



Applicable standards

IEC 60601-1:2005 + A1:2012 + A2:2020
IEC 60601-1-2:2014 + A1:2020
EN ISO 14971:2019
ISO 10993-1:2018
2011/65/UE Directive
EN ISO 15223-1:2021
IEC 60601-1-6:2010 + A1:2013 + A2:2020
IEC 60601-1-11:2015 + A1:2020
ATS/ERS Guidelines(2019 update)
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 μ A medium
Backup battery voltage	none
Batteries charger	none
Life time	5 years
Connectivity	Bluetooth® 5.0 ready
Mouthpieces	Ø 30 mm (1.18 inch)

Type of electrical protection	Internal power supply
Safety level for shock hazard	Type BF Apparatus
IP protection level	IP22
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 15% 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 H ₂ O/L/s
Temperature sensor	none
Measured parameters	FEV1, PEF
Memory capacity	the application on the smart phone stores data

Certificates & Registrations

CE 0476	MDR 2017/745
FDA 510 (k)	K181666
Health Canada	96378 (class II)
EMDN liv.4	Z121501
CND code	Z12150102
GMDN code	46906
Ministry of Health	2494874/R