spiroclinic® | Pro

User Manual

Welcome to SpiroClinic Pro

Before using your SpiroClinic Pro device and mobile application, please ensure that you have read this user manual, all labeling and information provided with the product. The user manual can be downloaded and/or printed from Inofab Health website and Apps.

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INDEX

1. Introduction

1.1. Product Description

SpiroClinic Pro is a spirometer that pairs (via Bluetooth®) and operates with smart devices running iOS, Android, or Windows. SpiroClinic Pro measures and displays certain parameters of lung function of the user. The user performs a spirometry test as described in the *Performing A Lung Function Test* section of this user manual.

Briefly, as the user exhales or inhales through the device airway, internal ultrasonic sensors detect the velocity of the exhaled/inhaled air, the device converts this information into spirometric data and displays it on the SpiroClinic Application. The SpiroClinic App prompts and guides the user throughout the test for accurate data collection and registration. The app can be downloaded on Apple's App Store, Google Play Store, Huawei App Gallery or Microsoft Store.

SpiroClinic Pro consists of a handpiece, a removable airway(SpiroWay Pro), and a dock station(SpiroClinic Dock).

Dock Station (SpiroClinic Dock) automatically captures ambient conditions and gives the information directly to SpiroClinic Application. Users review this information and can change or approve the ambient conditions.

The device is powered by 2 x AA batteries for the handpiece and 2 X AA batteries for the dock. SpiroClinic Pro works with the SpiroWay Pro Airway and a conventional bacterial viral filter(BVF)..

1.2. What's in the box?

The SpiroClinic Pro box contains:

- SpiroClinic Pro Handpiece
- SpiroClinic Pro Dock
- SpiroWay Pro Airway
- Mini screwdriver

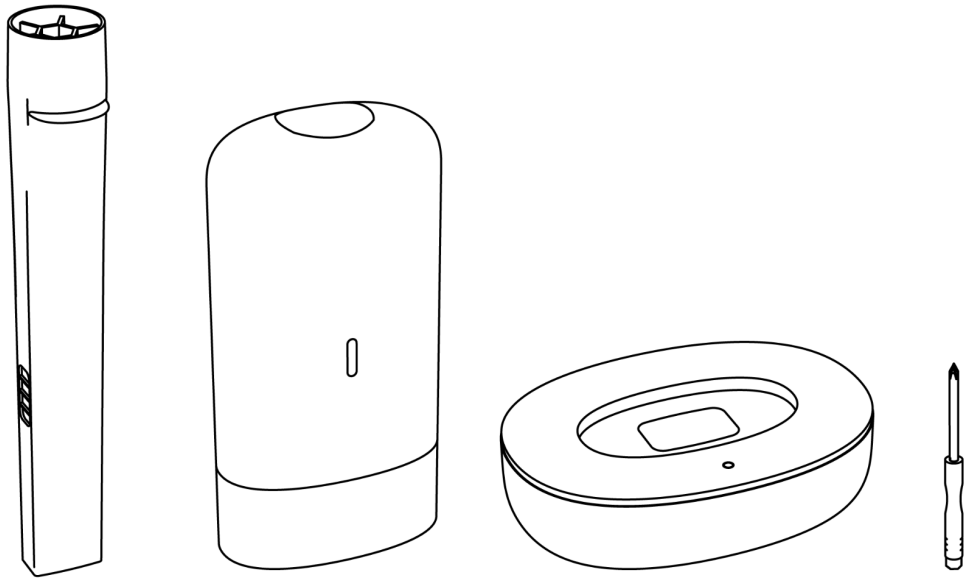


Figure 1: SpiroClinic Pro Box Content.

Caution: Please check to ensure that there is no visible damage on any of the components of the SpiroClinic Pro. If the damage is present, do not use or attempt to repair the device, please contact the manufacturer directly.

1.3. Intended Use

SpiroClinic Pro is intended to be used as a professional spirometer for lung function testing. See the *Parameters* section for more information on measured parameters. The SpiroClinic Pro is indicated for:

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

and should be used by:

- healthcare professionals such as lab technicians, physicians, nurses, occupational health professionals etc.

1.4. Restrictions on use and Contradictions

Any diagnosis of conditions or prescribed treatments should be made only by a qualified healthcare professional. The healthcare professional should take into consideration the outcomes of a medical examination, the patient's clinical history and results of any other tests deemed necessary, in addition to the test results provided by SpiroClinic Pro.

SpiroClinic Pro is a multi-user device. The device can log the information and test results that belong to each specific patient. For each new patient, a new patient account must be created on the SpiroClinic App, so that each user's personal information and test results can be stored and logged.

A new disposable bacterial viral filter must be used for each new user.

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

Performing spirometry 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 for patients with 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 the patient experiences pain during the maneuver. Patients with potential contraindications that would prevent testing in the primary care setting may be tested in a pulmonary function laboratory where operators are more experienced and there may be access to emergency care if needed. Furthermore, because spirometry requires the active participation of the patient, inability to understand directions or unwillingness to follow the directions of the operator will usually lead to submaximal test results.

Relative Contraindications for Spirometry;

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

- ➢ Acute myocardial infarction within 1 wk
- ➢ Systemic hypotension or severe hypertension
- ➢ Significant atrial/ventricular arrhythmia
- ➢ Non-compensated 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 wk
- ➢ Recent concussion with continuing symptoms
- ➢ Eye surgery within 1 wk

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 wk
- ➢ Abdominal surgery within 4 wk
- ➢ Late-term pregnancy

Infection control issues;

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

Please ask the patient if they have or suspect having any of the conditions above before use of the Spiro Clinic Pro.

1.5. Parameters

The SpiroClinic Pro 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 taml 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 taml 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 taml inspiration.	L/s
MMEF	Mean Mid-Expiratory Flow — synonymous with FEF_{25-75}	L/s
FEF_{25}	Forced Expiratory Flow at 25% of vital capacity — synonymous with MEF_{75}	L/s
FEF_{50}	Forced Expiratory Flow at 50% of vital capacity — synonymous with MEF_{50}	L/s
FEF_{75}	Forced Expiratory Flow at 75% of vital capacity —synonymous	L/s

	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

The recommended number of trials per spirometry session is 3, however, the user may perform up to 8 trials. The best values obtained from the spirometry tests performed in one session are displayed on the app interface. Users and healthcare professionals have the option to view the results of each spirometry trial performed in a spirometry session separately.

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

Caution: Interpretation of spirometry results or diagnosis of any medical conditions must only be made by a qualified physician or allied health care professional experienced in spirometry.

2. Operation

2.1. Operating Environment

The SpiroClinic Pro is designed for use in a clinical setting by multiple users.

The operating conditions for the SpiroClinic Pro are specified as:

Temperature: +15°C to +35°C
Relative Humidity: 10% to 85%

The storage conditions for the SpiroClinic Pro are specified as:

Temperature: -20°C to +50°C
Relative Humidity: 0% to 90%
Pressure: 500 hPa to 1060 hPa

SpiroClinic Pro should not be used in rapidly changing environmental conditions even if the conditions are in the recommended range.

SpiroClinic Pro should not be used in the presence of flammable 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 Device should not be used with extremely high RF noise in the environment.

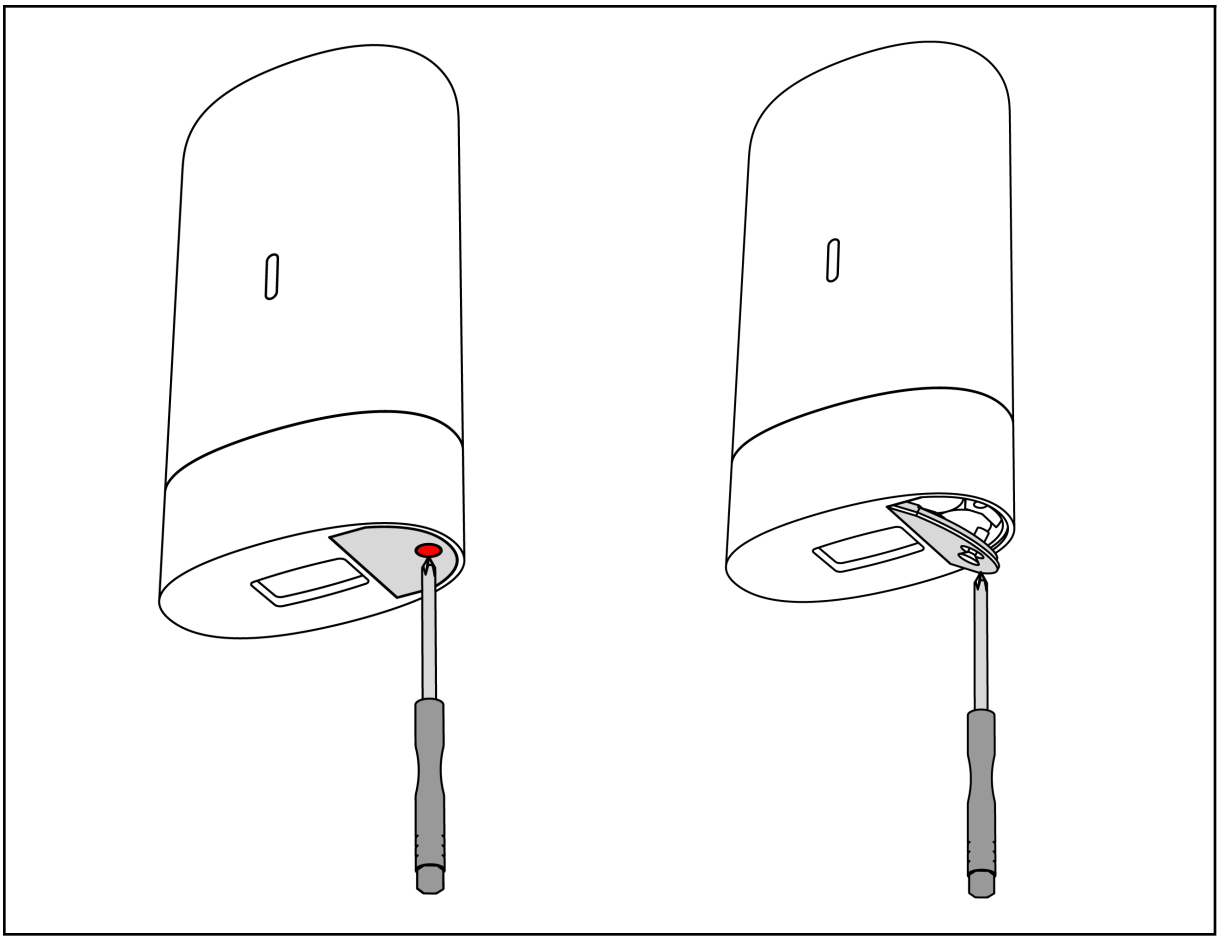
The Device Should not be used near the sources of strong electromagnetic radiation or sources of ultrasonic sound.

SpiroClinic Pro and its Dock should be in the range of bluetooth connection to the smart device they are connected to.

