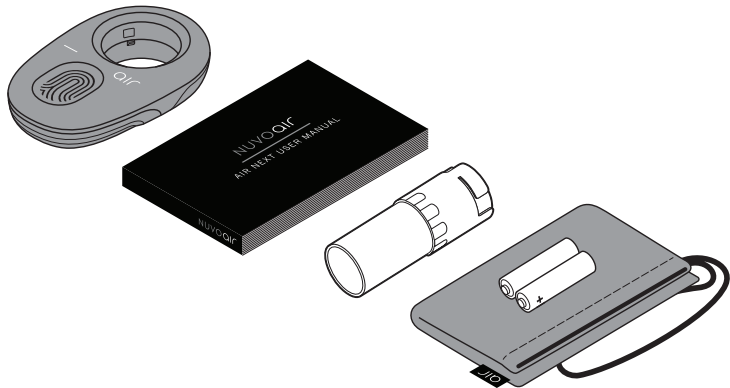


NUVOair

AIR NEXT USER MANUAL

WHAT'S IN THE BOX



SETTING UP YOUR DEVICE

1



Download the NuvoAir app from AppStore or Google Play Store.

2



Enable Bluetooth on your mobile device. Allow the app to access and use Bluetooth and follow the instructions on the screen.

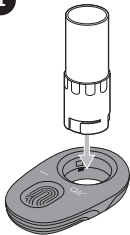
3



The spirometer lights up when it is connected to the mobile device.

PERFORM A LUNG FUNCTION TEST

1



Insert a new turbine by sliding it through the device.

2



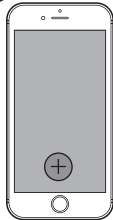
Turn the turbine clockwise until it locks into place.

3



Create an account or sign in to an existing one and select your profile.

4

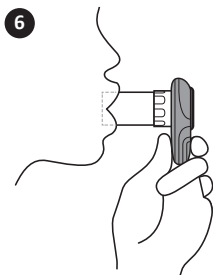


Tap the plus button to perform a lung function test.

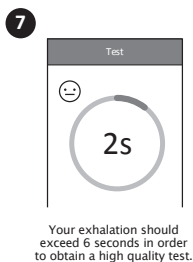
PERFORM A LUNG FUNCTION TEST



Take a slow deep breath – as deep as you can.



Close your lips **around** the opening of the turbine.

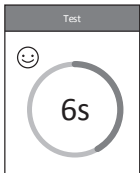


Blow as hard and as fast as you can into the mouthpiece.

PERFORM A LUNG FUNCTION TEST

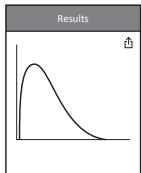
BATTERY CHECK

8



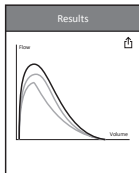
Keep going until you have completely emptied your lungs.

9



You should rest 15 to 30 seconds before starting a new test.

10



You can share the test via e-mail.

Perform a minimum of 3 tests for high quality results. The app displays the best result.

Settings

Battery: 100 %

Open app settings to check battery levels.

INDICATIONS FOR USE

Air Next is intended to be used by:

- Healthcare professionals trained to perform spirometry tests on patients of age ≥ 5 years old, > 10 kg and ≥ 110 cm.
- Adults trained by healthcare professionals ("competent adults"). Competent adult can assist a child who is ≥ 5 years old, > 10 kg and ≥ 110 cm.

Air Next is intended to perform basic lung function and spirometry testing.

The actual diagnosis shall be done by a healthcare professional so home use is only for indicative purpose.

GENERAL INFORMATION

Air Next works with iOS and

Android devices and connects via bluetooth. Air Next is powered by 2×1.5 V AAA alkaline batteries. If the batteries are replaced or when the device is discarded, dispose the device as electronic waste.

Air Next is designed to work with single-use NuvoAir disposable turbines. When performing a spirometry test, the user exhales into the turbine. The air-flow generated sets a rotor in motion. Air Next registers the speed of the spinning rotor, converts it and transfers the data via Bluetooth to the smartphone app.

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 Healthcare professional.

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

Air Next 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 Next 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 and ETSI's EN 300 328. It is a medical device class IIa ("two a") product. Air Next is constantly controlled during its production, therefore the product conforms to the essential requirements set by the Council Directive 93/42/EEC for medical devices.

- Use only with iOS and Android

devices specified on our website www.nuvoair.com.

- Use only in environments specified in this user manual.
- Do not expose to liquids.
- Air Next is not made with natural rubber latex.
- Should you lose the battery hatch with required and device specific information on it, the guarantee will no longer be valid and NuvoAir cannot provide further support or guarantee the condition or functionality of the product.

