

NOxBOX[®]+



breath analysis is the new blood test

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Introduction

Intended Use

The NOxBOX+ will be used by suitably trained and qualified health professionals for monitoring levels of nitric oxide (NO) and nitrogen dioxide (NO₂) delivered to a patient undergoing nitric oxide therapy.

NO is administered as a selective pulmonary vasodilator for conditions such as:

- Persistent pulmonary hypertension in newborn babies (blue baby syndrome)
- Adult respiratory distress syndrome
- For acute post-operative cardiac patients

This equipment should be used by suitably trained and qualified health professionals.

If the instrument is being used as part of the NOxBOXmobile delivery system, it is important that the user reads and understands the NOxBOXmobile Operating Manual.



NOxBOXmobile
Delivery System

Instrument Contents List

Key:

1. NOxBOX+
2. Mains power adapter
3. Magnum screwdriver
4. Calibration screwdriver
5. PU tubing with luer locks
6. Water trap
7. Nafion tubing
8. Calibration T-piece adapter
9. NOxBOX+ manual
10. PU tubing with female luer lock



Instrument Layout

General Description

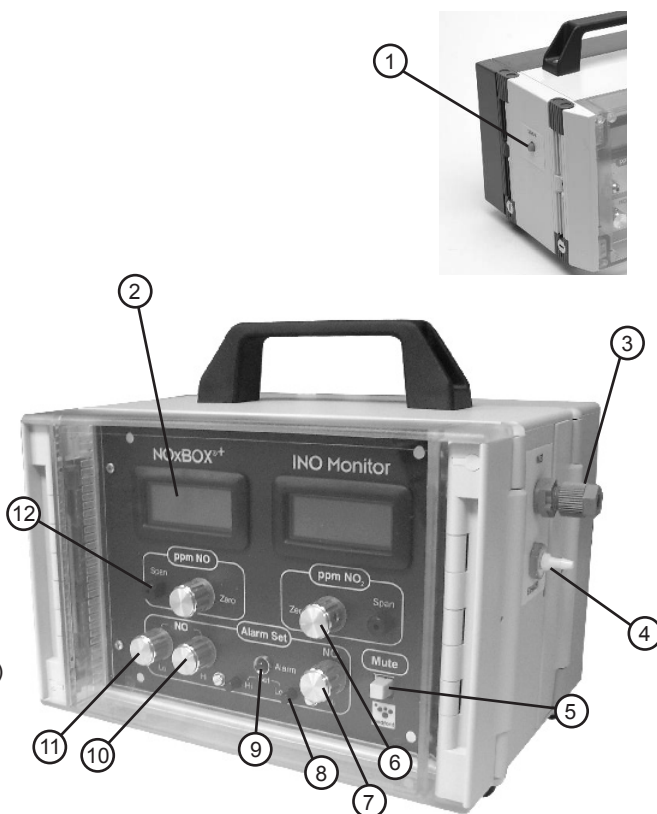
The NOxBOX+ is used as a side stream monitor for NO and NO₂ in the inspiration air delivered to patients undergoing inhaled nitric oxide therapy.

The instrument is designed to be situated close to the patient's bedside ventilator and is powered by a replaceable battery pack or mains power pack connected to the DC supply socket on the back. The monitor uses an electrochemical sensor to sample the gas and converts the sensor output voltages into meaningful digitally displayed results. Gas concentrations are measured in the range 0-200ppm NO and 0-50ppm NO₂ in increments of 0.1ppm, and analytical sensitivities of 0.2ppm (200ppb) are possible. The instrument is equipped with high NO and low NO alarms, and a high NO₂ alarm, to alert the clinician to concentrations that are outside of the tolerance range. There is also a low battery alarm.

The sensor is protected from high levels of moisture condensate, which could damage it, by using a sampling conditioning system prior to gas entering the sensor.

NOxBOX+ and Key:

1. On/off switch
2. LCD display (×2)
3. Inlet
4. Exhaust
5. Mute button
6. Zero dial (×2)
7. NO₂ high alarm set
8. Alarm set buttons (high and low)
9. Red alarm LED
10. NO high alarm set
11. NO low alarm set
12. Span adjustment screw (×2)



Warnings

Use

The product is intended for use by health professionals and emergency medical staff. It is recommended for ventilated patients only. Alternative equipment should be used for spontaneously breathing patients and environmental measurement.



