



User Manual for Spiromagic®

Document ID: 201-IFU-001

Version: 1.0

Language: English (EN)

Spiromagic ApS

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1. Introduction & package contents

Congratulations on your new electronic spirometer. With this device, and its accompanying app, you can measure your lung function and view all your measurements wherever you are, giving you an in-depth understanding of your respiratory health. Please keep this user manual for future reference, or access the digital version (eIFU) at <https://guide.spiromagic.com> .

1.1 Package contents

- 1 pc Spiromagic® device with integrated mouthpiece.
- 1 pc Storage pouch.
- 1 pc Printed user manual / Quick Guide.
- 2 pc 1.5 V non-rechargeable AAA batteries.

2. Intended purpose & indications

The device is used for pulmonary function testing to measure how much and how fast the user can exhale air from the lungs.

- **Intended use:** Spiromagic® measures patients' respiratory parameters, including FEV1, FEV6, FVC, the FEV1/FVC ratio and PEF.
- **Target population:** The device is designed for measuring lung function in adults and children aged 6 years and older. Children under 14 years of age must be supervised by an adult.
- **Personal use (home use):** The device is intended for personal use. To prevent cross-contamination, never share your personal device with others.
- **Clinical use (professional):** The device can be used by healthcare professionals for multi-patient testing when using single-use disposable mouthpieces and proper disinfection procedures. Device measurements serve as a supplement to other sources of clinical information.

3. Contraindications (when NOT to use the device)

The device must not be used if you answer yes to any of the following:

- **Within the past month:**
 - Surgery or trauma to the chest, abdomen, eyes, or brain (including severe concussion).
 - Heart attack (myocardial infarction), stroke, or collapsed lung (pneumothorax).
- **Current conditions:**
 - **Cardiovascular:** Severe high blood pressure (hypertension), unstable cardiac arrhythmia, or blood vessel dilation (aneurysm).
 - **Contagious respiratory infection:** E.g., active COVID-19 or tuberculosis.
 - **Acute, severe shortness of breath:** Seek immediate emergency medical attention instead of performing a measurement.
 - **Inability to perform:** The user is physically or cognitively unable to safely perform a forced exhalation maneuver.

Note: If you are uncertain about your medical condition or your physical ability to perform a forced exhalation, always consult your physician prior to use.

4. Limitations & important warnings ⚠

Read all information in the user manual before use.

- **No activity during use:** The device must not be used while walking, driving, or operating machinery. You must sit still and remain at rest during testing.
- **Physical conditions:** Symptoms such as acute shortness of breath may affect the safe operation of Spiromagic®.
- **Medication adjustment:** Do not use the device's measurements to alter your prescribed medication dosage without first consulting your doctor.
- **App settings:** Incorrect personal data entered into the app (age, height, sex) will lead to inaccurate reference values (% Predicted) and may result in misinterpretation.
- **Handling:** Never attempt to disassemble the device. If internal biological contamination is suspected, the device must be discarded.
- **Drying:** Always allow a washed mouthpiece to dry completely before use. Never store a wet mouthpiece in a closed box or bag.

5. Getting started (setup and app)

Follow the instructions below to connect your spirometer to the app.

NOTE: Your Spiromagic® device must be connected through the Spiromagic® app and NOT via your phone or tablet's native Bluetooth settings menu.

Minimum smartphone/tablet requirements

- **Operating system:** iOS 13.4 or newer / Android 6.0 or newer.
- **Wireless connection:** Bluetooth 4.2 or newer (Bluetooth Low Energy – BLE).
- **Internet:** Required for initial setup and data synchronization:

To connect the Spiromagic device to the app:

1. Ensure your mobile device is connected to the internet 📶.
2. Enable Bluetooth 📶 in your device settings.
3. Download and install the Spiromagic® app from the App Store (Apple) or Google Play (Android).



4. Open the app, tap *Sign Up*, and create your user profile by entering date of birth, sex, height, weight, and ethnicity.

For healthcare professionals

The profile information is used to calculate the reference values (% Predicted). Therefore, the profile must be updated before performing a measurement on a new patient. For further information, see Section 7.1.1.

