healthmark
INDUSTRIES CO.
health care products
800-521-6224
www.hmark.com

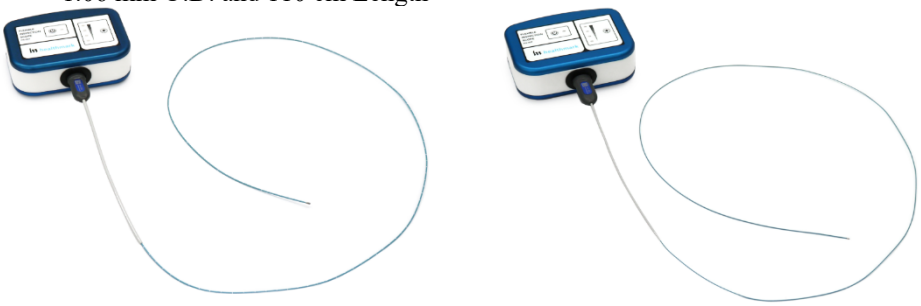
Instructions for Use: Flexible Inspection Scope Kit-HDMI

Brand Name of Product	Flexible Inspection Scope Kit-HDMI
Generic Name of Product	Flexible Inspection Scope Kit-HDMI
Product Code Number(s)	FIS-007H, FIS-007HB, CT-101, CT-102, CT-103
Intended Use	For visually inspecting items.
Range of Applications for Product	Enhance visual inspection by providing lighted magnification, image capture and the option for documentation in hard-to-see crevices, channels, and lumens in the areas if instruments that are not visible to the unaided eye.

Key Specifications of Product	**Flexible Inspection Scope™ FIS-007H**
	• CT-101 1.90 mm OD and 110 cm Length
	• CT-102 1.06 mm OD and 110 cm Length
	• Optical
	  ○ Resolution Format
	  ○ CT-102 1.06 mm: 40,000 pixels (or 200- x 200 pixels)
	  ○ CT-101 1.90 mm: 160,000 pixels (or 400- x 400 pixels)
	  ○ Field of View: 120° in air
	  ○ Angle of view: 0°
	
	HDMI Control Module (2 mm): Control module housing Camera processor and LED illumination HDMI
	• Dimensions: 5.24- x 3.90- x 1.85 inches
	• Weight: 1.20 pounds
	• Digital Inspection Scope Connection
	• Illumination Control
	• Power Cycle
	• Power Input: 100- to 240 volts (V) alternating current (ac), ≈1 ampere (A), 47- to 63 hertz (Hz) (from wall outlet)
	• Power Output: 5 V, 2 A (to enclosure)
	• System Power Button
	• All scope lengths and both diameters
	• HDMI Mini to HDMI Cable
	• Easily change from small and large diameter scopes
	
	Light Settings:
	There are four light settings operated by one-button.
	
	Blinking Light:
	Indicates transmitting video data
	• Splash proof (IPX5 Rating)
	• Requires external power.
	
	Box Features:
	• No Documentation capabilities
	• Power plug
	• Power Button (on top of the Box)
	• Catheter Holders- Integrated rubber catheter holder
	
	Flexible Inspection Scope Software Requirements:
	• Compatible with Windows 10 Operating System.
	• No Software-plug into any HDMI monitor.

Shipping & Storage

Shipping Conditions & Requirements	N/A
Storage Conditions	**Storage and transport** Humidity: 10- to 100% relative humidity (rh) (or condensing) Temperature: −20- to 60 °C Air Pressure: 600- to 900 hectopascals (hPa) (or millibars [mb]) **Normal Operation** Humidity: Zero (0)- to 100% rh Temperature: 5- to 40 °C
Packaging Contents	N/A
Shelf Life	*Warranty*: One-year from the date of purchase.

