HarmonyAIR® ALYON

Surgical Lighting System

APPLICATION

The surgical lighting system is a variable pattern, variable intensity surgical lighting fixture designed to provide visible illumination of the surgical field or the patient for the operating room staff. The system also facilitates monitor mounting and transmission of video and control signals.

This product may contain communication devices. A medical image communications device provides electronic transfer of medical image data between medical devices. It may include a physical communications medium, modems, interfaces, and a communications protocol.



DESCRIPTION

- The surgical lighting system is a customizable lighting system, providing high quality illumination for surgical and diagnostic applications.
- The lighthead is designed to provide cool, shadow-reduced, color-corrected lighting. Light intensity level can be adjusted by the surgeon, or other sterile surgical team members, using control push buttons on the system lighthead. Illumination pattern size is varied by rotating the lighthead light handle and auto-intensity automatically adjusts the light output to keep the light intensity delivered to the operation site consistent when the lighthead is moved or spot size adjusted. Adaptive Lighting compensates for obstructions to the lighthead by dimming blocked LEDs and boosting unobstructed LEDs. Lighting intensity is monitored and controlled from a wall control unit. In addition to lighthead intensity control, the wall control unit monitors and operates camera features and overall system diagnostics.
- The system can be configured to meet the needs of a wide variety of applications. The system may be configured for effective use in exam and treatment rooms, hospital emergency departments and hospital intensive care units.
- The surgical lighting system can be purchased with provisions to support a HD in-light camera and is also able to support a variety of video and control signals transmitted through cabling that can be installed within optional video monitor arms. The monitor arms are not provided with video cabling. Contact STERIS regarding monitor arm cabling.
- The ceiling mounting plate is designed for compatibility with existing installations. The suspension system provides continuous 360° rotational positioning for light arms and 330° rotation for monitor arms.

STANDARDS

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

- Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance [ANSI/AAMI ES60601-1:2005+A1;A2]
- Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance [CSA C22.2#60601-1:2014 Ed.3+A2]
- Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability [IEC 60601-1-6:2010 Ed.3 +A1;A2]
- Medical Electrical Equipment - Part 2-41: Particular Requirements for the Basic Safety and Essential Performance of Surgical Luminaires and Luminaires for Diagnosis [IEC 60601-2-41:2021 Ed.3]
- IEC 60601-1:2005/AMD 2:2020
- IEC 60601-2-41:2021
- IEC 60601-1-2 Ed. 4.1:2020
- IEC 60601-1-6:2010 (Third Edition) + A1:2013 + A2:2020
- IEC 62304:2006–AMD1:2015

FEATURES

Power balancing LEDs allow for adjustment of the lights pattern size (focal point) while maintaining excellent uniformity of illumination across the beam. Each lighthead provides color corrected, naturally appearing white light with a general color rendering index (CRI) up to 98, deep saturated red color rendering index (Ra) up to 97, and adjustable color temperatures between 3,500K and 5,000K in four distinct settings. LED emitters are designed to emit light in the visible spectrum, with little or no ultra-violet and infra-red light. LED light reduces heat on surgical field for increased patient safety and improved surgical team comfort.

Illumination intensity for the lighthead can be adjusted up to approximately 160,000 lux (14,800 fc), by using the surgeon's push button controls located on the light handle, wall control unit, or compatible OR Integration systems.

Each lighthead features individual intensity control, but all lightheads on a single system can be turned on or off

simultaneously from any one lighthead. The operator can adjust the pattern size for lightheads during a procedure by rotating the light handle. Lighthead pattern sizes are adjustable to diameters between 6.3" (160 mm) and 11.0" (280 mm) in four preset options.

Adaptive lighting and Auto Intensity features keep consistent illumination while pattern size is adjusted and compensate for obstructed LEDs by dimming blocked LEDs and boosting non-obstructed LEDs.

Task and ambient light modes can be used when surgical lighting is not needed for ancillary tasks and to illuminate the OR.

The lightweight suspension system is designed to allow frequent lighthead positioning through a wide range of motion without binding or drifting. The suspension system also features low-height lighthead positioning, allowing for low lateral illumination.

The system allows for up to four total arms that can be customized with lightheads or optional accessories.

