

 healthmark

FLEXIBLE INSPECTION SCOPE

USER MANUAL & SOFTWARE INSTALLATION GUIDE





Flexible Inspection Scope

FIS-005SK & FIS-005

Product Manual



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Symbol Descriptions



Read this operating manual for additional warnings and instructions for use.



WARNING



Date of manufacture



GENERAL WARNINGS

1. Follow the instructions for cleaning, disinfecting and sterilizing provided in this document.
2. Do not steam sterilize the Flexible Inspection Scope.
3. Do not attempt to service any part of this product.
4. To ensure operator safety, read and understand this manual before using the Flexible Inspection Scope.
5. 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.
6. Carefully inspect the external surfaces of the Flexible Inspection Scope and any accessories to assure they are smooth and free of any protrusions or sharp edges.
7. Do not bend device below a 0.85" (21.6 mm) radius; this may cause damage to the device.
8. Do not apply excessive force to the Flexible Inspection Scope. If you feel resistance, or an obstruction hinders the path of the Flexible Inspection Scope, you may gently attempt to manipulate or rotate the device to avoid the obstacle. You may also slowly withdraw a short distance and try advancing again. Applying excessive force to the Flexible Inspection Scope can result in damage to the device.
9. Avoid rubbing the Flexible Inspection Scope against sharp edges. This can cause damage to the device.



Intended Use

The Flexible Inspection Scope is used for visual inspection of items.

Indications for Use

Visual Inspection of channels, lumens and inner components items to visually verify that they are free of damage and debris.

Contraindications for Use

Not for human use.

Product Description

The Flexible Inspection Scope allows for enhanced visual inspection by providing light, vision, magnification and the option for documentation in hard-to-see crevices, channels, and lumens in items – areas as small as 2 mm and not visible to the unaided eye.

The Flexible Inspection Scope can be used with a PC running MS Windows versions 7, 8, or 10.

Flexible Inspection Scope (FIS-005SK) Product Contents:

- Flexible Inspection Scope (FIS-0005)

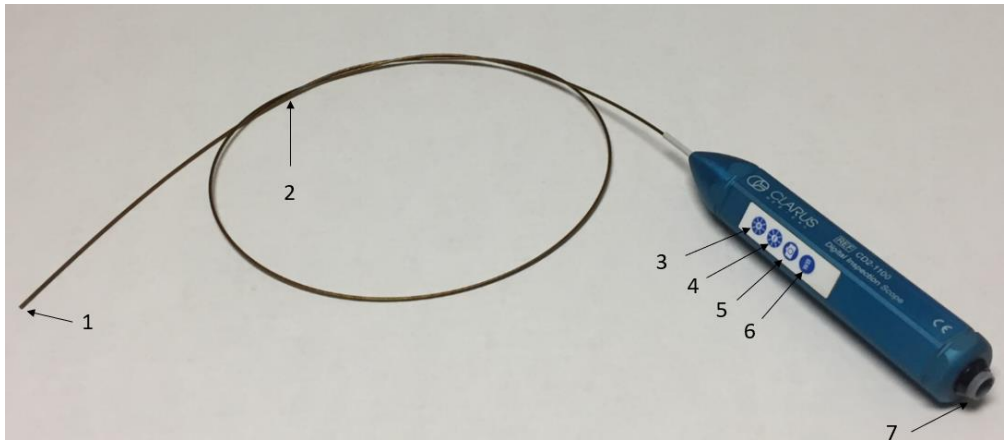
- Camera Cable

- USB Flash Drive (Containing Flexible Inspection Scope Viewer Software & Instructions for Use)

Flexible Inspection Scope Features

The user features of the Flexible Inspection Scope (FIGURE 1) and Accessories (FIGURE 2) are shown in the following illustrations.

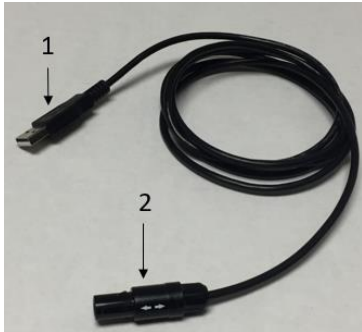
FIGURE 1: Flexible Inspection Scope Features and Connections



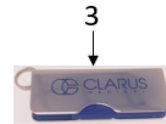
#	Name	Function
1	Distal Camera	Distal portion of Flexible Inspection Scope that contains the camera lens.
2	Flexible Working Length	The portion of the Flexible Inspection Scope that is inserted into a device during visual inspection.
3	Brightness Increase (+) Button	Press button to increase illumination intensity.
4	Brightness Decrease (-) Button	Press button to decrease illumination intensity.
5	Handpiece Capture Image Button	Press button to capture video or image.
6	White Balance Button	Press to white balance the image.
7	Camera Cable Connection	Connects the Controller Handpiece to USB on computer.

FIGURE 2: Flexible Inspection Scope Accessories

Camera Cable



USB Flash Drive



#	Name	Function
1	USB (Type-A Male) Connector	Plugs into USB port on computer.
2	Camera Connector	Plugs into Flexible Inspection Scope.
3	USB Flash Drive	Plugs into USB Port on computer for downloading Flexible Scope Viewer Software and Instruction for Use.
4	Soaking Cap	

Flexible Inspection Scope Device Mount Accessory Components (sold separately)

The following components are optional:

- Flexible Arm, Manfrotto, 520 mm, Model 237HD
- Nano Clamp, Manfrotto, Model 386BC-1
- Super Clamp, Manfrotto, Model 635

Unpacking the Device

The Flexible Inspection Scope has been thoroughly inspected and carefully packaged before shipping. Once the unit is removed from its container, it should be carefully inspected for shipping damage. If there is any damage, contact the shipping carrier and Healthmark Industries immediately.



WARNING: Do not attempt to use the Flexible Inspection Scope if it appears to be damaged.



WARNING: The Flexible Inspection Scope is **NOT STERILE** as



supplied from Healthmark Industries. The user must follow the protocol for cleaning and disinfecting or sterilizing described in the Instructions for Cleaning and Disinfecting or Sterilizing section.

Inspection

Prior to use, inspect the Flexible Inspection Scope for signs of wear or damage. Operation can be verified by following the steps in the Verifying Operation section of this manual.



WARNING: Carefully inspect the external surfaces of the Flexible Inspection Scope and any accessories to assure they are smooth and free of any protrusions or sharp edges.

Routine Maintenance

There are no user serviceable parts within the Flexible Inspection Scope. No user maintenance beyond cleaning is required. Refer all service or replacement needs to Healthmark Industries. The contact information is listed at the end of this document.

Flexible Inspection Scope Viewer Software

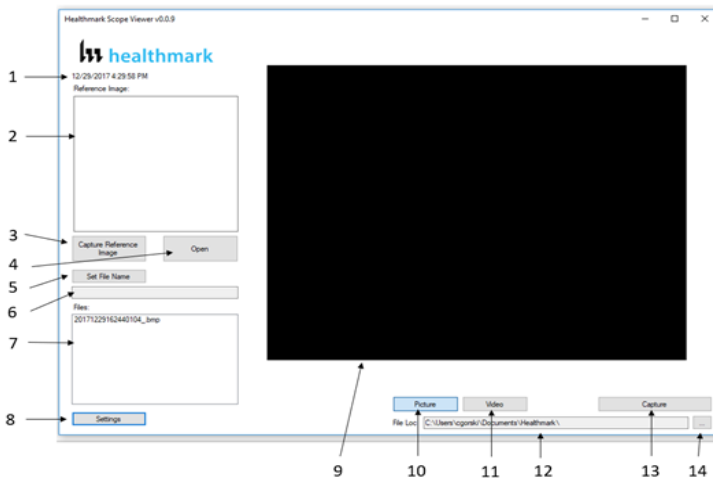
IMPORTANT: Before connecting the Flexible Inspection Scope, install the scope Viewer Software from the USB Flash drive on a computer.

System Requirements: MS Windows versions 7, 8, or 10.

Connecting Flexible Inspection Scope

1. Connect the Camera Cable to the Flexible Inspection Scope.
2. Plug in the USB Connector to the USB port in your computer.

Flexible Inspection Scope Viewer Software

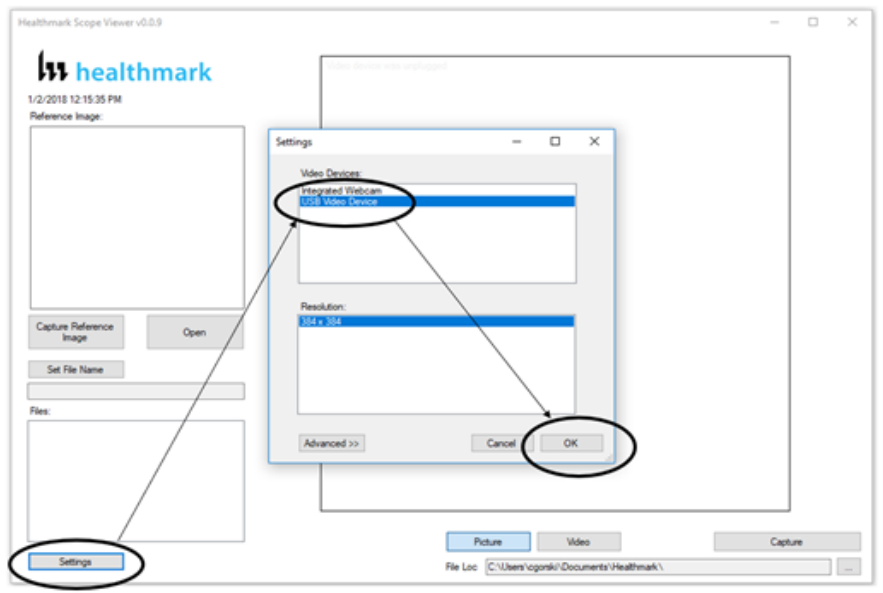


#	Name	Function
1	Date & Time	Date and time display
2	Reference Image Window	Displays a Reference Image
3	Capture Reference Image Button	Captures still image being displayed in the Main Image Window
4	Open Button	Opens the file location (File Loc) where images are being saved and allows you to select image that is displayed in Reference Image Window
5	Set File Name Button	Click to identify a default name that will be included with the file name when capturing images
6	File Name Box	Text box for creating a File Name
7	Files Box	Displays captured images that are routed and stored in the area being shown in File Loc
8	Settings Button	Click to select the video camera and resolution settings
9	Main Image Window	Displays the image from the camera
10	Picture Button	Click to select the picture option when capturing still images
11	Video Button	Click to select the video option when capturing video images
12	File Loc Box	Location where captured images are being saved.
13	Capture Button	Option to click for capturing images. Also used to start/stop video images.
14	Ellipse Button	Opens window for browsing file locations to save images

Selecting the Video Device or Camera

Follow the directions below to select the video device or camera used to capture images using the Flexible Scope Viewer Software.

