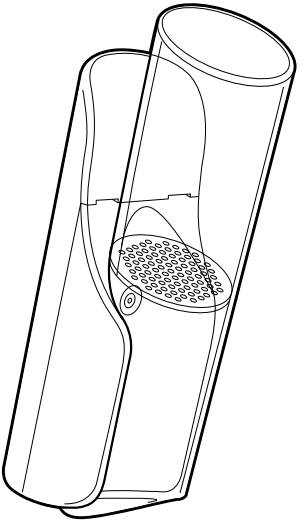
AioCare™

Instructions for use AioCare spirometry system



EN

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Remote monitoring system with
spirometer and peak flow meter module
and pulse oximeter.

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1. Description of the AioCare system

The AioCare system was developed at Healthup by a team of experts with practical experience in designing and manufacturing medical devices and software development.

The main novelty of our system is the unique combination of measurement sensors, developed measurement channel and functional application, cooperating with iOS and Android operating systems.

AioCare - a remote monitoring system with a spirometer module, which is used to perform a spirometry test. These tests are the basis for functional diagnostics and evaluation of mechanical properties of the respiratory system. It allows the recording of the spirogram and the evaluation of the intensive inspiratory-expiratory manoeuvres and maximum flow-volume/volume curves time and values associated with them, such as force vital capacity (FVC). In addition, it is possible to register the spirogram as part of the diastolic test. These measurements are used in the diagnosis and monitoring of lung diseases and interventions during the treatment of certain types of respiratory diseases.

AioCare also acts as a peak flow meter, measuring peak expiratory flow (PEF) as well as the pulse oximeter, measuring the average pulse and the level of oxygenation of the blood (SpO_2).

Pulse oximetry testing in the AioCare device is carried out by using the reflective, optical sense MAX30102 from Maxim Integrated Circuits. It is located in the upper part of the measuring module. The MAX30102 sensor is an integrated pulse oximeter for measuring heart rate and blood oxygenation level (SpO_2). It consists of two LEDs, a photo-detector, optical components and low-noise electronic components together with an external light-levelling module. It is powered by two voltage sources (the 1.8 V source supplies the electronic components and the 3.3 V source the LED). Data is transmitted using the standard I2C serial interface.

Indications for use:

The AioCare spirometer is intended for use by a doctor or a patient under the supervision of a doctor or a technician. The device is intended for testing lung function and may perform spirometry tests in adults and children > 5 years old only under the supervision of an adult. The values of standards and interpretative results are not calculated for children under 5 years old.

Intended use:

1. Evaluation of respiratory system function in the presence of:
   a. subjective symptoms (dyspnoea, whistling, coughing, expectoration, orthopnoea, chest pain),
   b. subjective symptoms (abnormal breathing sounds, emphysema features, prolonged expiratory phase, cyanosis, chest deformities, clubbed fingers)
   c. abnormalities in additional examinations (abnormalities in chest X-ray,

hypoxemia, hypercapnia, polyglobulia - increased hematocrit value)
2. Screening of persons with risk factors (smoking, exposure to toxic factors - dusts, gases).
3. Respiratory testing in systemic diseases.
4. Perioperative risk assessment:
   a. non-pulmonary surgery,
   b. thoracic surgery.
5. Evaluation of the state of respiratory system activity before the beginning of strenuous physical activity.
6. Monitoring of treatment:
   a. bronchospasmodic drugs,
   b. corticosteroids (asthma, COPD, interstitial lung diseases),
   c. other medicines (e.g. antibiotic therapy in cystic fibrosis),
   d. dehydrating drugs in congestive heart failure.
7. Self-monitoring of respiratory system functions by the patient at home:
   a. subjective and objective symptoms (dyspnea, swings),
   b. exacerbations of respiratory diseases, including asthma, chronic obstructive pulmonary disease,
   c. after a lung transplantation.

1.1 Contraindications for the spirometry test

1. Absolute contraindications:
   - fresh (during hospitalization) myocardial infarction,
   - fresh (during hospitalization) CNS stroke,
   - aneurysms (risk of rupture of the aneurysm and haemorrhage at increased chest pressure),
   - fresh ophthalmic surgery (e.g. cataract surgery),
   - increased intracranial pressure,
   - hemoptysis of unknown etiology,
   - pneumothorax.
2. Relative contraindications:
   - the presence of a condition that may affect the reliability of the results obtained (e.g. nausea, vomiting, constant coughing),
   - condition after abdominal or intra-abdominal surgery,
   - the chest (postoperative pain which makes it impossible to perform breathing manoeuvres properly during the examination),
   - dizziness, heart rhythm disorders,
   - a significant degree of desaturation when oxygen therapy is discontinued for the duration of the study.

Contraindications for a peak flow meter test: No contraindications.

2. Construction of the AioCare spirometry system

AioCare is a portable spirometer for functional tests of the respiratory system.
The AioCare spirometry system consists of:

- measuring module with flow tube,
- mobile application to be installed from AppStore or Google Play.

2.1. Equipment

- MicroGard II PTF- antibacterial filter (use-by date on the foil seal of the package, do not use after its expiration, disposable filter),
- nose clip Vyaire V-892892 - use-by date on the foil seal of the package, do not use after its expiration, disposable clip),
- USB cable,
- quick manual.

The spirometric system allows:

- the performance of tests:
  - spirometry (parameters: PEF, FVC, FEV1, FEV1 /FVC ratio, FEF25, FEF50, FEF75),
  - peak flow meter (PEF),
  - pulse oximetry (the average pulse and SpO_2).
- Archiving of research results in the application,
- Creating a patient file.

Measuring module in combination with a mobile device:

The task of the measuring module is to convert the parameters of the flow of inhaled and exhaled air into an electrical signal. The signal created in the module is processed by the microcontroller of the spirometer and sent via Bluetooth® 4.0 to the mobile application, where the data is converted into curves and numerical values of the parameters displayed on the mobile device screen.

3. Operating conditions and equipment classification

Ambient temperature optimal for measuring: +15 to +40 °C, humidity relative: 15-93%
Storage: from 5 °C to 70 °C, humidity <30-70 % Internal powered device
Product class II A

The above mentioned conditions of the device are recommended for work in home and specialist rooms in the health service: diagnostic offices, general clinics.

3.1. Technical parameters

Sensor type for flow measurement:	Thermal
Tests:	FVC, pre- and post- (bronchodilator)

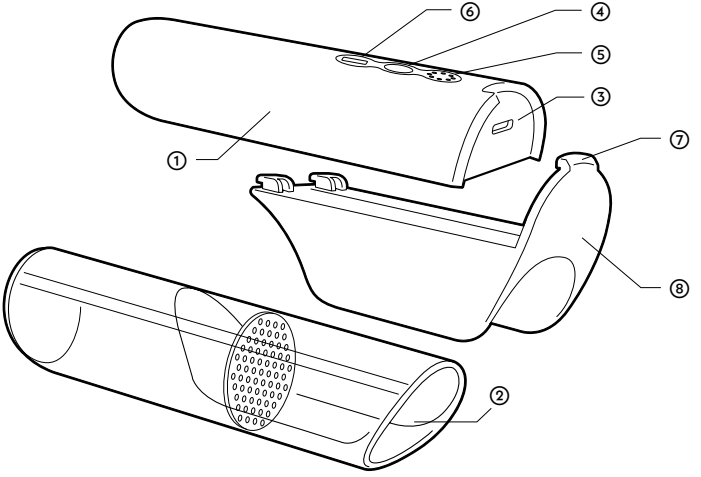
Spirometric flow measurement range:	0-16 l/s
Flow accuracy:	±5% or 200 mL/s
Resistance:	< 0.5 cm H_2O/L/s
Volume range:	0-8 litres
Volume accuracy:	±2,5% or 50 ml, whichever is greater
Linearity:	2,5%
Flow measurement resolution:	Measured 5 ml/sec, usable 10 ml/sec
Accuracy/Repeatability:	Standard: ATS/ERS 2019
Automatic BTPS correction:	Built-in sensors for measuring temperature, pressure and humidity
Type of sensor for pulse oximetry measurement	Optical, reflective (in accordance with ISO 80601-2-61:2017)
Saturation measurement range	70%-100%
Saturation measurement accuracy	3,15%
Pulse measurement range	30BPM – 180BPM
Pulse measurement accuracy	60BPM – 164BPM ± 3BPM
Determination of t0:	Algorithmic
Expiratory impedance:	< 0,15 kPa/(l/s) at 14l/s
Protection of the casing against water ingress, according to IEC 60529 (spirometer elements)	IP 22
Communication:	Bluetooth® 4.0. Low Energy
Bluetooth® frequency:	2.4-2.48 GHz
Measurement frequency:	100 Hz
Internal power supply:	Battery (LiPo 3.7 V)
50 mA power consumption:	50 mA
Dimensions:	118x38x48 mm
Weight:	0,3 kg

