Press Release

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Medical Lighting 11 May 2023

Medical lighting innovations require integrated approach to testing

Munich. Integrated approaches to the testing of medical lamps are becoming increasingly necessary in the face of factors including expansion of hospital infrastructure, medical trends, and technical innovations such as LED and AI. TÜV SÜD Product Service provides manufacturers with explanations of both the requirements under the Medical Device Regulation (MDR) and requirements in the fields of product safety and occupational health and safety (OH&S)

“The dynamic pace of technological progress is enabling medical lighting technology to enter ever broader fields of application, from disinfection, phototherapy and endoscopy to infant radiant warmers and surgical lasers”, says Florian Hockel, TÜV SÜD Segment Leader Light and Multimedia. Experts estimate that by 2033, the market will almost double from its current level of around eight billion US dollars. As an integral part of healthcare facilities, medical lighting not only plays a central role in the comfort and safety of both patients and medical professionals; it also enables exact diagnoses to be made, and thus even better medical care to be provided. Ever bigger innovative leaps and modern lighting trends have the aim of facilitating the work of medical staff while reducing energy demand at the same time. As an example, the transition to LED lighting also offers greater longevity plus a more pleasant colour temperature that is similar to that of natural light and can be adjusted more precisely to the specific medical tasks on hand. The high colour rendering of LED lamps not least enables more accurate diagnoses to be made and treatment to be more effectively targeted.

From radiant warmers to surgical lasers – an overview of the broad standards landscape

CE marking is the end-point of a conformity assessment procedure in accordance with the MDR (see MDR, Article 20). The characteristics tested include effective light output and radiation characteristic (glare). Other important aspects are luminous flux, colour temperature and light stability (flicker). In cases where a lighting system for a medical product is purchased separately, problems sometimes arise if the parameters are not matched to the subsequent application. In some cases, this may mean

restarting the entire product development from scratch and can thus cause market entry to be delayed, involving unplanned secondary costs that could otherwise have been avoided.

The basic safety and essential performance requirements for medical electrical equipment, including medical lighting, are set forth in the EN 60601 series of standards. Where infant radiant warmers are concerned, for example, one clause of the standard is dedicated to the explicit testing of infrared radiation. For example, the maximum irradiance must not exceed 60 mW/cm^2 at any point of the mattress area; in the near-infrared range it is 10 mW/cm^2. During the test, the experts set the distance between the radiator and the mattress as specified in the standard and detect the intensity using grids, IR detectors such as pyranometers, and spectrometers.

Critical aspects alongside medical safety include product safety of lamps and luminaires and lighting concepts for rooms. The EN 12464-1 standard includes policies for lighting in indoor workplaces including healthcare facilities. Important aspects include visual function, visual comfort and mental wellbeing. “Testing covers more than the illuminance level, coefficient of reflection or glare. Additionally relevant in Germany is Part 3 of the DIN 5035 standard (DIN 5035-3), addressing artificial light and lighting in the health sector. Other important factors are the evenness of the light, the colour rendering and the supply of daylight in a room”, says Florian Hockel. Taken together, these factors keep accidents at work to a minimum, reduce the likelihood of occupational diseases and even impact on staff productivity. In addition to technical aspects, a further focus is on economic efficiency.

TÜV SÜD experts are represented worldwide. They are familiar with national and local directives and standards, which may make laboratory test planning more efficient and thus speed up market access. Automated measuring systems in cutting-edge testing laboratories ensure even better data quality and even shorter testing times.

Further information:

- www.tuvsud.com/mdr
- www.tuvsud.com/lighting

Note for editorial staff: The press release and high-resolution photo are available on the Internet at www.tuvsud.com/newsroom.

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