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

Brand Name of Product	Flexible Inspection Scope Kit - USB
Generic Name of Product	Flexible Inspection Scope Kit - USB
Product Code Number(s)	FIS-007U, FIS-007USK, FIS-007UB, CT-101, CT-102
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 areas of instruments that are not visible to the unaided eye.

Key Specifications of Product	**Flexible Inspection Scope- FIS-007U**
	• CT-101 1.9 mm OD and 110 cm length
	• CT-102 1.06 mm OD and 110 cm length
	• Optical
	   o Resolution format:
	   o CT-102 1.06 mm— 40,000 or 200 x 200 pixels
	   o CT-101 1.9 mm — 160,000 or 400 x 400 pixels
	   o Field of View: 120° in air
	   o Angle of view: 0°
	USB Control Module: Control Module housing Camera processor and LED illumination:
	• Dimensions: 5.25 in x 3.90 in x 1.85 in
	• Weight: 1.20 lbs
	• Digital Inspection Scope Connection
	• Illumination Control- LED in the Control Module
	• Power Cycle
	• USB Camera 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)
	• No external power needed
	
	Flexible Inspection Scope Software Requirements:
	• Compatible with Windows 10 Operating systems
	• USB Flash Drive includes Software

Shipping & Storage	
Shipping Conditions & Requirements	N/A
Storage Conditions	**Storage and transport** Humidity: 10 to 100 %rh (condensing) Temperature: -20 to 60 °C Pressure: 600 to 900 hPA **Normal Operation** Humidity: 0 to 100 %rh (condensing) Temperature: 5 to 40 °C
Packaging Contents	N/A
Shelf Life	Warranty: one year from 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.

USB Control Module: (**Fig 1**)
    1. Digital Inspection Scope Connection
    2. Illumination Control
    3. Power Cycle
    4. USB (Type C) on the right side of the box

Figure 1

Flexible Inspection Scope™: (**Fig 2**)
    • CT-101 1.9 mm O.D. and 110 cm length
    • CT-102 1.06 mm O.D. and 110 cm length
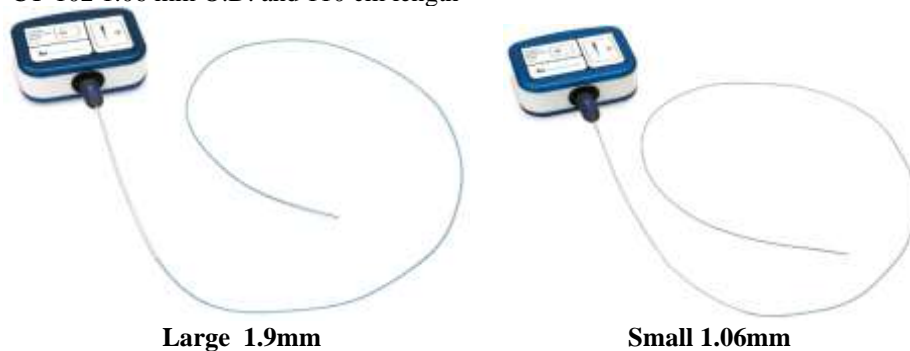
Large 1.9mm   **Small 1.06mm**
Figure 2

Flexible Inspection Scope™ Features
Light/Illumination Settings: (**Fig 3**)
    • 5 light settings
        o Light on control indicats setting level |

- o   Fifth setting is OFF
- Press light button to advance to next setting
- Fifth setting turns the light OFF

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 = ± 0.5 cm)
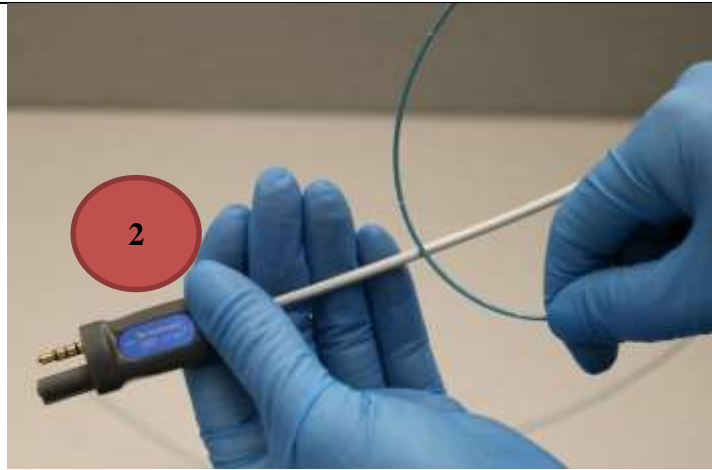
Figure 6

