

SurgiTel®
A Division of General Scientific Corp.

SurgiCam® HD Digital Camera System
(Doc. No. 26425A)

Two Year Limited Warranty

General Scientific Corp. ("GSC") warrants SurgiCam® HD (Product) against defects in material or workmanship as follows:

ORIGINAL PRODUCT: GSC will repair the product with new or refurbished parts, free of charge, for a period of two (2) years from the date of original purchase in the event of a defect or defects in materials or workmanship.

REPAIRS: GSC will repair or replace defective parts with new or refurbished parts, free of charge. The warranty of repairs is limited for a period equal to the remainder of the original limited warranty period on the original product, or for ninety (90) days after the date of the repair or replacement, whichever is longer.

This warranty is extended only to the original purchaser. A purchase receipt, bill of sale or other proof of date of original purchase will be required before warranty service is rendered. This warranty covers only failures due to defects in materials and workmanship which occur during normal use. The warranty does not cover damages which occurred in shipment, cosmetic damage, damage that is attributable to acts of God, failures which are caused by products not supplied by the warrantor, or failures which result from accident, misuse, abuse, neglect, mishandling, faulty installation, misapplication, improper installation, operation or maintenance, alteration, modification, introduction of sand, humidity or liquids, line power surge, improper voltage supply, lightning damage, or subjecting the product to operating/environmental conditions in excess of the maximum values or below the minimum values set forth in the applicable specifications, or products serviced by anyone other than GSC.

This warranty is invalid if the factory-applied serial number has been altered or removed from the product or if the camera casing has been opened. This warranty does not cover products sold AS IS or WITH ALL FAULTS. This warranty excludes all optical lenses.

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Some states do not allow the exclusion or limitation of incidental or consequential damages, or allow limitations on how long an implied warranty lasts, so the above exclusions or limitations may not apply to you. This warranty gives you specific legal rights and you may also have other rights which vary from state to state. If a problem with this product develops during or after the warranty period, please contact:

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1. Introduction

Thank you for choosing the SurgiCam® HD Digital Camera System. Designed from the ground up with ease-of-use in mind, this digital video camera will allow you to simply and easily record procedures from your perspective.

We suggest that you take a few minutes to consult this manual before you begin to use your SurgiCam® HD Digital Camera System. By doing so, you will reap the full benefits of what your digital camera has to offer.

1.1. The SurgiCam® HD Digital Camera System

The SurgiCam® HD Digital Camera is a digital video device. Compared to an analog device, the SurgiCam® HD Digital Camera digitally acquires video data, compresses it and transfers it to your computer in its digital form over the USB standard.

The lenses of your SurgiCam® HD Digital Camera System have been pre-calibrated in order to obtain the clearest and sharpest picture in operating room light conditions. This eliminates most of the adjustments you would normally have to perform.

Each individual lens is calibrated for use on your own camera at a distance to match your normal working distance. It is possible to operate the camera from a different focal distance; however, some adjustments are required.

Your SurgiCam® HD Digital Camera System may be used with lenses other than the ones it came with. If you choose to do so, please contact your General Scientific Corp. representative for information about different magnification lenses available.

Specifications:

- Video Resolutions: choose from 1080p, 720p or 480p
- Video Framerates: choose from 20, 25, or 30fps
- Screenshot resolution: 2MP
- File format: AVI



The digital camera requires good lighting conditions to perform optimal quality video and images. The camera does not perform well in less illuminated conditions. The use of a complementary head light is recommended.

1.2. Sterilization



DO NOT STERILIZE THE CAMERA.

Attempting to sterilize the camera or any other part will most likely damage it.

The SurgiCam® HD Digital Camera must not be sterilized. It is designed to be used in a non-sterilized zone. It is recommended to perform the adjustments before its use in a surgical environment. When mounted on an operating room tripod, the use of a protective sterile drape is strongly recommended.

1.3. Interference from Other Equipment

The SurgiCam® HD Digital Camera System was designed to minimize electrical interference problems that may result from using high power electrical equipment in the vicinity of the camera. An auto-reset feature has been developed and implemented into the camera that will detect that condition and automatically reset the camera to its initial state. If the Camera hasn't recovered from an interference problem within a short delay, you can manually reset it by unplugging it and plugging it back in.

1.4. Lens Options

Three magnification lens options (2x, 3x and 5x) are available for the SurgiCam® HD. Some procedures may require wide field-of-view images and others greater details of objects. Lower magnification power lens will allow wider field-of-view and higher magnification power lens show more details of objects.

- **2x lens** offers a wider field-of-view with minimal loss of image detail.
- **3x lens** offers an optimal balance between magnification (or detail) and field-of-view and is suitable for most procedures.
- **5x lens** offers greater image quality with reduced field-of-view.

