



# HARMONY® LED385 EXAMINATION LIGHTING SYSTEM

## APPLICATION

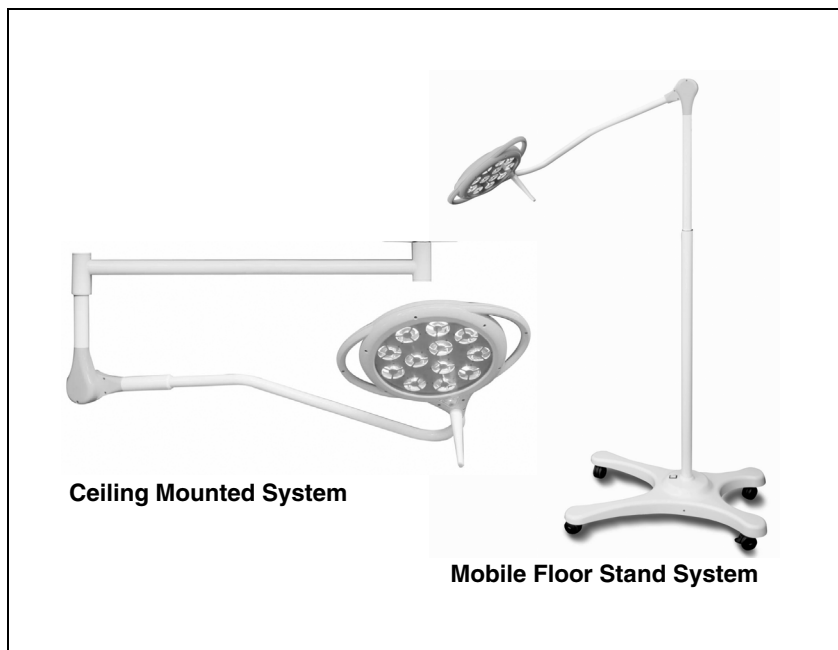
The Harmony LED385 Examination Lighting System, available in two configurations, is a variable intensity light for examination, treatment, critical care and emergency areas.

## DESCRIPTION

The Harmony LED385 Examination Lighting System provides high quality illumination for examination applications. Lighting intensity level is adjustable with pushbutton controls on the lighthead. Available configurations include a ceiling mounted system and a mobile stand. The ceiling mounted system has the same mounting pattern as the Harmony® LA 300 Examination Lighting System and Amsco® Examiner® 10 Examination Lighting System. This allows these lights to be easily upgraded, provided the ceiling structure meets the requirements outlined in the equipment drawing.

## LIGHTING SYSTEM CONFIGURATIONS

**Ceiling Mounted System** is suspended on a seamless, vertical tube. The horizontal extension arm slips onto the lower end of the vertical tube and is secured by an external retaining ring. A canopy is furnished to conceal the



(Typical only – some details may vary.)

mounting plate and power supply. STERIS recommends a minimum ceiling height of 8'8" (2642 mm) to maximum ceiling height of 11' (3353 mm). The ceiling mounted unit is equipped with a single 31-1/2" (800 mm) horizontal extension arm, supporting a standard Harmony LED385 spring arm and lighthead. This allows for an approximate 5' 6" (1676 mm) radial coverage area.

**Mobile Floor Stand System** consists of a vertical support tube, spring arm, lighthead and base. The system is supported by a sturdy base with rear mounted lockable, ball-bearing casters. The stand is 68-15/16" (1751 mm) in height with a 23-5/8" x 31-1/2" (600 x 800 mm) base. Mobile stand includes a 10' (3 m) power cord.

