Remember
It is important to adhere to the following specified conditions:

• Ambient temperature: +10°C to +35°C
• Humidity: 20% to 80% RH (non-condensing)
• Mobile phones, cordless phones and gas emitting appliances might interfere with the instrument and should therefore be kept away from the instrument. Interference could make it impossible to perform a measurement.
• Exhaled breath contains water vapor which can condense inside the instrument. When excessively used in a short period, there is a risk for condensation of water inside NIOX VERO®. Normally a maximum of 10 exhalations/hour can be performed with NIOX VERO® during continuous use. However, it is possible to perform 20 exhalations in one hour if the instrument is paused for a minimum of 30 minutes prior to the next session of exhalations. Exhalations include failed and successful measurements.
• Avoid spilling water or other fluids on the instrument or Sensor.
• Always use a closed case or bag (NIOX VERO® bag recommended) for transportation and storage of NIOX VERO®.
• It is recommended, after inserting a new sensor, to wait for three hours with the instrument switched on before performing a measurement.
• Operational life-time for NIOX VERO® Instrument: Maximum 5 years in use or 15 000 measurements or the expiration date stated on the device, whichever comes first.
• Operational life-time for NIOX VERO® Sensor: Maximum 12 months after opening package and installed in NIOX VERO® or expiration date as stated on the Sensor, whichever comes first.

WARNING!
Use of substances containing alcohol close to the NIOX VERO® instrument may cause erroneous measurement results.

DO NOT clean the instrument or handle with alcohol or any spray or wipe containing alcohol!

Do not use substances containing alcohol on or close to the NIOX VERO® instrument. This includes any cleaning agents used to clean the facility, or other equipment in the area, as well as alcohol wipes or sprays used on patients.

CAUTION!: Do not use NIOX VERO® in the proximity of areas where volatile substances such as organic fluids or disinfectants are being used. Special attention should be paid to aerosols and disinfection baths, either open vessels or ultrasonic baths.

Refer to the NIOX VERO User Manual for complete review of all cautions, warnings, preventive care and troubleshooting.
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Chapter 1 NIOX VERO® Nasal measurement mode

1 NIOX VERO® Nasal measurement mode

1.1 Before using NIOX VERO®
NIOX VERO® may only be operated as directed in this manual by trained healthcare professionals. Trained status is achieved only after careful reading of this manual. Read the entire instructions for use and make certain that you fully understand the safety information.

This is an amendment to the NIOX VERO User Manual. Carefully read the NIOX VERO User Manual and the NIOX VERO® Nasal Measurement Mode User Manual before performing NIOX VERO Nasal measurements.

1.2 About this manual
For instruction on how to view the software version number installed in the instrument, refer to the NIOX VERO User Manual.

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

This User Manual provides instructions on how to operate NIOX VERO® in Nasal Measurement mode.
It contains numbered step-by-step instructions with screens and illustrations. Choices within steps are displayed with bullet points.

1.3 Compliance
NIOX VERO® and NIOX® Panel are CE-marked according to In Vitro Diagnostics Device Directive 98/79/EC.
NIOX Patient filter is CE marked according to Medical Devices Directive 93/42/EEC
NIOX VERO® is RoHS compliant.

1.4 Responsible manufacturer and contacts
Mailing address:
Circassia AB, P.O. Box 3006
SE-750 03 Uppsala, Sweden

Visiting address:
Hansellisgatan13
SE-754 50 Uppsala

www.circassia.com
www.niox.com

1.5 Warnings

- Do not use substances containing alcohol on or close to the NIOX VERO® instrument. This includes any cleaning agents used to clean the facility, or other equipment in the area, as well as alcohol wipes or sprays used on patients.

