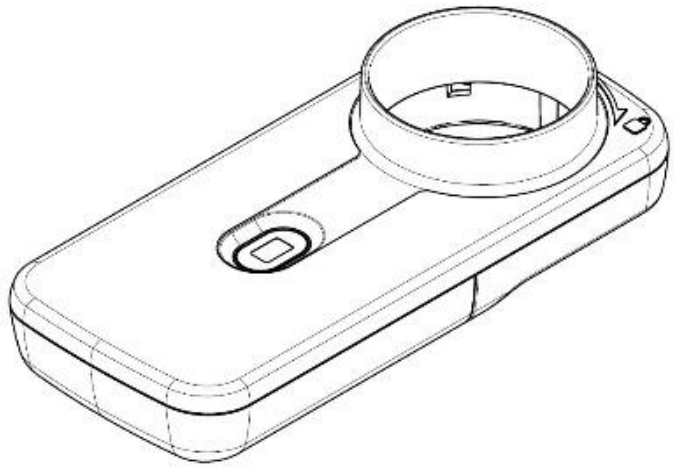
SPIROBANK Oxi



Before you use your Spirobank Oxi, please read this user manual, the labels and all the information provided with the product.

User Manual Rev 1.5 Publication date 04.02.2022

CE 0476

WARNING: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR BY REQUEST OF A PHYSICIAN

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

Before you use your Spirobank Oxi, please read this user manual, the labels and all the information provided with the product.

Before connecting **Spirobank Oxi** to a smartphone, install the MIR SPIROBANK application, available by smartphone in both iOS and Android operating systems. The application enables display of the data measured by the device.
The package includes:

- The **Spirobank Oxi** device
- The turbine sensor (FlowMir®) disposable or turbine reusable
- plastic mouthpiece
- 2 AAA batteries
- The User Manual

After removing the device from its packaging, check that there is no visible damage. If it looks damaged, do not use the device and send it straight back to the manufacturer for replacement, where appropriate.

Keep the original packaging!
If your product has a problem, use the original packaging to ship it back to your local distributor or to the manufacturer.
The manufacturer's address is as follows:

EUROPE and WORLDWIDE:
MIR SRL VIA DEL MAGGIOLINO, 125 - 00155 ROME (ITALY)
Tel. +39 0622754777 - Fax +39 0622754785
Website: www.spirometry.com - Email: mir@spirometry.com

United States of America
MIR Medical International Research USA, Inc.
5462 S. Westridge Drive
New Berlin, WI 53151 - USA
Tel + 1 (262) 565 – 6797
Fax + 1 (262) 364 – 2030
Website: www.spirometry.com - Email: mirusa@spirometry.com

MIR cannot be held responsible for any damage caused by users failing to follow these instructions and/or the warnings contained in this manual.

1. INTRODUCTION

1.1 Intended use

Spirobank Oxi, spirometer and pulse oximeter, is intended to be used by a physician or by a subject under the instruction of a physician or the patient to assess lung function. The device is designed for adult and pediatric patients, excluding infants and neonates, and can be used at home, in a factory, pharmacy, hospital or medical surgery.

1.1.1 Restrictions on Use

Analysis of the test results alone will not be enough to diagnose your clinical condition; you will need a medical examination which will take your clinical history into account as well as any other tests recommended by the physician.
Diagnosis and appropriate treatments are to be made and given only by a qualified physician.

The device is intended for use by one patient only at a time. Take care not to attribute the measurements from one patient to another. Before using the device on a new patient, first erase the previous patient's data from the memory and enter the new user's details data (date of birth, origin, weight, height, gender).
At each change of patient clean the device and check that a new FlowMir® is being used or disinfect the re-usable turbine and the mouthpiece, as described in point 3.

1.2 Description of product

Spirobank Oxi is a pocket-sized system for measuring the following respiratory parameters:

- PEF (Peak Expiratory Flow)
- FEV1 (Forced Expiratory Volume in 1 sec)
- FVC (Forced Vital Capacity)
- FEF2575 (Average flow between 25% and 75% of the FVC)
- FEV6 (Volume expired in the initial 6 seconds of the test)
- FEV1/FVC (Tiffeneau index)

The device also measures the parameters related to the oximetry test in particular:

- SpO2 (percentage of oxygen saturation in the blood)
- BPM (heart rate)

The device connects to a smartphone via Bluetooth SMART technology. Connection is automatic once the **MIR SPIROBANK** application has been installed on the smartphone.

Measurement is performed by a turbine sensor, and is based on the infrared interruption principle. This principle ensures that the measurement is accurate and reproducible.

The advantages of this type of sensor are:

- Unaffected by the humidity and density of the gas
- Shockproof and unbreakable
- Inexpensive to replace

Spirobank Oxi can use either the FlowMir® disposable turbine or the reusable turbine with plastic mouthpiece.

The **F/V** version calculates also the following parameters:

- **FIVC -** Forced Inhalation Vital Capacity
- **FIV1 -** Forced Inspiratory Volume in the 1st second
- **PIF -** Peak Inspiratory Flow
- **FEF25 -** Forced Expiratory Flow at 25% of FVC
- **FEF50 -** Forced Expiratory Flow at 50% of FVC
- **FEF75 -** Forced Expiratory Flow at 75% of FVC
- **EVol -** Extrapolated Volume

- **FEV05 -** Forced Expiratory Volume in the initial 0,5 seconds of the test
- **FEV075 -** Forced Expiratory Volume in the initial 0,75 seconds of the test
- **FEV2 -** Forced Expiratory Volume in the initial 2 seconds of the test
- **FEV3 -** Forced Expiratory Volume in the initial 3 seconds of the test
- **FET -** Forced Expiratory Time
- **PEF Time -** Time to achieve 90% of the PEF

Also in the **F/V** version, the **Flux / Volume curve** (expiratory and inspiratory) is enabled in real time during the execution of the spirometry.

The measurements are transferred in real time from the device to the smartphone.

1.3 Information on the parameters measured by Spirobank Oxi

Spirometry tests

PEF is the maximum speed of the air when you exhale as hard as possible after filling your lungs completely.
FEV1 is the volume of air expelled during the first second of the same exhalation.
FVC is the volume of air expelled during the total exhalation.
FEF2575 is the average flow between 25% and 75% of the total volume of air expelled during the total exhalation (FVC).
FEV6 is the volume expired in the initial 6 seconds of the test.

In addition to these parameters, the following parameters are also calculated in the **F/V** version:

PIF is the maximum speed of the air when you inspire as hard as possible after the exhalation.
FIV1 is the volume of air inspired during the first second after the exhalation.
FIVC is the volume of air inspired during the total inspiration.
FEF25 is the Forced Expiratory Flow at 25% of FVC
FEF50 is the Forced Expiratory Flow at 50% of FVC
FEF75 is the Forced Expiratory Flow at 75% of FVC
EVol is the back Extrapolated Volume
FEV05 is the Forced Expiratory Volume expired in the initial 0,5 seconds of the test
FEV075 is the Forced Expiratory Volume expired in the initial 0,75 seconds of the test
FEV2 is the Forced Expiratory Volume expired in the initial 2 seconds of the test
FEV3 is the Forced Expiratory Volume expired in the initial 3 seconds of the test
FET is the Forced Expiratory Time and measures the length of the expiration in seconds
PEF Time is the Time to achieve 90% of the PEF

For each of these parameters, the result is a number shown on the smartphone screen.
A high number (associated with a green light) usually means that the air is moving easily through your lungs. If you have asthma (or another respiratory disease) and have an obstructive episode, the air cannot generally be expelled as forcefully as possible, so your parameters will be lower.

Spirobank Oxi is a valid help in identifying whether there is an obstruction at a determined time and of what type of obstruction it is.
Regular use of the device enables tracing the possible variations of the parameters. These variations might require suitable treatment, according to the prescription of the physician.
As well as viewing the **measurements** of the respiratory parameters, the device also provides a **normal baseline value**.

Oximetry tests
During the oximetry test the device provides the instantaneous value of:
SpO2 (percentage of saturated oxygen in the blood)
BPM (heart rate)

1.4 Determining your baseline values

The importance of any changes in airflow from one measurement to the next depends upon how much they are different from the baseline value you should reach when you are in healthy physical condition.

The application can calculate the predicted value, i.e. the expected value for healthy people, depending on age, height, gender, and origin. The application calculates the predicted value that has been endorsed by ATS (American Thoracic Society): GLI-2012 All-Age Multi-Ethnic Reference Values by Philip H. Quanjer, Sanja Stanojevic, Janet Stocks, Tim J. Cole. For the PEF parameter, the predicted values are calculated according to Knudson, R. J., Slatin R. C., Lebowitz, M. D., Burrows, B., The Maximal Expiratory Flow-Volume Curve – Normal Standards, Variability, and Effects of Age, AM REV RESPIR DIS, 1976 113;587-600.

It is important to know that these predicted values are average numbers for large groups of people. The patient may have a higher measurements than the predicted value while not being healthy. Or the patient may have lower measurements than the average and still be healthy.

2. USE OF Spirobank Oxi

2.1 Inserting the batteries

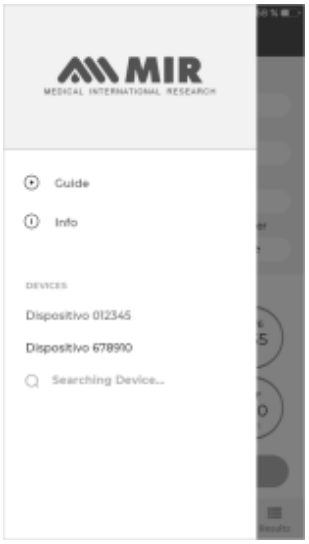
Follow the instructions in the Maintenance section for correct battery insertion.

2.2 Installing the MIR SPIROBANK application

First you need to install application on your remote device (smartphone or tablet). The application is available for smartphone/tablet in both iOS and Android environments.
Once the application is available, enter the patient's data; MIR SPIROBANK application will automatically calculate the baseline reference values.

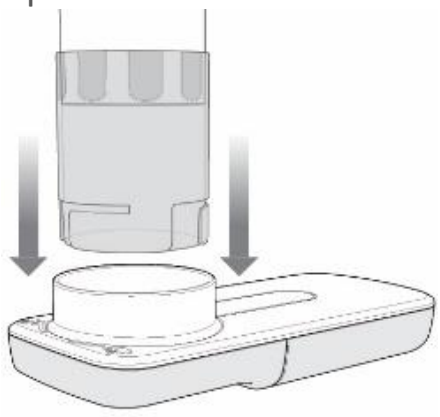
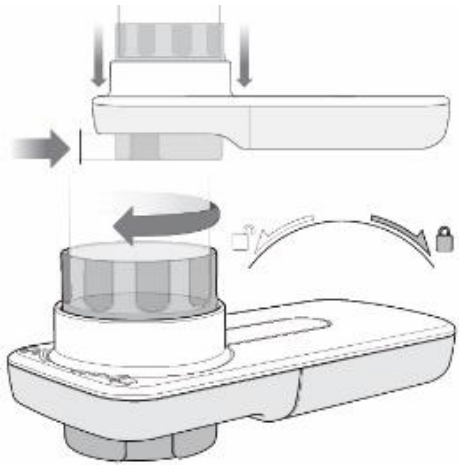
2.3 Connection between Spirobank Oxi and smartphone

The connection between the **Spirobank Oxi** and the smartphone is automatic. To check whether there is a connection, read the messages from the application.



