HarmonyAIR® G-Series (Gen 2)

Surgical Lighting System

APPLICATION

The system is designed to illuminate operating room surgical fields. The system can be adjusted for light intensity in a fixed or variable pattern size.

The system is designed to replace existing surgical lights, or to be installed as part of major renovations to existing facilities or in new facilities. The ceiling mounting plate is compatible with most existing installations.

DESCRIPTION

The system is a configurable, modular lighting system, providing high quality illumination for surgical and diagnostic applications.

The system can be configured to meet the needs of a wide variety of applications ranging from simple diagnostic procedures performed in outpatient surgery centers, to more complicated procedures performed in major acute care suites. Locations of use include operating rooms, exam and treatment rooms, hospital emergency departments and hospital intensive care units.

A wall-mounted panel provides a user interface for controlling lightheads and camera features. The wall-mounted panel monitors LED module status and can be used to control light intensity, as well as camera features such as focus, camera rotation and zoom. In addition, the lightheads can be turned on and off, and their intensity can be controlled using conveniently located surgeon's controls on the light handle of each lighthead. The surgeon's push button controls include a one-touch command to turn all lightheads on simultaneously to their previous settings.

Lightheads provide cool, shadow controlled lighting. The system can be ordered with one, two or three lightheads mounted to a suspension system capable of continuous 360° rotational positioning. The lightheads are available in both adjustable and fixed pattern models. The illumination pattern size is adjusted by rotating the handle.

Most systems can be configured (at time of order) to include one or two flat panel video monitor support

STANDARDS

All components of the lighting system meet the applicable requirements of the following standards and/or regulations and carry the appropriate symbols:

- **IEC 60601-1: Medical Electrical Equipment.** Part 1: General requirements for safety. Third Edition, 2005.
- **ANSI/AAMI ES60601-1:2005**
- **CAN/CSA C22.2 No. 60601-1,** Third Edition
- **IEC 60601-2-41:2009, Second Edition: Medical Electrical Equipment, Part 2-41:** Particular Requirements for the Safety of Surgical Luminaires and Luminaires for Diagnosis.
- **IEC 60601-1-2:2007.** Medical Electrical Equipment-Electromagnetic Compatibility Requirements and Tests.
- **IEC 60825-1.** Laser Standard.
- E**N1041: 2009.03.27** Information Supplied by the Manufacturer with Medical Devices.
- **CE Mark to Directive 93/42/EEC (Medical Device Directive).**

FEATURES

Lightheads offer an adjustable pattern size and provide naturally appearing white light with a general color rendering index (CRI) up to 96 and a deep saturated red color rendering index (Ra) up to 98, and a color temperature of 4400 Kelvin. The lightheads dissipate heat away from the surgical field for patient safety and surgical team comfort.

Adjustable pattern size is accomplished with a dual-lens configuration. By rotating a sterilizable lighthandle, the operator can adjust the pattern size to a diameter within the range of 180-280 mm (7-11"). Regardless of the pattern size chosen, illumination across the beam remains smooth.

Illumination intensity can be adjusted up to 160,000 lux using surgeon pushbutton controls located on the handle bezel, or from a wall-mounted, user interface panel. Each lighthead features individual intensity control, but all

lightheads on a single system can be turned off simultaneously from any one lighthead.

The lighthead's perimeter features a continuous, non-sterile grasping surface for positioning by the circulating nurse or other non-sterile surgical participants.

Suspension System is lightweight and highly customizable to meet the needs of today's operating room. The system is highly customizable with multiple options for accessory mounts such as single monitors, side-by-side monitors, radiation shields, or ConnectPoint offerings. A robust braking system provides effortless maneuverability without binding or drifting.

Control Center produces control voltage for each lighthead in the system as well as the optional video camera module. The intensity of each lighthead can be remotely adjusted to one of seven discrete levels, or can be turned off completely. Each lighthead is identified by an easy-to-read number on the wallmounted user interface panel (control panel). The number is duplicated on the suspension system for the appropriate lighthead. The mounted controls operate on 100-240 Vac, 50/60 Hz delivered to a maximum of three dc power supplies. Each dc power supply delivers 24 Vdc per lighthead. In a multiple lighthead system, all canopy-mounted control electronics are dual-powered for reliability. The wall-mounted control panel is powered by low-voltage direct current. Canopy- or ceiling-mounted controls and power supplies are compatible with the following ratings: 100 - 240 Vac, 5 - 2 A maximum for a three-lighthead system. Earth leakage is limited to less than 3 mA. Refer to Notes and Utility Requirements for further information.

