

wheezo[®]

Digital Wheeze Monitor
Model WZO01



OWNER'S MANUAL

**For monitoring use only.
Read instructions before use for wheezo® digital wheeze monitor**

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INTRODUCTION

Thank you for purchasing wheezo Digital Wheeze Monitor by Respiro. This manual provides important information to help you use the monitoring system properly. Before using this product, please read the Owner's Manual thoroughly.

Developed by leading respiratory specialists, wheezo accurately records breathing sounds and detects and analyses wheeze, a typical sign of asthma. Easy to use, the wheezo ecosystem of breath sensor, app and cloud storage provides a service to record and review your wheeze rate results and history, including symptoms and triggers and medication schedule and usage, correlated with environmental data such as weather, pollen and air quality. Over time, by eliminating guesswork and increasing your awareness and knowledge of how asthma affects you, wheezo may help you and your doctor better manage your asthma.

INTENDED USE

wheezo is intended to monitor wheeze, an abnormal breath sound and sign of airflow limitation in the lungs. It is the sound the doctor listens for with a stethoscope when examining a patient during an asthma flare-up.

wheezo is intended to monitor wheeze in adults and children over 2 years with diagnosed asthma. Adults should assist children under 14 years old. Regular use of wheezo during daily activities will help inform patients about whether their wheeze rate is increasing, decreasing or remaining stable.

GENERAL INFORMATION

wheezo works with iOS and Android devices and connects via Bluetooth®. When taking a wheeze rate, the user holds the breath sensor to their trachea (windpipe) on the lower part of the neck. The breath sensor acquires, filters and digitises the breath sounds and transfers the data via Bluetooth® to the app where it is analysed for the presence of wheeze to return a numeric wheeze rate. The app controls the recording process and provides feedback on the user's progress. All recorded data is automatically uploaded to the user's account on the secure wheezo cloud server when an active internet connection is made.



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

- Use only with iOS and Android devices specified on our website **wheezo.com**
- Use only an AC adaptor that complies with IEC 60950-1 or IEC 60601-1* for charging
- The USB port on the bottom of the breath sensor is only for charging of the internal battery
 - USB-Type A to Micro USB charging cable (in earlier models)
 - USB-Type A to USB-C charging cable (in new models)
- To prevent entanglement and strangulation, do not place the USB charging cable provided in reach of children
- Use only in environments specified in this Owner's Manual
- Do not expose to liquids
- Do not tamper with the blue sensor diaphragm
- Do not expose the device to extreme temperatures – very hot or very cold, high humidity, dust or direct sunlight. wheezo should be used in temperatures 0° – 40° C.
- Do not drop the device or treat it roughly in any way
- Never attempt to repair the device yourself. Opening of wheezo invalidates all guarantee claims
- Degraded sensors and microphones can affect performance
- The normal function of the product may be disturbed by strong Electro-Magnetic Interference. If so, simply reset the product to resume normal operation by following the instruction manual. In case the function cannot resume, please use the product in a different location
- In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2012/19/EU, do not dispose of this product as unsorted municipal waste. Follow local, state and national governing ordinances and recycling instructions reading disposal or recycling of the device

*IEC 60950-1 is the reference standard for power supplies under Information Technology Equipment. IEC60601-1 is the international basic safety and essential performance standard for electrical medical equipment and medical electrical systems.

WHAT'S IN THE BOX

wheezo Breath Sensor

Charging cable

Quick Start Guide

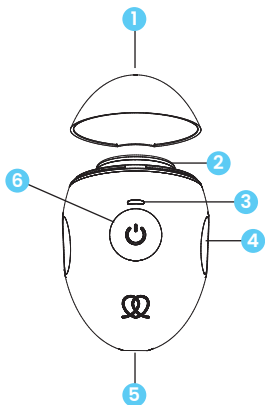


Figure 1.

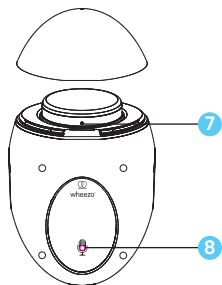


Figure 2.

