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Letter to the Editor

Response to comment on 'Comparative validation of handheld fractional exhaled nitric oxide measurements'

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We thank the authors for their interest in our publication 'Comparative validation of handheld fractional exhaled nitric oxide measurements' and for the opportunity to clarify raised concerns.

First, we would like to stress that we do believe in the feasibility of a handheld FeNO measurement device like the Vivatmo Me. It gives physicians the opportunity to measure a FeNO in different settings, for example in the emergency room, and to monitor patients closely at home. Our article is meant to raise awareness of differences in measurements between devices and to improve the user-friendliness and accuracy of the measurements.

The first concern raised is about the possible bias in comparing the Vivatmo Me with the NIOX VERO instead of the golden standard Chemiluminescence Detector Analyzer. Therefore, we called the research a 'comparative' validation and not a 'true' validation study. We acknowledge that also the NIOX VERO has an error margin in its accuracy compared to the golden standard (±5 ppb for values <50 ppb and 10% for values >50 ppb [1]). However, among electrochemical sensors used to measure FeNO, the NIOX VERO is widely utilized in clinical practice and has undergone multiple-validation studies [2,3]. Therefore, any observed differences in outcomes between the Vivatmo Me and the NIOX VERO should be considered, as they may impact clinical diagnosis and phenotyping.

Another concern was the difference in attempts used to achieve a successful measurement between the devices. The authors state that this disparity could have caused the overall lower outcomes of the Vivatmo Me. As mentioned in the discussion section of the article, we ourselves raised this concern as well. However, by comparing the median measured FeNO value per cluster of attempts, no correlation was found between the number of attempts and a decrease in measured FeNO value [4]. Takalo et al. [5] found small differences between successive measurements, of which there was no systematic decrease in the second measurement compared to the first. Accordingly, the number of attempts was not found to influence the measured FeNO values.

Finally, the concern of prior experience with the NIOX VERO was mentioned. It is true that part of the patients that participated in this study had regular FeNO checkups with the NIOX VERO before and were therefore 'trained' in its usage. However, the patient group also included patients with no FeNO device experience and patients that were already trained in the usage of the Vivatmo Me. We did not notice a difference between the trained and untrained patients for achieving a successful FeNO measurement with the Vivatmo Me. Within this study, patients were instructed by an experienced physician following the manufacturers guidelines. Possibly, training the patients in the use of the device could improve the success rate. However, in a real-world setting, training is not feasible when (new) patients come into the clinic.

We appreciate the constructive feedback from the authors and hope that our concerns raised about the Vivatmo Me regarding user-friendliness and accuracy can be considered for improvement of this and future devices.

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Declaration of interest

The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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References

1. Circassia AB. Niox Vero airway inflammation monitor gebruiksaanwijzing [Internet]. Oxford: Circassia AB; 2023. Available from: https://www.niox.com
2. National Institute for Health and Care Excellence. Measuring fractional exhaled nitric oxide concentration in asthma: nIOX MINO, NIOX VERO and NObreath [Internet]. London: National Institute for Health and Care Excellence; 2014. Available from: https://www.nice.org.uk/guidance/dg12

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3. Alving K, Anolik R, Crater G, et al. Validation of a new portable exhaled nitric oxide analyzer, NIOX VERO®: randomized studies in asthma. Pulm Ther. 2017;3(1):207–218. doi: 10.1007/s41030-017-0032-8
4. van Deelen S, Tramper-Stranders GA, Hendriks RW, et al. Comparative validation of handheld fractional exhaled nitric oxide measurements. Expert Rev Med Devices. 2025;22(6):643–650. doi: 10.1080/17434440.2025.2499652
5. Takalo R, Piirilä P, Sovijärvi ARA. Repeatability of successive measurements with a portable nitric oxide analyser in patients with suggested or diagnosed asthma. Scand J Clin Lab Invest. 2008;68(8):739–747. doi: 10.1080/00365510802621158