SPIROHOME®

ULTRASONIC SPIROMETER

The document will be signed after revision.

	FUNCTION	DATED	SIGNED
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REVISION RECORD

REVISION NUMBER	DATE	COMMENTS	SIGNED
00	24.02.2019	Initial Issue	

Spirohome® Clinic

User Manual

1. Preface

1.1 Spirohome® Clinic user manual version history

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

This revision of the Spirohome® Clinic user manual applies to Spirohome® Clinic 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® Clinic

The Spirohome® Clinic 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 clinical setting by healthcare professionals**.

1.3 About this user manual

This user manual should be read by users of the device prior to operating the Spirohome® Clinic. 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.

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Spiroway® Clinic 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

İnofab Sağlık Teknolojileri A.Ş

ODTÜ Teknokent Silikon Blok

K:1 NO:15-A Ankara/Turkey

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www.spirohome.io

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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 or authorities as required by local legislation. The operator 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® 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 cause damage to or use the mouthpieces with physically compromised filters.

Be sure to keep hands clear from being caught between components during assembly.

To insert the disposable mouthpiece into the device, tear the bottom part of plastic wrapping off and hold mouthpiece by the top part of the plastic wrapping. Remove top part of plastic wrapping once mouthpiece is inserted fully into the device.

Do not expose the device to liquids, prevent any liquids from entering the device. In the event of a liquid spill on or around the Spirohome® Clinic, 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 the patient'S clinical history, the data presented by the Spirohome® Clinic.
Please ensure that the personal data of the patient such as height, weight, age, sex and ethnicity are entered according to their current state and that the values are entered correctly.

Please ensure that the ambient temperature requested for BTPS correction on the app interface is entered correctly according to the current ambient temperature during testing.

Regardless of the data presented on the Spirohome® Clinic, if the patient feels unwell or has respiratory illness symptoms please perform further care and testing of the patient.

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

If the Spirohome® Clinic 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 the Spirohome® Clinic for any other purpose than its intended use. Spirohome® Clinic is not recommended for children under the age of 5.

The Spirohome® Clinic is to be used with the Spiroway® disposable mouthpiece, with a new disposable mouthpiece used for each new patient. After use by a patient, ensure that the device is cleaned and disinfected (see Maintenance section of this manual), a new mouthpiece is used for the next patient and a new account is created on the app for the new user.

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.

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 allow patients to walk or run while taking a lung function measurement using Spirohome® Clinic spirometer. Do not perform a spirometry test on patients with food or objects in their 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 ask the patient to 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.

Remove disposable mouthpiece by holding flanges on the mouthpiece to avoid direct contact with patient mucosa-contacting part of the mouthpiece.

Environment and storage:
Store and operate the device as specified in this user manual as alternative methods or conditions of storage may affect device function and/or accuracy. Operate 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® Clinic in dust/dirt and moisture free conditions. The pouch provided with the device may be utilized to keep the device protected. Before each operation of the device, always check that the device is free from contaminants and does not have any visible damage.

To prevent damage to the Spirohome® Clinic 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® 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.

Maintenance:
The operator 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® Clinic is a *multi-user* device. For each new patient, ensure that a new patient account is created and their personal data is entered into the system prior to conducting any tests.

Do NOT share the Spiroway® disposable mouthpiece, amongst patients. Any new user of the device must use a new Spiroway® disposable mouthpiece.

