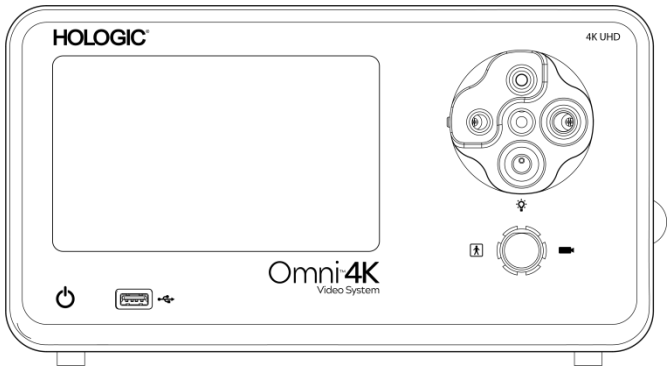
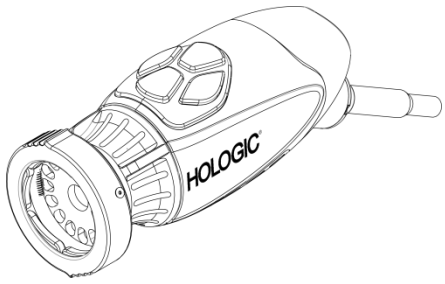
Omni™ 4K Video System

User Manual





REF 83-10-4010
83-10-4120
83-10-1000

Distributed by:

HOLOGIC®

Rx only

Proprietary Information

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The manufacturer reserves the right to revise this publication and to make changes from time to time without obligation to notify any person of such revisions or changes unless otherwise required by law.

720-00041 Rev A – User Manual, 83-10-4010 Camera System, 4K

July 2020

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Warnings and Cautions

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.

An exclamation mark within a triangle is intended to indicate an alert the user to the presence of important operating and maintenance instructions in the manual. This symbol is used to indicate Warnings and Cautions.

Warnings

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

1. 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 connecting and using this equipment.
2. This equipment is designed for use by a qualified physician, having complete knowledge of the use of this equipment and the procedure to be performed. This equipment is intended for use in a medical facility except for areas of high electromagnetic disturbance such as near Magnetic Resonance Imaging (MRI) equipment.
3. This equipment should be installed and tested prior to use. Before each use, inspect the equipment for signs of damage due to reprocessing or other handling and ensure the equipment is suitable for use. A pre-operative check should be performed prior to administration of patient anesthesia to ensure all desired functions are operational and that a viable surgical image is being displayed on the surgical monitor and there are no signs of damage to the equipment. Before each use or after a change in viewing modes/settings, the operator should check to ensure the view observed through the endoscope provides a live image (rather than a stored one) of proper color and size and has the correct image orientation.
4. For the protection of the patient, it is required to have a back-up system ready for use in the event of primary equipment failure.
5. This equipment may present a risk of electric shock. To reduce this risk, this equipment must only be connected to a supply mains with protective earth.
6. This equipment presents a risk of burns and fire. The internal LED light source generates high temperatures and high energy radiated light maybe transmitted from the light emission window of the endoscope, giving rise to high temperatures in front of the light emission window. Thermal damage to the patient's tissue (for example, permanent tissue damage or coagulation) may result from prolonged exposure to intense illumination in small cavities or if the endoscope tip is placed in close proximity to tissue. To reduce the risk of burns and fire, avoid contacting the light guide connections and endoscope tip to skin or flammable materials (and other equipment) when these accessories are used. Always place the light source on Standby (no illumination) when the endoscope is removed from the body and not being used. Allow the endoscope and light cable and couplings to cool prior to detaching couplings. The camera head, during normal use, may generate surface temperatures in excess of 41 ^{0} C.
7. This equipment presents a risk of producing temporary blindness and eye damage. The internal LED light source is capable of generating intense direct light. To reduce this risk, never look directly at the light source output or the light source tip or endoscope when in use.

8. 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. To reduce this risk, this equipment should not share an electric outlet or grounding with life support or life sustaining equipment.

9. Loss of power to the equipment may result in a risk to the patient. An uninterruptable power supply is recommended.

10. 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 or create a risk of fire. Always set up the console to position the appliance inlet (where the power cord is attached to the equipment) so that it is readily accessible.

11. Use only the provided medical grade power cord and replacement fuses specified by the manufacturer to reduce the 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.

12. Use only manufacturer's specified compatible accessories and peripheral equipment. Use of non-approved equipment may create a risk of electrical shock or cause loss of function.

13. This equipment generates and radiates RF energy which may affect the normal function of nearby installed equipment. Equipment that generates and radiates RF energy may affect the normal function of the Omni 4K video system. When choosing a location for the Omni 4K video system, consult the "Electromagnetic Compatibility" section of this manual to ensure proper function with other installed equipment.

14. 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.

15. Avoid dropping the camera system or rough handling. The camera system contains precisely aligned optical components and other sensitive components prone to damage by mechanical shock.

16. 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 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. 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.

17. Do not use the equipment in the presence of flammable liquids, gases or other materials susceptible to ignition due to electrical sparking.

18. Before each use, the compatibility of the endoscopic equipment with any accessories and/or energized endotherapy devices should be checked according to any criteria for safe use defined in the instructions for use.

19. Possibly hazardous optical radiation emitted from this product. Do not stare at operating lamp (light source). May be harmful to the eye. Avoid looking into lamp (light turret apertures) and active light emitting points (light guide tip and endoscope tip) and always keep these active light emitting points directed away from operator, patient and bystanders eyes.

20. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

21. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the camera system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

22. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

23. Electromagnetic interference including emissions from High Frequency surgical devices (Radio Frequency (RF) or Electrosurgical Units (ESU) or similar terms) may cause irregular behavior and/or malfunction of the Omni 4K video system and may cause interference with or loss of the video image being displayed on the surgical monitor. To reduce the chance of interference, or if interference occurs, High Frequency consoles and cables should be located away from the Omni 4K video system and should be located on separate supply circuits to reduce disturbances.

Cautions

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

1. Carefully unpack this unit and check if any damage occurred during shipment. If damage is detected, refer to the Warranty, Service, and Repair section of this manual.
2. This equipment generates heat and cooling fans operate 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 and ensure the equipment stated operating conditions listed herein.
3. There is a risk of equipment damage if the equipment if subjected to cleaning or sterilization methods not approved by the manufacturer. To reduce the risk of loss of function and/or damage to the equipment, only use the approved cleaning and sterilization methods described herein and ensure the head connector soaking cap provided is used during sterilization processes. Do not immerse the console in liquid.
4. 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.
5. If the device is connected to a network, ensure that the network is secure and appropriate preventative measures (for example, firewalls, network access authentication, malware detection software, etc.) are implemented to prevent device exposure to malware.
6. This device utilizes an 802.11 a/b/g/n/ac transceiver for wireless communication to the optional tablet device. These devices operate in the 2.4 and/or 5 GHz ISM bands. Locate the device away from other sources of RF energy in these frequency bands to reduce the chance of interference.

Note: The warranty is void if any of these warnings or cautions are disregarded.

Note: Report any serious event, as defined in the European Medical Device Regulations (EU MDR 2017/745), involving the device to the manufacturer and, if applicable, to the national Competent Authority of the Member State.

Symbol Definitions

In addition to the cautionary symbols already listed, other symbols found on the Omni 4K video system and in this manual have specific meanings that clarify the proper use and storage of the Omni 4K video system. The following list defines the symbols associated with this product:

Caution - precaution or warning notice

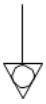
Operating Instructions

Humidity range

Pressure range

Temperature range

Type BF Equipment



Equipotentiality

Protective Ground Earth

Fuse rating

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact the manufacturer or other authorized disposal company to decommission your equipment.

A lightning bolt within a triangle is intended to warn of the presence of hazardous voltage. Refer all service to authorized personnel.

Power Standby/On

Light Source

Video Camera

Universal Serial Bus

Non-ionizing Radio Frequency Electromagnetic Radiation

CE Mark

Available by Prescription Only

Fragile

Keep Dry

This Side Up

Manufacturer

Date of Manufacture

Distributor

Serial Number

Reference or Catalog Number

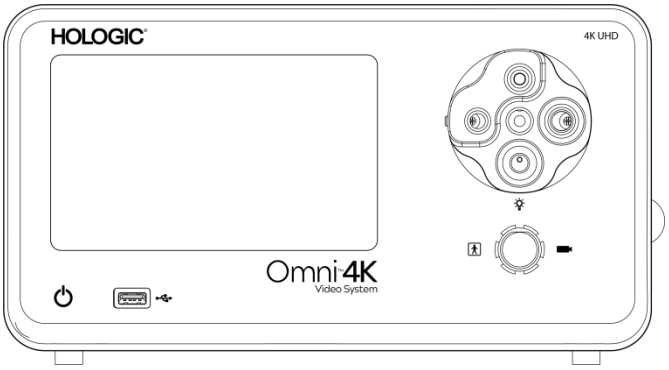
Authorized Representative in the European Community

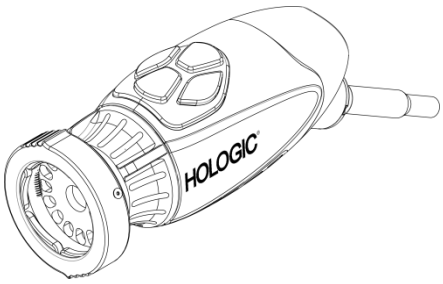
Underwriters Laboratories Safety Mark

Non-Sterile

Medical Device

Product Description





The Omni 4K video system is an Ultra High-Definition camera used to capture still and video images of endoscopic or general surgical applications. The system also incorporates an internal light source featuring a Turret Light Guide Adapter which accepts various light guides. The Omni 4K video system consists of a console and a camera head from the list below:

Part Number	Component
83-10-4010	4K UHD CAMERA CONTROL UNIT, HOLOGIC
83-10-4120	4K UHD CAMERA HEAD, INTEGRATED, 1CMOS, HOLOGIC
83-10-1000	TABLET, HOLOGIC

The Omni 4K video system is approved for use with various peripherals and connection cables which can be purchased separately.

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

Intended Use

The Omni 4K video system, with integrated LED light source and image/video capture, is to be used when performing a variety of minimally invasive surgical procedures and for general medical visualization and video archive applications. The Omni 4K video system incorporates a remote camera head which displays the image, as presented through an endoscope, microscope, integrated or coupled optics, onto a viewing 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 or an optional secondary remote control mobile device.

The Omni 4K video system is intended to be used in a controlled operating room environment with compatible devices by qualified medical personnel. The camera heads are provided non-sterile. The endoscopic camera head may be sterilized by steam autoclave or other prescribed sterilization methods. The system has a 3 year expected service life.

