

NIOX VERO®

Nasal Measurement Mode

User Manual



CE

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 vapour 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.
5 years in use shall be defined as starting from the first NO measurement taken using the device.

- 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.

Patient filters and nasal kits are labeled as single use only. Always use a new patient filter and nasal kit for each patient. Reuse between patients could increase the risk of cross-contamination or cross-infection. The same filter and nasal kit can be reused in one patient for multiple attempts in the same session.

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.

1 NIOX VERO® Nasal measurement mode	3	6 Safety information	20
1.1 Before using NIOX VERO®	3	6.1 Warnings.....	20
1.2 About this manual.....	3	6.2 Cautions.....	20
1.3 Compliance	3	6.3 Limited warranty.....	20
1.4 Responsible manufacturer and contacts	3	6.4 Support	20
1.5 Warnings	3	7 NIOX VERO® Nasal Technical Specification	21
1.6 Intended Use.....	4	7.1 Electromagnetic emissions	21
2 Product description	5	7.2 Performance data	21
2.1 Nasal accessories and parts	5	7.3 Linearity	21
2.2 NIOX VERO® accessories and parts.....	5	7.4 Precision	21
2.3 Main View.....	6	7.5 Accuracy	21
3 Nasal NO measurements	6	7.6 Essential performance	21
3.1 Preparation for Nasal (nNO) measurement.....	6		
3.2 Perform Nasal measurement	8		
3.3 Expiration against Resistance (ER-nNO).....	9		
3.4 Tidal Breathing (TB-nNO).....	11		
3.5 Alert codes and actions	11		
4 Nasal measurements with NIOX® Panel	12		
4.1 Installation of NIOX® Panel	12		
4.2 Setup.....	12		
4.3 Perform Nasal measurements with NIOX® Panel	13		
5 Preventive care	19		
5.1 General care NIOX VERO®.....	19		
5.2 Cleaning procedure	19		
5.3 Disposal of nasal kits.....	19		
5.4 Return shipments	19		





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.

Symbol	Description
WARNING	Indicates a potentially hazardous situation that, if not avoided, can result in bodily harm or injury.
CAUTION	Indicates a potentially hazardous situation that, if not avoided, can damage a product or system, cause loss of data or harm to business.
Note	Alerts the reader to important information on the proper use of the product, user expectations, error situations, and actions related to these.

1.2 About this manual

NIOX VERO® Nasal Measurement Mode User Manual - English 002346 version 05, February 2021.

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 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 VERO Patient filter and NIOX VERO Nasal kits are CE marked according to Medical Device Regulation
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:
Hansellsgatan 13
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.**



- 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 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.
- 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.
- Patient filters are labeled for single use only. Always use a new patient filter for each patient. Reuse between patients could increase the risk of cross-contamination or cross-infection. The same patient filter can be reused in one patient for multiple attempts in the same session.
- 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, vapours or liquids.
- Nasal kit should be used immediately after opening.
- Nasal kits are labeled for single use only. Always use a new nasal kit for each patient. Reuse between patients could increase the risk of cross-contamination or cross-infection. The same nasal kit can be reused in one patient for multiple attempts in the same session.

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. NIOX VERO is intended for near patient testing.

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

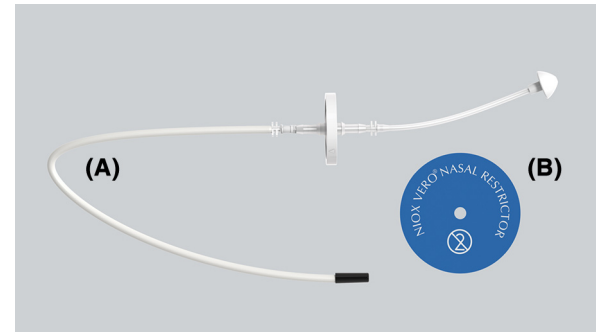


Measurement of nNO with the NIOX VERO Nasal Measurement Mode is non-invasive, simple, safe and repeatable in patients age 5 and above when measured according to the NIOX VERO Nasal Measurement Mode User Manual. Suspected cases of PCD following screening with nNO should be confirmed according to published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

