



GO SPIRO[®]

INSTRUCTIONS FOR USE

Rx Only (USA)

EU	REP
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Australia Sponsor:

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Manufactured by:

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Manufactured for:

Monitored Therapeutics, Inc.
5160 Blazer Pkwy
Dublin, OH 43017
USA

Made in the UK

Introduction

If you received a GoSpiro® and these instructions, your physician has determined that monitoring your lung function will improve the ability to manage your respiratory condition. It was also determined that you would be capable of testing yourself, using your phone to collect, display and transmit the data to a remote computer where your physician can review the data you've collected.

Intended Use: The GoSpiro is intended to be used by adults and children over 5 years old in physician's offices, clinics, and home settings to conduct basic lung function and spirometry testing.

Your physician or their healthcare professional will have installed the App on your phone and instructed you how to use it. However, it is important for you to have a set of instructions to refer to should you need step-by-step assistance. This Instructions For Use will assist you with using your GoSpiro spirometer with your phone App.



For complete USA Instructions-for-Use, or for EU/UK Technical Manual in electronic format, visit: <http://monitoredrx.com/product/go-spiro/> (see Documents)

Cautions



CAUTION:

You Must Read this Instructions-for-Use Before Using the GoSpiro Spirometer.



CAUTION:

Children under the age of 10 may require parental assistance to perform tests or operate a tablet or smartphone application.



CAUTION:

Protect your smartphone or tablet from use by untrusted individuals and connection to untrusted websites.

1. Description of GoSpiro®

The GoSpiro Spirometer system includes the GoSpiro Body, Vertical Turbine Assembly, a Charging Station and a software App for your smartphone.

The only control on the GoSpiro is a power button next to an LED status indicator.

The charging station includes a USB cable which should be connected to a USB power source (computer or USB charging adapter). The charging station is keyed to assure alignment of the GoSpiro with its charging connection.

The GoSpiro is designed to enable holding by either right or left handed individuals.

1. If you use your right hand to hold the GoSpiro, install the Turbine Assembly as follows:
2. Insert the Turbine Assembly into the body of the GoSpiro with its mouthport in the direction away from the purple power button.
3. Turn the turbine assembly clockwise 90° and it will click-lock in place.
4. If you use your left hand, install the Turbine Assembly as follows:
5. Insert the Turbine Assembly into the body of the GoSpiro with its mouthport towards the purple power button.
6. Turn the turbine assembly clockwise 90° and it will click-lock in place.
7. Do not force the Turbine Assembly past the 90° position.



2. Pairing Your GoSpiro With Your Smartphone

PART 1: GoSpiro – Pairing on the App

1. **ON YOUR PHONE:**
Open the GoSpiro Setup/Pairing section on your App
2. **ON THE GOSPIRO:**
PRESS and HOLD the power button for about 6 seconds UNTIL it beeps. The LED will stop blinking and turn purple.
3. Follow the instructions on the phone's screen; the first pairing step will begin.
4. Press the appropriate button on the screen if successful.
5. If pairing fails, start again at Step 1.

3. Taking A Measurement

1. Open the GoSpiro App on your smartphone or tablet.
2. Press the power button on the top of the GoSpiro.
3. The light will flash rapidly and then stay on.
NOTE: If the light does not stop flashing, the device is not paired correctly; repeat PART 1: GoSpiro – Pairing on the App
4. The light will turn green when the GoSpiro is ready for a measurement.
5. Put the Nose Clip on, then put the Mouthpiece in your mouth, behind your teeth and begin breathing quietly.
6. Follow the instructions on your app. When instructed, take as deep a breath as you can.
7. As soon as your lungs are full, (**IMPORTANT: Do not hold your breath**) immediately exhale as fast and as hard as you can until you hear the tone indicating that you've reached a plateau.
8. After the tone, take as deep a breath in as you can.
9. Take the mouthpiece out of your mouth.

WARNINGS:

Contraindications: Do not use the GoSpiro if you have any of the following unless your physician has cleared you to perform forced exhaled lung function measurements. Failure to obtain approval from your physician if you have any of these could result in serious injury or death:

