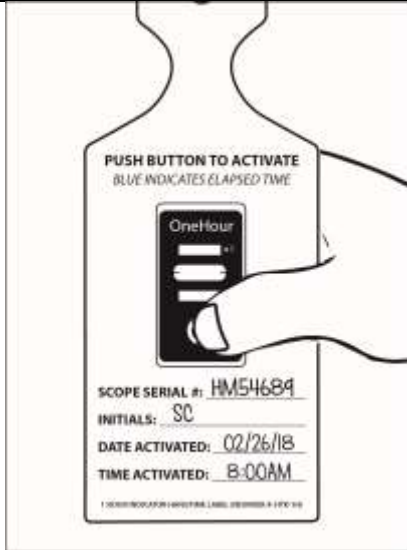



Instructions for Use: Single-Use 1 Hour Indicator

Brand Name of Product	Single-Use 1 Hour Indicator
Generic Name of Product	1 Hour Indicator
Product Code Number(s)	HTK-1H
Intended Use	To monitor elapsed time and whether predefined elapsed time has been reached or exceeded.
Range of Applications for Product	
Key Specifications of Product	<ol style="list-style-type: none"> 1 hour run-time. Push button activation on top of strip. Non-toxic, latex-free, silicone free and PVC free. Adhesive is pressure sensitive (-40°C to 110°C). The 1-Hour timeline after activation has begun has an accuracy of +/-10%.

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions	Store in cool, dark environment at room temperature.
Packaging Conditions	
Shelf Life	3 years from date of manufacture.

Instructions for Using Product	
Description of Use(s)	To indicate that the one hour hold time limit between pre-cleaning and manual cleaning has or has not been exceeded.
Preparation for Use	
Diagrams (drawings, pictures)	<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p>Figure 1</p> </div> <div style="text-align: center;">  <p>Figure 2</p> </div> </div>

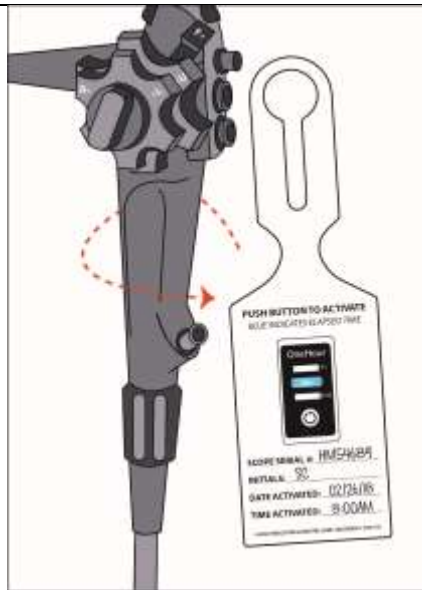


Figure 3



Figure 4

Steps for Use of Product	<ol style="list-style-type: none"> 1. Fill in the information on the designated lines (i.e., date, name of processor, etc.). Then, firmly squeeze the button to activate the indicator between 2 fingers ensuring the button has fully collapsed (if activation line does not appear within 2 minutes, re-squeeze the button). (Fig. 1) 2. When the blue activation line appears, the indicator has begun logging time. (Fig. 2) 3. Loop the self-looping label to the device. (Fig. 3) 4. The blue dye will continue to progress until the maximum elapsed time has been reached. (Fig. 4). If reprocessing has been delayed beyond the allotted time indicated on the indicator, follow the manufacturer's policy for delayed reprocessing of the endoscope.
Interpretation of Results	Failure to adequately squeeze can extend the delay the time for indication.
Contraindications of Test Results	
Documentation	
Special Warnings and Cautions	For indoor use only. Not for use outdoors or high or low temperature conditions, such as a refrigerator.
Disposal	Single-use. Dispose of in compliance with facility policy.

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	Single use per device. The 1-Hour timeline after activation has begun has an accuracy of +/- 10%,
Related Healthmark Products	
Other Product Support Documents	Labeling Brochure, Labeling Price List
Reference Documents	Support for documenting 1 Hour hold time between precleaning and manual cleaning.

Customer Service Contact	Healthmark Industries Company, Inc. 33671 Doreka Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com
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2018-04-16 Suzanne Latta