

EVALUATION OF THE EASYONE™ SPIROMETER FOR PAEDIATRIC USE: A PILOT STUDY

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Background

- Spirometers for paediatric use must be well constructed, be accurate at both high and low volumes and flows and be easy to hold in a child's hands. Mouthpiece size, child incentive software, stringent infection control needs, and ease of use of software are also important.
- Most spirometers are marketed directly for adult patient use. The current ATS Standardization of Spirometry is largely focused on adult testing, and spirometers are usually marketed with agreement to those recommendations. [1]
- The ndd Medical Technologies EasyOne™ spirometer has features suitable for testing children.

Aim

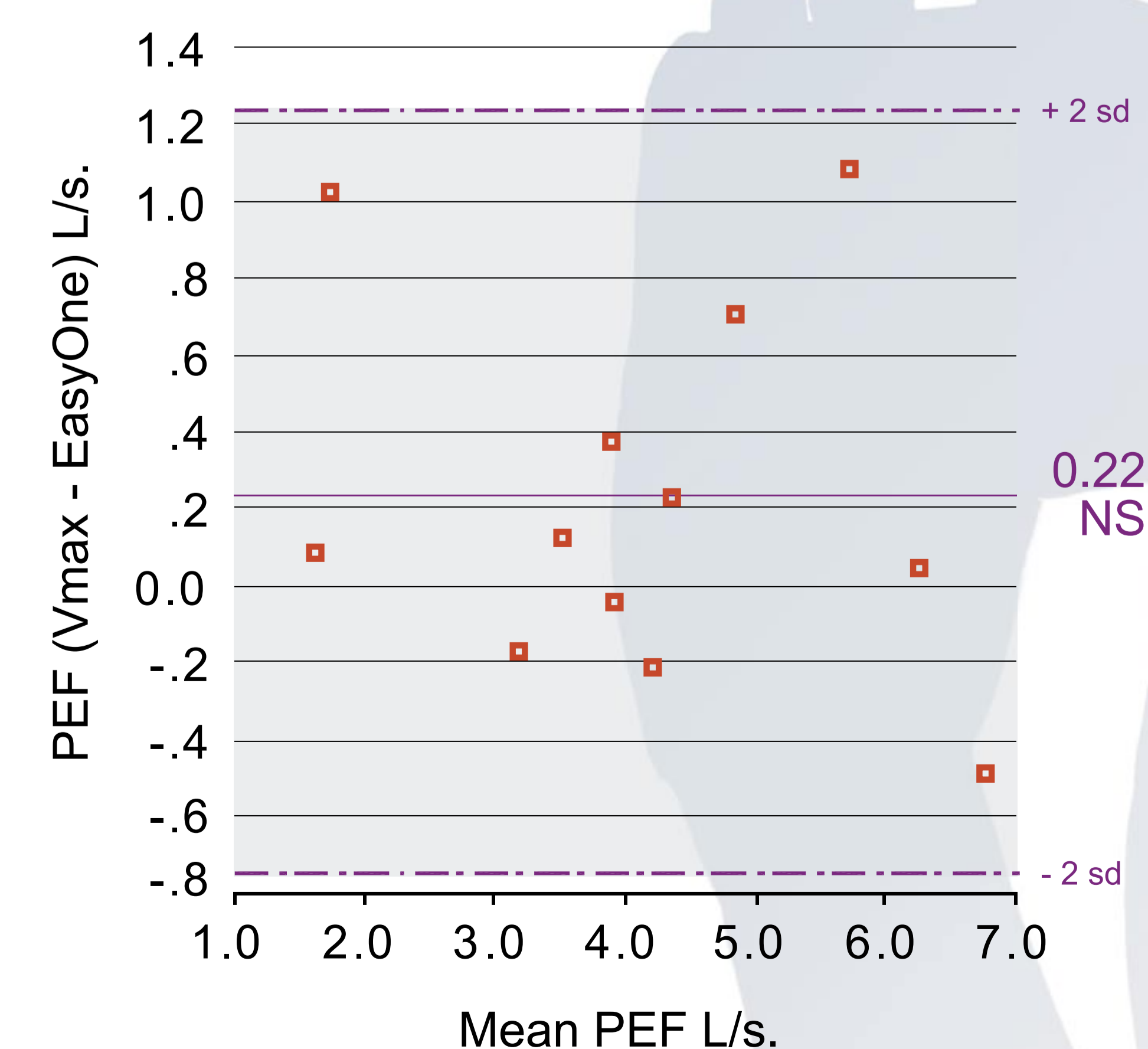
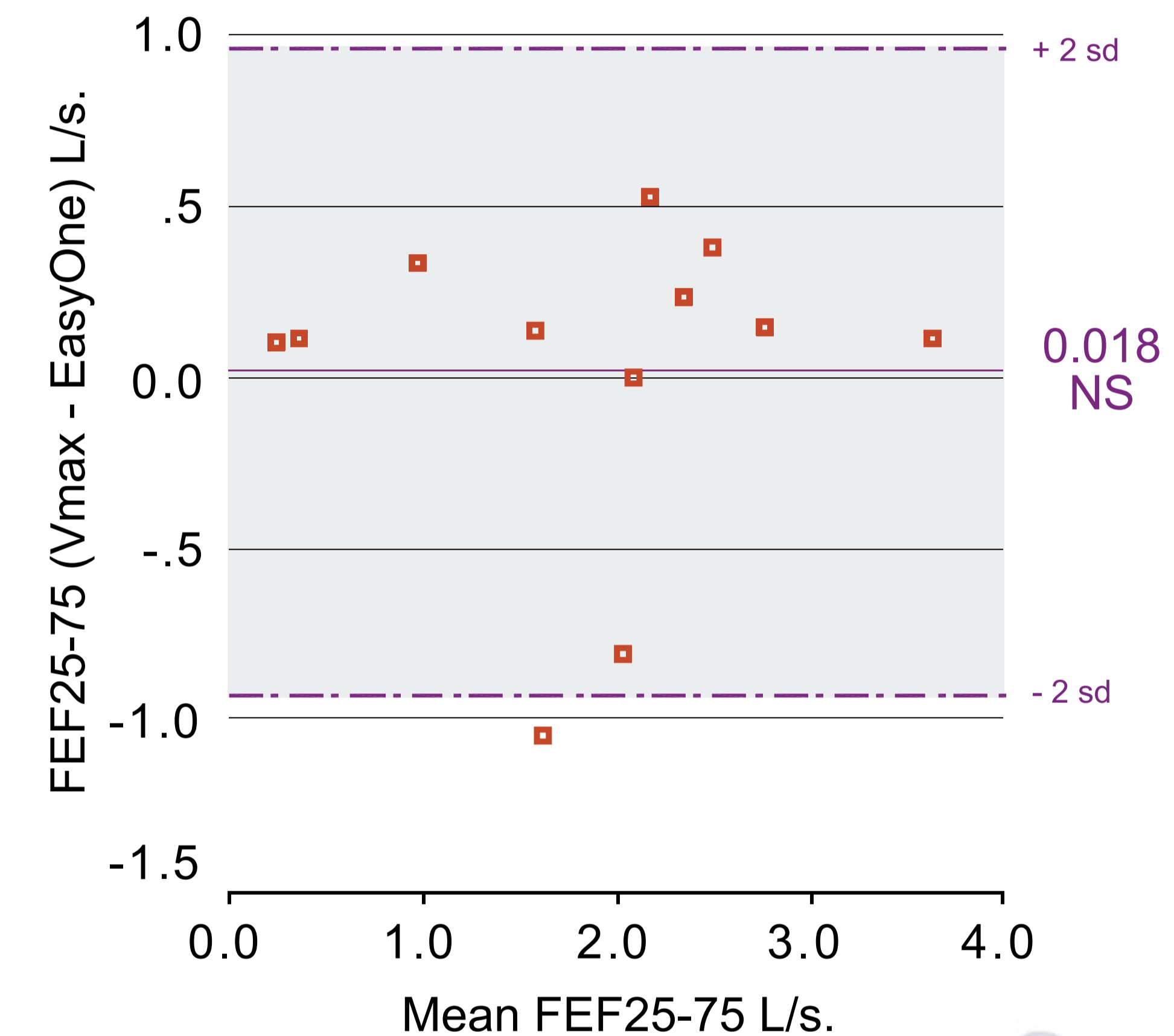
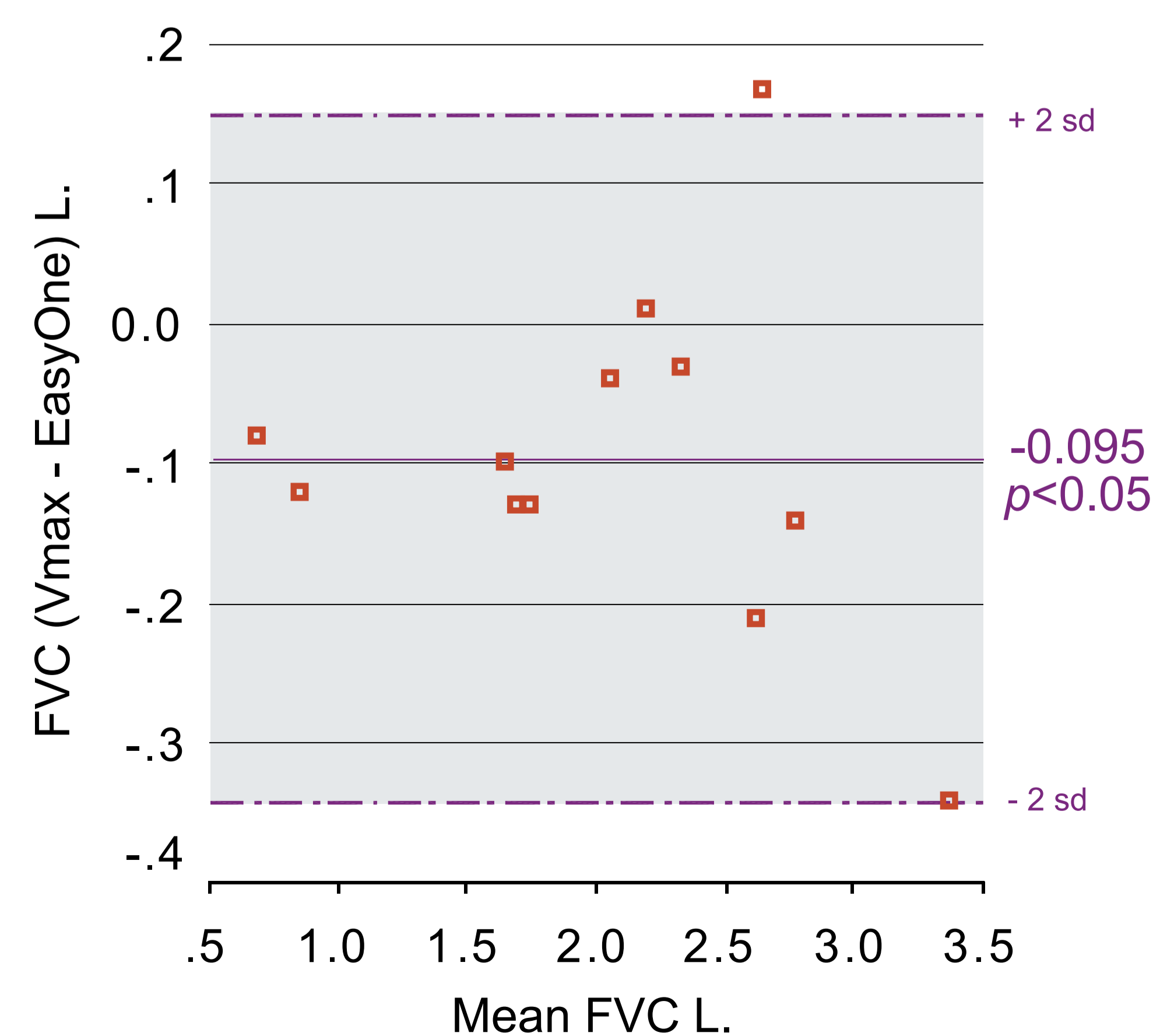
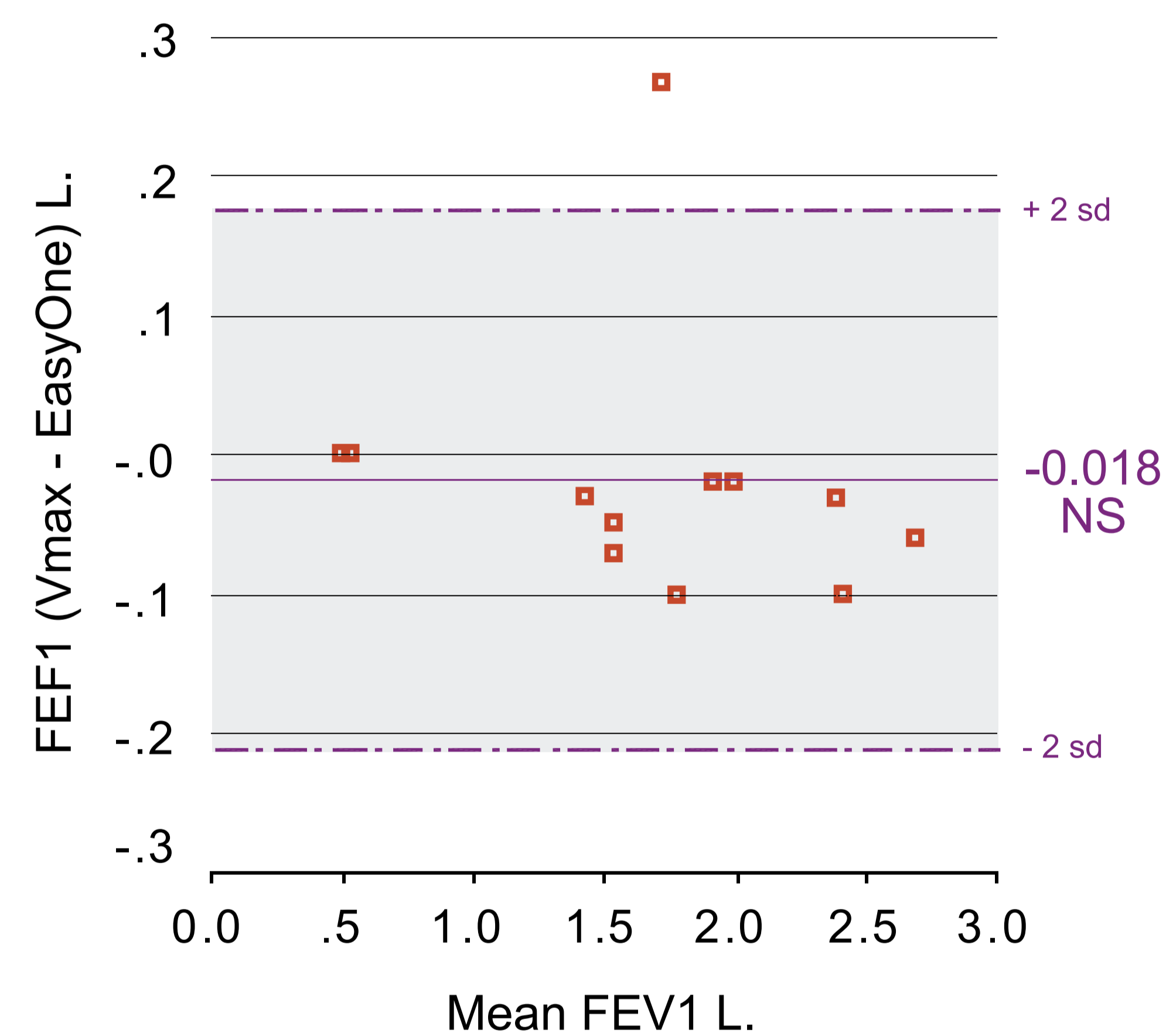
To investigate the accuracy of the EasyOne spirometer for use in a paediatric service.

