AioCare Spirometry System User Manual

AioCare

- digital spirometry system with the peakflometry module

CE 2274

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1. Description of AioCare system

AioCare has been developed at Healthup by a team of experts with practical experience in design and manufacture of medical devices and software development.
The main innovation of our system is a unique combination of measurement sensors, our proprietary measurement channel, and a functional application working on iOS and Android operating systems.

AioCare – remote monitoring system with the spirometer module, used for conducting spirometry. These are basic tests for conducting functional diagnostics and assessment of mechanical properties of the respiratory system. It allows the user to record the spirogram and assess breathing maneuver of forced expiration/inspiration, and the maximum flow-volume loop/volume-time curve, and the values related to them, such as forced vital capacity (FVC). In addition, you can record spirograms following bronchodilation. These measurements are used in diagnostics and monitoring of lung conditions and intervention during the treatment for certain types of respiratory diseases.

AioCare also works as a peak flow meter, measuring peak expiratory flow (PEF).

INDICATIONS FOR USE:

The AioCare spirometer is intended to be used by a physician or by a patient under the instruction of a physician or paramedic. The device is intended to test lung function and can make spirometry testing in adult people and children>5 years old, only under supervision and guided by the adult. Standard values and interpretation results have not been calculated for children less than 5 years old.

Application:

1. Respiratory system function assessment in the presence of:

   a. signs (dyspnoea, wheezing, coughing, expectorating, orthopnoea, pain in the chest),
   b. symptoms (abnormal breathing sounds, features of emphysema, prolonged expiration phase, cyanosis, deformations of the rib cage, nail clubbing)
   c. abnormal additional tests (abnormal x-ray of the lungs, hypoxemia, hypercapnia, polyglobulia – increased values of haematocrit)
2. Screening tests in persons with risk factors (smoking, exposure to toxic factors, dusts, gases).
3. Examination of the respiratory system in systemic conditions
4. Assessment of risk in the perioperative period:
   a. extrapulmonary surgeries
   b. thoracic surgeries
5. Assessment of the respiratory function prior to strenuous physical activity.
6. Monitoring of treatment with:
   - bronchodilators,
   - corticosteroids (asthma, COPD, interstitial lung diseases),
   - other medicines (e.g. antibiotic therapy in cystic fibrosis),
   - diuretics in congestive heart failure
7. Self-monitoring of the respiratory function by the patient in home environment:
   a. signs and symptoms (dyspnoea, wheezing)
   b. exacerbations of respiratory diseases, including asthma, chronic obstructive pulmonary disease
   c. following lung transplantation

1.1 Contraindications for spirometry testing

1. Absolute contraindications:

- recent (in the hospitalisation period) myocardial infarction,
- recent (in the hospitalisation period) cerebral stroke,
- aneurysms (risk of aneurysm rupture and bleeding after increased pressure in the chest),
- recent ophthalmic surgery (e.g. cataract surgery),
- increased intracranial pressure,
- haemoptysis of unknown aetiology,
- pneumothorax.

2. Relative contraindications:

- a condition that may affect the results (e.g. nausea, vomiting, persistent coughing),
- a condition following abdominal,
- or thoracic surgery (post-operative pain precluding correct breathing manoeuvres during the test),
- dizziness, arrhythmias,
- significant desaturation after interruption of oxygen therapy for the duration of the test.

1.2. Contraindications for peak flow measurement

No contraindications for peak flow measurement.

2. Structure of AioCare spirometry system

AioCare is a portable spirometer for the testing of the respiratory function. AioCare spirometry system comprises:

- measuring module with a flow tube
- mobile application for installation from AppStore or Google Play

Recommended Accessories (all accessories are only recommended, none of the below mentioned accessories are included with AioCare, nor are they marketed or sold by HealthUp):

- MicroGard II PTF Filter Mouthpiece, (510(K) Number: K111408).
- Vyaire V-892892 Nose Clip, Single patient use {Class 1, 510(k), UDI 14250892903009.
- USB cable
- abbreviated instructions for use

The spirometry system is capable of:
1. Testing:

a. spirometry (parameters: PEF, FVC, FEV1, FVC/FEV1 ratio, FEF25, FEV50, FEV75)

b. peak flow measurement (PEF)

2. Archiving of testing results in the application.

3. Creating patient's personal file.

2.1 Measuring module combined with mobile device

The purpose of the measurement module is to transform the patient's inhalation and exhalation parameters into electric signal. The signal generated in the module is processed by the spirometer's microcontroller and sent through Bluetooth 4.0 to the mobile application where the data are processed into graphs and numeric values of parameters displayed on the screen of a mobile device.

2.1.1 Operating conditions and device class

Optimum ambient temperature for measurement: +15 to +40 °C, relative humidity: 15-93%
Storage: from +5°C to +45°C, humidity <70 %
Internally powered device
Product class II A
The device operating conditions mentioned above make it suitable for operation in home conditions and in professional health care facilities: diagnostic surgeries, general clinics.

2.1.2 Technical data.

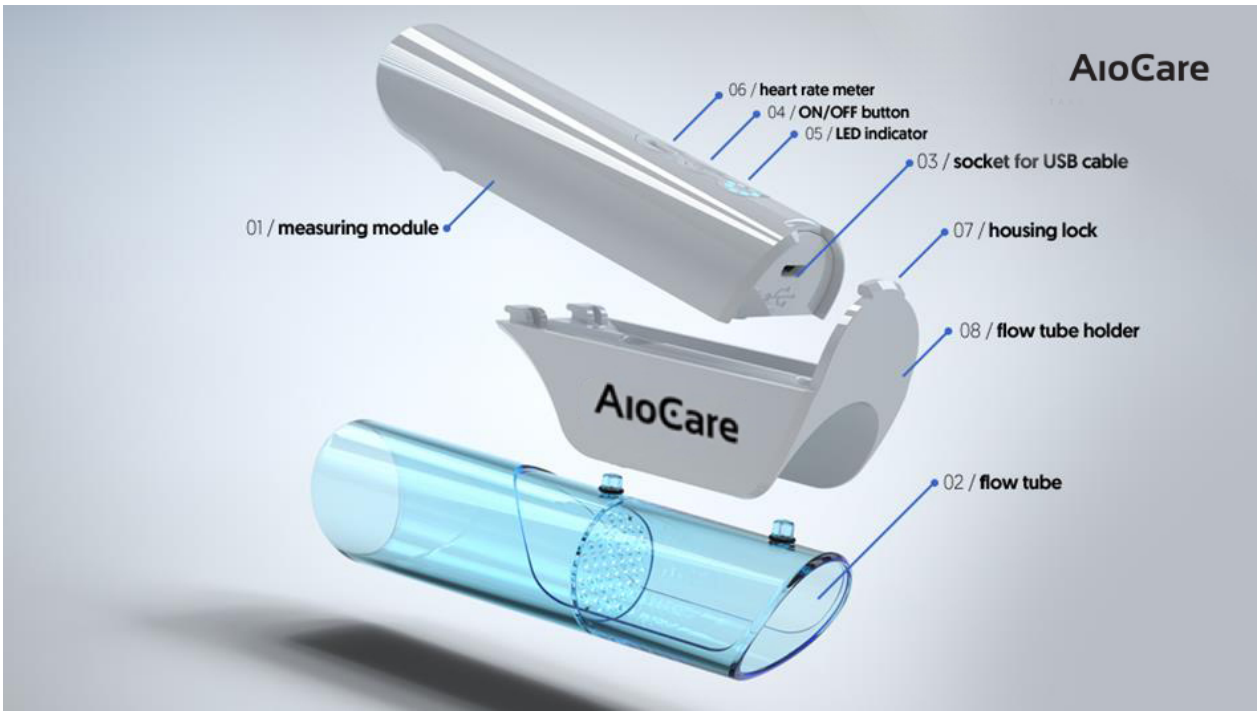
Type of sensor for flow measurement	Thermal

Tests	Pre- and post- FVC (bronchodilator)
Range of spirometry flow rate measurement	0-16 L/s
Flow Accuracy	±5% or 200 mL/s
Flow Resistance	<0.5 cm H2O/L/s
Volume Range	0-8 Liters
Volume accuracy	±3% or 50 mL, whichever is greater
Linearity	3% (0.4L and 0.6L)
Flow rate measurement resolution	measured 5 mL/s, used 10 mL/s
Reliability/reproducibility	Meets or is better than the ATS 2005 standard (0.05 L or 3% from the readout, whichever is larger)
Automatic BTPS conversion	in-built measurement sensors: air temperature, pressure and humidity
Determination of t0	Algorithmic
Expiratory lung impedance	<0.15 kPa/(L/s) with flow rate 14L/s
Dynamic flow resistance	<0.5 cm H2O/L/s
Protection of enclosure against moisture ingress, acc. to IEC 60529 (elements of the spirometer)	IP 22
Communication	Bluetooth 4.0 Low Energy
Bluetooth Operation frequency	2.4 to 2.4800 GHz
Measurement frequency	100 Hz
Internal power supply	Battery (LiPo 3.7 V)
Power consumption 50 mA	50 mA
Dimensions	118x38x48 mm
Weight:	0.3 kg

Parameters:

FVC	Forced Vital Capacity
FEV1	Forced Expiratory Volume in 1 sec.
FVC/FEV1 ratio	Ratio between FVC and FEV1
FEF25	Flow at 25% of the FVC
FEF50	Flow at 50% of the FVC
FEF75	Flow at 75% of the FVC
PEF	Peak Expiratory Flow

2.1.3 Schematic structure of AioCare



2.1.4 AioCare assemblies

The parameters of all parts are exactly reproducible. A flow tube is connected to the measurement module through the tube grip. The air flows through two air channels and one bypass fluid channel. Prior to testing a new patient, the bacterial filter found in the package should be connected to the tube. The measurement tube maintains its parameters until mechanical destruction.

3. Testing

3.1 Calibration of the spirometry system

The device is calibrated by the manufacturer. The sensor and flow tube are calibrated in the full range of flow rates

measured using a precise flow generator and don't require the user to conduct any calibration during the warranty period.

