

ICS 11.040.60

CCS C41



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 12257-2023

Replacing GB 12257-2000

Laser therapeutic equipment - He-Ne laser equipment

激光治疗设备 氦氖激光治疗机

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Foreword

This document is in accordance with the provisions of GB/T 1:1-2020 "Guidelines for Standardization Work Part 1: Structure and Drafting Rules for Standardization Documents" drafting: This document replaces GB 12257-2000 "General Technical Conditions for He-Ne Laser Therapy Machines": In addition to rectification and editorial changes, the main technical changes are as follows:

- Changed the scope of application of the standard (see Chapter 1, Chapter 1 of the:2000 edition);
- Deleted terms and definitions (see Chapter 3 of the:2000 edition);
- Deleted product composition and basic parameters (see Chapter 4 of the:2000 edition);
- Added "laser peak wavelength" (see 4:2:1);
- Changed the "laser mode" (see 4:2:2, 5:2:2 of the:2000 edition);
- Changed the "laser terminal output power" (see 4:2:3, 5:2:1, 5:6, 5:7 of the:2000 edition);
- Added "laser output mode and its time characteristics" (see 4:2:6);
- Added "the exposure limit of the treatment machine" (see 4:2:7);
- Added "aiming system (if applicable)" (see 4:3);
- Added "transmission system" (see 4:4, 5:8 of the:2000 edition);
- Changed the "timing device" (see 4:5, 5:5 of the:2000 edition);
- Added "Laser safety goggles (if applicable)" (see 4:6);
- Changed "Security" (see 4:7, 5:9, 5:10, 5:11 of the:2000 edition);

1 Scope

GB/T 12257-2023 is the Chinese national standard on laser therapeutic equipment - he-ne

laser equipment, in the field of health care technology. The /T suffix marks it as a recommended standard: it is not compulsory by itself, but it becomes binding as soon as a contract, a tender or a customer specification calls it up - which in practice is how most foreign buyers meet it. It was issued on 23 May 2023 by the State Administration for Market Regulation; Standardization Administration of China, and has been in force since 1 June 2024. Classification: ICS 11.040.60, CCS C41. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This document specifies the requirements and test methods for helium-neon laser therapy machines: This document is applicable to the helium-neon laser treatment machine (hereinafter referred to as the treatment machine) with a wavelength of 632.8nm for human body irradiation:

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text: Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document:

GB 7247:1-2012 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 9706:222 Medical electrical equipment Part 2-22: Basic safety and fundamentals of surgical, orthopedic, therapeutic and diagnostic laser equipment Specific requirements for this performance

GB/T 14710 Environmental requirements and test methods for medical electrical appliances

YY/T 0758 General Requirements for Medical Laser Optical Fibers

YY9706:102 Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility Content requirements and tests

3 Terms and Definitions

This document does not have terms and definitions that need to be defined:

4 Requirements

1 Normal working conditions The manufacturer shall at least specify the following normal operating condition parameters:

--- ambient temperature;

---Relative humidity;

---using electric: 4:

2 Therapeutic Lasers 4:2:

1 Laser peak wavelength $632.8\text{nm} \pm 10\text{nm}$: 4:2:

2 Laser mode Fundamental or higher-order modules: