STERIS

XLED™ SURGICAL LIGHTING SYSTEMS

APPLICATION

The extensive modular XLED™ range is suitable for the specific needs of all types of surgery.

XLED™ surgical lighting systems offer variable field diameter, color temperature and intensity, providing operating theatre staff with effective lighting of the surgical field and patient. They are equipped with built-in ambient lighting as standard.

A XLED™ surgical lighting system consists of one or more light heads among 4 different sizes, available in single and dual cardanic versions, with or without HD video wiring**.** The system also facilitates monitor mounting and transmission of video and control signals.

(Typical only – some details may vary.)

DESCRIPTION

The XLED™ Surgical Lighting System is a modular and configurable lighting system, providing high quality illumination for surgical and diagnostic applications. XLED™ light heads are available in four different sizes - one, two, three or four spots – with fixed or adjustable color temperature. The XLED™ surgical lighting 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. Available configurations include one, two or three light heads, with one or two video monitor supports (on one or two mounts).

Light heads and camera features can be monitored and controlled from different control systems: direct **local control** is possible using the keypad located on the light head yoke; a **wall-mounted panel** provides a user interface to control the intensity of light heads, and camera features thanks to the touch screen. Illumination pattern size can be adjusted by the surgeon, or another sterile surgical team member, by rotating **the sterile handle** on XLED3 and XLED4 light heads. Light heads and camera features can also be controlled from the **Harmony iQ ™ Integration System.**

The XLED™ surgical lighting 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 designed for compatibility with existing installations. The modular design of the XLED™ surgical lights with 1, 2, 3 or 4 spots minimizes the obstructing surface and thus allows excellent laminar flow compatibility. The suspension system is capable of providing continuous 360° rotational positioning.

STANDARDS

The XLED™ Surgical lighting range has been designed in compliance with international medical electrical equipment regulations:

- **International Standard:**

IEC 60601-2-41 (EN 60601-2-41) Particular requirements for the basic safety and essential performance of surgical luminaires.

- **International Standard:**

IEC 60601-1 (EN 60601-1)
General requirements for basic safety and essential performance applicable to medical electrical equipment.

- **International Standard:**

IEC 60601-1-2 (EN 60601-1-2) electromagnetic compatibility.

- **CE Marking according to EEC Directive 93/42.**

Intended use: The XLED™ surgical lighting system is a surgical light offering variable color temperature, variable field diameter and intensity, providing operating theatre staff with effective lighting of the surgical field or patient while limiting the associated thermal energy. The XLED™ surgical lighting system should only be used by qualified staff authorised to work in the surgical platform.
XLED™ surgical lights are class 1 medical devices and are registered with the ANSM (French national medicinal product and healthcare product safety agency).

FEATURES

An XLED™ surgical light consists of one or more light heads among **4 different sizes**. XLED1 light head has a span of 49 cm (19,3'') and contains 20 LEDs. XLED2 light head has a span of 66.5 cm (26.2'') and contains 40 LEDs. XLED3 and XLED4 light heads have respectively a span of 69.5cm (27.4'') /78.5cm (30.9'') and contain 60/80 LEDs. The **Wavelens™ Technology** is built-in as standard on XLED 3-spots and XLED 4-spots to adjust the **pattern** of light. This patented technology enables a wide range of pattern size adjustment while maintaining excellent uniformity of illumination across the beam.
Ambient lighting is built-in as standard to deliver approximately 100 Lux of light for minimally invasive surgery. All light heads dissipate heat away from the surgical field for patient safety and surgical team comfort.

Fixed Color Temperature

XLED™ surgical lights provide color-corrected, natural appearing **white light** with a color rendering index **(CRI) of 95**, a rendering index of red tones **(R9) of 97** and a color temperature of **4400 Kelvin.**

XLED1 - single spot, single cardanic – is a **small and fixed pattern** light head that provides a **16 cm** (6.3'') diameter light pattern with a depth of illumination (L1+L2) of 58 cm (22.8'') at 60% of Ec (IEC 60601-2-41, 2009). Illumination intensity can be adjusted up to **90,000 Lux.** The power consumption is 25W. **XLED2** and **XLED3** can be equipped with HD video wiring to be camera-ready lighting systems.

