GoSpiro® Spirometer

(Model Number 45-90058)

TECHNICAL MANUAL

EU and UK

EC REP

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Made in the UK

CE 1639

Contents

1. INTRODUCTION

Thank you for choosing the GoSpiro® Spirometer from Monitored Therapeutics. You should have been trained on the use of the GoSpiro by your physician, healthcare provider or their technical associate when you received this device. Please take the time to familiarize yourself again with the instructions for use detailed in this manual by reading the entire manual before use. Additional step-by-step pictures are at the end of this manual.

ASSISTANCE:

For further information please refer to our website: www.monitoredrx.com. If you need assistance using your GoSpiro, either contact the healthcare provider who prescribed its use or contact Monitored Therapeutics at 1.614.761.3555.

The GoSpiro spirometer transmits real-time lung function data to computers, tablets or smartphones over a Bluetooth connection for tele-healthcare 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. It 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. No data or graphics are displayed by the GoSpiro. Only your healthcare provider (HCP) will have access to the data measured by the GoSpiro. Your HCP may give you instructions and/or a display device to see some of your test results.

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

This spirometer uses a vertical turbine volume sensor. 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.

GoSpiro® is a registered trademark of Monitored Therapeutics, Inc.

FCC ID: A8TBM77SPPSYC2A

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 interferences, and (2) this device must accept any interference received, including interferences that may cause undesired operation.

2. INDICATION FOR 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.

3. PACKAGE CONTENTS

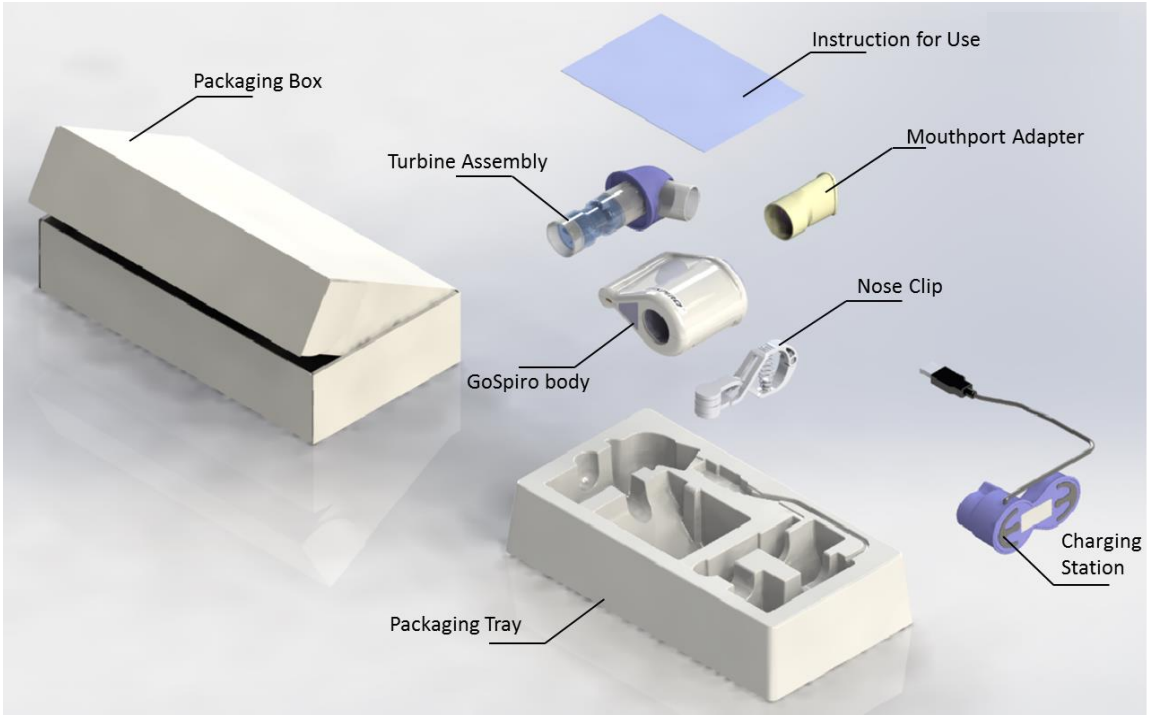

Figure 1 GoSpiro Package Contents

4. DESCRIPTION OF GOSPIRO

The GoSpiro Spirometer includes 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.

