

Smart One and Smart One Oxi



Smart One

Smart One is a **portable PEF and FEV1 meter** that allows for **easy** and **quick monitoring of lung health**.

Smart One Oxi

Smart One Oxi - the version with oximetry - also allows for the measurement of blood oxygen levels (SpO2%) and heart rate (BPM) through an integrated touch oximeter.



Main features

♦ Ideal for respiratory diseases

Asthma, Cystic Fibrosis, COPD, Exercise-induced asthma

App-based \

1-second test with results always available on the smartphone through the free dedicated MIR SMART ONE App

Pair & Play 🔪

Pairing between device and app via Bluetooth





Sp02% reflectance sensor (touch)

Measurement of blood oxygen levels (Sp02%) and heart rate (BPM)



A study on a population of 47 children with mild-moderate asthma demonstrated that integrating an Education Program with a Mobile Health Program, such as the Smart One app, promotes patient empowerment and self-management, as well as quality of care and quality of life.



Compatible turbine

	Mouthpiece	Turbine Disinfection	Turbine Calibration	Pack	Antiviral Filter
Reusable Turbine	Included Reusable	Not required	Not required	Individually sealed 1 unit/box	Not required

MIR SMART ONE App



Free dedicated app designed for Smart One and Smart One Oxi

Anytime, anywhere

The advantage of a **smart** device is its connection to the app.

MIR SMART ONE is available for free download on the Play Store and App Store.

Specifically designed for Smart One and Smart One Oxi, the MIR SMART ONE App offers **ease of use**, **secure and organized data storage**, **and simple and fast sharing of test results with your doctor** for timely and personalized management of the disease.

- N Pairing between the app and spirometer via Bluetooth connection
- Sharing test results in PDF format with healthcare professionals via email, WhatsApp, SMS, Cloud, Drive, Bluetooth, AirDrop, and other apps
- Niew and storage of spirometry and oximetry test results in the app
- Draft of a personalized electronic diary with options to set symptoms and add notes for each test

Instructions for use

Spirometry and Oximetry tests in 5 easy steps!



1. Download the MIR SMART ONE app



2. Connect the device to the app via Bluetooth



the test you want to perform



4. Perform the test



 View the results and share them with your doctor



Measured parameters

	Spirometry	Oximetry
Smart One	FEV1 and PEF	_
Smart One Oxi	FEV1 and PEF	Sp02%min, Sp02%mean, Sp02%max, BPMmin, BPMmean, BPMmax, Ttotal

