spirohome® | Personal

User Manual

Welcome to SpiroHome Personal

Before using your SpiroHome® Personal (Ref No: 01000) device and mobile application, please ensure that you have read this user manual and all product labelling. This user manual is available digitally or for print through the Inofab Health Apps and Inofab Health websites.

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1. INTRODUCTION

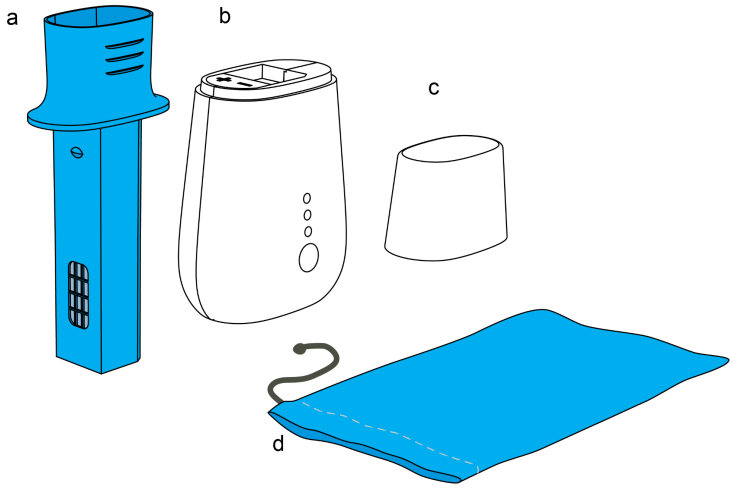
1.1. PRODUCT DESCRIPTION

The SpiroHome® Personal is a portable spirometer that pairs (via Bluetooth®) with smart devices running iOS or Android SpiroHome® applications. The SpiroHome® Personal measures and displays information about the user's lung function. The user performs a spirometry test with the device as described in the "Spirometry Measurement" section of this user manual. The ultrasonic sensors within the SpiroHome® Personal detect the volume and speed of air moving through the device and display this as spirometric data on theSpiroHome® app. The app guides the user throughout the test session. The SpiroHome® App can be downloaded from GooglePlay or App Store. The device is powered by standard 2 x AAA Alkaline batteries. SpiroHome® Personal is used with the SpiroWay® Reusable mouthpiece.

1.2. WHAT'S IN THE BOX

Your SpiroHome® Personal box contains:

- SpiroHome® Personal Device (b)
- SpiroWay® Reusable mouthpiece (a)
- SpiroHome® Personal Cap (c)
- User Manual
- Carrying pouch (d)



⚠ **CAUTION**: Please check that there is no visible damage on any device components. If any damage is present, do not use or attempt to repair the device but contact the manufacturer

directly.

1.3. INTENDED USE

The SpiroHome® Personal is intended to be used as a portable spirometer in the lung function testing of:

- children (over the age of 5) and adults who may have a chronic pulmonary disease including, but not limited to, asthma, chronic obstructive pulmonary disease and cystic fibrosis.

ⓘ **Note:** A competent adult should assist patients (children or older patients) who may need assistance.

1.4. RESTRICTIONS ON USE AND CONTRAINDICATIONS

Diagnosis of medical conditions or prescription of treatments can only be made by a qualified healthcare professional who may use results obtained with the SpiroHome® Personal as adjunct information when performing a full medical examination that has taken into consideration your clinical history and other test results.

SpiroHome® Personal is a single-user device and is to be used by a single user. If the device will be used by a new user, ensure that the data of the previous user is erased from the device memory, their account is removed from the app and a new user account is created for the new user. The device must also be cleaned and disinfected according to the information given in this user manual before use by a new user.

A SpiroWay® Reusable mouthpiece must not be shared between users, including family members. A new mouthpiece must be used for a new user.

Spirometry tests should only be performed if you are not experiencing any shortness of breath, are in good health and capable of performing a lung function test. Test results may otherwise be unreliable.

Failure to perform the required breathing maneuver correctly during a test may lead to inaccurate and unacceptable results. More information about how to perform a spirometry test correctly is described in this user manual. The device should not be used if test accuracy and/or reliability is jeopardized by these or other external factors.

Spirometry tests can be physically demanding. The forced expiratory maneuver used in spirometry increases intrathoracic, intraabdominal, and intracranial pressures. Potential risks of spirometry are primarily related to maximal pressures generated in the thorax and their impact on abdominal and thoracic organs, venous return and systemic blood pressure, and expansion

of the chest wall and lung. The physical effort required can increase myocardial demand. Caution must be used if you have medical conditions that could be adversely affected by these physiological consequences. Although such risks are likely to be minimal for spirometry in most patients, the potential risks associated with testing should always be weighed against the benefit of obtaining information about lung function. Spirometry should be discontinued if you experience pain during the maneuver. If you have any of these potential contraindications please seek spirometry testing in primary care settings or pulmonary function laboratories where you will be under the supervision of healthcare professionals and there may be access to emergency care if needed.

