

CLARIO.

Instruction for Use

SpiroClinic

781300USEN | Version 03.00



Table of Contents

Table of Contents.....	2
1. Notes on Safety in this Instruction Manual	4
2. INTRODUCTION	4
2.1. Product Description.....	4
2.2. What’s in the box?.....	5
2.3. Indications for Use	6
2.3.1. Intended Purpose	6
2.3.2. Indications and Intended Use	6
2.3.3. Restrictions	6
2.3.4. Possible adverse effects.....	6
2.3.5. Contraindications.....	7
3. OPERATION.....	8
3.1. Operation Conditions	8
3.2. Storage / Transport Environment	8
3.3. Setting Up Your Device.....	9
3.3.1. Setting Up iSpiro Pro	9
3.3.2. Bacterial Viral Filter (BVF).....	10
3.3.3. Setting Up SpiroClinic Application	11
3.3.4. Setting Up iSpiro Pro Before Use	12
3.4. Device Indicators.....	14
3.5. How to perform a Lung function test.....	15
3.5.1. General Method Performing a Spirometry Test with SpiroClinic	15
3.5.2. Types of Breathing Maneuvers	18
4. MAINTENANCE	23
4.1. Performance and calibration check.....	23
4.2. Cleaning and disinfection procedure	24
4.2.1. Cleaning and disinfection agents.....	24
4.2.2. Cleaning and Disinfection of iSpiro pro unit and Cradle.....	25
4.2.3. Cleaning and Disinfection of SpiroWay Pro Reusable	27
4.3. Batteries	28
4.3.1. Instructions for battery replacement	28
4.4. Disposal of iSpiro Pro.....	30
4.5. Software Update	30
5. TROUBLESHOOTING	31
6. SIGNS AND SYMBOLS.....	33

7. TECHNICAL FEATURES 36

 7.1. Summarized technical data.....36

 7.2. Device Parameters37

8. SAFETY WARNINGS AND PRECAUTIONS 39

 8.1. Notes on Safety in this Instruction Manual39

 8.2. List of safety warnings and precautions..... 40

 8.3. Safety information regarding electromagnetic compatibility42

 8.4. IT Networks43

9. ORDERABLE ACCESSORIES 44

10. TERMS OF WARRANTY 44

11. ELECTROMAGNETIC COMPATIBILITY 45

12. BLUETOOTH WIRELESS COMMUNICATIONS 49

13. FCC / IC NOTICE 50

14. MANUFACTURER INFORMATION 52

781300_SpiroClinic_IFU_USEN_V03.00_2026-01-30

1. Notes on Safety in this Instruction Manual

Following the ANSI (American National Standards Institute) recommendations for safety notes, specific passages of this instruction manual are clearly marked as safety notes.

Degree of Danger	Injury to persons	Damages to property	Meaning of Indicator
	X		DANGER indicates an immediate hazardous situation, which, if not avoided, will result in serious injury or death. Limited to extremely dangerous situations.
	X		WARNING indicates a potential hazardous situation, which, if not avoided, may result in serious injury or death.
	X	(X)	Caution indicates a potentially hazardous situation, which, if not avoided, may result in minor or slight injury. Also used to indicate precarious procedures.

Additional safety symbols used in this user manual.

			General Warning Sign
			General mandatory action sign

2. INTRODUCTION

2.1. Product Description

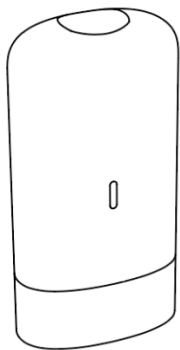
SpiroClinic is a portable spirometry system, which is operated by a healthcare professional, composed of iSpiro Pro ultrasonic spirometer and the companion

software application. The iSpiro Pro spirometer unit pairs (via Bluetooth) and operates with smart devices (IOS and Android) or computers (Windows) that runs SpiroClinic software application. The SpiroClinic measures and displays certain parameters of the 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. As the user exhales into the device, internal ultrasonic sensors detect the velocity of the expired air; the device converts this information into spirometric data and displays it via the SpiroClinic application. The iSpiro Pro is powered by standard 2 x AA Alkaline batteries and used in combination with the SpiroWay Pro Reusable airway.

2.2. What’s in the box?

Your SpiroClinic box contains:

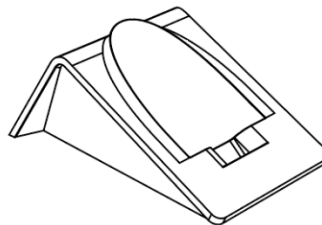
- iSpiro Pro (spirometer sensor unit) (a)
- SpiroWay Pro Reusable (b)
- Cradle (c)
- Quick-Start Guide
- AA Batteries
- Mini Screwdriver (d)



a



b



c



d



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.

2.3. Indications for Use

2.3.1. Intended Purpose

SpiroClinic is intended for basic lung function and spirometry testing.

2.3.2. Indications and Intended Use

SpiroClinic is intended to be used by adults and children over 5 years old in physician's offices and clinics to conduct basic lung function and spirometry testing.

2.3.3. Restrictions

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

The SpiroClinic must be used by a single user at any one time. If the iSpiro Pro will be used by a new user, it must be cleaned and disinfected according to the information given in this user manual before use.

The SpiroWay Pro Reusable must be cleaned and disinfected after each patient.

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.

2.3.4. Possible adverse effects

Spirometry tests can be physically demanding. The forced expiratory maneuver used in spirometry increases intrathoracic, intra-abdominal, 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. In rare cases, spirometry testing can lead to syncope, shortness of breath and dizziness due to extensive exhalation.

2.3.5. Contraindications

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
- Noncompensated 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 week

Due to increases in intrathoracic and intraabdominal 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

Spirometry should be discontinued if the patient experiences pain during the maneuver. Relative contraindications do not preclude spirometry but should be considered when ordering spirometry. The decision to conduct spirometry is to be determined by the ordering healthcare professional on the basis of their evaluation of the risks and benefits of spirometry for the particular patient. Potential contraindications should be included in the request form for spirometry.

3. OPERATION

Mode of Operation: There are no minimum or maximum limits to the period of device use ('on' time) or disuse ('off' time). The device will time-out and automatically switch off if it is not actively used for a period of time. Batteries of the device should be removed if it will not be used for more than a month.

3.1. Operation Conditions

The required operation conditions for the iSpiro Pro are:

- Ambient temperature: +15°C to +35°C
- Relative Humidity: 30% to 85%
- Pressure: 700 hPa to 1060 hPa

The iSpiro Pro 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.

3.2. Storage / Transport Environment

The required storage conditions for the iSpiro Pro are:

- Ambient temperature: -20°C to +50°C
- Relative Humidity: 15% to 95%

- Pressure: 600 hPa to 1200 hPa

The required transport conditions for the iSpiro Pro are:

- Ambient temperature: -20°C to +50°C
- Relative Humidity: 15% to 95%
- Pressure: 600 hPa to 1200 hPa

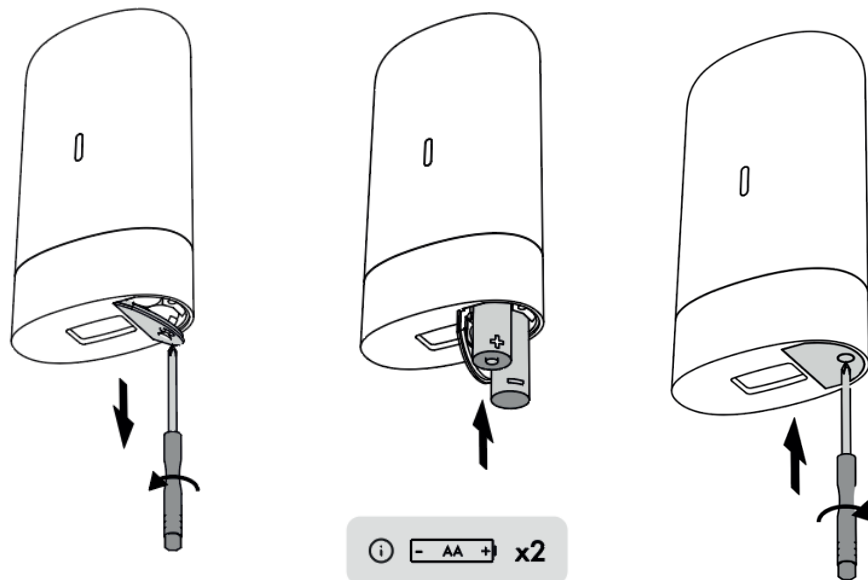
The iSpiro Pro should not be used in the presence of inflammable liquids or detergents, nor in the presence of inflammable anesthetic gases (oxygen or nitrogen).

3.3. Setting Up Your Device

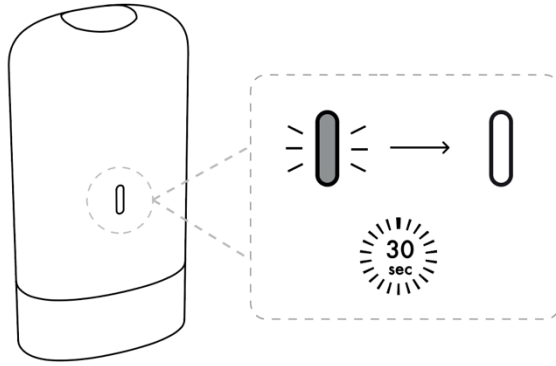
ASSISTANCE: If you need assistance setting up, using or maintaining your iSpiro Pro please contact Customer Care.

3.3.1. Setting Up iSpiro Pro

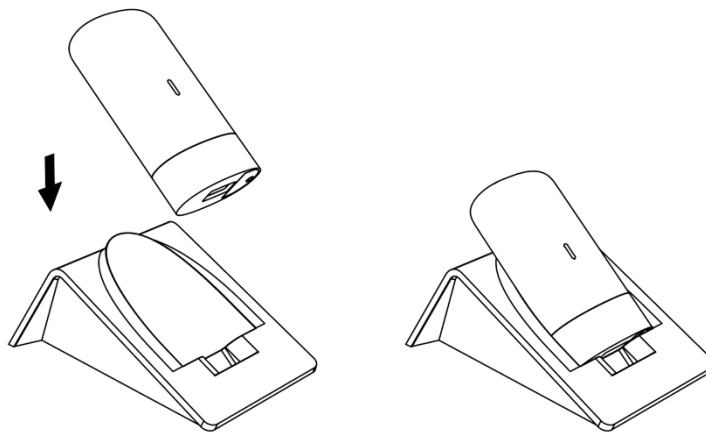
1. Unscrew and open the battery cap, insert the AA batteries with correct orientations. After the installation of the batteries, close and screw the battery cap.



2. LED indicator will turn on in white color and then turn off again after 30 seconds.



3. Keep the iSpiro Pro device on its cradle while it is not in use.



3.3.2. Bacterial Viral Filter (BVF)

iSpiro Pro and Spiroway Pro Reusable are intended to be used with a BVF.



Do not use SpiroClinic without a 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 Reusable. 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:

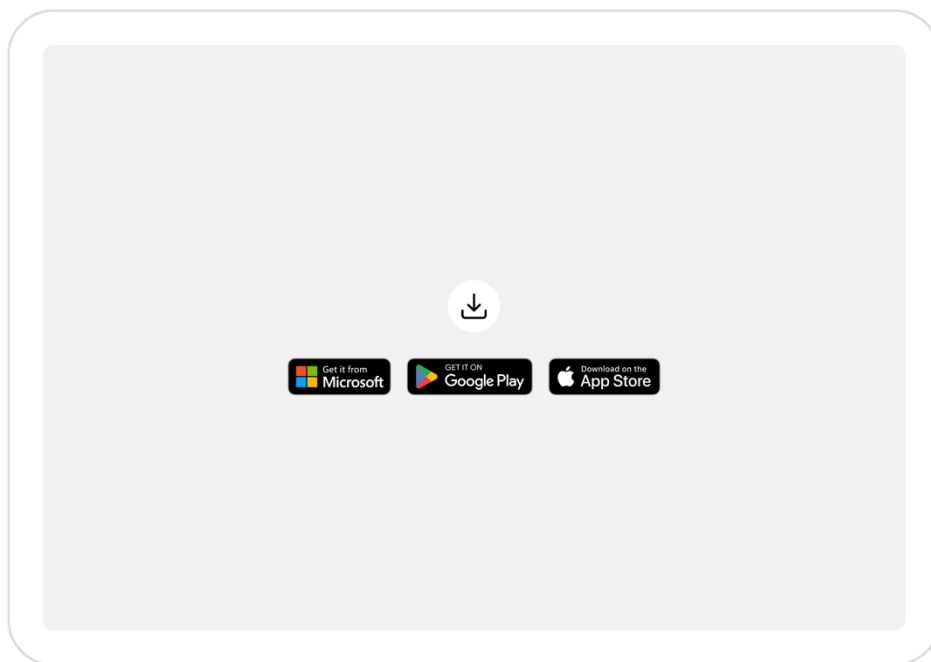
Resistance: 0-80 kPa*(s/l)

Inner Diameter: 30mm

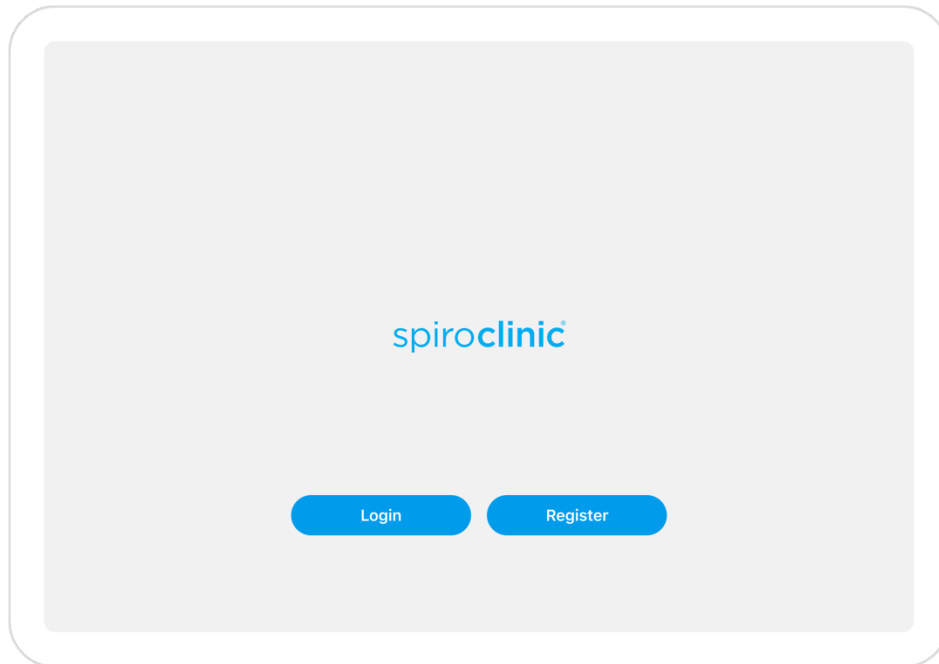
Recommended BVF: MicroGard II by Vyair Medical Ref: V-892380

3.3.3. Setting Up SpiroClinic Application

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



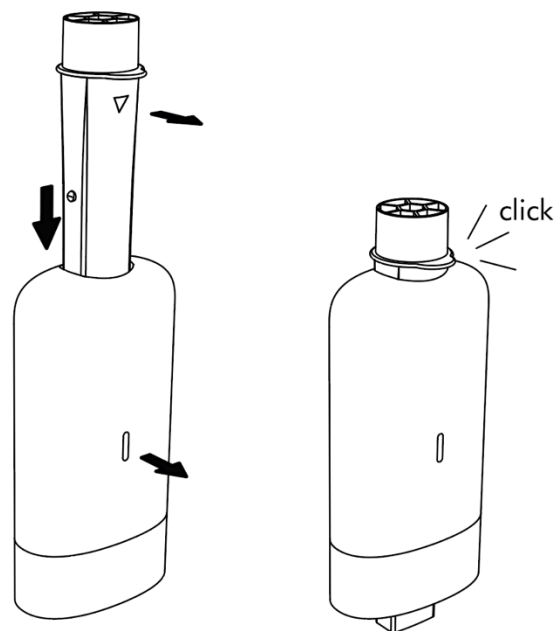
Follow the steps given in the app to create a user account or login to an existing account.



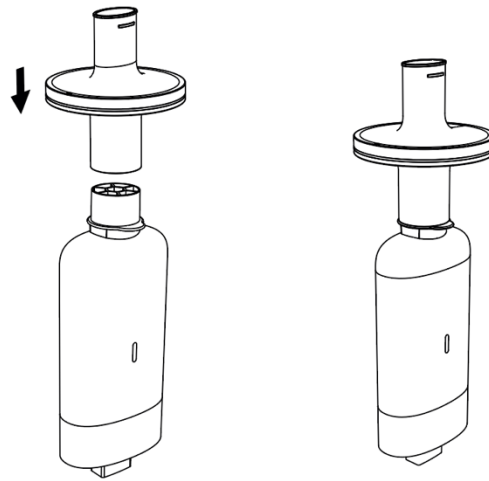
Enable Bluetooth® on the smart device or PC and pair it with the SpiroClinic Pro by following the instructions on the app.

3.3.4. Setting Up iSpiro Pro Before Use

4. To use the device, first insert the Spiroway Pro Reusable. Pay attention to the orientation of the Spiroway Pro Reusable.



5. Attach the Bacterial Viral Filter to Spiroway Pro Reusable.



Risk of Cross-Contamination

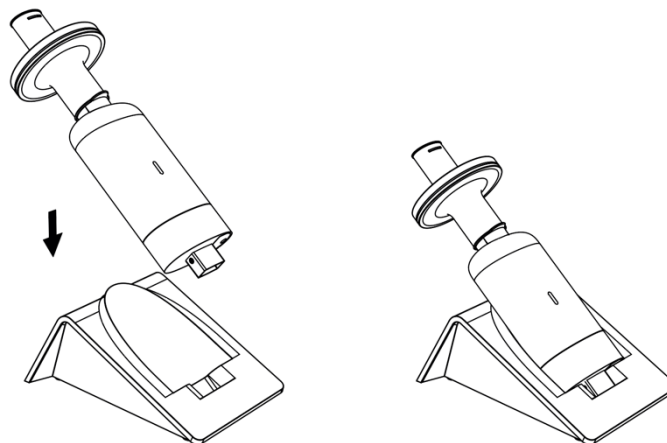
Do not use iSpiro Pro device without a Bacterial Viral Filter (BVF).

Do not share the BVF between users.

Risk of Inaccurate test

Make sure the BVF is attached all the way without any air leaks

6. Place the device on its cradle for the zero-flow calculation. After the zero-flow calculation is completed, the device can be used.



7. Follow the directions on the SpiroClinic Application.

3.4. Device Indicators

There is 1 LED light strip located on the front of the device. The LED light may be turned on or flashing in various colors in various patterns. The LED light indicates the status of the device. Please see the following information for guidance on LED light indications.

Table 2: Device Led Indicators	
LED Display	Indication/s
The LED is Off	The device is in sleep
The LED is switched on in white, stays open for 25 seconds, and then fades out completely in 1 second.	The device is Powered up
The LED lights up in blue and stays on until another LED animation is played by the firmware.	The device is connected.
The LED fades in and out in cyan in 1.4 seconds period continuously.	Zero-Flow calculation is performed.
LED turns and remains green.	Test started.
I. The LED lights up in red and stays on until another LED animation is played by the firmware.	Measurement Error.
The LED fades in and out in white in 1.4 seconds period continuously.	Firmware update.
The LED lights up in red for 3 seconds, then slowly fade out completely in 10 seconds.	Low Battery.
I. First, the LED lights up in magenta for 300 ms. II. Then, the LED is turned off for 300 ms. This pattern is repeated continuously	The device needs to be placed on the Cradle.

The LED lights up in blue, then slowly fades out completely in 1 second.

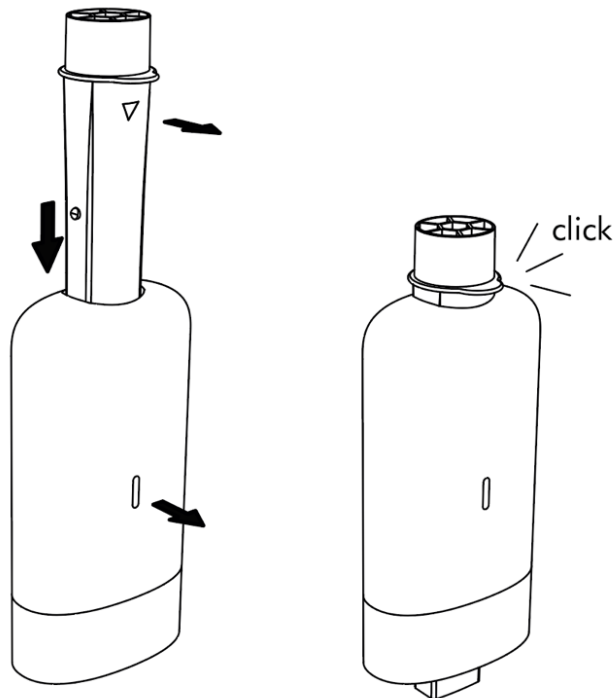
BLE Disconnected.

3.5. How to perform a Lung function test

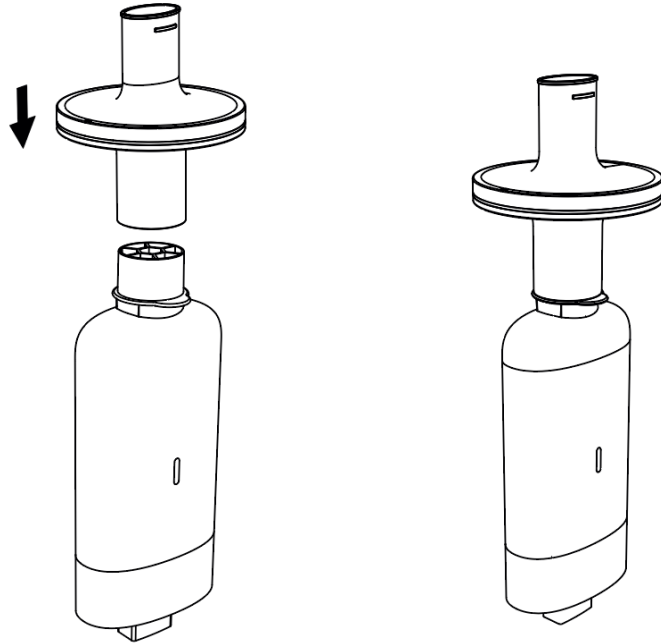
Lung function tests should be conducted according to ATS standards (see Graham B, Steenbruggen I, Miller M, et al. Standardization of spirometry 2019 update. An official American Thoracic Society and European Respiratory Society technical statement. Am J Respir Crit Care Med. 2019; 200:e70–e88).

3.5.1. General Method Performing a Spirometry Test with SpiroClinic

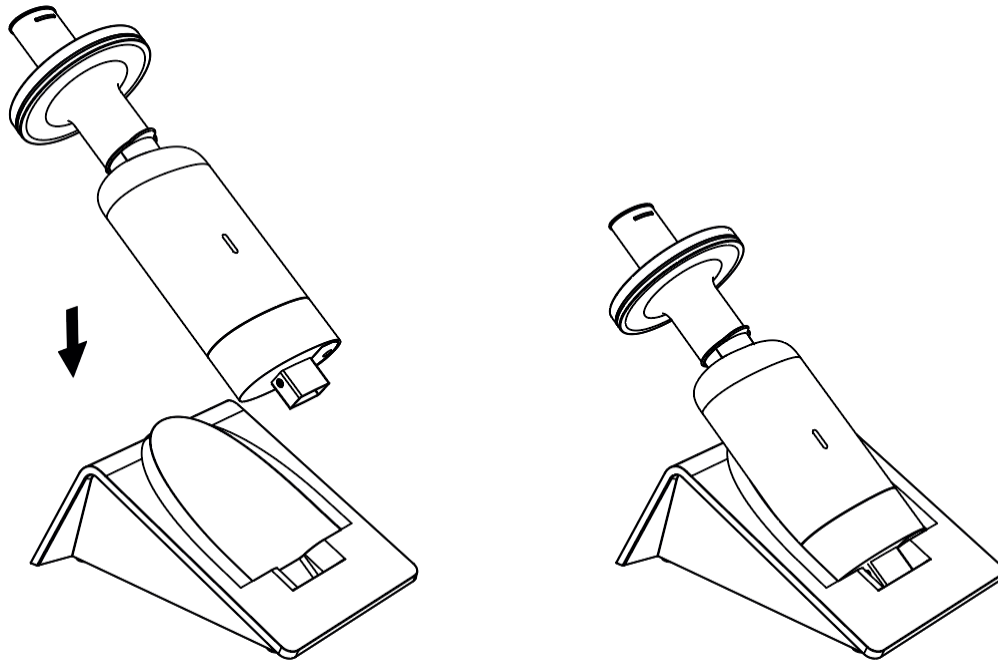
1. Make sure the device has batteries and power.
2. Insert the SpiroWay Pro Reusable into the device in the correct orientation. A ‘click’ will be heard when the SpiroWay Pro Reusable is inserted correctly all the way into the handpiece.



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



4. Place the iSpiro Pro on Cradle.



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.

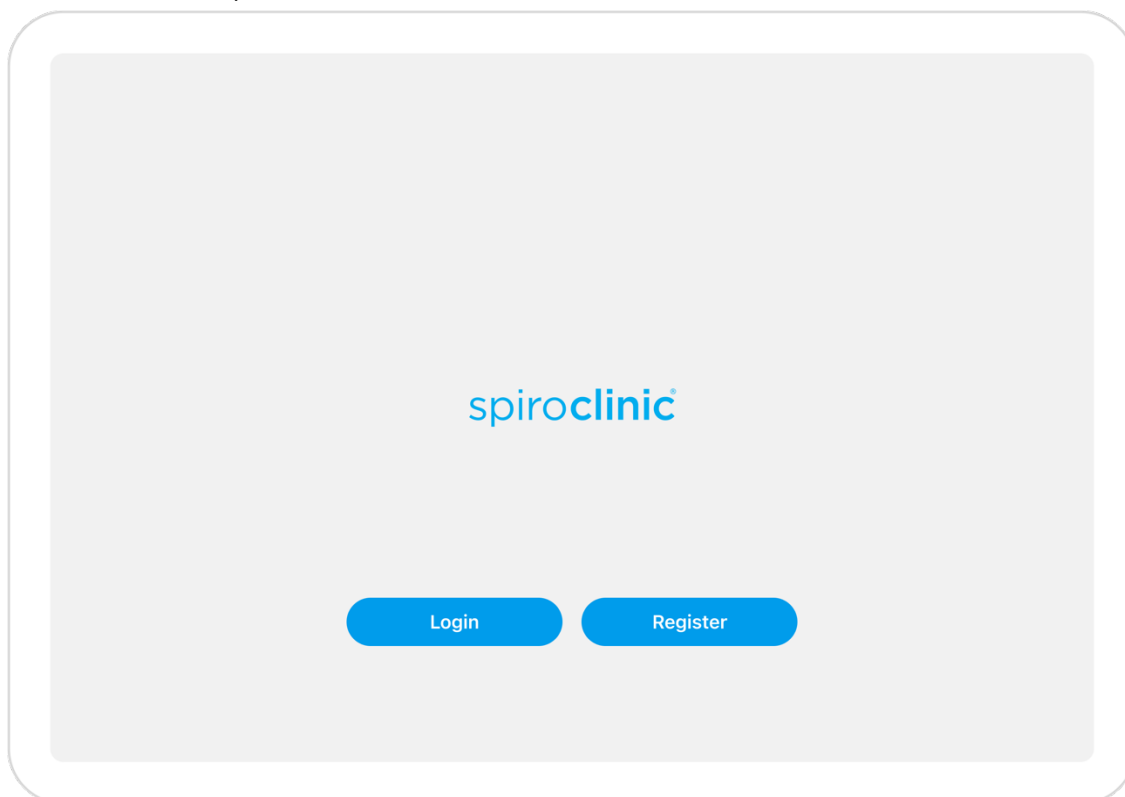


Entering the correct information is critical for calculating expected values.

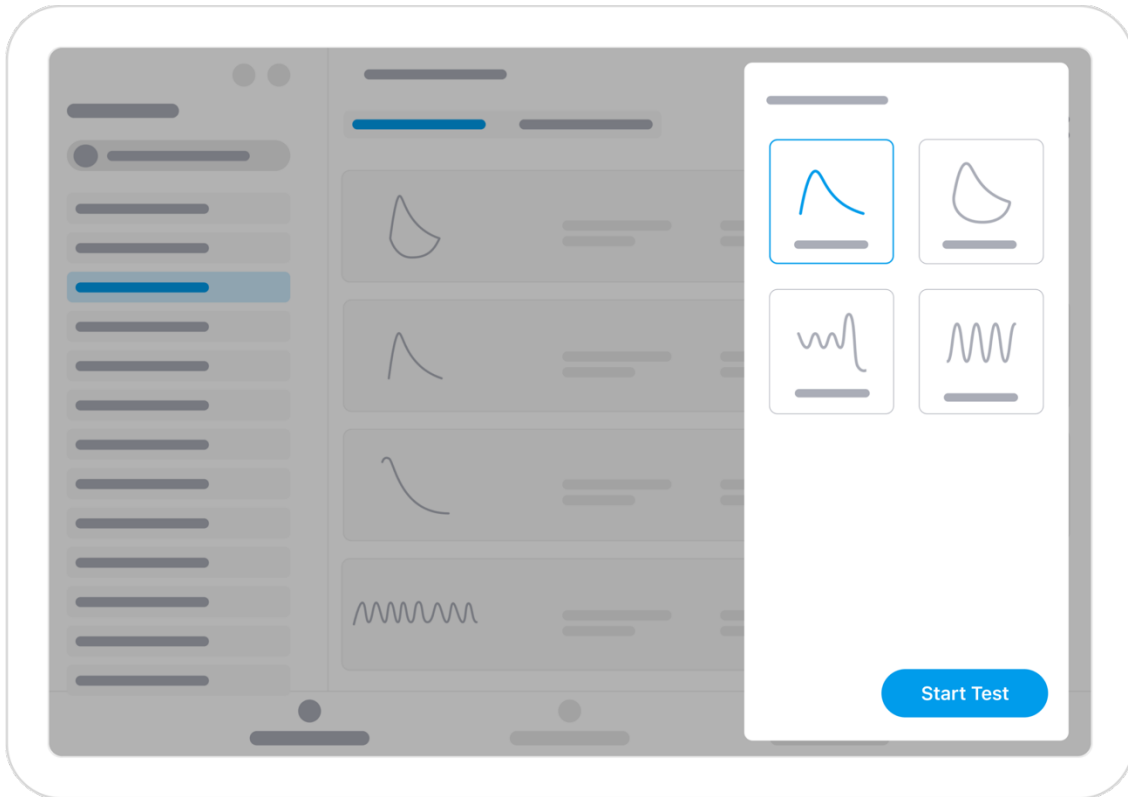


Correct patient information needs to be entered for each individual patient. Performing tests with someone else's information may result in faulty results.

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 Cradle. 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.



Not sealing the tightly around the mouthpiece of the BVF may result in faulty results.

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.
10. After the test, Spiroway Pro Reusable needs to be removed by the protrusion at the side without touching the rest of the Spiroway Pro Reusable.

3.5.2. 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. Enter required ambient conditions like temperature and relative humidity or approve the conditions provided by an external sensor, and then, adjust zero flow level for the device.



Make sure the ambient condition values are correct as the measurement may be significantly affected by a wrong value.

4. Patients 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 forceful expiration, and the test begins with a direct forceful 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.



Make sure the patient keeps steadily holding the device the entire time.



Not sealing the tightly around the mouthpiece of the BVF may result in faulty results.

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.

Full Loop Test Breathing Maneuver:

1. Ensure that the device is connected. Select the Full Loop test mode and the test screen will appear.
2. Enter the required ambient conditions like temperature and relative humidity or approve the conditions provided by an external sensor, and then, adjust zero flow level for the device. To get ready, the patient should inhale and exhale normally a couple of times.



Make sure the ambient condition values are correct as the measurement may be significantly affected by a wrong value.

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. Patients 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 forceful expiration, and the test begins with a direct forceful 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.



Make sure the patient keeps steadily holding the device the entire time.



Not sealing the tightly around the mouthpiece of the BVF may result in faulty results.

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 at the beginning of the test, in Tidal FVL test mode. In FVL test mode, the data starts to be calculated with any exhalation 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 like temperature and relative humidity or approve the conditions provided by an external sensor, and then, adjust zero flow level for the device.



Make sure the ambient condition values are correct as the measurement may be significantly affected by a wrong value.

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.



Make sure the patient keeps steadily holding the device the entire time.



Not sealing the tightly around the mouthpiece of the BVF may result in faulty results.

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 by like temperature and relative humidity or approve the conditions provided by an external sensor, and then, adjust zero flow level for the device.



Make sure the ambient condition values are correct as the measurement may be significantly affected by a wrong value.

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 fully 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.

4. MAINTENANCE

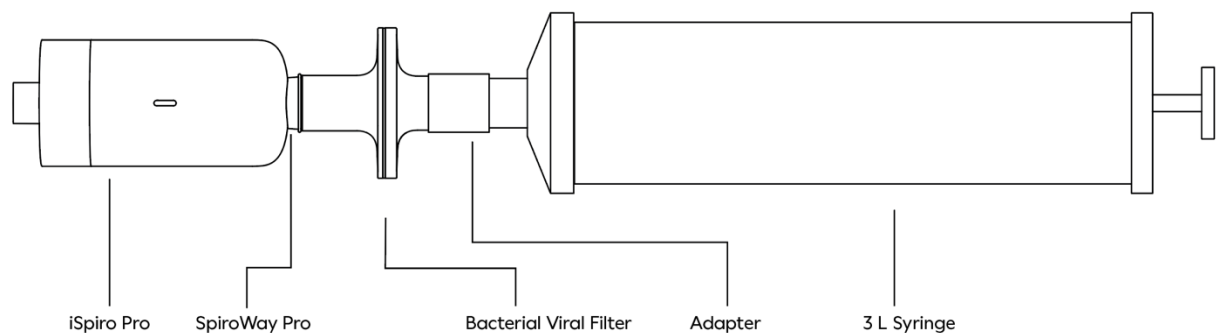
Handle the iSpiro Pro and SpiroWay Pro Reusable with care. Do not use the device or its accessories if they are visibly damaged, particularly if there is damage to the filters on the Spiroway Pro Reusable or deformation of the part itself. Store the iSpiro Pro and SpiroWay Pro Reusable in dust-, dirt-, and moisture-free conditions. Keep away from pets, pests and children. Before each use, always check that the device is free from contaminants and does not have any visible damage. If there are contaminants on the base (on or around the battery compartment) of the iSpiro Pro, do not use the device further and replace with a new device.

4.1. Performance and calibration check

The iSpiro Pro is provided to the user, factory-calibrated and does not require routine re-calibration. If you suspect performance errors in the iSpiro Pro, cease use of the device. Devices with confirmed performance errors should be returned to Clario.

It is advised by the American Thoracic Society (ATS) and European Respiratory Society (ERS) that periodic calibration-checks of spirometers are performed. Calibration check steps are as follows:

1. Check that the following items are available for setup:
 - a. A standard 3L calibration syringe
 - b. A bacterial viral filter (BVF) that is used with the device
 - c. 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.
3. Connect the device to the syringe as shown in the diagram.



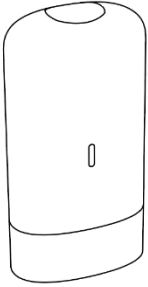
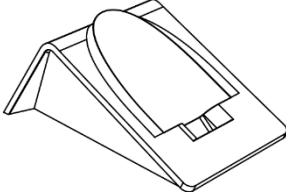

4. To perform the Calibration-Check, select Calibration-Check in the settings section of the SpiroClinic App.
5. Then choose the Calibration-Check type as Multi-Flow Calibration Check or Linearity Calibration Check and follow the instructions from SpiroClinic App.

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.

4.2. Cleaning and disinfection procedure

4.2.1. Cleaning and disinfection agents

The following cleaning/disinfectant agents may be used to clean and disinfect this device:

	<p>iSpiro Pro Unit</p>	<p>mikrozyd® sensitive wipes (Schülke & Mayr GmbH)</p>
	<p>Cradle Unit</p>	<p>mikrozyd® sensitive wipes (Schülke & Mayr GmbH)</p>
	<p>Spiroway Pro Reusable</p>	<p>For pre-cleaning Cidezyme Enzymatic Detergent (Advanced Sterilized Products)</p> <p>For disinfection Cidex OPA (Advanced Sterilized Products)</p>



Risk of Cross-Contamination

The SpiroWay Pro Reusable must not be shared between users without cleaning and disinfection.

The lifetime of the SpiroWay Pro Reusable is 1 month from the first use.



Thorough cleaning and disinfection of the iSpiro Pro device must be performed prior to the dedication of the iSpiro Pro device to a new user. If there is contamination on the base surface (on or around the battery compartment) of the iSpiro Pro device, the device must not be used and must be replaced. A new SpiroWay Pro Reusable must be used by the new user.

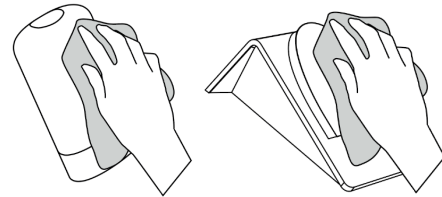
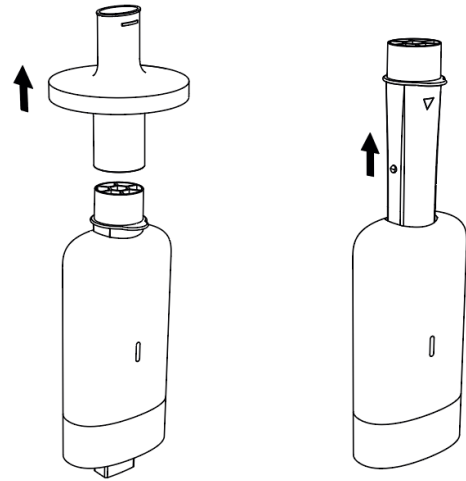
4.2.2. Cleaning and Disinfection of iSpiro pro unit and Cradle

You should clean the iSpiro Pro body after each use and whenever the device is visibly contaminated.

You **MUST** perform the cleaning step before performing the disinfection step. Cleaning will prevent the physical buildup of contaminants on device surfaces and remove larger debris. Disinfection kills and destroys pathogens such as bacteria, viruses, or other microorganisms which might still be present on device surfaces after initial cleaning.

Pre-Cleaning of SpiroClinic Main unit and Cradle:

1. Detach and dispose of any Bacterial and Viral Filter (BVF) connected to the SpiroWay Pro Reusable and then remove the SpiroWay Pro Reusable from the iSpiro Pro handpiece.
2. Separate the SpiroWay Pro Reusable for cleaning or dispose if the recommended lifetime has ended.
3. Remove all visible dirt/debris with a lint-free cloth. If necessary, wipe down the surface with a damp cloth and a suitable cleaning agent; e.g. Mild soap (diluted), Sodium hypochlorite bleach (10%) or Hydrogen Peroxide (1,5%).



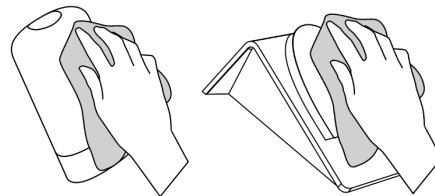
In case of persistent contamination use a cleaning brush to thoroughly remove all visible debris from surfaces, grooves, ridges and closures.



Prevent any excess liquids contained within the wipes from entering the components of the iSpiro[®] Pro. Never immerse the product in water or any other liquid solution.

Cleaning and disinfection of SpiroClinic Main unit and Cradle with Mikrozyd[®]:

1. Cleaning is performed with the first wipe. Pay attention that all surfaces are wiped, and that any visible surface contaminants are completely removed before proceeding to the disinfection step. In case visible surface contaminants remain,



another pre-cleaning step as described above might be necessary.



Prevent any excess liquids contained within the wipes from entering the components of the iSpiro® Pro. Never immerse the product in water or any other liquid solution.

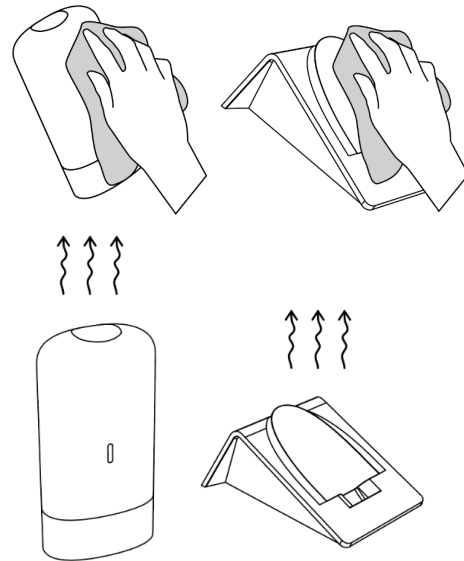


Cleaning and disinfection are separate steps. The disinfection process will be performed after the cleaning process as shown in the following step.



Ensure that all visible dirt is removed before disinfection.

2. For disinfection, thoroughly wipe all surfaces again with a fresh wipe, following the manufacturer's instructions for wiping technique and duration. Allow the active ingredient solution taking effect, ensure complete wetting of the area to be disinfected.



4.2.3. Cleaning and Disinfection of SpiroWay Pro Reusable

Cleaning and disinfection of SpiroWay Pro with Cidezyme and Cidex OPA:

1. **For pre-cleaning** of the part, follow the manufacturer's instructions on how to prepare the Cidezyme Enzymatic Detergent bath solution and soak and rinse the part. Rough dry the part before proceeding to the disinfection step.



Cleaning and disinfection are separate steps. The disinfection process is performed after the cleaning process.

2. **For disinfection**, follow the manufacturer's instructions for preparing the Cidex OPA solution and for soaking, rinsing and drying the pre-cleaned part.



Do not insert the SpiroWay Pro Reusable into your iSpiro Pro device until it is completely dry

4.3. Batteries

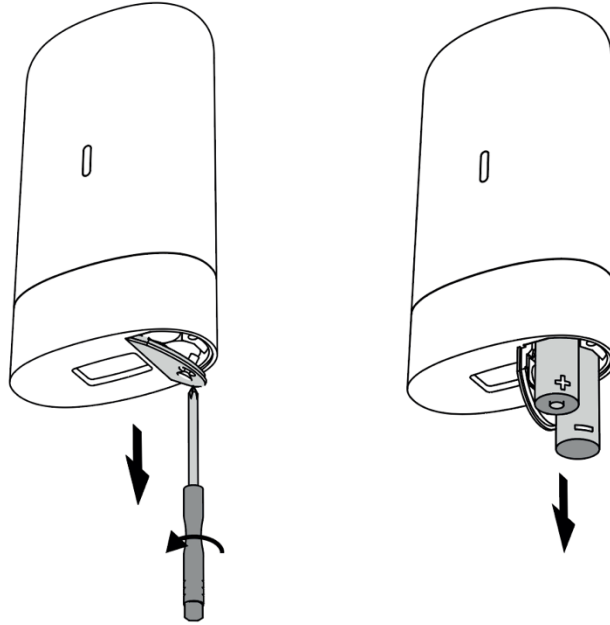
The iSpiro Pro device operates with 1.5V AA Alkaline batteries. The battery life of the iSpiro Pro is approximately 6–8 months, assuming 10 uses per day including calibration check. The battery charge level is continuously monitored by the device. The device will not turn on if the battery charge level is low and will make a beeping sound when batteries run out to notify you.



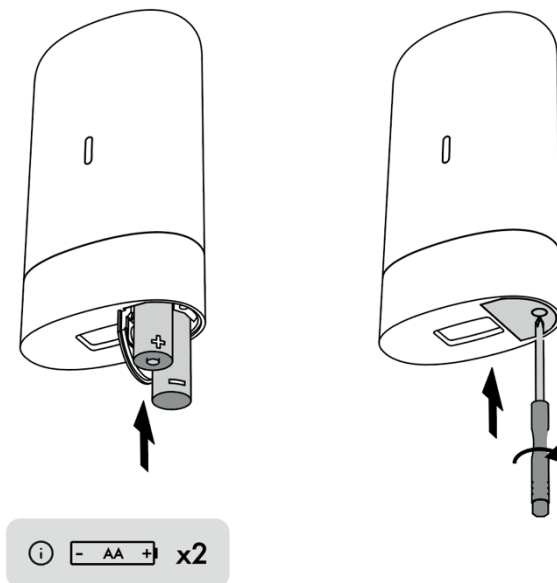
The batteries of the device should be removed if the device is not going to be used for more than a month.

4.3.1. Instructions for battery replacement

1. Unscrew and open the battery cap and remove the batteries.



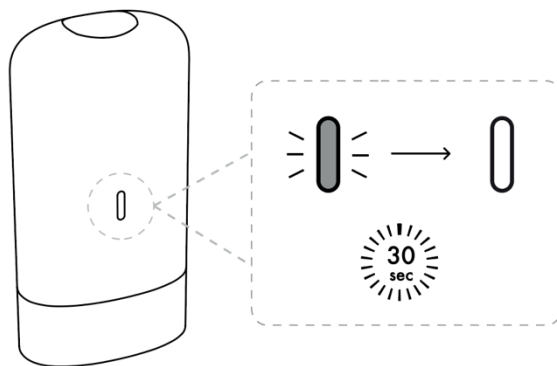
2. Insert the batteries considering the correct orientation. See the plus and minus signs inside the battery compartment. After the insertion of the batteries close the battery cap and tighten the screw.



CAUTION

Foreign conductive objects in the battery compartment may cause short circuits.

3. With the closure of the battery cap the LED indicator will turn on in white color and then turn off again after 30 seconds.



4.4. Disposal of iSpiro 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.

4.5. Software Update

Please make sure you are always using the up-to-date mobile application. To check and update your application;

- please go to the relevant app store in your smart device or PC and update if necessary.

You will be prompted for a firmware update by the application when needed. To update the firmware of your iSpiro Pro;

- Do not turn off your device and application,
- Keep iSpiro Pro close to your smart device or PC,
- Press update. The process can last several minutes.

5. TROUBLESHOOTING

Problem	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
The device cannot connect to a smart device via Bluetooth®	The smart device is out of range	Bring your smart device closer to the iSpiro Pro 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.
Test results are inconsistent	SpiroWay pro Reusable is dirty	Clean SpiroWay® Pro Reusable to ensure that the lumen is not obstructed or replace with a new Spiroway Pro Reusable
	SpiroWay pro Reusable is damaged	Replace SpiroWay® Pro Reusable
	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 set up zero flow level adjustment	The device is not on Cradle	Make sure the device is on Cradle
	Damaged or faulty SpiroWay Pro Reusable	Replace the SpiroWay Pro Reusable, contact the manufacturer.
	Faulty Cradle	Contact manufacturer.
The test does not start	Multiple possible causes	Quit test and start a new test
		Quit the application and start a new test

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	Bluetooth® connection disrupted	Reconnect the device and proceed with a new test
Test quality grade always low	Not performing test correctly	Refer to the section “ 2.5. How to perform a Lung function test ” in this Instructions for use.
Measurement error screen showed up	Flow limit exceeded	This device is intended to measure 0-14 L/s.
	SpiroWay® Pro is dirty	Clean SpiroWay® Pro to ensure that the lumen is not obstructed or replace SpiroWay® Pro
	SpiroWay® Pro is damaged	Replace SpiroWay® Pro
	Device malfunction	Contact manufacturer
Device error Indicator showed up	SpiroWay Pro Reusable is installed incorrectly	Refer to the user manual for proper installation of SpiroWay Pro Reusable
	There is a foreign object between the sensors.	Check iSpiro Pro device lumen and clean if necessary
	SpiroWay Pro Reusable is dirty	Clean SpiroWay Pro Reusable to ensure that the lumen is not obstructed or replace with a new Spiroway Pro Reusable
	SpiroWay Pro Reusable is damaged	Replace SpiroWay Pro Reusable
No LED indication when placing the batteries in the handpiece	Power is not completely emptied from the hardware	Wait 1 minute between removing old batteries and inserting new batteries.

For any other technical queries please call Clario’s Customer Care.

6. SIGNS AND SYMBOLS

The following type plate is provided on the device:


UDI  2025-01-01
 (01)04057155000863
 (11)250101
 (21)S401000001 **SN**

iSpiro Pro **MD** **R Only**







 0123


eResearchTechnology GmbH
 Sieboldstrasse 3 D-97230 Estenfeld

FCC ID : 2AAUFISPP01
 IC : 11335A-ISPP01  **R** 203-JN1425

The following labeling designs are provided with the Spiroway Pro Reusable Packaging:

SpiroWay Pro®
Reusable
Single-Pack

 **eResearchTechnology GmbH**
Sieboldstrasse 3 D-97230 Estenfeld

MD **R Only**   

REF 892225  0123 

UDI  (01)04057155000979
(10)892225240131 **LOT**

SpiroWay Pro®
Reusable
10-Pack


 **eResearchTechnology GmbH**
Sieboldstrasse 3 D-97230 Estenfeld













MD **R Only**   








REF 892226  0123 





UDI  (01)04057155000986
(10)892226240131 **LOT**

The following signs and symbols provided for the safe use and storage of your iSpiro® Pro

SYMBOL	EXPLANATORY TEXT
	Indicates the medical device manufacturer

	Date when the medical device was manufactured
	Manufacturer's catalog/reference number for the device
	Manufacturer's serial number
	Manufacturer's batch/lot code
	Device that needs protection from light sources
	Device that needs protection from moisture – Keep dry, keep away from rain
	Indicates the temperature limits to which the medical device can be safely exposed
	Indicates the range of humidity at which the medical device can be safely exposed
	Indicates acceptable upper and lower limits of atmospheric pressure for transport and storage.
	Device that may be used multiple times (multiple procedures) on a single patient
	Attention!
	Applied part of Type BF

	Instruction manual/booklet must be read
	Consult instructions for use or consult electronic instructions for use
	Possible source of interference
	On battery powered equipment
	Packaging is recyclable.
	Device should not be used if the package has been damaged or opened and user should consult the instructions for use for additional information
	Separate collection for waste of electrical and electronic equipment. Do not dispose of battery in municipal waste.
IP20	IP20: N1=2, Protected against solid foreign objects of 12,5 mm Ø and greater; N2=2, - No protection against ingress of water.
Rx Only	CAUTION: FEDERAL U.S. LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
CE 0123	CE sign with code number of the Notified Body. The certified quality management system of eResearchTechnology GmbH corresponds to the international standard of ISO 13485.
FCC	Meets FCC requirements per 47 CFR Part 15 Sensor unit FCC ID: 2AAUFISPP01
IC	ICC Identification Number Sensor Unit IC: 11335A-ISPP01

	Presents hazards in all MR environments.
	Giteki identification number Sensor Unit Giteki ID: 203-JN1425
	Medical Device
	Unique Device Identifier

7. TECHNICAL FEATURES

7.1. Summarized technical data

Flow / Volume Measurement Method	Ultrasonic pulse transit-time measurement
Power Supply	2 x 1.5V AA Alkaline or rechargeable batteries
Dimensions	150 x 77.6 x 42 mm
Weight (With batteries)	239 g
Weight (Without batteries)	192 g
Flow range	0 - 14 L/s
Maximum volume measured	10 L
Volume accuracy (Average)	± 2.50 % or 0.05 L (whichever is greater)
Flow Accuracy (Average)	± 10.00 % or 170 mL/s
Highest Expiratory Impedance*	Less than 150 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 Annex B with MicroGard II BVF*

7.2. Device Parameters

The iSpiro Pro records 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 — synonymous with MEF ₂₅	L/s




FEF_{25-75}	Forced Expiratory Flow from 25% to 75% of vital capacity — synonymous with MMEF	L/s
MET_{25-75}	Mid-Expiratory Time — synonymous with FET_{25-75}	s
$FEV_{0.75}/FEV_6$	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


8. SAFETY WARNINGS AND PRECAUTIONS

8.1. Notes on Safety in this Instruction Manual

Following the ANSI (American National Standards Institute) recommendations for safety notes, specific passages of this instruction manual are clearly marked as safety notes.

Degree of Danger	Injury to persons	Damages to property	Meaning of Indicator
	X		DANGER indicates an immediate hazardous situation, which, if not avoided, will result in serious injury or death. Limited to extremely dangerous situations.
	X		WARNING indicates a potential hazardous situation, which, if not avoided, may result in serious injury or death.
	X	(X)	Caution indicates a potentially hazardous situation, which, if not avoided, may result in minor or slight injury. Also used to indicate precarious procedures.

Additional safety symbols used in this user manual.

			General Warning Sign
			General mandatory action sign

8.2. List of safety warnings and precautions



Special warning should be given by handlers of the device to elderly, pediatric or differently-abled users prior to use of the device.



Do not use this device for any other purpose than its intended use to avoid potential dangers or harm to users. This device is not recommended for children under the age of 5.



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



Take care when inserting the Spiroway Pro Reusable into the device to avoid physical injury and/or damage to the device.



Do not use this device or its accessories if any parts are damaged, detached or blocked to avoid risk of choking or asphyxiation during use.



In case of adverse events related to device use, immediately cease further use to avoid harm or damage and notify relevant local authorities and the manufacturer.



Maximal inflation is unnatural; you may not have achieved it before, and it may seem somewhat uncomfortable.



Regardless of the data presented on this device, cease testing if you feel unwell or have respiratory illness symptoms and contact your healthcare provider immediately.



Medications and treatments based on device results must be directed only by a qualified doctor.



For your safety, if there is an excessive decrease in your FEV₁ 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 or sensations of dizziness during testing, cease device use and rest and inform your healthcare provider.



Do not walk or run whilst performing a lung function test with the SpiroClinic for your safety and to avoid result inaccuracies.



CAUTION

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 iSpiro Pro or SpiroWay Pro Reusable with any other users, including family members, to prevent the transmission of infectious material. The device must be cleaned and disinfected, a new Spiroway Pro Reusable must be used, and a new account must be created for a new user of the device.



Remove all batteries when the device will not be used for prolonged periods of time to prevent damage to the device through battery leakage or oxidation.



To protect the environment, dispose of the product only through local EPA or WEEE collection facilities.



CAUTION

Check the airway for foreign materials before each use to prevent risk of choking and to avoid measurement inaccuracies.



CAUTION

Coughing or spitting into the device may cause incorrect readings.



CAUTION

Keep the device dry. The limited Ingress Protection (IP20) rating of the iSpiro Pro device case will not prevent damage from water leaking into the case and damaging electronics.



CAUTION

Do not use accessories not described in this user manual to prevent damage to the device, measurement inaccuracies or risk of affecting electromagnetic performance.



CAUTION

Do not touch the filters on the Spiroway Pro Reusable and do not use if filters have been damaged. Damage to filters may result in measurement inaccuracies.



CAUTION

Device accuracy can be affected by extremes of temperature, humidity and altitude. Use, store and transport your device only as specified in this user manual.



CAUTION

The device may give inaccurate readings if operated in the presence of strong electromagnetic sources, such as electro-surgical equipment, magnetic resonance imaging devices or computed tomography (CT) equipment.



CAUTION

Do not use the device in the presence of direct air currents (e.g. wind), sources of heat or cold, direct sun rays, or other sources

of light or energy (such as heaters or radiators), dust, sand, or any other chemical substances as these conditions can affect the performance or the expected life of the iSpiro Pro device.

 **CAUTION**

If your device is damaged or malfunctioning, contact the manufacturer or distributor if purchased from a reseller. Unauthorized repairs will terminate the product warranty and may result in a faulty device.



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

 **CAUTION**

Do not share your SpiroClinic account information with unauthorized parties. This will help protect your personal data.



iSpiro Pro devices may be affected by electromagnetic interference. Please read EMC information and precautions provided in this user manual before use.



Do not use iSpiro Pro devices in the presence of external portable and mobile radio frequency (RF) communications equipment as this may affect data transmission.



Keep your iSpiro Pro device away from strong sources of magnetic and RF fields such as large electric motors, amateur radio transmitters, radar, anti-theft systems, stereo speakers, cell phones, and radio frequency identification (RFID). Television and radio transmitters could cause interference if the device is used close to them.



Federal Law (USA) restricts this device from being sold by or on the order of a physician.



Keep your device away from direct ionizing radiation sources



Keep your device away from direct non-ionizing radiation sources

8.3. Safety information regarding electromagnetic compatibility

The iSpiro Pro should not be operated at the same time as electrical devices with a high RF power output (e.g. HF surgical equipment) during intended use.

The iSpiro Pro may be affected by portable wireless communications equipment such as antennas, wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies, etc. A minimum distance of 30 cm (12 inches) should be kept between these and any part of the iSpiro Pro.

The use of accessories or components (e.g. transducers) other than those specified by the manufacturer may result in increased emissions or decreased immunity of the iSpiro Pro. The iSpiro Pro should not be used adjacent to or stacked with other equipment. If this is unavoidable the configuration in which it is used should be monitored closely to ensure that the device continues to function normally.

If there are electromagnetic fields from other electrical devices nearby whilst the iSpiro Pro is being used, the device may fail to respond or not function as normal. To restart the iSpiro Pro, remove the batteries and wait for 30 seconds, and then reinstall the batteries. If the problem persists, move the device away from sources of electromagnetic interference as described in the EMC compatibility section of this user manual.

8.4. IT Networks

Connection of the mobile application to an IT network that includes other equipment could result in previously unidentified risks to patients, operators, or third parties.

Subsequent changes to the IT network could introduce new risks and require additional analysis.

Changes to the IT network include:

- changes in the IT network configuration,
- connection of additional items to the IT network,
- disconnecting items from the IT network,
- update of equipment connected to the IT network, and
- upgrade of equipment connected to the IT network.

It is the user's responsibility to identify, analyze, evaluate, and control these risks. IEC 80001-1:2021 provides guidance to address these risks.

9. ORDERABLE ACCESSORIES

SpiroWay Pro Reusable Single-Pack (Ref number: 892215)

SpiroWay Pro Reusable 10-Pack (Ref number: 892216)

The SpiroWay Pro Reusable is the applied part of the iSpiro Pro device. To purchase these accessories please contact your local distributors or Clario.

10. TERMS OF WARRANTY

The iSpiro Pro hardware is guaranteed against manufacturing defects 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 iSpiro Pro including accessories is 5 years from purchase. There are no user serviceable parts in the iSpiro Pro product.

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

In any case, the entire liability of eResearchTechnology GmbH under the provision of this agreement shall be limited to the amount paid by the customer for the product.



No modification of this equipment is allowed.

11. ELECTROMAGNETIC COMPATIBILITY

Meeting the requirements for EMC (electromagnetic compatibility) and preventing the unsafe use of the device, medical devices including the iSpiro Pro manufactured by Clario conform to the EN60601-1-2 standard which defines the levels of immunity to electromagnetic interference as well as maximum levels of electromagnetic emissions for medical devices. For details, please see the following tables:

Table 1: Emission table for IEC 60601-1-2


Guidance and manufacturer's declaration – electromagnetic emissions		
ISpiro Pro battery-operated spirometer devices are intended for use in the electromagnetic environments specified below. Users of these devices should assure that they are used in such environments.		
Emission Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	ISpiro Pro uses RF energy for its internal function. Its Radio Bluetooth, BLE 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.
RF emissions CISPR 11	Class B	The iSpiro Pro devices are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	

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

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

Guidance and manufacturer's declaration – electromagnetic immunity				
iSpiro Pro battery-operated spirometer devices are intended for use in the electromagnetic environment specified below. Users of these devices should assure that they are used in such an environment.				
Immunity Standard	Test	IEC 60601 test level	Compliance level	Recommended separation distance
Electrostatic discharge (ESD) IEC 61000-4-2		±8 kV contact ±2, ±4, ±8 kV, ±15 kV Air	±8 kV contact ±2, ±4, ±8 kV, ±15 kV Air	The floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
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			
iSpiro Pro battery-operated spirometer devices are intended for use in the electromagnetic environment specified below. Users of these devices should assure that they are used in such an environment.			
Immunity test standard	IEC 60601 test level	Compliance level	Recommended separation distance
Radiated RF IEC 61000-4-3	385 MHz 27 V/m	27 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the iSpiro Pro devices including
	450 MHz	28 V/m	

	28 V/m		cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter.
	710, 745, 780 MHz 9 V/m	9 V/m	Recommend separation distance
	810, 870, 930, 1720, 1845, 1970, 2450 MHz 28 V/m	28 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz
	5240, 5500, 5785 MHz 9 V/m	9 V/m	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).
	80 MHz to 2.7 GHz 3 V/m	3 V/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 strength 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 iSpiro Pro devices are used exceeds the applicable RF compliance level above, the iSpiro 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 iSpiro Pro Ultrasonic device.

^b Over the frequency range 150 kHz to 80MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment.		
iSpiro Pro devices are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Users of iSpiro devices can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the iSpiro device as recommended below, according to the maximum output power of the communications equipment.		
Rated maximum output power of transmitter	Separation distance according to frequency of transmitter	
	80 MHz - 800 MHz $d = 0.35 \sqrt{P}$	800 MHz - 2500 MHz $d = 0.7 \sqrt{P}$
0.01 W	0.035 m	0.07 m
0.1 W	0.11 m	0.22 m
1 W	0.35 m	0.7 m
10 W	1.11 m	2.21 m
100 W	3.5 m	7 m
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.		

The iSpiro Pro has been tested in accordance with the recommendations of IEC TR 60601-4-2: Electrical medical equipment - Part 4-2: Guidance and design - Electromagnetic immunity.

Existing environmental interferences may cause deviations of the measurement values without impairing the device's function. The manufacturer considers a flow deviation of up to +/-10ml/s due to EMC interference to be acceptable. Therefore, it is recommended to keep a sufficient distance from possible sources of EMC interference when using the device.

The maximum recovery time of the operation after a TRANSIENT phenomenon is 5 seconds.

12. BLUETOOTH WIRELESS COMMUNICATIONS

Bluetooth is used to pair the iSpiro Pro with smart devices and transfer test data between them. Bluetooth data transfer involves the widely trusted use of pre-shared key authentication and encryption algorithms. The strength of Bluetooth security depends heavily on the length and randomness of the passkey used for Bluetooth pairing. Initial pairing involves mutual authentication between devices where a link key is set up between them for later authentication and encryption. Encryption of data sent between devices prevents unintended or malicious interference. Each iSpiro Pro will connect to the smart device it is paired with and will not be confused with other Bluetooth radio communications.

Frequency Band:	2400 MHz
Transmission Frequency Range:	2402 - 2480 MHz
Max Output Power:	0.7 dBm
Antenna gain:	5.3 dB

13. FCC / IC NOTICE

USA



ISpiro Pro

FCC ID: 2AAUFISPP01

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

This equipment has been tested and found to comply with the limits for a Class B digital device, @. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment

Canada

ISpiro Pro

IC: 11335A-ISPP01

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

14. MANUFACTURER INFORMATION

UK Responsible Person:
Exco Intouch Limited,
6th Floor City Gate East,
Tollhouse Hill, Nottingham,
NG1 5FS UK



Swiss Responsible Person:
PHT Corporation SarL,
Chemin Louis-Hubert 2,
1213 Petit-Lancy, Geneva,
Switzerland



©2025 eResearchTechnology GmbH or one of its affiliates All rights reserved.



eResearchTechnology GmbH Sieboldstraße 3
97230 Estenfeld, Germany
Tel: +49 9305 720-9891
Fax: +499305720-7891

