Spirodoc

User Manual Rev. 1.3

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1. EQUIPMENT AND ACCESORY LIST

Thank you for choosing a **MIR** product
MEDICAL INTERNATIONAL RESEARCH

The original packaging of the product contains one of the following spirometers with the following accessories:

spirometer configuration

Accesssories sold with SPIRODOC	COD.
Carrying bag **SPIRODOC**	672690
Device **SPIRODOC**	910575
User manual **SPIRODOC**	980205
USB cable	532365
Lithium-ion battery pack	970080
winspiroPRO CD	920100
1 noseclip	910320
4 paper mouthpieces *****	910300
1 reusable turbine	910002
3 disposable turbines	910001

Accessori	COD.
Battery charger with micro USB connector	920680

Spirometer and oximeter configuration

Accessories sold with SPIRODOC	COD.
Carrying bag **SPIRODOC**	672690
Device **SPIRODOC** with oximetry function	910570
User manual **SPIRODOC**	980205
USB cable	532365
Lithium-ion battery pack	970080
winspiroPRO CD	920100
1 noseclip	910320
4 paper mouthpieces *****	910300
1 reusable turbine	910002
3 disposable turbines	910001
1 oximetry sensor	919010

Accessori	COD.
Battery charger with micro USB connector	920680
Disposable adult oximetry sensor for extended length of time screening*****	919007
Extension cable for oximetry sensor	919090

*** disposable accessory: all other accessories are reusable**

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.
- If necessary pay attention to the correct polarity "+" & "-" when inserting the battery pack as indicated in the battery housing
- Set the device configuration (date, hour, predicted set, language, ecc) as described in paragraph 2.4

⚠ WARNING

Before connecting the SPIRODOC to the PC, the winspiroPRO PC software supplied with the device must be installed correctly in the PC. The device may be connected to the PC only after the winspiroPRO software has been installed. Once the new hardware is "recognised" by the PC the device may now be used with the winspiroPRO software.

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 guidelines:

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

Manufacturer's address:

MIR SRL
VIA DEL MAGGIOLINO, 125
00155 ROME (ITALY)

Tel ++ 39 0622754777
Fax ++ 39 0622754785
Web site: www.spirometry.com
Email: mir@spirometry.com

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 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.

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

2. INTRODUCTION

2.1 Intended use

The Spirodoc spirometer and pulse oximeter is intended to be used by a physician or by a patient under the supervision/instruction of a physician or paramedic.
The lung function testing device is capable of performing:

- spirometry testing in people of all ages, excluding infants and neonates
- oximetry testing in people of all ages.

It can be used in any setting.

2.1.1 User category

SPIRODOC spirometer + 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.

2.1.2 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 or by a trained paramedic under the supervision of a 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 whoever is legally responsible to supervise this person.

⚠ WARNING

When used as a pulse-oximeter, the SPIRODOC is intended for spot-checking, overnight sleep screening and/or continuous monitoring when used by a trained healthcare professional.

2.1.3 Operating Environment

SPIRODOC has been designed for use in the doctor’s office, in a hospital or directly by the patient to continuously monitor her/his physical conditions during routine daily activities. All information necessary for the proper use of the device in an electromagnetic environment (as required by the EN 60601-1-2 Standard) is available in Annex 3 of this manual.
Used at home, at work, at school or during physical activity, day after day the device records data and functional respiratory parameters for weeks or even months, helping the patient to better assess her/his own health.
The procedures for using the device at home are described according to the type of test to be made; the display will show all instructions (messages, suggestions etc.) step-by-step, which allows the patient to correctly perform tests and obtain correct results, to be analysed by the doctor.
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.

2.1.4 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.

2.1.5 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.

2.1.6 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 achieved the results obtained during spirometry testing may not be considered accurate, and "acceptable".
The acceptability of a test is the responsibility of the doctor. Special attention should be given when testing elderly patients, children and handicapped people.
The device should not be used if any conceivable or actual anomalies or malfunctions appear which may compromise the accuracy of the results.

WARNING

When used as a pulse oximeter the SPIRODOC has limited alarms, therefore the device requires that the user frequently observe the SpO2 and pulse rate on the display.

2.2 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 the Council Directive 93/42/EEC for MEDICAL DEVICES.
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 only and exclusively as a spirometer following the indications given by the manufacturer 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.
The device should not be used beyond the declared life span. The life span is strictly related to the life of the internal lithium battery pack. In normal conditions the lifespan of the battery pack 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.
In the event of any incident or accident of any kind resulting from the use of the device, the user is required to inform the manufacturer without delay, this procedure is laid down in Article.9 of the European Regulations No. 46/1997, which implemented the EC Directive No. 93/42.

2.2.1 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.

2.2.2 Turbine

Disposable turbine

⚠ **WARNING**

If you are going to perform a spirometry test with a disposable turbine it is important to use a new turbine for each new patient. The features, 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

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 turbine models.
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 bodies 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 the accuracy of the measurements.

2.2.3 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. Those required are a standard type with an outside diameter of 30 mm, they are commonly used 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.

2.2.4 I Oximetry sensor

The oximetry sensors which can be used with **SPIRODOC** are the following:

Manufacturer	Code	Description
BCI	1300	adult sensor (disposable)
BCI	3026	wrap-around sensor for infants

BCI	3043	universal Y sensor
BCI	3078	ear sensor
BCI	3178	pediatric finger sensor, reusable
BCI	3444	adult sensor reusable (Comfort Clip)
BCI	3044	adult finger sensor, reusable

These sensors require the use of an extension cable (product code 919200) for a proper connection to the device.
The same sensors are also available with a microconnector for a direct connection.

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, 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 an 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 measurement.

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.

2.2.5 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.
High-frequency emissions from "electronic" devices may interfere with the correct operation of the device. For this reason, certain minimum clearances (a few meters) should be observed when high-frequency appliances such as a TV, radio, portable phone, etc. and other electronic units are operated at the same time in the same room.
The device may give inaccurate readings if operated in the presence of strong electromagnetic sources, such as electrosurgical equipment, or in the presence of computed tomography (CT) equipment.

Do not use the device in the presence of magnetic resonance imaging (MRI) equipment. MRI equipment may cause an induced current to the oximetry sensor, resulting in patient injury.
If the PC and/or the printer connected to the SPIRODOC come into contact with the area containing patient data, ref. directive EN 60601-1-1, it is necessary that they conform to the directive 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.
Use only the battery type indicated in the § Technical specifications.
Remove the battery from the device if the machine is not used for a long period (several months).
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 of any person with mental handicap.

2.3 Unforeseen errors

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

Error on RAM memory
Recovery data
Please wait

If data has been successfully recovered, the device completes the standard turn on procedure, otherwise please contact an authorized technical assistance center or the manufacturer.
In case of a problem with the device, a message indicating the nature of the problem will appear on the screen, together with a warning “beep”.
Operation of the device beyond its declared life (see § 1.6 Technical Specifications) could cause a loss of data in the memory of the device (SRAM memory).
Errors in measurement or in interpretation can also be caused by:

- use by non-qualified or non-trained personnel, lacking ability or experience
- user error
- use of the device outside the guidelines described in this User's Manual
- use of the device even when some operational anomalies are encountered
- non-authorised servicing of the device.

2.4 Lithium-ion battery pack warning

The device is powered by a rechargeable lithium-ion battery pack. A charger is also supplied with the device which delivers 3.7 volts.

For proper use of the battery pack please read carefully the warning below

WARNING

Do not use the battery pack for any purposes different from those specified. The battery characteristics may change, consequently the battery life may be reduced significantly. The battery pack may generate an electrical overcharge which may cause acid leakage, overheating, smoke, breakage and fire.
Improper use of the battery pack may cause leakage, overheating, smoke, breakage and fire. This may cause performance deterioration and damage. This may also damage the protector installed in the battery pack. This may damage the device and harm the user. Please read the following instructions carefully.
If acid from the battery pack comes into contact with skin or clothing immediately wash with running water to avoid skin inflammation. 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.
If upon first use there is a bad smell, overheating or other anomalies do not use the battery pack and return it to the supplier or manufacturer.
Only use suitable battery chargers and follow the instructions.
Do not connect the battery to an electric plug or lighter.

During charging
Before charging the battery pack carefully read the user manual.