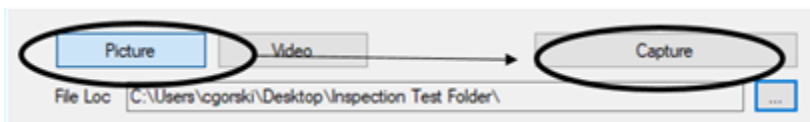
1. Click the 'Settings' Button in the lower left of the Flexible Inspection Scope Viewer Software to display video devices or cameras that are being detected by your computer. (FIGURE X)
2. Select a device for capturing images using the Flexible Inspection Scope Viewer.
 - a. The example below shows an Integrated Webcam and USB Video Device on the computer. Select the USB Video Device for the Flexible Inspection Scope.
3. Click 'OK' to view the selected Video Device.



Capturing Still Pictures

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

1. Select the 'Picture' Button on the software (FIGURE X).



2. Use any of the following options to capture an image:
 - a. Click 'Capture' on the Flexible Scope Viewer Software (FIGURE X above).

- b. Press the Handpiece Capture Image Button on the Flexible Inspection Scope.
- c. Press the space bar on your computer keyboard.

Note: When an image is captured, “**Picture Captured**” in red text will flash on the

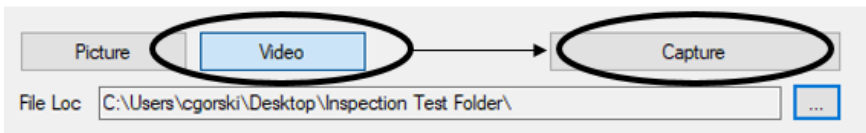
lower portion of the screen and a new file will appear in the Files Box (FIGURE X).



Capturing Video Images

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

1. Select the ‘Video’ Button on the software (FIGURE X).

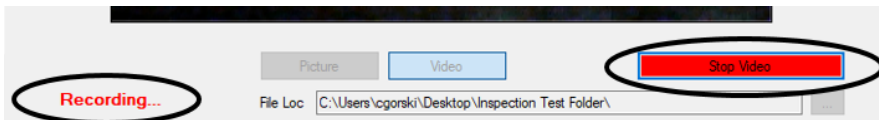


2. Use any of the following options to start and stop the video:
 - a. Click the ‘Capture’ Button on the Flexible Inspection Scope Viewer Software (FIGURE X above).
 - b. Press the Handpiece Capture Button on the Flexible Inspection Scope.
 - c. Press the space bar on your computer keyboard.
3. When the video is recording, “**Recording**” in red text (FIGURE X) will appear toward the bottom of the software window (FIGURE X).
4. To stop recording, use any method as described in Step 2 above for starting the video.

Note: The Image Capture Button will now read ‘Stop Video’ (FIGURE X) while recording.

5. Use any of the following options to start and stop the video:
 - d. Click the 'Capture' Button on the Flexible Inspection Scope Viewer Software (FIGURE X above).
 - e. Press the Handpiece Capture Button on the Flexible Inspection Scope Viewer Software.
 - f. Press the space bar on your computer keyboard.
6. When the video is recording, "**Recording**" in red text (FIGURE X) will appear toward the bottom of the software window (FIGURE X).
7. To stop recording, use any method as described in Step 2 above for starting the video.

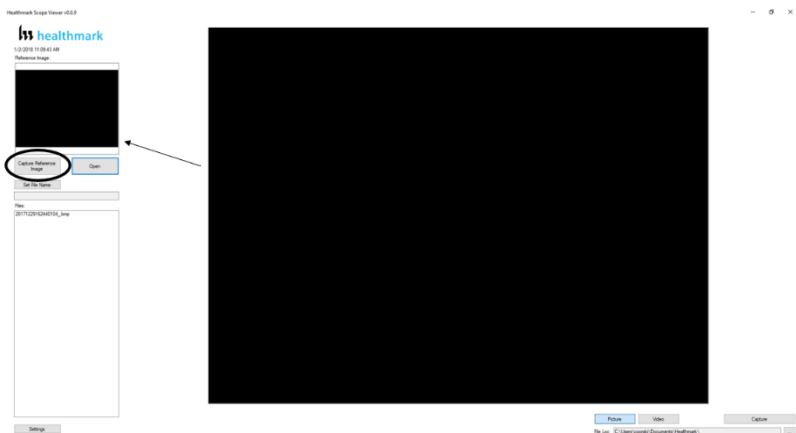
Note: The Image Capture Button will now read 'Stop Video' (FIGURE X) while recording.



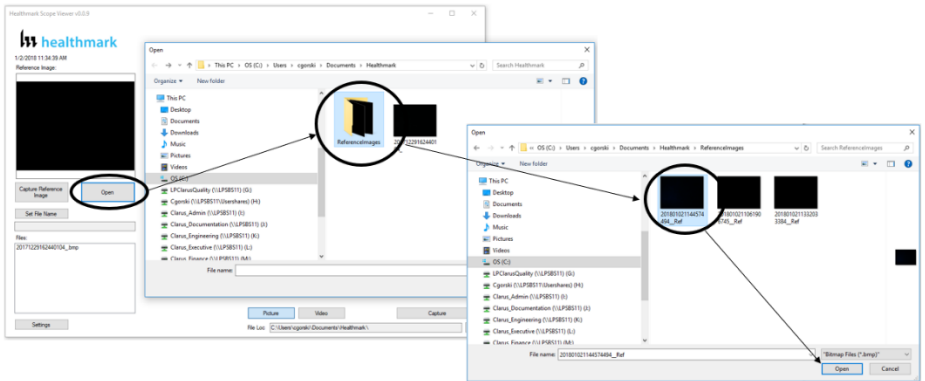
Displaying Reference Image

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

1. To display an image currently being displayed in the Main Image Window, click 'Capture Reference Image' Button (FIGURE X).
NOTE: The images will be saved in a file folder titled "Reference Images" in the designated File Loc.



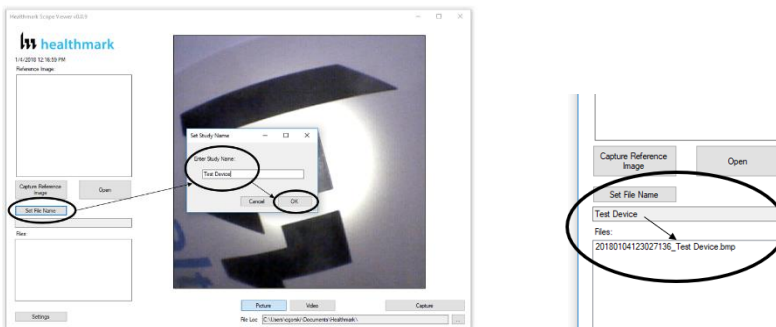
2. To display a saved image in the Reference Image Window from your File Loc:
 - a. Click the 'Open' Button (FIGURE X).
 - b. Click on the Reference Images Folder.
 - c. Select the file that you would like to display.
 - d. Click the 'Open' Button, to display the image in the Reference Image Window.



Setting File Name

Following the steps below allows you to create a file name that will appear after the underscore when capturing images using the Flexible Inspection Scope Viewer Software. (FIGURE X)

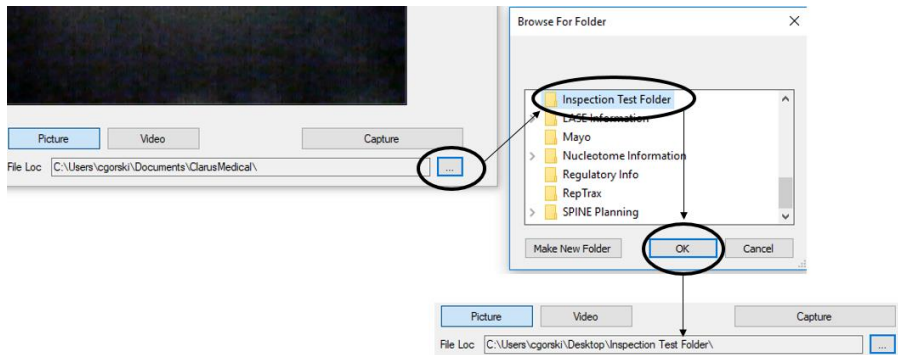
1. Click 'Set File Name' Button (FIGURE X).
2. Enter the characters that you would like to be included in file name.
3. Click the 'OK' Button to set as default name.



Setting Location for Saved Files

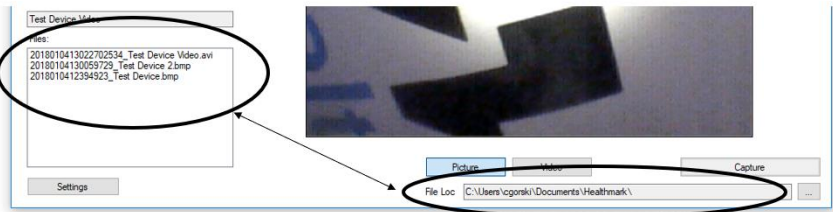
Following the steps below allows you to set the file location of saved images using the Flexible Inspection Scope Viewer Software.

1. Click the Ellipse Button (FIGURE X).
2. Select the file location where you would like to save captured images.
3. Click 'OK' to set the File Loc for saved files.



Deleting Saved Files

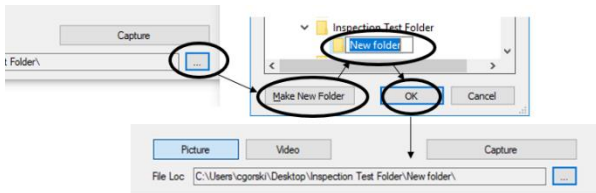
The Files Window (FIGURE X) in the Flexible Scope Viewer displays image files that are being stored in the File Loc (FIGURE X). To delete files, go the location (shown in the File Loc) on your computer, outside of the Flexible Scope Viewer software.



Creating New Folder Location for Saved Files (Move before deleting)

Following the steps below allows you to create a new file location for saved images using the Flexible Inspection Scope Viewer Software.

1. Click the Ellipse Button (FIGURE X).
2. Click the 'Make New Folder' Button.
3. Create a name for the new folder.
4. Click the 'OK' Button to create the new file in File Loc.



Performing Inspection

Following the steps listed below will ensure the proper use and best performance of the Flexible Inspection Scope. Follow these steps prior to inspection.

1. Secure the Flexible Inspection Scope into an arm fixture (optional).
2. Grasp the Flexible Inspection Scope near its distal end and gently insert the Flexible Working Length into the intended device as shown in FIGURE X.
3. Adjust light on the Flexible Inspection Scope with the plus (+) or minus (-) brightness button for ideal lighting.
4. Use short advancements while keeping your fingers close to the device's opening. View the monitor while inserting into the device. If an obstruction hinders the path of the Flexible Inspection Scope, gently attempt to manipulate or rotate the device to avoid the obstacle (FIGURE X).



FIGURE X: *Inserting the scope tip into device.*



FIGURE X



WARNING: The minimum bend radius of the Flexible Inspection Scope is 0.85" (21.6 mm). Do not bend the Flexible Inspection Scope into a sharper bend or damage to the device could occur.



WARNING: Do not apply excessive force to the Flexible Inspection Scope. If you feel resistance, or an obstruction hinders the path of the Flexible Inspection Scope, gently attempt to manipulate or rotate the device to avoid the obstacle. You may also slowly withdraw a short distance and try advancing again. Applying excessive force to the Flexible Inspection Scope past an obstacle could result in damage to the device.

