

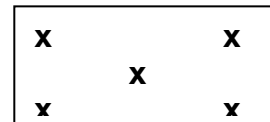
SonoCheck for ultrasonic cleaner

Functional test / validation test

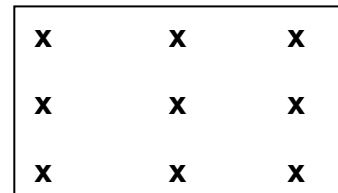
The functional test will check the uniform operation of the empty ultrasonic cleaner. In addition to this the functional test will also allow you to optimise your process in case of an unsatisfactory results (please refer to the **SonoCheck troubleshooting guide**).

The validation test will check the ultrasonic energy including a standard load to ensure that the ultrasonic cleaner is working to meet the requirement and will allow you to safely perform the routine test.

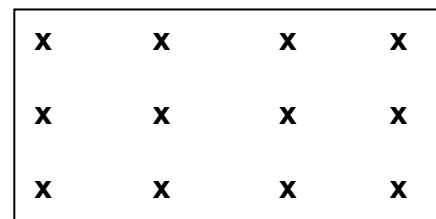
Both tests are performed under normal conditions as shown in the picture:



small
up to 5 ltrs



medium
5 to 20 ltrs



large
above
20 ltrs

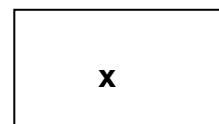
Routine test (test result must be positive!)

The routine test will monitor the performance in practise for your load safety.

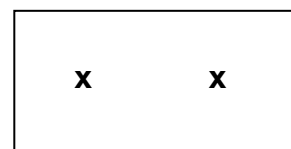
Parameters such as: Water level, de-gassing, instrument load and energy supplied by the transducers can vary the process, affecting its performance. Only the routine test will show a decrease in time avoiding a low efficient reprocessing of instruments.

The routine test is performed under normal conditions and with a normal load of instruments as shown in the picture.

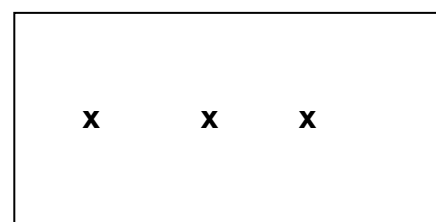
SonoCheck is always placed between your instruments. In addition weak spots may be checked separately.



small
up to 5 ltrs



medium
5 to 20 ltrs



large
above
20 ltrs

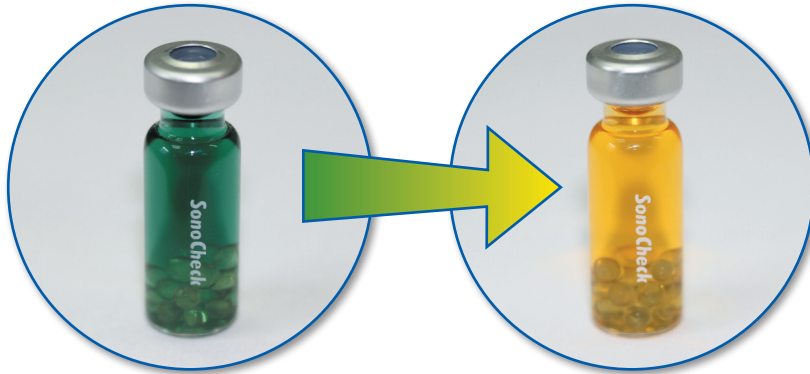
Quality assurance

- Use the **functional log book** and the **routine log book** to record your results
- Repeat the functional test after each service and as a quarterly check.
- When loading your ultrasonic cleaner do not place instruments on blind spots and avoid placing critical instruments on any weak spots.

SonoCheck

Troubleshooting Guide

X FAIL
(Negative result)
Insufficient energy.



✓ PASS
(Positive result)
Record result
according to your
department policy.

Parameters	Possible reasons	Corrective actions
Low energy (cycle time Instrument tray Instr. load)	Cycle time too short, the ultrasonic basket or the load may absorb too much energy	Test a longer cycle Test cycle without load (functional test) and avoid wire mesh trays Wire mesh trays absorb ultrasonic energy! Solid bottom trays are recommended
Water level	Reflection of ultrasonic energy on the surface may change energy distribution	Refer to the instruction manual for correct water level
De-gassing	Dissolved gasses may absorb ultrasonic energy	Refer to the instruction manual for proper de-gassing
Transducers	The efficiency of the transducers may decrease with age or individual transducers may be out of order	Redo the functional test and check the individual transducers

Note 1: The performance after a corrective action needs to be tested again with a new SonoCheck.