Do not charge near electric static generators,
Do not charge near a fire or extreme heat.
High temperatures may alter the characteristics of the internal protector, stop recharging or actually cause recharging with higher voltages. This may result in abnormal chemical reactions, acid leakage, overheating, smoke, breakage and fire.
The battery pack comes with an internal safety protector. Do not use the device near static electricity (superior to what is declared by the manufacturer). Static electricity may damage the internal protector causing acid leakage, overheating, smoke, breakage and fire.
Do not leave the battery pack charging longer than the average charging length of time specified.
Do not recharge near electric static generators

During battery pack use
Recharge the battery pack with a specifically designated battery charger and observe the charging procedure as specified by the manufacturer.

Recharging without adhering to proper recharging conditions may cause the battery to overcharge at extremely high voltage. Various abnormal chemical reactions may occur such as acid leakage, overheating of the battery, smoke emission, breakage and fire.

The battery pack may be used within a temperature range from −20°C e to approximately 60°C.
Do not heat or throw the battery in a fire.
Do not use or store the battery near a fire or if the temperature inside a vehicle may reach 60°C or become higher.
Do not immerge the battery pack in water or salt-water, and do not leave it wet.
Such events may damage the inner safety functions which could cause the battery to be charged at high voltage thus triggering abnormal chemical reactions leading to acid leakage, overheating, smoke, and fire.
Do not place the battery pack in your pocket or in a bag with other metallic objects such as coins, necklaces, scissors and screws.
Do not store the battery pack anywhere near these objects.
Do not short-circuit the positive (+) and negative (-) poles with metallic objects.
Do not connect the battery pack to an electric socket or to an automobile Sigarette lighter, ecc. If the battery is connected to a source of high voltage this high current surge may cause acid leakage, overheating, smoke, breakage and fire.

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 may be caused by the connection thus creating the possibility for acid leakage, overheating, smoke, breakage 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 in any way disassemble or modify the battery-pack; the battery pack comes with an internal safety protector, which if tampered with may cause acid leakage, overheating, smoke, breakage and/or fire.
Do not solder the battery pack.
Do not use a heavily scratched or deformed battery back as this may be cause for acid leakage, overheating, smoke, breakage and/or fire.

If the battery pack emanates a bad odor, 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 any further, as any of these events may cause acid leakage, overheating, smoke, breakage and/or fire.

When the battery pack is disconnected from the device or the charger verify the correct position of the (+) and (-) poles without forcing the connection.
Store the battery pack away from children's reach so as not to accidentally swallow the battery pack.

If a child uses the battery pack an adult must explain the proper use to the child.

Before using the battery pack carefully read the manual paying attention to all the recommendations for proper handling.

For information concerning the installation and removal of the battery pack carefully read the manual of the device.
The cycle-life of the battery pack is definite. If you notice a much shorter time usage between charges 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.

Keep the battery pack away from objects which may emit static electrical charges.

If the battery pack leads are dirty clean with a dry cloth prior to usage.
The battery pack may be stored within a temperature range between −20°C and 60°C
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 leaks acid or gives off a bad smell, move it away from flames.

Electrolyte leakage may cause a fire and the battery pack may emit smoke or even explode and ignite.

2.5 Labels and symbols

2.5.1 Identification label

The label shows:

- Serial number of the device
- Product name
- Name and address of the manufacturer
- Electrical safety symbol
- CE mark in compliance with the Directive 93/42 EEC.
- WEEE symbol

2.5.2 CE mark for medical devices

CE 0476

This product is certified to conform to the Class II requirements of the 93/42/EEC medical device directive.

2.5.3 Electrical safety symbol

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.

2.5.4 Warning symbol for the RS232 serial port

RS232

To connect to other devices such as PC or printer.
Use only the serial cable supplied by the manufacturer and observe the safety regulations of **IEC 60601-1-1.**

2.5.5 Warning symbol for the USB serial port

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.**

2.5.6 Warning symbol for the SpO2 port for oximetry

SpO2

2.5.7 Warning symbol for the WEEE

As laid down in the European Directive 2002/96/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.

2.5.8 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:

2.5.9 Product description

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: RS232, USB, Bluetooth.

Spirodoc… 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 over 6000 spirometry tests or for 1000 hours (or 40 days) 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 principal. This principal 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 clean the turbine between patients, to ensure the maximum level of hygiene and safety of the patient.

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…. is also able to transfer the stored test data through a simple acoustic coupling to a PC, so the patient can send test data by phone to the doctor. This method allows the doctor can check the patient's condition remotely.
SPIRODOC consente al paziente di trasferire i dati immagazzinati all'interno del dispositivo, utilizzando la connessione Bluetooth , al PC del medico. Pertanto il medico può valutare a distanza i parametri legati alla patologia del paziente.

SPIRODOC can also be connected to a PC (or to another computerised system) to configure the system. All spirometric test results plus the related subject 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 PC can be made in the following ways:

- via USB connection
- via Bluetooth 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
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 principal ensures accuracy and reproducibility, without requiring regular calibration.
The oximetry sensor can be disinfected with isopropilic alcohol.

2.6 Technical specifications

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

2.6.1 Features of the spirometer

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	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/tI	Average flow of inspiration, at rest	L/min
tI/Ttot	tE/(tI+tE)	\
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 $cmH_2O/L/s$

2.6.2 Oximeter features

Definitions:

Desaturation Event	Desaturation events SpO2 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 measured during sleep oximetry:

SYMBOL	DESCRIPTION	Units	
SpO2 Baseline	SpO2 Average in first three minutes	%	
SpO2 Min	SpO2 Minimum during period of analysis	%	
SpO2 Max	SpO2 Maximum during period of analysis	%	
SpO2 Mean	SpO2 Average during period of analysis	%	
BPM Baseline	Average pulse frequency in the first 3 minutes	BPM	
BPM Min	Minimum pulse frequency during the period of analysis	BPM	
BPM Max	Maximum pulse frequency during the period of analysis	BPM	
BPM Mean	Average pulse frequency during the period of analysis	BPM	
Recording time	Total time measure of SpO2	hh:mm:ss	
T < 90%	Time passed with SpO2 < 90 %	%	hh:mm:ss
T < 89%	Time passed with SpO2 < 89 %	%	hh:mm:ss
T < 88%	Time passed with SpO2 < 88 %	%	hh:mm:ss
T < 87%	Time passed with SpO2 < 87 %	%	hh:mm:ss
N° Events SpO2 <89%	Fall of SpO2 below 89% for at least 20 seconds	\	
Δ Index [12s]	Index of SpO2 fluctuation calculated in intervals of 12 seconds	\	
T< 40 BPM	Time passed with pulse frequency < 40 BPM	%	hh:mm:ss
T> 120 BPM	Time passed with pulse frequency > 120 BPM	%	hh:mm:ss
N° Events < 40 BPM	Bradycardia events during the entire period of analysis	\	

N° Events > 120 BPM	Tachycardia events during the entire period of analysis	\	
Tot. Desat. Events	Desaturation events during the entire period of the analysis	\	
ODI	Desaturation events by hour of analysis	1/h	
Mean Duration	Average duration of desaturation events	s	
Longest Duration	Longest duration of desaturation events	s	
Desaturation Peak	Minimum Sp02 during desaturation events	%	
Mean Desaturation	Average duration of desaturation events	%	
Mean Drop ∆SpO2	Average SpO2 fall with respect to baseline during the desaturation events	%	
Max Drop ∆SpO2	Maximum fall of SpO2 with respect of baseline during the desaturation events	%	
N° Pulse Variations	Variation of pulse frequency events during the entire period of the analysis	\	
Pulse Index	Variation of pulse frequency by hour of analysis	1/h	
NOD 4%	Time passed with SpO2 < 4 % with respect to SpO2 base for continual periods above 5 minutes	\	hh:mm:ss
NOD 89%	Time passed with SpO2 < 89 % for continued periods above 5 minutes	\	hh:mm:ss
NOD 90%	Time passed with SpO2 < 90 % for continued periods above 5 minutes with minimum value < 86 % (Nadir)	\	hh:mm:ss

∆=DELTA

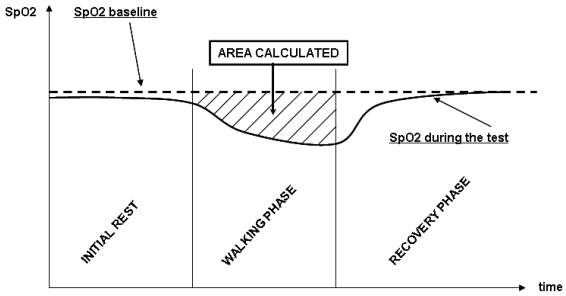
Parameters measured for six minute walk test analysis:

SYMBOL	DESCRIPTION	Units	
SpO2 Baseline	SpO2 average before walking	%	
SpO2 End	SpO2 after walking	%	
SpO2 Min	SpO2 minimum during walking	%	
SpO2 Max	SpO2 maximum during walking	%	
SpO2 Mean	SpO2 average during walking	%	
BPM Vaseline	Average pulse frequency before walking	BPM	
BPM End	Pulse frequency after walking	BPM	
BPM Min	Pulse frequency minimum during walking	BPM	
BPM Max	Pulse frequency maximum during walking	BPM	
BPM Mean	Pulse frequency average during walking	BPM	
T < 90%	Time passed with SpO2 < 90 %	%	hh:mm:ss
T < 89%	Time passed with SpO2 < 89 %	%	hh:mm:ss
T < 88%	Time passed with SpO2 < 88 %	%	hh:mm:ss
T < 87%	Time passed with SpO2 < 87 %	%	hh:mm:ss
T∆2 [∆SpO2≥ 2%]	Time passed during walking test with SpO2 < 2 % with respect to SpO2 base	hh:mm:ss	
T∆4 [∆SpO2 ≥ 4%]	Time passed during SpO2 walking test < 4 % with respect to SpO2 base	hh:mm:ss	
T< 40 BPM	Time passed with pulse frequency < 40 BPM	hh:mm:ss	
T> 120 BPM	Time passed with pulse frequency > 120 BPM	hh:mm:ss	
N° Events < 40 BPM	Bradycardia events during the entire period of analysis	\	

N° Events > 120 BPM	Tachycardia events during the entire period of analysis	\
Recording time	Total time measure of SpO2	hh:mm:ss
Baseline Time	Duration of baseline phase	hh:mm:ss
Walking Time	Duration of walking phase	hh:mm:ss
Recovery Time	Time for SpO2 value ≥ 99% of the average base value calculated during the initial phase of the test.	hh:mm:ss
Predicted	Predicted standard distance	m
Pred. Min	Predicted minimum distance	m
% Predicted Standard	% in variations of the distance covered with respect to predicted standard distance	%
% Pred. Min	% of variations of distance covered with respect to predicted minimum distance	%
AUC/Distance	Area under SpO2 curve base relative to distance covered	\
Dyspnea Borg CHG	Variation in grade of dyspnea during walking	\
Fatigue Borg CHG	Variations in level of fatigue during walking	\

Δ=DELTA

*There follows a description of the method for calculating the area below the SpO2 baseline curve:



Parameters requested for six minute walk test analysis

SYMBOL	DESCRIPTION	Units
Dyspnea Borg Baseline	Grade of dyspnea before walking	\
Dyspnea Borg End	Grade of dyspnea after walking	\
Fatigue Borg Baseline	Level of fatigue before walking	\
Fatigue Borg End	Level of fatigue after walking	\
Walked	Distance covered during walking	m

Parameters measured with SpO2 Analysis:

SYMBOL	DESCRIPTION	Units
SpO2 Baseline	SpO2 Average in first three minutes	%
SpO2 Min	SpO2 Minimum during period of analysis	%
SpO2 Max	SpO2 Maximum during period of analysis	%
SpO2 Mean	SpO2 Average during period of analysis	%

BPM Baseline	Average pulse frequency in the first 3 minutes	BPM	
BPM Min	Minimum pulse frequency during the period of analysis	BPM	
BPM Max	Maximum pulse frequency during the period of analysis	BPM	
BPM Mean	Average pulse frequency during the period of analysis	BPM	
Recording time	Total time measure of SpO2	hh:mm:ss	
T < 90%	Time passed with SpO2 < 90 %	%	hh:mm:ss
T < 89%	Time passed with SpO2 < 89 %	%	hh:mm:ss
T < 88%	Time passed with SpO2 < 88 %	%	hh:mm:ss
T < 87%	Time passed with SpO2 < 87 %	%	hh:mm:ss
N° Events SpO2 < 89%	Fall of SpO2 below 89 % for at least 20 seconds	\	
Δ Index [12s]	Index of SpO2 fluctuation calculated in intervals of 12 seconds	\	
T< 40 BPM	Time passed with pulse frequency < 40 BPM	%	hh:mm:ss
T> 120 BPM	Time passed with pulse frequency > 120 BPM	%	hh:mm:ss
N° Events < 40 BPM	Bradycardia events during the entire period of analysis	\	
N° Events > 120 BPM	Tachycardia events during the entire period of analysis	\	

Δ=DELTA

Measurement method:	Red and infrared absorption
Range of measurement %SpO_2:	0 – 100% (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:	20 – 300 BPM (with 1 BPM increments)
Cardiac pulse relolution	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

Acoustic signals:

- "Beep" with frequency of the cardiac pulse
- Continuous beep in the case of either %SpO_2 or cardiac pulse going outside of the programmed levels of alarm
- Continuous beep during oximetry measurement in the case of a low battery level.
- If the patient's finger is not inserted correctly or the connecter is not properly attached there will be an intermittent beeping sound for 10 seconds
- If the test has been interrupted due to low battery power an intermittent beeping will be heard for 10 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.

2.6.3 Other features

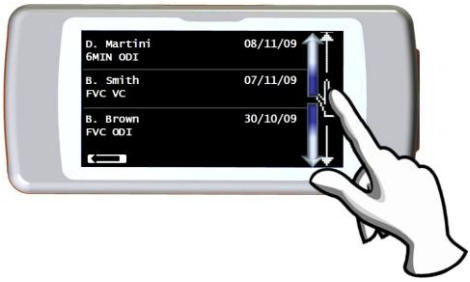
Memory	Memory capacity for over 6000 spirometric tests The precise number depends on the individual configuration, so it cannot be determined more closely
Display	STN graphic LCD,128x64 Pixel
Keyboard	Membrane keyboard with 6 keys
Interface	RS232, USB, Bluetooth
Duration of the CR2032 3V lithium battery (memory backup)	Circa 10 years, under normal conditions of use
Power supply	4 x AAA batteries 1.5V DC (type AAA), or through USB connection
Dimensions	60x145x30 mm
Weight	180 grams (including batteries)
Type of electrical protection	Class II device
Type of electrical protection	BF
Grade of protection against water ingress	IPX1 device, protected against water drops
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
Operating conditions	Temperature: MIN + 10 °C, MAX + 40 °C; Humidity: MIN 10% RH; MAX 95%RH
Applied norms	Electrical Safety Standard IEC 60601-1 Electro Magnetic Compatibility IEC 60601-1-2

3. FUNCTIONING OF THE SPIRODOC

3.1 Display

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

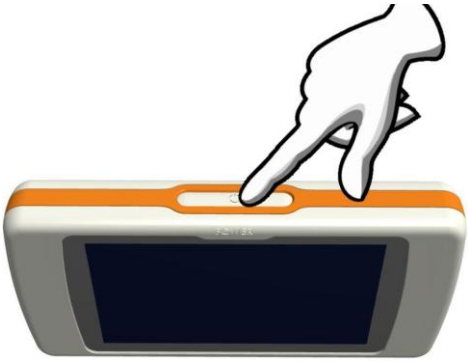
To visualize the list of information flick through the left part of the screen.



3.2 Accensione e spegnimento di SPIRODOC

To turn on the **SPIRODOC** press and release the key placed in the middle on the side of the device.

To turn off the **SPIRODOC** press the same key for at least two seconds.



3.3 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 go back
	To send data to a mobile phone 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 access all oximetry test options / To perform an SpO2/BPM test
	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
	To perform a slow vital capacity spirometry test VC
	To perform a maximum voluntary ventilation spimetry test MVV
	To perform a spirometry test with a broncodilator
	To print via Bluetooth connection

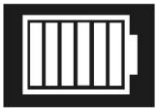
3.4 Energy saving

⚠ WARNING

When the device is on after approximately 10 seconds of disuse the display enters energy saving mode thereby lowering the display contrast level automatically.
If the device remains in disuse for approximately 5 minutes an acoustic signal will be emitted, furthermore if the display is not touched within another 10 seconds the device will turn off by itself.

The device can be turned off in any moment by pressing the ⏻ key.

The charging level of the battery pack is shown upon turning on the device 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.

