

# **Airofit PRO 2.0**

## User Manual

EN

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## **1 Purpose and Scope**

This user manual describes the functionality and intended usage of Airowit PRO 2.0.

## **2 Intended Use and Users**

The Airowit PRO 2.0 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 the Airowit PRO 2.0
- Personnel instructing the user of the Airowit PRO 2.0

The Airowit PRO 2.0 Breathing Trainer is used in conjunction with the Airowit software application operating on a smartphone - either Android or iOS.

### **2.1 Manufacturer's Liability**

Airowit A/S is only liable for equipment safety, reliability, and performance, provided that the Airowit PRO 2.0 is used in compliance with these instructions.

## **3 Safety Precautions**

### **3.1 Health Considerations when Using Airowit PRO 2.0**

To prevent damage to your Airowit PRO 2.0 Breathing Trainer or injury to yourself, read the following precautions in their entirety before using the Airowit system.

- To prevent the potential transmission of infections, we recommend that you do not share your Airofit PRO 2.0 with any other user, including family members. Moreover, your Airofit PRO 2.0 is calibrated for only one user's personalized data.
- The Airofit PRO 2.0 is manufactured in a safe environment. However, the Airofit PRO 2.0 is not provided as a sterile device – we recommend that you clean the Breathing Trainer prior to use.
- Do not use Airofit PRO 2.0 while performing any other activities (e.g., running, cycling, rowing, driving).
- Do not use Airofit PRO 2.0 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.
- The Airofit PRO 2.0 is suitable for ages 12 and over. Users under the age of 15 should only use Airofit 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 Airofit, 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 the Airofit PRO 2.0.
- If you have any medical conditions with your respiratory system, heart, or blood pressure, we recommend that you consult a doctor before using Airofit.
- Do not use Airofit to inhale any type of substance.

### **3.2 Contraindications**

To prevent damage to your Airofit PRO 2.0 or injury to yourself, read the following precautions in their entirety before using the Airofit 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 Airofit PRO 2.0 Breathing Trainer together with the Airofit mobile application and the selected sessions and programs. Always set resistance to the recommended settings.
- Do not drop your Airofit PRO 2.0. Dropping the Breathing Trainer may result in malfunction or cause a decline in performance.
- Ensure that the inhale/exhale vents located on the sides of Airofit PRO 2.0 are not obstructed while training.
- Do not immerse the E-Unit, or expose it to jets of water, or any other 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 Airofit PRO 2.0 is not dishwasher or autoclave safe. For cleaning instructions, refer to the Maintenance section.

- Ensure that your Airofit PRO 2.0 remains hygienic and in good working order. Always make sure that your device is dry before storing it. We advise you to store your Airofit PRO 2.0 in a suitable, clean, and hygienic way.
- Only use the supplied magnetic charging cable together with a CE-certified USB charger (refer to Technical Specifications).
- If you have more than one Airofit PRO 2.0 Breathing Trainer, do not swap the E-Units. Each E-Unit is calibrated precisely to the device, and swapping them will cause inconsistencies in measurement results.

## **4** Operation

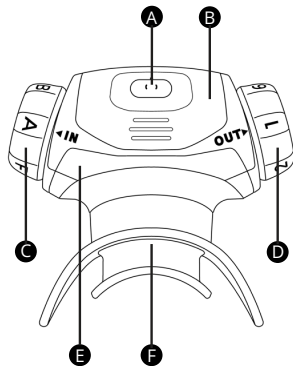
Your Airofit PRO 2.0 package consists of:

- Airofit PRO 2.0 Breathing Trainer
- Magnetic charging cable
- Airofit PRO 2.0 Quick Guide

### **4.1 Airofit PRO 2.0 System Description**

The Airofit PRO 2.0 system consists of the Airofit PRO 2.0 Breathing Trainer and the Airofit mobile application. The Breathing Trainer provides resistance to your inspiratory and expiratory breathing, while the application provides guidance to respiratory training and monitors your performance over time.

