Application of DIN SPEC 40170 for the evaluation of ultrasonic devices used in hospitals and dental practises for cleaning of surgical instruments.

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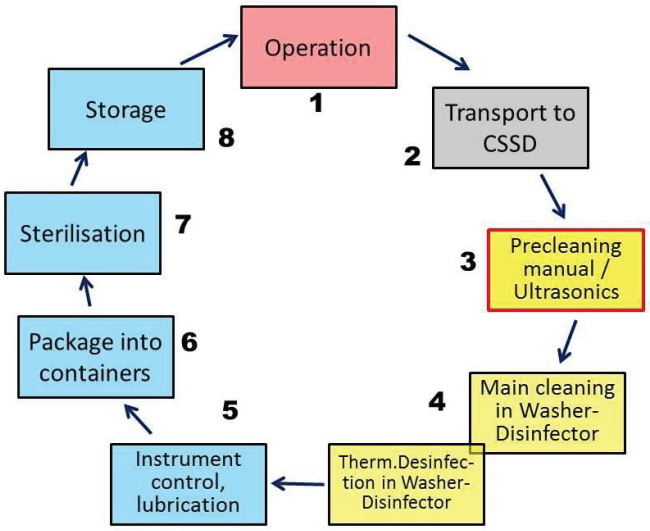
Introduction

In Hospitals, ultrasonic cleaning is a common step in the reprocessing of instruments after use in surgery. The complete cycle of instrument processing is shown in figure 1.



Figur 1: Instrument reprocessing cycle in hospitals. After surgical operation, instruments are transported to the CSSD (= Central Sterilisation Supply Department). This department is normally splitted into an "unclean" and a "clean" area. Step 3 is done in the unclean area, here the instruments are precleaned with ultrasonics and other methods. Then the instruments are cleaned and thermally disinfected in a fully automated step in washer-disinfector machines, similar to dish-washers, but built in a wall that is separating both areas. The instruments leave the machines into the clean area. Here, the instruments are checked, lubricated if necessary, sterilized, and stored until the next operation.

This process has to be validated periodically, normally once a year. While the main cleaning process in the washer-disinfector machines is nearly fully automated and process parameters are continuously monitored and recorded, the precleaning process in ultrasonic baths is less controlled, and quality test systems available up to now deliver only semi-quantitative results.

The development of surgical instruments to more complexity and a rising awareness of hygienic quality assurance in hospitals lead to the demand for more refined evaluation and validation, also of the manual processes in instrument reprocessing, and ultrasonic precleaning is considered to be a part of these manual processes [1].Therefore it was our approach to assess, whether and how the recently published DIN SPEC 40170 is suitable to be used to close this gap in hospital device qualification processes. And since dentists also work with ultrasonic baths, under less strict normative rules, we also assessed this method at dental practices.

DIN SPEC 40170

Title: Measurement and judgement of the cavitation noise.
Date of release: July 2013.
Main aspects: In ultrasonic baths used for cleaning processes, the major principle of cleaning activity is the occurrence of inertial cavitation, that is the rise and collapse (implosion) of small vacuum bubbles. Whenever these implosions occur at a boundary surface between medium and cleaning objects, a jet stream of water/cleaning agents is produced and hits the surface of the objects.

The imploding cavitation bubbles produce a broadband cavitation noise, which correlates with the occurrence and quantity of cavitation bubbles. According to DIN SPEC 40170, the cavitation noise is quantified by analyzing the spectrum of the acoustic sound pressure after Fourier transformation. In a first step, the maximum (highest peak) of the transformed spectrum of the acoustic sound pressure is determined (see example in figure 2, here the maximum is at 37 kHz), and the cavitation noise is measured at the 2.15 to 2.35 fold of the working frequency, in order to get as less disturbance as possible, caused by the sound pressure of resonance effects (overtones). In Appendix A of DIN SPEC 40170, an overview of assumed minimum cavitation noise levels is given, depending on the working frequency. The minimum values to be reached are:
26 dB at 25 kHz working frequency,
27 dB at 35 kHz working frequency, and
28 dB at 45 kHz working frequency.