3.5 Information

Turn on the **SPIRODOC** by pressing ⏻. The display will read:

device name **information**

Current date **Current time**

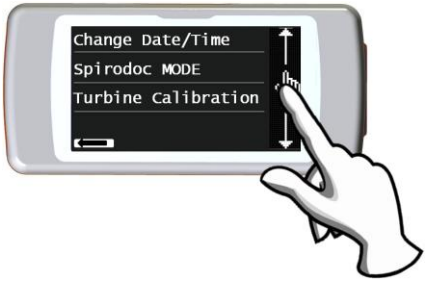
Without touching the display, after a few seconds the device will automatically return to the main screen.
The main screen can be customized by choosing one of two types of menus: “simplified menu” or “extended menu”. To choose the desired setting read the following parapraph 3.6.

3.6 Service menu

To access the menu touch the display when the following icon appears 
The service menu provides the following information:

- Language selection (English default)
- Turbine calibration
- Predicted values selection
- Delete Memory
- Change Date/Time
- Date Format
- Unit Format
- Turbine selection
- Standards setting
- LCD setting
- BLUETOOTH setting
- Firmware information
- Oximetry alarms
- SpO2 sampling rate
- Spirodoc mode
- Parameter settings
- Menu type

Scroll through the various options in the menu as per paragraph 3.1; once the option of interest is visualized, touch the display next to it.



Language selection
Select the language select option by touching the display and choose the desired language; automatically the desired language is set and the device will return to the service menu.

Turbine calibration
Once the option is highlighted the following password needs to be inserted:

1 2 2 3 3 3

Please refer to paragraph 3.6.1 per il corretto svolgimento di tale attività si faccia riferimento al paragrafo 3.6.1.

Selection of the Predicted values
Select the option by touching the display.
A list of Predicted values is visualized; select the desired Predicted value.

Adults	Pediatric
ERS	Knudson
Knudson	Knudson
USA	Knudson
ERS	Zapletal
MC-Barcelona	Zapletal

Select the pair of Predicted values; automatically the desired predicted values are set and the device will return to the service menu.

WARNING

If the NAHNES III standard is chosen the Predicted values cannot be set or modified.

Delete Memory
Select the option by touching the display.

To delete the memory of the device insert the following password by touching the numbers starting from left to right:

1 2 2 3 3 3

If an error occured during insertion of the password, the following message will appear:

Password Error
Press OK and try again

If you fail to insert the password again the device automatically returns to the service menu.

If instead the password was inserted correctly, the following message will appear:

Memory has been deleted

Afterward the device will automatically return to the service menu.

Change date and time
Select the option by touching the display.
In the date/time setting, the cursor _ indicates the item which will be modified.

Use the visualized numbers to modify item of interest, move on to the next item with OK.

Lastly by touching OK the settings will take effect and the device will return to the service menu; to return to the service menu without modifying any options touch  .

Date format
Select the option by touching the display.

day month year
month day year
year month day

Select the desired format; this will be set 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)

Scegliere la modalità desiderata; automaticamente questa viene impostata ed il dispositivo torna al menu di servizio.

Turbine selection
Select the option by touching the display.
Select the type of turbine to be used (reusable or disposable). The selection will be saved automatically and the device will return to the service menu.

Standards setting
Select the option by touching the display.
Select the standard (ATS/ERS or NHANES III); The selection will be saved automatically and the device will return to the service menu.

LCD setting
This menu allows for:

- Setting of display luminance and contrast.

  Two scales ranging from 0 to 31 allow to set these display parameters and see the effects in real time. Once the best combination has been obtained touch OK in the bottom right-hand of the display.

  Touch screen calibration function
  This function allows to check the proper response of the touch screen; the procedure is comprised of three parts:

  - touch the white dot on the upper right side
  - touch the white dot on the lower left side
  - touch the white dot in the center

  The touch screen will be calibrated according to the dimensions of the screen.

Bluetooth setting
Access the menu to search for available 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 can be memorized as a printer, a phone, or as a PC – On line; select an option.
In the “Bluetooth setting” menu the memorized devices can be viewed in the “printer” list, “telephone” list and the “PC – On line” list. 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. In the “Bluetooth setting” menu the “Bluetooth ON/OFF” option allows to enable/disable the Bluetooth function thereby improving the battery consumption of the device.

Firmware Information
The user can access the menu to view information of the version control of the following components:

- **Spirodoc**
- Bluetooth

After approximately 10 seconds the device automatically displays the Service Menu, otherwise press ⬅.

Oximetry Alarms
Access to this function allows the setup of reference values for SpO2 and BPM; an acoustic alarm will warn the user if the SpO2 and BPM during a test fall below the minimum or rise above the maximum set reference SpO2 and BPM values.

The cursor “_” in the beginning will be set on the minimum SpO2 value, use the visualized numbers to select the desired value. Move on to the next value by touching OK; once all four values have been set the user may activate or deactivate the acoustic alarm: Touch ON to activate the acoustic alarm during oximetry testing, or touch OFF to deactivate the acoustic alarm. To confirm the desired selection touch OK in the bottom right side of the display, automatically the device will return to the service menu.

SpO2 sampling rate
This function allows to set the time that elapses between values memorised between consecutive oximetry parameters; 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.

Spirodoc mode
The device can be setup in one of the following modes:

- Personal mode
- Doctor mode

Personal mode is set by the doctor when the device will be used by the patient for home care use; for health condition screening.
Doctor mode enables full use of the device for expert use.
By touching the desired mode the device is set and automatically returns to the service menu.

Parameter Settings
Three different types of parameter calculations can be selected for spirometry and oximetry testing.

- simplified
- personalized
- complete

With the simplified mode the user can only view the main parameters as per actual standards.
The personalized mode allows to select the parameters of interest.
The complete mode allows to view all the parameters that the device is capable of calculating.

Type of menu
The last item allows to personalize the menu of the main screen, the options are:

- simplified menu
- extended menu

Only the following icons can be viewed with the simplified menu:

- patient management
- spirometry
- oximetry
- database

The extended menu includes the same icons of the simplified menu and the icons representing the various types of the tests that the device is capable of performing.

To exit the settings of the service menu touch ⬅ in the bottom left hand side.

3.6.1 Patient Mode

This mode allows to simplify the use of the device for a patient during the day and lets the doctor setup various functions useful to assess the patient's state of health as it evolves in time.
In patient mode the main screen appears as follows.

The simplified service menu can be accessed by touching the icon in the bottom right-hand side, the following items are shown:

- Patient data
- Change date/time
- LCD setup
- Bluetooth setup
- Insert password

To access the service menu select the item "Inser password" and enter the following password:

1 2 2 3 3 3

In this mode the service menu displays the following items:

- Spirodoc mode
- Personal best
- Turbine setup
- Turbine calibration
- Oximetry setup
- Switch-on setup
- Questions setup
- Symptoms setup
- Predicted source selection
- Standard setup
- Language selection
- Memory deletion
- Communication type
- Units format
- Date format

Furthermore to the items in the previous paragraph the device allows to setup the following items:

- Personal best
- Questions setup
- Symptoms setup

Personal Best
One of the following four parameters can be used as a reference to be compared with at the end of a spirometry test:

FVC FEV1 PEF F2575

For each of the above four parameters it is possible to check the corresponding value of the test with a personal value set by the doctor or a predicted value taken from a predicted source, by selecting one of the two following items:

- Personal best value setup
- Use predicted source

Questions Setup
Specific questions can be written so that when the patient turns-on the device a table will be displayed with a series of questions. The following table displays the items which can be selected and the response options which can be used by the patient.

A multiple selection can also be implemented.

Symptoms Setup
Every time that a patient records a test the symptoms setup will have the patient answer a series of questions; the following table displays the items which can be selected and the response options that can be chosen by the patient:

Domanda	Possibili risposte		
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	LIGKT	DARK
Sputum increasing	NO		YES
breathlessness	NO	Effort	At rest
Fatigue	NO	MED	MAX
Chest tightness	NO	MED	MAX

Also in this case a multiple selection can be implemented.

3.6.2 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.
A calibration can only be performed with the reusable turbine.

Calibration of the turbine is performed using a calibration syringe to make a FVC test for the expired parameters and a FIVC test for the inspired parameters.
To access the calibration function, select the “Turbine Calibration” option from the Service Menu as explained in paragraph 3.6. Once the password has been inserted correctly the following screen will appear:

VOL. 300	BTPS	%Corr.
Ultima FVC	300	0.00
UltimaFIVC	300	0.00
Nuova FVC	000 ◄	
Nuova FIVC		

FVC=0 CALIBR. DI FABBRICA

The Old FVC and the Old FIVC values shown are those values from the last calibration performed.
The values under the **%Corr.** column indicate the correction factor. These are pre-set or 0 by default.

