spirobank *II*

User's Manual

User's Manual Rev. 2.2

Issued on: 09/05/2006
Approved on: 09/05/2006

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

The original packaging contains one of the following spirometers, complete with its standard accessories:

PRODUCT	CODE
spirobank *II* with oximeter	910570
spirobank *II* without oximeter	910575
4 x 1.5V AAA batteries	970080
USB connection cable	532365
This **spirobank *II*** User's Manual	980205
WinSpiro Pro installation CD	920100
Oximeter sensor (optional)	919010
Nose clip	910320
4 Paper mouthpieces	910300
3 Single patient turbine sensors	910001
1 Reusable turbine sensor	910000

Before using your spirobank *II* …
• Read this manual carefully, plus all labels and other product information supplied.
• If not fitted, install the operating battery taking care to connect the "+" and "-" battery poles correctly, as shown in the battery compartment.
• Set the device configuration as required (date, time, predicted values, device language etc.) as described in Paragraph 2.4.

Keep the original packaging!
In the event that your device requires attention then always use the original packaging to return it to the distributor or manufacturer.

In this case, please follow these guidelines:

- Return the complete device in the original packaging, and
- The transport (plus any customs or taxes) costs must be prepaid.

Manufacturer's address:

MIR SRL
VIA DEL MAGGIOLINO, 125
00155 ROMA (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, and the manufacturer therefore reserves the right to modify and to update the information contained in this User's Manual as required. Any suggestions and or comments regarding this product should be sent via email to: mir@spirometry.com. Thank you.
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 an incorrect use of the product.
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

INDEX

1. INTRODUCTION

1.1 Intended Use

1.1.1 User Category

The **spirobank *II*** spirometer + oximeter calculates a series of parameters relating to human respiratory function.
The product is therefore intended for use by a doctor or by a trained paramedic or technician under the supervision of a doctor, and has also been designed for home care by patients. Typically the doctor "prescribes" a spirometry test and is responsible for analysing and controlling 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 operated by the patient, then sufficient training must first be given to the patient by the doctor or by the trained paramedic under the supervision of the doctor.

ATTENTION ⚠

The manufacturer cannot be held responsible for any damage caused by the user of the device failing to follow the instructions and warnings contained in this manual.

If the user of the device is a person considered to be mentally infirm, then the operation of the device must be made under the supervision and responsibility of whoever is legally charged with the supervision of this person.

1.1.3 Operating environment

spirobank *II* has been designed for use in a doctor's office, in a hospital or directly by the patient during day-to-day activities for the continuous monitoring of physical conditions. All information necessary for the proper use of the device in electromagnetic environments (as required by the EN 60601-1-2 Standard) is available from the manufacturer.
Used at home, at work, at school or during sports, day by day the device records data and functional respiratory parameters for a period of weeks or months, assisting the patient in making a better assessment of 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 subject to correctly perform tests and obtain correct results, to be analysed by the doctor.
The instrument 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 instrument is not designed to be used in direct air currents (e.g. wind), sources of heat or cold, direct sun rays or other sources of light or energy, dust, sand or any other chemical substances.

The user and/or the doctor are responsible for ensuring that the device is stored and used in appropriate ambiental conditions.

ATTENTION ⚠

If the device is exposed to unsuitable ambiental conditions, this could cause the device to malfunction and to give incorrect results.

1.1.4 Who can or must make the installation

The device requires installation by qualified personnel. Normally the doctor configures the instrument before giving it to the patient for use at home.

1.1.5 Subject effect on the use of the device

A spirometry test should only be carried out when the subject is at rest and in good health, and thus in suitable testing conditions. A spirometry test requires the ***collaboration*** of the subject since the subject must make a complete forced expiration, in order to have a meaningful 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 subject's clinical condition. A detailed clinical history of the subject is also required together with the results of any other test(s) suggested by a doctor.
Test comments, a test interpretation and suggested courses of treatment must be given by a doctor.
Any symptoms that the subject 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 capacity of the subject in order to make a correct test, and the user, in the evaluation of test results, must also assess the degree of collaboration of each test carried out.
A spirometry test requires the full collaboration of the subject. The results depend on the person's capability to inspire and to expire all air completely and as fast 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 user. Special attention should be given to testing elderly subjects, children and handicapped people.
The device should never be used when it is possible or probable that the validity of the results may be compromised due to any such external factors.

1.2 Important safety warnings

spirobank *II* has been examined by an independent laboratory which has certified the conformity of the device to the European Safety Standards EN 601-1 and guarantees the EMC Requirements within the limits laid down in the European Standard EN 60601-1-2.

spirobank *II* is continually controlled during its production and therefore the product conforms to 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 that there is no visible damage. In case of damage do not use the device, return it to the manufacturer for repair.

ATTENTION ⚠

The safety and the correct performance of the device can only be assured if the user of the device respects all of the relevant safety rules and regulations.
The manufacturer cannot be held responsible for damage caused by the failure of the user 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.
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

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

1.2.2 Turbine

ATTENTION ⚠

Disposable turbine

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

Reusable turbine

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

should be performed according to the instructions contained in the User's Manual.

The following information applies to both turbine models.
The turbine must never be held under a jet of water or air and must never come into contact with high temperature fluids.
Do not allow dust or foreign bodies to enter the turbine sensor, in order to avoid incorrect functioning and possible damage. The presence of any impurities such as hair, sputum, threads etc. within the body of the turbine sensor may seriously compromise the accuracy of the measurements.

1.2.3 Mouthpiece

Any disposable mouthpieces included with the device are supplied only as a guide to the correct type and dimensions of the mouthpiece required for this device, they are clean but not sterile. To purchase appropriate mouthpieces, generally either paper or plastic, but in any case mono-use/disposable, we suggest that you contact your local distributor who supplied the spirometer.

ATTENTION ⚠

Use a bio-compatible mouthpiece to avoid any problems to the patient; unsuitable materials could cause a bad functioning of the instrument, and therefore the test results could be incorrect.

The user is responsible for obtaining the correct type of mouthpieces for the device. Those required are a standard type with an outside diameter of 30 mm, they are commonly used and in general easily procured.

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

1.2.4 Oximetry sensor

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

- BCI 1300 adult sensor (disposable)
- BCI 1310 reusable sensor
- BCI 3026 wrap-around sensor for infants
- BCI 3043 universal Y sensor
- BCI 3078 ear sensor
- BCI 3178 pediatric finger sensor, reusable
- BCI 3444 adult sensor reusable (Comfort Clip)
- BCI 3044 adult sensor, reusable, for finger.

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

ATTENTION ⚠

Incorrectly applied sensors or damaged cables may cause inaccurate readings. Using a damaged sensor may cause inaccurate readings, possibly resulting in patient injury or death. Inspect each sensor before use.

If a sensor appears damaged, do not use it. Use another sensor or contact your authorized repair centre for assistance.

Use only MIR sensors supplied with, or specifically intended for use with the **spirobank *II***. Use of 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.

ATTENTION ⚠

Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, patent blue V (PBV), and fluorescein may adversely affect the accuracy of the oximetry reading.

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

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

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

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

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

1.2.5 Device

ATTENTION ⚠

The maintenance operations detailed in this manual must be fully and accurately carried out. If these instructions are not followed this can cause measurement errors and/or an incorrect test interpretation.
Any modifications, adjustments, repairs or reconfiguration must be made by the manufacturer or by personnel authorised by the manufacturer. Never attempt to make a repair oneself. The set-up of configurable parameters should only be made by qualified personnel. However, an incorrect set-up of the parameters does not put the patient at risk.
High-frequency emissions from "electronic" devices may interfere with the correct operation of the instrument. For this reason, certain minimum clearances (a few metres) 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 instrument may give inaccurate readings if operated in the presence of strong electromagnetic sources, such as electrosurgical equipment, or in the presence of computed tomography (CT) equipment.

Do not use the instrument 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 instrument is connected to any other device then in order to maintain the essential safety characteristics laid down by IEC 60601-1-1, only equipment which complies to the current safety regulations may be used.

For the recycling of the **spirobank *II***, the accessories, any plastic consumable materials (mouthpieces) as well as the battery, use only the appropriate containers or return all such parts to the dealer or to a recycling centre. All applicable local regulations must be followed.
If any of these rules are not followed then MIR will decline all responsibility for any direct or indirect damages, however caused.
Use only the battery type indicated in the § Technical specifications.
Remove the battery from the device if the machine is not used for a long period (several months).
The instrument 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 Unforeseen errors

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

warning reparing test memory, please wait

If data have been succesfully repaired, the device completes the standard switch on process, otherwise please contact an authorised technical assistance point or the manufacturer.

