

stryker®

X8000 Light Source

REF 220-200-000



Rx ONLY

X8000 Light Source

User Guide

Contents

Warnings and Cautions	2
Symbol Definitions	4
Product Description and Intended Use	5
Setup and Assembly	8
Connecting the AC Power Cable	8
Connecting the Light Cable	8
System Operation	10
Powering the System On and Off	10
Selecting the Operation Mode	11
Adjusting the Brightness	11
Visual Display	12
Language Selection	13
Safety Shutoff	13
Checking the ESST Feature	14
Using the X8000 with a Voice-Controlled System Interface	15
Using the SFB Serial Interface	15
Troubleshooting	16
Cleaning and Maintenance	18
Cleaning the X8000	18
Caring for the Bulb Module	18
Replacing the Bulb Module	18
Replacing the Fuses	20
Disposing of the X8000	20
Technical Specifications	21
Electromagnetic Compatibility	22
Warranty	26
Service and Claims	27

Warnings and Cautions

Please read this manual and follow its instructions carefully. Certain symbols and the words warning, caution, and note carry special meanings and should be carefully reviewed:

WARNING



THE PERSONAL SAFETY OF THE PATIENT OR USER MAY BE INVOLVED. DISREGARDING THIS INFORMATION COULD RESULT IN SERIOUS INJURY TO THE PATIENT OR USER.

Caution

Special 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 manual.



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

WARNING



IMPORTANT SAFETY NOTICE: BEFORE OPERATING THIS DEVICE, PLEASE READ THIS OPERATING MANUAL THOROUGHLY AND CAREFULLY. WHEN USING THIS DEVICE WITH 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, INCLUDING THE X8000, 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. ADJUST THE BRIGHTNESS LEVEL OF THE LIGHT SOURCE 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 WHENEVER 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.

WARNING



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

1. Read this operating manual thoroughly, especially the warnings, and be familiar with its contents prior to using this equipment.
2. Carefully unpack the unit and check if any damage occurred during shipment. If damage is detected, please refer to the “Service and Claims” section in this manual.
3. Be a qualified physician, having complete knowledge of the use of this equipment.
4. Test this equipment prior to a surgical procedure. This unit was fully tested at the factory before shipment.
5. Attempt no internal repairs or adjustments that are not specifically detailed in the Troubleshooting, Cleaning and Maintenance sections of this operating manual.
6. Never sterilize any part of the X8000 console.
7. Disconnect the X8000 from the electrical outlet when inspecting the fuses.
8. No modification of this equipment is allowed.
9. To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth ground.
10. Do not position the console so that it is difficult to disconnect the power cord from the supply mains.
11. Never use this equipment in the presence of flammable or explosive gases.

The warranty is void if any of these warnings or cautions contained in this manual are disregarded. The user must also be ensure that:

- 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 requirements.

WARNING



FEDERAL LAW (UNITED STATES OF AMERICA) RESTRICTS THIS DEVICE TO USE BY, OR ON ORDER OF, A PHYSICIAN.

Symbol Definitions



Type CF Applied Part



Protective Earth Ground



Equipotentiality



Denotes compliance to CSA 22.2 No.601.1-M90 and UL60601-1.



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



Caution: Surface may be hot



The user must read the provided instructions to safely operate the device. Disregarding the information could result in serious injury to the patient or user.



Consult instructions for use



Caution (consult instructions for use)



Power on/off (alternates when button is pushed)



Alternating current



Device recycling code (applicable in China)



Relative humidity limitation



Temperature limitation



Pressure limitation



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



Product catalog number



Product serial number



Date of manufacture



Legal manufacturer



Fuse rating

Product Description and Intended Use

The Stryker X8000 Light Source is a light-generating unit designed to illuminate surgical sites during endoscopic applications. The X8000 uses a 300-watt xenon bulb to generate bright, crisp light, which it delivers to the surgical site via a fiberoptic light cable. The X8000 is compatible with all Stryker light cables, and, with the proper light cable and adapters, can connect to any flexible or rigid endoscope.

