The INNOVO Trial

Technical Guidelines

Funded by the Medical Research Council

Index

The information contained in this document is believed to be accurate and practices recommended in it are believed to be safe. The INNOVO Trial group cannot accept responsibility for the consequences of errors in or omissions from this document.

Introduction

Many hospitals across the UK plan to participate in The INNOVO Trial. Many of these already have experience with the application of inhaled nitric oxide whilst others will administer inhaled nitric oxide for the first time during the trial. The Technical Advisory Group recognise that there will be many variations in the equipment used in the delivery of nitric oxide. The purpose of this document is therefore not to demand standardisation of delivery systems but to provide centres with a set of guidelines relating to good clinical practice and health and safety at work.

Technical support will be available throughout the study from two sources. Firstly established nitric oxide units within particular regions will be encouraged to support centres wishing to establish nitric oxide systems. Secondly the research technician appointed to the trial and members of the technical advisory group can be contacted through the trial office and will endeavour to offer advice and assistance. A summary checklist is available (Appendix 1) and a list of useful addresses (Appendix 2).

1. Nitric Oxide Cylinders

a. Supply

- BOC will supply centres with nitric oxide free of charge (within the UK) for use in the trial, provided centres register with BOC by completing a short questionnaire describing their proposed use of inhaled nitric oxide (INO).
- Normal cylinder rental charges will still apply to trial registered hospitals even though the gas will be supplied free of charge.
- Nitric oxide will usually be supplied by BOC in AV (1500 L gas) cylinders, coloured pastel green with a yellow neck, containing 1000 parts per million (ppm) nitric oxide.
- 'New' sites will only be supplied with nitric oxide if an advisory board set up by BOC is satisfied that, on the basis of the questionnaire information, the gas will be delivered in a safe manner.

b. Handling

- Please read the BOC safety data sheet (Appendix 3).
- The cylinders should always be checked for leaks before use and the regulators attached and similarly checked before being taken to the bedside.
- Once at the bedside all cylinders should always be secured to prevent them being knocked over, either by chaining them to a wall or at the very least leaving them on a suitable trolley.
- There should always be at least one spare cylinder easily available, if possible near the bedside, so the cylinders can be swapped when required.
- The cylinders are opened and closed using the red and black wheel at the top of the cylinder.

N.B. The cylinder must never be turned on unless a regulator is firmly attached to the outlet of the cylinder, otherwise gas will escape rapidly at high pressure causing possible asphyxiation.

2. Nitric Oxide Regulators

- Only regulators constructed from stainless steel should be used for nitric oxide delivery, to prevent corrosion of internal parts and thus malfunction.
- There are usually two controls on regulators. The control nearest the cylinder sets the output pressure of the regulator, the other opens and closes the regulator allowing gas to flow to the nitric oxide flowmeter.
- The regulator reduces the pressure from the outlet of the cylinder to a level with which the flowmeter can cope.
- It will usually have two gauges measured in psi/bar.
- The gauge nearest the cylinder measures the pressure in the cylinder, this has a scale of 0 to 4000 psi (270 bar). A full cylinder will measure at least 1750psi (130 bar).
- The gauge furthest from the cylinder measures the outlet pressure of the regulator, this has a scale of 0 to 100 psi (7 bar) and is usually set at 15 to 30 psi (1-2 bar).

3. Nitric Oxide Flowmeters

- Flowmeters are used to set the dosage given to the patient. Bobbins and other metal components exposed to nitric oxide should be made of stainless steel.
- Flowmeters used should be able to deliver a range of gas flows sufficient to cover INO doses from 40 ppm down to less than 1 ppm.
- This can either be achieved using one flowmeter or by joining a high range and a low range flowmeter together. This allows coarse adjustment with the high range flowmeter and fine control with the low range flowmeter. The high range flowmeter should cover the range 0 to 0.8 litres per minute while the low range should cover the flow range 0 to 0.1 litres per minute. This should provide the accuracy and the range for all required doses.
- If only one flowmeter is being used it should have sufficient range to allow all necessary doses to be given.

4. Nitric Oxide Connections

- Any connections through which high concentrations of NO will flow should be made from either stainless steel or a PTFE derivative such as Teflon or PFA. Other plastics may absorb NO or Nitrogen dioxide (NO_2) and leach them out as NO_2 at a later stage resulting in toxic levels of NO_2 being administered to the patient
- This applies to all the connections between the regulator and the flowmeter and the flowmeter and the patient circuit.

