spirodoc

ENGLISH (EN)

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FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Thank you for choosing a **MIR** product

MEDICAL INTERNATIONAL RESEARCH

The following table describe the accessories which can be used with spirodoc:

REF	Description	
672679	Carrying case	✓
301069	Holder	✓
532367	USB cable	✓
\	MIR Spiro software	O
910001.	Disposable Turbine	✓
910004	FlowMIR with mouthpiece	✓
900604	Flowmeter (optional)	O
910002	Reusable turbine	O
919024_INV	Oximetry sensor	O
672673_T	Belt	O
301067	Shell holder	O
301068	Shell	O

✓ included O optional

Before using your Spirodoc

- Read carefully your User Manual and pay attention to all the warnings and labels including all relevant information included with the product.
- Set the device configuration (date, hour, predicted set, language, etc etc) as described in paragraph 2.6

⚠ **WARNING**

Before connecting SPIRODOC to a PC, carry out all the necessary steps to correctly install the MIR Spiro software, which can be downloaded from the MIR website.
Once the installation is complete, connect the device to the PC and a message will be shown on the screen recognising a new peripheral device.

Keep the original packaging!

In the unlikely event that you have a problem with your device please use the original packaging and return it to the distributor or manufacturer.

Should this be the case, please follow these guide line:

- Return the complete device in the original packaging.
- Shipping costs and any customs duties must be paid by the sender.

Manufacturer's address:

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MIR has a policy of continuous product development and improvement. MIR reserves the right to modify and update the information in this User's Manual as deemed necessary. Any suggestions and or comments regarding this product are appreciated and may be sent via email to: mir@spirometry.com.
MIR accepts no responsibility for any loss or damage caused by the user of the device due to instructions contained in this Manual and/or due to incorrect use of the product.
Please note that due to printing limitations, the screenshots shown in this manual may differ from the display of the machine and/or from the keyboard icons.
Copying this manual in whole or in part is strictly forbidden.

Notice
You must report any serious incidents occurring in relation to the device to the manufacturer and the competent authority of the Member State where the user and/or patient is established, in accordance with Regulation 2017/745.

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1. INTRODUCTION

1.1 Intended use

The **Spirodoc** 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 testing in adult and pediatric patients, excluding infants and neonates
- oximetry testing in people of all ages.

It can be used in hospital setting, physician's office, factory, pharmacy and home.

1.1.1 User category

Spirodoc spirometer and oximeter calculates a series of parameters relating to human respiratory function.
Typically the doctor "prescribes" a spirometry test and is responsible for analysing and checking the results obtained.

1.1.2 Ability and experience required

The correct use of the device, the interpretation of the results and the maintenance of the device all require qualified personnel. In the event that the device is to be operated by a patient, sufficient training must first be given to the patient by the doctor.

⚠ WARNING

The manufacturer cannot be held responsible for any damage caused by the user of the device failing to follow instructions and warnings in this manual.
If the user of the device is a person considered to be cognitively impaired the operation of the device must be made under the supervision and responsibility of the person legally responsible to supervise the cognitively impaired person.

⚠ WARNING

When used as a pulse-oximeter, Spirodoc is intended to provide measurements for diagnostic purposes. The trained healthcare professional can get to a diagnosis by means of spot-checking, overnight sleep screening, or prolonged monitoring.
Monitoring shall be performed for the time necessary and when the patient health conditions are such as to not show, imply or presume an immediate danger to the patient.
In fact, Spirodoc is not specifically intended to monitor vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient (for example, like intensive care monitors, emergency monitors).

1.1.3 Operating Environment

Spirodoc has been designed for use in hospital setting, physician's office, factory, pharmacy and home.
Used at home, day after day the device records data and functional respiratory parameters for weeks or even months, helping the doctor to assess the health patient.
The device is not intended for use in an operating theatre nor in the presence of inflammable liquids or detergents, nor in the presence of inflammable anaesthetic gases (oxygen or nitrogen).
The device is not designed to be used in direct air drafts (e.g. wind), sources of heat or cold, direct sunlight or other sources of light or energy, dust, sand or any chemical substances.

The user and/or doctor is responsible for ensuring that the device is stored and used in appropriate environmental conditions; in this regard reference is made to the specifications described in paragraph 2.7.3 below.

⚠ WARNING

Exposure to unsuitable environmental conditions may cause the device to malfunction, and to provide incorrect results.

1.1.4 Who can or must make the installation

The device requires installation by qualified personnel. The doctor will configure the device before handing it over to the patient for homecare use.

1.1.5 Patient effect on the use of the device

A spirometry test should only be carried out when the patient is at rest and in good health, in suitable testing conditions. A spirometry test requires the full ***collaboration*** of the patient since she/he must perform a complete forced expiration, in order to obtain a reliable test result.

1.1.6 Limitations of use - Contraindications

An analysis of the results of a spirometry test is not by itself sufficient to make a correct diagnosis of the patient's clinical condition. A detailed clinical history of the patient is also required together with the results of any other test(s) suggested by a doctor.
Test comments, a test interpretation and suggested therapeutic treatment must be given by a doctor.
Any symptoms that the patient has at the time of the test must be carefully considered before a spirometry test is made. The user is responsible to assess both the mental and the physical condition of the patient in order to perform a proper test, furthermore, in the evaluation of test results, the user must also assess the degree of collaboration of each test carried out.
A spirometry test requires the full collaboration of the patient.
The results depend on the person's ability to inspire as much air as possible and to expire all of the air as fast and for as long as possible. If these fundamental conditions are not respected then the results obtained during spirometry testing will not be considered accurate, and therefore the test results are "not acceptable".
The acceptability of a test is the responsibility of the doctor. Special attention should be given when testing elderly patients, children and people with disabilities. The device should not be used if any conceivable or actual anomalies or malfunctions appear which may compromise the accuracy of the results.

Spirometry has relative contraindications:
Due to increased myocardial demand or changes in blood pressure
- Acute myocardial infarction within 1 week
- Systemic hypotension or severe hypertension
- Significant atrial/ventricular arrhythmia
- Uncompensated heart failure
- Uncontrolled pulmonary hypertension
- Acute pulmonary heart
- Clinically unstable pulmonary embolism
- History of syncope related to forced expiration/cough

Due to increased intracranial/intraocular pressure
- Cerebral aneurysm
- Brain surgery within 4 weeks
- Recent concussion with persistent symptoms
- Eye surgery within 1 week

Due to increased sinus and middle ear pressure
- Sinus or middle ear surgery or infection within 1 week

Due to increased intrathoracic and intraabdominal pressure
- Presence of pneumothorax
- Thoracic surgery within 4 weeks
- Abdominal surgery within 4 weeks
- Pregnancy beyond term

Due to infection control problems
- Active or suspected transmissible respiratory or systemic infection, including tuberculosis
- Physical conditions predisposing to transmission of infection, such as haemoptysis, significant secretions or oral lesions or oral bleeding.

⚠ WARNING

When Spirodoc is used as a pulse oximeter with limited alarms setting, the SpO_2 and Pulse Rate shown on the display needs to be checked frequently.

1.2 Important safety warnings

Spirodoc has been examined by an independent laboratory which has certified the compliance of the device to the European Safety Standards EN 60601-1 and guarantees the EMC Requirements within the limits laid down in the European Standard EN 60601-1-2.
Spirodoc is continuously checked during manufacturing and therefore the product complies with the established security levels and quality standards laid down by by European Regulation (EU) 2017/745.
After removing the device from its packaging, check to see that there is no visible damage. In case of damage do not use the device and return it to the manufacturer for repair.

⚠ WARNING

The safety and the correct performance of the device can only be assured if the user respects all of the relevant safety rules and regulations.
The manufacturer will not be held responsible for damage due to user's neglect to correctly to follow these instructions.
The device must be used as described in this user manual with particular attention to the paragraph on INTENDED USE and utilizing only original spare parts and accessories. Use of non-original parts such as the turbine flow sensor and oximetry sensor or other accessories may cause errors in measurement and/or compromise the correct functioning of the device and is therefore 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 life span. In normal conditions the lifespan of the device is estimated to be around 10 years. The device constantly monitors the state of charge of this battery and a message informs the user when the battery is discharged.

1.2.1 Danger of cross-contamination

Two different types of turbine sensors can be used with the device, one is reusable and the other is single-patient disposable. A disposable mouthpiece is required in order to connect a patient to the spirometer. In order to avoid exposing the patient to the critical danger of cross-contamination, the reusable flow sensor must always be cleaned before each spirometry test, and a new disposable mouthpiece must always be used for each patient. The use of an anti-bacterial filter is at the discretion of the doctor. If a single-patient disposable turbine is used, then a new one must be used for each patient.

1.2.2 Turbine

Disposable turbine

⚠ WARNING

For spirometry testing with a disposable turbine it is important to use a new turbine for each new patient. The accuracy and hygiene of the disposable turbine can only be guaranteed if it has been conserved beforehand in its original sealed packaging The disposable turbine is made of plastic and its disposal after use should adhere to the local regulations and norms in force.

Reusable turbine

⚠ WARNING

The correct functioning of the re-usable turbine can only be guaranteed if it has been cleaned in the correct manner and is free from foreign bodies which could alter its movement. If the turbine has not been cleaned sufficiently this could cause cross-contamination from one patient to another. Periodic cleaning should only be done when the device is for personal use and will only be used by one patient. The cleaning of the turbine should be performed according to the instructions contained in the User's Manual.

The following information applies to both types of turbine.
The turbine must never be held under running water or direct air pressure and must never come into contact with hot fluids.
Do not allow dust or foreign matter to enter the turbine sensor which may alter the correct functioning and possibly cause damage.
The presence of any impurities such as hair, sputum, threads etc. within the body of the turbine sensor may seriously compromise measurement accuracy.

1.2.3 Mouthpiece

Any disposable mouthpieces included with the spirometer are only to be used as a reference guide to purchase the correct size mouthpiece required. These mouthpieces are clean but not sterile. To purchase appropriate mouthpieces, generally either paper or plastic, single-use/disposable, we suggest that you contact your local distributor.

⚠ WARNING

Use a bio-compatible mouthpiece to avoid any problems to the patient; unsuitable materials could cause the device to malfunction, consequently providing incorrect test results.

The user is responsible for obtaining the proper mouthpieces for the device. The required mouthpiece is a standard type with an outside diameter of 30 mm, is of common use and in general easily procured.

⚠ WARNING

To avoid environmental contamination caused by the disposal of used mouthpieces, the user must follow all the relevant local regulations.

1.2.4 Oximetry sensors

The included sensor code 919024_INV and the following oximetry sensors can be used with **Spirodoc**:

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
BCI	3044	Reusable hard finger sensor (adults)	919020

These sensors, , with the exception of the sensor MIR code 919020 which has the MIR connector with orange arrow, require the use of an extension cable for a proper connection to **Spirodoc**. Two cable lengths are available:

Cod. 919200_INV	length 1.5 m
Cod. 919210_INV	length 0.5 m

Prolonged use and/or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, blood circulation, and correct sensor alignment at least every 4 hours.

⚠ WARNING

Incorrectly applied oximetry sensors or damaged cables may cause inaccurate readings. Using a damaged oximetry sensor may cause inaccurate readings, possibly resulting in patient injury or death. Inspect each oximetry sensor before use.
If an oximetry sensor appears damaged, do not use it. Use another oximetry sensor or contact your authorized repair center for assistance.
Use only MIR oximetry sensors supplied with, or specifically intended for use with Spirodoc. Use of oximetry sensors not intended for use with the Spirodoc may cause inaccurate readings.
Oximetry measurements may be inaccurate in the presence of high ambient light. Shield the sensor area (with a surgical towel, for example) if necessary.

⚠ WARNING

Dyes introduced into the bloodstream (for example; to perform a diagnostic tests) such as methylene blue, indocyanine green, indigo carmine, patent blue V (PBV), and fluorescein may adversely affect the accuracy of the oximetry reading.
Any condition that restricts blood flow, such as the use of a blood pressure cuff or a device for systemic vascular resistance, may cause the inability to determine accurate pulse rate and SpO2 readings.
Remove fingernail polish and/or false fingernails before applying SpO2 sensors. Both may cause inaccurate oximetry measurements.
Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin, may adversely affect the accuracy of the oximetry measurement.

Optical cross-talk can occur when two or more sensors are placed in close proximity. Optical cross-talk may adversely affect the accuracy of the oximetry readings. The danger can be eliminated by covering each site with opaque material.
Obstructions or dirt on the sensor's emitter and/or detector may cause a sensor failure or inaccurate readings. Make sure there are no obstructions and the sensor is clean.
Autoclaving, ethylene oxide sterilizing, may cause sensor damage. Do not attempt to sterilize the sensor.
Unplug the sensor from Spirodoc before cleaning or disinfecting to prevent damaging sensor or device, and to prevent safety hazards for the user.

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 Spirodoc. The use of other types of cables can lead to inaccurate measurements.

1.2.6 Device

⚠ WARNING

The maintenance operations detailed in this manual must be fully and accurately carried out. If these instructions are not followed this may cause measurement errors and/or an incorrect test interpretation.
Any modifications, adjustments, repairs or reconfigurations must be made by the manufacturer or by personnel authorised by the manufacturer. Never attempt to make a repair on your own. The set-up of configurable parameters should only be made by qualified personnel. However, an incorrect set-up of the parameters in no way endagers the patient's health.
The use of accessories and cables other than those specified by the manufacturer may result in increased emissions or decreased immunity of the device.
Spirodoc should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, Spirodoc should be observed to verify normal operation in the configuration in which it will be used.
If the device is connected to other instruments, to satisfy the safety requirements of the system required by the standard CEI EN 60601-1, it is necessary to use exclusively devices compliant to the safety standard. Therefore the PC or the printer which the Spirodoc is connected must be compliant to the standard CEI EN 60601-1.
To dispose of the Spirodoc, the accessories, any plastic consumable materials (mouthpieces) as well as the battery, use only appropriate containers or return all such parts to the dealer or to a recycling center. All applicable local regulations must be followed.

