

Spirolab



User manual Rev. 3.2

Date issued 05.06.2025
Date approved 05.06.2025

ENGLISH (EN)

CE
0476

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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	Ukrainian
French	Brazilian	Chinese	
German	Polish		

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

REF	Description	
672684	Carrying case	✓
532367	USB cable	✓
910350	Thermal printer paper	✓
920660	Battery charger	✓
900595	MiniFlowmeter	✓
910002	Reusable Turbine	○
910004	FlowMir disposable turbine with cardboard mouthpiece	✓
919024	Oximetry Sensor	○

✓ included

○ optional

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 MIR Spiro software available on the MIR website. 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

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:

- spirometry tests for all patients older than three years.
- 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.

Spirometry testing has the following contraindications according to the information described in the ATS/ERS guidelines 2019 update:

- Acute myocardial infarction within 1 wk
- Systemic hypotension or severe hypertension
- Significant atrial/ventricular arrhythmia
- Noncompensated heart failure
- Uncontrolled pulmonary hypertension
- Acute cor pulmonale
- Clinically unstable pulmonary embolism
- History of syncope related to forced expiration/cough

- Cerebral aneurysm
- Brain surgery within 4 wk
- Recent concussion with continuing symptoms
- Eye surgery within 1 wk

Sinus surgery or middle ear surgery or infection within 1 wk

- Presence of pneumothorax
- Thoracic surgery within 4 wk
- Abdominal surgery within 4 wk
- Late-term pregnancy

Active or suspected transmissible respiratory or systemic infection, including tuberculosis Physical conditions predisposing to transmission of infections, such as hemoptysis, significant secretions, or oral lesions or oral bleeding

WARNING

When the spirolab device is used as an oximeter with limited alarm settings, the SpO2 and Pulse Rate shown on the display should 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 Regulation UE 2017/745 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 or 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.

The device should not be used beyond the declared lifetime. In normal working conditions, this is equal to approximately 10 years.

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.

It is necessary to report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established, in accordance with Regulation 2017/745.

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.

1.2.2 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 turbines.

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

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 carboxyhaemoglobin 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 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.

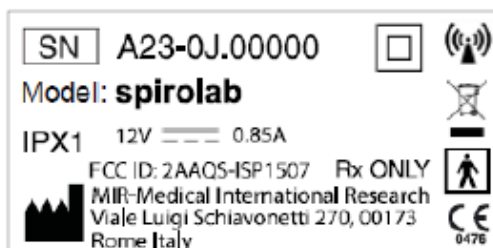
In particular, as far as electromagnetic immunity is concerned, Spirolab was tested as specified in Table 9 “Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment” of IEC 60601-1-2:2014, below, and as described in IEC 61000-4-3.

Test level		
Field	Modulation	Frequency
3V/m	AM 80% 1kHz	80MHz-1GHz
27V/m	PM 50% 18Hz	380MHz-390MHz
28V/m	PM 50% 18Hz	430MHz-470MHz
9V/m	PM 50% 217Hz	704MHz-787MHz
28V/m	PM 50% 18Hz	800MHz-960MHz
3V/m	AM 80% 1kHz	1GHz-2,7GHz
28V/m	PM 50% 217Hz	1,7GHz-1,99GHz
28V/m	PM 50% 217Hz	2,4GHz-2,57GHz
9V/m	PM 50% 217Hz	5,1GHz-5,8GHz

For each frequency band, tests were performed with a vertically and horizontally arranged antenna.

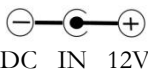
1.3 Labels and symbols

1.3.1 Identification label



The symbols are described in the table below:

SYMBOL	DESCRIPTION
Model	Product name
SN	Device serial number

SYMBOL	DESCRIPTION
	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 Regulation EU 2017/745
	Electrical safety symbol: as per IEC60601-1, the product and its component parts are typing 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
	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.
	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 FW8000/12
	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
	The symbol indicates that the product is a medical device
	The symbol indicates the Unique Identification of the Device
	The symbol indicates the device must not be exposed to direct sunlight
	The symbol indicates that the device must be kept dry
	Direct current

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 A digital instrument as per section 15 of the FCC Standards. These limits are designed to provide reasonable protection against harmful interference when the equipment is

operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

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	600-7000 Volts
Worker at a table	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; 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 are 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 the 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.

Following is a representative schematic of components and ports of the device:





- (1) Thermal Paper
- (2) Display
- (3) Mini USB Port
- (4) Power Button
- (5) MiniFlowmeter
- (6) Disposable Turbine “FlowMIR”
- (7) SpO2 port
- (8) MiniFlowmeter port
- (9) USB port
- (10) RJ45 port
- (11) DC IN 12V port

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 and 2019 update
- ISO 23747: 2015
- ISO 26782: 2009

Parameters measured:

Symbol	Description	U.m.
*FVC	Best FVC	L
*FEV1	Best FEV1	L
*PEF	Best PEF	L/s
FVC	Forced Vital Capacity	L
FEV1	Volume exhaled in 1 st second of the test	L
FEV1/FVC	FEV1/FVC x100	%
FEV1/VC	FEV1/ best between EVC and IVC x 100	%
PEF	Peak expiratory flow	L/s
PEF Time	Time to achieve 90% of the PEF	s
FEF-2575	Median flow between 25% and 75% of FVC	L/s
FEF7585	Median flow between 75% and 85% of FVC	L/s
FEF25	Maximum flow at 25% of FVC	L/s
FEF50	Maximum flow at 50% of FVC	L/s
FEF75	Maximum flow at 75% of FVC	L/s
FEV05	Volume exhaled after 0.5 seconds	L
FEV05/FVC	FEV05/FVC x 100	%
FEV075	Volume exhaled after 0.75 seconds	L
FEV075/FVC	FEV075/FVC x 100	%
FEV2	Volume exhaled in the first 2 seconds of the test	L

