

LETTER OF AUTHORIZATION

MIR - Medical International Research S.p.A., a company duly organised and existing under the laws of Italy with its head office located at Via del Maggiolino, 125 - 00155 Roma, Italy (hereinafter "MIR") hereby authorizes

Medita Co. Ltd a company duly organised and existing under the laws of Lithuania with its head office located at P. Baublio str. 2A, LT-08406 Vilnius, Lithuania (hereinafter "MIR PARTNER")

to use MIR proprietary trademarks, MIR Logo, MIR trade names, MIR advertising material and MIR products pictures (hereinafter the "MIR Proprietary Rights") to conduct the business of selling and servicing regarding the MIR products in the territory of Lithuania (hereinafter the "Business"), at the following terms and conditions.

1. In the conduction of the aforesaid Business, (MIR PARTNER) shall act only under its own name, carrying out its activities with a high-standard and professional diligence. (MIR PARTNER) shall have no authority or right to enter into any agreement on behalf of MIR, or to bind or obligate MIR in any way.
2. (MIR PARTNER) shall use MIR Proprietary Rights in accordance with any instruction which may be given by MIR, from time to time.
3. Nothing contained in this letter shall be construed to constitute a partnership nor an agency agreement nor to create in (MIR PARTNER)'s favour any right, title or interest therein, having MIR exclusive right, title and interest in and to MIR Proprietary Rights.
4. (MIR PARTNER) shall not do anything or commit any act which constitutes a breach of the terms and conditions of this letter of authorization or which might anyway prejudice or adversely affect MIR Proprietary Rights or the ownership by MIR thereof. In particular, (MIR PARTNER) shall not use any mark which is likely to be similar to or confused with the MIR Proprietary Rights.
5. This letter of authorization shall be effective from 07/03/2023 to 07/03/2024 without prejudice to the MIR's right to revoke such authorization letter at its sole discretion. The exercise by MIR of its discretionary revocation right shall not give rise to any obligation for MIR to compensate in any respect (MIR PARTNER).
6. (MIR PARTNER) shall discontinue all usage of any MIR Proprietary Rights upon the termination for any reasons of this authorization letter. Concurrently with, or promptly after, the termination of this authorization letter, whether by expiration of its terms or otherwise, (MIR PARTNER) shall return all

documents relating to MIR Proprietary Rights, retaining no copies or notes (whether written or digital).

7. (MIR PARTNER) acknowledges to hold harmless and indemnify MIR for every and all actual or contingent liability directly or indirectly connected with every breach by (MIR PARTNER) of the terms and conditions of this letter of authorization.

8. This letter of authorization shall be governed by and construed in accordance with Italian law and any dispute arising hereunder shall be submitted to the exclusive jurisdiction of the Italian Courts located in Rome.

Yours very faithfully,


MIR MEDICAL INTERNATIONAL RESEARCH S.p.A.
Via del Magliolino, 125
00155 Roma
C.F./P.I. 04564101006
Tel. 0622754777

MIR - Medical International Research S.p.A.
(Laura Precetti - Export Area Manager)

Acknowledged by

Generalinis direktorius
Aivaras Pliauckys

(MIR PARTNER)



ĮGALIOJIMO LAIŠKAS

MIR – Medical International Research S.p.A., tinkamai įsteigta kompanija, veikianti pagal Italijos įstatymus, kurios pagrindinis biuras įsikūręs adresu Via del Maggiolino, 125 – 00155 Roma, Italija (toliau – MIR)

šiuo dokumentu įgalioja

Medita Co. Ltd., tinkamai įsteigtą kompaniją, veikiančią pagal Lietuvos įstatymus, kurios pagrindinis biuras įsikūręs adresu P. Baublio g. 2A, LT-08406 Vilnius, Lietuva (toliau – MIR PARTNERIS)

naudoti MIR patentuotus prekės ženklus, MIR logotipą, MIR prekės ženklus, MIR reklamos medžiagą ir MIR produktų atvaizdus (toliau – MIR patentuotas teises), užsiimti MIR produktų pardavimo ir aptarnavimo verslu Lietuvos teritorijoje (toliau – VERSLU) šia tvarka ir sąlygomis:

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8. Šis įgaliojimo laiškas surašytas vadovaujantis ir laikantis Italijos įstatymų ir bet koks su tuo susijęs ginčas turės būti sprendžiamas pagal Romos Italijos teismų jurisdikciją.

Išversta teisingai pagal mano žinias ir įsitikinimus. Tekstas yra išverstas teisingai ir tiksliai bei be pakeitimų prasmėje.
Aš esu užtikrintas, kad lietuvių kalbos vertimas atitinka originalų dokumentą.



Vaidas Vilmantas (MB „Beikeris“, įm .k. 304539005)

Nuoširdžiai Jūsų

/parašas/

MIR – Medical International Research S.p.A.

(Laura Precetti – eksporto srities vadovė)

Pripažinta

Generalinis direktorius

Aivaras Pliauckys

(MIR PARTNERIS)

/parašas/

Antspaudas: „Lietuvos Respublika, Vilnius, uždaroji akcinė bendrovė „Medita“

DICHIARAZIONE DI CONFORMITA' CE DECLARATION OF CONFORMITY CE

(Allegato II escluso par.4)
(annex II excluding par.4)

MIR - Medical International Research S.p.A. fabbricante del seguente dispositivo:
MIR - Medical International Research S.p.A. manufacturer of the following device:

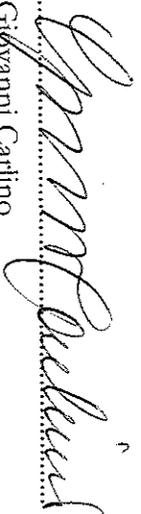
Tipo Spirometro / ossimetro
Type Spirometer / oximeter
Marca MIR - Medical International Research
Brandname

Nome Dispositivo Spirolab
Device name

Classe di rischio IIa
Risk Class

dichiara che questo è conforme ai Requisiti Essenziali della Direttiva 93/42 sui Dispositivi Medici e successive modifiche, e al D.Lgs 46/97 e successive modifiche ed integrazioni.
La presente dichiarazione è basata sul Certificato CE n. MED 9826 emesso da Kiwa Cermet Italia s.p.a., Via Cadriano 23, 40057 - Granarolo dell'Emilia (BO), Ente Notificato n.0476.
La presente dichiarazione viene emessa in conformità alla Direttiva 93/42 e sotto la sola responsabilità del fabbricante.
hereby declares that it complies with the Essential Requirements of directive 93/42/EEC concerning Medical Devices, and its amendments, and its transposition in the Member States.
This declaration is made on the basis of the CE Certificate n. MED 9826 issued by KIWA CERMET ITALIA s.p.a., Via Cadriano 23, 40057 - Granarolo dell'Emilia (BO), Notified Body n. 0476.
This declaration is issued in compliance with Directive 93/42 and under the sole responsibility of the manufacturer.

Roma, 09.05.2022
Lugo, data
Place, date


Giovanni Carlino
Amministratore Delegato
Chief Executive Officer

CE ATITIKTIES DEKLARACIJA (II priedas, išskyrus 4 dalį)

MIR – Medical International Research S.p.A. toliau nurodytų prietaisų gamintojas

Tipas: Spirometras / oksimetras

Prekės ženklas: MIR – Medical International Research

Prietaiso pavadinimas: Spirolab

Rizikos klasė: IIa

šiuo dokumentu skelbia, kad prietaisai atitinka esminius direktyvos 93/42/EEB bei jos papildymų ir perkėlimo į Valstybes Nares dėl medicinos prietaisų reikalavimus.

Ši deklaracija parengta remiantis KIWA CERMET ITALIA s.p.a., Via Cadriano 23, 40057 – Granarolo dell'Emilia (BO), notifikuotosios įstaigos nr. 0476, CE sertifikatu nr. MED 9826.

Ši deklaracija išleista atsižvelgiant į 93/42 direktyvą ir yra gamintojo atsakomybėje.

Roma, 2022-09-05

Vieta, data

/parašas/

Giovanni Carlino

Direktorius

Išversta teisingai pagal mano žinias ir įsitikinimus. Tekstas yra išverstas teisingai ir tiksliai bei be pakeitimų prasmėje.
Aš esu užtikrintas, kad lietuvių kalbos vertimas atitinka originalų dokumentą.

Vaidas Vilmantas (MB „Beikeris“, įm .k. 304539005)



PO-10DDC_Spirolab_2022_rev.1

puslapis 1 / 1

MIR – Medical International Research S.p.A.
Įstatinis kapitalas: 120.000,00 EUR
Įmonės kodas: 04564101006
Pagrindinis biuras: Via del Maggiolino 125 – 00155 Roma

Mirsl-medicalinternationalresearch@pec.it
El. paštas: mir@spirometry.com
T: +39 06 22 754 777 – F: +390 06 22 754 785
www.spirometry.com



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 (Ø 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
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)

MIR Spirolab duomenų lapas

Svoris	1450g įskaitant bateriją
Maitinimo šaltinis Sujungimas:	Pakartotinai įkraunama baterija ir elektros tinklas USB 2.0, Bluetooth® 2.1
Ekranas	7 colių spalvotas lietimui jautrus LCD tipo Skiriamoji geba 800 x 480
Tūrio matavimo riba	10 L
Srauto matavimo riba	± 16 L/s
Tūrio matavimo paklaida	±2,5% ar 50 mL
Srauto matavimo paklaida	±5% ar 200 mL/s
Galimi testai:	FVC, VC, IVC, MVV, PRE-POST
Matuojami parametrai:	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
Atminties talpa	iki 10000 testų

ADVANCED

SPIROLABTM

1.1.1. Stalnis autonominis ir kompiuterinis spirometras su oksimetrijos opcija

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

1.1.11. Integruotas spausdintuvas



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)



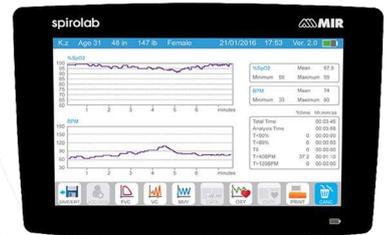
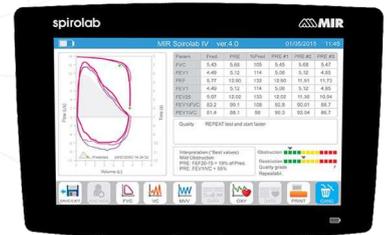
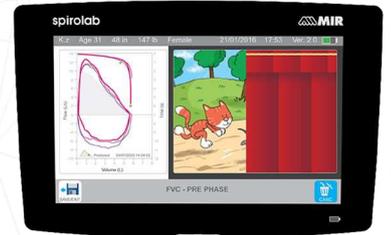
PC CONNECTION AVAILABLE

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

Terminis spausdintuvas. Popieriaus dydis 112mm



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

1.1.13.-4 Carrying case Nešiojimo dėklas

- Power supply/battery charger
- USB cable
- 1 Roll of thermal printer paper

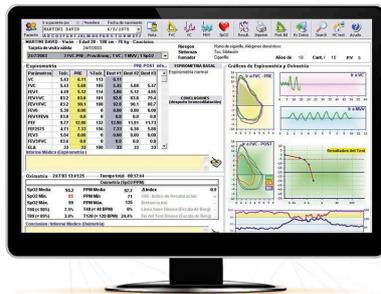
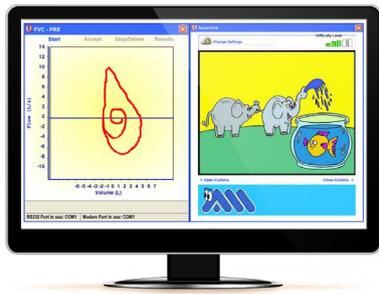
1.1.13.-2 Nosies spaustukai

- Noseclip
- PC Software license 1.1.13.-3
- PK programinė įranga
- Finger Probe



Compatible SOFTWARE

1.1.13-3 WinspiroPRO



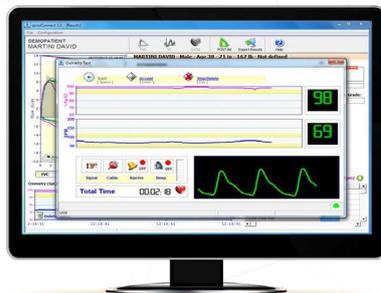
Pediatric Incentive (PATENTED) to improve patient compliance during the test.

1.1.4.

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

Pediatrinė paskata (Patentuota), kad padidinti paciento paklusnumą atliekant tyrimą

spiros Connect



MAIN FEATURES

Windows-based solution for Spirometry, Oximetry and Telemedicine.

