NIOX VERO® Airway Inflammation Monitor

User Manual

CE

NIOX VERO® User Manual English
000191-16 May 2023

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.

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.

1 Important information

1.1 Before using NIOX VERO® Airway Inflammation Monitor

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.

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® User Manual-item number 000191, version 16, was released May 2023. The software version number installed in the instrument can be found by viewing the settings. For instructions on how to view the software version number installed in the instrument, see section 5.6.5, View instrument information.
Information in this document is subject to change. Amendments will be made by Circassia as they occur. The User Manual provides instructions on how to operate NIOX VERO®. It contains numbered step-by-step instructions with screens and illustrations. Choices within steps are displayed with bullet points.

1.3 Compliance

NIOX VERO® is CE-marked according to In Vitro Diagnostics Directive 98/79/EC.
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:
Hansellisgatan 13
SE-754 50 Uppsala
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.
- NIOX VERO® can be operated with two different exhalation times, 10 seconds and 6 seconds. Incorrect use of the 6 second exhalation mode may result in falsely low FeNO values, which can lead to incorrect clinical decisions.

- 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. Refer to section 8.4, Disposal of instrument and accessories.
- 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 FeNO 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 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, vapors or liquids.

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 for use only as an In Vitro Diagnostic Device (IVD) and intended for near patient testing.

FeNO

FeNO is increased in some airway inflammatory processes such as asthma and decreases in response to anti-inflammatory treatment. FeNO measurement with NIOX VERO® is quantitative, non-invasive, simple, safe and is used as part of 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.

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.

nNO

Nasal Nitric Oxide has been shown to be decreased in patients with Primary Ciliary Dyskinesia (PCD). Measurement of nNO is a screening tool that can assist in the identification of cases of PCD according to ERS guidelines[1].

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.

1.7 Principals of Operation

NIOX VERO® is a small, portable system for the non-invasive, quantitative measurement of the fractional nitric oxide (NO) concentration in expired human breath (FeNO), a marker of airway inflammation and Nasal Nitric Oxide (nNO) in the aspirated air from the nasal cavity as a screening tool to assist in the identification of Primary Ciliary Dyskinesia.

The NIOX VERO® hand-held device includes a sampling and gas conditioning system and a man-machine interface (MMI). The user is guided through the breathing maneuver with the built-in touch-screen display by use of an interactive MMI. The valves and pumps of the instrument are automatically controlled to manage the inhaled sample appropriately via the instrument electronics and software program. Filtering of inhaled air eliminates contamination from ambient NO levels.

A built-in flow control keeps exhalation at 50 ml/s so that it is standardized for all patients. Results are processed using dedicated software and are expressed as Nitric Oxide concentration in parts per billion (ppb).

Each NIOX VERO® sensor is individually calibrated during manufacture. The sensor maintains its calibration during the sensor lifetime, no additional calibration is needed by the user. The device requires no maintenance or scheduled servicing.

There are international and country specific guidelines on the interpretation of results. For FeNO, the most commonly used is the American Thoracic Society guidelines: Dweik RA, Boggs PB, Erzurum SC, et al. Interpretation of exhaled nitric oxide levels (FeNO) for clinical applications: an official ATS clinical practice guideline, 2011. Am J Respir Crit Care Med. 2011; 184: 602-615.

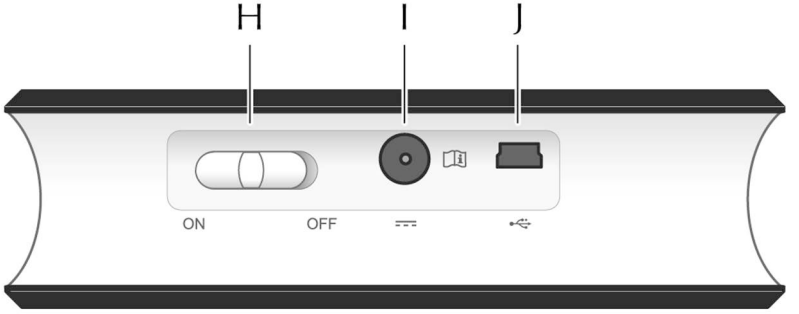
2 Product description

2.1 NIOX VERO® accessories and parts

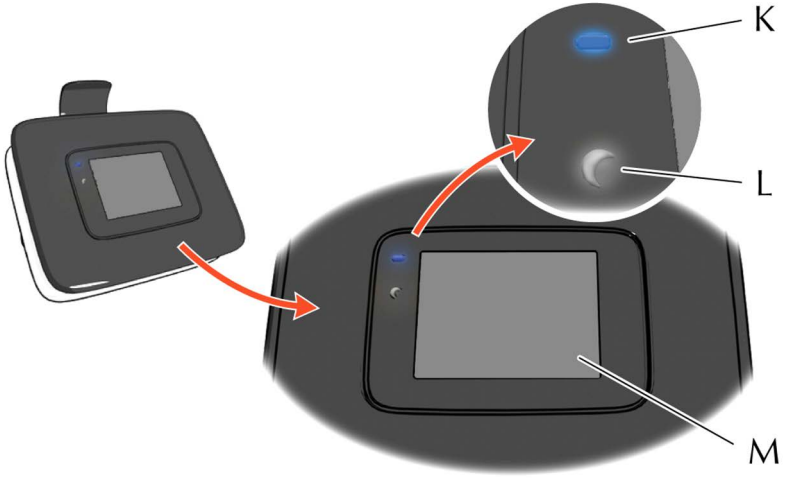
(A) Breathing handle and handle cap, (B) Sensor (supplied separately), (C) Instrument (including stand), (D) Rechargeable battery, (E) NIOX Panel USB memory stick, (F) USB cable, (G) Power adapter and power cord, (H) Patient filter (supplied separately)

Note: Only accessories and parts supplied by Circassia may be used.

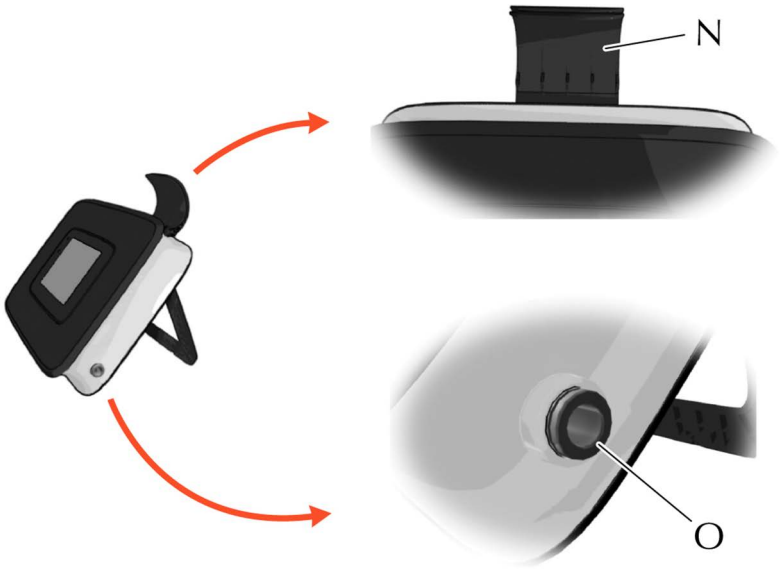
2.2 Instrument



(H) ON/OFF button, (I) Power adapter port, (J) USB port



(K) Battery LED - lit when battery is charging, (L) Standby LED - blinking in Standby/Sleep mode, (M) Touch panel Display

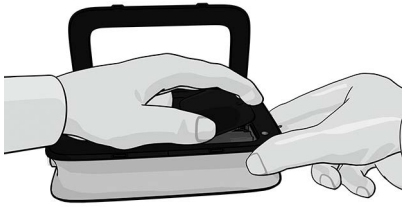


(N) Breathing handle holder, (O) Breathing handle port

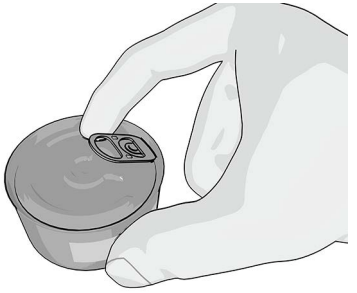
3 Installation and set up

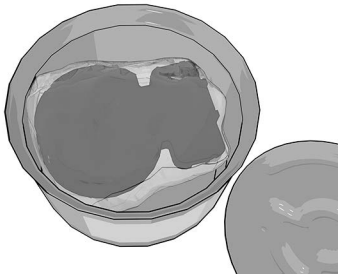
Open the package with care. Prior to installation, check that the package contains all the parts (see section 2.1). A screwdriver is required for opening the compartment lid and installation of sensor and battery. Remove the plastic film from the display.

1. Carefully place the instrument with the display facing down on a flat and clean surface, then unscrew and remove the compartment lid. There is a taper on the side of the lid for better grip when opening.



