AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.2. Declarația de conformitate CE	Declaratii de conformitate CE
I.3. Certificatul CE	Certificat CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
			spir			MIR				
DM000323219	SPIROMETRU	MIR	MINISPIR LIGHT		Italia	MIR S.R.L. - MEDICAL INTERNATIONAL RESEARCH	HEALTH MEDICAL SOLUTIONS S.R.L.	Rg04-000276	10-11-2021	
DM000323218	SPIROMETRU/OXIME	MIR	SPIROBANK II		Italia	MIR S.R.L. - MEDICAL INTERNATIONAL RESEARCH	HEALTH MEDICAL SOLUTIONS S.R.L.	Rg04-000276	10-11-2021	
DM000323217	SPIROMETRU/OXIME	MIR	SPIROBANK OXI		Italia	MIR S.R.L. - MEDICAL INTERNATIONAL RESEARCH	HEALTH MEDICAL SOLUTIONS S.R.L.	Rg04-000276	10-11-2021	
DM000323221	SPIROMETRU	MIR	SPIROBANK SMART		Italia	MIR S.R.L. - MEDICAL INTERNATIONAL RESEARCH	HEALTH MEDICAL SOLUTIONS S.R.L.	Rg04-000276	10-11-2021	
DM000323215	SPIROMETRU/OXIME	MIR	SPIROLAB		Italia	MIR S.R.L. - MEDICAL INTERNATIONAL RESEARCH	HEALTH MEDICAL SOLUTIONS S.R.L.	Rg04-000276	10-11-2021	
DM000323216	SPIROMETRU/OXIME	MIR	SPIRODOC		Italia	MIR S.R.L. - MEDICAL INTERNATIONAL RESEARCH	HEALTH MEDICAL SOLUTIONS S.R.L.	Rg04-000276	10-11-2021	

Содержит([Producatorul], 'MIR') И Содержит([Model], 'spir')

Digitally signed by Grabazei Alexandru
Date: 2023.07.03 11:47:16 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 45 din 09.06.2023

Solicitantul **FCPC „DataControl" S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemițanu, 17/6**, tel./fax: 022 27 37 12, e-mail: contact@datacontrol.md, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Product: SPIROMETER

Model: MINISPIR

911006,
911006T,
911006E0,
911006E1,
911006I0,
911006I1,
911003.

Se anexează următoarele acte:

1. Declarație de Conformitate CE
2. Certificatul de Conformitate CE
3. Actul prin care producătorul își desemnează reprezentantul
4. Declarație pe propria răspundere.

Data **09.06.2023**

Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitantul **F.C.P.C. "DataControl" S.R.L.**, cu sediul în **mun. Chișinău, str. N. Testemițanu 17/6**, tel./fax: **022 27 37 12**, e-mail: contact@datacontrol.md,

declar pe proprie răspundere, cunoscînd prevederile art. **352[1]** , Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele şi datele furnizate pentru notificarea dispozitivului medical:

Product: SPIROMETER

Model: MINISPIR

911006,
911006T,
911006E0,
911006E1,
911006I0,
911006I1,
911003.

Sunt autentice şi corespund realităţii

Alexandru Grabazei, director Semnătura _____

Data: **09.06.2023**

MIR
MEDICAL INTERNATIONAL RESEARCH

To: Whom It May Concern

Date: 07.06.2023.

Authorization

We, Company-manufacturer MIR SpA Medical International Research, viale Luigi Schiavonetti 270, 00173 Roma, manufactures medical devices like portable spirometers and oximeters, hereby appoint following company:

F.C.P.C. "DataControl" S.R.L.,

17/6, N.Testimiteanu street,

MD-2025, Chișinau, Republic of Moldova,

to be our authorized representative at the responsible authorities of the Republic of Moldova for registration, renewal, variation of registration etc. .

signature for and on behalf of Manufacturer

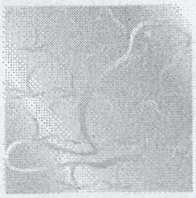
MIR MEDICAL INTERNATIONAL RESEARCH S.p.A.

