spirohome® | Personal

User Manual

Before using your Spirohome® device and mobile application, please ensure that you have read this user manual, labels and information on the product.

CONTENTS

INTRODUCTION

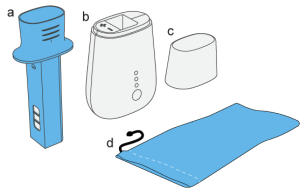
PRODUCT DESCRIPTION

The Spirohome® Personal is a portable spirometer that pairs (via Bluetooth®) and operates with smart devices running with iOS or Android. The Spirohome® Personal measures and displays certain parameters of lung function of the user. The user performs a spirometry test as described in the Performing A Lung Function Test section of this user manual. Briefly, as the user exhales into the device through its mouthpiece, internal ultrasonic sensors detect the volume and speed of the expired air, the device converts this information into spirometric data and displays it via the Spirohome® application on a connected smart device. The Spirohome® app prompts and guides the user throughout the test for accurate data collection and registration. The app can be downloaded on GooglePlay or on Apple's App Store. The device is powered by 2 x AAA Alkaline batteries. Spirohome® Personal works with the Spirohome® Reusable mouthpiece.

WHAT'S IN THE BOX

Your Spirohome® Personal box contains:

- Spirohome® Personal Device (b)
- Spirohome® Reusable mouthpiece (a)
- Spirohome® Personal Cap (c)
- User manual
- Quick start guide
- Carrying pouch (d)



CAUTION!: Please check to ensure that there is no visible damage on any of the components of the Spirohome® Personal. If damage is present, do not use or attempt to repair the device, please contact the manufacturer directly.

INTENDED USE

The Spirohome® Personal is intended to be used as a portable spirometer used in lung function testing. Through the forced expiratory maneuver of the patient, Spirohome® monitors PEF (Peak expiratory flow), FEV_1 (Forced expiratory volume in 1 second), FEV_6 (the volume of air forcefully exhaled after 6 seconds), $FEF_{25-75\%}$ (Forced Expiratory Flow during the mid (25 - 75 %) portion of the FVC) and FVC (Forced vital capacity). See Parameters section for more information about measured parameters. The Spirohome® Personal is indicated for:

- children (over the age of 5), adolescent or adult subjects who have been diagnosed with a chronic pulmonary disease including, but not limited to, asthma, chronic obstructive pulmonary disease and cystic fibrosis. These measurements can be used for the detection, assessment and monitoring of diseases affecting the lung function.

and should be used by:

- adults trained by healthcare professionals or who have read, understood and can apply the instructional material provided by the manufacturer ("competent adults"). A competent adult should assist a child user or users of older age who may need assistance with the associated technology.

RESTRICTIONS ON USE AND CONTRAINDICATIONS

Any diagnosis of your condition or prescribed treatments should be made only by a qualified healthcare professional who, in addition to the test results provided by Spirohome® Personal, will take into consideration the outcomes of a medical examination, your clinical history and results of any other tests deemed necessary.

Spirohome® Personal is to be used by only single user. The device can log the information and tests results that belong to one specific user. If another user intends to use the device, ensure that the personal data of the previous user is erased from device memory and the personal

data of the new user is entered into the system. The mouthpiece of the Spirohome® Personal should never be shared between users, including family members, and a new mouthpiece must be used for a new user.

The spirometry test should only be performed by users who do not experience any shortness of breath and are in good health for performing a lung function test. Test results of patients who do not meet these conditions may not be reliable. A correct spirometry test depends greatly on the user's ability to correctly perform the forced expiratory maneuver as described in this manual. Failure to perform a correct forced expiratory maneuver may lead to inaccurate and unacceptable results. Avoid using the device if the accuracy and reliability of test results may be jeopardized by external factors.

Some medical conditions may pose a relative danger to the patient or affect the validity of spirometry performance and results. These conditions include, but are not limited to, the following: acute disorders (e.g. active lung infection), illness or condition that may cause serious consequences if aggravated by forced expiration (e.g. dissecting / unstable aortic aneurysm, recent/current pneumothorax, recent surgery including ophthalmic, thoracic, abdominal or cerebral aneurysms, unstable angina), recent myocardial infarction (within one month), recent pulmonary embolism, undiagnosed chest conditions (e.g. haemoptysis of unknown origin), nausea, vomiting, severe respiratory distress, physical limitations or cognitive impairment or dementia. If you have or suspect having any of the conditions above, consult to your healthcare professional before using the Spirohome® Personal.

