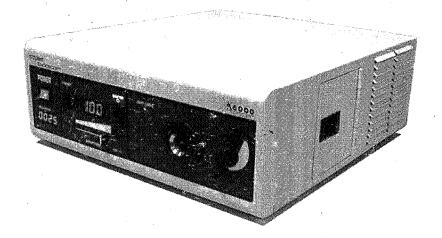
stryker° ENDOSCOPY

X-6000

Xenon Light Source

with ESST, Electronic Scope Sensing Technology

Operating & Maintenance Manual



Warnings & Cautions

TO AVOID POTENTIAL SERIOUS INJURY TO THE USER AND THE PATIENT AND/OR DAMAGE TO THIS DEVICE, THE USER MUST:

- Carefully unpack the unit and check if any damage occurred during shipment. If damage is detected, please see Service and Claims.
- 2. Read this operating manual thoroughly and be familiar with its contents prior to using this equipment.
- 3. Be a qualified physician, having complete knowledge of the use of this equipment.
- 4. Attempt no internal repairs or adjustments unless specifically instructed to do so in this operating and instruction manual.
- 5. Do not sterilize any part of the X-6000 console.
- 6. Disconnect the X-6000 from the electrical outlet when inspecting fuses.

This medical video light source was fully tested at the factory before shipment. As a precaution, however, it is recommended that the unit be tested prior to a surgical procedure.

The light source warranty is void if any of these warnings are disregarded.

NOTE

Stryker Endoscopy reserves the right to make improvements in the product(s) described herein. Product(s) therefore may not agree in detail to the published design or specifications. All specifications are subject to change without notice. Please contact your local Stryker Endoscopy Distributor listed on page 14 or phone your local Stryker Endoscopy sales representative or agent for information on changes and new products.

WARNING

Do not operate the X-6000 Light Source at greater than 50% output when using scopes larger than 6mm in diameter. The extra light is not necessary to produce an image and will excessively heat the tip of the scope.

Stryker Endoscopy accepts full responsibility for the effects on safety, reliability, and performance of the equipment only if:

- readjustments, modifications, and/or repairs are carried out exclusively by Stryker Endoscopy.
- The electrical installation of the relevant operating room complies with the applicable IEC, CEC, and NEC

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

Please read this manual and follow its instructions carefully. The words WARNING, CAUTION, and NOTE carry special meanings and should be carefully reviewed:

WARNING

The personal safety of the patient may be involved. Disregarding this information could result in injury to the patient.

CAUTION

Special service procedures or precautions must be followed to avoid damaging the instrument.

NOTE

Special information to make maintenance easier or important information more clear.



An exclamation mark within a triangle is intended to alert the user to the presence of important operating and maintenance instructions in the literature accompanying the product.



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



Denotes compliance to CSA Std. No. 601.1-M90 and UL2601-1.



Denotes conformance to:93/42/EEC Medical Device Directive.

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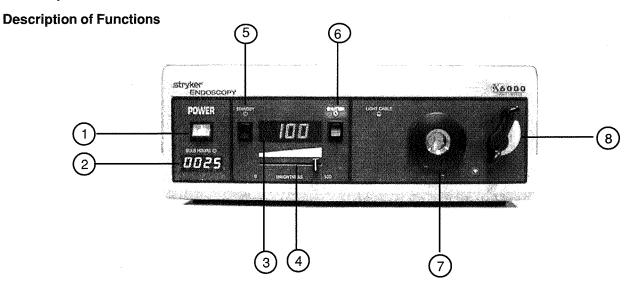
PRODUCT DESCRIPTION & USE

The Stryker Endoscopy X-6000 Xenon Light Source is a high performance device designed for use with Stryker Endoscopy medical video cameras to provide outstanding illumination of the surgical site across all endoscopic applications. With the proper light cable and adapters, it can be connected to any flexible or rigid endoscope.

The X-6000 is equipped with a special safety feature that when using an ESST cable, will prevent accidental burning caused by an unattended light cable. Electronic Scope Sensing Technology senses when the scope and the light cable are separated and places the light source in standby.

