

# NOxBOX<sup>®</sup> mobile



NOxBOXmobile with NOxBOX<sup>+</sup> or NOxBOXO<sub>2</sub>



CE  
0086

breath analysis is the new blood test

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## Introduction

Nitric oxide 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

Equipment should only be used by suitably trained and qualified health professionals.

## Intended use

The NOxBOXmobile is intended for use by healthcare professionals in a medical environment to administer nitric oxide (NO) to the breathing circuits of patients undergoing inhaled NO therapy. Used with a NOxBOX<sup>+</sup> or NOxBOX<sub>2</sub> inhaled NO therapy monitor, the NOxBOXmobile forms part of a monitoring and delivery system.

# System contents

## NOxBOX<sup>+</sup> monitoring instrument

1. NOxBOX<sup>+</sup>
2. Mains power adapter
3. Magnum screwdriver
4. Calibration screwdriver
5. Sample line
6. Water trap
7. Nafion tubing
8. Calibration T-piece adapter
9. Operating manual
10. PU tube from the nafion to the inlet



## NOxBOXO<sub>2</sub> monitoring instrument

1. NOxBOXO<sub>2</sub>
  2. Water trap
- Also supplied with (not shown):
- Mains power adapter
  - Calibration screwdriver
  - Bacterial filter
  - Sample line
  - Water trap drainage accessory
  - Calibration Y-piece adapter
  - Operating manual



## NOxBOXmobile delivery system

- A. Gas cylinder pressure gauges
- B. Changeover unit
- C. NOxAIR NO<sub>2</sub> environmental sensor
- D. Single stage regulator
- E. Outlet pressure gauge
- F. Trolley
- G. Low flow indicator
- H. High flow indicator
- I. NOxAIR NO environmental sensor
- J. Spanner attached by chain



## General description

The NOxBOXmobile is used to deliver NO gas, via appropriate flow meters, into a patient breathing circuit (see Warnings, page 5). When used with the NOxBOX<sup>+</sup> or NOxBOXO<sub>2</sub> it also acts as a side stream monitor for NO and NO<sub>2</sub> in the inspiration air delivered to patients. The NOxBOXO<sub>2</sub> also provides O<sub>2</sub> monitoring.

The system is mounted to an epoxy coated, mild steel trolley, and is designed to be situated close to the patient's bedside ventilator.

To avoid the sudden withdrawal of NO therapy, the event of which could be detrimental to the patient, the NOxBOXmobile has space for two 10-litre NO cylinders and an NO changeover system. This allows both cylinders to be attached simultaneously in order to deliver an uninterrupted flow of NO to the patient.

The system is fitted with stainless steel and PTFE-lined hoses, with quick-fit one-way valve connectors for ease of use. For safety, the high pressure gas bottles are connected via restrained stainless steel hoses. A pressure relief valve is provided on the low pressure side of the regulator.

The monitoring capability is provided by either the NOxBOX<sup>+</sup> or the NOxBOXO<sub>2</sub>, both of which are mains powered with a back-up battery power supply. The NOxBOX<sup>+</sup> batteries are replaceable and the the NOxBOXO<sub>2</sub> battery supply is rechargeable via the mains transformer pack. The battery is replaceable in the NOxBOX<sup>+</sup> and rechargeable via the mains transformer pack in the NOxBOXO<sub>2</sub>. The NOxBOX monitor uses electrochemical sensing technology to sample the gas, and a microprocessor to convert the output voltage from the sensor into a meaningful digitally displayed result.

### Monitoring ranges

| Monitor              | Measurement range |           | Sensitivity   |
|----------------------|-------------------|-----------|---|
| NOxBOX <sup>+</sup>  | NO                | 0-200ppm  | Increments of 0.1ppm.<br>Possible analytical sensitivities of 0.2ppm (20ppb).                           |
|                      | NO <sub>2</sub>   | 0-50ppm   |   |
| NOxBOXO <sub>2</sub> | NO                | 0-99.9ppm | Increments of 0.1ppm (NO and NO <sub>2</sub> ).<br>Possible analytical sensitivities of 0.2ppm (20ppb). |
|                      | NO <sub>2</sub>   | 0-19.9ppm |   |
|                      | O <sub>2</sub>    | 0-99.9%   |   |

The sensor is protected from potentially-damaging high levels of moisture condensate by using a sampling conditioning system prior to gas entering the sensor.