1.5. Connectivity and Interoperability

Because image frames captured by the SurgiCam® HD Digital Camera System are natively digital, its video data is easily transferred to another medium, image processing is hassle-free, noise and distortion are a non-issue, and image frames remaining are fully intact.

Furthermore, once your video footage has been recorded, you can edit it and save it in your preferred file format.

1.6. For your Protection

Your new SurgiCam® HD Digital Camera is designed to be used conjointly with your personal computer as a USB device. Before using the camera, you must ensure that your computer meets the requirements for this type of environment. For this reason, you should:



Never use the camera system as diagnostic equipment.



Ensure that the lens is securely tightened to the camera and that it will not come loose or fall during the intervention.



Hand tightening only, using a tool will most likely damage the lens.



If camera becomes uncomfortably warm during use, lower the frame rate to reduce power expenditure.



Do not operate camera at extreme temperatures. Normal operating temperatures are between 59°F (15°C) and 77°F (25°C).



Do not let the camera or any of its components near a child to avoid any risk of suffocation.



For external use only. Always keep the recommended distance between the camera and the sterilized zone.



Avoid any contact with water. Do not submerge under water.



Do not attach objects that are not designed to be used with the camera.

2. Hardware Setup

The SurgiCam® HD Digital Camera System is designed so that it requires very little effort to set up. The digital camera is delivered pre-attached to the accessories you have ordered. Some accessories may need to be setup on per-need basis.

2.1. Package Contents

The following equipment comes standard with any SurgiCam® HD Digital Camera System kit:

- One SurgiCam® HD Digital Camera
- One printed Quick-Start Guide
- One USB Drive with:
 - SurgiCam® HD software
 - Digital Manual
- Two hex keys

The following optional accessories may be included:

- Additional pre-calibrated camera lenses
- LED Light
- Fiber Optic Light
- Foot-Pedal System

2.2. Lens Iris Adjustment

A variable optical iris enables control of the amount of light provided to the image sensor. Figure 1 shows how to adjust the iris.

The size of iris will be adjusted by rotating the front ring on the lens. The adjustment of the iris size will change the amount of light to the image sensor. Clockwise will allow more light and counter clockwise will reduce the amount of light, allowing for greater depth of focus. (Figure 1)



Figure 1

A fully opened iris provides the maximum amount of light to the image sensor. The main advantage of using an open iris is to better adapt to various lighting conditions of different environments.

Conversely, a closed iris allows the minimum amount of light. The main advantage of using a closed iris is to increase the depth-of-focus, which is of paramount importance when the camera is mounted on your loupes or headlight. Video images may be “noisy” at first when the iris is closed in a poor lighting condition, but the combination with co-axial headlight illumination eliminates noise on images and greatly improves the depth-of-focus.

Optimizing the iris size with the combination of a headlight or other lights allows users to capture high quality video or snapshot images and achieve a long depth-of-focus.

2.3. Working Distance Adjustment

Lenses are calibrated at your normal working distance. Users proceeding with closer or further distances might experience blurred images as the camera would be out of the focus range.

For the maximum depth-of-focus and the highest image quality you need to adjust the lens iris (aperture) to the optimum/smallest size possible.

1. Hold the camera by aiming it at a target set to your desired working distance. *(Figure 2)*
2. Position the camera lens to the open iris position. (Note: The open iris position depth of focus will be 2 inches. A smaller iris will increase the depth of focus.) *(Figure 1, pg. 10)*
3. Adjust the camera (vertical direction and rotationally) so that the target is in the center of your monitor screen. *(Figure 3)*
4. Loosen the set screw on the side of the camera housing using the provided (.035") hex key. *(Figure 4, pg. 13)*
5. Rotate the rear ring of the lens of the camera, not just the lens, to achieve the best image. Rotating the lens to the right (clockwise) makes the distance longer, rotating to the left (counter clockwise) makes the distance shorter. *(Figure 5, pg. 13)*
6. When the best focus is found, lock the lens in position by tightening the set screw with your (.035") hex key. *(Figure 4, pg. 13)*
7. Minimize/optimize the size of the iris, but not so much that it is closed completely. The minimum/optimum iris size allows for the greatest depth of focus. *(Figure 1, pg. 10)*

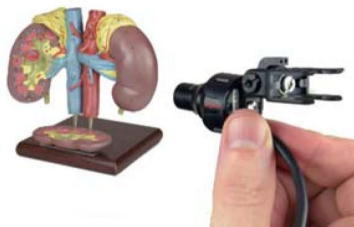


Figure 2

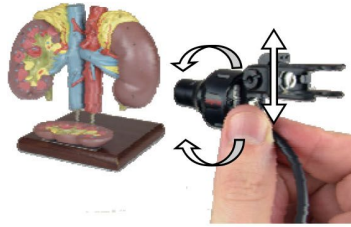


Figure 3



Any lens used in combination with a headlight should have a closed iris in order to increase the depth of field. It is strongly recommended to combine the use of the camera with a light source because of this benefit.