If any of these rules are not followed then MIR will decline all responsibility for any direct or indirect damages, however caused.
To supply power to the device use only the battery type indicated in the § Technical specifications.
The device may be powered through a PC by a USB cable. By this means, the device works both on line with the PC, or individually powered by the PC. Keep the device out of reach of children and any 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.
Spirodoc complies with the EN 60601-1-2:2015 standard on electromagnetic compatibility (EMC for electromedical devices) both in terms of immunity and emissions.
For the correct operation of the device, however, it is necessary not to use Spirodoc 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, Spirodoc and the other devices must be kept under observation to verify that they work normally.
Do not use the instrument in the presence of MRI equipment, which can generate an induced current in the sensor to measure oximetry, causing injury to the patient.

1.3 Lithium-ion battery pack warning

The device is powered by a rechargeable lithium-ion battery pack with a supply voltage of 3.7 V.
For proper use of the battery pack please read carefully the warning below

WARNING

Use only battery packs supplied by MIR.
Improper use of the battery pack may cause acid leakage, overheating, smoke, breakage an explosion and/or fire. Consequently the battery pack may be damaged or suffer a drop in overall performance. The internal battery pack safety sensor could also be damaged as well by any of the above events. Furthermore the user of the device could be harmed and other nearby appliances could be damaged as well.

Please read the following instructions carefully.

DANGER
Do not disassemble or modify the battery pack. The battery pack comes with an internal safety sensor; which if tampered with may cause acid leakage, overheating, smoke, breakage an explosion and/or fire.
Do not short-circuit the positive (+) and negative (-) poles with any metal objects.
Do not carry the battery pack in your pocket or in a bag with other metallic objects like necklaces, hairpins, coins or screws.
Do not store the battery pack near any such objects.
Do not warm-up or throw the battery pack in a fire.
Do not use or store the battery pack near a fire or in a vehicle where the temperature may reach 60°C or higher
Do not immerge the battery pack in water or salt-water, and do not leave it wet.
Such events may damage the internal battery safety sensor, thus causing the battery to be charged at a higher voltage, triggering abnormal chemical reactions leading to acid leakage, overheating, smoke, an explosion and/or fire
Do not charge the battery pack near a fire or in an extremely hot environment. High temperature may activate the internal battery safety sensor thus inhibiting the charge. The high temperature may also damage the internal battery safety sensor causing extremely high current surge; and consequently causing abnormal chemical reactions in the battery pack triggering acid leakage, overheating, smoke breakage, an explosion and/or fire.
Use only the battery charger supplied by MIR to recharge the battery pack. Recharging with an unsuitable charger in unconforming conditions may cause the battery pack to overcharge or the charging current to be extremely high thus causing abnormal chemical reactions in the battery pack triggering acid leakage, overheating, smoke breakage an explosion and/or fire.
Do not puncture the battery pack with sharp objects such as a nail.
Do not hammer, step-on, throw or cause a forceful impact to the battery-pack.
A damaged or deformed battery pack may cause internal short-circuits thus creating the possibility for acid leakage, overheating, smoke, breakage and/or fire.
Do not use a heavily scratched or deformed battery back as this may be cause for acid leakage, overheating, smoke, breakage and/or fire.
Do not solder directly on the battery pack.
Do not mount the battery pack inside the device with the + and – poles inverted.

If the battery leads do not connect easily to the battery charger or to the device do not apply excessive force. Check to see that the leads are properly aligned. If the leads are inverted, an inverse polarity connection may provoke acid leakage, overheating, smoke, breakage and/or fire.
Do not connect the battery pack leads to a wall socket or to the car lighter Under high voltage the battery may leak acid, overheat, emit smoke, explode and/or catch fire.
Do not use the battery pack for any other purpose other than those specified otherwise its features may be compromised, and its useful life reduced
If the battery acid inadvertently enters the eyes do not rub the eyes, instead wash the eyes with clean running water and call a doctor immediately.

WARNING
Do not leave the battery pack charging longer than the average charging length of time specified.
Do not place the battery in a micro-wave oven or in a pressurized container. Rapid overheating or loss of proofing may cause acid leakage, overheating, smoke, breakage and/or fire.
If the battery pack gives off a bad smell, if it generates heat, if it fades/deformes or if anything abnormal happens during storage, usage and recharging immediately remove the battery pack from the device or the battery charger and do not use it any longer, as any of these events may cause acid leakage, overheating, smoke, breakage and/or fire.

NOTE
The battery pack includes an internal safety protector. Do not use the battery pack where static electricity is present (higher than what is declared by the manufacturer.
If acid from the battery pack comes into contact with skin or clothing immediately wash with running water to avoid skin inflammation
Store the battery pack away from children's reach to avoid any accidental swallowing.
If a child uses the battery pack an adult must explain the proper use to the child.
Before using the battery pack read the manual carefully paying attention to all the recommendations for proper handling.
Please read the manual carefully to insert and remove of the battery pack in the device properly.
Before charging the battery pack read the manual carefully.

The battery pack life cycle is definite-. If you notice a much shorter time usage between charge please substitute the battery pack with a new one.
Remove the battery pack if its cycle life has expired.
When the battery pack has been removed from the device, ensure that the (+) and (-) leads have been isolated with electrical tape; to properly dispose of the battery pack please follow the local regulations or hand over the battery pack to a battery recycling center.
Prior to storage or for long periods of disuse of the device remove the battery pack and store in a place where the temperature and humidity fall within specified ranges.
If the battery pack leads are dirty clean with a dry cloth prior to usage.

The battery pack can be charged within a temperature range between 0°C and approximately 40°C.
The battery pack may be used and stored within a temperature range between -20°C and approximately 60°C.

1.4 Unforessen errors

In case device internal memory data are damaged, when the device is switched on, the following message appears:

ERROR IN MEMORY

In this case switch off the device and contact a technical service center.

1.5 Labels and symbols

1.5.1 Identification label and symbols

1.5.2 Symbols used

The symbols are described in the table below

SYMBOL	DESCRIPTION
Model	Product name
SN	Device serial number

SYMBOL	DESCRIPTION
	Manufacturer symbol
 0476	This product is certified CE to conform to the Class IIa requirements of the by European Regulation (EU) 2017/745.
	In accordance with the **IEC 60601-1** Standard, this product and its component parts are of **type BF** and therefore protected against the dangers of direct and indirect contact with electricity.
	To connect to other devices such as PC or printer. Use only the USB cable supplied by the manufacturer and observe the safety regulations of **IEC 60601-1-1.**
SpO2	Warning symbol for the SpO2 port for oximetry (Oximetry function is on request)
	**Warning symbol for the WEEE** As laid down in the European Directive 2012/19/EEC requirements regarding the disposal of electrical and electronic devices (WEEE), at the end of its useful life this device must not be thrown away together with normal domestic waste as it contains materials which would cause damage to the environment and/or represent a health risk. Instead it must be delivered to a WEEE authorised collection center, where the device will then be disposed of correctly. An alternative is to return the device without charge to the dealer or distributor, when a new equivalent device is purchased. Due to the materials used in the manufacturing of the device, disposing it as a normal waste product could cause harm to the environment and/or health. Failure to observe these regulations can lead to prosecution.
	The (ESD) symbol required by the international standard is used in the vicinity of any connector which has not undergone electrostatic discharge testing. In this device the electrostatic discharge tests have been performed
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.
FCC ID	Identification showing traceability to FCC compliance
Rx ONLY	Symbol for FDA regulation: use the device under the prescription of the physician
	Symbol for devices that include RF transmitters. The symbol is applied for products that include RF transmitters
	Instruction for use symbol. Refer to instruction manual. Read this manual carefully before using the medical device.
	Manufacturing date of the device
	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 Device Identification
	The symbol indicates that the device must not be exposed to direct sunlight
	The symbol indicates that the device must be kept dry

1.5.3 FDA and FCC Warnings

Spirodoc complies with Part 15 of the FCC Rules. The correct operation is subject to the following conditions:
(1) this device must not cause harmful interference
(2) this device must accept any interference received, including interference that may cause undesired operation.

Any modifications not expressly approved by this company could void the user's authority to operate the equipment.
NOTE: This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by simply turning the equipment off and on, the user is encouraged to try to correct the interference with one or more of the following ways:

- Reposition the receiving antenna.
- Increase separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for assistance.

Labels and symbols are displayed on the device as shown in the following images:

1.5.4 (ESD) Electrostatic discharge sensitivity symbol

⚠ WARNING

Pins of connectors identified with the ESD warning symbol should not be touched and the connections should not be made to these connectors unless ESD precautionary procedures are used.

Precautionary procedures are the following:

- Environmental procedures as: air conditioning, humidification, conductive floor coverings, non-synthetic clothing
- User procedures as: discharging one's body to a large metal object, using wrist strap connected to earth.

It is recommended that all staff involved receive an explanation of the ESD warning symbol and training in ESD precautionary procedures.

the electrostatic discharge is defined as an electric charge at rest. It is the sudden flow of electricity between two objects caused by contact, an electrical short, or dielectric breakdown. ESD can be caused by a buildup of static electricity by tribocharging, or by electrostatic induction. At lower relative humidity, as the environment is drier, charge generation will increase significantly. Common plastics generally will create the greatest static charges.
Typical electrostatic voltage values:

Walking across a carpet	1.500 – 35.000 volts
Walking over untreated vinyl floor	250 – 12.000 volts
Vinyl envelope used for work instructions	600 – 7.000 volts
Worker at a bench	700 – 6.000 volts

If two items are at different electrostatic charge levels, as they approach one another, a spark or Electrostatic Discharge (ESD) can occur. This rapid, spontaneous transfer of electrostatic charge can generate heat and melt circuitry in electronic components.
A latent defect can occur when an ESD sensitive item is exposed to an ESD event and is partially degraded. It may continue to perform its intended function, so may not be detected by normal inspection. Intermittent or permanent failures may occur at a later time.
Static dissipative material will allow the transfer of charge to ground or to other conductive objects. The transfer of charge from a static dissipative material will generally take longer than from a conductive material of equivalent size. Some well known insulators are common plastics, and glass. An insulator will hold the charge and cannot be grounded and conduct. the charge away.
Both conductors and insulators may become charged with static electricity and discharge. Grounding is a very effective ESD control tool, however, only conductors (conductive or dissipative) can be grounded.
The fundamental ESD control principles are:

- Ground all conductors including people
- Remove insulators, substitute with ESD protective versions
- neutralize with ionizers
- ESDS outside the EPA (ESD protected area) to be in packaging having ESD shielding property

1.6 Product description

The **Spirodoc** is a pocket spirometer, with an optional pulse oximetry module. It can operate either in stand-alone mode or it can be connected to a PC or to a printer using any one of several methods: USB, Bluetooth.

The device is specifically designed to measure a range of respiratory parameters and to monitor the saturation of oxygen in the blood and the heart beat. A quality control check is carried out internally on the measured parameters and the device has an internal memory sufficient for approximately 10.000 spirometry tests or at least 300 hours of oximetry monitoring.

Spirodoc is a powerful and compact measurement device, intended for use by a respiratory specialist or by a suitably trained general practitioner. The spirometer calculates up to 30 functional respiratory parameters providing the pharmacodynamic effects, i.e. the data comparison after the administration of a drug (PRE/POST) for a bronchodilator test or for a bronchial challenge test. A comparison of data is made between POST (after-drug) and PRE (before drug administration).

The flow and volume measurement sensor is a digital turbine, based on the infrared interruption principle. This transducer ensures the accuracy and the reproducibility of the measurements, without requiring periodic calibration.
The sensor features are listed below:

- Accurate measurement even at very low flow rates (end of expiration)
- Not affected by relative humidity and air density
- Shockproof and unbreakable
- Inexpensive to replace.

The turbine flow measurement sensor is available both in reusable and in single-patient disposable versions:

REUSABLE TURBINE

DISPOSABLE TURBINE

The following precautions must be observed to ensure that the characteristics of the turbine remain unaltered over time:

- for the disposable turbine: must always be substituted from one patient to the other.
- for the reusable turbine: always disinfect the turbine for testing from one patient to the next, to ensure the maximum level of hygiene and safety.

For a correct interpretation of a spirometry test, the measured values must be compared either to the so-called **normal or predicted values** which are calculated from the anthropometric details of the patient or, alternatively, to the **personal best values** from the clinical history of the subject. The personal best values can vary considerably from the predicted values, which are taken from "healthy" subjects.

Spirodoc can also be connected to a PC (or to another computerised system) to configure the instrument. All spirometry test data including the related patient details stored inside the device can be transferred from the device to the PC and then viewed on the PC (Flow/volume curves, spirometry parameters, plus optional oximetry parameters).
The connection to the MIR Spiro can be made via USB connection.

Spirodoc can perform FVC, VC & IVC, MVV and breathing profile tests, and calculates an index of test acceptability (quality control) plus the reproducibility of the spirometry tests carried out. The automatic test interpretation follows the latest 11 level ATS (American Thoracic Society) classification. Each test can be repeated as required. The best parameters are always available for review. The normal (predicted) values can be selected from several normal "sets". For example, within the European Union the majority of doctors use the ERS (European Respiratory Society) predicted values.

Oximetry function (optional)
The oximetry sensor has two light emitting diodes (LEDs), one emits in the visible spectre and one infrared. Both lights then pass through the finger and are "read" by the receiver. As these lights pass through the finger, a proportion of the light is absorbed by the blood and by the soft tissue, in function of the concentration of heamoglobin. The quantity of light absorbed, at each frequency, depends on the degree of oxygenation of the haemoglobin inside the soft tissue.
This measurement principle ensures accuracy and reproducibility, without requiring regular calibration.
The oximetry sensor can be disinfected with isopropilic alcohol.

