GENERAL INFORMATION

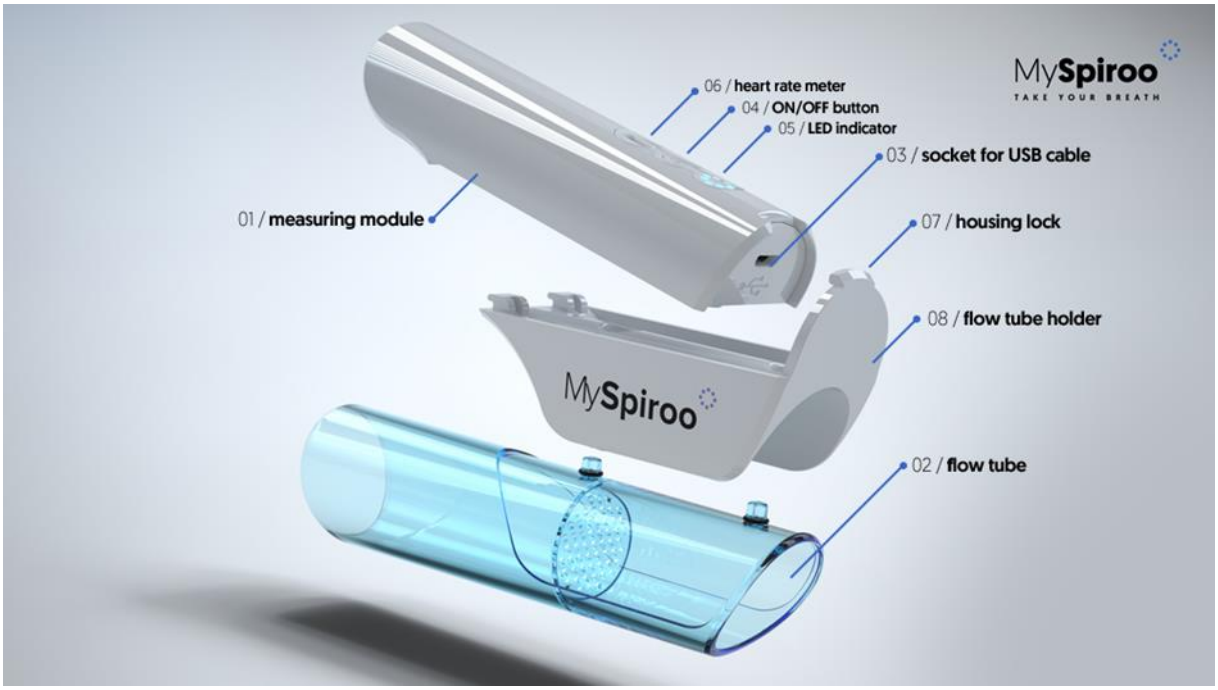
MySpiroo is a personal, connected and ultraportable spirometer with a dedicated mobile application for your smartphone. The device encompasses all of the most important and widely used spirometry parameters. The respiratory parameters that can be measured using MySpiroo include: FVC, FEV1, FEV1/FVC, PEF, FEF 25-75, VC, VPTEF_VE, TPTEF_TE, etc. Additionally, MySpiroo also measures cardiovascular (heart rate) and environmental parameters (temperature, pressure, humidity). The device works with iOS and Android operating systems. It is designed for self-monitoring by patients suffering from asthma, COPD and cystic fibrosis. MySpiroo is also available for physicians to examine their patient's spirometry parameters in-hospital/outpatient setting. With MySpiroo, you can archive your examination results in the application and MySpiroo Health Cloud.

MySpiroo spirometer consists of:

- Measuring unit which houses the electronic sensors
- Flow tube holder which is the attachment site for the flow tube to the measuring module
- Flow tube
- Mobile application available on the AppStore or Google Play
- USB cable

Additional equipment:

- Antibacterial mouthpiece filter (for single use)
- Nose clip



INTENDED USE

MySpiroo is a remote lung function monitoring system (spirometer) with additional features to measure peak flow, heart rate, temperature, atmospheric pressure and humidity. MySpiroo is intended to be used to monitory respiratory function by measuring:

- Respiratory parameters: FVC, FEV1, PEF, Tiffeneau-Pinelli Index (FEV1/FVC), FEF25, FEF50, FEF75, VPTEF_VE, TPTEF_TE
- Cardiovascular parameters: Heart rate
- Environmental parameters: Temperature, Atmospheric Pressure, Humidity

MySpiroo is intended for use by healthcare professional in in-hospital/outpatient setting or by patients suffering from asthma, COPD or cystic fibrosis who understand how to perform a high quality spirometry evaluation. Persons wanting to self-monitor may also use the device.
MySpiroo is not recommended for children under 5 years of age.