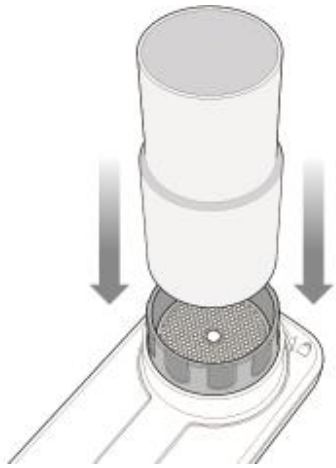
2.4 Performing the spirometry test

To perform the test correctly, follow the instructions below.

1 Push the FLowMir® turbine into the slot until it stops 	2 Turn the turbine clockwise until it stops 

3

Insert the mouthpiece at least 0.5 cm into the turbine socket



4

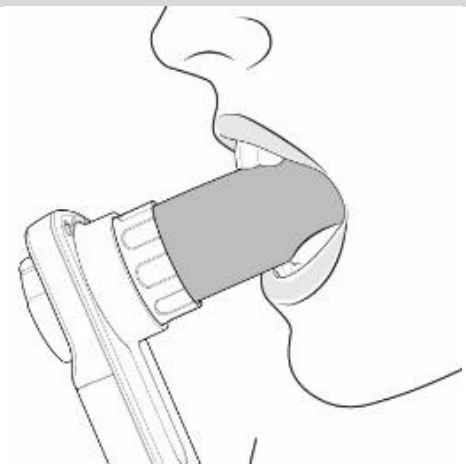
Pick up the **Spirobank Oxi** with your hands as if it were a mobile phone.

Make sure not to obstruct the turbine with your hand.

5

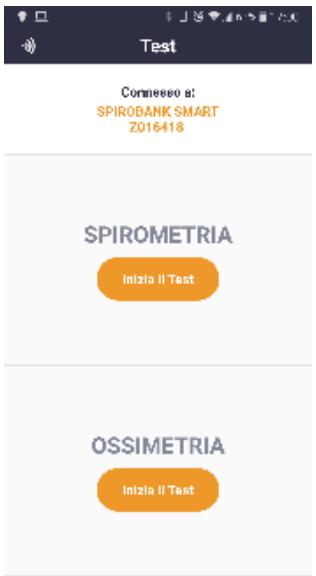
Insert the mouthpiece in your mouth beyond your teeth, and close your lips tightly over it so that the air you breathe has to pass only through the mouthpiece.

To prevent turbulence that might otherwise affect the results do not put your tongue in the mouthpiece. Do not bend your neck.



6

Tap the "Start Test" icon under SPIROMETRY on the app MIR SPIROBANK.



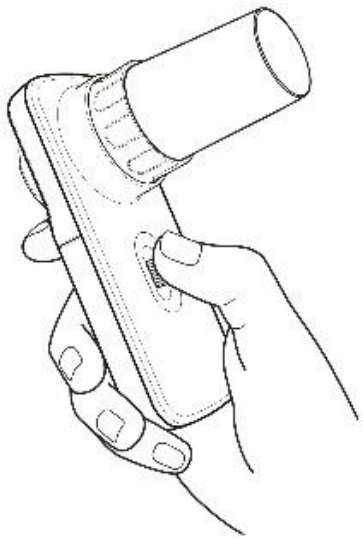
7	Take a deep breath and blow out as hard as you can. **It is best to do the test standing or sitting upright. (it makes no difference to test results)** 	
8	After exhalation, slowly remove the device from the mouth and check the data on the smartphone. **After taking the mouthpiece out of your mouth, avoid sudden movements because this will push air into the turbine and a flow value will be measured that may affect the test results.** Repeat the test three times. The MIR SPIROBANK will save the highest value.	

The device shows an error message if the exhalation start-up was not satisfactory and if the exhalation did not finish satisfactorily.

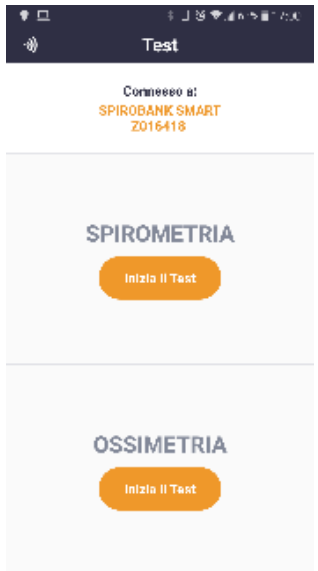
2.5 Performing the oximetry test

To perform the test correctly, follow the instructions below.