Instructions for Using Product	
Description of Use(s)	For visually inspecting items.
Preparation for Use	**Unpacking Flexible Inspection Scope:** Carefully inspect for shipping damage. If there is any damage, contact the shipping carrier and Heatlhmark customer service 800-521-6224 immediately. **HDMI Control Module: (Fig. 1).** 1. Digital Inspection Scope Connection 2. Illumination Control 3. Power Cycle 4. N/A 5. Mini HDMI Out 6. Power Input 7. System Power Button **Figure 1** **Flexible Working Length: (Fig. 2).** • 1.90 mm O.D. and 110 cm Length • 1.06 mm O.D. and 110 cm Length  **Large** **1.90 mm** **Small** **1.06 mm** **Figure 2**

Flexible Inspection Scope™ Features

Light/Illumination Settings: **(Fig. 3).**

- 5-light settings
  - Light on control indicated setting level
  - 5th setting is OFF
- Press light button to advance to next setting
  - 5th setting turns the light OF

Figure 3

Power Cycle Button

Press button to RESET camera (**Fig. 4).**

Figure 4

1. **Flexible Inspection Scope™ Plug (Fig. 5).**
   Contains camera video connection as well as LED Light for illumination.

Figure 5

2. **Flexible Working Length (Fig. 6).**
   The portion of the Flexible Inspection Scope™ that is inserted into an item during visual inspection. The measuring scale markings on the Flexible Working Length are in centimeters (accuracy = ± ½-cm).

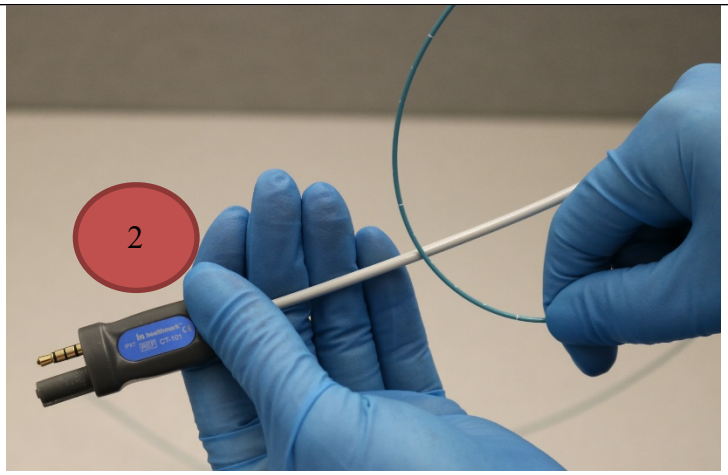


Figure 6

3. **Distal Camera (Fig. 7).**
   Distal portion of Flexible Inspection Scope™ that contains the camera lens.

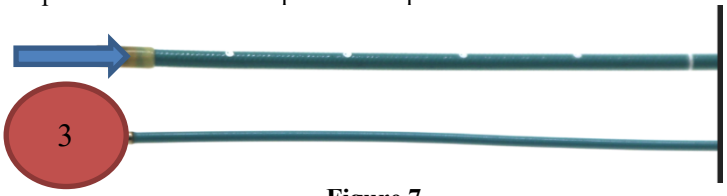
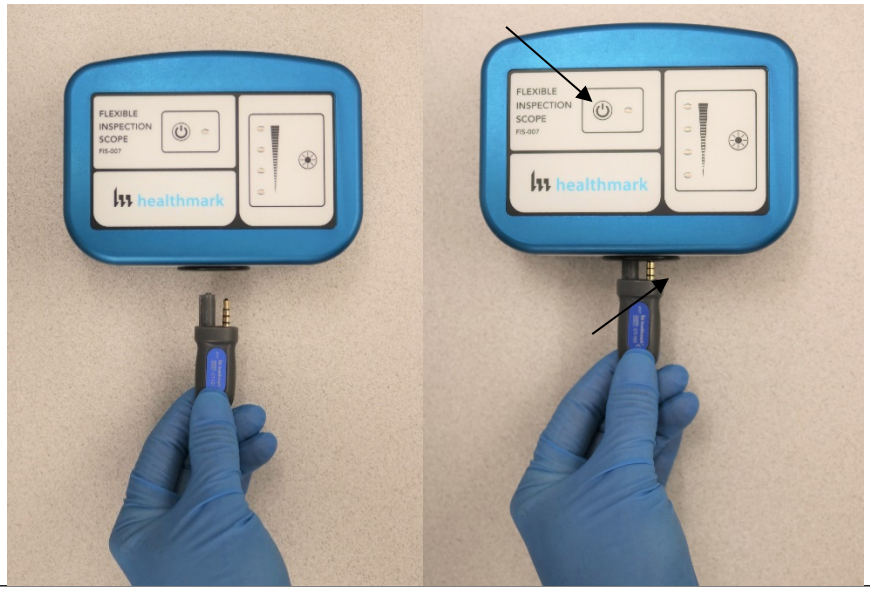


