

NOxBOX[®]_i & **NOxMixer**

**Technical Guide: Version 10.0 September 2016
(Software V.17.3)**



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NOTICES

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1 USER RESPONSIBILITY

The *NOxBOXi®* system will perform in accordance with the description detailed in this document and accompanying guides and/or labels when assembled, operated, stored, maintained, and repaired in accordance with the instructions provided.

This product must be checked and calibrated in-line with the outlined service schedule recommendations. A product found to be faulty should not be used. Any parts or accessories that are broken, damaged, missing, obviously worn, distorted, or contaminated should be replaced immediately.

In the event of the product requiring repair or replacement, it is recommended that the customer first contacts their distributor or technical support service for the *NOxBOXi* system. It is essential that only approved components are used to replace or repair any part of the *NOxBOXi* system, in accordance with the manufacturer's written instructions. The product must not be altered without prior written approval from the Technical Support department of NOxBOX Ltd.

This device has been designed and constructed with high-quality components to ensure accuracy, reliability, and compatibility. If third-party components are installed without prior consent from NOxBOX Ltd., NOxBOX Ltd. will not be liable for any incident that may occur as a result of this. This may also invalidate your warranty.

The product user bears sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, damage, or unauthorized alteration by any source not authorized to do so by NOxBOX Ltd.

Throughout this document, there are highlighted areas that contain information, warnings, or danger notifications:



Information: This statement contains important information that is highlighted for user awareness.



Caution: This statement contains information alerts that could help prevent a problem from occurring.



Warning: This statement contains important information that may affect the safety of the user and/or patient if the manual instructions are not followed.



Danger: This statement contains important information directly related to the safety of the user and/or patient if the manual instructions are not followed.

2 SAFETY



WARNING: Do not modify this equipment without authorization from the manufacturer.



WARNING: Read and understand this manual, including any inserts/amendments, before using the *NOxBOXi®* system. Only trained and responsible personnel should work with or around this equipment. Wear appropriate personal protective equipment (PPE) and, if applicable, turn off the power before performing any installation, maintenance, repair, or troubleshooting procedures.



WARNING: To avoid serious injury, pay attention to all precautionary labels that are attached to the equipment, cylinders, containers, and boxes before startup. Do not remove or obscure any label. If a label is missing, becomes worn, or is difficult to read, replace it with a new one. Labels are available from your NOxBOX Ltd. representative.



INFORMATION: This chapter contains information to promote safety in the operation and maintenance of this equipment. It is not intended to supersede, replicate, or replace any safety documentation or procedures provided from or established by official safety sources.

Read and understand the Safety Data Sheets (SDS) for the materials used with this equipment. All personnel who work in the vicinity of this equipment should read, understand, and follow all safety information contained in the SDSs and all government and facility safety regulations.

2.1 BASIC SAFETY RECOMMENDATIONS

- **Prevent formation of unsafe atmospheres**—Ensure that properly engineered ventilation and atmospheric monitoring systems are installed and operating properly. Creating a confined space presents the potential for unsafe atmospheres. If dangerous levels of a gas are detected, immediately evacuate the affected area. Do not re-enter the area until safe conditions are restored.
- **Ventilate working areas**—Prevent any leaking gases from accumulating. Vent all gases to the outside, in an area that is safely away from people. Before restarting the equipment, ensure that all parts affected by repairs have been restored to their proper operating condition and that the lines have no leaks.
- **Prevent injury**—Wear safety glasses and other appropriate PPE when the SDS, task, or code dictates. Ensure that all tools and instruments used are in good condition. Be aware that high-velocity gas may be released at vents and safety relief valves
- **Maintain safety devices**—Check all safety devices at least annually or as otherwise required by local codes or manufacturer recommendations. Properly maintain safety valves. Never bypass safety devices, and never operate the equipment outside its specified limits.
- **Ensure safe maintenance and repair**—Only qualified personnel should repair the equipment. Use strict lockout/tagout procedures to protect personnel from hazards related to unexpected energizing, startup, or the release of stored energy during servicing or maintenance.
- **Transportation**—When transporting the NOxBOX[®] system trolley, ensure that the correct procedure is followed. Always use the handle located at the front of the trolley. Ensure that the cylinders are securely fastened, and inspect for trip hazards (e.g., sample lines).



DANGER: Failure to properly isolate the equipment, electrical systems, and piping can cause asphyxiation, fire, and/or explosion. Positively isolate the equipment from the gas supply and the process material before performing any repair work. It is not sufficient to simply close the valves. The lines and tubing must be blanked or disconnected.



The NOxBOX system has not been tested for use in the MRI suite.

Consider the following when changing cylinders:

- Compressed gas cylinders can be extremely hazardous when misused or abused and can present a variety of hazards due to their pressure and/or content.
- Careful procedures are necessary for handling the various compressed gases, cylinders, regulators, or valves used to control gas flow.
- Compressed gases should be handled only by experienced and properly instructed persons.
- Cylinders should be stored in accordance with all local, state, and municipal regulations and in accordance with appropriate standards, for instance, those from the Compressed Gas Association and the National Fire Protection Association. Always follow the manufacturer's label.
- Gas cylinders must be secured at all times to prevent tipping. Use appropriate material, such as chains, plastic-coated wire cable, commercial straps, etc., to secure cylinders. Gas cylinders cannot be stored in public hallways or other unprotected areas.
- Cylinders containing compressed gases should not be subjected to a temperature above 51°C. Cylinders should not be subjected to artificially created low temperatures without approval of the supplier.
- The gas cylinders should be stored where they will not fall over or be damaged by falling objects. Never store a cylinder in an elevated location, because a fall could seriously damage the valve or the cylinder. If a cylinder is dropped or knocked over, check to see that components are not damaged and that the system connection remain secure.
- Handle the cylinder in a manner that will avoid jarring or dropping. Never drag, slide, or roll a cylinder; use a cylinder cart.
- Do not use the valve cover to lift cylinders; they could be damaged and become unattached.
- Never drop cylinders or permit them to strike against each other or against other surfaces violently.
- Check the identity of the gas by reading the label or other markings on the cylinder before using. If the cylinder content is not identified by marking, return the cylinder to the supplier without using it. Do not rely on the color of the cylinder for identification. Color-coding is not reliable because cylinder colors may vary with supplier.
- Removable-type valve protective caps should remain in place until you are ready to withdraw the content.
- Before using a cylinder, be sure it is properly secured to the trolley.
- Do not operate any equipment with leaks.
- Do not repair a cylinder leak or safety relief device leak. Do not ship any cylinders with leaks.
- Open the valve slowly and only with the NOxBOX Ltd. regulator in place. Stand with the cylinder between yourself and the regulator (cylinder valve outlet facing away) when opening the cylinder valve.
- Do not force connections that do not fit. Do not use an adaptor to connect a cylinder to the system.
- Always hand-operate the valve and protection cap to loosen it; do not use a hammer to pry or wedge it open.
- Avoid contact of oils, greases, flammables, and contaminates with the cylinders and valves.
- Close the cylinder valve and release all pressure before removing the regulator from the cylinder.
- Consider using the portable NO monitors as appropriate.
- Never attempt to repair or to alter cylinders, valves, or safety relief devices.
- Keep the cylinder valve closed at all times, except when the cylinder is in active use.
- For valves that are hard to open, or frozen because of corrosion, contact the supplier for instructions.

2.1.1 BASIC HAZARDS



DANGER: Additional hazards may be associated with the gases that are used in your application and with your equipment. Determine which hazards you may encounter, and be prepared to appropriately handle them. Refer to the SDS that was supplied with the gases and all government regulations and industry safety standards (e.g., COSHH in UK).

2.1.2 ASPHYXIATION



DANGER: Exposure to gases or vapors may cause asphyxiation. Proceed with caution and in accordance with the SDS.

Practically all gases can act as simple asphyxiates by displacing the natural oxygen in the air. To prevent serious personnel injury and possible death, provide adequate ventilation to the outside environment in areas where any process gas may accumulate. Consider the increased potential for asphyxiation when pressure testing or purging the equipment with nitrogen or other non-air gases.

2.1.3 ELECTROCUTION



DANGER: Electric shock can kill. Use extreme caution if troubleshooting or servicing this equipment. Do NOT bypass safety interlocks. An electrocution hazard exists even after the equipment has been de-energized. Only qualified personnel working in compliance with all customer requirements and applicable federal/national, state/provincial, and local codes shall perform the electrical wiring.

Adhere to the following guidelines to help guard against possible electrocution:

- Tampering with, or unauthorized substitution of, components may adversely affect the safety of this equipment. Use only factory-approved components for repair.
- Turn off the power before opening the equipment or before checking or replacing any component. Use tools designed for work on electrical equipment.
- Carefully follow all Hazardous Work Permit (HWP) and lockout/tagout procedures for your facility.
- Do not touch live electrical components inside the equipment; electric shock caused by voltage in the control circuits can kill.

2.1.4 PRESSURE



DANGER: Mishandling of pressurized process equipment or gas cylinders can result in death, serious injury, or property damage. Handle pressurized equipment and cylinders with extreme care and in accordance with the manufacturer's instructions.

The contents of this equipment are under pressure. Sudden or uncontrolled release of pressurized gas can cause serious injury. The gases themselves or objects propelled by the gases may strike personnel at high speed or possibly cause a spark-induced fire. Avoid high-pressure hazards through careful inspection and proper handling of equipment and cylinders. The pressure-relief devices (for example, safety valves, bursting discs) supplied with this equipment for over-pressure protection must be maintained at regular intervals to ensure their proper operation.

Be aware of the locations at which high-pressure gases exist and the precautions for operating or maintaining equipment that handles these gases.

2.1.5 TOXICITY



DANGER: Toxic gases can cause personnel injury or death through breathing, absorption through the skin, or swallowing. Provide adequate ventilation, appropriate personal protective equipment (PPE) and gas detection equipment.

This equipment contains toxic gases. Adequate ventilation of enclosed areas serves as the chief precaution against an accumulation of toxic gases. In addition, for highly toxic gases, install automatic devices to constantly monitor gas concentrations and set off alarms if the concentrations approach a danger point. NOxBOX Ltd. offer suitable gas detection alarms as system accessories.

Precautions against skin or eye contact with toxic gases include a thorough knowledge of the dangers, training for all personnel handling such gases, the development of procedures and equipment for handling them, and the use of special protective clothing and equipment (such as self-contained breathing apparatus (SCBA), portable gas monitors, protective garments, gloves, and face shields).

2.1.6 POISONS



DANGER: Poisonous gases can be fatal if inhaled, even in very small quantities. Provide adequate ventilation and appropriate personal protective equipment (PPE).

This equipment contains poisonous gases. The Threshold Limit Value (TLV) expressed as the Occupational Exposure Limit (OEL) for each gas refers, in general, to airborne concentrations at or below which nearly all workers may be repeatedly exposed without adverse effects. The TLV for the specialty gas used with this equipment are stated on the cylinder body labels and the SDS for the gas.

Use this gas only in well-ventilated areas. Precautions against skin or eye contact with poisonous gases include a thorough knowledge of the dangers, training for all personnel handling such gases, the development of procedures and equipment for handling them, and the use of special protective clothing and equipment (such as self-contained breathing apparatus (SCBA), portable gas monitors, protective garments, gloves, and face shields).

2.2 HAZARD LABELS

On locations of the NOxBOX[®]system where hazards may occur, labels such as the one shown in Figure 2-1: Example Hazard Label: No Pushing, warn you of any potential dangers. Read these labels carefully, and be prepared to handle any hazardous situations that may arise. If the labels become worn or difficult to read, contact your NOxBOX Ltd. representative for replacement labels.



Figure 2-1: Example Hazard Label: No Pushing

2.3 CLEANING PRECAUTIONS



WARNING: Some cleaning agents or solvents can emit toxic fumes. Conduct all cleaning operations in a well-ventilated area. Even though many cleaning agents are not highly toxic, take appropriate precautions.

All new equipment, as well as used equipment that may have become contaminated during service, must be thoroughly cleaned. Any residue could contaminate the process gas and may constitute a safety hazard.

Perform cleaning in accordance with applicable cleaning standards to ensure that the equipment has been safely prepared for the application for which it is to be used. Carefully inspect all cleaned parts. If any evidence of contamination is noted, clean the part again. NOxBOX Ltd. offers suitable instrument cleaning wipes as system accessories.

2.4 ELECTROMAGNETIC IMMUNITY

The *NOxBOX*[®] system complies with the directive EN60601-1-2 electromagnetic compatibility, but can be affected by cellular phones and electromagnetic interference exceeding the levels specified in EN55011:2007 Class B.

Guidance and Manufacturer's Declaration: Electromagnetic Immunity (IEC 60601-1-2)			
The <i>NOxBOX</i> _i system is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>NOxBOX</i> _i system should ensure that it is used in such an environment.			
Immunity Test			
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 6 kV air	± 6 kV contact ± 6 kV air	The floor should be wood, concrete, or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30 percent.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines	Mains power quality should be a typical hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to earth	± 1 kV line to line ± 2 kV line to earth	Mains power quality should be a typical hospital environment.
Voltage dips, short interruptions and voltage variations on power supply. IEC 61000-4-11	< 5 % UT (> 95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles < 5 % UT (95 % dip in UT) for 5 seconds	Met or exceeded.	Mains power quality should be a typical hospital environment.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a hospital environment.

Guidance and Manufacturer's Declaration: Electromagnetic Immunity (IEC 60601-1-2)			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V ms 150 kHz – 80 MHz outside ISM bands* 10 V ms 150 kHz – 80 MHz in ISM bands* 10 V ms 80 kHz – 2.5 GHz	10 V ms 150 kHz – 80 MHz outside ISM bands* 10 V ms 150 kHz – 80 MHz in ISM bands* 10 V ms 80 kHz – 2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the <i>NOxBOXi</i> system (including cables) than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: UT is the A.C. mains voltage before application of the test level.			
NOTE 2: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the <i>NOxBOXi</i> system is used exceeds the applicable RF compliance level above, the <i>NOxBOXi</i> system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the <i>NOxBOXi</i> system Over the frequency ranges 150 kHz to 80 MHz, field strength should be less than 3 V/m.			

2.5 NETWORK CONNECTIONS

The *NOxBOXi*® system is not to be connected to a network.

The *NOxBOXi* system is provided with a USB port. This is solely for the purpose of downloading system logs for record and analysis by a suitably qualified Systems Engineer.

2.6 APPLIED PARTS

The *NOxBOXi*® system has no applied parts. However, the NOxFLOW and Sample Line are treated as applied parts (apart from labeling requirements) as per BS EN 60601-1:2006 Section 4.6.

2.7 ISOLATION FROM MAINS



WARNING: Operators should not contact the patient while simultaneously being in contact with the *NOxBOXi*® system.

System shutdown is covered in section 6.13, Shutdown.

In order to isolate the system from the mains, unplug the Mains Power Supply. Position the system so that this can be easily accomplished.

3 EQUIPMENT DESCRIPTION

The NOxBOX Ltd. *NOxBOXⁱ* Intelligent Nitric Oxide Delivery and Monitoring System controls delivery of nitric oxide (NO) gas into the ventilator inspiratory limb of the patient breathing circuit to provide a consistent NO dose concentration in the inspired breath to the patient, as set by the user, for the purposes of Inhaled Nitric Oxide (INO) therapy.

The *NOxBOXⁱ* system is designed to be compatible with most ventilator models, using the NOxFLOW inline flow detection module to enable precise synchronized proportional NO delivery into the inspiratory limb.

To ensure patient safety, the *NOxBOXⁱ* system provides continuous monitoring of the inhalant sample, analyzing NO, oxygen (O₂) and nitrogen dioxide (NO₂) levels throughout treatment. It is also equipped with a full suite of alarms.

The *NOxBOXⁱ* system has an emergency override failsafe circuit for continuous application of NO. Refer to the NOxMixer table located on Page 14. The *NOxBOXⁱ* system has a simple delivery calculator and a set of look-up tables to enable best flow selection. Alternatively, the NOxMixer also allows the blending of NO and oxygen, as per the requirements, by making use of the oxygen flowmeter, as well as the needle valve.

For transport and transfer conditions, the *NOxBOXⁱ* system has a rechargeable internal battery that provides over four hours¹ of use from full charge when no mains power source is available.

The scope of patient treatment is defined and controlled by the NO drug labeling. The primary intended clinical setting is the Intensive Care Unit (ICU), with a secondary intended clinical setting for the transport of ICU patients.

3.1 INTENDED USE



INFORMATION: Always handle and store nitric oxide mixtures in accordance with federal/national, state/provincial, and local codes and regulations.



WARNING: In the event of an alarm triggering on the *NOxBOXⁱ* system, ***first take measures to protect the patient before troubleshooting or repairing the device.***



WARNING: The *NOxBOXⁱ* system is only intended for application of INO therapy in combination with air and oxygen mixtures.

The *NOxBOXⁱ* Nitric Oxide Delivery System is intended for use by healthcare professionals for the delivery and monitoring of NO, and the monitoring of NO₂ and O₂ in the inspiratory ventilator lines of a patient undergoing inhaled nitric oxide therapy (INO).

The NOxMixer is intended to deliver a continuous flow of nitric oxide (NO) from the *NOxBOXⁱ* system, mixed in line with oxygen (O₂) for use in inhaled nitric oxide therapy. The NOxMixer will be used in conjunction with manually bagging a patient.

The *NOxBOXⁱ* system with the NOxMixer is designed primarily for use in hospitals with the ability to provide continuous treatment for transit and transfer conditions within hospitals using the NOxMixer.

This system will perform as described within this Technical Guide, user interface instructions, and system labels and/or inserts, when assembled, operated, maintained, and repaired in accordance with the instructions defined within this Technical Guide.

The *NOxBOXⁱ* system + the NOxMixer must only be used in accordance with the indications and contraindications described in the nitric oxide drug packaging inserts and labeling. Refer to this material before use.

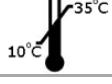
The *NOxBOXⁱ* system is only intended for use with, and connection to, the specified accessories and single-patient use disposables as detailed within this Technical Guide.

¹ With no alarm conditions.

3.2 SPECIFICATION AND ENVIRONMENT

NOxBOX _i [®] System Main Specifications					
Measuring Range	NO	0 – 99.9	ppm		
	NO ₂	0 – 19.9	ppm		
	O ₂	0 – 99.9	%		
NO Delivery Range (setpoint)	0.6 – 80 ppm (Note the system allows setting at <= 0.5 ppm, accuracy figures below are for >= 0.6 ppm, use of a lower setting is at customer responsibility)				
Standby Mode	Set 0 ppm				
NO input concentrations	100, 200, 225, 250, 300, 400, 450, 500, 800, 900 and 1000 ppm				
NO Delivery and Measurement resolution	0.1 ppm				
Means of disconnection	Mains power supply plug				
Mode of Operation:	Synchronous (0.5-50 l/min) or Continuous				
Sample Flow Rate:	Approx. 225 ml/min				
Gas Concentration Detection Principle:	Sealed electrochemical sensor				
Accuracy:	Monitoring:	NO and NO ₂ :+/-3% or 0.3 ppm whichever is the greater plus the accuracy of the calibration gas O ₂ +/- 3.5%			
	Automatic Mode	Delivery (measured dose):	At the point of sampling at the patient Y-piece the accuracy is that of the monitoring system above.		
		The system will serve the delivered concentration to the setpoint subject to the flow from the ventilator; see section “Maximum NO Dose Delivery” below for the setpoint range.			
		Delivery (with respect to setpoint):	Once the measured dose and setpoint agree, then the accuracy w.r.t. the setpoint is that of the monitoring system. Until the setpoint is reached, then the accuracy is that of the difference between setpoint and measured dose plus the accuracy of the monitoring system.		
	Manual Mode	Delivery (with respect to value advised by the Dose Calculator):	Dose calculator, continuous flow. The delivered dose will be +/-30% of the figure advised by the onscreen dose calculator. Monitoring can be used to determine the actual value.		
		Intermittent (non-continuous) ventilation. Accuracy has only been verified with a continuous flow use. Intermittent flow accuracy doses values must be determined by the customer.			
Display:	Touch screen LCD				
Alarms:	Audible and visible				
Setup time:	< 10 minutes				

NOxBOX_i® System Main Specifications

Response time:	< 10 seconds to 90% FSD NO < 40 seconds to 90 % FSD NO ₂ < 15 seconds to 90 % FSD O ₂
Operating Temperature:	10 °C – 40 °C
	
Operating Humidity:	15 % - 85 % RH non-condensing
Storage Temperature:	0 °C – 40 °C
Storage Humidity:	15 – 95% non-condensing
Operating and Storage pressure:	800 – 1200 mBar
Sensor Operating Life:	2 years
Sensor Resolution:	NO and NO ₂ 0.1 ppm O ₂ 1m Bar O ₂
NO Dose Delivery response time²:	Target <2 minutes.
NO Dose Delivery Over/Ubershoot	± 25% or 2.5 ppm, whichever is the greater.
Transient on dose setpoint change:	
Battery:	4 hours operation Li-ion Polymer 745396/3900mAh/22.2V Not User replaceable
Power Input:	GSM90B24-P1M 100 – 240 VAC, 50/60 Hz, 1.3-0.6 A
Dimensions:	330 mm x 250 mm x 108 mm
Weight:	6.2 kg
Construction:	Rigid polyurethane (PU)

NOxMixer Main Specifications

NO Dose Delivery range³:	0 – 231 ppm
NO Dose Delivery accuracy⁴:	± 30% or 3 ppm, whichever is the greater.
Input NO Flow Range:	50 – 600 ml/min @ 1.65bar
O₂ Flow Range:	2 – 25 l/min @ 4bar (+/- 0.5bar)
Continuous Supply:	Supply of 1.65bar from manual control valve. Minimum concentration: 100 ppm Maximum concentration: 1000 ppm
Rotameter Display (analogue):	Safety notice: NO drug in N ₂ balance is supplied as a dry gas and is non-oxygenated. It is important to ensure that the volume of this dry gas introduced into the ventilator lines is limited to prevent reducing oxygen supply to the patient or reduction in humidity conditions of ventilated supply.
Dimensions:	H185 x W65 x D60.8mm
Weight:	~0.3kg
Construction:	Rigid polyurethane (PU)

² The time between setting a new NO setpoint and the patient receiving it.

³ 231 ppm achieved by using 1000 ppm cylinders, range lowered to 23 ppm if used with 100 ppm cylinders.

⁴ The overall delivery range and accuracy is subject to the constraints of the NOxBOX_i system needle valve, ventilator, and circuit setup.



WARNING: The NOxBOX_i system is only intended for application of INO therapy in combination with air and oxygen mixtures.



WARNING: For high concentrations of NO exceeding 80 ppm, exposure should be limited to a maximum of 4 days in order to reduce the risk of sensor zero drift due to prolonged exposure. The NOxBOX_i system protects users from the adverse effects of sensor drift by performing a daily sensor zero calibration. If a sensor has drifted outside of acceptable limits, the zero calibration will fail.

3.3 ABBREVIATIONS, DEFINITIONS, AND ICONS

3.3.1 ABBREVIATIONS

NO	Nitric Oxide
NO ₂	Nitrogen Dioxide
O ₂	Oxygen
ppm	Parts per million

3.3.2 DEFINITIONS

NO Dose	User setting of NO dose to deliver to patient.
Elapsed Treatment Time	Total patient treatment time since first NO dose delivery.
Current Dose Treatment Time	Time current dose setting has been administered to patient.
Alarms	Alarm history tab: shows alarm list from current session.
Settings	User settings tab: access to user-adjustable system settings.

3.3.3 ICONS OVERVIEW

General Navigation



- Service Engineer area: press to access.
- Press Next to proceed to the next screen.
- Press Back to return to the previous screen.
- Skip step-by-step quick start guide instruction screens.
- Press to accept or confirm the statement on-screen.
- Press to decline or deny the statement on-screen.
- Grayed-out buttons indicate that they are temporarily disabled. An action or test must be performed or completed to activate.
- Edit value.
- Home Screen.
- Scroll is disabled.

