



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

YY 9706.270-2021

**Medical electrical equipment - Part 2-70: Particular
requirements for the basic safety and essential performance of
sleep apnoea breathing therapy equipment**

医用电气设备 第2-70部分：睡眠呼吸暂停治疗设备的基本安全和基本性能专用要求

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Foreword

This document was issued on 6 September 2021 by the National Medical Products Administration and takes effect on 1 May 2024.

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

1 Scope

YY 9706.270 is the mandatory Chinese standard for sleep apnoea therapy equipment, the CPAP and bilevel devices used at home every night by a very large and growing number of Chinese patients. It sets the particular requirements for basic safety and essential performance on top of the general medical electrical safety standard, covering the pressure delivered and its stability, the response to leak, the rebreathing safeguards, the noise that determines whether the patient tolerates the device at all, and the behaviour on power interruption. Unlike a life-support ventilator the failure mode is not immediate death, which is exactly why compliance has to be enforced rather than assumed: the harm from an ineffective device is silent and cumulative. Being a YY standard without the /T suffix, compliance is compulsory. It takes effect in May 2024.

About this edition

YY 9706.270-2021 is the current edition. It was issued on 6 September 2021 and has been in force since 1 May 2024.

The interval between issue and effect is the transition period. It exists so that producers, laboratories and buyers can requalify products, revise procedures and use up documentation before the new text becomes the one that applies. The date on this page is

the official one from the record of the Standardization Administration.

Classification and status

The YY prefix marks an industry standard, issued by the authority for its sector rather than by the national body. It applies within that industry, and it becomes binding in the same ways a recommended national standard does: when a contract, a regulation or a declaration of conformity names it.

How a Chinese national standard is set out

Chinese national standards are drafted to the rules of GB/T 1.1, which fixes the order in which a standard is set out. The document opens with a foreword recording the issuing bodies, the relationship to any previous edition and the technical committee responsible for it. Clause 1 is the scope. Clause 2 lists the normative references - the other standards that have to be applied together with this one, and without which its requirements cannot be met. Clause 3 gives the terms and definitions. The technical clauses follow: the requirements themselves, the test or measurement methods by which conformity is established, the inspection rules that say how a lot is sampled and judged, and, for a product standard, the provisions on marking, packaging, transport and storage. Annexes, normative or informative, come last.

YY 9706.270-2021 runs to 30 pages in the English translation. What is delivered is the complete document in that order: every clause, every table, every figure and every annex of the Chinese original, with the same numbering, so that a reference to a clause number in a contract or a test report points to the same place in both languages.

About this English translation

The English edition of YY 9706.270-2021 is a full translation of the official Chinese text, not a summary, an abstract or a machine rendering left unchecked. Clause and subclause numbers, table and figure numbers and annex letters are those of the original, because they are what a specification, a purchase order or a test report cites.

Technical terms are translated against the vocabulary standards of the same field, so that a term used in YY 9706.270-2021 reads the same way as in the other Chinese standards it is used beside. Where a term has an established English form in an ISO or IEC document on the same subject, that form is used; where China's term has no foreign counterpart, it is translated literally and the Chinese is kept alongside it rather than replaced by an approximation.

Quantities, units and symbols are carried over unchanged. Chinese standards use SI, so a value in the translation is the value in the original document, not a conversion, and a limit read from the English text is the limit that will be applied by a Chinese inspection body

reading the Chinese one.

This page is compiled from the official publication record: the standard number and both titles, the issuing bodies, the dates of issue and effect. The requirements, limits, tables and test conditions are in the document itself.

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