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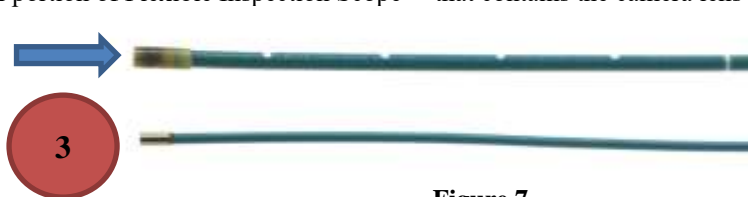   Distal portion of Flexible Inspection Scope™ that contains the camera lens


Figure 7

SOFTWARE INSTALLATION:

Note: This section is done only once when connecting the scope to the computer for the first time.

- System Requirements: MS Windows version 10
- Install the Flexible Inspection Scope™ Software from the USB flash drive on a computer

Note: If you have any IT policies that may block this installation, please contact your IT team to give access to Healthmark scope viewer to install.
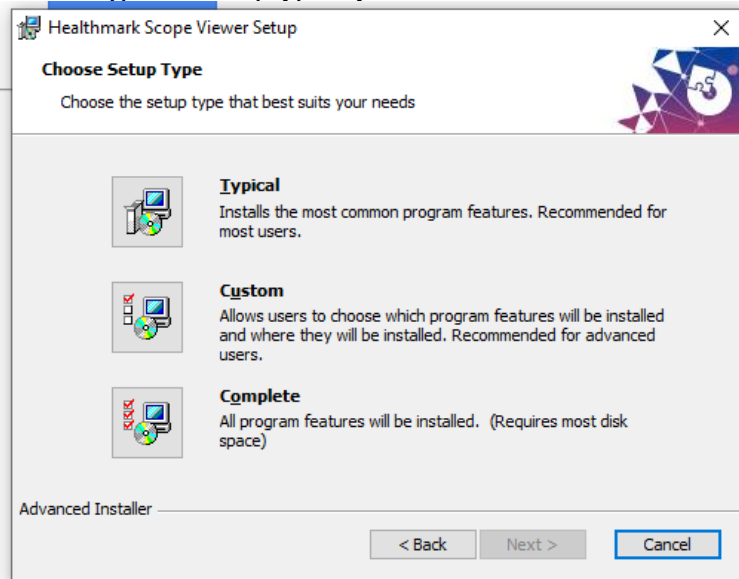
1. Insert the USB Flash drive into your computer, and double click on the *Healthmark Scope Viewer* installer package to begin installation
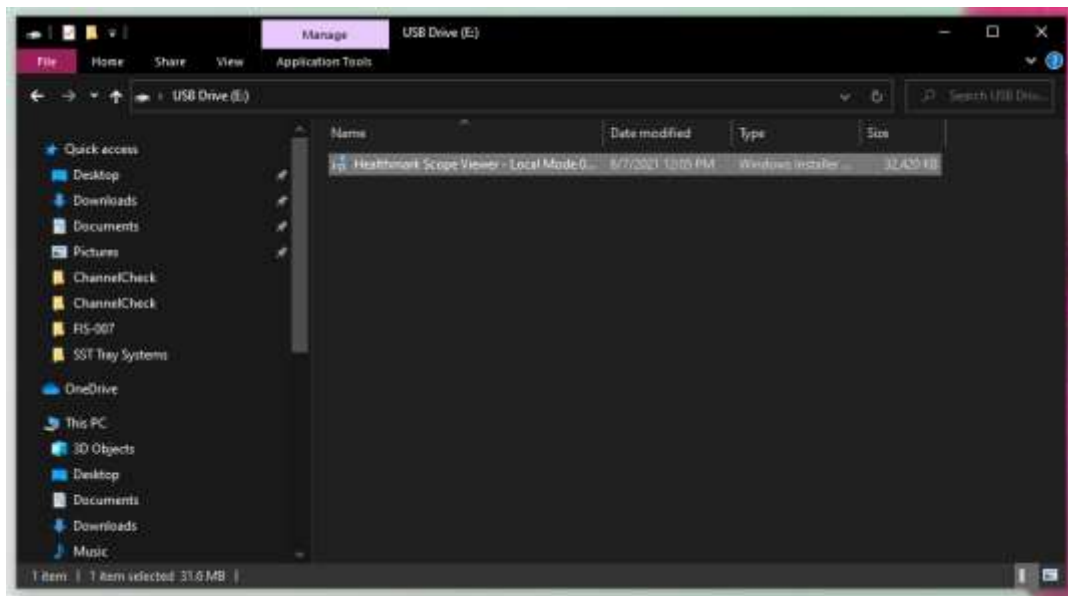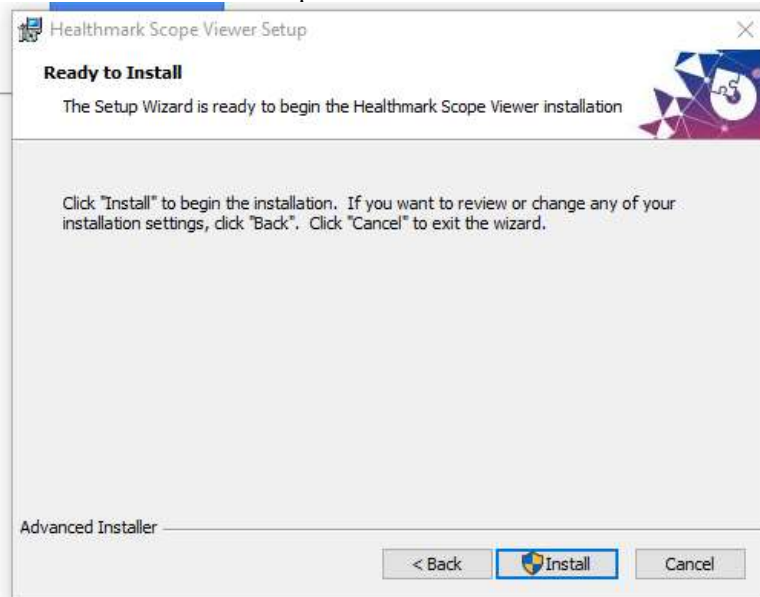

