



**HOME CARE,
YES please**



«OUR» NUMBERS

28

Years
of Experience

100

Countries use our
medical devices

8

International
Patents

16%

Invested
in Research

THE FIRST COMPANY

TO DEVELOP APP-BASED SPIROMETERS FOR HOMECARE

MARKET

Because of **pandemic**, routine **face-to-face** testing has stopped.

MIR provides a solution to help respiratory professionals to continue to **monitor their patients** with COPD, cystic fibrosis, Asthma and ILD's safely, accurately and above all remotely.

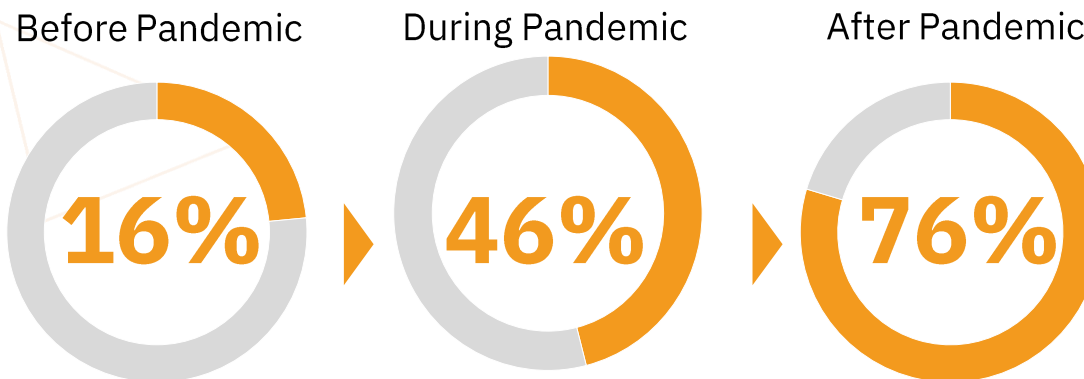
MIR Personal Spirometers and Apps

Allow patients to **perform the test in their own home**, perform a live video medical consultation in real-time with the HCP or just send test result to the HCPs or to the study team for analysis.

¹ Source: [McKinsey & Company](#)

STATS

CONSUMERS ADOPTION



HEALTHCARE PROVIDERS

50-175x

of telehealth visits (vs. pre-Covid)

57%

viewing telehealth more favorably

THE OUTPUT OF REMOTE PATIENT MONITORING IS
AS GOOD AS FACE-TO-FACE VISIT ¹



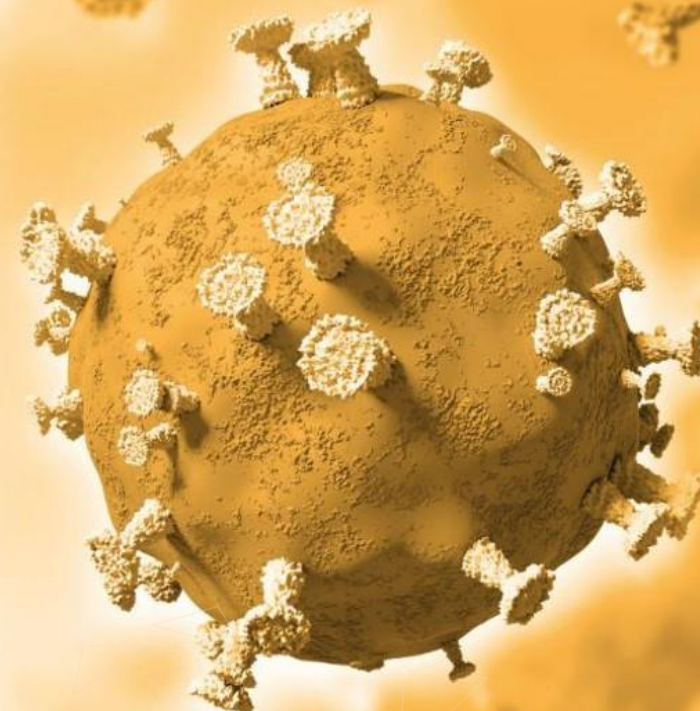
▶ In the UK, we equipped about **10,000 patients** throughout NHS