2. Open the sensor can.



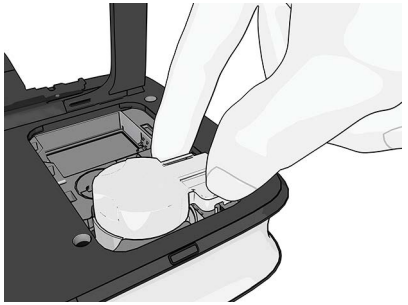


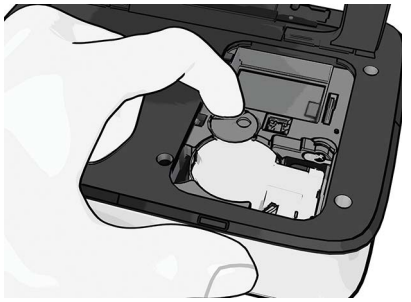
WARNING! Open the sensor can with care. The inside of the opening may have sharp edges.

3. Open the sensor package.

WARNING! Do not touch or clean the white sensor membrane.
CAUTION! The sensor should only be stored in its original unopened package or installed in a NIOX VERO® instrument.

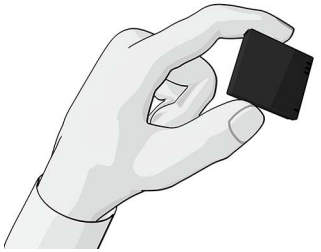
4. Insert the sensor and turn the swivel clockwise until locked.



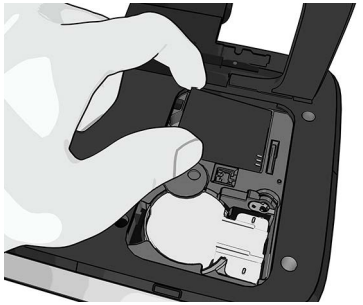


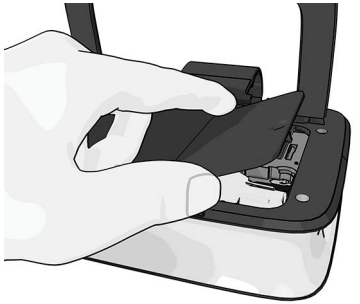
5. Open the battery package.

Note: Only use the correct rechargeable battery supplied by Circassia. (Type No BJ-G510039AA, Article No 12-1150)



6. Insert the rechargeable battery and replace the lid. Tighten the screw by using a screwdriver.

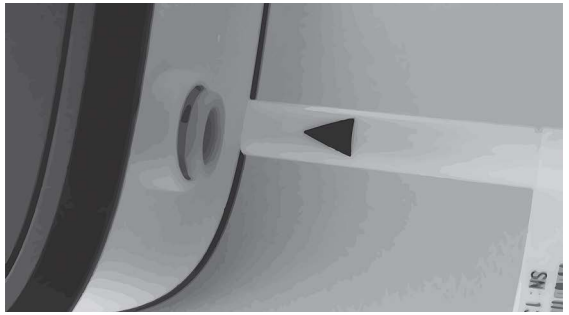




7. Take the breathing handle tube and push the end of the tube into the breathing handle port slowly until the triangle is no longer visible. The breathing handle and the patient filter are Applied parts Type B.

Note: Only attach the breathing handle supplied by Circassia. Article No 12-1010

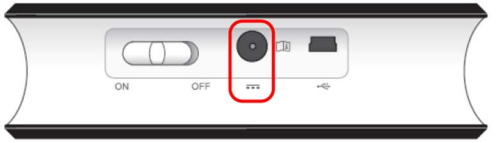
Note: Use care not to bend the handle tube.



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

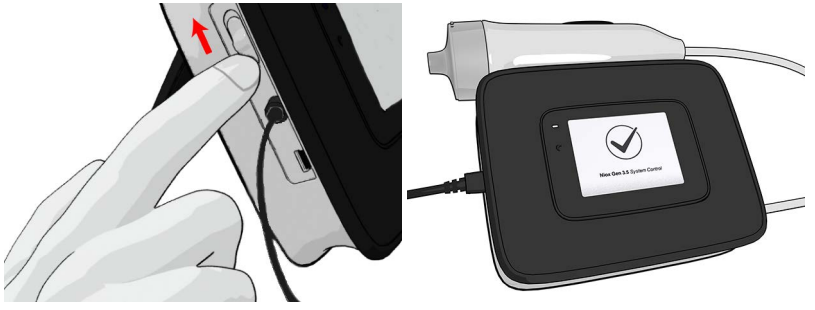
8. Attach the power adapter to the instrument and then to the power outlet. When installing the unit, either use a socket outlet with a readily accessible power switch, or connect the AC cord plug to an easily accessible socket outlet near the equipment. If a fault should occur during operation of the unit, use the power switch to cut the power supply, or remove the AC cord plug.

Note: Only use the power adapter supplied by Circassia with the instrument. Article No 12-1120.



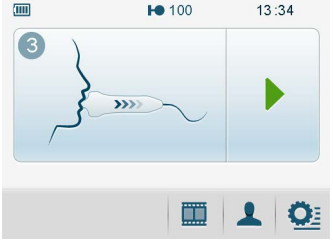
9. Position the instrument with the stand folded out.

10. Start the instrument by sliding the ON/OFF button to **ON** and allow the instrument to start up and perform the internal check and measurement procedures.



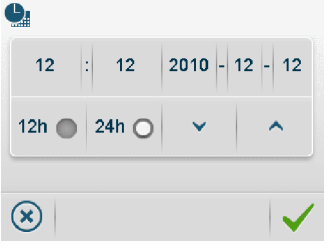
CAUTION! After inserting a new sensor it is recommended to wait for three hours with the instrument switched on before performing a measurement.

11. When the internal check is completed, the main menu appears.



12. Select the **Settings** button on the main menu.
13. Select **Time and date**.

This opens the time and date setting view.



14. Select between 12h US and 24h ISO time and date format.

15. Set time by pressing the button for hour. It changes color to blue. Change the value to the current hour by pressing the increase or decrease buttons. Repeat this procedure for minute, year, month and day.

16. Select **OK** to accept the changes and return to the main menu.

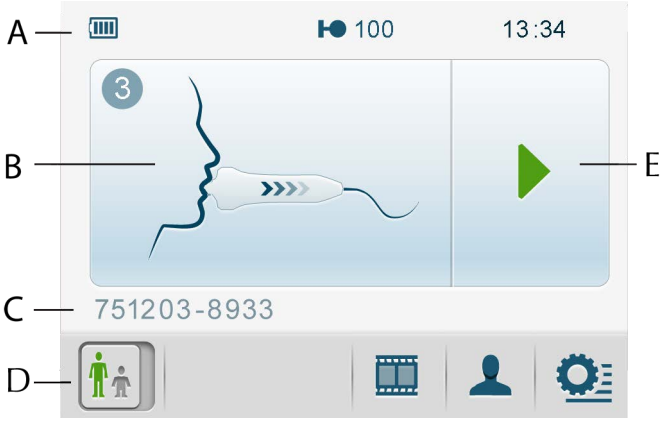
    The **Undo** button closes the view without saving any changes.
17. Select the **Settings** button on the main menu.
18. Select the **Breathing handle** button. This opens the Breathing handle view.
19. Select the **Reset Breathing handle** button. The breathing handle information view opens to confirm insertion of the breathing handle.
20. Select the **OK** button to confirm insertion of a new breathing handle. This sets the remaining measurements to 1000 and expiry date one year from the current date.
    The **Return** button returns to Settings view <u>without</u> registering change.

4 User interface

4.1 Main and settings view

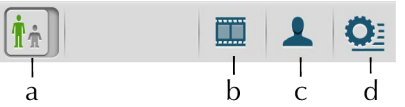
This section describes the main view, settings view, menus and symbols. Buttons and symbols are further described in section 10.

4.2 Main View



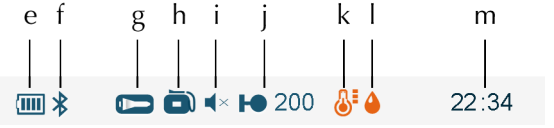
(A) Status bar, (B) Instructive demonstration, (C) Patient ID, (D) Main menu, (E) Start measurement button

4.2.1 Main menu



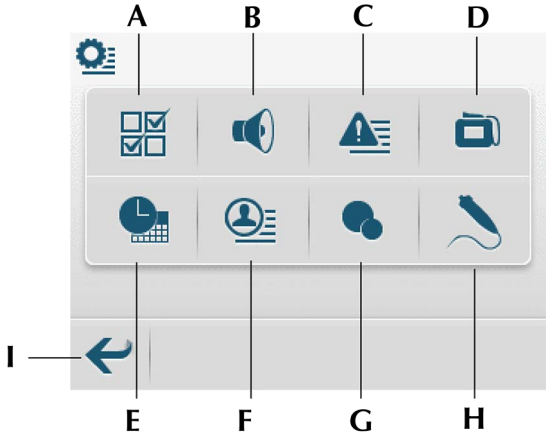
(a) Measurement mode 10s/6s (only shown when 6s is an option, for more information see section 5.6.7, Enable/disable 6 second (6s) measurement mode, (b) Demo, (c) Patient ID entry, (d) Settings