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 device directive.



IP classification: indicates that the device is protected against solid objects over 2.5 mm entering as well as falling drops of water, if the case is disposed up to 15° from vertical.



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



Manufacturer's LOT batch/lot code.



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



The symbol is used in accordance with IEC 60601-1-2:2014 (ED, 4) for products including radio transmitters and in accordance with EN 300 328.



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



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 interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC ID Identification showing traceability to FCC compliance.

Caution: Federal law restricts this device to sale by or on the order of a physician

OPERATING ENVIRONMENT

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

Air Next 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.

NUVOAIR DISPOSABLE TURBINE

Air Next is designed to be used with NuvoAir disposable single use turbines. The disposable turbine is indicated for single use single patient only. The 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 use turbine cannot be used to perform a spirometry test on another individual (person). You can purchase new single use turbines at www.nuvoair.com

CAUTION: RISK OF CROSSCONTAMINATION

Each new individual that uses Air Next shall use a new unused disposable NuvoAir disposable turbine. If the turbine is not

replaced between individuals there is a high risk of infectious cross contamination.

AIR NEXT TESTS PARAMETERS SUCH AS:

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.

PEF (Peak Expiratory Flow) The maximum flow rate (l/s) during a forced maximal expiratory effort after a full inspiration.

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 perform up to 8 tests.

Displayed test are compared to a reference table (GLI) and displayed as percent predictive value (%pred.).

The reference used in Air Next uses expected normal lung function values such as for FEV1, FVC, FEV1/FVC and PEF are based on ethnicity, gender, age and height. Interpretation of spirometry results should be made by a physician or allied health care professional with sufficient training in the performance and interpretation of spirometry.

Note: Home use of Air Next is intended only for indicative purpose. Interpretation of the test results and diagnosis shall be done by a healthcare professional.

MAINTENANCE

Handle Air Next 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 Next 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 batteries of Air Next are replaceable.

ACCESS TO BLUETOOTH

Enable Bluetooth on your mobile device in order to pair with the Air Next. You can enable Bluetooth in your mobile device settings. Check your device manual on how to do this.

ELECTROMAGNETIC COMPATABILITY

Test	Standard	Class/ Severity level	Test result
Emission (IEC 60601-1-2 section 7.2)			
Radiated emission Frequency range: 30 - 1000 MHz	CISPR 11	Group 1 Class B	Complies
Immunity (IEC 60601-1-2 section 8.9)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	10.0 V/m 80 MHz + 2.7 GHz, 80% AM, 1 kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies (Table 9), from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies

BLUETOOTH PROXIMITY

Make sure that the Air Next is within the Bluetooth proximity of your phone. If your phone is too far away from the Air Next, the connection could be lost.

FCC RADIO FREQUENCY INTERFERENCE STATEMENT

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. 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 or more 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.

NuvoAir is not responsible for any radio or communication interference caused by using other than specified or recommended cables and battery or by unauthorized changes or modifications to this equipment. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

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 interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

TROUBLESHOOTING

- Make sure that the NuvoAir Disposable Turbine is correctly inserted into Air Next.
- Make sure that the turbine is not spinning before you do a test.
- Make sure that Air Next has sufficient battery levels.
- Make sure that Bluetooth is enabled on your mobile device.
- Make sure the app is allowed to use Bluetooth.
- The device can be affected by its environment if it is too bright. Try dimming the light or move to a darker location.

TECHNICAL FEATURES

Environment of use	All settings
Patient Population	Adults and pediatric patients over 5 years old
Technology for measure flow and volume	Bidirectional turbine with infrared interruption
Energy Type	Two AAA 1.5V Alkaline batteries
Physical Configuration	Touchscreen on smartphone or tablet
Operating environment	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 ALT: ≤ 5000 m
Dimensions	98 x 62 x 26 mm
Weight	75g
Volume accuracy	±3% of reading or ±0.050 L, whichever is greater
Volume range	0.5-8L

Flow range	0-14L/s
Flow accuracy	±5% or 200 mL/s
Flow resistance	<0.5 cmH ₂ O/L/s
Communication	Bluetooth
Coaching	Display of flow-time curves, timer and effort during test
Life expectancy	10 years
Regulations applicable:	MDD 93/42 /EEC ISO 26782 ISO 23747 Electrical Safety IEC 60601-1 Electro Magnetic Compability IEC 60601-1-2 EN 300 328 FCC Part 15, Subpart B, C
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B

NuvoAir AB

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NuvoAir 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.nuvoair.com

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