In the case of a problem with the device, a message indicating the nature of the problem will appear on the screen, together with a warning “beep”.

Operation of the device beyond its declared life (see § 1.6 Technical Specifications) could provoke a loss of data in the memory of the device (SRAM memory).

Errors in measurement or in interpretation can also be caused by:

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

1.4 Labels and symbols

1.4.1 Identification label

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

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 RS232 serial port

RS232

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

1.4.5 Warning symbol for the USB serial port

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

1.4.6 Warning symbol for the SpO2 port for oximetry

SpO_2

1.4.7 Warning symbol for the WEEE

As laid down in the European Directive 2002/96/EEC requirements regarding the disposal of electrical and electronic devices (WEEE), at the end of its useful life this device must not be thrown away together with normal domestic waste as it contains materials which would cause damage to the environment and/or represent a health risk. Instead it must be delivered to a WEEE authorised collection centre, 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.

1.4.8 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 turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the 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.

1.5 Product description

spirobank *II* is a pocket spirometer, with an optional pulse oximetry module. It can operate in stand alone mode and it can be connected to a PC or to a printer using any one of several available methods: RS232, USB, Bluetooth.

spirobank *II* is specifically designed to measure a range of respiratory parameters and to monitor the saturation of oxygen in the blood and the heart beat. A quality control check is carried out internally on the measured parameters and the device has an internal memory sufficient for over 6000 spirometry tests or for 1000 hours (or 40 days) of oximetry monitoring.

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

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

- Accurate measurement even at very low flow rates (end of expiration)
- Not influenced by gas humidity nor density
- Shockproof and unbreakable
- Inexpensive to replace.

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

REUSEABLE TURBINE

DISPOSABLE TURBINE

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

- for the disposable turbine: must always be substituted between patients.
- for the reusable turbine: always clean the turbine between patients, to ensure the maximum level of hygiene and safety for the patient.

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

spirobank *II* is also able to transfer the stored test data through a simple acoustic coupling to a PC, so the patient can send test data by phone to the doctor. In this way the doctor can check the patient’s condition remotely.

spirobank *II* can also be connected to a PC (or to another computerised system) to configure the system. All spirometric test results plus the related subject details stored inside the device can be transferred from the device to the PC and then viewed on the PC (Flow/volume curves, spirometry parameters, plus optional oximetry parameters).
The connection to the PC can be made in the following ways:

- through the RS232 port or
- through the USB port

spirobank *II* gives an automatic interpretation of each spirometry test carried out, and assigns a “traffic light” feedback (green, yellow or red) to each test or series of tests. The set up of the traffic light settings is made by the doctor responsible for the system configuration.

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

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

The operating battery is a 3V lithium battery, and the battery life is about 5 years, depending on the use of the device.

1.6 Technical specifications

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

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%	FEV1/FVC x 100	%
FEV1/VC%	FEV1/VC x 100	%
PEF	Peak expiratory flow	L/s
FEF2575	Average flow between 25% and 75% of the FVC	L/s
FEF25	Forced Expiratory Flow at 25% of FVC	L/s
FEF50	Forced Expiratory Flow at 50% of FVC	L/s
FEF75	Forced Expiratory Flow at 75% of FVC	L/s
FEV6	Volume expired in the initial 6 seconds of the test	L
FEV6%	FEV1/FEV6 x 100	%
FET	Forced expiratory time	s
VEXT	Extrapolated volume	mL
FIVC	Forced inspiratory volume	L

FIV1	Volume inspired in the 1st second of the test	L
FIV1%	FIV 1 %	%
PIF	Peak inspiratory flow	L/s
MVVcal	Maximum voluntary ventilation calculated on FEV1	L/s
VC	Slow vital capacity (expiratory)	L
IVC	Slow inspiratory vital capacity	L
IC	Inspiratory capacity	L
ERV	Expiratory reserve volume	L
TV	Current volume	L
VE	Ventilation per minute, at rest	L/min
RR	Respiratory frequency	Breath/min
t_I	Average time of inspiration, at rest	s
t_E	Average time of expiration, at rest	s
TV/t_I	Average flow of inspiration, at rest	L/min
$t_I/Ttot$	$t_E/(t_I+t_E)$	\
MVV	Maximum voluntary ventilation	L/min

* = 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 Features of the oximeter

Definitions:

Desaturation Event	Desaturation events SpO2 fall >= 4% in a limited period of 8-40 sec and successive rise > = 2% within a total period of 150 sec.
Total Pulse rate Variation	Pulse rate rise >= 10 BPM in limited period of 8-40 sec and successive fall >=8 BPM during a total period of 150 sec.

Parameters measured during sleep oximetry:

SYMBOL	DESCRIPTION	Units
SpO2 Baseline	SpO2 Average in first three minutes	%
SpO2 Min	SpO2 Minimum during period of analysis	%
SpO2 Max	SpO2 Maximum during period of analysis	%
SpO2 Mean	SpO2 Average during period of analysis	%
BPM Baseline	Average pulse frequency in the first 3 minutes	BPM
BPM Min	Minimum pulse frequency during the period of analysis	BPM
BPM Max	Maximum pulse frequency during the period of	BPM

	analysis		
BPM Mean	Average pulse frequency during the period of analysis	BPM	
Recording time	Total time measure of SpO2	hh:mm:ss	
T < 90%	Time passed with SpO2 < 90 %	%	hh:mm:ss
T < 89%	Time passed with SpO2 < 89 %	%	hh:mm:ss
T < 88%	Time passed with SpO2 < 88 %	%	hh:mm:ss
T < 87%	Time passed with SpO2 < 87 %	%	hh:mm:ss
N° Events SpO2 <89%	Fall of SpO2 below 89% for at least 20 seconds	\	
Δ Index [12s]	Index of SpO2 fluctuation calculated in intervals of 12 seconds	\	
T< 40 BPM	Time passed with pulse frequency < 40 BPM	%	hh:mm:ss
T> 120 BPM	Time passed with pulse frequency > 120 BPM	%	hh:mm:ss
N° Events < 40 BPM	Bradycardia events during the entire period of analysis	\	
N° Events > 120 BPM	Tachycardia events during the entire period of analysis	\	
Tot. Desat. Events	Desaturation events during the entire period of the analysis	\	
ODI	Desaturation events by hour of analysis	1/h	
Mean Duration	Average duration of desaturation events	s	
Longest Duration	Longest duration of desaturation events	s	
Desaturation Peak	Minimum Sp02 during desaturation events	%	
Mean Desaturation	Average duration of desaturation events	%	
Mean Drop ΔSpO2	Average SpO2 fall with respect to baseline during the desaturation events	%	
Max Drop ΔSpO2	Maximum fall of SpO2 with respect of baseline during the desaturation events	%	
N° Pulse Variations	Variation of pulse frequency events during the entire period of the analysis	\	
Pulse Index	Variation of pulse frequency by hour of analysis	1/h	
NOD 4%	Time passed with SpO2 < 4 % with respect to SpO2 base for continual periods above 5 minutes	\	hh:mm:ss
NOD 89%	Time passed with SpO2 < 89 % for continued periods above 5 minutes	\	hh:mm:ss
NOD 90%	Time passed with SpO2 < 90 % for continued periods above 5 minutes with minimum value < 86 % (Nadir)	\	hh:mm:ss

Δ=DELTA

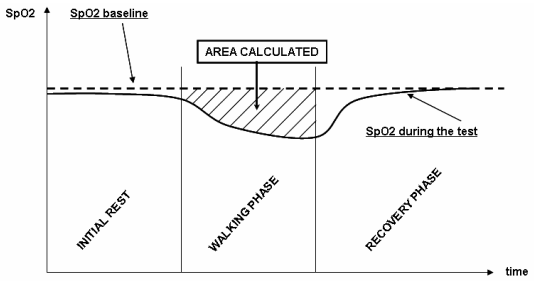
Parameters measured for six minute walk test analysis:

SYMBOL	DESCRIPTION	Units
SpO2 Baseline	SpO2 average before walking	%
SpO2 End	SpO2 after walking	%
SpO2 Min	SpO2 minimum during walking	%

