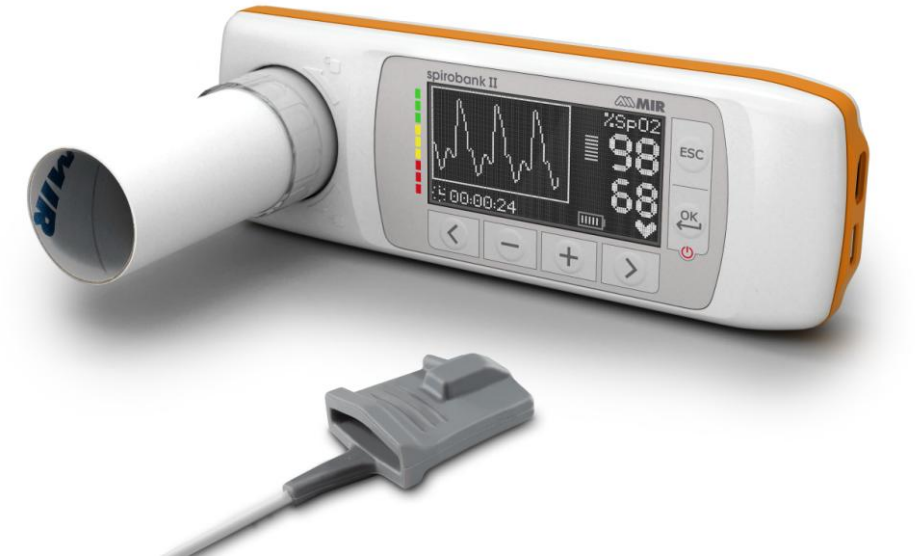
Spirobank II
Bluetooth low energy



User manual rev. 1.1

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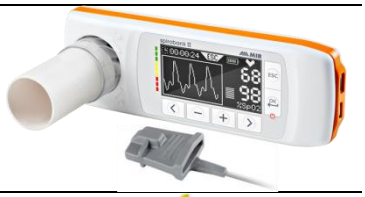
Thank you for choosing a **MIR** product

MEDICAL INTERNATIONAL RESEARCH

Spirobank II is sold in three different configurations; the following table describes these three configuration and the relevant functions:

Spirobank II ®	Basic	Advanced	Advanced Plus
			
Additional parameters	—	✓	✓
POST Bronchodilator test	✓	✓	✓
Bluetooth 2.1	—	✓	✓
Oximeter	—	○	✓
Battery charger	—	○	✓

✓ Standard ○ Optional — Not Available

⚠ WARNING

The paper mouthpiece, the nose clip and the disposable turbine with mouthpiece in the equipment should be considered disposable products.

Before using your SPIROBANK II

- Read carefully your User Manual and pay attention to all the warnings and labels including all relevant information included with the product.
- Set the device configuration (date, hour, predicted set, language, etc etc) as described in paragraph 2.5

⚠ WARNING

Before connecting the SPIROBANK II to another device, the application must be installed correctly in the device. The device may be connected to the PC only after the winspiroPRO software has been installed. Once the new hardware is "recognized" 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 and 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 are appreciated and may be sent via email to: mir@spirometry.com.
MIR accepts no responsibility for any loss or damage caused by the user of the device due to instructions contained in this Manual and/or due to incorrect use of the product.
Please note that due to printing limitations, the screenshots shown in this manual may differ from the display of the machine and/or from the keyboard icons.

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

1. INTRODUCTION

1.1 Intended use

The **SPIROBANK II** spirometer and pulse oximeter is intended to be used by a physician or by a patient under the instruction of a physician.
The device is intended to test lung function and can make:

- 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, excluding during patient transport outside a healthcare facility.

1.1.1 User category

SPIROBANK II 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.

1.1.2 Ability and experience required

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

⚠ **WARNING**

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

⚠ **WARNING**

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

1.1.3 Operating Environment

SPIROBANK II 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).
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 1.6.3 below.

⚠ **WARNING**

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

1.1.4 Homecare usage

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

1.1.5 Patient effect on the use of the device

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

1.1.6 Limitations of use - Contraindications

An analysis of the results of a spirometry test is not by itself sufficient to make a correct diagnosis of the patient's clinical condition. A detailed clinical history of the patient is also required together with the results of any other test(s) suggested by a doctor.
Test comments, a test interpretation and suggested therapeutic treatment must be given by a doctor.
Any symptoms that the patient has at the time of the test must be carefully considered before a spirometry test is made. The user is responsible to assess both the mental and the physical condition of the patient in order to perform a proper test, furthermore, in the evaluation of test results, the user must also assess the degree of collaboration of each test carried out.
A spirometry test requires the full collaboration of the patient. The results depend on the person's ability to inspire as much air as possible and to expire all of the air as fast and for as long as possible. If these fundamental conditions are not respected then the results obtained during spirometry testing will not be considered accurate, and therefore the test results are "not acceptable".
The acceptability of a test is the responsibility of the doctor. Special attention should be given when testing elderly patients, children and 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 SPIROBANK II has limited alarms, therefore the device requires frequent display observation of SpO2 and pulse rate.

1.2 Important safety warnings

SPIROBANK II 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.
SPIROBANK II 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.. In normal conditions the lifespan of the device is estimated to be around 10 years.
The device constantly monitors the state of charge of this battery and a message informs the user when the battery is discharged.
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.

