

## Spirobank II



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Thank you for choosing a **MIR** product

MEDICAL INTERNATIONAL RESEARCH

The following table describes the contents of the package e the accessories which can be used with spirobank II:

REF	Description	
672679	Carrying case	✓
532367	USB cable	✓
\	Software MIR Spiro	○
910002	Reusable turbine	○
910004	Disposable turbine	✓

✓ included      ○ optional

### Before using your Spirobank II

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

### WARNING

Before connecting spirobank II to a PC, please carry out all the necessary steps for the correct installation of the MIR Spiro software that can be downloaded from the MIR website. Once the new hardware is "recognized" by the PC the device may now be used with the MIR Spiro software.

### Keep the original packaging!

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

Should this be the case, please follow these guidelines:

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

Manufacturer's address:

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MIR has a policy of continuous product development and improvement. MIR reserves the right to modify and update the information in this User's Manual as deemed necessary. Any suggestions and or comments regarding this product are appreciated and may be sent via email to: [mir@spirometry.com](mailto:mir@spirometry.com).

MIR accepts no responsibility for any loss or damage caused by the user of the device due to instructions contained in this Manual and/or due to incorrect use of the product.

Please note that due to printing limitations, the screenshots shown in this manual may differ from the display of the machine and/or from the keyboard icons.


Copying this manual in whole or in part is strictly forbidden.

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

**CE**  
**0476**

## 1. INTRODUCTION

### Configuration

	
	<b>Spirobank II BASIC</b>
<b>Spirometry</b>	FVC-VC
<b>Rechargeable via USB</b>	✓
<b>MIR Spiro</b>	○

✓ yes    ○ optional    × no

#### 1.1 Intended use

The **Spirobank II** spirometer is intended to be used by a physician, by a licensed healthcare professional or by a patient under the instruction of a physician or of a licensed healthcare professional.

The device is intended to test lung function and can make:

- spirometry testing in adult and pediatric patients, excluding infants and neonates

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

##### 1.1.1 User category

**Spirobank II** spirometer + oximeter calculates a series of parameters relating to human respiratory function.

Typically the doctor “prescribes” a spirometry test and is responsible for analysing and checking the results obtained.

##### 1.1.2 Ability and experience required

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

### WARNING

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

If the user of the device is a person considered to be cognitively impaired the operation of the device must be made under the supervision and responsibility of the person legally responsible to supervise the cognitively impaired person.

##### 1.1.3 Operating Environment

**Spirobank II** has been designed for use in hospital setting, physician's office, factory, pharmacy.

The device is not intended for use in an operating theatre nor in the presence of inflammable liquids or detergents, nor in the presence of inflammable anaesthetic gases (oxygen or nitrogen).

The device is not designed to be used in direct air drafts (e.g. wind), sources of heat or cold, direct sunlight or other sources of light or energy, dust, sand or any chemical substances.

The user and/or doctor is responsible for ensuring that the device is stored and used in appropriate environmental conditions; in this regard reference is made to the specifications described in paragraph 1.6.3 below.

### WARNING

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

##### 1.1.4 Patient effect on the use of the device

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

##### 1.1.5 Limitations of use – Contraindications

An analysis of the results of a spirometry test is not by itself sufficient to make a correct diagnosis of the patient's clinical condition. A detailed clinical history of the patient is also required together with the results of any other test(s) suggested by a doctor.

Test comments, a test interpretation and suggested therapeutic treatment must be given by a doctor.

Any symptoms that the patient has at the time of the test must be carefully considered before a spirometry test is made. The user is responsible to assess both the mental and the physical condition of the patient in order to perform a proper test, furthermore, in the evaluation of test results, the user must also assess the degree of collaboration of each test carried out.

A spirometry test requires the full collaboration of the patient. The results depend on the person's ability to inspire as much air as possible and to expire all of the air as fast and for as long as possible. If these fundamental conditions are not respected then the results obtained during spirometry testing will not be considered accurate, and therefore the test results are "not acceptable".

The acceptability of a test is the responsibility of the doctor. Special attention should be given when testing elderly patients, children and handicapped people.

The device should not be used if any conceivable or actual anomalies or malfunctions appear which may compromise the accuracy of the results.

Spirometry has relative contraindications, as reported in the 2019 update of the ATS/ERS guideline:

Due to increased myocardial demand or changes in blood pressure

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

Due to increased intracranial/intraocular pressure

- Cerebral aneurysm
- Brain surgery within 4 weeks
- Recent concussion with persistent symptoms
- Eye surgery within 1 week

Due to increased sinus and middle ear pressure

- Sinus or middle ear surgery or infection within 1 week

Due to increased intrathoracic and intraabdominal pressure

- Presence of pneumothorax
- Thoracic surgery within 4 weeks
- Abdominal surgery within 4 weeks
- Pregnancy beyond term

Due to infection control problems

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

## 1.2 Important safety warnings

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

**Spirobank II** is continuously checked during manufacturing and therefore the product complies with the established security levels and quality standards laid down by Regulation (EU) 2017/745 for medical devices.

After removing the device from its packaging, check to see that there is no visible damage. In case of damage do not use the device and return it to the manufacturer for repair.

### WARNING

The safety and the correct performance of the device can only be assured if the user respects all of the relevant safety rules and regulations.

The manufacturer will not be held responsible for damage due to user's neglect to correctly 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 or other accessories may cause errors in measurement and/or compromise the correct functioning of the device, and is therefore not permitted.

