

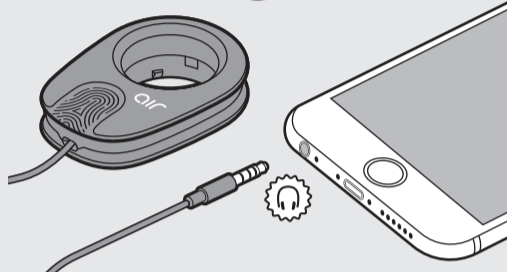
SETTING UP YOUR DEVICE

1



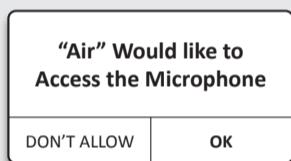
Download the Air Smart Spirometer app from the App Store.

2



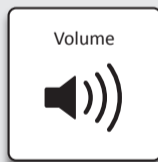
Connect the spirometer to your phone and open the app.

3



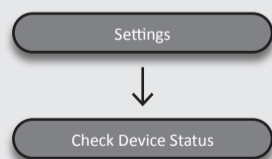
Tap **OK** to allow access to your phone's microphone.

4



Increase the volume to the maximum level.

5



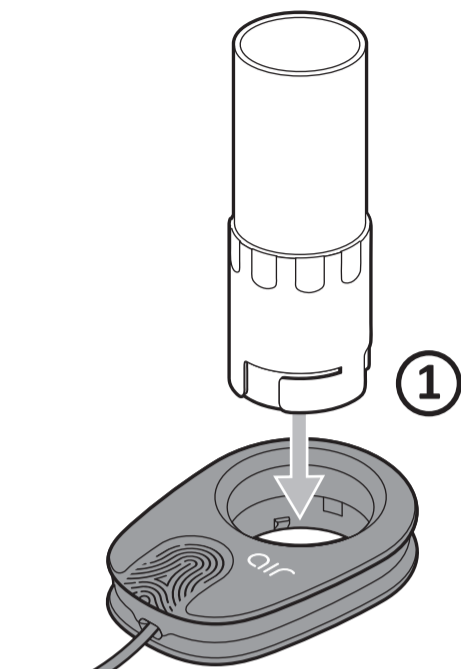
Make sure the spirometer has a functioning battery.

6

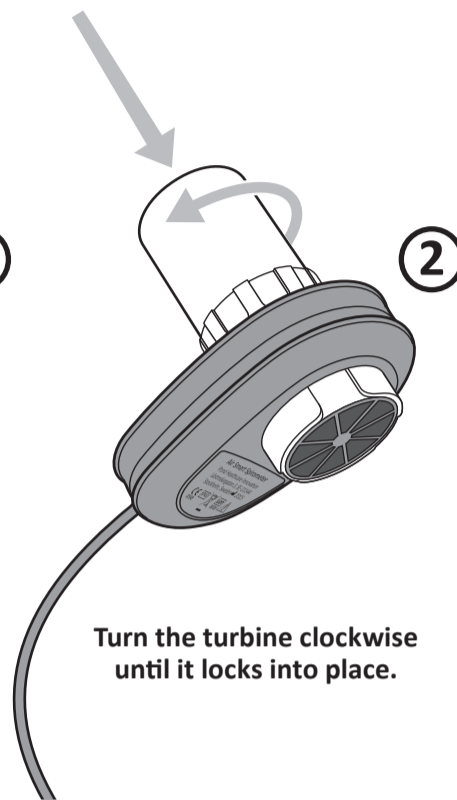
Device Status **OK**

You are now ready to perform a lung function test!

PERFORM A LUNG FUNCTION TEST



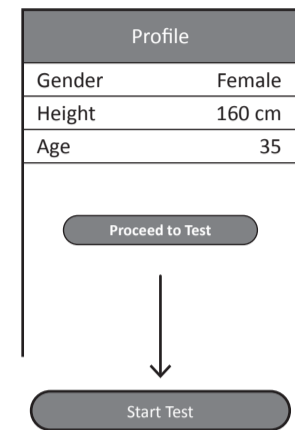
Insert a new FlowMir® turbine by sliding it through the device.



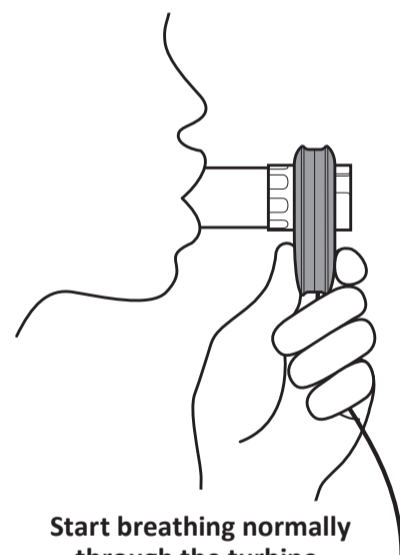
Turn the turbine clockwise until it locks into place.



