

Technical Equivalence of NIOX PRO® and NIOX VERO® in Fractional Exhaled Nitric Oxide (FeNO) Measurement

Comprehensive internal verification and gas testing confirm identical analytical performance, accuracy and reliability between NIOX PRO® and NIOX VERO®.



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Introduction

The role of FeNO testing in asthma management

Fractional exhaled nitric oxide (FeNO) testing is an established, evidence-based tool for assessing airway inflammation associated with asthma.¹⁻³ Nitric oxide (NO) is produced in the respiratory tract, and elevated levels in exhaled breath are a recognised biomarker of type-2 inflammation in the airways, driven by the cytokines IL-4 and IL-13, and typically characterised by the infiltration of eosinophils.⁴

By quantifying FeNO, clinicians gain an objective and reproducible insight into the underlying inflammatory process, information that complements traditional clinical assessment and lung function testing.⁵⁻⁶ Elevated FeNO levels support the diagnosis of asthma where type-2 inflammation is suspected, while persistently high or increasing values may indicate poor adherence to inhaled corticosteroids (ICS) or the need for treatment adjustment.^{2,3} Conversely, low FeNO readings can help identify patients unlikely to benefit from corticosteroid therapy.⁷

FeNO testing has been incorporated into several national and international asthma management guidelines, including those from NICE/BTS/SIGN and GINA, recognising its role in improving diagnostic accuracy and guiding therapy decisions.^{3,8,9} The test is simple, non-invasive and provides immediate results, enabling more personalised and effective asthma care.^{2,5}

The NIOX® technology platform

For almost three decades, NIOX® technology has set the global standard for FeNO measurement.¹⁰ Developed through extensive clinical collaboration and scientific research, NIOX® devices provide clinicians with accurate and reproducible FeNO readings to support confident decision-making.^{5,6}

At the core of the NIOX® platform is a proprietary electrochemical sensor that measures NO concentrations in exhaled breath with exceptional sensitivity and precision.¹¹ The sensor's performance is governed by a sophisticated algorithm that accounts for flow rate, exhalation time and environmental conditions, ensuring that every measurement reflects a true representation of airway inflammation. This technology has been validated in numerous clinical and laboratory studies and forms the basis of millions of FeNO tests performed worldwide.^{10,12}

NIOX® systems are designed to make high-quality FeNO testing accessible in any clinical environment, from specialist respiratory clinics to primary care settings. Each generation of device builds upon the same proven measurement principle, while enhancing usability, reliability and workflow integration. This commitment to technological continuity means that results remain consistent and comparable across the NIOX® product range, supporting long-term monitoring and research applications.^{5,11}

All NIOX® devices are designed to conform fully to the ATS / ERS recommendations of FeNO testing¹³, and feature a unique test method that requires the patient to inhale through the device to minimise the impact of ambient NO.¹⁰ Ambient NO can vary from 2 - 500 ppb¹⁴, which could potentially skew measurements if not removed.

Introducing NIOX PRO®

NIOX PRO® represents the next generation of FeNO measurement, maintaining the same proven technology that powers NIOX VERO® while introducing an enhanced user experience. The internal measurement system, sensor technology and analytical algorithms remain identical to those of NIOX VERO®, ensuring continuity in clinical performance and data integrity. The design evolution of NIOX PRO® focuses on usability, connectivity and workflow improvements to further simplify FeNO testing in busy clinical environments.

Further to this, all improvements to the user experience of NIOX PRO® have been designed exclusively on feedback collected from NIOX VERO® users.

Objective of this white paper

This white paper presents the technical validation demonstrating that NIOX PRO® delivers equivalent FeNO measurement accuracy to NIOX VERO®. Through comparative gas testing across clinically relevant NO concentrations, the results confirm that NIOX PRO® maintains the same precision and reliability that clinicians and researchers have come to expect from the NIOX® platform.