Note 2: The normal time needed for a colour change is below 1 min but in the case of absorbed energy, time may take up to several minutes.



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**MAKE IT
VISIBLE!**

Safety Data Sheet

According to Regulation (EC) Nr. 2015/830

Trade name: SonoCheck
Revision Date: 26.07.2016
Version: 3.0



01. Identification of the substance / mixture and of the company

Trade name

SonoCheck

Relevant identified uses

To provide a pass/fail detection of cavitation energy within an ultrasonic bath.

Manufacturer / supplier

Pereg GmbH

Street

Porschestraße 12

Postal code

DE – 84478 Waldkraiburg

Telephone / Fax / E-Mail

+49 (0) 8638 84100 / +49 (0) 8638 84162 / E-mail: info@pereg.de

Emergency Telephone Number

Tel. +49 89 19240 (Poison Centre Munich)

02. Hazards identifications

Classification of the substance or mixture

This substance does not meet the criteria for classification in accordance with Regulation No1272/2008/EC.

Adverse environmental and human health effects

Not required.

03. Composition / information on ingredients

Description of the mixture

SonoCheck contain reagents and dye in aqueous solution

Hazardous ingredients

Bromthymol blue

Content: < 0,1%

Chloroform: Index-Nr.: 602-006-00-4; CAS-Nr.: 67-66-3, UN-Nr.:1888

Content: < 0,1%

Categorization: H302, 315, 319, 331, 351, 361d, 372

P202, 260, 302+352, 304+340,305+351+338, 308+313

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

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04. First aid measures

General information

No special measures required

Following inhalation

If inhaled, remove to fresh air. If breathing is difficult, get medical attention.

Following skin contact

Rinse with water

Following eye contact

Rinse with water (10-15min). In case of irritating effect get medical attention.

Following ingestion

Get medical attention.

Notes for the doctor

No data

05. Firefighting measures

Suitable extinguishing media

Foam, Carbon dioxide, extinguishing powder. Subject to normal conditions incombustible. Use fire extinguishing methods suitable to surrounding conditions.

Unsuitable extinguishing media

No data

Special hazards arising from the substance and combustion products

When strong heating, formation of small amounts of hydrochloric acid possible.

Advice for fire-fighters

Fire-fighters should be equipped with self-contained breathing apparatus to protect against potentially toxic and irritating fumes.

06. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid contact with soil.

Environmental precautions

Do not allow to enter the sewerage system. Do not allow to enter groundwater or surface water.

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Methods and material for containment and cleaning up

Absorb with an inert dry material and place in an appropriate waste disposal container. Disposal considerations: see section 13.

Advices on how to clean up a spill

Wash affected area as usual.

07. Handling and storage

Precautions for safe handling

Don't open vial. Handle with care.
No special measures required

Advice on general occupational hygiene

Don't eat and drink at work. No smoking. Keep away from food.
Avoid contact with skin and eyes.

Conditions for safe storage, including any incompatibilities

Store in original packaging. Store at +2 °C to +25 °C.
Store protected from light, heat and chemicals.
When the container is closed no incompatibilities are known.

Incompatible substances or mixtures

When the container is closed no incompatibilities are known.

Specific end use(s)

SonoCheck use only for checking the ultrasonic energy in the preparation of surgical instruments.

08. Exposure controls / personal protection

Control parameters

Bromthymol blue

N/A

Chloroform:

National limit values

Occupational exposure limit values (Workplace Exposure Limits)

Country	Name of Agent	CAS-Nr.	Identifier	TWA [ppm]	TWA [mg/m ³]	STEL [ppm]	STEL [mg/m ³]	Source
EU	Chloroform	67-66-3	IOELV	2	10			2000/39/EC
DE	Chloroform	67-66-3	AGW	0,5	2,5	1	5	TRGS 900

Notation:

STEL Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified

TWA Time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average

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Relevant DNELs/DMELs/PNECs and other threshold levels

human health values

Name of agent	Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Chloroform	DNEL	0,94 mg/kg	human, dermal	worker (industry)	chronic - systemic effects
Chloroform	DNEL	2,5 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
Chloroform	DNEL	2,5 mg/m ³	human, inhalatory	worker (industry)	chronic - local effects
Chloroform	DNEL	333 mg/m ³	human, inhalatory	worker (industry)	acute - systemic effects