SETTING UP YOUR DEVICE

MySpiroo spirometer is operated by MySpiroo application on iOS and Android. The device requires the current version (iOS version 8 or later/Android version 4.1 or later) of the application. The device will be compatible with iPhone 5s or later.

In order to prepare the device for operation please follow the instructions below:

1. Make sure the system contains all elements (iPhone, MySpiroo Application, Measuring module, flow tube holder, flow tube, antibacterial filter)
2. Download the MySpiroo Application from Apple App Store or Google and install it according to the instructions displayed on the screen of your mobile device
3. Turn on MySpiroo with the ON/OFF button
4. Pair the device with the MySpiroo Application
5. Check the battery level of the device (can be done through the application)
6. Connect the flow tube to the measuring module
7. Attach the antibacterial filter to the flow tube
8. Follow in-app instructions to conduct: spirometry, heart rate, peak flow

Your MySpiroo spirometer will communicate with your mobile device by Bluetooth 4.0 (BLE) technology. The messages are displayed in the mobile application on the screen of your smartphone. Additionally, there are LEDs on the MySpiroo device.

The meaning of LEDs messages:

One-time flashing of all the diodes one by one 360° to the moment the light is steady	Starting the device
Diodes flashing in a sequence in a circular cycle to the moment the light is steady	Pairing of the MySpiroo device with a Smartphone
All the LEDs flashing smoothly	Bluetooth data transmission during the measurement
4 of 8 diodes flashing	Low battery level - connect to a power source
Another one LED is flashing in the charging mode	Representation of the battery charge level

PERFORMING TESTS

Spirometry

Positioning: sitting upright, feet flat on the floor. Loosen any tight-fitting clothing. If you have dentures you can leave them in. Use chair with armrest.

(a) Open the MySpiroo application.
(b) Choose “Spirometry” from the quick-action menu.
(c) Prepare the MySpiroo device.
(d) Put on the nose clip.
(e) Click start on your mobile device whenever you are ready.
(f) Take two normal breaths through the mouthpiece.
(g) Maximal inspiration
(h) Exhale completely for >6 seconds
(i) Continue to breathe normally through the measuring system.
(j) Repeat the f – i sequence at least 3 times but no more than 8 (3 correct measurements are required to do the test).
(k) If the test was performed properly, the results will be visible on the screen of your mobile device.

The maneuver should meet the end-of-test criteria (exhaling for ≥6s with <50 mL being exhaled in the last 2 seconds.

Peak expiratory flow test

Positioning: conventionally PEF is measured with the patient standing.

(a) Open the MySpiroo application.
(b) Choose “Peak Flow” from the quick-action menu.
(c) Prepare the MySpiroo device.
(d) Click start on your mobile device whenever you are ready.
(e) Take two quiet breaths through the mouthpiece.
(f) Inhale deeply
(g) The mouthpiece of the device is placed in the patient’s mouth with lips closed around it/
(h) Patient blows out forcefully and rapidly in a single exhalation. Repeat the f – g sequence 2 more times.
(i) If the test was performed properly the results will be visible on the screen of your mobile device.

Heart rate measurement

(a) Open the MySpiroo application.
(b) Choose “Heart Rate” from the quick-action menu.
(c) Prepare the MySpiroo device.
(d) Press your finger against the heart rate sensor on the measuring module.
(e) Click start on your mobile device whenever you are ready.
(f) If the test was performed properly the results will be visible on the screen of your mobile device.

Zero Flow

The purpose of Zero Flow is to increase the accuracy of the measurements conducted by the MySpiroo system.

(a) Place the MySpiroo device horizontally, away from sources generating air movement.
(b) Select the flow zeroing function in the mobile application.
(c) Wait for 5 seconds.
(d) You will be informed about the progress of the process by a bar graph on the screen of the mobile device.

Parameters measured during tests.