5. Nitric Oxide Delivery

- In continuous flow infant ventilators nitric oxide should be delivered into the circuit in the inspiratory limb after any humidification has taken place and preferably more than 20cm from the patient end.
- The measurement system should be placed in the expiratory limb of the system as close to the patient as possible (See diagram 1).
- The continuous flow of gas ensures that the concentration of INO will remain constant and will be unaffected by all changes to ventilation**, except changes of ventilator flow rates.**
- The dose can be easily calculated on continuous flow ventilators using the formula below:-

$$\frac{\text{Nitric Oxide flow rate(Litres/Min)}}{\text{Ventilator flow rate(Litres/Min)}} \times \text{Nitric Oxide cylinder concentration(ppm)} = \text{Dose}$$

e.g.:-

$$\frac{0.2 \text{ Litres/Min}}{10 \text{ Litres/Min}} \times 1000 \text{ ppm} = 20 \text{ ppm continuous dose}$$

- Use of the formula does not mean that analysers do not need to be used, as leaks in the delivery system can occur causing changes in dosage.
- The INO level measured by the analyser should coincide with the dose set, calculated using the formula above. Any major discrepancy must be investigated immediately and its cause rectified.
- Nitric oxide reacts with oxygen to form NO_2, the higher the dose of INO and/or FiO_2 the greater the amount of NO_2 produced. It is therefore important to always purge the delivery system of old gas. If this is not done the patient will first receive any gas still in the system from previous use, which will have converted to NO_2, and will receive a very high dose of NO_2 until the fresh gas starts to reach the patient.

- Providing the analyser is calibrated and functioning correctly, NO_2 readings above 2.4 ppm should be investigated with view to possibly reducing the NO dose.

6. Nitric Oxide Analysers

- There are two main types of nitric oxide analysers available, electrochemical and chemiluminescence.
- Electrochemical analysers are the ones most commonly used in hospitals because of their small size and relatively low cost.
- These analysers can be used to measure nitric oxide and nitrogen dioxide. They either come as two separate units, one for NO and one for NO_2, or can be combined into one unit for ease of use.
- The concentrations on these analysers are displayed in parts per million (ppm). Both the NO and the NO_2 analysers have very limited accuracy below 1 ppm and while this is perfectly adequate for clinical purposes they are not suitable for environmental monitoring.
- A drying system of some sort should be placed between the patient circuit and the analyser as water can cause the fuel cell to malfunction resulting in the analyser failing to work.
- Chemiluminescence analysers were originally designed to measure environmental levels of NO and NO_2. They are therefore able to measure down to much lower concentrations of gas. This is not particularly useful in medical terms except for checking environmental levels and the effectiveness of scavenging systems. These analysers tend to be large, cumbersome and noisy as well as relatively expensive when compared to electrochemical systems and therefore unlikely to be particularly useful for INO measurement during the trial.

7. INO dosage

- In **term babies**, gestational age equal to or greater than 34 weeks, the trial starting (and maximal) dosage of INO is 20 ppm, which would then be weaned down, after a 1 hour stabilisation period, to the minimum necessary dosage to sustain a clinically significant response. A response is defined as an increase in post ductal PaO_2 of more than 3 kPa (22.5 mmHg) in the initial 15 minutes of giving INO. The ventilation should remain constant during this initial 15 minutes to prevent outside factors influencing the response.
- In **preterm babies**, gestational age less than 34 weeks, a dose response study is being undertaken to determine the most effective dose. The study will include doses from 5 to 40 ppm. Doses above 40 ppm will not be used.
- For centres not in the dose response study, until the results of the dose response study are available, a dose level starting at 5 ppm will be used. If no satisfactory response is achieved, the dose will be doubled to 10 ppm, then if necessary doubled again to 20 ppm, then again if required to 40 ppm. If at any point, after having achieved a response (an increase in post ductal PaO_2 of more than 3 kPa (22.5 mmHg)), an increase in dose does not produce a further significant increase in the response, then the dose should be dropped down to the previous level and maintained at that level.
- In **all babies** it is essential that after a period of stabilisation, for the INO dose to be maintained at the lowest possible effective level. Failure to ensure the lowest possible INO dose will result in increased INO and ventilator dependence. It is suggested that reverse dose response weaning is undertaken. This means that the INO dose is repeatedly reduced by approximately 10% every 2-3 minutes until a decrease (2-3 %) in oxygen saturations is noted. The INO should then be increased to the level it was at prior to the decrease in oxygenation. This should be re-evaluated every 12 hours.
- **Non responder** are those babies not showing an increase in post ductal PaO_2 of more than 3 kPa (22.5 mmHg) in the initial 15 minutes of giving INO. Continue on INO, at 5 ppm, for 12 hours and then if there is still no response they should be weaned off INO. Weaning should be carried out in a reverse dose response fashion. Some babies, even some of those who appear not to have responded to INO, remain dependant on the INO, so that doses as low as 0.3 ppm may be required for a few days during the final weaning process.
- When **weaning** INO is withdrawn completely it may help to temporarily increase the FiO_2 by up to 40% to finally wean the INO, especially in difficult cases.
- The INO administration circuit should remain attached to the ventilator for a further 24 hours to ensure stability after successful weaning from INO.

