Quick, easy and accurate FeNO and nNO measurements at the point-of-care

FeNO KNOWHOW

CIRCASSIA
NIOX® is a widely used, non-invasive, point-of-care medical technology that enables clinicians to objectively assess airway inflammation with a quick measure of fractional exhaled nitric oxide (FeNO).

NIOX results are reliable, providing an accurate result in a single measurement. Measurement results are only delivered if the test has been carried out correctly in the correct conditions.

To date, over 18 million tests have been performed using a NIOX device, supporting clinicians to enhance the accurate diagnosis and better personalised control of all inflammatory asthma patients.

FeNO KNOWHOW

>18m NIOX tests performed since 2000²
Current challenges within asthma diagnosis and management

Obtaining an accurate asthma diagnosis can be a challenge as many diseases present with symptoms similar to asthma.3

Traditional methods of asthma assessment only give part of the picture, as they are only indirectly associated with airway inflammation.4

As a result, asthma is often misdiagnosed or under-diagnosed. Studies of adults diagnosed with asthma suggest that up to 30% do not have clear evidence of the condition. Some patients may have had asthma in the past, but it is likely that many will have had an incorrect diagnosis.5

Due to asthma’s heterogenic characteristics making it difficult to treat and manage the disease, clinicians may prescribe corticosteroids to confirm or rule out asthma. This trial-and-error approach means effective ongoing management can be hard to achieve, and increases the cost of the condition to both patients and health services.

A test before treatment approach, integrating FeNO measurement into existing monitoring tools, can inform more effective and economical inhaled-corticosteroid prescribing decisions in patients with non-specific respiratory symptoms, unclear asthma, and insignificant bronchodilator reversibility.

2.5mn
People in Australia currently have asthma. Its more common in males aged 0-14, but among those aged 15 and over, asthma is more common in females. The rate of asthma among Indigenous Australians is almost twice as high as that of non-Indigenous Australians.6

30% of patients are misdiagnosed as having asthma7

Hospitalisations in 2014-15 where asthma was the main diagnosis6

39,500
There were 419 deaths due to asthma in 20147

$655 million
Spent on asthma in 2008-98

50% prescription pharmaceuticals
30% out of hospital medical services
20% admitted patient costs

FeNO testing complements existing monitoring tools

According to guidelines, patients should be diagnosed with asthma using a variety of clinical tools including patient and family history, physical examination, symptoms, lung function tests such as spirometry, and biomarkers such as FeNO. (NHLBI 2007, NICE 2017, GINA 2018)

Measuring both inflammation and bronchoconstriction is the optimal way to diagnose, treat, and manage asthma symptoms.

FeNO is a biomarker of airway inflammation
(Inflammation can lead to airway hyperresponsiveness and airway obstruction)

FeNO testing complements existing monitoring tools

We are recommending objective testing with spirometry and FeNO for most people with suspected asthma; a significant enhancement to current practice.

Professor Mark Baker
Director of the Centre for Guidelines at NICE

Spirometry measures airway obstruction
In combination with spirometry, FeNO testing provides complementary objective information about the condition of the airways.

Regular FeNO testing aids medicine optimisation

Regular FeNO testing of asthma patients with NIOX was shown to help measure allergic eosinophilic driven airway inflammation, optimise corticosteroids dose and has been shown in studies to reduce asthma attacks by up to 50%.

Exacerbation rate reduction

NIOX VERO-guided treatment significantly reduced exacerbation rates in both children and adults.

NIOX VERO® easily integrates into your clinical workflow
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<table>
<thead>
<tr>
<th>Percentage of exacerbation rates in children (per year)*</th>
<th>Percentage of exacerbation rates in adults (per year)*</th>
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<tbody>
<tr>
<td>In children</td>
<td>In adults</td>
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<tr>
<td>Usual Car (n=88)</td>
<td>FeNO-guided group (n=93)</td>
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<tr>
<td>75</td>
<td>25</td>
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<tr>
<td>50</td>
<td>24%</td>
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<tr>
<td>P=0.017</td>
<td>reduction 46%</td>
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<tr>
<td>P=0.024</td>
<td>reduction 22%</td>
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Productivity
The NIOX VERO delivers an accurate FeNO result in a single measurement at the point of care! Only one successful measurement is required to obtain an accurate result with results in approx. 1 minute, allowing more time to be focused on treatment and adherence to anti-inflammatory therapy.

Suitable for adults and children
The NIOX VERO features 3 different animations to help adults and children complete the measurement, all of which can be viewed on a larger screen when connected to a PC.

2 exhalation modes
10 seconds (adults and children)
6 seconds (for children who are not able to perform the 10 second test)

Quality control
The NIOX VERO performs internal QC checks every time on start-up and features 2 NO scrubbers (one in the breathing handle and one in the device) to exclude the effect of ambient NO. This ensures a consistent result, no matter the environment.

Exhalation flow control
NIOX VERO will only generate a measurement result if the flow rate and test has been completed within the defined flow rate parameters of 50 ml / second.

