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

YY/T 1438-2026

Replacing YY/T 1438-2016

**Anesthesia and respiratory equipment - Peak expiratory flow
rate for evaluating spontaneously breathing lung function**

麻醉和呼吸设备 评价自主呼吸者肺功能的呼气峰值流量计

(English Translation)

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References

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document replaces YY/T 1438-2016 "Peak Expiratory Flow Meter for Evaluating Lung Function in Spontaneously Breathing Individuals with Anesthesia and Respiratory Equipment".

Compared with YY/T 1438-2016, apart from structural adjustments and editorial changes, the main technical changes are as follows.

---Added terms and definitions for "Manufacturer," "Model or Type Reference Number," and "Responsible Party" (see 3.3, 3.4, and 3.7);

---The markings on PEFM have been changed (see 5.2.1, 2016 version 5.2.1);

---The labeling on the PEFM packaging has been changed (see 5.2.2, 2016 version 5.2.2);

---The contents of the instruction manual have been revised (see 5.3, 2016 version 5.3);

---The technical specification has been amended (see 5.4, 2016 version 5.4);

---The requirements for airflow resistance have been changed (see 7.3, 2016 version 7.3);

---The impact of handheld PEFM drops has been changed (see 10, 2016 edition 10);

This document is modified to adopt ISO 23747:2015 "Anesthesia and respiratory equipment - Evaluation of spontaneously breathing lung function. peak expiratory flow meters".

The technical differences between this document and ISO 23747:2015, and the reasons therefor, are as follows.

---GB 9706.1-2020, a normative reference, has replaced IEC 60601-1:2005 to adapt to my country's technical conditions;

---The normative standard GB/T 16886.1 has replaced ISO 10993-1:2009 to adapt to my country's technical conditions;

---The normative standard GB/T.19974 has been used instead of ISO 14937 to adapt to my country's technical conditions;

---YY/T 0466.1-2023, a normative reference, has replaced ISO 15223-1:2012 to adapt to my country's technical conditions;

---The term "medical device" has been removed to align with my country's technological requirements.

The following editorial changes have been made to this document.

---The introduction has been modified;

---When planning and designing products applicable to this document, the environmental impact of the product throughout its entire life cycle should be considered.

The environmental factors are given in Appendix B and the note "More environmental impact factors are mentioned in GB/T 42062" are moved to the next section.

The words were correct;

Appendix F has been removed;

---Corrected an editing error in B.4.5 of ISO 23747:2015.changed "qn 1wqn" in linearity to "qn 1>= "qn" and "qn 1uqn" should be changed to "qn 1<=qn";

---Reference ISO/T R16142.2006 has been removed.

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the National Technical Committee on Standardization of Anesthesia and Respiratory Equipment (SAC/TC116).

Introduction

To ensure that healthcare professionals can safely and reliably use peak expiratory flow (PEF) measurement devices when diagnosing and monitoring lung and airway conditions.

It is crucial to establish minimum requirements for peak expiratory flow rate measurement and to develop standards for it.

This document is based on the latest available methods and waveforms for testing peak expiratory flow meters (PEFM).

In this document, the provisions of the basic principles are provided in Appendix A and marked with an asterisk (*) in the main text.

When planning and designing products applicable to this document, the environmental impact of the product throughout its entire life cycle should be considered. Environmental factors are detailed in the appendix.

As shown in Record B.

Note: More environmental impact factors are mentioned in GB/T 42062.

Anesthesia and respiratory equipment evaluation of spontaneously breathing patients Peak expiratory flow meter for lung function

1 Scope

This document specifies the requirements for peak expiratory flow meters (PEFMs) intended for use in evaluating the lung function of spontaneously breathing individuals.

This document applies to all medical devices used to measure peak expiratory flow in spontaneously breathing individuals, regardless of whether they are comprehensive pulmonary function devices.

It is either a part or a separate medical device.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included.

For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies.

This document.

GB 9706.1-2020 Medical electrical equipment - Part 1: General requirements for basic safety and basic performance (IEC 60601-1) 2012, MOD) GB/T 16886.1 Biological evaluation of medical devices - Part 1: Evaluation and testing in the risk management process (GB/T 16886.1-2022, ISO 10993-1:2018, IDT) GB/T.19974 Characteristics of sterilizing agents for sterilization of medical and health care products and development, validation and routine control of sterilization processes for medical devices General requirements (GB/T.19974-2018, ISO 14937:2009, IDT) YY/T 0466.1-2023 Symbols for medical devices used to provide information to manufacturers - Part 1: General requirements (ISO 15223-1.

2021, MOD)

3 Terms and Definitions

The following terms and definitions apply to this document.

Note: The index of defined terms arranged alphabetically can be found in Appendix C.

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