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Device comparison overview

NIOX PRO® and NIOX VERO® share the same fundamental measurement technology that has defined the NIOX® platform for many years. Both devices utilise the same electrochemical sensor, measurement algorithm, and gas flow control system to quantify fractional exhaled nitric oxide (FeNO) concentrations accurately and consistently.

The design philosophy behind NIOX PRO® was not to alter the proven measurement mechanism, but to enhance the overall user experience. This evolution reflects direct feedback from clinicians and healthcare professionals who rely on FeNO testing in daily practice. As such, while the measurement internals remain identical, improvements have been introduced in areas such as interface design, data handling, and operational convenience.

These refinements support faster, more intuitive operation, enhanced connectivity, and improved integration into modern clinical workflows, all without compromising the scientific integrity or measurement accuracy that users associate with NIOX® technology.

Feature	NIOX VERO®	NIOX PRO®	Comment
Measurement principle	Electrochemical detection of NO in exhaled breath	Same	Identical measurement mechanism
Sensor technology	Proprietary NIOX® electrochemical sensor	Same	No change in design or specification
Measurement algorithm	NIOX® validated algorithm	Same	Algorithm unchanged
Calibration method	Automated factory calibration with no need for servicing or recalibration	Same	Identical calibration process
Measurement range (FeNO)	5 - 300 ppb	Same	Equivalent range
Measurement range (nNO)	5 - 2000 ppb	Same	Equivalent range
Accuracy and precision	Within device specification	Same	Equivalent verified performance
Breath humidity control	Utilises FeNO Dry® technology to remove excess humidity from human breath	Same	Equivalent breath humidity control performance
Buffer chamber for flushing sample over sensor	Contains a NIOX Aerocore® buffer chamber to hold and flush samples over the sensor	Same	Same internals for measurement analysis
Zero Scrubber	Contains a NIOX NeutroNO® Zero Scrubber for use in baseline measurement	Same	Identical baseline measurement procedure

Feature	NIOX VERO®	NIOX PRO®	Comment
Breathing Handle	Breathing Handle that contains a NIOX NeutroNO® Scrubber to remove ambient NO	Same technology, with an extended tubing to improve patient comfort	Identical removal of ambient nitric oxide from the measurement with a more comfortable length
Patient Filter	FeNO Protect Patient Filter® with ≥99.99% Bacterial Filtration and ≥99.97% Viral Filtration ¹⁵	Same filtration material and results, new oval shape to better contour to the mouth	Improved ergonomics of mouth filter with same filtration material
Warm-up and system test time	60 seconds	Same, with new abilities to preview animations and access settings	New user experience to minimise wait time
Analysis time	70 seconds	Same	Same measurement calculation time
Ambient NO testing	Ability to perform an ambient NO test with the device	Same	Identical abilities
Device lifespan	5 years or 15,000 measurements, whatever comes first	6 years or 15,000 measurements, whatever comes first	NIOX PRO® features an extended lifespan of 6 years
Intended use	Measurement of FeNO in clinical assessment of airway inflammation in conditions such as asthma	Measurement of FeNO in clinical assessment of airway inflammation	Identical clinical indication, with removal of disease restrictions
User interface	Basic 3.5 inch restricted colour touchscreen with bespoke user interface	Enlarged 7 inch HD full colour touchscreen with brand new nioxOS® user interface	Improved usability
Connectivity	Micro-USB access and Bluetooth 2.0 chipset. Support for Windows only.	USB-C and Bluetooth Low Energy 5.0 chipset. Support for Windows, iOS, MacOS, iPadOS, Linux and Android.	Improved data transfer and system integration

Improvements to condensation management

As part of the NIOX PRO® development, the internal design of a valve within the device has been refined to improve condensation management. In NIOX VERO®, vapour droplets could occasionally collect within this component, limiting the device to a maximum of ten measurements per hour or 20 measurements per hour if there was a 30 minute break. By inverting the geometry of the valve in NIOX PRO®, this pooling effect has been effectively eliminated, allowing unrestricted measurement throughput.

