| | |
|---|---|
| **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, CT-103, CT-104 |
| **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 of 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**<br>• CT-101 1.90 mm OD and 110 cm length<br>• CT-102 1.06 mm OD and 110 cm length<br>• CT-103 1.90 mm OD and 60 cm length<br>• CT-104 1.90 mm OD and 200 cm length<br>• Optical:<br>o Resolution format:<br>o CT-104 1.90 mm: 160,000 pixels (or 400 x 400 pixels)<br>o CT-103 1.90 mm: 160,000 pixels (or 400 x 400 pixels)<br>o CT-102 1.06 mm: 40,000 pixels (or 200- x 200 pixels)<br>o CT-101 1.90 mm: 160,000 pixels (or 400- x 400 pixels)<br>o Field of View: 120° in air<br>o Angle of view: 0°.<br><br>**USB Control Module: Control Module housing Camera processor and LED illumination:**<br>• Dimensions: 5.25- x 3.90- x 1.85 inches<br>• Weight: 1.20 pounds<br>• Digital Inspection Scope Connection<br>• Illumination Control- LED in the Control Module<br>• Power Cycle<br>• USB Camera Cable<br>• Easily change from small and large diameter scopes.<br><br>Light Settings:<br>There are four (4) light settings operated by one button.<br><br>Blinking Light (Indicates transmitting video data):<br>• Splash proof (IPX5 Rating)<br>• No external power needed.<br><br>**Flexible Inspection Scope Software Requirements:**<br>• Compatible with Windows 10 and 11 Operating systems.<br>• USB flash drive includes operating software. |

| **Shipping & Storage** | |
|---|---|
| **Shipping Conditions & Requirements** | N/A |
| **Storage Conditions** | **Storage and transport**<br>• Humidity: 10–100% relative humidity (rh) (or condensing)<br>• Temperature: −20- to 60 °C (–4- to 140 °F)<br>• Pressure: 600- to 900 hPA.<br><br>**Normal Operation**<br>• Humidity: 0–100 % rh<br>• Temperature: 5- to 40 °C (41- to 104 °F). |
| **Packaging Contents** | N/A |

| | |
|---|---|
| **Shelf Life** | Warranty: one (1)-year from date of purchase. |

| **Instructions for Using Product** | |
|---|---|
| **Description of Use(s)** | For visually inspecting items. |
| **Preparation for Use** | **Unpacking Flexible Inspection Scope:**<br>Carefully inspect for shipping damage. If there is any damage, contact the shipping carrier and Heatlhmark customer service 800-521-6224 immediately.<br><br>**USB Control Module: (Fig. 1).**<br>1. Digital Inspection Scope Connection<br>2. Illumination Control<br>3. Power Cycle<br>4. USB (Type C) on the right side of the box<br><br>  <br><br>**Figure 1**<br><br>**Flexible Inspection Scope™: (Fig. 2).**<br>A. CT-101: 1.90 mm Outside Diameter (O.D.) and 110 cm length<br>B. CT-102: 1.06 mm O.D. and 110 cm length.<br>C. CT-103: 1.90 mm O.D. and 60 cm length.<br>D. CT-104: 1.90 mm O.D. and 200 cm length.<br><br>  <br>**Figure A** **Figure B** **Figure C** **Figure D**<br><br>**Figure 2**<br>**Flexible Inspection Scope™ Features** |

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

- Five (5) light settings
  - Light on control indicates setting level
  - 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)

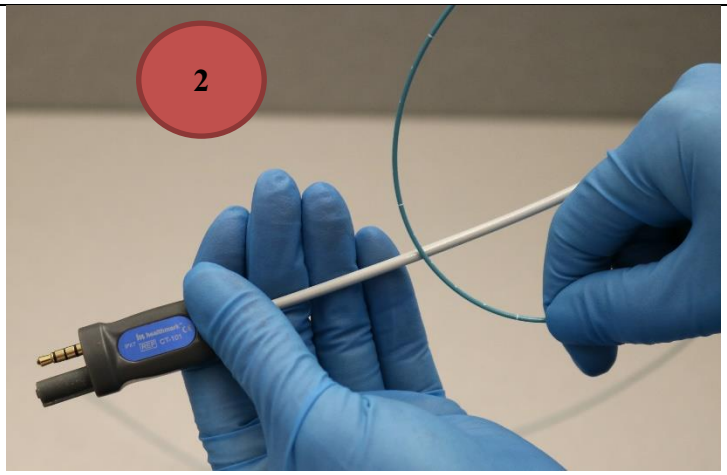



**Figure 6**

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

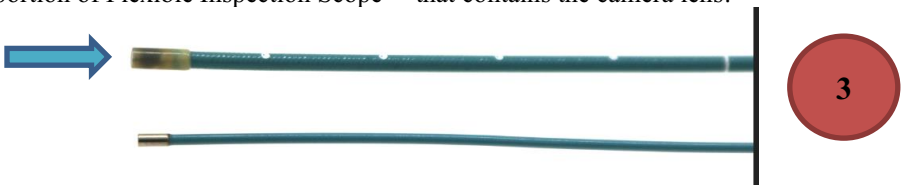



**Figure 7**

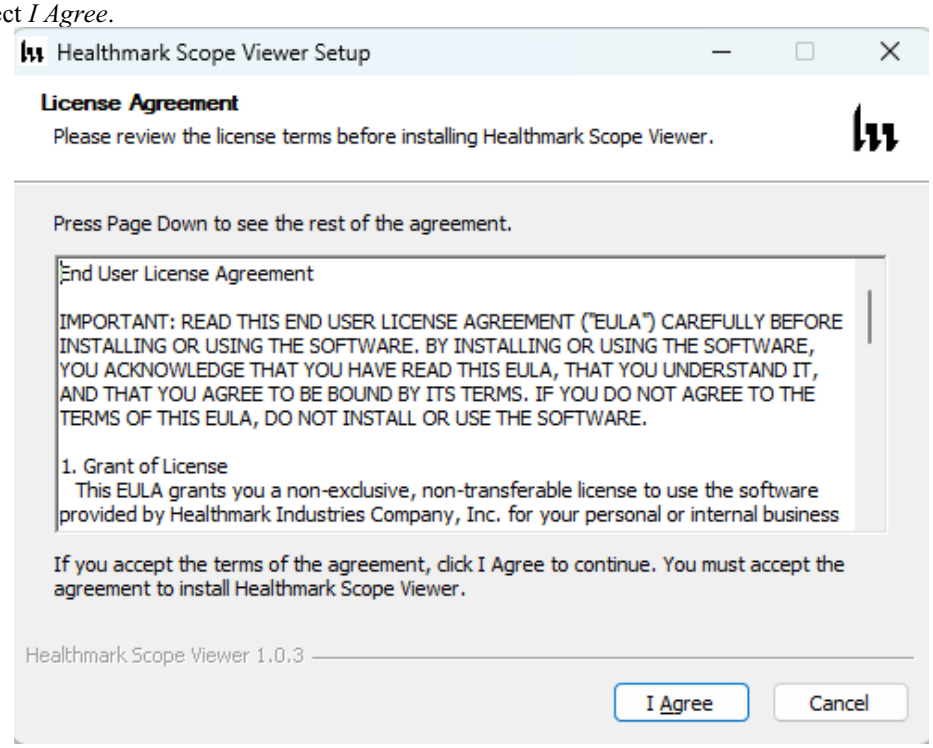
## Software Installation: Gen 2

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

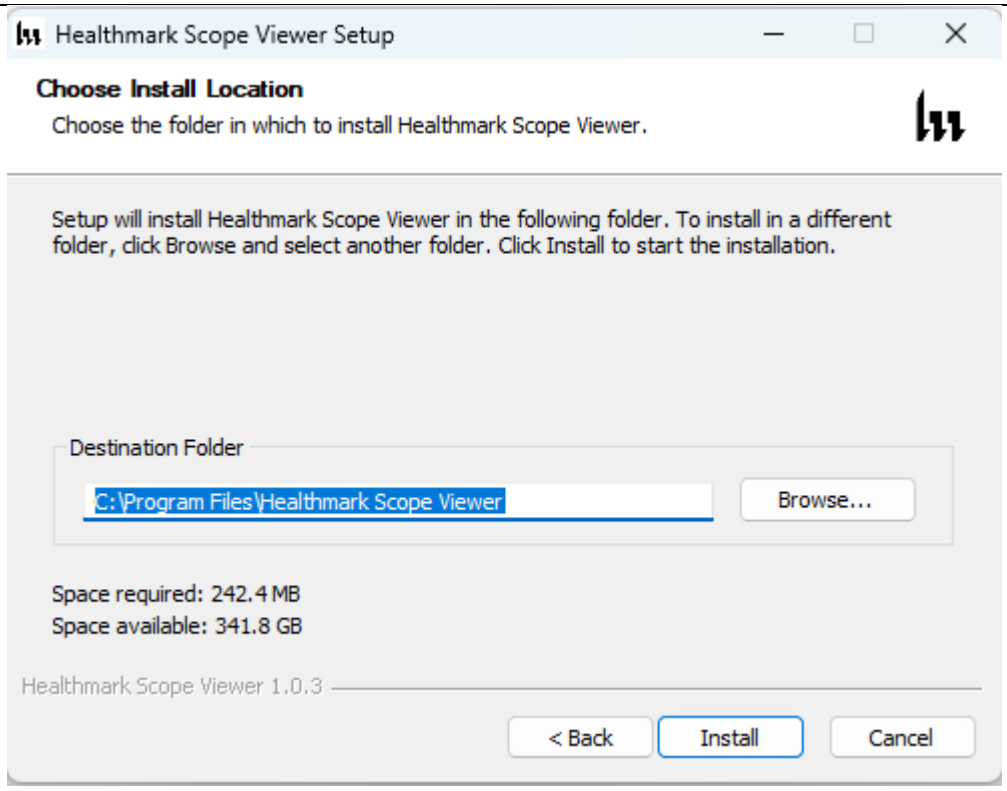
- System Requirements: MS Windows 10 or 11
- Install the Healthmark Scope Viewer Software from the USB flash drive on a computer or through the hmark.com product software page.