▶ In the USA, we equipped about **30,000 patients**, including **19,000** out of **22,000 patients** affected by CF

LONG-COVID SEQUELAE

While clinical trials for safe and effective antiviral agents are ongoing, and vaccine development programs are being accelerated, **long-term sequelae of SARS-CoV-2 infection have become increasingly recognized and concerning.** ²



¹ Source: MIR 2021 customer interview, feedback from Clinicians and KOLs we currently supply

² Source: [Long-Term Respiratory and Neurological Sequelae of COVID-19](https://www.nih.gov/news-events/press-releases/statement-long-term-respiratory-and-neurological-sequelae-covid-19) - NIH.org | [Coronavirus-covid-19/long-term-effects-of-coronavirus-long-covid](https://www.nhs.uk/news/2021/06/coronavirus-long-term-effects/) – NHS.uk



Personal Health, Mobile Health and Remote Patient Monitoring



SPIROBANK SMART Medical Device for Patient



01

Patient performs the test remotely with a personal, easy-to-use and inexpensive medical device



MIR SPIROBANK APP Mobile APP for Patient

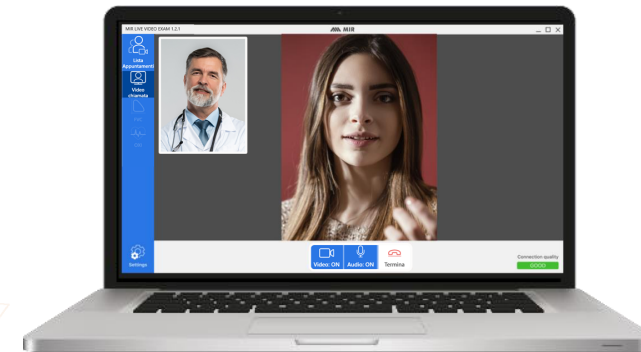


02

Mobile APP performs test remotely. Also, connects with Medical Software for real-time support of the Healthcare Provider (HCP)



LIVE VIDEO EXAM Medical Software for HCP



03

HCP views test results in real-time, adds notes and therapeutic plans, saves, and shares results in PDF format

01

SPIROMETER



COMPATIBLE TURBINES



Single-Patient
**Reusable
Turbine**



**Disposable
Turbine**
FlowMIR™



CERTIFIED ACCURACY



- ISO 23747 (for Spirometry)
- ISO 26782 (for PEF)
- ATS-ERS: PW24 e FT26
- ISO 10993-1: 2018
- EN ISO 15223:2016
- IEC 60601-1:2005 + A1: 2012
- EN 60601-1-2: 2015
- and more

PORTABLE



Dimensions:

1.93 x 4.29 x 0.82"
(49 x 109 x 21 mm)

Weight:

14 oz (60.7 g)



- No Display
- No Keyboard
- No Memory
- No Configuration Required
- 2x AAA Alkaline Batteries

Patient only interacts with the App installed on his Smartphone.

Test results are automatically stored on Patient's Smartphone.

02

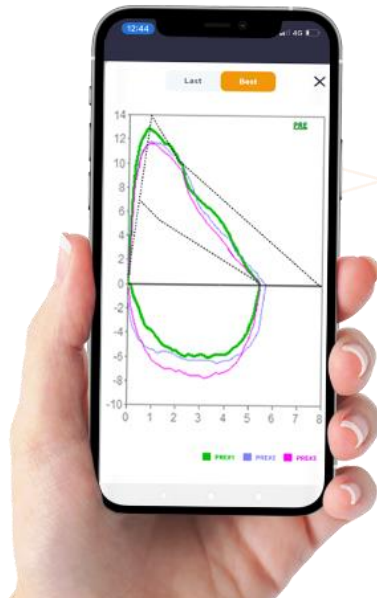
MIR SPIROBANK APP Mobile App For Patient



