spirohome® | Clinic

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® Clinic is a portable spirometer that pairs (via Bluetooth®) and operates with smart devices running with iOS (Android and Windows will be supported in future). The Spirohome® Clinic 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 and inhales into the device through its mouthpiece, internal ultrasonic sensors detect the volume and speed of the expired and inspired air respectively, the device converts this information into spirometric data and displays it via the Spirohome application. The Spirohome app prompts and guides the user throughout the test for accurate data collection and registration. The app can be downloaded on App Store (Android and Windows will be supported in future). The device is powered by 2 x AAA Alkaline batteries. The Spirohome® Clinic works with the Spiroway Disposable mouthpiece.

WHAT'S IN THE BOX

Your Spirohome® Clinic box contains:

- Spirohome® Clinic Device
- Spirohome® Clinic Cap
- User manual
- Quick start guide
- Calibration Certificate

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

INTENDED USE

The Spirohome® Clinic is intended to be used as a portable spirometer used in lung function testing for several parameters. See Parameters section for more information about measured parameters. The Spirohome® Clinic is indicated for:

- children (over the age of 6), 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 conditions or prescribed treatments should be made only by a qualified healthcare professional who, in addition to the test results provided by Spirohome® Clinic, will take into consideration the outcomes of a medical examination, the patient's clinical history and results of any other tests deemed necessary.

Spirohome® Clinic is a multi-user device. The device can log the information and tests results that belong to each specific patient. For each new patient, a new patient account must be created on the Spirohome® Clinic app,

so that each users's personal information and test results can be stored and logged.

A new Spiroway® Disposable mouthpiece must be used for each 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 patient's ability to correctly perform the perform the expiratory/inspiratory maneuvar as described in this manual. Failure to perform a correct maneuver may lead to inaccurate and unacceptable results. The device should not be used 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. Please ask the patient if they have or suspect having any of the conditions above before use of the Spirohome® Clinic.

PARAMETERS

The Spirohome® Clinic 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
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

Parameters	Definition	Unit
FIV_1	Forced inspiratory volume after 1 second	L
FIVC	Forced inspiratory vital capacity	L
PIF	Peak inspiratory flow	L/s
FIF_{25-75}	Forced inspiratory flow at 25% of vital capacity — synonymous with MIF75	L/s
FIV1/FIVC	Ratio of FIV1 to FIVC	--
R50 (FEF_{50}/FIF_{50})	Ratio of flow at 50% of expiration and flow at 50% of inspiration — synonymous with FEF_{50}/FIF_{50}	--
VC	Vital capacity, from slow expiration	L
VC_{in}	Inspiratory vital capacity, from slow inspiration	L
VC_{ex}	Expiratory vital capacity, from slow expiration	L
ERV	Expiratory reserve volume	L
IRV	Inspiratory reserve volume	L
IC	Inspiratory capacity from end of tidal breathing	L
Rf	Respiratory frequency	1/min
VT	Tidal volume	L
MVV	Maximum voluntary ventilation	L/min
MVV_6	Maximum voluntary ventilation for 6 seconds	L/min
MVV_{time}	Duration of the trial in seconds	s

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. Users and healthcare professionals 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 the patient's respiratory health. The patient's personal best value for a spirometry session should be discussed with them for medical interpretation.

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® Clinic is designed for use in a clinical setting, by more than one user.

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

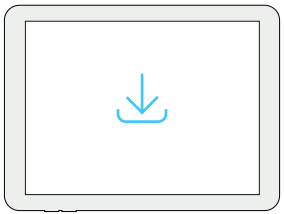
The storage conditions for the Spirohome® Clinic are specified as:
Temperature: -20°C to +60°C
Relative Humidity: 0% to 85%
Pressure: 500 hPa to 1060 hPa

The Spirohome® Clinic 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.