Chapter 1 NIOX VERO® Nasal measurement mode

- NIOX VERO® should only be operated by healthcare professionals.
- Operate NIOX VERO® as stated in this manual. Circassia accepts no responsibility for damaged equipment or faulty results, if the equipment is not handled according to this manual.
- When selecting an accessory for your NIOX VERO® product keep in mind that an accessory not recommended by Circassia AB may result in loss of performance, damage to your NIOX VERO® product, fire, electric shock, injury or damage to other property. The product warranty does not cover product failure or damage resulting from use with non approved accessories. Circassia takes no responsibility for health and safety problems or other problems caused by the use of accessories not approved by Circassia.
- NIOX VERO® should not be used adjacent to or stacked with other electronic equipment.
- Only use the power supply provided. Pull the plug when disconnecting NIOX VERO® from the power outlet.
- Use only the breathing handle supplied by Circassia.
- No modification of NIOX VERO® instrument, handle or Sensor is allowed.
- Do not drop the instrument or subject it to strong impact.
- Do not use a damaged NIOX VERO® instrument or damaged components.
- Keep the instrument and Sensor out of water. Ensure that no liquid is spilled or dropped on the instrument or Sensor.
- Do not heat or dispose of the instrument or Sensor in fire. Refer to “Disposal of instrument and accessories” on.
- NIOX VERO® and the NO scrubber in the breathing handle contains potassium permanganate. Used or expired instruments and breathing handles should be disposed of as hazardous waste in accordance with local waste disposal regulations.
- The breathing handle must not be used after expiration date.

- Patient filters should be used immediately after opening.
- NIOX VERO® Sensor contains chemicals that could be harmful if swallowed.
- Be careful when opening the Sensor can. The inside of the opening may have sharp edges.
- Do not touch or clean the white Sensor membrane.
- After inserting a new Sensor it is recommended to wait for three hours with the instrument switched on before performing a measurement.
- Make sure to use the correct measurement mode, otherwise incorrect measurement results might be obtained.
- Do not reuse patient filters.
- Do not use NIOX VERO® in the proximity of areas where volatile substances such as organic fluids or disinfectants are being used. Special attention should be paid to aerosols and disinfection baths, either open vessels or ultrasonic baths. Do not use the instrument in the presence of flammable anesthetic, vapors or liquids.
- Nasal Kit should be used immediately after opening.
- Do not reuse Nasal Kit.

1.6 Intended Use

NIOX VERO® measures Nitric Oxide in human breath (Fractional exhaled Nitric Oxide, FeNO) and Nasal Nitric Oxide (nNO) in the aspirated air from the nasal cavity.

FeNO

FeNO is increased in some airway inflammatory processes such as asthma and decreases in response to anti-inflammatory treatment. FeNO measurements with NIOX VERO are quantitative, non-invasive, simple and safe and should be used as part of regular assessment and monitoring of patients with these conditions. NIOX VERO is suitable for patients age 4 and above for FeNO measurements.
As measurement requires patient cooperation, some children below the age of 7 may require additional coaching and encouragement. NIOX VERO should be used as directed in the NIOX VERO User Manual.

- **CAUTION!** NIOX VERO for FeNO measurement can be operated with two different exhalation times, 10 seconds and 6 seconds. The 10 second test is the preferred mode. For children who are not able to perform the 10 second test, the 6 second test is an alternative. The 6 second test should be used with caution in patients over the age of 10 years. It should not be used in adult patients. Incorrect use of the 6s exhalation mode may result in falsely low FeNO values, which can lead to incorrect clinical decisions.

**nNO**

Nasal Nitric Oxide has been shown to be decreased in patients with Primary Ciliary Dyskinesia (PCD), and measurement of nNO can assist in the identification of cases of PCD according to ERS guidelines1.

Measurement of nNO with the NIOX VERO Nasal Measurement Mode is non-invasive, simple, safe and repeatable in patients age 5 and above when measured according to the NIOX VERO Nasal Measurement Mode User Manual. Suspected cases of PCD following screening with nNO should be confirmed according to published recommendations for PCD diagnosis and management.


