HarmonyAIR® A-Series

Surgical Lighting System

APPLICATION

The HarmonyAIR A-Series 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 HarmonyAIR A-Series Surgical Lighting System is a modular lighting system, providing high quality illumination for surgical and diagnostic applications.

The lighthead is designed to provide cool, shadow-reduced, color-corrected lighting. The system mitigates air turbulence for laminar airflow systems and allows for smoke and heat evacuation. 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. Lighting intensity is monitored and controlled from a wall mounted Integrated Wall Control (IWC). In addition to lighthead intensity control, the IWC monitors and operates camera features and monitors overall system diagnostics.

The system can be configured to meet the needs of a wide variety of applications ranging from simple diagnostic procedures to outpatient surgery centers, as well as major surgical suites in large teaching hospitals. 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 4K or 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 is capable of providing continuous 360° rotational positioning for light arms and 330° rotation for monitor arms. Stops on monitor arms are adjustable post-installation and provide 12 different stop mounting locations.

SPECIFICATIONS

Electricity	Control Center is compatible with the following ratings: 120-240 Vac 7 - 3 Amps, Current leakage is limited to less than 2 mA for Integrated Wall Control (IWC). Typical lighthead power consumption is 40 W for A-Series lighthead with auto intensity off.

STANDARDS

Each system meets applicable requirements of the following listings and standards, and carries the appropriate symbols:

- International Standard: IEC 60601-1: Medical Electrical Equipment. Part 1: General requirements for safety. Third Edition, 2005+Corr.1:2006+Corr.2:2007+A1:2012
- International Standard: IEC 60601-2-41:2009, Second Edition: Medical Electrical Equipment, Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis.
- CAN/CSA C22.2 No. 60601-1:2014 Ed. 3
- ANSI/AAMI ES60601-1:2005 ▪ IEC 60601-1-2:2014
- IEC 60601-1-6:2010+AMD1:2013
- IEC 62304:2006+A1:2015

FEATURES

WaveLens Technology enables a wide range of pattern size adjustment while maintaining excellent uniformity of illumination across the beam. Lightheads are available in a fixed or adjustable color version. Each lighthead provides color corrected, naturally appearing light with a general color rendering index (CRI) up to 97,a deep saturated red color rendering index (Ra) up to 98, and a color temperature of 4400 (±300) Kelvin for the fixed color version and a range of 3500-5100 (±200) Kelvin for the adjustable color version. 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 handle bezel, Integrated Wall Control (IWC), 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 11.8" (300 mm). Each lighthead is also equipped with a continuous non-sterile grasping surface for positioning the lighthead and non-sterile control of intensity for non-sterile personnel.

The aluminum lightweight suspension system is designed to allow frequent lighthead positioning through a wide range of motion without binding or drifting. A-Series features a patent pending braking system that can allow up to 5+ years without the need for brake tension adjustment. The suspension system also features low-height lighthead positioning, allowing for low lateral illumination.

The system is built using a modular suspension which allows future growth of the system via the addition of two auxiliary arms supporting eight different accessories. Lightheads can be removed and replaced as required or individual lightheads can be replaced with an upgraded version when available.

Each system can support up to four lightheads on one IWC. 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 IWC. The number is duplicated on the suspension system for the appropriate lighthead.

4K or High Definition (HD) video capability is available for the lighting system and must be ordered specifically at the time of sale. Refer to SD930 for information about the STERIS HD camera module and STERIS HD-Ready system. Refer to 11033843 for information about 4K camera module.

NOTE: For camera ready systems, only the lowest lighthead on the primary and/or secondary spindle (up to two spindles) is capable of transmitting video signals.

CONSTRUCTION

Each lighthead is constructed of lightweight, durable materials.

The A-Series lighthead optical system consists of multiple Light-Emitting Diode (LED) light sources, Total Internal Reflection (TIR) optics and Harmony Wave Lenses. This state of-the-art design provides for brilliant, though cool, illumination and a usable LED life of approximately 60,000 hours.

