



USER MANUAL

V3.6

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1. INTENDED USE AND USERS

The Airofit Breathing Trainer is intended to exercise the muscles of the respiratory system.

The intended users are

- The personal user of the Airofit Breathing Trainer
- Personnel instructing the user of the Airofit Breathing Trainer

1.1 MANUFACTURER'S LIABILITY

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

2. SAFETY PRECAUTIONS

2.1 WARNING CATEGORIES

Warnings indicate alerts during the operation of Airofit. Warning list can be found in Section 9.

2.2 CAUTIONS

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

Immediately stop the program exercise if you feel any physical discomfort.



If you feel light headed or dizzy while exercise with Airofit, you should stop and check if the resistance wheels for the inspiratory and expiratory settings are correct



If you are suffering from a cold, sinusitis, or respiratory tract infection, we advise you not to use the Airofit Breathing Trainer until symptoms has disappeared.



To prevent the potential transmission of infections, we recommend that you do not share your Airofit Breathing Trainer with another user, including family members



The Airofit Breathing Trainer is manufactured in a safe environment. However, the Airofit Breathing Trainer is not provided sterile – we recommend that you clean the Breathing Trainer prior to use



Do not use Airofit Breathing Trainer in case of

- spontaneous pneumothorax (a collapsed lung that was not due to traumatic injury e.g. broken rib)
- a collapsed lung due to a traumatic injury that has not healed fully
- a burst eardrum that has not healed fully, or any other condition of the eardrum
- asthma with frequent severe exacerbations



Do not use Airofit Breathing Trainer simultaneously with other activities (eg. running, cycling, rowing, driving)



Do not use Airofit Breathing Trainer more than 60 minutes per day

The Airofit Breathing Trainer is suitable for ages over 12. If you are under the age of 15, you should only use Airofit with supervision from an adult.

If you have any medical conditions with your respiratory system, heart or blood pressure, we recommend that you consult your doctor before using Airofit Breathing Trainer

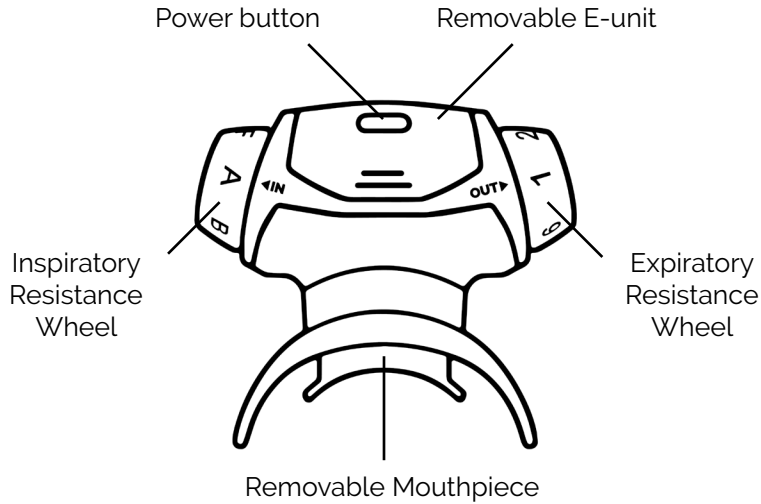


3. OPERATION

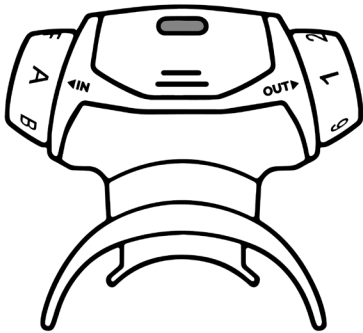
3.1 AIROFIT SYSTEM DESCRIPTION

The Airofit is a system consisting of the Airofit Breathing Trainer and the Airofit Application. The Airofit Breathing Trainer provides resistance to your breathing. Together with the sensors in the Airofit Breathing Trainer, the application provides you with exercise information and your exercise progress over time.