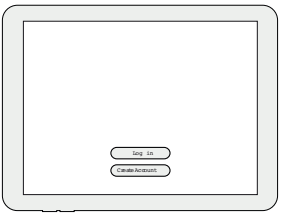
SETTING UP YOUR DEVICE

1



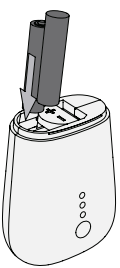
Download the Spirohome® Clinic app from the App Store (Android and Windows will be supported in future) into a smart device.

2



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

3



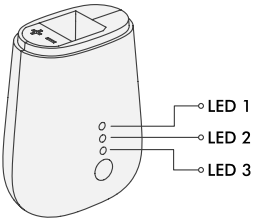
Remove the battery cover by sliding it, place the batteries in the correct orientation, slide the battery cover back to the closed position and press on the power button for one second to switch the device on as shown.

4

Enable Bluetooth® on the smart device and pair the Spirohome® Clinic with the 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 colours 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 number 1 is constantly yellow.	The baseline setup has been unsuccessful.
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 green in reverse order and remain switched off.	The device is switching off.

PERFORMING A LUNG FUNCTION TEST

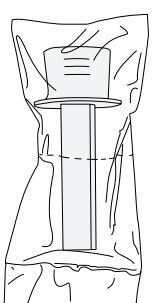
There are several types of tests and different parameters related to lung function that can be involved in a spirometry test. Each type of spirometry test requires a specific breathing maneuver in order to detect the parameters related to that particular test type. However, the general method of performing a spirometry test remains the same for all test types. Please keep reading for more information about test types, test parameters, breathing maneuvers and understanding the quality of test results.

General Method For Performing a Spirometry Test with The Spirohome® Clinic:

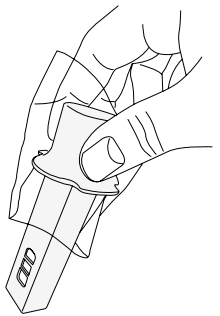
1. Open the cap of Spirohome® Clinic device.

2. Remove the Spiroway® Disposable mouthpiece from its plastic packaging and insert it all the way into the Spirohome® Clinic in the correct orientation (as shown).

2.a. Tear the bottom part of the mouthpiece's plastic package and do not touch the mouthpiece with bare hands.



2.b. Hold the mouthpiece with the upper part of the plastic package.

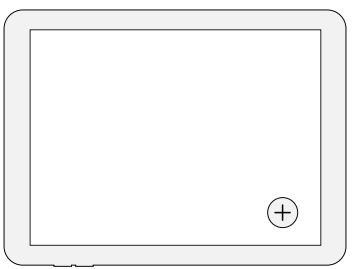


2.c. Insert the mouthpiece all the way into the Spirohome® Clinic device in the correct orientation.

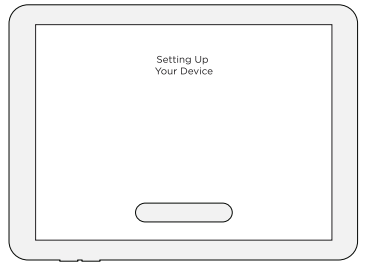
3. A 'click' will be heard when the mouthpiece is inserted correctly all the way into the device.

4. Open the Spirohome App on a smart device. If you are not registered, register to the Spirohome app by creating a new user account and then log in. If the patient is not registered, enter the patient information in the new patient section and register the patient.

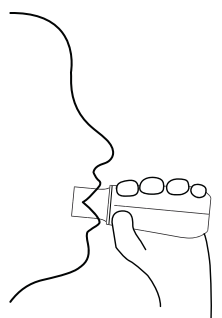
5. Select the patient name from the patient list and tap the plus button on the screen to start the test procedure from the patient details page.



6. The first steps will be to select test mode and enter the ambient conditions like temperature and relative humidity and then to setup a baseline for the device. To perform baseline setup stabilize the device during the baseline setup. Alternatively, place the device on a flat surface and allow the baseline setup to be completed. Make sure that there is no airflow around the device during the baseline setup.



7. The app will prompt the operator to start a spirometry test. The patient must place the mouthpiece in their mouth, past their teeth (necessary for measurement accuracy) and form a tight seal around the mouthpiece with their lips.



