

NIOX MINO[®]

Technical Specifications

OPERATING AND MEASUREMENT CONDITIONS

Ambient temperature	60 to 85°F (16 to 30°C)
Atmospheric pressure range	10 to 15 psi (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, 99°F (37°C), 14.7 psi (1013 hPa), 100% RH

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
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 [®] instrument from Aerocrine.

SOFTWARE

Memory capacity: 3000 measurements
(Instrument memory)

DIMENSIONS, WEIGHT AND SHELF-LIFE

Height, Width, Depth	9.1" (230 mm), 5.0" (128 mm), 3.8" (96 mm)
Weight including sensor	1.8 lb (0.8 kg)
Shelf-life	Minimum 3 years at time of delivery or 3000 measurements, whatever comes first.

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)
Power consumption	< 15 VA

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 50

Sensor* and filters** for 50 measurements.

Item number 03-4002

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 50, 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 Program

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

K101034 CE

NIOX MINO is 510(k) cleared (K101034) by FDA.

NIOX MINO is CE-marked according to In Vitro Diagnostic Device Directive 98/79/EC and approved for clinical use. 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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AeroCrine



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