HDC-300

Titan HD Camera System
Operating Manual

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1. INTRODUCTION

The Sunoptic Technologies High Definition Camera System is a head-mounted surgical camera used to capture still and video images of surgical procedures.

You have chosen the best and we would like to make sure you receive optimal results with your new Camera System by using it correctly.

This Operator Manual will help you to install, operate and clean the Camera System. It will give you maintenance and service guidelines as well as recommendations for best performance results.

⚠ Federal law (United States of America) restricts this device to use by, or on the order of, a physician.

1.1. INDICATIONS FOR USE

The intended use of this device is to display, record and play back surgical procedures. The HD Camera is not intended to diagnose, prevent, monitor, treat or alleviate disease, injuries or handicaps, nor for the investigation, replacement or modification of the anatomy or of a physiological process, and is not to be used with or as an endoscope or related system. This device has no essential performance as defined in IEC 60601-1. Should this device fail to operate, a suitable backup should be available for any procedure in which this device may be used.

There are no known contraindications.

The HD Camera is intended to be used in a controlled operating room environment with compatible devices by qualified medical personnel. The camera system and head are provided non-sterile.

1.2. FUNCTION OF DESIGN

The HD Camera System comprises a camera head that couples to a light source which captures video and/or still images and console which displays these captures onto an external monitor. Displayed images and videos may be captured and stored internally or transferred or transmitted via a variety of means, controlled through the device's integrated touch panel.

1.3. SPECIFICATIONS

PARAMETER	VALUE	
Power Requirements	Voltage: 100-240VAC Frequency: 50/60Hz Power: 2.9A – 1.27A	
Video Outputs	2x HDMI, 2x DVI	
Connectivity	5 x USB 2.0 ports 1 x Ethernet port 1 x RJ11	1 x Camera Input
Internal Storage	500GB	
Console Dimensions	13"W x 15.25"L x 5.25"T	
Console Weight	16.0 lbs.	
Camera Head Weight	0.85 lbs.	
Transport & Storage Conditions	-40 to 122ºF (-40 to 50ºC) 10 to 90%, non-condensing	
Operating Conditions	50 to 86ºF (10 to 30ºC) 30 to 75% RH, non-condensing	

1.4. CLASSIFICATIONS

PARAMETER	VALUE
System Classification	FDA Class I EU Class I Health Canada Class I
Design Criteria	IEC 60601-1 Ed. 3.1: 2012
EMC Certifications	CISPR 11 Class A IEC 60601-1-2 Ed. 4
CE Marking	CE Marking for MDD 93/42/EEC
Protection against electric shock.	Class I [grounded]
Degree of protection against harmful ingress of water	Camera Console is [IPX-0]; no protection.
Degree of safety in the presence of Flammable Anesthetics	Equipment is NOT suitable for use in the presence of flammable anesthetics.
Mode of operation	Continuous

2. GENERAL WARNINGS

Use of this equipment may present hazards to the user and/or patient. Before operating this device, please read this operating manual thoroughly and follow all warnings, cautions, and instructions for use. The words warning, caution, and note carry special meaning and should be carefully reviewed:

WARNING: Indicates risks to the safety of the patient or user. Failure to follow warnings may result in injury to the patient or user.

CAUTION: Indicates risks of improper use and/or damage to the equipment. Failure to follow cautions may result in loss of function or product damage.

NOTE: Indicates special information to clarify instructions or present additional useful information.

The appropriate "WARNING", "CAUTION" or "NOTE" symbol in this manual is intended to alert the user to the presence of important operating and maintenance instructions in the manual.

Warnings
To avoid potential serious injury to the user, patient, and/or damage to this device, please note the following warnings:

- Failure to follow instructions in this manual may lead to serious injury or damage to the equipment. Read this operating manual thoroughly, especially the warnings, and be familiar with its contents before using this equipment.
- This equipment is designed to be used by a qualified physician, having complete knowledge of the use of this equipment and the procedure to be performed.
- This equipment should be installed and tested prior to use. A pre-operative check should be performed prior to administration of patient anesthesia to ensure all desired functions are operational, that a viable surgical image is being displayed on the monitor, and there are no signs of damage to the equipment.
- It is recommended to have a back-up system ready for use in the event of primary equipment failure.
- This equipment must be connected to a supply mains with protective earth to reduce risk of electric shock.
- This equipment must not share the same electrical outlet or grounding with life support or life sustaining equipment. In the case of equipment failure, this equipment may draw excessive power from the supply circuit and interrupt service to other equipment powered by the same circuit.
- An uninteruptable power supply is recommended.
- Always set up the console in a location that allows adequate ventilation (airflow) to the console. Insufficient ventilation may cause the console to overheat and shut down and create risk of fire. Always set up the equipment so that the appliance inlet is readily accessible.
- Use only medical grade power cords and replacement fuses specified by the manufacturer to reduce risk of harm resulting from fire or interruption of mains circuit. Follow the instructions provided herein and always remove power from the device prior to inspection or replacement of fuses.

