Over 1 million successful tests performed

Aerocrine - Revolutionizing the way asthma is managed

Aerocrine is a medical technology company focused on improving the management and care of patients with inflammatory airway diseases. As the pioneer and leader in airway inflammation monitoring and treatment, Aerocrine is revolutionizing the way asthma is managed.

NIOX MINO® - The market leader in Asthma Inflammation Monitoring

Over 1 million successful tests performed

NIOX MINO® Data Manager

For more efficient management of patient data, Aerocrine has developed the new NIOX MINO® Data Manager. NIOX MINO® uses IR communication for easy transfer of patient data to a PC. Historical patient data can be followed over time and presented graphically.

NIOX MINO® - The Asthma Inflammation Monitor

Aerocrine is a medical technology company focused on improving the management and care of patients with inflammatory airway diseases. As the pioneer and leader in airway inflammation monitoring and treatment, Aerocrine is revolutionizing the way asthma is managed.

The founders of Aerocrine emerged from the highly prestigious Karolinska Institute in Sweden where they were the first to identify Nitric Oxide (NO) as a marker of airway inflammation. Aerocrine has taken this significant discovery from laboratory to clinical practice and is now established in some of the world’s largest nations. Over 1 million tests have been successfully performed with NIOX MINO®.

The New NIOX MINO®
Asthma Inflammation Monitor
From the company that’s revolutionizing the way asthma is managed
Asthma is defined as a chronic inflammatory process, which leads to airway inflammation and increased responsiveness to asthma triggers. Until now, routine measurement of the level of inflammation has not been possible. Controlling the inflammation, rather than its consequences, can dramatically improve the treatment and care of your asthma patients.

Linking on the patient’s history, subjective evaluation of current symptoms, and lung function test results is considered reactive symptom control. Be proactive – measure what really matters – exhaled Nitric Oxide (eNO) for inflammation status. This means that you can detect a deterioration in the patient’s asthma before it causes problems.

NIOX MINO® – allows personalized asthma care

Inflammation measurement with NIOX MINO offers personalized asthma care that can dramatically improve the treatment and care of your asthma patients. The patient’s understanding of how to perform the test.

The NIOX Value – the new Gold Standard in Inflammation Monitoring

• It predicts asthma relapse.
• It optimizes dose-adjustments
• It improves symptom control, including nocturnal symptoms and lung function test results is considered reactive symptom control.
• It is cost effective
• It improves the patient’s understanding and improves adherence to treatment
• It is easy to use
• It is optimized dose-adjustment
• It predicts asthma exacerbation

Accurate results

NIOX MINO with its pre-calibrated NO sensor provides a NIOX Value that is immediate, accurate, reproducible and of clinical significance.14,15

Infection control

A disposable bacterial and viral filter prevents contamination.

Dynamic flow control

The built-in flow regulator makes it easy, even for young children, to keep a constant flow rate of 50 mL/sec during the exhalation.

Quality assured

An automatic surveillance procedure continually checks for malfunction of the device and the NO sensor.

Inhalation of NO-free air

Suitable for adults and children from 7 years of age or older with a body weight of 10 kg or more. Section 3.4

NIOX MINO with its pre -calibrated NO sensor provides a NIOX Value that is immediate, accurate, reproducible and of clinical significance.14,15

NIOX MINO® – convenient for you and your patients to use

NIOX MINO® uses IR communication for easy transfer of patient data to a PC...

Data transfer to a PC...

Test Cards (smart cards) for convenient patient data storage.

Data Storage

Printed test cards make it possible to create patient reports that can be printed or stored on a computer.

Additional features

NIOX MINO®

• CE marked for clinical use
• Suitable for adults and children from 7 years of age or older with a body weight of 10 kg or more. Section 3.4

NIOX MINO®

• CE marked for clinical use
• 510(k) cleared by FDA

NIOX MINO®

• Suitable for adults and children from 7 years of age or older with a body weight of 10 kg or more. Section 3.4

NIOX MINO®

• Award-winning ergonomic design
• Collaborative design with market leaders with the greatest experience in urinary inflammation.

Ask Aerocrine – you get help from the world’s most eminent clinical experts

As a valued user of NIOX MINO, Aerocrine will support you and answer your questions.