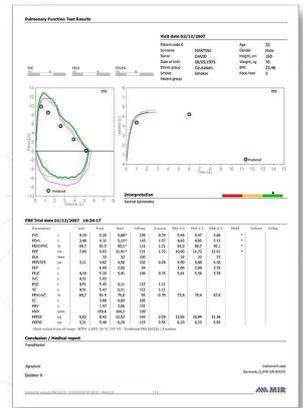
Wide range of predicted sets and values, including **GLI Predicted sets, LLN and Z-score.**

Embedded **EHR/EMR connectivity.**

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

MEDICAL REPORT

Specialized and **customizable printout**



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

flowMIR™ Disposable Turbine



Mouthpiece

Included Disposable

Turbine Disinfection

Not required

Turbine Calibration

Not required

Packaging

Individually sealed: 60 or 10 units / box

Antiviral Filter

Available Disposable

Reusable Turbine



Required, Not Included

Required

Required

1 unit in Carton box

Required Disposable

PLAY VIDEO



SCIENTIFIC PUBLICATIONS



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
 power Rechargeable battery and mains
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 ∅ 30 mm (1.18 inch)
Type of electrical Internally powered
Protection 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 IPX1 appliance protected against
against water penetration 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
 FEV0.5/FVC, FEV0.75, FEV0.75/FVC,
 FEV2, FEV2/FVC, FEV3, FEV3/FVC,
 FEV1/FEV6, PEF, FEF25, FEF50,
 FEF2575, FEF7585, FET, Vext, ELA,
 FIVC, FIV1, PIF, FIV1/FIVC, FIF25,
 FIF75, R50, MVVcal, PIF, IRV, VC,
 IVC, IC, ERV, IRV, FEV1/VC, TV, VE,
 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)
 46906 (spiro), 45607 (spiro + oxy)
GMDN code 1272475/R (spiro)
Ministry of Health 1272476/R (spiro + oxy)
 1645455/R (spiro)

Spirolab



User manual Rev. 1.8

Date issued
Date approved

04.05.2020
04.05.2020

TABLE OF CONTENTS

1.	INTRODUCTION	6
1.1	Intended use	6
1.1.1	User type	6
1.1.2	Ability and experience required.....	6
1.1.3	Where the device is used.....	6
1.1.4	Individual patient factors that can affect use of the product	7
1.1.5	Limitations of use – Contraindications	7
1.2	Important safety warnings	8
1.2.1	Risk of cross contamination	8
1.2.2	Turbine.....	9
1.2.3	Mouthpiece	9
1.2.4	Sensor for oximetry	10
1.2.5	USB connection cable	11
1.2.6	The unit.....	11
1.2.7	Warnings for use in electromagnetic environments.....	12
1.3	Labels and symbols.....	13
1.3.1	ID label.....	13
1.3.2	FCC certification label.....	14
1.3.3	Electrostatic discharge symbol	15
1.4	Product description.....	16
1.5	Technical specifications.....	18
1.5.1	Spirometer specifications	18
1.5.2	Oximeter specifications	20
1.5.3	Other features.....	22
2.	USING THE SPIROLAB	24
2.1	Turning the spirolab on and off.....	24
2.2	Saving energy.....	26
2.3	Main screen.....	27
2.4	Symbols and icons	27
2.5	Service menu	27
2.5.1	Calibrating turbines.....	32
2.6	Patient data	34
2.6.1	Entering new patient data	35
2.6.2	Editing patient data.....	36
2.7	Viewing stored data	37
2.7.1	How to search the archives.....	37
2.7.2	Viewing archived data.....	37
2.7.3	Displaying the last test session	39
2.8	Online mode (connected to a PC)	39
2.9	Performing a spirometry test	40
2.9.1	FVC test.....	41
2.9.2	VC test.....	42
2.9.3	MVV test.....	42
2.9.4	Running POST tests after the administration of a drug.....	43
2.10	Displaying and reading spirometry results	44
2.10.1	Interpreting spirometry results	44
2.11	Performing oximetry.....	46
2.11.1	Instructions for using the sensor on adult patients	48
3.	DATA TRANSMISSION.....	49
3.1	Data transmission via Bluetooth	49
3.2	Connecting with a PC via USB port.....	50
3.3	Printing data.....	51
3.4	Up-dating internal software	52

4. MAINTENANCE 52

4.1 Cleaning and checking reusable turbines.....52

4.1.1 Checking correct turbine function53

4.2 Cleaning the oximetry sensor54

4.3 Recharging the battery pack.....54

4.4 Replacing the thermal paper55

5. TROUBLE SHOOTING AND SOLUTIONS57

Guarantee conditions59

Thank you for choosing a MIR product
MEDICAL INTERNATIONAL RESEARCH

This manual refers to the spirolab generation with serial number as follows:

A23-0J.xxxxx

Where:

A23-0J is the root

xxxxx is a sequential number.

The internal software is available in the following languages:

English	Spanish	Russian	Romanian
Italian	Portuguese	Turkish	
French	Brazilian	Czechoslovak	
German	Polish	Vietnamese	

The following table describes the contents of the package and the accessories that can be used with spirolab:

REF	Description	
672684	Carrying case	✓
910320	Plastic noseclip	✓
532367	USB cable	✓
910300	cardboard mouthpiece	✗
\	User manual - winspiroPRO CD	✓
910350	Thermal printer paper	✓
920690XX	Battery charger	✓
900595	MiniFlowmeter	✓
910002	Reusable Turbine	○
910004	Disposable Turbine	○
912024	Oximetry Sensor	○

✓ included

○ optional

1.1.13.-1 Popierinis kandiklis (vi enkartinis)



WARNING

The nose clip, mouthpiece and turbine with mouthpiece that come supplied with the device are to be treated as single-use disposable items.

The accessories supplied are ticked on the cover of the "New spirolab device equipment", supplied with the device.

Before using your spirolab...

- Carefully read the user manual, the labels and all the information supplied with the device
- Configure the device (date, time, assigned values, language etc.) as described in section 2.5



WARNING

Before connecting spirolab to a PC, install the winspiroPRO software supplied with the device.

Once the software has been correctly installed, connect the device to the PC; a message will appear that confirms the recognition of a new peripheral device.

Keep the original packaging!

In the event of a problem with the product, use the original packaging and send it to your local distributor or to the manufacturer.

If the device is being sent for repair, the following rules apply:

- Goods must be sent in their original packaging;
- Costs involved in sending the product are at the sender's expense.

Manufacturer's address

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MIR implements a policy of constant product improvement and the technology we use is in a state of continuous evolution. For this reason, the company reserves the right to up-date these instructions if necessary. If you have any suggestions that you consider useful, please send an e-mail to the following address: mir@spirometry.com. Thank you.

MIR does not accept any responsibility for any harm or damage caused by users failing to follow the instructions or failing to heed the warnings in this manual.

Total or partial copying of this manual is forbidden.

1. INTRODUCTION

1.1 Intended use

The Spirolab spirometer and pulse oximeter is intended to be used by a physician, by a licensed healthcare professional or by a patient under the instruction of a physician or of a licensed healthcare professional.

The device is intended to test lung function and can make:

- for spirometry tests in adult and pediatric patients, excluding infants and neonates
- for oximetry tests in people of all age.

It may be used in in hospital setting, physician's office, factory, pharmacy.

1.1.1 User type

The **spirolab** spirometer and oximeter (optional) provides information about a series of parameters relating to human respiratory function.

Use of the device is usually "prescribed" by a doctor, who is responsible for analysing and checking the results and the data gathered during the test period.

1.1.2 Ability and experience required

The technique for using and maintaining the device along with the ability to interpret the results provided calls for a qualified health worker.

WARNING

MIR will not be held responsible for any harm or damage of any kind caused by mistakes made by users failing to heed the warnings in this manual.

If a spirolab user is a person who is incapable of looking after him or herself, the device must be used under the supervision and responsibility of the person who is legally in charge of that person.

When the spirolab device is used as an oximeter, it is intended for spot checks.

1.1.3 Where the device is used

The **spirolab** device was designed for use in hospital setting, physician's office, factory, pharmacy.

The product is not suitable for use in operating theatres or in the presence of flammable liquids or detergents, or where there are anaesthetic gas mixtures that become flammable in the presence of air, oxygen or nitrous oxide.

The product is not suitable for use where it may be exposed to air currents (e.g. the wind), sources of heat or cold, direct sunlight or other sources of light or energy, dust, grit or chemical substances.

It is the responsibility of the user to ensure that the product is used and stored under the proper environmental conditions. For further information, refer to the instructions in section 1.5.3 below.



WARNING

If the device is subject to climate conditions other than those shown in section 1.5.3, it is possible that malfunctions may occur and/or that incorrect results may be displayed.

1.1.4 Individual patient factors that can affect use of the product

The spirometer can only be used when the patient is resting and in good health, or at least in a state of health that is compatible with the test being carried out. Performing the test calls for the *collaboration* of the patient, who must exhale forcefully to ensure that the parameters measured provide reliable results.

1.1.5 Limitations of use – Contraindications

An analysis of the results of spirometry alone is not sufficient to provide a diagnosis of a patient's clinical condition. A diagnosis can only be made in conjunction with an examination that takes the patient's case history into account, as well as the results of other tests recommended by the doctor.

Comments, diagnoses and appropriate therapeutic treatments are made by the doctor.

Any symptoms must be evaluated before spirometry is carried out. The doctor who prescribes use of the device must first ascertain the physical/psychological capacity of the patient to assess his or her suitability for performing the test. The same doctor must subsequently evaluate the data gathered by the device to estimate the degree of *collaboration* for each test carried out.

A correct spirometry test calls for a patient's complete collaboration. The results obtained depend on the patient's ability to inhale and exhale as quickly as possible. If these key conditions cannot be met, the spirometry results will not be reliable or, as doctors say, will be "unacceptable". The *acceptability* of a test is the doctor's responsibility. Extra care must be taken when dealing with elderly patients, children or differently-able persons.

The product must not be used if malfunctions or faults are detected or suspected as these may compromise results.



WARNING

When the spirolab device is used as an oximeter, it has a limited alarm system and for this reason the SpO2 and pulse rate shown on the display need to be checked frequently.

1.2 Important safety warnings

Spirolab devices have been examined by an independent laboratory that has certified their conformity with EN 60601-1 safety standards and guaranteed that their electromagnetic compatibility is within the limits laid out in EN 60601-1-2.

Spirolab devices are subject to continuous checks during production and therefore comply with the safety and quality standards laid down in Council Directive 93/42/EEC for Medical Devices.

Once the device has been removed from its packaging, examine it carefully to make sure there are no signs of damage. In the event of any damage, do not use the device but return it immediately to the manufacturer for possible replacement.



WARNING

Patient safety and device performance are only guaranteed if warnings and current safety standards are complied with.

The manufacturer declines all responsibility for harm or damage caused by failure to follow the instructions of use.

The product must be used as described in the User Manual, especially as regards § Intended Use, and only original accessories as specified by the manufacturer are to be used. The use of non-original turbine sensors, oximetry sensors or other accessories might cause erroneous readings or compromise the correct functioning of the device. For this reason, the use of such items is not permitted.

In particular, the use of cables other than those specified by the manufacturer could cause increased emissions or lower electromagnetic immunity from the device and result in improper operation.

Do not use the product if it has passed its shelf life. In normal working conditions, this is equal to approximately 10 years.

The battery charge level is constantly monitored by the device itself. The device will display a message warning the user if the battery is flat.

In the event of any incident arising from use of the device, we strongly advise the user to inform his or her doctor, who will then complete the procedure laid down by Article 9 of Legislative Decree No. 46/1997 implementing EC Directive No. 93/42.

1.2.1 Risk of cross contamination

So as to avoid any risk of cross contamination, it is imperative to use a single-use mouthpiece for each individual patient.

The device may be used with two types of turbine sensors: a reusable one and a disposable one.

Reusable turbine sensors must be cleaned before being used on a new patient. The use of an anti-bacterial viral filter is left to the doctor's discretion.

The disposable turbine sensor must be replaced for each patient.

1.1.13.-6 Antibakteriniai, priešvirusiniai filtrai

1.2.2 Turbine

Disposable turbine

⚠ WARNING



If you decide to use the spirometer with a “disposable” turbine, it is important to use a new turbine for each patient.

Adequate hygiene, safety and operational conditions of “disposable” turbines are only guaranteed if said turbines are preserved in the original, sealed packaging. “Disposable” turbines are made of plastic; to dispose of the turbines, please comply with local legal requirements.

Reusable turbine

⚠ WARNING



The correct use of a “reusable” turbine is guaranteed only and exclusively if it is “clean” and free from foreign bodies that alter the motion of the blades. If a reusable turbine is not properly cleaned, it can cause cross infection between patients. Periodical cleaning of the device is only sufficient if that device is used exclusively by the same patient. For further details about cleaning, refer to the appropriate section in this User Manual.

