NUVOAIR

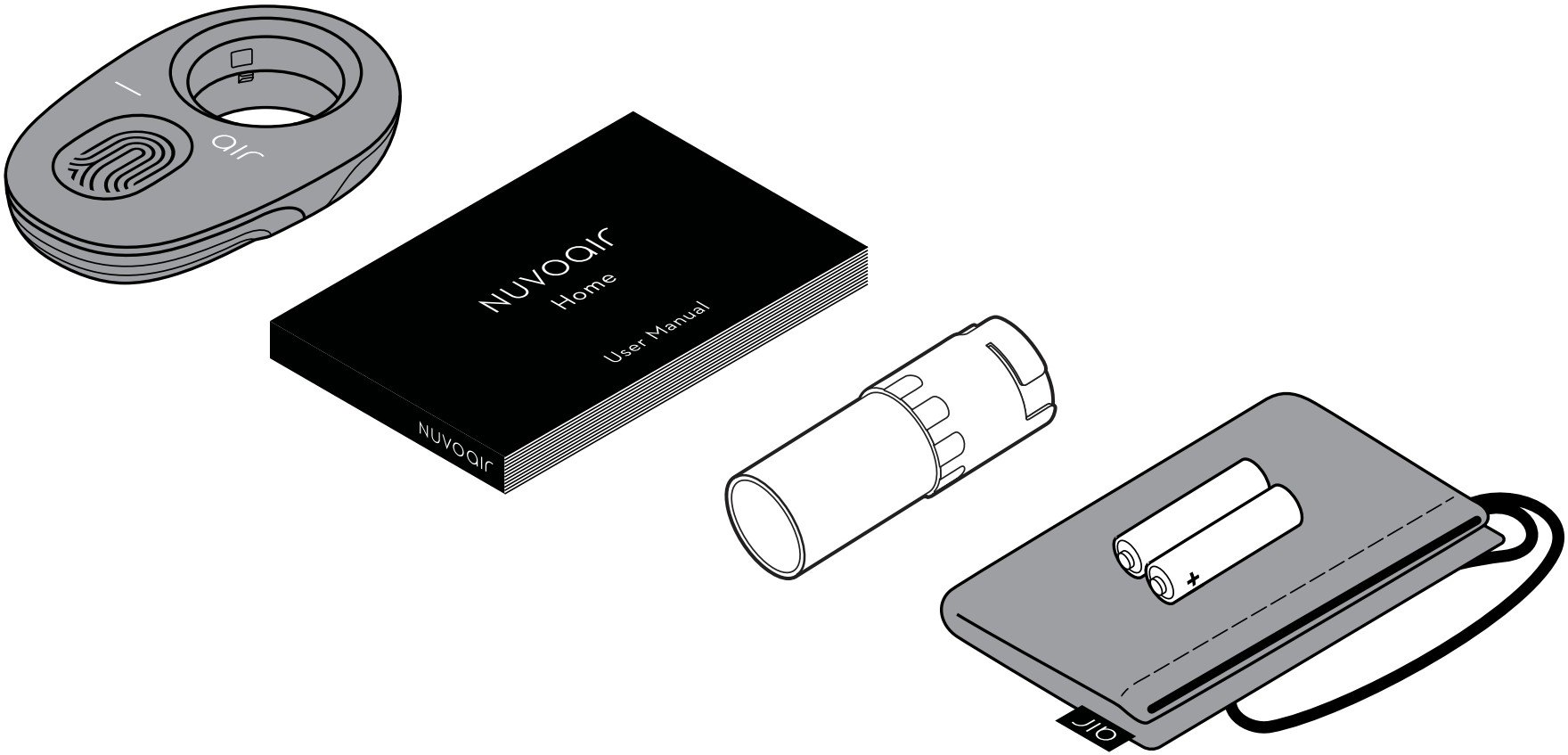
Home

User Manual

EN

WHAT'S IN THE BOX

Air Next v 1.0



ASSEMBLY OF YOUR DEVICE

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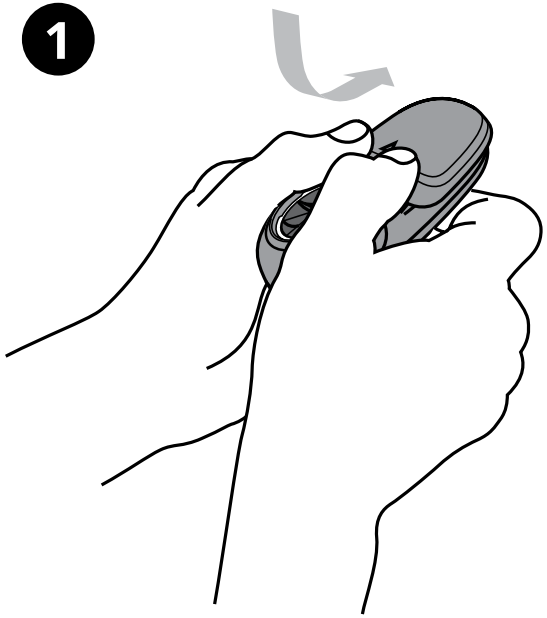
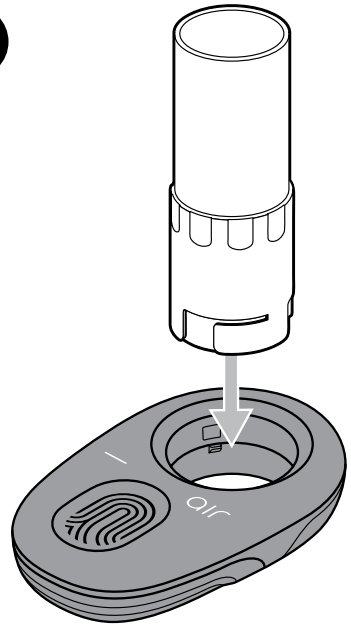
1



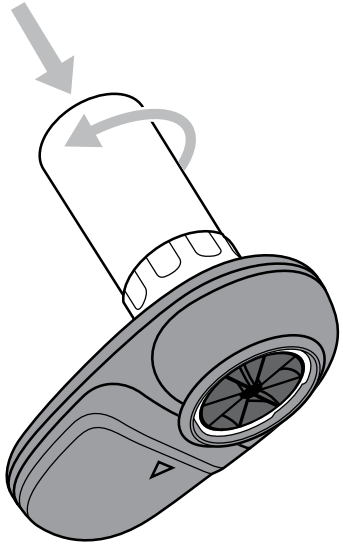
Open the battery cover by pressing down and pushing with your thumbs. Insert the 2 AAA 1.5V batteries, and put back the cover.

2



Insert a new turbine by sliding it through the device.

3



Turn the turbine clockwise until it locks into place.

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SETTING UP YOUR APP