1. Protective cap
2. Sensor diaphragm (applied part)
3. LED indicator
4. Finger grips

5. USB charging port
6. Power button
7. Air vent
8. Background microphone

SMART DEVICE COMPATIBILITY

Owner supplied smart device

Made for iPhone 6s and up running iOS 13 or later

Select Android devices

WHEEZE RATE PRINCIPLE

Wheezing is an abnormal breath sound which serves as physiological sign of airflow limitation in the lungs associated with asthma. Wheeze rate is the percentage of the recorded breath sounds occupied by wheeze. Monitoring and tracking wheeze rate over time may help patients and their health professional assess day to day care.

LIMITATIONS OF USE AND CONTRAINDICATIONS

wheezo is a home monitoring device not intended for diagnostic use. When wheezo is used to monitor wheezing in lung conditions such as asthma, the user should be under the care of a licensed healthcare professional. The most common causes of recurrent wheezing are asthma and chronic obstructive pulmonary disease (COPD), however any inflammation in the patient's throat or larger airways can cause wheezing. Common causes include infection, an allergic reaction or a physical obstruction such as a tumour or a foreign object that has been inhaled.

A licensed healthcare professional's advice is required to understand the meaning and importance of wheeze rate.

Vocal cord dysfunction (VCD).

wheezo may not be suitable for use by people diagnosed with VCD. VCD causing audible wheeze may interfere with the device's ability to analyse breath sounds for wheeze rate associated with lung conditions.

WARNINGS

- If the user is feeling breathless, or experiencing other symptoms, it is important to prioritise treatment over taking a wheeze rate. Do not delay treatment.
- Regardless of the wheeze rate, if the user has signs and symptoms such as chest tightness, shortness of breath, coughing or wheezing, they should always follow their healthcare professional's advice.
- In a severe asthma attack, there may be no wheeze. This is called 'silent chest' and may be life-threatening.

SETTING UP Wheezo FOR THE FIRST TIME

1. wheezo breath sensor is powered by a built-in rechargeable battery. Before using for the first time, plug one end of the USB charging cable supplied into the end of the device and the other end into a compliant AC adaptor. Charge it for up to three hours before first use. A fully charged battery typically lasts up to 20 recordings.
2. While charging, the breath sensor's LED indicator will flash green. When it is fully charged, the LED will display solid green.
3. Download the wheezo app from the App Store or Google Play and launch it to connect the breath sensor to the app.
4. Enable Bluetooth® on your mobile device. Allow the app to access and use Bluetooth® and follow the instructions on the screen.
Note: Android requires Location Services to be enabled for the initial Bluetooth® pairing.
5. Remove wheezo breath sensor's protective cap and turn it on by holding the power button down until the LED indicator flashes blue indicating it is ready to pair with your smart device.
6. When wheezo breath sensor and your smart device are paired, the LED indicator will display solid blue.
7. If you require assistance to set up your wheezo, please contact support@wheezo.com



ACCESS TO BLUETOOTH®

Enable Bluetooth® on your smart device in order to pair with wheezo breath sensor. You can enable Bluetooth® in your smart device settings. Check your smart device manual on how to do this.

BLUETOOTH® PROXIMITY

Make sure that wheezo breath sensor is within Bluetooth® proximity of your smart device. If your smart device is too far away from the breath sensor, the connection could be lost.

OPERATING ENVIRONMENT

wheezo has been designed for use in a quiet environment e.g. home, school or office. It is not designed to be used in direct air currents (e.g. wind), source of heat or cold, direct sun rays or other source of light or energy, dust, sand or any other chemical substances or performance will be affected.

TAKING A WHEEZE RATE

1. wheezo needs to be used in a quiet place. No talking, TV or music and limit movement.
2. wheezo is designed to be applied to the trachea (windpipe). Using the finger grips on the sides as a guide, firmly hold the breath sensor's blue diaphragm (applied part) to the side of your trachea on the lower part of the neck. Tap Start recording on the app and breathe normally.
3. Keep breathing normally until the app has completed the recording and analysis of your breath sounds. wheezo needs between 30 – 60 seconds to analyse your breath sounds for wheeze rate, depending on the background noise and the correct position of the sensor. If you have a blocked nose, it is recommended to open your mouth while recording.

