#### ADVANCED

# SPIROBANK II SMART®

Handheld, Stand-alone, Tablet-Based and PC-Based Spirometer, with Oximetry option

A versatile Spirometer and Oximeter, with Tablet (iPad and Android) and PC connection.



# MAIN features



#### **REAL-TIME** TEST

Spirometry: FVC, VC, IVC, MVV, PRE/POST Bronchodilator comparison Oximetry (optional): Spot test (SpO2, BPM)

#### PC AND TABLET CONNECTION

Real time test on Tablet (via Bluetooth 4.0) and PC (via USB), connect with your EHR/EMR, back-up internal memory and more



#### CARRY 日 **EVERYWHERE**

High resolution backlight display, long battery life, large internal storage, carrying case included

#### **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 510 (k)



## **DISTINCTIVE** features



#### PREDICTED **SETS & VALUES**

Large Selection, including comparison %Pred, Zscore and LLN. Include GLI on App and PC

#### **INTUITIVE APP** FOR TABLET

Including Virtual via HL7, Calibration check and more

#### **EHR/EMR** CONNECTIVITY

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Via PC, integration with Assistant, data transfer patient database (HL7,GDT) Via Tablet, automatic share to Remote Server



#### COVID-19 PREVENTION

Complete Disposable Set with Antiviral filter. Bluetooth connection to test at safety distance

#### **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

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- Carrying case
- USB cable
- Noseclip

- V PC Software license With Oximetry Option:
- Finger Probe

# Compatible SOFTWARE

Download on the App Store

#### REAL TIME TEST

Spirometry: FVC Pre, FVC Post, VC. Oximetry: SpO2 (%), Pulse (BPM)

Spirometry parameters: FVC, FEV1, FEV1%, PEF, FEF25–75, FET, Lung Age, VC, IVC

Pediatric Incentive (PATENTED)

Calibration (on iOS) with personalized printed report.

#### PC SOFTWARE

Embedded EHR/EMR connectivity (HL7, GDT, more)

NET VERSION available, share one database between different PC workstations

Pediatric Incentive (PATENTED)

Interpretation and Quality Control Grade according to latest Spirometry Standards

#### FEATURES

Predicted Sets include GLI, Predicted Values include Zscore and LLN

EHR/EMR direct integration via HL7 standards

Virtual Assistant: during and after the spirometry test.

Customizable PDF Medical Report to print and share

#### REAL TIME TEST

Spirometry: FVC-Pre, FVC-Post, VC-Pre, MVV, Bronchoprovocation tests, Bronchial Challenge

Oximetry: SpO2 (%), Pulse (BPM)

Customizable PDF report

#### MEDICAL REPORT



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#### Spiro Connect

**NIR Spiro App** 

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#### PC SOFTWARE

Direct integration with your EHR/EMR via HL7 or Exchange Protocol.

Spirometry: FVC-Pre, FVC-Post, VC-Pre Oximetry: SpO2 (%), Pulse (BPM)

Customizable PDF report

# Compatible TURBINES

|                                    | Mouthpiece                | Turbine<br>Disinfection | Turbine<br>Calibration | Packaging                                       | Antiviral<br>Filter     |
|------------------------------------|---------------------------|-------------------------|------------------------|---|-------------------------|
| flowMIR ™<br>Disposable<br>Turbine | Included<br>Disposable    | Not<br>required         | Not<br>required        | Individually<br>sealed: 60 or<br>10 units / box | Available<br>Disposable |
| Reusable<br>Turbine                | Required,<br>Not included | Required                | Required               | 1 unit in<br>Carton box                         | Required<br>Disposable  |