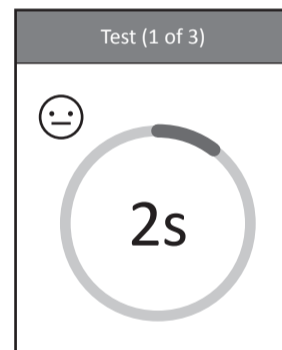
Tap **Start Test**.



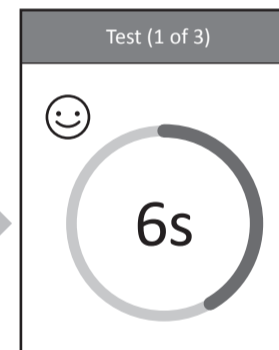
Fill in the profile information and tap **Proceed to Test**. Read the information on the screen and tap **Start Test** when you are ready.



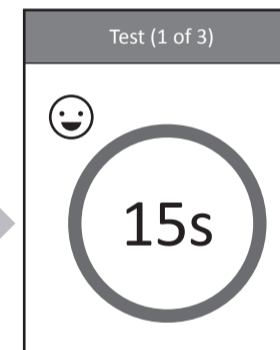
Start breathing normally through the turbine.



Take a deep breath and exhale as forcefully as possible, and empty your lungs completely.



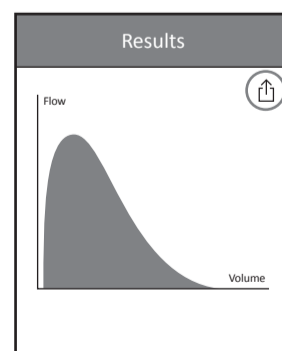
You should exceed 6 seconds of exhalation to obtain a high quality spirometry test.



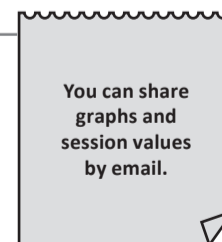
The maximum time allowed for a test is 15 seconds.



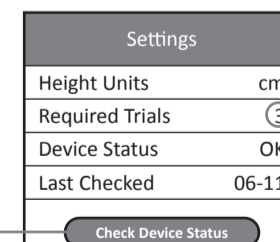
When the first test is completed, rest for 15 to 30 seconds before tapping **I'm ready!**



Once you have performed all the tests included in the session, the final results will be displayed.



ADDITIONAL SETTINGS



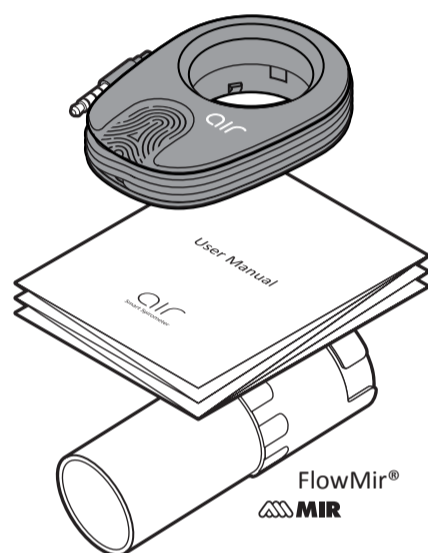
Perform a battery status check of the spirometer.

Change the number of test per session (we recommend 3).



Smart Spirometer
J10

WHAT'S IN THE BOX:



Air Smart Spirometer



Designed by Pond
in collaboration with
Novartis Pharma

Pond Healthcare Innovation AB
Lästmakargatan 3, SE-11144 Stockholm, Sweden
Version 1.0 © 2015 Pond Healthcare Innovation AB

Pond Healthcare Innovation AB guarantees that the product is free from material and fabrication defect, under normal use conditions and under the warranty period. For more information about the warranty, for reclamation or to provide feedback, please visit www.smartspirometry.com

INTENDED USE

Air Smart Spirometer is intended to measure the forced expiratory volume in 1 sec (FEV1) and the forced vital capacity (FVC) in a forced expiratory maneuver. These measures can be used for the detection, assessment and monitoring of certain lung diseases. The Air Smart Spirometer is intended to be used by:

- Healthcare professionals trained to perform spirometry tests on patients.
- Adults trained by healthcare professionals or through self-learning who understand how to perform a high quality spirometry test.

