

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