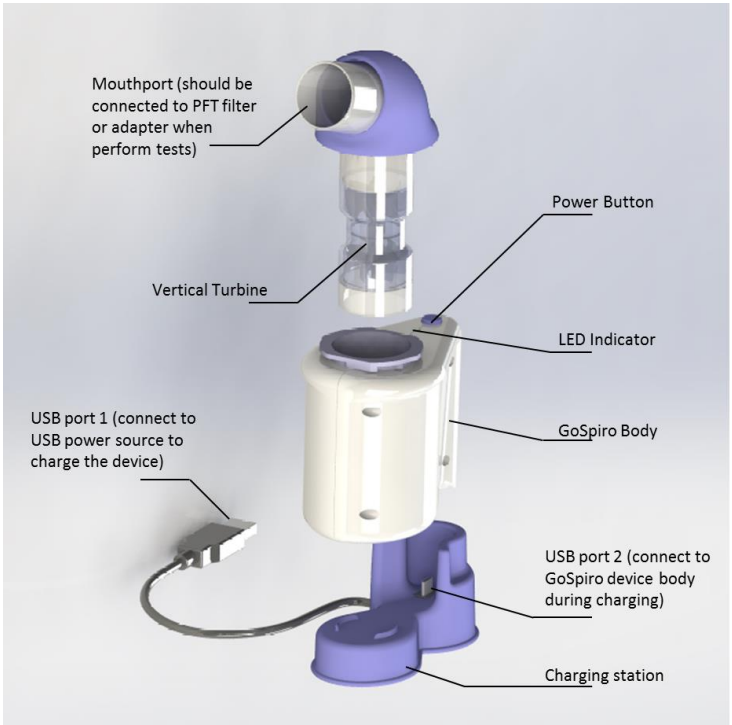

Figure 2 Physical Description of GoSpiro Device

5. WARNINGS AND CAUTIONS

WARNING: Messages that alert you to conditions that could place the patient or operator at risk.

CAUTION: Messages that alert you to conditions that may result in 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.

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

WARNING: 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.

WARNING: 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.

WARNING: The accuracy performance of GoSpiro can be affected by the patient spitting or coughing into GoSpiro during expiration without use of a filter. 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.

WARNING: Do not use without the recommended filter for multi-patient use.

WARNING: 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 filters that matches the number of tests you were told to perform and the frequency of filter changes.

WARNING: If the GoSpiro is used for more than one patient without a mouthport filter, the turbine assembly must be replaced or undergo high level disinfection before use on another patient to prevent cross-contamination.

WARNING: 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. Do not expose to bottom of the GoSpiro to a strong light source.

WARNING: Do not attempt to perform any service or any modifications of this equipment.

WARNING: Do not use accessories not described in this manual.

WARNING: It is unsafe to interconnect this GoSpiro device to other equipment not described in this manual.

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. See Section 8 Getting Started for more information.**

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.

WARNING: 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.

WARNING: Do not use the GoSpiro in a moving vehicle. Use in a moving vehicle may result in inaccurate results.

WARNING: Only IEC 60601-1 or IEC 60950-1 certified products should be used with the GoSpiro charging station or for data collection.

CAUTION: 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.

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

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

WARNING: Medication decisions must be only under the direction of a physician.

WARNING: The GoSpiro must not be used for more than an accumulated use of 24 hours (approximately 1400 testing sessions) on a single patient. It is expected that the GoSpiro will typically be used about 1 time per week for 1 minute per testing session.

CAUTION: ATS/ERS recommendations indicate that all spirometers used in laboratories be calibrated or have the calibration verified daily.

