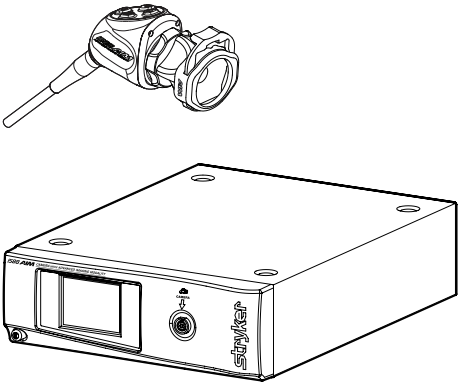
1588 AIM Video Camera

REF 1588-010-000
REF 1588-210-105
REF 1588-610-122
REF 1588-710-105



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Warnings and Cautions

Please read this manual and follow its instructions carefully. 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 to the equipment. Failure to follow cautions may result in product damage.
Note	Clarifies the instructions or presents additional useful information.
	An exclamation mark within a triangle is intended to alert the user to the presence of important operating and maintenance instructions in the manual.
	A lightning bolt within a triangle is intended to warn of the presence of hazardous voltage. Refer all service to authorized personnel.

Cautions

To avoid potential damage to this device, please note the following cautions.

1. Carefully unpack this device and check if any damage occurred during shipment. If damage is detected, refer to the standard warranty.
2. Never sterilize the camera console, because the delicate electronics cannot withstand this procedure.
3. Ensure that the electrical installation of the relevant operating room complies with the NEC and CEC guidelines.
4. Always treat the camera system with care. The camera system contains sensitive parts that are precisely aligned and may suffer damage if dropped or mistreated.
5. Ensure that readjustments, modifications, and/or repairs are carried out by persons authorized by Stryker Endoscopy.

Warnings: General

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

1. Must be a qualified physician to use this equipment.
2. Read this operating manual thoroughly, especially the warnings, and be familiar with its contents before connecting and using this device.
3. Test this equipment prior to a surgical procedure. This unit was fully tested at the factory before shipment.

4. The camera head surface may exceed 41 °C (106 °F) in operating conditions with high ambient temperatures and it should be handled with caution.
5. The camera head and coupler are shipped non-sterile. You must sterilize these devices before the first use and after each use. To prevent device damage and infection risk to the patient or user, follow all cleaning and sterilization instructions in this manual.
6. Do not position the console so that it is difficult to disconnect the power cord from the supply mains.
7. To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
8. Multiple portable socket-outlets shall not be placed on the floor.
9. Never use the camera system in the presence of flammable or explosive gases.
10. Disconnect the console from the electrical outlet when inspecting fuses.
11. Do not remove covers on the console, as doing so may cause damage to electronics and/or electric shock.
12. Do not disassemble any part of the camera head; doing so may break the seals, causing leakage and/or electric shock.
13. Attempt no internal repairs or adjustments not specifically detailed in this operating manual.

Warnings: ENV Mode

WARNING - IMPORTANT SAFETY NOTICE - LASER RADIATION:

- Endoscopic Near-Infrared Visualization (ENV) mode controls a Class 1M laser emitted from the L10 LED Light Source with AIM Technology (0220-220-300).
- Use of controls or performance of procedures other than those specified herein can result in hazardous laser radiation exposure and can cause severe eye injury to the patient or user.
- To avoid exposure to laser radiation, follow all warnings and guidelines presented below and throughout this user manual.

1. Before using ENV mode, read and be familiar with all instructions and warnings found in this user manual and in user manual P27006 (English) or P27009 (multilingual) for the L10 LED Light Source with AIM Technology.
2. Protect the 1588 AIM Video Camera against unqualified use.
3. Wear eye protection as appropriate. Refer to any applicable regional regulations or standards for personal protective equipment.
4. Do not manipulate tissue while ENV mode is enabled. The camera is intended to visualize tissue manipulation only while ENV mode is off.
5. When using ENV mode, do not view the light output with optical instruments (for example, microscopes or magnifiers). Do not direct the light output in ENV mode into an area where such instruments are likely to be used.
6. Do not enable ENV mode when the endoscope is outside of the patient's body.
7. When ENV mode is enabled, never look into the following apertures or direct the light emitted from the apertures toward another person:
    - the light cable connection on the light source (if the cable is not attached)
    - the end of the light cable (if the SafeLight adapter is attached)

- the endoscope tip

8. When ENV mode is enabled, never leave a SafeLight adapter attached to the light cable without an endoscope attached. Laser radiation can continue to emit from the adapter.
9. Disconnect the light cable from the light source only when the light source is powered off or in Standby mode.

Operating a Light Source

Please note the following special warnings to avoid user or patient injury or product damage when using a system with a light source.

WARNING - IMPORTANT SAFETY NOTICE - HIGH TEMPERATURES:

- When using a light source, fire and/or severe injury may result to the patient, user or inanimate objects if the instructions in this manual are not followed.
- All light sources can generate significant amounts of heat (exceeding 41 °C/106 °F) at the scope tip, the scope light post, the light cable tip, and/or near the light cable adapter. Higher levels of brightness from the light source result in higher levels of heat. Always adjust the brightness level of the camera and the monitor before adjusting the brightness level of the light source. If the brightness level of the light source can be adjusted, set it to the minimum brightness necessary to adequately illuminate the surgical site.
- In addition, adjust the internal shutter of the camera higher in order to run the light source at a lower intensity. Avoid touching the scope tip or the light cable tip to the patient, and never place them on top of the patient, as doing so may result in burns to the patient or user. In addition, never place the scope tip, the scope 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 before the scope is removed from the light cable or the device is unattended. The scope tip, scope 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.

The warranty is void if any of the above warnings or cautions are disregarded.

Product Description and Intended Use

The Stryker 1588 AIM (Advanced Imaging Modality) Video Camera with Infrared Compatibility (or “1588 AIM Camera”) is an endoscopic camera system that is used to produce still and video images in the surgical field during surgical endoscopic procedures. The system is sensitive in the visible and infrared spectrum. The optical image is transferred from the surgical site to the camera head by a variety of rigid and flexible scopes which are attached to the camera head. The system consists of a camera control unit (CCU) and a camera head with an integral cable that connects to the CCU.

A coupler is also available for attaching a scope to the camera head. The available models for each part are listed below.

Note - For complete system requirements to use the camera’s Endoscopic Near-Infrared Visualization (ENV) mode, see Stryker user manual P27006 (English) or P27009 (multilingual) for the L10 LED Light Source with AIM Technology (0220-220-300).

Console	
1588-010-000	1588 AIM Camera Control Unit
Camera Heads	
1588-210-105	1588 AIM Camera Head, C-Mount
1588-310-130	1588 Pendulum Camera Head with Integrated Coupler [1,2]
1588-610-122	1588 AIM Camera Head with Integrated Coupler
1588-710-105	1588 AIM Inline Camera Head, C-Mount
Coupler	
1588-020-122	AIM Coupler, 18 mm, C-Mount [3]

[1] Complete instructions are available in Stryker user manual P29925 (English) or P29926 (multilingual).

[2] Not compatible with ENV mode when the camera is used with the L10 LED Light Source with AIM Technology.

[3] Complete instructions are available in Stryker user manual P30104.

The 1588 AIM console is also packaged with the following connection cables:

- Remote cables, 2.5 mm to 3.5 mm (Qty: 2)
- DVI-I cable (Qty: 1)
- Hospital-grade power cord (Qty: 1)

Contact your Stryker representative for availability of other cables that may be required for alternate configurations.

Indications

The Stryker 1588 AIM (Advanced Imaging Modality) Video Camera with Infrared Compatibility is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery wherever a laparoscope/endoscope/arthroscope is indicated for use.

A few examples of the more common endoscopic surgeries are listed below.

- laparoscopic cholecystectomy
- laparoscopic hernia repair
- laparoscopic appendectomy
- laparoscopic pelvic lymph node dissection
- laparoscopically assisted hysterectomy
- laparoscopic and thorascopic anterior spinal fusion
- anterior cruciate ligament reconstruction
- knee arthroscopy
- shoulder arthroscopy
- small joint arthroscopy
- decompression fixation
- wedge resection
- lung biopsy
- pleural biopsy
- dorsal sympathectomy
- pleurodesis
- internal mammary artery dissection for coronary artery bypass
- coronary artery bypass grafting where endoscopic visualization is indicated
- examination of the evacuated cardiac chamber during performance of valve replacement

The users of the Stryker 1588 AIM Video Camera with Infrared Compatibility are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

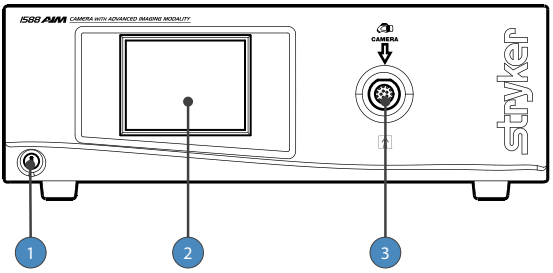
The Camera Console

The camera console—or Camera Control Unit (CCU)—is the control center for the 1588 AIM Camera, and it processes the video and photographic images produced during the surgical procedure.

