NOXTEC
NIPPON GASES

NTX_2210IU: "Instructions for Use (EN)"

CE
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1. User Responsibilities

NOXtec device will operate and must be set up, operated, maintained and repaired in accordance with the information contained in this Manual, the Technical Manual, the device label and other documents attached to the device by the manufacturer.

NOXtec should be ONLY used in accordance with the Intended Use contained in this manual (section 6.1). Do not use this unit for other purposes than those specified by the manufacturer.

NOXtec should be checked periodically by qualified personnel. If the device is defective, broken or with visible mechanical deformations, turn it off and do not use it for clinical activities.

Do not use disposables different to those recommended by the manufacturer. If any part of the device, or a disposable, is damaged, contaminated or defective, replace it immediately.

Should the device need to be repaired or replaced, it must be reported to the technical service and must be repaired only by qualified personnel authorized and certified by NOXtec Development S.L.

Check regional legislation or restrictions that must be applied to the sale or use of this device in your country. Use only NO mixed cylinders approved for medical use and handle and store them in accordance with the regulations in force in your country.

WARNING: Users of this product are responsible for any malfunction resulting from improper use, defective maintenance, improper repair, damage or alteration by any person or entity other than NOXtec Development S.L. or authorized by this manufacturer.

WARNING: The user is RESPONSIBLE for reporting to the manufacturer about any serious incidence that happens related with this device.

2. Symbols

Symbols used

Symbol	Description
Note	Provides additional information or clarification
	Indicates the way of using the device properly and those conditions that may damage it
WARNING	Represents a hazardous situation regarding procedures or operating conditions mentioned in this manual that may result in injury or death of the user or the patient if operation is not correctly performed
	Consult this this manual
	Manufacturer address
	Serial number
	Do not reuse, one use only
	Applicable part type B
	Gas inlet port
	Gas outlet port
	USB connector. This is intended for connecting NTFS or FAT / FAT32 formatted USB memory for data and logs collection or for technical purpose only.
	Ethernet connector. This is for remote technical assistance only.
	Storage and transport pressure limit; indication on the packaging.

	Storage and transport relative humidity limit; indication on the packaging.
	Product reference

3. Safety Warnings

- Read and follow all cautions and warnings.
- Read this manual before using NOXtec.
- To dose manually, if the device is not already dosing, it is necessary to 1) purge the inlet line for 5 seconds and 2) to disconnect the dosing tube from the patient circuit and keep the device dosing to the environment for 2-3 minutes before connecting back the dosing tube to the inspiratory limb and dose NO to patient.

Note: NOXtec does not automatically vent the circuit before starting to dose in standby or in manual mode.

- NOXtec is intended to be used by healthcare professionals only.
- The use of accessories or cables not specified by NOXtec Development S.L. may lead to an increment in radiofrequency (RF) emissions or a decrement in the immunity of the device.
- This device may cause RF interference or may disturb the operation of other devices closed to it. Mitigation may be necessary, such as re-orientation or re-location of the NOXtec or the other devices or the use of proper shielding.
- NOXtec needs special cautions regarding Electro-magnetic compatibility (EMC) and needs to be installed and commissioned in accordance with EMC information supplied.
- Portable and mobile RF communications devices can affect the device.
- NOXtec should not be used very closed or stacked with other devices, unless it is strictly necessary in which case, it should be verified the device operates as expected in the configuration that it will be used.
- Do not touch the enclosure of NOXtec if it is damaged to avoid possible electrocution by accessing to 220 V.
- To avoid the risk of electric shock, this device should only be connected to a main with protective earth.
- If the internal power supply of the device fails, do not replace it, or other internal components, by your own. Do not use the unit and call to the specialized technical support for assistance.
- Do not open the unit if you have not been trained and certified previously for technical support by the manufacturer of the product. Do never touch internal electronic boards without using the proper electrostatic discharge protection.
- The unit incorporates an Ion-Lithium battery to power the unit in case of main power failure. This must be replaced by qualified technical personnel only. Incorrect replacement may cause a serious hazardous situation including excessive temperatures, fire or explosion.
- When the device is not dosing, it is highly recommended to close the NO cylinders and manually purge the inlet lines to depressurize the system.
- It is responsibility of the user to replace the N_2/NO cylinder once it is depleted to avoid treatment interruption and consequently negative effect on the patient state.
- The option for automatic cylinder exchange can be enabled or disabled by the user. If it is disable the device does not guarantee to continue supplying gas to patient if the cylinder that is selected runs out of gas. Then, disabling this functionality is not recommended for clinical applications.

4. Definitions and Abbreviations

Definitions and abreviations

Abbreviation	Description
NO	nitric oxide
NO_2	nitrogen dioxide
O_2	oxygen
N_2	nitrogen
ppm	Parts per million
PaO2	Oxygen pressure in arterial blood
m	Meters
mm	Millimetres
Kg	Kilograms
L	Liters
H	Hour
min	Minutes
s	Seconds
ºC	Celsius degrees
V	Volts
A	Amps
HFOV	High-Frequency Oscillatory Ventilation
Hz	Hertz

W	Watts
EMC	Electromagnetic compatibility
RF	Radiofrequency
Respiratory flow or bias flow	Flow of gas in the inspiratory limb from the ventilator to the patient
Dosing flow	Flow of NO injected to the inspiratory limb that is mixed with the flow in the inspiratory limb to dose NO to the patient
EEPROM	Electrically Erasable Programmable Read-Only Memory. Data remains stored when the memory is not powered electrically, or when the device is off.

5. Scope

This manual is the Instructions for Use for the next devices NOXtec. This is covering:

- NOXtec 1000 Nitric oxide monitor and delivery system,
- NOXtec 2000 Nitric oxide monitor and delivery system (semi-automatic and manual mode)

The features of the device models and the elements to take in consideration to be able to use NOXtec safety, the intended use and the different modes of operation of the device are included in this manual

It is very important to read this manual carefully before using NOXtec. Images and diagrams are included to support the user to understand better the device and to use it in the best way and easier.

This document is subject to periodic reviews. If the changes introduced are not safety critical, the new version of the manual wont be submitted by default to all users.

For any query regarding this manual or about the use of NOXtec devices, please contact the manufacturer:

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Moralzarzal – 28411, Madrid, (Spain)
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email: noxtec@noxtecdevelopment.com

6. General Description of the Device

NOXtec is a device for dosing and monitoring nitric oxide. It is used for inhale NO therapy for adults, children and new-borns. NOXtec monitors the concentration of NO, NO_2 as well as O_2 delivered to patients.

Dosing, monitoring and user interface modules are autonomous and independent. This means that, in a hypothetical failure situation in one of the modules, the others will continue operating normally, increasing the patient safety.

The thresholds of the monitoring module alarms, as well as for the alarms of the dosing module, are pre-programmed in EEPROM to ensure that in case of failure in the user interface, it will not affect the performance of the audible alarms. Additionally, audible alarms in dosing and monitor modules are independent.

The NOXtec dosing module has an automatic NO cylinder exchange system that increases unit autonomy and patient safety. Additionally, this module includes an automatic venting system for avoiding the use of the stationary gas into the internal pipes of the dosing module before starting to deliver NO gas to the patient. This is for minimizing the undesirable concentrations of NO_2 generated due to the reaction between the NO and the O_2 when the gas is stationary in the circuit that could be delivered to the patient at the beginning of the treatment.

The device has an exhaust port in the back panel for the evacuation of all gases released into the device, i.e. sampling gas, venting gas, etc. Connect a 22mm tubing from the exhaust port to the extraction system of the room, to a scavenging system or to absorbents to ensure minimizing the NO and NO2 concentration into the room where the device is used.

The different characteristics of the NOXtec models 1000 and 2000 are summarized in the following table:

Difference between device model 1000 and 2000

Model	Dosing modes	Automatic cylinder exchange	Automatic calibration of gases sensors	Manual dosing mode (Emergency)	Range of dosing flow (L/min)*	Purging system
1000	Real time, Automatic, Semi-automatic & Manual	Yes	Yes	Yes	0 – 4	Automatic and manual
2000	Semi-automatic & Manual	No	Yes	Yes	0 - 1	Manual

* Check the detailed values in Section 19.3.

6.1. Intended Use

This device is intended for delivering certain concentration of Nitric Oxide (NO) gas to patients that require this gas from 0 to 100ppm. It is intended for the treatment of:

a) persistent pulmonary hypertension in new-born,

b) hypoxic respiratory insufficiency in new-born,

c) acute post-operative cardiac patients,

d) acute respiratory distress syndrome,

e) pulmonary hypertension,

f) severe hypoxemia.

NOXtec 1000 is the fully equipped device and NOXtec 2000 is the manual semi-automatic dosing system with monitoring.

Depending on the model, NOXtec measures the patient's flow in the inspiratory limb and calculates the N_2/NO flow required to dose a certain concentration of NO to the inspiratory limb according to the concentration of NO in the cylinder. It also takes a sample of the gas supplied to the patient to measure the concentration of NO, NO_2 and O_2 in the mixture.

The device should be used by trained healthcare personnel for the treatment of new-born, children and adults. Patients with special needs such as new-born or children should be supervised by healthcare personnel throughout the treatment.

The device should be connected to the main but also includes an internal battery for keeping the power for few hours. No connectivity to a server is required. The device is used in combination with 22mm, 15mm or 12mm ventilatory circuit. Use only disposable kits recommended by the manufacturer.

It is not expected that the patient interacts with the device, but that it is handled by qualified health personnel. NOXtec must only be installed by qualified personnel.

NOXtec should be used in dry places, indoors only, and with a temperature between +10ºC and 40ºC.

The device is intended to be used in a hospital environment. It incorporates a manual dose bypass that can be used in case of device failure. If the device is used for transporting the patient, special care should be taken by the user to ensure patient security (i.e: correct and safety connection of the circuit, pre-selection of the manual flow position, extra-monitoring in case of neonate applications, etc.).

NOXtec is intended for the treatment or alleviation of diseases. The model 1000 has a RS232 port for synchronizing information with certain intensive care unit ventilators (see Table in Chapter 22, column RS232). Use this functionality only with compatible ventilators certified by this manufacturer.

The software of the unit (User Interface and dosing and monitor firmware) can be updated locally or remotely but only by authorized and qualified personnel.

WARNING: In case the device is used for intra or extra-hospital transportation, the user must take care of the patient and monitor it properly.

Note: Check the detailed measurement parameters for more details of the range of operation of the device. It is not recommended to use the device out of the specified operation ranges.

6.1.1. Benefit Expected Using the Device

NO is an endothelium-derived relaxing factor synthesized from L-arginine by the enzyme NO synthase. It has been identified as an important, short-acting, endogenous vasodilator. In patients with pulmonary hypertension, inhaling a low dose of NO as a gaseous vasodilator has been shown to induce selective vasodilation in ventilated lung areas. It achieves this without the disadvantages attributed to systemically infused vasodilators e.g. systemic vasodilation and an increase in pulmonary right-to-left shunt with a consecutive fall in PaO2. Thus, inhaled NO reduces pulmonary hypertension in the severe adult respiratory distress syndrome and in persistent pulmonary hypertension of the new born, and improves arterial oxygenation by redistributing pulmonary blood flow away from the shunt and towards areas with almost normal ventilation/perfusion ratios. The bronchodilator effect of NO may be an alternative therapy for treating asthma and bronchospasm.

6.1.2. Side Effect and Contraindication of Using NO

Nitric oxide may cause serious side effects including:

- noise breathing (the most common side effect),
- difficulty breathing,
- blood in the urine,
- low blood pressure, and
- collapsed lung

Medical support is required in case of the symptoms listed above.

WARNING: If a patient experiences any side effect bothering him/her or that does not go away, notify the local healthcare authority for registering the side effect. Note that other non-described potential side effects could be identified.

6.2. Operating Principle

NOXtec 1000 measures flow in the inspiratory limb provided by the ventilator to the patient and delivers an accurate dose of NO to the patient in a controlled and convenient manner. NOXtec 2000 deliver the gas in a constant flow without measuring the flow in the inspiratory limb. The device also monitors the concentration of NO, NO_2 and O_2 that the patient is receiving sampling the inspiratory limb as close as possible to the patient.

The concentrations of NO cylinders are 400, 800, 900 and 1000 ppm diluted in N_2 by default but it could be used with whatever cylinder from 200 to 1,500 ppm. However, the concentration(s) that will be available in the device is customised by mean of the configuration file; i.e. if the user will use only 800ppm, the device can be configure to have only that concentration available. The concentration of the cylinders can be selected through the user interface and the information is stored in the EEPROM of the dosing module. However, note that the list of permitted concentration of cylinders to be use with a devices is configurable. If the cylinder that the user wants to use is not in the list, contact with the technical support for update the configuration of the device.

A pressure regulator is needed attached to the gas cylinder to reduce the cylinder pressure down to 4bar. It is connected to NOXtec using self-sealing quick connectors. NOXtec measures the pressures before and after the regulator and has an automatic system to exchange them when the one that is in use is below a pre-set threshold. It also includes a manual and automatic purging system for venting the gas remaining into the low-pressure circuit, or in the flexible hoses, for replacing the cylinder(s) as well as before and after the therapy.

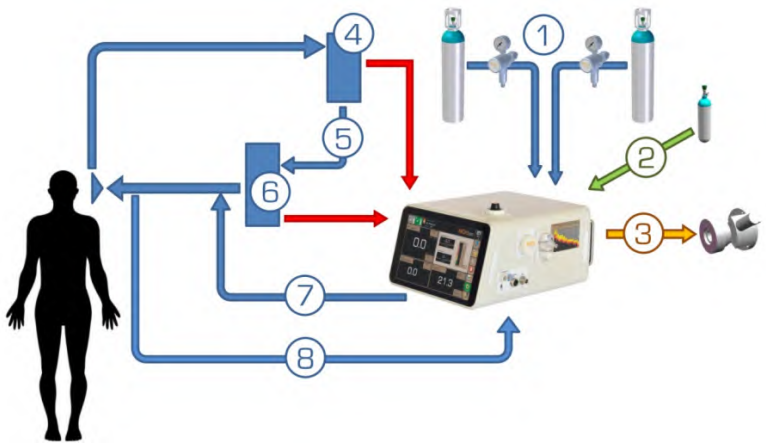
The cylinder gas is connected to the inlet connector of the dosing system; a normally open pneumatic circuit composed by electro-valves and sensors. NOXtec also incorporates a manual flow controller for dosing when the user requires it, in emergency situations or for dosing under critical failure conditions.

The microcontroller that incorporates the dosing module receives the target dose in ppm, selected through the user interface, and converts it into the required dosing flow as a function of the flow in the inspiratory limb defined and the concentration of gas in the cylinder in use. Either manual or automatic dosing flows are monitored by a dosing flow sensor for increasing the device accuracy. When the device is dosing automatically, this measurement is used as feed-back to the dosing system and generate alarms in case the dose is out of specification (high, low or unstable flow).

On the other hand, the NOXtec monitoring module measures the concentration of NO, NO_2 and O_2 that the patient is receiving by sampling the gas through the water trap and the 3 gases sensors. These sensors have to be previously calibrated through the user interface using a calibration gas cylinder connected to the rear input of the device.

The user interface shows NOXtec functionalities and the measurements, permits setting the dose to the patient and guides the user throughout the use of the unit.

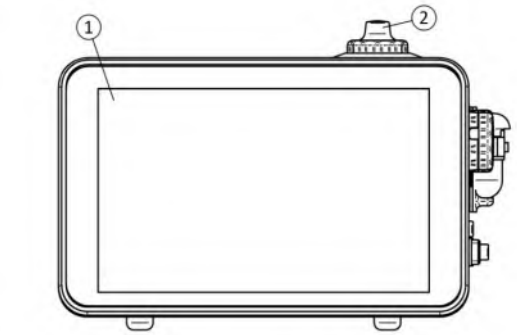
Components needed to use the device, and th general installation of the device ein the respiratory circuit are described in the next Figure. Dosing system is implemented in version 1000 and 2000 and the second NO cylinder and the flow sensor is only available in version NOXtec 1000.