Symbol	Description	U.m.
FEV2/FVC	FEV2/FVC x 100	%
FEV3	Volume exhaled in the first 3 seconds of the test	L
FEV3/FVC	FEV3/FVC x 100	%
FEV6	Volume exhaled in the first 6 seconds of the test	L
FEV1/FEV6	FEV1/FEV6x100	%
FEV1/PEF	FEV1/PEF (empey's index)	L/L/s
FEV1/FEV0.5	FEV1/FEV0.5	\
FET	Forced exhalation time	s
EVOL	Extrapolated volume (also VEXT or BEV)	mL
FIVC	Forced Inhalation Vital Capacity	L
FIV1	Volume inspired in the 1 st second	L
FIV1/FIVC	FIV 1%	%
PIF	Peak inspiratory flow	L/s
FIF25	Maximum flow at 25% of FIVC	L/s
FIF50	Maximum flow at 50% of FIVC	L/s
FIF75	Maximum flow at 75% of FIVC	L/s
FEF50/FIF50	FEF50/FIF50 x 100	%
MVVcal	Max. voluntary ventilation calculated based on FEV1	L/s
VC	Slow Expiratory Vital Capacity	L
EVC	Expiratory Vital Capacity	L
IVC	Inspiratory Vital Capacity	L
IC	Inspiratory capacity: (maximum between EVC and IVC) -ERV	L
ERV	Expiratory reserve volume	L
IRV	Inspiratory reserve volume	L
VT	Tidal Volume	L
VE	Minute ventilation at rest	L/min
RR	Respiratory frequency	Breaths/min
t _i	Average inspiratory time at rest	s
t _E	Average exhalation time at rest	s
TV/t _i	Mean inspiratory flow at rest	L/min
t _i /t _{TOT}	t _i /(t _i +t _E)	\
MVV	Maximum voluntary ventilation	L/min
ELA	Estimated Lung Age	years

*= 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		Reusable paediatric soft sensor	
Range (SpO ₂)	Arms (%)	Range (SpO ₂)	Arms (%)
70-100 %	± 1.470	70-100 %	± 1.390
70-80 %	± 1.626	70-80 %	± 1.851
80-90 %	± 1.667	80-90 %	± 1.397
90-100 %	± 0.941	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.

Any SpO₂ simulators should not be used to validate the accuracy of the oximeter, they can only be used as functional testers to verify its accuracy and alarm system (when needed).

Definitions

Desaturation event	Drop in SpO ₂ $\geq$ 4% in a 8- 40 sec period limited and subsequent rise $\geq$ 2% inside an overall period of 150 sec.
Pulse variation event	Rise in Pulse $\geq$ 10 BPM in a 8- 40 sec limited period and subsequent drop $\geq$ 8 BPM inside an overall period of 150 sec.

Oximetry test parameters:

Symbol	Description	u. m.
%SPO ₂ min	Minimum SPO ₂ during the test	%
%SPO ₂ max	Maximum SPO ₂ during the test	%
BPM min	Minimum BPM during the test	BPM
BPM max	Maximum BPM during the test	BPM
Median %SPO ₂	Median SPO ₂	%
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 SpO ₂ less than 90%	%-hh:mm:ss
T<89%	Time with SpO ₂ less than 89%	%-hh:mm:ss
T5	Time with SpO ₂ 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% SpO ₂
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	$\pm$ 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.

1.5.3 Oximetry alarms description

Spirolab is equipped with audio and visual alarm indicators to alert the operator to provide prompt patient attention or to abnormal device conditions. **Spirolab** detects both patient and equipment alarms. Both, patient alarms and equipment alarms are identified as **medium priority** as defined in IEC 60601-1-8 standard.

Medium Priority Alarms

Medium priority alarms signal potential problems with the equipment or other non-life-threatening situations. Medium priority auditory alarms are sounded as three beeps.

The intended operator's position for correctly perceiving a visual alarm signal is 1 meter.

Alarm Summary

Spirolab detects both patient and equipment alarms. Alarm indicators remain active for as long as the alarm condition is present.

WARNING

Verify all alarm settings and limits before oximetry test starts to ensure that they are set as intended. Setting ALARM LIMITS to extreme values can render the ALARM SYSTEM useless. A hazard can exist if different presets are used on multiple devices in one care area.

The alarm system provides **medium priority** alarm conditions for:

- Low and high SpO₂ level;
- Low and high Pulse Rate level;
- Sensor disconnected;
- Finger is not positioned properly
- Low battery level.

Each alarm condition causes the generation of a **visual alarm** signal. The oximetry tests are intended not to be continuously attended by an operator in normal use, so additional **auditory alarm** signals are generated.

Patient (physiological) Alarms

If patient SpO₂ or pulse readings are equal to or above the upper alarm limit, or if they are equal to or below the lower alarm limit, the device will signal a medium priority alarm.

Patient Alarm Description	Factory default	Adjustment Options	Increment
SpO ₂ High Alarm Limit	99%	85-99%	1%
SpO ₂ Low Alarm Limit	85%	85-99%	1%
Pulse Rate High Alarm Limit	120 bpm	30-240 bpm	1 bpm
Pulse Rate Low Alarm Limit	60 bpm	30-235 bpm	1 bpm

Equipment (technical) Alarms

- Sensor disconnected;
- Finger not inserted
- Low battery level.