Symbol	Description	Unit
FVC	Forced vital capacity The volume delivered during expiration made as forcefully and completely as possible starting from full inspiration.	L
FEV1	Forced expiratory volume in one second The volume exhaled during the first second of a forced expiratory maneuver started from the level of total lung capacity.	L
PEF	Expiratory peak flow The maximum flow generated during expiration performed with maximal force and started after a full inspiration.	L/min
FEF25 FEF50 FEF75	Instantaneous forced expiratory flow when 25% (50%, 75%) of the FVC has been expired The value of airflow after expired 25% (50%, 75%) of forced vital capacity during forced expiratory maneuver.	L/min
Tiffeneau	Tiffeneau-Pinelli Index (FEV1/FVC ratio) The ratio between forced expiratory volume in one second (FEV1) to forced vital capacity (FVC - the volume of air breathed out after the deepest inhalation).	%
VPTEF/VE	Ratio of volume to peak tidal expiratory flow to total expiratory volume. Ratio between the volume during maximal flow generated during expiration (VPTEF) to total expiratory volume (VE).	%
TPTEF/TE	Ratio of time to peak tidal expiratory flow to total expiratory time Ratio between the time to maximum flow generated during expiration (TPTEF) to total expiratory time.	%
BEV	Back extrapolation volume Initial value of volume from when the other spirometry parameters are calculated (obtained as the volume from start of measurement to the point of crossing to tangent to the steepest slope on the volume-time curve).	L
ET	Expiration time	s

Explanation to the units: L – liters, L/min – liters per minutes, % – percent, s – seconds.

LIMITATIONS OF USE

Contraindications for Spirometry measurement

Absolute contraindications:

- Recent (during hospitalization) heart attack;
- Recent (during hospitalization) stroke;
- Aneurysms;
- Recent eye operation (e.g. cataract surgery);
- Increased intracranial pressure;
- Coughing up blood with no established cause;
- Collapsed or punctured lung.

Relative contraindications

- Presence of a condition that may affect the reliability of the results (e.g. nausea, vomiting, permanent cough);
- Condition after abdominal surgery or a surgery within the chest (postoperative pain preventing correct execution of the test);
- Dizziness, abnormal heart rhythm;
- Undertaking oxygen therapy, if interruption of it may cause significant decrease of blood oxygen levels.

Contraindications for Heart Rate measurement

No contraindications exist to heart rate measurement.

Contraindications for Peak Flow measurement

No contraindications exist to peak flow measurement.

OPERATING ENVIRONMENT

MySpiroo has been designed for use in a doctor's office, in a hospital setting or at home. It is not allowed to use the device in the following, adverse ambient conditions: - moist or humid environments - dust and flammable gases, vapors or solvents, strong electrostatic fields, etc.

MAINTENANCE

MySpiroo can be used as a spirometer, peak flow meter, heart rate monitor, and a monitor for environmental conditions (temperature, atmospheric pressure, humidity) in the end users vicinity. Only the original parts and accessories comply with the device, there are no third party companies that create accessories for MySpiroo. Failure to comply with this warning could result in equipment damage, incorrect measurement and loss of warranty.

The antibacterial mouthpiece filter included in the box is a disposable element. It is recommended to use MADA filters; with diameter of 29 mm. The use of a disposable antibacterial filter is necessary when using MySpiroo to test different patients. Failure to comply with this warning could result in secondary or cross-infection.

Charging

MySpiroo spirometer is a battery-powered device. A fully charged battery lasts for 5.5-6 hours with continuous use. You will be informed about the state of the battery on the mobile application or with LED diodes on the housing of the device. Flashing 4 of 8 diodes indicate low battery level. In this case please

perform a test within a few minutes and charge the device by using the included USB cable connected to any PC/Mac- type equipment.

Cleaning

The flow tube must be clean, dry with air flow canals free of foreign bodies. The tube should be thoroughly washed after each test. Possible foreign bodies and visible contamination should be removed with a soft cloth.

WARNING: It is necessary to make sure the flow tube does not contain any residue fluid every time after washing it. The air canals of the tube should be thoroughly dried. Failure to adhere to this warning may result in damaging the device and incorrect measurements.

The flow tube may be washed in running water. MySpiroo should not be washed in a dish washer.

Everyday maintenance:

- Check the patency of the flow tube;
- Check the mechanical condition of the flow tube and measurement unit.