1.2.1 Danger of cross-contamination

In order to avoid exposing the patient to the critical danger of cross-contamination use a single-patient disposable turbine , then a new one must be used for each patient.

1.2.2 Turbine

Disposable turbine

⚠ WARNING

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

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

1.2.3 Mouthpiece

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

⚠ WARNING

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

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

⚠ WARNING

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

1.2.4 Oximetry sensors

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

Manufacturer	Code	Description
BCI	1300	adult disposable sensor
BCI	3026	wrap-around reusable sensor for infants
BCI	3043	Universal reusable Y sensor
BCI	3078	Reusable 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 **SPIROBANK II**. Two cable lengths are available:

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

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

⚠ WARNING

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

WARNING

Dyes introduced into the bloodstream (for example; to perform a diagnostic tests) such as methylene blue, indocyanine green, indigo carmine, patent blue V (PBV), and fluorescein may adversely affect the accuracy of the oximetry reading.

Any condition that restricts blood flow, such as the use of a blood pressure cuff or a device for systemic vascular resistance, may cause the inability to determine accurate pulse rate and SpO2 readings.
Remove fingernail polish and/or false fingernails before applying SpO2 sensors. Both may cause inaccurate oximetry measurements.

Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin, may adversely affect the accuracy of the oximetry measurement.

Optical cross-talk can occur when two or more sensors are placed in close proximity. Optical cross-talk may adversely affect the accuracy of the oximetry readings. The danger can be eliminated by covering each site with opaque material.
Obstructions or dirt on the sensor's emitter and/or detector may cause a sensor failure or inaccurate readings. Make sure there are no obstructions and the sensor is clean.

Autoclaving, ethylene oxide sterilizing, may cause sensor damage. Do not attempt to sterilize the sensor.

Unplug the sensor from SPIROBANK II before cleaning or disinfecting to prevent damaging sensor or device, and to prevent safety hazards for the user.

1.2.5 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.
Do not modify this equipment without authorization of the manufacturer.
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.
Technical description indicates, manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to service personnel in parts repair.
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.
The use of accessories and cables other than those specified by the manufacturer may result in increased emissions or decreased immunity of the device.
SPIROBANK II should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, SPIROBANK II should be observed to verify normal operation in the configuration in which it will be used.
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 device is connected to other instruments, to satisfy the safety requirements of the system required by the standard CEI EN 60601-1, it is necessary to use exclusively devices compliant to the safety standard. Therefore the PC or the printer which the SPIROBANK II is connected must be compliant to the standard CEI EN 60601-1.
To dispose of the SPIROBANK II, the accessories, any plastic consumable materials (mouthpieces) as well as the battery, use only appropriate containers or return all such parts to the dealer or to a recycling center. All applicable local regulations must be followed.
If any of these rules are not followed then MIR will decline all responsibility for any direct or indirect damages, however caused.
To supply power to the device use only the battery type indicated in the § Technical specifications.
The device may be powered through a PC by a USB cable. By this means, the device works both on line with the PC, or individually powered by the PC.
Keep the device out of reach of children and of any person with mental handicap.

1.3 Lithium-ion battery pack warning

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

WARNING

Use only battery packs supplied by MIR

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

Please read the following instructions carefully.

DANGER
Do not disassemble or modify the battery pack. The battery pack comes with an internal safety sensor; which if tampered with may cause acid leakage, overheating, smoke, breakage an explosion and/or fire.

Do not short-circuit the positive(+) and negative (-) poles with any metal objects.
Do not carry the battery pack in your pocket or in a bag with other metallic objects like necklaces, hairpins, coins or screws.
Do not store the battery pack near any such objects.

Do not warm-up or throw the battery pack in a fire.

Do not use or store the battery pack near a fire or in a vehicle where the temperature may reach 60°C or higher

Do not immerge the battery pack in water or salt-water, and do not leave it wet.
Such events may damage the internal battery safety sensor, thus causing the battery to be charged at a higher voltage, triggering abnormal chemical reactions leading to acid leakage, overheating, smoke, an explosion and/or fire

Do not charge the battery pack near a fire or in an extremely hot environment. High temperature may activate the internal battery safety sensor thus inhibiting the charge. The high temperature may also damage the internal battery safety sensor causing extremely high current surge; and consequently causing abnormal chemical reactions in the battery pack triggering acid leakage, overheating, smoke breakage, an explosion and/or fire.

Use only the battery charger who comply with the characteristics defined in point 1.6.3 of this manual to recharge the battery pack. Recharging with an unsuitable charger in unconforming conditions may cause the battery pack to overcharge or the charging current to be extremely high thus causing abnormal chemical reactions in the battery pack triggering acid leakage, overheating, smoke breakage an explosion and/or fire.

Do not puncture the battery pack with sharp objects such as a nail.
Do not hammer, step-on, throw or cause a forceful impact to the battery-pack.
A damaged or deformed battery pack may cause internal short-circuits thus creating the possibility for acid leakage, overheating, smoke, breakage and/or fire.

Do not use a heavily scratched or deformed battery back as this may be cause for acid leakage, overheating, smoke, breakage and/or fire.

Do not solder directly on the battery pack.

Do not mount the battery pack inside the device with the + and – poles inverted.
If the battery leads do not connect easily to the battery charger or to the device do not apply excessive force. Check to see that the leads are properly aligned. If the leads are inverted, an inverse polarity connection may provoke acid leakage, overheating, smoke, breakage and/or fire.