5. Once the device has reached the end of the area you are inspecting, retract the scope slowly while looking for debris or damage.

Verifying Operation

Following the steps listed below will ensure the proper use and performance of the Flexible Inspection Scope. This is recommended to confirm the operation of the scope the scope's operation needs to be checked.



WARNING: The minimum bend radius of the Flexible Inspection Scope is 0.85in. Do not bend the Flexible Inspection Scope into a sharper bend or damage to the device could occur.

IMAGE

1. Open the Flexible Inspection Scope Viewer software on your computer. An image from the camera should appear on your computer monitor.
2. If the image does not appear true white when the camera is pointed at a white object (FIGURE X), direct the Distal Camera toward a solid white object such as a blank white sheet of paper. Press the White Balance (WB) Button on the Flexible Inspection Scope and release when the image on your monitor appears white.



Before



After

ILLUMINATION

1. The illumination capability of the Flexible Inspection Scope can be verified prior to use. Once the scope is connected to your computer with the power on, the distal tip of the Flexible Inspection Scope will cast visible light from its tip and can be observed on any surface to which it is directed
2. The Flexible Inspection Scope will default to the minimum light intensity setting when started. To adjust the lighting, press (in increments or hold) the Brightness Increase (+) Button or the Brightness Decrease (-) Button on the Digital Inspection Scope.

Instructions for Cleaning and Disinfecting or Sterilizing



WARNING: The Flexible Inspection Scope is provided non-sterile. Before initial use and after each use, the external surfaces of the Flexible Inspection Scope should be cleaned.

WARNING: Place the Soaking Cap on the Camera Connector prior to soaking or steaming the Flexible Inspection Scope. Repeated exposure to fluids will corrode the contacts of the Camera Connector.

PREPARATION FOR CLEANING THE FLEXIBLE INSPECTION SCOPE

The Flexible Inspection Scope has fluid ingress protection rating of IPX7 and can withstand immersion in fluid up to 1 meter for up to 30 minutes.

Do not soak the Flexible Inspection Scope without the Soaking Cap on the Camera Connector. Repeated exposure to fluids will corrode the contacts of the Camera Connector.

Note: The Flexible Inspection Scope Camera Cable is not waterproof and may be cleaned with wipes, such as CaviWipes™ or similar products. Do not soak Camera Cable.

To clean, disinfect, or sterilize the Flexible Inspection Scope follow CHART 1 below.

**CHART 1
Compatible Cleaning and Disinfecting or Sterilizing Methods for Flexible Inspection Scope**

Method	Flexible Inspection Scope
Enzymatic cleaning solutions	YES
Neutral pH soap and water	YES
Isopropyl alcohol wipes	YES
Glutaraldehyde solution	YES
OPA	YES
Ethylene Oxide Gas (EtO)	YES
STERIS SYSTEM 1E®	YES



WARNING: Cleaning does not disinfect or sterilize the Flexible Inspection Scope. Be sure to follow your institution’s specific cleaning and disinfecting or sterilizing procedures in consultation with this manual. The user is responsible to ensure that their procedures result in disinfection or sterilization, whichever is required.



WARNING: Use only cold soak disinfecting or sterilizing solutions that are approved for use with endoscopes and endoscopic accessories.



WARNING: Do not use caustic or harsh detergents to clean the Flexible Inspection Scope. The optical surfaces of the Flexible Inspection Scope will be damaged from exposure to aggressive cleaning agents.



WARNING: Do not reprocess the Flexible Inspection Scope using steam sterilization, or dry heat. Use of these processes will result in damage to the instrument, and void its warranty.
WARNING: The optics of the Flexible Inspection Scope will be damaged or degraded if left exposed to cleaning or disinfecting solutions for extended periods of time. Do not exceed the disinfectant solution manufacturer’s recommended exposure times for cleaning and disinfecting.



WARNING: Do not allow liquids to dry on the lens of the distal tip of the Flexible Inspection Scope. Dried residue is difficult to remove and will leave deposits that obscure the image of the Flexible Inspection Scope.



WARNING: Do not clean, disinfect, or sterilize the Flexible Inspection Scope or its accessories using an ultrasonic cleaner, washer sanitizer, washer pasteurizer, washer sterilizer, steam autoclave, or any method with a processing temperature above 60°C (140°F).

Compatible Cleaning Methods

Enzymatic Cleaning Solutions

Neutral pH soap and water

Isopropyl alcohol wipes

INSTRUCTIONS FOR CLEANING

1. Follow the cleaning agent manufacturer's instructions for use and precautions regarding health hazards, dispensing, measuring, and storage of cleaning agents.
2. Unplug and disconnect all components from the Flexible Inspection Scope prior to cleaning.
Note: The Flexible Inspection Scope Camera Cable is not waterproof and may be cleaned with wipes, such as CaviWipes™ or similar products.
3. **Secure the Soaking Cap on the Flexible Inspection Scope Camera Connector.**
4. Place the Flexible Inspection Scope in a bath of enzymatic detergent that has been prepared according to the manufacturer's instructions. Soak the device in detergent for the duration specified by the manufacturer.
5. Use clean cotton gauze pads that are saturated with the detergent solution to wipe down all surfaces of the Flexible Inspection Scope. Use soft brushes with the detergent solution to remove any residues from areas that cannot be reached with the gauze pads.
6. Rinse all components with copious amounts of cool (not cold) flowing utility (tap) water for 45 to 60 seconds.
7. Dry with a soft, lint-free cloth or sponge.



WARNING: Follow the disinfectant manufacturer's instructions for disinfecting.



WARNING: High level disinfecting does not result in terminal sterilization. Bacterial endospores may remain viable after high level disinfecting.

HIGH LEVEL DISINFECTING USING COLD SOAKING SOLUTIONS

1. Select only the disinfecting solutions listed above in the Compatible Disinfecting Methods section of this manual.
2. Follow all recommendations regarding health hazards, dispensing,

measuring and storage from the manufacturer of the cleaning and disinfecting agents.

3. Complete the previously described INSTRUCTIONS FOR CLEANING section of this manual before proceeding with high level disinfecting.
4. Secure the Soaking Cap on the Flexible Inspection Scope Camera Connector.
5. Soak the Flexible Inspection Scope in the selected disinfecting solution per the solution manufacturer’s instructions for high level disinfecting.
6. Rinse the Flexible Inspection Scope with critical (sterile) water, again following the instructions of the disinfecting solution manufacturer.
7. Dry with a sterile, soft, lint-free cloth or sponge. Ensure that the distal tip and proximal end of the Flexible Inspection Scope are dried. Air drying could leave deposits on these optical surfaces which could result in a degraded image.

Complete the previously described INSTRUCTIONS FOR CLEANING section of this manual before proceeding with sterilizing.

The Flexible Inspection Scope is compatible with STERIS SYSTEM 1E by STERIS Corporation. Follow the instructions provided with the STERIS equipment for sterilization processing.

Disposal of Waste Products

The Flexible Scope does not produce any waste materials.

Troubleshooting and Repair Service

Condition	Appearance	Cause	Correction
No Image	Main Image Window is black.	The Inspection Scope was not connected to computer when the software was opened.	Unplug USB Connection on Camera Cable and plug in again.
No Image	Main Image Window is black.	USB Video Device not selected, or without the scope connected.	If image does not appear, go 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.	Check the Camera Cable connections and make sure computer is powered on.
Low Light	No image or very dark image. Weak light pattern when scope pointed	Light Setting too low.	Press Increase (+) Brightness Button to increase light output.

	at surface.		
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.* (The user must judge when the Flexible Inspection Scope is no longer adequate for use, but as a guide, when 10% of the image or illumination has been degraded or lost it is recommended that a replacement be acquired).
No image or distorted image	No image or heavily distorted, cracked appearance.	Broken image sensor and/or internal cables.	Replace Flexible Inspection Scope.*
Overly bright image	White-out type reflection.	Light Intensity is too bright.	Press Decrease (-) Brightness Button to decrease light output
Blurry Image or overly bright image	Distorted image. Light often reflects back and image appears brightly colored.	Debris or film on lens.	Wipe off end of Flexible Inspection Scope with soft cloth.
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 name does not exist.	Set up a new Windows File Loc folder.
Rapidly takes pictures automatically	'Picture Captured' keeps flashing and Image files are created rapidly.	PC's internal camera is selected as the video device in Settings.	Disable the PC's internal camera (see Advanced Settings below).

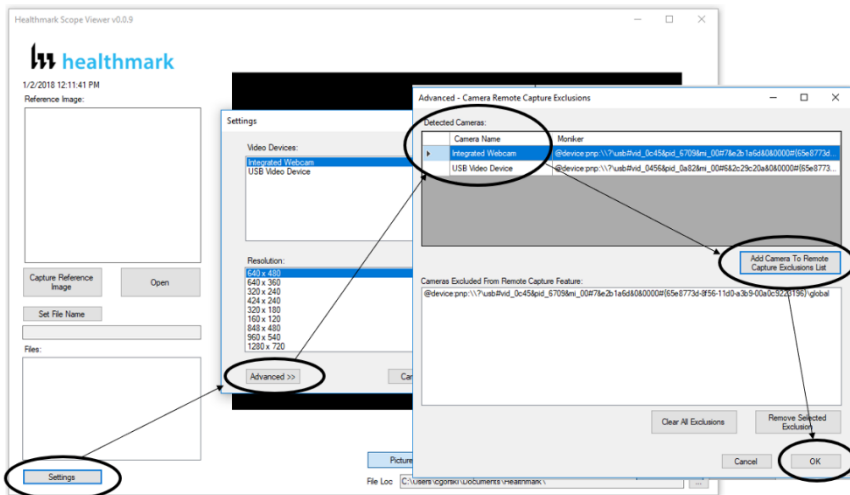
* Please contact Healthmark Industries for a Return Materials Authorization to have the scope evaluated.

Advanced Settings

Disabling Other Video Devices

Follow the instructions below to disable video devices or cameras from capturing images when using the Flexible Inspection Scope Viewer.

1. Click the 'Settings' Button to show the video devices or cameras that are being detected by your computer. (FIGURE X)
2. Click the 'Advanced' Button to bring up the "Advanced – Camera Remote Capture Exclusions" tab.
3. In the section under Detected Cameras, select the device you would like to disable for use with the Flexible Inspection Scope Viewer. In the example below, the Integrated Webcam is selected.
4. Click 'Add Camera to Remote Capture Exclusions List' to disable the selected device.
5. Click 'OK'.