(Laura Precetti – MIR Export Area Manager)

FCPC "DATACONTROL" S.R.L. DataControl IDNO 1003600007935

MIR – Medical International Research S.p.A.
Cap. Soc.: Eur 120.350,00 i.v.
PI / CF / Reg. Imp.: 04564101006
Sede Legale (Head Office): Viale Luigi Schiavonetti 270 – 00173 Roma

PEC: mirsrl-medicalinternationalresearch@pec.it
E.: mir@spirometry.com
T. +39 06 22 754 777 – F. +39 06 22 754 785
www.spirometry.com



CERTIFICATE

Reg. Numero / *Reg. Number*	MDR 00020-A	Revisione / *Revision*	0
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*	2023-02-16
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

Sede Legale e Operativa
Via del Maggiolino, 125 - 00155 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*

FCPC "DATACONTROL" S.R.L. DataControl IDNO 1003600007935

Presidente / President
Giampiero Belcredi
Firmato digitalmente da: BELCREDI GIAMPIERO
Data: 17/02/2023 09:07:28

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwa.it

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MDR 00020-A	Revisione / *Revision*	0
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*	2023-02-16
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*

Classe di rischio / *Risk class:*
II a

Nome / *Name:*
Elettrocardiografo / *Electrocardiograph*

Nome commerciale / Brandname:
Cardionica

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

Classe di rischio / *Risk class:*
II a

Nome / *Name:*
Ossimetro / *Oximeter*

Nome commerciale / Brandname:
Spirodoc

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

Classe di rischio / *Risk class:*
II a

Nome / *Name:*
Spirometro / *Spirometer*

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

Classe di rischio / *Risk class:*

Presidente / President
Giampiero Belcredi

Firmato digitalmente da: BELCREDI GIAMPIERO
Data: 17/02/2023 09:11:15

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
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CERTIFICATE

Reg. Numero / *Reg. Number*	MDR 00020-A	Revisione / *Revision*	0
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Scadenza / *Valid until*	2028-02-15	Ultima modifica / *Last change date*	2023-02-16
Data Scadenza Precedente / *Previous Expiry*			

Allegato tecnico al Certificato
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi / *Devices identification:*

II a

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

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*

Nome commerciale / Brandname:
Spirolab

Classe di rischio / *Risk class:*
II a

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

Nome commerciale / Brandname:
Spirodoc

Classe di rischio / *Risk class:*
II a

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

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

Classe di rischio / *Risk class:*
II a

DATACONTROL S.R.L. DataControl IDNO 1003600007935

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
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www.kiwa.it

Organismo Notificato n. 0476
Notified Body nr. 0476

Presidente / President
Giampiero Belcredi

Firmato digitalmente da: BELCREDI GIAMPIERO
Data: 17/02/2023 09:12:19

CERTIFICATE

Reg. Numero / *Reg. Number*	MDR 00020-A	Revisione / *Revision*	0
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*	2023-02-16
Data Scadenza Precedente / *Previous Expiry*			

Allegato tecnico al Certificato
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi / *Devices identification:*

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

Nome commerciale / Brandname:
Spirobank Oxi; Smart One Oxi

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

Classe di rischio / *Risk class:*
II a

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

Nome commerciale / Brandname:
Mouthpiece

Classe di rischio / *Risk class:*
II a

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

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*

Nome commerciale / Brandname:
Single patient reusable turbine

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: 17/02/2023 09:12:48

CERTIFICATE

Reg. Numero / *Reg. Number*	MDR 00020-A	Revisione / *Revision*	0
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.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
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Organismo Notificato n. 0476
Notified Body nr. 0476

Presidente / President
Giampiero Belcredi
Firmato digitalmente da: BELCREDI GIAMPIERO
Data: 17/02/2023 09:13:15

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

DATACONTROL S.R.L. FCPC IDNO 1003600007935

Presidente / President
Giampiero Belcredi

Firmato digitalmente da: BELCREDI GIAMPIERO
Data: 17/02/2023 09:17:27

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
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E-mail: info@kiwacermet.it
www.kiwa.it

Organismo Notificato n. 0476
Notified Body nr. 0476

Nome del Fabbricante: *Name of the Manufacturer:*	MIR - Medical International Research S.p.A.
Sede Legale: *Registered Place of Business:*	Via del Maggiolino 125, 00155 Rome, Italy
Numero di Registrazione Unico (NRU): *Single Registration Number (SRN):*	IT-MF-000014026

Il Fabbricante rilascia sotto la sua responsabilità esclusiva la presente Dichiarazione di Conformità UE e dichiara che il seguente dispositivo medico è conforme ai requisiti del Regolamento (UE) 2017/745 relativo ai dispositivi medici.
The Manufacturer issues under its own exclusive responsibility this EU Declaration of Conformity and declares that the following medical device is in compliance with the requirements of Regulation (EU) 2017/745 on medical devices.