Relative Contraindications for Spirometry;

Due to increases in myocardial demand or changes in blood pressure;

- ➢ Acute myocardial infarction within 1 week
- ➢ Systemic hypotension or severe hypertension
- ➢ Significant atrial/ventricular arrhythmia
- ➢ Uncompensated heart failure
- ➢ Uncontrolled pulmonary hypertension
- ➢ Acute cor pulmonale
- ➢ Clinically unstable pulmonary embolism
- ➢ History of syncope related to forced expiration/cough

Due to increases in intracranial/intraocular pressure;

- ➢ Cerebral aneurysm
- ➢ Brain surgery within 4 weeks
- ➢ Recent concussion with continuing symptoms
- ➢ Eye surgery within 1 week

Due to increases in sinus and middle ear pressures;

- ➢ Sinus surgery or middle ear surgery or infection within 1 wk

Due to increases in intrathoracic and intra abdominal pressure;

- ➢ Presence of pneumothorax
- ➢ Thoracic surgery within 4 weeks
- ➢ Abdominal surgery within 4 weeks
- ➢ Late-term pregnancy

Infection control issues;

- ➢ Active or suspected transmissible respiratory or systemic infection, including tuberculosis
- ➢ Physical conditions predisposing to transmission of infections, such as hemoptysis, significant secretions, or oral lesions or oral bleeding

If you have or suspect having any of the conditions above, consult your healthcare professional before using the SpiroHome® Personal.

1.5. PARAMETERS

The SpiroHome® records and displays the following spirometry data:

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

	—synonymous with MEF_{25}	
*FEF_{25-75}	Forced Expiratory Flow from 25% to 75% of vital capacity — synonymous with MMEF	L/s
*MET_{25-75}	Mid-Expiratory Time — synonymous with FET_{25-75}	s
*$FEV_{0.75}/FEV_6$	The ratio of $FEV_{0.75}$ to FEV_6	--
*FEV_1/FEV_6	The ratio of FEV_1 to FEV_6	--
*FEF_{50}/FVC	The ratio of FEF_{50} to FVC	1/s
*MMEF/FVC	The ratio of MMEF to FVC	1/s
*FET	Forced Expiratory Time	s
*BEV	Back extrapolated volume	L
*FIV_1	The forced inspiratory volume within 1 second	L
*FIVC	Forced inspiratory vital capacity	L
*PIF	Peak inspiratory flow	L/s
*FIF_{25-75}	Forced inspiratory flow at 25% of vital capacity — synonymous with MIF_{75}	L/s
*FIV_1/FIVC	The ratio of FIV_1 to FIVC	--
*R_{50} (FEF_{50}/FIF_{50})	The ratio of flow at 50% of expiration and flow at 50% of inspiration — synonymous with FEF_{50}/FIF_{50}	--
*VC	Vital capacity, from slow expiration	L
*VC_{in}	Inspiratory vital capacity, from slow inspiration	L
*VC_{ex}	Expiratory vital capacity, from slow expiration	L
*ERV	Expiratory reserve volume	L
*IRV	Inspiratory reserve volume	L
*IC	Inspiratory capacity from end of tidal breathing	L

*Rf	Respiratory frequency	1/min
*VT	Tidal Volume	L
*MVV	Maximum voluntary ventilation	L/min
*MVV_6	Maximum plat voluntary ventilation for 6 seconds	L/min
*MVV_{time}	Duration of the trial in seconds	s

**Depending on the Software Version and Region, these parameters may not be available, please contact your local distributor or Inofab for more information.*

The recommended number of trials per spirometry session is 3, however, you may perform up to 8 trials. The best values obtained from the spirometry trials performed in one session are displayed on the app. You also have the option to view each individual trial result of a spirometry session.

The device provides a reference value. This is calculated from large epidemiological studies and requires your height, weight, age, sex and ethnicity information. Your results are compared to the reference values as a percent predictive value indicator of your respiratory health. Your personal best value for a spirometry trial can be discussed and with your healthcare provider for medical interpretation.

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

2. OPERATION

2.1. OPERATING ENVIRONMENT

The SpiroHome® Personal is intended to be used in home settings. It is not intended for use in clinical settings such as hospitals or private clinics.

The required operation conditions for the SpiroHome® Personal are:

Ambient temperature: +15°C to +35°C
Relative Humidity: 10% to 85%
Pressure: 700 hPa to 1060 hPa

The SpiroHome® Personal should only be used within the ambient temperature, relative humidity and ambient pressure ranges given above. The device should remain within this range for at least 1 hour before use.

Storage / Transport Environment

The required storage conditions for the SpiroHome® Personal are:

Ambient temperature: -20°C to +60°C
Relative Humidity: 5% to 85%
Pressure: 700 hPa to 1060 hPa

The required transport conditions for the SpiroHome® Personal are:

Ambient temperature: -20°C to +60°C
Relative Humidity: 5% to 85%
Pressure: 700 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 anesthetic gases (oxygen or nitrogen).

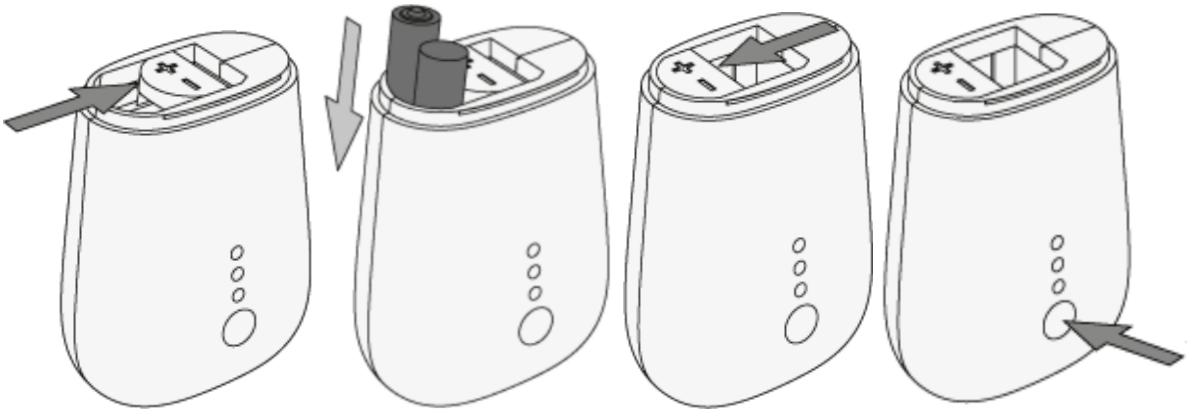
The device should not be used in direct air currents (e.g. wind), sources of heat or cold, direct sun rays or other sources of light or energy, dust, sand or any other chemical substances.