The X8000 is equipped with Electronic Scope Sensing Technology (ESST), a special safety feature that helps prevent accidental burns caused by a light cable that is not connected to the scope. For more information, refer to the section “Checking the ESST Feature”. When operated with an ESST light cable, the X8000 senses when the scope and the light cable are separated and places the light source in Standby mode. In Standby mode, the X8000 will reduce light output to a minimum, preventing the light cable from generating excessive heat.

WARNING



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 AN INANIMATE OBJECT IF NOT USED PROPERLY. DO NOT PLACE THE SCOPE OR THE LIGHT CABLE ON THE PATIENT OR ON THE DRAPES OR OTHER FLAMMABLE MATERIAL, EVEN WHEN THE DEVICE IS IN STANDBY MODE.

The Stryker X8000 Light Source consists of one of each of the following:

- light source console
- power cord
- xenon bulb module (spare or replacement bulb modules can be purchased separately as P/N 220-201-000)

The features of the X8000 console are described below (see Figures 1 and 2).

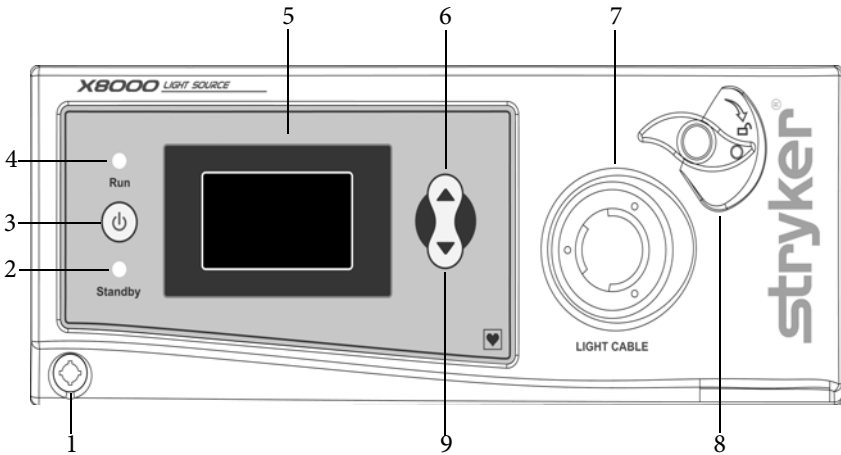


Figure 1 Front panel of the X8000 console

1. **Power Button:** Powers the unit on and off.
2. **Standby LED:** Illuminates when the unit is operating in the Standby mode. In Standby mode, light output is reduced to a minimum level.
3. **Mode Button:** Selects either Standby or Run mode when pressed. Standby is the default mode when the light source is powered on.
4. **Run LED:** Illuminates when the unit is operating in the Run mode. In Run mode, light output is determined by the up and down switches.
5. **LCD:** Indicates the light intensity level (0-100%), bulb hours and language.

6. **Up Button:** Increases light intensity in Run mode.
7. **Cable Clamp:** Grasps the light-source end of an inserted fiberoptic cable. (When no cable is inserted, the bulb automatically turns off to save bulb hours.)
8. **Jaw Handle:** Opens the fiberoptic-cable holder.
9. **Down Button:** Decreases light intensity in Run mode.

