



AirSonea™ Wheeze Monitor Operator's Manual

www.airsonea.com/getstarted

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Important Things to Know About Your AirSonea™

Intended Use

The AirSonea is intended to detect and measure wheeze in diagnosed asthmatics. The device is intended for pediatric and adult use.

Components

- AirSonea Device
- Controller APP
- USB Power Cable
- AirSonea Operator's Manual
- *Consumer supplied phone*

CAUTIONS:

Please read the entire AirSonea Operator's Manual before using for the first time.

- Before use for the first time, completely charge your AirSonea.
- AirSonea will not record a measurement while charging.
- Always close sensor head when charging the battery.
- When the AirSonea is used to measure wheezing in lung conditions such as asthma, the user should be under the care of a physician or other licensed healthcare professional. A licensed health care professional's advice is required to understand the meaning and

importance of the measurements you get with AirSonea.

- The AirSonea is not intended for use to establish the diagnosis of asthma.
- The AirSonea will not return a WheezeRATE value if you are in an area that does not have wireless coverage. Never delay treatment to obtain a WheezeRATE measurement if you are having symptoms of asthma.
- The AirSonea is not intended for use with children under the age of two years.
- Consult your physician or licensed health care professional to obtain advice on the interpretation of the WheezeRATE value.
- No matter what your WheezeRATE measurement is, signs and symptoms of chest tightness, shortness of breath, coughing and wheezing should be addressed by following your physician's advice.
- Follow instructions carefully in order to obtain a correct measurement.
- Always perform your measurement in a quiet place.
- The device may not operate correctly if used in a noisy environment.

- The device may not operate correctly if there is too much movement during the measurement.
- The AirSonea should be operated by users 18 years old or children under adult supervision.
- The USB port at the bottom of the device is for charging AirSonea only.

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.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Understanding WheezeRATE

A WheezeRATE (Wz%) measurement is the percent of time you are wheezing during the 30 second measurement. Wheezing is one of the primary signs and symptoms of asthma.

- People with asthma should be under the care of a physician or other qualified healthcare provider.
- Consult your physician or healthcare provider to obtain advice on the interpretation of the WheezeRATE value.

- If wheeze is detected and you are not under the care of a healthcare professional you should contact a physician.
- If wheeze is detected and you are under the care of a healthcare professional always follow their advice and treatment plan.

How Your AirSonea Works

The device uses a contact sensor placed near the trachea to collect breath sounds for analysis. The breath sounds are captured and digitized. Data are transferred via Bluetooth® controller to the target host mobile platform. The platform then transfers the file to the server via the cellular data network or WiFi (choice is dependent on user platform preferences). The file is received by the server using an error corrected transmission method and is processed by the Server for analysis of WheezeRATE.

The results are sent back to the mobile platform for viewing of the WheezeRATE value.

Description

AirSonea

1. LED Process Indicator
2. USB Charging Port (bottom)
3. Built-in Rechargeable batteries
4. Bluetooth® connectivity
5. Power Slide button
6. Sensor



FIGURE 1: Device

What to do when you first get the AirSonea

PLEASE READ THE ENTIRE AIRSONEA OPERATOR'S MANUAL BEFORE USING FOR THE FIRST TIME.

*If you do not understand the instructions, email us at **service@isoneamed.com**.*

Pairing the AirSonea to Your Smartphone

Use the Quick Start card that came with this product or go to **www.AirSonea.com/GetStarted** to download the AirSonea App.

This process will connect your AirSonea device with your phone. This will allow the AirSonea and phone to communicate with each other.

1. Power on the AirSonea by sliding the **Power Slide button**.

This will activate the AirSonea Phone App on your phone. Once this is done, the AirSonea and your smartphone have successfully “paired” and communication is established. You are now ready to take a WheezeRATE measurement.

The registration of your AirSonea will occur automatically with your first measurement.

Taking a WheezeRATE Measurement

Taking a WheezeRATE measurement requires the proper placement of the sensor on your neck.

*On screen information in the form of **HINT screens** (Figure 2) display information on how to make a measurement. There is also an ambient noise indicator that alerts the user if the environment is too loud to record a measurement.*

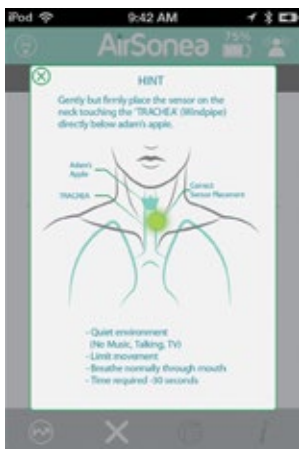


FIGURE 2: HINT Screen

Instructions for taking a measurement

1. On the AirSonea slide the Power Slide button to the ON position extending the Sensor head.

- The AirSonea Phone App will automatically open to the [Home Screen \(Figure 3\)](#) on your smartphone.
- The LED on the AirSonea will be solid blue, indicating it is ready to measure.



