Instructions for Use

Healthmark Inspection Scope Camera FIS-001
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1.0 INTRODUCTION
The Healthmark Inspection Camera is intended for inspection of medical and surgical instrumentation after cleaning, and prior to sterilization, or post sterilization. It may be used on the outside or inside surfaces of instruments including devices such as arthroscopy routers, shavers, reamers, and Yankauer etc.…

2.0 PURPOSE
This Instructions For Use (IFU) manual describes how the camera device is to be used. Software installation instructions are also included.

This IFU contains essential information on using this device safely and effectively. Before use, thoroughly review and be familiar with this manual and the manuals of all equipment that will be used during the inspection procedure. Use the devices as instructed. Keep this and all related instruction manuals in a safe, accessible location. If you have any question or comment about any information in this IFU, please contact Healthmark at (800) 521-6624 x6657 or e-mail at hmitdesk@hmark.com.

3.0 GENERAL DESCRIPTION
The Healthmark Inspection Camera has an extrusion with a light source and camera lens at the distal tip. The outer diameter of the extrusion and camera head is 3.1mm max. The device should never be inserted into a lumen or working space smaller than 3.2mm in diameter. Any smaller lumen may cause the device to become stuck, rendering the inspected equipment unusable, and possibly damaging the camera device.

- Use this device only in spaces 3.2mm or larger in diameter.

The camera extrusion is 50cm from the distal tip to the control handle. Using the camera device in lumens longer than this may lead to inadequate inspection because the target areas to be inspected may be beyond the effective focal length of the device.

- Ensure that all areas of equipment to be inspected are accessible by the inspection camera; failure to do so may lead to inadequate inspection.

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Healthmark Inspection Camera

- Proximal End
- Distal End
- Handle
- Extrusion
- Distal Tip
- Camera Handle

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4.0 SOFTWARE INSTALLATION

4.1 System Requirements:

The computer in which the software will be installed must meet the following requirements:

- Platform: Windows XP or Windows 7 (32-bit or 64-bit)
- RAM: 4GB minimum
- One USB 2.0 port

4.2 Procedures:

The Healthmark Inspection Camera software installation consists of two (2) steps:

1) Device Driver Installation, and
2) Application Software Installation.

4.3 Device Driver Installation

4.3.1 Turn on the Target Computer.

4.3.2 Proceed to log into the Windows desktop environment.

4.3.3 Do not connect any Healthmark camera device to the computer during the installation process unless instructed to do so.

4.3.4 Obtain the Installation software on the flash drive provided and insert it into the port of the target computer. Then open “My Computer” and look for the Healthmark CD drive.

4.3.5 Double click on the Healthmark drive to open the software folder.
4.3.6 Determine System Architecture of target computer:

Determine whether your computer is running a 32-bit version or 64-bit version of the Windows operating system. If you need more information regarding how to check, you may refer to http://support.microsoft.com/kb/827218 for more details.

4.3.7 Locate the proper device driver installer:

Open the Healthmark folder. Depending on 32-bit or 64-bit system architecture, double click and open the “32bit_driver” or “64bit_driver” folder accordingly.

4.3.8 Initiating the driver installer - double click and run the following file:

4.3.8.1 For 32-bit system: Cy2510Installation.msi

4.3.8.2 For 64-bit system: Cy2510Installation_x64.msi

4.3.8.3 Then proceed as guided by a series of pop-up dialog boxes from the InstallShield Wizard. Click the “Next” Button to continue.

4.3.8.4 Review and accept the License Agreement. Click the “Next” Button to continue.
4.3.8.5 On the “Customer Information” page, enter the desired information. Then click the “Next” button.

4.3.8.6 On the “Setup Type” page, choose “Complete” option to install all necessary components. Then click the “Next” Button.

4.3.8.7 Click the “Install” Button on the next dialog box screen.
4.3.8.8 After clicking “Install” on the “Ready to Install the Program” screen, a Windows dialog box with the title “User Account Control,” may pop up and display a question similar to:

“Do you want to allow the following program from an unknown publisher to make changes to this computer?”

