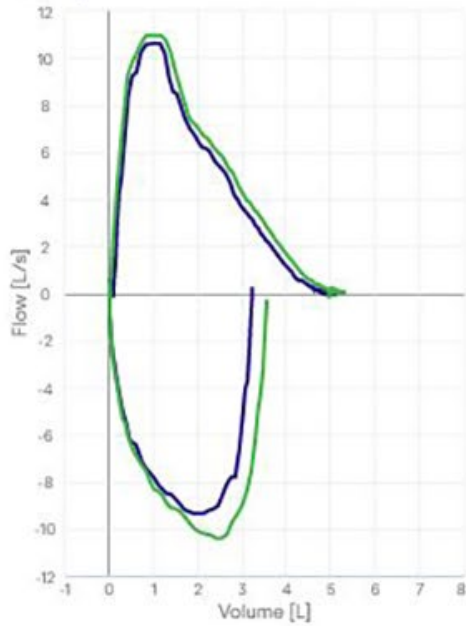




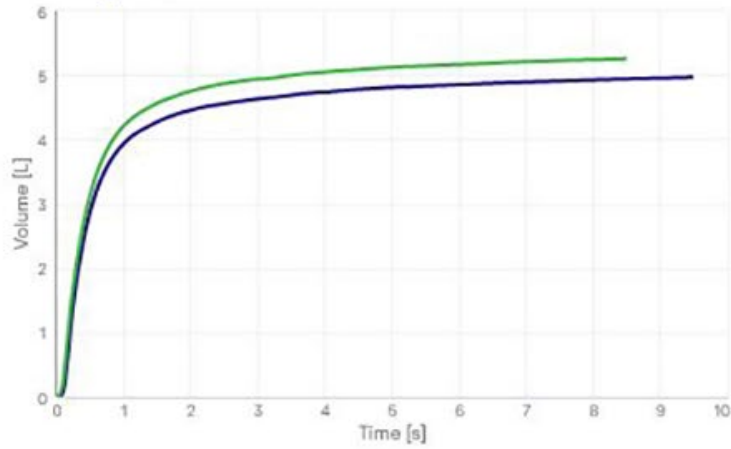
# AioCare Spirometry Better Diagnostics Better Lives

A completely mobile and flexible approach

### FLOW/VOLUME



### VOLUME/TIME



# AioCare system specifications

## Measurement

Tests

SVC Slow spirometry, FVC - Forced spirometry, BRT - Bronchodilator Responsiveness Test, SpO2 & Heart rate, Peakflow Diary



## Parameters

Slow parameters

VC, IC, ERV, VT, IRV

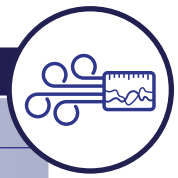
Forced parameters

FEV1, FVC, FEV1/FVC, FEV1/VC, PEF, FEF25, FEF50, FEF75, FEF25-75, FEV6, FIVC, PIF, FIF25, FIF50, FIF75

Technical parameters

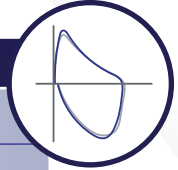
|          |   |
|----------|---|
| VPTEF    | Volume to Peak Tidal Expiratory Flow  |
| ERV      | Expiratory Reserve Volume   |
| TPTEF    | Time to reach Peak Tidal Expiratory Flow  |
| TPTEF/TE | Time to reach Peak Tidal Expiratory Flow as a proportion of Total Expiratory time                               |
| TPEF     | Time to Peak Expiratory Flow. Time from the start of the forced exhalation to the point of Peak Expiratory Flow |
| RT       | Rise Time. Time required for a signal to change from 10% to 90% of the Peak Expiratory Flow                     |
| TPTEF VC | Ratio of Volume to peak expiratory flow to total expiratory volume  |
| VPTEF/VE | Ratio of Volume to peak expiratory flow to total expiratory volume  |
| VT       | Volume Tidal  |
| FET      | Forced Expiratory time  |
| BEV      | Back Extrapolated Volume  |





