SPIROHOME®

ULTRASONIC SPIROMETER

The document will be signed after revision.

	FUNCTION	DATED	SIGNED
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REVISION RECORD

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00	24.02.2019	Initial Issue	

Spirohome® Personal

User Manual

1. Preface

1.1 Spirohome® Personal user manual version history

Version Number	Publication Date	Description
Rev.00	24.02.2019	Initial version for market launch

This revision of the Spirohome® Personal user manual applies to Spirohome® Personal devices with a serial number between S011900001-S011900150.

Version histories of all Spirohome® user manuals can be found on the Spirohome® website www.spirohome.io.

For any queries relating to the revision history of the user manual or product, please contact your Spirohome® dealer or manufacturer.

1.2 Intended use of the Spirohome® Personal

The Spirohome® Personal is a prescription device for diagnostic spirometry testing of adult and pediatric patients over the age of 5 who have been diagnosed with a chronic pulmonary disease including, but not limited to, asthma, chronic obstructive pulmonary disease and cystic fibrosis. **It is to be operated in the home setting by competent adult patients or caregivers of patients.**

1.3 About this user manual

This user manual should be read by users of the device prior to operating the Spirohome® Personal. Store this user manual in a clean and easily accessible place for future reference.

1.4 Legal Information

Contents of the user manual may be subject to change. Please refer to the Spirohome® website for the latest version of user manuals. No part of this manual may be reproduced without the written permission from Inofab.

Spirohome® is a registered trademarks of İnofab Sağlık Teknolojileri A.Ş.

Spiroway® s a registered trademarks of İnofab Sağlık Teknolojileri A.Ş.

Bluetooth® is a registered trademark of Bluetooth SIG, Inc.

1.5 Electromagnetic Compatibility

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications made to this equipment not expressly approved by Inofab Sağlık Teknolojileri A.Ş. may void the FCC authorization to operate this equipment.

1.6 Product Disposal

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

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

1.7 Manufacturer Information

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2. Safety Information

2.1 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.

General:
The manufacturer is not responsible for any damage/harm to either the device or user which has resulted from nonadherence to the warnings, precautions and instructions given in the official device user manual, labeling and other informational material.

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

Product and components:
Do not use the device if there is any damage is present on the device or its components upon removal from packaging, and return the product to the supplier.

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 cause damage to or use the mouthpieces with physically compromised filters.

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

Data:
Only a qualified healthcare professional can make a diagnosis with, in addition to other medical testing and your clinical history, the data presented by the Spirohome® Personal.

Please ensure that your personal data such as height, weight, age, sex and ethnicity are entered according to your current state and that the values are entered correctly.

Regardless of the data presented on the Spirohome® Personal, if you feel unwell or have respiratory illness symptoms please contact your healthcare provider immediately.

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.

If your Spirohome® Personal is damaged or malfunctioning or you encounter data that you cannot make sense of, contact the manufacturer directly and cease use.

Users:
Do not use your Spirohome® Personal for any other purpose than its intended use. Spirohome® Personal is not recommended for children under the age of 5.

Do not share your Spirohome® Personal with any other users, including family members, as the Spirohome® Personal and Spiroway® reusable mouthpiece 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 used and a new account is created for the user on the app.

For patients who require assistance by competent caregivers, special warnings regarding the Spirohome® Personal should be provided by the caregiver to the patient prior to using the device.

Testing:
One 'use' of the spirometer is defined as one complete spirometric testing session (can include up to 8 individual successive spirometry tests). The mouthpiece should be fully inserted before and during a test. Start test again if mouthpiece dislodges during testing.

You MUST use a mouthpiece during testing. Blowing into the device directly will cause incorrect measurements and potential harm to both the user and device.

Make sure the base of the device lumen is clear of fingers or any other materials that may be blocking this exit as measurement by the device may be affected.
Do not 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.

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.

Environment and storage:
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 section of this user manual) to avoid malfunction and/or display of incorrect results.

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.

To prevent damage to the Spirohome® Personal 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.

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.

Maintenance:
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.

All repairs, modifications or reconfigurations must be performed only by the manufacturer, an opened device casing will terminate product warranty.

2.2 Restrictions on use and contraindications
Spirohome® Personal must only be used by a *single user*. If the device will be passed on to a new user, 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 prior to conducting any tests.

Do NOT share the Spiroway® reusable mouthpiece, including with family members. Any new user of the device must use a new Spiroway® reusable mouthpiece.

The spirometry tests 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.

Failure to perform the specific breathing maneuver of a particular spirometry test correctly may lead to inaccurate and/or unacceptable results. Refer to the Breathing Maneuvers section of this user manual for more information.

Some medical conditions may pose a danger to you 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 your healthcare professional before using the*** **Spirohome® Personal*.***

2.2 Signs and symbols

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

Markings	Descriptions
	“Manufacturer” The name and the address of the manufacturer is adjacent to the symbol.
‘FCC ID’	Unique identifier given by the Federal Communications Commission
‘Rx Only’	Prescription-only device
	Disposal in compliance with Waste Electrical and Electronic Equipment Directive
	Temperature limit

	Humidity limit
	Atmospheric pressure limit
	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
LOT	Lot Number
REF	Ref Number

IP	IP Number
	Device includes RF transmitters
	The instruction manual/booklet must be read.