“Program name:…Cy2510Installation_x...msi”

In case this Windows dialog box pops up, click the “Yes” Button to continue.

4.3.8.9 Another Windows Security pop-up dialog box (shown below) may appear and display a question:

“Windows can’t verify the publisher of this driver software.”

Choose the option, “Install this driver software anyway.”

4.3.8.10 Review the next pop-up dialog box. Then click the “OK” Button to proceed.
4.3.8.11 At the InstallShield Wizard Completed screen, click the “Finish” Button to proceed.

4.3.9 Connect a Healthmark Inspection Camera to USB2.0 port of the computer using the provided USB cable.

4.3.10 A Windows balloon message may pop up at the lower right-hand corner and display a message: “Installing device driver software”.

4.3.11 When the Windows finishes installing the device driver, another balloon message may pop up at the lower right-hand corner and display a message:

“Sanovas zvCy2510 winUSB” and “Device driver software installed successfully.”
4.4 Application Software Installation

If the Healthmark Application Software has been installed on the computer before, continue to install the new application software to obtain the latest software update.

4.5 Locate the application software installer on software CD:

Open the HealthMark_Install_Package folder, and locate the file “setup.exe”.

4.6 Double click and run the file “setup.exe” from the “HealthMark_Install_Package” folder.

4.7 Install .NET Microsoft Framework 4.0 if prompted.

If the computer has not previously been installed with Microsoft .NET framework 4.0 or above, a pop-up dialog box will appear to install the required .NET framework files. Click on the “Install” Button to install .NET Microsoft framework 4.0.

The installing process for Microsoft .NET Framework 4.0 may take a few minutes.
4.8 Proceed with installation wizard until finished.

If Microsoft .NET Framework 4.0 or above are installed successfully, proceed by clicking the “Next” Button.

4.9 Review and accept the License Agreement. Click the “Next” Button to continue.

4.10 On the “Customer Information” page, enter the desired information. Then click the “Next” button.
4.11 On the “Setup Type” page, choose “Complete” option to install all necessary components. Then click the “Next” Button.

![Complete Setup Type Page]

4.12 Click the “Install” Button on the next dialog box screen, “Ready to Install the Program.”

![Ready to Install the Program]

4.13 A Windows “User Account Control” pop-up dialog box may appear and display a question:

“Do you want to allow the following program from an unknown publisher to make changes to this computer?”

“Program name: …HealthmarkInstallation.msi”.

If this dialog box appears, click “Yes” to continue.
4.14 When the InstallShield Wizard is completed, click the “Finish” Button to end the installation.

![InstallShield Wizard Completed](image)

4.15 Connect a Healthmark Inspection Camera device to the computer.

4.16 Starting the Program

Double click the “HealthMark1.0.6.14.exe” shortcut from the Desktop to run the program.

![HealthMark1.0.6.14](image)

If the shortcut is not available, navigate to the folder C:\Sanovas\Healthmark1.0.6.14, and locate the “HealthMark.exe” program. Double click and run the program.

4.17 An “Imaging Software” dialog box will then appear. Click the “OK” Button to proceed.

![Imaging Software](image)
4.18 The Main window of the camera software will now appear:

![Main window of camera software](image)

If any of the above pop-up dialog box does not come up, please refer to troubleshooting or contact Sanovas for support.

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5.0 MITIGATING RESIDUAL DEVICE RISKS

5.1 Do NOT immerse / submerge the camera device in liquid as a residual risk of user shock remains in this scenario.

5.2 Do NOT make rapid hand motion with the device as the flexible shaft section may whip and cause eye-injury or abrasion on impact with body parts.

5.3 Do NOT use the device to poke or attempt to pierce any object as it may cause serious eye-injury or abrasion on impact with body parts in addition to device damage.

5.4 Do NOT subject the device to excessively high temperatures above 120 °F as the materials of construction are not designed to operate under these conditions.

5.5 Do NOT allow the device to be subject to any liquid splash as a residual risk of user shock remains in this scenario.

5.6 Do NOT grasp and handle the device from the camera head as a residual risk of fatigue damage to the distal tip of the device remains in this scenario.

