MONITORED THERAPEUTICS INC

GoSpiro™ Spirometer

(Model Number 45-90058)

Instructions For Use

Distributed by:
Monitored Therapeutics, Inc.
5940 Venture Dr., Suite C
Dublin, OH 43017
Phone 1.614.761.3555
www.monitoredrx.com

Manufactured for:
12th Man Technologies, Inc.
7245 Garden Grove Blvd., Suite C
Garden Grove, CA 92841
1.714.705.4578

Contents:

1. Introduction

Thank you for choosing the GoSpiro™ Spirometer from Monitored Therapeutics. Please take a moment to familiarize yourself with the instructions for use detailed in this manual. For further information please refer to our website: www.monitoredrx.com.

The GoSpiro spirometer transmits real-time spirometric flow and volume data followed by diagnostic-quality spirometry measurements to computer tablets or smartphones running data collection software meeting the GoSpiro interface protocol over a Bluetooth connection for telehealthcare applications. The GoSpiro performs full flow-volume loops including inspiratory and expiratory data. The internal program performs all of the calculations for measurements to meet American Thoracic Society and European Respiratory Society requirements and has built-in quality control measurements and transmits indices of measurement quality including time to peak flow, back-extrapolated volume, total expiratory time, end-expiratory flow detection and identification of a cough during the measurement.

The GoSpiro is powered by a rechargeable Lithium battery and is charged via its USB charging station connected to a USB power source.

This device uses a turbine spirometer with a vertical turbine volume sensor to achieve a lower flow velocity detection sensitivity of 0.025L/sec. The turbine transducer measures expired air directly at B.T.P.S. (body temperature and pressure with saturated water vapor) thus avoiding the inaccuracies of temperature corrections. This transducer is insensitive to the effects of condensation and temperature and avoids the need for individual calibration prior to performing a test.

2. Package Contents

2.1. GoSpiro Spirometer
2.2. Charging Station
2.3. Mouthport Adapter
2.4. Disposable Mouthport Filter
2.5. Nose Clip
2.6. Instructions For Use

3. Intended Use

The GoSpiro Spirometer is intended to be used in adults and children over 5 years old in homecare and other non-institutional environments to conduct diagnostic spirometry testing for use in the management of common respiratory diseases such as asthma or COPD.

4. Warnings and Cautions

WARNING: Messages that alert you to conditions that may result in death or serious injury.

CAUTION: Messages that alert you to conditions that may result in minor injury or damage to equipment.

CAUTION: Read the manual before use

WARNING: The instrument is not suitable for use in the presence of explosive or flammable gases, flammable anesthetic mixtures or in oxygen rich environments.

CAUTION: The use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

CAUTION: Medical electrical equipment needs special precautions regarding electromechanical compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the accompanying documents. Electromechanical interference can affect the accuracy of the GoSpiro measurements.

CAUTION: 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.

CAUTION: The accuracy performance of GoSpiro can be affected by the patient spitting or coughing into GoSpiro during expiration without use of a filter or screen mouthport adapter. Accuracy can also be affected by extremes of temperature, humidity and altitude.

Caution: The accuracy performance of the GoSpiro can be affected if the bottom of the GoSpiro is exposed to a strong light source while operating the spirometer.

Caution: The mouthport filter should only be used on single patient. Follow manufacturer's instructions for replacement. Use by more than a single patient can cause transmission of infectious material.

Caution: No modification of this equipment should be performed.

Caution: 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.**

Caution: The charging station is keyed to assure alignment of the GoSpiro with its charging connection. Do not force the GoSpiro into the charging station.

Caution: 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.

Caution: Keep the GoSpiro dry. The Ingress Protection (IP) rating of the GoSpiro case will not prevent damage from water making contact with case, leaking into the case and damaging the electronics.

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.

