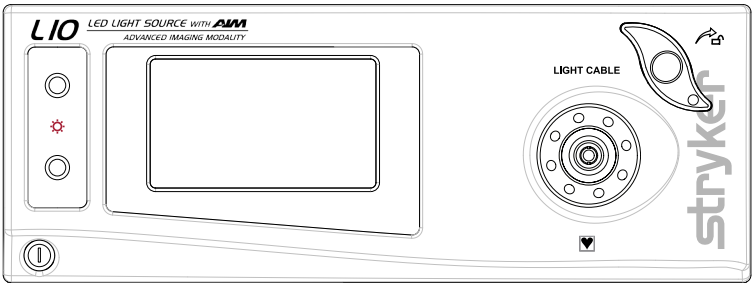
stryker®

L10 LED Light Source with AIM Technology

REF 0220-220-300



CE Rx ONLY

Contents

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, see the standard warranty.
2. Never sterilize the console. The delicate electronics cannot withstand a sterilization procedure.
3. Ensure that the electrical installation of the relevant operating room complies with the NEC and CEC guidelines.
4. Attempt no maintenance or adjustments that are not specifically detailed in this user manual.
5. Ensure that any modifications or repairs are carried out by persons authorized by Stryker. No modification of this equipment is allowed by the user.

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. Do not position the console so that it is difficult to disconnect the power cord from the supply mains.
5. Never block the rear or side vents of the console. Failure to follow this instruction can result in device damage or a possible fire.
6. To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth ground.
7. Multiple portable socket-outlets shall not be placed on the floor.
8. Never use this equipment in the presence of flammable or explosive gas.
9. Disconnect the console from the electrical outlet when inspecting fuses or making any repairs. Refer all repairs to authorized personnel.
10. Do not remove covers on the console, as doing so may cause damage to electronics and/or electric shock.

Warnings: Laser

IMPORTANT SAFETY NOTICE - LASER RADIATION:
The L10 LED Light Source with Advanced Imaging Modality Technology (or "L10 AIM Light Source") is a laser product that uses a Class 1 laser (IRIS mode) and a Class 1M laser (ENV mode).

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 prevent exposure to laser radiation, follow all warnings and guidelines presented below and throughout this user manual.

1. Observe the warning label shown below (located on the rear panel).

2. Protect the L10 AIM Light Source 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 activated. The 1588 AIM Video Camera is intended to visualize tissue manipulation only while ENV mode is off.
5. Do not view the laser output in ENV mode with telescopic optical instruments (for example, microscopes or magnifiers). Do not direct the laser output in ENV mode into an area where such instruments are likely to be used.
6. Do not activate ENV mode when the endoscope is outside of the patient's body.
7. When ENV mode is activated, 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 activated, never leave a SafeLight adapter attached to the light cable without an endoscope attached. Laser radiation can continue to emit from the adapter.
9. Power off the light source (or place it in Standby mode and disable ENV mode and IRIS mode) before connecting or removing the light cable, endoscope, or disposable fibers.

Operating a Light Source

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

IMPORTANT SAFETY NOTICE - HIGH TEMPERATURES:
Before operating this device, please read this operating manual thoroughly and carefully. 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 result in higher levels of heat. Adjust the brightness level of the camera and the monitor 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 and disable ENV 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 L10 LED Light Source with Advanced Imaging Modality Technology (or "L10 AIM Light Source") is a light-generating unit designed to illuminate surgical sites in the following applications: visible light (White Light mode), near-infrared fluorescence (ENV mode), and near-infrared transillumination (IRIS mode).

- **White Light mode:** The light source uses light-emitting diode (LED) technology to generate bright, crisp light in the visible light spectrum that is intended to illuminate surgical sites during endoscopic procedures. The light is delivered to the surgical site through an endoscope via a fiber optic light cable.
- **ENV mode:** The light source uses laser technology to generate light in the near-infrared light spectrum, which is intended to enable fluorescence imaging of anatomy that has been targeted with the contrast agent indocyanine green. The light is delivered to the surgical site through an endoscope via a fiber optic light cable.
- **IRIS mode:** The light source uses laser technology to generate light in the near-infrared light spectrum that is intended to transilluminate the ureter during open or laparoscopic surgical procedures. The light is delivered to the surgical site via a disposable fiber.

The light source is equipped with a safety feature that minimizes light output if the fiber optic light cable is not connected to the scope adapter, which prevents exposure to laser radiation, high-intensity light, and accidental burns. For more information, see the section Checking the ESST Feature.

Indications

The L10 AIM Light Source and SafeLight™ Cable are indicated for use to provide real-time endoscopic visible and near-infrared fluorescence imaging. The L10 AIM Light Source and SafeLight Cable enable surgeons to perform minimally invasive surgery using standard endoscope visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near-infrared imaging.

Fluorescence imaging of biliary ducts with the L10 AIM Light Source and SafeLight Cable is intended for use with standard-of-care white light and, when indicated, intraoperative cholangiography. The devices are not intended for standalone use for biliary duct visualization.

The L10 AIM Light Source is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.

ENV Mode Requirements

The equipment listed below is required to achieve the intended results when using the light source in Endoscopic Near-Infrared Visualization (ENV) mode. Any model listed for the camera head and laparoscope may be used. Intended results will not be achieved if any equipment is substituted.

ENV mode is intended to be used with a contrast agent drug called indocyanine green (ICG). AIM IC-GREEN® (NDC # 69705-101-02) includes the required ICG supplies. See the Using AIM IC-GREEN in ENV Mode section for more detail.

Note: Regulation of ICG varies by country. In certain countries, ICG is not registered for use as a pharmaceutical product. Contact your local Stryker distributor for more information on the availability of ICG at your location.

Before using ENV mode, read and be familiar with the warnings and instructions provided with each device in the system.