8. The patient should now perform the breathing maneuver. Please continue to the Type of Breathing Maneuvers section for more information.

Types of Breathing Maneuvers

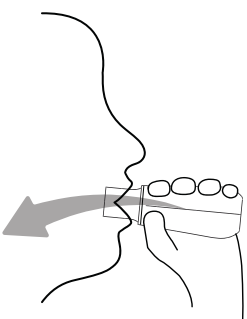
The Forced Vital Capacity (FVC) Test Breathing Maneuver:

1. Ensure that the device is connected. Select the FVC test mode and the test screen will appear.

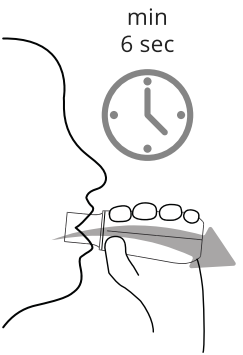
2. Then setup baseline for the device.

3. The patient will now need to perform a forced expiratory maneuver. To get ready, patient should inhale and exhale normally a couple of times.

4. Ask the patient to place the mouthpiece in his/her mouth, past his/her teeth and ensure that his/her lips are tightly sealed around the mouthpiece, then patient take a slow and deep breath, filling his/her lungs as much as possible.



5. Keeping his/her lips sealed tightly around the mouthpiece, patient must blow out the inhaled air and empty his/her lungs as hard and fast as he/she can into the mouthpiece and keep blowing for at least 6 seconds without breaking the seal of his/her lips.



6. When performing the forced exhalation, the patient must make sure to keep blowing until completely emptying his/her lungs. Patient may use a nose clip to help him/her to exhale only through his/her mouth during the forced exhalation maneuver.

7. The patient may remove the mouthpiece from his/her mouth and resume normal breathing once the breathing maneuver has been completed.

8. The test results will be displayed on the app screen. Give feedback to the patient on his/her effort by looking at the test results. The patient will need to perform 2 more tests by repeating this breathing maneuver. However, please make sure that the patient has time to rest between tests and feels well enough to continue.

Tidal Forced Vital Capacity (Tidal FVC) Test Breathing Maneuver:

1. Ensure that the device is connected. Select the Tidal FVC test mode and the test screen will appear.

2. Enter the required ambient conditions (makes sure you entered the correct values as the measurement may be significantly affected by a wrong value) like temperature and relative humidity and then setup baseline for the device.

3. Ask the patient to place the mouthpiece in his/her mouth, past his/her teeth and ensure that his/her lips are tightly sealed around the mouthpiece.

4. To get ready, the patient should inhales and exhales normally a couple of times, then takes a slow and deep breath, filling your lungs as much as possible.

5. Keeping his/her lips sealed tightly around the mouthpiece, he/she must blow out this inhaled air and empty his/her lungs as hard and fast as he/she can into the mouthpiece and keep blowing for at least 6 seconds without breaking the seal of his/her lips.

6. When performing the forced exhalation, the patient must make sure to keep blowing until completely emptying his/her lungs. Patient may use a nose clip to help him/her to exhale only through his/her mouth during the breathe maneuver.

7. The patient may remove the mouthpiece from his/her mouth and resume normal breathing once the breathing maneuver has been completed.

8. The test results will be displayed on the app screen. Give feedback to the patient on his/her effort by looking at the test results. The patient will need to perform 2 more tests by repeating this breathing maneuver. However, please make sure that the patient has time to rest between tests and feels well enough to continue.

NOTE: The difference between Tidal FVC and FVC is that the patient can breathe normally in the begining of the test, in Tidal FVC test mode. In FVC test mode, the data starts to be calculated with any exhale maneuver, but in Tidal FVC mode the data starts to be calculated with the forced exhalation maneuver.

The Flow Volume Loop (FVL) Test Breathing Maneuver:

1. Ensure that the device is connected. Select the FVL test mode and the test screen will appear.

2. Enter the required ambient conditions (makes sure you entered the correct values as the measurement may be significantly affected by a wrong value) like temperature and relative humidity and then setup baseline for the device.