PARAMETERS

The Spirohome® Personal records and displays the following spirometry data:

Parameters	Definition	Unit
FVC	Forced Vital Capacity — The volume of air that can forcibly be blown out after full inspiration	L
$FEV_{0.75}$	Forced Expiratory Volume after 0.75 seconds: The volume of air that can forcibly be blown out in 0.75 seconds, after full inspiration.	L
FEV_1	Forced Expiratory Volume after 1 second	L
FEV_3	Forced Expiratory Volume after 3 seconds	L
FEV_6	Forced Expiratory Volume after 6 seconds	L
$FEV_{0.75}$/FVC	Ratio of $FEV_{0.75}$ to FVC	--
FEV_1/FVC	Ratio of FEV_1 to FVC	--
FEV_3/FVC	Ratio of FEV_3 to FVC	--
FEV_6/FVC	Ratio of FEV_6 to FVC	--
PEF	Peak Expiratory Flow — The maximal flow rate achieved during the maximally forced expiration initiated at full inspiration.	L/s
MMEF	Mean Mid-Expiratory Flow — synonymous with FEF_{25-75}	L/s
FEF_{25}	Forced Expiratory Flow at 25% of vital capacity — synonymous with MEF_{75}	L/s
FEF_{50}	Forced Expiratory Flow at 50% of vital capacity — synonymous with MEF_{50}	L/s

Parameters	Definition	Unit
FEF_{75}	Forced Expiratory Flow at 75% of vital capacity — synonymous with MEF_{25}	L/s
FEF_{25-75}	Forced Expiratory Flow from 25% to 75% of vital capacity — synonymous with MMEF	L/s
MET_{25-75}	Mid-Expiratory Time — synonymous with FET_{25-75}	s
$FEV_{0.75}/FEV_6$	Ratio of $FEV_{0.75}$ to FEV_6	--
FEV_1/FEV_6	Ratio of FEV_1 to FEV_6	--
FEF_{50}/FVC	Ratio of FEF_{50} to FVC	1/s
MMEF/FVC	Ratio of MMEF to FVC	1/s
FET	Forced expiratory time	s
BEV	Back extrapolated volume	L

The recommended number of tests per spirometry session is 3, however, the user may perform up to 8 tests. The best values obtained from the spirometry tests performed in one session is displayed on the app interface. You or your healthcare provider also have the option to view the results of each spirometry test performed in a spirometry session separately.

The device also provides a reference value (obtained from large epidemiological studies) based on the patient's height, weight, age, sex and ethnicity. Test results from spirometry tests are compared to the reference value and displayed as a percent predictive value indicator of your respiratory health. Your personal best value for a spirometry session can be discussed and with your healthcare provider for medical interpretation or diagnosis.

CAUTION!: Interpretation of spirometry results or diagnosis of medical conditions, if any, is to be made by a physician or allied health care professional with sufficient training in the performance and interpretation of spirometry.

OPERATION

OPERATING ENVIRONMENT

The Spirohome® Personal is designed for use at home, by a single user. It is not intended for use in clinical settings such as an operating room or private clinics.

The operating conditions for the Spirohome® Personal is specified as:
Temperature: +15°C to +35°C
Relative Humidity: 10% to 85%

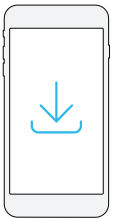
The storage conditions for the Sprihome Personal is specified as:
Temperature: -20°C to +60°C
Relative Humidity: 0% to 85%
Pressure: 500 hPa to 1060 hPa

The Spirohome® Personal should not be used in the presence of inflammable liquids or detergents, nor in the presence of inflammable anaesthetic gases (oxygen or nitrogen).

The device should not be used in direct air currents (e.g. wind), sources of heat or cold, direct sun rays or other sources of light or energy, dust, sand or any other chemical substances.

