

NOxBOX[®] O₂



Operating Manual



CE
0086

saving lives, one breath at a time

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Intended use

The NOxBOX[®]O₂ is intended for use by healthcare professionals for monitoring the levels of nitric oxide (NO), nitrogen dioxide (NO₂) and oxygen (O₂) delivered to a patient undergoing inhaled nitric oxide therapy (INO).

Environment

The NOxBOX[®]O₂ complies with the directive EN60601-1-2 electromagnetic compatibility but can be effected by cellularphone and by electromagnetic interference exceeding the levels specified in EN50082:1

Warnings

- Nitric oxide (NO):
At room temperature and atmospheric pressure, NO is a colourless, odourless, toxic, non-flammable gas. It can combine with atmospheric oxygen to form NO₂.
NO is a corrosive and oxidising substance, slightly heavier than air.
Current UK HSE guidelines for occupational exposures state that concentrations greater than 1ppm over an eight-hour timeframe (weighted average) should be avoided.
Just a few breaths of NO at a concentration of 200-700ppm is likely to produce severe pulmonary damage, which may result in fatal pulmonary oedema after 5-8 hours.
- Nitrogen dioxide (NO₂):
NO reacts rapidly with oxygen to produce NO₂. NO₂ may react further to form nitric and nitrous acid. This unwanted by-product needs to be monitored carefully and kept below 0.5ppm for most applications.
NO₂ is extremely toxic. Current UK HSE guidelines suggest a long-term exposure limit of 1ppm. Breathing as little as 25ppm of NO₂ over an eight-hour period may cause pulmonary signs and symptoms, after a virtually asymptomatic interval between five and 48 hours. Delayed pulmonary oedema may occur after exposure to 100-150ppm for only 30-60 minutes.
The equipment is not fit for use in the presence of a flammable gas anaesthetic mixture with air or nitrous oxide.
- **IMPORTANT:** Never use alcohol, cleaning agents containing alcohol, or other organic solvents to clean the monitor. Vapours from such chemicals will damage the internal sensors. Bedfont produce alcohol-free instrument cleaning wipes for this purpose.
- Under no circumstances should the instrument be immersed in or splashed with liquid.
- A low battery is indicated through the 'BATlow' alarm. Ensure that the unit is plugged in and power is switched on.
- Pressing and holding the mute button for three seconds will silence the alarms for approximately two minutes.
- If the alarm sounds and 'H2O' flashes on the display, it means that the watertrap is full and should be emptied immediately.
- The bacteria filter supplied with the NOxBOX[®]O₂ is single patient use only.
- Calibration should be checked regularly, in accordance with the instructions on page 9.
- If the alarm sounds and 'PMP/B' flashes on the display, check the tubing for blockages and kinks.
- The sample line and inline protective filter are for single use.

- The nitric oxide sensor is cross-sensitive to nitrogen dioxide, but not significantly enough to affect the unit during use.
- Temperature may affect the accuracy of the NOxBOX[®]O₂. The instrument should be calibrated at the temperature at which it is expected to be used. If the NOxBOX[®]O₂ is used at a lower temperature than when it was calibrated, readings may be lower; if used at a higher temperature than when

calibrated, readings may be higher.

Bedfont will make available on request circuit diagrams, components part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designed by the manufacturer as repairable, following service training.

Specification

Measuring range:	0-99.9 ppm NO 0-19.9 ppm NO ₂ 0-100% O ₂
Sample flow rate:	Approx. 250 ml/min
Detection principle:	Sealed electrochemical sensor
Accuracy:	<5% of reading
Display:	Graphical LCD
Alarms:	Audible and visible
Warm-up time:	<2 minutes
Response time:	<10 seconds to 90% FSD NO <30 seconds to 90% FSD NO ₂
Operating temperature:	10-40°C
Operating Humidity:	30-75%
Sensor operating life:	1-2 years
Sensor resolution:	0.1ppm NO and NO ₂
Battery life (approx.):	4-6 hours (operational)
Power input:	230v, 50Hz/60Hz (optional 115v)
Dimensions:	240 (D) × 210 (W) × 140 (H) mm
Weight:	Approx. 4 kg (including batteries)
Construction:	Aluminium