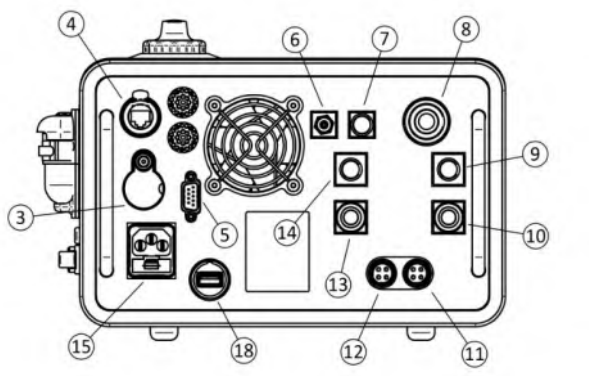


1. NOXtec device
2. Calibration cylinder
3. Exhausted gas
4. Ventilator
5. Inspiratory limb
6. Flow sensor
7. Dosing flow
8. Sampling flow

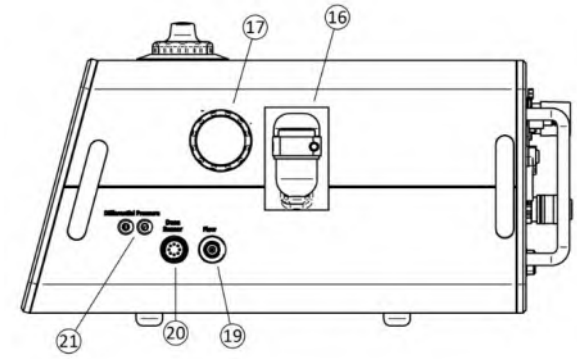
General diagram of the connections

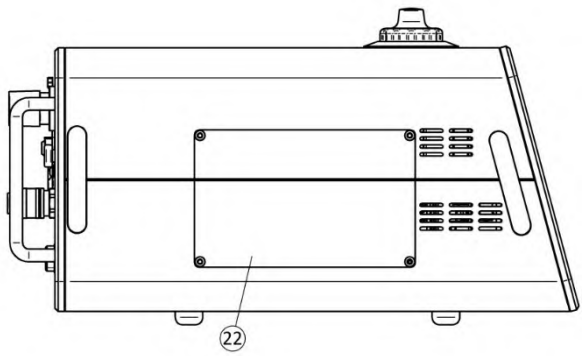
6.3. Applicable and Connectors of the Device





1. Screen (LCD touch screen
2. Control button
3. On/Off button
4. Ethernet port (for technical support only)
5. RS232 port (for reading the flow in the inspiratory limb from some ventilator
6. Calibration gas inlet
7. Manual purge of calibration gas
8. Venting outlet
9. Manual purging for cylinder 1
10. Cylinder 1 inlet connection
11. Cylinder 1 pressure sensor connection
12. Cylinder 2 pressure sensor connection (for 1000 ONLY)
13. Cylinder 2 inlet connection (for 1000 ONLY)
14. Manual purging for cylinder 2 (for 1000 only)
15. Power cord connection



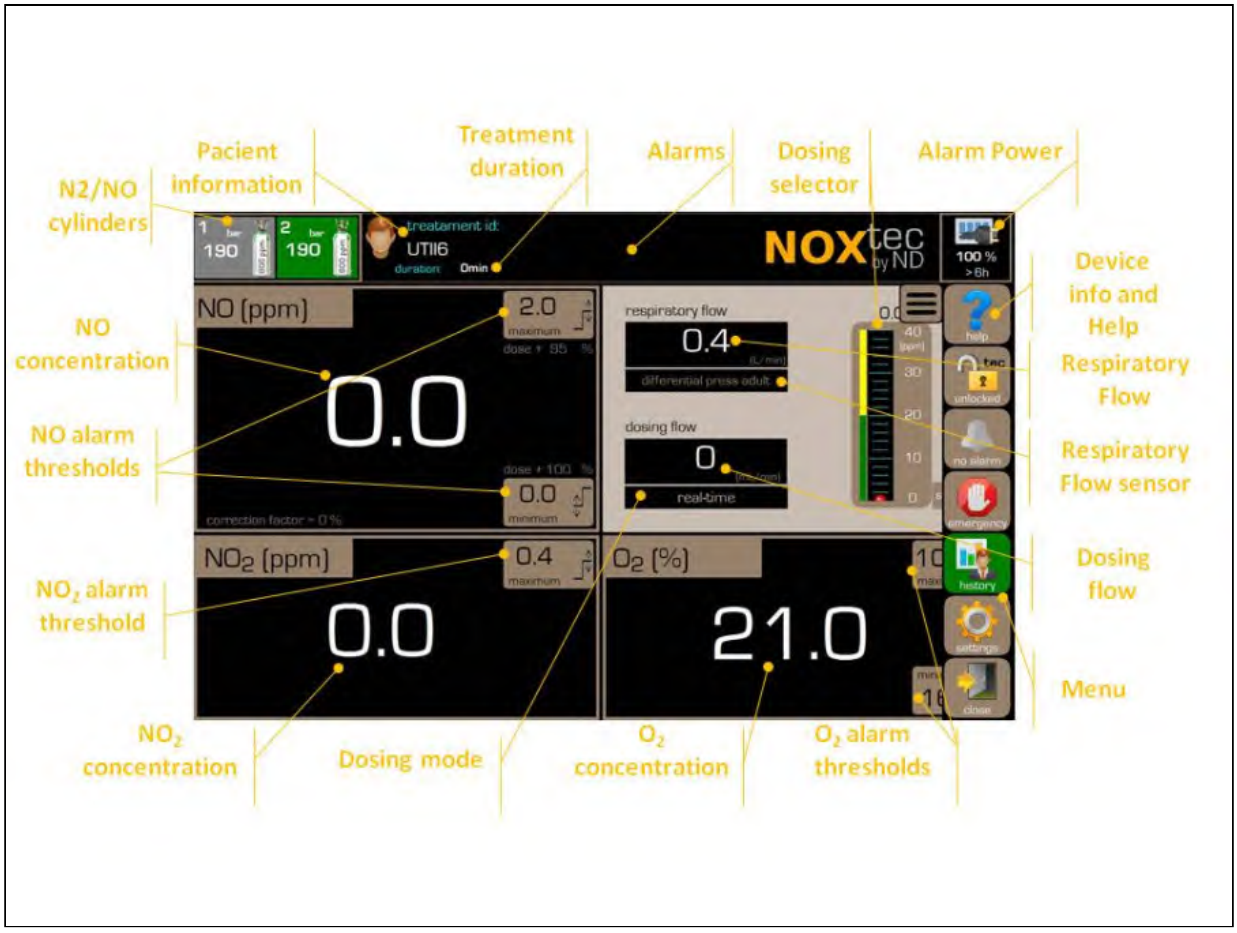


16. Water trap
17. Manual flow control (bypass) for dosing
18. USB port
19. NO dosing outlet
20. Hot wire flow in the inspiratory limb sensor connector (for 1000 only)
21. Pneumatic connector for the differential pressure flow in the inspiratory limb sensor (for 1000 only)
22. Access lid for the gases (NO, NO_2 and O_2) sensor manifold

Description of the device connections

7. User Interface description

The main screen of the User Interface allows the user to access to the most used parameters during the therapy. Measurement of the gases delivered to the patient and other measurements required for the unit control are as well displayed. The User Interface can be operated by the touch screen (not all functionalities) or by the control knob in the top left of the device.

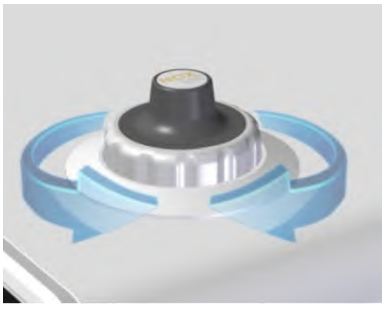


User interface description

7.1. Control Knob Button

NOXtec has a control knob button for navigating through the different options in the menu or magnitudes and for setting the desired values.

Turn around clockwise or anticlockwise the control knob to navigate through out the menu options and for increasing or decreasing a selected magnitude.

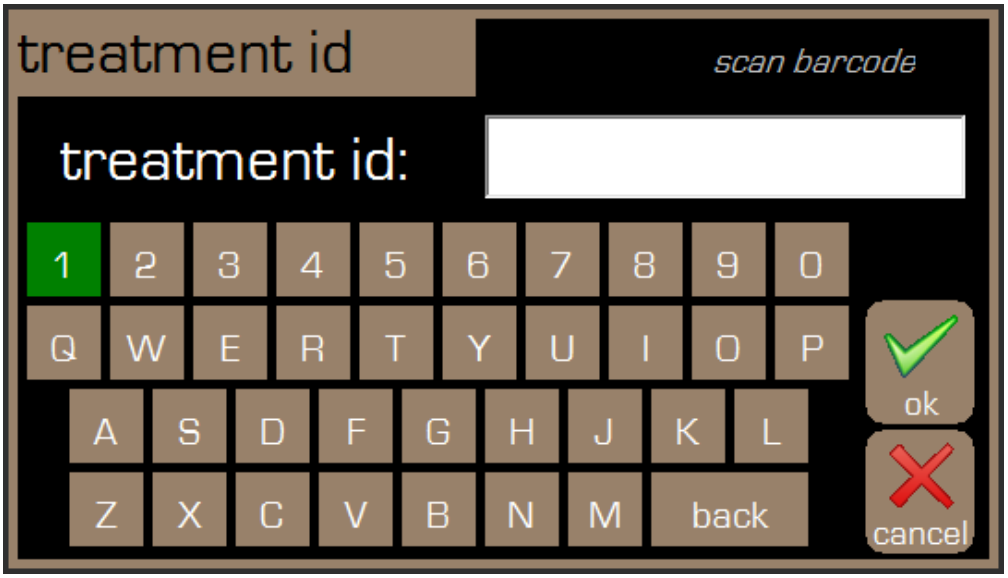


Push down the control knob to select an option or to confirm a new value.

The appointed or selected option, magnitude or device functionality in the menu is shown with the background in green. When the background is cyan, the option is ready for changing the corresponding value.

7.2. Patient Identification

When NOXtec is started, or the user selects the option to start a new treatment, the patient identification window is shown. The treatment id can be entered manually or by a barcode scanner connected to the USB port.



User interface: patient ID form

When the id is entered, it is displayed in the central top side of the User Interface (see Section 7.3).

For starting a new treatment without cycling OFF and ON the unit, follow the next steps:

[Configurable] The device can be configured by mean of the configuration file to avoid the request for the patient id. If this option is enabled, the patient id will be automatically created by mean of: "serial" + "yy" + "mm" + "dd" + "hh" + "nn", where:

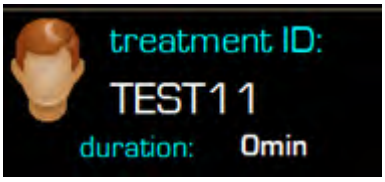
- serial: is the device serial number,
- yy: the year when the treatment was started,
- mm: the month when the treatment was started,
- dd: the day when the treatment was started,
- hh: the hour when the treatment was started,
- mm: minutes when the treatment was started.

Should you want to change the configuration, consult to the technical staff.

7.3. Patient Information Area

Patient information area is in the central top side of the User Interface. It is displaying the next information:

- Patient ID (or treatment ID),
- Treatment duration.



The treatment ID is used for identifying the change of status of the unit and the measurements saved into the internal memory. It allows retrieving the information for further analysis.

7.4. N_2/NO Cylinder Area

Treatment N_2/NO cylinders' area is in the top left side of the User Interface. There are some parameters accessible:

- Pressure of gas into each cylinder,
- Concentration of NO in the cylinder,
- Time remaining.

The cylinder that is selected for the treatment is identified because the background is in green. For example, according with this picture, it is the cylinder 1.

Time remaining depends of the: a) average flow used for the treatment, b) accuracy of the cylinder volume, c) configuration of the cylinder volume in the device, d) temperature changes.

Note: NOXtec device can be used only with cylinders of the same concentration. Combination of 2 cylinders with different concentrations is not allowed.

WARNING: Time remaining is only a reference and cannot be used to decide when a cylinder in use needs to be replaced. It is responsibility of the user to ensure replacing the cylinder in time to avoid interruption of the treatment.

7.5. Battery Area

Battery area is in the top right side of the User Interface. The battery charge (in percentage) and the autonomy time are shown in that area. The colour of the numbers identifies the status of the battery:

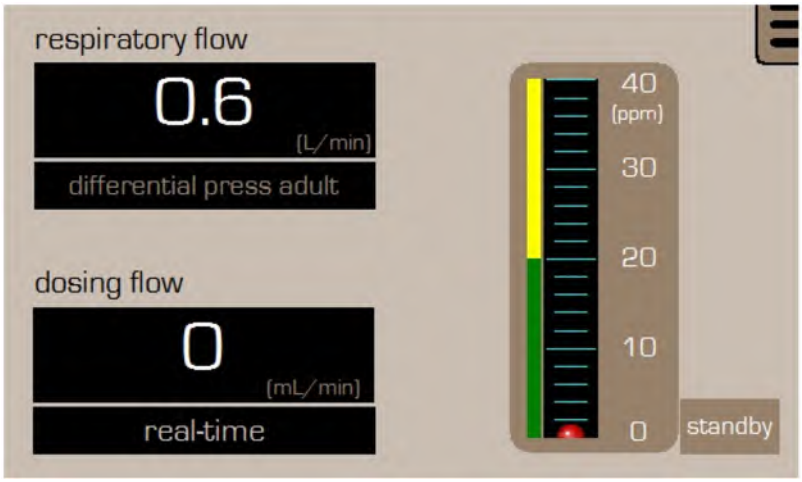
- (white, or primary font color) battery is not charging nor discharging. Battery is full.
- (cyan, or thirdly colour) battery is discharging. Timing is the autonomy time discharging.
- (white, or primary font colour) battery is charging. Timing is the charging time.

In case it is required a replacement of the battery, this must be carried out by qualified technical personnel in accordance with the manufacturer's instructions.

7.6. NO Set Point Area

The NO set point area is in the right center-top side of the User Interface. Some information is displayed:

- Respiratory flow sensor (average of the flow in the inspiratory limb)
- Respiratory flow sensor selected (it could be hidden by configuration),
- Dosing flow (it could be hidden by configuration),
- Dosing mode selected (it could be hidden by configuration),
- Set point value (it could be hidden by configuration),
- Set point object,
- Status of the device: dosing, standby.



User interface: set point area

The functionality of this area is explained in Section 7.13.

[Configurable] The set point value could be always visible if it is enabled by configuration file.

7.6.1. Waiting Mode

If the user needs to stop dosing to the paint OR if the device needs to be prepared certain time in advance of the beginning of the treatment, the waiting mode is required.

The waiting mode of the device is keeping the dosing set point in cero. The device incorporates a fast button to set the dose to cero. The device can be on in waiting time as long as needed.

If the device is in standby mode for longer than 1minute with the respiratory flow not equal to cero, a warning will be display.

Note: If the NO set point is set when the unit is in standby to start dosing, the device will OLWAYS perform an automatic venting as described in the Section 7.14.3.

7.7. Measurement Area

The rest of the User Interface is destinated to the measurements of the gases. Unit measures NO, NO_2 and O_2.

The measurements have also limits for alarms generation in the way:

- NO measurement: has minimum and maximum thresholds limits, that are defined in percentage of the NO dosing set point and are calculated and displayed in ppm.
- NO_2 measurement: has only maximum threshold limit.
- O_2 measurement has minimum and maximum threshold limits defined in percentage.

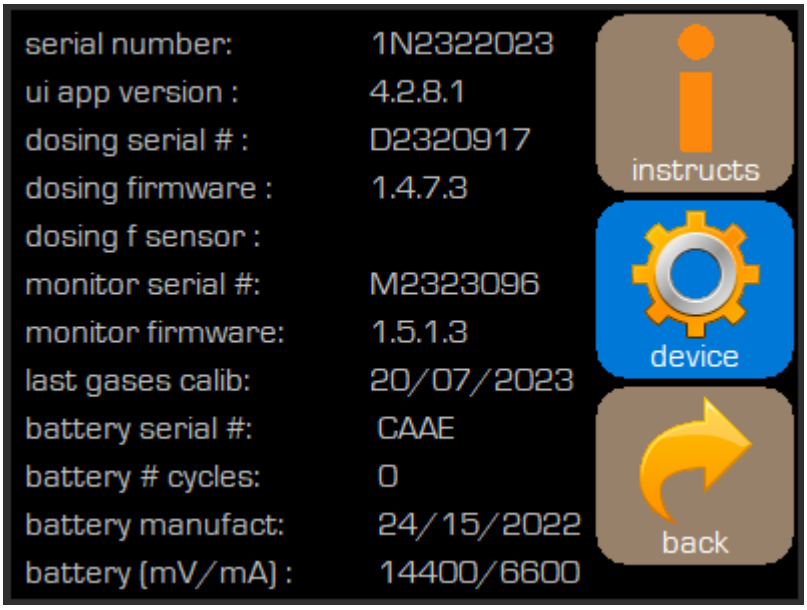
7.8. Help

Help button has a menu with different options:

User interface: help options

- **Instructs:** Interactive videos describing the use of the device. I.e. NO cylinders, connecting the flow in the inspiratory limb sensor, turning off the device, etc.

- **Device:** this menu also shows the data of the device as the version of the software, the date of manufacture, etc.



7.9. Locking the Screen

The screen of the device can be locked for facilitate cleaning the device when it is in operation and for preventing accidental manipulation of the User Interface which may cause undesirable or dangerous situations. Disabled functionalities will be displayed greyed-out.

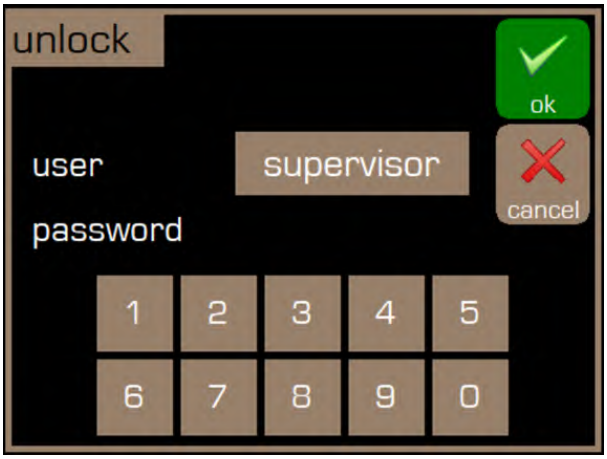
When the lock icon is pressed for unlocking the User Interface, a confirmation window is shown. In the confirmation window the user profile can be selected between as described in the next table.

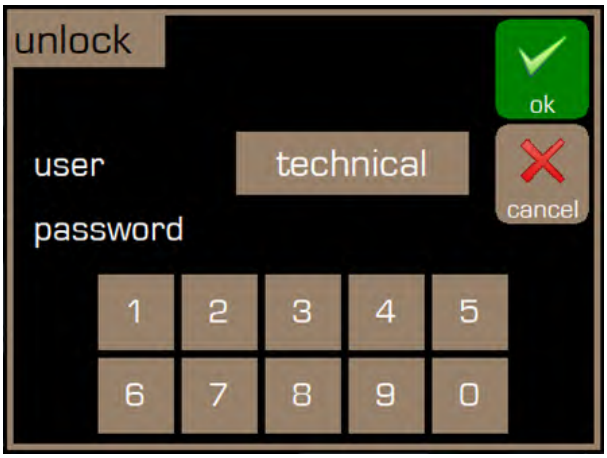
Different user profile rights

User	Password	Access right	Observations
Standard	NO	Limited to change dosing	(optional) can be enabled or disabled in the configuration file
Supervisor	Only required if Standard user is enabled	All except advanced settings and calibration of flow	N/A
Technical	YES	All	N/A

If *standard or supervisor* user is selected to unlock the User Interface, it will be unlocked with restricted access. When the User Interface is unlocked with *technical* user profile all functionalities will be accessible.

Click in user for selecting the user and type the password, if corresponds, for unlock the device with the corresponding access rights.