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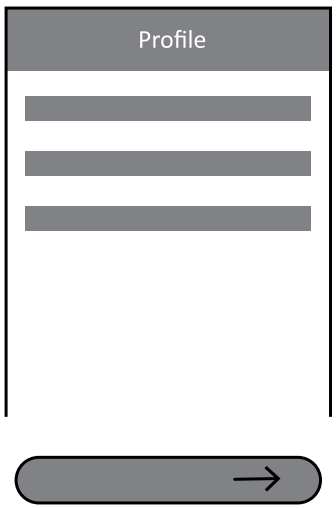
Download on the App Store

GET IT ON Google Play

Download the NuvoAir Home app from Google Play store or AppStore to your smartphone.

5



Open the application, create an account and follow the instructions on the screen.

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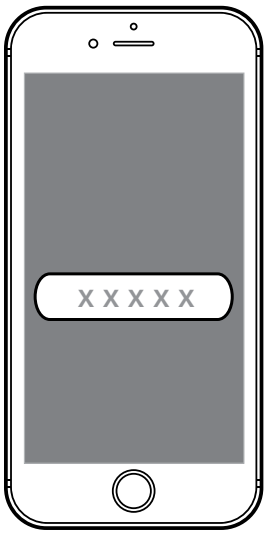

Enter your provider code to access your mobile application

SETTING UP YOUR APP

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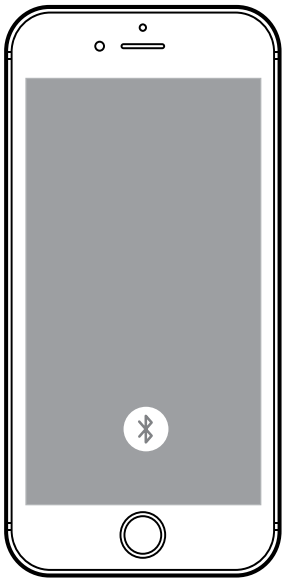
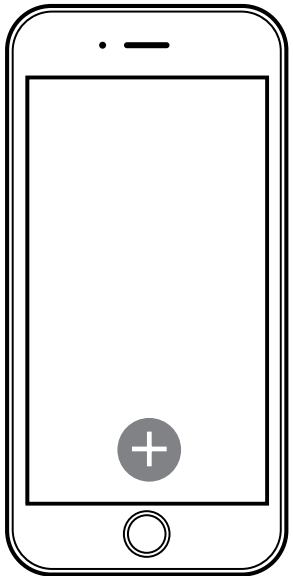


Make sure Bluetooth is active on your smartphone.

