MIR

Spirolab

All-in-one Desktop Spirometer

for rapid and comprehensive reporting

Supported tests

Spirometry: FVC, VC, MVV, PRE/POST bronchodilator comparison

Oximetry (optional): Spot test (SpO2%, BPM)

Key features

All-in-one
Complete spirometer, all-in-one touchscreen and integrated printer for testing without the need for a computer

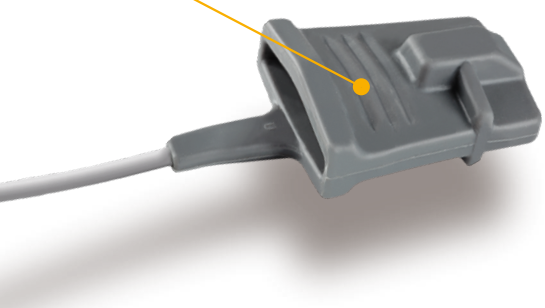
Connection to external Postscript Printer

Integrated thermal printer
Customizable print and detailed immediate test reports.
80<120 prints with a single roll*.
(Paper size 112 mm;
Paper weight 56g +/- 4 gr/m2)

Calibration
Available on device, with calibration report printable by the instrument

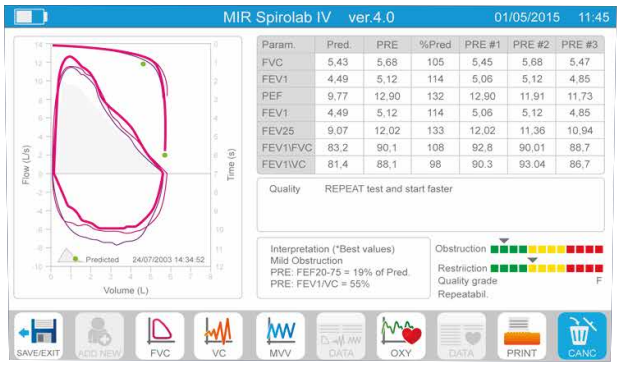
7” colour touchscreen
Intuitive interface and clear data display

SpO2% Sensor
Oximetry sensor to detect blood oxygen saturation



*Using non-original MIR paper rolls or heavier than indicated can irreparably damage the printer

Real-time tests



Integrated temperature sensor

Automatic BTPS Conversion

Long-lasting rechargeable battery

Long-lasting rechargeable lithium battery for extended autonomy in Stand Alone mode

Large internal memory

Storage up to 10,000 spirometric tests or 500 hours of oximetry

Predicted values

Wide selection of predicted values including GLI, ERS and others, directly on the device and in PC mode

EMR/EHR connectivity

Integration via **MIR Spiro** software with EMR/EHR (in HL7, GDT, FHIR, EXCHANGE PROTOCOL)

Pediatric incentive

Compatible turbines

		Mouthpiece	Turbine disinfection	Turbine calibration	Packaging	Antiviral filter
FlowMIR® disposable turbine		Disposable included	Not required	Not required	Individually packaged: packs of 60 pieces	Optional
Reusable turbine		Required, not included	Required	Required	Pack of 1 unit	Recommended by ATS

How to use

Spirolab works both in **Stand Alone** mode
and connected to **PC via USB**

MIR Spiro software

- **Comprehensive software for spirometry and oximetry**
- **Designed to be integrated with EMR/EHR**
- **Complies with the latest ATS/ERS guidelines**
- **Available for desktop and laptop use**
- **MacOS and Windows**

All MIR professional devices
work with **MIR Spiro** software,
the latest generation software
for spirometry and oximetry.

Platinum Card

To subscribe to a Platinum
subscription plan
it is necessary to **have**
the MIR Spiro Platinum Card.