Main Monitor



- Alarm inactive
- Active alarm
- Muted alarm (for 2 minutes)
- Edit NO dose
- Upper alarm/limit setting
- Lower alarm/limit setting
- Delete entry

User Setting Screen



- Manual Override calculator: Shows approximate dose value from each manual override setting (50-600ml) for patient ventilator flow setting.
- Zero calibration: Sensor zero baseline test. System prompt reminder once every 24 hours during use. Can initiate from Settings screen.
- Increase value.
- Decrease value.

3.3.4 REAR LABEL SYMBOLS



- Lists name and contact details of device manufacturer.
- Year of manufacture: date shown below this symbol indicates the year the device was made.
- Device serial number.
- Consult the Instructions for Use.
- Caution: specific warnings or precautions for use of this device are listed in accompanying documents.
- Equipment is governed by the WEEE directive. Contact your distributor for correct disposal of this device.
- CE Marked device. Symbol certifies that the product meets EU consumer safety, health, and environmental requirements for this product type.
- Oxygen inlet port.
- MET mark

3.3.5 FRONT LABEL SYMBOLS



- Intelligent delivery: the system is in fully adaptive delivery mode that controls the NO dose delivery to the patient to the most efficient and safe delivery profile.
- Manual override continuous flow: for emergency backup and manual bagging of patients. The NO flow is one of the selected flows set by the user. This flow is continuous and cannot adapt to changing conditions. Patient monitoring must be observed by the operator to ensure correct dose levels are achieved.
- Oxygen + NO outlet port.

3.3.6 POWER SUPPLY SYMBOLS

	Dangerous Voltage.
	Indoor Use Only.
	Class II Equipment.

3.3.7 ACCESSORY LABEL SYMBOLS

	Type B Applied Part: non-conductive.
	Single patient use device.
	Latex Free product.
	Device should not be used after the end of the year, month, or day shown.

3.3.8 MANUAL OVERRIDE FLOW SELECTOR VALVE MARKINGS

50	50 cc/min	Note that all values shown are approximate to +/- 15%. Refer to the Look-up Tables for indication of dose per ventilator flow rate. Monitoring of patient dose must be implemented when using Manual Override Flow Delivery of NO.
100	100 cc/min	
200	200 cc/min	
300	300 cc/min	
400	400 cc/min	
500	500 cc/min	
600	600 cc/min	

3.4 SYSTEM COMPONENTS

Each *NOxBOX_i* system and NOxMixer system has a unique serial unit identification number using the following format.

NI10001

NM0002

This is located on the device label (see Figure 3-1 and Figure 3-2) attached to the rear of the device, and should be quoted when contacting the manufacturer or distributor for servicing and repairs.

Additionally, the rear label on the *NOxBOX_i* system identifies the manufacturer contact details and year of device manufacture.

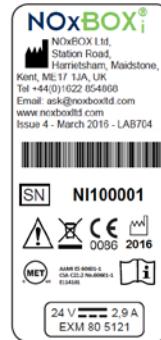


Figure 3-1: *NOxBOX_i* System Device Label

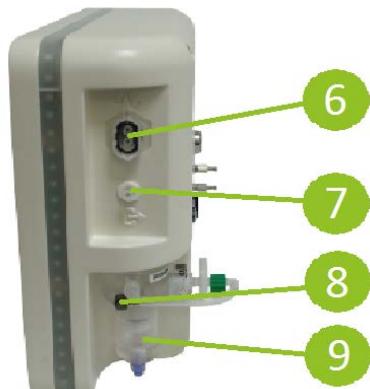


Figure 3-2: NOxMixer Device Label

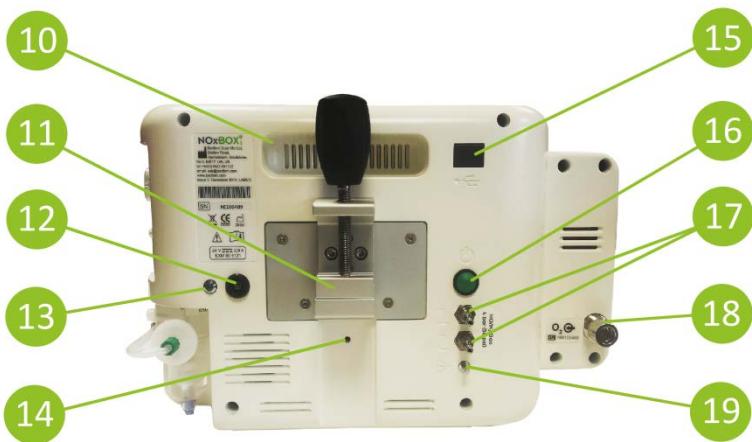
3.4.1 NOxBOX SYSTEM FEATURES



1. Oxygen Flowmeter
2. Oxygen/ NO Mix Outlet Port
3. Touch Screen Display
4. Mode Selection Valve
5. Manual Override Flow Control Valve



6. NOxFLOW Sensor Connector
7. NOxFLOW Dose Connector
8. Patient Sample Inlet
9. Water Trap Bowl



10. Handle
11. Euro Rail Clamp
12. Power Inlet Socket
13. Charging Indicator LED
14. Zero Inlet
15. USB Port
16. Power Button
17. NOxBOX System Gas Inlets: 4 bar max.
18. Oxygen Inlet Port
19. Gas Line Purge Needle

3.4.1.1 SYSTEM FEATURES

	18. NOxBOXi System Nitric Oxide Regulator (x2) – Gas connection type dependent on supplier.
	19. NOxBOXi System Supply Lines (x2)
	20. NOxBOXi Power Supply (x1) – 4 International AC plug adaptors included.
	21. Oxygen hose. Gas connection dependent on supplier.

3.5 NOxBOX, EFFECT ON VENTILATOR CIRCUIT

The NOxBOXi® system has two main connections to the patient ventilator circuit. These produce the following effects:

1. **At the NOxFLOW:** NO/N₂ concentrated gas is delivered into the inspiratory limb of the ventilator circuit in direct proportion to the ventilator air flow. The proportion of gas added is adjusted depending on the desired patient dose and the concentration of the NO gas supply. For example, to achieve a 20 ppm dose from a 400 ppm cylinder supply, the NOxBOXi system is adding 5 percent more gas to the air volume being delivered by the ventilator.
2. **At the Sample Line:** The NOxBOXi system samples a side-stream from the ventilator gases at a nominal rate of 225 ml/min (0.225 L/min).

3.5.1 OXYGEN DILUTION

Adding the NO/N₂ gas to the circuit has the effect of proportionally diluting the delivered oxygen concentration. The *NOxBOX_i* system monitors the oxygen level being delivered to the patient to assist the user in monitoring this effect. Oxygen dilution is directly related to the proportion of NO gas that is added to the circuit. The NOxMixer allows you to set the desired flow rate so that NO and O₂ blend can be achieved as required.

Worked example:

For a 20 ppm dose from a 400 ppm cylinder: 5 percent NO/N₂ gas is added to the ventilator air flow; the O₂ is therefore diluted by 5 percent of its original value.

If the O₂ was originally 50 percent v/v, the O₂ concentration after the NO is introduced will be approximately 47.5 percent v/v.

3.5.2 MEASURED MINUTE VOLUME

The measured volume ventilation may be modified slightly by the net effect of the *NOxBOX_i* system adding and removing gases from the ventilator circuit. This may require some modifications to ventilator settings to compensate.

Added minute volume of NO gas can be calculated using:

$$\frac{\text{NO Dose} \times \text{Minute Volume}}{\text{Cylinder Concentration} - \text{NO Dose}} = \text{Added minute volume}$$

Worked Example:

Minute volume = 10 L/min

Dose = 10 ppm

Cylinder concentration = 400 ppm

Then the added minute volume may be calculated:

$$(10 \times 10) / (400 - 10) = 0.26 \text{ L/min}$$

To calculate the net change, subtract the *NOxBOX_i* system sampling rate from the added minute volume:

$$0.26 - 0.225 = 0.035 \text{ L/min}$$

3.5.3 TRIGGER SENSITIVITY

When using synchronized ventilator modes, the net change of gas volume flow caused by the *NOxBOX_i* system may trip the trigger flow setting. Always check the trigger sensitivity of the ventilator after connecting the *NOxBOX_i* system to the patient circuit.

3.5.4 MAXIMUM NO DOSE DELIVERY

The *NOxBOX_i* system is capped at a maximum dose capability of 80 ppm in the software; however, for a dose above 80 ppm and up to 231 ppm dose, the NOxMixer can be used (see Table 3.2).

Additionally, the maximum flow capability of the *NOxBOX_i* system is physically limited. This will cause some dose limitations at higher ventilator flow rates.

The *NOxBOX_i* system is compatible with a wide range of NO supply concentrations. Note that the physical flow limitation has less effect on a 1000 ppm cylinder supply compared to the 100 ppm supply.

See Figure 3-3, Graph of the *NOxBOX_i* System Maximum Dosing Capability.

The NOxBOXⁱ® System Maximum Dosing Capability

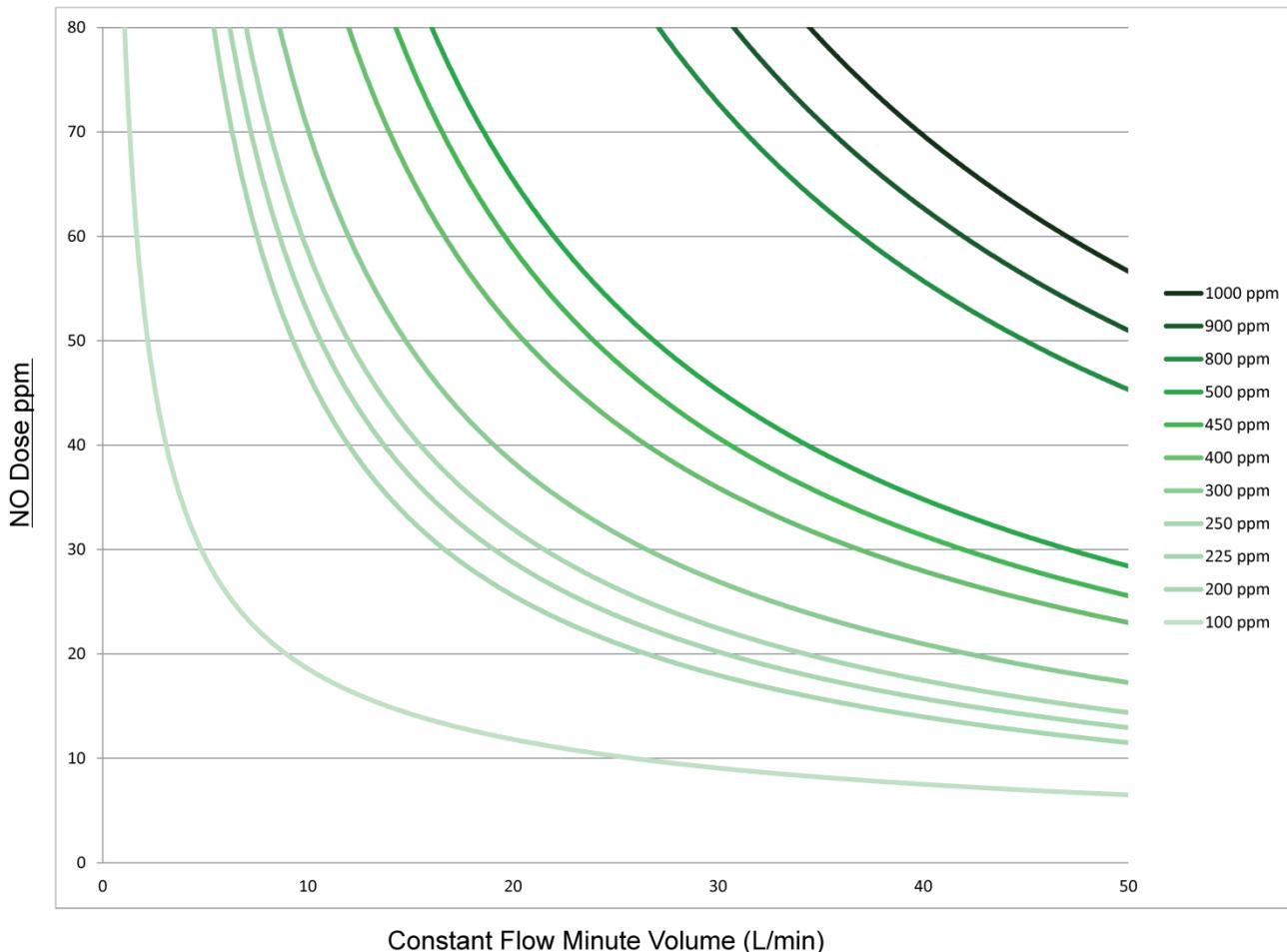


Figure 3-3: Graph of the NOxBOXⁱ System Maximum Dosing Capability

4 INSTALLATION



WARNING: Installation of the NOxBOX Ltd. NOxBOXⁱ® system involves potentially hazardous procedures. Only trained and qualified personnel who have read and understand the instructions in this manual shall install this equipment. Wear appropriate PPE and, if applicable, turn off the power before performing any installation, maintenance, repair, or troubleshooting procedures.



INFORMATION: The customer is responsible for obtaining information on any applicable federal/national, state/provincial, and local codes or insurance requirements that affect piping and electrical installation and for obtaining all necessary approvals.

4.1 UNPACKING INSTRUCTIONS

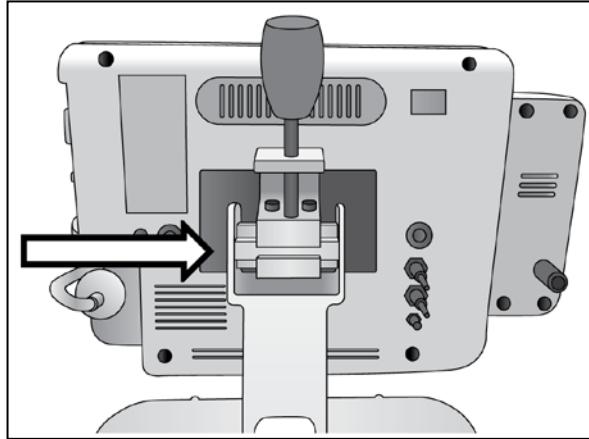
On first receiving this system, the NOxBOXⁱ® system should be carefully removed from its packaging and visually inspected. Ensure that all system components are present and free from visible defect, wear, and damage. Immediately connect the device to mains power.

4.2 ASSEMBLE DELIVERY UNIT TO TROLLEY

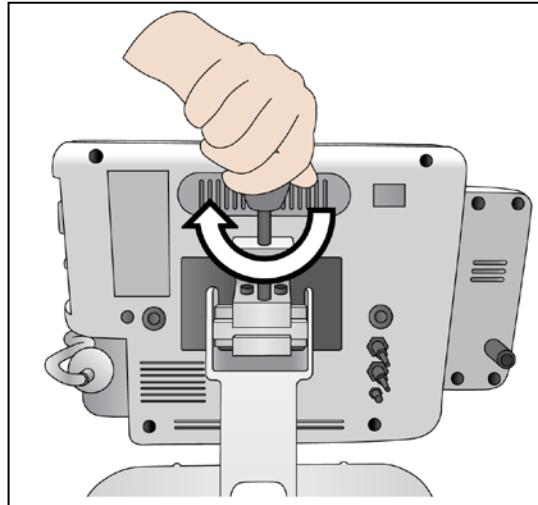


WARNING: When attaching or detaching the head unit from the trolley, the system brakes must be applied to stabilize the trolley to prevent accident or injury.

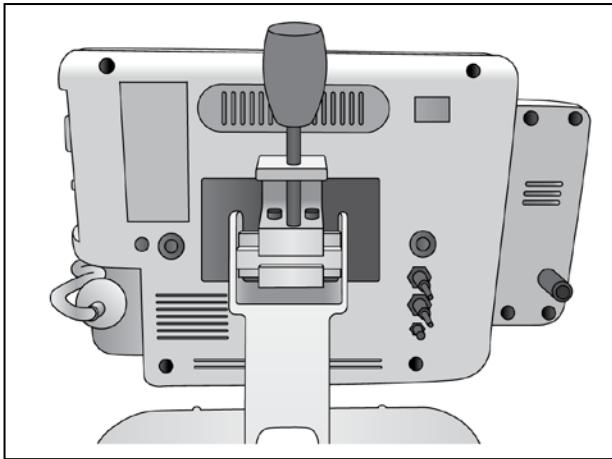
1. Open the rear clamp of the NOxBOX® system head unit by twisting the knob counter-clockwise to ensure sufficient space to mount the trolley.



2. Locate the clamp over the cross-section mounting pole on the trolley.



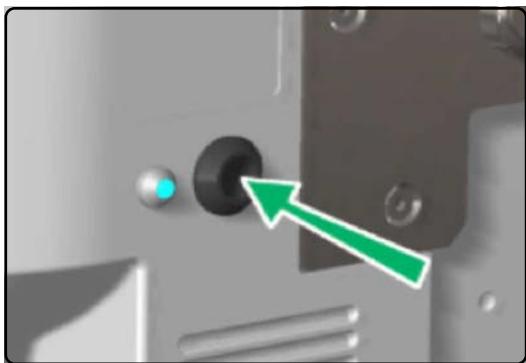
3. Support the NOxBOX system head unit with one hand, while using another hand to rotate the knob clockwise until the clamp closes tight on the cross-section pole.



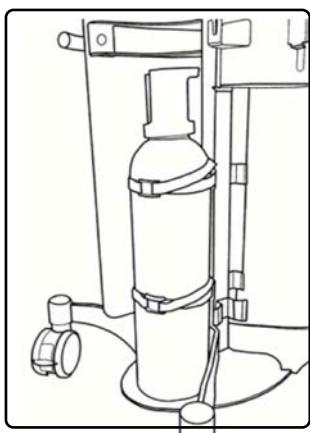
4. Ensure that there is no movement in the NOxBOX system head unit and the clamp has locked correctly as shown.

4.3 SETUP INSTRUCTIONS

To setup the *NOxBOX_i*® system and prepare it for use:



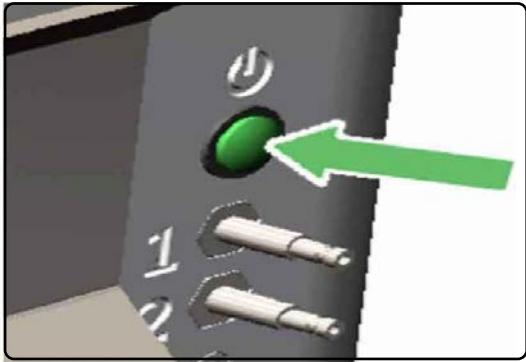
1. Ensure that the system trolley brakes are engaged during setup and while in use.
2. Insert the monitor end of the power cord into the power socket, which is located at the rear of the monitor, and push it in until the locking mechanism clicks.
3. Connect the power supply plug to a hospital-grade electrical outlet that is backed up by an emergency power generator.



4. Secure each cylinder to the trolley using the straps provided. The maximum NO cylinder that the trolley can accommodate is 25 liter water capacity (maximum height is 1.2 m). Additional space has been provided on the trolley for a small oxygen cylinder if desired.
- Note:** Handle the cylinders with care. Refer to section 2.1, Basic Safety Recommendations, for additional safety considerations.
5. Select the number of available *NOxBOX_i* system NO supply cylinders that are being setup on the system (one or two).



6. Ensure that the system is set to intelligent delivery; the mode selection valve should be in the vertical position, as shown here.
7. If using the *NOxBOX_i* system in Manual Mode, the manual control valve located immediately below this switch should be set appropriately for the patient (see Section 6.12 for details).

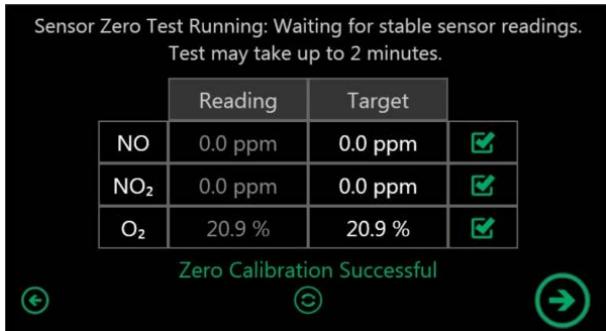


8. When you are ready to set up for use, press the power switch located at the rear of the monitor. After the power is turned on, the *NOxBOX*_i system runs through a startup procedure. Once complete, the system will guide you through system setup procedures.



9. As the system starts up, it will run through some self-test procedures to ensure correct function ability. The alarm strip should light up red and the alarm should sound.
10. If the *NOxBOX*_i system fails to alarm or display the red alarm strip, there is a system fault. **Do Not** use this system for patient treatment, as this may result in the system not being able to correctly alert the medical user to an alarm condition during use.
11. The alarm strip and alarm sound should automatically switch off once the system enters the zero screen. If this does not happen, then there is a system fault. **Do Not** use the system.
12. Sensor Zero Test: The system performs an automatic sensor zero test to establish a baseline reading for the sensors.
13. Once complete, the system will display whether the zeroing process was successful and proceeds to the home screen.
14. If any sensor fails the test, this may indicate an aged or failed sensor. Try a retest . If the retest fails, call the Service Department.

NOTE: It is strongly recommended that the unit not be used with the patients, as system stability and accuracy will be compromised.



4.4 CONNECTING NO GAS CYLINDERS

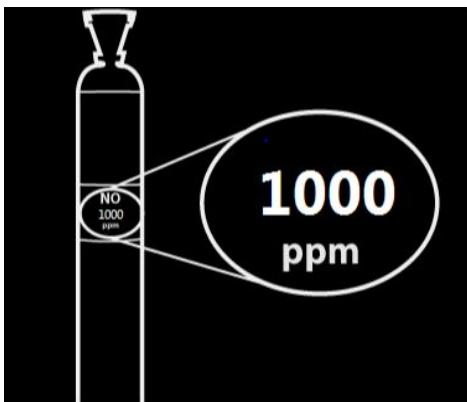
Calibration	Last Run:	Date Due		
Pump Calibration	27 Aug 2016	26 Sep 2016		
NO Calibration	29 Aug 2016	28 Sep 2016		
NO ₂ Calibration	27 Aug 2016	26 Sep 2016		
Vent Calibration	27 Aug 2016	26 Sep 2016		

Step-by-Step Guide **Skip to System Tests**
 Skip to Dose **Service Engineer**

- Set up the system as follows using the on-screen Quick Start Guide (QSG) instructions:

NOTE: For experienced users, the “Skip to System Tests” button will bypass the on-screen QSG and skip to system setup tests. Alternatively the “skip to dose” button will bypass both on-screen QSG and the system test.

See Chapter 6.3 for detailed instructions on how to use the touch screen interface.



- Check that the *NOxBO_i*® system NO cylinder concentration matches the value shown on the system screen. This is the value on which delivery calculations will be based.

NOTE: Do not use any supply cylinder that does not match this value.

If there is a problem, contact your Service Engineer to resolve the issue before attempting to deliver NO to a patient.



- Check the regulator sealing surfaces and connector thread. If your model has non-metal sealing elements, ensure that they are present and undamaged, showing no cracks, pock-marks, etc.



WARNING: If the regulator has sustained visible damage on the valve connection surfaces, do not use as it could be extremely dangerous.



WARNING: Ensure that the supply line is correctly attached to the regulator output before opening the cylinder valve. NO gas will escape at high volume, which may quickly create a poisonous atmosphere.



WARNING: Never disconnect the supply line from the regulator when the pressure gauge indicates that the line is pressurized. If the cylinder valve is open, the NO gas will escape at high velocity and volume, which may quickly create a poisonous atmosphere.



4. Attach the regulator to the cylinder valve connection, as shown. Tighten the connection using the hand wheel. Do not use a tool to tighten the regulator.



5. If the supply line is not already connected to the regulator, then click the quick-connector over the port on the regulator, as shown. Ensure that the collar on the quick-connect is drawn back before fitting. The quick-connect will click positively into place and lock, creating an air-tight seal.



Collar drawn back

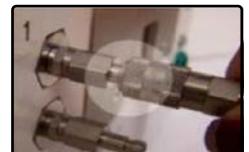


Collar sprung forward

6. Connect the line from the regulator on Cylinder 1 to Port 1, at the back of the monitor.
7. Ensure that the collar on the hose is drawn back before fitting onto the port stump. The collar should spring forward and lock into place with a positive click.