2.2. SETTING UP YOUR DEVICE

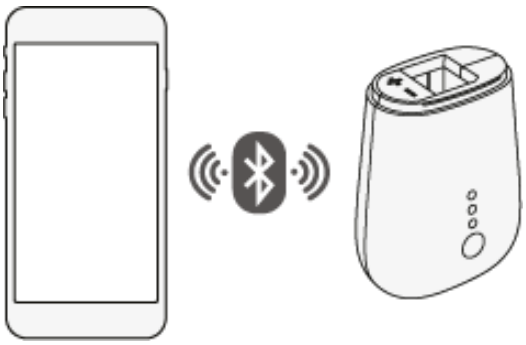
1. Download theSpiroHome® app from the App Store or Google Play Store into your smart device.

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

3. Slide open the battery cover, insert the AAA alkaline batteries in the correct orientation, slide the battery cover back to the closed position and press the power button for 1 second to switch on the device as shown



4. Enable Bluetooth® on your smart device and pair the SpiroHome® Personal with your smart device by following the instructions on the app.



2.3. DEVICE INDICATORS

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

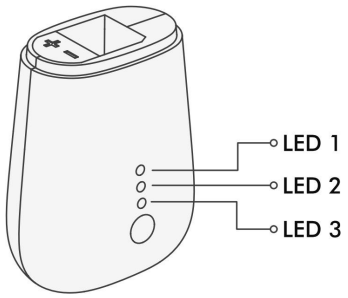


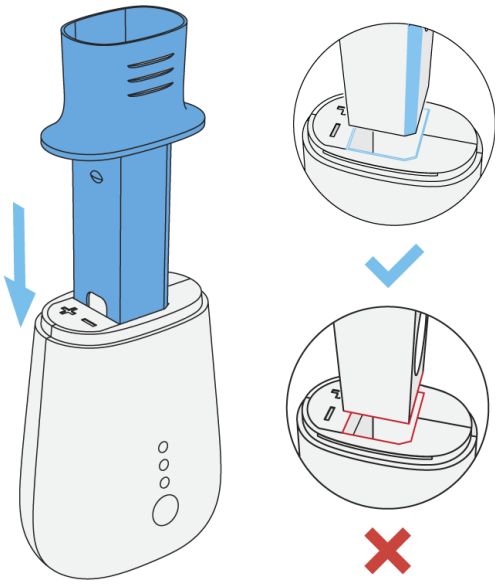
Table 2: Device Led Indicators	
LED Display	**Indication/s**
None of the LEDs are on.	The device is switched off
LED indicators are consecutively flashing green.	The device is switching on
LED number 3 is constantly flashing green.	The device is switched on
LED number 2 is fading blue.	The device is connected to the app. Bluetooth connection has been established.
LED number 2 and LEDs 1 and 3 together are flashing yellow in turn.	The zero flow level adjustment is setting up.
LED number 1 is constantly blue.	The device is ready for a test.
During a test, LED number 1 is constantly flashing blue.	The test has timed-out (there has been no inhalation/exhalation over a while)
During zero flow level adjustment setup LED number 1 is constantly yellow.	The zero flow level adjustment setup has been unsuccessful.
All LEDs are flashing red.	The zero flow level adjustment setup has been unsuccessful. (Mouthpiece is removed)

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

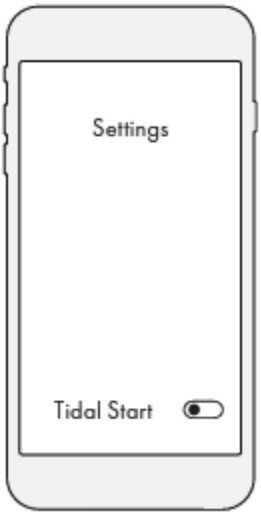
2.4. PERFORMING A LUNG FUNCTION TEST

1. Sit upright with your back straight and your feet flat on the ground.

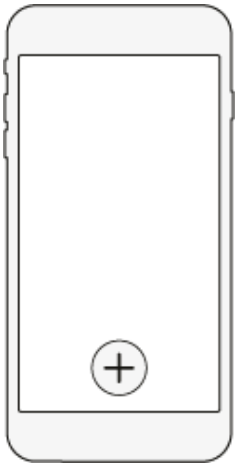
Remove the SpiroWay® Reusable mouthpiece from its plastic packaging and insert it all the way into the SpiroHome® Personal in the correct orientation (as shown). You will hear a click when the mouthpiece is fully inserted into the device.