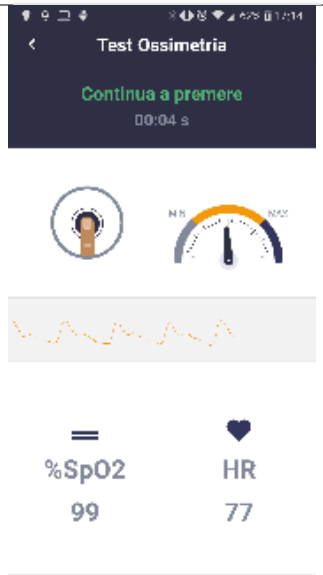
1 Place the thumb of the hand holding the **Spirobank Oxi** on the sensor as in the image



2 Tap the "Start Test" icon under OXIMETRY on the MIR SPIROBANK application.



3 During the test the perfusion index is reported with a bar indicator.
Minimum duration of a test is 30 seconds.



The device displays an error message if the sensor is not functioning and if the finger is not positioned on the sensor.
If the signal detected is not of sufficient quality to estimate the oximetry parameters; the parameters are not displayed.

2.6 Evaluating the test

For the spirometry measurements, three individual tests are made in each test, after which the **MIR SPIROBANK** application automatically selects the highest value and compares it with the baseline value (personal best value) set during configuration.
For the oximetry measurements, each test saved in the memory appears in the Results section, which contains the value of SpO2, the value of cardiac frequency, the date and time of the test and any notes.

WARNING: ASK YOUR PHYSICIAN OR LICENSED HEALTHCARE PROFESSIONAL TO WATCH YOU USING THE Spirobank Oxi BEFORE RELYING ON ANY MEASUREMENT.

WARNING: WHEN Spirobank Oxi IS USED TO MONITOR A LUNG CONDITION SUCH AS FOR EXAMPLE ASTHMA YOU SHOULD BE UNDER THE CARE OF A PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL.

WARNING: THE PLAN OF ACTION PROVIDED BY YOUR PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL WILL INDICATE WHICH ACTION TO TAKE IN A CASE IN WHICH THERE ARE RELEVANT VARIATIONS IN VALUES.

WARNING: INDEPENDENTLY OF YOUR VALUES, AND EVEN WHERE THE DEVICE IS NOT INDICATING ALARMS, IF YOU ARE SHOWING SIGNS AND SYMPTOMS SUCH AS THORACIC CONSTRICTION, SHORT BREATH, COUGH OR DYSPNOEA, CONTACT YOUR PHYSICIAN OR LICENSED HEALTHCARE PROFESSIONAL.

2.6.1 Results diary

The test results are automatically stored on the smartphone and can be displayed later.

2.7 Important safety warnings

⚠ **Warning: indicates a potentially hazardous situation which, if not prevented, could result in minor or moderate injury to the user or patient or damage the device.**

⚠ For monitoring elderly patients and children, and differently-able persons, the supervision of an adult is required.

⚠ The manufacturer cannot be held responsible for damage caused by the failure of the user to follow these instructions correctly.

⚠ Only original accessories as specified by the manufacturer must be used with the device.

⚠ Check that no impurities or foreign bodies, such as skin or hairs, have accumulated inside the turbine. Any modifications not expressly approved by this Company could compromise use of the device by the user.

⚠ Check that there are no elements obstructing the oximetry sensor. Any modifications not expressly approved by this Company could compromise use of the device by the user.

⚠ In the event of an accident of any kind arising from use of the device, you are strongly recommended to inform your physician so that he/she can notify the authorities as required by local legislation.

⚠ The device 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 chemical substances.

⚠ Use and store the device in compliance with the environmental conditions specified in the Technical Specifications. If the device is exposed to environmental conditions other than those specified, it might malfunction and/or display incorrect results.

⚠ The maintenance operations set out in the User Manual must be carried out with the utmost care. Failure to follow the instructions may lead to measurement errors or misinterpretation of the measured values.

⚠ Do not modify the device without authorization from the manufacturer.
All modifications, adjustments, repairs, reconfigurations must be performed by the manufacturer or by authorized personnel.
If problems arise, do not try to repair the device yourself.

2.8 Data security warnings

The smartphone stores the user's personal data.
Potential threats such as the following:

- Malware installation
- Physical access to the smartphone
- Interception of communications
- Physical damage to the smartphone
- Theft of the smartphone

could have an impact on the integrity or confidentiality of such data, such as:

- Accessing of data in memory by unauthorized persons
- Loss of data in memory
- Inability to use smartphone for communications
- The integrity check of the data is made automatically and in case of transmission error it will create a corruption of the data and the file will be illegible.

The following actions help reduce the risk of such events:

- Do not open or install files from suspicious sources
- Use antivirus software
- Back up your data periodically
- Do not leave your smartphone unattended
- Use a password to access the data
- Always check that the data used to send the results of the tests are correct

2.9 Warnings for use in electromagnetic environments

Due to the increasing number of electronic devices (computers, cordless phones, cell phones, etc.) medical devices may be susceptible to electromagnetic interference from other equipment.
This electromagnetic interference could cause the medical device to malfunction, such as an accuracy of measurement that is lower than the declared one, and create a potentially unsafe situation.
Spirobank Oxi complies with EN 60601-1-2:2015 on electromagnetic compatibility (EMC for medical devices) for both immunity and emissions.
For the device to function properly, however, the following precautions must be taken:

- Make sure that the Spirobank Oxi and the smartphone on which the MIR SPIROBANK application is installed are no more than 2 metres apart.
- Do not use Spirobank Oxi near other devices (computers, cordless phones, cell phones, etc.) that generate strong electromagnetic fields. Keep the above-described equipment at a distance of at least 30 centimetres. If a use under lower distances is necessary, Spirobank Oxi and the other devices should be kept under observation to verify that they are functioning normally.