Allow the NuvoAir Home app access and use Bluetooth.

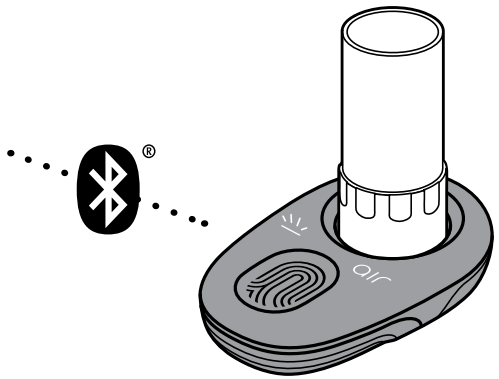
8



Press the blue + button at the bottom center of the screen.

Select Lung Function Test (Spirometry).

9



The phone will look for the spirometer. Select the spirometer.

The spirometer will light up once a connection is established.

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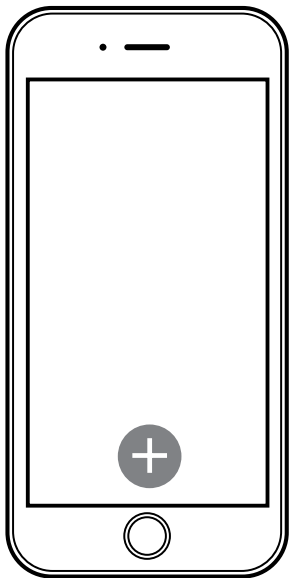
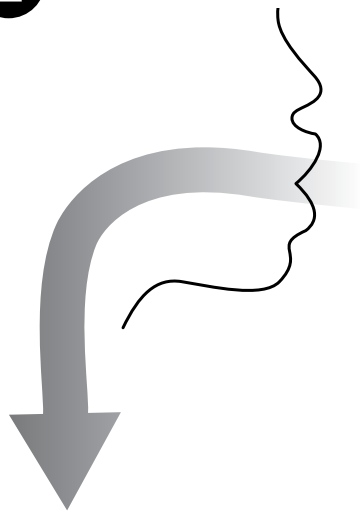
PERFORM A LUNG FUNCTION TEST

1



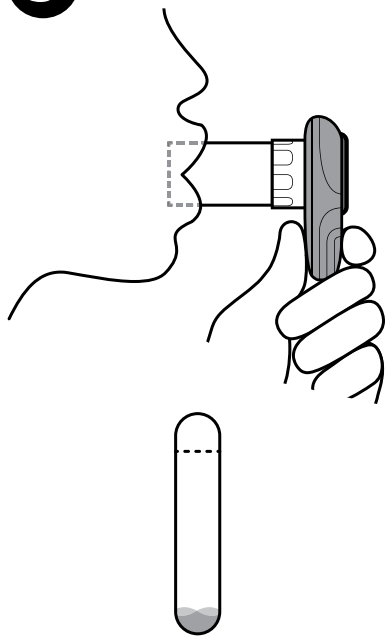
Start spirometry test by pressing the plus button.

2



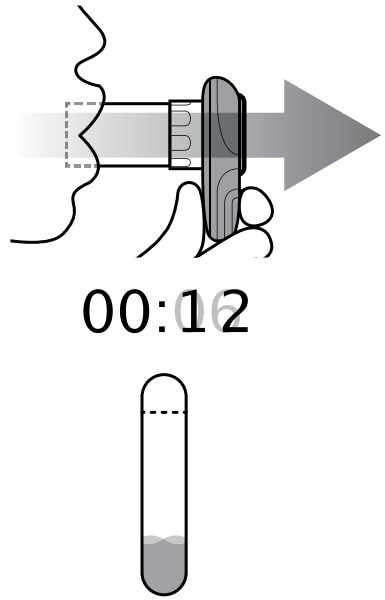
Take a deep breath - as deep as you can

3



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

4



Exhale as **hard and** as **fast** as you can through the turbine. The counter starts as you exhale.