- Use only manufacturer's specified compatible accessories and peripheral equipment. Use of non-approved equipment may cause loss of function.
- Before each use, check the outer surface of this equipment to be used to ensure that there are no rough surfaces, sharp edges, or protrusions that can cause injury.
- Avoid dropping the camera system or rough handling. The camera system contains sensitive components prone to damage by mechanical shock.
- This device complies with the IEC 60601-1 safety standard. When peripherals are connected to this device, a Medical Electrical (ME) System is formed and the system should be evaluated for conformance to IEC 60601-1 safety standards. When used with other equipment, the leakage currents may be additive. The person creating the ME system is responsible to comply with the applicable safety regulations and safety standards for their location. Connect only IEC 60601-1 approved equipment to this device. Never touch peripheral equipment connections on this device and the patient at the same time. This can create a risk of shock to the patient.
- Do not use the equipment in the prescence of flammable liquids, gases, or other materials susceptible to ignition due to electrical sparking.
- This equipment generates and radiates EMI which may affect the normal function of nearby installed equipment. Equipment that generates and radiates EMI may affect the normal function of the HD Camera System. Place the equipment away from strong EMI sources.
- Data stored on the HDC-300 may be sensitive data that could breach patient confidentiality if the data is accessed by an unauthorized user. It is the user's responsibility to protect any sensitive data stored on this device.

Cautions

To prevent improper use and/or damage to this device, please note the following cautions:

- Carefully unpack this unit and check if any damage occurred during shipment. If damage is detected, refer to the Warranty and Return Policy section of this manual.
- This equipment generates heat and uses cooling fans during normal use. To reduce the risk of overheating and possible loss of function and/or damage to the equipment, install the equipment in a well-ventilated space within the operating conditions listed herein.
- There is a risk of damage to the equipment if the equipment is subjected to cleaning or sterilization methods not approved be the manufacturer. To reduce risk of loss of funtion and/or damage to the equipment, only use the approved cleaning and sterilization methods described herein.
- High frequency surgical devices may cause interference with the video image displayed on the surgical monitor. To reduce this risk, high frequency devices and imaging equipment should be located on separate supply circuits.
- There are no user serviceable parts inside the console or camera heads. There are hazardous voltages present inside the console. Do not remove the cover. Return the device to the manufacturer for service.
- Ensure that the HDC-300 is setup in a manner that any cables that are connected to the console or head are not a tripping hazard during use.
- The internal storage hard drive may fail. The user is responsible for making appropriate backups of important data to mitigate the risk of data loss.
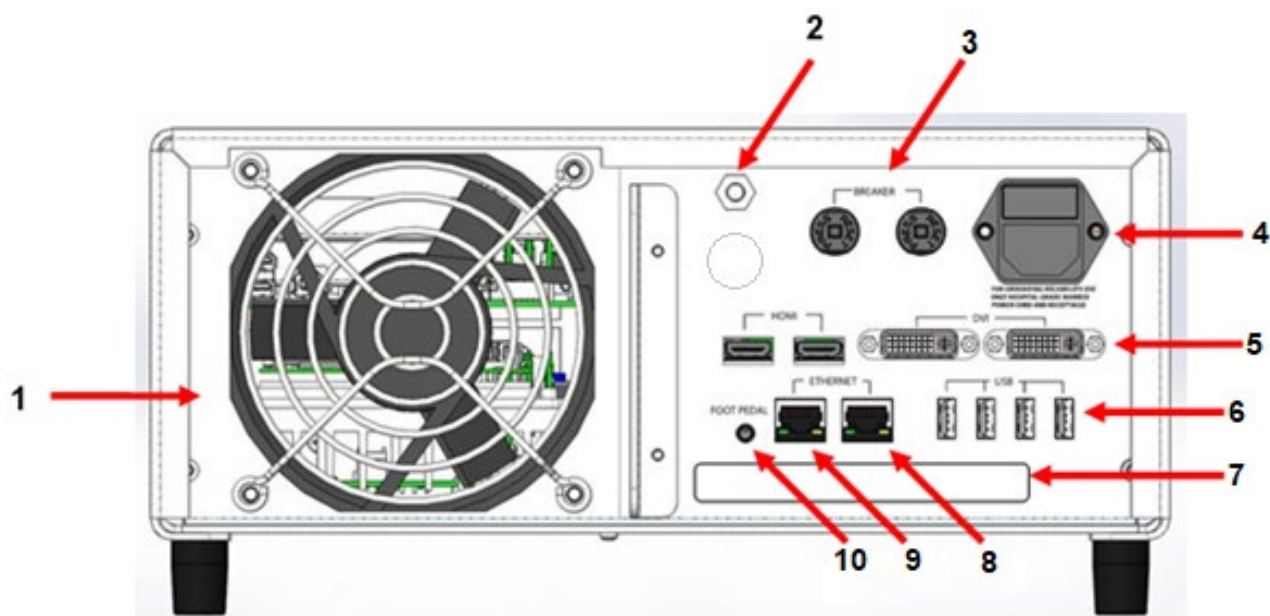- **NOTE:** The warranty will become void if any of these warnings or cautions are disregarded.