Nome Modello: *Model Name:*	MiniSpir
Codice commerciale: *Commercial code:*	911006, 911006T, 911006E0, 911006E1, 91100610, 91100611, 911003
UDI-DI di Base: *Basic UDI-DI:*	805299032052-053D4
Destinazione d'uso: *Intended use:*	Lo spirometro MiniSpir è destinato all'uso da parte di personale medico, da un professionista sanitario autorizzato o di un paziente sotto la supervisione di un medico. Il dispositivo ha lo scopo di testare la funzionalità polmonare e può eseguire test spirometrici su persone di tutte le età, esclusi neonati e neonati Può essere utilizzato in fabbrica, farmacia, ospedale o studio medico *MiniSpir spirometer is intended to be used either by a physician, respiratory therapist, technician or patient under physician supervision.* *The device is intended to test lung function and can make spirometry testing in people of all ages excluding infants and neonates.* *It can be used in hospital setting, physician's office, factory, pharmacy.*
Classe di Rischio: *Risk Class:*	IIa
Regola di classificazione *Classification Rule*	Regola 10, terzo trattino *Rule 10, third indent*

Procedura di valutazione della conformità applicata: *Conformity assessment procedure performed:*	**Allegato IX, capi I e III** *Annex IX, chapter I and III*
Organismo Notificato (ON): *Notified Body (NB):*	Kiwa Cermet Italia S.p.A.
Numero identificativo ON: *NB identification number:*	0476
Identificativo del Certificato rilasciato: *Identification of issued Certificate:*	MDR 00020-A

Lista delle Specifiche Comuni (SC) a cui il dispositivo medico è conforme:
List of Common Specifications (CS) to which the medical device is conform to:

Nessuna SC applicabile.
No applicable CS.

Data e Luogo *Date and Place*	Roma 16.02.2023 *Rome 16th February 2023*
Ruolo, nome e firma Role, name and signature	Amministratore Delegato *Chief Executive Officer* Ing. Giovanni Carlino

ADVANCED

SPIROLAB®

Desktop, Stand-alone and PC-based Spirometer, with Oximetry Option

All-in-one Spirometer with 7" display, Embedded Printer and Oximetry option, to carry on the go

MIR
MEDICAL INTERNATIONAL RESEARCH

www.spirometry.com

MAIN features

REAL-TIME TEST

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

CARRY EVERYWHERE

7" LCD Color Touchscreen Display, Long-lasting rechargeable battery, massive Internal Storage

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)

PC CONNECTION AVAILABLE

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

CALIBRATION SOFTWARE

Available on device, with printable calibration report (no separate software required)

DISTINCTIVE features

PREDICTED SETS & VALUES

Large Selection, including GLI, comparison %Pred, Z-score and LLN

PRINTED EMBEDDED

Thermal printer. Paper size 112mm. Direct external print also available via PC software

PEDIATRIC INCENTIVE

Real-time animation on display to improve patient compliance during the test

COVID-19 PREVENTION

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

Always INCLUDED

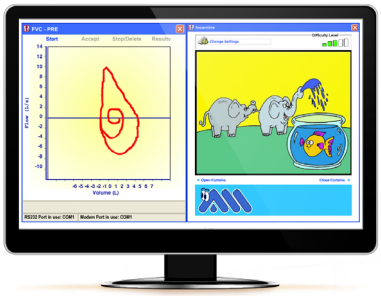
- Carrying case
- Power supply/battery charger
- USB cable
- 1 Roll of thermal printer paper
- Noseclip
- PC Software license

With Oximetry Option:

- Finger Probe

Compatible SOFTWARE

winspiroPRO



Pediatric Incentive (PATENTED) to improve patient compliance during the test.

Acceptabilty Messages, Test interpretation and Quality Control Grade according to the latest **Spirometry Standards**

MAIN FEATURES

Windows-based solution for Spirometry, Oximetry and Telemedicine.