XLED2 - two spots, single or dual cardanic - is a **fixed pattern** light head that provides a **25 cm** (9.8'') diameter light pattern with a depth of illumination (L1+L2) of 65.9 cm (25.6'') at 60% of Ec (IEC 60601-2-41, 2009). Illumination intensity can be adjusted up to **110,000 Lux.** The power consumption is 50 Watts (+5W with camera).

XLED3 - three spots and **XLED4** - four spots - single or dual cardanic, are equipped with the patented **Wavelens™ Technology.**. The operator adjusts the pattern size by rotating the sterilizable light handle. XLED3 and XLED4 pattern sizes are adjustable to diameters between **25 cm** (9.8") and **30 cm** (11.8") with a depth of illumination (L1+L2) of respectively 63.8 cm (24.8'') and 51 cm (20.1''), at 60% of Ec (IEC 60601-2-41, 2009). Illumination intensity can be adjusted up to **160,000 lux.** The power consumption of XLED3 is 70W (+5W with camera) and 85 Watts for XLED4.
Illumination intensity can be adjusted using the local control located on the light head yoke, or the wall-mounted user interface panel. The intensity of each light head can be adjusted to one of nine possible lighting levels, or can be turned off completely.

Optional Adjustable Color Temperature

The adjustable color temperature option is available on the complete range of XLED™ surgical lights. Four color temperatures can be adjusted: **3500 Kelvins, 4000 Kelvins, 4500 Kelvins and 5000 Kelvins**. The complete range of XLED™ with adjustable color temperature provides homogeneous and consistent light across the different color temperature: a color rendering index **(CRI) of 95** at the four color temperature, a rendering index of red tones **(R9) of 91 at** 3 500 Kelvins and **R9 of 97** at the three color temperatures of 4000 Kelvins, 4500 Kelvins and 5000 Kelvins.

XLED1 - single spot, single cardanic – is a **small and fixed pattern** light head that provides a **13 cm** (5.1'') diameter light pattern with a depth of illumination (L1+L2) of 43 cm (16.9'') at 60% of Ec (IEC 60601-2-41, 2009). Illumination intensity can be adjusted up to **90,000 Lux.** The power consumption is 20 Watts.

XLED2 - two spots, single or dual cardanic - is a **fixed pattern** light head that provides a **19 cm** (7.9'') diameter light pattern with a depth of illumination (L1+L2) of 54.5 cm (21.5'') at 60% of Ec (IEC 60601-2-41, 2009). Illumination intensity can be adjusted up to **110,000 Lux.** The power consumption is 30 Watts (+5W with camera).

XLED3 - three spots and **XLED4** - four spots - single or dual cardanic, are equipped with the patented **Wavelens™ Technology.** XLED3 and XLED4 pattern sizes are adjustable to diameters between **19 cm** (7.9") and **24 cm** (9.5") with a depth of illumination (L1+L2) of respectively 50 cm (19.7'') and 42 cm (16.5''), at 60% of Ec (IEC 60601-2-41, 2009). Illumination intensity can be adjusted up to **160,000 lux.** The power consumption of XLED3 is 70W (+5W with camera) and 85 Watts for XLED4.
Illumination intensity and color temperature can be adjusted using the local control located on the light head yoke, or the wall-mounted user interface panel. The intensity of each light head can be adjusted to one of nine possible lighting levels, or can be turned off completely. Adjustable color temperature option needs to be requested at the time of sale.

The XTND™ Suspension System is lightweight and designed for limitless, continuous light head positioning without drifting. Light heads, camera-ready light heads, monitors, cameras and radiation protection shields can be mounted. The XTND™ suspension system allows configuration with up to five suspension arms, three arms on the main spindle and two on auxiliary spindles. Different arm lengths are available depending on the type of spindle. On the main spindle, arms can be up to 1150 mm, and up 1350 mm on the auxiliary spindle. Extension arms up to 2250 mm exist, for hybrid room applications for example. The dual or single cardanic yoke options offer a wide range of motions and positioning and allow to adapt to different ceiling height. The XTND™ Suspension System is designed to evolve after installation, one or more additional spindles can be added if needed.