*(Note: If you have any IT policies that may block this installation, please contact your IT team to give you access to Healthmark Scope Viewer Software to install.)*

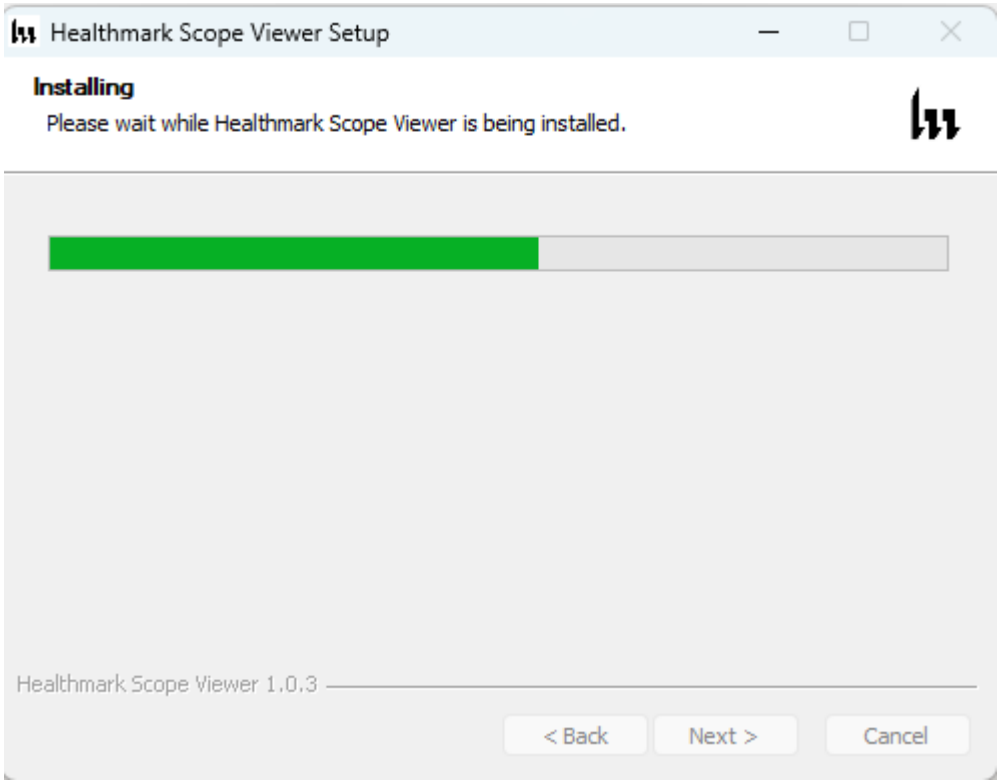
1. Insert the USB Flash drive into your computer, when you have finished reading the End User agreement, select *I Agree*.



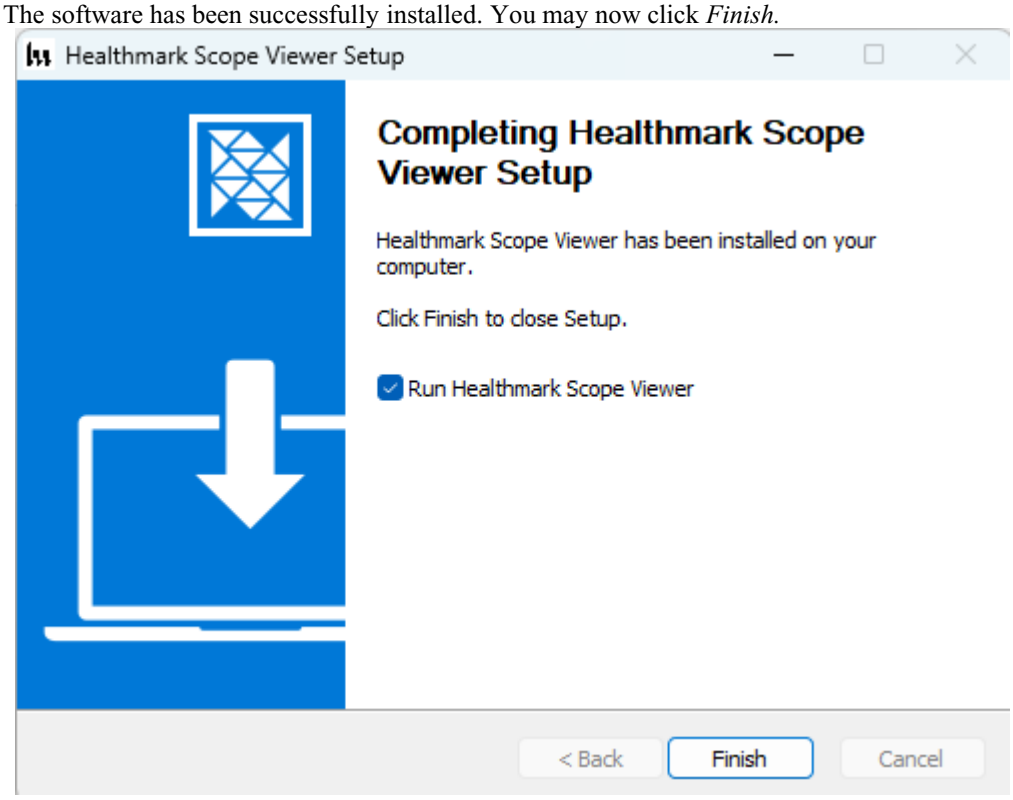

2. Select a destination folder, and then click *Install*




3. Follow instructions on screen. Wait for software to be installed.

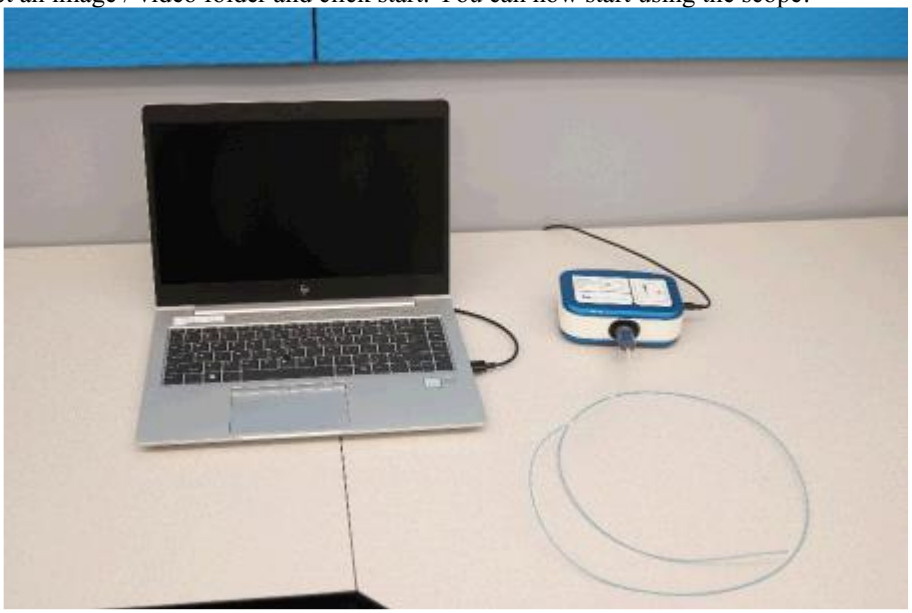


4. The software has been successfully installed. You may now click *Finish.*




**STARTING SOFTWARE & CONNECTING SCOPE TO PC:**

1. Open the Windows PC Healthmark Scope Viewer software.
2. Connect the Control Module to PC using USB Cable.
3. Plug the Flexible Inspection Scope™ into the Control Module.
4. The settings will automatically open, and you will be prompted to select a camera **(Fig 1)**.
    a. Here you will select the *USB Video Device* option.
    b. If *USB Video Device* does not show up, try selecting the *Reload Cameras* option to the right of the camera selection.
5. Select an image / video folder and click start. You can now start using the scope.



**Verifying Operation**

Following the steps listed below will ensure the proper use and performance of the Flexible Inspection Scope™. The Flexible 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 or tablet monitor.
- A blinking light on the Control Module near the *Power Cycle* button that indicates the image feed is
- transmitting.
- White light emitting from the distal end of the Flexible Inspection Scope™.
- An LED light on the control module top panel that indicates the light intensity of the device.

## Using Software

Once the software is opened, settings will automatically pop up and you will be prompted to select a camera (USB Video Device). You will also be prompted to select a file path where images and videos will be saved to, and a subfolder within that file path. Once all of these have been properly selected, click start to begin your inspection.