The following information is valid for both types of turbine.

Never expose turbine sensors to jets of water or air or allow contact with hot liquids.

To avoid malfunctions or damage, do not introduce dust or foreign bodies into the turbine sensor. The presence of foreign bodies (such as hairs, saliva etc.) inside the turbine flow meter can compromise the accuracy of readings.

1.2.3 Mouthpiece

The single-use mouthpieces that come supplied with the device are provided as a sample to demonstrate the correct type and size. They must be considered clean but not sterile. We recommend that you contact the local distributor where you bought your spirometer to obtain additional mouthpieces. These are usually made of cardboard or plastic and are always for single use only.

⚠ WARNING

Use biocompatible mouthpieces to avoid problems for the patient; unsuitable materials might cause the device to malfunction and compromise the accuracy of readings.

It is the responsibility of the user to provide suitable mouthpieces. These items generally have a standard 30 mm external diameter and are commonly used by health workers. They are widely available.

 **WARNING**

To avoid contamination of the environment caused by the disposal of used mouthpieces, the user must comply with all the local regulations in force.

1.2.4 Sensor for oximetry

In addition to the sensor code number 919024 supplied with the device, the following specific sensors can also be used for different types of patients:

Manufacturer	Code	Description	MIR code
Envitec	RS-3222-12	Reusable small soft sensor (paediatric)	939006
Envitec	RM-3222-12	Reusable medium soft sensor (adults)	939007
Envitec	R-3222-12	Reusable large soft sensor (adults)	939008

These sensors require the use of the extension cable item code 919200 (length 1.5 m) for connection with the **spirolab** device.

Prolonged use of a sensor or the patient's condition may mean that the location of the sensor has to be changed periodically. Change the position of sensors every 4 hours. Moreover, check the condition of the skin and blood flow, and ensure the sensor is properly aligned.

 **WARNING**

The incorrect use of a sensor or sensor cable and the use of a faulty sensor or sensor cable may compromise the accuracy of readings, and indeed generate seriously incorrect readings of the patient's condition. Check every sensor carefully before use.

Do not use sensors that appear to be or are damaged. If you do not have any more working sensors, contact your local distributor who supplied the device.

Only use MIR sensors that have been specifically designed to work with spirolab. The use of other sensors may provide faulty readings.

Oximetry results may be faulty if the test is performed under very bright conditions. If necessary, cover the sensor (e.g. with a clean cloth).

 **WARNING**

Any colouring agent present in the blood (e.g. for performing diagnostic tests), such as methylene blue, indocyanine green, indigo carmine, patent blue-V (PBV), can compromise the accuracy of oximetry readings.

Any condition that restricts the flow of blood, e.g. the use of a cuff to measure blood pressure, can compromise the accuracy of SpO₂ and pulse rate readings. False nails and nail varnish must be removed before using the sensor as they might compromise the accuracy of oximetry readings.

Significant levels of dysfunctional haemoglobin such as carboxyhemoglobin or methemoglobin affect the accuracy of oxygen readings.

If two or more oximetry sensors are positioned near each other, optical interference may occur. Such interference can compromise the accuracy of oxygen readings. To eliminate any such interference, cover the sensors with an opaque material.

Dirt or obstructions that block the red light on the sensor or that block the detector may provide inaccurate readings or sensor malfunctions. Always make sure that the sensor is clean and free of obstructions.

Never place the sensor in an autoclave. Do not sterilise the sensor.

Before cleaning the sensor, disconnect it from the spirolab unit to prevent damage to the sensor and device and to avoid compromising user safety.

1.2.5 USB connection cable

Incorrect use or application of the USB cable may produce inaccurate measurements, which will show very inaccurate values of the patient's condition. Carefully inspect each cable before use.

Do not use cables that appear to be or are damaged. If a new cable is required, contact your local distributor.

Use only cables supplied by MIR, specifically designed to be used with Spirolab. The use of other types of cables can lead to inaccurate measurements.

1.2.6 The unit



WARNING

All the maintenance operations described in the User Manual must be carried out with great care. Failure to follow these instructions may lead to incorrect readings or the incorrect interpretation of readings that have been taken.

Do not modify the device without authorisation from the manufacturer.

All modifications, adjustments, repairs and reconfigurations must be performed by the manufacturer or by personnel authorised by the manufacturer. In the event of problems, do not attempt to make repairs. The setting of configurable parameters

must be performed by qualified staff. The incorrect setting of parameters, however, will not compromise a patient's state of health.

On request, the manufacturer can provide electrical diagrams, parts lists, descriptions and calibration instructions to assist the technicians with repairs.

The use of accessories and cables other than those specified by the manufacturer may result in increased emissions or decreased device immunity.

The spirolab device should not be used close to or stacked with other equipment; if it must be used close to or stacked with other equipment, spirolab should be observed to verify normal operation in the configuration in which it will be used.

If the device is used in conjunction with other items of equipment, only equipment that complies with current safety regulations can be used so as meet the safety standards laid down by IEC EN 60601-1; consequently, the PC or printer to which spirolab is connected should comply with IEC EN 60601-1.

As regards the disposal of spirolab devices, accessories, plastic consumables (mouthpieces), removable components and items that are subject to ageing (e.g. the battery pack), only use suitable containers or, better, send the materials to the device retailer or an approved disposal centre. Local legal requirements in force must be complied with in all cases.

Failure to comply with the above mentioned regulations will relieve MIR of all responsibility from any direct or indirect claim for damages.

Use only the battery pack specified in § Technical Specifications.

Keep the device out of the reach of children and differently-able persons.

1.2.7 Warnings for use in electromagnetic environments

Due to the increasing number of electronic devices (computers, cordless phones, cell phones, etc.) medical devices may be subject to electromagnetic interference caused by other equipment.

Such electromagnetic interference could cause the medical device to malfunction, such as a lower measurement accuracy than stated, and create a potentially dangerous situation.

Spirolab complies with the EN 60601-1-2:2015 standard on electromagnetic compatibility (EMC for electromedical devices) both in terms of immunity and emissions.

For the correct operation of the device, however, it is necessary not to use Spirolab near other devices (computers, cordless phones, cell phones, etc.) that generate strong magnetic fields. Keep these devices at a minimum distance of 30 centimeters. If it is necessary to use it at shorter distances, Spirolab and the other devices must be kept under observation to verify that they work normally.

Do not use the instrument in the presence of MRI equipment, which can generate an induced current in the sensor to measure oximetry, causing injury to the patient.

1.3 Labels and symbols

1.3.1 ID label



The symbols are described in the table below:

SYMBOL	DESCRIPTION
Model	Product name
SN	Device serial number
	Manufacturer's name and address
	CE mark for medical devices: this product is a Class IIa medical device that is certified and in compliance with the requirements of Council Directive 93/42/EEC
	Electrical safety symbol: as per IEC60601-1, the product and its component parts are type BF and therefore offer protection against electrical shocks
	Class II equipment symbol: as per IEC60601-1, the product complies safety requirements of Class II equipment while so charging the battery
	WEEE symbol is mandatory to European Directive 2012/19/EEC on Waste Electrical and Electronic Equipment. On completion of its useful life, this appliance must not be disposed of as urban waste but must be sent to an authorised WEEE waste disposal centre. The device can also be sent back to the original supplier free of charge when a new equivalent model is bought. Due to the materials used in its manufacture, disposal of the device as urban waste could harm the environment and/or health. There are legal penalties in place for those who fail to observe the legal requirements mentioned here
IPX1	Information on protection against ingress of liquids. The label indicates the degree of protection against ingress of liquids (IPX1). The device is protected against vertically falling drops of water

SYMBOL	DESCRIPTION
	Antenna symbol for devices that include RF transmitters
FCC ID	FCC Identification code indicating traceability to FCC compliance
Rx ONLY	Reference to US FDA regulations: use the device on prescription
	Instruction for use symbol. Refer to instruction manual. Read this manual carefully before using the medical device
	Production date of the device
	USB port warning label. For connecting the device to a PC. Only use cables supplied by the manufacturer and observe the IEC 60601-1 safety standards
SpO2	SpO2 oximetry port warning label
	Electrostatic discharge symbol. This symbol is used near every connector that has been excluded from the electrostatic discharge test. In this device the electrostatic discharge tests have been performed.
 DC IN 12V	Label relating to the method for charging the battery pack. The symbol is screen-printed next to the connector for connecting the battery charger. Only use the charger supplied by the manufacturer. Features of the battery charger: model AC/DC 12W-N1EFM
	Temperature limits: indicates the temperature limits to which the medical device can be safely exposed
	Humidity limitation: indicates the range of humidity to which the medical device can be safely exposed
	Pressure limitation: indicates the range of pressure to which the medical device can be safely exposed

1.3.2 FCC certification label

Spirolab complies with section 15 of the FCC standards. Operation of the device is subject to the following conditions:

- (1) This device must not cause harmful interference
- (2) This device can be subjected to all types of interference, including those which may cause undesired effects

Any modifications made without the express approval of this company may compromise the use of the device by the user.

NOTE: This device has been subjected to tests that confirm it complies with the limits of a class B digital instrument as per section 15 of the FCC Standards. These limits have been

set to provide appropriate protection against interference when the device is used in the home. This device generates, uses and can emit radio signals and, if not installed or used as per instructions, can create interference with radio communications.

The absence of interference cannot however be guaranteed for all installations.

If this device causes interference to radio or TV reception (that can be determined by turning the device on and off), we recommend the user corrects the interference by adopting one of more of the counter measures listed below:

- Change the angle or position of the antenna.
- Increase the distance between the device and the appliance receiving the signal.
- Connect the device to a different power socket than the one used by the appliance receiving the signal.
- Contact the supplier or radio/TV technician for expert advice.

The symbols defined may be found on the device ID label.

1.3.3 Electrostatic discharge symbol

This symbol is used near every connector that has been excluded from the electrostatic discharge test.



WARNING

The contacts of connectors identified with the ESD warning symbol should not be touched and connections should not be performed before appropriate precautionary electrostatic discharge (ESD) measures are undertaken.

Below are examples of such precautionary measures:

Environmental procedures: air conditioning, humidification, conductive floor-covering substances, use of non-synthetic clothing

User procedures: discharge using large metal objects; use of an ESD wrist strap.

Any staff that uses devices affected by electrostatic discharge should receive adequate explanations concerning the ESD symbol and adequate training on the effects of electrostatic discharge and on the measures to be undertaken to prevent such effects.

An electrostatic discharge is defined as an electric charge at rest. It is the sudden flow of electricity between two objects in contact, an electrical short or a dielectric breakdown. ESD may be caused by a build-up of static electricity or by electrostatic induction. At low relative humidity, charge generation will increase significantly due to the dry environment. Common plastics create higher charge levels.

Typical values of voltages caused by electrostatic discharges are shown below:

Walking on a carpet

1500-35000 Volts

Walking on an untreated vinyl floor

250-12000 Volts

Vinyl envelopes used to organise documents
Worker at a table

600-7000 Volts
700-6000 Volts

If two elements have different charge values, their coming into contact could cause an electrostatic discharge spark. This quick and spontaneous transfer of charge can lead to overheating or melting of circuits in electronic components.

A latent defect can occur when an element sensitive to ESD is exposed to an ESD event and is partially damaged by it. The device can continue to function normally and the damage may not be detected by routine checks, but intermittent or persistent damage can occur even after a long time.

With ESD materials, charges go to ground or to another conductive object that the material contacts. Dissipative materials allow charges to flow to ground more slowly than with conductive materials of equal size. Common plastics and glass can act as insulators. An insulator retains charges and these cannot be transferred to ground. Both conductors and insulators can be charged with electrostatic charges and discharged. Grounding is a very efficient instrument against ESD, but only conductors can be connected to ground. The fundamental principles of control against ESD are:

- Grounding of all conductors, including people
- Removing insulators and replacing them with ESD-safe versions
- Using ionisers
- Paying attention to areas that are not ESD-safe, e.g. using ESD-safe product packaging

1.4 Product description

Spirolab is a portable spirometer that can also features a pulse oximeter feature (optional). The device can operate completely autonomously or can be connected to a personal computer by means of USB or Bluetooth connections; the device can be connected to an external printer via USB.



The device is intended for measuring respiratory parameters and monitoring oxygen saturation and pulse rate. The device carries out a control test on the quality of the readings taken and can save the results of about 10,000 spirometric tests or about 500 hours of oximetry data.

Spirolab is intended for use by medical specialists and it provides them with a powerful but compact tool that can process about 30 functional parameters. The device also provides a pharmacodynamic response, i.e. the % comparison of spirometric data measured before and after (PRE/POST) administration of a drug for bronchial provocation or bronchodilation. The POST data measured after administering the drug is compared with the PRE data obtained before administration.