REAL TIME SPIROMETRY TEST ON YOUR SMARTPHONE

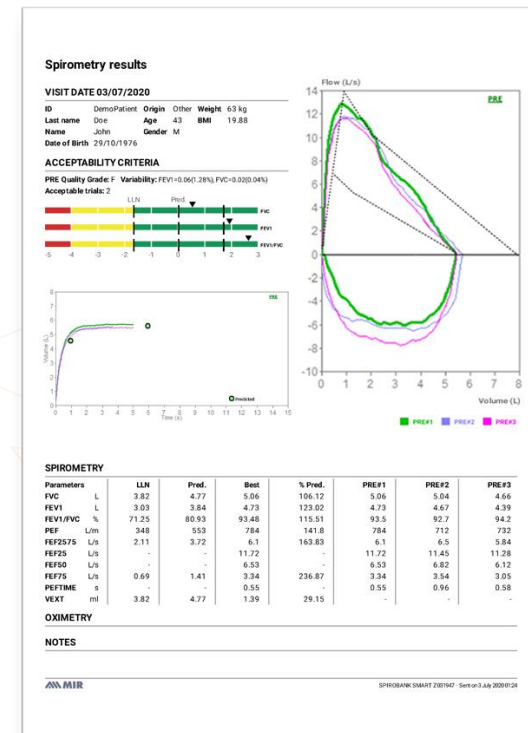
MAIN FEATURES

- Spirometry test via mobile App
- Automatic connection via Bluetooth Smart BLE 4.0
- Suitable for all ages excluding newborns and infants
- GLI-2012 predicted sets for spirometry reference value



DISTINCTIVE FEATURES

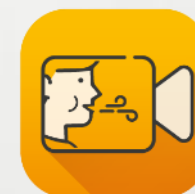
- Acceptability messages and real-time animation on Smartphone
- E-diary, where symptoms and notes can be added for each test.
- Easy-to-read graphic trends for self-monitoring of spirometry.
- Professional PDF printout (share via email, WhatsApp and other apps)
- Live Video Consultation available



03

LIVE VIDEO EXAM

Software for
Healthcare Providers



A STEP AHEAD OF THE TRADITIONAL HOME CARE SOLUTIONS,
A **NEW GOLD STANDARD IN TELEMEDICINE**

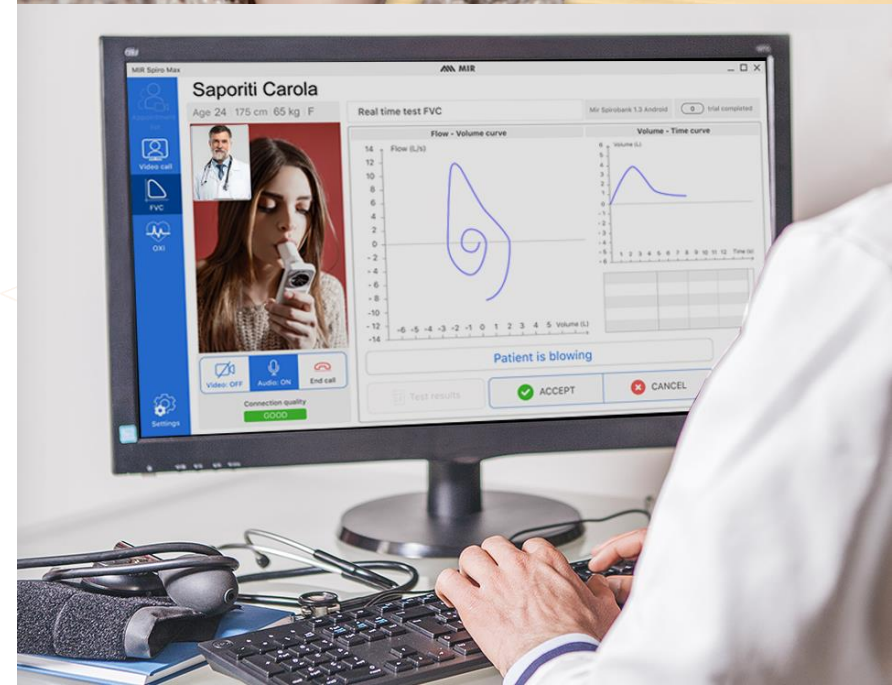
Windows-based medical app for interactive remote patient monitoring.