To perform a calibration:
1 - Insert the volume in **cL** of the calibration syringe in use (e.g. for a 3L syringe, insert 300 cL).

2 - Insert in both fields New FVC and New FIVC the FVC & FIVC values obtained by a measurement made with the calibration syringe, by using the numbers that appear in the bottom of the screen. After inserting the values of each parameter 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 ESC icon the device will automatically return to the service menu without applying any correction.
If the FVC and FIVC values produce a correction factor that is >10%, the FVC and FIVC values will not be accepted. This means that the device cannot correct 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, insert the number **0** in the New FVC and New FIVC fields. With the OK icon return to the Service Menu.

NOTE

Each time a calibration is made the new correction factors are algebraically added to the previous correction factor. Therefore, before making a new calibration make sure to delete the actual calibration in use as described above.
For an accurate and reliable calibration the syringe volume must be at least 3 L.

⚠ 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 spirobank II 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.

3.7 Patient Data

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

Modify the current patient data

Create a new patient

3.7.1 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 touchscreen keyboard. Touch the OK icon to move on to the next screen

Second screen (sirname)
As above insert the sirname 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			Standard NAHNES III
Group	% correction		
Without correction	100%		Caucasian
Caucasian	100%		Mexican-American
Oriental	100%		Afro-American
Hong Kong Chinese	100%		Other
Giapanese	89%		
polinesian	90%		
North Indian	90%		
South Indian	87%		
Pakistani	90%		
African descendant	87%		

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

FVC, FEV1, FEV3, FEV6, VC

For NAHNES III standards, the correction is based on several theoretical formulas (as described in the publication).

Once the ethnic group is set the device saves the data and autonmatically returns to the main screen.
To interrupt the data insertion, touch the ESC icon and the device will automatically return to the main screen.

3.7.2 Patient data modification

The icon  allows to modify current patient data; by accessing this function the patient data is presented on the various screens; modify the data by using the alfanumerical key which are shown time and again.

Touch the  icon to return to the main screen without modifying any data

3.8 Visualization of memory data

3.8.1 Database research modality

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 sirname.

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 sirname or sirname initial; once having inserted the sirname touch the OK icon. Visualized data corresponds to all test sessions of that particular patient.

NOTE

Test session 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.

3.8.2 Visualization of database info

The result of a search performed in one of the described methods in paragraph 3.8.1 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 as in paragraph 3.1 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 via Bluetooth to a printer the parameters of a selected test.

To view the parameters of a selected test.

The user may return to the previous screen by using the icon.

WARNING

Printing via Bluetooth is possible only after setting at least one printer from the Bluetooth printer list. Refer to paragraph 3.6 for proper setup of this function. If no printer has been selected the device will show the following message:

EMPTY LIST
Device search
Touch OK to confirm

By touching the OK icon the device will search for any nearby devices; if any devices are found these can be memorized in the specific Bluetooth list.

3.9 Display of last session from current patient.

Case I^{o} : simplified menu

To view the last spirometry tests performed by the current patient touch the icon.

In the spirometry menu the icon allows to access the most recently perfomed tests

To display the most recent oximetry tests performed by the current patient touch the icon.

Inside the oximetry menu the icon allows to access all data from the most recent tests.

3.10 PC On line mode (connected to a PC)

In the PC on-line mode the spirometer becomes a fully functional laboratory spirometer which works in real-time connected to a PC.
PC interface is via USB cable or Bluetooth connection.

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.

Connected to a portable PC the **Spirodoc** can be used for epidemiological studies conducted in occupational environment, schools, etc etc..

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 remotely controlled from the device itself. The default settings of the PC software will be transferred to the device and will remain in the device even when used in stand-alone mode; for example when the Spirodoc is connected to the PC and the user selects the type of turbine (disposable or reusable) the selection will be saved in the device and remain effective even when the Spirodoc is used in stand-alone mode. So pay attention to the type of turbine setting.

3.11 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 touchscreen 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.
- 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.

WARNING

While performing a test make sure not to interrupt the test prematurely or turn off the device by accidentally touching the screen.

By touching the  icon the user may access the spirometry testing area from the simplified menu mode. With the extended menu the main screen will display the different types of spirometry tests as follows:

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 info 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 3.8.2

3.11.1 FVC test

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

INSPIRE slowly
EXPIRE quickly
INSPIRE slowly

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 holding 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 when the minimum expiry time has been reached.

WARNING

Accurate spirometry testing requires that the patient expire absolutely 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 (FVC+FEV1) and will automatically display the results of this 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 check 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.

Six seconds from the start of the forced expiratory test, the **Spirodoc** emits a continuous beep. This is useful for the doctor to understand if the patient has reached the minimum expiry time, as per the requirements of the major international pneumology associations.

3.11.2 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 to carry out the test properly.

3.11.3 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

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

3.11.4 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 follow the instructions below:

Simplified menu

To access the spirometry area touch the  icon on the main screen and subsequently touch the  icon.

A “POST” test refers to a spirometry test after having administered to a patient a pharmacological bronchodilation protocol. Before carrying out the test is is necessary to indicate the drug dosage administered as a reference when checking the results of the measured parameters.

The following parameters will be displayed related to the selected patient:

- 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.

3.12 Viewing the spirometric results

Following a FVC test, the spirometry test results are shown. The first screen displays:

- The main parameters FVC, FEV1, FE1%, PEF of the best trial from all the tests performed durin the session.
- The percentage change compared to the predicted values.
- A Flow/Volume graph of the Forced Vital Capacity

The graph is a preview, to view the whole test simply touch the graph and automatically the device will show the entire graph rotated 90° clockwise on the display. By touching the graph again the device will return to the original preview.

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

3.12.1 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 obstruction
- Mild obstruction
- Moderate obstruction
- Moderately severe obstruction
- Severe obstruction
- Very severe obstruction

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 manouvers performed.

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

PRE test
A = At least to acceptable manouvers, 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 (1) FEV1 values matching within 100 mL
B= two acceptable (1) FEV1 values matching within 200 mL
C= two acceptable (1) FEV1 values that do not match within 200 mL
D= only one acceptable (1) FEV1 manoeuvre
F= No acceptable (1) 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

FLOW DROP 50%

If there is a drop in the flow of 50% and a recovery within the first second. The following message appears:

Coughing during test

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;

3.13 Oximetry Testing

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

⚠ WARNING

If SPIRODOC has been purchased *without* the oximetry option only spirometry testing can be performed.
If the oximetry option is purchased afterwards, please contact a service center or the manufacturer to activate the oximetry function.

⚠ WARNING

The oximetry sensor used in the manual is only one of the different types of sensors which can be used listed in paragraph 2.2.4. 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.

Il sensore descritto di seguito rappresenta solamente un esempio. Con SPIRODOC possono essere utilizzati tutti i sensori descritti nel paragrafo 2.2.4. MIR non raccomanda l'uso di un particolare sensore; viene lasciata al medico la scelta in merito.
Durante i test di ossimetria SPIRODOC non può essere spento, per spegnere il dispositivo bisogna prima interrompere il test che è in esecuzione, questo

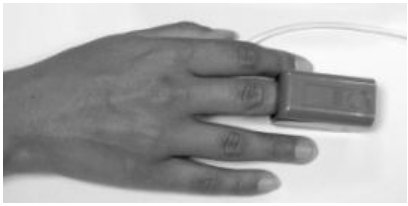
permette di evitare interruzioni indesiderate che potrebbero compromettere la veridicità dei dati ottenuti.

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. Position the sensor so that the cable is underneath the palm of the hand. This enables the light source to remain on the fingernail and the detector on the bottom part of the finger.



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 ten 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 not inserted

At the same time **SPIRODOC** emits an acoustic signal for 10 seconds.
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 signal for 10 seconds.
If the signal reaches the sensor properly, after a few seconds the device will emit an acoustic signal while also displaying the values on screen.

At the same time **SPIRODOC** emits an acoustic signal for 10 seconds.

The alarms can be customized for any oximetry test, the procedure is described in paragraph 3.6.

During oximetry testing if the SpO2 and blood pulse rate fall below the bottom threshold or raise above the threshold, the **SPIRODOC** will emit a continuous acoustic signal 'beep' until such situation persists. This function can be disabled for sleep oximetry testing.