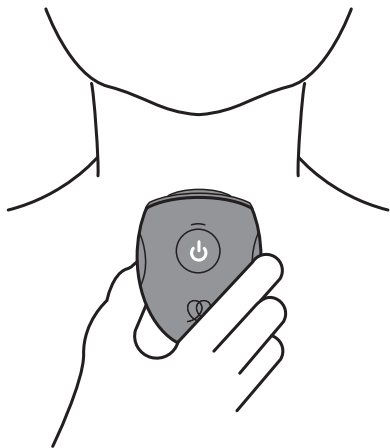


Figure 3.

4. Your wheeze rate will be displayed. Follow the instructions in the app to set up an account so you can store your history of recordings, wheeze rate results and other information securely on the cloud.
5. Turn the breath sensor off by holding the power button until the LED goes out. Note that it will automatically turn off after 2 minutes of remaining idle in order to save power.



DATA SYNCING

wheezo is capable of operating offline. The app can store 15 of the most recent wheeze rate results locally on the smart device and they will be uploaded to the cloud when the app regains an active internet connection. When the app needs to save a new wheeze rate and has already stored 15 results, the wheeze rates will be overwritten by the new wheeze rate.

LED STATUS INDICATIONS

Solid blue	wheezo breath sensor connected to smart device
Flashing blue	wheezo breath sensor searching for connection with smart device
Flashing blue & white	wheezo breath sensor searching for a smart device it has already been paired with
Solid yellow	An error has occurred
Flashing yellow	Low battery Background microphone obstructed
Solid green	Fully charged
Flashing green	Charging

MAINTENANCE & CLEANING

wheezo breath sensor does not require professional maintenance. If you have a problem you cannot resolve through reviewing this manual, email us at support@wheezo.com

Handle the wheezo breath sensor carefully. Use the protective sensor cap and store it in clean and moisture free conditions. Before use, always check that the device is free from dust, contamination or any particles. To clean the device, use a damp cloth without any detergents.

RECHARGING THE BATTERY

The built-in Lithium-Ion Polymer battery is a rechargeable battery.

Locate the USB connector on the bottom of your device. Insert the USB cable provided into the USB port. Should your device have a charge port cover, pull this out prior to charging.

Recharging the battery requires up to 3 hours. Approximately 20 wheeze rates can be performed per charge. This device requires a compliant AC adaptor with minimum output of 0.5A*.

Note: wheezo will not enter record mode during charging.

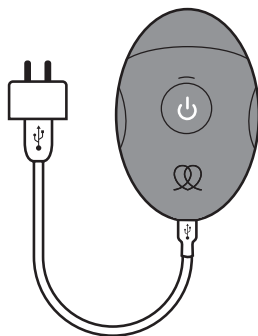


Figure 4.

*IEC 60950-1 is the reference standard for power supplies under Information Technology Equipment. IEC60601-1 is the international basic safety and essential performance standard for electrical medical equipment and medical electrical systems.

TROUBLESHOOTING

If you follow the recommended action but the problem persists, or there is unexpected operation or events, please email support@wheezo.com

Do not attempt to repair the wheezo breath sensor by yourself and never under any circumstances try to disassemble the breath sensor.

Problem	Possible cause(s)	Solution(s)
Low Battery	wheezo breath sensor battery is running low	Charge wheezo by connecting it to a USB charger using the cable provided
Breath not detected	wheezo breath sensor not positioned correctly on trachea (windpipe)	Make sure wheezo sensor is held gently to your trachea on the lower part of your neck.
	Environment is too noisy	Taking of wheeze rate should be done in a quiet environment. No talking, no TV or radio and no excessive movement
	Inaudible breath	Try opening your mouth and observe the breath sound visualiser on the app screen
Couldn't find breath sensor in the app	wheezo breath sensor is not switched on	Switch wheezo breath sensor on prior to starting a wheeze rate recording by holding the power button
	wheezo breath sensor is not paired with the smart device via Bluetooth®	Pair wheezo breath sensor to the smartphone via Bluetooth®
	Bluetooth® is not enabled on your smart device	Make sure Bluetooth® is enabled on your smart device
	wheezo breath sensor is trying to connect to its last paired smartphone. LED indicator flashing alternate blue and white	Make sure the smart device is within Bluetooth® range. Turn off the wheezo breath sensor. Once off, hold the power button for 5 seconds until the LED indicator changes from flashing blue and white to flashing blue.
Background noise microphone obstructed	You are holding your hand over the microphone on the back of wheezo breath sensor	Position your fingers on the finger grips on the side of wheezo breath sensor to ensure your hand is not obstructing the microphone on the back. Refer to Figure 2.

