

**Aerocrine**

**NIOX MINO<sup>®</sup>**  
**Quality Control Procedure**  
**User Manual**

510(k)  
K072816 **CE**<sub>0413</sub>

**NIOXMINO<sup>®</sup>**  
Airway Inflammation Monitor



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Quality Control Procedure User Manual EPM-000073, version 04, May 2008. **This manual applies to instruments with software version 1430.**

Information in this document is subject to change. Amendments will be made available by Aerocrine Inc. as they occur.

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## Support

Please contact Aerocrine Inc., Technical Support if you encounter problems performing the external Quality Control Procedure, which you can not solve with the actions stated in this manual.

For contact details, see back-page.

## Cautions

- A NIOX MINO<sup>®</sup> is only validated for clinical use following a qualification of a Biological Control Tester and completed Full and Daily external QC procedures according to this manual. The NIOX MINO qualification will run for a period of four days. The Biological Control Tester qualification takes three days and the instrument can be valid for clinical use on the fourth day.
- If repeated measurements for two days in a row show values lower than 5 ppb, or if the Biological Positive Control is not approved, do not use NIOX MINO. Contact Aerocrine Inc. Technical Support.
- When not in use, the QC Sensor should be stored in the plastic bag provided. The same storage conditions as for NIOX MINO Sensor apply.
- Do not use the external Quality Control test tools to make clinical evaluations with NIOX MINO. NIOX MINO QC Sensor and QC Filter are only to be used for quality control purposes.
- When not in use, the QC Filter should be stored in the plastic bag provided. The zip-lock must be closed in order to avoid contamination.

**For Definitions, see page 17**

## Introduction

There is a mandatory external Quality Control (QC) Procedure for NIOX MINO that includes a Daily Quality Control and a Full Quality Control (See QC Procedure overview, page 3).

This manual describes the external Quality Control Procedure for NIOX MINO. The internal controls are described in the NIOX MINO User Manual.

The external Quality Control Procedure for NIOX MINO is simple and easy to perform. ***In addition to many internal checks and self tests of NIOX MINO, the external Quality Control Procedure provides the user with further confidence that the system is operating within its specifications.*** Tests performed with NIOX MINO during the Quality Control Procedure will not affect the number of remaining tests on the NIOX MINO Sensor.

**If the Quality Control Procedure is not followed, a Lock-out function is activated and it will not be possible to do any normal  $FE_{NO}$  measurements with the instrument until a Full QC is performed (see page 18).**

# QC Procedure Overview

## Read this prior to First start up of NIOX MINO®

### **Caution!**

A NIOX MINO is **only** validated for clinical use following a qualification of a Biological Control Tester (see page 15) and completed valid Full and Daily QC procedures according to this manual. **The NIOX MINO qualification will run for a period of four days.** The Biological Control Tester qualification takes three days and the instrument can be valid for clinical use on the fourth day.

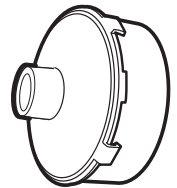
### **Full QC Procedure** (for details, see page 14)

The Full QC should be done by a Biological Control Tester and is prompted for:

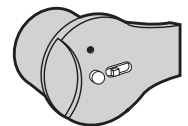
- When a new instrument is used for the first time.
- Every time a new NIOX MINO Sensor has been inserted.
- After every 45 measurements or every 7 days, whichever comes first.

### **The Full QC Procedure consists of:**

- The **Biological Positive Control** is performed using exhaled breath samples from one or more Biological Control Testers. The Tester conducts a standard exhalation test, and the instrument is expected to display a result within the Tester's "normal range".
- Nitric Oxide free sample using NIOX MINO QC Filter (1)** performed with a filter, specially designed to present a human sample, free of NO. When the instrument completes its analysis of this sample, it should display a result below the detection limit (< 5 ppb) of the instrument.
- Simulated exhaled breath samples using NIOX MINO QC Sensor (2)**, specially designed to provide electronic signals to NIOX MINO, simulating exhaled breath samples containing Nitric Oxide (NO) at 15ppb and 75ppb. These levels are considered to mimic testing at the clinical "normal", and at the clinical "high" range, respectively.