User interface: unlock screen

7.10. Settings

Settings are divided in four groups:

- **Calibrate:** for performing the calibration of the gases' sensor, verify them, calibrating the flow sensor, displaying the flow for the different positions of the manual bypass flow controller and measure the concentration of gases in the room.
- **Monitor**: is used for enabling the change of the alarm thresholds and for setting the actual concentration of the NO and NO_2 into the calibration cylinder.
- **Dosing**: is used for setting the dosing module parameters
- **Technical (only for technical user profile)**: for setting up the device and change critical dosing parameters. These parameters do not require continuous access.

When a parameter in one of the setting's group is changed, the font colour of the changed parameter is greyed-out. The parameter is sent to the corresponding board and when the board responds with the positive answer it is returned to yellow colour as confirmation. If it is not returned in 5 seconds, repeat the operation.

7.10.1. Calibrate Group

User interface: calibration setting options

In the calibrate group (picture above, left - super-user profile, right - technical profile) the following functions can be accessed:

- **Autocalib**: to perform an automatic calibration of the gases sensors (See Chapter 14).
- **Verify**: to verifies the calibration of the gases sensors (See section 14.1).
- **Meas. room**: to measure the NO, NO_2 and O_2 concentration on the room. The duration of the procedure is about 1 minute. During that time, the patient won't be monitored. For this option, the user must remove the sampling line from the patient circuit. The device will sample the gas from the ambient and will display the results in the measurement area during a period of 10min. After that time, the measurements will be vanished.
- **Calib flow**: To calibrate the high and low-flow proportional valves automatically. The device will take gas from the treatment cylinders and will verify the flow for positions along the range of the valves control.

WARNING: Flow calibration can not be performed with the patient connected. It is only intended for technical personnel when they are performed the routinely revision of the device.

- **Bypass**: To show the flow in the 12 positions of the manual bypass flow controller. Values are all read only.

7.10.2. Monitoring Group

User interface: monitor setting options

In the monitoring group (picture above, left - super-user profile, right - technical profile) the following options can be accessed:

- **Change the alarm limits:** When the alarm thresholds are disabled, clicking or touching the option will enable the thresholds values, and vice-versa, and the setting window is closed. If the gases threshold values were enabled, the color of the numbers will change to secondary color (yellow by default).

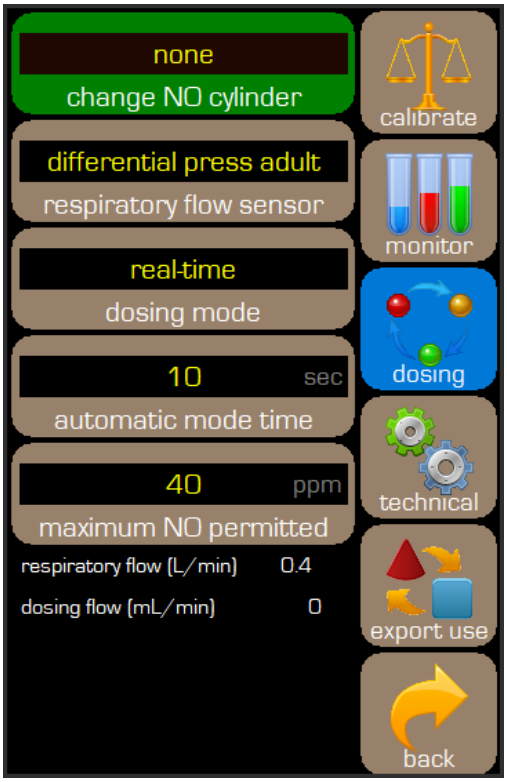
[configurable] Note the device can be configured by mean of configuration file for starting with the option "change the alarm limits" enable or disable. Should you want to change the configuration, consult to the technical staff.

Note: If NOXtec is in manual mode, the NO alarm thresholds are changed in ppm and in the rest of the modes, it will be changed in % according to the NO dosing set point and the calculated ppm will be displayed.

- **Calibration NO value:** to edit the NO target value of the calibration cylinder. Use the quality certificate attached to the cylinder to get the actual NO measurement. It is used for the automatic gases sensor calibration.
- **Calibration NO_2 value:** to edit the NO_2 target value of the calibration cylinder. Use the quality certificate attached to the cylinder to get the actual NO measurement.
- **Calibration lowest O_2 value:** This parameter is not editable.
- **Calibration highest O_2 value:** This parameter is not editable
- **Pressure calibration cylinder:** This is the measurement of the pressure of the inlet of the calibration gas cylinder.
- **Measurements of flows:** (read only) flow in the inspiratory limb in L/min and dosing flow in mL/min.

7.10.3. Dosing Group (for NOXtec 1000 only)

In the dosing group the following options can be accessed:



User interface: dosing setting options

- **Change NO cylinder**: allows the user to swap manually the cylinder in use. The Cylinder exchange function continue working as expected (see Chapter 15 for more information about the automatic cylinder exchange system).

> **Note:** for swapping the cylinders, it is necessary that the backup cylinder is open, with enough gas and correctly connected to the device gas inlet.

- **Respiratory flow sensor**: allows the user to change the flow sensor selected (see Chapter 10). The options available are shown below:

Those sensors that will not be used by the customer can be independently hidden by means of the configuration file (contact with the manufacturer representative for changing in the configuration).

(Configurable) those sensors that will not be use in the routine can be hidden by mean of the configuration file. Consult to the technical service for more information.

> **Note:** When the unit is dosing, it is not permitted to change the respiratory flow sensor used; this option will be disabled.

- **Dosing modes**: allows the user to change the dosing modes. The available options are:

(Configurable) those modes that will not be use in the routine can be hidden by mean of the configuration file. Consult to the technical service for more information.

- **Automatic mode time**: It is the time during which the measurement of the flow in the inspiratory limb is averaged to calculate and update the dosing flow in automatic mode (see section 9.2). This parameter can be set between 3 and 20 seconds. It is also used for updating the respiratory flow and the dosing flow in the user interface.

- **Maximum NO dose allowed (for 1000 only):** To limit the maximum NO dose that can be set in the User Interface. This parameter can be set in the range of 20 to 100ppm.

7.10.4. Technical Group (for NOXtec 1000 and partially for NOXtec 2000)

In the advanced group the following options can be accessed:

User interface: technical setting options

- **NO cylinder concentration (for NOXtec 1000 only)**: It is the NO concentration in N_2 into the treatment cylinder. The allowed concentrations is defined in a list included into the configuration file and can be between 200 and 1500ppm.
- **NO cylinder volume (for NOXtec 1000 only)**: It is the water volume of the treatment cylinder. This parameter is to calculate the time remaining. This parameter has to be set between 2 and 20L.
- **Cylinder warning pressure**: this is the threshold pressure used to trigger a low level alarm when the pressure into the cylinder in use is lower than this threshold. Alarm is only triggered when the treatment backup cylinder is empty or when the automatic cylinder exchange is disabled. The value can be set between 50 bar and the cylinder critical pressure value.
- **Cylinder critical pressure:** This is the threshold pressure used to trigger the high pressure alarm when the pressure into the cylinder is lower than this threshold. This threshold also trigger the automatic swap of the cylinder in the devices NOXtec 1000. This value can be set in a range between 7 bar and the cylinder warning pressure.
- **Automatic cylinder exchange (for NOXtec 1000 only):** Enable or disable the automatic cylinder swapping system (see Chapter 15).
- **Automatic compensation (for NOXtec 1000 only):** To enable or disable th automatic compensation in automatic and real-time modes. (see Section 11.1).
- **Battery critical level**: Define the threshold value for triggering the battery alarm. This value can be defined between 10 and 25%. When the battery is discharging, alarms will be triggered according to the values shown in the following table.

Alarms for battery charge level

Battery charge level	Type of alarm
> 2x battery critical level	None
< 2x battery critical level AND > battery critical level	Low level
< battery critical level	High level

- **Language:** To change the language of the User Interface. For the changes to take place, the device must be restarted.

The languages available are: English, Spanish, Portuguese, French, Italian, Turkish, German and Polish.

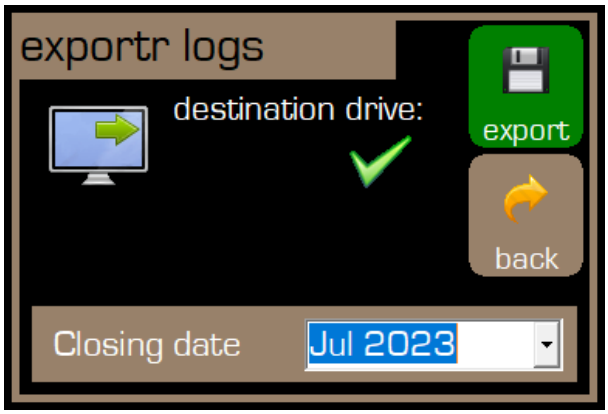
7.10.5. Export Use

The export use functionality permits to export the monthly use of the device to an external pendrive connected to the USB port in the back of the device. When the month is selected and the export button pressed, the device will create a .csv file with the next information:

- PatientID: it is referred to the id used when the patient stated the treatment. Note that the patient ID can be created automatically if this option is enabled (contact with technical service if required).
- StartDate: It is the moment when the device was powered on before the start of the treatment.
- EndDate: It is the moment when the device was powered off after the end of the treatment. Note it is possible to reopen a closed treatment and continue with the treatment in other date.
- Duration: It is the time the device was dosing, no matter if they were interruption in the middle, with the same patient ID.
- Number of monitor records: number of events recorded and related with the monitor module.
- Number of dosing records: number of events recorded and related with the dosing module.
- Result: final results if the next criteria are fulfilled.

The criteria for considering that a record is part of the use of the device per month are:

- Treatment was closed in the selected month, does not matter when it was started,
- Duration of the treatment is equal or higher than 15min.



7.11. Treatment History

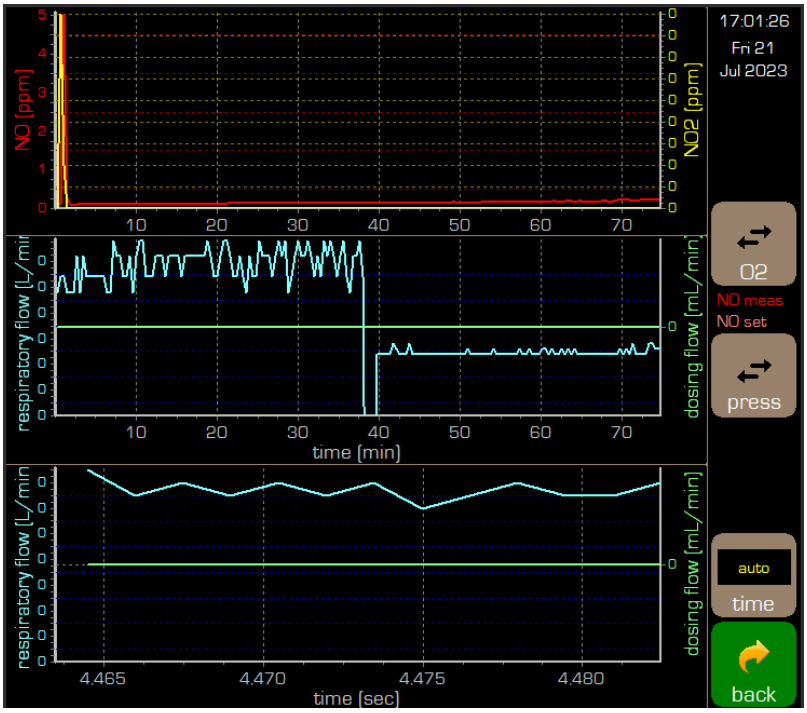
NOXtec is registering the treatment to the patient and is showing it in graphic format by means of the button "history".

Measurements are **continually** registered in the graph every 20sec, except in the case of the respiratory flow where the sampling rate is 250msec. The graphs include all measurements:

- Flow in inspiratory limb,
- Dosing flow,
- pressures into the cylinders,
- Device pressure inlets,
- Regulated pressure,
- Venting pressure,
- NO, NO_2 and O_2 measurements,
- Sampling flow,

- Pressure into the gases sensors.

The time scale can be changed by the user. An example of the data registered by the system is shown in the following figure:



User interface: graphs

7.12. Records

Close function can be used for powering off the unit, and also for:

- **Creating new treatment:** See Section 7.2.
- **Exporting log files:** See Section 7.12.1.
- **TeamViewer:** This function is for technical support only. Accessing to this functionality will bring to the top of the screen the credentials for accessing to the unit by mean of TeamViewer.
- **Shutting down:** To turn off the unit.

User interface: close area options

7.12.1. Data and logs records

The measurements displayed in the graphs are saved into the internal hard disk of the device together with the changes of status of the dosing and monitor modules. This information can be used for several purposes:

- Improving the use of the device,
- Evaluate technical failures,
- Analyses accidents or adverse event involving patient.

Data logged is composed of two files: measurements (gases measurements, pressures, flow, etc.) and logs (change of status of the modules: alarms, operations, commands, etc.). These files are in binary format and can be exported to a USB pendrive for further analysis using the external software NOXtec Viewer (see Section 7.11.2).

7.12.2. NOXtec viewer

NOXtec viewer is an application, independently of the device, that is used for reading the log and data binary file registered by NOXtec for further analysis.

Should the user need to analyse data registered, contact to the technical support for accessing to the software *NOXtec Viewer*. This is disclosed separated.

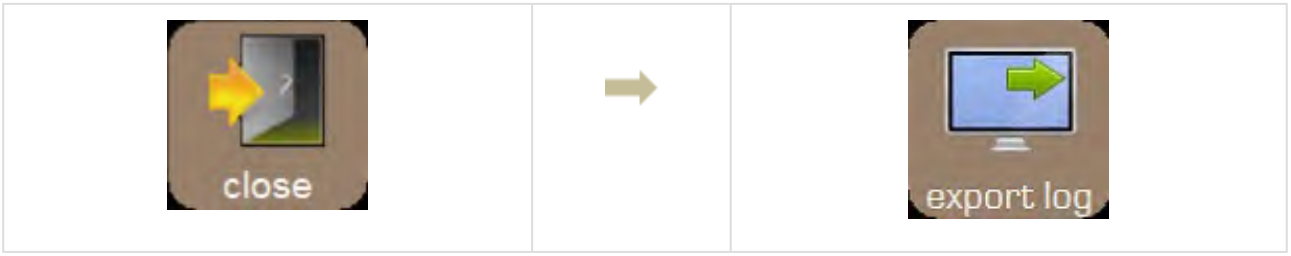
7.12.3. Exporting Log Files

To export the files, follow these next steps:

1. Connect a memory stick to the USB port.

2. Go to the option described next.

3. Disconnect the memory stick from the device.



7.13. Configuration Before Start Dosing

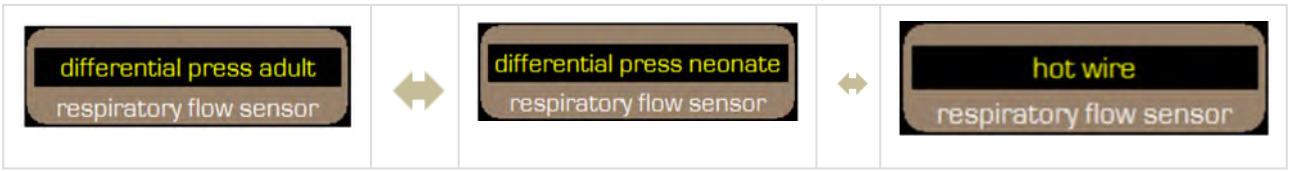
This is recommended to verify certain parameters before starting dosing:

1. *Verify there is no alarm condition:* Alarm condition should be solved in order to start dosing with the device. However, device can start dosing in presence of some alarm's conditions (see Section 16.4).

2. *Check the battery level:* battery should be charged to ensure autonomy in case of main power failure.

3. (ONLY for NOXtec 1000) *Check that the configuration of the sensor for measuring the flow in the inspiratory limb is correct.* If the sensor is not correct or it is not available, semi-automatic or manual mode can be used for dosing. Follow these steps for checking or configuring the correct flow sensor:

Turn around and press the control button to access to the available options.



4. (ONLY for NOXtec 1000) Check that the NO concentration of the cylinders is properly set in the device.

To change it, follow these steps:

5. (ONLY for NOXtec 1000) Set the maximum dosing value allowed.

WARNING: Incorrect selection of the NO concentration of the cylinders can cause patient to be over or under dose.

Note: Concentration of NO in the cylinder can only be changed with Technical Profile's rights.

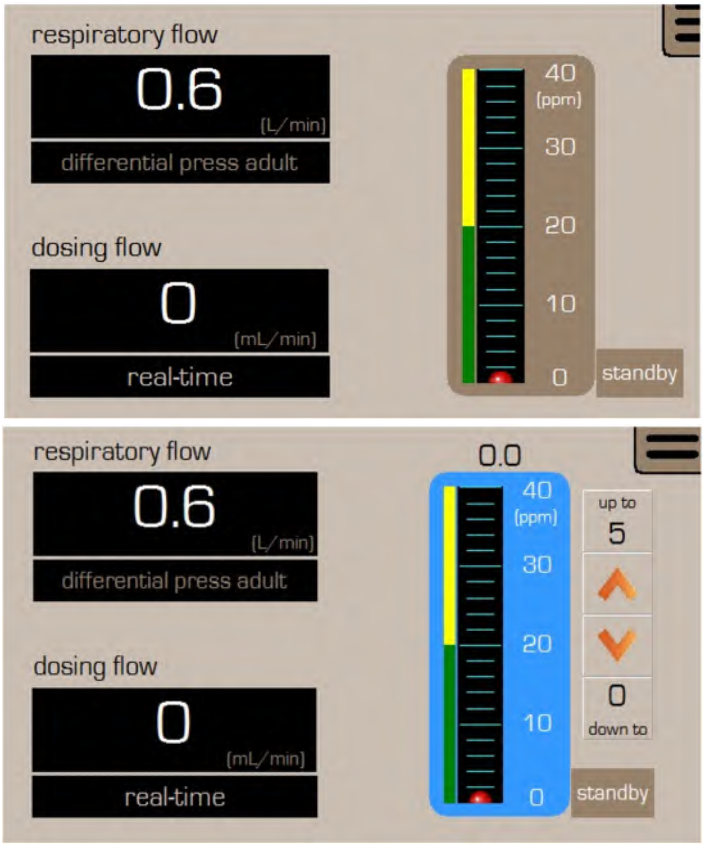
6. (ONLY for NOXtec 1000) Check that the cylinder size is properly set in the device

7. *Check leaking in the monitor module.* Close with the finder the inlet of the water trap and wait for obstruction line alarm to appear. It will happen in about 20sec.