2.10 Notes on FCC certification

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment 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 help.

3. MAINTENANCE AND CLEANLINESS

Spirobank Oxi is a device requiring little maintenance. The following operations must be carried out regularly:

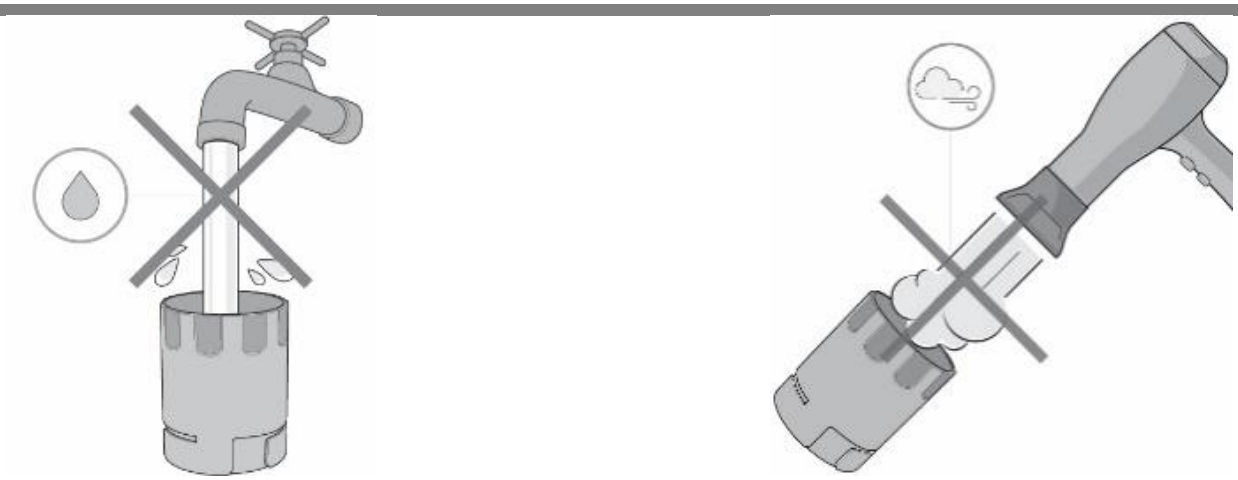
- Cleaning the reusable turbine
- Replacing the FlowMir® turbine
- cleaning of the device
- replacing batteries

The calibration of the device can be verified by carrying out a test for measuring FVC by using a calibration 3 litre syringe.

3.1 Cleaning of the reusable turbine

The following instruction should be applied in a case of reusable turbine. If the FlowMir is used, replace it after each session.

To avoid irreparable damage to the turbine, do not use detergents including alcohol or oily substances and do not immerse the turbine in water or solutions at high temperatures. Never try to sterilise the turbine in boiling water. Never try to clean the turbine under a direct jet of water or other liquids. If you do not have liquid detergents available, the turbine must be washed at least with clean water.



Correct functioning of the turbine is guaranteed only if it is “clean” and free of foreign bodies which interfere with its movement. The presence of dust or foreign bodies (such as hairs, sputum etc.) could slow or block the moving parts of the turbine and make the result less accurate, or damage the turbine itself. After each use, check the cleanliness of the turbine.

To clean the turbine, pull it out of the **Spirobank Oxi** socket by turning it counterclockwise and simply pulling it out. To make it easier to pull out, push the base of the turbine gently with a finger. Weekly cleaning is recommended. Immerse the turbine flowmeter in warm soapy water and shake the turbine for 2-3 minutes.

The hand dishwashing detergent that was tested includes the following ingredients: Aqua, coco glucoside, myristyl glucoside, lauryl glucoside, sodium chloride, sodium gluconate, sodium citrate, allyl caproate, ethylene brassylate, methyldihydrojasmonate).
Rinse in clean water and shake gently to remove any excess water. Allow to air dry on a towel. Store in a clean, dry place in your home.

After cleaning, insert the turbine into the socket in the direction indicated by the screen-printed closed padlock symbol on the **Spirobank Oxi**. To insert the turbine correctly, push it down and turn clockwise until it stops, to make sure it is fully inserted into the plastic container.

3.2 Cleaning of the mouthpiece

Make sure to clean the mouthpiece after each use. To clean the mouthpiece, simply pull it apart from the turbine. Using the same method as for the turbine, immerse the mouthpiece in warm soapy water and shake the mouthpiece for 2-3 minutes. Rinse in clean water and shake gently to remove any excess water. Allow to air dry on a towel. Store in a clean, dry place in your home.

After cleaning, insert the mouthpiece in the turbine, by pressing lightly.

3.3 Replacing the FlowMir® turbine

After each session, then every time you change patients, replace the FlowMir® turbine with a new one. Then detach the one applied to **Spirobank Oxi**, operating in reverse order to the one described in point 2.4; then apply a new FlowMir® before performing a new test session. The FLowMir® used must be disposed of in accordance with the local laws in force.