4.2.2 Status bar



(e) Battery status, (f) Bluetooth enabled (in this position a USB connection may be indicated instead), (g) Breathing handle has expired or is about to expire - blinking symbol, (h) Instrument has expired or is about to expire - blinking symbol, (i) Sound disabled, (j) Sensor status and number of remaining measurements, (k) Temperature outside of specification, (l) Humidity outside of specification, (m) Time

4.3 Settings view

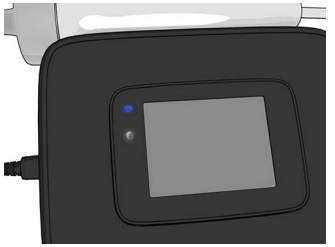


(A) Modes configuration - see section 5.6.6,
(B) Volume settings - see section 5.6.2, (C) Alert log - see section 5.6.4,
(D) Instrument & Sensor info - see section 5.6.5, (E) Time and date settings - see section 5.6.1, (F) Measurement log - see section 5.6.3, (G) Ambient measurement - see section 5.5, (H) Breathing handle status and settings - see section 8.2, (I) Return to main view

5 Using NIOX VERO®

5.1 Start the instrument from power save mode

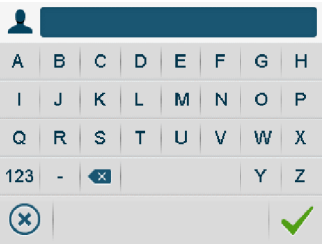
If NIOX VERO® is in **standby** or **sleep mode** simply touch the display to activate it.



5.2 Register patient ID (optional)

Note: **If Patient ID is used, it must be entered before each measurement, even if it is the same patient. Local Regulations on Patient information privacy must be considered when using unique patient identifiers.**

1. Select the **Register patient ID** button from the main menu. 



2. Enter up to 12 characters (alpha or numeric).
3. Select the ABC-button to activate a keyboard with the alphabet. The 123-button changes view back to the numerical keyboard.
4. Select **OK** button to confirm the registration.

Use the **Erase** button to erase.
Use the **Undo** button to undo a registration.

5.3 Measure FeNO

Verify proper preparations before performing a measurement with NIOX VERO®. A basic preventive inspection is recommended before each use (see section 8.1.1).

WARNING! Always use a new patient filter for each patient. Reuse between patients could increase the risk of cross-contamination or cross-infection. The same filter can be reused in one patient for multiple attempts in the same session.

5.3.1 Preparation for measurement

1. Lift the breathing handle from the holder and remove the handle cap.
2. Obtain a new patient filter. Attach the patient filter to the breathing handle. Make sure to twist the patient filter in place until it clicks into place.

Note: **Store the patient filters in the original box prior to use.**

Note: **Do NOT use sharp objects to open the patient filter packaging. Do not touch the filter membrane.**

Note: **Patient filters should be used immediately after opening.**

Note: **There is a risk of leakage if the filter is not correctly attached to the breathing handle and this may result in incorrect measurement values.**

Note: **Do not switch OFF the instrument during measurement procedure.**

3. Give the breathing handle to the patient and guide the patient to provide a breath sample as described in the next section.

5.3.2 Measurement

1. Empty the lungs by breathing out thoroughly.
2. Close the lips around the mouthpiece on the patient filter so that no air leakage occurs.

3. Inhale deeply through the patient filter to total lung capacity. During inhalation, the cloud on the display moves upwards.

Note: The procedure is activated by inhaling air from the handle or by pressing the start measurement button.

4. Exhale slowly through the filter while keeping the cloud within the limits as indicated on the display (the white lines).

5. The instrument display and audio signals guide the user to the correct exhalation pressure.

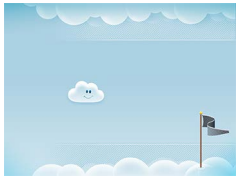
A continuous sound indicates correct pressure with a frequency proportional to the pressure.

An intermittent high frequency sound - too strong pressure

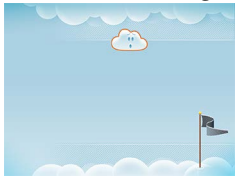
An intermittent low frequency sound - too weak pressure

Exhalation with:

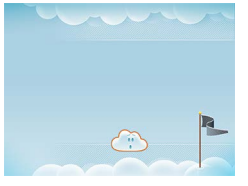
Pressure correct



Pressure too strong



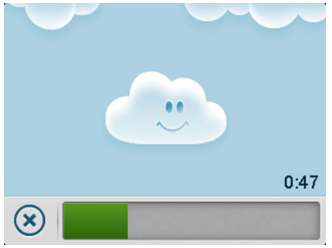
Pressure too weak



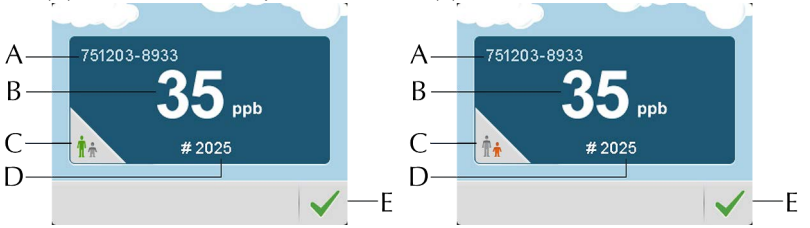
6. Exhale until the cloud has passed the flag.

7. The instrument will analyse the sample and generate a result in approximately one minute.

Note: Do not exhale or inhale through the patient filter during the analysis process.



8. The result is then displayed: (A) Patient ID - if applicable, (B) FeNO value in ppb (parts per billion), (C) Measurement mode 10s/6s, (D) Measurement sequence number, (E) OK - returns to main view.



5.3.3 Perform 6s NO measurement

- NIOX VERO® 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.

WARNING! Incorrect use of the 6s exhalation mode may result in falsely low FeNO values, which can lead to incorrect clinical decisions.

6 second measurement mode is not activated by default, refer to section 5.6.7, Enable/disable 6 second (6s) measurement mode.

1. Change to **6s Measurement mode** by selecting the 10s button (green man symbol) on the main menu.

2. The button changes to 6s measurement mode (orange, small child symbol).

3. The 6s measurement mode is illustrated with an orange start button.

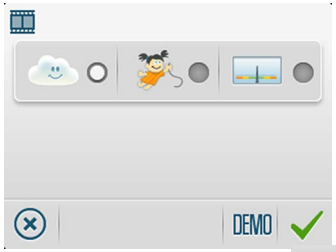
4. Perform measurement as instructed in section 5.3.2, Measurement.
5. Wait for the result.
6. The result screen displays the icon for 6s measurement.

Note: The device will always return to the default 10s mode after a 6s measurement.

5.4 Demonstration mode

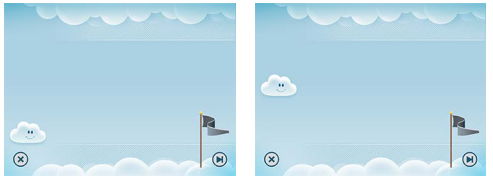
To help professionals in guiding patients, the instrument contains three animated demonstrations with visual and audio guides of the different stages of a measurement procedure.

1. Select the **Animation** button on the main menu.
2. Select which animation to use (Cloud, Balloon or Meter)

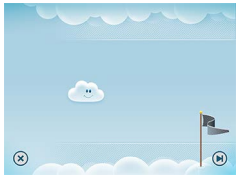


3. Select the **Demo** button. DEMO
4. Select the **Forward** button to move to the following sequence.
5. The **Undo** button closes the demonstration and returns to animation select.
6. Select **OK** button to confirm the changes
7. The **Undo** button returns to the main menu without saving changes.

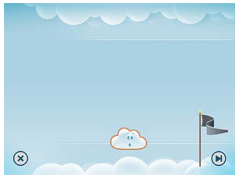
a. Inhalation through the breathing handle.



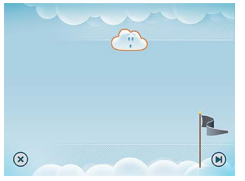
b. Exhalation through the breathing handle with correct pressure.



c. Exhalation through the breathing handle with pressure too weak.



d. Exhalation through the breathing handle with pressure too strong.



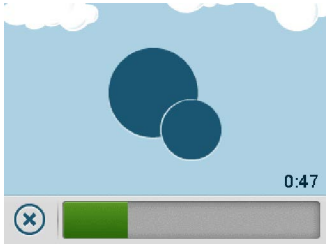
5.5 Measure ambient NO

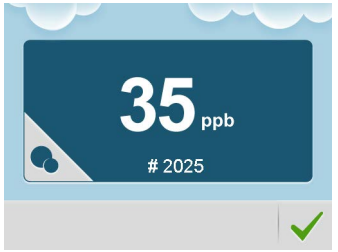
Note: An ambient measurement may be requested by technical support during troubleshooting.

Note: An ambient measurement is counted as one measurement on NIOX VERO® Sensor and the instrument.

1. Attach a patient filter to the breathing handle until it clicks into place.

2. Select the **Settings** button on the main menu.
3. Select **Ambient Measurement** button.
4. Select the **Start measurement** button.
5. The progress bar is visible until the measurement is finished and the result is displayed: Ambient measurement value (in ppb), measurement mode and measurement sequence number.





