AioCare Spirometry System User Manual

- system for remote monitoring, with a spirometer, peak flow meter and pulse meter module

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Manufacturer:
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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 manoeuvre 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. The spirometer has been designed for use by technicians and physicians conducting respiratory tests, but may be also used by patients for self-monitoring, provided that they understand the test instructions. Standard values and interpretation results have not been calculated for children less than 5 years old.

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

INTENDED PURPOSE:

1. Diagnostics of respiratory diseases in patients of all ages except for neonates and infants as part of out-patient and in-patient care:
2. 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)
3. Screening tests in persons with risk factors (smoking, exposure to toxic factors, dusts, gases).
4. Examination of the respiratory system in systemic conditions
5. Assessment of risk in the perioperative period:
    a. extrapulmonary surgeries
    b. thoracic surgeries
6. Assessment of the respiratory function prior to strenuous physical activity.
7. Monitoring of respiratory diseases in patients of all ages except for neonates and infants as part of out-patient and in-patient care:
    a. 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
    b. Objective assessment of the course of disease and impact of illnesses on the respiratory function.
    c. Monitoring of the effects of treatment known to have damaging action on the respiratory tract.
    d. Monitoring of the respiratory function in patients following transplantation of the lungs and other organs (kidneys, bone marrow – GVH, BOOP).
    e. Monitoring of the respiratory function in individuals exposed to toxic agents at the workplace.
8. 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

Equipment:

- bacterial filter – the use-by date is indicated on the welded film of the packaging, don't use after expiry
- nose clip – the use-by date is indicated on the welded film of the packaging, don't use after expiry
- USB cable
- abbreviated instructions for use

The spirometry system is capable of:
1. Testing:

a. spirometry (parameters: FVC, FEV1, PEF, Tiffeneau, FEF25, FEF50, FEF75, VPTEF_VE, TPTEF_TE)
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: 30-75%
Storage: from +5°C to +45°C
Internally powered device
BF applicator
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
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
Measurement frequency	100 Hz
Internal power supply	Battery (LiPo 3.7 V)
Power consumption 50 mA	50 mA
Storage Conditions	from +5°C to +45°C
Device operating conditions	from +15°C to +40°C
Dimensions	118x38x48 mm
Weight:	0.3 kg

