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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	**Flexible Inspection Scope Features and Connections- FIS-005**
	● Overall length of Digital Inspection Scope- 128cm (50.4").
	● Weight- 18.2 grams (0.64oz.)
	● Optical
	  ○ Field of View- 120º in air
	  ○ Angle of View- 0º
	● 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.
	
	Flexible Inspection Scope Accessories- FIS-005SK
	● 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.

	Flexible Inspection Scope Software- Requirements
	• Compatible with Operating systems of Windows 10 or above only.

Shipping & Storage	
Shipping Conditions & Requirements	N/A
Storage Conditions	N/A
Packaging Contents	N/A
Shelf Life	N/A

Instructions for Using Product	
Description of Use (s)	Use the inspection scope to directly inspect internal channels.
Preparation for Use	• Remove the USB stick and plug into USB port. 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.
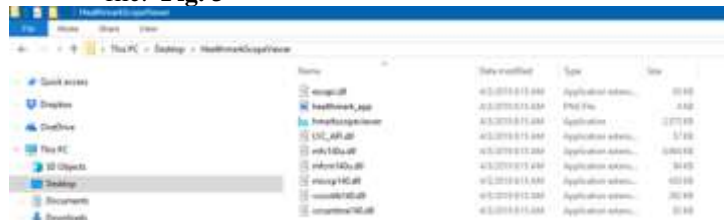2. Once the folder is open, click on hmarkscopeviewer.exe file. **Fig. 3**

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.
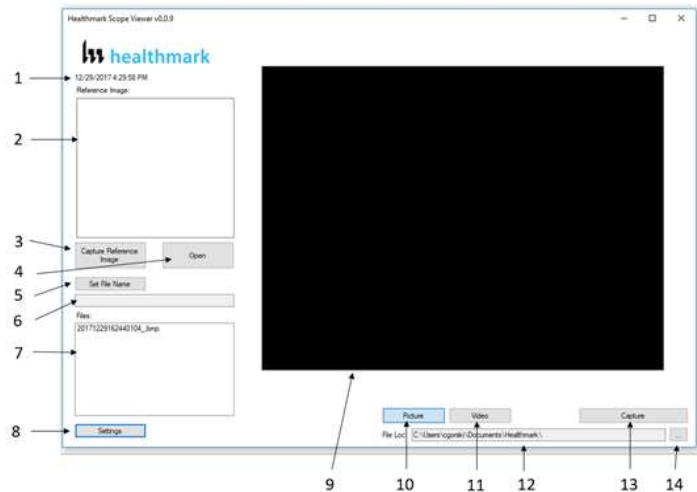

Figure 4

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.
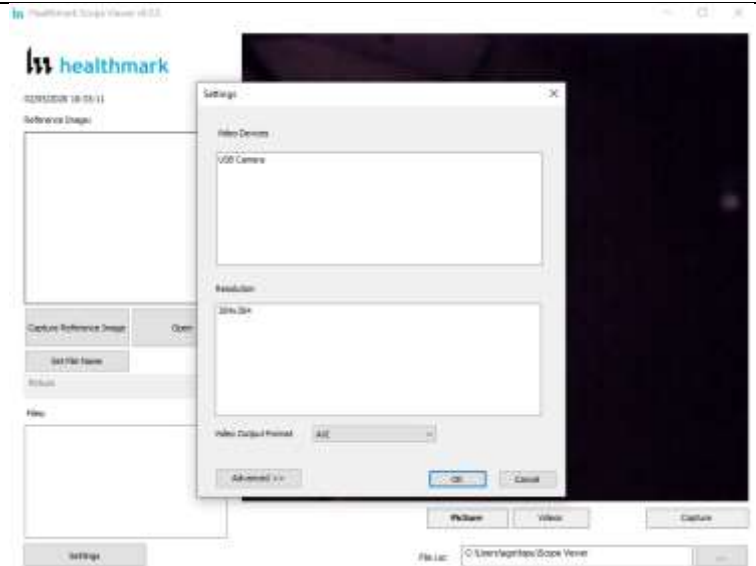3. Click 'OK' to view the selected Video Device.

Figure 5

Changing the Video Output Format Fig. 6

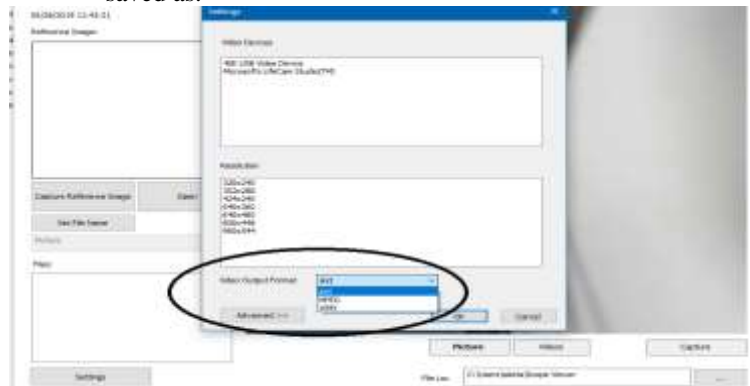1. Select from the down arrow to change which format to be saved as.