We are in touch with the world’s most eminent clinical experts and always aim to provide you with the latest information regarding the clinical use of inflammation measurement.

Asthmatic patient data can be transferred to a printer via the IR port...

...or to a printer

Patient data can be transferred to a printer via the IR port.

The procedure can be performed without the need for any special equipment or training.

Practically takes no time to perform, can be repeated as often as necessary for either early or usual home treatment of asthma.

Inflammation measurement with NIOX MINO offers personalized asthma care that can dramatically improve the treatment and care of your asthma patients.

An accurate and reliable NIOX value is vitally important for both the physician and the patient. The NIOX Value together with other diagnostic parameters is the basis for important decisions concerning the patient’s asthma management.

NIOX MINO® has a built-in, highly sensitive quality assurance system that will always guarantee an exact and accurate measurement that can be relied upon – The NIOX Value.

The procedure can be performed using either audio or visual feedback.

The procedure can be performed using either audio or visual feedback.

The patient data can be transferred to a printer via the IR port.

The procedure can be performed using either audio or visual feedback.

The patient data can be transferred to a printer via the IR port.

The procedure can be performed using either audio or visual feedback.

The patient data can be transferred to a printer via the IR port.
Over 1 million successful tests performed.

Aerocrine - Revolutionizing the way asthma is managed

Aerocrine is a medical technology company focused on improving the management and care of patients with inflammatory airway diseases. As the pioneers and leaders in eNO technology to monitor and manage airway inflammation, Aerocrine markets NIOX® Mini and NIOX® Mini Plus. Both products enable fast and reliable measurement of airway inflammation and thereby play a crucial role in more effective treatment and follow-up of patients with inflammatory airway diseases such as asthma.

The founders of Aerocrine emerged from the highly prestigious Karolinska Institute in Sweden where they were the first to identify Nitric Oxide (NO) as a marker of airway inflammation. Aerocrine has taken this significant discovery from laboratory to clinical practice and is now established in some of the world’s largest markets. Over 1 million tests have been successfully performed with NIOX MINO.

NIOX MINO - The market leader in Asthma Inflammation Monitoring

A N E W D I M E N S I O N I N A S T H M A C A R E

NIOX MINO Data Manager

For more efficient management of patient data, Aerocrine has developed the NIOX MINO Data Manager. NIOX MINO uses infrared communication for easy transfer of patient data to a PC. Historical patient data can be followed over time and presented graphically.

Notice: eNO (exhaled NO) is produced in the epithelial cells of the bronchial wall as a part of the inflammatory process. Elevated NO production indicates acute inflammation.

This promotion of endogenous NO by cellularly active NO synthase (NOS), which is expressed in epithelial cells, indicates increased NO production and tissue injury.

The NO produced is rapidly scavenged, and the levels are very low under normal conditions.

Increased levels are often seen in disease states where NO production increases when there is obstruction or irritation of the airways. This stimulates the release of NO from the epithelial cells, which is a marker of inflammation and airway hyper-responsiveness.

NO is also produced in the bronchial muscle, where high levels are found in asthma, chronic obstructive pulmonary disease (COPD), and other inflammatory conditions.

NO production increases when there is obstruction or irritation of the airways. This stimulates the release of NO from the epithelial cells, which is a marker of inflammation and airway hyper-responsiveness.

Increased levels are often seen in disease states where NO production increases when there is obstruction or irritation of the airways. This stimulates the release of NO from the epithelial cells, which is a marker of inflammation and airway hyper-responsiveness.

NO is also produced in the bronchial muscle, where high levels are found in asthma, chronic obstructive pulmonary disease (COPD), and other inflammatory conditions.
The NIOX Value – the new Gold Standard in Inflammation Monitoring.

The value you get from NIOX, the NIOX Value, is always quality assured. Various factors can influence the measurement of the patient’s inflammation. An accurate and reliable value is vitally important for both the physician and the patient.

The NIOX Value together with other diagnostic parameters is the basis for important decisions concerning the patient’s asthma management program.

NIOX MINO has a built-in highly sensitive quality assurance system that will always guarantee an exact and accurate measurement that can be relied upon – The NIOX Value.

