STERIS®

HarmonyAIR® G-Series (Gen 2)

Surgical Lighting System

Operator Manual

en
11028645
Revision E

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A Word from STERIS

1.1 Introduction

This manual contains important information on proper use and care of this surgical lighting system. All operators and department heads are urged to carefully review and become familiar with the warnings, cautions and instructions contained herein. Your new surgical lighting fixture features an advanced, state-of-the-art design, with cool, shadow-reduced light and ease of maneuverability. It produces light of a quality necessary for the most demanding and complex of surgical procedures.

A thorough preventive maintenance program is essential for safe and proper operation of your surgical light. You are encouraged to contact STERIS concerning annual maintenance agreements. Under the terms of this agreement, preventive maintenance, adjustments and replacement of worn parts are done on a scheduled basis to verify lighting fixture performance according to its specifications and to help avoid untimely or costly downtime. STERIS maintains a nationwide staff of well-equipped, factory-trained technicians to provide this service, as well as expert repair services. Contact STERIS for details.

1.2 Indications for Use

The surgical lighting system is a fixed or variable pattern, variable intensity surgical lighting fixture designed to provide visible illumination of the surgical field or the patient for the operating room staff.

1.3 Advisory

The following is an important message from STERIS about the advantages and limitations associated with the use of high intensity surgical lighting systems.

Because of the variety of surgical procedures performed and the wide range of individual preferences of surgical staffs, it is desirable that a surgical lighting system be capable of selective control across a wide range of illumination intensities. The Illuminating Engineering Society (IES) stresses that in addition to providing control of intensity, surgical lighting systems should provide shadow control, correct color rendition, and a suitable depth of field to provide sharp, consistent lighting into deep body cavities. As illumination levels increase, however, radiant heat also increases. Therefore, the IES cautions that for most operations, radiant heat should be kept to a minimum. The user of surgical lights should utilize the lowest possible illumination level suitable for the procedure, especially in certain neurological or intestinal procedures on delicate, thin, dry or abnormal tissue. Furthermore, for the protection of surgically exposed tissues and for the comfort and efficiency of the surgeon and assistants, radiant energy can be effectively controlled by limiting the time of exposure at higher illumination levels. Extra care must be taken when the light fields from multiple lightheads are overlapped on the surgical site, since this condition creates a risk of too much heat.

An international standard for the safety of surgical lights established by the International Electrotechnical Commission (IEC) sets minimum and maximum levels of illumination and maximum levels of radiant heat that can be emitted from a single surgical luminaire. The system has been designed to comply with this international standard and to provide a wide range of illumination levels while minimizing the potentially damaging infrared heat in the surgical field.

The illumination level of surgical lights can be adjusted through several intensity settings via conveniently located controls on either the wall mounted control center or the lighthead handle. The illumination level also decreases as the pattern size increases. Maximum illuminance can reach 160 klx for the smallest pattern size of the lighthead and can be adjusted by intensity control or pattern size control throughout the entire range specified by the IEC.

Serious incidents that have occurred in relation to this medical device should be reported to the manufacturer and competent authority in the country where the incident occurred.

1.4 Addresses

STERIS Ireland Limited
IDA Business and Technology Park
Tullamore
County Offaly

R35 X865 ■ Ireland

STERIS Corporation
2720 Gunter Park East
Montgomery, AL 36109 ▪ USA
334-277-6660/800-444-9009
www.steris.com

Class 1 Equipment

Ordinary Equipment (enclosed equipment without protection from ingress of water)

Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.

Suitable for continuous operation.

The base language of this document is ENGLISH. Any translations must be made from the base language document.

Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste. It must be collected separately and must be disposed as per local regulations. Contact your authorized representative for information concerning the decommissioning of your equipment.

1.5 Associated Publications

Equipment Drawing Number	Equipment Drawing Title
P136824469	Installation Instructions HarmonyAIR Surgical Lighting System G Series Remote Panel Control and Wall Control
11028646	HarmonyAIR G-Series (Gen 2) Surgical Lighting System Installation Instructions
11028645	HarmonyAIR G-Series (Gen 2) Surgical Lighting System Operator Manual
P764339236	HarmonyAIR G-Series (Gen 2) Surgical Lighting System Maintenance Manual
11028924	HarmonyAIR G-Series (Gen 2) Tech Data
11028830	Harmony ConnectPoint (Model G-Series Gen 2) Installation Instructions
11028831	Harmony ConnectPoint (Model G-Series Gen 2) Operator Manual

1.6 Waste Disposal Guidelines

WARNING

DISPOSAL HAZARD:

This product contains materials which may require disposal through appropriately licensed and permitted hazardous waste management firms. The materials listed in this manual are contained within the system. When disposing of the lighting fixture or its parts, ensure proper disposal of hazardous and other regulated waste in compliance with national, state, and local WEEE/RoHs regulations.

Electronic and Electrical Parts–not known to require special disposal methods at date of this manual.

Metal Parts–made from aluminum (Al), steel (Fe), cast iron (Fe), copper (Cu), and copper alloys (Cu/x), plastic, synthetic rubber, plating (Cr, Ni, Zn, Au), and adhesives not known to require special disposal methods at date of this manual.

Polyvinylchloride (PVC) –The approximate weight of PVC within a system varies with configuration and options, ranging between 0.2 lb (0.1 kg) and 1.9 lb (0.9 kg).

Symbols

The following symbols appear on the system.

Table 2-1. Symbol Definitions

Symbol	Definition
	ON-OFF
	Lighthead (designation and intensity)
	LED Module(s) Requires Service
	Protective Earth (Ground)
 or 	Attention, consult manual for further instructions
	Consult instructions before use
	Maximum Load Hazard (maximum load given on label)
	Hot, Potential Burn Hazard
SN	Serial Number of Unit
REF	Equipment or Reorder Number
LOT	Batch Code
	Symbol Indicating the Legal Manufacturer Name and Address
	Symbol Indicating the Date of Manufacture (YYYY-MM-DD)
V~	Voltage Rating of Unit, Alternating Current
A	Amperage Rating of Unit

Table 2-1 Symbol Definitions (Continued)

Symbol	Definition
	Frequency Rating of Unit
	Increase Intensity (Surgeon's Control Buttons or Wall Control)
	Decrease Intensity (Surgeon's Control Buttons or Wall Control)
	Camera ON/OFF indicator
	Zoom
	Rotate
	Manual Focus
	Auto Mode (Brightness or Focus)
	Potential Impact Hazard
	Potential Pinch-Point Hazard
	Keep Dry
	Single Use
	Do Not Use If Packaging Damaged
	Keep From Sunlight
	Use By Date
	Brightness
	Battery Backup
	Fault
	Laser Radiation

Table 2-1 Symbol Definitions (Continued)

Symbol	Definition
MD	Medical Device
UDI	Unique Device Identifier
CE 2797	CE Mark with Notified Body Reference Number
EC REP	Authorized Representative in the European Community
	Product Is Not Made With Natural Rubber Latex
STERILE EO	Sterilized Using Ethylene Oxide
	Single Sterile Barrier System
	Single Sterile Barrier System with Protective Packaging Outside

Safety Precautions

The following *Safety Precautions* must be observed when operating or servicing this equipment.

WARNING indicates the potential for personal injury.

CAUTION indicates the potential for damage to equipment.

For emphasis, certain *Safety Precautions* are repeated throughout the manual. It is important to review all *Safety Precautions* before operating or servicing the unit.

Strictly following these *Safety Precautions* enhances your ability to safely and effectively use the unit and helps to avoid improper maintenance methods which may damage the unit or render it unsafe. It is important to understand that these Safety Precautions are not exhaustive; Customers are encouraged to develop their own safety policies and procedures to enhance and complement these *Safety Precautions.*

WARNING

PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD

- Safe and reliable operation of this equipment requires regularly scheduled preventive maintenance, in addition to the regular performance of routine maintenance. Contact STERIS Service Engineering to schedule preventive maintenance.
- Repairs and adjustments to this equipment should be made only by fully qualified service personnel. Maintenance performed by inexperienced, unqualified personnel or installation of unauthorized parts could cause personal injury, invalidate the warranty or result in costly equipment damage. Contact STERIS Service regarding service options.
- Do not attempt to clean lighthead/monitor unless power is turned off and the lighthead/monitor has cooled sufficiently.
- Do not attempt to adjust suspension system. Refer servicing to qualified service personnel.
- No part of this system shall be serviced while in use with a patient.
- Flat Panel Monitor spring arm uses adjustable tension force to support monitor weight. Do not remove monitor from the arm unless the arm has been locked in place by a trained and authorized technician.
- Lighthead arm uses adjustable tension force to support lighthead weight. Do not remove lighthead from the arm unless the arm has been locked in place by a trained and authorized technician.
- Do not modify this equipment without authorization of the manufacturer.

If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of operation.

Use of this equipment adjacent to other equipment should be avoided due to risk of improper operation of the powered device. Observe equipment used adjacent to this equipment for proper operation prior to use.

Portable RF communications equipment, including peripherals such as antenna cables and external antennas, should be used no closer than 12" (305 mm) to any part of the surgical lighting system, including cables specified by STERIS. Degradation of equipment performance could result.

Portable and mobile RF communications equipment used in close proximity to the wall control or canopy controls units may temporarily affect the operation of the equipment.

Use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of this device as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the system. Accessories or replacement parts not listed in the Operator or Maintenance Manuals should not be used.

Avoid potential EMISSIONS interference. The system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

Accessories or replacement parts not listed in the Operator Manual or Maintenance Manual should not be used as it may affect EMC or result in equipment damage.

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

Monitor mount may fall down if the max. load capacity is exceeded. Exceeding the maximum approved load capacity can cause the monitor mount or its components to become loose and fall.

- Do not exceed the maximum load capacity of the monitor mount.
- Do not hang or mount further loads on the spindle arm, spring arm, adaption, or monitor mount.

Avoid damage after collisions. The monitor mount may become damaged and fail if it collides with other objects, walls, or ceilings.

- Check the monitor mount for potential damage after collisions.
- Inform the operator if in doubt.

WARNING

PERSONAL INJURY HAZARD

Harm due to contraindication. The product may cause harm in case of the following contraindications:

- The monitor mount may move by itself in strong magnet fields and must not be used in their proximity.
- Application parts of type BF or CF according to IEC 60601-1 must not be connected directly to monitor mount.

Avoid looking directly at high-intensity light from the lighthead. Eye injury may result.

WARNING

POSSIBLE PATIENT INJURY HAZARD

Failure to engage the disposable light handle cover completely may result in cover falling from lighthead during the procedure.

Cables or accessories other than those supplied by STERIS may affect EMC performance.

WARNING

STERILITY ASSURANCE HAZARD

Do not use the surgeon's control buttons when the plastic light handle is being used unless a disposable sterile cover is installed. If the plastic light handle is used without a disposable cover, the sterility of the surgical environment may be compromised.

Do not use disposable handle covers if the packaging has been damaged, torn or opened, as the sterility of the cover may be compromised.

WARNING

BIOHAZARD

Sterile disposable covers for handles and camera are intended for single use only.

Universal precautions must be observed when disposing of any single use disposable item.

WARNING

DISPOSAL HAZARD

This product contains materials which may require disposal through appropriately licensed and permitted hazardous waste management firms. The materials listed in this manual are contained within the system. When disposing of the lighting fixture or its parts, ensure proper disposal of hazardous and other regulated waste in compliance with national, state and local WEEE/RoHs regulations.

WARNING

SHOCK AND BURN HAZARD

Disconnect all utilities to lighting fixture before servicing. Do not install the lighting fixture unless all utilities have been properly locked out. Always follow OSHA Lockout-Tagout and electrical safety-related work practice standards.

WARNING

EXPLOSION HAZARD

Do not use this lighting system in the presence of flammable anesthetics.

WARNING

ELECTRIC SHOCK HAZARD

Do not remove covers or perform service other than as described in this operator manual. Refer servicing to qualified service personnel.

Do not remove wall control covers. Servicing must be performed by qualified service personnel.

The OFF position on the system ON/OFF touch pad of the wall control turns off control to camera and lightheads, but system is still energized. This mode is referred to as STANDBY, and the ON/OFF LED flashes once per second while system is in this mode.