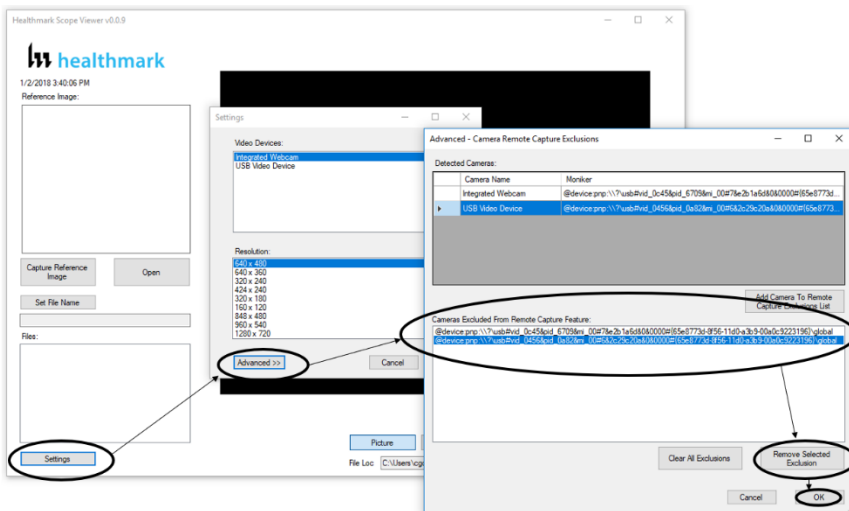
Enabling Other Video Devices

Follow the following instructions to enable devices that are disabled.

1. Click the 'Settings' Button to show the video devices or cameras that are being detected by your computer. (FIGURE X)
2. Click the 'Advanced' Button to bring up the "Advanced – Camera Remote Capture Exclusions" tab.
3. There are two ways to enable devices being detected by your computer,
 - a. Click the 'Clear All Exclusions' Button to enable all devices being detected by your computer, or



- b. select a single device in the “Cameras Excluded from Remote Capture Feature” then click ‘Remove Selected Exclusion to enable the selected video device or camera.
4. Click ‘OK’.



Warranty

The Flexible Inspection Scope is warranted, when new, to be free of defects in material and workmanship and to perform in accordance with the manufacturer’s specifications when subject to normal use service for a period of 1 year from the date of purchase. Healthmark Industries, at its option, will either repair or replace any components found to be defective or at variance from manufacturer’s specifications within this time at no cost to the purchaser. It shall be the purchaser’s responsibility to return the device directly to Healthmark Industries after receiving a Returned Material Authorization Number from Healthmark Industries Customer Service Department. Prior to returning the device, it shall be the purchaser’s responsibility to clean and disinfect the device and to package it in a manner that minimizes the possibility of shipping damage.

EXCEPT TO THE EXTENT PROVIDED ABOVE, HEALTHMARK INDUSTRIES MAKES NO REPRESENTATION OR WARRANTY TO THE PURCHASER OR TO ANY THIRD PARTY, WHETHER WRITTEN, ORAL, STATUTORY, EXPRESS OR IMPLIED, CONCERNING THE DEVICE, INCLUDING BUT NOT LIMITED TO ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO



EVENT SHALL HEALTHMARK BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER FOR BREACH OF ANY WARRANTY, FOR BREACH OR REPUDIATION OF ANY OTHER TERM OR CONDITION OF SALE, OR FOR LIABILITY ON THE BASIS OF NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, EVEN IF HEALTHMARK SHALL HAVE BEEN ADVISED IN ADVANCE OF THE LIKELIHOOD THEREOF.

REPAIR OR REPLACEMENT OF THE DEVICE AS PROVIDED ABOVE SHALL BE THE SOLE AND EXCLUSIVE REMEDY FOR ANY BREACH OF THE WARRANTY GIVEN ABOVE.

Specifications

Power Source

Electrical Power for the Flexible Inspection Scope is supplied by a USB port on a computer.

Illumination Source

LED within the Flexible Inspection Scope Handpiece

Physical Properties

Size

	Flexible Inspection Scope, Model FIS-005
Working Length	110 cm (43.3")
Scope Diameter (Distal Camera)	1.9 mm (0.075")
Flexible Inspection Scope Diameter	31.8 mm (1.25")
Overall Length of Flexible Inspection Scope	45 cm (17.7")

Weight

Flexible Inspection Scope: 18.2 grams (0.64oz)

Optical

Field of View 120° in air

Angle of View 0°

Connectors

USB Type A Male Connector

Accessories Included

Camera Cable

USB Flash Drive

Soaking Cap



Environmental Conditions

Storage and transport

Humidity: 10 to 100% (condensing)
Temperature: -20°C to +60°C
Pressure: 600 hPA to 900 hPA

Normal Operation

Humidity: 0-100% (condensing)
Temperature: +5°C to +40°C

Waterproof Rating

IPX7

Manufacturer

Healthmark Industries
33671 Doreka
Fraser, MI 48045
www.hmark.com
healthmark@hmark.com
Tel 800.521.6224



MPS Medical Product Services
Borngasse 20
35619 Braunfels, Germany





healthmark
INDUSTRIES CO.
health care products

800-521-6224
www.hmark.com

Instructions for Use: Flexible Inspection Scope Kit

Brand Name of Product	Flexible Inspection Scope Kit
Generic Name of Product	Flexible Inspection Scope Kit
Product Code Number(s)	FIS-005, FIS-005SK
Intended Use	For visually inspecting instruments.
Range of Applications for Product	Instruments that require visual inspection by providing light, vision, magnification and the option for documentation in hard-to-see crevices, channels and lumens in instruments that are not visible to the unaided eye.
Key Specifications of Product	<p>Flexible Inspection Scope Features and Connections- FIS-005</p> <ul style="list-style-type: none">● Overall length of Digital Inspection Scope- 128cm (50.4”).● Weight- 18.2 grams (0.64oz.)● Optical<ul style="list-style-type: none">○ Field of View- 120° in air○ Angle of View- 0°● Distal Camera 1.9 mm (0.075”)- Distal portion of the Inspection Scope that contains the camera lens.● Flexible Working Length 110cm (43.3”)- The portion of the scope that is inserted into an instrument during visual inspection.● Brightness increase button and decrease button- To increase illumination and decrease illumination intensity.● Handpiece Capture Image Button- Press button to capture video or image.● White Balance Button- Press to white balance the image.● Camera Cable Connection- Connects the Controller Handpiece to USB on computer. <p>Flexible Inspection Scope Accessories- FIS-005SK</p> <ul style="list-style-type: none">● USB (Type-A Male) Connector- Plugs into USB port on computer.● Camera Connector- Plugs into Digital Inspection Scope.● USB Flash Drive- Plugs into USB Port on computer for downloading software and instruction for use.● Soaking Cap.

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions	
Packaging Conditions	
Shelf Life	

Instructions for Using Product	
Description of Use(s)	Use the inspection scope to directly inspect internal channels.
Preparation for Use	<p>Before connecting the Flexible Inspection Scope, install the Healthmark software from the USB Flash drive on a computer. System requirements: MS Windows versions 7, 8 or 10.</p> <ol style="list-style-type: none"> 1. Remove the USB stick and plug into USB port. 2. Window will pop up on the computer stating, 'Install software'. (If it does not come up, go to launch files explorer, scroll down and click USB Disk).  <ol style="list-style-type: none"> 3. Under 'General Options' click on 'Open folder to view files'.  <ol style="list-style-type: none"> 4. Double click Healthmark_Viewer_Setup to install software.



5. The Healthmark Scope Viewer Software screen comes up and click 'Next>'.



6. Welcome to the Healthmark Scope Viewer Software Setup Wizard screen appears and click 'Next>'.



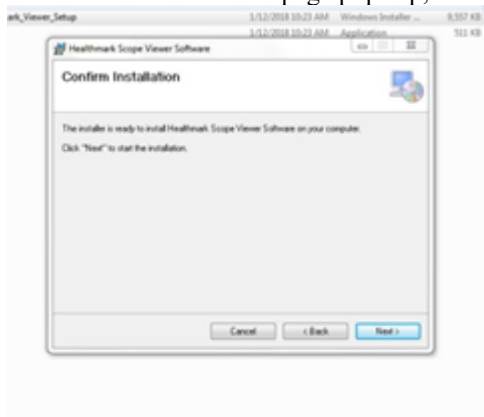
7. The License Agreement page comes up and click 'I Agree' in License Agreement.



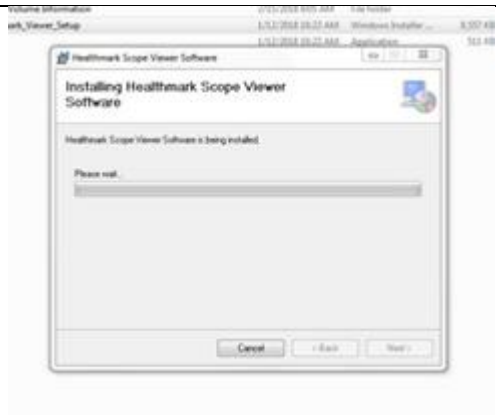
8. Then click 'Next>'.



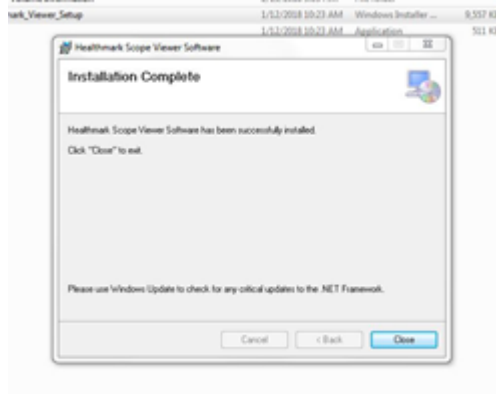
9. The Confirm Installation page pops up, click 'Next>'.



10. Installing Healthmark Scope Viewer Software is being installed.



11. Installation Complete Screen comes up and click 'Close'.



12. Once the installation is complete, remove the USB.



13. Then take the round cable connector and plug into the top of the Flexible Inspection Scope.



14. Plug in the USB Connector to the USB port in your computer.



VERIFYING OPERATION

IMAGE-

1. Open the Healthmark Viewer Software on the computer. An image from the camera should appear on the computer monitor.



2. If the image does not appear true white when the camera is pointed at a white object, direct the Distal Camera toward a solid white object such as a blank white sheet of paper. Press the White Balance (WB) Button on the Digital Inspection Scope and release when the image on your monitor appears white.



Before



After

ILLUMINATION

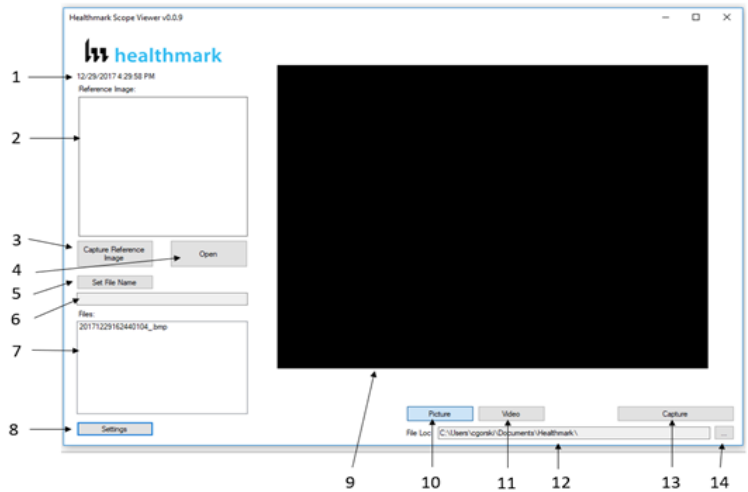
1. The illumination capability of the Flexible Inspection Scope can be verified prior to use. Once the scope is connected to the computer with the power on, the distal tip of the Flexible Inspection Scope will cast visible light from its tip and can be observed on any surface to which it is directed. The Flexible Inspection Scope will default to the minimum light intensity setting when started. To adjust the lighting, press (in increments or hold) the Brightness Increase (+) Button or Brightness Decrease (-) Button on the Flexible Inspection Scope.