Do not connect the battery pack leads to a wall socket or to the car lighter Under high voltage the battery may leak acid, overheat, emit smoke, explode and/or catch fire.

Do not use the battery pack for any other purpose other than those specified otherwise its features may be compromised, and its useful life reduced

If the battery acid inadvertently enters the eyes do not rub the eyes, instead wash the eyes with clean running water and call a doctor immediately.

WARNING
Do not leave the battery pack charging longer than the average charging length of time specified.

Do not place the battery in a micro-wave oven or in a pressurized container. Rapid overheating or loss of proofing may cause acid leakage, overheating, smoke, breakage and/or fire.

If the battery pack gives off a bad smell, if it generates heat, if it fades/deformes or if anything abnormal happens during storage, usage and recharging immediately remove the battery pack from the device or the battery charger and do not use it any longer, as any of these events may cause acid leakage, overheating, smoke, breakage and/or fire.

NOTE
The battery pack includes an internal safety protector. Do not use the battery pack where static electricity is present(higher than what is declared by the manufacturer.

If acid from the battery pack comes into contact with skin or clothing immediately wash with running water to avoid skin inflammation

Store the battery pack away from children's reach to avoid any accidental swallowing.
If a child uses the battery pack an adult must explain the proper use to the child.

Before using the battery pack read the manual carefully paying attention to all the recommendations for proper handling.
Please read the manual carefully to insert and remove of the battery pack in the device properly.
Before charging the battery pack read the manual carefully.

The battery pack life cycle is definite-. If you notice a much shorter time usage between 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.
If the battery pack leads are dirty clean with a dry cloth prior to usage.

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

1.4 Labels and symbols

1.4.1 Identification label

The label shows:

- Serial number of the device (SN)
- Product name (REF)
- Antenna symbol for devices whom include RF transmission
- Name and address of the manufacturer
- Electrical safety symbol
- CE mark in compliance with the Directive 93/42 EEC.
- WEEE symbol
- FCC ID identification according to FCC standard
- Symbol for FDA regulation (Rx ONLY)
- Index protection against the penetration of external agents (IPX1)

1.4.2 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.

1.4.3 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.

1.4.4 Warning symbol for the USB

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.**

1.4.5 Warning symbol for the SpO2 port for oximetry

SpO2

1.4.6 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.

1.4.7 FDA and FCC Warnings

SPIROBANK II 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:

SpO2

1.4.8 (ESD) Electrostatic discharge sensitivity symbol

The (ESD) symbol required by the international standard EN 60601-1-2 is used in the vicinity of any connector which has not undergone electrostatic discharge testing.

⚠ WARNING

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

Precautionary procedures are the following:

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

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

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

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

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

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

1.4.9 Information regarding the protection against the ingress of liquids

The label

IPX1

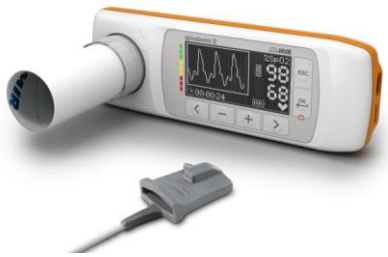
The symbol describes the protection of the device against the ingress of liquids. The device is protected from the vertical fall of water drop.

1.4.10 Symbol for devices that include RF transmitter

The symbol is required from the standard CEI EN 60601-1-2: 2007 point 5.1.1, for devices that include RF transmitters.

1.5 Product description

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



The device is specifically designed to measure a range of respiratory parameters and to monitor the saturation of oxygen in the blood and the heart beat. A quality control check is carried out internally on the measured parameters and the device has an internal memory sufficient for approximately 10.000 spirometry tests or at least 900 hours of oximetry monitoring.

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

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

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

To ensure that the characteristics of the turbine remain unaltered over time replace always it from one patient to the other.

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.

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

SPIROBANK II can perform FVC, test, 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 principle ensures accuracy and reproducibility, without requiring regular calibration.
The oximetry sensor can be disinfected with isopropilic alcohol.

1.6 Technical specification

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

1.6.1 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	%
PEF	Peak expiratory flow	L/s
FEF2575	Average flow between 25% and 75% of the FVC	L/s

*= best values

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

1.6.2 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 for the oximetry test:

Symbol	Description	Units
%SPO2 min	Minimum SPO2 during the test	%
%SPO2 max	Maximum SPO2 during the test	%
BPM min	Minimum BPM during the test	BPM
BPM max	Maximum BPM during the test	BPM
%SPO2 mean	Average SPO2	%
BPM mean	Average BPM	BPM

Δ=DELTA

Parameters requested for six minute walk test analysis

Measurement method:	Red and infrared absorption
Range of measurement %SpO_2:	0 – 99% (with 1% increments)
SpO_2 Resolution	1%
%SpO_2 accuracy:	± 2% between 70-100% SpO2
Average number of heart beats for the %SpO_2 calculation:	8 beats
Range of measurement of cardiac pulse:	18 – 300 BPM (with 1 BPM increments)
Cardiac pulse resolution	1 BPM
Accuracy of cardiac pulse:	± 2 BPM or 2% whichever is greater
Average interval for the calculation of cardiac pulse:	8 seconds
Signal quality indication:	0 - 8 segments on display

Acoustic signals:

- "Beep" with frequency of the cardiac pulse
- "Beep" with special alarm frequency in the case of either %SpO_2 or cardiac pulse going outside of the programmed levels of alarm
- "Beep" with special alarm frequency 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 unexpected event an intermittent beeping will be heard for 5 seconds when the device is switched on again