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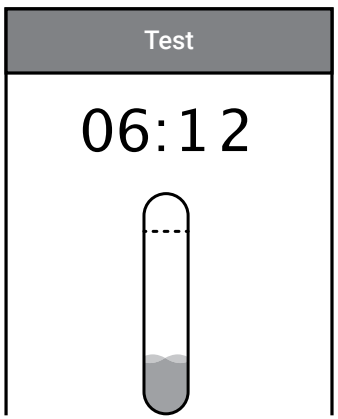
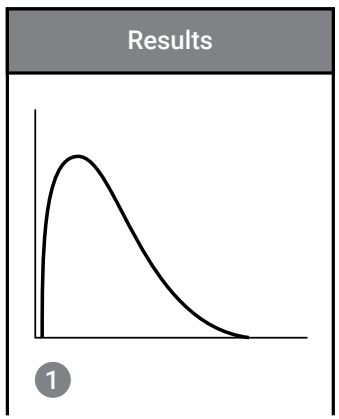


Your exhalation should exceed 6 seconds to obtain a high quality test.

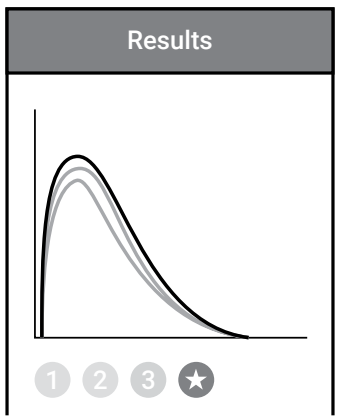
Keep going until you have completely emptied your lungs.

6



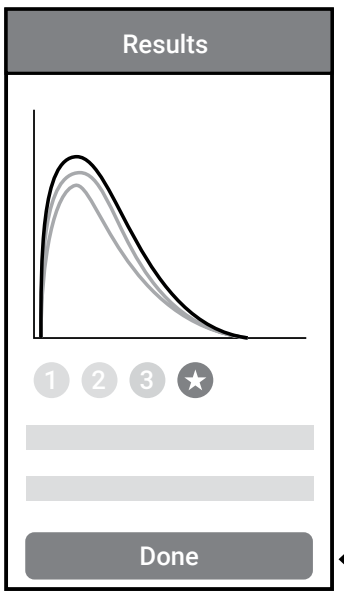
Rest for 15-30 seconds before starting a new test.

7



Do at least 3 tests for high quality results. The app will display the best results under the star tab.

8



Save the spirometry session by pressing Done. Results are automatically shared with your clinicians through the provider code. To share a pdf, go to the detailed results and click share.

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DATA SHARING

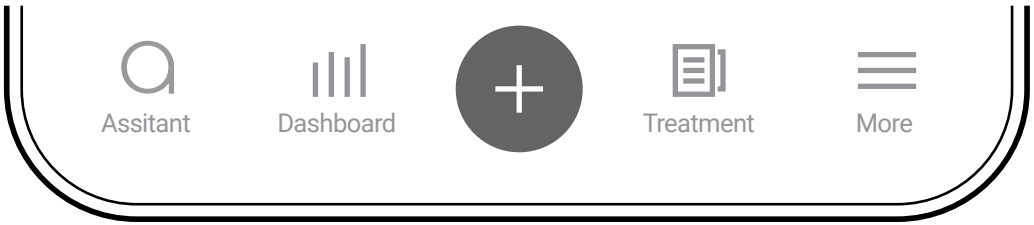
1

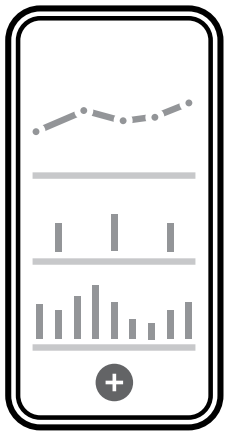
Your data is shared with your caregiver through the unique provider code entered.

Your caregiver can check your data remotely through the caregiver portal.

Contact support@nuvoair.com if you would like to stop sharing data with your caregiver.

NUVOAIR HOME APP STRUCTURE





5 SECTIONS

The NuvoAir Home App has 5 main sections for navigation.