Healthmark Viewer Software Fig. 1

1. Date and Time Display
2. Reference Image Window- Displays a Reference Image.
3. Capture Reference Image Button- Captures still image being displayed in the Main Image Window.
4. Open Button- Opens the file location (File Loc) where images are being saved and allows you to select image that is displayed in Reference Image Window.
5. Set File Name Button- Click to identify a default name that will be included with the file name when capturing images.
6. File Name Box- Text box creating a File Name.
7. Files Box- Displays captured images that are routed and stored in the area being shown in File Loc.
8. Settings Button- Click to select the video camera and resolution settings.
9. Main Image Window- Displays the image from the camera.
10. Picture Button- Click to select the picture option when capturing still images.
11. Video Button- Click to select the video option when capturing video images.
12. File Loc Button- Location where captured images are being saved.
13. Capture Button- Option to click for capturing images. Also used to start/stop video images.
14. Ellipse Button- Opens window for browsing file locations to save images.

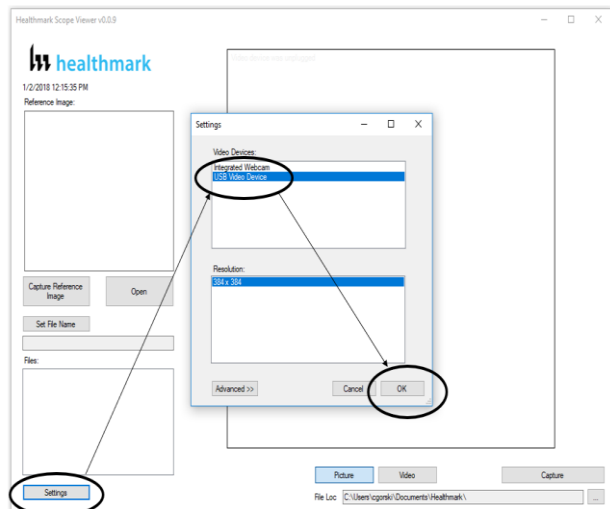
Figure 1



Selecting the Video Device or Camera Fig. 2

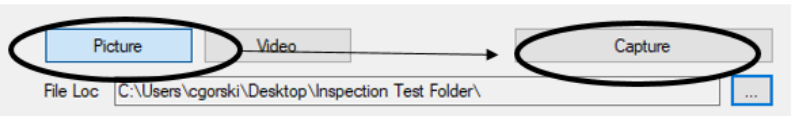
1. Click the 'Settings' Button in the lower left of the Healthmark Scope Viewer Software to display video devices or cameras that are being detected by your computer.
2. Select a device for capturing images using the Healthmark Scope Viewer.
 - A. The example below shows an Integrated Webcam and USB Video Device on the computer. Select the USB Video Device for the Flexible Inspection Scope.
3. Click 'OK' to view the selected Video Device.

Figure 2



Capturing Still Pictures

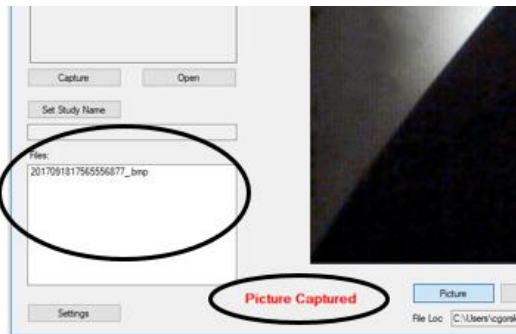
1. Select the 'Picture' Button on the software. **Fig. 3**



2. Use any of the following options to capture an image:
 - A. Click 'Capture' on the Healthmark Viewer Software. **Fig. 3**
 - B. Press the Handpiece Capture Image Button on the Flexible Inspection Scope.
 - C. Press the spacebar on your computer keyboard.

NOTE: When an image is captured, "Picture Captured" in red text will flash on the lower portion of the screen and a new file will appear in the Files Box. **Fig. 4**

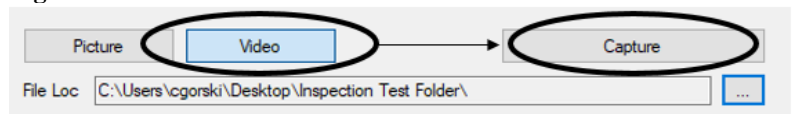
Figure 4



Capturing Video Images

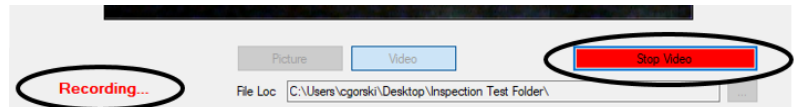
1. Select the 'Video' Button on the Software. **Fig. 5**

Figure 5



2. Use any of the following options to start and stop the video:
 - A. Click the 'Capture' Button on the Healthmark Viewer Software. **Fig. 5**
 - B. Press the Handpiece Capture Button on the Flexible Inspection Scope.
 - C. Press the spacebar on the computer keyboard.
3. When the video is recording, "Recording" in red text will appear toward the bottom of the software window. **Fig. 6**
4. To stop recording, use any method as described in Step 2 above for starting the video. **NOTE:** The Image Capture Button will now read 'Stop Video' while recording. **Fig. 6**

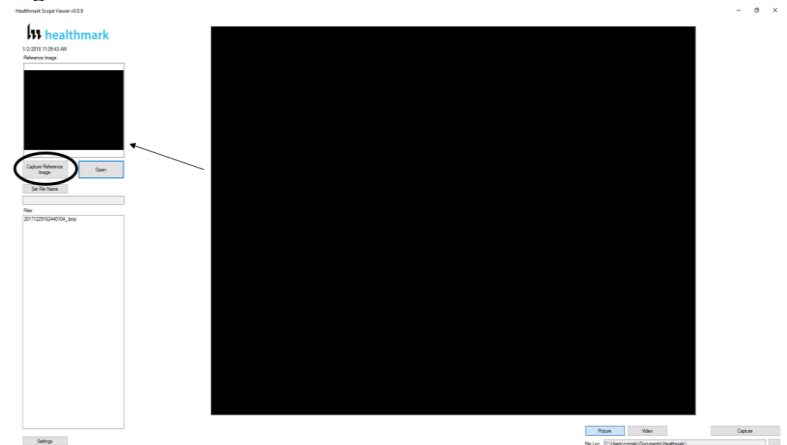
Figure 6



Displaying Reference Image

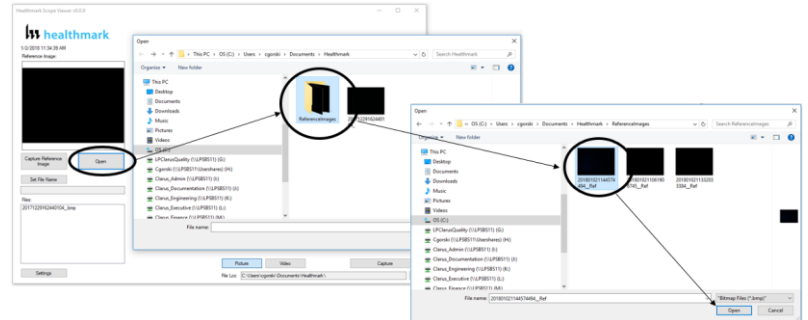
1. To display an image currently being displayed in the Main Image Window, click 'Capture Reference Image' Button. **NOTE:** The images will be saved in a file folder titled "Reference Images" in the designated File Loc. **Fig. 7**

Figure 7



2. To display a saved image in the Reference Image Window from you File Loc:
 - A. Click the 'Open' Button. **Fig. 8**
 - B. Click on the Reference Images Folder.
 - C. Select the file that you would like to display.
 - D. Click the 'Open' Button, to display the image in the Reference Image Window.

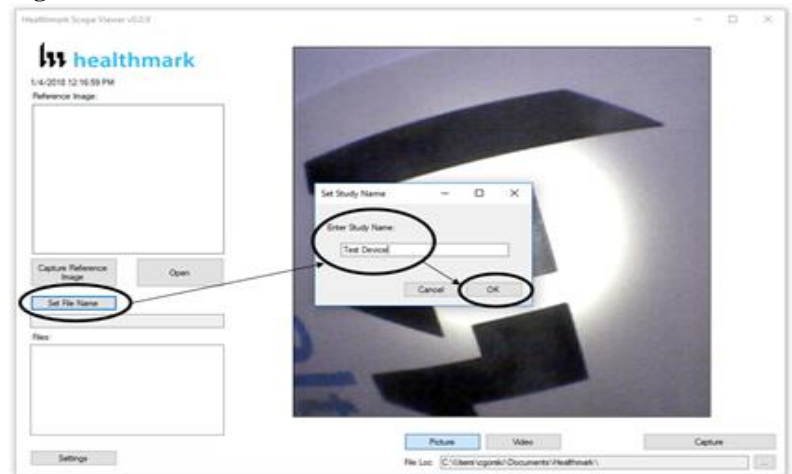
Figure 8



Setting File Name

1. Click 'Set File Name' Button. **Fig. 9**
2. Enter the characters that you would like to be included in file name. **Fig. 9A**
3. Click the 'OK' Button to set as default name.

Figure 9



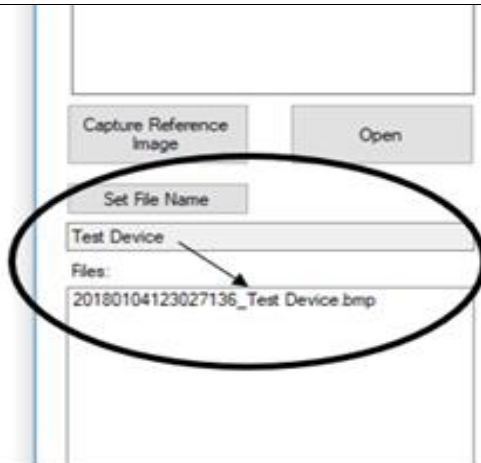
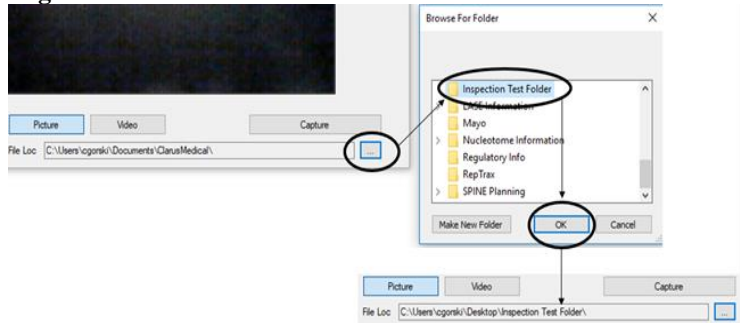


Figure 9A

Setting Location for Saved Files

1. Click the Ellipse Button. **Fig. 10**
2. Select the file location where you would like to save captured images.
3. Click 'OK' to set the File Loc for saved files.