The spirometry tests should only be performed by patients 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 of the patient 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 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. ***Ensure that the patient does not have or suspects having any of the conditions above, and exercise care and precaution before making a professional medical decision to allow the patient to use the Spirohome® Clinic.***

2.2 Signs and symbols

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

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® Clinic

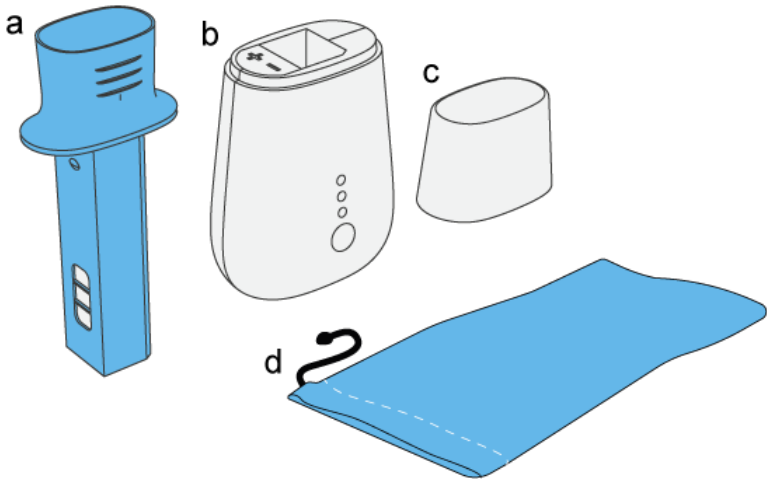
3.1 Product description

The Spirohome® Clinic is a portable spirometer that pairs (via Bluetooth®) to smart devices running with iOS or Android. The Spirohome® Clinic 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® Clinic application on a connected smart device. The Spirohome® Clinic app prompts and guides the user throughout the test for accurate data collection and display. The Spirohome® Clinic app can be downloaded on GooglePlay or on Apple's App Store. The device is powered by 2 x AAA Alkaline batteries. Spirohome® Clinic works with the Spiroway® disposable mouthpiece.

3.2 The Spirohome® Clinic System

The Spirohome® Clinic System consists of:

- Spirohome® Clinic (b)
- Spiroway® disposable mouthpiece (a)
- Spirohome® Clinic *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® Clinic. If damage is present, do not use or attempt to repair the device, please contact the manufacturer directly.

Connected smart device requirements:

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

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

3.3 Orderable accessories

New or replacement Spirohome® Clinic accessories may be ordered from www.spirohome.io. When placing an order, please be sure to note the accessory reference number.

Accessory Name	**Reference Number**
Spiroway Disposable Mouthpiece	04000
Spirohome® Clinic 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® Clinic

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

The Spirohome® Clinic app can also be installed on a clinic or office desktop PC running on Windows. It is the responsibility of the clinic or healthcare institution to protect the device with antivirus software and a firewall, to install critical Windows updates, and to provide the general safety of the PC from cyber or other attacks.

Spirohome® Clinic 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® Clinic platform

Access to your Spirohome® Clinic 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® Clinic 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. It is the responsibility of the institution to back-up any data that is stored on the servers of the healthcare institution or on the smart device itself.

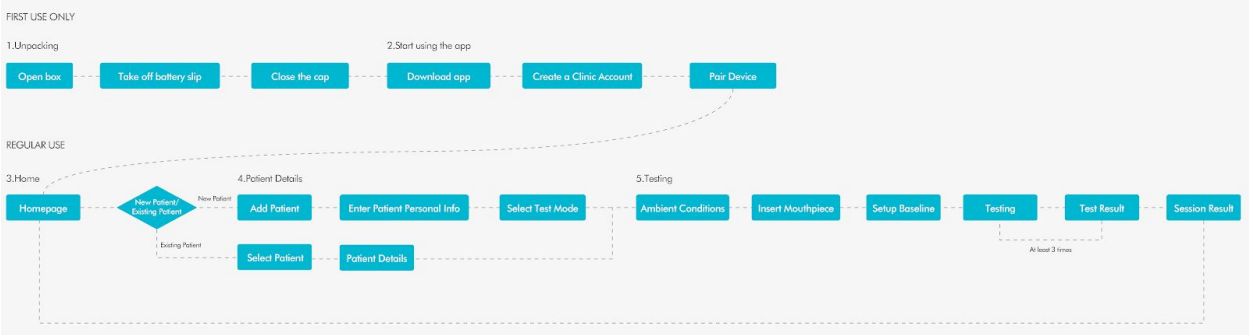
5. Spirohome® Clinic and smart device connectivity

5.1 Connectivity of the Spirohome® Clinic platform

The Spirohome® platform allows a range of devices to connect to a central network. Several smart devices with the Spirohome® Clinic 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® Clinic: An overview



6.2 Operating environment

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

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

The *storage conditions* for the Spirohome® Clinic is specified as:
Temperature: -20°C to +50°C
Relative Humidity: 5% to 95%
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.

