

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-006SK, VS-118-200
Intended Use	For visually inspecting instruments.
Range of Applications for Product	Instruments that require visual inspection by providing lighted magnification , image capture 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>Control Box</p> <ul style="list-style-type: none"> ● Control box width- 50.8mm (2.0in) ● Weight-1.7lbs. ● Power source- External power source 5V ● Continuous adjustable light output ● Overall length- 177.8mm (7.0) <p>Flexible Inspection Scope-FIS-006SK</p> <ul style="list-style-type: none"> ● 1.18mm diameter ● 3mm-50mm depth of field ● Image- Pixel size 200x200 ● 12x magnification ● 40,000 pixel or 200 x 200 format ● Optical <ul style="list-style-type: none"> ○ Field of view- 120° in air ○ Angle of view- 0° ● Distal Camera 1.2mm- Distal position 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 ● DVI Interface ● Image control and parameter are settable using Application software ● Stand alone operation enabled using only external power supply ● Capture still and video image ● Able to save the parameter data <p>Videoscope- VS-118-200</p> <ul style="list-style-type: none"> ● 1.18 mm x 200 cm L diameter ● 3mm-25mm depth of field ● Field of view- 102° ● 40,000 pixel or 200 x 200 format ● Proximal illumination end- universal ACMI adapter <p>Flexible Inspection Scope Accessories-FIS-006</p> <ul style="list-style-type: none"> ● Power Cord <ul style="list-style-type: none"> ○ Consumption of electric current: Maximum 600mA or less ● USB 2.0 cable (A-Micro B)- Plugs into USB port on the computer <ul style="list-style-type: none"> ○ USB Flash Drive- Plugs into USB Port on computer for downloading software and instruction for use ○ Power supply voltage range: 4.5V - +5.5V ○ Consumption electric current: Max. 600mA or less ● Distal camera with connectors- Plugs into control box ● Manual ● Quick Start Guide <p>Flexible Inspection Scope Software- Requirements</p> <ul style="list-style-type: none"> ● Compatible with Operating systems of Windows 10 or above only.

Shipping Conditions & Requirements	
Storage Conditions	<ul style="list-style-type: none"> • Temperature for operational use- 15°C-33°C (59°F-91°F) • Storage temperature- -25°C -50°C (-13°F-122°F) • Store control box in a clean, cool dry environment. • 0-95% RH
Packaging Contents	
Shelf Life	

Instructions for Using Product



Description of Use(s)	For visually inspecting instruments.
Preparation for Use	<p>The device driver must be installed before the software is installed and before the FIS is plugged into the computer. Later on, for future use, you don't have to install the device driver.</p> <p>DEVICE DRIVER INSTALLATION:</p> <p>Note: This section is done only once, when connecting the scope to the computer for the first time.</p> <p>The device driver installation procedure is shown below.</p> <ol style="list-style-type: none"> 1. Remove the USB stick and plug into the USB port. Fig. 1  <p style="text-align: center;">Figure 1</p> <ol style="list-style-type: none"> 2. Open the USB stick folder. You will see two folders in it. <ul style="list-style-type: none"> • Healthmark Scope Viewer • Software Driver 3. Copy the contents of both folders of the USB stick to your PC and then disconnect the USB. 4. Next, To use the FIS-006 plug in the AC adapter into the back of the control box, then plug in the power cord into the power outlet. Fig. 2  <p style="text-align: center;">Figure 2</p> <ol style="list-style-type: none"> 5. Plug in the Flexible Inspection Scope connectors (light source and camera cable connector) into the two portals located in the front of the control box. 6. Align the red dot on the camera cable connection pins with the red dot on the connector portal on the control box. Note: Detach the silver soaking cap from the proximal connection (pins) on the camera cable prior to connecting to the control box. Fig. 3



Figure 3

7. Plug in the USB connector to the USB port into your computer and into the back of the control box. **Fig. 4, 4A**



Figure 4



Figure 4A

8. Press the ON/OFF button to ON (will turn green when powered on). **Fig. 5**



Figure 5

9. Go to the search bar and type in Device Manager and click on Device Manager.
10. Then you will see "FIFB-040K-01" in "Other devices" section