2. The Welcome to the Healthmark Scope Viewer Setup Wizard screen pops up and click on *Next*
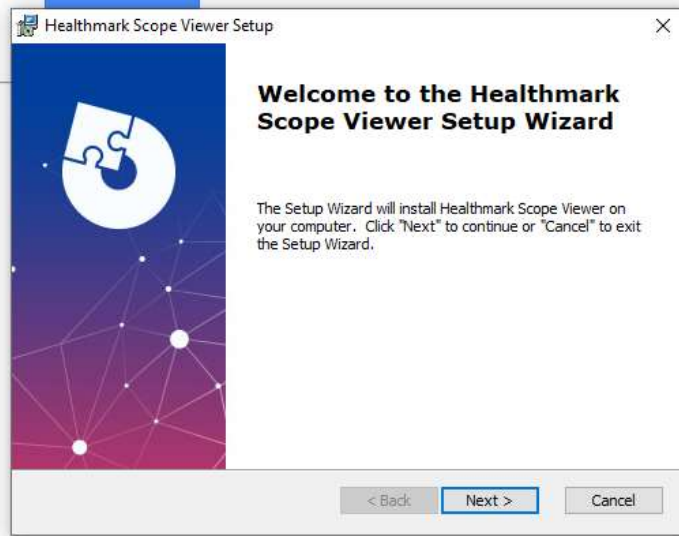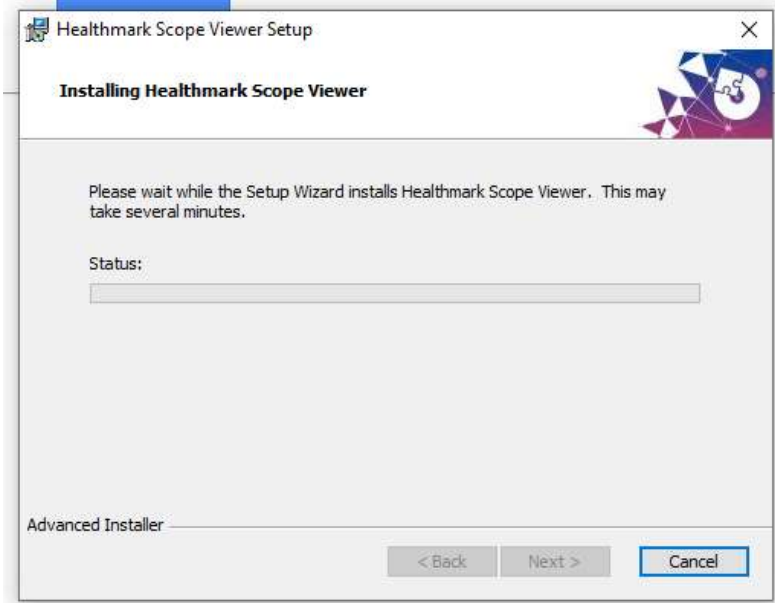
3. Next click on the first tab *Typical* or setup type of your choice, click *Next*
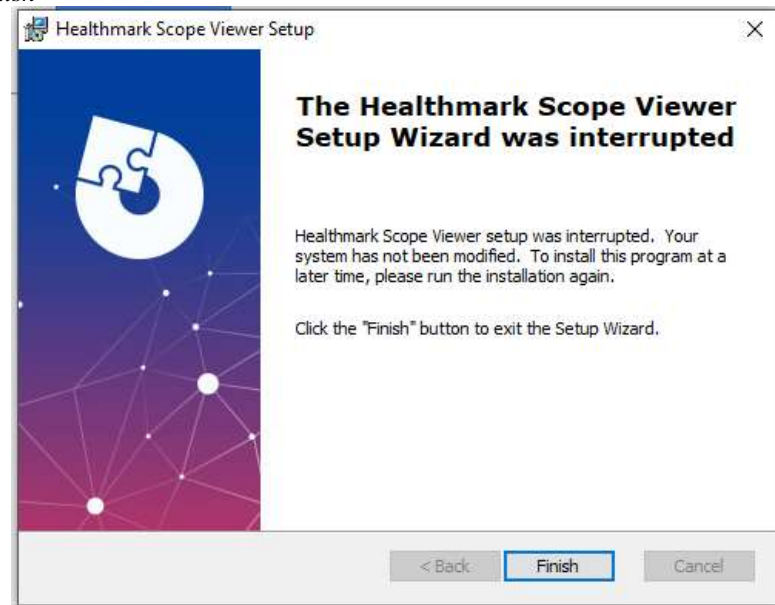