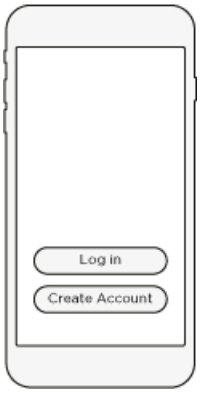
The instrument may give inaccurate readings if operated in the presence of strong electromagnetic sources, such as electrosurgical equipment, or in the presence of computed tomography (CT) equipment.

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

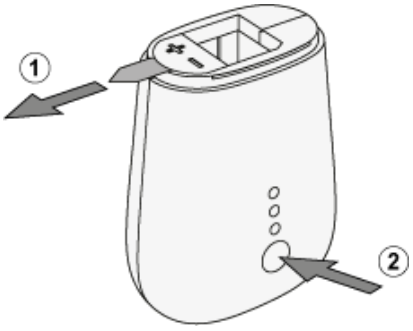
6.3 Setting up the Spirohome® Clinic

1.Download the Spirohome® Clinic app from the App Store or Google Play Store onto a smart device.

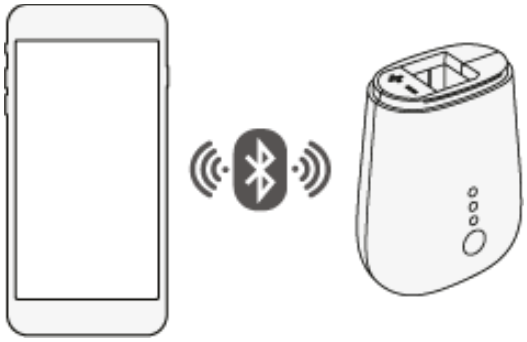
2. Follow the steps given on the app screen to create a new user account for a new patient or log in to an existing account of a patient.



3. Pull out the battery protector (1) and press the power button (2) for one second to switch on the device.

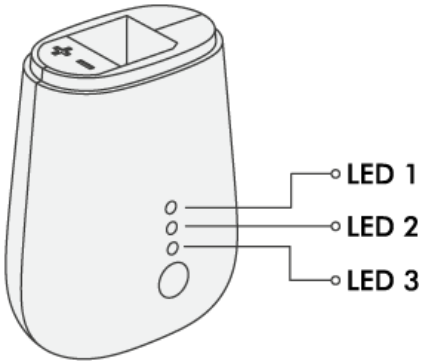


4. Enable Bluetooth® on the smart device, and select the Spirohome® Clinic from available devices. The device should now be paired.



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® Clinic

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
Volume accuracy (Average)	2.01 %
Flow accuracy (Average)	± 1.822 %
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 the smart device closer to the Spirohome® device
	Smart device Bluetooth® is disabled	Enable Bluetooth® of the smart device
	Bluetooth® connection not working properly	The smart device will need Bluetooth® version 4.0 or higher. Find and select Spirohome® Clinic from list of detected devices.
Test results are inconsistent	Spiroway® disposable mouthpiece is dirty	Use a new Spiroway® disposable mouthpiece
	Spiroway® disposable mouthpiece is damaged	Replace Spiroway® disposable mouthpiece
	Spirometry test was performed incorrectly	Refer to Performing a Lung Function Test in user manual or refer video tutorial on app
	Spiroway® disposable mouthpiece is installed incorrectly	Refer to the user manual for proper installation of Spiroway® disposable mouthpiece

