



**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY 0789-2024

**Laser therapeutic equipment - Q-switched ophthalmic laser
equipment**

激光治疗设备 调Q眼科激光治疗机

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1 Scope

YY 0789 is the mandatory standard for the Q-switched ophthalmic laser, the instrument used above all for YAG capsulotomy, cutting the clouded posterior capsule that develops after cataract surgery, and for iridotomy. Q-switching concentrates the pulse into nanoseconds, producing optical breakdown at the focus rather than heating, which is what lets it cut tissue inside the eye without an incision and also what makes precision in energy, pulse and aiming a safety requirement: the retina is a few millimetres behind the target. The YY prefix without /T makes compliance compulsory in China. For a manufacturer or an importer of ophthalmic YAG lasers for the Chinese market, this is the governing standard.

This document specifies the product classification and requirements for Q-switched ophthalmic laser therapeutic equipment and describes the corresponding test methods. This document applies to Q-switched ophthalmic laser therapeutic equipment (hereinafter referred to as therapeutic equipment).

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through the normative references in the text. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB 7247.1-2012 Safety of Laser Products - Part

3 Terms and Definitions

There are no terms or definitions that require definition in this document.

4 Product Classification

In accordance with the laser terminal pulse output mode, the therapeutic equipment can be divided into single pulse output and pulse train output; in accordance with the number of sub-pulses in a single output, the pulse train output mode can be divided into double pulse, triple

5.1.3.2 Single pulse output laser pulse width If the therapeutic equipment has a single pulse output mode, under the single pulse output mode, the deviation between the measured value of the laser pulse width and the nominal value shall not exceed 20%; the nominal range of the laser pulse width can also be given, and the measured value shall be within the nominal range. The nominal value and range of the pulse width shall not be greater than 6 ns.

5.1.3.3 Laser pulse train width If the therapeutic equipment has a pulse train output mode, under each pulse train output mode, the deviation between the measured value of the laser pulse train width and the nominal value shall not exceed 20%; the nominal range of the laser pulse train width can also be given, and the measured value shall be within the nominal range.

5.1.3.4 Sub-pulse width and sub-pulse interval If the therapeutic equipment has a pulse train output mode, the deviation between the measured value of the sub-pulse width and the nominal value shall not exceed 20%; the nominal range of the sub-pulse width can also be given, and the measured value shall be within the nominal range. Both the nominal value and range of the sub-pulse width shall not be greater than 6 ns. At the same time, under each pulse train output mode, the deviation between the measured value of the sub-pulse interval and the nominal value shall not exceed 20%; the nominal range of the sub-pulse interval can also be given, and the measured value shall be within the nominal range.

5.1.3.5 Pulse (pulse train) repetition frequency or interval If the pulse (pulse train) output of the therapeutic equipment is repeatable, the deviation between the measured value of the pulse (pulse train) repetition frequency or interval and the nominal value shall not exceed 20%.

5.1.4 Terminal output energy of laser pulse (pulse train) If the terminal output energy of the laser pulse (pulse train) cannot be adjusted, under each laser pulse output mode, the deviation between the measured value of the terminal output energy of the laser pulse (pulse train) and the nominal value shall not exceed 20%. If the terminal output energy of the laser pulse (pulse train) is adjustable, under each laser pulse output mode, the

deviation between the measured value in the adjustment range and the preset value shall not exceed 20%.

5.1.5 Laser output energy reproducibility The laser output energy reproducibility shall not exceed 20%.

5.1.6 Laser output beam convergence angle The deviation between the measured value of the laser output beam convergence angle and the nominal value shall not exceed 20%; the nominal range of the beam convergence angle can also be given, and the measured value shall be within the nominal range.

5.1.7 Laser output focal spot diameter The deviation between the measured value of the laser output focal spot diameter and the nominal value shall not exceed 20%; a nominal range of the focal spot diameter can also be given, and the measured value shall be within the nominal range.

5.2 Aiming System

5.2.1 Aiming light wavelength The deviation between the measured value of the peak wavelength of the aiming light and the nominal value shall not exceed 10 nm; a nominal range of the peak wavelength can also be given, and the measured value shall be within the nominal range.

5.2.2 Aiming light power The aiming light power shall not be greater than 1 mW.

5.2.3 Coincidence of aiming light At the focal plane, the aiming light and the therapeutic laser shall coincide.

5.3 Laser Radiation at Slit Lamp Microscope and Eyepiece

5.3.1 Slit lamp microscope Slit lamp microscope shall comply with the requirements of YY/T 0065.

5.3.2 Laser radiation at eyepiece The laser radiation at the eyepiece of the slit lamp microscope shall not exceed the Class 1 AEL value in GB 7247.1-2012.

5.4 Safety The therapeutic equipment shall comply with the requirements of GB 9706.1, GB 9706.222 and GB 7247.1-2012.

5.5 Electromagnetic Compatibility The therapeutic equipment shall comply with the requirements of YY 9706.102.

6.1 Therapeutic Laser

6.1.1 Laser wavelength Use a wavelength meter or spectrometer for measurement and determine whether the results meet the requirements of 5.1.1.

6.1.2 Laser mode Use a laser beam analyzer for measurement and determine whether the

results meet the requirements of 5.1.2.

6.1.3 Laser pulse characteristics

6.1.3.1 Laser pulse output mode Use a photoelectric probe and an oscilloscope for measurement, record the output waveform and determine whether the results meet the requirements of 5.1.3.1.

6.1.3.2 Single pulse output laser pulse width Use a photoelectric probe and an oscilloscope for measurement, take the time difference between 50% peak power points as the pulse width, and determine whether the results meet the requirements of 5.1.3.2. If the pulse energy is adjustable, select measurement points within the entire energy adjustment range to verify the pulse width.

6.1.3.3 Laser pulse train width Use a photoelectric probe and an oscilloscope for measurement and determine whether the results meet the requirements of 5.1.3.3.

6.1.3.4 Sub-pulse width and sub-pulse interval Use a photoelectric probe and an oscilloscope for measurement, take the time difference between 50% peak power points as the sub-pulse width, and determine whether the results meet the requirements of 5.1.3.4. If the pulse energy is adjustable, select measurement points within the entire energy adjustment range to verify the pulse width.

6.1.3.5 Pulse (pulse train) repetition frequency or interval Use a photoelectric probe and an oscilloscope for measurement and determine whether the results meet the requirements of 5.1.3.5.

6.1.4 Terminal output energy of laser pulse (pulse train) In various output modes, use a laser energy meter to measure the energy of the terminal pulse Or directly use a beam analyzer or other suitable instruments for measurement and determine whether the results meet the requirements of 5.1.7.

6.2 Aiming System

6.2.1 Aiming Light wavelength Use a spectrometer for measurement and determine whether the results meet the requirements of 5.2.1.

6.2.2 Aiming light power Use a laser power meter for measurement and determine whether the results meet the requirements of 5.2.2.

6.2.3 Coincidence of aiming light Check at the focal plane using a slit lamp microscope and determine whether the results meet the requirements of 5.2.3.

6.3 Laser Radiation at Slit Lamp Microscope and Eyepiece

6.3.1 Slit lamp microscope In accordance with the method specified in YY/T 0065, conduct the measurement and determine whether the results meet the requirements of 5.3.1.