3. About the Spirohome® Personal

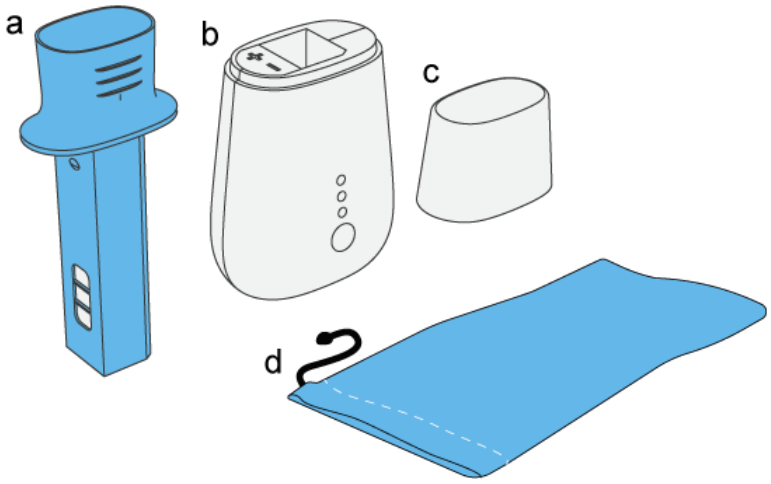
3.1 Product description

The Spirohome® Personal is a portable spirometer that pairs (via Bluetooth®) to 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 *How to perform 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 display. The Spirohome® 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 Spiroway® reusable mouthpiece.

3.2 The Spirohome® Personal System

Your Spirohome® Personal System consists of:

- Spirohome® Personal (b)
- Spiroway® reusable mouthpiece(a)
- Spirohome® Personal *cap(c)*
- 2 x AAA Batteries
- 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.

Connected smart device requirements:

Spirohome® Personal with iOS device: Requires İOS 11.0 or later. Compatible with Iphone 5s or later, iPad Air Wifi or later, and Ipod touch.

Spirohome® Personal with Android device: Requires Android API level 21 (Lollipop 5.0) or later.

3.3 Orderable accessories

You can order new or replacement Spirohome® Personal accessories from www.spirohome.io. When placing your order, please be sure to note the accessory reference number.

Accessory Name	**Reference Number**
Spiroway® Reusable Mouthpiece	03000
Spiroway® Disposable Mouthpiece	04000
Spirohome® Personal Cap	01104
Spirohome® Pouch	01509

4. Cybersecurity

To protect your device and data, please read and apply the following guidance.

4.1 About cybersecurity and your Spirohome® Personal

The Spirohome® Personal platform involves the connection of your Spirohome® Personal device to the Spirohome® Personal app. The data you enter and record with your Spirohome® Personal device via the Spirohome® Personal app is stored on a SQL-server database.

Spirohome® Personal automatically connects to the network. It will still work off-line, and transfer data to the network as soon as a connection is established. Both the local database (connected smart device) and server-based database (Spirohome® database on the network) is encrypted.

4.2 Passwords on the Spirohome® Personal platform

Access to your Spirohome® Personal device is granted through the entry of a username and password which you will create at first set-up of the device and app. It is the responsibility of the user to change or update password information at regular intervals (every 3 months) for ensuring security. Please choose a password that is strong and difficult to be copied by unauthorized users. The minimum requirements for a Spirohome® password is using at least 8 characters, at least one uppercase and one lower case alphabetic characters and at least one number.

4.3 Software Updates

In order to improve the Spirohome® app features or incorporate new security features, Spirohome® software updates may be sent to your smart device. Your device will be sent notifications about installing the latest update to the app. If warning notifications for software updates are ignored, access to testing on the app may be barred until the update has been installed. This is to ensure that important improvements to app features and security have been updated for your safety.

4.4 Data back-ups

Any data that is stored on Spirohome® servers are periodically backed-up. Spirohome® devices must be connected to a network to allow for data on the device to be transferred, stored and regularly backed-up on Spirohome® servers. For any data that is stored on personal servers or smart devices, it is the responsibility of the user to back this data up.

4.5 Security breaches

1. Change password, password is checked every time you log in. Changing password on one connected device will log you out of all connected devices.

2. If your password has been breached, try resetting your password through your registered email address by clicking 'Forgot Password'.
3. Contact manufacturer

4.6 Lost or stolen devices

If your Spirohome® Personal device is lost or stolen, please report the issue immediately and directly to you Spirohome® Personal provider. Your provider will ensure that your device is locked for use by any unauthorized users.

Your device is paired to your user account. A device cannot be designated to two different user accounts.