1.7 Technical specification

A comprehensive description of the main features of the device, the flow and volume measurement turbine and also of the oximetry sensor follows:

1.7.1 Features of the spirometer

This device meets the requirements of the following standard:

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

Measured parameters:

Symbol	Description	Units
*FVC	Best FVC	L
*FEV1	Best FEV1	L
*PEF	Best PEF	L/s
FVC	Forced Vital Capacity	L
FEV1	Volume expired in the 1st second of the test	L
FEV1/FVC	FEV1/FVC x 100	%
FEV1/VC	FEV1 / best between EVC and IVC x 100	%
PEF	Peak expiratory flow	L/s
FEF2575	Average flow between 25% and 75% of the FVC	L/s
FEF25	Forced Expiratory Flow at 25% of FVC	L/s
FEF50	Forced Expiratory Flow at 50% of FVC	L/s
FEF75	Forced Expiratory Flow at 75% of FVC	L/s
FEV3	Volume expired in the initial 3 seconds of the test	L
FEV3/FVC	FEV3/FVC x 100	%
FEV6	Volume expired in the initial 6 seconds of the test	L
FEV6%	FEV1/FEV6 x 100	%
FET	Forced expiratory time	s
EVOL	Extrapolated volume (see also VEXT and BEV)	mL
FIVC	Forced inspiratory volume	L
FIV1	Volume inspired in the 1st second of the test	L
FIV1/FIVC	FIV 1 %	%
PIF	Peak inspiratory flow	L/s
MVVcal	Maximum voluntary ventilation calculated on FEV1	L/s
VC	Slow vital capacity (expiratory)	L
EVC	Slow espiratory vital capacity	L
IVC	Slow inspiratory vital capacity	L
IC	Inspiratory capacity (max between EVC and IVC) - ERV	L
ERV	Expiratory reserve volume	L
TV	Current volume	L
VE	Ventilation per minute, at rest	L/min
RR	Respiratory frequency	Breath/min
t_I	Average time of inspiration, at rest	s
t_E	Average time of expiration, at rest	s
TV/t_I	Average flow of inspiration, at rest	L/min
t_I/t_{TOT}	$t_I/(t_I+t_E)$	\
MVV	Maximum voluntary ventilation	L/min
ELA	Estimated lung age	year

*= best values

Flow/volume measurement system	Bi-directional digital turbine
Temperature sensor	semiconductor (0-45°C)
Measurement principle	Infrared interruption
Volume range	10 L
Flow range	± 16 L/s
Volume accuracy	± 3% or 50 mL
Flow accuracy	± 5% or 200 mL/s
Dynamic resistance at 12 L/s	<0.5 $cmH_2O/L/s$

1.7.2 Oximeter features

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 **hard** sensor for **adults**		Reusable **soft** sensor for **adults**		Reusable **paediatric soft** sensor	
Range (SpO2)	**Arms (%)**	**Range (SpO2)**	**Arms (%)**	**Range (SpO2)**	**Arms (%)**
70-100 %	1.19	70-100 %	± 1.470	70-100 %	± 1.390
70-80 %	0.554	70-80 %	± 1.626	70-80 %	± 1.851
80-90 %	1.32	80-90 %	± 1.667	80-90 %	± 1.397
90-100 %	1.45	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 SpO_2 simulators should not be used to validate the accuracy of the oximeter, they can only be used as functional testers to verify its precision and the alarm system (when it is necessary).

Definitions:

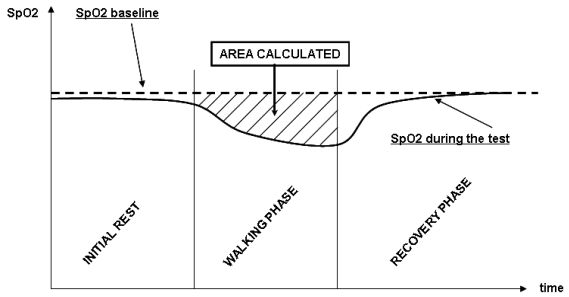
Desaturation Event	Desaturation events SpO_2 fall ≥ 4% in a limited period of 8-40 sec and successive rise ≥ 2% within a total period of 150 sec.
Total Pulse rate Variation	Pulse rate rise ≥ 10 BPM in limited period of 8-40 sec and successive fall ≥ 8 BPM during a total period of 150 sec.

Parameters for the oximetry test:

Symbol	Description	Units
%SPO2 min	Minimum SPO2 during the test	%
%SPO2 max	Maximum SPO2 during the test	%
BPM min	Minimum BPM during the test	BPM
BPM max	Maximum BPM during the test	BPM
%SPO2 mean	Average SPO2	%
BPM mean	Average BPM	BPM
T Total	Total test time	hh:mm:ss
T Analysis	Total measurement time (test time minus the zeros)	hh:mm:ss
T<90%	Time with SPO2 below 90%	%-hh:mm:ss
T<89%	Time with SPO2 below 89%	%-hh:mm:ss
T<88%	Time with SPO2 below 88%	%-hh:mm:ss
T<87%	Time with SPO2 below 87%	%-hh:mm:ss
Ev%SPO2<89	SpO2 fall below 89% for at least 20 seconds	/
Δ Index	SpO2 Fluctuation index calculated on 12 second intervals	/
T<40BPM	Test time with pulse rate <40 BPM	%-hh:mm:ss
T>120BPM	Test time with pulse rate >120 BMP	%-hh:mm:ss
Ev<40BPM	High heart rate events, during the analysis period	/
Ev>120BPM	Tachycardiac (high heart rate) events, during the analysis period	/
%SPO2 start	Initial phase %SpO2 base value, before walking test	%
%SPO2 end	Final SPO2 reading during walking phase	%
BPM end	Final BPM reading during walking phase	BPM
%SPO2 Base	Initial phase SPO2 base value, before walking test	%
BPM start	Initial phase BMP base value, before walking test	BPM
T Baseline	Duratation of base phase	hh:mm:ss
T Walking	Duration of walking phase	hh:mm:ss
T Recovery	Duration of recovery phase	hh:mm:ss
Distance	Distance covered	m
T2%Δ SPO2	Time spent during the walking test, with SpO2<2% compared to the SpO2 base value	hh:mm:ss
T4%Δ SPO2	Time spent during the walking test, with SpO2<4% compared to the SpO2 base value	hh:mm:ss
Predicted	Standard predicted distance	m
Predicted min	Minimum predicted distance	m
% Predicted	% variation of the distance covered compared to the standard predicted distance	%
%Predicted min	% variation of the distance covered compared to the minimum predicted distance	%
AUC/Distance*	Area below the SpO2 base curve compared to the distance covered	/
Dyspnea Base	Degree of breathlessness prior to the walking test	Borg
Dyspnea End	Degree of breathlessness at the end of the walking test	Borg
Dyspnea CHG	Variation in the degree of breathlessness during the walking test	/
Fatigue Base	Degree of tiredness prior to the walking test	Borg
Fatigue End	Degree of tiredness at the end of the walking test	Borg
Fatigue CHG	Variation in the degree of tiredness during the walking test	/
Diastolic Base	Starting diastolic value	mmHg
Systolic Base	Starting systolic value	mmHg

Symbol	Description	Units
Diastolic Fine	Final diastolic value	mmHg
Systolic Fine	Final systolic value	mmHg
Steps	Estimation of the steps taken by the patient during the test	/
VMU**	Number of movements made by the patient during the test	/
O2-GAP***	Estimation of the percentage of oxygen to administer to the patient	%
O2	percentage of oxygen administered to the patient before test	L/min-%
SPO2 Base	SPO2 base value for the SPO2 and ODI tests	%
BPM Base	BPM base value for the SPO2 and ODI tests	BPM
ODI	Desaturation events per hour of analysis	1/h
Mean Dur. Desat.	Average duration of the desaturation event	s
Tot Desaturat.	Number of desaturation events during the entire analysis period	/
Longest Desat.	Duration of the longest desaturation event	s
Desatur. Peak	Minimum SpO2 value during a desaturation event	%
BPM Index	Number of events of variation of the Pulse rate per hour of a analysis	/
Mean Desaturat.	Average of the desaturation troughs	s
Mean Drop	Average SpO2 fall compared to the base value during the desaturation events	s
Max Drop	Maximum fall in the SpO2 compared to the saturation events	s
BPM Variation	Number of variations in the Pulse Rate during the entire analysis period	/
NOD4%	Number of events with SpO2<4% compared to the SpO2 base value for a continuous period of at least 5 minutes	/
NOD89%	Number of events with SpO2<89% for a continuous period of at least 5 minutes	/
NOD90%	Number of events with SpO2<90% for a continuous period of at least 5 minutes with min value <86% (Nadir)	/
t.NOD4%	Time with SpO2<4% compared to the SpO2 base value for a continuous period of at least 5 minutes	hh:mm:ss
t.NOD89%	Time with SpO2<89% for a continuous period of at least 5 minutes	hh:mm:ss
t.NOD90%	Time with SpO2<90% for continuous periods of at least 5 minutes with mim value <86% (Nadir)	hh:mm:ss

*Below is a description of the method for calculating the area below the SpO2 baseline curve:



** "index movement". The parameter is expressed in VMU and is used to quantify patient movement during oximetry testing.
*** O_2 GAP index estimates the percentage of oxygen to be administered to a patient by using the (6MWT).

The following table lists all the symbols used for the parameters in the service menu under item "Set parameters" describing to which test each is related to and if optional:

Symbol	Symbol in menu "Set parameters"	Test	Optional
%SPO2 min	\	all	no
%SPO2 max	\	all	no
BPM min	\	all	no
BPM max	\	all	no
%SPO2 mean	\	all	no
BPM mean	\	all	no
T Total	\	all	no
T Analysis	\	all	no
T<90%	T<90%	all	yes
T<89%	T<89%	all	yes
T<88%	T<88%	all	yes
T<87%	T<87%	all	yes
Ev%SPO2<89	Ev%SPO2<89	all	yes
Δ Index	Δ INDEX	all	yes
T<40BPM	t<40BPM	all	yes

Symbol	Symbol in menu "Set parameters"	Test	Optional
T>120BPM	t>120BPM	all	yes
Ev<40BPM	Ev<40BPM	all	yes
Ev>120BPM	Ev>120BPM	all	yes
%SPO2 start	\	6MWT	no
%SPO2 end	\	6MWT	no
BPM end	\	6MWT	no
%SPO2 Base	\	6MWT	no
BPM start	\	6MWT	no
T Baseline	\	6MWT	no
T Walking	\	6MWT	no
T Recovery	\	6MWT	no
Distance	\	6MWT	no
T2%Δ SPO2	T2%ΔSPO2	6MWT	yes
T4%Δ SPO2	T4%ΔSPO2	6MWT	yes
Predicted	PREDICTED	6MWT	yes
Predicted min	PRED.MIN	6MWT	yes
% Predicted	%PREDICT.	6MWT	yes
%Predicted min	%PRED.MIN	6MWT	yes
AUC/Distance	AUC/DIST.	6MWT	yes
Dyspnea Base	BASE DYSP	6MWT	yes
Dyspnea End	END DYSP	6MWT	yes
Dyspnea CHG	CHG DYSPN	6MWT	yes
Fatigue Base	BASE FATIG	6MWT	yes
Fatigue End	END FATIG	6MWT	yes
Fatigue CHG	CHG FATIG	6MWT	yes
Diastolic Base	BASE DIAST.	6MWT	yes
Systolic Base	BASE SYST.	6MWT	yes
Diastolic Fine	END DIAST.	6MWT	yes
Systolic Fine	END SYST.	6MWT	yes
Steps	STEPS	6MWT	yes
VMU	VMU	6MWT	yes
O2-GAP	O2 GAP	6MWT	yes
O2	O2	6MWT	yes
SPO2 Base	\	ODI	no
BPM Base	\	ODI	no
ODI	ODI	ODI	yes
Mean Dur. Desat.	MEAN DUR	ODI	yes
Tot Desaturat.	TOT DESAT	ODI	yes
Longest Desat.	LONG.DURAT	ODI	yes
Desatur. Peak	DES.PEAK	ODI	yes
BPM Index	BPM INDEX	ODI	yes
Mean Desaturat.	MEAN DESAT	ODI	yes
Mean Drop	MEAN DROP	ODI	yes
Max Drop	MAX DROP	ODI	yes
BPM Variation	BPM VAR.	ODI	yes
NOD4%	NOD4%	ODI	yes
NOD89%	NOD89%	ODI	yes
NOD90%	NOD90%	ODI	yes
t.NOD4%	t.NOD4%	ODI	yes
t.NOD89%	t.NOD89%	ODI	yes
t.NOD90%	t.NOD90%	ODI	yes

Δ=DELTA

Parameters requested for six minute walk test analysis

Symbol	Description	Units
Dyspnea Baseline	Grade of dyspnea before walking	Borg
Dyspnea End	Grade of dyspnea after walking	Borg
Fatigue Baseline	Level of fatigue before walking	Borg
Fatigue End	Level of fatigue after walking	Borg
Diastolic Base	Starting diastolic value	mmHg
Systolic Base	Starting systolic value	mmHg
Diastolic Fine	Final diastolic value	mmHg

Systolic Fine	Final systolic value	mmHg
O2	Percentage of oxygen administered to the patient before test	L/min-%
Walked	Distance covered during walking	m

Measurement method	Red and infrared absorption
Range of measurement %SpO_2	0 – 99% (with 1% increments)
SpO_2 Resolution	1%
%SpO_2 accuracy	± 2% between 70-100% SpO2
Average number of heart beats for the %SpO_2 calculation	8 beats
Range of measurement of cardiac pulse	30 – 254 BPM (with 1 BPM increments)
Cardiac pulse resolution	1 BPM
Accuracy of cardiac pulse	± 2 BPM or 2% whichever is greater
Average interval for the calculation of cardiac pulse	8 seconds
Signal quality indication	0 - 8 segments on display
Wavelengths and maximum optical output power average of the oximetry sensors (919024, 919020)	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.

1.7.3 Oximetry alarms description

Spirodoc is equipped with audio and visual alarm indicators to alert the operator to provide prompt patient attention or to abnormal device conditions. **Spirodoc** 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 auditiry alarms are sounded as three beeps.
The intended operator's position for correctly perceiving a visual alarm signal is 1 meter.