## 4.2 Getting to Know the Airofit PRO 2.0



**A** Power Button






**B** Removable E-Unit

**C** Inspiratory Resistance Wheel

**D** Expiratory Resistance Wheel

**E** Trainer Unit

**F** Removable Mouthpiece

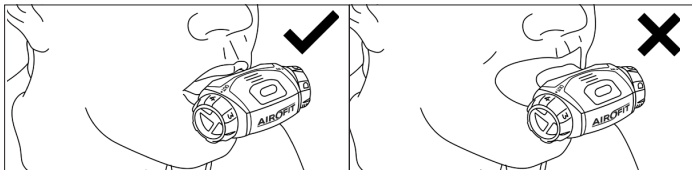
	<p><b>Power Button</b></p> <p>Press the Power button to turn ON the Airofit PRO 2.0 Breathing Trainer. It will begin to blink green to indicate that the device is ON - at this point, it is ready to be paired with the mobile application.</p> <p>To turn the device OFF, press the Power button once again.</p>
	<p><b>Removable Mouthpiece</b></p> <p>The Mouthpiece is made of a softer material than the rest of the Airofit PRO 2.0 Breathing Trainer to ensure complete comfort during exercise.</p> <p>To use it, gently bend the sides of the Mouthpiece and put it in your mouth.</p>
	<p><b>Removable E-Unit</b></p> <p>The E-Unit contains electronic components. Do not immerse the E-Unit, or expose it to jets of water, or any other liquids.</p> <p>To clean or charge your Airofit PRO 2.0 Breathing Trainer, firmly squeeze the grips and 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 Airofit PRO 2.0 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. Attach the magnetic cable to charge. When the light is blinking green, the cable is attached correctly, and your E-Unit is charging.</p> <p>When fully charged, the light will show as solid green</p>



### 4.3 Using the Airofit Correctly

When using the Airofit PRO 2.0 Breathing Trainer, you should be relaxed and sitting upright. Keep your head facing straight forward, as looking down can cause more salivation. Do not hold the Airofit PRO 2.0 Breathing Trainer with your hand during training unless absolutely necessary. If you must, hold it with your hand on the E-Unit and make sure that 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. The Mouthpiece bite block should be gripped between your teeth.



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

Airofit PRO 2.0 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 Airofit PRO 2.0 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 Airofit PRO 2.0 Breathing Trainer fully before resuming usage.

(Youtube: Airofit PRO - Care and Maintenance)

### 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 the Mouthpiece in warm water (below 60°C). After washing, shake off and blow through the Trainer Unit to remove excess water, making sure it's completely dry before reassembling. The Airofit PRO 2.0 Breathing Trainer is not autoclave or dishwasher safe.

### Weekly Maintenance

Once a week, 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 Airofit PRO 2.0 Breathing Trainer fully at least once a month, even when not in use, to avoid complete battery depletion.

## **6** Getting Started with Airofit PRO 2.0

### 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 Trainer Unit and Mouthpiece in warm water, wipe them with a clean towel, and let them air dry. When the E-Unit is fully charged and the Trainer Unit and Mouthpiece are completely dry, you can reassemble the Breathing Trainer. ***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 app will guide you through the initial steps of your Airofit journey.

### 6.1 Lung Test

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

The lung test records your

- Accessible Lung Capacity, your active lung volume
- Inhale strength, your Maximal Inspiratory Pressure (MIP)
- Exhale strength, your Maximal Expiratory Pressure (MEP)

These measures are evaluated based on your gender, age, and height (as set in your profile). The percentages (0-200%) show how you compare to other users in the same demographic group as you.

## **6.2 Start Training**

Based on the goal selected in the Airofit app, you will find training recommendations within the app. Prepare your trainer by setting the correct 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.