Measurement result memory
NIOX VERO stores the measurements completed on the device, enabling the user to track results over time (not just a single point measurement). Reports can be exported using NIOX Apps software which is included with the device at no additional charge.

Service and maintenance free
NIOX VERO is service and calibration free so there are no hidden annual servicing or calibration costs. Accurate results are obtained throughout the lifetime of the device. Each NIOX VERO sensor is individually calibrated during manufacture. The sensor maintains its calibration during the sensor lifetime, with no additional calibration required by the user.

After-sales service
NIOX VERO has a dedicated field team to provide hands on practical demonstration and training. A Technical Support Hotline is also available via telephone, email and to provide remote diagnostic support if required.

Heritage
NIOX is the global market leader for FeNO measurement, pioneering the use of nitric oxide as a measure of airway inflammation, and enabling clinicians to enhance the diagnosis and management of asthma patients since the early 2000’s.

Clinical evidence
The majority of studies referenced in PubMed have utilised NIOX as the FeNO methodology, with evidence ranging from randomised controlled trials to multi and single centre observational studies.
Nasal NO (nNO) application with NIOX VERO®

nNO is a sensitive and specific marker for Primary Ciliary Dyskinesia (PCD)

NIOX VERO Nasal Application provides a non-invasive and cost-efficient way to differentiate patients with PCD from healthy individuals.\(^{17}\)

**What is the role of nasal Nitric Oxide (nNO)?**

- nNO has been shown to be decreased in patients with PCD.
- Measurement of nNO can assist in the identification of cases of PCD according to ERS guidelines.\(^{16}\)
- Non-invasive screening of patients with low risk can help to rule out non PCD cases and avoid further invasive and expensive confirmatory tests, whilst not missing true cases.

**NIOX VERO CE-marked nNO application for helping to differentiate patients with PCD from healthy individuals\(^{17}\)**

- Two options for measuring, either tidal measurement or exhalation against a resistor
- 30 second aspiration time
- Battery and mains powered
- Documented clinical data for helping to differentiate patients with known PCD from healthy individuals

Today, the NIOX VERO is the only fully portable point of care device for FeNO and nNO measurement, with a 10s and 6s FeNO measurement mode for adults and children, and two nNO measurement modes for differentiating patients with PCD from healthy individuals.\(^{17}\)

Substantial savings can be achieved by reducing the number of children who need invasive, cumbersome and expensive confirmatory diagnostic tests\(^{17}\), making the NIOX VERO an optimal device for Paediatric Departments.

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Diagnosis of PCD is often delayed or missed completely

One study reported **70%** of patients had over **50** appointments before diagnosis was made\(^{15}\)
How to perform a FeNO measurement

1. Empty lungs by breathing out thoroughly
2. Inhale deeply through mouthpiece to total lung capacity
3. Exhale slowly through mouthpiece and follow on-screen display to complete the test
4. See result. FeNO measurement will appear in approximately 1 minute

Using NIOX VERO® with other monitoring tools helps to:

- Identify ICS-responsive patients\(^{18,19}\)
- Optimise the dose of Inhaled Corticosteroids (ICS)\(^{20-22}\)
- Monitor patient adherence\(^{23,24}\)
- Reduce the likelihood of exacerbations in patients at risk for future events\(^{25,26}\)
- Identify asthmatics who are possible candidates for treatment with a biologic
- Improve cost efficiency\(^{27-29}\)

With NIOX VERO, measuring FeNO is quick, accurate and simple - in approximately 1 minute, you will be equipped with greater insight to guide assessment and treatment of allergic/eosinophilic airway inflammation.\(^1,4\)

Important Information regarding NIOX VERO

NIOX VERO is a portable system for the non-invasive quantitative simple and safe measurement of Nitric Oxide (NO) in human breath (FeNO) and Nasal Nitric Oxide (nNO) in the aspirated air from the nasal cavity.

For FeNO: Nitric Oxide is frequently increased in some inflammatory processes such as asthma and decreases in response to anti-inflammatory treatment. FeNO measurements should be used as part of a regular assessment and monitoring of patients with these conditions. NIOX VERO FeNO is suitable for patients age 4 and above. As measurement requires patient cooperation, some children below the age of 7 may require additional coaching and encouragement.

NIOX VERO FeNO can be operated with 2 different exhalation times, 10 seconds and 6 seconds. The 10 second mode is the preferred mode. For children who are not able to perform the 10 second test, the 6 second is an alternative. The 6 second test should be used in caution with patients over the age of 10. It should not be used in adult patients. Incorrect use of the 6 second exhalation test may result in falsely low FeNO values, which can lead to incorrect clinical decisions.

For nNO: nNO has been shown to decrease in patients with Primary Ciliary Dyskinesia (PCD) and measurement of nNO can assist in the identification of cases of PCD. Measurement of nNO is suitable for patients age 5 and above. Suspected cases of PCD following screening with nNO should be confirmed according to published recommendations for PCD diagnosis and management.
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