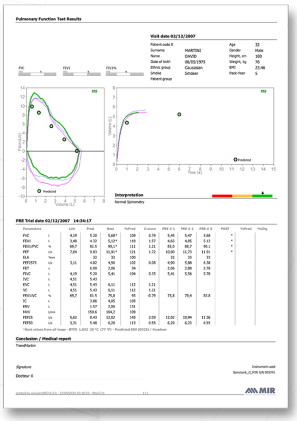
Wide range of predicted sets and values, including **GLI Predicted sets, LLN and Z–score**.

Embedded **EHR/EMR connectivity.**

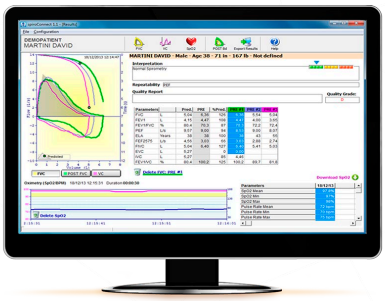
NET VERSION available, share one database between different PC workstations.

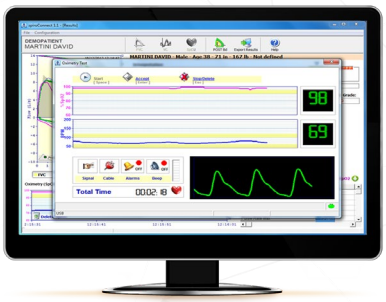
MEDICAL REPORT

Specialized and **customizable printout**



spiro Connect





MAIN FEATURES

Windows-based solution, **direct integration** with your EHR/EMR.

Real time test include **Spirometry** and **Oximetry**

Standardized communication in **HL7 or Exchange Protocol**.

Select patient info directly from your own **EHR/EMR**

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

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

Compatible TURBINES

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

PLAY VIDEO

SCIENTIFIC PUBLICATIONS

TECHNICAL datasheet

PRODUCT CODES - Spirolab Configurations
911080E0 – Spirometer • 911080E1 - Spirometer with reusable turbine
911081E0 - Spirometer + Oximeter • 911081E1 - Spirometer + Oximeter with reusable turbine

Technical specification

Width	220 mm
Length	210 mm
Thickness	51 mm
Weight	1450 g (battery pack included)

Sensors

miniflowmeter (code 900595)
for reusable and disposable turbine
dimension (∅ 30 mm, 42 mm)

Reusable soft, adult, MIR sensor for oximetry tests (code 919024) only spirolab code 911081

Power supply	Rechargeable battery and mains
power	Ni-MH, 6 elements
Current capacity	4500 mAh
Consumption	average 250 mA
Backup battery voltage	none
Batteries charger	Output voltage=12 V, current=1A, compliant with EN 60601-1
Autonomy	~10 hours
Connectivity	USB 2.0, Bluetooth® 2.1
Display	7 inch colour touch screen LCD
Display	with 800x480 resolution
Keyboard	absent, touchscreen
Mouthpieces	Ø 30 mm (1.18 inch)
Type of electrical Protection	Internally powered Class II while charging battery
Safety level for shock hazard	Type BF Apparatus
Conditions of use	Apparatus for continuous use

Storage conditions	Temperature:	MIN -40 °C, MAX +70 °C
	Humidity:	MIN 10% RH; MAX 95%RH
Transport conditions	Temperature:	MIN -40 °C, MAX +70 °C
	Humidity:	MIN 10% RH; MAX 95%RH
Operating conditions	Temperature:	MIN + 10 °C, MAX + 40 °C
	Humidity:	MIN 10% RH, MAX 95%RH

Applied norms	Electrical Safety EN 60601-1 Electro Magnetic Compatibility EN 60601-1-2
Degree of protection against water penetration	IPX1 appliance protected against water leaks

Codes and equipments

911080E0	spiro
911080E1	spiro with reusable turbine
911080E2	spiro with 120 FlowMir
911081E0	spiro+oxy
911081E1	spiro+oxy with reusable turbine
911081E2	spiro+oxy with 120 FlowMir