3.2 GETTING TO KNOW THE AIROFIT BREATHING TRAINER



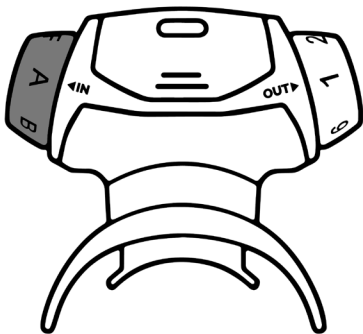
Power Button



Click the key to turn ON the Airofit Breathing Trainer. The green LED flashes rapidly (Twice per sec) to indicate searching for the Bluetooth connection. When the Breathing Trainer has connected to the App, the LED flashes slowly (Once per 3 seconds). To turn OFF the Breathing Trainer, hold down the key for 3 seconds.

The Breathing Trainer will turn OFF by itself if not connected in 2 minutes

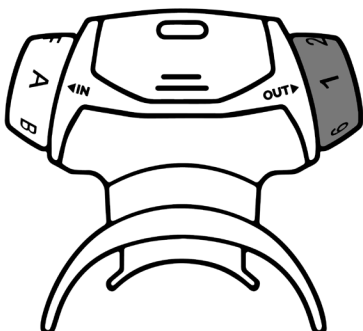
Inspiratory Resistance Wheel



The wheel with the letters allows you to set your Inspiratory Resistance. The letter F being the highest, and A being the lowest resistance.

Remember to adjust according to recommendations in each training session.

Expiratory Resistance Wheel

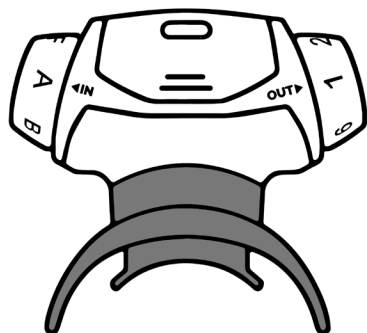


The wheel with the numbers allows you to set your Expiratory Resistance. The number 6 being the highest, and 1 being the lowest resistance.

Remember to adjust according to recommendations in each training session.



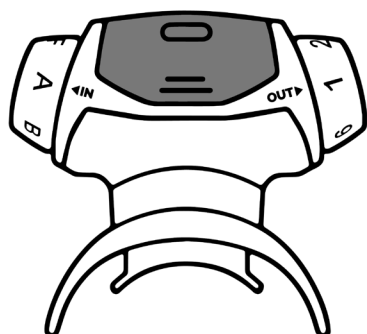
The Mouthpiece



The mouthpiece is softer than the rest of the breathing trainer, to ensure complete comfort during exercise.

To use it, gently bend the sides of the mouthpiece and put it in your mouth.

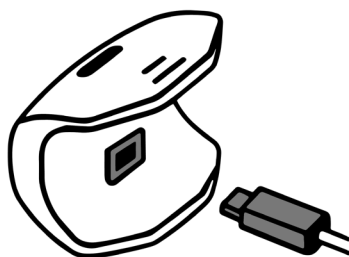
Removable E-Unit



This part contains all electronics. To clean or charge your Airofit Breathing Trainer, hold the grips and remove the E-Unit from the rest of the body.

Make sure that the E-Unit does not get in contact with any liquids.

Charging



You will find the charging plug on the inside of the E-Unit. Insert your Micro USB cable to charge. If the button is blinking green, you have inserted your cable correctly and your Airofit is charging.

Once fully charged, the button will remain green.

During charging, you can still be connected to the App to check the condition of the Breathing Trainer.

3.3 USING THE AIROFIT CORRECTLY

You shall be relaxed and standing or sitting upright. Make sure that the openings near the dials are not obstructed.

Place the Airofit Breathing Trainer in your mouth so that your lips cover the outer shield of the mouthpiece to make a seal and that the mouthpiece bite blocks are gripped between your teeth.

Look straight forward - looking down can cause more salivating.

When starting the exercise, the Airofit Breathing Trainer requires a short offset (zeroing) of the pressure measurement. Do not breath into the device during this process but wait for the instructions of respiration exercise.

3.4 MOUTHPIECES

You have received an extra mouthpiece with your Airofit Breathing Trainer. You can change the mouthpieces and try the extra one, to see which one fits you the best.



4. MAINTENANCE

Please follow the guidelines below to ensure that your Airofit Breathing Trainer remains hygienic and in good working order.

Because the Airofit Breathing Trainer will be exposed to saliva during use, it is important to clean it frequently.

Always store your Airofit Breathing Trainer in the provided storage pouch or another suitable clean and hygienic way. Always make sure that your Airofit Breathing Trainer is dry before storing in a closed container.