¹. Lucas JS, Barbato A, Collins SA, et al. European Respiratory Society guidelines for the diagnosis of primary ciliary dyskinesia. *Eur Respir J* 2017; 49: 1601090

2 Product description

2.1 Nasal accessories and parts



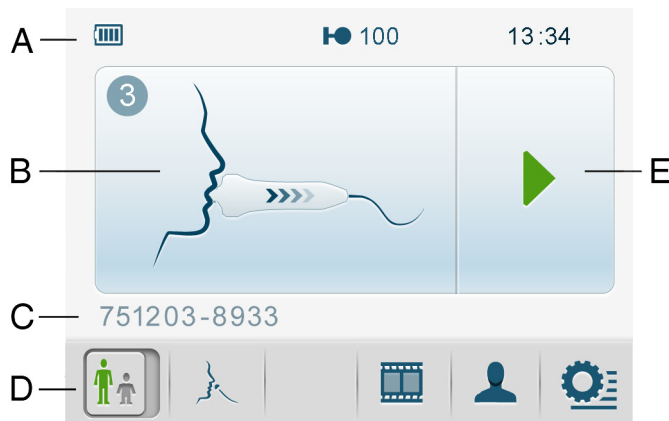
(A) NIOX VERO® Nasal Kit, Article No 12-1065 Pediatric, 12-1045 Adult,
(B) NIOX VERO® Nasal Restrictor, Article No 12-1033 (for use together with NIOX VERO® Patient filter)

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)

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.

WARNING! Always use a new nasal kit and patient filter (when using ER-nNO method) for each patient. Reuse between patients could increase the risk of cross-contamination or cross-infection. The same filter and nasal kit can be reused in one patient for multiple attempts in the same session.

3.1 Preparation for Nasal (nNO) measurement

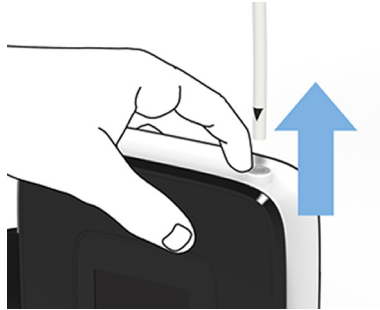
Verify proper preparations before performing a nasal measurement with NIOX VERO®. A basic preventive inspection is recommended before each use, refer to the NIOX VERO User Manual.

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.

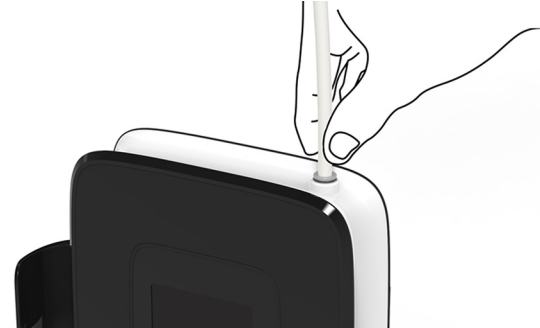
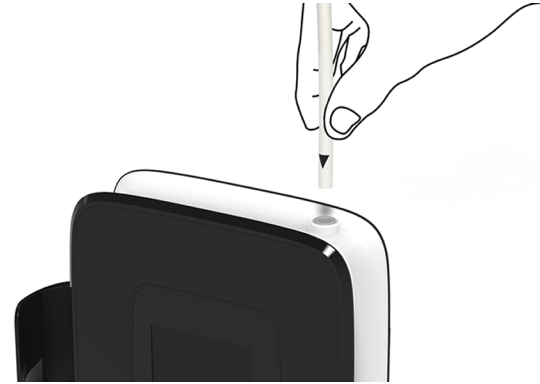
3.1.1 Attach the Nasal Kit to NIOX VERO instrument

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.