## Flow measurement

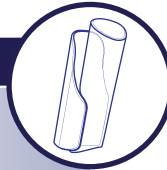
|                                    |                                      |
|------------------------------------|--------------------------------------|
| Sensor type for flow measurement   | Thermal                              |
| Spirometric flow measurement range | 0–16 l/s                             |
| Flow accuracy                      | ±5% or 200 mL/s                      |
| Resistance                         | <0.5 cm H <sub>2</sub> O/L/s         |
| Volume range                       | 0–8 litres                           |
| Volume accuracy                    | ±2.5% or 50 ml, whichever is greater |
| Linearity                          | 2.5%                                 |



## Volume integration

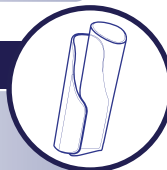
|                                 |   |
|---------------------------------|---|
| Flow measurement resolution     | Measured 5 ml/sec, usable 10 ml/sec                             |
| Accuracy/Repeatability          | Standard: ATS/ERS 2019  |
| Automatic BTPS correction       | Built-in sensors for measuring temperature, pressure & humidity |
| Determination of t <sub>0</sub> | Algorithmic   |
| Expiratory impedance            | <0,15 kPa/(l/s) at 14l/s  |

## Technical



|  |                           |
|--|---------------------------|
| 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   | 118 x 38 x 48 mm          |
| Weight   | 0,3 kg                    |

## Standards, directives and material clearances





|                   |  |
|-------------------|--|
| Standards         | ATS/ERS 2019, EN 60601-1, EN 60601-1-2, EN 62304, EN 62366, EN ISO 14971, EN ISO 10993-1 |
| Directives        | 93/42/EEC amended by 2007/47/EC, RoHS 2011/65/EU compliant                               |
| Market clearances | CE 2294  |





## Doctor / Patient application



|                        | Phone  | Tablet                |
|------------------------|--|-----------------------|
| Operating system       | iPhone 6 and next generations phones, iOS 9.0 or higher  | X                     |
|                        | Android 5.0 or higher  | Android 5.0 or higher |
| App Store availability | Download from AppStore or GooglePlay Store   |                       |
|                        |   |                       |

## Online panel



Requirements  
No specific requirements  
Internet connection

**AioCare Panel**



## Highest quality standards

**FEV1**  
Accuracy

**FVC**  
Accuracy

**ATS/ERS**

Implemented 2019 guidelines



Patient Validation Tests



Multicenter Observation Study



National obstruction Diagnostic Program



Accuracy Validation Report, May 2020

# AioCare + MicroGard™ II Filter Protects patients

High level validated cleaning methods

Protect patients, staff and device from cross-contamination by using the MicroGard™ II in-line filter.

MicroGard II filters provide 99.999% viral and bacterial efficiency against cross contamination (Nelson Test Report 1003754).





## **The AioCare spirometer and antibacterial/viral filter MicroGard II respectively manufactured by HealthUp and Vyaire were tested according to ATS/ERS Standardization of Spirometry 2019.**

This testing is to verify the quality of the results considering accuracy, repeatability, linearity and resistance to flow of the combination.

All 50 AioCare spirometers (which have been tested using MicroGard II antibacterial/viral filters) have met the full criteria described in ISO23747:2015 and ISO26782:2009 standards. The variety of waveforms in both standards encompass the characteristics seen in the population of patients.

- Accuracy, repeatability and linearity for waveforms C1-C11 (applies to 26782:2009 standard) are within the permissible error range.
- Accuracy, repeatability and linearity for waveforms C12-C13 tested on heated and humidified air as well as impedance test (applies to 26782:2009 standards) are within the permissible error range.
- Accuracy, repeatability, linearity for profiles A and frequency response (applies to 23747:2015 standard) are within the permissible error range.
- Accuracy, repeatability, linearity for profiles A 300l/min and 600l/min as well as impedance tests (applies to 23747:2015 standard) are within the permissible error range.

### **ISO 26782:2009**

Anaesthetic and respiratory equipment – Spirometers intended for the measurement of time forced expired volumes in humans

