Recommendation by the Quality Task Group (66/67:2023)

The use of ultrasonic cleaners for precleaning medical devices

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1. Introduction

To enhance the cleaning process, the use of an ultrasonic bath is a long-established and proven method that is used for precleaning when reprocessing medical devices.

ULTRASONIC WAVES are mechanical waves generated by transducers. The effects of these high-frequency sound waves (ultrasonic waves in the 35–40 kHz range are used in medical device reprocessing) are based on cavitation. The ultrasonic waves typically lead to the formation of cavitation bubbles which, on implosion, blast off the adhering soil residues from rigid surfaces.

ULTRASONIC WAVES are mechanical waves generated by transducers.

Cleaning and disinfection are essentially two separate reprocessing steps.

TREATMENT IN THE ULTRASONIC BATH is just a precleaning step. It is not a standalone cleaning solution and is not a substitute for disinfection!

TREATMENT IN THE ULTRASONIC BATH is not a standalone cleaning solution.

Therefore, **PRECLEANING** must always be followed by cleaning and disinfection, preferably in a washer-disinfector (WD). Details are given in the "Guideline for validation of manual cleaning and manual chemical disinfection of medical devices".

PRECLEANING must always be followed by cleaning and disinfection.

2. Selecting a suitable ultrasonic bath

The ultrasonic bath can be used to preclean non-critical, semi-critical and critical medical devices. It is used for precleaning resistant soils or areas that are difficult to access. But an ultrasonic bath is not suitable for all medical devices, such as e.g. **MOTOR SYSTEMS OR FLEXIBLE MATERIALS**. Whether a medical device is compatible with ultrasonic cleaning can be determined by consulting the reprocessing instructions of the medical device manufacturer.

An ultrasonic bath is not suitable for **MOTOR SYSTEMS OR FLEXIBLE MATERIALS**.

3. Ultrasonic bath equipment

- Size as needed
  - for DIN/ISO baskets
  - for small components
- Lid; preferably switch on the bath only with lid closed (aerosol formation, noise protection)
- Filling level indicator
- Integrated water outlet
- Manual control elements on the front panel
- Display or switch
  - Time switch
  - Integrated temperature display with warning or switch-off facility, if necessary. **A TEMPERATURE** of 40°C should not be exceeded (protein fixation).
- Extractor with connection to the exhaust air, if necessary
- Connectors for lumened medical devices, if necessary
- Hanging baskets or insert baskets, depending on area of use
  - Basket supports (spacers to floor) for holding wire baskets
  - Hanging baskets (especially for small devices)
  - Small insert beakers, insert baskets, including holder
    For cleaning small glass or plastic components in liquids, or for cleaning very small stainless steel or plastic components, e.g. drills or needles
    - Cassette holders for accommodating DIN cassettes in dental practices
    - Spoon carriers for secure fixation of impression spoons in dental practices and dental laboratories.

A **TEMPERATURE** of 40°C should not be exceeded (protein fixation).

- Ultrasonic frequency and selectable modes
  - The standard frequency can be found in the manufacturer's instructions.
  - Using the generator, in some ultrasonic cleaners a specific frequency range can be regulated around the main frequency, thereby creating the different modes.
  - Degas – for degassing
  - Sweep – uniform, gentle cleaning
  - Pulse – for stubborn stains
  - Or, an alternating combination of Sweep and Pulse, if necessary

The correct **ACCESSORIES** protect the medical devices.

The correct **ACCESSORIES** make it easier to operate the ultrasonic cleaner and, at the same time, protect the ultrasonic bath and medical devices.

4. Ultrasonic bath varieties

4.1. Tabletop ultrasonic cleaners

Tabletop ultrasonic cleaners are installed on a work surface on the unclean side of the RUMED.

- Fast installation/start-up
- Easy handling for repairs (dispatch for repair)
- Depending on size, the working height must be observed

4.2. Built-in ultrasonic cleaners

Built-in ultrasonic cleaners are installed in workbench systems on the unclean side of the RUMED.

- Undercounter installation provides for hygienic and unencumbered work surfaces
- Ultrasonic generators installed in undercounter cabinet
- Optionally, non-ultrasonic cleaning bath to expand the workstation

4.3. Integrated ultrasonic cleaners

Ultrasonic cleaners can also be integrated into washer-disinfectors (WDs).

5. Process chemicals

The use of process chemicals (detergents) improves the cleaning performance. Demineralised water should preferably be used.

DETERGENTS must be suitable for use in an ultrasonic bath.

- Only **DETERGENTS** declared suitable for use in an ultrasonic bath by the manufacturer should be employed. The process chemicals used should be tailored to the nature of the adhering soils (e.g. mucus, bone residues, ointment residues, etc.). Mildly alkaline and/or enzymatic detergents can be used.
- The use of disinfectant detergents is not recommended because they usually achieve a less good cleaning performance compared with non-disinfectant detergents.

The detergents used in an ultrasonic bath should be tailored to the other process chemicals employed in the other reprocessing steps (e.g. in the WD). Otherwise, the medical devices must be thoroughly rinsed after withdrawing them from the ultrasonic bath to ensure that any entrained detergent residues will not adversely affect the subsequent reprocessing process (foam formation, interactions).

NOTE: Seek the advice of the process chemicals' manufacturer to rule out any interactions.

6. Operation

The ultrasonic bath can achieve effective results only if operated as instructed.

6.1. Personal protection

Personal protection equipment (PPE) must be worn when working in the decontamination area and handling process chemicals (see German Technical Regulations on Biological Substances *TRBA 250* and on Hazardous Substances *TRGS 401* as well as safety data sheets for the process chemicals).