Your local Stryker Endoscopy sales representative will perform at least one in-service at your convenience to help you set-up your equipment and instruct you and your staff in its operation and maintenance. Please contact your local Stryker Endoscopy sales representative to schedule an in-service after your equipment has arrived.

A Stryker Endoscopy X-6000 Xenon Light Source consists of the light source console unit, power cord, lamp, and video cable. Replacement or spare lamps can be purchased separately. The X-6000 Xenon Light Source is compatible with all Stryker Light Cables.

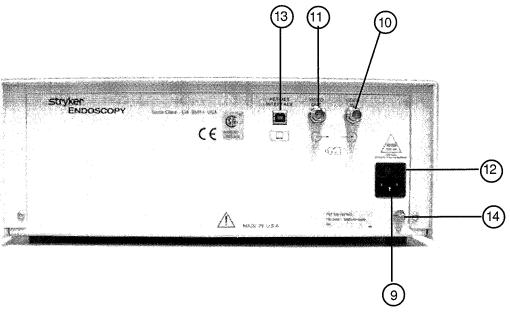


Front Panel

- 1 Power Turns unit power "On" or "Off".
- 2 Hour Meter Displays cumulative number of hours lamp has operated since last lamp change.
- 3 Brightness Display LED Indication (0-100%) of light intensity level.
- 4 Brightness Control Slide Bar Used to increase or decrease light intensity.
- 5 Standby Momentary switch to reduce lamp intensity to a low level for endoscope removal or direct (non-video) viewing through endoscope. STANDBY is the default setting when the light source is turned on. The unit is in Standby when the Standby word and symbol are lit.

- 6 Shutter Toggle switch used to turn the automatic Shutter on and off. The Shutter is on when the Shutter word and symbol are lit.
- 7 Cable Port for light source end of fiber optic cable. When no cable is present, the lamp automatically turns off to save bulb hours.
- 8 In/Out Opens fiber optic cable holder.

Description of Functions continued



Rear Panel

- 9 AC Inlet Power inlet which accepts 100 240VAC, 50 / 60 Hz.
- 10 Video IN BNC connector for camera video input.
- 11 Video OUT BNC connector for camera video loop through.
- 12 Fuse Holder Contains two 8A fuses.
- **13 Hermes** Connector for operation with Hermes Operating Room Control Center.
- **14 Equipotential Plug** Plug for common grounding with other equipment.

TURNING UNIT ON

Confirm that the X-6000 contains a properly installed lamp. If no lamp is installed, see REPLACING THE LAMP before proceeding.

Connect Hospital Grade power cord to AC inlet (9). Connect to Hospital Grade power receptacle. Turn front panel POWER switch (1) on.

STANDBY will illuminate indicating unit is in STANDBY mode. The lamp will not illuminate until the fiber optic CABLE port is opened.

CONNECTING LIGHT CABLE

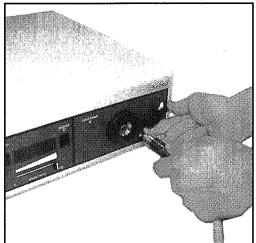
The X-6000 Xenon Light Source is compatible with all Stryker Light Cables.



Cleaning and maintenance for the Light Cable should be done according to the manufacturer's instructions.

Turn the IN/OUT control (8) clockwise to open the fiber optic cable clamp (see figure 1). The lamp will illuminate when the clamp is opened.

Figure 1



NOTE Do not allow the lamp to turn on and off repeatedly. See the note LAMP CARE under "Caring for Your X-6000".

WARNING



High intensity light present, do not look directly into the cable port.

Insert a clean and dry ESST fiber optic cable into the CABLE port (7) until the cable connector snaps into place. A non-ESST cable should be inserted into the cable port until it stops. Release the IN/OUT control to hold the cable in place. Pull gently on the fiber optic cable to test that it is securely seated in the CABLE port.

NOTE Cables of less than 5mm outside diameter may intrude into the light source. A glass window prevents contact with the lamp. Do not force the fiber optic cable past resistance.