A turbine inside the device that uses the interruption of infra-red light as its operating principle, measures volume and flow rate. This operating principle ensures accurate, reproducible results without needing periodic recalibration.

The key features of this type of sensor are as follows:

- Accurate readings even with low air flow rates (end of exhalation)
- Not affected by humidity and gas density
- Unbreakable and shock resistant
- Inexpensive to replace

The turbine volume and flow sensor is available in disposable and reusable versions.



REUSABLE TURBINE



DISPOSABLE TURBINE

In order to preserve the characteristics of the turbines, it is important to observe the following precautions:

- For the disposable turbine: always replace following patient spirometric tests
- For the reusable turbine: always disinfect before use on a new patient to ensure the best possible hygiene and safety standards

To properly interpret the results of a spirometry test, it is essential to compare them with the so-called **normality values** that are calculated using standardised patient data or with **personal reference values** associated with that specific patient's clinical history.

An individual patient's clinical history values can vary significantly from normality values that always refer to a “healthy” subject.

Spirolab can be connected to a PC or another computerised system. The spirometric data from every test is stored in the device and can be transferred to a PC and displayed (flow/volume curves, spirometric parameters, oximetric parameters optional). The device can be connected to a PC via a micro USB port.

Spirolab performs FVC, VC & IVC and MVV tests and the ventilatory profile, as well as an acceptability (quality control) and reproducibility index of the spirometry test carried out by the patient. The automatic interpretation function uses 11 levels as per ATS (American Thoracic Society) classification. Every single test can be repeated. The best functional parameters will always be available for fast re-reading. The normality values (theoretic) can be selected from those available. For instance, in European Union countries, doctors generally use the values recommended by the ERS (European Respiratory Society).

Oximetry function

The oximetry sensor features two light emitting diodes (LED); one emits visible red light and the other infra-red. Both bands of light pass through the finger to reach a light detector. During the passage through the finger, some of the light is absorbed by the blood and soft tissue depending on the concentration of haemoglobin. The amount of each light frequency absorbed depends on how oxygenated the blood is inside the tissue. This operating principle ensures accurate and reproducible readings without the need to constantly calibrate the device.

The oximetry sensor can be disinfected with Isopropyl alcohol.

1.5 Technical specifications

Below is a complete description of the specifications for the device, the turbine volume and flow sensor and the oximetry sensor.

1.5.1 Spirometer specifications

This device meets the requirements of the following standard:

- ATS Standardization of Spirometry 2005
- ISO 23747: 2015
- ISO 26782: 2009

1.1.2.

Parameters measured:

Matuojami parametrai

Symbol	Description	U.m.
*FVC	Best FVC	L
*FEV1	Best FEV1	L
*PEF	Best PEF	L/s
<u>FVC</u>	Forced Vital Capacity	L
<u>FEV1</u>	Volume exhaled in 1st second of the test	L
<u>FEV1/FVC</u>	FEV1/FVC x100	%

Symbol	Description	U.m.
<u>FEV1/VC</u>	FEV1/ best between EVC and IVC x 100	%
<u>PEF</u>	Peak expiratory flow	L/s
<u>PEF Time</u>	Time to achieve 90% of the PEF	s
<u>FEF-2575</u>	Median flow between 25% and 75% of FVC	L/s
<u>FEF7585</u>	Median flow between 75% and 85% of FVC	L/s
<u>FEF25</u>	Maximum flow at 25% of FVC	L/s
<u>FEF50</u>	Maximum flow at 50% of FVC	L/s
<u>FEF75</u>	Maximum flow at 75% of FVC	L/s
<u>FEV05</u>	Volume exhaled after 0.5 seconds	L
<u>FEV05/FVC</u>	FEV05/FVC x 100	%
<u>FEV075</u>	Volume exhaled after 0.75 seconds	L
<u>FEV075/FVC</u>	FEV075/FVC x 100	%
<u>FEV2</u>	Volume exhaled in the first 2 seconds of the test	L
<u>FEV2/FVC</u>	FEV2/FVC x 100	%
<u>FEV3</u>	Volume exhaled in the first 3 seconds of the test	L
<u>FEV3/FVC</u>	FEV3/FVC x 100	%
<u>FEV6</u>	Volume exhaled in the first 6 seconds of the test	L
<u>FEV1/FEV6</u>	FEV1/FEV6x100	%
<u>FEV1/PEF</u>	FEV1/PEF (empey's index)	L/L/s
<u>FEV1/FEV0.5</u>	FEV1/FEV0.5	\
<u>FET</u>	Forced exhalation time	s
<u>EVOL</u>	Extrapolated volume	mL
<u>FIVC</u>	Forced Inhalation Vital Capacity	L
<u>FIV1</u>	Volume inspired in the 1st second	L
<u>FIV1/FIVC</u>	FIV 1 %	%
<u>PIF</u>	Peak inspiratory flow	L/s
<u>FIF25</u>	Maximum flow at 25% of FIVC	L/s
<u>FIF50</u>	Maximum flow at 50% of FIVC	L/s
<u>FIF75</u>	Maximum flow at 75% of FIVC	L/s
<u>FEF50/FIF50</u>	FEF50/FIF50 x 100	%
<u>MVVcal</u>	Max. voluntary ventilation <u>calculated</u> based on FEV1	L/s
<u>VC</u>	Slow Expiratory Vital Capacity	L
<u>EVC</u>	Expiratory Vital Capacity	L
<u>IVC</u>	Inspiratory Vital Capacity	L
<u>IC</u>	Inspiratory capacity: (maximum between EVC and IVC) -ERV	L
<u>ERV</u>	Expiratory reserve volume	L
<u>IRV</u>	Inspiratory reserve volume	L
<u>VT</u>	Tidal Volume	L
<u>VE</u>	Minute ventilation at rest	L/min
<u>RR</u>	<u>Respiratory frequency</u> RF	Breaths/min
<u>tI</u>	Average inspiratory time at rest	s

MVV apskaičiuota s

Symbol	Description	U.m.
tE	Average exhalation time at rest	s
TV/tI	Mean inspiratory flow at rest	L/min
$tI/tTOT$	$tI/(tI+tE)$	\
MVV	Maximum voluntary ventilation	L/min
1.1.3. ELA	Estimated Lung Age	years

ELA Apytikris plaučių amžius metais

* = best values

Flow/volume sensor	Bi-directional turbine
Temperature sensor	semiconductor (0-45°C)
Method of detection	Infra-red interruption
Maximum volume measured	10 L
Flow rate	± 16 L/s
Volume accuracy (ATS 2019)	± 2.5% or 50 mL
Flow accuracy	± 5% or 200 mL/s
Dynamic resistance at 12 L/s	<0.5 cmH ₂ O/L/s

1.5.2 Oximeter specifications

For oximetry measurements, the device complies with the requirements of the following standard:

ISO 80601-2-61:2017 Medical electrical equipment - particular requirements for basic safety and essential performance of pulse oximeter equipment

Reusable soft sensor for adults	
Range (SpO ₂)	Arms (%)
70-100 %	± 1.470
70-80 %	± 1.626
80-90 %	± 1.667
90-100 %	± 0.941

Reusable paediatric soft sensor	
Range (SpO ₂)	Arms (%)
70-100 %	± 1.390
70-80 %	± 1.851
80-90 %	± 1.397
90-100 %	± 0.652

The Arms (Accuracy Root Mean Square), as recalled in the above mentioned standard, represents the accuracy of the device in terms of the mean square error of each SpO₂ measurement, obtained by pulse oximetry, in relation to the respective SaO₂ reference value, obtained by co-oximetry.

The ranges listed show the different oxygen saturation ranges for which the accuracy has been calculated.

The accuracy of the device can be assessed with a tester.

Definitions

Desaturation event Drop in SpO₂ ≥ 4% in a 8- 40 sec period limited and subsequent rise ≥ 2% inside an overall period of 150 sec.

Pulse variation event Rise in Pulse ≥ 10 BPM in a 8- 40 sec limited period and subsequent drop ≥ 8 BPM inside an overall period of 150 sec.

Oximetry test parameters:

Symbol	Description	u. m.
%SPO2 min	Minimum SPO2 during the test	%
%SPO2 max	Maximum SPO2 during the test	%
BPM min	Minimum BPM during the test	BPM
BPM max	Maximum BPM during the test	BPM
Median %SPO2	Median SPO2	%
Median BPM	Median BPM	BPM
T Total	Duration of the test	hh:mm:ss
Analysis T	Total measuring time (duration of test excluding zeroes)	hh:mm:ss
T<90%	Time with SpO2 less than 90%	%-hh:mm:ss
T<89%	Time with SpO2 less than 89%	%-hh:mm:ss
T5	Time with SpO2 less than 5% of the mean value	%-hh:mm:ss
T<40BPM	Time passed with Pulse rate <40 BPM	%-hh:mm:ss
T>120BPM	Time passed with Pulse rate <120 BPM	%-hh:mm:ss

Method of detection	Red and infra-red light absorption
Measuring range of %SpO ₂	0 – 99% (with 1% increments)
Resolution of SpO ₂	1%
Accuracy of %SpO ₂	$\pm 2\%$ between 70-99% SpO2
Number of beats for calculating the median SpO ₂ %	8 beats
Pulse rate measuring range	18 – 300 BPM
Resolution of pulse rate	1 BPM
Pulse rate accuracy	± 2 BPM or 2% of highest value
Interval for calculating median pulse rate	8 seconds
Signal quality	0 - 8 display segments
Wavelengths and maximum optical output power average of oximetry sensors (919024)	Red light: 660 nm, 2.0 mW (**) Infrared light: 905 nm, 2.4 mW (**)
Wavelengths and optical output power of oximetry sensors (Envitec sensors)	Red light: 660 nm, 3.5-4.5 mW (**) Infrared light: 905 nm, 3.5-4.5 mW (**)

(**) This information may be useful to the doctor.

Acoustic signalling:

- Beeps with frequency depending on pulse rate
- Sounds in the event of exceeding pre-set threshold values of the %SpO₂ or pulse rate

- Sounds during oximetry if battery low
- Sounds in the event of no signal present (finger not inserted properly, connector not properly attached)
- Sounds the next time the device is turned on following an interrupted test due to low battery

The specifications that apply to oximetry and pulse rate are the same regardless of the sensor used as long as it is one of those mentioned beforehand.

1.5.3 Other features

Memory	The memory can store the data from over 10,000 spirometric tests. The exact number has not been established as it depends on the configuration set by the doctor
Display	7 inches colour touch screen LCD Display with 800x480 resolution
Keypad	Touch screen
Interface	USB, Bluetooth
Bluetooth interface	Frequency range: 2402-2480 MHz Output power: 0,001W Frequency tolerance: 20 ppm Type of antenna: permanently attached Antenna gain: 0 max dBi
Battery pack lifespan	About 10 years of use
Power supply	NiMH rechargeable 7.2V battery pack (6 batteries, 1.2V each), 4000 mAh
Battery charger	Model AC/DC 12W-N1EFM
Autonomy	~10 hours
Dimensions	Main body 220x210x51 mm
Weight	Central unit 1450 g (including battery pack)
Type of electrical protection	Internally powered
	Class II while charging battery
Degree of electrical protection	BF
Degree of protection against water penetration	IPX1 appliance protected against water leaks
Safety level in the presence of flammable anaesthetic gases, oxygen and nitrogen	Appliance not suitable
Conditions of use	Device for continuous use
Storage conditions	Temperature: MIN -40 °C, MAX + 70 °C Humidity: MIN 10% RH; MAX 95%RH Athmospheric pressure: 50kPa, 106 kPa

Transport conditions	Temperature: MIN -40 °C, MAX + 70 °C Humidity: MIN 10% RH; MAX 95%RH Atmospheric pressure: 50kPa, 106 kPa
Operating conditions	Temperature: MIN + 10 °C, MAX + 40 °C; Humidity: MIN 10% RH; MAX 95%RH Atmospheric pressure: 70kPa, 106 kPa
Applicable standards	IEC 60601-1:2005 + A1: 2012 (Electrical Safety) IEC 60601-1-2:2015 (EMC) ATS/ERS Guidelines: 2005 ISO 26782: 2009 ISO 23747: 2015 EN ISO 14971: 2012 ISO 10993-1: 2018 2011/65/UE Directive EN ISO 15223:2016 EN IEC 60601-1-6: 2010+Amd2013 ISO 80601-2-61: 2017 IEC 60601-1-8: 2006
Key performance (in accordance with IEC 60601-1: 2005 + A1: 2012)	Error of displayed numeric value: Flow measurement percentage error < $\pm 5\%$ Measurement of oximetry parameters with accuracy as defined in the table on § 1.5.2
Emission limits	CISPR 11 Group 1 Class B
Electrostatic discharge protection	8kV contact, 15kV air
Magnetic field immunity	30 A/m
Radio Frequency Immunity	3V/m @ 80-2700 MHz

MIR will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those part of the device that are designated by MIR as repairable by service personnel.