Spirometry

Flow sensor	bi-directional digital turbine
Volume rate	10 L
Flow range	±16L/s
Volume accuracy	±2.5% or 50 mL
Flow accuracy	±5% or 200 mL/s
Dynamic resistance	<0.5 cm H2O/L/s
Temperature sensor	semiconductor (0-45°C)
Test available	FVC, VC, IVC, MVV, PRE-POST
Measured parameters	FVC, FEV1, FEV1/FVC%, FEV1/PEF, FEV1/VC, FEV1/FEF0.5, DTPEF, 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	Up to 10000 tests

Oximetry (on request)

Measurement method	Red and infrared absorption
SpO2 range	0-99%
SpO2 accuracy	± 2% between 70-99% SpO2
Average number of heart beats for the %SpO2 calculation	8 beats
Pulse Rate range	18-300 BPM
Pulse Rate accuracy	± 2BPM or 2% whichever is greater
Average interval for the calculation of cardiac pulse	8 seconds
Signal quality indication	0 - 8 segments on display
Test available	spot
Measured parameters	SpO2% min, max, average BPM min, max, average Test duration % Bradycardia Duration (<40 BPM) % Tachycardia Duration (>120 BPM) % of Time with SpO2 ≤ 90% (T90%, T89%), T5
Memory capacity	about 500 hours oximetry

Certificates & Registrations

CE 0476	MED 9826
FDA 510 (k)	K 052140
Health Canada	71191 (class II)
CND code	Z12150102 (spiro) Z1203020408 (spiro + oxy)
GMDN code	46906 (spiro), 45607 (spiro + oxy)
Ministry of Health	1272475/R (spiro) 1272476/R (spiro + oxy) 1645455/R (spiro)

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ADVANCED

MINISPIR™

Handheld, PC-based Spirometer

Real-Time Flow/Volume and Volume/Time curves on your PC for a comprehensive Spirometry.

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www.spirometry.com

MAIN features

REAL-TIME TEST

Spirometry: FVC, VC, IVC, MVV, PRE/POST Bronchodilator comparison

PLUG AND PLAY

Power via USB, no internal memory, no display, no maintenance, carrying case included

COMPLIANCE ATS/ERS 2019

And other Standards including ISO 26782 (for Spirometry), ISO 23747 (for PEF), and more. CE0476, FDA 510 (k)

SPIROMETRY PARAMETERS

Spirometry: FVC, FEV1, FEV1/FVC%, FEV3, FEV3/FVC%, FEV6, FEV1/FEV6%, PEF, FEF25, FEF50, FEF75, FEF2575, FET, ELA, EVOL, FIVC, FIV1, PIF, FIV1/FIVC%, PIF, IRV, VC, IVC, IC, ERV, FEV1/VC%, VT, VE, Rf, tI, tE, ti/tTOT, VT/tI, MVV

PC CONNECTION VIA USB

Real-time test on PC screen, connect with your EHR/EMR, print Medical Report and more

DISTINCTIVE features

PREDICTED SETS & VALUES

Large Selection, including comparison %Pred, Z-score and LLN. Include GLI equations

GENERAL PRACTICE

Easy-to-Use, real time spirometry curve and complete test results available in PC-mode

EHR/EMR CONNECTIVITY

Via PC, integration with patient database on your EHR/EMR (in HL7, GDT)

COVID-19 PREVENTION

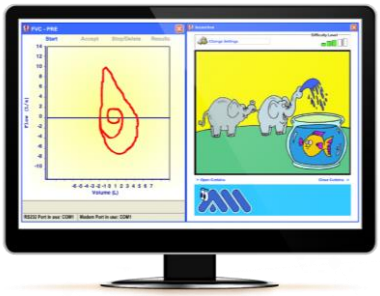
Complete Disposable Set with Antiviral filter available, to reduce risk of cross-contamination

Always INCLUDED

- Carrying case
- Noseclip
- PC Software license

Compatible SOFTWARE

winspiroPRO



Pediatric Incentive (PATENTED) to improve patient compliance during the test.

Acceptabilty Messages, Test interpretation and Quality Control Grade according to the latest **Spirometry Standards**

MAIN FEATURES

Windows-based solution for Spirometry, Oximetry and Telemedicine.