2. Select whether you prefer to perform tests in Tidal Start or not. Toggling on Tidal Start will mean that you will have to start test maneuver with tidal breathing before a forced expiration

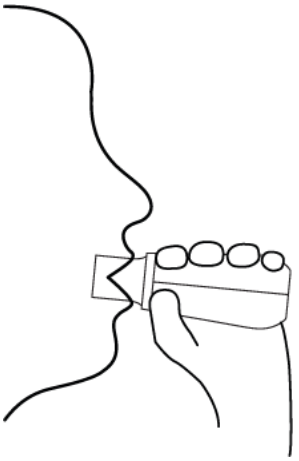


3. Open the SpiroHome® App on your smart device and make sure you are signed in. Tap the '+' button to start the test procedure.



4. Follow the instructions that appear on the screen. The first step will be to record a zero flow level adjustment for the device. You will need to leave the device on a flat surface for this process to be completed.

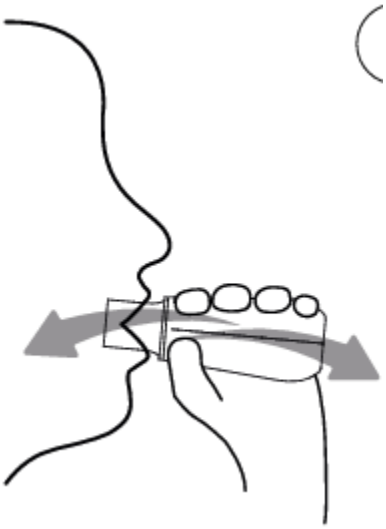
5. Place the mouthpiece in your mouth, past your teeth, and form a tight seal around the mouthpiece with your lips.



6. You will now need to perform a forced expiratory maneuver.

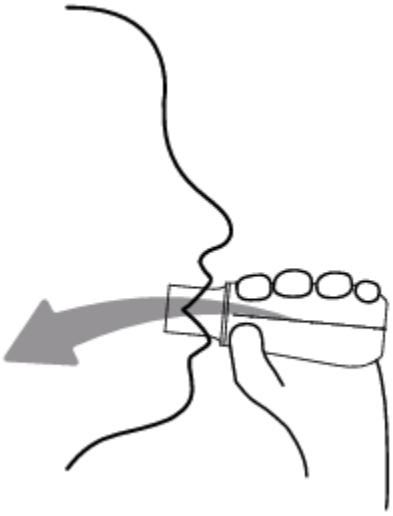
a. **Tidal Start Enabled:**

To ready yourself, inhale and exhale normally a couple of times, then take a **fast and deep** breath, filling your lungs completely. Do not hold breath for longer than 2 seconds.*

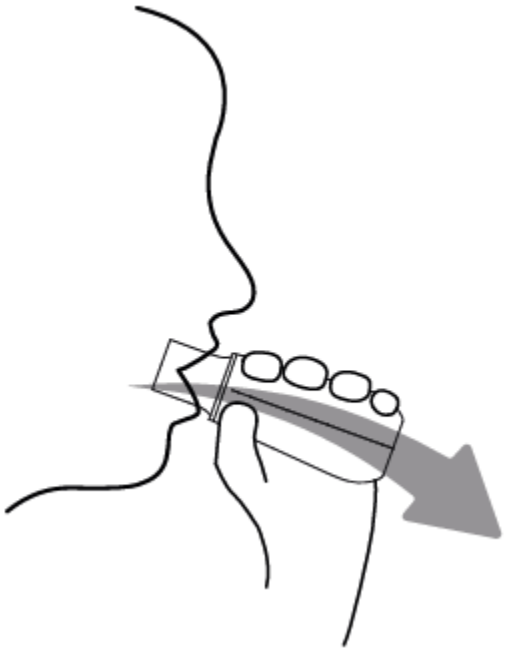


b. Tidal Start Disabled:

If you toggle off Tidal Start from the app settings, you do not need to breathe normally several times into the mouthpiece before a forceful expiration, and the test begins with a direct forceful expiration. When ready, fill your lungs quickly and completely with air.

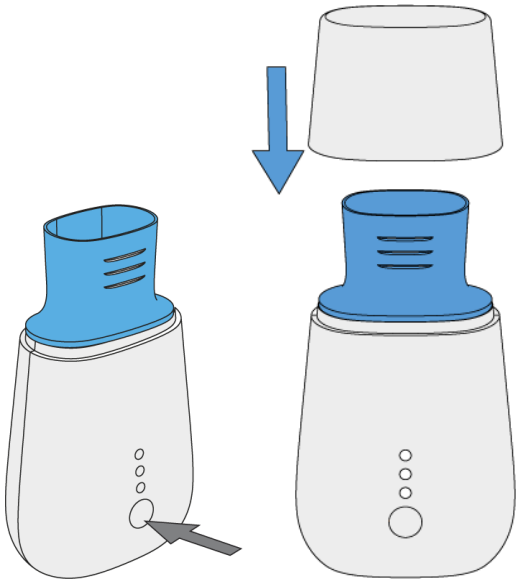


7. Without hesitation and with your lips sealed tightly around the mouthpiece blow out the air in your lungs as **hard and fast** as you can. **Keep blowing until you hear a beep**. You feel like you have completely emptied your lungs. You may use a nose clip at the beginning of the session to ensure that you are exhaling only through your mouth.



8. Repeat these steps for each successive trial, ensuring that you rest for at least 20 seconds between each trial.

9. After completing your spirometry session, switch off the device by pressing the power key. Use the cap to protect the mouthpiece from contamination when the device is not in use.