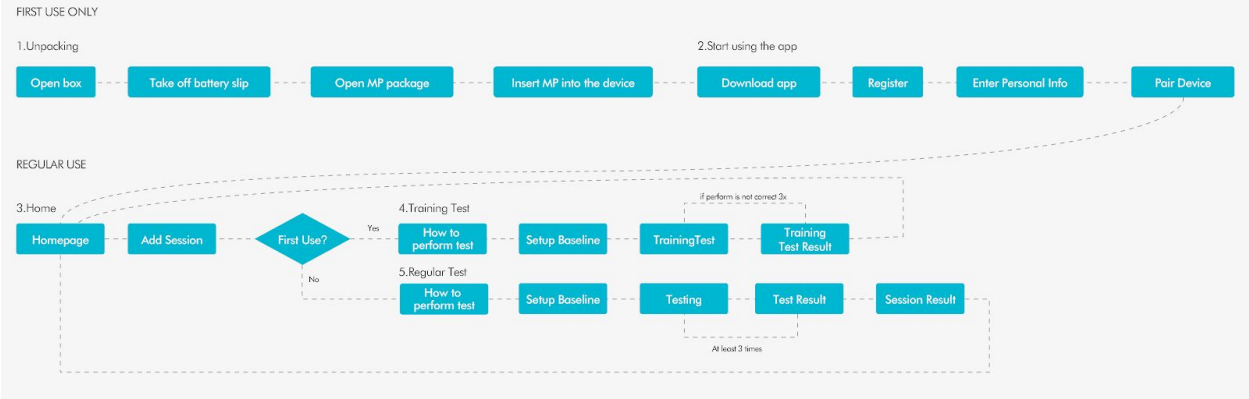
5. Spirohome® Personal and smart device connectivity

5.1 Connectivity of the Spirohome® Personal platform

The Spirohome® platform allows a range of devices to connect to a central network. Several smart devices with the Spirohome® Personal app can connect to and share information on a central database. Access to a patient's information from different devices requires that the same user account information is entered on all devices.

6. Operating the device

6.1 How to use the Spirohome® Personal: An overview



6.2 Operating environment

The Spirohome® Personal is designed for use in a home setting. It should not be used in a clinical setting such as a hospital or private clinic.

.
The *operating conditions* for the Spirohome® Personal is specified as:
Temperature: 15°C to +40°C
Relative Humidity: 5% to 95%

The *storage conditions* for the Spirohome® Personal is specified as:
Temperature: -20°C to +50°C
Relative Humidity: 5% to 95%
Pressure: 500 hPa to 1060 hPa

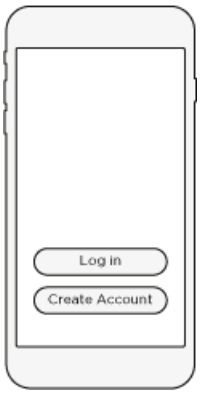
The Spirohome® Personal should not be used in the presence of inflammable liquids or detergents, nor in the presence of inflammable anaesthetic gases (oxygen or nitrogen).

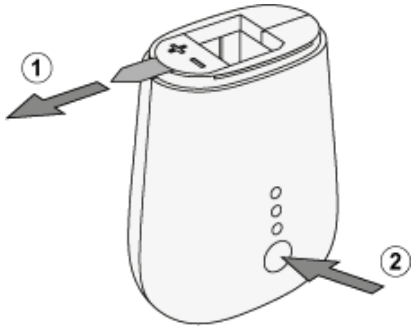
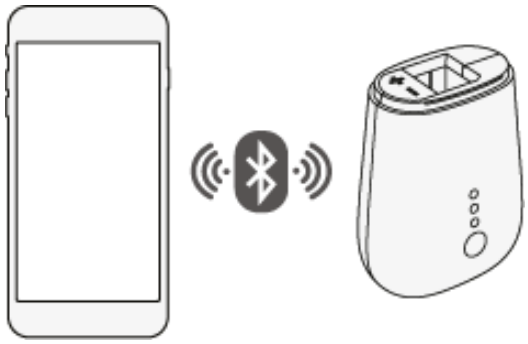
The device should not be used in direct air currents (e.g. wind), sources of heat or cold, direct sun rays or other sources of light or energy, dust, sand or any other chemical substances.

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.

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 only as specified by the manufacturer, it may to avoid interference to radio communications.

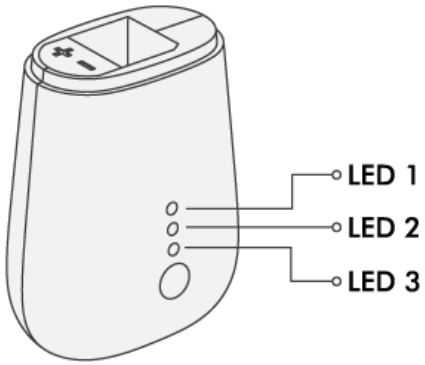
6.3 Setting up your Spirohome® Personal

1.Download the Spirohome® Personal app from the App Store or Google Play Store onto your smart device. 	**2.** Follow the steps given on the app screen to create a new user account or log in to your existing account. 
3. Pull out the battery protector (1) and press the power button (2) for one second to switch	**4.** Enable Bluetooth® on your smart device, and select your Spirohome® Personal from

on the device.  	available devices. Your device should now be paired. 

