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

NObreath® #knowyourFeNO 15 YEARS Improving asthma management

CE 2797

MADE IN THE UK

Aids in the diagnosis and management of asthma, one breath at a time.

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Contents

Fractional Exhaled Nitric Oxide (FeNO)

Fractional exhaled Nitric Oxide (FeNO) is a good marker for eosinophilic airway inflammation, and is considered to be a good indicator of corticosteroid response[1].

Nitric oxide (NO) is a gas produced by cells involved in the inflammation associated with allergic or eosinophilic asthma, measured in parts per billion (ppb) in the air you slowly exhale out of your lungs[2].

The FeNO (Fractional exhaled Nitric Oxide) NObreath® device can be used for the detection and management of inflamatory airway conditions such as asthma[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].

FeNO measurement is a simple, rapid, highly reproducible, and non-invasive method of airway inflammation assessment, which until now, has been an expensive test to deliver in everyday practice[3].

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[3].
Aids in identifying patients who do/do not require on-going treatment[3].
Shows patient compliance[3].

Aids in differentiating between allergic (eosinophilic) and non-allergic asthma[3].

Shown to be superior to the majority of conventional tests of lung function, such as peak flow recording and spirometry[5].

NObreath® Features

An ergonomic design, fully-portable and incorporated with antimicrobial technology for optimum infection control.

Clinically Proven

Fairly Priced

Low Maintenance

ANTIMICROBIAL TECHNOLOGY

FeNO Testing Without Limits*

Easy Use

Adult and Child Testing

Subject to correct use, maintenance and service. Tested up to 29,000 tests.

For more information on this product call us now on +44(0)1622 851122 or email ask@bedfont.com

Measuring FeNO with NObreath®

IT'S AS EASY AS:

Treatment Planning with NObreath®

FeNO testing with the NObreath® couldn't be easier:

Test, Treat, Repeat™

Regular FeNO measurements indicate levels of airway inflammation, which can help Healthcare Professionals personalise treatment plans for patients, by helping titrate Inhaled Corticosteroids (ICS) dosing and evaluate patient adherence to treatment.

Technical Specification

Concentration range		5 - 500 ppb
Display		Full colour touchscreen
Detection principle		Electrochemical sensor
Repeatability		± 5 ppb of measured value ≤ 50 ppb ± 10% of measured value > 50 ppb
Accuracy		± 5 ppb of measured value ≤ 50 ppb ± 10% of measured value > 50 ppb
Power	**NObreath® Device**	1 x main rechargeable Li-ion battery – Approx. 100 uses on fully charged battery Model: RRC1120. Voltage: 3.6 V / 3.7 V Capacity: 2350 mAh / 2000 mAh 2 x Li-ion coin cell batteries – Approx. 5 years Model: LIR2032/LIR2032H. Voltage: 3.7 V. Capacity: 45 mAh/70 mAh Model: LIR2450. Voltage: 3.7 V. Capacity: 120 mAh
	Plug	Input: 100 - 240 V ~ 50/60 Hz., 0.2 A Output: 5.0 V, 1.0 A
T_{90} response time		≤ 10 seconds
Temperature	**Operating**	15 - 30°C
	Storage/transport	0 - 50°C
	Calibration	21°C ± 4°C (17°C - 25°C)
Humidity	**Operating**	20 - 80% RH (non-condensing)
	Storage/transport	5 - 95% RH (non-condensing)
Operating/transport/ storage altitude		- 1700 ft. to 6300 ft.
Operating/transport/storage pressure		800 - 1080 mbar
Expected sensor operating life		5 years (subject to servicing)
Limit of Detection		5 ppb
Sensor drift		< 5% per annum
Dimensions		Approx. 90 mm x 159 mm x 59 mm
Weight		Approx. 400 g
NObreath® Materials		Case: polycarbonate/ABS blend with antimicrobial technology
Breath test time	**Adult**	12 seconds
	Child	10 seconds
	Ambient	30 seconds
Warm-up time		≤ 60 seconds
Maximum ambient operating level		350 ppb NO
CO cross interference		45 ppm ≤ 17.6 ppb

NOTE: *Exhaled flow during FeNO measurement at 50 ml / sec ± 10% at 10 cm H_2O.*

Consumables

NObreath® Mouthpiece

The NObreath® uses a single-patient use mouthpiece, which contains an integrated infection control filter that removes and traps > 99% of airborne bacteria and > 98% of viruses[7].

Dimensions	Approx. 180 mm x 25 mm x 15 mm
Weight	Approx. 14 g
Material	Polypropylene
Shelf life	5 Years

FeNOchart™

FeNOchart™ is a free patient management software, available with every NObreath®. FeNOchart™ enables you to track patients' progress, view live readings, download results plus much more.

NObreath® Educational Portal

Bedfont® have put together a collection of valuable resources for healthcare professionals, including; a series of training videos on asthma and FeNO, links to relevant global asthma and FeNO guidelines, webinars presented by key asthma specialists, and much, much more.

Check out everything you need to know about Asthma, FeNO and NObreath® here:

www.nobreathfeno.com/educational-portal/

SDK by Bedfont® Scientific Ltd.