*provided with all MIR professional devices, available for purchase online (mymir.spirometry.com) or from your trusted MIR distributor

Measured parameters

	From MIR Spiro software via connection to the device	From device in Stand Alone mode
Spirometry	FVC, FEV1, PEF, FEF75, FEF25-75, FET, FEV1/FVC, FEV6, FEV1/FEV6, FEF25, FEF50, FIVC, FEV1/VC, ELA, MVV(cal), Time to PEF, FEV0.5, FEV0.5/FVC, FEV0.75, FEV0.75/FVC, FEF75-85, Extr. Vol, VC, EVC, IVC, IC, VC, ERV FEV3, FIV1, FIV1/FIVC, PIF, FEV3/FVC, PIF, FEV2, FEV2/FVC, FIF25, FIF50, FIF75, R50, FEV1/PEF (EI), FEV1/FEV0.5 (RFEV), TV, VE, RR, tI	VC, FEV1, FEV1/ FVC, FEV1/VC, PEF, FEF25, FEF50, FEF75, FEF25-75, FEF75-85, ELA, extrapolated Vol, FET, Time to PEF, FEV0.5, FEV0.5/FVC, FEV0.75, FEV0.75/ FVC,FEV2, FEV2/ FVC, FEV3, FEV3/ FVC, FEV6, FEV1/ FEV6, FEV1/PEF, FEV1/FEV0. 5, FIVC, FIV1, FIV1/FIVC, PIF, FIF25, FIF50, FIF75, FEF50/FIF50, VC, IVC, IC, ERV, IRV, Rf, VE, VT, tI, tE, VT/tI, tE/tTOT, MVV (measured), MVV (calculated)
Oximetry (optional)	SpO2% [Baseline, Min, Max, Mean], Wrist Rate [Baseline, Min, Max, Mean], T90, T89, T88, T5, Index [12s], SpO2% Events, Wrist Rate Events [bradycardia, tachycardia], Tot Time, Measured Time	SpO2% [Baseline, Min, Max, Mean], Wrist Rate [Baseline, Min, Max, Mean], T90, T89, T88, T5, Index [12s], SpO2% Events, Wrist Rate Events [bradycardia, tachycardia], Tot Time, Measured Time

Datasheet

code 911080xx (spiro) code 911081xx (spiro+oxy)

Size	220 x 210 x 51 mm
Weight	1450 g (battery pack included)
Sensors	·For reusable and disposable miniflowmeter turbines (code 910595) ·For spirolab code 911081 only Reusable soft adult sensor for oximetry test (code 919024)
Power supply	Ni-MH rechargeable battery pack, 6 elements
Current	4500 mAh
Consumption	medium 250 mA
Backup battery voltage	absent
Charge Batteries	output voltage=12 V, current=1A, compliant with EN 60601-1
Autonomy	~10 hours
Connectivity	USB 2.0, Bluetooth® 5
Display	7 inch colour touchscreen resolution 800x480 pixels LCD
Keyboard	absent, touchscreen
Mouthpiece	Ø 30 mm (1.18 inches)
Type of electrical protection	Internally powered Class II while battery is charging
Safety level due to shock hazard	Type BF device
Terms of use	Device for continuous use
Storage conditions	Temp: MIN -40°C, MAX+60°C Humidity: MIN 10% RH; MAX 95%RH
Transport conditions	Temp: MIN -40°C, MAX +60°C Humidity: MIN 10% RH; MAX 95%RH
Operating conditions	Temp: MIN +10°C, MAX +40°C Humidity: MIN 10% RH, MAX 95%RH
Degree of protection against water penetration	IPX1
Spirometry	
Sensor	two-way digital turbine
Volume range	10 L
Flow range	±16L/s
Volume accuracy	±2.5%o50mL
Flow accuracy	±5% or 200 mL/s
Dynamic resistance	<0.5 cm H2O/L/s
Temperature sensor	semiconductor (0-45°C)

