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Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans

Matériel d'anesthésie et de réanimation respiratoire — Débitmètres à débit de pointe expiratoire pour l'évaluation de la fonction pulmonaire chez les êtres humains respirant spontanément

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This second edition cancels and replaces the first edition (ISO 23747:2007), which has been technically revised.

Introduction

The development of a standard for PEAK EXPIRATORY FLOWRATE (PEF) measurement is considered important for clinicians to use in diagnosing and monitoring lung and airway conditions by ensuring that all MEDICAL DEVICES for such purposes meet minimum levels for safety and performance. An agreed standard means that a PEAK EXPIRATORY FLOW METER (PEFM) can be tested to meet the same requirements with the latest accepted methods. Clinicians and patients can then be confident that a PEFM is fit for the purposes for which it is intended.

The American Thoracic Society has been foremost in proposing initial standards for testing a PEFM (see Reference [15]). They have proposed 26 waveforms suitable for testing PEF, which are deemed suitable for checking that a PEFM can correctly measure PEF.

The work of Miller et al. (see Reference [18]) first showed the problem of PEFM inaccuracy and they have subsequently defined the population characteristics of the PEF profile (see Reference [21]) and demonstrated limitations of pump systems for testing a PEFM (see Reference [20]). The European Respiratory Society has published a comprehensive statement on PEF (see Reference [21]).

This International Standard is based on the best currently available evidence concerning the methods and waveforms suited for testing a PEFM (see Reference [17]).

Throughout this International Standard, text for which a rationale is provided in Annex A, is indicated by an asterisk (*).

In this International Standard, the following print types are used:

— Requirements and definitions: roman type.

— *Test specifications: italic type.*

— Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

— TERMS DEFINED IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans

1 Scope

This International Standard specifies requirements for a PEAK EXPIRATORY FLOW METER (PEFM) intended for the assessment of pulmonary function in spontaneously breathing humans.

This International Standard covers all MEDICAL DEVICES that measure PEAK EXPIRATORY FLOWRATE in spontaneously breathing humans either as part of an integrated lung function MEDICAL DEVICE or as a stand-alone MEDICAL DEVICE.

Planning and design of products applying to this International Standard are to consider the environmental impact from the product during its life cycle. Environmental aspects are addressed in Annex E.

NOTE Additional aspects of environmental impact are addressed in ISO 14971.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1:2009, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60601-1:2005+A1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE An alphabetized index of defined terms is found in Annex G.

3.1
BTPS
body temperature (37 °C), at the measured pressure when saturated with water vapour

3.2
DWELL TIME
DT
time for which the expiratory flowrate is in excess of 90 % of the achieved PEF