6. 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:

6.1. Hemoptysis (coughing up blood) of unknown origin
6.2. Presence of a pneumothorax (collapsed lung)
6.3. Presence of unstable cardiovascular status:
  6.3.1. Recent (within one month) myocardial infarction (heart attack)
  6.3.2. Uncontrolled hypertension (high blood pressure)
  6.3.3. Pulmonary embolism (blood clot in your lungs)
  6.3.4. History of a hemorrhagic cerebrovascular event (stroke)
  6.3.5. Unstable angina (chest pain)
6.4. Recent thoracic (chest), abdominal or eye surgery (2 weeks)
6.5. Nausea, vomiting or abdominal pain
6.6. Thoracic or abdominal aneurysms (weak blood vessels in your chest or abdomen)
6.7. History of syncope (fainting) associated with forced exhalation
6.8. Active tuberculosis or Hepatitis B

7. ENVIRONMENT

7.1. Operating Environment

7.1.1. GoSpiro is designed for use in physician's offices, clinics and in home settings .
7.1.2. Use in temperatures outside the range of 17°C to 35°C (63°F to 95°F), should be avoided.
7.1.3. GoSpiro is designed to operate at altitudes from sea level up to 2588 meters (8491 feet). Use in altitudes outside the range should be avoided.
7.1.4. 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.
7.1.5. The environment must be free of excessive vibrations, and sources of electrical noise.

7.2. Transport/Storage Environment

7.2.1. The GoSpiro must only be transported or stored in the temperature range of -20°C to 70°C (4°F to 158°F).
7.2.2. The GoSpiro must be only exposed to relative humidity levels between 15%RH to 95%RH (50hPa maximum), non-condensing.

8. GETTING STARTED

8.1. The GoSpiro is designed to enable two different mouthport positions for holding by either right or left handed individuals.

8.2. If you use your right hand to hold the GoSpiro, install the Turbine Assembly as following (steps showing in Figure 3):

8.2.1. Insert the Turbine Assembly into the body of the GoSpiro with its mouthport in the direction away from of the purple power button.

8.2.2. 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.**

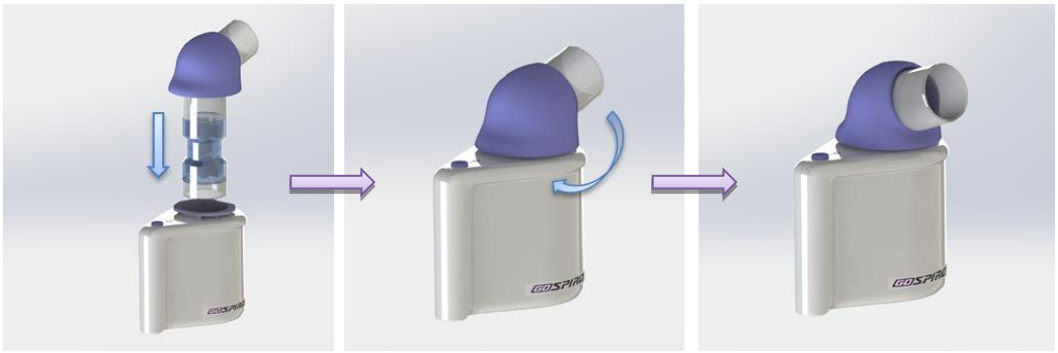

Figure 3 Insert transducer for right hand use

8.3. If using your left hand to hold the GoSpiro is more comfortable for you, install the Turbine Assembly as following (steps showing in Figure 4):

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

8.3.2. 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.**

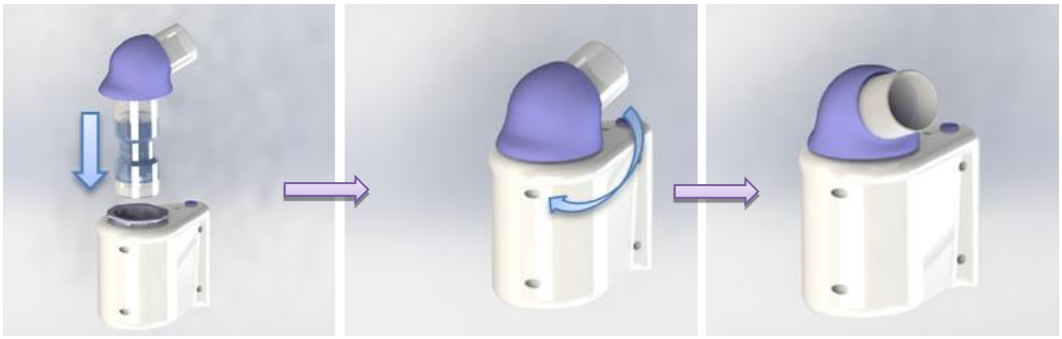

Figure 4 Insert transducer for left hand use

8.4. If using the GoSpiro for more than one patient, it is mandatory that a filter be used to prevent cross contamination between patients.

