

Minispir Datasheet

	From Minispir software via connection to the device
Spirometry	FVC, FEV1, PEF, FEF75, FEF25-75, FET, FEV1/FVC, FEV6, FEV1/FEV6, FEF25, FEF50, FIVC, FEV1/VC, ELA, MVV(cal), Time to PEF, FEV0.5, FEV0.5/FVC, FEV0.75, FEV0.75/FVC, FEF75-85, Extr. VoL, VC, EVC, IVC, IC, VC, ERV FEV3, FIV1, FIV1/FIVC, PIF, FEV3/FVC, PIF, FEV2, FEV2/FVC, FIF25, FIF50, FIF75, R50, FEV1/PEF (EI), FEV1/FEV0.5 (RFEV), TV, VE, RR, tI

Size	49.7 x 142 x 26 mm
Weight	65 g
Turbines	·Reusable Turbine (code 910002) ·Disposable turbine (code 910004)
Supply voltage	5V USB connection
Nominal electrical power	0.25W
Nominal input current	50mA max
Backup battery voltage	absent
Connectivity	USB 2.0
Display	absent
Mouthpiece	Ø 30 mm (1.18 inches)
IP protection level	IPX1
Electrical protection	Class II device
Electrical safety level	Type BF device
Terms of use	Device for continuous use
Storage conditions	Temp: MIN -40°C, MAX+70°C Humidity: MIN 10% RH; MAX 95%RH
Terms of use	Temp: MIN +10°C, MAX +40°C Humidity: MIN 10% RH, MAX 95%RH
PC Software	Minispir
Memory capacity	PC software database

Spirometry	
Flow sensor	two-way digital turbine
Flow Range	± 16 L/s
Volume accuracy (ATS 2019)	± 2.5% or 50 mL
Flow accuracy	± 5% or 200 mL/s
Dynamic resistance	< 0.5 cm H2O/L/s
Temperature sensor	semiconductor(0-45°C)
Available tests	FVC, VC, IVC, MVV, PRE-POST
Measured parameters	FVC, FEV1, FEV1/FVC%, FEV3, FEV3/FVC%, FEV6, FEV1/FEV6%, PEF, TPEF, FEF25, FEF50, FEF75, FEF2575, FEF7585, FET, FEV05, FEV05%, FEV075, FEV075%, FEV2, FEV2%, ELA, BEV, FIVC, FIV1, PIF, FIV1/FIVC%, PIF, IRV, VC, IVC, EVC, IC, EI, RFEV, ERV, FIVC, FIV1/FIVC, FEV1/VC%, FIF25, FIF50,FIF75, R50, VT, VE, RR, tI, tE, ti/tTOT, VT/tI, MVV, MVV cal, MV
Certificates and registrations	
CE 0476	MDR 2017/745
FDA 510 (k)	K 122384
Health Canada	71191 (Class II)
EMDN liv.4	Z121501
CND Code	Z12150102
GMDN Code	46906 (spiral)
Ministry of Health	2494682/R (911006IO) 2494688/R (911006II)
Applicable regulations	Electrical Safety IEC 60601-1 Electro Magnetic Compatibility EN 60601-1-2 ISO 26782: 2009 ISO 23747: 2015 ATS/ERS:2005, 2019(update) IEC 60601-1-6:2010 IEC 60601-1-9:2007+AMD1:2013 IEC 62304:2006 + A1:2015 ISO 10993-1:2018

Compliance with guidelines and standards

Spirometry: ATS/ERS 2005 + update to 2019;
ISO 23747: 2015; ISO 26782: 2009