Healthup Health & Design	R&D documentation	
AioCare spirometer accuracy validation		
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ABSTRACT

Performance of AioCare spirometer was estimated using 100 randomly selected spirometers from production series MS072019. The protocol of measurement was based on the Annex C of ISO 26782:2009 norm. Mean absolute error and percentage error was calculated for FEV1, FEV6 and FVC parameters for each tested waveform C1-C11. The results showed that 88% of all volume parameters readings were measured with percentage error less than 1%. The mean percentage error equaled 0.53 (95%CI: 0.51-0.54). All devices met ATS/ERS 2019 accuracy criteria with the maximum error of 2,3%.

1. INTROCUCTION

Production process of the spirometers require appropriate quality control tests. According to the current ATS/ERS Standardization of Spirometry Update 2019: "*Manufacturers must ensure that all spirometers meet the standards contained in the current update of ISO 26782*"[1]. ISO 26782:2009 norm[2] describes procedures, protocols of tests and defines performance requirements for accuracy, repeatability and linearity for spirometry equipment. The current requirements for manufacturer states that the maximum permissible error is equaled ±2.5% of the reading (or 0.05 L, whichever is greater; it means that the criterion ±0.05 L is used for the values of volume parameter less than 2 liters).

AioCare spirometer meets all performance criteria described in International Standards. In this report detailed results of performance analysis of measuring volume parameters by AioCare spirometer is presented.

AIOCARE SPIROMETER

AioCare is a personal, connected and ultra-portable spirometer with a dedicated mobile application for a smartphone (see fig. 1.1.). This IIa class medical device encompasses all the most important and widely used spirometry parameters. It is intended to be used by a physician or by a patient under the instruction of a physician or paramedic and it is an innovation to the classic spirometer used currently in an outpatient setting in hospitals, and clinics only by qualified medical professionals.

[1] Graham, Brian L., et al. "Standardization of spirometry 2019 update. An official American thoracic society and European respiratory society technical statement." American journal of respiratory and critical care medicine 200.8 (2019): e70-e88.

[2] https://www.iso.org/standard/43761.html (available: May 2020).

AioCare technology uses thermal-based flow sensor technology to provide an accurate measuring volume parameters. The entire measurement revolves around a change of temperature caused by air flow in isolated measuring channel and a related change in voltage of micro heaters located symmetrically along the flow direction.

Apart from the full spirometry, AioCare also works as a peak flow meter, measuring peak expiratory flow (PEF) and pulsometer, measuring mean heart rate (HR).

Fig. 1.1. AioCare spirometer.

3. DATA

100 AioCare spirometers from production series executed in 2019 (no. MS072019) were randomly selected (ordering number of each spirometer was taken from serial number; then 100 numbers were randomly selected using uniform distribution). All spirometers were successfully validated according to internal quality control procedure (consistent with Annex C of ISO 26783:2009 norm). During this procedure standard C1-C11 waveforms were generated by Flow/Volume Simulator (Series 1120) by Hans-Rudolph three times and the mean values of FEV1, FEV6 and FVC were calculated which were used in performance analysis.

Data measurement protocol (a part of quality control procedure):

The ISO norm describes in detail the procedure of performing waveforms during the validation study. Based on B.3 section, the test protocol was evaluated in following steps:

a) Acclimatize the test apparatus and the spirometer at an ambient temperature, pressure and relative humidity.
b) Connect the spirometer to the air source with disposable antibacterial filter.
c) Discharge defined test profiles C1 to C11 with ambient air to the spirometer and measure FEV1, FEV6 and FVC (if appropriate) three times for each defined test profile.

4. METHODS

The performance of the accuracy was estimated as the absolute mean error (defined as the mean difference between the readings from the tested device and the reference value) or absolute mean percentage error calculated for FEV1, FEV6 and FVC, separately. Mean errors in liters were calculated for all waveforms, but the waveforms C6 and C8 were excluded from calculation of percentage error, because of small reference values for volume parameters (below 1 L) which means that the criterion ±0.05 L is used as a maximum permissible error, instead of 2.5% of the reading. All mean errors were calculated with 95% confidence intervals (95% CI).

5. RESULTS

Results of performance analysis showed that the 88% of readings of volume parameters from selected AioCare spirometers were measured with percentage error less than 1%. Mean absolute percentage error for all volume parameters equaled 0.53% (95%CI: 0.51-0.54). Mean absolute error for separate parameters and separate waveforms were showed in figures 5.1-5.4 and in tables 5.1-5.2.

