

# **Airocure**

## User Manual

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## 1. Purpose and Scope

This user manual describes the functionality and intended usage of Airocure.

## 2. Intended Use and Users

Airocure is intended to exercise the muscles of the respiratory system.

***This product is not intended to diagnose, treat, cure, or prevent any disease.***

Intended users are:

- End user of Airocure
- Personnel instructing the user of Airocure

The Airocure Breathing Trainer is used in conjunction with the Airocure software application operating on a smartphone - either Android or iOS.

### 2.1 Manufacturer's Liability

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

### **3. Safety Precautions**

#### **3.1 Health Considerations when Using Airocure**

To prevent damage to your Airocure Breathing Trainer or injury to yourself, read the following precautions in their entirety before using the Airocure 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 Airocure Breathing Trainer is not provided as a sterile device – we recommend that you clean it prior to use.
- Do not use Airocure while performing any form of physical activity (e.g. running, cycling, rowing, driving).
- Do not use Airocure 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.
- Airocure is suitable for ages 12 and over. Users under the age of 15 should only use Airocure 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 Airocure, 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 Airocure.
- If you have any medical conditions with your respiratory system, heart, or blood pressure, we recommend that you consult a doctor before using Airocure.
- Do not use the Airocure Breathing Trainer to inhale any type of substance.

### **3.2 Contraindications**


To prevent damage to your Airocure Breathing Trainer or injury to yourself, read the following precautions in their entirety before using the Airocure 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 Airocure Breathing Trainer together with the Airocure 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 Airocure device is not dishwasher or autoclave safe.
- Ensure that your Airocure 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 Airocure 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).

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- If you have more than one Airocure device, do not swap the E-Units.

## **4. Operation**

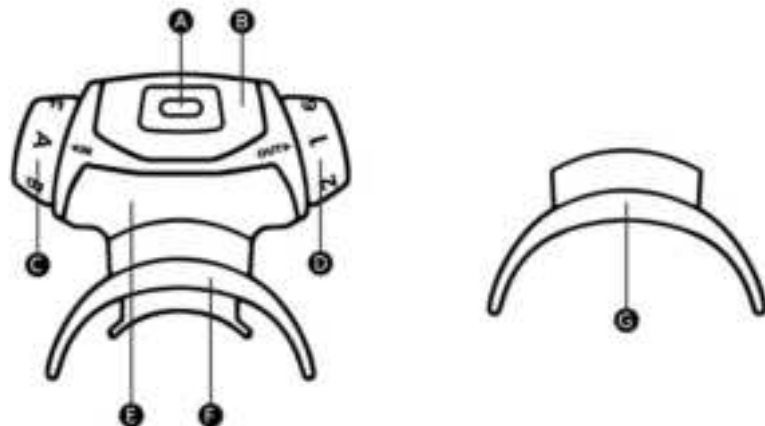
Your Airocure package consists of:

- Airocure Breathing Trainer
- Simple Mouthpiece
- Advanced Mouthpiece
- Magnetic charging cable
- Mesh bag
- Airocure Quick Guide
- Airocure User Manual

### **4.1 Airocure System Description**




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



#### 4.2 Getting to Know the Airocure Breathing Trainer



- A** Power Button
- B** Removable E-Unit
- C** Inspiratory Resistance Wheel
- D** Expiratory Resistance Wheel
- E** Trainer Unit
- F** Removable Mouthpiece Advanced
- G** Removable Mouthpiece Simple



	<p><b>Power Button</b></p> <p>Press the Power Button to turn ON the Airocure 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.</p> <p>To turn the device OFF, press Power Button once again.</p>
	<p><b>Mouthpieces</b></p> <p>The mouthpieces are made of a softer material than the rest of the Airocure Breathing Trainer to ensure complete comfort during exercise.</p> <p>To use the mouthpiece, gently bend the sides of the mouthpiece and put it in your mouth.</p>
	<p><b>E-Unit</b></p> <p>The E-Unit contains electronic components. Do not expose it to any liquids.</p> <p>To clean or charge your Airocure Breathing Trainer, firmly squeeze the grips and pull to remove the E-Unit from the rest of the Trainer.</p>

	<p><b>Trainer Unit</b></p> <p>The term 'Trainer Unit' is used for your Airocure Breathing Trainer once the E-Unit and mouthpiece are removed.</p>
	<p><b>Charging</b></p> <p>The charging port can be found on the inside of the E-Unit. Insert the magnetic charging cable to charge. If the light is blinking green, the cable is inserted correctly, and your E-Unit is charging. When fully charged, the light will show as solid green.</p>

### 4.3 Using Airocure Correctly

When using the Airocure 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 Airocure 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.

Airocure 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.

#### **4.4 Mouthpieces**

The Airocure Breathing Trainer comes with two mouthpieces, Mouthpiece Simple and Mouthpiece Advanced. Try each mouthpiece to see which one fits you best.

### **5. Maintenance**

Always make sure that your device is dry before storing it. We advise you to store your Airocure 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 Airocure 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 and wipe it with a dry clean cloth. **Do not clean the E-Unit with liquids of any kind.**

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 Airocure Breathing Trainer is not autoclave or dishwasher safe.

#### **Weekly Maintenance**

Once a week, remove both the E-Unit and the mouthpiece from the Airocure 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.

### **Monthly Maintenance**

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

## **6. Getting Started with Airocure**

### **First-time use essentials**

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 expose it to any liquids.**

### **Sign-up procedure**

The Airocure app will guide you through the initial steps of your Airocure journey.

### **6.1 Breathing Performance Test**

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

The Breathing Performance 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 (G)

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 app. 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 app contains your training history so that you can access your Breathing Performance 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](mailto: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 <sub>2</sub> O	Pressure exerted by a column of water of 1 cm in height. 1 cmH <sub>2</sub> 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 – 6.0 liters
Respiratory pressure	Inspiratory strength: Normal range: 20 - 170 cmH <sub>2</sub> O Average: 75 ±25 cmH <sub>2</sub> O  Expiratory strength: Normal range: 20 - 230 cmH <sub>2</sub> O Average: 95 ±35 cmH <sub>2</sub> O
Airflow resistance	Resistance to airflow during respiration

## 7. Troubleshooting

Please contact us at [support@airofit.com](mailto:support@airofit.com) for troubleshooting guidance.





## 8. Technical Specifications

### 8.1 Airocure Breathing Trainer

Description	Notes
<b>Air resistance</b>	
Inhalation air resistance	A-F: 20-200 cmH <sub>2</sub> O / (at 1 liter/sec)
Exhalation air resistance	1-6: 20-200 cmH <sub>2</sub> O / (at 1 liter/sec)
<b>Material</b>	
Mouthpieces	TPE (Medical)
Housing	ABS
<b>Battery</b>	

Rechargeable	3.7V Li-ion, 35mAh
Capacity	10 hours
Charger	5V, min 100mA
Charging time	8 hours
Charger plug	Magnetic connector
<b>Communication</b>	
Bluetooth	BLE version 4.1
<b>Dimensions</b>	
Size	70mm x 77mm x 33mm
Weight	45g
<b>Smartphone App</b>	

IOS version	11 or newer
Android version	7 or newer

## 8.2 Environment

Description	Notes
<b>Operating conditions</b>	
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	IP65
<b>Storage and transport conditions</b>	
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 Airocure training system is designed according to the Medical Device Directive - MDD 2007/47/EC. The Airocure system is manufactured with compliance to medical device **Class I**.

The Airocure 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 Airocure 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 license-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. Airocure 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.

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