The NOxBOX<sup>+</sup> is equipped with high NO and low NO alarms, and a high NO<sub>2</sub> alarm, to alert the clinician to concentrations that are outside the tolerance range.

The NOxBOXO<sub>2</sub> is equipped with high NO and low NO alarms, a high NO<sub>2</sub> alarm, and a low O<sub>2</sub> alarm, to alert the clinician to concentrations that are outside the tolerance range.

Optional environmental gas detectors (NOxAIR) can be provided to warn personnel of NO leaks. Dedicated NO and NO<sub>2</sub> alarm monitors continually analyse the ambient air for very small concentrations. Alarms indicate that levels are in excess of pre-set limits.



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# Warnings

## Use

The NOxBOX<sup>+</sup> and NOxBOXO<sub>2</sub> are intended for use by health professionals and emergency medical staff. The systems are recommended for ventilated patients only. The NOxBOXO<sub>2</sub> can be used to monitor spontaneously breathing patients and environmental measurement. If either product is used during intermittent flow ventilation, the NO may mix erratically with air. This may result in the patient receiving peak concentrations of NO that are greater than the calculated dose.

## NO and NO<sub>2</sub>

**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 NO<sub>2</sub>.

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

**NO<sub>2</sub>:** Unfortunately, NO reacts rapidly with oxygen to produce NO<sub>2</sub>, which may react further to form nitric and nitrous acid. This unwanted by-product needs to be monitored carefully and kept below 0.5ppm.

NO<sub>2</sub> is extremely toxic. Current HSE guidelines suggest a long-term exposure limit of 1ppm. Breathing as little as 25ppm of NO<sub>2</sub> 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 NO<sub>2</sub> in a concentration of 200-700ppm is likely to produce severe pulmonary damage and could result in fatal pulmonary oedema after 5-8 hours.

### **Local area alarm**

The NOxBOXmobile can be supplied with two portable alarms to monitor the local environment and warn staff if levels of NO and/or NO<sub>2</sub> rise above the occupational safety limit. The portable alarms can be worn by an individual, positioned in the vicinity of the patient, or left on the hooks provided on the NOxBOXmobile. Bedfont recommends that they are placed appropriately to monitor the environment as close to the staff working area as possible.

**NOTE:** The audible alarms are designed to alert staff in the immediate vicinity; they are not designed to be heard from a long distance away or in a different room.

### **The NO/N<sub>2</sub> gas mixture**

It is advisable that the gas mixture used for this therapy should be of medical grade and a concentration of no greater than 1000ppm in N<sub>2</sub>. This mixture is not supplied by Bedfont. Exact specification of the gas and cylinder should be obtained from the gas supplier.

### **Handling the trolley**

Care and consideration should be taken when using the NOxBOXmobile and NOxBOX monitors due to the corrosive and toxic properties of the gas and the high pressure it is under. Caution and proper manual handling technique should be used when moving the heavy gas cylinders, which weigh at least 15kg. Ensure that the brakes are applied to the wheels of the trolley before removing or replacing the gas cylinders.

Always review the gas manufacturer's safety data before using NO. Appropriate safety wear should be used in accordance with these instructions.

Open the gas valve slowly on both cylinders separately, using the correct spindle key, if appropriate. Never force the tap. If it is too stiff, return the cylinder to the supplier.

### **Pressure relief valve and safety relief valve**

The NOxBOXmobile is fitted with a pressure relief valve on the second stage regulator. Should the scrubber activate, it is possible the NO could be released into the atmosphere. If NO and/or NO<sub>2</sub> levels rise above the occupational safety limit, staff will be warned by the portable alarms and the agreed procedures should be followed.