Available tests	FVC, VC, IVC, MVV, PRE-POST
Measured parameters	FVC, FEV1, FEV1/FVC%, FEV1/PEF, FEV1/VC, FEV1/FEV0.5, PEF Time, FEV 0.5, FEV0.5/FVC, FEV0.75, FEV0.75/FVC, FEV2, FEV2/FVC, FEV3, FEV3/FVC, FEV6, FEV1/FEV6, PEF, FEF25, FEF50, FEF75, FEF2575, FEF7585, FET, Vext, ELA, EVOL, FIVC, FIV1, PIF, FIV1/FIVC, FIF25, FIF50, FIF75, R50, MVVcal, PIF, IRV, VC, EVC, IVC, IC, ERV, IRV, FEV1/VC, TV, VE, RR, ti, te, ti/t-tot, tv/ti, MVV
Memory capacity	more than 10,000 tests
Oximetry (on request)	
Measurement method	Infrared absorption
SpO2% Range	0-99%
Accuracy of SpO2%	± 2% between 70-99% SpO2%
Average number of beats for SpO2% calculation	8 beats
Cardiac pulse range	18-300 BPM
Cardiac pulse accuracy	± 2BPM or 2% the greater of the two
Mean interval for calculation of heartbeat	8 seconds
Signal quality indication	0 - 8 segments on screen
Test available	spot
Measured parameters	SpO2% min, max, average Min, Max, Avg BPM Test duration % Duration of bradycardia (<40 BPM) % Duration of tachycardia (>120 BPM) % Time with %SpO2 ≤ 90% (T90%, T89%), T5
Memory capacity	about 500 hours of oximetry

Certificates and registrations	
CE 0476	MDR 2017/745
FDA 510 (k)	K 052140
Health Canada	71191 (Class II)
EMDN liv.4	Z121501
CND Code	Z12150102
GMDN Code	46906 (spiral), 45607 (spiro + oxy)
Ministry of Health	2494321/R (code 911080I1) 2494344/R (code 911081I1) 2494441/R (code 911080I0) 2494453/R (code 911081I0)
Applicable regulations	Electrical Safety IEC 60601-1 Electro Magnetic Compatibility EN 60601-1-2 ISO 80601-2-61:2017 ISO 26782: 2009 ISO 23747: 2015 ATS/ERS:2005, 2019(update) IEC 60601-1-6:2010 IEC 60601-1-8:2006+ AMD1:2012 IEC 60601-1-9:2007+AMD1:2013 IEC 62304:2006 + A1:2015 ISO 10993-1:2018 Directive 2014/53/EU RED IEC 62311:2019 EN 62311:2020

Compliance with guidelines and standards

Spirometry: ATS/ERS 2005 + update to 2019;
ISO 23747: 2015; ISO 26782: 2009
Oximetry: ISO 80601-2-61:2017

ITALY

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MIR
MEDICAL INTERNATIONAL RESEARCH

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
C642759

Initial certification date:
16 January 2024

Valid:
16 February 2024 – 15 February 2027

This is to certify that the management system of

MIR Medical International Research S.P.A.

Viale Luigi Schiavonetti, 270 - 00173 Rome (RM) - Italy

has been found to conform to the Quality Management System standard:

ISO 9001:2015

This certificate is valid for the following scope:

Design, manufacturing and sales of medical devices and accessories for lung function and cardiovascular system and analysis (IAF 19, 14, 29)

Place and date:
Vimercate (MB), 01 February 2024

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 003 A
SGA N° 003 D
SGE N° 007 M
SCR N° 004 F
EMAS N° 009 P
PRD N° 003 B
PRS N° 094 C
SSI N° 002 G

Membro di MLA EA per gli schemi di accreditamento SGQ, SGA, PRD, PRS, ISP, GHG, LAB e LAT, di MLA IAF per gli schemi di accreditamento SGQ, SGA, SSI, FSM e PRD e di MRA ILAC per gli schemi di accreditamento LAB, MED, LAT e ISP

For the issuing office:
DNV - Business Assurance
Via Energy Park, 14, - 20871 Vimercate (MB) - Italy

Claudia Baroncini
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
C642756

Initial certification date:
16 January 2024

Valid:
16 February 2024 – 15 February 2027

This is to certify that the management system of

MIR Medical International Research S.P.A.

