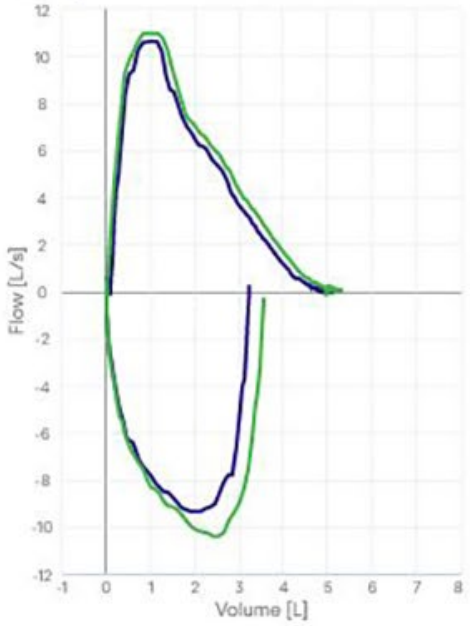
AioCare Spirometry
Better Diagnostics
Better Lives

A completely mobile and flexible approach

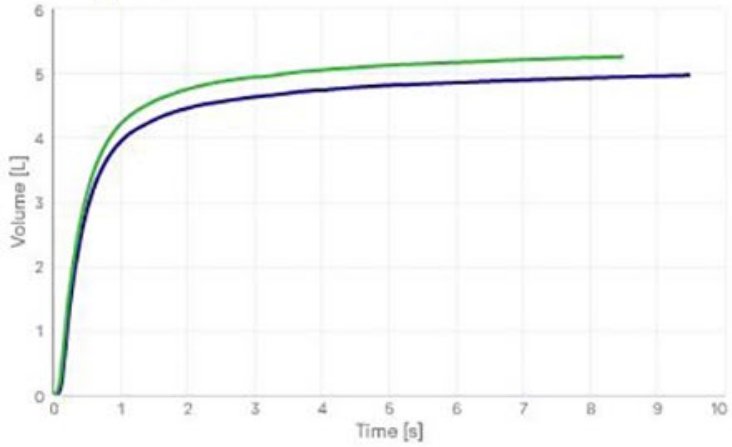
pt medical

vyaire™ MEDICAL

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 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 & humidity
Determination of t0	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

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

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

Requirements	No specific requirements Internet connection AioCare Panel

Highest quality standards

FEVI
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 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/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

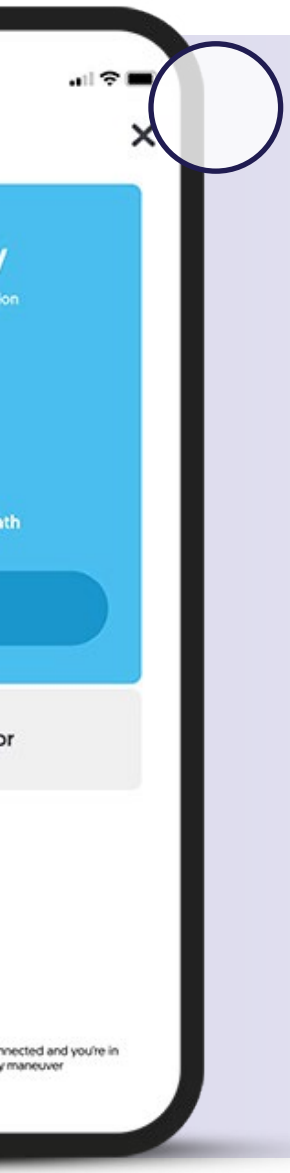
Server / Backend

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 funtionality in **SentrySuite.** Enter full trend reports and combine with other pulmonary funtion 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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