3. PRODUCT OVERVIEW

3.1. Camera Console

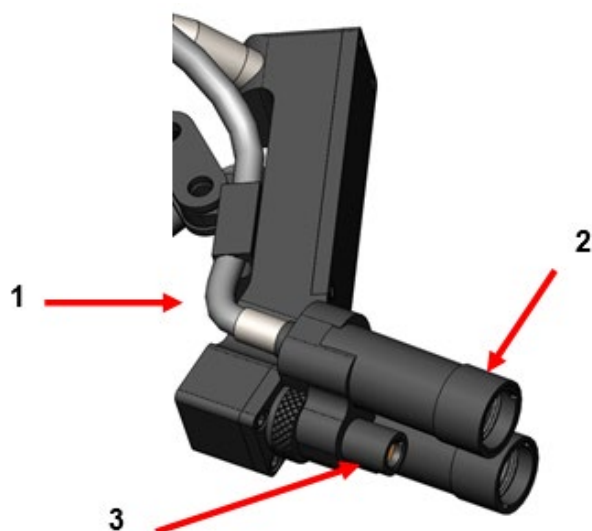| No.	Name	Function
1	Touch Screen	UI control for Camera Console
2	ON/OFF Button	Turns the unit on or off
3	USB	USB attached storage
4	Camera Port	Camera head connection

No.	Name	Function
1	Fan	Provides air flow for cooling of unit
2	Grounding Connector	For electric potential equalization
3	Circuit Breakers	Over current protection
4	AC Power Entry and Switch	Accepts AC Power cord and switches on AC power
5	Video Output Ports	From left to right: HDMI 1: Stabilized video output HDMI 2: Raw video output DVI 1: Stabilized video output DVI 2: Raw video output
6	USB Ports	Firmware Update only
7	Label	Regulatory Product Label
8	RJ11 Jack	Factory Programming Port
9	Ethernet Port	Allows user to connect to stabilizer via Ethernet
10	2.5mm Mini Jack Receptacle	Footswitch connection

3.2. Camera Head
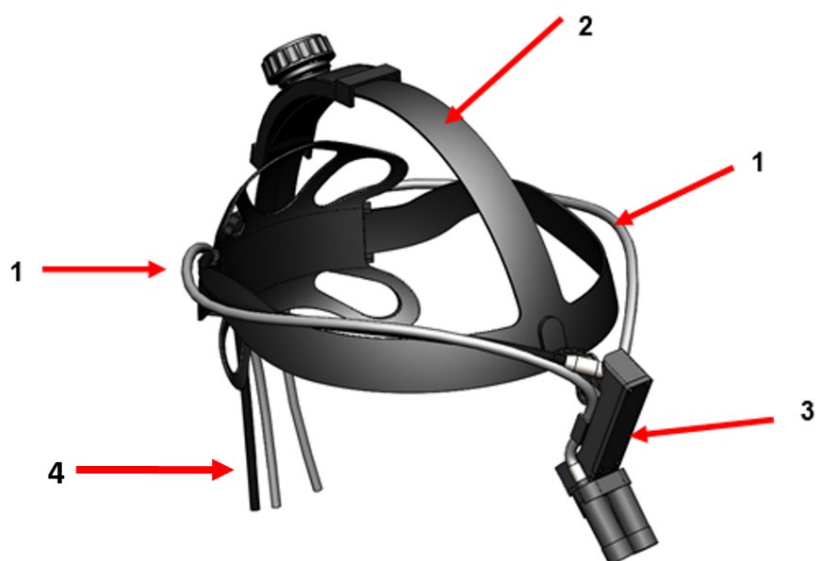
No.	Name	Function
1	Fiber Optic Cables	Transmit light from external light source
2	Headband	Adjustable headband system
3	Camera Module	Record video
4	Camera Cable	Connects Camera Module to the console. Cannot be detached from camera module.

3.3. Camera Module

No.	Name	Function
1	Fiber Optic Cable	Transmit light from external light source
2	Headlight Module	Projects light onto surgical site
3	Camera Lens	Lens through which video is recorded

4. SETUP

4.1. Console Setup

Place the camera console on a stable surface (cart, counter, stand, etc.).