3. Ask the patient to place the mouthpiece in his/her mouth, past his/her teeth and ensure that his/her lips are tightly sealed around the mouthpiece, then takes a slow and deep breath, filling his/her lungs as much as possible.

4. Keeping his/her lips sealed tightly around the mouthpiece, he/she must blow out this inhaled air and empty his/her lungs as hard and fast as he/she can into the mouthpiece and keep blowing for at least 6 seconds without breaking the seal of his/her lips.

5. After the patient exhales whole air from the lungs, without breaking the seal of his/her lips, patient must inhale completely to fill his/her lungs. When performing this breathing maneuver, the patient must make sure to keep blowing until he/she has completely emptied his/her lungs. Patient may use a nose clip to help him/her to inhale and exhale only through his/her mouth during this breathing maneuver.

6. The patient may remove the mouthpiece from his/her mouth and resume normal breathing once the breathing maneuver has been completed.

7. The test results will be displayed on the app screen. Give feedback to the patient on his/her effort by looking at the test results. The patient will need to perform 2 more tests by repeating this breathing maneuver. However, please make sure that the patient has time to rest between tests and feels well enough to continue.

Tidal Flow Volume Loop (Tidal FVL) Test Breathing Maneuver:

1. Ensure that the device is connected. Select the Tidal FVL test mode and the test screen will appear.

2. Enter the required ambient conditions like temperature and relative humidity and then setup baseline for the device.

3. Ask the patient to place the mouthpiece in his/her mouth, past his/her teeth and ensure that his/her lips are tightly sealed around the mouthpiece.

4. To get ready, the patient inhales and exhales normally a couple of times, then takes a slow and deep breath, filling his/her lungs as much as possible.

5. Keeping his/her lips sealed tightly around the mouthpiece, he/she must blow out this inhaled air and empty his/her lungs as hard and fast as he/she can into the mouthpiece and keep blowing for at least 6 seconds without breaking the seal of his/her lips.

6. After the patient exhales whole air from the lungs, without breaking the seal of his/her lips, patient must inhale completely to fill his/her lungs. When performing this breathing maneuver, the patient must make sure to keep blowing until he/she has completely emptied his/her lungs. Patient may use a nose clip to help him/her to inhale and exhale only through his/her mouth during this breathing maneuver.

7. The patient may remove the mouthpiece from his/her mouth and resume normal breathing once the breathing maneuver has been completed.

8. The test results will be displayed on the app screen. Give feedback to the patient on his/her effort by looking at the test results. The patient will need to perform 2 more tests by repeating this breathing maneuver. However, please make sure that the patient has time to rest between tests and feels well enough to continue.

NOTE: The difference between Tidal FVL and FVL is that the patient can breathe normally in the begining of the test, in Tidal FVL test mode. In FVL test mode, the data starts to be calculated with any exhale maneuver, but in Tidal FVL mode the data starts to be calculated with the forced exhalation maneuver.

The Maximum Voluntary Ventilation (MVV) Test Breathing Maneuver:

1. Ensure that the device is connected. Select the MVV test mode and the test screen will appear.

2. Enter the required ambient conditions (makes sure you entered the correct values as the measurement may be significantly affected by a wrong value) like temperature and relative humidity and then setup baseline for the device.

3. Ask the patient to place the mouthpiece in his/her mouth, past his/her teeth and ensure that patient's lips are tightly sealed around the mouthpiece.

4. When the test starts, the patients should inhale and exhale normally at least 3 times with the steady tidal volumes,(all tidal volumes should be close to each other 60%), then inhale and exhale completely filling and emptying their lungs, repeatedly, uninterrupted, without breaking the seal of their lips for at least 12 seconds. Patient may use a nose clip to help him/her to inhale and exhale only through his/her mouth during this breathing maneuver.

5. Actively encourage the patient to breathe deeply and rapidly moving as much air as possible for at least 12 seconds.

6. The patient may remove the mouthpiece from his/her mouth and resume normal breathing once the breathing maneuver has been completed.