5. Contraindications

WARNING: 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:

5.1. Hemoptysis (coughing up blood) of unknown origin
5.2. Presence of a pneumothorax (collapsed lung)
5.3. Presence of unstable cardiovascular status:
  5.3.1. Recent (within one month) myocardial infarction (heart attack)
  5.3.2. Uncontrolled hypertension (high blood pressure)
  5.3.3. Pulmonary embolism (blood clot in your lungs)
  5.3.4. History of a hemorrhagic cerebrovascular event (stroke)
5.4. Recent thoracic (chest), abdominal or eye surgery (2 weeks)
5.5. Nausea, vomiting or abdominal pain
5.6. Thoracic or abdominal aneurysms (weak blood vessels in your chest or abdomen)
5.7. History of syncope (fainting) associated with forced exhalation

6. Environment

6.1. **Operating Environment**
  6.1.1. GoSpiro is designed for use at home or other non-institutional environment.
  6.1.2. Use in temperatures outside the range of 17°C to 35°C, should be avoided.
  6.1.3. GoSpiro is designed to operate at altitudes from sea level up to 2588 meter (8493 feet). Use in altitudes outside the range should be avoided.
  6.1.4. GoSpiro is intended to be used indoors only. Use in humid environments outside the range of 30%RH to 75%RH, non-condensing, and ambient pressure outside the range of 700hPa to 1060hPa, should be avoided.
  6.1.5. The environment should be free of excessive vibrations, and sources of electrical noise.

6.2. **Transport/Storage Environment**
  6.2.1. The GoSpiro should only be transported or stored in the temperature range of -20°C to 70°C
  6.2.2. The GoSpiro should be only exposed to relative humidity levels between 15% to 95%, non-condensing

7. Getting Started

7.1. The GoSpiro is designed to enable two different mouthport positions for holding by either right or left handed individuals.
7.2. If you use your right hand to hold the GoSpiro, install the Turbine Assembly as following (steps showing in Figure 1):
  7.2.1. Insert the Turbine Assembly into the body of the GoSpiro with its mouthport in the direction away from of the purple power button.
  7.2.2. Turn the turbine assembly clockwise 90° and it will click-lock in place.

Caution: Do not force the turbine beyond the 90 degree position when inserting or removing the turbine from the GoSpiro housing. **Note the direction of insertion and removal for left or right hand use.**

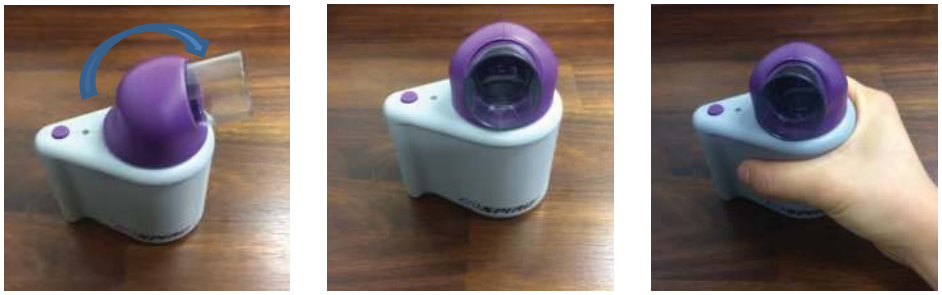

Figure 1 Insert transducer for right hand use

7.3. If using your left hand to hold the GoSpiro is more comfortable for you, install the Turbine Assembly as following (steps showing in Figure 2):

7.3.1. Insert the Turbine Assembly into the body of the GoSpiro with its mouthport towards the purple power button.

7.3.2. Turn the turbine assembly clockwise 90° and it will click-lock in place.

Caution: Do not force the turbine beyond the 90 degree position when inserting or removing the turbine from the GoSpiro housing. **Note the direction of insertion and removal for left or right hand use.**

