

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

**YY 9706.272-2021**

---

**Medical electrical equipment - Part 2-72: Particular requirements for the  
basic safety and essential performance of home healthcare  
environment ventilators for ventilator-dependent patients**

医用电气设备 第2-72部分：依赖呼吸机患者使用的家用呼吸机的基本安全和基本  
性能专用要求

---

**Issued on: September 6, 2021**

**Implemented on: May 1, 2024**

---

**Issued by: National Medical Products Administration**

## Table of Contents

Foreword

1 Scope

2 Normative references

3 Terms and definitions

### 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.

It is classified under Chinese classification C46.

All technical content of this part is mandatory. "Medical Electrical Equipment" is divided into two parts.

--- Part 1: General and side-by-side requirements;

--- Part 2: Specific requirements. This part is part 2-72. This section is drafted in accordance with the rules given in GB/T 1.1-2009. This part is part 2 of YY 0600.2-2007 "Special Requirements for Basic Safety and Main Performance of Medical Ventilators. Dependent Breathing" Compared with YY 0600.2-2007, the main technical changes other than editorial changes are as follows.

--- Increased the scope and expanded the scope to include the ventilator and its accessories (if the characteristics of these accessories will affect the basic safety of the ventilator) full and basic performance), so the scope of application of this section is not limited to the ventilator itself (see.201.1.1);

--- Added the basic performance of the specified ventilator and its accessories (see.201.4.3);

--- Increased the ventilation performance test (see.201.4);

--- Increased the mechanical strength test (refer to YY 9706.111-2021) (see 211.10.1.1);

--- Added new symbols (see.201.7);

--- Added requirements for ventilators as components of medical electrical systems (see.201.6);

--- Added shell integrity test (see.201.11.6.6);

--- Added cleaning and disinfection procedure test (refer to YY 9706.111-2021) (see.201.11.6.6);

--- Increased the possibility of contamination when the breathing gas is delivered to the patient through the air path (see.201.11.6.6);

--- Modified the alarm state requirements for expiratory branch obstruction (continuous airway pressure) (see.201.12.4.107, 51.107 of the 2007 edition). This section uses the redrafting method to modify the adoption of ISO 80601-2-72:2015 "Medical Electrical Equipment Part 2-72: Dependence on Ventilators" Particular requirements for basic safety and basic performance of domestic ventilators used by patients. Compared with ISO 80601-2-72:2015, the main differences are as follows.

--- Regarding normative reference documents, this part has made adjustments with technical differences to adapt to the technical conditions of our country and the circumstances of the adjustment. The situation is reflected in the.201.2 "Normative Reference Documents", and the specific adjustments are as follows. \* ISO 594-1:1986 (see.201.101.2.1) is replaced by GB/T 1962.1 which is equivalent to adopting international standards; \* ISO 594-2:1998 (see.201.101.2.1) is replaced by GB/T 1962.2, which is equivalent to adopting international standards; \* ISO 4135:2001 (see.201.3) is replaced by GB/T 4999, which is equivalent to adopting international standards; \* Replace IEC 60601-1:2012 with GB 9706.1-2020, which is modified to adopt international standards (see full text); \* Replace ISO 32:1977 with GB 50751-2012 (see.201.7.2.101); \* Replacing ISO 5367:2000 with YY 0461 which is equivalent to adopting international standards (see.201.102.3); \* Replacing ISO 80601-2-55:2011 with YY 0601 modified to adopt international standards (see.201.12.4.101, .201.12.4. 104); \* Replacing IEC 60601-1-8:2012 with YY 9706.108-2021 modified to adopt international standards (see.201.3, 208, 208.6.12.101); \* Replacing ISO 9360-1:2000 with YY/T 0735.1 which is equivalent to adopting international standards (see.201.3, .201.102.4.2); \* Replace ISO 9360-2:2001 with YY/T 0735.2 which is equivalent to adopting international standards (see.201.102.4.2); \* Replace ISO 23328-1:2003 with YY/T 0753.1 which is equivalent to adopting international standards (see.201.102.5); \* Replacing ISO 23328-2:2002 with YY/T 0753.2 which is equivalent to adopting international standards (see.201.3.202, 201.102.5); \* Replacing ISO 8185:2007 with YY 0786 modified to adopt international standards (see.201.3, .201.102.3, .201.102.4.1); \* Replacing ISO 5359:2008 with YY/T 0799 which has been modified to adopt international standards (see.201.7.2.101, .201.101.1); \* Replace ISO 80369-1:2010 with YY/T 0916.1 which is equivalent to adopting international standards (see.201.101.2.2.5, \* Replace ISO 5356-1:2004 with YY/T 1040.1 which is equivalent to adopting international standards (see.201.101.2.1, \* Replacing IEC 60601-1-6:2010 (see.201.3, 206) with YY/T 9706.106 which is an international standard; \* Replaced IEC 60601-1-2:2014 with YY 9706.102-2021 (see 202); \* Replaced IEC 60601-1-11:2015 with YY 9706.111-2021 (see.201.11.6.6, .201.11.6.7, 211, 211.8.4.101, 211.10.1.1); - ISO 7396-1:2007 is replaced by ISO 7396-1 (see.201.3, .201.4.11.101.1, .201.4.11.101.2).

