

Personal Smart

SPIROBANKTM

SMART

App-Based Spirometer

The simplest device for accurate
Remote Patient Monitoring and
Homecare. Real time test available on
Smartphone via **Bluetooth[®]**



MAIN features



AUTOMATIC PAIR AND PLAY

Automatic pairing via **Bluetooth**. Real-time test result available 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 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)



COVID-19 PANDEMIC

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



LIVE VIDEO EXAM

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



READY TO CONNECT

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 19 Spirometry parameters available via SDK!

Always INCLUDED

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

Compatible SOFTWARE

MIR SPIROBANK APP

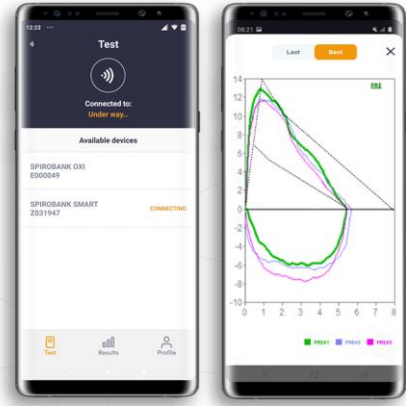
Mobile App (iOS and Android), for real time Spirometry test, directly on your Smartphone via **Bluetooth**

Add **Oximetry** results manually on the APP



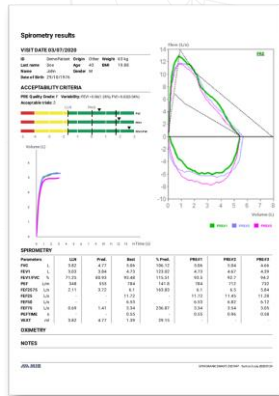
REAL TIME TEST

Spirometry: PEF, FVC, FEV1, FEV1/FVC, FEF25/75, FEV6, VEXT, DTPEF, FEF75, FEF25, FEF50



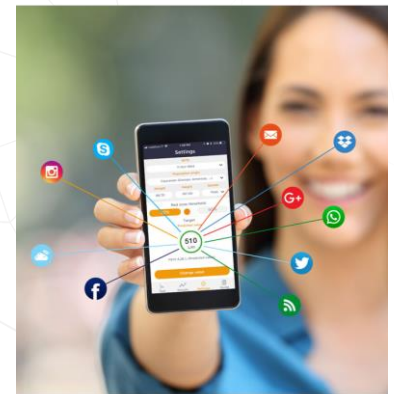
MEDICAL REPORT

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



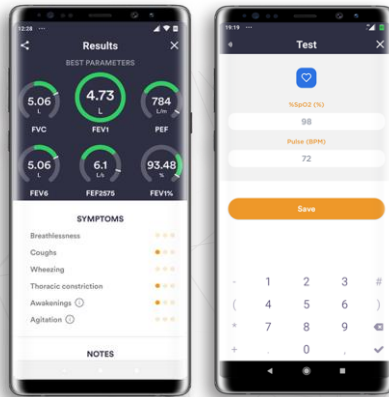
SHARE RESULTS

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



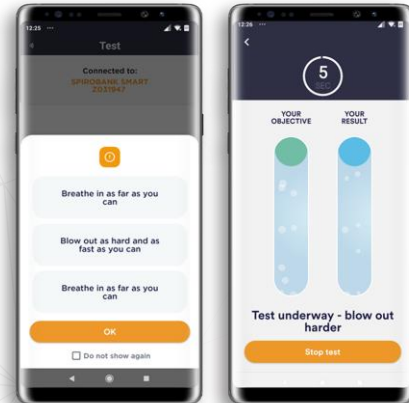
PERSONAL TREND

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



| | Mouthpiece | Turbine Disinfection | Turbine Calibration | Packaging | Antiviral Filter |
|---------------------------------|---------------------|----------------------|---------------------|-------------------------------------------|------------------|
| Single Patient Reusable Turbine | Included Reusable | Not required | Not required | Individually sealed: 1 unit / box | Not required |
| flowMIR™ Disposable Turbine | Included Disposable | Not required | Not required | Individually sealed: 60 or 10 units / box | Not required |



PLAY VIDEO



SCIENTIFIC PUBLICATIONS



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 | 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 | 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 | 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, 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 | 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, 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) |

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)



Disposable Turbine (code 910004)

| | |
|---------------------|----------------------------------------|
| 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 (Stand by)

Connectivity Bluetooth® 4.0
for S/N < Z099220

Bluetooth® 5 ready
for S/N > Z099220

Mouthpieces \varnothing 30 mm (1.18 inch)

Type of electrical protection Internally powered

Safety level for shock hazard Type BF Apparatus

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 |

| | |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Spirometry

| | |
|----------------------------|--------------------------------------------------|
| Flow sensor | bi-directional digital turbine |
| Flow range | \pm 16L/s |
| Volume accuracy | \pm 2.5% or 0,05 L |
| Flow accuracy | \pm 5.0% or 0,20 L/s |
| Dynamic resistance | <0.5 cm H ₂ O/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 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 |