Figure 7

Switching to a Different Flexible Inspection Scope™ on the Control Module

1. Press the *Power* button on the Control Module.
2. Disconnect the current Flexible Inspection Scope from the Control Module
3. Repeat the steps in the "STARTING SOFTWARE & CONNECTIONS SCOPE TO PC" procedure.

Diagrams (drawings, pictures)	**Inserting Scope in Item**



<table>
<tr><td></td><td>
Figure 1

Rotating Device to Avoid Obstacle

Figure 2</td></tr>
<tr><td>Steps for Use of Product</td><td>Performing Inspection
Following the steps listed below will ensure the proper use and best performance of the Flexible Inspection Scope™. Follow the steps prior to inspection.
1. Grasp the Flexible Inspection Scope™ near its distal end and gently insert the Flexible Working Length into the intended item as shown in. (Fig. 1 above).
2. Adjust light with the Illumination button on the Control Box for ideal lighting.
3. Use short advancements while keeping your fingers close to the device’s opening. View the monitor while inserting into the item. If an obstruction hinders the path of the Flexible Inspection Scope™, gently attempt to manipulate or rotate it to avoid the obstacle. (Fig. 2 above).
4. Once the Flexible Working Length has reached the end of the area you are inspecting, retract the scope slowly, while looking for debris or damage.
5. When switching between control boxes, power off the control box that is in use, then disconnect the Flexible Inspection Scope from the control box.
6. If the HDMI control box is in use, power off the control box, disconnect the Borescope Catheder and along with the power adapter.

NOTE: If unable to exchange catheters by recycling power, close the program and open again.</td></tr>
<tr><td>Interpretation of Test Results</td><td>N/A</td></tr>
<tr><td>Contraindications of Test Results</td><td>N/A</td></tr>
<tr><td>Documentation</td><td>N/A</td></tr>
<tr><td>Special Warnings and Cautions</td><td>• To ensure operator safety, read and understand this IFU before using the Flexible Inspection Scope™.
• Do not attempt to use the Flexible Inspection Scope™ if it appears to be damaged.
• The Flexible Inspection Scope™ is not sterile as supplied. The user must follow the protocol for cleaning and disinfecting, or sterilizing described in the instructions for Cleaning and Disinfecting or Sterilizing section.
• Do not attempt to service any part of this product.
• To ensure operator safety, read and understand this IFU before using the Flexible Inspection Scope™.
• The Flexible Inspection Scope™ emits visible light energy from its distal end when powered on. Avoid looking directly at this emitted light or directing it toward others.</td></tr>
</table>

<table>
<tr><td></td><td>

Do not bend the Flexible Inspection Scope™ to a radius less than ½-inch (12.7 mm). This may cause damage.
Do not apply excessive force to the Flexible Inspection Scope™. Applying excessive force to the Flexible Inspection Scope™ can result in damage.

If you feel resistance, or an obstruction hinders its path, you may gently attempt to manipulate or rotate the scope to avoid the obstacle.
You may also slowly withdraw it a short distance and try advancing again.

</td></tr>
<tr><td>Disposal</td><td>This can be disposed of the same as standard electrical products. Follow your local regulations for disposal of electrical components.</td></tr>
</table>

<table>
<tr><th colspan="2">Reprocessing Instructions</th></tr>
<tr><td>Point of Use</td><td>N/A</td></tr>
<tr><td>Preparation for Decontamination</td><td>N/A</td></tr>
<tr><td>Disassembly Instructions</td><td>Disconnect the Flexible Inspection Scope™ from the control module prior to cleaning/disinfecting.</td></tr>
<tr><td>Cleaning – Manual</td><td>
Cleaning Between Uses:
Wipe down the Flexible Inspection Scope™ with a compatible wipe. Follow the wipe manufacturer's (Mfr.'s) Instructions for Use (IFU) for appropriate wipe usage. Click here to see the Chemical Compatibility Chart (PDF) for approved cleaning agents.