A calibration check can be provided using 3 L syringe. The procedure of calibration checking realizes the following steps:
-Turn off the BTPS correction in Settings
- Adjust the AioCare spirometer to the output of the syringe
- Run standard spirometry test in the AioCare mobile application (Patient or PRO)
- Perform a few waveforms (3-5) using 3 L syringe ad different flowrates.
Check if the FVC parameter values are within calibration limits, e.g. +/-3% (+/- 0.09 L)

If a device fails its calibration check, then a new calibration procedure by manufacturer is required. With normal use, calibration check is recommended as a part of the annual routine maintenance service. This service is available at health care facilities or at the headquarters of AioCare manufacturer. The calibration check is free of charge. Client covers the shipment cost only.

3.2. Flow-volume loop

The patient is breathing through the bacterial filter and flow tube. After several quiet breathing cycles, s(he) exhales as deep as possible and takes as quick and deep breath as possible and then exhales as quick and deep as possible. This maneuver is repeated several times.

3.3. Spirometry

Prior to the test, rest for at least 15 minutes. For safety reasons (possible fainting), a spirometry test is conducted usually in a sitting position. Prior to measurement, attach the bacterial filter and the nose clip to the flow tube, make several quiet breathing cycles, and make a slow, deepest possible exhalation, followed by quickest and deepest possible inhalation. After that, make deepest possible forced exhalation continued for as long as possible. The measurement may be repeated after regular breathing is restored, but not earlier than after 30 seconds. At least 3 correct measurements, long for 6 seconds are required, and when there is no reproducibility – no more than 8 measurements. The flow-volume loop should be measured correctly at least 3 times. The measurements are considered reproducible if the two highest FVC values differ from each other by no more than 150 ml and also the two highest FEV1 values differ from each other by no more than 150 ml. The result of measurement are maximum FEV1 and FVC values which don't need to be obtained in the same test.

CAUTION: Do not repeat the spirometry test more than two times per day (16 flows). It may cause false results and in a consequence, false indications for your treatment.

3.4. Flow reset

To increase the accuracy of measurement. Place AioCare in a horizontal position away from sources generating the air flow and trigger the flow resetting function in the mobile application. The resetting is 5 seconds long, and the user is informed on its progress by visual representation on the display of the mobile device.

4. INTERACTION WITH PATIENT:

4.1. Preparing AioCare for operation

To prepare the device to operation, first clean the AioCare and do the following:

Setting up your device:

1. Make sure the system contains all elements (iPhone, AioCare Application, Measuring module, flow tube holder, flow tube, mouthpiece with built in antibacterial filter)

2. Download the AioCare Application from Apple App Store or Google and install it according to the instructions displayed on the screen of your mobile device

3. Turn on AioCare with the ON/OFF button

4. Pair the device with the AioCare Application: on the application select pair, and select the model number of the device you would like to pair with.

5. Check the battery level of the device (can be done through the application)

6. Connect the flow tube to the measuring module

7. Attach the mouthpiece to the flow tube

8. Follow in-app instructions to conduct: spirometry, peak flow

4.2 Communication between AioCare device and user

Your AioCare spirometer will communicate with your mobile device by Bluetooth 4.0 (BLE) technology. The messages are displayed in the mobile application on the screen of your smartphone. Additionally, there are LEDs on the AioCare device.

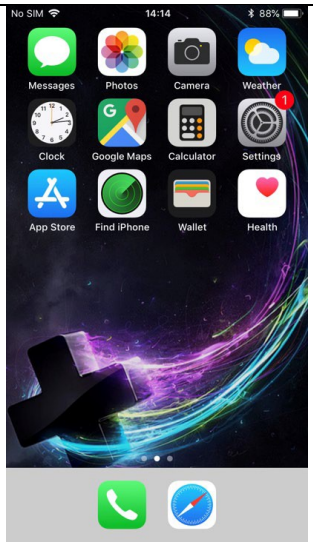
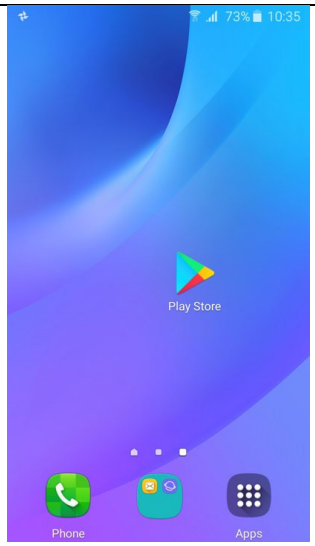
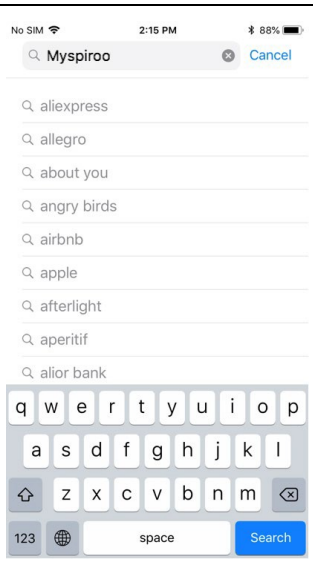
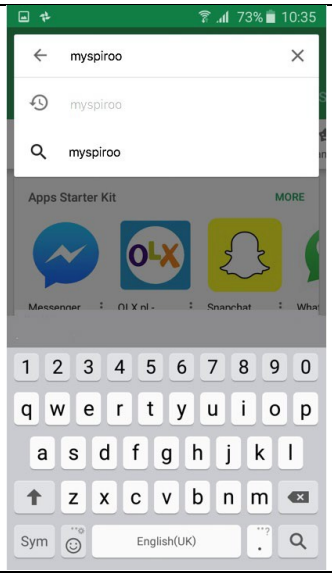
The meaning of LEDs messages:

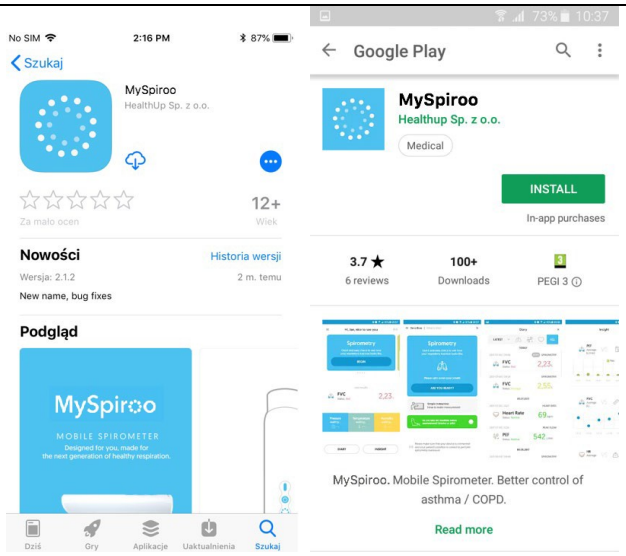
One-time flashing of all the diodes one by one 360° to the moment the light is steady	Starting the device
Diodes flashing in a sequence in a circular cycle to the moment the light is steady	Pairing of the AioCare device with a Smartphone
All the LEDs flashing smoothly	Bluetooth data transmission during the measurement
4 of 8 diodes flashing	Low battery level - connect to a power source
Another one LED is flashing in the charging mode	Representation of the battery charge level

4.3 Hardware and software requirements for the mobile device

AioCare spirometer is operated through AioCare applications for iOS and Android. These applications are available at Apple App Store and Google Play. The applications work on versions at least iOS 9.0+ and Android API 21+ (5.0). The communication between AioCare and applications in via Bluetooth 4.0 (BT LE). The mobile devices on which the applications are installed must be equipped with that version. iPhone version must be at least iPhone 5S. We don't recommend operating the application on tablets or iPads.

How to install:

Please find and open the application App Store or Google Play on your device	 
Please click on App Store or Google Play search field to enter the name of the application: AioCare	 

Click „Install” to download and install the application on your device.	
After correct installation of the app you have to click to open the app.	

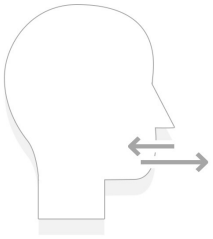
Prepare for measurement

Spirometry

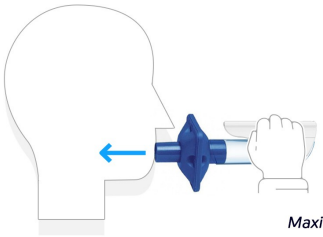
Positioning: sitting upright, feet flat on the floor. Loosen any tight-fitting clothing. If you have dentures you can leave them in. Use chair with armrest.

(a) Prepare the AioCare device by attaching the mouthpiece with a built-in antibacterial filter.
(b) Open the AioCare application.
(c) Choose “Spirometry” from the menu.
(d) Place AioCare device on a flat surface and wait 5 seconds for zero flowing. Put on the nose clip.
(e) Click start on your mobile application whenever you are ready.
(f) Take two normal breaths through the mouthpiece.
(g) Take maximal inspiration
(h) Make force exhalation for at least 6 seconds
(i) Place device on side and press “stop” in the application.
(j) Repeat the f – j sequence at least 3 times correctly out of 8 tries.
(k) If the test was performed properly, the results will be marked with a green mark visible on the screen of your mobile device.

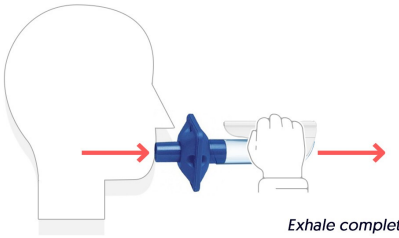
The maneuver should meet the end-of-test criteria (exhaling for ≥6s with <50 mL being exhaled in the last 2 seconds.