Test does not start - Cannot set up baseline	Direct air current in environment	Close the cap of the Spirohome® Clinic 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 the patient starts 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, the patient must take a short breath through the spirometer before breaking the seal of their 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 the smart device from its settings menu
Error 02	Batteries of the Spirohome® Clinic 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 the Spirohome® Clinic 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 the Spirohome® Clinic

7.1 How to perform a spirometry test

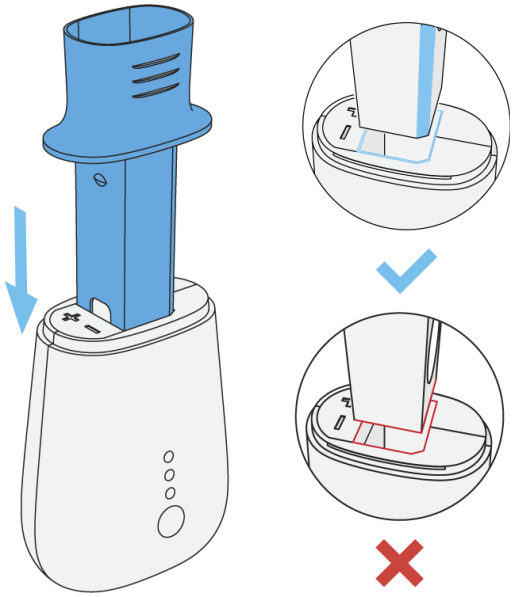
There are several types of tests and different parameter relating to lung function that can be involved in a spirometry test. Each type of spirometry test requires a specific breathing maneuver in order to detect the parameters related to that particular test type. However, the general method of performing 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, the patient may perform up to 8 tests. The best values obtained from the spirometry tests performed in one session is displayed on the app interface. There is also an 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® Clinic:

1. Remove the Spiroway® disposable mouthpiece from its plastic packaging and insert it all the way into the Spirohome® Clinic as shown. A ‘click’ will be heard when the

mouthpiece is inserted correctly all the way into the device. A click will be heard when the Spiroway® disposable mouthpiece is inserted correctly and fully into the Spirohome® Clinic.



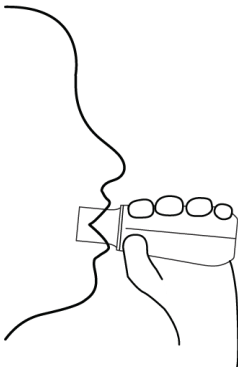
2. Load the Spirohome® Clinic App on the smart device and sign in to the patient's account.

3. When you have selected the patient's account and ensured that their personal details entered into the app are correct, you may proceed to testing.

4. Tap the 'plus' button (shown) to start a new test for the patient.

5. 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.

6. The app will prompt the operator to start a spirometry test. Ask the patient to place the mouthpiece in their mouth, past their teeth, and form a tight seal around the mouthpiece with their lips.



7. Perform the breathing maneuver related to the particular spirometry test. Please see the Breathing Maneuvers section of this user manual for more information.

7.2 Spirometry Parameters

The Spirohome® Clinic 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® Clinic 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

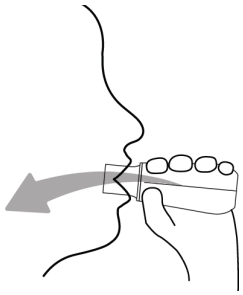
The device also provides a reference value (obtained from large epidemiological studies) based on the patient's height, weight, age, sex and ethnicity. The patient's spirometry test results compared to the reference value and displayed as a percent predictive value indicator of the patient's respiratory health. The patient's personal best value for a spirometry session can be discussed with the patient, to provide them with 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.

