed Handpieces from our website www.mk-dent.com/downloadcenter.

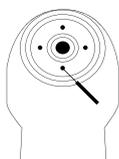
6.3 Maintenance & service

 CAUTION	CAUTION
	Inappropriate maintenance or service may result in dysfunctions and/or deterioration. → Always perform proper maintenance and service.

7 Removal of dysfunctions

7.1 Cleaning of the spray nozzle

 WARNING	WARNING
	Damage to pulpal or teeth A too low quantity of spray water may result in an overheating of the instrument and can lead to resulting injuries. → Check the canals of the spray water regularly and, in case of blocking, clean the spray nozzle with the enclosed pin.



☞ Carefully remove any blockages of the canals of the spray water with the enclosed pin.

7.2 Storage

- ☞ Store the cleaned and sterilized instruments in a dry, dark and cool place, sheltered from dust and germs.
- ☞ Please pay attention to the date of expiry of the sterilization liquid.

8 Tools & spare parts

Replacement turbine Prime Line	Standard head: HP21KL/WL/SL/NL Small head: HP22KL/WL/SL/NL
Replacement turbine Classic Line	Standard head HC21K/KL/W/WL/S/SL/N/NL Small head: HC22K/KL/W/WL/S/SL/N/NL
Nozzle pin	AC0001
Dental brush for the maintenance of the spindle	AC0003
Holding-force measurement tool for the spindle	RT1020
Lubrication tool for the maintenance of the rotor	LT1012
Lubrication tool for the maintenance of the spindle	LT1014
Premium Service Oil	LU1011
Premium Service Oil for KaVo® QUATTROCARE	LU1022

i KaVo® is a registered trademark. MK-dent does not have any economical connection to the company mentioned above.

9 Warranties

MK-dent provides the end user a warranty for proper function, immaculate material and workmanship for a period of 24 months (Prime Line)/18 months (Classic Line) after purchasing. Relevant for this is the invoice date.

In case of justified complaints MK-dent carries out a free repair or a possible free replacement. This will be decided by MK-dent. Other claims of any kind, in particular damage compensation are excluded. In the event of default, gross negligence or intent, this shall only apply unless there are compelling legal regulations.

MK-dent is not liable for defects and their consequences that have arisen whose arising may be due to natural wear, improper handling, improper cleaning, or maintenance, non-compliance with operating or manual instructions, calcination or corrosion, contaminated air and water supply or chemical or electrical influences that are unusual or not permitted according to MK-dent's instruction for use or to other manufacturer's instructions.

The warranty does usually not cover lamps, light conductors made of glass fibers, glassware, rubber parts and the color fastness of plastic parts.

All liability is excluded if defects or their consequences arise because of interventions or modifications on the product by the end user or by a third party not authorized by MK-dent.

Warranty claims will only be accepted if the product is submitted with a proof of purchase in the form of an invoice or a copy of the delivery note. Dealer, purchase date, model and serial number must be clearly visible.



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