Collar back, introduce to port



Push onto port, collar springs forward and locks in place

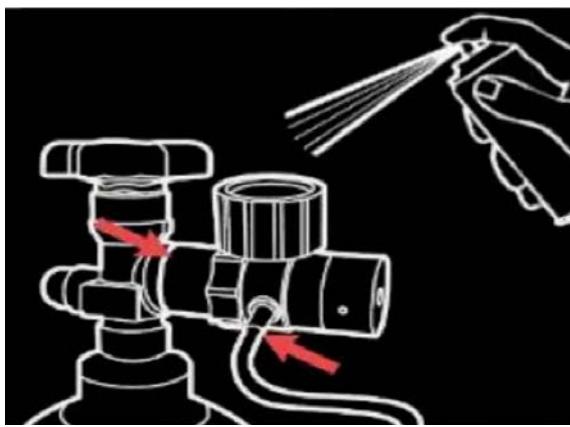
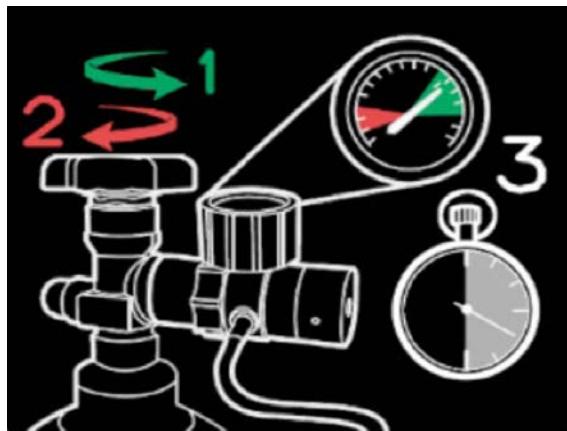
8. To test the connection, gently pull back on the rear of the connector. Ensure that you are not pulling on the collar release element. The connection should be secure.



When the needle is in the green area, the cylinder is full



The needle must point to at least 20 bar (above the red area)



9. Check that each supply cylinder has sufficient contents to commence treatment: Fully open the cylinder valve, then fully close the valve. A supply cylinder should have a fill pressure greater than 20 bar before continuing treatment.

10. If the gauge needle is in the red area, the cylinder is empty and must not be used for treatment. Replace this supply cylinder to begin setup. If the cylinder is empty, the system test for cylinder pressure contents in the onscreen QSG will pause setup.

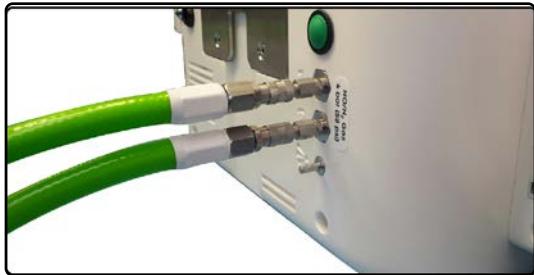
11. To test that each supply line is correctly setup, perform a high-pressure leak test as follows:

- With the valve open, note where the pressure gauge needle is pointing.
- Close the cylinder valve and observe the gauge for 30 seconds.
- If the needle remains constant, the line is correctly set up; press the check mark.
- If the needle shows a drop in pressure, a leak exists; press the X.

12. **If a leak is detected:** If the line has failed the high-pressure test, then investigate the connections for any leaks:

- With pressure in the lines, use liquid leak detector around the regulator seal and hose connections and look for bubbling in the fluid.
- Purge the hose line pressure before removing and reattaching the regulator to the cylinder. The pressure gauge should always read 0 bar before disconnecting the regulator from the cylinder.
- Rule out leaks in the external regulator and supply line: Ensure the regulator supply line connector is correctly locked to the regulator outlet, and the collar of the connector on the free-end of the line is pulled back (sealed). (see step 7.) Open the cylinder to pressurize only the regulator and the supply line (free end not attached to the monitor). Close the cylinder valve and observe the needle for 30 seconds.
- Purge the hose line pressure; connect the free end of the hose back onto the inlet port on the monitor.

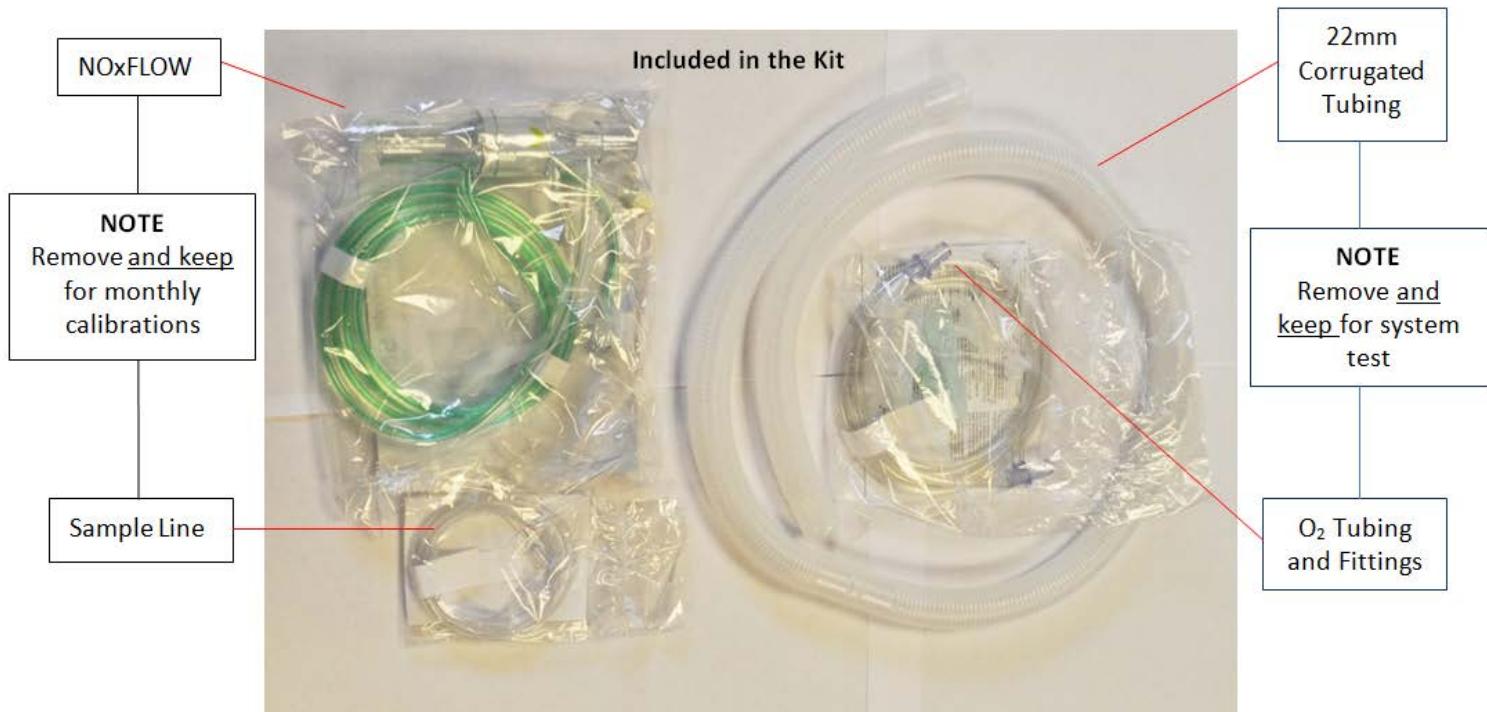
-
13. Once all connections have been remade, retest the pressure hold. If the line fails again, the system will prompt the user to connect the second line instead. Call the Service Engineer to ensure that any problem with the first supply line can be resolved, or replace the system as soon as practical.
-

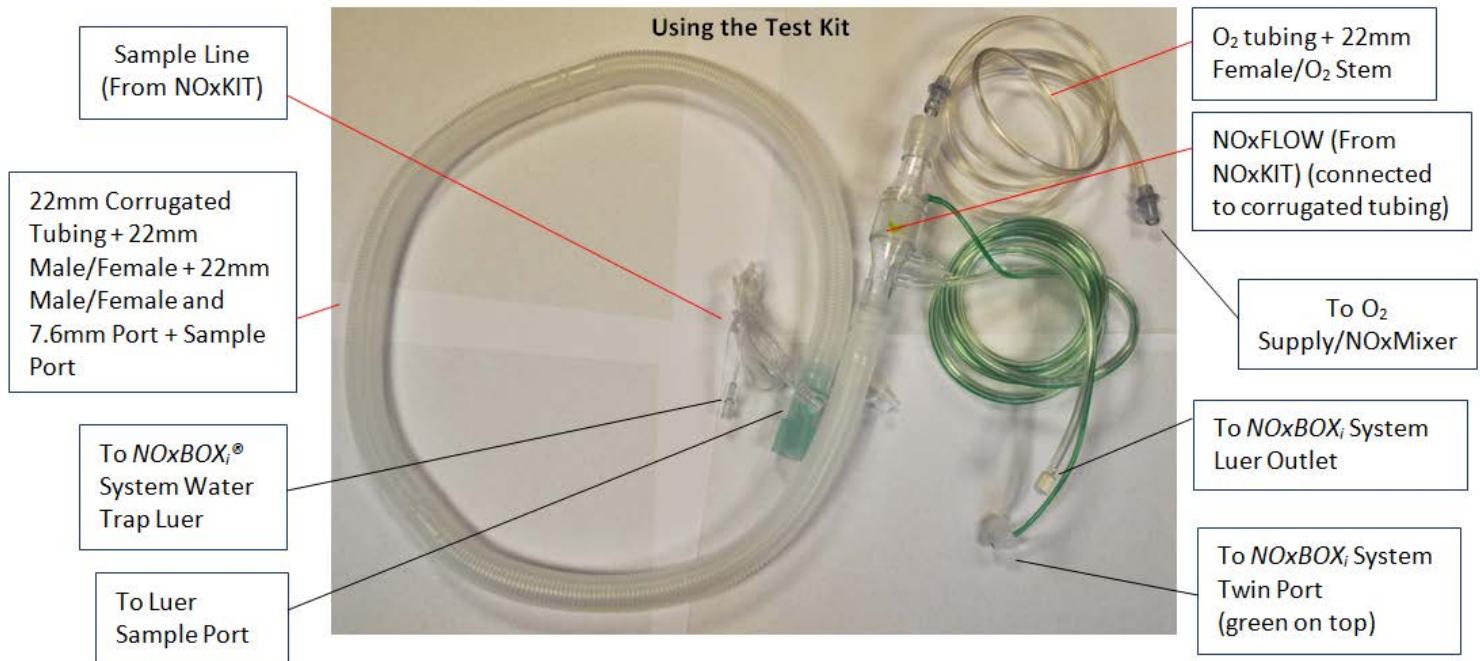
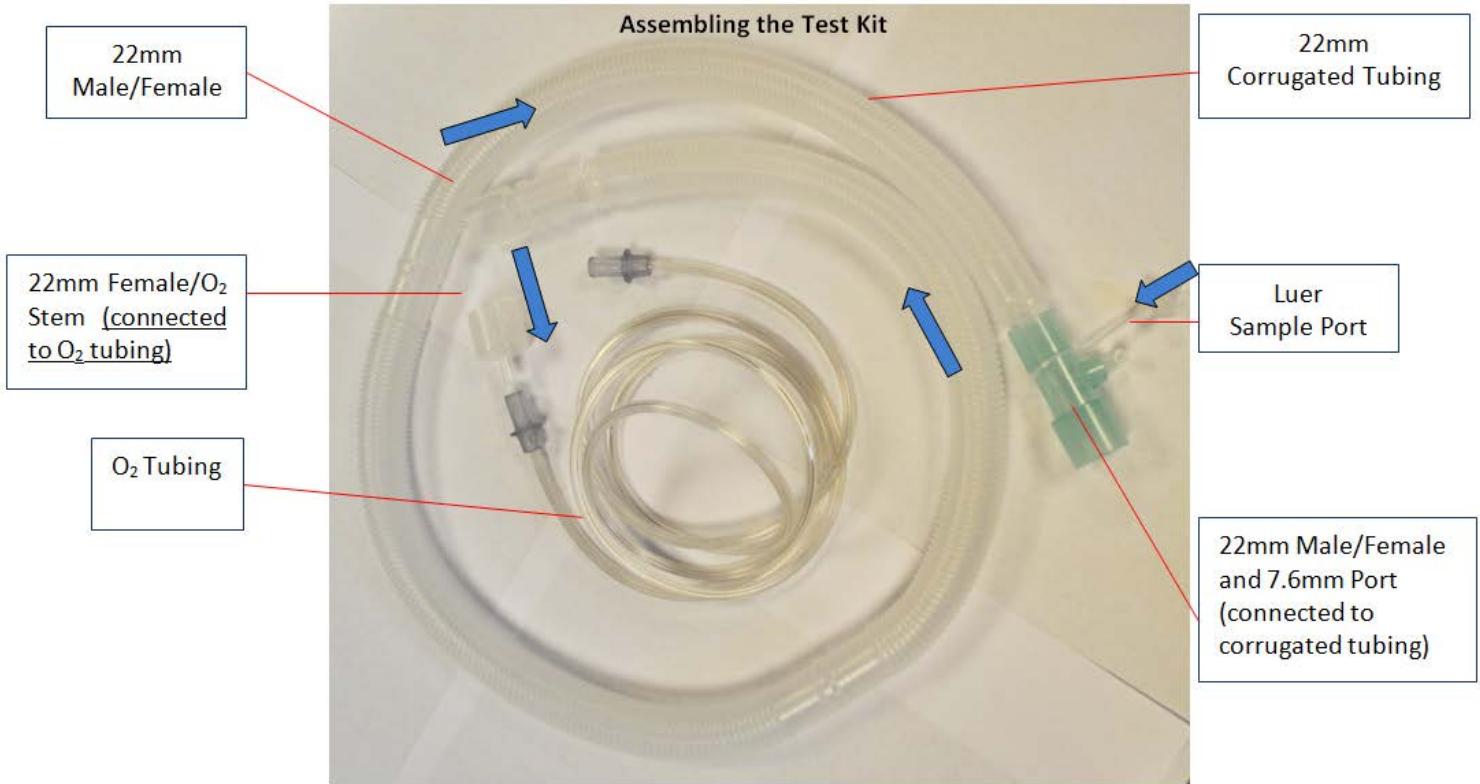


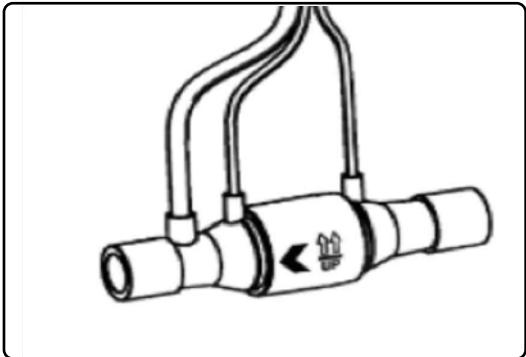
14. Repeat the steps above for the second supply line.

If both lines fail after following the above procedure, this may indicate an internal leak in the system. The system must be inspected and repaired by a qualified Service Engineer before being used.

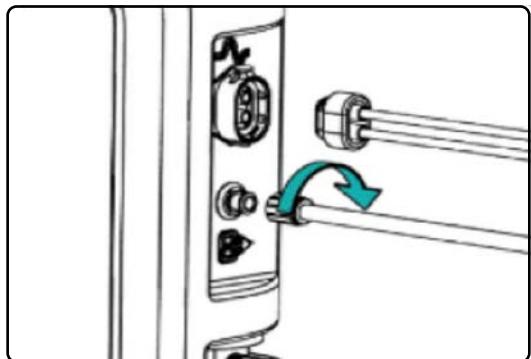
4.5 SYSTEM TEST SETUP



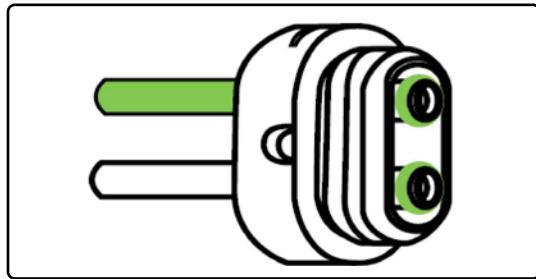




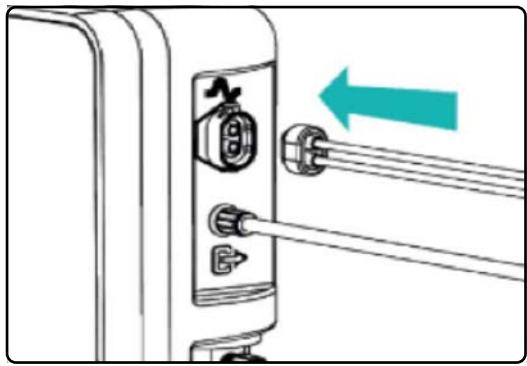
1. Unwrap a new NOxFLOW sensor, and unroll the lines.



2. Identify the single dose-line luer connector, and attach to the monitor dose luer port as shown. Twist the connector to lock.



3. Identify the twin sensor line connector.
4. Verify that both O-rings are present before connecting to the *NOxBOX_i* system.



5. Push the sensor line connector into the socket on the side of the *NOxBOX_i* system monitor (the green tube is uppermost).
6. The connector will click in place when it is locked. To assist with insertion, the release button (located on the underside of the socket) may need to be depressed while attaching the connector.

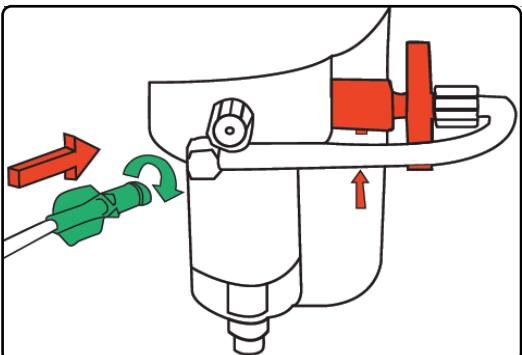


7. **Attention:** before first use of the NOxBOX_i system, the Water Trap Hydrophobic Filter (FIL063) must be fitted.

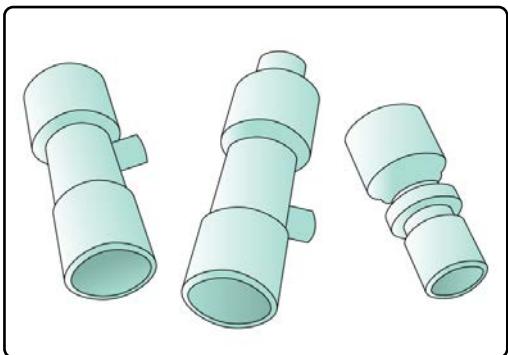


7.a Fit green luer to filter.

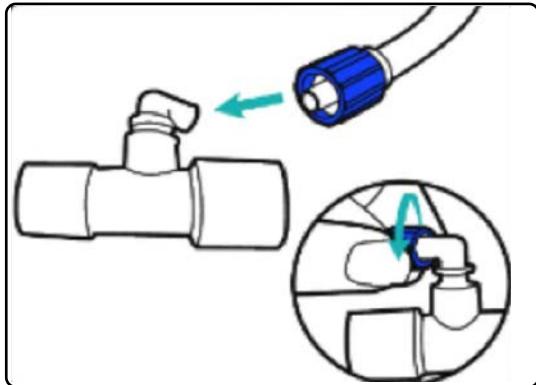
7.b Fit luer to water trap.



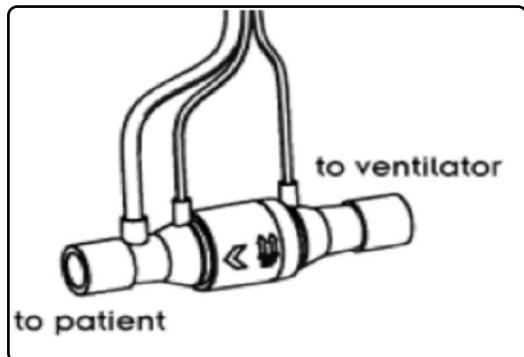
8. Unwrap the patient filter and attach the new filter to the rear of the water trap by using the quick-release connector, then use the fastening luer lock to complete the connection.
9. Connect the sample line.



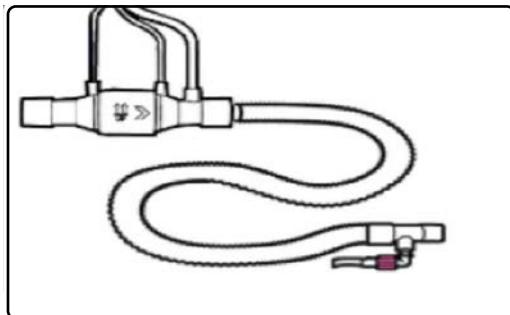
10. Select the NOxKIT that matches the patient ventilator circuit size (10mm, 15mm, or 22mm).



11. From the NOxKIT, select the male-female single-sized connector, and assemble one of the female luer ports by pushing it firmly home into the side port of the adaptor. Screw the male luer lock at the end of the sample line onto the ventilator adaptor.



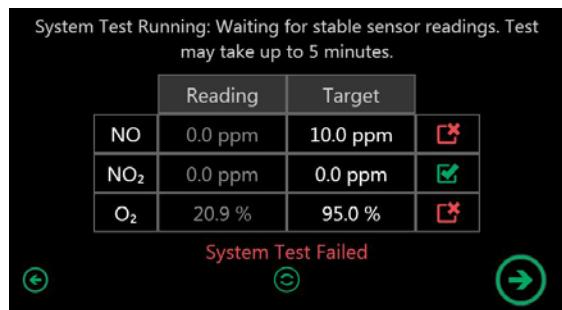
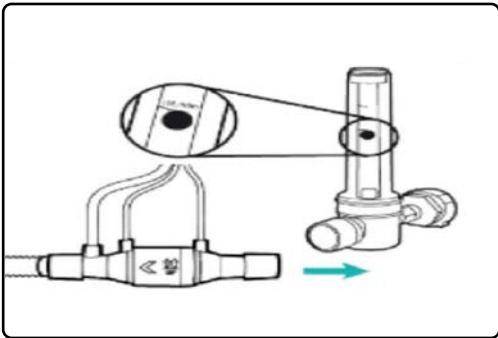
12. The NOxFLOW is marked with a flow direction arrow in green. This points in the direction of the ventilator air flow, towards the patient sampling point.



13. Select 1 meter of new ventilator tubing that corresponds with the chosen ventilator connections kit size.
14. Connect the 1 meter ventilator tubing to the patient (arrow) end of the NOxFLOW sensor. Connect the sample line adaptor to the free-end of the ventilator tubing, as shown in the diagram at the left.



WARNING: NO₂ is extremely toxic. The system test is performed to ensure that the Test Line is correctly assembled and the NOxBOX_i system is functioning correctly before connecting to a patient. It is vital that this step is done to check system function and flush out any NO₂ build-up before connecting to a patient.



15. Connect the Test Line Assembly to a regulated oxygen supply. Ensure that the valve on each NO supply cylinder is fully open. Set the oxygen flow rate to 10 L/min, and then press the Next button on the monitor to initiate the system test.

