EN ISO 17664-1 Manufacturer information for the processing of medical devices

Classification according to RKI guideline:	HAHNENKRATT products:
Semi-critical A	1) Mouth Mirrors, stainless steel or plastic, Laryngeal Mirrors, Handles stainless steel or plastic 2) Photo mirrors, photo mirrors with handle 3) Periodontometer 4) Explorers
Critical A	5) MICRO Mirrors

CE

Short information

Thermal disinfection (cleaning, disinfection, drying)

Processing should preferably be done by machine in accordance with the RKI recommendation.

1. Thermal Disinfector (washer), e.g. from Miele with Vario-program. It must reach an A_0 value of at least 3000.
2. Neodisher® MediClean Dental from the Dr. Weigert company.
3. Neodisher® Z from the Dr. Weigert company.
4. Suitable instrument rack or sieve tray.

Also follow the instructions for use at all times for the products and devices to be used. Observe standards EN ISO 15883-1 and EN ISO 15883-2.

Information from EN ISO 17664-1, 6.7.2.1: If your Thermal Disinfector is compliant with the ISO 15883 standards, you may use the programs recommended by the manufacturer.

Sterilization

According to German Federal Health Gazette risk assessment and classification of medical devices:

Semi-critical A: Sterilization (X)= optional step

Critical A: Sterilization X = Generally sterilization with moist heat

Steam sterilization using a fractionated vacuum method at 134°C in a device in accordance with EN 13060:

1. Fractionated pre-vacuum method (at least 3-fold)
2. Sterilization temperature 134°C (-0/+3°C)
3. Exposure time: minimum 5 minutes (full cycle)
4. Drying time: minimum 10 minutes

Observe standard EN ISO 17655 for sterilization with moist heat.

Supplementary information: Processing for instruments that were NOT disassembled

The following is published in the Federal Health Gazette dated 04/2006 under point 4.4:
Disassembly of demountable instruments while observing personal protection measures.
This applies to both automatic and manual cleaning and disinfection and was recommended by the Robert Koch Institute (RKI).

An external validation was successfully performed in 2016 for our **HAHNENKRATT** instruments (mouth mirrors and handles) using instruments that were **NOT** disassembled:

1608.1255-HAHN_ValBericht_RDG_ ThermalDisinfector
1608.2906-HAHN_ValBericht_Autoklav

It is your responsibility to follow this validation. The processor is responsible for ensuring that the actual processing carried out - with the equipment, materials and personnel deployed - obtains the desired results in the processing facility.

The entire manufacturer's information you will find on the subsequent pages, is available at www.hahnenkratt.com or please send an email: service@hahnenkratt.com.

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Critical A	5) MICRO Mirrors

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⚠ Warnings

Observe the usual accident prevention regulations
We are not aware of any warnings if the instructions for use of the devices and the disinfection and cleaning solutions used are observed.

Observe the point "Inspection and Functional Check" before initial use

Appendix 1:	1) Mouth mirrors	Warnings + tips for processing and handling
Appendix 2:	2) Photo mirrors	Tips for processing and handling
	3) Periodontal Probes	-.-
	4) Explorers	-.-
Appendix 3:	5) MICRO Mirrors	Warnings + tips for processing and handling

Limitation of processing

Repeated reprocessing has minimal effect. The end of a product's service life is determined by wear and tear and damage due to use, such as:

- Scratches caused by mechanical cleaning (Appendix 1, Fig. 3)
- Damages, e.g. caused by rotating instruments
- Lime residues (Appendix 1, Fig. 4), e.g., if the decalcification of the thermal disinfector is not correctly adjusted

The end of a product's service life varies and is therefore to be determined by the user.

Instructions

The entire procedure must also be carried out prior to first use.

The procedures described are well known and based on standard equipment and consumable materials.

Point of use

Carry out reprocessing only in the rooms/areas designated for this. Observe the effective hygiene measures in accordance with the country-specific guidelines.

Storage and Transport

Storage and transport must be carried out in the rooms and containers designated by the practice.

Wet disposal
Immediately after the instruments have been used on a patient, place them in a disinfection bath filled with a suitable cleaning/disinfection agent (e.g. ID 212 without aldehyde from DÜRR, alkaline cleaning agent with a pH of 10). This prevents the surface drying of residues (protein fixing). Follow the ID 212 directions for use regarding dosage and exposure time.

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Alternative:

Dry disposal
Collection of medical devices (dry disposal) after appropriate pretreatment or patient treatment

Procedure from LZK BW (Baden Württemberg Chamber of Dentists) AA02-1, 06/2018:

1. Storage of instruments
   In appropriate collection containers, e.g., sealable plastic cases

   Careful storage (no throwing in) of the instruments, with the aid of instrument forceps if necessary.