5.6 Change settings

5.6.1 Change time and date

1. Select the **Settings** button on the main menu.
2. Select the **Time and Date** button.
   For more details refer to section 3.

5.6.2 Change sound volume

1. Select the **Settings** button on the main menu.
2. Select the **Sound** button.
3. The settings for sound and volume opens.

4. Select **Decrease/Increase** to adjust volume.
5. The volume bar indicates the set volume.
6. Select the **OK** button to save settings and return to the settings view.

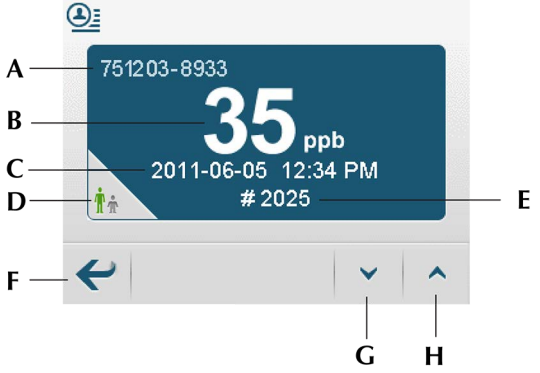
   The **Undo** button closes the view without saving changes.
7. The status bar indicates mute status when the sound volume is set to zero.

5.6.3 View measurement logs

All measurement results are stored in the instrument and can be viewed at any time.

1. Select the **Settings** button on the main menu.
2. Select **Patient Measurements log** view button.

3. The selected log will display the following:



(A) Patient ID - if defined, (B) FeNO value, (C) Measurement date and time, (D) Measurement mode 10s/6s, (E) Measurement sequence number, (F) Return to settings (G) Backward, (H) Forward

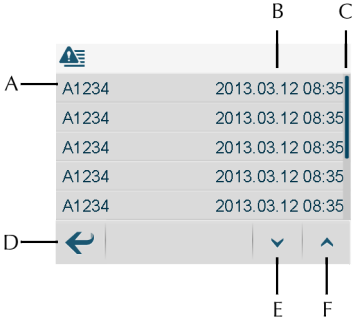
4. Browse through the measurement logs using the **Backward** and **Forward** buttons.

5. Select the **Return** button to return to settings.

5.6.4 View alert logs

Alerts are stored in the instrument and can be viewed at any time. The alert codes are for Circassia Technical Support use.

1. Select the **Settings** button on the main menu.
2. Select **Alert log** button.



(A) Alert code (for technical support purpose only), (B) Date and time of alert, (C) Scroll list (blue) (D) Return - returns to previous view, (E) Backward (F) Forward

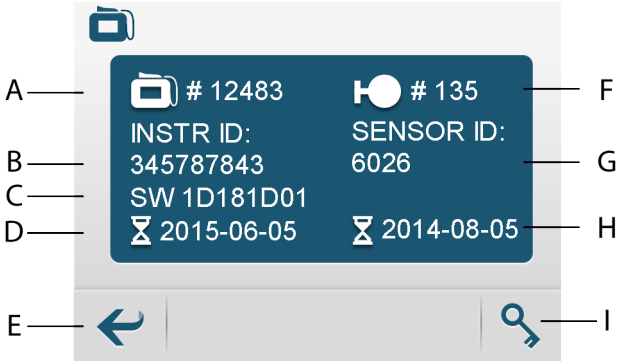
3. Select the **Return** button to return to settings.

5.6.5 View instrument information

Detailed information about the instrument and sensor can be viewed.

1. Select the **Settings** button on the main menu.
2. Select the **Instrument** button.

3. This opens the Instrument information view displaying the following:



(A) Numbers of remaining measurements on the instrument, (B) Instrument serial number, (C) Software version number, (D) Instrument expiration date, (E) Return to settings, (F) Numbers of remaining measurements on the sensor, (G) Sensor serial number, (H) Sensor expiration date, (I) Enter configuration code (only used on request from Circassia)

5.6.6 Turn QC functionality on or off

Note: An optional External Quality Control (QC) procedure is available for NIOX VERO®. Refer to the NIOX VERO® External Quality Control user manual. Contact your local Circassia representative for further information.

1. Select the **Settings** button on the main menu.
2. Select the **Modes configuration** button.
3. Select the check box to activate QC functionality. QC

The optional QC procedure is available when a user requires added assurance that the system is operating within the specifications. This procedure requires qualification of at least one positive and a negative control by performing three qualifying measurements within a fourteen-day period.

Positive controls are obtained from office staff who have a stable FeNO value providing a normal biological FeNO sample. Negative control samples are taken from an NO free gas sample automatically generated from ambient air drawn through the breathing handle.

Once the qualification process is completed, a QC sample is performed daily. If the qualified QC user's daily measurement falls within ±10 ppb from the mean (average) value, and the negative control is approved, the QC has passed.

5.6.7 Enable/disable 6 second (6s) measurement mode

1. Select **Settings** in the main menu.
2. Select **Modes configuration**.
3. Check the **10s/6s** icon to enable using the 6s mode. Uncheck to disable.
4. Press **OK**.

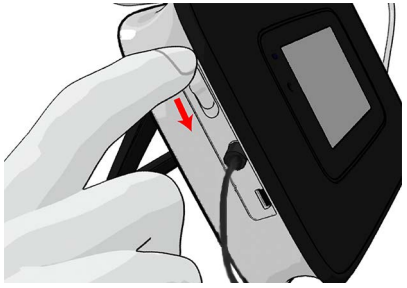
5.6.8 Activate Nasal measurement mode

To unlock Nasal measurement mode in NIOX VERO® a configuration code is required.

Contact the local Circassia sales representative for further information.

5.7 Turn off the instrument

1. To turn off the instrument, slide the **ON/OFF** button to **OFF**.



Note: Before transportation remove the used patient filter (if still attached) and attach the handle cap.

Note: Always use a closed bag or case (NIOX VERO® bag recommended) for transportation and storage of the instrument.

6 Using NIOX VERO® with NIOX® Panel

The NIOX VERO® instrument can be used together with NIOX® Panel. NIOX® Panel is a PC application and visual aid allowing you to operate the instrument from a PC.

6.1 Warnings

- NIOX® Panel shall only be operated by trained healthcare professionals.
- Operate NIOX® Panel 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® Panel product keep in mind that an accessory not recommended by Circassia may result in loss of performance, damage to your NIOX® Panel 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.
- If the equipment is used in a manner not specified by Circassia, the protection provided by the equipment may be impaired.
- Modification of NIOX® Panel application is not allowed.
- Do not use damaged components.

6.2 Installation of NIOX® Panel

NIOX® Panel System requirements

- Windows® 7, Windows® 8 (RT versions excluded), Windows® 10 or Windows® 11
- .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

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 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**.
9. The application is now available on the start menu.

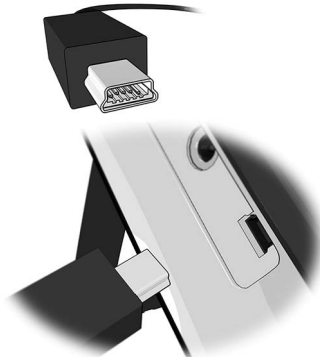
6.3 Connect to a PC via USB

In order for NIOX VERO® to be able to communicate with a PC, you may use a USB cable.

An alternative option is Bluetooth communication (see how to enable Bluetooth in the next section).

Note: Only USB cables supplied by Circassia may be used. Article no 12-1002

1. Plug the USB cable into the instrument and connect it to a PC.



2. An enabled USB connection is indicated on NIOX VERO® by a symbol on the status bar.

Note: If the instrument is in power saving mode no connection will be established.

6.4 Connect to a PC via Bluetooth

6.4.1 Activate Bluetooth functionality

1. Select the **Settings** button on the main menu.

2. Select the **Measurement Mode** button. This opens the Configuration modes view.
3. To enable Bluetooth, check the checkbox. (Unchecking the box disables Bluetooth communication.)

Select **OK** to confirm change.
This returns to the Settings view.
An enabled Bluetooth function is indicated by a symbol on the status bar (provided that the instrument is not connected to a PC via cable).

Refer to the PC User Manual on how to enable Bluetooth on the PC.

6.4.2 Connect by Bluetooth in NIOX® Panel

1. Select in the NIOX® Panel window
2. A search view opens, select to search for devices.
3. Select the instrument and click OK.

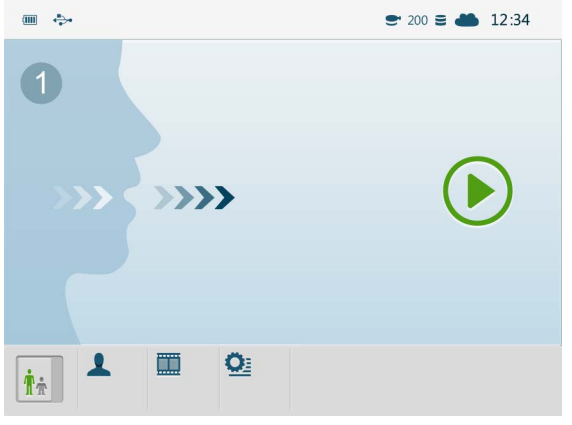
Note: If the instrument is in power saving mode no connection will be established.