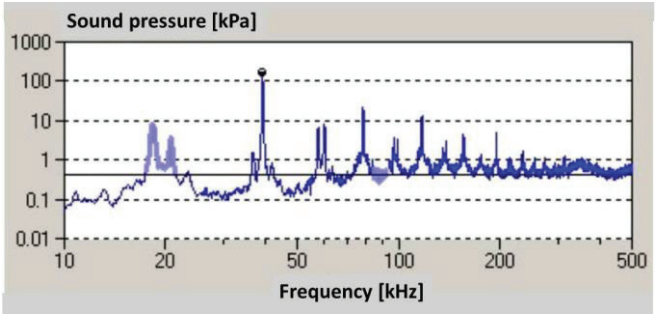


Figure 2: Fourier transformed spectrum of the acoustic sound pressure. In this example, the working frequency (highest peak) is at 37 kHz. Other local maxima are due to resonance effects (harmonic and sub harmonic). The cavitation noise is measured between the first (here double peak) and second harmonic overtone, at the 2.15 to 2.35 fold of the working frequency. In this example, it is between 79.6 kHz and 87.0 kHz (area is marked in light blue).

Methods / Execution of tests in the field:

We used a calibrated hydrophone (Reson), an analog digital converter (TiePie) and our in-house developed software to perform the measurements according to the directions given in DIN SPEC 40170. A single measurement is done during a period of 100 milliseconds, and the working frequency (where maximum sound pressure occurs) is determined. Then the cavitation noise level is determined at a range between the 2.15 fold and 2.35 fold of the working frequency. The average cavitation noise level together with the working frequency during this 100 millisecond period is recorded.

In our field tests, we set the number of single measurements to be done at a value of 100, so the software will perform subsequent single measurements (and calculations), so that (depending on the performance of the computer system), ever 0.5-1 seconds, a single measurement is performed. So in total, one test comprising 100 single measurements takes around 70 seconds. All data given in this publication are average values of 100 single measurements, except data in figure 4, here the time resolved single measurement data are shown.

Every ultrasonic bath was assessed in this way several times. That means whenever possible, we started with fresh and deionized water for the first measurement, than we degassed the bath for 5 or 10 minutes by leaving the ultrasonic switched on. Than we performed the second measurement, and after adding cleaning chemicals (detergents, which lower the surface tension of the medium), we performed the third measurement.

In some of the hospitals, it was not possible for us to empty the tank and refill with fresh deionized water, due to the work load of the department. In this case, we just performed 2 measurements of the bath. Here, the first measurement was performed with previously filled water and cleaning chemicals. The second measurement was performed with the same medium after 10 minutes of degassing by ultrasonic action. Whenever possible, we also measured the power consumption with a device logging the data every second. Temperature was also monitored, and it was always within a range of 30°C - 40°C.

Results

(1) Field tests in hospitals

Five ultrasonic devices were assessed in different hospitals in Germany. At three of these hospitals (A, B, and D) it was not possible to replace the tank filling with fresh deionized water, so this value (column "M-1" in table 1, and lacking blue bars in figure 3) could not be taken. So we just measured the cavitation noise level directly after switching on the device (M-2), and again after 10 minutes of operation (M-3).

In hospital A, both values of the cavitation noise level are close together (29.5 and 29.3 dB), and also the power consumption does not alter significantly (560 and 562 W, respectively).

In hospital B, the cavitation noise level raised from the first (36.3 dB) to the second measurement (35.5 dB) by 1.1 dB, and we could also observe a rising in the power consumption (5.6%). Device settings were not changed between both assessments.

In hospital C, we had the possibility to fill the bath with fresh and deionized water. The first measurement was performed directly after filling, and the second after additional 10 minutes of degassing. Corresponding cavitation noise levels (19.9 dB and 23.2 dB) were both significantly under the recommended level of 27 dB as listed in Appendix A of DIN SPEC 40170. After adding cleaning chemicals (MediClean Forte, 1% final concentration) a significant rise of cavitation noise level could be observed (32.7 dB, which is an increase of 9.5 dB compared to the preceding measurement M-2), while no changes in the power consumption could be observed.