⚠ **Important:** This procedure describes how to perform the forced expiratory maneuver when 'Tidal Mode' is selected on the SpiroHome® application.

'Tidal Mode' requires you to breathe normally several times into the mouthpiece at the beginning of the test before a forceful expiration is performed.

If you deselect 'Tidal Mode' from the app settings, you do not need to breathe normally several times into the mouthpiece at the beginning of the before a forceful expiration, and the test begins with a direct forceful expiration.

2.4.1. End of Forced Expiration (EOFE)

The end of a forced expiratory maneuver is referred to as 'End of Forced Expiration' or 'EOFE'. The EOFE is important in recognizing when a true FVC measurement has been achieved. Any of the following three cases will indicate an EOFE:

1. Expiratory plateau (≤0.025 L in the last 1 s of expiration)
2. Expiratory time ≥15 s
3. FVC is within the repeatability tolerance of or is greater than the largest prior observed FVC *

*More information in section 2.5

2.5. UNDERSTANDING THE TEST QUALITY

After each test session, the quality of your test will be graded based on how well you performed the breathing maneuver and whether your results are acceptable, usable or neither. This grading relates to the consistency of your blows, not the health of your lungs.

The American Thoracic Society (ATS) and European Respiratory Society (ERS) grade FVC and FEV_1 parameters in children and adults as given in the table 3;

Table 3: Summary of Acceptability, Usability, and Repeatability Criteria for FEV_1 and FVC

Acceptability and Usability Criterion	Required for Acceptability		Required for Usability	
	FEV_1	**FVC**	**FEV_1**	**FVC**
Must have BEV ≤5% of FVC or 0.100 L, whichever is greater	Yes	Yes	Yes	Yes
Must have no evidence of a faulty zero-flow setting	Yes	Yes	Yes	Yes
Must have no cough in the first second of expiration*	Yes	No	Yes	No
Must have no glottic closure in the first second of expiration*	Yes	Yes	Yes	Yes
Must have no glottic closure after 1 s of expiration	No	Yes	No	No
Must achieve one of these three EOFE indicators: 1. Expiratory plateau (≤0.025 L in the last 1 s of expiration) 2. Expiratory time ≥15 s 3. FVC is within the repeatability tolerance of or is greater than the largest prior observed FVC †	No	Yes	No	No
Must have no evidence of obstructed mouthpiece or spirometer	Yes	Yes	No	No
Must have no evidence of a leak	Yes	Yes	No	No
If the maximal inspiration after EOFE is greater than FVC, then (FIVC — FVC) must be ≤0.100 L or 5% of FVC, whichever is greater ‡	Yes	Yes	No	No
Repeatability criteria (applied to acceptable FVC and FEV_1 values)				
Age > 6 yr:	The difference between the two largest FVC values must be ≤0.150 L, and the difference between the two largest FEV_1 values must be ≤0.150 L			
Age ≤ 6 yr:	The difference between the two largest FVC values must be ≤0.100 L or 10% of the highest value, whichever is greater, and the difference between the two largest FEV_1 values must be ≤0.100 L or 10% of the highest value, whichever is greater			

EOFE = end of forced expiration

* Occurs when the patient cannot expire long enough to achieve a plateau (e.g., children with high elastic recoil or patients with restrictive lung disease) or when the patient inspires or comes off the mouthpiece before a plateau. For within-maneuver acceptability, the FVC must be greater than or within the repeatability tolerance of the largest FVC observed before this maneuver within the current prebronchodilator or the current post-bronchodilator testing set.

** This criterion is not used, as there is no parameter calculated using the inspiration maneuver in SpiroHome® Personal.

Although the performance of a maximal forced inspiration is strongly recommended, its absence does not preclude a maneuver from being judged acceptable, unless extrathoracic obstruction is specifically being investigated.

Table 4: Grading System for FEV_1 and FVC (Graded Separately)

Grade	Number of Measurements	Repeatability: Age >6 yr	Repeatability: Age ≤6 yr *
A	≥ 3 acceptable	Within 0.150 L	Within 0.100 L *
B	2 acceptable	Within 0.150 L	Within 0.100 L *
C	≥ 2 acceptable	Within 0.200 L	Within 0.150 L *
D	≥ 2 acceptable	Within 0.250 L	Within 0.200 L *
E	≥ 2 acceptable	> 0.250 L	> 0.200 L *
	OR 1 acceptable	NA	NA
U	0 acceptable AND ≥ 1 usable	NA	NA
F	0 acceptable and 0 usable	NA	NA

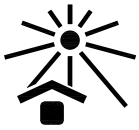
* Or 10% of the highest value, whichever is greater; applies for age 6 years or younger only.

NA: Not Applicable

2.6. SIGNS AND SYMBOLS

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

Table 5: Markings & Descriptions

Markings	Descriptions	Markings	Descriptions
	"Manufacturer" This symbol accompanied by the name and the address of the manufacturer adjacent to the symbol		User Manual
	Sign of Conformity		Type BF of Medical Electrical Equipment
	Disposal in Compliance with WEEE	SN	Serial Number
	Temperature Limit	LOT	Lot Number
	Humidity Limit	REF	Ref Number
	Atmospheric pressure limitation	IP22	IP Number
	Do not use if the package is damaged		The device includes RF transmitters
	Keep away from sunlight		The instruction manual/booklet must be read.
	Keep dry		Caution

2.7. TECHNICAL FEATURES

Flow / Volume measurement method	Ultrasonic Transducer Measurement
Power Supply	2 x 1.5V AAA Alkaline 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)	2.00 % or 0.05 L
Highest Expiratory Impedance*	48.54 Pa*s/L
Volume resolution	1 mL
Flow resolution	1 mL/s
Medical device class	Class IIA
Wireless connection	BLE 4.2

**Tested according to ISO26782 AnnexB*

2.8. SAFETY WARNINGS AND PRECAUTIONS

⚠**Important**: Please adhere to all safety warnings, precautions and recommendations given in this user manual as failure to comply may result in measurement errors, display of incorrect results or possible harm to the device or the user. The manufacturer is not responsible for any damage or harm to the device or user that is the direct result of non-compliance to these warnings and precautions other instructional materials provided with the device.