3.2. Measured spirometric parameters

- FVC – Forced Vital Capacity,
- FEV1 – Forced Expiratory Volume in 1 sec.
- FEV1/ FVC ratio – ratio between FEV1 and FVC (Tiffeneau-Pinelli index),
- FEF25 – flow by 25% FVC,
- FEF50 – flow by 50% FVC,
- FEF75 – flow by 75% FVC,
- PEF – peak exhaust flow,
- TPTEF/TE – ratio of peak expiratory flow time to peak expiratory time,
- VPTEF/VE – ratio of volume at peak exhaust flow to exhaust volume.

4. Construction diagram of the AioCare [Diagram 1]

① Measuring module
② Flow tube
③ USB socket
④ ON/OFF button
⑤ LED indicator
⑥ Pulse (HR) and saturation (SpO_2) meter
⑦ Housing latch
⑧ Tube holder



5. Components of AioCare

The parameters of all elements are exactly reproducible. A flow tube is connected to the measuring module through the tube holder. The air flow is carried out through two air channels and a microflow channel. Before starting to examine a new patient, an antibacterial filter should be attached to the tube. The measuring tube maintains its parameters until mechanical damage.

6. Research

6.1. Calibration of the spirometry system

Calibration of the device is carried out at the manufacturer. The sensor and flow tube are calibrated over the full range of measured flows using a precision flow generator and do not require calibration by the user before first use.

A calibration check can be carried out with a 3L syringe. The procedure to check the calibration consists of the following steps:

① Turn off the BTPS correction in Settings.
② Attach the spirometer to the syringe.
③ Start a standard spirometry test in the AioCare mobile application (Patient or PRO).
④ Perform several manoeuvres (3-5) using a 3L syringe with different flows.

Check that the FVC parameter values are within the calibration limits, e.g. +/- 3% (+/- 0.09 L).

If the equipment does not pass the calibration check, a new calibration by the manufacturer is required. In normal use it is recommended to check the calibration as part of the annual routine maintenance. This service is available in healthcare facilities or at the headquarters of the AioCare manufacturer. Calibration check is free of charge. The customer covers only the shipping cost.

6.2. Flow zeroing

It aims to increase the accuracy of the measurement. The AioCare spirometer should be placed horizontally, away from sources generating air movement, and the flow zero function should be called up in the mobile application.

Zeroing takes 5 seconds and the user is informed about its progress through a visual presentation on the mobile device screen.

6.3. Dynamic spirometry

The patient breathes through an antibacterial filter and a flow tube. After taking a few calm breaths, he/she exhales as deep as possible and then exhales as quickly and intensely as possible. This manoeuvre is repeated several times.

You should rest for at least 15 minutes before the test. The spirometry test is for safety reasons (for fear of fainting) usually performed in a sitting position.

Before measurement, an antimicrobial filter is attached to the flow tube (**NOTE**: in the case of cough infections with individual use of the device and always with AioCare in outpatient or hospital conditions) and a nose clamp and after a few calm breaths, a slow, deepest exhalation should be made, followed by the fastest and deepest possible inhalation. This should be followed by a deep, violent exhalation that continues for as long as possible.

After the breathing has been regulated, the measurement must be repeated no sooner than after 30 seconds. A minimum of 3 correct measurements must be taken, lasting at least 6 seconds, and no more than 8 if not repeated. The flow - volume curve should be measured correctly at least 3 times. They are reproducible if the two highest FVC values do not differ by more than 150 mL and the two highest FEV1 values also do not differ by more than 150 mL.

The result of the measurement is the maximum values of FEV1 and FVC, which need not be obtained in the same tests.

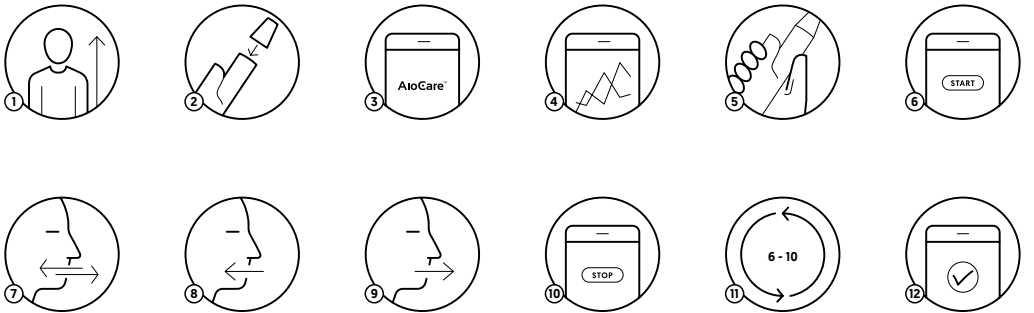
ATTENTION: Do not repeat the spirometry test more than twice a day (16 flows). This may cause false results and consequently false indications for treatment.

Instruction:

1. Position: seat upright, feet flat on the floor. Loosen tight clothing. If you have dentures, you can take them out. Use a chair with an armrest preferably.
2. Prepare the AioCare by connecting the mouthpiece with an antibacterial filter.
3. Open the AioCare application.
4. Select "Spirometry" from the menu.
5. Place the AioCare device on a flat surface and wait 5 seconds until the device is reset. Put the clip on the nose.
6. Click start in the mobile application when you are ready.
7. Take a few normal breaths through the mouthpiece.
   Finish the last one with a slow and deep breath.
8. Take a deep breath.
9. Exhale for at least 6 seconds.
10. Place the device on its side and press "stop" in the application.
11. Repeat the sequence 6-10 at least 3 times correctly from 8 possible attempts.
12. If the test was performed correctly, the results will be marked with a green sign on the mobile device screen.

The manoeuvre should meet the end-of-test criteria (exhalation for ≥6 s at <25 ml exhaled air for at least 1 second.

Spirometry test [Diagram 2]



6.4. Peak Exhaust Flow Test (PEF)

Positioning: usually PEF is measured standing up.
① Prepare the AioCare by connecting a mouthpiece with an anti-microbial filter.
② Open the AioCare application.
③ Select "Peak Flow Meter" from the menu.
④ Place the AioCare device on a flat surface and wait 5 seconds to reset the flow.
⑤ Click the Start button on the mobile device when you are ready.
⑥ Take in air and blow it out quickly and firmly, with your lips closed around the mouthpiece.
⑦ Repeat sequence 6 twice more.
⑧ If the test was carried out correctly, the results will be shown on the mobile device screen.