Indications/Contraindications

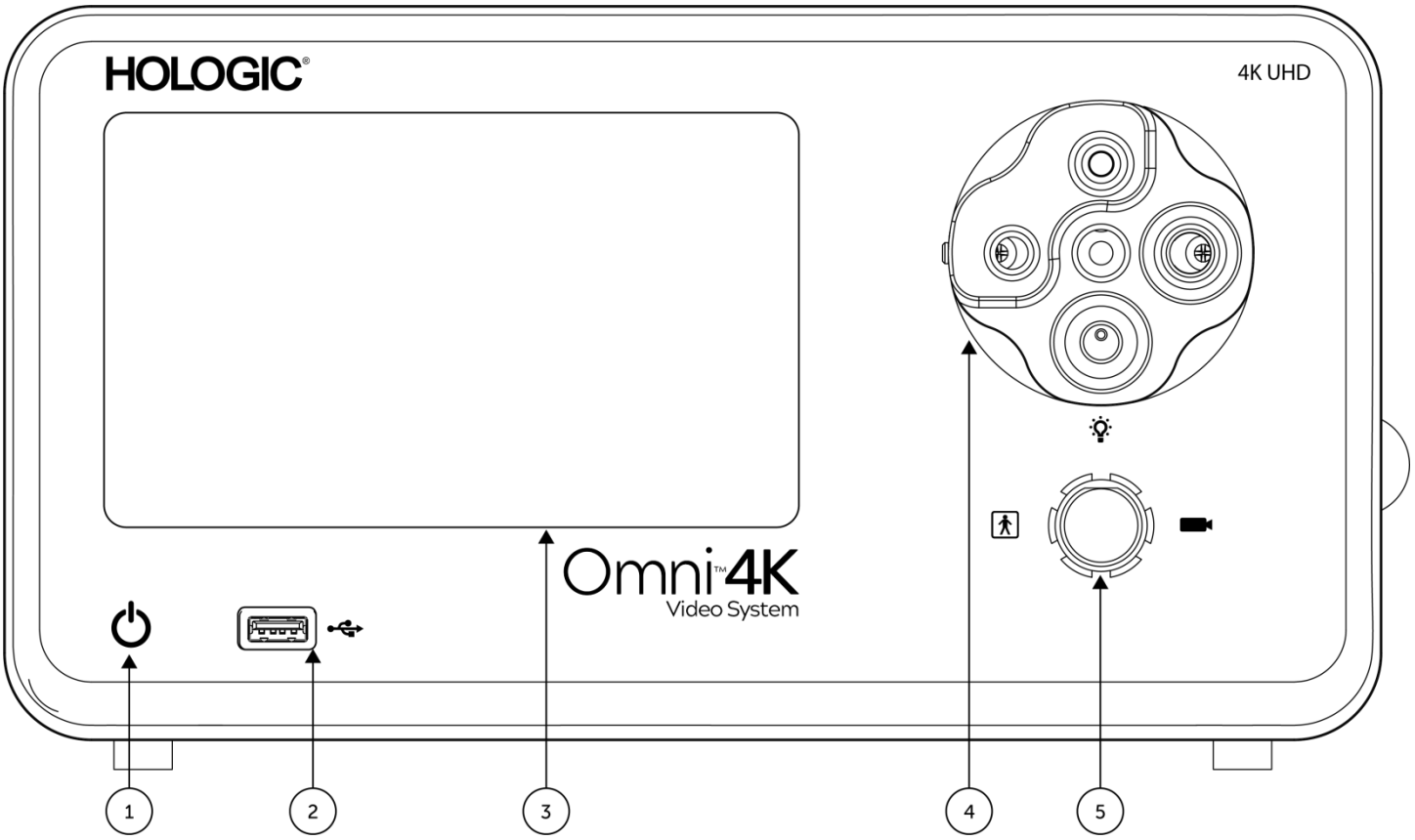
The Omni 4K video system is indicated for use in diagnostic and operative endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening. The Omni 4K video system is indicated for use with a compatible camera head and other accessory devices including an endoscope, optical coupler, and light cable.

There are no known contraindications.

The Camera Console

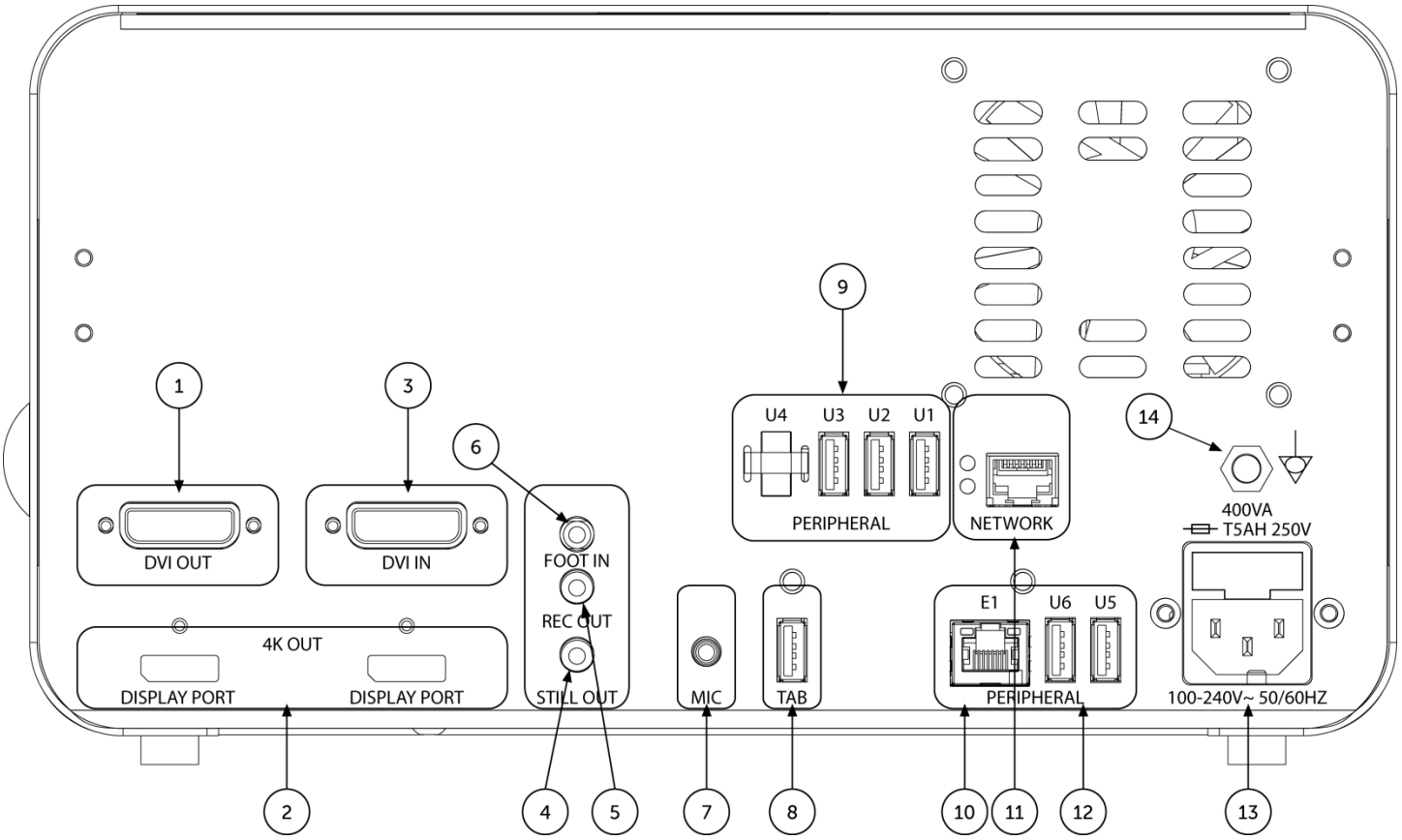
The **camera console** or **Camera Control Unit (CCU)** is the control center for the Omni 4K video system and processes the live video and still images captured during the surgical procedure. The console front panel features a touch screen, where user menus can be accessed, including the camera controls for adjusting the enhancement level, light level, zoom, and white balance, as well as allowing the selection of camera profile settings that optimize camera performance for various, specific surgical procedures.

Front Panel



1.	**Power Switch**	Camera ON or STANDBY switch
2.	**USB Port**	Allows for saving videos and still images to a USB device
3.	**Touch Screen**	Allows navigation through different menus for controlling the camera and adjusting the system settings
4.	**Turret Light Guide Adapter**	Accepts a variety of light guide adapters
5.	**Camera Connector Port**	Connects to a remote camera head

Rear Panel



Rear Panel Diagram

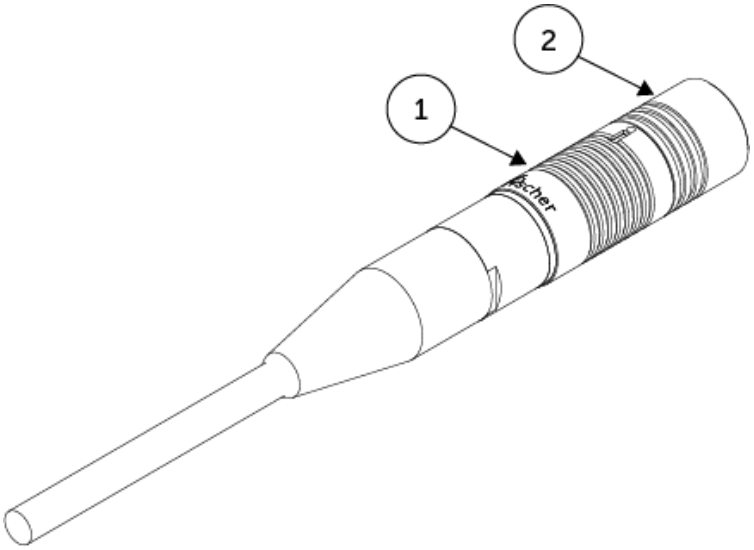
1.	**DVI Out**	1080p (HD) Digital video outputs
2.	**DisplayPort**	4K (UHD) DisplayPort video outputs
3.	**DVI In**	Digital video input
4.	**Still Out**	Connects to a video accessory remote switch
5.	**Rec Out**	Connects to a video accessory remote switch
6.	**Foot In**	Connects to accessory remote footswitch
7.	**Mic In**	Connects to accessory microphone
8.	**Tablet**	Connects to the accessory tablet
9.	**USB 2.0 Ports**	Connects to accessories via three (3) USB 2.0 Ports
10.	**Peripherals**	Connects to peripherals via one (1) Ethernet connection
11.	**Network**	Connects to a network via a high speed Ethernet connection
12.	**USB 3.0 Ports**	Connects to accessories via two (2) USB 3.0 Ports
13.	**AC Power Inlet**	Connects to separable power cord, to connect to supply mains
14.	**Equipotential Ground Plug**	Connects to system or chassis ground

The Camera Heads

The camera head connects to the camera console and captures video and still images, which it relays to the camera console.

Warning: The camera head is not an Applied Part and is not intended for patient contact.

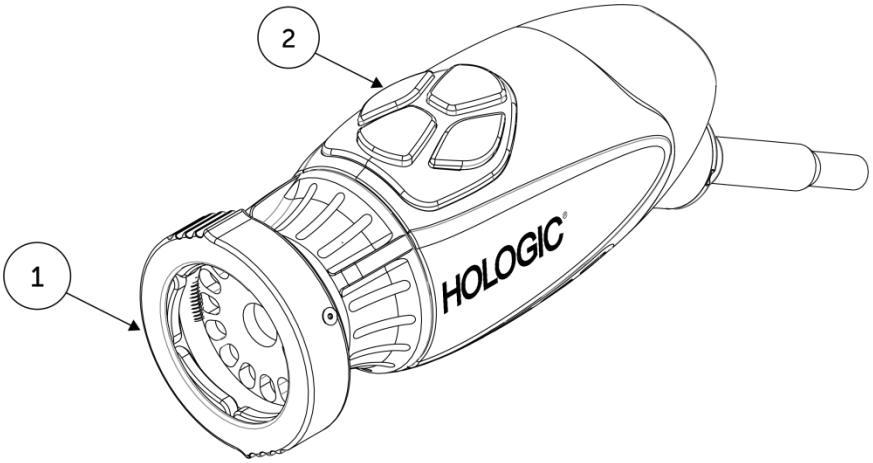
All camera heads utilize a cable connector to connect to the camera console. To insert or remove the camera head connector, use the grip feature on the connector, do not pull on the cable to attempt to disconnect the connector.



All camera heads include a removable soaking cap to be used during cleaning and sterilization processes.