Method

- Compare spirometry measures in a group of children tested using the EasyOne™ and a Laboratory-based SensorMedics Vmax 20c™ spirometer.
- The EasyOne was used in PC-mode without the child incentive display.
- The EasyOne does not require re-calibration. Calibration checks were made prior to each session using a 3-Litre Calibration syringe. The Vmax was calibrated prior to each session using the same syringe.
- Children attending clinics were initially tested on the Vmax and then on the EasyOne™ spirometer.
- Following the BTS/ARTP Spirometry guidelines, the children stood and wore noseclips.[2]
- Agreement assessed using SPSS software with Student's paired-T tests and Bland Altman plots.

Results

- 12 children agreed to be studied. (4M: 8F, ages 5-15, 10.4 mean (3.6 (SD))
- Spirometry on both systems was determined to be acceptable and reproducible.[2]
- Child illnesses were asthma (2), post-Chronic Neonatal Lung Disease (2), Cystic Fibrosis (7), and pre-scoliosis correction (1).
- Only the FVC parameter showed a statistically significant bias of 95ml in favour of the EasyOne™.



Discussion

- FVC bias of 95ml (EasyOne™) unlikely to be clinically significant. Repeatability of 100ml is sought in children.[2]
- The small sample size may be why statistical significance was not seen for the other biases.
- The EasyOne™ spirometer appears to have the required accuracy for use in paediatrics.
- Given the EasyOne's™ accuracy, proceed to design a full evaluation trial for paediatrics. This should be a multiple arm study - e.g. 30 asthmatics, 30 CF, 30 controls.
- Further investigation of the acceptability of the EasyOne™ should include studying the two modes of use (portable and PC-based), the child incentive software, and the utility of the quality grading system.

Conclusions

- In paediatrics, EasyOne™ spirometry measures compare well with the Vmax Laboratory-based spirometer.
- Further full evaluation warranted.

Acknowledgements

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References

1. Standardization of Spirometry, 1994 Update. American Thoracic Society. Am J Respir Crit Care Med, 1995. **152**(3): p. 1107-36.
2. Guidelines for the measurement of respiratory function. Recommendations of the British Thoracic Society and the Association of Respiratory Technicians and Physiologists. Respir Med, 1994. **88**(3): p. 165-94.