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

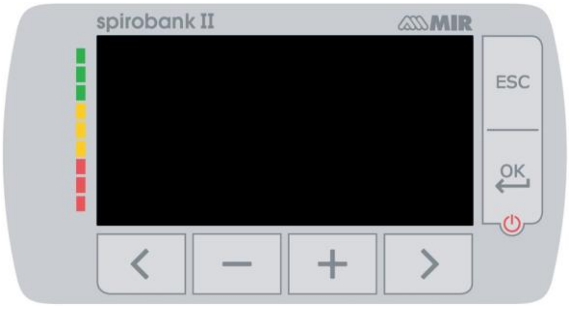
1.6.3 Other features

Memory	Memory capacity for over 10000 spirometric tests The precise number depends on the individual configuration, so it cannot be determined more closely
keyboard	membrane keyboard with 6 keys
Display	Display LCD 160x80 monochromatic
Interface	USB, Bluetooth
Bluetooth interface	frequenzy range = 2402-2480 MHz rated RF power output = 7.5 dBm maximum trasmit power type of antenna = drawn on the board
Duration of the 3,7V lithium battery	Approx 500 charge cycles, under normal conditions of use
Power supply	Battery pack Li-ion 3.7 V 1100mAh
Battery charger	Voltage = 5VDC Current = 500 mA or higher Connector = micro USB type B
Dimensions	160x55.2x25mm;
Weight	Central unit 140g (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
Transport condition	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
Essential performances (according to EN 60601-1:2007)	Accuracy of spirometry parameters compliant to ATS standard Measure of the oximetry parameters with accuracy defined in table on page 13

2. FUNCTIONING OF THE SPIROBANK II

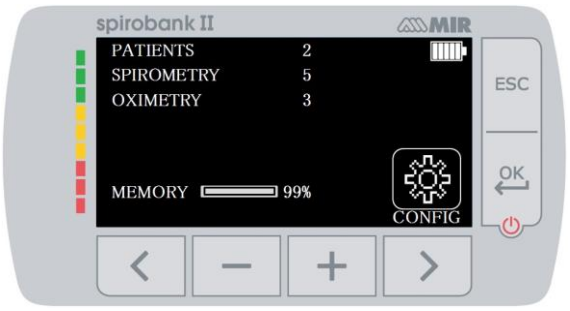
2.1 switch on and switch off the device

To switch on the **SPIROBANK II** push OK



The first screen shows the manufacturer logo, information of date and hour set on the device.If no key are touched, after a few seconds the device shows the main screen.

The second screen shows the information as in the image beside. He key > allows to visualize the service menu; with these voices it is possible to configure the device in the correct way.
If any keys are touched, then the device goes to the main screen.



To switch off the device push OK.

⚠ WARNING

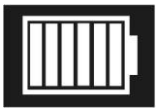
SPIROBANK II does not switch off completely but goes in stand by status with a very low power consumption. Some functions are ready and the device updates date and hour or to switch on the device using other remote controllers when required. For this the symbol in use is ⏻ corresponding to the stand by status.

2.2 Energy saving

⚠ WARNING

When the device is turned on after approximately 1 minute of disuse the display enters energy saving mode thereby automatically lowering the display contrast level.
If the device remains in disuse for approximately 5 minutes and is not connected to a PC or battery charger; the device will emit an acoustic warning signal and turn off.

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

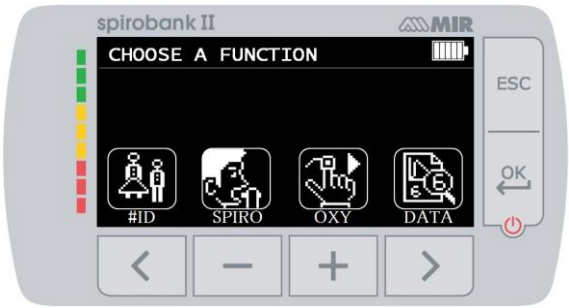


This image indicates that the battery pack is fully charged(6 indicators). A drop of the battery pack charge is displayed with a reduction of the indicators.

2.3 Main screen

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

patient data management area
spirometry area
oximetry area
archive area



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

2.4 Symbols and Icons

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

ICON	DESCRIPTION
	To access the default settings (service menu)
	To access patient data from the main display
	To perform a new test of a patient recalled from the patient records.
	To insert new patient data
	To modify patient data.
	To display the most recent tests of a patient
	To show the last test performed
	To access the database of the performed tests.
	To search a test with the date of birth of a patient

ICON	DESCRIPTION
	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)
	Male sex patient selection
	Female sex patient selection
	To access all oximetry test options / To perform an SpO2/BPM test
	To access spirometry testing type
	to perform a forced vital capacity test FVC/search FVC tests in memory
	To perform a spirometry test with a broncodilator
	To check the alarms and alarm thresholds during oximetry testing
	To check the alarms and alarm thresholds during oximetry testing when at least one parameter is turned OFF
	Enabled alarm waring during oximetry testing To temporarily disable the alarm
	Disabled alarm warning during oximetry testing To temporarily enable the alarm

2.5 Service menu

To enter the service menu press the key > on the second screen corresponding to the icon

It is also possible to enter in the service menu when the device showa the main screen, pressing the key ESC and then the key >.
The service menu shows the following list of voices:

- Change date/time
- LCD settings
- Bluetooth suspend
- Select language
- Delete memory
- Select predicted
- Turbine calibration
- Oximetry setup
- Date format
- Unit format
- Info firmware

To select the desired voice use the keys < and >, then enter using the key OK.