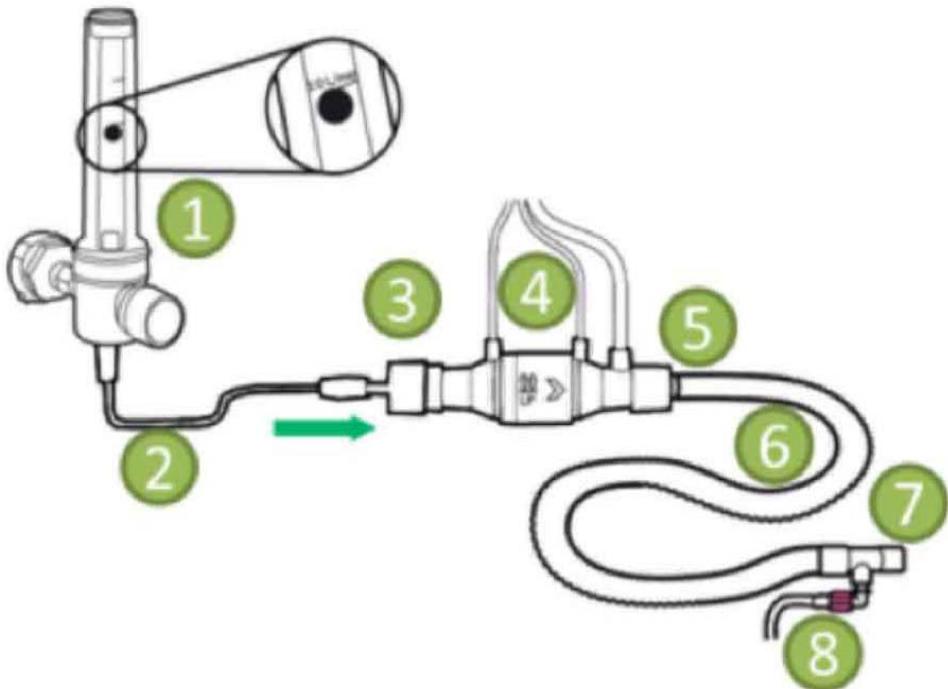
16. A process animation will be displayed as the system performs the system test. During this time, the system will deliver NO into the ventilator test line to achieve an equivalent dose of 10 ppm. The monitor will display whether the system test was successful or not.

17. If the system test failed, follow the diagnostic tips to make corrections:
 - a. Ensure that all connections on the Test Line Assembly are made as directed.
 - b. Ensure that the NOxFLOW sensor is orientated with the oxygen flow in the direction of the arrow marking (the dose portion closest to the sample end of the test line.)
 - c. Ensure that the valves are open on all NO supply cylinders.
 - d. Check that the oxygen flow is set to 10 L/min.

18. If the system test fails a second time, the unit cannot be used for intelligent automated delivery. Call the System Engineer, and replace the system.

19. Once the system test has passed; shut off the O₂ flow, and disconnect the tested Line Assembly from the supply line. The verified Line Assembly is ready to connect into the patient ventilator circuit

SYSTEM TEST CIRCUIT



System Test Circuit

1. Oxygen flow meter
2. Oxygen tubing
3. 22F – 4.6mm connector
4. NOxFLOW™
5. 15M-15M, 22F-15M, 22F-22M or 15M-22M connector
6. 1m corrugated tubing (15mm or 22mm)
7. 15M – 15M – luer port or 22M – 22F – luer port connector
8. NOxBOX_i® System sample line



INFORMATION: If the NOxBOX_i system is not to be used within the next 10 minutes, turn off the cylinder valves, detach the supply lines from Port 1 and Port 2, and release the line pressure using the purge needle located at the back of the monitor. Then, re-attach the supply lines to Port 1 and Port 2.



WARNING: If the NOxBOX_i system is left pressurized for more than 10 minutes while not in use, repeat the system test. Connect the line
Perform assembly to the oxygen supply, as described in steps 11-17.
Press Next. The system test will run automatically.

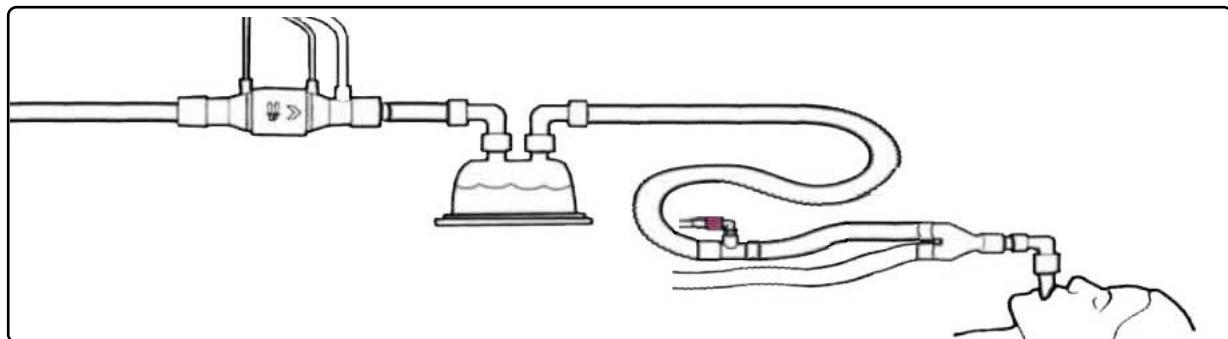
-
20. Connect the NOxBOX_i system to the patient ventilator inspiratory limb. See Section 5.3 for Patient Circuit connection diagrams.

The sample point adaptor should be connected approximately 30 cm behind the Y-Piece to prevent contamination of the sample from exhaled breath.

21. Connect the upstream end of the NOxFLOW sensor to the upstream inspiratory limb tubing.

The NOxFLOW should be situated upstream of the humidifier.

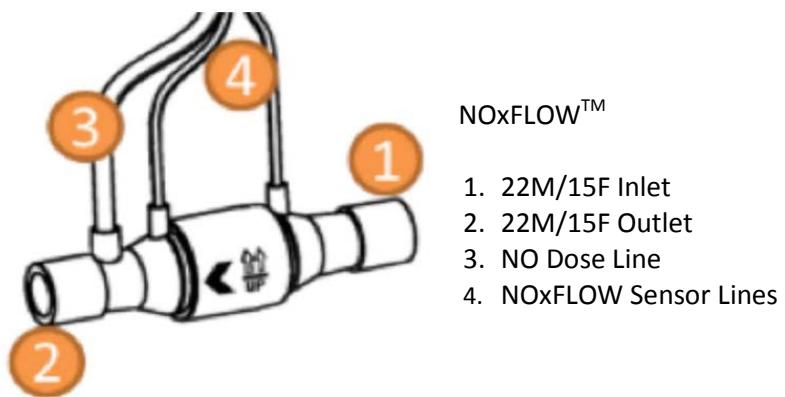
Maintain the optimum 1m distance of ventilator tube between the sample point and the dose introduction point on the NOxFLOW for best performance (between 0.7 and 1.3m is ideal). The system is now ready for dose entry and alarm setting procedures.



Ventilator inspiratory limb showing NOxFLOW placement before humidifier.

5 PATIENT CIRCUIT SETUP

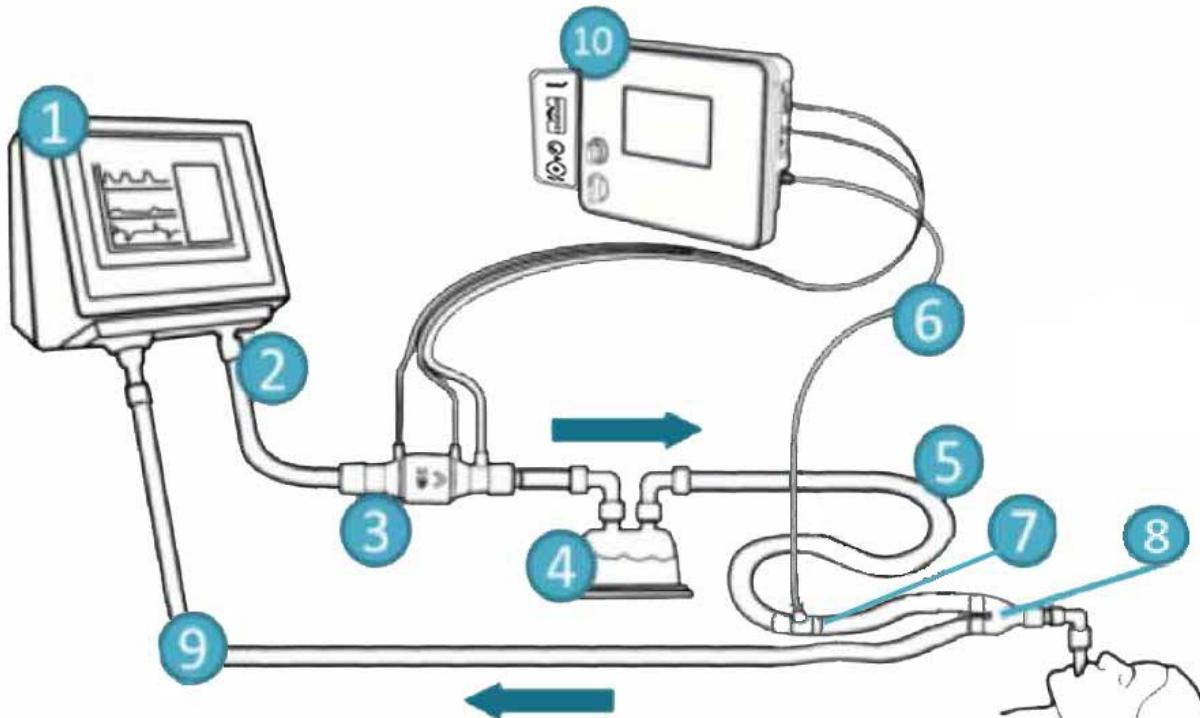
5.1 NOxFLOW



NOxFLOW™

1. 22M/15F Inlet
2. 22M/15F Outlet
3. NO Dose Line
4. NOxFLOW Sensor Lines

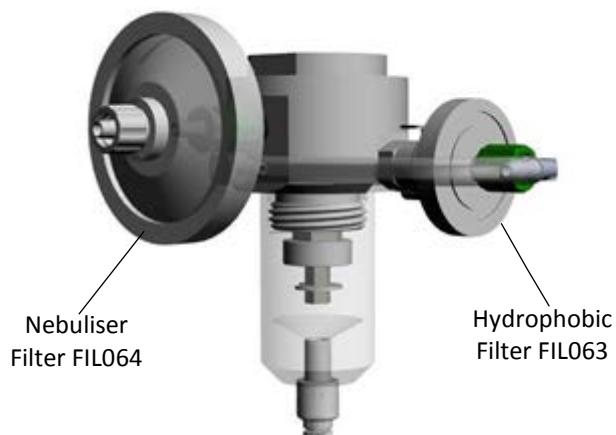
5.2 VENT CIRCUIT (EXAMPLE 1)



- | | |
|------------------------------------------------------|----------------------------------------------------------------|
| 1. Ventilator | 6. NOxBOXi® System Sample Line |
| 2. Ventilator Inspiratory Port | 7. 10M-10F, 12M-12F, 15M-15F or
22M-22F luer port connector |
| 3. NOxFLOW™ (use 22F or 15M to vent tube adaptors) | 8. Patient Y-Piece |
| 4. Humidifier | 9. Expiratory Limb |
| 5. 0.7m-1.3m Corrugated Tubing (10mm, 15mm, or 22mm) | 10. NOxBOXi + NOxMixer |

NOTE: To improve accuracy, it is recommended to have approximately 30cm between the patient Y-Piece (8) and the Sample Line Connector (7) where possible.

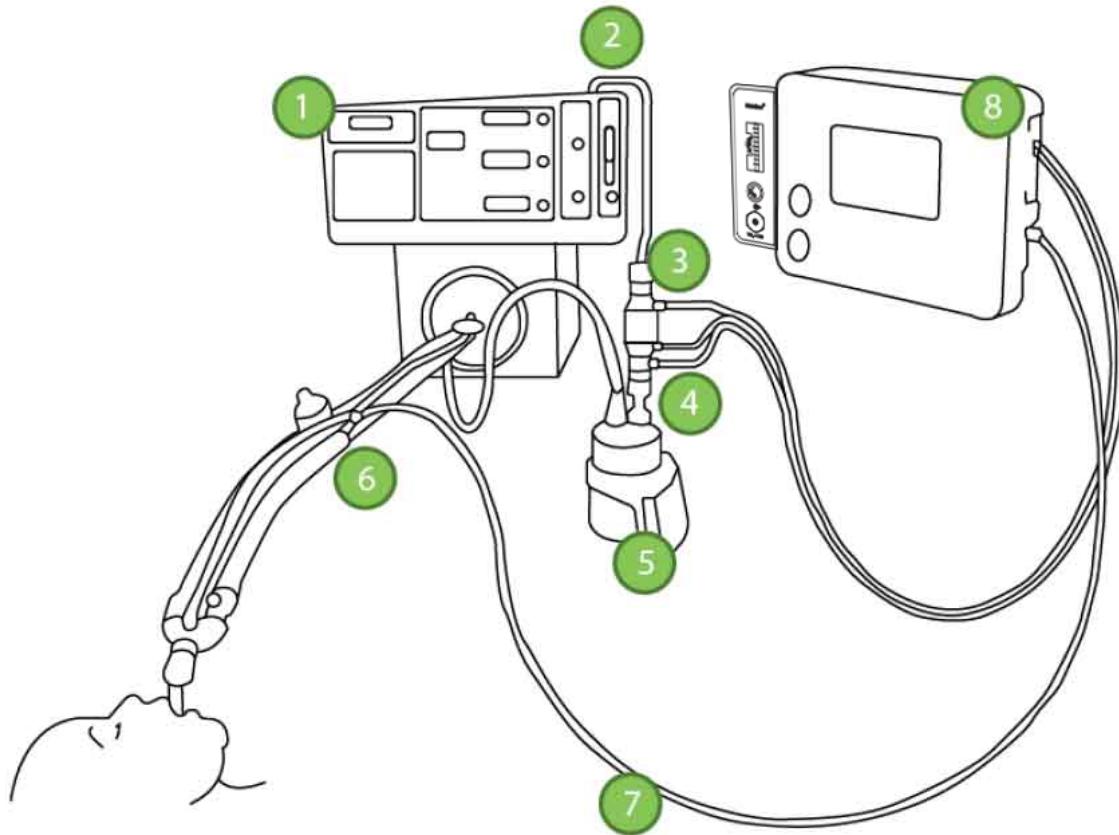
NOxBOX_i System Water Trap



NOTE: When the NOxBOX_i system is used in conjunction with a nebuliser setup, the nebuliser filter FIL064 should be connected to the inlet of the water trap. The nebuliser filter is a 50 mm 1 micron hydrophilic filter designed to allow moisture to pass into the water trap but prevent nebulised solutions from being drawn into the NOxBOX_i system, which could cause an occlusion.

In some cases, the filter may require replacing at 12 hour intervals and will only be supplied as an optional extra on request.

5.3 VENT CIRCUIT (EXAMPLE 2)



1. Ventilator (for instance Sensormedics 3100a)
2. Ventilator bias flow outlet
3. NOxFLOW™ (use 22F or 15M to vent tube adaptors)
4. One-way valve
5. Humidifier
6. Sampling point
7. NOxBOX_i® System Sample Line
8. NOxBOX_i + NOxMixer

5.4 MANUAL BAGGING AND EMERGENCY BACKUP

5.4.1 INTRODUCTION

When using the NOxMixer for manual bagging, emergency backup, or Neopuff circuit, the Manual Override Mode must be selected (see section 6.12). Adaptors for the below circuits can be obtained from NOxBOX Ltd. to ensure compatibility.

Monitoring of the dose should be carried out by connection of the sample line to the manual bagging circuit/emergency backup.

The correct NO dose can be calculated and adjusted either by changing of the manual control valve position or adjusting the flow rate of the O₂ source using the flow meter on the NOxMixer (see sections 6.12.1 and 6.12.2).

NOTE: The NO dose is delivered from the outlet of the NOxMIXER during manual bagging and Emergency Backup Mode.

5.4.2 MANUAL BAGGING SETUP

Manual Bagging Setup

1. Calculate the NO dose based on the intended O₂ flow rate using the Lookup Tables (see section 6.12.2) or the On-Screen-Guide, and rotate the dose knob to the desired value (see Figure 5-1).
2. Turn off the oxygen flow meter on the NOxMIXER.
3. Attach the oxygen hose to the inlet port located on the back of the NOxMixer, and then attach the other end to the external oxygen source (cylinder or wall). Check the specifications for pressure information.
4. Connect the manual bagging line to the NOxMixer outlet.
5. Connect the sample line from the patient circuit to the NOxBOX_i[®] system.
6. Set the oxygen flow to the desired rate on the NOxMixer. Ensure that the height of the O₂ flow ball center is at the correct flow meter measurement.
7. Move the Manual Mode selection valve to the position identified in Figure 5-2 to engage the Manual Override Mode (see section 6.12.3).

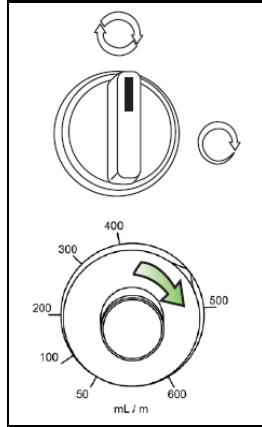


Figure 5-1

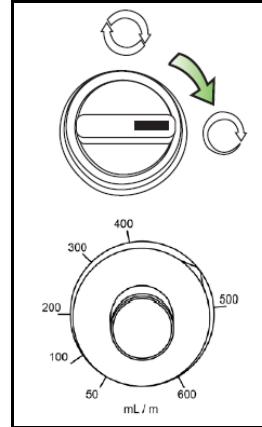
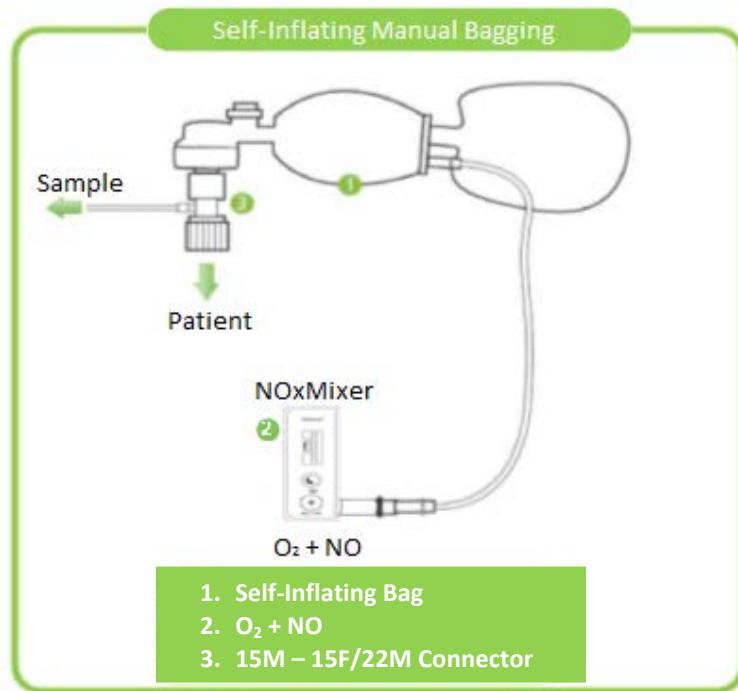
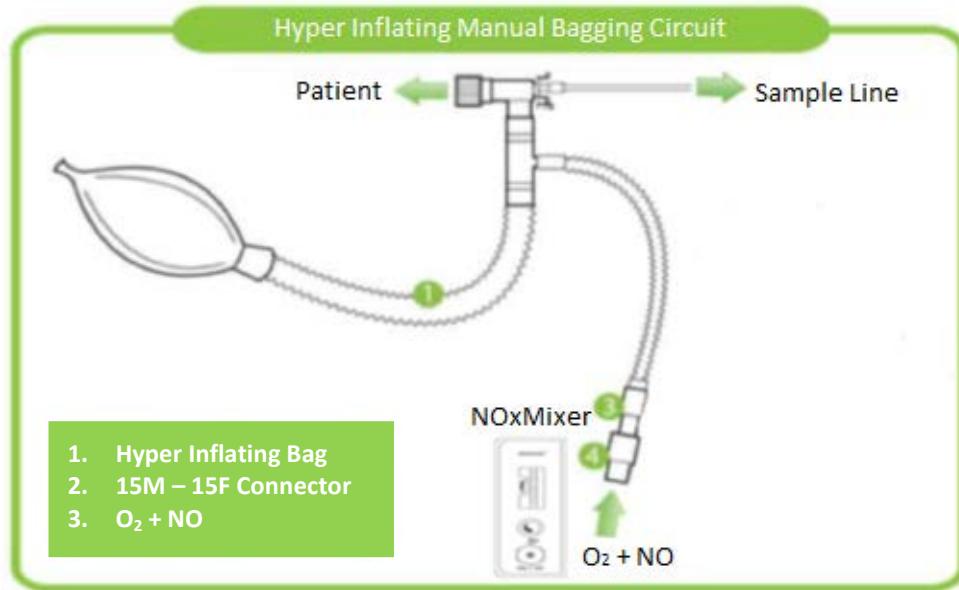


Figure 5-2

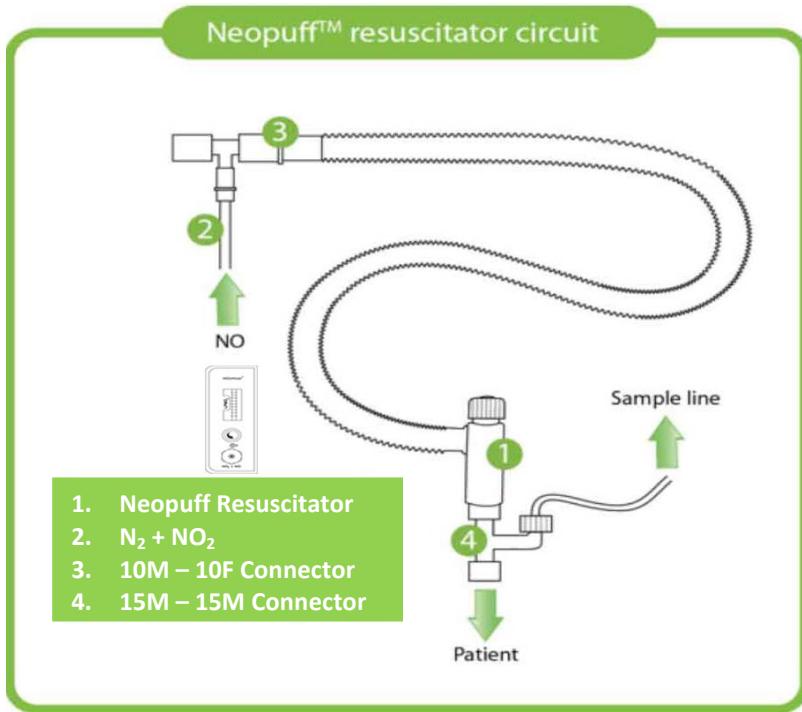
5.4.3 SELF-INFLATING MANUAL BAGGING DIAGRAM



5.4.4 HYPER INFLATION MANUAL BAGGING DIAGRAM



5.4.5 NEOPUFF RESUSCITATOR DIAGRAM



5.4.6 EMERGENCY BACKUP SETUP

1. Calculate the NO dose based on the ventilator flow rate using the Lookup Tables (see section 6.12.2) or the On-Screen-Guide, and rotate the dose knob to the desired value (see Figure 5-3).
2. Ensure that the oxygen flow meter on the NOxMIXER is turned OFF.
3. Attach the end of the NOXKIT-EMER tubing to the outlet of the NOxMIXER.
4. Disconnect the NO dose line from the *NOxBOX_i* system. Attach the connector end of the NOXKIT-EMER tubing to the NO dose line.
5. Move the Manual Mode selection valve to the position identified in Figure 5-4.