8. Methaemoglobin

- The binding of NO to haemoglobin results in the production of methaemoglobin. This is not in itself toxic, but methaemoglobin is not able to carry oxygen. Therefore high levels of methaemoglobin will reduce the oxygen carrying capacity of the blood.
- When initially connecting INO to a patient, a measurement of the methaemoglobin level should be taken after one hour. Thereafter whilst using INO it is recommended that measurements of methaemoglobin should be carried out every 12 hours.
- With doses of INO of less than 20 ppm you would not expect to see methaemoglobin levels in excess of 2%.
- Thus a level of 2% should be considered a warning level, and if methaemoglobin levels rose to 4% INO dosage should be reduced and the level rechecked after 1 hour. If the levels have not fallen substantially, INO administration should if possible reduced further. If at any time the methaemoglobin percentage exceeds 7% stop INO and consider treatment of methaemoglobinemia with a dose of 1-4mg/kg I.V. of methylene blue.

9. Scavenging

- It is unclear whether it is necessary to scavenge waste ventilator gas where NO is used in a well ventilated hospital environment. Centres who have monitored environmental NO and NO_2 levels under such circumstances have demonstrated extremely low level of NO and NO_2.
- Of greater concern is the accidental escape of concentrated gas, particularly in an enclosed environment. This is extremely preventable with good staff training in cylinder handling and leak testing.
- All hospitals are recommended to conduct a Control of Substances Hazardous to Health (COSHH) assessment of their proposed use of INO. This should take into account known hazards in the context of the particular site.
- Detailed, sensitive environmental monitoring with a chemiluminescence analyser may be undertaken to confirm or exclude the need for particular scavenging policies.
- However, during the trial it is suggested that NO and NO_2 be scavenged or absorbed from ventilator waste gas. This can be done using an active or passive exhaust collection system, such as an anaesthetic gas scavenging system or an ‘exhaust pipe’ to an external wall. Alternatively a commercially available absorptive system can be used.
- Environmental safety monitors should be employed which will give early warning of high NO_2 levels such as may occur in an undetected cylinder leak.

10. HFOV and Nitric Oxide

- Oscillators can easily be used in conjunction with INO without providing too many extra problems.
- There are three main types of high frequency oscillator used at the moment, the SLE high frequency oscillator, the Drager Babylog oscillator and the Sensormedics oscillator. Of the three most commonly used, two, the SLE high frequency oscillator and the Drager Babylog oscillator, INO should be delivered in the same way as the standard ventilators of that type.
- The other commonly used oscillator made by Sensormedics presents a few more problems. The recommended method of delivery of INO to the ventilator and measurement of the dose given is as seen in Diagrams 2.
- Scavenging from Sensormedics oscillators can at this present time only be achieved using a device manufactured by Sensormedics.
- With all oscillators greater care should be taken to prevent water reaching the measurement device as the oscillatory flow of gas tends to push water into the measurement tubing.
- A note should also be made of the high flow rates often used by oscillatory ventilators leading to a high consumption of nitric oxide.