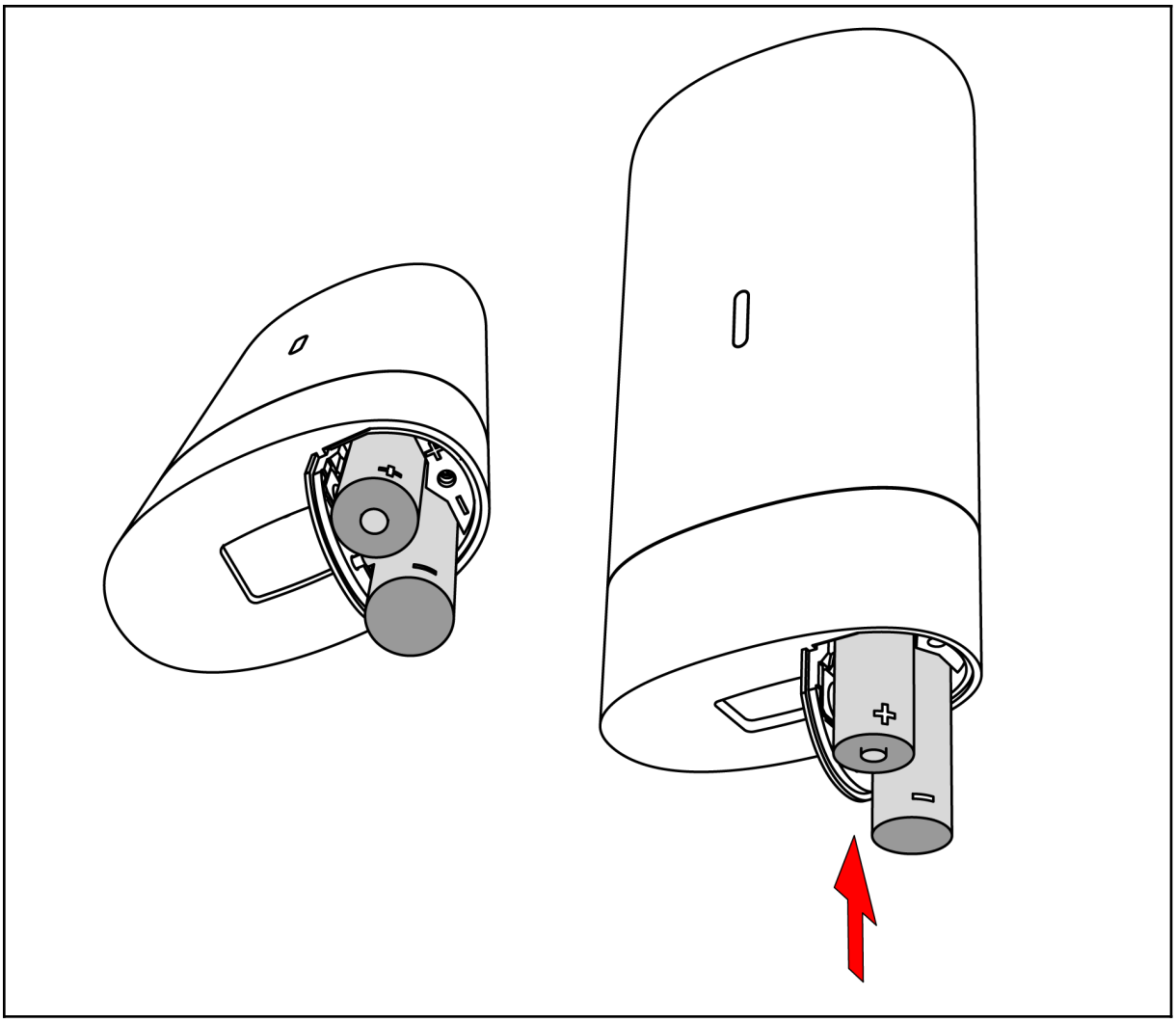
2.2. Setting up the Device

2.2.1. Handpiece

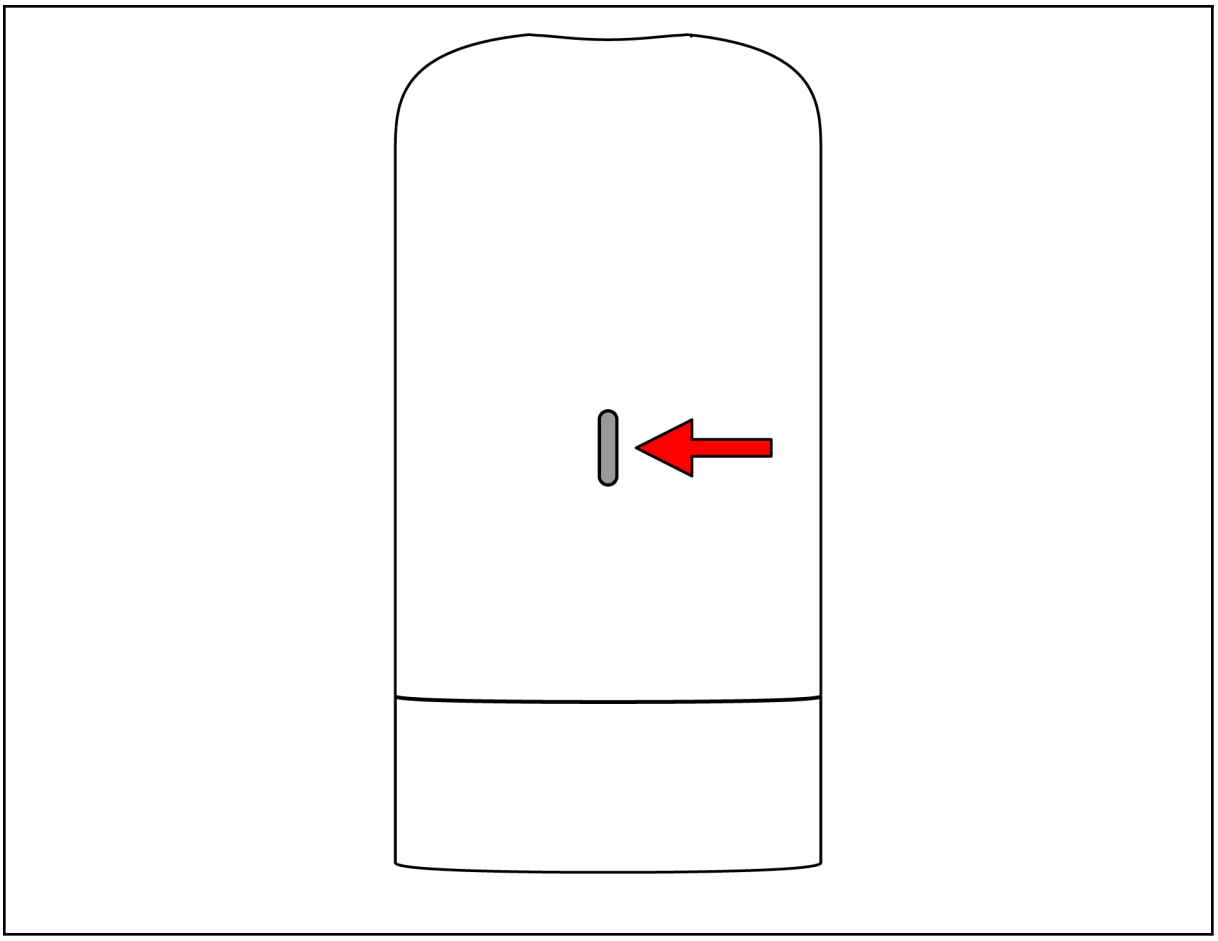
Remove the battery cover by unscrewing it with the screwdriver provided with the device.



Place the AA batteries in the correct orientation, screw the battery cover back to the closed position.

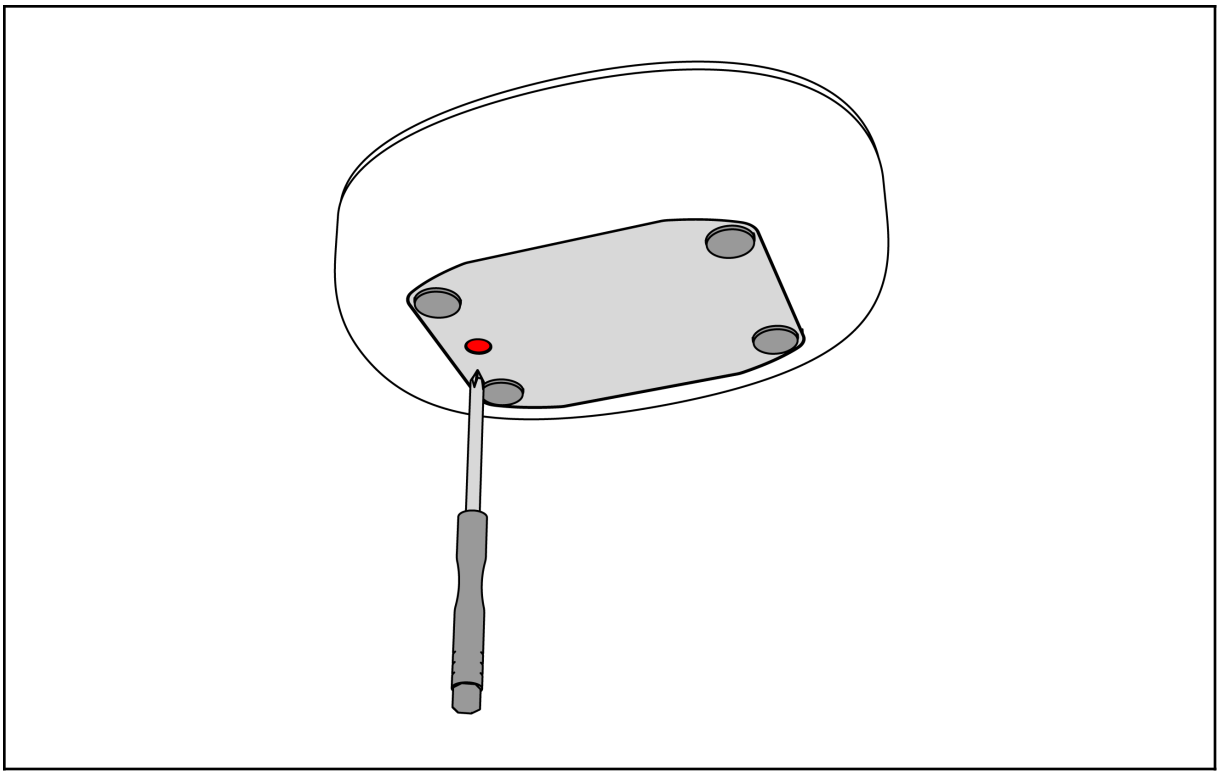


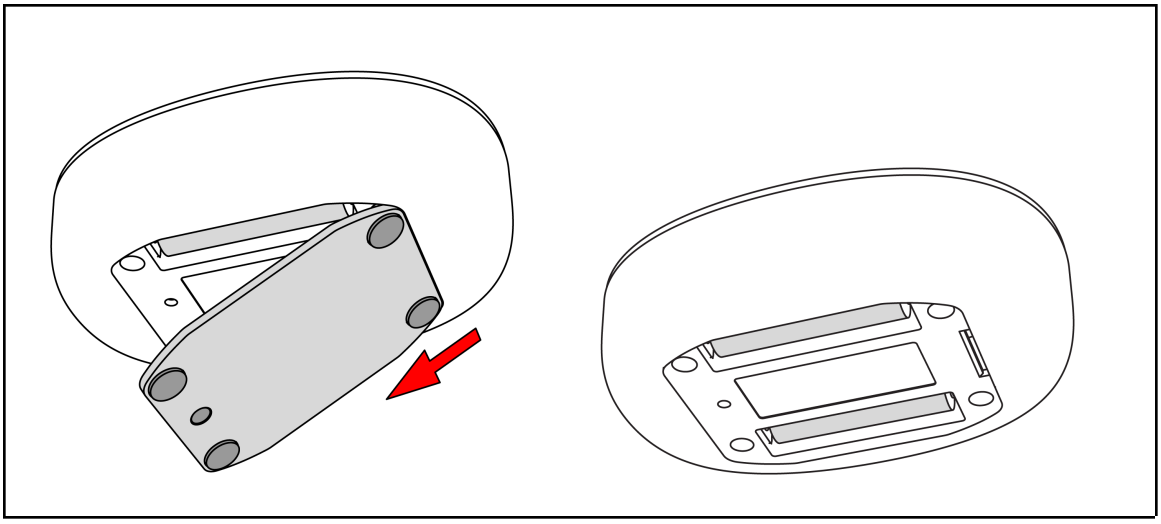
The handpiece should give an indication light and be ready to use.



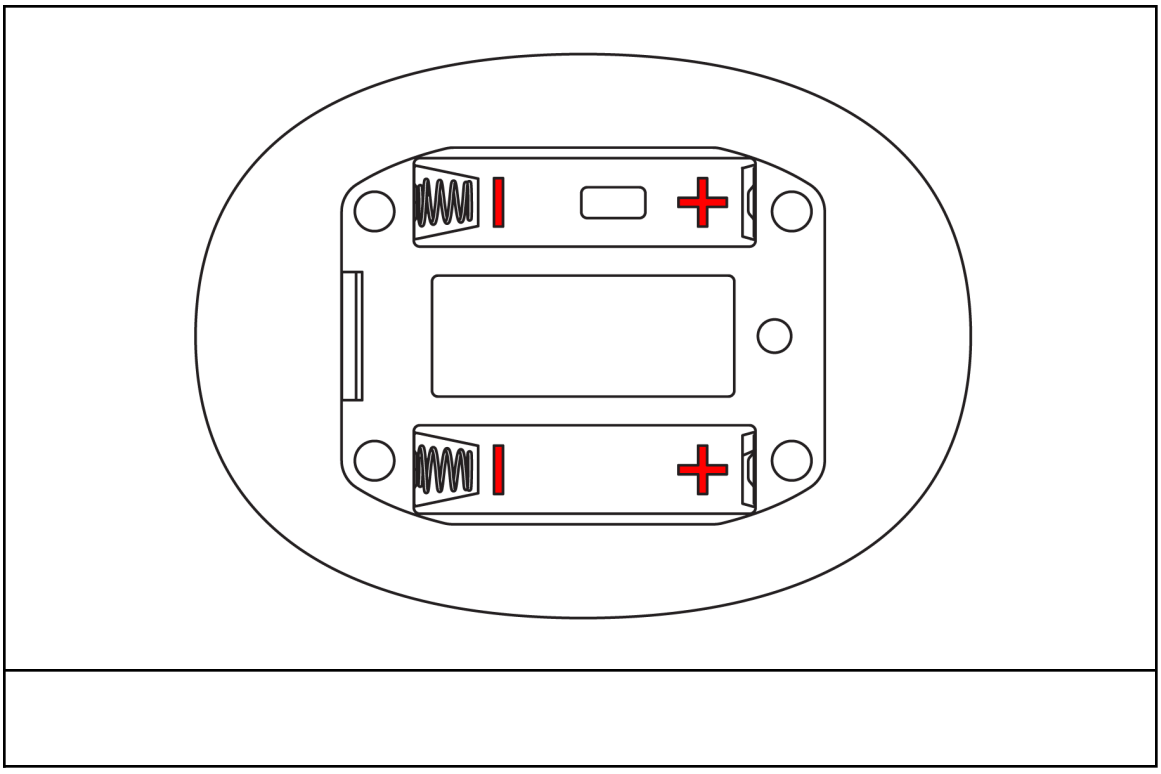
2.2.2. Dock

Remove the battery cover by unscrewing it with the screwdriver provided with the device.

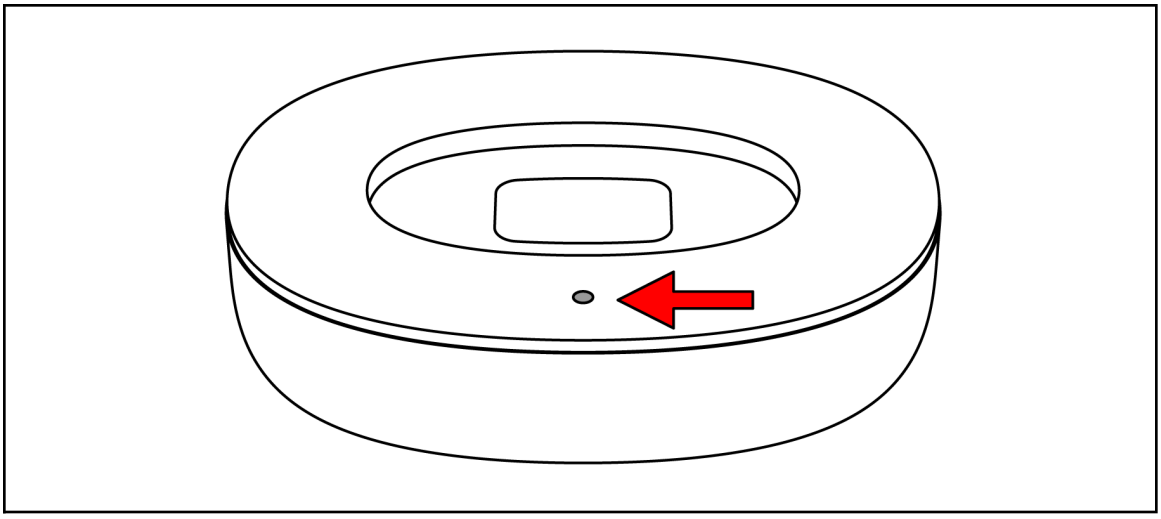




Place the AA batteries in the correct orientation, screw the battery cover back to the closed position.