7. The test results will be displayed on the app screen. If the test fails, give feedback and guide the patient for another trial. Encourage them to breathe deep and fast and try to reach at least 12 seconds. However, please make sure that the patient has time to rest between tests and feels well enough to continue.

The Slow Vital Capacity (SVC) Test Breathing Maneuver:

1. Ensure that the device is connected. Select the SVC test mode and the test screen will appear.

2. Enter the required ambient conditions (makes sure you entered the correct values as the measurement may be significantly affected by a wrong value) like temperature and relative humidity and then setup baseline for the device.

3. Ask the patient to place the mouthpiece in his/her mouth, past his/her teeth and ensure that his/her lips are tightly sealed around the mouthpiece.

4. When the test starts, the patient should inhale and exhale at least 3 times with the steady tidal volumes,(all tidal volumes should be close to each other 60%), then he/she should inhale gently, slowly and as deep as he/she can and fill.

5. After that the patient should exhale the whole air in his/her lungs gently and slowly until he/she feels that all the air in his/her lungs feel completely empty without breaking the seal of his/her lips.

6. When performing this breathing maneuver, the patient must make sure to keep blowing until he/she feels like he/she has completely emptied his/her lungs. Patient may use a nose clip to help him/her to inhale and exhale only through his/her mouth during this breathing maneuver.

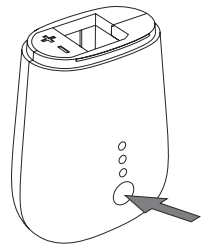
7. The patient may remove the mouthpiece from his/her mouth and resume normal breathing once the breathing maneuver is complete.

8. The test results will be displayed on the app screen. Give feedback to the patient on his/her effort by looking at the test results. The patient will need to perform 2 more tests by repeating this breathing maneuver. However, please make sure that the patient has time to rest between tests and feels well enough to continue.

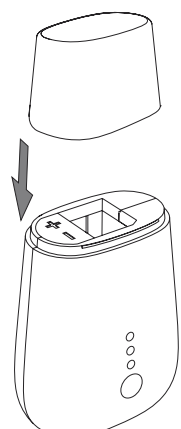
End of the Tests

Once all tests have been satisfactorily completed, you will be able to view the session results on the results page of the app. After end the spirometry session, remove and immediately dispose the mouthpiece via pushing the notch without touching the top part of the mouthpiece(a). Turn the device off by pressing the power button(b), close the cap off(c) and store the device according to the storage requirements until the next use.

a. Removing mouthpiece



b. Turning off the spirometer



b. Closing the cap

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.

Note that the acceptibiltiy of the test is purely decided by the doctor/operator etc.

Grading of the FVC and FVL tests 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.

Grading of the SVC test;

Grade	Criteria
A	At least 3 acceptable trials AND the difference between the best VC values is equal to or less than 150 mL
B	At least 2 acceptable trials AND the difference between the best VC values is equal to or less than 150 mL.
C	At least 2 acceptable trials but the results are not reproducible according to 'B'.
D	One acceptable test.
F	No acceptable test.

SIGNS AND SYMBOLS

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

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
	Atmospheric pressure limitation
	Do not use if package is damaged
	Keep away from sunlight
	Keep dry

Markings	Descriptions
	Single use only
	Type BF of Medical Electrical Equipment
SN	Serial Number
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 mm
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 user's failure to follow the warnings and guidelines given in this manual or in other instructional materials provided with the device. Please note that special WARNING should be given by handlers of the device to elderly, pediatric or differently-able users prior to use of the device.

Regardless of the data presented on the Spirohome® Ultrasonic Spirometer, if the patient feels unwell or has respiratory illness symptoms, they should cease use of the device. Only a doctor can decide on an appropriate treatment plan for the patient 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 the 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 patient's 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 Spirohome device 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.