Visual Alarm Indicator

When the alarm is activated through over limitation of physiological alarm, corresponding data area will view in reverse (video) mode. When the alarm is activated by more than one physiological alarm condition, each parameter will be displayed in reverse mode. If the alarm is triggered by a technical condition, the relevant warning message is displayed, for example:

WARNING
FINGER not inserted

Auditory Alarm Indicator

Audible alarms can be heard in a quiet environment. The medium priority audible alarm has a "u-du-du" tone that repeats every 5 seconds. The acoustic alarm signal can be temporarily disabled while an alarm condition is in progress. The duration of the paused audio, the time interval in which the alarm system or part of the alarm system does not generate an audible alarm signal, is a maximum of 2 minutes.

The sound pressure level of the alarm tone is about 55 dB, in complies with the standard.

Other beeps (acoustic signals):

- Pulse tone, beeps at frequency depending on Pulse rate
- 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.

1.5.4 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	Standard 5.0
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 FW8000M/12 (Friwo 12 W medical power supply)
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 + 75 °C

	Humidity: MIN 10% RH; MAX 95%RH Atmospheric pressure: 50kPa, 106 kPa
Transport conditions	Temperature: MIN -40 °C, MAX + 75 °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 + A2:2020 IEC 60601-1-2:2014 + A1:2020 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-8:2007/A1:2012 IEC 60601-1-9:2007 + A1:2013 ISO 80601-2-61: 2017 ATS/ERS Guidelines: 2005, 2019 update ISO 26782: 2009 ISO 23747: 2015 ISO 14971: 2019 ISO 10993-1: 2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 62366-1:2015 + A1:2020 IEC 62304:2006 + A1:2015 Directive 2014/53/UE RED IEC 62311:2019
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 Oximetry specification"
Emission limits	CISPR 11 Group 1 Class A*
Electrostatic discharge protection	8kV contact, 15kV air
Magnetic field immunity	30 A/m
Radio Frequency Immunity	3V/m @ 80-2700 MHz

*The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

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

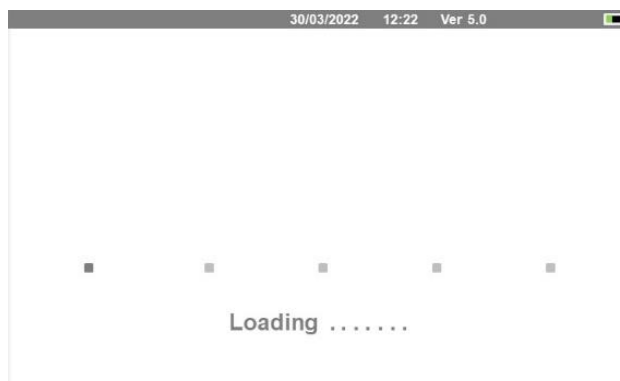
To turn the **spirolab** on, press then release the button on the front of the unit.



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.

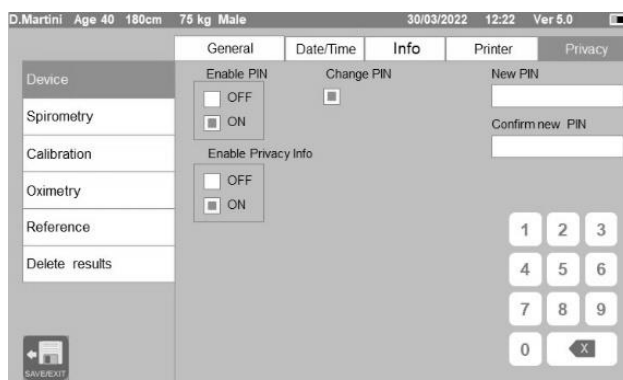


Pressing OK then a message requires to confirm the use of a PIN: press OK to continue or Undo to skip this function.



- 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**

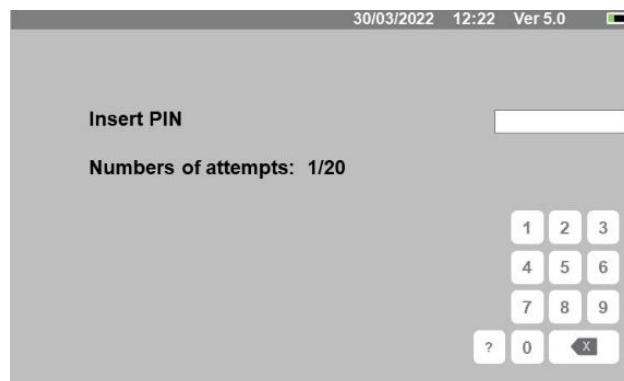


- Press  to return to the main screen.

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.

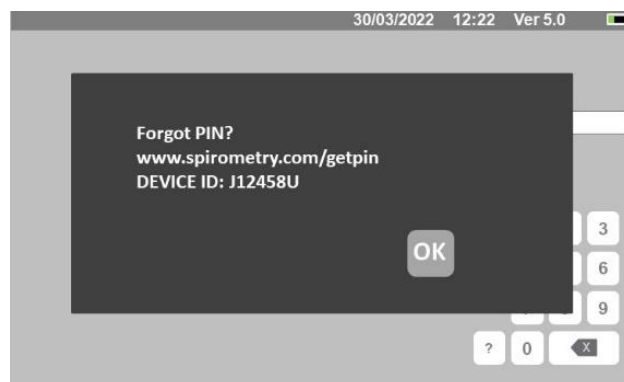


If the user forgot the PIN send an inquiry to the following website:

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 settings during an oximetry test
	To indicate the oximetry sensor is properly connected during testing
	To indicate that the finger is inserted properly.
	Acoustic alarm alert active. Press to mute for 2 minutes
	To print a test
	To delete a test
	To cancel an operation
	To reverse the paper feed direction (counterclockwise direction)

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.