3.4 Cleaning of the device

Clean the device every time you change patients.
Use only the substances and methods listed in this chapter to clean the device.
Recommended cleaning agents are:

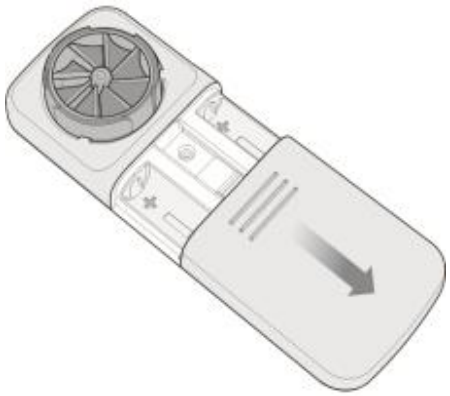
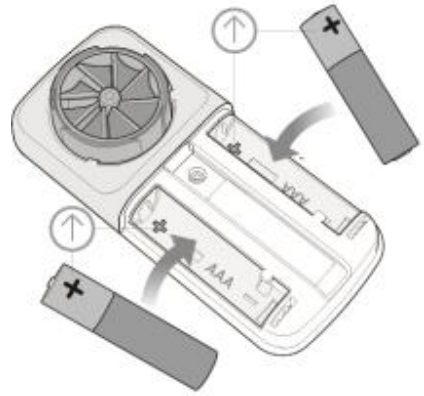
- Mild soap (diluted)

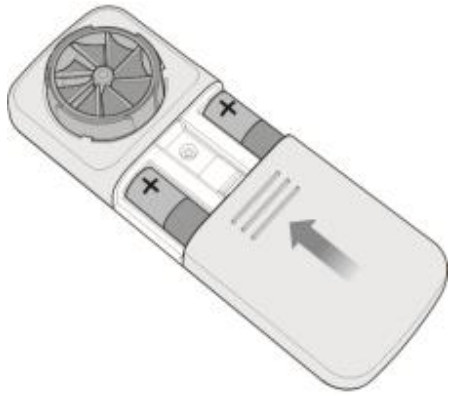
- Sodium hypochlorite bleach (10% diluted)
- Hydrogen peroxide (1.5%)

Do not use alcoholic solutions. The use of such solutions can cause cloudiness on the surface.
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.
Never immerse the device in water or other fluids.

3.5 Replacing batteries

The device continuously monitors the battery level. A message on the smartphone display alerts the user when the device battery is low. When the batteries are completely charged the device has an operational span of five years or 1000 tests, whichever comes first.

1	Remove the battery cover on the back of the **Spirobank Oxi.** 	2	Remove the two batteries and replace them with two new ones, following the polarity as indicated by the symbols in the battery compartment. 

3	Reposition the battery cover. 	**Used Spirobank Oxi batteries should only be disposed of in special containers or preferably returned to the dealer or to a special collection centre.** **In any case, all applicable local regulations must be complied with.**

4. ERROR MESSAGES & TROUBLESHOOTING

4.1 Error messages

If you encounter any problems when using the **Spirobank Oxi**, a message will appear on the smartphone display to warn of the malfunction.

MESSAGE	POSSIBLE CAUSE	SOLUTION
Bluetooth	Bluetooth is deactivated	To perform measurements with the device, you must activate Bluetooth on the smartphone. Exit the application and activate Bluetooth from the smartphone settings menu.
Battery low	When the **Spirobank Oxi** batteries are below 15% charge	Replace the **Spirobank Oxi** batteries

4.2 Troubleshooting

If you receive an unusually low reading, it could mean that your FlowMir® meter is broken, or that the reading is accurate and your asthma is getting worse.
Check that the FlowMir® is not broken. Scrupulously follow the instructions to obtain accurate results.
If problems occur when using the device, the following points should be checked.

PROBLEM	POSSIBLE CAUSE	SOLUTION
Spirobank Oxi cannot connect with the smartphone	The Bluetooth connection is not working properly	Look for **Spirobank Oxi** on the list of recognized devices. For correct use, the smartphone needs Bluetooth version 4.0 or higher
The test results are unreliable	The turbine may be dirty	Clean the turbine as described in section 3.1. Replace the FlowMir® with a new one, by contacting the manufacturer

PROBLEM	POSSIBLE CAUSE	SOLUTION
The oximetry test has not been stored	The test was performed wrongly	Repeat the test, following the directions displayed on the screen. Avoid sudden movements when you finish exhaling
	The turbine has not been inserted properly	Insert the turbine from the front of the device by pushing it all the way down and turning it clockwise. See the *Performing the test* section
	The test lasted less than 30 seconds or the average value of the finger pressure was unsatisfactory	Repeat the test following the instructions given on the display and wait at least 30 seconds for the test to complete.

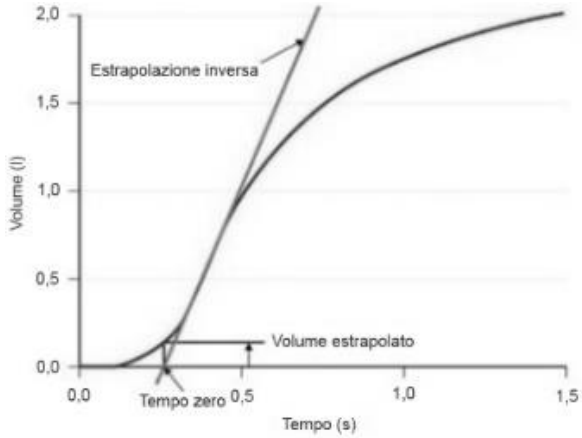
5. ACCURACY AND RELIABILITY

This device meets the requirements of the following standard:
ATS/ERS TASK FORCE: Standardization of lung function testing (volume 26/numbers 1-5: 2005)