If the alarms are activated during oximetry testing the  icon will always show up on screen.
The alarms function can be activated/deactivated even during oximetry testing. By touching the  icon the screen on the right-hand side will appear which allows to check the threshold values; to activate/deactivate the alarms function simply touch the ON or OFF icons. If the screen remains untouched for a few seconds the device will return to the screen of the oximetry test in progress.

For information concerning the proper setup of this function please refer to paragraph 3.6.

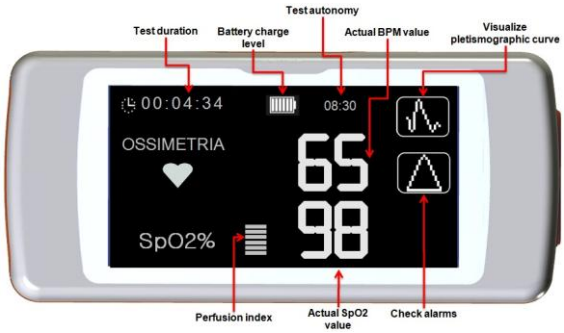
WARNING

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

During any oximetry testing in stand-alone mode the display will always show the battery pack level:
The numeric values display the hours and minutes left.

During a test the display will show the following information:



3.13.1 Walk test (6MWT)

Access the oximetry area by touching the  icon from the main screen, next select the test by touching the  icon.

The walk test is comprised of three stages:

- Initial rest

- walking
- recovery

Initial Rest

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 (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 left up to the doctor. The device does not indicate this stage. (at the beginning of this stage the timer is reset to zero).To end the test simply touch the STOP icon.

At the end of the test the data required for the calculation the following parameters must be inserted;

- Baseline DYSPNEA
- Final DYSPNEA
- Baseline FATIGUE
- Final FATIGUE
- Distance (meters)

These parameters follow the Borg scale and can have the following values: 0, 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, the distance covered is indicated in meters.
The Borg scale coefficients represent the following severity values:

SCALE	SEVERITY
0	None
0.5	Very Very Slight (Just Noticeable)
1	Very Slight
2	Slight
3	Moderate
4	Some What Severe
5	Severe
6	“
7	Very Severe
8	“
9	Very Very Severe (Almost Maximum)
10	Maximum

All the data from the walk test can be viewed in the following 6 screen shots and can also be printed by following the instructions found in paragraph 4.2.

If the test results are printed, the paper report will only show the data related to the “walking” stage of the test; please view the examples attached in this user manual.
Touch the STOP icon to end the test at any time.

WARNING

One of the parameters calculated during a walk test is the so-called Recovery Time. The Recovery Time is defined as the time taken for the SpO2 value to return to at least 99% of the average base value calculated during the initial stage of the test.

3.13.2 Sleep Oximetry

To access the oximetry area from the main screen touch the  icon, next select the  icon to select the test.

This test records overnight patient parameter variations.
After approximately 5 minutes, **SPIRODOC** will enter standby (energy saving) mode; it stops beeping and the display turns off. The led signal remains on. To check that the device is functioning properly during standby mode, press ⏻, after 1 minute **SPIRODOC** will return to standby mode.

Should the signal die during standby mode the device will automatically exit the standby mode and a warning message will appear (sensor unplugged or finger not detected correctly).
The data shown is the same as described in the previous test, except for information in this present mode, which has not been envisaged for this test.
After the required time the test can be interrupted as previously described.
To print data see Paragraph 4.2.; an example of a test printout report can be found in this user manual.

3.13.3 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 during a length of time decided by the doctor.

During the test the display shows the information that appears in the image to the right. The BEEP and ALARM icons allow to modify the following settings:

- **BEEP**, allows to activate/deactivate the heart beat acoustic signal during the test.
- **ALARM**, allows to activate/deactivate the thershold alarms as descrive in paragraph 3.6.

Unlike the sleep oximetry test, the display does not enter standby mode, thus always remaining on.
To end the test simply touch the STOP icon.
Please refer to paragraph 4.2 for a data printout; an example can be found in the attachments inside this user manual.

3.13.4 Instructions for Adult Single 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 "wrap" type sensor.

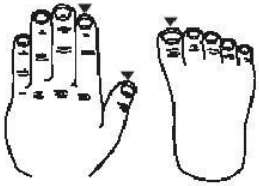
WARNING

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

WARNING

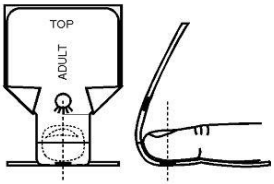
The adult single patient sensor is ideal for patients weighing more than 30 kg. It should not be used on patients who suffer from allergic reactions to adhesive tape. The sensor is specifically designed for single use only.

- 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.

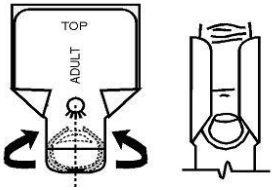


- Remove nail polish or artificial fingernails.

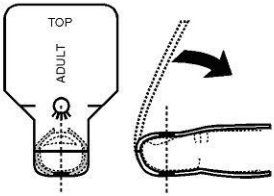
- Insert the patient's digit in the sensor nail-side up, lining up the digit's pad over the detector. The sensor's positioning line runs across the mid axis of the fingertip



- Wrap the bottom adhesive around the digit, being careful not to cover the nail.



- Fold the sensor's top over the digit, making sure the light source is directly over and in-line with the detector. Wrap the adhesive around the finger or toe to secure the sensor. 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.
Avoid over tightening the adhesive tape; a sensor wrapped too tightly can produce inaccurate saturation measurements. .
To reduce chances of entanglement it is recommended to fasten the cable to the wrist with a bandage.

4. DATA TRANSMISSION

WARNING

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

WARNING

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

4.1 Data Transmission via Bluetooth to a cell phone

SPIRODOC incorporates a "Bluetooth" wireless data transmission system. This radio wave connection allows **SPIRODOC** to connect to a suitable mobile phone. All the data in **SPIRODOC** can be transferred with this method of data transmission.
The step by step procedure is described below.

4.1.1 Preliminary Operations

WARNING

Data transmission through Bluetooth connection requires the phone number of the center where the data will be received (the doctor's office, a telemedicine service center, etc.) The telephone number setup is done by means of the service menu. (please see paragraph 3.6) Furthermore it is necessary to setup a mobile phone to create a connection; for this matter also refer to paragraph 3.6.

4.1.2 Bluetooth data transmission.

- Turn on the **SPIRODOC**
- Touch the  icon on the main screen
- The type of transmission selected is shown, if this is correct then confirm with OK to activate the connection to the default device that was initially setup
- Upon request from the mobile phone insert the PIN code which corresponds to the Serial number, SN, of the **SPIRODOC** which can be found on a label on the bottom-side of the device.
- The next stages of the connection are performed
- Once the connection is up and running the data is transferred to the mobile phone
- At the end of the data transfer the following message is shown "transmission complete"

At this stage the screen will show the following information:

- The device with which the connection was implemented (described in the initial setup)
- The PIN code (which corresponds to the device serial number)

To stop the Bluetooth connection during the data transfer simply touch the STOP icon, by doing so the connection will be terminated and the device will return to the main screen.
If no device was setup for the data transmission a message will appear on screen which allows the device to search for compatible devices. Once the device is setup the connection commences automatically.

Should there be any errors during the data transfer the message on the right will appear on screen.
The device will automatically return to the main screen; repeat the procedure again.

4.2 Data transmission via Bluetooth for printing

WARNING

Data printing from the patient management function will only work if the printer too has a Bluetooth connection; another possible solution is with the use of a USB adaptor installed on the printer, thus enabling a Bluetooth connection.

The Bluetooth system enables **SPIRODOC** to transfer test data directly to a Bluetooth enabled printer. The procedure is listed below:

4.2.1 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.

If no device was setup to print via Bluetooth a message will appear on screen which allows the device to search for compatible devices. Once the device is setup the connection commences automatically for the printout.

During the search for compatible devices to connect via bluetooth, SPIRODOC always checks the address of the device. If a previously registered device should change name it will be automatically upgraded.
Should there be any errors during the data transfer the message on the right will appear on screen.
The device will automatically return to the main screen; repeat the procedure again.

4.3 PC connection via USB port

WARNING

Before connecting spirobank *II* by USB to a PC, winspiroPro must be installed to interface with the device.
It is important prior to initiating the following procedure to know the version of the operating system 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 winspiroPRO is already installed on the PC then a new installation is not required.

Before connecting the SPIRODOC via USB to the PC, the WinspiroPRO 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 winspiroPRO 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 winspiroPRO User Manual carefully.