FIGURE 3: Home Screen

2. To start the measurement place the AirSonea to your neck and breathe normally through an open mouth. [\(Figure 4\)](#)



FIGURE 4: Proper Placement of Sensor

3. When the Sensor is placed properly, swipe the Start button in the center of the phone screen. (Figure 5)



FIGURE 5: Start Measurement Screen

4. To ensure proper placement the AirSonea will perform a Pre-Screening Test for 5 seconds. (Figure 6)

The AirSonea listens to your breath sounds for 5 seconds.



FIGURE 6: Pre-Screening Test

As you continue to hold the AirSonea in the proper position the AirSonea will begin the WheezeRATE Measurement. (Figure 7)

The AirSonea Screen on your smartphone will count down the seconds remaining for the measurement. Continue to breathe normally through an open mouth, limiting your movement, and avoid talking or other loud noises.

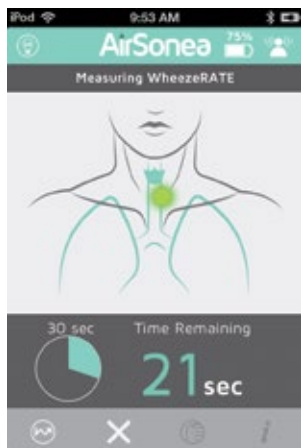


FIGURE 7: WheezeRATE
Measurement Screen

When the measurement is complete you will get audible and visual instructions to remove the AirSonea from your neck. The AirSonea Phone App will now transmit your recording. (Figure 8)

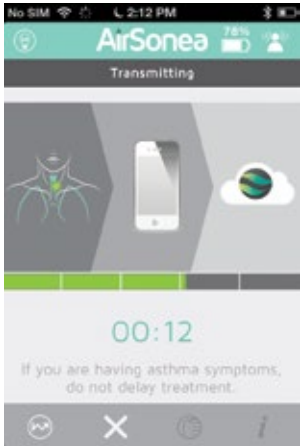


FIGURE 8: Transmitting Data Screen

The data transmission screen will display the progress during the transmission. The recording is analyzed and a WheezeRATE value is returned and displayed on the AirSonea phone app. (Figure 9)

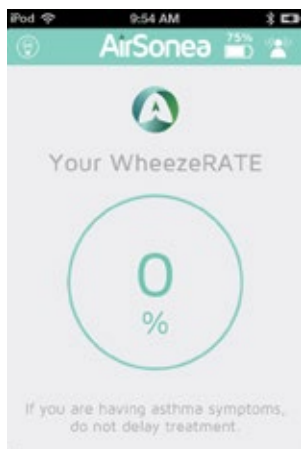



FIGURE 9: WheezeRATE Value

CAUTIONS:

- The AirSonea will not return a WheezeRATE value if you are in an area that does not have wireless coverage.
- Never delay treatment to obtain a WheezeRATE measurement if you are having symptoms of asthma.
- If you are having shortness of breath or chest tightness do not delay treatment regardless of the WheezeRATE measurement.

Troubleshooting

Screen Hints, Cautions and Error Correction

Instructions in the form of: [Hints](#), [Cautions](#), [Error and Corrective Action messages](#) are always available on the AirSonea Phone App. They are found by tapping on the  in the top left side of phone screen.

Caution screens display any time there is an error during the measurement. These caution screens explain the error and provide information for correcting the error.

The HINT Screen

The HINT screen is available on any of the screens. These screens provide instructions and guidance while measuring your WheezeRATE.

(Figure 10)

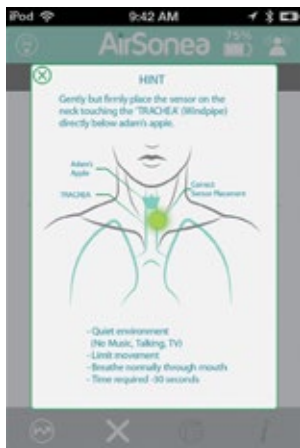


FIGURE 10: HINT Screen

Caution Screens

Caution screens appear when there has been an error during the pairing of the two devices, if there was an error during the measurement, or if an error during transmission of the data over the network occurs. These caution screens explain the error and also instruct you on the corrective action to take. They include:



FIGURE 11: Unable to pair devices

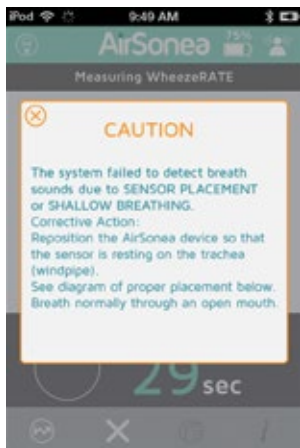


FIGURE 12: Sensor Placement Error

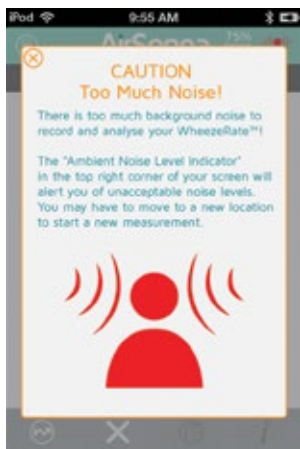


FIGURE 13: Too Much Noise



FIGURE 14: Too Much Movement

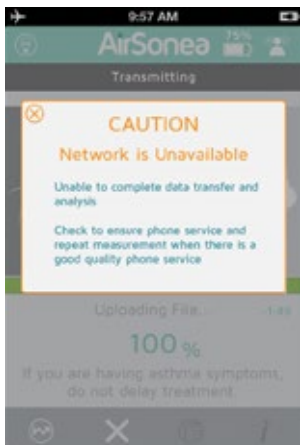


FIGURE 15: Transmission Failure

Maintenance

Should you have a problem with your AirSonea, review the Maintenance and Troubleshooting Sections in this manual.

If the problem is not resolved, email us at **service@isoneamed.com**.

CAUTION:

- Do not immerse the AirSonea in any liquid.
- The USB port on the bottom of the device is for recharging of the internal batteries.
- The device may not operate properly in a noisy environment.
- Do not remove, change or otherwise tamper with battery. Doing so may cause injury.
- Device contains a Lithium-Ion polymer battery. Dispose of according to local regulations.
- Do not expose the device to extreme temperatures—very hot or very cold, humidity, dust or direct sunlight. AirSonea should be used in ambient temperatures between 10 - 45°C.
- Do not drop the device or treat it roughly in any way.

- Never attempt to repair the device yourself. Any unauthorized opening of the device invalidates all guarantee claims.

Recharging the batteries

The USB cable provided is inserted into the USB port on the bottom of the AirSonea device.

- AirSonea will not record a measurement while charging. Disconnect AirSonea from charging cable before attempting a measurement.
- Always close the sensor head when charging the battery.
- The built-in Li-Ion 500 mAh is a rechargeable battery.
- To fully charge battery requires 4 hours.
- The battery last approximately 100 measurements per charge.

Cleaning Procedure

To clean the sensor head, use a moist cloth with detergent or soap and rub gently until clean.

Disinfecting Procedure

To disinfect the sensor head, use a moist cloth with 70% isopropyl alcohol and rub gently for one minute.

Specifications

AirSonea is a non-sterile product

Technical Specifications

AirSonea™

Physical Dimensions

Weight: 3.6 oz. (102g)

Body: 4.3 in. x 1.9 in. x 1.0in.

(110mm x 49mm x 25mm)

One external USB 2.0

One rechargeable 500mAH Li-Ion
Battery pack

100 measurements per charge

Memory display capacity:









10 last measurement

Operational Environment

- Ambient Operating Temperature
Range: 10 – 45°C
- Storage Temperature Range:
10 – 55°C
- Humidity: 10 – 90%

Care and Safety Information

- Do not remove, change or otherwise tamper with battery. Doing so may cause injury.
- Do not expose the device to extreme temperatures, humidity, dust or direct sunlight.
- Do not drop the device or treat it roughly in any way.
- Never attempt to repair the device yourself. Any unauthorized opening of the device invalidates all guarantee claims.
- Device contains a Lithium-ion polymer battery.
- If battery becomes damaged, handle with care:
 - Do not use the device.
 - Do not transport the device.
 - Dispose of according to local regulations.

Symbol	Description
	Company Trade Name
	Device Trade Name
P/N	Product Number
Lot No. = S/N	Lot Number/ Serial Number
Manufacturing Date	Manufacturing Date
	Read package insert before use
	Separated collecting of electrical and electronic equipment
	Manufacturer Details
	CE Mark
	RF electromagnetic energy
	Keep dry

LIMITED WARRANTY

This Limited Warranty shall not become effective unless the Original Purchaser completes Section 11 below and returns the completed Limited Warranty Form to ISONEA at the address set forth in Section 8 within 30 days of purchase.

1. Limited Warranty

ISONEA warrants that the product(s) described in Section 11 below (the “Product”) shall be free from material defects in workmanship and materials, according to manufactures specifications under normal use from the date of original purchase of the Product, for the period set forth in Section 2 below (“Warranty Period”), except as otherwise stated herein. The Original Purchaser’s sole and exclusive remedy and entire liability of ISONEA under this Limited Warranty will be, at ISONEA’s option at no charge to the Original Purchaser.

