YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0932-2014

Medical luminaires - Medical head-mounted luminaires

医用照明光源 医用额戴式照明灯

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Table of Contents

1 Scope

YY/T 0932 is the product standard for the medical headlamp, the head-mounted luminaire a surgeon or examiner wears to put light exactly where they are looking. It belongs to the Chinese series on medical illumination sources. A headlamp is judged on the characteristics that decide whether it helps or hinders: illuminance at working distance, the size and evenness of the spot, colour rendering good enough to distinguish tissue, and the absence of heat and weight that make it unusable over a long procedure. Battery behaviour and the security of the head mount complete the picture. For a manufacturer or an importer of surgical and examination headlights for the Chinese market, this is the governing product standard.

This Standard specifies the requirements and test methods of head-mounted luminaries. Medical head-mounted luminaries are clinically worn on the doctor's head for diagnostic examination and illumination of patients.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 5702-2003, Methods of measuring the color of light sources

GB/T 7922-2008, Method of measuring the color of light sources

GB 9706.1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

GB/T 14710-2009, Environmental requirement and test methods for medical electrical

equipment

GB/T 16886.1-2011, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

GB/T 16886.5-2003, Biological evaluation of medical devices - Part 5: Test for in vitro cytotoxicity

GB/T 16886.10-2005, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

GB/T 20145-2006, Photobiological safety of lamps and lamp systems

JB/T 7403-1994, Illuminance meter

ISO 15004-2: 2007, Ophthalmic instruments -Fundamental requirements and test methods - Part 2: Light hazard protection

3 Terms and definitions

For the purpose of this document, the following terms and definitions apply.

3.1 medical head-mounted luminaries Lighting device worn on a doctor's head for diagnostic examination of patients.

4.1 Optical requirements

4.1.1 Illuminance The manufacturer shall specify the illumination at the specified distance from the light outlet, with a tolerance of ±20%.

4.1.2 Spot diameter The manufacturer shall specify the spot diameter at the specified distance from the light outlet, with a tolerance of ±10%.

4.1.3 Color rendering index The color rendering index of emitted light shall be >= 85.

4.1.4 Color temperature The color temperature of emitted light shall be between 3 000 K ~ 6 700 K.

4.2 Headband adjustment range (if applicable) The adjustment range of headband shall be no less than 520 mm ~ 640 mm.

4.3 Brightness adjustment function The light output shall be adjustable from at least 10% of the maximum value to the maximum value, and an indication of the relative light intensity ratio or intensity change direction corresponding to the maximum light intensity shall be given.

4.4 Material biocompatibility Application site materials in direct contact with the operator's skin, such as headbands, shall be proven to be biocompatible in one of the following ways:

a) According to the biological evaluation principles of GB/T 16886.1-2011, the following

requirements shall be met: -- No cytotoxicity; -- No delayed-type hypersensitivity. Emphasize the light of the light source to the maximum position; respectively measure the spot diameter in horizontal direction and vertical direction at the distance specified by the manufacturer, and calculate the average value.

5.1.4 Color rendering index

5.1.4.1 Equipment For the spectral radiation measurement system, the spectral measurement range is not less than 380 nm ~ 780 nm, the wavelength resolution is not more than 2 nm, and the relative spectral radiance difference is not more than 1%.

5.1.4.2 Steps The wavelength step of the spectral radiation system is selected at 5 nm. Measure the relative spectral power distribution S(lambda) of the light source when the light intensity setting of the light source is adjusted to the maximum value.

5.1.4.3 Calculation It shall be carried out according to the provisions of GB/T 5702-2003 and GB/T 7922- 2008.

5.1.5 Correlated color temperature According to the relative spectral power distribution S (lambda) of the light source measured in 5.1.3.2, calculate the color coordinates u and v according to GB/T 5702-2003, and then find the corresponding correlated color temperature according to the blackbody radiation trajectory in the uv chromaticity coordinate diagram.

5.2 Headband adjustment range Check with a general measuring tool.

5.3 Brightness adjustment function Proceed according to the method of 5.1.2.

5.4 Biocompatibility of materials

5.4.1 General The following materials can be finished parts or test pieces processed by the same method. The shape and size of test materials shall be prepared and treated according to the test requirements.