

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 \pm 10% BTPS Body Temperature Pressure Saturated, 37°C, 1013 hPa, 100% RH

PERFORMANCE DATA

Measurement range	5 to 300 ppb
Lowest detection limit	5 ppb
Measurement time	< 2 min
Temperature stabilization time	\leq 30 min
Linearity	Squared correlation coefficient $r^2 \geq 0.998$. Determination based on the regression analysis using standard gas reference samples at six different concentration levels covering the operating measurement range.
Precision	<p>Analytical precision: < 3 ppb of measured value < 30 ppb, < 10 % of measured value \geq 30 ppb.</p> <p>Expressed as one standard deviation for replicate measurements with the same instrument, using a certified gas concentration of Nitric Oxide reference standard.</p> <p>Clinical precision: < 3 ppb of measured value < 30 ppb <10% of measured value \geq 30 ppb</p> <p>Determination based on consecutive measurements from the same patient, performed by different operators.</p>
Accuracy	<p>Analytical Accuracy: ± 5 ppb or max 15 %</p> <p>Expressed as the upper 95% confidence limit, based on mean of absolute differences from certified gas concentration of Nitric Oxide reference standard.</p>
Method comparison	<p>± 5 ppb for values < 50 ppb ± 10 ppb for values 50 – 100 ppb ± 25 ppb for values > 100 ppb</p> <p>Expressed as the difference, using one standard deviation, between a NIOX MINO measurement value and the corresponding value measured with NIOX instrument from Aerocrine.</p>

EXHALATION TIME	10 seconds, clinical use 6 seconds, research use
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SOFTWARE	Memory capacity: 1500 measurements (Instrument memory)
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DIMENSIONS, WEIGHT AND SHELF-LIFE

Height, Width, Depth	240 mm, 130 mm, 100 mm
Weight including sensor	0.8 kg
Shelf-life Minimum 3 years at time of delivery or 1500 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)



NIOX MINO *Item number 03-1000*

Contains: NIOX MINO device, AC/DC Adapter, Bag, User Manual, Test Cards and Service Card.

NIOX MINO MONITORING SYSTEM 100 *Item number 03-4500*

Contains: NIOX MINO, Sensor* and filters** for 100 measurements.

NIOX MINO MONITORING SYSTEM 300 *Item number 03-4501*

Contains: NIOX MINO, Sensor* and filters** for 300 measurements.

Accessories



NIOX MINO TEST KIT 100 *Item number 03-4000*
Sensor* and filters** for 100 measurements.

NIOX MINO TEST KIT 300 *Item number 03-4001*
Sensor* and filters** for 300 measurements.

*** NIOX MINO Sensor**

Pre-calibrated disposable sensor for 100 or 300 measurements.
Shelf-life: 15 months from date of manufacture and in unopened primary package.

**** NIOX Filter**

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



NIOX MINO Test Card (smart card)
2000 measurements memory capacity.
Standard: for 10 seconds exhalation, clinical use. *Item number 03-1301*
Special: 6 seconds exhalation, research use. *Item number 03-1302*

NIOX MINO Data Manager *Item number 03-5000*
For transfer of measurement values to a PC.



NIOX MINO is CE-marked according to Medical Device Directive MDD 93/42/EEC and approved for clinical use in EEC countries. NIOX MINO is 510(k) cleared (K072816) by FDA. US Patent 5,447,165, US Patent 5,922,610, US Patent 6,038,913, US Patent 6,063,027, US Patent 6,099,480, US Patent 6,149,606, US Patent 6,183,416, US Patent 6,511,425, US Patent 6,626,844, US Patent 6,723,056, US Patent 6,733,463, US Patent 6,761,185, US Patent 7,014,692, US Patent 7,270,638, US Patent D448,693, US Patent D457,231, US Patent D492,035, US Patent D496,667 and patents pending.

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A NEW DIMENSION IN ASTHMA CARE

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