Relax and keep calm your breath



Maximal inspiration

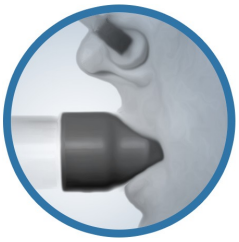


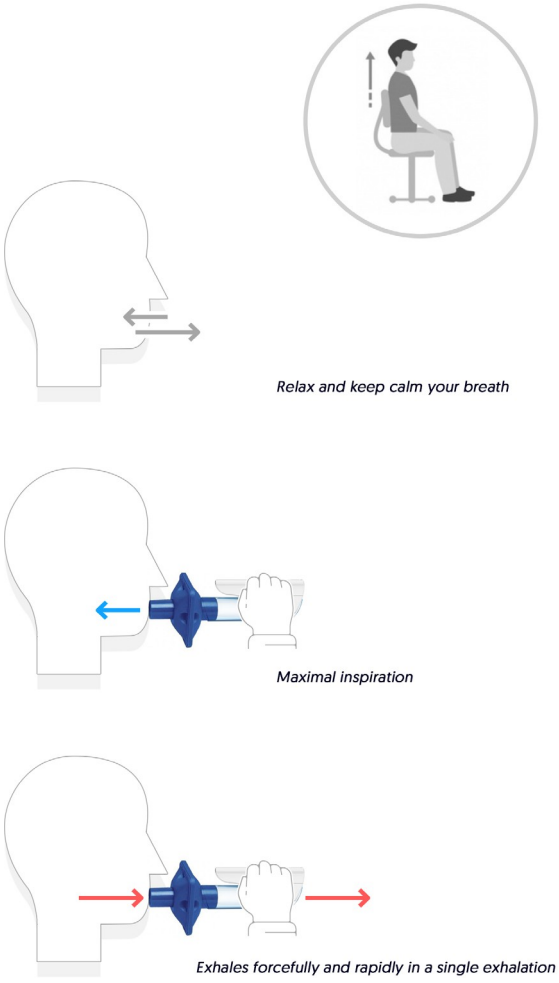
Exhale completely for >6 seconds

Peak expiratory flow test

Positioning: conventionally PEF is measured with the patient standing.

(a) Prepare the AioCare device by attaching the mouthpiece with a built-in antibacterial filter.
(b) Open the AioCare application.
(c) Choose “Peak Flow” from the menu.
(d) Place AioCare device on a flat surface and wait 5 seconds for zero flowing.
(e) Click start on your mobile device whenever you are ready.
(f) Inhale deeply
(g) Take the mouthpiece in the mouth with lips closed around it
(h) Patient exhales forcefully and rapidly in a single exhalation. Repeat the f – g sequence 2 more times.
(i) If the test was performed properly the results will be visible on the screen of your mobile device.





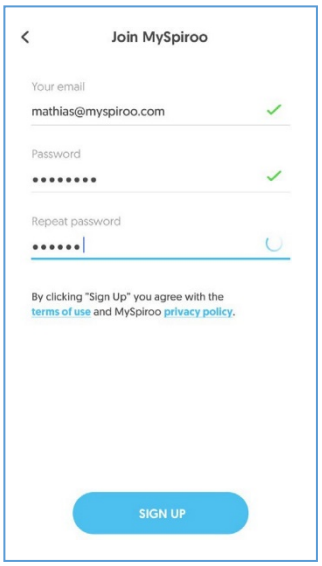
4.4. First launch of application

Upon installing the AioCare application, to continue using it, you need to create a doctor's or user's account, or log in if such account is already in the system.

CAUTION: You should contact the manufacturer if you need any advice on installing or using, or to report unexpected operation or event.

Log in

If you already have an account, you can log in by using the “Zaloguj” [Log in] button, entering your assigned ID and password received from your doctor.



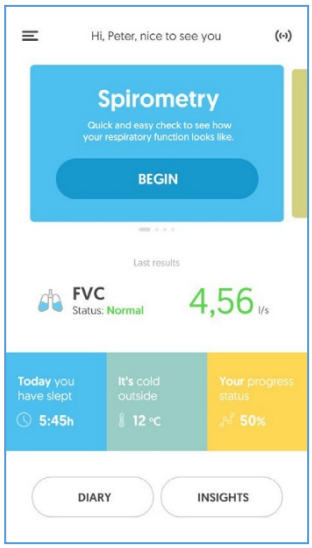
Main screen

On the main screen, you have access to the following functionalities:

Button opening the application main menu containing:

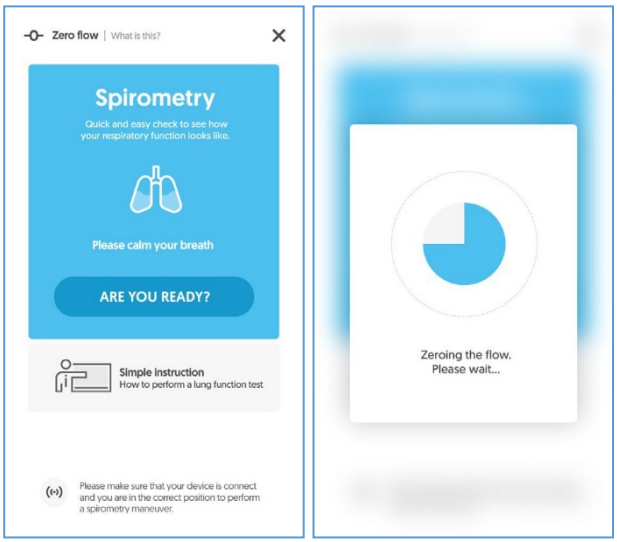
- Button to start a spirometry test
- Log
- Statistics
- My device
- My profile
- Help
- Shop
- Settings
- About us

1. User welcome screen
2. Icon of connection to device
3. Button to start a spirometry test
4. Result of the last spirometry measurement
5. Information on ambient condition: pressure, temperature and humidity.
6. Button opening the Log
7. Button opening the Statistics

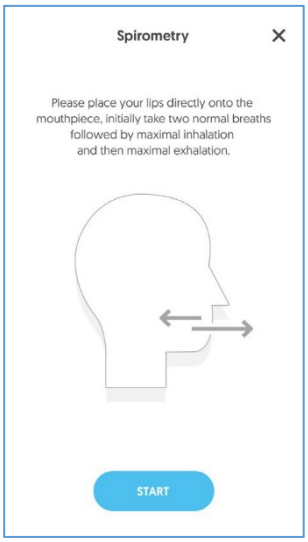


4.5. Conducting a test

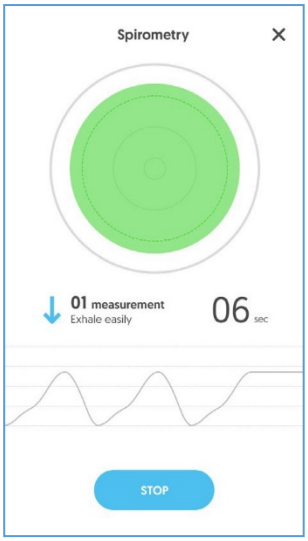
A spirometry test begins by pressing “Start” on the main screen. It redirects to the test screen. Make sure the device has been connected and paired with the application, then reset the flow.



The next step displays the measurement preparation screen. Prepare the spirometer, filter and nose clip. When the patient is ready, press “Start”.



Next displayed is the “live” measurement screen with visualisation and graph of the flow rate in real time. Measurement is stopped by pressing the “Stop” button.

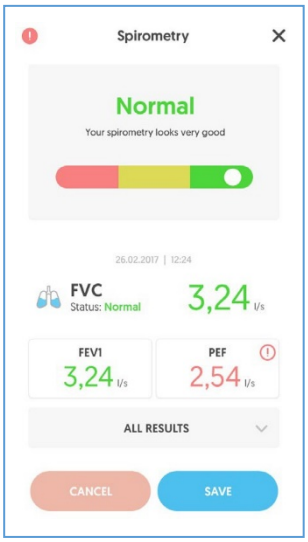


You can find App Guidebook in our website in section Support.

4.6.Measurement results

Spirometry

The first screen shows the interpretation of results, and all measured spirometry parameters are shown at the bottom. Measurement results can be recorded or discarded by pressing the appropriate button on the screen. If the measurement is carried out incorrectly, the application indicates an error in the left upper corner of the screen and marks incorrect test.



5. AioCare spirometer maintenance

5.1 Operation guidance

Tests and safety

AioCare has been tested by an independent laboratory which has certified the conformity of the device with the European standard for electric safety and for home use (EN 60601-1 and EN 60601-11) and warrants its conformance with electromagnetic compatibility requirements set out in the EN 60601-1-2 European standard.
AioCare is constantly controlled in the manufacturing cycle, which ensures that the safety levels and quality standards set out in Council Directive 93/42/EEC on medical devices are met.

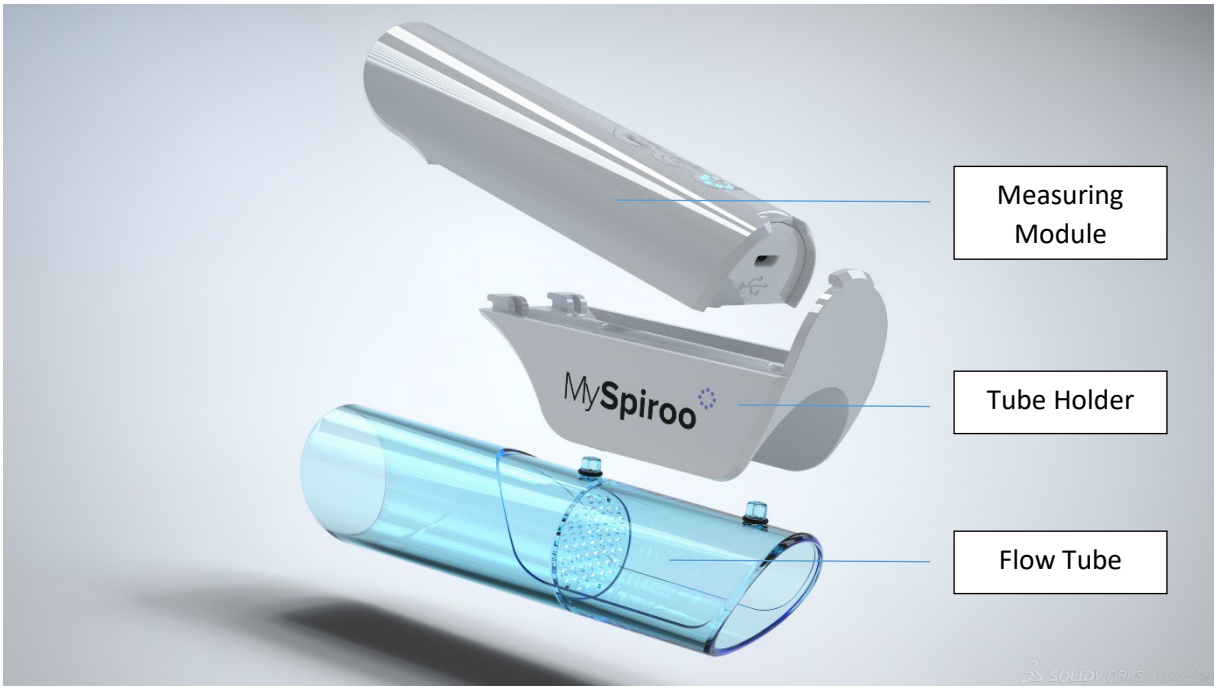
CAUTION: Safety and correct operation of the device can be ensured only when the user complies with all essential safety principles and regulations.
The manufacturer is not liable for any damage caused by failure to comply with the user manual.
This device may be used only as a spirometer, with the use of only original spare parts and accessories.
Failure to comply with this caution may lead to device damage, incorrect measurement and the loss of warranty.

