Vyntus™ series with pneumotach sensor technology; International Organization for Standardization (ISO) 26782 dynamic waveform test results

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Introduction

International guidelines[1] recommend the validation of clinical diagnostic spirometry systems against a known and accepted standard. Spirometers are now required to meet International Organization for Standardization (ISO) 26782 standards, which specifies requirements for spirometers intended for the assessment of pulmonary function in humans weighing more than 10 kg.[2] Consistent with other analyses in the literature[3-5], we used the 13 dynamic waveforms required by ISO 26782[2] to drive a computer-controlled mechanical syringe for the validation of Vyntus™ SPIRO, Vyntus™ PNEUMO and Vyntus™ IOS* Pulmonary Function Systems (Vyaire Medical, Mettawa, IL, USA) equipped with a pneumotach sensor using the software platform SentrySuite™ 3.20 (Vyaire Medical, Mettawa, IL, USA).

Method

Volume-time waveforms for evaluation of forced expired volume at 1 second (FEV1), forced expired volume at 6 seconds (FEV6), and forced vital capacity (FVC)

A production spirometry device was connected through a MicroGard™ filter and ultrasonic sensor adaptor to a pump system for testing, oriented as it would be for human testing. The 13 ATS waveforms were generated by discharging the syringe into the spirometry device three times under ambient conditions. All readings were recorded.

Accuracy test

The average of the three tests under ambient conditions is compared with the targeted standard value in the following way:

- Deviation = average – standard
- Percentage deviation = 100 * (average-standard) / standard

The accuracy validation limits for volumes, which include the waveform generator inaccuracy according to ISO 26782[2], were set to ±3.5% of reading or ±0.050L, whichever is greater. However, current 2019 ERS/ATS spirometry guidelines narrowed these limits to ±2.5% of reading.[1] These limits include the allowable inaccuracy for the pump system.

Repeatability test

The FEV1, FEV6, and FVC data from the accuracy test are used to derive the range of the three recordings:

- Range = maximum - minimum

The repeatability validation limits for the volume measured at ambient conditions are ± 2.5% or ± 0.050 L, whichever is greater. A repeatability error occurs if the range or percentage range exceeds these limits.

Results

Accuracy testing results (mean) are summarized in Figure 1 A-I showing values compared to those set by ERS/ATS.[1] Repeatability testing results are summarized in Figure 2 A-I.