   Appropriate personal protective equipment (e.g., hand, eye, mouth and nose protection) must be used.

   A long processing interval should be avoided (Recommendation: The 6-hour rule for the wait time should not be exceeded; the manufacturer's instructions must be observed).

2. Separation of waste
   In sufficiently sturdy, leak-proof and, if necessary, moisture-resistant garbage bags.

Preparation for decontamination

Follow the standard instructions for instruments in your practice. No other special requirements need to be followed for this HAHNENKRATT instruments.

The Robert Koch (RKI) Institute recommends: Disassembling instruments in accordance with personal protection measures.

See also page 1 Brief information, here the information regarding our validation with HAHNENKRATT instruments (mouth mirrors and handles) that were **NOT** disassembled for validation.

Machine processing – cleaning, disinfection, drying

Processing should preferably be done by machine in accordance with the RKI recommendation.

Equipment

1. Thermal Disinfector (washer), e.g., from Miele with Vario program. It must reach an A_0 value of at least 3000.
2. Neodisher® MediClean Dental from the Dr. Weigert company.
3. Neodisher® Z from the Dr. Weigert company.
4. Suitable instrument rack or sieve tray.

Also follow the instructions for use at all times for the products and devices to be used. Observe standards EN ISO 15883-1 and EN ISO 15883-2.

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Critical A	5) MICRO Mirrors

Information from EN ISO 17664-1, 6.7.2.1: If your Thermal Disinfector is compliant with the ISO 15883 standards, you may use the programs recommended by the manufacturer and do **not** have to follow our below validated processing procedure.

Procedure, validated

1. Take the instruments out of the disinfection bath and rinse thoroughly under running potable water immediately before the automated processing (at least 10 seconds). No residues from the cleaning/disinfection agent should be transferred to the Thermal Disinfector.
2. Place the instruments in a suitable instrument rack or sieve tray.
3. Place the instrument rack/sieve tray in the Thermal Disinfector so that the spray jet comes into direct contact with the instruments.
4. Start the Vario program including thermal disinfection. Thermal disinfection is carried out with an A_0 value of at least 3000.
5. Program:
   - 1 min. pre-washing with cold water
   - Emptying
   - 3 min. pre-washing with cold water
   - Emptying
   - 10 min. washing at 55°C with 0.5% neodisher® MediClean Dental alkaline cleaning agent
   - Emptying
   - 3 min. neutralization with warm tap water (>40°C) and 0.1% neodisher® Z neutralizer, Dr. Weigert, Hamburg
   - Emptying
   - 2 min. intermediate flushing with warm tap water (>40°C)
   - Emptying
   - Thermal disinfection with demineralized water at 92°C for at least 5 min.
   - Automatic drying, around 60°C for 30 min.
6. Remove the instruments at the end of the program cycle and dry them with compressed air according to the RKI recommendation. With instrument racks/sieve trays, pay special attention to the drying of hard-to-reach areas.
7. Check for intactness and cleanliness with a suitable magnifying glass. An 8X magnification is usually enough for a visual check. If there is still residual contamination after the automatic processing, cleaning and disinfection should be repeated until all visible traces of contamination have been eliminated.

Make sure the decalcification is correctly adjusted, otherwise white water spots and deposits will be left on the mirror surface. Only put completely dry instruments in the sterilizer in order to prevent limescale deposits and/or water spots (Appendix 1, Fig. 4).

Manual processing – cleaning

Disinfect instrument prior to manual cleaning.

Cleaning materials: e.g., a soft brush

Treatment chemicals: ID 212 from DÜRR, alkaline cleaning/disinfection agent with a pH of 10

Clean the instruments according to the usage directions for the treatment chemicals and cleaning agents. Please refer to the concentration, temperature and contact time specified by the manufacturer of the cleaning agent.

It is necessary to ensure that all areas of the instrument are reached. In particular, this also applies to all transitions such as mirror to frame and frame to welded stem.

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1. Pre-wash for minimum 1 minute under running potable water with a soft brush to remove coarse impurities.
2. Place in ID 212 cleaning solution at 2% concentration for minimum 5 minutes.
3. Clean transitions and threaded areas with a soft brush.
4. Rinse threaded openings with syringe.

After cleaning, rinsing should be done with fully desalinated, deionized water for minimum 1 minute in order to prevent limescale residues on the instrument, which leave behind white deposits or water spots.