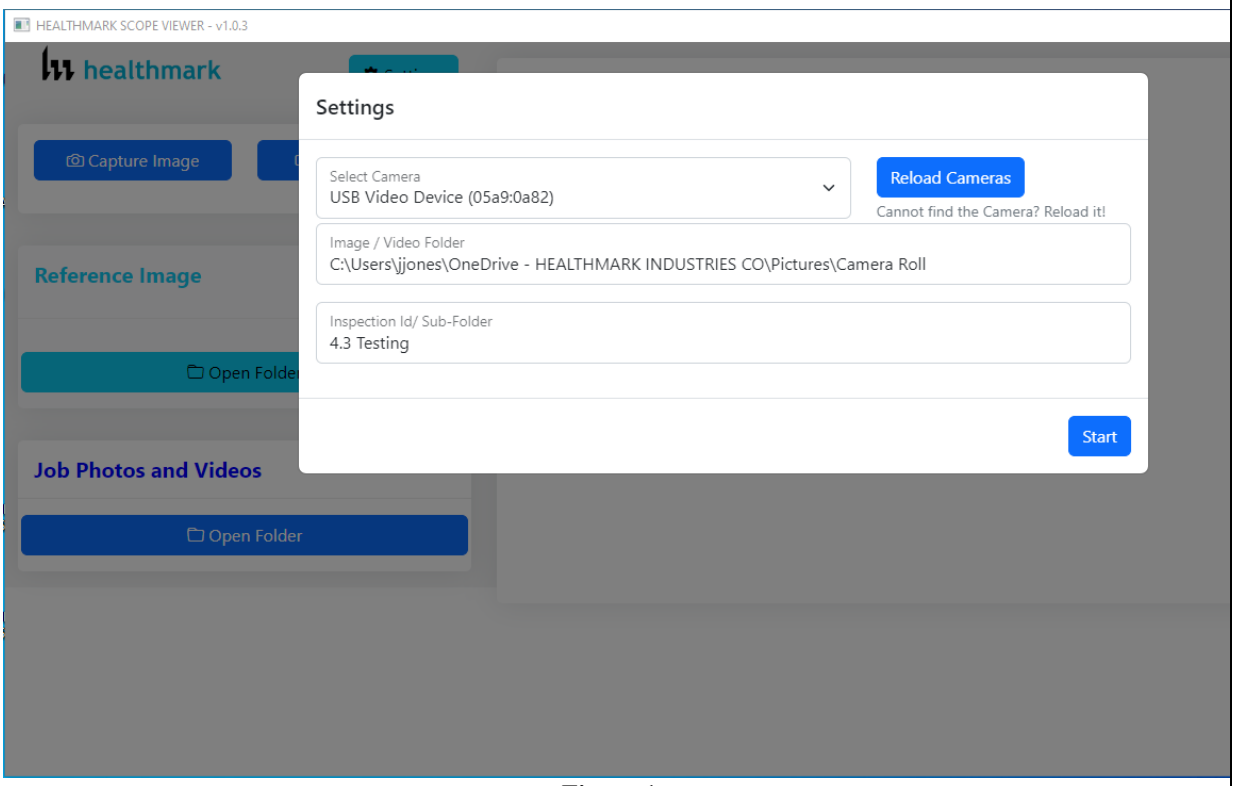



**Figure 1**

Next Step:

1. *Capture Image Button:* Captures images and adds them to the file location selected by the user (selected in settings under the "Image / Video Folder").
2. *Record Video Button:* Click to record video. Click again to stop recording video.
3. *Settings Button:* Click to pull up screen in **(Fig. 1)**. For selecting camera and file location.
4. *Main Image Window:* Displays the image from the camera.
5. *Capture Button:* Captures a reference image and saves it to the *Reference Image Folder.* **(Fig. 2).**
6. *Reference Image Window:* Displays a reference image.
7. *Open Folder Button:* Allows selection of a reference image from the *Reference Image Folder.*
8. *Job Photos and Videos Section* **(Fig. 3)**: Directly clicking a photo or video will allow you to preview that photo or video.
    a. *Open Folder Button:* Opens your files where your pictures and videos are being saved.

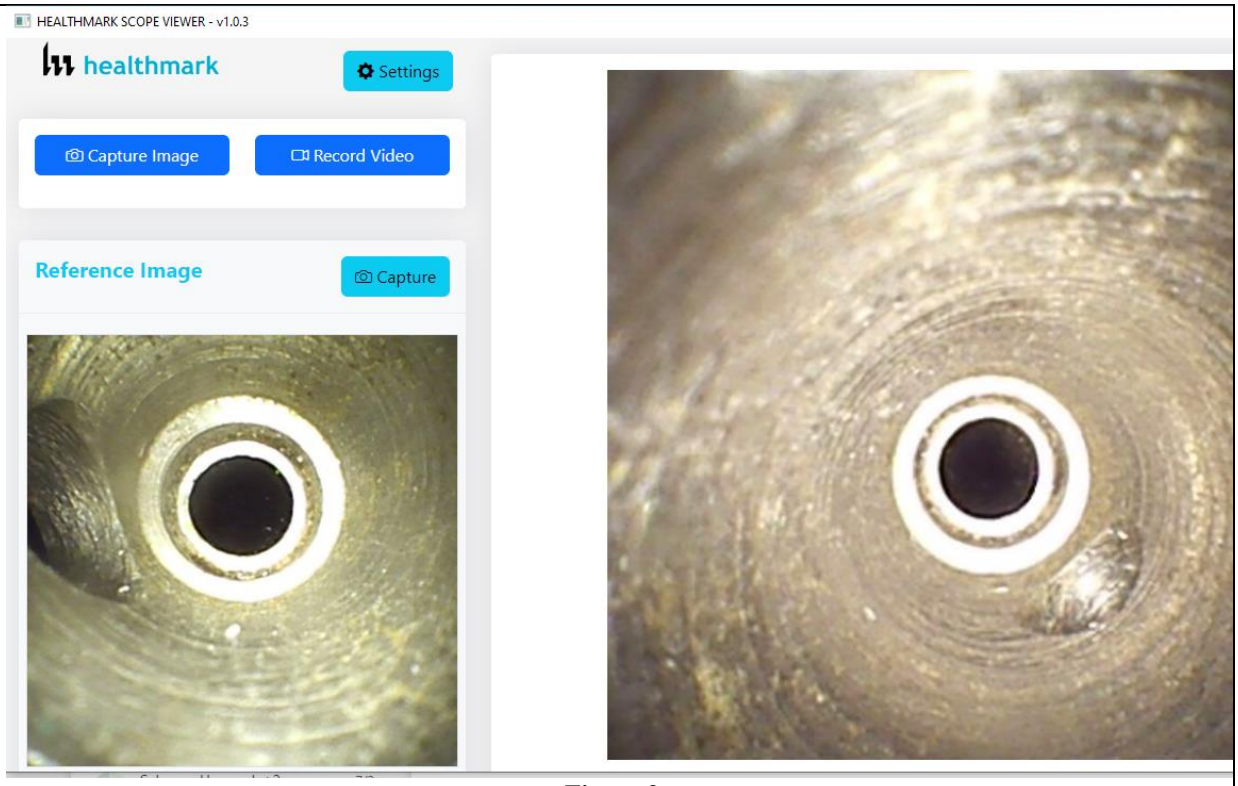



**Figure 2**

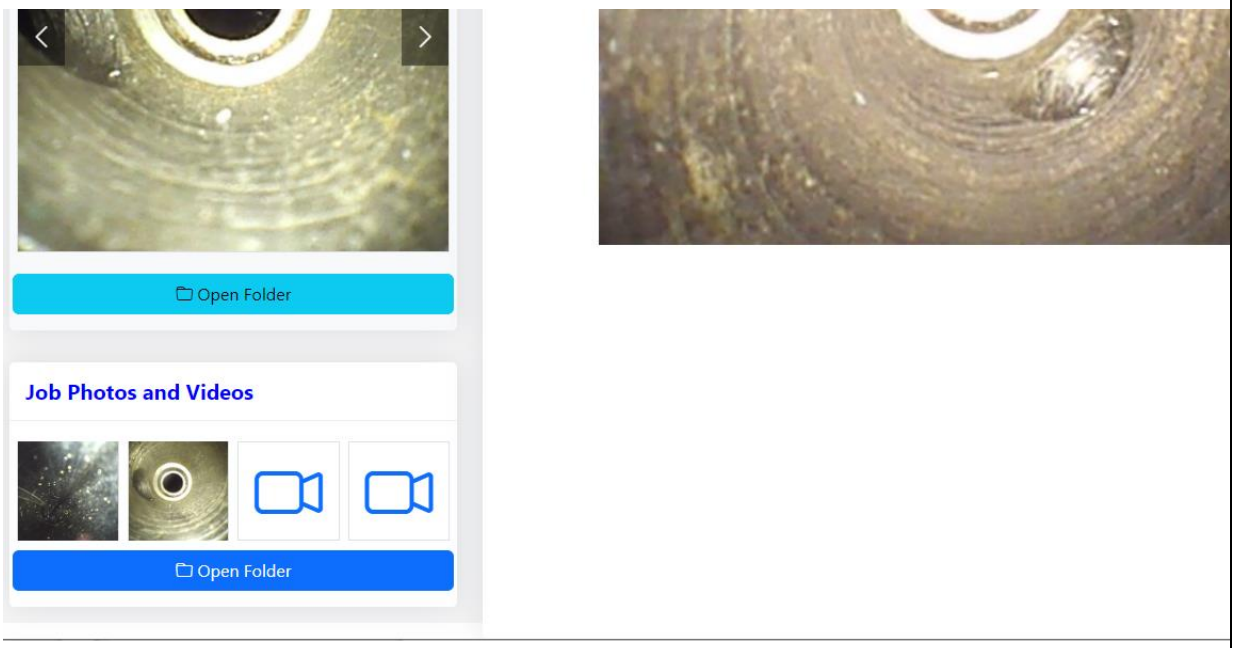



**Figure 3**

**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. 4).**

1. Click the *Settings* button to the right of the Healthmark logo in 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. Select the *USB Video Device* for the Flexible Inspection Scope™.
3. Click *Start* to view the selected video device.