Mean values of absolute %error (95%CI) for separate parameters:
- FEV1: 0.53% (0.50% - 0.55%)
- FEV6: 0.53% (0.51% - 0.53%)
- FVC: 0.51% (0.49% - 0.54%)

Mean values of absolute error (in liters) for separate parameters:
- FEV1: 21.7 mL (20.5 mL - 22.9 mL)
- FEV6: 28.2 mL (26.7 mL - 29.6 mL)
- FVC: 27.6 mL (26.3 mL - 29.0 mL)

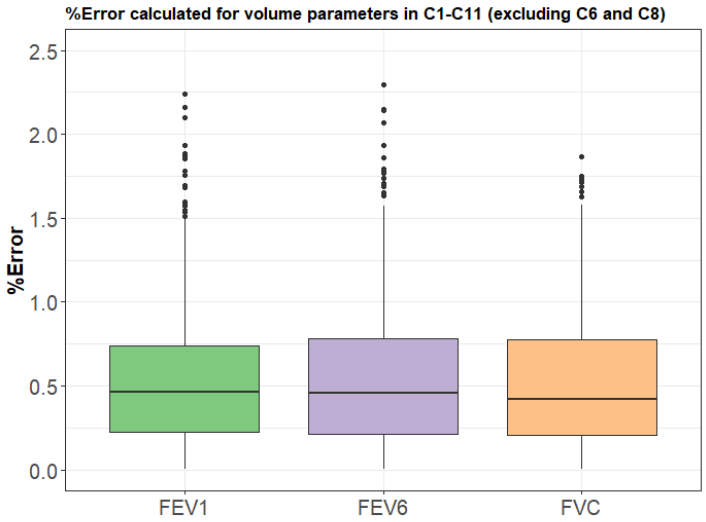

Fig 5.1. Absolute %error for volume parameters in C1-C11 waveforms (excluding C6 and C8).

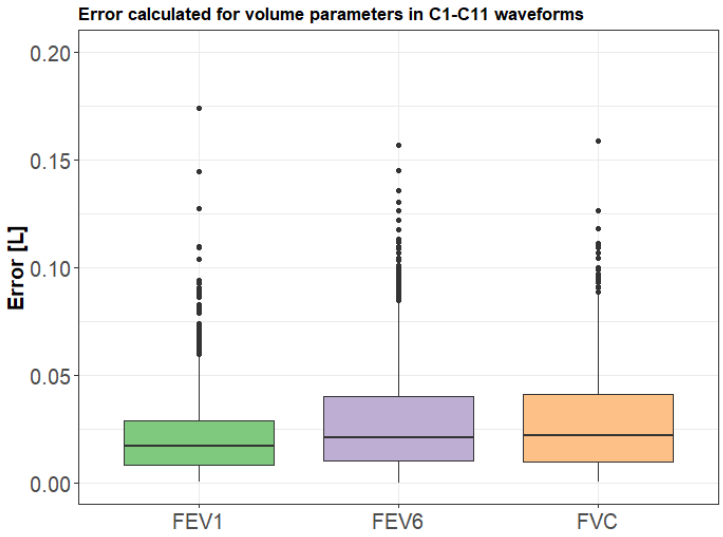

Fig 5.2. Absolute error for volume parameters in C1-C11 waveforms.

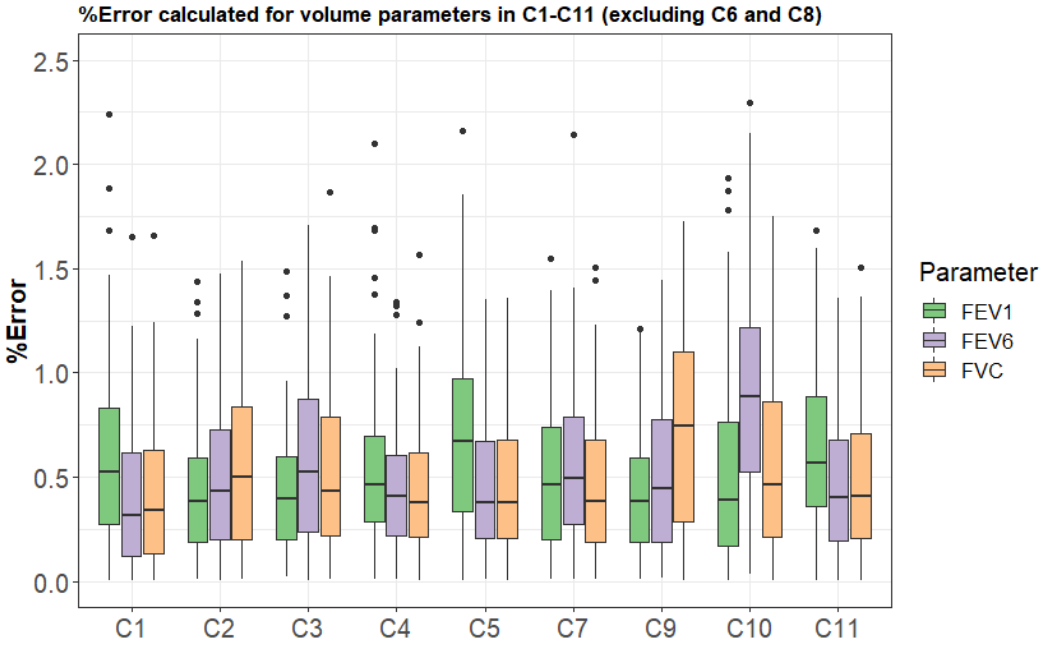

Fig. 5.3. Absolute %error for volume parameters calculated for separate C1-C11 waveforms.