Check for intactness and cleanliness with a suitable magnifying glass. An 8X magnification is usually enough for a visual check. If there is still residual contamination after the automatic processing, cleaning and disinfection should be repeated until all visible traces of contamination have been eliminated.

Manual processing - disinfection

Treatment chemicals: ID 212 from DÜRR, alkaline cleaning/disinfection agent with a pH of 10

Disinfect the instruments according to the usage directions for the disinfection and/or cleaning agents. Please refer to the concentration, temperature and contact time specified by the manufacturer of the cleaning agent.

Place cleaned instruments for disinfection in a second disinfection bath containing ID 212.

Application concentration:	2%
Exposure time:	Minimum 5 minutes

Rinse threaded openings with syringe

It is necessary to ensure that all areas of the instrument are reached. In particular, this also applies to all transitions such as mirror to frame and frame to welded stem.

After disinfecting, rinsing should be done with fully desalinated, deionized water for at least 15 seconds in order to prevent limescale residues on the instrument, which leave behind white deposits or water spots.

Manual processing - drying

Preferably with compressed air according to RKI recommendation. With instrument racks, pay special attention to the drying of hard-to-reach areas.

Only put completely dry instruments in the sterilizer in order to prevent limescale deposits and/or water spots (Appendix 1, Fig. 4).

Maintenance

The medical device does not require maintenance.

Inspection and functional check

Carry out a visual inspection for non-conformances, damages and wear and tear. It is recommended to use a device with optical magnification for better visual inspection. Faulty and/or defective instruments should be discarded. This includes instruments with rough and/or protruding corners, edges, etc.

For further product-related information on inspection and functional checks, see:

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1) Mouth Mirrors	Appendix 1
5) MICRO Mirrors	Appendix 3

Packaging

Use standardized packaging material (EN ISO 11607-1) designed for this purpose. The packaging must be large enough so that no stress is placed on the seal. Sterile barrier systems must be checked for integrity prior to use. If the sterile barrier system is damaged, the packaged products must be reprocessed.

Sterilization

According to German Federal Health Gazette 2012-55:1244-1310 "Hygiene requirements for the reprocessing of medical devices," page 1248, Table 1. Risk assessment and classification of medical devices:

Semi-critical A: Sterilization (X)= optional step

Critical A: Sterilization X = Generally sterilization with moist heat

Equipment: Steam sterilizer, with moist heat according to EN ISO 17665

Only put completely dry instruments in the sterilizer in order to prevent limescale deposits and/or water spots.

Procedure, validated:

Steam sterilization using a fractionated vacuum method at 134°C in a device in accordance with EN 13060:

1. Fractionated pre-vacuum method (at least 3-fold)
2. Sterilization temperature 134°C (-0/+3°C)
3. Exposure time: minimum 5 minutes (full cycle)
4. Drying time: minimum 10 minutes

Observe standard EN ISO 17655 for sterilization with moist heat.

In order to prevent spot formation and corrosion, the steam have to be free of any other substances. The maximum load for the sterilizer must not be exceeded when sterilizing several instruments.

Storage

The packaged sterile goods must be protected from dust, humidity and (re)contamination during transport and storage.

The determination of the duration of sterility of the end product is the responsibility of the body performing the final packaging (sterile barrier system or packaging system) in the dental practice. (See also "Packaging")

Additional information

Any serious incidents that occur in connection with the product must be reported to the manufacturer and to the competent authority of the member state in which the user and/or patient is located.

Ensure that the maximum load of the devices is not exceeded.

The entire procedure must also be carried out before initial use.

Observe the national regulations for disposal.

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Observe your country's applicable legal requirements for the reprocessing of medical devices. You can find information about this at www.rki.de.

The instructions provided above have been validated by the medical device manufacturer as being SUITABLE for the preparation of a medical device for reuse. It is the responsibility of the user to ensure that the carried out processing performed in the processing area in the practice – including the professional equipment, materials and personal used – achieves the desired result. This usually requires validation and routine monitoring of the procedure in the processing area in the practice.

Any deviation from this provided instructions should be carefully evaluated for effectiveness and any possible negative consequences by the practice's safety officer.

All serious incidents that occur in connection with the product must be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is registered.

Please observe the instructions for use of the equipment used and those of the manufacturer(s) and ensure that the maximum load of the devices is observed.

Information from EN ISO 17664-1: Biocompatibility may be impaired if rinsing agents are used.

Please observe the national regulations for disposal.

Please observe the legal provisions for the processing of medicinal products applicable in your country. Information is available, for example, at www.rki.de

The instructions listed above have been validated as SUITABLE for preparing a medicinal product for reuse by the manufacturer of the medicinal product. The processor is responsible for ensuring that the actual processing carried out - with the equipment, materials and personnel deployed - obtains the desired results in the processing facility. This usually requires validation and routine monitoring of the procedure in the processing facility.