Change date/time

When setting the date and time, the cursor ▲ indicates the data item which is being modified. Use the keys — and + to modify the data item of interest, move on to the next data item by pressing OK. Press OK so that the new settings will take effect and to return to the service menu. To return to the service menu without modifying the item data press ESC.

LCD settings

Change and set brightness and contrast using — e + keys. It is possible to switch from a parameter to the other using < and >. To return to the service menu press ESC.

Bluetooth suspend

The Bluetooth function is automatically activated when the device switchs on.
With this menu voice it is possible to suspend the function, the Bluetooth will come active automatically at the next device switch on.

Select language

Select the desired item using the < and > keysand press OK, the language is now set and the device will return to the Service Menu.

Delete Memory

To delete the memory of the device insert the following password by touching the numbers shown below:

< — — + + +

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

⚠WARNIG
Password Error **Press OK to try again**

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

⚠WARNIG
Please wait **erasing memory**

After approximately 30 seconds the following message will appear:

⚠WARNIG
Memory deleted

Press OK to return to the service menu.

Select standard

Select the standard to be used (ATS/ERS, or NHANES III) with the keys < and >, then press OK, the setting takes effect and the device returns to the Service Menu.

⚠ WARNING

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

Select predicted
A list of predicted values is shown; select the Predicted value desired.

Adult	Pediatric
ERS	Knudson
Knudson	Knudson
USA	Knudson
ERS	Zapletal
MC-Barcelona	Zapletal
JRS	Knudson
Pereira	Pereira

Select with < and > the pair to use and press OK. The Predicted values are set and the device returns to the Service Menu.

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

- show current values
- modify calibration
- factory defaults

Selection of the first item shows the percent correction applied in that moment.
The item "modify calibration" allows to insert new calculated values referred to a new test with a calibration sirynge. A password is required to access this option;insert the following password starting from left to right:

The item "factory defaults" erases the previous calibration values and restores the two percentage corrections to zero percent correction factor; in this case a password is required as explained above.
To perform this procedure correctly please refer to paragraph 2.5.1.

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

- Alarms Setting
- Default alarms

Alarms setting
Access to this function allows to setup the parameters linked to the oximetry

First parameter is the alarm intensity: it can be possible to set the type and volume. Use < and > to switch from a parameter to the other, then — e + are useful to set the desired value: the select icon is the grey one. Press OK to change screen. Step following steps allow to set the threshold value for %SpO2 and BPM. An acoustic alarm will warn the user if the SpO2 and BPM during a test fall below the minimum threshold or rise above the maximum threshold of the SpO2 and BPM values previously set.

Use keys — and + to decrease/increase the values and select moving the arrow with the keys < and >.
At the end press OK to return to the service menu.

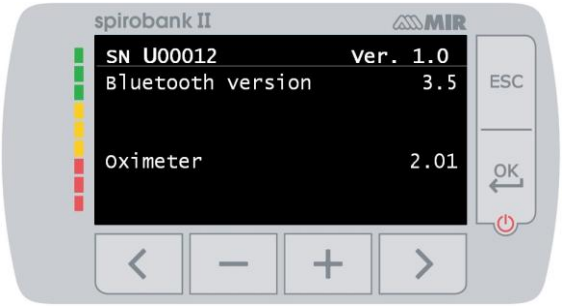
WARNING

If the maximum value of a %SpO2/BPM parameter is set lower or equal to the minimum value the setting will not take effect. The device will emit an acoustic warning and automatically return to the setting of the minimum value.

UNIT format
The voice allows to choose one of the following option:
Imperial (in,lb)
Metric (cm kg)

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

Info firmware
In this menu the user may view information regarding the components version presents in the device:



- Bluetooth version
- Bluetooth PIN
- Oximeter

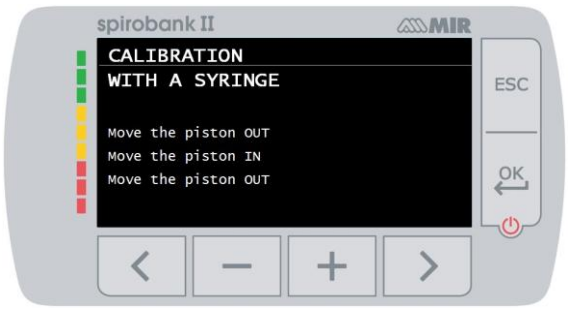
After approximately 10 seconds the device will automatically return to the service menu, otherwise press ESC.
Once all of the items in the service menu have been set it is possible to exit the menu by pressing ESC.

2.5.1 Turbine calibration

WARNING

The turbine flow sensor does not require calibration, however regular cleaning of the turbine is necessary . The disposable turbine is check before the application of the external packaging, for this reason it doesn't requires a periodic calibration. If a calibration must be performed the following guidelines should be carefully noted.

Turbine calibration is performed with a calibration syringe to simulate a FVC test for the expired parameters and a FIVC test for the inspired parameters.
To enter the calibration function, select the "Turbine Calibration" option from the Service Menu (as explained in paragraph 2.5). To enter the new calibration values choose the item "Modify calibration" in the submenu, enter the password and insert the new calibration values. Make three manoeuvres with a sirynge as described by the screen on the device, then **SPIROBANK II** calculates the FVC and FIVC values.
Press ESC.