In particular, the use of cables other than those specified by the manufacturer could cause increased emissions or lower electromagnetic immunity from the device and result in improper operation.

The device should not be used beyond the declared life span.. In normal conditions the lifespan of the device is estimated to be around 10 years.

The device constantly monitors the state of charge of this battery and a message informs the user when the battery is discharged.

Notice

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

### 1.2.1 Danger of cross-contamination

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

### 1.2.2 Turbine



#### Disposable turbine



**For spirometry testing with a disposable turbine it is important to use a new turbine for each new patient. The accuracy and hygiene of the disposable turbine can only be guaranteed if it has been conserved beforehand in its original sealed packaging**

**The disposable turbine is made of plastic and its disposal after use should adhere to the local regulations and norms in force.**



#### Reusable turbine



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

The following information applies to both types of turbine.

The turbine must never be held under running water or direct air pressure and must never come into contact with hot fluids.

Do not allow dust or foreign matter to enter the turbine sensor which may alter the correct functioning and possibly cause damage.

The presence of any impurities such as hair, sputum, threads etc. within the body of the turbine sensor may seriously compromise measurement accuracy.

### 1.2.3 Mouthpiece

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



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

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



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

### 1.2.4 USB connection cable

Incorrect use or application of the USB cable may produce inaccurate measurements, which will show very inaccurate values of the patient's condition. Carefully inspect each cable before use.

Do not use cables that appear to be or are damaged. If a new cable is required, contact your local distributor.

Use only cables supplied by MIR, specifically designed to be used with Spirobank II. The use of other types of cables can lead to inaccurate measurements.

### 1.2.5 Device

 **WARNING**

The maintenance operations detailed in this manual must be fully and accurately carried out. If these instructions are not followed this may cause measurement errors and/or an incorrect test interpretation.

Do not modify this equipment without authorization of the manufacturer.

Any modifications, adjustments, repairs or reconfigurations must be made by the manufacturer or by personnel authorised by the manufacturer. Never attempt to make a repair on your own. The set-up of configurable parameters should only be made by qualified personnel. However, an incorrect set-up of the parameters in no way endangers the patient's health.

Technical description indicates, manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to service personnel in parts repair.

The use of accessories and cables other than those specified by the manufacturer may result in increased emissions or decreased immunity of the device.

Spirobank II should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, Spirobank II should be observed to verify normal operation in the configuration in which it will be used.

If the device is connected to other instruments, to satisfy the safety requirements of the system required by the standard CEI EN 60601-1, it is necessary to use exclusively devices compliant to the safety standard. Therefore the PC or the printer which the Spirobank II is connected must be compliant to the standard CEI EN 60601-1.

To dispose of the Spirobank II, the accessories, any plastic consumable materials (mouthpieces) as well as the battery, use only appropriate containers or return all such parts to the dealer or to a recycling center. All applicable local regulations must be followed.

If any of these rules are not followed then MIR will decline all responsibility for any direct or indirect damages, however caused.

To supply power to the device use only the battery type indicated in the § Technical specifications.

The device may be powered through a PC by a USB cable. By this means, the device works both on line with the PC, or individually powered by the PC.

Keep the device out of reach of children and of any person with mental handicap.

### 1.2.6 Warnings for use in electromagnetic environments

Due to the increasing number of electronic devices (computers, cordless phones, cell phones, etc.) medical devices may be subject to electromagnetic interference caused by other equipment.

Such electromagnetic interference could cause the medical device to malfunction, such as a lower measurement accuracy than stated, and create a potentially dangerous situation.

Spirobank II complies with the EN 60601-1-2:2015 standard on electromagnetic compatibility (EMC for electromedical devices) both in terms of immunity and emissions.

For the correct operation of the device, however, it is necessary not to use Spirobank II near other devices (computers, cordless phones, cell phones, etc.) that generate strong magnetic fields. Keep these devices at a minimum distance of 30 centimeters.

If it is necessary to use it at shorter distances, Spirobank II and the other devices must be kept under observation to verify that they work normally.

### 1.3 Lithium-ion battery pack warning

The device is powered by a rechargeable lithium-ion battery pack with a supply voltage of 3.7 V.

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

 **WARNING**

Use only battery packs supplied by MIR

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

Please read the following instructions carefully.

**DANGER**

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

Do not short-circuit the positive(+) and negative (-) poles with any metal objects.

Do not carry the battery pack in your pocket or in a bag with other metallic objects like necklaces, hairpins, coins or screws.

Do not store the battery pack near any such objects.

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



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

Do not immerge the battery pack in water or salt-water, and do not leave it wet.

Such events may damage the internal battery safety sensor, thus causing the battery to be charged at a higher voltage, triggering abnormal chemical reactions leading to acid leakage, overheating, smoke, an explosion and/or fire

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

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

Do not puncture the battery pack with sharp objects such as a nail.

Do not hammer, step-on, throw or cause a forceful impact to the battery-pack.

A damaged or deformed battery pack may cause internal short-circuits thus creating the possibility for acid leakage, overheating, smoke, breakage and/or fire.

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

Do not solder directly on the battery pack.

Do not mount the battery pack inside the device with the + and – poles inverted.

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

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

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

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

#### WARNING

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

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

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

#### NOTE

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

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

Store the battery pack away from children's reach to avoid any accidental swallowing.