## The Selections Checked Below Apply To This Equipment

### CONFIGURATION

#### ☐ Ceiling Mounted

- ☐ Ceiling plate, vertical tube, 31-1/2" (800 mm) horizontal suspension arm and a standard Harmony LED385 spring arm and lighthead

#### ☐ Mobile Floor Stand Fixture

- ☐ 25-5/8 x 31-1/2" (600 x 800 mm) base, 68-15/16" (1751 mm) high vertical stand with a standard Harmony LED385 spring arm and lighthead

### ACCESSORIES

- ☐ Sterile Handle Kit  
(one required for each lighthead)

Item \_\_\_\_\_

Location(s) \_\_\_\_\_

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## STANDARDS

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

- **AAMI-UL Standard 60601-1:** UL Standard for Safety. Medical Electrical Equipment, Part I: General Requirements for Safety, First Edition.
- **CAN/CSA-22.2 No. 601.1-M90:** Medical Electrical Equipment, Second Edition, Part I: General Requirements for Safety. General Instruction No. 1; Supplement 1; 1994 R (1997).
- **IEC/EN 60601-1:** Medical Electrical Equipment, Part I: General Requirements for Safety, Incorporates: Corrigendum July 1994; Includes Amendments A1: 1993, A11: 1993, A12: 1993, A2: 1995 and A13: 1996, IEC 601-1: 1988 plus A1: 1991 plus A2: 1995 plus Corrigendum 1995 Modified.
- **IEC/EN 60601-1-2:** Medical Electrical Equipment, Part 1-2: General Requirements for Safety. Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
- **IEC 60601-2-41:** First Edition, 2000-02: Medical Electrical Equipment, Part 2-41: Particular Requirements for the Safety of Surgical Luminaires and Luminaires for Diagnosis.
- **Medical Device Directive (93/42/EEC):** Compliance for CE Marking.
- **EN 60601-1:1993:** Amendment 2, 1995, Electrical Safety
- **EN 60601-1-2:2001:** Electromagnetic Compatibility

## FEATURES

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Each lighthead provides naturally appearing white light with a color rendering index of >90 and a color temperature of 5,000 Kelvins. Light-emitting diode (LED) emitters are designed to emit light in the visible spectrum, with little or no ultraviolet and infra-red light. LED-emitted light reduces heat for increased patient safety and improved doctor comfort.

**Illumination intensity** is adjustable at the lighthead from approximately 24,000 to 50,000 lux (2,200 to 5,500 fc) by using the pushbutton controls located on the lighthead. The lighthead is equipped with two non-sterile handles for positioning the lighthead. Lightweight suspension system is designed for limitless and continuous lighthead positioning without binding or drifting.

**Modular suspension.** State-of-the-art electrical connectors allow lighthead reconfiguration within the limits of the installed suspension arms. Lighthead can be removed and replaced as required.

## CONSTRUCTION

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The Harmony LED385 Examination Lighting System is constructed of lightweight, durable materials. The Harmony LED385 lighthead optical system consists of LED light sources.

The clear window is molded of optical grade high impact polycarbonate material and is sealed into the lighthead to prevent the accumulation of dust on the system's optics. The

lighthead spring arm has an adjustable counterbalance mechanism for effortless vertical positioning. Electrical commutators, located within the suspension system, transmit power and control signals while providing continuous rotation. The lighthead yoke rotation points include adjustable brakes to maintain lighthead position.

## OPTIONS

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All Harmony LED385 Examination Lighting Systems are designed to conform with seismic installation requirements.

## 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 light system configuration to be installed. The data provided on the equipment drawing (available separately from STERIS) shows the maximum loads and moments for the Harmony LED385 Examination Lighting System.

## NOTES

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

1. Ceiling structure must adequately support light system which weighs and exerts a moment as indicated on the equipment drawing (available separately from STERIS).
2. Leveling nuts compensate for ceiling irregularities (nuts not provided by STERIS).
3. Fixture must be grounded. Adequate ground must be provided by running a separate ground wire to ceiling structure.
4. STERIS recommends general illumination in an examination room of 2,152 lux (200 fc) at the examination site.
5. Explosion Hazard – Do not use in the presence of flammable anesthetics.