If any damage is present on the device or its components upon initial unboxing of the product then do not use the device and return it to the supplier.

Do not use this SpiroHome® Personal for any other purpose than its intended use.

Competent adults assisting pediatric, elderly or differently-abled users should inform them about the safety warning and precautions given in this user manual before the use of the device.

Regardless of the data presented on the SpiroHome® Personal, if you feel unwell or have respiratory distress symptoms cease device use and contact your healthcare provider immediately.

If there is an excessive decrease in your FEV_1 value then cease use of the device and inform your healthcare provider.

Do not perform more than 8 spirometry trials in one spirometry session. If you experience pain during the maneuver, cease device use and rest.

Maximal inflation is unnatural and if you have not achieved it before it may seem somewhat uncomfortable. If you feel sensations of dizziness or giddiness during pulmonary function sessions, then cease device use and inform your healthcare provider.

Do not walk or run whilst performing a lung function test with the SpiroHome® Personal.

Do not perform a spirometry test with food or objects in your oral cavity as this may lead to risk of choking.

Do not share your SpiroHome® Personal with any other users, including family members. The SpiroHome® Personal and SpiroWay® Reusable is to be used by a SINGLE user only.

If the device is to be used by a new user: Clean and disinfect device and cap according to instructions in the Maintenance section of this user manual AND use a new mouthpiece for the new user AND create a new account for the new user on theSpiroHome® app.

To prevent damage to the device due to battery leakage or oxidation, remove all batteries if the SpiroHome® device is not to be used or is to be stored for a long time.

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

Check the device and components for foreign bodies or surface impurities before each use as this could lead to inaccuracies in test measurements. Coughing or spitting into the device may cause incorrect readings.

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 device, immediately remove batteries and let the device dry thoroughly before use.

If you experience any adverse events using the device, report immediately to your healthcare provider and local authorities as required by local legislation. Please seek to also report such incidents to the manufacturer.

Do not use the SpiroHome® Personal with a charging smart device. Make sure the smart device is unplugged from its charger before conducting a spirometry test.

Use only original accessories specified and provided by the manufacturer. Accessories that are not original will cause inaccurate readings, or harm to the user and/or device.

Do not hold the mouthpiece from the filters located on the mouthpiece. Do not use the mouthpiece if these filters have been physically compromised.

Store and operate the device only as specified in this user manual (see Section 3.1) to avoid device malfunction and/or incorrect measurements.

Do not use the device in the presence of strong electromagnetic sources, such as electrosurgical equipment, or the presence of computed tomography (CT) equipment.

Do not attempt to repair, modify or reconfigure the device. Contact the manufacturer/distributor/retailer directly if your SpiroHome® Personal is damaged or malfunctioning or you encounter data that you cannot make sense of. Unauthorised repairs, modifications or reconfigurations of the device will void the warranty of the product.

Follow all data security warnings and recommendations for your personal smart device as per it's manufacturer's instructions to protect your personal data.

Do not share your SpiroHome® account information with unauthorized parties.

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

3. MAINTENANCE

Handle your SpiroHome® Personal and SpiroWay® Reusable mouthpiece with care.

Store the SpiroHome® Personal and SpiroWay® Reusable in dust/dirt- and moisture-free conditions. You may utilize the pouch provided with the product to device and components.

Before each use, always check that the device and components are free from contaminants and do not have any visible damage.

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

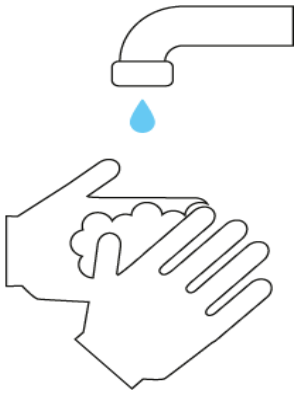
The SpiroHome® Personal does not require routine calibration as it uses ultrasonic flow measurement technology. If you suspect a problem with the calibration of the device, cease use and contact the manufacturer immediately.

3.1. CLEANING AND DISINFECTION PROCEDURE

You should clean the SpiroHome® Personal body and cap at least once a week or whenever the device is visibly contaminated. You must perform the cleaning step before performing the disinfection step. Regular cleaning will prevent the physical buildup of contaminants on device surfaces. Disinfection kills and destroys pathogens such as bacteria, viruses, or other microorganisms which might still be present on device surfaces after initial cleaning.

