Personal Smart

SMART ONE

App-Based Spirometer

The simplest device for Personal Care. Real time test available on Smartphone and Tablet via Bluetooth Smart 4.0





SMARTONE



MAIN features



AUTOMATIC PAIR AND PLAY

Automatic pairing via Bluetooth BLE. Real-time test result on your Smartphone and Tablet

MOBILE APP INCLUDED

Intuitive App for selfmanagement of lung conditions, always included for iOS and Android

MEASURED PARAMETERS

Spirometry Parameters: PEF, FEV1

COMPLIANCE ATS/ERS 2019

And other Standards including ISO 26782 (for Spirometry), ISO 23747 (for PEF), and more. CE0476, FDA 510 (k)



DISTINCTIVE features



SPIROMETRY GUIDELINES

Suitable for all ages from 5 to 93 years and multiethnic groups (GLI predicted sets)

PERSONAL CARE

Ideal in the selfmanagement of Asthma, COPD, CF and other chronic lung disease

MEDICAL REPORT

Share with anyone at anytime via eMail, Whatsapp, SMS, Cloud, Drive and other Apps Ð

COVID-19 PANDEMIC

Avoid going to the hospital or medical offices during COVID-19 pandemic

GO-TO-MARKET TOOLKIT

Software Development Kit available for System Integrators and App Developers. OEM service available for Spirometry and Oximetry.



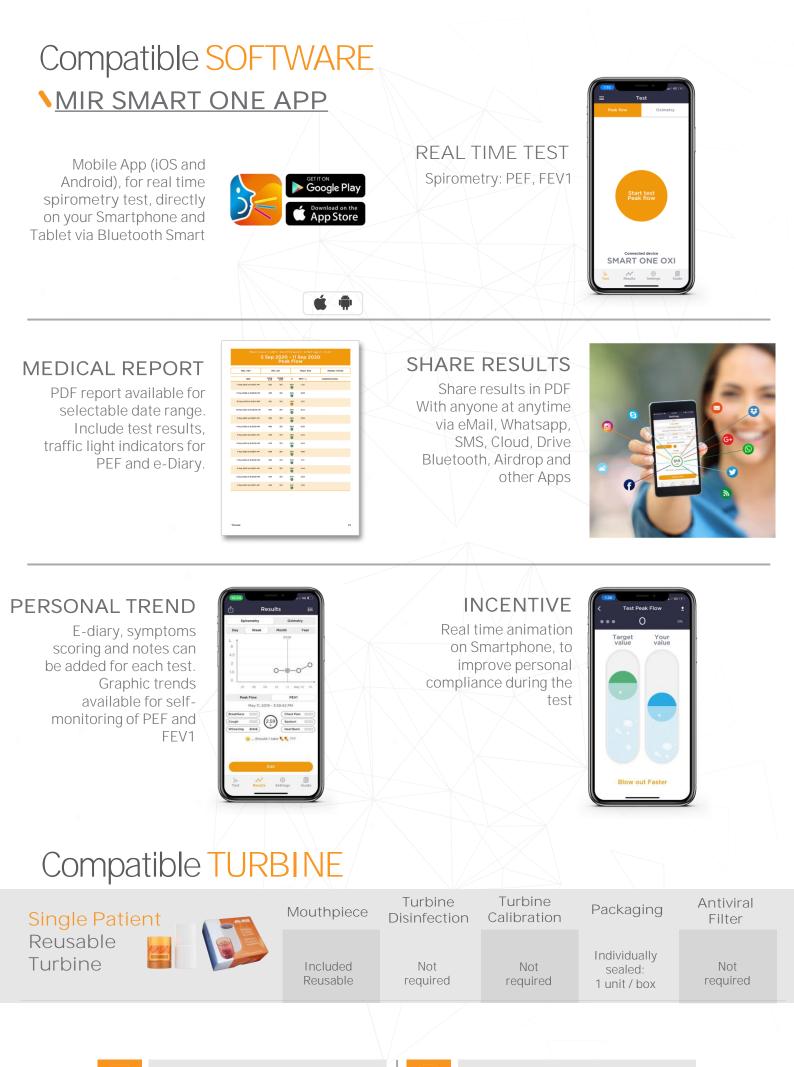
Learn more about available SDK and OEM

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Always INCLUDED

- > 2x AAA 1.5V Batteries
- Single Patient Reusable Turbine
- Plastic reusable mouthpiece