7.14. Starting Dosing

For starting dosing, rotate the control knob button until the background of the dosing button becomes green. Press the control knob and the button will become in blue. Touching the NO set point button will become in blue directly. Turn it anti-clockwise to increase the NO setting value or clockwise for decreasing it.

The value in ppm can be increased in steps of 5 ppm using the button in the right of the set point button. Dosing can be stopped stray pressing the value cero.



User interface: set dose selection

Note that the maximum permitted dosing value is that one appearing on the top of the dosing icon.

When the user confirms a new set point, a message box will appear asking for the confirmation to use those parameters for dosing the patient. The color of the message on the starting dosing confirmation windows will variate depending on the dosing set in the following way:

Meaning of the colours of starting dosing message

Color	Set point (ppm)	Meaning
white	< 20	Usual dose
Yellow	> 20 and < 40	Dosing is higher than usual (next picture)
Red	> 40 and < 80	Dosing is too high (picture below)
Blue	> 80	Dosing could be dangerous to patient

User interface: starting dosing window

7.14.1. Waiting for Stability

When the set point of NO is changed - does not matter if it is started, increased, decreased or stopped - the device will take 1 minute to update the thresholds of NO for alarm generation. This 1minute time is called "waiting for stability" and is displayed in the User Interface, below the NO measurement.

If the change of the NO set point is an increment of the value, the upper limit of the alarm is increased according to the new set point and the lower limit will remain unchanged during that waiting for stability time. If the change is a decrement of the dose, the lower limit of the alarm will be decreased and the upper limit will be the one kept unchanged during the waiting time.

7.14.2. Accuracy of the Dosing

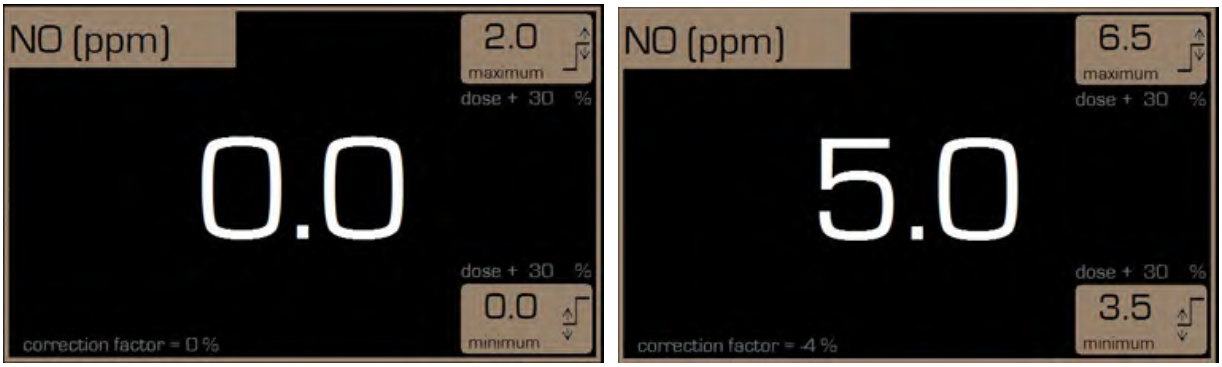
Five factors could affect the accuracy of the expected dose:

1. Wrong configuration of the respiratory circuit. This includes leaking, mixing chamber and other factors.
2. Actual gas concentration of the treatment cylinders. Accuracy can variate depending on the gas manufacturer.
3. Accuracy of the gas calibration cylinder for performing the calibration of the monitor,
4. Accuracy of the respiratory flow sensor. This depends mainly of possible turbulences into the sensor.
5. Dosing flow accuracy. This also includes shift in the offset if the dosing flow is very low (<20mL/min),

The difference between the dosing set point and the concentration measured in the monitor is up to +/-20% in normal conditions.

A correction factor could be applied in NOXtec 1000 in real time, automatic mode (see Section 11.1), as well as in semi-automatic dosing mode (see Section 11.2).

The correction factor is displayed at the bottom left corner of the NO measurement area (0% in the example).



User interface: NO measurement area

7.14.3. Automatic Venting Before Dosing

When the dosing is set, the device performs an automatic venting. This process is splitted in two phases:

- Inlet venting: venting of the gas in the inlet of the device and cylinder hose. It takes about 7 seconds.
- Outlet venting: venting of the device automatic and manual dosing module. It takes about 6 seconds.

7.15. Turning the Device Off

For turning the device off, it is mandatory to stop dosing. If the device is in emergency mode and it was previously used in semi-automatic, automatic or real-time mode, it is mandatory to change to semi-automatic, automatic or real-time mode for stop dosing.

Once the device is in Standby mode, there are 2 ways to turn the device off:

- Pressing the ON/OFF push button in the back of the device,
- Following the next steps in the User Interface:

These options will trigger the turning off process. Follow the instruction of the turning off window for safety turn the device off. It is necessary to close the NO cylinders and to vent the pressure line manually to ensure the device is not pressurized when not working. For venting the device manually, press the manual purge buttons in the back of the device.

Note: NOXtec should not be turned off when the device is dosing.

Note: It is recommended to open the manual flow regulator (bypass) up to the maximum for about 10 seconds to depressurize the dosing outlet when the device is off.

WARNING: Be aware of disconnecting the dosing tube if the patient is still connected to the ventilatory circuit.

In case of emergency, if the device cannot be turned off or the User Interface is not responding, press the ON/OFF button until the device goes completely off. Check the fan in the back pannel to ensure the device is off.

WARNING: To power on the device after turning it off, wait at least 10 seconds. Check the fan in the backplane of the device is off to ensure the device is off.

8. Initial Checks

8.1. Before Turning On

Check the expiration date of the NO cylinders stated in the label attached.

Make sure that all connections have been made as described in section *"9. Connecting the device"*. Check that the device and its accessories are not damaged or wrongly connected, and that they have not been used in another patient either.

WARNING: If the device, or the parts, are broken, deformed or visible contaminated then device should not be used.

WARNING: The components of the patient circuit are for single use. Do not reuse then to avoid microbial contamination.

Open the cylinders slowly and check their pressure on the pressure gauge included in the pressure regulators. Close the regulator again and wait for 2minutes. After that time, if the pressure is not the original one +/- 5 bar, it is due to leaking in the system. In this event, call for technical support.

If there is not a leak in the connection of the cylinder, open the cylinder slowly for having the device ready for operation.

⚠ Opening gas cylinder quickly can cause a sudden increase of pressure in the regulator, that could be damaged or create a hazardous situation.

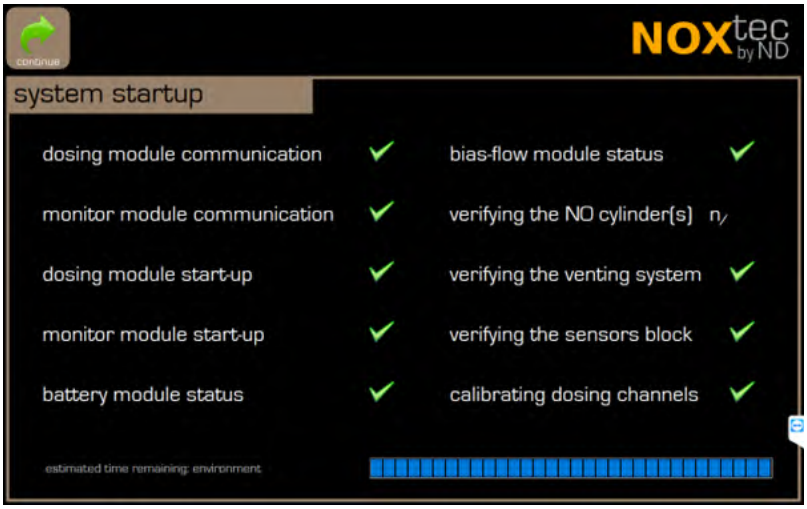
⚠ Close the cylinder and check if the pressure in the gauge stays in the same position (+/- 5 bar). If the pressure is not maintained, the pressure regulator or the device is leaking and should be review by the technical support.

8.2. Initial Automatic System Verification

Once the NOXtec is powered-on, the "System start-up" screen is shown to indicate the evolution and results of the initial checking self performed by the device. If the result of all the testing is correct, NOXtec will move forward to the main screen automatically and it will be ready to start a therapy.

If the critical control testing (left column) is passed but one of the secondary testing (right column) fails, a warning will be displayed on top of the screen. The device lets the user continue to the main screen by pressing the "continue" button.

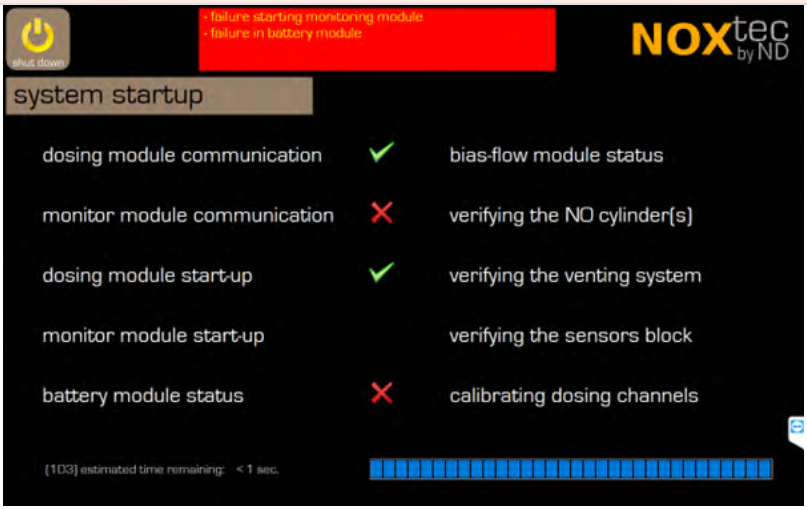
WARNING: User is the responsible to solve the problems detected before start using the device with a patient. However, device will not allow starting dosing in a high-level alarm condition.



User interface: initial verification windows without error

If one of the critical control testing (left column) fails, the device cannot be used. In this case, the alarm window will appear (in the top) with red background and the "continue" button will appear disabled. Restart the device to try to recover the unit functionality. If there are not backup units, use the manual dose bypass in case of emergency.

WARNING: If the errors detected cannot be solved by restarting the system, contact with a specialized technical service.



User interface: initial verification windows with error

WARNING: For fully powering off the device when there is an error in the left column, please, press the power on button until the fan in the back of the device is off. This normally take around 30-35 seconds.

9. Operational Dosing Modes (ONLY for NOXtec 1000)

NOXtec dosing module can be operated in different modes that differ in:

- The way the flow in the inspiratory limb is measured to calculate the dosing flow required for dosing certain NO concentration,
- The way the dosing flow is calculated and updated to dose.

These modes have been implemented to meet the needs of all users in different applications (see the comparative table in Section 9.5).

Note: The operation mode selected does not require to be changed often but during the device setup or when the user wants to operate the device in different way. When the device is turned on, the latest used mode will be the one selected in the unit.

9.1. Real time

In this mode, the flow in the inspiratory limb is determined by mean of a flow sensor inserted into the circuit or by mean of a direct communication between the ventilator and the device using a RS232 cable. The flow is acquired 100 times per second and at each point the dosing flow is recalculated and the proportional valves adjusted to ensure the dosing flow follows all time the respiratory cycle of the ventilator.

9.2. Automatic

In this mode, the flow in the inspiratory limb is acquired as in the real time mode. However, an average of the flow is calculated every the automatic-mode time (can be between 5 and 20 seconds). The dosing flow is calculated and the proportional valves adjusted when the respiratory flow average is calculated.

The procedure to set the automatic-mode time is described in the section 13.8.3.

9.3. Semi-Automatic

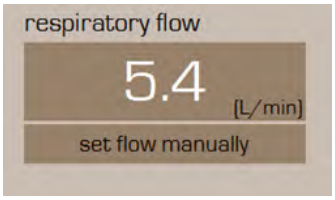
In this mode, the flow in the inspiratory limb is not measured or collected from the ventilator. Its value is set manually on the main screen.

The user has to get from the ventilator the average of the total flow in the inspiratory limb and type it manually in the user interface. The best parameter is:

Average Total Flow Inspiratory Limb = Volume/min + bias flow.

Some ventilators do not display the bias flow, in which case, the user can start assuming the standard 2 to 4 L/min for normal ventilation and allow NOXtec to track the flow to compensate it.

In this mode, the dosing flow is constant and is only recalculated when the total respiratory flow in the inspiratory flow is manually changed (see below the object to set the flow) or when dosing set point value is updated by the user.



The semi-automatic mode is intended mainly for intra-hospital transportation or when the respiratory circuit needs to be simplified as much as possible for particular application. This mode can also be used when the respiratory sensor flow is broken, until a new one is calibrated and inserted in the circuit.

Note: Gas measurements out of range alarms continue operating normally in semi-automatic mode.

WARNING: The user is responsible for setting up the flow in the inspiratory limb in the User Interface correctly. Incorrect setting of the flow in the inspiratory limb could cause large difference between the NO dosing setting point and the measurement.

9.4. Manual (Emergency Mode)

Manual mode is intended for two main situations:

1. The patient is in critical situation and a rescue breathing (Ambu bagging) is needed, with a constant flow of oxygen coming from an external source,
2. The dosing electronic automatic system is not working and it is required a **fully pneumatic way** for dosing the patient.

When the unit is off, the dosing electronic automatic system is disabled. The manual flow regulator connects the cylinder(s) with the dosing outlet to dose patient in a **fully pneumatic way** if it is required.

In this mode the flow in the inspiratory limb is not measured. Manual mode can be used in combination with the monitor module for better control of the dosing. Dose is controlled by means of the manual dosing bypass located on the right side of the device.

Note: When the device is dosing and it is changed to emergency mode, NO alarm limits will be kept as in the previous mode. In case the limits need to be changed set up them manually in ppm instead of percentage of dosing as in the rest of the modes.

9.4.1. Selecting the manual flow position

Define the respiratory flow used, depending on the type of emergency situation: a) in patient emergency, the constant flow in the external source of oxygen or gas, b) in automatic system, average total flow in the ventilator.

- In the table attached to the device, or in the user interface, select first in the top row the defined flow,
- Search down to the closer dosing that the patient is receiving,
- Search left to the position required in the manual flow controller.

Manual Mode (800 ppm cylinder)												
manual dose												
manual	vent f	expected dose (ppm) vs resp. Flow & manual position										
L/min	1	2	3	4	5	8	10	12	15	20	25	50
[A] 0,03	25	13	8	6	5	3	3	2	2	1	1	1
[B] 0,08	58	30	20	15	12	8	6	5	4	3	2	1
[C] 0,09	68	36	24	18	15	9	7	6	5	4	3	1
[D] 0,12	88	46	32	24	19	12	10	8	7	5	4	2
[E] 0,19		70	48	37	30	19	15	13	10	8	6	3
[F] 0,29			70	54	44	28	22	19	15	11	9	5
[G] 0,59					85	55	45	38	30	23	19	9
[H] 1,07						95	78	66	53	41	33	17
[I] 2,12									99	77	62	32
[J] 3,14											89	47
[K] 4,74												69

User interface: manual dosing set point selection

When the emergency mode button is pressed, the manual control table will be displayed in the User Interface. The User Interface has a visual support for helping setting the position of the manual flow regulator.

The way this user support works is as follow (see the sequence in the button as well):

- Touch on the screen on top of the table or press the control scroll knob and a square object will appear on the manual table dosing in blue colour,
- Rotate the scroll to move horizontally the square object to select the flow used to ventilate the patient,
- Touch again on the screen or press the control knob,
- Rotate the scroll to move vertically the square object to select the closer dosing set point.

- On the green square, the user can find the position for the NOXtec manual flow control to adjust the dose to the patient.

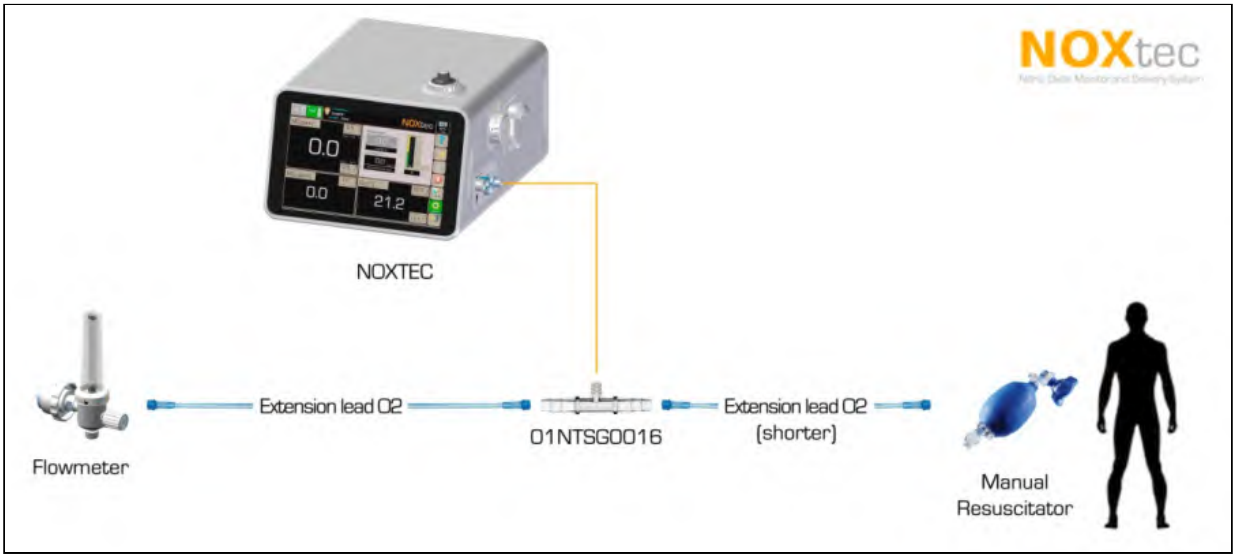
9.4.2. Using manual mode in Emergency situation for the patient

In the event of an emergency situation to the patient that required the use of Ambu bagging, follow the next steps:

1. Press in the User Interface, in the options area, the emergency button,
2. Set the manual flow control in the correct position as described in the previous Section,
3. Change the dosing line coming from the ventilatory circuit by the one coming from the emergency circuit,

Note: The emergency kit should be prepared in advance of the emergency situation to accelerate the set up process when the emergency situation occurs. The position of the manual flow controller should be defined in advance as described in the previous Section

Ensure that the respiratory circuit is set as shown on the next figure:



FOTO

Emergency circuit configuration

9.5. Comparison table between the different dosing modes

The different operative modes are compared in the next table.