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# Maintenance

## By user

For each new patient, the pipe and connector from the meter to the ventilation circuit need to be changed. Only tubing or other parts that have been approved by Bedfont should be used.

## By qualified technician

The operation of the device should be checked on a quarterly basis. All parts need to be checked for signs of wear or corrosion.

The Viton O-rings, flow indicator and regulator fittings need special attention and should be replaced immediately if worn. A pressure test should be carried out to ensure that there is no leak in the system allowing NO escape or air to ingress. Details of how to conduct this test are available from Bedfont on request.

## Cleaning

All parts in contact with the patient circuit must be replaced at the start of any new treatment.

### **IMPORTANT: DO NOT USE CLEANING MATERIALS CONTAINING ALCOHOL**

None of the equipment should ever be immersed 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.

**NOTE:** For routine maintenance on the NOxBOX<sup>+</sup>, please refer to the NOxBOX<sup>+</sup> Operating Manual. For routine maintenance on the NOxBOXO<sub>2</sub>, please refer to the NOxBOXO<sub>2</sub> Operating Manual.

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# Operation

## **NOxBOXmobile commissioning**

The NOxBOXmobile is supplied as an assembled system; however, as the system has a high pressure gas handling system, it needs to be commissioned before use. Please contact Bedfont for further details.

Carefully remove the trolley from the packing case and pallet.

## **NOxBOX<sup>+</sup> monitor**

If supplied, remove the NOxBOX<sup>+</sup> from its packaging and mount it on the NOxBOXmobile shelf. The NOxBOX<sup>+</sup> is supplied separately as a complete assembly, ready for instant use. Prior to shipment, each instrument is zeroed with pure air and calibrated with certified NO/N<sub>2</sub> and NO<sub>2</sub>/air mixtures.

## **NOxBOXO<sub>2</sub> monitor**

If supplied, remove the NOxBOXO<sub>2</sub> from its packaging and place the rubber feet onto the NOxBOXmobile shelf.

The NOxBOXO<sub>2</sub> is supplied separately as a complete assembly, ready for instant use. Prior to shipment, each instrument is zeroed with pure air and calibrated with certified NO/N<sub>2</sub> and NO<sub>2</sub>/air mixtures.

## **Environmental NO and NO<sub>2</sub> monitors**

If supplied, remove the monitors from their packaging and hang them on the hooks on the front of the NOxBOXmobile. Prior to use, the manufacturer's instructions should be followed and the monitors should be switched off when not required.

Read the Operation Manuals for the NO and NO<sub>2</sub> monitors carefully before use.

## Installing a gas cylinder

Apply the brakes to the wheels before installing the gas cylinders. The gas cylinder needs to be placed carefully onto the trolley as the cylinders can weigh more than 15kg.

Place the cylinder behind the lip on the base plate to ensure that it is correctly positioned. It is essential to restrain the cylinder using the polyester webbing straps provided to prevent it from accidentally falling.

The black buckles should 'click' closed and be adjusted to ensure that the cylinders are held securely. Before connecting the cylinder to the system, make sure that the regulator tap has been switched off to prevent gas from escaping. This depends on the type of cylinder in use:

- If using BS14, provided by BOC, twist the adapter nut onto the cylinder thread and tighten it using the spanner provided. Ensure that the PTFE washer is in place in the gas cylinder connector (see 'B', page 3).
- If using INOMax, provided by INO Therapeutics, screw the connector on and tighten by hand only.
- If using Kinox, provided by Air Liquide, screw the connector fitted with an O-ring (rotating black plastic connector) onto the bottle top and tighten by hand only. If the fitting does not have an O-ring, a spanner must be used to tighten it.
- If another manufacturer's gas is used, seek advice from the supplier or contact Bedfont.

