**Instructions for Use: FlexiCheck™**

<table>
<thead>
<tr>
<th>Brand Name of Product</th>
<th>FlexiCheck™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic Name of Product</td>
<td>Cleaning challenge device for automated endoscope reprocessors (AER’s)</td>
</tr>
<tr>
<td>Product Code Number(s)</td>
<td>FLEXCHK-101, FLEXCHEK-102</td>
</tr>
<tr>
<td>Purpose of Product</td>
<td>To provide a standardized challenge to cleaning function of AER’s.</td>
</tr>
<tr>
<td>Range of Applications for Product</td>
<td>For use in AER’s with a cleaning cycle</td>
</tr>
</tbody>
</table>
| Key Specifications of Product | • Test coupon with 2 test soils representative of soils found in flexible endoscopes: blood and polysaccharide  
• Single channel lumen holder and flexible tube designed as a surrogate to the internal channel of a flexible endoscope. The holder unscrews, for placement of the test coupon. |

**Shipping & Storage**

<table>
<thead>
<tr>
<th>Shipping Conditions &amp; Requirements</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage Conditions</td>
<td>Store in the protective foil pouch at 2°C – 25°C</td>
</tr>
</tbody>
</table>
| Packaging Conditions | • Each coupon in an individual water tight foil pouch.  
• 25 tests per box.  
• Holder sold separately. |
| Shelf Life | 18 months from date of manufacturer. Consult package for expiration date. |

**Instructions for Using Product**

<table>
<thead>
<tr>
<th>Description of Use (s)</th>
<th>To challenge the cleaning function of AER’s with a standardized soil test inside a surrogate device.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation for Use</td>
<td></td>
</tr>
<tr>
<td>Diagrams (drawings, pictures)</td>
<td></td>
</tr>
</tbody>
</table>

**Steps for Use of Product**

1. Unscrew the FlexiCheck™ holder.  
2. Detach part A (marked with slot) from part B.  
3. Open protective pouch of FlexiCheck™ and insert the test coupon (part C) in part B.  
   Do not touch the area covered by with the test soil.  
4. Close FlexiCheck™ holder by screwing part A to part B.  
5. Connect the holder with one of the channel irrigation systems of the AER (luer-lock).  
6. Start the wash cycle according to the AER manufacturer’s IFU.  
7. At the end of the cycle, retrieve the holder from the AER.  
8. Open the holder by unscrewing part A from part B and remove the test coupon without touching the soiled areas.  
9. Visually inspect the coupon for residual soils.
## Interpretation of Results

<table>
<thead>
<tr>
<th>Result</th>
<th>Polysaccharide soil completely removed, but visible blood fibrin remains</th>
<th>Blood test soil completely removed, but visible polysaccharide remains</th>
<th>Polysaccharide soil completely removed, but visible blood remains</th>
<th>Some or all of both soils remain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
<td>Protein hydrolyzing parameters not optimal</td>
<td>Polysaccharide dissolving parameters not optimal</td>
<td>Water soluble proteins are being denatured by heat and/or disinfection chemicals</td>
<td>Poor water flow.</td>
</tr>
<tr>
<td>Optimization</td>
<td>Insufficient cleaning time, incorrect temperature, poor detergent efficacy or incorrect dosing</td>
<td>Insufficient cleaning time, incorrect temperature, poor detergent efficacy or incorrect dosing</td>
<td>Water temperature is too high or disinfecting agents are being introduced during the wash cycle.</td>
<td>Poor connection to the FlexiCheck, an incorrect or failed cleaning program, or major functional failure of the machine</td>
</tr>
</tbody>
</table>

## Contraindications of Test Results

**Documentation**
Record results on log sheet located at hmark.com

**Special Warnings and Cautions**

**Disposal**
Dispose of in a biohazard container

## Reprocessing Instructions

**Point of Use**

**Preparation for Decontamination**

**Disassembly Instructions**

**Cleaning – Manual**

**Cleaning – Automated**

**Disinfection**

**Drying**

**Maintenance, Inspection, and Testing**

**Reassembly Instructions**

**Packaging**

**Sterilization**

**Storage**

**Additional Information**

## Related Healthmark Products

- EndoCheck™ for Blood
- EndoCheck™ for Protein
- ChannelCheck™
- HangTimeKit™

## Other Product Support Documents

- ProFormance Brochure
- ProFormance Price List

## Reference Documents

- FlexiCheck™ Videos
- FlexiCheck™ Log Sheet
- FlexiCheck™ Sample Policy
- FlexiCheck™ Validation Study
- Instructions for Ultrasonic & Lumen Tests
- Troubleshooting Guide for FlexiCheck™

## Customer Service Contact

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2018-10-23 Ralph J Basile