9. PAIRING YOUR GOSPIRO® WITH A GOHOME™ AND/OR SMARTPHONE

Your GoSpiro should have been paired with your smartphone already. If your GoSpiro has not already been paired (the communications between them set up), then you need to follow the steps in section 9.1. If your GoSpiro has been paired already, proceed to Section 10, Performing Tests. Also read the GoSpiro App Quick Start Guide for displaying and transmitting your data that came with your GoSpiro.

WARNING: Only IEC 60601-1 or IEC 60950-1 certified products should be used with the GoSpiro charging station or for data collection.

9.1. Pairing the GoSpiro with a data collection device

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

9.1.2. Select the "GoSpiro Setup" option on your smartphone.

9.1.3. Press and hold the GoSpiro's purple power button for at least 6 seconds. The buzzer will sound for 2 seconds and the LED on the GoSpiro will light up PURPLE.

9.1.4. Following the instructions on the screen, press the "OK" button on the screen.

9.1.5. The smartphone will now scan for the GoSpiro, locate it, and configure it. Press the "DONE" button and then the GoSpiro will turn off.

9.1.6. After the pairing process, every next time you power on your GoSpiro and select the GoSpiro App, it will flash its LED in blue, showing that it is now searching for a device it's already been paired with. If the data collection device is nearby, GoSpiro will build the connection in 4 to 5 seconds and then its LED will turn solid blue, and there will be a short beep of the buzzer, then you could use your GoSpiro to perform tests.

10. PERFORMING TESTS

The GoSpiro spirometer transmits real-time lung function data and diagnostic quality indices to computers, tablets or smartphones running GoSpiro compatible data collection software. The GoSpiro transmission interface is via 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 detection during the measurement identification.

WARNING: 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. Do not expose the bottom of the GoSpiro unit to a strong light source.

10.1. Attach the user supplied filter to the mouthport on the GoSpiro. If your filter has a 27 mm ID round outlet, attach the mouthport adapter to the filter.
10.2. Select the GoSpiro App on your smartphone.
10.3. Press the purple power button on the GoSpiro and the LED will rapidly blink blue.
10.4. Once the GoSpiro is paired with the data collection device, the LED will be steady blue.

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

10.5. Sit straight up in a chair with your feet flat against the floor.
10.6. 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.
10.7. Relax, breathe out and then take as deep a breath as you possibly can to fill your lungs to their maximum capacity.
10.8. As soon as your lungs are full, 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.
IMPORTANT: Do not hold your breath after you have inhaled to your maximum inhalation before blowing out.
10.9. Take the filter port or adapter out of your mouth.
10.10. The test is now complete and the GoSpiro will transmit the data from your test.

11. BATTERY MANAGEMENT

11.1. Battery Level
11.1.1. Data collection devices can inquire the battery charge level from the GoSpiro.
11.1.2. If the battery level is lower than 5%, the GoSpiro will shut itself down after turning the LED indicator red and sounding a warning beep. This is to prevent use of the GoSpiro when battery levels are approaching the level at which results may not be reliable.
11.2. Charging
11.2.1. To charge the GoSpiro, plug the GoSpiro onto the charging station as shown in Figure 5.

Figure 5 Plug GoSpiro onto charging station

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.

WARNING: Only IEC 60601-1 or IEC 60950-1 certified products should be used with the GoSpiro charging station or for data collection.

11.2.2. Plug the USB cable into a USB port of a computer or USB power source as shown in Figure 6. The Charging Station has a rating of 5V, 500mA.

Figure 6 Plug USB cable into USB port of computer or USB power source

11.2.3. The GoSpiro cannot be used while charging.

11.3. Battery Information

11.3.1. Following 300 cycles of charging, the charge capacity of the battery will remain above 80% of the initial capacity.

