

AiroQur

User Manual

EN

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1 Purpose and Scope

This user manual describes the functionality and intended usage of AiroQur. The AiroQur Breathing Trainer is used in conjunction with the Airofit software application operating on a smartphone - either Android or iOS.

2 Intended Use and Users

Chronic Obstructive Pulmonic Disease, also known as COPD, is an umbrella term used to describe certain types of lung diseases such as emphysema, chronic bronchitis, and refractory asthma (COPD Foundation). Living with COPD limits people from doing physical activity. Airofit users who suffer from such diseases claim that they can improve their Vital Capacity and general wellbeing within weeks of starting to train with the device.

Intended users are:

A) Patients with medical conditions such as:

- Chronic obstructive pulmonary disease (COPD)
- Asthma
- Long-Covid
- Obstructive Sleep Apnea (OSA)

B) Healthcare professionals

The Airofit Medical app and device system has the intended purpose of providing home-based lung testing and app-guided respiratory muscle training sessions and training protocols to improve vital lung capacity, inhaling and exhaling strengths of for example COPD and asthma patients. The Airofit training system uses the flow resistance methodology, which is seen to provide similar results as the Threshold method currently used as standard method.

The intensity of the training sessions is individually customized and adjusted according to the user's current physical strength and shape based on data and expert assisted consultation. Health professionals, such as physicians and physiotherapists, can remotely through an online dashboard monitor their patients' lung training progression and their regular testing of calculated vital lung capacity.

AiroQur is not a toy. This product is designed for breathing exercises only. Any other use is not recommended. This product is not intended to diagnose, treat, cure, or prevent any disease.

2.1 Manufacturer's Liability

Airofit Medico A/S is only liable for equipment safety, reliability, and performance, provided that AiroQur is used in compliance with these instructions.

3 Safety Precautions

3.1 Health Considerations when Using AiroQur

To prevent damage to your AiroQur Breathing Trainer or injury to yourself, read the following precautions in their entirety before using the AiroQur system.

- To prevent the potential transmission of infections, we recommend that you do not share your device with any other user, including family members. Moreover, your device is calibrated for only one user's personalized data.
- The device is manufactured in a safe environment. However, the AiroQur Breathing Trainer is not provided as a sterile device – we recommend that you clean it prior to use.
- Do not use AiroQur while performing any form of physical activity (e.g. running, cycling, rowing, driving).
- Do not use AiroQur for more than 60 minutes per day.
- Respiratory training can cause dizziness. We recommend that you remain seated after training and breathe normally for a minimum of 1-2 minutes before moving on to other activities.
- AiroQur is suitable for ages 12 and over. Users under the age of 15 should only use AiroQur under the supervision of an adult.
- Immediately stop the exercise if you feel any physical discomfort.
- If you feel light-headed or dizzy while exercising with AiroQur, you should stop and check the resistance wheel's inspiratory and expiratory settings.
- If you are suffering from a cold, sinusitis, or other respiratory tract infection, we advise you to wait until all symptoms have disappeared before using AiroQur.
- If you have any medical conditions with your respiratory system, heart, or blood pressure, we recommend that you consult a doctor before using AiroQur.
- Do not use the AiroQur Breathing Trainer to inhale any type of substance.

3.2 Contraindications

To prevent damage to your AiroQur Breathing Trainer or injury to yourself, read the following precautions in their entirety before using the AiroQur system. Use appropriate caution in the following situations:

- A history of spontaneous pneumothorax (collapsed lung), i.e., not due to traumatic injury.
- A traumatic pneumothorax that has not fully healed.
- A burst eardrum that has not healed fully, or other conditions of the eardrum.
- The subgroup of asthma patients with unstable asthma with abnormally low perception of dyspnea (shortness of breath) are also unsuitable candidates for Inspiratory Muscle Training (IMT).