11. Hand Ventilation with Nitric Oxide

- In some ventilation systems it may be possible to connect a bag into the expiratory limb of the tubing and thus give hand ventilation using the ventilator circuit and INO supply (Diagram 3).
- If this is not possible a separate circuit should be set up to enable hand ventilation with INO.
- This is especially important in patients who are highly sensitive to INO, as discontinuation of the INO even for suctioning and physiotherapy, can lead to marked patient desaturation.
- The INO should be introduced to the hand ventilation circuit at the same point as the fresh gas.
- The flow rate of NO for the required dose can be calculated using the same formula as for the ventilator dose. e.g. :-
  $\frac{\text{0.05 L/Min (NO Flow)}}{\text{5 L/Min (Fresh gas Flow)}}$ X 1000 ppm (NO Concentration) = 10 ppm (NO Dose)
- If a separate INO delivery system is used for hand ventilation care must be taken to switch off the nitric oxide flow after use.

12. Nitric oxide delivery systems

NO can be delivered using existing ventilator systems using adaption systems illustrated by the diagrams. However, we recommend that one of the following commercially available systems is used. These are safer than an adapted system, although they are more expensive. As new systems may come onto the market during the course of the trial please visit our INNOVO website http://eps.lshtm.ac.uk/msu to find out about new products.

Please contact the following companies directly for further information.

Bedfont Scientific Ltd.
Bedfont House
Holywell Lane
Upchurch
Kent ME9 7HN
Tel +44 (0) 1634 375 614
Fax +44 (0) 1634 378980
Email: info@bedfont.com

Datex Ohmeda Ltd.
Great North Road
Hatfield
Herts AL9 5EN
Tel +44 (0) 1707 263 570
Fax +44 (0) 1707 260 065

Draeger Medical Ltd.
The Willows
Mark Road
Hemel Hempstead
Hertfordshire HP2 7BW
Tel +44 (0) 1442 213 542
Fax +44 (0) 1442 240 327
Email/website: http://www.draeger.co.uk

E.M.E. (Electro Medical Equipment) Ltd.
60 Gladstone Place
Brighton
Sussex BN2 3QD
Tel +44 (0) 1273 645 100
Fax +44 (0) 1273 645 101
Email: info@eme-med.co.uk

Siemens Medical Plc.
Sir William Siemens House
Princess Road
Manchester M20 2UR
Tel +44 (0) 161 44 65 393
Fax +44 (0) 161 44 65 392

SLE (Specialized Laboratory Equipment) Ltd.
Twin Bridges Business Park
232, Selsdon Road
South Croydon
Surrey CR2 6PL
Tel: +44 (0) 181 681 1414
Fax: +44 (0) 181 649 8570
Email: admin@sle.co.uk

13. Potential Problems When Using Nitric Oxide

- If the patient suddenly desaturates the cause is usually unrelated to INO delivery, therefore routine diagnostic and treatment steps should be undertaken as for any ventilated patient. It is however always worthwhile in these circumstances checking to confirm that the INO flowmeter is still reading the same flow as previously and the INO dose is the same on the analyser.
- If the INO dose has changed significantly (e.g. ± 25%) then check to see that there is still gas in the cylinder, the INO delivery tubing has become disconnected from the ventilator circuit or if there is a gas leak in the INO delivery circuit.
- If the cylinder is empty, change the cylinder and if possible use a separate supply of nitric oxide to hand ventilate the patient.
- If there is a suspicion of a cylinder leaking, turn the cylinder off using the red and black wheel on top of the cylinder and if possible start hand ventilation with INO from a separate source.
- The INO delivery circuit should then be swapped onto a fresh cylinder and the possibly faulty one taken away to be checked.
- If the analyser starts reading almost zero ppm INO, it could be caused by disconnection from the ventilator circuit or water getting into the analyser cell or obstructing the analyser tubing.
- If the cell is wet it should be disconnected from the patient and allowed to dry.

Checklist for Setting Up INO

- Collect cylinder and see that it contains 1000ppm medical grade nitric oxide in nitrogen by checking the label attached to the top of the cylinder and the value printed on the side of the cylinder.
- Check the cylinder is turned off then attach the regulator to cylinder and make sure it is tight.
- First making sure the regulator is turned off, switch on the cylinder and check for leaks, either by listening or using leak detection spray.
- Using the regulator gauge check there is sufficient gas in the cylinder.
- Take the cylinder to the bedside, attach the flowmeter to the regulator and check all connections for leaks.
- Make sure the cylinder is secure and in no danger of falling over.
- Flush the delivery system with fresh gas to get rid of any NO_2 that may have formed while the circuit was out of use.
- Connect the INO delivery system and the analyser to the vent circuit as shown in diagrams 1 or 2.
- Attach the scavenger system to the ventilator.
- Turn on the INO analyser.
- Make sure the regulator is turned on and if required the output pressure is adjusted to a suitable level. Usually around 15 to 30 psi (1-2 bar).
- Set the INO flow rate to the level required, calculated using the formula below:-

$$\frac{\text{Nitric oxide flow rate (Litres/min)}}{\text{Ventilator flow rate (Litres/min)}} \times 1000 \text{ ppm} = \text{Dose}$$