11.3.2. On a single battery charge the GoSpiro can perform at least 140 measurements.

11.3.3. The battery of the GoSpiro must be replaced only by a factory trained technician.

12. 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.

⚠ **CAUTION:** ATS/ERS recommendations indicate that all spirometers used in laboratories be calibrated or have the calibration verified daily.

13. CLEANING

Single Patient Use at Home:

The case of the GoSpiro may be cleaned using a damp cloth. The mouthport adapter must be cleaned after each use by removing it from the GoSpiro (Figure 7). 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.

Figure 7. Remove mouthpiece adapter and soak

Clinic or Physician Offices:

The case of the GoSpiro may be cleaned using a damp cloth or hospital approved disinfectant wipe. The mouthport adapter or filter are single patient use accessories and must be discarded after each use.

The turbine transducer requires no routine maintenance or cleaning. However, should you believe that the transducer needs to be cleaned, it may be cleaned by the following procedure:

13.1. Remove the transducer by rotating the mouthpiece holder assembly 90° counterclockwise and gently pulling from the GoSpiro housing.
If you hold the GoSpiro with your right hand, remove transducer following steps in figure 9:

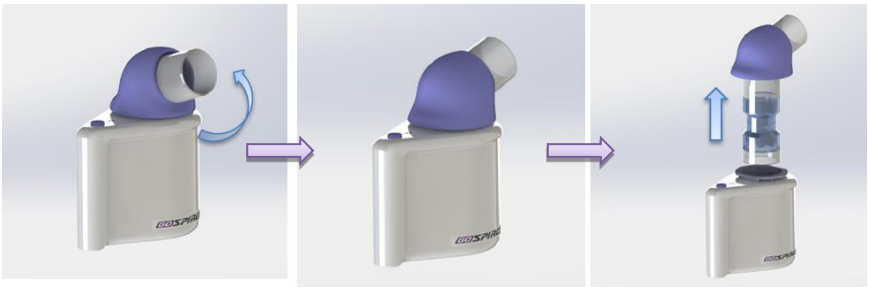

Figure 8 removal of transducer if you use GoSpiro with right hand

If you hold the GoSpiro with your left hand, remove transducer following steps in figure 8:

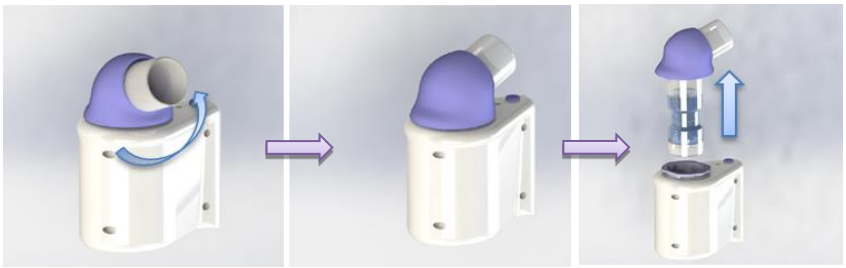

Figure 9 removal of transducer if you use GoSpiro with left hand

WARNING: The mouthport filter and/or mouthport adapter must only be used on a single patient. Follow the manufacturer's instructions for replacement. Use by more than a single patient can cause transmission of infectious material.

CAUTION: 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.

13.2. The transducer may now be immersed in 1 teaspoon of dishwashing detergent (such as Palmolive) mixed in 3.5 cups of warm water for routine cleaning for a period not exceeding 10 minutes. (Alcohol and chlorine based solutions must be avoided.)

13.3. After cleaning, the transducer must be completely rinsed in distilled water and allowed to air dry.

13.4. Visually check parts to see that they are free of any visible soil or build-up. If any is seen, repeat the cleaning steps.

13.5. Re-assemble the transducer into the GoSpiro housing by reversing the steps shown for disassembly.

WARNING: If the GoSpiro is used for more than one patient without a mouthport filter, the turbine assembly must be replaced or undergo high level disinfection before use on another patient to prevent cross-contamination.