# Also available in MORE CONFIGURATIONS







| Technical<br>Specification | Spirobank II<br>Smart  | Spirobank II<br>Advanced   | Spirobank II<br>Basic   |
|----------------------------|--|--|---|
| TYPE OF SPIROMETER         | StandAlone + PC + App,<br>with Oximetry Option   | StandAlone + PC, with Oximetry Option  | StandAlone + PC   |
| COMPATIBLE<br>TURBINES     | flowMIR™ Disposable Turbine,<br>Reusable Turbine Flowmeter   | flowMIR™ Disposable Turbine,<br>Reusable Turbine Flowmeter   | flowMIR™ Disposable Turbine,<br>Reusable Turbine Flowmeter  |
| COMPATIBLE<br>SOFTWARES    | MIR Spiro App, Winspiro PRO,<br>spiro Connect  | Winspiro PRO, spiro Connect  | Winspiro PRO, spiro Connect   |
| EXTERNAL CONTROL           | Real-Time test on Tablet screen and PC<br>screen, connect with your EHR/EMR,<br>back-up internal memory, and much<br>moreReal-Time test on PC screen, connect<br>with your EHR/EMR, back-up internal<br>memory, and much more<br>Connect to your PC via USB (no<br>Bluetooth)Real-Time test on PC screen, connect<br>with your EHR/EMR, back-up internal<br>memory, and much more<br>Connect to your PC via USB (no<br>Bluetooth 2.0Connect to your Tablet via Bluetooth<br>Smart BLE 4.0Real-Time test on PC screen, connect<br>with your EHR/EMR, back-up internal<br>memory, and much more<br>Connect to your PC via USB and<br>Bluetooth 2.0   |  | Real-Time test on PC screen, connec<br>with your EHR/EMR, back-up interna<br>memory and much more<br>Connect to your PC via USB                         |
| EHR CONNECTIVITY           | Via PC: integration with patient<br>database on your EHR/EMR (in HL7,<br>GDT)<br>Via APP: transfer data to a remote<br>server in HL7 standards   | Via PC, integration with patient<br>database on your EHR/EMR (in HL7,<br>GDT)  | Via PC, integration with patient<br>database on your EHR/EMR (in HL7,<br>GDT)   |
| MEASURED<br>PARAMETERS     | Spirometry: FVC, VC, IVC, MVV, PRE-<br>POST Bronchodilator comparison<br>Oximetry (optional): Spot test (SpO2,<br>BPM)<br>Spirometry: FVC, FEV1, FEV1/FVC%,<br>DTPEF, FEV 0.5, FEV0.5/FVC%, FEV2,<br>FEV0.75, FEV0.75/FVC%, FEV2,<br>FEV2/FVC%, FEV3, FEV3/FVC%, FEV6,<br>FEV1/FEV6%, PEF, FEF25, FEF50,<br>FEF75, FEF25-75, FEF75-85%, FET,<br>Vext, ELA, EVOL, FIVC, FIV1, PIF,<br>FIV1/FIVC%, TIF25, FIF50, FIF75,<br>R50, PIF, IRV, VC, IVC, IC, ERV,<br>FEV1/VC%, TV, VE, RR, t1, tE, t1/t-tot,<br>TV/t1, MVV<br>Oximetry (Optional): SpO2% (min, max,<br>average), BPM (min, max, average),<br>Test duration, % Bradycardia Duration<br>(<40 BPM), % 1achycardia Duration<br>(<120 BPM), % of Time with SpO2 ≤<br>90% (T90%, T89%)<br>on MIR Spiro App:<br>Spirometry: FVC, VC, PRE/POST<br>Bronchodilator comparison<br>Parameters: FVC, FEV1, FEV1%, PEF,<br>FEF25–75, FET, Lung Age, VC, IVC.<br>Oximetry (Optional): %SpO2 [Baseline,<br>Min, Max, Mean], Pulse Rate [Baseline,<br>Min, Max, Mean] Events. | Spirometry: FVC, VC, IVC, MVV, PRE-<br>POST Bronchodilator comparison<br>Oximetry (optional): Spot test (SpO2,<br>BPM)<br>Spirometry: FVC, FEV1, FEV1/FVC%,<br>DTPEF, FEV 0.5, FEV0.5/FVC%, FEV2,<br>FEV0.75, FEV3, FEV3, FVC%, FEV6,<br>FEV1/FEV6%, PEF, FEF25%, FEF50%,<br>FEF75%, FEF25-75%, FEF75-85%, FET,<br>Vext, ELA, EVOL, FIVC, FIV1, PIF,<br>FIV1/FIVC%, FIF25%, FIF50%,<br>FIF75%, R50, PIF, IRV, VC, IVC, IC, ERV,<br>FEV1/VC%, TV, VE, RR, ti, te, ti/t-tot,<br>TV/ti, MVV<br>Oximetry (Optional): SpO2% (min, max,<br>average), BPM (min, max, average), Test<br>duration, % Bradycardia Duration (>40<br>BPM), % of Time with SpO2 ≤ 90%<br>(T90%, T89%) | Spirometry: FVC, VC, IVC, PRE/POST<br>Bronchodilator comparison<br>Spirometry: FVC, VC, IVC, IC, ERV,<br>FEV1, FEV1%, PEF, FEF 25-75, FET,<br>EVOL, ELA |



### **TECHNICAL** datasheet

PRODUCT CODES - Spirobank II Smart Configurations 911028E0 – Spirometer • 911028E1 - Spirometer with reusable turbine 911029E0 - Spirometer + Oximeter • 911029E1 - Spirometer + Oximeter with reusable turbine

