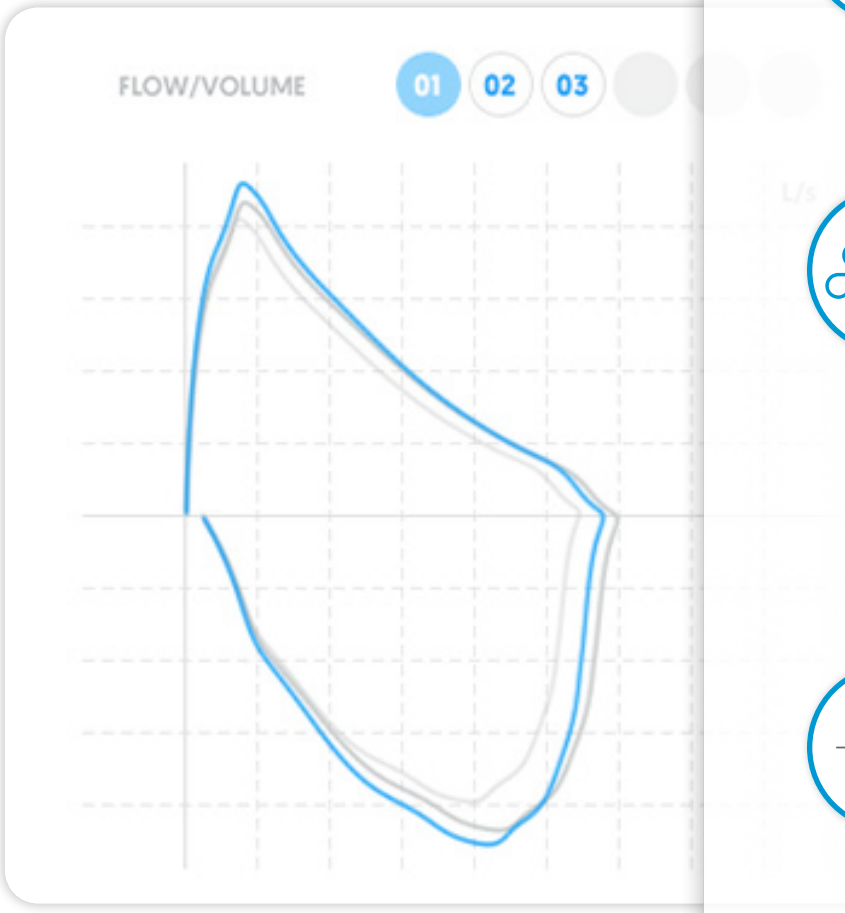
AioCare Doctor
Better Diagnostics

Technical Specifications

vyaire™
MEDICAL

AioCare System Specifications



Measurement

Tests	FEV1, FVC, FEV1/FVC, PEF, FEF25, FEF50, FEF75, FEF25-75, FEV6, VPTEF_VE, TPTEF_TE, FIVC, PIF, MIF25, MIF50, MIF75, peak flow meter (PEF), SpO_2/HR

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 H2O/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 and humidity
Determination of t0	Algorithmic
Expiratory impedance	<0,15 kPa/(l/s) at 14l/s

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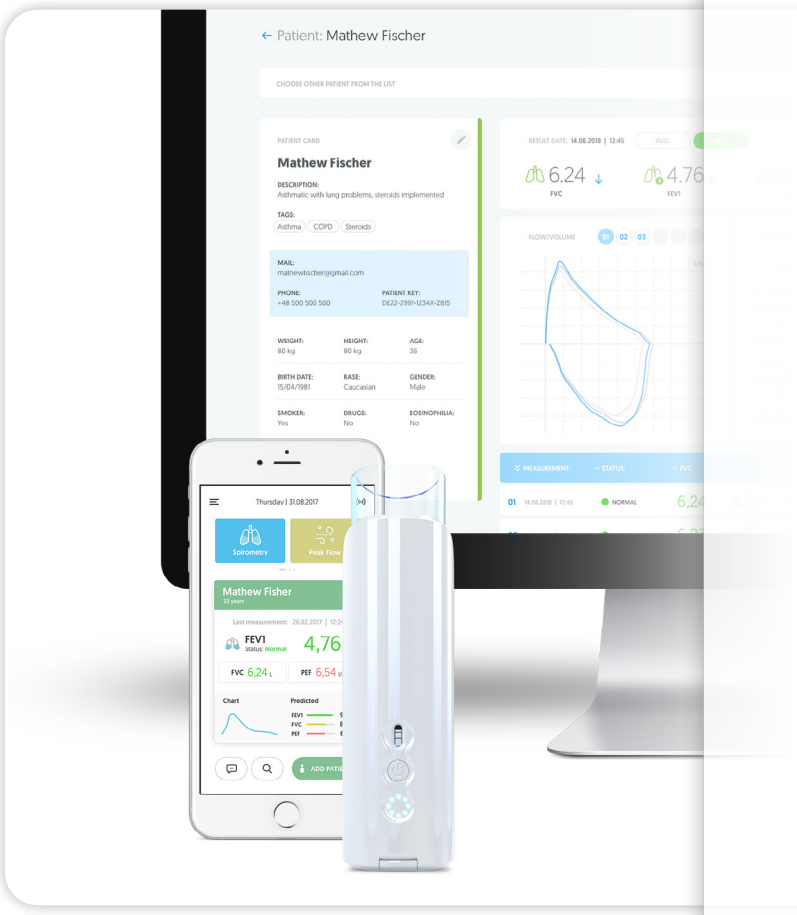
Technical

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	118x38x48 mm
Weight	0,3 kg

Standars, 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

AioCare System Specifications



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 Download on the App Store · GET IT ON Google Play	

Online Panel

No specific requirements.
Internet connection.