3.3 General Safety Cautions

- Only use the AiroQur Breathing Trainer together with the Airofit Medical mobile application and the selected sessions and programs. Always set resistance to the recommended settings.
- Do not drop your device. Dropping it may result in malfunction or cause a decline in performance.
- Ensure that the inhale/exhale vents located on the sides of the device are not obstructed while training.
- Do not expose the E-Unit to any liquids. For cleaning instructions, refer to the Maintenance section.
- Never use scouring pads, abrasive cleaning agents, or aggressive liquids such as petrol or acetone to clean the device. The AiroQur device is not dishwasher or autoclave safe.

- Ensure that your AiroQur device remains hygienic and in good working order. Always make sure that your device is dry before storing it. We advise you to store your AiroQur device in a suitable, clean, and hygienic way.
- Only use the supplied charging cable together with a CE-certified USB charger (refer to Technical Specifications).
- If you have more than one AiroQur device, do not swap the E-Units.

4 Operation

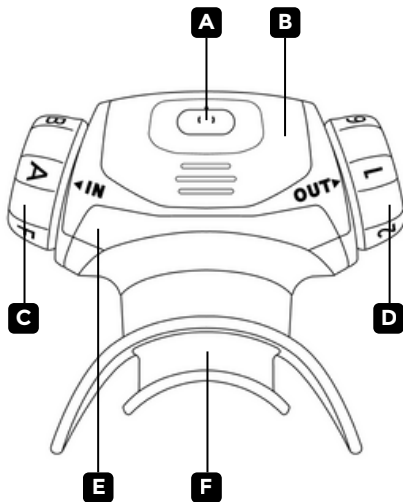
Your AiroQur package consists of:

- AiroQur Breathing Trainer
- 2x Advanced Mouthpiece
- Magnetic charging cable
- Mesh bag
- AiroQur User Manual

4.1 AiroQur System Description

The AiroQur system consists of the AiroQur Breathing Trainer and the Airofit Medical mobile application. The AiroQur Breathing Trainer provides resistance to your inspiratory and expiratory breathing, while the Airofit Medical application provides guidance to your respiratory training and monitors your performance over time.

4.2 Getting to Know the AiroQur



A Power Button

B Removable E-Unit

C Inspiratory Resistance Wheel

D Expiratory Resistance Wheel

E Trainer Unit

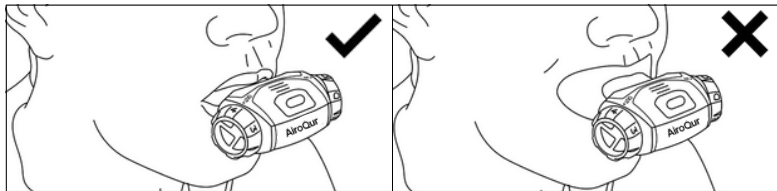
F Removable Mouthpiece

	Power Button Press the Power Button to turn ON the AiroQur Breathing Trainer. It will begin to blink green to indicate that the device is ON - at this point, it is ready to be paired with the mobile application. To turn the device OFF, press the Power button once again.
	Removable Mouthpiece The mouthpieces are made of a softer material than the rest of the AiroQur Breathing Trainer to ensure complete comfort during exercise. To use it, gently bend the sides of the Mouthpiece and put it in your mouth.
	Removable E-Unit The E-Unit contains electronic components. Do not expose it to any liquids. To clean or charge your AiroQur Breathing Trainer, firmly squeeze the grips and pull to remove the E-Unit from the rest of the Trainer.
	Trainer Unit The term 'Trainer Unit' is used for your AiroQur Breathing Trainer once the E-Unit and mouthpiece are removed.
	Charging The charging port can be found on the inside of the E-Unit. Attach the magnetic cable to charge. When the light is blinking green, the cable is attached correctly, and your E-Unit is charging. When fully charged, the light will show as solid green

4.3 Using the AiroQur Correctly

When using the AiroQur Breathing Trainer you should be relaxed and sitting upright. Hold the device with your hand on the E-Unit. Make sure the openings near the resistance wheels are not obstructed.

Place the device in your mouth so that your lips cover the outer shield of the mouthpiece and make a complete seal. If you are using the Advanced Mouthpiece, the bite blocks should be gripped between your teeth. Keep your head facing straight forward, as looking down can cause more salivation. Do not hold the AiroQur Breathing Trainer with your hands during training unless absolutely necessary.