The screen requires to insert the volume of the syringe in use**; SPIROBANK II** so calculates the correction percentage between the reference and the calculated value. It can be possible to change the syringe volume using — and +, then press OK. At this point two new correction values are shown. Press OK to apply these correction, otherwise press ESC to set the factory calibration values (0%).

If the FVC and FIVC correction factors are > 10% the following message appears on the screen:

⚠ WARNING
The calibration Is out of range

The FVC and FIVC values will not be accepted. This means that the device is not capable of correcting such a large calibration error In this case:

- Check the correct functioning of the **SPIROBANK II** with a new turbine and/or
- Clean the turbine.

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

⚠ WARNING

In line with the publication "Standardised Lung Function Testing" of the European Respiratory Society (Vol 6, Supplement 16, March 1993), the air expired from the mouth is at a temperature of circa 33/34 °C.
The expired flow and volume, to be converted to BTPS conditions (37 °C) must be increased by 2.6% - this is derived from the BTPS factor of 1.026 at a temperature of 33°C, which represents a correction of 2.6%. In practice the BTPS factor for the expired flow and volumes is therefore constant and equal to 1.026.
For the inspired volumes and flows, the BTPS factor depends upon the ambient temperature as the air inspired is at ambient temperature.
For instance at an ambient temperature of 20°C with relative humidity at 50%, the BTPS factor is 1.102, a correction of +10.2%.
The correction of the inspired volumes and flows is made automatically as the machine has an internal temperature sensor; the BTPS values are thus calculated.
If a 3L syringe is used to make the calibration and if the 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.

2.6 Patient Data

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

Insert a new patient
Modify current patient data *

2.6.1 Inserting data of a new patient

Press < and insert the patient information in the required sequence.

First screen (date of birth, weight, height and sex)

Use — and + to set the correct value; use instead < and > to switch from one to another parameter. 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

Second screen (ethnic group)

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

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

Standard NAHNES III
Caucasian
Mexican-American
Afro-American
Other

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

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

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

2.6.2 Patient data modification

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

⚠ WARNING

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

2.7 Visualization of memory data

2.7.1 Database research modality

From the main screen it is possible to access the database of the device by using the  icon (key >).
Three 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 date of birth: patient date of birth must be inserted; after all the data has been inserted press OK 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 press OK. 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.

2.7.2 Visualization of database info

The result of a search performed in one of the described methods in paragraph 2.7.1 can be viewed in the adjacent image. By selecting the desired session one may access the performed tests

Use the keys < and > to select the desired test.
Once a testing session has been selected the database screen will show the adjacent image. The two icons on the lower part of the screen allow access to the following functions:

(key —) to make a new test on the current patient

(key +) to show the parameters of the selected test

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

2.8 On line mode

In the on-line mode the **SPIROBANK II** becomes a fully functional laboratory device which works in real-time connected to a device us a tablet. The connection is wireless via Bluetooth.

The **SPIROBANK II** becomes an intelligent transducer for the measurement of volume and flow while the tablet controls the device including the on and off function.
Opening the application automatically starts the Bluetooth connection with spirobank II and the connection remains active until the application is closed. Even if the Spirobank II is switched off, starting the application the Bluetooth will automatically turn on it again.
This application enables complete control of the device. Connected to a tablet the **SPIROBANK II** 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 **SPIROBANK II** also plots the most refined indices such as the ventilatory profile and the extrapolated volume (Vext).
The application on the tablet incorporates the most up to date bronchial provocation protocols displaying the dose-response and time-response of the FEV1
For more details on the correct use of the application please refer to the relevant user manual.

⚠ WARNING

When the device is connected to the table it can be only remotely controlled. The default settings of the tablet software will be transferred to the device and will remain in the device even when used in stand-alone mode.

2.9 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 **SPIROBANK II** with both hands or grasp it like a mobile phone. The display must always face the patient taking the test.
- Place the upper part of the mouthpiece in the mouth making sure that no air leaks from the sides of the mouth.

⚠ WARNING

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

⚠ WARNING

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

By pressing — relative to icon, the user may access the spirometry testing area which includes the following tests:

FVC spirometry testing
VC type spirometry test
MVV type spirometry test
test with broncodilator (POST)

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

To end a test press ESC key

2.9.1 FVC test

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

INSPIRE all the air
EXPIRE fully with force
INSPIRE fully with force

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

⚠ WARNING

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

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

2.9.2 POST test, after drug administration

⚠ WARNING

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

To carry out a POST test please access to the spirometry area pressing — and subsequently pressing >.

A POST test is a spirometry test following the administration of a drug of some kind, usually a bronchodilator. The sign "POST Phase" is shown on the screen of the device (center) on the first screen of the spirometry area.. The following tests made by the patient show the following parameters:

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

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

2.10 Viewing the spirometric results

Following a FVC test, the spirometry test results are shown. The first screen displays
a Flow/Volume graph of the Forced Vital Capacity
pressing OK it is be possible visualize the best value of FVC, FEV1, FEV1% and PEF with the percentage change compared to the predicted values.

By scrolling with ◄ and ► it is possible to view all the parameters next to the chosen predicted values.

2.10.1 Spirometry test interpretation

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

- Normal spirometry
- obstruction/restriction mild
- obstruction/restriction moderate
- obstruction/restriction moderate severe
- obstruction/restriction severe
- obstruction/restriction very severe

A last level of interpretation is "restriction+obstruction"; the indication on the traffic lights will be the worst case between restriction and obstruction.