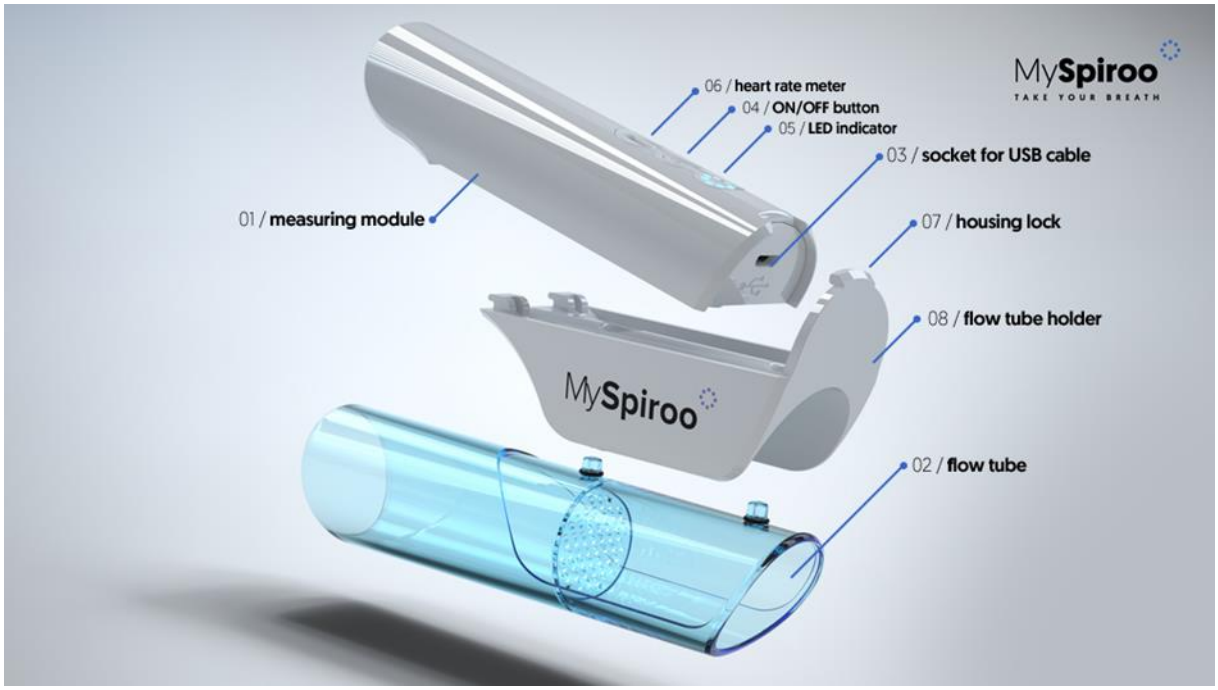


Figure 1 Structure of AioCare.

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 prior to first use.
All spirometry standards (including ATS/ERS) recommend that the reliability of pulmonary measurement devices should be checked at least once daily with a 3L calibration syringe when AioCare is used in clinical and hospital environment.
With normal use, calibration or calibration check is recommended as part of the annual routine maintenance service. This service is available at health care facilities or at the headquarters of AioCare manufacturer.

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 manoeuvre 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 (IMPORTANT: in the case of infection accompanied by coughing when the device is used individually, and always when AioCare is used in clinical or hospital environment) 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 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 200 mL and also the two highest FEV1 values differ from each other by no more than 200 mL. The result of measurement are maximum FEV1 and FVC values which don't need to be obtained in the same test.

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. Conducting testing

4.1. Preparing AioCare for operation

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

4.2 Communication between AioCare device and user

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.

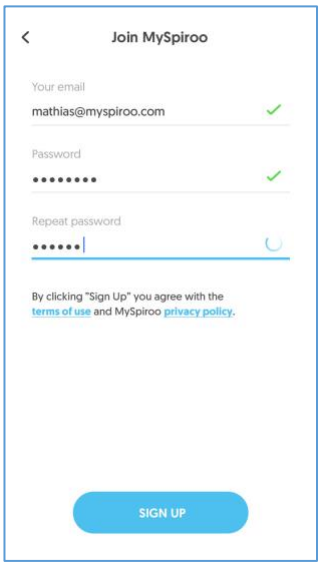
4.4. First launch of application

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.



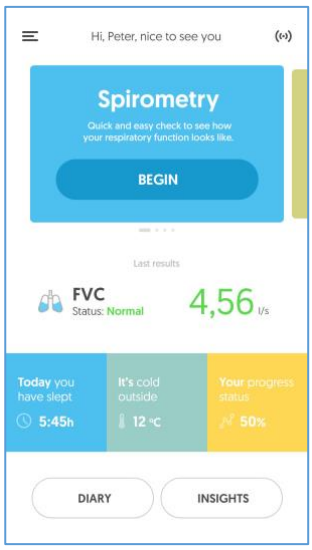
Main screen

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

Button opening the application main menu containing:

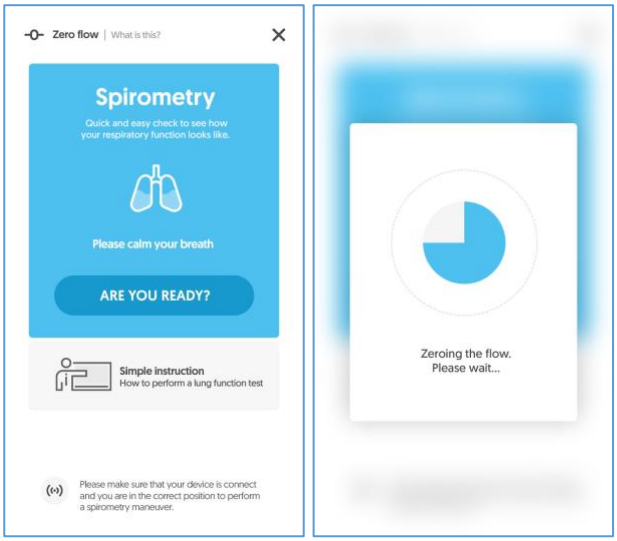
- Button to start a spirometry test
- Log
- Statistics
- My device
- My profile
- Help
- Shop
- Settings
- About us