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

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

Please read the manual carefully to insert and remove of the battery pack in the device properly.

Before charging the battery pack read the manual carefully.

The battery pack life cycle is definite-. If you notice a much shorter time usage between charges please substitute the battery pack with a new one.

Remove the battery pack if its cycle life has expired.

When the battery pack has been removed from the device, ensure that the (+) and (-) leads have been isolated with electrical tape; to properly dispose of the battery pack please follow the local regulations or hand over the battery pack to a battery recycling center.

Prior to storage or for long periods of disuse of the device remove the battery pack and store in a place where the temperature and humidity fall within specified ranges.

If the battery pack leads are dirty clean with a dry cloth prior to usage.

The battery pack can be charged within a temperature range between 0°C and approximately 40°C

The battery pack may be used within a temperature range between -20°C and approximately 60°C.















The battery pack may be stored within a temperature range between -20°C and approximately 60°C.

## 1.4 Labels and symbols

## 1.4.1 Identification label and symbols



The symbols are described in the table below:

SYMBOL	DESCRIPTION
<b>Model</b>	Product name
<b>SN</b>	Device serial number
	Manufacturer's name and address
	CE mark for medical devices: this product is a Class IIa medical device that is certified and in compliance with the requirements of Regulation (EU) 2017/745 for medical devices.
	Electrical safety symbol: as per IEC60601-1, the product and its component parts are type BF and therefore offer protection against electrical shocks
	WEEE symbol is mandatory to European Directive 2012/19/EEC on Waste Electrical and Electronic Equipment. On completion of its useful life, this appliance must not be disposed of as urban waste but must be sent to an authorised WEEE waste disposal centre. The device can also be sent back to the original supplier free of charge when a new equivalent model is bought. Due to the materials used in its manufacture, disposal of the device as urban waste could harm the environment and/or health. There are legal penalties in place for those who fail to observe the legal requirements mentioned here
<b>IPX1</b>	Information on protection against ingress of liquids. The label indicates the degree of protection against ingress of liquids (IPX1). The device is protected against vertically falling drops of water
	Antenna symbol for devices that include RF transmitters
<b>FCC ID</b>	FCC Identification code indicating traceability to FCC compliance
<b>Rx ONLY</b>	Reference to US FDA regulations: use the device on prescription
	Instruction for use symbol. Refer to instruction manual. Read this manual carefully before using the medical device
	Production date of the device
	USB port warning label. For connecting the device to a PC. Only use cables supplied by the manufacturer and observe the IEC 60601-1 safety standards
	Electrostatic discharge symbol. This symbol is used near every connector that has been excluded from the electrostatic discharge test. In this device the electrostatic discharge tests have been performed.
	Temperature limits: indicates the temperature limits to which the medical device can be safely exposed
	Humidity limitation: indicates the range of humidity to which the medical device can be safely exposed
	Pressure limitation: indicates the range of pressure to which the medical device can be safely exposed
<b>MD</b>	The symbol indicates that the product is a medical device
<b>UDI</b>	The symbol indicates the Unique Device Identification
	The symbol indicates that the device must not be exposed to direct sunlight
	The symbol indicates that the device must be kept dry

### 1.4.2 FDA and FCC Warnings

**Spirobank II** complies with Part 15 of the FCC Rules. The correct operation is subject to the following conditions:

- (1) this device must not cause harmful interference
- (2) this device must accept any interference received, including interference that may cause undesired operation.

Any modifications not expressly approved by this company could void the user's authority to operate the equipment.

**NOTE:** This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

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

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

### 1.4.3 (ESD) Electrostatic discharge sensitivity symbol



#### WARNING

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

Precautionary procedures are the following:

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

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

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

Typical electrostatic voltage values:

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

If two items are at different electrostatic charge levels, as they approach one another, a spark or Electrostatic Discharge (ESD) can occur. This rapid, spontaneous transfer of electrostatic charge can generate heat and melt circuitry in electronic components.

A latent defect can occur when an ESD sensitive item is exposed to an ESD event and is partially degraded. It may continue to perform its intended function, so may not be detected by normal inspection. Intermittent or permanent failures may occur at a later time.

Static dissipative material will allow the transfer of charge to ground or to other conductive objects. The transfer of charge from a static dissipative material will generally take longer than from a conductive material of equivalent size. Some well known insulators are common plastics, and glass. An insulator will hold the charge and cannot be grounded and conduct. the charge away.

Both conductors and insulators may become charged with static electricity and discharge. Grounding is a very effective ESD control tool, however, only conductors (conductive or dissipative) can be grounded.

The fundamental ESD control principles are:

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

## 1.5 Product description

The **Spirobank II** is a pocket spirometer. It can operate either in stand-alone mode or it can be connected to a PC or to a printer using any one of several methods: USB.

The device is specifically designed to measure a range of respiratory parameters. A quality control check is carried out internally on the measured parameters and the device has an internal memory sufficient for approximately 10.000 spirometry tests.

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

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

The sensor features are listed below:

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

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



**REUSABLE TURBINE**



**DISPOSABLE TURBINE**

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

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

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

The personal best values can vary considerably from the predicted values, which are taken from “healthy” subjects.

**Spirobank II** can also be connected to a PC (or to another computerised system) to configure the instrument. All spirometry test data including the related patient details stored inside the device can be transferred from the device to the PC and then viewed on the PC (Flow/volume curves, spirometry parameters).