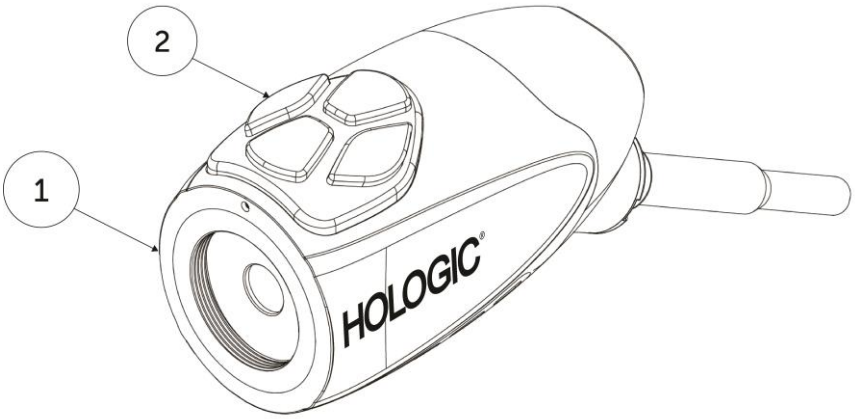
1.	**Cable Connector**	Connects the camera head to the camera console
2.	**Soaking Cap**	Protects the cable connector during cleaning and sterilization

Integrated Camera Head (83-10-4120)



1.	**Grabber**	Accepts a compatible endoscope
2.	**Head Buttons**	Four programmable buttons that can activate various functions of the camera.

C-Mount Camera Head (83-10-4110)



1.	**C-mount threads**	Connects to a c-mount coupler
2.	**Head Buttons**	Four programmable buttons that can activate various functions of the camera.

Compatible Equipment

The Omni 4K video system is compatible with the following equipment:

Catalog Number	Description
83-12-2601	HD MONITOR, 26IN, HOLOGIC
83-12-3102	4K UHD MONITOR, 31IN, HOLOGIC
83-12-4001	4K UHD OFFICE MONITOR, HOLOGIC
83-18-1004	CAMERA HEAD TRAY, HOLOGIC
83-20-5003	5MM LIGHT GUIDE, BLUE, HOLOGIC
83-20-50031	WOLF LIGHT GUIDE POST ADAPTER, HOLOGIC
83-20-50032	ACMI LIGHT GUIDE POST ADAPTER, HOLOGIC
83-20-50033	STORZ LIGHT GUIDE POST ADAPTER, HOLOGIC
83-26-7100	TABLET TETHER CABLE, HOLOGIC
83-26-8325	DISPLAY PORT CABLE, 25FT, HOLOGIC
83-26-8360	DISPLAY PORT CABLE, 6FT, HOLOGIC
83-26-9010	US POWER CORD, HOLOGIC
UPDR80MD	MEDICAL PRINTER SONY
UPCR81MD	COLOR PRINT PACK SONY
UPCR80MD	A4 COLOR PRINT PACK SONY
FS-24	FOOTSWITCH SONY FS-24
USM64XB	USB-X 64GB FLASH DRIVE

Setup and Interconnection

Note: Instructional training, or inservice, is an integral part of the Omni 4K video system. Your local sales representative will perform at least one inservice at your convenience to help set up your equipment and instruct you and your staff on its operation and maintenance. To schedule an inservice, contact your local sales representative after your equipment has arrived.

Setting up the Omni 4K video system involves three steps:

1. Setting up the console & monitor
2. Setting up the camera head with illumination, if applicable
3. Setting up the compatible accessories, if applicable

A typical installation is illustrated in Figure 1 for reference.

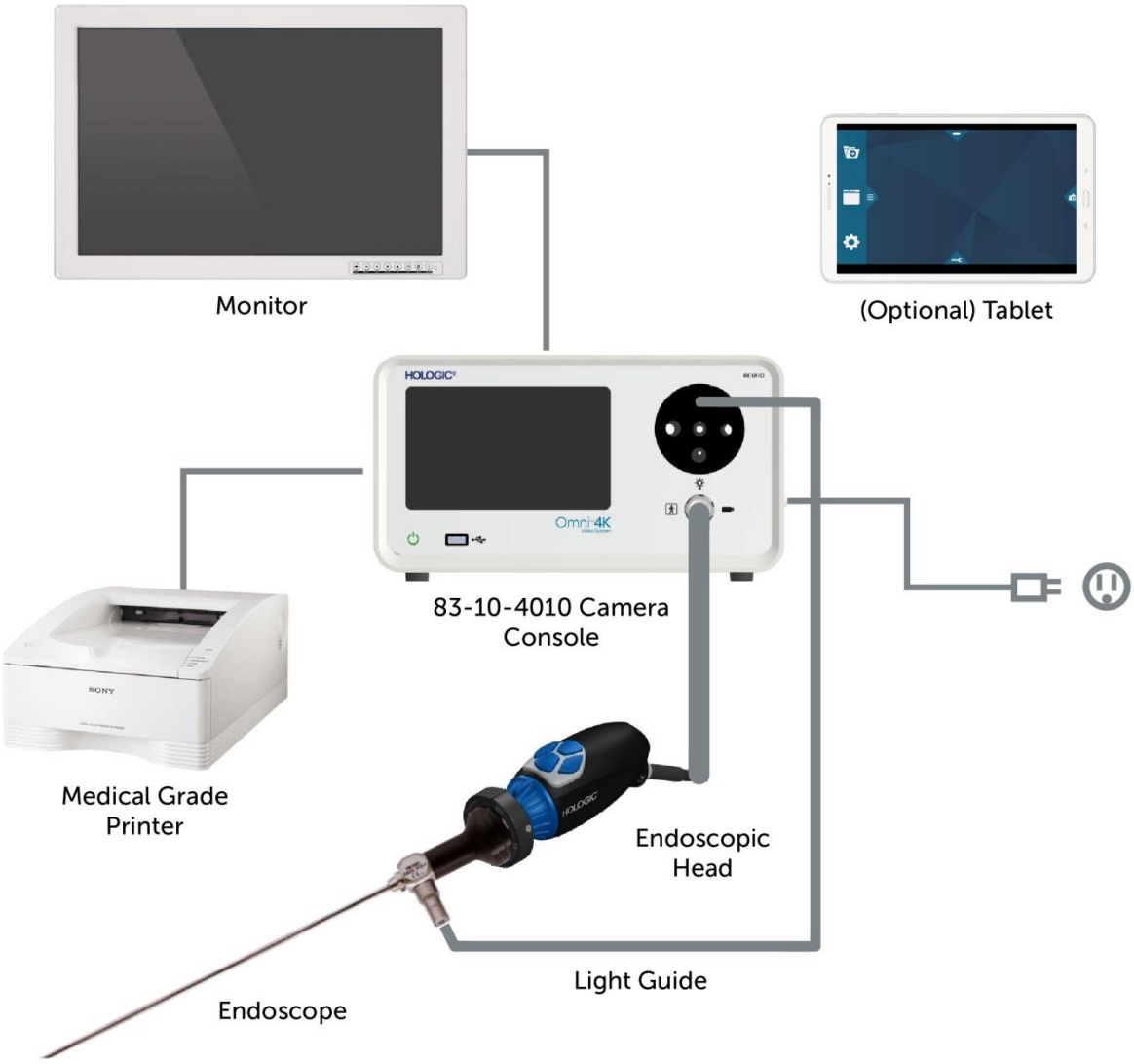


Figure 1 – Installation/System Setup Illustration

Setting Up the Console & Monitor

1. Place the Hologic Camera Console in a well-ventilated location (video cart shelf, etc).
2. Setup compatible monitor per the manufacturer's specifications. Only IEC60601-1 approved monitors are allowed to be connected to the camera system.
3. Connect the video output.
4. Connect a DisplayPort video cable to the DisplayPort output on the rear panel of the Omni 4K video system console (a DVI cable may be used instead of DisplayPort).
5. Connect the other end of the DisplayPort cable to the DisplayPort input of the monitor.
6. Connect the AC Power cord.
7. Plug the AC power cord into the power inlet module on the rear panel of the Omni 4K video system.
8. Connect the other end to a grounded outlet (100-240 V~, 50-60Hz).
9. Ensure that the console is located and positioned so that the appliance inlet (where the power cord is connected to the equipment) is readily accessible.
10. After AC power is applied and the unit is powered ON, ensure a color bar pattern appears on the monitor. A live image will only be displayed when a camera head is connected to the console.
11. Review camera settings and profiles. Make any changes as needed via the console or tablet menu as required.

NOTE: An additional monitor may be connected to any of the remaining camera video outputs on the rear panel.

Setting Up the Camera Heads

If using the endoscopic camera head:

1. Insert the camera head connector into the camera receptacle on the front panel of the console. Alignment marks are provided on the camera head connector to ensure proper orientation.

NOTE: Ensure the camera head connector contacts are clean and dry prior to insertion.

Setting Up the Light Source (applicable for 83-10-4010)

WARNING

IMPORTANT SAFETY NOTICE:

When using a light source, fire and/or severe injury may result to the patient, user, or inanimate objects. Light sources generate significant amounts of heat at the endoscope tip, the endoscope light post, the light cable tip, and/ or near the light cable adapter. Maintain the light source at a minimum as higher levels of brightness from a light source may result in higher levels of heat.

To reduce the risk of injury, avoid patient and user contact with the endoscope tip or light cable tip, and never place them on top of the patient, as doing so may result in burns to the patient or user.

To reduce the risk of fire, never place the endoscope tip, the endoscope light post, the light cable adapter, or the light cable tip on the surgical drapes or other flammable material, as doing so may result in fire.

Always place the light source in standby mode whenever the endoscope is removed from the light cable or the device is unattended. The endoscope tip, endoscope light post, light cable adapter, and light cable tip will take several minutes to cool off after being placed in standby mode, and therefore may still result in fire or burns to the patient, user, or inanimate objects.

If using the internal light source:

1. Rotate the light source turret to the appropriate light guide receptacle.
2. Insert the light guide cable into the light guide receptacle on the front panel of the console.
3. Attach the other end of the light guide cable to the endoscope.
4. Attach the endoscope to the camera head grasping mechanism.
5. Press the Light Source On/Standby Switch to ON to activate LED light engine.

NOTE: If there is no Light Guide cable connected to the Omni 4K video system console, pressing the On/Standby button will not activate the LED light engine until one is connected.

NOTE: If using 83-10-4010 with an external light source, please refer to the corresponding light source user manual.

Setting Up the Compatible Equipment

Connect other compatible accessories and peripheral equipment, as applicable.

- Use Figure 1 and the rear panel labeling as a guide to connect other compatible equipment, if desired.
- Connect only IEC60601-1 approved equipment.
- See *720-00042 User Guide Supplement, DICOM, Omni 4K video system* for use of the camera system in a DICOM environment.

System Operation

For the protection of the patient, perform a complete system test prior to initiating a surgical procedure.

Pre-Operative Check

For the protection of the patient, it is essential that the system setup is complete, functional, and produces a viable image on the surgical monitor prior to administration of patient anesthesia or starting a case. Pre-operative checks should include functionality of peripheral equipment, optical accessories, and illumination.

Before use, check that the light source activates standby mode upon removal of light guide.

Before each use, the operator should check to ensure that essential camera controls are functioning as needed for the intended procedure. During use, after changing camera system settings or initiating image or video capture, the operator should check that the image displayed is live, of proper color and size, and properly oriented.

White Balance

When the camera head connector is inserted, the User is required to white balance the camera. Pressing any of the four head buttons activates the white-balance function. The white balance function is used to correct slight color differences that exist between different light sources or endoscopes.

Perform the white balance procedure before every surgical procedure.

Note: Ensure that an endoscope and light source are attached to the camera, and that the camera, light source and monitor are powered on before adjusting the white balance.