Figure 6

Capturing Still Pictures

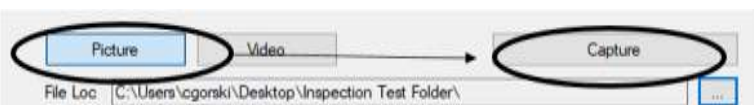1. Select the 'Picture' Button on the software. **Fig. 7**

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**
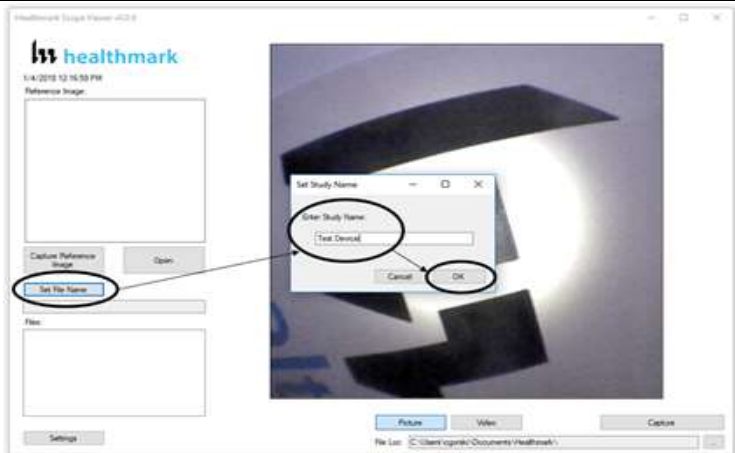3. Click the 'OK' Button to set as default name.
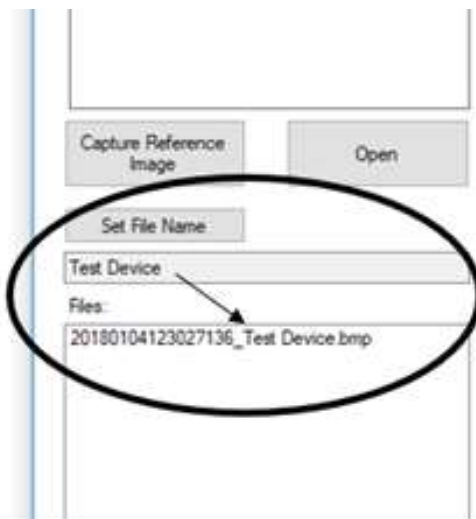
Figure 13

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
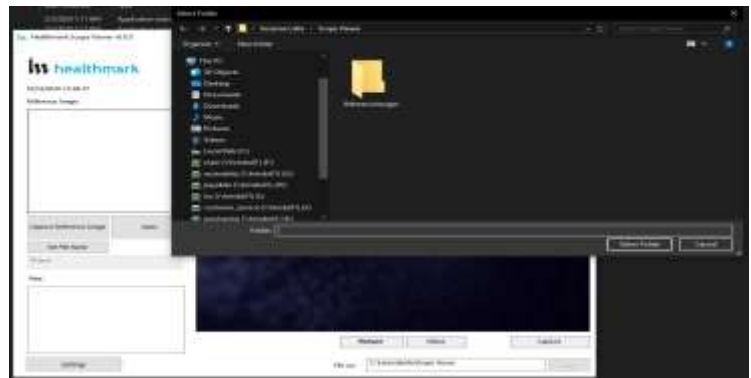
Figure 16
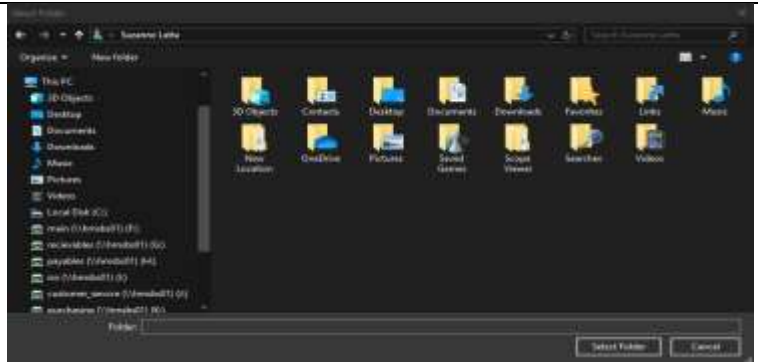
Figure 17

