Personal Smart

SMARTONE ® OXI

App-Based Spirometer with embedded Oximeter.

The simplest device for Personal Care.
Real time test available on
Smartphone and Tablet
via Bluetooth 5-ready









MAIN features



AUTOMATIC PAIR AND PLAY

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



MOBILE APP INCLUDED



MEASURED PARAMETERS

Spirometry Parameters: PEF, FEV1

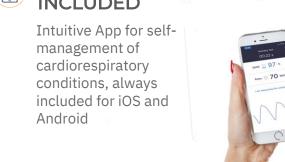
Oximetry Parameters:

%SpO2min, %SpO2mean, %SpO2max, BPMmin, BPMmean, BPMmax, Ttotal



COMPLIANCE ATS/ERS 2019

And other Standards including ISO 26782 (for Spirometry), ISO 23747 (for PEF), ISO 80601-2-61 (for Oximetry) and more. CE0476, FDA Pending









DISTINCTIVE features



SPIROMETRY GUIDELINES

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



REAL-TIME OXIMETRY

Innovative reflectance pulse-oximetry sensor (Touch). Easy to use and accurate.



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

 Plastic reusable mouthp

- 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 and Oximetry** test, directly on your Smartphone and Tablet via Bluetooth



REAL/TIME TEST

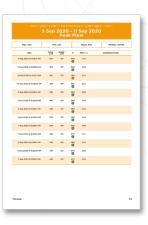
Spirometry: PEF, FEV1 Oximetry: SpO2% (mean), Pulse BPM (mean)





MEDICAL REPORT

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



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 selfmonitoring of PEF, FEV1 and SpO2





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 OXI

Smart One

Spirobank Oxi

Spirobank Smart

	-			
TYPE OF SPIROMETER	App-Based, for Personal Care, with Oximetry Option	App-Based, for Personal Care	App-Based, for Remote Patient Monitoring, with Oximetry Option	App-Based, for Remote Patient Monitoring
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	MIR Spirobank App, iSpirometry App
EXTERNAL CONTROL	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 5-ready	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 5-ready	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 5-ready	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 5-ready
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. Real time plethysmographic curve.	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, 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.	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.
MEASURED PARAMETERS	Spirometry Parameters: PEF, FEV1 Oximetry Parameters: %Sp02min, %Sp02mean, %Sp02max, BPMmin, BPMmean, BPMmax, Ttotal on MIR Smart One App: Spirometry Parameters: PEF, FEV1 Oximetry Parameters: Sp02 (%), Pulse (BPM)	Spirometry Parameters: PEF, FEV1	Spirometry Parameters: PEF, FEV1, FVC, FEV1/FVC, FEF2575, FEV6, VEXT, DTPEF, FEF75, FET, FEF25, FEF50, FIVC, FIV1, PIF, FEV3, FEV05, FEV075, FEV2 Oximetry Parameters: %Sp02mean, %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	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



Oximetry Parameters: SpO2 (%), Pulse (BPM)

TECHNICAL datasheet

PRODUCT CODE 911120

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)

Mouthpiece Power supply Consumption

Autonomy

Connectivity

Ø 30 mm (1.18 inches) 2 batteries AAA 1.5 V max 12 mA

average 8 μA (Stand by) 5-10 years (Stand by)

IP22

Bluetooth® 5-ready Internally powered

protection Safety level for shock hazard

Conditions of use

Type of electrical

IP protection level

Type BF Apparatus

Storage conditions

Apparatus for continuous use

MIN -25 °C, MAX + 70 °C

Humidity:

Temperature:

MIN 10% RH; **MAX 93% RH**

Operating Conditions

MIN + 5 °C, Temperature:

MAX + 40 °C

Humidity:

MIN 10% RH,

MAX 93% RH

Shipping conditions

MIN -25 °C, Temperature:

MAX + 70 °C

Humidity:

MIN 10% RH; **MAX 93% RH**

Applicable standards

ATS/ERS: 2005, 2019 Update

ISO 26782: 2009 ISO 23747: 2015 EN ISO 14971: 2019 ISO 10993-1: 2018 2011/65/UE Directive EN ISO 15223:2016

IEC 60601-1:2005 + A1: 2012

EN 60601-1-2: 2015

IEC 60601-1-6:2010+Amd2013

IEC 60601-1-11: 2015 ISO 80601-2-61: 2017

Spirometry

bi-directional digital turbine Flow sensor

Flow range 16L/s (960 L/m)

Volume range 10 L

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 (@ 12 L/s) **Temperature sensor** none

Available test Peak Flow **Measured parameters** FEV1, PEF

Memory capacity the application on the remote device

(smartphone/tablet) memorizes data

Oximetry

Measuring method double wavelength %Sp02 range 70%-100% %SpO2 accuracy ±1.9%

Average number of 12 beats beats for the calculation

% Sp02

Pulse Rate range 30-200 BPM **Pulse Rate accuracy** ±3% Average interval for 12 seconds

BPM calculation

Quality signal indicator 0-8 lines **Available tests** spot

Measured parameters $%SpO_{2MIN}$, $%SpO_{2MEAN}$,

%SpO_{2MAX},

BPM_{MIN}, BPM_{MEAN}, BPM_{MAX},

 $\mathsf{T}_{\mathsf{TOTAL}}$

Red 660 nm **Wavelength sensors** Infrared 880nm

Maximum optical output power

1.2 mW

Certification & registration

CE 0476 MED 9826 FDA 510 (k) pending **Health Canada** pending **CND Code** Z12150102 **GMDN Code** 46906