⚠ **WARNING: DO NOT** place console in an area where it can be exposed to liquids.

⚠ **WARNING: DO NOT** use in any environment with explosive or flammable gases.

⚠ **WARNING: DO NOT** obstruct the bottom intake or rear exhaust vents of the camera console. 5" or approx. 13mm clearance is required above and behind the console for adequate airflow. The console should not be placed in which its exhaust can interfere with other devices, nor should it be placed near any heat generating devices.

4.2. Connecting Camera Head

⚠ **CAUTION:** THE CAMERA CABLE SHOULD BE CONNECTED AND DISCONNECTED BY GRASPING FROM THE RIGHT-ANGLE CONNECTOR ONLY. PULLING BY THE CABLE MAY DAMAGE THE DEVICE (THIS DAMAGE IS NOT COVERED BY PRODUCT WARRANTY).

Connect the camera head to the console by first aligning the red dot located on the right-angle connector with the red dot located on the console front panel receptacle. Insert firmly until the right-angle connector is fully seated.

4.3. Connecting External Monitor

The camera console has (4) video output connections located on the rear panel. All (4) outputs may be used simultaneously. Please refer to the rear panel diagram for a description of each output.

4.4. Connecting Mains Power

Ensure that the rear power switch is in the OFF position and connect a medical-grade AC power cord to the power inlet located under the rear power switch.

⚠ **CAUTION:** Electromagnetic interference (EMI) may affect the HD camera system operation. Place the HD camera system away from strong EMI sources.

4.5. Powering the Unit

After ensuring that all external devices are properly connected, apply mains power to the unit by turning on the rear mains power switch. The switch will illuminate GREEN. Once power is applied to the unit, the ON button on the front panel will flash blue until the unit has fully booted. The Sunoptic splash screen will appear on the touch screen

Allow approximately 1 minute for the system to boot.

4.6. Shut Down

To turn the unit off, push front panel push button, and wait for the unit to shut down. Once the touchscreen is off, turn the rear mains switch OFF.

5. OPERATION

⚠ **NOTE:** Many functions of the camera console are displayed on an external monitor. The external monitor must be connected to a stabilized video output connector (HDMI 1 or DVI 1) to view these on-screen menus and displays.

### 5.1. Using Touchscreen Interface

The main interface of the camera console is a 5-inch capacitive touch screen. This screen provides full functionality including an onscreen keyboard for entering case information and enables users to interact with the recorder module without an external keyboard.

Most screens will feature HOME and RETURN icons. Pressing the HOME icon will return the user to the HOME SCREEN from any point in the menu system. Pressing the RETURN icon will return the user to the previous menu.

5.2. Home Screen

The home screen is the first screen displayed after the camera console boots. The user can return to this screen at any point in the menu system by pressing the HOME icon.
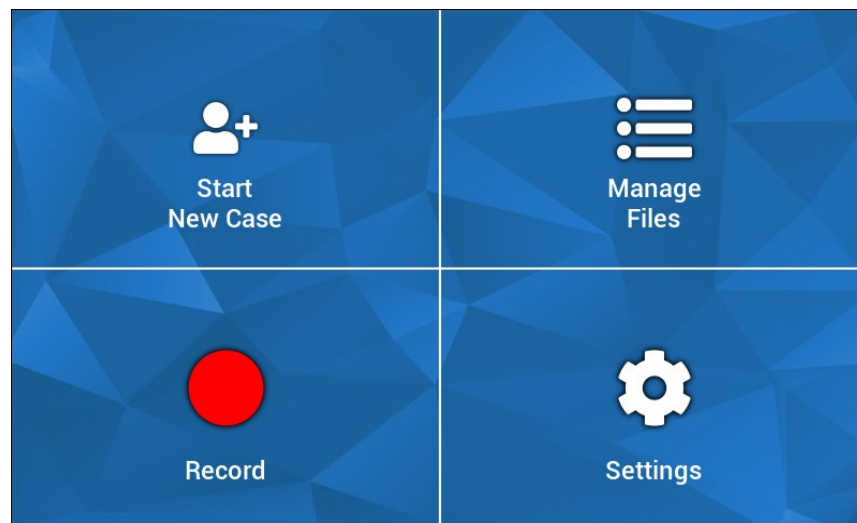
- Start New Case – menu for creating a new case file
- Manage files – menu for browsing case files stored on the device
- Record – menu for camera control
- Settings – menu for adjusting settings such as camera settings and recorder settings

5.3. Start New Case

The Start New Case menu prompts the user to enter the case information for a newly created case file. Touching the value field will initiate an onscreen keyboard. Users should input the appropriate information and press enter when finished. When all value fields are adequately filled, users can confirm case file creation with the GREEN check icon and will be taken to the RECORD screen. Otherwise, users can press the RETURN or HOME icons to exit.

