ISO 26782:2009-07 (E)

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

Contents

Page

Foreword iv

Introduction v

1 *Scope 1

2 Normative references 1

3 Terms and definitions 2

4 General requirements 4
4.1 Electrical safety 4
4.2 Mechanical safety 4

5 Identification, marking and documents 4
5.1 Marking of the scale or display 4
5.2 Legibility of markings 5
5.3 Durability of markings 5
5.4 Marking of the spirometer or its packaging 6
5.5 Instructions for use 6
5.6 Technical description 8

6 *Measurement range 8

7 Performance requirements 8
7.1 Accuracy 8
7.2 Recording time 9
7.3 Graphical display aspect ratios 9
7.4 Volume recording 9
7.5 *Start of forced exhalation 9
7.6 *End of forced exhalation 9
7.7 Linearity 9
7.8 Repeatability 9
7.9 Expiratory impedance 10

8 Constructional requirements 10
8.1 Effects of dropping components of a hand-held spirometer or accessory 10
8.2 Calibration 10
8.3 Dismantling and re-assembly 10

9 Cleaning, sterilization and disinfection 10
9.1 Re-usable spirometer and parts 10
9.2 Spirometer and parts requiring processing before use 11
9.3 Spirometer and parts delivered sterile 11

10 Biocompatibility 11

Annex A (informative) Rationale 12

Annex B (normative) Testing accuracy, linearity and impedance of spirometers 16

Annex C (normative) * Defined test profiles 20

Annex D (informative) Environmental aspects 23

Annex E (informative) Reference to the essential principals 24

Bibliography 26

Alphabetized index of defined terms used in this International Standard 27