Symbols

 Direct Current

Degree of protection against electric shock:

 Type BF applied part

Type of protection against electric shock:

Internally Powered Equipment

Class I equipment; (earthed)



Attention: Consult accompanying documents

Degree of protection against ingress of liquid:

IPX0 - not protected against water ingress

Instrument layout

- | | | | |
|----|--|----|---|
| 1 | NO high control knob | 12 | Exhaust |
| 2 | NO low control knob | 13 | Inlet |
| 3 | NO ₂ high control knob | 14 | IEC power socket 230v
(115v, optional) |
| 4 | O ₂ low control knob | 15 | Anti-surge fuses |
| 5 | Manual zero | 16 | Charging LED |
| 6 | LCD screen | 17 | On/off Switch |
| 7 | Mute button | 18 | Water trap |
| 8 | NO/NO ₂ /O ₂ calibration adjusters | 19 | Luer lock release valve |
| 9 | Water trap sensor | 20 | Protective filter |
| 10 | Zero reference | 21 | USB (optional) |
| 11 | Cut-off valve | | |



Operation

The NOxBOX[®]O₂ is supplied assembled and ready for use. Prior to shipment, all units are zeroed with pure air and calibrated with certified NO in N₂ and NO₂ in air.

Pre-use checks

- Ensure that the water-trap is empty before use.
- If the water trap needs emptying, use the supplied drainage syringe by screwing onto the water trap Luer lock on the rear of instrument (see Instrument layout, page 5) and drain the water if required.
- Calibration is recommended once a week during use, or once a month during storage. Bedfont recommends that the unit is calibrated prior to use if calibration has not been carried out within these timescales. Follow the instructions for calibration on page 9.
- Checking the function of this critical care piece of equipment is important and these instructions must be adhered to.

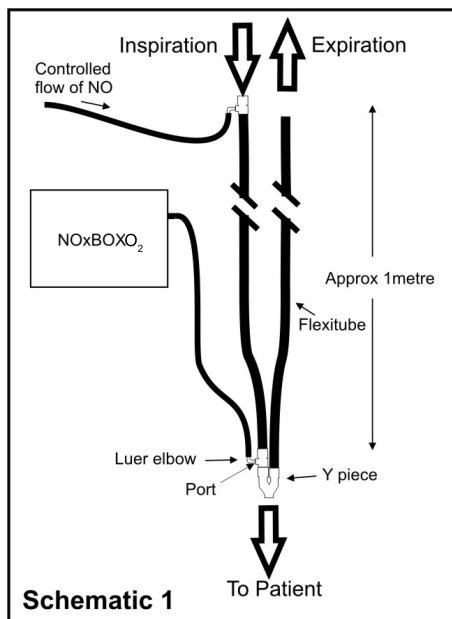
Connection to a ventilator circuit

The NOxBOX[®]O₂ is connected to the patient ventilator circuit using a kit such as

Note: Bedfont recommend zeroing the NOxBOX[®]O₂ daily when in use, using the manual zero button illustration on page 5.

the NOxKIT-V, which can be supplied by Bedfont (see Spares, page 11). This allows the NOxBOX[®]O₂ to be used with different types of ventilator. The NOxBOX[®]O₂ should be connected on the inspiratory limb of the ventilator circuit and as close to the patient as possible. This gives the most accurate representative sample of gas the patient is receiving.

A schematic of the NOxBOX[®]O₂ connection is shown below in Schematic 1:



Setting up the NOxBOX O₂

1. Connect the power lead to the NOxBOX[®]O₂ via the socket on the rear panel (please see instrument layout). Connect to the electricity supply. The charging LED located at the back of the monitor should now be illuminated.
2. Switch the monitor on using the on/off switch on the back of the unit. The green LED should light up. The NOxBOX[®]O₂ monitor will begin auto zeroing and 'Zeroing' will be displayed while this process takes place.

Note: If 'BATlow' flashes on the display, it means that the battery requires charging. Connect the mains power lead to NOxBOX[®]O₂ before continuing.