GENERAL INFORMATION

The Air Smart Spirometer works with iPhone and connects via its cable to the headphone input jack. The Air Smart Spirometer has a built-in battery designed to function for at least 2 years or 1 000 single tests. When the battery is drained, dispose of the device as electronic waste. The Air Smart Spirometer is designed to work with disposable and single use FlowMir® turbines. When performing a spirometry test, the user exhales into the turbine. The airflow generated sets a rotor in motion. The Air Smart Spirometer registers the speed of the spinning rotor, converts it and transfers the data to the smartphone with the Air Smart Spirometer app. The app can be downloaded for free on Apple's App Store. The app guides the user, performs calculations and displays results.

LIMITATIONS OF USE & CONTRAINDICATIONS

A spirometry test should only be carried out when the user is at rest (i.e. does not experience shortness of breath) and in good health, and thus in a suitable condition for the test.

An analysis of the results of a spirometry test alone is not sufficient to make a diagnosis of a clinical condition. Test interpretation and suggested treatment must be provided by a physician.

A correct spirometry test depends on the user's capability to inhale and exhale all air completely and as fast as possible. If these fundamental conditions are not respected then the results obtained during spirometry testing will not be accurate, and therefore the test results are "not acceptable".

The acceptability of a test is the responsibility of the user. Special Attention should be given when testing the elderly, disabled and children.

The device should never be used when it is possible or probable that the validity of the results may be compromised due to any external factors.

Some conditions may pose a relative danger to a patient or affect the validity of spirometry performance and results. These include, but are not limited to the following: unstable cardiovascular status, unstable angina, recent myocardial infarction (within one month) or pulmonary embolism; haemoptysis of unknown origin; recent pneumothorax; thoracic, abdominal or cerebral aneurysms; recent thoracic, abdominal or eye surgery; acute disorders such as nausea or vomiting; severe respiratory distress; physical limitations; cognitive impairment, dementia.

IMPORTANT SAFETY WARNINGS

The Air Smart Spirometer should never be used with a charging phone. Make sure the phone is unplugged before conducting a spirometry test. Don't use the device with a connected AC/DC adaptor.

Once removed from its packaging, check that there is no visible damage on the device. In the case of damage do not use it and return it to the seller.

Air Smart Spirometer has been examined by an independent laboratory which has certified the conformity of the device to the European Safety Standards EN 60601-1 and guarantees the EMC Requirements within the limits set in the European Standard EN 60601-1-2. It is a medical device directive class IIa ("two a") product. Air Smart Spirometer is constantly controlled during its production, therefore the product conforms to the essential requirements set by the Council Directive 93/42/CEE for medical devices.

Explanation of the safety signs and symbols marked on the device:



Manufacturer's name and address.



CE mark: indicates that the device is certified that it conforms to the requirements of the 93/42/EEC medical 0476 device directive.



IP classification: indicates that the device is protected against solid objects over 1 mm entering as well as sprayed water.



Waste electrical and electronic equipment: Dispose accordingly. Do not dispose as unsorted municipal waste.



Manufacturer's batch/lot code.



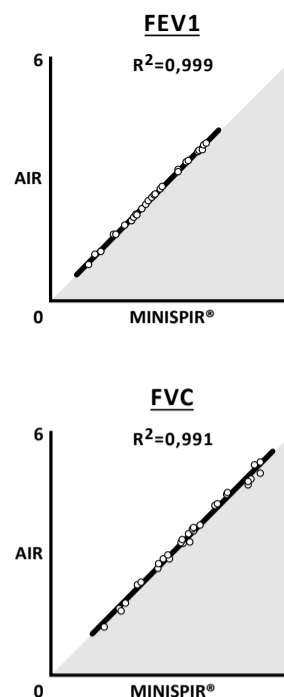
Follow operating instructions: indicates the need for the user to consult the instructions for important information.



Type BF applied part: Device that has conductive contact or medium to long term contact with the patient in order to fulfil the intended use.

QUALITY OF PERFORMANCE

To validate Air Smart Spirometer performance, we connected the device in parallel to an ERS/ATS approved spirometer (MiniSpir®). In this set up, both devices received the same airflow at the same time. The obtained results for FVC and FEV1 was plotted on a graph and the correlation coefficient (r) was calculated. The correlation between Air Smart Spirometer and MiniSpir® was excellent with R² values of 0.999 for FEV1 and 0.991 for FVC.



OPERATING ENVIRONMENT

Air Smart Spirometer has been designed for use in a doctor's office, in a hospital setting or at home.

Air Smart Spirometer is not intended for use in an operating theatre nor in the presence of inflammable liquids or detergents, nor in the presence of inflammable anaesthetic gases (oxygen or nitrogen). The device is not designed to be used in direct air currents (e.g. wind), sources of heat or cold, direct sun rays or other sources of light or energy, dust, sand or any other chemical substances.