The ON/OFF switch under the canopy only removes power from the load side of the system. Any system wiring located between this switch and the utility junction box is still energized.

Avoid electric shock hazard. The monitor mount may be live when connected to a supply network without protective ground conductor.

- To avoid the risk of electric shock, the monitor mount may only be connected to a supply network with protective ground conductor.
- If in doubt, ask the operator whether the monitor mount has been installed properly.

Avoid electric shock hazard. The monitor mount may be live and must be treated carefully during cleaning and disinfection:

- If a mains plug is present, please disconnect it.
- Do not use spray cleaning and/or disinfecting agents sprays.
- Do not spray fluid into sockets or monitor mount openings. Do not allow fluid to penetrate them.

WARNING

PINCHING HAZARD

Pinch points are created during extreme articulation of the suspension system. Do not place hands on or near the suspension knuckle during lighthead articulations.

CAUTION

POSSIBLE EQUIPMENT DAMAGE

Appropriate components of this lighting system have been tested and found in compliance with IEC 60601-1-2, Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic Compatibility (EMC). There is, however, a potential for electromagnetic or other interference between this equipment and other devices. Should you experience interference, relocate this device or minimize the use of the affected equipment while this device is in operation.

When installing or removing the video camera, be careful to place it in a secure location to prevent it from rolling, dropping and breaking. Also, to avoid scratching the lens surface, do not stand camera up with lens side facing down.

Use of any disinfectant solution OTHER than those listed here may cause discoloration or deformation on the lens surface:

- Coverage® Plus Germicidal Surface Wipes Disinfecting/Deodorizing/Cleaning Wipes
- Quaternary Ammonium Compound (Quats) with Ethanol solvent
- Quaternary Ammonium Compound (Quats) with Isopropyl Alcohol (IPA) solvent
- Quaternary Ammonium Compound (Quats) with IPA + 2-Butoxyethanol solvent
- Quaternary Ammonium Compound (Quats) + Biguanide
- H2O2 (Hydrogen Peroxide)
- Neutral Cleaners

The use of H2O2 + PAA (Hydrogen Peroxide + Peracetic Acid) is strongly discouraged for use on all STERIS products.

Always follow manufacturer instructions for concentrations and use of cleaning products.

Avoid discoloration of the wall control. Do not clean wall control with povidoneiodine solutions or allow such solutions to contact bezel, bezel label and display surfaces.

Prevent leakage of fluids into interior of lighthead, monitor, or wall control. Ensure no excess fluids remain on lighthead, monitor, or panel during and after cleaning.

Cleaning and disinfecting agents used on this lighting system must be certified by their manufacturer to be compatible with the following materials: polycarbonate, polyetherimide, santoprene.

DO NOT SPRAY any cleaning product directly onto the lighthead, monitor, wall control, or any system components. Clean wall control with a clean, lint-free cloth dampened with 90% isopropyl alcohol. For other system components, dampen a clean, soft cloth with the cleaning solution and wring out the excess moisture.

Do not use floor cleaners on this equipment.

Do not scratch the lens when cleaning; always wear rubber gloves and use only a clean, white, lint-free cloth when wiping external surfaces.

Do not attempt to replace LED modules on the lighthead. Refer servicing to qualified service personnel.

Prevent leakage of fluids into interior of lighthead, monitor, or wall control. Any such leakage could impair or damage the lighting system.

Avoid discoloration of control center keypad and display. Do not clean control center with povidone-iodine solutions or allow such solutions to contact keypad and display surfaces.

Do not bump lightheads into walls or other equipment.

To avoid inadequate balancing, load added to single monitor yoke or dual monitor yoke must not exceed 15 kg (33 lb) per monitor.

Avoid damage to the monitor mount. To avoid damage to the monitor mount:

- Do not use force when moving the monitor mount into the limit positions.
- Avoid collisions with other components.

Technical Specifications

4.1 Application Specification

The HarmonyAIR® G-Series (Gen 2) Surgical Lighting System will be sold for use in operating rooms, trauma rooms, exam rooms and critical care areas in major metropolitan hospitals, community hospitals, clinics, physician offices and outpatient surgery centers. The product is well suited to specialty and general-purpose operating rooms, exam and trauma bays along with critical care rooms, and is intended to cover all of the surgical lighting needs within a hospital and surgery center. This product fills a lower tier of price and performance than the HarmonyAIR® A-Series system. The HarmonyAIR® G-Series (Gen 2) systems provide a lower cost, de-featured lighting system using LED technology which will be affordable to global developed countries and will serve as a value offering for North America.

Intended Medical Indication:

The HarmonyAIR® G-Series (Gen 2) System can be used in a variety of applications, including diagnostic procedures performed in outpatient surgery centers, operating rooms, intensive care units, and major acute care suites.

Intended Patient Population:

There are no restrictions on patient populations.

Intended part of the body or type of tissue applied to or interacted with:

This device will not directly interact with the patient but will interact with the caregiver. The hands, arms, and torso may be used to operate the lighthead and/or camera controls or to adjust the lightheads.

Intended user profiles:

Surgical staff members are the intended operators of this device. The Operator Manual is written at a level consistent with this intended user.

Intended conditions of use:

This equipment is designed to be used in operating rooms, trauma rooms, exam rooms, and critical care areas of hospitals, clinics, physician offices and outpatient surgery centers that meets the environment requirements of the operator manual. This equipment is suitable for continuous operation.

Operating principle:

Illumination is provided via high intensity white LEDs focused through a polycarbonate lens. The lens can be rotated via the light head handle to control the light pattern size.

The illumination level of HarmonyAIR® G-Series (Gen 2) Surgical Lights can be adjusted through several intensity settings via controls on either the wall-mounted control center or the light head handle. Increasing the pattern size can also decrease the luminance level.

4.2 Component Identification

Standard G-Series (Gen-2) Components

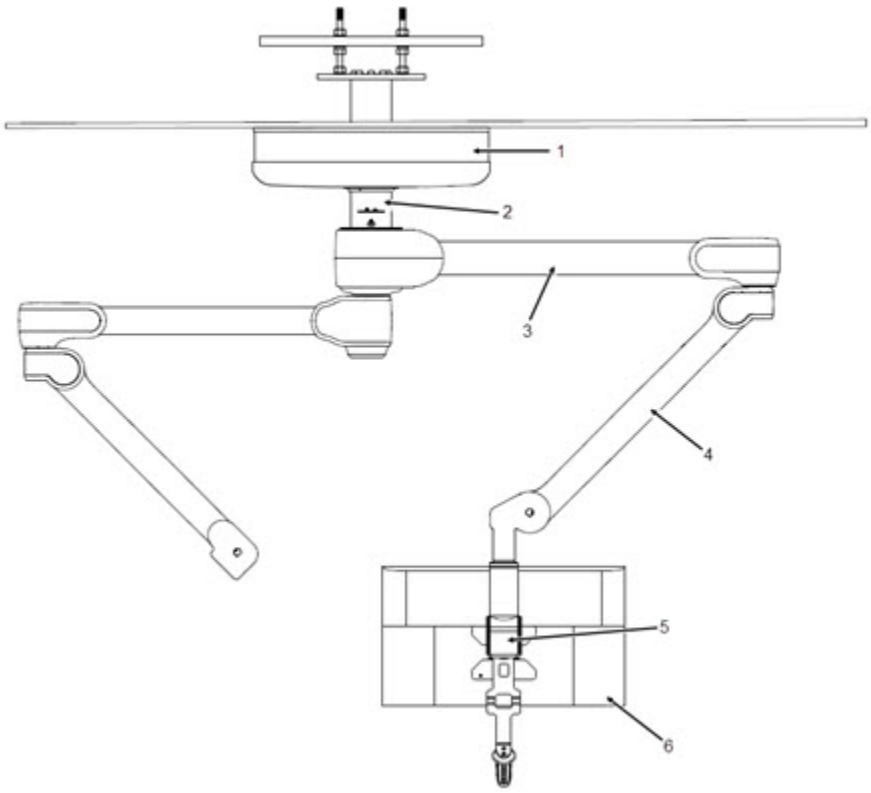


Figure 4-1. Standard G-Series (Gen-2) Components

1. Canopy
2. Down tube
3. Spindle arm
4. Spring arm
5. Attachment yoke
6. End device (e.g., monitor)

Central Tandem Components

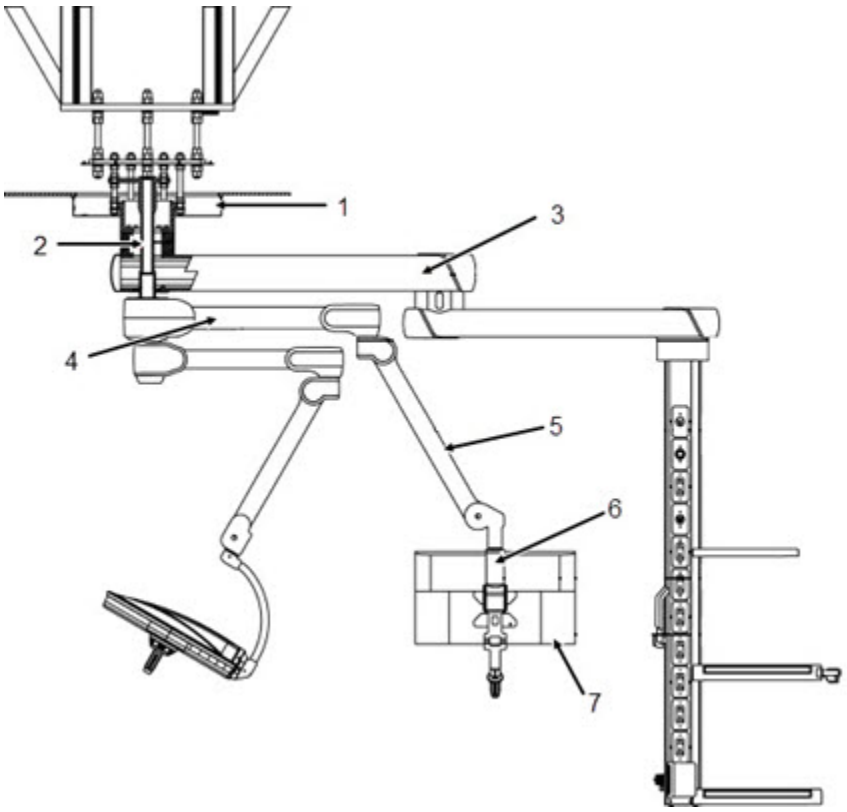


Figure 4-2. Central Tandem Components

1. **Canopy**
2. **Down tube**
3. **Central Tandem EMS arm system**
4. **Spindle arm**
5. **Spring arm**
6. **Attachment yoke**
7. **End device (e.g. monitor)**

4.3 Lighthead Optical Performance

IMPORTANT: *Values are typical for the small pattern size at highest intensity setting (unless otherwise noted) at 100 cm (39-3/8') from the lighthead. Definitions and measurements are in accordance with IEC 60601-2-41.*

Table 4-1. Lighthead Optical Performance

Feature	G5 Lighthead
Maximum Central Illuminance	160,000 lux
Peak Total Irradiance	< 500 W/m^2
Fixed Pattern Size	18 cm (7")
Adjustable Pattern Size	18 cm (7")–28 cm (11")
D50 Diameter	62% of small beam pattern (see Pattern Size)
Depth of Illumination (to 20%) (to 60%)	 97 cm (38") 53 cm (21")
Color Temperature (CCT)	4,400K ± 300K
General Color Rendering Index (CRI)	Up to 96
Deep Saturated Red Color Rendering Index (R9)	Up to 98
Shadow Control — Single Mask	44%
Shadow Control — Double Mask	43%
Shadow Control — Cavity	100%
Shadow Control — Single mask w/ Cavity	44%
Shadow Control — Double mask w/ Cavity	43%
LED Life	50,000 hours at full intensity

4.4 Essential Performance

Essential Performance (EP) for surgical luminaires:

1. **Peak central illuminance (measured at 1m from the luminaire) within the range from 40 klx to 160 klx.**
2. **Peak central irradiance (measured at any distance along the beam axis) less than 1000 W/m².**
3. **Provide white light to illuminate the operating field. (The apparent whiteness of the light can be verified by visual observation.)**
4. **Loss of illumination could result in delay of surgical procedure.**
5. **In extreme cases of electromagnetic interference, the operator may experience temporary loss of light function or camera operation. This can be corrected by removing the source of interference and power cycling the light if necessary.**

4.5 Environmental Conditions

Table 4-2. Three Lighthead System (system running)

For sealed-ceiling applications	Control Center Ambient = 60°C (140°F) Maximum Room Ambient = 20 to 25°C (68 to 77°F)
Interstitial space temperature has minimal effect on the canopy ambient in a completely sealed ceiling application.	
For vented-ceiling applications (1/4" [6 mm] minimum gap between ceiling and ceiling plate)	Control Center Ambient = 60°C (140°F) Maximum Room Ambient = 20 to 25°C (68 to 77°F)
To avoid adverse thermal effects on canopy control electronics, thermal contributions from interstitial space and room ambient temperatures must NOT result in canopy ambient temperatures exceeding 60°C (140°F).	
Recommended Transport/Storage Temperature (not exceeding 15 weeks)	2 to 38°C (36 to 100°F)
Recommended Relative Humidity	30 to 75%
Atmospheric Pressure	500 to 1060 hPascals
RPC: Interstitial space temperature when RPC is mounted above ceiling	45°C (113°F)

4.6 Power Requirements

Table 4-3. Power Requirements

Three-Lighted System	100 – 240 Vac, 50/60 Hz 5-2A 500 Watts at 100 Vac 480 Watts at 240 Vac
Typical Lighthead Wattage	40 Watts

Operating Instructions

5.1 Pre-operation Checklist

Equipment Drawings showing all of the space and utility requirements were sent to the purchaser after the order for this surgical light was received. The clearance space shown on the drawing is necessary for proper installation, operation and maintenance of this fixture.

Installation Instructions were furnished with the system.

If any of these documents are missing or misplaced, contact STERIS, giving the serial and model numbers of the equipment. Replacement copies will be sent to you promptly.

WARNING

WARNING–ELECTRIC SHOCK HAZARD

Do not remove covers or perform service other than as described in this operator manual. Refer servicing to qualified service personnel.

1. **Check Suspension Movement — Check all suspension joints for compromised integrity, such as loose fasteners or components.**

   WARNING

   PINCHING HAZARD

   Pinch points are created during extreme articulation of the suspension system. Do not place hands on or near the suspension knuckle during lighthead articulations.

   ☐ **Verify that suspension system moves through all articulations smoothly without binding. Lightheads and monitors should move smoothly and easily. When positioned, the lighthead support arms (or monitor support arms) should not drift. If binding or drifting is present in suspension movements, call your STERIS service representative to make adjustments.**

2. Check System Operation — Verify that electrical power to the control center is on.

WARNING

ELECTRIC SHOCK HAZARD

The OFF position on the system ON/OFF touch pad of the wall control turns OFF control to camera and lightheads, but system remains energized. This mode is referred to as STANDBY, and the ON/OFF LED flashes once per second while system is in this mode.

☐ When wall control ON/OFF switch is OFF, wall control ON/OFF LED flashes. Turn control ON by pressing wall control ON/OFF touch pad. Verify that wall control touch pads function. Check intensity levels for each system lighthead. If optional camera module is installed, check camera controls.

NOTE: Turn power OFF to each lighthead using intensity controls, and to optional camera (if installed) when testing is complete.

☐ Check Module Failure Indicators: If LED Module(s) Requires Service graphic on wall control display is lit, one or more modules may require service.

☐ Check Module Failure LED: If the LED on any of the lightheads is blinking, one or more LED modules may require service. Check lighthead status LED.

☐ Check Intensity Controls at Each Surgeon's Control: Verify that the intensity level can be increased and decreased at each lighthead using the surgeon's control buttons.

3. Check Optional Video Camera Operation — Turn the surgical lighting system ON. Install video camera in light handle. Press the Camera Control button on the touch pad to turn on the camera.

☐ Video: Verify that a clear signal is reaching the video display device (monitor) from the camera. (Check cable connection between video output connector at HD Hub Enclosure and monitor, if necessary.)

☐ Wall Control: Verify zoom, rotation and focus functions with the control center switches.

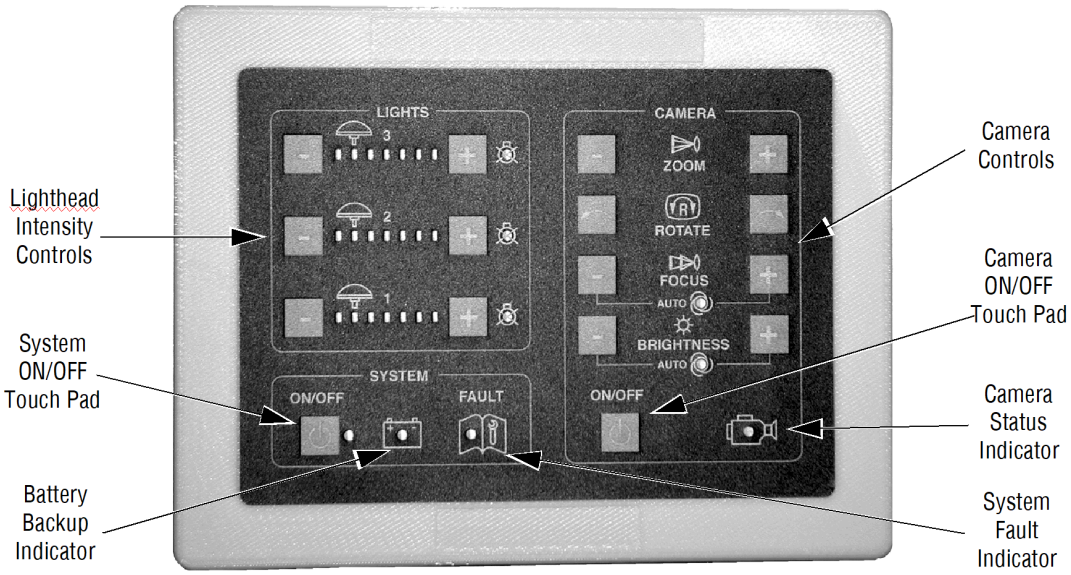
4. Check Optional Monitor Support Arms

☐ The system can include up to three lightheads and up to two monitor arms or Harmony® ConnectPoint with three other arms with lightheads or flat panel monitors.

5.2 Intensity Controls

The wall-mounted system wall control allows the user to adjust the lighthead intensity level by pressing membrane switches (or buttons). Each lighthead is capable of seven light intensity levels, 1 being the lowest intensity and 7 being the highest. An identifying number on the control display corresponds to the same number on the lighthead suspension arm. Additionally, each lighthead has its own onboard intensity control located above the light handle adjacent to the lens. These controls are usually referred to as the surgeon's control buttons or as the surgeon's control (see *Figure 5-1*).

Figure 5-1. Wall Control (with Optional Camera Controls)



Activate the HarmonyAIR G-Series (Gen 2) Surgical Lighting System

WARNING

ELECTRIC SHOCK HAZARD

⚠ The OFF position on the system ON/OFF touch pad of the wall control turns off control to camera and lightheads, but system is still energized. This mode is referred to as STANDBY, and the ON/OFF LED flashes once per second while system is in this mode.

Refer to *Figure 5-1.* Press ON/OFF touch pad. This turns the system on in active mode and restores system lightheads to same intensity levels as before system was turned OFF.

When the system is ON, ON/OFF LED glows green and it does not blink (i.e., is steady). This state is referred to as ACTIVE mode. When the system ON/OFF switch is pressed while system is ACTIVE, system switches to STANDBY mode. In STANDBY mode all lights turn off, the optional camera module (if present) turns off, and ON/OFF LED glows green and blinks.

- **Intensity levels for one to three lightheads can be controlled remotely from one wall control.**
- **A given lighthead's surgeon's control buttons adjust the intensity level for that lighthead.**

IMPORTANT: *Avoid control faults. Do not continuously press and hold wall control buttons for more than 40 seconds.*

Wall Control Unit

WARNING

EXPLOSION HAZARD

Do not use this lighting system in the presence of flammable anesthetics.

1. **Press the selected + button to activate the corresponding lighthead.**
   - **Pressing the + button repeatedly incrementally increases the intensity of light from the lighthead (until reaching maximum intensity).**
   - **Pressing the - button repeatedly reduces light intensity until reaching a minimum level. Continuing to press - button (for two seconds) at any intensity level causes the lighthead to shut off. (Pressing that lightheads + button restores light to the lighthead at previous level.) Refer to *Table 5-1* for a summary of wall control intensity functions.**

2. Once the lighthead is selected, press either the button to increase light intensity level (+), or the button to decrease light intensity level (-).

Table 5-1. HarmonyAIR G-Series (Gen 2) Surgical Lighting System Intensity Control

Module State	Module Intensity	Button Pressed	Duration of Switch Press	Operation
OFF	N/A	+	Any	Module turns ON at stored intensity setting
ON	Any except highest	+	Any	Module increases to next higher intensity setting
ON	Highest	+	Any	Module remains at highest intensity setting
OFF	N/A	-	Any	Module remains OFF
ON	Lowest	-	Less than 2 seconds	Module remains at lowest intensity setting
ON	Lowest	-	2 seconds or longer	Module initially remains at lowest intensity setting and after two seconds turns OFF
ON	Any except lowest	-	Less than 2 seconds	Module decreases to next lower intensity setting
ON	Any except lowest	-	2 seconds or longer	Module initially decreases to next lower intensity setting and after two seconds turns OFF
Either	Any	Either	40 seconds or longer	Switch Fault: Depending upon the switch pressed and the initial conditions of the system module state and intensity, the control of the system module follows one of the sequences listed above. After 40 seconds, the switch is disabled. All other switches remain operational. Full control of system module intensity remains available at the lighthead user interface.

3. At the wall control press and hold the - button until the light goes out.

NOTE: For longer module life, use lowest intensity level suitable for surgical procedure

Surgeon's Intensity Control Buttons

Refer to *Figure 5-2*.

Figure 5-2. G5 Lighthead

1. **Grasp the handle of the appropriate lighthead. A ring of membrane buttons (bumps) are located on the control bezel adjacent to the lighthead lens.**
2. **Press any of the surgeon's intensity control buttons molded with + symbols to increase the lighthead intensity. Press any of the surgeon's control buttons molded with - symbols to decrease lighthead intensity.**
3. **To turn lighthead OFF, press and hold any of the - membrane buttons until the light goes out.**

   NOTE: Press the decrease intensity button (-) on the lighthead surgeon's control for an additional two seconds, to turn OFF all lightheads in the system.

5.3 G5 Lighthead Module Status Indications

LEDs on the wall control indicate HarmonyAIR G-Series (Gen 2) Surgical Lighting System module status. If the wall control module status LED is lit, it indicates the module(s) has failed. A failed module(s) should always be changed at the earliest opportunity.

Another module status LED is located on each lighthead. See *Figure 5-3*. When flashing, the lighthead LED indicates the module(s) have malfunctioned or the power supply needs to be re-calibrated.

- **Check the module status LED each time the surgical light is used.**
- **If the module status LED is blinking, call your STERIS service representative. After the lighthead has been re-calibrated or repaired, LED indicators on lighthead and wall control stop blinking.**

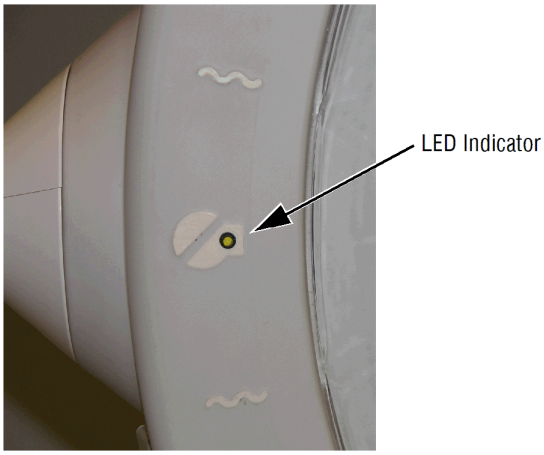


Figure 5-3. G5 Lighthead Module Status Indicator

5.4 G5 Lighthead Positioning

Lightheads can be positioned by using either the sterile handle, or by grasping the non-sterile handle around the lighthead housing. Each lighthead can be positioned as listed from outside or from within the sterile field. To optimize shadow control, position the lighthead as appropriate before starting the intended surgical procedure.

