

Ensuring Cavitation in a Medical Device Ultrasonic Cleaner

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Abstract

Background: Ultrasonic cleaners are used for fine cleaning of medical devices, removing soil from joints, crevices, lumens, and other areas that are difficult to clean using other methods. To accomplish this fine cleaning, ultrasonic cleaners use a process known as cavitation. To understand the function of the cavitation process on items that require enhanced cleaning, a study was conducted to determine whether four commercially available products claiming to test for cavitation actually detect cavitation activity.

Methods: Each of the products selected for the study were placed into a Mason jar containing cleaning solution at temperatures of 77°F (25°C) and 100°F (38°C), with no cavitation energy generated. The jars were agitated by vigorous manual shaking for five seconds (one time per minute for 15 minutes) by the same operator. The results of the commercial testing products were interpreted according to manufacturers' instructions for use and recorded following the 15-minute agitation process. Each test was repeated three times.

Results: Three of the four commercially available tests claiming to detect cavitation were demonstrated to not be specific to cavitation. Each of the three tests satisfied

the criteria for passing when in the absence of cavitation.

Conclusion: Cavitation is an important and necessary function of all ultrasonic cleaners. The results of the study clearly demonstrate that even when no cavitation is being produced, certain tests will still provide results indicating the presence of cavitation. Those tests do not distinguish between cavitation energy and the other parameters in an ultrasonic cleaner.

According to the Food and Drug Administration (FDA), an ultrasonic cleaner (Figure 1) [Marielyn: Please place Figure 1 on second page of article (i.e., general rule: don't place figures on first pages of articles).] is a Class 1 medical device "intended for cleaning medical instruments by the emission of high frequency soundwaves."¹ Ultrasonic cleaning equipment is not designed for disinfection or sterilization; instead, it is used for fine cleaning, removing soil from joints, crevices, lumens, and other areas that are difficult to clean using other methods.² To accomplish this fine cleaning, ultrasonic cleaners use a process known as cavitation. Cavitation is necessary to produce the cleaning action of an ultrasonic cleaner.³⁻⁵

Most ultrasonic cleaners consist of an electronic generator and numerous ultrasound transducers. An electrical signal from the generator causes the transducers to oscillate and produce high-frequency sound waves. These sound waves compress and decompress molecules in the solution, producing alternating cycles of high and low pressure. Cavitation occurs when the low-pressure cycles create microscopic bubbles that implode during the high-pressure cycle. The cavitation process results in a mechanical scrubbing action that dislodges debris and cleans the surfaces of the items placed in the ultrasonic cleaner.²⁻⁵

Manufacturers' instructions for use (IFUs) often recommend ultrasonic clean-

Key Takeaways

- Ultrasonic cleaning equipment is used for fine cleaning, removing soil from joints, crevices, lumens, and other areas that are difficult to clean using other methods. To achieve this fine cleaning, ultrasonic cleaners use a process known as cavitation.
- AAMI standards require a specific test for the presence of ultrasonic energy; therefore, cavitation within the cleaning liquid is required.
- Four products intended for testing cavitation in ultrasonic cleaners were tested to determine whether they could actually detect cavitation activity.
- Only one product indicated that no cavitation was detected, whereas the other three products passed all tests, indicating that cavitation was detected despite no cavitation being present.

ing for effective processing of surgical instruments with otherwise inaccessible areas. The Association for the Advancement of Medical Instrumentation (AAMI) also recommends performing ultrasonic cleaning in accordance with the device manufacturer's IFU and (1) on items where ultrasonic cleaning is not contraindicated in the device manufacturer's IFU, (2) after gross soil and detergents have been removed from the items, and (3) with fresh cleaning solution specifically labeled for use in ultrasonic cleaning equipment.²

Ultrasonic cleaning should be followed by thorough rinsing with clean water to remove bath residues and contaminants. Ultrasonic equipment should be cleaned in accordance with the manufacturer's IFUs each day it is used.² AAMI further recommends following performance verification test methods and performing daily cavitation testing when using the equipment.²

AAMI recommends that medical facility personnel ensure their ultrasonic cleaners are producing cavitation and have the ability to remove a test soil from external and internal surfaces of items cleaned ultrasonically. It is essential to ensure that the verification products used to test ultrasonic cleaners are actually testing for the correct parameters and that the statements made in the testing product IFUs are accurate. Healthcare facility personnel should have a clear understanding of what these products are testing for and the significance of the ultrasonic cleaner test.

A lack of understanding regarding the purpose of ultrasonic cleaners has resulted in longstanding concerns about their functionality. Further, sterile processing departments (SPDs) have only had nonstandardized methods for testing the functionality of ultrasonic cleaners. For example:

- For the "foil test," a piece of aluminum foil is placed into the ultrasonic bath and observed for perforation or destruction caused by cavitation.
- For the "glass slide test," the frosted portion of a glass slide is marked with a pencil, placed into the ultrasonic bath, and observed for removal of the marks.
- For the "ceramic disc test," an unglazed ceramic disc with a flat finish is marked



Figure 1. Ultrasonic cleaner

with a pencil, placed into the ultrasonic bath, and observed for removal of the marks.