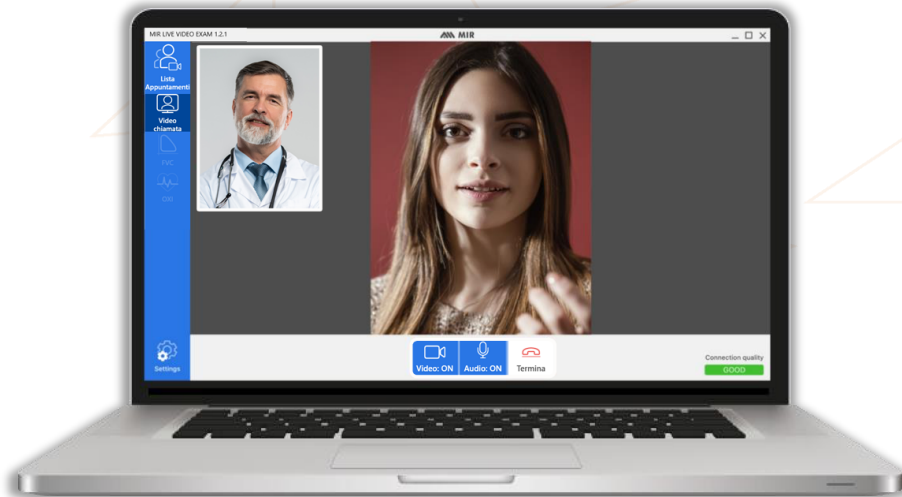
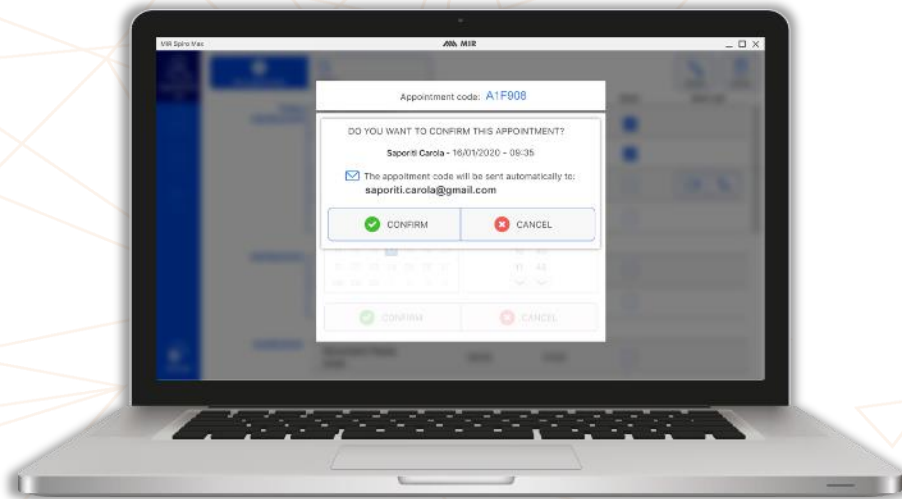
The Live Video Exam allows patients to perform the **Spirometry test** remotely, with the full support of the Health Care Professionals (HCP) in real-time.

LIVE MEDICAL SUPERVISION

Test execution is supervised and **managed 100%** by the HCP.

Live medical supervision increases patient cooperation in performing the test and is essential in obtaining **optimal test results**.





SECURE CONNECTION

Data coming from patient's smartphone are sent DIRECTLY to the doctor's PC:

- With Low Latency
- With No Privacy Issues
- With No Need For Server Storage or Web-Based Services



MIR cannot read, access, or listen to personal communications because they are protected by end-to-end encryption.