4. Click *Install* and wait for installation to complete

Healthmark Scope Viewer Setup ×

Installing Healthmark Scope Viewer

Please wait while the Setup Wizard installs Healthmark Scope Viewer. This may take several minutes.

Status:

Advanced Installer

< Back   Next >   Cancel

5. Next, Click *Finish*

Healthmark Scope Viewer Setup ×

The Healthmark Scope Viewer Setup Wizard was interrupted

Healthmark Scope Viewer setup was interrupted. Your system has not been modified. To install this program at a later time, please run the installation again.

Click the "Finish" button to exit the Setup Wizard.

< Back   Finish   Cancel

STARTING SOFTWARE & CONNECTING SCOPE TO PC:
(Fig 8)
1. Open the Windows PC viewer software
2. Connect the Control Module to PC using USB Cable
3. Plug the Flexible Inspection Scope into the Control Module
4. In the viewer software, click *Settings* and Select *USB Video Device*, click on the desired resolution, select the preferred Video Output Format, and then Click *OK*
5. Press the Power Cycle Button

Figure 8

6. Now you can start using the scope.

Verifing Operation

Following the steps listed below will ensure the proper use and performance of the Flexible Inspection Scope™. The Flexile Inspection Scope™ can be checked for normal operation by connecting it as described in the Startup section of this IFU.

Normal operation includes:

- An image appearing on your computer monitor or HDMI Monitor
- A blinking light on Control Module near the *Power Cycle* button indicates the image feed is transmitting
- White light will emit from the distal end of the Digital Inspection Scope
- An LED light on the control module top panel indicates the light intensity of the device.