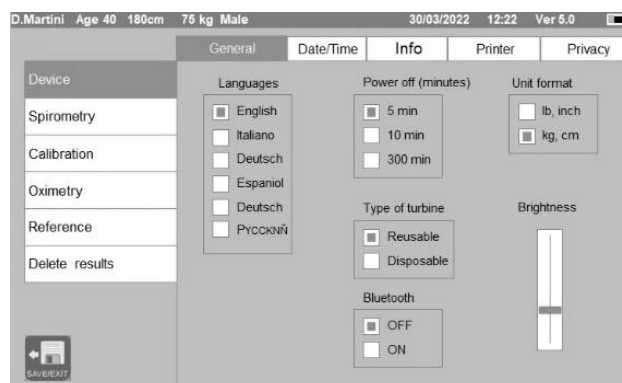
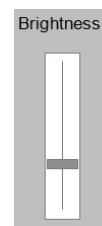
Device

The section is divided into:

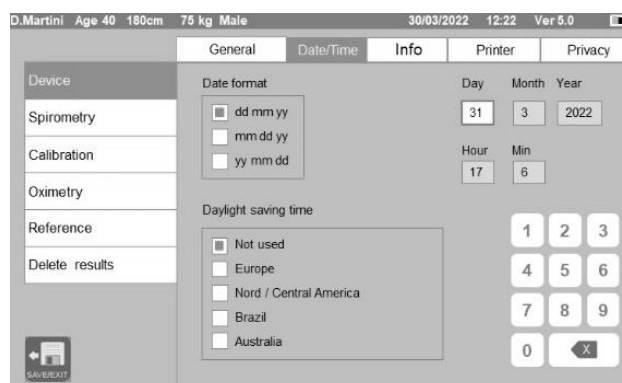
- General
- Date/Time
- Info
- Printer
- Privacy

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.



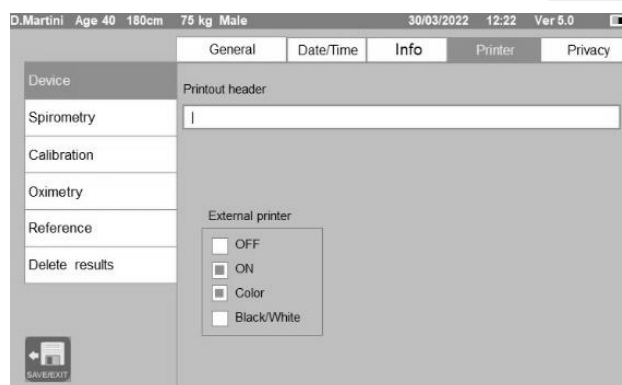
To set the correct date and time, tap the box to bring up the cursor; use the numeric keypad on the lower right to set the correct value. The area “Daylight saving time” allows to set the automatic time change depending on the geographic area which you stay. The device recognizes the date changes until 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.



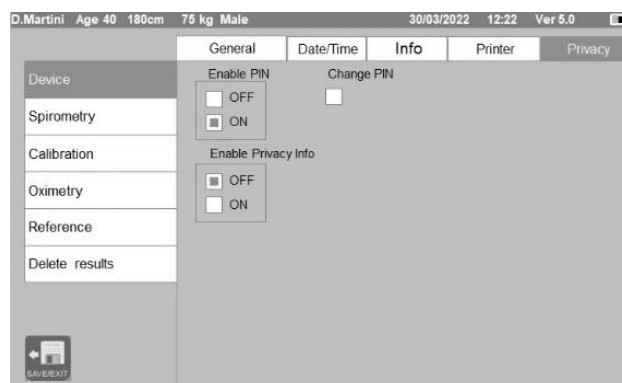
In the "Privacy" section the user can enable or disable:

- the PIN
- the Privacy information

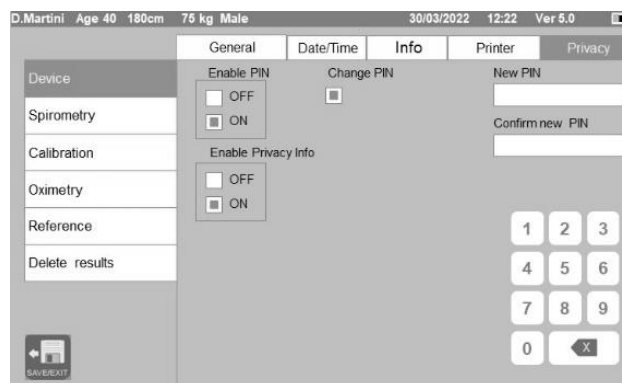
The device has a **default PIN** set, which is the following:

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.