SDK & API

Software Development Kit
Tools for Developers

VALIDATED SOFTWARE PACKAGES TO **DEVELOP A 3rd PARTY SOFTWARE**
AND MEDICAL APP **WITH LIMITED TIME AND EFFORTS**



MIR's SDK features:

- Communication with MIR devices
- Reference values (19 sets of equations)
- Test interpretation (auto-diagnosis, acceptability, QCG, variability, etc.)
- Flow/Volume and Flow/Time curves
- Complete Spirometry printouts



SOFTWARE DEVELOPMENT KIT

BENEFITS FOR VENDORS INCLUDE:

- Building a Spirometry app without specific / required skills
- Dramatically reduced time-to-market
- Validated SDK
- Tailoring to specific market requirements
- Easy integration – the sample app uses the SDK as if it were the vendor's app



Clinical Evaluation Clinical Research Projects & Partnerships



COMPARISON AGAINST 2 LAB-BASED DESKTOP SYSTEMS

conducted by an Independent NHS board in Glasgow UK

source:

Paul Burns

Clinical Scientist

Royal Hospital for Children, Glasgow

AIM OF THE CLINICAL EVALUATION

To validate the Spirobank Smart spirometer against NDD Easy on PC and the Jaeger Masterscreen to ensure no clinically significant differences between the devices.

METHOD

- Biological quality control was performed over a 2 week period.
- 5 physiologists performed their Spirometry on the 3 devices for 5 days.
- The intra-test coefficient of variation for each device was analyzed.

CONCLUSION

"The mean bias for FEV1, FVC, FEF25-75 and PEF was clinically acceptable when comparing the Spirobank® to the NDD and Masterscreen PFT."

The measures of FEV1, FVC, FEF25-75 and PEF were comparable to the NDD Easy on-PC and Jaeger Masterscreen PFT."

*The intra test coefficient of variation for the **Spirobank Smart** has met clinical standards and shows **no significant difference between the other 2 devices.***



MIR APP-BASED SPIROMETERS IN MEDICAL PUBLICATIONS

SPIROBANK SMART

Comparison of a portable smart spirometer against 2 lab based desktop systems

Paul Burns - Clinical Scientist, Royal Hospital for Children, Glasgow

MAY 14, 2020

[READ ON-LINE](#)

SPIROBANK SMART

Lung function variability in children and adolescents (LUV study): protocol for a prospective interventional trial in healthy individuals and patients with asthma

Eirini Sofia Frima, Ilias Theodorakopoulos, Dimos Gidaris, Nikolaos Karantaglis, Grigorios Chatziparasidis, Panagiotis Plotas, Michael B Anthracopoulos, Sotirios Fouzas

MARCH 30, 2020

[READ ON-LINE](#)

SPIROBANK SMART

Effect On Asthma Control Using A Novel Digital Self-Management System: A Physician Blinded Randomised Controlled Cross-Over Pilot Trial

Henrik Ljungberg, Anna Carleborg and Björn Nordlund

FEBRUARY 13, 2020

[READ ON-LINE](#)

SPIROBANK SMART

A4932/P1 43 - User Experience of patientMpower Electronic Health Journal for Pulmonary Fibrosis in Volunteers Recruited Via the PF Warriors Support Group

C. Edwards, B. Vick, E. Costello

FEBRUARY 13, 2020

[READ ON-LINE](#)

SPIROBANK SMART

Patient-Reported and Patient-Recorded Outcomes in Interstitial Lung Diseases and Pulmonary Hypertension

Monique Wapenaar - de Korver

OCTOBER 29, 2019

[READ ON-LINE](#)

SPIROBANK SMART

Wearable Ultrafine Particle and Noise Monitoring Sensors Jointly Measure Personal Co-Exposures in a Pediatric Population

Douglas Leaffer, Christopher Wolfe, Steve Doroff, David Gute, Grace Wang and Patrick Ryan

JANUARY 23, 2019

[READ ON-LINE](#)