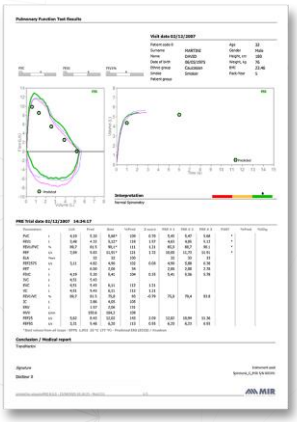
Wide range of predicted sets and values, including **GLI Predicted sets, LLN and Z–score**.

Embedded **EHR/EMR connectivity.**

NET VERSION available, share one database between different PC workstations.

MEDICAL REPORT

Specialized and **customizable printout**



spiro Connect

MAIN FEATURES

Windows-based solution, **direct integration** with your EHR/EMR.

Real time test include **Spirometry**

Standardized communication in **HL7 or Exchange Protocol**.

Select patient info directly from your own **EHR/EMR**

Spirometry test: FVC-Pre, FVC-Post, VC-Pre

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

Compatible TURBINES

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

PLAY VIDEO

SCIENTIFIC PUBLICATIONS

Also available in **MORE CONFIGURATIONS**

Technical Specification	Minispir	Minispir Light
TYPE OF SPIROMETER	PC-Based	PC-Based
COMPATIBLE TURBINES	flowMIR™ Disposable Turbine, Reusable Turbine Flowmeter	flowMIR™ Disposable Turbine
COMPATIBLE SOFTWARES	Winspiro PRO, spiro Connect	Winspiro Light
EXTERNAL CONTROL	Real time test on PC screen, connect with your EHR/EMR, back-up database on PC memory and much more Connect to your PC via USB	Real time test on PC screen, print visit report, back-up database on PC memory and much more Connect to your PC via USB
EHR CONNECTIVITY	Via PC, integration with patient database on your EHR/EMR (in HL7, GDT)	
MEASURED PARAMETERS	Spirometry: FVC, VC, IVC, MVV, PRE/POST Bronchodilator comparison Spirometry: FVC, FEV1, FEV1/FVC%, FEV3, FEV3/FVC%, FEV6, FEV1/FEV6%, PEF, FEF25, FEF50, FEF75, FEF2575, FET, ELA, EVOL, FIVC, FIV1, PIF, FIV1/FIVC%, PIF, IRV, VC, IVC, IC, ERV, FEV1/VC%, VT, VE, Rf, tI, tE, ti/tTOT, VT/tI, MVV	Spirometry: FVC, VC, PRE/POST Bronchodilator comparison Spirometry: FVC, FEV1, FEV6, FEV1/FVC, PEF, FEF2575, ELA, FIVC, IVC, EVC

COMPARE ON WEBSITE

TECHNICAL datasheet

PRODUCT CODES – 911006E0 - Spirometer; 911006E1 - Spirometer with reusable turbine

Technical specification

Width	49.7 mm
Length	142 mm
Thickness	26 mm
Weight	65 g

Turbine

Reusable turbine (code 910002

Disposable turbine (code 910004)

Supply voltage	5 V d.c. USB connection
Rated electrical power	0.25 W
Rated input current	50 mA max
Backup battery voltage	none
Connectivity	USB 2.0
Display	none
Mouthpieces	Ø 30 mm (1.18 inch)
IP protection level	IPX1
Type of electrical protection	Class II device
Safety level for shock hazard	Type BF Apparatus
Conditions of use	Apparatus for continuous use
Storage conditions	Temperature: MIN -20 °C, MAX +60 °C Humidity: MIN 10% RH; MAX 95%RH
Operating Conditions	Temperature: MIN +10 °C, MAX +40 °C Humidity: MIN 10% RH MAX 95%RH
Memory capacity	database PC software
PC software	winspiroPRO
Applicable standards	IEC 60601-1:2005 + Amd1:2012 EN 60601-1-2: 2015 ISO 26782: 2009 ISO 23747: 2015 ATS/ERS: 2005, 2019 update ISO 80601-2-61: 2017