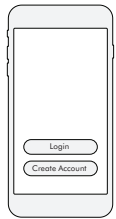
SETTING UP YOUR DEVICE

1



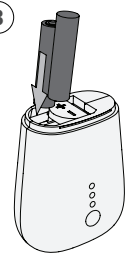
Download the Spirohome® Personal app from the App Store or Google Play Store onto your smart device.

2



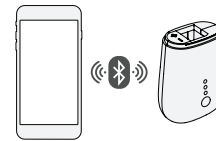
Follow the steps given in the app to create an account as a new user or log in to your existing account.

3



Remove the battery cover by sliding it, place the batteries in the correct orientation, slide the battery cover back to the closed position and press on the power button for one second to switch the device on as shown.

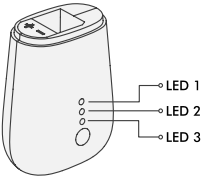
4



Enable Bluetooth® on your smart device and pair the Spirohome® Personal with your smart device, following the instructions on the app.

DEVICE INDICATORS

There are 3 LED lights located on the front of the device. The LED lights may be turned on or flashing various colors and/or in various patterns. The LED lights indicate the current status of the device. Please see the following information for guidance on LED light indications.

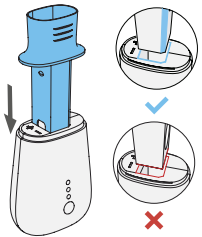


LED Display	Indication/s
None of the LEDs are on	The device is switched off
LED indicators are consecutively flashing green	The device is switching on
LED number 3 is constantly flashing green	The device is switched on
LED number 2 is fading blue	The device is connected to the app. Bluetooth connection has been established.
LED number 2 and LEDs 1 and 3 together are flashing yellow in turn.	The baseline is setting up.
LED number 1 is constantly blue.	The device is ready for a test.
During a test, LED number 1 is constantly yellow.	The test has timed-out (there has been no inhalation/ exhalation over a period of time)
During baseline setup LED umber 1 is constantly yellow.	The baseline setup has been unsuccessful.

LED Display	Indication/s
All LEDs are flashing red.	There is a foreign object between the sensors. Check device error in troubleshooting (section)
LEDs are consecutively flashing yellow.	Over-the-air connection is being established.
LED number 3 flashes red three times.	Battery low warning.
LEDs flash in reverse order and remain switched off.	The device is switching off.

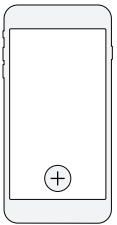
PERFORMING A LUNG FUNCTION TEST (9 STEPS)

1



Remove the Spirohome® Reusable mouthpiece from its plastic packaging and insert it all the way into the Spirohome® Personal in the correct orientation (as shown). You will hear the click when you correctly insert the Spirohome® Resusable mouthpiece into the Spirohome® Personal.

2

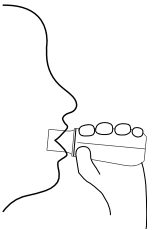


Open the Spirohome® App on your smart device and make sure you are signed in. Tap the plus button to start the test procedure.

3

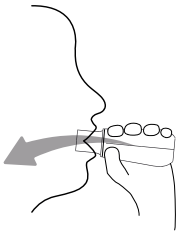
Follow the instructions that appear on the screen. The first step will be to record a baseline for the device.

4



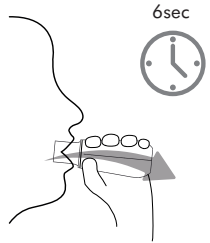
Place the mouthpiece in your mouth, past your teeth (necessary for measurement accuracy) and form a tight seal around the mouthpiece with your lips.

5



You will now need to perform a forced expiratory maneuver. To ready yourself, inhale and exhale normally a couple of times, then take a slow and deep breath, filling your lungs as much as possible.

6



With your lips sealed tightly around the mouthpiece blow out this inhaled air as hard and fast as you can into the mouthpiece, keep blowing for at least 6 seconds without breaking the seal of your lips, and at the end of the 6 seconds inhale a small amount of air to signal the end of your exhalation.