### **ISO 23747:2015**

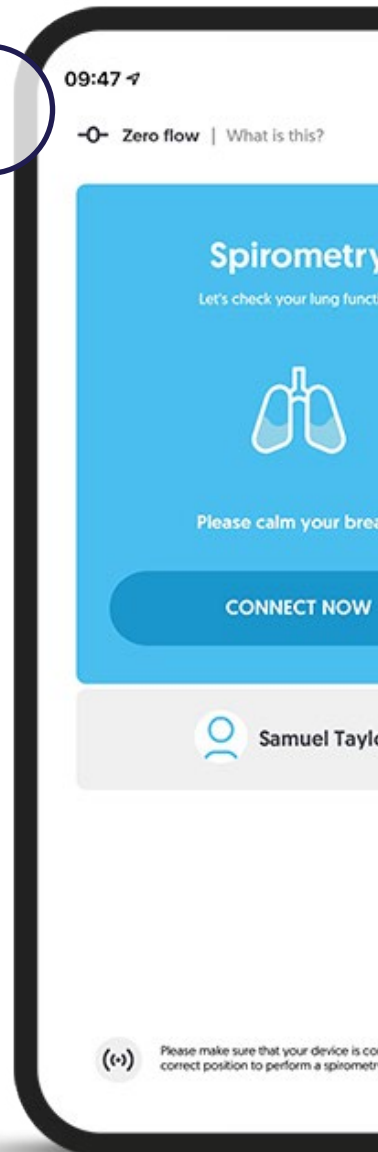
Anaesthetic and respiratory equipment – Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans

# Server / Backend



## CONNECTION BLUETOOTH 4.0

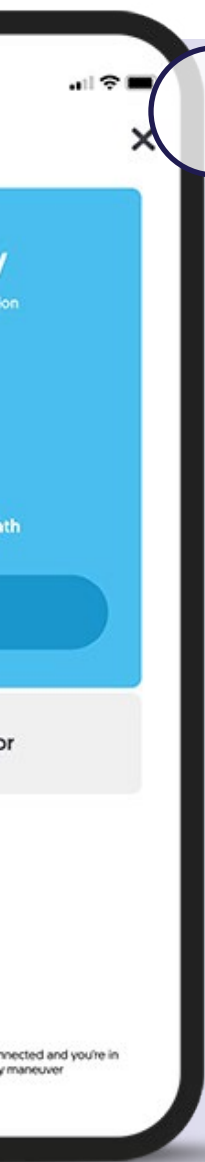
Connection secured by AES-128 encryption with Electronic CodeBook (ECB) and directly in the application by authorization of connection with the chosen AioCare spirometer.



AioCare infrastructure is supported by Amazon AWS platform. AWS provides physical security and we are operating from Central Europe region that has its DataCenter located in Frankfurt, Germany. AWS infrastructure meets all the required standards: ISO/IEC, CSA/CCM, ITAR, CJIS, HIPAA and IRS. The code runs on AWS Elastic Container Service infrastructure and its access and management is fully automated using PK/SSH security. Any manual intervention is only available to AWS System Administrator. In addition, access to any Data is restricted for specific IP addresses. Only services necessary for user operation are available from the internet, using always HTTPS protocol. The many modules that compose AioCare Solution are written in PHP v8.1 and node.js v18.1, using a Relational DataBase (MySQL8.2).

Access to data through the API is possible only after providing correct user credentials, that will grant the user a JWT token, that is only valid for the next 2hours on Web and 24hours on Mobile, after that period the user needs to authenticate again.





**DATA TRANSFER**  
 Transfer secured by SSL certificate (Secure Socket Layer)



**API (REST)**  
 Integration with any data system or platform



**HIS (HL7)**  
 Integration with Hospital Information System

**AIOCARE SERVER**  
 AMAZON AWS  
 ISO 27001



**SentrySuite™ SOFTWARE**

Profit from pulmonary expert reviews due to the peer review functionality in **SentrySuite**. Enter full trend reports and combine with other pulmonary function test measures, as bodyplethysmography



**AioCare on-line panel**  
 Data aggregate in the desktop version for doctors

The app allows 3 different roles, and requires different layers of authentication:



**System Administrator**  
 - Email/Password  
 - 2FA using email code  
 - IP restriction



**Doctor**  
 - Email/Password  
 - 2FA using email code



**Patient**  
 - Email/Password

All authentication data (ie: password) is stored encrypted and its access is fully restricted and audited. Any manually required intervention needs to be authorized by the DB administration and is fully audited. Data backups are performed daily and are automated and stored for the previous 7 days.

## REFERENCES

1. Based on the Bio Burden DIN EN ISO 11737-1: Report 18AA0088

The contents of this publication may differ from the current approval of the product or service in your country.

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### MICROGARD™ II FILTER SENTRYSUITE™ SOFTWARE

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