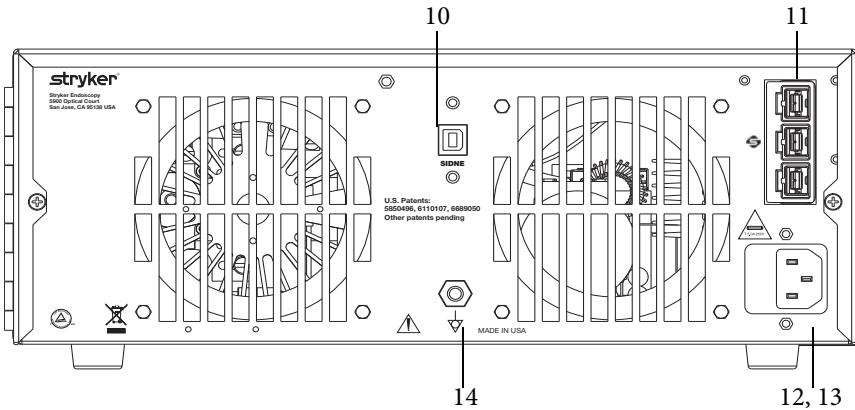


Figure 2 Rear panel of the X8000 console

10. **Voice-Control Port:** Connects to Stryker voice-control systems.
11. **SFB Series Connectors:** Enables FireWire connection with Stryker FireWire devices. Provides connection for remote diagnoses and future software upgrades.
12. **AC Inlet:** Connects to the provided power cord for AC power supply.
13. **Fuse Holder:** Contains two T 5.0 AH 250 V fuses.
14. **Equipotentiality Plug:** Provides a grounding post for common grounding with other equipment. Connects to a potential equalization conductor. The resulting medical electrical system shall follow all applicable IEC 60601-1 requirements.

Setup and Assembly

Note Your local Stryker Endoscopy sales representative will perform inservice training at your convenience to instruct you and your staff on the safe and effective operation and maintenance of the X8000, and to help set up the equipment. Please contact your local Stryker Endoscopy sales representative to schedule an inservice after the equipment has arrived.

Note When selecting a setup location for the X8000, consult the “Electromagnetic Compatibility” section included in this manual to determine the best location.

To set up the X8000, make the following connections:

- Connect the AC power cable
- Connect the light cable

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.

WARNING



WHEN THE X8000 IS INTERCONNECTED WITH OTHER MEDICAL ELECTRICAL 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 ALL SYSTEMS ARE INSTALLED ACCORDING TO THE REQUIREMENTS OF IEC 60601-1-1.

Connecting the Light Cable

WARNING



USE ONLY NONCONDUCTIVE FIBEROPTIC CABLES WITH THE X8000 TO MAINTAIN ELECTRICAL ISOLATION.

Note

The X8000 Light Source is compatible with all Stryker Light Cables.

1. Lock open the cable clamp by turning the jaw handle clockwise until it stops (see Figure 3).



Figure 3 Locking open the cable clamp

WARNING



KEEP FINGERS AWAY FROM THE CABLE CLAMP AS THE CLAMP MAY INADVERTENTLY DEPLOY AND CAUSE INJURY.

WARNING



DO NOT LOOK DIRECTLY INTO THE CABLE PORT. THE HIGH-INTENSITY LIGHT MAY CAUSE DAMAGE TO THE EYES.

2. Insert a clean, dry fiberoptic cable into the cable port until the jaw latch releases and the jaw clamps the cable in place (see Figure 4). Pull gently on the fiberoptic cable to test that it is securely seated in the cable port.



Figure 4 Inserting the light cable into the cable port

3. Connect an endoscope to the opposite end of the fiberoptic cable.

4. To remove the light cable, press the Mode button to put the unit into Standby mode. Then turn the jaw handle clockwise until it latches fully open.

WARNING



IF THE LIGHT SOURCE IS NOT IN STANDBY MODE PRIOR TO REMOVING THE CABLE, THE HIGH INTENSITY LIGHT WILL SHINE DIRECTLY OUT OF THE LIGHT SOURCE BRIEFLY BEFORE TURNING OFF, POSSIBLY CAUSING INJURY TO THE USER'S EYES.

Note

The Light Source will default to Standby mode when a light cable is inserted.

System Operation

Note

Before operating the X8000, see the “Setup and Assembly” section of this manual.

Powering the System On and Off

Caution

Do not power the system on and off in rapid succession. Allow the bulb to run for at least five minutes once it has been powered on, before turning the power off. Failure to do so can cause the bulb to rapidly darken and fail.

To power on the X8000:

1. Confirm that the X8000 contains a properly installed bulb. The bulb handle must be turned all the way to the left, to ensure proper latching. If no bulb is installed, follow the instructions in the “Replacing the Bulb” section of this manual before proceeding.
2. Press the power switch on the front panel. The Standby LED will illuminate, indicating the unit is in Standby mode.