The connection to the MIR Spiro can be made via USB connection.

**Spirobank II** can perform FVC, VC & IVC, MVV and breathing profile tests, and calculates an index of test acceptability (quality control) plus the reproducibility of the spirometry tests carried out. Automatic functional interpretation involves the levels defined by the 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.

## 1.6 Technical specification

A comprehensive description of the main features of the device, the flow and volume measurement turbine.

### 1.6.1 Features of the spirometer

This device meets the requirements of the following standard:

- ATS Standardization of Spirometry 2005, 2019 update
- ISO 23747: 2015
- ISO 26782: 2009

#### Measured parameters:

Symbol	Description	Units
*FVC	Best FVC	L

Symbol	Description	Units
*FEV1	Best FEV1	L
*PEF	Best PEF	L/s
FVC	Forced Vital Capacity	L
FEV1	Volume expired in the 1 <sup>st</sup> second of the test	L
FEV1/FVC	FEV1/FVC x 100	%
PEF	Peak expiratory flow	L/s
FEF2575	Average flow between 25% and 75% of the FVC	L/s
FET	Forced expiratory time	s
EVol	Extrapolated volume	mL
VC	Slow vital capacity (expiratory)	L
IVC	Slow inspiratory vital capacity	L
IC	Inspiratory capacity (max between EVC and IVC) - ERV	L
ERV	Expiratory reserve volume	L
ELA	Estimated lung age	year

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 (ATS 2019)	± 2.5% or 50 mL
Flow accuracy	± 5% or 200 mL/s
Dynamic resistance at 12 L/s	<0.5 cmH <sub>2</sub> O/L/s

### 1.6.2 Other features

Memory	Memory capacity for over 10000 spirometric tests The precise number depends on the individual configuration, so it cannot be determined more closely
keyboard	membrane keyboard with 6 keys
Display	Display LCD 160x80 monochromatic
Interface	USB
Duration of the 3,7V lithium battery	Approx 500 charge cycles, under normal conditions of use
Power supply	Battery pack Li-ion 3.7 V 1100mAh
Battery charger	Voltage = 5VDC Current = 500 mA or higher Connector = micro USB type B
Dimensions	160x55.2x25mm;
Weight	Central unit 140g (including batteries)
Type of electrical protection	Internally powered
Degree of electrical protection	BF
Grade of protection against water ingress	IPX1 device, protected against water drops
Safety level in the presence of inflammable anaesthetic gas, oxygen or nitrogen	Device not suitable
Conditions of use	Device for continuous use
Storage conditions	Temperature: MIN -20 °C, MAX + 60 °C Humidity :MIN 10% RH; MAX 95%RH Athmospheric pressure: 50kPa, 106 kPa
Transport condition	Temperature: MIN -20 °C, MAX + 60 °C Humidity :MIN 10% RH; MAX 95%RH Athmospheric pressure: 50kPa, 106 kPa
Operating conditions	Temperature: MIN + 10 °C, MAX + 40 °C; Humidity: MIN 10% RH; MAX 95%RH Athmospheric pressure: 50kPa, 106 kPa
Applied norms	IEC 60601-1:2005 + A1: 2012 (Electrical Safety) IEC 60601-1-2:2015 (EMC) ATS/ERS Guidelines: 2005, 2019 update ISO 26782: 2009 ISO 23747: 2015 EN ISO 14971: 2019 ISO 10993-1: 2018 2011/65/UE Directive EN ISO 15223-1:2021

EN IEC 60601-1-6: 2010+Amd2013

IEC 60601-1-8: 2006

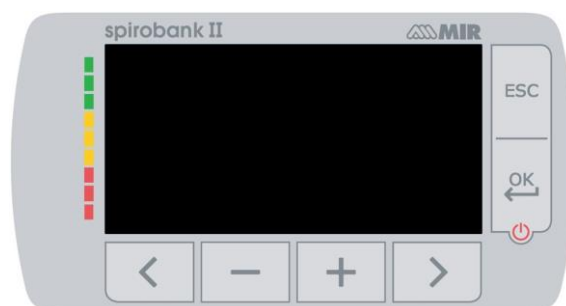
Essential performances (according to IEC60601-1: 2005 + A1: 2012)	Error of displayed numeric value: Flow measurement percentage error $< \pm 5\%$
Emission limits	CISPR 11 Group 1 Class B
Electrostatic discharge protection	8kV contact, 15kV air
Magnetic field immunity	30 A/m
Radio Frequency Immunity	3V/m @ 80-2700 MHz

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

## 2 FUNCTIONING OF THE Spirobank II


### 2.1 Switch on and switch off the device

To switch on the Spirobank II push 

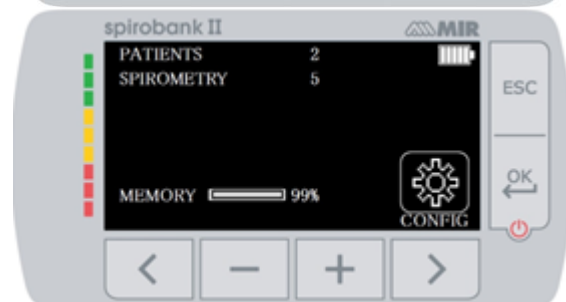


The first screen shows the manufacturer logo, information of date and hour set on the device. If no key are touched, after a few seconds the device shows the main screen.