The results of these methods may not always be clear because each test requires subjective interpretation. The glass slide and ceramic disc tests demonstrate the removal of soil from a surface but do not specifically detect cavitation. The foil test detects cavitation; however, the findings of pings and dimples in the foil must be subjectively interpreted by personnel and compared with the original test. (Note: Ultrasonic probes are available to test energy level.)

Following AAMI's recommendation of daily cavitation testing² and The Joint Commission's standard for identifying, maintaining, inspecting, and testing of all inventoried medical equipment,⁶ the number of available products claiming to test ultrasonic cleaners for cavitation, soil removal, temperature, and cleaning solution concentration has increased. Of note, these products do not distinguish whether the failure is with the cavitation process or with other parameters of the ultrasonic cleaning process.

The ability to test for cavitation is important because an ultrasonic cleaner is purchased for its ability to produce a cavitation energy that removes soil from joints, crevices, and other areas that otherwise are difficult to clean. Without knowing whether cavitation is effective, the ultrasonic unit may be nothing more than an expensive soaking tank.

Sterile processing departments have only had nonstandardized methods for testing the functionality of ultrasonic cleaners.

For the previous 10 years, the SPD at the medical facility (located in the Midwestern United States) where this study was conducted has been using a product that specifically tests the cavitation process. Using this product has helped SPD personnel identify and resolve issues with the ultrasonic cleaner related to the cavitation process.

Recently, the SPD was approached by other companies promoting less expensive products that were claimed to be equivalent to the test the SPD had been using. To evaluate these products, objective data were needed to support switching to an alternative test or to continue using the existing test. A decision was made to test the various products to determine the efficacy of each test.

The objectives of this study were to identify a simple method for comparing the various commercially available products and to determine whether cavitation could be detected by one or more of the products.

Products Used

Four products (labeled A, B, C, and D) intended for testing cavitation in ultrasonic cleaners were identified for inclusion in the study.⁷⁻¹¹ To obtain information about each product and determine its mode of action, the author reviewed the manufacturers' IFUs and searched published literature for relevant research and nonresearch evidence specific to each product.

Product A

Product A⁷ has been available commercially for 16 years. It is intended to detect cavitation and consists of a capped vial with a blue-green solution. The product turns yellow only when it is exposed to cavitation energy produced by an ultrasonic cleaner; it does not detect or measure soil removal.⁷ This product indicates sufficient ultrasonic activity by exhibiting a color change from blue/green to yellow, which is caused by a chemical reaction in the vial triggered by cavitation. A validation paper¹² is available, and published articles support the use of product A.^{4,5}

Product B

Product B^{8,9} has been available commercially for eight years. According to the manufactur-

er's IFU, the product is designed to monitor the cleaning efficiency of the ultrasonic cleaners by checking time, temperature, transducers, cavitation, and detergent.⁹ Product B consists of an aluminum strip with blue dye in a square, which is placed in a holder that allows exposure of the blue square. When cleaning conditions are effective, the blue dye on the monitor is dissolved. The presence of a large amount of blue dye remaining on the monitor reflects a serious deficiency in the ultrasonic cleaning efficiency.⁹ No validation paper could be found on the company website or during the literature search to support the ability of this product to produce repeatable results.

Product C

Product C¹⁰ has been available commercially for one year. According to the manufacturer's IFU, this ultrasonic indicator provides an objective test to evaluate the ultrasonic cycle throughout the tank. "Problems such as insufficient energy, water level, improper temperature and degassing may have an impact on results," stated the manufacturer.¹⁰ The indicator consists of a small piece of plastic containing synthetic test soil that mimics blood and common tissues found on devices commonly cleaned in ultrasonic cleaners. Per the IFU, the product is placed into a wire basket holder with a lid, the lid is closed, and the testing unit is placed into the ultrasonic cleaner. No validation paper could be found on the company website or during the literature search to support the ability of this product to produce repeatable results.

Product D

This product¹¹ has been on the market for less than one year. According to the manufacturer's website, the product monitors the strength of cavitation in an ultrasonic cleaner.¹¹ In addition, using dual soil spots to mimic blood and tissue removal from both difficult-to-clean surfaces and instrument parts, the product measures temperature, the presence and concentration of detergent, and the length of the ultrasonic cleaning cycle. The test indicator consists of a piece of paper with two blue ink spots. The indicator is placed into a holder that covers one square and exposes the other square. When the

indicators are exposed to an ultrasonic cleaning cycle, the blue ink is removed by cavitation. No validation paper could be found on the company website or during the literature search to support the ability of this product to produce repeatable results.

Methods

The researcher developed a test to determine the capability of each testing product to detect cavitation. When developing the test, the ability to replicate it easily in any SPD was considered important. The cleaning solution selected for the study is the solution used by the medical facility in its ultrasonic cleaners, and the specifications for dilutions and temperature complied with the IFUs of the cleaning solutions.

Each of the four commercially available tests selected for inclusion in the study were placed into a Mason jar containing cleaning solution with no cavitation energy generated (Figure 2). The four Mason jars were filled with 500 mL utility water mixed with a hospital-approved cleaning solution^{13,14} at a dilution of 0.5 oz per gallon of AAMI TIR34:2014¹⁵ utility water and a temperature of 77°F (25°C).