cod. 911100xx

Datasheet Smart One

Weight Turbine Single Patient Reusable Turbine with Mouthpiece (code 910013) Power supply 2 batteries AAA 1.5 V Consumption Backup battery voltage Batteries charger Lifetime 5 years Connectivity Bluetooth 5.0 ready Mouthpieces Ø 30 mm (1.18 inch) Type of electrical protection Safety level for shock hazard IP protection level Conditions of use Storage conditions Fupe in MIN -25 °C, MAX+70 °C Humidity: MIN 10% RH; MAX 93%RH Operating conditions Temp: MIN -5°C, MAX +40 °C Humidity: MIN 10% RH; MAX 93%RH Femp: MIN -25°C, MAX +70 °C Humidity: MIN 10% RH; MAX 93%RH Perp: MIN -25°C, MAX +70 °C Humidity: MIN 10% RH; MAX 93%RH IEC 60601-1-2:005 + A1:2012 + A2:2020 IEC 60601-1-2:2014 + A1:2020 EN ISO 14971:2019 ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-1:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009 ISO 23747: 2015	Dimensions	49 x 109 x 21 mm
with Mouthpiece (code 910013) Power supply 2 batteries AAA 1.5 V Consumption max 12 mA Stand by 8 µA medium Backup battery voltage Batteries charger none Lifetime 5 years Connectivity Bluetooth 5.0 ready Mouthpieces Ø 30 mm (1.18 inch) Type of electrical protection Safety level for shock hazard IP protection level Conditions of use Storage conditions Temp: MIN -25 °C, MAX+70 °C Humidity: MIN 10% RH; MAX 93%RH Temp: MIN -25 °C, MAX +40 °C Humidity: MIN 15% RH; MAX 93%RH Shipping conditions Temp: MIN -25 °C, MAX +70 °C Humidity: MIN 10% RH, MAX 93%RH Femp: MIN -25 °C, MAX +20 °C Humidity: MIN 10% RH, MAX 93%RH Femp: MIN -25 °C, MAX +20 °C Humidity: MIN 10% RH, MAX 93%RH IEC 60601-1-2:2014 + A1:2012 + A2:2020 IEC 60601-1-2:2014 + A1:2019 ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009	Weight	60.7 g (batteries included)
Power supply Consumption Backup battery voltage Batteries charger Lifetime Lifetime Syears Connectivity Bluetooth 5.0 ready Mouthpieces Ø 30 mm (1.18 inch) Type of electrical protection Safety level for shock hazard IP protection level Conditions of use Storage conditions Storage conditions Temp: MIN -25 °C, MAX +70 °C Humidity: MIN 10% RH; MAX 93%RH Temp: MIN -25 °C, MAX +70 °C Humidity: MIN 10% RH; MAX 93%RH Temp: MIN -25 °C, MAX +70 °C Humidity: MIN 10% RH; MAX 93%RH Shipping conditions Temp: MIN -25 °C, MAX +70 °C Humidity: MIN 10% RH, MAX 93%RH Shipping conditions Temp: MIN -25 °C, MAX +70 °C Humidity: MIN 10% RH, MAX 93%RH IEC 60601-1-2:2014 + A1:2020 IEC 60601-1-2:2014 + A1:2020 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009	Turbine	Single Patient Reusable Turbine
Consumption max 12 mA Stand by 8 μA medium Backup battery voltage Batteries charger Lifetime 5 years Connectivity Bluetooth 5.0 ready Mouthpieces Ø 30 mm (1.18 inch) Type of electrical protection Safety level for shock hazard IP protection level Conditions of use Storage conditions Temp: MIN -25 °C, MAX +70 °C Humidity: MIN 10% RH; MAX 93%RH Operating conditions Temp: MIN -25 °C, MAX +70 °C Humidity: MIN 15% RH; MAX 93%RH Temp: MIN -25 °C, MAX +70 °C Humidity: MIN 10% RH, MAX 93%RH Shipping conditions Temp: MIN -25 °C, MAX +70 °C Humidity: MIN 10% RH, MAX 93%RH IEC 60601-1:2005 + A1:2012 + A2:2020 IEC 60601-1-2:2014 + A1:2020 EN ISO 14971:2019 ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009		with Mouthpiece (code 910013)
Stand by 8 μA medium Backup battery voltage Batteries charger Lifetime Connectivity Mouthpieces Ø 30 mm (1.18 inch) Type of electrical protection Safety level for shock hazard IP protection level Conditions of use Storage conditions Temp: MIN -25 °C, MAX+70 °C Humidity: MIN 10% RH; MAX 93%RH Temp: MIN -25°C, MAX +40 °C Humidity: MIN 15% RH; MAX 93%RH Shipping conditions Temp: MIN -25°C, MAX +70 °C Humidity: MIN 10% RH, MAX 93%RH Femp: MIN -25°C, MAX +70 °C Humidity: MIN 10% RH, MAX 93%RH Applicable standards IEC 60601-1-2:2014 + A1:2020 EN ISO 14971:2019 ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-1:2015 + A1:2013 + A2:2020 IEC 60601-1-1:2015 + A1:2019 ISO 26782: 2009	Power supply	2 batteries AAA 1.5 V
Backup battery voltage	Consumption	max 12 mA
Batteries charger none Lifetime 5 years Connectivity Bluetooth 5.0 ready Mouthpieces Ø 30 mm (1.18 inch) Type of electrical protection Internal power supply protection Type BF Apparatus Batteries charge Internal power supply protection Type BF Apparatus Conditions of use Apparatus for continuous use Storage conditions Temp: MIN -25 °C, MAX +70 °C Humidity: MIN 10% RH; MAX 93%RH Temp: MIN -25 °C, MAX +70 °C Humidity: MIN 10% RH, MAX 93%RH IEC 60601-1:2005 + A1:2012 + A2:2020 IEC 60601-1:2005 + A1:2012 + A2:2020 IEC 60601-1-2:2014 + A1:2020 EN ISO 14971:2019 ISO 1993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-1:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009		Stand by 8 µA medium