Alarm Summary
Spirodoc 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 SpO_2 level;
- Low and high Pulse Rate level;
- Sensor is unplugged
- Finger inserted incorrectly
- Battery level is insufficient

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 SpO_2 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
High SpO_2 Alarm Limit	99%	85-99%	1%
Low SpO_2 Alarm Limit	85%	85-99%	1%
High Pulse Rate Alarm Limit	120 bpm	30-240 bpm	1 bpm
Low Pulse Rate Alarm Limit	60 bpm	30-235 bmp	1 bpm

Equipment (technical) Alarms
- Sensor is unplugged
- Finger inserted incorrectly
- Battery level is insufficient

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 inserted incorrectly

Auditory Alarm Indicator
Audible alarms can be heard in a quiet environment. The medium priority audible alarm has a "du-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):

- "Beep" with frequency of the cardiac pulse
- If the oximetry test has been interrupted due to low battery an intermittent beeping will be heard for 5 seconds when the device is switched on again

The specifications for both the oximetry and for the cardiac pulse are the same regardless of which of the above mentioned oximetry sensors is used.

1.7.4 Other features

Memory	Memory capacity for over 10000 spirometric tests The number depends on the individual configuration, so it cannot be determined more closely
keyboard	Absent, display touch screen
Display	Black and White LCD touchscreen with 160x80 resolution
Interface	USB, Bluetooth
Bluetooth interface	frequenzy range = 2402-2480 MHz rated RF power output = 0.001 W frequency tolerance = 20 ppm type of antenna = permanently attached gain of antenna = 0 max dBi
Duration of the 3,7V lithium battery	Approx 500 charge cycles, under normal conditions of use
Power supply	Battery pack Li-ion 3.7 V 1100mAh
Battery charger	Voltage = 5VDC Current = 500 mA Connector = micro USB type B
Dimensions	101x48x16 mm; turbine housing 46x47x24 mm
Weight	Central unit 99g (including batteries) Turbine housing 17g
Type of electrical protection	Internally powered
Degree of electrical protection	BF
Grade of protection against water ingress	IPX1
Safety level in the presence of inflammable anaesthetic gas, oxygen or nitrogen	Device not suitable
Conditions of use	Device for continuous use
Storage conditions	Temperature: MIN -20 °C, MAX + 60 °C Humidity :MIN 10% RH; MAX 95%RH Athmospheric pressure: 50kPa, 106 kPa
Transport condition	Temperature: MIN -20 °C, MAX + 60 °C Humidity :MIN 10% RH; MAX 95%RH Athmospheric pressure: 50kPa, 106 kPa
Operating conditions	Temperature: MIN + 10 °C, MAX + 40 °C; Humidity: MIN 10% RH; MAX 95%RH Athmospheric pressure: 70kPa, 106 kPa
Applied norms	IEC 60601-1:2005 + A1: 2012 (Electrical Safety) IEC 60601-1-2:2015 (EMC) ATS/ERS Guidelines: 2005 ISO 26782: 2009 ISO 23747: 2015 EN ISO 14971: 2019 ISO 10993-1: 2018 2011/65/UE Directive EN ISO 15223-1:2021

	EN IEC 60601-1-6: 2010+Amd2013 ISO 80601-2-61: 2017 IEC 60601-1-8: 2006 IEC 60601-1-11: 2015 Directive 2014-53-EU-RED
Essential performances (according to IEC 60601-1:2005 + A1:2012)	Error of displayed numeric value: Flow measurement percentage error < ± 5% Measure of the oximetry parameters with accuracy defined in table on § 1.7.2
Emission limits	CISPR 11 Group 1 Class B
Electrostatic discharge protection	8kV contact, 15kV air
Magnetic field immunity	30 A/m
Radio Frequency Immunity	10V/m @ 80-2700 MHz

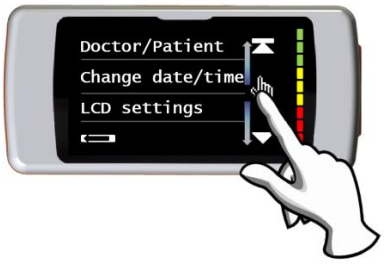
MIR will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those part of the device that are designated by MIR as repairable by service personnel.

2. FUNCTIONING OF THE SPIRODOC

2.1 Display

The device does not have a keyboard. The touch screen type display allows access to all functions by simply touching the display. The controls on the touch screen change dynamically based on the functions performed.
To access a specific function touch the corresponding icon on the display.

To visualize the list of information scroll through the left part of the screen.



2.2 Switching on and off the Spirodoc

To turn on the **Spirodoc** press and release the power key placed in the middle on the side of the device.
If the spirodoc is connected to USB or power supply is not possible to switched OFF

Upon turning on the device the very first image displayed refers to the manufacturer including the date and time setting.
Without touching the display after a few seconds the device automatically moves on to the main screen

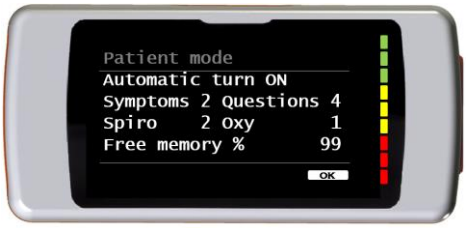
By touching the **i** icon different information is visualized according to which mode; Doctor or Patient the device has been set to

Doctor Mode
The information displayed are:

- Spirometry parameter setting
- Oximetry parameter setting
- Spirometry and oximetry tests in memory
- Free memory available

Patient Mode
The information displayed are:

- Number of activated symptoms
- Number of activated questions
- Spirometry and oximetry tests in memory
- Free memory available



To turn off **Spirodoc** press the key placed on top and subsequently touch OK on the bottom right side of the screen. It is possible to turn off the device by keeping the top key pressed.
The message on the right side is shown after pressing the key on top It serves as a guide to follow the procedure properly.

2.3 PIN request

After the first screen the device will ask the user to protect the access with a PIN.
Press OK if you want to set a personal PIN
or
press ⟵ to skip this function.

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

Insert a PIN using the numeric keyboard and press **OK**
Repeat the PIN and press **OK**

Then the device shows 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.

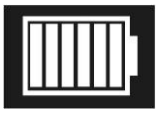
2.4 Energy saving

⚠ WARNING

When the device is turned on after approximately 1 minute of disuse the display enters energy saving mode thereby automatically lowering the display contrast level.

If the device remains in disuse for approximately 5 minutes and is not connected to a PC or battery charger; the device will emit an acoustic warning signal and turn off.

When the device is turned on the battery charge level is shown with the symbol:



This image indicates that the battery pack is fully charged(6 indicators). A drop of the battery pack charge is displayed with a reduction of the indicators.

2.5 Main screen

On the main screen, while in Doctor Mode the following areas can be accessed:

 patient data management area

 oximetry area

 spirometry area

 archive area

 testing without patient data area

If the device is set on "Patient" mode (see paragraph 3.6.1) the main screen will show a different configuration as displayed on the right side:

 symptoms questions

 oximetry test

 spirometry test

 most recent test archive

 send data via Bluetooth

This screen allows the patient to access more quickly the dedicated functions. For further information please view paragraph 3.6.1.

2.6 Symbols and Icons

The icons used in the various function screens are shown in the following table:

ICON	DESCRIPTION
	To access the default settings (service menu)
	To access patient data from the main display
	To perform a new test of a patient recalled from the patient records.
	To insert new patient data
	To modify patient data.
	To display the most recent tests of a patient
	To show the last test performed
	To go back
	To send data via Bluetooth
	To access the database of the performed tests.
	To search a test with the date of birth of a patient
	To search a test starting from a specific date onwards (partial database)
	To flick through a database from beginning to end and viceversa (complete database)
	Patient search through family name.
	Male sex patient selection
	Female sex patient selection
	To perform tests without having to insert patient data
	To access all oximetry test options / To perform an SpO2/BPM test
	To perform an SpO2/BPM test

ICON	DESCRIPTION
	To perform a sleep oximetry test
	To perform a 6MWT/ to move on to the walking phase of the test
	Tom move on to the recovery phase of the 6MWT
	To access spirometry testing type
	To perform a Forced Vital Capacity test FVC/search FVC tests in memory
	To perform a Slow Vital Capacity test VC/ search VC tests in memory
	To perform a Maximum Voluntary Ventilation test MVV/ search MVV tests in memory
	To perform a spirometry test with a bronchodilator
24h	Search in memory oximetry tests lasting more than 12 hours
	To print via Bluetooth connection
	To view the plethysmographic curve in real-time while performing an oximetry test
	To check the alarms and alarm thresholds during oximetry testing
	To check the alarms and alarm thresholds during oximetry testing when at least one parameter is turned OFF
	Auditory alarm enabled during oximetry test. Press it to pause audio for 2 minutes
	Auditory alarm is temporarily paused during oximetry test. Press it to turn the auditory alarm back ON
	Symptoms selection in **PATIENT** mode

2.7 Service menu

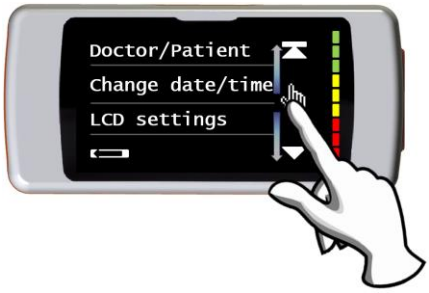
To enter the service menu touch the display when the following icon appears  and keep pressing for a few seconds.
Insert the PIN; if the PIN is not set insert the default PIN which is the following:

1 2 2 3

The service menu shows different items according to whether the device is set to either Patient or Doctor mode; The item "**Spirodoc** mode" is the first one displayed in both modes. The configuration of the item menus for the two modes is the following:

Patient mode		Doctor mode	
• Doctor/Patient	• Theoretical Author	• Doctor/Patient	• Turbine Calibration
• Type of ignition	• Standard Setting	• Change date/time	• Set language
• Patient DATA	• Turbine Type	• Set LCD	• Date format
• Set Oximetry	• Turbine Calibration	• Set Bluetooth	• Units of measurement
• Set Questions	• Set Language	• Ignition Type	• Clear archive
• Set symptoms	• Date Format	• Set Oximetry	• Security Info
• Personal best	• Unit of measurement	• Theoretical Author	• Firmware Info
	• Clear archive	• Set Standard	• Print Settings
		• Set parameters	
		• Turbine type	

Scroll through the various items of the menu as explained in paragraph 2.1; once the item of interest is shown touch the corresponding item



2.7.1 Doctor Mode

In Doctor Mode the user has access to all the functions of the device for professional use, unlike Patient Mode which is restricted to a simplified use of the device. (Please view paragraph 2.7.2).
The following items are those shown in the service menu when in Doctor Mode.

Doctor/Patient
This function allows to set one of the two modes:

- Patient mode
- Doctor mode

The first one is set by the doctor when the device will be used by the patient for homecare use; the second mode instead allows full access to all the functions of the device when used directly by the doctor.
Select the desired mode, press the OK icon, automatically the mode will be set and the device will return to the service menu. The service menu will show a different configuration according to which mode has been selected.
For more information concerning device functioning in patient mode please view paragraph 2.7.2

Change date/time
Select the item by touching the display.
When setting the date and time, the cursor _ indicates the data item which is being modified. Use the numbers shown to modify the data item of interest, move on to the next data item by touching OK. Touch OK so that the new settings will take effect and to return to the service menu. To return to the service menu without modifying the item data touch ⬅.

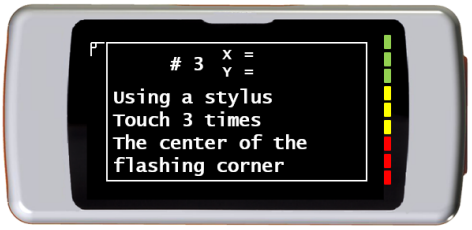
LCD Settings
This item allows to:

- Brightness and contrast setting of the display
  With two scales which go from 0 to 31 it is possible to set the parameters of the display and view in real time its effect. Once the best combination of brightness and contrast is obtained touch OK on the bottom right side of the display

- Calibrate the touch screen function
  This function is used to check the proper response of the touch screen; the device initially request a confirmation, touching OK icon the calibration begin

  There are four phases as follows:

  - Touch three times the top left-hand point of the display
  - Touch three times the top right-hand point
  - Touch three times the bottom right hand point
  - Touch three times the bottom right hand point



  The reference area is the one inside the flashing outline.
  This procedure will then be set up in function of the dimensions of the display.

This procedure must be carried out using the tip of a touch-screen "pointer" held vertically at 90 degrees to the display.
if the calibration is made correctly then the device shows:

Calibration is OK

Otherwise the user is requested to repeat the calibration procedure.
The procedure cannot be cancelled once started, so carry out the procedure correctly to return to the service menu.

Bluetooth Settings

Once in the menu it is possible to select the activation mode of the Bluetooth function. The "Activation" item allows to select from the following options; "On request" and "always on"; in the first case the function is activated only when requested(for example to print a test),otherwise it remains off thus allowing to save energy; by selecting the option "Always on" this function is always activate and ready for use(for example to transfer data to a mobile phone.)
Access this menu to search for active Bluetooth devices, touch the option "Search Device"; **Spirodoc** will start to search for Bluetooth devices in the area; once one or more devices are found the display will list these devices with their respective names. By touching the device of interest it will be memorized as a printer, a phone, or as a PC – On line; select an option.
In the "Bluetooth setting" menu any previously memorized devices can be viewed in the "printer" list, "telephone" list or the "PC – On line" list. Next to the device name a corresponding icon (telephone, printer or PC) will appear. Any device from these lists can be set as the default device (the device that **Spirodoc** will automatically connect to via Bluetooth) by entering in the lists, touching the display and selecting the device. A listed device can be eliminated from the list. (in this specific case the user will confirm the deletion with the OK icon.)
So as not to make any modifications touch the ⬅ icon in the bottom left side

Turn ON mode
This function enables the device to turn on automatically at a predetermined time. The device will automatically turn on and commence a sleep oximetry test (this test is also capable of monitoring the patient all day long, and includes as a step counter and a triaxial accelerometer to measure the VMU)
The device will turn off automatically at a predetermined time.

WARNING

If the automatic turn-ON function is set it will be impossible to turn off the device during the test. The closed lock icon located on the top center of the screen warns the user of the current setting.

Select the item by touching the display and choose between the following options:

- Manual
- Automatic

Manual turn-ON: allows to set the turning on of the device by using the specific ON/OFF key.
Automatic turn-on: enables the programming of the frequency and duration the device turns on. Select the desired item and press OK.
If the user selects automatic turn-on she/he may choose from the following options:

- One time only
- Once a week
- Monday to Friday
- Saturday-Sunday
- Every day

For each option a menu appears to set the day and time that the device will turn on and off.