**Capturing Still Pictures**

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

Select the *Capture Image* button.


**Figure 4**

(*Note: When an image is captured, "Image Saved!" will show in a green bar at the top 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 *Record Video* Button (**Fig. 5).**

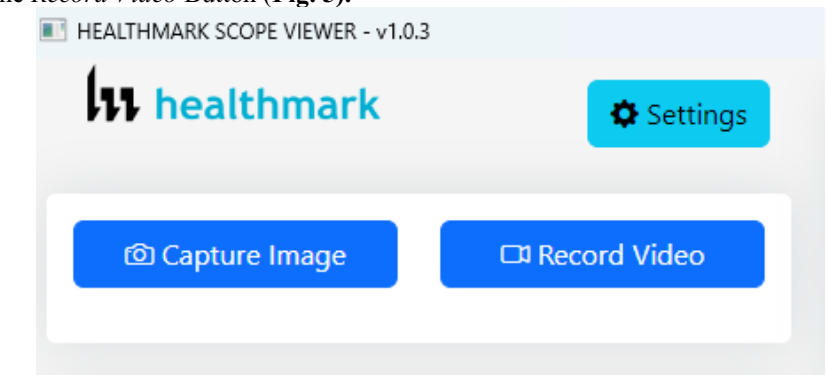



**Figure 5**

1. When a video is recording, the *Record Video* box will turn into a red *Stop Recording* box.
2. To stop recording, click *Stop Recording.* **(Fig. 6).**

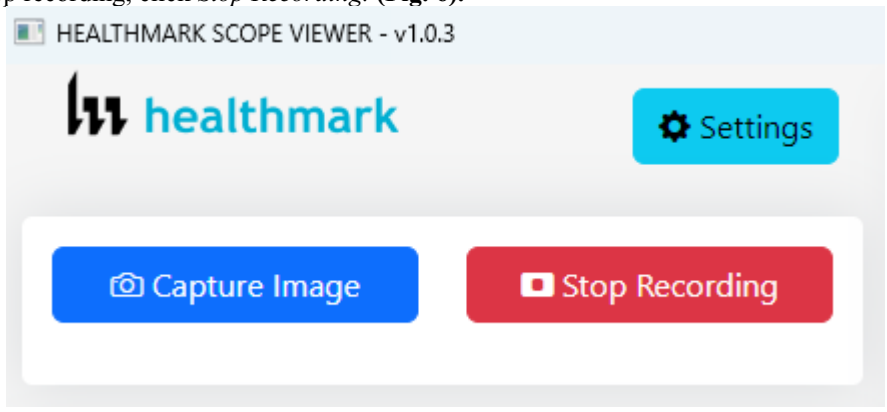



**Figure 6**

**Setting Location for Saved Files**

Following the steps below allows you to customize where your files will be stored. The details in the *Image / Video Folder* are where your images and videos will be saved. This can be found in the *Settings* section of the software.

1. Click the *Image / Video Folder* button.
2. Select the file location you want to save captured images. (**Fig. 7).**

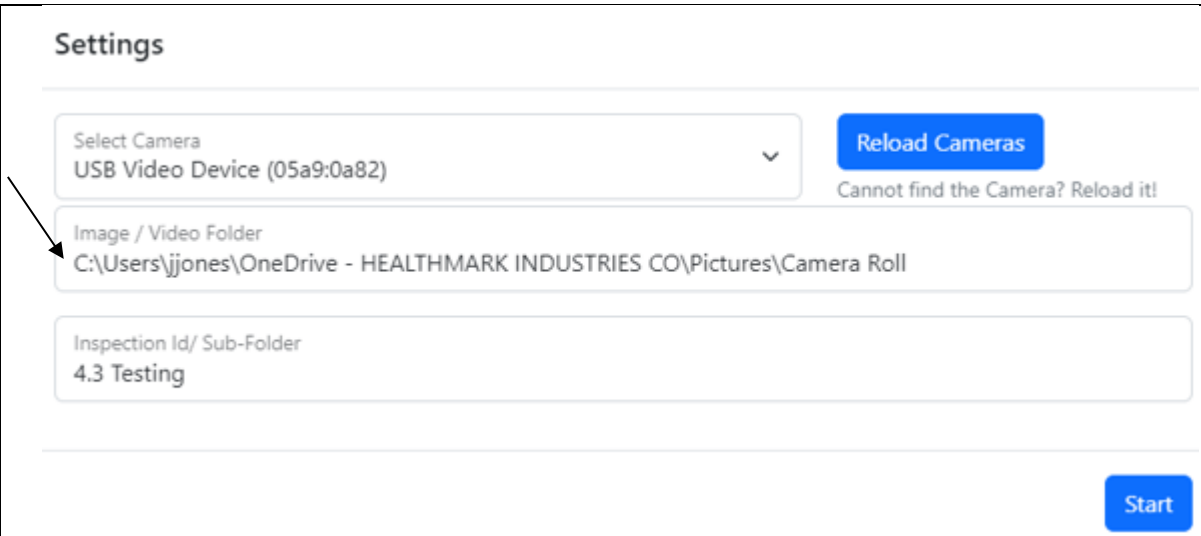



**Figure 7**

**Setting File Location – Sub-Folder**
The user will have the option to select a sub-folder for further organization within the initial folder.

1. Click in the *Inspection ID/ Sub-folder.*
2. Enter the characters that you would like to be included in the file name. (**Fig 8).**