6.5 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 your 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 you can start to operate your NIOX VERO® instrument via your PC.

Note: When starting NIOX® Panel for the first time the connectivity details dialog box opens.



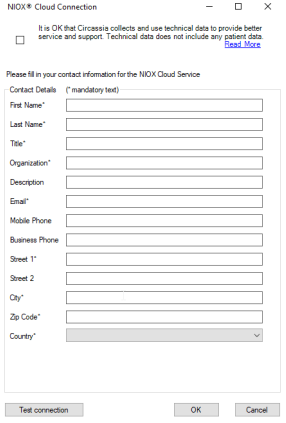
6.5.1 NIOX® Panel connectivity module

The connectivity module in NIOX Panel utilizes Microsoft's secure cloud service, Microsoft Azure, to automatically transmit technical data from the device via the internet to Circassia.

Technical data such as time stamp, alert codes and number of remaining measurements on the device and sensor are received. This information will ensure better customer support.

Circassia recommends completion of the details dialogue box to allow receipt of technical data and provide better support to its customers.

Mandatory fields are marked with a *. Complete these, leave the box checked, and click OK to continue.



When connection to Microsoft Azure is established a cloud icon is shown in the status bar.

If the connection to Microsoft Azure is lost or the user has chosen to not send technical data, the cloud icon is crossed over .

To decide at a later stage to allow Circassia to collect data, press cancel and the dialog box will open again next time NIOX® Panel is started, or click on the cloud icon in the status bar.

To reject collecting of Circassia technical data (not recommended) uncheck the box in the bottom of the window and click OK.

Note: Only technical data and no patient data is collected by Circassia.

Changing contact details

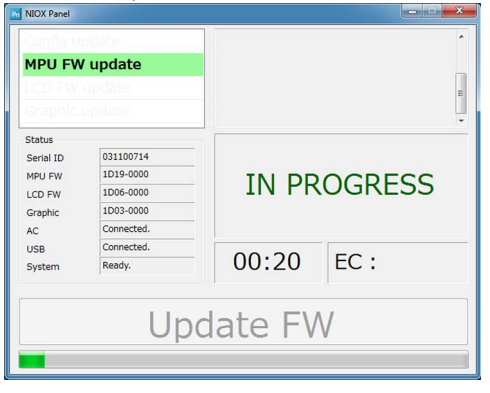
To edit contact details click on the cloud icon in the status bar to open the contact details dialog box.

6.6 Firmware update

Note: If NIOX VERO® firmware is not the latest NIOX® Panel will prompt for a firmware update.

Note: Do not disconnect the USB or power cable during firmware update.

1. Connect the instrument via USB. Make sure that the power cable is connected.
2. Press the update firmware button and wait for the update to be finished.



3. The instrument will automatically restart and reconnect to NIOX® Panel when the update is finished.

Note: Once FW update is complete NIOX® Panel will restart.

6.7 Using NIOX® Panel

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

6.7.1 Measure FeNO

See section 5.3, Measure FeNO

CAUTION! Do not disconnect the instrument from the PC during measurement and analysing process.

6.7.2 Demonstration mode

See section 5.4, Demonstration mode

6.7.3 Change settings

See section 5.6, Change settings

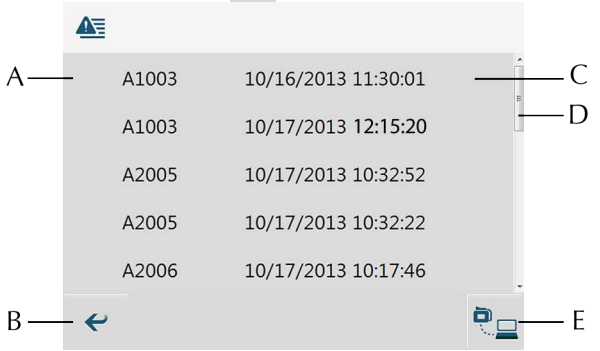
6.7.4 View measurement logs

See section 5.6.3, View measurement logs

6.7.5 View alert logs

Alerts are stored in the instrument and can be viewed at any time. The alert codes are for Circassia Technical Support use.

1. Select the **Settings** button on the main menu.
2. Select the **Instrument** button.
3. Select **Alert log** button.



(A) Alert code, (B) Return button - returns to settings view, (C) Date of alert, (D) Scroll bar, (E) Download device data (only used upon request by Circassia)

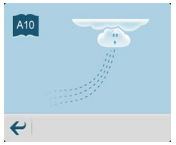
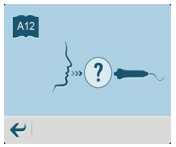
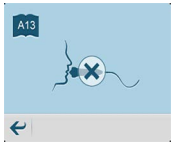
6.7.6 Perform Nasal measurements

Refer to the NIOX VERO® Nasal measurement mode user manual (002346).

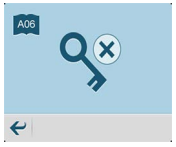
7 Troubleshooting

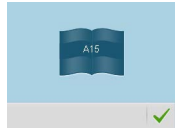
7.1 Alert codes and actions

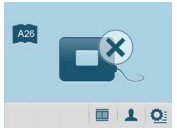
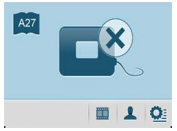
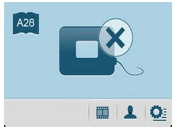
Alert messages and other information are shown as a code on the instrument display. The tables below provide the alert codes and recommended actions to be taken for an alert code. If the alert persists, contact your local Circassia representative or Circassia Technical Support.

User alerts	Screen	Action
A10		**Exhalation too strong** Press Return and repeat the measurement with less exhalation force.
A11		**Exhalation too weak** Press Return and repeat the measurement with greater exhalation force.
A12		**Measurement failed** No exhalation detected or the user failed to exhale within 15 seconds of inhaling. Press Return button. Repeat the procedure and exhale into the instrument directly after inhalation.
A13		**Analysis interrupted** Repeat the measurement and do not breathe through the handle during analysis.
A21		**Measurement failed** Remove any sources of disturbance (such as cordless phones/mobile phones or gas emitting appliances). Then press Return. When the instrument is ready for use repeat the measurement. If the alert persists, restart the instrument.

Instrument alerts	Screen	Action
A01		**Unstable temperature** Make sure that the ambient temperature is between +10°C and +35°C. Wait for the sensor to stabilise. If necessary move the instrument to another location and restart the instrument.
A02		**Sensor stabilization** Remove any sources of disturbances (such as cordless phones, mobile phones or gas emitting appliances). Wait for the sensor to stabilise.

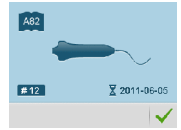
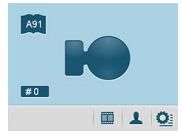
Instrument alerts	Screen	Action
A03		**Unstable humidity** Make sure that the ambient humidity is between 20% and 80%. Wait for the sensor to stabilise. If necessary move the instrument to another location and restart the instrument.
A04		**Count down time** The remaining time until the instrument is ready to use.
A05		**Lock MMI** When the instrument is connected to a PC the main view buttons will be locked.
A06		**Configuration code error** Only provided by Circassia upon request. The configuration code entered is incorrect. Enter correct configuration code. If this error continues to be shown, contact Circassia Technical support.
A07		**Lid open warning** Check if the battery or sensor lid is open and close if needed. Click the OK button when finished.

Instrument alerts	Screen	Action
A08		**Battery problem** Low power in battery or other failure. Change the battery and click the OK button when finished.
A09		**Condensation countdown** Too frequent use of the instrument. Remaining time until instrument has dried out.
A15		**Condensation alert** Reduce frequency of measurements. Continue measuring at this frequency causes condensation in the instrument and will make the instrument unusable for 30 minutes.
A22		**Memory access failure** Contact Circassia Technical support.

Instrument alerts	Screen	Action
A25		**Temperature or base line failed to stabilise within 30 minutes** Check that the ambient temperature and relative humidity is within specification. If necessary, move the instrument to another location and restart the instrument.
A26		**Self test failure** The self test of the instrument failed. Restart the instrument. If alert code persists contact Circassia Technical support.
A27		**Internal hardware error unrecoverable** Contact Circassia Technical support.
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.

Instrument alerts	Screen	Action
A29		**Analysis failure** Ambient measurement failure. Click the OK button and obtain a new measurement.
A30		**Bluetooth connection error** Check the Bluetooth connection with the PC. When finished click the OK button.
A31		**USB connection error** Check the USB connection with the PC. When finished click the OK button.
A40		**No sensor inserted** Insert sensor. See section 8.2.2 (replacement of sensor) or section 3 (initial placement of sensor).

Instrument alerts	Screen	Action
A41		**Sensor error** Remove any sources of disturbance (such as cordless/mobile telephones or gas emitting appliances). When the instrument is ready for measurement try to repeat the measurement. If alert persists, power off the instrument, remove and insert the sensor and restart the instrument.
A42		**Sensor warning** Contact Circassia Technical support. This warning indicates that the sensor may soon stop working due to battery failure.
A80		**The instrument is about to expire** Order a new instrument. This alert is visible when less than 500 measurements remain or less than 120 days until expiry date. Press OK to acknowledge.
A81		**The sensor is about to expire** Order a new sensor. This alert is visible when less than 10% of the measurements remain or less than 2 weeks until expiry date. Press OK to acknowledge.