Each system can support up to three lightheads on one wall control unit. The intensity of each lighthead can be remotely adjusted to one of ten levels or can be turned off completely. Lightheads can also be placed into “task mode” which brings the light down to a ~5% intensity to be used in the OR for ancillary tasks outside of the surgical field. Each lighthead is identified by an easy-to-read number on the display screen of the wall controller. The number is duplicated on the suspension system for the appropriate lighthead.

High definition (HD) video capability is available for the lighting system and must be ordered specifically at the time of sale.

NOTE: For HD-ready systems, only the lowest lighthead on the primary mount is capable of transmitting HD video signals.

MONITOR ARMS

Hospitals and clinics often require advanced audio-visual support in proximity to the patient surgical site at or near the sterile field. Depending on the area of the facility in which they are working and the procedure they are performing, hospital staff may require the use of multi-monitor feeds. The monitor support options are suited to both specialty and general-purpose operating rooms and all critical care areas; and are intended to augment all the lighting needs within a hospital. Flexibility and leading performance characteristics make these video monitor support arms useful and function across a wide range of potential applications, from the largest teaching hospitals to the smallest surgical facility.

Monitor arms are not pre-wired. Contact STERIS for monitor arm wiring information.

VIEWING

Monitors tilt independently to suit the needs of different viewers. The monitor yoke rotates 320° about the end of the spring arm. This monitor spring arm features expanded upward range of motion (up 45°, down 70°).

Single or dual monitor mounts do not include internal wiring when shipped from the factory. Maximum allowable total monitor weight for Single Monitor is 33 lb (15 kg). Maximum allowable total monitor weight for Dual Monitor is 33 lb (15 kg) per monitor. Maximum monitor size for both the single and dual monitor mount is 32" (813 mm).

INSTALLATION

A mounting plate is provided for installation to an above-ceiling support structure (support structure is not supplied by STERIS). A canopy is also furnished to conceal the ceiling plate. A flexible gasket seals the gap between the canopy and ceiling.

OPTIONAL ACCESSORIES

The sterile, disposable cover used on the standard lighthead handle allows members of the surgical team to grasp and adjust the standard lighthead handle, while allowing access to all surgeon's lighthead controls.

A separately-available sterilizable silicone sleeve, can be purchased to allow the surgeon access to lighthead-mounted controls during procedures.

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.

STERIS also provides complete video integration services.

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. The maximum loads and moments for various configurations of the surgical lighting system are listed in the equipment drawings.

NOTES

Reference equipment drawings for detailed installation requirements. This document is not intended as a complete pre-installation or planning guide.

1. Ceiling structure must adequately support surgical lighting system which weighs and exerts a moment as indicated in the equipment drawings.
2. Fixture must be grounded. Adequate grounding must be provided by running a separate ground wire to ceiling structure.
3. STERIS recommends general illumination in operating room of 2152 lux (200 fc).
4. Power Requirement: Wall Control Unit – refer to equipment drawings for specifics.
5. Explosion Hazard: Do not use in the presence of flammable anesthetics.
6. Product surfaces of the Wall Control Unit shall be cleaned with hospital-grade isopropyl alcohol (90% solution) applied only via a clean, lint-free cloth.

UTILITY REQUIREMENTS

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

Electricity – Control Center is compatible with the following ratings: 100-240 Vac 4 - 2 Amps.

Typical lighthead power consumption is 40 W for lighthead with auto intensity off.

MOUNTING ARRANGEMENT

The system is mounted to a ceiling plate provided by STERIS. Ceiling plate is attached to an above-ceiling support structure (not provided by STERIS) located per STERIS recommendations (see equipment drawings for specifications and details).

Refer to the Following Equipment Drawing for Installation Details	
Equipment Drawing Number	**Equipment Drawing Title**
11042951	Light Arm Articulation
11042952	Single Monitor Articulation
11042425	ConnectPoint Arm Detail
11042953	Dual Monitor Articulation
11041488	HarmonyAIR ALYON Surgical Lighting System, Operator Manual
11041489	HarmonyAIR ALYON Surgical Lighting System, Installation Manual

Selections Checked Below Apply To This Equipment

OPTIONAL ACCESSORIES

- ☐ Sterile Disposable Light Handle Covers
- ☐ Sterile Disposable Camera Covers
- ☐ Universal Mounting Adapter
- ☐ High Definition (HD) Camera Module

Item:	
Locations:	

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.

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