- Vuser manual
- App for Smartphone and Tablet (iOS and Android)



PLAY VIDEO

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SCIENTIFIC PUBLICATIONS

Also available in MORE CONFIGURATIONS









Technical Specification	Smart One	Smart One OXI	Spirobank Smart	Spirobank Oxi
TYPE OF SPIROMETER	App-Based, for Personal Care	App-Based, for Personal Care, with Oximetry Option	App-Based, for Remote Patient Monitoring	App-Based, for Remote Patient Monitoring, with Oximetry Option
COMPATIBLE TURBINES	Single Patient Reusable Turbine	Single Patient Reusable Turbine	flowMIR™ Disposable Turbine, Single Patient Reusable Turbine	flowMIR™ Disposable Turbine, Single Patient Reusable Turbine
COMPATIBLE SOFTWARES	Smart One App	Smart One App	MIR Spirobank App, iSpirometry App	MIR Spirobank App
EXTERNAL CONTROL	Real time test on SmartPhone/Tablet screen. No internal memory, no display. Data are not stored in the device memory. Connect to your Smartphone/Tablet via Bluetooth Smart BLE 4.0	Real time plethysmographic curve and test result on SmartPhone/Tablet screen. No internal memory, no display. Data are not stored in the device memory. Connect to your Smartphone/Tablet via Bluetooth Smart BLE 4.0	Real time test on Smartphone screen. No internal memory, no display. Data are not stored in the device memory. Connect to your Smartphone via Bluetooth Smart BLE 4.0	Real time plethysmographic curve and test result on SmartPhone screen. No internal memory, no display. Data are not stored in the device memory Connect to your Smartphone via Bluetooth Smart BLE 4.0
EHR CONNECTIVITY	Ready-to-Connect with 3rd party Apps for Professional and Personal Care and Clinical Trials	Ready-to-Connect with 3rd party Apps for Professional and Personal Care and Clinical Trials	Ready-to-Connect with 3rd party Apps for Professional and Personal Care and Clinical Trials	Ready-to-Connect with 3rd party Apps for Professional and Personal Care and Clinical Trials
REAL TIME TEST	Simple and intuitive App for Smartphone and Tablet, always included for iOS and Android E-diary, symptoms and notes can be added for each test. Test Results can be shared in PDF (via Whatsapp, E-mail, other Apps), and printed directly (via Bluetooth printer). Real time animation, to help performing a good test. Easy-to-read graphic trends for self-assessment.	Simple and intuitive App for Smartphone and Tablet, always included for iOS and Android E-diary, symptoms and notes can be added for each test. Test Results can be shared in PDF (via Whatsapp, E- mail, other Apps), and printed directly (via Bluetooth printer). Real time animation, to help performing a good test. Easy-to-read graphic trends for self-assessment. Real time plethysmographic curve.	Simple and intuitive App for Smartphone, always included for iOS and Android E-diary, symptoms and notes can be added for each test. Test Results can be shared in PDF (via Whatsapp, E-mail, other Apps), and printed directly (via Bluetooth printer). Real time animation, to help performing a good test. Easy to read Spirometry Guidelines for test compliance.	Simple and intuitive App for Smartphone, always included for iOS and Android E-diary, symptoms and notes can be added for each test. Test Results can be shared in PDF (via Whatsapp, E-mail, other Apps), and printed directly (via Bluetooth printer). Real time animation, to help performing a good test. Easy to read Spirometry Guidelines for test compliance. Real time plethysmographic curve.
MEASURED PARAMETERS	Spirometry Parameters: PEF, FEV1	Spirometry Parameters: PEF, FEV1 Oximetry Parameters: %SpO2min, %SpO2mean, %SpO2max, BPMmin, BPMmean, BPMmax, Ttotal on MIR Smart One App: Spirometry Parameters: PEF, FEV1 Oximetry Parameters: SpO2 (%), Pulse (BPM)	Spirometry Parameters: PEF, FEV1, FVC, FEV1/FVC, FEF2575, FEV6, VEXT, DTPEF, FEF75, FET, FEF25, FEF50, FIVC, FIV1, PIF, FEV3, FEV05, FEV075, FEV2 Oximetry Parameters: %Sp02min, %Sp02mean, %Sp02max, BPMmin, BPMmean, BPMmax, Ttotal on MIR Spirobank App: Spirometry Parameters: PEF, FEV1, FVC, FEV1/FVC, FEF2575, FEV6, VEXT, DTPEF, FEF75, FEF25, FEF50 Oximetry Parameters: Sp02 (%), Pulse (BPM)	Spirometry Parameters: PEF, FVC, FEV1, FEV1/FVC, FEF2575, FEV6, VEXT, DTPEF, FEF75, FET, FEF25, FEF50, FIVC, FIV1, PIF, FEV3 FEV05, FEV075, FEV2 on MIR Spirobank App: PEF, FEV1, FVC, FEV1/FVC, FEF2575, FEV6, VEXT, DTPEF, FEF75, FEF25, FEF50 on iSpirometry App: PEF, FVC, FEV1, FEV1/FVC, FEF2575, FEV6



