Recommendations by the Quality Task Group (66): General Principles for Using Ultrasound for Cleaning Medical Devices* – Part 1

Ultrasonic cleaning has for a long time now proved to be a well- known and tried and tested cleaning method used in precision mechanics workshops as well as for instrument reprocessing. In some Anglo-Saxon countries precleaning is carried out in general in an ultrasonic basin. *In Germany ultrasonic precleaning is recommended especially for "problem instruments", i.e. for instruments which, because of their design or due to particularly stubborn soils, call for intensive mechanical cleaning or precleaning before being reprocessed in the washer-disinfector.*

1. Ultrasonic action

Ultrasonic waves are mechanical waves that spread out in liquid media and whose intensity declines in line with each square metre distance. They are generated by transducers using either magnetic or electrical energy (piezoelectric effect). Ultrasonic waves are broken when they hit against solid objects and walls. The ➔ **ULTRASONIC BASINS NORMALLY USED** in medical technology operate in the frequency range 32 – 50 kHz.

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The solution in the ultrasonic basin is heated because of the ultrasonic energy alone. Under no circumstances should ➔ **TEMPERATURES** exceed 45°C, because this would give rise to protein denaturation. For that reason it is recommended that the temperature be monitored.

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Ultrasonic action is based on what is known as 'cavitation', occurring mainly at the boundary surfaces between water and solid objects. This gives rise to cavities containing gas at negative pressure. Collisions between the cavities (implosion of the cavitation bubble) generates pressure values that can be as high as 100 bar, in turn, leading to mechanical removal of soil particles from solid surfaces (*blasted off*).

In elastic objects, e.g. medical devices (MDs) made of rubber, latex or silicone rubber, this effect is greatly attenuated because of the flexibility of the material.

Ultrasonic waves are screened off by instruments arranged with one layer above the other. Likewise, only to a limited extent can the ultrasonic waves reach cavities and covered surfaces.

Investigations have shown that distribution of the energy can vary greatly in a bath in accordance with the

- Filling level
- Temperature
- Type of load
- Arrangement of load

in turn, resulting in very different cleaning *performances* (see Part 2) (Fig. 1).

An ➔ **ULTRASONIC BATH DETACHES THE SOILS** from the surface but does not rinse them off. For that reason appropriate methods must be used to remove the soils. This can be done either manually or in a machine.

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* This updated recommendation replaces Recommendations 8 and 9.
These recommendations give an overview of the basic principles of ultrasonic for cleaning and its practical application. They do not deal with ultrasonic basins integrated into washer-disinfectors.

2. Ultrasonic basin fittings

Depending on the make, the fittings can include:

- Temperature measurement
- Thermostat
- Time switch
- Lid
- Cycle indicator
- Holder for loading rack
- Level indicator
- Degassing programme
- Setting for performance and frequency
- Connectors for hollow instruments

3. Amenability of medical devices to precleaning in an ultrasonic basin

Not all medical devices are declared as being compatible with ultrasonic treatment.

Normally, suitable MDs are sonicated for 3 – 5 min. In principle, the ➔ **MANUFACTURERS' INSTRUCTIONS** must be observed. Any deviations from these are made because of material compatibility, cleaning requirements and the validated reprocessing methods specified by the manufacturer. ✦

➔ The **INSTRUCTIONS OF THE MEDICAL DEVICE MANUFACTURERS** must definitely be observed (DIN EN ISO 17664).

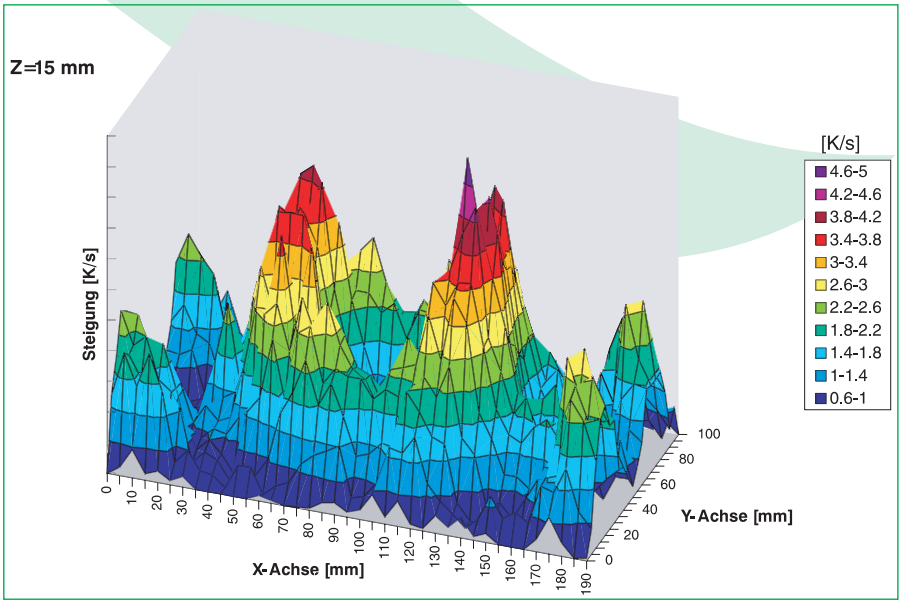

Fig. 1: Field distribution and intensities of the cavitation field in one level of a commercially available ultrasonic basin, photographed with thermistor probe

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