4.4 PC connection via Bluetooth

The bluetooth connection to the PC allows for the USB ports to remain unused while still having a connection whereby the **SPIRODOC** is directly managed by the winspiroPRO software (as with a USB connection)
SPIRODOC is capable of performing on-line real time spirometry tests via Bluetooth connection.

⚠ WARNING

To function properly the PC must have Bluetooth connectivity embedded or must be equipped with an external Bluetooth USB dongle. Before starting the Bluetooth connection procedure it is necessary to have previously performed the procedure described in paragraph 3.6 (BLUETOOTH setup).

For proper peripheral management please refer to the software user manual on line.

4.5 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 "winspiroPro" software manual.

5. MAINTENANCE

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

- Cleaning and checking the reusable turbine.
- Changing the disposable turbine before each test.
- Cleaning the oximetry sensor (for reusable sensors).
- Changing the adhesive tape of the oximetry wrap sensor.
- Changing the battery.

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.

5.1 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.

⚠ ATTENZIONE

È buona norma controllare periodicamente che all'interno della turbina non siano depositate impurità o corpuscoli estranei come peli o peggio capelli. Questa eventualità infatti potrebbe frenare o bloccare l'equipaggio mobile della turbina compromettendo l'accuratezza della misura.

Prima di ogni utilizzo effettuare il test descritto al paragrafo 5.1.1 seguente che permette di controllare lo stato di efficienza della turbina, se il risultato del test è negativo operare come segue.
Per pulire la turbina **riutilizzabile** estrarla dall'apposito alloggiamento ricavato su **SPIRODOC** ruotando in senso antiorario ed esercitando una semplice trazione. Per facilitare l'estrazione è utile esercitare una lieve spinta sulla base della turbina aiutandosi con un dito.
Immergere la turbina in un liquido detergente a freddo ed agitarla in maniera da rimuovere le possibili impurità depositate all'interno; lasciarla immersa per il tempo suggerito dal produttore della soluzione detergente e riportato nelle istruzioni d'uso.

⚠ WARNING

To avoid damage beyond remedy 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.

MIR suggests the use of Perasafe, manufactured by Dupont, which has been tested on all MIR sensors.

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 5.1.1; if the turbine is still malfunctioning please replace it with a new one.

⚠ WARNING

When using disposable turbines, do not carry out any cleaning procedure. A new disposable turbine must be used for a new patient.

5.1.1 Proper turbine operation check

- Turn on **SPIRODOC** and setup the device to perfom 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

5.2 Oximetry sensor cleaning

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.

WARNING

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

5.3 Changing the adhesive wrap sensor

The adhesive tape is made with latex-free material.

- Gently remove the used adhesive tape from the sensor and dispose of it.
- The back of the sensor has alignment pins. Place the sensor with the alignment pins facing the adhesive part of the tape and align the pins to the holes on the tape.
- Push the sensor so as to insert the pins into the holes of the tape. Lift both the sensor and the tape and check that the pins of the sensor are properly aligned.

WARNING

It is highly suggested to use a new piece of adhesive tape for each patient, or as required.

5.4 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 <u>not</u> to use the device while the battery is charging.
Always disconnect the battery charger from the device when the charge cycle has terminated.

6. 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:

6.1 Causes and solutions

The SPIRODOC will not turn on

- The battery pack could be completely discharged; recharge the device by connecting it to the battery charger.
- The device internal software is lost. Connect the device to the PC via USB and proceed to download the internal software. For further information please refer to the winspiroPRO user manual available inside the software itself.

While in use the device turns off and on again.
- An internal error has occured, please check on the website www.spirometry.com for new internal software upgrades. Should there be a newer internal software version please upgrade the device by using the winspiroPRO software. For further information please refer to the winspiroPRO user manual available inside the software itself.

At the end of a spirometry test the data measurements are not reliable.
- Clean the turbine as shown in paragraph 5.1; if necessary replace the turbine with a new one.

Memory loss due to an unexpected event
- The database has been lost. Contact a local technical service center.

WARNING

Before contacting a technical assistance center, please try downloading the database from the device to the PC using the winspiroPRO software. This procedure is necessary as 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.

srl MEDICAL INTERNATIONAL RESEARCH
Via del Maggiolino 125, 00155 Roma - ITALY

Declaration of CE Conformity

Quality Management System according to the requirements of Annex II of the Medical Device Directive 93/42/EEC implemented by the Legislative Decree 46 dated 24/02/97

Notified Body CERMET No. 0476 - *Certificate* No. MED – 9826

MIR srl Medical International Research, declares that the Device subject of this declaration together with its standard accessories conforms to the requirements of the Council Directive 93/42/EEC Annex I.

Device Description	**Spirometer/Oximeter**
Device Name	**spirobank *II***
Classification	**IIa**
This Device is marked	**CE0476**

Any modifications to the Device which are not authorised by MIR will invalidate this Declaration

Roma **01 / 01/ 2006**

Paolo Sacco Bochetti
President of the Board of Trustees.

Rev.0 – Mod. PO-10DDC_**SPIRODOC**

LIMITED WARRANTY CONDITIONS

spirobank *II*, 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 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.

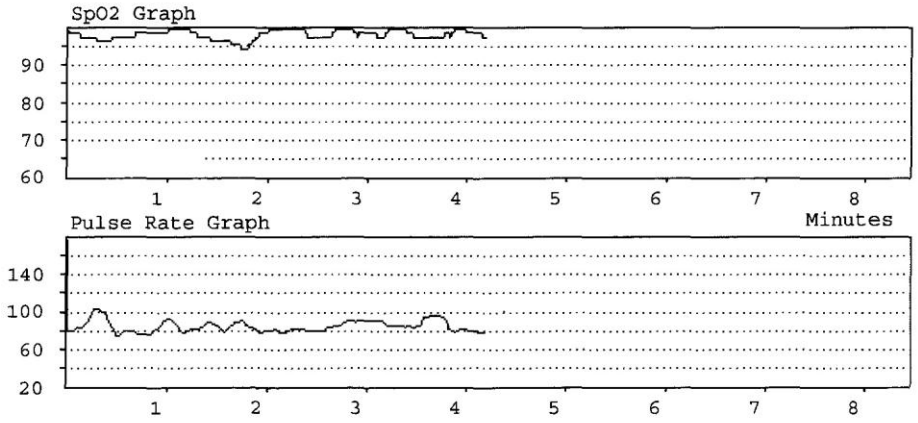
MIR – Medical International Research reserves the right to modify the device if required, and a description of any modification made will be sent along with the returned goods.

ALLEGATO 1 OXIMETRY TEST REPORTS EXAMPLES

Oximetry - Sleep Test

Name A B | Date 30/03/06 | Time 10:10

Age 38 | Height cm 182 | Wheight kg 70 | Sex M



Recording Time			00:04:10	Analysis Time			00:04:10
%SPO2				BPM			
Baseline	97	Mean	97.5	Baseline	85	Mean	84.9
Minimum	94	Maximum	99	Minimum	75	Maximum	104

N. SpO2 Events <89%	0	N. Bradycardia Events < 40 BPM	0
Delta Index [12 sec]	0.9	N. Tachycardia Events >120 BPM	0

	% time	hh:mm:ss		% time	hh:mm:ss
T90 (SpO2 <90%)	0%	00:00:00	T < 40 BPM	0%	00:00:00
T89 (SpO2 <89%)	0%	00:00:00	T >120 BPM	0%	00:00:00
T88 (SpO2 <88%)	0%	00:00:00			
T87 (SpO2 <87%)	0%	00:00:00			

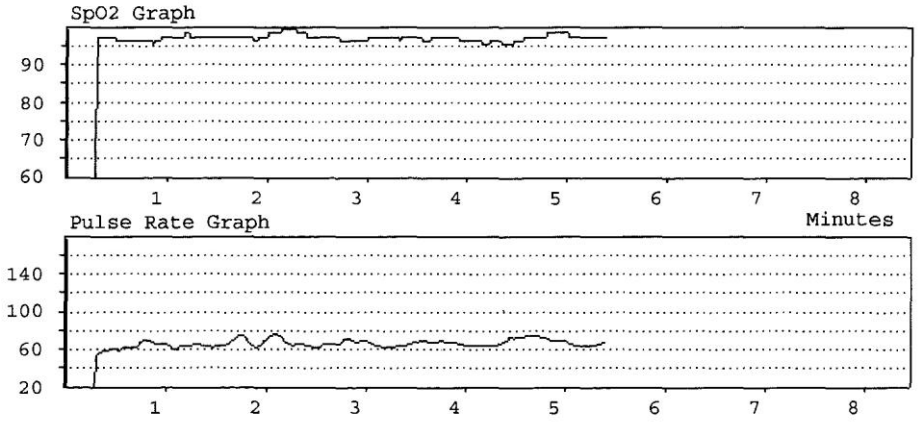
Total Desaturation Events	1	Total Pulse Rate Variations	5
ODI (Desaturation Index)	14.3	Pulse Rate Variation Index	71.4
Mean Duration (s)	50.0		
Longest Duration (s)	50	NOD -4%[Baseline-4%]	00:00:00
Desaturation Peak [Nadir] (%)	94	NOD 89[<89%]	00:00:00
Mean Desaturation (%)	94	NOD 90[<90%; Nadir<86%]	00:00:00