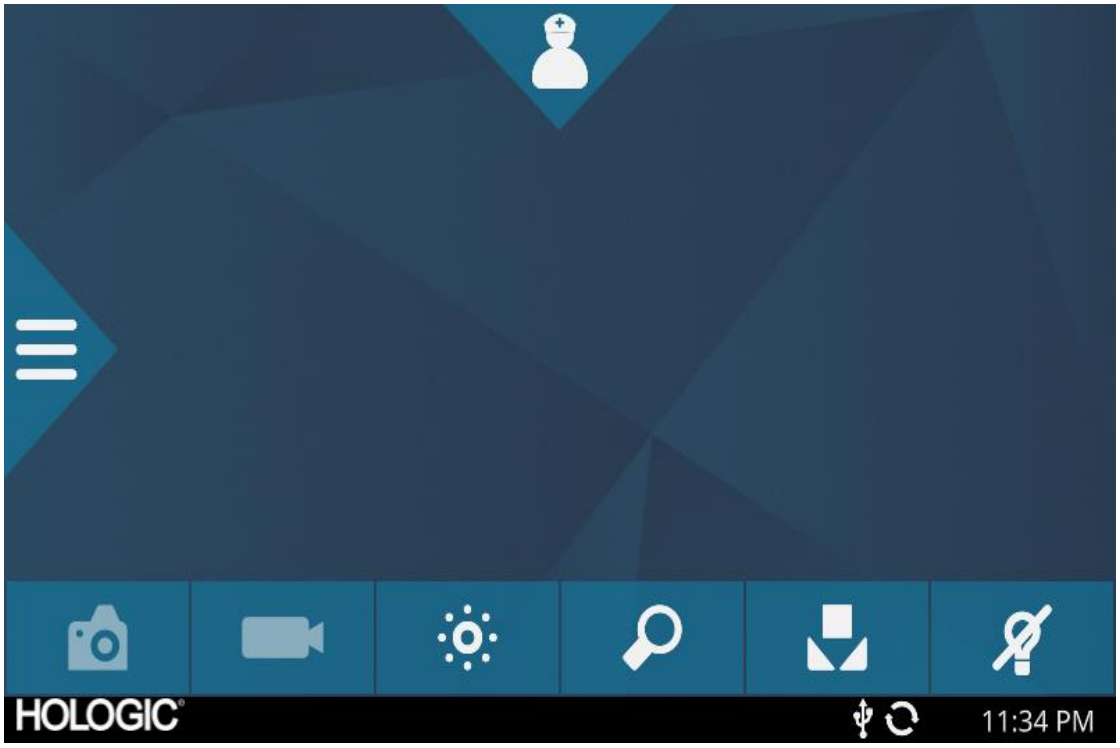
1. Point the endoscope at several stacked 4”x4” (10cm x 10cm) white gauze pads, a white laparoscopic sponge, or any clean white surface.
2. Look at the monitor and make sure that no glare is visible off of the white surface.
3. Press any camera head button until White Balance indicator is displayed on the video monitor.
4. Continue pointing the endoscope at the white surface until the video monitor indicates that white balance process is complete. The video picture may change color. If you cannot achieve an acceptable white balance, refer to the “Troubleshooting” section of this manual.
5. After white balance has been achieved, all head buttons revert to their standard functions (which may be configured using the Profile submenu of the Settings Menu).
6. White balance may also be initiated from the Console front panel or via the tablet.

Using the Console Touchscreen Interface

The touchscreen interface on the console provides controls for operating the camera and selecting system settings. Controls are located in a series of menus highlighted below.

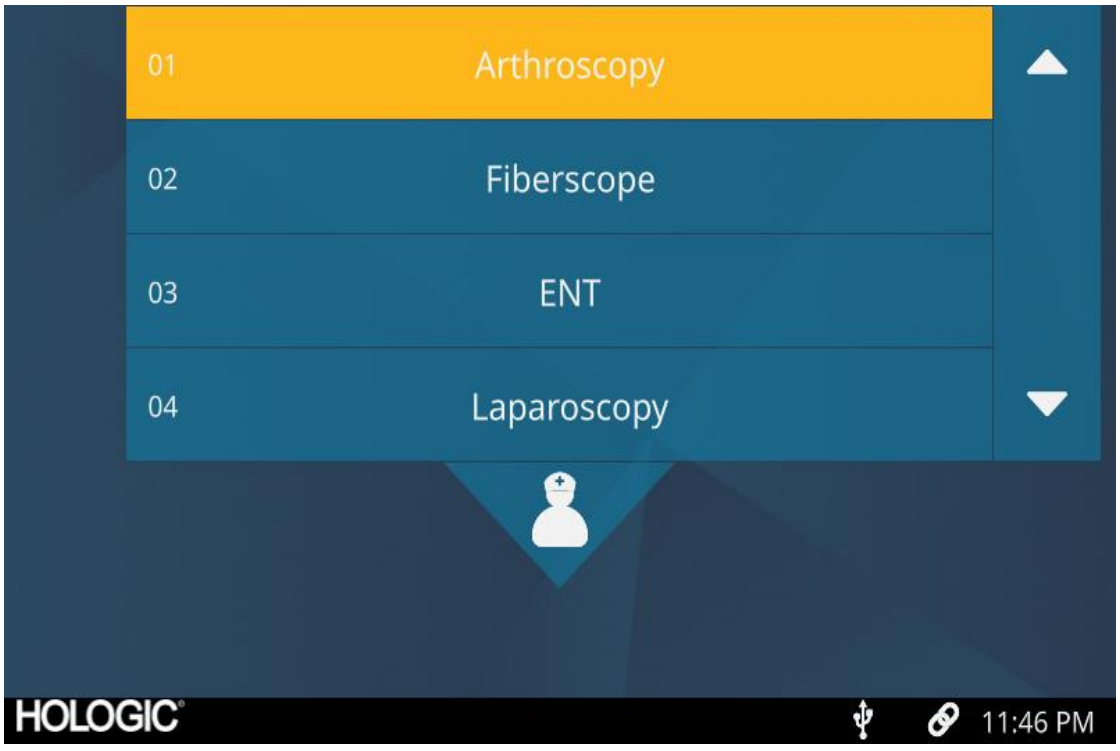
Console Home Screen

The Home screen is the default screen. Use the buttons to choose camera profiles, operate the camera, and to navigate to other menus.



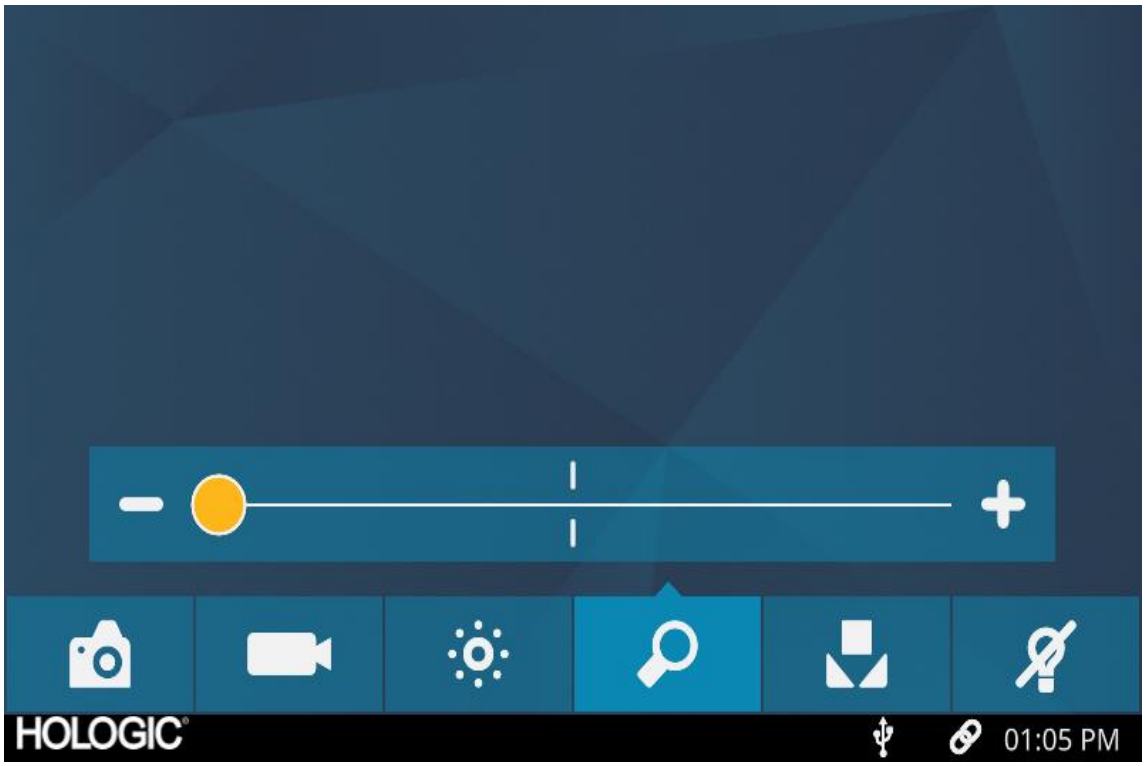
Profile

The Profile tab provides options for selecting a camera profile.



Console Toolbar

The Toolbar provides options for frequently used camera functions.



