



**APPLICATION**

The Harmony vLED Surgical Lighting 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**

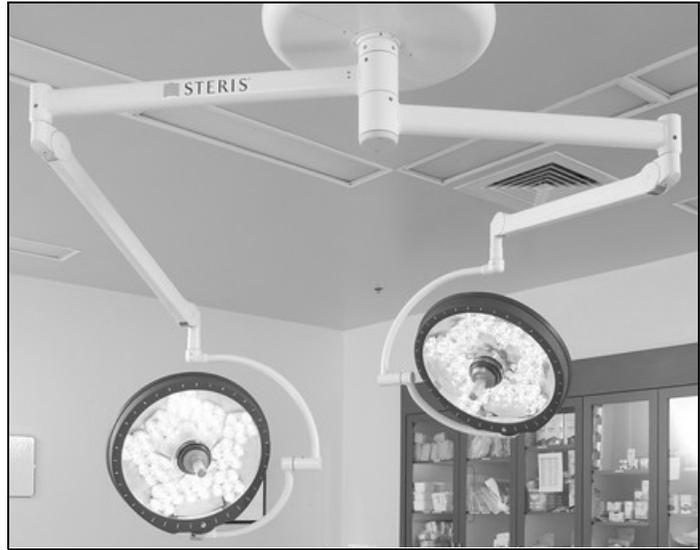
The Harmony vLED Surgical Lighting System is a configurable, modular lighting system, providing high quality illumination for surgical and diagnostic applications.

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 lighthoods and camera. 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 lighthoods can be turned on and off, and their intensity can be controlled using conveniently located surgeon's controls on the lighthandle of each lighthead. The patented surgeon in-light controls include a one-touch command to turn all lighthoods on simultaneously to their previous settings.

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

Most Harmony vLED Surgical Lighting Systems can be configured (at time of order) to include one or two video monitor support arms.



(Typical – details may vary.)

**STANDARDS**

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

- **International Standard: IEC 60601-1: Medical Electrical Equipment.** Part 1: General requirements for safety. Third Edition, 2005.
- **ANSI/AAMI 60601-1:2005**
- **CAN/CSA C22.2 No. 60601-1, Third Edition**
- **International Standard: 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.
- **IE 60878:** Graphic Symbols for Electrical Equipment in Medical Devices.
- **EN1041: 2009.03.27** Information Supplied by the Manufacturer with Medical Devices.
- **CE Mark to Directive 93/42/EEC (Medical Device Directive).**
- **AAMI 11607: 2006.01.01,** Packaging for Terminally Sterilized Medical Devices (Notified Body–ITS/ETL SEMKO 0413).

Item \_\_\_\_\_  
 Location(s) \_\_\_\_\_  
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## FEATURES

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Lighthead models are either **adjustable pattern** or **fixed pattern models**.

Both lighthead models 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 lighthead models 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 lighthead handle, 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.

**Fixed pattern** lighthead models provide a 180 mm (7") diameter, non-adjustable pattern.

**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 lighthead models 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.

**vLED Suspension System** is lightweight and designed for a wide range of lighthead positioning without binding or drifting. The dual or single cardanic yokes offer a wide range of motions and positioning.

**vLED Control** 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 wall-mounted 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.

## CONSTRUCTION

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The system's lighthead uses a dual-lens configuration for adjustable-pattern and a single-lens design for fixed-pattern lighthead models. Lighthead models are constructed of lightweight, durable materials.

The optical system consists of multiple Light Emitting Diode (LED) light sources, Total Internal Reflection (TIR) optics and optical lenses. The lighthead models are fitted with multiple module assemblies mounted to, and aimed from, a precisely machined aluminum cover. Each module is mounted with six (vLED) individual LED emitters coupled with a TIR optic. This state-of-the-art design provides for brilliant, though cool, illumination and a usable LED life of approximately 50,000 hours.

The system's lenses are made from optical grade shatter resistant material and are sealed into the lighthead to prevent accumulation of dust.

Lighthead assembly is suspended from a horizontal arm, which rotates around a main spindle. Suspension arm assemblies are specifically designed to support lighthead models or monitors.

The suspension main spindle is attached to the ceiling plate, which mounts to the facility's above-ceiling support structure (support structure is not provided by STERIS). The main spindle contains a precision bearing allowing continuous 360° rotation of the extension arms. Extension arms designed to support monitors are equipped with stops and rotate 270°. Each extension arm supports one lighthead. Lighthead spring arms also provide continuous 360° rotation and an adjustable counterbalance mechanism for effortless vertical positioning. Refer to equipment drawing for further information.

