IEC 60601-2-41 Standard ed.3

Under the Surgical Lights: Enhancing operational safety and performance for patients and OR staff

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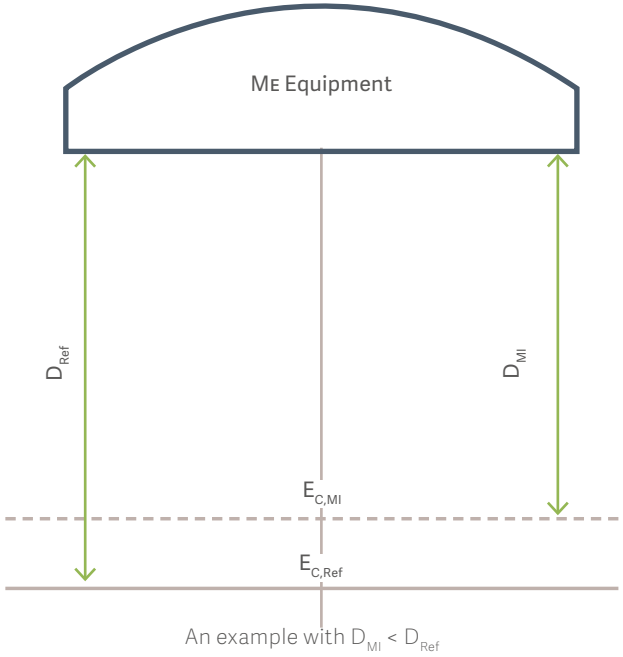
Central illumination

Illumination refers to the amount of light falling on a surface. It is measured in lux using a luxmeter, a device that quantifies light intensity.

For surgical lights, the central illumination is measured at two different distances:
- The reference distance (D_{Ref}) defined by the manufacturer.
- The maximum illumination distance (D_{MI}).

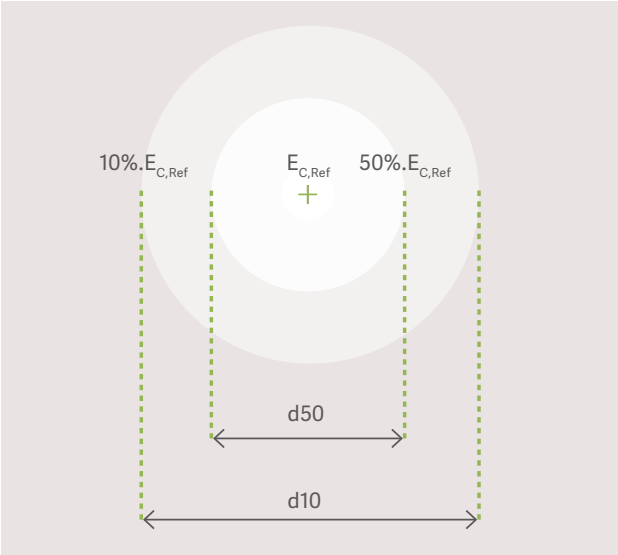


The maximum illumination at D_{Ref} ($E_{C,Ref}$) must be in between 40,000 and 160,000 lux. Maximum illumination at D_{MI} ($E_{C,MI}$) must never exceed 160,000 lux.

Light field diameter

The light field diameter defines the area on a horizontal plane where light is available — essentially, the width of the illuminated zone.
Central illumination refers to the point where the light intensity is at its maximum; as you move away from the center, the light gradually decreases.

Two light field diameters are measured:
- d10: The diameter where the center is at $E_{C,Ref}$ (maximum illumination at the reference distance), and the outer limit corresponds to 10% of $E_{C,Ref}$
- d50: The diameter where the center is at $E_{C,Ref}$ and the outer limit corresponds to 50% of $E_{C,Ref}$



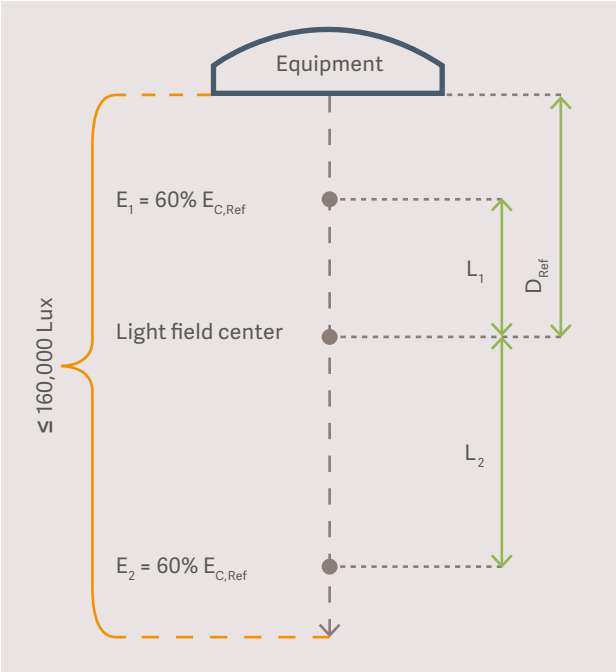
Lighting distribution
A gradual variation in illuminance from the center to the edge of the beam, combined with a wide, evenly lit working area, reduces glare, helping to prevent eye fatigue and blurry vision. The IEC standard specifies a ratio used to assess lighting quality: **d50/d10 > 0.5.** That means that d50 must be at least half of d10. The closer d50 is to d10, the more homogeneous the light field, resulting in a better-defined working area.