If turn ON mode was previously enabled, and the user turns on the device at a different time from that of the programmed time, the device will show the screen on the right. To continue touch the OK icon and insert the PIN. If the PIN is not set insert the default PIN which is the following:

1 2 2 3

by touching the ⬅ the device will turn off.

Oximetry setup

When entering the Oximetry Setting menu the following items are shown:

- Alarms Setting
- SpO2 Sampling Rate
- Pulse tone ON/OFF
- Default alarms

Alarms setting

Access to these settings is password protected and allows the user to set the lower and upper threshold values for SpO_2 and Pulse Rate; during the test, an acoustic alarm will warn the user if the SpO_2 and / or Pulse Rate values fall below the minimum threshold or exceed the previously set maximum threshold.
The configurable parameter are the lower/upper thresholds of the SpO_2 and Pulse Rate parameters. For each parameter is possible to set the alarm ON or OFF and to change the *Default threshold value* by the *modify* icon  .

The table shows the lower and upper threshold values may be set:

Alarm Limit	Minimum	Maximum
SpO_2 min	85	99
SpO_2 max	85	99
BPM min	30	235
BPM max	30	240

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.

Once the upper threshold of Pulse Rate has been set, confirming with OK, the sequence will continue with the ON/OFF setting of the following alarm conditions:

- Finger not inserted
- Sensor unplugged
- Battery discharged

The image illustrates an example of setting for an alarm condition: in this case it is the alarm for *"finger is not correctly inserted "* .

SpO2 sampling rate
This function allows to set the time that elapses between the sampling/recording of two consecutive oximetry readings; touch one of the two visualized icons: 2 seconds or 4 seconds, then touch OK to set the selected value and the device will automatically return to the service menu.

Pulse tone ON/OFF
This setting enables the Pulse rate tone (audible beep) during oximetry testing.

WARNING
The Pulse rate tone (beep) is always disabled during sleep oximetry testing

Default alarms (factory setting)
This function allows to restore all factory default alarms setting. To confirm touch the "YES" icon. The settings return to the *factory values*.
The image on the right shows the factory default alarms setting.

After a few seconds, the device will show the oximetry setting menu.

Select predicted
Select the item by touching the display.
A list of predicted values is shown; select the Predicted value desired.

Adult	Pediatric
ERS	Knudson
Knudson	Knudson
USA	Knudson
ERS	Zapletal
MC-Barcelona	Zapletal
JRS	JRS
PEREIRA	PEREIRA
CHINESE HK	CHINESE HK

Select the pair to use and touch OK. The Predicted values are set and the device returns to the Service Menu.

Select standard
Select the item by toughing the display.
Select the standard to be used (ATS/ERS, or NHANES III) and touch OK, the setting takes effect and the device returns to the Service Menu.

WARNING
If the NHANES III standard is selected it is not possible to set or modify the predicted values.

Set parameters

It is possible to select the type of calculated parameters during spirometry and oximetry testing. For each of the two categories the user may select from the following three options:

- simplified
- personal
- complete

The "simplified" mode only allows for the main parameters to be viewed according to the main standards in effect. In paragraphs 2.7.1. and 2.7.2 these parameters are shown.
In "personal" mode the user may select which parameters will be displayed. The parameters highlighted in white will be displayed. To remove a parameter from the list simply touch the white highlighted parameter and it will turn grey.
In "complete" mode at the end of a test all the parameters that the device is capable of calculating will be shown.

⚠ WARNING

The parameters of the "simplified" mode are always shown regardless of which mode has been selected.

⚠ WARNING

Certain oximetry parameters are grouped together according to the kind of information displayed; by selecting one parameter from a group all the other parameters belonging to the same group will selected automatically.

⚠ WARNING

When the NHAHES III standard is selected the spirometry parameter setup function will be automatically disabled.

Select turbine
Select the option by touching the display.
Select the type of turbine to be used (reusable or disposable) and press OK. The turbine selection will be saved automatically and the device will return to the Service Menu.

Turbine calibration
Select the Turbine Calibration item and choose from the following options:

- show current values
- modify calibration
- factory defaults

Selection of the first item shows the percent correction applied in that moment.
The item "modify calibration" allows to insert new calculated values to perform a new calibration. A password is required to access this option; insert the PIN by touching the numbers; if the PIN is not set digit the default PIN which is the following:

1 2 2 3

The item "factory defaults" erases the previous calibration values and restores the two percentage corrections to zero percent correction factor; in this case a password is required as explained above.
To perform this procedure correctly please refer to paragraph 2.7.3.

Select language
Select the desired item by touching the display and press OK, the language is now set and the device will return to the Service Menu.

DATE Format
Select the item by touching the display.

day	month	year
month	day	year
year	month	day

Select the desired format and press the OK icon; the selection will be saved automatically and the device will return to the service menu.

UNIT format
Select the option by touching the display.

Imperial	(in,lb)
Metric	(cm kg

Select the desired format and press OK; the selection will be saved automatically and the device will return to the service menu.

Delete Memory

Select the desired item by touching the display.
To delete the memory of the device insert the PIN or the default PIN by touching the numbers. The default pin is::

1 2 2 3

If the password was not properly inserted the message below is shown:

Password Error **Press OK to try again**

If the user fails to enter the correct password three consecutive times the device will automatically turn off.
If instead the password was properly inserted the message below will be displayed:

Please wait **erasing memory**

After approximately 30 seconds the following message will appear:

Memory deleted

The device will now return to the service menu.

Security (or Privacy)

In the "**Security**" 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"**

Info firmware
In this menu the user may view the current software version of the following components:

- **Spirodoc**
- Bluetooth
- Oximeter

After approximately 10 seconds the device will automatically return to the service menu, otherwise touch ⟵.
Once all of the items in the service menu have been set it is possible to exit the menu by touching ⟵ on bottom left side of the screen.

Print Settings
Select the item by tapping on the display.
You can select between:

- black/white print
- colour print.

2.7.2 Patient Mode

Patient mode allows for a simplified use of the device for homecare use by a patient. In this mode the doctor may also set/visualize certain functions useful to comprehend the state of health of a patient and how it evolves in time.

By touching the icon for a few seconds the user will access the simplified service menu which is comprised of the following items:

- Change date/time
- LCD settings
- Configuration
- Bluetooth settings
- Info firmware

To access the Patient Mode service menu select the item "Configuration" and insert the PIN or the default PIN which is the following:

1 2 2 3

The service menu will display the following items:

- Doctor/Patient

- Turn ON mode *
- Patient data *
- Oximetry setup *
- Set questions
- Set symptoms
- PERSONAL best
- Select predicted *
- Select standard *
- Select turbine *
- Turbine calibration *
- Select language *
- Date format *
- Unit format *
- Delete memory *

Some of the items in Patient Mode can be found in Doctor Mode (please view the items with *) These items are explained in paragraph 2.7.1 (Doctor Mode) All other items are exclusive to Patient Mode and are described below.

PERSONAL Best
The user may select the reference parameter to be used to compare against the spirometry test report. The following parameters can be selected:

FVC FEV1 PEF FEF2575

Each one of the four parameters can be compared against either a personal best value of the patient or a Predicted value by selecting one of the two items below:

- Set personal value.
- Use predicted value

Set questions
This option allows to select specific questions that the patient will answer upon turning on the device.
The following table shows the items that can be set and the possible patient answers:

Questions	Possible answers	
Taken drug?	**No**	**Yes**
Taking oxigen?	**No**	**Yes**
Are you working?	**No**	**Yes**
Mood		

Set symptoms
This setting contains a list of questions that a patient will answer every time a test is recorded. The following table shows all the items that can be selected and the possible patient replies:

Symptom	Answer		
Tiredness on waking	NO	MED	MAX
Daytime drowsiness	NO	MED	MAX
Breathless on waking	NO	MED	MAX
Troubled Sleep	NO	MED	MAX
Wheezing	NO	MED	MAX
Cough	NO	MED	MAX
Sputum production	NO	CLEAR	DARK
Sputum increasing	NO		YES
Breathlessness	NO	EFFORT	REST
Fatigue	NO	MED	MAX
Chest tightness	NO	MED	MAX

Once a symptom is selected by the doctor, the patient may skip the question and move on to the next one.

2.7.3 Reusable turbine calibration

⚠ WARNING

The turbine flow sensor does not require calibration, however regular cleaning of the turbine is necessary . If a calibration must be performed the following guidelines should be carefully noted.
The calibration procedure can only be performed with the reusable turbine.

Turbine calibration is performed with a calibration syringe to simulate a FVC test for the expired parameters and a FIVC test for the inspired parameters.
To enter the calibration function, select the "Turbine Calibration" option from the Service Menu (as explained in paragraph 2.7).

To enter the new calibration values choose the item "Modify" in the submenu, enter the password and insert the new calibration values

Before inserting the new calibration values be sure to check that the syringe volume corresponds to the value on the top right side of the screen. To change the syringe volume touch the ⬅ icon, this way the cursor allows to insert the correct volume of the syringe being used for the calibration test.
In the FVC and FIVC fields insert the FVC and FIVC parameters measured in the calibration test with the calibration syringe, by using the numbers visualized on the bottom of the screen. Once the data for each parameter has been inserted touch the OK icon.
Insert both the FVC and the FIVC values. If the calculated correction factors are acceptable (<10%), these are displayed next to the New FVC and New FIVC parameters. The message ENTER OK TO CONFIRM will appear.
By touching the ⬅ icon the device returns to the previous step.
If the FVC and FIVC correction factors are > 10% theFVC and FIVC values will not be accepted. This means that the device is not capable of correcting such a large calibration error In this case:
- Check the correct functioning of the **Spirodoc** with a new turbine and/or
- Clean the turbine.

To erase the calibration in use and to reset the original factory calibration, use the item "Factory defaults" from the Calibration menu

⚠ WARNING

In line with the publication "Standardised Lung Function Testing" of the European Respiratory Society (Vol 6, Supplement 16, March 1993), the air expired from the mouth is at a temperature of circa 33/34 °C.
The expired flow and volume, to be converted to BTPS conditions (37 °C) must be increased by 2.6% - this is derived from the BTPS factor of 1.026 at a temperature of 33°C, which represents a correction of 2.6%. In practice the BTPS factor for the expired flow and volumes is therefore constant and equal to 1.026.
For the inspired volumes and flows, the BTPS factor depends upon the ambient temperature as the air inspired is at ambient temperature.
For instance at an ambient temperature of 20°C with relative humidity at 50%, the BTPS factor is 1.102, a correction of +10.2%.
The correction of the inspired volumes and flows is made automatically as the machine has an internal temperature sensor; the BTPS values are thus calculated.
If a 3L syringe is used to make the calibration and if the Spirodoc is calibrated correctly then the FVC (syringe) value will be:
3.00 (FVC) x 1.026 (BTPS) = 3.08 L (FVC at BTPS).
If the ambient temperature is 20°C, the FIVC (syringe) value will be:
3.00 (FIVC) x 1.102 (BTPS) = 3.31 L (FIVC at BTPS).
The user must be aware that the volume of the syringe shown by the machine is converted to BTPS conditions, so that the "increase" of the results with respect to the expected values does not constitute an error.
For instance, if the calibration procedure is carried out with measured data:
FVC = 3.08 L and FIVC = 3.31 L at an ambient temperature of 20°C the resulting correction factor becomes:

EXPIRATION	**.00%**
INSPIRATION	**.00%**

This does not represent an error but is a logical consequence of the above detailed explanation.

NOTE

A calibration may also be performed with the MIR Spiro software included with the device. For more information concerning the on line calibration procedure using MIR Spiro please read the on line MIR Spiro manual

2.8 Patient Data

From the main screen the user can access the patient data management by using the icon . By entering this menu it is possible to:

Modify current patient data *
Insert a new patient

*this function is visualized only if a patient file was previously inserted in the database
If the database is empty the device will automatically direct the user to insert the name of the patient.

2.8.1 Inserting data of a new patient

Touch the icon and insert the patient information in the required sequence.

First screen (name)
Write the name of the patient with the touch screen keyboard. Touch the OK icon to move on to the next screen

Second screen (surname)
As above insert the surname of the patient and touch the OK icon.

Third screen (date of birth, weight, height and sex)
By using the visualized numbers in the bottom of the screen, set the day, month, year of birth, height and weight of the patient. The last data to insert is the sex of the patient, which can be chosen by selecting one of the following icons:

 Male  Female

To move from one item to the next touch the OK icon.

Fourth screen (ethnic group)

Setting of the correction factor: these values allow to adjust the test data as a function of the ethnic group of the patient (it is possible to opt for "without correction");

Standard ATS/ERS	
Group	% correction
Without correction	100%
Caucasian	100%
Oriental	100%
Hong Kong Chinese	100%
Japanese	89%
Polynesian	90%
North Indian	90%
South Indian	87%
Pakistani	90%
African descendant	87%
Aboriginal	85%

Standard NAHNES III
Caucasian
Mexican-American
Afro-American
Other

When using ATS/ERS standards, the correction is applied to the predicted values of the following parameters:

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

When using NAHNES III standards, the correction is based on several theoretical formulas (as per NAHNES III standards).
Once the ethnic group is set the device saves the data and automatically returns to the main screen.
To interrupt the data insertion, touch the ESC icon and the device will automatically return to the main screen.

2.8.2 Patient data modification

The icon  allows to modify current patient data; by entering in this function the patient data is presented on the various screens; modify the data by using the alphanumerical key which are shown time and again.
Touch the  icon to return to the main screen without modifying any data.

⚠ WARNING

A new patient is not created from the previous patient when selecting this function. Patient info however can be modified. Future tests will be associated to the patient always identified by the same ID code, unique to that specific patient.

2.9 Visualization of memory data

2.9.1 Database research modality

⚠ WARNING

The database only contains tests performed before the current test session. To analyze data related to the current test session please refer to paragraph 2.9

From the main screen it is possible to access the database of the device by using the  icon.
Four methods of research are available:


Reseach by patient date of birth.
Research by the date of testing.

Visual of all tests in the database starting form the most recent.

Research by patient surname.

