

FeNO - Fast. Non-Invasive. Clinically Relevant.

**Objective biomarker for airway inflammation
supporting diagnosis, treatment decisions and therapy monitoring**

Exhaled Nitric Oxide (FeNO)

Exhaled nitric oxide (FeNO) is a biomarker for airway inflammation.

It supports diagnosis, therapy monitoring and treatment decisions in respiratory diseases such as asthma.

FeNO helps identify patients who are likely to benefit from inhaled corticosteroids and supports therapy monitoring over time.

It may also help predict exacerbations and guide treatment adjustments.



Clinical Value of FeNO

- Objective biomarker for type 2 airway inflammation
- Supports asthma diagnosis, even when spirometry is normal
- Helps identify patients likely to benefit from inhaled corticosteroids
- Enables therapy monitoring and adjustment
- Supports early detection and prevention of exacerbations



Operational & Cost Efficiency

- One test includes measurements before and after bronchodilator
- No sensors or absorbers to replace
- No expiration dates
- No device-specific filters or mouthpieces
- Predictable total cost of ownership
- Free device replacement after 3 years or 1,500 tests

Technology & Performance Advantages

Measurement Process

Fast and reliable FeNO measurement

- Ambient measurement, zero calibration and FeNO plateau in one test sequence (~1 minute)
- Flow-controlled measurement according to FeNO guidelines
- Low airway resistance during inspiration

Integrated Diagnostics

FeNO and spirometry in one system

- Combined FeNO and spirometry diagnostics
- One guided workflow
- One integrated clinical report

Measurement Accuracy

Precise and guideline-compliant diagnostics

- Precise flow measurement for low and high flow rates
- COV monitoring and flow protocol documentation
- Supports standardized FeNO assessment

Cloud-Based Analysis

Smart data processing and support

- Cloud-based data processing
- Enables remote support and system monitoring
- Supports spirometry interpretation

Device Specification

Technical Parameters

Measurement Principle	Any Oscillometry, Forced Oscillation Technique	Forced Spirometry	Exhaled Nitric Oxide (FeNO)
Sensor Technology	Differential pressure Flow measurement: Lilly-type screen pneumotachograph Pressure measurement: Differential pressure to ambient Flow Range: ± 4 L/s Flow resolution: 2 mL/s Flow accuracy: ±2% or 0.020 L/s Pressure Range: ± 500 Pa Pressure resolution: 0.01 Pa Pressure accuracy: 3% Impedance Range: 0 – 2 kPa*s/L Impedance accuracy: 10% Resistance: ±0.16 kPa*s/L at 5 Hz (system with accessories and filter)	Differential pressure Flow measurement: Lilly-type screen pneumotachograph Flow Range: ±14 L/s Flow resolution: 2 mL/s Flow accuracy: ±2% or 0.020 L/s (except peak flow) Flow accuracy: ±5% or 0.200 L/s (peak flow) Volume Range: 0 – 9 L Volume resolution: 1 mL Volume accuracy: ±2% or 0.050 L Resistance: ±0.15 kPa*s/L, up to 14 L/s (system with accessories and filter)	Nitric oxide gas sensor Nitric Oxide (NO) measurement: electrochemical FENO Range: 1 – 300 ppb FENO resolution: 0.3 ppb FENO accuracy: ±2 ppb below 50 ppb ± 10% 50 ppb and above Subtraction of ambient concentration of chemical NitricOxide-Scrubber to consider ambient nitric oxide for analysis.
Actuator Technology	Loudspeaker Frequencies (single frequency): 5, 10, 20 Hz Frequencies (pseudo random noise): 5, 7, 11, 13, 17, 19, 23, 29, 31, 37 Hz Output pressure: ≤ 40 Pa (peak-to-peak)	none	none
Dead Space	40 mL (effective)	n.a.	n.a.
Data acquisition	Digital Resolution: 16 Bit Sampling rate: 500 Hz (pressure, flow)	Digital Resolution: 16 Bit Sampling rate: 500 Hz (flow)	Analogue
Calibration	No calibration needed Optional device check with 1.5 kPa*s/L reference test load (hardware included)	No calibration needed Optional device check with 3L calibration syringe (hardware not included)	Factory re-calibration Devices are regularly exchanged
Hygiene	Two-level cross-infection prevention Level 1: Single-Use Pulmonary Filter Level 2: Airflow channel and other relevant accessories can be chemically disinfected, and steam sterilized		
Reference Models	Berger 2021 (adults) Nowinski 2008 (adolescents) Calogero 2013 (children)	GLI 2012 (Global Lung Initiative)	American Thoracic Society 2011
System requirements app	Cross-platform, Bluetooth Low Energy Operating systems: Windows 10, Windows 11, iOS14+ Bluetooth Low Energy: 4.2+		
Interoperability	All data can be shared in real-time in all standard data formats as well as custom data formats. Data types: Reports (pdf), individual clinical outcome parameters (see list above), graphs (png, svg), results of cloud-based physiological interpretation, artefacts, audit trail and other meta data Technology: cloud-based data endpoint, push model preferred (fire-and-forget) Markup: json, xml, custom Standards: HL7, DICOM, CDISC, email and other		
Device properties	Desktop Dimensions (WxDxH): 29x14x45 cm 8x6x17 in Weight: 2 kg / 4.4 lb	Handheld Dimensions (WxDxH): 14x20x9 cm 6x8x4 in Weight: 600 g / 1.2 lb	
Power supply	Battery powered Batteries: Li-ion batteries (built-in) Charging: rechargeable, charger included (5V, min. 10W, USB-A connector) Charging cycle: typically optionally daily (overnight) or once per week (over the weekend)		

Technical Standards

Class IIa Medical Device	Medical Device Regulation 2017/745 of the European Commission
Airway Oscillometry	Technical standards for respiratory oscillometry Official European Respiratory Society Technical Standard
Forced Spirometry	Standardization of Spirometry 2019 Update Official American Thoracic Society and European Respiratory Society Technical Statement
Forced Spirometry	ISO 26782:2009 Anaesthetic and respiratory equipment – Spirometers intended for the measurement of time forced expired volumes in humans
Physiological Interpretation	ERS/ATS technical standard on interpretive strategies for routine lung function tests Official European Respiratory Society Technical Standard

Clinical Parameters

Exhaled Nitric Oxide (FeNO)			
Clinical Outcome	Fractional concentration of Exhaled Nitric Oxide	FENO50	The fractional concentration of exhaled nitric oxide is a noninvasive marker of airway inflammation in asthma and many other disease entities, including COPD and cystic fibrosis.
Quality	Mean Exhalation Flow Rate	MEFR	Parameter indicating mean exhalation flow rate is 0.05 L/second (±10%) during the time of the exhalation.