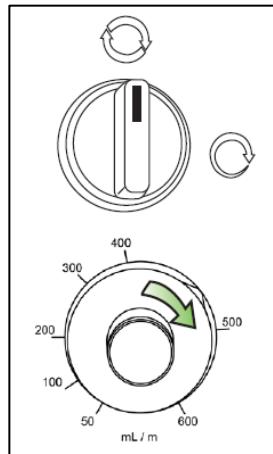


Figure 5-3

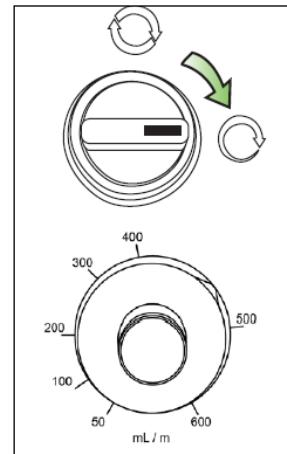


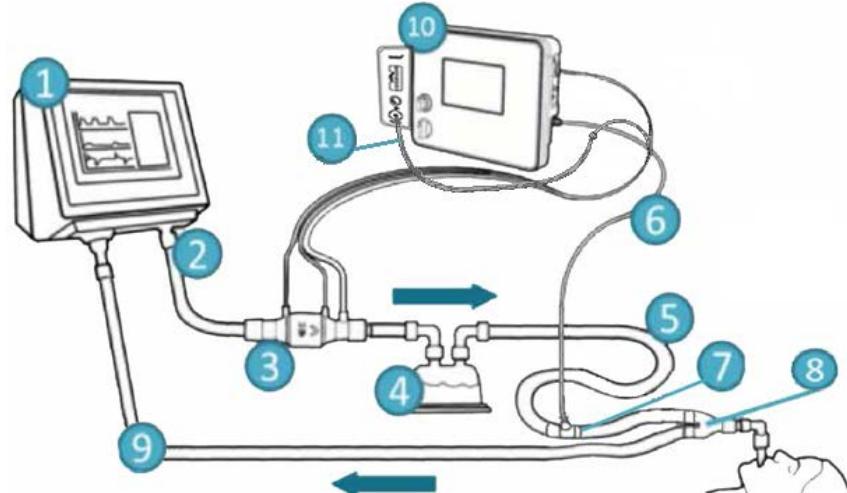
Figure 5-4

WARNING: To ensure that the proper NO dose is delivered, ensure that the oxygen flow meter on the NOxMIXER is turned OFF when using it with the ventilator.



Ensure that the ventilator is running and its flow rate matches the settings used for the NO dose calculations (with the Lookup tables or On-Screen-Guide).

1. Ventilator
2. Ventilator Inspiratory Port
3. NOxFLOW™ (use 22F or 15M to vent tube adaptors)
4. Humidifier
5. 0.7m-1.3m Corrugated Tubing (15mm or 22mm)
6. *NOxBOX_i* System Sample Line
7. 10M-10F, 12M-12F, 15M-15F or 22M-22F luer port connector
8. Patient Y-Piece
9. Expiratory Limb
10. *NOxBOX_i* + NOxMixer
11. Emergency Backup Line NOXKIT-EMER.



NOTE

The NOXKIT-EMER tubing needs to be connected to the Emergency Backup System (see Number 11).

6 OPERATION



WARNING: Operation of the NOxBOX Ltd. *NOxBOX_i*® system involves potentially hazardous procedures. Only trained and qualified personnel who have read and understood the instructions in this manual shall operate this equipment. Wear appropriate PPE and, if applicable, turn off the power before performing any installation, maintenance, repair, or troubleshooting procedures.

WARNINGS:

- The *NOxBOX_i* system is designed to be used solely with nitric oxide (NO). As such, the *NOxBOX_i* system must be operated in accordance with the indications and contraindications depicted in the NO drug literature and labeling. Please refer to these materials before use.
- When an alarm condition occurs, first ensure the safety of the patient before attending to the alarm diagnosis and/or system repair.
- The *NOxBOX_i* system is provided with a compatible external power supply. No other power supply should be substituted for use, as this may cause unexpected system performance that places the patient at risk. Additionally, it could also cause irreparable damage to the system.
- Devices that radiate high-intensity electromagnetic radiation could affect the correct operation of the *NOxBOX_i* system. Ensure that continuous monitoring of the system is carried out when such devices are in operation within close proximity to the patient.
- Do not improvise the *NOxBOX_i* system connections, components, or devices. Use only approved and supplied parts.



CAUTION: Do Not immerse the system monitor in liquid. Never use alcohol-based cleaning agents or those containing other organic solvents to clean the system. Vapors from such chemicals will damage the internal sensors. Alcohol-free instrument cleaning wipes are available from NOxBOX Ltd.



CAUTION: Check all safety devices at least annually or as otherwise required by local codes or manufacturer recommendations.

Properly maintain safety valves. Never bypass safety devices, and never operate the equipment outside its specified limits.



INFORMATION: Any accessory items, such as a ventilator or humidifier, must be operated and maintained in accordance with the manufacturer's instructions for the item. It is not the scope of this manual to describe the operation and control of such items.

The *NOxBOX_i* system performs two main functions:

1. Delivery control of NO into the inspiratory limb of the patient ventilator circuit.
2. Simultaneous monitoring of the inhalant sample to verify the NO dose level and the oxygen concentration being delivered to the patient and ensuring NO₂ levels are within acceptable limits.

These two functions operate in coordination to enable efficient dose delivery and maintain consistent drug administration conditions. In the event of a problem occurring in either of the functions (e.g., a delivery module failure), the secondary function (e.g., monitoring) will still fully function. In the same way, during basic maintenance routines such as zero-calibration, the delivery channel remains uninterrupted.

The system has a non-electronic Emergency Backup Delivery Mode NOxMixer to ensure that, in the event an Automatic Intelligent Delivery System failure, the NO drug can still be administered to the patient while a substitute system is implemented.

6.1 GAS DELIVERY SYSTEM

WARNING: At room temperature and atmospheric pressure, nitric oxide (NO) is a colourless, odourless, toxic, gas. NO is a corrosive and oxidizing substance. Refer to the gas SDS for safe handling information.



NO can combine with atmospheric oxygen to form nitrogen dioxide (NO_2). NO reacts rapidly with oxygen to produce NO_2 , which may further react to form nitric and nitrous acid in the presence of water (H_2O). This unwanted by-product needs to be monitored carefully and kept below 0.5 ppm for most applications, as NO_2 is extremely toxic and a severe pulmonary irritant.

The NO gas is a mixture of NO buffered in nitrogen. It is stored in high-pressure gas cylinders at a nominal fill of 150–200 bar (supplier dependent). A high-pressure regulator is attached to the valve connector of the gas cylinder. This regulator is set to a fixed outlet pressure of 4 bar when the cylinder valve is open, and a high-pressure contents gauge displays the actual fill-pressure of the cylinder.

A supply line hose connects between the regulator and the *NOxBOX_i*® system via quick-connect fittings. The *NOxBOX_i* system trolley can accommodate up to two NO cylinders, which are connected to the inlet Port 1 and Port 2 at the rear of the system respectively.

Inside the *NOxBOX_i* system, the two gas lines are combined through a robust automatic change-over system into a single inlet point. The auto change-over function will only draw from one supply cylinder until that cylinder is spent. Once this happens, the second line is opened to ensure a continuous delivery of NO to the patient.

The NO dose is entered, the ventilator flow pattern and volume are detected by the *NOxBOX_i* system, and the flow of NO delivered into the patient circuit is controlled to achieve the desired dose for the given conditions.

In the event of a malfunction in the automatic delivery circuit, the system alarms will display and sound to instruct you to engage the Manual Override Flow Mode. This is a backup delivery function that delivers the NO gas flow rates between 50–600ml. You can select the flow rate that best matches the current patient dose level using either the on-board simple delivery calculator, or by referring to the dose Look-Up Tables provided with the *NOxBOX_i* system.

6.2 MONITORING SYSTEM



WARNING: The sample stream flow rate is set to 225 ml/min. Check the trigger sensitivity of a ventilator in Synchronized Mode when using the *NOxBOX_i*® system to ensure that it is not being tripped by the sample stream flow.



INFORMATION: For patients on very low tidal volumes, it may be necessary to increase the bias flow to reduce the effective leak created by the *NOxBOX_i* system sample rate. For example, increasing bias flow from 2 L/min to 8 L/min can reduce apparent leak from 78% to 20%, and effectively reduce risk of NO_2 build-up.

A sample point is located close to the patient Y-Piece, which takes a small sample from the delivered inhalant gas mixture, pulled at a steady rate by the internal sample pump.

The sample gas is conditioned by passing through a water trap to remove condensate and a drying tube to achieve correct humidity, before passing across the three gas sensors where the sample is analyzed for the three constituent gases of interest NO, NO₂, and O₂.

An electronically controlled valve within the sample circuit can be switched to perform an automatic zero-calibration function. This allows the monitor to take a baseline reading of clean air to check and correct for sensor drift.

6.3 TOUCH SCREEN INTERFACE

6.3.1 BRIEF NAVIGATION GUIDE

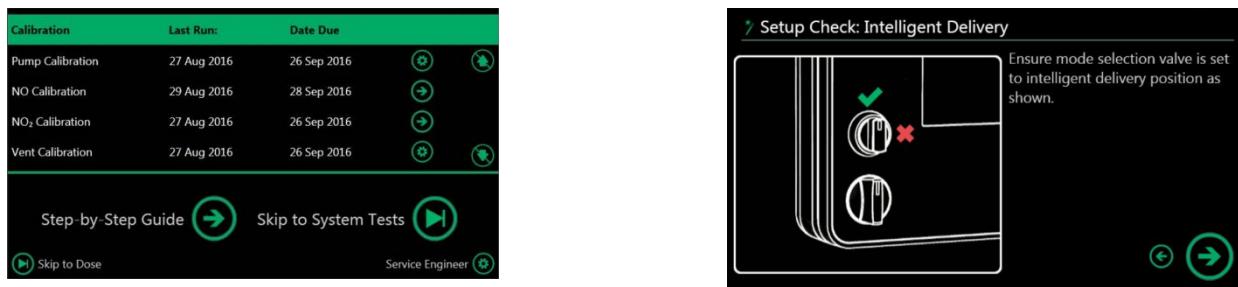


- The service key enables the Service Engineer log-in.
- Press this Next key to proceed to the next screen.
- Press this Back key to return to the previous screen.
- Press this key to accept or confirm the statement on-screen.
- Press this key to decline or deny the statement displayed on-screen.
- A grayed-out button indicates that the button is temporarily disabled. An action or test must be performed or completed to activate.
- Home Screen.
- Scroll is disabled.

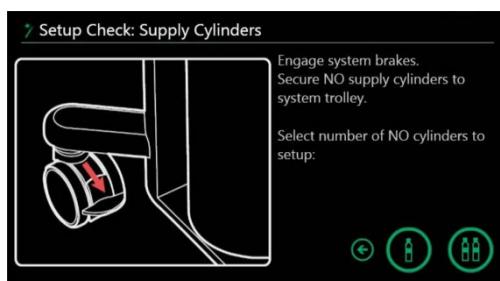
6.3.2 ON-SCREEN USER GUIDE

The *NOxBOX_i*® system has an integrated Quick Start Guide (QSG) that displays step-by-step instructions on the screen.

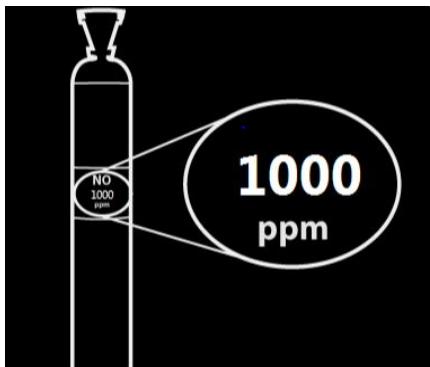
To navigate through these screens, follow the instructions by pressing the Next or Back buttons:



The system will guide you through either a single- or double-cylinder setup. Select the button that corresponds to the number of supply cylinders that are to be set up:



Check the gas supply concentration, and inspect the regulator for visible damage.



Setup Check: Inspect Regulator

Check regulator seals, surfaces and hose connections are free from visible damage.
Do not use damaged equipment.

Next Step

Attach the Regulator and connect the Supply Line.

Attach Regulator

Attach regulator to cylinder #1. Tighten firmly by hand.

Next Step

Connect Supply Line

Push and click-to-lock hose connector onto port #1 at rear of monitor.

Next Step

Open the cylinder valve, and then close the cylinder valve. Check the gauge reading, and then perform a Pressure Hold Test

Open Cylinder Valve

Fully open valve on cylinder #1. Gauge reading should be more than 20 bar to commence therapy.
If needle in red zone, cylinder needs to be replaced to complete setup.

Next Step

Supply Pressure-Hold Test

Close valve on cylinder #1. Observe gauge needle for 30 seconds.
Did needle remain stationary?

Next Step

Connect the NOxFLOW Sensor

Connect NOxFlow Sensor

Remove packaging from a new NOxFlow. Carefully uncoil the lines.

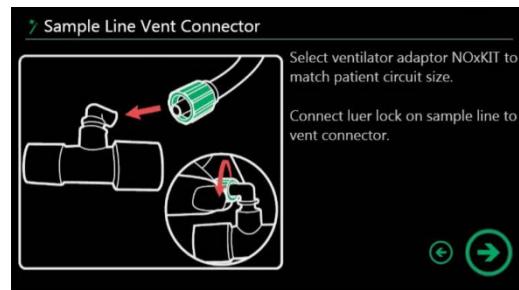
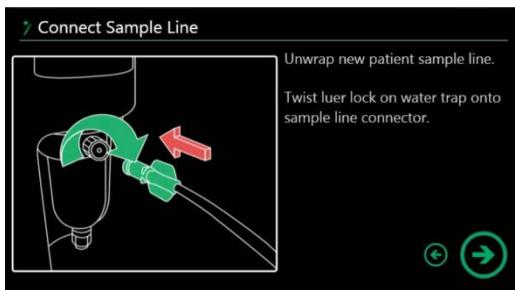
Next Step

Connect NOxFlow: Dose Line

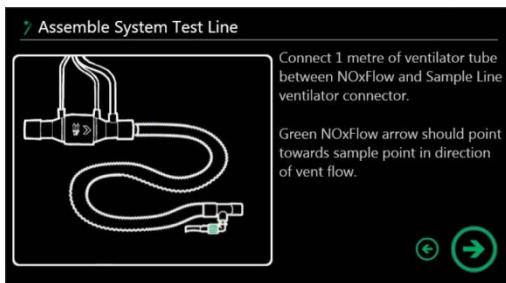
Screw luer lock on NOxFlow dose line to monitor port.

Next Step

Connect the Sample Line



Assemble the System Test



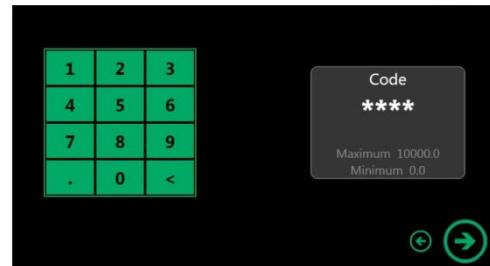
Users experienced in setting up the *NOxBOX* system may want to skip the detailed QSG. From the Home Screen, press Skip to System Tests.



The System must be correctly set up before running the System Tests. The on-screen or printed QSGs are provided to help with the correct set up. Experienced users may also skip directly to dose if they believe that the therapy is needed instantly by pressing Skip to Dose.

The system must be correctly set up before skipping to dose. The QSG and system tests are provided to help with the correct setup, and ensure functionality.

Service Engineers performing routine maintenance can directly access the Service Engineering Screens from the Home Screen. A valid Service Engineering Code is required to access this area.



6.4 SYSTEM TESTS

The *NOxBOX_i* system runs some system tests during startup to ensure correct function and safe operation.



The first of these tests is the Sensor Zero test. This requires no special setup to run correctly. The system will automatically draw an atmospheric sample of gas to establish a baseline for correct sensor operation.

The test lasts approximately two minutes. Once completed, the system will display pass or fail information for each sensor. In the event of a test failure, press Next and follow the on-screen instructions. The Home Screen will be displayed on successful completion.

Sensor Zero Test Running: Waiting for stable sensor readings.
Test may take up to 2 minutes.

	Reading	Target
NO	0.0 ppm	0.0 ppm
NO ₂	0.0 ppm	0.0 ppm
O ₂	20.9 %	20.9 %

Zero Calibration Successful

...

Sensor Zero Test Running: Waiting for stable sensor readings.
Test may take up to 2 minutes.

	Reading	Target
NO	0.0 ppm	0.0 ppm
NO ₂	0.0 ppm	0.0 ppm
O ₂	0.0 %	20.9 %

Zero Calibration Failed

...

From the Home Screen, the second test is the main System Test. This test requires the user to set up a test circuit. The system test is assessing whether the delivery and monitoring functions are operating correctly. Additionally, this is an important step to ensure that any buildup of NO₂ in the system head that may have occurred during storage is flushed out before connecting to the patient.

Assemble System Test Line

Connect 1 metre of ventilator tube between NOxFlow and Sample Line ventilator connector.
Green NOxFlow arrow should point towards sample point in direction of vent flow.

...

System Test Running: Waiting for stable sensor readings. Test may take up to 5 minutes.

	Reading	Target
NO	10.0 ppm	10.0 ppm
NO ₂	0.0 ppm	0.0 ppm
O ₂	96.0 %	95.0 %

...

The System Test may take up to five minutes to run. Once complete, the system will display pass or fail information for each sensor. In the event of a test failure, press Next and follow the on-screen instructions.

System Test Running: Waiting for stable sensor readings. Test may take up to 5 minutes.

	Reading	Target
NO	10.0 ppm	10.0 ppm
NO ₂	0.0 ppm	0.0 ppm
O ₂	94.9 %	95.0 %

System Test Successful

...

System Test Running: Waiting for stable sensor readings. Test may take up to 5 minutes.

	Reading	Target
NO	0.0 ppm	10.0 ppm
NO ₂	0.0 ppm	0.0 ppm
O ₂	20.9 %	95.0 %

System Test Failed

...

Once completed successfully, the *NOxBOX_i* system is ready for attachment to the patient to commence treatment.

6.5 CONNECTING TO PATIENT VENTILATOR

The sample point adaptor should be connected approximately 30 cm behind the Y-Piece to prevent contamination of the sample from exhaled breath. Connect the upstream end of the NOxFLOW sensor to the upstream inspiratory limb tubing. The NOxFLOW should be situated upstream of the humidifier. Maintain the optimum 1m distance of ventilator tube between the sample point and the dose introduction point on the NOxFLOW for best performance (between 0.7 and 1.3m is ideal). The system is now ready for dose entry and alarm setting procedures.

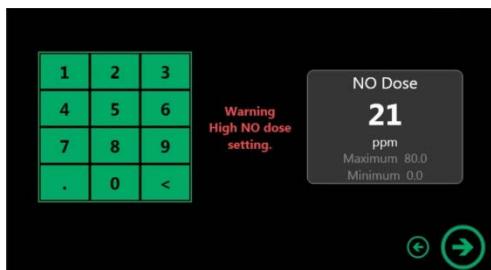
See section 5, Patient Circuit Setup, for detailed guidance.

6.6 DOSE ENTRY AND ALARM SETTING

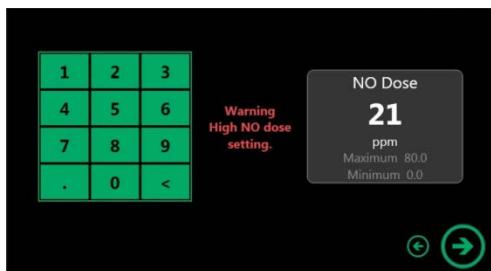
The *NOxBOX*[®] system provides a direct-input dose control with a resolution of 0.1 ppm across the dose range from 0.6–80.0 ppm. The alarm setting for the monitored gases have suggested default values that can be fully edited for the individual case.



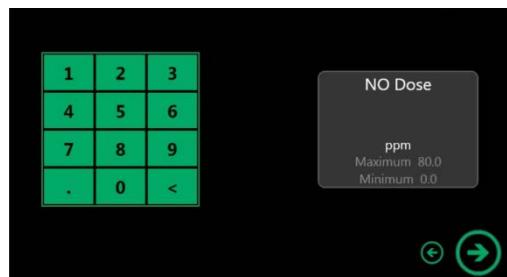
INFORMATION: Dose and alarm entry screens have limits on the values that can be set. These are displayed on each screen; the system will not allow the user to enter values outside these limits.



1. Enter a dose value between zero and 80 ppm using the keypad.
2. Press the delete key to correct entry errors.



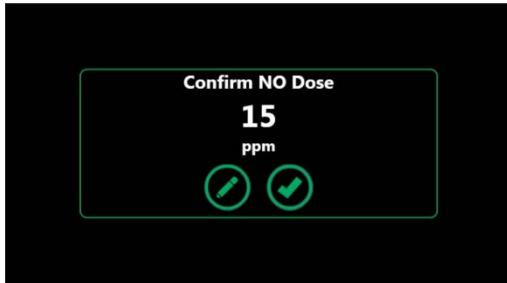
If the dose entered is greater than 20 ppm, a warning will appear to alert you that a high clinical dose value has been entered.



If a dose value of zero is entered, the system will alert the user that this will stop the treatment.

NOTE: All alarms will still function unless the regulator hoses are disconnected, where the system will enter Standby Mode.

3. Press Next to continue.



4. The system will display a confirmation screen for the dose entered.
5. To accept the displayed value, press the check mark.
6. To change this value, press the Edit button.

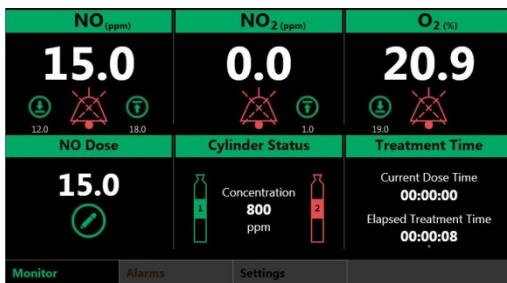


The system displays a summary of the entered dose and calculated alarm values.

- The system calculates a default alarm value for the NO High Alarm based on the confirmed NO dose entry.
 - The system calculates a default alarm setting for the NO Low Alarm based on the confirmed NO dose entry.
 - The system has a default NO₂ High Alarm setting of 1 ppm.
 - The system has a default O₂ Low Alarm setting of 19 percent.
7. To accept the displayed settings on this screen, press Next.
 8. To change any value, press the corresponding Edit button.

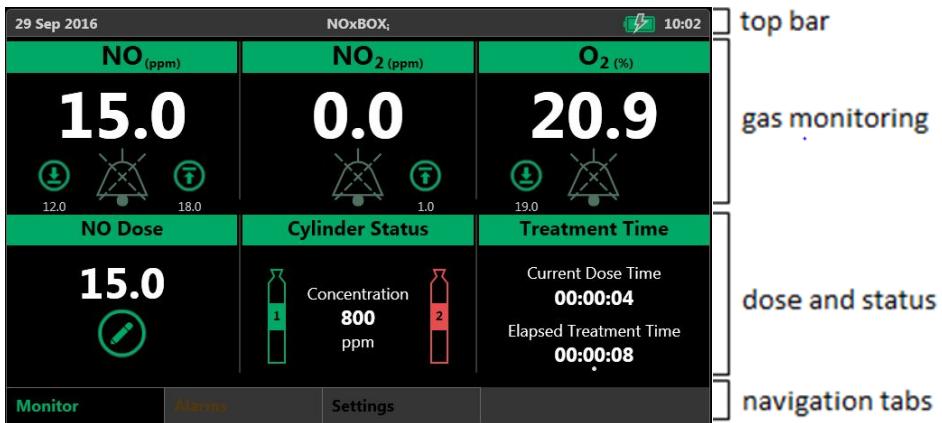


9. A final screen is displayed to commit the new dose setting to the patient. Press the check mark to commence delivery of this dose.
10. Press the cross (X) to reject this dose and return to the summary table of values for editing.



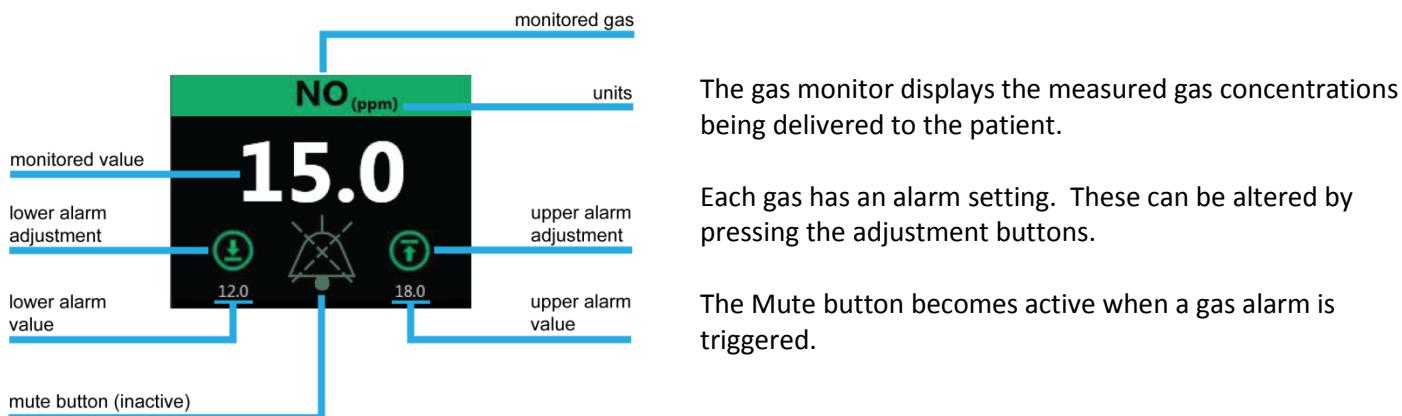
11. The system will display the main monitor screen. The system displays the gas concentrations being delivered to the patient.
12. During the first 30 seconds of delivery at a new dose level, the system will automatically mute the gas level alarms.