Video camera (optional) can be included in camera-ready lighting systems. This option must be requested at time of sale. Camera-ready capability is not available as a field upgrade or add on.

NOTE: For a camera-ready system, a video camera can be purchased and added to the system at any point in time.

OPTIONS

Optional Video Camera — The HD camera module is a high resolution, full-featured, color, digital video camera that can be mounted as an optional component to the camera-ready system light handle. A lighthead's mechanical and optical performance is not compromised by the unobtrusive, integrated camera module (when installed). The camera module provides a quality video image that enables the Customer to document surgical procedures for a variety of applications, including teaching and archival purposes. The camera module complies with relevant safety standards for use in medical or surgical contexts. The video camera is located in the sterile handle of the lighthead, where it provides an unobstructed view of the surgical site. The control panel provides a convenient means of controlling the many built-in camera features: zoom, rotate, focus and brightness. Automated features include focus and brightness. Video access to the signal originates at the ceiling plate, or at a video rack. The HD video signal format is DVI on HDMI connector (720p/60 Hz.).

The high-resolution HD Camera Module provides state of the art video capability using an HD CMOS sensor with approximately 1,000,000-pixel resolution. The camera provides a 120X zoom ratio (10X optical + 12X digital) so that fine detail is easily visible. The camera focal distance ranges from 10 mm (wide angle) to 800 mm (telephoto). The signal-tonoise ration exceeds 50 dB for exceptionally clear images. The compact camera is protected by a strong, molded urethane housing. The HD camera has an optical glass lens that provides a clear video image while sealing the camera optics from dust and fluids.

The camera module is designed for quick, tool-free attachment or removal from the lighthead, allowing a single camera to be shared among multiple lighting systems.

The system must be pre-ordered camera-ready to provide full video camera capability. Camera-ready systems, as ordered from the factory, are ready to accept an HD camera Module. The control center automatically detects the HD camera module when installed into the lighthead. All in-light camera functions are controlled from the control center. The HD camera installs into the bottom primary (lowest) lighthead. Only one HD camera-ready lighthead can be used per wall controller. Every camera-ready"system has video signal wiring pre-installed in the suspension system arms. Wiring is connected at the rotating joints through multiple dedicated commutators to provide unlimited rotation of each joint of the suspension system for ease in positioning the lights for optimal illumination of the surgical site.

The camera module draws its power directly from the camera-ready wiring harness. The lighting system must be ordered camera-ready to provide the proper power requirements for the camera module. A Camera Component Kit is also required and must be installed in the canopy.

HD Accessories — A sterile disposable camera cover is available (with an integral clear lens) to maintain the video signal quality while allowing members of the surgical team to grasp the camera module to aim the camera or adjust the pattern size or intensity of the light.

HD Camera Cleaning — The HD Camera Module contains electronics which may be damaged if immersed in liquid or exposed to temperatures above 50°C. Therefore, the camera module is not suitable for liquid or steam sterilization. The outer surface can be cleaned with chemicals recommended by STERIS (see Operator Manual 11028645).

Optional Flat Panel Monitor — Arm The system can use an optional Single Flat Panel Monitor (SFPM) arm or a Dual Flat Panel Monitor (DFPM) arm to support a video monitor. The Flat Panel Monitor (FPM) is designed for use in hospital operating rooms, outpatient surgery centers or intensive care units. The FPM can be ordered with or without a primary surgical lighting system.

Hospitals and outpatient clinics often require advanced audiovisual support in close proximity to the patient surgical site. Depending on the area of the facility in which they are working and the specialty they are performing, hospital staff may require the use of multi-monitor feeds.

The FPM is a flexible system of mechanical interconnections enabling users to define the system configuration, allowing the system to accommodate different styles of power inputs and signal inputs within a facility or even within a given room. All electrical and signal configurations are determined by the Customer and installed by third-party providers.

SFPM or DFPM mounts do not include internal wiring when shipped from the factory. Maximum allowable total monitor

weight for SFPM is 15 kg (33 lb). Maximum allowable total monitor weight for DFPM is 10.5 kg (23 lb) per monitor.

Viewing – Monitors are mounted in landscape orientation and tilted independently, on two separate axes, to optimize screen view.

The monitor spring arm yoke rotates 315° (SFPM)/320° (DFPM) around the end of the spring arm. Monitor spring arm features an adjustable upward range of motion to avoid hitting the ceiling.

Empty suspension allows for either high or low voltage wiring arrangement. (Wiring not provided by STERIS.)