The Flexible Inspection Scope™ is made of the same material as other common endoscopes. Any wipe, solution, or low temperature (≤ 60 °C (140 °F) method intended for the reprocessing of endoscopes is likely compatible with the Generation II Flexible Inspection Scope™ Catheters if used according to the product labeling.

Solution Containing (Flexible Inspection Scope Only):
<table>
<tr><td>Alcohol Ethoxylates</td><td>Neutral or Near-Neutral pH Detergents</td></tr>
<tr><td>Enzymatic Cleaning Solutions</td><td>Enzymatic Detergents</td></tr>
<tr><td>Glutaraldehyde</td><td>Hydrogen Peroxide (7.35%) with Peracetic Acid (0.23%)</td></tr>
<tr><td>Accelerated Hydrogen Peroxide (AHP)</td><td>Ortho-phthalaldehyde (OPA)</td></tr>
<tr><td>Peracetic Acid</td><td>Sodium Borated, Decahydrate</td></tr>
<tr><td>Sodium Xylene Sulfonate</td><td>Tetrapotassium Pyrophosphate</td></tr>
<tr><td>Trisodium nitrilotriacetate</td><td></td></tr>
</table>

The Flexible Inspection Scope™ has fluid ingress protection rating of IPX7 (Waterproof) and can withstand immersion in fluid up to one (1)-meter (m) in depth for up to 30 minutes.

Control Module HDMI has a fluid ingress protection rating of IPX4 (Water resistant) can withstand splashing water from any direction.

For Thorough Cleaning: Cables
Follow the cleaning agent Mfr.'s IFU.

Unplug and disconnect all components from the Control box prior to cleaning.
Do not submerge or soak the cable for disinfection (cable is not waterproof).
Wipe thoroughly with non-linting wipe moistened with facility approved neutral detergent. Use the appropriate brushes with detergent solution to remove any residues from areas that cannot be reached with the wipes.

For Thorough Cleaning: Control Module

Unplug and disconnect all components from the Control box prior to cleaning.
Do not submerge or soak the cable for disinfection (Control Box is not waterproof).
Wipe thoroughly with non-linting wipe moisture with facility approved neutral detergent. Use the appropriate brushes with detergent solution to remove any residues from areas that cannot be reached with the wipes.

NOTE: Do NOT soak. Control Module and cable are not waterproof and should not be immersed.
</td></tr>
<tr><td>Cleaning – Automated</td><td>N/A</td></tr>
</table>

Disinfection

Control Module and Cables
These may be cleaned with alcohol based disinfectant wipes.

Compatible agents (wipes and Solutions) for disinfecting Flexible Inspection Scope™ and Control Module:

- Hydrogen peroxide
- Isopropyl alcohol (IPA)
- Sodium hypochlorite (Bleach)
- Ortho-phenylphenol (OPP)
- Quaternary ammonium

High-Level Disinfection (Flexible Inspection Scope™ Only)

- Select only the disinfecting solutions listed in the compatible disinfecting methods.
- Follow all recommendations regarding health hazards, dispensing, measuring, and storage from the Mfr. of the cleaning and disinfecting agents.
- Soak the Flexible Inspection Scope™ in the selected disinfecting solution per the solution Mfr.'s IFU.
- Rinse the Flexible Inspection Scope™ with critical (sterile) water, again, following the instructions of the disinfecting solutions Mfr.

Reprocessing Chemical Compatibility Chart (PDF): Click here.

Drying

Flexible Inspection Scope™ Only

- Dry with a sterile, non-Linting wipe or sponge.
- Ensure that the distal tip and proximal ends are dried.
- Air drying could leave deposits on the optical surfaces, which could result in a degraded image.

