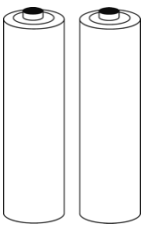
aerobit

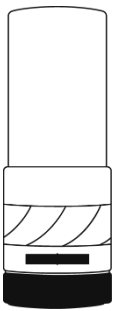
PeakFlow+ User Manual

WHAT'S IN THE BOX

Aerobit PeakFlow+ Device



2x AAA Batteries



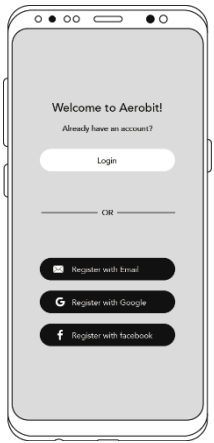
Reusable Turbine with Mouthpiece

SETTING UP YOUR DEVICE

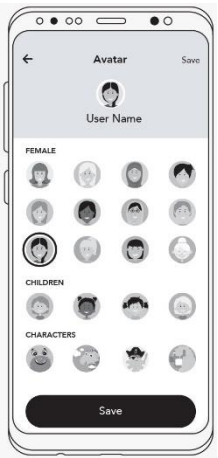
GET IT ON Google play

Download on the App Store

1) Download the Aerobit App from Google Play store or Apple App Store

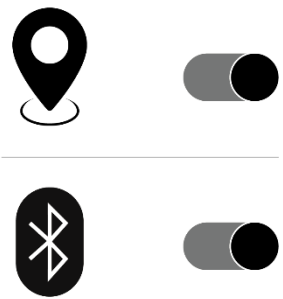


2) Login or Register on the App using Email, Facebook or Google Account

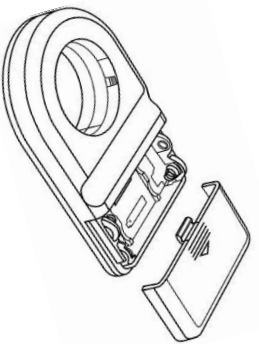


3) Enter information such Age, Gender, Ethnicity, Avatar etc when prompted

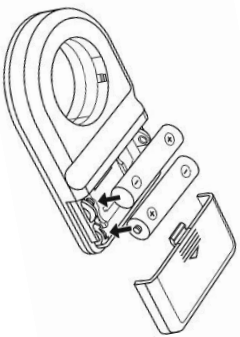
SETTING UP YOUR DEVICE



4) Enable Bluetooth and GPS from your phone settings.

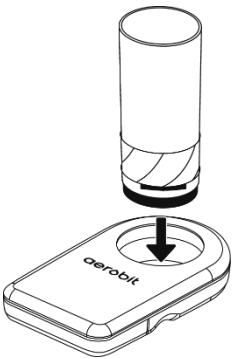


5) Open the battery latch from behind by gently pushing on the grips and pulling it downwards

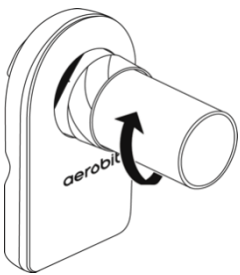


6) Insert the two AAA batteries into the battery cabinet. Close the battery latch until it snaps in place

PERFORMING A PEAK FLOW TEST



4) Insert the turbine in the device, gently push inside to make sure it has reached the end

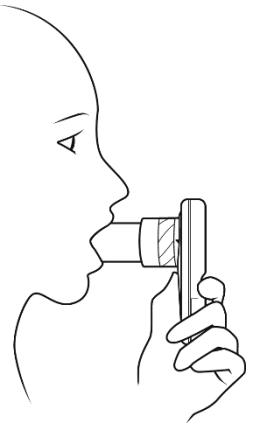


5) Rotate the turbine clockwise to lock it in place.

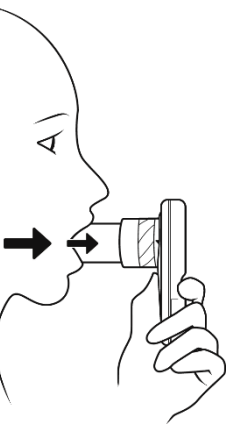
6) On the Aerobit App, Go to Peak Flow test tab and tap the Plus icon

PERFORMING A PEAK FLOW TEST

7) Inhale deeply.