Using Software
Healthmark Scope Viewer Software (Fig 9)

1. *Capture button*: Captures a Reference Image and saves it to the Reference Image folder
2. *Main Image Window*: Displays the image from the camera
3. *Reference Image Window*: Displays a reference image
4. *Clear Button*: Removes the image from the Reference image window
5. *Open Reference Image button*: Allows you to select a reference image from the Reference Image folder
6. *Settings Button*: Click to select the video camera and resolution settings
7. *File Location Button*: Click to change location where captured images are being saved
8. *File Location Window*: Shows the file path where captured images are being saved currently
9. *Capture Image Button*: Captures images and adds them to the File Location selected by the user (as shown in the File Location Window)
10. *Capture Video button*: Click to record video. Click again to stop recording video
11. *File Prefix*: Type in text that you would like included in the file name of Captured Images.
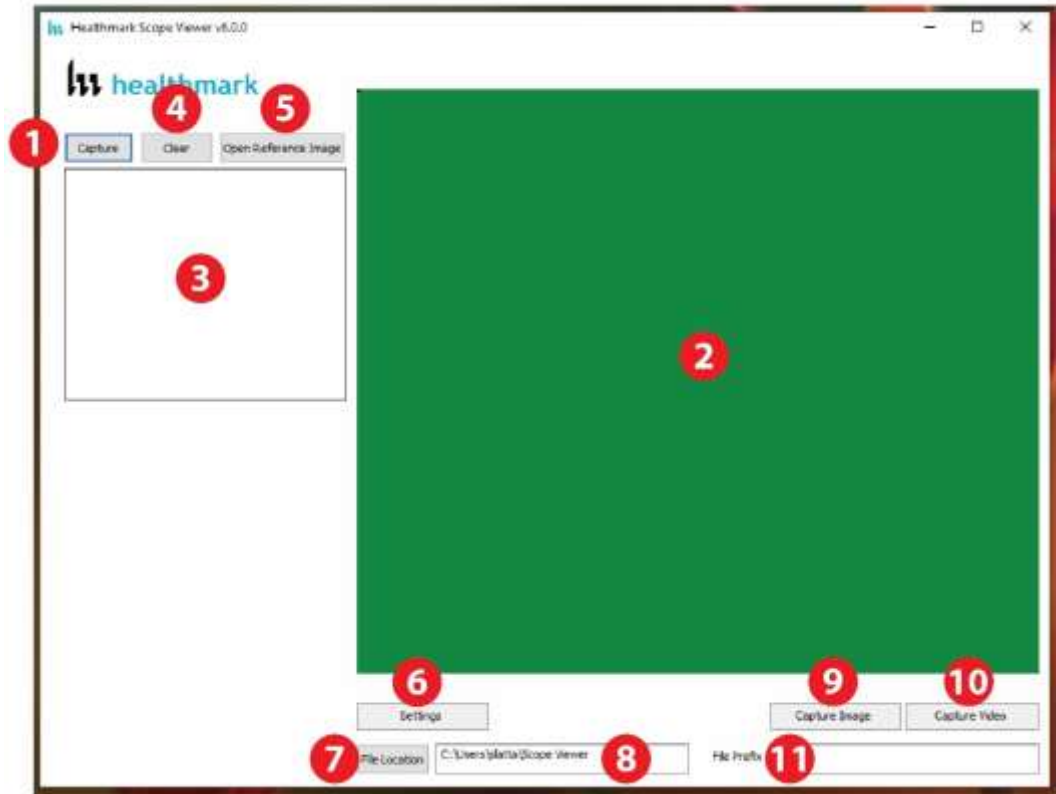
Figure 9

Selecting Video Device or Camera
Follow the directions below to select the video device or camera used to capture images using the Flexible Inspection Scope™ Viewer Software. (**Fig 10**)