2. USING THE SPIROLAB

2.1 Turning the spirolab on and off

To turn the **spirolab** on, press then release the button on the front of the unit.



When you turn on the device, the first screenshot shows the internal software loading progress.



Only the first time the device will ask the user to protect the access with a PIN:

According to GDPR (General Data Protection Regulation) the user, can do this by inserting a PIN.

Press OK if you want to set a personal PIN

or

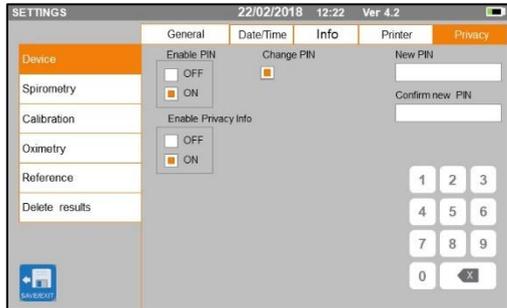
Press *Undo* to skip this function.



Pressing OK then a message requires to confirm the use of a PIN: press OK to continue or Undo to skip this function.



- Press OK on the following screen
- The PIN must have 4 numbers.
- Insert a PIN in the field “**New PIN**” using the numeric keyboard,
- Repeat the PIN in the field “**Confirm new PIN**”.
- If the PIN is correct a popup will appear with the following message:



Change PIN Successful

- Press **OK**
- Press  to return to the main screen.

From this moment each time the device is switched on the PIN needs to be inserted.

If the PIN is incorrect the user can try again; (the device allows 20 attempts per day).

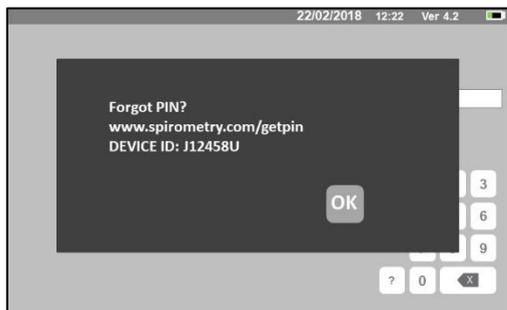
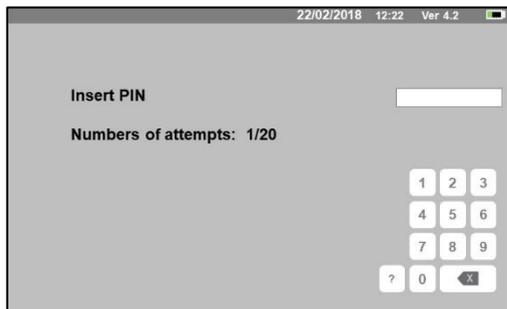
After 20 attempts the user needs to wait for the next day to unlock the device.

If the user forgot the PIN send an inquiry to the following website:

www.spirometry.com/getpin

Complete the fields and insert the DEVICE ID shown on the popup on the screen.

After the registration the system will send an e-mail to the address inserted on the web site with the PIN to unlock the device.



At the end the main screen will appear



To turn **spirolab** off, press the power button on the front of the unit.

⚠ WARNING

Spirolab does not turn off completely but enters an ultra-low standby mode; some features remain active to allow the device to keep the date and time updated and to be activated remotely if required. For this reason, the power key's symbol is , corresponding to the standby mode.

2.2 Saving energy

The internal battery pack charge is shown in the upper right hand corner of the display by the symbol:



If the battery symbol is all green, then the battery pack is charged.

⚠ WARNING

To charge the battery pack, only use the charger supplied by the manufacturer.

2.3 Main screen

The device's features can be accessed from the main screen. The following section details the features of each icon.



2.4 Symbols and icons

The following table shows the icons displayed on the various screens and what they mean

ICON	DESCRIPTION
	To access initial settings (service menu)
	To enter new patient data
	To edit patient data/To rerun an archived patient test
	To access file containing tests performed
	To save the settings and return to the main screen
	To exit without save and to return to the previous screen
	To view the last spirometry session for the current patient
	To view the last oximetry session for the current patient
	To test oximetry
	To test FVC spirometry
	To test VC spirometry
	To test MVV spirometry
	To run a bronchodilator test (POST)
	To check the alarms and thresholds set during an oximetry test
	To check the oximetry sensor is properly connected during testing
	To check the presence of a signal during the oximetry test
	To print a test
	To delete a test
	To cancel an operation

2.5 Service menu

To access the menu, press the icon .

To view headings, enter the PIN set or, if was not inserted a personal PIN, enter the default PIN which is the following:

1 2 2 3

If the personal PIN is missed touch the ? to unlock the device sending an enquire on the internet site described before (point 2.1).

In this screen, you can also change the brightness of the display by tapping the orange cursor vertically. The brightness will change in real time.

The service menu will display the following heading sequence:

- Device
- Spirometry
- Calibration
- Oximetry
- References
- Delete archive

Tap the desired heading to select it.

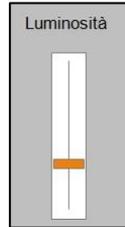
Device

The section is divided into:

- General
- Date/Time
- Info
- Printer
- Privacy

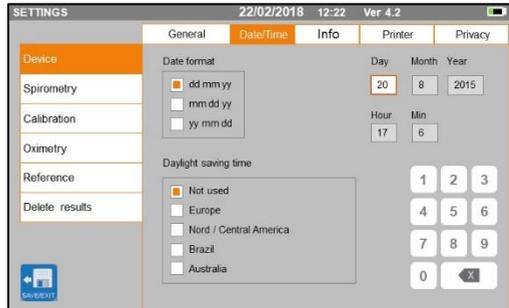
Select the desired settings by tapping the white box; the selection is highlighted by an orange box.

For the brightness of the display, move the orange cursor vertically until the desired brightness.



To set the correct date and time, tap the box to bring up the cursor; use the numeric keypad on the lower right to set the correct value.

The area “Daylight saving time” allows to set the automatic time change depending on the geographic area which you stay. The device recognizes the date changes until 2026.



The "Info" section displays the hardware and software versions of the device's most significant components, in addition to the serial number.

In the "Printer" section, you can set the print header. Tap the white space under "printout header" to bring up the virtual numeric keyboard. You can enter characters until the string is complete.

In the area “External printer” it is possible to enable or disable the external printout via USB connection, or to choose the printing colour type in case of use of the external printer via USB.

The printer to use must be postscript type.

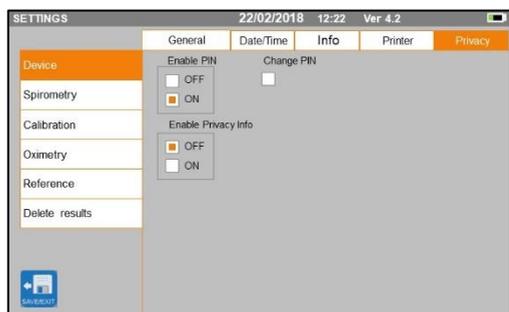
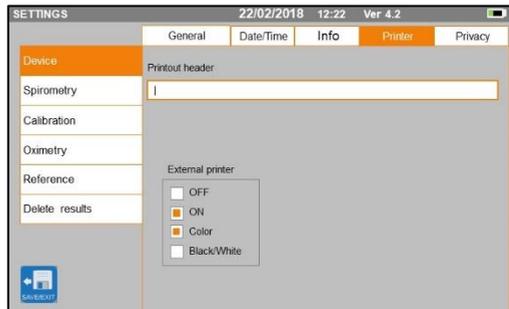
In the “Privacy” section the user can enable or disable:

- the PIN
- the Privacy information

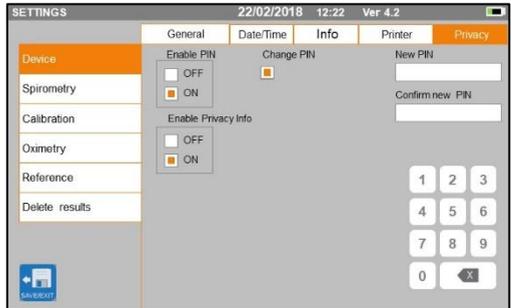
The device has a **default PIN** set, which is the following:

1 2 2 3

In this section it is possible to change the PIN enabling “**Change PIN**”.



On the screen a numeric keyboard will appear with the fields to change the PIN.



Spirometry

The section is divided into:

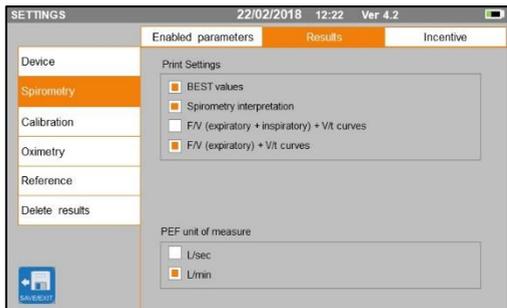
- Parameters
- Outcome
- Incentives

In the “Parameters” section, you can select the values that will be displayed at the end of a test; these will be stated on the printout. Here too, the selection is highlighted by an orange box.



In the “Results” section, you can choose what to include in the printout from among the following items:

- Best values
- Interpretation of spirometry results
- F/V (expiratory + inspiratory) and V/t curves
- F/V expiratory only curve and V/t curves



This section allows to choose the unit of measure to show the PEF value: L/sec or L/min

In the "Incentive" section, you can configure the paediatric incentive to improve spirometric performance.

The incentive may be enabled or disabled; should it be enabled, by selecting "ON" on the left, you must enter the age threshold up to which the incentive is displayed; use the numeric keypad on the bottom to set this value.

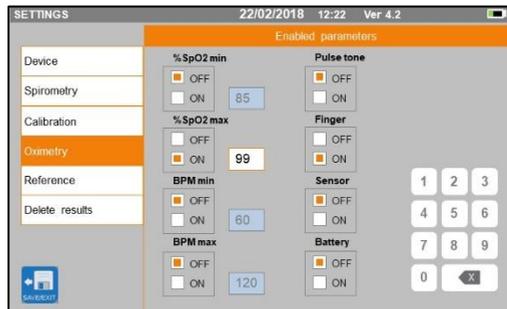


Calibration

For calibration, see paragraph 2.5.1 below.

Oximetry

In this section, you can configure all alarms related to an oximetry test. By setting the desired alarms to "ON", you will activate a box where you can set the relevant threshold value using the numeric keypad.



WARNING

If the maximum value of a parameter is less than or equal to the minimum value, the setting process will not proceed. A beep will sound and the device will automatically return to the screen for setting the minimum value.

References

This section allows you to set the predicted value used between:

Adults	Children	1.1.4 Vaikai
ERS	Knudson	
Knudson	Knudson	

Adults	Children
USA	Knudson
ERS	Zapletal
MC-Barcelona	Zapletal
JRS-JAPAN	JRS-JAPAN
Chinese H.K.	Chinese H.K.
Pereira	Pereira
CECA1971	Knudson
NHANES III	NHANES III
GLI	GLI
Padilla-Perez	Knudson

If you choose the last predicted value NHANES III, the limitations provided for in the past by the standard NHANES III will be applied.

 **WARNING**

If you set the predicted value NHANES III are disabled the VC and MVV tests.

Delete archive

Using the numeric keyboard, enter the PIN set to permanently delete all the tests stored in the device.

2.5.1 Calibrating turbines

 **WARNING**

**The turbine does not need calibration, just a periodical clean.
The disposable turbine is inspected before it is sealed in the package, and hence does not need calibration.
If, however, if you want to carry out a calibration, bear the following in mind.
Calibration can be carried out on reusable and disposable turbines.**

Calibration takes place based on the FVC (expiratory) and FIVC (inspiratory) values measured during a test performed with a calibrated syringe.

To access the calibration setting, select the service menu item "Calibration"; the first screen, "Last values", allows you to check current percentages applied by the device.

By choosing "New calibration", you can calculate new conversion factors. Make a test using the syringe calibration. Make the following acts in the same sequence:

- Make an inspiration manoeuvre
- Make an expiration manoeuvre
- Make an inspiration manoeuvre once again



On the display it is shown the graphic of the test.

Then tap .

If calibration correction is $< 10\%$ then the values are shown as in the following screen.

Tap "OK" to set the new correction values.