Any deviation from these instructions should be carefully evaluated by the safety officer of the practice in terms of efficacy and potential negative consequences.

Manufacturer contact

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Appendix 1 - Mouth mirrors + Laryngeal mirrors

⚠ Product-related warnings

Fig. 1: MEGA FS, ULTRA FS, SAphir FS

- **Mouth Mirrors and Laryngeal mirrors are not suitable for ultrasonic cleaning.**
  (AKI Edition 4/2016)

- **Glass breakage**

  1) The glass can break if processing is made incorrectly, e.g., if high pressure is used to remove encrusted impurities.

  2) The mirror glass can break and/or splinter during use, e.g., if pressure is applied to the glass.

Fig. 2: RELAX

Therefore, take **precautionary measures** – especially with children and difficult patients – such as using a rubber dam or saliva ejector, which prevents biting or clenching.

If necessary, remove the mirror pieces using appropriate tools, e.g., tweezers or an aspirator. **Ensure proper protection against glass particles with regard to risk of injury and infection.**

Our tip: **SAphir FS Rhodium** mouth mirror REF 6080 with sapphire-hard glass.
Also observe the precautionary measures with this mouth mirror with respect to residual risk of glass breakage.

Tips for processing + handling

Fig. 3: Scratches/Cleaning strips

- **1. Mechanical impairment (scratches)**
  Do not use **hard brushes** or sponges. They can scratch the surface of the mirror and damage the coating of all front surface mouth mirrors (Fig. 3).

- **2. Limescale deposits and residues**
  When using a W/D for processing, make sure the decalcification is correctly adjusted.
  With manual processing, rinsing after cleaning should be done with fully desalinated,
  deionized water in order to prevent limescale residues on the instrument, which leave behind white deposits or water spots that burn into the surfaces of the following mirrors and cannot be removed (Fig. 4):

  SEplus, Economy (rear surface mirrors)
  ULTRA FS, ULTRAvision FS (front surface mirrors)

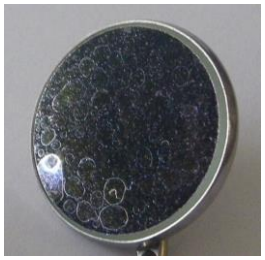

Fig. 4: Water spots

Our tip: **MEGA FS Rhodium, SAphir FS Rhodium**
Rhodium acts as a non-stick coating. Rhodium is acid resistant like gold. Combined with the non-stick effect, limescale residues can therefore be easily removed using acidic cleaners (e.g., neodisher N).

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- **3. Please avoid "short" autoclave programs with high temperature changes at the same time**
  Glass has a different coefficient of expansion than stainless steel. A quick and high temperature change can cause stress to the glass and can lead to a glass breakage / glass cracking.
- **4. Incorrect mounting of a standard mouth mirror on a handle**
  When mounting the mouth mirror on a handle, bear in mind that very high forces are generated especially during final tightening of the mouth mirror, which can have an adverse affect on the welding if it is subjected to it. Therefore, always hold the mouth mirror by the stem – **not** the frame. This way, you can screw on the handle and firmly tighten the screw thread with one last strong twist **without** damaging/deforming the welding and/or frame, which would impair the secure connection of the mirror (Fig. 5+6+7).

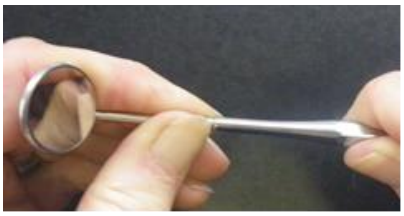
Fig. 5


Fig. 6

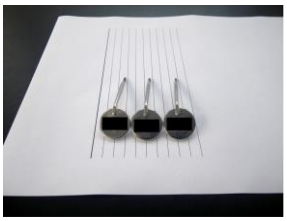
Fig. 7

Our tip: **MEGA Rhodium, ULTRA** (Fig. 1)
RELAX Rhodium, RELAX Ultra (Fig. 2)
The frame and stem or frame and stem including handle are made of one single piece.

Inspection and functional check

However, the mouth mirror is inspected prior to sterilization to ensure it is working properly.

Performance criteria

- Mirror is free of defects such as cracks, nicks and scratches
- Mirror frame and stem are securely connected (see also point 4 above)
- Mirror glass sits securely in the frame
  With mouth mirrors and laryngeal mirrors, unfavorable conditions can negatively impact the construction. The following have therefore to be avoided: Ultrasonic cleaning, high and rapid temperature changes (short program), incorrect mounting of the mouth mirror/laryngeal mirrors on the handle (see point 4 above).