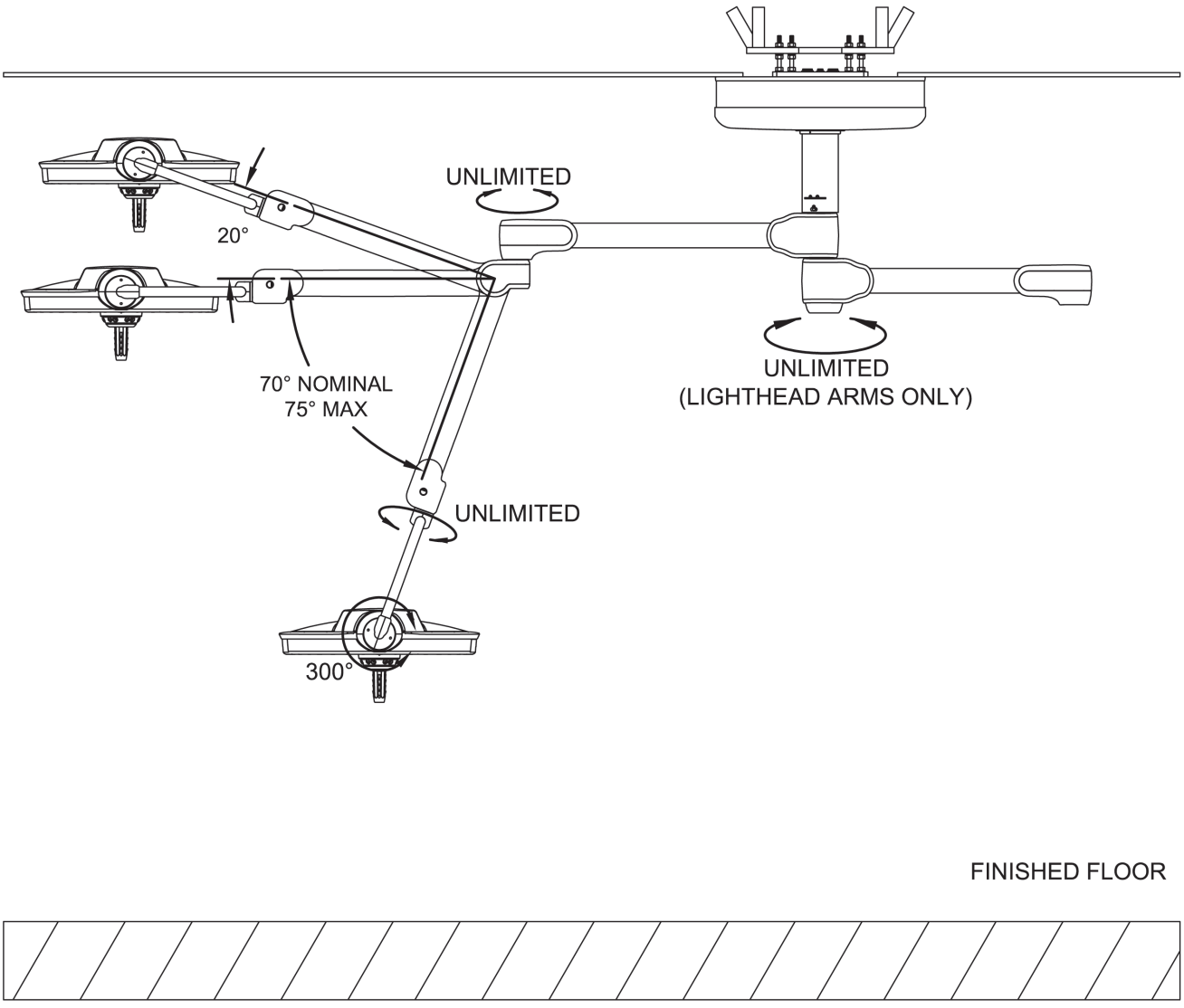


Figure 5-4. G5 Lighthead Positioning

HarmonyAIR G-Series (Gen 2) Surgical Lighting System Lighthead/Spring Arm Assemblies may:

See *Figure 5-4* .

1. **Rotate continuously around central hub;**
2. **Rotate continuously at horizontal suspension arm/spring arm connection;**
3. **Rotate continuously at spring arm/yoke connection;**
4. **Tilt forward or backward in yoke approximately 300°; and**
5. **Move up or down by pivoting at suspension elbow 20° up, and 75° down (total range: 95°).**

5.5 G5 Lighthead Pattern Adjustment

CAUTION

POSSIBLE EQUIPMENT DAMAGE HAZARD

Do not bump lightheads into walls or other equipment.

G5 lighthead is available in fixed or adjustable pattern size. For adjustable pattern size, the illumination pattern can be adjusted to any size between the maximum diameter and minimum diameter. Refer to *Figure 5-5.*

- **Adjust the light pattern by rotating the light handle clockwise to decrease pattern size.**
- **Rotate the handle counterclockwise to increase pattern size.**

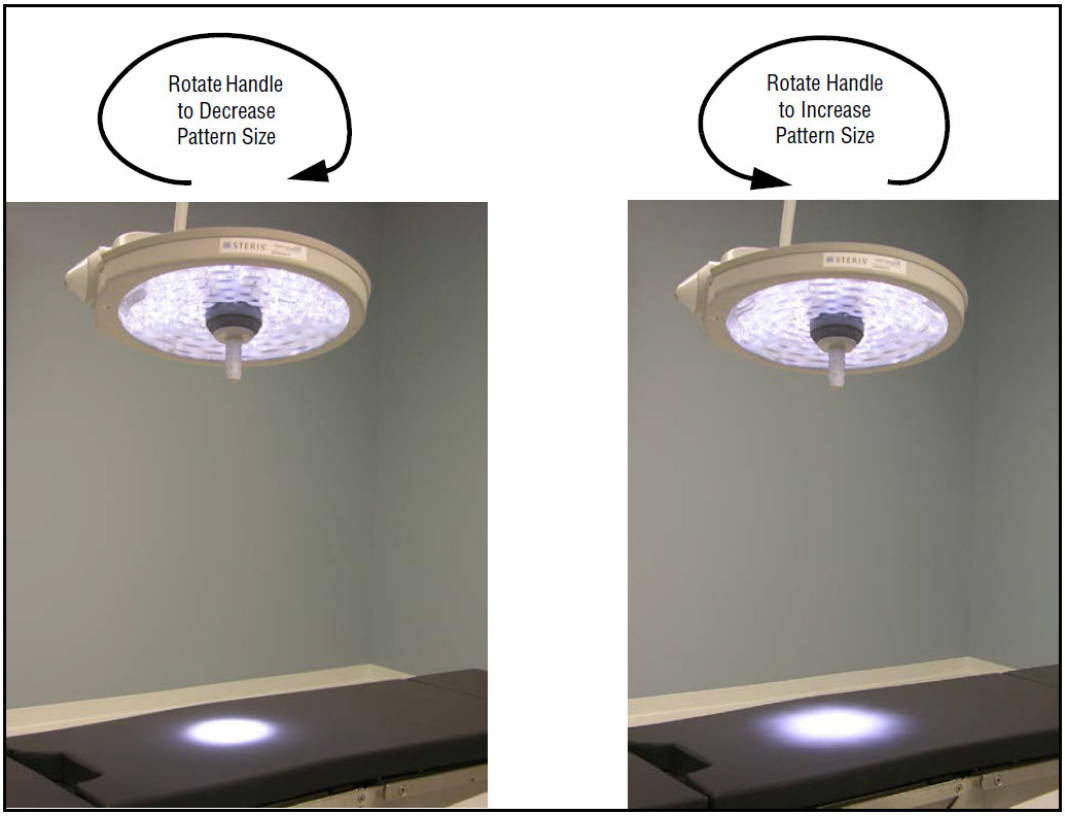


Figure 5-5. G5 Lighthead Pattern Adjustment

5.6 Light Handles

Light handles are used to position the lightheads, allow access to intensity control on each lighthead and to adjust lighthead pattern size.

If the light handle adaptor is not already in place, align the tab on the adaptor with the channel in the mounting ring and thread the adaptor in until fully engaged. (See *Figure 5-6).*

The plastic light handle can be removed for cleaning or sterilization by unscrewing it from the handle adaptor. The light handle can be sterilized using standard hospital cycles. Do not use the lighthead during a sterile procedure unless a disposable cover is installed on the light handle.

1. **Prior to starting a procedure, ensure that the light handle is in place. Install the light handle by threading onto the adaptor and firmly tightening (see *Figure 5-6).***
2. **Remove the sterile light handle cover from its packaging and install onto the light handle (see *Figure 5-6).***

   NOTE:

   Sterile light handle covers, STERIS catalog #LB53, have been sterilized by the use of ethylene oxide per ANSI/AAMI/ISO 11135- 1.

Sterilizable Surgeon Control Handle

The sterilizable surgeon control handle may be used in place of a plastic light handle and a disposable sterile light handle cover. (See *Figure 5-7).*

Prior to starting a procedure, install a clean, sterilized handle by screwing it onto the threaded handle adaptor. Ensure handle is firmly tightened prior to use. The gap between the flange on the sterilizable handle and the surgeon's control buttons prevent accidental contact with the non-sterile surface of the buttons.

Cleaning Recommendations

1. **Remove visible debris by means of manual or automated cleaning using an enzymatic or neutral PH cleaner/detergent and water. Any cleaner used must be compatible with aluminum and silicone.**
   - **Remove silicone insert from Sterilizable Surgeon Control Handle before cleaning. Disassemble completely before cleaning.**
   - **Follow instructions supplied with the cleaning agent regarding temperature and dilution rates.**
   - **Use a brush or cloth if needed.**
2. **Rinse thoroughly.**

Sterilization Recommendation

1. **Metal handle and silicone ring must be sterilized before use in any surgical procedure.**
2. **When placing handle and ring in the sterilizer for processing, the best practice is to orient all objects with openings downward, as if to allow water (or air) to flow out.**
3. **Sterilize handle and silicone ring separately (disassembled, but in the same chamber) using a cycle with either of the following parameters:**
   - **Prevacuum**
     - **Temperature: 270°F (132°C)**
     - **Exposure Time: 4 minutes**
   - **Gravity**
     - **Temperature: 270°F (132°C)**
     - **Exposure Time: 10 minutes**

NOTE:

Before using silicone ring, note the following:

1. Reuse limit is 1,000 cycles.

2. Replace ring if yellowing, deformation, cracking or other signs of deterioration are present.

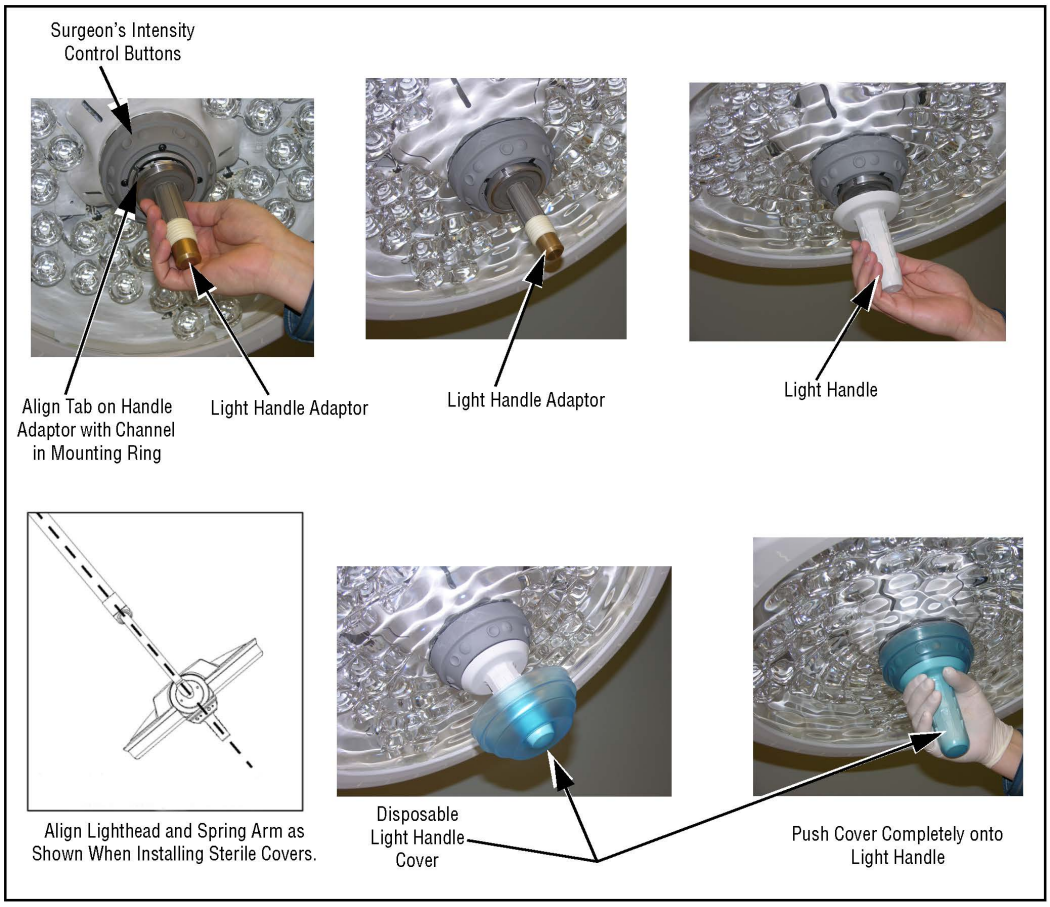


Figure 5-6. Standard Light Handle

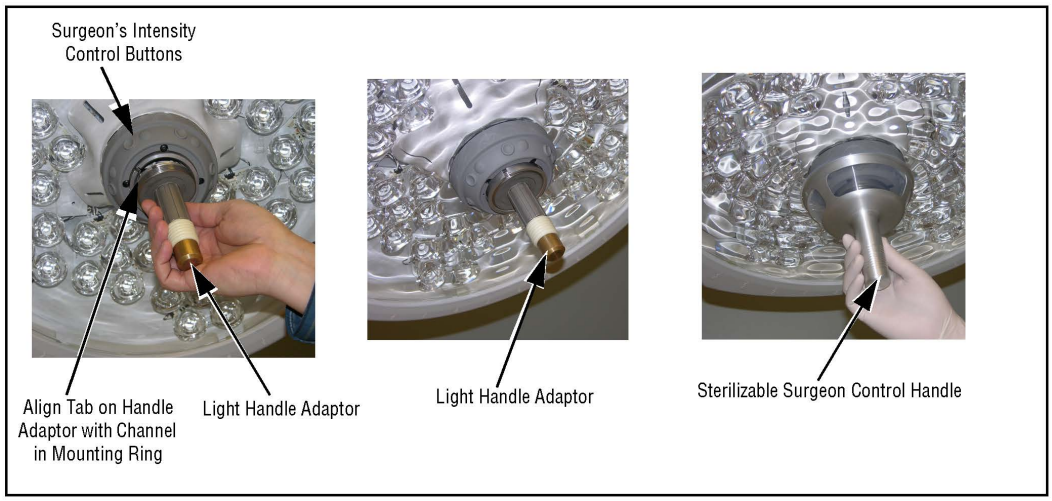


Figure 5-7. Sterilizable Surgeon Control Handle

5.7 Monitor Arms

The system can be equipped with one or two monitor support arms.

NOTE: Central Tandem systems only allow for support of one (1) single flat panel monitor.

WARNING

PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD

Flat Panel Monitor arm uses adjustable tension force to support equipment weight. Do not remove monitor from the arm unless the arm has been locked in place by a trained and authorized technician.

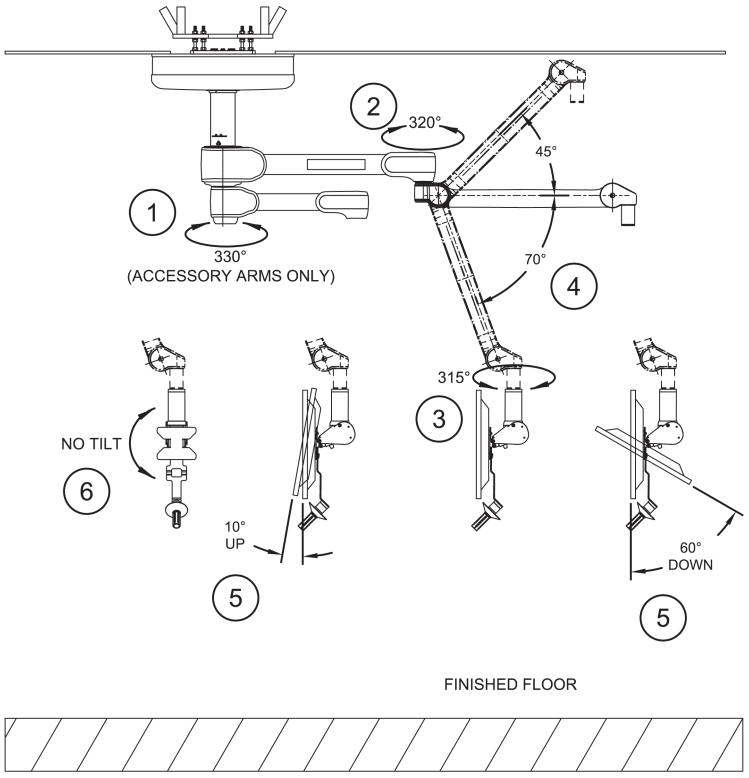


Figure 5-8. HarmonyAIR G-Series (Gen 2) Surgical Lighting System Monitor Arm

Monitor arms can be included in the system either as the uppermost arm on the central spindle, or upper- and lower-most arms on the central spindle.

Monitor arms are capable of the following articulations: (1) rotate 330° at the central spindle; (2) rotate 320° at the horizontal extension arm; (3) rotate 315° at the yoke transition; (4) move up by pivoting at spring arm knuckle 45° up; move down by pivoting at spring arm knuckle 70° down. Flat panel monitor (FPM) yoke tilts (5) forward 10° or backward 60° in yoke. See *Figure 5-8*.

- **Refer to separate operating instructions supplied with the monitor.**
- **Input signals to monitors can be routed through the suspension wiring from an external video source (not provided by STERIS).**

5.8 G-Series (Gen 2) Monitor Mount

WARNING

PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD

Monitor mount may fall down if the max. load capacity is exceeded. Exceeding the maximum approved load capacity can cause the monitor mount or its components to become loose and fall.

- Do not exceed the maximum load capacity of the monitor mount.
- Do not hang or mount further loads on the spindle arm, spring arm, adaption or monitor mount.

Avoid damage after collisions. The monitor mount may become damaged and fail if it collides with other objects, walls, or ceilings.

- Check the monitor mount for potential damage after collisions.
- Inform the operator if in doubt.

WARNING

ELECTRIC SHOCK HAZARD

Avoid electric shock hazard. The monitor mount may be live when connected to a supply network without protective ground conductor.

- To avoid the risk of electric shock, the monitor mount may only be connected to a supply network with protective ground conductor.
- If in doubt, ask the operator whether the monitor mount has been installed properly.

WARNING

PERSONAL INJURY HAZARD

Harm due to contraindication The product may cause harm in case of the following contraindications:

- The monitor mount may move by itself in strong magnet fields and must not be used in their proximity.
- Application parts of type BF or CF according to IEC 60601-1 must not be connected directly to monitor mount.

Monitor Mount Description

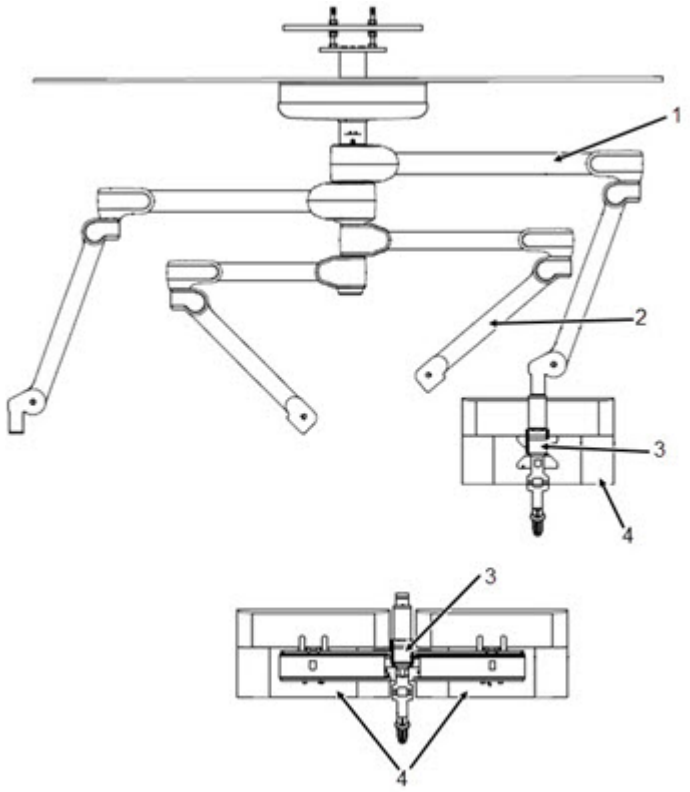


Figure 5-9. Monitor Mount Description

1. **Extension arm**
2. **Spring arm**
3. **Adaption**
4. **End device (e.g., monitor mount)**

NOTE: Central Tandem systems only allow for support of one (1) single flat panel monitor.

Operating Monitor Mount

CAUTION

POSSIBLE EQUIPMENT DAMAGE

Avoid damage to the monitor mount. To avoid damage to the monitor mount:

- Do not use force when moving the monitor mount into the limit positions.
- Avoid collisions with other components.

The monitor mount may collide with other components when it is moved.

- Check the environment for potential collision hazards before swivelling, adjusting the height or tilting.

1. **Hold monitor mount on optional handles or on monitor and slowly move it into desired position to swivel or tilt the monitor mount or adjust its height.**

   The rotation range and height limit ends – depending on the variant – at the internal limit stops of the spindle arm, spring arm, and adaption.

   If spindle arm, spring arm, adaption, or monitor mount do not remain stationary in set position, spring force, brake force, or possibly the friction must be adjusted by a service technician. Contact STERIS.

5.9 Video Camera Installation or Removal

Installation

If the lighting system is camera-ready, the bottom-most lighthead on the central spindle (lighthead 1) is the only lighthead in the system capable of accepting a camera module. Unless the system has been preconfigured for video (i.e., is camera-ready), it is not possible to install a camera module.

CAUTION

POSSIBLE EQUIPMENT DAMAGE

When installing or removing the video camera be careful to place it in a secure location to prevent it from rolling, dropping and breaking. Also, to avoid scratching the lens surface, do not stand camera up with lens side facing down.

---

1. **Rotate lighthead until lens faces the room ceiling.**
2. **Remove standard light handle and lighthead adaptor by unthreading it from the support mounting ring.**
3. **The camera is secured to the lighthead by threading it into the same support used by the standard handle.**
   a. **Align the post with recess, this should align system connector properly, and install camera assembly to lighthead. See *Figure 5-10.***
   b. **Turn ON camera at the wall control.**
   c. **Verify all functions of the camera operate correctly using the wall control.**
4. **Once camera functions are verified, press the OFF touch pad on the face of the wall control.**

Removal

1. Rotate lighthead until perpendicular to floor.
2. Unthread camera housing from mounting ring and remove.
3. Install standard handle.