Front Panel

The console front panel features a touchscreen, where different menus can be accessed, including the controls for adjusting the Light Level, Zoom Level, and White Balance, as well as allowing the selection of Surgical Specialty settings that optimize camera performance for specific surgical procedures. The touchscreen also allows activation of remote outputs, which are commonly used with a Stryker digital capture console to record images and video.

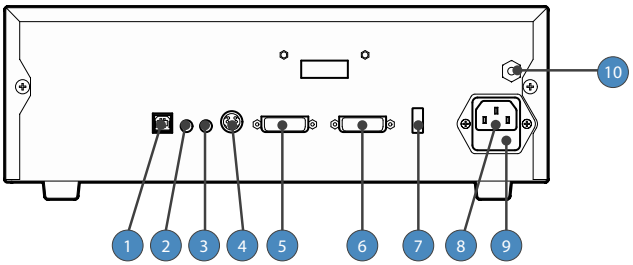
See the Operation section for more detail on using the front panel.



1. **Power Switch**	Powers the camera ON and OFF
2. **Touchscreen**	Allows navigation through different menus for controlling the camera and adjusting the video settings
3. **Camera-Connector Port**	Connects to the 1588 AIM Camera Head

Rear Panel

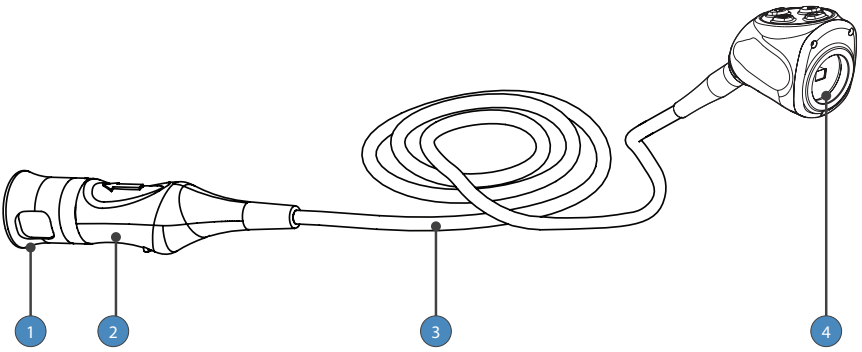
The console rear panel provides ports for connecting the 1588 AIM Camera to viewing and recording equipment, such as video monitors and Stryker device control consoles.



1. **Device Control Port**	Connects to a Stryker device control console (such as the SDC3 or SIDNE®) to enable voice operation and/or graphic tablet control
2. **Remote Out 1**	Connects to a video accessory remote input
3. **Remote Out 2**	Connects to a video accessory remote input
4. **S-Video Out**	Analog video output
5. **DVI Out 1**	Digital video output
6. **DVI Out 2**	Digital video output
7. **Light Source Port**	Connects to Stryker light source
8. **AC Power Inle**t	Connects to AC mains with separable power cord
9. **Fuse Panel**	Contains two 1.6A 250V fuses (slow blow, high breaking capacity 1500A, size 5 mm x 20 mm)
10. **Equipotential Ground Plug**	Connects to a potential equalization conductor. The resulting medical electrical system shall follow all applicable IEC 60601-1 requirements.

The Camera Head

The camera head connects to the camera console and produces video and photographic images, which it relays to the camera console. Several controls are accessible through a button keypad located on the top of the camera head (see the Operation section).

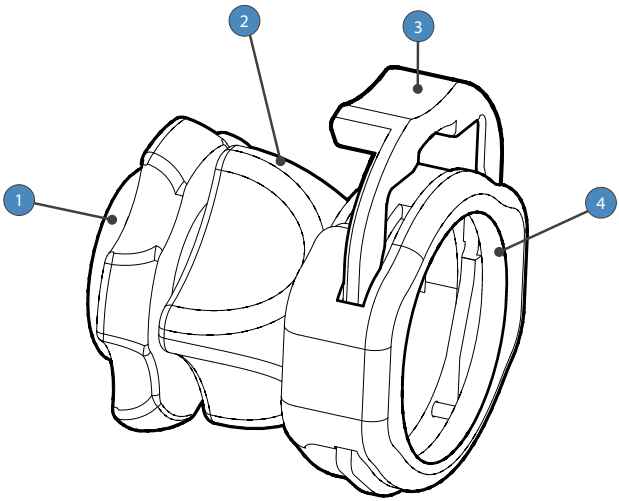


1. **Soaking Cap**	Protects the cable connector during cleaning, disinfection, and sterilization
2. **Cable Connector**	Connects the camera head to the camera console
3. **Camera Cable**	The camera cable length is 10 feet (3.05 m)
4. **Camera Head**	Produces photographic and video images, provides camera controls, and connects with a focusing coupler.

The C-Mount Coupler

The coupler threads onto the face of the camera head, enabling a scope to be attached to the camera. It provides a focusing ring to adjust image sharpness.

It is recommended to use the camera with the AIM Coupler (1588-020-122). The AIM Coupler enables use of ENV mode when the camera is connected to the L10 LED Light Source with AIM Technology. Refer to Stryker user manual P30104 for complete AIM Coupler instructions.



1. **Rear Adapter**	Threads onto the camera head
2. **Focusing Ring**	Adjusts the coupler focus
3. **Endobody Clamp**	Secures the scope to the coupler
4. **Scope End**	Receives the endoscope

Setup

Stryker Endoscopy considers instructional training, or inservice, an integral part of the 1588 AIM Camera. Your local Stryker Endoscopy 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 Stryker Endoscopy representative after your equipment has arrived.

Setting up the 1588 AIM Camera involves three steps:

1. **Setting up the console**
2. **Setting up the camera head**
3. **Setting up the coupler**

WARNING -

- Always connect the console to an appropriate power source, using a hospital-grade power cord. Loss of AC power will cause the camera to shut down and the surgical image to be lost.
- Only connect items to the 1588 AIM Camera that have been specified for use with the camera system. Connecting incompatible equipment may cause unexpected results.
- When the camera system is used with other equipment, leakage currents may be additive. Ensure that all systems are installed according to the requirements of IEC 60601-1.
- Equipment which employs RF communications may affect the normal function of the 1588 AIM Camera. When choosing a location for the camera system, consult the Electromagnetic Compatibility section to ensure proper function.
- 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.

Setting Up the Console

Refer to the instructions below and the wiring diagram on the following page for a typical 1588 AIM Camera configuration.

1. Connect the console's AC power to a hospital-grade outlet.
2. Connect one of the console's DVI outputs to an available DVI input on a Stryker digital capture console such as the SDC3 (0240–060–100).
    - The 1588 AIM console can also be connected to additional SDC video inputs or directly to one or more display monitors; the rear panel provides one analog and two digital-video outputs:

Output Type	Output	Cable	Connector
Analog	S-VHS 1*	S-VHS	4 pin Mini-Din (push-only connectors)
Digital (standard)	DVI-I1** and DVI-I2**	DVI	29 pin (push-only connectors, with two tightening knobs)

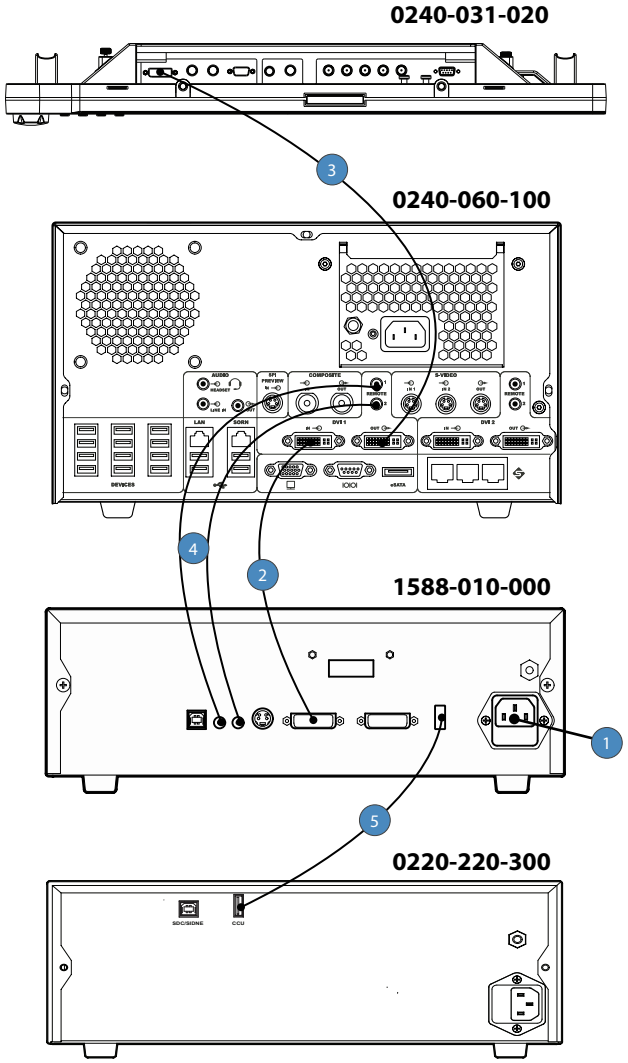
* On some monitors, S-VHS inputs may be labeled Y/C.