NO and NO₂

NO:

Clinical research has indicated that administering a low concentration of NO assists oxygen uptake in patients who are breathing pure oxygen, usually through a ventilator, but not responding sufficiently.

NO is a corrosive and oxidising substance, which is slightly heavier than air. At room temperature and atmospheric pressure, it is a colourless, toxic, non-flammable gas. It can also combine with atmospheric oxygen to form NO₂.

Current UK HSE guidelines for state that occupational exposure to concentrations greater than 1ppm over an eight-hour timeframe (weighted average) should be avoided.

NO₂:

Unfortunately, NO reacts rapidly with oxygen to produce NO₂, which may react further to form nitric and nitrous acid. This unwanted by-product needs to be monitored carefully and kept below 0.5ppm.

NO₂ is extremely toxic. Current HSE guidelines suggest a long-term exposure limit of 1ppm. Breathing as little as 25ppm of NO₂ during an eight-hour timeframe may cause adverse pulmonary signs and symptoms after a virtually asymptomatic interval of between five and 48 hours. Delayed pulmonary oedema may occur following exposure to 100-150ppm for only 30-60 minutes, while a few breaths of NO₂ in a concentration of 200-700ppm is likely to produce severe pulmonary damage, which could result in fatal pulmonary oedema after 5-8 hours.

For alternative applications, please address enquiries to Bedfont Scientific Ltd, who can supply specialist equipment.

Sensor

The NO sensor is cross-sensitive to NO₂.

Both the NO and NO₂ sensors can be irreparably damaged by water or high humidity. Care should be taken in humidified applications that the Nafion drying tube and water trap are correctly connected and in good condition. The water trap should not be allowed to overflow with condensate.

Sensor

Please ensure that the alarms are set correctly and fully operational prior to each use.

Maintenance

Routine Maintenance:

The Nafion tube on the NOxBOX+ should be changed once it has started to discolour (transparent to brown), or every six months.

The water trap on the NOxBOX+ should be emptied when half full and replaced every six months.

A service manual is available upon request.

Cleaning:

To clean the NOxBOX+, disconnect the unit from the mains plug if applicable. **DO NOT USE CLEANING MATERIALS CONTAINING ALCOHOL.** Never immerse any of the equipment in liquid. The unit and system can be cleaned using a sponge or cloth dampened with soapy water, or a wipe impregnated with a non-acidic and non-alcoholic cleaning agent. Bedfont produces instrument cleansing wipes for this purpose.

Batteries:

The NOxBOX+ should be used or stored with adequate battery life, or connected to mains supply.

Note: Only the mains pack supplied (Globtek GTM41060 1809) should be used. Use of any other mains pack may cause permanent damage to the NOxBOX+ and could result in fire or electrical hazard.

Batteries should be checked periodically and replaced as often as is necessary. Remove the batteries if the NOxBOX+ will be out of use for a prolonged period.

To change the batteries, unscrew the three black knurled knobs on the base of the unit.

All batteries must be changed simultaneously, inserting the first new battery negative terminal first.

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

Please ensure that all parts and accessories are regularly checked for damage and correct function.

Operation

The NOxBOX+ is supplied complete and ready for use. All NOxBOX+ units are zeroed with pure air and calibrated with certified NO in NO₂ and NO₂ in air mixtures prior to shipment.


Connection to the patient

The instrument is connected to the patient ventilator using a kit such as Bedfont's NOxKIT. This allows the NOxBOX+ to be used with all types of ventilator.

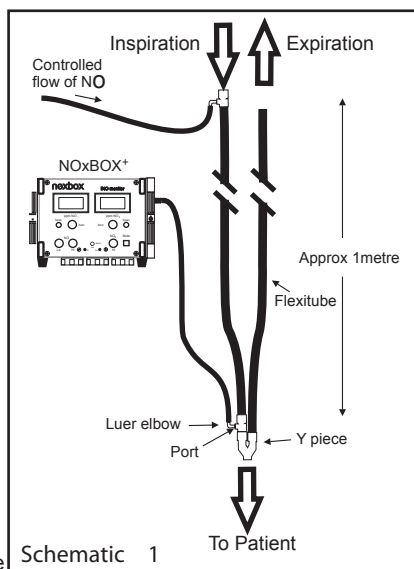
Schematic 1 (opposite) shows the connection to a typical ventilator.