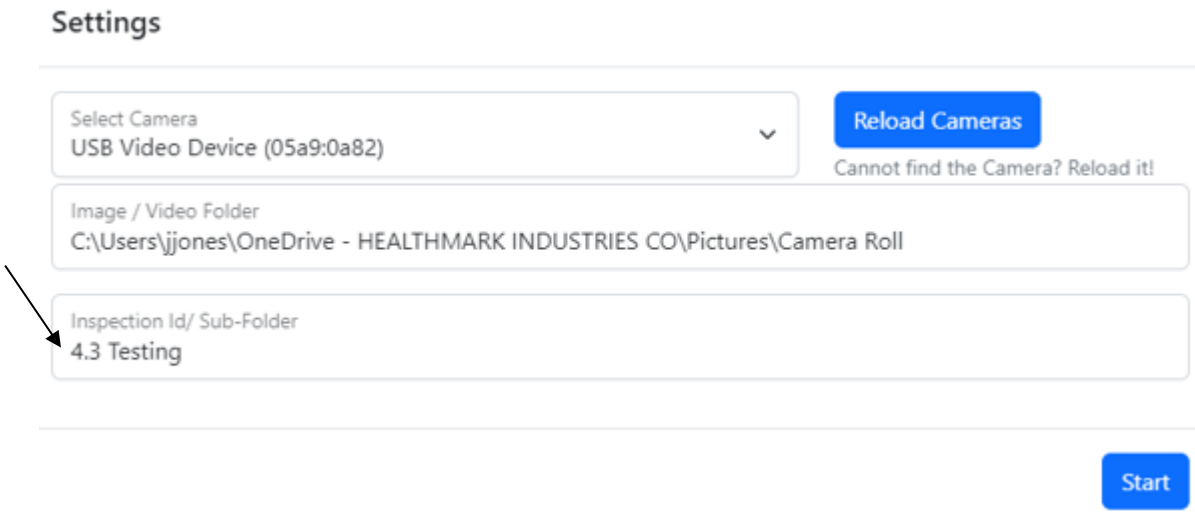



**Figure 8**

**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 specified in the* ***File Location*** *field.* (**Fig. 9).**

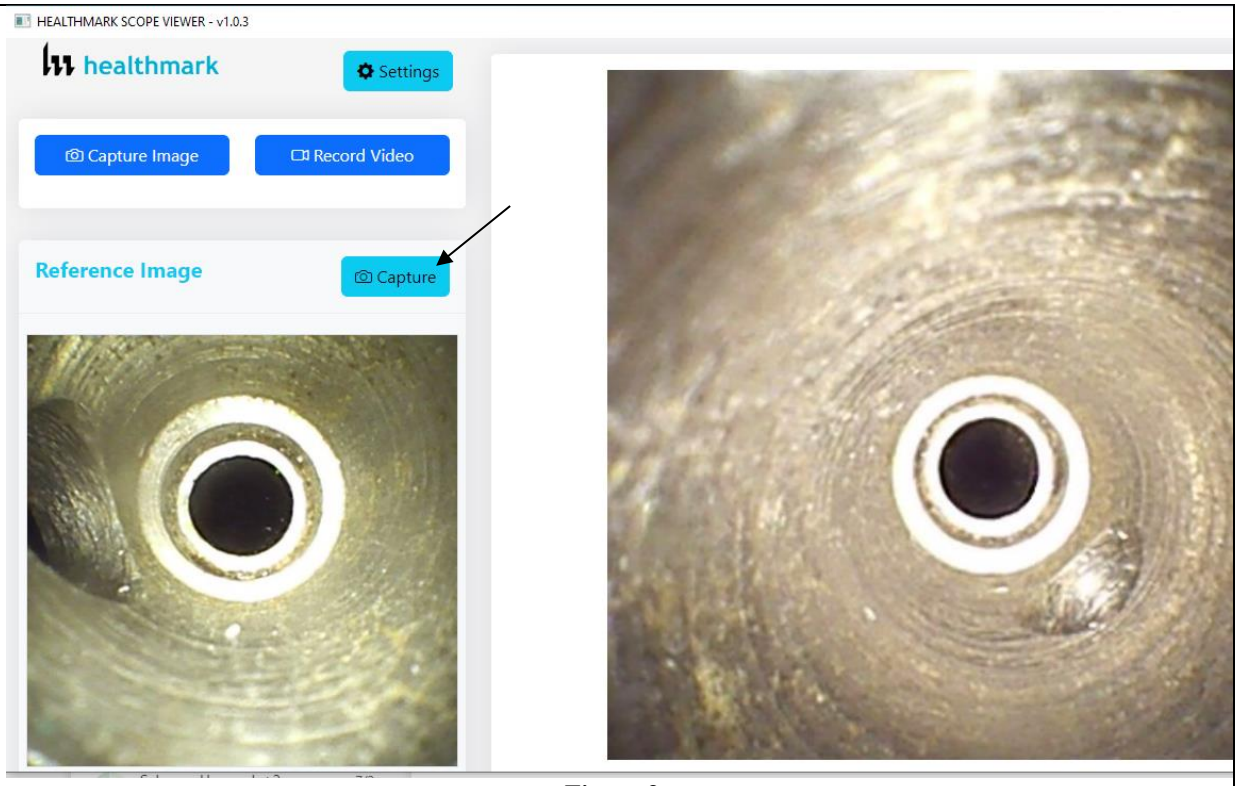



**Figure 9**

To display a saved image in the *Reference Image Window* from your *File Location*:
a. Hover over the *Reference Image* window.
b. When your mouse is over the image, two arrows (forward and reverse arrows) will appear (shown in **Fig. 10**) to allow you to scroll through your reference images.

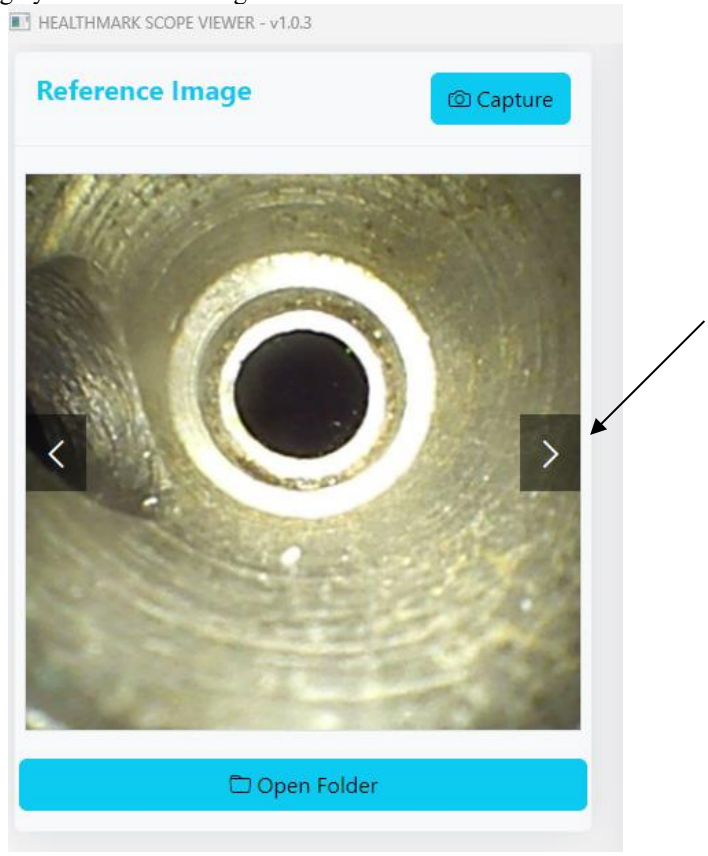



**Figure 10**

*(Note: Clicking any of the images in either the Reference Image window or in the Jobs and Videos window will pull up a preview of that image. At the bottom of the screen, the image can be individually renamed or deleted.)* ***(Fig. 11)***.

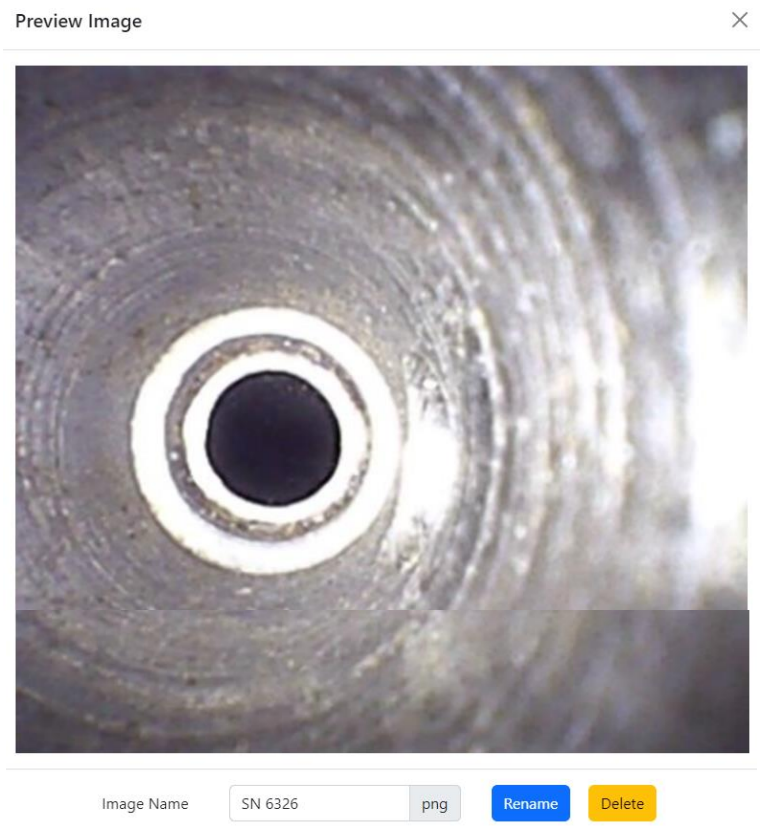



**Figure 11**

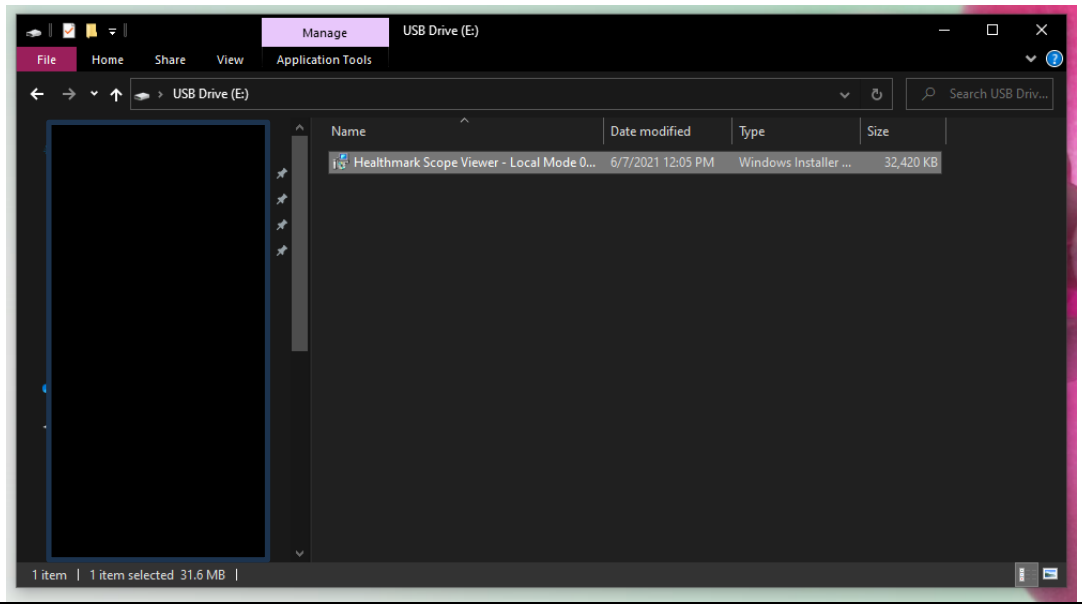
- **SOFTWARE INSTALLATION: Gen 1**

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

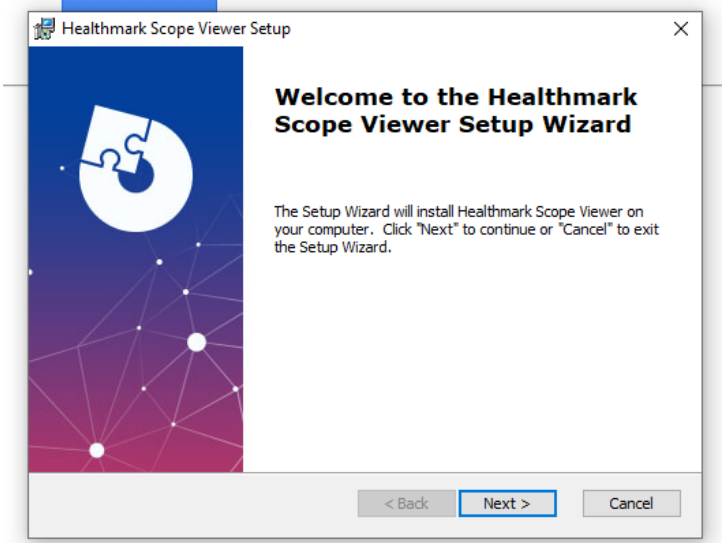
- System Requirements: MS Windows 10
- Install the Flexible Inspection Scope™ Software from the USB flash drive onto a computer.

