



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

YY 0307-2022

Replacing YY 0307-2011

**Laser therapeutic equipment - Nd: YAG laser therapeutic
equipment**

激光治疗设备 掺钕钇铝石榴石激光治疗机

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Table of Contents

Foreword	3
1 Scope	6
2 Normative References	6
3 Terms and Definitions	7
4 Product Classification	7
5 Requirements	7
6 Test Methods	13

Foreword

This document was issued on 18 May 2022 by the National Medical Products Administration and takes effect on 1 June 2025.

It is a YY standard without the /T suffix: compliance is mandatory in China.

It replaces YY 0307-2011, which is superseded.

1 Scope

YY 0307-2022 is the Chinese mandatory standard for neodymium-doped yttrium aluminium garnet (Nd:YAG) laser therapeutic equipment, covering machines that emit at 1 064 nm and at the frequency-doubled 532 nm line. It exists because these two wavelengths behave very differently in tissue and are used for opposite clinical purposes: 1 064 nm passes deep and is used to coagulate and cut, while 532 nm is absorbed strongly by haemoglobin and melanin and is used on vascular lesions and pigmented spots. The dose that treats at one wavelength burns at the other, so the numbers the manufacturer prints on the machine are the safety barrier, and this standard is what forces those numbers to be true. It fixes what has to be declared - terminal output power, pulse energy, pulse duration, repetition rate, spot size, and the tolerance on each - and specifies the test methods used to verify every declared figure, along with the requirements for the aiming beam, the treatment applicator and the protective filters. Being a YY standard without the /T suffix, compliance is compulsory for anything placed on the Chinese market. It was issued on 18 May 2022 by the National Medical Products Administration and takes effect on 1 June 2025, replacing YY 0307-2011 and absorbing YY 1300-2016.

This document specifies the requirements and test methods for Nd: YAG laser therapeutic equipment (hereinafter referred to as therapeutic equipment).

This document is applicable to Nd: YAG laser therapeutic equipment with a wavelength of 1,064 nm and 532 nm.

This document does not apply to Nd: YAG laser therapeutic equipment for ophthalmology.

2 Normative References

The contents of this document 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 Safety of Laser Products - Part 1: Equipment Classification and Requirements

GB 9706.1 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and

Essential Performance

GB 9706.19 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of

Endoscopic Equipment

GB 9706.20 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of

Diagnostic and Therapeutic Laser Equipment

GB/T 14710 Environmental Requirement and Test Methods for Medical Electrical Equipment

GB/T 26599.1 Lasers and Laser-related Equipment - Test Methods for Laser Beam Widths, Divergence Angles and Beam Propagation Ratios - Part 1: Stigmatic and Simple Astigmatic Beam

YY/T 0758 General Requirements for Medical Laser Fiber

YY 1057 General Specifications for Medical Foot Switch

YY 9706.102 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety

and Essential Performance - Collateral Standard: Electromagnetic Compatibility -
Requirements and Tests

ISO 11146-2 Lasers and Laser-related Equipment - Test Methods for Laser Beam Widths,

5 Requirements

5.1.5 Terminal laser output power (or energy)

5.1.5.1 Continuous output

The manufacturer shall specify the terminal laser output power and the tolerance; the tolerance

shall not exceed $\pm 20\%$.

If the power is adjustable, the manufacturer shall specify the setting range, tolerance and step;

the tolerance shall not exceed $\pm 20\%$.

5.1.5.2 Free-oscillating pulse output

5.1.5.2.1 Terminal laser pulse energy

The manufacturer shall specify the terminal laser pulse energy and the tolerance; the tolerance

shall not exceed $\pm 20\%$.

If the energy is adjustable, the manufacturer shall specify the setting range, tolerance and step;

the tolerance shall not exceed $\pm 20\%$.

NOTE 1: if the therapeutic equipment expresses the laser output value with the energy density, then,

the "terminal laser pulse energy" in this clause is modified into "terminal laser energy density".

NOTE 2: if the therapeutic equipment expresses the laser output value with the average power,

then, the "terminal laser pulse energy" in this clause is modified into "terminal laser average power".

NOTE 3: if the therapeutic equipment expresses the laser output value by the pulse power (that is,

the laser output value is adjusted by setting the pulse power), then, the "terminal laser pulse energy" in this clause is modified into "terminal laser pulse power".

5.1.5.2.2 Maximum pulse power

The manufacturer shall specify the nominal value and tolerance of the maximum pulse power

of the terminal (corresponding to 10% pulse duration and 50% pulse duration); the tolerance

shall not exceed ? 20%.

NOTE: if the therapeutic equipment expresses the laser output value by the pulse power (that is,

the laser output value is adjusted by setting the pulse power), then, the "maximum pulse power" in this clause is modified into "maximum pulse energy".

5.1.5.3 Q-switched pulse output (including picosecond pulse)

5.1.5.3.1 Terminal laser pulse energy

The manufacturer shall specify the terminal laser pulse energy and the tolerance; the tolerance

shall not exceed ? 20%.

If the energy is adjustable, the manufacturer shall specify the setting range, tolerance and step;

the tolerance shall not exceed ? 20%.

NOTE: if the therapeutic equipment expresses the laser output value by the energy density, then,

the "terminal laser pulse energy" in this clause is modified into "terminal laser energy density".

5.1.5.3.2 Maximum peak power

The manufacturer shall specify the nominal value and tolerance of the maximum peak power

of the terminal; the tolerance shall not exceed ? 20%.

5.1.5.4 Pulse train output

5.1.5.4.1 Terminal laser pulse train energy

The manufacturer shall specify the terminal laser pulse train energy and the tolerance; the