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Second edition  
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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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## Contents

	Page
<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 General requirements</b> .....	<b>3</b>
4.1 Safety for a PEFM that utilizes electricity.....	3
4.2 Mechanical basic safety for all PEFMS.....	3
<b>5 Identification, marking and documents</b> .....	<b>3</b>
5.1 Marking of the scale or display.....	3
5.2 Marking of the PEFM or packaging.....	4
5.2.1 Marking of the PEFM.....	4
5.2.2 Marking of the PEFM packaging.....	4
5.3 Instructions for use.....	5
5.4 Technical description.....	5
<b>6 PEFM measurement range</b> .....	<b>5</b>
<b>7 Performance requirements</b> .....	<b>6</b>
7.1 Error of measurement.....	6
7.2 Linearity.....	6
7.3 Resistance to flow.....	6
7.4 Frequency response.....	6
<b>8 Dismantling and reassembly</b> .....	<b>6</b>
<b>9 Effects of mechanical ageing</b> .....	<b>6</b>
<b>10 Effects of dropping a hand-held PEFM</b> .....	<b>7</b>
<b>11 Cleaning, sterilization, and disinfection</b> .....	<b>7</b>
11.1 Reusable PEFM and parts.....	7
11.2 PEFM and parts delivered sterile.....	7
<b>12 Compatibility with substances</b> .....	<b>7</b>
<b>13 Biocompatibility</b> .....	<b>7</b>
<b>Annex A (informative) Rationale for tests and examples of test apparatus</b> .....	<b>8</b>
<b>Annex B (normative) Determination of error, repeatability, and resistance to PEFM output</b> .....	<b>11</b>
<b>Annex C (normative) Determination of frequency response</b> .....	<b>14</b>
<b>Annex D (normative) Test methods for determination of the effects of dismantling, ageing and dropping</b> .....	<b>16</b>
<b>Annex E (informative) Environmental aspects</b> .....	<b>18</b>
<b>Annex F (informative) Reference to the Essential Principles</b> .....	<b>20</b>
<b>Annex G (informative) Terminology — Alphabetized index of defined terms</b> .....	<b>24</b>
<b>Bibliography</b> .....	<b>25</b>

## 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](http://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](http://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.

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## 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.