Viale Luigi Schiavonetti, 270 - 00173 Rome (RM) - Italy

has been found to conform to the Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope:

Design, manufacturing and sales of medical devices and accessories for lung function and cardiovascular system and analysis

Place and date:
Vimercate (MB), 01 February 2024

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 003 A
SGA N° 003 D
SGE N° 007 M
SCR N° 004 F
EMAS N° 009 P
PRD N° 003 B
PRS N° 094 C
SSI N° 002 G

Membro di MLA EA per gli schemi di accreditamento SGQ, SGA, PRD, PRS, ISP, GHG, LAB e LAT, di MLA IAF per gli schemi di accreditamento SGQ, SGA, SSI, FSM e PRD e di MRA ILAC per gli schemi di accreditamento LAB, MED, LAT e ISP

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Claudia Baroncini
Management Representative

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CERTIFICATE

Reg. Numero / *Reg. Number*	MDR 00020-A	Revisione / *Revision*	1
Primo rilascio / *First issue date*	2023-02-16	Valido da / *Valid from*	2023-02-16
Scadenza / *Valid until*	2028-02-15	Ultima modifica / *Last change date*	2023-07-10
Data Scadenza Precedente / *Previous Expiry*			

Certificato UE del Sistema di Gestione della Qualità
EU Quality Management System Certificate

Kiwa Cermet Italia certifica che, sulla base dei risultati delle valutazioni effettuate, il Sistema di Gestione della Qualità dell'Organizzazione:
Kiwa Cermet Italia certifies that, on the basis of the assessment carried out, the Quality Management System of the Organization:

MIR - MEDICAL INTERNATIONAL RESEARCH S.p.A.

Operatore economico / *Economic operator:* Fabbricante

SRN: IT-MF-000014026

Sede Legale e Operativa / Legal and Operational Headquarters
Viale Luigi Schiavonetti 270 - 00173 Roma (RM) - Italia

E' conforme ai requisiti applicabili del Regolamento (UE) 2017/745, Allegato IX capo I e III, per le seguenti tipologie di dispositivi:
Is in compliance with the applicable requirements of Regulation (EU) 2017/745, Annex IX Chapter I and III, for the following devices types:

Z120503 - Elettrocardiografi */ Electrocardiographs*

Z1203020408 - PULSOSSIMETRI */ PULSE OXIMETERS*

Z12150102 - Spirometri per picco di flusso */ Peak flow spirometers*

Z12150180 - Strumentazione per spirometria - accessori hardware */ Spirometry instruments - hardware accessories*

Kiwa Cermet Italia S.p.A.
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Organismo Notificato n. 0476
Notified Body nr. 0476

Presidente / President
Giampiero Belcredi

Firmato digitalmente da: BELCREDI GIAMPIERO
Data: 10/07/2023 15:59:30

CERTIFICATE

Reg. Numero / *Reg. Number*	MDR 00020-A	Revisione / *Revision*	1
Primo rilascio / *First issue date*	2023-02-16	Valido da / *Valid from*	2023-02-16
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Data Scadenza Precedente / *Previous Expiry*			

Allegato tecnico al Certificato
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi / *Devices identification:*

Tipologia / *Type:*
Z120503 - Elettrocardiografi / *Electrocardiographs*

Nome / *Name:*
Elettrocardiografo / *Electrocardiograph*

Modello / Model:
Cardionica

Nome commerciale / Brandname:
Cardionica

Classe di rischio / *Risk class:*
II a

Tipologia / *Type:*
Z1203020408 - PULSOSSIMETRI / *PULSE OXIMETERS*

Nome / *Name:*
Ossimetro / *Oximeter*

Modello / Model:
Spirodoc

Nome commerciale / Brandname:
Spirodoc

Classe di rischio / *Risk class:*
II a

Tipologia / *Type:*
Z12150102 - Spirometri per picco di flusso / *Peak flow spirometers*

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Organismo Notificato n. 0476
Notified Body nr. 0476

Presidente / President
Giampiero Belcredi
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CERTIFICATE

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Data Scadenza Precedente / *Previous Expiry*			

Allegato tecnico al Certificato
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi / *Devices identification:*

Nome / *Name:*
Spirometro / *Spirometer*

Modello / Model:
Spirobank Smart; mSpirometer; AsthmaTuner; Smart One; cSpirometer

Nome commerciale / Brandname:
Spirobank Smart; mSpirometer; AsthmaTuner; Smart One; cSpirometer

Classe di rischio / *Risk class:*
II a

Nome / *Name:*
Spirometro / / *Spirometer*

Modello / Model:
MiniSpir; MiniSpir Light POST BD

Nome commerciale / Brandname:
MiniSpir; MiniSpir Light POST BD

Classe di rischio / *Risk class:*
II a

Nome / *Name:*
Spirometro con o senza ossimetro / *Spirometer with or without oximeter*