** The DVI connectors can also output analog SXGA signals through a DVI-I to VGA adapter.

When using any device with unterminated analog video inputs, connect a cable from the VIDEO OUT of that device to the VIDEO IN on the monitor.

3. Connect the DVI output from the Stryker digital capture console to the DVI input on the display monitor. (The VisionPro 26" LED Display (0240-031-020) is shown as an example in the following diagram.)
4. Using the provided remote cables, connect remote outputs 1 and 2 from the 1588 AIM console to a Stryker digital capture console. (The remote inputs should be connected to the same channel as the video input.)
    - Devices connected to the remote outputs can be operated using the console touchscreen or the P button on the camera head. See the Operation section for details.
    - Once connected to the 1588 AIM Camera, the SDC3 can control ENV, Dynamic Range Enhancement, and Strobe functions. The user can also customize button configurations through the SDC3.
5. Connect a USB A-to-A cable from the Light Source output on the 1588 AIM console to the CCU input on the L10 LED Light Source with AIM Technology (0220-220-300) or the Precision LED Light Source (0220-220-000). It is recommended to use the USB cable (P30883) provided with the Stryker light source, as use of third-party cables may prevent the devices from properly communicating.
    - To use ENV mode, the 1588 AIM Camera requires a connection to the L10 LED Light Source with AIM Technology.
    - The 1588 AIM Camera Head can be programmed to toggle Run/Standby controls on the light source. Contact a Stryker representative for more information about enabling this advanced feature.

Wiring Diagram

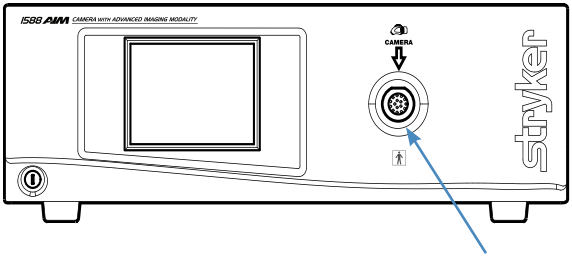


Setting Up the Camera Head

WARNING - Do not severely bend the camera cable or damage may result.

1. Unscrew the soaking cap from the cable connector on the camera head.
2. Align the arrow on the cable connector with the arrow above the camera-connector port on the front console panel.

3. Push in the connector until it locks in place.



Note - To unplug the camera from the console, grasp the knobbed portion of the connector and pull straight out.

Setting Up the Coupler

Steps 1–3 below provide instructions for connecting 1588 AIM Camera Heads to the AIM Coupler, 18 mm, C-Mount (1588-020-122). Refer to the bullets below for possible system variations:

- When using the 1588 AIM Camera Head with Integrated Coupler (1588-610-122), skip to step 2.
- When using the 1588 Pendulum Camera Head with Integrated Coupler (1588-310-130), see Stryker user manual P29925 (English) or P29926 (multilingual).
- When using a direct-coupled C-Mount endoscope (a scope that requires no coupler), thread the endoscope directly into the camera head until it forms a tight seal, and skip to step 3. (C-Mount endoscopes are not compatible with camera heads that have an integrated coupler.)

WARNING -

- When attaching or removing the coupler, grip only the rear adapter, as twisting other parts of the coupler with force may result in mechanical damage.
- Do not overtighten the coupler (or a direct-coupled C-mount scope), as this may damage the front window of the camera.

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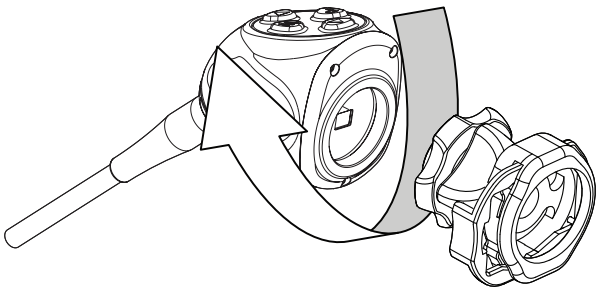
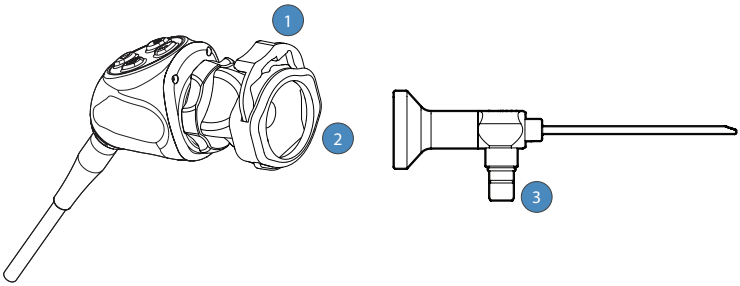
1. Attach the coupler to the camera head.
    - Gripping the rear adapter, screw the coupler clockwise onto the camera head until it forms a tight seal (1588-210-105 and 1588-710-105 only).



Note - To remove the coupler, grip the rear adapter and unscrew the coupler counterclockwise from the camera head.

2. Attach an endoscope to the coupler.
   WARNING - Before each use, check the outer surface of the endoscope to ensure there are no rough surfaces, sharp edges, or protrusions.

   Note - For a list of endoscopes that are compatible with ENV mode, see Stryker user manual P27006 (English) or P27009 (multilingual) for the L10 LED Light Source with AIM Technology.



   - Remove the coupler dust cap if it is present.
   - Depress the endobody clamp (1) and insert a scope into the endobody (2).
   - Release the endobody clamp to secure the endoscope.

3. Attach a light cable from the light source to the light post on the endoscope (3).

   Note - A scope adapter may be required to connect the cable to the endoscope. See the light cable user manual for more detail.

   Note - Only the Stryker AIM SafeLight™ cable (0233-050-300) is compatible with ENV mode. ENV mode will not function if other cables are used. Refer to the AIM SafeLight cable user manual (P27701) for complete cable instructions.

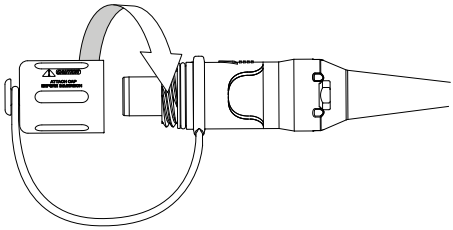
   WARNING - When connecting an AIM SafeLight cable to the endoscope, always connect the scope adapter to the endoscope before connecting the adapter to the cable. If ENV mode is enabled and the adapter is not connected to the scope, laser radiation will emit from the adapter that can cause severe eye injury to the patient or user.

Installing the Soaking Cap

Before reprocessing the camera head, the soaking cap must be installed to avoid damaging the cable connector.

CAUTION -
Failure to properly tighten the soaking cap will corrode the connector pins and void the warranty.

- To install the soaking cap, screw the cap onto the threads of the cable connector until it forms a tight seal.
- To remove the soaking cap, unscrew the cap and pull it away from the cable connector.

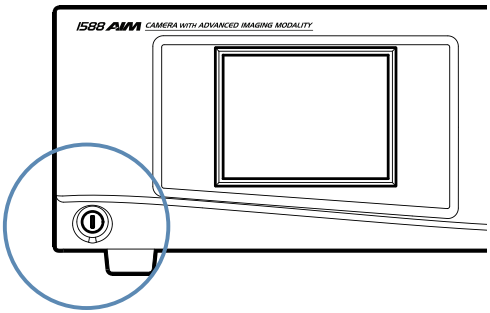


Operation

Note - Before operating the device, ensure all system components have been set up according to the instructions in the Setup section.

Powering the Console On/Off

WARNING - Before using the camera in a surgical procedure, test all system components to ensure proper function. Ensure that a video image appears on all video monitors before beginning any procedure.



1. Power on the monitor.
2. Press the power switch on the console to power the console on or off.

Note - A color bar pattern will appear on the monitor if the camera head is not connected to the camera console. If the color bar appears, refer to the Setting Up the Camera Head section to connect the camera head.