Procedure

Visual and/or manual inspection with regard to the performance criteria (see above).

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Impact on patient safety and safe use

Without the inspection and functional check, it's possible that due to incorrect handling/processing parts of the mouth mirror may come off and fall into the patient's mouth during treatment, e.g. the frame detaches from the stem or the mirror from the frame. Especially in the case of laryngeal mirrors that are applied up to the throat, a loosening part can lead to further complications, such as swallowing or inhalation. The usual complications associated with such occurrences can occur. Safe use is no longer guaranteed.

Faulty and/or defective instruments have to be discarded.

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Appendix 2 - Photo mirrors, photo mirrors with handle

Tips for processing + handling

We recommend the manual processing of this instrument.

Handle, anodised aluminium

- **DO NOT use corrosive, acidic products,** so-called refresh products, such as Neodisher N. These are frequently used in thermal disinfectors.
  The acid would etch off the anodised layer of the aluminium handle.

  Neodisher® Mediclean Dental and Neodisher® Z from the Dr. Weigert Company do not contain any corrosive substances.

- The handles of the dental photography mirrors are made of anodised aluminium. Practical experience has shown that care must be taken when processing anodised aluminium in order to ensure that a disinfectant and cleaning agent suitable for aluminium is used. Other agents destroy the anodised layer. The thermal disinfector is only suitable for reprocessing anodised instruments to a certain degree. (see also Miele Instructions for Use PG8591_106070961)

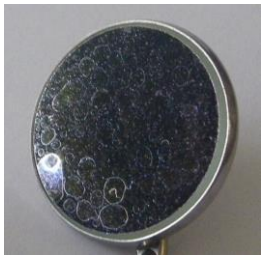
Mirror, front surface

- **1. Mechanical impairment (scratches)**
  Do not use **hard** brushes or sponges. These may scratch the surface of the mirror and directly attack the reflective coating in the case of all front surface mouth mirrors. (Fig. 3)

- **2. Lime deposits and residues**
  If you process with an WD/thermal disinfector, make sure that the decalcification is set correctly. In case of manual processing, rinsing after cleaning should take place using fully demineralised and deionised water to prevent, for example, the formation of lime residues on the instrument, which leave white deposits or water spots and which burn onto the surface of ULTRA mirrors and can no longer be removed (Fig. 4):

  Our tip: **FS Rhodium**
  Rhodium acts as a non-stick coating. Rhodium is acid-resistant as a precious metal like gold. In combination with the non-stick effect, lime residues can therefore be easily removed by acidic cleaning agents (e.g. Neodisher N).

Fig. 3 Scratches/cleaning streaks



FId. 4 Lime stains

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Appendix 3 - MICRO Mirrors

⚠ Product-related warnings

Observe the information on precautions provided with each product package.

Cleaning and Handling: Because of the necessary small dimension the mirror glass thickness is only 0.3 mm. Therefore the handling and especially the cleaning has to be done with utmost care. Pressure/stress can damage the glass. Please avoid crusts and therefore clean the instrument immediately in disinfection solution after the treatment.

Do not use Ultrasonic Cleaner.

MICRO

The stem of this Mouth Mirror is **not suitable** for bending**.**

PRODUCT-RELATED WARNINGS

⚠ **Precaution: Apply a cofferdam to the patient before using the Micro Mirror to exclude any danger of aspiration or swallowing of the mirror glass.**

The mirror glass is adhered with an adhesive into the casing which allows sterilization up to 180°C.

It is a physical principle: the smaller the dimension of the adhesive surface, the smaller the adhesion capacity. The surface of the Micro Mirror is rather small, thus it could happen in rare cases that the adhesion weakens, for example if the stem is bent near the frame of the mirror. Therefore: Check the Micro mouth mirror before and after each use.

MICROflex

By bending and twisting the stem, the MICROflex can be optimally adapted to the individual treatment situation.

PRODUCT-RELATED WARNINGS

⚠ **Please observe the precaution mentioned under point 1**

⚠ **Please observe the following instructions when bending:**

- Do **not bend** in the area of the mirror glass. The glass could break or fall out. **Therefore, check on tightness of the glass before each use.**
- Due to the material the flexibility is reduced by frequent bending step by step (principle of cold working). Bending becomes stiffer and the material gets cracked. **Therefore, check the stem for intactness before each use.**
- Maintain a **bending radius of at least 3mm** (e.g. by using round pliers as e.g. KNIPEX 22 05 140). Avoid absolutely sharp bends.