- 1.1. Hemoptysis (coughing up blood) of unknown origin
 - 1.2. Presence of a pneumothorax (collapsed lung)
 - 1.3. Presence of unstable cardiovascular status:
 - 1.3.1. Recent (within one month) myocardial infarction (heart attack)
 - 1.3.2. Uncontrolled hypertension (high blood pressure)
 - 1.3.3. Pulmonary embolism (blood clot in your lungs)
 - 1.3.4. History of a hemorrhagic cerebrovascular event (stroke)
 - 1.3.5. Unstable angina (chest pain)
 - 1.4. Recent thoracic (chest), abdominal or eye surgery (2 weeks)
 - 1.5. Nausea, vomiting or abdominal pain
 - 1.6. Thoracic or abdominal aneurysms (weak blood vessels in your chest or abdomen)
 - 1.7. History of syncope (fainting) associated with forced exhalation
 - 1.8. Active tuberculosis or Hepatitis B
- The instrument is not suitable for use in the presence of explosive or flammable gases, flammable anesthetic mixtures or in oxygen rich environments.
 - Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC). Electromagnetic interference can affect the accuracy of the GoSpiro measurements.
 - Portable and mobile radio frequency (RF) communications equipment can affect the transmission of data from medical electrical equipment. Do not use the GoSpiro in the presence of external radio equipment.
 - Keep GoSpiro away from strong sources of magnetic and RF fields, such as large electric motors, amateur radio transmitters, radar, anti-theft systems (including demagnetizers), stereo speakers, cell phone, and radio frequency identification (RFID). Note that the presence of RFID may not be obvious. Be aware that television and radio transmitters could cause interference if the device is used close to them.
 - The accuracy performance of GoSpiro can be affected by the patient spitting or coughing into GoSpiro during expiration without use of a filter or mouthport adapter. Accuracy can also be affected by extremes of temperature, humidity and altitude. Do not use or store in temperatures that exceed those listed in these instructions.
 - The mouthport filter and/or mouthport adapter must only be used on a single patient. Replace the filter in accordance with the instructions that come with it. Use by more than a

single patient can cause transmission of infectious material. Be certain to purchase an adequate supply of commercially available filters that matches the number of tests you were told to perform and the frequency of filter changes. Filters must be FDA 510(k) cleared, CE marked, or have other appropriate regulatory clearance for use for pulmonary function testing, and have a resistance of less than 0.08 kPa/L/sec (0.8 cmH₂O/L/s).

- Do not attempt to perform any service or any modifications of this equipment.
- Do not use accessories not described in this manual. Avoid exposing the GoSpiro to direct sunlight, dusty conditions, damp environments, heating appliances or radiators as these conditions can affect the performance or the life expectancy of the GoSpiro.
- Do not use the GoSpiro in a moving vehicle. Use in a moving vehicle may result in inaccurate results.
- Keep the GoSpiro dry. The limited Ingress Protection (IP22) rating of the GoSpiro case will not prevent damage from water making contact with case, leaking into the case and damaging the electronics.

CAUTIONS

- Do not force the turbine beyond the 90-degree position when inserting or removing the turbine from the GoSpiro housing as it can break the locking tabs. Note the direction of insertion and removal for left- or right-hand use.
- The charging station is keyed to assure alignment of the GoSpiro with its charging connection. Do not force the GoSpiro into the charging station.



PLEASE NOTE: The product you have purchased should not be disposed of as unsorted waste. Please utilize your local EPA or WEEE collection facilities for the disposal of this product.

CLEANING

The case of the GoSpiro may be cleaned using a damp cloth. The mouthport adapter should be cleaned after each use by rotating and removing it from the GoSpiro. Soak the mouthport adapter in 1 teaspoon of dishwashing detergent (such as Palmolive) mixed in 3.5 cups of warm water for ten minutes. Following soaking, the mouthport adapter must be rinsed clean and allowed to air dry before replacing it on the GoSpiro.

For high-level disinfection, see the GoSpiro Technical Manual online at monitoredrx.com.

SPECIFICATIONS

Transducer Type	Bi-directional vertical turbine
Volume Accuracy	±3% of reading, or 0.05 Liters, whichever is greater. Volume measurements are at BTPS conditions
Maximum Volume	8 Liters maximum
Flow Accuracy	±5% of reading, or 200 mL/sec, whichever is greater
Maximum Flow	14 Liters per second
Flow Sensitivity:	Better than 0.025 L/sec
Dynamic Impedance at 14 L/s	Turbine only: 0.070 kPa per L/s Turbine + mouthport adapter: 0.146 kPa per L/s
Recording Time	≥30s
Power Supply	Rechargeable Lithium battery
Battery life	Greater than 40,000 measurement cycles with recharging
Operating current	100 mA peak
Dimensions (GoSpiro)	80mm (W) x 100mm (D) x 120mm (H)
Dimensions (Charging Station)	50mm (W) x 100mm (D) x 50mm (H)
Weight (including battery)	125 g
Operating Conditions	17°C to 35°C, 30%RH to 75%RH, non-condensing, 70kPa to 106kPa
Transport and Storage Conditions	-20°C to 70°C, 15% to 95% RH, non-condensing

NEED HELP?

Contact your Care Provider or Study Coordinator at:

Contact the Monitored Therapeutics, Inc. Customer Support Center

Call: 614.761.3555
Monday – Friday, 8:30 a.m. – 5:00 p.m., EST

Email: support@monitoredRx.com

*You will need to have your serial number ready when you call.
You can find the serial number on your GoSpiro box or see
the label on the bottom of your GoSpiro device.*

Any serious incident that has occurred in relation to the GoSpiro should be reported to Monitored Therapeutics, Inc. and to the competent authority of the Member State (EU) in which the user or patient is established.

For more information:



Email: info@monitoredRx.com
Visit: www.monitoredRx.com
Call: 614.761.3555

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