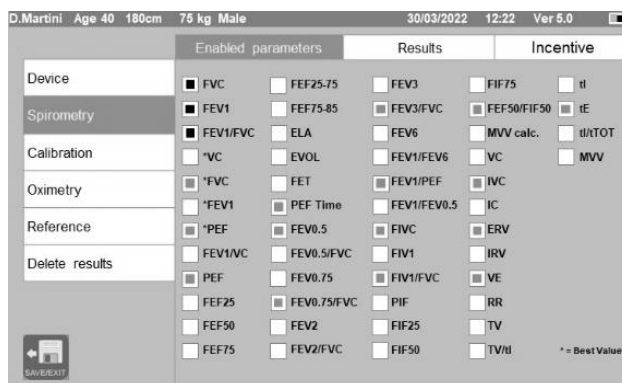


Spirometry

The section is divided into:

- Parameters
- Outcome
- Incentives

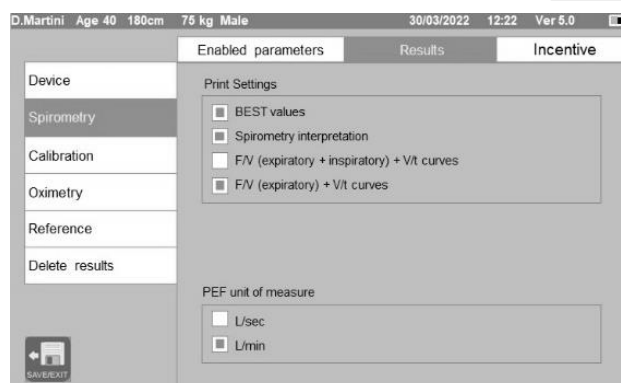
In the "Parameters" section, you can select the values that will be displayed at the end of a test; these will be stated on the printout. Here too, the selection is highlighted by an orange box.



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

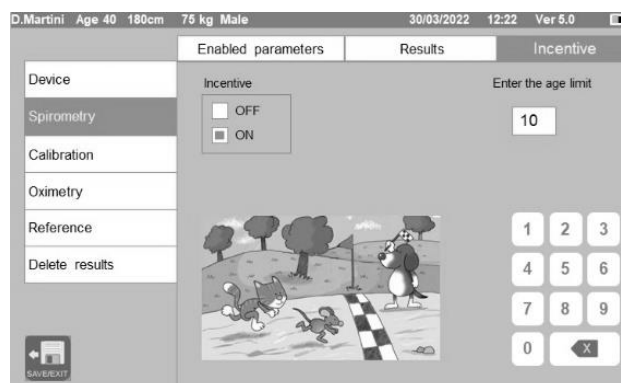
- Best values
- Interpretation of spirometry results
- F/V (expiratory + inspiratory) and V/t curves
- F/V expiratory only curve and V/t curves

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.



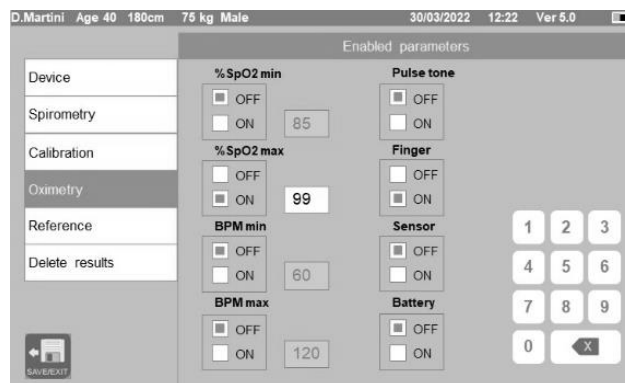
Calibration

For calibration, see paragraph 2.5.1 below.

Oximetry

Access to these settings is **password protected** and it is possible to configure both the physiological alarms - the lower and upper threshold values of the SpO2 and Pulse Rate parameters - and the technical alarms

By setting the physiological alarms to "ON", the box is enabled to set the 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
ERS	Knudson
Knudson	Knudson
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
 - In the syringe maneuver, the flow must enter within the red lines.
 - you start with a very low flow
 - intermediate flow
 - high flow until the red lines are covered.

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

Then tap .

by setting the **Syringe value** for example 300 (cL) shows the following screen

Set by entering the data related to the parameters:

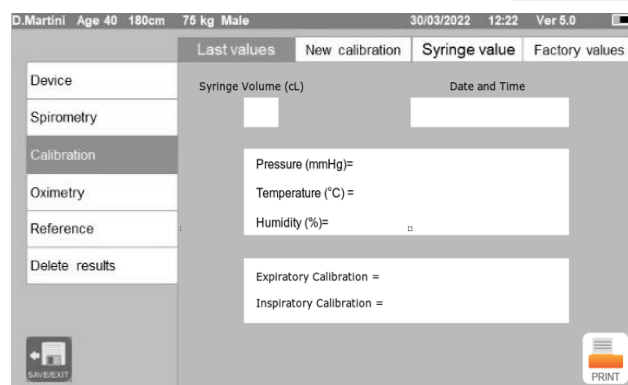
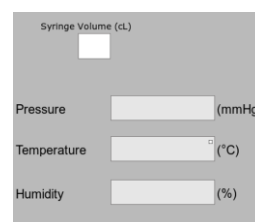
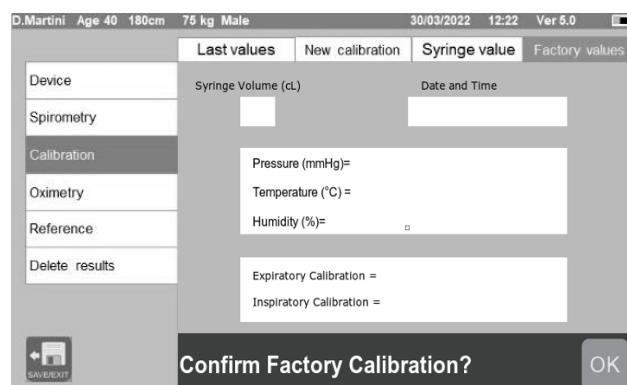
- Pressure
- Temperature
- Humidity

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 MIR Spiro software. For details about the calibration procedure using this software, refer to the MIR Spiro 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 mandatory. Tap the grey space to access the various fields and make entries using the virtual keyboard on the screen. Selecting "Personal Best" the patient will be managed using the special predicted values defined by the physician; for ore details concerning the Personal best management, please refer to additional information at the end of this point.