5.2. Reprocessing

5.2.1. General information about reprocessing:

AioCare device has three main parts:

- Measuring Module
- Tube Holder
- Flow Tube



Warning: To avoid damage to the measuring module of the AioCare device, disconnect the flow tube and flow tube holder prior to initiating the process of cleaning and disinfection!

All the maintenance operations described in the User Manual must be carried out with great care. Failure to follow these instructions may lead to incorrect readings or the incorrect interpretation of readings that have been taken.

To avoid malfunctions or damage, do not introduce dust or foreign bodies into the flow tube. The presence of foreign bodies (such as hairs, saliva etc.) inside the flow tube can compromise the accuracy of readings.

All modifications, adjustments, repairs and reconfigurations must be performed by the manufacturer or by personnel authorized by the manufacturer.

5.2.2. MAINTENANCE

AioCare devices need little maintenance. You should periodically:

- Clean and check the reusable flow tube
- Replace the flow tube when it has changed its properties (mechanical damage like scratches, scattered debri, dirt impossible to clean)
- Clean the measuring module using a recommended cleaning wipe.

In the event of problems, do not attempt to make repairs.

The setting of configurable parameters must be performed by qualified staff. The incorrect setting of the device place a patient at risk.

5.2.3. PROCEDURE OF CLEANING AND DISINFECTION FOR MULTIPLE PATIENT USE (IN HEALTHCARE SETTINGS):

In order to maintain device functionality, ensure accuracy of measurements and prevent cross-contamination, always keep the device clean. When performing measurements, always use a disposable, single-use bacterial filter. If the device is used without a filter, there is a risk of contaminating the measurement channels and, consequently, inaccurate measurements may be obtained. If the device is used by several patients, a mouthpiece filter must be used to avoid cross-contamination.

Always use biocompatible filters to avoid problems - unsuitable materials might cause the device to malfunction and compromise the accuracy of readings. The device may be used with any types of filters, cleared by FDA, with 30 mm diameter. The filters provide an easy way to help ensure protection from cross-contamination which keeps both the patient and operator safe without compromising on system performance.

The MicroGard® II (510(K) Number: K111408) was tested with AioCare spirometer and is recommended to use with the AioCare device.

5.2.3.1. Cleaning and checking the flow tube

Cleaning agent: PDI Sani-Cloth AF3 Germicidal Disposable Wipe Ready-to-Use (RTU) (EPA Registration #9480-9)

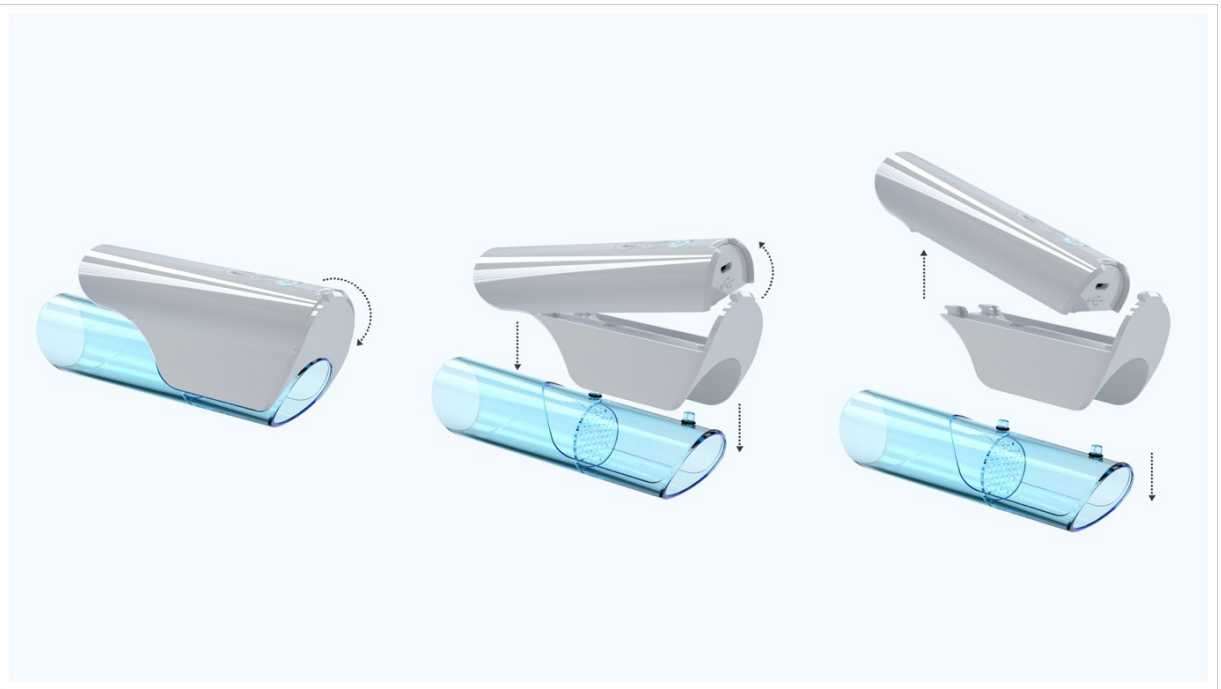
Contact Temperature: 20 to 25°C

The flow tube and the tube holder must be cleaned at every change of the patient, i.e. before applying it to a new patient!

A simple clean before every use will ensure that the flow tube stays clean and keeps working as it should.

Step 1.

To clean the flow tube, remove it from the measuring module by pressing the place above the USB hole and pulling gently. To facilitate removal, you can push the tube holder gently with a finger. To disconnect the flow tube from the tube holder pull gently. (Picture 1)



Picture 1.

After disconnecting the tube holder from the measurement module, the measurement module should be cleaned using alcohol free wipes for cleaning and disinfection of medical devices.

AioCare recommends the use a **SaniCloth AF3 Germicidal Disposable Wipe**, that have been validated on the device.

Using the Sani-Cloth AF3 Germicidal Disposable Wipe, wipe back and forth across the test area of the surface cover, parallel to the seams, until the bulk of the soil is removed. After the initial removal of the bulk soil residue, inspect the cover for remaining soil. If any visible soil particulate is present, use a new disposable wipe, repeat the wiping process until visible soil is removed. Once the bulk soil residue is removed, use a new disposable wipe and wipe back and forth twice across the test area.

Step 2. If dirt is visible in the flow tube, it is recommended to carefully remove the dirt with a brush after rinsing. After that clean flow tube with running water. Let the tube dry for 5 minutes.

Step 3. Clean the tube holder with running water and gentle soap if you see the visible dirt on the surface. If any dirt is still visible, continue cleaning until completely removed.

Step 4. Cleaned and dried parts: please read carefully point 5.2.3.2. Disinfection methods for multiple patient use

Step 5. Checking correct measurement function

Turn the AioCare on and act as if you wanted to perform a spirometry test. Take the device in one hand and move it slowly from right to left and vice versa so that air passes through the tube.

If you see the movement of the diagram in the mobile application, the device is working and it is ready to work.

5.2.3.2. Disinfection methods for multiple patient use:

WARNING: Do not sterilize by means of radiation or steam.

Disinfectant:
1. Ecolab OxyCide Daily Disinfectant Cleaner (EPA Registration #1677-237)
2. PDI Sani-Cloth AF3 Germicidal Disposable Wipe Ready-to-Use (RTU) (EPA Registration #9480-9)

Temperature: 20 to 25°C

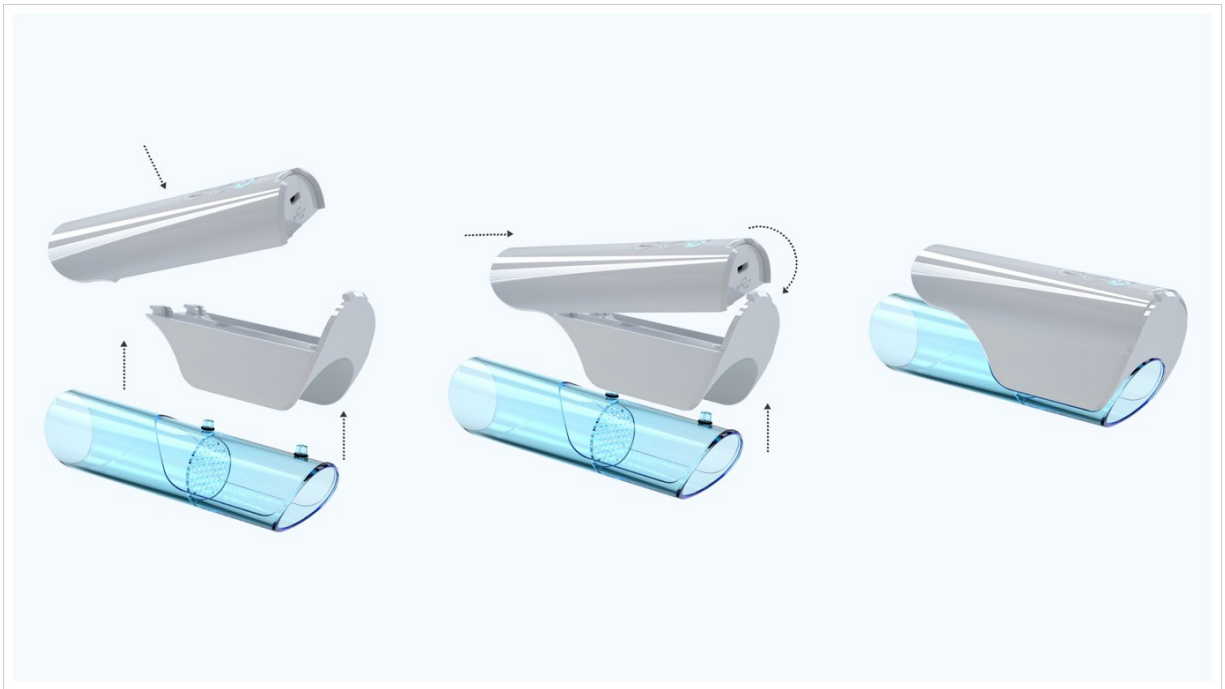
Step 1. The flow tube holder and flow tube, should be manually cleaned and disinfected by immersion in a disinfecting agent.