Light Source

0220-220-300 L10 LED Light Source with AIM Technology

Camera Control Unit

1588-010-000 1588 AIM Camera Control Unit[1]

Camera Head

1588-210-105 1588 AIM Camera Head, C-Mount[1]
1588-610-122 1588 AIM Camera Head with Integrated Coupler[1]
1588-710-105 1588 AIM Inline Camera Head, C-Mount[1]

Coupler

1588-020-122 AIM Coupler, 18 mm, C-Mount[2]

Laparoscope

0502-537-010 AIM, 5.4 mm, 0°, HD Laparoscope, 30 cm[3]
0502-537-030 AIM, 5.4 mm, 30°, HD Laparoscope, 30 cm[3]
0502-937-010 AIM, 10 mm, 0°, HD Laparoscope, 33 cm[3]
0502-937-030 AIM, 10 mm, 30°, HD Laparoscope, 33 cm[3]

AIM SafeLight Cable

0233-050-300 AIM SafeLight Fiber Optic Cable, 5.0 mm x 10 ft (3.05 m)[4]

Indocyanine Green

AIM IC-GREEN[5]

[1] See Stryker user manual P29923 (English) or P29924 (multilingual). [2] See Stryker user manual P30104 . [3] See Stryker user manual P27900. [4] See Stryker user manual P27701.

[5] See AIM IC-GREEN instructions for use packaged with NDC # 69705-101-02.

IRIS Mode Requirements

The equipment listed below is required to achieve the intended results when using the light source in Infrared Illumination System (IRIS) mode during laparoscopic surgical procedures. Any model listed for the camera control unit, camera head, coupler, and laparoscope may be used. Intended results will not be achieved if any equipment is substituted.

Of the equipment listed below, only the light source and disposable fiber are required to achieve the intended results when using IRIS mode during open surgical procedures.

Before using IRIS mode, read and be familiar with the warnings and instructions provided with each device in the system.

Light Source

0220-220-300 L10 LED Light Source with AIM Technology

Camera Control Unit

1588-010-000 1588 AIM Camera Control Unit[1]
1488-010-000 1488 HD 3-Chip Camera Control Unit[2]
1488-010-001 1488 HD 3-Chip Camera Control Unit with DVI Fiber Output[2]

Camera Head

1588-210-105 1588 AIM Camera Head, C-Mount[1]
1588-610-122 1588 AIM Camera Head with Integrated Coupler[1]
1588-710-105 1588 AIM Inline Camera Head, C-Mount[1]
1488-210-105 1488 HD 3-Chip Camera Head, C-Mount[2]
1488-610-122 1488 HD 3-Chip Camera Head with Integrated Coupler[2]
1488-710-105 1488 HD 3-Chip Inline Camera Head, C-Mount[2]

Coupler

1588-020-122 AIM Coupler, 18 mm, C-Mount[3]
1488-020-122 1488 HD 18 mm Coupler, C-Mount[4]

Laparoscope

0502-537-010 AIM, 5.4 mm, 0°, HD Laparoscope, 30 cm[5]
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0502-937-010 AIM, 10 mm, 0°, HD Laparoscope, 33 cm[5]
0502-937-030 AIM, 10 mm, 30°, HD Laparoscope, 33 cm[5]

Light Cable

Any Stryker light cable

Disposable Fiber

0220-180-518 IRIS Ureteral Kit[6]

[1] See Stryker user manual P29923 (English) or P29924 (multilingual).
[2] See Stryker user manual P18966 (English) or P18972 (multilingual).
[3] See Stryker user manual P30104.
[4] See Stryker user manual P18968.
[5] See Stryker user manual P27900.
[6] See Stryker user manual P26059.

Note: IRIS mode is also compatible with the following Intuitive Surgical® robotic camera systems:

Intuitive Surgical® Robotic System
da Vinci® Xi System
da Vinci® Si System with Firefly™ mode

IRIS sensitivity is enhanced in the Intuitive Surgical® da Vinci® System by the use of Firefly™ mode.

The Stryker light source and disposable fiber listed above are required to use Intuitive Surgical® robotic camera systems with IRIS mode.

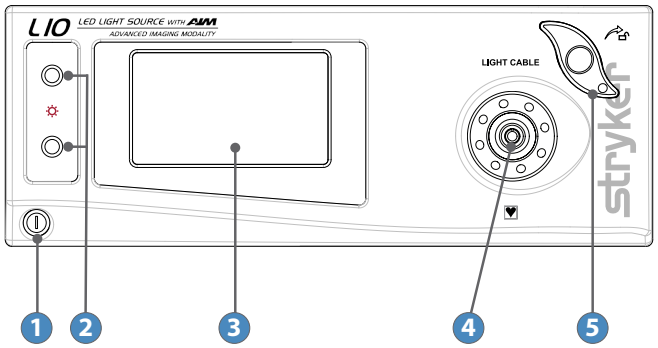
General Compatibility

- All Stryker light cables are compatible with the L10 AIM Light Source when used in White Light mode or IRIS mode. ENV mode requires the AIM SafeLight cable (0233-050-300).
- Using the proper scope adapter, the Stryker light cable can connect the light source system to any flexible or rigid endoscope. Before using another manufacturer's equipment, thoroughly read the accompanying documents for all warnings and instructions.

Console Features

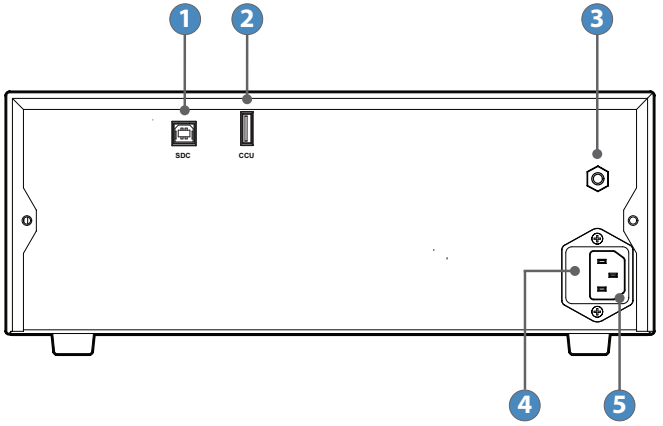
The features of the L10 AIM Light Source are described below.

Front Panel



1.	**Power Button**	Powers the unit on and off
2.	**IRIS Connectors**	For connecting the light source ends of the IRIS Ureteral Kit (0220-180-518). Location of Class 1 laser emissions when IRIS Ureteral Kit is connected and IRIS mode is activated.
3.	**Touchscreen**	Provides user controls and system feedback
4.	**Light Cable Connection**	For connecting the light-source end of the light cable. Location of Class 1M laser emissions when AIM SafeLight cable is connected and ENV mode is activated.
5.	**Jaw Handle**	Opens and closes the clamp in the light cable connection

Rear Panel



1.	**SDC connection**	Connects to Stryker SDC for voice and device control with a USB A-to-B cable
2.	**CCU connection**	Connects to Stryker 1588 AIM Camera Control Unit with the provided USB A-to-A cable
3.	**Equipotential Ground Plug**	Connects to a potential equalization conductor. The resulting medical electrical system shall follow all applicable IEC 60601-1 requirements.
4.	**Fuse Panel**	Contains two T 5.0AH 250V (slow blow, high breaking capacity 1500A) fuses
5.	**AC Inlet**	Connects to AC mains with the provided, separable power cord

Setup

Stryker considers instructional training, or inservice, an integral part of the L10 AIM Light Source. Your local Stryker 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 representative after your equipment has arrived.