| Technical specification  |   |                                      | Spirometry  |   |  |
|--|---|--------------------------------------|---|---|--|
| Width<br>Length<br>Thickness<br>Weight   | 55 mm<br>160 mm<br>25 mm<br>140 g (battery pa   | ck included)                         | Flow sensor<br>Flow range<br>Volume accuracy<br>Flow accuracy<br>Dynamic resistance | bi-directional digital turbine<br>±16L/s<br>±2.5% or 50 mL<br>±5% or 200 mL/s<br><0.5 cm H20/L/s  |  |
| urbine   |   | Temperature sensor<br>Test available | semiconductor (0-45°C)<br>FVC, VC, IVC, MVV, PRE-POST                               |   |  |
|  | Reusable turbine (c   | code 910002                          | Measured parameters   | FVC, FEV1, FEV1/FVC%, DTPEF,<br>FEV 0.5, FEV0.5/FVC%, FEV0.75,<br>FEV0.75/FVC%, FEV2, FEV2/FVC%<br>FEV3, FEV3/FVC%, FEV6,<br>FEV1/FEV6%, PEF, FEF25, FEF50,<br>FEF75, FEF25-75, FEF75-85%, FE |  |
|  | Disposable turbine  | (code 910004)                        |   |   |  |
| Power supply   | Rechargeable Lith<br>1100 mAh   | nium-Ion 3.7V,                       |   | Vext, ELA, EVOL, FIVC, FIV1, PIF,<br>FIV1/FIVC%, FIF25, FIF50, FIF75,<br>R50, PIF, IRV, VC, IVC, IC, ERV,   |  |
| Current capacity   | 1100 mAh  |                                      |   | FEV1/VC%, TV, VE, RR, t <sub>1</sub> , t <sub>E</sub> , t <sub>1</sub> /t- <sub>tot</sub> ,   |  |
| Consumption ~20-30 mA (durin<br>Batteries charger voltage=5 V DC,<br>current=minimum |   | n 500 mA,                            | Memory capacity   | TV/t <sub>1</sub> , MVV<br>Up to 10000 tests  |  |
|  | Connector: micro<br>compliant with EN   |                                      | Oximetry (on request)   |   |  |
| Autonomy<br>Connectivity   | 50 hours<br>USB 2.0, Bluetoot   |                                      | Measurement method  | Red and infrared absorption   |  |
| Display<br>Keyboard<br>Mouthpieces<br>Type of electrical                             | LCD monochrome, 160 × 80 pixel<br>membrane keyboard with 6 keys<br>Ø 30 mm (1.18 inch)<br>Internal power supply                     |                                      | SpO2 range<br>SpO2 accuracy<br>Average number of<br>heart beats for the             | 0-99%<br>± 2% between 70-99% SpO2<br>8 beats  |  |
| protection<br>Safety level for   | Type BF Apparatu  | 21                                   | %SpO2 calculation<br>Pulse Rate   |   |  |
| shock hazard   | туре вт пррагате  |                                      | Range   | 30-300 BPM  |  |
| Conditions of use  | Apparatus for continuous use  |                                      | Accuracy  | ± 2BPM or 2% whichever is greater   |  |
| Conditions of storage  | Temperature:  | MIN -20 °C,<br>MAX + 60 °C           | Averaging interval for<br>Signal quality indication<br>Test available               | 8 seconds average<br>0 - 8 segments on display<br>spot  |  |
|  | Humidity:   | MIN 10% RH;<br>MAX 95%RH             | Measured parameters   | SpO2% min, max, average<br>BPM min, max, average  |  |
| Operating Conditions   | Temperature:  | MIN + 10 °C,<br>MAX + 40 °C          |   | Test duration<br>% Bradycardia Duration (<40 BPM)<br>% Tachycardia Duration (>120 BPM   |  |
|  | Humidity:   | MIN 10% RH,<br>MAX 95%RH             |   | % of Time with SpO2 ≤ 90% (T90%<br>T89%)  |  |
| Applied norms  | Electrical Safety Standard<br>IEC 60601-1:2005 + A1: 2012<br>Electro Magnetic Compatibility<br>EN 60601-1-2:2015<br>ISO 26782: 2009 |                                      | Memory capacity   | up to 300 hours oximetry  |  |
|  |   |                                      | Certificates & Registrations  |   |  |
|  |   |                                      | CE 0476   | MED 9826<br>K 061712<br>Z12150102 (spiro)   |  |
|  | ISO 23747: 2015<br>ATS/ERS: 2005, 2019 update   |                                      | FDA 510 (k)<br>CND code   |   |  |
|  |   |                                      | GMDN code   | Z1203020408 (spiro + oxi)<br>46906 (spiro), 45607 (spiro + oxi)   |  |



#### ITALY

MIR Head Office Via del Maggiolino, 125 00155 Roma Tel. +39 06 22 754 777 Fax +39 06 22 754 785 Mir.spirometry.com

#### USA

MIR USA, Inc. 5462 S. Westridge Drive New Berlin, WI 53151 Phone +1 (262) 565-6797 Fax +1 (262) 364-2030

#### FRANCE

MIR Local Office Jardin des Entreprises, 290, Chemin de Saint Dionisy 30980 LANGLADE (France) Phone +33 (0)4 66 37 20 68 Fax +33 (0)4 84 25 14 32 Rev.5