The second screen shows the information as in the image beside. He key  allows to visualize the service menu; with these items it is possible to configure the device in the correct way.

If any keys are touched, then the device goes to the main screen.



To switch off the device push 

#### WARNING

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

### 2.2 Energy saving

#### WARNING

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





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

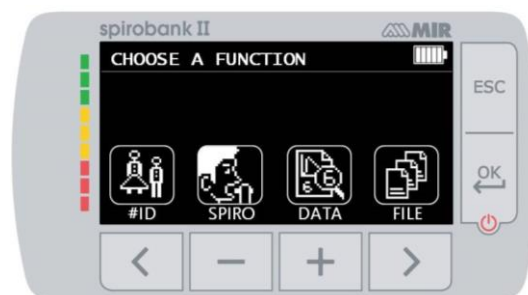


This image indicates that the battery pack is fully charged(6 indicators). A drop of the battery pack charge is displayed with a reduction of the indicators.

### 2.3 Main screen

On the main screen, the following areas can be accessed :

-  patient data management area
  -  spirometry area
  -  archive area
  -  archive area (for BASIC version)
- Main screen for BASIC version



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



## 2.4 Symbols and Icons

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

ICON	DESCRIPTION
	To access the default settings (service menu)
	To access patient data from the main display
	To perform a new test of a patient recalled from the patient records.
	To insert new patient data
	To modify patient data.
	To display the most recent tests of a patient
	To show the last test performed
	To access the database of the performed tests.
	To access the database of the performed tests (in BASIC version)
	To search a test with the date of birth of a patient
	To search a test starting from a specific date onwards..(partial database)
	To flick through a database from beginning to end and viceversa (complete database)
	Male sex patient selection
	Female sex patient selection
	To access spirometry testing type
	to perform a forced vital capacity test FVC/search FVC tests in memory
	To perform a slow vital capacity spirometry test VC/ search VC tests in memory
	To perform a maximum voluntary ventilation spimetry test MVV/ search MVV tests in memory
	To perform a spirometry test with a broncodilator

## 2.5 Service menu

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

It is also possible to enter in the service menu when the device shows the main screen, pressing the key **ESC** and then the key .

The service menu shows the following list of items:

- Change date/time
- LCD settings
- Select language
- Delete memory
- Select standard
- Select predicted
- Select turbine
- Turbine calibration
- Date format
- Unit format
- Info firmware

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

### Change date/time

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

### LCD settings

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

### Select language

Select the desired item using the and keys and press , the language is now set and the device will return to the Service Menu.

### Delete Memory

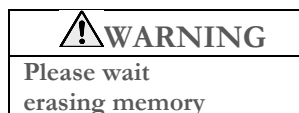
To delete the memory of the device insert the following password by touching the numbers shown below:



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



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



After approximately 30 seconds the following message will appear:



Press to return to the service menu.

**Select standard**

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



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

**Select predicted**

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

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

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

**Select turbine**

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

**Turbine calibration**

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

- show current values
- modify calibration
- factory defaults

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



The item “factory defaults” erases the previous calibration values and restores the two percentage corrections to zero percent correction factor; in this case a password is required as explained above.

To perform this procedure correctly please refer to paragraph 2.5.1.





**Spirometry setup**

It is possible to select the type of calculated parameters during spirometry testing. The user may select from the following two options:

- simplified
- personal

The “simplified” mode only allows for the following parameters:

FVC    FEV1    PEF    FEF2575    FET    VEXT    ELA (for FVC test)  
           VC    IVC    IC    ERV    IT (for VC test)

In “personal” mode the user may select which parameters will be displayed. The parameters highlighted in white will be displayed. Select a parameter with  and . Choose a parameter to show using  and delete a parameter with .

 **WARNING**

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

 **WARNING**

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

**DATE Format**

The voice allows to choose one of the following option:



day    month    year  
 month    day    year  
 year    month    day

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

**UNIT format**

The voice allows to choose one of the following option:


Imperial    (in,lb)  
 Metric    (cm kg)

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

**Info firmware**

In this menu the user may view information regarding the components version presents in the device.

After approximately 10 seconds the device will automatically return to the service menu, otherwise press .

Once all of the items in the service menu have been set it is possible to exit the menu by pressing .



In BASIC version the screen shows only Serial number and internal software version.

2.5.1 Reusable turbine calibration

 **WARNING**

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

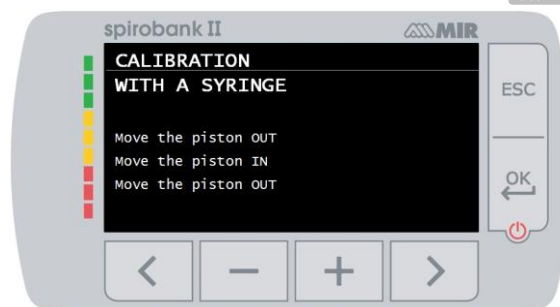
The calibration procedure can be performed on the reusable turbine and on the disposable turbine.

Turbine calibration is performed with a calibration syringe to simulate a FVC test for the expired parameters and a FIVC test for the inspired parameters.

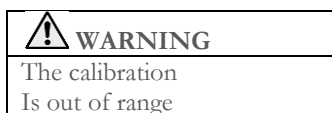
To enter the calibration function, select the “Turbine Calibration” option from the Service Menu (as explained in paragraph 2.5). To enter the new calibration values choose the item “Modify calibration” in the submenu, enter the password and insert the new calibration values. Make three manoeuvres with a syringe as described by the screen on the device, then **Spirobank II** calculates the FVC and FIVC values.

