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# Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time forced expired volumes in humans

*Matériel d'anesthésie et de réanimation respiratoire — Spiromètres destinés au mesurage des volumes expiratoires forcés chronométrés chez les humains*

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ISO 26782:2009(E)

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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 26782 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

# Introduction

A **spirometer** is a medical device that records physiological lung ventilation volumes within the range of the vital capacity.

The timed volumes that a **PATIENT** is able to expel after a maximal inspiration give a reliable method of assessing lung function. These spirometric assessments are used, for example, to screen individuals at risk of lung disease, to give objective measures in the presence of lung disease, to evaluate symptoms and pre-operative risk and to record the effect of therapeutic intervention. A **SPIROMETER** can also be used in evaluating pulmonary disability, public health and clinical trials.

The American Thoracic Society (ATS) and the European Respiratory Society (ERS) have been instrumental in developing recommendations for the standardization of lung function testing, including guidelines for spirometry [6], [7]. There is however no recognised international or national standard for **SPIROMETERS** with reliance for accuracy, repeatability, etc. based on objective test methodology and on meeting defined tolerances when tested with a carefully selected set of defined test profiles such as those published by the ATS.

This International Standard addresses this problem by developing a standard for a **SPIROMETER** to give the clinician the confidence that any **SPIROMETER** used meets agreed standards of accuracy, repeatability, electrical safety, etc.

The minimum safety requirements specified in this particular International Standard are considered to provide a practical degree of safety in the operation of **SPIROMETERS**.

The requirements are followed by specifications for the relevant tests.

A “rationale and guidance” section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex A. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of this International Standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this International Standard.

In this document, the following print types are used:

— requirements, compliance with which can be verified, and definitions: roman type;

— notes and examples: smaller roman type;

— *description of type of document change, and test methods: italic type;*

— **TERMS DEFINED IN THIS DOCUMENT: SMALL CAPITALS.**

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