Technical Guidance Document: LED Surgical Task Lighting

LED surgical task light. *Photo credit: Steris Corp.*

The U.S. Department of Energy's (DOE) Hospital Energy Alliance (HEA) brings together leading hospitals and national associations in a strategic alliance designed to improve energy efficiency and reduce greenhouse gas emissions of healthcare systems throughout the country. By leveraging access to advanced technologies emerging from the national laboratories, HEA members are creating a national forum for the industry to share evidence-based technology solutions and influence the energy performance of medical equipment and systems.

In October 2010, acknowledging rapid improvements in light-emitting diode (LED) technology, the HEA Lighting Project Team selected LED surgical task lighting as a project to explore in 2011. A scoping study was completed in January 2011, characterizing the energy-savings potential of currently available LED products relative to tungsten-halogen (halogen) and high-intensity discharge (HID) benchmarks.[i] This fact sheet was subsequently developed to provide objective guidance to hospital owners and managers seeking to acquire high-performance LED surgical task lights.

Why Use LEDs for Surgical Task Lighting?

LED technology is advancing into new categories of white light applications, including surgical task lighting, where early indications suggest significant potential for energy savings and reduced maintenance. The halogen lamps typically used in surgical task lights suffer from relatively low luminous efficacy (lumens of light output per watt of input power), which is only worsened by filters that must be used to reduce the amount of non-visible radiation they emit. LED surgical task lights typically do not require such filtering media, and their higher efficacy can allow for reductions in connected load of 50 percent or more, with potential for additional energy savings through constant-color dimming and reduced cooling load in the operating room. Furthermore, while halogen lamps are typically rated for just 1,000 to 3,000 hours and fail catastrophically (sudden and without warning), LED surgical task lights are generally rated for 25,000 to 40,000 hours and are expected to "fail" by gradually fading in brightness. Table 1 summarizes some of the primary benefits of LED surgical task lights. LED technology may offer additional benefits, including enhanced mitigation of shadows cast by surgical staff, as demonstrated in Figure 1.[ii] Some products even allow for color adjustment. At present, however, independent test data are generally not readily available, performance in the later years of the product's lifetime can only be estimated, and products are relatively expensive on a first-cost basis. Thorough product specification and evaluation are essential for a successful LED surgical task lighting project.

Table 1. Potential Advantages of LEDs

Parameter	Benefit
Efficacy	LEDs require less wattage to produce equivalent light levels.
Heat in Beam	Substantial thermal energy must be conducted away from LEDs, but they radiate relatively little ultraviolet (UV) or infrared (IR) energy.
Dimmability	Although system compatibility must be verified on a case-by-case basis, LEDs may offer dimming without color shift or flicker, thereby yielding additional energy savings.
Maintenance	LEDs promise significantly greater life and a non-catastrophic failure mechanism.

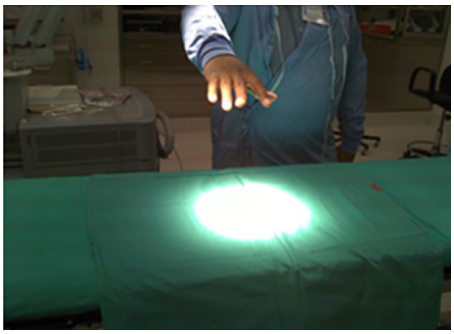

Figure 1. Shadow Dilution
Photo credit: Cleveland Clinic

Industry Standard Performance Metrics

The U.S. Food and Drug Administration (FDA), which grants marketing clearance for medical devices, issued product testing guidance in 1998 for surgical task lights.[iii] This guidance encouraged adherence to the International Electrotechnical Commission (IEC) draft standard 60601-2-41, the second edition of which was published in 2009.[iv] Many of the IEC criteria closely resemble criteria offered by the Illuminating Engineering Society of North America (IESNA or IES) in Section 4.11 of its American National Standard, which have remained essentially unchanged since 1995.[v]

The IEC criteria are currently used by FDA Accredited Persons performing third-party inspection of surgical task lights.[vi] Considering existing protocol and the relatively high cost of testing products in this category of medical equipment, it is recommended that the IEC criteria continue to serve as the basis for product specifications. However, the IES recommendations merit consideration, and surgical staff should be surveyed to identify any refinements needed to satisfy the requirements of various surgical procedures. Additionally, in retrofit or upgrade applications, existing equipment should be audited to provide an accurate measure of baseline performance. Such an audit could uncover any deterioration of the UV-IR filters used for halogen products.

The IEC standard provides definitions for a number of terms used herein. Note that "depth of illumination" was originally defined by the IEC as the combined distance upward and downward to points at 20 percent of the central illuminance, but this value was changed to 60 percent in the second edition of the standard. Many product datasheets have not been updated since the standard was revised, so comparison between product ratings must be performed with care to ensure manufacturers are consistently reporting depth of illumination based on the current edition.