Extensive internal testing confirmed that this modification has no impact on FeNO measurement accuracy or device performance, ensuring that NIOX PRO® maintains the same high standard of analytical reliability as NIOX VERO®, but improving testing capacity for busy clinics and research.

Extension of the NIOX® Breathing Handle

To enhance patient comfort during testing, the tubing connecting the NIOX® Breathing Handle has been extended in NIOX PRO®. The new design allows for a more relaxed and natural posture while

performing the FeNO measurement, supporting a smoother and more comfortable testing experience.

Comprehensive internal testing conducted throughout the development of NIOX PRO® demonstrated no significant difference in FeNO measurement results between the original and extended handle lengths. The mean variation observed was less than 1 ppb (0.44 ppb), confirming that this ergonomic enhancement has no impact on measurement accuracy or device performance.¹⁶

Introduction of a new shaped FeNO Protect Patient Filter®

With NIOX PRO®, a newly designed oval-shaped FeNO Protect Patient Filter® has been introduced to enhance ergonomics and ease of use. The revised shape provides a more comfortable fit to the mouth and improved handling during testing while maintaining the same filtration performance and protective function as the original design.¹⁵

Comprehensive internal testing conducted throughout the development of NIOX PRO® demonstrated no significant difference in FeNO measurement results, flow rate or dead-space volume between the original and new filter designs.

Extension of device lifespan

NIOX PRO® has an additional year of life when compared to NIOX VERO®. Our manufacturing partner has performed an extended lifespan test under controlled conditions. The NIOX PRO® passed this test.¹⁷

Summary of equivalence

NIOX PRO® and NIOX VERO® share complete internal and functional equivalence in all aspects related to FeNO measurement accuracy and performance. The enhancements introduced in NIOX PRO® are limited to usability, ergonomics and workflow optimisation, with no alteration to the measurement sensor, analytical algorithm or performance specifications.

Where design modifications have been implemented, such as improved condensation management, an extended breathing handle and a newly shaped FeNO Protect Patient Filter®, extensive internal testing has demonstrated that any observed differences are negligible and have no measurable impact on FeNO readings or overall device accuracy.

This continuity of design ensures that clinicians transitioning from NIOX VERO® to NIOX PRO® can do so seamlessly, maintaining consistent results, operational familiarity and established clinical confidence.

Regulatory submission

The device has been submitted for CE marking under the European in Vitro Diagnostic Regulation (IVDR). It will also be submitted for clearance from the U.S. Food and Drug Administration (FDA) in 2026, using the NIOX VERO® as the predicate device. These approvals will confirm that NIOX PRO® meets all applicable safety, performance and quality requirements. This ensures that healthcare professionals and researchers can adopt NIOX PRO® with full confidence in its regulatory compliance and equivalence of performance to NIOX VERO®.

Accuracy, precision and linearity

Accuracy, precision and linearity are critical performance parameters for FeNO measurement systems. These characteristics determine the reliability of readings across the full measurement range and ensure that results are both reproducible and traceable to recognised reference standards. Because NIOX PRO® and NIOX VERO® share identical internal components and measurement algorithms, equivalence in performance across all three parameters was expected. This has been confirmed through extensive internal gas testing and technical validation.

Exhaled NO - performance data

NIOX PRO® uses the same electrochemical sensor technology as NIOX VERO® to analyse NO.

Like NIOX VERO®, NIOX PRO® is verified to fulfil the specified performance under a temperature range of +10 to +35 °C, relative humidity range of 20-80% and pressure range of 700-1060 hPa.

Measurement range - FeNO: 5 to 300 ppb

Lowest Detection Limit: 5 ppb

Determination by analysing gas concentrations around and below the detection limit. 5 ppb was the lowest detectable level.

Linearity

As with NIOX VERO®, the linearity of NIOX PRO® is as follows:

Squared correlation coefficient $R^2 \geq 0.998$, slope 1.00 ± 0.05 , intercept ± 3 ppb.