It is recommended that the agent has B, F (yeasts) and V (enveloped virus) properties.

It is recommended that the product has a neutral pH.

Method 1.

1. The tube, disconnected from the measurement module, clean with using a SaniCloth AF3 Germicidal Disposable Wipe.
2. Prepare a container with 5L of cold water. Dilute OxyCide Daily Disinfectant Cleaner at a 1:43 ratio in tap water, stir, and leave for 15 minutes. After this period, stir again and place the flow tube and tube holder into the container for 15 minutes.
3. After 15 minutes, remove and rinse with water (deionized water is recommended).
4. Leave to dry for 15 minutes or blow compressed medical air for 1 minute.
5. The flow tube and a tube holder should be connected back to the measurement module of the device. The spirometer is ready to be used again after inserting a new antibacterial filter.



6. Turn the AioCare on and act as if you wanted to perform a spirometry test. Take the device in one hand and move it slowly from right to left and vice versa so that air passes through the tube.If you see the movement of the diagram in the mobile application, the device is working and it is ready to work.

Method 2 for flow tube holder and flow tube cleaning:

1. Cleaning and disinfection based on washer disinfector (WD)

WARNING: The equipment used for cleaning/disinfection should meet the requirements of ISO 15883-1: Washer-disinfectors -- Part 1: General requirements, terms and definitions and tests. Always follow your heathcare facility disinfection guidelines and procedures.

The medical device is a thermostable product, the recommended level of disinfection is A0 600.

It is recommended to use deionized water until the thermal disinfection phase.

As a cleaning agent, it is recommended to use neodisher MediClean Forte

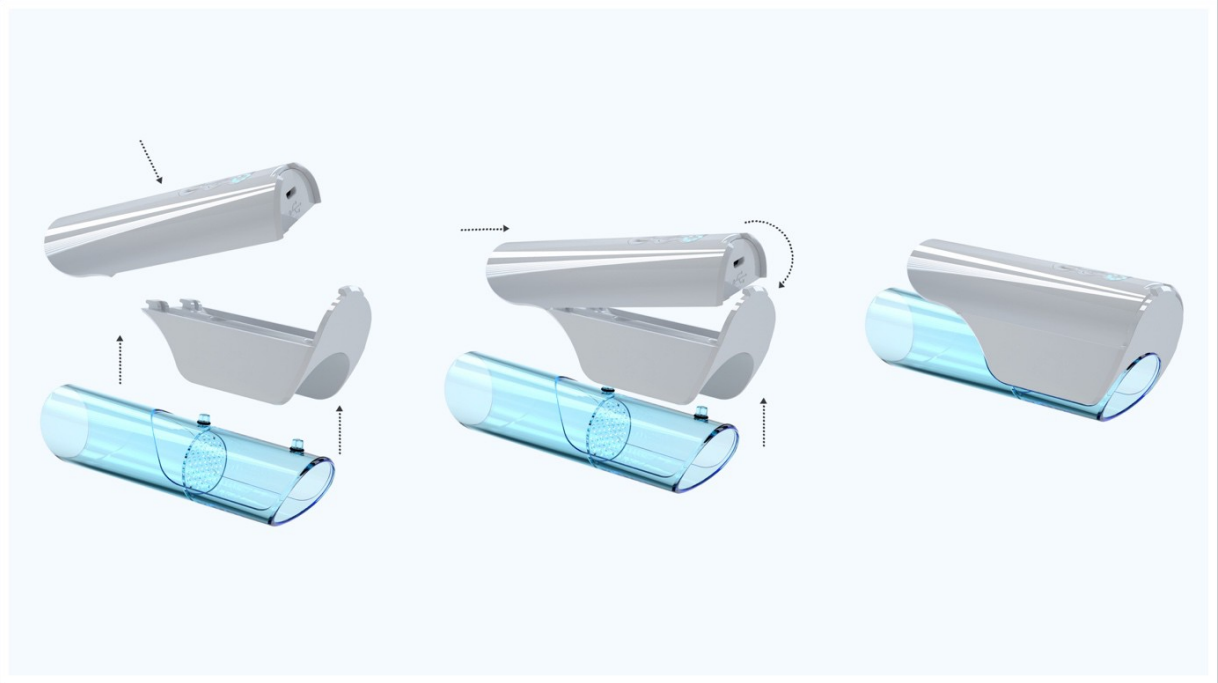
It is acceptable to use flushing agents, eg. Neodisher MediKlar.

Recommended Program:

1. Initial rinse using cold water for 2 minutes
2. Clean using neodisher MediClean Forte 5 mL/L 55 Celsius, for 10:00 minutes

3. Rinse (1) using cold water
4. Rinse (2) using deionized water
5. Thermal disinfection at 90 Celsius, for 5:00 minutes, deionized water + neodisher MediKlar 0.5 mL/L
6. Dry at 90 C for 15:00 minutes

If dirt is visible during manual or machine cleaning, it is recommended to carefully remove the dirt with a brush after rinsing. After completing the cleaning process and drying, the flow tube and a tube holder should be connected back to the measurement module of the device. The spirometer is ready to be used again after inserting a new antibacterial filter.



⚠ **WARNING:** Multiple thermal disinfection of the flow tube may cause visible changes in the structure of the material (clouding of the material). This does not deteriorate the technical properties of the product or the results of measurements.

The preferred method of disinfection is **immersion in a disinfecting agent.**

The carried out decontamination process is effective and does not affect damage to the device.

5.2.3.3. If the device is determined not to be visually clean at the end of the cleaning step, you should either repeat the relevant previous cleaning steps or safely dispose of the device to the closest medical equipment disposal place.

5.2.3.4. If you followed the cleaning instruction, but the device doesn't work after the cleaning process, please contact the producer.

5.2.3.5 If you have any other additional questions about cleaning or disinfection or reprocessing, feel free to contact the Healthup team: info @AioCare.com, or call+48 798545240.

5.2.4. PROCEDURE OF CLEANING FOR SINGLE PATIENT USE (HOME USE):

In order to maintain microbiological purity and accurate measurements, it is important to keep the device clean. It is recommended to always perform the measurements using a disposable filter. If the device is used without a filter, there is a risk of pollution of the measurement channels and, consequently, inaccurate measurements may be obtained. If the device is used by only one patient at home, there is no risk of cross contamination, but the antibacterial filter is recommended to keep the device clean.

Always use biocompatible filters, cleared by FDA to avoid problems- unsuitable materials might cause the device to malfunction and compromise the accuracy of readings. The device may be used with any types of filters, cleared by FDA, with 30 mm diameter.

The MicroGard® II (510(K) Number: K111408) was tested with AioCare spirometer and is recommended to use with the AioCare device.

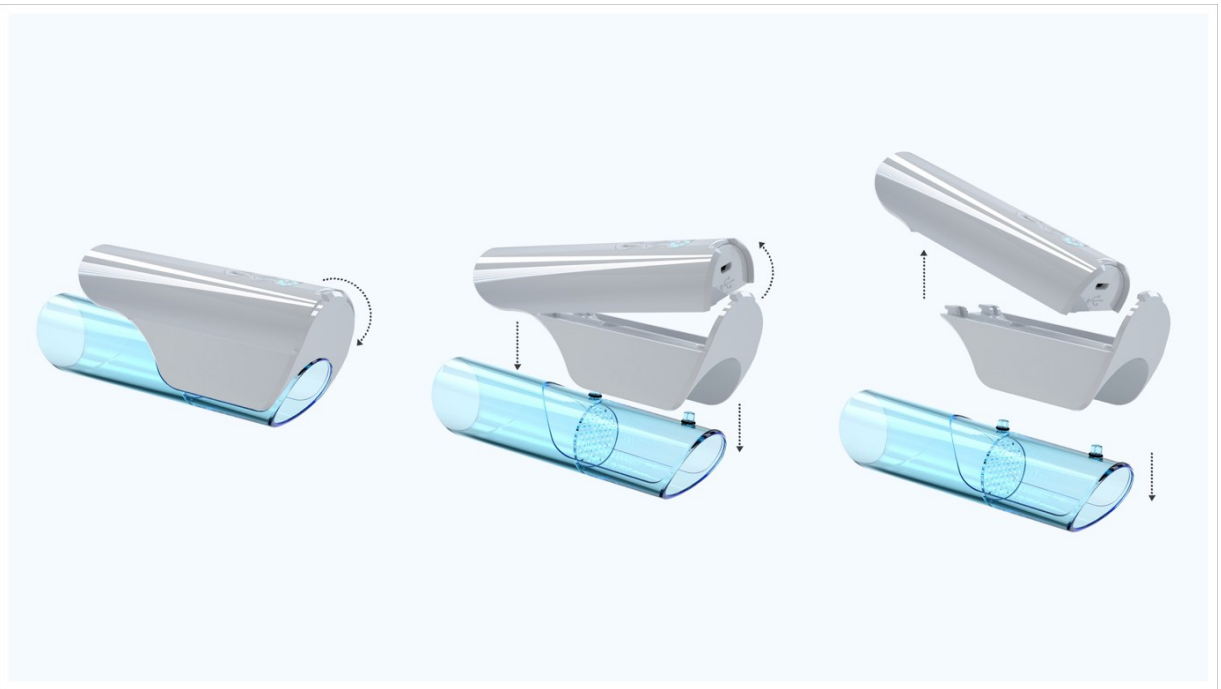
5.2.4.1. Cleaning procedure:

- Cleaning agent: PDI Sani-Cloth AF3 Germicidal Disposable Wipe Ready-to-Use (RTU) (EPA Registration #9480-9)
- Soap
- tap water

Temperature: 20 to 25°C

Step 1.

To clean the flow tube, remove it from the measuring module by pressing the place above the USB hole and pulling gently. To facilitate removal, you can push the tube holder gently with a finger. To disconnect the flow tube from the tube holder pull gently. (Picture 1)



Picture 1.