Instrument alerts	Screen	Action
A82		**The breathing handle is about to expire** This alert is visible when less than 100 measurements remain or less than 2 weeks until expiry date. Press OK. Prepare to change breathing handle.
A90		**All measurements on the instrument have been used** It is still possible to view measurements stored in the instrument memory.
A91		**All measurements on the sensor have been used.** Replace the sensor, see section 8.2.2.
A92		**Instrument expiration date has passed** It is still possible to view measurements stored in the instrument memory.
A93		**Sensor expiration date has passed.** Replace the sensor, see section 8.2.2.

Instrument alerts	Screen	Action
A94		**The breathing handle has expired** Press OK. Change breathing handle. See section 8.2.1. **CAUTION!** The breathing handle's NO scrubber contains potassium permanganate and should be disposed of as hazardous waste in accordance with local waste disposal regulations.
A95		**Breathing handle expiration date has passed** Replace the handle, see section 8.2.1. It is still possible to view measurements stored in the instrument memory.

8 Preventive care

8.1 General care

In the following sections, actions for preventive care are described. Do NOT try to repair the instrument. Any attempt will make the warranty invalid and performance according to the specifications cannot be guaranteed.

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.

1. Clean the instrument with a cloth dampened with water or a **mild** soap solution.

CAUTION! Minimise use of solvents

2. Clean the breathing handle with a cloth dampened with water or a **mild** soap solution.

Note: The breathing handle and patient filter are not intended for sterilisation.

WARNING!

- The breathing handle and the instrument can not be cleaned with an aerosol.
- Do not use disinfectants or wipes containing alcohol, these might permanently damage the sensor and instrument.
- Do not use spray detergents.

- 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.
- This device is not user serviceable. Do not open the device except for sensor or battery replacement as outlined in this manual.
- Never attempt to perform sensor or battery replacement while the device is in operation.
- Do not modify the handle tube.

8.1.1 Preventive inspections

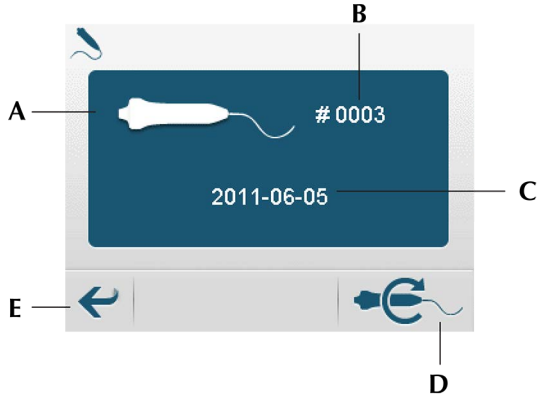
Before each measurement verify that NIOX VERO® is working properly, is not damaged and that normal operating conditions are fulfilled (see section 9.6).

If any item is missing or damaged, contact your local Circassia representative or Circassia Technical support.

8.2 Change disposals

8.2.1 Change breathing handle

The breathing handle contains a NO scrubber which can be used for 1000 measurements or one year, whichever comes first. The breathing handle view is used for viewing the status of the breathing handle and for resetting breathing handle usage parameters.



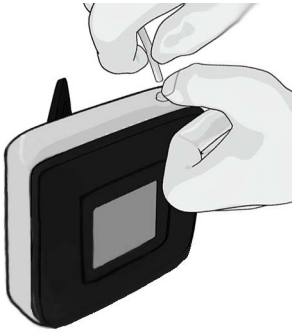
(A) Breathing handle symbol, (B) Remaining number of measurements, (C) Expiration date, (D) Breathing handle reset button, (E) Return button

Note: The breathing handle status icon appears blinking in the status bar two weeks prior to expiration or when 10% of its capacity is left.

Perform the following steps to change the breathing handle:

1. Place the device on its side on a level secure surface.

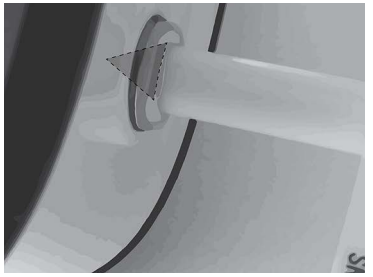
2. Remove the used handle from the instrument by pushing the socket into the device and gently pull out the tube.
3. Discard the breathing handle.



CAUTION! The breathing handle contains potassium permanganate and should be disposed of as hazardous waste in accordance with local waste disposal regulations.

Do not re-use an expired breathing handle.

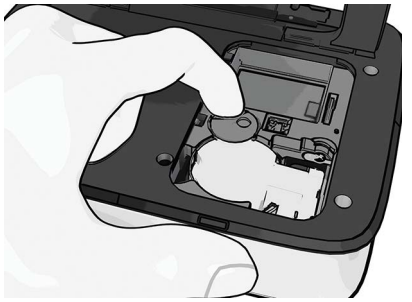
4. Attach a new breathing handle to the instrument by pushing the tube into the socket until the triangle is no longer visible.
5. Select the **Settings** button in the main menu.
6. Select **Breathing handle** button.
7. Select the **Reset Breathing handle** button.
8. The breathing handle information view opens to confirm replacement of the breathing handle. Select the **OK** button to confirm insertion of a new breathing handle and to set the remaining measurements to 1000 and expiration date one year from the current date.



Note: **The Return button returns to settings view <u>without</u> registering change.**

8.2.2 Exchange of NIOX VERO® Sensor

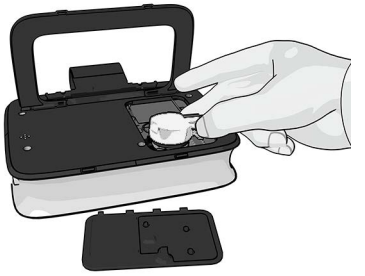
1. Turn off the instrument.
2. Open the compartment on the back of the instrument using a screwdriver. Turn the swivel to release the sensor.



3. Remove the old sensor.
4. Replace with a new sensor.

   WARNING! Make sure to not touch or clean the white sensor membrane.

   WARNING! Be careful when opening the sensor can. The inside of the opening may have sharp edges.



5. Turn the swivel to lock.
6. Replace the compartment lid.

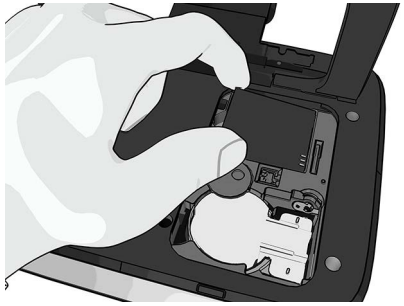
CAUTION! Make sure there is no foreign material or particles in the sensor compartment before closing it.

8.2.3 Change battery

If the rechargeable battery is no longer charging properly, malfunctioning, or requires charging more frequently than normal, then it needs to be replaced.

Note: **Only rechargeable batteries supplied by Circassia may be used. (Type No BJ-G510039AA, Article No 12-1150)**

The battery is placed in the compartment on the back of the instrument.



1. Turn off the instrument.
2. Open the compartment lid (see section 8.2.2).
3. Remove the old battery and insert a new battery.
4. Close the compartment lid.

CAUTION! Used batteries should be recycled according to the local recycling program for rechargeable batteries.

8.3 Operational life-time

8.3.1 NIOX VERO® instrument

Maximum 5 years from first use or 15 000 measurements, whichever comes first.

The user is prompted for expiry parameters via the device display. It is not possible to perform further measurements after expiry, although stored measurement data can still be retrieved.

8.3.2 NIOX VERO® Sensor

Operational life-time is maximum 12 months after opening package and installation in NIOX VERO® or until expiration date as stated on the sensor, whichever comes first.

The sensor will expire after the pre-programmed number of measurements have been depleted, or after one year (whichever comes first). When there is less than 10% of the number of the measurements left, or less than two weeks of use remaining, a message is shown on the display.

8.3.3 NIOX VERO® Patient filter

The shelf life of the NIOX VERO® Patient Filter in its unopened primary package is three years from manufacturing date.

The NIOX VERO® Patient Filter must be replaced for every patient. Reuse between patients could increase the risk of cross-contamination or cross-infection. The same filter can be reused in one patient for multiple attempts in the same session.

8.4 Disposal of instrument and accessories

WARNING! NIOX VERO® and the breathing handle contain potassium permanganate. Used or expired instruments and handles should be disposed of as hazardous waste in accordance with local waste disposal regulations.

Used or expired sensors should be recycled according to the local recycling program for electronic equipment.

Used batteries should be recycled according to the local recycling program for rechargeable batteries.

Used patient filters should be recycled according to the local recycling program for biohazard waste.

Note: There is a Lithium Manganese Dioxide ($LiMnO_2$) backup battery inside the instrument in addition to the replaceable and rechargeable battery.

Note: There is a silver-oxide battery and a $LiMnO_2$ battery in the sensor.