6.7 MAIN SCREEN DISPLAY



Top bar	Displays system time and date Battery status icon
Gas monitoring	Measured values of NO, NO ₂ , and O ₂ being delivered to patient Gas alarm setting display Gas alarm adjustment buttons Gas alarm mute buttons
Dose and status	Current NO dose setting NO dose edit button NO supply cylinder indicators NO supply cylinder concentration setting reminder Treatment time clocks
Navigation tabs	

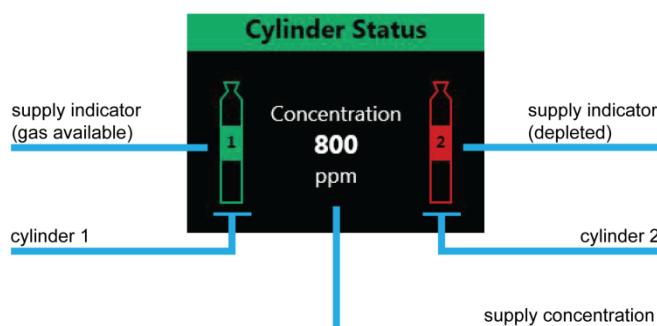
6.7.1 DETAILED AREAS OF MAIN SCREEN





The dose setting to be delivered to the patient is displayed in the NO Dose box.

Press the Edit button to change the delivered dose.



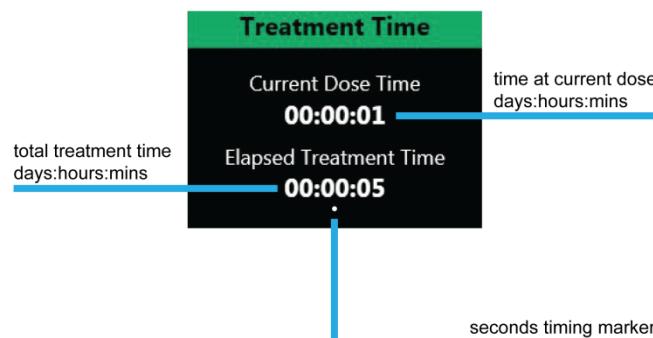
The NO supply cylinder status shows cylinders connected to the *NOxBOX_i* system.

The supply indicators warn when the cylinders are low. Check the pressure gauge on the regulator to confirm.

The system concentration setting must match the supply cylinders. Call the Service Engineer if this needs adjusting.



WARNING: The cylinder status is not an accurate representation of the gas remaining and, therefore, the cylinder pressure gauges should be checked to confirm.



The treatment time clocks show:

Total time patient has been on the *NOxBOX_i* system

Time patient has been receiving current dose

Both clocks show the time elapsed as:
Days : Hours : Minutes

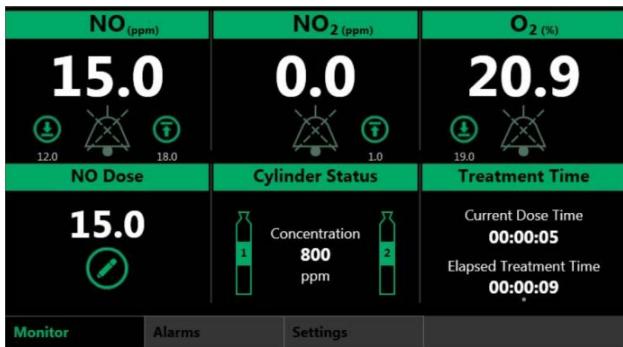
The seconds timing marker is below the lower clock.



Battery indicator icon: 1: on mains; 2: full charge; 3: charge low; 4: battery empty.

6.7.2 TABBED NAVIGATION

When in normal operation, the system will show the main monitoring and delivery screen.

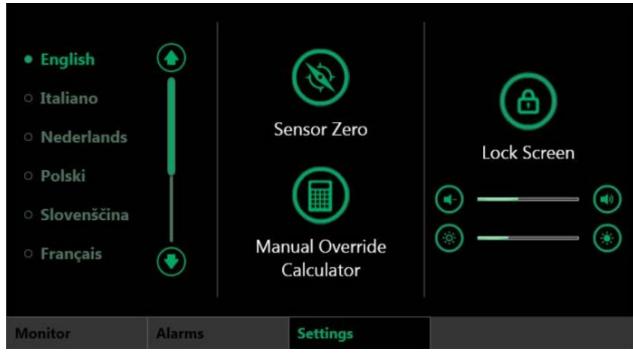


The Main Screen has tabbed navigation elements to allow the user to check the alarm history status for this treatment.

The figure shows the alarm history screen. It lists four alarms with columns for Description, Time, Date, and Resolved. The alarms are: Water Trap Full (Time: 15:03, Date: 08 Sep 2016, Resolved: -), O₂ Low Alarm (Time: 15:02, Date: 08 Sep 2016, Resolved: 15:03), NO Low Alarm (Time: 14:57, Date: 08 Sep 2016, Resolved: 14:58), and Zero Calibration Overdue (Time: 14:54, Date: 08 Sep 2016, Resolved: 14:55). At the bottom, there are tabs for 'Monitor', 'Alarms', and 'Settings', with 'Alarms' highlighted.

Alarm Description	Time	Date	Resolved
Water Trap Full	15:03	08 Sep 2016	-
O ₂ Low Alarm	15:02	08 Sep 2016	15:03
NO Low Alarm	14:57	08 Sep 2016	14:58
Zero Calibration Overdue	14:54	08 Sep 2016	14:55

The tab navigation also allows the user to adjust some settings preferences, such as language or screen brightness. From here, it is also possible to access the service engineering screens.



6.7.3 CHANGE DOSE AND ALARMS



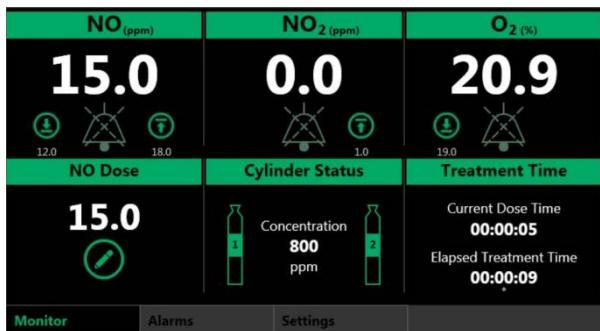
INFORMATION: When changing the dose, the system recalculates the alarm values to appropriate levels for the new dose setting. These values can be confirmed or edited before returning to the Main Screen.



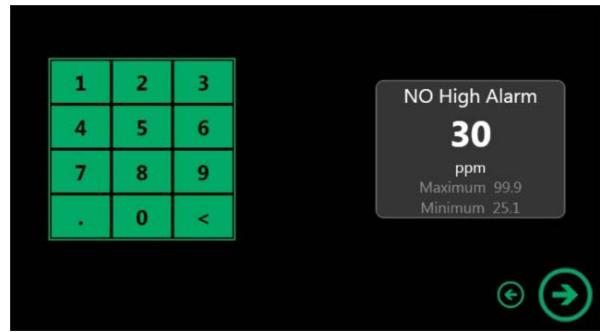
To change the dose from the main screen, press the dose Edit button.



The system will display the direct entry dose keypad. Follow the system instructions the same as when setting the initial dose.



To change the gas alarm settings, press the button corresponding to the alarm to edit (image shows edit high NO alarm).

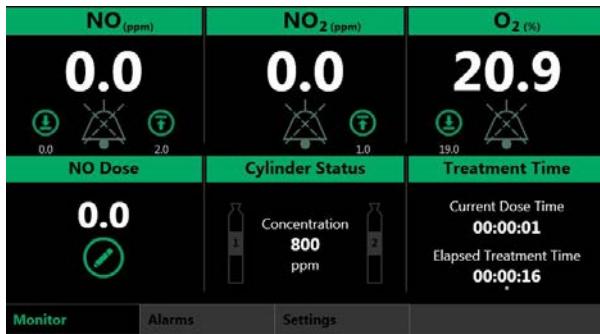


The edit dose screen shows the current alarm value. Press the Delete arrow to clear this value and input a new value.

Press Next to proceed; the system will return to the Main screen once the new setting is accepted.

NOTE: The alarm settings have limits beyond which it will not allow the alarm to be set.

6.7.4 STANDBY MODE



To enter Standby Mode, set the dose to 0 ppm, turn off the cylinder valve, and remove and depressurize the regulator hoses.

6.8 SCREEN LOCK

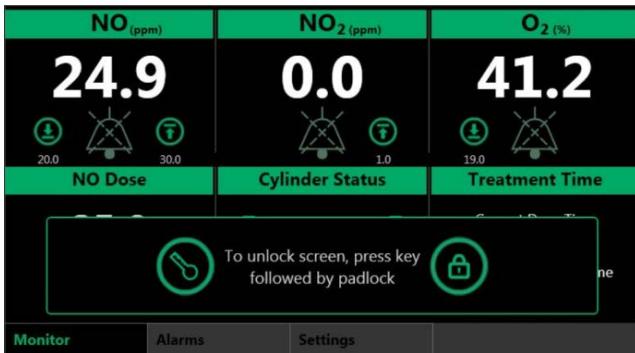


INFORMATION: In the event of an alarm, the screen will automatically unlock.

The Main Monitor Screen automatically locks itself if no interaction has occurred for 2–3 minutes. This helps prevent accidental interaction with the system settings.



When the screen lock engages, it appears on the screen for 10 seconds. This is then hidden so the full monitoring screen can be seen.



If the screen is touched anywhere while the screen lock is active, the screen unlock message will appear.

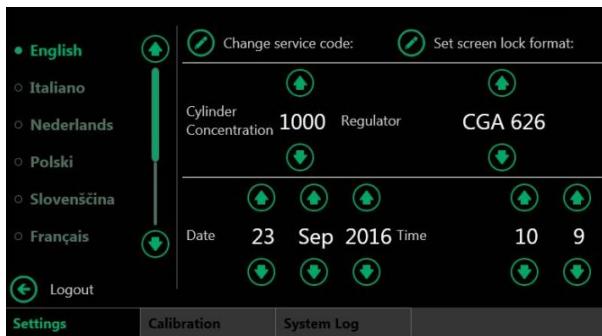


The system may be set so that the screen can only be unlocked with up to a 4-digit code. In this instance, a keypad is displayed.

Tap in a valid code, and press Accept to unlock the screen.

If the screen lock code has been forgotten, contact the Service Engineer.

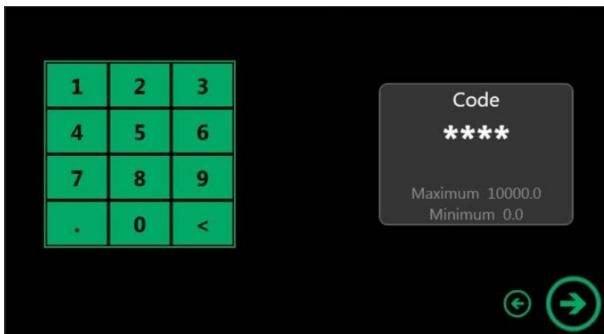
6.8.1 SETTING THE SCREEN LOCK FORMAT



The screen lock format is set in the Service Engineer area. The system default setting is for a standard (non-coded) screen unlock.

To change the screen lock format, log into the Service Engineer area and select “Set screen lock format.”

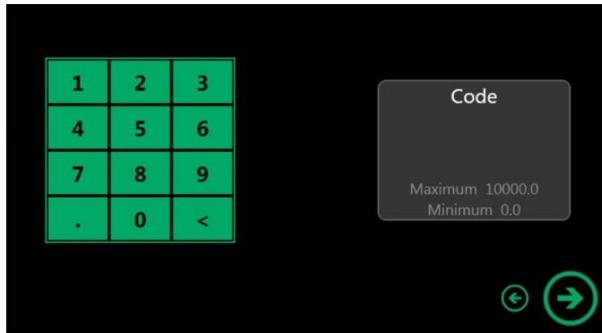
NOTE: The Service Engineer area is only available from the Start Screen.



To set screen format to a code unlock:
Enter up to a 4-digit code, and press next.

This is now the code needed to unlock the screen.

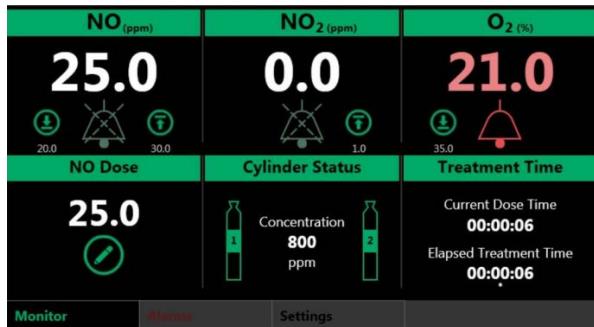
NOTE: System alarms will automatically unlock the screen.



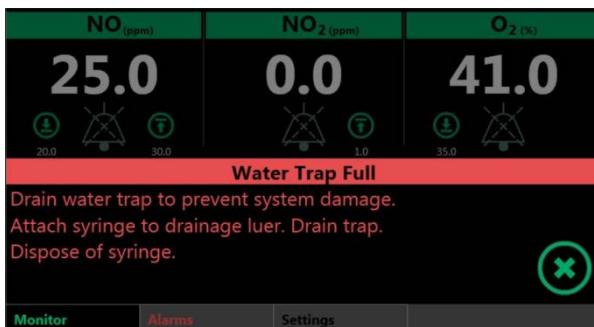
To set the screen format back to the standard non-coded format:

Select “Set screen lock format.” On the Keypad Screen, leave the field blank and press Next.

6.9 ALARMS



In the event of a monitored gas alarm being triggered, the monitored value flashes red and the gas alarm mute button becomes active. Press the mute button for a two-minute mute of the audible alarm element.



Alarm notices for detected alarm conditions are displayed across the lower half of the Main Monitor screen.

Pressing the buttons on the message will temporarily mute the audible alarm and dismiss the banner message.

Alarm Description	Time	Date	Resolved
Water Trap Full	15:03	08 Sep 2016	-
O ₂ Low Alarm	15:02	08 Sep 2016	15:03
NO Low Alarm	14:57	08 Sep 2016	14:58
Zero Calibration Overdue	14:54	08 Sep 2016	14:55

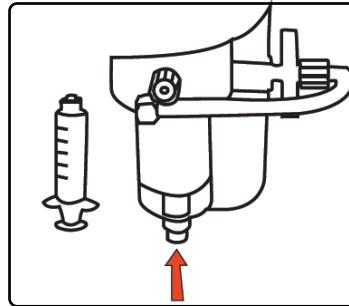
Navigation tabs at the bottom include 'Monitor', 'Alarms' (highlighted in red), and 'Settings'.

The Alarm History screen displays the last 20 alarm conditions in a scrollable list. The alarm description is color-coded to indicate the alarm priority. Any unresolved alarms are displayed at the top of the list.

The alarm trigger time and date are recorded in the table. Once the alarm is resolved, the time is recorded next to the entry. The full alarm history is recorded in the Treatment Log and can be recovered by a Service Engineer via a download function.

6.9.1 RED BANNER ALARMS

Supply Critical, Delivery Fault, Water Trap, Sample Line Blockage, Vent Flow Idle, and Battery Critical alarms are displayed in a single banner message with a basic guide instruction for alarm resolution. Press the cross (X) button to mute the alarm for two minutes and dismiss the banner message.



Drain the water trap using a disposable luer lock syringe. Attach it to the self-sealing plug located at the base of the water trap, and withdraw the plunger.

Unscrew the syringe, and dispose of it as per local guidelines.



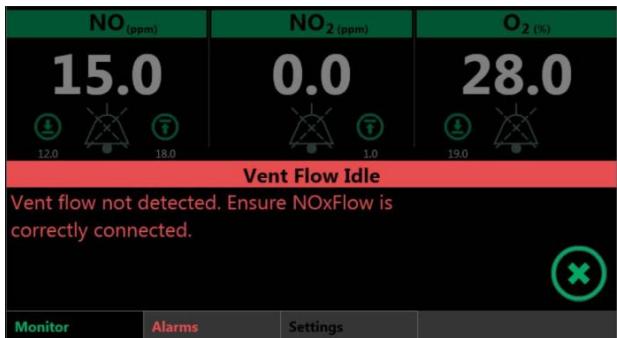
Check the sample line for kinks, knots, or pinching along the length of the line. Free the line to resolve.

If the line is damaged or blocked internally, replace it with a new sample line.



Restore the mains power to the *NOxBOX_i*® system. If it is not possible to restore the mains power, ensure the Manual Override is prepared to be switched on. See Section 6.12.

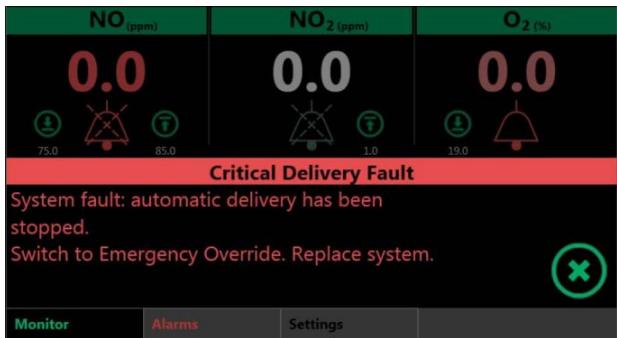
The system will automatically shut down when the battery charge runs out.



No vent flow detected by the NOxFLOW for more than 30 seconds.

Ensure that the NOxFLOW is installed correctly in the patient inspiratory limb. The green printed arrow points towards the patient.

This message may also appear where insufficient ventilator flow is present, such as with very low tidal volume applications. Increasing the bias flow may help resolve this alarm.



The NOxBOX_i system has detected a critical fault within the intelligent delivery system, and can no longer guarantee safe delivery function.

Engage the Manual Override (see Section 6.12), and replace the system as soon as practical.

Contact the Systems Engineer.

6.9.2 GAS SUPPLY ALARMS



An amber banner warning alarm is triggered when one cylinder is running low while there is a good second supply cylinder detected. To resolve this alarm, switch off the empty gas cylinder at the valve. Remove the gas supply line from the rear of the monitor and depressurize the line.

The system will automatically switch to the full cylinder for continuous treatment.

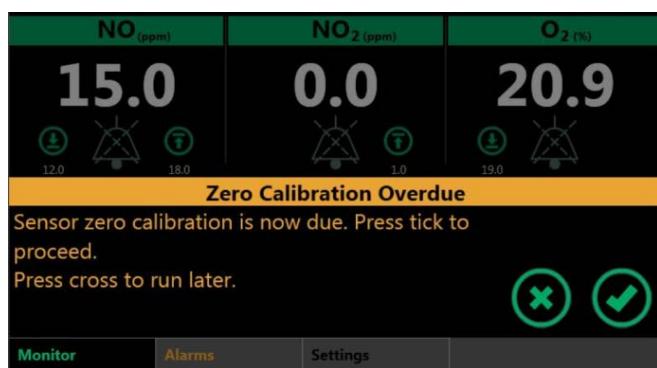
Alternatively, press the cross button to mute the alarm for 24 hours and discuss the banner message.



A red banner critical alarm is triggered when the current supply cylinder is running low and there is either no other cylinder detected or the pressure detected in the other cylinder is also running low. To resolve this alarm, follow the on-screen instructions to connect a new supply cylinder to the alternate NO inlet at the rear of the monitor.

The system will automatically switch to the full cylinder when the current supply cylinder runs too low.

6.9.3 CALIBRATION OVERDUE



Zero Calibration:

During operation, the system requires a zero calibration once every 24 hours. The first zero is performed during setup as part of the system tests.

An amber reminder message flags up after 24 hours use to prompt the user to perform the zero test. The test takes approximately two minutes to complete and requires no special connections.

During this test, the monitoring and alarms are offline; however, delivery remains unaffected. Refer to Section 6.10 for full details.

6.9.4 OTHER ALARMS AND SYSTEM ALERTS



Manual Override:

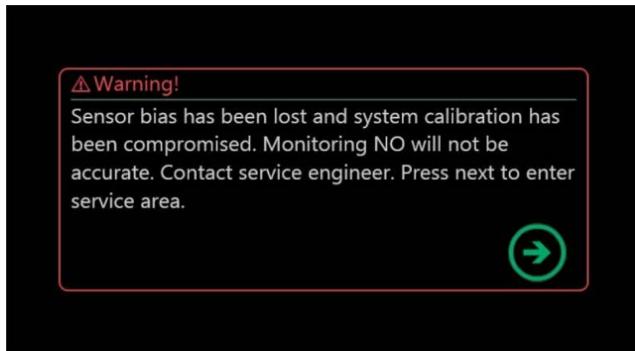
See section 6.12. This alarm banner will display when the Manual Override Mode is engaged.



The NOxBOXi System Diagnostics:

The system performs self-tests at setup and during operation to ensure that safe performance is maintained. In the event that a critical test fails, the system will display a full-screen notice indicating that the system can no longer be used safely.

Engage the Manual Override Mode, and replace the system as soon as practically possible. Alert the Systems Engineer.

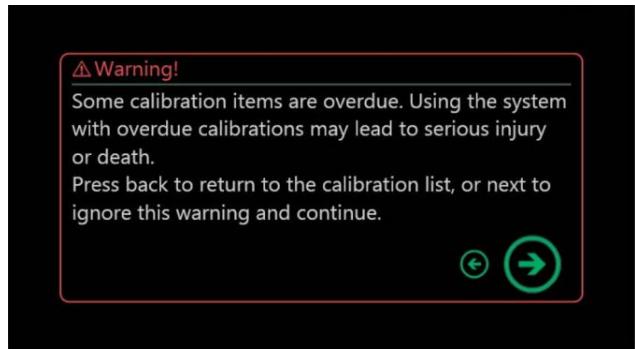


Sensor Bias Lost:

System sensors require a constant, very low trickle charge to maintain their calibration. The system will extend bias settling time. In the event that the system is not stored on mains power charge, after an extended period of time, the battery may completely discharge and the sensors will lose their calibration bias.

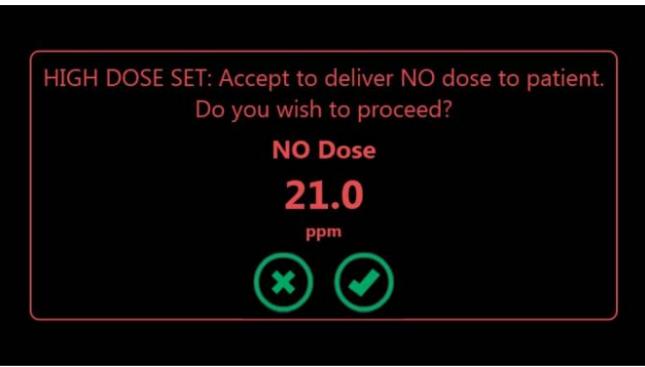
If this has occurred, the system will display this screen at startup.

The system must be fully calibrated before use to ensure correct and safe system performance. Contact the Service Engineer.



Calibration Overdue Warning:

The system will display this warning if the user proceeds without calibrating when the calibration is overdue.



High Dose Set:

Setting the NO dose above 20 ppm will display warning messages so the user is aware that a high clinical dose setting has been selected.

Before administering a high dose setting to the patient, the system will display this warning to alert the user to the dose setting selected.