If the values are $> 10\%$ then the following message appears on the screen:

WARNING! CORRECTION too high



The FVC and FIVC values are not accepted. This means that the system is unable to correct such a large calibration error. In this case:

- check that the **spirolab** is working properly by fitting a new turbine and/or
- clean the turbine in question.

To cancel the calibration in use and restore the factory settings, select "Factory values" from the calibration menu.

Then tap .

 **WARNING**

According to the *"Standardised Lung Function Testing"* publication of the European Respiratory Society (Vol 6, Supplement 16, March 1993), air expelled from the mouth has a temperature of about 33/34°C.

To convert the volumes and air flow rates to BTPS (37 °C) conditions, they must be increased by a factor of 2.6%. The BTPS factor for a temperature of 33°C is 1.026, which is in fact a correction of 2.6%. In practice, the BTPS factor for expiratory volumes and flow rates is constant and equal to 1.026.

The BTPS factor for inspiratory volumes and flow rates depends on ambient temperature, as air that is inhaled is at that temperature.

For instance, with an ambient temperature of 20 °C with Relative Humidity of 50%, the BTPS factor is 1.102, which represents a correction of +10.2%.

The correction of inspiratory volumes and flow rates is performed automatically thanks to an ambient temperature sensor that measures the temperature inside the device and allows the BTPS factor to be calculated.

If a 3-litre syringe is used for the test and if the spirolab device is perfectly calibrated, the FVC (syringe) value measured will be:

$3.00 \text{ (FVC)} \times 1.026 \text{ (BTPS)} = 3.08 \text{ L (FVC at BTPS)}$.

If the ambient air temperature is 20 °C, the FIVC (syringe) value measured will be: $3.00 \text{ (FIVC)} \times 1.102 \text{ (BTPS)} = 3.31 \text{ L (FIVC at BTPS)}$.

The user must be aware that the volume of the syringe shown was converted to BTPS and the "alterations" of the results when compared with expected values do not therefore represent an error.

For example, if you perform calibration with the data measures:

FVC = 3.08 L and FIVC = 3.31 L at an ambient temperature of 20 °C, the correction coefficient will be:

EXPIRATORY	.00%
INSPIRATORY	.00%

To repeat, this is NOT an error but the logical consequence of what was explained above.

NOTE

Calibration can also be performed using the winspiroPRO software that comes supplied with the device. For details about the calibration procedure using this software, refer to the winspiroPRO online manual.

2.6 Patient data

From the main screen, you can access the patient data management area:

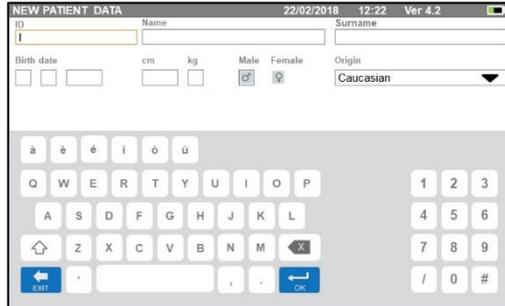
- create a new patient profile or check for existing patients in the archives
- change current patient data



2.6.1 Entering new patient data



This screen provides access to all patient data. The ID code is not required. Tap the grey space to access the various fields and make entries using the virtual numeric keyboard on the screen. Tapping the "Origin" field brings up a drop down menu where you can choose the desired value.



The icon  allows you to delete the last character entered.

The icon  allows you to enter uppercase characters.

The icon  allows you to enter information in the next field.

The icon  allows you to return to the main screen without saving data.

The icon  allows you to save your entries and return to the main screen.

WARNING

The data required to create a patient profile is:

- name
- surname
- sex

If any of these items of information are not inserted, the patient profile is not created when you tap .

In the "Origin" field, the following options will appear:

ATS/ERS standards		NHANES III standards	
Group	% correction		
No group selected	100%	Caucasian	
Caucasian	100%	Afro-American	
Oriental	100%	Mexican-American	
Hong Kong Chinese	100%	Others	
Japanese	89%		
Polynesian	90%		
North Indian	90%		
South Indian	87%		
Pakistani	90%		
Of African descent	87%		
Aborigine	85%		

In the case of ATS/ERS standards: depending on the ethnic group set, the correction percentage acts on the predicted values of the following parameters:

FVC, FEV1, FEV3, FEV6, FIVC, FIV1, EVC, IC, VC, ERV, TV, TV/ti

In the case of NHANES III standards: depending on the ethnic group set, different predicted formulae are taken into account (in accordance with the reference standard). Once the desired ethnic group has been selected, the device completes defining the patient parameters and returns automatically to the main screen.

In the case of GLI for every Ethnic group the device applies a different table to calculate the predicted values and not a correction percentage.

2.6.2 Editing patient data



Select the icon and use the screen as described in section 2.6.1.

WARNING

Selecting this function does not create a new patient as described beforehand, but changes the data of the same patient and associates future test data with that patient, who is always identified with the same unique ID code.

2.7 Viewing stored data

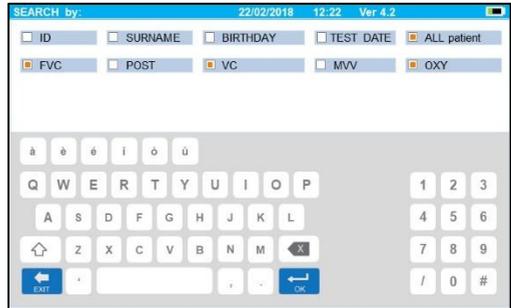
2.7.1 How to search the archives



In the main screen, you can access the data present in the device archive by using the above icon.

You can choose to search by:

- ID
- Surname
- Date of birth
- Test date
- All



Or select the type of test:

- FVC
- POST
- VC
- MVV
- OXY

Each option selected will bring up a box in which you can enter the search data.

2.7.2 Viewing archived data

The archive displays the list of patients, starting with the most recent.

Select the patient required by tapping the line (which becomes orange) and choose one of the enabled functions listed at the bottom of the screen.

The enabled icons are coloured, while the grey ones are disabled.

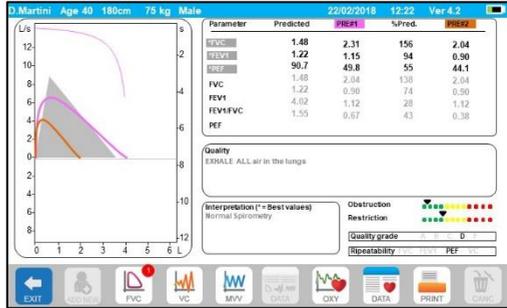
To quit the archive, use the icon .



To view the spirometry tests performed by the selected patient,



use the icon . The information is displayed as in the image on the right. On the left you have the test trend in graph form (Flow/Volume and Volume/Time), while on the right you have various quality-related messages and the values of the parameters selected in the service menu. By swiping your finger in the parameter area, you can view other parameters selected in the service menu.



You can delete one of the tests performed as follows: tap the column relating to the test data to be deleted; the data will be selected by two bands on the left and right;



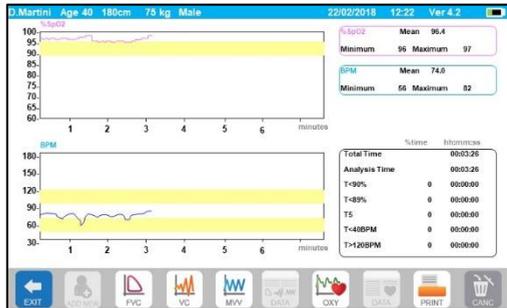
now tap the icon  on the lower right. And tap "OK" in the popup window which appears on the screen.

At each screen, you can go back to the previous step by tapping .

To view the selected patient's



oximetry tests, use the icon . The data is displayed as in the image to the right, with the graphic trend of the % SpO2 and BPM always on the left and the numerical values of the various parameters on the right. You may cancel the test by using the



icon  on the lower right.

If you want to perform a new test on the selected patient from this screen, you can use the icon for the test to be performed; a message is displayed to confirm whether or not you wish to perform a new test on

the selected patient. Tap "YES" to confirm or "NO" to go back.

If the patient has performed several spirometry or oxymetry tests, the initial list indicates (in brackets next to the type of test) the number of tests saved.

To view tests other than the first, tap the icons  (for spirometry) or  (for oxymetry).

2.7.3 Displaying the last test session

During test sessions, the spirometer automatically saves up to 8 FVC tests. From the main screen, using the icon:

-  in the case of spirometry tests
-  in the case of oxymetry tests

you can view the best three session tests (where PRE1 is the best). At the end of the session, when you enter a new subject or switch to a POST phase, the 3 best tests of the previous session are automatically saved in the archive. These, therefore, can be retrieved from the archive and printed, either together or individually.

Numbers may appear on the main screen, next to the spirometry test icons, for example:



The number inside the red circle represents, in this case, the FVC tests performed in the current session.

2.8 Online mode (connected to a PC)

This function acts like an actual laboratory-based real time spirometer connected to a PC. Connection to the PC can be performed by USB or by a wireless Bluetooth connection.

Spirolab becomes an intelligent sensor for measuring volume and flow rate while the PC controls the functions, including turning on and off.

When connected to a laptop, **spirolab** can be used for epidemiological tests in workplaces, schools etc.

In addition to the usual spirometric parameters and F/V curves in real time, this system can also gather more sophisticated information such as ventilatory profiles and extrapolated volume (Vext) data.

The computer software allows the use of more up-dated bronchial provocation protocols and can display FEV1 dose and time-responses.

! WARNING

When the device is connected to a PC, it cannot be remotely operated. The settings on the PC are transferred to the device and remain active any other time you use the device remotely. For example, if you use spirolab connected to the PC and you set a particular turbine (disposable or reusable), this will remain the default turbine any other time you use the device remotely. It is important, therefore, to be careful when setting the type of turbine.

2.9 Performing a spirometry test

! WARNING

While performing tests, unplug the charger from spirolab.

To correctly perform a spirometry test, observe the following instructions to the letter.

- Slide the turbine fully into position in the MiniFlowmeter then turn it clockwise until it clicks into place.
- Connect the MiniFlowmeter to spirolab as show in the image on the right.
- Slide the mouthpiece at least 0.5 cm along the groove on the turbine.
- Fit the nose clamp over the patient's nostrils to prevent air from escaping.



- Take the MiniFlowmeter with both hands or, alternatively, hold it as you would a mobile phone.
- Introduce the mouthpiece into the mouth behind the teeth, making sure that air does not escape from the sides of the mouth

! WARNING

The proper positioning of the mouthpiece behind the teeth is essential to eliminate any turbulence that might have a negative effect on the test parameters.

! WARNING

We recommend that the patient stays upright during the test and bends forward during exhalation to allow the abdominal muscles to facilitate the expulsion of air.

The main screen contains the following icons to perform various types of tests:



FVC Spirometry test



VC spirometry test



MVV spirometry test



Test with bronchodilator (POST)

To end a test, tap .

2.9.1 FVC test



To perform an FVC test, follow the instructions below:

INHALE all the air

EXHALE forcefully ($\geq 6s$)

INHALE forcefully

The test can be started (optionally) by breathing at rest. When you are ready, inhale as quickly as possible (it is easier if you open your arms wide) and expel all the air in your lungs with as much force as you can. Without removing the mouthpiece, complete the cycle by inhaling as quickly as possible. The latter step can be omitted if calculation of the inhalation parameters (FIVC, FIV1, FIV1%, PIF) is not required.

The inhalation stage can also be performed before putting the mouthpiece in your mouth. Following a slow deep intake of breath, the next exhalation should be performed with as much force as possible and as quickly as possible.

After 6 seconds of exhalation, the device will emit a continuous beep that tells you that the minimum exhalation time has passed. This is the minimum time required by the main International Pulmonology Associations.



WARNING

Remember that for accurate spirometry results, it is essential that all the air is expelled from the lungs.

The test can be repeated as often as required without the mouthpiece having to be removed from the mouth. In this case, the **spirolab** will automatically recognise the longer cycle (longer FVC+FEV1) and present the relative readings.

On completion of the test, tap .

During the test, the **spirolab** emits repeated beeps, the frequency of which is directly

proportional to the speed at which air is being inhaled and exhaled. This helps the doctor understand when the rate of air flow is approaching zero and therefore when the patient has exhausted the volume available in exhalation and inhalation.

The section dedicated to maintenance also describes how this feature is also useful for easily checking that the volume and air flow sensors are working properly.

Apart from requiring a deep exhalation of breath for the results of an FVC test to be reliable, the Forced Expiratory Time (FET) must also be long enough to allow the complete expulsion of all the air in the lungs.

2.9.2 VC test



Ventilatory profile

You can start testing Slow Vital Capacity by breathing at rest. After three or four similar consecutive breaths, a continuous beep warns the user that the ventilatory profile has been measured and that VC or IVC can now be measured.