Setting up the L10 AIM Light Source involves four steps:

- Connecting the AC power cable
- Connecting a USB cable to the Camera Control Unit
- Connecting a Light Cable
- Connecting an IRIS Ureteral Kit

Always connect the light source 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 light source that have been specified for use with the light source. Connecting incompatible equipment may cause unexpected results.

When the light source is used with other equipment, leakage currents may be additive. To minimize leakage current that may travel to the patient or user, any Type CF applied part should be used only with other Type CF applied parts. 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 light source. When choosing a location for the console, 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. The console must also be positioned on its feet; do not operate the unit upside down or on its side.

Connecting the AC Power Cable

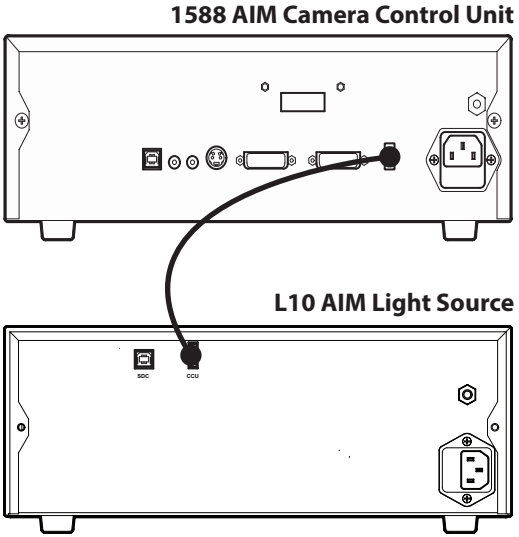
1. Plug in the AC power cord to the AC Inlet on the rear console panel.
2. Plug in the other end of the AC cord to a hospital-grade outlet.

Connecting to the Camera Control Unit

To activate ENV mode, the L10 AIM Light Source must be connected to the 1588 AIM Camera. White Light mode and IRIS mode do not require connection to the camera.

Note: The 1588 AIM camera head can be programmed to control some functions of the L10 AIM Light Source, such as toggling Active/Standby or adjusting some settings in ENV mode. Contact a Stryker representative for more information about enabling this advanced feature.

1. Using a USB A-to-A cable, connect the CCU port on the L10 AIM Light Source to the Light Source port on the 1588 AIM Camera Control Unit.



Connecting a Light Cable

To activate ENV mode, an AIM SafeLight cable (0233-050-300) must be connected to the light source. White Light mode and IRIS mode will function when other Stryker light cables are connected.

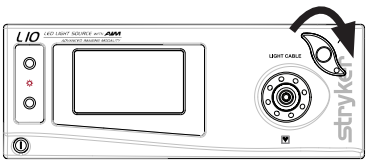
Power off the light source (or place it in Standby mode and disable ENV mode and IRIS mode) before connecting or removing the light cable or endoscope.

Keep fingers away from the light cable connection as the clamp may inadvertently deploy and cause injury.

The light cable connection on the light source emits a Class 1M laser when ENV mode is activated. To assure proper and safe laser application, connect only the AIM SafeLight cable to the light source. Do not attempt to use any other fiber optic light cables with ENV mode.

Do not operate the light source in ENV mode with an AIM SafeLight cable that is cut or damaged. If the AIM SafeLight cable breaks during operation, place the light source in Standby mode and disable ENV mode, then replace the cable.

1. Make sure the light source is powered off, or place it in Standby mode and disable ENV mode.
2. Lock open the clamp in the light cable connection by turning the jaw handle clockwise until it stops.



3. Insert a clean, dry light cable into the cable connection until the jaw clamps the cable in place. Pull gently on the cable to test that it is securely seated in the cable connection.
4. Connect an endoscope to the opposite end of the light cable.

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

Before each use, check the outer surface of the endoscope to ensure there are no rough surfaces, sharp edges, or protrusions.

Note: To remove the light cable, place the light source in Standby mode and disable ENV mode. Then, turn the jaw handle clockwise until the latch opens.

Connecting an IRIS Ureteral Kit

To activate IRIS mode, an IRIS Ureteral Kit (0220-180-518) must be connected to the light source. White Light mode and ENV mode do not require connection to an IRIS Ureteral Kit.

The IRIS connectors on the light source emit a Class 1 laser when IRIS mode is activated. To assure proper and safe laser application in IRIS mode, connect only the Stryker IRIS Ureteral Kit to the IRIS connectors. Do not attempt to use any other fiber optic light guides or emitting fibers.

Do not attempt to operate the light source with an IRIS Ureteral Kit that is cut or damaged. If the IRIS Ureteral Kit breaks during operation, disable IRIS mode, then replace the Kit.

Before connecting or using an IRIS Ureteral Kit, read and be familiar with all warnings in this user manual and the IRIS Ureteral Kit user manual (P26059). Use of controls or performance of procedures other than those specified can result in hazardous laser radiation exposure.

To connect an IRIS Ureteral Kit:

1. Make sure the light source is powered off, or place it in Standby mode and disable IRIS mode.
2. Insert the light source ends of both fibers into the IRIS connectors on the front panel of the light source.

Operation

Before operating the light source, read and be familiar with all warnings in this user manual. Failure to follow these warnings can result user or patient injury.

Before operating the L10 AIM Light Source, ensure all system components have been set up according to the instructions in the Setup section.

ENV mode requires all of the equipment listed in the ENV Mode Requirements section in order to achieve the intended results.

IRIS mode requires all of the equipment listed in the IRIS Mode Requirements section in order to achieve the intended results.

Powering the Console On and Off

1. To power on the console, press the power button on the front panel. The touchscreen will display the default White Light screen and indicate that the light source is in Standby mode.

   Note: The light source will not illuminate unless a light cable is connected to the cable port.