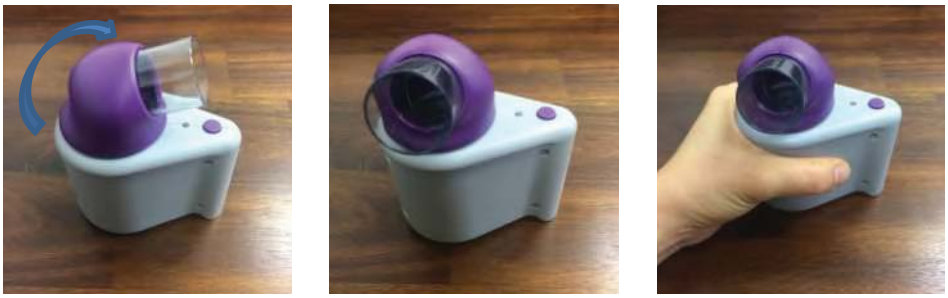

Figure 2 Insert transducer for left hand use

8. Pairing your GoSpiro with your CareConnect and/or Smartphone

If your GoSpiro has not come with a data collection device that has already been paired (the communications between them set up), then you need to follow the steps in section 7.1. If your GoSpiro has been paired already, proceed to Section 8, Performing Tests.

8.1. **Pairing the GoSpiro with the primary data collection device**

8.1.1. Ensure that the GoSpiro is turned OFF (no LED is lit).

8.1.2. Select the GoSpiro application on the data collection device and then select the option to “Set up GoSpiro” (This may be on a “Settings” page).

8.1.3. Press and hold the GoSpiro’s purple power button for at least 6 seconds and the LED on the GoSpiro will light up PURPLE.

8.1.4. If the application does not automatically scan for new devices, press the SCAN button.

8.1.5. The data collection device will now scan for the GoSpiro, locate it, configure it and turn then turn the GoSpiro off. If other unpaired Bluetooth devices besides the GoSpiro are found in the vicinity, you may be prompted to select one to connect to, instead of automatic connection occurring. If so, select the GoSpiro

8.2. **Pairing the GoSpiro with a secondary data collection device**

8.2.1. Ensure that both the GoSpiro and the primary data collection device are turned OFF.

8.2.2. Follow the steps in section 7.1 to pair the second device.

8.3. **Understanding Pairing Status with the GoSpiro**

8.3.1. When the GoSpiro is powered on, it flashes its LED while it is searching for the data collection device. The color of the LED is used to determine whether it is searching for a primary device (typically a CareConnect), or a secondary data collection device (typically a smartphone).

8.3.2. If the LED is flashing BLUE, the GoSpiro is searching for a CareConnect or primary data collection device.

8.3.3. If the LED is flashing YELLOW, the GoSpiro is searching for the secondary device.

8.3.4. To toggle between the primary and secondary data collection devices, follow the steps below:

8.3.4.1. Ensure that the GoSpiro is switched OFF.

8.3.4.2. Press AND RELEASE the power button to turn the unit on.

8.3.4.3. While the GoSpiro is powered on, press and hold the power button for at least six (6) seconds until a short beep is heard.

8.3.4.4. The GoSpiro will then shut itself off. The next time you turn on the GoSpiro it will be searching for the other data collection device.

9. Performing Tests

The GoSpiro spirometer transmits real-time spirometric flow and volume data followed by diagnostic quality spirometry indices to computer tablets or smartphones running data collection software meeting the GoSpiro interface protocol over a Bluetooth connection. The GoSpiro performs full flow-volume loops including inspiratory and expiratory data. The internal program has built-in quality control measurements and transmits indices of measurement quality including time to peak flow, back-extrapolated volume, total expiratory time, end-expiratory flow detection and cough during the measurement identification.

9.1. Be certain that the data collection device is powered on and is running the appropriate data collection software.

9.2. Press the purple power button on the GoSpiro and the LED will rapidly blink blue (yellow when searching for the secondary data collection device).

9.3. Once the GoSpiro is paired with the data collection device, the LED will be steady blue (steady yellow for the secondary data collection device).