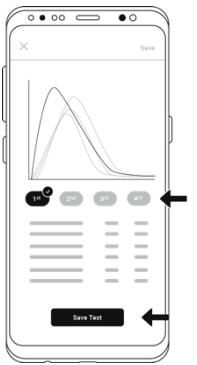


8) Seal your lips onto the mouthpiece.

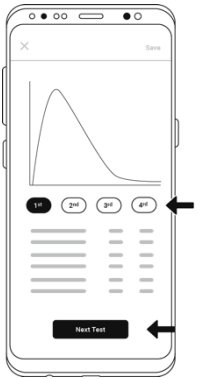


9) Exhale as fast as possible into the turbine.
Note: Your exhalation should exceed 6 seconds for accurate results

PERFORMING A PEAK FLOW TEST



10) The App will display the PEF, FEV1 values along with the graph. Tap Next Test for conducting next test (repeat steps 7 to 9). Take at least 10 seconds rest between each test.



11) After completing four tests, the device will go to Standby mode and the App will display the best of the four tests. Tap save test to save the results for future reference

INDICATIONS FOR USE

PeakFlow+ is intended for monitoring PEF (Peak Expiratory Flow Rate) and FEV1 (Forced Expiratory Volume in one second) for patient home use. The device is designed for paediatric to adult patients.

Patients below 16 years shall be supervised by an adult during the use of this device.

When the device is used to monitor lung conditions such as asthma and chronic obstructive pulmonary disease (COPD), the user should be under the care of a licensed health care professional.

GENERAL INFORMATION

PeakFlow+ is used to measure a person's PEF (Peak Expiratory Flow) and FEV1(Forced Expiratory Volume). PEF is the fastest speed a person can blow air out of the lungs after taking in as big a breath as possible.

Forced Expiratory Volume (FEV1) is a measure of the volume of air expelled in 1- second.

PeakFlow+ has the following frequently used operations: -

1) Attaching the Aerobit Turbine to PeakFlow+ device
2) Pairing with a Smartphone via Bluetooth
3) Performing a set of test
4) Viewing results on the Aerobit App.

PeakFlow+ works with iOS and Android devices and connects via Bluetooth. PeakFlow+ is powered by 2 x 1.5 V AAA Alkaline batteries. Depending on the usage and manufacturer, each set of new batteries should last for about six to eight months. If the batteries are replaced or when the device is discarded, dispose the same as electronic waste. Use Alkaline batteries only.

PeakFlow+ is designed to work with Aerobit Reusable Turbines. When performing a test, the user exhales into the turbine. The airflow generated sets a rotor in motion. PeakFlow+ registers the speed of the spinning rotor, converts it and transfers the data via Bluetooth to the smartphone app.

CAUTION

When a peak flow meter is used to watch lung conditions such as asthma, the user should be under the care of a physician (or other licensed health care professional). A licensed health care professional's advice is required to understand the meaning and importance of the measures you get with your peak flow meter, and to decide on an appropriate treatment plan.

LIMITATIONS OF USE & CONTRAINDICATIONS

A peak flow test should only be carried out when the user is at rest (i.e. does not experience shortness of breath) and in good health, and thus in a suitable condition for the test.

An analysis of the results of a peak flow test alone is not enough to make a diagnosis of a clinical condition. Test interpretation and suggested treatment must be provided by a Healthcare professional.
A correct peak flow test depends on the user's capability exhale all air completely and as fast as possible. If these fundamental conditions are not respected then the results obtained during testing will not be accurate, and therefore the test results are "not acceptable".

The acceptability of a test is the responsibility of the user. Special attention should be given when testing the elderly, disabled and children.

The device should never be used when it is possible or probable that the validity of the results may be compromised due to any external factors.
Some conditions may pose a relative danger to a patient or affect the validity of peak flow performance and results. These include, but are not limited to unstable cardiovascular status, unstable angina, recent myocardial infarction (within one month) or pulmonary embolism, haemoptysis of unknown origin, recent pneumothorax, thoracic, abdominal or cerebral aneurysms, recent thoracic, abdominal or eye surgery, acute disorders such as nausea or vomiting, severe respiratory distress, physical limitations, cognitive impairment, dementia.