Connect an endoscope to the opposite end of the fiber optic cable.

ESST FUNCTION CHECK

When using a special ESST light cable, perform the following test:

Before every surgical procedure, test the ESST function by removing the light cable from the scope adapter. Verify the unit defaults to STANDBY.

WARNING



Failure of the unit to default to STANDBY may indicate a fault with the ESST function. In this case, do not assume ESST safety function.

NOTE The ESST function only works when the light source is used in conjunction with a special ESST cable and adaptor.

CONNECTING VIDEO SIGNALS

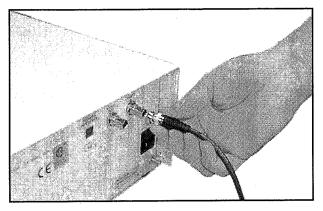


Figure 2

Plug a video camera into the VIDEO IN connector (10) on the rear panel (see figure 2). This input is 75 ohm terminated. Use the buffered VIDEO OUT (11) to connect to a monitor or video peripheral if desired.

SETTING DESIRED MODE

Press STANDBY (5) to release the STANDBY mode.

Select the desired mode of shutter control by placing the Shutter Switch (6) in either the "On" or "Off" position. When the Shutter is "On", the light source will automatically adjust brightness based on input video signals.

ADJUSTING BRIGHTNESS

The Stryker Endoscopy X-6000 features two modes of controlling light intensity in the surgical site. When the Shutter is "On", the light source will respond to input from the camera to automatically alter light levels in the surgical site as the medical video camera and endoscope approach or withdraw from anatomical tissues or structures. When the Shutter is "Off", the light source maintains a constant light level and the light source does not adjust its intensity during the procedure.

AUTO SHUTTER ON

When the Auto Shutter is "On", the light intensity is automatically adjusted to maintain a constant brightness on the monitor, as the need for light intensity varies. You must have a Stryker Endoscopy medical video camera connected to the VIDEO IN connector (10) for AUTO mode to work properly.

NOTE

The Brightness Control Slide Bar (4) must be used to set an acceptable light level around which the unit automatically adjusts (based on the video input signal from the camera). For optimal performance the Brightness Display LED (3) should be set between 30 -70%.

Place the Shutter Switch (6) to the "On" position to select the AUTO mode. The word "Shutter" and the Shutter symbol will illuminate.

To increase brightness, slide the Brightness Control (4) to the right. Slide the Brightness Control (4) to the left to decrease brightness.

AUTO SHUTTER OFF

When the Auto Shutter is "Off", the light intensity does not automatically adjust, but can be manually adjusted to be in a stationary position. Place the Shutter Switch (6) to the "Off" position to manually adjust brightness.

To increase brightness, slide the Brightness Control Slide Bar (4) to the right until the desired brightness level is achieved. The light source is at the maximum intensity when the brightness display LED (3) reads 100%. The light source is at the minimum intensity when the brightness display LED (3) reads 00%.

CAUTION

Always adjust the light source to the minimum illumination necessary to achieve optimum illumination of the endoscopic scene. Please be aware of the heat energy generated at the distal tip of the endo scope. The higher the intensity setting on the light source, the more heat energy that will be generated at the endoscope tip.

STANDBY

WARNING



To prevent possible ignition of flammable materials, place the light source in STANDBY mode whenever the endoscope is removed from a non-ESST fiber optic cable.

When using an ESST fiber optic cable, the unit will automatically go to STANDBY when the endoscope is removed from the light cable.

Press the STANDBY button (5) to reduce the light intensity to the minimum setting. The word STANDBY and the STANDBY symbol will illuminate.

Press this button a second time to return to the previous mode of operation.

HERMES

There is one interface connection on the rear panel for the Hermes Operating Room Control Center. The Light Source must be Hermes Ready (indicated by sticker, figure 3) in order to work with Hermes System. For more information about using the Hermes System, refer to the Hermes Operating Room Control Center User Manual).

Figure 3



INTERCONNECT SECTION

Described in this section is a sample system. The numbers next to each connection refer to the step in the accompanying instructions.