Some IEC criteria provide fixed minimum requirements or maximum restrictions, such as the 1000 W/m^2 limit for total irradiance. Other criteria provide ranges of acceptable values. For example, major surgical luminaires (task lights or lamp-heads) and surgical luminaire systems (having multiple lamp-heads) must produce 40,000 to 160,000 lux of central illuminance. Because the value required by surgical staff may fall anywhere within this wide range, specifications should establish a set of narrower sub-ranges, where each sub-range is tailored to the requirements of the associated surgical procedure. The number of lamp-heads should be determined in advance, since together they must not exceed 160,000 lux.

Color Characteristics

The IEC criteria for correlated color temperature (CCT) and chromaticity coordinates also require greater specificity. Two light sources of equivalent CCT are generally expected to have equivalent color appearance, with both being yellowish-white, bluish-white, or something in between. But if their chromaticity coordinates do not lie near the Planckian locus, they can appear greenish or pinkish in color. The National Electrical Manufacturers Association (NEMA), in cooperation with the American National Standard Lighting Group (ANSLG), defined the Duv metric to supplement CCT, thereby limiting such color variation.[vii]

The NEMA/ANSLG standard simplifies specification of chromaticity, with allowable measured Duv values ranging from -0.006 to 0.009 as a function of nominal CCT. Table 2 demonstrates that the NEMA/ANSLG criteria are more stringent than the IEC criteria. The red text indicates five of the six IEC boundary points fall well outside NEMA/ANSLG tolerances for white light, suggesting the need for evaluation of Duv in addition to the IEC criteria for CCT and chromaticity coordinates.

Similarly, the General Color Rendering Index (CRI or R_a) may not provide an adequate measure of the ability of a light source to enable color discrimination. CRI measures color fidelity of the test source when lighting a set of pastel-colored objects, relative to a reference source (incandescent or daylight depending on CCT). Supplementing CRI, the Special Color Rendering Index R_9 evaluates the ability of a source to render a saturated red object (having peak reflectance from 745 to 805nm), but it is not clear whether these two metrics together provide an adequate measure of color rendition in surgical lighting applications.

The Color Quality Scale (CQS) was developed by the National Institute of Standards and Technology (NIST) as an alternative to CRI, after studies found CRI did not correlate well with color preference for some light source types, including LEDs.[viii] CQS is largely modeled after CRI, with one major difference being the use of saturated colors in lieu of pastels. Surgical staff may wish to perform field investigations

Table 2. IEC Chromaticity Boundaries[1]

IEC point	x coord.	y coord.	CCT (K)	Duv
A	0.310	0.375	6355	0.026
B	0.310	0.307	6886	-0.007
C	0.341	0.307	5006	-0.023
D	0.420	0.370	3008	-0.012
E	0.445	0.422	3010	0.006
F	0.380	0.422	4289	0.020

[1]Software allowing calculation of CCT and Duv from chromaticity coordinates is available upon request from Yoshi Ohno at NIST.

to determine whether CQS offers any advantages over the CRI and R_9 metrics.

Another potential concern is that some surgical task lights may produce color variation across the surgical field. This would not be evident from test data, and could occur when an LED surgical task light incorporating LEDs of more than one nominal CCT is partially obstructed by surgical staff. Ultimately, the color quality of a surgical task light is best judged visually by surgical staff, and in a mock-up scenario whereby the surgical task light is used to illuminate a realistically simulated patient.

Lifetime Characteristics

Although the lifetime of other components (such as power supplies) should be considered, LED useful lifetime is typically defined as the hours of operation until light output depreciates to some percentage of initial output. A value of 70 percent is often used in architectural applications, denoted L_{70}. Meanwhile, IEC stipulates that light output "shall not vary by more than 20 percent during use," with compliance to be verified after 10 days of cycled operation.

IES LM-80 provides a standard method for long-term testing of lumen (brightness) maintenance for LED light sources, but this method is not applicable to complete luminaires (such as surgical task lights) without consideration of case temperature and drive current when operated in situ.[ix] Furthermore, such data have typically only been collected for the first 6,000 to 10,000 hours of operation, requiring estimation of lumen maintenance later in life.

There is currently no standard method of extrapolating rated lifetimes from LM-80 test data. Until the much-anticipated IES TM-21 is published, LED luminaire manufacturers are free to choose their own method of curve-fitting to LM-80 data.[x]

Halogen lamps produce approximately 95 percent of initial output at 70 percent of their rated life, at which time these catastrophically failing lamps may be replaced as part of a scheduled group-relamping program.[xi,xii] Criteria for initial LED light output should be established with an understanding of benchmark (halogen) lumen maintenance. For example, if a given LED light-head initially produces 125,000 lux and its rated useful lifetime is based on the hours of operation to 80 percent of initial output (L_{80}), then it would be a suitable replacement for a halogen light-head initially producing 105,000 lux.