An optional **HD video camera** can be included in camera-ready lighting systems (XLED2 and XLED3 light heads). This option must be requested at time of sale. Camera-ready capability is not available as a field upgrade or add-on, although a camera can be purchased and added to a camera-ready system at a later date.

XLED™ controls allow adjustment of intensity for each light head in the system, as well as control of the optional video camera module. Each light head is identified by an easy to read number on the wall-mounted user interface panel (control panel). In a multiple light head system, all canopy-mounted control electronics are dual-powered for reliability.

CONSTRUCTION

Light heads are constructed of lightweight and durable materials. The aluminium foundry cover offers excellent manoeuvrability and heat conduction. The XLED™ light head optical system consists of multiple Light Emitting Diode (LED) light sources, optics and patented Wavelens™ system (available on XLED3 and XLED4). The XLED™ light heads are fitted with multiple module assemblies mounted to and aimed from the precisely machined aluminium cover.
Each module is mounted with four individual LED emitters coupled with an optic.

XLED™ surgical light with fixed color temperature uses one unique white LED with a usable LED life of approximately 50 000 hours. XLED™ surgical light with adjustable color temperature is obtained by associating two white LEDs with different optical characteristics providing a usable LED life of approximately 60 000 hours. In both cases, all of the LEDs aim at the same point, offering unparalleled shadow dilution. This state-of-the-art design provides for brilliant, though cool, illumination.

XLED™ lenses and windows (clear shield) are made from an optical grade, scratch resistant PMMA material (poly methyl methacrylate), allowing an excellent light transmission coefficient. Light head assembly is suspended from a horizontal arm, which rotates around a main spindle. Suspension arm assemblies are specifically designed to support light heads,

monitors or cameras: the main spindle of the suspension is attached to the ceiling plate, which mounts to the above-ceiling support structure. The main spindle contains a precision bearing allowing continuous 360° rotation of the extension arms for the light heads. Extension arms designed to support monitors are Each extension arm supports one piece of equipment: light head, monitor-holder, camera-holder, radiation protection shield...
Light head spring arms also provide continuous 360° rotation and an adjustable counterbalance mechanism for effortless vertical positioning. Please refer to equipment drawings for further information. Electrical commutators located within the suspension system transmit power, control and video signals while providing continuous rotation. All rotation points include adjustable brakes to prevent drift.

OPTIONAL STERIS HD CAMERA

The STERIS HD camera module is a High-Definition (HD) block camera. This HD camera can be mounted as an optional component in **XLED2** and **XLED3** camera-ready light heads. This integrated video camera maintains the optical and mechanical performance of the lighting system while providing an unobstructed view of the surgical site. Its high-quality video images enable users to document surgical procedures for a variety of applications, including teaching and archival purposes.

The HD camera module uses a full-featured, color, digital video camera 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 light head, where it provides an unobstructed view of the surgical site. The control panel provides a powerful, yet convenient, means of controlling the many built-in camera features, including zoom, focus and brightness. The camera can also be controlled from the yoke of camera-ready light heads.

The HD camera module provides state of the art video capability using a 1/3 type HD CMOS sensor with approximately 2 000 000-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-to-noise ratio exceeds 50 dB for exceptionally clear images. Automated features, such as auto zoom, auto focus and auto brightness, provide excellent video images without direct user control. Available HD signal format is YPbPr. 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 the control center.

The camera module is designed for quick, tool-free attachment or removal from the light head, allowing a single camera to be shared among multiple lighting systems.
All camera-ready XLED™ lighting systems have video signal wiring pre-installed in the suspension system arms. This wiring is connected at the rotating joints through dedicated commutators to provide unlimited rotation of each joint of the suspension system. These innovative commutators allow easy positioning of the lights for optimal illumination of the surgical site. They also reduce the number of interconnections, preserving the integrity of the HD signal and ensuring its optimal transmission.

Camera module utility requirements – The HD 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.