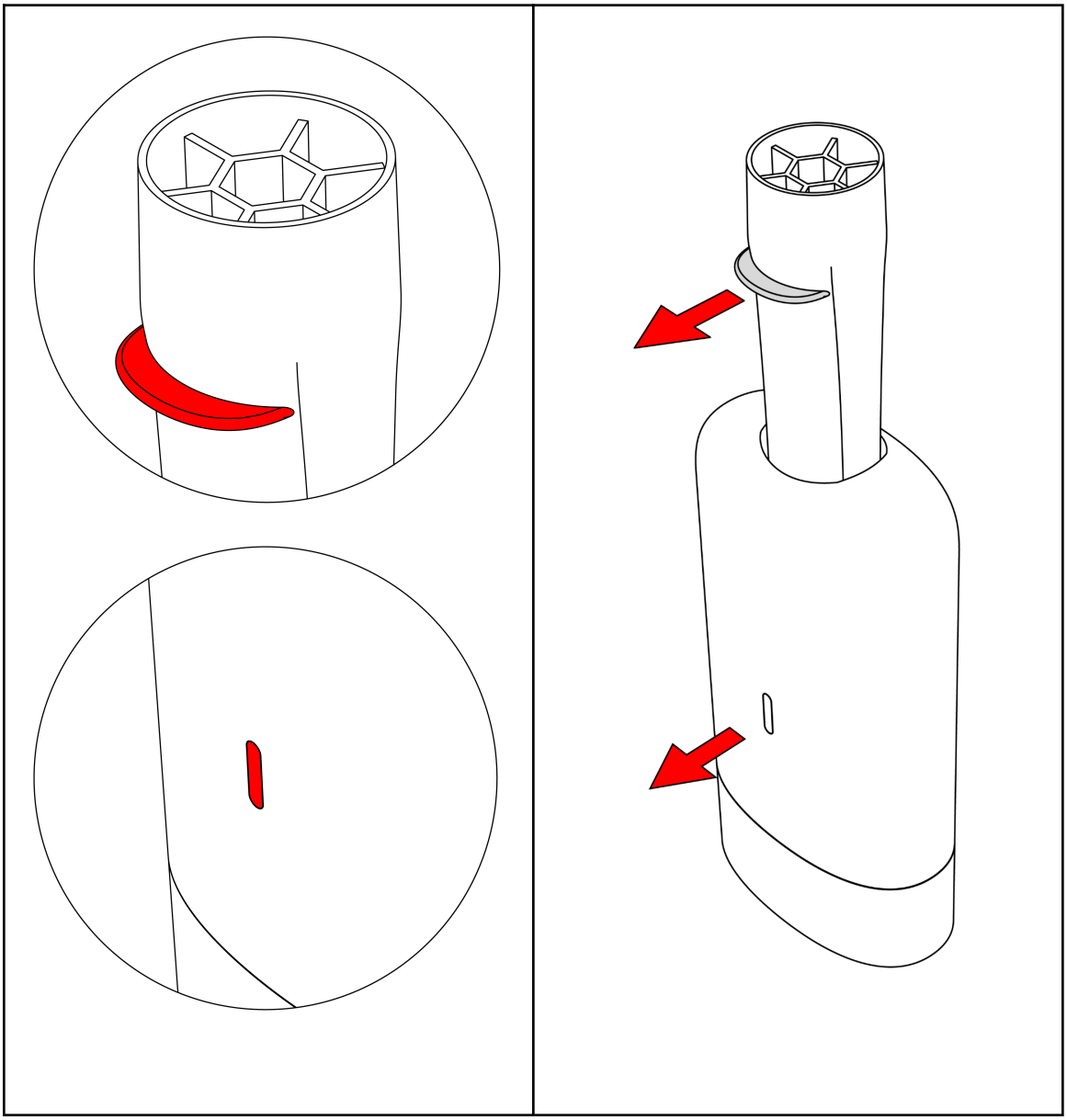


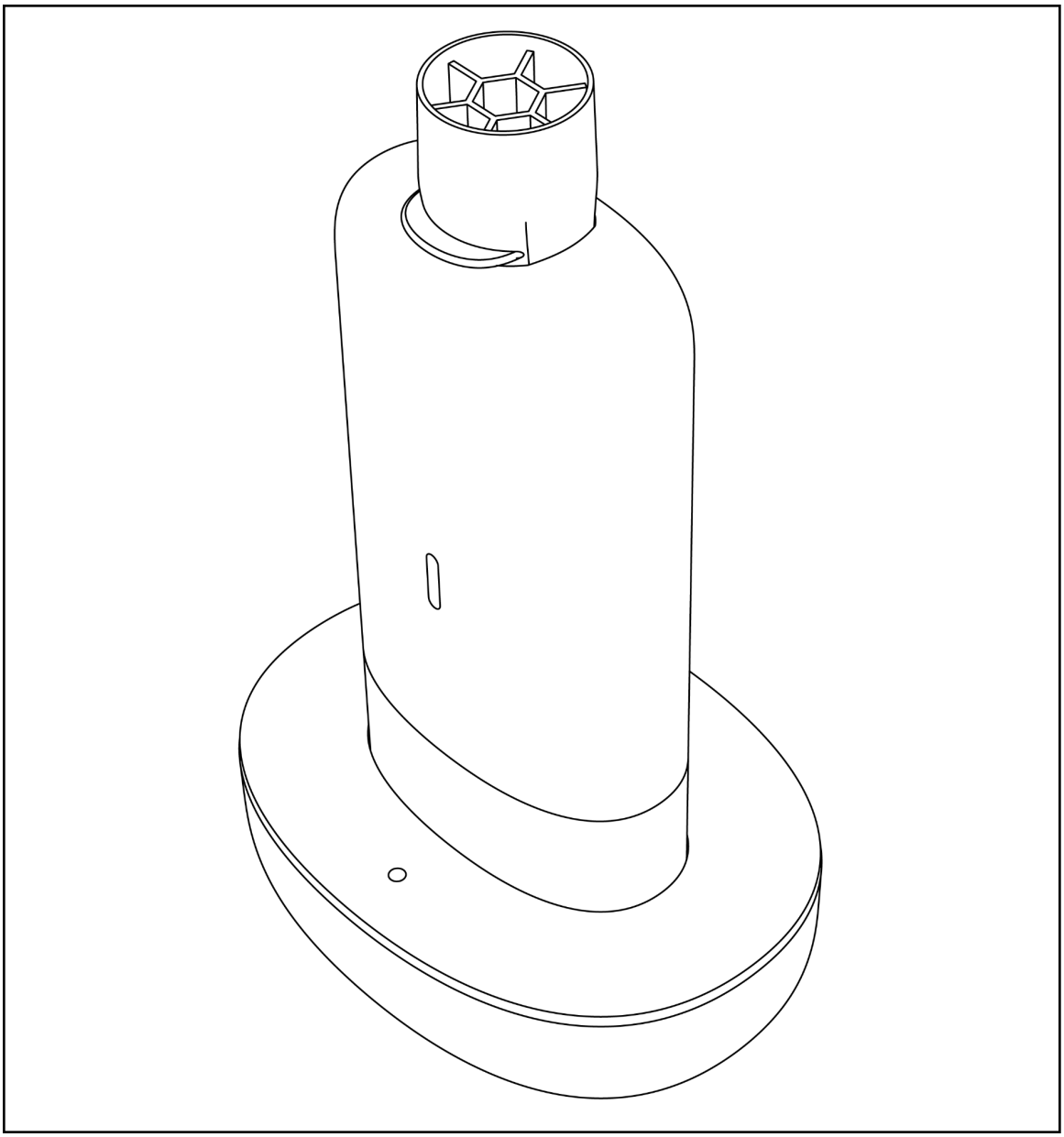
The dock should give an indication light and be ready to use.



2.2.3. Airway

Insert the SpiroWay Pro to the body with the **handle** forward.





2.2.4. Bacterial Viral Filter (BVF)

Attach Bacterial Viral filter (BVF) to the SpiroWay Pro which is attached to the SpiroClinic

Pro and make sure it is fit and sealed.

Do not use SpiroClinic without BVF. Do not use BVF more than once, and adhere to user instructions of the used BVF.

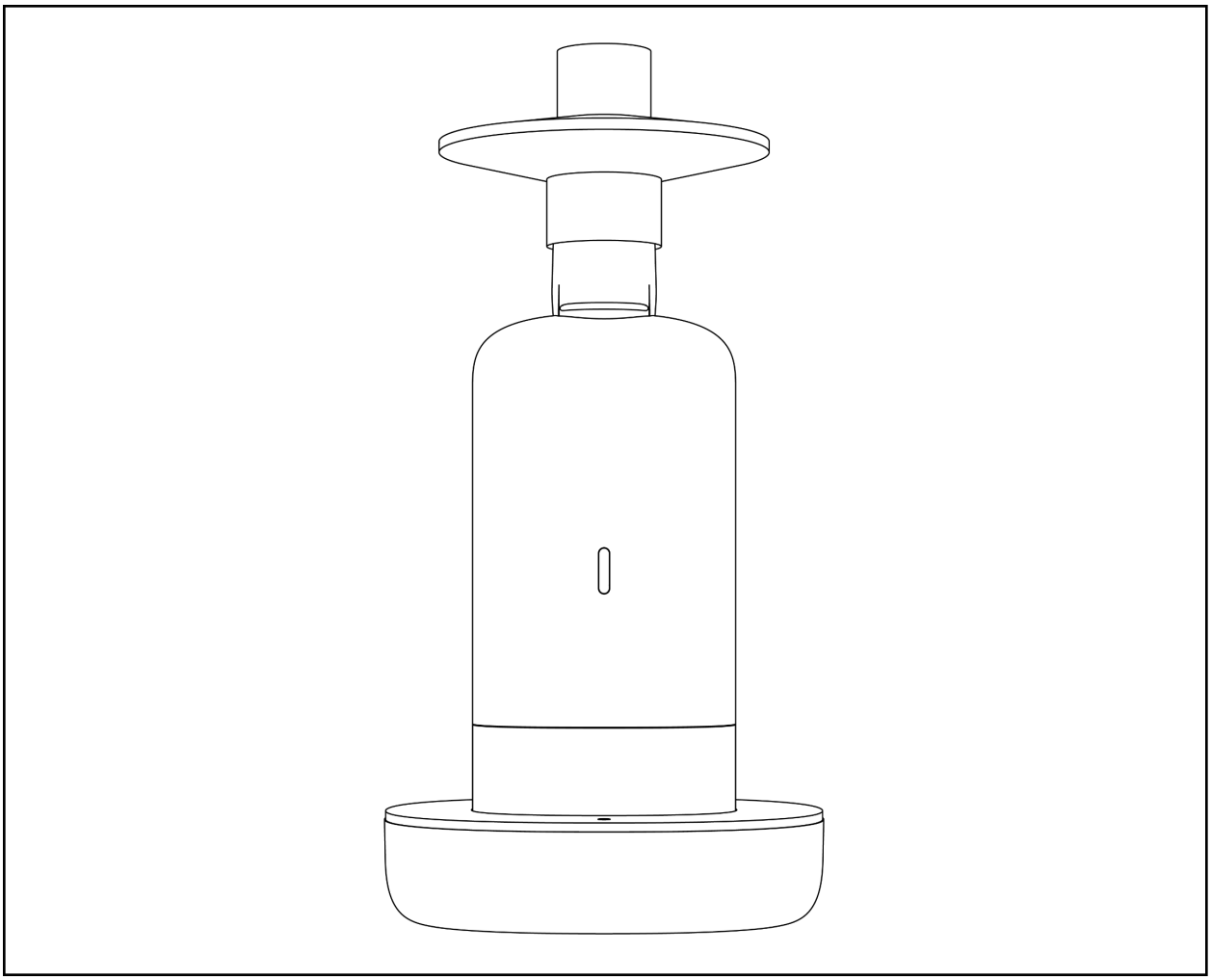
Not all BVFs will make a sealed fit to SpiroWay Pro. Furthermore, some BVFs may not have the required low resistance, quality, or repeatability to ensure accurate measurements and effective protection against cross-contamination.

Use the Bacterial Viral Filters with the technical specifications provided below:

Resistance: 0-80 kPa*(s/l)

Inner Diameter: 30mm

Please only use the BVFs which complies to the specifications provided by the manufacturer.



2.2.5. Application

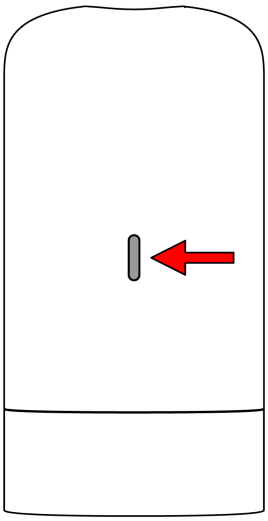
Download the SpiroClinic App from the App Store, Google Play Store, or Microsoft Store onto a smart device or PC.

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

Enable Bluetooth® on the smart device or PC and pair it with the SpiroClinic Pro by following the instructions on the app.