(1)



(2)

### **Daily QC Procedure** (for details, see page 13)

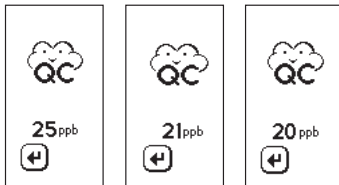
In addition to the Full QC the Daily QC should be done by a Biological Control Tester as prompted daily when the instrument is to be used and before measurements are performed with patients.

**The Daily QC is the same as step A of the Full QC Procedure**

## Biological Control Tester Qualification

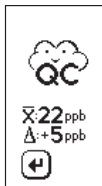
*(More than one person can be qualified at the same time using personal NIOX MINO QC Cards, see page 5. See page 15 on how to qualify additional Biological Control Testers.)*

Perform three  $FE_{NO}$  measurements, one per day within seven days in order to qualify a Biological Control Tester. A mean value is calculated from the three measurements that should be between 10-40 ppb for the Tester to be qualified. On the fourth day the  $FE_{NO}$  measurement performed during the Daily QC must be within  $\pm 10$  ppb from the mean value for the Biological Positive Control to be passed. (Tester qualification details, see page 15)



Day 1      Day 2      Day 3

$FE_{NO} 1 + FE_{NO} 2 + FE_{NO} 3 = \text{Sum divided by } 3 = \text{Mean Value } (\bar{X})$  (within 10-40 ppb)



**Mean Value** subtracted by  $FE_{NO} 4 = \text{Difference } (\Delta)$  (within  $\pm 10$  ppb of the Mean Value).

(See **Moving Mean** description in Definitions section, page 17, for further information).

Day 4

$FE_{NO} 4$

A person qualified as a Biological Control Tester can perform the Daily or Full QC Procedures on more than one instrument the same day with the same NIOX MINO QC Card.

# First start up of NIOX MINO<sup>®</sup>

## — Qualification Day 1

You must follow the steps below to unlock your NIOX MINO, and get the device ready for  $FE_{NO}$  Measurements. The procedural steps are identical with a Full QC.

### Note!

The normal operating conditions for NIOX MINO should be adhered to when performing the external Quality Control procedures. The ambient NO level should be below 50 ppb as the exhaled test sample otherwise might be affected by such elevated NO levels. See NIOX MINO User Manual for normal operating conditions and instructions how to measure ambient NO.

1. Refer to the *Installation* section - in the *NIOX MINO User manual* - on how to start up the instrument and install a NIOX MINO Sensor.

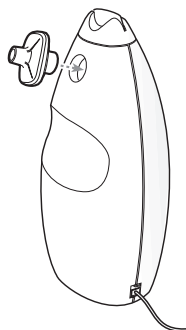
2. A QC icon is shown and the instrument is locked.

### Biological Control Tester Qualification

3. Use a new **white** personal NIOX MINO QC Card and write the name of the candidate Biological Control Tester on the card (see page 15 for more information on qualification of the Biological Control Tester).

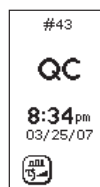
4. Remove the **blue** NIOX MINO Test Card (if inserted).

5. Insert the **white** personal NIOX MINO QC Card (QC text forward).



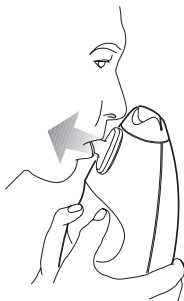
6. Attach a NIOX<sup>®</sup> Filter.