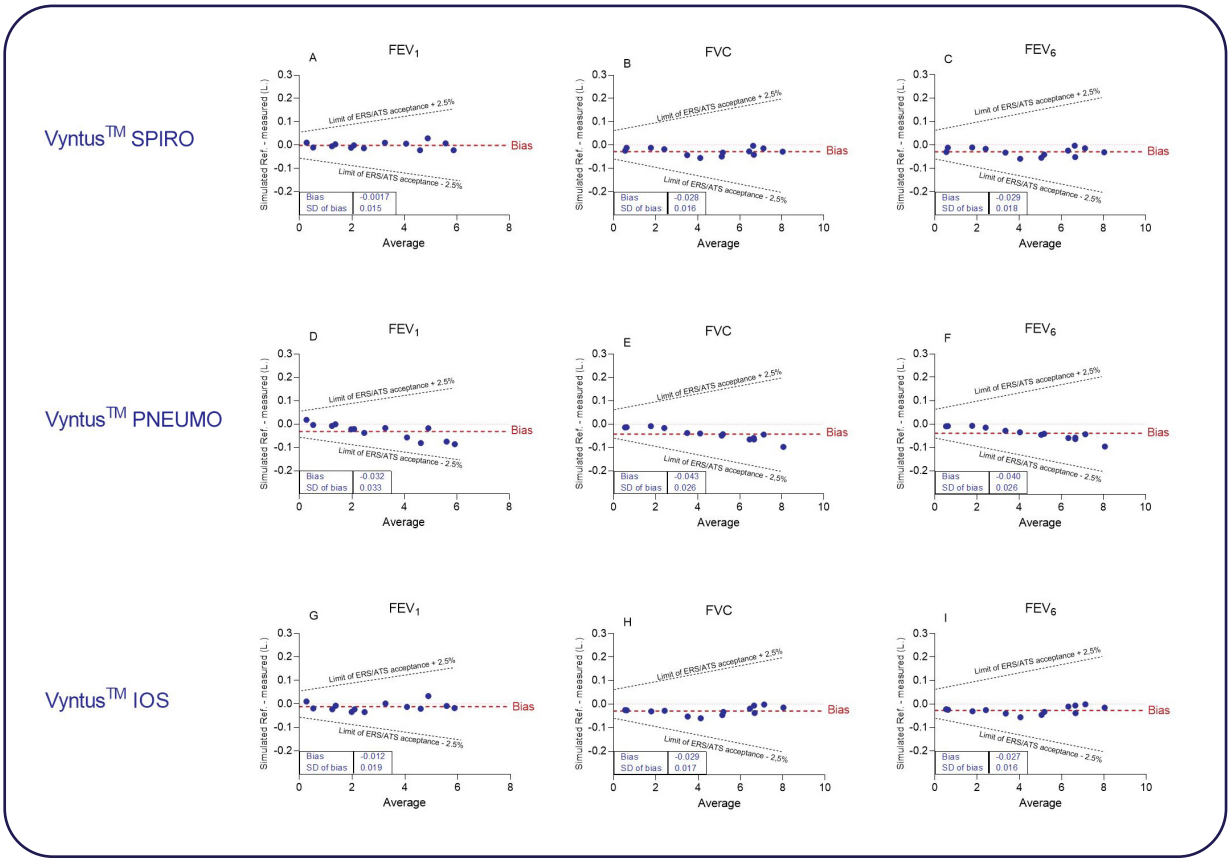

Figure 1 Accuracy of FEV_1, FVC and FEV_6

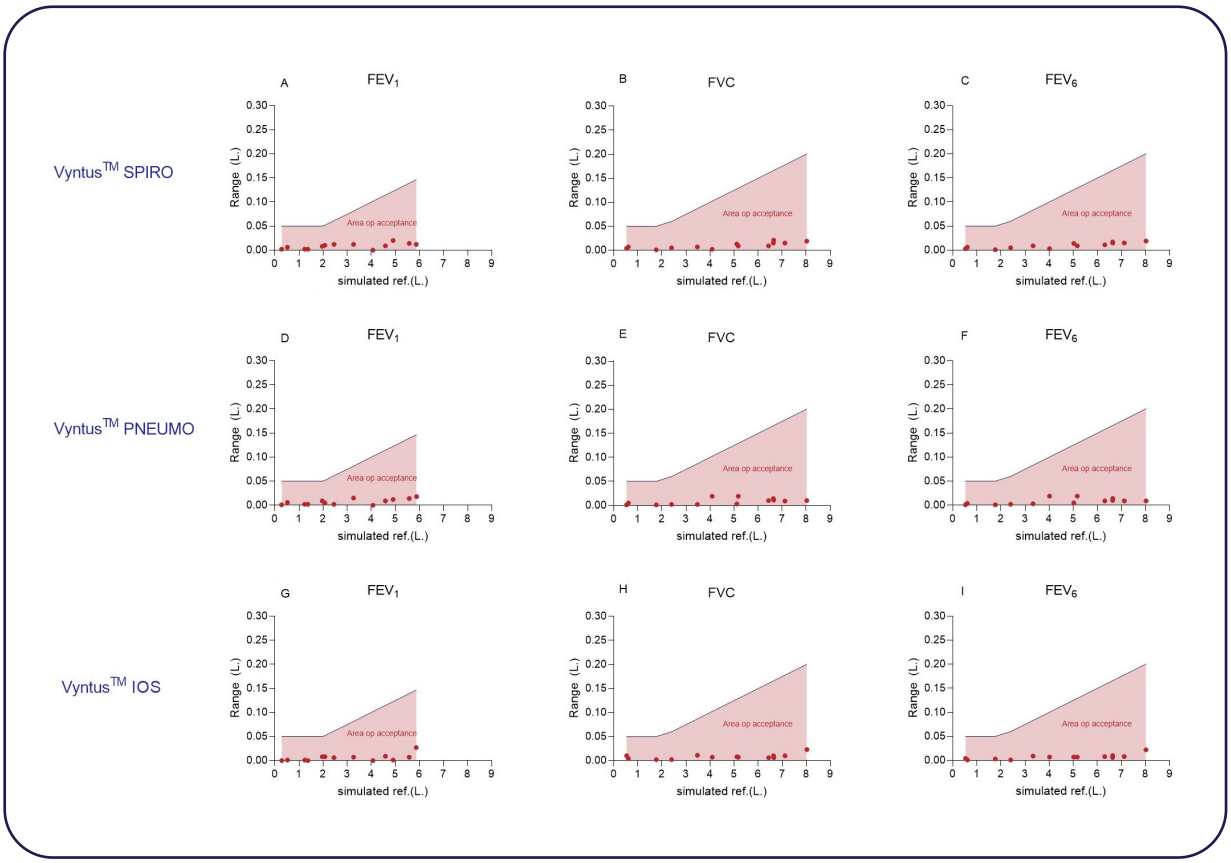

Figure 2 Repeatability of FEV_1, FVC and FEV_6

Conclusion

Testing of the Vyntus™ SPIRO, Vyntus™ PNEUMO and Vyntus™ IOS with pneumotach sensor, in combination with the SentrySuite™ software platform, shows all ISO waveform and ERS/ATS requirements have been met with no failure (100% passing). From these results we can conclude that all three Vyntus systems with a pneumotach sensor in combination with the SentrySuite software platform passed all ISO standard waveform requirements.

REFERENCES

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*Vyntus Pneumo and IOS are not cleared for FDA 510K and are not available in the US market.

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