INSTALLATION

A single mounting suspension plate is provided for installation to an above-ceiling support structure. A canopy is also provided to conceal the ceiling plate; rounded and flat options are available. Both canopy options are pre-cut in order to easily upgrade an existing and already set up configuration with auxiliary spindles. The suspension plate is ready for the mounting of additional spindles. Suspension tubes from 200 mm up to 1200 mm are available. Plug connectors, reducing the number of interconnections and large inner diameters of the suspension (52 mm for the main spindle and 55 mm auxiliary spindle) allow an easy installation.

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 the surgical table.

STANDARD ACCESSORIES

XLED™ **sterilizable handles** can be sterilized (autoclave temperature: US and Canada: 121-132-135°C/250-270-275°F; 30-4-3minutes/cycle – France: 134°C; 18 minutes/cycle – Comply with national regulations for other countries). **Adapters** for other models of handles and **disposable sterile covers** for handles and the video camera are also available.

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.

SUPPORT STRUCTURE

The ceiling structure must be levelled and must adequately support the surgical lighting system configuration to be installed. A large range of ceiling structures are available to fit different site requirements and existing lighting configurations. Data provided on the equipment drawings (available separately from STERIS) shows the maximum loads and moments for all XLED™ lighting system configurations.

NOTES

Important: Reference equipment drawings for detailed installation requirements. This technical data sheet is not intended as a complete pre-installation or planning guide. Please consult equipment drawings for critical dimensions and tolerances.

1. Ceiling structure must adequately support the surgical lighting system which weighs and exerts a moment as indicated on the equipment drawing (available separately from STERIS).
2. Ceiling hardware compensates for ceiling irregularities. Customer is responsible for ensuring an adequate concrete slab.
3. Fixture must be grounded. Adequate grounding must be provided by running a separate ground wire to the ceiling structure.
4. STERIS recommends general illumination (supplied by a third party) in the operating room of approx. 2000 Lux at

the surgical site. This 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 anaesthetics.
6. Installation of the power supply must comply with all applicable building codes and industrial standards for country, State and local, or otherwise.
7. XLED™ surgical light shall be considered minor surgical light. It means that XLED™ surgical lights shall mandatory be installed in operating fields with at least a combination of two surgical lights, in order to create a surgical lighting system. This combination is fail safe, as a minimum illuminance will be always provided to the operating area in case of single fault condition of surgical light.