Electrical commutators located within the suspension system transmit power and control signals while providing continuous rotation. All rotation points include adjustable brakes to prevent drift.

The lighting system can be installed to conform with most seismic installation requirements.

## OPTIONS

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### Optional Harmony® Video Camera

The **Harmony Camera** is a digital video camera with digital and analog outputs that can be mounted as a replacement lighthead on the Harmony vLED Surgical Lighting System. 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 uses a full-featured, color, digital video camera (with analog and digital outputs) that complies with relevant safety standards for use in medical or surgical contexts. Its exceptionally small size allows it to be 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, focus and brightness. The video signal from the camera is available at the canopy controls in either S-video or composite video format.

The camera module provides state-of-the-art video capability using single-chip CCD image sensor with approximately 380,000-pixel resolution. The camera provides a 40X zoom ratio (10X optical, 4X digital) for fine detail visibility. The camera focal distance ranges from wide angle (10 mm [3/8"]) to telephoto (1000 mm [39-3/8"]). The signal-to-noise ratio exceeds 50dB for exceptionally clear images. Automated features, such as auto zoom, auto focus and auto brightness, provide excellent video images without direct user control. For more demanding video applications, manual mode allows the user full control of all camera features. The video image orientation is controlled by rotating the camera using control or an optional ACT Enabled<sup>®</sup> electronic interface device.

**Harmony vLED Surgical Lighting System must be pre-ordered camera-ready to provide full video camera capability.** The camera module is designed to allow quick, tool-free attachment or removal from the lighthead, enabling a single camera to be shared among multiple lighting systems. The compact camera is protected by a strong, molded urethane housing. A molded polycarbonate lens provides a clear video image while sealing the camera optics from dust and fluids.

The camera module is available in two versions:

- NTSC video format
- PAL video format

Every "camera-ready" Harmony vLED Surgical Lighting 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.

**Camera Module Utility Requirements** – 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.

### **Optional Flat Panel Monitor Arm**

The Harmony vLED Surgical Lighting System can use an optional Flat Panel Monitor Arm (FPM) to support a video monitor. The 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 audio-visual 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.

Single FPM or Dual FPM monitor mounts do not include internal wiring when shipped from the factory. Maximum allowable total monitor weight for single FPM is 12 kg (26 lb); for dual FPM is 20 kg (44 lb).

**Viewing** – Monitors can be mounted in landscape or portrait orientation and tilted independently, on two separate axes, to optimize screen view. The monitor yoke rotates 320° 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 painted metal surfaces of extruded aluminum and steel suspension components are treated with a baked-enamel powder coating. Covers at knuckles and similar areas are made from engineering-grade plastic.

**FPM 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 normally comfortable viewing height (i.e., eye-level).

**Area of Coverage**<sup>1</sup> – 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<sup>®</sup> Electronic Interface**

The STERIS ACT Enabled electronic interface permits networking of the Harmony vLED Surgical Lighting System with various third-party control or automation systems. These third-party aspects provide users with remote control over many features of the surgical lighting system.

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<sup>1</sup>. Consult equipment drawings for critical dimensions and tolerances.

## INSTALLATION

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A single or tandem mounting plate is provided for installation to an above-ceiling support structure (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

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**Sterile disposable cover for** standard lighthandle allows members of surgical team to grasp and adjust standard lighthandle, while providing access to all surgeon's lighthandle 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.

An optional **service disconnect switch** can be mounted remotely in a location of the Customer's choice. The switch can be used to interrupt the ac voltage to the lighting system, and the battery backup voltage (when the latter is available). The service disconnect switch completely disconnects all power from the system. The switch should not be used as a routine on/off switch.

## PREVENTIVE MAINTENANCE

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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.

## SUPPORT STRUCTURE

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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 Harmony vLED Surgical Lighting System.

## NOTES

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**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. Power Requirement – vLED Control Center.
6. Explosion Hazard – Do not use in the presence of flammable anesthetics.
7. Installation of power supply must comply with all applicable building codes and industrial standards for country, state and local, or otherwise.