Console Functions

Zoom 

White Balance 

Still Image Capture 

Video Record 

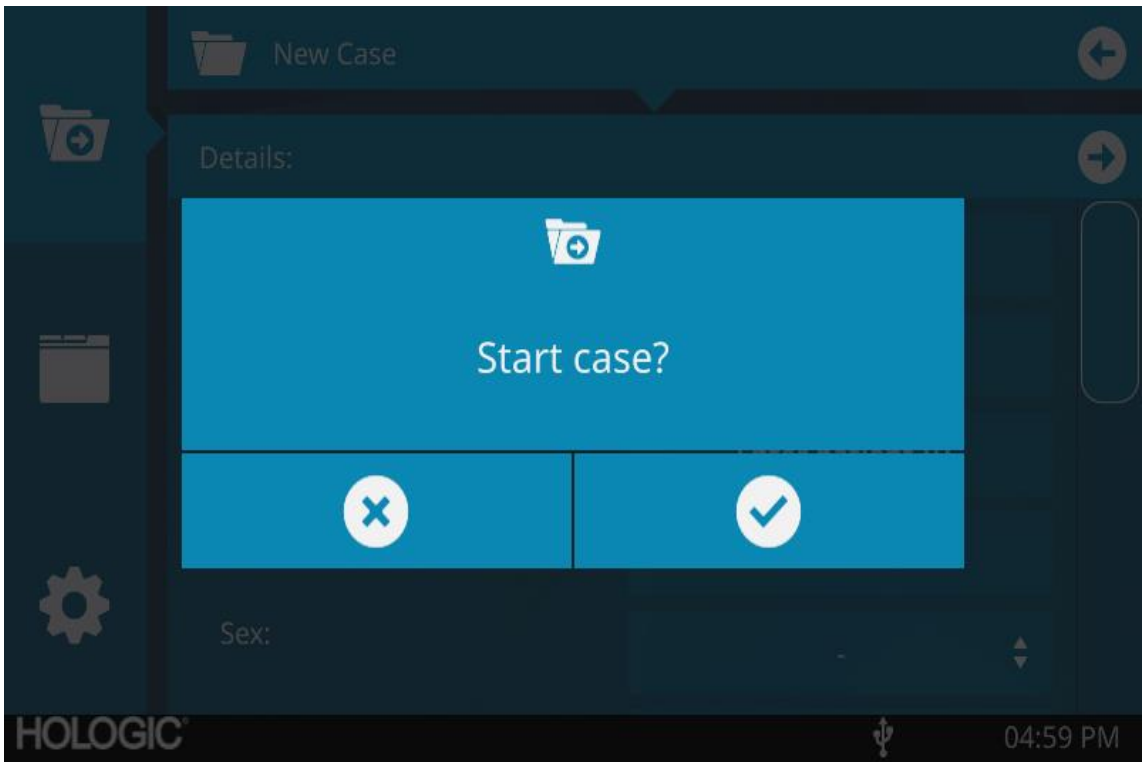
Brightness 

Light Source Standby 

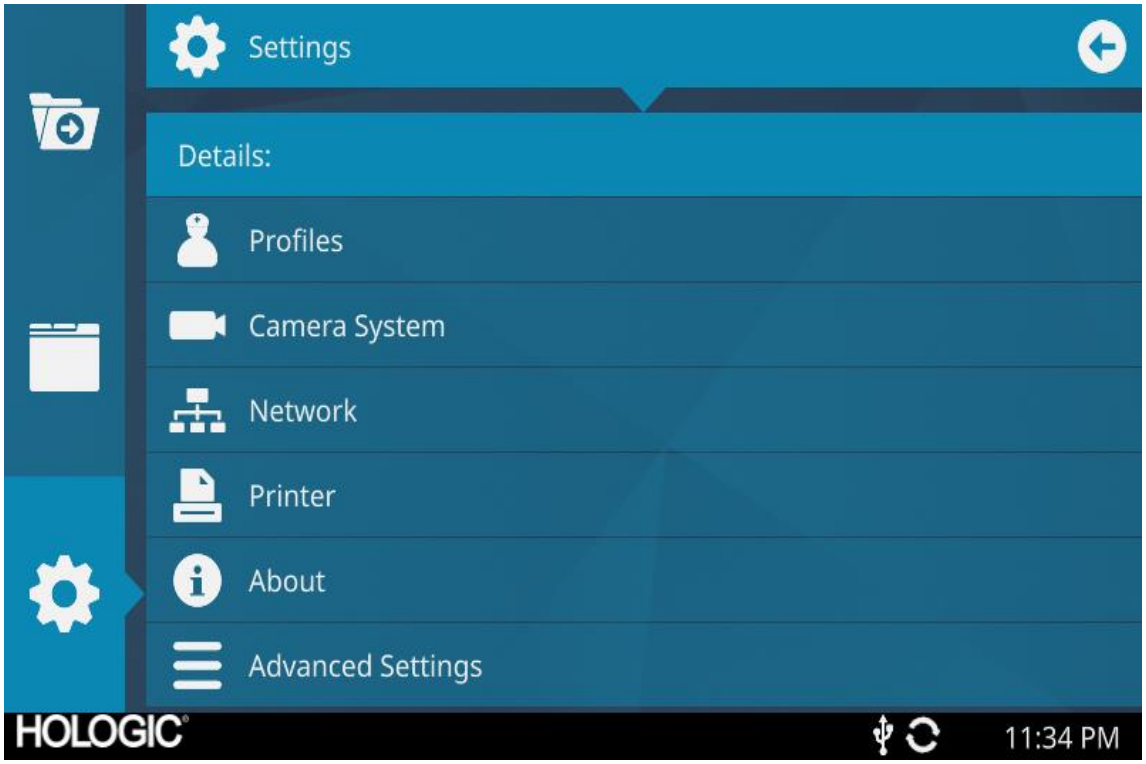
Console Menu

The Menu tab provides options for case management and camera system settings.

Console Start Case



Console Settings



Using the Tablet Interface

The tablet provides an additional interface for image and video capture functionality and for adjusting system settings.

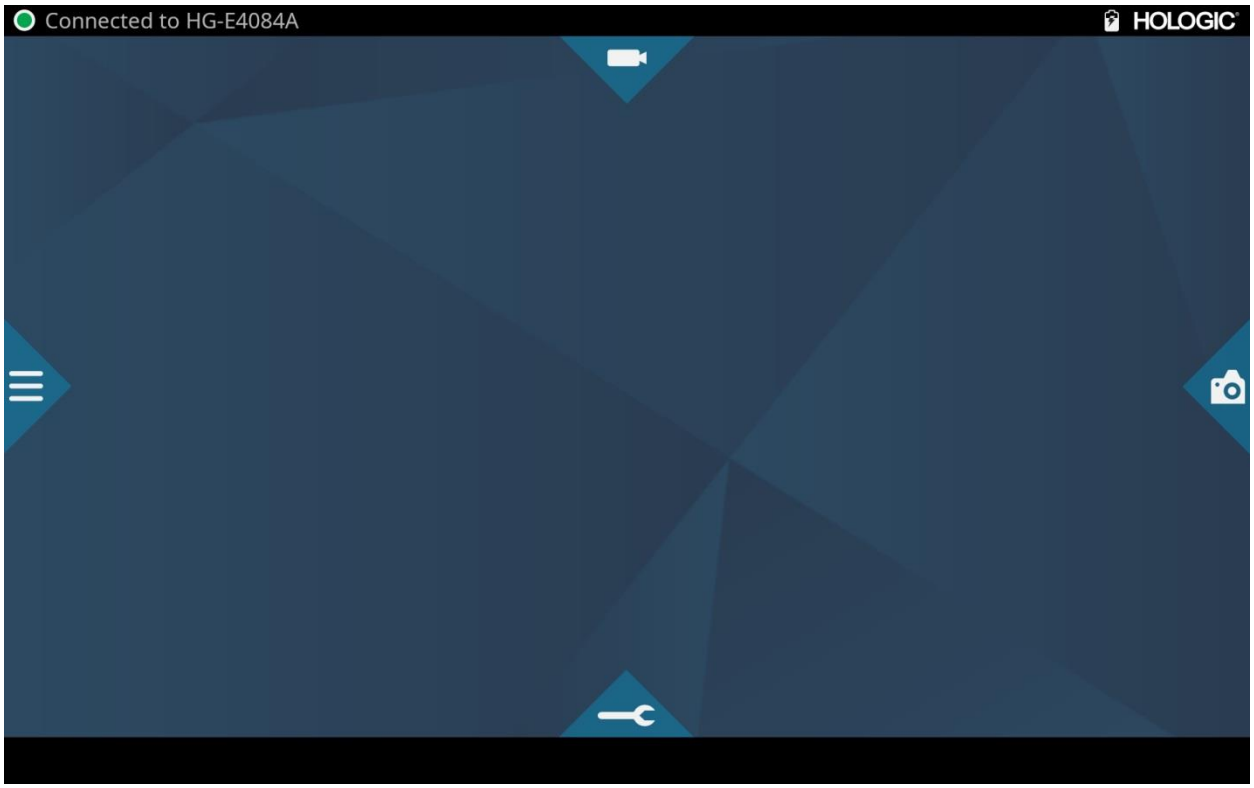
Tablet screens and menu selections are described in the section herein.

Tablet Set Up

The tablet may be set up for wireless or tethered (cabled, non-wireless) connection to the Camera Console Unit. For wireless use, ensure that the tablet's Wi-Fi is turned on and connected to the Camera Console Unit's wireless network. For tethered operation, the Camera Console Unit's Wi-Fi may be turned off and the tablet should be connected directly to the Camera Console using the supplied Tablet Tether Cable. The tablet manufacturer's charging cable is only used for charging the tablet from a wall outlet.

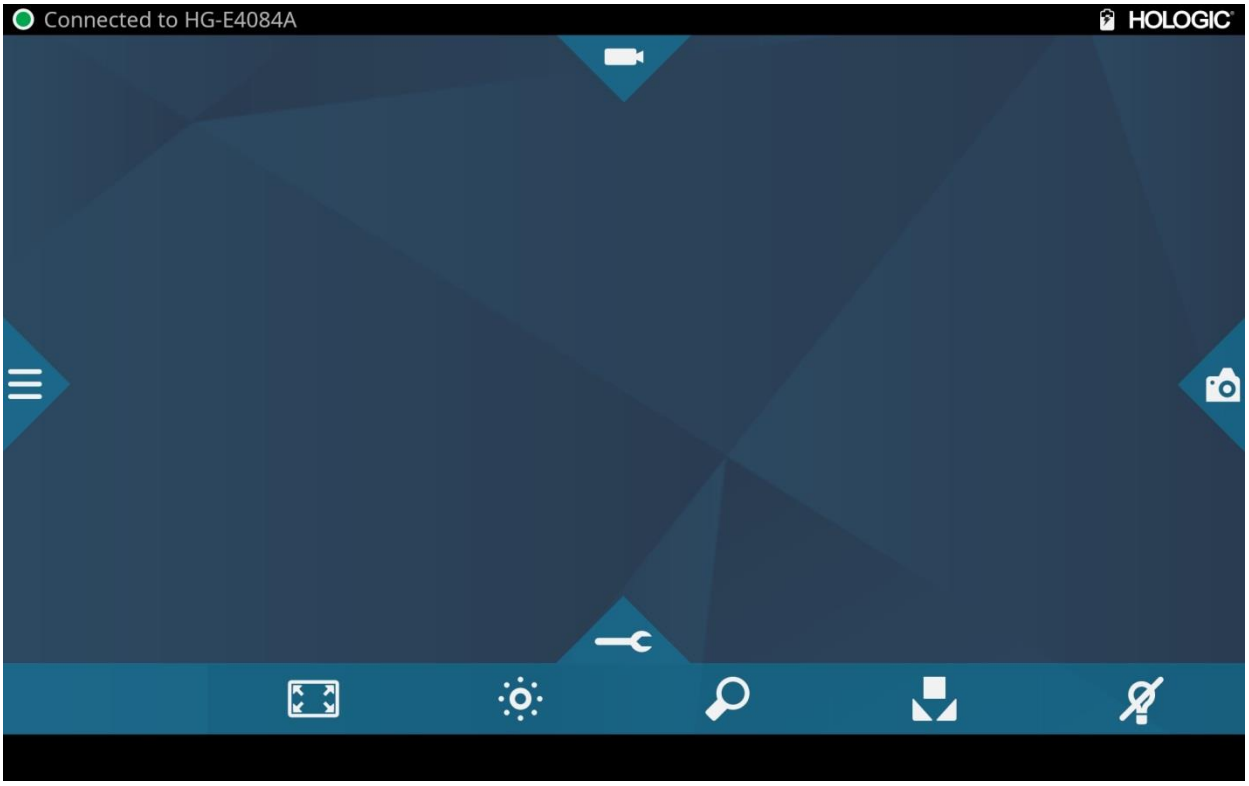
Tablet Home Screen

The Home screen is the default screen. Use the buttons to start new cases, access case history, and navigate to other menus.



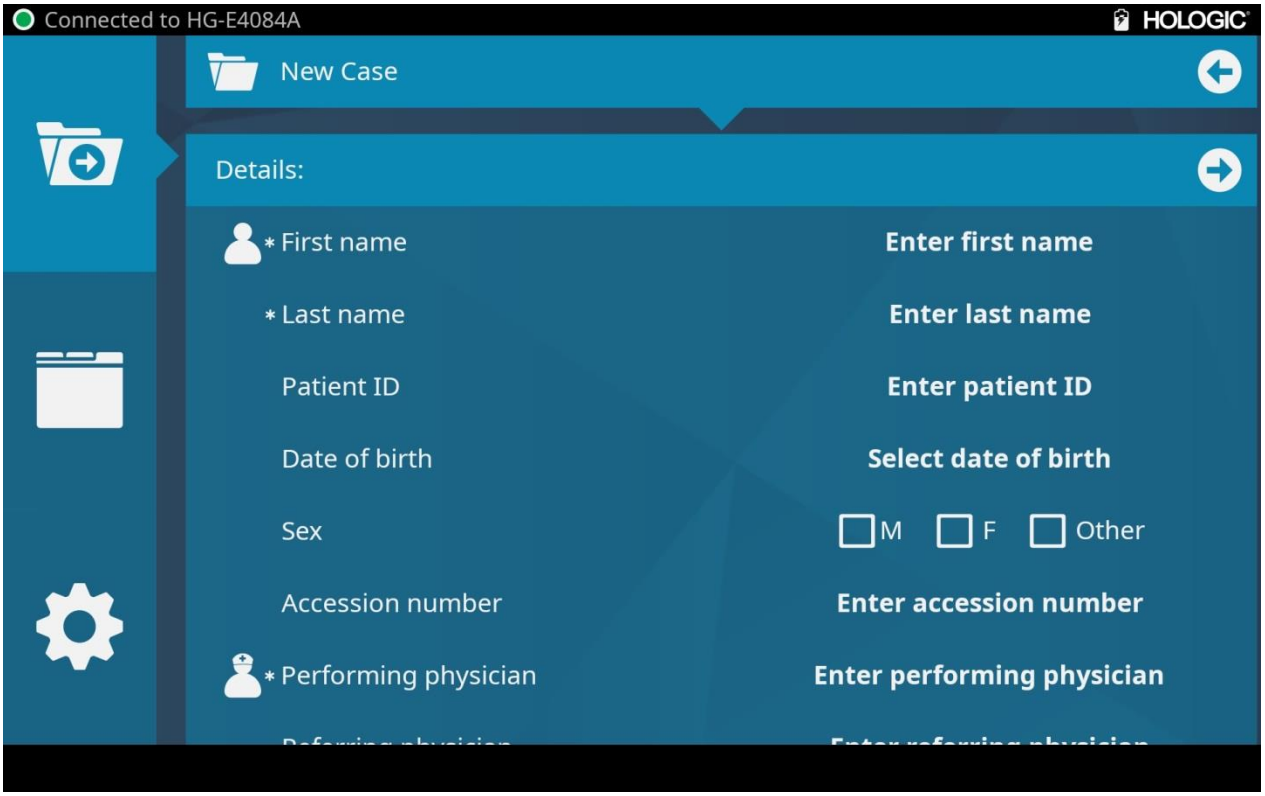
Tablet Toolbar

The toolbar provides options for frequently used functions.