6.4 Device indicators

There are 3 LED lights located on the front of the device. The following picture shows the assigned numbers to each LED.



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 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.
All LEDs are flashing red.	There is a foreign object between the sensors. (TOF out of range error)
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.

6.5 Technical features of the Spirohome® Personal

Flow / Volume measurement method	Ultrasonic Transducer Measurement
Power Supply	2 x 1.5V AAA batteries
Dimensions	110 x 63 x 41 mm
Weight (With batteries)	90 g
Weight (Without batteries)	67 g
Flow range	0 - 14 L/s
Maximum volume measured	10 L
FVC accuracy (Average)	± 2 %
FEV1 accuracy (Average)	± 2 %
PEF accuracy (Average)	± 1.9 %
Dynamic resistance at 14 L/s	68.2 Pa*s/L
Volume resolution	1 mL

Flow resolution	1 mL/s
Medical device class	Class IIA
Wireless connection	BLE 4.2

6.6 Troubleshooting and error messages

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 the battery cap is in the 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.
Test results are inconsistent	Spiroway® mouthpiece is dirty	Clean Spiroway® mouthpiece to ensure that the lumen is not obstructed or replace with a new mouthpiece
	Spiroway® mouthpiece is damaged	Replace Spiroway® mouthpiece

	Spirometry test was performed incorrectly	Refer to How to Perform a Lung Function Test in user manual or refer video tutorial on app
	Spiroway® mouthpiece is installed incorrectly	Refer to the user manual for proper installation of Spiroway® mouthpiece
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.
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
Test does not end and keeps going	Inhalation at the end of test not performed	After a forced exhalation, take a short breath through the spirometer before breaking the seal of your lips around the mouthpiece. The device ends the measurement when it detects a small amount of negative volume

Error Messages		
Message	**Possible Cause**	**Solution**

Error 01	Bluetooth® is disabled	Enable Bluetooth® on your smart device from its settings menu
Error 02	Batteries of the Spirohome® Personal need to be replaced	Replace batteries as described in the Maintenance section of this user manual
Error 03	Components not attached correctly.	Ensure that the mouthpiece is attached to your Spirohome® Personal device correctly
	Sensors are obstructed.	Ensure that the components are clean and clear of foreign body materials.
	Test was not performed correctly.	Repeat the test following the rules and conditions specified in the Performing a Lung Function Test section of this user manual.
Error 04	Flow measurement limit is exceeded	Consult the manufacturer or healthcare provider
Error 05	Sensor Error	Consult Manufacturer
Error 06	Device disconnected during test	Relaunch app and start test again
Error 07	Self sensors test failed	Check lumen of device to ensure that sensors are not obstructed
		Contact Manufacturer
Error 08	Poor or no internet connection	Check to ensure that smart device is connected to the internet

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

7. Spirometry with your Spirohome® Personal

7.1 How to perform a spirometry test

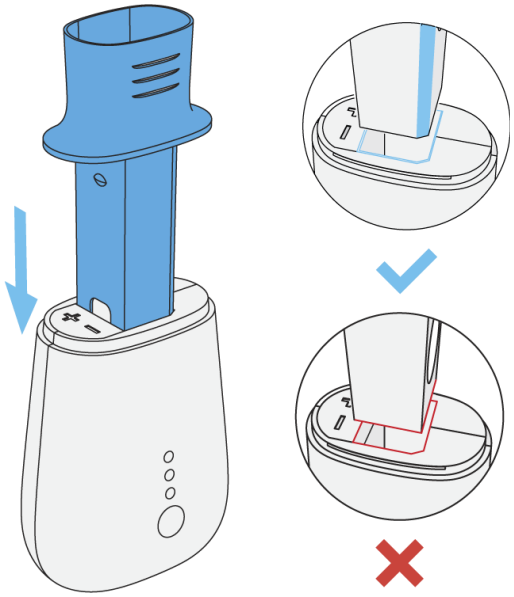
There are several types of tests and different parameter relating to lung function that can be involved in a spirometry test. Each type of spirometry test requires a specific breathing maneuver in order to detect the parameters related to that particular test type. However, the general method of performing 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.

Note: One spirometry ***session*** refers to a full set of spirometry tests performed in one sitting. The recommended number of ***tests*** per spirometry session is 3, however, you may perform up to 8 tests. The best values obtained from the spirometry tests performed in one session is displayed

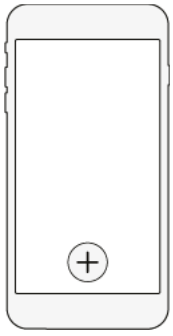
on the app interface.You also have the option to view the results of each spirometry test performed in a spirometry session separately.

