

Validation of SonoCheck

for the

Monitoring of Ultrasonic Energy of Ultrasonic Cleaner

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Summary

SonoCheck, a new test for monitoring the ultrasonic energy in ultrasonic cleaner used for reprocessing surgical instruments was successfully validated. In the validation tests it was shown that SonoCheck will indicate ultrasonic energy needed to induce cavitation and give additional informations regarding the energy level. Thermal disinfection will not influence the result of SonoCheck. Due to the design of the product no residue will be left in the bath when performing the test and therefore SonoCheck can also be used to check the ultrasonic energy during the actual reprocessing of surgical instruments for load safety.

Key words: Cavitation; Reprocessing of instruments; Ultrasonic energy; Ultrasonic cleaner; Validation

Introduction

Ultrasonic cleaning is used in many occasions for special cleaning purposes in hospitals. It is often used for pre-cleaning but in some countries it is used for the reprocessing of instruments instead of washer-disinfectors. One advantage of an ultrasonic cleaning bath is that the instruments are fully immersed into the cleaning solution and do not depend on a spray system. The main advantage of ultrasonic cleaning is the phenomenon of cavitation. For washer-disinfectors the mechanical cleaning efficiency is very important whereas in ultrasonic cleaner the mechanical cleaning, achieved by cavitation, is even more crucial. Cavitation is able to efficiently remove soil from instruments even without breaking down the chemical structure of the soil like certain detergents would do. Cavitation can therefore effectively clean instruments mainly because of the mechanical force of the imploding bubbles even without strong chemical parameters like alkaline solutions at a high temperature. Of course ultrasonic cleaning also depends on many parameters which have to be within certain limits to operate successfully. The preparation of the ultrasonic bath including clean and properly de-gassed water at the right level is important for the ultrasonic energy to function. But even with optimal set conditions certain instruments, materials or overloading may reduce the ultrasonic energy below effective limits. Since all these parameters are changing during practical work it is necessary to monitor the ultrasonic energy for safety while reprocessing instruments.

Materials and methods

1. General requirements

Validation is the proof a certain method will reproducibly fulfil the requirements for its intended use (Lit. 1). For successful ultrasonic cleaning sufficient energy level is necessary to induce cavitation responsible for the mechanical cleaning effects. A test to monitor the ultrasonic energy therefore has to indicate positive parameters for cavitation. For example an existing test, the foil test (picture 1 / Lit. 2) will achieve this by perforating a thin aluminium foil (60 X 70 X 0.025mm, picture 2). The new developed SonoCheck (picture 3) will indicate sufficient ultrasonic energy levels for cavitation by a colour change from green to yellow (picture 4) caused by a chemical reaction triggered by cavitation. This type of chemical reaction where chlorine or hydrochloric acid is released from an organic molecule is generally referred to as the dosimeter for cavitation (Lit.: 3). A positive function of an ultrasonic cleaner has to be clearly indicated as well as a non-functioning one. Additional information regarding equipment with reduced energy level will be helpful for trouble shooting and optimisation. Parameters used during the reprocessing cycle other than ultrasonic waves like hot water should not give a positive result.



picture 1: Foil test (negative result); magnified 10 times



picture 2: Foil test perforated by cavitation (positive result); magnified 10 times



picture 3: SonoCheck before use (negative result)



picture 4: SonoCheck (positive result)

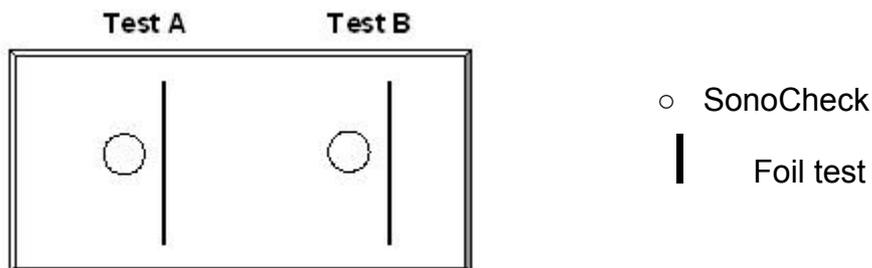
2. Test methods

2.1) Influence of hot water

High temperatures for reprocessing of surgical instruments are either used during the washing stage to increase the efficiency of alkaline detergents or for disinfecting purposes. When checking the influence of heat, water at 95°C was applied for 10 minutes. This temperature test was repeated 6 times with SonoCheck and the foil test (Aluminium foil: 80X80X0.020 mm).