Spirometry

Flow sensor	bi-directional digital turbine
Volume range	10 L
Flow range	±16L/s
Volume accuracy (ATS 2019)	±2.5% or 50 mL
Flow accuracy	±5% or 200 mL/s
Dynamic resistance	<0.5 cm H2O/L/s
Temperature sensor	semiconductor (0-45°C)
Test available	FVC, VC, IVC, MVV, PRE-POST
Measured parameters	FVC, FEV1, FEV1/FVC%, FEV3, FEV3/FVC%, FEV6, FEV1/FEV6%, PEF, FEF25, FEF50, FEF75, FEF2575, FET, ELA, EVOL, FIVC, FIV1, PIF, FIV1/FIVC%, PIF, IRV, VC, IVC, IC, ERV, FEV1/VC%, VT, VE, Rf, t_I, t_E, ti/t_{TOT}, VT/t_I, MVV

Oximetry (optional)

Measurement method	Red and infrared absorption
SpO2 range	0-99%
SpO2 accuracy	± 2% between 70-99% SpO2
Average number of heart beats for the %SpO2 calculation	8 beats
Pulse Rate range	30-300 BPM
Pulse Rate accuracy	± 2BPM or 2% whichever is greater
Average interval for the calculation of cardiac pulse	8 seconds
Signal quality indication	0 - 8 segments on display
Test available	spot
Measured parameters	SpO2% min, max, average BPM min, max, average Test duration % Bradycardia Duration (<40 BPM) % Tachycardia Duration (>120 BPM) % of Time with SpO2 ≤ 90% (T90%, T89%)

Certificates & Registrations

CE 0476	MED 9826
FDA 510 (k)	K 122384
Health Canada	71191 (class II)
CND code	Z12150102
GMDN code	13680
Ministry of Health	678828/R

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MEDICAL INTERNATIONAL RESEARCH

MIR MiniSpir datasheet
code 911006 (spiro); 911010 (spiro+oxy)

Applicable standards	IEC 60601-1:2005 + Amd1:2012 EN 60601-1-2: 2015 ISO 26782: 2009 ISO 23747: 2015 ATS/ERS: 2005, 2019 update ISO 80601-2-61: 2017

Technical specification

Width	49.7 mm
Length	142 mm
Thickness	26 mm
Weight	65 g

Turbine

Reusable turbine (code 910002)

Disposable turbine (code 910004)

Supply voltage	5 V d.c. USB connection
Rated electrical power	0.25 W
Rated input current	50 mA max
Backup battery voltage	none
Connectivity	USB 2.0
Display	none
Mouthpieces	Ø 30 mm (1.18 inch)
IP protection level	IPX1
Type of electrical protection	Class II device
Safety level for shock hazard	Type BF Apparatus
Conditions of use	Apparatus for continuous use
Storage conditions	Temperature: MIN -20 °C, MAX +60 °C Humidity: MIN 10% RH; MAX 95%RH
Operating Conditions	Temperature: MIN +10 °C, MAX +40 °C Humidity: MIN 10% RH MAX 95%RH
Memory capacity	database PC software
PC software	winspiroPRO

Spirometry

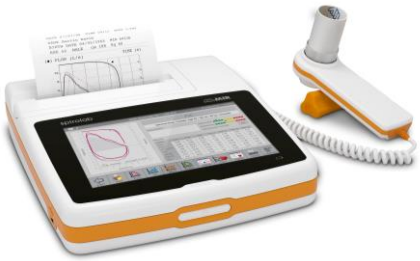
Flow sensor	bi-directional digital turbine
Volume range	10 L
Flow range	±16L/s
Volume accuracy (ATS 2019)	±2.5% or 50 mL
Flow accuracy	±5% or 200 mL/s
Dynamic resistance	<0.5 cm H2O/L/s
Temperature sensor	semiconductor (0-45°C)
Test available	FVC, VC, IVC, MVV, PRE-POST
Measured parameters	FVC, FEV1, FEV1/FVC%, FEV3, FEV3/FVC%, FEV6, FEV1/FEV6%, PEF, FEF25, FEF50, FEF75, FEF2575, FET, ELA, EVOL, FIVC, FIV1, PIF, FIV1/FIVC%, PIF, IRV, VC, IVC, IC, ERV, FEV1/VC%, VT, VE, Rf, t_I, t_E, ti/t_{TOT}, VT/t_I, MVV

Oximetry (optional)