## **UTILITY REQUIREMENTS**

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

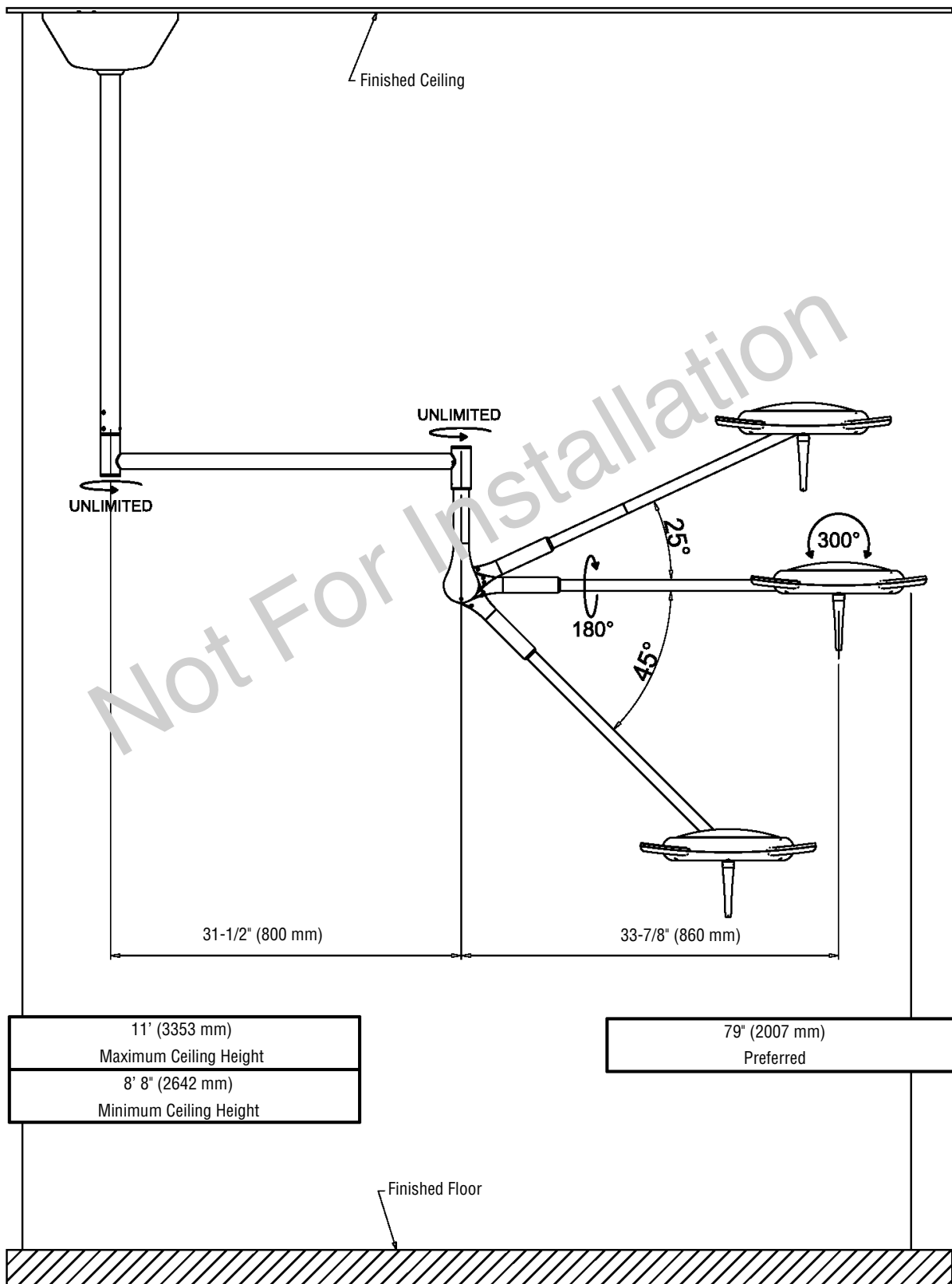
**Electricity** – Systems are compatible with the following ratings:

- 100- 240 Vac, 50/60Hz; .06-.03 Amps. Current leakage is limited to less than 300 microamperes.