FPM metal surfaces are treated with a baked-enamel powder coating. Covers at knuckles and similar areas are made from engineering-grade plastic.

Monitor Spring Arm Maneuverability – The fixture can move freely throughout its range of maneuverability without drifting when positioned at any point. The monitor may be positioned at any comfortable viewing height (i.e., eye-level).

Area of Coverage[1] – Horizontal arm rotates 270° around the hub. The single FPM spring arm (attached to the end of the horizontal arm) rotates 310°.

FPM Notes – Customer is responsible for ensuring that ceiling or wall structure adequately supports the fixture. See weights and moments listed on equipment drawing. Also:

1. Mounting plate must be level.
2. The system must be properly grounded.
3. The Customer is responsible for compliance with applicable local and national codes and regulations.

FPM Utility Requirements – Electrical power requirements for monitors must be determined and properly configured by a qualified technician. Video signal type to monitors must be determined and properly configured by third-party video system integrator (video wiring and configuration services not provided by STERIS).

ACT Enabled Electronic Interface — The STERIS ACT enabled electronic interface permits networking of the surgical lighting system with various thirdparty control or automation systems. These third-party aspects provide users with remote control over many features of the surgical lighting system.

INSTALLATION

A single or tandem mounting plate is provided for installation to an above-ceiling support structure (above-ceiling support structure is not supplied by STERIS). See equipment drawings for specifications and details. A canopy is also furnished to conceal the ceiling plate; a flexible gasket seals the gap between the canopy and ceiling.

The lighting system can be mounted in various locations above the surgical site, including centrally; to the right or left (or both); as well as at the head or foot (or both) with respect to surgical table.

The standard wall-mounted control extends less than 6 mm (1/4") beyond wall surface. Electrical connections are not provided by STERIS.

STANDARD ACCESSORIES

Sterile disposable cover for standard lighthandle allows members of surgical team to grasp and adjust standard lighthead handle, while providing access to all surgeon's lighthead controls. Disposable sterile covers for flat-panel handles and video camera are also available.

Automatic battery backup changeover allows the lighting system to automatically switch to hospital 24 Vdc emergency power supply in the event of Vac power interruption. Emergency dc power supply is not provided by STERIS.

SUPPORT STRUCTURE

The ceiling structure (installed by a third party prior to lighting system installation) must be level and must adequately support the surgical light system configuration to be installed. Data provided on the equipment drawing (available separately from STERIS) shows the maximum loads and moment forces for all configurations of the system.

PREVENTIVE MAINTENANCE

A global network of skilled service specialists can provide periodic inspections and adjustments to help ensure low-cost peak performance. STERIS representatives can provide information regarding annual maintenance programs.

NOTES

Important: Reference equipment drawings for detailed installation requirements. This technical data sheet is not intended as a pre-installation or planning guide.

1. Ceiling structure must adequately support surgical light system which weighs and exerts a moment as indicated on the equipment drawing (available separately from STERIS).
2. Ceiling hardware compensates for ceiling irregularities (hardware not provided by STERIS). Customer is responsible for ensuring an adequate ceiling structure.
3. Fixture must be grounded. Adequate ground must be provided by running a separate ground wire to ceiling structure.
4. STERIS recommends general illumination (supplied by a third party) in operating room of 2152 lux at the surgical site. Recommendation does not apply to ambulatory surgical center, emergency room or critical care unit applications.
5. Explosion Hazard – Do not use in the presence of flammable anesthetics.
6. Installation of power supply must comply with all applicable building codes and industrial standards for country, state and local, or otherwise.

UTILITY REQUIREMENTS

CUSTOMER IS RESPONSIBLE FOR COMPLIANCE WITH APPLICABLE LOCAL AND NATIONAL CODES AND REGULATIONS.

1. *Consult equipment drawings for critical dimensions and tolerances.*

Electricity – Canopy-mounted controls are compatible with the following ratings:

- 100 - 240 Vac, 50/60Hz.
- 100 - 240 Vac, 5 - 2 A maximum for a three-lighthead system.
- Remote Power Control (RPC) box is required for a tandem mount installation.
- All power supplies have a battery connection for automatic battery backup switching. The ceiling mounted power supplies need a DC-DC converter (not provided by STERIS) capable of regulating down to 20 VDC. Refer to equipment drawing (10067777).
- Earth current leakage is limited to less than 3mA.
- Ceiling plate desired mounting height is at or slightly above the finished ceiling. Distance between finished ceiling and upper edge of canopy controls power supply enclosure should be 3 -6 mm (1/8-1/4"). If ceiling plate is mounted below the finished ceiling, a minimum 3 mm (1/8") gap must be maintained between the power supply enclosure and the ceiling plate.