7. Touch the display to activate the instrument.



8. Perform  $FE_{NO}$  measurement.

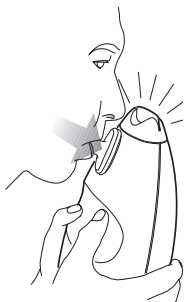
- a. Empty lungs      b. Inhale deeply through the filter to total lung capacity



In addition you can also look at the display using a mirror

The cloud on the display is inflated and the top light is turned off while you inhale

- c. Exhale slowly through the filter for 10 seconds



Listen to the sound signals and view the top light:

Continuous sound and steady light = OK

Intermittent high sound and flickering light = too hard exhalation

Intermittent low sound and flickering light = too weak exhalation

Sound ceases with a click, and top light is turned off when the exhalation is approved



OK

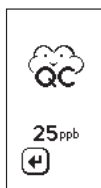


Too hard



Too weak

9. Wait for result (1:40 min.).



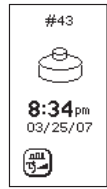
**Note!**

Error Code E 2214 indicates that the measured  $FE_{NO}$  value is too low for the Biological Positive Control step (<5ppb).

10. Enter the  $FE_{NO}$  value into the Biological Control Tester Log in the QC Procedure Log Book. (Each Tester must have a personal log).

11. Press the return arrow.

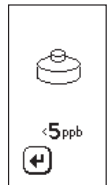
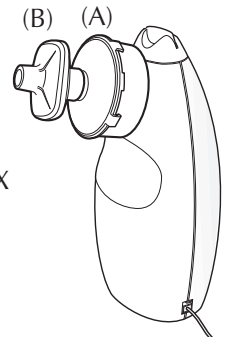
## Nitric Oxide free sample using NIOX MINO® QC Filter



### Note!

- Visually inspect the QC Filter before each measurement and check that it is not damaged. Take care not to drop it or to subject it to any strong mechanical impact.
- The QC Filter has a shelf-life of 1 year from the date of manufacture.

12. Attach the QC Filter (A) to the NIOX MINO patient filter opening.
13. Attach the NIOX® Filter (B) to the QC Filter.
14. Touch the display to activate the instrument.
15. Perform a measurement according to step 8 - with the NIOX Filter and the QC Filter attached.
16. Wait for result (1:40 min.).
17. Check that the reading is shown as **<5 ppb**.
18. Press the return arrow.
  - If the test fails, an error message is shown. Click the return arrow on the display and restart the QC Filter procedure from step 14. If the test fails again, contact Aerocrine, Inc.
19. **Remove the QC Filter from NIOX MINO after completed exhalation.**



### Caution!

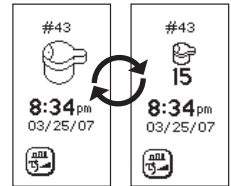
When not in use, the QC Filter should be stored in the plastic bag provided. The zip-lock must be closed in order to avoid contamination.

## Simulated exhaled breath samples using NIOX MINO® QC Sensor

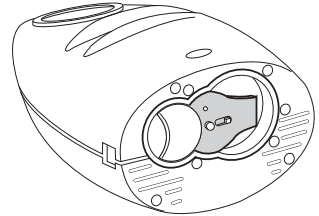
### Note!

Visually inspect the QC Sensor before each measurement and check that it is not damaged. Take care not to drop it or to subject it to any strong mechanical impact.

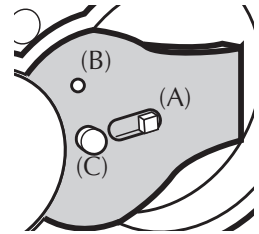
20. An alternating sensor symbol / sensor 15 symbol shows that the instrument is ready for QC Sensor tests.
21. Disconnect NIOX MINO from the power supply.
22. Remove NIOX MINO Sensor according to steps 1 to 3 in the Exchange sensor section in NIOX MINO User Manual. Place the sensor in a safe place face up (white face up) while performing the QC Sensor test.
23. Insert the QC Sensor according to steps 4 to 5 in the Exchange sensor section in NIOX MINO User Manual.