2. To power off the console, press the power button on the front panel.

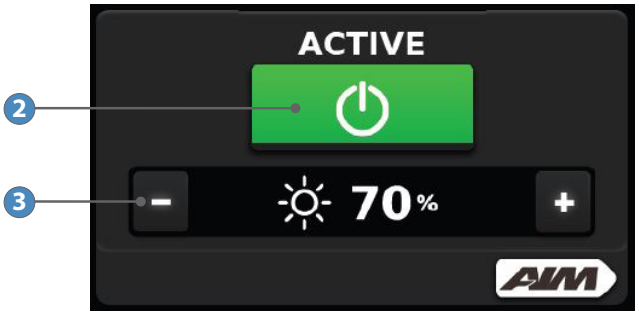
Activating White Light Mode

White Light mode activates the LED diodes in the light source so it can generate visible light.

Note: Activating White Light mode is also required as a preliminary step to activate ENV mode or IRIS mode. While ENV mode is activated, it automatically disables the white light output. While IRIS mode is activated, the user can return to the White Light screen to toggle the white light output to Active or Standby.

Follow the steps below to activate White Light mode.

1. Ensure a Stryker light cable is connected to the light source. See the Connecting a Light Cable section for more information.
2. On the default White Light screen, press the **touchscreen power button** so it appears green and the word "Active" appears above it.
3. Adjust the **White Light brightness level** by pressing the plus or minus buttons.



Placing the Light Source in Standby Mode

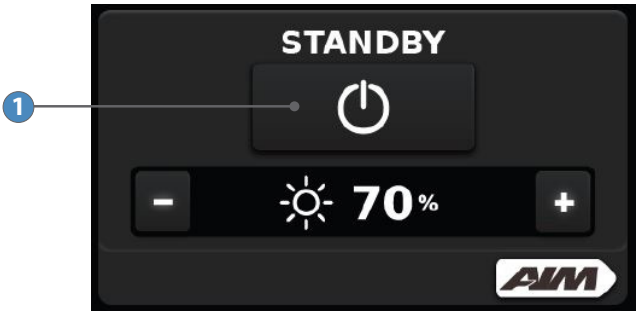
Standby mode reduces white light output to a minimum, thereby reducing the heat generated at the tip of the light cable or scope when the light source is not being used.

To help prevent burns to the patient, user or inanimate objects and possible fire, always put the light source in Standby mode whenever the endoscope is removed from the light cable.

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 and/or burns to the patient, user or inanimate objects if not used properly. Do not place the scope or the light cable on the patient, on the drapes, or other flammable material, even when the device is in Standby mode.

To place the light source in Standby mode:

1. On the default White Light screen, press the **touchscreen power button** so it appears gray and the word "Standby" appears above it.



Activating ENV Mode

Endoscopic Near-Infrared Visualization (ENV) mode activates the Class 1M laser in the light source and enables fluorescence imaging.

Before using ENV mode, read and follow all warnings in this user manual. Use of controls or performance of procedures other than those specified can result in hazardous radiation exposure. Laser emissions from the light source in ENV mode can cause injury to the user or patient's eyes.

See the ENV Mode Requirements section for equipment requirements. Use ENV mode only with the specified equipment.

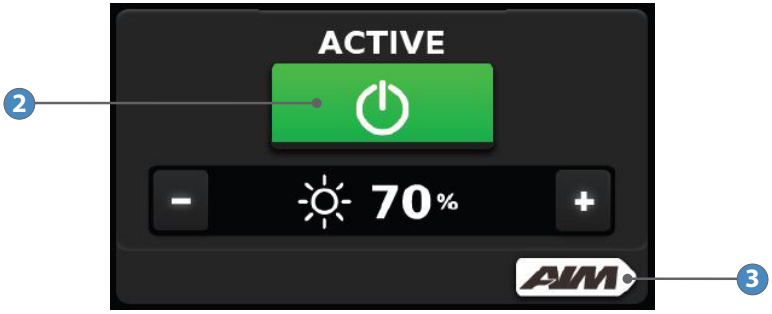
Note: See the 1588 AIM Video Camera user manual (P29923 English, P29924 multilingual) for additional controls over ENV fluorescence.

Follow the steps below to activate ENV mode.

1. Ensure an AIM SafeLight cable is connected to the light source. ENV mode will not function unless an AIM SafeLight cable is properly connected. See the Connecting a Light Cable section for more information.

   Note: When an AIM SafeLight cable is properly connected to the light source, an image of a light cable with a green connector will appear at the top-right of the touchscreen in ENV mode.

2. On the default White Light screen, press the **touchscreen power button** so it appears green and the word "Active" appears above it.
3. Press the **AIM button**.

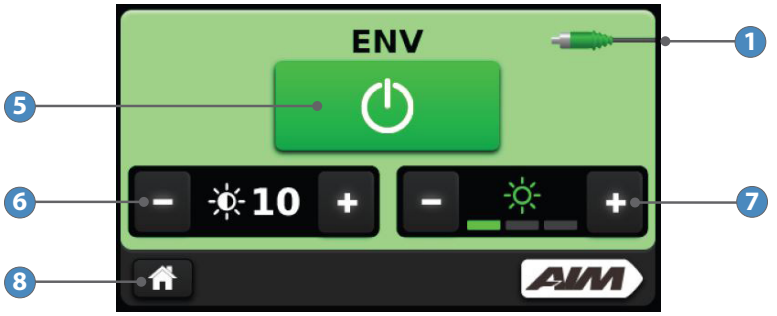


4. On the Advanced Imaging Modality screen, press the **ENV mode button**.

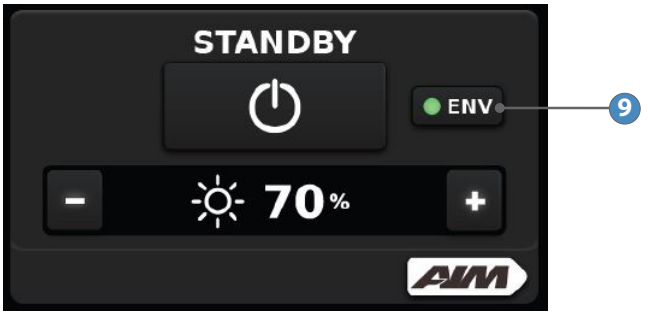
Note: When the ENV mode button is green, the L10 AIM Light Source is properly connected to the 1588 AIM Camera Control Unit and the AIM SafeLight Cable, and ENV mode can be activated. If the ENV mode button is gray, required equipment may not be properly connected and ENV mode is not available. Refer to the Setup section.