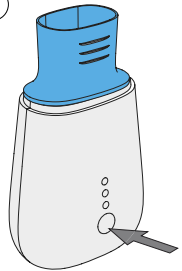
When performing the forced exhalation, be sure to keep blowing until you feel like you have completely emptied your lungs. You may use a nose clip to help you exhale only through your mouth during the forced exhalation maneuver.

7

15-30sec

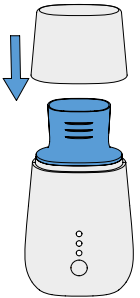
Repeat these steps for each successive spirometry test, ensuring a 15-30 second resting period between each test.

8



When you have completed your tests and viewed your test results, switch off the device by pressing the power key.

9



Keep closed to your device's cap after turn your device off in order to contamination risk of the mouthpiece.

UNDERSTANDING THE TEST QUALITY

After each test session, a quality grading will be displayed on the app to provide information about how well the breathing maneuver was performed and whether the results are acceptable or not. Grading of the FVC test in children and adults, according to the American Thoracic Society guidelines;

Grade	Criteria
A	≥ 3 acceptable tests with repeatability within 0,150 L For ages 2-6, 0,100 L, or 10% of the highest value, whichever is greater.
B	≥ 2 acceptable tests with repeatability within 0,150 L For ages 2-6, 0,100 L, or 10% of the highest value, whichever is greater.
C	≥ 2 acceptable tests with repeatability within 0,200 L For ages 2-6, 0,150 L, or 10% of the highest value, whichever is greater.
D	≥ 2 acceptable tests with repeatability within 0,250 L For ages 2-6, 0,200 L, or 10% of the highest value, whichever is greater.
E	One acceptable test.
F	No acceptable tests.

SIGNS AND SYMBOLS

Please note the following signs and symbols provided for the safe use and storage of your Spirohome® Personal.

Markings	Descriptions
	"Manufacturer" This symbol accompanied by the name and the address of the manufacturer adjacent to the symbol
	Sign of Conformity
	Disposal in Compliance with WEEE
	Temperature Limit
	Humidity Limit

Markings	Descriptions
	Atmospheric pressure limitation
	Do not use if package is damaged
	Keep away from sunlight
	Keep dry
	Single use only
	Type BF of Medical Electrical Equipment
SN	Serial Number

Markings	Descriptions
LOT	Lot Number
REF	Ref Number
IP	IP Number
	Device includes RF transmitters
	The instruction manual/booklet must be read.

TECHNICAL FEATURES

Flow / Volume measure method	Ultrasonic Transducer Measurement
Power Supply	2 x 1,5V AAA batteries
Dimensions	110 x 63 x 41
Weight (With batteries)	90g
Weight (Without batteries)	67g
Flow range	0 - 14 L/s
Maximum volume measured	10 L
Volume accuracy	2.00%
Dynamic resistance at 14 L/s	86 Pa*s/L
Volume resolution	1 mL
Flow resolution	1 mL/s
Medical device class	Class IIA
Wireless connection	BLE 4.2

SAFETY WARNINGS AND PRECAUTIONS

IMPORTANT! Please adhere to the recommendations, warnings and guidelines set out in this user manual as failure to comply may result in measurement errors, display of incorrect results or harm to the user.

The manufacturer is not responsible for any damage or harm to the device or user which has resulted from the users failure to follow the warnings and guidelines given in this manual or in other instructional materials provided with the device. Please note that assisting competent adults should provide special WARNING to elderly, pediatric or differently-able users prior to use of the device.

Regardless of the data presented on the Spirohome® Ultrasonic Spirometer, if you feel unwell or have respiratory illness symptoms please contact your healthcare provider immediately. Only your doctor can decide on an appropriate treatment plan for you based on respiratory data obtained with the Spirohome® Spirometer.

If any damage is present on the device or its components upon removal from packaging, do not use the device and return it to the supplier.

Do not use Spirohome® for any other purpose than its intended use. Spirohome® is not recommended for children under the age of 6.

Do not expose the device to liquids, prevent any liquids from entering the device. In the event of a liquid spill on or around Spirohome®, immediately remove batteries and let the device dry thoroughly before use.

The instrument may give inaccurate readings if operated in the presence of strong electromagnetic sources, such as electrosurgical equipment, or in the presence of computed tomography (CT) equipment.