Precautions to be taken	Risk
Do not reach into the ultrasonic bath while it is in operation	Damage to tissues /periosteum
Always close the ultrasonic bath lid while it is in operation	Aerosol inhalation, hearing damage
Rinse or brush hollow instruments below water level	Risk of splashing

6.2. Proper operation

6.2.1. Commissioning/start-up

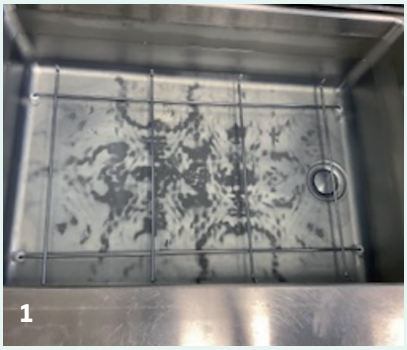
- Use cold water to **FILL** because the solution will be heated additionally by ultrasound over time. Protein denatures as from around 40°C and may adhere to the instruments. Temperatures above 40°C must be avoided.
- Fill the bath manually to the defined filling level and then add the correct amount of detergent. Precise dosing instructions are given in a standard operating procedure. Alternatively, an automated dosing device can be used.
- Degas the solution before commissioning. To do this, start the ultrasonic bath with solution but without a load and observe the **DEGASSING TIME** specified by the manufacturer. Gases in the solution which would impede ultrasonic cleaning are removed.

Use cold water to **FILL**.

Observe the **DEGASSING TIME** before commissioning.

6.2.2. Operation

- Medical devices must not be placed directly on the bottom of the bath since this could damage the bottom of the bath (Fig. 1). Therefore, always use suitable wire basket racks or hanging baskets (Figs. 2–3).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- It may be advisable to use an additional fixation accessory for very small or delicate parts, e.g. for gentle positioning (Fig. 4).


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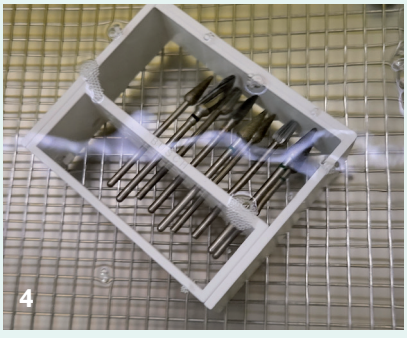
Hanging basket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Tray for milling components

- Place medical devices in the bath with joints opened to 90°
- The medical devices must be completely submerged in the solution
- Place devices in the bath without creating bubbles; fill lumens with the solution since cavitation is only effective in areas filled with solution.

- The sonication time is generally 3–5 min (note manufacturer's instructions).
- Avoid acoustic shadowing from overloading the ultrasonic bath as this impedes the ultrasonic effects
- Visually inspect devices after withdrawing them from the ultrasonic bath and reclean manually, if necessary
- Always rinse devices before proceeding to the next process steps unless compatibility and effectiveness are guaranteed without this step (risk assessment).

6.2.3. Changing the solution

Replace the **CLEANING SOLUTION** at least every working day.

Replace the **CLEANING SOLUTION** immediately if there is visible soiling as well as at least every working day and more often if instructed by the manufacturer. Clean and disinfect the ultrasonic bath after emptying it at the end of the working day (flush out the drain hose).

7. Routine checks

ROUTINE CHECKS must be set out in standard operating procedures.

All equipment used in the reprocessing process must undergo periodic **ROUTINE CHECKS** of operational safety and this must be documented. The scope of the checks, their conduct and intervals must be set out in standard operating procedures.

The **FOIL TEST** is used for functional testing of an ultrasonic bath.

The **FOIL TEST** based on IEC/TR 60886 (1987-03) is recommended for functional testing of an ultrasonic bath (Investigations on test procedures for ultrasonic cleaners) when first installed and then at regular intervals (e.g. weekly/monthly). The economic operator is responsible for the frequency of implementation.

The foil test is an easy method to demonstrate the intensity and distribution of cavitation in an ultrasonic bath. To that effect, a sheet of aluminium foil (household foil) spread across a foil test frame is placed obliquely in the ultrasonic bath. Depending on the sonication time, the aluminium foil is perforated or destroyed to a certain degree by the cavitation. Suitable frames for performing the foil test can be ordered as accessories for the ultrasonic bath.

The **TEST CONDITIONS** must always be the same.

To assure the reproducibility of the test results it is important that the **TEST CONDITIONS** should always be the same:

- Fill the ultrasonic bath to the level indicator
- Temperature of the sonication solution
- Degassing
- Aluminium foil (brand, strength)
- Frame positioning
- Sonication time
- Detergent type and concentration

The perforated areas of the foil should have roughly the same extension and distribution – they are never identical.

The foils can be archived as a scan or photo. More information on the foil test can be found in Annex 12 of the "Guideline for validation of manual cleaning and manual chemical disinfection of medical devices".

Replace the solution after the foil test and clean the bath thoroughly to remove all foil residues.

8. Ultrasonic baths for robotic and minimally invasive surgical (MIS) instruments

ROBOTIC INSTRUMENTS can be cleaned in special ultrasonic cleaners.

Effective ultrasonic cleaning is assured for **ROBOTIC INSTRUMENTS** when through continuous movement the medical device's components and cable winches are optimally exposed to ultrasonic sonication. To achieve this, the following properties are combined in special ultrasonic cleaners for optimal detachment of contamination:

- Enhanced precleaning through a combination of ultrasound, rinsing and movement
- Connectors for medical device lumens
- Individual flushing of channels and simultaneous individual patency testing of lumens
- Document by printing the protocol or forwarding it to the electronic documentation system, if necessary.

References see p. 283