

EN ISO 17664 Manufacturer information for the processing of resterilizable 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 Handles REF 422 + 423, chrome-plated 3) WHO Periodontal probes 4) Probes 5) PULLover tweezers
Critical A	6) MICRO Mirrors



Date: 2020-12

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 DIN EN ISO 15883-1 and DIN EN ISO 15883-2.

Information from DIN EN ISO 17664:2018-04, 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
3. Exposure time: 5 minutes (full cycle)
4. Drying time: 10 minutes

Observe standard DIN EN ISO 17655 for sterilization with moist heat.

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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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 Handles REF 422+423	Tips for processing and handling
Appendix 3: 3) WHO Periodontal Probes 4) Explorers 5) PULLover tweezers	Tips for processing and handling
Appendix 4: 6) MICRO Mirrors	Warnings + tips for processing and handling

Limitations on reprocessing

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 disinfectant is not correctly adjusted

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

Instructions

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.

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:

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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.

HAHNENKRATT mouth mirrors and handles can – if these are used together – also be processed in their assembled state in accordance with validation report 2016 (see additional information).

Machine processing – cleaning, disinfection, drying

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

Equipment

5. Thermal Disinfector (washer), e.g., from Miele with Vario program. It must reach an A_0 value of at least 3000.
6. neodisher® MediClean Dental from the Dr. Weigert company.
7. neodisher® Z from the Dr. Weigert company.
8. 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 DIN EN ISO 15883-1 and DIN EN ISO 15883-2.

Information from DIN EN ISO 17664:2018-04, 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.

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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.

Information from DIN EN ISO 17664: Biocompatibility may be affected by the use of rinsing agents.

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.

1. Pre-wash for 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 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 1 minute in order to prevent limescale residues on the instrument, which leave behind white deposits or water spots.

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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.

Information from DIN EN ISO 17664: Biocompatibility may be affected by the use of rinsing agents.

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: 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.

Information from DIN EN ISO 17664: Biocompatibility may be affected by the use of rinsing agents.

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.

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

- 1) Mouth Mirrors
- 6) MICRO Mirrors

- Appendix 1
- Appendix 4

Packaging

Use standardized packaging material (DIN EN ISO 11607-1) designed for this purpose. The packaging must be large enough so that no stress is placed on the seal.

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 DIN EN ISO 17665

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

Procedure:

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

5. Fractionated pre-vacuum method (at least 3-fold)
6. Sterilization temperature 134°C
7. Exposure time: 5 minutes (full cycle)
8. Drying time: 10 minutes

Observe standard DIN 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.

Follow the instructions for use of the device manufacturer as well as the manufacturer of the sterile packaging.

Storage

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

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.

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Observe the national regulations for disposal.

The basis for this manufacturer information are validations carried out by the accredited Zwisler laboratory.

Validation reports:

1707.2770-hahnenkratt_manual reprocessing in 2017
1707.2765-hahnenkratt_automatic reprocessing in 2017
1707.3109-hahnenkratt_sterilisation process in 2017
1411.2519-hahnenkratt_washer in 2016 (RELAX)
1412.0229-hahnenkratt_autoclav in 2016 (RELAX)

Validation reports for instruments in assembled condition valid only for HAHNENKRATT mouth mirrors and handles matched to HAHNENKRATT tolerances include:

1608.1225-HAHN_ValBericht_RDG_Thermodes in 2016
1608.2906-HAHN_ValBericht_Autoklav in 2016

Manufacturer contact

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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.