5.7 Do NOT use the device handle to strike or hit any object. Serious harm to body and/or device may result.

5.8 Do NOT over bend the flexible device shaft to a point of kinking. It may cause damages to electronic components and render the camera un-operational.

5.9 Do NOT plug the USB cable into any port other than a USB2.0 (or later version) port on a computer.

5.10 Use only the USB cable provided with the device. Using other cables may lead to interference with surrounding electronic devices and potential performance deterioration.

5.11 Do NOT attempt to disassemble or repair the device yourself. Doing so voids the limited warranty and could cause harm to the user and/or the device.

6.0 TROUBLESHOOTING

Please read through the following guide and verify your installation. If you encounter problems running the software, contact Sanovas for support.

6.1 Software Updates

Please make sure you have the latest version of software and firmware on the camera.

6.2 Compatibility

Software, Firmware and Hardware components all have version requirements in order to function as described. Refer to Software Release Notes for any known compatibility requirements and/or issues.

6.3 Administration Privileges

Administration privileges are necessary in order to install Healthmark software on a computer. Please contact your IT administrator for support.
6.4 Device driver installation verification

After you install the device driver and connect the Healthmark Inspection Camera, locate the Device Notification icon at the lower right-hand corner.

![Device Notification Icon]

Click on the Device Notification icon. If the device driver installation was successful and the provided Healthmark device is valid, the option “Eject Cyp-ver1.7” should be available.

Otherwise, uninstall the device driver “Cy2510Installation_x64” or “Cy2510Installation_x32,” under the Windows Control Panel and reinstall the device driver again.

![Eject Cyp-ver1.7 Option]
6.5 Install Device Driver on Windows 8 or higher

The Healthmark software requires a platform of either Windows XP or Windows 7. However, if it is necessary to install it on a Windows 8 system, the driver signature verification will need to be disabled in order to install unsigned drivers. Follow the procedures below:

6.5.1 Press the Win + C keyboard combination to bring up the Charms Bar, and click on the Settings Charm.

6.5.2 Go to Control Panel by clicking on the Change PC settings link.
6.5.3 When the Control Panel opens, click and switch to the “Update & recovery” section.

6.5.4 Click on the “Recovery” option on the left hand side.

6.5.5 Once selected, you will see an advanced startup section appear on the right hand side. Click on the “Restart now” button.
6.5.6 Once the computer has been rebooted, choose the “Troubleshoot” option.

![Choose an option](image)

6.5.7 Click on “Advance options”.

![Advanced options](image)

6.5.8 Click “Startup” Settings.

![Advanced options](image)
6.5.9 Click “Restart”.

### Restart to change Windows options such as:

- Enable low-resolution video mode
- Enable debugging mode
- Enable boot logging
- Enable Safe Mode
- Disable driver signature enforcement
- Disable early-launch anti-malware protection
- Disable automatic restart on system failure

6.5.10 A list of startup settings will be shown. Press F7 to choose “Disable driver signature enforcement”.

### Startup Settings

Press a number to choose from the options below:

Use number keys or function keys F1-F9.

1) Enable debugging  
2) Enable boot logging  
3) Enable low-resolution video  
4) Enable Safe Mode  
5) Enable Safe Mode with Networking  
6) Enable Safe Mode with Command Prompt  
7) Disable driver signature enforcement  
8) Disable early-launch anti-malware protection  
9) Disable automatic restart after failure

6.5.11 The computer will then reboot and the unsigned drivers should be able to install without any Windows error message.

6.5.12 Reinstall the device driver per IFU procedures.
7.0 MOUNTING THE HANDLE ON A TRIPOD

There is a screw hole for mounting the handle on a tripod or a hanger that can be utilized.

A metric M6 x 1 Screw can be used to mount the handle.