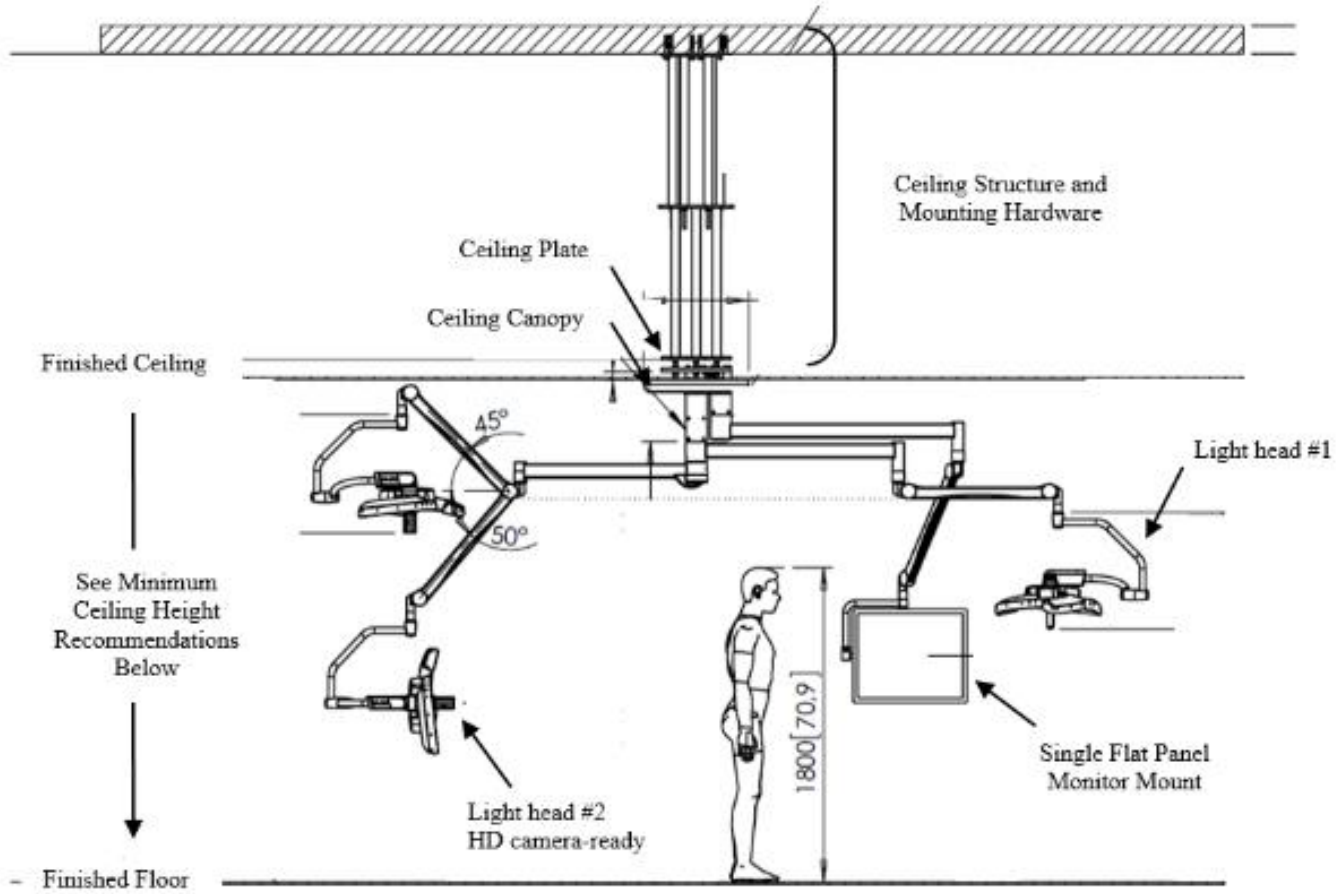
UTILITY REQUIREMENTS

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

Electricity – The system is compatible with the following ratings:

- 100 – 120/220-240 VAC 50/60Hz;
- 500 VA max (power supply unit) – 150 VA (backup unit)
- For the optional battery backup: 2x12V 24Ah, sealed lead, with a standalone operation of minimum 1 hour 30 minutes, and up to 21 hours, depending on the configuration (see Equipment Drawing for more details).
- Transport / storage: temperature 0°C-65°C, humidity 10-85% non-condensing,
pressure 500 to 1060hPa, do not store outside
- Operation: temperature 10°C-40°C, humidity 10-75%, pressure 800 to
1060hPa.

<u>XLD3370DXC</u> – Configuration with 2 dual cardanic XLED3 lightheads including 1 HD camera-ready and 1 monitor-holder



