YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0792-2024

Ophthalmic instruments - Endoilluminators

眼科仪器 眼内照明器

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1 Scope

YY 0792 is the mandatory standard for the endoilluminator, the fibre light probe introduced into the eye during vitreoretinal surgery to illuminate the retina from inside. Its central requirement is a photochemical one: the retina is being lit at close range for an hour or more by a source bright enough to work by, and the light dose, particularly in the blue and ultraviolet part of the spectrum, has to stay below the threshold for phototoxic damage while remaining bright enough for the surgeon. The standard sets those limits and the measurements that demonstrate them. The YY prefix without /T makes compliance compulsory in China. For a manufacturer or an importer of vitrectomy light sources and probes, this is the governing standard.

This Document specifies the general requirements and light radiation safety requirements for endoilluminator light sources and light guides used for endoillumination in ophthalmic surgery; and describes the corresponding test methods. This Document applies to endoilluminator light sources and light guides used for endoillumination in ophthalmic surgery.

2 Normative References

The provisions in following documents become the essential provisions of this Document

through reference in this Document. For the dated documents, only the versions with the dates indicated are applicable to this Document; for the undated documents, only the latest version (including all the amendments) is applicable to this Document.

GB/T 5702 Method of measuring the color rendering properties of light sources

GB/T 7922 Method of measuring color of light sources

GB 9706.1-2020 Medical electrical equipment - Part

1.General requirements for basic safety and essential performance (IEC 60601-1.2012, MOD)

GB/T 14233.1-2022 Test methods for infusion, transfusion, injection equipment for medical use - Part

3 Terms and Definitions

For the purposes of this Document, the following terms and definitions apply.

4.1 Endoilluminator light source

4.1.1 Output half-divergence angle The manufacturer shall provide the nominal value of the output half-divergence angle of the endoilluminator light guide, with a tolerance of ±10%.

4.1.2 Central illuminance The manufacturer shall provide the maximum central illuminance of the endoilluminator light guide at the recommended working distance, with a tolerance of ±25%.

4.1.3 Color rendering index (CRI) The general CRI (Ralpha) of the emitted light from the endoilluminator light guide shall be no less than 85. NOTE. If the endoilluminator is equipped with a safety filter, the CRI of the emitted light shall be reduced. The manufacturer needs to state the risk of reduced CRI in the instruction manual.

4.1.4 Correlated color temperature The correlated color temperature of the emitted light from the endoilluminator light guide shall be 3000 K to 6700 K.

4.1.5 Light source requirements for camera systems (if applicable) For light sources suitable for use in camera systems, the matching relationship of the spectral response of the corresponding camera system detector shall be provided. Based on the green light radiant flux Phieg in the wavelength range of 515 nm to 545 nm, the manufacturer shall provide nominal values for the ratio of red light radiant flux Phier to Phieg in the wavelength range of 630 nm to 660 nm, AND the ratio of blue light radiant flux Phieb to Phieg in the wavelength range of 435 nm to 465 nm, with a tolerance of ±20%. If the light source claims to be unsuitable for the above response ranges, the distribution and matching ratio for the corresponding response range shall be provided.

4.1.6 Lamp failure prevention function The light source shall have preventative and emergency measures against lamp failure. These measures shall employ a lamp usage time counting device or a backup lamp switching method.

5.1 Endoilluminator light source

5.1.1 Output half-divergence angle The output half-divergence angle shall be the angle at which the irradiance is equal to half the maximum irradiance when measured through a 1 mm aperture. The uncertainty of the angle shall be less than 1°. For endoilluminator that produces a uniform beam with a diameter less than 1 mm on the retina at the recommended working distance, a measuring aperture equal to the diameter of the endoilluminator light guide probe shall be used. For endoilluminator that cannot produce a uniform beam on the retina at the recommended working distance, a measuring aperture with a diameter of

0.03 mm shall be used.

5.1.2 Central illuminance Set the light source intensity to its maximum position and measure using an illuminance meter at the recommended working distance.

5.1.3 Color rendering index

5.1.3.1 Apparatus A spectral radiometric measurement system with a spectral measurement range of at least 380 nm to 780 nm, a wavelength resolution of no more than 2 nm, and a relative spectral radiance difference of no more than 1%.

5.1.3.2 Procedure Control the test environment; the ambient illuminance shall not exceed 1 lx. Maintain a stable power supply to the light source at its nominal voltage, with voltage stability controlled within ±2%. The light source warm-up time shall be no less than 30 min. Select a wavelength interval of 5 nm for the spectral radiometric system. Measure the relative spectral power distribution S(lambda) of the light source when the light intensity setting is adjusted to its maximum value.

5.1.3.3 Calculation It shall be conducted according to GB/T 5702 and GB/T 7922. A horizontal platform 1 m above the top surface of the test-purposed board. 5.2.2.4.3 Test procedure The light guide is first placed naturally and horizontally on the platform; and measure the center illuminance according to the method in 5.1.2, recorded as E

0.Fix one end of the light guide and allow the other end to fall freely from that height onto the test-purposed board. Each end of the light guide is dropped 3 times; and then the light guide is restored to its natural and horizontal position. The center illuminance is measured according to the method specified in

5.1.2 and recorded as E

1.The light attenuation rate eta is calculated according to Formula (4).

5.2.3 Dimension It is measured using general measuring tools.

5.2.4 Insulation requirements After moisture pretreatment according to the provisions of

5.7 in GB 9706.1-2020, the test shall be conducted according to the provisions of

8.8.3 in GB 9706.1-2020.

5.2.5 Sterility The test shall be conducted according to the sterility test method in General Rule 1101 of the Pharmacopoeia of the People's Republic of China (2020 Edition, Volume IV).

5.2.6 Ethylene oxide residue The test shall be conducted according to the method in Clause 9 of GB/T 14233.1-2022.

5.3 Light radiation hazards of the endoilluminator

5.3.1 Determination of irradiance, spectral irradiance, and spectral weighted irradiance for Group 1 and Group 2 instruments For endoilluminator that produces a uniform beam with a diameter greater than 1 mm on the retina at the recommended working distance, the following requirements shall be met. To determine the irradiance or spectrally weighted irradiance of standard/collimated endoilluminator light guides, the maximum radiant power or spectrally weighted radiant power of each light source at maximum intensity over an average region with a diameter of 1 mm is measured at a distance of 15 mm from the exit aperture. To determine the irradiance or spectrally weighted irradiance of light guides for wide angle/diffusing and chandelier, the maximum radiant power or spectrally weighted radiant power of each light source at maximum intensity over an average region with a diameter of 1 mm is measured at a distance of 18 mm from the exit aperture. To determine the irradiance or spectrally weighted irradiance of endoilluminator light guide with pic/forceps, the maximum radiant power or spectrally weighted radiant power of each light source at maximum intensity over an average region with a diameter of 1 mm is measured at a distance of 1 mm from the tip expected to contact the macula. For endoilluminator that produces a uniform beam of light less than 1 mm in diameter on the retina at the recommended working distance, a measuring aperture with the same diameter as the endoilluminator light guide probe is used. When the working distance differs from the above, measurements are performed at the manufacturer-specified working distance. Measurements are performed in water or a saline solution. The spectrally weighted irradiance at maximum light intensity is equal to the maximum spectrally weighted radiant power over an area with diameter of 1 mm divided by the area (7.9 x 10^-3 cm^2). For endoilluminator that cannot produce a uniform beam of light on the retina at the recommended working distance, a measuring aperture with a diameter of

0.03 mm is used. Appendix A provides a method for measuring maximum spectral irradiance in water.