Designed for developers who want to bring accurate health monitoring and real-time data to their apps, our software development kits (SDK) offer a direct link to Bedfont's trusted medical devices. Whether you're building an app for asthma management or personalised wellness, our SDKs provide secure, compliant, and straightforward connectivity. Give your users the power of clinical-grade insights with just a few lines of code. Turn your app into a health solution today!

An SDK is a Software Development Kit, a collection of tools, libraries, documentation, and code samples. Developers can use SDKs to build applications for specific platforms, frameworks, or programming languages. An SDK is designed to simplify and speed up development by providing all the components needed to create software for a particular environment. There is also a Flutter wrapper that lets developers use Flutter to write iOS and Android interfaces with a single, unified codebase.

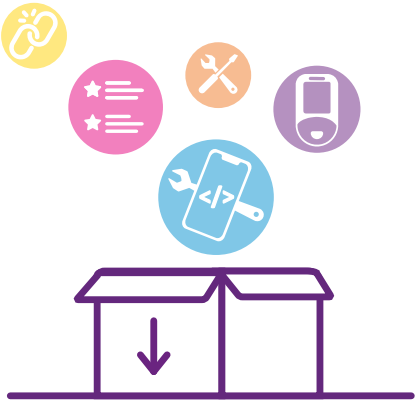
NObreath® Integration

Our NObreath® SDK is designed to enable you to integrate the functionality of our NObreath® FeNO devices into your software application.

The NObreath® SDK offers the following functionality for iOS and Android devices:

- Start test.
- Get FeNO reading in parts per billion (ppb).
- Start retest.
- Disable the touch interface.
- Multiple device connection.
- Get battery status.
- Get model.
- Get firmware version.
- Disable sounder.

You can choose which of these functions to use.



For more information and to apply please visit:

www.bedfont.com/sdk/

NObreath® Interpretation Chart

Using FeNO to assist diagnosis and management of Asthma

Measuring airway inflammation with NObreath® can help monitor the effectiveness of medication and can be used to predict the risk of Asthma attacks*.

ATS/ERS Clinical Guidelines Summary For Interpreting FeNO Levels[8,9,10]

The American Thoracic Society (ATS) and the European Respiratory Society (ERS) guidelines provide recommendations for interpreting FeNO levels for use in the diagnosis and management of asthma.

Aid in diagnosis using the NObreath® FeNO device			
FeNO (ppb) Levels	**LOW** **< 25 ppb** **(< 20 ppb in children)**	**INTERMEDIATE** **25 - 50 ppb** **(20 - 35 ppb in children)**	**HIGH** **> 50 ppb (> 35 ppb in children) or rise in FeNO of > 40% from previously stable levels**
Symptomatic (chronic cough and/or wheeze and/or shortness of breath during past 6 weeks)	**Eosinophilic airway inflammation unlikely Alternative diagnosis Unlikely to benefit from ICS	Be cautious Evaluate clinical context Monitor change in FeNO over time	**Eosinophilic airway inflammation present Likely to benefit from ICS

Alternative considerations (if Allergic Asthma has been dismissed)[10]

- Non-Allergic Asthma
- Chronic cough
- Vocal Cord Disfunction
- Gastroesophageal Reflux Disease (GERD)[10]

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].

* 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.

Monitoring (in patients with diagnosed asthma) using the NObreath® FeNO device			
FeNO (ppb) Levels	**LOW** **< 25 ppb** **(< 20 ppb in children)**	**INTERMEDIATE** **25 - 50 ppb** **(20 - 35 ppb in children)**	**HIGH** **> 50 ppb (> 35 ppb in children) or rise in FeNO of > 40% from previously stable levels**
Symptomatic (chronic cough and/or wheeze and/or shortness of breath during past 6 weeks)	Possible alternative diagnosis Unlikely to benefit from increase in ICS	Persistent allergen exposure Inadequate ICS dose Poor adherence Steroid resistance	Persistent allergen exposure Poor adherence or inhaler technique Inadequate ICS dose Risk of exacerbation Steroid resistance ICS withdrawal or dose reduction may result in relapse Poor adherence or inhaler technique
Symptoms Absent	Adequate ICS dose Good adherence ICS taper	Adequate ICS dosing Good adherence Monitor change in FeNO	

NICE/BTS/SIGN Guidelines for interpreting FeNO levels[11]

The National Institute for Health and Care Excellence (NICE), the British Thoracic Society (BTS), and the Scottish Intercollegiate Guidelines Network (SIGN) updated and published a joint guideline on asthma diagnosis, monitoring, and chronic asthma management.

Diagnosis	
Adults	**Children**
> 50 ppb or higher	> 35 ppb or higher
• FeNO testing recommended first-line testing in asthma diagnosis for adults and children. • If the first test is diagnostic, further diagnostic testing is not required.	
Management	
• FeNO testing has been acknowledged as a tool in asthma management. • Aids to inform healthcare professionals when changing or adjusting asthma therapy. • Recommending FeNO use for asthma monitoring in adults.	

NOTE: *This interpretation chart is based on both UK joint guidance from NICE, BTS, and SIGN and ATS/ERS guidance. Alternative guidelines may exist; please refer to your local or national guidance when interpreting FeNO results.*

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