From left to right

1. **ASSISTANT**
2. **DASHBOARD**
3. **+ BUTTON**
4. **TREATMENT/RESULTS**
5. **MORE MENU**

1. ASSISTANT

Insights generated by the NuvoAir Home are found under the Assistant tab.

2. DASHBOARD

The Dashboard shows historical data for saved results and entered information.

Two main views: Trends & Results.

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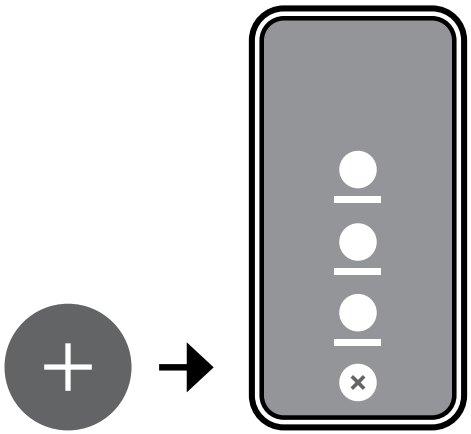
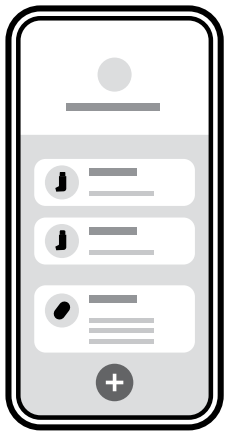


3. + BUTTON

The round blue + Button opens up a menu of possible actions

This is where you can actively add information about your progress, whether it's about updating a treatment change or recording your health parameters, e.g. taking a spirometry or answering a symptoms questionnaire.

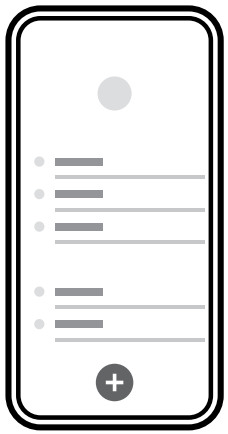


4. TREATMENT/RESULTS

Under the Treatment tab, added medications and treatment items are listed.

If NuvoAir Home has a disease specific module activated, in which a Treatment or Action Plan is available, the Treatment/Action Plan will be shown here.

If this feature is not activated, this tab will list results instead.



5. MORE MENU

Under the More menu, functionality & features used less often can be found. The More Menu includes subsections like:
Settings, Connected Devices, User Profile, Data Sharing, About the App, Contact information and more.

INDICATIONS FOR USE

NuvoAir Home is intended to perform lung function measurements and to be used in the self-management and monitoring of diseases affecting the respiratory system.

NuvoAir Home interfaces and collects data and information from other devices and databases to function as a platform for the self-management and monitoring of diseases affecting the respiratory system.
NuvoAir Home enables users to share data remotely with their caregivers by means of a web portal.

INTENDED USERS

NuvoAir Home is intended to be used by patients diagnosed with a respiratory disease who are older than 5 years of age, have a body weight of > 10 kg and are ≥110 cm tall.

GENERAL INFORMATION

NuvoAir Home app works on iOS phones (iPhone 6, and above / iOS version 12 and above) and Android Phones (Android smartphones ≥25.000 Antutu Score and Android OS versions 5.0 and above). The Air Next spirometer can only be used with mobile devices that have Bluetooth connectivity.

When doing a spirometry test, the user exhales into the turbine. The airflow 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.

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

Air Next is constantly controlled during its production, the product conforms to the essential requirements set by the Council Directive 93/42/EEC for medical devices.

- Use only with compatible iOS and Android devices specified on our website:
  www.nuvoair.com
- Use only in environments specified in this user manual.
- Do not expose the device 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 offer further support or guarantee the condition or functionality of the product.

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NUVOAIR DISPOSABLE TURBINE

Air Next is designed to be used with NuvoAir disposable 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, to avoid incorrect functioning and possible damage. The presence of any impurities such as hair, sputum (coughed up a mixture of saliva and mucus), threads etc, within the body of the turbine sensor may seriously affect the accuracy of the measurements.

SAFETY WARNINGS

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.

Users with visual impairment may need support when using the mobile application.

Children younger than 13 years of age shall be surpervised by trained adults when using NuvoAir home.

NuvoAir disposable turbines are indicated for single patient single use only.

Air Next is not intended for use in an operating theatre nor in the presence of inflammable liquids, or inflammable anaesthetic gases (oxygen or nitrogen).