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

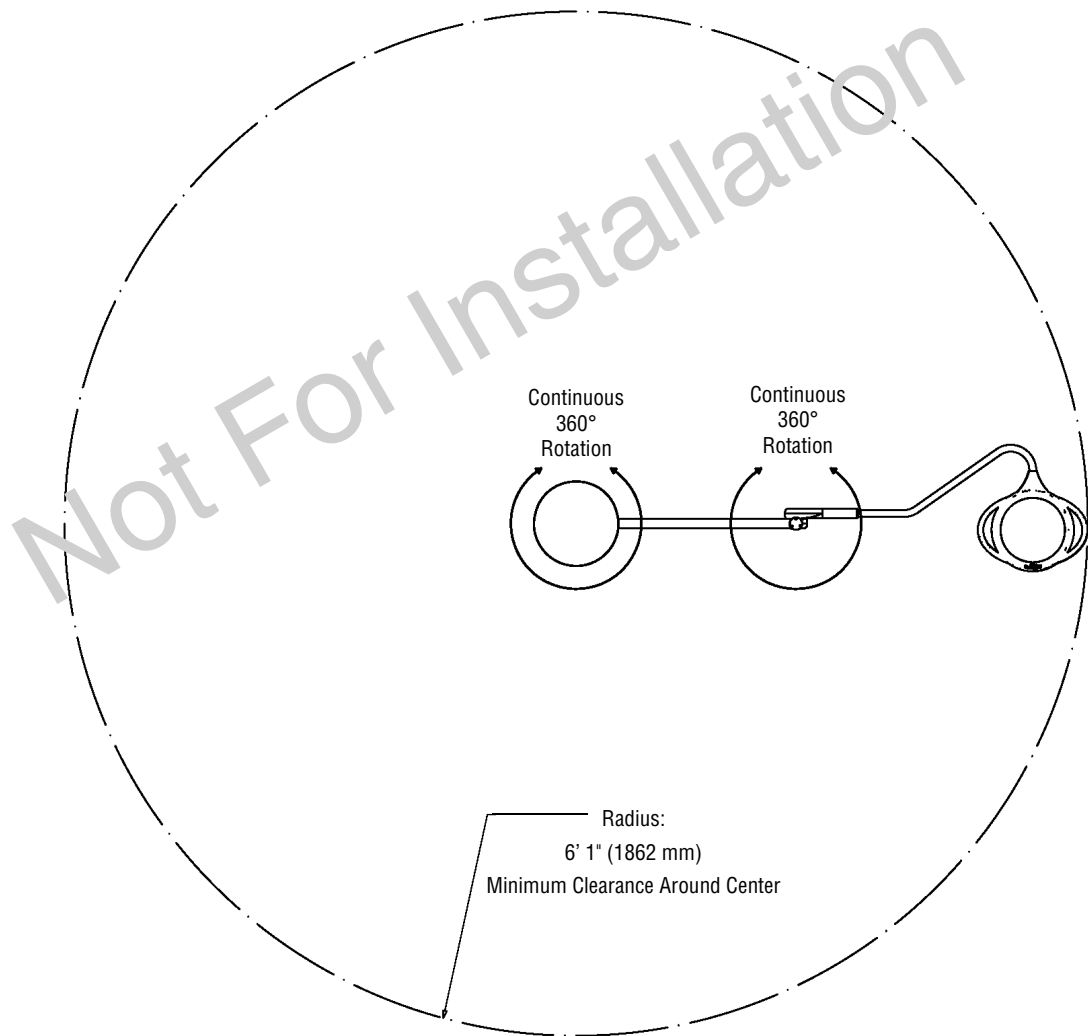
Drawing not to scale, dimensions shown are typical