2. Warranty Period

The Product and its components, excluding batteries and accessories, will be covered for a period of 1 year from the date of purchase.

3. Replacement Parts and Product

ISONEA may, at its option, replace any defective Product, part or component thereof with any reconditioned product or part that ISONEA reasonably determines is substantially equivalent or superior in all material respects to the defective Product or part. Replacement products and parts will be warranted for the remainder of the Warranty Period or 90 days, whichever is longer, and subject to the same limitations and exclusions set forth in this Limited Warranty. All products and parts replaced by ISONEA shall become property of ISONEA upon replacement.

4. Exclusions

This Limited Warranty does not cover:

- a. Shipping costs.
- b. Products that, in ISONEA's judgment have been subjected to abuse, alteration, modification, tampering, negligence, misuse, faulty installation, lack of reasonable care, accident, or other external causes.
- c. Product whose serial numbers have been altered, tempered with, defaced or removed.
- d. Products that have been subjected to improper or incorrectly performed maintenance or repair.
- e. Product not used according to manufacturer specifications.

5. Submitting Claim

Upon discovery of any defect in Product, the Original Purchaser shall notify ISONEA in writing at the address set forth in Section 8 below. ISONEA shall evaluate the product within a reasonable time period, and if ISONEA determines that defect in question is covered by this Limited Warranty, ISONEA shall replace the product or part in question as soon as practicable.

6. Disclaimers

EXCEPT FOR THE LIMITED WARRANTY SPECIFIED HEREIN, THE PRODUCT IS PROVIDED "AS-IS" WITHOUT ANY WARRANTY OF ANY KIND WHATSOEVER INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. IF ANY IMPLIED WARRANTY CANNOT BE DISCLAIMED IN ANY TERRITORY WHERE A PRODUCT IS SOLD, THE DURATION OF SUCH AN IMPLIED WARRANTY SHALL BE LIMITED TO AS EXPRESSLY COVERED UNDER THE LIMITED WARRANTY PROVIDED HEREIN. THE ENTIRE RISK AS TO THE QUALITY, SELECTION AND PERFORMANCE OF THE PRODUCT IS WITH THE ORIGINAL PURCHASER.

7. Limitation of Liability

TO THE MAXIMUM EXTENT PERMITTED BY LAW, ISONEA IS NOT LIABLE UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQITABLE THEORY FOR ANY LOSS OF USE OF THE PRODUCT, INCONVENIENCE OR DAMAGES OF ANY CHARACTER, WHETHER DIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL, RESULTING FROM THE USE OF THE PRODUCT, RELATING TO WARRANTY SERVICE, OR ARISING OUT OF ANY BREACH OF THIS LIMITED WARRANTY, EVEN IF ISONEA HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THE SOLE REMEDY FOR A BREACH OF THE FOREGOING LIMITED WARRANTY IS REPLACEMENT OF THE DEFECTIVE OR NON-CONFORMING PRODUCT OR PART. THE MAXIMUM LIABILITY OF ISONEA UNDER THIS WARRANTY IS LIMITED TO THE PURCHASE PRICE OF THE PRODUCT COVERED BY THE WARRANTY. THE FORGOING EXPRESS WRITTEN WARRNTIES AND REMEFIES ARE EXCLUSIVE AND ARE IN LIEU OF ANY OTHER WARRANTIES OR REMEDIES, EXPRESS, IMPLIED OR STATUTORY.

Some states do not allow exclusions or limitation or incidental or consequential damages, so the above limitations may not apply. This Limited Warranty provides specific legal rights, and you may also have other rights which vary from state to state.

8. Notices

All notices and other communications provided herein shall be sent to the address, fax number or email listed below:

iSonea Limited
125 South Tremont
Oceanside, CA 92054
Fax: 1-760-547-1614
Email: Service@isoneamed.com

9. Governing Law

This Limited Warranty shall be governed by the laws of California.

10. Transfer

This Limited Warranty is not assignable or otherwise transferrable without express written consent of iSonea Limited.

Warranty Registration Card

NAME

ADDRESS

EMAIL ADDRESS

TELEPHONE

NAME OF PRODUCT

SERIAL NUMBER

DATE OF PURCHASE



Suite 1 1233 High Street
Armadale, Victoria 3143
Australia
Service@lsoneamed.com

**Manufactured for:
iSonea (Israel) Ltd.**

16 Palyam Avenue, Haifa 33095 Israel

**Distributor:
Pulmosonix Pty. Ltd.**

Suite 1, 1233 High Street
Armadale, Victoria 3143 Australia

For additional information,
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9:00 AM to 4:00 PM PST
or email service@isoneamed.com