How to turn on and connect the device

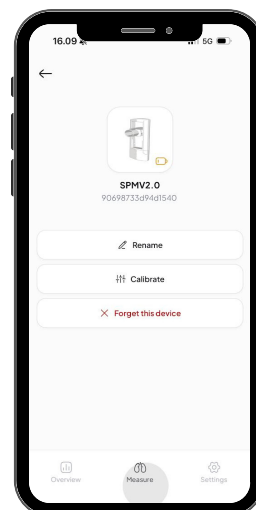
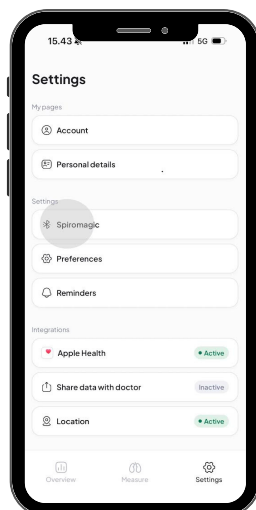
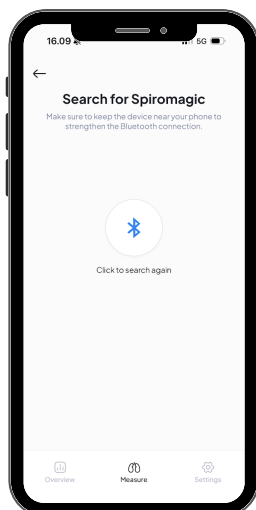
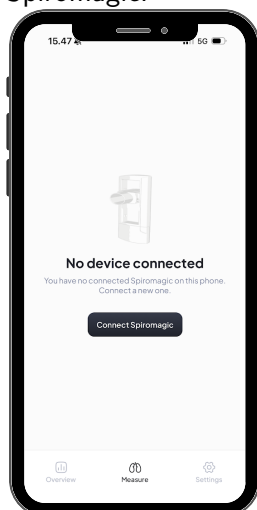
1. Turn on your Spiromagic® by rotating the mouthpiece outwards until it is perpendicular to the device, as shown below.

**Spiromagic is turned off****Spiromagic is turned on**

2. The spirometer can be added in two ways:

(a) Through Measurement

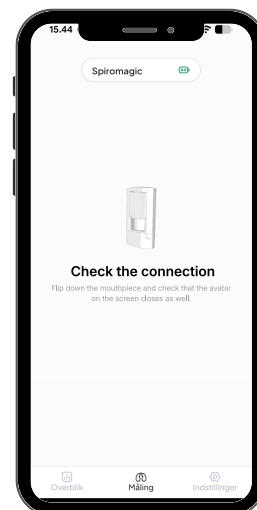
In the app, go to *Measurement* → tap *Connect Spiromagic* → search for and select your Spiromagic.



Check the connection

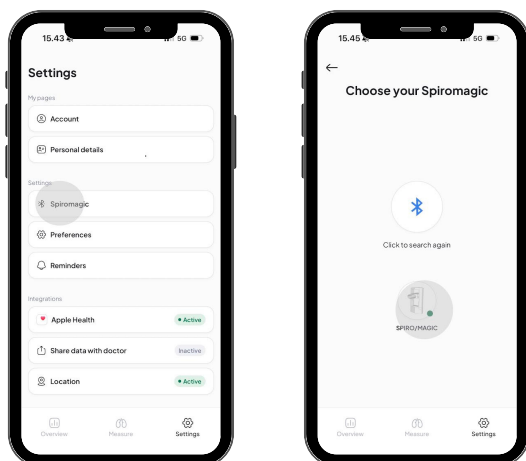
To verify that the app is connected to the correct spirometer, the first time you connect the device, flip the mouthpiece down (turn it off) and check that the avatar on the screen also closes.

If the avatar does not respond, remove your device and re-establish the connection; read more about this in the section [7.1.2.](#)

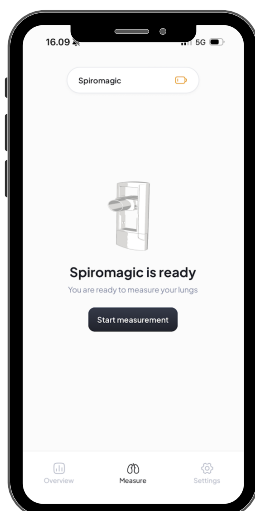


(b) Through *Settings*

In the app, go to *Settings* → *Spirometer* → search for and select your Spiromagic.



(c) Wait until *Spiromagic is ready* appears on the screen.

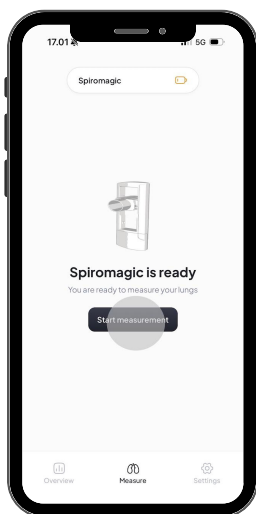


6. Operation and performing a measurement

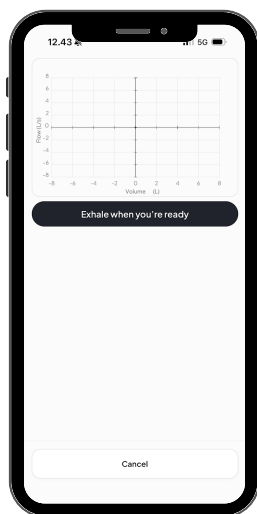
6.1 How to take a measurement

- **Pre-use inspection:** Inspect the device for visible damage. Do not use the device if it is damaged.