## UTILITY REQUIREMENTS

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

**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-lighthouse system.
- Remote power control box with battery backup option required for operation under battery backup.
- 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 Harmony vLED Surgical Lighting System is part of a tandem mounting configuration. Refer to Harmony EMS builder program and equipment drawings for information.*

## THREE LIGHTHEAD SYSTEM CANOPY CONTROLS ENVIRONMENTAL REQUIREMENTS (System Running)

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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

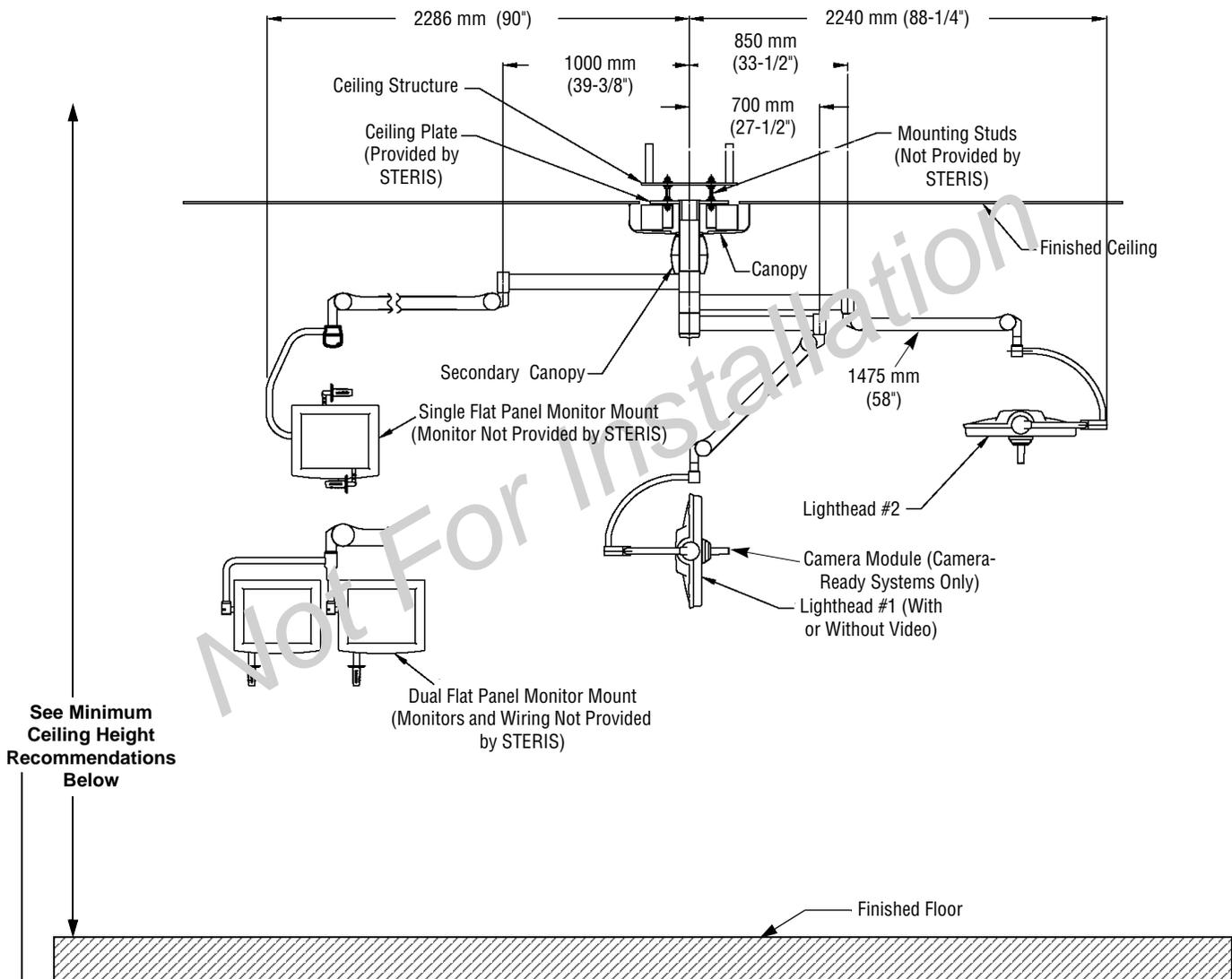
### Room Ambient

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).