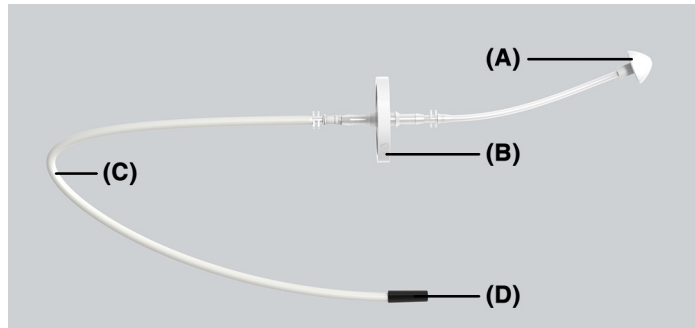
3. Take the nasal kit, remove the cap from the end of the tube and push it into the breathing handle port slowly until the triangle is no longer visible.



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.





(A), Nasal Olive, (B) Nasal Filter, (C) Nasal Tube, (D) Cap

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.

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.



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.

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 a 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.

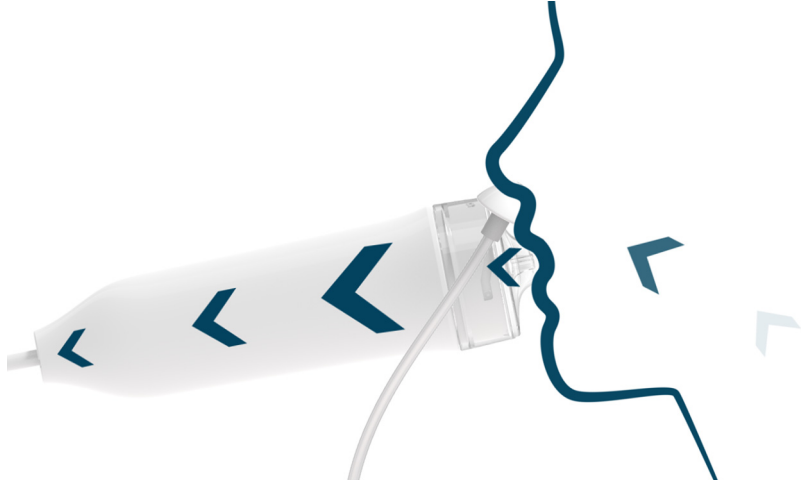
Note: Use the patient filter and the nasal kit directly after it has been opened.



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. 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 analyse 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 analyse the sample. After the aspiration is complete, remove nasal olive from the nostril and wait for the result.

3.5 Alert codes and actions

User alerts	Screen	Action
A28		Internal hardware error recoverable 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.
A29		Analysis failure Ambient measurement failure. Click the OK button and obtain a new measurement.

For additional alert codes, refer to the NIOX VERO User Manual.

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.

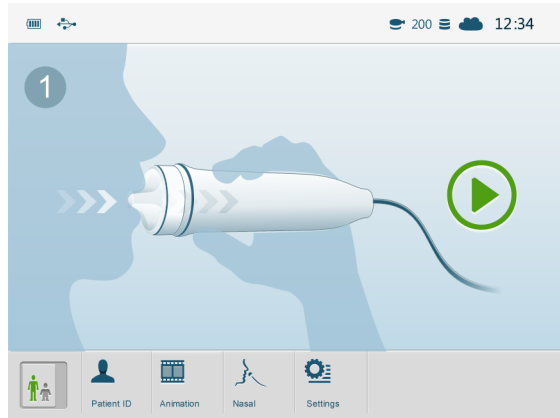
8. When the installation is complete, click **Close**.
The application is now available on the start menu.

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.