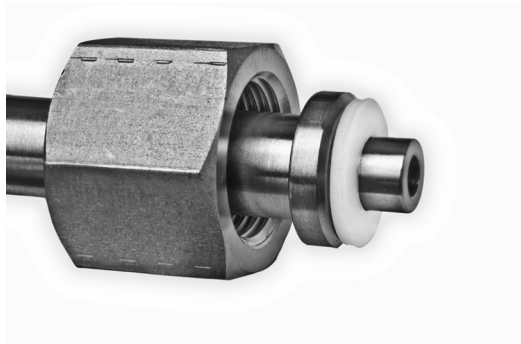
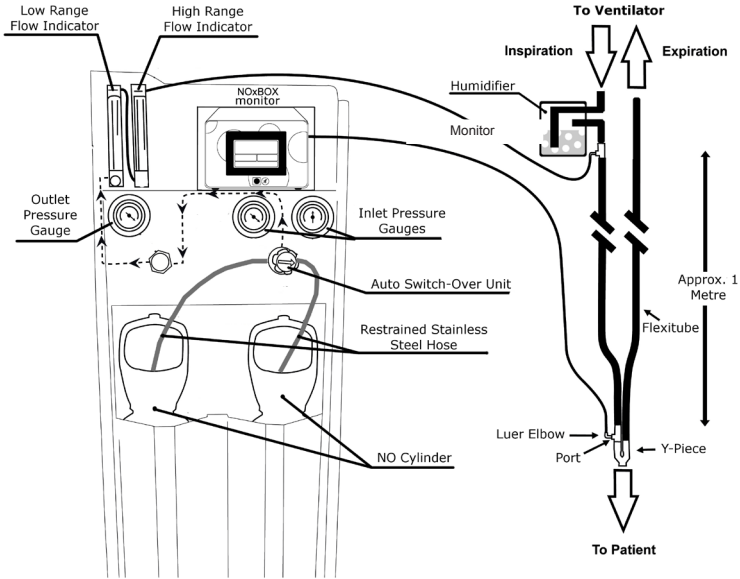


Fig A

# Operation

## Schematic 1



**Note: Where a humidifier is in the ventilator circuit the NO dose line must be attached after the humidifier (as indicated above)**

1. Ensure that the brakes are engaged and that the trolley is positioned on a solid, level surface before carrying out the following actions. Failure to do so could cause the flow meters to be inaccurate or unstable.
2. Open the gas valve slowly on both cylinders separately using the correct spindle key, if appropriate. Never force the tap. If it is too stiff, return the cylinder to the supplier.

NOTE: At this stage, ensure that there is enough gas in both cylinders to attempt the required therapy. If there is not, remove the cylinders (see 'Installing a gas cylinder', page 9), and install full cylinders before continuing.

3. The gas cylinders are connected via a changeover regulator unit to a second stage regulator, which reduces the pressure to a safe, useable level and ensures a constant rate of flow.

4. One of the first stage regulators has an adjustment knob which can be turned through 180 degrees to select the left or right gas supply as the source. The arrow on the selection knob should point to the delivery gas cylinder and away from the standby cylinder. As the gas delivery cylinder empties and the outlet pressure drops below the pressure of the standby cylinder, the gas will begin to flow from the standby cylinder. The source selection knob should then be turned through 180 degrees so that the arrow points towards the standby cylinder. The empty cylinder can then be replaced without interrupting the gas flow.
5. After the fixed second stage of regulation, the gas flow is applied to the outlet connector via two adjustable flow meters (one low range – 10-100cc/min; one high range – 60-600cc/min), enabling the desired flow rate to be set.
6. The inlet gauges on the lower panel give an indication on the amount of NO in each cylinder. The pressure should be approximately 150 bar for a new cylinder. If the pressure is less than 10 bar, the second cylinder should be used.
7. If the inlet pressure is less than 6.8 bar during administration of therapy, the second bottle of gas (if connected and turned on) will automatically switch over using the changeover unit, provided that it is connected and turned on, and will continue to supply NO to the patient. The control regulator (see figure B) should be turned so that the arrow is pointing towards the full cylinder and away from the empty one. The empty cylinder should be replaced immediately and turned on if appropriate (see Installing a gas cylinder, page 9).



Fig B

8. Following the above procedure will allow the changeover unit to automatically switch cylinders if the first cylinder becomes low during use, to ensuring an uninterrupted supply of NO to the patient.
9. The desired flow rate is set using the flow adjustment knob located on the front of the low range flow meter.
10. Once therapy is complete, ensure that the cylinder control valves are turned off and allow the residual pressure inside the equipment to be released.