When starting the exercise, the Breathing Trainer requires a short offset (zeroing) of the pressure measurement. Do not breathe into the Trainer during this process. Wait for the instructions to begin the respiration exercise.

AiroQur Breathing Trainer should not be used in conjunction with other physical activities. Breathing training while performing other physical exercises will compromise the oxygenation of the locomotor muscles.

5 Maintenance

Always make sure that your device is dry before storing it. We advise you to store your AiroQur Breathing Trainer in a suitable, clean, and hygienic way. Fully charge your device if you are storing it for more than a week without use to avoid full battery depletion. Remember to charge the AiroQur Breathing Trainer fully before resuming usage.

Daily Maintenance

As the device will be exposed to saliva during use, it is important to clean it frequently. We recommend cleaning your device after each training session.

Always remove the E-Unit before cleaning the device. ***Do not immerse the E-Unit, or expose it to jets of water, or any other liquids.***

We recommend washing the Trainer Unit and mouthpiece in warm water (below 60°C). After washing, shake off and blow through the Trainer Unit and mouthpiece to remove excess water, making sure it's completely dry before reassembling. The AiroQur Breathing Trainer is not autoclaving or dishwasher safe.

Weekly Maintenance

Once a week, remove both the E-Unit and the mouthpiece from the AiroQur Breathing Trainer to be able to clean it better. Use a drop of dish soap in water to wash your Trainer Unit and mouthpiece thoroughly. Once washed, hold the Trainer Unit under running water, allowing it to run through. Shake off excess water, blow through the Trainer Unit, and dry with a clean towel. Let it air dry. Make sure the device is completely dry before reassembling.

Charge your E-Unit fully at least once a week, even when not in use, to avoid complete battery depletion.

6 Getting Started with AiroQur

First-time use guide

Before you start your training, it is recommended to charge the E-Unit until the light is solid green. While the E-Unit is charging, rinse the rest of the Trainer Unit and Mouthpiece in warm water. ***The E-Unit contains electronics; do not immerse the E-Unit, or expose it to jets of water, or any other liquids.***

Sign-up procedure

The Airofit Medical application will guide you through the initial steps of your Airofit journey.

6.1 Lung Test

As instructed in the AiroQur app, you will initially perform a Lung Test to establish your breathing condition. The app notification will pop up when you should take the test.

The Lung Test records your

- Maximum breath volume, the maximum amount of air you can exhale after filling your lungs completely
- Inspiratory strength, the maximum inspiratory pressure that you can produce against a high resistance level (F)
- Expiratory strength, the maximum expiratory pressure that you can produce against a high resistance level (6)

The coloured bars indicate your performance compared to a similar population (age, height, weight, etc.) The percentages and arrows (up or down) relate to your progress between your current and previous test results.

6.2 Start Training

You will find your personalized training session within the Airofit Medical mobile application. Prepare your Breathing Trainer by setting the resistance levels and follow the app guidance to start the training. When your exercise is finished, the result screen will appear in the app, and you will see a summary of your training.

6.3 Training History

The Airofit Medical mobile application contains your training history so that you can access your Lung Test and completed training sessions at any time.

6.4 Settings

You can update your profile in the settings. Your account is protected by a password, which can be reset. If you have any questions about training, you can get them answered by contacting our support at support@airofit.com. You can also report a problem if you find something wrong with the app. The app also contains the Terms and Conditions (requires internet connection) and the Privacy Policy, which you agreed to when you created your account.

6.5 Fundamentals in Breathing Performance

Term	Description
cmH ₂ O	Pressure exerted by a column of water of 1 cm in height. 1 cmH ₂ O = 0.980665 hPa (or mbar)
Maximum breath volume	The maximum amount of air you can exhale after filling your lungs completely. Average range of the general adult population: 3.0 – 5.0 liters
Respiratory pressure	Inspiratory Strength: Normal range: 20 - 170 cmH ₂ O Average: 75 ±25 cmH ₂ O Expiratory Strength Normal range: 20 - 230 cmH ₂ O Average: 95 ±35 cmH ₂ O
Airflow resistance	Resistance to airflow during respiration