(***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.*)

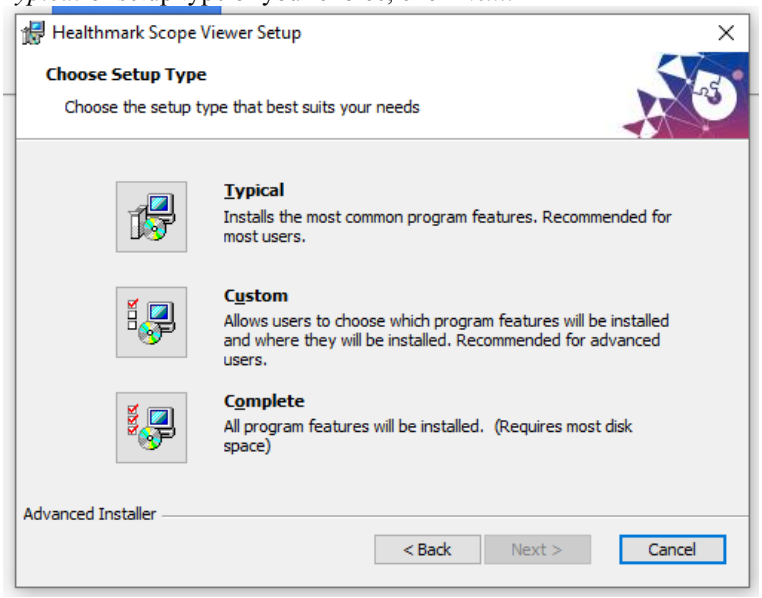
1. Insert the USB Flash drive into your computer and double click on the *Healthmark Scope Viewer* installer package to begin installation.



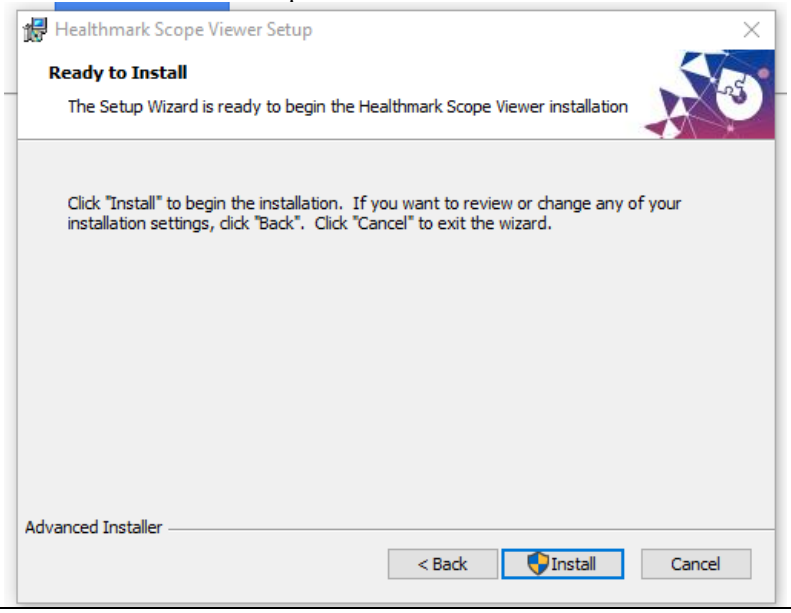
2. The “Welcome to the Healthmark Scope Viewer Setup Wizard” screen pops up. Click on *Next.*

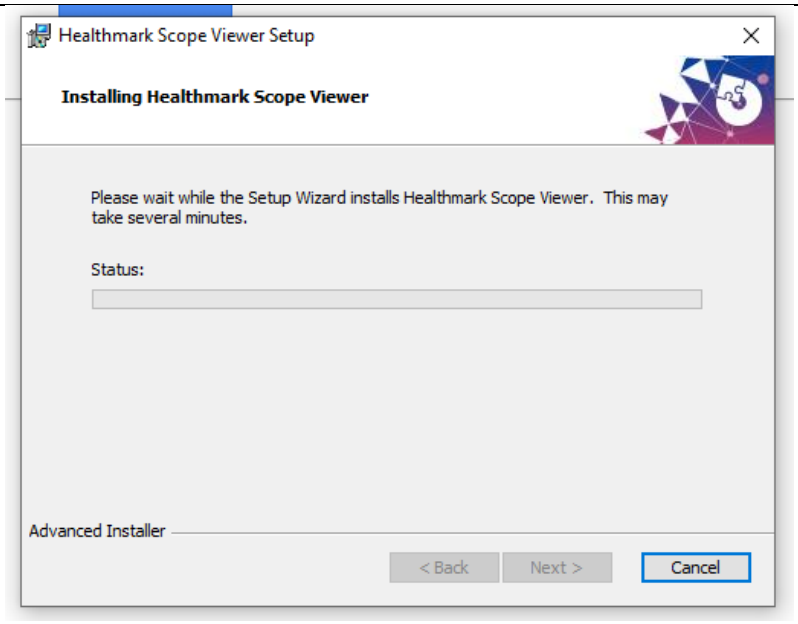



3. Select the first tab *Typical* or setup type of your choice, click *Next.*

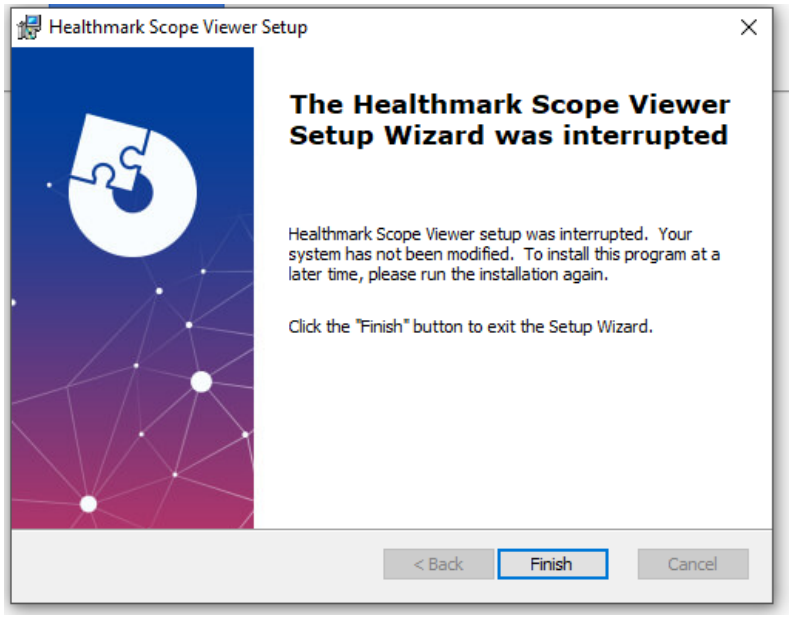



4. Click *Install* and wait for installation to complete.






5. Click *Finish.*




**STARTING SOFTWARE & CONNECTING SCOPE TO PC:**
**(Fig 8).**

1. Open the Windows PC Healthnmark Scope 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.

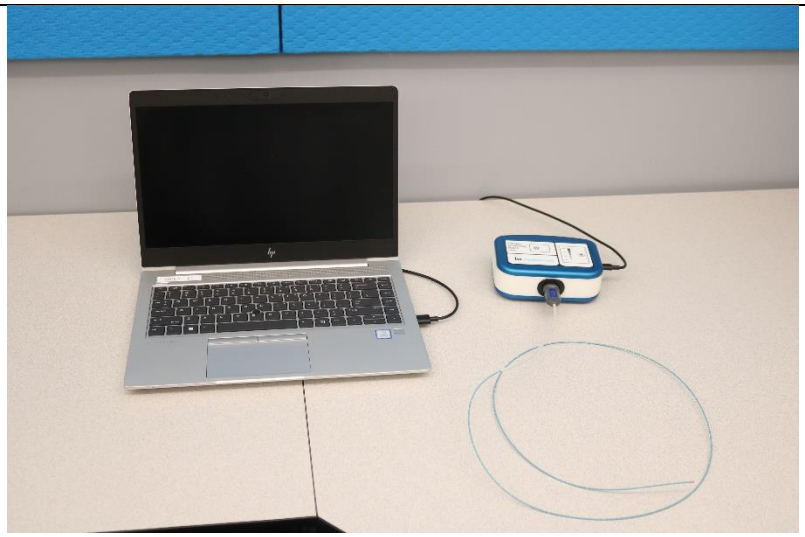


**Figure 8**

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 Flexible 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 or tablet monitor.
- A blinking light on Control Module near the *Power Cycle* button that indicates the image feed is transmitting.
- White light emitting from the distal end of the Flexible Inspection Scope™.
- An LED light on the control module top panel indicates the light intensity of the device.

## Using Software: Option 2

**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 live 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 selection of a reference image from the *Reference Image Folder*.
6. *Settings Button*: Click to select the video camera input 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 the text you want included in the file name of each captured image.