3. Once the auto zeroing process is complete, check that the NO and the NO₂ readings are 0.0ppm, and that the O₂ reading is 20.9% ($\pm 0.2\%$) absolute.
4. To calibrate the unit, follow the procedure on page 9.
5. Connect the inlet to the water-trap on the rear of the NOxBOX[®]O₂ using the sampling system provided, then to the inspiratory limb of the ventilator circuit, usually at the Y-piece (see Schematic 1, page 6).



NOTE: Ensure the filter is connected as above before use.

Setting alarms

Alarms can be set for high and low levels of NO, high levels of NO₂ and low levels of O₂. These four controls are located by the manual zero button on the right-hand side of the monitor, in a secure compartment (see Instrument layout, page 5).

Setting the high NO alarm

- Adjust the 'NO Hi' control knob in the secure compartment (see Instrument layout, page 5) on the right-hand panel until the desired value is displayed and is stable.

Setting the NO low alarm

- To set the alarm, adjust the 'NO Low' control knob in the secure compartment (see Instrument layout, page 5) on the right-hand panel until the desired value is displayed and is stable.
- The minimum value the NO alarm can be set to is 0ppm.

Setting the NO₂ high alarm

- To set the alarm, adjust the 'NO₂ Hi' control knob in the secure compartment (see Instrument layout, page 5) on the right-hand panel until the desired value is displayed and is stable.
- The minimum value the NO₂ alarm can be set to is 0ppm.

Setting the O₂ low alarm

- To set the alarm, adjust the 'O₂ Low' control knob in the secure compartment on the right-hand panel until the desired value is displayed and is stable.

Note: When the alarm is activated, the corresponding section of the front panel display will flash and an audible alarm will sound. The audible alarm can be silenced for approximately two minutes by pressing and holding the 'Mute' button (see Instrument layout, page 5) under the front panel LCD display for three seconds. The display will continue to flash while the alarm is silenced.

Calibration

Calibration of the NOxBOX[®]O₂ should be carried out once a week during use and once a month during storage.

A well ventilated area should be chosen and the NOxAIR personal alarms should be used during the procedure.

Nitric oxide (NO)

IMPORTANT:

- Before carrying out any calibration procedure, it is essential for the NOxBOX[®]O₂ to complete the auto zeroing process.
- A certified gas cylinder containing 25ppm NO balanced in nitrogen, supplied by Bedfont, should be connected to the calibration Y-piece adapter through the female luer lock.
- Open the regulator and connect the calibration gas cylinder to it.
- The flow is automatically set to approximately 1 litre per minute (± 0.2 ltr/minute) using the regulator.
- Allow approximately three minutes for the reading to stabilise.
- The display reading can be adjusted to show the value given on the calibration gas cylinder by turning the 'NO span' potentiometer screw on the side of the monitor (see Instrument layout, page 5) using the calibration screwdriver supplied.
- Disconnect and turn off the gas supply.
- Allow the NOxBOX[®]O₂ monitor to zero before starting the NO₂ calibration procedure.

Nitrogen dioxide (NO₂)

- A certified gas cylinder containing 10ppm NO₂ balanced in air, supplied by Bedfont, should be connected to the calibration Y-piece adapter through the luer lock, shown in the photograph below.
- Open the regulator and connect the calibration gas cylinder to it.
- The flow is automatically set to approximately 1 litre per minute (± 0.2 ltr per minute) using the regulator.
- Allow approximately three minutes for the reading to stabilise.
- The display reading can be adjusted to read the value given on the calibration gas cylinder by turning the 'NO₂ span' potentiometer screw on the side of the instrument (see Instrument layout, page 5) using the calibration screwdriver supplied.
- Disconnect and turn off the gas supply.

Oxygen (O₂)

- The O₂ reading can be adjusted using the O₂ span potentiometer to 20.9% (following the steps for NO₂ calibration or on ambient air).



Maintenance

Calibrate the NOxBOX[®]O₂ in accordance with procedure on page 9.

Check that the water trap is empty before each use. Empty it after each use with the drainage syringe supplied.

Sensors will need to be changed periodically. The life expectancy of the sensors is between one and three years.