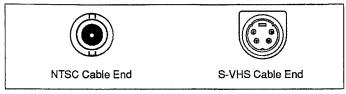
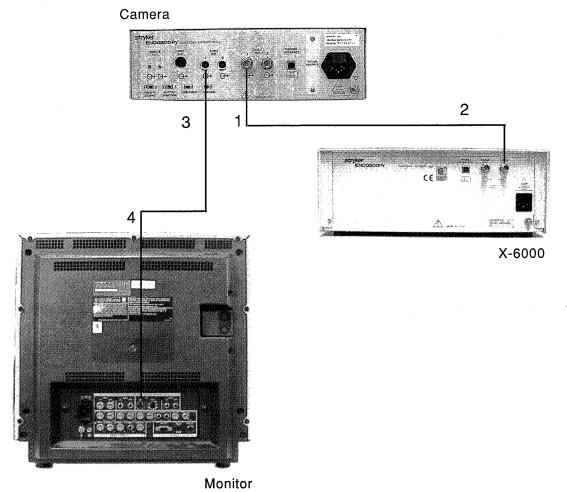


Figure 4

Two types of cables are used in wiring video systems, NTSC cables which have a BNC connector, and S-VHS cables which have a 4 pin Mini-Din connector (See Figure 4). BNC connectors are push and turn type connectors while S-VHS cables are push only type connectors. On some monitors, S-VHS inputs may be labeled Y/C. S-VHS and Y/C describe the same input.



SAMPLE SYSTEM

Equipment Used: Camera, Light Source and Monitor

- 1. Connect a NTSC cable to the VIDEO 1 OUT (1) on the rear panel of the camera.
- Connect the other end of this cable to the VIDEO IN (2) on the light source.
- 3. Connect a S-VHS cable to the S-VHS Out 1 on the rear panel of the camera.
- 4. Connect the other end of the S-VHS cable to the Y/C input on the rear of the monitor.

CARING FOR YOUR X-6000

LAMP CARE

The X-6000 uses a Xenon Cermax lamp. The lamp life is approximately 500 hours with proper usage. To maximize life follow these guidelines:

- 1. If the lamp face is touched, even slightly, clean it with a cotton swab and alcohol.
- Do not turn the lamp on, off, then back on again.
 The lamp should be allowed to run for at least five
 minutes once turned on. Failure to do so can
 cause the lamp to rapidly darken and fail.
- 3. The X-6000 has been designed to start the lamp under most conditions, even when it is hot. However, if the lamp does not start within 10 seconds, turn the X-6000 off and wait at least five minutes for the lamp to cool before restarting. Further attempts to start the lamp can damage the lamp and possibly the internal circuitry.

REPLACING THE LAMP MODULE



Replace with Stryker part number 220-185-300 only.

You should replace the lamp module when the Hour Meter indicates 500 hours or when light output from the lamp no longer allows sufficient illumination of the surgical site.

If possible, you should replace the lamp module between surgical procedures. On occasion, a lamp near 500 hours of accumulated operation will extinguish.

NOTES

- 1. Do not operate the X-6000 with a burned out lamp or with no lamp installed.
- 2. Using a non-Stryker replacement bulb module may result in unreliable and inadequate light ouput. Light levels may vary significantly.

WARNING



During operation the lamp and the housing around the lamp may be hot. Do not change the lamp until it cools.

WARNING



Ensure all power is removed from the unit prior to changing the lamp module.

- a. Turn off the unit and unplug it from the power source.
- b. Slide the lamp door latch on the side of the unit toward the rear of the unit and pull out on the door (see figure 5).

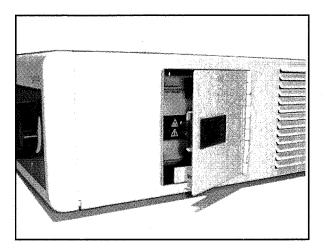


Figure 5

- c. Grasp the lamp module by the handle and remove the lamp (see figure 6).
- d. Slide in the new lamp module until it is fully seated on the mating connectors.
- e. Plug the power cord into the light source and turn the unit on.