TECHNICAL datasheet PRODUCT CODE 911100

Technical specification			Applicable standards	IEC 60601-1:2005+Amd1:2012	
Width Length Thickness Weight	49 mm 109 mm 21 mm 60.7 g (batteries	s included)		EN 60601-1-2: 2015 EN ISO 14971: 2019 ISO 10993-1: 2018 2011/65/UE Directive	
Turbine	Single Patient Reusable Turbine with Mouthpiece (code 910013)			EN ISO 15223:2016 IEC 60601-1-6:2010+Amd2013 IEC 60601-1-11: 2015 ATS/ERS Guidelines ISO 26782: 2009 ISO 23747: 2015	
		X/Λ	Spirometry		
Power supply Consumption	2 batteries AAA max 12 mA Stand by 8 uA m		Flow sensor Flow range	bi-directional digital turbine ±16L/s	
Backup battery Voltage Batteries charger Autonomy Connectivity Mouthpieces	none 5-10 years Bluetooth® 4.0 Ø 30 mm (1.18 inch)		Volume accuracy Peak Flow accuracy Dynamic resistance Temperature sensor Test available Measured parameters	±2.5% or 0,05 L ±10% or 0,33 L/s <0.5 cm H2O/L/s none Peak Flow FEV1, PEF	
Type of electrical protection Safety level for	Internal power supply		Memory capacity	the application on the smart phone memorizes data	
shock hazard	Type BF Apparatus				
Conditions of use	Apparatus for continuous use		Certificates & Registrations		
Conditions of storage	Temperature: Humidity:	MIN -25 °C, MAX +70 °C MIN 10% RH; MAX 93%RH	CE 0476 FDA 510 (k) Health Canada CND code GMDN code	MED 9826 K181666 96378 (class II) Z12150102 46906	
Operating Conditions	Temperature: Humidity:	MIN +5 °C, MAX + 40 °C MIN 10% RH, MAX 93%RH	Ministry of Health	1380054/R	
Shipping conditions	Temperature: Humidity:	MIN -25 °C, MAX +70 °C MIN 10% RH; MAX 93%RH			



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