SPIROBANK SMART

Clinical effect on uncontrolled asthma using a novel digital automated self-management solution: a physician-blinded randomised controlled crossover trial

Henrik Ljungberg, Anna Carleborg, Hilmar Gerber, Christina Öfverström, Jakob Wolodarski, Faiza Menshi, Mikaela Engdahl, Marianne Eduards, Björn Nordlund

JANUARY 1, 2019

[READ ON-LINE](#)

SPIROBANK SMART

P224 / A1866 - Use of a Mobile Application (patientMpower) to Capture Longitudinal Data on Air Quality and Home Spirometry in United States Based Pulmonary Fibrosis Patients

Martin S. Holmes, Colin Edwards, Eamonn Costello

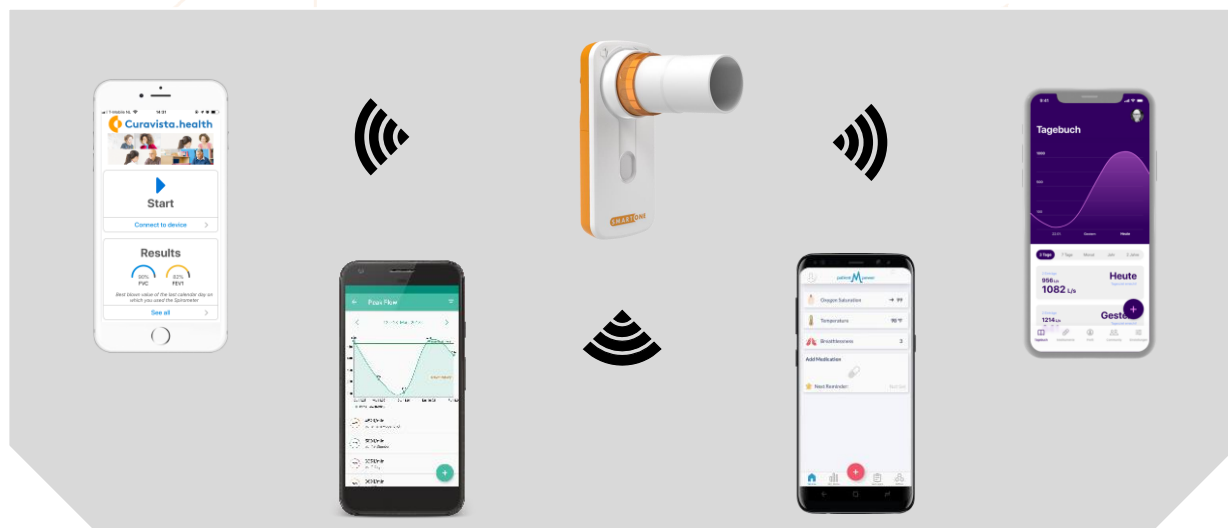
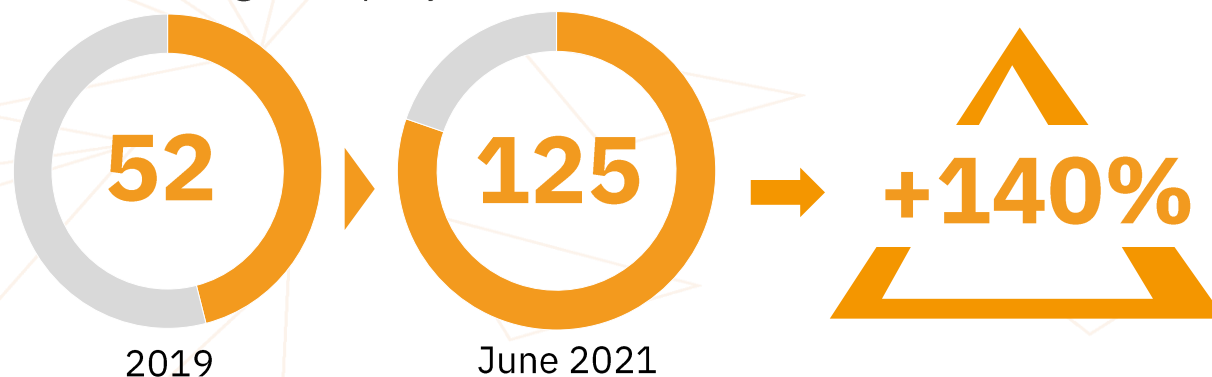
JANUARY 1, 2019