NIOX VERO® is RoHS compliant.

8.5 Return shipments

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

9 Safety information

9.1 Warnings

See section 1.5, Warnings

9.2 Cautions

- Mobile phones, cordless phones and gas emitting appliances might interfere with the instrument and could make it impossible to perform a measurement.
- The instrument might produce some heat during normal operation. The temperature could increase up to 5°C above the ambient temperature. Make sure that the ventilation slots are not blocked. Do not place the instrument on a bed, sofa, carpet or other soft surface.
- **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.
- The sensor shall be kept in its original unopened package prior to installation. For transportation and storage conditions, refer to section 11.16.
- The sensor is sensitive to changes in ambient temperature and humidity. Best performance is achieved if the ambient conditions are stable. Refer to the recommended environmental conditions on section 9.6. Keep the unit away from windows, direct sun, radiators, stoves or open fire in order to avoid unstable conditions.
- When transporting the unit from one location to another a prolonged stabilisation period before measurement might be required. Refer to the recommended transportation conditions in the section 11.16, Instructions for transport and storage. Always use a bag for transportation.
- Make sure that the gas outlet (four parallel slots to the left of the lid) on the rear side of the device is not covered.
- The device contains a Lithium-ion Battery which may cause an increased risk of heat, smoke or fire if handled incorrectly; do not open, crush, heat above 60°C or incinerate.
- Be careful when opening the sensor can. The inside of the opening has sharp edges.
- Keep the sensor out of reach of children.
- Any person who connects external equipment to signal input and signal output ports of this device has formed a Medical Electric System and is therefore responsible for the system to comply with the requirements of IEC 60601-1.
- A PC connected to the USB connector has to be certified for one of the standards IEC 60601-1, IEC 60950 or comparable with safety extra low voltage on the USB ports.
- The connected PC should be placed out of reach from the patient. Do not, simultaneously, touch the connected PC and the patient.

9.3 Substances disturbing FeNO measurement

Known patient factors that could interfere with FeNO measurements are described in the ATS/ERS Recommendations for Standardised Procedures for the Online and Offline Measurement of Exhaled Lower Respiratory Nitric Oxide and Nasal Nitric Oxide, 2005 (Am j Respir Crit Care Med 2005; 171:912-930)

9.4 Electromagnetic immunity

NIOX VERO® has been tested to comply with the emission and immunity requirements described in the parts of the IEC 61326 series for electrical equipment for measurement, control and laboratory use, and found to comply with IEC 60601-1-2:2007 General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests.

CAUTION! The test limits are designed to provide protection against harmful interference in a typical medical installation. However, because of the increased use of radio-frequency transmitting equipment and other sources of electrical noise emitters in the healthcare and home environments, such as base stations for radio, cellular/cordless telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast, it is possible that high levels of such interferences due to close proximity or strength of a source, may result in disruption of performance of the instrument. If abnormal performance is observed, it may be necessary to reorient or relocate the NIOX VERO®.

WARNING! NIOX VERO® should not be used adjacent to or stacked with other electronic equipment.

9.5 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

9.6 Operating conditions

Ensure stable operating conditions by avoiding placement of the instrument in direct sunlight, near sources radiating heat, or ventilation. NIOX VERO® operates within specification at the following conditions:

- NO in ambient air up to 300 ppb

To verify NO in ambient air, perform an ambient measurement, see section 5.5.

- Temperature range of +10°C to +35°C
- A relative humidity range of 20% to 80%, non condensing
- An atmospheric pressure range of 700 hPa to 1060 hPa

Performance shall be sustained when measuring continuously at a pace of up to 10 measurements / hour.

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. See also section 9.2.

9.6.1 Limited warranty

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

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

9.6.2 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.

9.7 Information Security

Circassia maintains a cybersecurity program which includes assessing our security risks and taking mitigations to prevent unauthorized access.

The NIOX VERO® device does not connect to hospital networks or the internet when operating as intended in the healthcare providers setting. It communicates with connected NIOX® Panel Application through USB or Bluetooth. The NIOX® Panel is a PC application that only communicates device data to the Microsoft Azure Cloud using HTTPS-encrypted communication to a Web application programming interface

9.7.1 Access to the NIOX® Panel application and the NIOX VERO® device

Unauthorized access through the internet to NIOX® Panel on a local PC is mitigated by application password, SQL protection, and .Net obfuscation.

Reverse engineering to the software, firmware, and hardware of the NIOX VERO® device is prevented by source code obfuscation, firmware encryption, restricted communication protocols as well as use of a proprietary operating system designed for the device.

Unauthorized access of information from the NIOX VERO® device through a Bluetooth connection is prevented by a Bluetooth security PIN hardcoded into the Panel software and the encryption of connection data per Symantec.

The Panel installation USBs are locked to write access and the user shall follow their own IT policy to ensure the workstation/network malware protection is enabled to prevent the USB drive from being compromised with malware.

The users shall follow the physical security policy in their local healthcare providers system to prevent any unauthorized physical access to the device or the NIOX® Panel.

9.7.2 Access to Patient identifiable information

Circassia does not collect any personal identifiable information from the user or patient, but only receives technical data such as timestamps, alert codes, and the number of remaining measurements on the device and sensor for customer support purposes, if the user permits.

The patient ID is optional information that can be entered by users and used to distinguish patients for each measurement. The user shall comply with local regulations on patient information privacy when generating and using unique patient identifiers.

9.7.3 Data transfer and Cloud storage protection

An Azure Cloud Security System is utilized to ensure the safety of data transfer and storage.

The data is encrypted when it is sent from the application to the cloud and when it is written to the storage. The access to the storage account is controlled by Role-based Access Control and Azure Active Directory and can only be granted by using shared access signatures. The authentication method for each access is tracked by using analytics.

10 Reference information

10.1 Buttons and descriptions

10.1.1 Control buttons


OK - accept changes/verify result


Undo - closes view without saving changes


Return


Erase button


Skip


Decrease/step downwards


Increase/step upwards


Check box (not active)


Check box (active)


Delete


Edit


Set configuration

Demo


Reset handle

Time/date (active for resetting)


Start ambient measurement


Start 10s measurement

Start 6s measurement

10.1.2 Main menu buttons


Measurements mode 10s


Measurements mode 6s


Settings


Demo


Patient ID

10.1.3 Settings view buttons


Configuration


Volume


Alert logs


Instrument status


Time and date


Patient measurements


Ambient measurements


Breathing handle status


Enable Bluetooth

10.2 Symbols and descriptions

10.2.1 Status bar


Battery - fully charged


Battery ≤87% charge


Battery ≤62% charge


Battery ≤37% charge


Battery ≤12% charge


Bluetooth enabled


Instrument connected via USB


Audio - mute

Breathing handle - about to expire or has expired (blinking)

Instrument - about to expire or has expired (blinking)

Sensor status - followed by number of measurements remaining

Sensor status - no sensor

Warning - temperature is not within operating conditions range

Warning - humidity is not within operating conditions range

Time

Connected to Microsoft Azure (Only shown in NIOX® Panel status bar)

Not connected to Microsoft Azure (Only shown in NIOX® Panel status bar)

10.2.2 Display

Analysis progress bar

Volume bar

General warning

Screen code - correct

Screen code - incorrect

Result screen - Ambient measurement

Cloud - pressure within limits

Cloud - goal reached

Cloud - warning pressure too high or too low

10.3 Symbol explanation

Responsible manufacturer

The product meets the requirements of applicable European directive

Electrical safety Type B applied parts:
Breathing handle and patient filter

European Directive 2012/19/EU related to the disposal of electrical and electronic devices. The product should be recycled according to the local program for electronic equipment.

European Commission Directive 2006/66/EC related to all batteries and accumulators applies to this product. The battery in this product should be recycled according to the local program for batteries.

Consult instructions for use

Expiration date

Transport and storage temperature limitation

For single use only

In Vitro Diagnostic Device

Transport and storage relative humidity limitation

Transport and storage atmospheric pressure limitation

Equipment protected throughout by DOUBLE INSULATION or REINFORCED INSULATION

The Device includes a Radio Frequency (RF) transmitter (Bluetooth)

NRTL-listed

Prescription use only

Manufacturing Date

Medical Device

11 Technical data

11.1 Dimensions and weight

Height: 145 mm
Width: 185 mm
Depth: 41 mm
Weight of instrument including sensor: 1kg

11.2 Electrical data

Electrical safety classification:	The equipment complies with the requirements according to IEC 60601-1 and IEC 61010-1. Class II ME EQUIPMENT while externally powered, and as INTERNALLY POWERED ME EQUIPMENT while powered by battery.
Mains Voltage:	100-240 V ~47-63 Hz
Secondary voltage (external power adapter):	5 V ⎓
Power consumption:	< 15 VA

11.3 Noise level

< 65 dBA, at a distance of 1 m

11.4 Exhaled NO - performance data

The instrument is verified to fulfill the specified performance under a temperature range of +10 to +35 °C, relative humidity range of 20-80% and pressure range of 700-1060 hPa.

Measurement range:
FeNO: 5 to 300 ppb
Lowest Detection Limit: 5 ppb
Determination by analysing gas concentrations around and below the detection limit. 5 ppb was the lowest detectable level.