ENGLISH

Oximetry - Walk Test (6MWT)

Name A B | Date 27/03/06 | Time 10:17

Age 38 | Height cm 182 | Wheight kg 70 | Sex M



Recording Time	00:05:22	Analysis Time	00:02:18
Baseline Time	00:02:06	Walking Time	00:02:18
		Recovery Time	00:00:00

%SPO2		Mean	96.5	BPM		Mean	66.6
Baseline	96.8	End	96	Baseline	65.7	End	72
Minimum	95	Maximum	99	Minimum	63	Maximum	73

T -2% (Delta SpO2 >= 2%)	22:09:03	N. Bradycardia Events < 40 BPM	0
T -4% (Delta SpO2 >= 4%)	17:02:01	N. Tachycardia Events >120 BPM	0

	% time	hh:mm:ss		% time	hh:mm:ss
T90 (SpO2 <90%)	0%	00:00:00	T < 40 BPM	0%	00:00:00
T89 (SpO2 <89%)	0%	00:00:00	T >120 BPM	0%	00:00:00
T88 (SpO2 <88%)	0%	00:00:00			
T87 (SpO2 <87%)	0%	00:00:00			

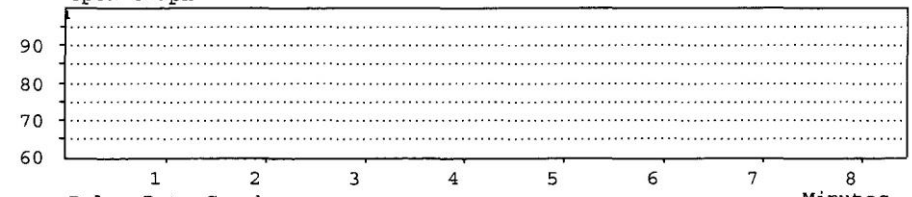
Distance (m)		Dyspnea (Borg scale)	
Walked	0	Baselin 0 End 0	CHG 0
Predicted (Standard)	754	0%	
Predicted (Minimum)	601	0%	
AUC/Distance	27.0	Fatigue (Borg scale)	
		Baselin 0 End 0	CHG 0

Oximetry - SpO2/BPM

Name A B | Date 22/03/06 | Time 14:48

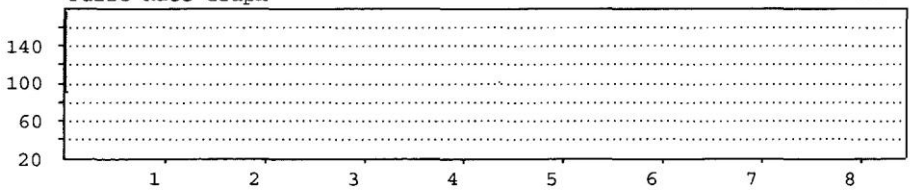
Age 38 | Height cm 182 | Wheight kg 70 | Sex M

SpO2 Graph



Pulse Rate Graph

Minutes



Recording Time	00:00:00	Analysis Time	00:04:10

%SPO2				BPM			
Baseline	0	Mean	97.0	Baseline	0	Mean	91.0
Minimum	97	Maximum	97	Minimum	91	Maximum	91

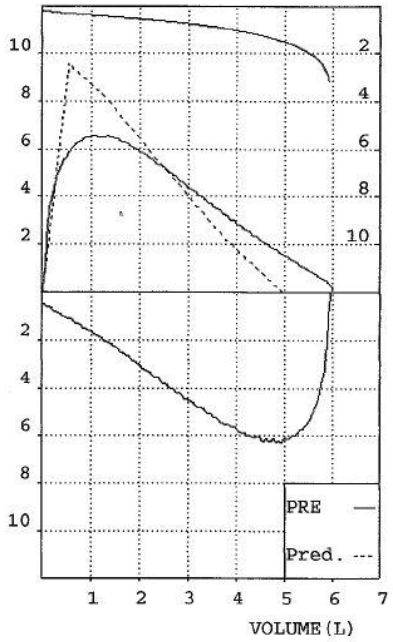
N. SpO2 Events <89%	0	N. Bradycardia Events < 40 BPM	0
Delta Index [12 sec]	0	N. Tachycardia Events >120 BPM	0

	% time	hh:mm:ss		% time	hh:mm:ss
T90 (SpO2 <90%)	0%	00:00:00	T < 40 BPM	0%	00:00:00
T89 (SpO2 <89%)	0%	00:00:00	T >120 BPM	0%	00:00:00
T88 (SpO2 <88%)	0%	00:00:00			
T87 (SpO2 <87%)	0%	00:00:00			

ALLEGATO 2 SPIROMETRY TEST REPORT EXAMPLE

Test Date	15/09/09	10:12	BTPS 1.092	Standard		ERS /	ATS
Name						ID#	8
Birth Date	04/11/1967	Age 41	Height cm 182	Weight kg	70	Sex	M
PRE File N°	8			Predicted	ERS		

(+) FLOW (L/s)



Parameter	PRE	Predicted	%
*FVC	6.03	5.08	119
*FEV1	4.59	4.15	111
*PEF	6.55	9.56	69
FVC	6.03	5.08	119
FEV1	4.59	4.15	111
FEV1/FVC	76.1	79.8	95
PEF	6.55	9.56	69
F2575	4.19	4.47	94
FEF25	6.41	8.28	77
FEF50	4.37	5.28	83
FEF75	2.19	2.34	94
FEV3	6.02	4.83	125
FEV3/FVC	99.8	95.1	105
FEV6	6.03	5.08	119
FEV1/FEV6	76.1	81.7	93
FET	3.03	6.00	51
EVol	120	-	-
FIVC	6.14	5.08	121
FIV1	4.71	4.15	113
FIV1/FIVC	76.7	79.8	96
PIF	6.30	9.56	66
ELA	41	41	100
#MVV	160.7	145.6	110

* = Best Value
\# = Calculated Value

INTERPRETATION: Normal Spirometry

QUALITY CONTROL GRADE: F

REPEATABILITY : None

ANNEX 3 INFORMATION FOR CORRECT USE IN AN ELECTROMAGNETIC ENVIRONMENT

Guidance and manufacturer's declaration – electromagnetic emissions		
The **spirobank *II*** is intended for use in the electromagnetic environment specified below. The customer or the user of the Spirobank II should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The **SPIRODOC** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The **spirobank *II*** is intended for use in the electromagnetic environment specified below. The customer or the user of the **spirobank *II*** should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. In the event of disruption due to ESD during oximetry test, the device recovers from any disruption within 30 s. (according to ISO 9919).
Electrical fast transient/burst IEC 61000-4-4	±1 kV for input/output lines		Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	Not Applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
       Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	 3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	 [*3*] V [*3*] V/m	Portable and mobile RF communications equipment should be used no closer to any part of the **spirobank *II***, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=[\frac{3.5}{3}]\sqrt{P}$ $d=[\frac{3.5}{3}]\sqrt{P}$ 80 MHz to 800 GHz $d=[\frac{7}{3}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation

			distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE *U*T is the a.c. mains voltage prior to application of the test level.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **spirobank *II*** is used exceeds the applicable RF compliance level above, the **spirobank *II*** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **spirobank *II***.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the spirobank *II*

The **spirobank *II*** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **spirobank *II*** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **spirobank *II*** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d=[\frac{3.5}{3}]\sqrt{P}$	**80 MHz to 800 MHz** $d=[\frac{3.5}{3}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d=[\frac{7}{3}]\sqrt{P}$
0.01	0.12	0.24	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	5.28	5.28	1.056
100	11.66	11.66	23.32

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.