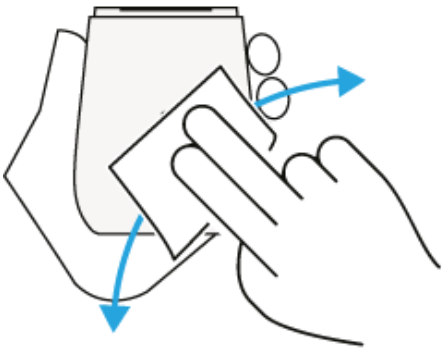
1. **Wash Hands**

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



2. **Perform cleaning**

First, remove the SpiroWay® Reusable from the SpiroHome® Personal device. Using a disinfectant* (Hydrogen peroxide >= 1 - < 2.5%, Glycolic acid >= 1 - < 2.5%) wipe, wipe all accessible surfaces of the device and cap using moderate pressure for at least 30 seconds to remove contaminants. Be gentle and use care when wiping the sensors to avoid damaging them.

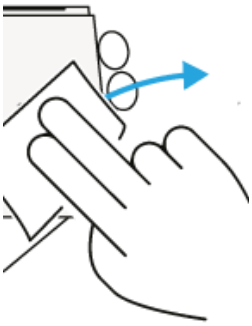


Wipe all accessible surfaces of the device and cap, using moderate pressure, as shown.

⚠ **Caution:** Prevent any excess liquids contained within the wipes from entering the components of the SpiroHome® Personal. Never immerse the product in water or any other liquid solution.

3. **Perform disinfection**

To disinfect the device and cap use a new disinfectant* (Hydrogen peroxide >= 1 - < 2.5%, Glycolic acid >= 1 - < 2.5%) wipe to wipe over all accessible surfaces again using moderate pressure and for the contact time recommended by the wipe manufacturer.



**Incidin™ OxyWipe S is a ready-to-use cleaner and disinfectant (H_2O_2-based) with broad spectrum efficacy available at https://inofab.io/wipes*

4. **Wash Hands**

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

3.2. CLEANING THE SPIROWAY® REUSABLE

To clean the SpiroWay® Reusable Mouthpiece once a week and whenever visibly soiled;

- ➢ Add dishwashing detergent (e.g. those containing 5-15% anionic surfactant, 5% nonionic surfactant) to warm water to create a soapy solution.
- ➢ Shake the mouthpiece gently in the soapy solution.
- ➢ Hold the mouthpiece under running tap water to rinse, do not rub
- ➢ Leave the mouthpiece upright on a clean lint-free cloth at room temperature until it is completely dry.

⚠ **CAUTION:** Do not insert the SpiroWay® Reusable mouthpiece into your SpiroHome® Personal device until it is completely dry

The SpiroWay® Reusable should be replaced every 3 months. The SpiroWay® Reusable mouthpiece must be replaced if you used or suspect having used the mouthpiece whilst having a bacterial or viral infection. Replace the SpiroWay® Reusable immediately if the filters are damaged or whenever a risk of contamination is suspected.

⚠ **CAUTION: Risk of Cross-Contamination**

The SpiroWay® Reusable mouthpiece is indicated for single-patient-use only to prevent any potential of cross-contamination. Thorough cleaning and disinfection of the device must be performed prior to use by a new user. A new mouthpiece must be used by the new user.

To purchase new mouthpieces, contact authorized local distributors or, if there is no local distributor, contact Inofab Health at www.inofab.health .

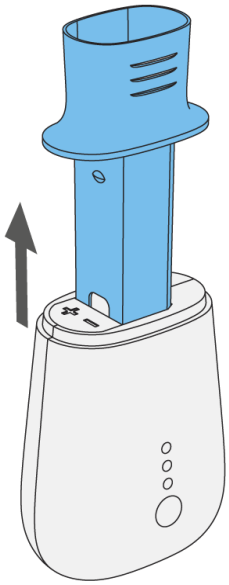
3.3. BATTERIES

The SpiroHome® device operates with 1.5V AAA Alkaline batteries. The battery life of the SpiroHome® is approximately 12-18 months, assuming daily use of the device. The battery charge level is continuously monitored by the device. The device will not turn on if the battery charge level is low and will make a beeping sound to notify you.

⚠**WARNING:** The batteries of the device should be removed if the device is not going to be used for more than a month.

