

Attachment 4 Exhaled Nitric Oxide SOP

NIOSH/RHD

FeNo Station Instructions

Equipment Information

1. Ensure that there are no electronic devices (including mobile phone) near the NIOX MINO, as this may interfere with sampling.
2. Keep the unit away from windows, sunshine, or radiators to avoid unstable conditions.
3. Be in the habit of noting the number of tests remaining on the sensor and checking the expiration dates of the sensor, machine, and filters.

Setting Up (first day)

1. Make sure sensor is secure at the bottom of the unit:





2. Plug in the NIOX MINO.
3. Allow the NIOX MINO to warm up and stabilize (up to 30 minutes, usually 5-10 minutes).



4. When the NIOX MINO is ready for use, the screen shows a smiling cloud with the time.
5. Touch the display screen. The NIOX MINO is ready for measurement when the blue light on top is lit and the screen shows a blowing cloud.


QC Checks (beginning of each shift)

1. At the beginning of each shift, perform an ambient NO check.

2. Attach a new patient filter to the unit. Press the mode button  and then press the Ambient  measurement button.

3. Wait for approximately 4 minutes (you will see a countdown on the display) and then record the value on the top of the log sheet.

4. At the beginning of each shift, the tech will perform a calibration they will be using.


5. Press the mode button and then press the QC  button



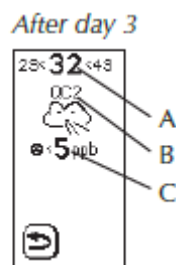
6. Select your assigned QC tester number using the number pad.

7. Perform a normal FeNO test.

8. Remove the filter and immediately attach the red QC plug.

9. Press the forward icon  on the display. Wait approximately 5 minutes for the analysis to complete and the result to be displayed.

- A. Positive control result: FeNO value and limits (mean value +/- 10 ppb)
- B. QC tester number
- C. Negative control result (should be < 5 ppb)



10. If either the positive or negative control fails have one of the other QC testers perform the QC test.
- 11.

Subject Testing

1. Ask the worker the exclusion question on the back of their control card: “Do you have a breathing problem requiring oxygen or problems taking deep breaths?” If the answer is yes, thank them and tell them they do not need to complete this test.
2. Fill in the log sheet for the subject, including answering the questions and making a note of any medications, recent illnesses, and any nitrate rich foods eaten recently.
3. Review the exhaled NO procedure with the subject.

4. Enter the subject ID by selecting the ID button on the main screen:



- a. Input the subject ID using the number buttons— this is on the control card
- b. Select OK to accept the ID. You will now see the ID at the top of the main screen.

5. Ask the subject to place a clean filter into the port on the machine.

6. Have the subject sit in a chair facing the mirror. Make sure the screen is in Ready for Measurement Mode and you can see the Subject ID at the top of the screen

- a. Empty lungs prior to beginning—do not place mouth on mouthpiece.



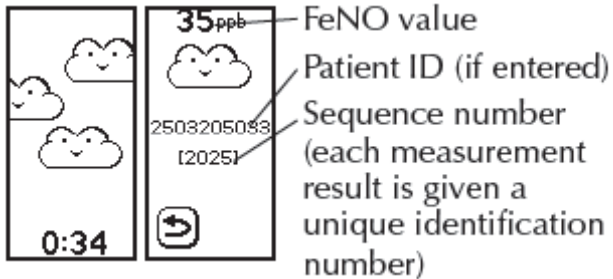
- b. Place mouth on mouthpiece and create a tight seal. Inhale deeply through the filter to total lung capacity (i.e., breathe in and fill lungs completely). The cloud will inflate.



- c. Exhale normally and evenly through the filter for 10 seconds, keeping the cloud in the middle of the screen. During exhalation, coach the participant and let them know if they should be breathing harder or softer to keep the cloud in the center. Also let them know when they are half way or almost done (use bar underneath the cloud as a guide) with their exhalation.



7. If the measurement is good, the screen will display a cloud scene and the timer will start counting down from one and a half minutes.



- a. When the result is ready, the unit will “chime” and the reading will appear on the screen (in ppb).
- b. **Record the measurement on the Log Sheet.** The NIOX MINO will also store the data. To access the data, select the Mode and then Measurement:

Select Mode



Select Measurement results



- c. Press the “Return” icon to go back to the main menu.



8. If the measurement is bad, the screen will display an error code (beginning with “E”). Please refer to manual to see list of error codes.

- a. Record the error code on the log sheet and explain to the subject what they need to do differently on the next trial.
- b. Press the “Return” icon to go back to the main menu.



9. Repeat the test up to **6 times** until each subject records **one good measurement**.

Note:

Leave the unit plugged in at all times, otherwise you will have to wait for it to stabilize upon reconnection, which may take up to 30 minutes.

- 1.

Script for coaching:

At this station, we are going to measure inflammation in your lungs. First, you will breathe out all the way, not using the machine. Then you will place your mouth on mouthpiece and create a tight seal. Take a full breath in through the machine. Then breathe out evenly through the filter until I tell you to stop (about 10 seconds). You will watch the screen in the mirror and you will see a cloud on the display. Try to keep the cloud in the middle of the shaded area. If the cloud is at the top of the screen you are blowing too hard and if the cloud is at the bottom of the screen you are not blowing hard enough. I will coach you through the procedure. Do you have any questions?

1. Breathe out as much as possible. Empty your lungs
2. Now put the mouthpiece in your mouth and take a deep breath in
3. And blow out steadily... keep going... keep going...
4. Stop.