The Wave Lenses are made from an optical grade, shatter resistant acrylic and polycarbonate material. Lenses are sealed into the lighthead to prevent accumulation of dust or fluid in system optics.

The lighthead is mounted to a combined horizontal and spring arm assembly (suspension arm), which rotates around a main spindle. Suspension arm assemblies are specifically designed to support lightheads. The main spindle is attached to the ceiling plate, which mounts to the facility's above-ceiling support structure (support structure is not supplied by STERIS). The main spindle contains precision bearings allowing continuous 360° rotation of the extension arms. Each suspension arm supports one lighthead. Lighthead spring arms also provide continuous 360° rotation and an adjustable counterbalance mechanism for effortless vertical positioning. Electrical commutators located within the suspension system transmit power and control signals, while video (optional) signals are transmitted via a Fiber Optic Rotary Joint (FORJ) while providing continuous rotation. All rotation points utilize a patent pending brake ring technology which allows 5+ years without the need for adjustment of the braking tension.

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 supported by the main spindle, or on an auxiliary secondary spindle (up to two).

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 (standard 20° upper stop can be changed to 30°, or 40° upper stop point).

Single or dual monitor mounts do not include internal wiring when shipped from the factory. Maximum allowable total monitor weight for Single Monitor is 35 lb (16 kg). Maximum allowable total monitor weight for Dual Monitor is 26.5 lb (12 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. Integrated Wall Control (IWC) extends approximately 4" (102 mm) beyond wall surface.

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.

An available sterilizable handle is included, and additional handles can be purchased to allow the surgeon access to lighthead-mounted controls during procedures.

An optional ambient light fixture can be installed at the system hub. The ambient light sheds low-level green light which provides illumination in the surgical suite. Illumination from the ambient light fixture can be configured to operate manually (turned on or off at the IWC), or the ambient light can be configured to operate automatically (turns off when any system lighthead is turned on and turns on when all system lightheads are turned off). When configured for automatic operation, the ambient light can still be manually turned on or off at the control center. Up to two ambient lights can be controlled by one IWC.

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 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 footcandles).
4. Power Requirement: Integrated Wall Control (IWC) – refer to equipment drawings for specifics.
5. Explosion Hazard: Do not use in the presence of flammable anesthetics.
6. Product surfaces of the Integrated Wall Control (IWC) shall be cleaned with hospital-grade isopropyl alcohol (90% solution) applied only via a clean, lint-free cloth.

Refer to the Following Equipment Drawing for Installation Details	
Equipment Drawing Number	**Equipment Drawing Title**
11015056	Light Arm Articulation
11015057	Spring Arm Articulation
11015058	Auxiliary Arm Detail
11015059	Dual Monitor Articulation

Selections Checked Below Apply To This Equipment

OPTIONAL ACCESSORIES

- ☐ Sterile Disposable Light Handle Covers
- ☐ Sterile Disposable Camera Covers
- ☐ Monitor Handles
- ☐ Ceiling Mounted Ambient Light
- ☐ Auxiliary Arm Mount (Up to Two per Primary Spindle)
- ☐ High Definition (HD) Camera Module (Refer to SD930)
- ☐ 4K Camera Module (Refer to 11033843)

AUXILIARY ARM ACCESSORIES

- ☐ Camera Ready Lighthead
- ☐ Non-Camera Ready Lighthead
- ☐ Radiation Shield
- ☐ Free5 Camera System
- ☐ Single Monitor Mount
- ☐ Dual Monitor Mount
- ☐ Harmony ConnectPoint (All Power)
- ☐ Harmony ConnectPoint (Video)

Item:	
Locations:	

For Further Information, contact:

STERIS Corporation
5960 Heisley Rd.
Mentor, OH 44060–1834 ▪ USA
440–354–2600 ▪ 800–548–4873
www.steris.com

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

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

©2021, STERIS Corporation.
All rights reserved.

This document is intended for the exclusive use of STERIS Customers, including architects or designers. Reproduction in whole or in part by any party other than a Customer is prohibited.