8.0 PREPARATION & POWER-UP

8.1 Turn ON the PC the Software is installed on.

8.2 Plug the Type Mini-B side of the provided USB 2.0 Cable to the camera handle.

The Mini-B connector looks like:

8.3 Plug the Type A side of the provided USB 2.0 Cable to the computer where the Healthmark software is installed.

The Type A connector looks like:
8.4 Starting the GUI

To run the Healthmark software, locate and double-clicking on the Healthmark program icon on the Windows desktop.

If the shortcut is not available, the application file should be in a folder named C:\Sanovas\ It can also be executed from this folder.

The information pop up window will appear with the following information:

If the Information Popup Box does not come up, try restarting the application or reinstalling the software.

If the popup still does not come up, the Hardware (Device) may be damaged and/or not plugged in properly.

When the Information Popup Box comes up, continue by selecting the “OK” button.

The User Graphical User Interface (GUI) will display on the screen.

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9.0 **GRAPHICAL USER INTERFACE (GUI)**

If the Software and Hardware are both operational and compatible the following program window will appear on the screen (video will be live).

Date & Time are reported on the top right corner.

![Program Window]

9.1 Changing Instrument Name

The Instrument information can be changed so that each video and image taken can be stored in a user defined location. To do this, click on the box that says **<Enter Surgical Instrument Information>**. A key-board will popup enabling the user to change the name of the test/procedure.

![Keyboard Popup]

With either the keyboard on screen or an externally attached keyboard type the name of the test/procedure followed by the “Enter” key.

All images & videos captured will now be stored under the folder.

`ImageData\Date_<Surgical Instrument Information Entered>`
For example:

2013-11-18_SuctionTube

There is no limit to the number of characters that can be entered in this field.

Once the inspection procedure is completed, the name can be modified and the next inspection image data will be stored under the new label.

9.2 Taking Photo(s) Using GUI

To take a still image snapshot, click the “PHOTO” button once.

Each time a photo is captured the capture count will be incremented under the button.

If the “Capture Photo as Reference” radio button is NOT selected, the images will be stored in the folder defined by the Procedure Window.

Files can be retrieved from:

ImageData\Date_< Surgical Instrument Information Entered >
If the “Capture Photo as Reference” radio button is selected, the images will be stored in the “reference” folder under ImageData.

Files can be retrieved from:
ImageData\reference.

The images will be stored in the ImgTimeStamp.png format.

For example:

**Img20131118113255000**, where

- **2013** is the year 2013
- **11** is the 11th month of the year
- **18** is the day of the month
- **113255000** is the time of day the image is taken.

### 9.3 Taking Photo(s) using the button on the device handle

To capture a still image using the Control Handle, press the “PHOTO” button

This will be equivalent to using the GUI and the results will be the same.

Photo Button on handle is as follows:

![Camera Icon](camera_icon.png)

User will observe the image capture behavior in the GUI as previously explained.
9.4 Recording Video(s) Using GUI

To record video, click the “RECORD” button once.

![Screenshot of the GUI with the RECORD button highlighted]

Each time a video is recorded, the time of the video stored will be provided under the button; this will be for the last video that is being recorded. When recording video, the button color will change to red.

The videos will be stored in the VidTimeStamp.avi format.

For example:

Vid20140321101505000, where

- **2014** part is the year 2014
- **03** part is the 3rd month of the year
- **21** part is the day of the month
- **101505000** part is the time of day video recording began.

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9.5 Stop Recording Video(s)
To stop recording video, the “RECORD” button will be clicked once again.
Once the “Record” Button is pressed a second time, the button color will change back to black.

9.6 Recording Video(s) Using Button on Handle
To record video using the Control Handle, press the “REC” button once. This will be equivalent to using the GUI, and the results will be the same.

Record Button on handle is as follows:

![REC button](image)

User will observe the behavior in the GUI as previously explained.

9.7 Stop Recording Video(s) Using Button on Handle
To stop recording video using the Control Handle, press the “REC” button once again. This will be equivalent to using the GUI, and the results will be the same.

Record Button on handle is as follows:

![REC button](image)

User will observe the behavior in the GUI as previously explained.
9.8 Increasing the Illumination Level Using GUI

The “Up Arrow” next to “Illumination” button can be clicked to increase the brightness of the camera light (LEDs).