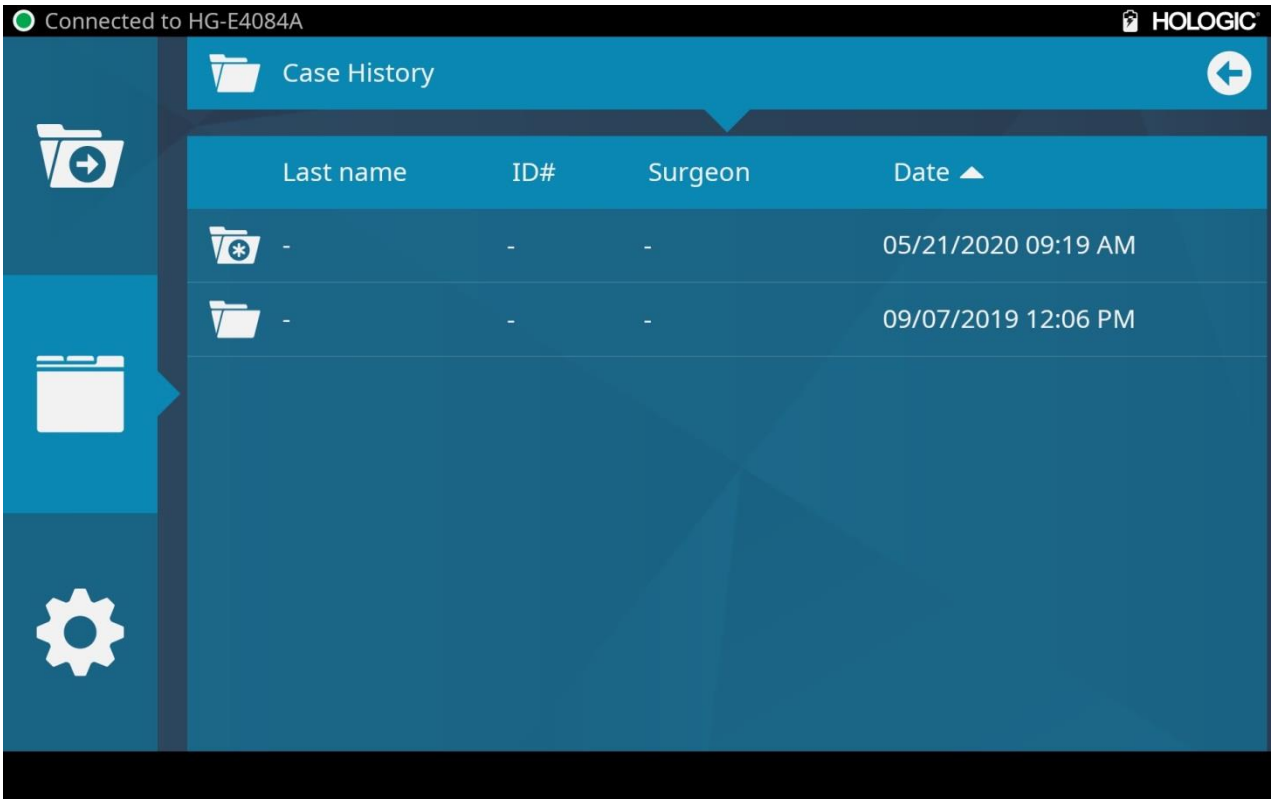
New Case

Access the new case settings in order to enter patient information and other important case data. The new case may be started immediately or saved for a later start time. In order to start a new case, users are required to enter a minimum of information as configured in the Menu settings.



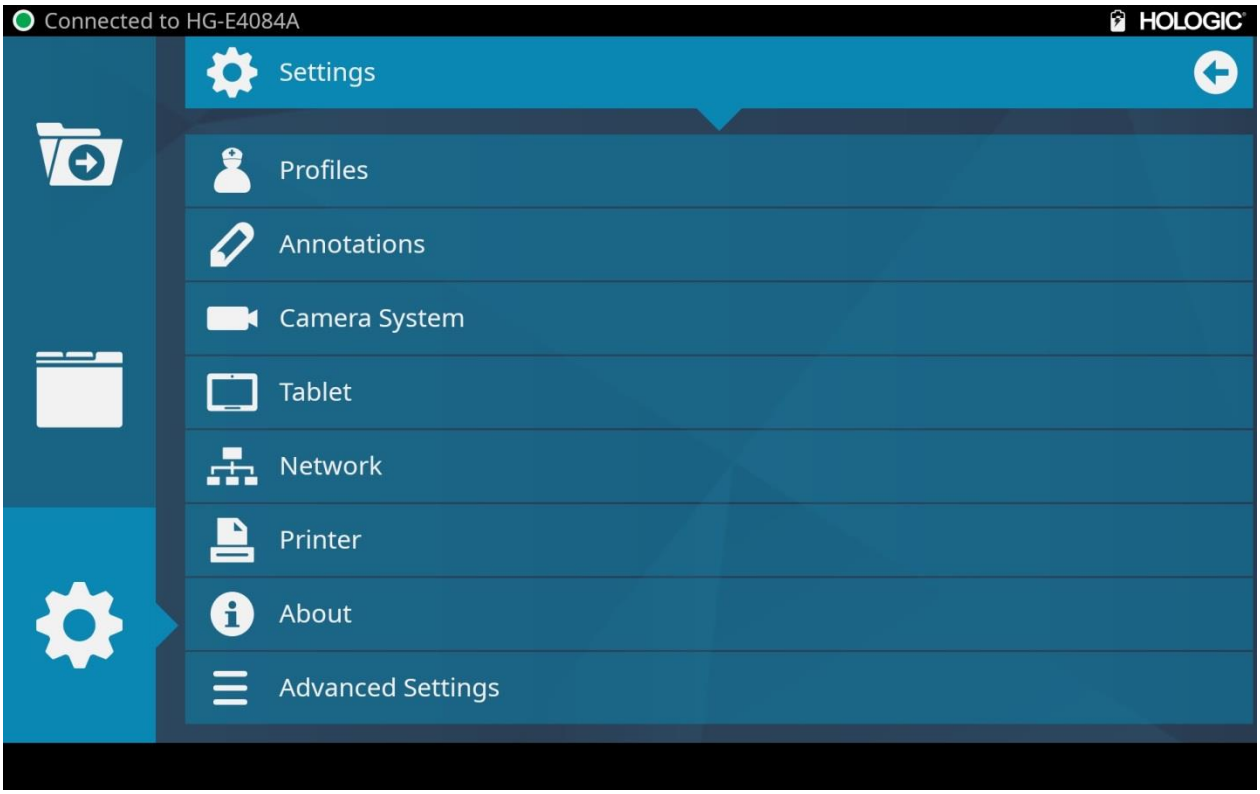
Case History

Case history provides options for managing case data.



Settings

The settings provide options for the configuration of the system.



Troubleshooting

Problem	Possible Solution
No color bar	• Ensure the video-out from the console is connected to the video-in on the monitor. • Ensure all video systems are powered on. • Ensure that the camera head is not connected to the console. • Turn off the console, wait 3 seconds, and turn it back on.
Incorrect picture color	• Perform the white balance procedure. (See the "White Balance" section of this manual.) • Check the color settings on the monitor.
White balance (WB) quality not good	• See the solution for "Picture is too dark." • See the solution for "Picture is too bright." • Perform the white-balance procedure with the light source connected to the endoscope. Use the device's LED light source or a separate xenon light source (no fluorescent lighting).
Picture is too dark	• Increase the camera brightness • Check the fiber-optic light cable for excessive broken fibers. • Check the endoscope for damage.
Picture is too bright	• Decrease the camera brightness.
Noise or snow on picture when using electrocautery probes	• Plug the electrocautery generator into a separate electrical outlet and separate the Omni 4K video system power cord from the electrocautery power cord. • Separate the camera cable from the electrocautery cable. • Reposition the electrocautery grounding pad on the patient.
Noise or snow on picture when not using electrocautery probes	• Reduce Enhancement. • Check for and replace faulty video cables.
No video picture when the camera head is plugged in	• Check to ensure that all devices in the video system are plugged in and powered on. • Check the connector on the camera-head cable for broken pins. • Detach the camera head from console and reconnect • Turn off the console, wait 3 seconds, and turn it back on.
Image is not well centered	• Release the endoscope from the coupler and then reconnect it. Make sure the endoscope is seated correctly in the coupler.
Foggy picture (loss of definition and clarity)	• Refocus the camera. • Refocus the coupler. • Clean and dry the camera, endoscope, and coupler windows.

Problem	Possible Solution
Optics are dirty	• Rotate the endoscope. If dust particles in the picture rotate, the dust is located on the endoscope itself. Follow the manufacturer's instructions for cleaning the eyepiece and negative lens. • If particles in the picture do not move when you rotate the endoscope, the particles are located on the coupler or camera. Remove the endoscope and clean the windows on the coupler and camera with a dry or alcohol-tipped cotton swab. • Ensure all components are completely dry before reassembling them, or fogging may result.
Blurry picture	• Ensure the coupler or camera is in focus. • Increase the enhancement.

Note: If this troubleshooting guide does not resolve the problem, contact Hologic Technical Support (1-800-442-9842 or GssTechSupport2@hologic.com). Refer to the "Warranty, Service, and Repair" section of this manual.

Cleaning, Reprocessing, and Maintenance

The camera console may be cleaned, but not sterilized.

The endoscopic camera heads and couplers must be cleaned and sterilized before each use following the guidelines herein.

Cleaning the Camera Console

Disconnect the console from the AC power source before cleaning.

CAUTION: Never immerse or sterilize the camera console as this will damage the camera console and void the warranty.

Should the camera console need cleaning, wipe it down with a sterile cloth and mild cleaning solution.

Reprocessing the Camera Head

NOTE: Only camera heads marked Autoclave can withstand steam sterilization. Autoclaving camera heads that do not bear this marking will result in product damage.

Warning: Failure to use provided soaking cap during sterilization processes may cause damage to the device and loss of function.

Autoclave

Manufacturer: Santa Barbara Imaging Systems

Method: Steam Sterilization (Autoclave)

Device: Hologic System Camera Heads marked Autoclave, Wrapped

Notes: Failure to use provided soaking cap during sterilization processes may cause damage to the device and loss of function.