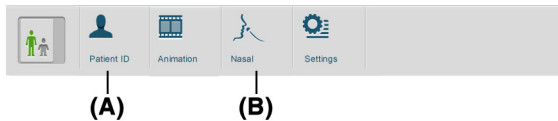


4.3 Perform Nasal measurements with NIOX® Panel

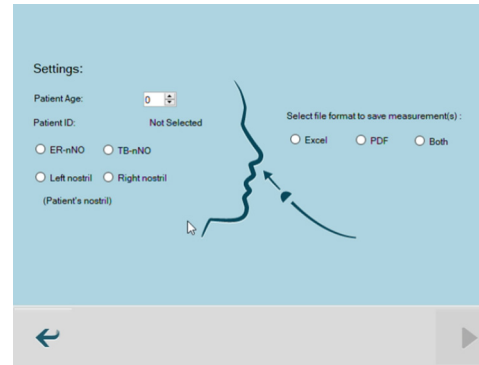
WARNING! Always use a new nasal kit and patient filter (when using ER-nNO method) for each patient. Reuse between patients could increase the risk of cross contamination or cross-infection. The same filter and nasal kit can be reused in one patient for multiple attempts in the same session.

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 computers Desktop.

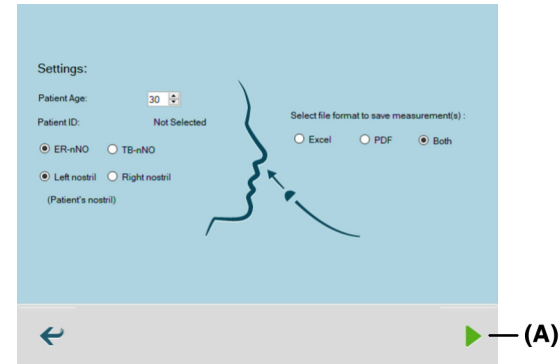
4.3.1 Expiration against Resistance (ER-nNO)

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 a 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 a ER-nNO Nasal measurement with NIOX Panel.

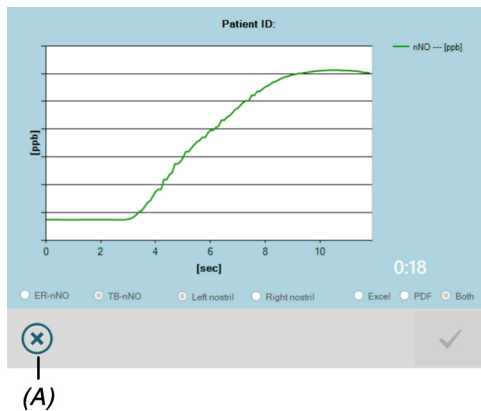
Note: If measurement is started before patient is ready, there is an option to abort measurement, it is not recorded as a measurement on sensor or instrument.

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 analyse the sample. After the aspiration is complete, remove nasal olive from the nostril and wait for the result.

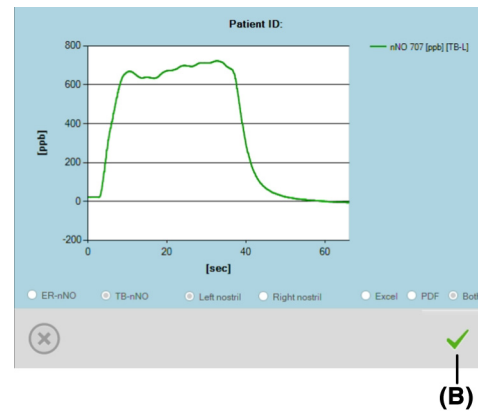
Note: By selecting the abort button (A) the measurement is cancelled. This can be pressed in the measurement or analysis period to abort the measurement.



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.