NOTE: Case files can be created without entering any information. The file name will be automatically generated with a timestamp.

5.4. Record

The Record menu shows all the controls for recording video and images. Non-actionable icons will be dim (i.e. Pause icon will do nothing when not recording).
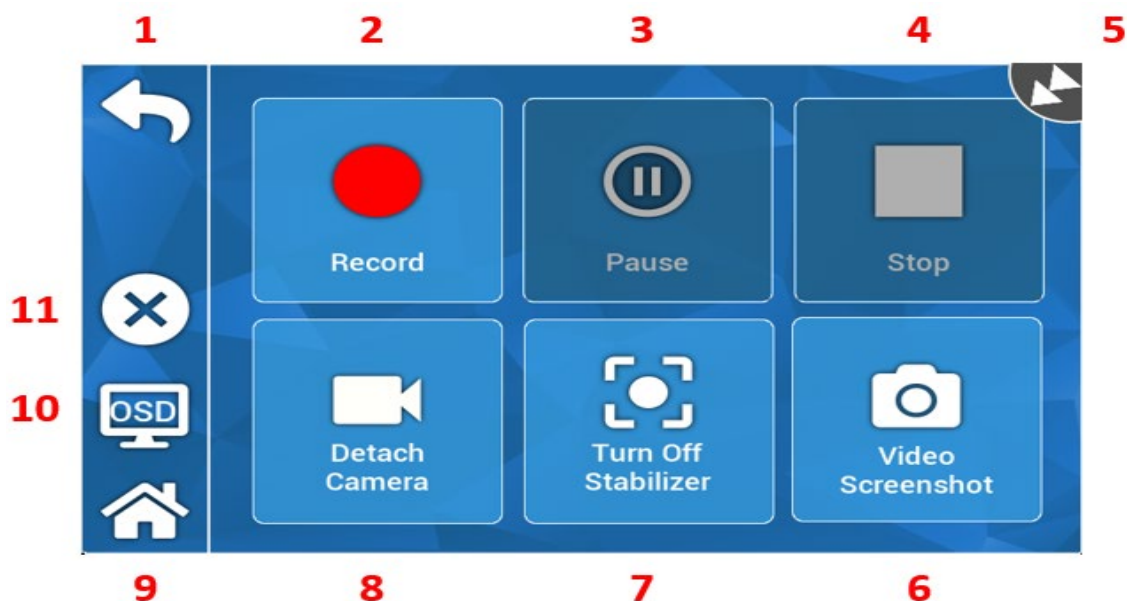
Actions:

1. Return – go back to the previous menu
2. Record – initiate video recording
3. Pause – halt video recording
4. Stop – halt video recording and close the index
5. Status Icon - shows the current status of the recorder
6. Video Screenshot – capture a still image
7. Turn Stabilization ON/OFF – toggles video stabilization ON/OFF. NOTE: this feature only works when external monitors are connected to a video output that supports stabilization.
8. Detach/Attach camera – disconnects/reconnects camera from the recorder module
9. Home – return to the home screen
10. OSD – "On Screen Display" setting. Cycles through the different settings for superimposing information on the image screen such as remaining HDD space and recording time.
11. X – close case file and return to the home screen

5.5 Manage Files

The Manage Files menu provides the user controls to browse, view, and manage case files loaded on the recorder HDD.

⚠ **NOTE:** users must have an external monitor connected to view the file browser.

