

PRODUCT CODES – 911006E0 - Spirometer; 911006E1 - Spirometer with reusable turbine

Technical specification

Width	49.7 mm
Length	142 mm
Thickness	26 mm
Weight	65 g

Turbine



Reusable turbine (code 910002)
Disposable turbine (code 910004)

Supply voltage	5 V d.c. USB connection
Rated electrical power	0.25 W
Rated input current	50 mA max
Backup battery voltage	none
Connectivity	USB 2.0
Display	none
Mouthpieces	Ø 30 mm (1.18 inch)
IP protection level	IPX1
Type of electrical protection	Class II device
Safety level for shock hazard	Type BF Apparatus

Conditions of use	Apparatus for continuous use
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Storage conditions	Temperature:	MIN -20 °C, MAX +60 °C
	Humidity:	MIN 10% RH; MAX 95%RH

Operating Conditions	Temperature:	MIN +10 °C, MAX +40 °C
	Humidity:	MIN 10% RH MAX 95%RH

Memory capacity	database PC software
PC software	winspiroPRO
Applicable standards	IEC 60601-1:2005 + Amd1:2012

EN 60601-1-2: 2015
ISO 26782: 2009
ISO 23747: 2015
ATS/ERS: 2005, 2019 update
ISO 80601-2-61: 2017

Spirometry

Flow sensor	bi-directional digital turbine
Volume range	10 L
Flow range	±16L/s
Volume accuracy (ATS 2019)	±2.5% or 50 mL
Flow accuracy	±5% or 200 mL/s
Dynamic resistance	<0.5 cm H ₂ O/L/s
Temperature sensor	semiconductor (0-45°C)
Test available	FVC, VC, IVC, MVV, PRE-POST FVC, FEV1, FEV1/FVC%, FEV3, FEV3/FVC%, FEV6, FEV1/FEV6%, PEF, FEF25, FEF50, FEF75, FEF2575, FET, ELA, EVOL, FIVC, FIV1, PIF, FIV1/FIVC%, PIF, IRV, VC, IVC, IC, ERV, FEV1/VC%, VT, VE, Rf, t _f , t _E , t _i /t _{TOT} , VT/t _f , MVV
Measured parameters	

Oximetry (optional)

Measurement method	Red and infrared absorption
SpO2 range	0-99%
SpO2 accuracy	± 2% between 70-99% SpO2
Average number of heart beats for the %SpO2 calculation	8 beats
Pulse Rate range	30-300 BPM
Pulse Rate accuracy	± 2BPM or 2% whichever is greater
Average interval for the calculation of cardiac pulse	8 seconds
Signal quality indication	0 - 8 segments on display
Test available	spot
Measured parameters	SpO2% min, max, average BPM min, max, average Test duration % Bradycardia Duration (<40 BPM) % Tachycardia Duration (>120 BPM) % of Time with SpO2 ≤ 90% (T90%, T89%)

Certificates & Registrations

CE 0476	MED 9826
FDA 510 (k)	K 122384
Health Canada	71191 (class II)
CND code	Z12150102
GMDN code	13680
Ministry of Health	678828/R

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