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	
Group	% correction
No group selected	100%
Caucasian	100%
Oriental	100%
Hong Kong Chinese	100%
Japanese	89%
Polynesian	90%
North Indian	90%
South Indian	87%
Pakistani	90%

NHANES III standards	
Caucasian	
Afro-American	
Mexican-American	
Others	

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

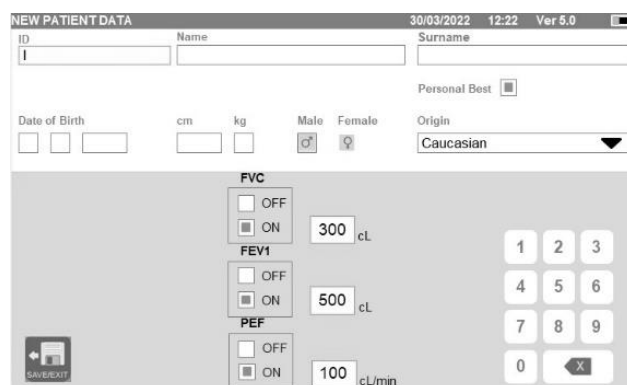
In the case of NHANES III standards: depending on the ethnic group set, different predicted formulae are taken into account (in accordance with the reference standard).

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.

Setting the Personal Best value for the patient the physician can define the predicted values for FVC, FEV1 and PEF parameters. The following screen will be enabled, where it will be possible to set which parameter manage with Personal Best and the value.

When Personal Best are enabled the print reports show a dedicated area describing which parameters are enabled.



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.

! WARNING

The physician can modify the “Personal Best” management enabling or disabling the “Personal Best”. The new settings will be applied only to the new session. Data in archive are not modified.

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.

If FVC, FEV1 or PEF are highlighted in red in the results area this means that they are set in with "Personal best" predicted values. The Personal Best setting can be found on the header row next to patient data ("PB" after patient gender).

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.

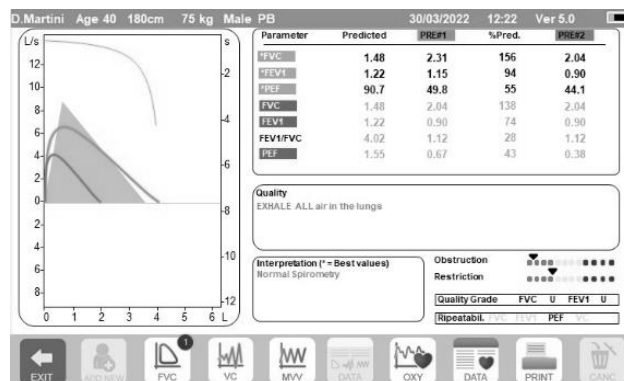
At each screen, you can go back to the previous step by tapping .

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 oximetry 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 oximetry).

2.7.3 Displaying the last test session

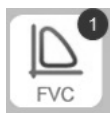
During test sessions, the spirometer automatically saves up to 8 FVC tests. From the main screen, using the icon:

-  in the case of spirometry tests

-  in the case of oximetry 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.

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 directly operated. The settings on the PC are transferred to the device and remain active any other time you use the device directly. 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, until the device is restarted. 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 test 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. 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:

Select patient to perform POST BD test						30/03/2022	12:22	Ver 5.0
#ID	Name	Birth date	cm	kg	Gender			
12587	D. Martini	05 / 05 / 1985	178	80	Male			
FVC(2), VC(1), MVV						RESTRICTION		
15945523 a	K. Brown	05 / 05 / 1956	158	59	Female			
FVC(2), OXY(1)						MIXED		

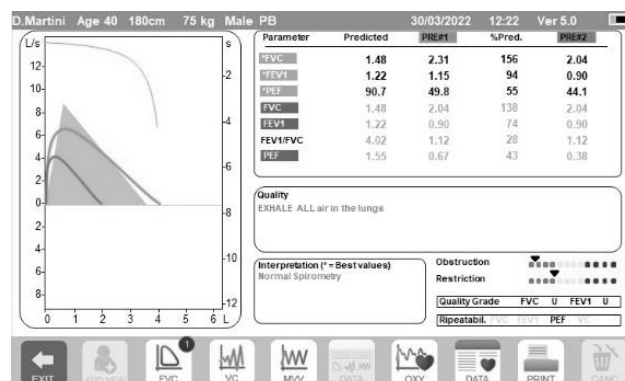
- The values for the test performed;
- The values of the best PRE test performed by the same patient on the same day (i.e. in the same session);
- The percentage change between PRE and POST values (in the column labelled CHG).