Research by patient date of birth: patient date of birth must be inserted; after all the data has been inserted touch the OK icon. All data visualized concerns tests performed by patients whose date of birth corresponds to the inserted date of birth.

Database by date of testing: requires the insertion of the date when the test was performed; once all the date information has been inserted touch the OK icon. The data returned by the device are all the test sessions performed during that specific day.

Complete database: shows data starting from the most recent session. The end of the database is signalled by a double beep. The database search is resumed from the last session.

Research by surname: requires insertion of patient surname or surname initial; once having inserted the surname touch the OK icon. Visualized data corresponds to all test sessions of that particular patient.

NOTE

Test session in Doctor Mode refers to (spirometry PRE, POST and oximetry) tests gathered from one patient on the same day. So a visualized session in the database can be composed of different tests which as a whole allow the doctor to evaluate the health of a patient at that specific date.
Test session in Patient Mode refers to spirometry PRE tests and oximetry tests performed within a 20 minute time span.
A new session is activated upon turning on the device , if the time of start of the previous session was more than twenty minutes from the actual time.
If the device remains on for more than 20 minutes the current testing session will continue until the device turns off.

The user must select the type of test results to be viewed by using the screen on the right. The user may perform multiple searches as shown next

FVC VC MVV POST

SPOT SLEEP 6 MWT Holter

Once the desired tests have been selected the corresponding icons will become highlighted. By pressing the OK icon a list of corresponding test results in the database will appear. The "ALL" icon will select all the tests simultaneously.

The 24h icon restricts the search to all oximetry tests lasting longer than 12 hours.

2.9.2 Visualization of database info

The result of a search performed in one of the described methods in paragraph 2.9.1 can be viewed in the adjacent image. By touching the desired session one may access the performed tests

Once a testing session has been selected the database screen will show the adjacent image. By scrolling the screen the user may select the desired test of a session.
The three icons on the lower part of the screen allow access to the following functions:

To perform a new testing session with the selected patient.

To send to a printer the parameters of a selected test.

To view the parameters of a selected test.

For the FVC tests the flow-volume and time-volume curves are displayed as shown in the image on the right side, to view the test parameters simply touch the screen
The following screen shots display the previously selected parameters from the service menu including the percentage change from the predicted values.

Oximetry tests display the selected parameters from the service menu and are shown just like the spirometry parameters above.
The user may return to the previous screen by using the ⬅ icon.

The icons ◄◄ and ►► are displayed only if there are more than 32 tests in memory. These icons let the user scroll blocks of 32 sessions at a time.

2.10 Display of last test session from current patient

To view the last spirometry tests performed by the current patient touch the icon.
Inside the spirometry menu the icon allows to access the most recently performed tests

To visualize the last oximetry tests of the current patient touch the icon on the main screen.
Inside the oximetry menu the icon allows to access all data from the most recent tests.

If no test has been performed yet but a previous test session of the patient under examination already exists in the database, the previous procedure allows to view the previous test session. If instead both the last test session and previous test session are available the procedure allows to select which session to view as can be seen on the screen to the right.

If a patient has instead performed a test in the current session and previous tests are archived, the following screenshot is displayed:

2.11 PC On line mode (connected to a PC)

In the PC on-line mode the **Spirodoc** becomes a fully functional laboratory device which works in real-time connected to a PC. PC interface is via USB cable.
The **Spirodoc** becomes an intelligent transducer for the measurement of volume and flow while the PC controls the device including the on and off function.
Other than the usual spirometric parameters and the F/V in real-time the **Spirodoc** also plots the most refined indices such as the ventilatory profile and the extrapolated volume (Vext).
The PC software incorporates the most up to date bronchial provocation protocols displaying the dose-response and time-response of the FEV1

⚠ WARNING

When the device is connected to the PC, it cannot be controlled directly. The settings defined on the PC are then transferred to the device and remain set even in subsequent direct use; if, for example, a turbine (disposable or reusable) is set while using the SPIRODOC connected to the PC, it will remain as the default in any subsequent use of the device in direct mode until the device is restarted. Therefore, pay attention to the type of turbine set.

2.12 Spirometry testing

In order to perform proper spirometry testing the following instructions are to be followed carefully:

- Insert the turbine in the appropriate housing until it reaches the mechanic stop and successively rotate the turbine clockwise until it stops. Insert the mouthpiece at least 0.5 cm inside the groove of the turbine.
- Place the noseclips on the nose so as not to let any air out of the patient's nostrils.
- Hold the **Spirodoc** from both ends with both hands or grasp it like a mobile phone. The touch screen must always face the patient taking the test.
- Place the upper part of the mouthpiece in the mouth making sure that no air leaks from the sides of the mouth.

WARNING

Correct positioning of the mouthpiece extending under the dental arch in the patient's mouth is fundamental so as to avoid any turbulence which could erroneously affect the spirometry results.

WARNING

If possible it is recommended to stand up while performing the test. During expiration it is recommended to bend forward the upper part of the body so as to release all the air out with the aid of the abdominal muscles.

By touching the  icon the user may access the spirometry testing area which includes the following tests:

FVC spirometry testing
VC type spirometry test
MVV type spirometry test
test with broncodilator

Once a test is selected the screen will display information concerning the type of turbine in use (reusable or disposable) including the necessary information to complete the test in the correct manner.

WARNING

A test is saved with the name of the last patient displayed. If a test refers to a previously saved patient, then prior to performing a test the user must recall that patient from the database as described in paragraph 2.9.2

To end a test press the power (ON/OFF) key placed on the top side of the device pressed

2.12.1 FVC test

Proper execution of a FVC test must take into account the phases as described on the screen, more specifically:

INSPIRE quickly
EXPIRE forcefully
INSPIRE forcefully

It is possible (and may be helpful) to start the test by breathing at rest for a few moments. When ready to start *inspire slowly as much air as possible* (made easier by raising the arms wide apart) and then *make a complete expiration as fast as possible*. Then with the mouthpiece always held firmly in the mouth, complete the cycle by inspiring again as quickly as possible. This final inspiration may be left out if the inspiratory parameters (FIVC, FIV1, FIV1%, PIF) are not of interest.
The optional initial inspiration phase can also be performed before inserting the mouthpiece in the mouth.
After inspiring slowly and deeply, the following expiration must be made with the maximum effort by expiring all the air in the lungs as fast as possible.
After 6 seconds of expiration the device will emit a continuous beep, this helps the user to understand whether the minimum expiry time has been reached, as recommended by the main international respiratory institutions.

WARNING

Accurate spirometry testing requires that the patient expire all the air in the lungs.

The test may be carried out several times by repeating the cycle without taking the mouthpiece out of the mouth, in which case **Spirodoc** recognises the best test (largest FVC+FEV1) and will automatically display the results of the best test.
To end the test touch the OK icon.
During the test the **Spirodoc** emits "beeps", the frequency of which are directly proportional to the inspired and expired velocity of the air. This helps the doctor understand when the velocity of the air is approaching zero, and the patient has almost exhausted all of the inspired or expired volume.
In the maintenance section an explanation is given as to how this feature can also function as a very simple checking system for the correct operation of the mobile "rotor" of the turbine.
For the FVC test to be judged as acceptable, besides breathing as deep as possible, it is also required that the forced expiratory time (FET) is sufficiently long to allow for the complete expiration of all air contained in the lungs.

2.12.2 Test VC

Ventilatory Profile

The slow vital capacity test can be started by carrying out several breaths at tidal volume. After three or four such breaths an acoustic signal will be emitted to confirm that the ventilatory profile has been measured and that the patient may immediately proceed to perform the VC or IVC test.

Expiratory Slow Vital Capacity: VC
After the acoustic signal *inspire slowly* as much as air as possible and *expire slowly* as much air as possible.

Inspiratory Slow Vital Capacity: IVC
After the acoustic signal *exspire slowly* as much as air as possible and *inspire slowly* as much air as possible.
To end the test touch the OK icon.
Follow the indications on the display carefully in order to carry out the test properly.

⚠ WARNING

To perform a test in the service menu with the item "PARAMETER setting", at least one parameter related to this test must be activated/chosen, otherwise the icon will be disabled.

2.12.3 MVV Test

Start the test by carrying out a series of forced inspirations and expirations with the maximum possible amplitude. The suggested frequency is 30 breaths per minute. The test will end automatically after 12 seconds.

⚠ WARNING

To perform a test in the service menu with the item "Set parameter", at least one parameter related to this test must be activated/chosen, otherwise the icon will be disabled.

⚠ WARNING

The disposable mouthpiece and the disposable turbine must be replaced after a single patient test session.

2.12.4 POST test, after drug administration

⚠ WARNING

To carry out a POST test it is necessary to have carried out at least one PRE FVC test the same day; it is not possible to do a POST test on the PRE VC or MVV tests; it is however possible to do a POST VC or MVV test if the database already contains at least one PRE test carried out on the same day.

To carry out a POST test please access to the spirometry area touching the  icon on the main screen and subsequently touching the  icon.

A POST test is a spirometry test following the administration of a drug of some kind, usually a bronchodilator. The sign POST is shown on the screen of the device (top right) during the following tests. On the RHS of the screen there is the icon  which enables you to see all of the results from the PRE test as well as the relevant predicted values. The following tests made by the patient show the following parameters:

- Those values related to the test performed
- Those values related to the best PRE test performed by the same patient the same day.(that is in the same test session)
- The percentage variation between the PRE and POST values (in the CHG column)

It is not possible to perform a POST test with a patient whose PRE testing was not carried out on the same day.
If during a POST session a new patient is inserted or another is recalled from the archive the device will automatically exit the current POST session.

2.13 Viewing the spirometric results

Following a FVC test, the spirometry test results are shown. The first screen displays:
- the Forced Vital Capacity Flow/Volume graph.
- the main parameters FVC, FEV1, FEV1%, PEF best acceptable in the session
- the percentage ratio compared to theoretical values

By scrolling on the right hand side of the screen it is possible to view all the parameters next to the chosen predicted values.

2.13.1 Spirometry test interpretation

Spirometry test interpretation is based on the Forced Vital Capacity (FVC) test. The test interpretation is indicated with one the following messages:

- Normal Spirometry
- Mild obstruction
- Moderate obstruction
- Moderate severe obstruct.
- Severe obstruction
- Very severe obstruction
- Mild Restriction
- Moderate Restriction
- Moderate Severe Restriction
- Severe Restriction
- Very severe Restriction
- Obstruct. + Restrict

For a POST test the messages are the same but instead of dealing with an "obstruction" the POST test refers to a "restriction".

Through the use of a mathematical analysis applied to certain indices and parameters calculated in the FVC test, the **Spirodoc** is capable of producing a list of quality control comments useful to assess the quality and reproducibility of the manouvres performed.

The quality control check assigns a letter for the current spirometry session as described below:

PRE test
A = At least to acceptable manouvres, with the highest two FEV1 values matching to within 100 mL and the largest two FEV6 values within 100 mL
B= At least two acceptable manoeuvres, with the FEV1 values matching to within 101 to 150 mL
C= At least two acceptable manoeuvres, with FEV1 values matching to within 151 to 200 mL
D= only one acceptable manoeuvres, or more than one, but the FEV1 values not matching to within 200 mL (with no interpretation).
F= No acceptable manoeuvres (with no interpretation).

POST test
A = two acceptable FEV1 values matching within 100 mL
B= two acceptable FEV1 values matching within 200 mL
C= two acceptable FEV1 values that do not match within 200 mL
D= only one acceptable FEV1 manoeuvre
F= No acceptable FEV1 manoeuvres

An acceptable manoeuvre means: good start and satisfactory exhalation (duration and flow)

Several *comments* related to the single test are calculated, however **Spirodoc** will only point out the most relevant to facilitate the test interpretation.

ERROR IN Vext and PEFT
If the extrapolated volume Vext is greater than 500 mL or more than 5% of the FVC, **or** if the PEFT (time to peak flow) is greater than 200 ms, this message is shown:

Repeat test and blow faster

FET ERROR
If the **FET** is less than the minimum (6 seconds), this message is shown:

Expiry time insufficient < 6s

FLOW ERROR
If the last point of the F/V curve is greater than 200 mL/s, this indicates that the expiration was not complete and thus this message is shown:

Blow out all air in lungs

Between tests, the **Spirodoc** checks the repeatability of the following parameters:

PEF repeatable when the difference between the two largest PEF is ≤ 0.67 L/s;
VC repeatable when the difference between the two largest VC ≤ 150 mL;

If FVC is > 1.0 L then:
FEV1 repeatable when the difference between the two largest FEV1 is ≤ 150 mL;
FVC repeatable when the difference between the two largest FVC is ≤ 150 mL;

if FVC is ≤ 1.0 L then:

FEV1 repeatable when the difference between the two largest FEV1 is ≤ 100 mL;
FVC repeatable when the difference between the two largest FVC is ≤ 100 mL;

2.14 Oximetry Testing

⚠ WARNING

Check if the oximetry function is available in the device, this function is an option in some models.

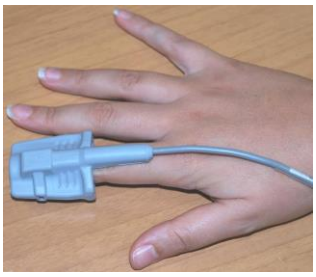
Spirodoc is able to perform 3 different types of oximetry tests, which will be described in the following paragraphs.

⚠ WARNING

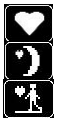
The oximetry sensor used in the manual is only one of the different types of sensors which can be used listed in paragraph 1.2.4. MIR does not recommend any particular sensor; the doctor will chose the sensor which she/he believes to be more suitable.
During oximetry testing the Spirodoc cannot be turned off. To turn off the device the oximetry test must be stopped first. This has been implemented so as to avoid any unwanted interruptions which could compromise the accuracy of the data.

For the non-invasive measurement of *SpO_2 oxygen saturation* and blood pulse rate, utilize the re-usable finger sensor. This sensor is recommended for patients weighing more than 20 Kg while remaining still during testing. For the 6 minute walk test other types of sensors are recommended which are less influenced by the movement of the hand.
To carry out an oximetry test:

- Connect the sensor to the device: insert the connector with the arrow (printed on the connector) face-up, as shown:
- Choose a high perfusion site, easily adaptable to the sensor.
- Insert the finger into the sensor until the finger touches the end of the probe. Ensure that the bottom part of the finger completely covers the detector. If the finger cannot be placed properly inside the sensor try another finger.
- Place the sensor so that the cable rests on the back of the hand. This ensures that the light source rests. On the side of the nail and the reader on the lower part of the hand.