11. Right click on "FIFB-040K-01" and Select "Update driver". **Fig. 6**

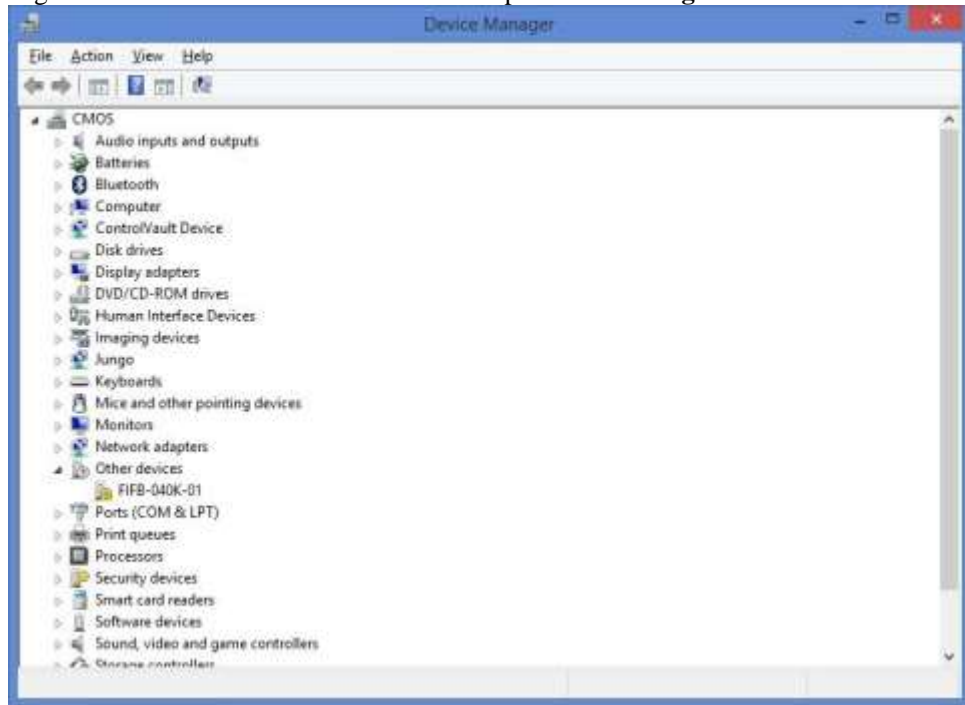


Figure 6

12. "Update Driver Software FIFB-040K-01" window opens. Select "Browse my computer for driver software". **Fig. 7**



Figure 7

13. Browse and Select the Software-Driver folder on your PC , which you have copied from the USB stick

14. Click on next.

15. Click on Install to start installing Device driver software. **Fig. 8**

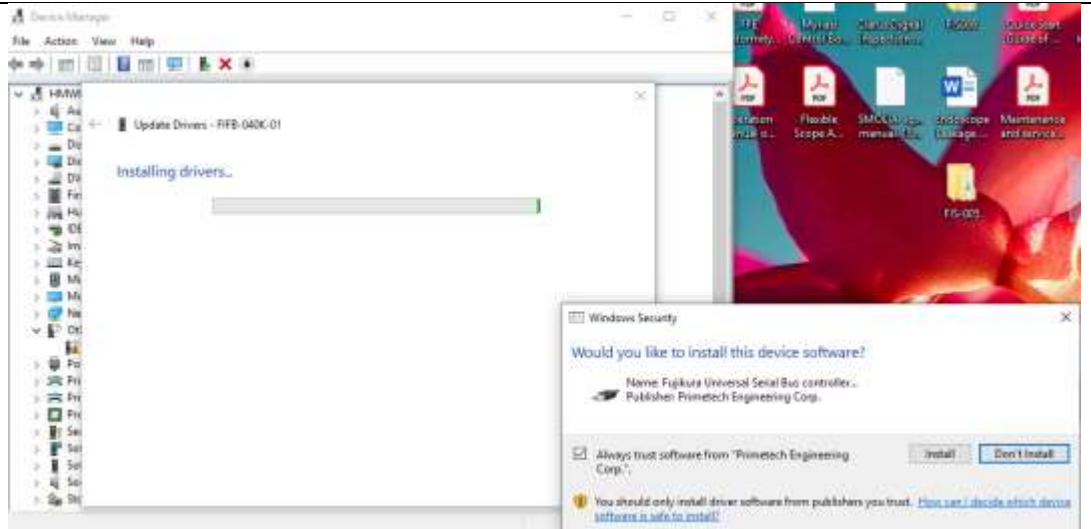


Figure 8

16. After it gets updated, "Windows has finished installing the driver software for this device" message is displayed. Click "Close". **Fig. 9**