Lifetime 5 years Connectivity Bluetooth 5.0 ready Mouthpieces Ø 30 mm (1.18 inch) Type of electrical protection Internal power supply Safety level for shock hazard Type BF Apparatus IP protection level IPX2 Conditions of use Apparatus for continuous use Storage conditions Temp: MIN −25 °C, MAX+70 °C Humidity: MIN 10% RH; MAX 93%RH Operating conditions Temp: MIN −25 °C, MAX +40 °C Humidity: MIN 15% RH; MAX 93%RH Shipping conditions Temp: MIN −25 °C, MAX +70 °C Humidity: MIN 10% RH, MAX 93%RH Applicable standards IEC 60601-1:2005 + A1:2012 + A2:2020 IEC 60601-1-2:2014 + A1:2020 EN ISO 14971:2019 ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-6:2010 + A1:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009		none
Connectivity Bluetooth 5.0 ready Mouthpieces Ø 30 mm (1.18 inch) Type of electrical protection Safety level for shock hazard IP protection level Conditions of use Storage conditions Temp: MIN -25 °C, MAX +70 °C Humidity: MIN 10% RH; MAX 93%RH Operating conditions Temp: MIN -5°C, MAX +70 °C Humidity: MIN 15% RH; MAX 93%RH Temp: MIN -25°C, MAX +70 °C Humidity: MIN 15% RH; MAX 93%RH Shipping conditions Temp: MIN -25°C, MAX +70 °C Humidity: MIN 10% RH, MAX 93%RH Applicable standards IEC 60601-1-2:2014 + A1:2012 + A2:2020 IEC 60601-1-2:2014 + A1:2019 ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009	Batteries charger	none
Mouthpieces James Wilson Wilson Wilson	Lifetime	-
Type of electrical protection Safety level for shock hazard IP protection level Conditions of use Apparatus for continuous use Storage conditions Temp: MIN -25 °C, MAX+70 °C Humidity: MIN 10% RH; MAX 93%RH Operating conditions Temp: MIN +5 °C, MAX +40 °C Humidity: MIN 15% RH; MAX 93%RH Shipping conditions Temp: MIN -25°C, MAX +70 °C Humidity: MIN 10% RH, MAX 93%RH Shipping conditions Temp: MIN -25°C, MAX +70 °C Humidity: MIN 10% RH, MAX 93%RH Applicable standards IEC 60601-1:2005 + A1:2012 + A2:2020 IEC 60601-1-2:2014 + A1:2020 EN ISO 14971:2019 ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009		-
Type BF Apparatus		
Safety level for shock hazard IP protection level IPX2	Type of electrical	Internal power supply
Shock hazard IPX2 IPX2		
IP protection level		Type BF Apparatus
Conditions of use Apparatus for continuous use Storage conditions Temp: MIN -25 °C, MAX+70°C Humidity: MIN 10% RH; MAX 93%RH Temp: MIN +5 °C, MAX +40 °C Humidity: MIN 15% RH; MAX 93%RH Shipping conditions Temp: MIN -25°C, MAX +70 °C Humidity: MIN 10% RH, MAX 93%RH Applicable standards IEC 60601-1:2005 + A1:2012 + A2:2020 IEC 60601-1-2:2014 + A1:2020 EN ISO 14971:2019 ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009		
Storage conditions		
Humidity: MIN 10% RH; MAX 93%RH Temp: MIN +5 °C, MAX +40 °C Humidity: MIN 15% RH; MAX 93%RH Temp: MIN -25°C, MAX +70 °C Humidity: MIN 10% RH, MAX 93%RH Applicable standards IEC 60601-1:2005 + A1:2012 + A2:2020 IEC 60601-1-2:2014 + A1:2020 EN ISO 14971:2019 ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009		
Operating conditions Temp: MIN +5 °C, MAX +40 °C Humidity: MIN 15% RH; MAX 93%RH Temp: MIN -25°C, MAX +70 °C Humidity: MIN 10% RH, MAX 93%RH Applicable standards IEC 60601-1:2005 + A1:2012 + A2:2020 IEC 60601-1-2:2014 + A1:2020 EN ISO 14971:2019 ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009	Storage conditions	
Humidity: MIN 15% RH; MAX 93%RH Temp: MIN -25°C, MAX +70°C Humidity: MIN 10% RH, MAX 93%RH Applicable standards IEC 60601-1:2005 + A1:2012 + A2:2020 IEC 60601-1-2:2014 + A1:2020 EN ISO 14971:2019 ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009		
Shipping conditions Temp: MIN -25°C, MAX +70 °C Humidity: MIN 10% RH, MAX 93%RH Applicable standards IEC 60601-1:2005 + A1:2012 + A2:2020 IEC 60601-1-2:2014 + A1:2020 EN ISO 14971:2019 ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009	Operating conditions	1
Humidity: MIN 10% RH, MAX 93%RH IEC 60601-1:2005 + A1:2012 + A2:2020 IEC 60601-1-2:2014 + A1:2020 EN ISO 14971:2019 ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009		
Applicable standards IEC 60601-1:2005 + A1:2012 + A2:2020 IEC 60601-1-2:2014 + A1:2020 EN ISO 14971:2019 ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009	Shipping conditions	The state of the s
IEC 60601-1-2:2014 + A1:2020 EN ISO 14971:2019 ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009		
EN ISO 14971:2019 ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009	Applicable standards	
ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009		
2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009		
EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009		ISO 10993-1:2018
IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009		2011/65/UE Directive
A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009		EN ISO 15223-1:2021
IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines(2019 update) ISO 26782: 2009		
ATS/ERS Guidelines(2019 update) ISO 26782: 2009		A2:2020
ISO 26782: 2009		
ISO 23747: 2015		
		ISO 23747: 2015