Setting up the NOxBOX+:

The front panel is protected by a transparent cover. For access to the knobs and switches, release the latches on each side securing the front cover and remove.

1. Connect the power supply (globtek GTM41060 1809) to the DC supply socket on the rear of the device as required.
2. Switch on the NOxBOX+ using the red button behind the panel on the left-hand side. An audible alarm will sound briefly and the red alarm LED will flash.
3. If the battery symbol  is visible in the left-hand LCD display panel, the batteries must be changed in accordance with the procedure on page 5.
4. Please see page 8 for calibration instructions.
5. The instrument is purged using pure air for at least five minutes to ensure that the display reading is stable. Readings can be zeroed by turning the zero knobs.
6. Connect the inlet to the NOxBOX+ using the sampling system shown right to the inspiratory limb of the ventilator circuit (see Schematic 1, above).

The best representation of what is being inhaled is achieved by sampling gas just before it reaches the patient. Use an appropriate T-connector with a luer lock to connect to the clear polyurethane tube supplied.



Operation



- Exhaust gases are released into atmosphere or a scavenging system if provided. The flow must not be restricted, and should not have any degree of vacuum if being scavenged. A maximum pressure of 80cm water gauge should be applied.
- The flow rate is set using the dial on the 'low flow' flow meter. It is approximately 100-200ml per minute, depending on sample pressure, which should be between 5-80cm water gauge.

Setting the Alarm

- Press the central black button on the front panel to display the alarm setting on the LCDs.
- To alter the settings, press the central black button and turn the appropriate dial (↗ to increase, ↘ to decrease) until the required limit is displayed in the LCD. Ensure that this value has stabilised before continuing.
- Release the central black button to revert the LCD display to show the gas concentrations applied.

When the alarm is activated, the red LED on the front panel will flash and an audible alarm will sound. The audible alarm can be silenced for approximately two minutes.

Calibration

Calibration should be carried out as frequently as deemed necessary, however the minimum recommended requirement is weekly calibration during use, or monthly during storage. Calibration should always be carried out in a well-ventilated location.

Nitric Oxide (NO)

1. **IMPORTANT:** It is essential to purge the instrument with pure air and to ensure that both LCD displays read zero ppm before beginning any calibration procedure. The unit can be zeroed by adjusting the zeroing dial beneath the LCD displays.
2. A certified gas cylinder containing 25ppm NO in nitrogen, supplied by Bedfont, should be connected to the calibration T-piece adaptor through the grey luer lock, as shown in the photograph opposite.
3. The flow is automatically set to approximately 1 litre per minute (± 0.21 /min) using the regulator.
4. Allow at least four minutes for the reading to stabilise.
5. The reading can be adjusted to display the value given on the calibration gas cylinder by turning the 'span', potentiometer screws using the calibration screwdriver supplied.





Nitrogen Dioxide (NO₂)

Repeat steps 2-5 for NO calibration using a certified NO₂ in air mixture, ideally at 10ppm.

Spares

Part Number:	Description:
NO-S-V	Replacement NO sensor for NOxBOX+
NO2-S-V	Replacement NO ₂ sensor for NOxBOX+
NOXBOX+	Sample conditioning system – complete
NOXNAF-V	Nafion drying tube
NOXWT-V	Water trap
18-0210	Pack of 6 size C batteries
NOXMAIN-V	Mains adaptor
NOX-T-CAL	Calibration system consisting of T-piece, calibration adaptor and restrictor
058-20-01010-V*	Calibration gas: 10ppm NO in N ₂ (58-l disposable cylinder)
058-18-00520-V*	Calibration gas: 25ppm NO in N ₂ . (58-l disposable cylinder)
CCG-V*	Carry case to hold cans and regulators
NOXBOX-PLUS-CALKIT	Comprises the three items marked *
RECYCLER-V	Puncture tool for recycling empty cans
WIPES	Instrument Cleansing Wipes