NOTE: Because of the low flow rates of therapy and the high pressure involved, the canisters can take some time to empty. Observe the inlet gauges on the lower panel to ensure that all of the pressure has been removed from the system before any other action is carried out.

11. Once all of the pressure has been released, the NOxBOXmobile can safely be moved. Ensure that the brakes are disengaged before moving the unit. Failure to do so can cause the trolley to become unstable.
12. Ensure that the cylinder control valves are closed whenever the equipment is not being used.

## Setting up the NOxBOX monitor

For instructions on setting up the NOxBOX<sup>+</sup> or NOxBOXO<sub>2</sub>, please see the NOxBOX monitor Operating Instructions.

## Setting the dose

The dose of NO delivered to the patient is defined by the acting clinician.

The approximate dose of NO delivered to the patient can be set using the flow indicator by carrying out the calculation. A worked example is also included for your reference:

$$\text{Flow indicator reading (cc/min)} = \frac{1000 \times \text{Ventilator flow setting (l/min)}}{\left( \frac{\text{NO cylinder concentration (ppm)}}{\text{NO delivered to patient (ppm)}} - 1 \right)}$$

$$20 \text{ (cc/min)} = \frac{1000 \times 5 \text{ (l/min)}}{\left( \frac{1000 \text{ (ppm)}}{4 \text{ (ppm)}} - 1 \right)}$$

If preferred, the value can be looked up using the chart on the reverse of the Quick Start Guide. The level is accurately confirmed by the display of NO ppm, as shown in the left LCD display on the NOxBOX<sup>+</sup>, or top centre of the LCD display on the NOxBOXO<sub>2</sub>.

If necessary, the dose can be fine-tuned using the flow indicator valve, while referring to the NOxBOX monitor. Allow time between adjustments so that the pneumatic pathways can be thoroughly purged. For large incremental changes, this may take up to three minutes.

## Manual bagging option

The layout of the manual bagging option of the NOxBOXmobile is shown below in figure C.



Figure C

The regulated gas is connected to the rear of the manual bagging option. The gas flow can then be directed using the switching control knob.

When the control knob points towards 'ventilator', the gas will be directed to the two main flow meters and the standard operating conditions should be followed.

To use the manual bagging option, turn the control knob so that it points towards 'manual'. This will direct the gas to the flow meter on the manual bagging option, which allows the desired NO flow rate to be set using the fine-control valve.

The O<sub>2</sub> inlet is to the rear of the unit and is fitted with a BS5682 1998 fitting. Connect the pipe to an appropriate O<sub>2</sub> outlet. The O<sub>2</sub> flow meter can then be used to set the desired O<sub>2</sub> flow rate using the fine-control valve.

The outlets for NO and O<sub>2</sub> are located on the right-hand side of the bagging unit, as shown in FIG C. To reset the flow to the standard ventilator setting, turn the control knob towards 'ventilator'.

## Warnings

There may be a delay when switching between the two settings and setting up the correct rate of flow.



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# Calibration

## **NOxBOXmobile flow meter and pressure regulators**

Calibration of the flow meter and pressure gauges is not necessary because they are used as guides. The actual dose of nitric oxide is controlled and monitored by the NOxBOX<sup>+</sup> or NOxBOXO<sub>2</sub> unit.

Calibration of the system 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)**

To calibrate the NOxBOX<sup>+</sup> please refer to the NOxBOX<sup>+</sup> Operating Manual.

To calibrate the NOxBOXO<sub>2</sub>, please refer to the NOxBOXO<sub>2</sub> Operating Manual.