• It predicts asthma relapse.
• It optimizes dose-adjustments.
• It’s a predictor of steroid response.
• It improves the patient’s understanding and adherence to treatment.
• It’s cost effective.
• It’s easy to use.

Inflammation measurement with NIOX MINO offers personalized asthma care that can dramatically improve the treatment and care of your patients.

Inflammation Monitoring

The NIOX Value together with other diagnostic parameters is the basis for important decisions concerning the patient’s asthma management program.

NIOX MINO has a built-in, highly sensitive quality assurance system that will always guarantee an exact and accurate measurement that can be relied upon – The NIOX Value.

• It predicts asthma relapse.
• It optimizes dose-adjustment.
• It’s a predictor of steroid response.
• It improves the patient’s understanding and adherence to treatment.
• It’s cost effective.
• It’s easy to use.

It takes less than 2 minutes to get an eNO value of the inflammation. With results in hand, you and your patient get immediate feedback on the inflammatory status. The patient’s inflammation has not been possible.

NIOX MINO – allows personalized asthma care

Inflammation measurement with NIOX MINO offers personalized asthma care that can dramatically improve the treatment and care of your patients.

The value you get from NIOX, the NIOX Value, is always quality assured. Various factors can influence the measurement of the patient’s inflammation. An accurate and reliable value is vitally important for both the physician and the patient.

The NIOX Value together with other diagnostic parameters is the basis for important decisions concerning the patient’s asthma management program.

NIOX MINO has a built-in, highly sensitive quality assurance system that will always guarantee an exact and accurate measurement that can be relied upon – The NIOX Value.

• It predicts asthma relapse.
• It optimizes dose-adjustment.
• It’s a predictor of steroid response.
• It improves the patient’s understanding and adherence to treatment.
• It’s cost effective.
• It’s easy to use.

The NIOX Value – the new Gold Standard in Inflammation Monitoring.

The value you get from NIOX, the NIOX Value, is always quality assured. Various factors can influence the measurement of the patient’s inflammation. An accurate and reliable value is vitally important for both the physician and the patient.

The NIOX Value together with other diagnostic parameters is the basis for important decisions concerning the patient’s asthma management program.

NIOX MINO has a built-in, highly sensitive quality assurance system that will always guarantee an exact and accurate measurement that can be relied upon – The NIOX Value.

• It predicts asthma relapse.
• It optimizes dose-adjustment.
• It’s a predictor of steroid response.
• It improves the patient’s understanding and adherence to treatment.
• It’s cost effective.
• It’s easy to use.

Inflammation measurement with NIOX MINO offers personalized asthma care that can dramatically improve the treatment and care of your patients.

Inflammation Monitoring

The NIOX Value together with other diagnostic parameters is the basis for important decisions concerning the patient’s asthma management program.

NIOX MINO has a built-in, highly sensitive quality assurance system that will always guarantee an exact and accurate measurement that can be relied upon – The NIOX Value.

• It predicts asthma relapse.
• It optimizes dose-adjustment.
• It’s a predictor of steroid response.
• It improves the patient’s understanding and adherence to treatment.
• It’s cost effective.
• It’s easy to use.
Asthma is defined as a chronic inflammatory process, which leads to airflow limitation and increased responsiveness to asthma triggers. Until now, routine measurement of the level of inflammation has not been possible. Controlling the inflammation, rather than its consequences, can dramatically improve the treatment and care of your asthmatic patients.

By proactively measuring what really matters — exhaled Nitric Oxide (eNO) — you can detect a deterioration in the patient’s asthma before it causes problems.