environmental values

Name of agent	Endpoint	Threshold level	Environmental compartment	Exposure time
Chloroform	PNEC	0,56 mg/kg	soil	continuous
Chloroform	PNEC	0,048 mg/l	sewage treatment plant	continuous
Chloroform	PNEC	0,015 mg/l	marine water	continuous
Chloroform	PNEC	0,09 mg/kg	marine sediment	continuous
Chloroform	PNEC	0,45 mg/kg	freshwater sediment	continuous
Chloroform	PNEC	0,146 mg/l	freshwater	continuous
Chloroform	PNEC	0,133 mg/l	water	continuous
Chloroform	PNEC	0,146 mg/l	freshwater	short-term (single instance)
Chloroform	PNEC	0,015 mg/l	marine water	short-term (single instance)
Chloroform	PNEC	0,048 mg/l	sewage treatment plant	short-term (single instance)
Chloroform	PNEC	0,45 mg/kg	freshwater sediment	short-term (single instance)
Chloroform	PNEC	0,09 mg/kg	marine sediment	short-term (single instance)
Chloroform	PNEC	0,56 mg/kg	soil	short-term (single instance)

Exposure controls

Individual protection measures (personal protective equipment)

Eye protection

Use eye protection (Chemical splash goggles).

Hand protection

Wear chemical resistant gloves.

Inhalation protection

In case of vapor or aerosol.

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Environmental exposure controls

Keep away from drains, surface and ground water.

09. Physical and chemical properties

Appearance

Physical state: Glass vial with liquid
Colour: blue-green solution
Odour: no data available
Odour threshold: no data available

Other physical and chemical parameters

pH (value): neutral
Melting point/freezing point: no data available
Initial boiling point and boiling range:(1013 hPa) ca. 100 °C
Flash point: no data available
Evaporation rate: no data available
Flammability (gas, solid) no data available
Explosive limits: no data available
Vapour pressure: no data available
Vapour density: no data available
Density: (20 °C) 1,0 g/ml
Solubility: Soluble in water
Partition coefficient: no data available
n-octanol/water
Auto-ignition temperature: no data available
Decomposition temperature: no data available
Viscosity: no data available
Explosive properties: no
Oxidizing properties: no

10. Stability and reactivity

Reactivity

SonoCheck is not reactive under normal ambient conditions.

Chemical stability

No decomposition if stored and handled as intended.

Possibility of hazardous reactions

No data

Conditions to avoid

Avoid temperatures above 60 °C

Incompatible materials

No data

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Hazardous decomposition products

Hazardous combustion products: see section 5.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Bromthymol blue:

No data

Chloroform:

Name of agent	Endpoint	Value	Species	Source
Chloroform	LD50	908 mg/kg	rat	ECHA

Skin corrosion/irritation

No data

Serious eye damage/eye irritation

Irritant effect

Respiratory or skin sensitisation

No data

Summary of evaluation of the CMR properties:

Carcinogenicity:

No data

Reproductive toxicity:

No data

Specific target organ toxicity - single exposure

No data

Specific target organ toxicity - repeated exposure

No data

Aspiration hazard

No data

Symptoms related to the physical, chemical and toxicological characteristics

If swallowed

Irritation of the mouth, throat, esophagus and gastrointestinal tract

If in eyes

Irritation of the eyes

If inhaled

No data

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If on skin

Irritation of the skin

Other information

No

12. Ecological information

Bromthymol blue:

No data

Chloroform:

Toxicity

acc. to 1272/2008/EC: Shall not be classified as hazardous to the aquatic environment.

Aquatic toxicity (acute)

Name of agent	Endpoint	Value	Species	Source	Exposure time
Chloroform	EC50	152,5 mg/l	aquatic invertebrates	ECHA	48 h
Chloroform	ErC50	13,3 mg/l	algae	ECHA	72 h

Aquatic toxicity (chronic)

Name of agent	Endpoint	Value	Species	Source	Exposure time
Chloroform	EC50	0,48 mg/l	microorganisms	ECHA	24 h
Chloroform	NOEC	13 mg/l	aquatic invertebrates	ECHA	21 d

Process of degradability

Name of agent	Process	Degradation rate	Time
Chloroform	biotic/abiotic	0%	14 d
Chloroform	Not readily biodegradable. Theoretical Oxygen Demand: 0,134 mg/mg Theoretical Carbon Dioxide: 0,3686 mg/mg Biochemical Oxygen Demand: 20 mg/g at 5 d		

Bioaccumulative potential

Does not significantly accumulate in organisms.

n-octanol/water (log KOW) 1,97 (25 °C) (Experimental data)

Mobility in soil

Henry's law constant 14.084 Pa m³/mol

The Organic Carbon normalised adsorption coefficient 1,939 - 2,565

Results of PBT and vPvB assessment

Data are not available.

Other adverse effects

Hazardous to water.

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13. Disposal considerations

Product

The disposal is regionally differently regulated, therefore the kind of disposal is to be inquired at the responsible authorities.