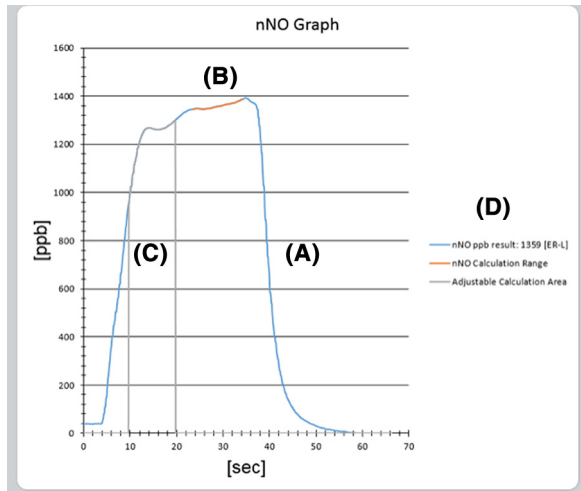
Note: If the option “No” is selected the file won’t be saved.



7. A save dialogue 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.



(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)

The screenshot shows the NIOX VERO software interface. At the top, there are two radio buttons: 'Set seconds' and 'Adjust width'. Below them, there are two sliders. The first slider is labeled 'Adjust width of selected area using "Adjust width":' and is set to 15 % of total graph. The second slider is labeled 'Adjust start position of selected area:' and is also set to 15 % of total graph. Below the sliders, the text 'converted to seconds: 10.1' is displayed. The main result is shown in red text: 'nNO result using graph: 1226 ppb'. At the bottom, there is a section titled 'Patient Information' with the following details: ID: 123456X, Age: 21, Used aspiration time: 30, and Date of measurement: 2017-08-11.

(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.

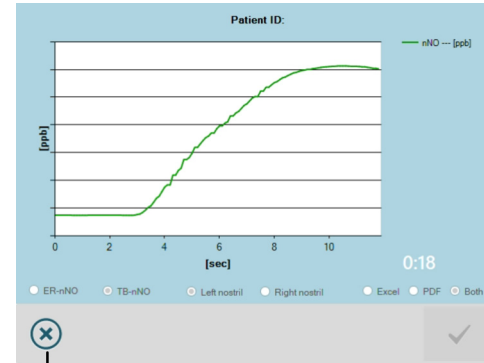
1. Before selecting the start measurement button make sure to instruct the patient to slowly inhale and exhale through the mouth.
2. Select start measurement button  to start a TB-nNO Nasal measurement with NIOX Panel.

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).

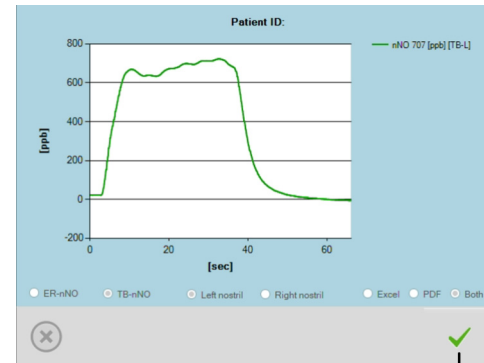
3. The instrument will aspirate for 30 seconds and then will start to analyse the sample. After the aspiration is complete, remove nasal olive from the nostril and wait for the result.

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



(A)

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

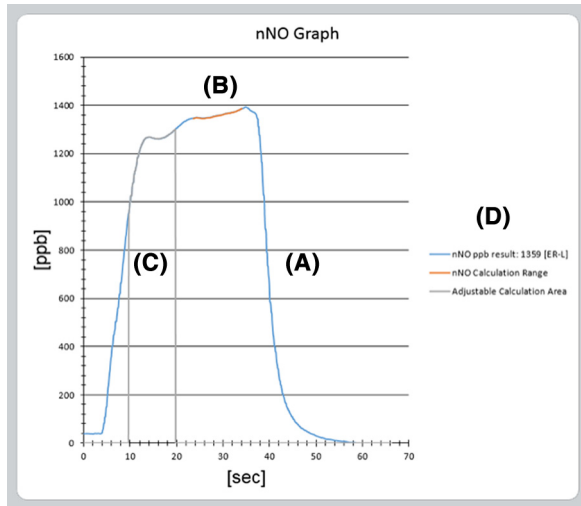


(B)