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 acceptable 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 Acceptability, Repeatability and quality messages

Acceptability, usability, and repeatability of FVC and FEV1 parameters for each single test are defined as summarized in Table 7 of the ATS/ERS 2019 guideline:

For FEV1 and FVC	Required for Acceptability		Required for Usability	
Acceptability and Usability Criterion	FEV1	FVC	FEV1	FVC
Must have EVOL (VEXT or BEV) <5% of FVC or 0.100 L, whichever is greater	YES	YES	YES	YES
Must have no cough in the first second of expiration*	YES	NO	YES	NO
Must have no glottic closure in the first second of expiration*	YES	YES	YES	YES
Must have no glottic closure after 1 second of expiration	NO	YES	NO	NO
Must achieve one of these three end of forced expiration (EOFE) indicators: 1. Expiratory plateau (<0.025 L in the last 1 second of expiration) 2. Expiratory time >15 seconds 3. FVC is within the repeatability tolerance of or is greater than the largest prior observed FVC †	NO	YES	NO	NO
Must have no evidence of obstructed mouthpiece or spirometer	YES	YES	NO	NO
Must have no evidence of a leak	YES	YES	NO	NO
If the maximal inspiration after EOFE is greater than FVC, then FIVC - FVC must be <0.100 L or 5% of FVC, whichever is greater‡	YES	YES	NO	NO
Repeatability criteria (applied to acceptable FVC and FEV1 values) Age > 6 years: The difference between the two largest FVC values must be <0.150 L, and the difference between the two largest FEV1 values must be <0.150 L Age ≤ 6 years: The difference between the two largest FVC values must be <0.100 L or 10% of the highest value, whichever is greater, and the difference between the two largest FEV1 values must be <0.100 L or 10% of the highest value, whichever is greater Abbreviations: EVOL (VEXT o BEV) = back-extrapolated volume; EOFE = end of forced expiration; FEV075 = forced expiratory volume in the first 0.75 seconds. The grading system (above Table 10) will inform the interpreter if values are reported from usable maneuvers not meeting all acceptability criteria. *For children aged 6 years or younger, must have at least 0.75 seconds of expiration without glottic closure or cough for acceptable or usable measurement of FEV0.75. † Occurs when the patient cannot expire long enough to achieve a plateau (e.g., children with high elastic recoil or patients with restrictive lung disease) or when the patient inspires or comes off the mouthpiece before a plateau. For within-maneuver acceptability, the FVC must be greater than or within the repeatability tolerance of the largest FVC observed before this maneuver within the current prebronchodilator or the current post-bronchodilator testing set. ‡ Although the performance of a maximal forced inspiration is strongly recommended, its absence does not preclude a maneuver from being judged acceptable, unless extrathoracic obstruction is specifically being investigated. The design of MIR spirometers with turbine is such that they are not subject to faulty zero-flow setting.				

For VC test the acceptability criteria according to ATS/ERS 2019 guideline is defined as follows: the VC test is considered acceptable if there is less than a 0.025 L volume increase over 1 second; in this case the test is deemed as having a plateau.

The Repeatability criteria in case of VC test is defined as follows:

Number of tests	3 acceptable tests are required
VC	The difference in VC between the largest and next largest manoeuvre must be ≤ smaller of the following: 0.150 L or 10% VC, for patient older than 6 years of age Or 0.100 L or 10% VC. For those aged 6 years or younger Otherwise, additional trials should be performed.

After each maneuver, ATS/ERS 2019 guideline provides a quality messages based on acceptability criteria define in table 7 of ATS/ERS 2019 guideline, as follows:

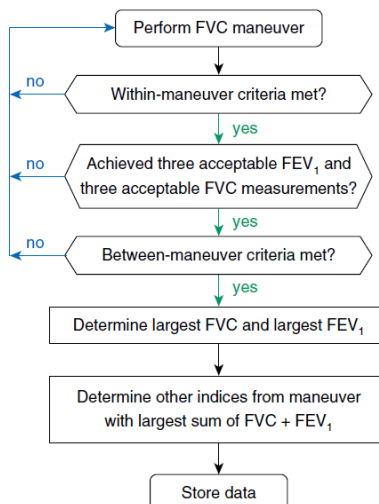
Warning message	Warning trigger	Instruction to patient
No plateau	no plateau and expiration < 15 s	keep going until completely empty
Hesitant start	EVOL (VEXT o BEV) exceeds limit	blast out immediately when completely full
Slow start	rise time > 150 ms	blast out immediately when completely full
Abrupt stop	suspected glottis closure	if you feel your throat closing, relax, but keep pushing
Cough in expiration	suspected cough in first second of expiration	try having a sip of water before the next blow
Hesitation at maximum volume	hesitation time > 2 s	blast out when completely full
Slow filling	mean inspiratory flow of the breath just prior to forced expiration is less than 2 L/s	breathe in faster before blasting out
Low final inspiration	FIVC < 90% FVC	after completely emptying your lungs, remember to

Warning message	Warning trigger	Instruction to patient
		breathe in - back to the top
Incomplete inspiration	FIVC < FVC	fill your lungs completely before blasting out – take the deepest breath possible

⚠ WARNING

The best test with the criteria defined in the ATS 2019 guideline is not considered to be the one with the best FVC+FEV₁ sum, but is chosen within those tests that meet the acceptability criteria of the above-mentioned guideline. Therefore, it is chosen in the context of those tests that did not provide error messages.

The following table defined in the ATS 2019 guideline defines the test selection criteria for acceptability and repeatability.



Further consideration and management of particular cases are detailed in the ATS/ERS 2019 guideline.

The quality grade of a test session is expressed with a letter, which separately refers to FVC and FEV₁, as described in Table 10 of the ATS/ERS 2019 guideline:

Grade	Number of Measurements	Repeatability: Age > 6 years	Repeatability: Age < 6 years*
A	≥ 3 acceptable	Within 0.150 L	Within 0.100 L*
B	2 acceptable	Within 0.150 L	Within 0.100 L*
C	≥ 2 acceptable	Within 0.200 L	Within 0.150 L*
D	≥ 2 acceptable	Within 0.250 L	entro 0.200 L*
E	≥ 2 acceptable or 1 acceptable	> 0.250 L N/A	> 0.200 L* N/A
U	0 acceptable AND ≥ 1 usable	N/A	N/A
F	0 acceptable AND 0 usable	N/A	N/A

The repeatability grade is determined for the set of prebronchodilator maneuvers and the set of post-bronchodilator maneuvers separately. The repeatability criteria are applied to the differences between the two largest FVC values and the two largest FEV₁ values. Grade U indicates that only usable but not acceptable measurements were obtained. Although some maneuvers may be acceptable or usable at grading levels lower than A, the overriding goal must be to always achieve the best possible testing quality for each patient. Adapted from *Am. J. Respir. Crit. Care Med.* 2017;196:1463–1472.