Slow Expiratory Vital Capacity: VC

After the beep, inhale as slowly as possible and subsequently exhale as slowly as possible.

Slow Inhalatory Vital Capacity: IVC

After the beep, exhale as slowly as possible and subsequently inhale as slowly as possible.

On completion of the test, tap .

2.9.3 MVV test



Start the test with a series of forced inhalations and exhalations at the fastest speed possible. The recommended frequency is 30 breaths/minute.

The test ends automatically after 12 seconds.



WARNING

To test the service menu test, check that the parameter relating to said test is enabled in "Set parameters"; otherwise, the icon will be disabled.



WARNING

It is important to remember to change the disposable mouthpiece and the disposable turbine at the end of a patient's test session.

2.9.4 Running POST tests after the administration of a drug

WARNING

To perform a POST test, the patient must have performed at least one PRE FVC test on the same day (i.e. in the same session); you cannot perform POST tests on PRE VC or MVV tests; conversely, you can perform POST VC or MVV tests, provided at least one PRE FVC test has been performed and archived on the same day.

To perform a POST test, proceed as follows:

Tap  on the main screen.

The screen on the right shows the list of all the patients who have performed a PRE test on the same day.

Select the patient required and choose one of the features enabled below.

The user is prompted to confirm the move to POST mode: tap "YES" to carry out the test in POST mode, or tap "NO" to go back.



ID	Name	Birth date	cm	kg	Gender	Restriction
12587	D. Martini	05 / 05 / 1985	178	80	Male	RESTRICTION
15945523 a	K. Brown	05 / 05 / 1996	158	59	Female	MIXED

By "POST" test, we mean a spirometry test performed after administering the patient a bronchodilator. The tests subsequently performed on the selected patient show the following parameters:

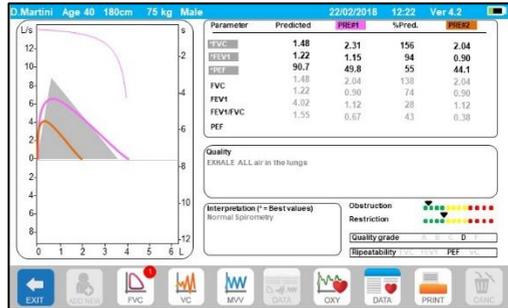
- The values for the test performed;
- The values of the best PRE test performed by the same patient on the same day (i.e. in the same session);
- The percentage change between PRE and POST values (in the column labelled CHG).

You cannot perform a POST test on a patient if the archive only contains PRE tests carried out on previous days (sessions other than the current one).

If, during a POST session, you create a new patient or retrieve another patient from the archive, the device automatically exits the current POST session.

2.10 Displaying and reading spirometry results

Once the FVC test has been completed, the spirometry results are displayed. The screen shows the Flow/Volume and Volume/Time graphs, the parameters selected in the settings relating to the best test among those performed in the session, and the percentage ratio compared to predicted values. Scroll through the parameters area to view any other parameters set.



2.10.1 Interpreting spirometry results

The interpretation of spirometry refers to Forced Vital Capacity (FVC) and is seen by means of indicator lighting.

The messages can include the following:

- ◆ Normal spirometry
- ◆ Slight obstruction/restriction
- ◆ Moderate obstruction/restriction
- ◆ Moderately severe obstruction/restriction
- ◆ Severe obstruction/restriction
- ◆ Very severe obstruction/restriction

The final interpretation level is "restriction + obstruction", where the indicator light indicates the worst parameter between restriction and obstruction.

Thanks to a mathematical analysis known as quality control that is applied to some indices and parameters calculated in FVC tests, the **spirolab** device can produce different comments that help to understand the reliability of tests carried out.

The quality control system uses letters as described below:

1st case: PRE test

A = at the end of two acceptable tests, the variation of the two highest FEV1 values and the two highest FEV6 values are less than or equal to 100 mL.

B = at the end of two acceptable tests, the variation of the two highest FEV1 values is between 101 and 150 mL

C = at the end of two acceptable tests, the variation of the two highest FEV1 values is between 151 and 200 mL

D = only one test was acceptable or there is more than one acceptable test but the variation of the two highest FEV1 values is greater than 200 mL

F = no acceptable test.

2nd case: POST bronchodilator test

A = two acceptable tests, the variation of the two highest FEV1 values is less than or equal to 100 mL.

B = two acceptable tests, the variation of the two highest FEV1 values is between 100 and 200 mL.

C = two acceptable tests, the variation of the two highest FEV1 values is greater than 200 mL.

D = one acceptable test

F = no acceptable test

"Acceptable" means: a good start and satisfactory exhalation (in duration and flow)

To facilitate understanding where much information is available regarding the same test, the **spirolab** device will only display the most significant data.

Vext and PEFT ERROR

If the extrapolated volume is :

For patients with age > 6 years > 150 mL or > 5% of FVC

For patients with age < 6 years > 80 mL or > 12.5% of FVC

PEFT (peak flow time) > 160 msec.

FET Error

If the FET is:

For patients with age < 10 years FET < 2 sec

For patients with age > 10 years FET < 6 sec

FLOW ERROR

If:

Flow > 100 mL in the last ½ second

Flow > 40 mL in the last ½ second

Between one test and the next, the **spirolab** device evaluates the repeatability of the following parameters:

PEF repeatable when the difference between the two furthest apart PEF values is ≤ 10%;

FEV1 repeatable when the difference between the two furthest apart FEV1 values is ≤ 150mL;

FVC repeatable when the difference between the two furthest apart FVC values is ≤ 150mL;

2.11 Performing oximetry

! WARNING

While performing tests, unplug the charger from spirolab.

! WARNING

Check that the oximetry function is available on the device you are using as it is optional on several models.

! WARNING

The description of the following sensor serves solely as an example. All the sensors described in section 1.2.4 can be used with the spirolab device. MIR does not recommend any particular sensor; the decision is left to the doctor's discretion. During oximetry tests, the spirolab device cannot be turned off. To turn it off, you have to interrupt an on-going test. This system prevents unwanted interruptions that might compromise the reliability of data.

To take a non-invasive reading of oxygen saturation SpO₂ and pulse rate, use the reusable finger sensor. This sensor is recommended for patients weighing over 20 Kg and with limited mobility or who remain still during tests; for tests carried out with the patient walking, other types of sensors that are less affected by movements of the hands are recommended.

To perform an oximetry test, proceed as follows:

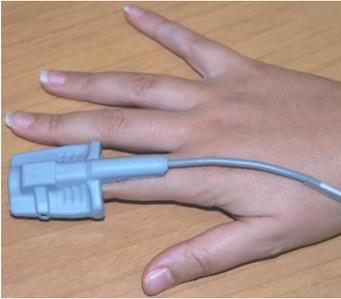
Connect the sensor to the device: insert the connector with the arrow facing up.

Choose a site with a good blood flow that is suitable for the sensor

Insert the finger all the way into the sensor. Make sure that the under part of the finger completely covers the detector. If you cannot position the finger properly, use a different finger.

Position the sensor so that the cable runs over the back of the hand. This ensures that the light source stays on the same side as the nails while the detector remains under the finger.





To enter the oximetry area, press  on the main screen. If the button is not enabled it means that your device is not equipped with the oximetry function.

 **WARNING**

If, before starting a test, the power supply is low, the following message will appear:

Low battery

In this case, press  to exit the test, otherwise the device will start the test a few seconds later.

If a test is interrupted for some unexpected reason, the next time the device is turned on, the following message will appear:

WARNING
the last oximetry test was improperly interrupted

At the same time, the device will beep intermittently for 4 seconds.
The spirolab will then display the main screen.

 **WARNING**

To avoid compromising the reliability of readings and to protect the sensor, do not twist the sensor cable without reason or use excessive force when using, connecting, disconnecting or putting away the oximeter sensor.

The first few seconds of a test are used for finding the strongest signal; once this has been found, the timer resets itself and the **spirolab** starts saving data.

If the sensor is not inserted correctly, icon  transforms into  and the icon  appears alongside it.

At the same time, the **spirolab** will beep (if set to do so in the service menu).

If the sensor has been inserted but the finger is not positioned correctly, the icon  transforms into  and the icon  appears alongside it. At the same time, the **spirolab** will beep (if set to do so in the service menu).

By tapping the  icon, you can pause the alarm for a few minutes. If the alert situation persists, after a few minutes the beeping resumes.

If the signal is received properly by the sensor, after a few seconds the device will begin to beep and display readings on the screen.

Alarms can be set for oximetry tests as explained in section 2.5.

If during a test, the %SpO₂ or BPM rate goes above or below its threshold, the **spirolab** emits a beep (if set to do so in the service menu) for as long as this anomaly continues.

WARNING

Tests are stored with the code of the last patient displayed; if this relates to a patient previously inserted, before carrying out the test retrieve a test carried out previously on the subject in question and proceed as described in paragraph 2.7.2.

During oximetry tests, the battery level is displayed. This lets you estimate how long the device will run for given the condition in which it is operating (display at maximum or energy saving mode).

To end a test, tap .

2.11.1 Instructions for using the sensor on adult patients

WARNING

The description of the following sensor serves solely as an example. Any of the sensors described in §1.2.4 can be used with the spirolab device MIR do not recommend any particular sensor; that decision is left to the doctor's discretion.

To monitor non-invasive readings of arterial blood oxygen saturation, we recommend the use of soft reusable sensors.

WARNING

The sensors are made from **PROTEIN FREE NATURAL LATEX** materials. The materials used in making the sensors have been subjected to stringent biocompatibility tests.

- Choose a suitable site for application on the patient's finger or toe that will allow the light source to line up directly with the detector. The preferred sites are the index finger or thumb.



- Remove any nail polish or false nails.
- Position the patient's finger in the sensor with the nail face up and place the pad of the finger over the detector. An imaginary line through the middle of the sensor should pass through the tip of the finger.
- Apply the adhesive tape to under part of the finger taking care not to cover the nail
- Fold the upper part of the sensor over the finger making sure that the light source is directly in line with the detector below it. Run the wire along the palm of the hand or sole of the foot and, if necessary, tape it in place.
- Connect the sensor to the device: insert the connector with the arrow (stamped on the connector) facing up and make sure that everything is working properly as described previously.

! WARNING

Do not twist the sensor cable without reason or use excessive force when using, connecting, disconnecting or putting away the oximeter sensor. If the sensor is fitted too tightly, it may create inaccurate saturation readings. We recommend using a sticking plaster to fix the sensor wire to the wrist.

3. DATA TRANSMISSION

! WARNING

Before beginning data transmission, read the instructions carefully and make sure you have fully understood them.

! WARNING

Bluetooth communication is considered an additional function. In the event of an interruption in transmission, we recommend the use of a more reliable USB port technology.

3.1 Data transmission via Bluetooth

Spirolab can be connected as a "slave device" to any other "master device". Therefore, you can connect **spirolab** to a PC or a mobile phone and control it using special applications.

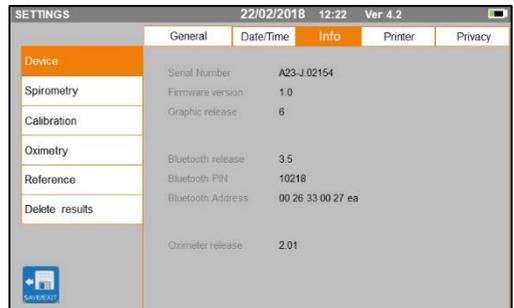
The connection uses the SPP (Serial Port Profile) protocol.
The following are required for such a connection to be made:

- **Spirolab** must have a Bluetooth feature (this feature is optional on some models).
- The "Bluetooth" setting must be set to "ON".

If these conditions are met, you can search for enabled devices from the "master" device.

Once **spirolab** has been identified, you will be prompted to enter your PIN; this information is found in the service menu in the "Device", "Info" section, as shown to the right.

Enter the value displayed and continue with the so-called "pairing" activity, i.e. pairing the **spirolab** "device" and the "master" device.



At this point, **spirolab** can use the connection via SPP (Serial Port Profile) protocol. For details on using the protocol, please contact the manufacturer.

Similarly, **spirolab** can be connected to a PC on which you have installed winspiroPRO. Once connected as described above, winspiroPRO becomes an interactive panel to control **spirolab**, and hence perform wireless "online" spirometry and oximetry tests that will be stored directly within the software.

3.2 Connecting with a PC via USB port

WARNING

Before connecting the spirolab to the PC via USB, you need to install the winspiroPro program that allows you interface with the device.

Before starting to use the following procedure it is important to know the version of the operating system on the PC you will be connecting with (click on "system" in the Control Panel to see information the installed OS).

