Measure breath nitric oxide for airway inflammation with the NObreath® FeNO monitor

Improving asthma management, one breath at a time.

www.bedfont.com
Contents

Fractional Exhaled Nitric Oxide (FeNO) 4
Benefits of performing FeNO tests 4
NObreath® features 7
Measuring FeNO with NObreath® 8
Technical specification 9
Interpretation chart 10-11
References 10-11
Airway inflammation is a central process in asthma and other lung diseases\(^1\). Being able to detect eosinophilic airway inflammation and monitor a patient’s response to treatment is regarded as a gold standard in the management of respiratory diseases. It is becoming increasingly recognised that the measurement of FeNO in particular constitutes a novel way to monitor separate aspects of diseases. These include asthma, COPD and interstitial lung diseases that are not assessed by other means, such as lung function\(^2\). Nitric oxide measurement is not intended as a stand-alone method for diagnosis and should be used in conjunction with other evaluation methods and tests\(^3\).

Using FeNO measurements to evaluate airway inflammation in asthma represents a significant advance in respiratory medicine\(^4\), but until now it has been an expensive test to deliver in every day practice.

**Benefits of performing FeNO tests:**

- Non-invasive, quick and easy to perform\(^4\)
- Shows patient’s response to treatment, enabling the correct prescription of medication and safer/monitored adjustments
- Shows patient compliance
- Shown to be superior to the majority of conventional tests of lung function, such as peak flow recording and spirometry\(^4\)
- Aids in identifying patients who do/do not require on-going treatment\(^5\)
- Aids in differentiating between allergic (eosinophilic) and non-allergic asthma\(^6\).
Each NObreath® comes complete with:

50 mouthpieces: specifically designed with the latest bacterial filtration to remove 99.9% of airborne bacteria from the patient’s breath. These can be used up to 3 times per patient, dramatically reducing the cost of testing for FeNO.

NObreathFlo™: An eye level flow indicator makes keeping a constant flow during exhalation easy, even for young children. Using the NObreathFlo™ and mouthpieces provided allows the user to comply with ATS/ERS guidelines for FeNO testing.

<table>
<thead>
<tr>
<th>Order code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>NTK50</td>
<td>50 mouthpieces and 1 NObreathFlo™</td>
</tr>
</tbody>
</table>

Carry case: for protecting the NObreath® whilst in storage or when being transported.

50 alcohol free cleaning wipes: wipes/gels containing alcohol cannot be used on the NObreath® or any of its components. Order code: WIPE-V
**NObreath® features**

**Battery indicator**
The NObreath® requires 3 AA batteries, making it totally portable and easy to transport.

**Colour touchscreen**
For quick and easy use, with visual prompts for patients whilst taking a test to ensure correct results every time.

**Adult and child profiles**
To ensure the best sample times.

**Internal pump and NO scrubber**
Enabling warm up and recovery time to be a maximum of 60 seconds by constantly presenting the sensor with NO-free ambient air.
Measuring FeNO with NObreath® it’s as easy as 1, 2, 3

1. Inhale

2. Exhale

3. Readings instantly available

56 ppb
## Technical specification

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration range</td>
<td>5-300ppb</td>
</tr>
<tr>
<td>Display</td>
<td>Colour LCD with touchscreen</td>
</tr>
<tr>
<td>Detection principle</td>
<td>Electrochemical sensor</td>
</tr>
<tr>
<td>Repeatability</td>
<td>±5ppb of measured value ≤50ppb</td>
</tr>
<tr>
<td></td>
<td>±10% of measured value &gt;50ppb</td>
</tr>
<tr>
<td>Accuracy</td>
<td>±5ppb of measured value ≤50ppb</td>
</tr>
<tr>
<td></td>
<td>±10% of measured value &gt;50ppb</td>
</tr>
<tr>
<td>Power</td>
<td>3 x AA (LR6 or equivalent) up to 120 tests</td>
</tr>
<tr>
<td></td>
<td>2 x CR2032 lithium coin cell</td>
</tr>
<tr>
<td>T&lt;sub&gt;90&lt;/sub&gt; response time</td>
<td>&lt;10 seconds</td>
</tr>
<tr>
<td>Operating temperature</td>
<td>10-30ºC</td>
</tr>
<tr>
<td>Storage/transport temperature</td>
<td>10-30ºC</td>
</tr>
<tr>
<td>Operating/storage/transport pressure</td>
<td>Atmospheric ±10%</td>
</tr>
<tr>
<td>Operating humidity</td>
<td>10-80% (non-condensing)</td>
</tr>
<tr>
<td>Storage/transport humidity</td>
<td>25-75%</td>
</tr>
<tr>
<td>Storage operating life</td>
<td>1-2 years</td>
</tr>
<tr>
<td>Sensor sensitivity</td>
<td>5ppb</td>
</tr>
<tr>
<td>Sensor drift</td>
<td>&lt;5% per annum</td>
</tr>
<tr>
<td>Dimensions</td>
<td>Approx. 152 x 87 x 47mm</td>
</tr>
<tr>
<td>Weight</td>
<td>Approx. 400g (including batteries)</td>
</tr>
<tr>
<td>Materials</td>
<td>Case: polycarbonate/ABS blend with elastomeric overmould</td>
</tr>
<tr>
<td></td>
<td>NObreath Flo™: polycarbonate/ABS blend</td>
</tr>
<tr>
<td></td>
<td>Mouthpiece: polypropylene</td>
</tr>
<tr>
<td>Breath test time</td>
<td>Adult 12 seconds/child 10 seconds</td>
</tr>
<tr>
<td>Warm-up time</td>
<td>&lt;60 seconds</td>
</tr>
<tr>
<td>Ambient air test</td>
<td>30 seconds</td>
</tr>
<tr>
<td>Maximum ambient operating level</td>
<td>350 ppb NO</td>
</tr>
</tbody>
</table>
**Interpreting FeNO Readings**