Do not allow users to walk or run while taking a lung function measurement using Spirohome® spirometer. Do not perform a spirometry test with food or objects in oral cavity to avoid risk of choking.

To prevent damage to the Spirometry Module due to battery leakage or oxidation, remove all batteries if the Spirometry Module is not to be used or is to be stored for a long period of time.

Dispose of device and/or device batteries responsibly as required by local legislation.

Do not share your Spirohome® Personal with any other users, including family members, as the Spirohome® Personal and Spirohome® Reusable is to be used by a single user only. If a new user is to use the device, ensure that the device is cleaned and disinfected (see Maintenance section of this manual), a new mouthpiece is attached and a new account is created for the user on the app.

The Spirohome® Personal must only be used with the original accessories specified and provided by the manufacturer. Use of unspecified mouthpieces may cause inaccurate test readings, or damage/harm to the user and/or device. Do not cause damage to or insert the mouthpiece holding the filters located on the barrel of the mouthpiece. Do not use the mouthpiece if the filters have been physically compromised.
The user should periodically check to ensure that foreign bodies or impurities are not present on visible and accessible areas of the device as this could lead to inaccuracies in test measurements. Coughing or spitting into the device may cause incorrect readings.

Pulmonary function tests require maximum effort on the part of the patient and may lead to sensations of dizziness or giddiness. Do not perform more than 8 spirometry tests in one spirometry session. If you sense dizziness while performing a test, stop the test immediately and rest.

In the occurrence of any adverse events, report immediately to your doctor and/or authorities as required by local legislation. The user should also report such incidents to the manufacturer.

The Spirohome® Personal should never be used with a charging smart device. Make sure the smart device is unplugged from its charger before conducting a spirometry test.

Store and use the device as specified in this user manual as alternative methods or conditions of storage may affect device function and/or accuracy. Use only in specified environments/conditions (see Operating Environment) to avoid malfunction and/or display of incorrect results.

All repairs, modifications or reconfigurations must be performed only by the manufacturer. If your Spirohome® Personal is damaged or malfunctioning or you encounter data that you cannot make sense of, contact the manufacturer or distributor, if purchased from a reseller, directly to avoid incorrect measurements or potential harm. Do not attempt to repair the device yourself, an opened device casing will terminate product warranty.

Please follow all data security warnings and recommendations for your personal smart device as per its manufacturer's instructions as your personal data, which will include that recorded and stored on the Spirohome® App, may otherwise be at risk. The user is encouraged to not share their Spirohome® app account information with unauthorized parties.

The Spirohome® Personal conforms to EN 60601-1, EN 60601-1-11, EN 60601-1-2 and EN 300 328. As this device operates with RF technology, it must be used as only specified by the manufacturer, it may to avoid interference to radio communications.

MAINTENANCE

For the Spirohome® Personal, routine calibration is not necessary due to the ultrasonic flow measurement technology used. The Spirohome® Ultrasonic Spirometer does not require calibration; however, it is advised by the American Thoracic Society (ATS) that periodic calibration be performed with such devices to ensure the reliability of the tests. If there is a problem with the calibration, contact the manufacturer immediately and do not perform tests with the device.

Handle your Spirohome® Personal and Spirohome® Reusable mouthpiece with care. Do not use if the mouthpiece is visibly damaged, particularly if there is damage to the filters.

Store the Spirohome® Personal in dust/dirt and moisture free conditions. You may utilize the pouch provided with the device to keep the device protected. Before each use, always check that the device is free from contaminants and does not have any visible damage.

Proper cleaning and disinfection of your Spirohome® Personal is important for the safe use of the device. With regular cleaning, you can prevent the physical buildup of contaminants on your device. A cleaning process must always precede a disinfection process. Disinfection destroys any pathogens such as bacteria, viruses or other microorganisms that might still be present on device surfaces after an initial cleaning process. Regular, thorough cleaning and disinfection of your device protects both you and others from the potential transmission of infections resulting from contact with the device. Be sure to wash your hands with soap before and after each use of the device.

NOTE: One 'use' of the spirometer is defined as one complete spirometry session (can include up to 8 individual successive spirometry tests).