Maintenance, Inspection, and Testing

- **Prior to use, carefully inspect the external surfaces of the Flexible Inspection Scope™ and any accessories** to ensure they are smooth and free of any wear or damage (i.e., protrusions or sharp edges).
- Flexible Inspection Scope™ have no user:
  - serviceable parts.
  - maintenance beyond cleaning.
- Refer all service or replacement needs to Healthmark Industries.
- Light leaks may be common and possibly noticeable when inspecting the flexible portion of the Flexible Inspection Scope™.
  - This does not influence its function, but it should be monitored for light output.
  - Overly dark images on your monitor may be caused by damaged light fibers and may require repair or replacement of the Flexible Inspection Scope™.

Troubleshooting and Servicing

Condition	Appearance	Cause	Correction
No image	Main image Window is black.	The Inspection Scope was not connected to the computer when the software was opened.	Unplug USB Connection on Camera Cable and plug in again.
No image	Main image Window is black.	1. USB Video Device not selected, or without the scope connected. 2.Check HDMI Monitor "Input" Selection	If no image, to the 'Settings' Tab and select USB Video Device.
No light	No light when scope pointed at surface.	No power to light source or power connections are not secure.	1.Check the Camera Cable connections and make sure the computer is powered on.

				2. HMDI is “ON”.
	Low light	No image or very dark image. Weak light pattern when scope pointed at surface.	Light setting too low.	Cycle through light intensity levels/settings until a clear image is obtained.
	Low light	No image or very dark image. Weak or light pattern when scope pointed at surface.	Broken light fibers in scope.	Replace Flexible Inspection Scope™ • Decide if the Scope is no longer adequate for use. • Recommendation is when 10% of the image or illumination has been degraded/ lost to replace the scope.
	No image or distorted image	No image or heavily distorted, cracked appearance.	Broken image sensor and/or internal cables.	1.Press Power Cycle button 2.Replace Flexible Inspection Scope™.
	Overly bright image	White-out type reflection	Light intensity is too bright	Cycle through light intensity levels/settings until a clear image is obtained.
	Blurry image or overly bright image	Distorted image. Light often reflective and image appears brightly colored.	Debris or film on lens.	Wipe off end of Flexible Inspection Scope™ with non-Linting wipe.
	Image does not capture	When you click the Capture Button, the still image or video is not captured.	The File Loc path may have changed, or the folder names do not exist.	Set up a new Windows File Loc folder.
	Rapidly takes pictures automatically	‘Pictured Captured’ keeps flashing and Image files are created rapidly.	PC’s internal camera is selected as the video device is Settings.	Disable the PC’s internal camera (See Advanced Settings below).

Reassembly Instructions	N/A
Packaging	N/A
Sterilization	**Do Not autoclave** the Flexible Inspection Scope™. See the Chemical Compatibility Chart (PDF): Click here. **Low Temperature Sterilization Systems (Flexible Inspection Scope Only)** Ethylene Oxide (EtO) — STERRAD® 100S System (Standard) STERRAD® NX System (Standard, Advanced) — STERRAD® 100NX System (Standard) STERIS® Liquid Chemical Sterilization Systems — STERIS V-PRO® Low Temperature Sterilization Systems (Non-Lumen Cycle)

Storage	• Storage and transport
	  ○ Humidity: 10 to 100% rh
	  ○ Temperature: −20- to 60 °C
	• Pressure: 600- to 900 hPa
	  ○ Normal Operation
	  ○ Humidity: Zero (0) to 100% rh
	  ○ Temperature: 5- to 40 °C

Additional Information	1. If upon inspecting an item it is determined not to be clean, reprocess according to the Mfr.'s IFU. 2. Facility needs to do a multidisciplinary risk assessment to determine the requirement and frequency for cleaning disinfection and sterilization. This assessment should be based upon clinical use of items and reprocessing instructions.
Related Healthmark Products	N/A
Other Product Support Documents	ProSys™ Brochure, ProSys™ Price List
Reference Documents	N/A
Customer Service Contact	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com