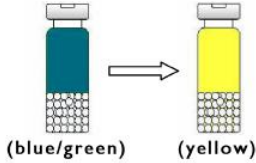




<b>Brand Name of Product</b>	Sonocheck™ Ultrasonic Function Test
<b>Generic Name of Product</b>	Indicator for cavitation energy in an ultrasonic bath.
<b>Product Code Number(s)</b>	TI-108
<b>Purpose of Product</b>	To provide a pass/fail detection of cavitation energy within an ultrasonic bath.
<b>Range of Applications for Product</b>	Tabletop ultrasonic, single or multi-level sonic, MIS instrument cleaners utilizing ultrasonic cleaning, automated instrument washers with an ultrasonic bath stage.
<b>Key Specifications of Product</b>	Color change from blue/green to yellow indicates cavitation energy is present.

<b>Shipping &amp; Storage</b>	
<b>Shipping Conditions &amp; Requirements</b>	Do not allow to freeze.
<b>Storage Conditions</b>	2°C– 25°C. Do not allow to freeze.
<b>Packaging Contents</b>	30 SonoCheck™ test vials per box.
<b>Shelf Life</b>	12 months from date of manufacture. See package label for expiration date.

<b>Instructions for Using Product</b>															
<b>Description of Use(s)</b>	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.														
<b>Preparation for Use</b>	<ol style="list-style-type: none"> <li>Prepare a bath of cleaning solution (water and detergent) in compliance with instructions for use by the sonic manufacturer and the detergent manufacturer.</li> <li>De-gas the bath in accordance with ultrasonic manufacturer's instructions.</li> <li>Ensure that the bath is within the proper temperature range as provided by the detergent manufacturer.</li> </ol>														
<b>Functional / Operational Qualification (OQ)</b>	<table border="1"> <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> <b>Figure 1 Functional Qualification Testing</b> (e.g., new installation, major repair)            Small tank = Up to 5 ltrs / 1.3 Gallons            Medium tank = 5 to 20 ltrs / 1.3 to 5.3 Gallons            Large tank = Above 20 ltrs / 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													
<b>Steps for Use of Product Performance Qualification / Routine Testing (PQ)</b>	<p><b>Routine Testing for Single Bay or Multi-Level Sonic:</b></p> <ol style="list-style-type: none"> <li>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. <b>(Fig. 2)</b></li> </ol> <p><b>Single Bay</b></p> <table border="1"> <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> </tbody> </table> <p><b>Figure 2 Routine Testing</b> (e.g., daily testing)</p> <ol style="list-style-type: none"> <li>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. <b>(Fig. 3)</b> <ul style="list-style-type: none"> <li>If using a multi-level sonic, place a minimum amount of one SonoCheck™ vial in each basket on each level of the multi-level sonic, in the middle of the tray/basket.</li> </ul> </li> </ol> <p><b>Multi-Level Bays</b></p> <table border="1"> <thead> <tr> <th>Multi-Level Sonic (3)</th> </tr> </thead> <tbody> <tr> <td>X</td> </tr> <tr> <td>X</td> </tr> <tr> <td>X</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>Multi-Level Dual Tank/Bay (6)</th> </tr> </thead> <tbody> <tr> <td>X</td> </tr> <tr> <td>X</td> </tr> <tr> <td>X</td> </tr> </tbody> </table>	Small Tank	Medium Tank	Large Tank	x	x	x	Multi-Level Sonic (3)	X	X	X	Multi-Level Dual Tank/Bay (6)	X	X	X
Small Tank	Medium Tank	Large Tank													
x	x	x													
Multi-Level Sonic (3)															
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	<p><b>Figure 3 Routine Testing</b> (e.g., daily testing)</p> <p>3. Run the equipment as directed by the ultrasonic manufacturer and record the test results on the <a href="#">Log Sheet</a> located on hmark.com.</p> <p>4. All SonoCheck™ vials should change from blue/green to yellow (<b>Fig. 4</b>) within specified time. The time needed for the color change will indicate the level of energy and degree of cavitation provided by the ultrasonic cleaner.</p> <div style="text-align: center;">  <p><b>Figure 4 Color Change</b></p> <ul style="list-style-type: none"> <li>• A change slower than average will indicate a weak spot.</li> <li>• A negative result will indicate a blind spot of ultrasonic energy.</li> </ul> </div> <p>5. In case of an unsatisfactory result, refer to the SonoCheck™ troubleshooting guide.</p>
<b>Interpretation of Results</b>	<ul style="list-style-type: none"> <li>• Color change from blue/green to yellow indicates presence of cavitation energy.</li> <li>• Time for color change indicates the strength of cavitation energy.</li> <li>• Failure for color change to yellow indicates a failure to achieve sufficient cavitation energy to clean.</li> <li>• Ultrasonic energy is localized and failure to achieve color change may indicate one or more sonic transducers are failing.</li> </ul>
<b>Contraindications of Test Results</b>	In the presence of very powerful cavitation energy, color of SonoCheck™ liquid may go completely clear (no color). This can be interpreted as a passed test.
<b>Documentation</b>	<ul style="list-style-type: none"> <li>• If conducting routine testing, use the <a href="#">Log Sheet</a> to record your results.</li> <li>• Report any unsatisfactory results to the proper management for corrective action according to the policy of your facility.</li> </ul>
<b>Disposal</b>	<ul style="list-style-type: none"> <li>• SonoCheck™ vials should be disposed of in a biohazard container according to your facility guidelines regarding disposing biohazard. This is recommendation is an additional measure of safety; not because of the chemicals, but because it is being used in equipment used for decontamination.</li> </ul>

<b>Reprocessing Instructions</b>	
<b>Point of Use</b>	N/A
<b>Preparation for Decontamination</b>	N/A
<b>Disassembly Instructions</b>	N/A
<b>Cleaning – Manual</b>	N/A
<b>Cleaning – Automated</b>	N/A
<b>Disinfection</b>	N/A
<b>Drying</b>	N/A
<b>Maintenance, Inspection, and Testing</b>	N/A
<b>Reassembly Instructions</b>	N/A
<b>Packaging</b>	N/A
<b>Sterilization</b>	N/A
<b>Storage</b>	2°C –25°C. Do not allow to freeze.
<b>Additional Information</b>	N/A

<b>Related Healthmark Product(s)</b>	USTK-1L (weekly ultrasonic test kit), TWTL-1L (weekly tunnel washer test kit)
<b>Other Product Support Documents</b>	<ul style="list-style-type: none"> <li>• ProFormance™ Product Brochure</li> <li>• ProFormance™ Price List</li> <li>• Functionality/Operational Qualification Testing Log Sheet</li> <li>• Routine Testing Log Sheet</li> <li>• SonoCheck™ Trouble Shooting Guide</li> <li>• SonoCheck™ Weekly Log Sheet</li> <li>• PB-Automated Washer Tests</li> <li>• PB-Ultrasonic Lumen Tests</li> </ul>

<b>Reference Documents</b>	Validation of SonoCheck™ for the Monitoring of Ultrasonic Energy of Ultrasonic Cleaner, Martin Pfeifer
<b>Customer Service Contact</b>	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a> <a href="http://www.hmark.com">www.hmark.com</a>

2021-03-30 Ralph J Basile