If a new user is to use the device, ensure that the device is cleaned and disinfected (see Maintenance section of this manual) between each user and a new disposable mouthpiece is attached. Also ensure that you select the new patient (or add new patient if that patient is not created in the account) on the Spirohome® Clinic App before performing a spirometry session with the device.

The Spirohome® Clinic 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 device should be checked periodically 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. The patient should not perform more than 8 spirometry tests in one spirometry session. If the patient senses dizziness while performing a test, stop the test immediately and allow the patient to rest.

The patients should be advised to report any adverse events immediately to the doctor and/or authorities as required by local legislation. The user should also report such incidents to the manufacturer.

The Spirohome® Clinic 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 the Spirohome® Clinic is damaged or malfunctioning, 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 the smart device used in conjunction with the Spirohome® Clinic as per its manufacturer's instructions as the patients' personal data recorded and stored on the Spirohome® Clinic App, may otherwise be at risk. The user is encouraged to not share Spirohome app account information with unauthorised parties.

The Spirohome® Clinic 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

Handle the Spirohome® Clinic and Spiroway® Disposable mouthpiece with care. Do not use the device or its accessories if they are visibly damaged, particularly if there is damage to the filters on the mouthpiece.

Store the Spirohome® Clinic in dust/dirt and moisture free conditions. The pouch provided with the device may be used to keep the device protected. Before each use, always check that the device is free from contaminants and does not have any visible damage. After use by each new user, clean and disinfect the device according to the instructions given in this section.

Proper cleaning and disinfection of your Spirohome® Clinic is important for the safe use of the device. With regular cleaning, the physical build up of contaminants on the device can be prevented. 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 the device protects both handlers and users of the device from the potential transmission of infections resulting from contact with the device. Handlers and users of the device should be sure to wash 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).

CALIBRATION-CHECK

Due to the ultrasound-based technology for air flow analysis, routine calibration of the Spirohome® Clinic is not necessary and technically there is no mechanism provided to user to calibrate the device. The device is factory calibrated and are calibration can only be done by the manufacturer. However, it is advised by the American Thoracic Society (ATS) that periodic calibration-checks of spirometers are performed.

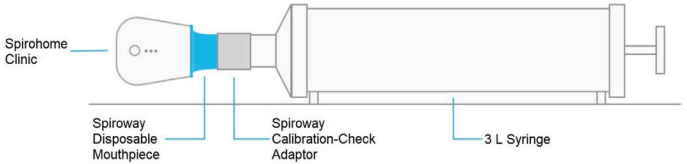
Preparation of Calibration Check

1. To check the calibration of the Spirohome® Clinic, a standard 3L calibration syringe and a Spiroway® Calibration-Check Adaptor must be used in the following calibration-check procedures.

2. To ensure that the temperature inside the syringe and the room are the same. This is necessary to prevent failed caibration-check due to temperature differences. You can push and draw piston of 3 L calibration syringe a few times to balance the temperature inside and outside the piston.

NOTE: Avoid placing the body of the syringe near heat sources, or warming its casing with hands.

3. Connect the device to the syringe as shown in the diagram.



4. To perform the Calibration-Check, select Calibration-Check in the settings section of the Spirohome app.

5. Then choose the Calibration-Check type.

Multi-Flow Calibration-Check:

One expiration for three different flow rates (given below) is simulated in this type of Calibration-Check;

1. Select Multi-Flow Calibration-Check type from Spirohome app.

2. Setup baseline for the device. For this step stabilize the device during the baseline setup.

3. Move the syringe to the most open (full of 3 liters air) position.

4. Transfer the air in the 3-liter syringe to the device in approximately 1 second (~ 3 L / s flow rate) as directed by the Spirohome application.

5. In case of not achieving flow rate at the specified speed, the application will be displayed as a **speed error** and you will be asked to repeat it at that speed.

6. If air is delivered at the right speed and the air flow rate measured by the device to be less than ± 3.5% error rate from given air flow rate, the application will ask you to switch to a 2nd speed measurement test. If the error rate is more than ± 3.5%, it will be displayed as a calibration error.