Stop Treatment Set:

To stop administering Inhaled NO therapy, set the *NOxBOX* system dose level to zero.

The system will display warning messages so the user is aware that the stop delivery of Treatment Mode has been selected.

Before stopping the treatment, the system will display this warning to alert the user.

6.10 ZERO CALIBRATION DURING DELIVERY

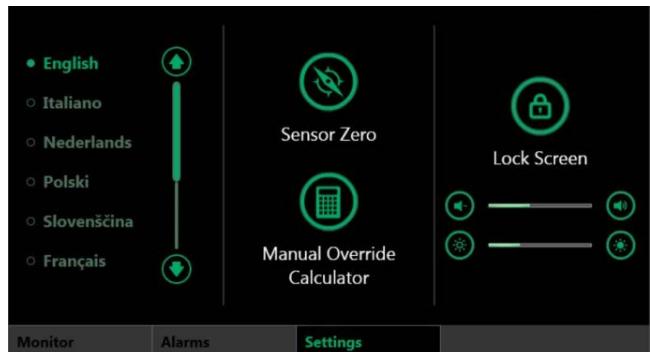


INFORMATION: Zero Calibration is an important maintenance test that the system can run without interruption to the NO dose delivery function. Zero calibration takes approximately 2–3 minutes to complete, during which time the monitoring and alarm functions will be offline. No special connections or tools are required to perform zero calibration, just follow the simple on-screen instructions.

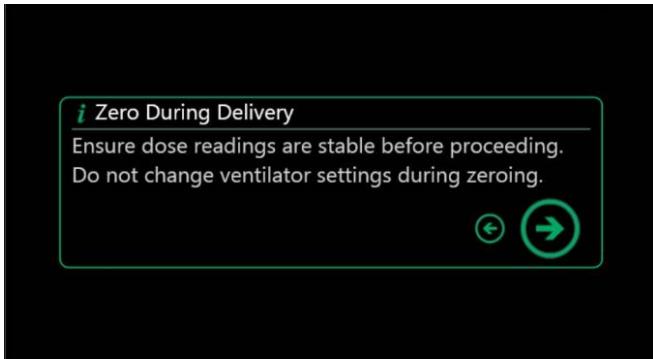
Zero Calibration is automatically performed on system power-on. The results of the zero calibration are displayed during the setup procedure before performing the system test.

During use, the system automatically reminds you once every 24 hours to perform the zero calibration procedure. This helps maintain the accuracy of the monitoring system and is a regular quick check to ensure safe performance of the system.

You can perform the zero calibration procedure at any time. To perform a zero calibration from the main screen:



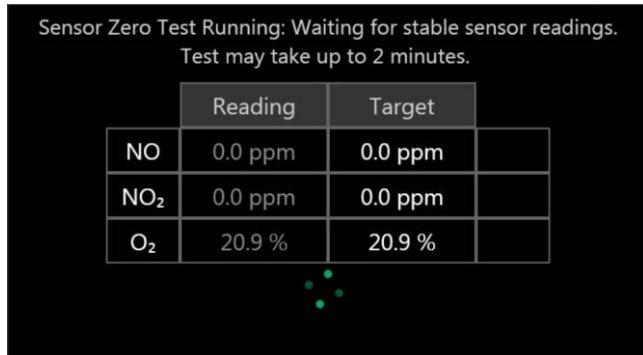
1. Select the Settings tab, and press Sensor Zero.



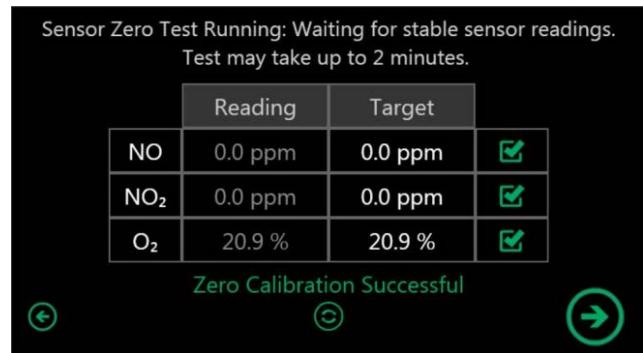
2. When entering the zero calibration screens from either the alarm state flag or from the Settings Screen, the following message is displayed.

3. Press Next to continue with the zero calibration.

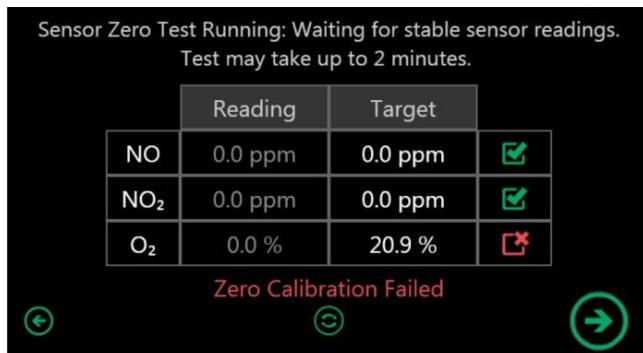
4. Press Back to return to the previous screen.



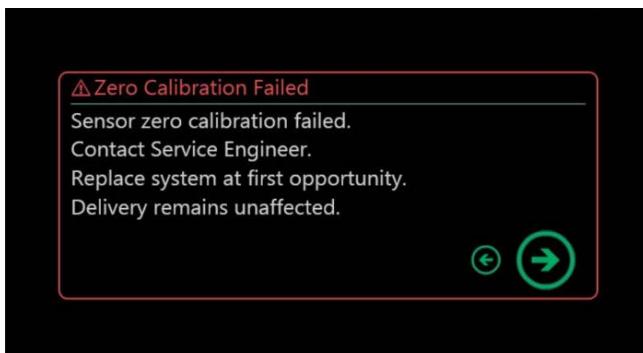
5. The zero test will take approximately 2 minutes to run. A progress animation is displayed under the test table.



6. If all sensors perform within the expected parameters, a “Zeroing Successful” message is displayed, with green check marks against each sensor result.
7. Press Next to return to the main screen. The monitored gas values will take a minute to read the true gas delivery values.



8. If one or more sensors fail to perform within the expected parameters during the zero calibration, a “Zeroing Failed” message will appear, and any sensors that failed to meet the performance criteria will display a red cross next to them.
9. Press Next for instructions.



10. If the zero calibration fails, the system will prompt to contact the service engineer and replace the system as soon as possible. The system will still return to its normal monitoring display and can be used to deliver NO, but caution must be used when operating the system with an active sensor fault.

6.11 USER SETTINGS SCREEN



Changing Display Language:

On the User Settings Screen, change the system display language by selecting the appropriate name



Change volume and brightness

Alter the volume of the screen interactive ‘beep’:

1. volume up.
2. volume down.

NOTE: This does not affect the volume of any system alarm.

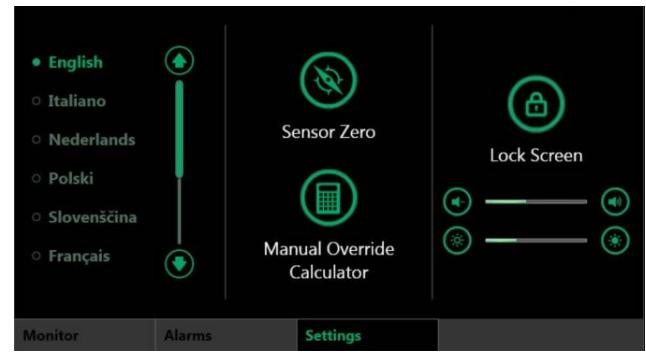
Similarly, adjust the display brightness:

3. brightness up.
4. brightness down.

Access Zero Calibration:



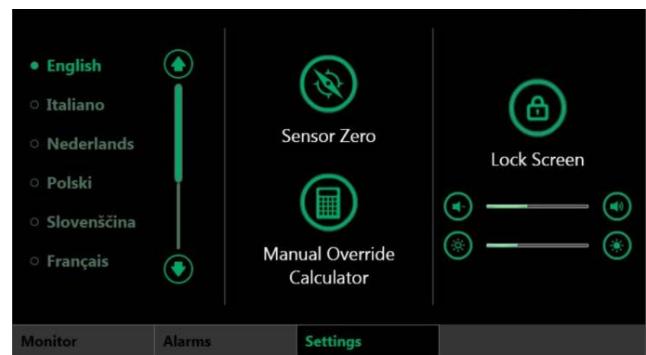
The User Settings Screen provides access to the daily zero calibration function. A reminder is displayed on the main monitor each time this is due (once every 24 hours from system startup). The notice can be dismissed if the timing is not suitable (e.g., patient dose recently changed and still adjusting).



Access the Calculator:



The Manual Override Calculator (refer to section 6.12.1) provides guidance to select a simple delivery bypass setting from 50-600ml to best match the patient requirements.



Calibration	Last Run:	Date Due		
Pump Calibration	27 Aug 2016	26 Sep 2016		
NO Calibration	29 Aug 2016	28 Sep 2016		
NO ₂ Calibration	27 Aug 2016	26 Sep 2016		
Vent Calibration	27 Aug 2016	26 Sep 2016		

Step-by-Step Guide Skip to System Tests

Skip to Dose Service Engineer

Access to Service Engineer Area:



The Service Engineer functions can only be accessed from the Start Screen. A valid code is required to access this area to prevent an accidental change to vital system settings.

6.12 MANUAL OVERRIDE—MANUAL BAGGING AND EMERGENCY BACKUP

The NOxBOX_i[®] system is equipped with a manual override delivery option to ensure continuous NO delivery via NOxMixer, for instance, during manual bagging operation. In case of extreme conditions such as complete power loss or a catastrophic failure of the Intelligent Delivery System, Manual Override can also be used as an emergency backup (see section 5.5 for setup).

NOTE: During manual override, NO will only be delivered from NOxMixer.



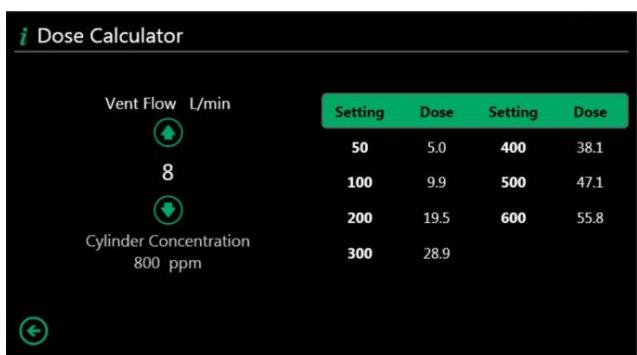
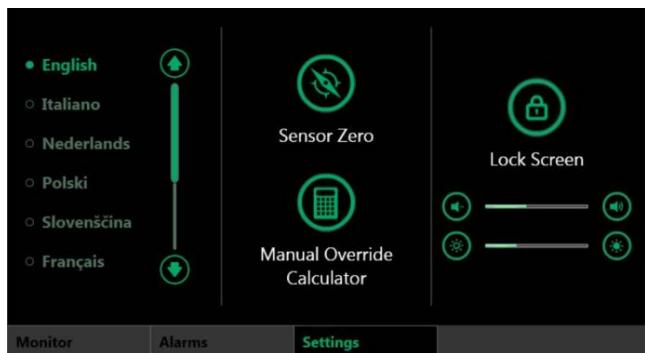
Warning: During manual override mode, the NOxBOX_i system has the potential to deliver very high doses of NO, possibly exceeding the measuring range of the NO sensor.

There are three controls associated with manual override delivery:



At commencement of NO delivery to the patient, it is advisable to check which flow setting on the Manual Override System would best suit the current treatment session, and set the flow selector valve to this value.

6.12.1 DETERMINE CORRECT FLOW SETTING



1. Access the Manual Override Calculator from the User Settings Screen

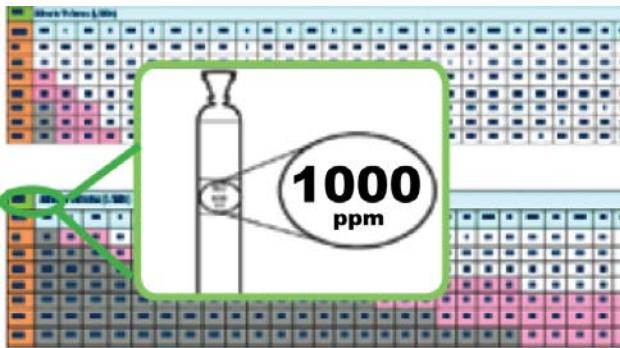
2. Use the arrow keys to adjust the ventilator minute flow to match the patient ventilator settings.

3. The calculator table indicates the approximate expected NO dose delivery for each of the NO flow settings (50–600ml) combined with the vent/oxygen flow.

4. Turn the Manual Override manual flow control valve to the value that most closely matches the desired dose in the event of engaging the Manual Override for both manual bagging and emergency backup.

5. Once flow is set, the system is ready to allow safe engagement of the Manual Override Mode if required during this treatment.

6.12.2 USING THE PRINTED LOOK-UP TABLES



Alternatively, the lookup tables in the operating instructions could be used to determine proper dose settings. Select the table for the NO cylinder concentration being used.

A printed lookup table for NO cylinder concentrations. A green circle highlights a cylinder icon and the number '1000 ppm'.

Find the flow settings on the horizontal line that most closely matches the patient settings.

Each line setting from 50-600 ml displays the approximate expected NO dose delivery for the particular patient flow based on a 1m length of tubing between the NOxFLOW and the sample line connection.

Turn the Manual Override Flow Valve to the setting most closely matched to the desired patient dose.

6.12.3 ENGAGE MANUAL OVERRIDE – MANUAL BAGGING AND EMERGENCY BACKUP

Ensure the Manual Override Flow Valve is positioned to the most appropriate flow setting (see right).

Turn the mode selection valve to the manual override position.

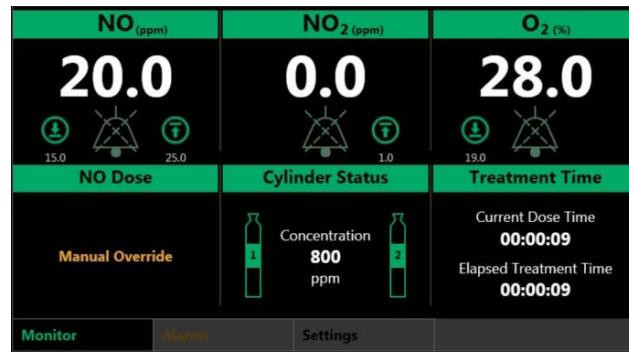
The system will now deliver a continuous stream of NO from the outlet of the NOxMIXER.

For the setup procedure for Manual bagging and Emergency backup, refer to section 5.5.



The system screen will display a warning message that the system is delivering through the Manual Override Mode. Press the cross (X) to dismiss this message.





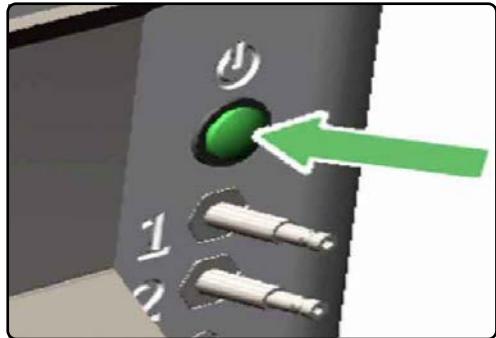
The “NO Dose” area of the Main Screen shows a constant reminder that the system is on Manual Override. To revert to intelligent delivery, position the mode selection valve to vertical.

6.12.4 MANUAL OVERRIDE FLOW SELECTOR: APPROXIMATE NO FLOW VALUES

50	50 cc/min
100	100 cc/min
200	200 cc/min
300	300 cc/min
400	400 cc/min
500	500 cc/min
600	600 cc/min

Note all values shown are approximate to +/- 15%. Refer to the Look-up tables for indication of the dose per ventilator flow rate. Monitoring of patient dose must be implemented when using Manual Override flow delivery of NO.

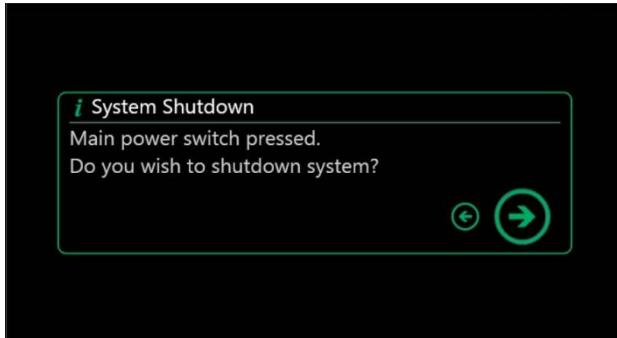
6.13 SHUTDOWN



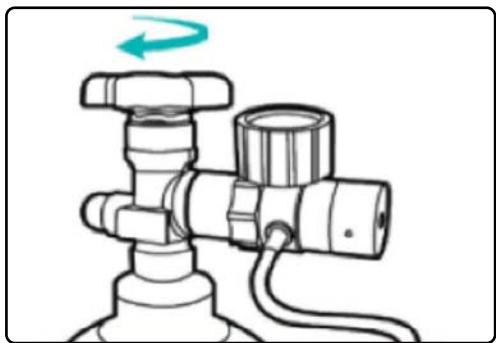
When ready to shut down the system, press and hold the power button on the monitor for two seconds until the System Shutdown screen is displayed.



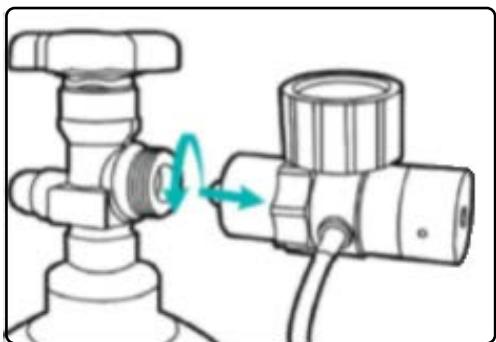
CAUTION: Do not hold the green power button down for more than 3 seconds as this could damage the NOxBOX_i® system.



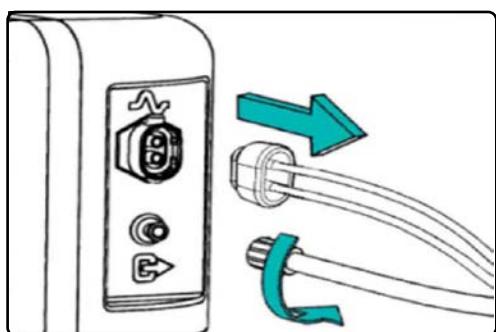
Confirm shutdown on screen.
Follow on-screen instructions.



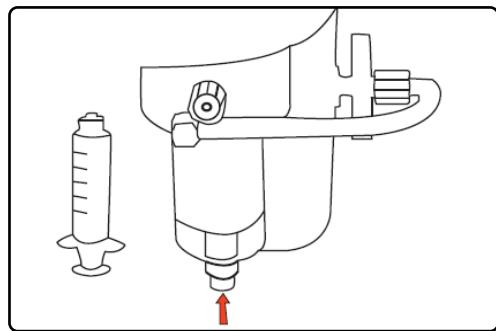
Fully close each cylinder and depressurise the supply lines using the purge needle.



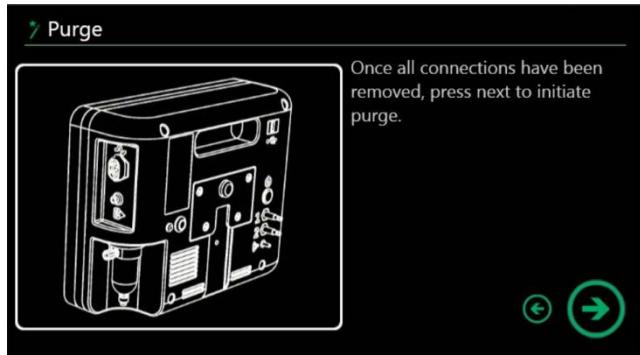
Remove the regulator from each cylinder and stow it on the system trolley.



Remove all single-patient use devices from the monitor and dispose of them according to local regulations.



Drain the water trap and dispose of the drainage syringe. Recommend cleaning inside the water trap with instrument wipes before storage.



On completion of the last instruction screen, the system will purge and shut down safely ready for storage.

NOTE: Alarm band and sound will be heard on shutdown. System should be stored attached to suitable mains supply.

7 MAINTENANCE AND REPAIR



WARNING: Maintenance and repair of the NOxBOX Ltd. NOxBOX_i[®] system involves potentially hazardous procedures. Only trained and qualified personnel who have read and understood the instructions provided by NOxBOX Ltd. shall work on this equipment. Wear appropriate PPE, and, if applicable, turn off the power before performing any installation, maintenance, repair, or troubleshooting procedures.



WARNING: NOxBOX_i system gas regulators can only be serviced and repaired by the manufacturer or suitably qualified engineers working in appropriate conditions who have undergone formal training with BPR Medical. Regulators are safety critical devices. No tools should be used on these devices for any reason.



Caution: Never bypass safety devices, and never operate the equipment outside its specified limits.



Caution: Check all safety devices at least annually or as otherwise required by local codes or manufacturer recommendations. Properly maintain safety valves. Never bypass safety devices, and never operate the equipment outside its specified limits.



Information: All repairs and component replacements must be undertaken by a suitably qualified Service Engineer. Please contact your supplier for service advice and support. The system may only be serviced and repaired in accordance with the maintenance written instructions provided by NOxBOX Ltd. The system should not in any way be altered without approval from the manufacturer. All replacement components must be approved for use with the system. The system user has sole responsibility for any malfunction that arises from improper use, incorrect maintenance, faulty repair, damage, or alteration by any individual not qualified by NOxBOX Ltd. to undertake these measures.

The NOxBOX_i system must be subjected to regular service inspection and maintenance routines as defined by NOxBOX Ltd. A faulty or defective system should not be used. System components that are damaged, broken, missing, visibly worn, deformed, or contaminated should be replaced or repaired immediately.

7.1 PERIODIC MAINTENANCE

Reliable and robust system performance is dependent on maintaining and servicing the *NOxBOX_i* system in accordance with the advice and training provided with this unit. Table 7-1 lists periodic maintenance tasks for the *NOxBOX_i* system.

Table 7-1
Periodic Maintenance Tasks

Frequency	Task(s)
During Use	<p>Check the NO supply cylinder pressure gauge daily. Cylinders with lower than 20 bar pressure must be replaced.</p> <p>Perform a zero calibration of the sensor (the system will prompt you to do this once every 24 hours).</p> <p>Drain the water trap when the Water Trap Full alarm sounds.</p>
Between Patients	<p>Dispose of single-patient use items.</p> <p>Replenish the system kitting for any single-patient use items.</p> <p>Replace and report any damaged or missing accessory and connection items.</p> <p>Perform a full-scale sensor calibration (this must be performed by trained personnel).</p> <p>Drain water trap and clean with NOxBOX Ltd. approved wipes.</p> <p>Clean unit with NOxBOX Ltd. approved wipes.</p>
Every 30 days	<p>Perform a full-scale sensor calibration (this must be performed by trained personnel).</p> <p>Perform a Pump calibration (this must be performed by trained personnel).</p> <p>Perform a Vent calibration (this must be performed by trained personnel).</p>
Every 12 months	Perform a 12 month service or return to NOxBOX Ltd. for this service.
Every 24 months	Perform a 24 month service or return to NOxBOX Ltd. for this service.

7.2 SYSTEM SETTINGS

The Service Engineer section is password protected to prevent accidental alteration of the system by an untrained user. In the event of forgetting the Service Engineer code, please contact your distributor or NOxBOX Ltd. for assistance.

7.3 CLEANING THE *NOxBOX_i* SYSTEM



WARNING: Ensure that the unit is turned off and the power cord is completely disconnected before cleaning the *NOxBOX_i* system.