Figure 5-10. Optional Camera Installation

5.10 Install Disposable Sterile Camera Cover

IMPORTANT:

Use new covers for each handle for each procedure where the monitor is used.

Covers are sterile and shipped in a protective wrapper. Wear sterile gloves when removing covers from packaging. When installing covers, follow sterility assurance procedures as outlined by facility protocols.

NOTE:

Sterile camera covers, STERIS catalog #LB54, have been sterilized by the use of ethylene oxide per ANSI/AAMI/ISO 11135–1.

Figure 5-11. Install Disposable Sterile Camera Cover

WARNING

BIOHAZARD

⚠ Sterile disposable covers for handles and camera are intended for single use only. Universal precautions must be observed when disposing of any single use disposable item.

See *Figure 5-11*.

1. **Remove cover from packaging.**
2. **Place cover over camera module until it is firmly in place.**

5.11 Video Camera Operation

The optional video camera is integrated into a removable handle that can be fitted to a camera-ready lighthead. Whenever the video option is used, a separate sterile disposable cover must be fitted over the camera before each procedure. See *Section 5.10, Install Disposable Sterile Camera Cover*. This cover allows the camera to be grasped and used in the same way as a standard handle, including positioning the lighthead for optimal illumination, adjusting lighthead intensity and pattern size, as well as positioning the video image field for the best view of the procedure. The sterile cover must be removed from the camera and discarded after each procedure.

Once the video camera module has been installed in the lighthead, the camera may be turned on at the wall control by pressing the camera ON/OFF switch. Once the camera is initialized, its functions can be controlled by the wall control. Full control of all camera functions is available through the membrane switches on the wall control. Camera features are summarized on *Table 5-2*:

Table 5-2. HarmonyAIR G-Series (Gen 2) Surgical Lighting System Camera Features Summary

Feature	Wall Control
Camera Power	X
Zoom	X
Rotate	X
Auto/Manual Brightness	X
Brightness	X
Auto/Manual Focus	X
Focus	X

Wall control touch pads are used to control the following camera functions:

- **Zoom–For determining the level of detail visible in the image field. The Zoom function adjusts the image field continuously between two extremes:**
  - **(Telephoto). At extreme telephoto, the camera captures an image showing great detail in a small area.**

    NOTE: At extreme telephoto, any motion of the lighthead/camera may be exaggerated (jerky). The field of focus has little depth at this extreme, forcing the Auto Focus function (if enabled) to refocus the camera when any object (such as a hand) enters the image field, or if camera position is adjusted. The camera is also sensitive to light level changes at extreme telephoto. Minimum distance for HD camera is 800 mm (31") when using extreme telephoto zoom.
  - **(Wide Angle). At extreme wide angle, the camera captures a large image with less detail than telephoto.**

    NOTE: At extreme wide angle, the image field possesses a greater depth of focus and less sensitivity to light level changes.
- **Rotate–Use this function to change orientation of the video field. Image field can be rotated in either clockwise or counterclockwise directions. Rotation is 360° continuous.**
- **Brightness–Use this function to affect the overall brightness (or darkness) of the video image. Brightness control can be set to adjust itself automatically.**
  - **Auto Brightness–Use this setting to allow the camera's electronic controls to automatically adjust the brightness level.**
  - **Manual Brightness–Use this setting to manually adjust the brightness setting when the automatic controls do not provide an acceptable image. (Refer to *Table 5-3*).**

  ***Table 5-3* summarizes the brightness and focus controls available to the operator.**

Table 5-3. Brightness and Focus Mode Summary

Brightness/-Focus Mode	Brightness/ Focus LED Indicator	Switch Pressed	Operation
Auto	ON	- (Brightness or Focus)	– Mode switched to Manual. – Mode LED indicator turned OFF. – The camera brightness decreases as long as the - brightness switch is pressed. – Brightness or focus decreases stop when the camera reaches its internal lower limit.
Auto	ON	+ Brightness or Focus	– Mode switched to Manual. – Mode LED indicator turned OFF. – The camera brightness or focus increases as long as the + brightness switch is pressed. – Brightness or focus increases stop when the camera reaches its internal upper limit.
Auto	ON	+ and - Brightness or Focus	– Mode remains in Automatic.
Manual	OFF	+ Brightness or Focus	– The camera brightness or focus increases as long as the + switch is pressed. – Brightness or focus increases stop when the camera reaches its internal upper limit.
Manual	OFF	- Brightness or Focus	– The camera brightness or focus decreases as long as the - switch is pressed. – Brightness or focus decreases stop when the camera reaches its internal lower limit.
Manual	OFF	+ and - Brightness or Focus	– Mode switched to automatic. – Camera automatically adjusts brightness or focus. – Mode LED indicator turned ON.

- Manual Focus–Use this function to manually set the focus. The Auto Focus function must be toggled off to enable manual focusing. Adjust the clarity of focus by pressing the + or - touch pads. *Table 5-3* summarizes the brightness and focus controls available to the operator.

  Zoom is defined by two extremes: short, indicating little zoom has been used; or long, indicating zoom has been extended toward its maximum limit. Overall distance between the object and the camera, plus the length of zoom, affects the camera's ability to achieve a sharp focus. The greater the zoom length, the less capability the camera has to establish a sharp focus.

  NOTE: + touch pad moves the lens slightly closer to subject; - touch pad moves the lens slightly away from subject.

- Auto Focus–Use this function to toggle Auto Focus on or off. When Auto Focus is ON, the camera automatically focuses on the object in the image field closest to the camera lens. When Auto Focus is turned OFF, the camera maintains focus on the last object upon which it was focused, until Auto Focus is turned back on.

NOTE: It may be necessary to toggle Auto Focus OFF when using the camera at extreme telephoto (close up), to prevent the camera from refocusing on hands and other objects introduced into the image field while video imaging procedures.

5.12 Guidelines for Maximizing Video Image

Observe the following guidelines to aid in maximizing video imaging effectiveness.

- **Energize the light at medium setting, and position the front face of the camera module approximately 39" (1 m) from the surgical site.**
- **Using the zoom switches on the wall control, zoom in or out (+ or -) until the desired image fills the viewing screen of the monitor.**

  NOTE: Zooming completely out causes image distortion within the illuminated area.

  If the light pattern does not fill the monitor's screen, the image inside the pattern may be distorted.

  Reposition the camera to orient the focal point (center of the desired image) at the center of the viewing screen.

Adjust zoom and rotation as needed:

- **The camera may be zoomed to the full 40x zoom (10x optical, 4x digital) and rotation orientation adjusted as needed.**
- **Clockwise and/or counterclockwise orientation is adjusted by using the curved arrow(s) on the wall control.**

As instruments are introduced to and removed from the surgical field, the auto focus attempts to focus on the nearest object, possibly causing the image to blur intermittently. To prevent this effect, once the camera has been positioned and focused onto the surgical site, the manual focus mode may be engaged to maintain image clarity during the procedure.

For deep cavity illumination, it may be necessary to engage the manual focus to focus beyond the nearest object (i.e., the surface area surrounding the incision) so that the desired image can be viewed clearly.

5.13 ACT Enabled System

The system can be configured to operate using voice activated controls or touch-panel displays. The STERIS-provided portion of this system is an interface point between the system and the operating room control system (integration). Refer to the operator manual and technical specifications provided with the integration system for specific details.

NOTE: The lighting system must be ON when operating with the integration system.

To enable the ACT interface refer to Installation Instructions ACT Interface Kit for Harmony/STERIS LC Surgical Lighting and Visualization System, P129388-191

Routine Maintenance

6.1 Cleaning The Equipment

Cleaning Equipment

WARNING

PERSONAL INJURY AND/OR POSSIBLE EQUIPMENT DAMAGE HAZARD

Do not attempt to clean lighthead/monitor unless power is turned off and the lighthead/monitor has cooled sufficiently.

WARNING

ELECTRIC SHOCK HAZARD

Avoid electric shock hazard. The monitor mount may be live and must be treated carefully during cleaning and disinfection:

- If a mains plug is present, please disconnect it.
- Do not use spray cleaning and/or disinfecting agents sprays.
- Do not spray fluid into sockets or monitor mount openings. Do not allow fluid to penetrate them.

WARNING

RISK OF CONTAMINATION AND INFECTION OF PATIENTS

Certain parts of the product are made of plastic. Solvents may dissolve plastic. Concentrated acids, caustic solutions and media with more than 60% alcohol may cause material embrittlement. Damaged parts may fall into open wounds. If cleaning fluid is allowed to penetrate the device, surplus cleaning agent may drip into open wounds.

- Make sure that no fluid penetrates into the device during cleaning.
- To avoid damage to plastic parts, do not use scouring agents, alkaline, acidic or corrosive cleaning agents.
- Do not use bleaching agents on stainless-steel parts.

CAUTION

POSSIBLE EQUIPMENT DAMAGE

Use of any disinfectant solution OTHER than those listed here may cause discoloration or deformation on the system components:

- Coverage® Plus Germicidal Surface Wipes Disinfecting/Deodorizing/Cleaning Wipes
- Quaternary Ammonium Compound (Quats) with Ethanol solvent
- Quaternary Ammonium Compound (Quats) with Isopropyl Alcohol (IPA) solvent
- Quaternary Ammonium Compound (Quats) with IPA + 2-Butoxyethanol solvent
- Quaternary Ammonium Compound (Quats) + Biguanide
- H2O2 (Hydrogen Peroxide)
- Neutral Cleaners

The use of H2O2 + PAA (Hydrogen Peroxide + Peracetic Acid) is strongly discouraged for use on all STERIS products.

Always follow manufacturer instructions for concentrations and use of cleaning products.

Avoid discoloration of the wall control. Do not clean wall control with povidoneiodine solutions or allow such solutions to contact bezel, bezel label and display surfaces.

Prevent leakage of fluids into interior of lighthead or wall control. Ensure no excess fluids remain on lighthead or panel during and after cleaning.

Cleaning and disinfecting agents used on this lighting system must be certified by their manufacturer to be compatible with the following materials: polycarbonate, polyetherimide, santoprene.

DO NOT SPRAY any cleaning product directly onto the lighthead, monitor, wall control, or any system components. Clean wall control with a clean, lint-free cloth dampened with 90% isopropyl alcohol. For other system components, dampen a clean, soft cloth with the cleaning solution and wring out the excess moisture.

STERIS recommends the following equipment for use when cleaning the surgical lighting system:

- **Pail**
- **Sponge**
- **Lint-Free Cloth Wipes**
- **Rubber Gloves**
- **Mild Household Detergent (e.g., Dishwashing Liquid)**

General Cleaning/Disinfecting Procedure

WARNING

PERSONAL INJURY HAZARD AND/OR EQUIPMENT DAMAGE HAZARD

Do not attempt to clean lighthead unless power is turned off and the lighthead has cooled sufficiently.

CAUTION

POSSIBLE EQUIPMENT DAMAGE

Use of any disinfectant solution OTHER than those listed here may cause discoloration or deformation on the lens surface:

- Coverage® Plus Germicidal Surface Wipes Disinfecting/Deodorizing/Cleaning Wipes
- Quaternary Ammonium Compound (Quats) with Ethanol solvent
- Quaternary Ammonium Compound (Quats) with Isopropyl Alcohol (IPA) solvent
- Quaternary Ammonium Compound (Quats) with IPA + 2-Butoxyethanol solvent
- Quaternary Ammonium Compound (Quats) + Biguanide
- H2O2 (Hydrogen Peroxide)
- Neutral Cleaners

The use of H2O2 + PAA (Hydrogen Peroxide + Peracetic Acid) is strongly discouraged for use on all STERIS products.

Always follow manufacturer instructions for concentrations and use of cleaning products.

Avoid discoloration of the wall control. Do not clean wall control with povidoneiodine solutions or allow such solutions to contact bezel, bezel label and display surfaces.

Prevent leakage of fluids into interior of lighthead, monitor, or wall control. Ensure no excess fluids remain on lighthead, monitor or panel during and after cleaning.

Cleaning and disinfecting agents used on this lighting system must be certified by their manufacturer to be compatible with the following materials: polycarbonate, polyetherimide, santoprene.