6.5. Pulse (HR) and saturation (SpO_2)

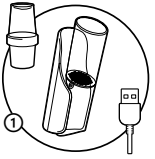
① Warm your fingers if they are cold. If you have painted your nails, it is best to remove the nail polish before taking a measurement.
② Open the AioCare application.
③ Select "Pulse oximetry" from the menu.
④ Click the Start button on your mobile device when you are ready.
⑤ Place your finger on the heart rate monitor (without applying much pressure) completely covering the red light.
⑥ Hold your finger still on meter for 10 seconds.
⑦ If the measurement has been carried out correctly, the average pulse rate and SpO_2 result will be displayed on the mobile device screen.

7. Operating the device

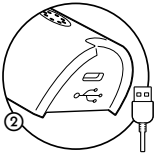
7.1. Preparing the AioCare device for operation

In order to prepare the device for work, you must perform the following steps after washing the AioCare spirometer:
① Make sure that the system contains all the components (measuring module, flow tube holder, flow tube, mouthpiece and antibacterial filter).
② Download AioCare from the Apple App Store or Google Play and install it according to the instructions displayed on your mobile device screen.
③ Turn on AioCare using ON/OFF button.
④ Pair your device with the AioCare application, select “Pair” and choose the model number of the device you want to pair with.
⑤ Check the battery level of your device (this can be done with the application).
⑥ Connect the flow tube to the measuring module.
⑦ Attach the mouthpiece to the flow tube.
⑧ Follow the instructions in the application.

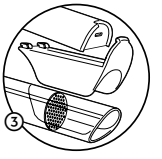
7.1.Preparing the AioCare device for operation [Diagram 3]



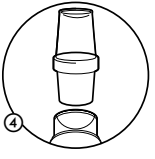
Make sure the system contains all elements



Check the charging state of the device



Connect the flow tube with the measuring module



Attach the antibacterial filter to the flow tube

Turn the spirometer on with ON/OFF button

Download the application and install

7.2. Communication between AioCare and the user

The AioCare spirometer communicates with a mobile device using Bluetooth® 4.0 (BLE) technology. The messages are displayed in the mobile application on the smartphone screen. Additionally, there are LEDs on the AioCare device. These are blue monochromatic LEDs.

Meaning of LED messages:

All LEDs flash one after the other by 360° until the light is stable:	Starting up the device
The LEDs flash sequentially in a circular cycle:	Pairing AioCare with your smartphone
All LEDs blink smoothly:	Bluetooth data transmission during measurement
4 of 8 LEDs flash:	Low battery - connect to power source
More LEDs light up during charging 0-12%: all LEDs flash (0 on + 1 blinking) 13-24%: 1 light on (1 on + 1 flashing) 25-37%: 2 LEDs on (2 on + 1 flashing) 38-49%: 3 LEDs on (3 on + 1 flashing) 50-61%: 4 LEDs on (4 on + 1 flashing)	Battery charge level display
62-74%: 5 LEDs on (5 on + 1 flashing) 75-86%: 6 LEDs on (6 on + 1 flashing) 87- 94%: 7 LEDs on (7 on + 1 flashing) 95-100%: 8 LEDs are on (-)	Battery charge level display

7.3. Hardware and software requirements for a mobile device

The AioCare spirometer is operated via AioCare applications for iOS and Android systems.

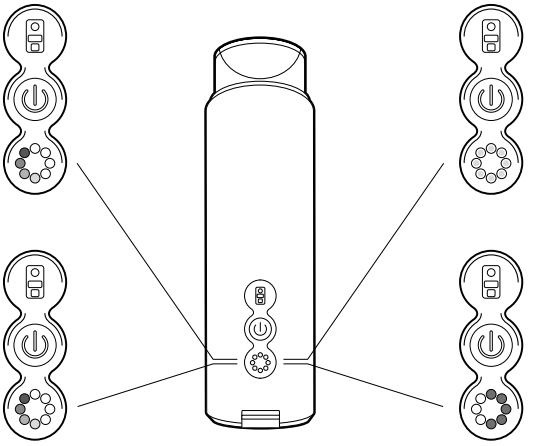
The applications are available in Apple App Store and Google Play. The applications work at least on iOS 9.0+ and Android API 21+ (5.0) versions. Communication of the AioCare spirometer - Applications is via Bluetooth® 4.0 (BT LE). This version of the module must be equipped with mobile devices on which applications will be installed.

The iPhone version is a minimum iPhone 5S. We do not recommend the use of applications on tablets and iPads.

Communication between AioCare and the user [Diagram 4]

One-time flashing of all the diodes ony 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: synchronization of AioCare device with a smartphone.



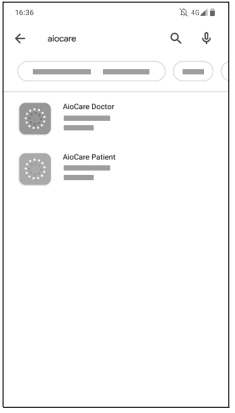
All the LEDs flashing smoothly: Bluetooth® data transmission during the measurement.

4 of 8 diodes flashing: low battery level - connect to a power source. Another one LED is flashing in the charging mode - represents the battery charge level.

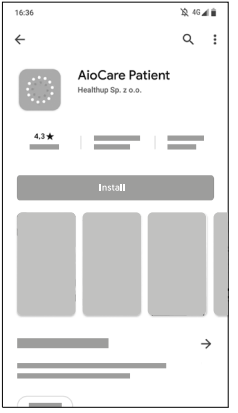
7.4. Application installation

[Diagram 5]

Find the App Store or Google Play icon on your smartphone.



Click the App Store or Google Play icon and search for an application called AioCare. Select the application version: AioCare Doctor - for the Doctor or AioCare Patient - for the Patient



Click "Install" to download the application and install it on your phone. When the installation is complete, click the "open" button.

7.5. First start-up of the application

After installing the AioCare application, in order to continue using it, it is necessary to create a doctor's or user's account or log in, if such an account is already in the system.

The user should contact the manufacturer if it is necessary to advise on installation, use, as well as to inform about an unexpected action or event.

Log in

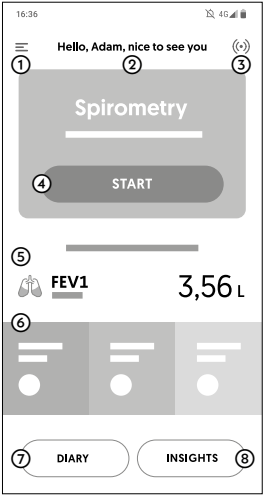
If you already have an account, you can use the "Login" button to log in with your assigned ID and password received from your doctor.

Main screen

On the main screen the user has access to the following features:

① A button that opens the main application menu which consists of:
- Start button for spirometry test,
- Diary,
- Insights,
- My device,
- My profile,
- Help,
- Shop,
- Settings,
- About us

② Welcome User
③ Connection to device icon
④ Start button for spirometry test
⑤ Last spirometric measurement result
⑥ Weather conditions: pressure, temperature and humidity.
⑦ Diary button
⑧ Insights button



[Diagram 6]

Doctor application home screen

On the main screen user has access to the following functionalities:

① Main menu button of the application, containing:
- Buttons to start the examination,
- My device,
- My profile,
- Support,
- Store,
- Settings,
- About us

② Date

③ Device connection status and notification icon

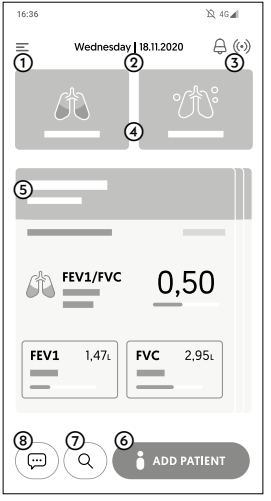
④ Buttons to start the examination

⑤ Patient's card with the results of the last examination

⑥ Button for adding a new patient card

⑦ Search button

⑧ Chat button



[Diagram 7]

Carrying out the test [Diagram 8]

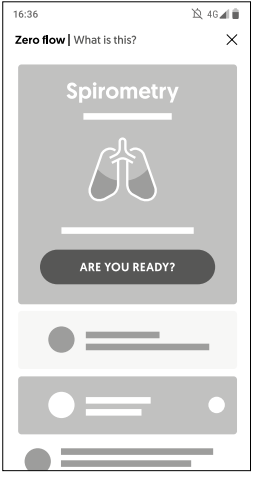
① The spirometry test starts by pressing the "Start" button on the main screen. This leads to the test screen. Make sure that the device is connected and paired with the application and then perform flow zeroing.