Note

The bulb will not illuminate unless a light cable is installed in the cable port.

To power off the X8000:

1. Put the light source unit into Standby mode.
2. Disconnect the light cable from the X8000 console.
3. Run the fan for at least one minute to cool the unit.
4. Press the power switch on the front panel of the X8000.

WARNING



TO ALLOW FOR ADEQUATE COOLING, NEVER BLOCK THE REAR OR SIDE FAN VENTS. FAILURE TO FOLLOW THIS INSTRUCTION MAY RESULT IN DAMAGE TO THE X8000 OR A POSSIBLE FIRE.

Selecting the Operation Mode

The X8000 has two operation modes, Run and Standby.

- **RUN mode:** The Run mode is used during normal operation. It enables light output to be controlled by the brightness controls on the front console panel.
- **STANDBY mode:** The Standby mode is used when the X8000 is powered on, but not in use. It reduces the light output to a minimum, thereby reducing the heat generated at the tip of the light cable or scope when the X8000 is not being used.

To select either the Run or Standby mode, press the Mode Button. The LED for the selected mode will illuminate.

WARNING



TO HELP PREVENT BURNS TO THE PATIENT, USER OR INANIMATE OBJECTS AND POSSIBLE FIRE, ALWAYS PUT THE **X8000** 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**.

Adjusting the Brightness

The X8000 has up and down buttons for adjusting the bulb brightness.

Press the up arrow to increase brightness, and press the down arrow to decrease brightness. The selection will appear on the LCD as a percentage between 0 and 100.

When in Standby mode, the previous Run mode brightness level appears in the upper right-hand corner. The Run mode brightness level can be reset while still in Standby mode, by pressing the up and down buttons.

WARNING



THE HIGHER THE BRIGHTNESS, THE MORE HEAT ENERGY THAT WILL BE GENERATED IN THE SCOPE AND THE TIP OF THE CABLE. ALWAYS ADJUST THE BRIGHTNESS LEVEL OF THE CAMERA AND THE MONITOR BEFORE ADJUSTING THE BRIGHTNESS LEVEL OF THE LIGHT SOURCE. ADJUST THE BRIGHTNESS LEVEL OF THE LIGHT SOURCE TO THE MINIMUM BRIGHTNESS NECESSARY TO ILLUMINATE THE SURGICAL SITE. FAILURE TO FOLLOW THIS

INSTRUCTION COULD RESULT IN FIRE OR BURNS TO THE PATIENT, USER OR AN INANIMATE OBJECT. IN ADDITION, ADJUST THE INTERNAL SHUTTER OF THE CAMERA HIGHER IN ORDER TO RUN THE LIGHT SOURCE AT A LOWER INTENSITY.

WARNING



THE SURFACE TEMPERATURE NEAR THE SCOPE ADAPTER AND AT THE TIP OF THE SCOPE MAY EXCEED 41°C IF THE UNIT IS OPERATED AT HIGH LEVELS OF BRIGHTNESS FOR EXTENDED PERIODS OF TIME. THE HEATED SCOPE AND ADAPTER MAY CAUSE BURNS TO THE PATIENT, USER OR AN INANIMATE OBJECT.

Visual Display

The X8000 provides feedback through the LCD.

- **Brightness:** The LCD display shows the intensity level of the light as a percentage between 0 and 100. For example, if the LCD shows “70,” the light output to the fiberoptic cable is running at 70 percent of capacity.
- **Bulb Hours:** The LCD display shows how many total hours the bulb has operated. For example, if the LCD shows “250,” the bulb has operated 250 total hours. The bulb hours will flash after 500 hours, and the LCD will display “Replace Bulb” after 1000 hours.
- The LCD also displays warning and error codes. The table below lists and defines the warning and error codes displayed.