Field tests in hospital D show a stable cavitation noise level, power consumption data could not be recorded, since power connection was not reachable.

In hospital E, in the first step (M-1) the bath was tested with freshly filled, deionized water, resulting in a cavitation noise level of 26.6 dB. After 10 minutes of degassing, the second measurement was performed. During this measurement, we monitored a sudden loss, as well of the power consumption, as of the cavitation noise level. Since the data given in figure 3 (M-2) show only average values of the n=100 single measurements, the time resolved single measurements of M-2 are shown below in figure 4.

Table 1: Data gained by field tests in hospitals

Client	Tank Vol.	Working frequency	Cavitation noise level & Power consumption		
			M-1	M-2	M-3
A	32 L	34.4 kHz	n/a n/a	29,5 dB 560 W	29,3 dB 562 W
B	32 L	35.2 kHz	n/a n/a	36,6 dB 643 W	38,5 dB 679 W
C	32 L	36.7 kHz	19,9 dB 292 W	23,2 dB 290 W	32,7 dB 291 W
D	32 L	40.1 kHz	n/a n/a	36,7 dB n/a	36,7 dB n/a
E	26 L	36.0 kHz	26,6 435 W	17,1 dB 364 W	n/a n/a

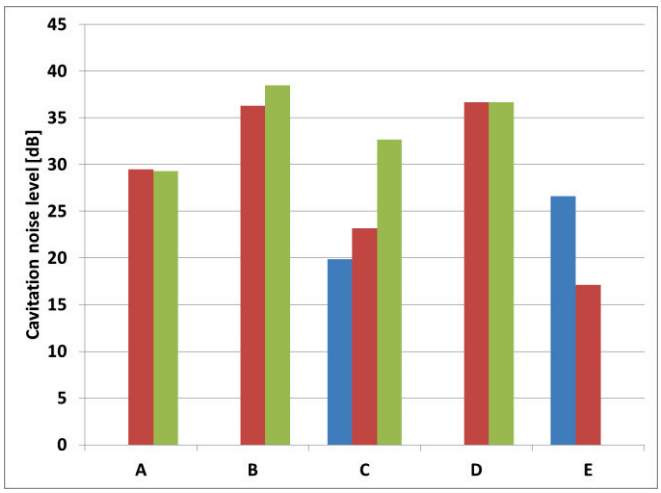


Figure 3: Cavitation noise levels of ultrasonic cleaning devices in five hospitals (A-E). Each bar represents the average of 100 single measurements.

In hospital C and E, we had the possibility to refill the ultrasonic bath with fresh and deionized water, before we started the tests. So the blue bars (C, E) show cavitation noise levels with fresh and deionized water.

In hospitals A, B, D, we had to start the tests with already prepared medium (water + detergent): red bars in A, B, D show the results of a first measurement, green bars show measurements of water with detergent after a period of 10 minutes degassing by ultrasonic action. In hospital C, the green bar also shows the cavitation noise level after 10 minutes degassing and then adding of detergent.

In all hospitals, the detergent used was MediClean Forte, with 1 % final concentration. Temperature was also monitored, and it was always in the range according to DIN SPEC 40170 (that is 30-50°C).

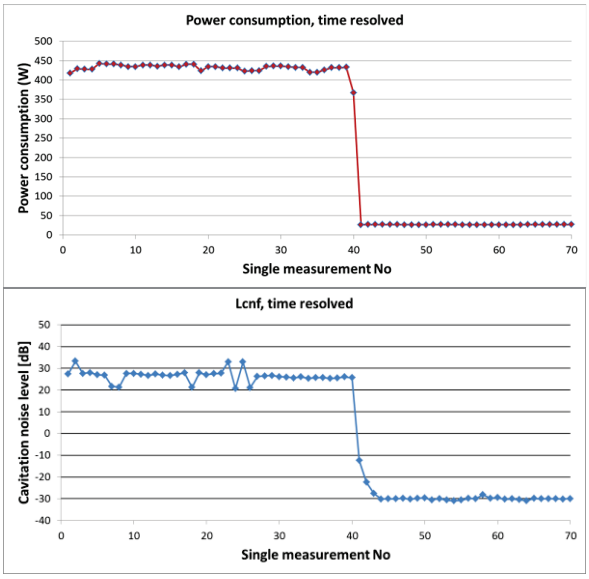


Figure 4: Time resolved single measurement data of hospital E, series M-3. During this series we observed a breakdown of both the power consumption and the cavitation noise level (L_{cnf}). (Compare red bar in figure three, "E", which gives the average L_{cnf} value of 100 single measurements.) Therefore, the average value given in figure 3 will not be taken into account in the discussion of the other data, it is discussed separately.