② The next step is to present the preparation screen for measurement. Prepare the spirometer, filter and nose clip. When the patient is ready, press the "Start" button.

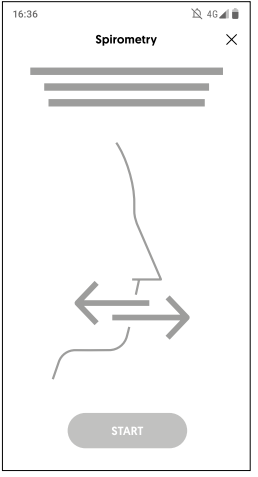
③ A "live" measurement screen is then presented, showing a visualisation and flow chart in real mode.

④ The measurement is stopped by using the "Stop" button.

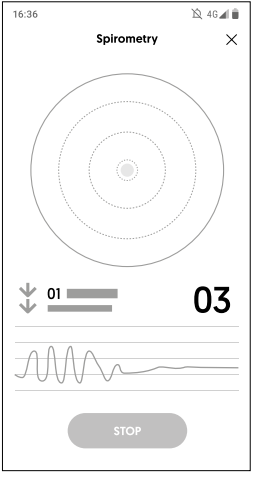
Step ①



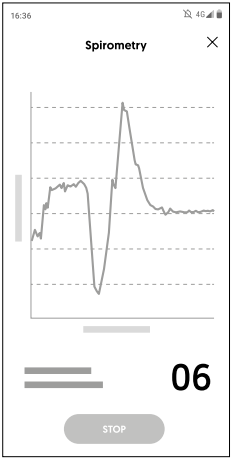
Step ②: View for the application in the Patient version



Step ③: View for the application in the Patient version



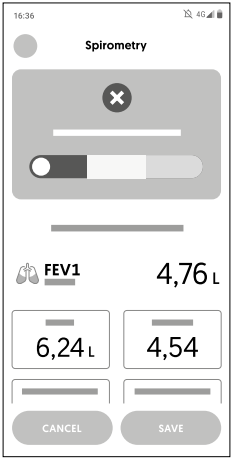
③ View for the application in the Doctor version



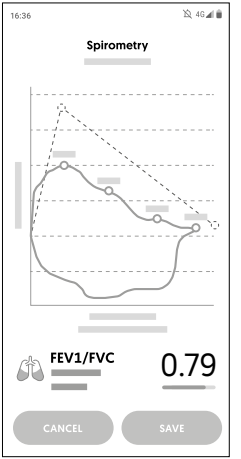
Measurement results

The first screen shows the interpretation of the results, and below all measured spirometric parameters are presented. The measurement results can be saved or rejected by pressing the appropriate button on the screen. If the measurement was made incorrectly, the application indicates an error in the upper left-hand corner of the screen and marks the incorrectness of the test.

View for the application in the Patient version



View for the application in the Doctor version



8. Maintenance of the AioCare spirometer

8.1. Usage guidelines

• Testing and safety

AioCare has been tested by an independent laboratory which confirms the compliance of the product with the European standard for electrical safety and home use (standard EN 60601-1 and EN 60601-11) and guarantees compliance with the electromagnetic compatibility requirements of the European standard EN 60601-1-2.

AioCare is constantly monitored during the production cycle to ensure compliance with the safety levels and quality standards set out in Council Directive 93/42/EEC concerning medical devices.

The safety and correct operation of the device can only be ensured if the user complies with all relevant safety rules and regulations.

The manufacturer is not liable for damage caused by the user's failure to follow the instructions. The device may only be used as a spirometer, using only original spare parts and accessories. Failure to comply with this warning may result in damage to the device, incorrect measurements and loss of warranty.

8.2. Maintenance

8.2.1. General information on reprocessing

AioCare consists of three main parts:
• Measuring module,
• Tube holder,
• Flow tube.

To avoid damaging the AioCare measuring module, disconnect the flow tube and the holder of the flow tube before starting the cleaning and disinfection process!

All operations described in this manual should be carried out with great care. Failure to follow the instructions in this manual may lead to erroneous readings from the device or to incorrect interpretation of the test results.

To avoid malfunction or damage, do not allow dust or foreign bodies to enter the flow tube. The presence of foreign bodies (such as hair, saliva, etc.) inside the flow tube may compromise the accuracy of the readings. All modifications, adjustments, repairs and reconfigurations must be carried out by the manufacturer or by personnel authorised by the manufacturer.

8.2.2. Daily maintenance

AioCare devices require little maintenance. Periodically:
- Clean and check the cleanliness of the reusable flow tube,
- Replace the flow tube when it has changed its properties (mechanical damage such as scratches, cracks, dirt that cannot be cleaned),
- Clean the measuring module with a cleaning cloth with the recommended cleaning agent. In case of problems do not attempt to repair it yourself.

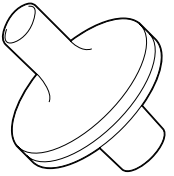
The setting of configurable parameters must be done by qualified personnel.
If the device is incorrectly adjusted, usage might cause a risk for the patient.

8.2.3. Cleaning and disinfection procedure for re-use between patients (health centre conditions)

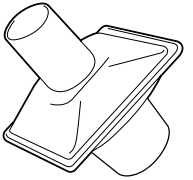
To maintain the functionality of the device, ensure accuracy of measurements and prevent cross-contamination, always keep the device clean. Always use a disposable antibacterial filter when taking measurements. If the device is used without a filter, there is a risk of contamination of the measuring channels, resulting in inaccurate measurements. If the device is used by several patients, the filter must be used to avoid cross-contamination.

Always use biocompatible filters to avoid problems - unsuitable materials can damage the device and interfere with the accuracy of readings. The device can be used with different types of filters, certified 30 mm diameter. The filters are a simple way to ensure protection against cross-contamination, both for patient and operator safety, without compromising AioCare system performance.

The Vyaire MicroGard® II (510 (K): K111408) or Vitalograph ECO Bacterial Viral Filters (BVF) CE 0086, Art, number: 2820/28501) have been tested in operation with the AioCare spirometer and are recommended for safe usage with the device.



Vyaire MicroGard® II 510 (K)



Vitalograph ECO Bacterial Viral Filters (BVF)

8.2.3.1. Cleaning and inspection of the flow tube

Cleaning: PDI Sani-Cloth AF3 Germicidal Dispipeable Wipe Ready-to-Use (RTU) (EPA registration 9480-9). Contact temperature: 20 to 25°C.

The flow tube and tube holder must be cleaned after each patient - before being used by the next patient!

Simple cleaning before each use will ensure that the properties of the tube are maintained and that the measurement results are correct.

① To clean the flow tube, remove the tube from the measuring module by pressing over the USB port and pulling gently. To facilitate removal, you can gently push the tube holder with your finger. To remove the flow tube from the holder, gently pull [Diagram 9].

After disconnecting the tube holder from the measuring module, the measuring module should be cleaned with non-alcoholic cloths for cleaning and disinfection of medical devices. AioCare recommends the use of the Sani-Cloth AF3 disposable bactericidal tissue, which has been approved on the device.

Using the disposable Sani-Cloth AF3 Bactericide wiper, wipe back and forth across the test area of the surface coverage, parallel to the seams, until visible dirt is removed.