Comparison between the different dosing modes

Dosing mode	Respiratory flow	Dosing flow update mode	Compensation	Recommended use	Limits of alarms
Real-time	Respiratory flow or RS232	Every 10ms	Yes, mode described in 15.1	Normal ventilation	Enabled in % of set point
Automatic	Respiratory flow or RS232	Every the automatic mode time	Yes, mode described in 15.1	Normal ventilation	Enabled in % of set point
Semi-automatic	Set manually in User Interface	When NO set time or respiratory flow are manually changed	Yes, mode described in 15.2	Transportation or in the event of failure in the respiratory flow sensor	Enabled in % of set point
Manual (Emergency)	Not measurement	Change on	No	Emergency situation	Enable in ppm

10. Respiratory flow sensor (ONLY for NOXtec 1000)

Device can be used with differential pressure or hot wire flow sensor. **Note that only one can be use at the same time**.

The advantages and limitations of the respiratory flow sensors are summarized in the following table:

Comparison between the different respiratory flow sensors

Sensor	Measurement range (L/min)	Advantages	Disadvantages
Adult differential pressure	2 – 120	Easier to connect in the ventilatory circuit. Longer distance to the circuit Directional measurement, positive and negative values	Lower accuracy. Incompatible with HFOV for frequencies higher than 3Hz.
New-born differential pressure	0.5 – 60		
Adult hot wire	0.5 – 120	Highest accuracy across the range Faster response. Fully compatible with HFOV	More difficult to connect in the ventilatory circuit No-directional. Only positive measurements registered

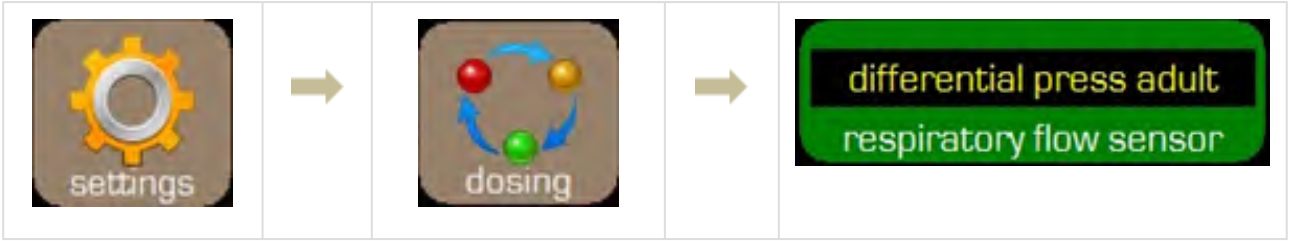
10.1. Synchronization with ventilators

The device is able to read by RS232 the flow in the inspiratory limb from the ventilator. It is mandatory that the ventilator incorporates a way to read the total flow in the inspiratory limb, including the bias flow. However, not all the ventilators that include this functionality are already implemented in NOXtec device. See the Section 25: "Compatibility with ventilators" to check the ventilators that are already implemented in NOXtec.

Connect a standard RS232 cable to the connector in the back of the device and change the respiratory flow sensor in the User Interface to the ventilator to be used.

10.2. Selecting the respiratory flow sensor

In the User Interface, select the corresponding sensor as below:



- Turn around the scroll knob to select the sensor and press it to select the flow sensor.

Note that there are several ventilatory modes available in the ventilator. It is highly recommended to test the ventilator' setup that will be used in clinical application in advance as a training.

Respiratory flow sensors that will not be used can be hidden by mean of the configuration file of the User Interface (consult to a technician for more details; it is explained in the Technical Manual).

Hot wire sensor is used for all type of patients. In the case of using differential pressure sensor, when the kits provided by the manufacturer is used, the device will detect automatically if the sensor in use is the appropriated for the application intended by mean of the type of water trap connected.

WARNING: Please, use always the kits provided by the manufacturer to avoid mistake in the detection of the sensor and warranty the safety of the patient.

11. Dosing Compensation

Despite there is no direct communication between the dosing and monitor modules, NOXtec 1000 and 2000 incorporate 2 compensation procedures. They are described in the following table:

Compensations modes

Id	Dosing modes	Model applicable
1	automatic and real-time	1000
2	semi-automatic	1000 and 2000

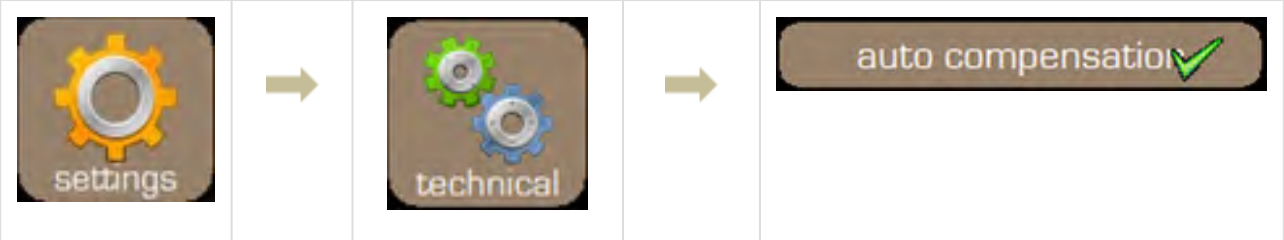
11.1. Compensation for automatic and real-time modes

When the device is dosing in real-time or in automatic mode, the unit can calculate the difference between the dosing set point and NO measurement. Then a compensation will be applied to the calculation of the dosing flow to ensure minimising the difference between both magnitudes.

This is due to the cumulative errors of those factors that affect the accuracy in the dosing:

- Accuracy of the concentration of the NO in the cylinder,
- Accuracy of the gases sensor calibration process, including the accuracy of the NO concentration into the calibration cylinder,
- Accuracy of the inspiratory limb flow measurement.

This compensation can be triggered automatically every 1 minute or it can be applied manually. For setting the automatic trigger, unlock the screen with technical profile and access to the function:



The automatic compensation can be enabled or disabled.

If the automatic trigger is disabled, the compensation can only be applicable by touching the NO measurement.

This compensation will not be applied in the event of:

- Device is not dosing,
- Device is not in automatic or real-time mode,
- Device is "waiting for stability" (see Section 7.14.1)
- flow in the inspiratory limb sensor is not working correctly or the offset calibration process failed,
- Monitor is in calibration process.

The compensation is actually applied to the NO concentration in the cylinder. As an example, in the case of a device using cylinders of 800ppm of NO, if the device is measuring 9 ppm of NO and the set point is 10ppm, the system will apply a correction of +10% to the cylinder concentration to be 880ppm.

Maximum compensation applicable every minute is +/-15%.

Manual compensation cannot be applied into the time frame of 15 seconds, does not matter if the user touch the NO measurement more often.

The compensation factor applicable has a maximum of:

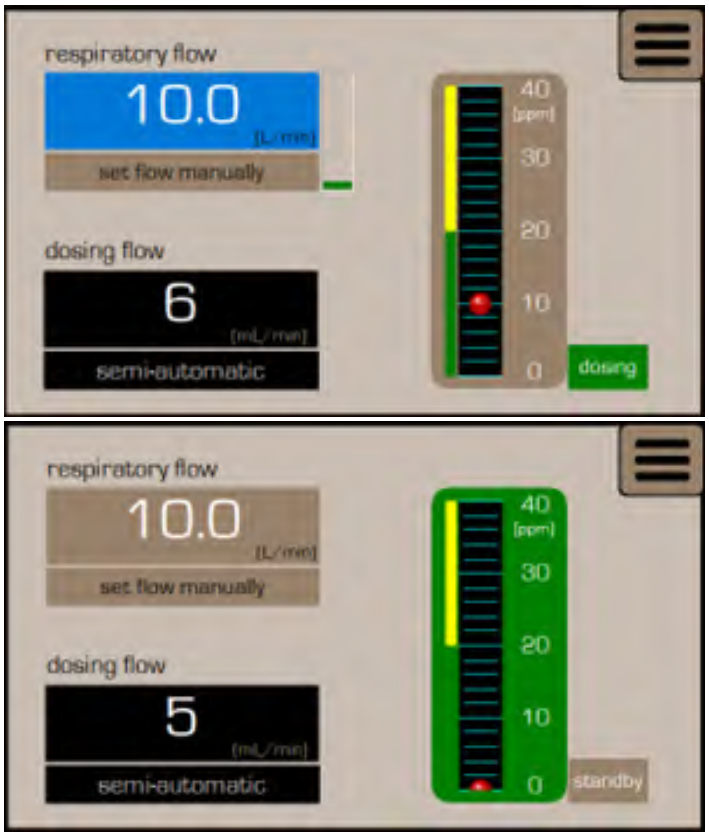
- +/-30%, if the dosing flow is higher than 20 mL/min
- +/-70%, if the dosing flow is between 5 and 20 mL/min.

This functionality is not safety critical.

11.2. Compensation for semi-automatic mode

Determining the flow in the inspiratory limb (the flow) according to the ventilator parameter is not a stray forward activity (see the Section 9.3).

Compensation in semi-automatic mode is only applied when the set flow is selected and in blue color (Figure of the left, it is not selected kin the Figure of the right). A progress bar is displayed in the right side of the set flow object that is increasing from down to top.



User interface: semi-automatic mode compensation selection

When the bar reaches the top, a new flow value is calculated by means of applying a compensation to the current flow value that is equal to the percentage of difference between the NO set point and the NO measurement. For

example, in the case the flow is set 10 L/min, if the device is measuring 9 ppm of NO and the set point is 10ppm, the system will apply a correction of +10% to the set flow to be 11 L/min.

The progress bar indicates the time pending to the next correction. Time between consecutive corrections is 30 seconds. The progress bar in green means the compensation is within the +/- 50% of the original set value. The progress bar in red means the compensation is in the maximum of +/- 50% of the original set value.

When the compensation is in the maximum, the user should verify the flow and unselect and select the flow again to reset the original set value.

11.3. Overdosing protection

The device is able to stop dosing in semi-automatic, automatic and real time mode if the dosing registered by the monitor exceeds 100ppm. This is an option that can be configured in the factory only. In this situation, it is possible to continue dosing with the manual regulator.

WARNING: Overdosing could be related with the configuration of the respiratory circuit. It is responsibility of the user to ensure the correct use of the device to avoid unexpected overdosing.

12. Parts and Accessories

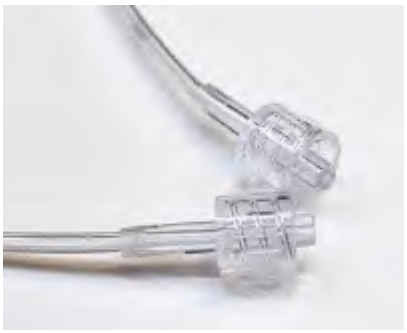
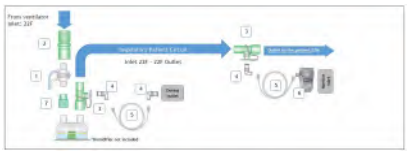
WARNING: Do not use or attach items not specified by the manufacturer.

List of parts and accessories

Picture	Reference	Description
Pressure regulator for cylinder N_2/NO		
	P000577	Supply regulator NOXtec - ISO 5145 N29
	P000601	Supply regulator NOXtec - CGA 330
	P000603	Supply regulator NOXtec - CGA 626
	P000605	Supply regulator NOXtec - CGA 660
	P000607	Supply regulator NOXtec - ITC EP6 M
	P000609	Supply regulator NOXtec - BS 341 N3
	P000611	Supply regulator NOXtec - BS 341 N14
	P000613	Supply regulator NOXtec - DIN 477 #14
	P000615	Supply regulator NOXtec - UNI 11144 Nº 5
Pressure regulator for calibration cylinder		
	P000581	Calibration regulator NOXtec - ITC EP6 M
Gases sensors block		

Picture	Reference	Description
	P000176	NOXtec - Analogue Sensors Module - MF4
Hot wire cable		
 	P000364	Hot wire cable
	P001126	Hot wire cable (straight connector)
	P000003	Hot wire extension cable
Main cord		
	P000617	Main Cable EU
	P000619	Main Cable UK
	P000621	Main Cable USA
	P000623	Main Cable Israel
	P000625	Main Cable India
Hot wire flow sensor		

Picture	Reference	Description
	P000362	Disposable hot wire sensor
Differential pressure flow sensor		
 	P000633	Paediatric differential pressure sensor
	P000631	Adult differential pressure sensor
Water trapping		
	P000627	Water trapping (white). When using differential pressure sensor, the white water trap is used in combination with adult to ensure the correct configuration of the sensor.
	P000629	Water trapping (blue). When using differential pressure sensor, the blue water trap is used in combination with the neonate sensor.
Sampling lines		

Picture	Reference	Description
	P000687	Sampling/dosing line 1.8m
	P000685	Sampling/dosing line 3.0m
Disposable delivery and monitoring kits		
	P000699	Kit Differential Pressure for 22mm
	P000700	Kit Differential Pressure for 22mm with Humidifier
	P000701	Kit Hot Wire for 22mm
	P000702	Kit Hot Wire for 22mm with Humidifier
	P000703	Kit Differential Pressure for 15mm
	P000704	Kit Differential Pressure for 15mm with Humidifier
	P000705	Kit Hot Wire for 15mm
	P000706	Kit Hot Wire for 15mm with Humidifier
	P000707	Kit Differential Pressure for 10mm
	P000708	Kit Differential Pressure for 10mm with Humidifier
	P000709	Kit Hot Wire for 10mm
	P000710	Kit Hot Wire for 10mm with Humidifier
	P000711	Kit Hot Wire for Stephan Ventilator 10/15mm

Picture	Reference	Description
	P000713	Kit for 22mm without sensor
	P000714	Kit for 22mm with humidifier without sensor
	P000717	Kit for 15mm without the sensor without sensor
	P000718	Kit for 15mm with humidifier without sensor
	P000719	Kit for 10mm without sensor
	P000720	Kit for 10mm with humidifier
	P000721	Kit for 22m no dosing
	P000723	Kit for 15m no dosing
	P000725	Kit for 10m no dosing
Emergency kits		
	P000737	Kit Basic Emergency

Applicable parts of this device are all components of the kits mentioned in the above table plus the control button on the top of the device.

The rest of the components and applicable parts are included into the next table.

Components and applicable parts

Function	Specification	Manufacturer	Reference	Length
220 VAC	3-way, phase, neutral and earth of 10A 220v, IEC C13	Generic	Generic	1.8m
Hot wire	6-way, special wire for hot wire (for 1000 ONLY) and extension	NOXtec	P000364 and P000003	1.5m

RS232	(optional, only for synchronization with ventilators) Male, DB9 female, 9 ways, 3x twisted pairs. (for 1000 ONLY)	Multicomp	11.99.6218	1.8m

12.1. NO and NO_2 Absorbents

NOXtec has been tested and approved with SLE NO and NO_2 absorbents. Consult to the manufacturer if you want to use one.

Note: Using NO and NO_2 absorbent is NOT mandatory to use NOXtec in clinical application. It is only to ensure the device is not releasing NO in the room where the device is used.

12.2. Single and Multiple Use

The device is a multiple use device and can be used for 10 years. It is recommended a full assessment when the device is 5 years old. The device must be adequately cleaned between patient, but no special process is required (see Chapter 18). The device cannot be sterilised.

All disposable kits are for single use ONLY. Do not reuse any disposable kit with several patients; it could be cause of cross-contamination.

13. Connecting the Device

For connecting the device and have it ready for dosing, follow these steps:

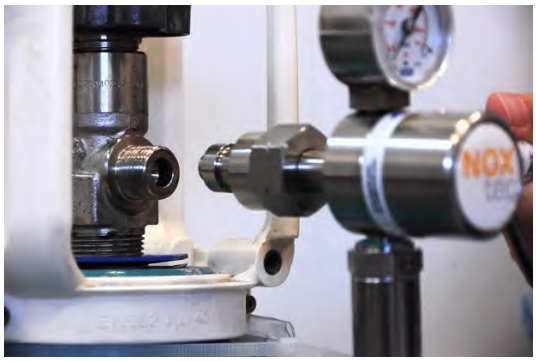
1. Connect the power cord.

Connecting the power cord

WARNING: In the current version, the LAN port is used exclusively for remote maintenance. Do not connect the device to the network when it is in clinical use.

WARNING: The USB port of the computer is exclusively for connecting a USB memory in NTFS or FAT / FAT32 format for extracting data registers related with patients from the device.

2- (ONLY for NOXtec 1000 and 2000) Connect the **pressure regulators** to the cylinders: screw into the cylinder valve to ensure there is not leaking in the connection and keeping the pressure gauge upright.



Connecting the cylinde regulator

Note: The regulators are manufactured according to the standard required by the user. Some of the standard are left thread and other right thread

3. (ONLY for NOXtec 1000 and 2000) Insert the **regulator hose connector** to the NO input port ( ) and connect the **regulator pressure sensor cable** to the pressure sensor connector (black cable with connector).

Connecting the cylinder regulator host to the back of the device

Note: To remove the connector, slide the moving part as shown in previous figures.