Modello / Model:
Spirolab

Nome commerciale / Brandname:
Spirolab

Classe di rischio / *Risk class:*
II a

Nome / *Name:*
Spirometro con o senza ossimetro / / *Spirometer with or without oximeter*

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CERTIFICATE

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Data Scadenza Precedente / *Previous Expiry*			

Allegato tecnico al Certificato
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi / *Devices identification:*

Modello / Model:
Spirodoc

Nome commerciale / Brandname:
Spirodoc

Classe di rischio / *Risk class:*
II a

Nome / *Name:*
Spirometro con o senza ossimetro // / *Spirometer with or without oximeter*

Modello / Model:
Spirobank II; Spirobank II with Bluetooth smart

Nome commerciale / Brandname:
Spirobank II; Spirobank II with Bluetooth smart

Classe di rischio / *Risk class:*
II a

Nome / *Name:*
Spirometro con ossimetro / *Spirometer with oximeter*

Modello / Model:
Spirobank Oxi; Smart One Oxi

Nome commerciale / Brandname:
Spirobank Oxi; Smart One Oxi

Classe di rischio / *Risk class:*
II a

Tipologia / *Type:*
Z12150180 - Strumentazione per spirometria - accessori hardware / *Spirometry instruments - hardware accessories*

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CERTIFICATE

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Allegato tecnico al Certificato
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Identificazione dei Dispositivi / *Devices identification:*

Nome / *Name:*
Boccaglio in plastica / *Plastic mouthpiece*

Modello / Model:
Mouthpiece

Nome commerciale / Brandname:
Mouthpiece

Classe di rischio / *Risk class:*
II a

Nome / *Name:*
Turbina con boccaglio in carta monouso / *Disposable turbine with cardboard mouthpiece*

Modello / Model:
FlowMIR; Nuvoair

Nome commerciale / Brandname:
FlowMIR; Nuvoair

Classe di rischio / *Risk class:*
II a

Nome / *Name:*
Turbina riusabile con boccaglio in plastica monouso / *Reusable turbine with single use plastic mouthpiece*

Modello / Model:
Single patient reusable turbine

Nome commerciale / Brandname:
Single patient reusable turbine

Classe di rischio / *Risk class:*
II a

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Organismo Notificato n. 0476
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CERTIFICATE

Reg. Numero / *Reg. Number*	MDR 00020-A	Revisione / *Revision*	1
Primo rilascio / *First issue date*	2023-02-16	Valido da / *Valid from*	2023-02-16
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Data Scadenza Precedente / *Previous Expiry*			

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia.
The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.
Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza periodica.
This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the aforementioned types of devices that are subject to periodic survey.
L'allegato tecnico è parte integrante del presente Certificato
The technical sheet is an integrating part of this Certificate.

Kiwa Cermet Italia S.p.A.
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Organismo Notificato n. 0476
Notified Body nr. 0476

Presidente / President
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Data: 10/07/2023 16:03:16

CERTIFICATE

Storia del Certificato
Certificate History

Rev. *Rev.*	**Data** *Date*	**Descrizione modifica** *Description of Change*	**Rapporto di valutazione[1] del** *Certificate History*
0	16/02/2023	Certificazione iniziale *Initial certification*	Rapporto di audit del / *Audit report dated:* 10-11-12/01/2023 Analisi documentazione tecnica del / *Technical documentation analysis dated:* 14/11/2022; 12/01/2023; 13/01/2023 Valutazione dati clinici del / *Clinical data assessment dated:* 03/05/2022; 12/01/2023; 13/01/2023
1	10/07/2023	Modifica indirizzo sede legale e operativa / Change of legal and operational headquarters address	Rapporto di audit del / *Audit report dated:* 30/05/2023 Analisi documentazione tecnica del / *Technical documentation analysis dated:* 18/04/2023, 26/04/2023

[1] I rapporti di valutazione sono disponibili su richiesta / Assessment reports are available upon request

Kiwa Cermet Italia S.p.A.
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Presidente / President
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