

# NIOX MINO<sup>®</sup>

## Technical Specifications

### OPERATING AND MEASUREMENT CONDITIONS

Ambient temperature	16 to 30°C
Atmospheric pressure range	700 to 1060 hPa
Humidity	20 to 60% RH (non-condensing)
Ambient NO concentration	< 300 ppb
Exhaled flow rate during measurement	50 ml/s ± 10% BTPS Body Temperature Pressure Saturated, 37°C, 1013 hPa, 100% RH

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### EXHALED NO - PERFORMANCE DATA

Measurement range	5 to 300 ppb
Lowest detection limit	5 ppb Determination by analyzing gas concentrations around and below the detection limit. 5 ppb was the lowest detectable level.
Exhalation time	10 seconds, clinical use 6 seconds, research use
Measurement time	< 2 min
Temperature stabilization time	≤ 30 min
Linearity	Squared correlation coefficient $r^2 \geq 0.998$ , slope 0.95 - 1.05, intercept ±3 ppb. Determination based on the pooled regression analysis from 10 instruments using standard gas reference samples at 7 different concentration levels covering the operating measurement range.
Precision	< 3 ppb of measured value < 30 ppb, < 10 % of measured value ≥ 30 ppb.  Expressed as one standard deviation for replicate measurements with the same instrument, using a certified gas concentration of Nitric Oxide reference standard.
Accuracy	Analytical Accuracy: ±5 ppb or max 10 %  Expressed as the upper 95% confidence limit, based on absolute differences for concentrations ≤ 50 ppb and relative differences for concentrations > 50 ppb, from certified gas concentration of Nitric Oxide reference standard.
Method comparison	< 10 ppb for values ≤ 50 ppb < 20 % for values > 50 ppb  Expressed as the difference between a NIOX MINO FeNO value and the corresponding FeNO value measured with NIOX <sup>®</sup> instrument from Aerocrine.

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### NASAL NO (Research application) — PERFORMANCE DATA

Measurement range	5 to 1700 ppb
Lowest detection limit	5 ppb
Sampling flow rates	2 ml/s or 5 ml/s

### SOFTWARE

Memory capacity: 3000 measurements  
(Instrument memory)

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### DIMENSIONS, WEIGHT AND SHELF-LIFE

Height, Width, Depth	230 mm, 128 mm, 96 mm
Weight including sensor	0.8 kg
Shelf-life	Minimum 3 years at time of delivery or 3000 measurements, whatever comes first.

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### ELECTRICAL DATA

According to IEC 60601-1 Class II Type B	
Main voltage	100 to 240 V ~ 50 to 60 Hz
Secondary voltage	6 V DC (external power adapter)

# NIOX MINO®



## NIOX MINO

Item number 09-1000

Contains: NIOX MINO instrument, Power Supply unit, NO Scrubber, USB cable, Visual Incentive (software program for PC), QC plug and User Manual

## Accessories

### NIOX MINO TEST KIT 100

Sensor\* and filters\*\* for 100 measurements.

Item number 03-4000

### NIOX MINO TEST KIT 300

Sensor\* and filters\*\* for 300 measurements.

Item number 03-4001



#### \* NIOX MINO Sensor

Pre-calibrated disposable sensor for 100 or 300 measurements. Shelf-life: Maximum 12 months when mounted in NIOX MINO or expiration date as stated on the sensor, whichever comes first.

#### \*\* NIOX® Filter

Disposable filter to be changed for every patient. Bacterial, viral filter according to Medical Device Directive Class IIa.



### NIOX MINO NO Scrubber

Item number 09-1300

### NIOX MINO Data Management

For transfer of patient data and measurement values to a PC and EMR (Electronic Medical Record)

Item number 09-1026

### NIOX MINO Bag

Bag for transportation and storage of NIOX MINO when not in use.

Item number 09-1020

### NIOX MINO Nasal (Research application)

NIOX MINO Sampling Adapter

Item number 09-1050

NIOX Nasal I Paediatric (Pkg/10 incl. 1 Nasal Filter)

Item number 06-1200

NIOX Nasal II Adults (Pkg/10 incl. 1 Nasal Filter)

Item number 06-1300



NIOX MINO is CE-marked according to In Vitro Diagnostic Device Directive 98/79/EC and approved for clinical use. NIOX MINO is 510(k) cleared (K101034) by FDA. US Patent 5,447,165, 5,922,610, 6,038,913, 6,063,027, 6,099,480, 6,149,606, 6,183,416, 6,511,425, 6,626,844, 6,723,056, 6,733,463, 6,761,185, 7,014,692, 7,270,638, D448,693, D457,231, D492,035, D496,667 and patents pending.

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