Personal Smart

SPIROBANK SMART

App-Based Spirometer

The simplest device for accurate Remote Patient Monitoring and Homecare. Real time test available on Smartphone via Bluetooth Smart 4.0









MAIN features



AUTOMATIC PAIR AND PLAY

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



MEASURED PARAMETERS

Spirometry Parameters on App: FVC,FEV1, FEV1/FVC, PEF, FEF2575, FEF25, FEF50, FEF75, DTPEF, VEXT, FEV6



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



(1)



SPIROMETRY GUIDELINES

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

COVID-19

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

PANDEMIC

LIVE VIDEO EXAM

Connect with your Healthcare provider in real-time, from the comfort of your home

READY TO

With 3rd party Apps for Professional Care, Personal Care and Clinical Trials

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



Up- to 30 Spirometry parameters available via SDK!

Always INCLUDED

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

- App for Smartphone (iOS and Android)

Compatible SOFTWARE

MIR SPIROBANK APP

Mobile App (iOS and Android), for real time Spirometry test, directly on your Smartphone via Bluetooth Smart 4.0

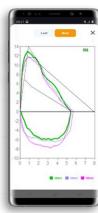
> Add Oximetry results manually on the APP



REAL TIME TEST

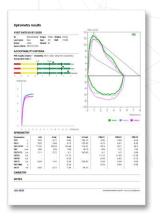
Spirometry: PEF, FVC, FEV1, FEV1/FVC, FEF25/75, FEV6, VEXT, DTPEF, FEF75, FEF25, FFF50





MEDICAL REPORT

Professional PDF report Including Acceptabilty Messages, Quality Control Grade, Acceptable Trials. Variability of FEV1 and FVC, Pictograms



SHARE RESULTS

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



PERSONAL TREND

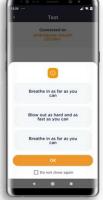
E-diary, symptoms and notes can be added for each test. Oximetry results can also be added manually on the App





INCENTIVE

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





Compatible TURBINES

Single Patient Reusable Turbine



Mouthpie
Included

се Not required

Turbine Disinfection

Calibration

Turbine

Not

required

Packaging

Antiviral Filter

Individually sealed: 1 unit / box

Not required

flowMIR™

Disposable Turbine



Included Disposable

Reusable

Not required

Not required

Individually sealed: 60 or 10 units / box

Not required









Also available in MORE CONFIGURATIONS









Technical Specification	Spirobank Smart	Spirobank Oxi	Smart One	Smart One OXI
TYPE OF SPIROMETER	App-Based, for Remote Patient Monitoring	App-Based, for Remote Patient Monitoring, with Oximetry Option	App-Based, for Personal Care	App-Based, for Personal Care, with Oximetry Option
COMPATIBLE TURBINES	flowMIR™ Disposable Turbine, Single Patient Reusable Turbine	flowMIR™ Disposable Turbine, Single Patient Reusable Turbine	Single Patient Reusable Turbine	Single Patient Reusable Turbine
COMPATIBLE SOFTWARES	MIR Spirobank App, iSpirometry App	MIR Spirobank App	Smart One App	Smart One App
EXTERNAL CONTROL	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	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
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, 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.	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.
MEASURED PARAMETERS	Spirometry Parameters: PEF, FVC, FEV1, FEV1/FVC, FEF2575, FEV6, VEXT, DTPEF, FEF75, FET, FEF25, FEF50, FIV1, 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	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, BPMmean, BPMmean, Total 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, FEV1	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)





TECHNICAL datasheet PRODUCT CODE 911105

Technical specification

Width 49 mm Length 109 mm Thickness 21 mm

Weight 60.7 g (batteries included)

Turbine



Reusable Turbine with plastic 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

Disposable Turbine (code 910004)

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 (Stand by)
Connectivity Bluetooth® 4.0
Mouthpieces Ø 30 mm (1.18 inch)
Type of electrical Internally powered

protection

Safety level for Type BF Apparatus

shock hazard

IP protection level IP22

Conditions of use Apparatus for continuous use

Storage conditions

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 ±16L/s

Volume accuracy ±2.5% or 0,05 L Flow accuracy ±5.0% or 0,20 L/s Dynamic resistance <0.5 cm H2O/L/s

Temperature sensor none Test available FVC,

Measured parameters FEV1, PEF, FVC, FEV1/FVC ratio,

FEV6, FEF2575

Additional parameters available with

F/V version

FIVC, FIV1, PIF FEF25, FEF50, FEF75, EVol, FEV05, FEV075, FEV2, FEV3, FET, PEF Time

Memory capacity the

the application on the smart phone memorizes data

Certificates & Registrations

CE 0476 MED 9826 by Kiwa-Cermet FDA 510(k) K072979

CND code Z12150102 GMDN code 46906