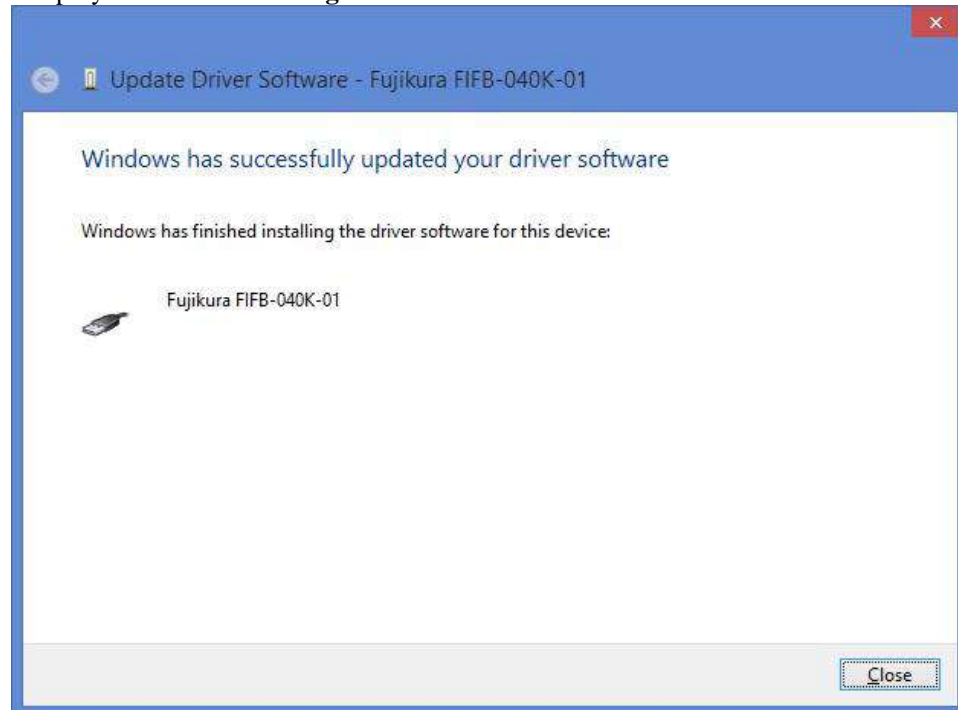


Figure 9

CONNECTING SCOPE TO PC:

1. To use the FIS-006 plug in the AC adapter into the back of the control box, then plug in the power cord into the power outlet. **Fig. 1**



Figure 1

2. Plug in the Flexible Inspection Scope connectors (light source and camera cable connector) into the two portals located in the front of the control box.
3. Align the red dot on the camera cable connection pins with the red dot on the connector portal on the control box. **Note:** Detach the silver soaking cap from the proximal connection (pins) on the camera cable prior to connecting to the control box. **Fig. 2**



Figure 2

4. Plug in the USB connector to the USB port into your computer and into the back of the control box. **Fig. 3, 3A**



Figure 3



Figure 3A

5. Press the ON/OFF button to ON (will turn green when powered on). **Fig. 4**



Figure 4

STARTING SOFTWARE

1. Open the folder Healthmark Scope Viewer from your PC.
2. Once the folder is open, click on hmarkscopeviewer.exe file. **Fig. 5**

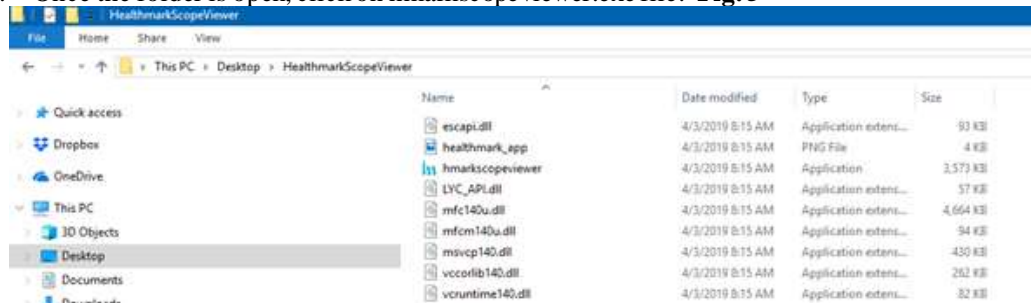


Figure 5

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.

VERIFYING OPERATION

IMAGE-

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

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, turn the black knob on the control box to the right to increase the brightness or turn the knob to the left to decrease the brightness on the Flexible Inspection Scope.

USING SOFTWARE

Healthmark Viewer Software Fig. 6

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.