Precision

As with NIOX VERO®, the precision of NIOX PRO® is as follows:

< 3 ppb of measured value for values < 30 ppb, < 10% of measured value for values ≥ 30 ppb.

Expressed as one standard deviation for replicate measurements with the same device, from certified gas concentration of NO.

Accuracy

As with NIOX VERO®, the accuracy of NIOX PRO® is as follows:

± 5 ppb for measured values < 50 ppb or 10% of measured value for values ≥ 50 ppb.

Expressed as the upper 95% confidence limit, based on absolute mean of differences from certified gas concentration of NO.

Method comparison

< 10 ppb for values ≤ 50 ppb, < 20% for values > 50 ppb. Expressed as the difference between a NIOX VERO® FeNO value and the corresponding FeNO value measured with NIOX PRO® device from NIOX®.

Inhalation parameters

Just like NIOX VERO®, the inhalation parameters for NIOX PRO® are as follows:

Inhale to TLC (Total Lung Capacity) before start of exhalation. Inhalation in device is triggered by a pressure of -3 cm H₂O.

Exhalation parameters

Just like NIOX VERO®, the exhalation parameters for NIOX PRO® are as follows:

Exhalation time:

Preferred mode - 10 seconds

Paediatric mode - 6 seconds

All exhalations are to be performed at an exhalation pressure of 10 - 20 cm H₂O, to maintain a fixed

flow rate of 50 ± 5 ml/s. The device stops the measurement at pressures outside the interval. Warning alerts sounds at 10 - 12 and 18 - 20 cm H₂O.

Internal testing

To ensure that the elements across the two devices are equivalent, NIOX Group has performed extensive testing to demonstrate the two devices accuracy and repeatability.

Test one: Technical verification

Our manufacturing partner conducted a comprehensive verification of the internal components of both NIOX VERO® and NIOX PRO® to confirm that all measurement-related elements are equivalent.

The assessment included a detailed comparison of hardware, sensor configuration, electronic assemblies and software elements. The results confirmed that the core measurement components and algorithms are unchanged between the two devices. The verification concluded with a full technical pass, confirming that NIOX PRO® is internally equivalent to NIOX VERO® in all aspects relevant to FeNO measurement accuracy and performance.

Test two: Analytical performance testing

The precision of NIOX PRO® was evaluated and compared with that of NIOX VERO® through two studies carried out by NIOX®'s manufacturing partner and by internal testing, each conducted under controlled laboratory conditions. The studies demonstrate that NIOX PRO® achieves equivalent measurement performance to NIOX VERO® across a clinically relevant range of NO concentrations.

NIOX PRO®:

NIOX®'s manufacturing partner conducted an assessment on NIOX PRO® devices to determine repeatability and compliance with established performance specifications. The acceptance criteria for the precision of measurements are outlined as < 3 ppb for measured values < 30 ppb, or <10% of measured value for values ≥ 30 ppb.

Five NIOX PRO® instruments were tested over a ten-day period at NO concentrations of 5 ppb, 25 ppb, 75 ppb, and 200 ppb, with two replicates of each concentration taken on each device. The mean daily measurement results for each concentration are presented in Table 1.

		Test gas concentration (ppb)			
		5	25	75	200
Gas concentration measurement value	Day 1	4.7	24.4	75.1	200.8
	Day 2	5.2	24.7	74.2	198.7
	Day 3	5.3	25.1	75.9	200
	Day 4	4.9	25	75.3	199.8
	Day 5	5	25.2	75.7	198.1
	Day 6	5.1	24.8	75	200.3
	Day 7	5	25.1	75.1	200
	Day 8	5.2	24.6	74.7	200.5
	Day 9	5	25	75.2	200.2
	Day 10	5.4	24.2	74.9	199.9

	Overall mean	5.1	24.8	75.1	199.8
	Mean coefficient of variation (CV)	8.7%	1.9%	0.8%	0.5%

Table 1: Daily gas concentration measurements (two replicates) in 5 NIOX PRO® devices at 5, 25, 75, and 200 ppb, mean, overall mean and mean CV provided for each concentration.