Always remove the E-unit before cleaning with water or other liquids.

After each training we recommend that you wash the device in warm water. Shake off excess water and dry with a clean towel.

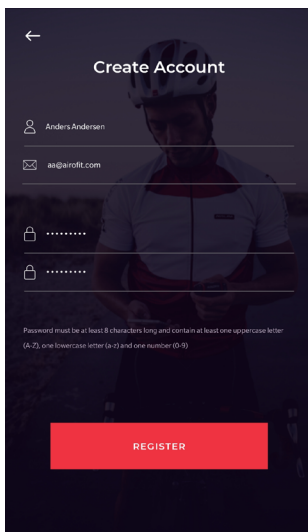
Once a week, remove the mouthpiece from the device to be able to clean it better. Use a mild disinfectant solution instead of water. The disinfectant solution used must be intended for use on equipment that meets the mouth, such as used for baby bottles. If in doubt, ask your pharmacist.

After, hold the Airofit Breathing Trainer under running water, allowing it to run through. Shake off excess water and dry with a clean towel.

5. GETTING STARTED WITH AIROFIT APPLICATION

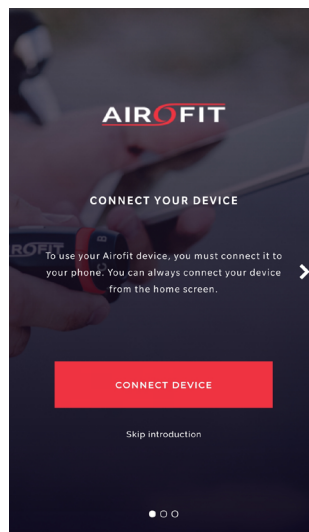
Start by charging your Airofit Breathing Trainer until the green LED is steady.

When you have installed the Airofit Application on the smartphone, you can start your registration and training. After, you can connect the Airofit device to your smartphone.



Register

Before you can use the Airofit Application you need to create your Airofit account.



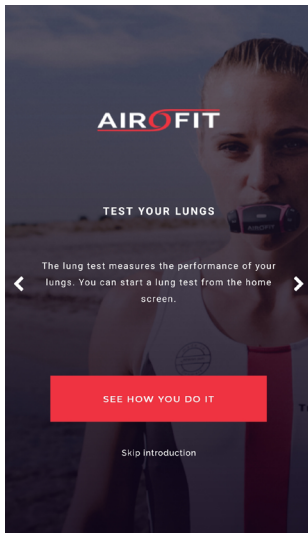
Connect

Turn on the Airofit device. Press Connect Device on the screen on your smartphone.

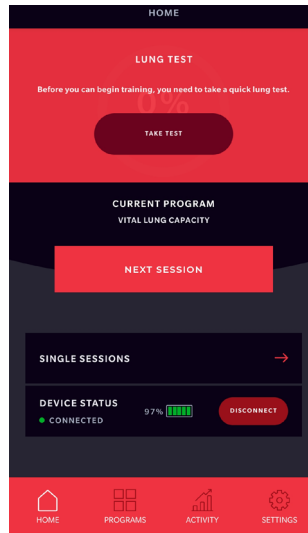


Connect

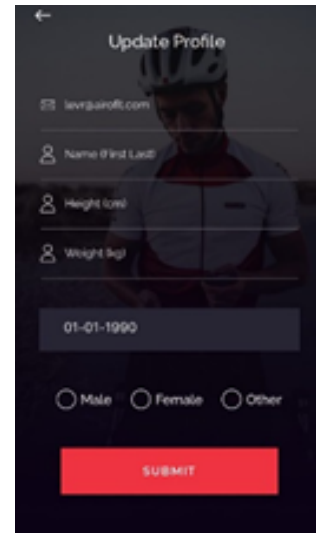
Follow the instructions on the screen of your phone. Remember to turn your Bluetooth on.



Test your lungs
Watch the instruction video showing how to take the lung test.



Home screen
You will be directed right to the home screen after the introduction is finished.



Update profile
Click on "SETTINGS" in the menu bar at the bottom of the screen. Select "UPDATE PROFILE".

6. TRAINING WITH AIROFIT

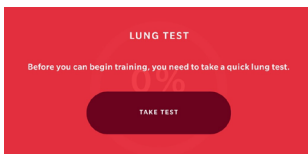
6.1 LUNG TEST

As instructed above, initially you shall make a lung test to establish your breathing condition. We recommend that occasionally during your exercise program, you make a lung test to see the improvements to your breathing condition.