2.3. Device Indicators

2.3.1. Handpiece

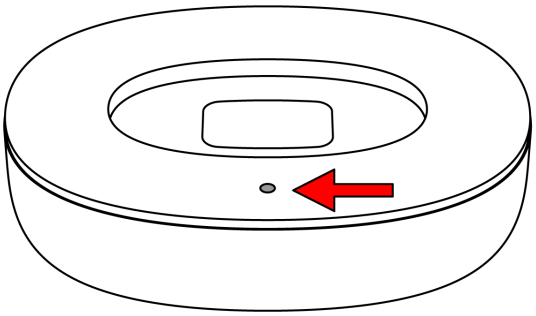
There are LED lights located on the front of the device. These LED lights may be turned on and/or flashing various colors in various patterns. The LED lights indicate the current status of the device. Please see the following information for guidance on LED light indications.	

LED Display	Indication/s
LED turns on for 10s in white	The handpiece is switching on.
The LED lights in green for 5s and turns off.	The handpiece is connected to the app. Bluetooth® connection has been established.
The LED is breathing in and out in blue.	The device Is woke
The LED is fading in and out in yellow.	The zero flow level adjustment is setting up.
The LED is a constant blue.	The handpiece is in test mode.
During a test, the LED turns constant yellow.	The test has timed-out (there has been no inhalation/exhalation over a period of time)

The LED is flashing red.	There is a foreign object between the sensors. (Check device error in troubleshooting section)
The LED is flashing yellow and red.	Over-the-air connection is being established.
The LED turns on as solid red and fades out slowly (in 10s).	Battery low warning.
The LED is flashing in yellow.	The handpiece is not on the dock.
The LED is a constant red	Device is put in the dock backwards.

2.3.2. Dock

There is an LED light located on the front of the device. This LED light may be turned on and/or flashing various colors in various patterns. The LED light indicates the current status of the device. Please see the following information for guidance on LED light indications.



LED Display	Indication/s
LED turns on for 10s in white	The dock is switching on.
The LED lights in green for 5s and turns off.	The dock is connected to the app. Bluetooth ® connection has been established.
The LED is breathing in and out in blue.	The device Is woke
The LED is fading in and out in yellow.	The zero flow level adjustment is setting up.

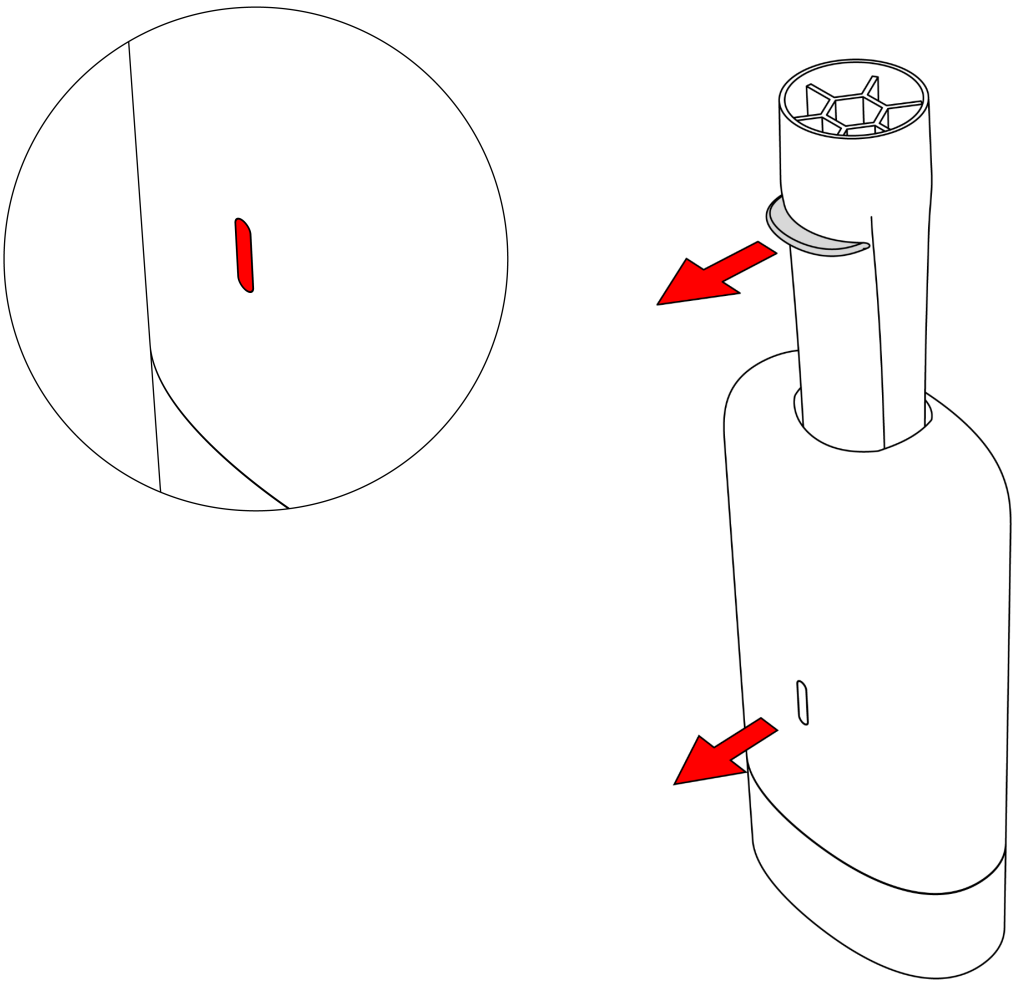
The LED is a constant blue.	The device is in test mode.
The LED turns on as solid red and fades out slowly (in 10s).	Dock Battery is low.
The LED is flashing in yellow.	The handpiece is not on the dock.
The LED is flashing yellow and red.	Over-the-air connection is being established.
The LED is flashing in red	Environmental conditions are not suitable for testing.
The LED is a constant red	Device is put in the dock backwards.

2.4. Performing a Lung Function Test

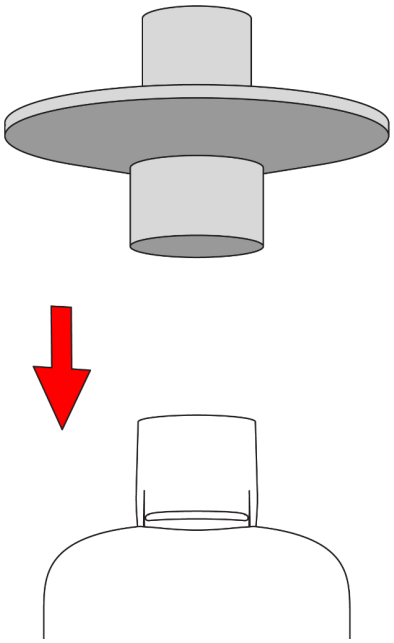
There are several types of tests and different parameters related to lung function that can be involved in a spirometry test. Each type of spirometry test requires a specific breathing maneuver in order to detect the parameters related to that particular test type. Please keep reading for more information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

2.4.1. General Method Performing a Spirometry Test with SpiroClinic Pro:

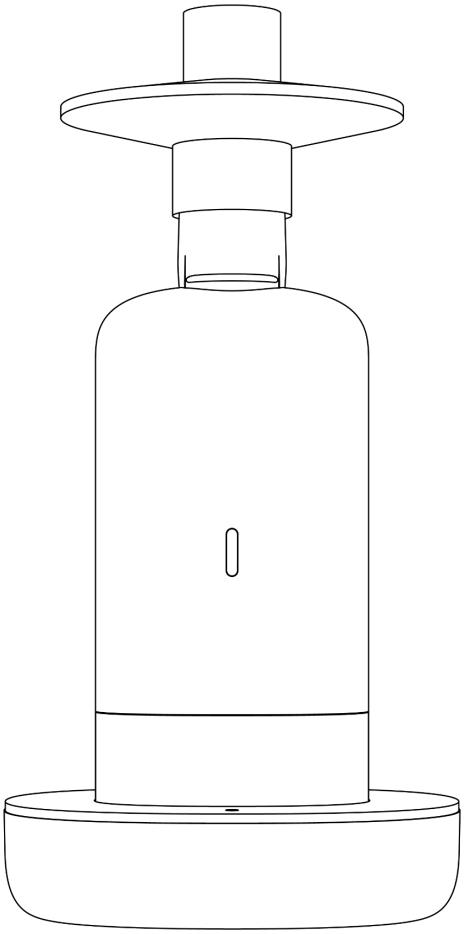
1. Make sure that the device and dock has batteries and is powered.
2. Insert the SpiroWay Pro into the device in the correct orientation. A ‘click’ will be heard when the SpiroWay Pro is inserted correctly all the way into the handpiece.



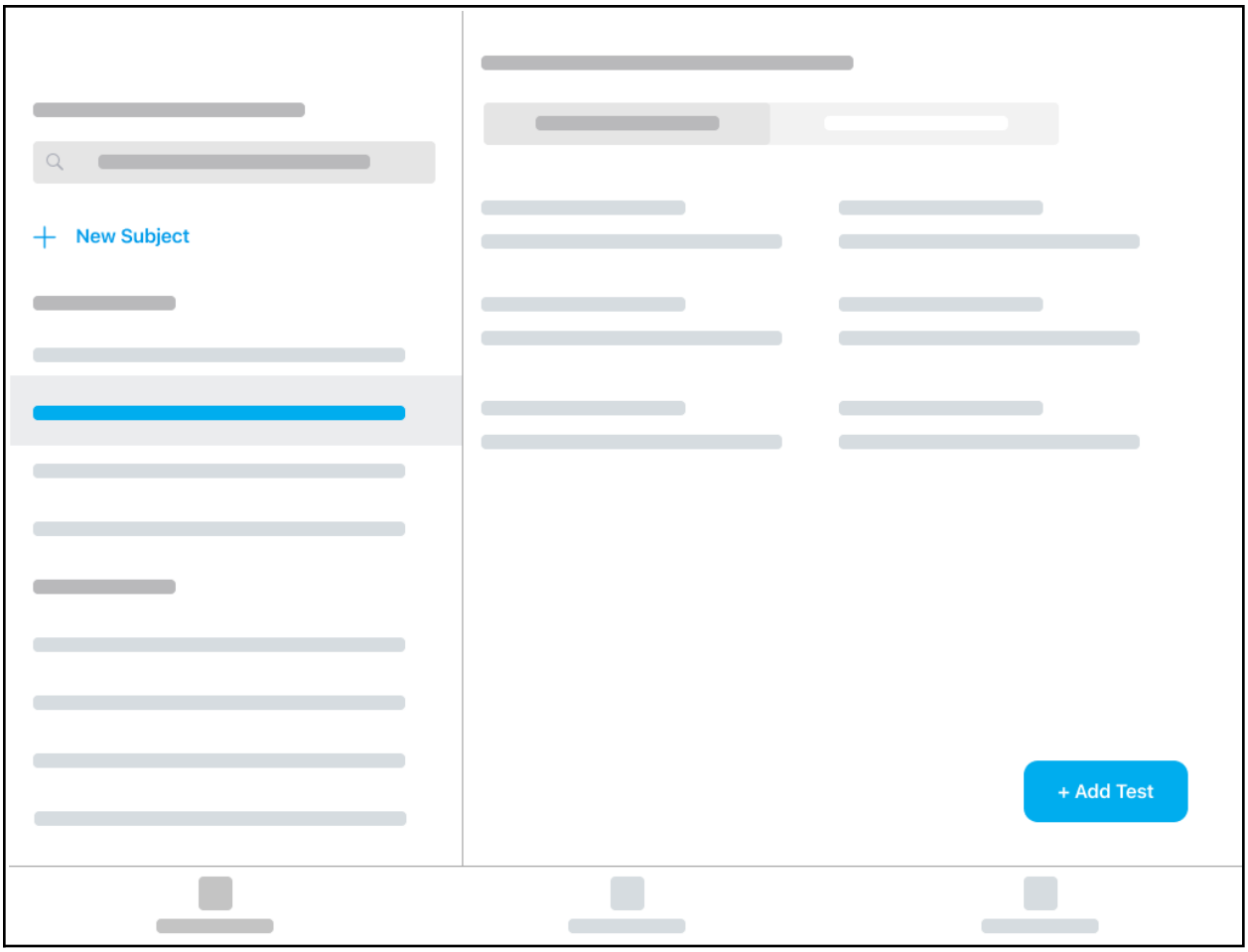
3. Attach a newly opened bacterial viral filter to the SpiroWay Pro.



4. Place the handpiece on the dock.

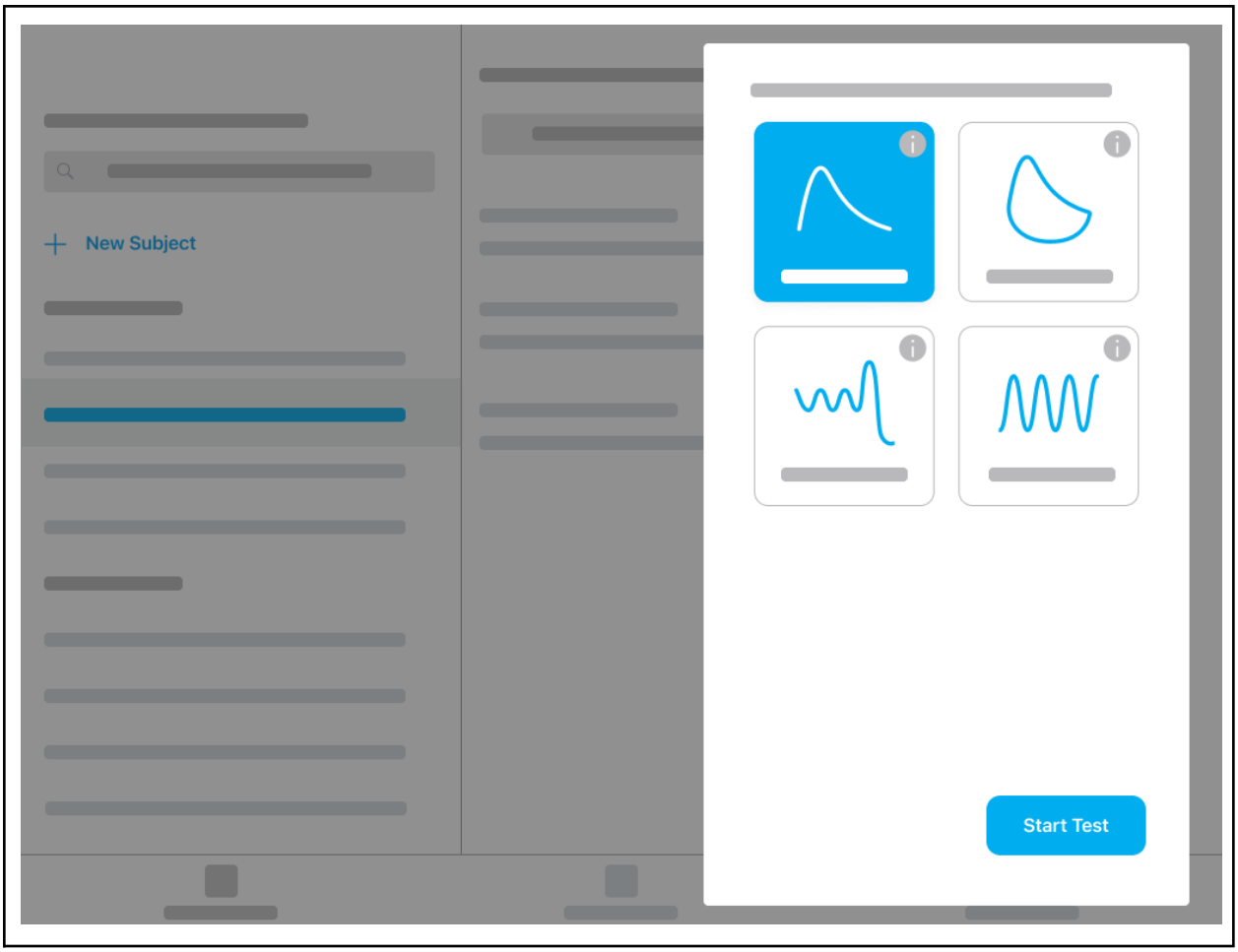


5. Open the SpiroClinic App on your smart device or PC. Log into your account or if you do not have one then first create a new user account. Select patient name from the patient list, or create a new patient account and enter the patient's information. Entering the correct information is critical for calculating expected values.

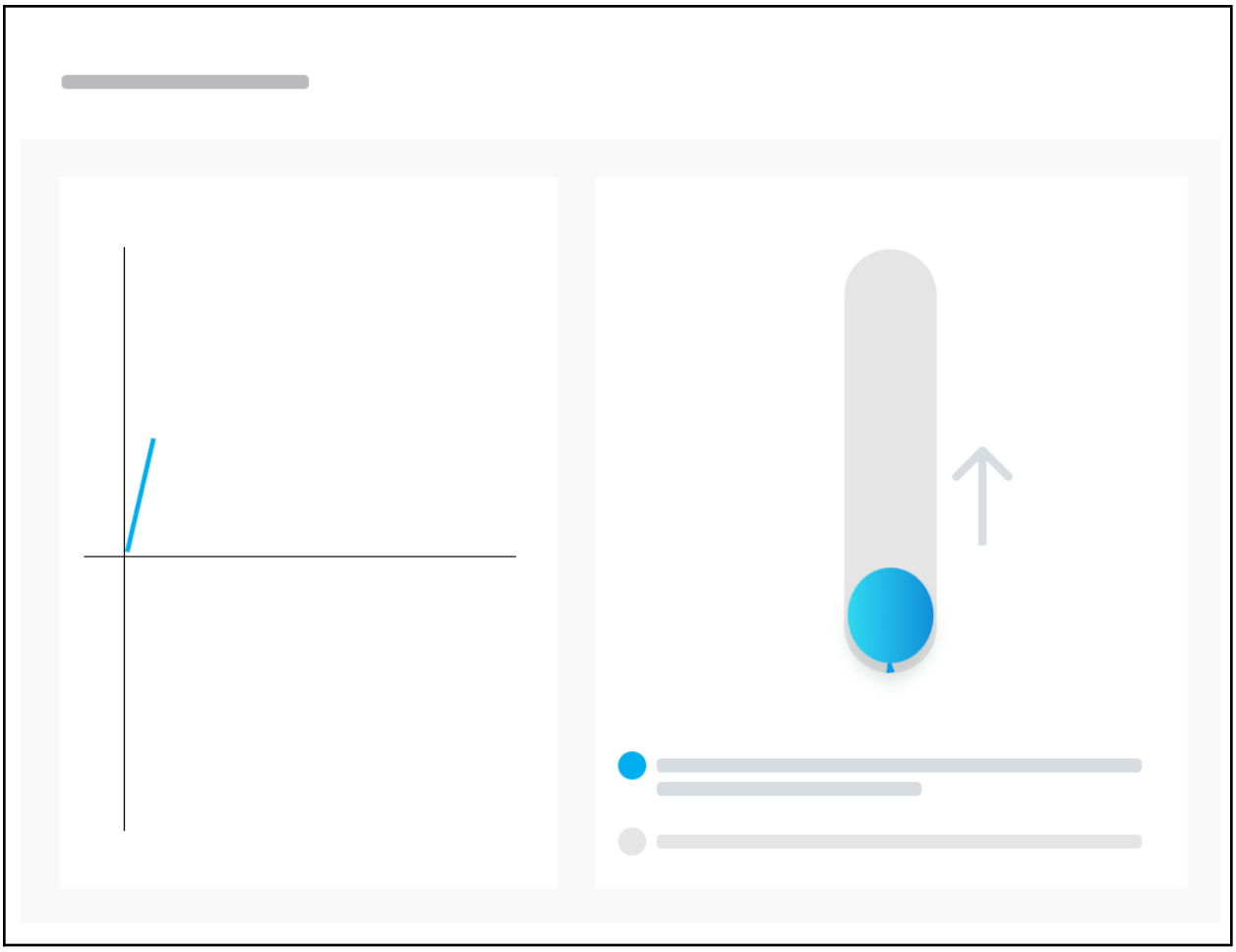


6. After selecting the patient from the patient list, tap the plus button on the screen to start the test procedure.

7. Select the desired test mode and then follow prompts for the device to automatically adjust the zero-flow level. The device can perform the zero-flow level adjustment only if it is on the dock. Make sure that there is no airflow around the device during the zero-flow level adjustment process.



8. The app will prompt the operator to start a spirometry test. Ask the patient to sit with their back straight and feet resting on the ground. The patient will then need to place the BVF (Bacterial Viral Filter) in their mouth, past their teeth. (necessary for measurement accuracy) and form a tight seal around it with their lips.



9. The patient should now perform the breathing maneuver related to the particular spirometry test. Please see the *Type of Breathing Maneuvers* section for more information.

2.4.2. Types of Breathing Maneuvers

➢ **Expiration-Only (Ex-Only) Test Breathing Maneuver:**

1. Ensure that the device is connected. Select the Ex-Only test mode and the test screen will appear.
2. Read and follow the steps on the SpiroClinic application.
3. Follow the prompts from the SpiroClinic application for zero-flow level adjustment.

4. Patient will need to perform a forced expiratory maneuver.

    a. **Tidal Start On:** To ready the patient, direct him/her to inhale and exhale normally a couple of times through the device, then ask to take a fast and deep breath, filling lungs completely. Do not let the patient hold breath for longer than 2 seconds.

    b. **Tidal Start Off:** If the Tidal Start toggles off from the app settings, the patient does not need to breathe normally several times into the Airway before a forcetam expiration, and the test begins with a direct forcetam expiration. When the patient is ready, direct them to fill lungs quickly and completely with air.

5. Ask the patient to place the mouthpiece of the BVF in his/her mouth, past his/her teeth and ensure that his/her lips are tightly sealed around the mouthpiece of the BVF, then the patient takes a fast and deep breath, filling his/her lungs as much as possible. The breath taken should not be kept for more than 2 seconds.

6. Keeping his/her lips sealed tightly around the mouthpiece of the BVF, the patient must blow out the inhaled air and empty his/her lungs as hard and fast as the patient can into the device and keep blowing until completely emptying his/her lungs without breaking the seal of his/her lips.

7. If it takes more than 15 seconds to empty all the air from his/her lungs with the right performance, the test will be completed automatically. The patient may use a nose clip to help him/her to exhale only through his/her mouth during the forced exhalation maneuver.

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

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

NOTE: The difference between **Tidal Ex-Only** and **Ex-Only** is that the patient should breathe normally at the beginning of the test, in **Tidal Ex-Only** test mode. In **Ex-Only** test mode, the data starts to be calculated with any exhale maneuver, but in **Tidal Ex-Only** mode, the data starts to be calculated with the deep inhalation maneuver.

➢ **<u>Full Loop Test Breathing Maneuver:</u>**

1. Ensure that the device is connected. Select the Full Loop test mode and the test screen

will appear.

2. Approve the required ambient conditions provided by SpiroClinic Dock (make sure the values are correct as the measurement may be significantly affected by a wrong value) like temperature and relative humidity and then adjust zero flow level for the device. To get ready, the patient should inhale and exhale normally a couple of times.

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

4. Patient will need to perform a forced expiratory maneuver.

    a. **Tidal Start On:** To ready the patient, direct him/her to inhale and exhale normally a couple of times, then ask to take a fast and deep breath, filling lungs completely. Do not let the patient hold breath for longer than 2 seconds.

    b. **Tidal Start Off:** If the Tidal Start toggles off from the app settings, the patient does not need to breathe normally several times into the Airway before a forcetam expiration, and the test begins with a direct forcetam expiration. When the patient is ready, direct them to fill lungs quickly and completely with air.

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

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

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

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

➢ **The Maximum Voluntary Ventilation (MVV) Test Breathing Maneuver:**

1. Ensure that the device is connected. Select the MVV test mode and the test screen will appear.
2. Enter the required ambient conditions (make sure you entered the correct values as the measurement may be significantly affected by a wrong value) like temperature and relative humidity and then adjust zero flow level for the device.
3. Ask the patient to place the mouthpiece of the BVF in his/her mouth, past his/her teeth and ensure that the patient's lips are tightly sealed around the mouthpiece of the BVF.
4. When the test starts, the patients should inhale and exhale normally at least 4 times, then inhale and exhale completely filling and emptying their lungs, repeatedly, uninterrupted, deeply, without breaking the seal of their lips for at least 12 seconds. The patient may use a nose clip to help him/her to inhale and exhale only through his/her mouth during this breathing maneuver.
5. Actively encourage the patient to breathe deeply and rapidly move as much air as possible for at least 12 seconds.
6. The patient may remove the mouthpiece of the BVF from his/her mouth and resume normal breathing once the breathing maneuver has been completed.
7. The test results will be displayed on the app screen. If the test fails, give feedback and guide the patient for another trial. Encourage them to breathe deep and fast and try to reach at least 12 seconds.

➢ **The Slow Vital Capacity (SVC) Test Breathing Maneuver:**

1. Ensure that the device is connected. Select the SVC test mode and the test screen will appear.
2. Enter the required ambient conditions (make sure you entered the correct values as the measurement may be significantly affected by a wrong value) like temperature and relative humidity and then adjust zero flow level for the device.
3. Tell the patient to wear a nose clip and ask the patient to place the mouthpiece of the BVF in his/her mouth, past his/her teeth and ensure that his/her lips are tightly sealed around the mouthpiece of the BVF.

4. When the test starts, the patient should inhale and exhale normally at least 4 times, then the patient should inhale as deep as the patient can and fill his/her lungs completely.

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

6. When performing this breathing maneuver, the patient must make sure to keep blowing until the patient feels like the patient has completely emptied his/her lungs.

7. The test can also be performed by performing the breath maneuver in the opposite direction. When the test starts, the patient should inhale and exhale normally at least 4 times, then the patient should exhale as deep as the patient can and empty his/her lungs completely. After that, the patient should inhale all the air in his/her lungs until s/he feels completely taml without breaking the seal of his/her lips.

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

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

2.5. Understanding the Test Quality

After each test session, quality grading will be displayed on the app to provide information about how well the breathing maneuver was performed. Note that the acceptability of the test is purely decided by the doctor/operator etc. This grade refers to the consistency of the patient's maneuvers, not the health of the patient's lungs.

Grading of the FVC and FEV_1 parameters in children and adults, according to the American Thoracic Society (ATS) and European Respiratory Society (ERS) guidelines;

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

*For children aged 6 years or younger, must have at least 0.75 seconds of expiration without glottic closure or cough for acceptable or usable measurement of FEV0.75.

† 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.

‡ 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.

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 label, signs and symbols provided for the safe use and storage of the SpiroClinic Pro.

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

	Temperature Limit
	Humidity Limit
	Atmospheric pressure limitation
	Do not use if the package is damaged
	Keep away from sunlight
	Keep dry
	Explanatory information
	Type BF of Medical Electrical Equipment
	Serial Number

LOT	Lot Number
REF	Ref Number
IP	IP Number
	Antenna symbol for devices that include RF transmitters
	The instruction manual/booklet must be read.
	Caution
	User Manual
	Bluetooth

2.7. Technical Features

Flow / Volume measurement method	Ultrasonic transducer measurement
Power Supply Handpiece	2 x 1.5V AA alkaline batteries
Power Supply dock	2 X 1.5V AA Alkaline batteries
Dimensions handpiece	150 x 77 x 42 mm
Dimensions dock	32 x 128 x 93 mm
Weight handpiece (With batteries)	239 gr

Weight handpiece (Without batteries)	192 gr
Weight dock (With batteries)	196 gr
Weight dock (Without batteries)	150 gr
Weight of the Airway	21 gr
Flow range	0 - 14 L/s
Maximum volume measured	10 L
Volume accuracy (Average)	2.00 %
Resistance*	130 Pa x s/L*,**
Volume resolution	1 mL
Flow resolution	1 mL/s
Medical device class	Class IIA
Wireless connection	BLE 4.2

** When tested according to ISO 26782:2009 Annex B including all accessories.*
******Note:*** *System resistance may vary depending on the bacterial viral filter used.*

2.8. Safety Warnings and Precautions

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

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

The patient should be informed that maximal inflation is unnatural; the patient may not have achieved it before, and it may seem somewhat uncomfortable.

Regardless of the data presented on the SpiroClinic Pro, if the patient feels unwell or has respiratory illness symptoms, they should cease use of the device. Only a doctor can decide on an appropriate treatment plan for the patient based on respiratory data obtained with the SpiroClinic Pro spirometer.

Healthcare professionals can end the session for the patient's safety when there is an excessive decrease in the FEV_1 value.

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

Do not use SpiroClinic Pro for any other purpose than its intended use. The SpiroClinic Pro is not recommended for children under the age of 5.

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

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

Do not allow users to walk or run while taking a lung function measurement using SpiroClinic Pro spirometer. Do not perform a spirometry test with food or objects in the patient’s oral cavity to avoid the risk of choking.

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

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

Ensure that the device is cleaned and disinfected (see Maintenance section of this manual) between each user and a new disposable bacterial viral filter is attached. Also, ensure that you select the new patient (or add a new patient if that patient does not already have an account) on the SpiroClinic App before performing a spirometry session with the device.

The SpiroClinic Pro must only be used with the original accessories specified and provided by the manufacturer. Use of the airways, bacterial viral filters or other accessories that are not recommended by the manufacturer may cause inaccurate test readings, or damage/harm to the

user and/or device. Do not cause damage to the filters located on the barrel of the airway and do not touch the filters when handling or inserting the airway into the device. Do not use the airway if the filters have been physically compromised.

The device should be checked periodically to ensure that foreign bodies or impurities are not present on visible and accessible areas of the device as this could lead to inaccuracies in test measurements. Coughing or spitting into the device may cause incorrect readings.

Pulmonary function tests require maximum effort on the part of the patient and may lead to sensations of dizziness or giddiness. The patient should not perform more than 8 spirometry tests in one spirometry session. If the patient experiences pain during the maneuver, stop the test immediately and ensure the patient rests.

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

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

Store and use the device as specified in this user manual (*3.1 OPERATING ENVIRONMENT*) as alternative methods or conditions of storage may affect device function and/or accuracy. Use only in specified environments/conditions (see Operating Environment) to avoid malfunction and/or display of incorrect results. Store and use the device away from sources of vibration, ionizing radiation and non-ionizing radiation.

All repairs, modifications or reconfigurations must be performed only by the manufacturer. If the SpiroClinic Pro is damaged or malfunctioning, contact the manufacturer or distributor if purchased from a reseller, directly to avoid incorrect measurements or potential harm. Do not attempt to repair the device yourself, an opened device casing will terminate the product warranty.
Please follow all data security warnings and recommendations for the smart device used in conjunction with the SpiroClinic Pro as per its manufacturer's instructions as the patients' personal data recorded and stored on the SpiroClinic App, may otherwise be at risk. The user is encouraged to not share SpiroClinic App account information with unauthorised parties.

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

Handle SpriClinic Pro and all its accessories with care and make sure not to drop or expose to any extreme stress.

When inserting the SpiroWay Pro airway into the SpiroClinic Pro device be caretam not to get your skin caught and pinched between the components.

Make sure the patient does not block or obstruct the airflow while handling the device during the test.

3. Maintenance

Handle SpiroClinic Pro and SpiroWay Pro with care. Do not use the device or its accessories if they are visibly damaged or deformed, particularly if there is damage to the filters on the airway.

Store the SpiroClinic Pro in dust-, dirt-, and moisture-free conditions. Before each use, always check that the device is free from contaminants and does not have any visible damage. After use by each new user, clean and disinfect the device according to the instructions given in this section.

Proper cleaning and disinfection of your SpiroClinic Pro and SpiroWay Pro Airway are important for the safe use of the device. With regular cleaning, the physical build-up of contaminants on the device can be prevented. Cleaning process must always precede a disinfection process for the SpiroClinic Pro handpiece and dock station. For SpiroWay Pro Airway the cleaning process is enough.

Disinfection destroys any pathogens such as bacteria, viruses or other microorganisms that might still be present on device surfaces after an initial cleaning process. Regular, thorough cleaning and disinfection of the device protects both handlers and users of the device from the potential transmission of infections resulting from contact with the device. Handlers and users of the device should be sure to wash hands with soap before and after each use of the device.

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

3.1. Calibration-Check

Due to the ultrasound-based technology for airflow analysis, routine calibration of the SpiroClinic Pro is not necessary and technically there is no mechanism provided to the user to calibrate the device. The device is factory calibrated and a re-calibration can only be done by the manufacturer. However, it is advised by the American Thoracic Society (ATS) and European Respiratory Society (ERS) that periodic calibration-checks of spirometers are performed.

3.1.1. Preparation of Calibration Check

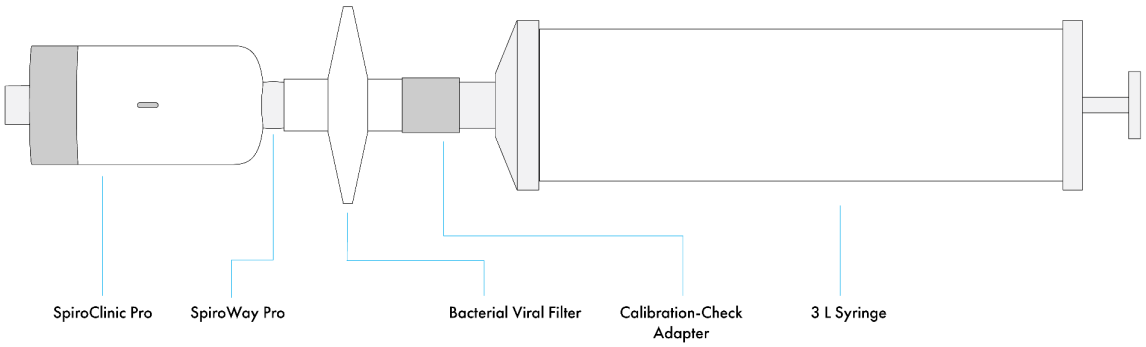
1. Check that the following items are available for setup:

    - A standard 3L calibration syringe
    - A bacterial viral filter (BVF) that is used with the device
    - An adapter to fit a 3L calibration syringe to the BVF

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

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

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



4. To perform the Calibration-Check, select Calibration-Check in the settings section of the SpiroClinic App.

5. Then choose the Calibration-Check type as Multi-Flow Calibration Check or Linearity Calibration Check and follow the instructions from SpiroClinic App.

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

3.2. Cleaning and Disinfection

Important!: The SpiroClinic Pro must be cleaned and then disinfected between each new patient.

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

2. **Cleaning the SpiroWay Pro**

Detach and dispose of any BVF mouthpieces connected to the SpiroWay Pro and then remove the SpiroWay Pro from the SpiroClinic Pro handpiece.

To clean the SpiroWay Pro after each patient 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 SpiroWay Pro gently in the soapy solution.
- Hold the SpiroWay Pro under running tap water to rinse
- Leave the upright on a clean lint-free cloth at room temperature until it is completely dry.

CAUTION: Do not insert the SpiroWay Pro into the SpiroClinic Pro device until it is completely dry.

The SpiroWay Pro Airway should be replaced every 3 months. The SpiroWay Pro Airway must be replaced if the patient has or suspected to have a bacterial or viral infection Replace the SpiroWay Pro whenever a risk of cross-contamination is suspected.

3. **Cleaning the SpiroClinic Pro Handpiece and Dock**

Once the SpiroWay Pro has been removed, use a a disinfectant* (Hydrogen peroxide >= 1 - < 2.5%, Glycolic acid >= 1 - < 2.5%) to wipe (for at least 30 seconds) all accessible surfaces of the device and dock to remove all visible contaminants as shown below. Please be extra caretam and gentle when cleaning the sensors to avoid any damage to them. Clean the SpiroClinic Pro handpiece between each new patient.

Wipe all accessible surfaces of the device and dock, using moderate pressure.

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

4. **Disinfecting the SpiroClinic Pro Handpiece and Dock**

After cleaning all accessible surfaces of the device and dock with a disinfectant* (Hydrogen peroxide >= 1 - < 2.5%, Glycolic acid >= 1 - < 2.5%) wipe, use a second fresh wipe to wipe over all surfaces again using moderate pressure and for the contact time recommended by the wipe manufacturer to achieve disinfection.
**Incidin™ OxyWipe S is a ready-to-use cleaner and disinfectant (H_2O_2-based) with broad spectrum efficacy available at*
https://en-uk.ecolab.com/offerings/pre-impregnated-wipes/incidin-oxywipe-s

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

CAUTION: Risk of Cross-Contamination!

SpiroClinic Pro may be used by multiple users, however, the cleaning and disinfection procedure described for the device and the airway must be performed between each new user. A new Bacterial Viral Filter must be used for each new user. This is important to prevent the risk of cross-contamination between users.

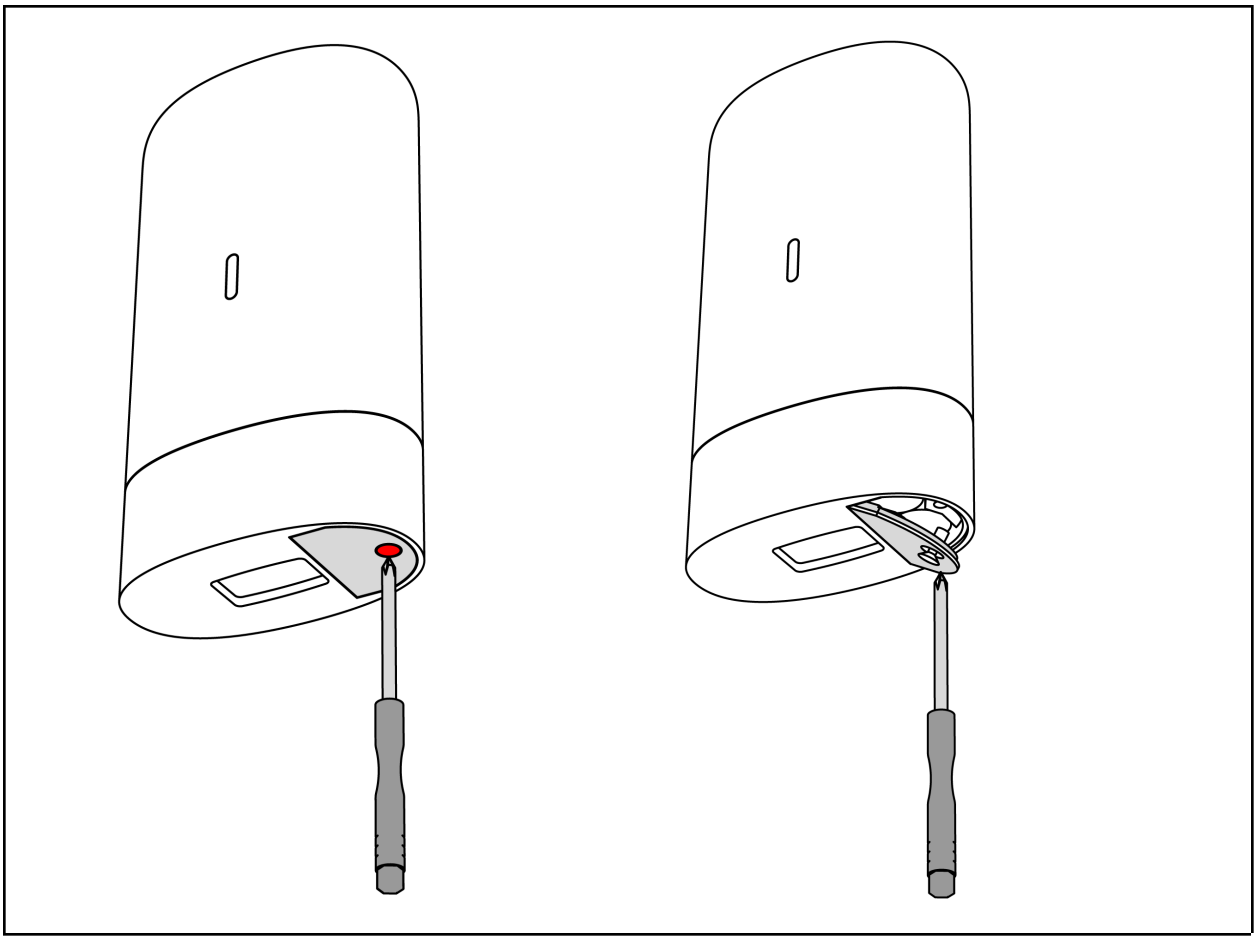
Do not use harsh detergents or other chemicals that are not recommended by the manufacturer as they can damage the device, cause micro-cracks or erase labelings of the device.

3.3. Batteries

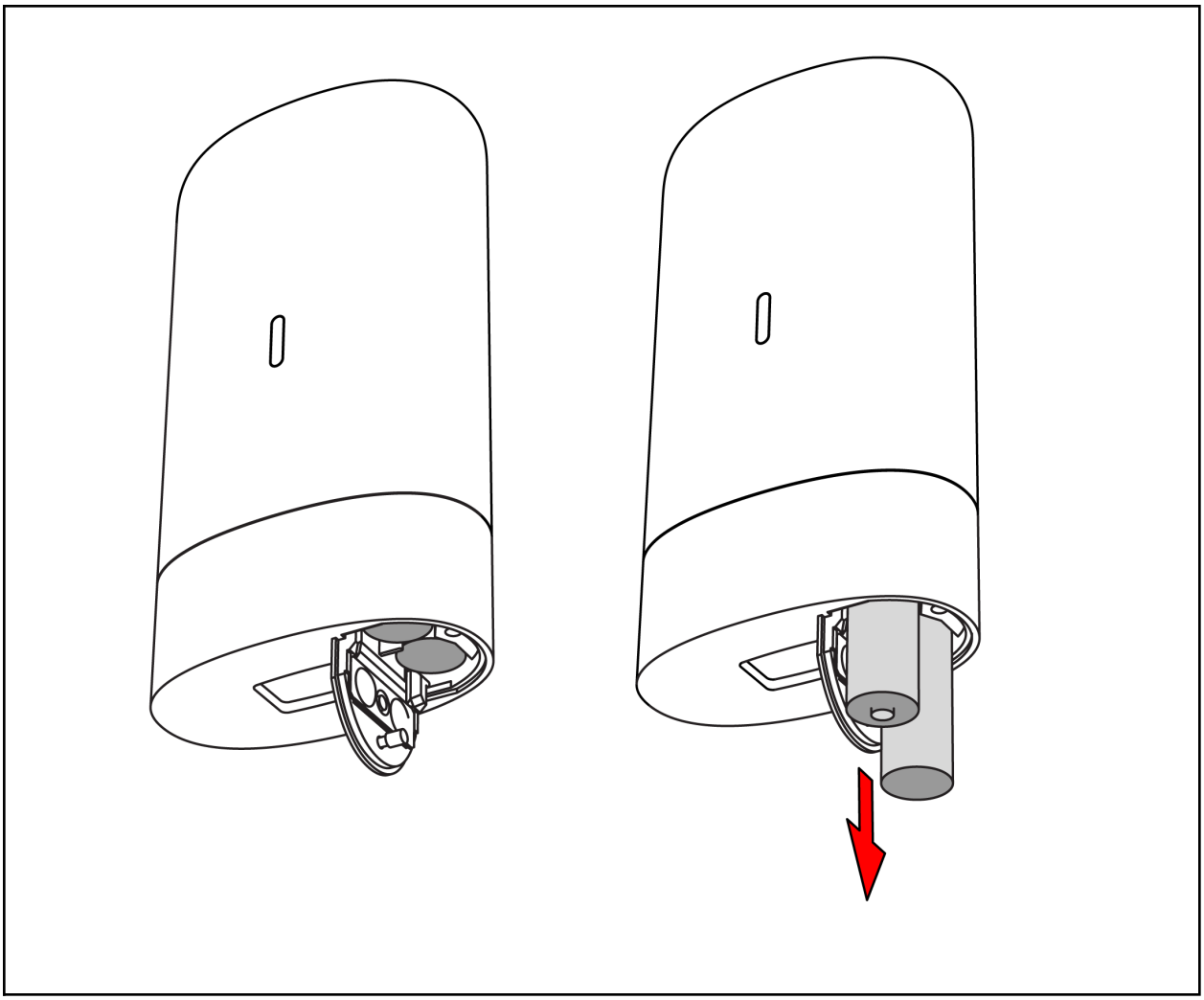
The SpiroClinic Pro device must be powered by 1.5V AA Alkaline batteries. The battery life of the SpiroClinic Pro is approximately 12-18 months when one session (2 tests) is performed per day. The battery charge level is continuously monitored by the device. When the device battery charge level is low, the device will not turn on and the device will notify the user as described in the *Device Indicators* section of this user manual. The batteries of the device should be removed if the device is not going to be used for more than a month.

3.3.1. Instructions for Handpiece Battery Replacement

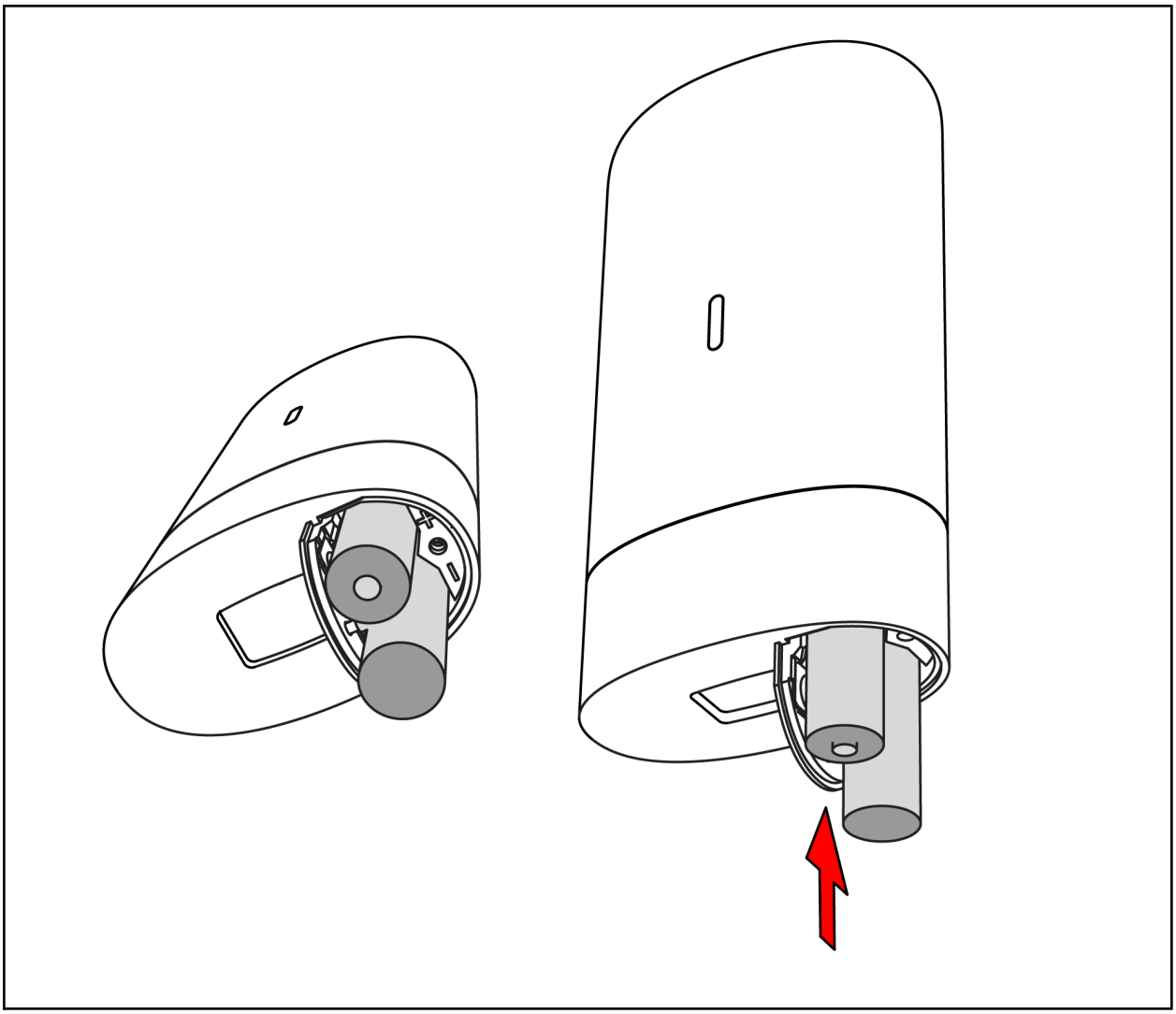
1. Unscrew the battery cap using the screwdriver provided.



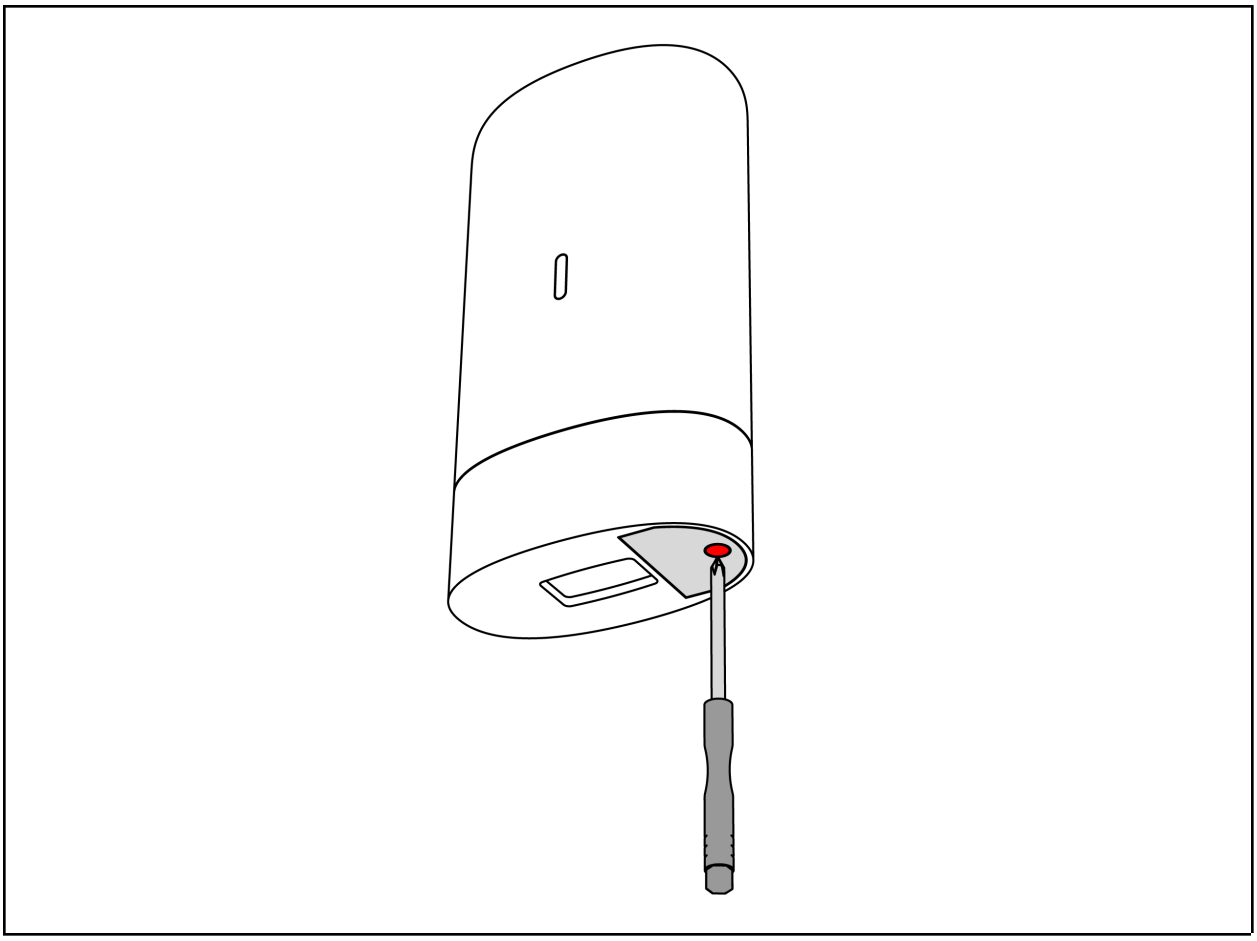
2. Remove the battery cover as shown.
3. Remove the empty batteries.



1. Place the new batteries in the correct orientation.



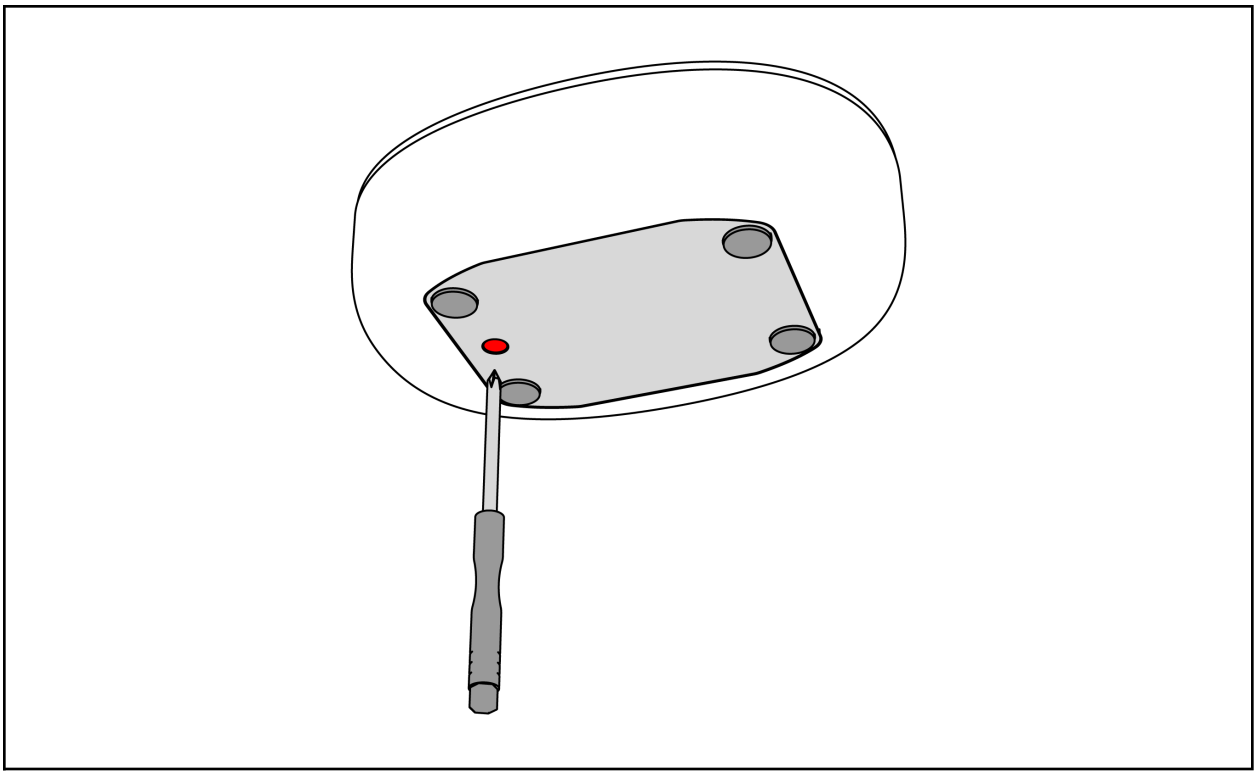
2. Screw the battery cap back on



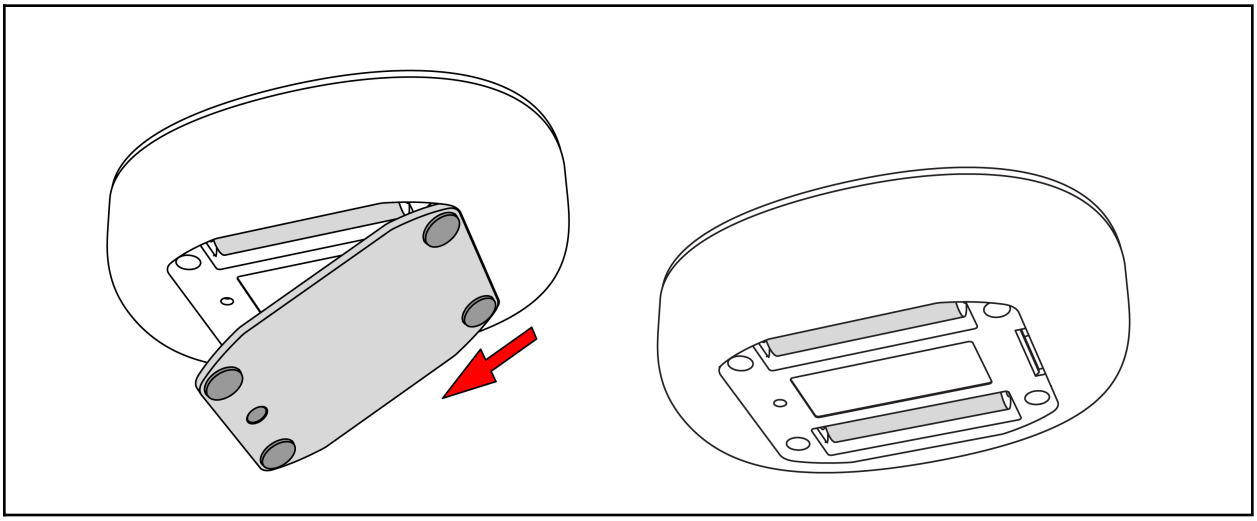
3. Store the device according to the storage requirements until next use.

3.3.2. Instructions for Dock Battery Replacement

1. Unscrew the battery cap using the screwdriver provided.

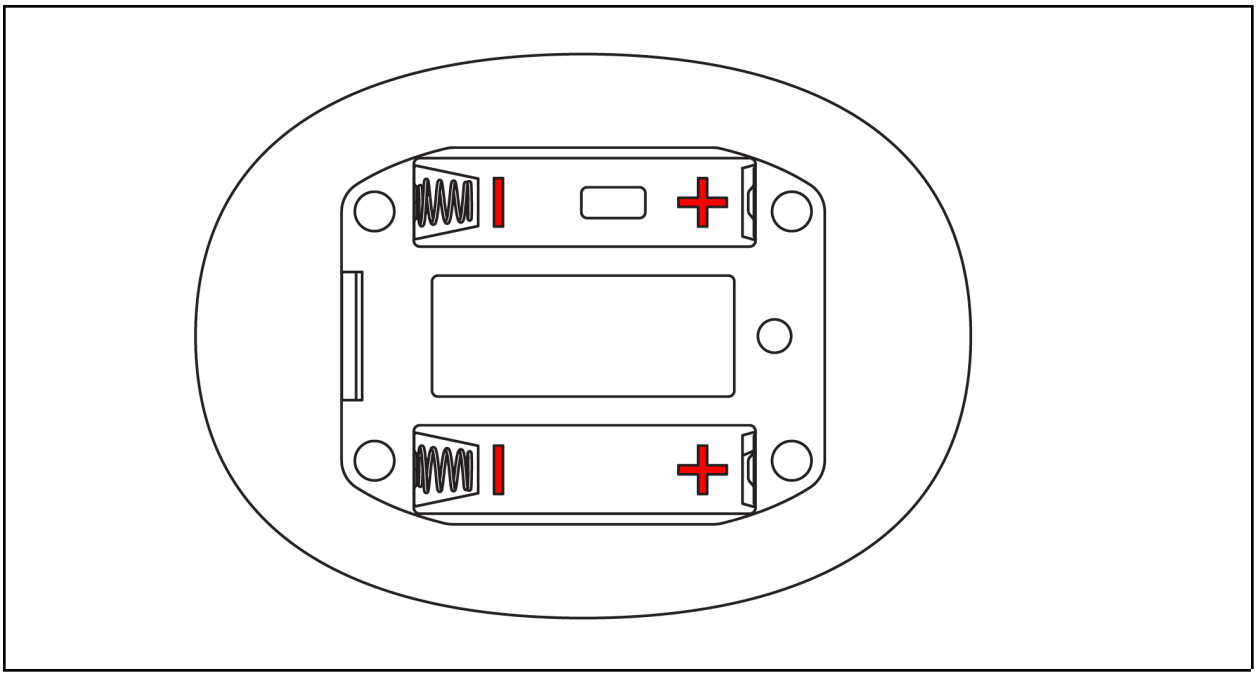


2. Remove the battery cover as shown.

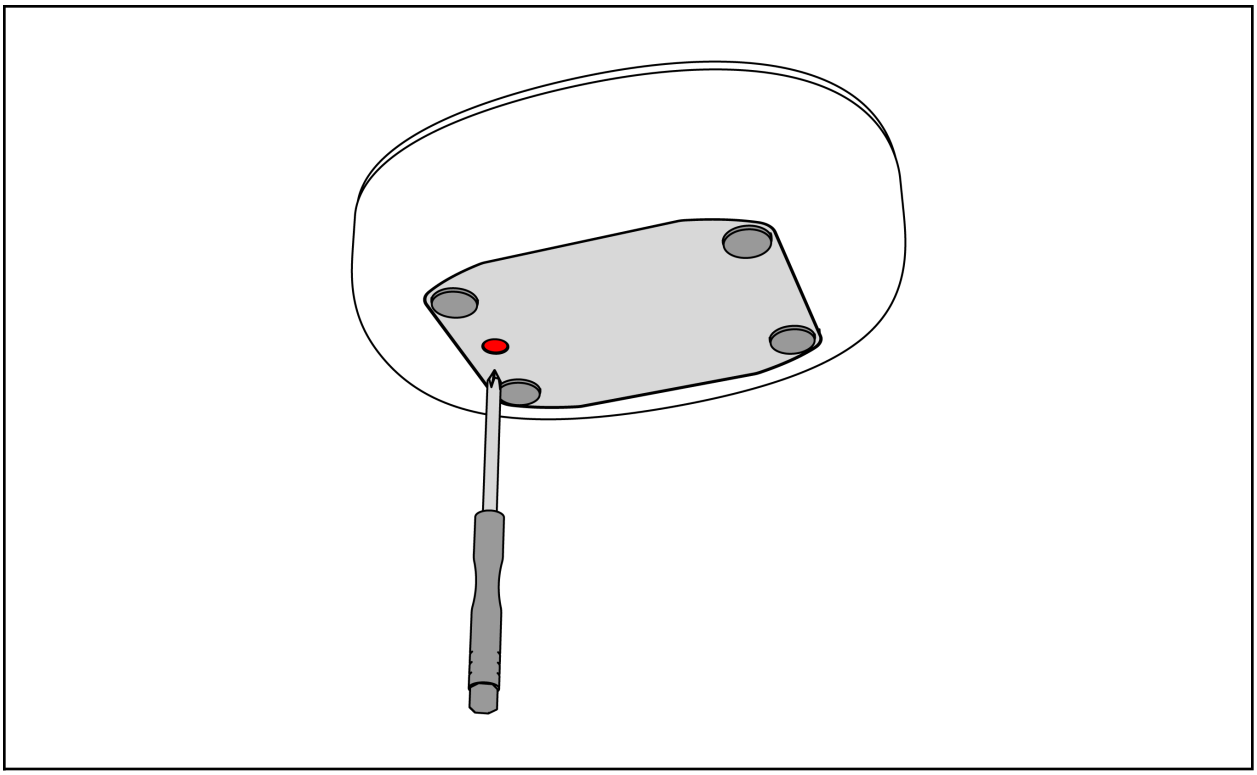


3. Remove the empty batteries.

4. Place the new batteries in the correct orientation.



5. Screw the battery cap back on



6. Store the device according to the storage requirements until next use.

4. Disposal of SpiroClinic Pro

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.

5. Troubleshooting

Problem	**Possible Cause**	**Solution**
The device appears to be not off and not discoverable by the App	Multiple possible causes	Check battery orientation and correct polarities
		Remove the batteries, wait 30 seconds and reinstall batteries

		Replace batteries
		Check that battery cap is in the lock position, or if it is is broken, contact manufacturer
The device cannot connect to a smart device via Bluetooth®	The smart device is out of range	Bring your smart device closer to the SpiroClinic device
	Smart device Bluetooth® is disabled	Enable Bluetooth® of your smart device
	Bluetooth® connection not working properly	Your smart device will need Bluetooth® version 4.0 or higher.
Test results are inconsistent	SpiroWay Pro is dirty	Make sure the airway is clean. Especially the sensor openings need to be clean and without any damage.
	SpiroWay Pro is damaged	Replace SpiroWay Pro
	Spirometry test was performed incorrectly	Refer to Performing a Lung Function Test in the user manual or refer video tutorial on app
	SpiroWay Pro is installed incorrectly	Refer to the user manual for proper installation of SpiroWay Pro
	The device has lost its calibration.	Perform the Calibration-Check and contact the manufacturer if you have any calibration error.
The test does not start - Cannot perform zero flow level adjustment	Handpiece is not on the Dock	Make sure the Handpiece is on its dock
		Remove causes of direct air current e.g. air conditioner, opened window, fan, etc.
	Damaged or faulty SpiroWay Pro	Replace the SpiroWay Pro, contact the manufacturer
	Error with the dock station	Remove the batteries of the dock station, wait for 30 seconds and reinstall the batteries. If problem persists, contact the manufacturer
The test does not start - animated	Multiple possible causes	Quit test and start a new test
		Quit the application and start a new test

balloon is not moving		Switch the device on and off again to reset
Test Starts before you start blowing	Vigorous handling of the device	Keep the device as stable as possible after starting a test
Device disconnected during test	BLE connection dropped	Reconnect device and proceed with a new test
Test quality grade always low	Not performing test correctly	Repeat the test following the rules and conditions specified in the *Performing a Lung Function Test* section of this user manual.
Measurement error screen displayed	Flow limit exceeded	This device is intended to measure 0-14 L/s.
	SpiroWay Pro is dirty	Replace SpiroWay Pro
	SpiroWay Pro is damaged	Replace SpiroWay Pro
	Device malfunction	Contact manufacturer
Device error screen displayed	SpiroWay Pro is installed incorrectly	Refer to user manual for proper installation of SpiroWay Pro
	There is a foreign object between the sensors	Check SpiroWay Pro to ensure that the lumen is not obstructed
	SpiroWay Pro is dirty	Replace SpiroWay Pro airway
	SpiroWay Pro is damaged	Replace SpiroWay Pro airway
Device is not connecting to the dock station	Error with the dock station	Remove the batteries of the dock station, wait for 30 seconds and reinsert the batteries. If the problem persists, contact the manufacturer

No LED indication when placing the batteries in the handpiece	Power is not tamly emptied from the hardware	Wait 1 minute between removing old batteries and inserting new batteries.

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

6. Orderable Accessories

- SpiroWay Pro (Reference number:16000)
- SpiroClinic Screwdriver (Reference number:13118)
- SpiroClinic Pro Hardcase (Reference number:13503)
- SpiroClinic Pro Dock (Reference number:15000)

To purchase these accessories, contact your local distributors or, if there is no local distributor or you can not reach them, contact İnofab at https://www.inofab.health/.

7. Terms of Warranty

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

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

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

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

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

- Improper installation or operation of the device
- Use of the product for purposes other than those specified in this user manual
- Damage due to failure to follow instructions
- Damage due to unauthorised repair, modification or reconfiguration performed on the device

- Damage caused by fall, hit, lack of proper care or maintenance
- Damage caused by abnormal physical or electrical stress or defects of the main electric supply (battery cell) or of equipments
- If the serial number is altered, deleted, removed or rendered illegible

8. Electromagnetic Compatibility

Meeting the requirements for EMC (electromagnetic compatibility) and preventing the unsafe use of the device, medical devices including SpiroClinic Pro 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

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">SpiroClinic Pro 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.</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="2">The SpiroClinic Pro 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.</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><td>Emissions are not applicable because SpiroClinic Pro does not connect to mains supply but operates with AA batteries.</td></tr>
<tr><td>Voltage fluctuations / flicker emissions IEC 61000-3-3</td><td>Not applicable</td><td></td></tr>
</table>

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

Guidance and manufacturer's declaration – electromagnetic immunity			
SpiroClinic Pro 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	NA	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			
SpiroClinic Pro 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**
Conducted RF IEC	NA		Portable and mobile RF

61000-4-6 Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	communications equipment should be used no closer to any part of the SpiroClinic Pro devices including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. Recommend separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
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 SpiroClinic Pro devices are used exceeds the applicable RF compliance level above, the SpiroClinic Pro device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SpiroClinic Pro 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.

SpiroClinic Pro devices are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customers or the users of these SpiroClinic Pro devices can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SpiroClinic Pro 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 √P	**80 MHz - 800 MHz** d = 0.35 √P	**800 MHz - 2500 MHz** d = 0.7 √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.

9. Manufacturer Information

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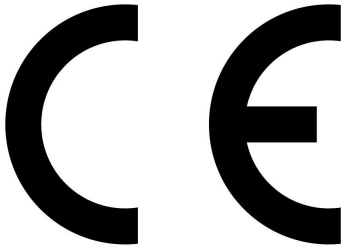

The SpiroClinic Pro Ultrasonic Spirometer and Accessories are CE certified (NB1984) products.