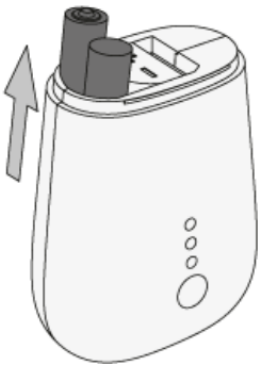
Instructions for battery replacement

1. Remove cap and SpiroWay® mouthpiece from the device.

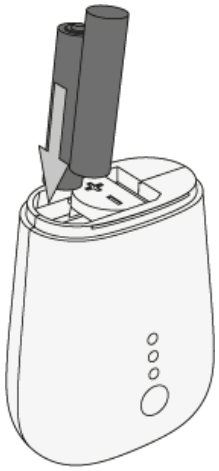


2. Slide battery cover to open position.

3. Remove the empty batteries.

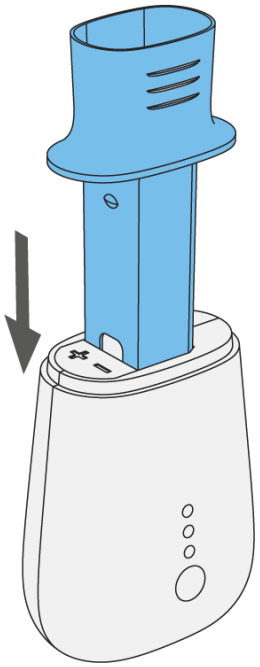


4. Insert new batteries in the correct orientation.

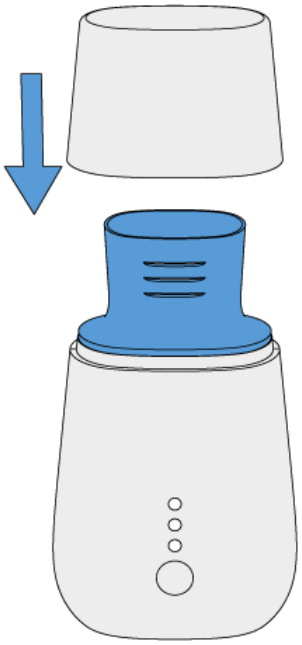


5. Slide the battery cover back to the closed position.

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



7. Place cap on device to protect mouthpiece from contamination during storage.



3.4. DISPOSAL OF SPIROHOME

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

recycling for electric and electronic devices.

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

4. TROUBLESHOOTING

Problem	Cause	Solution
Device not turning on	Multiple possible causes	Check battery orientation and correct polarities
		Remove the AAA batteries, wait 30 seconds and reinstall AAA batteries
		Replace AAA batteries
		Check that battery cap is in the lock position, or if the cap is broken, contact manufacturer
SpiroHome® cannot connect to a smart device via Bluetooth®	The smart device is out of range	Bring your smart device closer to the SpiroHome® device
	Smart device Bluetooth® is disabled	Enable Bluetooth® on 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 the list of detected devices.
Test results are inconsistent	SpiroWay® mouthpiece is dirty	Clean SpiroWay® to ensure that the lumen is not obstructed or replace with a new mouthpiece
	SpiroWay® mouthpiece is damaged	Replace SpiroWay®
	SpiroWay® mouthpiece is installed incorrectly	Refer to the user manual for proper installation of SpiroWay®
	Spirometry test was performed incorrectly	Refer to “Spirometry Measurement” in the user manual or refer video tutorial on app
The test does not start - Cannot set up	Direct air current in the environment	Close the cap of the SpiroHome® to avoid effects of environmental flow

zero flow level adjustment		Place the device on a flat surface
		Remove causes of direct air current e.g. air conditioner, opened window, fan, etc.
The test does not start - balloon animation is not moving	Multiple possible causes	Quit test and start a new test
		Quit the application and start a new test
		Switch the device off and turn on again to reset
Test starts before you start blowing	Rough handling of the device	Keep the device as stable as possible after starting a test
Device disconnected during test	The device is turned off accidentally or due to rough handling during use	Switch the device on again and proceed with a new test
	Bluetooth® connection disrupted	Reconnect the device and proceed with a new test
Test quality grade always low	Not performing the test correctly	Repeat the test following the rules and conditions specified in the “Spirometry Measurement” section of this user manual.
Measurement error screen showed up	Flow limit exceeded	This device is intended to measure 0-14 L/s.
	SpiroWay® mouthpiece is dirty	Clean SpiroWay® to ensure that the lumen is not obstructed or replace SpiroWay®
	SpiroWay® mouthpiece is damaged	Replace SpiroWay®
	Device malfunction	Contact manufacturer
Device error screen showed up	SpiroWay® mouthpiece is installed incorrectly	Refer to the user manual for proper installation of SpiroWay®
	There is a foreign object between the sensors.	Check SpiroHome® device lumen and clean if necessary

	SpiroWay® mouthpiece is dirty	Clean SpiroWay® to ensure that the lumen is not obstructed or replace with a new mouthpiece
	SpiroWay® mouthpiece is damaged	Replace SpiroWay®

For any other technical queries please call our customer service on +90 312 988 03 08 or e-mail support@inofab.health

5. ORDERABLE ACCESSORIES

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

To purchase these accessories please contact your local distributors or İnofab Health at www.inofab.health .

6. TERMS OF WARRANTY

SpiroHome ® Personal, together with any accessories provided, is guaranteed for 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 any 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. The product must be returned with 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 falls, hit, lack of proper care or maintenance
- Damage caused by abnormal physical or electrical stress or defects of the electric supply (battery cell) or of equipments

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

7. 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 8: Emission table for IEC 60601-1-2

<table>
<tr><th colspan="3">Guidance and manufacturer’s declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">SpiroHome battery-operated spirometer devices are intended for use in the electromagnetic environments specified below. Users of these devices should assure that it is used in such environments.</td></tr>
<tr><th>Emission Test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td rowspan="3">SpiroHome Personal uses RF energy for its internal function. Its Radio Bluetooth, BLE and WLAN module also complies with the national regulations. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby
electronic equipment. However, a separation distance of 30 cm
shall be maintained.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class B</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td colspan="3">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.</td></tr>
</table>

Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	Emissions are not applicable because SpiroHome Personal does not connect to mains supply but operates with AAA batteries

Table 9: 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 an 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 must remain at the recommended separation distance to SpiroHome® device and components including device cables. Seperation distances depend on the frequency of the transmitter and are calculated according to the following equations. Recommend separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

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.

8. MANUFACTURER INFORMATION

Name: İnofab Sağlık Teknolojileri A.Ş.

Address: Üniversiteler Mah. İhsan Doğramacı Blv. No:17/115 Çankaya / Ankara / Turkey

Phone: +90 312 988 03 08

Web: https://www.inofab.health

CE

The SpiroHome® Ultrasonic Spirometer and Acecessories are CE certified (NB1984) products.