The product is not intended to be used as a diagnostic device.

Users shall use a treatment/action plan given by their Healthcare professional in the treatment/action plan feature of their NuvoAir Home mobile application.

Treatment/Action plans shall be filled in the presence of or with the support of a healthcare professional

Users must either receive training on how to do correct spirometry tests during onboarding or have (evidence of) prior training.

CONTRAINDICATIONS

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 (*heart and blood vessels*) status, unstable angina (*chest pain*), recent myocardial infarction (*heart attack, within one month*) or pulmonary embolism (*blood clot in the lung*), haemoptysis (*coughing up blood*) of unknown origin, recent pneumothorax (*collapsed lung*), thoracic, abdominal or cerebral aneurysms (*weak blood vessels in your chest, stomach or head*), recent thoracic (*chest*), abdominal (*stomach*) or eye surgery, acute disorders such as nausea or vomiting, severe respiratory distress, physical limitations, cognitive impairment, dementia.

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 fulfil 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.

EN

OPERATING ENVIRONMENT

NuvoAir Home mobile software and the Air Next spirometer are intended to be used by patients in a home setting (both indoors and outdoors), the web-based portal has been designed for use in a doctor's office, and in a hospital setting.

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.

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.

AIR NEXT MEASURES 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 among tests performed in a session.

The recommended number of tests per session is three (3) and the user should not do more than eight (8) tests in a row.

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

The predicted reference values for FEV1, FVC, FEV1/FVC and PEF used in NuvoAir Home are based on ethnicity, gender, age and height.

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

ACCESS TO BLUETOOTH

Enable and allow use of Bluetooth on your mobile device to pair with the Air Next.
You can enable Bluetooth in your mobile device settings. Check your smartphone's manual on how to do this.

BLUETOOTH PROXIMITY

Make sure that the Air Next is within 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

The Air Next Spirometer has been tested and found to follow the limits for a Class B digital device, under part 15 of the FCC Rules. These limits are designed to give 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 following the instructions, may cause harmful interference to radio communications. But, no guarantees exist that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be figured 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 move 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 use 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.

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ELECTROMAGNETIC COMPATIBILITY

Test	Standard	Class/Severity Level	Test Result
Emissions (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 electro-magnetic 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 (18Hz or 217 Hz), FM 1 kHz	Complies

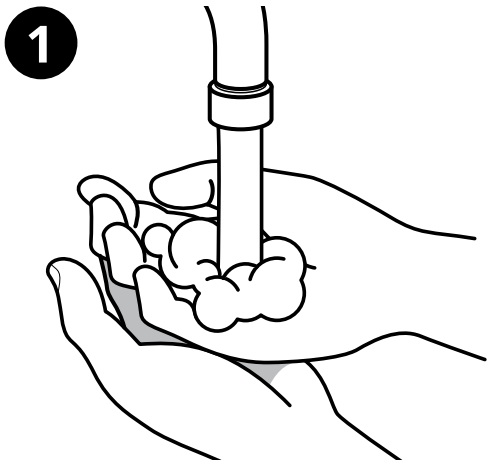
MAINTENANCE

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 is powered by 2 x 1.5 V AAA alkaline batteries. The batteries of Air Next are replaceable. If the batteries are replaced, they shall be disposed according to local regulation, when the device is discarded, dispose the device as electronic waste. Battery levels can be checked under settings in the mobile application.

Air Next is designed to work with single-use NuvoAir disposable turbines.
You can buy new single use turbines by visiting www.nuvoair.com

For technical assistance on your current device or for information on how to buy a new device go to NuvoAir.com

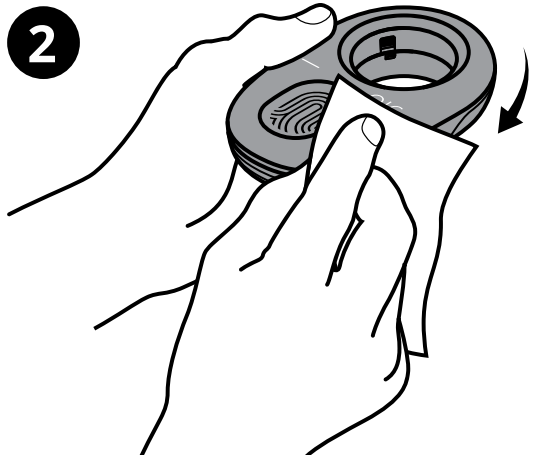
CLEANING & DISINFECTING



The Air Next device must be cleaned and then disinfected regularly.