14. HIGH LEVEL DISINFECTION

If the GoSpiro is being used for multiple patients and has been used without a filter, the turbine must be replaced or undergo a high level disinfection as follows:

14.1. Follow the cleaning steps in Section 13 prior to disinfection.
14.2. Soak the turbine in Metricide™ (glutaraldehyde) for 45 minutes.
14.3. After disinfections, the transducer must be completely rinsed in distilled water and allowed to air dry.
14.4. Re-assemble the transducer into the GoSpiro housing by reversing the steps shown for disassembly.
14.5. Perform and verification or calibration of the GoSpiro to confirm accuracy performance.

15. ACCESSORIES

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

15.1. Nose Clip (Part Number 50-90059) Any available nose clip may be substituted.
  15.1.1. The Nose Clip is used with GoSpiro during testing.
  15.1.2. Squeeze the Nose Clip to spread the foam pads.
  15.1.3. Place the Nose Clip vertically on your nose so the pads sit on the outside of each nostril.
  15.1.4. Release the squeezing of the Nose Clip and it should seal your nasal passages. Assure that no air exists through your nose. This will prevent air leaking out of your nose that would not be captured by the sensor at your mouth.
  15.1.5. Squeeze the Nose Clip to release it from your nose.
15.2. Mouthport Filter (Part Number 50-146400)
  15.2.1. The Mouthport filter must be a 30mm ID, CE mark or other regulatory body cleared Pulmonary Function Test filter and have a resistance less than 0.08 kPa per L/s. These can be purchased from Monitored Therapeutics or other medical suppliers on the internet.
  15.2.2. The Mouthport filter is a single-patient use device and must not be cleaned.
  15.2.3. Filters that fit the GoSpiro can obtained from A-M Systems, Inc. (a-msytems.com). These include:
    15.2.3.1. VBMAX30E (VBMax™ PFT Filter, E-Series, 34mm OD) Catalog Number: 146400 (oval port)
15.3. Mouthport Adapter (Part Number 55-90206)

15.3.1. The mouthport adapter connects to the turbine assembly or mouthport filter and has a stainless-steel screen to protect the GoSpiro from secretion you might exhale during your test. It is designed to protect your GoSpiro.

15.3.2. The mouthport adapter does not filter out bacterial or viruses. It must not be used by more than one person. It will not protect from disease transmission between patients.

Please contact your distributor or www.monitoredrx.com for pricing and purchasing options. Note that other mouthpieces that have standard 27 mm fittings may also be used.

16. MAINTENANCE

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

16.1. Replace the Turbine Assembly with a new one every 12 months as preventive maintenance.

16.2. If the Turbine Assembly is exposed to dust or material in the GoSpiro, follow the cleaning procedures in Section 13.

16.3. Clean the mouthport adapter after each use..

WARNING: If the GoSpiro is used for more than one patient without a mouthport filter, the turbine assembly must be replaced or undergo high level disinfection before use on another patient to prevent infection.

17. SERVICING

Routine maintenance consists of regular calibration checks every two years and cleaning of the transducer. The GoSpiro must 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 1.614.761.3555 if your GoSpiro requires service, repair or if you need technical assistance. Before returning your 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.**

WARNING: Do not attempt to perform any service or any modifications of this equipment.

18. 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.