[100%] would indicate highest level possible.

[000%] would indicate lowest level possible. (LEDs Turned OFF)

The LED brightness is increased by 10% every time the button is pressed.

The GUI will have a different representation of each level selected.

Once 100% is reached if the increase button is pressed again, the LEDs will be turned OFF.

9.9 Increasing the Illumination Level Using Button on Device Handle

To increase the brightness of the camera LEDs, press the “Up Arrow” on the Control Handle. This will be equivalent to using the GUI, and the Illumination change results will be the same.

Up/Down Button on handle is as follows:

The user will observe the Illumination change behavior in the GUI as previously explained.

[100%] would indicate highest level possible.

[000%] would indicate lowest level possible. (LEDs Turned OFF)

The LED brightness is increased by 10% every time the button is pressed.

The GUI will have a different representation of each level selected.
Once 100% is reached if the increase button is pressed again, the LEDs will be turned OFF.

9.10 Decreasing the Illumination Level Using GUI

The “Down Arrow” next to “Illumination” button can be clicked to decrease the brightness of the camera light (LEDs).

[000%] would indicate lowest level possible. (LEDs Turned OFF)

The LED brightness is decreased by 10% every time the button is pressed.

The GUI will have a different representation of each level selected.

Once 0% is reached if the decrease button is pressed again, the LEDs will be turned ON at 100%.

9.11 Decreasing the Illumination Level Using Button on Device Handle

The “Down Arrow” next to “Illumination” button can be clicked to decrease the brightness of the camera LEDs.

The results will be the same.

Up/Down Button on handle is as follows:

![Up/Down Button](image)

The user will observe the Illumination change behavior in the GUI as previously explained.

[000%] would indicate lowest level possible. (LEDs Turned OFF)

The LED brightness is decreased by 10% every time the button is pressed.
The GUI will have a different representation of each level selected. Once 0% is reached if the decrease button is pressed again, the LEDs will be turned ON at 100%.

9.12 Reviewing Stored Images/Video
To review previously stored images or recorded video select the “MENU” button with a single click.

A single click on the “MENU” button will take user to “Tools” Box.

Under the “Tools” Box, select “REVIEW” button with a single click.

A new window with all working folders will be displayed.

Select the folder to be opened.

Click on “OPEN” button to select the folder for review.
A file managing/selecting window will popup, enabling user to select an image or video to replay.

Select the file to be reviewed by double-clicking on it.

The image/video will be displayed in a new window.

To quit, select the “x” button in the Setup Box and “EXIT” button in the Tools Box.
This will take user to the startup interface.

10.0 ACCESSORIES

USB 2.0 Cable:

A standard, RoHS Compliant, USB2.0 Cable, with Type A to Mini B connections, is the only device accessory. Standard cable length is 6ft (2m).

11.0 MAINTENANCE

11.1 Cleaning

The device handle can be cleaned with a damped cloth or wipe with alcohol.

It should not be soaked or dunked into any liquid solution.

**The electronics are NOT designed to be soaked.**

**The Unit will STOP working if submerged under any liquid.**

11.2 Storage

The device can be stored in -20°C to +55°C.

Keep away from liquids, dust and magnetic fields while storing.

12.0 USER NOTICES

12.1 The device does NOT have Field-Wiring Terminal Boxes.

12.2 The device does NOT produce Ionizing Radiation.

12.3 The device is RoHS Compliant.

12.4 The device handle may get warm to the touch. This is normal.

12.5 The device has NOT been tested with MAC OS, older Windows operating systems, or any Virtual Machine and the results are not guaranteed in terms of functionality and performance.

12.6 There would be NO risk in plugging the device to a USB2.0 compliant port on a PC or tablet running an unsupported OS.

12.7 Plugging the device to a non-compliant USB port (i.e. USB 1.0 or USB 1.1 capable only) will not damage the device; however it will NOT function as intended.

12.8 Training is required for end users to use this device.

12.9 The device can and will be packaged in single or bulk quantities.

12.10 The device will be packaged in a way that the flexible shaft is not kinked during the shipment.