---

**2 Product description**

**2.1 Nasal accessories and parts**

(A) NIOX VERO® Nasal Kit, Article No 12-1065 Pediatric, 12-1045 Adult,
(B) NIOX VERO® Nasal Restrictor, Article No 12-1033 (for use together with NIOX VERO® Patient filter)

**2.2 NIOX VERO® accessories and parts**

(C) NIOX VERO® Breathing Handle, Article No 12-1010 (supplied with NIOX VERO®)
(D) NIOX VERO® Patient Filter, Article No 12-1018 (supplied separately)
Chapter 3 Nasal NO measurements

2.3 Main View

(A) Status bar, (B) Instructive demonstration, (C) Patient ID, (D) Main menu, (E) Start measurement button

2.3.1 Main menu

(a) Measurement mode 10s/6s, (b) Nasal measurement mode, (c) Demo, (d) Patient ID entry, (e) Settings

3 Nasal NO measurements

Nasal measurements can be performed either using the Tidal Breathing (TB-nNO) method or by the velum closed with Expiration against Resistance (ER-nNO) method. Nasal measurements can be performed either on the left or the right nostril.

3.1 Preparation for Nasal (nNO) measurement

Verify proper preparations before performing a nasal measurement with NIOX VERO®. A basic preventive inspection is recommended before each use, refer to the NIOX VERO User Manual.

Note: Measurements can be performed without NIOX Panel software, however, if done, there is no graph available. Only the value will show on the display screen.

3.1.1 Attach the Nasal Kit to NIOX VERO instrument

1. Place the device on its side on a level secure surface.
2. Disconnect the breathing handle from the instrument by pushing the socket into the device and gently pull out the tube.
3. Take the nasal kit, remove the cap from the end of the tube and push it into the breathing handle port slowly until the triangle is no longer visible.

**Note:** There is lubricant on the end of the tube for easier attachment to the NIOX VERO.

**Note:** The triangle should not be visible when assembled correctly.

3.2 Perform Nasal measurement

Nasal measurements can be performed with either Expiration against Resistance (ER-nNO) method (see section 3.3) or Tidal Breathing (TB-nNO) method (see section 3.4).

**Note:** Make sure patient does not inhale by nose during the nasal measurement.

**Note:** The patient should not perform nasal NO measurements if there is evidence of blood in the nostrils.

**Note:** Prior to performing nasal NO measurements, the patient should be comfortably seated and have thoroughly cleared the nasal passage.

**Note:** There are two phases of the nasal measurements. A measurement period where the instrument aspirates for 30 seconds, and an analysis period where the instrument analyses the sample for 30 seconds.
Chapter 3 Nasal NO measurements

**Note:** Performing a nasal measurement without using the NIOX Panel (see section 4.3, Perform Nasal measurements with NIOX® Panel) will not produce a graphical result, it will only give the numerical result of nasal nitric oxide measurement on the NIOX VERO screen.

**CAUTION!** Make sure to use the correct size olives, the seal between the olive and nostril must be airtight to ensure correct measurement result.

(A) Nasal Olive Adult, (B) Nasal Olive Pediatric

**CAUTION!** Do not insert the Nasal Olive inside the nostril. The larger part of the Nasal Olive should remain outside the nostril.

(A) Nasal Olive Adult, (B) Nasal Olive Pediatric

**CAUTION!** Ensure that the sampling hole in the Nasal Olive is aligned with the nasal passage and not blocked. A blocked sampling hole will influence the measurement result.

**Note:** If an error occurs see “Alert codes and actions” on page 11.
Chapter 3 Nasal NO measurements

3.3 Expiration against Resistance (ER-nNO)

ER-nNO Nasal measurements shall be performed while exhaling through the mouth towards a restrictor (breathing handle), this generates a pressure that makes sure the velum is closed. The NIOX VERO Breathing Handle with a patient filter and the NIOX VERO restrictor is used as the restrictor in this breathing method. The breathing handle is NOT connected to the NIOX VERO when used in this manner.