4. Connect the **venting hose** (Ø 22 mm) to the venting port and:

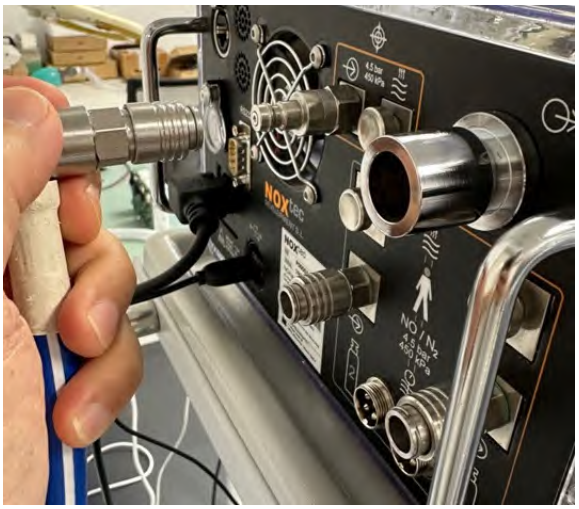
a) connect the tube to a scavenging system,

b) conduct the tube to outside of the operation room,

c) Connect an absorbent to the outlet.

Connecting the exhaust port

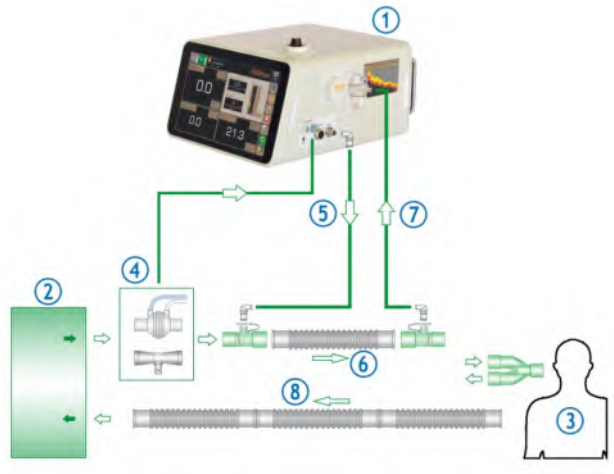
5. (Optional) If the user will perform the calibrations of the gases sensor by themself, Insert the **calibration cylinder** regulator hose connector to the calibration gas inlet port (⟵) as shown in next figures.



Connecting the calibration gas cylinder

Note: To remove the connector, slide the moving part as shown in the next figure

6. Assemble the patient circuit as shown in the following image. Note the version NOXtec 2000 has not the flow sensor.



1. NOXtec device
2. Ventilator
3. Patient
4. Flow sensor
5. Dosing flow
6. Mixing chamber
7. Sampling flow
8. Exhausted gas

Connecting the patient circuit: generalities

WARNING: Replace disposables before starting the treatment of a new patient. Use only the disposables recommended by the device manufacturer

Note: For selecting the respiratory flow sensor, see Chapter 12.

7. Locate the **water trap** in its receptacle and insert it until the "click",

Connecting the water trap

Note: To remove the water trap, press the grey button on the top of the receptacle.

8. Connect one of the ends of the **sampling gas tube** to the water trap and the other end into the T-shape connector provided for this purpose in the patient circuit.

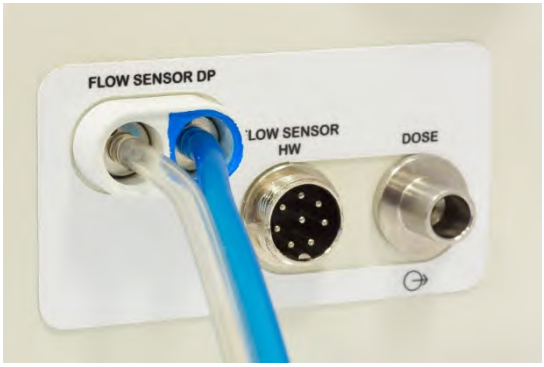
Connecting the sampling line

9. (ONLY for NOXtec 1000) Connect **the flow sensor in the inspiratory limb** or **connect the RS232 cable between the ventilator and NOXtec.** Sensor should be connected in the dry area of the circuit and not immediately in the outlet of the ventilator. In the case of ventilators with integrated humidifier, differential pressure sensor cannot be used and the hot wire sensor must be connected in the wed area but ensure it is located perpendicular to avoid water condensation touching the wire. It is mandatory to avoid turbulences. There are 3 models of respiratory flow sensors: a) hot wire sensor, b) differential pressure sensor, and c) RS232 cable.

a. **Hot wire sensor**: place the sensor in the patient circuit as shown in the next Figure and connect the cable to the sensor and to the electrical connector (*"FLOW SENSOR"*).

Connecting the hot wire sensor in the respiratory circuit

b. **Differential pressure sensor**: place the sensor in the patient circuit as shown in the next Figure. Connect it to the differential pressure sensor (Flow sensor DP) connection. Note that blue pneumatic port is connected in the inlet of the flow (to the ventilator).



Connecting the differential pressure sensor in the respiratory circuit

Note: Connect the sensor in a laminar flow area. Do not connect the sensor straight in the outlet of the ventilator and avoid tube diameter reductor in the inlet of the sensor.

Note: In the differential pressure sensor, the blue tube is the inlet of the sensor and must be connected to the tube coming from the ventilator.

Note: In the case of ventilator with humidifier integrated (into the device) the differential pressure sensor cannot be used due to incompatibility.

Note: In the case of ventilator with humidifier integrated the hotwire sensor must be connected in vertical position to avoid condensation of water touching the wire.

c. **Connect the RS232 cable**: It must be connected between the ventilator and NOXtec. The ventilator should be configure to send data by RS232 accordingly. Select the ventilator in the User Interface (settings/dosing/flow sensor).

Connecting the RS232 cable

10. (ONLY for NOXtec 1000 and 2000) Connect one end of the **dosing tube** to the NO dose outlet (DOSE) and the other end into the connector provided for this purpose in the T-shape connector in the patient circuit.

Connecting the dosing line

WARNING: In the case of using differential pressure sensor, match between the flow sensor and the water trap to avoid unnecessary warning in the user interface, i.e. if the sensor is the adult one the water trap must be th white one and if the sensor is neonate the water trap should be the blue one.

13.1. Connecting the Device to NO Source in the Wall

Despite it is not conventional for iNO applications, it is possible to connect the device to a source of NO piped in the Wall.

The hose for the inlet gas should be customised for the particularities of the system installed in the hospital. Special care should be taken for avoiding the contamination of the NO in the circuit to avoid high concentration of NO_2.

In the inlet of the pressure sensor, a mimic connector must be connected to simulate pressure in the cylinder. In this case, failures in the inlet pressure will be detected by the device in the low pressure value.

The pipe to the wall should be connected in the channel 1 of the device. If backup cylinder is not connected, disable the automatic cylinder exchange for avoiding undesirable warning during the treatment. Please, contact with our technical department for more information about how to perform the connection of the device and its components.

It is highly recommended anyway to use a backup cylinder in the second channel of the device to be prepared in case of failure in the NO source.

WARNING: Contamination in the piped gas can deliver high concentration of NO_2 to the patient and negative impact in his/her disease.

13.2. Connection to Scavenging System

All the gases released into the device are conducted to the exhaust port in the back of the device. It ensures the room where the treatment take place is free of NO and NO_2 gases by connecting the exhaust port to a scavenging system or to absorbents.

The device also permits measurement of the concentration of gases in the environment using the monitor module. In the current version, it is required to remove the sampling line from the circuit. During the measurement of the concentration of gases in the environment, the patient will not be monitored.

In case that the continue monitoring of the gases' concentration into the environment is required, external handset devices are recommended.

14. Automatic Gases Sensors Calibration

NOXtec has a system to perform the calibration of the gases sensors automatically connecting a calibration cylinder to the back of the device. However, the user must trigger the start of the process to ensure it is always performed with the consent of the user.

The automatic calibration can be performed even with the device connected to a patient in treatment.

To perform the automatic calibration process, connect the regulator of the calibration cylinder to the calibration cylinder and to the calibration gas inlet in the back of the device.

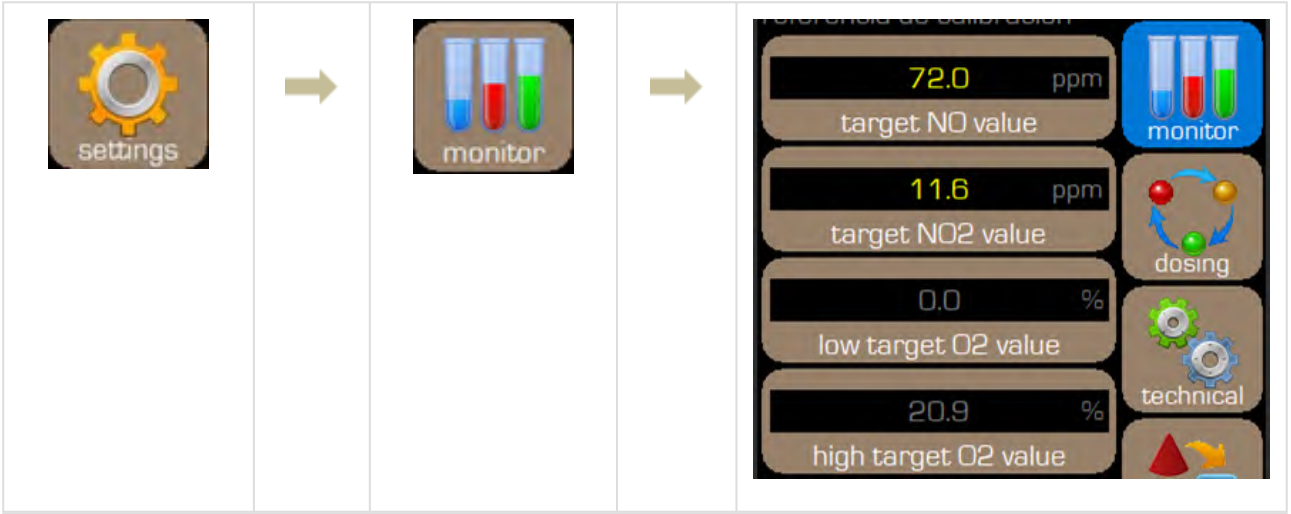
Connecting the device for automatic calibration

Slowly open the calibration cylinder and check the pressure in the regulator gauge. Close it for 1 minute and verify the pressure again to ensure there is not leaking in the calibration channel or cylinder regulator.

⚠ If the cylinder is opened too fast, the pressure in the regulator can increase suddenly creating a potential hazardous situation.

⚠ Close the cylinder and call to the technical service if the device is leaking.

Set the calibration target values for NO and NO_2 according to the calibration quality control certificate following these steps:

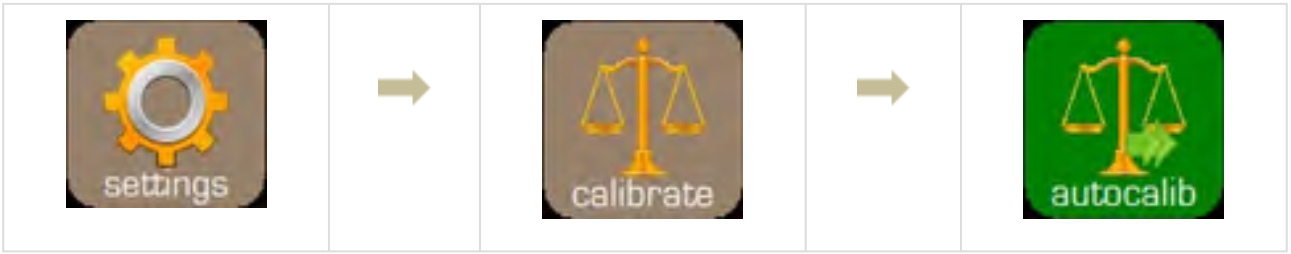


Note: It is recommended to carry out an automatic calibration before starting a new treatment.

Note: take from the quality control certificate the actual values instead of the expected.

Note: Calibration parameters for oxygen cannot be modified by the user.

The automatic calibration can be triggered following these steps:



The calibration process takes between 3 and 5 minutes. Before starting the calibration, the sampling tube must be removed from the water-trap to ensure the correct offset condition.

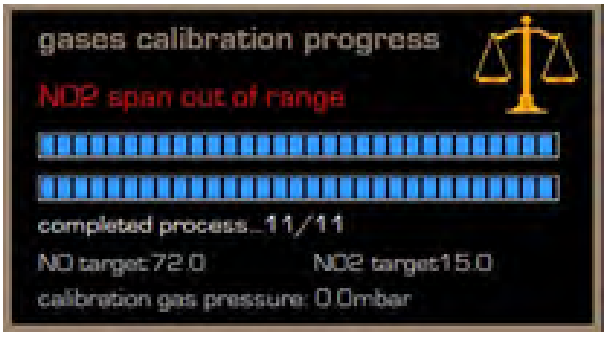
Message for starting automatic calibration

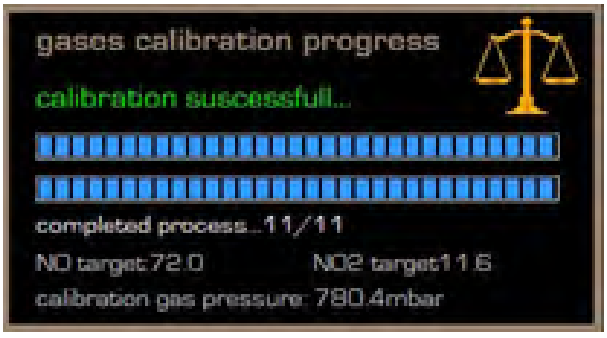
When the calibration is taking place, the User Interface appears as shown below.

Calibration process in progress

WARNING: The calibration process is indicated with the text "cal" in the monitor measurements. During the calibration process the device is not monitoring the patient.

At the end of the calibration process, the result is presented in red when fail, or in green when it was performed successfully.





Message at the end of the calibration process

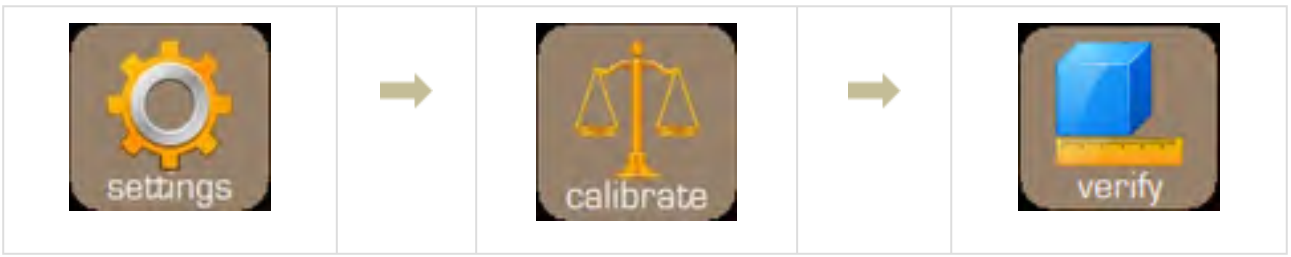
WARNING: Reconnect the sampling tube to the water trap at the end of the calibration as it is shown in the video that appears on the screen.

The accuracy of the gas sensors decreases around 3% each month. For this reason, it is required to perform the calibration of the gas sensors at least once a month.

14.1. Verification of the Calibration

The calibration of the gas sensors can be verified. This is a quick process that takes between 2 and 3 minutes and consists on passing gas from the calibration cylinder trough the sensors for measuring their concentrations and compare them with the actual values in the cylinder.

To trigger the automatic verification of the calibration, connect the calibration cylinder, check there is not leaking in the monitor channel, including the regulator as described above, and follow these steps:



The verification is successful if the concentration values of NO, NO_2 and O_2 do not differ by 8% from the actual values selected in the User Interface, in which case the values will be displayed in green. Otherwise they will be displayed in red colour.

15. Cylinder Exchange (NOXtec 1000)

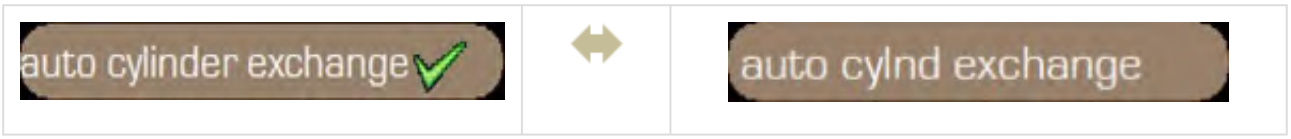
There are two ways to swap the cylinders in NOXtec 1000 device: a) manually, or b) automatically.

For changing the cylinder manually, access to the option:

NOXtec measures the high pressure in the cylinders and uses these measurements for swapping the cylinders automatically when the pressure in the cylinder in service is below the *"critical pressure"*. This option can be enabled or disabled.

To enable or disable automatic cylinder exchange follow these steps:

Options enabled are:



The "*critical pressure*" is the pressure used by the system to trigger the swapping of cylinder (threshold pressure). It could be defined in the User Interface in the range between 7 and 25 bar. To set this value, follow these steps:

The automatic swapping of cylinder will take place when:

- Automatic cylinder exchange is enabled,
- Pressure in the cylinder in use is bellow the "*critical pressure*",
- Pressure in the back cylinder is higher than the "*critical pressure*",
- Pressure in the inlet of the device of the channel where the backup cylinder is connected is within the correct range (see specifications in the Section 19.4).

The identification of the cylinder in use is identified in the top left corner of the User Interface (see Section 7.4).

If the automatic cylinder exchange option is disabled, the device will generate a high-level alarm if the high pressure into the cylinder in operation is below the "*critical pressure*", does not matter what is the gas pressure in the backup cylinder.

Additionally, NOXtec has a "*warning pressure*" level that must be set to at least 1 bar higher than the "*critical pressure*" value. This is used for generating a low-level alarm if the high pressure in the operative cylinder is lower than the "*critical pressure*" and the backup cylinder is not ready for operation, or the automatic cylinder exchange functionality is disabled. To set the "*warning pressure*" value, follow these steps:

NOXtec generates a high-level, low-level alarm or warning when the cylinders are in these conditions:

Response of the system for treatment cylinder conditions

Cylinder pressure	Both full	One in warning	One empty	One empty, one in warning	Both empty
Action	No action	No action	Change cylinder	No action	Both open
Alarm	N/A	N/A	Warning	Low level	High level

Note: Whenever a cylinder is exchanged or just before starting dosing, an automatic venting of the gas into the device internal pipes is performed.