Warnings	
	• This device must be cleaned and sterilized prior to the first use and after every subsequent use. • Wear appropriate protective equipment: gloves, eye protection, etc. • Use only the sterilization cycles outlined in this document. Using unspecified sterilization cycles may damage the device or result in incomplete sterilization resulting in patient risk. • Separate the camera head and endoscope prior to cleaning, disinfection, or sterilization. If a C-mount camera is used, separate the coupler and endoscope prior to cleaning, disinfection, or sterilization. If the coupler and camera head are cleaned, disinfected, or sterilized as a single unit, disconnecting the coupler during use will compromise the sterility of the two products. (Refer to the coupler and endoscope product manuals for reprocessing instructions.)
Cautions	
	• Always install the soaking cap on the camera cable connector prior to processing the camera. Failure to properly install the soaking cap will corrode the connector pins and void the warranty. • Use only the approved cleaning procedure outlined herein. Use of other cleaning procedures, including cleaning agents and germicidals, not specified in this document may cause product damage. • Inspect the camera cable for cuts and breaks before soaking in any fluid. • Return any damaged camera to manufacturer for service. • Never soak the camera in the same tray with sharp instruments. • Do not use brushes or pads with metal or abrasive tips during manual cleaning, as permanent scoring or damage could result. • To minimize galvanic corrosion, avoid soaking dissimilar metals in close proximity. • Only camera heads marked autoclave can withstand steam sterilization. Autoclaving camera heads that do not bear this marking will result in product damage. • Allow the camera head to cool before connecting it to the console. • Connecting the camera head while it is still hot may result in system error.
Limitations on Reprocessing	
	• Do not cross-sterilize the device. Using multiple sterilization methods may significantly reduce the performance of the device. • Do not leave the device in solutions longer than necessary. This may accelerate normal product aging. • Proper processing has a minimal effect on this device. End of life is normally determined by wear and damage due to use. **Note: Damage incurred by improper processing will not be covered by the warranty.**

<table>
<tr><th colspan="2">Instructions</th></tr>
<tr><td>Point of use:</td><td>

Wipe excess soil from the device using disposable paper towels.
If an automated reprocessing method will be used, rinse any channels in the device with 50mL of sterile distilled water immediately after use.

</td></tr>
<tr><td>Containment and transportation:</td><td>

Reprocess the device as soon as reasonably practical following use[1].
Transport the device in a tray to avoid damage.

</td></tr>
<tr><td>Preparation for cleaning:</td><td>

Separate the endoscope from the camera head. If a C-Mount camera head is being used, separate the coupler from the camera head.
Prepare an enzymatic cleaning solution, such as Steris Prolystica 2X Concentrate Enzymatic Cleaner, according to the manufacturer's instructions. When using Steris Prolystica 2X Concentrate Enzymatic Cleaner we recommend 1/4 oz (ounce) per gallon with distilled or Reverse Osmosis (RO) treated water.
Wipe the entire device with the cleaning solution using a clean cloth.
Install the soaking cap.
Immerse the device in the cleaning solution. Using a syringe, inject any inside regions of the device with 50mL of the detergent to ensure all parts of the device are reached.
Soak the device in the detergent for a minimum of 15 minutes.

</td></tr>
<tr><td>Cleaning: Automated</td><td>
Equipment: Washer/Disinfector, detergent (such as Steris Prolystica 2X Concentrate Enzymatic Cleaner)

Mechanical Washer Cycle Parameters:
<table>
<tr><th>Treatment</th><th>Minimum Time (mm:ss)</th><th>Minimum Temperature</th><th>Cleaning Solution</th></tr>
<tr><td>Enzyme Wash</td><td>04:00</td><td>60° C</td><td>Steris Prolystica 2X Concentrate Enzymatic Cleaner
1/4 oz. per gallon</td></tr>
<tr><td>Wash</td><td>02:00</td><td>Hot Tap Water</td><td>Steris Prolystica 2X Concentrate Neutral Detergent
1/4 oz. per gallon</td></tr>
<tr><td>Rinse</td><td>02:00</td><td>70° C</td><td>N/A</td></tr>
<tr><td>Dry</td><td>15:00</td><td>80° C</td><td>N/A</td></tr>
</table>
</td></tr>
</table>

[1] A 120 minute wait time was used during cleaning validation to simulate worst case conditions.

Instructions	
Cleaning: Manual	**1. Brush** ○ Prepare enzymatic cleaner (such as Steris Prolystica 2X Concentrate Enzymatic Cleaner) according to the manufacturer's instructions. When using Steris Prolystica 2X Concentrate Enzymatic Cleaner we recommend 1/4 oz (ounce) per gallon with distilled or Reverse Osmosis (RO) treated water. ○ While immersed in the cleaning solution, thoroughly brush the exterior of the device with a soft-bristled brush, focusing on any mated or rough surfaces. Brush each device for one (1) minute. Brush all moveable parts in all extreme positions. ○ Using a syringe, inject any lumen or mated surface with 50mL of the cleaning solution a minimum of five (5) times. **2. Rinse** ○ Rinse the device, individually, with distilled or Reverse Osmosis (RO) treated water for one (1) minute to ensure all detergent residue is removed. Flush lumens and mated surfaces using a syringe five (5) times with 50ml. Continue to rinse each device, individually, for a minimum of 30 seconds. ○ Drain excess water from the device and dry it using a clean cloth or pressurized air. ○ Visually inspect the device for cleanliness, paying close attention to hard-to-reach areas. If visible soil remains, repeat steps 1 and 2. **3. Soak** ○ Prepare neutral detergent (such as Steris Prolystica 2X Concentrate Neutral Detergent) according to the manufacturer's instructions. When using Steris Prolystica 2X Neutral Detergent we recommend 1/4 oz (ounce) per gallon with distilled or Reverse Osmosis (RO) treated water. ○ Fully immerse the device and use a syringe to inject any lumens and mated surfaces with 50mL of the detergent solution. ○ Soak the device for a minimum of 15 minutes. **4. Brush** ○ While immersed in the cleaning solution, thoroughly brush the exterior of the device using a soft-bristled brush for one (1) minute. Brush all moveable parts in all extreme positions. ○ Using a syringe, inject 50mL of the detergent into any lumens or mated surfaces a minimum of five (5) times. **5. Rinse** ○ Rinse the device, individually, with cold tap water for one (1) minute to ensure all detergent residue is removed. Flush lumens and mated surfaces using a syringe five (5) times with 50ml. Continue to rinse each device, individually, for a minimum of 30 seconds. ○ Drain excess water from the device and dry it using a clean cloth or pressurized air. ○ Visually inspect the device for damage and cleanliness, paying close attention to hard-to-reach areas. If visible soil remains, repeat steps 4 and 5. Camera heads with damage to the camera head or cable jacket should not be sterilized and should be returned to manufacturer for repair.
Disinfection:	N/A

<table>
<tr><th colspan="2">Instructions</th></tr>
<tr><td>Drying:</td><td>See method described above in Mechanical or Manual cleaning section.</td></tr>
<tr><td>Maintenance:</td><td>No particular requirements.</td></tr>
<tr><td>Inspection and Function Testing:</td><td>Inspect the device for any damage. If the camera head is damaged or the cable is cut or kinked or if the cable jacket has been cut or otherwise damaged, do not sterilize the camera head. Return camera heads with damage to manufacturer for repair.</td></tr>
<tr><td>Packaging:</td><td>No particular requirements.</td></tr>
<tr><td>Sterilization:</td><td>Note: Ensure the soaking cap is installed prior to subjecting the device to sterilization processing.
<table>
<tr><td colspan="2">Steam Pre-vacuum Parameters</td></tr>
<tr><td>Minimum Temperature</td><td>132°C (270°F)</td></tr>
<tr><td>Minimum Exposure Time</td><td>4 minutes</td></tr>
<tr><td>Dry Time</td><td>30 minutes</td></tr>
</table>
Note: After autoclaving, set unit aside for a minimum of 15 minutes to allow equipment to cool before connecting to the control unit or attaching an endoscope. Connecting the camera head while it is still hot may result in system error.</td></tr>
<tr><td>Storage:</td><td>Never store the device in a non-ventilated, humid environment such as a carrying case. This may present an infection control risk.</td></tr>
<tr><td>Additional Information:</td><td>None.</td></tr>
<tr><td>Contact:</td><td>See last page of this manual for local representative contact information.</td></tr>
</table>

WARNING: While these reprocessing instructions have been validated by the manufacturer as being CAPABLE of preparing the device for re-use, it remains the responsibility of the processor to ensure that the reprocessing as actually performed, using equipment, materials, and personnel in the reprocessing facility, achieve the desired result. This normally requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Sterrad®

NOTE: Only camera heads marked Autoclave are materially compatible with Sterrad. Omni 4K video system Camera Heads are validated for Sterilization Assurance using the Sterrad® Systems listed below.

- **Sterrad® System 100S Short Cycle**
- **Sterrad® System NX Standard Cycle**
- **Sterrad® System 100NX™ Standard Cycle**
- **Sterrad® System 100NX™ Duo Cycle**

Please consult the instructions provided by Sterrad for using STERRAD® 100S Short Cycle, NX™ Standard Cycle, or 100NX™ Standard and Duo Cycle Sterilization Systems.

If Sterrad sterilization is used, please note the following:

1. Clean and prepare the camera head and cable as recommended in the "Reprocessing the Camera Head" section. Ensure the soaking cap is installed.
2. Allow the camera head, cable, coupler, and endoscope to completely dry before reassembly. Any moisture on the threads will cause the c-mount camera and c-mount coupler windows to fog during use.

Warning: Not all sterilization trays are compatible with STERRAD® systems. Using an incompatible tray may result in incomplete device sterilization. Consult the instructions that came with your sterilization tray to determine which sterilization method is compatible with your tray and devices.

User Maintenance

Replacing the Fuses

To avoid the risk of fire, use only fuses of the value specified on the fuse label located on the rear panel of the console.

1. Unplug the power cord from the wall outlet and remove the cord from the console.
2. Unlatch the fuse holder above the AC inlet and remove it. (You may need to press the tab on the fuse holder with a slender screwdriver to release the latch.)
3. Replace the fuse with the same value and rating, as indicated on the rear panel.
4. Reinstall the fuse holder until the tab snaps in place.

Periodic Maintenance Schedule

To ensure safe operation of the Omni 4K video system you should periodically perform the following procedure:

At a minimum of every 12 months, check to ensure the earth leakage current is <500µA (<300µA in U.S.A.), ground protective earth impedance is <0.1 ohms, power consumption is less than or equal to the rated power, and the unit will pass a dielectric withstand test of 1500V without breakdown. See IEC 60601-1 for test methods. If the unit fails these tests, contact Hologic Technical Support (1-800-442-9842 or GssTechSupport2@hologic.com).

Note: Refer questions about this or other operating details not included in this manual to your sales representative.

Disposal

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 Omni 4K video system must be disposed of according to local laws and hospital practices.

WARNING: The Omni 4K video system console contains a lithium coin battery. The battery must be disposed of properly.

NOTE: Lithium batteries contain perchlorate material and special handling may apply. Please recycle according to local laws and practices.

Technical Specifications

NOTE: Technical data is subject to modification, revision and improvement without notice.