Volume max	10 l
Volume accuracy: the higher value between	±2.5% and ±0.05 l (ATS 2019)
Max. peak flow	960 l/min (16 l/s)
Peak flow accuracy: higher value between	±10% and ±20 l/min (±0.33 l/s)

Time zero

At the point of peak expiratory flow (PEF), a tangent is drawn with a slope equal to PEF and its intersection on the abscissa defines TIME ZERO. The back extrapolated volume is the volume of gas that has already been exhaled at the point of TIME ZERO as defined by back extrapolation. The method to determine the time elapsed by TIME ZERO, t0, is given by the following equation:



$$\text{Time zero} = t_{PEF} - (V_{PEF}/PEF)$$

Where
PEF is the peak expiratory flow;
t_{PEF} is the elapsed time at PEF;
V_{PEF} is the expired volume at PEF

For the oximetry measurements, the device conforms to the requisites of the following standard:
ISO 80601-2-61:2017 Medical electrical equipment – particular requirements for basic safety and essential performance of pulse oximeter equipment

Range (SpO2)	Arms (%)
70-100 %	± 1.90
70-80 %	± 2.32
80-90 %	± 1.71
90-100 %	± 1.43

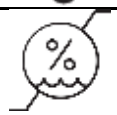
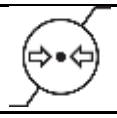
The Arms (Accuracy Root Mean Square), as mentioned in the above-cited standard, represents the accuracy of the device in terms of mean quadratic error of each SpO2 measurement, obtained by pulse oximetry, in relation to the respective reference value of SaO2, obtained by co-oximetry.
The listed ranges show the different saturation intervals of oxygen for which the accuracy has been calculated.
The accuracy of the device cannot be assessed with a tester.

6. LABELS & SYMBOLS

ID label

The label shows:

Symbol	Description
Model:	Product Name
SN	Series number of the device
	Manufacturer's name and address: MIR s.r.l. Medical International Research, via del Maggiolino 125, 00155 Rome, Italy
0476	This product is a certified Class IIa medical device, and complies with the requirements of Directive 93/42/EEC
	In accordance with **IEC 60601-1** the product and its applied parts are **type BF** and thus protected against the risks of electrical leakage.
	This symbol is required by European directive 2012/19/EU on waste electrical and electronic equipment (WEEE). At the end of its useful life this device must not be disposed of as normal domestic waste. Instead it must be delivered to a WEEE authorised collection centre for collection of waste from electrical and electronic equipment. As an alternative, the device may be returned without charge to the dealer or distributor, when it is replaced by another equivalent device. Due to the construction materials used for the device, disposal as normal waste could cause harm to the environment and/or health. Failure to observe these regulations can lead to prosecution.
IP22	Indicates the degree of resistance to liquids. The device is protected against falling drops of water if it is arranged at up to 15° from the vertical.

Symbol	Description
	The symbol is used to indicate that the product contains RF transmitters.
FCC ID	Identification showing traceability in compliance with FCC Standards
	Instructions for use symbol. Read this manual carefully before using the medical device
	Production date
Rx ONLY	Reference to US FDA regulations: use the device on prescription
	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

7. TECHNICAL SPECIFICATIONS

Measured spirometry parameters:

Peak Expiratory Flow	PEF (L/min)
Expiratory Volume in one second of testing	FEV1 (L)
Forced Vital Capacity	FVC (L)
Expiratory Volume in the initial 6 seconds of the test	FEV6 (L)
Average flow between 25% and 75% of the FVC	FEF2575 (L/s)
Tiffeneau index	FEV1/FVC

Measured oximetry parameters:

Mean saturation percentage of oxygen in the blood during the test	SpO2 (%)
Average heart rate during the test	BPM (heartbeats per minute)

Additional measured spirometry parameters in the F/V version only:

Peak Inspiratory Flow	PIF (L/min)
Inspiratory Volume in one second of the inspiration	FIV1 (L)
Forced Inspiratory Vital Capacity	FIVC (L)
Expiratory Volume in the initial 0,5 seconds of the test	FEV05 (L)
Expiratory Volume in the initial 0,75 seconds of the test	FEV075 (L)
Expiratory Volume in the initial 2 seconds of the test	FEV2 (L)
Expiratory Volume in the initial 3 seconds of the test	FEV3 (L)
Maximum Flow at 25% of FVC	FEF25 (L/s)
Maximum Flow at 50% of FVC	FEF50 (L/s)
Maximum Flow at 75% of FVC	FEF75 (L/s)
Extrapolated Volume	EVol (mL)
Forced Expiratory Time	FET (s)
Time to achieve 90% of the PEF	PEF Time (ms)

Others technical specifications

Measuring system	Bi-directional turbine (rotary blade)
Spirometry principle of measurement	Infrared interruption
Oximetry principle of measurement	Reflective LED sensor, with double wavelength
Max. peak flow	PEF 960 l/min (16 l/s)
Volume max	FEV1, FEV6, FVC: 10l
Volume accuracy (ATS 2019)	The greater value between ± 2.5% and ± 0.05 l
Peak flow accuracy	The greater value between ± 10% and ± 20 l/min (± 0,33 l/s)
Dynamic resistance at 12 l/s	<0.5 cm H_2O/L/s
SpO2 measurement range	70%-100%
SpO2 accuracy	±1.9%