Select one of the tests that can be performed with **Spirodoc**
To access the oximetry area touch the  icon on the main screen and subsequently select the type of oximetry test to carry out.



SpO2/BPM spot test
Sleep oximetry test (ODI)
Six minute walk test

If the following message appears upon start-up:

WARNING OXIMETER NOT PRESENT

This means that your device does not have this function.
If instead the following message appears:

WARNING THE OXIMETER IS NOT ENABLED

This means that the oximetry function is included, however the internal application has yet to be enabled. In this case please contact a service center or the manufacturer.

⚠ WARNING

Before carrying out a test, if the power supply value is low the following message will appear:

Low battery level

Touch the ESC icon to exit the test, otherwise after a seconds will start the test.
In the event that a test is interrupted due to a complete battery discharge, the next time the device is turned on the following message is displayed:

WARNING
Wrong interruption of last oximetry test

At the same time an intermittent beep is emitted for 4 seconds.
Subsequently the Spirodoc returns to the main screen.

⚠ **WARNING**

Avoid twisting the sensor's cable as this may compromise measurement accuracy and the integrity of the sensor itself, also do not apply excessive force when using, connecting, disconnecting or storing the oximetry sensor.

The first few seconds are used to find the best signal possible; after which the **Spirodoc** timer resets itself and the device starts recording data.
For any type of oximetry test if the sensor is not properly connected the following message will be displayed on screen after a few seconds:

WARNING
Sensor unplugged

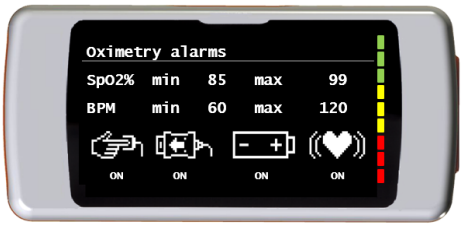
At the same time **Spirodoc** emits an acoustic alarm (if previously set in the service menu).

If the sensor has been connected properly but the finger has not been properly inserted in the sensor the following message will be displayed on screen.

WARNING
Finger not inserted

At the same time **Spirodoc** emits an acoustic alarm (if previously set in the service menu).
If the signal reaches the sensor properly, after a few seconds the device will emit the pulse tone an acoustic signal while also displaying the values on screen.
The alarms can be customized, the procedure is described in paragraph 2.7.1.
During oximetry testing if the SpO2 and/or the Pulse rate fall below the lower threshold or raise above the upper threshold, **Spirodoc** will emit an acoustic alarm '(if previously set in the service menu.)' until such situation persists. For sleep oximetry testing the Pulse rate tone is always disabled.

If all the alarms are activated during oximetry testing the  icon will always show up on screen.
By touching this icon during a test the device will display for a few seconds the alarm settings as can be seen from the image on the right. The alarm thresholds that have been previously set in the service menu are also visible. After a few seconds the device returns to the current test screen.



If the  icon shows up during a test, one or more alarms have been disabled in the OFF position in the service menu. The user may always check the alarm situation by touching the above icon

Upon activating an alarm among those chosen the  will be visualized. By touching the icon the corresponding alarm will not emit an acoustic signal for two minutes. In this case the icon will be shown as  to then return to the previous icon when the two minutes are over.
For information concerning the proper setup of this function please refer to paragraph 3.6.

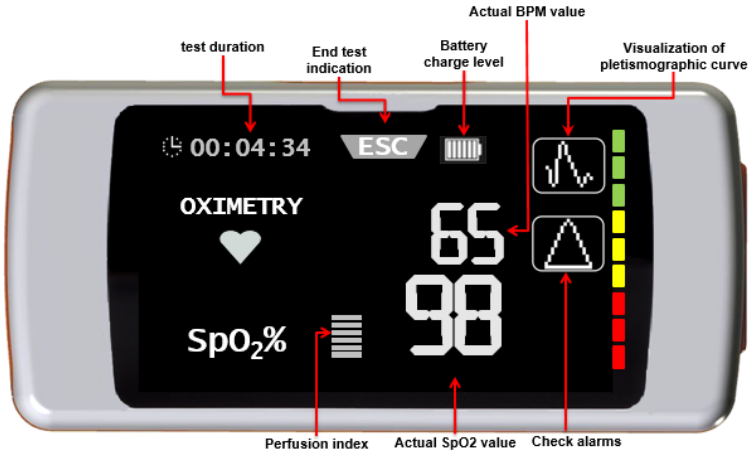
⚠ **WARNING**

A test is saved with the name of the last patient displayed. If a test refers to a previously saved patient, then prior to performing a test the user must recall that patient from the database as described in paragraph 3.8.2

⚠ **WARNING**

A test is archived with the name of the last patient displayed; if this relates to a previously entered patient, before carrying out the test recall a test previously carried out on the subject in question and operate as described at the end of section 2.8.2.
During the SpO2 and 6MWT oximetry tests, the battery pack charge level is shown, allowing an estimate of the available autonomy, which may vary depending on the state the device is in (display illumination at maximum or in economy mode).

During a test the display will show the following information:



To end an oximetry test press the power ON/OFF key. If the ESC icon is touched the image to the right will be displayed for a few seconds

2.14.1 Walk test (6MWT)

To access the oximetry area touch the icon on the main screen; then select the test with the icon.
The walk test is comprised of three stages:

- Initial rest
- walking
- recovery

WARNING

During testing proper step-counter reading is obtained by positioning the device on the chest as shown in the image on the right side.

The holder is optional and is provided only if requested.

Initial rest stage

In this stage the display will show the following data:

- Test time duration
- Signal quality indication
- Current stage
- SPO2 percentage value and the cardiac pulse rate(BPM) (heart symbol)

The "initial rest" stage must continue for a minimum of 2 minutes, after which the icon will appear on screen. Simply touch the icon to move on the next "walking" stage. If the user does not move on to the "walking" stage, a few seconds before reaching the 6 minute mark the **Spirodoc** will emit an acoustic signal "beep" as a warning, and automatically enter the "walking" stage.
The number of bars (▬ symbol), on the right upper of the screen is proportional to the quality of the oximetry signal: the higher the quality of the signal the more bars will be shown (maximum 7). Place a finger into the sensor in order to obtain the highest quality signal possible.

Walking Stage

At the beginning of the "walking" stage the timer is reset to zero so that the user can immediately see of the duration of each single phase. The data on the display is the same as shown before.

This stage will continue for a minimum of 2 minutes, after which the icon appears on screen. To move to the next "recovery" stage touch the icon for a few seconds. If the "walking" stage continues for more than 6 minutes **Spirodoc** will emit an acoustic

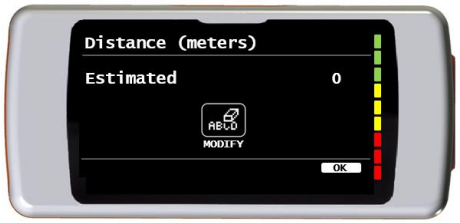
signal "beep" and after 6 minutes are up the device will automatically move on to the "recovery" stage and the timer will be reset to zero again.

Recovery stage

The duration of this stage is entirely up to the doctor and it is not indicated in any way (at the beginning of this stage the timer resets to zero).

To end the test press the ON/OFF key. At the end of the test the estimated distance walked during the walk stage is displayed.

The user may accept this value or manually insert the distance walked by touching the icon. Next the device will require the user to insert other data related to the state of health of the patient. By touching the "Yes" icon the user will view the screenshots to insert the following data



- Taken oxygen?
- Baseline DYSPNEA
- Final DYSPNEA
- Baseline FATIGUE
- Final FATIGUE
- Baseline Diastolic
- Baseline Sistolic
- Final Diastolic
- Final Sistolic

Touching "NO" icon, the device shows immediately the test parameters.

WARNING

If in the voice "set parameters" of the service menu, the parameters dyspnea, fatigue, diastolic and systolic are disabled, at the end of the test, the device requests only the distance walked.

For oxygen administration purposes the device allows to select from:

NO	L/min	%
Not administered	administered in L/minute	administered in %

If oxygen was administered to the patient before testing, the user may insert a value by using the screen on the right side. By using the L/min unit decimal values may be inserted (icon); when using % only whole values may be used.
The acceptable range of values for the two units are:

Unit	Minimum	Maximum
L/min	0.1	6.5
%	20	99

The dyspnea and fatigue parameters are represented in the Borg scale and can have the following values in the table to the right.
The coefficients of the Borg scale are represented by the following severity values:

Scale	Severity
0	None
0.5	Very Very Slight (Just Noticeable)
1	Very slight
2	Slight
3	Moderate
4	Somewhat severe
5	Severe
6	"
7	Very severe
8	"
9	Very very severe (almost maximum)
10	maximum

The distance walked by the patient (expressed in meters) is automatically estimated by the accelerometer in the device which calculates the number of steps. However it is possible to modify the estimated distance walked by using the icon.
The diastolic and systolic values are expressed in millimeters of mercury (mmHg).
Data is inserted using the visualized numbers, to move on to the next value touch the **OK** icon.
Test data from a walk test can be printed by following directions explained in paragraph 4.2. When the test results are printed, the paper report only shows the data related to the walking stage. To view an example please see the attached reports included in this manual.

WARNING

At the end of a 6MWT the device also displays the Recovery Time; this is the time necessary for the SpO2% to return to ≥ to 99% compared to the average SoO2 recorded during the initial rest stage of the test.

2.14.2 Sleep Oximetry

The accelerometers in the device also record the position of the patient during the test and the type of movement of the patient.
When the patient is lying down the **Spirodoc** recognizes the prone or supine position, and whether the patient is lying down either on the left or right side. If the patient is standing up the **Spirodoc** will record whether the patient is still or moving including the entity of the movement that is if he/she is moving slowly, medium or at fast speed.
If the patient starts walking the device will count how many steps he/she took and as a consequence the distance walked.
Beyond the SPO2% and BPM measurements the doctor (on the PC) will also have the following data available:

- Patient position during sleep*
- type of movement*
- oximetry perfusion index*
- steps estimate
- VMU

* in graphic form

To monitor and record such information the device must be placed on the patient as previously described in paragraph 3.13.1.
To perform this test touch the from the main screen and subsequently select the test with the icon.

After approximately 5 minutes from the beginning of the test the **Spirodoc** will automatically enter energy saving mode shutting down the backlight of the display. If the signal is lost during the energy saving mode the device will automatically abandon the standby mode and will visualize a message describing the problem (sensor not inserted or finger not inserted correctly).
The data displayed is the same as that of the previous test apart from the possibility to view the trend of the plethysmographic curve.
On the top part of the screen is displayed the battery charge level to the right of the ESC icon.
After the useful period the test can be interrupted by following the procedure previously described.
The results can be printed by following the explanation in paragraph 3.1.

WARNING

During a sleep oximetry test in stand alone mode the display will show the battery level by indicating the hours left, or the minutes left if the battery autonomy is less than one hour. The battery autonomy can vary according to whether the device is in energy saving mode or with the backlight display on at max level.

2.14.3 Oximetry SpO2/BPM

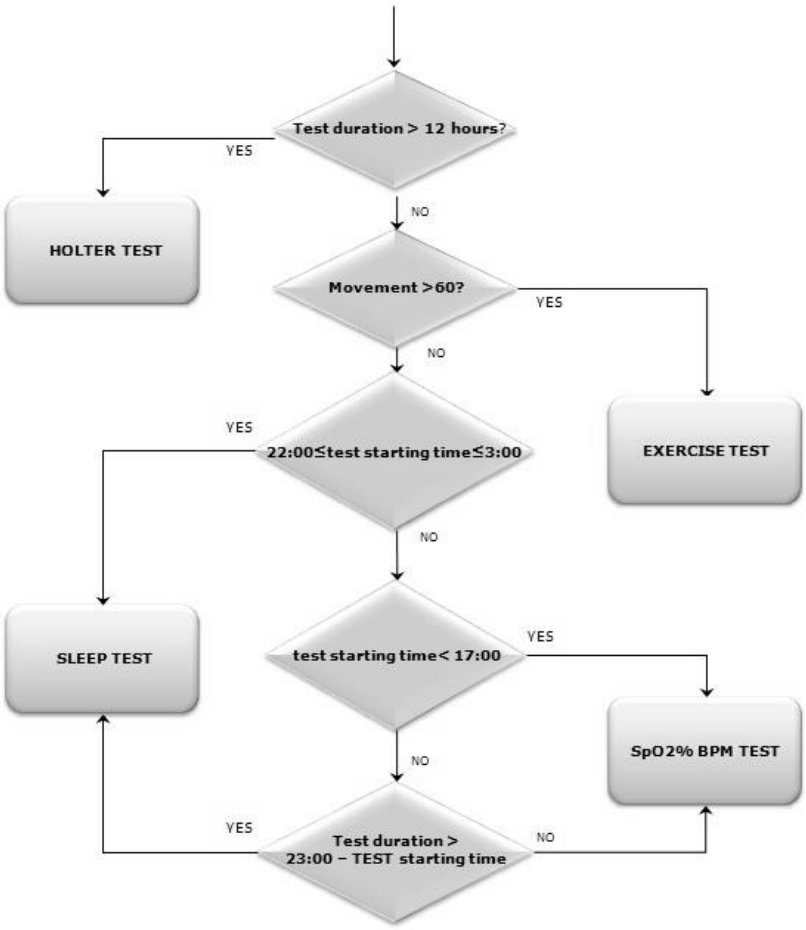
To access the oximetry area form the main screen touch the icon, next select the icon.
The test duration is unlimited and the aim is to record variations of the oximetry values for a length of time as per doctor's requirements.
During the test the display shows the information that appears in the image to the right.
The two icons below allow to:

- visualize the plethysmographic curve
- , allows to check the service menu alarm settings.