After initial removal of the contaminants, check the holder for any remaining contamination. If visible dirt is present, use a new disposable cloth, repeat the wiping process until visible dirt is removed.

After removing the remaining dirt, use a new disposable cloth and wipe the entire housing parts back and forth twice across.

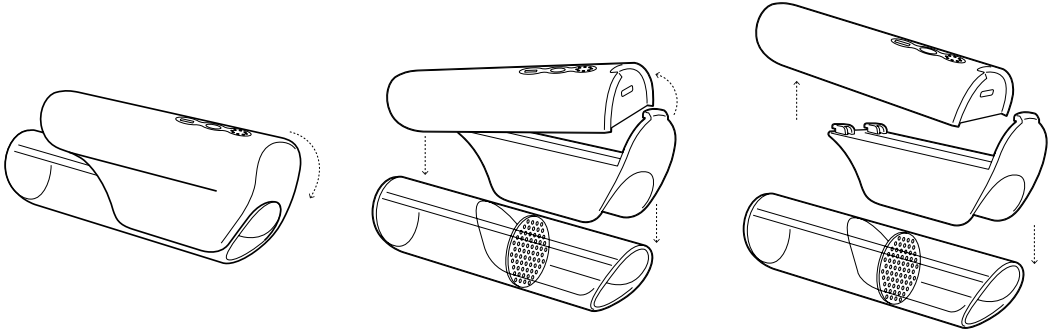
② In case of visible contaminants in the flow tube, it is recommended to thoroughly remove them with the brush after rinsing. Then clean the flow tube with running water. Allow the tube to dry for 5 minutes.

③ Clean the tube holder under running water with mild soap if you notice visible dirt on the surface. If the dirt is still visible, continue cleaning until completely removed.

④ Clean and dry components: read carefully section 8.2.3.2. Disinfection methods for multiple patient use.

⑤ Checking the correctness of the measurement function: turn on AioCare and proceed as if you wanted to perform a spirometry test. Take the device in one hand and slowly move it from right to left and vice versa so that air passes through the tube. If you see the diagram move in the mobile application, the device works and is ready to use.

Cleaning of the flow tube [Diagram 9]



8.2.3.2. Disinfection methods for multiple patient use

Do not sterilize with radiation or steam.

Disinfectant:
1. Ecolab OxyCide Daily disinfectant (EPA registration No. 1677-237).
2. PDI Sani-Cloth AF3 disposable bactericidal ready to use wipes (RTU) (EPA registration 9480-9).

Temperature: from 20 to 25°C.

① Clean and disinfect the flow tube holder and flow tube manually by immersion in disinfectant.
It is recommended that the agent should have properties B, F (yeast) and V (encapsulated virus). It is recommended that the product has a neutral pH.

- **Method 1** [Diagram 10]

1. The detached tube should be cleaned with a disposable Sani-Cloth AF3 wipe.
2. Prepare a container with 5l of cold water. Dilute OxyCide Disinfectant 1:43 in tap water, stir and leave for 15 minutes. After that time, stir again and place the flow tube and tube holder in the container for 15 minutes.
3. After 15 minutes, remove and rinse with water (deionised water is recommended).
4. Leave to dry for 15 minutes or blow with compressed medical air for 1 minute.
5. The flow tube and tube holder should be attached again to the measuring module of the device. The spirometer is ready for reuse after inserting a new antimicrobial filter.

Checking if the measuring function is correct:
Turn on AioCare and proceed as if you wanted to perform a spirometry test. Take the device in one hand and slowly move it from right to left and vice versa so that air passes through the tube. If you see the diagram move in the mobile application, the device works and is ready to use.

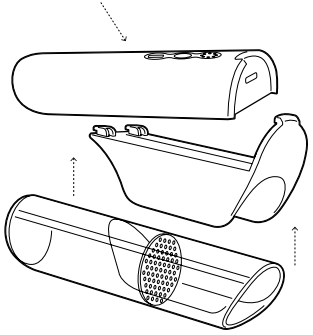
- **Method 2** [Diagram 11]

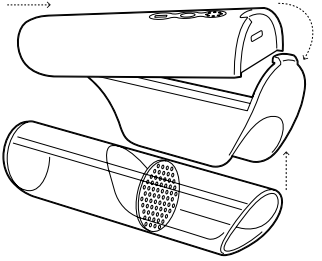
Equipment used for cleaning/disinfection should meet the requirements of ISO 15883-1: Washer-disinfectors - Part 1: General requirements, conditions and definitions and tests. Always follow guidelines and procedures for the disinfection of healthcare facilities.

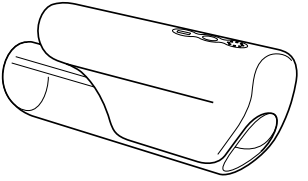
The medical device is a thermostable product, the recommended level of disinfection is A0 600. It is recommended to use deionised water up to the thermal disinfection phase.

The use of neodisher MediClean Forte is recommended as a cleaning agent. Rinsing agents such as Neodisher MediKlar are permitted.

Cleaning of the flow tube - method 1 [Diagram 10]







Recommended programme:

1. Initial rinsing with cold water for 2 minutes.
2. Clean with neodisher MediClean Forte 5 ml/L 55 degrees Celsius for 10 minutes.
3. Rinse (1) with cold water.
4. Rinse (2) with deionised water.
5. 90°C thermal disinfection. For 5 minutes, deionised water + neodisher MediKlar 0.5 ml/l.
6. Dry at 90°C for 15 minutes.

The flow tube and tube holder should be re-attached with the measuring module of the device. The spirometer is ready for reuse after inserting a new antibacterial filter.

Repeated thermal disinfection of the flow tube may cause visible changes in the material structure (turbidity of the material). This does not impair the technical properties of the product or measurement results. The preferred method of disinfection is to immerse in the disinfectant. The disinfection process is effective and does not damage the device.

If at the end of the cleaning stage it is found that the device is not visually clean, repeat the relevant previous cleaning steps or safely dispose of the device at the nearest medical device disposal site.

If you follow the cleaning instructions but the device does not work after the cleaning process, please contact the manufacturer.

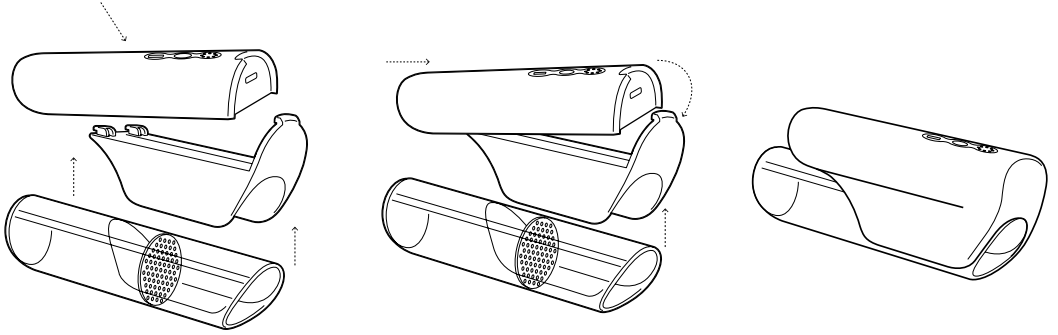
If you have additional questions about cleaning, disinfection or reprocessing, please contact the Healthup team: info@AioCare.com or call + 48 798545240.

8.2.3.3. Cleaning procedure for the device used by 1 patient (domestic use)

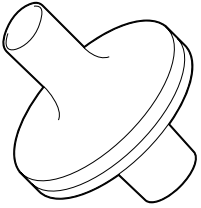
To maintain microbiological purity and accurate measurements, it is important to keep the device clean. It is recommended to always take measurements with a disposable filter. If the device is used without a filter, there is a risk of contamination of the measuring channels, resulting in inaccurate measurements. If the device is used by only one patient at home, there is no risk of cross-contamination, but it is recommended to use an antibacterial filter to keep the device clean.