1. Open a new Patient Filter and insert an new Nasal Restrictor into the Patient Filter, so that it rests on top of the white filter pad.

Note: Do not use the Patient Filter without the NIOX VERO Nasal Restrictor.

Note: Use the Patient Filter directly after it has been opened.

Note: The Patient filter and the restrictor is for single patient use only.

2. Attach the Patient Filter to the Breathing Handle until it clicks into place.

3. Give the breathing handle to the patient, put the Olive to the selected nostril and instruct the patient to inhale to total lung capacity and to begin exhaling into the patient filter once their lips are tightly sealed around it. The patient will have to exhale steadily and continuously for 30 seconds.
Chapter 3 Nasal NO measurements

4. Start Nasal measurement by selecting the Nasal icon (A)

5. Enter patient ID (optional) and then start the nasal measurement by pressing the start measurement button (B)

Note: If measurement is started before patient is ready, there is an option to abort measurement, it is not recorded as a measurement on sensor or instrument.

6. The instrument will aspirate for 30 seconds, and then will start to analyze the sample. After the aspiration is complete, remove nasal olive from the nostril and wait for the result.
3.4 Tidal Breathing (TB-nNO)
TB-nNO measurements shall be performed while breathing normally through an open mouth.

1. Put the Olive to the selected nostril and instruct the patient to slowly inhale and exhale through the mouth.

2. Start Nasal measurement by selecting the Nasal icon (A)

3. Enter patient ID (optional) and then start the nasal measurement by pressing the start measurement button (B)

Note: If the measurement is started before patient is ready, there is an option to abort measurement, it is not recorded as a measurement on sensor or instrument.

4. The instrument will aspirate for 30 seconds and then will start to analyze the sample. After the aspiration is complete, remove nasal olive from the nostril and wait for the result.

3.5 Alert codes and actions

<table>
<thead>
<tr>
<th>User alerts</th>
<th>Screen</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>A28</td>
<td><img src="A28.png" alt="Image" /></td>
<td>Internal hardware error recoverable&lt;br&gt;Check that the Sensor, battery and lid is in its correct position, also make sure that the tube is not folded. When finished restart the instrument.</td>
</tr>
<tr>
<td>A29</td>
<td><img src="A29.png" alt="Image" /></td>
<td>Analysis failure&lt;br&gt;Ambient measurement failure. Click the OK button and obtain a new measurement.</td>
</tr>
</tbody>
</table>

For additional alert codes, refer to the NIOX VERO User Manual.
Chapter 4 Nasal measurements with NIOX® Panel

4 Nasal measurements with NIOX® Panel

Using NIOX Panel provides the ability to see the nNO measurement graphically, produce the file and print the results.

NIOX® Panel System requirements

- Windows® 7, Windows® 8 (RT versions excluded) or Windows® 10
- .NET Framework 4.5
- 1 GHz or faster processor
- 256 MB RAM (512 MB RAM recommended)
- 250 MB of video graphics RAM
- 250 MB of available hard-disc space
- 1024x768 screen resolution
- Generic Microsoft Bluetooth driver *

* Needed for Bluetooth communication

4.1 Installation of NIOX® Panel

The NIOX® Panel software is supplied on a USB storage device.

1. Insert the USB storage device in the computer's USB port.
2. Select the file named setup.exe.
3. If .NET Framework 4.5, VC++ 2013 or SQL Server Compact is not installed, an installation wizard for each of the programs opens, one at the time.
4. Select to accept license agreement for the programs.
5. Follow the instructions and wait for the programs to install.
6. The Installation wizard for NIOX® Panel Nasal opens.
7. Follow the instructions and install the program.

Note: Last step of installation “Removing backup files” takes a few minutes.