5. On the ENV mode screen, press the **touchscreen power button** so it appears green, which indicates the mode is activated.

   Note: Press the touchscreen power button again to disable ENV mode; the button will appear gray. (When ENV mode is disabled, White Light mode will reactivate. To deactivate the White Light, press the Home button to return to the White Light mode screen, and press the touchscreen power button so it appears gray.)



6. Adjust the **backlight level** by pressing the plus or minus buttons. Backlight increases or decreases the brightness of the surrounding anatomy that is not displayed as glowing green on the display monitor.
7. Adjust the **ENV laser level** by pressing the plus or minus buttons. ENV laser level affects the fluorescing green appearance of the camera image.
8. Press the **Home button** to return to the White Light screen.
9. If ENV mode is still activated when the user returns to the White Light screen, an **ENV indicator button** appears to the right of the touchscreen power button. Press the ENV indicator button to return to the ENV mode screen.



Activating IRIS Mode

Infrared Illumination System (IRIS) mode activates the Class 1 laser in the light source and enables use of the IRIS Ureteral Kit.

> Before using IRIS mode, read and follow all warnings in this user manual and the IRIS Ureteral Kit user manual (P26059). Use of controls or performance of procedures other than those specified can result in hazardous radiation exposure.
>
> See the IRIS Mode Requirements section for equipment requirements. Use IRIS mode only with the specified equipment.

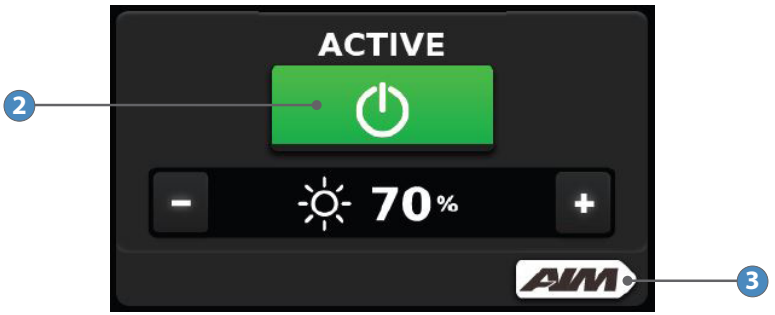
Note: If ENV mode is activated, it must be disabled before activating IRIS mode.

Follow the steps below to activate IRIS mode.

1. Ensure an IRIS Ureteral Kit is connected to the light source. IRIS mode will not function unless an IRIS Ureteral Kit is properly connected. See the Connecting an IRIS Ureteral Kit section for more information.

   Note: When an IRIS Ureteral Kit is properly connected to the light source, an image of two red fibers will appear at the top-left of the touchscreen in IRIS mode. (If only one fiber is connected, an image of one red fiber and one gray fiber will appear on the touchscreen.)

2. On the default White Light screen, press the **touchscreen power button** so it appears green and the word "Active" appears above it.
3. Press the **AIM button**.

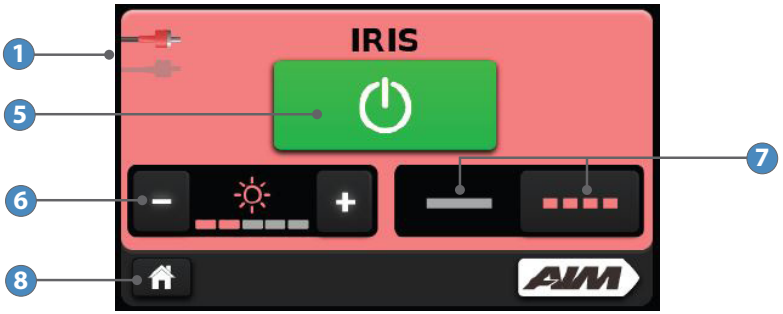


4. On the Advanced Imaging Modality screen, press the **IRIS mode button**.

Note: When the IRIS mode button is red, the L10 AIM Light Source is properly connected to the IRIS Ureteral Kit and IRIS mode can be activated. If the IRIS mode button is gray, required equipment may not be properly connected and IRIS mode is not available. Refer to the Setup section.

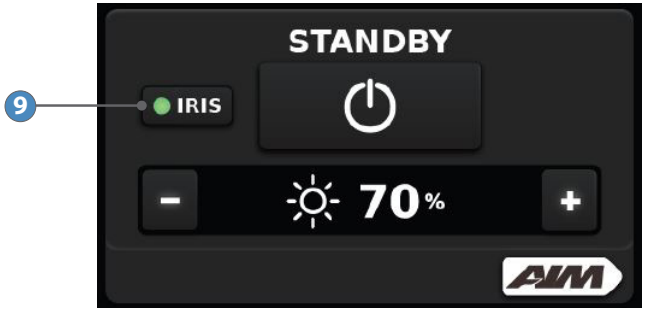
5. On the IRIS mode screen, press the **touchscreen power button** so it appears green, which indicates the mode is activated.

Note: Press the touchscreen power button again to disable IRIS mode; the button will appear gray.



6. Adjust the **IRIS brightness level** by pressing the plus or minus buttons.
7. Press the solid line or the dotted line to toggle the IRIS light output between the **continuous or pulsating** setting, respectively.
   - In the continuous setting, the laser energy is continuous.
   - In the pulsating setting, the laser energy pulses in a repeating pattern of 0.5 second on/0.5 second off (1 pulse cycle per second).
8. Press the **Home button** to return to the White Light screen.

9. If IRIS mode is still activated when the user returns to the White Light screen, an **IRIS indicator button** appears to the left of the touchscreen power button. Press the IRIS indicator button to return to the IRIS mode screen.



Using AIM IC-GREEN in ENV Mode

Endoscopic Near-Infrared Visualization (ENV) mode is intended to be used with a contrast agent drug called indocyanine green (ICG). **AIM IC-GREEN®** (NDC # 69705-101-02) includes the required ICG supplies.

Note: Regulation of ICG varies by country. In certain countries, ICG is not registered for use as a pharmaceutical product. Contact your local Stryker distributor for more information on the availability of ICG at your location.