Always use biocompatible filters, approved by the relevant authorities, to avoid problems - unsuitable materials can cause malfunctions and impair the accuracy of readings. The device can be used with all types of filters, registered by the relevant authorities, with a diameter of 30 mm.

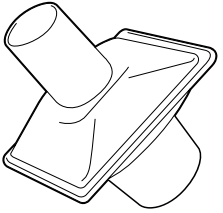
Cleaning of the flow tube - method 2 [Diagram 11]



The Vyaire MicroGard® II (510 (K): K111408) or Vitalograph ECO Bacterial Viral Filters (BVF) CE 0086, Art, number: 2820/28501) have been tested with the AioCare spirometer and are recommended for safe usage with the device.



Vyaire MicroGard® II 510 (K)



Vitalograph ECO Bacterial Viral Filters (BVF)

8.2.3.4. Cleaning procedure

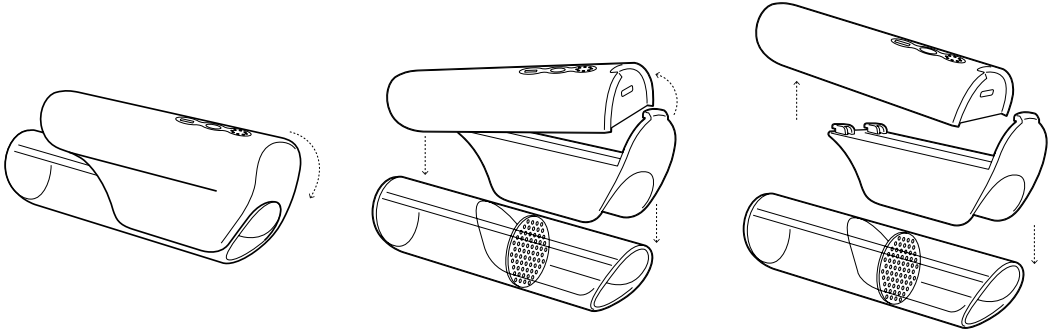
- Cleaner: PDI Sani-Cloth AF3 Germicidal Dispipeable Wipe Ready-to-Use (RTU) (EPA registration 9480-9),
- Soap,
- Tap water.

Contact temperature: 20 to 25°C.

① To clean the flow tube, remove the tube from the measuring module by pressing over the USB port and pulling gently. To facilitate removal, you can gently push the tube holder with your finger. To remove the flow tube from the holder, gently pull [Diagram 12]
After detaching the tube holder from the measuring module, the measuring module should be cleaned with alcohol-free cleaning and disinfection cloths for medical devices. AioCare recommends the use of the Sani-Cloth AF3 disposable bactericidal tissue, which has been approved on the device.

Using the disposable Sani-Cloth AF3 Bactericide wiper, wipe back and forth across the test area of the surface coverage, parallel to the seams, until visible dirt is removed. After initial removal of the contaminants, check the holder for any remaining contamination. If visible dirt is present, use a new disposable cloth, repeat the wiping process until visible dirt is removed. After removing the remaining dirt, use a new disposable cloth and wipe the entire housing parts back and forth twice across.

Cleaning procedure [Diagram 12]



② In case of visible contamination in the flow tube, it is recommended, to thoroughly remove them with a brush after rinsing. Then clean the flow tube with running water. Allow the tube to dry for 5 minutes.
③ Clean the tube holder under running water with mild soap if you notice visible dirt on the surface. If the dirt is still visible, continue cleaning until completely removed.
④ Leave the parts to dry for 15 minutes after cleaning.
⑤ Connect the flow tube and tube holder back to the unit's measuring module. The spirometer is ready for reuse.
⑥ Checking if the measuring function is correct: turn on AioCare and proceed as if you wanted to perform a spirometry test. Take the device in one hand and slowly move it from right to left and vice versa so that air passes through the tube. If you see the diagram move in the mobile application, the device works and is ready to use.

- If at the end of the cleaning stage it is found that the device is not visually clean, repeat the relevant previous cleaning steps or safely dispose of the device at the nearest medical device disposal site.

- If you follow the cleaning instructions but the device does not work after the cleaning process, please contact the manufacturer.

- If you have additional questions about cleaning, disinfection or reprocessing, please contact the Healthup team: info@AioCare.com or call + 48 798545240.

9. Power supply

The AioCare spirometer is powered by a 3.7 V LiPo battery, placed in the measuring module housing, with a capacity of 300mAh. A fully charged battery is sufficient for 5.5-6 hours of continuous operation. The user is informed about the battery status in the mobile application or by means of the LEDs on the device housing. When 4 out of 8 LEDs light up, it indicates low state of battery charge. The device should then be switched off completely within a few minutes and charged using the supplied USB cable connected to any PC/Mac device.

9.1. Operating the AioCare spirometer power supply

The measuring module has 2 charging functions:

1. Wired, via USB cable

The battery should be charged using the built-in charging system, which protects it from damage during charging and ensures its long life.
To start charging, connect the USB power cord on one side to the charging socket in the housing of the measuring module, and on the other side to any PC/Mac power source which is connected to the 230V power supply. This will cause the LEDs on the device's casing to light up, signaling the correct charging process. During the

charging of the measuring module, the spirometer functions are disconnected, no tests can be performed (the device cannot be switched on with the 'ON/OFF' button). To fully charge the battery, the charging process should take 3.5 hours. When fully charged, 8 of the 8 LEDs will light up again.

2. Wireless, using NFC technology (any NFC charger with the certificate of approval for sale on the EU market)

The battery should be charged using the built-in charging system, which protects it from damage during charging and ensures its long life. To start charging with NFC technology, the flow tube must be removed from the measuring module. Then place the measuring module with the side without buttons on the NFC charger. This will cause the LEDs on the device's casing to light up, signaling the correct charging process.
When charging the measuring module, the spirometer functions are disconnected and no tests can be performed. (the device cannot be switched on with the 'ON/OFF' key). To fully charge the battery, the charging process should take 3.5 hours. The charging time may depend on the power of the charger used. When fully charged, 8 of the 8 LEDs will light up again.

Use only the equipment specified by the manufacturer to power the unit so as not to damage the unit.

During standard operation, the LEDs indicate the battery charge level according to the model below:

0–12%	flashing lights	**62–74%**	5 LEDs are on
13–24%	1 LED is on	**75–86%**	6 LEDs are on
25–37%	2 LEDs are on	**87– 94%**	7 LEDs are on
38–49%	3 LEDs are on	**95–100%**	8 LEDs are on
50–61%	4 LEDs are on		

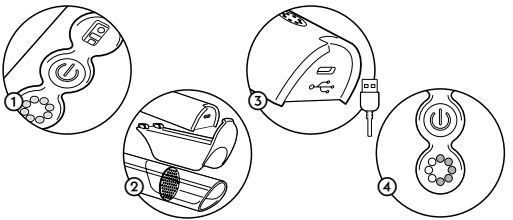
While charging, the LEDs indicate the current battery level according to the model below:

0–12%	1 LED is flashing
13–24%	1 LED is on + 1 flicker
25–37%	2 LEDs are on + 1 flicker
38–49%	3 LEDs are on + 1 flicker
50–61%	4 LEDs are on + 1 flicker
62–74%	5 LEDs are on + 1 flicker
75–86%	6 LEDs are on + 1 flicker
87–99%	7 LEDs are on + 1 flicker
100%	8 LEDs are on

How to charge:

① Turn the device off with the ON / OFF button, press the button for 1 second. The button will not turn off the unit when charging wired or wirelessly.
② Remove the cover of the USB socket.
③ Plug the micro USB cable supplied with the device into the micro USB socket of AioCare and connect it to a power source (any USB port), the LEDs at the top of AioCare should flash to show the current battery level.
④ When the device is fully charged, 8 LEDs are switched on.