Controlling Remote Video Accessories

The camera can remotely control up to two functions of a video accessory, such as a Stryker digital capture console. Commonly this enables the user to capture images or start and stop video recording.

Remote video accessories can be controlled with the camera head's P button or the console touchscreen. See the following sections, Using the Camera Head Buttons and Using the Touchscreen Interface.

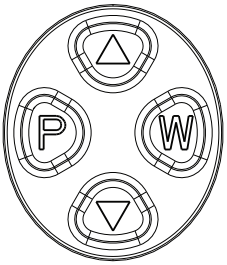
Note - Controls for capturing photos or recording video require connecting a video accessory to the console. See the Setup section for more detail.

Using the Camera Head Buttons

The camera head features a four-button keypad for controlling the device. The default button functions are described below.

The camera head buttons can be customized differently for each surgical specialty. See the Programming Camera Head Buttons section for more detail. The button configuration for the

selected surgical speciality will appear on the display monitor when the camera head is connected to the console. The button configuration will disappear once the P button is pressed.



P (Picture) Button

The P button controls up to two functions of a remote video accessory. Commonly this enables the user to capture images or start and stop video recording. (See the Controlling Remote Video Accessories section for connection requirements.)

- Press the P button for less than two seconds to select Remote 1. One beep will sound. When the camera is connected to a Stryker digital capture console, this will **Capture a Photo**.
- Press the P button for more than two seconds to select Remote 2. Two beeps will sound. When the camera is connected to a Stryker digital capture console, this will **Start or Stop Video Recording**.

W (White Balance) Button

The W button activates the White Balance function or the Zoom Cycle function.

- Press the W button for less than two seconds to activate the **Zoom Cycle** function. Each press raises the Zoom Level in eight steps. When the Zoom Level reaches its maximum, pressing the button again cycles the level back to the lowest setting.
- Press the W button for more than two seconds to activate the **White Balance** function. White Balancing will correct slight color differences that exist between different light sources or endoscopes. See the Performing the White Balance Test section below.

Up and Down Buttons

The up and down buttons change functionality depending on the conditions:

Conditions	Functionality of Up/Down buttons
• Default	• Up and down buttons increase or decrease the **Automatic-Shutter Light Level** in eight steps.
• ENV mode is enabled (see the ENV Mode section for detail)	• Press the up button for less than two seconds to activate the **Backlight Cycle** function. Backlight affects the brightness of surrounding anatomy that is not displayed as fluorescing green. ✓ Each press raises the Backlight Level in 10 steps. When the Backlight Level reaches its maximum, pressing the button again cycles the level back to the lowest setting. ✓ The Backlight Level will appear on the display monitor. (Note: Although Backlight Level can be adjusted in 10 steps, the display monitor indicator will only change every two button presses.) • Press the down button for less than two seconds to activate the **ENV Gain Cycle** function. ENV Gain affects the fluorescing green appearance of the camera image. ✓ Each press raises the ENV Gain Level in six steps. When the ENV Gain Level reaches its maximum, pressing the button again cycles the level back to the lowest setting. ✓ The ENV Gain Level will appear on the display monitor.
• ENT/Skull Surgical Specialty is selected [1] (from the camera console Home screen)	• Up button activates the **Automatic-Shutter Light Cycle** function. Each button press raises the Light Level in eight steps. When the Light Level reaches its maximum, pressing the up button again cycles the level back to the lowest setting. • Down button activates the **Dynamic Range Enhancement (DRE) Desaturation (Desat)** function. The DRE Desat function desaturates red colors on the display monitor. ✓ Each button press toggles the function on and off. **Note:** DRE mode is on by default when the ENT/ Skull surgical specialty is selected. DRE mode illuminates darker posterior cavities on the display monitor.

Conditions	Functionality of Up/Down buttons
[1] The down button will also activate the DRE Desat function in the Arthroscopy, Cystoscopy, and Laparoscopy surgical specialties when DRE mode is on. DRE mode can be turned on via the touchscreen DRE menu or by programming DRE Toggle to another camera head button. Contact a Stryker representative for assistance with button programming.	 When DRE mode is on, a light bulb icon appears in the top-left corner of the display monitor.  When DRE Desat is on, an indicator appears below the light bulb icon.

Programming Camera Head Buttons

The camera head buttons can be customized differently for each surgical specialty. **Contact a Stryker representative for assistance with button programming.**

The button configuration for the selected surgical speciality will appear on the display monitor when the camera head is connected to the console. The button configuration will disappear once the P button is pressed.

The following functions can be programmed to the buttons:

Function Name	Function Description
NO FUNCTION	No function
LIGHT UP	Increase light level
LIGHT DOWN	Decrease light level
LIGHT CYCLE	Increase light until maximum level, then cycle back to minimum level
ZOOM IN	Increase zoom level
ZOOM OUT	Decrease zoom level
ZOOM CYCLE	Increase zoom until maximum level, then cycle back to minimum level
ENHANCE UP	Increase enhance level (sharpens camera image)
ENHANCE DOWN	Decrease enhance level (sharpens camera image)
ENHANCE CYCLE	Increase enhance until maximum level, then cycle back to minimum level (sharpens camera image)

Function Name	Function Description
PICTURE	Enable picture function on SDC3 / Activate Remote 1 cable
RECORD	Enable record on SDC3 / Activate Remote 2 cable
WB	Enable White Balance
LS TOGGLE	Toggle white light on/off from light source
INSFLTR TOGGLE	Toggle insufflator stop/start
DEV CNTRL MENU	Edit device control menu on the SDC3
WINGMAN CNTRL	Activate control of Wingman® Scope Holder (holding button will allow Wingman to move)
DRE TOGGLE	Toggle DRE mode on/off
ENV TOGGLE	Toggle ENV mode on/off
STROBE TOGGLE	Toggle strobe mode on/off. Strobe mode is an optional mode that can be used only in the Arthroscopy surgical specialty when the camera is connected to the L10 LED Light Source with AIM Technology (0220-220-300) or the Precision LED Light Source (0220-220-000).  When Strobe mode is on, this icon appears in the top-left corner of the display monitor.

Using the Touchscreen Interface

The touchscreen interface on the console provides controls for adjusting or capturing the video image. The menus are described below.

Home Screen

The Home Screen is the default screen. It displays the current camera mode and it provides access to subsequent menus and common camera functions.

1. Use the arrows to scroll through preset camera settings designed for **Surgical Specialties**. Choose from:

   — Arthroscopy
   — Cystoscopy
   — ENT/Skull
   — Flexi-Scope
   — Hysteroscopy
   — Laparoscopy
   — Laser
   — Microscope
   — Standard

2. Press and hold the WB button for two seconds to activate the **White Balance** function. See the Performing the White Balance Test section for more detail.

   ✓ A checkmark appears on the button after White Balance is complete.

3. Press the camera button to **Capture a Photo**.

   ✓ A single beep will sound to indicate that a signal for capture/record has been sent to the digital capture console.

4. Press the **DRE button** to navigate to the DRE mode screen. This button will appear only when the Arthroscopy, Cystoscopy, ENT/Skull, or Laparoscopy surgical specialty is selected.

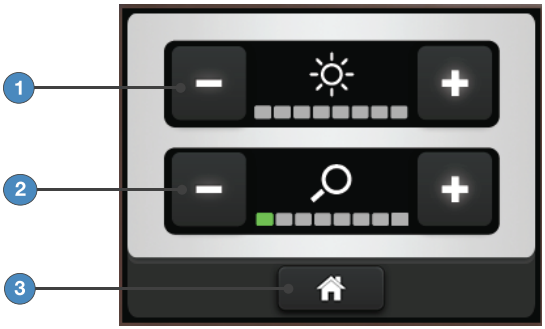
5. Press the record button to **Record a Video**. Press again to stop recording.

   ✓ A double beep will sound to indicate that a signal for capture/record has been sent to the digital capture console.

6. Press the **Settings** button to navigate to the Menu screen.

Menu Screen

The Menu screen provides options for adjusting the camera picture.



1. Press the plus or minus button next to the brightness icon in order to increase or decrease the **Automatic-Shutter Light Level**.

   ✓ The level is indicated by the filled bars under the icon and on the display monitor.

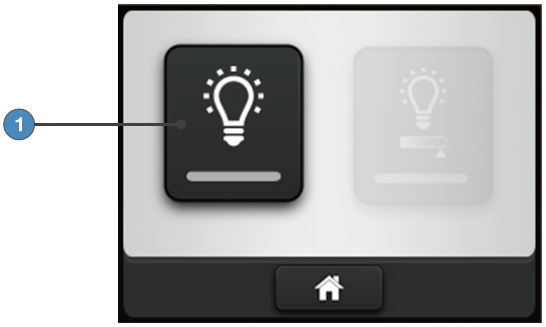
2. Press the plus or minus button next to the zoom icon in order to increase or decrease the **Zoom Level** (magnification).