### **Understanding training levels**

- Beginner: Low pressure loads with short breathing cycles
- Intermediate: Medium pressure loads with medium breathing cycles
- Expert: High pressure loads with long breathing cycles

### **Understanding training duration**

Training duration can vary between 1-10 minutes. We strongly recommend that you always take a short break after every 3 minutes of training.

## **6.3 Training History**

The app contains your training history so that you can access your lung test and training session results 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. Preferences for background music and guidance sound can be turned on/off for your training exercise. If you have any questions about training, you can get them answered by clicking on the FAQ button. 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)
Accessible Lung Capacity	The total of usable reserves of lung capacity which you can access
Lung capacity compliance	Compliance in percent is evaluated with respect to gender, age and height
Respiratory pressure	Maximal Inspiratory Pressure (MIP): Normal range: 20 - 170 cmH <sub>2</sub> O Average: 75 ±25 cmH <sub>2</sub> O  Maximal Expiratory Pressure (MEP): Normal range: 20 - 230 cmH <sub>2</sub> O Average: 95 ±35 cmH <sub>2</sub> O

Term	Description
Airflow resistance	Resistance to airflow during respiration
Breathing compliance	Compliance is evaluated with respect to gender, age and height
Exercise level	Beginner Intermediate Expert

## **7** Warning Notifications

The list of warning notifications:

Battery low (20%)	The battery on your Airofit device is low. Please charge as soon as possible.
Battery low (5%)	The battery on your Airofit device is critically low and it might turn off unexpectedly. Please charge it as soon as possible.
Too much variant	Failed to properly calibrate the device. Please make sure you're not breathing into the device and the device is not cold (please warm it up in your hand before trying again).

## 8 Troubleshooting

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

## 9 Technical Specifications

### 9.1 Airofit PRO 2.0 Breathing Trainer

Description	Notes
<b>Air resistance</b>	
Inhalation air resistance	A-F: 10-250 cmH <sub>2</sub> O at (1 liter/sec)
Exhalation air resistance	1-6: 10-200 cmH <sub>2</sub> O at (1 liter/sec)
<b>Monitoring</b>	
Accessible Lung Capacity	0.5 - 10.0 liters
Respiratory pressure	10 - 230 cmH <sub>2</sub> O

Description	Notes
Lung capacity compliance	0 to 200%: Low: < 2.5 liter Medium: 2.5 - 4.5 liter High: > 4.5 liter
MIP/MEP compliance	0 to 200%: Low: < 70% Medium: 70 - 140% High: > 140 %
Breathing compliance	0 to 100%: Acceptable: 20-40 % Fair: > 40-60 % Good: > 60-80 % Perfect: > 80 %
Exercise level	0 to 100% of MIP/MEP Beginner: < 50% Intermediate: 70% Expert: > 90 %
Exercise settings	Air resistance settings Beginner: (D4, C3, B2) Intermediate: (E5, D4, C3) Expert: (F6, E5, D4)



Description	Notes
<b>Material</b>	
Mouthpiece	TPE
Housing	ABS
<b>Battery</b>	
Rechargeable	3.7V Li-ion, 35mAh
Capacity	8 hours
Charger	5V, min 100mA
Charging time	8 hours
Charger plug	Magnetic connector
<b>Communication</b>	
Bluetooth	BLE version 5.1
<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

## 9.2 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	IP64
<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
<b>Electrical shock prevention</b>	
Electrical safety	Type B
Leakage current	< 0,5mA
EMC	IEC 60601-1-2

## 9.3 Standards

The Airofit PRO 2.0 training system is designed according to the Medical Device Directive - MDD 2007/47/EC. The Airofit system is manufactured with compliance to medical device ***Class I***.

The Airofit 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

## 9.4 Radio Equipment Compliance

The Airofit 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

## **10** Airofit Limited Warranty

Airofit Sport 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 Sport 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 time period of 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 Airofit Customer Support. 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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