Charging the device [Diagram 13]



9.2. Changing the battery

The battery is not replaceable.

Replacing the battery on your own may result in:
- **damage to the measuring module**
- **explosion or ignition of a battery**
- **damage to the battery**
- **electrocution**
- **burn**
- **loss of guarantee on the entire AioCare spirometry system**

Battery life is planned for 500 full charge cycles or 1 year of continuous 6-hour use per day. If this number is exceeded, the efficiency of the battery can drop to 60% of its service life. This will result in faster discharging of the battery.

According to the manufacturer, the life expectancy of the battery is 2 years and determines its suitability for use. The AioCare system is used at the sole responsibility of the user after 2 years from the moment of its first use.

10. Disposal

Dispose of this equipment in accordance with the national regulations in force in your country. Do not place used appliances or batteries in normal waste containers. Contact your recycling company for this purpose. The device may be handed over to the manufacturer, distributor or recycler. If the battery inside the device is damaged, the product must be returned to the manufacturer.

11. Warranty

The device has a two-year warranty period.

The warranty does not cover damages caused by using the device contrary to the instructions for use, improper use of the device or failure to observe the safety conditions and warnings contained in this manual in point 5.1.

The repair or replacement described in this guarantee applies to goods returned at the expense of customers to our authorised service centres. Please contact your local supplier or manufacturer for details on the service in your country. You are responsible for all costs of transport, customs clearance and delivery for damaged goods.

12. Working environment

Optimum ambient temperature for the measurement:	From +15°C to +40°C
Storage conditions:	From 5°C to +70°C, humidity <30 - 70%
Operating conditions:	From +15°C to +40°C, humidity <70%

13. Malfunctions and malfunctioning

In the event of any malfunction, defect, deterioration in the characteristics or performance of the device, as well as anomalies in its marking or in the instructions for use which may or could have led to the death or serious deterioration of a patient or user of the device, the user should immediately stop using the device and contact the manufacturer by email or telephone to provide a description of the defect and receive the necessary instructions for further handling of the device.

14. Information on compliance with FCC USA

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.

AioCare has been designed and complies with the safety requirements for mobile radio exposure in accordance with FCC §2.1093 and KDB 447498 D01.

15. Information on compliance with ISED Canada

This device is compatible with RSS ISED. Operation is subject to the following two conditions:

① this device may not cause harmful interference; and

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

This device complies with the safety requirements for exposure to radio waves according to RSS-102 Issue 5 for portable use.

16. Symbols used by the manufacturer

Statutory plate

SN	example: MS-032019000114 (where 03 is the month of production, 2019 - production year, 0001- copy number, 14 - hardware number)
	Warning symbol for WEEE; waste electrical components; disposal in accordance with national regulations
	Electrical safety symbol - Type BF applicator according to IEC 60601-1
CE	CE - symobol means that the product has a Class IIa certificate of conformity with the requirements of Directive 93/42/EEC concerning medical devices
	USB symbol - use only the USB cable supplied by the manufacturer and comply with the safety provisions of IEC 60601 -1 -1
	Symbol - always read the instructions

	Compliant device with part 15 of the provisions FCC (Federal Communications Commission)
	Symbol - Manufacturer (Address details) Date next to factory - Date of manufacture of the product
	Dangerous for magnetic resonance imaging (MR)
	Bluetooth®
	Symbol - "Device includes transmitter radio (RF)"; electromagnetic compatibility compatibility
	IP22- degree of protection provided by the housing of the electrical equipment against foreign bodies and harmful effects of water penetration
	Non-sterile product
	Read the online manual

17. Declaration of conformity

AioCare - a remote monitoring system, consisting of a spirometer, a peak flow meter module and a heart rate monitor, integrated with mobile devices through Bluetooth® LE communication, with diagnostic software for mobile devices and database software supporting analyses - as an active Class IIa diagnostic medical device (classification rule 10), meets the essential requirements of the Regulation of the Minister of Health of 17 February 2016 on 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 was carried out in accordance with Annex II to the above Regulation / Directive, with the participation of notified unit No. 2274: TÜV Nord Polska Sp. z o.o.
40-085 Katowice, 29 Mickiewicza Street.

18. Questions and problems - FAQ

1. How to register for the AioCare application?

To register to the application, on the initial screen, click the "Join AioCare" button and then enter the email to which you want to register your account and password

consisting of at least 8 characters, including at least one lowercase and capital letter, one digit and one special character).

2. I have been logged out of the application. How to log in to the AioCare app again?

In order to log in to the application, on the initial screen, you need to click the "Already have an account?" button and then enter the login and password provided during account registration.

3. I forgot my AioCare password and I cannot log in to the application.

In order to restart your AioCare application password, on the initial screen, you need to click the "Already have an account?" button, then click the "Forgot your password" button and enter the email address that was registered in the AioCare system. A message with a link to restart the password will be sent to the email address provided. For security reasons, the link is active only for 60 minutes after the message is generated.

4. How to change the password in the application?

At the moment, changing the password is done by restarting the password. To do this, see section 3.

5. The application does not see the AioCare device on the device list despite the Bluetooth® module being turned on.

The problem occurs mainly on mobile devices based on the Android system. The reason for this is the different types of system overlays of mobile device manufacturers, so the Bluetooth® module may operate in different ways. In order for the application to "see" and connect to the AioCare device, the GPS module must be activated in the mobile device.

6. I cannot connect to the AioCare device.

If you have problems connecting to your AioCare device, please refer to the instructions below:

① Close the AioCare application so that it does not work in the background.
② Switch off the Bluetooth® module and the GPS/Localization module on your mobile device.
③ Switch off your AioCare device.
④ Start the AioCare application.
⑤ Go through the pairing/connection path of your device with the application and follow the instructions displayed on the screen.

In order to increase the likelihood of your device connecting to the application, we recommend switching on the GPS module on your mobile device.

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

This message appears when there is no internet connection. The report is generated from the server, not in the application, so in order to download the report it is necessary to have an Internet connection. We recommend checking the connection from your mobile device to the Internet.

8. What should I do if, despite the end of blowing by the patient, the application still detects the air flow.

If the application still detects airflow even though the patient has finished blowing into AioCare, finish the test and reset the airflow and start a new test.

9. Is an internet connection required when using the application?

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

1. in a situation when the user wants to create a new account (register to the application).
2. in a situation when the user logs in to his/her account.
3. in a situation when the user wants to perform the first spirometry test on the AioCare device newly connected to the application.

4) In a situation when the user wants to generate a test report.

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

10. How to synchronise data with the server?

Data synchronization takes place in the background of the application and is performed automatically when the application detects an internet connection.

11. Why does the application require further measurements when 3 measurements have been taken?

For measurements to qualify for a correctly performed test in accordance with international standards, the criterion of correctness of measurements as well as the criterion of repeatability of measurements must be met at the same time during the test.

12. What is the criterion for repeatability of measurements?

The measurement repeatability criterion consists in comparing the FVC and FEV1 values in the two best measurements. For the repeatability criterion to be met, the difference between the FVC and FEV1 values in the two best measurements must not exceed 150 ml.

13. What is the criterion for correct measurements?

The criterion for correct measurements is to obtain a minimum of three correct measurements (green dots) in one test.

14. What does the red dot mean when measuring?

A red dot during the measurement means that an error occurred during the measurement. This condition can be indicated by a number of reasons, e.g. BEV error, plateau error, exhaust time error, detected cough, data error, etc.

15. What does the green dot mean when measuring?

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

16. What is a BEV error?

The BEV error occurs when during the measurement the exhaust is too slow.

17. What is a plateau error?

A plateau error occurs when the measurement is completed before recording no flow for at least 1 second.