Follow these precautions when cleaning the *NOxBOX_i* system:

- The sensors inside the system can be damaged by exposure to alcohol or volatile organic compound (VOC) spray or fumes. Do not use alcohol- or VOC- based cleaners on this system. Alcohol-free instrument cleaning wipes are available from NOxBOX Ltd. that are suitable for cleaning the *NOxBOX_i* system monitor.
- Clean external surfaces and the touchscreen panel using a damp, soft, lint-free cloth.
- Do not spray or splash cleaning fluids directly onto the system surfaces. Apply cleaning fluids with a clean, soft lint-free cloth, and avoid excessive wetting of the system. Take extra care around all connectors to prevent fluid from entering and damaging the system.
- Only use mild soap and water or an approved disinfectant for cleaning the *NOxBOX_i* system. Always follow manufacturer's recommendations when using any disinfectant.

- Do not clean the system with organic solvents, glass cleaner, petroleum-based solvents, alcohol, or acetone-based solvents.
- Do not autoclave or gas-sterilize the system.
- Do not use any abrasive cleaning pads or cleansing fluids on the *NOxBOX_i* system, and take particular care not to scratch the touchscreen panel.
- To prevent damage to the touchscreen, avoid excessive pressure when cleaning the touch screen panel.
- Ensure that the system is completely dry before returning it to use after cleaning. Alcohol-free instrument wipes approved for use with the *NOxBOX_i* system are available from NOxBOX Ltd.

7.4 CALIBRATION



Caution: Temperature may affect the accuracy of the *NOxBOX_i*® system monitoring function. The instrument should be calibrated at the temperature at which it is expected to be used.



Caution: In order to correctly calibrate the *NOxBOX_i* system, ensure that the pump flow is checked and, if necessary, adjusted before performing sensor calibrations.



Caution: Always perform a sensor zero calibration before performing the full-scale calibration.

7.5 SYSTEM REPLACEMENT PARTS

Picture	Item	Order Code(s)
	2 x Regulator (refer to NO gas supplier for valve connection designation)	
	2 x Regulator hoses	FXS543

Picture	Item	Order Code(s)
	Mains Power Supply Model: GSM90B24-P1M Input: 100-240VAC, 50/60Hz, 1.3-0.6A Output: 24V = 3.75A, 90W MAX Use only this power supply	<i>NOxBOXi</i> System-MAIN
	Oxygen Hose (refer to gas supplier for connection designation)	CON178
	Portable ambient alarms for NO and NO ₂ :	
NO Alarm		NOXAIR-NO-V
NO ₂ Alarm		NOXAIR-NO2-V

7.6 DISPOSABLE SYSTEM ACCESSORIES

The following single-patient use accessories are available from NOxBOX Ltd. for the *NOxBOXi®* system.

Part Code	Description	Image
NOXFLOW-2	Size 2 single use flow control unit	
NOXBOXI-SAMPLE	Sample line for <i>NOxBOXi®</i> system	
WT-DRAIN	Water trap drainage syringe	
FIL063	Hydrophobic Filter	
FIL064	Nebuliser filter	

Part Code	Description	Image
NOXFLOW-CON	Single use 22f – 15m straight ventilator/humidifier connector for NOXFLOW-2	
FXS555	22mm One-way valve for use with certain HFO ventilators.	
NOXKIT- EMER	Single use 1.8m tubing with a female luer for connection between NOxMixer and NOxFLOW during Emergency Backup Mode.	
NOXKIT-2-22	Single use delivery and sampling kit - include 3 x 22mm male - 22mm female, 7.6 port connector, 1.8m Sample line, 1 x Elbow luer lock, NOXFLOW-2, Water trap drainage syringe, FIL063 (hydrophobic filter)	
NOXKIT-2-15	Single use delivery and sampling kit - includes 1 x 15mm male - 15mm female, 7.6 port connector, 2 x 15mm male - 15mm male 1 x Elbow luer lock, NOXFLOW-2, Water trap drainage syringe, 1.8m Sample line, FIL063 (hydrophobic filter)	

Part Code	Description	Image
NOXKIT-2-12	Single use kit for adapting 10mm kit to 12mm circuits, FIL063 (hydrophobic filter)	
NOXKIT-1-10	Single use delivery and sampling kit - includes 2 x 10mm male - 10mm male, 7.6 port connector, 1 x 10mm male - 10mm female, 1 x Elbow luer lock, NOXFLOW-2, Water trap drainage syringe, 1.8m Sample line, FIL063 (hydrophobic filter)	
NOXBOX-I TEST	System test kit – Includes 1,200mm corrugated tubing – sample line – oxygen line – 22f – 6mm oxygen line connector – NOXFLOW.	
CON158	Gas sampling port connector for manual bagging.	

7.7 WARRANTY

For a period of twelve (12) months from the date of shipment, NOxBOX Ltd. warrants the *NOxBOXi®* system and trolley (excluding parts listed below) to be free of defects in materials, workmanship and to conform to the description of the product contained in this Technical Guide, provided that the same is properly operated under the conditions of normal use, that regular periodic maintenance and service is performed and that replacements and repairs are made in accordance with the instructions provided. NOxBOX Ltd.'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, in its original packaging and prepaid* to NOxBOX Ltd. or the local representative.

This warranty shall not apply if the product has been repaired other than by NOxBOX Ltd., an authorised NOxBOX Ltd. representative trained in repairs or in accordance with those individuals trained by NOxBOX Ltd. in repairs, or altered by anyone other than NOxBOX Ltd., or if the product has been subject to abuse, misuse, negligence, or accident.

*Prepaid means packing, carriage, taxes, import duties and any other costs incurred in sending the product back for repair/replacement and the same for return.

8 ALARMS TROUBLESHOOTING



Information: The *NOxBOXi®* system is equipped with audible and visible alarm notifications; this chapter is a guide to the alarm conditions that can occur and common actions for alarm resolution. All alarms are graded into high priority or medium priority alerts.



Information: In all instances of alarms sounding, the health and condition of the patient must be ensured before attempting to resolve any issue with the *NOxBOXi* system.

8.1 ALARM PRIORITIES

The system alarms are color-coded to help identify the priority of the detected issue. Additionally, the two alarm priorities each have an audible warning to help differentiate them.

Priority	Color	Meaning
High	Red 5-Tone Pattern and Red L.E.D. Alarm Strip	Critical problem detected. Condition poses immediate threat to patient health or correct functioning of the <i>NOxBOXi®</i> system monitor. Alarm condition should be diagnosed and resolved immediately.
Medium	Amber 3-Tone Pattern	Problem detected. Condition may impair the functioning of the <i>NOxBOXi</i> system. If left unresolved, the problem may worsen and cause a high-priority alarm condition.

NOTE: When an alarm sounds and displays, the health and condition of the patient must be ensured before attempting to resolve any *NOxBOXi* system issue(s).

8.2 NOTIFICATIONS AT SWITCH ON

A series of screen notifications are identified below. These notifications may display at startup (before the Home Screen displays) if an issue is detected with the *NOxBOX_i*® system.

May Display at Startup (before the Home Screen displays)		
Notification	Possible Cause	Recommended Action
NOxBOX_i System Diagnostics	The <i>NOxBOX_i</i> system performs self tests at startup and during operation to maintain safe performance. If a critical test fails, a full-screen notice displays to identify that system use is not safe.	Press the on-screen reset button. If another system is not readily available and the patient requires therapy, start the Manual Override Mode, replace the system as soon as possible, and alert the Service Engineer.
Sensor Bias Lost	The NO sensor requires a constant, very low-trickle charge to maintain its calibration. When the system is not stored on the mains power charge, the battery may completely discharge after an extended period and the sensors lose their calibration bias.	When a power loss occurs, connect the unit to the mains power and allow 6 hours for unit charging before calibrating the NO sensor and re-commissioning the unit. If another system is not readily available and the patient requires therapy, start the Manual Override Mode, replace the system as soon as possible, and alert the Service Engineer.
	The NO sensor is sensitive to extreme temperature variation, contact with VOCs (e.g., alcohol-based cleaning products), strong fragrances, and direct contact with moisture/vibrations (such as during transit in a vehicle).	Follow normal setup steps. If the sensor zero fails, continue attempts until the unit passes. This may take up to 30 minutes.
	The NO sensor became unstable and may need to be replaced.	If another system is not readily available and the patient requires therapy, start the Manual Override Mode, replace the system as soon as possible, and alert the Service Engineer.

8.3 ALARM PRIORITY – ALARMS DURING THERAPY

A series of alarms are identified below. These alarms may be seen during therapy (once the device has been set up) if an issue is detected with the *NOxBOXi*[®] system.

Displays When a Critical Problem is Detected During Therapy		
Alarm	Possible Cause	Recommended Action
NO Low	Monitored NO gas levels being delivered to the patient dropped below the alarm setting boundary. The <i>NOxBOXi</i> system delivery system cannot maintain correct dose setting.	<p>Check for the following:</p> <ul style="list-style-type: none"> ✓ Supply cylinder concentration matches the system settings. If possible, change the NO supply cylinder for the correct concentration. If not, call the Service Engineer to resolve. ✓ Sample line is correctly attached to the ventilator circuit and the <i>NOxBOXi</i> system water trap inlet. ✓ Blockages in the sample line. ✓ Damage and/or leaks in the water traps (including the barrel thread). ✓ Breakages or leaks in the ventilator circuit. ✓ The supply cylinder is connected and open, there are no leaks, and the concentration matches the system settings. ✓ Orientation of the NOxFLOW is correct, including the flowline connection on the device. ✓ The NOxFLOW dose line and connection is connected, with no blockages or leaks. ✓ The NOxFLOW flow detection lines and connection (including O-rings) are connected, with no blockages or leaks.
	The ventilator minute volume may be too low.	Check the ventilator minute volume (see section 3.2, Specification & Environment, for flow specifications). If necessary, increase the ventilator bias flow.
	The NO low alarm may be inappropriately set by the user.	Check the NO Low alarm value, and reduce the value if the ventilator settings deem it necessary.
	The NO sensor requires replacing.	If another system is not readily available and the patient requires therapy, start the Manual Override Mode, replace the system as soon as possible, and alert the Service Engineer.
NO High	Monitored NO gas levels being delivered to the patient have risen above the alarm setting boundary. The <i>NOxBOXi</i> delivery system cannot maintain the correct dose setting.	<p>Check for the following:</p> <ul style="list-style-type: none"> ✓ Supply cylinder concentration matches the system settings. If possible, change the NO supply cylinder for the correct concentration. If not, call the Service Engineer to resolve. ✓ Ventilator circuit breakages or leaks, which may cause buildup of the NO concentration due to the lack of ventilator flow. ✓ Orientation of the NOxFLOW is correct, including the flowline connection on the device. ✓ Proper NOxFLOW connection (and O-rings) to the <i>NOxBOXi</i> system.
	The NO High alarm may be inappropriately set by the user.	Check the NO High alarm value, and increase the value if the ventilator settings deem it necessary.
	The NO sensor requires replacing.	If another system is not readily available and the patient requires therapy, start the Manual Override Mode, replace the system as soon as possible, and alert the Service Engineer.

Displays When a Critical Problem is Detected During Therapy

Alarm	Possible Cause	Recommended Action
NO₂ High	Monitored levels of NO ₂ gas being delivered to the patient have risen above the alarm setting boundary.	High NO dose settings on low ventilator flows with high O ₂ content may cause higher NO ₂ buildup than expected. Increase the ventilator bias flow to help reduce stagnation in the delivery.
	Poor quality NO cylinders can contain high levels of NO ₂ .	Connect a second supply cylinder to the alternate inlet port. Open the cylinder and disconnect the previous cylinder, forcing a cylinder changeover (this may resolve the issue).
	The NO high alarm is set to a default value of 1.0 ppm. NO₂ is extremely toxic and poses a risk to the patient's health.	The alarm value can be increased to a maximum of 5.0 ppm, if required. See the INO Guidelines for more information on maximum NO ₂ values during INO therapy.
	Incorrect placement of NOxFLOW and sample line.	See the Ventilator Circuit Diagram for correct placement of the NOxFLOW and sample line.
	While in Standby Mode, NO ₂ can build up in the supply lines.	Purge the supply lines (see the cylinder change procedure in section 4, Installation, in this Technical Guide).
	Stagnant gas is in the manual bag circuit, causing NO ₂ .	Purge the manual bag circuit before connecting it to the patient.
	The NO ₂ sensor may require replacing.	If another system is not readily available and the patient requires therapy, start the Manual Override Mode, replace the system as soon as possible, and alert the Service Engineer.
O₂ Low	Monitored levels of O ₂ gas being delivered to the patient have fallen below the alarm setting boundary.	<p>Check for the following:</p> <ul style="list-style-type: none"> ✓ Sample line blockages. ✓ Water trap damage and/or leaks (including the barrel thread). ✓ Sample line is correctly attached to the ventilator circuit and the NOxBOX_i system water trap inlet. ✓ Ventilator circuit breaks or leakages.
	The NO gas is balanced in N ₂ ; this is an asphyxiate gas. At high NO dose levels for low concentration cylinders (e.g., 200 ppm), the level of gas delivered into the ventilator stream can reduce the % v/v of O ₂ being delivered to the patient.	<p>Check the O₂ concentration setting at the ventilator.</p> <p>Check the O₂ alarm value and adjust it if deemed necessary.</p>
	The O ₂ sensor may require replacing.	If another system is not readily available and the patient requires therapy, start the Manual Override Mode, replace the system as soon as possible, and alert the Service Engineer.

Displays When a Critical Problem is Detected During Therapy

Alarm	Possible Cause	Recommended Action
Water Trap Full	<p>The water trap is filled with condensate from the sample line. If it overflows, the sample path will block, and water ingress to the <i>NOxBOX_i</i> system could cause damage to the system and gas sensors. Delivery accuracy is compromised and patient safety may be at risk.</p>	<p>Use a disposable male-luer lock syringe that is contained in the NOXKIT to empty the fluid from the water trap via the self-sealing drain tap located at the bottom of the water trap. Dispose of the entire syringe and contents according to local directives (e.g., sharps waste).</p> <p>The water trap uses a small float to activate the alarm. If no moisture is present, gently tap the barrel to see if the alarm float is in the OFF position.</p>  <p>If the issue persists, remove the barrel and check the alarm float position. Removing the water trap barrel dilutes the NO sample, causing an inaccurate dose and reading. Do not damage/cross-thread the water trap thread when replacing the barrel.</p>
Sample Line Block	<p>The sample line to the monitor is blocked, pinched, or occluded. Sample monitoring is affected, which may compromise delivery accuracy and patient safety.</p>	<p>Check the sample line for any pinch/crush points from external bodies, or check for blockages that may have occurred.</p> <p>Check whether the water trap requires emptying.</p> <p>Change the sample line and hydrophobic filter for blockages.</p> <p>If another system is not readily available and the patient requires therapy, start the Manual Override Mode, replace the system as soon as possible, and alert the Service Engineer.</p>
Battery Critical	<p>The <i>NOxBOX_i</i> system is running from an internal battery, and a critical battery charge level is detected. System power could fail within 10 minutes.</p> <p>A power failure will stop the delivery of NO in Synchronous Mode.</p>	<p>Reconnect the <i>NOxBOX_i</i> system to the mains using the <i>NOxBOX_i</i> system power supply. This ensures continued power of the system operation, and starts recharging the internal battery.</p> <p>Check that the blue (mains power) L.E.D. on the mains power plug is illuminated, which indicates the mains power supply is OK. If not, try a different mains power socket/power.</p> <p>Disconnect the power supply, and then reconnect. Check that the blue (charging) L.E.D. is illuminated, which indicates mains power supply is OK. If not, try a different mains power/power.</p> <p>If possible, replace the <i>NOxBOX_i</i> system power supply and alert the Service Engineer.</p> <p>If no mains power can be restored to the device, prepare to start the Manual Override Mode.</p>
Cylinder Supply Critical	<p>The available NO gas supply is running low and no alternate cylinder supply is detected.</p> <p>The NO gas supply treatment delivery will cease if no action is taken to replenish.</p>	<p>Install a new gas cylinder supply, and connect it to the alternate gas inlet port located at the rear of the <i>NOxBOX_i</i> system.</p> <p>If a new cylinder is already installed, ensure that the cylinder valve is fully open and connected to the inlet port located at the rear. This allows the device to use the supply for delivery.</p> <p>Check that the supply cylinder regulator gauges indicate adequate cylinder pressure (>20 bar).</p> <p>If it indicates adequate pressure, check for leaks.</p> <p>If issues continue, replace the regulator and alert the Service Engineer.</p>

Displays When a Critical Problem is Detected During Therapy

Alarm	Possible Cause	Recommended Action
Vent Flow Idle	The NOxFLOW has not detected any vent flow activity for an extended period of time during delivery (typically over 30 seconds).	<p>Check for the following:</p> <ul style="list-style-type: none"> ✓ Correct orientation of the NOxFLOW; the green arrow printed on the NOxFLOW should be pointing towards the patient, in the direction of the ventilator flow. ✓ NOxFLOW flow detection lines and connections are connected (including the O-rings), and there are no blockages or leaks. ✓ No serious leak or break exists in the ventilator circuit. Attend to the ventilator circuit requirements. ✓ Ventilator is connected and supplying sufficient flow.
	Dose is set to 0 ppm and disconnected from the vent circuit for standby.	Disconnect and purge the feed hoses.
Critical Delivery Fault	A critical fault is detected within the intelligent delivery system, and safe delivery function can no longer be guaranteed.	Check that the ventilator is connected and supplying sufficient flow.
	Occlusion on the NO outlet	<p>If another system is not readily available and the patient requires therapy, start the Manual Override Mode, replace the system as soon as possible, and alert the Service Engineer.</p> <p>Check for occlusions on the NO outlet, delivery line, or NOxFLOW. Once resolved, reset the dose to resume delivery.</p>
Touch Screen Will Not Respond	<p>A critical fault within the intelligent delivery system is detected, and delivery function can no longer be guaranteed.</p> <p>NO delivery to the patient may have stopped.</p>	If another system is not readily available and the patient requires therapy, start the Manual Override Mode, replace the system as soon as possible, and alert the Service Engineer.

MEDIUM-PRIORITY ALARMS DURING THERAPY

Displays When a Problem is Detected During Therapy		
Alarm	Possible Cause	Recommended Action
Zero Calibration	<p>During use, the <i>NOxBOX_i</i> system prompts you to perform a sensor zero every 24 hours to ensure accurate system performance by checking the gas sensor reading performance.</p> <p>NOTE: This test takes up to 2 minutes to perform. During this time, the monitored patient gases will be offline. The <i>NOxBOX_i</i> system continues to deliver NO during this time.</p>	<p>No special connections are required; the zero calibration is fully automatic.</p> <p>Press the tick to start the zero calibration.</p> <p>Zero calibration can be delayed if the system is not currently in a stable dose delivery state (e.g., if the patient dose has recently been changed and the system is still stabilizing to the new dose level).</p> <p>Dismiss this alarm message and perform the zero calibration when the notice appears next at the earliest convenience.</p>
Zero Calibration Fail	<p>One or all of the sensors have failed the zero (low) calibration. Ambient conditions may be affecting the zero sample.</p> <p>A sensor may be unstable, or residual gas may be present in the system.</p>	<p>Check the ambient NOxAIR monitor for high levels of NO. If high levels are detected, check the regulator(s) and supply line(s) for leaks.</p> <p>Repeat the zero calibration.</p> <p>Check that the zero port (located in the rear) is not blocked.</p> <p>If another system is not readily available and the patient requires therapy, start the Manual Override Mode, replace the system as soon as possible, and alert the Service Engineer.</p>
Cylinder Low	<p>Displays when an alternate viable gas supply is detected, but the current feed cylinder is nearly depleted.</p>	<p>Replace the cylinder with a new supply.</p> <p>Alternatively, once the cylinder is empty, fully close the cylinder valve. Remove the feed hose from the rear of the system. Release the pressure using the purge needle on the monitor.</p> <p>NOTE: Once the second cylinder begins to become depleted and the first cylinder has not yet been replaced in the interim, the “Cylinder Supply Critical” Alarm is triggered.</p>
Manual Override	<p>Manual Override Mode is started. The alarm activates to alert the user that the system is not delivering in Intelligent Mode. Changes to the ventilator setting or patient demand cannot be automatically detected and corrected by the <i>NOxBOX_i</i> system. A specific dose setting cannot be dialed in.</p> <p>The patient must be closely monitored, and it must be ensured that the gas alarms are correctly set to alert for any abnormal gas delivery behaviors.</p>	<p>This alarm resolves when the system is returned to the normal Intelligent Delivery Mode.</p>

8.4 GENERAL TROUBLESHOOTING

General Troubleshooting Issues		
Issue	Possible Cause	Recommended Action
The NOxBOX_i system turns on and off immediately. The NOxBOX_i system makes several attempts to start up, but it shuts down or it does not turn on at all.	Low battery power.	Connect the NOxBOX _i system to mains power, and then turn it ON. Check that the mains power is connected, and the battery is charging (see Battery Critical alarm).
	An internal fault occurred; the system shuts down to protect integral components.	If another system is not readily available and the patient requires therapy, start the Manual Override Mode, replace the system as soon as possible, and alert the Service Engineer.
Zero Calibration Fail	One or all of the sensors have failed the zero (low) calibration. Ambient conditions may be affecting the zero sample.	Check the ambient NOxAIR monitor for high levels of NO. If high levels are detected, check the regulator(s) and supply line(s) for leaks.
	One or all of the sensors may be unstable or residual gas may be in the system.	Repeat zero calibration. Check the blockages in the zero port (located in the rear). If another system is not readily available and the patient requires therapy, start the Manual Override Mode, replace the system as soon as possible, and alert the Service Engineer.
System Test Fail	The NOxBOX _i system failed the safety test, and cannot accurately deliver/monitor NO in the Intelligent Mode.	Check for the following: <ul style="list-style-type: none"> ✓ Oxygen source is flowing at 10 liters/minute. ✓ The NOxFLOW is connected to the oxygen source and the NOxBOX_i-TEST kit. ✓ Correct NOxFLOW orientation. ✓ NOxFLOW is connected to the NOxBOX_i system. ✓ Damage to the NOxFLOW flow detection lines and connector O-rings. ✓ The sample line is connected to the water trap and the NOxBOX_i-TEST kit. ✓ Damage to the water trap (including the barrel thread). Repeat the system test. If a second test fails, replace the NOxFLOW and sample line.
	One or all of the sensors are unstable.	If another system is not readily available and the patient requires therapy, start the Manual Override Mode, replace the system as soon as possible, and alert the Service Engineer.
Fluctuations/Oscillation s in Excess of 3 ppm.	May be due to NOxFLOW.	Ensure that the O-ring and NOxFLOW are present and connected.
	Mass flow sensor is due for service.	Contact the Service Engineer.
	HFO frequency.	Slightly adjust the frequency based on your clinical judgment.

8.5 NOxMIXER

NOxMIXER Issues		
Issue	Possible Cause	Recommended action
The NOxMixer is not delivering a dose (the NO monitor shows no NO dose).	Source of NO is not connected.	Ensure that the mode selector valve is correctly orientated. Ensure that all lines are connected.
The flow meter ball is stuck.	Moisture ingress	Contact the Service Engineer.
The Control knob is not working.	Could be loose/faulty/broken	Contact the Service Engineer.
The NOxMixer unit emits a sound when in use.	Due to vibration	Ensure that the O ₂ input line is connected correctly and secured. Ensure that all of the manual bagging lines are connected and secured. Check the O ₂ input line for leaks using a leak detector. If issues persist, revert to Intelligent Mode and replace the device when it is safe.
The NOxMixer flow meter does not register a flow rate.	Source of O ₂ is not connected.	Check that the oxygen supply is connected and turned on.

9 VENTILATOR MANAGEMENT

The *NOxBOX*® system sampling flow-rate is approximately 225 ml/min. Please be aware that direct ventilation on very low tidal volumes may be adversely affected due to high detected leak-rate (% leak rate) on the ventilator. This can also generate higher NO₂ values due to increased dwell time for the NO in the lines.

To counteract this effect, increasing the bias flow from 2 L/min to 8 L/min can significantly reduce the effects of both ventilator leak and NO₂ generation.

9.1 VENTILATOR COMPATIBILITY LIST

Please visit www.noxboxltd.com/vent_list for an up-to-date list of compatible ventilators.

NOTES



Station Road, Harrietsham,
Maidstone, Kent,
ME17 1JA, England

Tel: +44 (0) 1795 859430

Email: ask@noxboxltd.com

www.noxboxltd.com

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