Receiving a phone call while taking a wheeze rate

If a phone call is received while taking a wheeze rate, the process will stop. You may commence a new recording when the phone call has ended.



TECHNICAL SPECIFICATIONS

wheezo breath sensor is non-sterile product.

Dimensions	84mm x 54mm x 48mm
Weight	70g
Operating conditions	Ambient temperature: 0° – 40° C Humidity: 15 – 90% Atmospheric pressure 700 – 1060hPa
Transport and storage	Ambient temperature -20°C – +70° C Humidity: 15 – 90% Atmospheric pressure 700 – 1060hPa
Wireless communication	Bluetooth® ver V3.0+EDR Frequency Band: 2402~2480 MHz
Lithium-ion polymer battery Model SNO-602030PC by Starnovo Technology Co., Ltd.	300mAh 3.7V, 1.11Wh Complies with IEC 62133-2:2017
Battery protective device (PTC fuse) Model 435 by Littlefuse Inc.	5A, 32Vdc
Expected service life (including the internal battery)	3 years

wheezo has been examined by an independent laboratory which has certified the conformity of the device to the European Safety Standards EN 60601-1, EN60601-1-6 and guarantees the EMC Requirements within the limits set in the European Standard EN 60601-1-2, 60601-1-11 and ETSI's EN 300328, EN301489-1, 381489-17 and the international standard IEC 60068 for environmental testing IEC 62304 for medical device software.

FCC STATEMENT: 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.

CAUTION: Changes or Modifications not expressly approved by the party responsible could void the user's authority to operate this device.

NOTE: 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.



EXPLANATION OF SAFETY SIGNS AND SYMBOLS ON DEVICE AND PACKAGING

Symbol	Description
	Date of Manufacture
	Manufacturer: Respiri Limited, 9/432 St Kilda Road, Melbourne, VIC 3004, Australia
	Manufacturer's reference number
	Serial number
	Consult instructions for use
	Caution consult instructions for use for warnings and cautions
	Type BF-Applied part (patient isolation from electrical shock)
	Temperature limitation
	Humidity
	Atmospheric pressure
IP 42	Ingress protection
	Background noise microphone
	Indicates separate collection for electrical and electronic equipment (WEEE)
	Bluetooth®
	Indicates that the device meets applicable health, safety and environmental requirements (EU)
	Authorised European Representative: Compliance Management Solutions Europe, 2 Bulgaria Str. 2950 Petrich Bulgaria
	Indicates that the device meets applicable health, safety and environmental requirements (Great Britain)
UK-RP	UK Responsible Person: European Device Solutions Ltd. 15 Coanwood Drive, Whitley Bay, Tyne & Wear NE25 9GB, UK

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Respiri Limited is under license. Other trademarks and trade names are those of their respective owners.

©2021 Respiri Limited. All rights reserved. Wheezo is a trademark of Respiri Limited registered in Australia and other countries. iPhone is a trademark of Apple Inc. registered in the U.S. and other countries.

WHEEZO LIMITED WARRANTY AND RETURNS POLICY

This Limited Warranty and Returns Policy ("Limited Warranty") applies to the wheezo product, including accessories (the "Product") and is given by Respiro Limited to the individual or entity (the "Owner") who uses the Product which has been obtained from Respiro or a Respiro authorised dealer. This Limited Warranty applies only within countries where the wheezo app is available for customers to download and for customers located in such countries, and is not transferable.

APPLICATION OF AUSTRALIAN CONSUMER LAW

The following paragraph applies in Australia only.

Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

To the extent permitted by statute the liability, if any, of Respiro arising from any failure to comply with a statutory guarantee under the Australian Consumer Law, in relation to the supply of goods or services other than goods or services of a kind ordinarily acquired for personal, domestic or household use or consumption, is at Respiro's option limited to, in the case of goods:

- the replacement of the goods or the supply of equivalent goods;
- the repair of the goods;
- the payment of the cost of replacing the goods or of acquiring equivalent goods; or
- the payment of the cost of having the

goods repaired, and in the case of services:

- the supplying of the services again; or
- the payment of the cost of having the services supplied again.

