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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

Reference number
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 23747 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

Introduction

The development of a standard for peak expiratory flowrate (PEF) measurement is considered important for the enhancement of the ability of clinicians to diagnose and monitor lung conditions by ensuring that all devices for such purposes meet minimum levels for safety and performance. An agreed standard means that peak expiratory flow meters (PEFM) can be tested to meet the same requirements with the latest accepted methods. Clinicians and patients can then be confident that these PEFM are fit for the purposes for which they are intended.

The American Thoracic Society has been foremost in proposing initial standards for testing PEFM [14]. They have proposed 26 waveforms for testing PEF, which are deemed suitable for checking that these PEFMs can correctly measure PEF.

The work of Miller et al. [16] first showed the problem of PEFM inaccuracy and they have recently defined the population characteristics of the PEF profile [18] and demonstrated limitations of pump systems for testing PEFM [17]. The European Respiratory Society has published a comprehensive statement on PEF [18].

This International Standard is based on the best currently available evidence concerning the methods and waveforms suited for testing PEFM [15].

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

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 peak expiratory flow meters (PEFMs) intended for the assessment of pulmonary function in spontaneously breathing humans.

This International Standard covers all devices that measure peak expiratory flowrate in spontaneously breathing humans either as part of an integrated lung function device or as a stand-alone device.

Planning and design of products applying to this International Standard should 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 referenced documents are indispensable for the application of this document. 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, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management system*

ISO 14937, *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 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60601-1:2005, *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.

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 (3.3)