Press **ESC**.

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



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



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

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

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

### WARNING

In line with the publication "Standardized 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:

$$3.00 \text{ (FVC)} \times 1.026 \text{ (BTPS)} = 3.08 \text{ L (FVC at BTPS)}.$$

If the ambient temperature is 20°C, the FIVC (syringe) value will be:

$$3.00 \text{ (FIVC)} \times 1.102 \text{ (BTPS)} = 3.31 \text{ L (FIVC at BTPS)}.$$

The user must be aware that the volume of the syringe shown by the machine is converted to BTPS conditions, so that the "increase" of the results with respect to the expected values does not constitute an error.

For instance, if the calibration procedure is carried out with measured data:

FVC = 3.08 L and FIVC = 3.31 L at an ambient temperature of 20°C the resulting correction factor becomes:

EXPIRATION	.00%
INSPIRATION	.00%

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

### NOTE

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

## 2.6 Patient Data

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

Insert a new patient





Modify current patient data \*



### 2.6.1 Inserting data of a new patient

Press  and insert the patient information in the required sequence.

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

Use  and  to set the correct value; use instead  and  to switch from one to another parameter. Set the day, month, year of birth, height and weight of the patient. The last data to insert is the sex of the patient, which can be chosen by selecting one of the following icons:



Male



Female

#### Second screen (ethnic group)

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

Standard ATS/ERS		Standard NAHNES III
Group	% correction	
Without correction	100%	Caucasian
Caucasian	100%	Mexican-American
Oriental	100%	Afro-American
Hong Kong Chinese	100%	Other
Giapanese	89%	
Polinesian	90%	
North Indian	90%	
South Indian	87%	
Pakistani	90%	
African descendant	87%	
Aboriginal	85%	




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

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

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

To interrupt the data insertion, press **ESC** and the device will automatically return to the main screen.

### 2.6.2 Patient data modification

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

Press **ESC** icon to return to the main screen without modifying any data

#### WARNING

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

## 2.7 Visualization of memory data

### 2.7.1 Database research modality


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




Research by patient date of birth.



- Research by the date of testing.
- Visual of all tests in the database starting from the most recent.

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

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

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



### 2.7.2 Visualization of database info

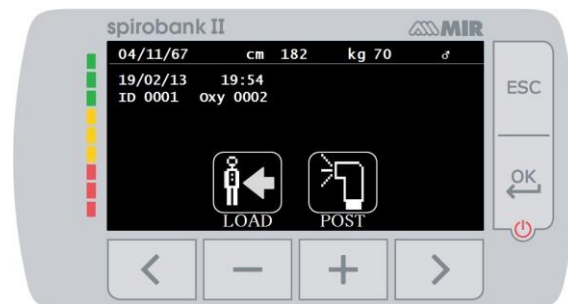
The result of a search performed in one of the described methods in paragraph 2.7.1 can be viewed in the adjacent image. By selecting the desired session one may access the performed tests

Use the keys  and  to select the desired test.

Once a testing session has been selected the database screen will show the adjacent image. The two icons on the lower part of the screen allow access to the following functions:

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

 (key ) to show the parameters of the selected test



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

### 2.8 PC On line mode (connected to a PC)

In the PC on-line mode the **Spirobank II** becomes a fully functional laboratory device which works in real-time connected to a PC. PC interface is via USB cable.

The **Spirobank II** becomes an intelligent transducer for the measurement of volume and flow while the PC controls the device including the on and off function.

Other than the usual spirometric parameters and the F/V in real-time the **Spirobank II** also plots the most refined indices such as the ventilatory profile and the extrapolated volume (Vext).

The PC software incorporates the most up to date bronchial provocation protocols displaying the dose-response and time-response of the FEV1

#### WARNING

When the device is connected to the PC, it cannot be controlled directly. The settings therefore defined on the PC are transferred to the device and remain set even in subsequent direct use; if for example a turbine (disposable or reusable) is set while using the **spirobank II** connected to the PC, this remains the default setting in any subsequent use of the device in direct mode, until the device is restarted. Please therefore pay attention to the type of turbine set.

### 2.9 Spirometry testing

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

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






#### WARNING

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

#### WARNING

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

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

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

\* not available in BASIC version

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

To end a test press **ESC** key

### 2.9.1 FVC test



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

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

It is possible (and may be helpful) to start the test by breathing at rest for a few moments. When ready to start *inspire slowly as much air as possible* (made easier by raising the arms wide apart) and then *make a complete expiration as fast as possible*. Then with the mouthpiece always held firmly in the mouth, complete the cycle by inspiring again as quickly as possible. This final inspiration may be left out if the inspiratory parameters (FIVC, FIV1, FIV1%, PIF) are not of interest.

The optional initial inspiration phase can also be performed before inserting the mouthpiece in the mouth.


After inspiring slowly and deeply, the following expiration must be made with the maximum effort by expiring all the air in the lungs as fast as possible.

After 6 seconds of expiration the device will emit a continuous beep, this helps the user to understand whether the minimum expiry time has been reached, as recommended by the main international respiratory institutions.

### WARNING

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

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

To end the test press .