1. **Click** *Settings* button in the lower left of the Scope Viewer software to display a list of video devices or cameras being detected by your computer
2. Select a device for capturing images using the Scope Viewer
   a. The example below shows a webcam and USB Video Device in the Settings box. Select the *USB Video Device* for the Flexible Inspection Scope™
   b. You can also select your preferred Video Output Format from the dropdown box
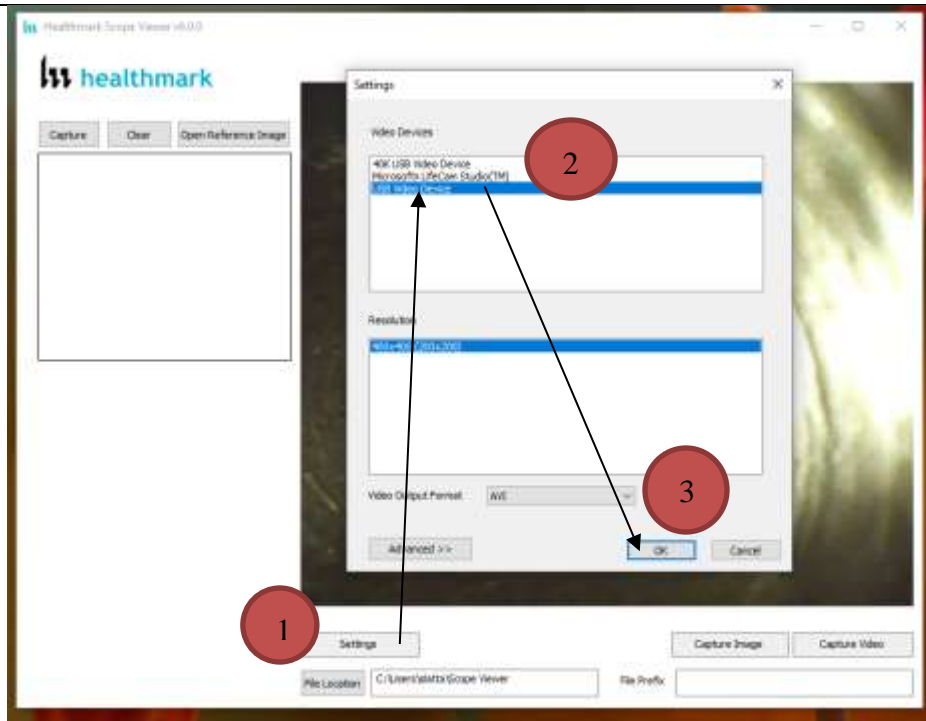3. Click *OK* to view the selected Video Device.

Figure 10

Capturing Still Pictures

Follow the instructions for capturing still pictures from the Main Image Window.

Select the *Capture Image* button. (**Fig 11**)

Figure 11

Note: When an image is captured, "Image Captured" in red text will flash on the lower portion of the screen and a new file will appear in the Files Location.

Capturing Video Images

Follow the instructions below for capturing video from the Main Image Window.

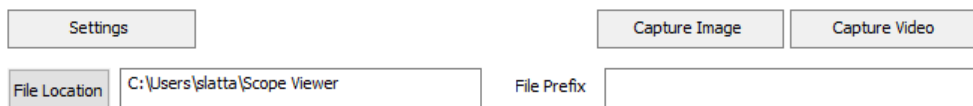1. Select the *Capture Video* Button (**Fig 12**)

Figure 12

2. When the video is recording "Recording…" in red text will appear toward the bottom of the software window
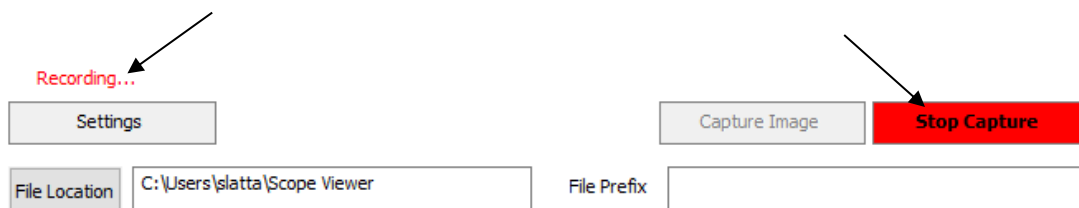3. To stop recording, click *Stop Capture*. (**Fig 13**)

Figure 13

Setting File Prefix

Following the steps below allows you to create a *file prefix* that will appear after the underscore of image file names save to the File Location specified by the user.

1. Click the field next to File Prefix
2. Enter the characters that you would like to be included in the file name. (**Fig 14**)

Figure 14

Setting Location for Saved Files

Following the steps below allows you to set the file location of saved images using the Scope Viewer software.