Any lens used in combination with an Image Stabilizer Arm should have an open iris in order to have the maximal amount of light for the camera.

2.4. Lens Replacement



Before removing the lens, ensure that you are in a dust free environment in order to minimize the risks of dust and grime collecting on the surface of the optical image sensor.

To replace the lens, unscrew the lens currently attached to the front of the SurgiCam® HD Digital Camera. Inspect the new lens to ensure it is clean and screw it in place. Never use a tool to remove or tighten the lens as it may damage it.

You may notice spots on the image that never move if there are specks of dust on the image sensor or the lens. Use an air can to blow dust or debris off the lens. Keep unused lenses in a dust free environment. Keep in mind, if you have trouble cleaning your SurgiCam, you may contact SurgiTel for a professional cleaning and refurbishment.

1. The set screw on the bottom of the SurgiCam HD holds the lens. The set screw can be tightened or loosened with a (.035") hex key. This tool is provided in your accessory kit. (Figure 4)
2. Remove the lens (counter clockwise) from the lens holder, by rotating the rear ring on the lens. (Figure 5)
3. Attach the new lens and tighten the set screw. (Figure 5)
(Note: Make sure the camera housing and lens are clean before assembling)
4. Adjust the working distance of your camera (refer to Section 2.3.).



Figure 4



Figure 5

2.5. Connecting to the Computer

The only connection required by the SurgiCam® HD Digital Camera System is to plug the camera cable into your computer's USB port.



Look for the USB symbol if you have problems locating a USB port.

3. Software Setup

3.1. System Requirements

- CPU running at 2 GHz or faster
- 4 GB system RAM
- 50 GB minimum hard disk space
- Either Microsoft Windows 7, 8, 8.1 or 10 (32 bit or 64 bit) operating system or OSX or greater

3.2. SurgiCam® HD Setup



Do not connect the SurgiCam® HD Digital Camera System to your computer's USB port before you are done with the software installation.



Verify that you are logged on to your Windows workstation as a user with Administrative privileges; otherwise the software may not work as expected.

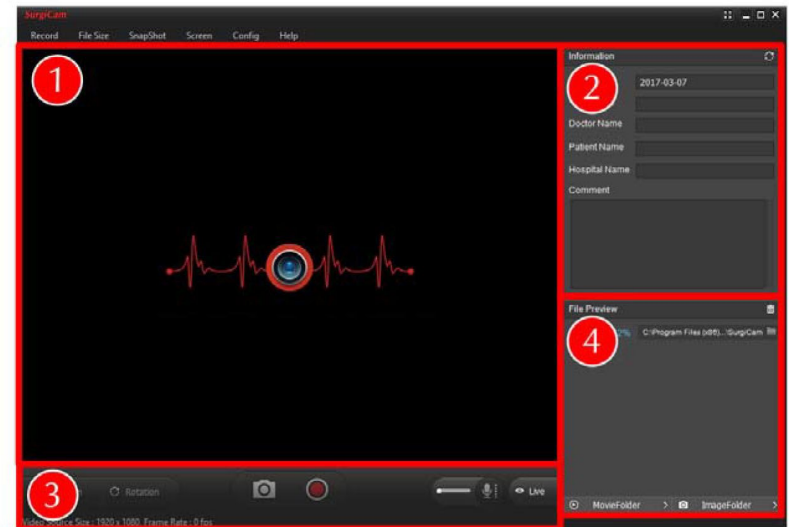
Insert the USB Drive into your computer and manually launch the SurgiCam-Setup program. Follow the on-screen instructions.

Once the software installation is complete you are ready to connect the SurgiCam® HD to an available USB port.

4. Using the Software

4.1. Interface Overview

1. Display panel
2. Information panel
3. Video control panel
4. File preview panel



4.1.1. Display Panel

The display panel is where the video preview is displayed. Full screen option can be enabled by using the **F9** key. To return to window mode press Esc.

4.1.2. Information Panel

The information panel is where you will enter any case specific information.

- The Date field is automatically populated with the current date.
- The File Name is a required field and this is how the video file will be named.
- The Doctor Name, Patient Name, Hospital Name, and Comments field are optional to fill out.