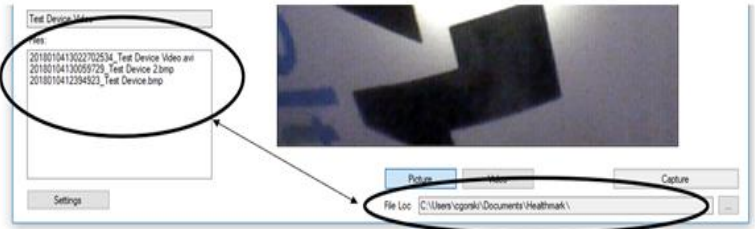
Figure 10



Deleting Saved Files

The Files Window **Fig. 11** in the Healthmark Viewer displays image files that are being stored in the File Loc **Fig. 11**. To delete files, go to the location (shown in the File Loc) on the computer, outside of the Healthmark Viewer Software.

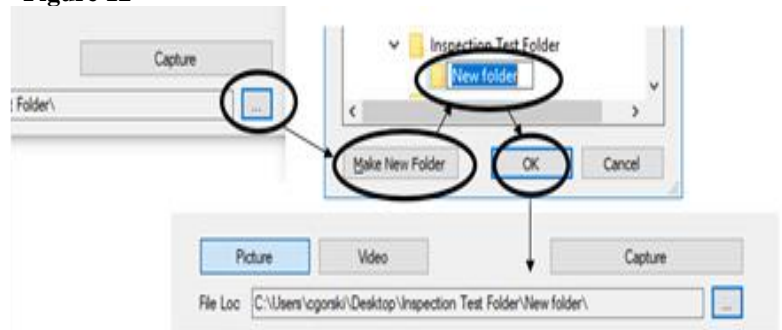
Figure 11



Creating New Folder Location for Saved Files (Move before Deleting)

1. Click the Ellipse Button. **Fig. 12**
2. Click the 'Make New Folder' Button.
3. Create a name for the new folder.
4. Click the 'OK' Button to create the new file in File Loc.

Figure 12



**Diagrams
(drawings,
pictures)**



Figure 1



Figure 2

**Steps for Use of
Product**

PERFORMING INSPECTION

1. Secure the Flexible Inspection Scope into an arm fixture (optional).
2. Grasp the Flexible Inspection Scope near its distal end and gently insert the Flexible Working Length into the intended instrument. **Fig. 1**

	<ol style="list-style-type: none"> 3. Adjust light on the Flexible Inspection Scope with the plus (+) or minus (-) brightness button for ideal lighting. 4. Use short advancements while keeping your fingers close to the instrument's opening. View the monitor while inserting into the device. If an obstruction hinders the path of the Flexible Inspection Scope, gently attempt to manipulate or rotate the device to avoid the obstacle. Fig. 2 5. Once the Distal End of the scope has reached the end of the area that is being inspected, retract the scope slowly while looking for debris or damage.
Documentation	
Special Warnings and Cautions	<ul style="list-style-type: none"> ● Do not attempt to use the Flexible Inspection Scope if it appears to be damaged. ● The Flexible Inspection Scope is NOT STERILE. Follow the instruction for cleaning, disinfecting and sterilizing provided in this document. ● Do not autoclave or dry heat the Flexible Inspection Scope. ● Avoid looking directly at the light emitted from the distal end when the scope is powered on. ● Do not bend device beyond a 0.85" (21.6mm) radius; this may cause damage to the device. ● Do not apply excessive force to the Flexible Inspection Scope. If there is resistance, or an obstruction hinders the path of the scope, gently attempt to manipulate or rotate the device to avoid the obstacle. Also, slowly withdraw a short distance and try advancing again. ● Applying excessive force to the scope past an obstacle can result in damage to the device. ● Avoid rubbing against sharp edges, as this can also damage the device. ● Do not clean, disinfect, or sterilize the Flexible Inspection Scope or its accessories using an ultrasonic cleaner, washer sanitizer, washer pasteurizer, washer sterilizer, steam autoclave, or any method with a processing temperature above 60°C (140°F).
Disposal	

Reprocessing Instructions	
Point of Use	
Preparation for Decontamination	
Disassembly Instructions	Disconnect the Camera Cable from the Flexible Inspection Scope prior to cleaning.
Cleaning – Manual	<p>Cleaning Between Uses:</p> <ul style="list-style-type: none"> ● Use pre-moistened cleaning wipe. See Chemical Compatibility Chart for approved cleaning agents click here. ● Follow the wipe manufacturer's IFU. <p>NOTE: The soaking cap forms a waterproof seal to protect the proximal connection (pins) on the Camera</p>

	<p>Cable Connection of “handle” for sterilant(s) and/or disinfectants. The soaking cap is intended to protect the pins on the camera cable connection (proximal end of the handle) from exposure to liquids. The presence of water on the connector after processing is normal. The connector may be dried with compressed air. Repeated exposure to fluids will corrode the contacts of the Camera Connector.</p> <p>For Thorough Cleaning: Follow the cleaning agent manufacturer’s instructions for use.</p> <ol style="list-style-type: none"> 1. Unplug and disconnect all components from the Digital Inspection Scope prior to cleaning. 2. Secure the Soaking Cap on the Flexible Inspection Scope Camera Connector. 3. Place the scope in a bath of enzymatic detergent and soak the device for the duration specified by the manufacturer (in fluid up to 1 meter for up to 30 Minutes). 4. Wipe thoroughly with a 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. 5. Rinse with low linting wipe moistened with AAMI Utility Water for 45 to 60 seconds, dry with low linting wipe. <p>Reprocessing Chemical Compatibility Chart click here:</p>
Cleaning – Automated	
Disinfection	<ul style="list-style-type: none"> ● Select only the disinfecting solutions listed in the Chemical Compatibility Chart. ● Follow the disinfection manufacturer’s instructions for use. ● Complete the steps described in the above Cleaning section. ● Secure the Soaking cap on the Flexible Inspection Scope Camera Connector. ● Soak the Flexible Inspection Scope with critical (sterile) water, again following the instructions of the disinfecting solution manufacturer. ● Dry with a sterile, non-linting wipe. Ensure that the distal tip and proximal end of the Flexible Inspection Scope are dried. Air drying could leave deposits on these

	<p>surfaces which could result in a degraded image.</p> <p>Reprocessing Chemical Compatibility Chart click here:</p>
Drying	
Maintenance, Inspection, and Testing	<ul style="list-style-type: none"> Inspect the Flexible Inspection Scope for signs of wear or damage. No serviceable parts within the Flexible Inspection Scope. No user maintenance beyond cleaning is required. Refer all service or replacement needs to the manufacturer. Inspect the external surfaces of the Flexible Inspection Scope and any accessories to assure they are smooth and free of any protrusions or sharp edges.
Reassembly Instructions	
Packaging	
Sterilization	<p>The FIS-005 does not require terminal sterilization. It is compatible with low-temperature sterilization modalities. See the Reprocessing Compatibility Chart click here:</p>
Storage	<ul style="list-style-type: none"> Store the instrument no higher than 60°C or lower than -20°C. Store the equipment in a clean, dry and ventilated location.
Additional Information	<ul style="list-style-type: none"> If upon inspecting an item it is determined not to be clean, reprocess according to the manufacturer's instruction for use. 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	<p>Video Inspection Scope with Display, optical inspection products.</p>
Other Product Support Documents	<p>ProSys™ Brochure, ProSys™ Price List</p>
Reference Documents	
Customer Service Contact	<p>Healthmark Industries Company, Inc 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com</p>






Instructions for Use: Flexible Inspection Scope Kit

Brand Name of Product	Flexible Inspection Scope Kit
Generic Name of Product	Flexible Inspection Scope Kit
Product Code Number(s)	FIS-005, FIS-005SK
Intended Use	For visually inspecting instruments.
Range of Applications for Product	Instruments that require visual inspection by providing light, vision, magnification and the option for documentation in hard-to-see crevices, channels and lumens in instruments that are not visible to the unaided eye.
Key Specifications of Product	<p>Flexible Inspection Scope Features and Connections- FIS-005</p> <ul style="list-style-type: none">● Overall length of Digital Inspection Scope- 128cm (50.4”).● Weight- 18.2 grams (0.64oz.)● Optical<ul style="list-style-type: none">○ Field of View- 120° in air○ Angle of View- 0°● Distal Camera 1.9 mm (0.075”)- Distal portion of the Inspection Scope that contains the camera lens.● Flexible Working Length 110cm (43.3”)- The portion of the scope that is inserted into an instrument during visual inspection.● Brightness increase button and decrease button- To increase illumination and decrease illumination intensity.● Handpiece Capture Image Button- Press button to capture video or image.● White Balance Button- Press to white balance the image.● Camera Cable Connection- Connects the Controller Handpiece to USB on computer. <p>Flexible Inspection Scope Accessories- FIS-005SK</p> <ul style="list-style-type: none">● USB (Type-A Male) Connector- Plugs into USB port on computer.● Camera Connector- Plugs into Digital Inspection Scope.● USB Flash Drive- Plugs into USB Port on computer for downloading software and instruction for use.● Soaking Cap.

	<p>Flexible Inspection Scope Software- Requirements</p> <ul style="list-style-type: none"> • Compatible with Operating systems of Windows 10 or above only.
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Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions	
Packaging Contents	
Shelf Life	

Instructions for Using Product	
Description of Use (s)	Use the inspection scope to directly inspect internal channels.
Preparation for Use	<ul style="list-style-type: none"> • Remove the USB stick and plug into USB port.  <ol style="list-style-type: none"> 1. Then take the round cable connector and plug into the top of the Flexible Inspection Scope.  

2. Plug in the USB Connector to the USB port in your computer.



STARTING SOFTWARE

1. Open the folder Healthmark Scope Viewer from your PC.
2. Once the folder is open, click on hmarkscopeviewer.exe file. **Fig. 3**

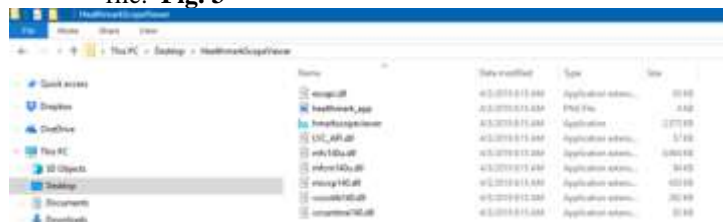


Figure 3

3. When you click on the .exe file, for the first time you will see a dialog box for codec installation.
4. Automatically codec pack is installed. This is essential for properly running the software. 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 codec pack.
5. After this, The Healthmark scope viewer software dialog box opens up. Now you can start using the scope.

USING SOFTWARE

Healthmark Viewer Software Fig. 4

1. Date and Time Display
2. Reference Image Window- Displays a Reference Image.
3. Capture Reference Image Button- Captures still image being displayed in the Main Image Window.
4. Open Button- Opens the file location (File Loc) where images are being saved and allows you to select image that is displayed in Reference Image Window.
5. Set File Name Button- Click to identify a default name that will be included with the file name when capturing images.

6. File Name Box- Text box creating a File Name.
7. Files Box- Displays captured images that are routed and stored in the area being shown in File Loc.