30-DAY RETURN POLICY

If you purchased the Product directly from Respiro, then you may return the Product within 30 days of receiving it. In order for a refund under this Return Policy to be granted, you must request a Return Merchandise Authorisation (RMA) number from Respiro during the 30-day period following the date you received the Product from Respiro. You may request a RMA number by submitting a request to support@respiro.co. The Product must be received in "as new" condition by Respiro within 3 weeks from the date on which the RMA was issued in order for you to receive a refund.

If the Product is returned to Respiro in accordance with this Return Policy, Respiro will credit the account you used to make the original purchase with the full purchase price you paid for the Product and any applicable taxes minus any shipping and handling charges you paid when you purchased the Product. You are responsible for and must prepay all return shipping charges and you assume all risk of loss or damage to the Product while in transit back to Respiro.

The time to credit your account may vary, depending on processing time. Please allow up to seven business days for Respiro to credit the account used to make the original purchase. If you received a damaged Product directly from Respiro, please contact support@respiro.co.

Purchases through an Authorised Dealer: If you purchased the Product from a Respiro authorised retailer or distributor, please contact that retailer or distributor. You must follow the return policy of that authorised retailer or distributor.



MANUFACTURER'S LIMITED WARRANTY

The benefits to the Owner given by the warranty stated below are in addition to other rights and remedies the Owner may have under the Australian Consumer Law (and any other applicable law) in relation to the Product.

Respiri warrants to the Owner that the Product will materially conform to its published specifications and be free from defects in materials and workmanship under normal use for a period of the greater of 1 year or the amount of time required by applicable consumer regulations in the country of purchase and commencing on the date of delivery (the "Warranty Period").

If the Product proves defective during the Warranty Period, you must follow the instructions set out below for returning the Product, or part thereof, and Respiri will replace the Product with a product that is the same or equivalent to the Product you purchased.

A replacement Product assumes the remaining warranty of the original Product, or 30 days from the date of replacement, whichever is longer. Respiri reserves the right to replace any discontinued Product with a new product of comparable value and function.

HOW TO OBTAIN WARRANTY SERVICE

To obtain warranty service on a Product purchased directly from Respiri, contact support@respiri.co.

Respiri may require proof that you bought the Product directly from Respiri and of the date of purchase.

If Respiri determines that a Product is eligible for warranty replacement,

Respiri shall bear the costs associated with returning a Product under warranty. The Owner can claim these costs from Respiri by providing evidence of charges along with a refund request via email to support@respiri.co. Respiri is not responsible for items damaged or lost in transit. Replaced Products are the property of Respiri. The time to credit your account may vary, depending on processing time.

Please allow up to seven business days for Respiri to credit the account used to make the original purchase. If you received a damaged Product directly from Respiri, please contact support@respiri.co.

Purchases through an Authorised Dealer: If you purchased the Product from a Respiri authorised retailer or distributor, please contact that retailer or distributor. You must follow the return policy of that authorised retailer or distributor.

A replacement Product provided under this Limited Warranty will only be dispatched to addresses within countries where the wheezo app is available for customers to download and for customers located in such countries, and is not transferable.

Respiri covers the Product for the Warranty Period as long as proof of purchase can be provided, please contact support@respiri.co.

WHAT IS NOT COVERED?

Without limiting any rights and remedies the Owner may have under the Australian Consumer Law (and any other applicable law) in relation to the Product, this Limited Warranty will be void if the Product: (a) is used in any manner that is inconsistent with the intended purpose or design of the Product as described in Respiro's published documentation for the Product, (b) is altered in any way, including being opened, dismantled or otherwise disassembled, (c) is used or maintained in any manner that is inconsistent with Respiro's instructions or warnings included with the Product or (d) is subjected to any other misuse, abuse, neglect, accident, or external forces.

This Limited Warranty does not cover normal wear and tear.

Respiro does not warrant that the operation of the Product will be uninterrupted or error-free.