9.4. Attach the filter to the mouthport on the GoSpiro.

9.5. Sit straight up in a chair with your feet flat against the floor.

9.6. Put the nose clip on and the mouthpiece in your mouth behind your teeth and get a good seal around the mouthpiece with your lips. Make sure your tongue is not blocking the hole in the mouthpiece.
9.7. Breathe quietly by taking normal breaths. The LED will change to green.
9.8. After a few quiet breaths, breathe out and then take as deep a breath as you possibly can to fill your lungs to their maximum capacity.
9.9. Breathe out as hard and as fast as you can and keep blowing out for at least six seconds, then take a deep breath in.
9.10. Take the filter port out of your mouth.
9.11. The test is now complete and the GoSpiro will transmit the data from your test.

10. Battery Managements

10.1. **Battery Level**

10.1.1. Data collection devices can inquire the battery charge level from the GoSpiro.

10.2. **Charging**

10.2.1. To charge the GoSpiro, plug the GoSpiro onto the charging station as shown in Figure 3.

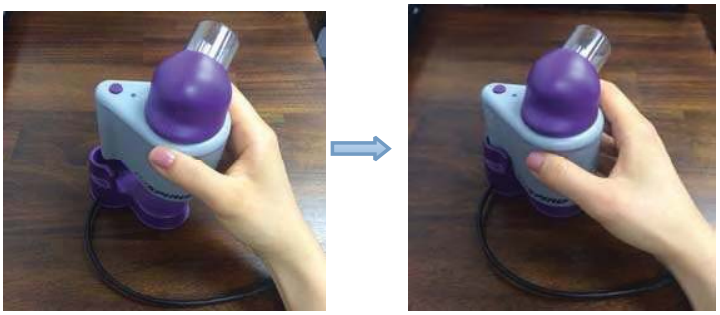

Figure 3 Plug GoSpiro onto charging station

10.2.2. Plug the USB cable into a USB port of a computer or USB power source as shown in Figure 4.

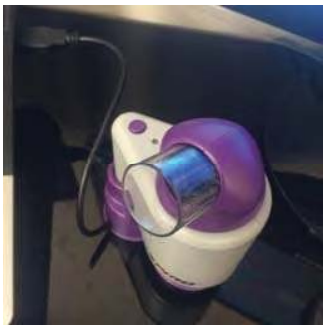

Figure 4 Plug USB cable into USB port of computer or USB power source

10.2.3. The GoSpiro cannot be used while charging.

10.3. **Battery Information**

10.3.1. Following 500 cycles of charging, the charge capacity of the battery will remain above 70% of the initial capacity.
10.3.2. On a single battery charge the GoSpiro can perform at least 140 measurements.
10.3.3. The battery of the GoSpiro should be replaced only by a factory trained technician.

11. Calibration

The GoSpiro is factory calibrated and should not require recalibration between factory servicing every two years. If errors in spirometer performance are suspected, the patient should be tested in a hospital or physician office laboratory. If performance errors are confirmed, the GoSpiro should be returned to Monitored Therapeutics for servicing and recalibration.

12. Cleaning

The casing of the GoSpiro may be cleaned using a damp cloth. Take care that no water is allowed to enter the unit. The mouthport adapter should be routinely cleaned by removing it from the GoSpiro (Figure 5) and soaking it in warm dishwashing water for ten minutes. Following soaking, the mouthport adapter should be rinsed clean and allowed to air dry before replacing it on the GoSpiro. The turbine transducer requires no routine maintenance or servicing. However, if you wish to clean the transducer it may be removed by the following procedure:

12.1. Remove the transducer by rotating the mouthpiece holder assembly anti clockwise by 90° and gently pulling from the GoSpiro housing.
If you hold the GoSpiro with your left hand, remove transducer following steps in figure 6:

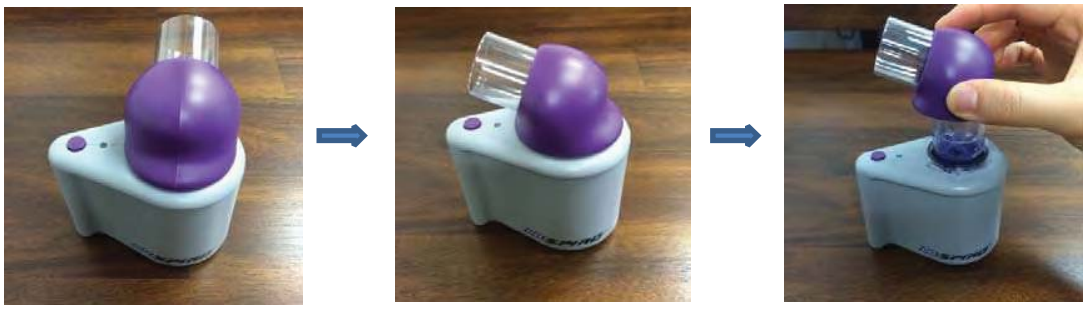

Figure 6 removal of transducer if you use GoSpiro with left hand

If you hold the GoSpiro with your right hand, remove transducer following steps in figure 7:

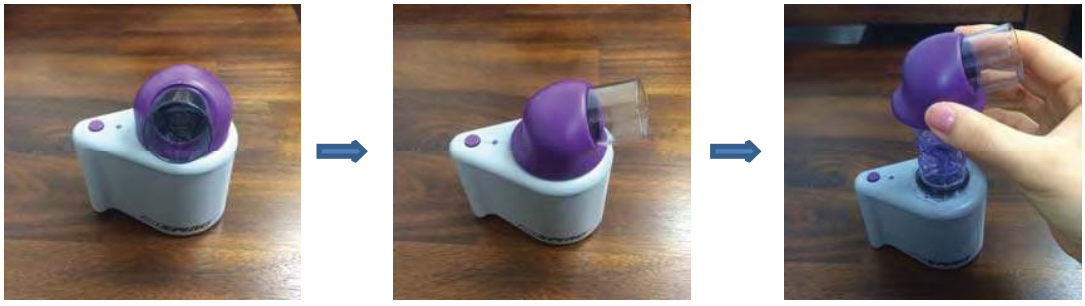

Figure 7 removal of transducer if you use GoSpiro with right hand

12.2. The transducer may now be immersed in warm soapy water for routine cleaning for a period not exceeding 10 minutes. (Alcohol and chlorine based solutions should be avoided.)
12.3. After cleaning, the transducer should be completely rinsed in distilled water and allowed to air dry.
12.4. Re-assemble the transducer into the GoSpiro housing by reversing the steps shown for disassembly.

13. Accessories

The following replaceable accessories are recommended for use with your spirometer.

13.1. Nose Clip (Part Number 45-90059)
13.2. Mouthport Filter (Part Number 45-90060)

Please contact your distributor or www.monitoredrx.com for pricing and purchasing options.

14. Maintenance

The GoSpiro is designed to require very low maintenance. Please observe the following precautions:

14.1. Replace the Turbine Assembly to a new one every 12 months as preventive maintenance.
14.2. If the Turbine Assembly is exposed to dust or material coughed into the GoSpiro, follow the cleaning procedures in Section 9.
14.3. Clean the mouth port at least weekly or sooner if contaminated by any material.

15. Servicing

Routine maintenance consists of regular calibration checks every two years and cleaning of the transducer. The GoSpiro should be returned to the factory every 2 years for transducer inspection and accuracy check unless local guidelines require a more frequent check.

Please contact info@monitoredrx.com or call 1.614. 761.7626 if your GoSpiro requires service, repair or if you need technical assistance. Before returning and product to Monitored Therapeutics, first obtain a Returned Goods Authorization (RGA) number. No product should be returned to Monitored Therapeutics except in accordance with the Warranty and Return Goods Policy below. **There are no user serviceable parts in the GoSpiro.**

16. Warranty and Liability

The GoSpiro hardware is guaranteed against manufacturing defects for 2 years.

