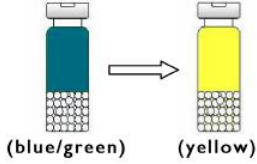


| | |
|--|---|
| Brand Name of Product | SonoCheck™ Ultrasonic Function Test |
| Generic Name of Product | Indicator for cavitation energy in an ultrasonic bath. |
| Product Code Number(s) | TI108 |
| Purpose of Product | To detect cavitation energy within an ultrasonic bath. |
| Range of Applications for Product | Tabletop ultrasonic, single or multi-level ultrasonic, MIS instrument cleaners utilizing ultrasonic cleaning, automated instrument washers with an ultrasonic bath stage. |
| Key Specifications of Product | Color change from blue green to yellow indicates cavitation energy is present. |

| Shipping & Storage | |
|---|---|
| Shipping Conditions & Requirements | Do not allow to freeze. |
| Storage Conditions | Temperature: 2- to 25 °C (35.6- to 77 °F). (Do not allow to freeze.) |
| Packaging Contents | 30 SonoCheck™ test vials per box. |
| Shelf Life | Twelve (12) months from date of manufacture. See package label for expiration date. |

| Instructions for Using Product | | | | | | | | | | | | | | | | | | |
|--|---|------------|-------------|------------|------------|-------------|------------|---|---|---|----------------------------|-------------------------------|---|---|---|---|---|---|
| Description of Use(s) | <ul style="list-style-type: none"> To test for the presence of cavitation energy inside of an ultrasonic bath. May be used for qualification testing after initial installation and after major repair as well as for routine testing to ensure proper performance. | | | | | | | | | | | | | | | | | |
| Preparation for Use | <ol style="list-style-type: none"> Prepare a bath of cleaning solution (water and detergent) in compliance with instructions for use (IFU) by the ultrasonic manufacturer (Mfr.) and the detergent Mfr. De-gas the bath in accordance with ultrasonic Mfr.'s IFU. Ensure that the bath is within the proper temperature range as provided by the detergent Mfr. | | | | | | | | | | | | | | | | | |
| Functional / Operational Qualification (OQ) | <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Small Tank</th> <th>Medium Tank</th> <th>Large Tank</th> </tr> </thead> <tbody> <tr> <td>x</td> <td>x</td> <td>x</td> </tr> <tr> <td>x</td> <td>x</td> <td>x</td> </tr> <tr> <td>x</td> <td>x</td> <td>x</td> </tr> </tbody> </table> <p style="text-align: center;">Figure 1: Performance Qualification (e.g., new installation, major repair) Small tank = Up to 5 liters (L) / 1.3 Gallons Medium tank = 5 to 20 L / 1.3 to 5.3 Gallons Large tank = Above 20 L / Above 5.3 Gallons</p> | Small Tank | Medium Tank | Large Tank | x | x | x | x | x | x | x | x | x | | | | | |
| Small Tank | Medium Tank | Large Tank | | | | | | | | | | | | | | | | |
| x | x | x | | | | | | | | | | | | | | | | |
| x | x | x | | | | | | | | | | | | | | | | |
| x | x | x | | | | | | | | | | | | | | | | |
| Steps for Use of Product Performance Qualification / Routine Testing (PQ) | <p>Operational Qualification for Single Bay or Multi-Level Ultrasonic:</p> <ol style="list-style-type: none"> Select the appropriate number of SonoCheck™ vials and choose the layout that matches the size of the equipment to be tested in a horizontal type of tank. (Fig. 2). <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th colspan="3">Single Bay</th> </tr> <tr> <th>Small Tank</th> <th>Medium Tank</th> <th>Large Tank</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">x</td> <td style="text-align: center;">x</td> <td style="text-align: center;">x</td> </tr> </tbody> </table> <p style="text-align: center;">Figure 2: Operational Qualification (e.g., daily testing)</p> <ol style="list-style-type: none"> Place the SonoCheck™ vials in an empty ultrasonic tray/basket (in the middle of the tray/basket) and place the tray/basket in the ultrasonic cleaner that has been de-gassed. (Fig. 3). If using a multi-level ultrasonic, place a minimum amount of one SonoCheck™ vial in each basket on each level in the middle of the tray/basket. (Fig. 3). <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Multi-Level Ultrasonic (3)</th> <th>Multi-Level Dual Tank/Bay (6)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> </tr> <tr> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> </tr> <tr> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> </tr> </tbody> </table> <p style="text-align: center;">Figure 3: Operational Qualification (e.g., daily testing)</p> | Single Bay | | | Small Tank | Medium Tank | Large Tank | x | x | x | Multi-Level Ultrasonic (3) | Multi-Level Dual Tank/Bay (6) | X | X | X | X | X | X |
| Single Bay | | | | | | | | | | | | | | | | | | |
| Small Tank | Medium Tank | Large Tank | | | | | | | | | | | | | | | | |
| x | x | x | | | | | | | | | | | | | | | | |
| Multi-Level Ultrasonic (3) | Multi-Level Dual Tank/Bay (6) | | | | | | | | | | | | | | | | | |
| X | X | | | | | | | | | | | | | | | | | |
| X | X | | | | | | | | | | | | | | | | | |
| X | X | | | | | | | | | | | | | | | | | |

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| | <p>4. Run the equipment as directed by the ultrasonic Mfr. and record the test results on a log sheet.</p> <p>5. All SonoCheck™ vials should change from blue green to yellow (Fig. 4) within the specified time. The time needed for the color change will indicate the level of energy and degree of cavitation provided by the ultrasonic cleaner in that location.</p> <div style="text-align: center;">  <p>Figure 4: Color Change</p> <ul style="list-style-type: none"> • A color change slower than average will indicate a weak spot. • A negative result will indicate a blind spot of ultrasonic energy. </div> |
| Interpretation of Results | <ul style="list-style-type: none"> • Color change from blue green to yellow indicates presence of cavitation energy. • Time for color change indicates the strength of cavitation energy. • Failure for color change to yellow indicates failure to achieve sufficient cavitation energy to clean. • Ultrasonic energy is localized, and failure to achieve color change may indicate one or more ultrasonic transducers are failing. |
| Contraindications of Test Results | In the presence of very powerful cavitation energy, the color of SonoCheck™ liquid may go completely clear (no color). This can be interpreted as a passed test. |
| Documentation | <ul style="list-style-type: none"> • (If conducting routine testing), use a log sheet to record your results. |
| Disposal | <ul style="list-style-type: none"> • SonoCheck™ vials should be disposed of in a biohazard container according to your facility guidelines regarding disposing biohazard. This recommendation is an additional measure of safety; not because of the chemicals, but because it is being used in equipment used for decontamination. |

| Reprocessing Instructions | |
|---|--|
| Point of Use | N/A |
| Preparation for Decontamination | N/A |
| Disassembly Instructions | N/A |
| Cleaning – Manual | N/A |
| Cleaning – Automated | N/A |
| Disinfection | N/A |
| Drying | N/A |
| Maintenance, Inspection, and Testing | N/A |
| Reassembly Instructions | N/A |
| Packaging | N/A |
| Sterilization | N/A |
| Storage | Temperature: 2- to 25 °C (35.6- to 77 °F). (Do not allow to freeze.) |
| Additional Information | N/A |

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| Related Healthmark Product(s) | USTK-1L (weekly ultrasonic test kit), TWTL-1L (weekly tunnel washer test kit) |
| Other Product Support Documents | N/A |
| Reference Documents | N/A |
| Customer Service Contact | <p>Healthmark, A Getinge company 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com www.hmark.com</p> |