Code	Definition	Recommended Action
E-1	All conditions are met for the bulb to illuminate, yet it remains off.	Return the X8000 for repair.
E-2	All conditions are not met for the bulb to illuminate, yet it remains on.	Return the X8000 for repair.
E-3	The bulb has higher than expected current or voltage applied to it.	Return the X8000 for repair.
E-4	The bulb is kept off because the ballast fan is not working properly.	Return the X8000 for repair.
E-5	The bulb is kept off because the bulb fan is not working properly.	Return the X8000 for repair.
Blinking 500	The bulb has exceeded its recommended lifetime of 500 hours.	Install a new Stryker bulb.

Code	Definition	Recommended Action
Replace Bulb	The bulb has reached 1000 hours and has exceeded its recommended lifetime of 500 hours.	Install a new Stryker bulb.

Language Selection

The X8000 LCD has the capability of displaying text in the following languages:

Danish	German	Polish
Dutch	Greek	Portuguese
English	Italian	Simplified Chinese
Finnish	Japanese	Spanish
French	Korean	Swedish

To select a particular language, perform the following steps:

1. Hold down the Up and Down buttons until the current language identifier appears.
2. Use Mode button to scroll through the available languages.
3. Hold down the Up and Down buttons (until the light source resumes normal operation) to lock in the selected language.

Safety Shutoff

The X8000 Light Source is equipped with a Safety Shutoff feature which will temporarily turn off the bulb in the event of excessive heat in the bulb assembly.

WARNING



ONCE THE LIGHT SOURCE COOLS DOWN (AFTER 7-10 MINUTES), POWER WILL RESUME TO THE BULB AND THE UNIT WILL RESTART IN STANDBY MODE. TO PREVENT FIRES AND ACCIDENTAL BURNS TO THE PATIENT, USER OR INANIMATE OBJECTS, ALWAYS PLACE THE SCOPES AND/OR FIBEROPTIC CABLES IN A SAFE PLACE, AND NOT ON THE PATIENT, DRAPES, OR OTHER FLAMMABLE MATERIAL, TO ENSURE SAFE RESUMPTION OF LIGHT OUTPUT. IF THE X8000 LIGHT SOURCE EXPERIENCES A TEMPORARY SHUTDOWN, IT IS RECOMMENDED THAT THE DEVICE BE RETURNED FOR SERVICE.

Caution

Do not abruptly interrupt power to the unit. This will turn off the fan and may cause severe damage to the internal cooling system.

Checking the ESST Feature

The X8000 is equipped with Electronic Scope Sensing Technology (ESST), a special safety feature that helps prevent accidental fires or burns to the patient or user caused by a light cable not connected to a scope. This feature will only work if the X8000 is used with an ESST light cable. When operated with an ESST light cable, the X8000 senses when the scope and light cable are separated, and places the light source in Standby mode. In Standby mode, the X8000 will reduce light output to a minimum, preventing the light cable from generating excessive heat.

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

1. Set up the X8000 system with an ESST light cable and scope, and then power on the system.
2. Place the X8000 in Run mode.
3. Remove the light cable from the ESST scope adapter.

The X8000 should return to Standby mode, indicating that the ESST feature is functioning properly.

WARNING



ALWAYS CHECK TO ENSURE THAT THE UNIT HAS SWITCHED INTO STANDBY MODE, BEFORE ASSUMING ESST SAFETY PROTECTION. IF THE UNIT FAILS TO RETURN TO STANDBY MODE, THERE MAY BE A FAULT WITH THE ESST FEATURE. IN THIS CASE, DO NOT ASSUME ESST SAFETY PROTECTION, AND RETURN THE UNIT FOR SERVICE.

WARNING



EVEN WITH ESST PROTECTION, OR WHEN THE X8000 IS IN STANDBY MODE, NEVER PLACE THE TIP OF THE LIGHT CABLE OR LIGHT CABLE ADAPTER DIRECTLY ON THE PATIENT, DRAPES OR OTHER FLAMMABLE MATERIAL, AS BURNS OR FIRE MAY RESULT. 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 AN INANIMATE OBJECT 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.

Using the X8000 with a Voice-Controlled System Interface

The X8000 can be used in conjunction with Stryker voice-control systems (SIDNE®). For more information about using the X8000 with Stryker voice-control systems, refer to the SIDNE® *Operating and Maintenance Manual* (P/N 1000-400-653).