Monitored Therapeutics, Inc. tests to ensure that the internal software meets the specification given in the product literature; it does not warrant that the software supplied in this package is suitable for your specific requirements or usage.

The warranty does not extend to any damage or corruption to the supplied media or documentation subsequent to your receipt of the product, however caused; nor does it extend to any damage or corruption of the program image on your computer subsequent to installation.

Monitored Therapeutics does not warrant the compatibility of the software or communications protocol on any computer, and takes no responsibility for any incompatibility or problems arising from the use of any operating systems or application programs on your computer, tablet or smartphone.

MONITORED THERAPEUTICS, INC. OR ITS SUPPLIERS SHALL, IN NO EVENT, BE LIABLE FOR SPECIAL, CONSEQUENTIAL, OR INDIRECT DAMAGES OR LOSS ARISING FROM THE USE OR MISUSE OF THIS PRODUCT, EVEN IF MONITORED THERAPEUTICS, INC. OR ITS SUPPLIERS HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN ANY CASE, THE ENTIRE LIABILITY OF MONITORED THERAPEUTICS, INC. UNDER THE PROVISION OF THIS AGREEMENT SHALL BE LIMITED TO THE AMOUNT PAID BY YOU FOR THE GOSPIRO.

Should you need to request replacement or repair of the software or documentation under the terms of this warranty or if you have any questions regarding this license agreement, please email info@monitoredrx.com stating the date of purchase, serial number and the name of the supplier if not purchased directly from Monitored Therapeutics.

17. Trouble Shooting Information

Should you encounter problems operating the GoSpiro consult the table below:

Problem	Possible cause	Solution
GoSpiro does not turn on.	Battery is completely discharged.	Recharge the battery.
GoSpiro turns on, then beeps three times and turns off.	Battery is discharged below operational levels.	Recharge the battery.
Blue LED light remains flashing (fast flash –10 times per second).	GoSpiro hasn't been paired with any tablet or smartphone.	Pair the GoSpiro with the tablet or smartphone that you want it to be paired with.
Two seconds after performing a forced exhalation, the GoSpiro does not beep and return results.	Turbine is still rotating due to air currents.	Ensure airflow in the room from a fan or air conditioner is not passing through the spirometer.

18. Electromagnetic Compatibility (this EMC compatibility table may be different since we are using a Lithium battery. Steve: Please review and comment)

Guidance and manufacturer's declaration – electromagnetic emissions
The GoSpiro is intended for use in the electromagnetic environment specified below. The customer or the user of the GoSpiro should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group2	The GoSpiro must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The GoSpiro is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply networks that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-3	Not applicable	
Voltage fluctuations/flicker emissions	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The GoSpiro is intended for use in the electromagnetic environment specified below. The customer or user of the GoSpiro should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95%dip in UT for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% (30% dip in UT) for 25 cycles. <5% (>95% dip in UT) for 5 s	Not applicable	
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the AC mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
The GoSpiro is intended for use in the electromagnetic environment specified below. The customer or user of the GoSpiro should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V rms 3 V/m	3 V rms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the GoSpiro, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency rangeb Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the GoSpiro is used exceeds the applicable RF compliance level above, the GoSpiro should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the GoSpiro. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the GoSpiro

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

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
W	$d=1.2\sqrt{P}$	$d=1.2\sqrt{P}$	$d=2.3\sqrt{P}$
0.01	0,12	0,12	0,23
0.1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Changes or modifications to the GoSpiro that are not expressly approved by Monitored Therapeutics can cause EMC issues with this or other equipment.
This instrument complies with directive EN60601-1-2 electromagnetic compatibility but can be affected by cellular phones and by electromagnetic interference exceeding levels specified in EN 50082-1:1992

