



Thank you for purchasing the Spiromagic® device.

This product, together with the Spiromagic® app, allows you to measure and track your lung function from the comfort of your home. Spiromagic® is your prime support tool which makes you aware of factors that have implications on your lung condition and training on a day-to-day basis.

In this manual, you will be instructed through all steps associated with setting up your Spiromagic® device and advised on key functions of the instrument.

We recommend that you safely store this user manual for future guidance.

Setup Requirements

Spiromagic® is designed to be used on the following devices:

iPod Touch (5. generation or newer) iPhone (5. generation or newer) iPad (air or newer)

The iOS on the above devices should be in version 8.1 or newer

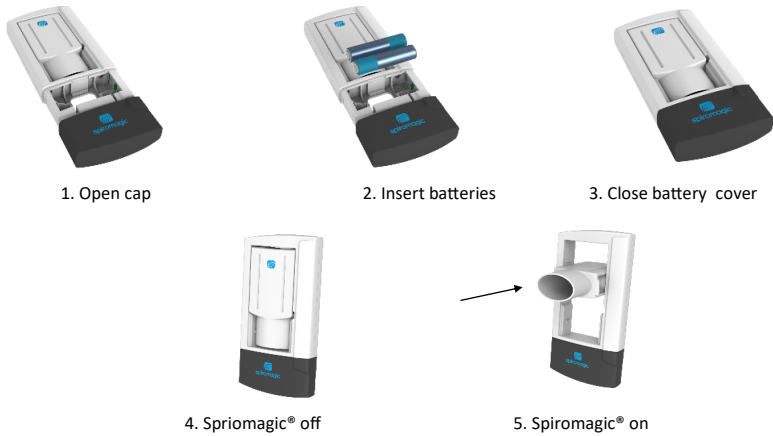
Download the app via this link: <https://itunes.apple.com/dk/app/spiromagic/id932783702?l=da&mt=8>
Alternatively, you can find Spiromagic® on the App Store, or scan the QR code provided at the bottom of this manual.

Package Contents

- Spiromagic® device + mouthpiece
- Spiromagic® pouch
- User manual
- 2 x 1.5V. AAA batteries

Insert Batteries

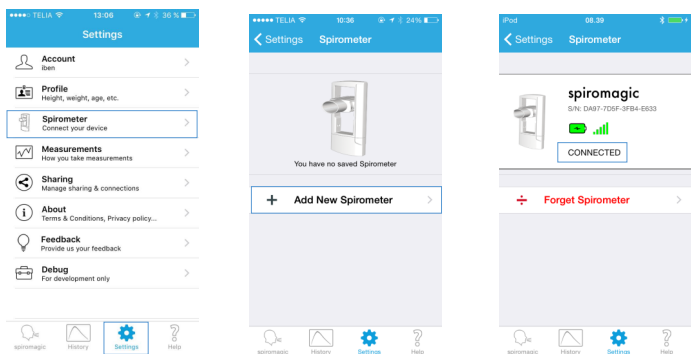
Pull the cap off as shown in picture 1. and insert the batteries. Put the cap back on by giving it a gentle press until it clicks.



Get Started

Follow the instructions below to connect your spirometer with the Spiromagic® app. Make sure you are connected to the internet.

- Download and install the Spiromagic® app. It is important that you follow the instructions that appear on the screen when you register and complete the personal profile.
- Before entering your personal information, you must create a login to the Spiromagic® app. This has to be done using your email and a self-selected password. If you lose access to your smartphone or tablet and want to maintain data on another device, it is important to create a login. After logging in, you can create your personal profile. It is essential for your information to be correct. Based on your information, the Spiromagic® app compares your lung function to the average lung function of a healthy individual that matches your profile.
- Select the 'Settings' menu. Then select 'Profile'.
- Enter your date of birth, sex, height, weight and ethnicity.
- Now you can connect your spirometer with the app. Turn on Bluetooth connection on your smartphone—This can be done in your smartphone settings.
- Open the Spiromagic® app.
- Go to settings menu. Select 'Spirometer' and then 'Add New Spirometer'. See pictures below.
- Turn on the spirometer as shown in picture 5 above. Wait until it says 'Connected'.



How to Use Spiromagic®

You are now ready to use your spirometer!

To take a measurement:

- Select "Spiromagic®" in the menu.
- Remain seated (unless your doctor tells you otherwise).
- Look straight ahead, straighten your posture, take a deep breath and hold the device steadily besides your mouth.
- While holding your breath, place the mouthpiece in your mouth with your lips firmly sealed around it.
- When 'Start' icon turns green, exhale as hard and as fast as you can, for as long as possible. Make sure not to block the mouthpiece with your tongue or teeth, as this restricts the air-flow and can affect the measurement.
- If any errors occur during measurement, the app will make a 'beeping' noise and deliver an error message.
- Shortly after the measurement is taken, the device is ready for a new test. The app will ask you to provide three measurements. (More than three measurements can be taken if necessary).
- When 3 measurements are taken press "Done" first, then "Save" to save your measurement. All your previous measurements can be found under "History", where you also can add comments to your measurements if needed.

Important Information for Users

Physical condition may have an effect on the use of Spiromagic®. Please consult a doctor if you are concerned about your condition affecting the measurements. Note that incorrect personal profile information can also negatively influence results.

Intended Use

The Spiromagic® device is intended to be used by COPD/Asthma patients in pulmonary function testing.