   ✓ The level is indicated by the filled bars under the icon and on the display monitor.

3. Press the **Home** button to return to the Home Screen.

DRE Mode Screen

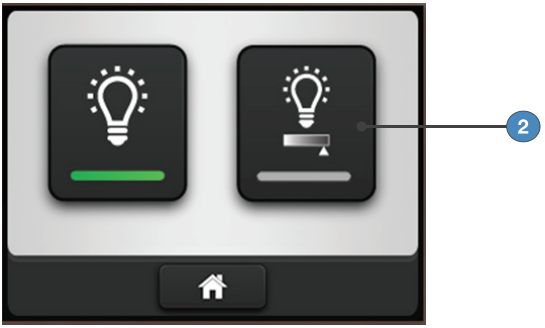
Dynamic Range Enhancement (DRE) Mode screen allows the user to turn DRE functions on and off. This screen is accessible only when the ENT/Skull, Arthroscopy, Cystoscopy, or Laparoscopy surgical specialty is selected.



1. Press the left button to turn on **DRE mode**. Press the button again to turn off DRE mode. DRE mode illuminates darker posterior cavities on the display monitor.

   ✓ When DRE mode is on, the bar at the bottom of the button will be green. The right button for the DRE Desat function will also become available.

Note - When the ENT/Skull surgical specialty is selected, by default DRE mode is on and the DRE Desat function is available.



2. Press the right button to activate the **DRE Desat** function. Press the button again to deactivate the function. DRE Desat desaturates red colors on the display monitor.

   ✓ When DRE Desat is on, the bar at the bottom of the button will be green.

Using the Camera in ENV Mode

In Endoscopic Near-Infrared Visualization (ENV) mode, the camera can visualize near-infrared light produced by the L10 LED Light Source with AIM Technology (0220-220-300). Controls for ENV mode are accessible via the light source or the camera console touchscreen and camera head buttons.

WARNING - Before using ENV mode, be familiar with the warnings in the Warnings: ENV Mode section of this user manual and all warnings and instructions in the light source user manual P27006 (English) or P27009 (multilingual). Failure to follow all warnings can result in severe eye injury to the patient or user.

Note - For complete system requirements to use ENV mode, see Stryker user manual P27006 (English) or P27009 (multilingual) for the L10 LED Light Source with AIM Technology.

The ENV button will appear on the Home screen or Menu screen when the following conditions are met:

- The camera console is connected to the L10 LED Light Source with AIM Technology
- A camera head is connected to the camera console
- The Laparoscopy Surgical Specialty is selected on the camera console
- The L10 LED Light Source with AIM Technology is connected to an AIM SafeLight cable (0233-050-300)
- A SafeLight scope adapter is connected to the SafeLight cable (see cable user manual P27701 for compatible adapter part numbers)

1. To enable ENV mode, ensure the light source is in Active mode. If the light source is not Active, the camera cannot enable ENV mode.

2. Press the ENV button at the bottom-right corner of the camera touchscreen.

✓ When ENV mode is enabled, the touchscreen and the ENV button change to a green background.

Note - When ENV mode is enabled, the White Balance function is disabled on the Home screen. The DRE button is also not available in ENV mode.

Note - When ENV mode is enabled, the brightness controls are disabled on the Menu screen. Instead, the user can adjust the Backlight Level and ENV Gain from the camera head up/down buttons. See the Using the Camera Head Buttons section for more information.

3. Press the ENV button to turn off ENV mode. The touchscreen background and ENV button will return to a gray color.

Performing the White Balance Test

Before each surgical procedure, perform the White Balance test to adjust the camera's perception of white so it can display other colors correctly.

1. Ensure that a scope and light source are attached to the camera system, and that the console, light source and monitor are powered on.
2. Point the scope tip at several stacked white gauze pads, a white laparoscopic sponge, or any clean white surface.
3. Look at the monitor and make sure there is no visible glare off of the white surface of the image.
4. Press and hold the camera head W button (or "WB" on the touchscreen) until the monitor displays the message "WHITE BALANCE IN PROGRESS."
5. Continue pointing the scope at the white surface until the video monitor displays the message "WHITE BALANCE COMPLETE." The image may change color. If you cannot achieve an acceptable White Balance, refer to the Troubleshooting section.

Advanced Features

The 1588 AIM Camera has additional features that are not detailed in this manual:

- Button programming
- Video image settings
- Touchscreen language settings
- Light source Run/Standby controls
- Other system settings

These advanced features require in-depth knowledge of the device and should be performed only by trained personnel. For access to advanced features, contact a Stryker representative.

Troubleshooting

Problem	Possible Solution
E1 error code	• Turn off the console, wait 3 seconds, and turn it back on.
E2 error code	• Turn off the console, wait 3 seconds, and turn it back on.
E3 error code	• Turn off the console, wait 3 seconds, and turn it back on.
E4 error code	• Ensure vent holes on console are not obstructed. • Turn off the console, wait 3 seconds, and turn it back on.
Touchscreen freezes	• Turn off the console, wait 3 seconds, and turn it back on.
“Restart Camera Console” message (Color bar background)	• Camera head temporarily shut down due to overcurrent. Turn off the console, wait 3 seconds, and turn it back on. • After sterilization, ensure the camera head has cooled down before connecting it to the console.
“System Error” message (Light blue background)	• No video detected. • After sterilization, ensure the camera head has cooled down before connecting it to the console. • Return the system for repair.
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 test. (See the Performing the White Balance Test section.) • Check the color settings on the monitor.

Problem	Possible Solution
White Balance quality is not good	• See the solution for Picture is too dark. • See the solution for Picture is too bright. • Perform the White Balance test with the light source connected to the scope. Use metal-halide, xenon, or LED lighting (no fluorescent lighting).
Picture is too dark	• Increase the camera Light Level with the camera head. • Increase the light source output. • Check the fiberoptic light cable for excessive broken fibers.
Picture is too bright	• Decrease the camera Light Level. • Decrease the light source output. • Turn off the DRE Desaturation function.
Noise or snow on picture when using electrocautery probes	• Plug the electrocautery generator into a separate electrical outlet and separate the 1588 AIM console 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	• Confirm all cable connectors are securely attached. • 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 the console and reconnect. • Turn off the console, wait 3 seconds, and turn it back on.
Image is not well centered	• Release the scope from the coupler and then reconnect it. Make sure the scope is seated correctly in the coupler.

Problem	Possible Solution
Variability in color reproduction between different light sources or peripherals	• Perform the White Balance test. (See the Performing the White Balance Test section.) • Check the settings on video peripherals. • Ensure the light source has a proper infrared filter (check with manufacturer specifications).
Foggy picture (loss of definition and clarity)	• Refocus the coupler. • Disassemble the scope, coupler, and camera head, and clean and dry all windows on the components.
Optics are dirty	• Rotate the scope. If dust particles in the picture rotate, the dust is located on the scope 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 scope, the particles are located on the coupler or camera. Remove the scope and clean the window on the front of the coupler with a dry or alcohol-tipped cotton swab. • Disassemble the scope, coupler, and camera head, and clean and dry all windows on the components. • Ensure all components are completely dry before reassembling them, or fogging may result.
Blurry picture	• Ensure the coupler or C-mount scope is in focus. • On the Home screen, ensure the Surgical Specialty is not set to FLEXI-SCOPE unless you are using a flexible scope. • Disassemble the scope, coupler, and camera head, and clean and dry all windows on the components.
Camera head button error symbol appears on display monitor: 	• Return the camera head to Stryker for service. • If the symbol appears, the camera head buttons are non-functional but the camera head will still provide a video signal to the console. The camera can be operated from the console.

Problem	Possible Solution
SIDNE device does not recognize camera head	• Contact your Stryker representative for compatibility settings.
ENV mode not enabled	• Confirm the camera console is set to the Laparoscopy Surgical Specialty. • Confirm a USB A-to-A cable is connected from the camera console to the L10 LED Light Source with AIM Technology • Confirm white light is activated on the light source

Note - If this Troubleshooting section does not resolve the problem, call Stryker Technical Support at 1-877-478-7953 (inside the U.S.) or refer to the standard warranty.

Reprocessing

The camera console is not intended to come into contact with the patient. It may be cleaned, but not sterilized. The camera head and coupler are used in the sterile field and therefore shall be cleaned and sterilized prior to every use.

- For instructions on reprocessing the 1588 Pendulum Camera Head with Integrated Coupler (1588-310-130), see user manual P29925 (English) or P29926 (multilingual).
- For instructions on reprocessing the AIM Coupler (1588-020-122), see user manual P30104.

