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









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 selfmanagement 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 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



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

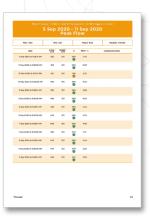
Spirometry: PEF, FEV1





MEDICAL REPORT

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



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 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









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 Consumption

2 batteries AAA 1.5 V

max 12 mA

Stand by 8 µA medium

Backup battery Voltage none
Batteries charger none
Autonomy 5-10
Connectivity Bluet
Mouthpieces Ø 30

none 5-10 years Bluetooth® 4.0 Ø 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 MIN 10% RH;

Humidity: MIN 10% RI

MAX 93%RH

Operating Conditions

Temperature:

MIN + 5 °C, MAX + 40 °C

Humidity:

MIN 10% RH,

narty.

MAX 93%RH

Shipping conditions

Temperature:

MIN -25 °C, MAX +70 °C

Humidity:

MAX + 70 °C MIN 10% RH; MAX 93%RH

Spirometry

Flow sensor bi-directional digital turbine

Flow range ±16L/s

 $\begin{array}{ll} \mbox{Volume accuracy} & \pm 2.5\% \mbox{ or 0,05 L} \\ \mbox{Peak Flow accuracy} & \pm 10\% \mbox{ or 0,33 L/s} \\ \mbox{Dynamic resistance} & < 0.5 \mbox{ cm H2O/L/s} \end{array}$

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