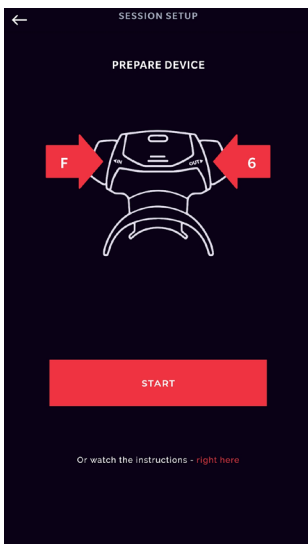
The lung test records your

- Vital lung capacity, i.e. your active lung volume
- Inhale strength, i.e. your Maximal Inspiratory Pressure (MIP)
- Exhale strength, i.e. your Maximal Expiratory Pressure (MEP)

Besides the actual measurements in liters and cmH₂O, measures of compliance are indicated. These measures are evaluated to your gender, age and height (as set in Profile) – according to ref. [1]. All percentages (0-200%) are related to your average of these evaluations.



Select "TAKE TEST" on the screen. You might need to turn your trainer on and reconnect.

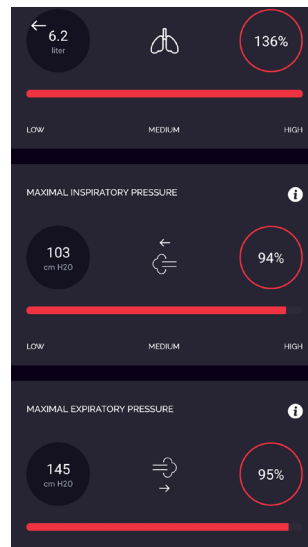


Make sure that you adjust the resistance wheels as shown on your screen. This applies every time you take a lung test or train.

To help you get familiar with the Airofit test and training session, we recommend that you start by watching the instruction videos at the bottom of the screen.

Select "right here" to watch the video.

Select "START" to take your Lung Test.



Here you can see your Vital Lung Capacity. Percentage and "LOW" to "HIGH" measurements show how your results compare with individuals your age, gender and size.

Inhale/Exhale Strength shows you maximal inspiratory/expiratory pressure.

These levels and numbers will be the starting point to measure and give feedback on your future exercises.

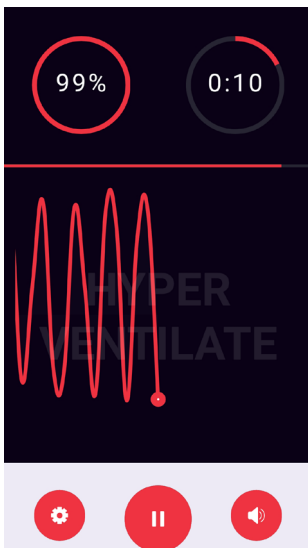


6.2 START TRAINING

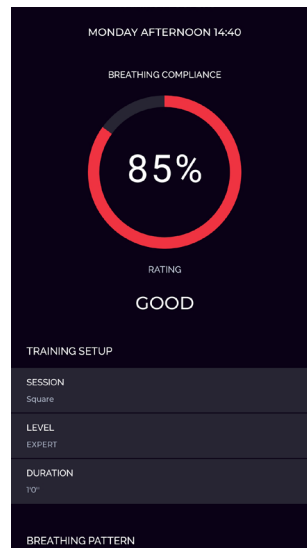
We recommend that you start with "INTRODUCTON" program until you are familiar with the training exercises. Respiratory training is like other forms of training, you need to train, but some training exercises are more specific. You don't need to finish a program to start another, but you can switch between them. Also, it is a good idea to mix your program training with single exercises from the single exercises menu. After being done with the Introduction, select any program you like to train. After clicking on "BEGIN YOUR TRAINING", you start by selecting training level:

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

Then you select the duration of your training. (1 - 10 minutes). We recommend that you start training 2x5 minutes every day. After a few trainings, we encourage you to train at least 2x10 minutes per day. We recommended to perform max 5 training exercises and max 60 minutes of training per day.