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

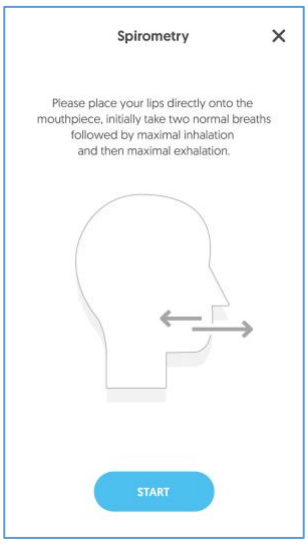


4.6. Conducting a test

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”.

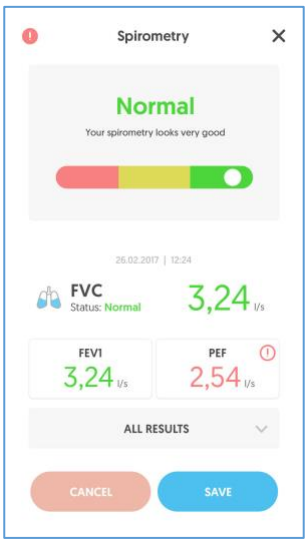


Next displayed is the “live” measurement screen with visualisation and graph of the flow rate in real time. Measurement is stopped by pressing the “Stop” button.

4.7 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.

Cleaning
The flow tube can be rinsed with water or washed with generally available washing agents. The tube must be cleaned up before first use and each time after measurement. The flow tube must be clean, dry and free from foreign bodies in the air flow channels. After each test, the tube should be thoroughly washed, and any foreign bodies and visible dirt removed using a soft cloth.
Disposable MADA 29 mm filters are recommended.

CAUTION: Each time make sure that the flow tube contains no liquid left after washing. The tube's air channels used for testing must be thoroughly dried up. Failure to comply with this caution may lead to device damage or incorrect measurement.

The flow tube can be washed with running water. **Don't wash AioCare in a dishwasher.**

Daily operation:
- check if there is no obstruction in the flow tube,
- check the mechanical condition of the flow tube and the measuring module.

CAUTION: Bacterial filter must be used. Don't use the same filter if you test different patients on the same AioCare device. Failure to comply with this caution may lead to cross- or secondary contamination.

PRECAUTIONS:

1. Don't use this device while charging!
2. 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.
3. 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!
4. Use the USB cable bundled with the product.
5. 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!
6. Protect against moisture and don't immerse in water. A dry anti-static cloth may be used for cleaning the spirometer proper (measurement module)!
7. 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.
8. 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!
9. 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.
10. The device must not be modified or tampered with.
11. Any mechanical damage to the device may cause its malfunction.
12. 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.

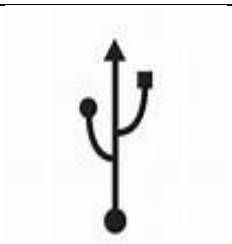
CAUTION: AioCare may give unreliable measurements if it's used in the presence of strong electromagnetic fields.

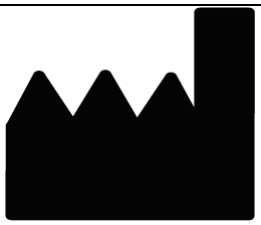
CAUTION: In the event of any incident or accident related to the use of this device, the user is required to immediately notify the manufacturer of this fact.

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

6. Meaning of symbols used by the manufacturer

Plate on AioCare device

SN	example: MS-16110001 (where 16 is the year of manufacture/11 – month of manufacture/ 0001-consecutive number of the piece)	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
FCC ID:	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)		**IP22-** protection level provided by the enclosure of electrical device against the ingress of foreign bodies and harmful effects of moisture ingress

7. Maintenance

Wipe the case of the measurement module with a soft cloth. **Never wash under running water!**

CAUTION: Don't let the device be poured over with a liquid. Failure to comply with this caution may lead to device damage or loss of warranty.

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.

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

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.

10. 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.

11. 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, and

(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.

12. 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.

13. Declaration of Conformity

AioCare – a remote monitoring system incorporating a spirometer, peak flow meter and heart rate 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, and also Radio Equipment Directive 2014/53/EU.

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.