18. What is the error during exhalation time?

Exhalation time error occurs when the measurement is completed within 6 seconds after the application detects exhaust.

19. What is a coughing error?

Exhalation time error occurs when the application detects a patient's cough during measurement.

20. What does it mean when the lights on the AioCare device start flashing even though no test has been carried out?

When the AioCare LEDs start flashing even though no test has been carried out, this means that the device battery is running low and AioCare must be connected for charging via the USB port or the NFC charger.

21. How to charge the device?

The device can be charged using the NFC charger or a standard USB cable. To connect the cable to the device, gently pull the clip on the back of the device next to the LEDs, and then slide the device in the opposite direction to the location of the clip. In the split top of the unit, there is a mini USB port on the back of the unit to which you connect the cable.

19. Training

The AioCare application contains several tips on how to take measurements correctly:

① Pop-up information / hints in the application about errors or warnings,

② The guide available on our website - how to use AioCare application can be easily found in the Support section,

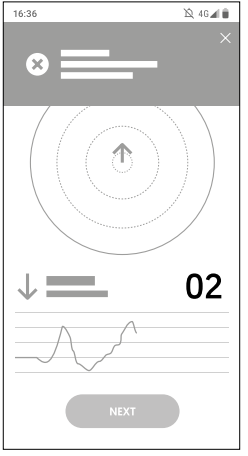
③ Explanatory video available in our application and on Vimeo,

④ FAQ available on our website - questions and problems concerning AioCare, you can easily find in the Help section,

⑤ Training sections in our application to perform better breathing and to force a breathing manoeuvre

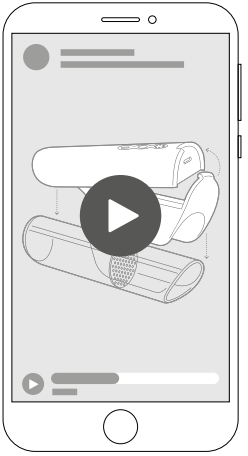
⑥ This manual is available both in our application and on our website in the Help section

① Hints in the application

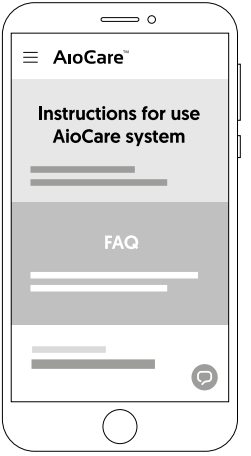


② **Guide available on our website**

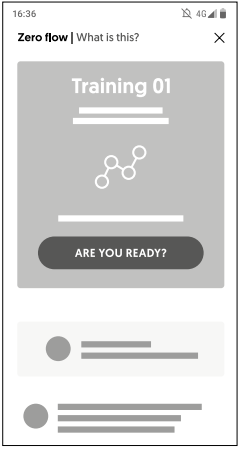
③ **Explanatory video** (vimeo.com/332398775)

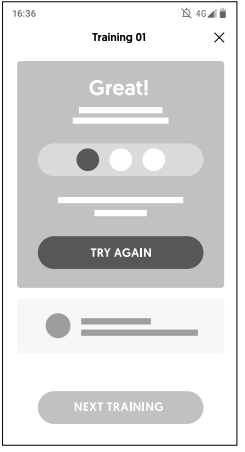


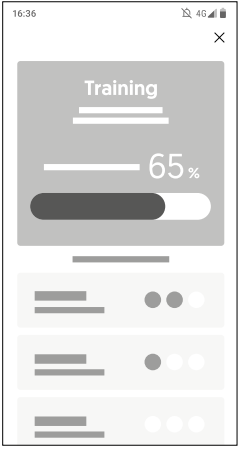
④, ⑥ **FAQ and digital manual**

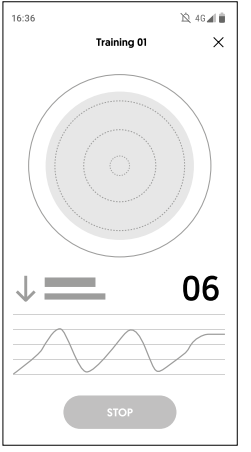


⑤ Training sections in our application









20. Precautions

Warning: Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or damage to the user or patient.

1. The use of a disposable antimicrobial filter is mandatory when testing different patients on the same AioCare device. Failure to comply with this warning may result in cross or secondary infection.

2. During charging, the battery should be at room temperature. Never expose it to temperatures below -10°C or higher than 45°C!

3. Use the USB cable provided with the device.

4. The battery can be recharged without being completely exhausted beforehand. Over time, the parameters of the battery deteriorate, so you can expect shorter operating times and the need for more frequent and longer charging!

5. Protect the device from moisture and do not immerse it in water. Use a dry antistatic cloth to clean the correct spirometer (measuring module)!

6. Do not disassemble the battery. Take care not to drop the device, especially on hard surfaces. Do not try to dry the appliance with another device or heat source such as a hair dryer or microwave oven.

7. If the device is damaged, switch it off and secure it against unintended use. Safe operation is not possible if the device is damaged:
- indicates visible mechanical damage!
- does not work properly (LED is not lit)!
- has been stored for a long time in unfavourable conditions (-10°C or higher than 45°C, high air humidity - over 70%)!
- has been damaged due to transport!

8. Operation under the following adverse environmental conditions is not permitted:
- Humidity or high air humidity - Dust and flammable gases, vapours or solvents
- Storms and storm conditions, such as strong electrostatic fields, etc.

9. No changes or modifications may be made to the device.

10. Any mechanical damage to this device may cause it to malfunction.

11. Using, operating and servicing the product in a manner inconsistent with the operating instructions is not permitted and may lead to damages caused by the user for which the manufacturer is not responsible.

12. Data security warnings: Your smartphone stores your personal data. Potential risks, such as:
• Installation of malicious software
• Physical access to the smartphone
• Physical damage to the smartphone
• Smartphone theft

It may affect the integrity or confidentiality of such data, such as:
• Access to data by unauthorised persons
• Loss of data
• Inability to use the smartphone for communication

The following measures help to reduce the risk of such events:
• Do not open or install files from suspicious sources
• Do not leave your smartphone unattended
• Use your password to access your data
• Check the correct email address to which the test results are to be sent

AioCare may give inaccurate measurements when used in the presence of high-intensity electromagnetic radiation sources.

If any incident or accident occurs as a result of using the device, the user must immediately inform the device manufacturer.

Failure to comply with the above warning may result in damage to the device and/or incorrect measurement.

20.1. Warnings for use in electromagnetic fields

Due to the growing number of electronic devices, such as computers, smartphones, medical devices may be susceptible to electromagnetic interference from other devices.
Such electromagnetic interference may cause the medical device to malfunction and create a potentially dangerous situation.
The AioCare spirometer complies with EN 60601-1-2: 2014 on electromagnetic compatibility (EMC for medical devices) both in terms of immunity and emissions.

However, the following precautions must be taken for the device to function properly:
• Make sure that AioCare and the smartphone on which the application is installed are within 2 meters from each other.
• Do not use AioCare near other devices (computers, cordless phones, mobile phones, etc.) that generate strong electromagnetic fields. Keep such equipment at a minimum distance of 7 meters.

20.2. Recommended separation distances for RF communication

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

The maximum transmitter output power (W)	Separation distance according to transmitter frequency (m)		
	150 kHz to 80 MHz d = nie dotyczy	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	1100
100	Not applicable	0,750	3500

For transmitters with a maximum output power not listed above, the recommended separation distance d in metres (m) may be estimated using the equation applicable to the transmitter frequency, where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer.

At 80 MHz and 800 MHz the distance for the higher frequency band applies.
This guidance may not apply in all situations. Electromagnetic wave propagation is influenced by absorption and reflection from structures, objects and people.

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