- Indocyanine green is a sterile, water soluble tricarbocyanine dye with a peak spectral absorption at 800 nm in blood or blood plasma.
- ICG contains not more than 5.0% sodium iodide.
- ICG is administered intravenously. Under sterile conditions, the ICG powder should be dissolved with the provided aqueous solvent. AIM IC-GREEN has a pH of approximately 6.5 when reconstituted.
- Use of the ICG dye promotes the fluorescing appearance of the camera image in ENV mode.

Each **AIM IC-GREEN** kit contains the following items:

- Six 25 mg vials of indocyanine green (ICG) imaging agent
- Six 10 mL ampules of aqueous solvent
- Instructions for use

See the ENV Mode Requirements section for complete hardware requirements. The contents of AIM IC-GREEN must be used only with the L10 AIM Light Source.

To use AIM IC-GREEN in conjuction with ENV mode, follow the instructions and warnings below. The instructions for use are also packaged with AIM IC-GREEN (NDC # 69705-101-02).

ICG Indications for Use

AIM IC-GREEN is indicated for use with the Stryker L10 LED Light Source with AIM Technology and SafeLight™ Fiber Optic Cable.

ICG Contraindications

AIM IC-GREEN contains sodium iodide. Use with caution in patients who have a history of allergy to iodides or iodinated contrast agents.

Pharmacology

Following intravenous injection, ICG is rapidly bound to plasma proteins, of which albumin is the principal carrier (95%). Simultaneous arterial and venous blood estimations have shown negligible renal, peripheral, lung or cerebrospinal uptake of the dye. ICG is taken up from the plasma almost exclusively by the hepatic parenchymal cells and is secreted entirely into the bile. ICG does not undergo significant extrahepatic or enterohepatic recirculation.

Warning

Anaphylactic deaths have been reported following ICG administration during cardiac catheterization.

Adverse Reactions

Anaphylactic or urticarial reactions have been reported in patients with or without history of iodide allergies. If an allergic reaction occurs, administer treatment with the appropriate agents: for example, antihistamines, corticosteroids, and epinephrine. Resuscitative measures may also be required.

Precautions

- Federal law (USA) restricts this device to use by, or on order of, a physician.
- Observe sterile handling techniques when preparing and administering the ICG solution. The inner contents of the ICG powder vial and aqueous solvent capsule are sterile. Handle them aseptically during the procedure to maintain the sterile field. Do not use any of these packages if they appear to be damaged or improperly sealed.
- Due to freeze drying, the ICG powder may lump together or cling to the vial. This is normal and the ICG should be suitable for use after reconstitution with the aqueous solvent. If a precipitate is present after preparation, however, discard the solution.
- Use only the aqueous solvent provided with the AIM IC-GREEN kit to dissolve the ICG powder. Commercially available water for injection may be incompatible and should not be used.
- Each preparation of the ICG solution should be used in only one patient. Once the ICG solution is prepared, it must be used within 6 hours. ICG is not stable in aqueous solution.
- Heparin preparations that contain sodium bisulfite reduce the absorption peak of ICG in blood. Do not use heparin preparations with sodium bisulfite as an anticoagulant for the collection of samples for analysis.
- Radioactive iodine uptake studies should not be performed for at least one week after the use of ICG.
- The potential for ICG to impair fertility or have a carcinogenic or mutagenic effect has not been studied. ICG should be administered to a pregnant woman only when clearly indicated. Exercise caution when administering ICG to a nursing woman. It is not known if ICG is excreted in human milk.
- ICG is generally injected through a shared intravenous line with no reported difficulties or unexpected results to date.
- Use ICG only at recommended doses and concentrations listed in this user manual.

Required Supplies

AIM IC-GREEN® (NDC # 69705-101-02) includes the required ICG supplies. Other items required to use AIM IC-GREEN shall be provided by the user.

Note: Regulation of ICG varies by country. In certain countries, ICG is not registered for use as a pharmaceutical product. Contact your local Stryker distributor for more information on the availability of ICG at your location.

Item	Description
AIM IC-GREEN	Includes six 25 mg vials of ICG powder and six 10 mL ampules of aqueous solvent
Sterile normal saline	Approximately 10 –12 mL following each ICG injection
Syringe (for ICG preparation)	Minimum volume of syringe: 10 mL
Syringes (for each ICG solution injection)	Minimum volume of syringes: 3 or 5 mL
Syringes (for each saline flush after ICG injection)	Minimum volume of syringes: 12 mL

ICG Preparation

Prepare the ICG solution following the steps below. The instructions yield a 2.5 mg/mL solution.

1. Open the aqueous solvent ampule.
2. Draw 10 mL of the solvent into a syringe.
3. Remove the flip cap off the vial containing 25 mg of the ICG powder.
4. Inject the 10 mL of aqueous solvent into the ICG vial through the stopper to dissolve the powder.
5. Gently shake the ICG vial to mix the solution. Ensure all ICG powder is dissolved in the solution.
6. Inspect the reconstituted solution for precipitation. If a precipitate is present, discard the solution and prepare a new vial as described above.

ICG Dosage

The typical dose administered is 2.5mg.

The total dose should be less than 2 mg/kg per patient.

Administration

1. Ensure there is a port available for the injection of the ICG solution followed by the saline flush.
2. Draw the required dosage of ICG solution for each planned imaging sequence into separate syringes.
3. Draw approximately 10 – 12 mL of normal saline for each planned imaging sequence into separate syringes.

   Note: There should be the same number of saline syringes (or more) than the prepared ICG solution syringes. If the saline syringes are prepared prior to the procedure, place them in a convenient and sterile location for use at the time of imaging.
4. Administer 2.5 mg of the prepared ICG solution intravenously.
   - For visual assessment of the major extrahepatic bile ducts, administer ICG at least **30 minutes prior** to near-infrared imaging.
   - For visual assessment of vessels, blood flow and related tissue perfusion, administer ICG **immediately before** near-infrared imaging.
5. Immediately follow each ICG injection with a tight bolus injection of approximately 10 – 12 mL of normal saline.

After each injection of ICG solution, the ENV mode should be able to visualize a fluorescence response in blood vessels and tissue within several seconds.

Note: Once the ICG solution is prepared, it must be used within 6 hours. If additional ICG solution is required to administer, reconstitute a second vial of ICG after the first reconstituted solution has been used completely.

ICG Overview

- Injection method: Intravascular
- Recommended dosage: Typically 2.5 mg

ICG Storage

- Discard any unused reconstituted ICG after the surgery is complete.
- Store AIM IC-GREEN at ambient room temperatures of 20 – 25 °C (68 – 77 °F).
- Do not use AIM IC-GREEN if the expiration date on the packaging has passed.