Measurement method	Red and infrared absorption
SpO2 range	0-99%
SpO2 accuracy	± 2% between 70-99% SpO2
Average number of heart beats for the %SpO2 calculation	8 beats
Pulse Rate range	30-300 BPM
Pulse Rate accuracy	± 2BPM or 2% whichever is greater
Average interval for the calculation of cardiac pulse	8 seconds
Signal quality indication	0 - 8 segments on display
Test available	spot
Measured parameters	SpO2% min, max, average BPM min, max, average Test duration % Bradycardia Duration (<40 BPM) % Tachycardia Duration (>120 BPM) % of Time with SpO2 ≤ 90% (T90%, T89%)

Certificates & Registrations

CE 0476	MED 9826
FDA 510 (k)	K 122384
Health Canada	71191 (class II)
CND code	Z12150102
GMDN code	13680
Ministry of Health	678828/R



Technical specification

Width	220 mm
Length	210 mm
Thickness	51 mm
Weight	1450 g (battery pack included)

Sensors

miniflowmeter (code 900595)
for reusable and disposable turbine
dimension (∅ 30 mm, 42 mm)

Reusable soft, adult, MIR sensor for oximetry tests (code 919024) only for spirolab code 911081

Power supply	Rechargeable battery and mains power Ni-MH, 6 elements
Current capacity	4500 mAh
Consumption	average 250 mA
Backup battery voltage	none
Batteries charger	Output voltage=12 V, current=1A, compliant with EN 60601-1
Autonomy	~10 hours
Connectivity	USB 2.0, Bluetooth® 2.1
Display	7 inch colour touch screen LCD Display with 800x480 resolution
Keyboard	absent, touchscreen
Mouthpieces	Ø 30 mm (1.18 inch)
Type of electrical protection	Internally powered Class II while charging battery
Safety level for shock hazard	Type BF Apparatus
Conditions of use	Apparatus for continuous use
Storage conditions	Temperature: MIN -40 °C, MAX +70 °C Humidity: MIN 10% RH; MAX 95%RH
Transport conditions	Temperature: MIN -40 °C, MAX +70 °C Humidity: MIN 10% RH; MAX 95%RH
Operating conditions	Temperature: MIN + 10 °C, MAX + 40 °C Humidity: MIN 10% RH, MAX 95%RH
Applied norms	Electrical Safety EN 60601-1 Electro Magnetic Compatibility EN 60601-1-2
Degree of protection against water penetration	IPX1 appliance protected against water leaks

Codes and equipments

911080E0	spiro
911080E1	spiro with reusable turbine
911080E2	spiro with 120 FlowMir
911081E0	spiro+oxy
911081E1	spiro+oxy with reusable turbine
911081E2	spiro+oxy with 120 FlowMir

Spirometry

Flow sensor	bi-directional digital turbine
Volume rate	10 L
Flow range	±16L/s
Volume accuracy	±2.5% or 50 mL
Flow accuracy	±5% or 200 mL/s
Dynamic resistance	<0.5 cm H2O/L/s
Temperature sensor	semiconductor (0-45°C)
Test available	FVC, VC, IVC, MVV, PRE-POST
Measured parameters	FVC, FEV1, FEV1/FVC%, FEV1/PEF, FEV1/VC, FEV1/FEF0.5, DTPEF, 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	Up to 10000 tests

Oximetry (on request)

Measurement method	Red and infrared absorption
SpO2 range	0-99%
SpO2 accuracy	± 2% between 70-99% SpO2
Average number of heart beats for the %SpO2 calculation	8 beats
Pulse Rate range	18-300 BPM
Pulse Rate accuracy	± 2BPM or 2% whichever is greater
Average interval for the calculation of cardiac pulse	8 seconds
Signal quality indication	0 - 8 segments on display
Test available	spot
Measured parameters	SpO2% min, max, average BPM min, max, average Test duration % Bradycardia Duration (<40 BPM) % Tachycardia Duration (>120 BPM) % of Time with SpO2 ≤ 90% (T90%, T89%), T5
Memory capacity	about 500 hours oximetry

Certificates & Registrations

CE 0476	MED 9826
FDA 510 (k)	K 052140
Health Canada	71191 (class II)
CND code	Z12150102 (spiro) Z1203020408 (spiro + oxy)
GMDN code	46906 (spiro), 45607 (spiro + oxy)
Ministry of Health	1272475/R (spiro) 1272476/R (spiro + oxy) 1645455/R (spiro)