Additional information

Disposal of this product should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Contaminated packaging

Disposal according to official regulations.

Uncontaminated packaging

Disposal according to official regulations.

14. Transport information

UN number

Void

UN proper shipping name

Void

Transport hazard class(es)

Void

Packing group

Void

Environmental hazards

No

Special precautions for user

No

Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

15. Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

Material safety evaluation

A material safety evaluation has not been carried out.

Regulation on combustible liquids

Class according 2009/104/EG (BetrSichV):

No

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Water hazard class

Water hazard class 1 (Self-assessment): slightly hazardous for water

Storage according TRGS 510 (Storage of hazardous substances in nonstationary containers)

Storage classes 10 to 13

16. Other information

Recommended application

For commercial purposes only.
Take notice of label / instruction for use.

Relevant R-, H- and EUH-phrases

H302 Harmful if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H331 Toxic if inhaled.
H351 Suspected of causing cancer.
H361d Suspected of damaging the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.

P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe gas/mist/vapours/spray. P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P302+P352 IF ON SKIN: Wash with plenty of water/....

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308+P313 IF exposed or concerned: Get medical advice/attention.

Disclaimer

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Key literature references and sources for data

Regulation (EC) No. 1907/2006 (REACH), amended by 2015/830/EU
Regulation (EC) No. 1272/2008 (CLP, EU GHS)

Changes to the previous version

Section 2: new regulation

Section 3: Classification updated and supplemented

Sections 8, 11, 12: information supplemented

Safety Data Sheet

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Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2000/39/EC	Comission Directive establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC
DNEL	Derived No-Effect Level
index No	the Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
IOELV	indicative occupational exposure limit value
MARPOL	International Convention for the Prevention of Pollution from Ships (abbr. of "Marine Pollutant")
PNEC	Predicted No-Effect Concentration
ppm	parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
ECHA	European Chemicals Agency

Validation of SonoCheck

for the

Monitoring of Ultrasonic Energy of Ultrasonic Cleaner

Martin Pfeifer, Waldkraiburg, Federal Republic of Germany, June 2002

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.

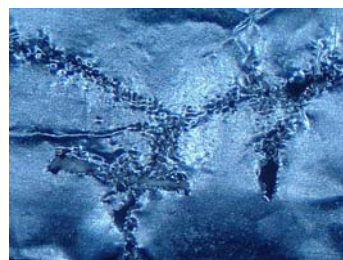
Materials and methods

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)

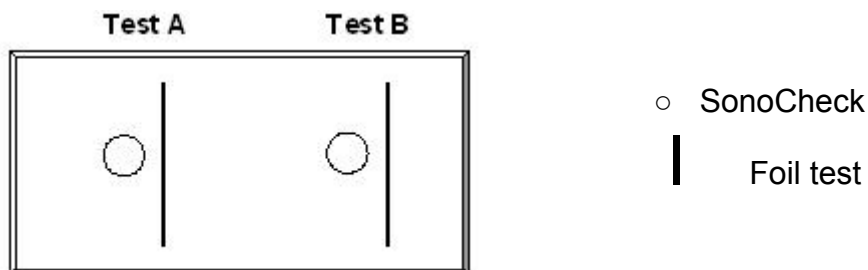
2. Test methods

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)																																																																														
SonoCheck	<table border="1"> <tr><td>-</td><td>-</td><td>-</td></tr> <tr><td>-</td><td>-</td><td>-</td></tr> </table>	-	-	-	-	-	-	<table border="1"> <tr><td>A</td><td>B</td><td>A</td><td>B</td><td>A</td><td>B</td></tr> <tr><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td></tr> <tr><td>A</td><td>B</td><td>A</td><td>B</td><td>A</td><td>B</td></tr> <tr><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td></tr> </table>	A	B	A	B	A	B	+	+	+	+	+	+	A	B	A	B	A	B	+	+	+	+	+	+	<table border="1"> <tr><td>A</td><td>B</td><td>A</td><td>B</td><td>A</td><td>B</td></tr> <tr><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td></tr> <tr><td>A</td><td>B</td><td>A</td><td>B</td><td>A</td><td>B</td></tr> <tr><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td></tr> </table>	A	B	A	B	A	B	-	-	-	-	-	-	A	B	A	B	A	B	-	-	-	-	-	-	<table border="1"> <tr><td>A</td><td>B</td><td>A</td><td>B</td><td>A</td><td>B</td></tr> <tr><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td></tr> <tr><td>A</td><td>B</td><td>A</td><td>B</td><td>A</td><td>B</td></tr> <tr><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td></tr> </table>	A	B	A	B	A	B	+	+	+	+	+	+	A	B	A	B	A	B	+	+	+	+	+	+
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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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