General method for performing a spirometry test with the Spirohome® Personal:

1. Remove the Spiroway® reusable mouthpiece from its plastic packaging and insert it all the way into the Spirohome® Personal as shown. A 'click' will be heard when the mouthpiece is inserted correctly all the way into the device.

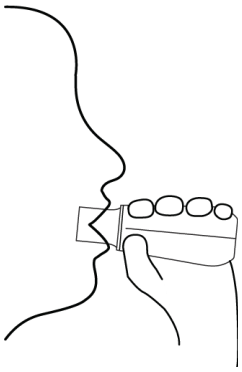


2. Load the Spirohome® Personal App on your smart device and sign in. Tap the 'plus' button (shown) to start a new test.



3. The first step will be to record a baseline for the device. To perform the baseline setup, place the device cap on and stabilize the device during the baseline setup. Alternatively, place the device on a flat surface and allow the baseline setup to be completed.

4. You will then be prompted to perform a spirometry test. Place the mouthpiece in your mouth, past your teeth, and form a tight seal around the mouthpiece with your lips.



5. Perform the breathing maneuver related to the specific test you wish to perform. Please see the Breathing Maneuvers section of this user manual for more information.

7.2 Spirometry Parameters

NOTE: Your Spirohome® Personal can measure all of the parameters listed below, however, the set of parameters actually displayed on the app will depend on the level of access to your test results that your Spirohome® user account has been granted.

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

Test	Primary Parameters*	Unit
FVC	BEV*	L
	FEF_{25} (MEF_{75})**	L/s
	FEF_{50} (MEF_{75})**	L/s
	FEF_{75} (MEF_{25})**	L/s
	FEF_{25-75} ($MMEF_{25-75}$)*	L/s
	FEF_{50}/FVC**	1/s
	FET*	s
	$FEV_{.75}$**	L
	FEV_1*	L
	FEV_3**	L
	FEV_6**	L
	$FEV_{.75}$/FVC**	-
	FEV_1/FVC*	-
	FEV_3/FVC**	-
	FEV_6/FVC**	-
	$FEV_{.75}$/FEV_6**	-
	FEV_1/FEV_6**	-

	FVC*	L
	PEF*	L/s
	MET_{25-75}**	s
	MMEF/FVC**	1/s
FVL	BEV*	L
	FEF_{25} (MEF_{75})**	L/s
	FEF_{50} (MEF_{50})**	L/s
	FEF_{75} (MEF_{25})**	L/s
	FEF_{25-75} ($MMEF_{25-75}$)*	L/s
	FEF_{50}/FVC**	-
	FET*	s
	$FEV_{.75}$**	L
	FEV_1*	L
	FEV_3**	L
	FEV_6**	L
	$FEV_{.75}$/FVC**	-
	FEV_1/FVC*	-
	FEV_3/FVC**	-
	FEV_6/FVC**	-
	$FEV_{0.75}$/FEV_6**	-
	FEV_1/FEV_6**	-
	FIF_{25-75} **	L/s
	FIVC*	L
	FIV_1**	L

	FIV_1/FIVC (FIR)**	-
	FVC*	L
	MET_{25-75}**	s
	MMEF/FVC**	-
	PEF*	L/s
	PIF*	L/s
	$R_{50}(FEF_{50}/FIF_{50})$**	-
SVC	VC*	L
	VCin*	L
	VCex*	L
	ERV*	L
	IC**	L
	IRV*	L
	VT*	L
MVV	MVV*	L/min
	MVV6*	L/min
	VT*	L
	RF*	1/min
	MVVtime*	s

*Primary parameters are displayed as default on the results screen of the app after each spirometry session.

** Secondary parameters are available in the 'See more parameters' section of the app after each spirometry session.

The definition of the parameters detected and displayed by the Spirohome® Personal is given below:

Abbreviations	Definition
BEV	Back extrapolated volume
ERV	Expiratory reserve volume - maximal volume of air that can be exhaled from the end-expiratory position
FEF_{25}	Forced expiratory flow at 25% of vital capacity
FEF_{25-75}	Forced expiratory flow from 25% to 75% of vital capacity
FEF_{50}	Forced expiratory flow at 50% of vital capacity
FEF_{75}	Forced expiratory flow at 75% of vital capacity
FEF_{50}/FVC	Ratio of FEV_{50} to FVC
FEF_{50}/FIF_{50}	Ratio of FEF_{50} to FIF_{50}
$FEV_{.75}$	Forced expiratory volume after 0.75 seconds
FEV_1	Forced expiratory volume after 1 second
FEV_3	Forced expiratory volume after 3 seconds
FEV_6	Forced expiratory volume after 6 seconds
$FEV_{.75}$/FVC	Ratio of $FEV_{.75}$ 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
$FEV_{.75}/FEV_6$	Ratio of $FEV_{.75}$ to FEV_6
FEV_1/FEV_6	Ratio of FEV_1 to FEV_6
FET	Forced expiratory time
FIF_{25}	Forced inspiratory flow at 25% of vital capacity
FIF_{25-75}	Forced inspiratory flow from 25% to 75% of vital capacity
FIF_{75}	Forced inspiratory flow at 75% of vital capacity
FIV_1	Forced inspiratory volume after 1 second