Additional technical information is available on request – please contact Bedfont or your local distributor.

Cleaning

Wipe the instrument and external surfaces with a product specifically developed for the purpose. Bedfont provides Instrument Cleansing Wipes.

IMPORTANT: Never use cleaning agents containing alcohol or other organic solvents as the vapours will damage the sensors.

Under no circumstances should the instrument be immersed in or splashed with liquid.

Returns procedure

If the equipment requires servicing, please contact Bedfont's Customer Repairs department before returning any goods. If the equipment was not purchased directly from Bedfont, please contact the local distributor.

- The Customer Repairs department will issue a Returns Number once the monitor serial number and a description of the fault are supplied.
- State the Returns Number when returning the monitor and ensure that full details, including telephone and fax numbers, are clearly provided.
- Bedfont advises using a courier service when returning monitors.
- Confirmation will be issued when goods are received.
- An Engineer's Report and a quotation for the repair will be sent following investigation. This includes an Authorisation Form.
- If the monitor is still in warranty, Bedfont will repair it and return it with an Engineer's Report, free of charge. If the monitor is found to simply require calibrating, a fee will be charged.
- If out of warranty, complete the Authorisation Form included with the quotation to proceed with the repair or calibration. Ensure that an Official Purchase Order Number is included, and return the instrument to Bedfont. Contact the Customer Repairs department Specialist if you have any queries.
- If it is decided not to proceed with the repair, a handling fee will be charged. Ensure that the completed Authorisation Form is returned to Bedfont with an Official Purchase Order Number.
- The equipment will be returned as soon as Bedfont has received all relevant paperwork. A carriage fee will be charged if the monitor is out of warranty.

Spares

Part number	Description
SEN021	Replacement NO sensor for NOxBOX [®] O ₂
SEN020	Replacement NO ₂ sensor for NOxBOX [®] O ₂
FXS414	Nafion drying tube
NOX02WT-COMplete	Water trap
BAT046	Power lead (UK)
BAT045	Power lead (EU)
NOX-Y-CAL	Calibration system (Y-piece and male luer)
058-18-00520-V	Calibration gas (25ppm NO in N ₂) 58-litre disposable cylinder
058-20-01010-V	Calibration gas (10ppm NO ₂ in air) 58-litre disposable cylinder
REGSS-1.0-V	Calibration regulator, pressure gauge and flow outlet
CCG-V	Carry case for cans and regulators
NOXKIT-V	A selection of connectors to attach NOxBOX [®] O ₂ to a ventilator
RECYCLER-V	Puncture tool for recycling empty cylinder
WIPES	Instrument Cleansing Wipes
FIL042A-IND	Protective Filter
FIL042A	Protective filters (pack of 25)
NOXO2-SL-2.5M	2.5m Sample line
NOXO2-PATIENT	2.5m sample line, protective filter, water trap emptying syringe
NOXO2-PATIENT-COMP	2.5m sample line, water trap, protective filter, water trap emptying syringe

The above spares are available from Bedfont Scientific Ltd, UK. For spares availability in all other countries, contact your local distributor. It is recommended that only Bedfont spares are used.

Warranty

Bedfont Scientific Limited warrants the NOxBOX[®]O₂ (excluding batteries) to be free of defects in materials and workmanship for a period of two years from the date of shipment. Bedfont's sole obligation under this warranty is limited to repairing or replacing, at its choice, any item covered under this warranty when such an item is returned intact, prepaid, to Bedfont Scientific Ltd or your local representative.

Note: Sensors are guaranteed for a period of six months from the date of shipment from Bedfont.

These warranties are automatically invalidated if the products are repaired, altered, or otherwise tampered with by unauthorised personnel, or have been subject to misuse, neglect or accident.



Do not dispose of any electronic equipment in domestic waste. At the end of the product's life, contact Bedfont or its distributor for disposal instructions.



Bedfont Scientific Ltd

Station Road, Harrietsham, Maidstone, Kent,

ME17 1JA, England

Tel: +44 (0)1622 851122

Fax: +44 (0)1622 854860

Email: ask@bedfont.com

www.bedfont.com

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