If winspiroPRO has already been installed, the following actions are not necessary.

To make the connection, insert the micro USB connector supplied with the **spirolab** into the USB port on the PC.

When you first connect, your PC, depending on the operating system version in use, will automatically install the Microsoft certified driver. For more support at this stage, refer to the WinspiroPRO software manual.

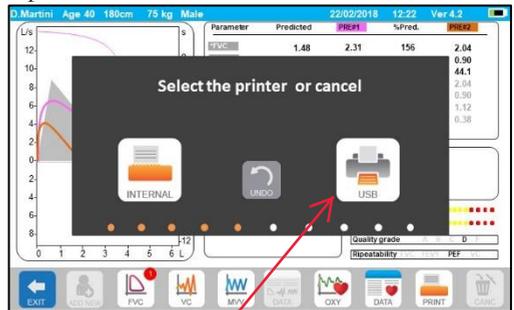


3.3 Printing data

Spirolab enables you to print both the last test performed and those stored in the archive.

To print the last test performed, retrieve the test using the icon  for spirometry or  for oximetry. When you have viewed the test, press the icon .

If in the service menu it was enabled the direct USB printing, then on the screen appears a banner which allows to choose the type of printer to use:



thermal printer

USB direct connection printer

1.1.12. USB tiesioginiam spausdintuvo pajungimui

Choose one function in 5 seconds (when all the balls become orange); if no function is selected, then after 5 seconds the thermal printed will start automatically.

If the direct USB printing is disabled, then touching the icon  will start automatically the thermal printer.

To print a test carried out in the past and stored in the archive, perform a search as described in section 2.7.1; once displayed, tap .

Also in this case it will appear the printing type: thermal printer or via USB connection.

The system prints the information selected in the "Spirometry" - "Results" settings.

3.4 Up-dating internal software

When the device is connected to a PC via the USB port, the **spirolab** internal software can be up-dated. Up-dates can be downloaded on registration from: www.spirometry.com. For further information about downloading up-dates, refer to the “winspiroPro” manual.

4. MAINTENANCE

WARNING

No part can be subjected to maintenance during use.

Spirolab devices need little maintenance. You should periodically:

- Clean and check reusable turbines
- Replacement disposable turbines at each test
- Clean the oximetry sensor (for reusable sensors)
- Recharge the internal battery pack

All the maintenance operations described in the User Manual must be carried out with great care. Failure to follow these instructions may lead to incorrect readings or the incorrect interpretation of readings that have been taken.

All modifications, adjustments, repairs and reconfigurations must be performed by the manufacturer or by personnel authorised by the manufacturer.

In the event of problems, do not attempt to make repairs.

The setting of configurable parameters must be performed by qualified staff. In no case does the incorrect setting of the device place a patient at risk.

4.1 Cleaning and checking reusable turbines

The volume and flow turbine sensors usable with **spirolab** are of two types: disposable and reusable. These guarantee great accuracy and have the added benefit of not needing to be periodically calibrated. A simple clean before every use will ensure that the turbine keeps working as it should (**only for reusable turbines**).

For disposable turbines, cleaning is not necessary as they are supplied clean and packaged in sealed envelopes. When you have finished using them, they should be discarded.

WARNING

It is good practice to periodically check that no impurities or foreign bodies such as skin or even worse, hairs have deposited inside the turbine. Such obstacles could slow or block the turbine blades and compromise the accuracy of readings.

Before every use, perform the test described in section 4.1.1 below that allows you to test the efficiency of the turbine. If the result is negative, act as follows.

To clean a **reusable** turbine, remove it from its housing in the MiniFlowmeter by turning it anti-clockwise and pulling gently. To facilitate removal, you can push the bottom of the turbine gently with a finger.

Soak the turbine in a cold liquid detergent and shake it so as to remove any impurities that have deposited inside; leave to soak for the period of time recommended by the detergent manufacturer that is shown in the instructions for use.

 **WARNING**

To avoid irreparable damage to the turbine, do not use alcohol or oil based detergent solutions and do not soak in water or hot solutions.

Never place the turbine in an autoclave. Do not sterilise the turbine.

Never clean the turbine under running water or spray with other liquids. If no liquid detergents are available, clean the turbine with at least clean water.

MIR recommends the use of Dupont Perasafe that has been tested on all MIR sensors.

Rinse the turbine by immersing it in clean water (**not hot**).

Shake off any excess water off the turbine. Leave the sensor to dry by placing it in an upright position on a dry surface.

Before re-fitting the turbine, check that it is working properly. It is good practice to visually check that the blades are moving freely. Place the turbine on its side and slowly move the blades left and right. They should rotate freely. If this is not the case, the accuracy of readings is no longer guaranteed and the turbine will have to be replaced.

On completion of cleaning, replace the turbine in its housing making sure that it is in the right position as shown by the closed padlock symbol on the MiniFlowmeter.

To insert the turbine correctly, push it fully in and turn it clockwise until it clicks into place inside the plastic housing.

To double check that the turbine is working correctly, repeat the checks described in 4.1.1; if the turbine is still problematic, replace it with another.

 **WARNING**

If disposable turbines are being used, do not perform any cleaning operations, but replace the turbine for a new patient.

4.1.1 Checking correct turbine function

- Turn the **spirolab** on and act as if you wanted to perform a spirometry test
- Take the MiniFlowmeter in one hand and move it slowly from right to left and vice versa so that air passes through the turbine,
- If the blades move correctly, the device will emit repeated beeps that vary in frequency with the flow of the air passing through

- If no beeps are emitted during this movement, clean the turbine.

4.2 Cleaning the oximetry sensor

The reusable oximetry sensor must be cleaned at every change of the patient, i.e. before applying it to a new patient.

Clean the sensor with a damp cloth containing water or a delicate soap solution. To disinfect the sensor, rub it with isopropyl alcohol. After cleaning, allow the sensor to fully dry.

Do not use abrasive or caustic agents to clean the sensor.

WARNING

**Do not sterilise by means of radiation, steam or ethylene oxide.
Always disconnect the sensor before cleaning or disinfection.**

Spirolab sensors are latex free.

4.3 Recharging the battery pack

WARNING

To charge the battery pack, only use the charger supplied by the manufacturer.

When the **spirolab** device is turned on, an icon shows the condition of the battery in the top right hand corner:



The maximum charge level is reached when the symbol is completely green.

If only part of the symbol is green or if the device doesn't turn on, you will need to recharge the battery pack as follows:

- Connect the battery charger to both the connector and the mains supply. A blue LED will light up in the lower right-hand corner.
- When charging is completed, the LED will turn green.



- When charged, disconnect the battery charger from the device and from the mains.

! WARNING

Do not use the device when it is recharging Always disconnect the charger when recharging has been completed

4.4 Replacing the thermal paper

The following procedure describes the steps to perform in order to replace in the correct way the thermal paper roll.



1) Open the lid of the thermal paper compartment and remove it from the device.
Remove the paper roll holder.



2) Insert the new roll of paper onto the paper roll holder and guide the thermal paper into the slots for the roller holder

3) Push the paper into the slot located under the traction reel (black rubber reel on the thermal printer); A sensor detects the paper and will automatically advance it.



If necessary make the paper advance by pressing the icon



on the touch screen. When done, press OK icon.



4) Slide the paper through the slot on the lid of the thermal paper compartment. Close the lid of the compartment

 **WARNING**

Operator shall not touch simultaneously the patient and the parts of non-medical equipment that are accessible to the operator during routine maintenance after removal of covers without the use of a tool.

5. TROUBLE SHOOTING AND SOLUTIONS

PROBLEM	MESSAGE	POSSIBLE CAUSE	SOLUTION
spirolab doesn't turn on	\	Battery pack may be flat	Charge the device using the charger unit
	\	The device may have lost internal software	Connect the device to a PC via USB and up-date the software; for further information, consult the online winspiroPRO User Manual
Message during switch on	Too many attempts for today	The user has exceeded the maximum number of attempts to insert the pin	Wait for the next day. The number of attempts will be resetted.
Message when the privacy info is enabled	To comply with privacy policy please update all connected devices	The privacy info is enabled	The message advises the user to update the software winspiroPRO installed on the PC to comply with privacy policy
Problems turning the device on	Ram error data recovery Please wait	The data in the device memory has been damaged	If the data has been correctly restored, the last standard turning on process will be repeated; if not, contact an authorised assistance centre or the manufacturer.
The device turns itself off then reboots while being used.	\	There is an internal error	Check ww.spirometry.com to see if an up-dated version of the software is available; if this is the case, download the software then up-date the device with the latest software winspiroPRO version. For further information, consult the online winspiroPRO User Manual.
	\	The turbine may be dirty	Clean the turbine as described in section 4.1; if necessary, replace the turbine with a new one
On completion of spirometry tests, the readings are not credible	\	The test was performed in the wrong manner	Repeat the test following the instructions shown on the screen

PROBLEM	MESSAGE	POSSIBLE CAUSE	SOLUTION
On completion of a spirometer test, some parameters are not displayed	\	Personalised parameter settings in the service menu	Check the heading parameter settings in the "Spirometry", "Parameters" section of the service menu as described in section 2.5
During an oximeter test the readings displayed are irregular, intermittent or wrong	\	The sensor is wrongly positioned or the patient's perfusion is poor	Reposition the oximeter sensor
	\	The patient moved	For accurate results, the patient must not make any sudden movements.
The display is not very bright during tests	\	The brightness level of the display automatically dims 5 minutes after a test starts. This function extends battery life	None
Problems with charging the battery pack	Defective battery	The battery pack is damaged or wrongly positioned	Contact technical services
Unforeseen memory error	Error in memory	The data stored in the archive have been damaged	Contact technical services
The device will freeze when unforeseen events occur	\	\	Press the on button 3 times; wait a few seconds and the device will reset then turn itself on,

 **WARNING**

Before contacting the service centre, if possible, download the device archive to the PC using the winspiroPRO program. This is necessary as the data may be lost during repair activities and also to protect the patient's privacy, as neither the manufacturer nor authorised personnel are allowed to see such data.

GUARANTEE CONDITIONS

The **spirolab** device and authorized accessories are guaranteed for a period of:

- 12 months in the case of professional use (doctor, hospital, etc.)
- 24 months where the product has been purchased by a patient for private use.

The guarantee takes effect from the date of purchase shown on the invoice or other document.

The guarantee period starts from the date of sale that must be confirmed by an invoice or sales receipt.

The product must be checked at the time of purchase or upon receipt and the manufacturer must be informed immediately of any complaints.

The guarantee covers repair, or (at the manufacturer's discretion) replacement of the product or defective components without any cost for labour or spare parts.

The batteries and components subject to wear and tear, including the reusable turbine, are excluded from the terms of this guarantee.

At the manufacturer's discretion, the guarantee does not apply to the following cases:

- Uses that are incorrect, improper or do not conform to the technical or safety standards in force in the country where the product is being used.
- Use of the product for purposes that differ from those in the Instructions for Use or failure to observe such instructions.
- Repair, adaptation, modification or manhandling by personnel who have not been authorised by the manufacturer.
- Damage caused by a lack of or by incorrect maintenance
- Damage caused by physical or abnormal electrical stress
- Damage caused by faults in the electrical systems or in items of equipment to which the device has been connected.
- Series number modified, erased, removed or obliterated.

The repairs and replacements mentioned in the guarantee take place on goods that have been returned to our authorised service centres. For further information about service centres, please contact your local distributor or the manufacturer.

The customer is responsible for the costs incurred for shipping, customs and the delivery of goods.

Every product or component part thereof sent for repair must be accompanied by a clear and detailed explanation of the fault. If the product or component part thereof is to be

sent to the manufacturer, this must be authorised in writing or by phone beforehand by the manufacturer.

MIR Medical International Research reserves the right to replace the product or make any changes to it that the company deems necessary.

Andrius Bardauskas

From: Remigijus Stankevičius
Sent: trečiadienis 2023 m. balandis 5 15:40
To: Andrius Bardauskas
Subject: FW: Spirolab issues

Pagarbiai,

Remigijus Stankevičius

From: Laura Precetti <laura.p@spirometry.com>
Sent: 2023 m. balandžio 4 d., antradienis 17:13
To: Remigijus Stankevičius <Remigijus.Stankevicius@medita.it>
Subject: R: Spirolab issues

Dear Remigijus,

sure, I hope to be helpful! :-)

[redacted] confirm you that they are the same parameters but written with a different spelling.

Please, let me know some details more about the new ongoing tenders: opening date, quantity requested, MIR model quoted..

Thank you and if you have further doubts, please ask me.

Best Regards

Laura Precetti
Export Area Manager
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MIR will be closed from Friday, April 7 to Monday, April 10



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