All measured values were within the predefined acceptance criteria of less than 3 ppb for measured values under 30 ppb, or less than 10% of measured value for values greater than or equal to 30 ppb. The mean results across the ten-day testing period were 5.1 ppb, 24.8 ppb, 75.1 ppb, and 199.8 ppb, demonstrating exceptional consistency and alignment with the verified gas concentrations.

A simple linear regression analysis was conducted to determine the correlation between the measured ppb by NIOX PRO® and the actual ppb of the measured sample (Figure 1). The regression analysis gave an average slope of 1.024, and an average intercept of 0.6 ppb. The R^2 value calculated was 0.999 demonstrating excellent agreement between the actual and measured concentrations. Therefore, confirming the high level of precision and repeatability of NIOX PRO® across the clinically relevant tested range.

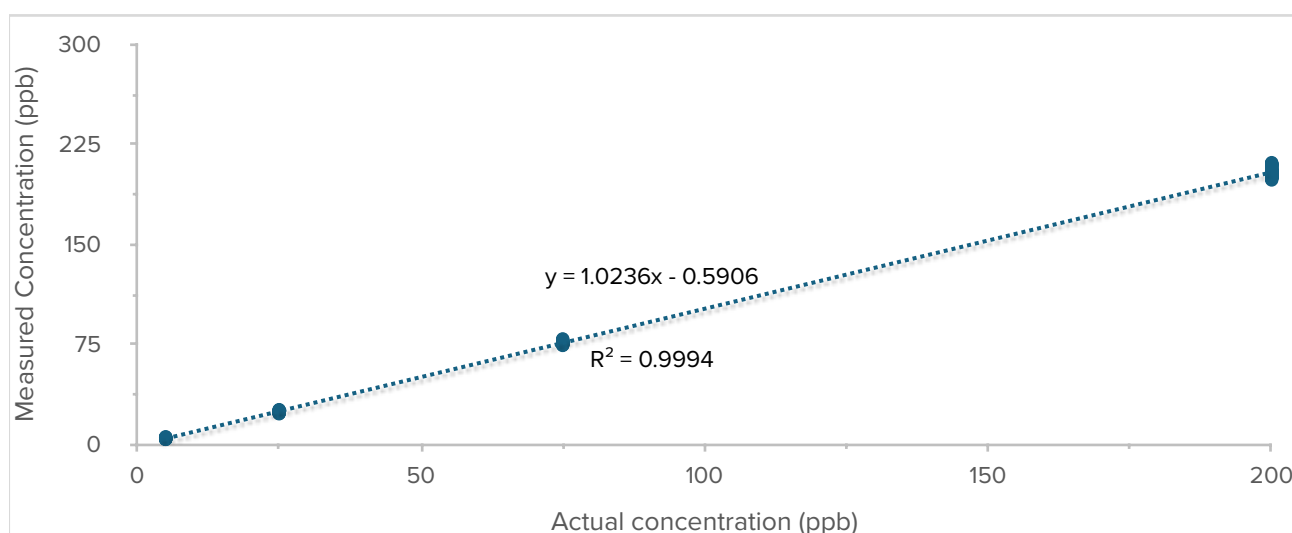


Figure 1: Linearity of NIOX PRO® measurements at 5, 25, 75, and 200 ppb. Plotted using each replicate ($n = 400$)

NIOX VERO®

In a separate precision assessment of 10 NIOX VERO® devices at 5, 25, 75 and 200 ppb, the regression analysis gave an average slope of 1.047 and average intercept of 0.5 ppb. The squared correlation coefficient R^2 was > 0.999 for all the 10 devices tested. The results conclude that NIOX VERO® linearity is within the specification of $R^2 > 0.998$.¹¹

Conclusion of analytical performance testing

Comparison of the studies' data clearly shows that NIOX PRO® performs to the same high standard of accuracy as NIOX VERO®. The R^2 values of 0.999 (NIOX PRO®) and 0.999 (NIOX VERO®) indicate an exceptionally strong correlation between the measured NO concentrations and the NO reference gas concentrations.