Through the use of a mathematical analysis applied to certain indices and parameters calculated in the FVC test , the **SPIROBANK II** 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 FEV1 values matching within 100 mL
B= two acceptable FEV1 values matching within 200 mL
C= two acceptable FEV1 values that do not match within 200 mL
D= only one acceptable FEV1 manoeuvre
F= No acceptable FEV1 manoeuvres

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

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

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

Repeat test and blow faster

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

Expiry time insufficient < 6s

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

Blow out all air in lungs

Between tests, the **SPIROBANK II** checks the repeatability of the following parameters:

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

if FVC is ≤ 1.0 L then:
FEV1 repeatable when the difference between the two largest FEV1 is ≤ 100 mL;
FVC repeatable when the difference between the two largest FVC is ≤ 100 mL;

2.11 Oximetry Testing

⚠ WARNING

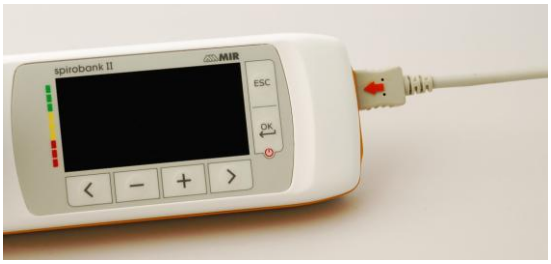
Check if the oximetry function is available in the device, this function is an option in some models.

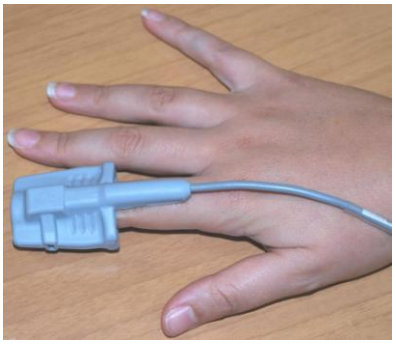
⚠ WARNING

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 SPIROBANK II cannot be turned off. To turn off the device the oximetry test must be stopped first. This has been implemented so as to avoid any unwanted interruptions which could compromise the accuracy of the data.

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

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





Select one of the tests that can be performed with **SPIROBANK II**
To access the oximetry area press + on the main screen; the test starts immediately

If the following message appears upon start-up:

WARNING OXIMETER NOT PRESENT

This means that your device does not have this function.

⚠ WARNING

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

Low battery level

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

WARNING
Wrong interruption of last oximetry test

At the same time an intermittent beep is emitted for 4 seconds.
Subsequently the SPIROBANK II 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 **SPIROBANK II** 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:

⚠ Sensor unplugged

At the same time **SPIROBANK II** emits an acoustic alarm (if previously set in the service menu).
If the sensor has been connected properly but the finger has not been properly inserted in the sensor the following message will be displayed on screen.

⚠ Finger Not inserted

At the same time **SPIROBANK II** emits an acoustic alarm (if previously set in the service menu).
If the signal reaches the sensor properly, after a few seconds the device will emit an acoustic signal while also displaying the values on screen.
The alarms can be customized, the procedure is described in paragraph 2.5.
During oximetry testing if the SpO2 and blood pulse rate fall below the bottom threshold or raise above the upper threshold, the **SPIROBANK II** will emit an acoustic alarm '(if previously set in the service menu.)' until such situation persists. For sleep oximetry testing the heart rate tone is always disabled.

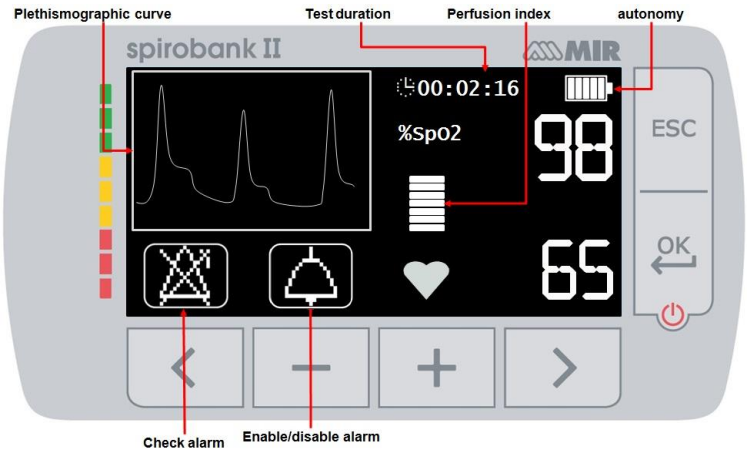
⚠ WARNING

A test is saved with the code of the last patient displayed. If a test refers to a previously saved patient, then prior to performing a test the user must recall that patient from the database as described in paragraph 2.7.2

⚠ WARNING

During oximetry testing the display will always show the battery pack level; thus providing an estimate of the actual charge level which can vary as a function of whether the device is in energy saving mode or with the backlight display at max level.

During a test the display will show the following information:



To end an oximetry test press ESC key.

2.11.5 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 SPIROBANK II listed in paragraph 1.2.4. 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.

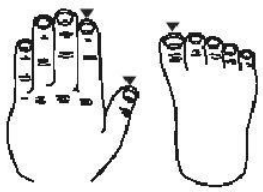
To perform a non-invasive continuous monitoring of arterial oxygen saturation it is recommended to use the reusable "wrap" type sensor.