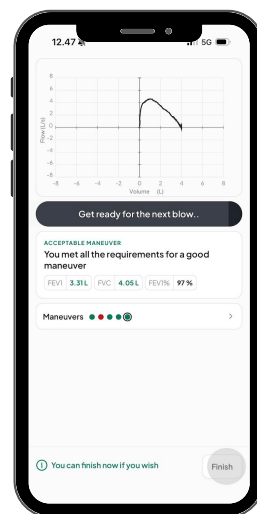
- **Clinical check (professional use only):** Ensure the patient profile is updated under Settings → Profile before testing a new patient, see section 7.1.2.
1. Tap *Start Measurement* in the menu.
 2. Sit down in a comfortable, upright position.
 3. Sit up straight, look directly ahead, and take a deep breath in.
 4. Place the mouthpiece in your mouth and seal your lips tightly around it. Ensure your tongue and teeth do not block the opening.
 5. Exhale as hard and fast as you can, continuing until your lungs are completely empty.
 6. The app records the test. Following the maneuver, the app counts down 30 seconds before the next attempt.
 7. Perform three acceptable maneuvers. Then tap *Save*.



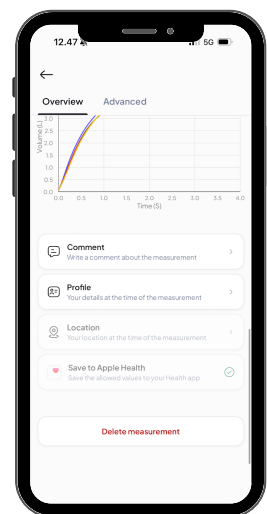
1. Tap *Start Measurement*.



2. Exhale when ready.



3. After three acceptable maneuvers, finish by tapping *Finish*.

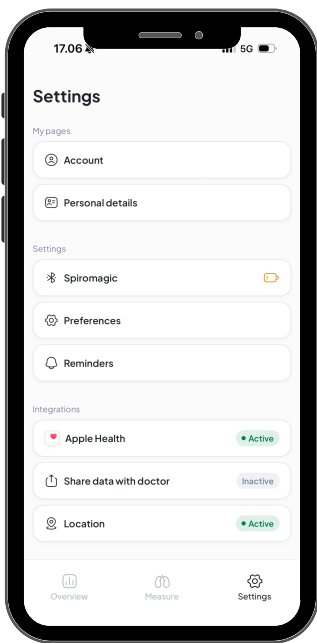


4. View the results of your latest measurement. You can add a comment, see advanced settings and delete the measurement.

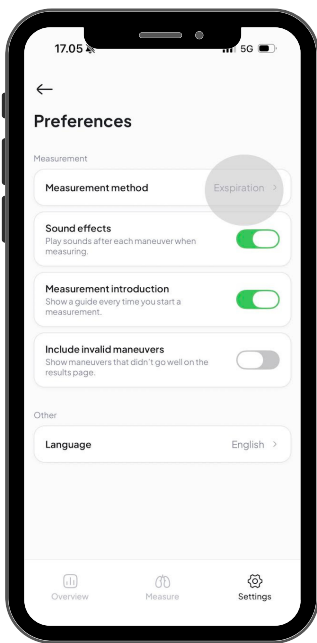
6.2 Inspiration (clinical/professional use only)

To obtain a complete measurement of inspiratory parameters (FIVC), remember to change the settings as shown in the pictures bellow. Instruct the patient as follows:

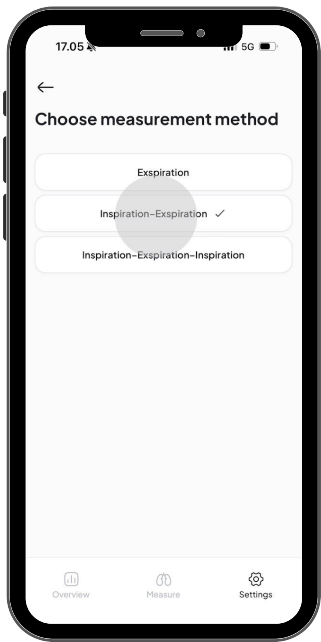
1. **Forced exhalation:** The patient first performs a full forced exhalation through the spirometer.
2. **Forced inhalation:** Immediately upon emptying the lungs (without removing the mouthpiece from the mouth) the patient takes a deep, forced, and rapid inhalation directly back through the spirometer.
3. Ensure a tight seal with the lips throughout both exhalation and inhalation.