IMPORTANT SAFETY WARNINGS

Once removed from its packaging, check that there is no visible damage on the device. In the case of damage do not use it and contact us immediately.

PeakFlow+ has been examined by an independent laboratory which has certified the conformity of the device to the ISO 60601-1 and guarantees the EMC Requirements within the limits set ISO 60601-1-2 and ETSI's EN300328. It is a medical device class IIa ("two a") product. PeakFlow+ is constantly controlled during its production, therefore the product conforms to the essential requirements set by the Council Directive 93/42/EEC for medical devices.

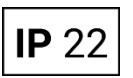
- Use only with iOS and Android devices specified on our website www.aerobithealth.com
- Use only in environments specified in this user manual.
- Do not expose to liquids.
- Should you lose the battery hatch with required and device

specific information on it, the guarantee will no longer be valid and Aerobit cannot provide further support or guarantee the condition or functionality of
the product.

Explanation of the safety signs and symbols marked on the device:

Manufacturer's name and address.

CE mark: indicates that the device is certified that it conforms to the requirements of the 93/42/EEC medical device directive.



IP classification indicates that the device is protected against solid objects over 2.5 mm entering as well as falling drops of water, if the case is disposed up to 15° from vertical.

Waste electrical and electronic equipment: Dispose accordingly. Do not dispose as unsorted municipal waste.

Manufacturer's Serial Number.

Manufacturer's product reference number

The symbol is used in accordance with IEC 60601-1-2:2014 (ED. 4) for products including radio transmitters and in accordance with EN 300 328.

Type BF applied part: Device that has conductive contact or medium to long term contact with the patient in order to fulfill the intended use.

Applied Part: The Aerobit PeakFlow+ and the Aerobit Reusable turbine are Type BF parts.

Follow operating instructions: Indicates the need for user to consult the instructions for important information.

OPERATING ENVIRONMENT

PeakFlow+ has been designed for use in a doctor's office, in a hospital setting or at home.

PeakFlow+ is not intended for use in an operating theatre nor in the presence of inflammable liquids or detergents, nor in the presence of inflammable anaesthetic gases (oxygen or nitrogen). The device is not designed to be used in direct air currents (e.g. wind), sources of heat or cold, direct sun rays or other sources of light or energy, dust, sand or any other chemical substances.

AEROBIT REUSABLE TURBINE

PeakFlow+ is designed to be used with a mouthpiece attached to an Aerobit Reusable turbine.
Before each use, the Reusable turbine should be cleaned, and a new unused mouthpiece should be used. For best results, use Aerobit Mouthpieces, visit aerobithealth.com for more info.

The integrity and functionality are guaranteed by:

• Never holding the turbine under a jet of water or air and never let it come into contact with high temperature fluids.
•Not allowing dust or foreign bodies to enter the turbine sensor, in order to avoid incorrect functioning and possible damage. The presence of any impurities such as hair, sputum, threads etc. within the body of the turbine sensor may seriously compromise the accuracy of the measurements.
• Avoiding environmental contamination by cleaning waste products, the user must adhere to all relevant regulations. The Reusable turbine must be properly disinfected before each test.

It is highly recommended to use Aerobit Reusable Turbine and Mouthpieces only, usage of third-party turbines or mouthpieces could seriously impact the accuracy of the readings and safety of the patient.

Cleaning the Aerobit Reusable Turbine

To clean the reusable turbine, please refer to the following procedure: -

1) Remove the Turbine from its compartment on the PeakFlow+ by turning it anti-clockwise and pressing lightly. It can be helpful to push it gently from underneath with one finger.

2) Immerse the turbine in the recommended cold detergent solution and move it within the liquid to remove any impurities which may be deposited inside.

3) Leave the turbine immersed for the time specified in the instruction of the solution. To avoid any kind of damage to the reusable turbine please do not use any alcoholic or oily substances, do not immerge the turbine in hot water or hot solution. Do not put the turbine under a direct jet of water or other liquid. If no detergent solution is available, clean the turbine in clean water.

4) Rinse the turbine by immerging it in clean water (not hot).

5) Shake off the excess water from the turbine and leave it to dry, standing it vertically on a dry surface.

6) Once the turbine has been cleaned insert the turbine tube in its place. To correctly insert the turbine push it to the end and turn it clockwise until reaching the wedge which ensures that the tube has been blocked inside the plastic casing.