SpO2 Max	SpO2 maximum during walking	%
SpO2 Mean	SpO2 average during walking	%
BPM Vaseline	Average pulse frequency before walking	BPM
BPM End	Pulse frequency after walking	BPM
BPM Min	Pulse frequency minimum during walking	BPM
BPM Max	Pulse frequency maximum during walking	BPM
BPM Mean	Pulse frequency average during walking	BPM
T < 90%	Time passed with SpO2 < 90 %	% hh:mm:ss
T < 89%	Time passed with SpO2 < 89 %	% hh:mm:ss
T < 88%	Time passed with SpO2 < 88 %	% hh:mm:ss
T < 87%	Time passed with SpO2 < 87 %	% hh:mm:ss
TΔ2 [ΔSpO2≥ 2%]	Time passed during walking test with SpO2 < 2 % with respect to SpO2 base	hh:mm:ss
TΔ4 [ΔSpO2 ≥ 4%]	Time passed during SpO2 walking test < 4 % with respect to SpO2 base	hh:mm:ss
T< 40 BPM	Time passed with pulse frequency < 40 BPM	hh:mm:ss
T> 120 BPM	Time passed with pulse frequency > 120 BPM	hh:mm:ss
N° Events < 40 BPM	Bradycardia events during the entire period of analysis	\
N° Events > 120 BPM	Tachycardia events during the entire period of analysis	\
Recording time	Total time measure of SpO2	hh:mm:ss
Baseline Time	Duration of baseline phase	hh:mm:ss
Walking Time	Duration of walking phase	hh:mm:ss
Recovery Time	Duration of recovery phase	hh:mm:ss
Predicted	Predicted standard distance	m
Pred. Min	Predicted minimum distance	m
% Predicted Standard	% in variations of the distance covered with respect to predicted standard distance	%
% Pred. Min	% of variations of distance covered with respect to predicted minimum distance	%
AUC/Distance	Area under SpO2 curve base relative to distance covered	\
Dyspnea Borg CHG	Variation in grade of dyspnea during walking	\
Fatigue Borg CHG	Variations in level of fatigue during walking	\

Δ=DELTA

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



Parameters requested for six minute walk test analysis

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

Parameters measured with SpO2 Analysis:

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

analysis

Δ=DELTA

Measurement method:	Red and infrared absorption
Range of measurement %SpO_2:	0 – 99% (with 1% increments)
%SpO_2 accuracy:	± 2% between 70-99% SpO2
Average number of heart beats for the %SpO_2 calculation:	8 beats
Range of measurement of cardiac pulse:	30 – 254 BPM (with 1 BPM increments)
Accuracy of cardiac pulse:	± 2 BPM or 2%
Average interval for the calculation of cardiac pulse:	8 seconds
Signal quality indication:	0 - 8 segments on display

Acoustic signals:

- "Beep" with frequency of the cardiac pulse
- Continuous beep in the case of either %SpO_2 or cardiac pulse going outside of the programmed levels of alarm
- Continuous beep during oximetry measurement in the case of a low battery level.

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

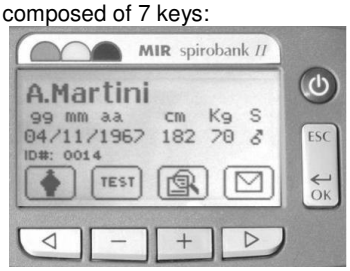
Memory	Memory capacity for over 6000 spirometric tests The precise number depends on the individual configuration, so it cannot be determined more closely
Display	STN graphic LCD,128x64 Pixel
Keyboard	Membrane keyboard with 6 keys
Interface	RS232, USB, Bluetooth
Power supply	4 x AAA batteries 1.5V DC (type AAA), or through USB connection
Dimensions	60x145x30 mm
Weight	180 grams (including batteries)
Type of electrical protection	Class II device
Type of electrical protection	BF
Grade of protection against water ingress	IPX1 device, protected against water drops
Level of safety in the presence of inflammable anaesthetic gas, oxygen or nitrogen	Device not suitable
Conditions of use	Device for continuous use

Storage conditions	Temperature: MIN 0 °C, MAX + 40 °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

2. FUNCTIONING OF THE SPIROBANK *II*

2.1 Keyboard

The **spirobank *II*** keyboard is composed of 7 keys:



Key functions are as followed:

1	⏻	On/Off
2 3	ESC OK	esc/ok previous page OSD key
4	◁	Scroll left OSD key
5	−	Scroll up OSD key
6	+	Scroll down OSD key
7	▷	Scroll right OSD key

Switching on spirobank *II*

To switch on **spirobank *II*** press ⏻ and then release.

Switching off spirobank *II*

To switch off **spirobank *II*** press ⏻ for at least two seconds.

CONFIRM: to confirm and pass to the next phase, use ▷ or OK

Symbols and Icons

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

ICON	DESCRIPTION
	To access the set up (Service Menu) of **spirobank *II***
	To manage or enter new patient data from the main screen
	To enter new patient data
	To carry out a bronchodilator test
	To make the test following the administration of a bronchodilator
	To modify patient data
	To carry out a spirometry or oximetry test
	To access previous tests
	To access to transmission data area
	To search for tests made
	To display oximetry test results of selected subject
	To display spirometry test results of selected subject
	To search test by subject ID code
	To search test from date and onwards (partial memory)
	To scroll through files on memory
	To search patient by subject surname
	To select male patient
	To select female patient
	To carry out a sleep oximetry test
	To carry out an oximetry test while walking/Go to walking phase during test

	To pass to the recovery phase during a walk test
	To carry out a FVC spirometry test
	To carry out a VC spirometry test
	To carry out a MVV spirometry test
	To access oximetry tests/To carry out an SpO2/BPM
	To display previous tests in memory
	To display next test in memory
	To print data in memory (through Bluetooth connection)
	To transfer data through a Bluetooth connection
	To transfer data through acoustic coupling

Attention 

IF no key is pressed the instrument after 1 minute will 'beep' and if no key is pressed after 10 seconds it will automatically switch off. If **spirobank *II*** is powered by a USB connection to a PC, the aforementioned function is disabled and the device is switched off using  .

The instrument can be switched off at any time by pressing and holding the  key for two seconds.

2.2 Battery Level

The symbol

shown in the second screen when the unit is turned on indicates that the battery is charged. The following symbol indicates Low Battery:

If the battery is discharged the following message appears:

BATTERY DISCHARGED

2.3 Information

Switch on **spirobank *II*** by pressing ⏻. The display will show:

- **spirobank *II*** – 0.1 (device name and software revision number)
- Power means (USB or battery symbol)
- Current date and time
- BTPS (Body Temperature Pressure Saturated)
- 🔧 icon (Access to the Service Menu)
- SpO2/BPM icon

Press OK to go to the second display. Press ESC to go directly to the main screen.

The second display will show:

- ATS/ERS Standard
- Subjects in memory (no. of registered patients)
- Spiro (no. of spirometry tests made)
- SpO2 (no. of oximetry tests made)
- Available memory (% value).

If there is no information or test data in memory, i.e. the memory is empty, all data is shown with 0 (null).

2.4 Initial Set-up

Switch on **spirobank *II*** by pressing and holding ⏻ and wait for the second screen. Press ◁ to access the service menu. The following screen “Service Menu” contains the following menu:

- Select Language (English default)
- Turbine Calibration
- Select Predicted Values
- Delete MEMORY
- Change Date/Time
- Date Format
- Units Format
- Turbine Setup
- Standard
- Phone Setup
- Bluetooth Setup
- Firmware Info

Select the required option using ◁ or ▷ and the ► symbol on the left of the screen; press OK to access options; select the required setup using the ◁ or ▷ arrow, then press OK to return to the Service Menu.

Select Language
Press OK to access the Menu, use ◁ or ▷ to select the required language and then press OK to register the change and return to the Service Menu.

Turbine Calibration
See Paragraph 2.4.1.

Select Predicted Values
Enter Menu with OK, then use ◁ or ▷ to select the required value and press OK again to return to the Service Menu.

Delete Memory
Enter Menu with OK, then enter the password (◁ once, twice −, three times ✚) and then press OK; if the password inserted in correct, the following message appears:

Test data has been cancelled

Change Date/Time
In the date and time setting, the ◄ arrow shown to the right of the field indicates the field to modify. Use − or ✚ to modify the selected option; use ▷ for the following option. Lastly, press OK to return to the Service Menu. To return to the Service Menu display without entering any changes press ESC.