1. Click the *File Location* button
2. Select the file location you want to save captured images. (**Fig 15**)

Figure 15

Displaying Reference Image

There are two ways to display a still image in the Reference Image Window on the Scope Viewer software.

1. To display an image currently being displayed in the Main Image Window, click the *Capture* button

*Note: The images will be saved in a file folder titled **Reference Images** in the designated File Location that the user specified in the **File Location** field.* (**Fig 16**)

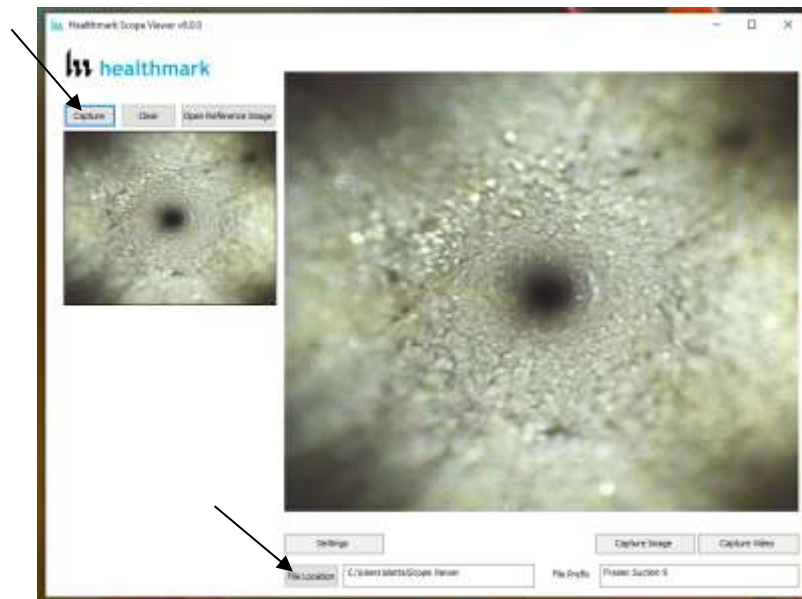**Figure 16**

2. To display a saved image in the Reference Image Window from your File Location:
   a. Click the *Open Reference Image* button
   b. Select the file you want to display
   c. Click the *OK* Button, to display the image in the Reference Image Window. (**Fig 17**)
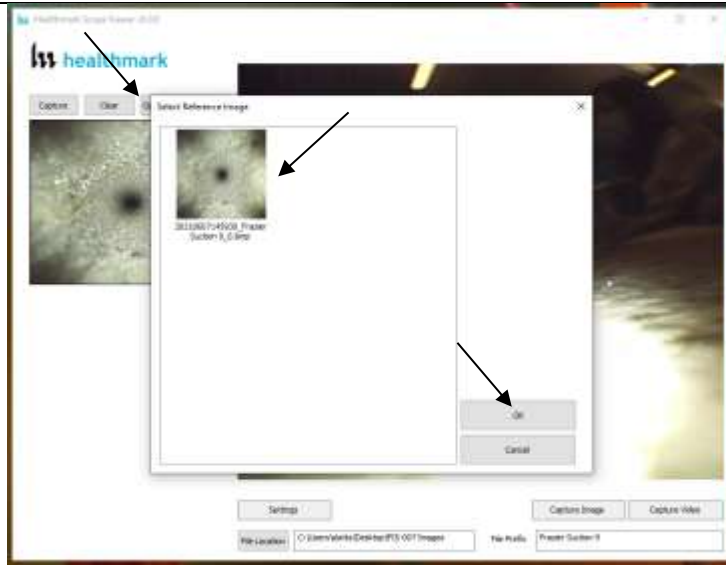
Figure 17

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

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

Diagrams (drawings, pictures)	**Inserting Scope in Item**
	Figure 1
	Rotating Device to Avoid Obstacle

	Figure 2

Steps for Use of Product	**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. (**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
	    a. View the monitor while inserting into the item
	    b. 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 USB control box is in use, power off the control box and disconnect the Borescope Catheder along with the power adapter.
	