The test was repeated with four Mason jars filled with 500 mL utility water mixed with the cleaning solution at a dilution of 0.5 oz per gallon and a temperature of 100°F (38°C). The temperature of the solution in each jar was verified by inserting a temperature probe¹⁶ into the cleaning solution immedi-

ately before the test products were placed into the jars. The jars were agitated by vigorous manual shaking for five seconds once each minute for 15 minutes. The 15-minute time frame was chosen because it is the standard time used at the medical facility for ultrasonic cleaning of instruments.

The test procedures were repeated three times at each of the two specified temperature points. The results of the commercial testing products were interpreted according to manufacturers' IFUs and recorded following the 15-minute process.

Results

The results of the product testing are shown in Table 1. Under testing conditions without ultrasonic cavitation, only product A indicated that no cavitation was detected. Products B, C, and D passed all tests, indicating that cavitation was detected despite no cavitation being present.

Discussion

Each of the products used in this study are intended to be placed in an empty ultrasonic cleaner to test for the presence of cavitation. This study was unique because the products were tested using manual shaking and soaking without cavitation; however, several passing test results were observed. The results showed that three of the four products failed to accurately assess cavitation because the dye/soil was removed when no cavitation was present.



Figure 2. Mason jars containing cleaning solution and the four products selected for inclusion in the study

Any test used to assess an ultrasonic cleaning system for the presence of cavitation in the cleaning fluid must be able to differentiate the difference between passive or moderate mechanical cleaning and cleaning produced by cavitation generated by ultrasonic energy.

These products appear to be sensitive to temperature and the presence of a detergent. The longer the product remains in the solution, the greater the opportunity for the dye/soil to be removed from the coupon by simple mechanical agitation. Product A, which is enclosed in a sealed, fluid-tight container, is not affected by its surroundings unless cavitation is present. Product A was the only product shown to demonstrate the absence of cavitation. This was the product that had been in use at the researchers' facility; therefore, this study verified that an effective product was being used by the facility.

Finally, the study confirmed that two separate tests are necessary (cavitation and soil removal) because the simple Mason jar test described here demonstrated that marketed products may not distinguish between the presence or absence of cavitation. The study also showed that other factors (e.g., temperature, cleaning solution) play a role in ultrasonic cleaning and also may need to be tested with some frequency. Demonstrating cavitation is an important aspect of ultrasonic cleaner functionality and instrumental in the provision of clean medical devices.

Ultrasonic cleaning is the combination of many factors, including mechanical (cavitation), chemical (cleaning solution) cleaning, and temperature. The ability to distinguish between these processes, demonstrating which are or are not occurring, is vital to solving cleaning issues and ensuring effective ultrasonic cleaning of medical devices. Sterile processing and biomedical personnel should understand these different parameters and

have the ability to test for the components essential to effective ultrasonic cleaning (e.g., temperature, cleaning solution, cavitation, cleaning ability). This is particularly important because AAMI standards require a specific test for the presence of ultrasonic energy, and therefore, cavitation within the cleaning liquid—not just passive cleaning efficacy—is required.

These tests should be part of a facility's quality management program, where the testing that is performed by facility personnel is known as a performance qualification step. Incorporating a quality management program into the facility's ongoing processes for verifying effective ultrasonic cleaning will reduce the risk of patient infection and improve patient outcomes.

Limitations

The limitations of the current study were that only two bath temperatures and one cleaning solution were used.

Conclusion

Cavitation produced by ultrasonic energy in an ultrasonic bath is an essential component of the cleaning system and is required to achieve adequate cleaning efficiency. Any test used to assess an ultrasonic cleaning system for the presence of cavitation in the cleaning fluid must be able to differentiate the difference between passive or moderate mechanical cleaning and cleaning produced by cavitation generated by ultrasonic energy.

This study demonstrated that only one product was capable of detecting the presence of cavitation produced within an ultrasonic bath. The other products tested

Product	Temperature	Result at 15 Minutes			Comment
		Test 1	Test 2	Test 3	
A	77°F (25°C)	Failure	Failure	Failure	No color change
B	77°F (25°C)	Pass	Pass	Pass	All blue coloring removed
C	77°F (25°C)	Pass	Pass	Pass	All pink coloring removed
D	77°F (25°C)	Pass	Pass	Pass	Slight hint of blue coloring remained
A	100°F (38°C)	Failure	Failure	Failure	No color change
B	100°F (38°C)	Pass	Pass	Pass	All soil removed
C	100°F (38°C)	Pass	Pass	Pass	All soil removed
D	100°F (38°C)	Pass	Pass	Pass	All soil removed

Table 1. Results of product testing. "Pass" indicates that cavitation was detected by the test per the instructions for use (IFU), whereas "failure" indicates that cavitation was not detected by the test per the IFU.

were readily cleaned by simple mechanical action with cleaning solutions in the absence of ultrasonic energy–induced cavitation and, therefore, proved inadequate for testing cleaning equipment for cavitation alone.

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