During the test the **Spirobank II** emits "beeps", the frequency of which are directly proportional to the inspired and expired velocity of the air. This helps the doctor understand when the velocity of the air is approaching zero, and the patient has almost exhausted all of the inspired or expired volume.

In the maintenance section an explanation is given as to how this feature can also function as a very simple checking system for the correct operation of the mobile "rotor" of the turbine.

For the FVC test to be judged as acceptable, besides breathing as deep as possible, it is also required that the forced expiratory time (FET) is sufficiently long to allow for the complete expiration of all air contained in the lungs.

### 2.9.2 Test VC



#### Ventilatory Profile

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

#### Expiratory Slow Vital Capacity: VC

After the acoustic signal *inspire slowly* as much as air as possible and *expire slowly* as much air as possible.

#### Inspiratory Slow Vital Capacity: IVC

After the acoustic signal *expire slowly* as much as air as possible and *inspire slowly* as much air as possible.

To end the test press **ESC**.

Follow the indications on the display carefully in order to carry out the test properly.

### 2.9.3 MVV Test

 Not available in BASIC version

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

 **WARNING**

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

 **WARNING**

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

### 2.9.4 POST test, after drug administration

 **WARNING**

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

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

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

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


It is not possible to perform a POST test with a patient whose PRE testing was not carried out on the same day.

If during a POST session a new patient is inserted or another is recalled from the archive the device will automatically exit the current POST session.


### 2.10 Viewing the spirometric results

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

a Flow/Volume graph of the Forced Vital Capacity

pressing  the parameters FVC, FEV1, FEV1%, PEF relative to the best acceptable in the session are displayed with the percentage ratio in relation to the theoretical values.



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

#### 2.10.1 Acceptability, Repeatability and quality messages

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

For FEV1 and FVC Acceptability and Usability Criterion	Required for Acceptability		Required for Usability	
	FEV1	FVC	FEV1	FVC
Must have EVOL (VEXT or BEV) <5% of FVC or 0.100 L, whichever is greater	YES	YES	YES	YES
Must have no cough in the first second of expiration*	YES	NO	YES	NO
Must have no glottic closure in the first second of expiration*	YES	YES	YES	YES
Must have no glottic closure after 1 second of expiration	NO	YES	NO	NO
Must achieve one of these three end of forced expiration (EOFE) indicators: 1. Expiratory plateau (<0.025 L in the last 1 second of expiration) 2. Expiratory time >15 seconds	NO	YES	NO	NO



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

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

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

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

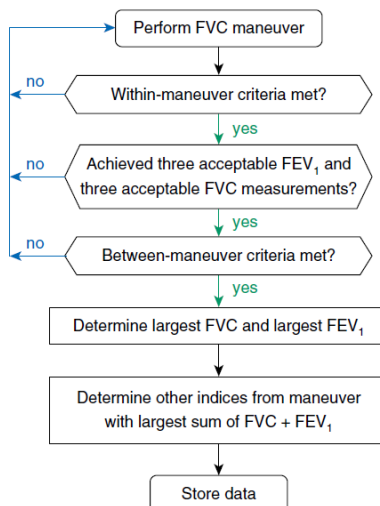
After each maneuver, ATS/ERS 2019 guideline provides a quality messages based on acceptability criteria define in table 7 of ATS/ERS 2019 guideline, as follows:

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

 **WARNING**

La prova migliore con i criteri definiti nella linea guida ATS 2019 non è considerata quella con la migliore somma FVC+FEV1, ma viene scelta nell'ambito dei test che soddisfano i criteri di accettabilità previsti dalla linea guida suddetta. Quindi viene scelta nell'ambito di quei test che non hanno fornito messaggi di errore.

La tabella seguente definita nella linea guida ATS 2019 definisce i criteri di scelta dei test per l'accettabilità e la ripetibilità.



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

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

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

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

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

### 2.10.2 Interpreting spirometry results

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

The messages can include the following:

- ◀ Normal spirometry
- ◀ Light obstruction/restriction
- ◀ Moderate obstruction/restriction
- ◀ Moderately severe obstruction/restriction
- ◀ Severe obstruction/restriction
- ◀ Very severe obstruction/restriction

The final interpretation level is "restriction + obstruction", where the indicator light indicates the worst parameter between restriction and obstruction.

## 3 DATA TRANSMISSION

### WARNING

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



### 3.1 PC connection via USB port

#### WARNING

Before connecting the Spirobank II via USB to the PC, the MIR Spiro software must be installed on the PC first to enable the software to interface with the device.

Before initiating the following procedure it is important to know the operating system version installed on the PC used for the connection (from control panel click on “System”, where the type of operating system installed on the PC can be checked). If MIR Spiro is already installed on the PC then a new installation is not required.

To make the connection, insert the mini USB connector supplied with **Spirobank II** as shown in the picture and attach the other connector to the USB port of the PC.

When initially making a connection, depending on the version of the operating system, the PC will either make an automatic driver installation (for Windows 98, 2000, ME) or request some information (for Windows XP, Vista and Seven). To avoid making any errors at this stage please read the Advanced section of the MIR Spiro User Manual carefully.



### 3.2 Internal software upgrade

**Spirobank II** internal software can be upgraded from a PC via USB connection. Upgrades can be downloaded by registering on [www.spirometry.com](http://www.spirometry.com). For further information on software upgrading please read the “MIR Spiro” software manual.