Date Format
Use ◁ or ▷ to select the required format and press OK to enter and return to the Service Menu.

Units Format
Access with OK and select imperial or metric, as required. Press OK again to return to the Service Menu.

Turbine Setup
Access with OK and select the required turbine (disposable or reusable). Press OK again to return to the Service Menu.

Standard
Access with OK and select the required standard using ◁ or ▷. Press OK to return to the Service Menu.

Phone Setup
Access with OK and then use the horizontal scroll arrow to select phone number (click on number to insert in connect list). Having set the option, press OK to confirm and to return to

the Service Menu.

Bluetooth Setup
Access with OK to search for available devices, select “Search Device” and then press OK; **spirobank *II*** will start to search for Bluetooth devices in the area; once one or more devices are found the screen will display profiles, press OK to set the device as printer or phone, select one of the two options and then press OK. On the “Bluetooth Setup” screen all devices entered on the “printer list” and on the “phone list” can be checked. A device can be set as default by accessing the lists with OK and then selecting the device, (to which **spirobank *II*** will automatically connect) or deleted from the list (in this case press OK on the bottom to confirm the deletion, or press ESC to go back and to not delete the device).

Firmware Info

Access through OK to view information on the revision of the following components, where available, of **spirobank *II*:**

- **spirobank *II***
- Bluetooth
- Display
- Oximetry

After approximately 10 seconds **spirobank *II*** automatically displays the Service Menu, otherwise press ESC.
Having set the parameters (from the Service Menu) press ESC to access the second screen, and then the main screen, as follows:

Which indicates:
- Patient name (A.Martin)
- Date of birth (dd mm yy)
- Height (cm)
- Weight (kg)
- Sex (S)
- Patient ID code
- Function icons

2.4.1 Turbine Calibration

Attention ⚠

The turbine flow sensor does not require calibration but needs only a regular cleaning. If a calibration must be made then the following guidelines should be carefully noted.
Calibration can be made only on the reusable turbine.

Calibration of the turbine is performed using a calibration syringe to make an FVC test for the expired parameters and an FIVC test for the inspired parameters.
To access the calibration function, select the "Turbine Calibration" option from the Service Menu with the horizontal scroll key and then press OK. The following screen appears:

VOL. 300	BTPS	%Corr.
Old FVC	300	0.00
Old FIVC	300	0.00
New FVC	000 ◄	
New FIVC		

FVC=0 FACTORY CALIBRATION

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

To make the calibration:
1 - Insert the volume in **cL** of the calibration syringe in use (e.g. for a 3L syringe, insert 300 cL).
2 - Insert both the FVC and FIVC values, obtained by the measurement made with the calibration syringe, in the New FVC and New FIVC field.

Press ▷ to select the value to be modified (SIRIN, New FVC, New FIVC).
Use **−** or **✚** to modify the parameter value selected.
Insert both the FVC and the FIVC values. If the calculated correction factors are acceptable (<10%), they are displayed beside the New FVC and New FIVC parameters. The message ENTER OK TO CONFIRM will appear.
Press ESC to return to the Service Menu without entering the correction.
If the FVC and FIVC values produce a correction factor that is >10%, the FVC and FIVC values will not be accepted. This means that the system cannot correct for 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 reset to the factory calibration, input **0** in the New FVC and New FIVC fields.
Then press OK to return to the Service Menu.

Note

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

Attention ⚠

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 explanation detailed above.

2.5 Patient Data

Switch on **spirobank *II*** by pressing ⏻, or if already switched on, press ◁ ( icon); to access the "PATIENT DATA MANAGEMENT" screen, the following table describes the functions and displayed icons.

Icon	Key	Description
	◁	To enter new patient data
	–	To make a bronchodilator test (i.e. make a test after drug administration with defined dosage; to carry out this test, a pre test is required)
	✚	To modify patient data already on file
	▷	To access memory

To enter new patient data
From the "Patient Data Management" menu press ◁ to access the data input screen.

First screen (name and surname)
Use ◁ and ▷ to select required letters; confirm or delete using − or ✚. To input surname press OK. The letters can also be selected automatically after a few seconds using the cursor.
Press OK to go to the next screen.

Second screen (date of birth, weight, height, sex)
Use − or ✚ to select date of birth, use ▷ to the right to set month, repeat to set year; continue setting data by entering patient height, weight and sex using the same ▷ key. The arrow ◄ shown to the right of the field indicates the numerical value that is being changed. After this operation use OK to go to the following screen; to return to the previous screen press ◁, or press ESC to exit set-up mode and go to the main screen.

Third screen (ethnic group)
Setting the correction factor: this value allows to adapt test data according to the patient ethnic group (the "no correction" option can also be set); press OK to complete the setting of parameters, the main screen then appears. In the event of an error during the setting of patient data press ◁ to go back to the previous screen.

Attention

The ESC/OK is a rocker-type key, i.e. it has two functions in one; press the bottom to use the enter function (OK); press the top to use ESC.

To interrupt data input press ESC, which then goes back to the main screen.

POST BD Test
Use − to set the spirometry test in "post" mode, i.e. after pharmacological bronchodilation. On next screen use POST BD to select either a POST or PRE test, using respectively − or ESC. Once entered, the  icon will appear on the upper right of the main screen for POST testing of the subject.
Before making the test enter the administered drug dosage in order to obtain an accurate comparison of the two phases.
After carrying out the POST test, press OK to return to the PRE phase after viewing results in memory; the following message appears: "Press OK to make new test on selected subject".

To access memory
From the "Patient Data Management" screen use ▷ to directly access the screen with the four memory search methods (§ 2.6).

Modifying patient data

In the "Patient Data Management" menu press ✚ which corresponds to the  icon. Modify data in the following screens by using the keys as described for entering new patient data.
To return to the main screen without changing any data press ESC.

2.6 Displaying data in memory

From the main screen press ✚ ( icon), to check patient data (choose between spirometry and oximetry) or to search for another patient's data; the following options are available:

KEY	ICON	FUNCTION
◁	SPIRO	Display spirometry tests of the selected patient
-	OXY	Display oximetry tests of the selected patient
▷	**M**	Access data in memory

Press ESC to return to the main screen.
Access the search menu to display data based on four different methods:

KEY	ICON	FUNCTION
◁	ID #	Search by ID Code
-	_/_/_	Display files from a date and onwards (partial memory)
✚	▽△	Display files from beginning to end (full memory)
▷	ABC	Search by initial letter of surname

Search by ID Code: enter the ID Code of the patient to be searched for; then press OK to access the data.

Partial Memory: enter test date of required file; after entering the date press OK to access data. The data will be shown starting from the date entered up to the last file on memory.

Full Memory: to show data in alphabetical order.
The last data are marked by a double beep, then the data shown begin from the first one recordered.

Search by Surname: enter patient surname, or first initial; then press OK to access the data.

Use ◁ and ▷ to display relevant patient test data.
Press ESC to return to the main screen without searching.

Use − from the data screen ( icon) to print out data through a Bluetooth connection (automatic); use ✚ to display all test data of relevant file on memory, use ◁ and ▷ to scroll through data; press OK to go back to the memory screen.
From this screen press OK to make a new test on the subject selected (press OK again), press ESC to return to the data stored.

2.7 Online operating mode (connected to a PC)

This operating mode is comparable to a laboratory spirometer, connected to a PC the device operates in real time. Connect the unit to a PC using either the USB cable or the RS 232 serial cable.
spirobank *II* thus acts as an intelligent sensor for flow and volume measurement while the PC controls functions, including the switching on and off of the unit.
Connected to a portable PC, **spirobank *II*** can carry out epidemiologic studies in work environments, school settings etc..
As well as the standard spirometric parameters and F/V curves in real time, the instrument also calculates more refined indices such as the ventilatory profile and the extrapolated volume (Vext).
The PC software also allows the latest bronchial challenge test protocols, with the graph of the FEV1 dose-response and time-response curves.

ATTENTION ⚠

If a turbine (disposable or reusable) is setup while using **spirobank *II***, the same will remain by default the next time the device is used in the remote mode. Attention must be given in the setting of the turbine.