To end the test pres the Power ON/OFF key.
To print the ttest results please refer to paragraph 3.1; an example of the printout is available in the attached reports of this manual

2.14.4 Patient mode oximetry

Patient mode oximetry tests are classified by the device according to certain parameter recordings. The criteria classification is shown in the flowchart below:



2.14.5 Instructions for Adult Patient Sensor

⚠ WARNING

The oximetry sensor used in the manual is only one of the different types of sensors which can be used with Spirodoc listed in paragraph 2.2.4. MIR does not recommend any one particular sensor, the decision is left to the doctor who will choose the sensor which she/he believes to be more suitable.

To perform a non-invasive continuous monitoring of arterial oxygen saturation it is recommended to use the reusable "soft" type sensor.

⚠ WARNING

The materials used for manufacturing the sensor are NATURAL LATEX PROTEIN FREE, and are subject to biocompatibility tests.

- Choose an application site on the patient's finger or toe where the light source will be directly over and in-line with the detector. The preferred sites are the forefinger or smaller thumb.
- Remove nail polish or artificial fingernails.

- Insert the patient's digit in the sensor nail-side up, lining up the digit's pad over the detector. The sensor's positioning line runs across the mid axis of the fingertip
- Fold the sensor's top over the digit, making sure the light source is directly over and in-line with the detector. Route the cable along the palm or the bottom of the foot, and secure with adhesive tape if necessary.
- Connect the sensor to the device: insert the connector with the arrow on the connector face-up and check the proper functioning of the sensor according to the previous instructions.

⚠ WARNING

Do not twist the cable or use excessive force when using, connecting, disconnecting, or storing the sensor.
To reduce chances of entanglement it is recommended to fasten the cable to the wrist with a bandage.

2.15 Testing without patient data

This function is available in Doctor Mode only, allowing the user to perform spirometry and oximetry testing without inserting any data related to the patient being tested.

The user may access this function by touching the icon on the main screen.
Within the screen area the user may access the following functions:

- spirometry test
- oximetry test
- walk test
- sleep oximetry
- send data via Bluetooth

WARNING

Spirometry test results do not include any automatic interpretation compared with the predicted values as no patient anthropometric data was previously included.

3. DATA TRANSMISSION

WARNING

Please read carefully and make sure to have properly understood the instructions before commencing the data trasmission.

WARNING

The Bluetooth wireless communication is intended as an add-on function. In case of Bluetooth transmission failure, we recommend the use of more reliable USB technology.

3.1 Printing a test

SPIRODOC makes it possible to print the tests carried out, both of the last session completed and of the tests in the archive, by means of a printer connected via USB.
The connection of SPIRODOC to a printer is made with a micro-USB to type A host adapter.
The printer must be a postscript printer.

3.1.1 How to print a test saved in the database

- From the main screen touch the icon
- Select a search method
- Select the test session in which the test of interest was performed
- Upon entering the test session select the test and touch the icon.

3.1.2 How to print a test of the last session

- From the main screen touch the icon for a spirometry test, for an oximetry test
- Touch then the icon
- Touch the icon corresponding to one of the test of the last session
- In the following screen touch the icon to show data of the test or the icon to print via Bluetooth connection the test.

3.2 PC connection via USB port

WARNING

Before connecting the Spirodoc via USB to the PC, the MIR Spiro software must be installed on the PC first to enable the software to interface with the device.
Before initiating the following procedure it is important to know the operating system version installed on the PC used for the connection (from control panel click on "System", where the type of operating system installed on the PC can be checked).
If MIR Spiro is already installed on the PC then a new installation is not required.

To make the connection, insert the mini USB connector supplied with **Spirodoc** as shown in the picture and attach the other connector to the USB port of the PC.
When initially making a connection, depending on the version of the operating system, the PC will either make an automatic driver installation (for Windows 98, 2000, ME) or request some information (for Windows XP, Vista and Seven). To avoid making any errors at this stage please read the Advanced section of the MIR Spiro User Manual carefully.

3.3 Internal software upgrade

Spirodoc internal software can be upgraded from a PC via USB connection. Upgrades can be downloaded by registering on www.spirometry.com. For further information on software upgrading please read the "**MIR Spiro**" software manual.

4. MAINTENANCE

⚠ WARNING

No part can be subjected to maintenance during use.

Spirodoc requires very little maintenance
The operations to perform periodically are:

- Cleaning and checking the reusable turbine.
- Cleaning the oximetry sensor.
- Cleaning of the device.
- Recharging the internal battery pack.

The maintenance operations described in the User's Manual must be carried out with extreme care. Failing to observe the instructions may cause errors in measurement or the misinterpretation of the measured values.
Modifications, adjustments, repairs, and reconfigurations must be carried out by the manufacturer or by qualified personnel.
In the unlikely event of a problem do not attempt to repair the unit.
The parameter configuration setup must be carried out by qualified personnel. In any case the risks pertaining to an incorrect configuration setting in no way endangers the patient.

4.1 Cleaning and checking the reusable turbine

Two types of turbines can be used with **Spirodoc.** The disposable turbine or the reusable turbine. Both guarantee precise measurements and have the advantage of requiring no periodic calibration. In order to maintain the default characteristics of the reusable turbine a simple cleaning procedure is required before use.
Cleaning of the disposable turbine is not required, as it is supplied clean in a sealed plastic bag. It must be disposed of after use.

⚠ WARNING

Periodically check the inside of the turbine to ensure that there are no impurities, corpuscles, or any foreign matter like hairs which could inadvertently block or even slow down the mobile equipment in the turbine and as a consequence compromise spirometry measurement accuracy.

Before use perform the test described in paragraph 4.1.1 which allows to the check the efficiency of the turbine. If the test result is negative perform the following procedure.
To clean the **reusable** turbine remove it from its housing by rotating it counter-clockwise and apply slight pressure with a finger from the bottom of the turbine to lift it out of its housing.
Immerse the turbine in a cold liquid solution and shake it so as to remove any impurities. Leave the turbine immersed for the time specified in the instruction of the solution.

⚠ WARNING

To avoid irreparable damage to the reusable turbine please do not use any alcoholic or oily detergent solutions, and do not immerge the turbine in hot water or hot liquids.
Do not place the turbine under a direct water jet or other liquid. If no detergent solution is available, clean the turbine in clean water. Do not use compressed air to clean the turbine.

Rinse the turbine by immerging it in clean water (**not hot**).
Shake off the excess water from the turbine and let it dry, position the turbine vertically on a dry surface.
Before inserting the reusable turbine in the device it is good practice to visually check that the rotor inside turns freely. Hold the turbine horizontally and slowly move it left and right and vice versa. You should be able to see the mobile equipment (blade) rotate freely. If this is not the case then the measurement accuracy can no longer be guaranteed and as such the turbine must be replaced.

Having completed the turbine cleaning procedure, insert the turbine in its housing making sure to turn it clockwise as shown by the symbol of the lock printed on **Spirodoc.**
The turbine is inserted properly by pushing it all the way in and subsequently rotating it clockwise until it stops; this bayonet mechanism ensures that the turbine is blocked inside the plastic casing.

To be absolutely certain that the turbine is functioning properly perform the checklist in paragraph 4.1.1; if the turbine is still malfunctioning please replace it with a new one.

⚠ WARNING

Do not carry out any cleaning procedures when using disposable turbines, a new disposable turbine must be used for every new patient.

4.1.1 Proper turbine operation check

- Turn on **Spirodoc** and setup the device to perform a spirometry test (for example **FVC**).
- Hold the **Spirodoc** with one hand and move it slowly sideways, having the air pass through the turbine.
- If the rotor spins properly the device will emit a series of acoustic signals "beeps". The beeping frequency is a function of the air flow passing through the turbine.
- If no beeps are heard while moving the device, proceed to clean the turbine

4.2 Oximetry sensor cleaning

The reusable finger sensor must be cleaned every patient change, so clean the sensor before to use this on a new patient.
Clean the sensor with a soft cloth moistened with water or a mild soap solution. To disinfect the sensor, rub with isopropylic alcohol.
Allow the sensor to dry completely after cleaning.
Do not use any abrasive or caustic material to clean the sensor.

⚠ WARNING

Do not sterilize by irradiation, steam or by using ethylene oxide.
Unplug the sensor from the device before cleaning or disinfecting it.

The sensor included with the **Spirodoc** is made with latex free material.

4.3 Cleaning of the device

Clean the device once a day or every time changes the patient. Use only the substances and methods listed in this chapter to clean the device.
Recommended cleaning agents are:

- Mild soap (diluted)
- Sodium hypochlorite bleach (10% diluted)

Moisten a soft cloth with a recommended solution, but not so much that the cloth drips, and lightly wipe the surface for 30 seconds. Let it air dry. Do not use ketonic solvents and aromatic solvents. Never put the device into water or other fluids.

4.4 Battery charging

Turn on **Spirodoc** and the following icon will appear on the main screen showing the charge level of the battery pack:

The maximum charge level is displayed with all 6 bars inside the battery.
If only one bar is shown or if the device will not even turn on the battery pack must be recharged in the following manner:

- Plug the battery charger into a socket and the battery charger cable into the micro USB connector of the device; the device in this phase is always turned on
- When the charging is complete the battery icon will display all six bars.
- At this point disconnect the battery charger from the device.

⚠ WARNING

It is recommended not to use the device while the battery is charging.
Always disconnect the battery charger from the device when the charge cycle has terminated.

⚠ 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. PROBLEM SOLVING

Please find below a list of problems that may arise when using **Spirodoc.**
Diagnostic messages are also shown on the display indicating the type of malfunction:

PROBLEM	MESSAGE	POSSIBLE CAUSES	REMEDY
Spirodoc does not turn on	\	The battery pack could be discharged	Connect the device to the battery charger.
	\	The battery pack has not been properly inserted in the device	Contact a technical service center
	\	The device may have lost its internal software	Connect the device to the PC with the USB cable and update the internal software; For more detailed information please consult the MIR Spiro software user manual available on line within the software itself.
Message during switch on	**Too many attempts for today**	The user has exceeded the maximum number of attempts to insert the pin	Wait for the next day. The number of attempts will be resetted.
Message when the privacy info is enabled	**To comply with privacy policy please update all connected devices**	The privacy info is enabled.	The message advises the user to update the software MIR Spiro installed on the PC to comply with privacy policy
Problem when turning on the device	**Error in ram memory Recovering data Please wait**	Memory data within the device has been damaged	If the data has been restored correctly the standard turn-on process will complete itself. If this process does not finalize contact an authorized technical service center.
The device turns off and subsequently turns on again.	\	An internal error has occurred.	Check on the following website www.spirometry.com for a more recent internal software release of the device. Update the internal software by downloading the latest release by using the MIR Spiro software For further information consult the MIR Spiro manual available on line within the software itself.
Spirometry test results are unreliable	\	The turbine may contain dirt or foreign matter.	Clean the turbine as explained in paragraph 4.1; if necessary replace the turbine with a new one.
	\	The test was not performed correctly.	Repeat the test and follow closely the indications shown on the screen.
Certain spirometry and/or oximetry parameters are not shown at the end of a test.	\	Personalized parameter setting in the service menu.	Check the parameter setting in the item "PARAMETER setting" within the Service Menu as explained in paragraph 2.7
During an oximetry test values are returned at irregular intervals, intermittent or simply wrong.	\	The sensor is positioned incorrectly or the patient perfusion is insufficient.	Riposition the oximetry sensor.
	\	The patient has moved.	To obtain accurate oximetry readings it is important that the patient must not move abruptly.
During oximetry testing the screen is barely readable	\	After a few minutes the screen backlight turns off automatically to save battery energy.	None
Problem during battery pack recharging	**Damaged battery pack**	The battery pack could be damaged or simply mispositioned.	Contact a technical service center

PROBLEM	MESSAGE	POSSIBLE CAUSES	REMEDY
Unforseeable error of the memory	**Error in memory**	Data in archive is damaged.	Contact a technical service center
The device has frozen due to an unforseeable event	\	\	Press the power (ON/OFF) key 3 times and wait approximately four seconds after which the device will reset itself and turn on again

⚠ WARNING

Before contacting a technical service center, please try downloading the database from the device to the PC using the MIR Spiro software. This procedure is necessary to save a backup in case all the data is accidentally lost during device repair. Furthermore the database could be of confidential nature and as such not accessible by authorized personnel and also subject to privacy laws.

LIMITED WARRANTY CONDITIONS

Spirodoc, together with its standard accessories is guaranteed for a period of:

- 12 months if intended for professional use (doctors, hospitals, etc.)
- 24 months if the product has been purchased directly by the end user.

The warranty is effective from the date of purchase shown on the relevant sales invoice or proof of purchase.

The warranty is effective from date of sale which must be shown on the relevant sales invoice or proof of purchase.

The device must be checked at the time of purchase, or upon delivery, and any claims must be made immediately in writing to the manufacturer.

This warranty covers the repair or the replacement (at the discretion of the manufacturer) of the product or of the defective parts without charge for the parts or for the labour.

All batteries and other consumable parts, reusable turbine included, are specifically excluded from the terms of this guarantee.

This warranty is not valid, at the discretion of the manufacturer, in the following cases:

- If the fault is due to an improper installation or operation of the machine, or if the installation does not conform to the current safety norms in the country of installation.
- If the product is utilised differently from the use described in the User's Manual.
- If any alteration, adjustment, modification or repair has been carried out by personnel not authorised by the manufacturer.
- If the fault is caused by lack of or incorrect routine maintenance of the machine.
- If the machine has been dropped, damaged or subjected to physical or electrical stress.
- If the fault is caused by the mains, or by a product to which the device has been connected.
- If the serial number of the device is missing, tampered with and/or not clearly legible.

The repair or replacement described in this warranty is supplied for goods returned at the customers' expense to our certified service centers. For details of these centers please contact your local supplier of the spirometer or contact the manufacturer directly.

The customer is responsible for the transportation and for all transport and customs charges as well as for delivery charges of the goods both to and from the service center.

Any device or accessory returned must be accompanied by a clear and detailed explanation of the defect or problem found. If units are to be returned to the manufacturer then written or verbal permission must be received before any devices are returned to MIR.

MIR S.p.A. – Medical International Research reserves the right to modify the device if required, and a description of any modification made will be sent along with the returned goods.