1. Tap *Settings* → *Preferences*.



2. Tap *Measurement method*.

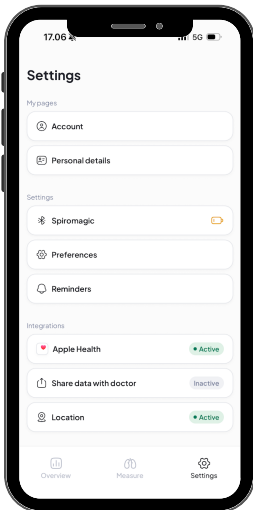


3. Select *Expiration – Inspiration* as the measurement method.

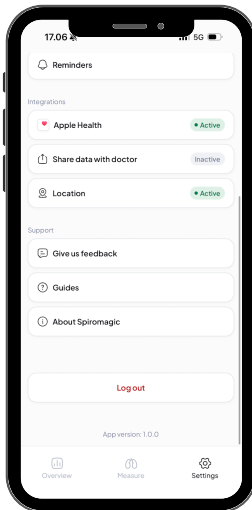
7. Other features in the Spiromagic® app

7.1 Features under *Settings*

Tap *Settings* in the navigation bar at the bottom of the screen. Here, you can manage and update your profile and customise the app's features according to your needs.



At the top of the page, you will find settings for your account, spirometer and preferences.



Scroll down to view the remaining settings and support options.

The different features available under *Settings* and support are described below.

7.1.1 My pages

- **Account**

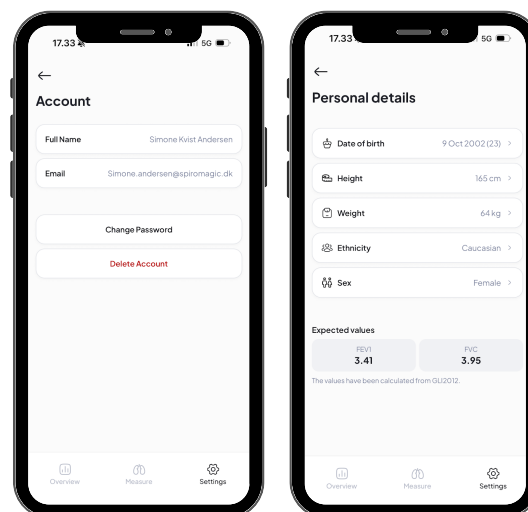
Here, you can change your name, password or delete your account. If you choose to change your password, you will receive an email containing a link to confirm the change.

- **Personal details**

Here, you can view and update your personal details by tapping the relevant field. The expected values are calculated automatically based on this information.

For healthcare professionals

Check and update the patient's personal details before performing a measurement on a new patient.



7.1.2 Settings

- **Spiromagic**

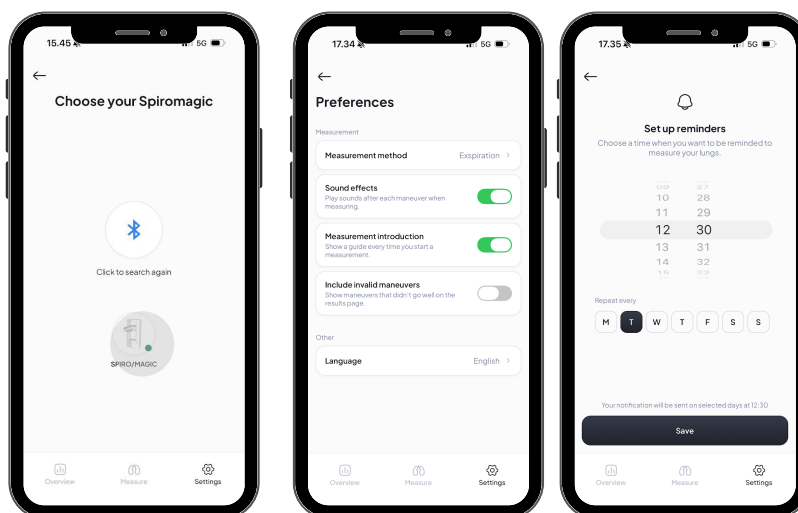
Here, you connect the app to your spirometer. You can view the active device, rename it, or remove ('forget') it to pair a new one or restart the connection.

- **Preferences**

Customize the app's display and features to suit your needs.

- **Reminders**

Set up automatic reminders for selected days and times so you remember your daily or weekly measurements.