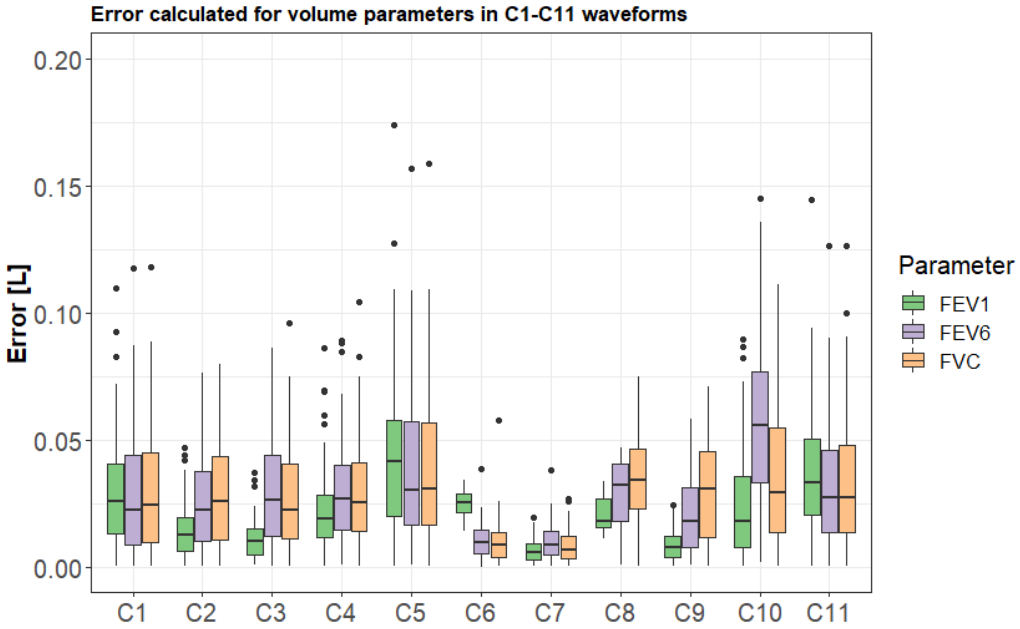

Fig. 5.4. Absolute error for volume parameters calculated for separate C1-C11 waveforms.

Tab. 5.1. Mean absolute percentage error [%] (95% CI)

Waveform	FEV1	FEV6	FVC
C1	0.60 (0.51-0.69)	0.41 (0.34-0.48)	0.42 (0.35-0.49)
C2	0.43 (0.37-0.49)	0.50 (0.43-0.56)	0.54 (0.47-0.62)
C3	0.43 (0.37-0.49)	0.57 (0.49-0.65)	0.52 (0.45-0.60)
C4	0.52 (0.44-0.60)	0.44 (0.38-0.50)	0.44 (0.38-0.50)
C5	0.70 (0.61-0.79)	0.47 (0.40-0.53)	0.46 (0.40-0.53)
C7	0.49 (0.42-0.56)	0.54 (0.47-0.62)	0.46 (0.39-0.52)
C9	0.41 (0.35-0.47)	0.51 (0.43-0.58)	0.74 (0.64-0.84)
C10	0.52 (0.43-0.61)	0.90 (0.79-1.00)	0.58 (0.49-0.67)
C11	0.64 (0.56-0.72)	0.48 (0.41-0.55)	0.49 (0.42-0.56)

Tab. 5.2. Mean absolute error [L] (95% CI)

Waveform	FEV1	FEV6	FVC
C1	0.029 (0.025-0.034)	0.029 (0.024-0.034)	0.030 (0.025-0.035)
C2	0.014 (0.012-0.016)	0.026 (0.022-0.029)	0.028 (0.024-0.032)
C3	0.011 (0.009-0.012)	0.029 (0.025-0.033)	0.027 (0.023-0.031)
C4	0.021 (0.018-0.024)	0.029 (0.025-0.033)	0.029 (0.026-0.033)
C5	0.043 (0.037-0.049)	0.039 (0.033-0.044)	0.038 (0.032-0.044)
C6	0.024 (0.024-0.025)	0.01 (0.009-0.012)	0.009 (0.008-0.011)
C7	0.006 (0.005-0.007)	0.01 (0.008-0.011)	0.008 (0.007-0.009)
C8	0.020 (0.019-0.022)	0.028 (0.026-0.031)	0.033 (0.030-0.036)
C9	0.008 (0.007-0.009)	0.02 (0.017-0.023)	0.030 (0.026-0.034)
C10	0.024 (0.020-0.028)	0.057 (0.05-0.063)	0.037 (0.031-0.043)
C11	0.037 (0.032-0.042)	0.033 (0.028-0.038)	0.033 (0.028-0.038)

6. CONCLUSIONS

The analysis showed high performance of AioCare spirometer in measuring spirometry parameters.

The results of accuracy tests showed in most of tested devices percentage error was less than 1%. Analysis of separate waveforms (C1-C11) showed that AioCare spirometer accurate measures spirometry parameters in wide range of volumes, also for the waveforms with low flow rates.