Using the SFB Serial Interface

The SFB serial connection on the rear panel of the X8000 enables FireWire connection to the Stryker Endoscopy Software Management site. Connecting to this site enables remote diagnostics and software updates.

- Note This system feature is not necessary for regular light-source operation.
- Note This system feature requires an additional device (i.e., a computer) to connect to the Software Management site.

Troubleshooting

Problem	Possible Solution
No light output	<ul style="list-style-type: none">• 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 bulb is properly seated in the bulb housing. The bulb handle should be turned all the way to the left within the light source.• Ensure the bulb is in operating condition. Replace the bulb if necessary.• Ensure the light cable is correctly engaged with the cable port. As a safety feature, the X8000 will provide no light output unless a fiberoptic light cable is properly seated in the cable port.• Ensure the bulb access door is completely shut.• Check for error codes E-1, E-2, E-3, E-4 or E-5. See the “Visual Display” section of this manual for details.• Check that vents are not obstructed.• If the safety shutoff has been activated, please return the X8000 for service. Please see the section entitled “Safety Shutoff” in this manual for additional information.

<p>Too much or too little light output</p>	<ul style="list-style-type: none"> • Ensure the light cable is correctly engaged with the cable port. • Ensure the bulb has adequate bulb life remaining. The bulb has a warranty of 500 hours. • Ensure the X8000 is in Run mode. (The Run LED should be illuminated.) If necessary, press the Mode button to switch from Standby to Run. If the unit remains in Standby: <ol style="list-style-type: none"> 1. Ensure the light cable is correctly engaged with the cable port. 2. If an ESST cable is connected to the X8000, ensure the cable is attached to the scope using an ESST scope adapter. • Use the up/down buttons to adjust the brightness. For details, see the “Adjusting the Brightness” section in this manual. • Ensure the fiberoptic cable is transmitting light properly. Hold the light-source end of the cable up to an overhead room light and look into the scope end of the light cable. If the pattern contains any black spots, the light cable may be worn out and may require replacement. • Ensure the light cable is of an adequate size for the application. The cable diameter may be too small to provide adequate light transmission for the medical video camera in the endoscopic application.
<p>Excessive glare in the video</p>	<ul style="list-style-type: none"> • Ensure the electronic shutter on the camera is operating properly to control the video signal brightness. If further light reduction is required, decrease the light source brightness with the down button.

Cleaning and Maintenance

Cleaning the X8000

WARNING UNPLUG THE X8000 BEFORE CLEANING THE UNIT.



1. Clean the external surfaces of the X8000 using a cloth or sponge dampened with a mild detergent or disinfectant.
2. Clean and maintain the light cable according to the manufacturer's instructions.

Caution Do not use any abrasive cleaners. Do not allow any liquid to drip into the unit.

Caution Do not sterilize or immerse the X8000.

Caring for the Bulb Module

The X8000 uses a Xenon bulb, which has a guaranteed life of 500 hours when used properly. Always follow these guidelines to ensure maximum bulb life:

1. Clean the bulb face with alcohol and a cotton swab if it is touched. Dirt or oil on the bulb face will cause the bulb to heat unevenly and fail.
2. Do not power on and off the bulb in rapid succession. Allow the bulb to run for at least five minutes once it has been powered on. Failure to do so can cause the bulb to rapidly darken and fail.
3. The X8000 has been designed to start the bulb under most conditions, even when it is hot. However, if the bulb does not start within 10 seconds after the X8000 has powered on, turn the unit off and wait at least five minutes for the bulb to cool before restarting. Further attempts to start the bulb can damage the bulb and possibly the internal circuitry.

Replacing the Bulb Module

Replace the bulb module when the LCD indicates 500 hours or when the bulb no longer sufficiently illuminates the surgical site. If possible, replace the bulb module between surgical procedures.

WARNING DURING OPERATION, THE BULB AND THE HOUSING AROUND THE BULB MAY BE HOT. WAIT AT LEAST THREE MINUTES FOR THE BULB TO COOL BEFORE HANDLING IT.