After disconnecting the tube holder from the measurement module, the measurement module should be cleaned using alcohol free wipes for cleaning and disinfection of medical devices. Healthup recommends the use a **SaniCloth AF3 Germicidal Disposable Wipe**, that have been validated on the device.

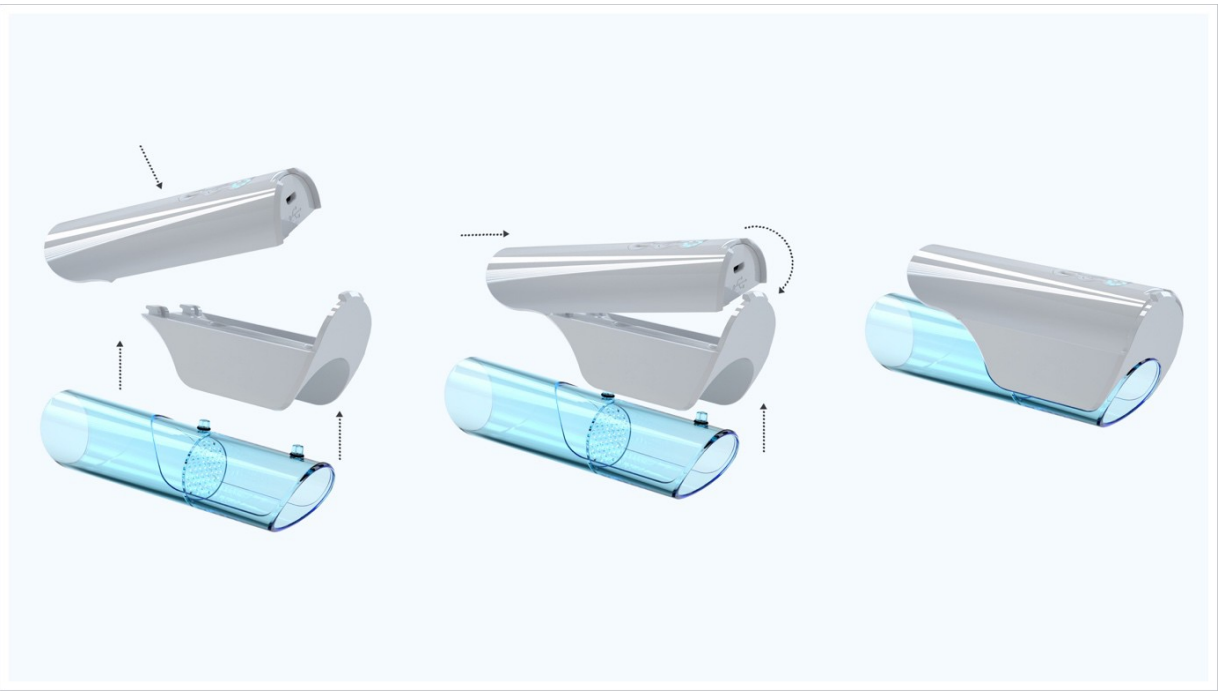
Using the Sani-Cloth AF3 Germicidal Disposable Wipe, wipe back and forth across the test area of the surface cover, parallel to the seams, until the bulk of the soil is removed. After the initial removal of the bulk soil residue, inspect the cover for remaining soil. If any visible soil particulate is present, use a new disposable wipe, repeat the wiping process until visible soil is removed. Once the bulk soil residue is removed, use a new disposable wipe and wipe back and forth twice across the test area.

Step 2. If dirt is visible in the flow tube, it is recommended to carefully remove the dirt with a brush after rinsing. After that clean flow tube with running water and soap. Let the tube dry for 5 minutes.

Step 3. Clean the tube holder with running water and gentle soap if you see the visible dirt on the surface. If any dirt is still visible, continue cleaning until completely removed.

Step 4. After completing the cleaning process let the parts dry for 15 minutes.

Step 5. The flow tube and a tube holder should be connected back to the measurement module of the device. The spirometer is ready to be used again.



Step 6. Checking correct measurement function:

Turn the AioCare on and act as if you wanted to perform a spirometry test. Take the device in one hand and move it slowly from right to left and vice versa so that air passes through the tube.

If you see the movement of the diagram in the mobile application, the device is working and it is ready to work.

A simple clean before every use will ensure that the device stays clean and keeps working as it should.

5.2.5. If the device is determined not to be visually clean at the end of the cleaning step, you should either repeat the relevant previous cleaning steps or safely dispose of the device to the closest medical equipment disposal place.

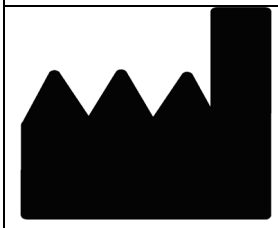
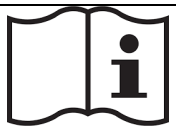
5.2.6. If you followed the cleaning instruction, but the device doesn't work after the cleaning process, please contact the producer.

5.2.7. If you have any other additional questions about cleaning or disinfection or reprocessing, feel free to contact the Healthup team: info @AioCare.com, or call+48 798545240.

6. Meaning of symbols used by the manufacturer

Plate on AioCare device

SN	example: MS-03201900011 4 (where 03 is the month of manufacture/2019 – year of manufacture/ 0001- consecutive number of the piece, 14- number of hardware)	CE	CE - this symbol means that the product has the certificate of compliance with Class IIa according to Directive 93/42/EEC on medical devices.
	WEEE warning symbol; waste – electric component; disposal in compliance with national regulations		USB symbol – use only the USB cable provided by manufacturer and comply with safety regulations defined by standard IEC 60601-1-1

	Electric safety symbol – BF applicator conforming to standard IEC 60601-1		Symbol – always consult the user manual
	Device complies with Part 15 of FCC (Federal Communications Commission) rules and regulations		Symbol - “This device contains a radio frequency (RF) transmitter”; conforms to electromagnetic compatibility
	Symbol - Manufacturer (Address and contact details) With date of production		**IP22-** protection level provided by the enclosure of electrical device against the ingress of foreign bodies and harmful effects of moisture ingress
	Magnetic resonance (MR) unsafe		Non-Sterile
	Bluetooth		Consult e-instruction for use

7. Maintenance

7.1. Operation of AioCare power supply

AioCare is powered by a 300mAh 3.7 V LiPo battery installed inside the measurement module. Fully charged battery is capable of working continuously for 5.5-6 hours. The user is notified on the battery status in the mobile application or through LED signals on the device casing. 4 out of 8 LEDs glowing means that the battery is low on power. In such event, stop the testing within several minutes and charge the device using the bundled USB cable attached to any PC/Mac device.

7.2. Battery charger

The measurement module has 2 charging functions:

1. Wired, through the USB cable

The battery should be charged based on the in-built charging system which protects it against damage during the charging and ensures its long life. To start charging, connect one side of the USB power cable to the charging socket in the casing of the measurement module, and the other side to any PC/Mac power source connected to the 230 V mains. This will make the LEDs on the device casing glow, which signals that the charging process is correct. During the charging of the measurement module, the functions of the spirometer are switched off, and you cannot do any testing at that time (the device cannot be turned on with the “ON/OFF” button). The charging process should last 3.5 hours for the battery to be fully charged. Full charge is signalled with another lighting up of all 8 LEDs.

2. Wireless, using NFC technology (any NFC charger with certificate of marketing in the EU market)

   The battery should be charged based on the in-built charging system which protects it against damage during the charging and ensures its long life. To start charging with NFC technology, disconnect the measurement tube from the measurement module. Then place the measurement module on the NFC charger with its no-buttons side. This will make the LEDs on the device casing glow, which signals that the charging process is correct. During the charging of the measurement module, the functions of the spirometer are switched off, and no testing can be conducted at that time (the device cannot be turned on with the “ON/OFF” button). The charging process should last 3.5 hours for the battery to be fully charged. Charging time may depend on the power rating of the charger used. Full charge is signalled with another lighting up of all 8 LEDs.

CAUTION: To avoid device damage, only the above-mentioned devices identified by the manufacturer should be used.

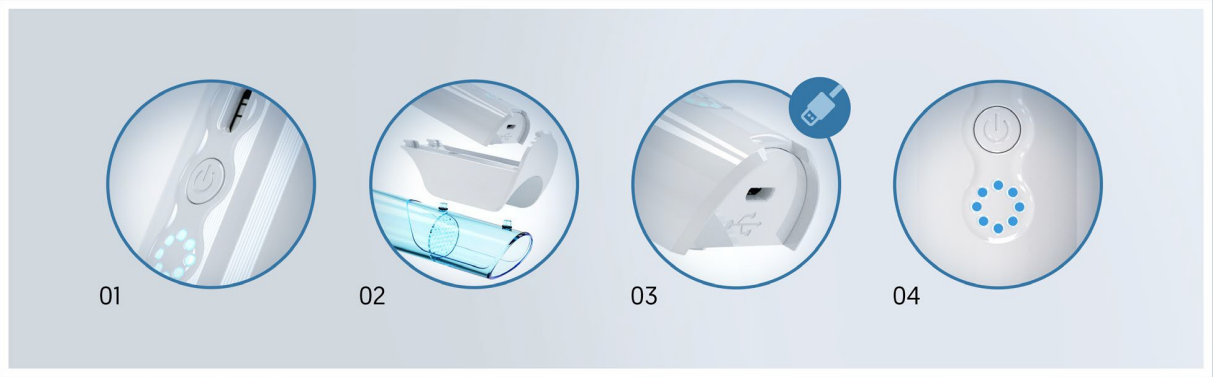
During standard operation the diodes indicate the battery level in accordance with the below model:

- 0-12%: flickering diodes
- 13-24%: 1 diode is turned on
- 25-37%: 2 diodes are turned on
- 38-49%: 3 diodes are turned on
- 50-61%: 4 diodes are turned on
- 62-74%: 5 diodes are turned on
- 75-86%: 6 diodes are turned on
- 87- 94%: 7 diodes are turned on
- 95-100%: 8 diode are turned on

When charging, the diodes inform about the current battery level in accordance with the below model:

- 0-12%: 1 diode flicker
- 13-24%: 1 diode is turned on + 1 flickers
- 25-37%: 2 diodes are turned on + 1 flickers
- 38-49%: 3 diodes are turned on + 1 flickers
- 50-61%: 4 diodes are turned on + 1 flickers
- 62-74%: 5 diodes are turned on + 1 flickers
- 75-86%: 6 diodes are turned on + 1 flickers
- 87- 99%: 7 diodes are turned on + 1 flickers
- 100%: 8 diodes are turned on

How to charge



01. Turn the device OFF, using ON/OFF button, please press the button for 1 second The button will not turn the device off when it is being charged via a wire or in a wireless manner.