FLOWMIR® TURBINE

Air Smart Spirometer is designed to be used with a disposable FlowMir® single user turbine. The single user turbine can be used multiple times in the same individual as long as its integrity and functionality is guaranteed by:

- Never holding the turbine under a jet of water or air and never let it come into contact with high temperature fluids.
- Not allowing dust or foreign bodies to enter the turbine sensor, in order to avoid incorrect functioning and possible damage. The presence of any impurities such as hair, sputum, threads etc. within the body of the turbine sensor may seriously compromise the accuracy of the measurements.
- Avoiding environmental contamination by cleaning waste products, the user must adhere to all relevant regulations.

THE SINGLE USER TURBINE CANNOT BE USED TO PERFORM A SPIROMETRY TEST IN ANOTHER INDIVIDUAL

You can purchase new FlowMir® single use turbines here: www.smartspirometry.com

DANGER OF CROSS-CONTAMINATION

Each new individual that uses the Air Smart Spirometer shall use a new unused disposable FlowMir® turbine. If the turbine is not replaced between individuals there is a high risk of infectious cross-contamination.

AIR SMART SPIROMETER TESTS AND DISPLAYS:

FEV1

(Forced Expiratory Volume in 1 second)

The volume of air (L) exhaled in the first second during a forced maximal expiratory effort after a full inspiration.

FVC

(Forced Vital Capacity)

The total volume of air (L) exhaled during a forced maximal expiratory effort after a full inspiration.

FEV1/FVC

(Ratio)

The calculated result obtained by dividing FEV1 with FVC.

The final results displayed in the application are always the best values obtained after performing the desired number of tests included in a session. The recommended number of tests per session is 3, however the user can select a different number (1 to 5) in the app settings.

Displayed test results are compared to a reference (NHANES III) as percent predictive value (% PRED).

The reference used in Air Smart Spirometer uses expected normal lung function values for FEV1, FVC and FEV1/FVC for Caucasians. Considerations are made based on gender, age and height.

Interpretation of spirometric results should be made by a physician or allied health care professional with sufficient training in the performance and interpretation of spirometry.

MAINTENANCE

Handle the Air Smart Spirometer device carefully. Store it in clean and moisture free conditions. Before use, always check that the device is free from dust, contamination or any particles.

Air Smart Spirometer does not require professional maintenance. If, however, the outside of the device needs to be cleaned make sure to only use a damp cloth without any detergents.

The Air Smart Spirometer device and the FlowMir® turbine are disposable and they shall not be opened or repaired by any means.

TECHNICAL FEATURES

Flow/volume measurement system	Bi-directional optical
Measurement method	Infrared interruption
Power supply	CR2 Lithium battery
Dimensions	79 x 56 x 20 mm
Weight	50g
Flow range	0 - 14 L/s
Dynamic resistance at 12 L/s	<0.5 cm H ₂ O/L/s
Operating conditions	T: min +10°C / max +40°C RH: min 10% / max 95% ALT: max 2000 m
Conditions of storage	T: min -20°C / max +60°C RH: min 10% / max 95% P: min 500 mBar / max 1060 mBar ALT: ≤ 5000 m
Life expectancy	2 years / 1.000 single tests

NOTEWORTHY

<p>ACCESS TO THE PHONE'S MICROPHONE</p> <p>The Air app needs to access your phone's microphone to function properly. You can allow the Air app to access it in your phone's settings menu.</p> <p>Settings → Privacy → Microphone.</p>
<p>PHONE'S MASTER VOLUME</p> <p>The device needs the phone's master volume to be set to the maximum level to function properly. Increase the volume with the side buttons or access volume settings from the control center by swiping up from the bottom of your screen.</p>

TROUBLESHOOTING

<p>BATTERY CHECK NOT PASSED</p> <p>Make sure that:</p> <ul style="list-style-type: none"> - The device is properly connected to the phone. - The volume is set to the maximum level. - There are no turbine in the device. <p>Still not working? If your device is more than 2 years old or has been used over a thousand times, the battery could be drained. You can purchase a new spirometer at www.smartspirometry.com</p>	<p>DEVICE NOT DETECTED</p> <p>Make sure that:</p> <ul style="list-style-type: none"> - The device is properly connected to the phone. - The FlowMir® turbine is correctly inserted into the device. - The device battery is not drained. <p>Still not working? The device can be affected by its environment if it is too bright. Try dimming the light or move to a darker location.</p>	<p>ERROR DURING TESTING</p> <p>If the user stops exhaling before 6 seconds has passed an error message is displayed. Try again and continue exhaling until you exceed 6 seconds.</p>
--	---	---