Both devices meet and exceed the established precision specifications of < 3 ppb for measured values < 30 ppb, or $< 10\%$ of measured value for values ≥ 30 ppb across the full measurement range, confirming that NIOX PRO® delivers equivalent analytical performance to NIOX VERO®. These results demonstrate continuity in data quality and reliability between the two generations of NIOX®

technology, ensuring confidence in FeNO measurement for clinical and research applications. The NIOX VERO® study also demonstrated a high level of repeatability between NIOX VERO® and its predecessor the NIOX MINO® device.⁵ Another study also has compared NIOX MINO® to the NIOX® Flex chemiluminescence device, demonstrating legacy in the accuracy and precision of NIOX® technology and NIOX®'s robust electrochemical system.¹⁸

Conclusion of internal testing

The internal testing programme undertaken for NIOX PRO® provides comprehensive evidence of its technical and analytical equivalence to NIOX VERO®. Through detailed component verification and controlled analytical performance testing, NIOX PRO® has been shown to deliver identical measurement accuracy, precision and linearity to its predecessor.

The technical verification confirmed that all measurement-critical components, including the sensor, algorithm and internal architecture, are unchanged between the two devices. This establishes a solid foundation for performance consistency and regulatory continuity.

The analytical performance results further validated this equivalence, with every NIOX PRO® measurement falling within the predefined acceptance criteria. Comparative testing against NIOX VERO® demonstrated virtually identical output across all NO concentrations, confirming full interchangeability of measurement results between the two devices.

These findings unequivocally demonstrate that NIOX PRO® maintains the same trusted analytical performance, accuracy and repeatability that have long defined the NIOX® platform. The updates introduced in NIOX PRO®, including ergonomic refinements, improved condensation management and enhanced usability, represent meaningful advancements in user experience without altering the core measurement technology.

In conclusion, the internal verification programme confirms that NIOX PRO® is an evolution of design rather than function: a device that preserves the proven accuracy and reliability of NIOX VERO® while providing an enhanced and more efficient user experience for clinicians and patients alike.

Conclusion

The evidence presented in this white paper demonstrates conclusively that NIOX PRO® delivers identical analytical accuracy, precision and linearity to NIOX VERO®, confirming full measurement equivalence between the two devices. Comprehensive internal verification and gas testing have validated that the sensor, measurement algorithm and performance specifications remain unchanged, ensuring that the proven reliability of the NIOX® platform continues uninterrupted.

All modifications introduced in NIOX PRO®, including improved condensation management, an extended breathing handle and a newly shaped FeNO Protect Patient Filter®, have been rigorously tested and shown to have no measurable impact on FeNO results or overall device performance. Where minor design changes were implemented, extensive internal testing confirmed that any effects were negligible, reinforcing the analytical stability and repeatability of the device.

The combination of identical measurement components and verified performance equivalence ensures seamless continuity for clinicians and researchers transitioning from NIOX VERO® to NIOX PRO®. Users can have complete confidence that FeNO readings remain directly comparable across devices, maintaining the same trusted accuracy that underpins the clinical validity of NIOX testing worldwide.

The device has been submitted for CE marking under the European in Vitro Diagnostic Regulation (IVDR). It will also be submitted for clearance from the U.S. Food and Drug Administration (FDA) in 2026, using the NIOX VERO® as the predicate device. Both CE marking under the European in Vitro Diagnostic Regulation (IVDR) and FDA clearance will further confirm that the device meets all applicable regulatory requirements for safety, performance and quality.

In conclusion, NIOX PRO® represents an evolution in usability and design, but is built upon the same scientific foundation that has defined NIOX® as the global standard in FeNO measurement. It offers healthcare professionals an enhanced user experience, improved workflow efficiency and full confidence in the continuity of measurement accuracy, delivering the same trusted results that clinicians and patients have relied upon for over two decades.

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