Minimum Ceiling Height Recommendations

System Configuration	Minimum Recommended Ceiling Height
XLD1000SSS / XLD1000SSST	Single Cardanic – 2492mm [98,1"]
XLD2000SSF / XLD2000SSFT	Single Cardanic – 2492mm [98,1"]
XLD2000DSF / XLD2000DSFT	Dual Cardanic – 2963mm [116,6"]
XLD3000SSW / XLD3000SSWT	Single Cardanic – 2492mm [98,1"]
XLD3000DSW / XLD3000DSWT	Dual Cardanic – 2863mm [112,7"]
XLD2000SXC / XLD2000SXCT	Single Cardanic – 2375mm [93,5"]
XLD2000DXC / XLD2000DXCT	Dual Cardanic – 2885mm [113,6"]
XLD2000DXC / XLD2000DXCT	Single Cardanic – 2375mm [93,5"]
XLD3000DXC / XLD3000DXCT	Dual Cardanic – 2876mm [113,2"]
XLD5000MXN	Monitor-Holder – 2413mm [95"]
XLD7000MXN	Monitor-Holder – 2413mm [95"]
XLD6000MXN	Camera-Holder – 2413mm [95"]
XLD3700DXW / XLD3700DXWT	Dual Cardanic –2863mm [112,7"]
XLD3700DXC / XLD3700DXCT	Dual Cardanic – 2876mm [113,2"]
XLD4700DXW / XLD4700DXWT	Dual Cardanic – 2863mm [112,7"]
XLD3600DXW / XLD3600DXWT	Dual Cardanic – 2863mm [112,7"]
XLD4600DXW / XLD4600DXWT	Dual Cardanic – 2863mm [112,7"]
XLD2200DXF / XLD2200DXFT	Dual Cardanic – 2872mm [113,1"]
XLD2200DXC / XLD2200DXCT	Dual Cardanic – 2885mm [113,6"]
XLD3100SXW / XLD3100SXWT	Single Cardanic – 2418mm [95,2"]
XLD3100SXC / XLD3100SXCT	Single Cardanic – 2418mm [95,2"]
XLD3200SXW / XLD3200SXWT	Single Cardanic – 2418mm [95,2"]
XLD3200SXC / XLD3200SXCT	Single Cardanic – 2418mm [95,2"]
XLD3200DXW / XLD3200DXWT	Dual Cardanic – 2863mm [112,7"]
XLD3200DXC / XLD3200DXCT	Dual Cardanic – 2885mm [113,6"]
XLD3270DXW / XLD3270DXWT	Dual Cardanic – 2872mm [113,1"]
XLD3270DXC / XLD3270DXCT	Dual Cardanic – 2885mm [113,6"]
XLD3277DXC / XLD3277DXCT	Dual Cardanic – 2885mm [113,6"]
XLD3300SXW / XLD3300SXW	Single Cardanic – 2418mm [95,2"]
XLD3300SXC / XLD3300SXCT	Single Cardanic – 2418mm [95,2"]
XLD3370SXW / XLD3370SXWT	Single Cardanic – 2532mm [99,7"]
XLD3370SXC / XLD3370SXCT	Single Cardanic – 2563mm [100,9"]
XLD3300DXW / XLD3300DXWT	Dual Cardanic – 2863mm [112,7"]
XLD3300DXC / XLD3300DXCT	Dual Cardanic – 2876mm [113,2"]
XLD3370DXW / XLD3370DXWT	Dual Cardanic – 2934mm [115,5"]
XLD3370DXC / XLD3370DXCT	Dual Cardanic – 2876mm [113,2"]
XLD3377DXC / XLD3377DXCT	Dual Cardanic – 2876mm [113,2"]
XLD4200DXW / XLD4200DXWT	Dual Cardanic – 2872mm [113,1"]
XLD4200DXC / XLD4200DXCT	Dual Cardanic – 2885mm [113,6"]
XLD4270DXW / XLD4270DXWT	Dual Cardanic – 2872mm [113,1"]
XLD4270DXC / XLD4270DXCT	Dual Cardanic – 2885mm [113,6"]
XLD4300DXW / XLD4300DXWT	Dual Cardanic – 2863mm [112,7"]
XLD3220SXC / XLD3220SXCT	Single Cardanic – 2533mm [99,7"]
XLD3220DXC / XLD3220DXCT	Dual Cardanic – 2885mm [113,6"]
XLD3320SXC / XLD3320SXCT	Single Cardanic – 2533mm [99,7"]
XLD3320DXC / XLD3320DXCT	Dual Cardanic – 2885mm [113,6"]
XLD4220DXC / XLD4220DXCT	Dual Cardanic – 2885mm [113,6"]
XHD3000DXW / XHD3000DXWT	Dual Cardanic – 2863mm [112,7"]
XHD3000DXC / XHD3000DXCT	Dual Cardanic – 2876mm [113,2"]
XHD3700DXW / XHD3700DXWT	Dual Cardanic – 2863mm [112,7"]
XHD3700DXC / XHD3700DXCT	Dual Cardanic – 2876mm [113,2"]

Important: Recommended minimum ceiling height varies by system configuration. These ceiling heights provide approximately 2000 mm (79") clearance between finished floor and the lowest light head. Recommended ceiling height dimensions assume that the XLED™ ceiling plate can be mounted flush with the finished ceiling. A ceiling plate installed at a lower mounting height reduces the floor to light head clearance by an equivalent distance. Please consult equipment drawings for complete and accurate dimensions and clearances.

For Further Information, contact:

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