7 Troubleshooting

General troubleshooting guidance is available online at: <https://www.airofit.com/faq/>

8 Technical Specifications

8.1 AiroQur Breathing Trainer

Description	Notes
Air resistance	
Inhalation air resistance	A-F: 10-250 cmH ₂ O at (1 liter/sec)
Exhalation air resistance	1-6: 10-200 cmH ₂ O at (1 liter/sec)
Material	
Mouthpiece	TPE (Medical)
Housing	ABS

Description	Notes
Battery	
Rechargeable	3.7V Li-ion, 35mAh
Capacity	10 hours
Charger	5V, min 100mA
Charging time	8 hours
Charger plug	Magnetic connector
Communication	
Bluetooth	BLE version 5.1
Dimensions	
Size	70mm x 77mm x 33mm
Weight	45g
Smartphone App	
IOS version	13 or newer
Android version	13 or newer

8.2 Environment

Description	Notes
Operating conditions	
Temperature indoor	15°C to 35°C
Temperature outdoor	0°C to 45°C
Relative humidity	10% to 90% RH
Pressure	960 hPa to 1,060 hPa
IP classification	IP64
Storage and transport conditions	
Temperature	-25°C to 50°C
Relative humidity	10% to 90% RH
Pressure	700 hPa to 1,060 hPa
Electrical shock prevention	
Electrical safety	Type B
Leakage current	< 0.5mA
EMC	IEC 60601-1-2:2014 EN 60601-1-2:2015

8.3 Standards

The AiroQur training system is designed according to the Medical Device Directive - MDD 2007/47/EC. The AiroQur system is manufactured with compliance to medical device **Class I**. The AiroQur system complies with the EU Directive on personal data security - 2016/680/EU. The major standards applied are:

Standard	Title	Date
IEC 60601-1 (ed. 3.1)	Medical electrical equipment General requirements for basic safety and essential performance	2012
IEC 60601-1-2	Medical electrical equipment Electromagnetic compatibility requirements and tests	2014
ISO 13485	Medical devices Quality management systems - Requirements for regulatory purposes	2016
ROHS (2011/65/EU)	Restriction of Hazardous Substances in electrical and electronic equipment	2011
REACH (EC 1907/2006)	Registration, Evaluation, Authorisation and Restriction of Chemical substances	2006
WEEE	Directive 2012/19/EU	2012

8.4 Radio Equipment Compliance

The AiroQur system complies with Radio Equipment Directive (RED) - 2014/53/EU.

The device complies with part 15 of the FCC Rules. **FCC ID: 2ATQX-AF003**

Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

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 and 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.

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s).

IC: 25191-AF003

Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicable aux appareils radio exempts de licence.

IC: 25191-AF003

L'exploitation est autorisée aux deux conditions suivantes:

1. L'appareil ne doit pas produire de brouillage
2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement

9 AiroQur Limited Warranty

Airofit Medico A/S warrants this product to be free from defects in material or workmanship for a period of twenty-four (24) months from the date of purchase, provided that the product is used in a home environment and according to this manual. This limited warranty does not cover failures due to abuse, accidental damage, or if repairs or attempts to repairs have been made by anyone other than Airofit Medico A/S. A defective product meeting the warranty conditions set forth herein will be replaced or repaired at no charge. In case of a defective product, return the product to the retailer from whom it was purchased (provided that the store is a participating retailer). Returns should be made within the warranty period. Proof of purchase is required.

Please check with the retailer for its specific return policy regarding returns or exchanges. This warranty gives you specific legal rights. You may have other rights which vary from state to state. Should you have any questions, contact your retailer. This product is not intended for commercial use, and accordingly, such commercial use of this product will void this warranty. All other guarantees, express or implied, are hereby disclaimed.

In case of an incident of this medical device, reporting must be made at The Danish Medicines Agency's website <https://laegemiddelstyrelsen.dk/en>. General inquiries may be reported by contacting dkma@dkma.dk.

***AiroQur is not a toy. This product is designed
for breathing exercises only. Any other use is not recommended.
This product is not intended to diagnose, treat, cure, or prevent any disease.***

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