Cleaning the Console

Should the console need cleaning, follow the warnings, cautions, and instructions below. The user shall provide the mild detergent (or standard disinfectant) and sterile cloth required for cleaning.

To avoid electric shock and potentially fatal injury, disconnect the console from the AC power source before cleaning.

CAUTION - Observe the following cautions to avoid damaging the console:

- Do not sterilize the console.
- Do not immerse the console in any liquid.
- Do not allow liquid to drip onto the console or collect on any of its surfaces.
- Do not spray cleaning liquid directly onto the console, power buttons, or connectors. Spray the cleaning liquid onto a cloth, and use the cloth to wipe the console.
- Do not clean the console with abrasive products or corrosive cleaning solutions.

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1. Spray a mild detergent or standard disinfectant onto a dry, sterile cloth. Do not saturate the cloth.
2. Wipe the console. Do not allow liquid to drip from the cloth or collect on the console.
3. When cleaning the front LCD screen, use extra care to prevent liquid from dripping or pooling on the bottom of the screen. Excess liquid can enter the console and cause product damage.
4. Visually inspect the external surface of the device for cleanliness, focusing on hard-to-reach areas. If visible soil remains, repeat steps 1– 3.

Cleaning, Disinfecting, and Sterilizing the Camera Head

These reprocessing instructions are provided in accordance with ISO 17664, AAMI TIR12, AAMI TIR30, AAMI ST79, and AAMI ST81. While they have been validated by Stryker 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), achieves the desired result. This normally requires routine monitoring and validation of the facility's reprocessing procedures. Stryker recommends users observe these standards when reprocessing medical devices.

Overview

Reprocessing the device involves manual or automated cleaning with two different detergents, optional disinfection, and sterilization.

- **Step 1** (required): Cleaning with Enzymatic Detergent
- **Step 2** (required): Cleaning with Non-Enzymatic Detergent
- **Step 3** (optional): Disinfection
- **Step 4** (required): Sterilization

Warnings

- This device must be cleaned and sterilized prior to the first use and after every subsequent use.
- Separate the camera head, coupler (1588-210-105 and 1588-710-105 only), and scope prior to cleaning, disinfection, or sterilization. Failure to follow this instruction will render the devices non-sterile. (Refer to the coupler and scope product manuals for reprocessing instructions for those devices.)
- Wear appropriate protective equipment: gloves, eye protection, etc.
- To avoid health risks from aerosol contamination, brush the device only when it is submerged in liquid.
- Use only the sterilization cycles outlined in this document. Using unspecified sterilization cycles may damage the device or result in incomplete sterilization.
- Sterilize only one camera head per tray, or incomplete sterilization may result. Follow any instructions provided with the sterilization tray or system regarding tray setup and other devices that may be sterilized within the same tray.

Cautions

- Always install the soaking cap prior to processing the camera. Failure to properly tighten the soaking cap will corrode the connector pins and void the warranty. Refer to the Installing the Soaking Cap section for more detail about installing the cap.
- Inspect the camera cable for cuts and breaks before soaking in any fluid. Return any damaged camera to Stryker 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.
- The device cannot withstand an automated disinfection method.
- The 1588 camera heads are not autoclavable. Steam sterilizing camera heads that are not marked **AUTOCLAVE** will result in product damage.
- Allow the camera head to cool before connecting it to the console. Connecting the camera head while it is hot may result in system error.
- When using Steris® liquid chemical sterilization, remove the camera head from the chamber once sterilization is complete, or moisture may condense inside the camera head and cause display defects.

Limitations on Reprocessing

- Do not cross-sterilize the device. Using multiple sterilization methods may significantly reduce the performance of the device.
- Repeated sterilization via Ethlyene Oxide or Sterrad® 100NX® can degrade the product's cosmetic appearance.
- Do not leave the device in solutions longer than necessary. This may accelerate normal product aging.
- Damage caused by improper processing is not covered by the warranty.

Materials and Equipment

All materials and equipment required to reprocess the camera head shall be supplied by the user unless otherwise noted.

Item	Description
All phases	
Gloves, eye protection, etc.	Wear protective equipment as required by the medical facility and procedure.
Cleaning	
Water basin	Large enough to accommodate camera head without excessive bending of cable
Enzymatic detergent [1]	Used in cleaning solution to remove surgical debris
Tap water	To prepare cleaning solutions
Syringe [2]	To inject detergent into hard-to-reach areas of device
Soft-bristle brush [3]	To clean exterior of device or hard-to-reach areas of device
Reverse osmosis/ deionized water [4]	To rinse device

Item	Description
Clean cloth or filtered pressurized air (≤40 psi)	To assist with drying
Non-enzymatic detergent [5]	Used in cleaning solution to remove surgical debris
Automated washer	For using the automated cleaning procedure
Disinfection	
Water basin	Large enough to accommodate camera head without excessive bending of cable
Disinfecting solution [6]	≥ 2.4% glutaraldehyde
Tap water	To prepare disinfecting solution
Reverse osmosis/ deionized water [4]	To rinse the device
Clean cloth or filtered pressurized air (≤40 psi)	To assist with drying
Sterilization	
Sterilization system [7]	· Sterrad 100S, 200, NX®, or 100NX · Steris/Amsco® V-PRO® 1, V-PRO 1 Plus, or V-PRO maX · Steris System 1®, System 1E®, System 1 Plus, or System 1 Express · Ethylene Oxide (EO)
Sterilization wrap [8,9]	To maintain sterile barrier
Sterilization tray [9]	Optional. Must be compatible with sterilization method.

[1] Cleaning was validated using ENZOL® Enzymatic Detergent at 1 oz/gal. at 35 °C.

[2] Cleaning was validated using a 50 mL syringe.

[3] Recommend to clean with an M16 soft-bristle brush.

[4] Cleaning was validated using reverse osmosis/deionized (RO/DI) water.

[5] Cleaning was validated using Prolystica® 2x Neutral Detergent at 1/8 oz/gal at 35 °C.

[6] Disinfection was validated using CIDEX® Activated at 25 °C with a soaking time of 45 minutes.

[7] Steris System 1, System 1 Plus, and System 1 Express are not intended for use in the U.S.

[8] Sterilization was validated using Kimberly-Clark® KC600 KIMGUARD sterilization wrap.

[9] For United States users: when sterilizing the device, use only sterilization wraps and sterilization trays that have been cleared by the FDA to use with the selected sterilization cycle.

Instructions for Reprocessing

Point of Use

- Disassemble the camera head from the scope and coupler. To disconnect the scope, depress the endobody clamp on the coupler and remove the scope from the coupler. To disconnect the coupler, grip the rear adapter of the coupler and unscrew it counterclockwise from the camera head.
- Wipe any excess soil from the device using a clean sterile cloth.
- If an automated reprocessing method will be used, rinse any hard-to-reach areas in the device with 50 mL of sterile distilled water immediately after use.

Containment and Transportation

- Reprocess the device as soon as reasonably practical following use.

  Note - Cleaning was validated with a 30 minute wait time.
- Transport the device in a tray to avoid damage. Follow the facility's internal procedures for the transportation of contaminated surgical instruments and devices.

Cleaning

Manual Cleaning

Note - For necessary materials and equipment, see the Materials and Equipment table.

1. **Soak**
   - Disassemble the camera head from the scope and coupler.
   - Ensure the soaking cap is installed. Refer to the Installing the Soaking Cap section for more detail about installing the cap.
   - Prepare an enzymatic detergent according to the manufacturer instructions.
   - Use a clean cloth to wipe the entire device with the detergent.
   - Fully immerse the device in the detergent. Use a syringe to inject 50 mL of the detergent into any crevices and mated surfaces to remove loose debris.
   - Soak the device in the detergent for 15 minutes.
2. **Brush**
   - Thoroughly brush the exterior of the device with a soft-bristle brush for 90 seconds, focusing on any mated or rough surfaces.
   - Use a syringe to inject 50 mL of the detergent into any crevices and mated surfaces 5 times.
   - When cleaning the 1588 AIM Camera Head with Integrated Coupler (1588-610-122), brush between all gaps and crevices while pushing down on the endobody clamp. Continue brushing all gaps and crevices while releasing the clamp to the initial position.
3. **Rinse**
   - Remove the device from the prepared detergent. Rinse the device with reverse osmosis/ deionized water at ambient temperature for 90 seconds or until all visible detergent residue is removed.

- Flush any crevices and mated surfaces 5 times. After all visible detergent residue is removed, continue to rinse for 30 seconds.
- Drain excess water from the device and dry it with a clean cloth or filtered pressurized air.
- Visually inspect the device for cleanliness, paying close attention to hard-to-reach areas. If visible soil remains, repeat steps 1– 3.