Error Messages

In the event of a light source error, an error message will display on the touchscreen. See the table below for details.

If the light source displays any error message, reboot the console. If the error recurs, it is recommended that the device be returned for service.

Code	Definition	Details
E-1	Over temperature (safety shutoff)	Output in White Light mode is disabled due to excessive heat in the console. All functionality is disabled.
E-2	Failure to color balance	The light source will not actively balance the light output color.
E-3	Power supply fan failure	The light source continues operating but generates excessive heat which may result in additional damage and/or compromised functionality.
E-4	Heat sink fan failure	The light source continues operating but generates excessive heat which may result in additional damage and/or compromised functionality.
E-5	Overcurrent LED failure	The light output color may drastically change, and the light source will not actively balance the light output color.
E-6	Software version mismatch	All light source functionality is disabled. Return to Stryker for service.
E-7	ENV power balance failure	The light source will not actively balance the backlight color until the console is rebooted.
E-8	IRIS power balance failure	IRIS mode is disabled.
E-9	ENV laser error	ENV mode is disabled.
E-10	System initiation error	All light source functionality is disabled. Return to Stryker for service.

Troubleshooting

Problem	Possible Solution
No output in White Light mode	• Ensure the AC power cord is properly connected to a hospital-grade power outlet and the inlet on the rear console panel. • Ensure the power switch on the front panel is powered on. (It will illuminate when powered on.) • Ensure all fuses are operating. See the Replacing the Fuses section of this manual for further instructions. • Ensure the light cable is correctly engaged with the cable port. As a safety feature, the light source will provide no light output unless the light cable is properly seated in the cable port. • Check that vents are not obstructed.
Too much or too little output in White Light mode	• Ensure the light cable is correctly engaged with the cable port. • Ensure that White Light mode is activated. (The brightness level should appear on the LCD.) • If necessary, press the White Light touchscreen power button to switch from Standby to Active. If the unit remains in Standby: (1) Ensure the light cable is correctly engaged with the cable port. (2) Ensure the light cable is attached to the scope using the appropriate scope adapter. • Ensure the light cable can transmit light properly. While the cable is completely disconnected, hold the light-source end of the cable up to an overhead room light and look into the scope end of the cable. If the pattern contains any black spots, the light cable may be worn out and may require replacement.
Excessive glare in the video	• Ensure the electronic shutter on the camera is operating properly to control the video signal brightness. • Decrease the White Light brightness level.

Problem	Possible Solution
Flickering light in the video	• Ensure a light cable is properly connected to the L10 AIM Light Source. • Place the light source in Standby mode and disable ENV mode, then remove the light cable from the light source. Reattach the light cable.
Frozen Touchscreen	• Turn off the console, wait 30 seconds, and then turn it back on.
Cannot advance past Advanced Imaging Modality screen	• Check connection of disposable fiber (to activate IRIS mode) • Check connection of AIM SafeLight cable and 1588 AIM Camera Control Unit (to activate ENV mode)

Note: If this troubleshooting guide does not resolve the problem, call Stryker Technical Support at 1-877-478-7953 (inside the U.S.) or see the standard warranty.

Maintenance

Cleaning the Light Source

Should the light source 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.

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.

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.

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.

Checking the ESST Feature

The L10 AIM Light Source is equipped with a safety feature called Electronic Scope Sensing Technology (ESST). The ESST feature prevents exposure to laser radiation that can cause severe eye injury and high-intensity light that can cause accidental fires or burns. The ESST feature will work only if the light source is used with a Stryker SafeLight cable or AIM SafeLight cable.

The ESST feature senses when the cable and SafeLight scope adapter are separated, and it places the light source in Standby mode and disables ENV mode. In this state, the light source reduces light output to a minimum, protecting the user and patient from laser radiation and high-intensity light.

To verify the ESST feature is functioning properly, perform the following test before every surgical procedure:

During the test, do not point the scope or light cable at anyone. Do not look directly into the scope tip or the end of the light cable. The laser radiation or high-intensity light emitted from the light source can cause severe eye injury.

Other than performing the ESST test while observing these precautions, the user should never disconnect a light cable when the light source is activated.

1. Set up the L10 AIM Light Source system with a SafeLight cable (or AIM SafeLight cable) and scope, including a SafeLight scope adapter.
2. Power on the console.
3. Activate White Light mode.
4. Activate ENV mode (if testing with an AIM SafeLight cable).
5. Disconnect the cable from the SafeLight scope adapter.

The light source should return to Standby mode (and disable ENV mode if testing with an AIM SafeLight cable). This indicates the ESST feature is functioning properly.

Always check to ensure that the unit has switched into Standby mode and ENV mode is disabled before assuming ESST safety protection. If the unit fails to return to this state, there may be a fault with the ESST feature. In this case, do not assume ESST safety protection, and return the unit for service.

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 light source 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.
4. Reinstall the fuse holder until the tab snaps in place.

Storage

Never store the light source in a non-ventilated, humid environment. This can damage the delicate electronics in the device.

Expected Service Life

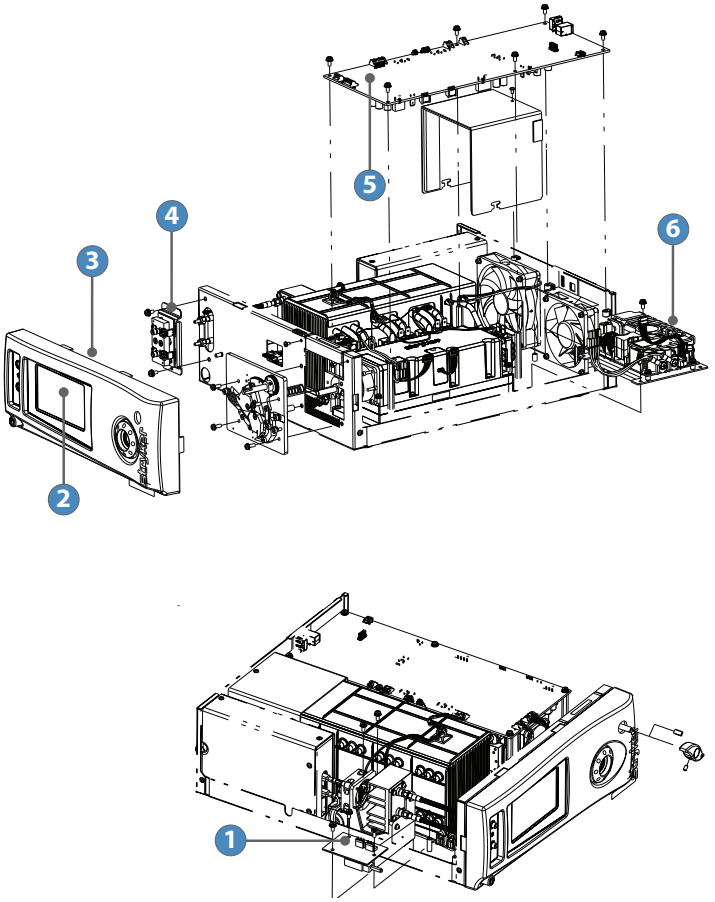
The L10 AIM Light Source has an expected service life of 2000 hours (2 years based on 1000 cases per year).