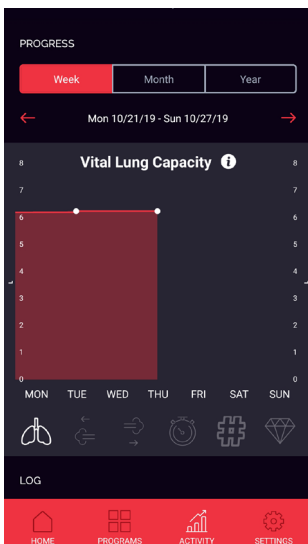
After clicking "START" button, your training exercise begins. When running a program, you can see how long the exercise has run so far and your compliance score in %. You can always stop, pause and restart an exercise. By clicking on the speaker icon, you can adjust the volume level of music and instruction.



When your exercise is finished, the result screen will appear. The percentage shows how well you can follow the guidance. It is your compliance score. Then you can see the summary of your training and your breathing pattern.

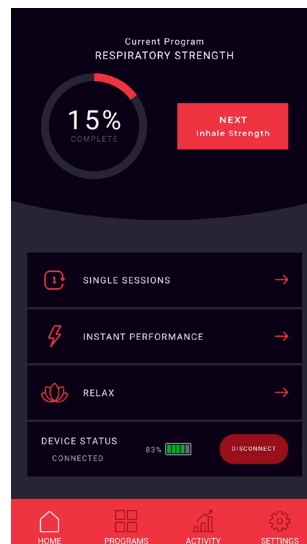
6.3 ACTIVITY AND HOME SCREEN

You can see your training activity and progress in several ways. To see the overview of your trainings, click on the "ACTIVITY" icon in the bottom of the screen on your phone. You can select the view on weekly, monthly or yearly basis.



On daily basis, the training activity shows:

- **Vital lung capacity**
The record of vital lung capacity
- **Max. inspiratory pressure**
The record of the inhale pressure
- **Max. expiratory pressure**
The record of the exhale pressure
- **Training time**
The duration of training
- **Number of trainings**
The duration of training
- **Exercise compliance**
The evaluation of your program exercise



Home screen shows the percentage of the selected program you have completed. You can find your training program below.

You can continue the next exercise of the training program by clicking on the button "NEXT".

If you want to train single exercises instead, press "SINGLE SESSIONS" menu.



7. SETTINGS

Several settings are required to have the optimal use of the training programs. Some settings require the smartphone is online and have access to the Airofit internet server.

7.1 ACCOUNT

The account data are stored locally on your smartphone. The email address and your name are also stored on the Airofit server. The account is protected by a password, which can be reset. You might also log out from your account.

7.2 AIROFIT BREATHING TRAINER

You can connect the Airofit Breathing Trainer by clicking on "CONNECT" button. When your trainer is connected, "BATTERY LEVEL" button shows how much percent of the battery on your trainer remains. You can see product's serial number and trainer's software version. In case of disconnection, you can still see the serial number (of the latest connected device). In case you select to do a calibration, you will be guided through the process.

7.3 PROGRAM

You can see what program you are currently training or select a new program. This section allows you to set up reminders for your training. You can set up daily reminder time (active from next training day).

7.4 EXERCISE

You can turn on/off your preferences for background music and guidance sound during your training exercise. You can allow/deny keeping your screen alive during training.

7.5 HELP

You can find the welcome tour in this section. If you have any questions about training, you can get them answered by clicking on FAQ button. You can also report a problem, if something with the App goes wrong.

7.6 ABOUT

This section shows the current App software version you are using. You can access the terms and conditions (require internet connection) as well as privacy policy which you have agreed to when you created your account.

Privacy policy (requires internet connection) contains:

- A description of the usage of your data by the Airofit server.
- Personal data are email address, first name, last name.
- Usage data concerns your setup of the smartphone.
- Your exercise data are only locally recorded on your smartphone

8. WARNING NOTIFICATION

The list of warning notifications:

Battery low (25%)	Charge the battery soon
Battery low (15%)	Charge the battery now
Battery low (5%)	Charge the battery now – your Airofit Breathing Trainer is not working anymore
Zeroing Failed	The initial offset (zeroing) of the pressure measurement failed. Do not breath into the device during this process



9. FAQs

My new App installation has lost my data and can't do a lung test

- Fully remove the App from your smartphone
- Turn off your smartphone and turn on again
- Reinstall the App

Why does my Airofit Breathing Trainer not connect to the App?