**NIOX MINO** — allows personalized asthma care

- **Cost effective**
- **Improves the patient’s understanding**
- **Predicts asthma relapse**
- **Predicts steroid response**
- **Both low and high NIOX Values are of clinical significance**
- **Acid-base status calculated**
- **Test results are quality assured**
- **System that will always guarantee an exact and accurate measurement**
- **CE marked for clinical use**
- **510(K) cleared by FDA**
- **Designed to comply with the ATS/ERS recommendations for measurement**
- **Accurate results**
- **Demonstration mode**

**NIOX MINO** — convenient for you and your patients to use

1. **Easy fingertip navigation**
2. **Dynamic flow control**
3. **Accurate results**
4. **Pre-calibrated disposable NIOX MINO Sensor**
5. **Patient data can be stored on smart cards**
6. **Patient data can be transferred to a printer via the IR port**
7. **Data Storage**
8. **Measurement data can be further exported for statistical analysis**
9. **Data can be presented graphically. The software also makes it easy to follow the patient’s historical data over time.**
10. **Infection control**
11. **Dynamic flow control**
12. **Accurate results**
13. **Pre-calibrated disposable NIOX MINO Sensor**
14. **Patient data can be stored on smart cards**
15. **Patient data can be transferred to a printer via the IR port**
16. **Data Storage**
17. **Measurement data can be further exported for statistical analysis**
18. **Data can be presented graphically. The software also makes it easy to follow the patient’s historical data over time.**
19. **Infection control**
20. **Extensive clinical publications**
21. **Award-winning ergonomic design**
22. **Collaborate with eNO pioneers and market leaders with the greatest experience in airway inflammation.**
23. **Ask Aerocrine — you get help from the world’s most eminent clinical experts.**

As a valued user of NIOX MINO, Aerocrine will support you and answer your questions. We are in touch with the world’s most eminent clinical experts and always aim to provide you with the latest information regarding the clinical use of inflammation measurement.

**The NIOX® Value — the new Gold Standard in Inflammation Monitoring**

The NIOX® Value, in conjunction with the NIOX MINO, allows you to take a closer look at the patient’s condition and how it is responding to treatment. The NIOX® Value is the new Gold Standard in Inflammation Monitoring and is a reliable and accurate measure of asthma inflammation. It is an objective and reproducible test of the patient’s inflammation status, leading to airflow limitation and increased responsiveness to asthma triggers. Until now, routine measurement of the level of inflammation has not been possible.

**Inflammation monitoring**

As a consequence of asthma inflammation, airway inflammation and challenges lead to airflow limitation and increased responsiveness to asthma triggers.

**Asthma is defined as a chronic inflammatory process, which leads to airflow limitation and increased responsiveness to asthma triggers.**

- **It predicts asthma relapse.**
- **It is cost effective.**
- **It improves the patient’s understanding and improves adherence to treatment.**
- **It’s a predictor of steroid response.**
- **Both low and high NIOX Values are of clinical significance.**

**NIOX MINO** — the Asthma Inflammation Monitor

- **The Asthma Inflammation Monitor**
- **The value you get from NIOX MINO, the NIOX Value, is always quality assured.**
- **It’s a predictor of steroid response.**
- **Both low and high NIOX Values are of clinical significance.**
- **ACCF/AHA practice guidelines recommend that patients with asthma who are experiencing symptoms despite being treated with inhaled corticosteroids should have their inflammation measured at least once per year.**

**Infection control**

A disposable filter and viral filter prevent contamination.

**Additional features**

- **No calibration or maintenance**
- **Optimum drawer and filters for at least 2 years**
- **Design is compliant with the ATS/ERS recommendations for standardized protocol for asthma control.**
- **Inhalation of NO-free air allows accurate absolute measure of exhaled NO.**
- **ISO 11843:2004 tested by FDA.**
- **CE marked for clinical use.**
Aerocrine - Revolutionizing the way asthma is managed

Aerocrine is a medical technology company focused on improving the management and care of patients with inflammatory airway diseases. As the pioneer and leader in eNO technology to monitor and manage airway inflammation, Aerocrine markets NIOX® and NIOX MINO® devices for exhaled nitric oxide measurement in adults and children. Aerocrine’s NIOX MINO® device for exhaled nitric oxide measurement in adults and children is CE-marked according to In Vitro Diagnostic Device Directive 98/79/EC and approved for clinical use. NIOX MINO® is 510 (k) cleared by FDA.

Now it’s even more useful in your clinic:

To date, more than 1 million tests have been successfully performed. The performance is self-documented in more than 20 clinical papers in peer-reviewed journals making NIOX MINO a market leader in monitoring airway inflammation. Aerocrine leverages its experience in measuring exhaled Nitric Oxide (eNO).