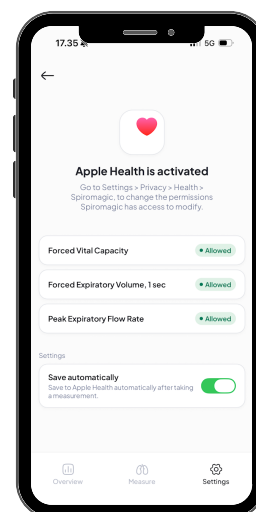


7.1.3 Integrations

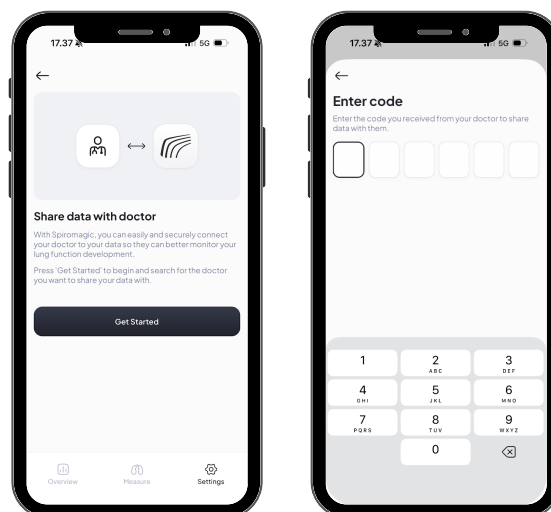
- **Apple Health - for iOS**

Here, you can enable automatic sharing of your measurements with Apple Health, by activating *Apple Health* and allowing the data to be shared. You can choose which information is shared. Here, you can enable the automatic sharing of your measurements to Apple Health. You choose which information to share.

- **Access control:** You can always turn off sharing again via the phone's own settings.

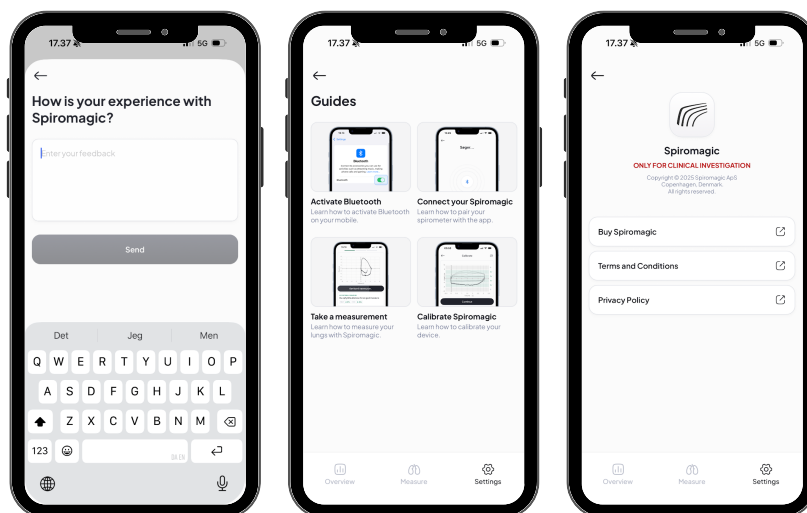


- **Share data with your doctor**
Here, you can share your measurements with your doctor or other healthcare professionals. The healthcare professionals will then get access to your results and can follow your lung function remote.
- **Activation:** Enter the six-digit code provided by your doctor to grant access to your data.
- **Consent:** You may withdraw your consent at any time.



7.1.4 Support

- **Give us feedback**
Here, you can share your experiences and suggestions for improvements. Your feedback helps us continuously improve Spiromagic.
- **Guides**
Here, you can find guides to the app's different features and instructions on how to use your Spiromagic.
- **About Spiromagic**
Here you can read our terms and conditions as well as our privacy policy.



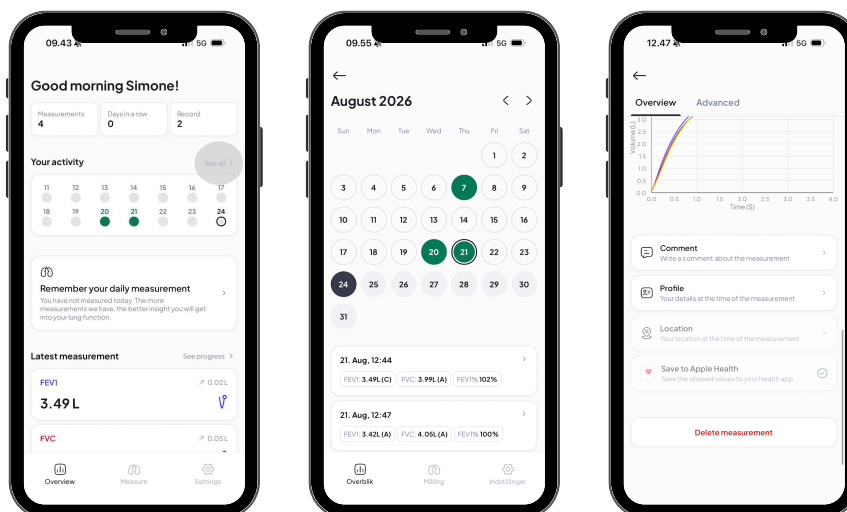
7.2 Features under Overview

Tap *Overview* in the navigation bar at the bottom of the screen. Here, you get a comprehensive overview of your measurements, your activity, and changes in your lung function. **View all measurements**