## Spares

### NOxBOX<sub>2</sub>

|           |  |
|-----------|--|
| SEN021    | Replacement NO sensor for NOxBOX <sub>2</sub>              |
| SEN020    | Replacement NO <sub>2</sub> sensor for NOxBOX <sub>2</sub> |
|           | Sample conditioning system – complete                      |
| FXS414    | Nafion drying tube   |
| NOXO2WT-V | Water trap   |
| BAT046    | Power lead (UK)  |
| BAT045    | Power lead (EU)  |
| NOX-Y-CAL | Calibration system consisting of Y-piece and male luer     |
| NOXKIT-V  | Selection of connectors NO and O <sub>2</sub> to vent      |
| FIL042    | Bacterial filter   |

### NOxBOX<sup>+</sup>

|              |  |
|--------------|--|
| NO-S-V       | Replacement NO sensor for NOxBOX <sup>+</sup>                    |
| NO2-S-V      | Replacement NO <sub>2</sub> sensor for NOxBOX <sup>+</sup>       |
| NOXBOX-SCS-V | Sample conditioning system – complete NOxBOX <sup>+</sup>        |
| NOXNAF-V     | Nafion drying tube   |
| NOXWT-V      | Water trap NOxBOX <sup>+</sup>                                   |
| 18-0210      | Pack of 6 size C batteries                                       |
| NOXMAIN-V    | Mains adapter  |
| NOX-T-CAL    | Calibration system (T-piece, calibration adapter and restrictor) |

### NOxBOX<sup>+</sup> and NOxBOX<sub>2</sub>

|                    |  |
|--------------------|--|
| 058-18 -00520-V*   | Calibration gas – 25ppm NO in N <sub>2</sub> (581 disposable cylinder)   |
| 058-20-01010-V*    | Calibration gas – 10ppm NO <sub>2</sub> in air (581 disposable cylinder) |
| REGSS-1.0-V*       | Stainless steel gas regulator – 1l/min flow rate                         |
| CCG-V*             | Carry case to hold cans and regulators                                   |
| NOXBOX-PLUS-CALKIT | Consists of the four items marked * above                                |
| RECYCLER-V         | Puncture tool for recycling empty canisters                              |
| WIPES              | Instrument cleansing wipes   |

### NOxBOXmobile spares

|        |   |
|--------|---|
| FIL020 | BS14 Gas cylinder connector washer (PTFE) |
|--------|---|

## Specification

|                     |  |
|---------------------|--|
| Dimensions:         | 1590(H) × 500(W) × 528(D) mm                     |
| Weight:             | Approx. 40kg (complete trolley and cylinders)    |
| Construction:       | Powder coated steel                              |
| Wheels:             | 75mm anti-static castors, with kick stop lock    |
| Flowmeters:         | 0-100cc/min and 0-600cc/min                      |
| Regulator:          | Single stage, stainless steel, 2 bar max. outlet |
| Changeover:         | Regulator stainless steel                        |
| Storage conditions: | Dry, clean atmosphere, 0-40°C                    |



# Troubleshooting


## Maintenance

**Q:** The NOxBOX monitor's 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 it to a patient to prevent damage to the sensor.

**Q:** The NOxBOX monitor's 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 monitor as a guide to orientate the water trap and Nafion tube. This will reduce the chance of it kinking in the future.

**Q:** The  symbol is displayed in the left-hand LCD display of the NOxBOX<sup>+</sup>. What do I do?

**A:** Change all six size C batteries before starting treatment.

**Q:** The battery alarm is flashing and sounding on the NOxBOXO<sub>2</sub>. What should I do?

**A:** This means that the battery charge is low. Plug the unit into the mains to recharge it.

**Q:** The cylinder connector does not fit on the gas cylinder.

**A:** Check that you are using the correct type of gas cylinder for the NOxBOXmobile. If not, order the correct gas cylinder.

**Q:** Why do I have a low reading for NO<sub>2</sub> while I am calibrating for NO, and vice versa?

**A:** Calibration gases of NO or NO<sub>2</sub> may contain small concentrations of impurities of NO<sub>2</sub> 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 NO<sub>2</sub> by <30% (e.g. a level of 10ppm NO<sub>2</sub> will give a reading of approximately 3ppm NO).

## Warranty

Bedfont Scientific Ltd warrants instruments of its manufacture to be free from defects in material and workmanship for a period of five 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, 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.







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