Table 1: System Information

Parameter	Parameter Value	
System Classification	FDA Class	Class II
	EU Class	Class I
	Health Canada Class	Class II
Safety Certifications	U.S.A. Certification	IEC 60601-1 Ed. 3.1: 2012
	Canadian Certification	CSA CAN/CSA-C22.2 NO. 60601-1:14
	EU Certification	IEC 60601-1 Ed. 3.1: 2012
EMC Certifications	CISPR 11 EMC Group	1
	CISPR 11 EMC Class	A
	EMC Certification	Radio Frequency Emissions in accordance with requirements of EN 60601-1-2: 2014 Radio Frequency Immunity in accordance with requirements of EN 60601-1-2: 2014
CE Marking	CE Marking for MDD 93/42/EEC	

Table 2: Safety, General Information

General Information/Classification of Equipment	Parameter Value
Classification of installation and use	Moveable, Class 1, Type BF Applied Part
Type of Equipment	Medical Device
Intended Use	See Indications/Contraindications section
Mode of Operation	Continuous operation
Supply connection	Appliance coupler

Table 3: Specifications

Parameter	Parameter Value	
Power Requirements (CCU)	Voltage: Frequency: Power:	100 – 240 V~ 50-60 Hz 400 VA
Video Outputs	DisplayPort (4K): DVI (1080P):	3840x2160, Progressive Scan 1920x1080, Progressive Scan
Vertical Scanning Frequency	60 Hz	
White Balance Range	3000 to 7500 K	
CCU Dimensions	Approximately:	6.5" (H) x 12.0" (W) x 14.5" (L) 16.5 cm (H) x 30.5 cm (W) x 36.8cm (L)
CCU Weight	Approximately:	208 oz 5900 g
Camera Head Dimensions	Integrated Head Approximately:	2.0" (H) x 1.6" (W) x 4.8" (L) 5.1 cm (H) x 4.0 cm (W) x 12.2 cm (L)
	C-Mount Head Approximately:	2.0" (H) x 1.6" (W) x 3.5" (L) 5.1 cm (H) x 4.0 cm (W) x 8.9 cm (L)
Camera Head Weight	Integrated Head Approximately:	18 ounces 510 g
	C-Mount Head Approximately:	16 ounces 454 g
Transport & Storage Conditions	Ambient Temperature: Relative Humidity: Atmospheric Pressure:	-40°F to 122°F [-40°C to 50°C] 10% to 90%, non-condensing 50.0 kPa to 106.0 kPa
Operating Conditions	Ambient Temperature: Relative Humidity: Atmospheric Pressure:	+50°F to 86°F [10°C to 30°C] 30% to 75%, non-condensing 70.0 kPa to 106.0 kPa

Table 4: Light Source Specifications

Parameter	Parameter Value	
LED Light Source Specifications	Color Temp	5700 K Nominal
	LED Life	30,000 hours
	Light Guide Port Turret	ACMI, Storz, Wolf and Olympus

Table 5: Radio Communications Specifications

Device	Frequency band (MHz)	Maximum Effective radiated power (ERP) (W)	Protocol	Modulation	Bandwidth (MHz)
Camera Console	2400-2474	47.4 mW (+16.8 dBm)	WLAN 802.11b WLAN 802.11g WLAN 802.11n	DSSS OFDM OFDM	22 22 40
Tablet	2412 – 2472	50.5 mW (+17.0 dBm)	WLAN 802.11b WLAN 802.11g WLAN 802.11n	DSSS OFDM OFDM	22 22 40
	2402 – 2480	10.2 mW (+10.1 dBm)	Bluetooth	DSSS	1.4
	2402 – 2480	1.2 mW (+0.8 dBm)	Bluetooth LE	FHSS	0.7
	2400 – 2484	1.2 mW (+0.8 dBm)	ANT+	FHSS	1
	5180 – 5825	25.7 mW (+14.1 dBm)	WLAN 802.11a WLAN 802.11n WLAN 802.11ac	OFDM OFDM OFDM	20 40 80

Please contact your local sales representative for information on changes and new products.

Electromagnetic Compatibility

Like other electrical medical equipment, the Omni 4K video system requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC), the Omni 4K video system must be installed and operated according to the EMC information provided in this manual.

NOTE: The Omni 4K video system has been designed and tested to comply with IEC 60601-1-2:2014 requirements for EMC with other devices.

⚠	Do not use cables or accessories other than those provided with the Omni 4K video system, as this may result in increased electromagnetic emissions or decreased immunity to such emissions.
	If the Omni 4K video system is used adjacent to or stacked with other equipment, observe and verify normal operation of the Omni 4K video system in the configuration in which it will be used prior to using it in a surgical procedure. Consult the tables below for guidance in placing the Omni 4K video system.
Caution	Equipment which employs RF communications may affect the normal function of the Omni 4K video system.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions		
Omni 4K video system is intended for use in the electromagnetic environment specified below. The customer or the user of Omni 4K video system should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment - guidance
RF emissions CISPR 11	Group 1	The Omni 4K video system is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This system is intended for use by health care professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the system or shielding the location. Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC61000-3-2	Class A	
Voltage Fluctuations/ flicker emissions IEC61000-3-3	Complies	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity			
Omni 4K video system is intended for use in the electromagnetic environment specified below. The customer or the user of Omni 4K video system should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Electrostatic Discharge (ESD) IEC61000-4-2	±8 kV contact ±15 kV air	±2,4,6,8 kV contact ±2,4,8,15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 10 %.
Electrical fast transient/burst IEC61000-4-4	±2 kV for power supply lines (directly coupled) ±1 kV for input/ output lines (capacitively coupled)	±2 kV for power supply lines (directly coupled) ±1 kV for input/ output lines (capacitively coupled)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kV differential mode ±2 kV common mode	±0.5, 1 kV differential mode ±0.5, 1, 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	0% Ut (100% dip in Ut) for 0.5 cycle 0% Ut (100% dip in Ut) for 1 cycle 70% Ut (30% dip in Ut) for 0.5 sec. 0% Ut (interruption) for 5 sec.	0% Ut (100% dip in Ut)for 0.5 cycle 0% Ut (100% dip in Ut) for 1 cycle 70% Ut (30% dip in Ut) for 0.5 sec. 0% Ut (interruption) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of Omni 4K video system requires continued operation during power mains interruptions, it is recommended that Omni 4K video system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power-frequency magnetic fields should not exceed levels characteristic of a typical commercial or hospital environment.
NOTE: Ut is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The Omni 4K video system is intended for use in the electromagnetic environment specified below.

The customer or the user of Omni 4K video system should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance[3]
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5 GHz	3 V/m 80MHz to 2.5 GHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[4], should be less than the compliance level in each frequency range. Specific guidance is given for some types of portable and mobile RF communications equipment on the following page. Other portable RF emitting equipment should be kept away at a minimum separation distance based on the maximum effective radiated power power specified by the manufacturer of the equipment. The required separation can be calculated[5] as: $d = 2.33 \times \sqrt{ERP}$ where d is the distance in meters (m) and ERP is the effective radiated power in watts (W). Interference may occur in the vicinity of equipment marked with the following: 
Conducted RF IEC 61000-4-6	3 V[1] (6 V[1] in ISM and amateur radio bands[2]) 150 kHz to 80 MHz	3 V[1] (6 V[1] in ISM and amateur radio bands[2]) 150 kHz to 80 MHz	

NOTE 1: A conducted interference level of 3 V corresponds to a field strength of 3 V/m. A conducted interference level of 6 V corresponds to a field strength of 6 V/m.

NOTE 2: The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 – 6.795 MHz; 13.553 – 13.567 MHz; 26.957 – 27.283 MHz; and 40.66 – 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 – 2.0 MHz; 3.5 – 4.0 MHz; 5.3 – 5.4 MHz; 7 – 7.3 MHz; 10.1 – 10.15 MHz; 14 – 14.2 MHz; 18.07 – 18.17 MHz; 21.0 – 21.4 MHz; 24.89 – 24.99 MHz; 28.0 – 29.7 MHz; and 50.0 – 54.0 MHz.

NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTE 4: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Omni 4K video system is used exceeds the applicable RF compliance level above, the Omni 4K video system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Omni 4K video system.

NOTE 5: For example:	ERP, effective radiated power in watts (W)	0.01	0.1	1.0	10	100
	d, distance in meters (m)	0.23	0.74	2.3	7.4	23

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The Omni 4K video system is intended for use in the electromagnetic environment specified below.

The customer or the user of Omni 4K video system should ensure that it is used in such an environment.

Recommended Separation Distances for Portable and Mobile RF Communications Equipment

The Omni 4K video system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Omni 4K video system can help prevent electromagnetic interference by maintaining minimum separation distances between portable and mobile RF communications equipment (transmitters) and the Omni 4K video system.

The Omni 4K video system has been tested for immunity at frequencies used by the following RF communications equipment:

Service	Minimum distance (m)	Maximum power (W)	Test frequency (MHz)	Immunity test level (V/m)
TETRA 400	0.3	1.8	385	27
FRS 460 GMRS 460	0.3	2.0	450	28
LTE Band 13, 17	0.3	0.2	710 745 780	9
CDMA 850 GSM 800 GSM 900 iDEN 820 LTE band 5 TETRA 800	0.3	2.0	810 870 930	28
CDMA 1900 DECT GSM 1800 GSM 1900 LTE Band 1, 3, 4, 25 UMTS	0.3	2.0	1720 1845 1970	28
Bluetooth LTE Band 7 RFID 2450 WLAN 802.11 b/g/n	0.3	2.0	2450	28
WLAN 802.11 a/n	0.3	0.2	5240 5500 5785	9

Warranty, Service, and Repair

Warranties

Except as otherwise expressly stated in the Hologic customer's agreement, Hologic warrants the Omni 4K video system to the original Hologic customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment ("Warranty Period"). Hologic does not warrant that use of this product will be uninterrupted or error-free, or that the product will operate with non-Hologic authorized third-party products.
HOLOGIC'S ENTIRE WARRANTY RESPONSIBILITY IS EXPRESSLY LIMITED TO REPAIR OR REPLACEMENT (AT HOLOGIC'S OPTION AND IN THE FORM ORIGINALLY SHIPPED) OF PRODUCT OR CORRECTION OF SERVICE SUBJECT TO ANY CLAIM, OR, AT HOLOGIC'S ELECTION, REPAYMENT OF, OR CREDITING CUSTOMER WITH, AN AMOUNT EQUAL TO THE HOLOGIC PRICE, FEE OR CHARGE THEREFOR. THE FOREGOING WARRANTIES ARE IN LIEU OF AND EXCLUDE ALL OTHER WARRANTIES NOT EXPRESSLY SET FORTH HEREIN, WHETHER EXPRESS OR IMPLIED BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. SUCH LIMITED WARRANTY IS GIVEN SOLELY TO THE ORIGINAL CUSTOMER AND IS NOT GIVEN TO, NOR MAY IT BE RELIED UPON BY, ANY THIRD PARTY INCLUDING, WITHOUT LIMITATION, CUSTOMERS OF CUSTOMER. THIS WARRANTY IS VOID UPON TRANSFER OF PRODUCT BY CUSTOMER TO ANY ENTITY WHO IS NOT AN AFFILIATE OF CUSTOMER. SOME STATES DO NOT ALLOW THE EXCLUSION OF IMPLIED WARRANTIES SO THE ABOVE EXCLUSIONS MAY NOT APPLY TO CUSTOMER. CUSTOMER MAY ALSO HAVE OTHER RIGHTS, WHICH VARY, FROM STATE TO STATE.

This warranty does not apply to any item that is: (a) repaired, moved, or altered other than by Hologic authorized service personnel; (b) subjected to physical (including thermal or electrical) abuse, stress, or misuse; (c) stored, maintained, or operated in any manner inconsistent with applicable Hologic specifications or instructions, including Customer's refusal to allow Hologic recommended software upgrades; or (d) designated as supplied subject to a non-Hologic warranty or on a pre-release or "as-is" basis..

Technical Support and Product Return Information

Contact Hologic Technical Support if the Omni 4K video system fails to operate as intended. If product is to be returned to Hologic for any reason, Technical Support will issue a Returned Materials Authorization (RMA) number. Return the Omni 4K video system according to the instructions provided by Technical Support. Be sure to clean and sterilize the product before returning it and include all accessories in the box with the returned unit.

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