Cardiac frequency measurement range	30-200 BPM
BPM accuracy	±3%
Communication interface	Bluetooth SMART (5-Ready)
Electrical power supply	2 x 1.5V AAA alkaline batteries
Measurements	Main body 109x49x21 mm
Weight	60.7 g (including batteries)
Type of electrical protection	Internal power supply
Level of electrical protection	BF type part applied
IP protection level	IP22
Applicable standard	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 15223:2016 IEC 60601-1:2005 + A1: 2012 EN 60601-1-2: 2015 EN IEC 60601-1-6: 2010+Amd2013 EN 60601-1-11: 2015 ISO 80601-2-61: 2017 IEC 62304:2006/A1:2015
Conditions of use	Device for continuous use
Conservation conditions	Temperature: MIN -25°C, MAX +70°C Humidity: MIN 10% UR; MAX 93% UR
Transport conditions	Temperature: MIN -25°C, MAX +70°C Humidity: MIN 10% UR; MAX 93% UR
Operating conditions	Temperature: MIN +5 °C, MAX +40 °C Humidity: MIN 15% UR; MAX 93% UR
LED sensor wavelengths	Red light: 660 nm** Infrared light: 880 nm**

Mean maximum optical power in output	1.2 mW

** this information can be useful for the physician.

⚠ Warning: Life time - the expected life time (or service life) of the device if properly used and stored is 5 years.

8. BLUETOOTH WIRELESS TECHNOLOGY INFORMATION

Bluetooth compliance:	Bluetooth 5-Ready
Operating Frequency:	from 2.4 GHz to 2.4835 GHz
Max Output Power:	TX: 0 dBm; 1 mW
Operating Range:	radius of 10 metres (range of vision)
Network Topology:	Star - bus
Operation:	Server
Antenna type:	Antenna integrated in the module
Modulation Technology:	FHSS
Modulation Type:	GFSK
Data Rate:	1 Mbit/second
Data latency:	7 – 40 ms
Data Integrity:	Adaptive frequency hop, Lazy Acknowledgement, CRC at 24 bit, message integrity check at 32-bit
Format:	Sending data packages every 60 ms. It includes 3 control bytes to enable the host to detect any missing packages and the device to re-transmit them.
Quality of Service:	This device uses Bluetooth Smart technology for wireless communications, so as to provide reliable communication in electrically noisy environments and transmit data packages every 60 ms. It includes 3 control bytes to enable the host to detect any missing packages and the device to re-transmit them. In the event of the connection being interrupted, the app

	changes status, from connected to not-connected, and becomes immediately available for a connection.
Bluetooth Profiles supported:	Profile based on GATT
Authentication and Encryption:	Supported
Encryption Key Size:	AES 128 bit with Counter Mode CBC-MAC and application level defined by the user

The Bluetooth® word mark and logo are registered trademarks owned by Bluetooth SIG, Inc.

8.1 Communication at radiofrequency (RF)

This device conforms to the FCC standards (United States Federal Communications Commission) and to the international standards on electromagnetic compatibility. The following information is provided in accordance with the FCC (Federal Communications Commission) rules.

The device complies to Part 15 of the FCC Standards. Operation is subject to the following conditions: (1) This device must not cause damaging interference and (2) this device must accept any interference received, including the interference which might cause an undesired functioning.

The device does not interfere with the radiofrequency signals transmitted from external sources. The FCC standards were conceived to provide reasonable protection against excessive radiofrequency interference and to prevent malfunctioning of the device caused by undesired electromagnetic interference.

8.2 Interference in radiofrequency (RF) caused by other wireless devices

The majority of consumer electronic devices on the same frequency band as used by Spirobank Oxi can prevent the uploader or the mobile device from receiving the data.

This equipment has been tested and conforms to the limits for Class B digital devices in accordance with Part 15 of the FCC Standards. These limits are conceived to provide reasonable protection from damaging interferences in a residential context. 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. It is not however possible to guarantee that these interferences will

not occur in a particular installation. The device causes damaging interference with the reception of radio or tv signals, which can arise by switching the equipment on or off; the user is advised to try to correct the interference by increasing the distance separating the equipment from the receiver.

9. WARRANTY TERMS

Spirobank Oxi is guaranteed for:

- 12 months in the case of professional use (physician, hospital structure, etc.)
- 24 months if the product is bought directly by the final user.

The warranty period is effective from the date of purchase, which must be proven by an invoice or sales receipt.

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, including the turbine flow meter, are specifically excluded from the terms of this guarantee.

The product warranty shall not apply, at the discretion of the manufacturer, in the following cases:

- Improper installation, improper operation of the device, or if the installation does not comply with local technical or safety regulations in the Country where the device was purchased
- Use of the product for purposes other than those provided or failure to follow instructions
- Repair, adaptation, modification or tampering by personnel not authorised by the manufacturer
- Damage caused by lack of or incorrect maintenance
- Damage caused by anomalous physical or electrical stresses
- Damage caused by defective electric supply or the equipment to which the product has been connected
- Serial number altered, deleted, removed or rendered illegible

The repair or replacement described in this warranty is provided for goods returned at the customers' expense to certified service centres authorized by the manufacturer. For details of these centres please contact either your local supplier or the manufacturer.

Customer shall be responsible for all transport, customs and delivery charges regarding the goods.

Each product, or accessory, sent in for repair must be accompanied by a clear and detailed explanation of the fault. Forwarding to the manufacturer requires the written permission of the manufacturer himself.

MIR Medical International Research reserves the right to replace the product or bring modifications deemed necessary to it.