NOTE: The unit must be on in order to reset the Hour Meter.

- f. Reset the lamp HOUR METER by pressing the RESET HOURS switch located near the lamp door (see figure 7).
- g. Close and latch the lamp door.

NOTE Always reset the HOUR METER after replacing the lamp.

DISPOSAL OF THE PRODUCT

The device must be disposed of according to local laws and hospital practices. The device does not contain any hazardous materials.

ELECTROMAGNETIC INTERFERENCE

The X-6000 Xenon Light Source has been designed and tested to comply with EN 60601-1-2:1993 requirements for electromagnetic compatibility with other devices. If interference is experienced, attempt to reposition video cables away from the Light Source, or isolate the power cord of the Light Source from other devices. If interference persists, send the unit to Stryker Endoscopy for repair.

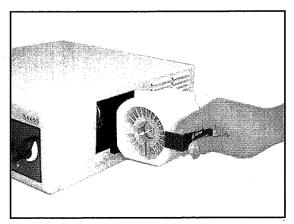


Figure 6

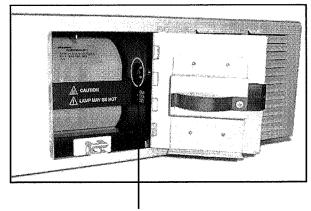


Figure 7

TROUBLESHOOTING

NO LIGHT OUTPUT

- Check the power cord to ensure it is plugged into the AC inlet (9) on the back of the unit and that the power cord is also plugged into a power source.
- Check that the front panel POWER switch (1) is switched "ON."
- Check the fuse compartment (12) on the back of the unit to ensure that all fuses are operating. See MAINTENANCE FUSE REPLACEMENT INSTRUCTIONS.
- Check the lamp housing to make sure a lamp is properly seated in the lamp housing.
- Check the lamp to ensure it is in operating condition. Replace if necessary.
- Check to see that a fiber optic light cable is seated correctly in the CABLE port.
 As a safety feature, the X-6000 will provide no light output unless a fiber optic light cable is seated in the CABLE port.
- · Ensure bulb access door is completely shut.

TOO MUCH ORTOO LITTLE LIGHT OUTPUT

- Check for proper seating of the fiber optic cable in the CABLE port.
- Check the HOUR METER display for adequate remaining lamp life.
- Check the light source intensity mode; If in STANDBY mode, depress the standby button.
- If the unit remains in STANDBY, check the following:
 - 1) Verify there is a light cable installed;
 - 2) If an ESST cable is connected, verify that a scope is attached to the light cable using an ESST scope adapter.
- If the Auto Shutter is "On", increase or decrease the intensity. See ADJUSTING BRIGHTNESS.
- If the Auto Shutter is "Off", increase or decrease the intensity. See ADJUSTING BRIGHTNESS.
- Check the fiber optic cable for adequate light transmission. Hold light source end
 up to an overhead room light and observe the scope end of the light cable. If the
 pattern contains any black spots, the light cable may be worn out and require
 replacement.
- Check the light cable for adequate size. Its diameter may be too small to provide adequate light transmission for the medical video camera in the endoscopic application.

EXCESSIVE GLARE IN THE VIDEO

Check the light source connection to the Stryker Endoscopy medical video camera.

The VIDEO OUT from the camera should connect to the VIDEO IN (10) on the back of the light source.

NOTE

Stryker Endoscopy has designed the AUTO SHUTTER feature of the X-6000 for use only with Stryker Endoscopy medical video cameras. The AUTO mode may provide inadequate or no automatic adjustment of light levels in the surgical site when connected to non-Stryker Endoscopy medical video cameras.

 Check the brightness control to make sure the Auto Shutter is "On". See ADJUSTING BRIGHTNESS. If the Auto Shutter is "Off", decrease the light intensity. See ADJUSTING BRIGHTNESS.

TOO MUCH RED COLOR IN THE VIDEO

- Ensure monitor and printer settings are correct.
- Some video cameras may require alignment for optimum performance with xenon light. Contact your local sales representative for more information.