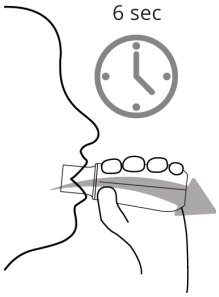
7.3 Types of breathing maneuvers

The Forced Vital Capacity Test Breathing Maneuver:

1. Ensure that the device is connected, the test screen is ready.
2. Ask the patient to place the mouthpiece is in their mouth past their teeth and ensure that their lips are tightly sealed around the mouthpiece.
3. To ready themselves, ask the patient to inhale and exhale normally a couple of times, then take a slow and deep breath, **filling their lungs completely**.



4. Keeping their **lips sealed tightly around the mouthpiece**, ask the patient to empty their lungs by blow **as hard and fast as they can** into the mouthpiece **for at least 6 seconds** without breaking the seal of their lips, and then **inhale a small amount of air to signal the end of their exhalation**. The patient may use a nose clip to help them exhale through only their mouth during this maneuver.



5. The patient may remove the mouthpiece from their mouth and resume normal breathing once the breathing maneuver has been completed.
6. Feedback about the test will be displayed on the app screen. The patient will need to perform 2 more tests by repeating this breathing maneuver. However, **ensure that the patient has rested between tests** and feels well enough to continue**.**
7. Once all tests have been satisfactorily completed, you will be able to view the session results on the results page of the app.
8. To end the spirometry session, remove and immediately dispose of the mouthpiece, turn off device, clean the device body (please refer to section 8.2 Cleaning and disinfection of the device), and store (the product pouch provided may be used) according to storage requirements until next use.

The Flow Volume Loop Test Breathing Maneuver:

1. Ensure that the device is connected, the test screen is ready.
2. 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 entered, the device is ready for the patient to perform the breathing maneuver.
4. Place the mouthpiece is in the patient's mouth past their teeth, and ensure their **lips are tightly sealed around the mouthpiece**.
5. To ready themself, ask the patient to inhale and exhale normally a couple of times, then take a slow and deep breath, **filling their lungs completely**.
6. Keeping their lips sealed tightly around the mouthpiece, ask the patient to **empty**

their lungs by blowing **as hard and fast as they can** into the mouthpiece **for at least 6 seconds** without breaking the seal of their lips. The patient may use a nose clip to help them exhale through only their mouth during this maneuver.

7. Ask the patient, without breaking the seal of their lips, to now **inhale completely filling their lungs.**
8. The patient may remove the mouthpiece from their mouth and resume normal breathing once the breathing maneuver has been completed.
9. Feedback about the test will be displayed on the app screen. The patient will need to perform 2 more tests by repeating this breathing maneuver. However, **ensure that the patient has rested between tests** and feels well enough to continue**.**
10. Once all tests have been satisfactorily completed, you will be able to view the session results on the results page of the app.
11. To end the spirometry session, remove and immediately dispose of the mouthpiece, turn off device, clean the device body (please refer to section 8.2 Cleaning and disinfection of the device), and store (the product pouch provided may be used) according to storage requirements until next use.

The Maximum Voluntary Ventilation Test Breathing Maneuver:

1. Ensure that the device is connected, the test screen is ready.
2. 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 entered, the device is ready for the patient to perform the breathing maneuver.
4. Ask the patient to place the mouthpiece in their mouth, past their teeth, ensure their l**ips are tightly sealed around the mouthpiece** and to **inhale and exhale completely filling and emptying their lungs, repeatedly, uninterrupted, without breaking the seal of their lips for at least 12 seconds**.
5. The patient may remove the mouthpiece from their mouth and resume normal breathing once the breathing maneuver has been completed.

6. Feedback about the test will be displayed on the app screen.
7. Once all tests have been satisfactorily completed, you will be able to view the session results on the results page of the app.
8. To end the spirometry session, remove and immediately dispose of the mouthpiece, turn off device, clean the device body (please refer to section 8.2 Cleaning and disinfection of the device), and store (the product pouch provided may be used) according to storage requirements until next use.

