

SMART ONE[™]

App-Based Spirometer

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



MAIN features



AUTOMATIC PAIR AND PLAY

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



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)



MOBILE APP INCLUDED

Intuitive App for self-management of lung conditions, always included for iOS and Android



DISTINCTIVE features



SPIROMETRY GUIDELINES

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



PERSONAL CARE

Ideal in the self-management 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



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



Always INCLUDED

- ✎ 2x AAA 1.5V Batteries
- ✎ Single Patient Reusable Turbine
- ✎ Plastic reusable mouthpiece
- ✎ User manual
- ✎ App for Smartphone and Tablet (iOS and Android)

Compatible SOFTWARE

MIR SMART ONE APP

Mobile App (iOS and Android), for real time spirometry test, directly on your Smartphone and Tablet via Bluetooth Smart



REAL TIME TEST
Spirometry: PEF, FEV1



MEDICAL REPORT

PDF report available for selectable date range. Include test results, traffic light indicators for PEF and e-Diary.

Test Date	PEF (L/min)	FEV1 (L)	PEF Status	FEV1 Status
2020-09-05 10:00	350	1.2	Green	Green
2020-09-05 11:00	340	1.1	Yellow	Yellow
2020-09-05 12:00	330	1.0	Red	Red
2020-09-05 13:00	320	0.9	Yellow	Yellow
2020-09-05 14:00	310	0.8	Green	Green
2020-09-05 15:00	300	0.7	Yellow	Yellow
2020-09-05 16:00	290	0.6	Red	Red
2020-09-05 17:00	280	0.5	Yellow	Yellow
2020-09-05 18:00	270	0.4	Green	Green
2020-09-05 19:00	260	0.3	Yellow	Yellow
2020-09-05 20:00	250	0.2	Red	Red

SHARE RESULTS

Share results in PDF With anyone at anytime via eMail, Whatsapp, SMS, Cloud, Drive Bluetooth, Airdrop and other Apps



PERSONAL TREND

E-diary, symptoms scoring and notes can be added for each test. Graphic trends available for self-monitoring of PEF and FEV1



INCENTIVE

Real time animation on Smartphone, to improve personal compliance during the test



Compatible TURBINE

Single Patient Reusable Turbine



Mouthpiece

Included Reusable

Turbine Disinfection

Not required

Turbine Calibration

Not required

Packaging

Individually sealed: 1 unit / box

Antiviral Filter

Not required

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: %SpO2min, %SpO2mean, %SpO2max, BPMmin, BPMmean, BPMmax, Ttotal on MIR Spirobank App: Spirometry Parameters: PEF, FEV1, FVC, FEV1/FVC, FEF2575, FEV6, VEXT, DTPEF, FEF75, FEF25, FEF50 Oximetry Parameters: SpO2 (%), 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

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

Turbine


Single Patient Reusable Turbine with Mouthpiece (code 910013)

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

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
Autonomy 5-10 years
Connectivity Bluetooth®4.0
Mouthpieces \varnothing 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 \pm 16L/s
Volume accuracy \pm 2.5% or 0,05 L
Peak Flow accuracy \pm 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