19. TROUBLE SHOOTING INFORMATION

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

Situation	LED indicator should be (colored)	LED indicator is now (colored)	Possible reason	Solution
When you try to power up the device, you pressed the purple power button.	Flashing blue	Steady purple	You kept pressing on the power button for over 6 seconds and the device entered pairing mode.	Press the power button for more than 2 seconds to power off the device. Then press on the power button momentarily to power the device on
		Red for 2 seconds with a long beep from the buzzer then turn itself off	Battery is discharged and has inadequate power	Charge the battery
		No response	Battery is discharged and has no power.	Charge the battery for at least 30 minutes. If there's still no response after pressing the power button momentarily, contact technical service.
		Flashing blue then turns solid blue with a short beep	Your GoSpiro has been paired with a GoHome, smartphone or tablet before. When you powered up the GoSpiro and also a compatible data collection device, they connected automatically.	You don't need to pair your GoSpiro again. You can perform test directly with this GoSpiro.
		Flashing blue then turns solid green with three short beeps	Your GoSpiro has been paired with a GoHome, smartphone or tablet before. Also the data collection device has started communicating with the GoSpiro and is waiting for data packets of flow and volume from the GoSpiro. That means you can start the test by breathing into the PFT filter or	You don't need to pair your GoSpiro again. You can start the test directly by breathing in and out of the mouthport of GoSpiro. Read the instructions for performing a lung function test in Section 10.
When you try to pair your GoSpiro with the primary data collection device, you press the SCAN button on the application of the data collection device. Then you choose PAIR on your data collection device after it found your GoSpiro via Bluetooth.	Flashing blue for 1 second with a short beep and turns your GoSpiro off automatically	No response (stays solid purple)	The GoSpiro did not go to automatic shutdown following pairing.	This doesn't mean your GoSpiro has a problem. You should just press on the power button for about 1 second to turn your GoSpiro off. Then you can power it up again to perform testing.
When you try to perform a test using a data collection app on a GoHome, smartphone or other tablet, after the app started.	Solid blue	Flashing blue rapidly	Your GoSpiro may have not been paired with a data collection device by your prescriber. If you never paired your GoSpiro with this GoHome, smartphone or tablet, pair it following the instruction in Section 9 "Pairing your GoSpiro with GoHome and/or smartphone". If you paired this GoSpiro with this GoHome, smartphone or tablet before, then it might be because it lost the pairing key.	If you paired this GoSpiro with this GoHome, smartphone or tablet before but for some reason they are not paired now. You should check the Bluetooth setting of your GoHome, smartphone or table and make sure the Bluetooth is open. Also, move the GoSpiro closer to the data collection device. Try to pair them again following the instruction in Section 9, "Pairing your GoSpiro with GoHome and/or smartphone".
When you followed the instructions of the data collection app and have finished performing a test.	Back to solid blue from solid green	Stays solid green	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.
			Turbine Assembly is not seated completely in the GoSpiro body.	Reseat the Turbine Assembly in the GoSpiro body. See Section 8 Getting Started.
If the LED indicator is in a wrong color or flashing pattern other than listed below, do not try to fix it yourself. Contact info@monitoredRx.com or call 1.614.761.3555 for technical assistance.				

20. ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration – electromagnetic emissions		
The GoSpiro Spirometer is intended for use in the electromagnetic environment specified below. The customer or the user of the GoSpiro Spirometer should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The GoSpiro Spirometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The GoSpiro Spirometer 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 61000-3-2	Class B	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

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 60601-1-2:2014 (4th Edition) test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, 4, 8 and 15 kV air	± 8 kV contact ± 2,4, 8 and 15 kV air	The relative humidity should be at least 5 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz PRR	± 2 kV for power supply lines 100 kHz PRR	Main power quality should be that of a typical home, commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 0.5 and 1 kV line(s) to line(s) ± 0.5, 1 and 2 kV line(s) to earth	Main power quality should be that of a typical home, commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0,5 cycle, @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% UT; 25/30 cycles,@ 0° 0 % U_T; 250/300 cycle	0 % U_T; 0,5 cycle, @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% UT; 25/30 cycles,@ 0° 0 % U_T; 250/300 cycle	Main power quality should be that of a typical home, commercial or hospital environment. If the user of the GoSpiro Spirometer requires continuous ability to charge the GoSpiro during power mains interruptions, it is recommended that the charger be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	30 A/m	30 A/m	Keep the GoSpiro away from sources of high levels of power line magnetic fields (in excess of 30 A/m) to reduce the likelihood of interference.
NOTE U_T is the AC mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
The GoSpiro Spirometer 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 60601-1-2:2014 (4th Edition) test	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment must be used no closer to any part of the GoSpiro Spirometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz	3 V rms 150 kHz to 80 MHz	$d = 1.2 \sqrt{P}$
	6 V rms in ISM and amateur radio bands 150 kHz to 80 MHz	6 V rms in ISM and amateur radio bands 150 kHz to 80 MHz	$d=0.58 \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 to 2700 MHz 80% AM at 1 kHz	10 V/m 80 to 2700 MHz 80% AM at 1 kHz	$d = 0.35\sqrt{P}$ 80 MHz to 800 MHz $d = 0.7\sqrt{P}$ 800 MHz to 2.7 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 meters (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 range. [b] Interference may occur in the vicinity of equipment marked with the following  l:
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 Spirometer is used exceeds the applicable RF compliance level above, the GoSpiro Spirometer 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 Spirometer. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the GoSpiro Spirometer			
The GoSpiro Spirometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the GoSpiro Spirometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and GoSpiro Spirometer 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 In meters		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
W	$d=1.2\sqrt{P}$	$d=0.35\sqrt{P}$	$d=0.7\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.38	0.11	0.22
1	1.2	0.35	0.7
10	3.8	1.11	2.21
100	12	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (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.