2.8 Spirometry Testing

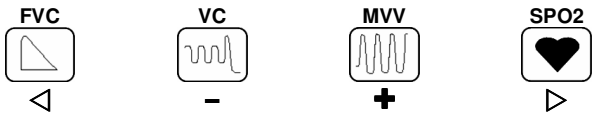
To make a correct spirometry test we recommend to follow carefully the following instructions:

- Insert the mouthpiece into the protruding part of the turbine, by at least 0.5 cm;
- Fit the nose clip onto the nose of the subject to ensure that air cannot escape through the nostrils;
- Hold **spirobank *II*** at either end in two hands, or alternatively hold it in one hand as you would a cell phone. In either case, the display should be facing the user;
- Insert the mouthpiece well into the mouth beyond the teeth, being careful to ensure that air cannot escape from the sides of the mouth;
- It is suggested to make testing in a standing position and during an expiration to lean forward, to help the expiratory action with a compression of the abdomen.

ATTENTION ⚠

Do not touch the keys during a test to avoid switching off the machine or stopping a test too soon.

On the main screen press – corresponding to TEST icon.
Then these icons are shown:



Press the key corresponding to the test required:

FVC Forced Vital Capacity
VC Slow Vital Capacity
MVV Maximum Voluntary Ventilation
SPO_2 Oximetry/Heart beat

The device displays the information regarding the turbine selected in the initial setting (reusable or single-patient disposable), there follows the necessary information for each screen in order to correctly carry out a test.

2.8.1 FVC Test

The phases as described on the screen must be followed, more specifically:

INSPIRE slowly
EXPIRE quickly
INSPIRE slowly

It is possible (and may be helpful) to start the test by breathing at rest for a few moments. When ready to start *inspire slowly as much air as possible* (made easier by holding 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 air as fast as possible.
After 6 seconds of expiration the instrument will emit a continuous beep, this helps the user to understand when the minimum expiry time has been reached.

ATTENTION ⚠

For accurate spirometry testing it is indispensable that all of the air contained in the lungs is expired.

The test may be repeated several times by repeating the cycle without taking the mouthpiece out of the mouth, in which case **spirobank *II*** recognises the best test (FVC+FEV1) and will automatically show the results of this best test.

To end the test press OK.
During the test **spirobank *II*** emits "beeps", the frequency of which is directly proportional to the inspired and expired air velocity. This is useful to the doctor to understand when the velocity of the air is approaching zero, and therefore the patient has almost exhausted all of the inspired or expired volume.
In the maintenance section an explanation is given as to how this feature can also function as a very simple check system for the correct operation of the mobile "rotor" of the turbine.
For the FVC test to be judged as acceptable, besides breathing as deep as possible, it is also required that the forced expiratory time (FET) is sufficiently long to allow for the complete expiration of all air contained in the lungs.

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

2.8.2 VC Test

Ventilatory Profile
The Slow Vital Capacity test can be started by carrying out several complete breaths at rest. After three or four such breaths a *beep* will sound to confirm that the ventilatory profile has been measured and now you can proceed to carry out the VC or IVC test.

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

Inspiratory Slow Vital Capacity: IVC
After the beep *expire slowly* as much air as possible and then *inspire slowly* as much air as possible.
To end the test press OK.

To correctly carry out this test, follow the indications as described on the display.

2.8.3 MVV Test

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

It is important that the disposable mouthpiece and turbine are changed at the end of each test.

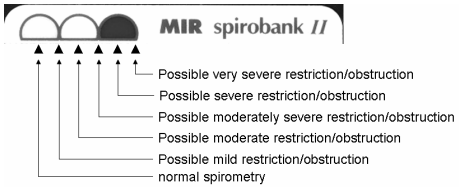
2.8.4 Reading messages

At the end of a test, a series of test messages are displayed followed by the measured parameters.
There follows first a description of these messages and the parameters, in the order in which they appear.

If for 6 seconds no key is pressed then the unit moves automatically to the next message or parameter.

2.8.5 Spirometry test interpretation

Spirometry test interpretation is based on the Forced Vital Capacity (FVC) test and is indicated both by a message and a **traffic light code** (green, yellow, red). For each test made, an arrow on the upper left part of the screen indicates the interpretation of that test. The connection between the traffic light colour and the test interpretation is shown below:



The algorithm utilized for the spirometry test interpretation is obtained by means of the flow chart in annex 3 of this manual.
Through an analysis applied to some of the indices and parameters calculated in the FVC test, **spirobank *II*** produces a variety of **quality control** *comments* useful for understanding the reliability of the test made.
Where several *comments* related to the single test are calculated, **spirobank *II*** will only show the most important to facilitate the test interpretation.

ERROR IN Vext and PEFT
If the extrapolated volume Vext is greater than 500 mL or greater than 5% of the FVC, or if the PEFT (time to peak flow) is greater than 300 ms, then the following comment is shown:

FIRST EXPIRATION TOO SLOW

FLOW DROP 50%
If the flow rate falls and then increases again by over 50% during the first second of a forced expiry, the following comment is shown:

COUGH DETECTED DURING TEST

FET error
If FET is under the predicted threshold the following message appears:

EXPIRY TIME INSUFFICENT <6S

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

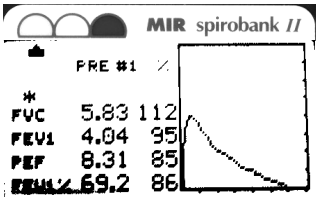
BLOW OUT ALL AIR IN LUNGS

Between two tests, **spirobank *II*** evaluates the reproducibility of the following parameters:

PEF ⇒ repeatible if ΔPEF < 10 %
FVC ⇒ repeatible if ΔFVC < 150 mL
FEV1 ⇒ repeatible if ΔFEV1 < 150 mL

2.8.6 Viewing the spirometric parameters

Following an FVC test, the spirometry test results are shown. The first screen displays the main parameters FVC, FEV1, FE1%, PEF, the percentage of the predicted values, the Flow/Volume chart plus a traffic light summary of the test interpretation (in the upper left part), as illustrated below.



The following screens show other values compared to the predicted values.

2.9 Oximetry testing

spirobank *II* can carry out 4 different types of oximetry tests, which are described in the following paragraphs.

ATTENTION ⚠

If **spirobank *II*** as been purchased without the oximetry option, then only spirometry tests can be made. If the oximetry option is purchased afterwards, then contact the service centre or the manufacturer to enable the function.
If during the oximetry testing the SpO2 blood pulse rate goes below the bottom threshold or goes over the top threshold, spirobank II will 'beep' until such situation persists. This option can be disenabled during sleep tests.
The values shown are set by default by **spirobank *II***.

ATTENTION ⚠

The sensor described below is for illustration purposes only. **spirobank *II*** is enabled for the use of any of the sensors described in the previous Paragraph 1.1.4. MIR does not recommend the use of a specific type of senor; any decision in regard is made by the individual doctor.

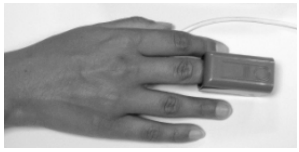
During the oximetry test **spirobank *II*** cannot be switched off, to switch off the device it is necessary to interrupt the test in progress, this avoids unwanted interruptions which could compromise the accuracy of the data obtained.

For the non-invasive measurement of the *SpO_2 oxygen saturation* and the *blood pulse rate,* utilize the re-usable finger sensor. This sensor is recommended for patients weighing > 20 Kg with limited activity.
spirobank *II* memorises the two oximetry values every 2 seconds.

Carry out an oximetry test as follows:

- Connect the sensor to the instrument: 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 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 is not able to be correctly positioned, use another finger.



- Position the sensor so that the cable is underneath the palm of the hand. This enables the light source to remain on the fingernail and the detector on the bottom part of the finger.
- From the main screen press **–** to access the test menu.
- Press ▷ to access oximetry.

If this message appears:

WARNING THE OXIMETRY DEVICE IS NOT AVAILABLE

your instrument does not include an oximeter.
Instead, If this message appears:

WARNING THE OXIMETRY DEVICE IS NOT ENABLED

your instrument includes an oximeter but the function has not been enabled. In this case contact a service centre or the manufacturer.

Alternatively, the display will show the screen with the oximetry tests that can be performed, specifically:

ICON	KEY	DESCRIPTION
	◁	Walk test - 6MWT
	-	Sleep oximetry
	▷	Oximetry (SpO2/BPM)

ATTENTION ⚠

In order not to compromise the reproducibility of the measurements and the integrity of the sensor, avoid twisting the sensor cable and handle with due care when using, connecting, disconnecting and when placing the finger into it.

During the first few seconds of the test the device searches for the best signal, after which the timer re-sets to zero and **spirobank *II*** starts to memorise the data.