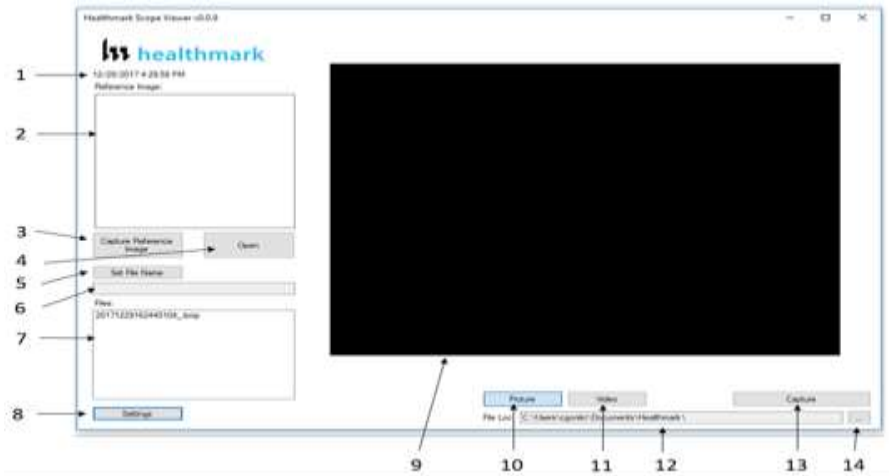


Figure 6

Selecting the Video Device or Camera Fig. 7

1. Click the 'Settings' Button in the lower left corner 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.

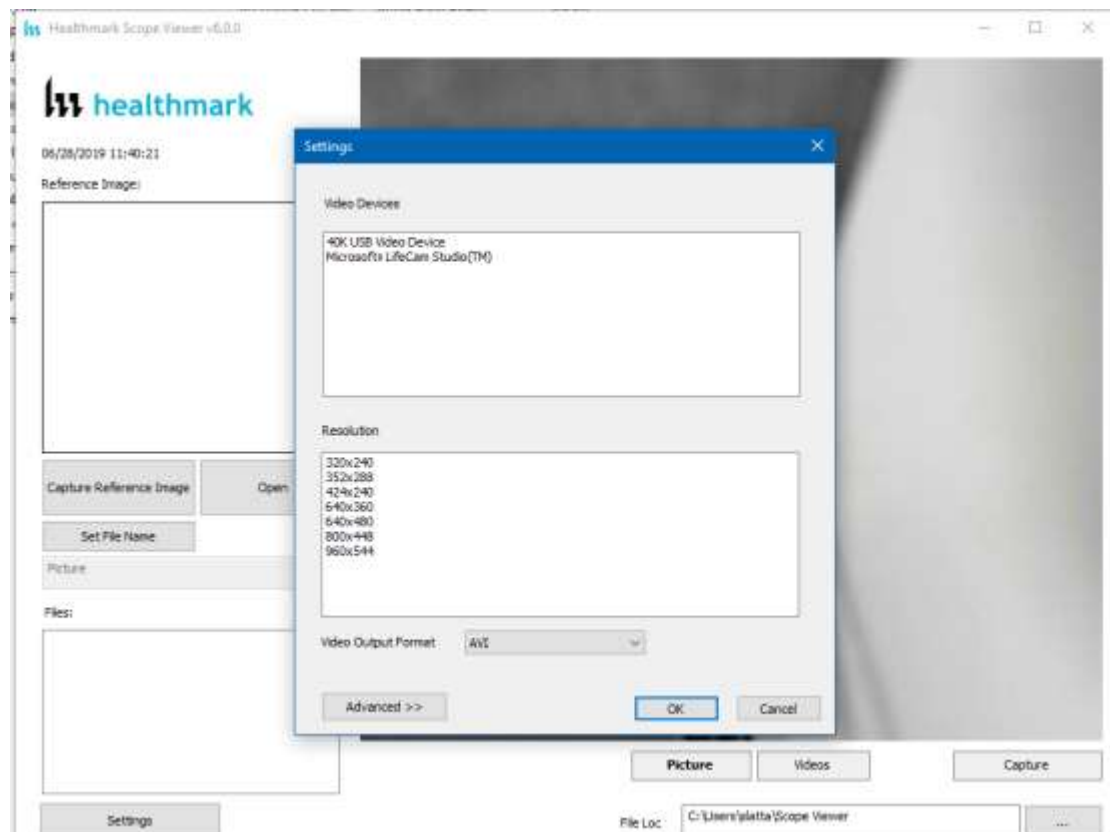


Figure 7

Changing the Video Output Format Fig. 8

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

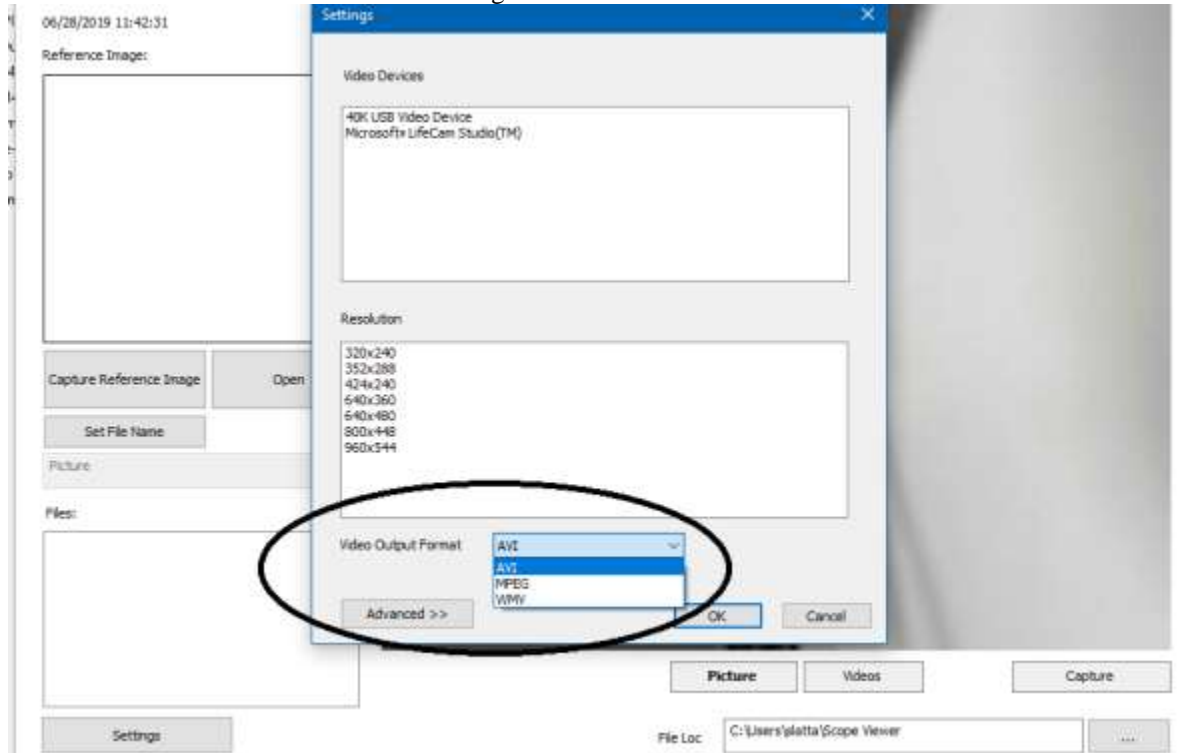


Figure 8

Capturing Still Pictures

1. Select the 'Picture' Button on the software. Fig. 9

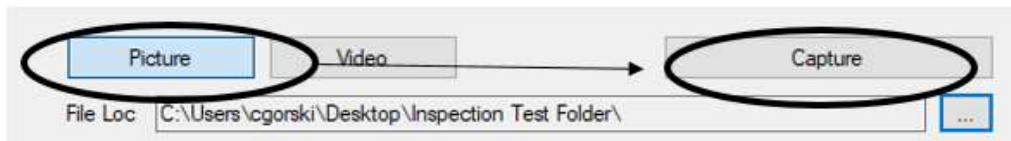


Figure 9

2. Use any of the following options to capture an image:
 - A. Click 'Capture' on the Healthmark Viewer Software. Fig. 9 Or
 - B. 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. 10

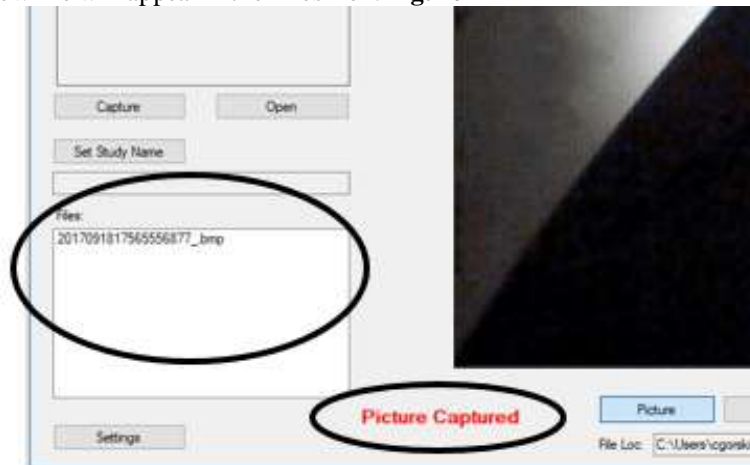


Figure 10

Capturing Video Images

1. Select the 'Video' Button on the Software. **Fig. 11**



Figure 11

2. Use any of the following options to start and stop the video:
 - A. Click the 'Capture' Button on the Healthmark Viewer Software. **Fig. 11**
 - B. 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. 12**
4. To stop recording, use any method as described in Step 2 above for stopping the video. **NOTE:** The Image Capture Button will now read 'Stop Video' while recording. **Fig. 12**

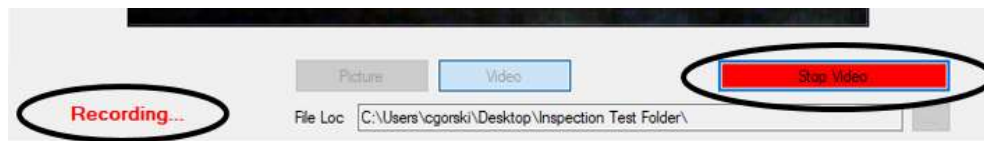


Figure 12

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. 13**



Figure 13

2. To display a saved image in the Reference Image Window from you File Loc:
 - A. Click the 'Open' Button. **Fig. 14**
 - 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.