Confirmed by research

99%

FEVI
Accuracy

98%

FVC
Accuracy

ATS/ERS

CRITERIA
Have been met

2019 GUIDELINE
IMPLEMENTATION PENDING

- Patient Validation Tests
- Multicenter Observation Study
- National COPD Diagnostic Program
- Accuracy Validation Report, May 2020

Click for more information

AioCare x MicroGard™ II Filter

The AioCare spirometer and antibacterial filter MicroGard II respectivley 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 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.

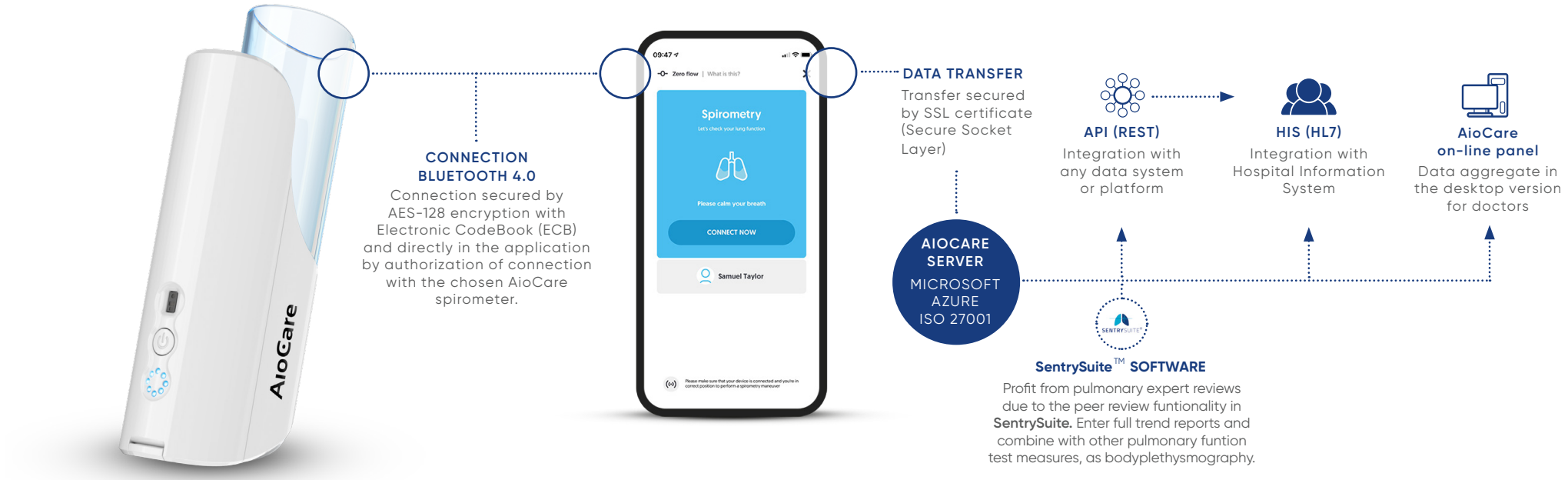
ISO 26782:2009

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



AioCare servers are supported by the Microsoft Azure platform. Azure Cloud provides physical security for servers that are colocated at the Data Center in Amsterdam, moreover it meets the standards ISO/IEC, CSA/CCM, ITAR, CJIS, HIPAA and IRS. Servers use the Debian Stretch operating system (support for updates until 2022).

The access and management of the servers is possible after the authorization with a private key by an encrypted SSH protocol. In addition, access is available only for predefined IP addresses. Only services necessary for operation are available from the internet, ie HTTP (automatic redirection to encrypted HTTPS protocol), HTTPS and chat service, are available only after the authorization by the API. Daily data backups are made on the Azure platform and are stored for 30 days. The application's logic is written in PHP 7 with the support of node.js technology for the chat module.

The Software is created using the Laravel 5 framework with tools to protect against the most common attacks. Access to data through the API is possible only after logging into the user account for which a unique token is created that allows access to AioCare services. The access to the admin panel is divided into three levels:

- **Administrator** (the possibility of establishing specific roles for each account)
- **Patient Manager** (management of specific patient accounts - anonymous data) and
- **Doctor Manager** (management of selected doctors' accounts).

Access to both the panel and the API is possible only using SSL encryption protocol. SSL (Secure Socket Layer) is a protocol designed to securely transfer data over the Internet. It ensures the confidentiality and integrity of data transmission. Thanks to SSL, all information is sent in an encrypted form so that during transmission they can not be read by unwanted persons.
All data is stored in the MySQL 5.5 database. Access to the database is not possible from outside - only from the local network using the login and password assigned by the administrator.

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

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