The Slow Vital Capacity Test Breathing Maneuver:

1. Ensure that the device is connected, the test screen is ready.
2. 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 entered, the device is now ready for the patient to perform the breathing maneuver.
4. Ask the patient to place the mouthpiece is in their mouth past their teeth, ensure their **lips are tightly sealed around the mouthpiece** and to **inhale and exhale normally**, for 3-5 breaths.
5. When prompted by the app, as the patient to **fully inhale and then fully exhale.**
9. The patient may remove the mouthpiece from their mouth and resume normal breathing once the breathing maneuver has been completed.
10. Feedback about the test will be displayed on the app screen. The patient will need to perform 2 more tests by repeating this breathing maneuver. However, **ensure that the patient has rested between tests** and feels well enough to continue**.**
11. Once all tests have been satisfactorily completed, you will be able to view the session results on the results page of the app.
12. To end the spirometry session, remove and immediately dispose of the mouthpiece, turn off device, clean the device body (please refer to section 8.2 Cleaning and disinfection of the device), and store (the product pouch provided may be used) according to storage requirements until next use.

7.4 Understanding test quality

After each test session,a quality grading will be displayed on the app to provide information about how well the breathing maneuver was performed, and 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 the Spirohome® Clinic

8.1 Calibration-check

Due to the ultrasound-based technology for air flow analysis, routine calibration of the Spirohome® Clinic 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 the Spirohome® Clinic, a standard 3L calibration syringe can be used in the following calibration-check procedures.

Multi-flow calibration-check: one inspiration and one expiration for three different flow levels (given below) is simulated.

• 3 L in approximately 0.5 s (flow rate of 6 L/s), trial accepted if the parameter FEF25-75 or FIF25-75 is between 5.50 L/s and 6.50 L/s.

• 3 L in approximately 3 s (flow rate of 1 L/s), trial accepted if the parameter FEF25-75 or FIF25-75 is between 0.75 L/s and 1.25 L/s.

• 3 L in approximately 6 s (flow rate of 0.5 L/s), trial accepted if the parameter FEF25-75 or FIF25-75 is between 0.40 L/s and 0.75 L/s.

To pass the complete calibration check, there must be *one* acceptable trial for each flow level.

Linearity calibration-check:

Same as Multi-flow calibration-check, however. *three* acceptable trials for each flow level are required.

Procedure for calibration-check:

1. Push and draw piston of 3 L calibration syringe a few times to balance the temperature inside and outside the piston. This is necessary to prevent failed calibration-check due to temperature differences. Avoid placing the body of the syringe near heat sources, or warming its casing with hands.

2. Insert a Spiroway® disposable mouthpiece into the Spirohome® Clinic device, and attach a Spirohome® adaptor for connection to the calibration syringe.
3. Check that the piston of the calibration syringe is fully inserted.
4. Attach the Spirohome® Clinic device to the nozzle of the calibration syringe.
5. From the Spirohome® Clinic app, select the type of calibration-check to be performed.
6. Allow the device to perform the baseline setup.
7. Following the prompts displayed on the app, pull the piston of the calibration syringe at the required speed displayed on the app.
8. With the same speed, push the piston back into the syringe.
9. Pull the piston briefly to signal the end of the calibration-check.
10. Repeat steps 7-9 if procedure is not accepted by the device.
11. Repeat the procedure for as many times required by the Multi-flow calibration-check or Linearity calibration-check, following the prompts displayed on the app.

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.