02. Remove the USB socket cover

03. Plug the micro USB cable included to your device to micro USB socket in AioCare, and plug to your energy source (any USB port), diodes on top AioCare should flashing showing current battery level

04. When device will be fully charged then 8 diodes are turned on

7.2.1. Battery replacement

The battery is not replaceable.

CAUTION: Replacing the battery on your own may result in:
- damage to the measurement module
- battery explosion or ignition
- damage to the battery
- electric shock
- burns
- loss of warranty for the entire AioCare spirometry system

The battery life is designed for 500 full charging cycles or 1 year of intensive use 6 hours a day. After that number is reached, the actual battery performance may fall to 60% of its nominal performance. This will result in quicker discharging of the battery.

Battery life is estimated by the manufacturer at 2 years and is a precondition for the device to be used. After 2 years of starting using the device, AioCare is used by the user only on their own responsibility.

8. Disposal

A device that is no longer needed or cannot be repaired should be disposed of in accordance with local regulations. Don't discard spent devices or batteries into ordinary garbage bins. Contact a recycling company to do that. The device may be returned to the manufacturer, distributor or a recycling company. If the battery inside the device is damaged, send the product back to the manufacturer.

9. Warranty and service

This device is covered by 2 years' warranty.

The warranty does not cover any damage caused by using the device inconsistently with the user manual, using the device inconsistently with its intended purpose, or failure to comply with safety requirements and cautions in Section 5.1 of this manual.

The repair or replacement described in this warranty is provided for goods returned at the customers' expense to our certified service centres. For details of these centres please contact either your local supplier or the manufacturer. The customer shall be responsible for all transport, customs and delivery cherges regarding the goods.

10. Operation Environment

Optimum ambient temperature for measurement:	From +15 to +40 °C
Storage Conditions	from +5°C to +45°C, humidity <70 %
Device operating conditions	from +15°C to +40°C, humidity <70 %

11. Defects and malfunction

If you notice any malfunction, defect, deterioration of features or performance of the product, or inappropriate marking or instructions for use that could have or can lead to death or significant health loss of the patient or product user, immediately stop using the product and contact the manufacturer by e-mail or telephone to describe the defect and receive the required instructions for how to further handle the product.

12. FCC Compliance Information

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

(2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The AioCare has been designed and complies with the safety requirements for portable RF exposure in accordance with FCC rule part §2.1093 and KDB 447498 D01.

13. ISED Canada Compliance Information

This device complies with ISED's license-exempt RSSs.

Operation is subject to the following two conditions:
(1) This device may not cause interference; and
(2) This device must accept any interference, including
interference that may cause undesired operation of the device

This device complies with the safety requirements for RF exposure in accordance with RSS-102 Issue 5 for portable use conditions.

[FR] Cet appareil est conforme aux RSS exemptés de licence d'ISED.

Le fonctionnement est soumis aux deux conditions suivantes:
(1) Cet appareil ne doit pas causer d'interférences; et
(2) Cet appareil doit accepter toute interférence, y compris
Interférences pouvant provoquer un fonctionnement indésirable de l'appareil

Cet appareil est conforme aux exigences de sécurité relatives à l'exposition RF conformément à la norme RSS-102 Édition 5 pour les conditions d'utilisation portables.

14. Declaration of Conformity

AioCare – a remote monitoring system incorporating a spirometer, peak flow meter, integrated with mobile devices through Bluetooth LE communication, with diagnostic software for mobile devices and analysis support database software – as a Class IIa active diagnostic medical device (classification rule 10), meets the essential requirements of the Regulation of the Minister of Health of 17 February 2016 on the essential requirements and conformity assessment procedures for medical devices (Journal of Laws of 2016, item 211) and Council Directive 93/42/EEC, as amended.

The conformity assessment procedure has been performed in accordance with Annex II to the above Regulation / Directive, with the participation of notified body No 2274: TÜV Nord Polska Sp. z o.o. 40-085 Katowice, ul. Mickiewicza 29.

15. Troubleshooting / guide

Questions and problems regarding AioCare- FAQ

How do I register to the AioCare application?

To register to the application, you need to click "Join AioCare" on the initial screen, and then enter the e-mail address to which you want to register an account and a password consisting of at least 8 characters (including at least one lowercase and uppercase letter, one digit and one special character)

I was logged out from the application. How do I log back into the AioCare app?

To login to the application, click "Already have an account?" on the initial screen, and then enter the login and password you chose during account registration.

I forgot my AioCare password and cannot log into the application.

To restart the password for the AioCare application, click "Already have an account?" button on the initial screen, then click "forgot password" button and enter the e-mail address that you registered in the AioCare system. A message with a link to restart the password will be sent to this e-mail address. For security reasons, the link is active only for 60 minutes from the moment of generating the message.

How to change the password in the application?

Password change can be done by restarting the password. To do this, see point 3.

The application does not see the AioCare device in the list of devices despite the Bluetooth module switched on.

The problem occurs mostly on mobile devices using the Android system. The reason for this are various types of system overlays from mobile device manufacturers, which makes the Bluetooth module work in different ways. In order for the application to "see" and connect to the AioCare device, the GPS module on the mobile device must be switched on.

Information:
The GPS signal is used only for a better connection of the mobile device to the AioCare device.

I cannot connect to the AioCare device.

If you have problems connecting to the AioCare device, please use the following instructions:
- Close the AioCare application so that it does not work in the background.
- Switch off the Bluetooth module and the GPS / Location module on the mobile device.
- Turn off the AioCare device.
- Turn on the AioCare application.
- Go through the pairing / connecting path of the device with the application and follow the instructions on the screen.

Please note:

In order to increase the probability of connecting the device with the application, we recommend turning on the GPS module in the mobile device.

When you try to export data / generate a report, the message "Export error" appears.

This message appears when the phone does not have Internet connection when you try to export. The report is sent from the AioCare server, therefore Internet connection is required to download the report. We recommend checking the connection from your mobile device to the Internet or connecting to the WiFi network.

What should I do in a situation when the patient stopped blowing but the application still detects the air flow.

If the application still detects the air flow despite the patient finishing blowing into the AioCare device, stop the test, reset the airflow again, and then start a new test.

Is Internet connection required for using the application?

To use the application it is not necessary to always connect your mobile device to the Internet. However, the application needs Internet access in four cases:

1. In a situation where the user wants to create a new account (register to the application).
2. In a situation where the user logs into his or her account.
3. In a situation where the user wants to perform the first spirometry test on the newly connected AioCare device.
4. In a situation where the user wants to generate a test report.

We recommend that the mobile device should have Internet connection at least once every 72 hours in order to synchronize data, and also to reduce the risk of losing medical data.

How to synchronize data with the server?

Data synchronization takes place in the background of the application's operation and is performed automatically when the application detects Internet connection, and does not require any user action.

Why does the application require further measurements when 3 correct measurements have already been made?

In order for the measurements to be qualified as a properly performed test in accordance with international standards, the test must meet the correctness of measurement criterion as well as the measurement repeatability criterion at the same time.

What is the measurement repeatability criterion?

The measurement repeatability criterion is based on comparing the FVC and FEV1 values in two measurements with the best results. In order for the measurement repeatability criterion to be met, the difference between the value of FVC and FEV1 in the two best measurements cannot be greater than 150 ml.

What is the correctness of measurement criterion?

The correctness of measurement criterion is based on obtaining in a single examination a minimum of three correct measurements (green dots).

What does the red dot during the measurement mean?

The red dot during the measurement means that an error occurred during the test. This condition can indicate various problems, e.g. BEV error, Plateau error, exhalation time error, detected cough, data error and other.

What does the green dot during the measurement mean?

A green dot during the measurement means that the test was carried out correctly without any errors.

What is the BEV error?
BEV error occurs when exhalation recorded during measurement is too slow exhalation.

What is the Plateau error?

The Plateau error occurs if the measurement had finished before the lack of flow has been recorded for at least 1 second.

What is an expiration time error?

Expiration time error occurs if the measurement had been completed before 6 seconds has passed from the moment application had detected expiration.

What is a cough error?

Cough error occurs when the application detects that a patient coughs during the measurement.

What does it mean when the LEDs on the AioCare device start to flash even though no exam is carried out at the moment?

If the LEDs of the AioCare device start to flash even though the test is not being carried out, it means that the device's battery is running low and the AioCare device should be charged by connecting it to the USB port or placing on the NFC charger.

How to charge the device?

The device can be charged by putting the device on the NFC charger or using a standard USB cable added to the packaging. To connect the cable to the device, gently pull the clip located on the back of the device next to the diodes, and then slide the device in the opposite direction from the position of the clip.

In the separated upper part of the device on the back side there is a mini USB port to which you can connect the cable.

You can find Guidebook in our website in section Support www.AioCare.com/support?

