Light. Insight. Life.

LED Light Engines as Substitutes for Halogen-Based Illumination in IVD

Volpi - A World Leader in Upgrades of Outmoded Instruments to Latest LED Technology with Minimal Regulatory Risk and Effort

The challenge

Many clinical chemistry and immunology readers on the market today for diagnostic testing still use halogen-bulb-based illumination modules with excitation filters to help obtain the photometric sample readout. Some of the analyzed signals used in these readouts have wavelengths of between 340 and 380 nanometers (nm). Because halogen bulbs emit light based on thermal radiation, their first-order emission spectrum can be modeled using a black body radiator.

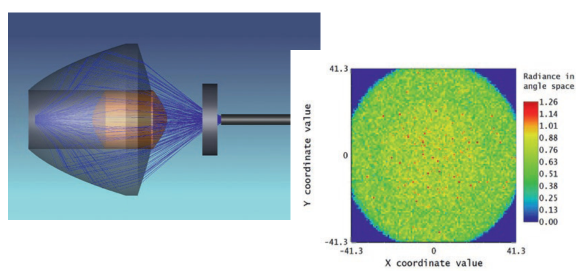
To increase the emitted intensity in the UV range and ensure a sensitive readout, the halogen bulb's tungsten filament has to be operated at a very high temperature. These high temperatures increase the evaporation rate of the tungsten from the filament and reduce the bulb's lifetime to several 100 hours of operation.

As the bulb's operating time is reduced, the instrument's downtime increases because of light bulb exchanges and the overall productivity of the lab is affected negatively. The lab's operating costs also rise because of the increased service demand from the halogen-based instruments.

The solution

The increased sophistication of light-emitting diode or LED wafer manufacturing through modified chemical vapor deposition (MCVD) processes, which tightly control layer constitution and thickness, and the use of conversion phosphors have enabled the commercial availability of high energy density LEDs.

These LEDs are available on a broad spectral range and are more reliable and longer lasting than halogen-based systems. LEDs have an operating life of up to 50,000 hours because of the slow reduction of their optical emission power during the light engine's operating life.



LED light coupling simulation

The use of microcontrollers and digitally-controlled electrical components in LED light engines has become common. They enable the cost-efficient design of feedback-controlled driving circuits, which increase the efficacy of a light engine by stabilizing the temperature and driving current of the LED dyes.

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These and other characteristics of LED light engines permit the development of a range of alternate architectures. These designs allow the substitution of existing shorter life, higher cost halogen-based solutions with smart, controlled LED-based engines with longer lives and lower service costs. The replacement of filter wheels for halogen light sources with electrically- switchable LED engines enables further gains in speed and reliability.

Challenges in LED retrofits of FDA-cleared instruments

To benefit from the application of new light-source designs in existing, FDA-cleared instruments, regulatory compliance must be considered. The FDA clears diagnostic tests in combination with a measurement system and procedure. Changes to the instrument can be made, but the nature of the change and the accompanying potential risk to patients determine the level of regulatory scrutiny.

The replacement of a diagnostic instrument's light engine is a critical change, but one that can be implemented under the FDA's "like for like" framework. This approach allows manufacturers to replace a specific component of an instrument, provided the new part is functionally equivalent to the one being replaced and the change presents little risk to patients.

Volpi has worked with a number of large, top 10 in vitro diagnostics companies as they replaced the existing light source in one or more of their Because of these experiences, the company has a thorough understanding of the FDA process required to make "like for like" changes. For manufacturers interested in upgrading an instrument or instruments to LED, Volpi delivers not only world-class opto-electronic engineering expertise, but unmatched "like for like" replacement experience with the FDA.

Volpi's experience has been that manufacturers wanting to replace their light source must reassess all the tests that the FDA has cleared for that instrument. However, the manufacturer can provide evidence to the agency that the replacement will not affect the quality of the data generated by the instrument. The following design considerations are required to convince the FDA that the replacement of the light source qualifies under the "like for like" framework.

