



Applicable standards

IEC 60601-1:2005+Amd1:2012
EN 60601-1-2: 2015
EN ISO 14971: 2019
ISO 10993-1: 2018
2011/65/UE Directive
EN ISO 15223:2016
IEC 60601-1-6:2010+Amd2013
IEC 60601-1-11: 2015
ATS/ERS Guidelines
ISO 26782: 2009
ISO 23747: 2015

Technical specification

Width 49 mm
Length 109 mm
Thickness 21 mm
Weight 60.7 g (batteries included)

Turbine



Single Patient Reusable Turbine with Mouthpiece (code 910013)

Power supply 2 batteries AAA 1.5 V
Consumption max 12 mA
Stand by 8 µA medium
Backup battery voltage none
Batteries charger autonomy none
5-10 years
Connectivity Bluetooth® 4.0
Mouthpieces Ø 30 mm (1.18 inch)

Type of electrical protection Internal power supply
Safety level for shock hazard Type BF Apparatus
Conditions of use Apparatus for continuous use

Conditions of storage Temperature: MIN -25 °C, MAX +70 °C
Humidity: MIN 10% RH; MAX 93%RH

Operating Conditions Temperature: MIN +5 °C, MAX + 40 °C
Humidity: MIN 10% RH, MAX 93%RH

Shipping conditions Temperature: MIN -25 °C, MAX +70 °C
Humidity: MIN 10% RH; MAX 93%RH

Spirometry

Flow sensor bi-directional digital turbine
Flow range ±16L/s
Volume accuracy ±2.5% or 0,05 L
Peak Flow accuracy ±10% or 0,33 L/s
Dynamic resistance <0.5 cm H2O/L/s
Temperature sensor none
Test available Peak Flow
Measured parameters FEV1, PEF
Memory capacity the application on the smart phone memorizes data

Certificates & Registrations

CE 0476 MED 9826
FDA 510 (k) K181666
Health Canada 96378 (class II)
CND code Z12150102
GMDN code 46906
Ministry of Health 1380054/R