7. Return the syringe to the most open (full of 3 liters air) position.

8. Transfer the air in the 3 liter syringe to the device in approximately 0.6 seconds (~ 5 L / s flow rate) as directed by the Spirohome application.

9. In case of not achieving flow rate at the specified speed, the application will be displayed as a **speed error** and you will be asked to repeat it at that speed.

10. If air is delivered at the right speed and the air flow rate measured by the device to be less than ± 3.5% error rate from given air flow rate, the application will ask you to switch to a 3rd speed measurement test. If the error rate is more than ± 3.5%, it will be displayed as a **calibration error**.

11. Return the syringe to the most open (full of 3 liters air) position.

12. Transfer the air in the 3 liter syringe to the device in approximately 0.4 seconds (~ 7 L / s flow rate) as directed by the Spirohome application.

13. In case of not achieving flow rate at the specified speed, the application will be displayed as a speed error and you will be asked to repeat it at that speed.

14. If air is delivered at the right speed and the air flow rate measured by the device to be less than ± 3.5% error rate from given air flow rate, the application will be displayed as **calibration valid**. If the error rate is more than ± 3.5%, it will be displayed as a **calibration error.**

15. After the Calibration-Check is completed, the result screen will appear and the measured values will be shown on this screen.If there is a problem with the calibration of the device is detected, contact the manufacturer immediately and do not perform any further tests with the device.

Linearity Calibration-Check:

One expiration for three different flow rates (given below) is simulated in this type of Calibration-Check;

1. Select Linearity Calibration-Check type from Spirohome app.

2. Perform to setup baseline for the device. For this step stabilize the device during the baseline setup.

3. Move the syringe to the most open (full of 3 liters air) position.

4. Transfer the air in the 3-liter syringe to the device in approximately 1 second (~ 3 L / s flow rate) as directed by the Spirohome application. Perform correctly this step 2 more times.

5. In case of not achieving flow rate at the specified speed, the application will be displayed as a **speed error** and you will be asked to repeat it at that speed.

6. If air is delivered at the right speed and the air flow rate measured by the device to be less than ± 3.5% error rate from given air flow rate, the application will ask you to switch to a 2nd speed measurement test. If the error rate is more than ± 3.5%, it will be displayed as a **calibration error.**

7. Return the syringe to the most open (full of 3 liters air) position.
8. Transfer the air in the 3 liter syringe to the device in approximately 0.6 seconds (~ 5 L / s flow rate) as directed by the Spirohome application. Perform correctly this step 2 more times.

9. In case of not achieving flow rate at the specified speed, the application will be displayed as a **speed error** and you will be asked to repeat it at that speed.

10. If air is delivered at the right speed and the air flow rate measured by the device to be less than ± 3.5% error rate from given air flow rate, the application will ask you to switch to a 3rd speed measurement test. If the error rate is more than ± 3.5%, it will be displayed as a **calibration error.**

11. Return the syringe to the most open (full of 3 liters air) position.

12. Transfer the air in the 3 liter syringe to the device in approximately 0.4 seconds (~ 7 L / s flow rate) as directed by the Spirohome application. Perform correctly this step 2 more times.

13. In case of not achieving flow rate at the specified speed, the application will be displayed as a **speed error** and you will be asked to repeat it at that speed.

14. If air is delivered at the right speed 3 times and the air flow rates measured by the device to be less than ± 3.5% error rate from given air flow rates, the application will ask you to switch to a 2nd speed measurement test. If the error rate is more than ± 3.5%, it will be displayed as a **calibration error.**

15. After the Calibration-Check is completed, the result screen will appear and the measured values will be shown on this screen.

If there is a problem with the calibration of the device is detected, contact the manufacturer immediately and do not perform any further tests with the device.

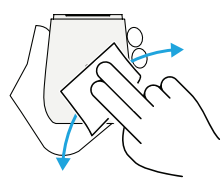
CLEANING AND DISINFECTION

IMPORTANT!: The Spirohome® Clinic must be cleaned and then disinfected between each new user.