To replace the bulb module:

1. Power down the X8000.
2. Open the bulb door (Figure 5).



Figure 5 Opening the bulb door

Note If the unit is on, opening the bulb door will turn off the bulb.

3. Rotate the handle to the right, grasp the bulb module by the handle, and remove the bulb (Figure 6).



Figure 6 Removing the bulb module

WARNING



DO NOT REACH INSIDE THE BULB DOOR FOR ANY REASON OTHER THAN REPLACING THE BULB MODULE. TOUCHING PARTS OTHER THAN THE BULB MODULE MAY CAUSE BURNS OR PRODUCT DAMAGE.

WARNING



DO NOT TOUCH ANY PART OF THE BULB MODULE EXCEPT FOR THE HANDLE. THE MODULE MAY BE VERY HOT AND CAUSE BURNS.

4. Insert the new bulb module (Stryker part number 220-201-000) along the guide rails until it is fully seated on the mating connectors.
5. Rotate the handle to the left to secure the bulb module within the light source.
6. Close and latch the bulb door.
7. Power on the unit.
8. Power on the bulb (if not already on) and verify that the LCD displays the bulb hours as “0”.

Note Using a non-Stryker replacement bulb module will result in no light output.

Caution **Do not operate the X8000 with a burned-out bulb or with no bulb installed.**

Replacing the Fuses

1. Unplug the light source from the AC outlet and remove the power cord from the rear of the unit.
2. Unlatch the fuse holder and remove the fuse(s).
3. Replace the fuse(s) with fuses of the same value and rating.

WARNING **TO HELP AVOID THE RISK OF FIRE, USE ONLY FUSES RATED AS SPECIFIED ON THE CONSOLE.**



4. Reinstall the fuse holder.

Disposing of the X8000

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

This product is considered electronic equipment. It must not be disposed of as unsorted municipal waste and must be collected separately. Please contact the manufacturer or other authorized disposal company to decommission your equipment.

Technical Specifications

Electrical

Primary:	100 - 120 VAC, 50/60 Hz, 450 W 220 - 240VAC, 50/60 Hz, 450W
Fuses (2):	T 5.0 AH 250 V

Dimensions

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)

Fiberoptic Cable Range:

2 mm to 6.5 mm diameter

Bulb

Type:	300 Watt Xenon (Elliptical)
Life:	Approximately 500 hours

Operating Conditions

10 to 40°C
30 to 75% Relative Humidity
700hPa to 1060hPa

Transportation & Storage

-20 to 50°C
10% to 75% Relative Humidity
700hPa to 1060hPa

Classifications

Class 1 Equipment
Type CF applied parts
Water Ingress Protection, IPX0 — Ordinary Equipment
Continuous Operation

Electromagnetic Compatibility

Like other electrical medical equipment, the X8000 requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC), the X8000 must be installed and operated according to the EMC information provided in this manual.

Note The X8000 has been designed and tested to comply with IEC 60601-1-2 requirements for EMC with other devices.

Caution **Portable equipment may affect the normal function of the X8000.**

WARNING



DO NOT USE CABLES OR ACCESSORIES OTHER THAN THOSE PROVIDED WITH THE X8000, AS THIS MAY RESULT IN INCREASED ELECTROMAGNETIC EMISSIONS OR DECREASED IMMUNITY TO SUCH EMISSIONS.

WARNING



IF THE X8000 IS USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT, OBSERVE AND VERIFY NORMAL OPERATION OF THE X8000 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 X8000.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions		
X8000 is intended for use in the electromagnetic environment specified below. The customer or the user of X8000 should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment - guidance
RF emissions CISPR 11	Class B	X8000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage Fluctuations/ flicker emissions IEC61000-3-3	Complies	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

X8000 is intended for use in the electromagnetic environment specified below. The customer or the user of X8000 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	±2,4,6kV contact ±2,4,8kV 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 line to line	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV differential mode ±2kV common mode	±0.5, 1kV differential mode ±0.5, 1, 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 X8000 requires continued operation during power mains interruptions, it is recommended that X8000 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	N/A	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

X8000 is intended for use in the electromagnetic environment specified below. The customer or the user of X8000 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	<p>Portable and mobile RF communications equipment should be used no closer to any part of the X8000 system, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p align="center">Recommended Separation Distance</p> $d = 1.17 \sqrt{P}$

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.