NOTE:

Recommended ceiling plate mounting tolerances differ when the system is part of a tandem mounting configuration. Refer to Harmony EMS builder program and equipment drawings for information.

NOTE: Remote Power Control (RPC) is required for a tandem mount installation.

THREE LIGHTHEAD SYSTEM CANOPY CONTROLS ENVIRONMENTAL REQUIREMENTS (System Running)

For sealed ceiling applications:

Canopy Ambient 60°C (140°F) Maximum

Room Ambient 25°C (77°F) Maximum

- Interstitial space temperature has minimal effect on the canopy ambient in a completely sealed ceiling application

For vented ceiling applications (6 mm [1/4"] minimum gap between ceiling and ceiling plate):

Canopy Ambient 60°C (140°F) Maximum

Room Ambient 25°C (77°F) Maximum

- 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).

Refer to the Following Equipment Drawing for Installation Details

Equipment Drawing Number	Equipment Drawing Title
P136824–469	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
XXXXX — (Part Number to be Provided)	HARMONYAIR G-SERIES (GEN 2) SURGICAL LIGHTING SYSTEM MAINTENANCE MANUAL
P764335994 (Update Part Number)	HARMONYAIR G-SERIES (GEN 2) SURGICAL LIGHTING SYSTEM INSTALL CHECKLIST
11028464	SUPPORT STRUCTURE DETAIL, G-SERIES (GEN 2)
11028465	STANDARD MOUNT DETAIL, G-SERIES (GEN 2)
10068139	CEILING ACCESS DETAIL
11028466	SPECIAL ABOVE CEILING MOUNT DETAIL, G-SERIES (GEN 2)
11028467	STRUCTURAL PLATE BOLT HOLE PATTERN, G-SERIES (GEN 2)
10068160	STRUCTURAL PLATE INSTRUCTIONS
11028468	TANDEM SUPPORT STRUCTURE MOUNTING HEIGHT DETAIL, G-SERIES (GEN 2)
11028469	TANDEM SUPPORT STRUCTURE MOUNTING HEIGHT DETAIL, G-SERIES (GEN 2)
11028470	TANDEM SUPPORT STRUCTURE MOUNTING HEIGHT DETAIL, G-SERIES (GEN 2)

Equipment Drawing Number	Equipment Drawing Title
11028471	TANDEM SUPPORT STRUCTURE MOUNTING HEIGHT DETAIL, G-SERIES (GEN 2)
11028472	TANDEM SUPPORT STRUCTURE MOUNTING HEIGHT DETAIL, G-SERIES (GEN 2)
11028473	TANDEM SUPPORT STRUCTURE MOUNTING HEIGHT DETAIL, G-SERIES (GEN 2)
11028474	TANDEM SUPPORT STRUCTURE MOUNTING HEIGHT DETAIL, G-SERIES (GEN 2)
11028475	TANDEM SUPPORT STRUCTURE MOUNTING HEIGHT DETAIL, G-SERIES (GEN 2)
11028476	TANDEM SUPPORT STRUCTURE MOUNTING HEIGHT DETAIL, G-SERIES (GEN 2)
11028477	TANDEM SUPPORT STRUCTURE MOUNTING HEIGHT DETAIL, G-SERIES (GEN 2)
11028478	TANDEM SUPPORT STRUCTURE MOUNTING HEIGHT DETAIL, G-SERIES (GEN 2)
11028479	TANDEM SUPPORT STRUCTURE MOUNTING HEIGHT DETAIL, G-SERIES (GEN 2)
11028480	SPRING ARM & LIGHTHEAD DETAIL, G-SERIES (GEN 2)
11028481	SFPM SPRING ARM & YOKE DETAIL, G-SERIES (GEN 2)
11028482	DFPM SPRING ARM & YOKE DETAIL, G-SERIES (GEN 2)
11028483	SPRING ARM & CONNECTPOINT DETAIL, G-SERIES (GEN 2)
11028484	CONNECTPOINT CONDUIT/JUNCTION BOX DETAIL, G-SERIES (GEN 2)
11028485	SPRING ARM & RSHIELD PROTECTIVE DEVICE DETAIL, G-SERIES (GEN 2)
11028647	EQUIPMENT DRAWING, LAMINAR FLOW MOUNT, G-SERIES (GEN 2)

For Further Information, contact:

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