- List Files – invokes the recorder file browser
- Directional keys – used to navigate the recorder file browser
- Enter – used to confirm or initiate an action
- Copy to USB – initiates the Copy command on the recorder file browser
- Close – closes the active case file and/or recorder menu
- Previous/Next – used to cycle through indexes found in a case file
- Play Video – starts index playback from the active case file. NOTE: still images will appear first in any case file index despite the order in which the indexes were created.
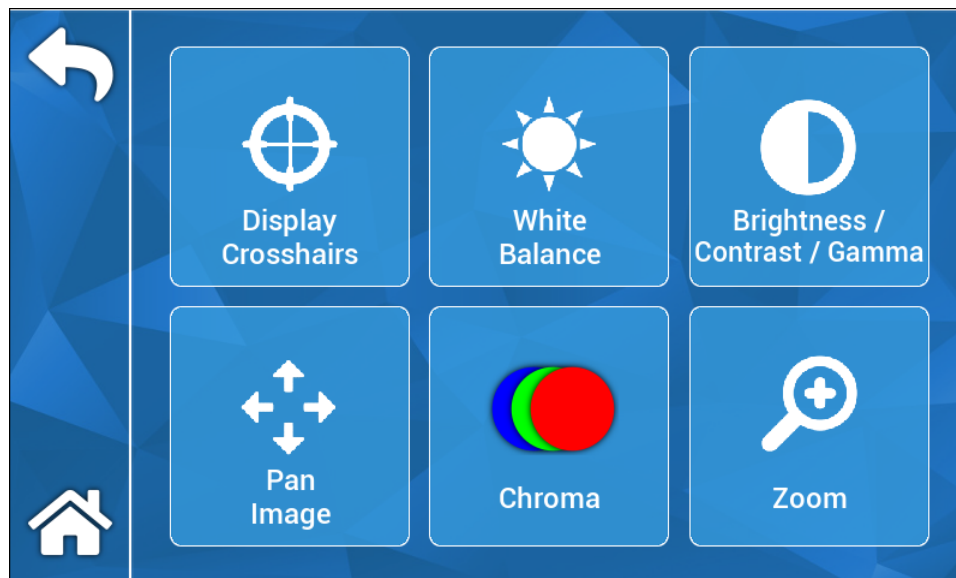- Turn Off OSD – disables the on-screen display on the external monitor
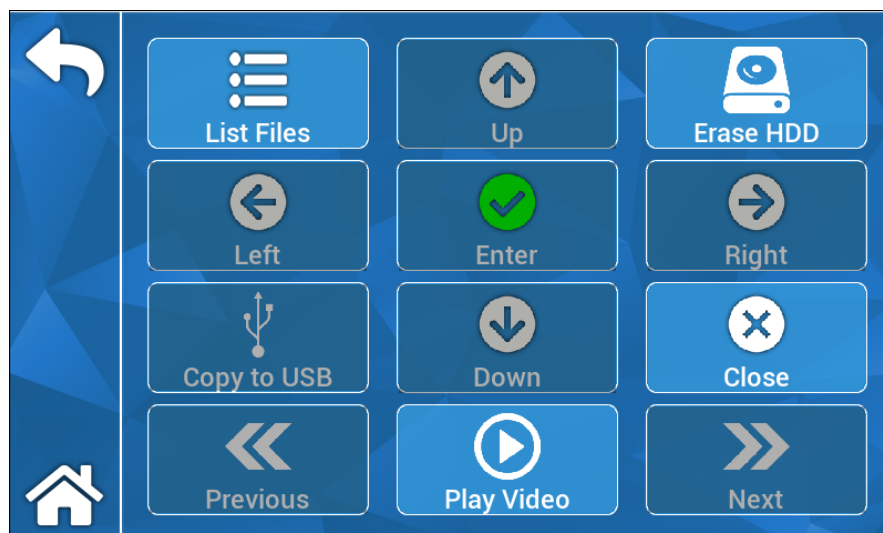
5.6 SETTINGS
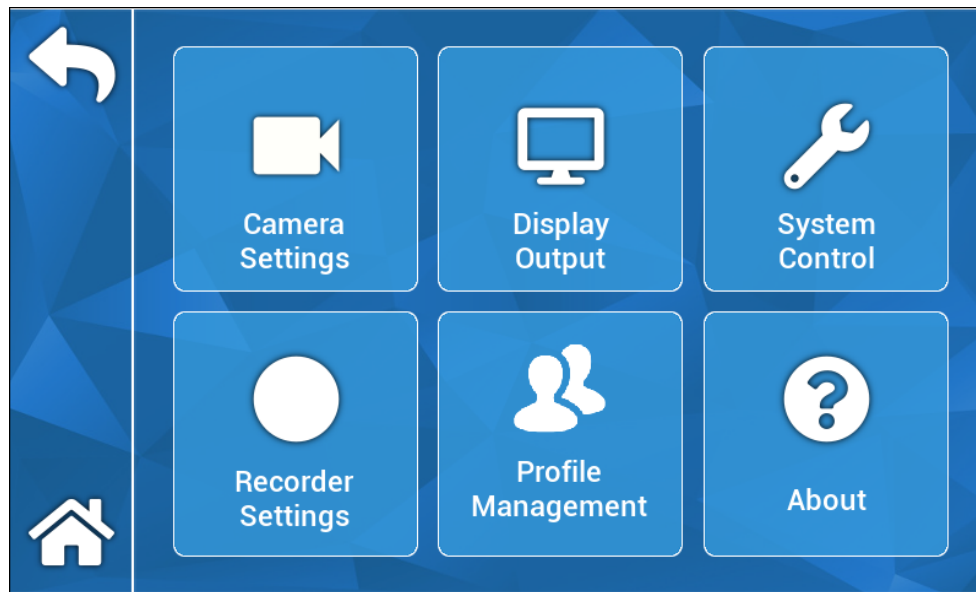
5.6.1 Camera Settings

The Camera settings menu allows users to adjust the color, zoom, brightness, and other image qualities according to their preference. All settings can be saved to a profile for simple user sharing and setup.