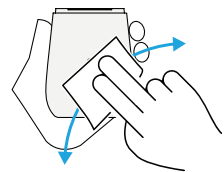
CLEANING AND DISINFECTION

The cleaning procedure and disinfection process is described below:

1. Before beginning the procedure wash hands thoroughly with soap and water.

2. Perform cleaning

Remove the Spiroway Reusable from the Spirohome Personal body if it is inserted. Use a high-level disinfectant (Sodium Hypochlorite) wipe for 30 seconds to remove all visible contaminants from all accessible surfaces of the device as shown below. Please be extra careful and gentle when cleaning the sensors to avoid any damage to them. You should clean the Spirohome Personal body and cap at least once a week or whenever the device is visibly contaminated.

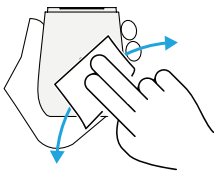


Wipe all accessible surfaces of the device and cap, using moderate pressure, as shown.

CAUTION!: Care must be taken to prevent any excess liquids contained within the wipes from entering the components of the Spirohome Personal. Never immerse the product in water or any other liquid solution.

3. Perform disinfection

After cleaning all accessible surfaces of the device and cap with a high-level disinfectant (Sodium Hypochlorite) wipe, use a second fresh wipe to wipe over all surfaces again using moderate pressure and for the contact time recommended by the wipe manufacturer to achieve disinfection.



Medipal® Chlorine Disinfectant wipes (Pal International Ltd.) is a high-level disinfectant wipes suitable for this purpose and available at https://www.palinternational.com/healthcare-wipes/disinfectant/.

4. Wash hands thoroughly after performing a cleaning or disinfection procedure, and before handling the cleaned or disinfected components again for packing and storage.

THE SPIROHOME REUSABLE

To clean the Spirohome® Reusable Mouthpiece once a week;

- Shake gently the mouthpiece in soapy warm water.
- Rinse the mouthpiece without any damaging the filters and rubbing under running water at room temperature until the foams are removed..
- Leaving upright on a clean lint-free cloth until it is completely dry at room temperature.
- Do not insert the Spirohome® Reusable mouthpiece to Spirohome® Personal device before it is completely dry.
- You should clean the mouthpiece whenever it is visibly contaminated.

The Spirohome® Reusable should be replaced every 3 months. The Spirohome® Reusable Mouthpiece must be replaced if the user used the mouthpiece whilst having a bacterial or viral infection. Replace the Spirohome® Reusable immediately if the filters are damaged or whenever a risk of cross contamination is suspected (such as possible use of the mouthpiece by other users).

CAUTION!: Risk of Cross-Contamination

Spirohome® Personal is designed to be used with the Spirohome® Reusable Mouthpiece. The mouthpiece is indicated for single-patient-use only. The mouthpiece must not be used by more than one user to prevent any potential of cross-contamination. Thorough cleaning and disinfection of the device must be performed prior to use by a new user. A new mouthpiece should be used for each user.

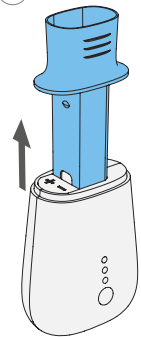
New mouthpieces can be purchased at www.spirohome.io. See Orderable Accessories section for more information.

BATTERIES

The Spirohome® device is suitable to work with any 1.5V AAA battery, including off-the-shelf AAA rechargeable batteries. The battery life of the Spirohome® is approximately 6-9 months, assuming daily use of the device. The battery charge level is continuously monitored by the device. When battery charge level is low, the device will not turn on and the device will make a beeping sound to notify the user. The batteries of the device should be removed if the device is not going to be used for more than a month.

INSTRUCTIONS FOR BATTERY REPLACEMENT

1

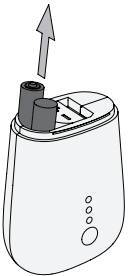


Open the cap and remove the Spirohome® mouthpiece from the device.

2

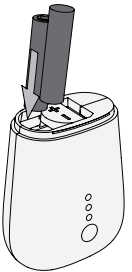
Remove the battery cover by pushing it as shown.

3



Remove the dead batteries.

4

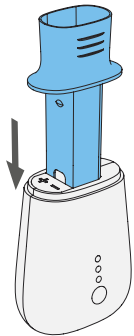


Place the new batteries in the correct orientation.