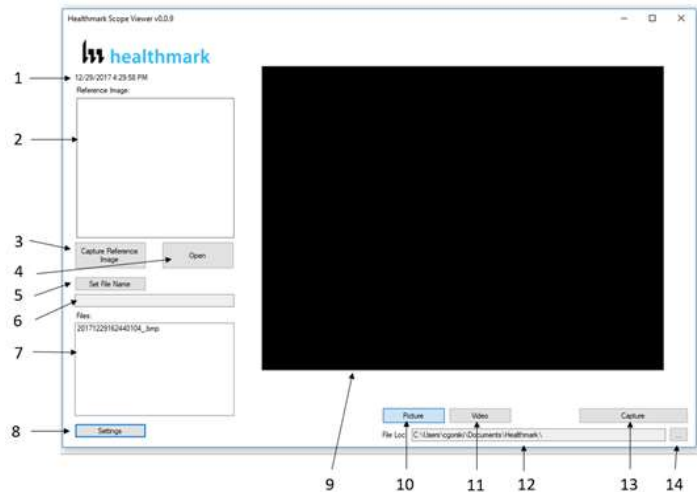


Figure 4

Selecting the Video Device or Camera Fig. 5

1. Click the 'Settings' Button in the lower left of the Healthmark Scope Viewer Software to display video devices or cameras that are being detected by your computer.
2. Select a device for capturing images using the Healthmark Scope Viewer.
 - A. Select the USB Camera for the Flexible Inspection Scope.
3. Click 'OK' to view the selected Video Device.

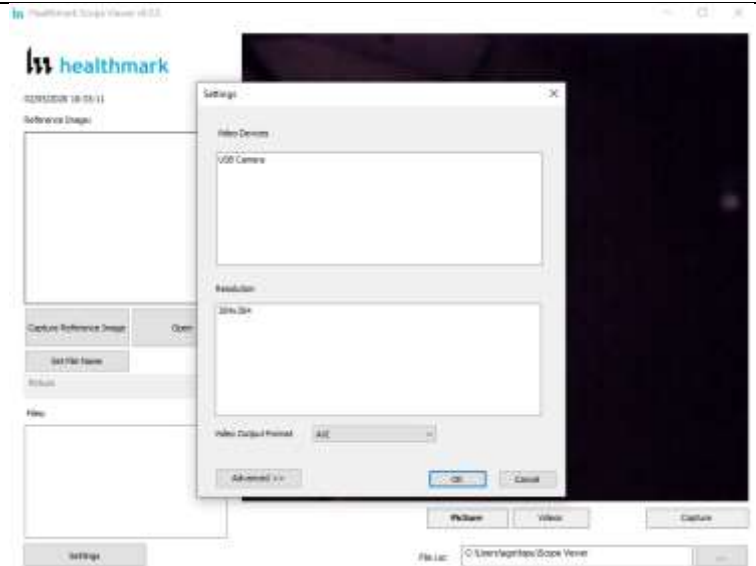


Figure 5

Changing the Video Output Format Fig. 6

1. Select from the down arrow to change which format to be saved as.

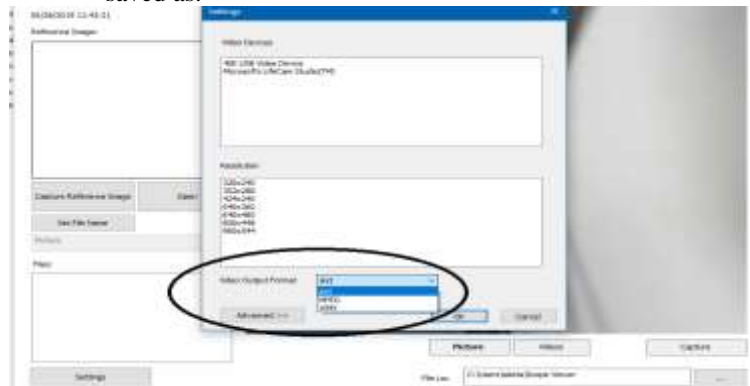


Figure 6

Capturing Still Pictures

1. Select the 'Picture' Button on the software. **Fig. 7**

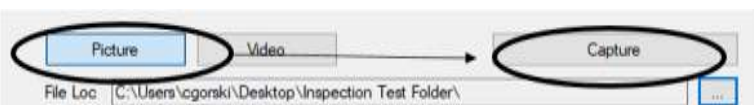


Figure 7

2. Use any of the following options to capture an image:
 - A. Click 'Capture' on the Healthmark Viewer Software. **Fig. 7**

B. Press the Handpiece Capture Image Button on the Flexible Inspection Scope.

C. Press the spacebar on your computer keyboard.

NOTE: When an image is captured, “Picture Captured” in red text will flash on the lower portion of the screen and a new file will appear in the Files Box. **Fig. 8**

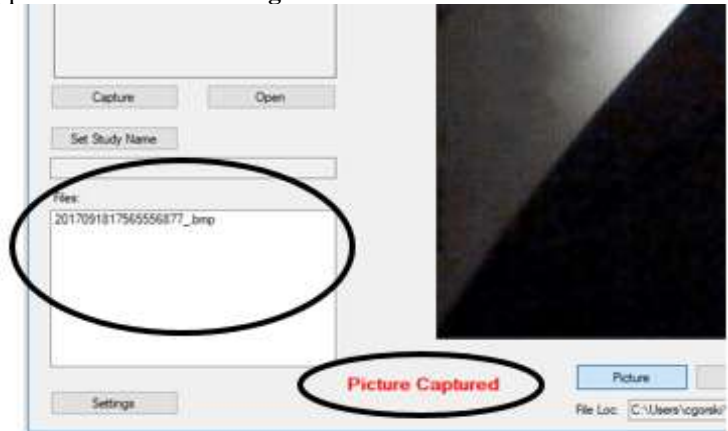


Figure 8

Capturing Video Images

1. Select the ‘Video’ Button on the Software. **Fig. 9**



Figure 9

2. Use any of the following options to start and stop the video:

A. Click the ‘Capture’ Button on the Healthmark Viewer Software. **Fig. 9**

B. Press the Handpiece Capture Button on the Flexible Inspection Scope.

C. Press the spacebar on the computer keyboard.

3. When the video is recording, “Recording” in red text will appear toward the bottom of the software window. **Fig. 10**

4. To stop recording, use any method as described in Step 2 above for starting the video. **NOTE:** The Image Capture Button will now read ‘Stop Video’ while recording. **Fig. 10**



Figure10

Displaying Reference Image

1. To display an image currently being displayed in the Main Image Window, click 'Capture Reference Image' Button.
NOTE: The images will be saved in a file folder titled "Reference Images" in the designated File Loc. **Fig. 11**



Figure 11

2. To display a saved image in the Reference Image Window from you File Loc:
 - A. Click the 'Open' Button. **Fig. 12**
 - B. Click on the Reference Images Folder.
 - C. Select the file that you would like to display.
 - D. Click the 'Open' Button, to display the image in the Reference Image Window.



Figure 12

Setting File Name

1. Click 'Set File Name' Button. **Fig. 13**
2. Enter the characters that you would like to be included in file name. **Fig. 13A**
3. Click the 'OK' Button to set as default name.

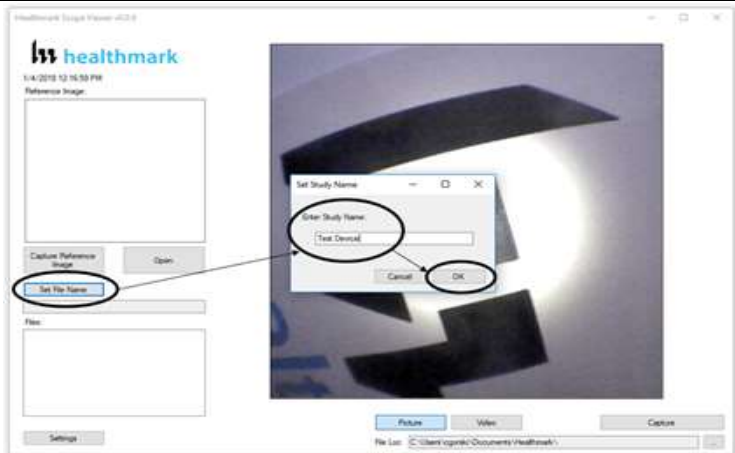


Figure 13

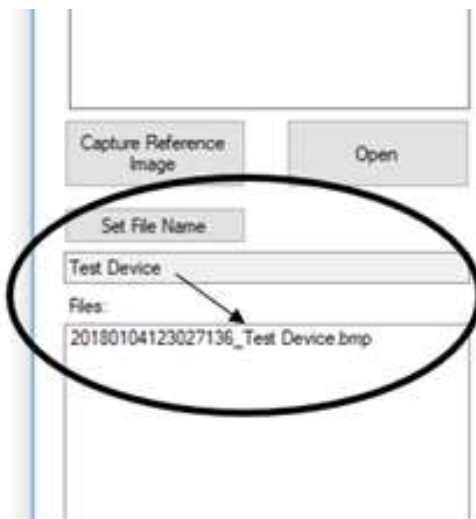


Figure 13A

Deleting Saved Files

The Files Window **Fig. 14** in the Healthmark Viewer displays image files that are being stored in the File Loc **Fig. 15**. To delete files, go to the location (shown in the File Loc) on the computer, outside of the Healthmark Viewer Software.



Figure 14

Location of Saved Files

1. By Default, images and videos get saved in the 'Scope Viewer' folder.
2. Reference images get save in the 'Reference Images' folder.
3. This rests in C:\Users\username\Scope Viewer.