FIV_1/FIVC	Ratio of FIV_1 to FIVC
FIVC	Forced inspiratory vital capacity
FVC	Forced vital capacity
IC	Inspiratory capacity - the sum of IRV and TV
IRV	Inspiratory reserve volume - maximal volume of air that can be inhaled from the end-expiratory position
MEF_{25}	Maximal instantaneous forced expiratory flow where 25 % of the FVC remains to be expired
MEF_{50}	Maximal instantaneous forced expiratory flow where 50 % of the FVC remains to be expired
MEF_{75}	Maximal instantaneous forced expiratory flow where 75 % of the FVC remains to be expired
MET_{25-75}	Time between 25% and 75% of the forced expired volume
MIF_{25}	Maximal instantaneous forced inspiratory flow where 25 % of the FVC remains to be expired
MIF_{75}	Maximal instantaneous forced expiratory flow where 75 % of the FVC remains to be expired
$MMEF_{25-75}$	Mean mid-expiratory flow from 25% to 75% of vital capacity
MMEF/FVC	Ratio of mean mid-expiratory flow to forced vital capacity
MVV	Maximum voluntary ventilation
MVV6	Maximum voluntary ventilation after 6 seconds
MVVtime	Time for MVV to be reached
PEF	Peak expiratory flow
PIF	Peak inspiratory flow
R_{50}	Ratio of FEF_{50} to FIF_{50}
RF	Respiratory frequency
VC	Vital capacity

VCex	Expiratory vital capacity
VCin	Inspiratory vital capacity
VT	Tidal volume

The device also provides a reference value (obtained from large epidemiological studies) based on the patient's height, weight, age, sex and ethnicity. Your spirometry test results 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.

If you wish for assistance in performing spirometry tests or understanding your test results, please contact your healthcare professional.

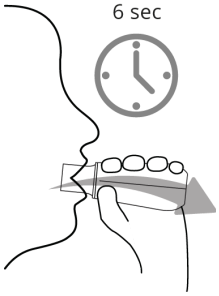
7.3 Types of breathing maneuvers

The breathing maneuvers involved in spirometry tests are physically-demanding for most patients. Please read the information below for the breathing maneuver you want to perform, and continue with testing only if you feel well enough to do so. Please cease testing if you feel dizzy or unwell.

The Forced Vital Capacity Test Breathing Maneuver:

1. Ensure that your device is connected, the test screen is ready.
2. To ready yourself, place the mouthpiece in your mouth (past your teeth and with your lips sealed tightly around it), inhale and exhale normally a couple of times, and then take a slow and deep breath, **filling your lungs completely**. NOTE: You may choose to place the mouthpiece in your mouth after drawing in air and filling your lungs completely, making sure to place the mouthpiece past your teeth and sealing your lips around it before proceeding to the next step.
3. With your **lips sealed tightly around the mouthpiece**, empty your lungs by blow **as hard and fast as you can** into the mouthpiece **for at least 6 seconds** (follow animated

guide on app screen) without breaking the seal of your lips, and then **inhale a small amount of air to signal the end of your exhalation**. You may use a nose clip to help you exhale through only your mouth during this maneuver.



4. You may remove the mouthpiece from your mouth and resume normal breathing once the breathing maneuver has been completed.
5. Feedback about the test will be displayed on the app screen. You may need to repeat this breathing maneuver until you have acceptable test results. However, **ensure that you have rested between tests** and feel well enough to continue**.** For more information about test quality grading refer to the *Understanding test quality* section of this user manual.
6. Once all tests have been satisfactorily completed, you will be able to view your session results on the results page of the app.
7. To end the spirometry session, remove mouthpiece, turn off device, and store (you may use product pouch) according to storage requirements until next use. If the mouthpiece requires cleaning, please refer to section 8.2 Cleaning the Spiroway® reusable mouthpiece.

The Flow Volume Loop Test Breathing Maneuver:

1. Ensure that your device is connected, the test screen is ready.
2. You must enter the environmental temperature as prompted by the app. **The temperature entered must be within 1°C or 1.8°F accuracy**.
3. After confirming the temperature you have entered, you are ready to perform the breathing maneuver.
4. To ready yourself, place the mouthpiece in your mouth (past your teeth and with

your lips sealed tightly around it), inhale and exhale normally a couple of times, and then take a slow and deep breath, **filling your lungs completely**. NOTE: You may choose to place the mouthpiece in your mouth after drawing in air and filling your lungs completely, making sure to place the mouthpiece past your teeth and sealing your lips around it before proceeding to the next step.