*Or 10% of the highest value, whichever is greater; applies for age 6 years or younger only

2.10.2 Interpreting spirometry results

The interpretation of spirometry refers to Forced Vital Capacity (FVC) and is seen by means of indicator lighting. This interpretation is calculated on the best manoeuvre according to the ATS /ERS 2019 guideline.

The messages can include the following:

- ◆ Normal spirometry
- ◆ Light 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.

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.

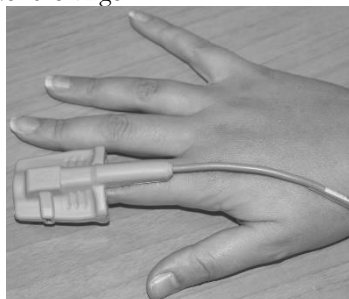
To perform an oximetry test, proceed as follows:

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.

When one of the activated alarm conditions occurs, Spirolab emits an acoustic signal and the icon is displayed on the screen  which if touched allows to mute the acoustic signal for 2 minutes, which will resume sounding if the alarm situation persists.

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).

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.

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 MIR Spiro Software.

The connection uses the SPP (Serial Port Profile) protocol.

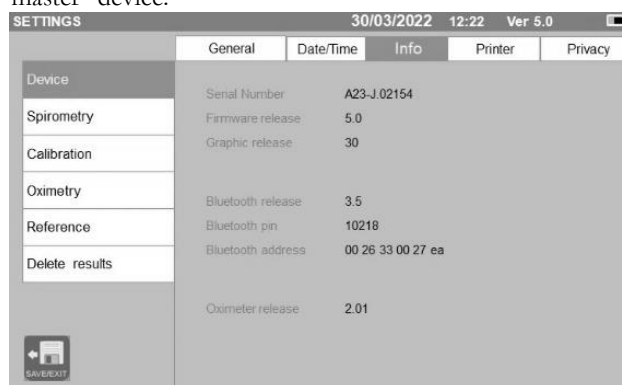
The following are required for such a connection to be made:

- **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 MIR Spiro. Once connected as described above, MIR Spiro 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 MIR Spiro 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 MIR Spiro 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 MIR Spiro 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

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 banner to select the printing type: thermal printer or via USB connection. The system prints the information selected in the "Spirometry" - "Results" settings.

During the printing phase, an icon will appear in the center of the screen to stop the printing phase, and the popup will appear that will allow you to select three icons (as in the figure below):

- OK to end the printing phase if there are no problems and show the spirometry results screen.
- OUT to reverse the forward direction of the house (counterclockwise direction) so that the house can be ejected in case of misplacement of the house.
- PAPER to advance the thermal paper at the end of printing in case more tests are to be printed successively.



3.4 Up-dating internal software

When the device is connected to a PC via the USB port, the **spirolab** internal software can be updated. Up-dates can be downloaded on registration from: www.spirometry.com. For further information about downloading up-dates, refer to the MIR Spiro 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)
- Device cleaning
- 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/disinfecting of the 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 of 1,15% sodium hypochlorite and shake it so as to remove any impurities that have deposited inside.
- Leave to soak for 15 minutes.

WARNING

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

- Rinse the turbine by immersing it in clean water (**not hot**) for at least 1 minute.
- 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 Device cleaning

Clean the device once a day or whenever the patient changes. To clean the device, use only the substances and methods listed in this paragraph. Recommended cleaners are:

- Mild soap (diluted)
- Sodium hypochlorite bleach (diluted 10%)
- Hydrogen peroxide (1.5%)

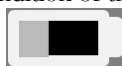
Moisten a soft cloth with a recommended solution, but not so much that the cloth drips and wipe the surface lightly for 30 seconds. Leave to air dry. Do not use ketone solvents (such as acetone) and aromatic solvents. Never immerse the device in water or other liquids.

4.4 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

4.5 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 inside the advancement roller (black roller of the thermal printer); a sensor will detect the presence of the paper and advance it automatically.
If necessary, advance the paper by pressing the icon on the display.

If necessary, advance the paper inward by pressing the centre button on the display.

When the paper is ready to print, press the OK icon.

4) Feed the paper through the thermal paper slot door slot and close the door.
And close the door.



WARNING

If you do not use the printer for a long time after cutting the thermal paper, the paper may be jammed. To avoid this situation, print more than 2 mm (2 inches) after cutting or push up the paper.

Do not retract the thermal paper more than 2.5 mm backward. If the thermal paper leaves the thermal head and rollers, the printer may not be able to feed the paper or a jam might occur.

Do not pull the paper forward or back after partially cutting. There may be a problem to move the paper.

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 update the software; for further information, consult the online MIR Spiro 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 reset.
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 MIR Spiro 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 www.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 MIR Spiro version. For further information, consult the online MIR Spiro User Manual.
On completion of spirometry tests, the readings are not credible	\	The turbine may be dirty	Clean the turbine as described in section 4.1; if necessary, replace the turbine with a new one
		The test was performed in the wrong manner	Repeat the test following the instructions shown on the screen
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 MIR Spiro 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.