DO NOT SPRAY any cleaning product directly onto the lighthead, monitor, wall control, or any system components. Clean wall control with a clean, lint-free cloth dampened with 90% isopropyl alcohol. For other system components, dampen a clean, soft cloth with the cleaning solution and wring out the excess moisture.

STERIS recommends the following procedures when cleaning the surgical lighting system:

1. **Ensure lighthead is turned off and has cooled sufficiently.**
2. **Wear rubber gloves.**
3. **Prepare an approved cleaning or disinfecting solution in accordance with the directions on the container's label.**
4. **DO NOT SPRAY any cleaning product directly onto the lighthead, monitor, wall control, or any system components. Clean wall control with a clean, lint-free cloth dampened with 90% isopropyl alcohol. For other system components, dampen a clean, soft cloth with the cleaning solution and wring out the excess moisture.**
5. **Thoroughly wipe the areas to be cleaned.**
6. **Rinse all surfaces with a clean soft cloth wipe and clear water.**
7. **Wipe all surfaces dry with a clean dry soft cloth.**
8. **Verify metal sterilizable handle (when used) is sterilized using a standard hospital cycle.**

   NOTE: Always sterilize metal sterilizable handle between procedures. Sterilize light handle using conventional hospital sterilization procedures and a standard sterilization prevacuum or gravity cycle.

Areas To Be Cleaned Before Each Use

WARNING

PERSONAL INJURY AND/OR POSSIBLE EQUIPMENT DAMAGE HAZARD

Do not attempt to clean lighthead/monitor unless power is turned off and the lighthead/monitor has cooled sufficiently.

CAUTION

POSSIBLE EQUIPMENT DAMAGE

Use of any disinfectant solution OTHER than those listed here may cause discoloration or deformation on the lens surface:

- Coverage® Plus Germicidal Surface Wipes Disinfecting/Deodorizing/Cleaning Wipes
- Quaternary Ammonium Compound (Quats) with Ethanol solvent
- Quaternary Ammonium Compound (Quats) with Isopropyl Alcohol (IPA) solvent
- Quaternary Ammonium Compound (Quats) with IPA + 2-Butoxyethanol solvent
- Quaternary Ammonium Compound (Quats) + Biguanide
- H2O2 (Hydrogen Peroxide)
- Neutral Cleaners

The use of H2O2 + PAA (Hydrogen Peroxide + Peracetic Acid) is strongly discouraged for use on all STERIS products.

Always follow manufacturer instructions for concentrations and use of cleaning products.

Avoid discoloration of the wall control. Do not clean wall control with povidoneiodine solutions or allow such solutions to contact bezel, bezel label and display surfaces.

Prevent leakage of fluids into interior of lighthead, monitor, or wall control. Ensure no excess fluids remain on lighthead or panel during and after cleaning.

Cleaning and disinfecting agents used on this lighting system must be certified by their manufacturer to be compatible with the following materials: polycarbonate, polyetherimide, santoprene.

DO NOT SPRAY any cleaning product directly onto the lighthead, monitor, wall control, or any system components. Clean wall control with a clean, lint-free cloth dampened with 90% isopropyl alcohol. For other system components, dampen a clean, soft cloth with the cleaning solution and wring out the excess moisture.

The following areas of the system must be cleaned and disinfected before each use of the lighthead.

- **Suspension Arm – Wipe the entire suspension arm, including the suspension fork and yoke.**
- **Lighthead – Wipe both top and side surfaces.**
- **Sterile Handle Support – Wipe all areas of the support, including those covered when the handle is installed.**
- **Lens —**

  IMPORTANT: Clean only the exterior surface of the lens.

  1. ***Remove the light handle.***
  2. ***Clean/disinfect the outer surface of the lens as outlined in General Cleaning/Disinfecting Procedure.***
  3. ***Wipe the outer surface of the lens with an anti-static cleaner and soft cloth.***
  4. ***Do not reinstall a light handle until immediately before the light is to be used in a surgical procedure.***
     - ***When using a sterilizable light handle, verify that it is sterilized according to facility sterile protocols between each surgical procedure.***
     - ***When using disposable sterile light handle covers, verify a new one is used for each procedure.***

       NOTE: Always sterilize metal sterilizable handle between procedures. Sterilize light handle using conventional hospital sterilization procedures and a standard sterilization prevacuum or gravity cycle.
- **Wall Control – Wipe panel with an anti-static cleaner and soft cloth. See *General Cleaning/Disinfecting Procedure* for cleaning instructions.**

6.2 Disinfection

The product is not intended for sterilization.

CAUTION

HEALTH HAZARD

Disinfecting agents may contain substances which are detrimental to your health and may cause injuries to the skin or eyes on contact or damage the respiratory organs if inhaled. Observe safety measures:

- Follow the hygiene guidelines.
- Observe the information supplied by the disinfecting agents manufacturer.
- Disinfect surfaces every work day and in the event of contamination

.

The standard disinfection procedure for the product is wipe disinfection. The operator is to determine hygiene guidelines and the corresponding safety measures for the disinfection procedure to be used.

- **Immediately disinfect the affected areas after contamination by potentially infectious material (e.g. blood, secretions or excrement).**
- **Observe application concentration.**
- **Do not spray for surface disinfection; wipe instead.**
- **Only use wiped areas after the time required for the disinfecting agents to take effect has passed and the surfaces have fully dried.**

6.3 Preventive Maintenance

WARNING

SHOCK AND BURN HAZARD

Disconnect all utilities to lighting fixture before servicing. Do not install the lighting fixture unless all utilities have been properly locked out. Always follow OSHA Lockout-Tagout and electrical safety-related work practice standards.

WARNING

ELECTRIC SHOCK HAZARD

- Do not remove covers or perform service other than as described in this operator manual. Refer servicing to qualified service personnel.
- The OFF position on the system ON/OFF touch pad of the wall control turns off control to camera and lightheads, but system is still energized. This mode is referred to as STANDBY, and the ON/OFF LED flashes once per second while system is in this mode.

WARNING

PERSONAL INJURY HAZARD AND/OR EQUIPMENT DAMAGE HAZARD

- Do not attempt to clean lighthead unless lighthead is turned off and has cooled sufficiently.
- Do not attempt to adjust suspension system. Refer servicing to qualified service personnel.
- No part of this system shall be serviced while in use with a patient.

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1. **Regular service and maintenance MUST be performed only by STERIS or a STERIS-trained technician. Any work performed by inexperienced or unqualified persons or the installation of unauthorized parts could cause personal injury, invalidate the warranty or result in costly damage.**
2. **Under no circumstances should this equipment be serviced without the Maintenance Manual. The Maintenance Manual can be purchased by contacting STERIS Customer Service.**
3. **A detailed Preventive Maintenance schedule and replacement parts list can be found in the Maintenance Manual. The Maintenance Manual can be purchased by contacting STERIS Customer Service.**
4. **Preventive Maintenance is essential in keeping this equipment in optimal working condition. STERIS recommends establishing an annual maintenance agreement with STERIS service.**
5. **Preventive Maintenance and regular service must be performed according to the Maintenance Manual in order to comply with the requirements for essential performance and compliance with electromagnetic compatibility.**

   IMPORTANT: Use only authorized STERIS replacement parts when conducting any maintenance on the equipment.

NOTE: Refer to the HarmonyAIR G-Series (Gen 2) Surgical Lighting System Installation Instructions (11028646) and HarmonyAIR G-Series (Gen 2) Surgical Lighting System Maintenance Manual (P764339–236) to safely replace components.

6.4 Inspect Suspension

Start at the highest point on the suspension, and work out toward the lightheads on each suspension arm. Verify proper operation of each braking point. If necessary, adjust each of the brakes in turn, with the goal of eliminating both binding and drift in the system. Refer to Maintenance Manual, if necessary.

6.5 Inspect Wall Control

1. **Check wall control operation by cycling it OFF and ON several times.**
2. **Cycle through intensity cycle for each lighthead controlled by the system.**
   - **Verify proper operation of all membrane switches (buttons).**
   - **Verify function of all video camera commands if the system is equipped with an optional video command menus.**

6.6 Optional Service Disconnect Switch

An optional switch (see *Figure 6-1*) is available to interrupt the ac voltage to the lighting system (and also dc battery backup voltage, if the latter is available).

- **This switch is referred to as a service disconnect switch and its purpose is to provide a method of temporarily removing power from the STERIS Lighting System without having to access the ON/OFF switch inside the canopy. It is important that you refer to Installation Instructions, P129388-228, included in the Optional Service Disconnect Switch Kit (P146670-049) for wiring details.**
- **The switch is mounted remotely, in a location chosen by the Customer.**

IMPORTANT: The service disconnect switch should not be used to routinely turn the system on and off.

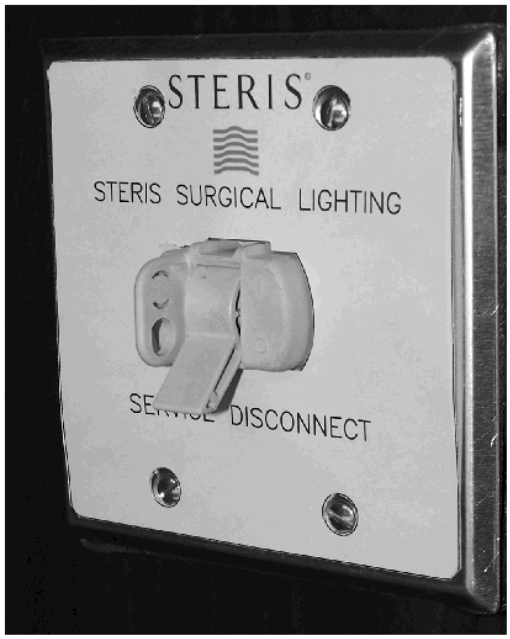

Figure 6-1. Optional Service Disconnect Switch

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Troubleshooting

7.1 Introduction

1. **Use operating instructions presented in Operator Manual to verify trouble symptoms.**
2. **After symptom has been verified, refer to the following Troubleshooting Guide. Select example that is most appropriate to your problem. Follow recommended correction.**

7.2 Camera Rotation Motor Over-Current (Code 4)

Condition

This fault indicates the camera rotation motor has experienced an over-current condition. This typically indicates the camera is not rotating smoothly inside the camera module assembly.

General Troubleshooting	Additional Information
Wall control displays flashing fault light.	1. **If camera is being used, remove and replace camera from lighthead. Retest camera.** 2. **Reset system by simultaneously pressing and holding on/off and LH1 minus (-) button for three seconds. System will reboot.** 3. **If flashing fault light persists, contact STERIS.**

7.3 Control System Cannot Communicate with Camera Module (Code 3)

Condition

This fault indicates the system cannot communicate with optional video camera. This fault is only reported if the system detects a camera is installed in lighthead number 1.

General Troubleshooting	Additional Information
Wall control displays flashing fault light.	1. **If camera is being used, remove and replace camera from lighhead. Retest camera.** 2. **Reset system by simultaneously pressing and holding on/off and LH1 minus (-) buttons for three seconds. System reboots.** 3. **If flashing fault light persists, contact STERIS.**

7.4 Current Regulation Fault (Code 10)

Condition

At least one lighthead reported an inability to maintain the correct drive current in multiple LED modules (20 mA above or below target current). This may be caused by an incorrectly adjusted power supply or by incorrectly trimmed LED modules.

General Troubleshooting	Additional Information
Control system fault.	1. **Reset system by simultaneously pressing and holding on/off and LH1 minus (-) buttons for three seconds. System reboots.** 2. **If flashing fault light persists, contact STERIS.**

7.5 Drive Controller Communication Failure (Code 9)

Condition

At least one lighthead reported an inability to communicate with at least one of its on-board drive controllers. The lighthead control board must be repaired or replaced.

General Troubleshooting	Additional Information
Control system fault	1. **Reset system by simultaneously pressing and holding on/off and LH1 minus (-) button for three seconds. System reboots.** 2. **If flashing fault light persists, contact STERIS.**

7.6 LH/MCU Firmware Mismatch (Code 14)

Condition

At least one lighthead's (LH) reported application firmware revision is newer than the image of the lighthead application firmware contained in the master control unit (MCU).