4. **Soak**
   - Prepare a non-enzymatic detergent according to the manufacturer instructions.
   - Fully immerse the device in the detergent. Use a syringe to inject 50 mL of the detergent into any crevices and mated surfaces.
   - Soak the device in the detergent for 15 minutes.
5. **Brush**
   - Thoroughly brush the exterior of the device with a soft-bristle brush for 90 seconds, focusing on any mated or rough surfaces.
   - Use a syringe to inject 50 mL of the detergent into any crevices and mated surfaces 5 times.
   - When cleaning the 1588 AIM Camera Head with Integrated Coupler (1588-610-122), brush between all gaps and crevices while pushing down on the endobody clamp. Continue brushing all gaps and crevices while releasing the clamp to the initial position.
6. **Rinse**
   - Remove the device from the prepared detergent. Rinse the device with reverse osmosis/ deionized water at ambient temperature for 90 seconds or until all visible detergent residue is removed.
   - Flush any crevices and mated surfaces 5 times. After all visible detergent residue is removed, continue to rinse for 30 seconds.
   - Drain excess water from the device and dry it with a clean cloth or filtered pressurized air.
   - Visually inspect the device for cleanliness, paying close attention to hard-to-reach areas. If visible soil remains, repeat steps 1– 6.

Automated Cleaning

Note - For necessary materials and equipment, see the Materials and Equipment table.

1. **Soak**
   - Disassemble the camera head from the scope and coupler.
   - Ensure the soaking cap is installed. Refer to the Installing the Soaking Cap section for more detail about installing the cap.
   - Prepare an enzymatic detergent according to the manufacturer instructions.
   - Use a clean cloth to wipe the entire device with the detergent.
   - Fully immerse the device in the detergent. Use a syringe to inject 50 mL of the detergent into any crevices and mated surfaces to remove loose debris.
   - Soak the device in the detergent for 15 minutes.
2. **Brush**
   - Thoroughly brush the exterior of the device with a soft-bristle brush for 90 seconds, focusing on any mated or rough surfaces.

- Use a syringe to inject 50 mL of the detergent into any crevices and mated surfaces 5 times.
- When cleaning the 1588 AIM Camera Head with Integrated Coupler (1588-610-122), brush between all gaps and crevices while pushing down on the endobody clamp. Continue brushing all gaps and crevices while releasing the clamp to the initial position.

3. **Rinse**
   - Remove the device from the prepared detergent. Rinse the device with reverse osmosis/ deionized water at ambient temperature for 90 seconds or until all visible detergent residue is removed.
   - After all visible detergent residue is removed, continue to rinse for 30 seconds.
4. **Automated Wash**
   - Place the device in the washer on an incline to facilitate drainage.
   - Program the washer using the following parameters:

Phase	Recirculation Time	Temperature	Detergent Type
Pre Wash	2 minutes	Cold water	N/A
Enzyme Wash	2 minutes	Hot water	Enzymatic detergent
Wash 1	2 minutes	Set point 66 °C (151 °F)	Non-enzymatic detergent
Rinse 1	2 minutes	Hot water	N/A
Dry Phase	7 minutes	115 °C (239 °F)	N/A

   - Filtered pressurized air can be used to aid in drying.
   - Visually inspect the device for cleanliness, paying close attention to hard-to-reach areas. If visible soil remains, repeat steps 1– 4.

High-Level Disinfection (Optional)

WARNING - The device must be sterilized after disinfection. Failure to sterilize the device before reuse presents an acute infection control risk to the patient.

Note - For necessary materials and equipment, see the Materials and Equipment table.

The device can be disinfected using a disinfecting solution that has the following active ingredient: ≥ 2.4% glutaraldehyde at 25 °C.

1. Clean and prepare the device as recommended in this user manual. Ensure the soaking cap is installed.
2. Prepare the disinfecting solution according to the manufacturer instructions.
3. Immerse the device in the solution, filling all mated surfaces and crevices.
4. Soak the device in the solution for 45 minutes.

5. Thoroughly rinse and flush the device with running, reverse osmosis/deionized water to remove the disinfectant.
6. Dry the device with a clean, lint-free cloth immediately after rinsing.

Sterilization

After performing the cleaning instructions specified above, perform one of the following sterilization cycles.

Note - For necessary materials and equipment, see the Materials and Equipment table.

Sterrad

1. Clean and prepare the device as recommended in this user manual. Ensure the soaking cap is installed.
2. If using a sterilization tray (optional), follow any additional instructions provided with the tray. Use only trays that are compatible with Sterrad.
3. Double wrap the device (or tray) prior to sterilization.
4. Sterilize the device following the instructions of the manufacturer, using the Sterrad 100S, 200, NX, or 100NX Sterilization System. Select the standard cycle.
5. After sterilization, allow the device to cool to room temperature before reconnecting it to a coupler or the console. Otherwise, the lens can fog during use or the console can produce a system error.

Steris/Amsco V-PRO

1. Clean and prepare the device as recommended in this user manual. Ensure the soaking cap is installed.
2. If using a sterilization tray (optional), follow any additional instructions provided with the tray. Use only trays that are approved for sterilization with V-PRO.
3. Double wrap the device (or tray) prior to sterilization.
4. Sterilize the device using one of the following V-PRO sterilization systems:
    - V-PRO 1 (Standard cycle)
    - V-PRO 1 Plus (Non-Lumen or Standard cycle)
    - V-PRO maX (Non-Lumen or Standard cycle)
5. After sterilization, allow the device to cool to room temperature before reconnecting it to a coupler or the console. Otherwise, the lens can fog during use or the console can produce a system error.

Steris System 1 / 1E / 1 Plus / 1 Express

Note - Steris System 1, System 1 Plus, and System 1 Express are not intended for use in the United States.

1. Clean and prepare the device as recommended in this user manual. Ensure the soaking cap is installed.
2. Following the instructions of the manufacturer, sterilize the device using one of the Steris systems below with the appropriate sterilant:
    - System 1 with Steris 20 Sterilant

- System 1E with S40™ Sterilant
- System 1 Plus with S40 Sterilant
- System 1 Express with S40 Sterilant

3. Remove the device from the Steris chamber once sterilization is complete, or moisture may condense inside the device windows and cause fogging.
4. After sterilization, allow the device to completely dry and cool to room temperature before reconnecting it to a coupler or the console. Otherwise, the lens can fog during use or the console can produce a system error.

Ethylene Oxide (EO)

1. Clean and prepare the device as recommended in this user manual. Ensure the soaking cap is installed.
2. If using a sterilization tray (optional), follow any additional instructions provided with the tray. Use only trays that are compatible with EO.
3. Double wrap the device (or tray) prior to sterilization.
4. Sterilize the device using the parameters below.

Preconditioning	
Wrapping	Double
Temperature	55 °C (131 °F)
Humidity	70% RH
Vacuum Set Points	1.3 psia
Time	30 min
Exposure	
Temperature	55 ± 2 °C (131 ± 5 °F)
Humidity	70% RH (50–80%) ± 5%
Concentration	725 mg/L, 100% EO
Time	1 hour
Aeration	
Temperature	35–39 °C (95–102 °F)
Time	12 hours

5. After sterilization, allow the device to cool to room temperature before reconnecting it to a coupler or the console. Otherwise, the lens can fog during use or the console can produce a system error.

Maintenance

Inspection

- Inspect the device on a continual basis for unacceptable deterioration such as (but not limited to) corrosion, discoloration, pitting, cracked seals, or abnormal noises. If a problem is observed or suspected, the device should be returned for service.
- Inspect all components for cleanliness. If fluid or tissue buildup is present, repeat the above cleaning and sterilization procedures.
- Inspect any cables for cuts and breaks. If visible damage is detected, the device should be returned for service.

Using Sterile Drapes

Using sterile drapes will ensure maximum longevity of the camera. For best results, follow the instructions provided by the drape manufacturer.

Storage

Store the device in a dry, clean, and dust-free environment at room temperatures.

Replacing the Fuses

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

1. Unplug the power cord from the wall outlet and remove the cord from the device.
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.
4. Reinstall the fuse holder until the tab snaps in place.

Periodic Maintenance Schedule

WARNING -
To ensure safe operation of the device, you should periodically perform the following procedure:

Every 12 months, check the earth leakage current to <500 µA (<300 µA in USA), ground protective earth impedance to <0.1 ohms, and power consumption less than or equal to rated power. Use a true RMS digital multimeter and safety analyzer to perform this test.

Note - Refer calibration and operating difficulties not detailed in this manual to your Stryker Endoscopy sales representative.

Expected Service Life

The 1588 AIM Camera Control Unit has an expected service life of 1540 uses (four years based on approximately two uses per day).

When camera heads 1588-210-105, 1588-610-122, and 1588-710-105 are sterilized with V-PRO, Sterrad, or Steris System 1/1E/1 Plus/1 Express, the expected service life is 280 reprocessing cycles (two years based on 140 cycles per year).