**Using NObreath® FeNO Monitor**

<table>
<thead>
<tr>
<th>FeNO (ppb)</th>
<th>Levels</th>
<th>Symptomatic (chronic cough and/or wheeze and/or shortness of breath during past 6 wk)</th>
<th>Possible Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LOW</strong> (&lt;25 ppb)</td>
<td></td>
<td><strong>Allergic airway inflammation unlikely</strong></td>
<td><strong>Non-allergic asthma</strong> (<strong>Allergic airway inflammation unlikely</strong></td>
</tr>
<tr>
<td><strong>INTERMEDIATE</strong> (25-50 ppb)</td>
<td></td>
<td></td>
<td><strong>Non-allergic asthma</strong></td>
</tr>
<tr>
<td><strong>HIGH</strong> (&gt;50 ppb)</td>
<td><strong>or rise in FeNO of &gt;40% from previously stable levels</strong></td>
<td></td>
<td><strong>Allergic airway inflammation likely to benefit from ICS</strong></td>
</tr>
</tbody>
</table>

- **FeNO (ppb)**
- **Levels**
- **Symptomatic (chronic cough and/or wheeze and/or shortness of breath during past 6 wk)**
- **Possible Diagnosis**

### FeNO Levels

- **LOW** (<25 ppb)
- **INTERMEDIATE** (25-50 ppb)
- **HIGH** (>50 ppb)

### FeNO Levels and Symptomatic Conditions

- **Low FeNO**
  - Allergic asthma unlikely
  - Unlikely to benefit from ICS

- **Intermediate FeNO**
  - Allergic asthma likely to benefit from ICS
  - Evaluate clinical context
  - Monitor change in FeNO over time

- **High FeNO**
  - Allergic asthma likely to benefit from ICS
  - Evaluate clinical context
  - Present from previously stable levels
  - Monitor change in FeNO over time

### Confounding Factors

- Smoking
- Obesity
- Nasal obstruction
- Cardiac disease/pulmonary hypertension/pulmonary embolism
- Gastroesophageal reflux disease
- Anxiety-hyperventilation
- Chronic obstructive pulmonary disease
- Vocal cord dysfunction
- Non-pulmonary/airway causes:
  - Anxiety-hyperventilation
  - Gastroesophageal reflux disease
  - Cardiac disease/pulmonary hypertension/pulmonary embolism
  - Gastroesophageal reflux disease

### Possible Diagnoses

- Non-allergic asthma
- Rhinosinusitis
- Reactive airways dysfunction syndrome
- Bronchiectasis
- Cystic fibrosis, primary ciliary dyskinesia
- Extended post-viral bronchial hyperresponsiveness
- Vocal cord dysfunction
- Non-pulmonary/airway causes:
  - Anxiety-hyperventilation
  - Gastroesophageal reflux disease
  - Cardiac disease/pulmonary hypertension/pulmonary embolism

### References

### Monitoring (in patients with diagnosed asthma) using the NObreath® FeNO monitor

<table>
<thead>
<tr>
<th>FeNO (ppb) Levels</th>
<th>LOW &lt;25ppb (&lt;20ppb in children)</th>
<th>INTERMEDIATE 25-50ppb (20-35ppb in children)</th>
<th>HIGH &gt;50ppb (&gt;35ppb in children) or rise in FENO of &gt;40% from previously stable levels</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Symptomatic</strong></td>
<td>Possible alternative diagnosis (see below)</td>
<td>Persistent allergen exposure Inadequate ICS dose Poor adherence Steroid resistance</td>
<td>Persistent allergen exposure Poor adherence or inhaler technique Inadequate ICS dose Risk for exacerbation Steroid resistance</td>
</tr>
<tr>
<td>Chronic cough and/or wheeze and/or shortness of breath during past 6 wk</td>
<td>Unlikely to benefit from increase in ICS</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Possible Diagnosis</strong></td>
<td>• <em>Non-allergic asthma (probably steroid unresponsive)</em> • Vocal cord dysfunction • Anxiety-hyperventilation • Bronchiectasis • Cardiac disease • Rhinosinusitis • Gastroesophageal reflux disease</td>
<td>Evaluate clinical context</td>
<td>• Allergic asthma • Atopic asthma • Allergic bronchitis • COPD with mixed inflammatory phenotype</td>
</tr>
<tr>
<td><strong>Asymptomatic</strong></td>
<td>Implies adequate dosing and good adherence to anti-inflammatory therapy ICS dose may possibly be reduced (repeat FeNO 4 weeks later to confirm this judgment; if it remains low then relapse is unlikely).</td>
<td>Adequate ICS dosing Good adherence Monitor change in FENO</td>
<td>ICS withdrawal or dose reduction may result in relapse Poor adherence or inhaler technique</td>
</tr>
</tbody>
</table>

#### Notes:


*FeNO is not a definitive indication of asthma and should be used in conjunction with (but not limited to) spirometry, patient history, symptoms.
**Allergic = Eosinophilic / Non-Allergic = Non-Eosinophilic
Contact Bedfont® or one of our worldwide NObreath® distributors for a free demonstration.

www.bedfont.com
Tel:+44 (0)1622 851122
E-mail: ask@bedfont.com

A full list of our worldwide distributors can be found at
www.bedfont.com/distributors/

Our family, innovating health, for yours.