WARNING: The user is responsible for replacing the cylinder(s) before it is completely exhausted to avoid a hazardous situation to the patient.

WARNING: The user is entirely responsible for the quality of the NO gas cylinder used with the device. The manufacturer only recommends the use of medical grade NO gases.

15.1. Different Modes of Automatic Cylinder Exchange

The device, by default performed the change of cylinder using the measurement of high pressure into the cylinder. However, if there is a change in the low pressure in the inlet of the device, the device will also perform an automatic change of cylinders. This could be due to:

- Error in the cylinder pressure regulator,
- The device is use connected to a pipe in the wall,
- The critical pressure of the cylinder is too low.

The parameters the device use for exchanging the cylinders are summarised in the next table.

Parameters for exchanging the cylinders

Type of change	Description	Condition	Change value (bar)
High pressure	The device used the high pressure into the cylinder.	By default	Critical pressure
Low pressure	The device use the pressure measured in the inlets of the device.	Error in the cylinder pressure regulator, the device is use connected to a pipe in the wall, the critical pressure of the cylinder is too low.	3.5 +/- 0.1 *

* If the pressure in the inlet of the device is over 6 bar, the device will asume there is a problem with the pressure regulator and will force an exchange of cylinder.

15.2. Cylinder Replacement

To replace the N_2/NO gas cylinder, follow the next steps:

1. Close the cylinder valve

2. Purge manually the system channel by pressing the corresponding manual purge button (PURGE).

Manual purging buttons

3. Verify in the user interface, or in the gauge of the corresponding cylinder regulator, that the high-pressure value is 0 bar.

4. Remove the depleted cylinder and replace it with another filled cylinder. Use cylinder with the same characteristics. Connect to the device as described in Chapter 9, points 2 and 3.

WARNING: Do not leave the gas cylinders in an unstable or unsafe position to avoid serious accidents.
WARNING: NOXtec only operates with cylinders with the same NO_2/NO concentration.

16. Alarms

The device has 3 level of alarms:

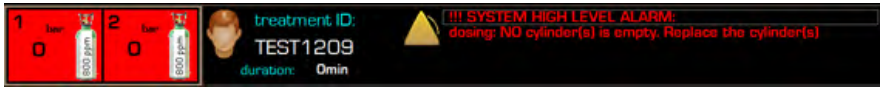
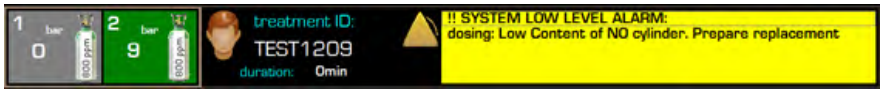
a) high level alarm, to indicate a risky situation to the patient,

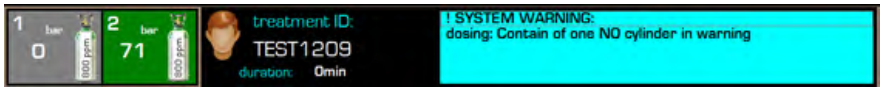
b) low level alarm, to indicate a not desired situation to the patient that came become in a critical situation to the patient in a short period of time,

c) additionally, the device has a warning to indicate that something can be improved to better experienced.

The visual alarms appear in the upper right of the User Interface. Audible alarms are generated with a specific pattern that identifies the level of the alarm or warning. The visual and audible difference between high level and low level alarms as well as the warnings is summarized in the following table:

Description of the different level of alarms

Alarm type	Visual	Audible pattern
High level	BACKGROUND: alternating between red and black; FONTS: Alternating between white and red 	The next pulse train* is repeated twice every 8seconds 
Low level	BACKGROUND: alternating between yellow and black; FONTS: alternating between black and yellow 	The next pulse train** is repeated once every 10seconds 

Alarm type	Visual	Audible pattern
Warning	BACKGROUND: cyan; FONTS: black 	Two pulses of 130ms spaced 190ms every 18seconds
No alarm	Device identification logo	Nothing

* The audible pattern of the high level alarm consists in two pulse trains. Each pulse train consist on:

- 5 audio bursts of a duration of 110ms,
- 80ms of silence between the 1st and the 2nd, and between the 2nd and the 3rd
- 250ms between the 3rd and the 4th burst.
- 80ms of silence between the 4th and the 5th burst
- Timing between the two pulse trains repetition is 850ms.

** The audible pattern of the low-level alarm consists in three audio bursts of 130ms separated 190ms.

16.1. Table of Alarms

List of alarms

Alarm	Level	Description	Action	Limits
Dosing module (ONLY for version 1000 and partially 2000)				

Alarm	Level	Description	Action	Limits
Failure state	High	The dosing module is not operative	Reboot the system, otherwise call for technical support	No limits
Content of the cylinder is low	High	Both cylinders are empty or the cylinder in use is empty and the automatic exchange function is disabled	Replace cylinder or turn the automatic cylinder exchange function on	Defined by the user: "settings – advanced - critical pressure" ±1 bar "settings – advanced - warning pressure" ±1 bar Warning created when one of the cylinders is empty
	Low	The cylinder in use is below the warning threshold and the automatic exchange function is disabled or the backup cylinder is empty		
Pressure in the inlet of the device (only NOXtec 1000) out of range	High	The pressure of the regulator of the cylinder-in-use and the one of the is out of range, AND The pressure of the regulator of the backup cylinder is also out of range OR the automatic cylinder exchange function is disabled	Check the cylinders pressure regulator OR turn on the automatic cylinder exchange function	Pressure in the inlet of the device must be between 2.5 and 6.0 bar
Regulated pressure out of range	High	The internal pressure regulated is out of limits	If dosing is out of range, go to emergency mode. Set the manual regulator in the right position according to the NO set point. Call to technical support for fixing the internal pressure regulator	Regulated pressure must be between: STANDBY: 1.5 and 3.0 bar DOSING: 1.5 and 2.5 bar

Alarm	Level	Description	Action	Limits
Venting line (for NOXtec 1000 and 2000)	Low	Venting line obstructed or with excessive vacuum	Check the venting line or disconnect the device from the extraction line. Connect a 22mm tubing to a ventilated place	Venting relative pressure must be higher than 0 bar and most not exceed 1 bar
Leaking by dosing outlet (ONLY for NOXtec 1000)	Low	Device is measuring unexpected flow throughout the dosing port	Device could be in standby mode with the manual dosing bypass open	Dosing flow is higher than 60 mL/min and device is in standby. Warning created above 30mL/min
Flow in the inspiratory limb sensor (ONLY for NOXtec 1000)	High	Error in the selected respiratory flow sensor	Replace flow in the inspiratory limb sensor. If not solved, use semi-automatic mode and call technical service	Error in the hot-wire or differential pressure sensor
Dosing flow feedback compensation out of range (ONLY for NOXtec 1000)	Low	Compensation of the difference between dosing flow measured and the target flow calculated is in the top limit	Perform a recalibration of the proportional valves	+/- 30%
Monitoring module				
Failure state	High	The monitor module is not operative	Reboot the system. Otherwise, turn off the device and report to technical service	No limits
Battery fault	High	Battery is malfunctioning		No limits

Alarm	Level	Description	Action	Limits
Flow or pressure in sensor out of control	Low	The pressure or flow inside the gases sensor chamber is out of range	Check the correct connection of the sensors block. Otherwise, call to the technical support	The sampling pump or pressure regulator control is out of the range that is between 200 and 700 UR. Controls are adjusted to get the flow and pressure in the range of ±5 mL/min and ±5 mbar respect to the target
Sampling line obstruction	High	There is an obstruction in the sampling line	Check that the sampling tube is not obstructed, and that the water trap is not full.	The flow through the sensors is less than 10 mL/min
NO concentration	High	The NO measurement is outside the thresholds specified	Check the system or relax the alarm thresholds if possible. Use the compensation factor option.	NO measurement out of the established range in the User Interface
NO_2 concentration	High	The NO_2 measurement is outside the thresholds specified	Check the ventilatory circuit. Verify that the flow in the inspiratory limb is not too low. Relax alarm thresholds if possible.	NO_2 measurement out of the established range in the User Interface
O_2 concentration	High	The O_2 measurement is outside the thresholds specified	Increase the O_2 concentration in the ventilator or add oxygen in the inspiratory line. Relax alarm thresholds if possible	O_2 measurement out of the established range in the User Interface

Alarm	Level	Description	Action	Limits
Calibration obsolete	Low	85% of the calibration period is over	Perform device calibration	Defined in the device configuration. By default it is 30 days.
	High	Calibration period is expired		
Water trap	High	The water trap is not connected	Connect the corresponding water trap according to the patient under study (adult or neonate).	Water-trap disconnected from the receptacle
Battery depleted	High	The battery charge is below the set limit	Connect the device to the main or turn it off and use the manual bypass for dosing	Defined by the user "settings monitor" ±1%. Device is power off automatically when the battery charge is below 10%.
Battery temperature	High	The battery temperature is too high	Immediately turn off the device and disconnect it from the main. Use the manual mode for dosing	Temperature above 70°C. Operative condition is recovered when temperature is below 60°C
Digital sensor block	High	Communication with the digital sensors is lost	Restart the device	No limits

In all cases, the position of the user respects the device for detecting and solving the problem that is creating the alarm condition must be 4m around the device.

System alarms are determined in most of the cases by comparing measurement of the corresponding parameter with thresholds established for it. Alarm triggers have a delay time between 2 and 10 seconds depending on the alarm.

In case that the device detects more than one alarm at the same time, it will only display the alarms with higher level. It means that:

- If the system has a high-level alarm on the monitor or dosing module and another high-level alarm, both will be shown together,

- If the system has a high-level alarm on the monitor or dosing module and another low-level alarm, only the high-level alarm will be displayed and the low level alarm will be omitted until the high-level alarm(s) is clear.

Other parameters of the alarm such as tone, rhythm, volume, etc., do not change during the use of the unit.

WARNING: Observe the alarm limits given in the table above and avoid disabling system alarms inadvertently.

WARNING: All system alarms have a time delay of 2 to 10 seconds.

Note: The system does not have volume level control.

16.2. Muting the Audible Alarms

There is an option to mute the audible system alarms from the User Interface. This avoids unwanted sounds when the user is aware of the alarm or warning situation. The audible alarm status is described below:

State of alarm muting

Alarm type	Description	Symbol
No alarm condition	There is neither an alarm condition for dosing nor for monitor	

Alarm type	Description	Symbol
Alarm condition	A warning, low level or high level alarm is present	
Alarm is muted	A warning or low level alarm condition is present and the audible sound was muted permanently. Audio will not be triggered again until another alarm conditions appear or one of the existing disappear	
Alarm is paused	A high level alarm condition is present and the audible sound was muted temporally. Audio will be triggered again after the alarm mute timeout, when another alarm conditions appear or one of the existing disappear Alarm mute timeout is 1min by default. It can be configured in the configuration file to be between 1 and 3min.	

Note: When the audible alarm corresponds to a high-level alarm, the alarm muting is not permanent and will be automatically unmuted after a time between 1 and 3 minutes, depending on the device configuration (audio paused).

Note: When the audible alarm is muted, the visual alarm remains on in the User Interface main window.

16.3. Alarm System Verification

Audible alarm in both monitor and dosing modules must be checked periodically to ensure they are working properly. Because both alarm modules operate independently, they must be checked independently. The best way to check the alarms is as follow:

- Monitor alarm, remove the water trap from the right side of the unit. In the alarm area of the main screen, a high-level alarm will appear indicating the water trap is not installed.
- Dosing alarm, disconnect both high pressure sensors from the back of the unit or close both cylinders and vent the hose using the manual venting push-button in the back of the device. A high-level alarm will appear indicating the cylinders are exhausted.

The alarm must be audible perceptible as indicated in the table above. Level of audio should be higher than 70 dba at 1m.

16.4. Dosing with alarm condition

If the device is in alarm condition, by default it is not possible to start dosing to patients, except in these situations:

Alarm conditions that inhibit the device to start dosing

Alarm	Reason
Leaking by dosing outlet (ONLY for NOXtec 1000)	The device can be dosing manually. When the device is connected to the respiratory circuit and not dosing, the device could measure variations in the dosing line due to the change of pressure in the inspiratory limb
Internal regulated pressure	When the device is not dosing, it is possible that the internal pressure goes up but as soon as the device starts doing, pressure will go down. It is due to not having an over-pressure release port on the internal regulator.

Alarm	Reason
NO concentration	Alarm could be enabled if the patient has been receiving NO manually or by other ways, even if the device was dosing not a long time ago
NO_2 concentration	
Sensor calibration obsolete	The calibration of sensor has not been performed yet
Water trap	Water trap is not connected into the frame.
Battery depleted	Battery is fully depleted but charging.

17. Trolley and Other Fixing Elements

The device trolley is designed for hosting:

- 2 treatment cylinders,
- 1 auxiliary cylinder.

Treatment cylinders are normally from 10 to 20L. However, there is a customised variant of the trolley for larger cylinder size that can be increased for up to 34L.

The auxiliary cylinder is for maximum of 5L/cylinder and the use depends on the user requirements:

- Calibration gas cylinder for performing the calibration of the device that can be done by the final user;
- Oxygen cylinder to be used by the physician in emergency situations, or
- Another smaller NO/N2 treatment cylinder for the event of quick transportation.

Picture of the trolley

Specifications of the trolley are included in the Section 22.1.

Cylinders are fixed with Velcro. User should ensure the correct placement of the cylinders in the trolley.

The trolley has 4 wheels with breaks to ensure fixing the trolley in the position where it will be used safely.

Wheels of the trolley

WARNING: Please, contact with the manufacturer to evaluate other ways to use the device in clinical applications.

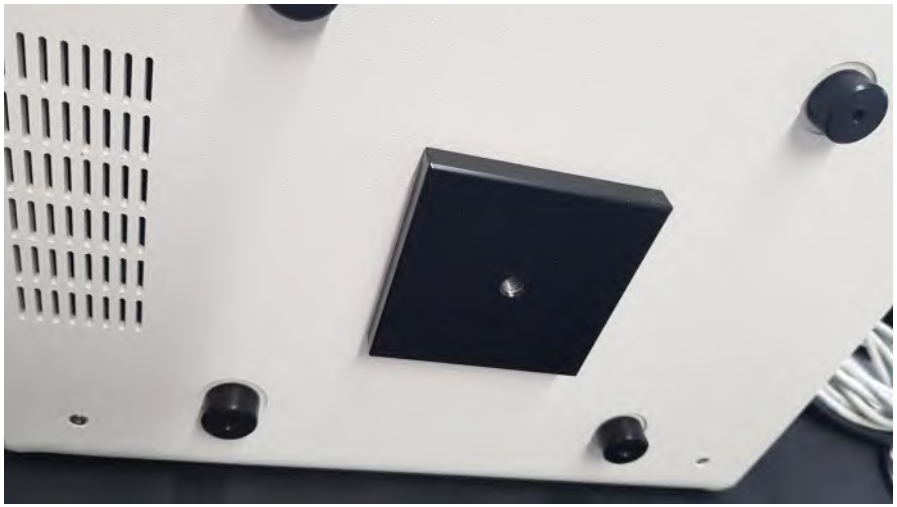
Note: User should ensure the correct placement of the cylinders in the trolley.

17.1. Releasing the Device from the Trolley

The device is fixed to the trolley by means of a single easy/rapid release screw (see Figure below) that curls in the lower part of the main box of the device. This system for releasing the device is intended to be operated by hand.

System for fixing the device to the trolley (trolley side)

The device can also be fixed to other elements in the hospital: trays, patient beds, other trolleys, pendant systems, etc.



System for fixing the device to the trolley (device side)

18. Cleaning and disinfection

Routine cleaning must be carried out at regular intervals according to local hospital guidelines.

WARNING: Lock the screen before cleaning the device if it is in use with patients for avoiding changing the treatment parameters accidentally.

 Cleaning and disinfection of the device must only be performed by trained employees.

 Do not sterilize the device in a steam autoclave or with liquid.

For manual cleaning of the device, use carefully a standard commercial cleaning agent and a damp cloth. All secretions and other visible deposits and contamination must be completely removed. It is important to dry the device after cleaning.

For manual disinfection, use standard wipes for surface disinfections and for cleaning the body of the unit, terminals and applicable parts. The touch screen can be cleaned with wipes with ammonium for better disinfection.

Once manual disinfection is complete, check the parts for visible residual contamination. If necessary, repeat the manual cleaning and disinfection process.

After the dwell time, the disinfectant must be completely rinsed off with aqua dest. Afterwards, the parts must be dried thoroughly.

18.1. Information about cleaning agents and disinfectants

It is recommended to use cleaning and disinfectant products that have been registered or approved by a prestigious healthcare authority such as the EPA (Environmental Protection Agency) or TGA (Therapeutic Goods Administration).

An ideal disinfectant must have high germicidal activity and rapidly kill a wide range of microorganisms, including spores.

 Do not use grease or oils for cleaning. Some of them may be incompatible with oxygen creating fire or explosion.

⚠ When using cleaning agents and disinfectants, pay attention to the correct concentration and dwell time to prevent damage to the materials.
⚠ When using agents other than those specified, please contact the manufacturer of the disinfectant to confirm its compatibility.
⚠ Cleaning and disinfection may be affected by the water quality, Use only demineralized water for all rinsing.

18.2. Disposing the Devices and the Kits

The devices must be disposed following the European directive for waste electrical and electronic equipment (WEEE). Please, consult the local authorities for proceeding.

All disposable parts must be disposed of in an environmentally friendly manner according to local hospital guidelines. Take into consideration potential contamination of the components of the kits to be disposed.