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

Drawing not to scale, dimensions shown are typical



See Minimum Ceiling Height Recommendations Below

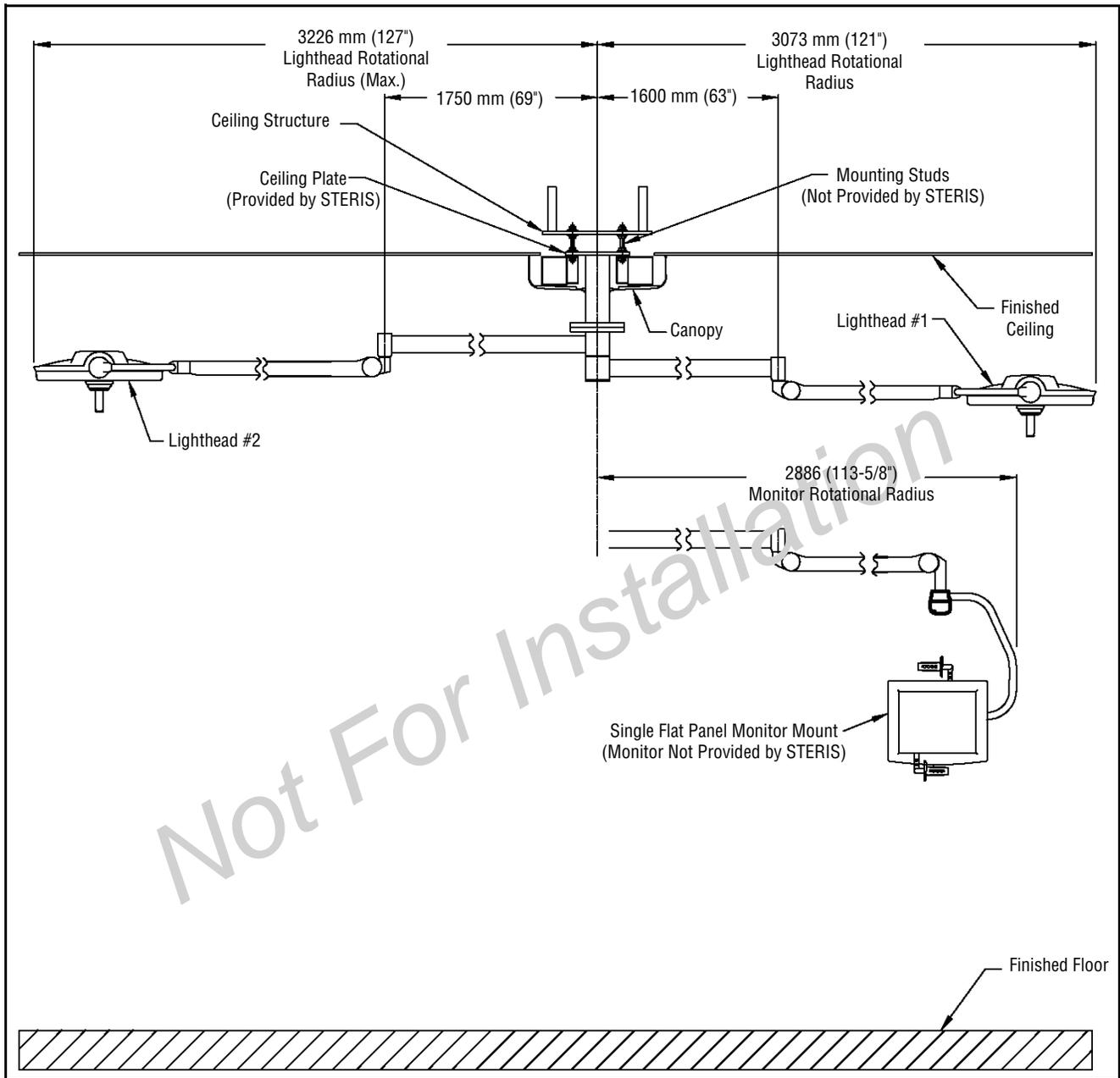
**Minimum Ceiling Height Recommendations**

System Configuration	Minimum Recommended Ceiling Height
Single Spindle	Dual Cardanic – 2743 mm [9' 0"] / Single Cardanic – 2388 mm [7' 10"]
Dual Spindle	Dual Cardanic – 2743 mm [9' 0"] / Single Cardanic – 2515 mm [8' 3"]
Triple Spindle	Dual Cardanic – 2769 mm [9' 1"] / Single Cardanic – 2616 mm [8' 7"]
Quadruple Spindle	Dual Cardanic – 2870 mm [9' 5"] / Single Cardanic – 2717 mm [8' 11"]