5

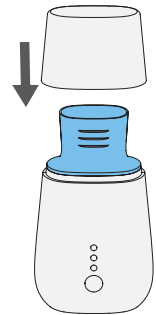
Slide the battery cover back to the closed position.

6



Insert the Spirohome® in the right orientation. Your device is now ready to use.

7



If the device is not to be used, keep close to your devices cap in order to contamination risk of the mouthpiece.

DISPOSAL OF SPIROHOME®

This product is not to be discarded as regular household waste but should be discarded as electronic waste in accordance with local regulations and returned to a collection point of recycling for electric and electronic devices.

Used batteries should be disposed of in designated battery recycling containers in accordance with local laws and regulations.

TROUBLESHOOTING

Problem	Cause	Solution
Device Not turning on	Multiple possible causes	Check battery orientation and correct polarities
		Remove the AAA batteries and wait 30 seconds and reinstall AAA batteries
		Replace AAA batteries
		Check that battery cap is in lock position, or if cap is broken, contact manufacturer
Spirohome® cannot connect to a smart device via Bluetooth®	Smart device is out of range	Bring your smart device closer to the Spirohome® device
	Smart device Bluetooth® is disabled	Enable Bluetooth® of your smart device
	Bluetooth® connection not working properly	Your smart device will need bluetooth® version 4.0 or higher. Find and select Spirohome® Personal from list of detected devices.

Problem	Cause	Solution
Test results are inconsistent	Spirohome® mouthpiece is dirty	Clean Spiroway® mouthpiece to ensure that the lumen is not obstructed or replace with a new mouthpiece
	Spirohome® mouthpiece is damaged	Replace Spirohome®
	Spirometry test was performed incorrectly	Refer to Performing a Lung Function Test in user manual or refer video tutorial on app
	Spirohome® mouthpiece is installed incorrectly	Refer to user manual for proper installation of Spirohome®
Test does not start - Cannot set up baseline	Direct air current in environment	Close the cap of the Spirohome® to avoid effects of environmental flow
		Place device on a flat surface
		Remove causes of direct air current e.g. air conditioner, opened window, fan, etc.

Problem	Cause	Solution
Test does not start - animated balloon is not moving	Multiple possible causes	Quit test and start new test
		Quit application and start a new test
		Switch device on and off again to reset
Test Starts before you start blowing	Vigorous handling of the device	Keep device as stable as possible after starting a test
Device disconnected during test	Device is turned off accidentally or due to rough handling during use	Switch device on again and proceed with a new test
	BLE connection dropped	Reconnect device and proceed with a new test
Test quality grade always low	Not performing test correctly	Repeat the test following the rules and conditions specified in the Performing a Lung Function Test section of this user manual.

Problem	Cause	Solution
Measurement error screen showed up	Flow limit exceeded	This device intended to measure 0-14 L/s.
	Spiroway mouthpiece is dirty	Clean Spiroway to ensure that the lumen is not obstructed or replace with a new mouthpiece
	Spiroway mouthpiece is damaged	Replace Spiroway
	Device malfunction	Contact manufacturer
Device error screen showed up	Spiroway mouthpiece is installed incorrectly	Refer to user manual for proper installation of Spiroway
	There is a foreign object between the sensors.	Check Spiroway to ensure that the lumen is not obstructed
	Spiroway mouthpiece is dirty	Clean Spiroway to ensure that the lumen is not obstructed or replace with a new mouthpiece
	Spiroway mouthpiece is damaged	Replace Spiroway

For any other technical queries please call our customer service on +90 312 988 03 08

ORDERABLE ACCESSORIES

- Spirohome® Reusable Mouthpiece (Reference number: 03000)
- Spirohome® Personal Cap (Reference number: 01104)
- Spirohome® Pouch (Reference number: 01509)

These accessories may be ordered from www.spirohome.io

TERMS OF WARRANTY

Spirohome® Personal, together with any accessories provided, is guaranteed for a period of 24 months, effective from the date of purchase, upon the provision of an invoice or sales receipt. The service life of the product is 5 years, effective from the date of purchase.