WARNING

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

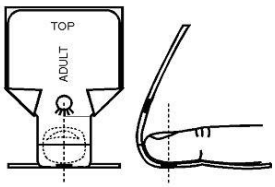
WARNING

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.

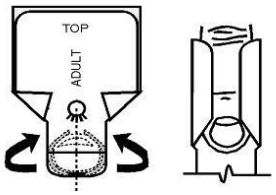


- Choose an application site on the patient's finger or toe where the light source will be directly over and in-line with the detector. The preferred sites are the forefinger or smaller thumb.

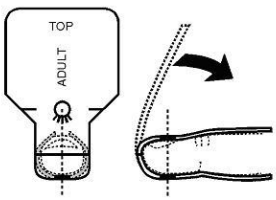
- Remove nail polish or artificial fingernails.



- 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.

3. DATA TRANSMISSION

⚠ WARNING

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

3.1 PC connection via USB port

⚠ WARNING

Before connecting the SPIROBANK II 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 **SPIROBANK II** 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.

3.2 Internal software upgrade

SPIROBANK II 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.

4. MAINTENANCE

SPIROBANK II requires very little maintenance
The operations to perform periodically are:

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

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

4.1 Oximetry sensor cleaning

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

⚠ WARNING

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

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

4.2 Changing the adhesive wrap sensor

The disposable 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

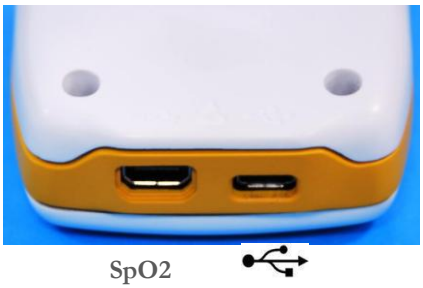
It is highly suggested to use a new piece of adhesive tape for each patient, or as required.

4.3 Battery charging

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

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

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



⚠ WARNING

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

5. PROBLEM SOLVING

PROBLEM	MESSAGE	POSSIBLE CAUSES	REMEDY
SPIROBANK II does not turn on	\	The battery pack could be discharged	Connect the device to the battery charger.
	\	The battery pack has not been properly inserted in the device	Contact a technical service center
	\	The device may have lost its internal software	Connect the device to the PC with the USB cable and update the internal software; For more detailed information please consult the winspiroPRO software user manual available on line within the software itself.
Problem when turning on the device	**Error in ram memory Recovering data Please wait**	Memory data within the device has been damaged	If the data has been restored correctly the standard turn-on process will complete itself. If this process does not finalize contact an authorized technical service center.
The device turns off and subsequently turns on again.	\	An internal error has occurred.	Check on the following website www.spirometry.com for a more recent internal software release of the device. Update the internal software by downloading the latest release by using the winspiroPRO software For further information consult the winspiroPRO manual available on line within the software itself.

PROBLEM	MESSAGE	POSSIBLE CAUSES	REMEDY
Spirometry test results are unreliable	\	The turbine may contain dirt or foreign matter.	Clean the turbine as explained in paragraph 5.1; if necessary replace the turbine with a new one.
	\	The test was not performed correctly.	Repeat the test and follow closely the indications shown on the screen.
Certain spirometry and/or oximetry parameters are not shown at the end of a test.	\	Personalized parameter setting in the service menu.	Check the parameter setting in the item "PARAMETER setting" within the Service Menu as explained in paragraph 2.5
During an oximetry test values are returned at irregular intervals, intermittent or simply wrong.	\	The sensor is positioned incorrectly or the patient perfusion is insufficient.	Riposition the oximetry sensor.
	\	The patient has moved.	To obtain accurate oximetry readings it is important that the patient must not move abruptly.
During oximetry testing the screen is barely readable	\	After a few minutes the screen backlight turns off automatically to save battery energy.	None
Problem during battery pack recharging	**Damaged battery pack**	The battery pack could be damaged or simply mispositioned.	Contact a technical service center
Unforseeable error of the memory	**Error in memory**	Data in archive is damaged.	Contact a technical service center
The device has frozen due to an unforseeable event	\	\	Press the power OK key 3 times and wait approximately four seconds after which the device will reset itself and turn on again

WARNING

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

Via del Maggiolino 125, 00155 Roma - ITALY

DECLARATION OF CONFORMITY CE
(annex II excluding par.4)

We hereby declare that the following device:

Type	**Spirometer/Oximeter**
Brandname	**MIR Medical International Research**
Device name	**spirobank II**
Class	**IIa**

Complies with the Essential Requirements of directive 93/42/EC concerning Medical Devices, and its amendments, and its transposition in the Member States.
This statement is made on the basis of the CE Certificate n. MED 9826 issued by Cermet, Notified Body n. 0476.

Rome 01.01.2014

Paolo Sacco Boschetti
The Chairman

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.

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 **SPIROBANK II** 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	The **SPIROBANK II** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
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 % *UT* (>95 % dip in *UT*) for 0,5 cycle 40 % *UT* (60 % dip in *UT*) for 5 cycles 70 % *UT* (30 % dip in *UT*) for 25 cycles <5 % *UT* (>95 % dip in *UT*) 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.
NOTE *UT* is the a.c. mains voltage prior to application of the test level.			

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.			
			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: 
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	[3] V [3] V/m	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz		
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.