Indication for Use

The Spiromagic® device is a spirometer which measures patients' respiratory parameters including FEV1, FEV6, ratio FEV1/FEV6 and PEF. The device is a portable, handheld spirometer designed for pulmonary function testing for adults and children at the age of 6, or older to be used in a variety of environments, such as hospital wards, health centers and private homes.

The Spiromagic® device is to be used by either physicians, respiratory therapists, technicians, patients or layman who are able to understand the instructions and operate the App. Children below the age of 14 need to be supervised by an adult.

The Spiromagic® device is a non-invasive, non-implantable and reusable device for a single user. It is however recommended that professionals using the device replace the mouthpiece when screening multiple users. The device's measurements are used as an addition to other clinical information sources.

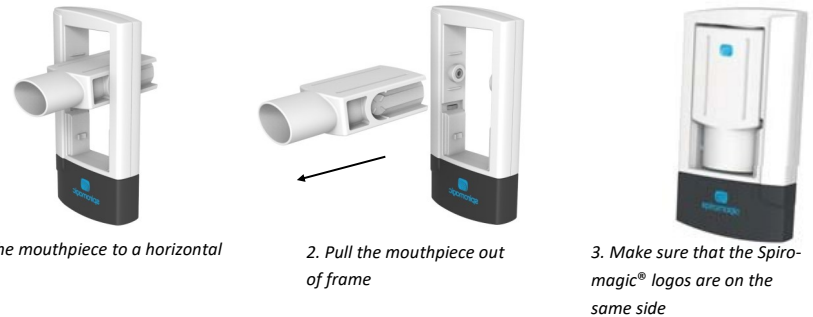
Values

Peak Expiratory Flow (PEF) - Maximum expiratory flow rate reached during the test

Forced vital capacity in one second (FEV1) - The amount of air blown out within one second.

Forced vital capacity in six seconds (FEV6) - The amount of air a blown out within six seconds. Under normal conditions, most of the air from lungs is exhaled within six seconds.

Ratio FEV1/FEV6—Ratio between FEV1 and FEV6



Change or Clean the Mouthpiece

You can clean or change the mouthpiece by taking it off. Tilt the mouthpiece up to a horizontal position and pull it out of frame as shown in the picture. The mouthpiece is applied in the same position as taken off. The mouthpiece can be washed in the dishwasher. It is recommended that the mouthpiece is washed in the temperature of at least 55 °C and a maximum of 80 °C.

Maintenance

- Clean the spirometer with a damp cloth after use. Do not use boiling water to disinfect the device.
- Do not use any kind of solvent cleaners.
- Clearly visible cracks and nicks indicate that the mouthpiece should be replaced with a new one.
- Always place the spirometer back into its fabric pouch after use to ensure maximum protection.
- Do not immerse the spirometer in water, as this will damage the device.
- Let the spirometer acclimate to room temperature if it has been stored below freezing temperature.

General Safety and Precautions

- Read all information in the quickguide before using the product.
- Do not use the spirometer while in motion.
- Do not give the product to children under the age of 14 without supervision. The product should be used accordingly.
- Treat the spirometer wisely. Do not drop it from great heights, do not step on it. Abuse can make the electronic device inoperative, or affect other spirometry functions.
- People with artificial heart/lung, or similar should not use the product without consulting a doctor first.
- The spiromagic® device will not necessarily function properly if it is used, stored or transported outside the advised temperatures (see specifications).
- Contaminated equipment should be destroyed. Do not send the unit back to Spiromagic® headquarters.
- It is recommended that you use only your own mouthpiece. When using the same mouthpiece between multiple users, risk of possible cross-contamination occurs.
- Do not disassemble the spirometer or try to service the product while using it.
- Only connect the spirometer to approved equipment.



Warranty

Any damage, or faulty operation by the spirometer, which has emerged within 2 years from the date of purchase despite correct use in relation to the user manual is covered by the warranty. This warranty covers only the person who purchased the product. If the warranty is valid, Spiromagic® will replace the spirometer with a new one. Repair or replacement of the spirometer is our only responsibility and further help is limited to the scope of the warranty. If you have any questions or regret the purchase of your spirometer, please feel free to contact us.

If you want to return the spirometer: Throw the mouthpiece out before returning your spirometer. Please send us an explanation of why you are not happy with the product.

Specifications

- Product Name: Spiromagic®
- Unit dimensions: L: 12cm W: 6.3cm D: 2cm
- Weight: 82,5g (with battery) and 59,3g (without battery).
- Measurement method: Automatic electronic measurement when exhaling in the spirometer.
- Energy: 2x1.5V. Non rechargeable AAA batteries
- Measuring value: Lung function based on breath and personal information. Results are shown in relation to the reference norms which are set by international standards.
- Operating temperature: + 17 ° C to + 35 ° C.
- Storage and transport temperature: -5 ° C to + 50 ° C.
- FCC ID: P14BL600. IC: 1931B-BL600
- Accuracy of measurements: ±3% for FEV1, PEF and FEV1/FEV6

Disposal

Never throw a spirometer out into a normal bin or container. The spirometer must be disposed as other electrical equipment. Always place the used batteries in a battery-friendly litter box.

Extra Equipment

Mouthpiece — Product number. 570002007612

Contact

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Read our Terms and Conditions on <http://spiromagic.dk/assets/Spiromagic-Terms-and-Conditions2.pdf>



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The manual follows:
 EN60601-1-2:2015, EN60601-1:2006 & WEEE directive 2012/19/EU