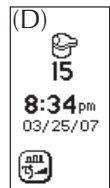
24. **Set the switch (A) on the QC Sensor to the 15 ppb level (see picture).**



25. Reconnect NIOX MINO to the power supply and check that the QC Sensor indicator (B) light turns on.
26. Wait for the instrument to display the 15 ppb test level screen (D).



27. Attach the NIOX® Filter.
28. Touch the display to activate the instrument.
29. Perform a measurement according to step 8.



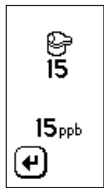
**Within 5 seconds after completing the exhalation, press the start button (C) on the QC Sensor.**

30. Wait for result (1:40 min.).

31. The reading must be between 10 and 20 ppb in order to be approved.  
- If the test fails, an error message is shown. Press the return arrow on the display and restart the QC Sensor 15 procedure from step 29. If the test fails again, contact Aerocrine Inc.

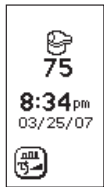
**Note!**

Error code E 2204 indicates that you might have forgotten to press the button (C) within 5 seconds of correct exhalation.



32. Change switch setting on the QC Sensor to the 75 ppb test level, press the return arrow on the display, and repeat steps 29-30 above.

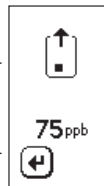
**Don't forget to press the button immediately after the exhalation.**



33. The reading must be between 67 and 83 ppb in order to be approved.  
- If the test fails, an error message is shown. Press the return arrow on the display and restart the QC Sensor 75 procedure from step 29. If the test fails again, contact Aerocrine, Inc.

**Note!**

Error code E 2205 indicates that you might have forgotten to press the button (C) within 5 seconds of correct exhalation.



34. Remove the **white** personal NIOX MINO QC Card and insert the **blue** NIOX MINO Test Card.

35. **Disconnect NIOX MINO® from the power supply and remove the QC Sensor (white) from the instrument immediately after it has been used, and insert the normal NIOX MINO Sensor (grey) into the instrument.**

**Caution!**

When not in use, the QC Sensor should be stored in the plastic bag provided. The same storage conditions as for NIOX MINO Sensor apply.

36. Reconnect NIOX MINO to the power supply and wait (approx. 5 minutes) before the instrument is ready for measurements.

- NIOX MINO may now be used for  $FE_{NO}$  measurements, **but a twinkling star to the left of the breathing cloud on the display indicates that the instrument is not qualified for clinical use.**
- You must perform the Biological Control Tester Qualification for two more days and run the first Daily QC on the fourth day in order to have the instrument qualified.
- A star <sup>1\*</sup> is also added in front of a  $FE_{NO}$  measurement result if measurements are performed with an unqualified NIOX MINO instrument or sensor.

# Qualification Day 2 and Day 3

1. A twinkling star to the left of the breathing cloud indicates that NIOX MINO is not validated for clinical use.
2. Perform the *Biological Control Tester Qualification* step 4-10, Qualification Day 1 (see page 5).
3. Remove the **white** personal NIOX MINO® QC Card and insert the **blue** NIOX MINO Test Card.
4. Press the return arrow.



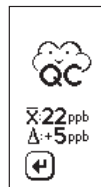
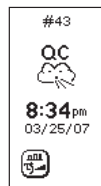
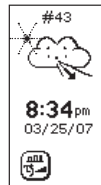
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## Note!

