

Quark NObreath

Nitric Oxide Monitor



Fast and reliable monitoring of airway inflammation!

- ▶ Non-invasive accurate measurement of Fraction of Exhaled Nitric Oxide (FeNO) in a few seconds
- ▶ Easy-to-use with color touchscreen display
- ▶ Unlimited tests and low cost per test
- ▶ Fully portable, battery-operated
- ▶ High accuracy and automatic calibration
- ▶ For adult and pediatric use
- ▶ Complies with ATS/ERS guidelines for nitric oxide measurement



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Quark NObreath is a portable test system for measuring “fractional exhaled nitric oxide” (FeNO) in parts per billion (ppb) in exhaled breath for use by healthcare professionals.

Exhaled NO is a validated marker for airway inflammation and, therefore, can be used for the detection, management and treatment of such pulmonary conditions such as asthma.

Quark NObreath measurement offers:

- ▶ Superior diagnostic capacity compared to other conventional tests
- ▶ The ability to evaluate potential inflammatory status of airways and to help in monitoring effectiveness of drug therapy
- ▶ Immediate and non-invasive determination of patient’s compliance with treatment, allowing a check of drug assumption regularity

With Quark NObreath, adults and children can be easily monitored and correctly assessed. The system provides a quick assessment of the airway inflammation and provides rapid results allowing the physician the ability to prescribe treatment.

Quark NObreath is ideal for pediatric applications and on non-cooperative subjects. It could also be used to monitor the level of nitric oxide in the surrounding ambient air.

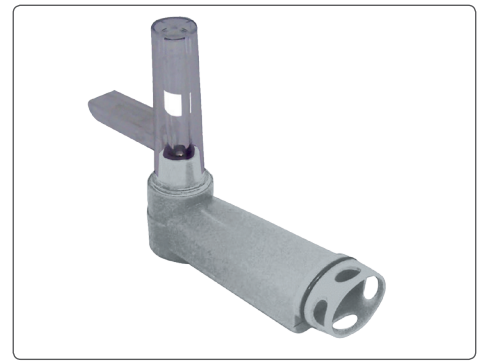
- ▶ Intuitive icons and acoustic signals for a simplified control of all main functions
- ▶ Battery operated (3 x AA).
- ▶ Flowmeter guarantees reliability and repeatability of each performed test
- ▶ Single-patient mouthpieces with antibacterial filter guarantee maximum protection from cross-contamination.

Automatic Calibration

Quark NObreath is calibrated automatically each time during the warm-up phase. The automatic calibration procedure includes a functionality check of the system.

ATS/ERS Conformity

Quark NObreath fully complies with all guidelines for monitoring nitric oxide defined by the American Thoracic Society (ATS) and European Respiratory Society (ERS) 2005.



Each flowmeter should be used for 50 tests



Single-patient mouthpieces

Applications

Quark NObreath features may be used in different application fields:

- ▶ Hospitals (Pulmonary, Allergy, Immunology, etc)
- ▶ Primary Care
- ▶ Pediatrics
- ▶ Occupational health
- ▶ Asthma care centers

Hardware Features

- ▶ Small, lightweight and portable system (400 gr) to insure optimal handling
- ▶ Electrochemical sensor guarantees unlimited testing during its duration (12 months)
- ▶ Large color LCD touchscreen

Adult and Child profiles to ensure the best sample times.

Calibration with room air.

General information on the device and on performed tests.

NObreath v1.0	
L/R	12 ppb
Cal	26-11-08
Tests	265

Internal pump and NO scrubber.



Easy and fast test execution

Inhalation

When the icon on the left appears, the patient should inhale as deeply as possible (not through the mouthpiece).

1



Start Exhalation

After 3 seconds, the screen shows a "start test" icon with the unit beeping twice to signal that the patient should start to exhale. The patient should exhale through the mouthpiece, ensuring that the ball in the flow indicator is within the white band.

2



Constant Exhalation

The exhalation time is approximately 12 seconds and a progress bar is shown at the bottom of the screen. Patient should continue to exhale until the unit beeps twice.

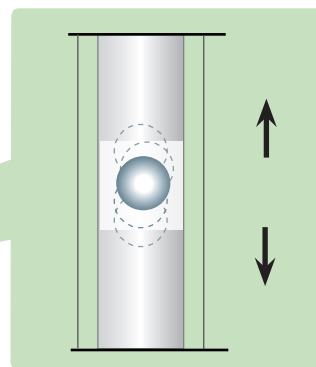
3



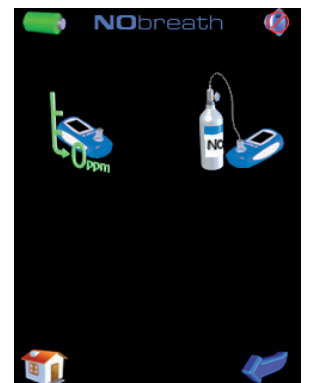
Test results

The test result (measured value in ppb) is shown on the display of the Quark NObreath.

4



The patient should keep constant exhalation flow by ensuring that the ball in the flowmeter indicator stays within the white band



Intuitive screenshots for easier operations and test execution



Carrying case for comfortable transport and storage

References

1. ATS/ERS Recommendations for Standardized Procedures for the Online and Offline Measurement of Exhaled Lower Respiratory Nitric Oxide and Nasal Nitric Oxide, 2005; American Journal of Respiratory and Critical Care Medicine; vol. 171: 912-930; 2005
2. Andrew D. Smith, Jan O. Cowan, Sue Filsell, Chris MacLachlan, Gabrielle Monti-Sheehan, Pamela Jackson and D. Robin Taylor. Diagnosing Asthma: Comparisons between Exhaled Nitric Oxide Measurements and Conventional Tests. Am J Respir Crit Care Med Vol 169. pp 473-478, 2004.
3. D R Taylor, MW Pinenburg, A D Smith and J C D Jongste. Exhaled nitric oxide measurements: clinical application and interpretation. Thorax 2006;61:817-827.
4. Shelhamer JH, Levine SJ, Wu T, Jacoby DB, Kaliner MA, Rennard SI. NIH conference: airway inflammation. Ann Intern Med 1995;123:288-304.

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Technical Specification

Features

NO Concentration Range	5-300 ppb
Accuracy	± 5 ppb of measured value ≤50 ppb ± 10% of measured value >50 ppb
Repeatability	± 5 ppb of measured value ≤50 ppb ± 10% of measured value >50 ppb
Breath test time	12 seconds
Response time	< 10 seconds
Warm-up time	< 2 minutes
Ambient air test	30 seconds

Sensor

Detection principle	Electrochemical sensor
Sensitivity	5 ppb
Operating life	12 months (6 months guarantee)
Sensitivity drift	< 5% year

Hardware

Dimensions (mm)	152(H) x 87(W) x 47(D)
Weight (g)	400
Power	4.5V DC, batteries 3 AA (LR6 or equivalent)
Battery life	> 120 test
Screen	Colour LCD touchscreen

Environmental Conditions

Operating temperature range	10-30°C
Operating relative humidity	10-80% (0-95%) non-condensing
NO concentration	< 350 ppb

Standard Packaging includes

Unit, flowmeter (1 piece), single-use mouthpieces (50 pieces), AA batteries (3), touchscreen pens (2), carrying case, user manual.

Safety & Quality Standards

Equipment complies with EN/EC 60601-1 - internal electrical source Type BF
 Quark NObreath is in compliance with the European Directive 93/42/CEE concerning medical devices.
 COSMED is an organisation whose quality management system is certified by CERMET according to UNI EN ISO 9001:2008 and UNI EN ISO 13484:2004



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