16. Coaching

AioCare application has few ways for your measurements to be carried out correctly:

1. Popup/tooltip information in your app about errors or warnings

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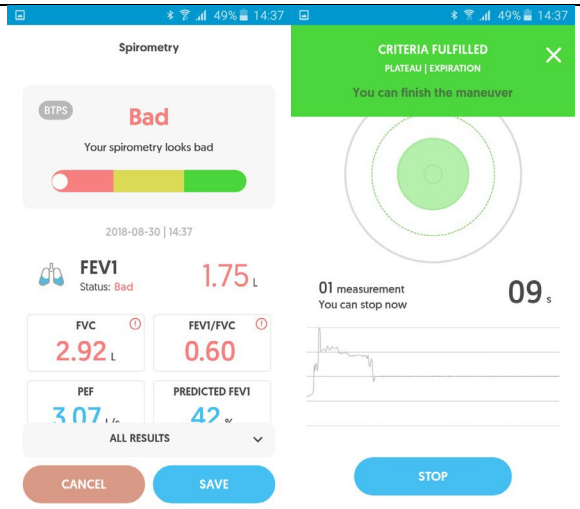
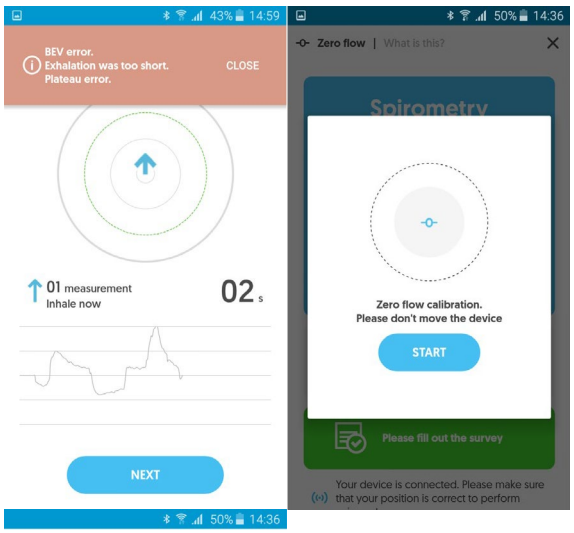
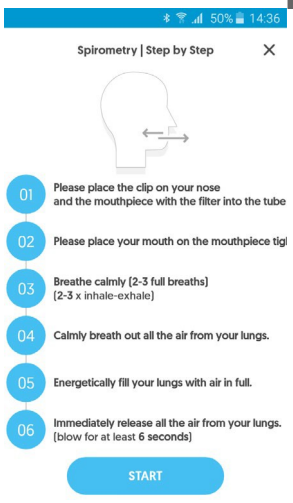
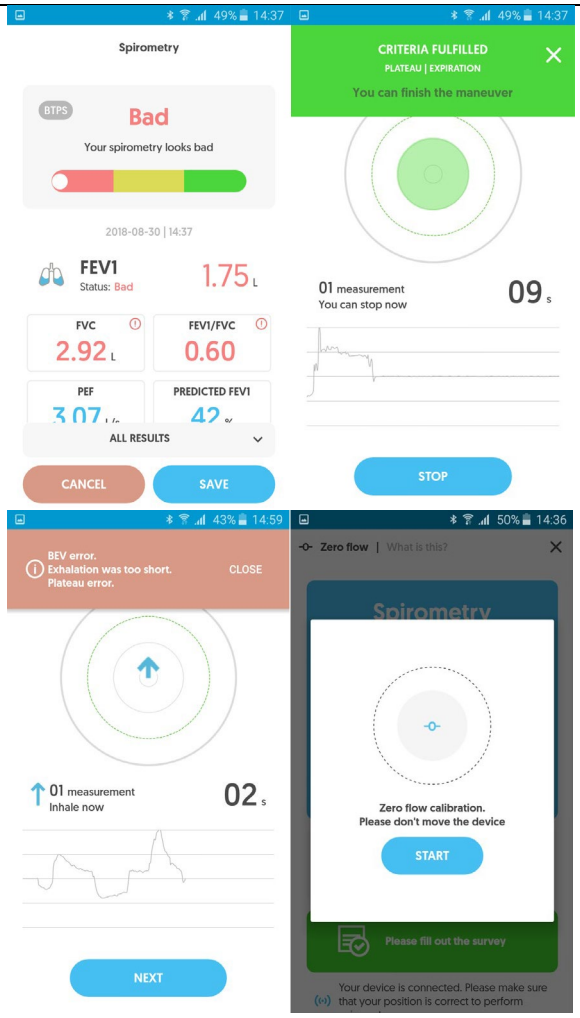


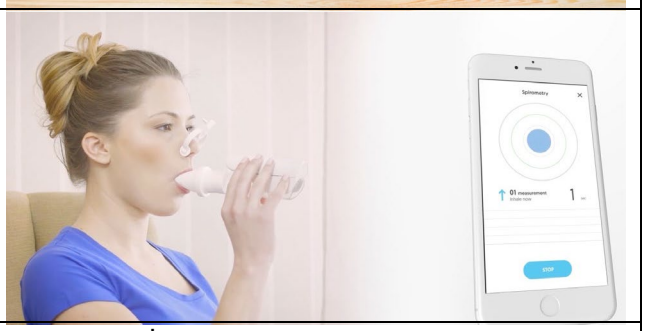


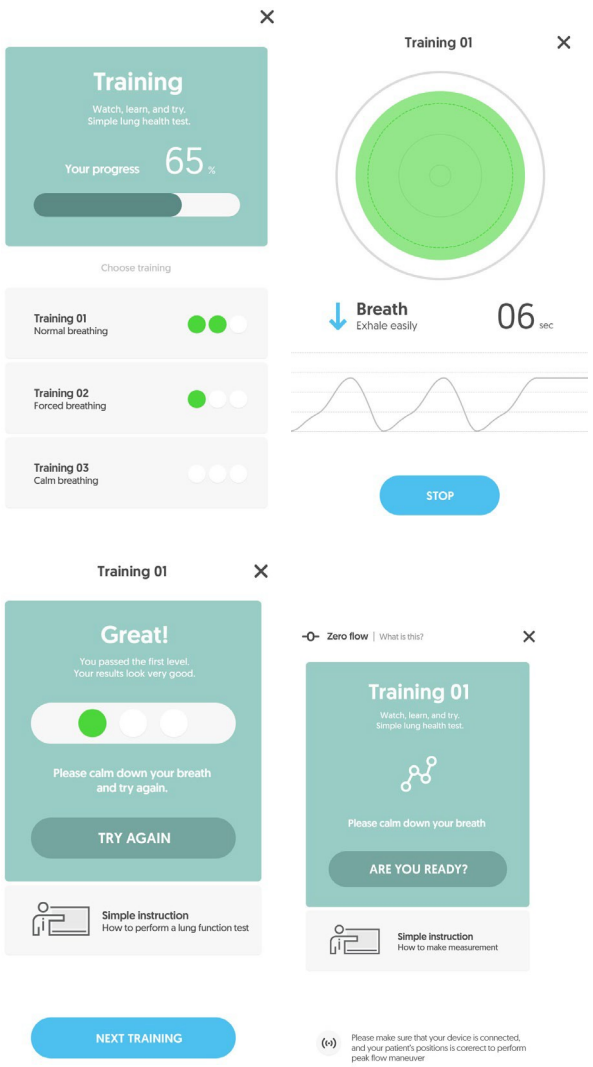


2. Popup/tooltip information in your app about errors or warnings

42



3. Guidebook available on our website – how to use AioCare App, you can easily find in section Support	
4. Explanatory video available in our app and on Vimeo	
5. FAQ available on our website – Questions and problems regarding AioCare, you can easily find in section Support	www.myspiro.com

6. Training sections in our app to better performance of breathing and forced breath maneuver	
7. This manual, available in app and also in our website, you can easily find in section Support	www.AioCare.com

17. Important Safety warnings

Warning: indicates a potentially hazardous situation which, if not prevented, could result in minor or moderate injury to the user or patient or damage the device.

1. Disposable filter must be used if you test different patients on the same AioCare device. Failure to comply with this caution may lead to cross- or secondary contamination.
2. While charging, the battery should be at a place with room temperature. Never expose to temperatures less than -10°C or more than 45°C!
3. Use the USB cable bundled with the product.
4. The battery may be charged even if it is not completely discharged. Battery performance deteriorates with time, so the device can work for a shorter time, and may need to be charged more frequently and longer!
5. Protect against moisture and don't immerse in water. A dry anti-static cloth may be used for cleaning the spirometer proper (measurement module)!
6. Don't dismantle the battery. Avoid dropping the device, especially on hard surfaces. Don't attempt to dry up the device using other equipment or source of heat, such as a hair drier or microwave oven.
7. If the device is damaged, it should be switched off and secured against unintended operation. This device cannot be used safely when it: - has evident signs of mechanical damage! - doesn't work correctly (LED not glowing)! - has been stored in adverse conditions (-10°C or above 45°C, high air humidity – more than 70%)! - has been damaged in transport!
8. The device must not be used in the following adverse ambient conditions: – Moisture or high air humidity – Dust and flammable gases, vapours or solvents – Storms and stormy conditions, such as strong electrostatic fields, etc.
9. The device must not be modified or tampered with.
10. Any mechanical damage to the device may cause its malfunction.
11. Any use, operation or maintenance of this product inconsistently with the user manual is not allowed, and may lead to user-caused damage for which the manufacturer is not liable.

12. ⚠ Data security warnings:

Your smartphones stores your personal data. Potential threats such as the following:

- Malware installation
- Physical access to the smartphone
- Physical damage to the smartphone
- Theft of the smartphone

Could have an impact on the integrity or confidentiality of such data, such as:

- Accessing data in memory by unauthorized persons
- Loss of data in memory
- Inability to use smartphone for communications

The following actions help reduce the risk of such events:

- Do not open or install files from suspicious sources
- Do not leave your smartphone anattended
- Use a password to access the data
- Verify the correct email address where to send the test results

CAUTION: AioCare may give unreliable measurements if it's used in the presence of strong electromagnetic fields.

CAUTION: In the event of any incident or accident related to the use of this device, the user is required to immediately notify the manufacturer of this fact.

Failure to comply with above caution may lead to device damage and/or incorrect measurement.

17.1. Warnings for use in electromagnetic field

Due to the increasing number of electronic devices like computers, smartphones, medical devices may be susceptible to electromagnetic interference from other equipment.
Such electromagnetic interference could cause the medical device to malfunction and create a potentially unsafe situation.
AioCare spirometer complies with EN 60601-1-2:2014 on electromagnetic compatibility (EMC for medical devices) for both immunity and emissions.
For the device to function properly, however, the following precautions must be taken:

• Make sure that AioCare and the smartphone on which the application is installed are no more than 2 metres apart.

• Do not use AioCare near other devices (computers, cordless phones, cell phones, etc.) that generate strong electromagnetic fields. Keep such equipment at a minimum distance of 7 metres.

17.2. Recommended separation distances for RF communication

The AioCare is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AioCare as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80 MHz d=not applicable	80 MHz to 800 MHz d=0,175 √P	800 MHz to 2,5 GHz d=0,35 √P
0,01	Not applicable	0,017	0,350
0,1	Not applicable	0,055	0,110
1	Not applicable	0,175	0,350
10	Not applicable	0,550	1,100
100	Not applicable	0,750	3,500

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.