8. When the installation is complete, click Close. The application is now available on the start menu.

4.2 Setup

1. Turn on the PC and monitor.
2. Turn on the instrument.
3. Select the Start or the Windows button normally found in the left lower hand corner of the monitor.
4. Select NIOX® Panel from the program list.
5. Plug the USB cable into the USB port on the NIOX VERO® and connect it to the USB port on the PC or connect by Bluetooth. This icon is shown on the display to indicate that a connection is established and NIOX VERO® is running remote controlled.
6. The NIOX® Panel application opens and it is possible to perform Nasal NO measurements.

4.3 Perform Nasal measurements with NIOX® Panel

*Note:* The buttons, symbols and views are similar on NIOX® Panel and on NIOX VERO®.

1. To enter patient ID, select patient id button. (A)

2. Select Nasal button. (B)

3. Select which expiration method to use, ER-nNO (see section 4.3.1) or TB-nNO (see section 4.3.2) and which nostril, left or right, patient age is optional.

4. Select which file format to save measurement curve, .xlsx, pdf or both. If the pdf file is chosen, an excel file is saved in the NIOX Nasal Measurements folder on the computer's Desktop.
Chapter 4 Nasal measurements with NIOX® Panel

4.3.1 Expiration against Resistance (ER-nNO)

ER-nNO Nasal measurements shall be performed while exhaling through the mouth towards a restrictor (breathing handle), this generates a pressure that makes sure the velum is closed. The NIOX VERO Breathing Handle with a patient filter and the NIOX VERO restrictor is used as the restrictor in this breathing method. The breathing handle is NOT connected to the NIOX VERO when used in this manner.

1. Open a new Patient Filter and insert an new Nasal Restrictor into the Patient Filter, so that it rests on top of the white filter pad.
2. Attach the Patient Filter to the Breathing Handle until it clicks into place.
3. Give the breathing handle to the patient, put the Olive to the selected nostril and instruct the patient to inhale to total lung capacity and to begin exhaling into the patient filter once their lips are tightly sealed around it. The patient will have to exhale steadily and continuously for 30 seconds.
4. Select start measurement button (A) to start an ER-nNO Nasal measurement with NIOX Panel.

Note: If measurement is started before patient is ready, there is an option to abort measurement, it is not recorded as a measurement on sensor or instrument.

Note: The y-axis does not show a nitric oxide value during the measurement and analysis periods. This is due to the entire sample having to cycle through the sensor (delayed analysis).

5. The instrument will aspirate for 30 seconds and then will start to analyze the sample. After the aspiration is complete, remove nasal olive from the nostril and wait for the result.

Note: By selecting the abort button (A) the measurement is canceled. This can be pressed in the measurement or analysis period to abort the measurement.
Chapter 4 Nasal measurements with NIOX® Panel

6. When selecting the OK button (B) an option to save the file will be shown.  
   **Note:** The measurement result will always be saved in the instrument memory.

7. A save dialog will be shown and an option to view the file.  
   **Note:** The Excel file has options to adjust width of the calculation area, or change the range of seconds used to calculate the measurement result.

   **Note:** The pdf-file shows the graph.
Chapter 4 Nasal measurements with NIOX® Panel

(A) Complete nNO curve data
- Blue line of graph
- 30 second aspiration measurement
- 30 second baseline measurement

(B) nNO calculation Range
- Orange section of graph
- nNO as calculated by NIOX VERO using clinically validated method

(C) Adjustable Calculation Area
- Grey section of graph

(D) nNO Value and Measurement information
- nNO in ppb
- Measurement Method (TB or ER)
- Nostril (L or R)

(E) User defined nNO Value
- Can change the adjustable calculation area
- Output is displayed in ‘red’ text

(F) Patient Information
- Patient ID
- Age
- Aspiration time (always 30sec)
- Date of Measurement
4.3.2 Tidal Breathing (TB-nNO)

TB-nNO measurements shall be performed while breathing normally through an open mouth.

1. Before selecting the start measurement button make sure to instruct the patient to slowly inhale and exhale through the mouth.