- **Qualification Day 3: If the mean value of the three qualification results (Day 1-3) does not fall between 10-40 ppb the error message E1210 is shown instead of the measurement result. Restart Biological Control Tester qualification from Qualification Day 1, with the same QC Card.**
  - Measure the environmental (ambient) level of NO if there is a big difference between two measurements. See NIOX MINO User Manual for instructions for how to measure ambient NO. If ambient is > 50 ppb, postpone individual measurement until ambient is < 50 ppb.
  - Measurements can be performed at any time of the day. However it is recommended that measurements are performed at the same time every day, e.g. if your first qualification measurement was performed in the morning, all subsequent measurements should also be performed in the morning.
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# Qualification Day 4

1. A twinkling star to the left of the breathing cloud indicates that NIOX MINO® is not validated for clinical use. The first Daily QC should be performed following the steps below.
2. Remove the **blue** NIOX MINO Test Card (if inserted).
3. Insert the **white** personal NIOX MINO QC Card.
4. The QC and breathing cloud icon indicates that the Biological Positive Control should be performed.
5. Attach a NIOX® Filter.
6. Touch the display to activate the instrument.
7. Measure  $FE_{NO}$  according to step 8, Day 1 (page 6).
8. Wait for result.
9. Enter the Moving Mean value ( $\bar{X}$ ) and the Difference value ( $\Delta$ ) (see Definitions, page 17) into the Biological Control Tester Log (see page 15).
10. The test result is approved if the **Moving Mean value is between 10 – 40 ppb** and the **Difference is within  $\pm 10$  ppb** of the currently valid Moving Mean value.
11. When the measurement is approved. Remove the **white** personal NIOX MINO® QC Card.
12. Reinsert the **blue** NIOX MINO Test Card.
13. Press the return arrow.
14. The first Daily QC is finalized and NIOX MINO is validated for clinical use.



**If the test result is not approved, see page 12.**

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**Note!**

If the candidate Biological Control Tester's value does **not** fall between 10– 40 ppb or if the difference is **more than**  $\pm 10$  ppb restart the Biological Positive Control from step 2 (see page 11) with another Biological Control Tester:

- The Biological Positive Control is approved if that Tester's measurement is approved according to the criteria above.
- NIOX MINO should be taken out of service if also the second Biological Control Tester's result is not approved.

Also check if the Biological Control Tester has:

- Any kind of allergy? Allergy may cause higher than normal values.
- Any cold?
- Eaten any nitrate-rich food?
- Taken any anti-inflammatory drug?
- Exercised in the past hour?

If only one Biological Control Tester is available, and the measurement is not approved, NIOX MINO should be temporarily removed from use until another Tester is available and the Quality Control Procedure can be repeated. Restart the Biological Control Tester Qualification from step 3, Qualification Day 1 to qualify another tester (see page 5).

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# Daily QC – Biological Positive Control

The **Daily QC** is a Biological Positive Control measurement ( $FE_{NO}$ ). This has to be performed by a Biological Control Tester and is prompted for every day when the instrument is to be used and before measurements are performed with patients.

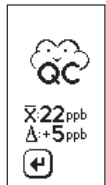
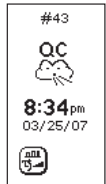
1. A twinkling star to the left of the breathing cloud indicates that NIOX MINO is not validated for clinical use and the **Daily QC** should be performed. **Only one Daily QC can be performed each day.**
2. Remove the **blue** NIOX MINO® Test Card (if inserted).
3. Insert the **white** personal NIOX MINO QC Card.
4. The QC and breathing cloud sign indicates that the Biological Positive Control should be performed.
5. Attach a NIOX® Filter.
6. Touch the display to activate the instrument.
7. Measure  $FE_{NO}$  according to step 8, Day 1 (page 6).
8. Wait for result.
9. Enter the Moving Mean value ( $\bar{X}$ ) and the Difference value ( $\Delta$ ) (see Definitions, page 17) into the Biological Control Tester Log (see page 15).
10. The test result is approved if the **Difference is within  $\pm 10$  ppb** of the currently valid Moving Mean value.
11. When the measurement is approved. Remove the **white** personal NIOX MINO QC Card.
12. Reinsert the **blue** NIOX MINO Test Card.
13. Press the return arrow.
14. The Daily QC is finalized and NIOX MINO is ready for  $FE_{NO}$  measurements.

