Comparison of Methods for Testing Ultrasound in the Cleaning Bath

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Introduction

Ultrasound assisted aqueous cleaning is an essential step during manufacturing and surface treatment of medical devices. To ensure reproducible surface treatment, monitoring and validation of the ultrasound parameters in the cleaning bath is required. Various phenomena are used to test ultrasound in a cleaning bath. One phenomenon is the erosive effect of ultrasound on solid surfaces due to cavitation. It is the basis of the aluminium foil test. Although very simple in application, quantitative data characterizing ultrasound power can hardly be obtained. Additionally, aluminum particles released from the damaged foil remain in the cleaning bath, which is not acceptable for medical device cleaning. Another phenomenon is a sonochemical reaction induced by ultrasound as used i.e. in the SonoCheck dosimeter [1]. Combined with a pH indicator SonoCheck vials show a color change from green to yellow under the influence of ultrasound which is used as visual test. A further phenomenon is the acoustic noise which is produced by the dynamics of the cavitation bubbles induced by ultrasound. The cavitation noise can be measured using a hydrophone and an appropriate analog-digital converter (cavimeter) [2]. In contrast to the qualitative aluminum foil and the SonoCheck tests, the cavimeter test yields a quantitative parameter (cavitation noise level) to characterize ultrasound. We present data of a comparative study of measuring the cavitation noise level and the spectroscopically quantified colorimetric change of the SonoCheck as function of the ultrasound power, the spatial position in the cleaning bath and the ultrasound frequency.

Materials & Methods

The ultrasound bath (KKS Ultraschall AG) of the size of (358 x 358 x 400) mm^3 was filled with a neutral, tenside containing cleaner (2 vol.% KKS-180-7131 + 0.5 vol.% KKS-180-7415; 60 ±2°C) to a height of 390 mm (Fig. 1).

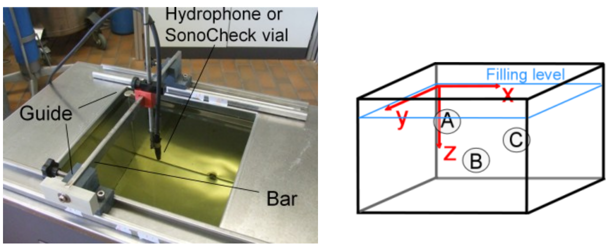

Figure 1: Ultrasound tank with positioning guide and holder for the hydrophone and the SonoCheck vial (left). Measuring points A, B and C (right).

Filling height of the bath during the experiments was maintained constant by a custom-made setup based on hydrostatic pressure levelling. Sixteen transducers with each 50 W were mounted at the bottom wall of the bath (maximal 800 W; 0.624 W/cm^2; 15.7 W/lt). Ultrasound power was determined from the electrical power drawn by the ultrasound generator. Bath heating power does not contribute to the measured power since it was supplied separately.

SonoCheck dosimeter vials originate from Pereg GmbH [1]. The green color of the solution in the SonoCheck vials originates from the pH indicator bromothymol blue at its p*Ka* point between 6 and 7. During ultrasound application protons are released due to the sonochemical reaction involving water and chloroform [3]. The produced protons shift the pH-depending equilibrium of bromothymol conformers to the acid form (yellow color). The color change was spectroscopically measured by placing the vials directly into the 1cm-cell holder of the spectrometer (PerkinElmer Lambda 25, software UV WinLab) (Fig. 2).

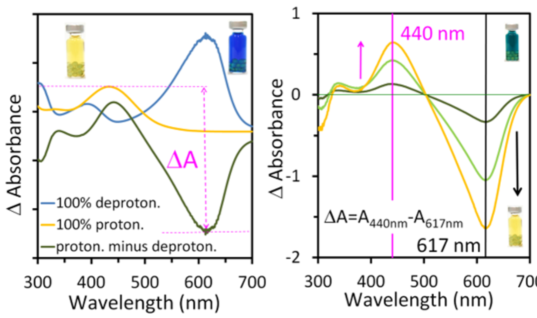

Figure 2: Left: Absorption spectra for completely deprotonated (blue) and protonated (yellow) indicator and difference spectrum for 100% conversion. The acid yellow and the alkaline blue SonoCheck were produced by injecting 1 µl of 1 N HCl and 1 N NaOH into the vial, respectively, using a syringe and a needle to pierce the cup. Right: Ultrasound induced absorption difference spectra of the SonoCheck. The green color of the SonoCheck before ultrasound application corresponds to ca. 50% deprotonated respective ca. 50% protonated state of the indicator.

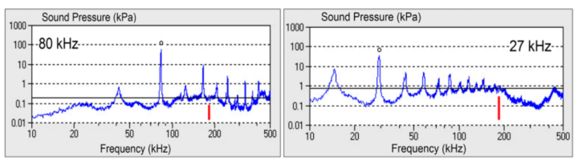

Figure 3: Frequency spectrum of the sound pressure for 27kHz (right) and 80 kHz (left) driving ultrasound frequency and indication of the region for determination of the cavitation noise level (red line).

The ultrasound pressure-frequency spectrum was monitored using a hydrophone (TC4034, Reson) connected to the KaviMeter (ELMA Hans Schmidbauer GmbH & Co. KG, Singen, DE). The cavitation noise level LKRZ as defined in [2] was determined in the frequency range of 183 ± 0.5 kHz [4] (Fig. 3).