CAUTION: RISK OF CROSS-CONTAMINATION

To avoid cross contamination, Aerobit Turbines are marked as single Patient Use accessories.

However, to avoid self-contamination, Aerobit Turbines should be properly cleaned before every use.

The Aerobit Reusable Turbine has a paper Mouthpiece attached at one end; a new unused mouthpiece must be used for each set of tests. Used mouthpieces must be discarded as household wastes.

The correct functioning of the re-usable turbine can only be guaranteed if it has been cleaned in the correct manner and is free from foreign bodies which could alter its movement. The cleaning of the turbine should be performed according to the instructions contained in the User's Manual.

PeakFlow+ Tests Parameters

FEV1(Forced Expiratory Volume in 1 second) The volume of air (l) A forced maximal expiratory effort after a full inspiration.

PEF (Peak Expiratory Flow) The maximum flow rate (l/s) during a forced maximal expiratory effort after a full inspiration.

The final results displayed in the application are always the best

values obtained after performing the 4 tests included in a session.

Displayed test are compared to a reference table (GLI) and displayed as percent predictive value (%pred.).

The reference used in PeakFlow+ uses expected normal lung function values such as for FEV1 and PEF are based on ethnicity, gender, age and height.

Note: Home use of PeakFlow+ is intended only for indicative purpose. Interpretation of the test results and diagnosis shall be done by a healthcare professional only.

STORAGE AND MAINTENANCE

Handle PeakFlow+ device carefully. Store it in clean and moisture free conditions. Before use, always check that the device is free from dust, contamination or any particles.
PeakFlow+ does not require professional maintenance. If, however, the outside of the device needs to be cleaned make sure to only use a damp cloth without any detergents. The batteries of PeakFlow+ are replaceable.

If the storage temperature is below 20C, allow the device to warm up before use.

If the storage temperature above 60C, allow the device to cool down before use.

Keep the PeakFlow+ device out of reach of infants, pets or pests.

ACCESS TO BLUETOOTH

Enable Bluetooth on your mobile device in order to pair with the PeakFlow+ device. You can enable Bluetooth in your mobile device settings. Check your device manual on how to do this.

BLUETOOTH PROXIMITY

Make sure that the PeakFlow+ is within the Bluetooth proximity of your phone. If your phone is too far

away from the PeakFlow+, the connection could be lost.

FCC RADIO FREQUENCY INTERFERENCE STATEMENT

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.

Aerobit is not responsible for any radio or communication interference caused by using other than specified or recommended cables and battery or by unauthorized changes or modifications to this equipment. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment. 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.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End user must follow the specific

operating instructions for satisfying RF exposure compliance.

IC Radio Frequency Interference Statement

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

- This device may not cause interference.

- This device must accept any interference, including interference that may cause undesired operation of the device.

The products are compliant with SAR for general population/uncontrolled exposure limits in IC RSS-102 and has been tested in accordance with the measurement methods and procedures specified in IEEE 1528.

The transmitter module may not be co-located with any other transmitter or antenna.

TROUBLESHOOTING

-Make sure that the Aerobit PeakFlow+ Reusable Turbine is correctly inserted into the device.

-Make sure the turbine is not spinning before starting the test.

-Make sure there is enough battery before you do a test.

-Make sure the environment is not too windy or bright.

-Make sure the Bluetooth is Enabled on your Smartphone

Unable to setup? Unexpected errors or outputs? Contact us immediately and we will be more than happy to help.

TECHNICAL FEATURES

Environment of use	Home, Clinic or hospital setting
Measurement method	Infrared Interrupt
Power Supply	2 x 1.5V AAA Alkaline battery
Flow Accuracy	±5%
Volume Accuracy	±3%
Operating Conditions	Temperature: 10°C – 40°C Or 50°F – 104°F Humidity: 10% - 90% Altitude: ≤2000m
Conditions of Storage	Temperature: -10°C – 70°C Or 14°F – 158°F Humidity: 10% - 90% Altitude: ≤2000m

Atmospheric Pressure	1000 hPa – 750 hPa
Communication	Bluetooth
Expected service life of PeakFlow+ and Aerobit Turbine	2 Years
Regulations applicable	ISO 23747 ISO 26782 IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11

In case of questions, feedbacks or concerns, please contact us at: -

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