## **Note!**

If the Difference is more than  $\pm 10$  ppb restart the Biological Positive Control from step 2 with another Biological Control Tester:

- The Biological Positive Control is approved if that Tester's measurement is approved according to the criteria above.
- NIOX MINO should be taken out of use if also the second Biological Control Tester's result is not approved.

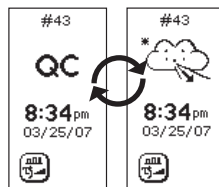
If only one Biological Control Tester is available, and the measurement is not approved, NIOX MINO should be temporarily removed from use until another Tester is available and the Quality Control Procedure can be repeated. Restart the Biological Control Tester Qualification from step 3, Qualification Day 1 to qualify another tester (see page 5).



# Full QC

The Full QC should be done by a Biological Control Tester and is prompted for:

- When a new instrument is used for the first time.
- Every time a new NIOX MINO<sup>®</sup> Sensor has been inserted.
- After every 45 measurements or every 7 days, whichever comes first.



## Note!

**If a Daily QC is already performed and a Full QC alert is shown the same day:**

1. Remove the **blue** NIOX MINO Test Card (if inserted).
2. Insert the **white** personal NIOX MINO QC Card
3. Perform step 12-36 from *Qualification Day 1*, (see page 7-9).

1. An alternating QC icon / breathing cloud with a twinkling star indicates that the **Full QC** should be performed.
2. Perform step 2-10 from Daily QC (see page 13). (*Biological Positive Control*)
3. Press the return arrow and perform step 12-36 from Qualification Day 1 (see page 5). (*Nitric Oxide free sample using NIOX MINO QC Filter and Simulated exhaled breath samples using NIOX MINO QC Sensor*)

## Additional QC measurements

An optional Full QC may be run instead of a Daily QC. Follow the instructions for the Full QC when the Daily QC is prompted. If the Daily QC already has been performed during the day and a NIOX MINO<sup>®</sup> QC card is re-inserted the Full QC will start from Step 12, Qualification Day 1 *Nitric Oxide free sample using NIOX MINO QC Filter*.

# Qualification of the Biological Control Tester

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**Note!**

The *Biological Control Tester Log* can be found in the NIOX MINO<sup>®</sup> QC Log book. The Biological Control Tester Log is a personal log. A new log is required for each Tester.

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Before you can use NIOX MINO with patients, a staff qualification procedure for the Biological Positive Control must be run. In this procedure, normal values are established for the Testers (staff members) who will perform the Biological Positive Control.

A minimum of one individual, but two individuals are recommended, need to qualify for this procedure. If possible identify a third individual to be a back-up.

A candidate Biological Control Tester will be qualified over the course of three days. Measurement values must be entered into the Biological Control Tester Log.

In order to stay qualified, a tester should make weekly measurements and enter the measurement value into the Biological Control Tester Log. A Biological Control Tester can perform the QC procedures on several NIOX MINO instruments.

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**Note!**

If the most recent Biological Positive Control measurement is older than a month, then the qualification is suspended and the Tester needs to re-qualify according to the qualification procedure. In this case a new Biological Control Tester Log should be used.

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## Selection of test persons

Identify the staff members that will be used for the Biological Control and who fulfill the following criteria:

- Over 18 years of age.
- No ongoing cold or known airway disease.
- No asthma diagnosed.
- Non smoker.
- Expected  $FE_{NO}$  values between 10 and 40 ppb.
- Preferably no allergy (except seasonal, see below).

Consider the following in order to obtain reliable results.

Before any measurement:

- Avoid nitrate rich food within 3 hrs before the measurement.
- Avoid any strenuous exercise at least 1 hour before the measurement.

Preferably do not perform a measurement in case of:

- Ongoing cold.
- Acute seasonal allergy.

