FeNO - Fast. Non-Invasive. Clinically Relevant.

LOTHAR MEDICAL

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

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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	Forced Spirometry	Exhaled Nitric Oxide (FENO)
Sensor Technology	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: ± 5 ppb below 50 ppb ± 10% 50 ppb and above
Data acquisition	Digital Resolution: 16 Bit Sampling rate: 500 Hz (flow)	Analogue
Calibration	No calibration needed Optional device check with 3L calibration syringe (hardware not included)	Factory re-calibration Devices are regularly exchanged
Hygiene	Standard Single-Use Pulmonary Filter	
Reference Models	GLI 2012 (Global Lung Initiative)	ERS 2017
System requirements app	Cross-platform, Bluetooth Low Energy Operating systems: 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, GDT, DICOM, CDISC, email and other	
Device properties	Handheld Dimensions (WxDxH): 14x20x9 cm 6x9x4 in Weight: 600 g / 1.1 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

Forced Spirometry	Standardization of Spirometry 2019 Update Official American Thoracic Society and European Respiratory Society Technical Statement
Peak Flow	ISO 26782:2009 Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time forced expired volumes in humans
FeNO	Exhaled biomarkers in lung disease Official European Respiratory Society Technical Standard
Physiological Interpretation	ERS/ATS technical standard on interpretive strategies for routine lung function tests Official European Respiratory Society Technical Standard

Clinical Parameters

Forced Spirometry			
Clinical Outcome	Forced expiratory volumes	FEV1, FEV3, FEV6	Forced expiratory volumes are used to categorize the severity of obstructive lung diseases, such as asthma and chronic obstructive pulmonary disease.
	Forced expiratory flows	PEF, FEF25, FEF50, FEF75, FEF2575	Forced expiratory flows are used in the diagnosis of obstructive ventilatory patterns.
	Forced expiratory capacity	FVC	FVC is an indicator for restrictive lung diseases, such as chest wall deformities and idiopathic pulmonary fibrosis.
	Forced inspiratory capacity	IVC	Comparison of the IVC with the FVC provides feedback to the operator on whether the patient began the forced expiration from full inflation.
	FEV1/FVC ratio	FEV1/FVC	The ratio of FEV1 to FVC is used as indicator for obstructive ventilatory patterns.
Quality	Back-extrapolated volume	BEV	Volume of gas that has already been expired from maximal lung volume to the start of the forced expiration.
	End of forced expiration	EOFE	Parameter indicating whether at least one of the three recommended indicators of EOFE has been achieved.
Exhaled Nitric Oxide (FENO)			
Clinical Outcome	Fractional concentration of Exhaled Nitric Oxide	FENO50	Fractional concentration of exhaled nitric oxide (NO) in the gas phase (ppb) at an exhalation flow rate of 50 mL/s.
Quality	Mean Exhalation Flow Rate	MEFR	Parameter indicating mean exhalation flow rate is 0.05 L/second (±10%) during the time of the exhalation.

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