5.6.1.1 Display Crosshairs

The Display Crosshairs icon will superimpose crosshairs on an external display. Useful when trying to align the camera image.

5.6.1.2 White Balance

Automatically adjusts chroma settings to create more accurate colors.

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Rev. A   (English)

5.6.1.3 Brightness/Contrast/Gamma

Brightness/Contrast/Gamma is a sub menu with sliders to adjust image brightness, contrast, and gamma. Pressing the Profiles icon will initiate the Profile Management menu, in which a user may save their changes to a user profile to enable faster setup in future uses.

5.6.1.4 Pan Image

Pan Image is a sub menu that allows users to digitally align the camera to the console. Pressing the Small Steps icon will allow finer panning and pressing the Large Steps icon will allow for panning of the camera in larger increments. Pressing the Center icon to restore the default pan location.

5.6.1.5 Chroma

The Chroma menu allows users to change the hue of the image via adjusting the onscreen sliders. Users can save their changes to an appropriate user profile by pressing the Profiles icon.

5.6.1.6 Zoom

The Zoom menu allows users to digitally adjust the camera zoom. This setting can also be saved to a user profile via pressing the Profiles icon.

5.6.2 Display Output

The Display output menu allows users to activate or deactivate video output to an external monitor.

5.6.3 System Control

System Control menu allows users to shut down or reboot the system.

5.6.4   Recorder Settings

The Recorder Settings menu invokes the recorder main menu. The user must be connected to an external monitor to view this menu. Settings such as On-Screen Display, recorder image quality, etc. can be changed in this menu.

The Recorder Settings menu also has a format HDD option. From the on-screen Main Menu, navigate to "Advanced." In this submenu, there will be an action titled "Format Recording Device." Press the enter icon to select the action and use the arrow icons to navigate to the desired device you wish to format. Confirm the selection by pressing the enter icon again.

5.6.5   Profile Management

Profile Management provides users a method of saving or recalling settings such as zoom level or image brightness. Pressing the Save Profile icon will save all user adjustable settings. Pressing the Factory Defaults icon will reset all settings to the default values.
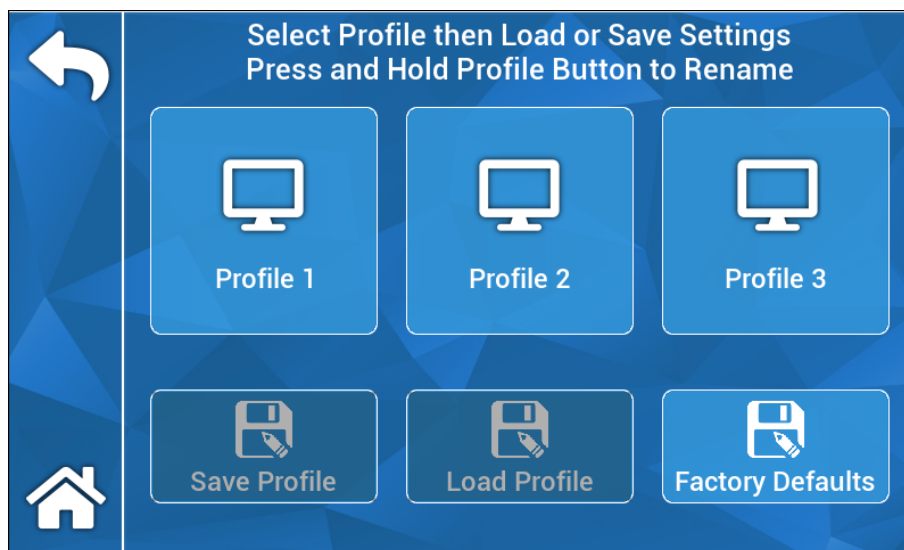
⚠ **NOTE:** the camera console will start with the last active profile.

5.6.6   About

The About menu displays the software and firmware versions of the camera console and allows a user to reset the device to factory default settings by pressing the factory reset icon. Additionally, if a USB flash drive loaded with the appropriate software is connected to the center-most rear USB port, the user may perform a software update.

5.7 FOOTSWITCH OPERATION

The TASCAM footswitch can be used as an auxiliary video control, giving users the ability to record, pause, and capture still images hands-free. Connect the footswitch 2.5mm mini jack to the receptacle located on the rear panel of the camera console.

No.	Name	Function
1	Stop	Stops video recording or playback.
2	Record/Pause	Start recording video or pause current recording
3	Photo	Captures still image

5.5. SOFTWARE UPDATE

Periodically, the software for the HD Camera System Console will be updated by the manufacturer. This software update will be provisioned to the customer via USB flash drive.