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

2. Perform cleaning

Remove the Spiroway Disposable mouthpiece attached to the Spirohome® Clinic body by pushing the notch, refraining from making contact with the mouth-contacting part of the mouthpiece. Using a high-level disinfectant (Sodium Hypochlorite) wipe, wipe (for at least 30 seconds) all accessible surfaces of the device to remove all visible contaminants as shown below. Please be extra careful and gentle when cleaning the sensors to avoid any damage to them. You should clean the Spirohome® Clinic body between each new patient.

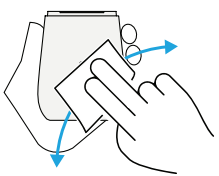


Wipe all accessible surfaces of the device, using moderate pressure, as shown.

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

3. Perform disinfection

After cleaning all accessible surfaces of the device 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 suitable for this purpose and available at www.palinternational.com/healthcare-wipes/disinfectant/

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

THE SPIROWAY® DISPOSABLE

The Spiroway® Disposable is a SINGLE-USER mouthpiece. It MAY NOT be cleaned and/or disinfected between patients, it MUST be changed between patient.

CAUTION: Risk of Cross-Contamination

Spirohome® Clinic may be used by multiple users, however, the cleaning and disinfection procedure described for the device must be performed between each new user AND a new Spiroway® Disposable mouthpiece must be used for each new user. This is important to prevent any risk of cross-contamination between users.

New mouthpieces can be purchased at www.spirohome.io

BATTERIES

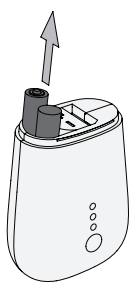
The Spirohome® device is suitable to work with any 1.5V AAA battery, including off-the-shelf AAA rechargeable batteries. The battery life of the Spirohome is approximately 3 months for one session (2 tests) by a day. The battery charge level is continuously monitored by the device. When the device battery 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

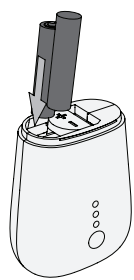
Open the cap and remove the battery cover by pushing it as shown.

2



Remove the dead batteries.

3



Place the new batteries in the correct orientation.

4

Slide the battery cover back to the closed position and close the cap

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, 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® Clinic from list of detected devices.

Problem	Cause	Solution
Test results are inconsistent	Spiroway® mouthpiece is dirty	With the condition that it is to be used by the same patient clean the Spiroway® Disposable Mouthpiece to ensure that the lumen is not obstructed or replace with a new mouthpiece
	Spiroway® mouthpiece is damaged	Replace Spiroway®
	Spirometry test was performed incorrectly	Refer to Performing a Lung Function Test in user manual or refer video tutorial on app
	Spiroway® mouthpiece is installed incorrectly	Refer to user manual for proper installation of Spiroway®
	Device may lost calibration.	Perform the Calibration-Check and contact the manufacturer if got any error.
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.
	Spiroway® Mouthpiece is not inserted	Insert Spiroway® Mouthpiece
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

Problem	Cause	Solution
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.
Measurement error screen showed up	Flow limit exceeded	This device intended to measure 0-14 L/s.
	Foreign object between sensors	Replace Spiroway®
	Spiroway® mouthpiece is damaged	Replace Spiroway®
	Device malfunction	Contact manufacturer or reseller
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	Replace Spiroway®
	Spiroway® mouthpiece is damaged	Replace Spiroway®
Device is not responding to button	Device error	Remove the batteries, wait 30 seconds and reinstall batteries

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

ORDERABLE ACCESSORIES

- Spiroway® Disposable Mouthpiece (Reference number:04000)
- Spiroway® Calibration-Check Adaptor (Reference number:06000-30 / 06000-35)
- Spirohome® Clinic Cap (Reference number: 02104)

These accessories may be ordered from www.spirohome.io

TERMS OF WARRANTY

Spirohome® Clinic, 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 authorised 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 where P is the maximum output power rating of the transmitter in watts (W) according to the 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

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

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Web
www.spirohome.io

CE

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

02504.08.01

User Manual