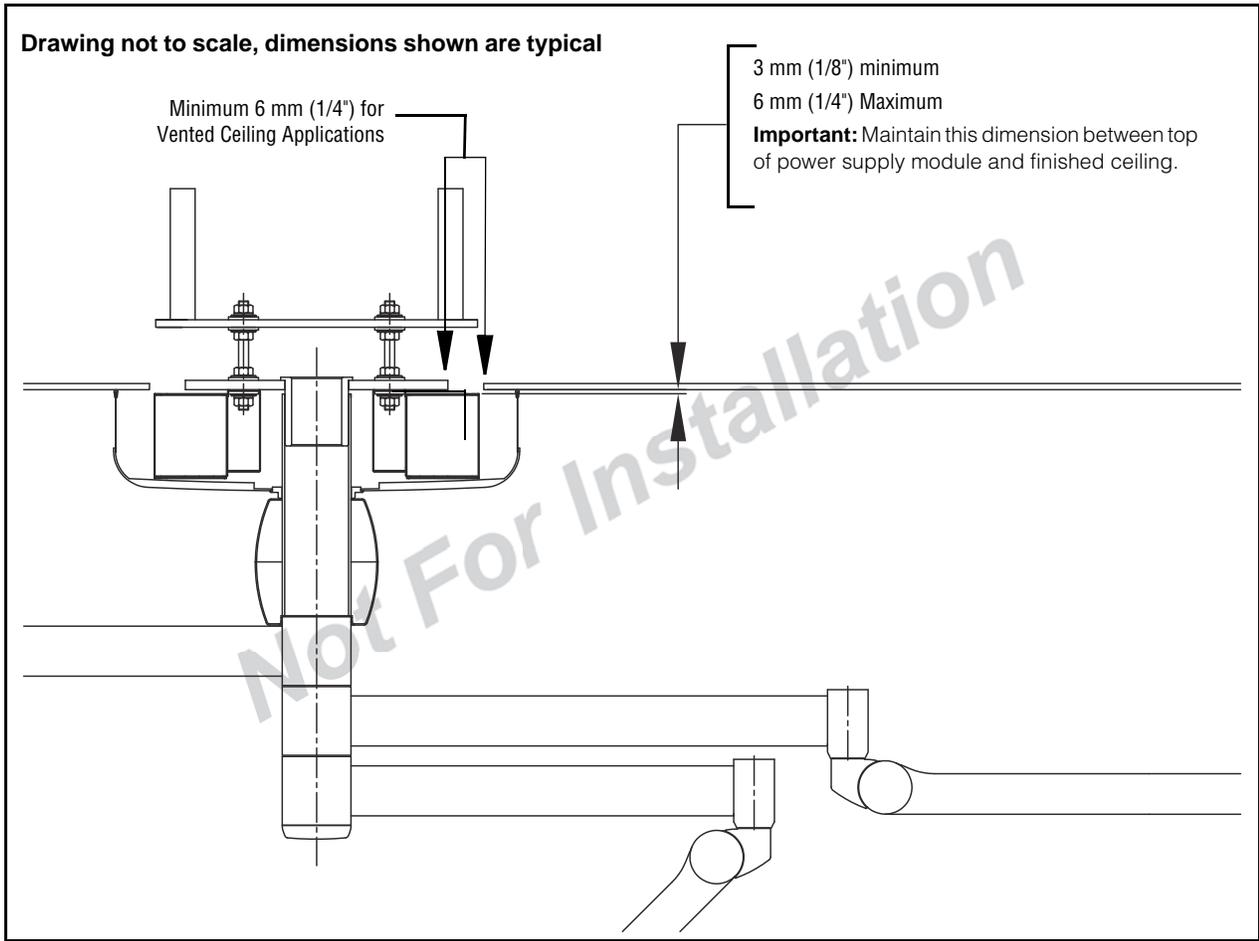
*NOTE: Tandem mounted systems vary between Flush Mount or Canopy Hood Mount. Canopy Hood Mount is 25 mm (1") below the finished ceiling (subtract 25 mm [1"] from the above clearance). Flush Mount is 152 mm (6") above the finished ceiling (add 152 mm [6"] to the above clearance).*

**Important:** Recommended minimum ceiling height varies by system configuration. These ceiling heights provide approximately 1956 mm (77") clearance between finished floor and lighthead. Recommended ceiling height dimensions assume that Harmony vLED ceiling plate can be mounted flush with the finished ceiling. A ceiling plate installed at a lower mounting height reduces the floor-to-lighthead clearance by an equivalent distance.

**Please consult equipment drawings for complete and accurate dimensions and clearances.**



**Harmony vLED Surgical Lighting System with Hybrid Extension Arm**



**Above-Ceiling Structure and Ceiling Plate Mounting Recommendations**

**For Further Information, contact:**



STERIS Corporation  
5960 Heisley Road  
Mentor, OH 44060-1834 • USA  
440-354-2600 • 800-548-4873  
www.steris.com



STERIS Ltd.  
Chancery House  
190 Waterside Road  
Hamilton Industrial Park  
Leicester LE5 1Qz  
United Kingdom



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