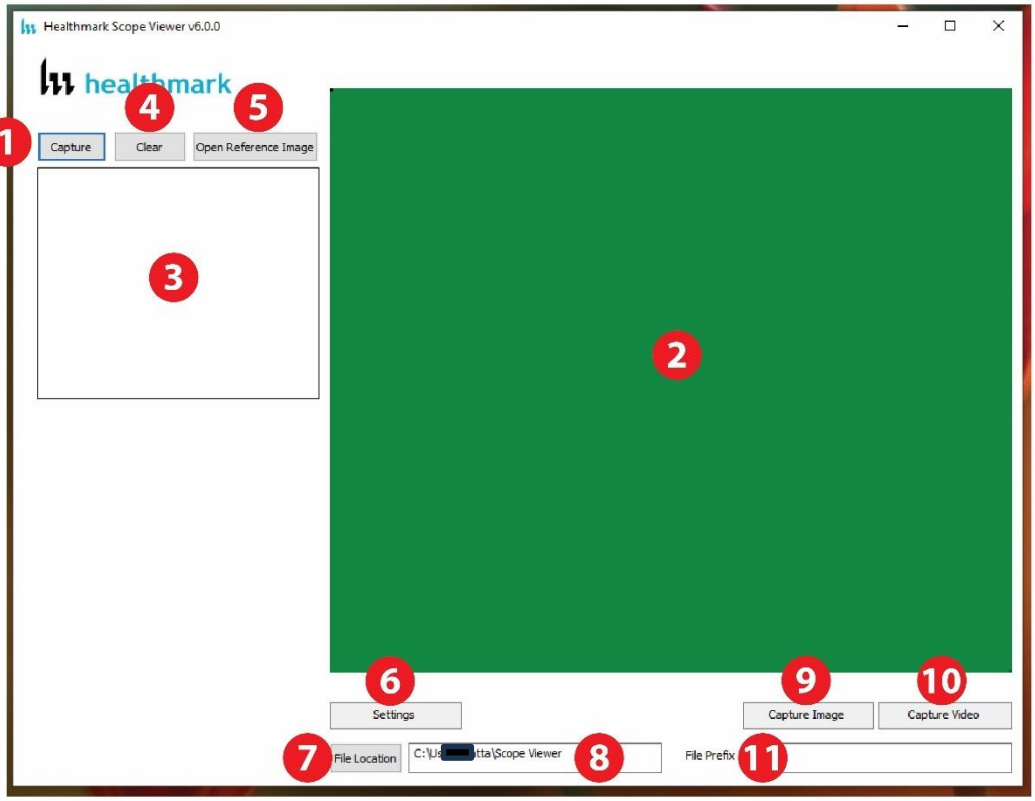



**Figure 9**

## 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.

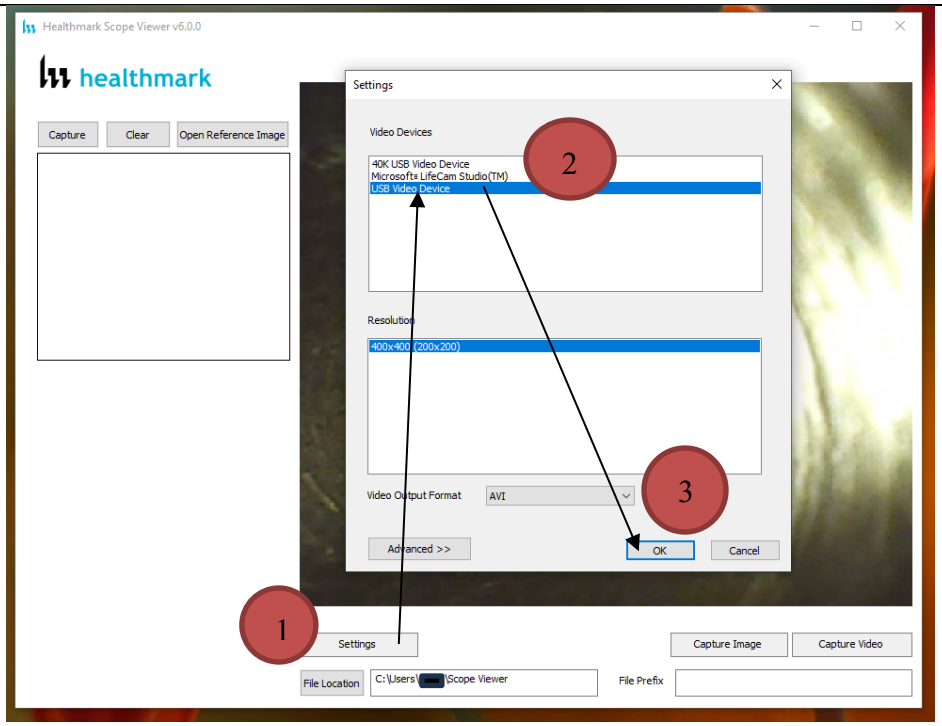



**Figure 10**

## Capturing Still Pictures

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

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

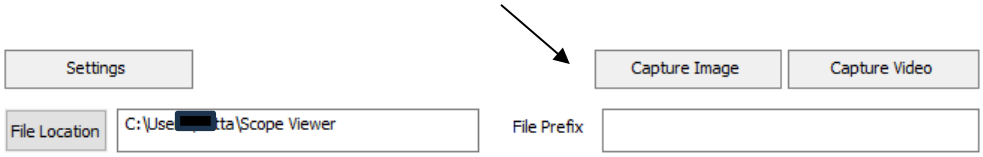



**Figure 11**

(*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).**

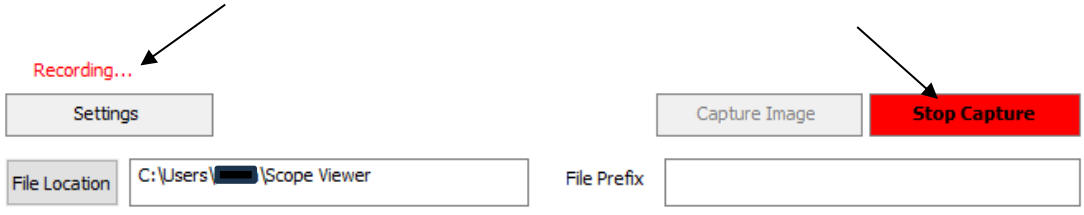



**Figure 13**

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

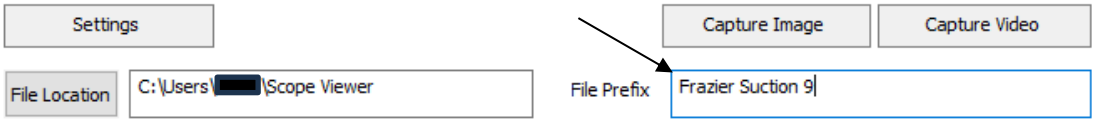



**Figure 14**

## Setting Location for Saved Files

Following the steps below will allow 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 specified in the* ***File Location*** *field.*) **(Fig. 16).**

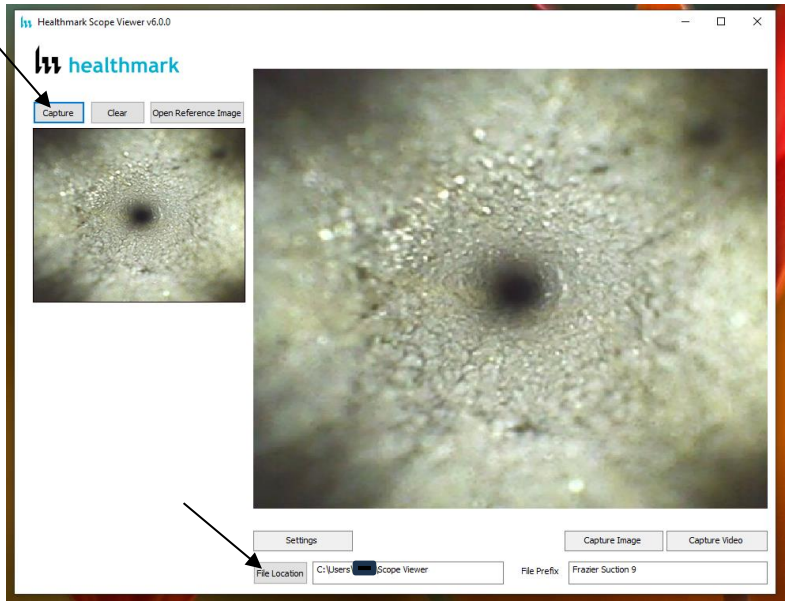



**Figure 16**

2. To display a saved image in the *Reference Image Window* from your *File Location*:
   a. Click the *Open Reference Image* button **(Fig. 16 above)**.
   b. Select the file you want to display (**Fig. 17 below).**
   c. Click the *OK* button to display the image in the *Reference Image Window*. (**Fig. 17).**