- Allow the analyser a few minutes to settle, then adjust the nitric flow as necessary to give the required dose.
- Set up a hand ventilation circuit, checking the delivery circuit as above.
- Make sure there are spare cylinders easily to hand to swap with the ones in use when required.
- Check a methaemoglobin level after 1 hour and then every 12 hours after that.

For technical advice and support contact:

Roger Smith

Research technician, Clinical Co-ordinating Centre at Leicester

Tel: 0116 254 1414 bleep 5151 Fax: 0116 258 5502

Email: roger.smith@ins.med.msmail.lri-tr.trent.nhs.uk

Or contact the Data Co-ordinating Centre 0207 927 2376/2169/2075

Appendix 2

Useful Names and Addresses

Bedfont Scientific Ltd.(Analysers)
Bedfont House
Holywell Lane
Upchurch
Kent
ME9 7HN

Tel: 01634 375614
Fax: 01634 378980
info@bedfont.co

BOC Special Gases (Gas and New user forms)
The Priestly Centre
10 Priestly Road
The Surrey Research Park
Guildford
Surrey
GU2 5XY

Tel: 01483 579857
Fax: 01483 32115

Draeger Medical Ltd. (Delivery systems and Scavenging)
The Willows
Mark Road
Hemel Hempstead
Hertfordshire
HP2 7BW

Tel: 01442 213542
Fax: 01442 240327
http:/www.draeger.co.uk

Intersurgical Ltd. (Tubing connectors)
Crane House
Molly Millars Lane
Wokingham
Berkshire
RG11 2RZ

Tel: 01734 795579
Fax: 01734 795555

KDG Mowbrey Ltd. (Flowmeters)
Tylers and Rotameter Works
Victoria Road
Burgess Hill
West Sussex
RH15 9LJ

Tel: 01293 525151

Logan Research Ltd. (Chemiluminescence analysers)
Unit B2
Spectrum Business Centre
Anthony's Way
Rochester
Kent
ME2 4NP

Tel: 01634 294900
Fax: 01634 294906

Micro Medical Ltd.(Analysers)
PO Box 6
Rochester
Kent
ME1 2AZ

Tel: 01634 843383
Fax: 01634 830814
e-mail: 100565.3321@compuserve.com.uk

Ohmeda (Analysers)
Ohmeda House
71 Great North Road
Hatfield
Herts
AL9 5EN

Tel: 01707 263570
Fax: 01707 259633

Sensormedics BV (Delivery Systems and Oscillator Scavenging)
5 Prospect Way
Butlers Leap
Rugby
Warks
CV21 3UU

Tel:01788 546380
Fax: 01788 546381

SLE (Delivery Systems and Scavenging)
Twin Bridges Business Park
232 Selsdon Road
South Croydon
Surrey
CR2 6PL

Tel: 0181 681 1414
Fax: 0181 649 8570
admin@sle.co.uk

Swagelock (Connectors and Tubing)
South London Valve and Fitting Co.
Regent Business Centre
Jubilee Road
Burgess Hill
West Sussex
RH15 9TL

Tel: 01444 248048
Fax: 01444 246324

Thermo Electron Ltd. (Chemiluminescence analysers)
830 Birchwood Boulevard
Birchwood
Warrington
Cheshire
WA3 7QZ

Tel: 01925 813600
Fax: 01925 812138

Roger Smith

INNOVO Trial Clinical Co-ordinating Centre
Department of Child Health
Leicester Royal Infirmary
Infirmary Square
Leicester LE1 5WW

Tel: 0116 254 1414 bleep 5151
Fax: 0116 258 5502
Email: roger.smith@ins.med.msmail.lri-tr.trent.nhs.uk

BOC

Appendix 3

Safety Data Sheet

Product : Compressed gas: Asphyxiant (NO<0.2%)