If the sensor has not been correctly inserted, the following message will appear:

WARNING
Sensor unplugged

If the sensor has been inserted but the finger is not inserted correctly, the following message will appear:

WARNING
FINGER not detected correctly

If the sensor correctly receives the signal, after a few seconds the device starts to 'beep' and the values will be displayed on the screen.

2.9.1 Walk Test (6MWT)

To make a walk test press ◁.
This test is made up of 3 phases:

- Initial rest
- Walking
- Recovery

Initial Rest
In this phase the display will show the following data:

- Test time duration
- Signal quality indication
- Current phase

- SPO2 % value and the instant cardiac pulse (heart symbol)

The duration of the test is minimum 2 minutes, then the screen shows  corresponding to the **−** key; press this key to pass to the following phase. If the phase lasts for more than 6 minutes then **spirobank *II*** will emit a 'beep' as a reminder to pass to the following walking phase.

The number of bars ("**I**" symbol), on the right upper of the screen is proportional to the quality of the oximetry signal: the higher the quality of the signal the more bars will be shown (maximum 7). Place finger into the sensor in order to obtain the highest quality of the signal.

Walking Phase

At the beginning of the phase the timer is reset to zero to give an accurate control of the duration of each single phase. The data on the display is the same as shown before.

The duration of this phase is minimum 2 minutes, then the  icon appears corresponding to **+**. Press this key for a few seconds to pass to the initial rest phase. If this phase lasts for more than 6 minutes then **spirobank *II*** will emit a 'beep' after which the device passes to the initial phase and the timer is re-set to zero.

Recovery Phase

The user can decide freely on the duration of this phase, the duration is not suggested (at the beginning of the phase the time is re-set to zero).

To end test press ESC and then ◁. This must be done each time the current test is interrupted.

At the end of the test the data required for the calculation of the parameters must be inserted; more specifically:

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

These follow the Borg scale and can have the following values: 0, 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, the distance covered is indicated in m. Use **−** and **+** to enter data; use OK to pass to next data.

Walk test data results are given in the following 6 screens.

To print data see Paragraph 3.3. The printout version of the test will only show the walk test results; an example of a test printout report is attached.

Press ESC and then ◁ to end test at any moment**.**

2.9.2 Sleep Oximetry

To activate this type of test press – ( ). This test records the variations that the parameters of the patient undergo over night.
After approximately 5 minutes, **spirobank *II*** will go on standby i.e., it stops beeping and the display turns off. The led signal remains on. To control the correct functioning while on standby, press ⏻, after 5 minutes **spirobank *II*** will return to standby.

If there is no signal while on standby the device will automatically exit this phase and a warning message will appear (sensor unplugged or finger not detected correctly).
The data shown are the same as described in the preceding test, except for information on this present phase, which has not been envisaged for this test.
After the required time the test can be interrupted as previously described.
To print data see Paragraph 3.3.; an example of a test printout report is attached.

2.9.3 SPO2 BPM Oximetry Test

ATTENTION ⚠

Note: the sensor described below is for illustration purposes only. **spirobank *II*** is enabled for the use of any of the sensors described in the previous Paragraph 1.1.4. MIR does not recommend the use of a specific type of senor; any decision in made by each individual doctor.

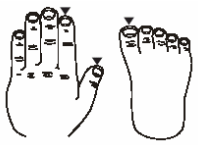
To perform a non-invasive continuous monitoring of arterial oxygen saturation it is recommended to use the reusable "wrap" sensor. The use of this sensor is indicated for patients weighing more than 30 Kg and contraindicated for patients with allergy to adhesive tape.

ATTENTION ⚠

The materials used for manufacturing the sensor are NATURAL LATEX PROTIEN free. The materials used for the sensor are subject to biocompatibility tests.

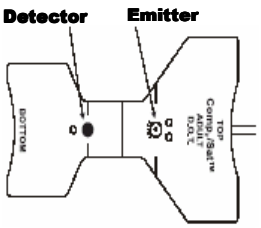
2.9.3.1 Wrap Sensor – Instructions for Use

- Select the most suitable point to apply the sensor. The index finger is preferred. Other suggested points may be the thumb, big toe or the smallest finger.

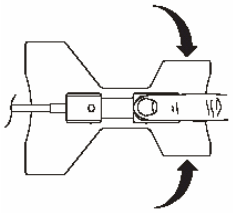


- It is recommended to use a new piece of adhesive tape for each patient or according to needs.
  See instructions for changing the adhesive tape.

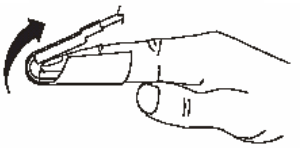
- Hold onto the shell at the corner and remove it gently from the sensor.



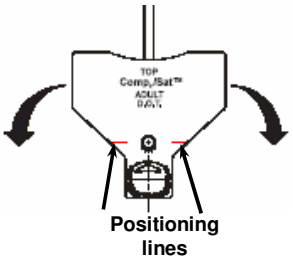
- Place finger, with nail face-up, on the bottom pad (longer probe) as shown. Fold the adhesive wing upwards over the sides of the patient's finger. Do not pull or stretch the adhesive tape. Do not cover the nail.



- Fold the pad of the emitter probe over the tip of the patient's finger. Separate the window of the emitter so that it is diametrically opposite the window of the detector.



- Fold the adhesive wings downwards around the finger. Do not pull or stretch the adhesive tape. Check that the positioning lines of the emitter and of the detector are aligned.



- Connect the sensor to the instrument: insert the connector with the arrow on the connector face-up and control the correct functioning according to the previous instructions.

ATTENTION ⚠

An over-tight sensor can produce inaccurate saturation measurements. Therefore avoid over tightening the adhesive tape.
It is recommended to fasten the cable to the wrist with a bandage.

2.9.3.2 Making a Test

To start the test, press ▷ from the oximetry test menu screen.

The display will show “oximeter (SpO2/BPM)”. The test duration is unlimited and the aim is to record variations of the oximetry values during a period as decided by the doctor.
As with the sleep oximetry test, after circa 5 minutes the **spirobank *II*** goes into standby, so the acoustic signal ceases and the display switches off, only the led remains illuminated. To control the correct functioning during the standby phase, press the key ⏻, then after 5 minutes **spirobank *II*** will return automatically to standby.
To end test press ESC and then ◁.
To print data see Paragraph 3.3.; an example of a test printout report is attached.
If the finger is removed from the sensor during the test, the following message will appear (even if on standby):

WARNING
Searching for signal, finger not inserted correctly

2.9.4 SPO2 BPM Test

This test allows the control of the oximetric data plus the cardiac pulse of a patient in real time.
The test can only be accessed when the device is switched on by pressing ▷ corresponding to ❤ on the first screen. To confirm press OK.
Relative data is memorised according to instructions shown on the screen prior to making the test (ID#: “1234” and SURNAME: “OXYTEST”). This data is required when searching the memory for related test data.
Test duration, SpO2 value and heart beat data are shown.
To end test see instructions contained in the previous paragraph.

3 DATA TRANSMISSION

ATTENTION ⚠

Read the instructions carefully before starting the data transmission, taking due care to ensure that all the information has been properly understood.

3.1 Wireless Data Transmission via Phone Line

This type of data transmission allows for the transfer of all data in the memory of **spirobank *II***. Through this method the doctor can control the information sent directly from the patient and assess any changes to the therapy in course from his/her PC.
To transfer the data memorised during various tests to the doctor’s PC, follow this procedure:

- Dial the doctor’s phone number (for example, the doctor’s office, telemedicine services, or any other structure) directly on the telephone at use.
- Place **spirobank *II*** and the phone on a level surface as shown in the figure:

The suitable distance between **spirobank *II*** and the phone receiver is between 2 and 5 cm

- Place the microphone of the telephone (the microphone is near the cable) near to the **spirobank *II*** as shown in the figure, with the phone receiver (beneath the device's ID label). The hole should be close to (2 to 5 cm) the microphone's hole positioned on the receiver.

Where necessary the distance between **spirobank *II*** and the receiver can be up to 1 metre, depending on the environmental noise, however the closer the receiver is to the hole of the **spirobank *II*** the more reliable will be the data transmission. The suggested distance for a reliable transmission is a few centimetres.