- Watch if the key is flashing when set on
- Make sure Bluetooth connection is enabled on your smartphone
- Make sure wireless connection is enabled on your smartphone
- If still not connected, fully close the App and reopen the App
- Check for any updates of the App

Why does my Airofit Breathing Trainer disconnect?

- Be careful not to push the key after connection is established
- Do not close the App while using the Breathing Trainer
- Do not move the Airofit Breathing Trainer more than 5 meters away from the smartphone

The exercises cause me to create a lot of saliva – is there anything I can do to stop this?

- Try pausing during your exercise (press pause in the App) to allow saliva in your mouth to clear
- Try taking the mouthpiece out of your mouth while swallowing. Put it back before continuing
- Alternatively, and if the exercise allows it, you can lie down while exercise with the Airofit Breathing Trainer

None of these will reduce the exercise effect

My exercise can't reach the exercise goal?

- If you can't reach the exercise goal on respiration pressure, select a lower level of exercise
- Try a calibration of the device

My results vary a lot, is this normal?

- The action of breathing is by its nature extremely variable and difficult to control accurately
- When you start exercise with the Airofit system you may find that your results vary widely between various exercises
- As you get used to the action of breathing against a resistance, you should find that your results become more consistent and controllable
- You may still find that there is a variation from day to day, depending upon your physical condition and state of mind on the day, just as any other form of exercise

I don't see any improvement – what can I do?

- If you do not see any improvement in the exercise progress, try increasing the level that you are exercise
- It is important that you are exercise against a load which is challenging to increase the strength of your respiratory breathing
- Note that after 6 to 8 weeks, your exercise improvements will tend to reach a level. After this, try to maintain your improved breathing results by continuing to exercise regularly.



11. TECHNICAL SPECIFICATIONS

11.1 AIROFIT BREATHING TRAINER

Description	Range	Comment
Air resistance		
Inhalation air resistance	A-F: 20-140 cmH ₂ O / (liter/sec)	Air resistance is limiting the airflow as part of the exercise
Exhalation air resistance	1-6: 30-200 cmH ₂ O / (liter/sec)	
Monitoring		
Vital lung capacity	0.5 - 10.0 liters	
Respiratory pressure	10 - 230 cmH ₂ O	
Lung capacity compliance	0 to 200%: Low: < 2.5 liter Medium: 2.5 – 4.5 liter High: > 4.5 liter	All compliance is evaluated to gender, age and height
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: 50 - 90% Expert: > 90 %	
Exercise settings	Air resistance settings Beginner: (D4, C3, B2) Intermediate: (E5, D4, C3) Expert: (F6, E5, D4)	Depending on lung capacity compliance (Low, Medium, High)
Material		
Mouthpiece	TPE	Not recorded in REACH directive
Housing	ABS	
Battery		
Rechargeable	3.7V Li-ion, 25mAh	
Capacity	10 hours	
Charger	5V, min 100mA	Not supplied
Charging time	2 hours	
Charger plug	USB micro	
Communication		
Bluetooth	BLE version 4.1	
Dimensions		
Size	70mm x 77mm x 33mm	
Weight	45g	
Smartphone App		
iOS version	11 or newer	
Android version	7 or newer	



11.2 ENVIRONMENT

Description	Range	Comment
Operating conditions		
Temperature indoor	15°C to 35°C	
Temperature outdoor	0°C to 45°C	
Relative humidity	10% to 90% RH	Non-condensing
Pressure	960 hPa to 1,060 hPa	
IP classification	IP54	
Storage and transport conditions		
Temperature	-25°C to 70°C	
Relative humidity	10% to 90% RH	Non-condensing
Pressure	700 hPa to 1,060 hPa	
Electrical shock prevention		
Electrical safety	Type B	
Leakage current	< 0.5mA	
EMC	IEC 60601-1-2	

11.3 STANDARDS

The Airofit system is designed according to the Medical Device Directive - MDD 2007/47/EC. The Airofit system complies to medical device **Class I**.

The Airofit system complies to 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 (2012/19/EU)	Waste Electrical and Electronic Equipment Directive – Category 5	2012



11.3 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-AF002

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, 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 licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). IC: 25191-AF002

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

12. VERSIONS

Ver.	Date	Changed	SW versions
3.6	24-09-2019	Updated to current status	1.04, 1.0.0