8.2 Cleaning and disinfection of the device

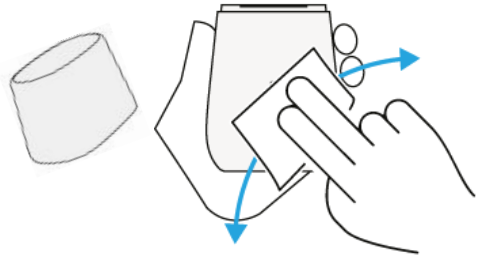
Proper cleaning and disinfection of the Spirohome® Clinic is important for safety and hygiene purposes. With regular cleaning, the physical buildup of contaminants on the device can be prevented. A cleaning process must always precede a disinfection process. Disinfection destroys any pathogens such as 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 all users and patients from the potential transmission of infections resulting from contact with the device. Be sure to wash hands with soap before and after each operation 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® Clinic

Remove and dispose of the Spiroway® disposable mouthpiece from the Spirohome® Clinic 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, and disinfection, after each patient.

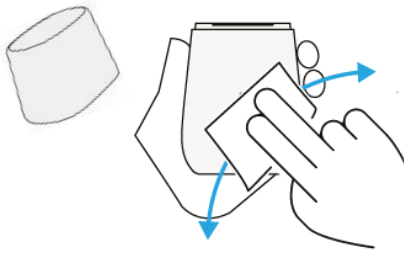


Wipe all accessible surfaces of the device and cap, using moderate pressure, as shown.

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

3. Disinfecting the Spirohome® Clinic

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. Disinfect the Spirohome® Clinic **after each patient,** 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.

Caution!: Risk of Cross-Contamination

Spirohome® Clinic is designed to be used with the Spiroway® disposable mouthpiece. The mouthpiece is indicated for *single-patient-use* only and must be disposed of immediately after use. 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.

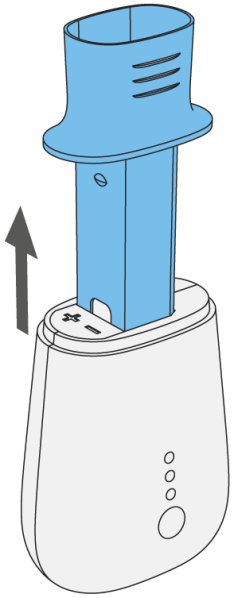
8.3 Replacing batteries

The Spirohome® Clinic 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 operator. The batteries of the device should be removed if the device is not going to be used for more than a month.

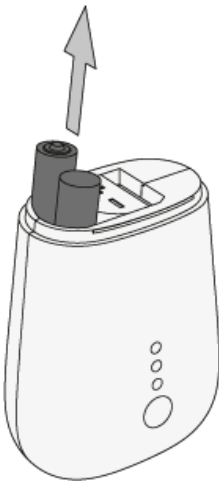
Instructions for battery replacement

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

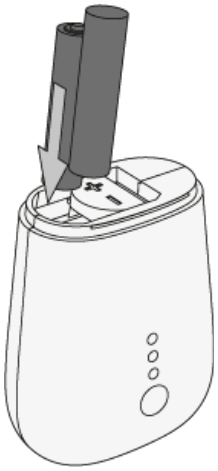


2. Remove the battery cover by sliding it as shown.

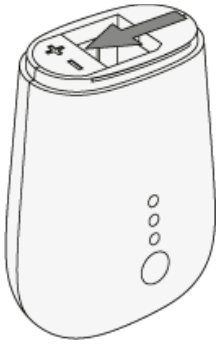
3. Remove the dead batteries.



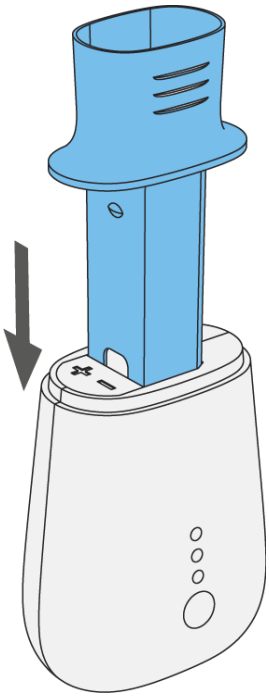
4. Place the new batteries in the correct orientation.



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



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



9. 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 customer 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

10. Appendix

10.1 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 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 environments.			
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 environments.			
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.