- From the main screen press ▷ corresponding to the  icon.
- Then press ✚ corresponding to the  icon.
- A confirmation for the transmission is requested by pressing OK, otherwise it is possible to exit the programme by pressing ESC.
- **spirobank *II*** now emits a series of acoustic signals indicating that the data transmission has started.
- Wait until **spirobank *II*** has completed the transmission (the instrument ceases to emit an acoustic signal).
- At the end of the transmission the message "TRANSMISSION TERMINATED" will appear.

At any time during the transmission the process may be terminated by pressing ESC.

During this procedure it is strongly suggested to:

- Eliminate all external noises;
- Do not touch or move **spirobank *II*** and the receiver;
- Be sure to have fully understood the procedure before starting the transmission.

ATTENTION ⚠

The data transmission is made through the fixed phone line of which the care and proper functioning depends on the national phone operators. The manufacturer is not liable for any eventual disservice or dysfunction caused by either the fixed or mobile operators.

High frequencies emitted by electronic devices can cause interference with the correct functioning of the instrument. For this reason a minimum safety distance (a few metres) must be maintained when in the same room another apparatus or device such as TV, radio, appliances, cell phones, radio phones etc. are being used.
If the instrument is connected to other devices (PC, printers, modem etc.) to preserve the characteristics of the safety system pursuant to the IEC 601-1-1 Standards, it is required that only devices complying with these safety regulations are used.

3.2 Data Transmission via Bluetooth to a cell phone

spirobank *II* includes a "Bluetooth" wireless data transmission system. This connection is through radio and allows **spirobank *II*** to be connected to a suitable cell phone. The method of data transmission allows the transferring of all the data in **spirobank *II***.
The sequence of operations to follow is described below.

3.2.1 Preliminary Operations

ATTENTION ⚠

The transmission of data through a Bluetooth connection requires the phone number of the unit where the data shall be transferred (the doctor's office, telemedicine service, etc.). To enter the telephone number, see the main menu when the machine is turned on. (Refer to Paragraph 2.4). A device must also be set up for the connection; refer to Paragraph 2.4 for further details.

3.2.2 Setting the Phone Number

- Turn on **spirobank *II*** by pressing ⏻
- On the first screen press ◁
- From the "Service Menu" select the option "phone set up" using − and ✚
- Press OK
- Enter the number by using ◁ and ▷ to select digits, and the OK to confirm the selected number.
- Return to the Service Menu by pressing OK
- From the "Service Menu" access the main screen by pressing ESC.

3.2.3 Bluetooth Data Transmission

- From the main screen press ▷ corresponding to the ✉ icon.

- Press ◁ corresponding to the  icon.
- The selected transmission will be shown, to confirm press OK to activate the connection with the default device set up.
- When required by the cell phone, enter the PIN code shown on the **spirobank *II*** display (corresponding to the serial number (SN) of the machine shown on the **spirobank *II*** ID label).
- The connection phases then follow.
- When the connection is completed the data transfer to the default modem starts.
- The message “transmission completed” appears at the end of the transfer.

The following information is now shown on the display:

- The device used for the connection (as described in the initial settings).
- The telephone number (as described in the initial settings).
- The preset PIN (corresponding to the serial number of the machine).

To interrupt the data transmission during the Bluetooth connection press ESC, to end the connection and return to the main screen.
Where no device has been setup for data transmission, a message will appear on the display to start searching for enabled devices. After setting the device the connection will start automatically.

3.3 Data Transmission via Bluetooth for printing

ATTENTION ⚠

Printing of data from the patient management function is enabled only if the printer has a Bluetooth connection; alternatively a USB key can be installed on the printer in order to enable a Bluetooth connection.

The Bluetooth system enables **spirobank *II*** to transfer test data directly to a Bluetooth enabled printer. The sequence of activities to be followed is:

- From the main screen select the test to be printed with ▷.
- On the next screen press – ( icon).
- Print either a spirometry or an oximetry test by selecting respectively ◁ or –.
- By choosing to print spirometry tests, the last test of the patient selected on the main screen will be shown.
- By selecting oximetry tests, the last test made pertaining to that patient will be printed.

Tests stored on memory can also be printed. Use the search method as described in Paragraph 2.6 to print out relevant tests.

- On the relevant test screen press ◁.
- **spirobank *II*** will carry out the connection.

- At the end of transmission **spirobank *II*** will show “CONNECTION COMPLETED”, and return automatically to the main screen.

To interrupt the Bluetooth connection during transmission press ESC to return to the main screen.
Where no printer has been set up, a message will appear to search for devices. After the device has been set up it will automatically be enabled for printing data.
When searching for enabled for Bluetooth devices, **spirobank *II*** will check the address of that device and where a previously registered device has changed name, it will be automatically updated.

3.4 Connection to a PC through USB port

ATTENTION ⚠

Before connecting **spirobank *II*** by USB to a PC, winspiroPro must be installed to interface with the device.
It is important prior to initiating the following procedure to know the version of the operating system installed on the PC used for the connection (from control panel click on “System”, where the type of operating system installed on the PC can be checked).

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.
At the first connection, the PC will request the installation of the driver corresponding to the new device being used; follow the automatic procedure in the operating system, enter the following path when the request for the driver appears.
For Windows 2000 and higher versions enter the following path:

C\Programmi\MIR\winspiroPro\DriverUSB\win2000-xp,

For Windows 98 enter the following:

C\Programmi\MIR\winspiroPro\DriverUSB\win98

To check the connection between the device and the PC, ensure that the led on the device is illuminated.

3.5 Connection to a PC through the RS 232

spirobank *II* can also be connected to a PC through the RS 232 serial port. This leaves the USB port free and the device is run directly by the software (as a USB connection). The picture shows the RS 232 connector attached to **spirobank *II***.
For the correct management of the device see the online manual of the software.

3.6 Upgrade Internal software

spirobank *II* software can be upgraded when connected to a PC (USB or RS232). Upgrades can be downloaded by registering on www.spirometry.com. For further information on upgrading software see the "winspiroPro" software manual.

4 MAINTENANCE

spirobank *II* is an instrument that requires very little maintenance. The operations to perform periodically are:

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

The maintenance operations described in the User's Manual must be carried out carefully. Failing to observe the instructions may cause errors in measurement or in the interpretation of the measured values.
Modifications, adjustments, repairs, and reconfiguration must be carried out by the manufacturer or by authorised persons.
In case of problems do not attempt to repair the unit.
The setting of configuration parameters must be carried out by qualified personnel. In any case the risks pertaining to incorrect configuration settings do not constitute a danger for the patient.

4.1 Cleaning and controlling the reusable turbine

The turbine utilized by **spirobank *II*** belongs to one of two categories: disposable and reusable. These guarantee precise measurements and have the great advantage of requiring no periodic calibration. In order to maintain the characteristics of the turbine a simple cleaning is required prior to each use (**only for the reusable turbine**). This operation will also guarantee perfect hygiene and the highest possible safety conditions for the patients.
Cleaning of the disposable turbine is not required, as it is supplied clean in a sealed plastic bag. It must be disposed of after use.

ATTENTION ⚠

It is good practice to control from time to time that dirt or foreign bodied are not deposited inside the turbine, such as threads or hair. Any such deposits could brake or block the rotation of the turbine blade and thus compromise the measurement accuracy.

To clean the **reusable** turbine, first remove it by pulling it gently from the **spirobank *II*** turning it anti-clockwise and pressing lightly. It can be helpful to push it gently from underneath with one finger.
Immerse the turbine in a cold sterilising liquid and move it within the liquid to remove any impurities which may be deposited inside. Leave it to soak for at least the time recommended by the producer of the cleaning solution, as shown in the relevant instructions (in general at least 20 minutes).

To avoid causing irreparable damage never place the turbine under a direct jet of water or any other liquid. Where no cleaning solutions are available it is however indispensable to clean the turbine in clean water.

Rinse the turbine by immerging it in clean water (**not hot**).
Shake off the excess water from the turbine and leave it to dry, standing it vertically on a dry surface.

To ensure that the turbine is functioning correctly before replacing it inside the instrument, it is good practice to make a visual check of the rotation blade. Placing the turbine tube horizontally and moving it gently from left to right and vice versa, the rotation blade (rotor) must rotate freely. Otherwise, accurate measurement is no longer guaranteed and the turbine must be replaced.

Once the turbine has been cleaned insert the turbine tube in its place following the instructions indicated by the closed lock symbol printed on the plastic casing of the **spirobank *II***.