(2) Field tests in dental practices

We performed field tests at three dental practices. Since dentists usually use small ultrasonic devices (table top, with a typical volume of 2-5 liters), it was always possible to start with a refilling of fresh and deionized water. The sequence of the measurements was analogous to that described above, we only reduced the degassing period between the first and the second measurement to 5 minutes. Results of both power consumption and cavitation noise levels are given in Table 2, and a diagram comparing cavitation noise levels in a graphic manner is shown in figure 4.

Table 2: Data gained by field tests in dental practices

Client	Tank Vol.	Working frequency	Cavitation noise level & Power consumption		
			M-1	M-2	M-3
X	4 L	57.5 kHz	33.0dB 146 W	33.8 dB 147 W	33.9 dB 146 W
Y	3 L	40.9 kHz	28.1 dB n/a	27.8 dB n/a	28.1 dB n/a
Z	3 L	39.1 kHz	22.6 dB 163 W	23.3 dB 162 W	30.5 dB 163 W

In dental practice X, the cavitation noise level is not changing much between first measurement (fresh deionized water), second measurement (deionized water after 5 minutes of degassing) and third measurement (addition of cleaning chemicals). It is always on a high level, in a range of 33-34 dB. Power consumption values are also stable during the different tests.

In dental practice Y, we observed a similar behavior between the three series, cavitation noise levels are in a range of 27.8-28.1.

In dental practice Z, the first measurement of fresh and deionized water gives a significantly weaker signal (only 22.6 dB), compared to X, Y. After 5 minutes degassing, the signal rises to 23.3 dB, and after adding detergent it rises significantly to 30.5 dB.

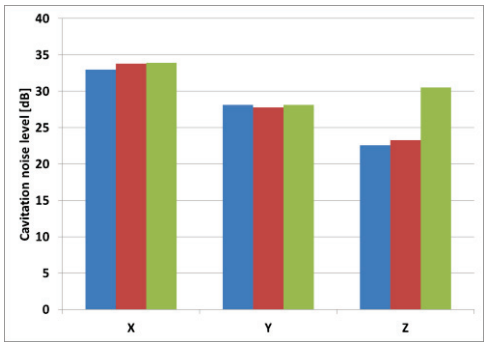


Figure 5: Cavitation noise levels of ultrasonic cleaning devices in 3 dental practices (X, Y, Z). Each bar represents the average of 100 single measurements.
Blue bars show values with fresh and deionized water as filling medium.
Red bars show values of the same medium after 5 minutes of degassing by ultrasonic action.
Green bars show cavitation noise levels after adding detergent into the degassed water.

Discussion

With clients A, B, D, cavitation noise levels do not significantly change before and after degassing of the medium (water/detergent). This is also the case with clients X and Y, where we performed the tests with fresh and deionized water, deionized water after degassing, and adding detergent. Variation of the noise level is 1.9 dB or less.

In contrast, with clients C and Z, we observed an increase of cavitation noise levels after degassing, and an even higher increase after adding detergent:

With Client C, increases are:
M-1 (fresh deionized water): 19.9 dB
M-2 (deionized & degassed): 23.2 dB (+3.3 dB related to M-1)
M-3 (adding detergent): 32.7 dB (+9.5 dB related to M-2)

With Client Z, increases are:
M-1 (fresh deionized water): 22.6 dB
M-2 (deionized & degassed): 23.3 dB (+0.7 dB related to M-1)
M-3 (adding detergent): 30.5 dB (+7.2 dB ‘ related to M-2)

So, if we separate all clients into two groups, that is client A, B, D, X, Y with **N**o significantly changing cavitation noise levels (“**N**-group”) and the group with **I**ncreasing levels (the I-group), it is eye-catching that in the N-group, the cavitation noise levels are already quite high at the first measurement (> 27.5 dB), while both devices in the I-group start with cavitation noise levels <22.6dB.