Compared with ISO 80601-2-72.2015, this part has made the following editorial changes.

- Deleted the foreword of ISO 80601-2-72.2015 and added the foreword of this part;
- Added guidelines for Appendix C (see.201.7.2.4.101);
- Added guidelines for Appendix D (see.201.7.2.13.101,.201.7.2.17.101);
- Added guidelines for Appendix BB (see.201.106.2);
- Added guidelines for Appendix CC (see.201.11.6.6);
- Added the guidelines of Appendix DD (see note in.201.3);
- Deleted Note 5 and Note 6 in.201.1.1;
- Deleted ISO 7010-M002 in.201.7.2.3;
- Modified "Table.201: D.1.101, Symbol 4" of.201.7.2.13.101 to "Table.201: D.2.101 Symbol 4";
- Modified "Table.201: D.1.101" of.201.7.2.17.101 to "Table.201: D.2.101";
- Modified "Repeat 2)~9)" in 10) of.201.12.1.103 to "Repeat 3)~9)";
- Modified "Repeat 2)~10)" in 11) of.201.12.1.103 to "Repeat 3)~10)";
- Modified "according to table.201.103 and table.201.104" in.201.12.4.103 to "according to table.201.104 and table.201.105";
- Modified the content in Appendix AA, and changed "201.7.9.2.9.101.1" to "201.7.9.2.9.101.2";
- Modified "201.9.6.2.101" in Table.201: C.103 to "201.9.6.2.1.101";
- Modify "201.7.9.2.13b)" in Table.201: C.103 to "201.7.9.2.13.101b)";
- Modified "201.7.9.2.13a)" in Table.201: C.103 to "201.7.9.2.13.101a)";
- Modify "201.7.9.2.9.101b)" in Table.201: C.103 to "201.7.9.2.9.101.1b)";
- Modify "201.7.9.2.9.101.2g)" in Table.201: C.103 to "201.7.9.2.9.101.2h)".
- Deleted references, normatively cited documents IEC 60601-1-3.2008, ISO 10651-3, ISO 10651-6, ISO 80601-2-12 and ISO 80601-2-70, added reference YY 0600.4, and adjusted the numbering of references. Please note that some content of this document may be patented. The issuing authority of this document assumes no responsibility for identifying these patents. This part is proposed by the State Drug Administration. This part is under the jurisdiction of the National Standardization Technical Committee of Anesthesia and Respiratory Equipment (SAC/TC116). This section is drafted by: Shanghai Dräger Medical Equipment Co., Ltd., Shanghai Medical Equipment Testing Institute. The main drafters of this section. Yan Cuiren, Yu Hongyi, Zhu Yancong, Ding Deping. The previous

versions of the standards replaced by this part are as follows.

---YY 0600.2-2007.

## Introduction

This part of YY 9706 specifies specific requirements for domestic ventilators used by ventilator-dependent patients. Such ventilators are intended for In a home care setting, patients using such devices rely on the ventilator for support to stay alive. In addition, such breathing is often used Where the machine is located, its power source is often unreliable. Such ventilators are often used by non-healthcare workers (inexperienced operators) with varying degrees of training. use under the supervision of the author). Ventilators that comply with this part may also be used in other settings (ie, healthcare facilities). In this section.

--- "Chapter" means one of seventeen numbered sections within the Table of Contents, including all branches (eg Chapter 7 contains 7.1 and 7.2 etc.); and

--- "Article" refers to a numbered sub-clause (eg,.201.7.1,.201.7.2 and.201.7.2.1 are sub-clauses of.201.7). In this section, when citing a chapter, use "Chapter X". In this section, when citing a supplement, only the number of the supplement is indicated. In this section, the conjunction "or" is used as "inclusive or". Thus, a statement is true if any combination of its conditions is reality. The text format used in this part conforms to the usage specified in Annex H of Part 2 of the ISO /IEC Directives. In this section, the following Auxiliary verbs have the following specific meanings.

--- "Should" means to comply with a requirement or a test that should be enforced in this part;

--- "Should" be expressed to comply with a requirement or a test recommended in this section, but not mandatory;

--- "Can" is used to describe the method allowed to achieve a requirement or a test. In this part of the text, the chapter, article number and table title are marked with "\*" to indicate that there is further explanation and explanation of the article in Appendix AA. illustrate. Medical Electrical Equipment Part 2-72. of home ventilators used by ventilator-dependent patients Particular requirements for basic safety and basic performance 201.1 Scope, Purpose and Related Standards Except for the following, Chapter 1 of GB 9706.1-2020 applies. 201.1.1 \*Scope 1.1 in GB 9706.1-2020 is replaced by the following. This part specifies the basic safety and essential performance of ventilators (hereinafter also referred to as ME EQUIPMENT) used in combination with accessories. Suction machine.

--- Intended for use in a home care environment;

--- Expected to be operated by inexperienced operators;

--- Intended for use on a ventilator to support the life of a patient.