Under *Your activity*, the green markers indicate the days on which you have taken a measurement within the past two weeks. Days without measurements are shown in grey, as illustrated on the right.

Tap *View all* to open a complete overview of your measurements, then select the specific measurement you wish to review. Here, you can:

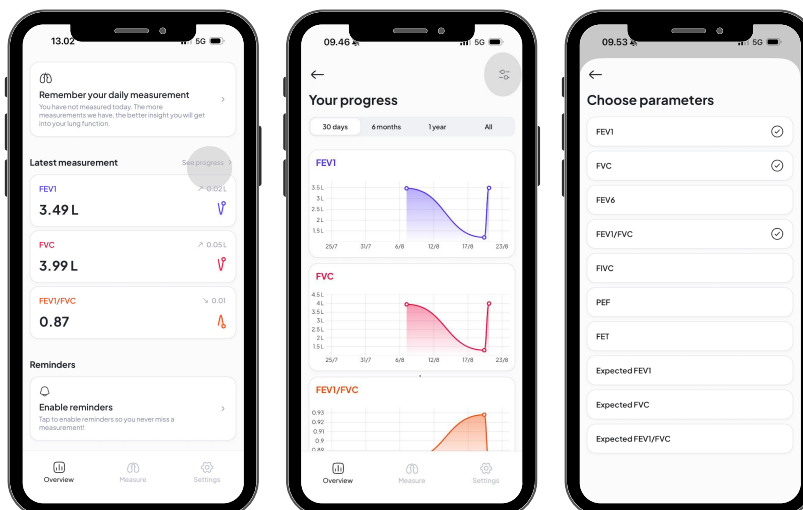
- View detailed data: Select either the *Overview* or *Advanced* tab for more detailed information about the measurement.
- Add a comment or delete the measurement.



View Your progress

Further down the page, you will find the results of your most recent measurement. By default, FEV1, FVC and FEV1/FVC are displayed, but you can choose from the parameters shown in the image on the far right.

- View progress over time: Tap *View progress* to see a graphical representation of your lung function. At the top of the screen, you can set the time interval to 30 days, 6 months, 1 year or All time.
- Select parameters: Tap the button in the upper-right corner (as shown in the middle image) to customise which parameters from your lung function test are displayed on the screen.



Tip

Set a reminder to help you remember to take your daily measurement.

8. Maintenance, cleaning & calibration

8.1 For personal use (home use)

- **Wiping the device:** Wipe the exterior surface with a clean, damp cloth. Never submerge the device in water.
- **Cleaning the mouthpiece:** Slide the mouthpiece off its holder. It can be hand-washed with warm water or cleaned in a dishwasher (55 °C – 80 °C). Do not use boiling water. Allow to air-dry completely before clicking it back into place.

8.2 For professional use (clinical use)

8.2.1 Cleaning and disinfection between patients

IMPORTANT: ⚠ The mouthpiece is single-use only in professional environments and must never be reused on another patient.

