Strong Partnerships Propel Innovation for Medical Devices

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Today's medical device manufacturers strive to innovate in a competitive climate where quick time to market and low cost are just as important as high-quality and long-lasting equipment. The strongly growing marketplace is crowded, and designers are constantly looking for quality improvements and design features that differentiate their products.

Devices such as endoscopes, dental equipment, surgical tools, and diagnostic machines oftentimes require fiber optics and LED light sources. Collaborating with a lighting expert will help make sure the lighting system is optimized for both the instrument design and the medical application and is designed in a way that keeps the equipment performing at a high level for years. A lighting partner can also help keep manufacturing costs down and streamline the path from idea to operating room.

SELECTING A PARTNER

When choosing a partner to work with on your lighting system, look for a company experienced in medical applications and check for quality management systems such as ISO 13485 that show they can provide the required documentation during the development phase and traceability for all components. Although most device manufacturers try to get products to market as quickly as possible, it can still take years to move from the first prototype, through regulatory approvals, and finally to a profitable product. This means you want to work with a company that can collaborate on long-term projects.

COMMUNICATION IS KEY

After selecting a lighting partner, involving them in the design process as early as possible will allow the most useful input into the lighting system. For example, if a diagnostic equipment company is working on a new spectroscope, sharing geometries, light data, lifetime expectations, and project timelines can speed up the entire project and help ensure the final product will run flawlessly with minimal maintenance.

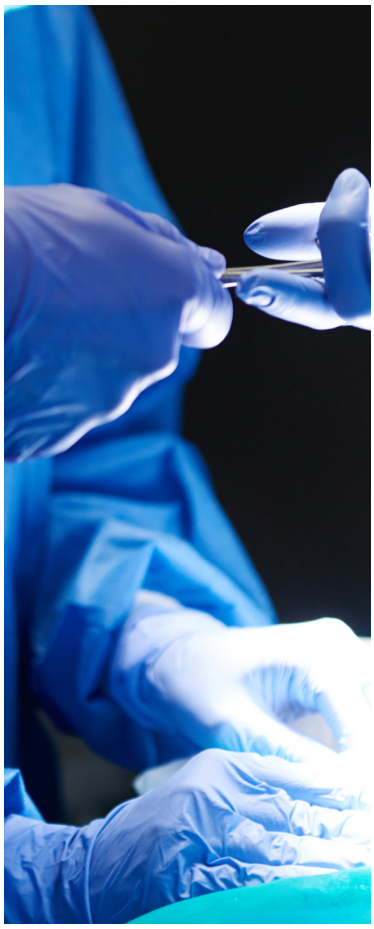
Early collaboration allows mechanical models of the lighting system and its components to be integrated into the overall design file for the instrument, making it easier to settle on a configuration that meets all requirements while ensuring manufacturability and cost efficiency. Specialized optical simulation software can be used to quantify potential light losses, demonstrate illumination patterns, identify

critical design paths, optimize a priori to minimize design loops, and identify weaknesses in existing designs.

Detailed information is necessary to design the best lighting system for a new instrument. Staying with the example of a diagnostic instrument, the required power output and wavelengths are important considerations. Also, be sure to discuss the light flux necessary to match the sensitivity of the overall system, the maximum temperature allowed in the system to avoid a negative influence on diagnosis, and the mechanical boundaries for the lighting system. This information can be used to design a lighting system that maximizes light output homogeneity and ensures colors don't drift. The overall design can also be improved by reducing light losses at interfaces such as the connection from the medical device to light source, the light source to the light guide, and the light guide to light output. Using light sources that need little or no maintenance or calibration might also be considered to lower the cost of ownership.

OPTIMIZING THE LIGHT SOURCE

Many of today's medical devices use LEDs because they are long-lasting and inexpensive compared to halogen or mercury lamps or xenon bulbs. However, LEDs require certain design considerations. Thermal modeling can help ensure LEDs achieve the longest lifetime possible by optimizing the component placement on the printed circuit board to ensure proper thermal transfer. At the same time, engineers can design electronics that improve the circuit board design, select the best LED substrate for the instrument and application, and perform electrical testing to optimize the lifetime.



For some applications, such as diagnostic instruments, the fact that LEDs inherently lose intensity over time is problematic and can sometimes even affect test results. In these cases, an active sensor control system that adjusts LED driving parameters based on output measurements for each LED is critical for keeping the light at a constant, defined intensity over the entire 20,000- to 30,000-hour lifetime of this light source.

TAKING THE PARTNERSHIP BEYOND DESIGN

When the latest medical device moves into real-world environments, new requirements and unique problems can arise. Analysis can provide the data necessary to meet new needs, understand the root causes of failures, support material and process selection, and provide general improvements to devices.

Various techniques are useful for analyzing the lighting systems of medical devices. For example, light beam characterization can be used to optimize spectral transmission, light power, and beam homogeneity. Thermal analysis will reveal the system's heat dissipation, which is important for improving light source stability and lifetime. Finally, chemical and surface analysis can be used to study the

influence of certain environments or treatments, such as disinfection and sterilization, on lighting components so that they can better withstand the environments in which they are used.

Collaborating with a partner that can perform multiple types of analyses can ensure a consistent approach is used. In addition, it can achieve faster results.

Although the pace of change in medical device design is fast, the industry remains collaborative. Cooperation with strong lighting experts can help from the design phase through to the comprehensive modeling, testing, and analysis necessary for troubleshooting and improving medical instruments.

About SCHOTT AG Lighting and Imaging

SCHOTT AG Lighting and Imaging develops, manufactures, and distributes fiber optic components for light and image transmission. Our portfolio comprises flexible and rigid components as well as hybrid products based on LED and fiber optic technology. We have been providing customized solutions to medical instrument manufacturers and working in medical applications for more than 50 years and have 130 years of experience in specialty glasses and materials. Our PURAVIS® high-performance glass optical fibers are ideal for many fluorescence-based diagnostic instruments because of their extremely long lifetimes, high color uniformity and light output, and improved transmission in the near-UV range.

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