## Qualify additional Biological Control Testers


You can qualify additional Biological Control Testers simultaneously with the first tester.

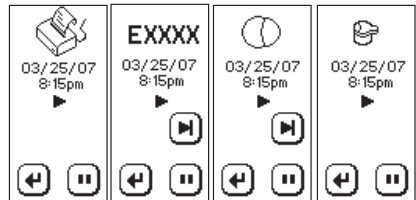
1. Perform step 3-10 from Qualification Day 1 (see page 5)
2. Remove the QC Card (white) and insert the Test Card (blue)
3. Perform steps according to Qualification day 2 to Qualification Day 4 (see page 10)

## Service print-outs

The QC measurement results can be found in the Service print-out listed after the error log and ambient measurement results. See NIOX MINO<sup>®</sup> User Manual on how to use the optional printer.

```
...
Error log:
03/15/06  5.23pm  E2106
...
Ambient results:
07/10/06  7.12am  <5ppb
09/12/06  9.56am  7ppb
...
QC measurements:
06/08/06  1.05pm  14ppb
06/08/06  1.08pm  75ppb
...
```

A skip button  will appear when the error log starts printing, during the print-out procedure, allowing the user to move to the ambient list. When the ambient list is printing it will allow the user to move to the QC list. There will also be a symbol indicating which list is currently subject for printing.



# Technical information

## Definitions

### QC:

Quality Control.

### NIOX MINO<sup>®</sup> QC Procedure:

Includes the Daily External QC Procedure and the Full External QC Procedure.

### Moving Mean:

First mean value is calculated from a candidate Biological Control Tester's first three qualification measurements. The next Moving Mean value is calculated when the Biological Control Tester performs a Daily or Full QC procedure after 7 to 30 days. The currently valid moving mean is presented on the NIOX MINO screen following a Biological Positive Control.

### Difference Value:

The difference between the measured  $FE_{NO}$  value and the currently valid moving mean during a Biological Positive Control.

### Biological Positive Control:

A  $FE_{NO}$  measurement by a Biological Control Tester compared to the currently valid Moving Mean to validate the NIOX MINO instrument and sensor. Performed during the Daily and Full QC Procedure.

### Biological Control Tester:

A person qualified to perform the Biological Positive Control measurements of the QC Procedure (preferably a member of the staff). The person must pass the initial three day qualification procedure to become an approved Biological Control Tester (see page 15).

### Biological Control Tester Log:

A log to enter the values from the Biological Positive Control measurements from the quality control procedures.

### Daily External Quality Control Procedure:

The **Daily QC** is a Biological Positive Control measurement ( $FE_{NO}$  measurement) this has to be done by a Biological Control Tester and is prompted for every day when the instrument is used and before measurements are performed with patients.

### Full External Quality Control Procedure:

The **Full QC** should be done by a Biological Control Tester and is prompted for:

- When a new NIOX MINO is used for the first time.
- Every time a new NIOX MINO Sensor has been inserted.
- After every 45 measurements or every 7 days, whichever comes first.

### NIOX MINO QC Card:

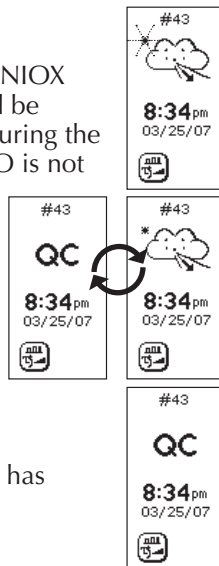
Personal card to activate the Quality Control Procedures and save Biological Positive Control measurement and qualification data.

Three QC cards are provided.



## Quality Control Alerts

- A twinkling star to the left of the breathing cloud indicates that NIOX MINO is not validated for clinical use and the Daily QC should be performed. (See Daily QC, page 13). (This icon is also shown during the Biological Control Tester qualification period when NIOX MINO is not qualified for clinical use.)
- An alternating QC icon / breathing cloud with a twinkling star indicates that a Full QC has to be performed. (See Full QC, page 14).
- A fixed QC icon indicates that the countdown time (see below) has expired and the instrument is locked.