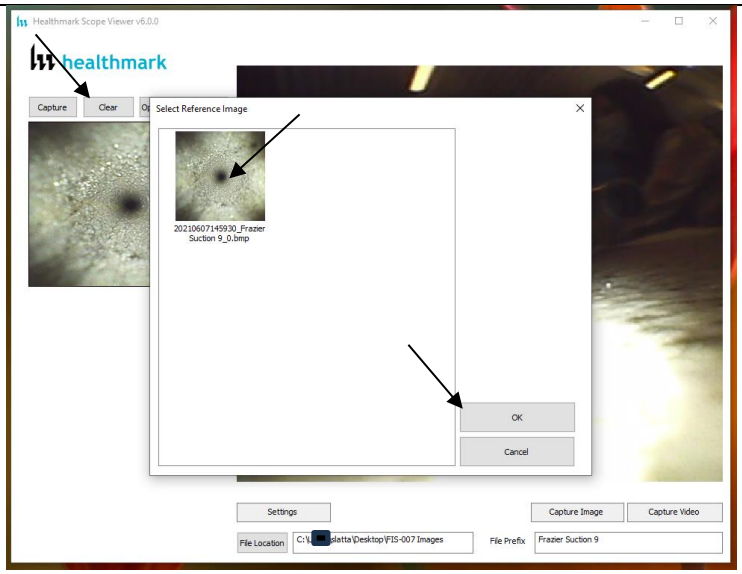



**Figure 17**

## 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.


**Inserting Scope in Item**

**Diagrams (drawings, pictures)**

**Figure 1**

**Rotating Device to Avoid Obstacle**

| | |
|---|---|
| |  <br>**Figure 2** |
| **Steps for Use of Product** | **Performing Inspection**<br>Following the steps listed below (prior to inspection) will ensure the proper use and best performance of the Flexible Inspection Scope™.<br>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).**<br>2. Adjust light with the *Illumination* button on the Control Box for ideal lighting.<br>3. Use short advancements while keeping your fingers close to the device's opening.<br>a. View the monitor while inserting into the item.<br>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).**<br>4. Once the Flexible Working Length has reached the end of the area being inspected, retract the scope slowly while looking for debris or damage.<br>5. When switching between Flexible Inspection Scope™, power off the Control Box that is in use, then disconnect the Flexible Inspection Scope™ from the Control Box.<br>6. If the USB Control Box is in use, power off the Control Box and disconnect the Flexible Inspection Scope™ along with the power adapter.<br><br>(***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** | • Read and understand the IFU before using the Flexible Inspection Scope™.<br>• Do **not** attempt to use the Flexible Inspection Scope™ if it appears to be damaged.<br>• The Flexible Inspection Scope™ is **not** sterile as supplied. The user must follow the protocol for cleaning and disinfecting or sterilizing as described in the instructions for "Cleaning and Disinfecting or Sterilizing" section.<br>• Do **not** attempt to service any part of this product.<br>• Avoid looking directly at the Flexible Inspection Scope's™ emitted light or directing it toward others. Do **not** bend the Flexible Inspection Scope™ to a radius less than half (1/2)-inch (12.7 mm). This may cause damage.<br>• Do **not** apply excessive force to the Flexible Inspection Scope™. Doing so can result in damage.<br>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.<br>o You may also slowly withdraw the Flexible Inspection Scope™ a short distance and try advancing again. |
| **Disposal** | This can be disposed of the same way as standard electrical products. Follow your local regulations for the 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. |

<table>
<tr><td>Cleaning – Manual</td><td>
Cleaning Between Uses:<br>
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.<br><br>
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.<br><br>
Solutions Containing (Flexible Inspection Scope™ Only)
<table>
<tr><td>Alcohol ethoxylates (AE)</td><td>Neutral or Near-Neutral pH Detergents</td></tr>
<tr><td>Enzymatic Cleaning Solutions</td><td>Enzymatic Detergents</td></tr>
<tr><td>Sodium borate, decahydrate (Borax or Boric acid)</td><td>Tetrapotassium pyrophosphate (TKPP)</td></tr>
</table>
<br>
Flexible Inspection Scope™ has a fluid ingress protection rating of IPX7 (Waterproof) and can withstand immersion in fluid up to one (1)-meter in depth for up to 30 minutes.<br><br>
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 (3) minutes.<br><br>
For Thorough Cleaning: Cables<br>
Follow the cleaning agent Mfr.'s IFU.<br>
1. Unplug and disconnect all components from the Control box prior to cleaning.<br>
2. Do not submerge or soak the cable for disinfection (cable is not waterproof).<br>
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.<br><br>
For Thorough Cleaning: Control Module<br>
1. Unplug and disconnect all components from the Control box prior to cleaning.<br>
2. Do not submerge or soak the cable for disinfection (Control Box is not waterproof).<br>
3. Wipe thoroughly with non-linting wipe moistened with facility approved neutral detergent.<br>
4. Use the appropriate brushes with detergent solution to remove any residues from areas that cannot be reached with the wipes.<br><br>
(Note: Do NOT soak. Control Module and cables are not waterproof and should not be immersed.)
</td></tr>
<tr><td>Cleaning – Automated</td><td>N/A</td></tr>
<tr><td>Disinfection</td><td>
Control Module and Cables<br>
These may be disinfected with alcohol based disinfectant wipes.<br><br>
Compatible agents (wipes and solutions) for disinfecting Flexible Inspection Scope™ and Control Module:<br><br>
• Hydrogen peroxide<br>
• Isopropyl alcohol (IPA)<br>
• Sodium hypochlorite (Bleach)<br>
• Ortho-phenylphenol<br>
• Quaternary ammonium.<br><br>
High-Level Disinfection (Flexible Inspection Scope™ Only)<br>
• Select only disinfecting solutions listed in the compatible disinfecting methods.<br>
• Follow all recommendations regarding a) health hazards, b) dispensing, c) measuring, and d) storage from the Mfr. of cleaning and disinfecting agents.<br>
• Soak the Flexible Inspection Scope™ in selected disinfecting solution per Mfr.'s IFU.<br>
• Rinse the Flexible Inspection Scope™ with Critical (sterile) Water, following the disinfecting solutions Mfr.'s instructions.<br><br>
Reprocessing Chemical Compatibility Chart (PDF): Click here
</td></tr>
<tr><td>Drying</td><td>
Flexible Inspection Scope™ Only<br>
• Dry with a sterile, non-linting wipe or sponge.
</td></tr>
</table>

- 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 (e.g., protrusions or sharp edges).
- Flexible Inspection Scopes™ have no user:
  - Serviceable parts.
  - Maintenance beyond cleaning.
- Refer all service or replacement needs to Healthmark, A Getinge company.
- 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 should be monitored for light output.
  - 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<br>2. Check HDMI Monitor "Input" Selection | If no image, go to the "Settings" Tab and select USB Video Device. |
| **No light** | No light when scope is 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.<br>2. HMDI is "ON". |
| **Low light** | • No image or very dark image.<br>• Weak light pattern when scope is 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.<br>• Weak or light pattern when scope pointed at surface. | Broken light fibers in scope | Replace Flexible Inspection Scope™<br>• Decide if the scope is no longer adequate for use.<br>• 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.<br>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. |

<table>
<tr><td></td><td>
<table>
<tr><td>Image does not capture</td><td>When you click the Capture Button, the still image or video is not captured.</td><td>The File Location path may have changed, or the folder names do not exist.</td><td>Set up a new Windows File Location folder.</td></tr>
<tr><td>Rapidly takes pictures automatically</td><td>“Pictured Captured” keeps flashing and image files are created rapidly.</td><td>PC’s internal camera is selected as the video device in Settings.</td><td>Disable the PC’s internal camera.</td></tr>
</table>
</td></tr>
<tr><td>Reassembly Instructions</td><td>N/A</td></tr>
<tr><td>Packaging</td><td>N/A</td></tr>
<tr><td>Sterilization</td><td>
<ul>
<li>Do NOT autoclave the Flexible Inspection Scope™.</li>
<li>See the Chemical Compatibility Chart (PDF): Click here.</li>
<li>Low-Temperature Sterilization Systems (Flexible Inspection Scope™ Only):</li>
</ul>
<table>
<tr><td>Ethylene Oxide (EtO)</td><td>STERRAD® 100S System (Standard)</td></tr>
<tr><td>STERRAD® NX System (Standard, Advanced)</td><td>STERRAD® 100NX System (Standard)</td></tr>
<tr><td>STERIS® Liquid Chemical Sterilization Systems</td><td>STERIS V-PRO® Low Temperature Sterilization Systems (Non-Lumen Cycle)</td></tr>
</table>
</td></tr>
<tr><td>Storage</td><td>
Storage and transport
<ul>
<li>Humidity: 10–100% rh (condensing).</li>
<li>Temperature: −20- to 60 °C (–4- to 140 °F).</li>
<li>Pressure: 600- to 900 hPa.</li>
</ul>
Normal Operation
<ul>
<li>Humidity: 0–100% rh (condensing)</li>
<li>Temperature: 5- to 40 °C (41- to 104 °F).</li>
</ul>
</td></tr>
<tr><td></td><td></td></tr>
<tr><td>Additional Information</td><td>
<ol>
<li>If (upon inspecting an item) it is determined not to be clean, reprocess according to the Mfr.’s IFU.</li>
<li>Facility needs to do a multidisciplinary-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.</li>
</ol>
</td></tr>
<tr><td>Related Healthmark Products</td><td>N/A</td></tr>
<tr><td>Other Product Support Documents</td><td>ProSys™ Brochure, ProSys™ Price List</td></tr>
<tr><td>Reference Documents</td><td>N/A</td></tr>
<tr><td>Customer Service Contact</td><td>Healthmark, A Getinge company<br>18600 Malyn Blvd.<br>Fraser, MI 48026<br>1-586-774-7600<br>healthmark@hmark.com<br>hmark.com</td></tr>
</table>