The device should not be submerged in liquid and detergent (liquid or otherwise) should not be used on the device.

Before beginning the cleaning and disinfection procedure, wash hands thoroughly with soap and water.



Clean using a damp cloth without any detergents.

Wipe all accessible surfaces of the device to remove all visible contaminants using moderate pressure. Make sure no excess liquid contained within the wipe enters the sensor openings as this could cause damage to the electronics inside the device.

Wipe for at least 2 min.

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CLEANING & DISINFECTING

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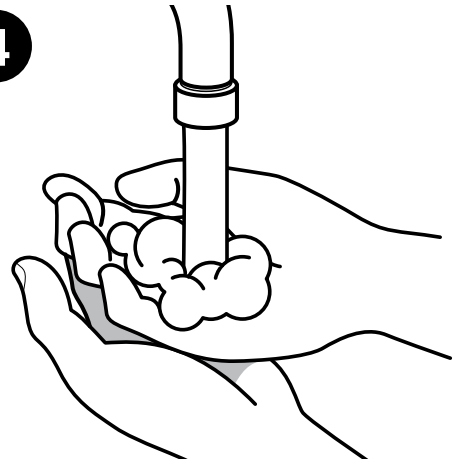
NOTE: Follow wipe manufacturer's instructions for use carefully. Usually, when wipes are being used for the first time in a day the container should be shaken and the first wipe should be removed from the container and discarded.

For a successful disinfection, open the battery hatch (see p. 4) and use at least three fresh intermediate-level disinfectant wipes (Sodium Hypochlorite) to wipe over all accessible surfaces of the device using moderate pressure.

Show special attention to seams and inner edges. Wipe for a contact time twice (2x) as long as the one recommended by the wipe manufacturer to achieve disinfection.

CAUTION: Care must be taken to avoid any electrical parts, including the batteries, during wiping.

4

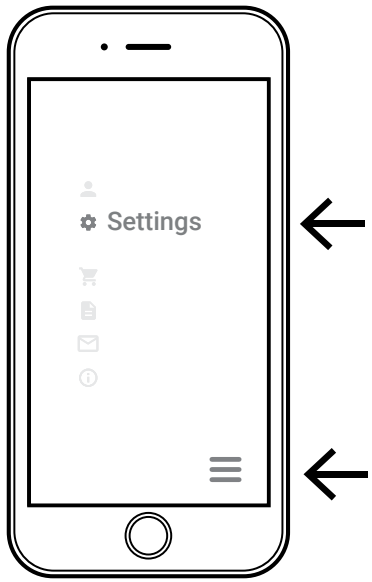


After the cleaning and disinfection procedure and before handling the cleaned and disinfected parts again for packing and storage, wash hands thoroughly.

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 enough battery levels.
- make sure your bluetooth connection is on
- Make sure the app is allowed to use Bluetooth.
- The device can be affected by its environment if too bright. Try dimming the light or move to a darker location.

BATTERY CHECK



Under app settings, choose Air Next to check battery levels of your spirometer.

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TECHNICAL FEATURES

Environment of Use	All settings
Technology for Measure Flow and Volume	Bidirectional turbine with infrared interruption
Energy Type	2 x AAA 1.5V Alkaline batteries
Batteries Life Expectancy	1 year
Physical Configuration	Touchscreen on smartphone or tablet
Operating Environment	T: min +10°C/max +40°C RH: min 10%/max 95% ALT: max 2000m
Conditions of Storage	T: min -20°C/max +60°C RH: min 10%/max 95% P: min 500 mBar /ALT: ≤ 5000m
Dimensions	98 x 62 x 26 mm
Weight	75 g
Volume Accurancy	±3% of reading or ±0.050 L, whichever is greater
Volume Range	0-10L

TECHNICAL FEATURES

Flow Range	0-16 L/s
Flow Accuracy	±5% or 200 mL/s
Flow Resistance	<0.5 cmH2O/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, Class B

EN

NuvoAir AB

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SE-11457 Stockholm, Sweden

NuvoAir AB guarantees that the product is free from material and fabrication defect, under normal use conditions and under the 2 year warranty statement period.

For more information about the warranty, for reclamation or to give feedback, please visit www.nuvoair.com or send an email to support@nuvoair.com

CE
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www.nuvoair.com