2.2) Indication of cavitation and correlation with existing test

For the indication of cavitation 2 SonoCheck tests were placed into an ultrasonic bath (Bandelin Sonorex TK 30, 36/144 W, 50 kHz) like shown in picture 5. The bath was filled to the right level with 1050 ml demin. water at 35°C without detergent and was de-gassed for 15 minutes. All the tests were done simultaneous with the foil test, a test which is already known and used to test ultrasonic cleaner. The cycle used for the ultrasonic cleaner was 4 minutes. The test was repeated 6 times and the results are shown in table 1. By placing silicone a material known to absorb ultrasonic energy into the bath the energy level was reduced below the necessary limit for cavitation. For this test the cycle was increased from 4 minutes to 8 minutes.



picture 5: location of the tests in the ultrasonic bath

2.3) Reading of ultrasonic energy levels

In addition to the yes/no answer if the ultrasonic energy is sufficient to induce cavitation, the time needed for the colour change will give informations regarding the energy level. For testing if SonoCheck can also indicate cavitation amongst instruments in a cleaning bath the same equipment and test preparation was used again (picture 5), but with an instrument load reducing the ultrasonic energy. To simulate a heavy instrument load, the ultrasonic basket was loaded with 15 stainless steel LumCheck devices.

3. Results (table 1)

3.1 Water at 95°C (table 1 / column 1)

Both methods tested did not show any cavitation, meaning no colour change of SonoCheck and no perforation of the foil. Negative results are shown in the table by a minus (-)

3.2 Functional ultrasonic cleaner (table 1 / column 2)

All SonoCheck vials changed to yellow after the ultrasonic cycle indicating a positive result. The actual time needed for the colour change was between 20 to 25 seconds. The foil test was removed after 30 seconds to prevent complete destruction of the foil. All foil tests showed perforation after removal indicating a positive result. Positive results are shown in the table by a plus (+).

3.3 Non functional ultrasonic cleaner (table 1 / column 3)

Neither the SonoCheck vials nor did the foil test indicated cavitation after the 8 minutes cycle indicating a negative result.

3.4 Ultrasonic cleaner with instrument load (table 1 / column 4)

SonoCheck did indicate cavitation with a longer time needed for the colour change (2 to 2,5 minutes). The foil test cannot be placed amongst the instruments .

| | Water at 95°C/10 min | Functional ultrasonic cleaner (4 minutes cycle) | Non functional ultrasonic cleaner (8 minutes cycle) | Ultrasonic cleaner with instrument load (4 minutes cycle) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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table 1

Discussion

SonoCheck can reproducibly indicate necessary energy level for cleaning by means of cavitation, therefore the new designed monitor for ultrasonic cleaner has been successfully validated. An easy to read colour change from green to yellow will indicate cavitation. In addition the time needed for the colour change will give useful information regarding the level of ultrasonic energy. The pre-prepared and closed design of SonoCheck helps to perform a reproducible test of the ultrasonic cleaner without leaving residues behind. SonoCheck is therefore excellent to monitor the ultrasonic efficiency amongst the instruments for load safety. This is difficult to be performed with the foil test because of aluminium residue left behind and possible reaction with alkaline detergent used. Sonocheck can monitor the ultrasonic energy for routine use as well as it can be used for optimisation during a functional test. Different levels of ultrasonic energy in ultrasonic cleaner (Lit. 4) are especially important and may further enhance weak spots in a loaded ultrasonic cleaner.

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