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**
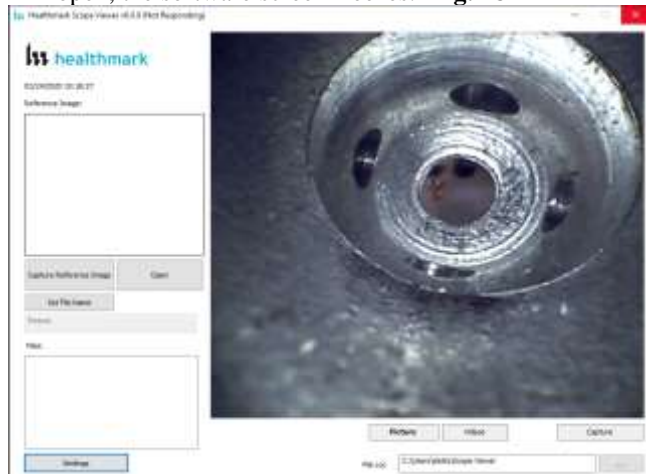
Figure 18

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.

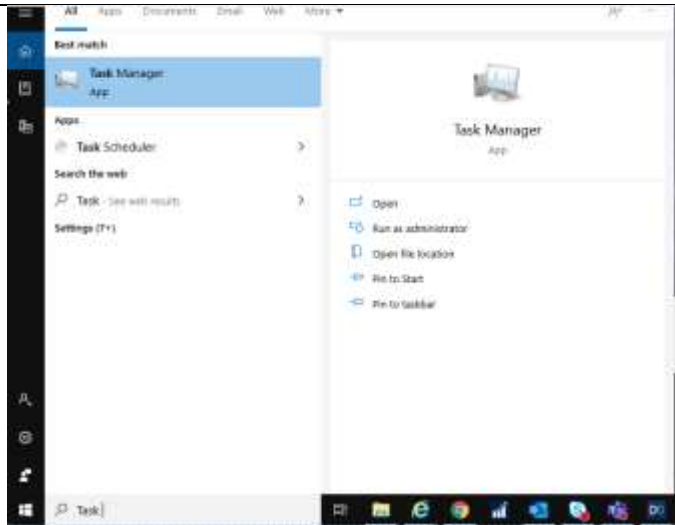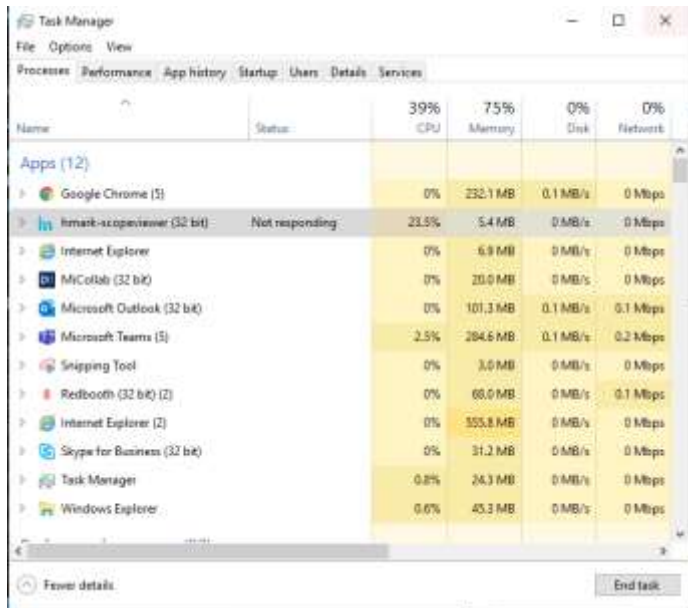|	
	Before After ILLUMINATION 1. The illumination capability of the Flexible Inspection Scope can be verified prior to use. Once the scope is connected to the computer with the power on, the distal tip of the Flexible Inspection Scope will cast visible light from its tip and can be observed on any surface 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.
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	N/A
Contraindications of Test Results	N/A
Documentation	N/A
Special Warnings and Cautions	- 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	N/A

Reprocessing Instructions	
Point of Use	N/A
Preparation for Decontamination	N/A
Disassembly Instructions	Disconnect the Camera Cable from the Flexible Inspection Scope prior to cleaning.
Cleaning – Manual	**Cleaning Between Uses:** 1. Use a pre-moistened cleaning wipe. See Chemical Compatibility Chart for approved cleaning agents click here: 2. Follow the wipe manufacturer's IFU. **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

	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.
	For Thorough Cleaning: Follow the cleaning agent manufacturer's instructions for use. 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. Reprocessing Chemical Compatibility Chart click here:
Cleaning – Automated	N/A
Disinfection	● 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. Reprocessing Chemical Compatibility Chart click here:
Drying	N/A

Maintenance, Inspection, and Testing	- 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	N/A
Packaging	N/A
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	- Store the instrument no higher than 60ºC or lower than -20ºC. - Store the equipment in a clean, dry and ventilated location.
Additional Information	- 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	N/A
Customer Service Contact	Healthmark Industries Company, Inc 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com

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