Specifying Products

Requirements will vary between hospitals and even between surgical suites, so a recommended specification structure is offered here in lieu of recommended criteria. The italicized text in brackets should be replaced with values determined after existing equipment has been audited and surgical staff have been surveyed:

- Input power, including power supply losses, shall not exceed [*specify value*] W.
- Central illuminance shall be no less than [*specify value not less than 40,000*] lux, or dimmable to this value.
- Central illuminance shall be no greater than [*specify value not greater than 160,000*] lux.
- Remaining illuminance shall be no less than
  - [*specify value*] percent with one mask
  - [*specify value*] percent with two masks
  - [*specify value*] percent with tube and no mask
  - [*specify value*] percent with tube and one mask
  - [*specify value*] percent with tube and two masks.
- Nominal correlated color temperature (CCT) shall be no less than [*specify value*] K and no greater than [*specify value*] K, or adjustable across this range.
- Measured CCT and D_{uv} shall comply with NEMA/ANSLG tolerances for white light.
- Measured R_9 shall be no less than [*specify value*].
- Light field diameter d_{10} shall be no less than [*specify value*] and no greater than [*specify value*], or adjustable across this range.
- Depth of illumination shall be no less than [*specify value*] and no greater than [*specify value*], or adjustable across this range.
- Rated useful lifetime, defined as the hours of operation at greater than 80 percent of initial light output, shall be no less than [*specify value*] hours.
- Dimming, if implemented, shall not compromise the above criteria or cause excessive flicker, harmonic distortion, or electromagnetic interference.

Note that while DOE recommends IES LM-79 testing for most LED lamps and luminaires, this methodology cannot be applied to most surgical task lights for characterization of luminous intensity.[xiii] Far-field goniophotometry would not capture the near-field convergence and subsequent divergence of the beam of light, as illustrated in Figure 2. In addition, knowledge of total initial light output (lumens) would be of limited value in this application.

Figure 2. Converging-Diverging Beam. (Image adapted from Skytron literature)

Suggested submittal requirements are then as follows:

- Submit product datasheet and installation instructions.
- Submit detailed product warranty.
- Submit IES LM-80 report and certificate clearly indicating actual in-situ LED case temperature, actual in-situ LED drive current, and expected lumen maintenance at end of rated useful life.
- Submit safety certification and file number for Medical Equipment per the National Electrical Code. Testing body shall be a U.S. Occupational Safety Health Administration (OSHA) Nationally Recognized Testing Laboratory (NRTL).
- Product shall be listed on the FDA Establishment Registration & Device Listing.[xiv]
- Submit test report from an FDA Accredited Person for third-party inspection indicating compliance with IEC 60601-2-41, clearly indicating the following measured values:
  - Input power (W) including power supply losses
  - Central illuminance E_c (lux) and corresponding measurement distance
  - Percent remaining illuminance with
    - One mask
    - Two masks
    - Tube and no mask
    - Tube and one mask
    - Tube and two masks
  - Correlated color temperature (K)
  - Chromaticity coordinates
  - Special color rendering index R_9
  - Light field diameter d_{10}
  - Depth of illumination.

These criteria and submittal requirements will facilitate the identification of high-quality products backed by trustworthy test data.

Verifying Performance

Lighting systems should be audited before and after any retrofit or upgrade. Existing luminaires should be cleaned, relamped and properly seasoned before any measurements are made. Measurement equipment should be selected for appropriate range and accuracy, in accordance with the IEC standard. The performance of LED surgical task lights should also be monitored periodically over time to ensure continued safe operation, and to see that lifetime claims are fulfilled for these relatively expensive products.

Sharing Experiences

HEA is a forum in which healthcare leaders work together with DOE, its national laboratories, and national building organizations to accelerate market adoption of advanced energy strategies and technologies. A primary function and benefit of membership is the ability to share experience with new technologies like LED surgical task lights. Similar forums are offered by HEA members, including the American Society for Healthcare Engineering (ASHE) and Practice Greenhealth, and additional information on LED technology can be found on the DOE SSL program website at www.ssl.energy.gov.

A Strong Energy Portfolio for a Strong America

Energy efficiency and clean, renewable energy will mean a stronger economy, a cleaner environment, and greater energy independence for America. Working with a wide array of state, community, industry, and university partners, the U.S. Department of Energy's Office of Energy Efficiency and Renewable Energy invests in a diverse portfolio of energy technologies.

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[vi] Third-Party Inspection (Devices) Accredited Persons Inspection Program. U.S. Food and Drug Administration. Accessed on May 3, 2011, at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ThirdPartyInspection/default.htm.

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[xiii] IES Testing Procedures Subcommittee on Solid-State Lighting. IES LM-79-08, "Electrical and Photometric Measurements of Solid-State Lighting Products." Illuminating Engineering Society, New York, NY. 2008.

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