2. Select start measurement button to start a TB-nNO Nasal measurement with NIOX Panel.

   **Note:** If measurement is started before patient is ready, there is an option to abort measurement, it is not recorded as a measurement on sensor or instrument.

   **Note:** The y-axis does not show a nitric oxide value during the measurement and analysis periods. This is due to the entire sample having to cycle through the sensor (delayed analysis).

3. The instrument will aspirate for 30 seconds and then will start to analyze the sample. After the aspiration is complete, remove nasal olive from the nostril and wait for the result.

   **Note:** By selecting the abort button (A) the measurement is canceled. This can be pressed in the measurement or analysis period to abort the measurement.

4. When selecting the OK button (B) an option to save the file will be shown.

5. A save dialog will be shown and an option to view the file.
Chapter 4 Nasal measurements with NIOX® Panel

**Note:** The measurement result will always be saved in the instrument memory.

**Note:** The pdf-file shows the graph.

(A) Complete nNO curve data
- Blue line of graph
- 30 second aspiration measurement
- 30 second baseline measurement

(B) nNO calculation Range
- Orange section of graph
- nNO as calculated by VERO using clinically validated method

(C) Adjustable Calculation Area
- Grey section of graph

(D) nNO Value and Measurement information
- nNO in ppb
- Measurement Method (TB or ER)
- Nostril (L or R)

(E) User defined nNO Value
- Can change the adjustable calculation area
- Output is displayed in ‘red’ text

(F) Patient Information
- Patient ID
- Age
- Aspiration time (always 30sec)
- Date of Measurement
5 Cleaning procedure

![No Alcohol](image)

WARNING! DO NOT clean the instrument or handle with products containing alcohol. This includes sprays or wipes containing alcohol!

WARNING! DO NOT clean area immediately surrounding the NIOX VERO® with products containing alcohol. This includes sprays or wipes containing alcohol.

For cleaning of the instrument see NIOX VERO User Manual.

**Note:** NIOX Nasal Kit are disposable items for single patient use only.

- If the any part of the Nasal Kit appears clogged, replace the Nasal Kit
- The NIOX Nasal Kit is for single patient use and do not need any cleaning.

6 NIOX VERO® Nasal Technical Specification

6.0.1 Electromagnetic emissions

CAUTION! This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

For guidance and manufacturer’s declaration - electromagnetic emissions see www.niox.com

6.1 Performance data

Measurement range: 5 to 2000 ppb
Lowest detection limit: 5 ppb
Sampling flow rates: 5 ml/s

6.2 Linearity

Squared correlation coefficient $r^2 \geq 0.998$

6.3 Precision

$< 3$ppb of measured value for values $< 30$ ppb, $< 10\%$ of measured value for values $\geq 30$ ppb. Expressed as one standard deviation for replicate measurements with the same instrument, using a certified gas concentration of Nitric Oxide reference standard.

6.4 Accuracy

$\pm 10$ ppb for measured values $< 50$ppb or $20\%$ of measured value for values $\geq 50$ ppb. Expressed as the upper 95% confidence limit, based on absolute mean of differences from certified gas concentration of Nitric Oxide.
6.5 Essential performance

Essential performance for NIOX VERO Nasal Measurement Mode consists of:

1. The measurement of the NO concentration of air aspirated from the nasal cavity
2. The measurement of nasal NO for screening of diseases such as primary ciliary dyskinesia according to ATS/ERS

NIOX VERO contains internal monitoring functionality for safety and essential performance parameters. Recurrent testing is not necessary to maintain essential performance or basic safety.
Based on the company’s intellectual property, Circassia develops and commercializes products for the monitoring of nitric oxide (NO) as a marker of airway inflammation, to improve the management and care of patients with inflammatory disease in the airways.

Patents:

Circassia's NIOX products are protected by a number of patents in the US, Europe and a range of other countries.