	***Note**: If unable to exchange catheters by recycling power, close the program and open again.*

Interpretation of Test Results	N/A
Contraindications of Test Results	N/A
Documentation	N/A

Special Warnings and Cautions	• 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.
	• 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.
	• Do **not** bend the Flexible Inspection Scope™ to a radius less than 0.50 in (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.
	    o If you feel resistance or an obstruction hinders its path, you may gently attempt to manipulate or rotate the scope to avoid the obstacle.
	    o You may also slowly withdraw it a short distance any try advancing again.

Disposal	This can be disposed of the same as standard electrical products. Follow your local regulations for disposal of electrical components.
Reprocessing Instructions	
Point of Use	N/A
Preparation for Decontamination	N/A
Disassembly Instructions	Disconnect the Flexible Inspection Scope™ from the control module prior to cleaning/disinfecting.
Cleaning – Manual	**Cleaning Between Uses:**

	Wipe down the Flexible Inspection Scope™ with a compatible wipe. Follow the manufacturer's (Mfr.'s) Instructions for Use (IFU) for appropriate wipe usage. See Chemical Compatibility Chart for approved cleaning agents click here:
	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)
	Flexible Inspection Scope™ has a fluid ingress protection rating of IPX7 (Waterproof) and can withstand immersion in fluid up to 1 m in depth for up to 30 minutes.
	Control Module USB has a fluid ingress protection rating of IPX5 (Water resistant) and can withstand a sustained, low pressure water jet spray for up to three minutes.
	For Thorough Cleaning: **Cables** Follow the cleaning agent Mfr.'s IFU. 1. Unplug and disconnect all components from the Control box prior to cleaning. 2. Do **not** submerge or soak the cable for disinfection (cable is not waterproof). . 3. 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. 4. Rinse with non-linting wipe moistened with AAMI Utility Water for 45 to 60 seconds, then dry with non-linting wipe.
	For Thorough Cleaning: **Control Module** 1. Unplug and disconnect all components from the Control box prior to cleaning. 2. Do **not** submerge or soak the cable for disinfection (Control Box is not waterproof). 3. 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. 4. Rinse with non-linting wipe moistened with AAMI Utility Water for 45 to 60 seconds, then dry with non-linting wipe.
	*Note: (**Do NOT soak**). Control Module and cables are not waterproof and should not be immersed.*
Cleaning – Automated	N/A
Disinfection	**Control Module and Cables** These may be cleaned with alcohol based disinfectant wipes.

Solution Containing (Flexible Inspection Scope Only)

Alcohol Ethoxylates	Neutral or Near-Neutral pH Detergents
Enzymatic Cleaning Solutions	Enzymatic Detergents
Sodium Borated, Decahydrate	Tetrapotassium Pyrophosphate

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

- Hydrogen Peroxide
- Isopropyl Alcohol (IPA)
- Sodium Hypochlorite (Bleach)
- Ortho-Phenylphenol
- Quaternary Ammonium.

High Level Disinfection (Flexible Inspection Scope™ Only)
- Select only disinfecting solutions listed in the compatible disinfecting methods
- Follow all recommendations regarding health hazards, dispensing, measuring, and storage from the Mfr. of cleaning and disinfecting agents.
- Soak the Flexible Inspection Scope™ in selected disinfecting solution per solution Mfr.'s IFU

	• Rinse the Flexible Inspection Scope™ with critical (sterile) water, again, following the disinfecting solutions Mfr.'s instructions. Reprocessing Chemical Compatibility Chart click here:
Drying	Flexible Inspection Scope™ Only • Dry with a sterile, non-linting wipe or sponge • Ensure the distal tip and proximal end are dried *Note: 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 Scopes™ have no user: o Serviceable parts o 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™. o This does not influence its function but should be monitored for light output o Overly dark images on the 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 Location path may have changed, or the folder names does 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

Reassembly Instructions	N/A
Packaging	N/A
Sterilization	**Do Not autoclave** the Flexible Inspection Scope™. See the Chemical Compatibility Chart 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 (condensing) Temperature: -20 to 60 °C Pressure: 600 to 900 hPA **Normal Operation** Humidity: 0 to 100 %rh (condensing) Temperature: 5 to 40 °C
Additional Information	1. If upon inspecting an item it is determined not to be clean, reprocess according to the manufacturer's instruction for use 2. Facility needs to do a multi-disciplinary risk assessment to determine the requirements 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

2021-12-09 Suzanne Latta