Changing the folder location for Saved Files

1. Click the ellipse button. **Fig. 15**
2. Select the folder where you want to save the images. **Fig. 16**
3. Click on 'Select Folder'. **Fig.17**



Figure 15

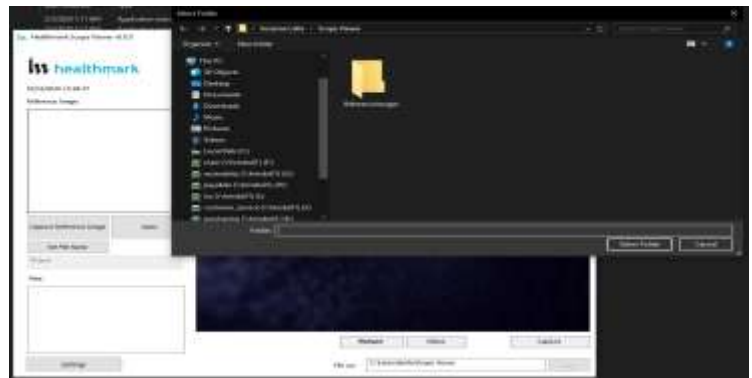


Figure 16

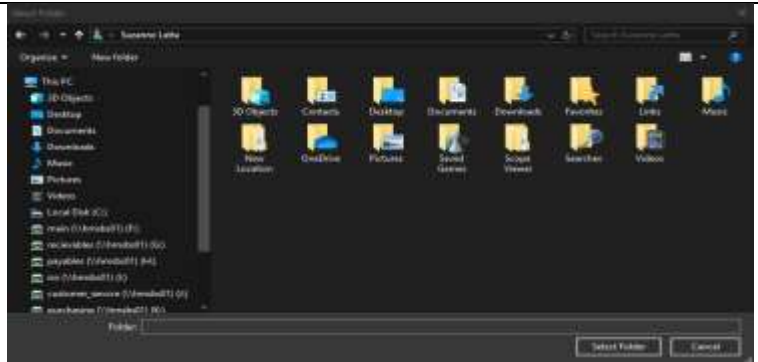


Figure 17

DISCONNECTING THE SCOPE

Instructions-

1. Always close the software and then disconnect the scope.
2. If you try to disconnect the scope while the software is open, the software screen freezes. **Fig. 18**

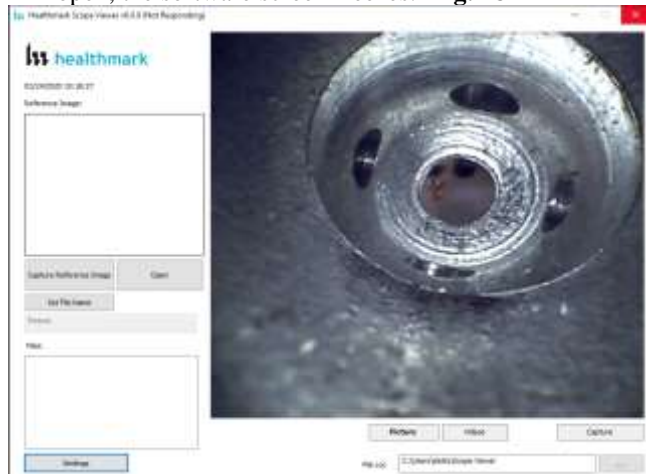


Figure 18

3. In such a situation when the screen freezes, you can open Task Manager from your computer and click on 'Flexible Inspection Scope Software' and forcefully end task by clicking on 'End Task'. **Fig. 19, Fig. 20**

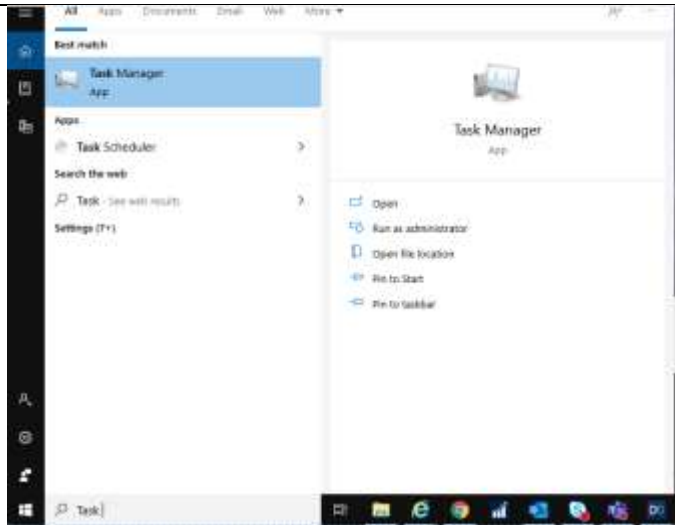


Figure 19

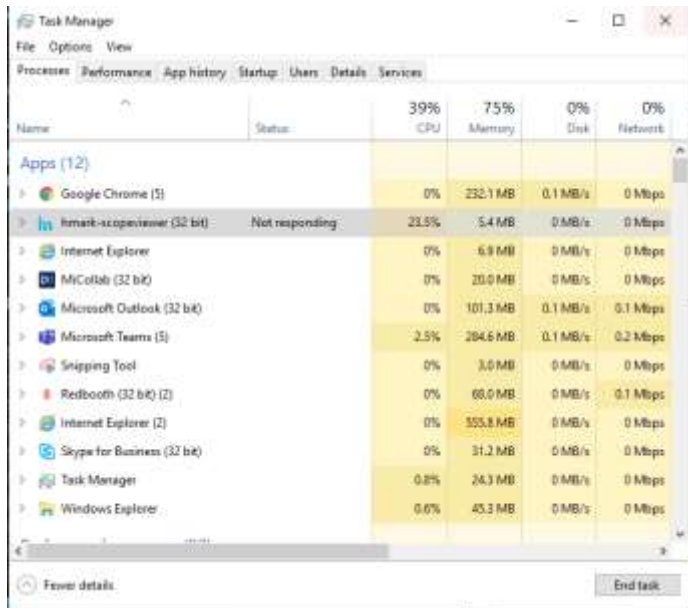


Figure 20

VERIFYING OPERATION

IMAGE-

1. If the image does not appear true white when the camera is pointed at a white object, direct the Distal Camera toward a solid white object such as a blank white sheet of paper. Press the White Balance (WB) Button on the Flexible Inspection Scope and release when the image on your monitor appears white.



ILLUMINATION

1. The illumination capability of the Flexible Inspection Scope can be verified prior to use. Once the scope is connected to the computer with the power on, the distal tip of the Flexible Inspection Scope will cast visible light from its tip and can be observed on any surface to which it is directed. The Flexible Inspection Scope will default to the minimum light intensity setting when started. To adjust the lighting, press (in increments or hold) the Brightness Increase (+) Button or Brightness Decrease (-) Button on the Flexible Inspection Scope.



Diagrams (drawings, pictures)



Figure 1



Figure 2

Steps for Use of Product

PERFORMING INSPECTION

1. Secure the Flexible Inspection Scope into an arm fixture (optional).
2. Grasp the Flexible Inspection Scope near its distal end and gently insert the Flexible Working Length into the intended instrument. **Fig. 1**
3. Adjust light on the Flexible Inspection Scope with the plus (+) or minus (-) brightness button for ideal lighting.
4. Use short advancements while keeping your fingers close to the instrument's opening. View the monitor while inserting into the device. If an obstruction hinders the path of the Flexible Inspection Scope, gently attempt to manipulate or rotate the device to avoid the obstacle. **Fig. 2**
5. Once the Distal End of the scope has reached the end of the area that is being inspected, retract the scope slowly while looking for debris or damage.

Interpretation of Test Results	
Contraindications of Test Results	
Documentation	
Special Warnings and Cautions	<ul style="list-style-type: none"> ● Do not attempt to use the Flexible Inspection Scope if it appears to be damaged. ● The Flexible Inspection Scope is NOT STERILE. Follow the instruction for cleaning, disinfecting and sterilizing provided in this document. ● Do not autoclave or dry heat the Flexible Inspection Scope. ● Avoid looking directly at the light emitted from the distal end when the scope is powered on. ● Do not bend device beyond a 0.85” (21.6mm) radius; this may cause damage to the device. ● Do not apply excessive force to the Flexible Inspection Scope. If there is resistance, or an obstruction hinders the path of the scope, gently attempt to manipulate or rotate the device to avoid the obstacle. Also, slowly withdraw a short distance and try advancing again. ● Applying excessive force to the scope past an obstacle can result in damage to the device. ● Avoid rubbing against sharp edges, as this can also damage the device. ● Do not clean, disinfect, or sterilize the Flexible Inspection Scope or its accessories using an ultrasonic cleaner, washer sanitizer, washer pasteurizer, washer sterilizer, steam autoclave, or any method with a processing temperature above 60°C (140°F).
Disposal	

Reprocessing Instructions	
Point of Use	
Preparation for Decontamination	
Disassembly Instructions	Disconnect the Camera Cable from the Flexible Inspection Scope prior to cleaning.
Cleaning – Manual	<p>Cleaning Between Uses:</p> <ol style="list-style-type: none"> 1. Use a pre-moistened cleaning wipe. See Chemical Compatibility Chart for approved cleaning agents click here: 2. <u>Follow the wipe manufacturer’s IFU.</u> <p>NOTE: The soaking cap forms a waterproof seal to protect the proximal connection (pins) on the camera cable connection of “handle” for sterilant(s) and/or disinfectants. The soaking cap is intended to protect the pins on the camera cable connection (proximal end of the handle) from exposure</p>

	<p>to liquids. The presence of water on the connector after processing is normal. The connector may be dried with compressed air. Repeated exposure to fluids will corrode the contacts of the Camera Connector.</p> <p>For Thorough Cleaning: Follow the cleaning agent manufacturer’s instructions for use.</p> <ol style="list-style-type: none"> 3. Unplug and disconnect all components from the Flexible Inspection Scope prior to cleaning. 4. Secure the Soaking Cap on the Flexible Inspection Scope Camera Connector. 5. The Flexible Inspection Scope Camera Cable is not waterproof. Therefore, do not submerge or soak the camera cable for disinfection. 6. Place the scope in a bath of enzymatic detergent and soak the device for the duration specified by the manufacturer (in fluid up to 1 meter for up to 30 Minutes). 7. Wipe thoroughly with a 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. 8. Rinse with low linting wipe moistened with AAMI Utility Water for 45 to 60 seconds, dry with low linting wipe. <p>Reprocessing Chemical Compatibility Chart click here:</p>
Cleaning – Automated	
Disinfection	<ul style="list-style-type: none"> ● Select only the disinfecting solutions listed in the Chemical Compatibility Chart. ● Follow the disinfection manufacturer’s instructions for use. ● Complete the steps described in the above Cleaning section. ● Secure the Soaking cap on the Flexible Inspection Scope Camera Connector. ● Soak the Flexible Inspection Scope in the selected solution per the solution manufacturer’s instructions for high level disinfection. ● Rinse the Flexible Inspection Scope with critical (sterile) water, again following the instructions of the disinfecting solution manufacturer. ● Dry with a sterile, non-linting wipe. Ensure that the distal tip and proximal end of the Flexible Inspection Scope are dried. Air drying could leave deposits on these optical surfaces which could result in a degraded image. <p>Reprocessing Chemical Compatibility Chart click here:</p>
Drying	

Maintenance, Inspection, and Testing	<ul style="list-style-type: none"> • Inspect the Flexible Inspection Scope for signs of wear or damage. • No serviceable parts within the Flexible Inspection Scope. No user maintenance beyond cleaning is required. Refer all service or replacement needs to the manufacturer. • Inspect the external surfaces of the Flexible Inspection Scope and any accessories to assure they are smooth and free of any protrusions or sharp edges.
Reassembly Instructions	
Packaging	
Sterilization	The FIS-005 does not require terminal sterilization. It is compatible with low-temperature sterilization modalities. See the Reprocessing Compatibility Chart click here .
Storage	<ul style="list-style-type: none"> • Store the instrument no higher than 60°C or lower than -20°C. • Store the equipment in a clean, dry and ventilated location.
Additional Information	<ul style="list-style-type: none"> • If upon inspecting an item it is determined not to be clean, reprocess according to the manufacturer's instruction for use. • 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	Video Inspection Scope with Display, optical inspection products.
Other Product Support Documents	ProSys™ Brochure, ProSys™ Price List
Reference Documents	CE Mark- CE Declaration of conformity according to European Directive 93/42/CE: transposed in national law, by Law 9434 of 18 January 1994 and its implementing Decree No. 98-292 of 16 March 1995: LTA Medical External brushes belong to class I, according to 'Annex 9 rule 1' of the Directive, non impantable, non-invasive device, dedicated to medical device cleaning before disinfection by physical means.
Customer Service Contact	Healthmark Industries Company, Inc 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com