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 light source according to local laws and hospital practices. Refer to the diagram below to identify components that must be recycled. (The console is shown with the chassis cover removed for clarity.)

Recycling Diagram



Item	Material	Qty.	Comments
1	PC Board	1	—
2	Touchscreen LCD	1	—
3	PC Board	1	Not shown above; behind touchscreen LCD
4	PC Board	1	—
5	PC Board	1	—
6	Power Supply	1	—
7	AC power cord	1	Not shown above
8	USB A-to-A cable	1	Not shown above

Technical Specifications

Electrical

Primary:	100 – 240 VAC, 50/60 Hz, 3.2 – 1.3 A
Fuses (2):	T 5.0AH 250V

Dimensions and Weight

Height:	4.75″(12.1 cm)
Width:	12.5″ (31.8 cm)
Depth:	16.8″ (42.7 cm)
Weight:	16.0 lbs. (7.3 kg)

Light Engine

Type:	Red LED, Green LED, Blue LED, 808 nm Laser, 830 nm Laser

Operating Conditions

Temperature:	10 – 30 °C
Relative Humidity:	25 – 75%

Transportation and Storage Conditions

Temperature:	-18 – 60 °C
Relative Humidity:	15 – 90%

Classifications and Approvals

Class I Equipment

Continuous Operation

Type CF Applied Part

Ingress Protection, IPX0—Ordinary Equipment

Class 1M Laser Product

Laser product classified per IEC 60825-1:2007, Safety of laser products – Part 1: Equipment classification and requirements

This product complies with IEC 60825-1:2007

This product complies with 21 CFR, Subchapter J, Parts 1040.10 and 1040.11, except for deviations pursuant to Laser Notice No. 50, dated July 26, 2001.

Laser Specifications

Emitted wavelength in ENV mode: 808 nm (Class 1M laser)

Emitted wavelength in IRIS mode: 830 nm (Class 1 laser)

Maximum output of laser radiation: Below Class 1M limit

Electromagnetic Compatibility

Like other electrical medical equipment, the L10 AIM Light Source requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC), the L10 AIM Light Source must be installed and operated according to the EMC information provided in this manual.

Note: The L10 AIM Light Source has been designed and tested to comply with IEC 60601-1-2 requirements for EMC with other devices.

Do not use cables or accessories other than those provided with the L10 AIM Light Source, as this may result in increased electromagnetic emissions or decreased immunity to such emissions.

If the L10 AIM Light Source is used adjacent to or stacked with other equipment, observe and verify normal operation of the L10 AIM Light Source 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 L10 AIM Light Source.

Equipment which employs RF communications may affect the normal function of the L10 AIM Light Source.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions		
L10 AIM Light Source is intended for use in the electromagnetic environment specified below. The customer or the user of L10 AIM Light Source should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment - guidance**
RF emissions CISPR 11	Class B	The L10 AIM Light Source 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			
L10 AIM Light Source is intended for use in the electromagnetic environment specified below. The customer or the user of L10 AIM Light Source 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	±6kV contact ±8kV air	±6kV contact ±8kV 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	±2kV line to ground ±1kV for input/output lines	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	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec.	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of L10 AIM Light Source requires continued operation during power mains interruptions, it is recommended that L10 AIM Light Source be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 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			
L10 AIM Light Source is intended for use in the electromagnetic environment specified below. The customer or the user of L10 AIM Light Source should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment:** **Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the L10 AIM Light Source system, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance** $d = 1.17 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5 GHz	3 V/m	$d = 1.17 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 \sqrt{P}$ 800 MHz to 2.5 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: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

L10 AIM Light Source is intended for use in the electromagnetic environment specified below.

The customer or the user of L10 AIM Light Source 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 L10 AIM Light Source system is used exceeds the applicable RF compliance level above, the L10 AIM Light Source system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the L10 AIM Light Source unit.

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

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the L10 AIM Light Source System

The L10 AIM Light Source system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the L10 AIM Light Source system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the L10 AIM Light Source system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power (W) of transmitter	**Separation distance (m) according to frequency of transmitter**		
	150 kHz to 80 MHz $d = 1.17 \sqrt{P}$	**80MHZ to 800 MHz** $d = 1.17 \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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

Green=selected mode is activated

Gray=Selected mode is disabled (or light source is in Standby mode)

White Light brightness level (white icon)

AIM button (navigate to Advanced Imaging Modality screen)

Home button (navigate to White Light screen)

Green=ENV mode is available

Gray=ENV mode is not available (connect required equipment to make the mode available)

Red=IRIS mode is available

Gray=IRIS mode is not available (connect required equipment to make the mode available)

AIM SafeLight cable is properly connected

Backlight level

ENV laser level (green icon)

ENV indicator button (mode is activated; press to return to ENV mode screen)

IRIS Ureteral Kit is properly connected (image of one red fiber appears for each fiber connected)

IRIS brightness level (red icon)

Continuous IRIS light output

Pulsating IRIS light output

IRIS indicator button (mode is activated; press to return to IRIS mode screen)

Device/Package Labeling

Consult instruction manual

Caution (consult instructions for use)

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

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

IRIS connector icon (on front panel)

Turn jaw handle in indicated direction to lock open the cable clamp

Type CF applied part

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

Class 1M laser product

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®

Stryker Endoscopy
5900 Optical Court
San Jose, CA 95138 USA
1-800-624-4422

U.S. Patents: www.stryker.com/patents

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