When camera heads 1588-210-105, 1588-610-122, and 1588-710-105 are sterilized with Ethylene Oxide, the expected service life is 140 reprocessing cycles (two years based on 70 cycles per year).

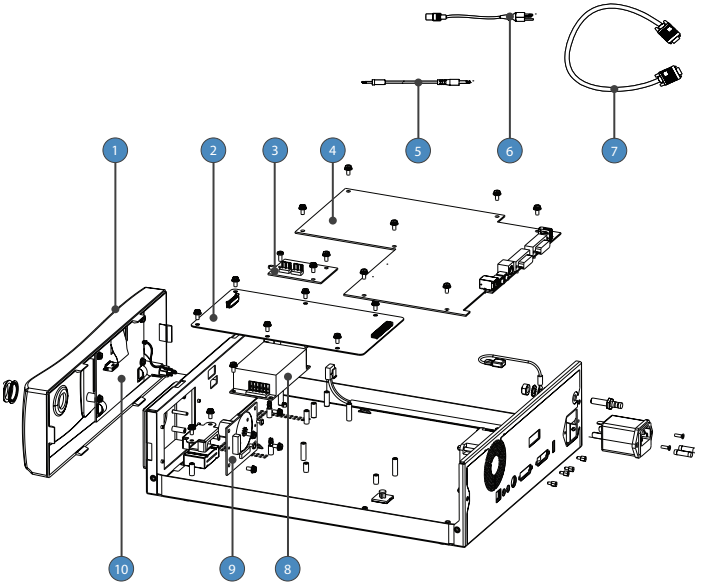
Disposal

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.

Dispose of the product according to local laws and hospital practices. Refer to the recycling diagram(s) to identify components that must be recycled. (Any covers may be shown removed for clarity.)

Recycling Diagrams

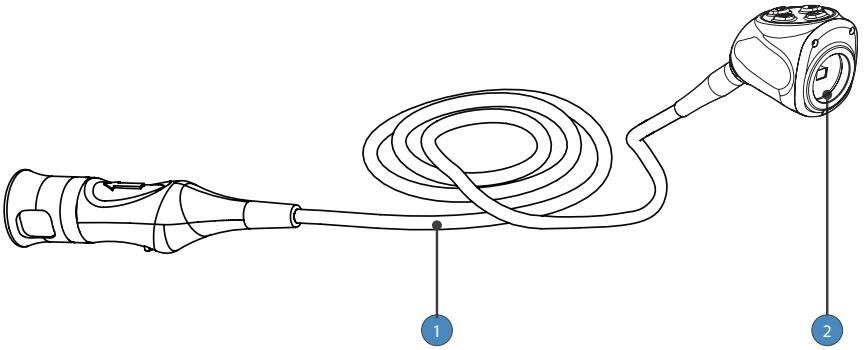
Console



Item	Material	Qty.	Comments
1	Touchscreen LCD	1	Not shown above; on front panel
2	PC Board	1	—
3	PC Board	1	—
4	PC Board	1	—
5	Remote Cable	2	Cable length abbreviated above
6	AC Power Cord	1	Cable length abbreviated above
7	DVI Cable	1	Cable length abbreviated above
8	Power Supply	1	—
9	PC Board	1	—
10	PC Board	1	—

Camera Head

Camera head model 1588-210-105 is shown below.



Item	Material	Qty.	Comments
1	Cable	1	—
2	Camera Head Enclosure (PC Boards)	1	The camera head enclosure that contains PC Boards is sealed and cannot be dismantled without special equipment and training.

Technical Specifications

60 Hz settings are displayed first. (50 Hz settings follow in parentheses.)

Imaging System

1/3” Progressive Scan CMOS

High Definition

Scanning System

Horizontal: 64.00 kHz (60.00 kHz)

Vertical: 60.02 Hz (50.00 Hz)

Video Outputs

Digital/Analog: Two Digital Video Interface (DVI)/RGBHV

1280 × 1024 (HD), 720p, 1080p (HDTV) format

Connector: 29-pin DVI-I

Y/C: One S-VHS

Connector: 4-pin mini-DIN

Mounting

Endoscope eyepiece used with C-mount coupler

C-mount camera head used with C-mount scopes

(C-mount coupler/scope thread: 1-32″ UN 2A)

Auto Shutter Range

1/60 (1/50) – 1/50,000 second

Operating Conditions

Temperature: 10 – 30 °C

Relative Humidity: 25 – 75%

Transportation and Storage Conditions

Temperature: -18 – 60 °C

Relative Humidity: 15 – 90%

Input Electrical Ratings

100-240V~ 50/60Hz 0.6A

Device Weight

10.8 lb (4.9 kg) Camera Console

1.0 lb (0.5 kg) Camera Head (approximate weight)

Dimensions

Camera Console: 12.5″ w × 4.0″ h × 15.25″ d

(31.8 cm w × 10.2 cm h × 38.7 cm d)

Camera Head Cable: 10 ft (3.05 m) sealed cable

Classification

Class I Equipment

Continuous Operation

Type BF Applied Part

Ingress Protection, IPX0—Ordinary Equipment (1588 AIM console)

Ingress Protection, IPX7—Protected against the effects of temporary immersion in water (1588 AIM Camera Heads)

Electromagnetic Compatibility

All electrical medical equipment requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC), the device must be installed and operated according to the EMC information provided in this manual.

Note: The device has been designed and tested to comply with IEC 60601-1-2 requirements for EMC with other devices.

Note: This equipment is for use in a professional healthcare environment. It is not for use in the radio frequency (RF) shielded room of a medical electrical system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.

Note: This equipment is not likely susceptible to interference from high frequency (HF) surgical instruments in the Special Environment of being in close proximity to an active HF surgical instrument. In the case that HF surgical interference is observed, adjust the separation distance of the equipment.

WARNING -

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

Guidance and Manufacturer's Declaration: Electromagnetic Emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function; therefore, its RF emissions are very low and are not likely to cause any interference in nearby equipment.
RF emissions CISPR 11	Class B	The device 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.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC61000-3-3	Complies	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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	±8kV contact ±15kV air	±8kV contact ±15kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2kV for power supply lines ±1kV for input/ output lines (if applicable)	±2kV line to ground ±1kV for input/output lines (if applicable)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV 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 0.5 cycle 0% Ut 1 cycle 70% Ut 25 cycles 0% Ut 5 seconds		Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.

Guidance and Manufacturer's Declaration: Electromagnetic Immunity			
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power-frequency magnetic fields should be at levels characteristic of a typical location in 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 device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment: Guidance**

Guidance and Manufacturer's Declaration: Electromagnetic Immunity			
Conducted RF IEC 61000-4-6	6 Vrms 150 kHz to 80 MHz	6 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 2\sqrt{P}$ 80 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range(b). Interference may occur in the vicinity of equipment marked with the following: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below.

The customer or the user of the device should ensure that it is used in such an environment.

(a) 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Tested Specifications for Immunity to RF Wireless Communications Equipment

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380–390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430–470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704–787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						

Tested Specifications for Immunity to RF Wireless Communications Equipment						
1720	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100–5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						
NOTE: Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of this device, otherwise the device performance could degrade.						

Symbol Definitions

This device and its labeling contain symbols that provide important information for the safe and proper use of the device. These symbols are defined below.

Touchscreen Interface/Display Monitor

White Balance button

Capture photo

Start/stop video recording

Settings button (navigate to Menu screen)

Brightness icon

Zoom icon

Home button (navigate to Home screen)

Endoscopic Near-Infrared Visualization (ENV) button (gray=mode is available but off)

Endoscopic Near-Infrared Visualization (ENV) button (green=mode is on)

Dynamic Range Enhancement (DRE) mode is on

Dynamic Range Enhancement (DRE) Desaturation (Desat) function is on

Strobe mode is on

Camera head button error (return for service if this appears on the display monitor)

Device/Package Labeling

Consult instructions for use

Caution (consult instructions for use)

Consult instruction manual

Federal law (USA) restricts this device to use by, or on order of, a physician

Device is shipped non-sterile and must be sterilized before use

Date of manufacture

Legal manufacturer

Product catalog number

Product serial number

The device meets requirements for safety and effectiveness set forth in MDD 93/42/EEC.

Stryker European representative

Denotes compliance to CAN/CSA C22.2 No 60601-1 and ANSI/AAMI 60601-1

Type BF applied part

1588 AIM Camera Head connection

Power on/off (power state alternates when button is pushed)

Equipotentiality

Alternating current

Fuse rating

Device recycling code (applicable in China)

This product contains electrical waste or electronic equipment. It must not be disposed of as unsorted municipal waste and must be collected separately.

User Manual

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

Radiation emitting

stryker®

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