Specification


Measuring Range:	0.2-200 ppm NO, 0.2-50 ppm NO ₂
Mode of operation:	Continuous
Sample Flow Rate:	Approx. 175 ml/min @ 30 mbar
Detection Principle:	Sealed Electrochemical Sensors
Sensor Resolution:	0.1ppm
Accuracy:	±5%
Interference:	0% - NO on NO ₂ sensor, <25% - NO ₂ on NO sensor
Display:	Dual LCD
Alarms:	Audible and visual, (Low NO; High NO ₂ ; High NO ₂ Low battery)
Warm Up Time:	<30 Secs
Response Time:	<10 secs to 90% FSD NO, <30 secs to 90% FSD NO
Operating Temperature:	 0 to 40°C
Operating Pressure:	5-80 mbar (cm water gauge)
Operating Humidity:	15-90%
Sensor Operating Life:	2-3 years - 6 months warranty
Power:	6 size C 1.5V alkaline batteries or AC-DC adaptor (100-240v, 0.6A, 50-60Hz)
Battery Life:	20 days (operational, no alarms), 1 year (storage)
Storage Conditions:	 Dry, clean atmosphere between 0 to 40°C
Transport/Storage Pressure:	800-1200 mbar
Transport/Storage Humidity:	15%-90% rh non condensing
Weight	2.3kg (including batteries)

Symbols

 Alternating current

 Direct current


Degree of protection against electric shock:

 Type BF applied part

Type of protection against electric shock:

Internally Powered Equipment

 Class II equipment (mains powered)

 Attention: Consult accompanying documents

Degree of protection against ingress of liquid:
IPXO

Degree of safety of application in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide: Equipment not suitable for use in the presence of flammable mixtures.

Environment

The NOxBOX complies with the directive EN60601-1-2 electromagnetic compatibility but can be affected by cellular phones and by electromagnetic interference exceeding the levels specified in EN50082:1.

Troubleshooting

Maintenance

Q The Nafion tube has turned brown. What does this mean?

A Too much humid air has passed through it. Stop using the device and change the Nafion tubing before connecting to a patient to prevent damage to the sensor.

Q The Nafion tube has a kink in it. What do I do?

A The Nafion tube must be replaced if it has a kink because it will be less effective. Use the diagram on the back of the NOxBOX+ as a guide to orientate the water trap and Nafion tube. This will reduce the chance of it kinking in the future.

Q This symbol [battery symbol] is displayed in the left-hand LCD display. What do I do?

A Change all six size C batteries before starting treatment.

Calibration

Q Why do I have a low reading for NO₂ while I am calibrating for NO, and vice versa?

A Calibration gases of NO or NO₂ may contain small concentrations of impurities of NO₂ or NO respectively, and so small responses may be perceived on the display not being calibrated. If this level is lower than 2ppm, disregard the reading and proceed with the calibration as described. The NO sensor is cross sensitive to NO₂ by <30% (e.g. a level of 10ppm NO₂ will give a reading of approximately 3ppm NO).

Warranty

Equipment Warranty

Bedfont Scientific Ltd warrants instruments of its manufacture (batteries, fuses, lamps and tubing, excluding filters and sensors) to be free from defects in material 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 item is returned intact and prepaid to the factory. The warranty does not apply to any products which have been repaired or altered by unauthorised persons, or which have been subject to misuse, negligence or accident.

Sensor Warranty

The electrochemical gas sensors are warranted for a period of six months of normal service. If a sensor was working satisfactorily, but ceases to function before the warranty period expires, the customer will receive credit towards the purchase of a new sensor on a pro rata basis. Customers with a warranty claim must return the sensor to the factory for evaluation. If it is determined that failure is due to faulty workmanship or materials, the sensor will be replaced at no cost to the customer.

Bedfont Scientific Ltd implements a procedure of continuously improving and updating their products and reserves the right to make changes to any of their products without prior notice.

Bedfont Scientific Ltd warrants the product (except batteries) to be free from defects in materials and workmanship for a period of one year 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 and prepaid to Bedfont Scientific Ltd or your local representative.

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

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



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



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ISO 9001:2008
Cert. No. FM 31664
ISO 13485:2003
Cert. No. MD 502905