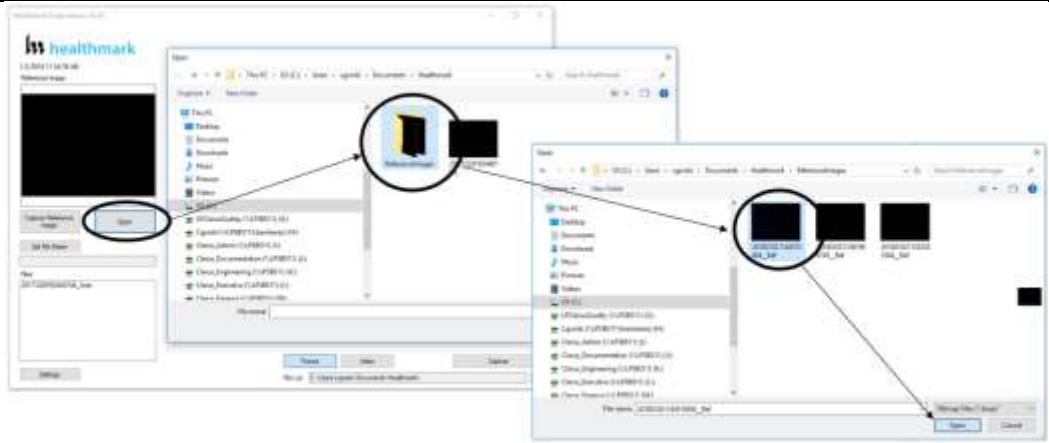


Figure 14

Setting File Name

1. Click 'Set File Name' Button. **Fig. 15**
2. Enter the characters that you would like to be included in the file name. **Fig. 15A**
3. Click the 'OK' Button to set as default name.