19. Symbols

	Type BF applied part. F-TYPE APPLIED PART complying with the specified requirements of EN60601-1:2006 to provide a higher degree of protection against electric shock than that provided by TYPE B APPLIED PARTS. Internally powered equipment
	Disposal in compliance with Environmental Protection Agency (or individual state) requirements in the US or WEEE requirements in the EU.
	Caution: Read the accompanying documents
	Manufacturer
	Serial number
	Bluetooth® Bluetooth is a registered trademark of Bluetooth SIG, Inc.
	Keep dry

20. Specifications

Measurements:

FEV0.75	Forced Expiratory Volume 0.75 seconds
FEV1	Forced Expiratory Volume 1 second
FEV3	Forced Expiratory Volume 3 seconds
FEV6	Forced Expiratory Volume 6 seconds
FVC	Forced Vital Capacity
PEF	Peak Expiratory Flow
FEF25 (MEF75)	Forced Expiratory Flow at 25%
FEF50 (MEF50)	Forced Expiratory Flow at 50%
FEF75 (MEF25)	Forced Expiratory Flow at 75%
FEF25-75 (MMEF)	Forced Expiratory Flow at 25%-75%
FIV1	Forced Inspiratory Volume 1 second
FIVC	Forced Inspiratory Vital Capacity
PIF	Peak Inspiratory Flow
FIF25 (MIF75)	Forced Inspiratory Flow at 75%
FIF50 (MIF50)	Forced Inspiratory Flow at 50%
FIF75 (MIF25)	Forced Inspiratory Flow at 25%
MET25-75	Mean Expiratory Time at 25%-75%
FEV0.75/FVC	Forced Expiratory Volume 0.75 seconds/ Forced Vital Capacity
FEV1/FVC (FER)	Forced Expiratory Volume 1 second/ Forced Vital Capacity
FEV3/FVC	Forced Expiratory Volume 3 seconds/ Forced Vital Capacity
FEV0.75/FEV6	Forced Expiratory Volume 0.75 seconds/ Forced Expiratory Volume 6 seconds
FEV1/FEV6	Forced Expiratory Volume 1 second/ Forced Expiratory Volume 6 seconds
FEF50/FVC	Forced Expiratory Flow at 50%/ Forced Vital Capacity
MMEF/FVC (FEF25-75/FVC)	Forced Expiratory Flow at 25%-75%/ Forced Vital Capacity
FIV1/FIVC (FIR)	Forced Inspiratory Volume 1 second/ Forced Inspiratory Vital Capacity
R50 (FEF50/FIF50)	Forced Expiratory Flow at 50%/ Forced Inspiratory Flow at 50%
FET	Forced Expiratory Time
Vext	Back Extrapolated Volume
PEAKTIME	Time to Peak Flow
POSSIBLE_COUGH	Possible Cough Identified
LAST500V	Volume increase during last 0.5 seconds of forced exhalation (terminal flow detection)

Specification:

Transducer Type	Bi-directional high sensitivity vertical turbine
Volume Accuracy	+-3% of reading, or 0.05 liters, whichever is greater. Volume measurements are given referenced to BTPS conditions
Maximum Volume	8 liters maximum
Maximum Flow	14 liters per second maximum
Flow Sensitivity:	Better than 0.025l/
Dynamic Impedance	137 pA(l/s), measured at 14 lps
Power Supply	Rechargeable Lithium battery
Battery life	Greater than 700,000 measurement cycles with recharging
Operating current	110 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)	300 g
Operating Conditions	17°C to 35°C, 30%RH to 75%RH, non-condensing
Transport and Storage Conditions	20°C to 70°C, 15% to 95% RH, non-condensing
Service Interval	2 years

FCC warning

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.

Caution: Any changes or modifications to this device not explicitly approved by manufacturer could void your authority to operate this equipment.

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.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.