5. With your **lips sealed tightly around the mouthpiece**, empty your lungs by blow **as hard and fast as you can** into the mouthpiece **for at least 6 seconds** (follow animated guide on app screen) without breaking the seal of your lips, and then **inhale a small amount of air to signal the end of your exhalation**. You may use a nose clip to help you exhale through only your mouth during this maneuver.
6. **Without breaking the seal of your lips, now inhale completely filling your lungs.**
7. You may remove the mouthpiece from your mouth and resume normal breathing once the breathing maneuver has been completed.
8. Feedback about the test will be displayed on the app screen. You may need to repeat this breathing maneuver until you have acceptable test results. However, e**nsure that you have rested between tests** and feel well enough to continue**.** For more information about test quality grading refer to the *Understanding test quality* section of this user manual.
9. Once all tests have been satisfactorily completed, you will be able to view your session results on the results page of the app.
10. To end the spirometry session, remove mouthpiece, turn off device, and store (you may use product pouch) according to storage requirements until next use. If the mouthpiece requires cleaning, please refer to section 8.2 Cleaning the Spiroway® reusable mouthpiece.

The Maximum Voluntary Ventilation Test Breathing Maneuver:

1. Ensure that your device is connected, the test screen is ready.
2. You must enter the environmental temperature as prompted by the app. **The**

temperature entered must be within 1°C or 1.8°F accuracy.

3. After confirming the temperature you have entered, you are ready to perform the breathing maneuver.
4. Place the mouthpiece in your mouth past your teeth and ensure your **lips are tightly sealed around the mouthpiece**.
5. I**nhale and exhale completely filling and emptying your lungs, repeatedly, uninterrupted, without breaking the seal of your lips for at least 12 seconds** (follow animated guide on app screen).
6. You may remove the mouthpiece from your mouth and resume normal breathing once the breathing maneuver has been completed.
7. Feedback about the test will be displayed on the app screen.
8. Once the test has been satisfactorily completed, you will be able to view your session results on the results page of the app.
9. To end the spirometry session, remove mouthpiece, turn off device, and store (you may use product pouch) according to storage requirements until next use. If the mouthpiece requires cleaning, please refer to section 8.2 Cleaning the Spiroway® reusable mouthpiece.

The Slow Vital Capacity Test Breathing Maneuver:

1. Ensure that your device is connected, the test screen is ready.
2. You must enter the environmental temperature as prompted by the app. **The temperature entered must be within 1°C or 1.8°F accuracy**.
3. After confirming the temperature you have entered, you are ready to perform the breathing maneuver.
4. Place the mouthpiece in your mouth past your teeth, and your **lips are tightly sealed around the mouthpiece** and **inhale and exhale normally**, for 3-5 breaths.
5. When prompted by the app, **fully inhale and then fully exhale.**
10. You may remove the mouthpiece from your mouth and resume normal breathing once the breathing maneuver has been completed.
11. Feedback about the test will be displayed on the app screen. You may need to repeat

this breathing maneuver until you have acceptable test results. However, **ensure that you have rested between tests** and feel well enough to continue**.** For more information about test quality grading refer to the *Understanding test quality* section of this user manual.

12. Once all tests have been satisfactorily completed, you will be able to view your session results on the results page of the app.
13. To end the spirometry session, remove mouthpiece, turn off device, and store (you may use product pouch) according to storage requirements until next use. If the mouthpiece requires cleaning, please refer to section 8.2 Cleaning the Spiroway® reusable mouthpiece.

7.4 Understanding test quality

After each test session,a quality grading will be displayed on the app to inform you about how well the breathing maneuver was performed, and if the results are acceptable or not.

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 age 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 age 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 age 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 age 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.

8. Maintenance of your Spirohome® Personal

8.1 Calibration-check

Due to the ultrasound-based technology for air flow analysis, routine calibration of your Spirohome® Personal is not necessary. However, it is advised by the American Thoracic Society (ATS) that periodic calibration-checks of spirometers are performed. To check the calibration of your Spirohome® Personal, you may compare the results from your device with spirometry test results you obtain from a clinic or spirometry laboratory.

If you believe that there is a problem with the calibration of the device, contact the manufacturer immediately and do not perform tests with the device.

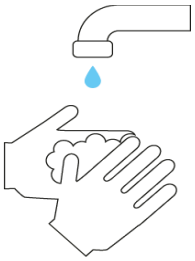
8.2 Cleaning and disinfection of the device

Proper cleaning and disinfection of your Spirohome® Personal is important for safety and hygiene purposes. 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.

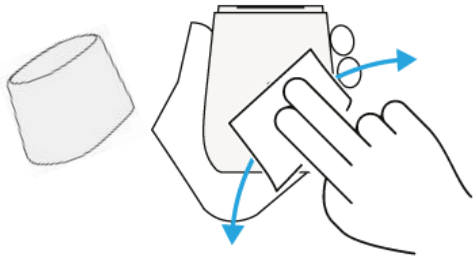
The cleaning procedure and disinfection process is described below:

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



2. Cleaning the Spirohome® Personal

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



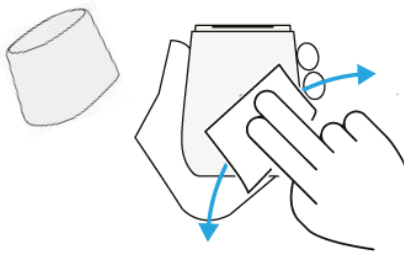
Wipe all accessible surfaces of the device and cap, using moderate pressure, as shown.