5. A save dialogue will be shown and an option to view the file.

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)

The screenshot shows the NIOX VERO interface. At the top, there are two radio buttons: "Set seconds" (unselected) and "Adjust width" (selected). Below these are two sliders. The first slider is labeled "Adjust width of selected area using 'Adjust width':" and has a value of "15 % of total graph". Below the slider, it says "converted to seconds: 10.1". The second slider is labeled "Adjust start position of selected area:" and has a value of "15 % of total graph". Below the sliders, the text "nNO result using graph: 1226 ppb" is displayed in red. At the bottom, there is a section titled "Patient Information" with the following details: ID: 123456X, Age: 21, Used aspiration time: 30, and Date of measurement: 2017-08-11.

(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 Preventive care

5.1 General care NIOX VERO®

For information on the preventive care and maintenance of NIOX VERO, refer to the NIOX VERO User Manual

5.2 Cleaning procedure



No Alcohol

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.

5.3 Disposal of nasal kits

Used nasal kits should be recycled according to the local recycling program for biohazard waste.

5.4 Return shipments

For return shipments, contact your local Circassia representative or Circassia AB.



6 Safety information

6.1 Warnings

See Warnings in the “Remember” section at the beginning of the User Manual, section 1.5, section 3, section 4.3 and section 5.2. For warnings specific to the operation of the NIOX VERO, refer to the NIOX VERO User Manual.

6.2 Cautions

See Cautions in the “Remember” section at the beginning of the User Manual, section 3.2, and section 7.2. For cautions specific to the operation of the NIOX VERO, refer to the NIOX VERO User Manual.

6.3 Limited warranty

Circassia provides a Limited Warranty for the instrument and accessories delivered. Conditions are defined when the items are purchased

DO NOT try to repair the instrument or any accessories. Any attempt will make the warranty invalid and performance according to the specifications cannot be guaranteed.

6.4 Support

Contact your local Circassia representative or Circassia Technical Support if you encounter problems which you cannot solve with the information in this manual.

For contact details, see back cover, and provide the following information:

- Your name, address and telephone number.
- Serial number for both the instrument, handle and sensor.
- Problem description (as thorough as possible)

- Alert codes or lists.
- Lot number of nasal kits



7 NIOX VERO® Nasal Technical Specification

7.1 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

7.2 Performance data

Measurement range: 5 to 2000 ppb

Lowest detection limit: 5 ppb

Sampling flow rates: 5 ml/s

7.3 Linearity

Squared correlation coefficient $r^2 \geq 0.998$

7.4 Precision

< 3ppb of measured value for values < 30 ppb, < 10% of measured value for values ≥ 30 ppb. Expressed as one standard deviation for replicate measurements with the same instrument, using a certified gas concentration of nitric oxide reference standard.

7.5 Accuracy

± 10 ppb for measured values < 50ppb or 20% of measured value for values ≥ 50 ppb. Expressed as the upper 95% confidence limit, based on absolute mean of differences from certified gas concentration of nitric oxide.

For FeNO technical specification refer to the NIOX VERO User Manual.

7.6 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.



Information in this document is subject to change.

Amendments will be made available by Circassia AB as they occur.

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.

Circassia AB, Hansellisgatan 13, SE-754 50 Uppsala, Sweden

Phone: +46 18 32 88 37, Fax: +46 18 32 88 38, E-mail: nioxtechsupport@circassia.com

www.niox.com

Copyright 2021 Circassia AB, Uppsala, Sweden.

Circassia is a registered trademark of Circassia Limited
NIOX, NIOX MINO and NIOX VERO are registered trademarks of Circassia AB.