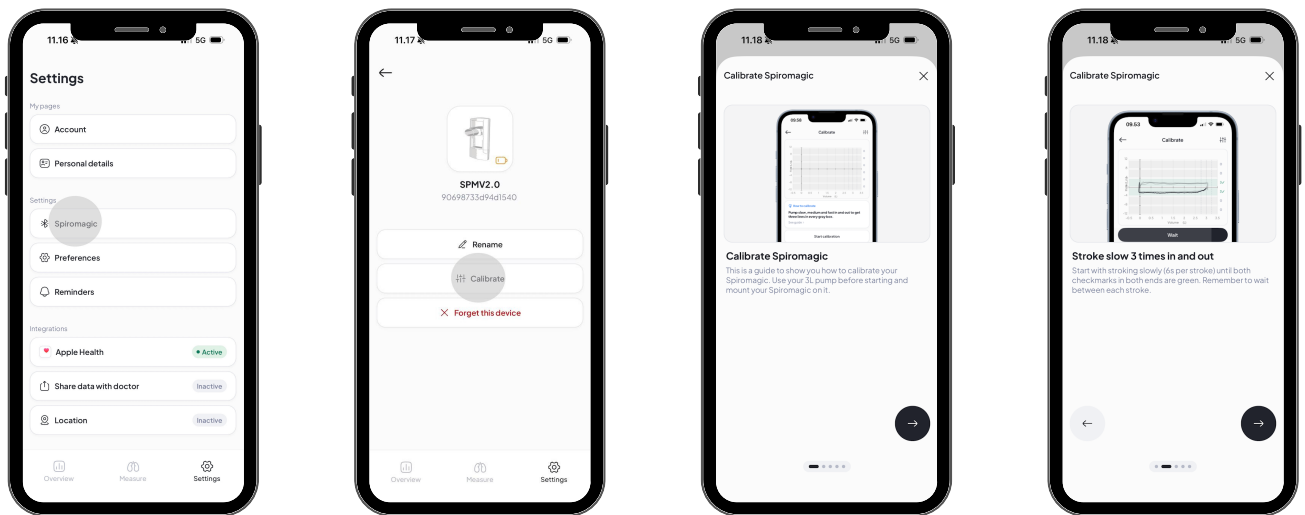
1. **Dispose of mouthpiece:** Flip the mouthpiece out, slide it off the holder, and dispose of it as biohazardous clinical waste.
2. **Clean the casing:** Wipe down the entire outer plastic surface of the spirometer with an alcohol wipe (70% ethanol/isopropyl alcohol).
3. **Gasket disinfection:**
 - (a) Take a clean cotton swab moistened with 70% ethanol/isopropyl alcohol (do not oversaturate).
 - (b) Gently insert the swab from the side of the device at the visible gasket opening and thoroughly wipe the surface.
 - (c) Allow the alcohol to air-dry completely prior to use on the next patient.
4. Never attempt to disassemble the device. Never submerge the device in water.



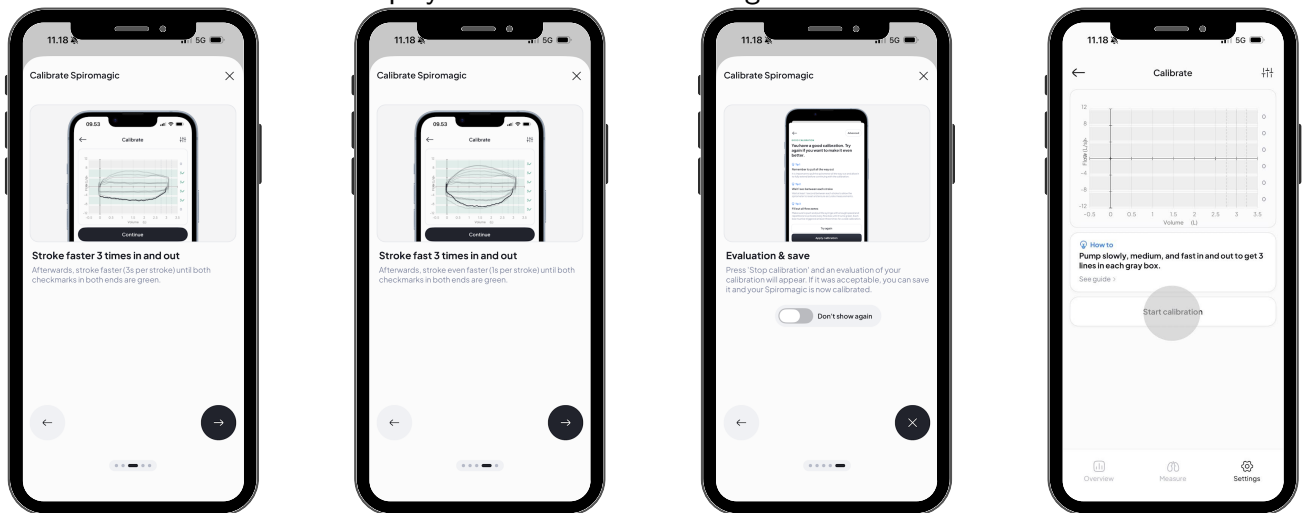
8.2.2 Calibration and functional check

In accordance with ISO 26782 and ATS/ERS guidelines, routine functional verification in clinical settings is recommended using a certified 3-liter calibration syringe:

1. Connect the device to the app via Bluetooth.
2. Attach a new mouthpiece and a suitable adapter for the 3L syringe.
3. Open the app, go to *Settings* → *Calibration*, and follow the on-screen prompts to fill and empty the syringe in smooth, steady strokes.



4. The app verifies whether the measurement falls within the accuracy tolerance of $\pm 3\%$. If the test fails, inspect the mouthpiece for leaks and repeat. If failure persists, do not use the device. Below are the instructions displayed before calibration begins.