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. Disinfecting the Spirohome® Personal

After cleaning accessible surfaces of the device with a high-level disinfectant (chlorine-based) wipe, use a second fresh wipe to wipe over all surfaces again with moderate pressure and contact time as recommended by the wipe manufacturer. You should disinfect the Spirohome®

Personal once a week, always performing the cleaning procedure before the disinfection procedure.



CaviWipes1™ Disinfectant wipes (Metrex Research LLC) is a high-level disinfectant wipes for this purpose and available at https://www.metrex.com/en-us/products/surface-disinfectants/caviwipes.

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

8.2 Cleaning the Spiroway® reusable mouthpiece

The Spiroway® reusable mouthpiece should be cleaned weekly or whenever it is visibly contaminated. Clean the Spiroway® reusable mouthpiece by gently agitating it in water containing dishwashing liquid, rinsing under clean water, and leaving upright on a lint-free cloth to air-dry completely.

Do not insert the Spiroway® reusable mouthpiece to Spirohome® Personal device until it is completely dry.

Replace the Spiroway® reusable mouthpiece:

- every 3 months
- if the user used the mouthpiece whilst having a bacterial or viral infection
- if the filters are damaged
- 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 Spiroway® reusable mouthpiece. The mouthpiece is indicated for *single-patient-use* only. The mouthpiece must not be used by more than one user to prevent the risk 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.*

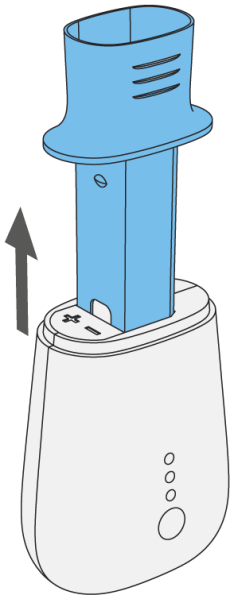
New mouthpieces can be purchased at www.spirohome.io. See the Orderable Accessories section of this user manual for more information.

8.4 Replacing batteries

The Spirohome® Personal should be powered by a standard 1.5V AAA battery. The battery life such batteries will be 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 a ‘beeping’ sound will 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.

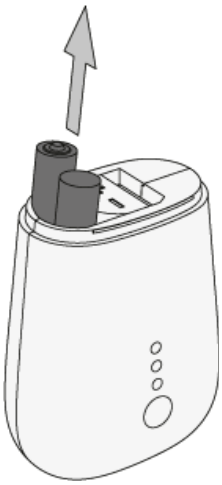
Instructions for battery replacement

1. Remove the Spiroway® reusable mouthpiece from the device.

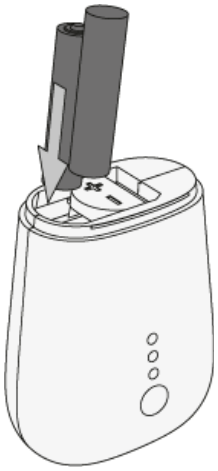


2. Remove the battery cover by sliding it as shown.

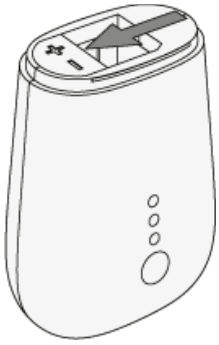
3. Remove the dead batteries.



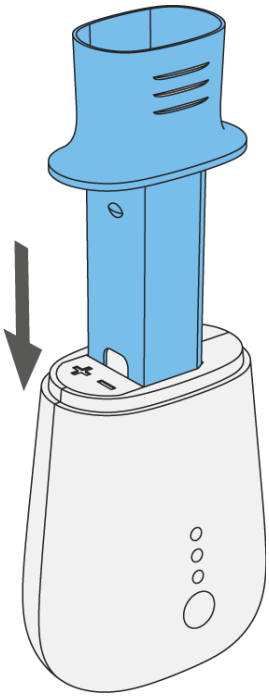
4. Place the new batteries in the correct orientation.



5. Slide the battery cover back to the closed position.



6. Insert the Spiroway® reusable mouthpiece in the right orientation. Your device is now ready to use.



9. Terms of warranty

9.1 Terms of warranty for the Spirohome® Personal

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 unauthorized repair, modification or reconfiguration performed on the device
- Damage caused by lack of proper care or maintenance
- Damage caused by abnormal physical or electrical stress or defects of the mains electricity supply or of equipment to which the product was connected to

- If the serial number is altered, deleted, removed or rendered illegible

9. Appendix

9.1 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 environments.		
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	NA	
Surge IEC 61000-4-5	NA	NA	
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	NA	NA	
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	NA 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 √P d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √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: 

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.