The user is responsible for checking the product for damage or missing components at the time of purchase or delivery, and claims must be made in writing to the manufacturer.

The customer must return goods for replacement or repair at the customer's expense to the authorized supplier or manufacturer.

Please provide with the returned product a clear written explanation of the fault or problem.

This warranty does not apply, at the discretion of the manufacturer, in the following cases:

- Improper installation or operation of the device
- Use of the product for purposes other than those specified in this user manual
- Damage due to failure to follow instructions
- Damage due to unauthorised repair, modification or reconfiguration performed on the device
- Damage caused by fall, hit, lack of proper care or maintenance
- Damage caused by abnormal physical or electrical stress or defects of the main electric supply (battery cell) or of equipments
- If the serial number is altered, deleted, removed or rendered illegible

ELECTROMAGNETIC COMPATIBILITY

Meeting the requirements for EMC (electromagnetic compatibility) and preventing the unsafe use of the device, medical devices including Spirohome® manufactured by Inofab Health Technologies conform to the EN60601-1-2 standard which defines the levels of immunity to electromagnetic interference as well as maximum levels of electromagnetic emissions for medical devices. For details, please see the following tables:

Table 1: Emission table for IEC 60601-1-2

Guidance and manufacturer's declaration – electromagnetic emissions		
Spirohome® battery-operated spirometer devices are intended for use in the electromagnetic environment specified below. Users of these devices should assure that it is used in such environment.		
Emission Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Spirohome® battery-operated devices use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Spirohome® devices are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Table 2: Immunity (Stimulation mode) table according to IEC 60601-1-2

Guidance and manufacturer's declaration – electromagnetic immunity			
Spirohome® battery-operated spirometer devices are intended for use in the electromagnetic environment specified below. Users of these devices should assure that it is used in such environment.			
Immunity Test Standard	**IEC 60601 test level**	**Compliance level**	**Recommended separation distance**
Electrostatic discharge (ESD) IEC 61000-4-2	±2 kV ±4 kV ±6 kV ±8 kV ±15 kV	±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic fast transient / burst IEC 61000-4-4	N/A	N/A	
Surge IEC 61000-4-5	N/A	N/A	
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	N/A	N/A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
Spirohome® battery-operated spirometer devices are intended for use in the electromagnetic environment specified below. Users of these devices should assure that it is used in such environment.			
Immunity Test Standard	**IEC 60601 test level**	**Compliance level**	**Recommended separation distance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	N/A 3 V/m 80 MHz to 2.7 GHz	 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Spirohome® devices including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. Recommend 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

Guidance and manufacturer's declaration – electromagnetic immunity			
Spirohome® battery-operated spirometer devices are intended for use in the electromagnetic environment specified below. Users of these devices should assure that it is used in such environment.			
Immunity Test Standard	**IEC 60601 test level**	**Compliance level**	**Recommended separation distance**
			where P is the maximum output power rating of the transmitter in watts (W) according to he transmitter manufacturer 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 symbol: 

Guidance and manufacturer's declaration – electromagnetic immunity			
Spirohome® battery-operated spirometer devices are intended for use in the electromagnetic environment specified below. Users of these devices should assure that it is used in such environment.			
Immunity Test Standard	**IEC 60601 test level**	**Compliance level**	**Recommended separation distance**
Note1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note2:** 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 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 Spirohome® devices are used exceeds the applicable RF compliance level above, the Spirohome® device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Spirohome® device. [b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment.

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

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz - 80 MHz $d = 0.35 \sqrt{P}$	**80 MHz - 800 MHz** $d = 0.35 \sqrt{P}$	**800 MHz - 2500 MHz** $d = 0.7 \sqrt{P}$
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

Recommended separation distances between portable and mobile RF communications equipment.

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

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: At 80MHz and 800MHz, the separation distance for the higher frequency range applies Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

MANUFACTURER INFORMATION

Name
İnofab Sağlık Teknolojileri A.Ş.

Address
Üniversiteler Mah. İhsan Doğramacı Blv. No: 19
Çankaya / Ankara / Turkey

Phone
+90 312 988 03 08

Web
www.spirohome.io

CE

The Spirohome® Ultrasonic Spirometer and Accessories are CE certified (NB1984) products.

User Manual