- (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 X8000 system is used exceeds the applicable RF compliance level above, the X8000 system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the X8000 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 X8000 System

The X8000 system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the X8000 system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the X8000 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 $d = 1.17\sqrt{P}$	80 MHz 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.

Warranty

Stryker Endoscopy warrants the X8000 Light Source against defects in both materials and workmanship to the registered owner at the time of purchase. All components except the bulb are covered by the warranty for a period of one year from the date of purchase. The bulb module is covered by the warranty for a period of 60 days from the date of purchase.

This warranty does not apply to any unit that has been subject to misuse, abuse, neglect, improper installation or operation, or that has been altered, adjusted, or tampered with by any person other than Stryker Endoscopy authorized service personnel.

The customer is responsible for returning the defective equipment to the factory at his or her own expense. Stryker Endoscopy or its representative will service the unit, repair or replace any defective parts thereof, and return the unit to the customer.

If, upon examination, it is determined that the fault has been caused by misuse or abnormal conditions of operation, the repairs will be billed to the customer in the same manner as out-of-warranty repairs.

Instruments repaired by Stryker Endoscopy will be issued a thirty-day warranty against defects in both materials and workmanship, provided the original warranty period has passed. Instruments submitted due to defects in materials and workmanship during the warranty period will be repaired at no charge to the customer.

The warranty as set forth herein is exclusive and in lieu of all other warranties, remedies, obligations, and liabilities of Stryker Endoscopy Inc., expressed or implied, including the implied warranties of merchantability and fitness for use and of consequential damages. These products are sold only for the purpose described herein, and such warranty runs only to the purchaser. In no event shall Stryker Endoscopy be liable for any breach of warranty in any amount exceeding the purchase price of the product.

No agent, employee, or representative of Stryker Endoscopy has the authority to bind the Company to any other warranty, affirmation, or representation concerning this instrument.

This warranty is valid only to the original purchaser of Stryker Endoscopy products obtained directly from Stryker Endoscopy or from a Stryker Endoscopy authorized agent. The warranty cannot be transferred or assigned by the original purchaser.

The X8000 Light Source warranty is void if any WARNINGS, CAUTIONS, or NOTES are disregarded.

Service and Claims

This equipment is carefully packaged to prevent damage during transit and is shipped freight outbound (F.O.B.) from San Jose, CA. Therefore, Stryker's responsibility for ensuring damage-free delivery totalled ends upon remission of the equipment to the carrier. Examine the shipment promptly upon receipt.

If the product packaging appears damaged at the time of delivery, immediately check the device for damage. If there is a malfunction, return the device to the distributor.

To return equipment damaged during shipment:

1. File a claim with both the carrier and the distributor.
2. Repack the equipment in its original shipping container and ship it prepaid and insured to:

Stryker Endoscopy
Customer Service Department
5900 Optical Court
San Jose, CA 95138
USA

If service is needed either during or after the warranty period:

1. Contact Stryker Endoscopy at 1-800-624-4422 or phone your local Stryker Endoscopy sales representative.
2. Package all the components carefully in the original shipping container if possible.
3. Ship the light source, prepaid and insured to:

Stryker Endoscopy Customer Service
Attention: Repair Department
5900 Optical Court
San Jose, CA 95138
USA

Note To maximize the longevity, performance, and safety of this device, package it in the original shipping container when storing or transporting.

Note The light source described in this manual is continually reviewed, and improvements may be made without notice. A replacement part may not appear the same as the original, but all parts with the same part number will be completely interchangeable.

stryker®



Stryker Endoscopy
5900 Optical Court
San Jose, CA 95138 USA
1-408-754-2000, 1-800-624-4422
www.stryker.com

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