General Troubleshooting	Additional Information
Firmware mismatch fault. Wall control displays flashing fault light.	1. **Reset system by simultaneously pressing and holding on/off and LH1 minus (-) buttons for three seconds. System will reboot.** 2. **If flashing fault light persists, contact STERIS.**

7.7 LED Module Failure (Code 7)

Condition

This fault indicates that at least one lighthead has detected an open-circuit condition in at least one drive output. This may be caused by faulty LED modules or by a wiring problem.

General Troubleshooting	Additional Information
LED module fault. Wall control displays flashing fault light.	1. **Reset system by simultaneously pressing and holding on/off and LH1 minus (-) buttons for three seconds. System will reboot.** 2. **If flashing fault light persists, contact STERIS.**

7.8 LED Module Over Current (Code 6)

Condition

This fault indicates that at least one lighthead has detected an over-current condition in at least one drive output, which has, as a result, been turned off. This may be caused by faulty LED modules or by a wiring problem.

General Troubleshooting	Additional Information
LED Module Over Current. Wall control displays flashing fault light.	1. **Reset system by simultaneously pressing and holding on/off and LH1 minus (-) buttons for three seconds. System will reboot.** 2. **If flashing fault light persists, contact STERIS.**

7.9 Light Does Not Turn On

Condition

Light does not turn on.

General Troubleshooting	Additional Information
Wall control displays flashing fault light.	1. **Reset system by simultaneously pressing and holding on/off and LH1 minus (-) buttons for three seconds.** 2. **System will reboot.** 3. **If flashing fault light persists, contact STERIS.**
Circuit breaker tripped at wall/canopy control.	1. **Check circuit breakers and turn ON if tripped to OFF.**

7.10 Light Flickers When Moved

Condition

Lighthead has slight flicker when moved.

General Troubleshooting	Additional Information
Contact problem at yoke commutator, horizontal/vertical arm commutator, or central hub commutator	1. **Contact STERIS.**

7.11 Light Pattern Does Not Change

Condition

The light pattern does not change as expected.

General Troubleshooting	Additional Information
Non-adjustable pattern model	1. **Verify that lighthead is an adjustable pattern model.** 2. **If an adjustable pattern model, contact STERIS.**

7.12 Lighthead/Monitor/Accessory Drifts Once Set in Position and Released

Condition

The position changes from where it was set.

General Troubleshooting	Additional Information
Incorrect brake adjustment	1. **Contact STERIS.**
Central hub not level	1. **Contact STERIS.**

7.13 Master Control Cannot Communicate with an Installed Lighthead (Code 2)

Condition

This fault indicates that one or more of the lightheads that were initially detected by the master control are no longer communicating with the master control

General Troubleshooting	Additional Information
Control system fault. Wall control displays flashing fault light.	1. **Reset system by simultaneously pressing and holding on/off and LH1 minus (-) buttons for three seconds. System will reboot.** 2. **If flashing fault light persists, contact STERIS.**

7.14 Poor Light Color, Pattern or Intensity

Condition

Poor light color, pattern or intensity

General Troubleshooting	Additional Information
Dirt/debris may be inside lighthead	1. **Contact STERIS.**

7.15 Power Supply Requires Adjustment (Code 11)

Condition

One or more of the system's power supplies have not yet been adjusted. Newly installed systems exhibit this fault until the power supply adjustment process is carried out, which is the only method of clearing this fault.

General Troubleshooting	Additional Information
Power supply adjustment needed. Wall control displays flashing fault light.	1. **Reset system by simultaneously pressing and holding on/off and LH1 minus (-) buttons for three seconds. System will reboot.** 2. **If flashing fault light persists, contact STERIS.**

7.16 Switch Fault (Code 5)

Condition

This fault indicates that one or more of the user interface bezel switches and/or one or more of the lighthead intensity control buttons has been detected as being stuck in the closed position. The switch that is at fault is deactivated and unusable.

General Troubleshooting	Additional Information
Touch pad held down too long	1. **Reset master control by cycling the main power.** 2. **If fault persists, contact STERIS.**
Button stuck — Wall control displays flashing fault light.	1. **Reset system by simultaneously pressing and holding on/off and LH1 minus (-) buttons for three seconds. System will reboot.** 2. **If flashing fault light persists, contact STERIS.**

7.17 Touchpad Assembly is Unlit/Non Functional

Condition

Touchpad assembly is unlit or it is nonfunctional.

General Troubleshooting	Additional Information
Circuit breaker tripped	1. **Verify with hospital maintenance that breaker is turned on for light.** 2. **Contact STERIS if problem persists.**
Main power issue	1. **Turn ON lighthead at the surgeon controls of the lighthead. If lighthead illuminates, then it is receiving 24 Vdc.** 2. **Contact STERIS.**

7.18 Unknown Lighthead Assembly ID (Code 8)

Condition

At least one lighthead reported configuration error. This could happen if a lighthead was loaded with incorrect firmware, if the lighthead size switch is set incorrectly, if the wrong model of lighthead was connected to the system or if the lighthead had a hardware failure.

General Troubleshooting	Additional Information
Wall control displays flashing fault light.	1. **Reset system by simultaneously pressing and holding on/off and LH1 minus (-) buttons for three seconds.** 2. **If flashing fault light persists, contact STERIS.**

7.19 Wall Control Cannot Communicate with Master Control (Code 1)

Condition

When the wall control cannot communicate with the master control, the master control cannot indicate to the wall control what should be displayed. The wall control detects that it cannot communicate with the master control, and automatically indicates the fault.

General Troubleshooting	Additional Information
Wall control displays flashing fault light and cannot communicate with master control.	1. **Reset system by simultaneously pressing and holding on/off and LH1 minus (-) buttons for three seconds. System will reboot.** 2. **If flashing fault light persists, contact STERIS.**

7.20 Wall Control Parameters Mismatch (Code 12)

Condition

At least one lighthead's adjustable parameters do not match the master control's copy of those adjustable parameters. This can happen if lightheads have been moved from one position on the suspension system to another.

General Troubleshooting	Additional Information
Wall control displays flashing yellow light. Control system problem.	1. **Reset system by simultaneously pressing and holding on/off and LH1 minus (-) button for three seconds. System will reboot.** 2. **If flashing fault light persists, contact STERIS.**

Replacement Parts

8.1 Recommended Spare Parts

The parts listed in this section are necessary to repair this unit in most instances.

Table 8-1. Recommended Spare Parts

Description	Part Number
Brake Screw, Lighthead Yoke	10095937
Brake Screw, Lighthead/Yoke Connection	10095936
Single Use LOCTITE®[1] 242	P129377-290
Plastic Light Handle	LB20
Sterilizable Surgeon Control Handle	LB23
Silicone Replacement	LB24
Sterile Cover for Light Handle	LB53
Sterile Cover for Camera	LB54

1. *LOCTITE® is a registered trademark of Henkel Corporation.*

EMC Compliance Technical Data

9.1 EMC Compliance Technical Data

Table 9-1. Requirements Applicable to All ME equipment and ME systems (per IEC 60601-1-2, Clause 5.2.2.1)

The HarmonyAIR™ G-Series (Gen 2) Surgical Lighting System is intended for use in the electromagnetic environment specified below. The Customer or the user of the HarmonyAIR™ G-Series (Gen 2) Surgical Lighting System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment Guidance**
RF emissions CISPR 11	Group 1	The HarmonyAIR™ G-Series (Gen 2) Surgical Lighting System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The HarmonyAIR™ G-Series (Gen 2) Surgical Lighting System is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	
The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is required), this equipment might not offer adequate protection to radio frequency communication services. The Customer might need to take mitigation measures, such as relocating or re-orientating the equipment.		

Table 9-2. Guidance and Manufacturer's Declaration – Electromagnetic Immunity for all ME Equipment and ME Systems (per IEC 60601-1-2, Clause 5.2.2.1)

The HarmonyAIR™ G-Series (Gen 2) Surgical Lighting System is intended for use in the electromagnetic environment specified below. The Customer or the user of the HarmonyAIR™ G-Series (Gen 2) Surgical Lighting System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line (s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	0% U_T for 0.5 cycle @ 0, 45, 90, 135, 180, 225, 270 and 315 degrees. 0% U_T for 1 cycle	>95% Dip for 0.5 cycle 60% Dip for 5 cycles 30% Dip for 25 cycles >95% Dip for 5 seconds 0% U_T for 0.5 cycle @ 0, 45, 90, 135, 180, 225, 270 and 315 degrees. 0% U_T for 1 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HarmonyAIR™ G-Series (Gen 2) Surgical Lighting System requires continued operation during power mains interruptions, it is recommended that the HarmonyAIR™ G-Series (Gen 2) Surgical Lighting System be powered from an uninterruptible power supply or a battery. (Tested at U_T = to 240V AC and U_T= 100Vac, 50Hz for each all test levels).
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Table 9-3. Guidance and Manufacturer's Declaration – Electromagnetic Immunity for ME Equipment and ME Systems that are not Life-Supporting (per IEC 60601-1-2, Clause 5.2.2.1)

The HarmonyAIR™ G-Series (Gen 2) Surgical Lighting System is intended for use in the electromagnetic environment specified below. The Customer or the user of the HarmonyAIR™ G-Series (Gen 2) Surgical Lighting System should assure 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 Radiated RF IEC 61000-4-3	3 Vrms (Outside ISM) 6 Vrms (In ISM Bands) 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz	(V1) = 3 Vrms (V2) = 6 Vrms (V3) = 10 Vrms (E1) = 3 V/m	Portable and mobile communications equipment should be separated from the HarmonyAIR™ Mobile Stand by no less than the distances calculated/listed below: D= (3.5/V1)(√P) D= (12/V2)(√P) D= (12E1)(√P) 80 to 800 MHz D= (23/E1)(√P) 800 MHz to 2.7 GHz where P is the max. power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.
Proximity Magnetic IEC 6100–4–39	8 A/m or 138.06 dBμ A/m (30 kHz) 65 A/m or 156.26 dBμ A/m (134.2 kHz) 7.5 A/m or 137.5 dBμ A/m (13.56 MHz)		8 A/m test only applies to Home Healthcare Fields

Table 9-4. Recommended Separation Distances Between Portable and Mobile RF communications Equipment and the HarmonyAIR G-Series (Gen 2) Surgical Lighting System (per IEC 60601-1-2, Clause 5.2.2.1)

The HarmonyAIR™ G-Series (Gen 2) Surgical Lighting System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The Customer or the user of the HarmonyAIR™ G-Series (Gen 2) Surgical Lighting System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HarmonyAIR™ G-Series (Gen 2) Surgical Lighting System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = [\frac{3.5}{3}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{3}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{3}]\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Table 9-4. Recommended Separation Distances Between Portable and Mobile RF communications Equipment and the HarmonyAIR G-Series (Gen 2) Surgical Lighting System (per IEC 60601-1-2, Clause 5.2.2.1) (continued)

The HarmonyAIR™ G-Series (Gen 2) Surgical Lighting System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The Customer or the user of the HarmonyAIR™ G-Series (Gen 2) Surgical Lighting System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HarmonyAIR™ G-Series (Gen 2) Surgical Lighting System as recommended below, according to the maximum output power of the communications equipment.

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (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: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

Recommendations regarding use of high frequency surgical equipment (per IEC 60601-1-2):

The HarmonyAIR™ G-Series (Gen 2) Surgical Lighting System is intended for use with high frequency surgical equipment to the following conditions:

1. All cables and attachments must be placed no closer than 1 meter (39.4") to the lighthead.

2. If degradation of performance is noted, the lighthead must be positioned more than 1 meter (39.4") from the HF surgical equipment.

WARNING

POSSIBLE EQUIPMENT DAMAGE

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12") to any part of the HarmonyAIR™ G-Series (Gen 2) Surgical Lighting System, including cables specified by STERIS. Otherwise, degradation of the performance of this equipment could result.

Examples of portable RF communications equipment include TETRA 400, GMRS 460, FRS 460, LTE Band 13 and 17, GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5, GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS, Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 and WLAN 802.11 a/n.