NIOX MINO’s Data Manager

For more efficient management of patient data, Aerocrine has developed a new software — NIOX MINO Data Manager. NIOX MINO uses IR communication for easy transfer of patient data to a PC. Historical patient data can be followed over time and presented graphically.

A NEW DIMENSION IN ASTHMA CARE

Aerocrine Inc., 562 Central Avenue, New Providence, NJ 07974
Phone: 908.358.4500, Fax: 908.358.4501, Email: info@aerocrine.com


© 2011 Aerocrine AB, SE-164 40 Solna, Sweden. All rights reserved.

NIOX MINO® NIOX and Aerocrine are registered trademarks of Aerocrine AB.
**Technical Specifications**

### Operating and Measurement Conditions

<table>
<thead>
<tr>
<th>Condition</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambient temperature</td>
<td>60 to 85°F (16 to 30°C)</td>
</tr>
<tr>
<td>Atmospheric pressure range</td>
<td>10 to 15 psi (700 to 1060 hPa)</td>
</tr>
<tr>
<td>Humidity</td>
<td>20 to 60% RH (non-condensing)</td>
</tr>
<tr>
<td>Ambient NO concentration</td>
<td>&lt; 300 ppb</td>
</tr>
<tr>
<td>Exhaled flow rate during measurement</td>
<td>50 mL/sec ± 10% BTPS</td>
</tr>
</tbody>
</table>

**Ambient NO concentration**

Body Temperature Pressure Saturated, 98.7°F (37°C), 14.7 psi (1013 hPa), 100% RH

### Performance Data

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement range</td>
<td>5 to 300 ppb</td>
</tr>
<tr>
<td>Lowest detection limit</td>
<td>5 ppb</td>
</tr>
<tr>
<td>Measurement time</td>
<td>&lt; 2 min</td>
</tr>
<tr>
<td>Temperature stabilization time</td>
<td>≤ 30 min</td>
</tr>
<tr>
<td>Linearity</td>
<td>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.</td>
</tr>
</tbody>
</table>

**Precision**

Analytical 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.

Clinical precision:

- < 3 ppb of measured value < 30 ppb
- < 10% of measured value ≥ 30 ppb

Determination based on consecutive measurements from the same patient, performed by different operators.

**Accuracy**

**Analytical Accuracy:**

± 5 ppb or max 15%

Expressed as the upper 95% confidence limit, based on mean of absolute differences from certified gas concentration of Nitric Oxide reference standard.

**Method comparison**

- ± 5 ppb for values < 50 ppb
- ± 10 ppb for values 50 – 100 ppb
- ± 25 ppb for values > 100 ppb

Expressed as the difference, using one standard deviation, between a NIOX MINO measurement value and the corresponding value measured with NIOX instrument from Aerocrine.

### Exhalation Time

10 seconds

### Software

Memory capacity: 1500 measurements (Instrument memory)

### Dimensions, Weight and Shelf-life

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height, Width, Depth</td>
<td>9.4” (240 mm), 5.1” (130 mm), 3.9” (100 mm)</td>
</tr>
<tr>
<td>Weight including sensor</td>
<td>1.8 lb (0.8 kg)</td>
</tr>
</tbody>
</table>

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-US

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

Item number 03-4500-US

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

Item number 03-4501-US

Accessories

NIOX MINO TEST KIT 100
Sensor* and filters** for 100 measurements.

Item number 03-4000-US

NIOX MINO TEST KIT 300
Sensor* and filters** for 300 measurements.

Item number 03-4001-US

* 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. 9 months after mounted in NIOX MINO.

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

NIOX MINO Quality Control Test Kit
Contains: NIOX MINO QC Sensor, QC Filter, QC Card.

Item number 03-4099

NIOX MINO Test Card (smart card)
2000 measurements memory capacity.
Standard: for 10 seconds exhalation, clinical use.

Item number 03-1301

NIOX MINO Data Manager
For transfer of measurement values to a PC.

Item number 03-5000

K072816
NIOX MINO, NIOX and Aerocrine are registered trademarks of Aerocrine AB.

A NEW DIMENSION IN ASTHMA CARE

Tel.: 1-800-361-6991
Email: sales@roxon.ca
www.roxon.ca