# Harmony LED385 Examination Lighting System – Ceiling Mounted System



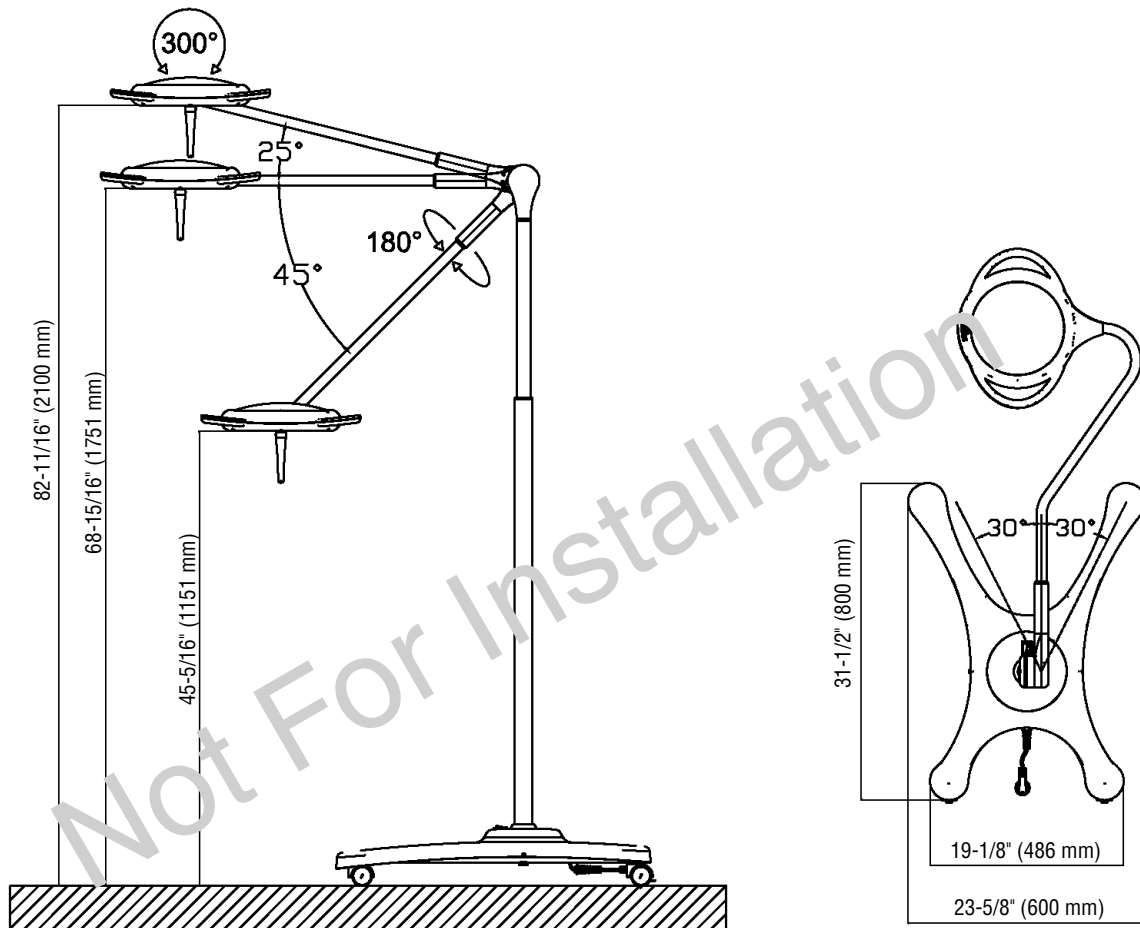
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# Harmony LED385 Examination Lighting System – Ceiling Mounted System



Drawing not to scale, dimensions shown are typical

# Harmony LED385 Examination Lighting System – Mobile Floor Stand System





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