11.5 Linearity

Squared correlation coefficient $r^2 \geq 0.998$, slope 0.95 -1.05,intercept ±3 ppb.

11.6 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.

11.7 Accuracy

±5 ppb for measured values < 50ppb or 10% 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.

11.8 Method comparison

< 10 ppb for values ≤ 50 ppb, < 20% for values > 50 ppb. Expressed as the difference between a NIOX MINO® FeNO value and the corresponding FeNO value measured with NIOX VERO® instrument from Circassia.

11.9 Inhalation parameters

Inhale to TLC (Total Lung Capacity) before start of exhalation. Inhalation in instrument is triggered by a pressure of -3 cm H_20.

11.10 Exhalation parameters

Exhalation time: Preferred mode: 10s
Paediatric mode: 6s
All exhalations are to be performed at an exhalation pressure of 10 - 20 cm H_2O, to maintain a fixed flow rate of 50 ±5 ml/s. The instrument stops the measurement at pressures outside the interval. Warning alerts sounds at 10 - 12 and 18-20 cm H_2O.

11.11 Essential performance

Essential performance for NIOX VERO® consists of

1. The measurement of the NO concentration of exhaled human breath
2. The control of exhaled breath for Asthma management 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.

11.12 Memory capacity

Up to 15,000 measurements, depending on the size of the measurement files.

11.13 Patient filter

The NIOX VERO® Patient Filter is labeled for single use only and must be replaced for every patient. Reuse between patients could increase the risk of cross-contamination or cross-infection. The same filter can be reused in one patient for multiple attempts in the same session.

Bacterial, viral filter, CE marked according to EU Medical Device Regulation 2017/745 Class I.

11.14 Bluetooth

NIOX VERO® has a Bluetooth class 2 receiver/transmitter with:

- Frequency band of 2402MHz~2480 MHz.
- Modulation method
  - 0,5BT Gaussian Filter 2 FSK modulation index: 0.28~0.35 (Basic Rate 1Mbps)
  - π/4-DQPSK (EDR 2Mbps)
  - 8DPSK (EDR 3Mbps)
- ERP
  - Power class 2

11.14.1 RED Directive

Hereby, Circassia, declares that this NIOX VERO® is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.

11.15 Rechargeable battery capacity

Only use the power adapter or USB cable supplied by Circassia to charge the battery.
Capacity: Approx. 30 measurements per day or 36 hours stand-by in 25°C environment condition.
Lifetime: At least one year with normal use.
Charging time: <8 hours under normal conditions.
Lowered capacity, and/or when 8 hours of charging time does not charge the battery fully, indicates that the battery should be replaced.
Battery Type No BJ-G510039AA, Article No 12-1150.

Note: To charge the battery by USB cable, the instrument needs to be powered off.

11.16 Instructions for transport and storage

CAUTION! Always use a closed bag or box for transportation and storage of NIOX VERO®.

1. Verify that the instrument is turned off and disconnected from the power supply.
2. Remove the patient filter and attach the protective cap on the handle.
3. Place the instrument and accessories in the bag and close bag.
4. Verify that the storage environment conditions are appropriate see recommendations for NIOX VERO® including sensor.

11.16.1 Transport and storage in unopened original package

	Temperature	Relative humidity (non condensing)	Atmospheric pressure
NIOX VERO® Instrument	10-35 °C	10-80%	500-1070 hPa
NIOX VERO® Sensor	5-35 °C	10-99%	700-1070 hPa

When transporting the instrument from one location to another with different ambient conditions, a prolonged stabilisation period might be required before measurements can be performed.

11.16.2 Transport and storage after package has been opened

	Temperature	Relative humidity (non condensing)	Atmospheric pressure
NIOX VERO® Instrument	10-35 °C	20-80%	700-1060 hPa
NIOX VERO® Sensor	10-35 °C	20-80%	700-1060 hPa

12 NIOX VERO® parts and accessories

CAUTION! When selecting an accessory for your NIOX VERO® 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.

12.1 Parts included in NIOX VERO® package (Article No. 12-1100)

NIOX VERO® Instrument (12-1000)

NIOX VERO® Breathing Handle (12-1010)

NIOX VERO® Handle Cap (12-1009)

NIOX VERO® Power Adapter (12-1120)

NIOX VERO® Power Cord (12-1130)

NIOX VERO® USB Cable (12-1002)

NIOX VERO® Battery (Type No BJ-G510039AA, Article No 12-1150)

NIOX VERO® Stand (12-1001)

NIOX VERO® User Manual (000191)

NIOX® Panel USB Memory stick (12-1003)

12.2 Accessories

NIOX VERO® Test Kit 100 (12-1810)
Contains: 1 Sensor* for 100 tests and 100 NIOX VERO® Filters

NIOX VERO® Test Kit 300 (12-1830)
Contains: 1 Sensor* for 300 tests and 300 NIOX VERO® Filters

NIOX VERO® Test Kit 500 (12-1850)
Contains: 1 Sensor* for 500 tests and 500 NIOX VERO® Filters

* NIOX VERO® Sensor
Pre-calibrated disposable sensor for 100, 300 or 500 measurements.
Operational life-time: Maximum 12 months when installed in NIOX VERO® or expiration date as stated on the sensor, whichever comes first.

NIOX® Apps (12-1004)

NIOX VERO® Nasal kit (12-1065 Pediatric, 12-1045 Adult)

13 Vigilance

Circassia, as a medical device manufacturer, must have a Vigilance system in place to report to health authorities, any adverse incidents that have occurred with its medical products.

The purpose of the Vigilance system is to ensure the health and safety of patients, users and others using medical products by reducing the likelihood of the same type of adverse incident being repeated. This is achieved by immediate notification of incidents to enable corrective and preventive actions.

An adverse incident is defined as: Any malfunction or deterioration in the characteristics and/or performance of a instrument, or any inadequacy in the labeling or instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his/her state of health.

Manufacturers of medical devices are obliged to report adverse incidents to national health authorities within 10 or 15 days, dependent on the severity of the incident.

Any user of Circassia's products who experience an adverse incident related to the product, must immediately report this to Circassia and the competent authority of the Member State where the incident occurred.

The report can be made by e-mail, fax, or telephone. The report should contain the following information:

- When and where did the incident occur?
- What product / accessory was involved?
- Was the incident related to instructions for use of the product?
- Was the risk foreseeable and clinically acceptable in view of potential patient benefit?
- Was the outcome adversely affected by a patient's pre-existing condition?

The report should be forwarded to Circassia's local representative as well as the competent authority in the Member State where the incident occurred.

14 Revision History

Revision	Changes
02	Initial release
03	Corrected typographical errors. /Added Windows 8.1 in requirements / NIOX® Panel connectivity module information added / Firmware Update added / Added symbol for NRTL / Modified Precision information / Added reference to NIOX® Patient
04	Added reference to PC user manual and symbol for prescription use
05	Added explanatory notes / Image updates/Added explanation of cloud icon / Added to statement on deciding at a later stage to allow data collection /Added “Changing contact details” /Changed reference to NIOX® Patient to NIOX® Apps
06	Updated system requirements and removed notes from 6.2 and 6.7.1
07	Added note on storing patient filters / Updated firmware version reference / Added reference to alert code A42 / Updated shelf life of patient filter to 3 years /Added section for “Essential Performance”
08	Changed Aerocrine to Circassia and modified information on patents / Changed web address from Aerocrine to NIOX®.
09	Changed “customer support” to “technical support” / Added clarification to the statement on the number of measurements that can be performed / Added warnings related to the use of alcohol / Changed responsible manufacturer address within Sweden / Moved and expanded warning related to use of alcohol / Added a bullet concerning replacing sensor or batteries while the device is in operation / Added a statement concerning used patient filters / Modified the bullet concerning the maximum number of exhalations.
10	Addition of nasal nitric oxide: Intended Use modified / Added “Activate Nasal measurement mode”/ Added “Perform Nasal measurements”
11	Clarified point on instrument operational life / Added NIOX® Panel CE marking /Added statement on NIOX® Panel SW / Updated firmware revision reference/ Updated phone number on cover
12	Updated firmware revision referenced / Modified note in 6.6 / Added symbol for manufacturing date
13	Updated firmware revision referenced
14	MDR updates: Modified the warning for Patient Filter reuse / Updated text describing disposal of electronic waste and added an alternative symbol / Added MD symbol / Created table for transport and storage conditions and removed initial transport conditions/ Removed note on Filters / In vigilance section, changed reporting days from 30 to 10/15 and added a statement about reporting to Circassia and the competent authority
15	Moved warning to warnings section / Remove software version from 1.2 / Minor updates to the intended use statement / Add section 1.7 Principals of Operation / Removed the word “caution” from 5.3.3 / Turn QC functionality on or off section, clarified / Added for Information Security / Changed R&TTE Directive to RED Directive / Revision History added / Removed TK 1000 (obsoleted)
16	Added Windows 11 as system requirement in section 6.1

Information in this document is subject to change.

Amendments will be made available as they occur.

Based on the company's intellectual property, NIOX® Group plc 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:

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

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