ICS 11.040.10
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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.287-2025

Medical electrical equipment - Part 2-87: Particular requirements for basic safety and essential performance of high-frequency ventilators

医用电气设备 第2-87部分：高频呼吸机的基本安全和基本性能专用要求

Issued on: February 26, 2025 **Implemented on: March 1, 2028**

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Foreword

This document was issued on 26 February 2025 by the National Medical Products Administration and takes effect on 1 March 2028.

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

It is classified under ICS 11.040.10, Chinese classification C46.

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. Medical Electrical Equipment is divided into two parts.

--- Part 1: General and parallel requirements;

--- Part 2: Particular requirements. This document is Part 2-87. This document is modified to adopt ISO 80601-2-87.2021 "

--- IEC 60068-2-27.2008 was replaced by the normative reference GB/T 2423.5-2019 to adapt to my country's technical conditions;

--- IEC 60068-2-31.2008 was replaced by the normative reference GB/T 2423.7-2018 to adapt to my country's technical conditions;

--- IEC 60068-2-64.2008 was replaced by the normative reference GB/T 2423.56-2018 to adapt to my country's technical conditions;

--- Replaced ISO 3744.2010 with the normative reference GB/T 3767-2016 to adapt to my country's technical conditions;

--- IEC 61672-1.2013 was replaced by the normative reference GB/T 3785.1 to adapt to my country's technical conditions;

--- Replaced IEC 60529.1989 AMD1.1999 AMD2.2013 with the normative reference GB/T 4208 to adapt to our Technical conditions of the country;

---Replaced IEC 60601-1.2005 AMD1.2012 AMD2 with normative references GB 9706.1-2020. 2020, to adapt to the technical conditions of our country;

--- Replaced ISO 80601-2-55.2018 with the normative reference GB 9706.255-2022 to adapt to my country's technical conditions;

--- Replaced ISO 7396-1.2016 with the normative reference GB/T 44059.1 to adapt to my country's technical conditions;

--- Replaced ISO 4871.1996 with the normative reference GB/T 14574-2000 to adapt to my country's technical conditions;

--- Replaced ISO 14937.2009 with the normative reference GB/T.19974 to adapt to my country's technical conditions;

--- ISO 7010 was replaced by the normative reference GB/T 31523.1 to adapt to my country's technical conditions;

--- ISO 32.1977 was replaced by the normative reference GB 50751 to adapt to my country's technical conditions;

--- Replaced ISO 23328-1.2003 with the normative reference YY/T 0753.1 to adapt to my country's technical conditions;

--- Replaced ISO 23328-2.2002 with the normative reference YY/T 0753.2 to adapt to my country's technical conditions;

--- Replaced ISO 5359.2014 with the normative reference YY/T 0799 to adapt to my country's technical conditions;

--- Replaced ISO 17664.2017 with the normative reference YY/T 0802 to adapt to my country's technical conditions;

--- Replaced ISO 80369-1.2018 with the normative reference YY/T 0916.1 to adapt to my country's technical conditions;

--- ISO 5356-1 was replaced by the normative reference YY/T 1040.1 to adapt to my country's technical conditions;

--- IEC 62366-1.2015 was replaced by the normative reference YY/T 1474 to adapt to my country's technical conditions.

--- Replaced ISO 18562-1.2017 with the normative reference YY/T 1778.1 to adapt to my country's technical conditions;

--- Replaced ISO 80601-2-74 with the normative reference YY 9706.274-2022 to adapt to my country's technical conditions; The following editorial changes were also made to this document.

--- IEC 60601-1-10 was replaced by the informative reference YY/T 9706.110 to adapt to my country's technical conditions (see Appendix AA.1);

--- IEC 60601-1-11.2015 was replaced by the informative reference YY 9706.111-2021 to adapt to my country's technical conditions (See Appendix AA.1);

---Replaced IEC 60601-1-12.2014 with the informative reference YY 9706.112-2021 to adapt to my country's technical conditions (See Appendix AA.1);

--- Replaced ISO 80601-2-84.2020 with the informative reference YY 9706.284-2023 to adapt to my country's technical conditions (See Appendix AA.1).

--- Added the release year of ISO 4135, modified the terminology source, changed 3.6.1.4 to 3.6.1.5, 3.1.4.13 to 3.1.4.15, 3.1.4.19 changed to 3.1.4.21, 3.1.4.22 changed to 3.1.4.24, 3.1.4.39.4 changed to 3.1.4.41.4, 3.1.4.47 changed to 3.1.4.48, 3.1.5.20 changed to

3.1.5.19 (see.201.3.208,.201.3.209,.201.3.222,.201.3.223,.201.3.227, 201.3.247,201.3.251,201.3.252,201.3.260,201.3.267,201.3.280);

---Added the release year YY 9706.274, and corrected the editorial error in the term source, changing.201.3.214 to 201.3.209 (see.201.3.235);

--- Modified the editorial error in the term source, changing 3.17 to 3.16 (see.201.3.269);

--- Deleted Appendix FF term index. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Technical Committee for Standardization of Anesthesia and Respiratory Equipment (SAC/TC116).

Introduction

The medical electrical equipment safety standards are also called the 9706 series of standards, which consist of general standards, parallel standards, special standards, guidelines and interpretations.

---General standards. safety standards that should be generally applicable to medical electrical equipment, that is, equipment that meets the definition of medical electrical equipment should meet this Basic standards.

--- Parallel standards. safety standards that should be generally applicable to medical electrical equipment, but in most cases are limited to those with certain specific functions or characteristics. Only devices that are suitable for this purpose need to meet such standard requirements.

---Special standards. safety standards that apply to a certain type of medical electrical equipment, and not all medical electrical equipment has a special standard. standard.

---Guidelines and interpretations. application guidance and interpretations of relevant requirements in the standards involved. Items marked with an asterisk (*) in this document have specific guidance and rationale related to that item in Appendix AA. The relevant contents are considered to be helpful for the correct application of this specific standard, and any version will be revised when the clinical application changes or the technology is updated. It will also be used when making necessary revisions. Medical electrical equipment Part 2-87: High frequency respiration Particular requirements for basic safety and essential performance of machines 201.1 Scope, purpose and related standards Except as follows, Chapter 1 of the general standard applies. Note. The general standard is GB 9706.1-2020. 201.1.1 *Scope replace. This document specifies the basic safety and essential requirements of high frequency ventilators (HFV) (hereinafter referred to as "ME EQUIPMENT") used in combination with accessories. performance. This document is intended for use in professional medical institutions by professional medical personnel for