## 4 MAINTENANCE

**No part can be subjected to maintenance during use.**

**Spirobank II** requires very little maintenance

The operations to perform periodically are:

- Cleaning and checking the reusable turbine.
- Changing the disposable turbine before each test.
- Cleaning of the device
- Recharging the internal battery pack.

The maintenance operations described in the User’s Manual must be carried out with extreme care. Failing to observe the instructions may cause errors in measurement or the misinterpretation of the measured values.

Modifications, adjustments, repairs, and reconfigurations must be carried out by the manufacturer or by qualified personnel.

In the unlikely event of a problem do not attempt to repair the unit.

The parameter configuration setup must be carried out by qualified personnel. In any case the risks pertaining to an incorrect configuration setting in no way endangers the patient.

#### 4.1 Cleaning and checking the reusable turbine

Two types of turbines can be used with **Spirobank II**. The disposable turbine or the reusable turbine. Both guarantee precise measurements and have the advantage of requiring no periodic calibration. In order to maintain the default characteristics of the reusable turbine a simple cleaning procedure is required before use.

Cleaning of the disposable turbine is not required, as it is supplied clean in a sealed plastic bag. It must be disposed of after use.

#### WARNING

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

Before use perform the test described in paragraph 4.1.1 which allows to check the efficiency of the turbine. If the test result is negative perform the following procedure.

To clean the **reusable** turbine remove it from its housing by rotating it counter-clockwise and apply slight pressure with a finger from the bottom of the turbine to lift it out of its housing.

Immerse the turbine in a cold liquid solution and shake it so as to remove any impurities. Leave the turbine immersed for the time specified in the instruction of the solution.

 **WARNING**

To avoid irreparable damage to the reusable turbine please do not use any alcoholic or oily detergent solutions, and do not immerse the turbine in hot water or hot liquids.

Do not place the turbine under a direct water jet or other liquid. If no detergent solution is available, clean the turbine in clean water. Do not use compressed air to clean the turbine.

MIR suggests the use of sodium hypochlorite, tested on all MIR sensors.

Rinse the turbine by immersing it in clean water (**not hot**).

Shake off the excess water from the turbine and let it dry, position the turbine vertically on a dry surface.

Before inserting the reusable turbine in the device it is good practice to visually check that the rotor inside turns freely. Hold the turbine horizontally and slowly move it left and right and vice versa. You should be able to see the mobile equipment (blade) rotate freely. If this is not the case then the measurement accuracy can no longer be guaranteed and as such the turbine must be replaced.

Having completed the turbine cleaning procedure, insert the turbine in its housing making sure to turn it clockwise as shown by the symbol of the lock printed on **Spirobank II**.

The turbine is inserted properly by pushing it all the way in and subsequently rotating it clockwise until it stops; this bayonet mechanism ensures that the turbine is blocked inside the plastic casing.

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

 **WARNING**

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

#### 4.1.1 Proper turbine operation check

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

#### 4.2 Cleaning of the device

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

Recommended cleaning agents are:

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

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

#### 4.3 Battery charging

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



The maximum charge level is displayed with all 6 bars inside the battery.

If only one bar is shown or if the device will not even turn on the battery pack must be recharged in the following manner:

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




**⚠ WARNING**

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

**⚠ WARNING**

Operator shall not touch simultaneously the patient and the parts of non-medical equipment that are accessible to the operator during routine maintenance after removal of covers without the use of a tool.

## 5 PROBLEM SOLVING

PROBLEM	MESSAGE	POSSIBLE CAUSES	REMEDY
Spirobank II does not turn on	\	The battery pack could be discharged	Connect the device to the battery charger.
	\	The battery pack has not been properly inserted in the device	Contact a technical service center
	\	The device may have lost its internal software	Connect the device to the PC with the USB cable and update the internal software; For more detailed information please consult the MIR Spiro software user manual available on line within the software itself.
Problem when turning on the device	<b>Error in ram memory Recovering data Please wait</b>	Memory data within the device has been damaged	If the data has been restored correctly the standard turn-on process will complete itself. If this process does not finalize contact an authorized technical service center.
The device turns off and subsequently turns on again.	\	An internal error has occurred.	Check on the following website <a href="http://www.spirometry.com">www.spirometry.com</a> for a more recent internal software release of the device. Update the internal software by downloading the latest release by using the MIR Spiro software For further information consult the MIR Spiro manual available on line within the software itself.
Spirometry test results are unreliable	\	The turbine may contain dirt or foreign matter.	Clean the turbine as explained in paragraph 5.1; if necessary replace the turbine with a new one.
	\	The test was not performed correctly.	Repeat the test and follow closely the indications shown on the screen.
Certain spirometry parameters are not shown at the end of a test.	\	Personalized parameter setting in the service menu.	Check the parameter setting in the item "PARAMETER setting" within the Service Menu as explained in paragraph 2.5
Problem during battery pack recharging	<b>Damaged battery pack</b>	The battery pack could be damaged or simply mispositioned.	Contact a technical service center
Unforeseeable error of the memory	<b>Error in memory</b>	Data in archive is damaged.	Contact a technical service center
The device has frozen due to an unforeseeable event	\	\	Press the power  key 3 times and wait approximately four seconds after which the device will reset itself and turn on again

**⚠ WARNING**

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

## LIMITED WARRANTY CONDITIONS

**Spirobank II**, together with its standard accessories is guaranteed for a period of:

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

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

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

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

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

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

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

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

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

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

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

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