⚠ **NOTE:** The user should back up any important data stored on the device before performing an update to minimize the risk of data loss during an update.

There are two main ways the software of the camera console can be updated:

METHOD #1 – Software Update through UI

1. While the console is ON, attach the Software Update USB to the center-most rear USB port.
2. Navigate to the ABOUT screen in the SETTINGS menu.
3. Press the Update Firmware icon.
4. The Camera Console will automatically update to the latest software.
5. Once the Camera Console finishes the update, the touchscreen will prompt the user to remove the Update USB and a Restart icon will appear.

⚠ **CAUTION: ENSURE THAT THE UPDATE USB IS REMOVED BEFORE RESTARTING THE CAMERA CONSOLE AFTER UPDATE.**

METHOD #2 – Software Update through Boot

1. While the console is OFF, attach the Software Update USB to the center-most rear USB port.
2. Turn on the console.
3. The Camera Console will detect the Software Update USB during the boot process and automatically update to the latest software.
4. Once the Camera Console finishes the update, the touchscreen will prompt the user to remove the Update USB and a Restart icon will appear.

⚠ **CAUTION: ENSURE THAT THE UPDATE USB IS REMOVED BEFORE RESTARTING THE CAMERA CONSOLE AFTER UPDATE.**

6. CLEANING AND DISINFECTION

Both the camera head and camera console may be cleaned, but not sterilized. Remove from power source before any cleaning is performed.

⚠ **CAUTION: DO NOT** immerse or sterilize the camera console as this will damage the camera console and void the warranty.

The camera head, camera console and headband can be wiped down with commercially available cleansers commonly used for disinfection of electronic equipment in hospitals such as ethyl or isopropyl alcohols, disinfecting sprays containing quaternary ammonium compounds, or hydrogen peroxide. The lenses should be cleaned only with lens tissue, available in any camera store; follow the directions on the package.

⚠ **WARNING: DO NOT** use strongly caustic or acidic cleansers such as "Clorox" hypochlorite bleach, ammonia, muriatic acid or similar products. Do not use acetone, methyl ethyl ketone or halogenated / chlorinated hydrocarbon solvents or cleansers containing any of these restricted compounds.

Apply cleaning agents by light spray or dampened towels.

⚠ **WARNING: DO NOT** pour liquids onto the device. Do not allow frank liquids to ingress the camera head or camera console seams or ventilation openings.

Follow all applicable blood borne pathogen procedures as required by OSHA and/or your hospital when cleaning and disinfecting the product.

7. MAINTENANCE, SERVICE AND REPAIR

7.1. User Service and Maintenance

The camera head and the camera console do not contain user serviceable parts.

Defective items or equipment are to be serviced and repaired exclusively by persons authorized by the manufacturer. All repair work shall employ original manufacturer's parts only.

7.2. Limited Warranty

The camera head and camera console carry a 3-year warranty from the date of shipment on workmanship and all defects of material, excluding fiber optic cables. Should your product prove to have such defects within three years of shipment, **Sunoptic Surgical**® will repair or replace the product or component part without charge. Should your product(s) need servicing under this warranty, please contact **Sunoptic Surgical**® or a local distributor for return authorization documentation. Please carefully pack the unit in a sturdy carton and ship it to the factory. Include a note describing the defects, your name, telephone number and a return address. Warranty does not cover equipment subject to misuse, accidental damage, normal wear and tear or if transferred to a new owner without authorization from **Sunoptic Surgical**®. This warranty gives you specific legal rights and you may also have other rights that vary from state to state.

7.3. Repair

You may return your product(s) for repair, shipping prepaid to the factory. Your product will be inspected, and an estimate of repair charges will be submitted to you for approval.

PHONE: +1 (877) 677-2832   INTERNATIONAL: +1 (904) 737-7611
FAX: +1 (904) 733-4832

8. END OF PRODUCT LIFE

This product contains electrical waste or electronic equipment. It must not be disposed of as unsorted municipal waste and must be collected separately in accordance with applicable national or institutional related policies relating to obsolete electronic equipment. The HD camera system must be disposed of according to local laws and hospital practices.

9. SYMBOLOGY

	Manufacturer
	Date of manufacture (YYYY-MM-DD)
EC | REP	Symbol for Authorized Representative in the European Community
⚠	Caution, consult accompanying documents
Rxonly	Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner)
	Consult Instructions for Use
CE	CE mark
	Not for disposal in general waste
	Caution: Hot Surface
	Caution: Dangerous Voltage
	Do not use if package is damaged
	AC Current
	Equipotentiality
	Power ON
O	Power OFF
	Protective Earth (Ground)