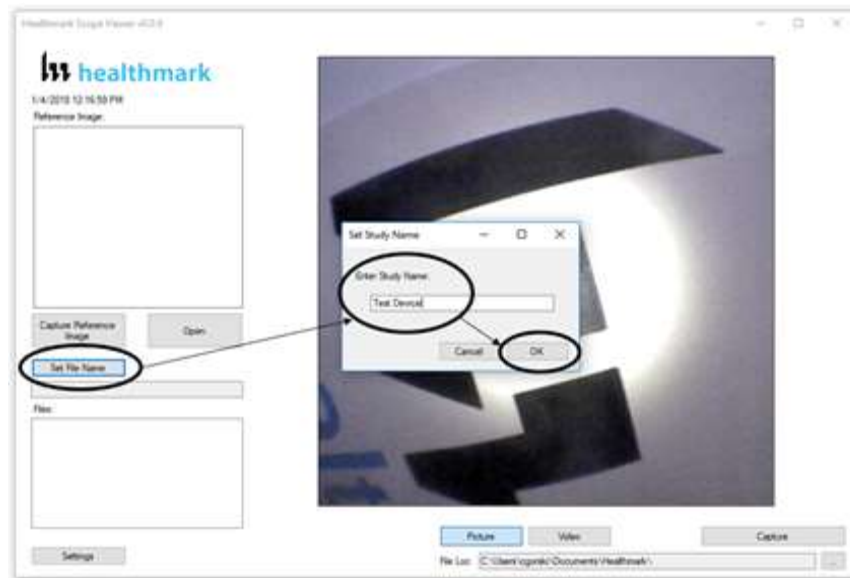


Figure 15

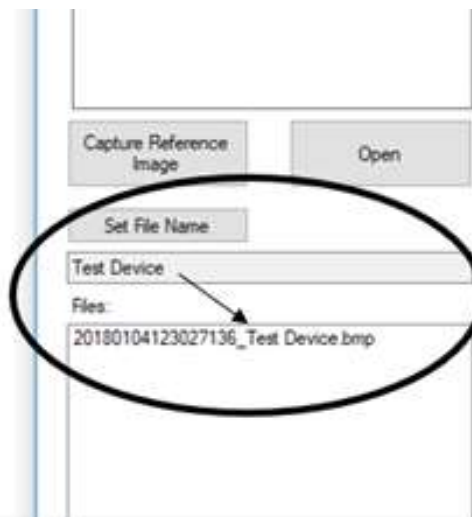


Figure 15A

Setting Location for Saved Files

1. Click the Ellipse Button. **Fig. 16**

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

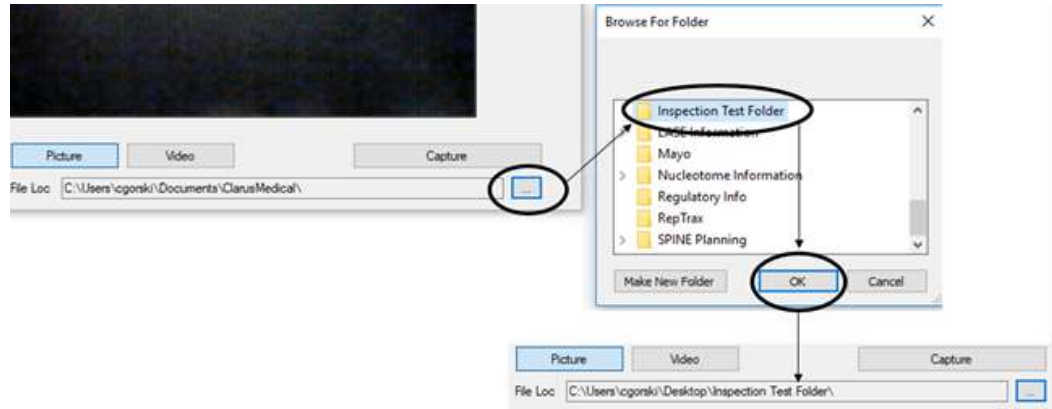


Figure 16

Deleting Saved Files

The Files Window **Fig. 17** in the Healthmark Viewer displays image files that are being stored in the File Loc **Fig. 17**. To delete files, go to the location (shown in the File Loc) on the computer, outside of the Healthmark Viewer Software.

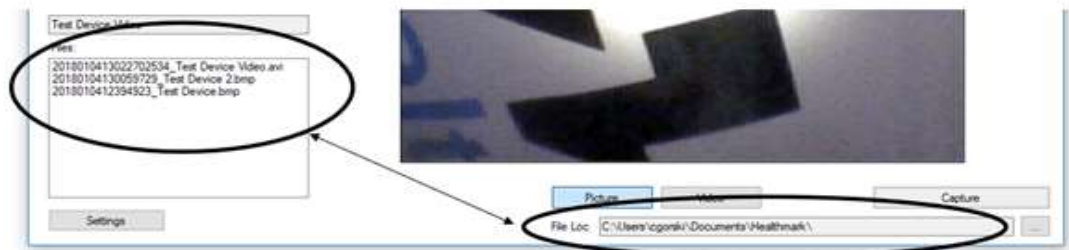


Figure 17

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

1. Click the Ellipse Button. **Fig. 18**
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 18

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.
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".

**Diagrams
(drawings,
pictures)**



Figure 1



Figure 2



Figure 3

**Steps for Use of
Product**

PERFORMING INSPECTION

1. Grasp the Flexible Inspection Scope near its distal end and gently insert the Flexible Working Length in the intended instrument. **Fig. 1**
2. Adjust the light on the Flexible Inspection Scope by turning the black knob (left to decrease or right to increase) on the control box for ideal lighting. **Fig. 2**
3. 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. 3**
4. 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**

1. Do not use Ethylene Oxide, autoclave, ultrasonic, chlorides, formaldehyde, or hydrogen peroxide.
2. Avoid damaging this product by dropping, spilling, or soaking in liquids.
3. Never look directly into the light source when it is on. Point its light away from others.
4. Check all items upon receipt to assure damage has not occurred during shipment.
5. Verify compatibility of all scopes and accessories attaching to the control box by contacting Healthmark.
6. Avoid storing the control box in areas of heavy traffic to prevent accidental physical damage.
7. Do not disassemble this product. There are no user-serviceable parts. Disassembly voids warranties.
8. Do not immerse the 160K video control box in any liquids.
9. Prior to use, check the outer surface of the control box, endoscope and any endoscopically-used accessories for rough surfaces, sharp edges, burrs or protrusions that may cause a safety hazard.
10. Do not puncture or incinerate the battery, this contains explosive/flammable material.
11. Do not expose the control board to high temperatures above 122°F/50°C.
12. Do not disassemble leaking battery.
13. The endoscope should be removed if the equipment is not likely to be used for some time. Store video Control box in a cool dry location out of direct sunlight.
14. Never expose the AC adapter to water or moisture; do not use if it is wet.
15. Do not disassemble the charger; there are no user-serviceable parts inside.
16. The control box is sealed with IP65 protection against ingress of fluids only when assembled. This means the unit is splash proof not soak-able.

Disposal	<ul style="list-style-type: none"> This can be disposed of the same as the standard electrical products. Follow your local regulations for disposal of electrical components.