FDA design considerations

- Spectral characteristics of broad-band emission
- vs. a combination of small emission bands
- Match of emission curve with filter curves
- Angular and spatial emission characteristics of LED dyes
- Noise characteristics
  - –The physical photon generation process
  - –Temperature effects
  - –Driver and control loop properties
- Reliability
  - –Operation point and thermal management
  - –LED-multiplexing without moving parts

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- The “like for like” approach: certification and compliance
  - –Differences in light properties at the sample and the detector
  - –Signal stability (temporal, spatial and angular) influencing factors
  - –Space and use cases of light engine that has to be emulated to maintain similar instrument operation conditions
- Start-up sequence
  - –Warm-up time
  - –Differences on interfaces due to technology advances

Volpi’s product solutions

To support diagnostic instrument manufacturers and users, Volpi has developed an industry-leading portfolio of Swiss-engineered LED light engine solutions. Volpi’s product menu enables instrument manufacturers to select, in consultation with the company’s team of opti-electronic experts, the replacement LED engine that is best for their instrument. The Volpi team believes that both engineering and regulatory expertise and experience must be the foundation of client solutions as they consider retrofitting their instruments.

Volpi’s LED solutions include high-power white LED light engines and enhanced white LED solutions. White LEDs eliminate the need for photometric filters and the light they emit varies in luminance very little over time. The company also offers multi-LED light engines. These light engines have an enhanced area of homogeneous illumination that enables two to three times higher sample throughput per day. Volpi also offers combined illumination sources that include UV-LED and halogen-bulb light engines.

Volpi’s service offering

Volpi supports its product portfolio with the very best service in the industry. The company uses a rigorous system engineering approach as it develops a custom solution for each client. Volpi calls on its extensive regulatory experience as it supports its customers in their discussions with the FDA and other regulatory agencies. This support includes providing experimental data on critical parameters associated with the retrofit for use with the appropriate regulatory agency. Volpi also readily provides documentation of its ISO 13485 and other quality system certifications.

Case study: Colorimeter

An instrument manufactured by a top-tier clinical in vitro diagnostics company used a halogen bulb for its original light source. The halogen source was coupled with Köhler optics. Volpi conducted a study that focused on a customer retrofit of the instrument’s original components with a high-power white LED.

Volpi undertook the study as part of its work with the customer because it aimed to demonstrate that retrofitting a diagnostic instrument with an LED light engine allowed manufacturers to overcome problems associated with other light sources. These challenges include matching the coupling condition to the fiber bundle, balancing power in emission channels and matching the stability characteristics of filtered LED output.

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Delivering the same quality of light through the measurement chain is key to success in retrofitting light engines in regulated IVD-instruments

Volpi compiled a detailed characterization of the halogen-bulb solution at the fiber output plane, and identified system and optical design matching characteristics. The company also characterized the stability of the lab-model of the retrofitted instrument and provided the lab-model to the customer for tests. Volpi supported the customer with the design of experiment with the lab-model light engine. Volpi's work in this case study was a success both in terms of retrofitting the light source itself and of helping to secure the appropriate approval from regulatory authorities.

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Conclusion

Volpi has built an enviable position as world expert in the retrofitting of diagnostic instruments with the latest LED light engines. These light engines provide purchasing and cost benefits, can be customized and enhance instrument performance. LEDs are available on a broad spectral range and are more reliable and longer lasting than halogen-based systems. The use of microcontrollers and digitally-controlled electronics components in LED light engines enable the cost-efficient design of feedback-controlled driving circuits, which increase efficacy.

But Volpi combines its opto-electronic engineering expertise with deep regulatory experience directly related to the retrofitting of diagnostic instrument light sources. The company has a thorough understanding of the FDA process required to make “like for like” changes because of its work with large in vitro diagnostic companies on these issues. For manufacturers interested in upgrading an instrument or instruments to LED, Volpi delivers not only engineering expertise, but unmatched “like for like” replacement experiencewith the FDA.

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