Depth of illumination

Surgeries are three-dimensional procedures, ranging from the incision point at the surface to the deepest cavities. That's why we define not only the light field diameter, but also the depth of illumination—also known as the volume of light or column of light.

The depth of illumination is composed of two different measurements: L1 + L2.
- The distance L1 is measured from the center of the light field D_{Ref} to the point where the illuminance reaches 60% of the central illuminance $E_{C,Ref}$, moving the photometer upward along the beam axis.
- The distance L2 is measured from the center of the light field D_{Ref} to the point where the illuminance reaches 60% of the central illuminance $E_{C,Ref}$, moving the photometer downward along the beam axis.

This measurement evaluates how much light remains inside the cavity during surgery and the ease of positioning of the light.



Shadow dilution

A test mask simulates the surgeon's head blocking light beams to dertermine the usable remaining light. All test dimensions are defined by the standard to ensure consistent comparisions among all surgical light suppliers.

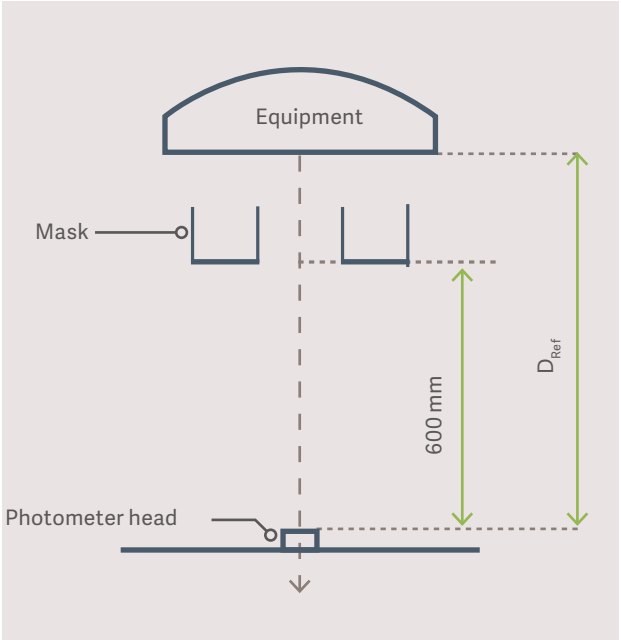
Test type include:

• One mask: This test simulates the remaining light when a surgeon is working beneath the light head. A 210 mm mask represents a human head.

• One simulated cavity: This test simulates the remaining light inside a cavity with a diameter of 50 mm and a depth of 75 mm. Some peripheral light beams are unable to reach inside the cavity.

• One mask and a simulated cavity: This simulates the remaining light with one surgeon beneath the light head using a 50 mm diameter and 75 mm deep cavity.

• Two masks and a simulated cavity: this test simulates the remaining light with two surgeons operating beneath the light head using a 50 mm diameter and 75 mm deep cavity.



Color temperature

Color temperature, also known as Correlated Color Temperature, refers to the light's color tone, measured in Kelvin (K).
Surgical lights must have a color temperature between 3,000K and 6,700K to provide color-neutral illumination that supports visibility and diagnostics.
Color temperatures above 5,000K are referred to as "cold colors" (bluish), while lower color temperatures (bet. 3,000 & 4,000K) are considered as "warm colors" (yellowish).

Color rendering index

The Color Rendering Index (CRI or Ra) measures the quality of the light in terms of how faithfully an object's colors are perceived. It is measured on a scale from 0 to 100, with 100 representing natural sunlight. The IEC standard requires a CRI > 85 to ensure accurate color judgment for diagnosis and effective tissue recognition by practitioners.
For R9, which refers to the rendering of strong red colors, the IEC standard does not specify a minimum required value; the results only need to be reported.

Optical radiations and patient safety

Lights emit optical radiation, which can be visible when it strikes a surface - or invisible such as UV (ultraviolet) and IR (infrared) radiations which may cause discomfort for the surgical team and poses potential photobiological hazards to tissues, skin and eyes.
The risks associated with UV and IR radiations are generally low, even when light fields overlap, due to established exposure limits.

However, the risk associated with blue light mainly concerns the patient, particularly when looking directly at the light source. In contrast, thermal risks caused by direct broadband radiations are more critical.

Excessive total irradiance can lead to a temperature rise at the surgical site, potentially resulting in thermal injury to the skin and any exposed tissue.

To prevent such unintended hazards, the IEC standard requires that, for a single surgical luminaire, the total irradiance in the illuminated area along the vertical axis shall not exceed 700 W/m².

The IEC standard recommends informing the surgical staff about the danger of overlapping light fields when irradiance exceeds 700 W/m² .

As a result, surgeons shall look out for signs of thermal effects on skin or exposed organs at the surgical site such as burns, tissue drying or desiccation.

Single fault safe

Illumination is crucial to OR safety. Single fault safe equipment is designed so that even in the event of a single fault, no safety hazard arises, and the main functions of illumination and maneuverability are maintained.

During a single fault condition that interrupts illumination, single-fault-safe lights can provide a minimum illuminance (40,000 lx) within one second of the interruption.

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