In hospital E, results are special, due to the breakdown of the device during M-2. Though normally this “bad result” is not worth being published, we state it is notable, since we assessed the bath further (data not shown) and found, that the malfunction occurred more or less periodically. Staff in hospital E was totally unaware of this fact, and our field test helped them to bring their device back to proper function. While *this* malfunction could also have easily been detected by only monitoring the power consumption (see figure 4), other malfunctions might occur in ultrasonic baths, which will not have an effect on power consumption. So cavitation noise measurement might be an independent and more direct tool to check and qualify ultrasonic cleaning devices in the context of the validation.

Taking into account that the minimum threshold level for inertial cavitation to occur is at ~27 dB according to DIN SPEC 40170, and that the addition of detergent is only an optional directive according to this norm, it seems necessary to us to define this parameter (addition of detergent) in more detail, and to get a more binding direction in DIN SPEC 40170.

In hospitals (and dental practices), ultrasonic cleaning devices are always used with added detergent, and it seems reasonable to us to qualify the devices under conditions close to the ones of everyday work. Data from the N-group (A, B, D, X, Y) suggest that neither degassing nor adding of detergent (X, Y) have a significant influence on the cavitation noise level, once the ultrasonic activity did already “jump” over the threshold level of a first appearance of inertial cavitation (~27 dB according to DIN SPEC 40170).

In contrast, under circumstances where this threshold is not reached by deionized water as sole medium (I-group: C, Z), it could be crucial to perform the test *with* detergent, in order to find out whether an appropriate cavitation noise level is reached under these (everyday work) conditions or not.

Another important aspect is the determination and definition of the cavitation noise threshold level, above which cavitation activity will occur. Basic research was performed by Sobotta & Jung [2], relating ultrasonic intensity to sound pressure at working frequency and cavitation noise at the 2.25 fold of the working frequency. The data suggest a direct proportional, perfect linear (correlataion coefficient: $R^2=1$) relationship of working frequency (f_0) and cavitation noise level (L_{cnf}), following the equation:

L_{cnf} [dB] = 0.1 f_0 [kHz] + 23.5

(see information on DIN SPEC 40170 given in the introduction).

But however striking this *suggested* linear correlation might be, taking DIN SPEC 40170 correctly, only three cavitation threshold levels are given for three corresponding frequencies (26 dB at 25 kHz; 27 dB at 35 kHz, and 28 dB at 45 kHz). So strictly speaking, the threshold levels are only defined for the three frequencies listed above.

A further investigation on the relation of working frequency and cavitation threshold levels seems necessary to us.

It also seems reasonable and helpful to us, to investigate the effect of adding detergent on cavitation noise levels in the same manner. Thus, on the one hand suitable one-component detergents could be characterized and defined to be used during device qualification (e.g. in hospitals, but it might also be applicable to other fields). On the other hand, these investigations could also contribute to a further characterization and definition of cavitation threshold levels as a function of working frequency.

Since in hospitals, dentistry, and many other fields of application, ultrasonic cleaning baths are always run *with* detergents, a device qualification with pure deionized water does not seem apt to us. Instead, we suggest the use of a suitable one-component detergent, which should be common, easy and safe to handle, and available worldwide in the same and defined quality (e.g. Sodium Lauryl Sulfate or Polysorbate (suitable for foodstuffs).

Literature

[1] DGSV. Leitlinie zur Validierung der manuellen Reinigung und manuellen chemischen Desinfektion von Medizinprodukten (Oktober 2013), http://www.dgsv-ev.de/conpresso/_data/Manuelle_Leitline_deutsch_Internet.pdf

[2] Sobotta, R., and Jung, C. Messung der Kavitationsrauschzahl. Fortschr. d. Akustik. DAGA 2005, S. 581-582