Results

SonoCheck absorbance (color) change increases within the first 15 s of reaction time whereby reaching almost 100% color conversion (green (50%) to yellow (100%)) (Fig. 4).

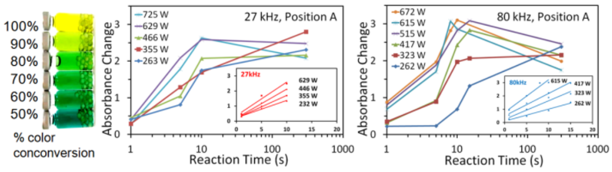

Figure 4: Effect of reaction time on SonoCheck absorbance change; inset: mean values for positions A, B and C; (left) visual impression of the color change in the vials.

For reaction times up to 15 s, the response of the color change to the ultrasound power is more pronounced at 80 kHz than at 27 kHz. For longer times (i.e. 300s), a complete conversion is obtained independently of the value of the ultrasound power and the ultrasound frequency (Fig. 5).

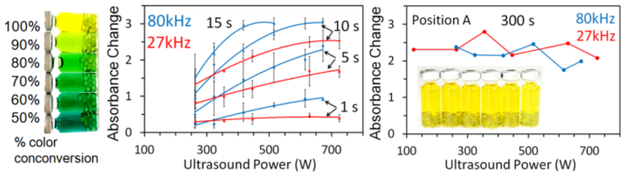

Figure 5: Effect of ultrasound power on SonoCheck absorbance change for different reaction times (mean values for positions A, B and C); (left) visual impression of the color change in the vials.

During the first 15 s, the absorbance (color) change is linearly related to the ultrasound energy (dosis effect). Ultrasound energy for 80kHz is more efficient than for 27kHz. The absorbance changes for 300s reaction time do not fit in the line reflecting saturation effects (Fig. 6).

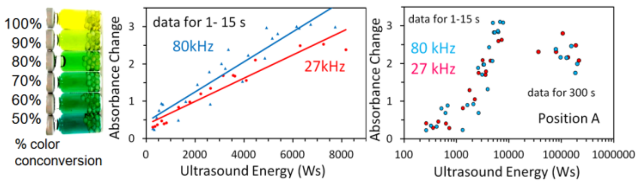

Figure 6: Effect of ultrasound energy on SonoCheck absorbance change; left figure: mean values for positions A, B and C; (left) visual impression of the color change in the vials.

SonoCheck absorbance (color) change occurs even at low cavitation noise level whereby the lower 80kHz induced LKRZ is more efficient than the higher 27kHz induced LKRZ. Thus, exceeding the LKRZ threshold for transient cavitation is not required for the absorbance change (Fig. 7).

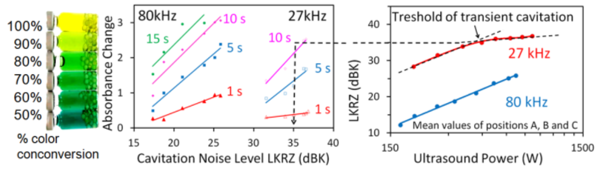

Figure 7: Relation between SonoCheck absorbance change and cavitation noise level (left) and ultrasound power dependence of the cavitation noise level LKRZ (right) (mean values for positions A, B and C). Visual impression of the color change in the vials left.

Discussion & Conclusions

Visually, the color change of SonoCheck can hardly be assigned to ultrasound power loss, of i.e. 50%, in particular for 27 kHz (Fig. 8). Thus, monitoring ultrasound power stability in the cleaning bath just by visual inspection of the color change is not sufficient for validation purposes.

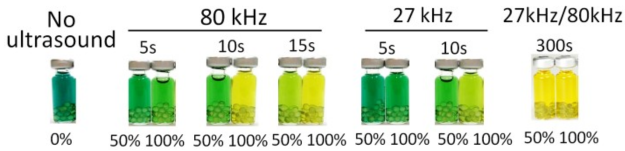

Figure 8: Visual impression of the color difference between SonoCheck vials when ultrasound power is reduced by 50% of the maximal power (750 W = 100%) using 5s, 10s, 15s or 300s reaction time (for each: left vial 50%, right vial 100%).

In contrast, the cavitation noise level is a quantitative, time independent parameter. It reflects the relevant physical phenomenon for the cleaning effect – the collapse of the cavitation bubbles (transient cavitation). Exceeding the noise region for transient cavitation relates to good cleaning conditions (Fig. 9) [4]. Therefore, it is an appropriate measure for monitoring and validation purposes. SonoCheck color change cannot be related to cleaning efficiency because the sonochemical reaction occurs already widely below the threshold of transient cavitation (compare Fig. 7 and Fig. 9).

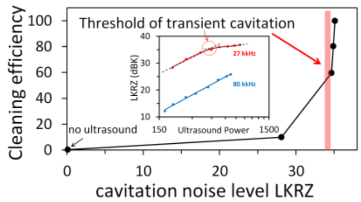

Figure 9: Cleaning efficiency determined on soiled titanium plates in relation to the cavitation noise level (data from [4]).

References

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[3] URL: http://www.healthmark.info/CleaningVerification /MSDS/SonoCheck_MSDS_E.pdf

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