### Note!

When the first  $FE_{NO}$  measurement is performed after a Full QC alert has been displayed (see above), a 24h countdown timer is started. During these 24 hours, the alert is continuously shown, and it is still possible to perform normal  $FE_{NO}$  measurements. **When the countdown time expires, a lock-out state is entered and no measurements can be performed.** The mandatory Full QC must then be run, see page 14. (This will only happen in case the Full QC has not been performed within the 24 hours.)

## Troubleshooting - Error codes

These error codes are specific for the Quality Control Procedure. For other error codes, refer to the *Error Codes* section in the *NIOX MINO® User Manual*.

Error messages and other information are shown as a code at the top of the unit display. (See example to the right.) The table below gives information on how to act upon an error code. If error persists, contact **Aerocrine Inc.**



Code	Action
E1210	The mean value of the three qualification results does not fall between 10-40 ppb. Restart Biological Control Tester qualification from Qualification Day 1. (With the same QC Card)
E2201	Result not within acceptable ranges. Press the return arrow and repeat the procedure.

E2204	Indicates that you might have forgotten to press the button on the QC sensor within 5 seconds of correct exhalation. Press the return arrow and repeat the procedure with QC Sensor set on 15ppb.
E2205	Indicates that you might have forgotten to press the button on the QC sensor within 5 seconds of correct exhalation. Press the return arrow and repeat the procedure with QC Sensor set on 75ppb.
E2210/11	Result out of range. Press the return arrow and repeat the procedure with QC Sensor set on 15ppb.
E2212/13	Result out of range. Press the return arrow and repeat the procedure with QC Sensor set on 75ppb.
E2214	FE <sub>NO</sub> value too low for the Biological Positive Control.
E2217	Result to high (>5ppb). Press the return arrow and repeat QC Filter procedure.
E2301-19	Remove any sources of disturbance (such as cordless or mobile telephones, or gas emitting appliances). When the unit is ready for measurement, try to repeat measurement. If error persists, unplug and connect power supply to restart unit.
E2320	Indicates that there could be something seriously wrong with the instrument; it may give falsely low FE <sub>NO</sub> values. Do not take any clinical decisions based on a value from an instrument that has shown error code E 2320.
E2322	Unplug and connect power supply to restart unit.
E5010–32	Check QC Card and that it is correctly inserted. Try with another card.

## Measurements not validated for clinical use

All FE<sub>NO</sub> measurement results marked with a star '\*' should be considered as not validated for clinical use.

The star is added in front of a FE<sub>NO</sub> measurement result if measurements are performed with a NIOX MINO<sup>®</sup> instrument or sensor that is not validated, i.e. if:

- Quality Control measurements are performed by a person not qualified as a Biological Control Tester.
- The Daily QC is not performed.
- The alert for the Full QC is shown prior to the measurement.
- The Difference from the currently valid Moving Mean is more than 10 ppb when the Biological Positive Control is performed.
- Special Mode (6 second exhalation) is used.





Information in this document is subject to change.  
Amendments will be made available by Aerocrine AB as they occur.

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Based on the company's intellectual property, Aerocrine develops and commercializes products for the monitoring of nitric oxide (NO) as a marker of inflammation, to improve the management and care of patients with inflammatory disease in the airways.

Patents:

US 5,447,165. US 5,922,610. US 6,038,913. US 6,063,027. US 6,099,480.  
US 6,149,606. US 6,183,416. US 6,511,425. US 6,626,844. US 6,723,056.  
US 6,733,463. US 6,761,185. US 7,014,692. US 7,270,638. US D448,693.  
US D457,231. US D492,035. US D496,667 and patents pending.

**Aerocrine**



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