Spirometry	
Flow sensor	bi-directional digital turbine
Flow range	±16L/s
Volume accuracy	±2.5% or 0,05 L
Peak Flow accuracy	±10% or 0,33 L/s
Dynamic resistance	<0.5 cm H2O/L/s
Temperature sensor	none
Measured parameters	FEV1, PEF
Memory capacity	The application on the smart
	phone stores data
Certificates	
& Registrations	
CE 0476	MDR 2017/745
FDA 510 (k)	K181666
Health Canada	96378 (class II)
EMDN liv.4	Z121501
CND code	Z12150102
GMDN code	46906
Ministry of Health	2494874/R

cod. 911120xx

Datasheet Smart One Oxi

Dimensions	49 x 109 x 21 mm
Weight	60.7 g (batteries included)
Turbine	Single Patient Reusable Turbine
	with Mouthpiece (code 910013)
Power supply	2 batteries AAA 1.5 V
Consumption	max 12 mA
	Stand by 8 µA medium
Lifetime	5 years
Connectivity	Bluetooth 5.0 ready
Mouthpiece	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	Temp: MIN -25 °C, MAX+70°C
	Humidity: MIN 10% RH; MAX 93%RH
Operating conditions	Temp: MIN +5 °C, MAX +40 °C
	Humidity: MIN 15% RH; MAX 93%RH
Shipping conditions	Temp: MIN -25°C, MAX +70 °C
	Humidity: MIN 10% RH, MAX 93%RH
Applicable standards	ATS/ERS 2005, 2019 update
	ISO 26782: 2009
	ISO 23747: 2015
	EN ISO 14971:2019
	ISO 10993-1:2018
	2011/65/UE Directive
	EN ISO 15223-1:2021
	IEC 60601-1: 2005 + A1:2012
	+ A2:2020
	IEC 60601-1-2:2014 + A1:2020
	IEC 60601-1-6:2010 + A1:2013
	+ A2:2020
	IEC 60601-1-11:2015 + A1:2020

	1
Spirometry	
Flow sensor	bi-directional digital turbine
Flow range	±16L/s (960L/m)
Volume range	10 L
Volume accuracy	±2.5% or ±0.05 L
Peak Flow accuracy	±10% or 0,33L/s
Dynamic resistance	<0.5 cm H2O/L/s (@ 12 L/s)
Temperature sensor	none
Available test	Peak Flow
Measured parameters	FEV1, PEF
Memory capacity	The application on the remote
	device (smartphone/tablet)
	stores data
Oximetry	
	Davida waxala zath
Measuring method	Double wavelength
%Sp02 range	70%-100%
%Sp02 accuracy	±1.9%
Average number of beats	12 beats
for the calculation % Sp02	
Pulse Rate range	30-200 BPM
Pulse Rate accuracy	±2 BPM
Average interval for	12 seconds
BPM calculation	
Quality signal indicator	0-8 lines
Available tests	Spot
Measured parameters	%Sp02min, %Sp02mean,
	%Sp02max, BPMmin, BPMmean,
	BPMmax, Ttotal
Wavelength sensors	Red 660 nm
	Infrared 880 nm
Maximum optical	1.2 mW
output power	
Certificates	
& Registrations	
CE 0476	MDR 2017/745
FDA 510 (k)	K230501
Health Canada	107185 (class II)
EMDN liv.4	Z121501
Codice CND	Z12150102
Codice GMDN	46906
	45607
	70001

ITALY

MIR Medical International Research S.p.A. Viale Luigi Schiavonetti, 270 00173, Rome Tel. +39 06 22 754 777

USA

MIR USA, Inc. 5462 S. Westridge Drive New Berlin, WI 53151 Tel. +1 (262) 565-6797 mir-usa@spirometry.com

FRANCE

MIR Local Office
Jardin des Entreprises, 290,
Chemin de Saint Dionisy
30980 LANGLADE
Tel. +33 (0)4 66 37 20 68
mirfrance@spirometry.com

BRAZIL

MIR Local Office Rua Pinheiro Machado, 2659 SI.303, Caxias do Sul RS Tel +55 5430253070 mirbrazil@spirometry.com

spirometry.com

in f 💿 🗅