Reprocessing Instructions	
Point of Use	
Preparation for Decontamination	<ul style="list-style-type: none"> Attach the soaking cap onto the camber connection to prevent the pins from being exposed 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>Note: Do not attempt to screw the soaking cap onto the connection pins as this will break the unit.</p> <ul style="list-style-type: none"> To remove, pull the soaking cap off from the proximal connection (pins). Do not unscrew the cap off as this will break the unit.
Disassembly Instructions	
Cleaning – Manual	<p><u>Control Box</u></p> <ol style="list-style-type: none"> Clean using isopropyl alcohol. Clean the control box immediately after the device has become contaminated. This will prevent patient material from adhering to the controller. Gently wipe all debris from the exterior surfaces using a non-linting wipe and water and add a low sudsing detergent, diluted in accordance with the detergent manufacturer’s instructions. After the control box has been thoroughly cleaned please store it in a clean and dry environment. <p><u>Cable</u></p> <ol style="list-style-type: none"> Use a pre-moistened cleaning wipe. See Chemical Compatibility Chart for approved cleaning agents click here; Follow the wipe manufacturer’s IFU. <p><u>Camera</u> Cleaning Between Uses:</p> <ol style="list-style-type: none"> Use a pre-moistened cleaning wipe. See Chemical Compatibility Chart for approved cleaning agents click here; Follow the wipe manufacturer’s IFU. <p>For Thorough Cleaning: Cable Follow the cleaning agent manufacturer’s instructions for use.</p> <ol style="list-style-type: none"> Unplug and disconnect all components from the Control box prior to cleaning. Cable is not waterproof. Therefore, do not submerge or soak the cable for disinfection. 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. Rinse with non-linting wipe moistened with AAMI Utility Water for 45 to 60 seconds, dry with non-linting wipe. <p>For Thorough Cleaning: Camera Follow the cleaning agent manufacturer’s instructions for use.</p> <ol style="list-style-type: none"> Unplug and disconnect all components from the Control Box. Secure the Soaking Cap on the Flexible Inspection Scope Camera Connector. Camera is waterproof and can be submerged. Wipe thoroughly with non-linting wipe with a facility approved neutral pH detergent. Use the appropriate brushes with detergent solution to remove any residues from the areas that cannot be reached with the wipes. Rinse with non-linting wipe moistened with AAMI Utility Water for 45 to 60 seconds, dry with non-linting wipe. <p>Reprocessing Chemical Compatibility Chart click here;</p>
Cleaning – Automated	
Disinfection	Control Box

	<p>Follow the disinfection agent manufacturer's instructions for use.</p> <ol style="list-style-type: none"> 1. Do not immerse the control box it is not waterproof. 2. Select only the disinfecting solutions listed in the Chemical Compatibility Chart. <p>Cable</p> <ol style="list-style-type: none"> 1. Do not immerse the cable. It is not waterproof. 2. Select only the disinfecting solutions listed in the Chemical Compatibility Chart. 3. Follow the disinfection manufacturer's instructions for use. <p>Camera</p> <p>Secure the Soaking cap on the Flexible Inspection Scope Camera Connector.</p> <ol style="list-style-type: none"> 1. Soak the Flexible Inspection Scope in the selected solution per the solution manufacturer's instructions for high level disinfection. 2. Rinse the Flexible Inspection Scope following the instructions of the disinfecting solution manufacturer. 3. Dry with a 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	<p>Troubleshooting:</p> <table border="1"> <thead> <tr> <th>Problem</th> <th>Possible Cause</th> <th>Action</th> </tr> </thead> <tbody> <tr> <td>Loss of Illumination</td> <td>Ac power is damaged</td> <td>Check power unit</td> </tr> <tr> <td>Loss of Image Quality</td> <td>Software Issue</td> <td>Return to default software setting</td> </tr> <tr> <td>Light Guide does not attach properly to the endoscope</td> <td>The endoscope and light source do not have a compatible coupling system</td> <td>Refer to the guide below and remove the adapter</td> </tr> </tbody> </table>	Problem	Possible Cause	Action	Loss of Illumination	Ac power is damaged	Check power unit	Loss of Image Quality	Software Issue	Return to default software setting	Light Guide does not attach properly to the endoscope	The endoscope and light source do not have a compatible coupling system	Refer to the guide below and remove the adapter
Problem	Possible Cause	Action											
Loss of Illumination	Ac power is damaged	Check power unit											
Loss of Image Quality	Software Issue	Return to default software setting											
Light Guide does not attach properly to the endoscope	The endoscope and light source do not have a compatible coupling system	Refer to the guide below and remove the adapter											
Reassembly Instructions													
Packaging													
Sterilization	<ul style="list-style-type: none"> • V-Pro Non-Lumen/Standard Cycle • Maximum number of sterilization cycles is 20. 												
Storage	<ul style="list-style-type: none"> • Temperature for operational use 0°C (32°F) to 40°C (104°F). • Storage temperature -10°C (14°F) to 60°C (140°F). 												
Additional Information													
Related Healthmark Products	Flexible Inspection Scope Kit												
Other Product Support Documents	ProSys™ Brochure, ProSys™ Price List												
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>												

Suzanne Latta