8.3 Battery replacement

When the app indicates a low battery status:

1. Remove the battery cover on the bottom of the device.
2. Remove old batteries and insert 2 new 1.5 V AAA batteries, ensuring correct polarity (+/-).
3. Replace the cover and press lightly until it clicks into place.



1. Pull off battery cover



2. Replace batteries



3. Replace cover and press lightly.

9. Troubleshooting

Problem / symptom	Possible cause	Solution
The app cannot find the spirometer.	Bluetooth is turned off.	Enable Bluetooth in your device's system settings.
The app cannot find the spirometer.	Pairing is attempted through the phone's system settings.	Disconnect the spirometer in the operating system's Bluetooth settings. Connect directly through the Spiromagic® app under <i>Settings</i> , or under <i>Measurement</i> → <i>Spirometer</i> .
The app does not start.	No internet connection.	Make sure that your device is connected to Wi-Fi or mobile data.
The measurement does not start / mouthpiece error.	The mouthpiece is misaligned or has not clicked fully into place.	Remove and reattach the mouthpiece (see Section 7.1). Make sure that you hear a distinct <i>click</i> .
The device does not turn on.	The batteries are depleted or inserted incorrectly.	Replace them with new AAA batteries and check the polarity (+/-).

10. Technical specifications & measured values

- **Measurement method:** Automated electronic measurement upon exhaling into spirometer.
- **Power / battery:** 2 × 1.5 V AAA non-rechargeable batteries.
- **Measurement accuracy:** $\pm 3\%$ for FEV1, FVC, PEF, and FEV1/FVC.
- **Operating temperature:** +17 °C to +35 °C.
- **Storage and transport:** -5 °C to +50 °C.
- **Ingress protection:** IP22 (protected against touch by fingers and vertically dripping water at a 15° tilt)
- **Expected service life:** 5 years under normal use in accordance with this manual.

10.1 Measured parameters

FEV1:	Forced Expiratory Volume in 1 second (liters).
FEV6:	Forced Expiratory Volume in 6 seconds (liters).
FVC:	Forced Vital Capacity – total exhaled volume (liters).
FEV1/FVC:	Ratio of FEV1 to FVC (Tiffeneau index).
PEF:	Peak Expiratory Flow – maximum expiratory flow rate (L/sek).
FIVC:	Forced Inspiratory Vital Capacity – total inhaled volume (liters).

11. Symbol glossary (ISO 15223-1)

Symbol	standard / references	Meaning and explanation
	ISO 15223-1 (5.7.7)	Medical Device: Indicates that the product is a certified medical device.
	ISO 15223-1 (5.4.3)	Consult Instructions for Use: Refer to the printed or electronic instructions for use (eIFU) at guide.spiromagic.com .
	ISO 15223-1 (5.4.4)	Caution / Warning: Read important warnings and safety instructions in the manual.
	EU MDR 2017/745	CE Marking: Complies with European Medical Device Regulation (Notified Body: SGS Fimko).
	IEC 60529	Ingress Protection Rating: Protected against access by fingers and vertically dripping water at a 15° tilt.
	ISO 15223-1 (5.1.1)	Manufacturer: Indicates the legal manufacturer of the device.
	EN 50419	Waste Electrical and Electronic Equipment: Device must not be disposed of as household waste.

12. Disposal

- **Spirometer and electronics:** Must be disposed of as electronic waste (WEEE) at an authorized recycling facility .
Reference: 412-FM-001 *Spiromagic Packaging Record*
- **Batteries:** Must be removed and deposited in designated battery collection containers.
- **Used disposable mouthpieces (clinical use):** Must be immediately disposed of as biohazardous clinical waste in accordance with local institutional guidelines. Spiromagic® assumes no liability for handling contaminated waste.

13. Warranty & contact

Any damage or defect occurring within 2 years from the date of purchase despite correct operation in accordance with this manual is covered by warranty. Warranty coverage applies to the original purchaser. Upon valid claim, Spiromagic® will replace the device with a new unit. Remember to detach and dispose of the mouthpiece prior to returning any device.

Reporting serious incidents: If a serious incident occurs in connection with the use of Spiromagic® (e.g., severe deterioration in health, injury, or risk thereof), it must be reported immediately to

Spiromagic ApS at info@spiromagic.dk and to the national competent authority of the state in which you reside (in Denmark: The Danish Medicines Agency via www.laegemiddelstyrelsen.dk).

Contact Manufacturer

Manufacturer: Spiromagic ApS
Address: Generatorvej 8D, st. th.
2860 Søborg, Denmark
Web: www.spiromagic.dk
Email: info@spiromagic.dk



Spiromagic® ApS



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