WARRANTY DISCLAIMER: To the greatest extent permitted by applicable law, this Limited Warranty replaces all other Respiro warranties, conditions, guarantees and liabilities whether oral, written, (non-mandatory) statutory, contractual, in tort or otherwise, including without limitation, and where permitted by applicable law, any implied conditions, guarantees, warranties or other terms as to satisfactory quality or fitness for purpose.

To the greatest extent permitted by applicable law, the warranties set forth in this limited warranty are exclusive and no other warranty, whether written or oral, expressed or implied, applies with respect to THE PRODUCT OR ANY SERVICES PROVIDED IN CONNECTION WITH THE PRODUCT, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF SUITABLE DESIGN, MERCHANTABILITY, SATISFACTORY QUALITY, FITNESS FOR A PARTICULAR PURPOSE (EVEN IF RESPIRO HAS BEEN INFORMED OF SUCH PURPOSE) OR AGAINST INTELLECTUAL PROPERTY

INFRINGEMENT.

IF ANY IMPLIED WARRANTY CANNOT BE DISCLAIMED UNDER APPLICABLE LAW, THEN SUCH IMPLIED WARRANTY SHALL BE LIMITED IN DURATION TO THE WARRANTY PERIOD SET FORTH ABOVE.

LIMITATION OF REMEDIES

SUBJECT TO ANY RIGHTS AND REMEDIES THE OWNER MAY HAVE UNDER THE AUSTRALIAN CONSUMER LAW (AND ANY OTHER APPLICABLE LAW) IN RELATION TO THE PRODUCT, THE REMEDIES IN THIS LIMITED WARRANTY ARE YOUR SOLE AND EXCLUSIVE REMEDIES IN CONNECTION WITH ANY DEFECT IN OR PROBLEM WITH THE PRODUCT, EVEN IF RESPIRO HAS BEEN NEGLIGENT.

Resellers, retailers, distributors, agents, or employees of Respiro are not authorised to make any modification, extension, or addition to this Limited Warranty.

To the greatest extent permitted by applicable law, Respiro does not assume any liability for loss of or damage to or corruption of data, for any loss of profit, loss of use of the Product or functionality, loss of business, damage to reputation, loss of contracts, loss of revenues or loss of anticipated savings, for any increased costs or expenses or for any indirect loss or damage, consequential loss or damage or special loss or damage.

To the greatest extent permitted by applicable law, Respiro's liability in connection with any To the greatest extent permitted by applicable law, Respiro's liability in connection with any defect in or problem with the Product shall be limited to the purchase value of the Product.

THE LIMITATIONS SET FORTH IN THIS LIMITED WARRANTY ARE INTENDED TO LIMIT THE LIABILITY OF RESPIRO AND SHALL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY.



OTHER IMPORTANT NOTICES

The rights provided to you under this Limited Warranty are provided in addition to all rights and remedies conveyed to you by applicable consumer protection laws and do not affect your legal (statutory) rights under your applicable national law.

The jurisdiction applicable to you may not allow the limitations of liability or damages set forth in this Limited Warranty, in which case such limitations shall only apply to you to the extent permitted in such jurisdiction.

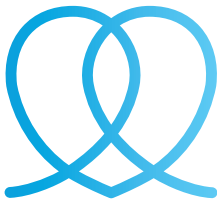
Your use of the wheezo app is subject to Respiro's App Terms and Conditions, which may change from time to time. You can find the latest version on our website at: wheezo.com/app/terms/ In the case of any inconsistencies between the App Terms and Conditions and this Limited Warranty, this Limited Warranty will prevail.

This Limited Warranty does not apply to any mobile device or the cellular and/ or other network or system on which the Product

(together with the wheezo app) operates. Therefore, Respiro will not accept any responsibility under this Limited Warranty for the operation, availability, coverage, services or range of the cellular or other network or system.

Always completely follow safety, use, operation, and maintenance instructions for the Product or any other Respiro product.

This Limited Warranty is governed by the laws of Victoria, Australia.



RESPIRI



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Respiri Limited

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For additional information email



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MADE IN AUSTRALIA

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Petrich Bulgaria

**UK
CA**

UK-RP

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Bay, Tyne & Wear NE25 9GB,
UK

Respiri Limited reserves the right to make changes and improvements to this manual and the products it describes at any time, without notice or obligation.