4.1.3. Video Control Panel

Controls:

- Resolution: Changes resolution of next recorded video
- Rotation: Changes rotation of next recorded video
- Snapshot: Takes a snapshot (F7)
- Record: Record (F5), Stop Recording (F4), [Not Displayed on bar, keyboard shortcut only – Pause Recording (F3)]
- Audio: Volume Control bar, Mute Button, Levels display
- Live: Click to change from playback mode to view live camera feed

To mute audio recording, the mute button must be toggled on prior to starting the recording. You may not toggle this option during recording.

4.1.4. File Preview Panel

This is the list of video and snapshot files you have recorded. To view a file in the display panel click on the file's thumbnail.

- Delete Button: This icon resembles a trash can. This button deletes the currently selected screenshot or video.
- Storage: This number displays the % of hard drive space available on the selected drive.
- Storage Directory: This displays the directory where captures will be stored. Clicking the folder icon here will change this location.
- Thumbnails: Click a thumbnail of a screenshot or video to review it in the display panel. Remember to click the "Live" button in the Video Control Panel to return to the live camera feed.
- MovieFolder/VideoFolder: Click these buttons to view the recorded media directories using Windows Explorer.

4.2. Operating the SurgiCam® HD Digital Camera System

4.2.1. Preview Mode

When you launch the SurgiCam® HD software with a SurgiCam® HD Digital Camera plugged into your computer, the software automatically switches to Preview mode. In this mode, the picture captured by the SurgiCam® HD Digital Camera is shown on screen, but nothing is being recorded on your computer's hard drive.

Before you start recording video footage, some adjustments should be done to ensure that you will obtain the best possible picture.

1. Center the SurgiCam® HD Digital Camera on the viewing area (This may not be relevant depending on how you use your SurgiCam® HD Digital Camera System).
2. Adjust the distance between the SurgiCam® HD Digital Camera and the viewing area to ensure that the image focus is perfect.
3. If required, fine-tune the picture using the controls available under the menu item Config -> Video Quality Settings.
4. If camera becomes uncomfortably warm during use, lower the frame rate to reduce power expenditure.

4.2.2. Recording Video Footage



Recording digital videos makes high demand of your computer's resources. For this reason, it is critical that you close all other applications before recording with the SurgiCam® HD software.



It is important to disable any screen savers or energy saving feature that may be enabled on your computer. Refer to your operating system documentation for specific instructions on how to disable these features.

Once you are done with the picture adjustment, you are ready to start recording video footage:

1. Fill the Information panel with any information relevant to the case you are recording.
2. Click the **Record** button or press the **F5** key to start recording. You will know that the software is recording because the recording icon will animate, and the recording time and file size will display at the bottom of the video control panel.
3. If, for some reason, you need to momentarily interrupt the recording, press the F3 key to **Pause** recording. Press it again to resume recording.
4. Once you are done with your case, press the animating **Record** button again or press the **F4** key to stop recording. The current project will be saved to disk in the SurgiCam® HD "movie" sub-folder.
 - The recorded video files will be saved in the Video folder.
 - The default save location may be changed in program settings



You should always make a backup copy of your original material before editing it. It is a good practice to move your material to a recordable media as soon as possible. You can always copy the files back to your computer if you need to edit them at a later time.

4.2.3. Video Playback

Once a video project has been captured, you will most likely wish to review it at a later date:

1. Click on the thumbnail of the media that you wish to view. Notice that the Information section is updated with information from the project you just selected.
2. Press the **Play** button to start playback.
3. You can change the current position within the video by using the slider in the Camera Control panel. Simply click and hold the scroll thumb and drag it to a new location.

4.2.4. Capturing Still Images From Recorded Videos

During video playback in the display panel, you can take a snapshot of a single image from what you see in the Display panel at any time by pressing the **Snapshot** button or the **F7** key.

- The recorded snapshot files will be saved in the Snapshot folder.
 - The default save location may be changed in program settings



You should rename the snapshot files that you wish to keep and move them to a different location using Windows Explorer or Finder as soon as possible.

5. Technical Support

If you encounter trouble with your SurgiCam® HD Digital Camera System or its accompanying software, follow the steps below to obtain assistance:

1. Consult this *User's Guide* for information related to the situation.
2. Check the Support section of our web site at www.surgitel.com/help.
3. Download the newest version of the SurgiCam HD software at www.surgitel.com/surgicam.
4. Contact us via email at: support@surgitel.com. Please include a detailed description of the situation.

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

[illegible]

[illegible]

The product complies with FCC requirements based on the Standard 47CFR Part 15 and Part 18. The test was performed accordance to the procedures from ANSI C63.4-2003.



***Tested To Comply
With FCC Standards***

The product complies with requirements of the EMC Directive 2004/104//EEC; Medical Directive 93/42/EEC. The product was tested accordance to EMC standards EN 55011:2007 and EN 60601-1-2:2007.



***Tested To Comply
With CE Directives***