The antibacterial filter with a mouthpiece in the set are disposable. MADA filters of 29 mm diameter are recommended.

WARNING: A disposable antibacterial filter is obligatory in case different patients are examined with the same MySpiroo device. Failure to adhere to this warning may result in cross or secondary infection.

Disinfection

Disinfection and sterilization are not necessary when using MySpiroo by one patient at home or using the antibacterial filters. The flow tube can be disinfected with disinfection liquids available on the market.

TECHNICAL PARAMETERS

Tests	FVC, SVC, pre- and post- (bronchodilator)
Operating conditions	T: min +17 /max +40 °C RH: 30-75 %
Conditions for storage	T: min +5 ° C/max +45 ° C RH: up to 93% noncondensing
Power supply	LiPo battery 3.7 V
Power consumption	50 mA
Dimensions	118x38x48 mm
Weight	0.3 kg

SAFETY PRECAUTIONS

MySpiroo has been tested by an independent laboratory, which confirms that the product complies with European safety standard EN 60601-1 and EN 60601-11 and guarantees the compliance with electromagnetic compatibility requirements defined by the European standard EN 60601-1-2. MySpiroo is continuously monitored during the production cycle, which ensures compliance with the safety levels and quality standards defined in the Directive 93/42/EEC concerning medical devices.

The safety and correct operation of the device can be ensured only if the user applies to all relevant safety rules and regulations. The manufacturer is not liable for damages caused by non-compliance with the user's instruction manual.

PRECAUTIONS:

1. The device must not be used while charging!
2. A disposable antibacterial filter is obligatory when examining patients using the same MySpiroo device. Failure to adhere to this warning may result in cross or secondary infection.
3. When being charged the battery should be kept in room temperature. It should never be exposed to temperatures below -10°C or above 45°C!
4. The USB cable attached to the device should be used.
5. The device can be charged at any time, even when the battery is not completely exhausted. In time, the battery properties deteriorate; therefore, the device may work for a shorter period and require more frequent and longer charging!
6. The device should be protected against moisture and never immersed in water. The actual spirometer (measurement unit) may be cleaned with a dry antistatic cloth.
7. The battery should not be disassembled. Caution should be taken not to drop the device, especially to hard surfaces. Do not try to dry MySpiroo using another device or heat source, e.g. a hair dryer or microwave oven.
8. If the device is damaged, it should be turned off and protected against non-intended use. Safe use is impossible if the device:

- Shows visible mechanical damage
- Does not function correctly (the LED is not lit)
- Was stored in unfavourable conditions for a long time (below -10°C or above 45°C, high humidity of above 70%)
- Was damaged during transportation.

9. The use of the device is not allowed in the following conditions:

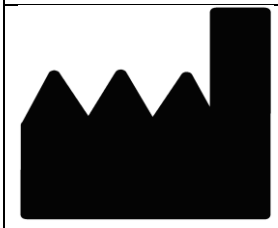
- Moisture or high humidity in the air
- Dust and flammable gases, vapours or solvents
- Storm and storm-like conditions, e.g. a powerful electrostatic field.

10. Any alterations or modifications of the device are forbidden.
11. All mechanical damage of the device may cause incorrect functioning.

12. Using, operating, and servicing of the device contrary to the instructions of this manual is not allowed and may lead to damage resulting from the user's fault, which the manufacturer is not responsible for.

MEANING OF SYMBOLS USED BY THE MANUFACTURER

SN	**Serial number**	CE	**CE- symbol indicates that the product has a certificate of conformity in Class IIa with the requirements of Directive 93/42/EEC concerning medical devices.**
	**Warning symbol WEEE; waste - electric elements; disposal in accordance with national regulations**		**USB symbol- use only a USB cable provided by the manufacturer and follow the safety regulations defined by IEC 60601 -1 -1 norm**

	**Symbol of the electrical safety - applicator of BF type according to IEC 60601-1 norm**		**Symbol - always read the user manual.**
FCC ID:	**Device compatible with Part 15 of FCC regulations (Federal Communications Commission)**		**Symbol - "The device contains a radio transmitter (RF)"; EMC compliance**
	**Symbol - Manufacturer (address data)**	**IP22- The degree of protection provided against intrusion of foreign matter and harmful effects of water, by mechanical casings and electrical enclosures.**	