19. Technical Specifications

19.1. Physical Specifications

Technical specifications: physical specifications of the device

Dimensions (mm) **(height x width x length)**	Main unit	190 x 300 x 345
	Trolley	1250 x 565 x 630
Weight (kg)	Main unit	8.4 (NOXtec 1000) 8.0 (NOXtec 2000)
	Trolley	41.5
Cylinders in Trolley	2 x from 10 to 20 L treatment cylinders, (optional) up to 2 x 34 L treatment cylinders 1x from 2 to 5 L calibration or O_2 cylinder	
Materials	Stainless steel AISI 304 and AISI 316, PTFE and ABS	
IP classification	20	

19.2. Operating and Storage Conditions

Technical specifications: operating and storage conditions

	Temperature (°C)	Humidity (%)	Relative pressure (kPa)
Operating conditions	10 – 40	15 – 90	65.0 – 101.5
Storage conditions	-10 – 60	15 – 90	50.0 – 101.5

19.3. Monitoring Module

Technical specifications: monitor module

Measuring principle of gases sensors	NO: 4 electrodes electrochemical
	NO_2: 4 electrodes electrochemical
	O_2: partial pressure electrochemical sensor
Measuring range	NO: 0 – 100 ppm (optional: could be incremented to 180 ppm)
	NO_2: 0 – 20 ppm

	O_2: 0 – 100 %
Measurement accuracy (%)	NO: ± 5
	NO_2: ± 10
	O_2: ± 3,5
Resolution	NO: 0.1 ppm
	NO_2: 0.1 ppm
	O_2: 0.1 %
Response time (seg)	NO: < 10
	NO_2: < 40
	O_2: < 20
Sampling line flow setpoint (mL/min)	90 – 200 (± 7 %)
Calibration cylinder input pressure (Bar)	Minimum 3.5, nominal 4.5, maximum 5.5
Operational life of the sensors (months)	12

Sound pressure (dba)	75 – 85 at 1 m distance.

19.4. Dosing module and User Interface

Technical specifications: dosing module

Dosing modes	Real time (ONLY for NOXtec 1000)
	Automatic (ONLY for NOXtec 1000)
	Semi-automatic (For NOXtec 1000 and 2000)
	Manual (For NOXtec 1000 and 2000)
Reference of manual dosing flow (for NOXtec 1000 and 2000) (L/min)	0 – 0.02 – 0.03 – 0.05 – 0.07 – 0.1 – 0.15 – 0.2 – 0.25 – 0.3 – 0.45 – 0.6 (± 30 %)
Cylinder inlet pressure (Bar)	Minimum 2.5, nominal 4.5, maximum 6.0
Cylinder exchange pressure (Bar)	Minimum 7, nominal 10, maximum 25 (3.5 bar if using device inlet pressure, or 6.0 bar if it is due to overpressure)
NO set range (PPM)	0.1 to 100

Accuracy of dosing (%)	± 10 (ONLY for NOXtec 1000)
Resolution dose (PPM)	0.1 (0.5 configured by default)
Minimum dose (PPM)	0.1 (0.5 configured by default)
Ventilator flow range (L/min)	0.5* – 120 (ONLY for NOXtec 1000)
Dosing flow (L/min)	NOXtec 1000: 0.01 – 3.60** NOXtec 2000: 0.01 – 0.80
Maximum pressure in device outlet (Bar)	2.0 ± 0.5
Set-up time	< 2 min fs
Screen	Colour LCD 10.1", 1280 x 800 pixels.
Sound pressure (dba)	75 – 85 at 1 m distance

* It is valid for constant flow application. Using ventilator, consider average flows higher than 1 L/min. Minimum respiratory flow detected by the device is 0.2L/min.

** Maximum dosing value could be higher, up to 5L/min for NOXtec 1000 or 1.2L/min for NOXtec 2000.

19.5. Electrical Specifications

Technical specifications: electrical

Power supply	100 – 240VAC, 50 – 60 Hz	
	Internal Lithium battery powered device	
	Device designed for continuous operation	
Fuse (230 VAC)	1.25A, Ø5mm x 20mm, FSF5x20 250V	
Fuse (115 VAC)	3.15A, Ø5mm x 20mm, FSF5x20 250V	
Battery	Duration	6h estimated
	Charging time	2.5 h
Normative	EN 60601-1-2:2015	
	EN 60601-1:2008 + A12:2015	
Classification	Class I, Type B	

19.6. Electromagnetic and RF Specifications

NOXtec is intended for use in an electromagnetic environment specified below. User of NOXtec should ensure that it is used in safe environment.

Technical specifications: guidance and manufacturer's declaration - electromagnetic emissions

Emission test	Conformity	Electromagnetic environment - Guide
RF emissions CISPR 11	Group 1	NOXtec uses RF energy only for its internal function. Therefore, their RF emissions are very low and are not likely to cause any interference to nearby electronic devices
RF emissions CISPR 11	Class B	NOXtec is suitable for use in all establishments, including domestic environment and those using the public low voltage power supply network that power buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Fluctuations of voltage/ flickers emission IEC 61000-3-3	Comply	

NOXtec is intended for use in an electromagnetic environment specified below. User of NOXtec should ensure that it is used in safe environment.

Technical specifications: guidance and manufacturer's declaration – electromagnetic immunity

Immunity test	Standard or test method	Level of conformity

Electrostatic discharge (ESD)	IEC 61000-4-2	±8 kV by contact ±2 kV, ±4 kV, ±8 kV, ±15 kV by air
Radiated RF EM fields	IEC 61000-4-3	3 V/m, 80 MHz – 2.7 GHz, 80% AM at 1 kHz
Proximity fields from RF wireless. Communication equipment	IEC 61000-4-3	See reference in Table below
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m, 50Hz or 60 Hz
Transient/fast bursts	IEC 61000-4-4	±2 kV, 100 kHz repetition frequency
Surges, line to line	IEC 61000-4-5	±0.5 kV, ±1 kV
Surges, line to ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V, 0.15 – 80 MHz 6V in ISM bands between 0.15 – 80 MHz 80% AM at 1 kHz
Voltage dips	IEC 61000-4-11	0 % U_T 0.5 cycle at 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚ and 315˚ 0 % U_T 1 cycle and 70% U_T 25/30 cycles. Singles phase at 0˚
Voltage drops, interruptions and voltage variations in the power input lines	IEC 61000-4-11	0 % U_T, 150/300 cycle

NOTE: U_T is the AC voltage supply before the application of the test level. Interference may occur in the vicinity of devices marked with the following symbol: 

NOXtec is intended for use in an electromagnetic environment in which RF radiations are controlled. User can help prevent electromagnetic interference by maintaining a minimum distance between portable or mobile RF communications devices (transmitters) and the NOXtec as recommended below, according to the maximum output power of the communications devices.

Technical specifications: recommended distances between portable or mobile RF communications devices and NOXtec

Maximum power output of the transmitter (W)	Distance according to the frequency of the transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.74
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters with a maximum output power not listed above, the recommended distance d in meters (m) can be determined using the equation applicable to the transmitter frequency, where P is the maximum power output in watts (W) according to the manufacturer of the transmitter.			

Note: At the frequencies of 80 and 800 MHz, the distance is applied for the highest frequency range.

Note: These guidelines cannot be applied in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Technical specifications: specifications for enclosure port immunity to RF wireless communication equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM ± 5kHz deviation 1kHz sine	2	0.3	28
710	704 - 787	LTE band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 900, iDEN 820, CDMA 850, LTE band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						

1720	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE band 1, 3, 4, 25, UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLN 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 - 5800	WLN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

WARNING: Expected service life of the unit will be compromised if the electro-magnetic environment is not appropriated.

WARNING: The device can show NO and/or NO_2 inspected alarm under the effect of electromagnetic radiation in the ranges of 250-325MHz and 385-450MHz.

20. Troubleshooting

Technical specifications: troubleshooting

Problem	Identification	Solution(s)
Failure in gases calibration: pump stability.	An error appears at the end of the calibration. The code can indicate in what step the failure occur.	• Repeat the calibration process • Ensure the sensors are not obsolete checking the caducity label • Check the correct connection of the calibration gas and that the cylinder is open • Otherwise, the problem is related with leaking or other pneumatical failure, them call the technical support.
Failure in gases calibration: offset of sensors		• Check the 2x CR2032 sensor block batteries • Wait until the NO reading is lower than 0.5ppm and the NO2 is lower than 0.2ppm and repeat the calibration process
Failure in gases calibration: span error on NO or NO_2		• Check the correct connection of the calibration gas and that the cylinder is open • Replace the corresponding gases cell
Failure in gases calibration: error in O_2 calibration		• Check the cell is not exposed to oxygen • Check the O_2 cell
Low pressure is too high	Low pressure out of range alarm	• Press the venting button of the gas channel • Check the cylinder is connected to the device and opened • If the problem persist, replace the pressure regulator

Low pressure is too low		
Regulated pressure is too high	Regulated pressure alarm	• Press the venting button of the cylinder in operation, OR • Open the manual regulator in position B if unit is not dosing • If the problem persist, call to technical support for adjusting regulator
Regulated pressure is too low		
Regulated pressure out of range. Cylinder was open suddenly		• Open the manual flow control in position B or C during few seconds until the error disappear
High pressure too low	Cylinder is empty	• Check the pressure sensor is connected to the device • Check the cylinder is opened • Check the sensor and cylinder are connected to the same channel • Replace the treatment cylinder
Error in automatic flow controller's calibration	Error in the calibration process or flow compensation is out of range	• Repeat the calibration of the flow controller • Check the cylinders are correctly connected an opened
Battery error	Communication error	• This alarm could be recovered automatically. • Otherwise, power off and on the device
	The charge of the battery appears as very low (less than 10%)	• Leave the device connected to the main during 2h before using it with patients
Low battery error and the device appears like disconnected from the main despite the main cable is connected	The low battery alarm appears The main connection symbol does not appear in top of the battery at the right top corner	• Unplug the main and plug it after few seconds • Check the fuse in the button of the main cord connector

Battery is not charging with the device off and plug to the main	Battery is not charged when device is connected to the main	• This happen in devices of 2017 and 2018. • Turn the device ON for charging
Battery is fully depleted and is not charging as expected	The device is on but battery charge is not increasing and the power lid could be not recognized	• Call to technical support for sending to the device the battery charging command and turn the device off, disconnect from the main for 2mins and turn it on again
Leaking in the outlet of the dosing module	The device is under dosing When the dosing outlet is closed with the finder, it is not pressurized after few seconds	• Call to the technical support for verifying the device.
Monitor is measuring the venting gas of the dosing module	When device start dosing or the cylinder is exchange, a high concentration of NO is read in the User Interface	• Call to the technical support for replacing the electro-valve of the outlet of the monitor module
Device is under dosing	When the inlet of the water trap is closed with the finger, it is not doing vacuum and the alarm of sampling line obstructed is not appearing	• Leaking in the monitor module • Electro-valve in the exhaust outlet of the monitor is not closing
Measurement of the flow in the inspiratory limb is not correct after 2 or 3 days	The wire of the hot wire sensor is dusty and must be clean	• Replace the sensor. It is not possible to clean the sensor during treatment
When the device NOXtec 1000 or NOXtec 2000 is turned on, it is starting as a monitor mode	The device does not detect the electronic dosing board or the initial verification fail	• Power off and power on again the device. Ensure the fan is off to turn it on again.

21. Control of the NO_2 Concentration

The NO_2 is generated due to the chemical reaction between the NO dosed by NOXtec and the O_2 in the inspiratory limb coming from the ventilator. The NO_2 concentration strongly depends on the next parameters:

- NO concentration. The higher ↑ the **NO** concentration is, the higher ↑ the **NO_2** concentration will be.
- O_2 concentration. The higher ↑ the **O_2** concentration is, the higher ↑ the **NO_2** concentration will be.
- Flow in the inspiratory limb. The higher ↑ the **flow in the inspiratory limb** is, the lower ↓ the **NO_2** concentration will be.
- Respiratory circuit. The longer ↑ the **NO gas remains in the respiratory circuit** (including humidifier vessel) the higher ↑ the concentration of **NO_2** will be.

The disposable kit supplied by the manufactured is optimized to achieve as low concentration of NO_2 as possible. Whatever modification the user does in the kit could result in an increment of the NO_2 concentration generated.

In the next table, it is presented a reference of the NO_2 concentration generated in different situations for user reference only. If the connection of the respiratory circuit is different to the description on the disposable kit information, the concentration of NO_2 could be significantly higher. The concentration of O_2 estimated in the table is for N_2/NO cylinder concentration of 800ppm.

Reference for NO2 concentration control

NO (ppm)	5 L/min				10 L/min			
	100% of O_2		21% of O_2		100% of O_2		21% of O_2	
	NO_2 (ppm)	O_2 (%)	NO_2 (ppm)	O_2 (%)	NO_2 (ppm)	O_2 (%)	NO_2 (ppm)	O_2 (%)
10	0.2	99.9	0.0	20.9	0.1	99.7	0.0	20.8
40	1.4	95.1	0.6	20.4	0.6	95.6	0.2	19.8

80	1.8	88.1	0.8	19.1	0.8	88.7	0.4	18.8
100	2.0	84.7	1.0	18.5	1.1	84.8	0.6	18.3

WARNING: The control of the NO_2 is exclusively related with the configuration of the kit and with the NO set point.

22. Compatibility with Ventilators

NOXtec measures the flow in the inspiratory limb and inject NO/N_2 gas in order to mix it with the gas coming from the ventilator and produce mixture containing the desired or set NO concentration (ppm). Inserting a flow sensor in the inspiratory limb of the patient's breathing circuit (differential pressure and hot wire disposable technologies are available) makes the device compatible with most of the ventilators available in the market and their corresponding ventilatory mode.

The list of the most typical ventilator used for NO is presented below. Note that the use of the device in anaesthesia machine is described as to be confirmed (TBC) because the connection of the dosing components into the anaesthesia circuit could requires special attention according to the device used. Please, contact the manufacturer for more information.

List of compatibility with ventilators

Ventilator list								
Manufacturer	**Model**	**Neonatal**	**Paediatric**	**Adult**	**Transport**	**High Frequency**	**Anaesthesia**	**RS232***
Acutronics Medical Systems AG	Fabian	•						
	Fabian HFO**	•				•		
Bio-Med devices Inc.	TV-100				•			
	Crossvent				•			
	MVP-10				•			
Bird Products Corp.	VIP Bird	•	•	•				

Bunnell	LifePulse HFJV					•		
Draeger	Atlan A350/A350 XL, Perseus A500, Zeus Infinity						TBC	
	Babylog 8000	•						
	Babylog 8000 plus	•				•		
	Evita XL	•	•	•				
	Evita V600, VN800		•	•				
	Babylog VN600, VN800	•				•		
	Evita Infinity V500	•	•	•				
	Savina 300	•	•					
GE Healthcare	Aespire 7100/7900, Aestiva/5 7900, Avance CS2						TBC	

	Centiva/5, 5 plus		•	•				
	Engstrom Carestation	•	•	•				
Hamilton	C6	•	•	•	•			•
	C1	•	•	•				•
	C3	•	•	•				•
	G5	•	•	•				•
	Galileo	•	•	•				
	S1	•	•	•				•
	T1				•			•
Löwenstein Medical	Leoni plus	•				•		
Infrasonics	Infant Star 950	•				•		
	Infant Start 100				•			
Metran Co. Ltd.	Humming X	•				•		

Getinge AB	Servo 300		•	•				
	Servo-i	•	•	•				
	Servo-n	•						
	Servo-s		•	•				
	Servo-c		•	•				
	Servo-u, Servo-u MR conditional	•	•	•				
	Servo-air, Servo-air NIV		•	•				
Newport™	E360	•	•	•				
	HT50		•	•				
	HT70 Plus		•	•				
	Wave E200	•	•	•				

Puritan Bennett™	7200 AE		•	•				
	560		•	•				
	840	•	•	•				
	980	•	•	•				
Respironics (Philips)	Espirit	•	•	•				
	E30		•	•				
	Trilogy Evo				•			
SensorMedics	3100A/B					•		
Inspiration Healthcare group	SLE5000	•				•		
	SLE6000	•				•		
Smiths Medical	Pneupac® babyPAC™				•			
	VentiPAC 200D				•			

	paraPAC plus				•			
	Pneupac® ParaPAC®				•			
Stephan Gmbh	Sophie	•				•		
	Stephanie	•	•			•		
	EVA NEO	•	•					
	EVE TR, EVE IN			•				
Viasys	Avea	•	•	•				
	Vela	•	•	•				
Vyaire Medical	Revel TM	•	•	•	•			

* In the case of devices with RS232 compatibility, the use of external respiratory sensor is not necessary if the RS232 cable is used. However, it is always possible to use the device with the external sensor without the RS232 cable even in those compatible devices.

** Compensation is required. In automatic or real-time modes, the device can overdose when high amplitude is selected.

Not all devices reported in the table had been tested in all respiratory mode. In some cases, a theoretical analysis has been performed.

23. Integration into the Hospital Information System

(ONLY NOXtec 1000) NOXtec device can be integrated with the hospital information system to send data that can be display and managed by the users in a central panel.

The connection with the device can be stablished by mean of:

- Ethernet connector,
- USB to RS232 adaptor connected in the USB port of the device.

Information transmitted is the next:

- Treatment time,
- NO set point,
- NO, NO_2 and O_2 measurements,
- NO upper and lower limits,
- NO_2 upper limit,
- O_2 upper and lower limits,
- Current date and time,
- Compensation factor,
- Pressure in cylinders,
- Respiratory flow,
- Dosing flow,
- Ventilator internal identification number,
- User Interface, dosing and monitor firmware versions.

The devices compatibles are summarised in the next table:

List of compatibility with HIS systems

Manufacturer	Data available	Driver	Connection
Cerner (Oracle)	All described	Hamilton S1	RS232

24. Warranty

NOXtec Development S.L. warrants this product against any manufacturing defect for a period of 12 months from the date of purchase. The warranty includes repairing, replacing or changing the product or components free of charge to the customer, including labour and materials.

This warranty does not include the following:

- Single patients use consumables or accessories such elements of the patient circuit, flow in the inspiratory limb sensor,
- Calibration gas cylinder,
- Replacement consumables as sensor block or single gas sensor,
- Damages arising out of negligence such us water into the device, physical damages, results of external fire or use of non-approved items,
- Use of the device not in accordance with the instructions contained in this manual.
- When the fault is caused by incorrect use of the unit.
- When the product has been opened or maintained by personnel or companies not authorized and trained by NOXtec Development S.L.

However, in all cases the defects must be notified in writing to the manufacturer during the warranty period.