[READ ON-LINE](#)

CURRENT INTEGRATIONS OF MIR SPIROMETERS IN 3RD PARTY APPS

Rapidly evolving integrators' base

Number of integrators per year





HOME CARE IS NOW

Product Configurations

OVERVIEW



MIR APP-BASED SPIROMETERS FOR REMOTE PATIENT MONITORING



1. SPIROBANK **SMART F/V**





1. SMART **ONE**

	SPIROBANK SMART 	SMART ONE 
Dimensions	1,93x4,29x082" (49x109x21 mm)	1,93x4,29x082" (49x109x21 mm)
Display	No	No
Weight	2,14 Oz (60.7 g)	2,14 Oz (60.7 g)
Carrying Case	N/A	N/A
Device Type	Personal Smart	Personal Smart
Real Time on PC	No	No
Real Time on SmartPhone/Tablet	Yes	Yes
Power Supply	2 batteries AAA 1,5V	2 batteries AAA 1,5V
Connectivity	Bluetooth 4.0	Bluetooth 4.0
Memory on Device	No	No

SENSOR

APP

PARAMETERS

	SPIROBANK SMART	SMART ONE
		
Flow Sensor Type	Turbine	Turbine
Disposable	Yes	No
Single-Patient Reusable	Yes	Yes
App (iOS & Android)	MIR Spirobank*	MIR Smart One
SDK (iOS & Android)	Yes	Yes
Parameters Spiro on App	PEF, FEV1, FVC, FEV1/FVC ratio, FEF2575, FEV6, Evol, PEF Time, FEF75, FEF25, FEF50	PEF, FEV1
Parameters Spiro via SDK	PEF, FVC, FEV1, FEV1/FVC, FEF2575, FEV6, Evol, PEF Time, FEF75, FET, FEF25, FEF50, FIVC, FIV1, PIF, FEV3, FEV05, FEV075, FEV2	PEF, FEV1

SPIROBANK SMART



ATS/ERS Guidelines: 2019
ISO 26782: 2009
ISO 23747: 2015
EN ISO 14971: 2012
ISO 10993-1: 2018
2011/65/UE Directive
EN ISO 15223:2016
IEC 60601-1:2005/A1:2012
EN 60601-1-2: 2015
EN 60601-1-6: 2010
EN 60601-1-11: 2015
IEC 62304:2006/A1:2015

SMART ONE



ATS/ERS Guidelines: 2019
ISO 26782: 2009
ISO 23747: 2015
EN ISO 14971: 2012
ISO 10993-1: 2018
2011/65/UE Directive
EN ISO 15223:2016
IEC 60601-1:2005/A1:2012
EN 60601-1-2: 2015
EN 60601-1-6: 2010
EN 60601-1-11: 2015
IEC 62304:2006/A1:2015

CE – FDA

COUNTRY

Regulatory Capabilities



**SPIROBANK
SMART**



SMART ONE

CE Mark	Yes	Yes
FDA	Yes 510(k) N. K072979	Yes, “OTC” 510(k) N. K181666
Argentina	Yes	Yes
Australia	Yes	Yes
Brazil	No	Yes
Canada (MDSAP)	Yes	Yes
China	Yes	Yes
Colombia	Yes	Yes
Croatia	No	Yes
Israele	Yes	Yes
Macedonia	Yes	Yes
Malaysia	Yes	Yes
Mexico	Yes	No
Paraguay	No	Yes
Saudi Arabia	Yes	Yes
Serbia	Yes	Yes
Singapore	No	Yes
Turkey	Yes	No
Taiwan	Yes	Yes
Ukraine	Yes	Yes

HOME CARE IS NOW

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