21. BLUETOOTH® WIRELESS COMMUNICATION

Bluetooth is a wireless technology standard for exchanging data over short distances from fixed and mobile devices and building personal area networks (PANs). IEEE standardized Bluetooth as IEEE 802.15.1. The maximum output power the Bluetooth radio is 2.5mW. The typical range of operation is approximately 30 feet (10 meters). Bluetooth is used to pair the GoSpiro with its data collection devices and transfer test data between them. Bluetooth links use optional pre-shared key authentication and encryption algorithms that are widely considered acceptably strong. The strength of Bluetooth security relies primarily on the length and randomness of the passkey used for Bluetooth pairing, during which devices mutually authenticate each other for the first time and set up a link key for later authentication and encryption. The Encryption procedure enables encryption of the data sent over the air-interface to prevent unintended eavesdropping. GoSpiro will only work with the data collection device that it has already been paired with and therefore would not be subject to confusion with other Bluetooth radios even if other GoSpiro are operating in its vicinity. The GoSpiro complies with IEC 60601-1-2 the standard for medical device electromagnetic compatibility but can be affected by cellular phones and other sources of electromagnetic interference see Section 19 Electromagnetic Compatibility.

FCC Notice "Declaration of Conformity Information"

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, it may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

22. 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 The APPLIED PARTS of GoSpiro include: Handheld Device, Turbine Assembly.
	Disposal incompliance with Environmental Protection Agency (for individual state) requirements in the US or WEEE requirements in the EU.
	CAUTION: Messages that alert you to conditions that may result in damage to equipment.
	CAUTION: Read the accompanying documents
	WARNING: Messages that alert you to conditions that could place the patient or operator at risk.
	Manufacturer
SN	Serial number

	Bluetooth® Bluetooth is a registered trademark of Bluetooth SIG, Inc.
REF	Reference Number
IP22	GoSpiro passed the IP22 test of water ingress of IEC60529 according to IEC60601-1-11.
	Radio-Frequency Interference may occur in the vicinity of equipment marked with this symbol.
c Nemko 219907 US Electrical Safety – UL60601	The GoSpiro is certified for the U.S. market to the applicable U.S. standards. A cNEMKOus mark means that the product is certified for both the U.S. and Canadian markets, to the applicable U.S. and Canadian standards.
CB	The CB Scheme utilizes CB Test Certificates to attest that the GoSpiro has successfully passed the test conditions and is in compliance with the requirements of the relevant IEC Standard(s).
CE 1639	CE Conformity Symbol
MD	Medical Device Symbol

23. SPECIFICATIONS

Parameters:

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
MVV (ind)	Maximal Voluntary Volume the largest possible volume of air the lungs can move per unit of time

BEV	Back Extrapolated Volume
PEAKTIME	Time of 10% to 90% Peak Flow
POSSIBLE_COUGH	Possible Cough Identified
EOFE	Volume increase during last 0.5 seconds of forced exhalation (Plateau detection)
TIME TO PEF	Time to Peak Flow
PREV_MIF	Mean Inspiratory Flow in previous breath
VC	Vital Capacity
EVC	Expiratory Vital Capacity
IC	Inspiratory Capacity
VT	Tidal Volume
Ti	Inspiratory Time
Te	Expiratory Time
IRV	Inspiratory Reserve Volume
ERV	Expiratory Reserve Volume
Ti/Ttot	Inspiratory Time/ Total Time
VT/Ti	Mean Inspiratory Flow
FR	Respiratory Frequency

Specification:

Transducer Type	Bi-directional high sensitivity 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 maximum
Flow Sensitivity:	Better than 0.025 L/sec
Dynamic Impedance	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)	300 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
Service Interval	2 years