To insert the turbine correctly push it and then turn it clockwise until it reaching the stop, which ensures that the tube has been blocked inside the casing.

If the disposable turbine is used do not clean it but change it after each test.

4.2 Changing the adhesive tape of the wrap sensor

The adhesive tape is made with latex-free material.

- Gently remove the used adhesive tape from the sensor and dispose of it.
- The back of the sensor has alignment pins. Place the sensor with the alignment pins facing the adhesive part of the tape and align the pins to the holes on the tape.

- Push the sensor so as to insert the pins into the holes of the tape. Lift both the sensor and the tape and check that the pins of the sensor are correctly aligned.

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

4.3 Changing the Batteries

If the message "**BATTERY DISCHARGED**" appears on **spirobank *II*** display, or if the instrument does not switch on, the batteries inside the compartment shown here under must be changed as per the following points:

- Remove the back cover by pressing and pushing it away from the device.
- Remove the discharged batteries.
- Replace with new batteries, inserting them properly into the slots.
- Close the battery compartment by replacing the back cover and sliding it towards the inside of the device.

ATTENTION ⚠

Use only 1.5 V type AAA lithium batteries or equivalent. When inserting the batteries in the battery slot, take care to correctly connect the "+" and "-" as shown inside (see figure below).

The device has an internal lithium battery for RAM memory; the average life is approximately 10 years. If the display shows the following message:

Warning change lithium battery

Call a service centre or the manufacturer for replacement.

5 PROBLEM SOLVING

There follows a list of problems that may arise when working with **spirobank *II***. Diagnostic messages are also shown on the display indicating the type of malfunction:

5.1 Causes and Solutions

- **spirobank *II* does not switch on**

Check that batteries are correctly inserted in the compartment on the back of the instrument. If they are correctly positioned then replace them with new ones.

- **During operation the machine switches itself off and on again**
  Change the batteries. Contact the technical service centre.

- **At the end of spirometry testing the test data is incorrect**
  Clean the turbine and then control it; use a new turbine.

- **All data in memory lost due to an unforeseeable event**
  All data in memory has been deleted. Contact the technical service centre.

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

Declaration of CE Conformity

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

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

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

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

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

Rome **01** / **01**/ **2006**

Simon Fowler
Sales Manager

Carmine Cerullo
Quality Manager

Rev.0 – Mod. PO-10DDC_**spirobank *II***

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 instrument 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 instrument has been connected.
- If the serial number of the instrument 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 centres. For details of these centres 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 centre.

Any instrument 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 instruments are returned to MIR.

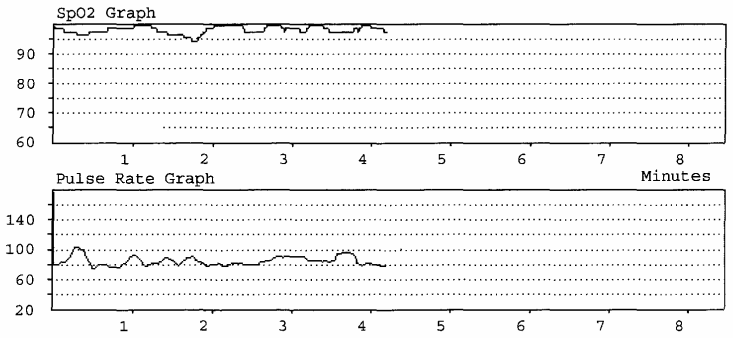
MIR – Medical International Research reserves the right to modify the instrument if required, and a description of any modification made will be sent along with the returned goods.

ANNEX 1 OXYMETRY TEST REPORT EXAMPLES

Oximetry - Sleep Test

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

Age 38 Height cm 182 Wheight kg 70 Sex M



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

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

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

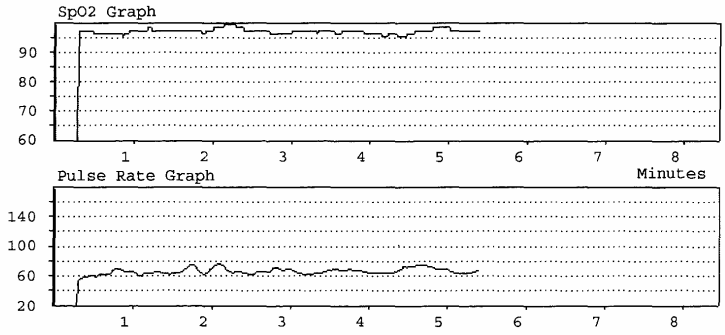
Total Desaturation Events	1	Total Pulse Rate Variations	5
ODI (Desaturation Index)	14.3	Pulse Rate Variation Index	71.4
Mean Duration (s)	50.0		
Longest Duration (s)	50	NOD -4%[Baseline-4%]	00:00:00
Desaturation Peak [Nadir] (%)	94	NOD 89[<89%]	00:00:00
Mean Desaturation (%)	94	NOD 90[<90%; Nadir<86%]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

Made by spirobank II Signature _____

Oximetry - Walk Test (6MWT)

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

Age 38 Height cm 182 Wheight kg 70 Sex M



Recording Time	00:05:22		Analysis Time	00:02:18	
Baseline Time	00:02:06		Walking Time	00:02:18	
			Recovery Time	00:00:00	
%SPO2		Mean 96.5	BPM		Mean 66.6
Baseline	96.8	End 96	Baseline	65.7	End 72
Minimum	95	Maximum 99	Minimum	63	Maximum 73

T -2% (Delta SpO2 >= 2%)	22:09:03		N. Bradycardia Events < 40 BPM		0
T -4% (Delta SpO2 >= 4%)	17:02:01		N. Tachycardia Events >120 BPM		0
	% time	hh:mm:ss		% time	hh:mm:ss
T90 (SpO2 <90%)	0%	00:00:00	T < 40 BPM	0%	00:00:00
T89 (SpO2 <89%)	0%	00:00:00	T >120 BPM	0%	00:00:00
T88 (SpO2 <88%)	0%	00:00:00			
T87 (SpO2 <87%)	0%	00:00:00			

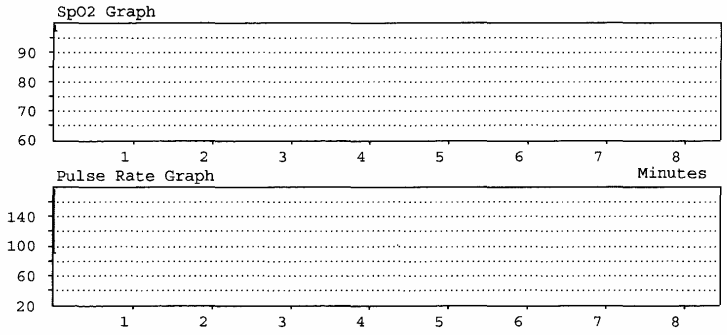
Distance (m)			Dyspnea (Borg scale)			
Walked	0		Baselin 0	End 0	CHG	0
Predicted (Standard)	754	0%				
Predicted (Minimum)	601	0%	Fatigue (Borg scale)			
AUC/Distance	27.0		Baselin 0	End 0	CHG	0

Made by spirobank II Signature _____

Oximetry - SpO2/BPM

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

Age 38 Height cm 182 Wheight kg 70 Sex M



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

%SPO2
Baseline 0 Mean 97.0
Minimum 97 Maximum 97

BPM
Baseline 0 Mean 91.0
Minimum 91 Maximum 91

N. SpO2 Events <89% 0
Delta Index [12 sec] 0

N. Bradycardia Events < 40 BPM 0
N. Tachycardia Events >120 BPM 0

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

	% time	hh:mm:ss
T < 40 BPM	0%	00:00:00
T >120 BPM	0%	00:00:00

Made by spirobank II Signature _____

ANNEX 2 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	
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 %.
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.
        Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	 3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	 [3] V [3] V/m	Portable and mobile RF communications equipment should be used no closer to any part of the **spirobank *II***, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=[\frac{3.5}{3}]\sqrt{P}$ $d=[\frac{3.5}{3}]\sqrt{P}$ 80 MHz to 800 GHz $d=[\frac{7}{3}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer

			and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE U_T is the a.c. mains voltage prior to application of the test level. NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **spirobank *II*** is used exceeds the applicable RF compliance level above, the **spirobank *II*** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **spirobank *II***. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.			

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

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

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

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

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

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

ANNEX 3 SPIROMETRY TEST INTERPRETATION FLOW CHART