MSDS Nr :300-10-0004B0C Version : 1 Date : 22 / 08 / 1

1 IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY
Product name Compressed gas: Asphyxiant (NO<0.2%)
Company identification see heading and/or footer
Emergency phone numbers see heading and/or footer

2 COMPOSITION/INFORMATION ON INGREDIENTS
Substance/Preparation Preparation
Components/Impurities Contains between 0% and 0.2% of Nitric oxide [O;R8A|T+;R26|C;R36/37/38]

3 HAZARDS IDENTIFICATION
Hazards identification In high concentrations may cause asphyxiation.
Compressed gas

4 FIRST AID MEASURES
Inhalation In high concentrations may cause asphyxiation. Symptoms may include loss of mobility/consciousness. Victim may not be aware of asphyxiation.
Delayed adverse effects possible.
Remove victim to uncontaminated area wearing self contained breathing apparatus. Keep victim warm and rested. Call a doctor. Apply artificial respiration if breathing stopped.
Ingestion Ingestion is not considered a potential route of exposure.

5 FIRE FIGHTING MEASURES
Specific hazards Exposure to fire may cause containers to rupture/explode.
Non flammable
Hazardous combustion products None
Suitable extinguishing media All known extinguishants can be used.
Specific methods If possible, stop flow of product.
Move container away or cool with water from a protected position.
Special protective equipment for fire fighters Use self-contained breathing apparatus.

6 ACCIDENTAL RELEASE MEASURES
Personal precautions Evacuate area.
Wear self-contained breathing apparatus when entering area unless atmosphere is proved to be safe.
Ensure adequate air ventilation.
Environmental precautions Try to stop release.
Clean up methods Ventilate area.

7 HANDLING AND STORAGE
Handling and storage Suck back of water into the container must be prevented.
Do not allow backfeed into the container.
Use only properly specified equipment which is suitable for this product, its supply pressure and temperature. Contact your gas supplier if in doubt.
Refer to supplier's container handling instructions.
Keep container below 50°C in a well ventilated place.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION
Exposure limit value for country UK: NO - LTEL: 25ppm; STEL: 35ppm
France: NO - VME: 25ppm
Personal protection Ensure adequate ventilation.
Do not smoke while handling product.

Safety Data Sheet

Product : Compressed gas: Asphyxiant (NO<0.2%)

MSDS Nr :300-10-0004BOC . **Version** : 1 **Date** : 22 / 08 /

9 PHYSICAL AND CHEMICAL PROPERTIES
Relative density, gas Lighter or similar to air
Solubility mg/l water Not known.
Appearance/Colour Colourless gas
Odour None

10 STABILITY AND REACTIVITY
Stability and reactivity Stable under normal conditions.

11 TOXICOLOGICAL INFORMATION
General Delayed fatal pulmonary edema possible.
LC50/1h (ppm) Nitric oxide - 115 ppm

12 ECOLOGICAL INFORMATION
General No known ecological damage caused by this product.

13 DISPOSAL CONSIDERATIONS
General Do not discharge into any place where its accumulation could be dangerous.
Gas may be scrubbed in water.
Gas may be scrubbed in alkaline solution under controlled conditions to avoid violent reaction.
Contact supplier if guidance is required.

14 TRANSPORT INFORMATION
UN Nr 1956 (Compressed gas)
Class/Div 2.2 (Non flammable, non toxic gases)
Labelling ADR Label 2: non flammable non toxic gas
Other transport information Avoid transport on vehicles where the load space is not separated from the driver's compartment.
Ensure vehicle driver is aware of the potential hazards of the load and knows what to do in the event of an accident or an emergency.
Before transporting product containers ensure that they are firmly secured and:
- cylinder valve is closed and not leaking
- valve outlet cap nut or plug (where provided) is correctly fitted
- valve protection device (where provided) is correctly fitted
- adequate ventilation.
- compliance with applicable regulations.

15 REGULATORY INFORMATION
Labelling of cylinders
-Symbols Road transport symbols are used and selected according to the most stringent product classification - EC or ADR .
Label 2: non flammable non toxic gas
-Risk phrases RAs Asphyxiant in high concentrations.
-Safety phrases S9 Keep container in well ventilated place.
S23 Do not breathe the gas.

16 OTHER INFORMATION
The hazard of asphyxiation is often overlooked and must be stressed during operator training.
Before using this product in any new process or experiment, a thorough material compatibility and safety study should be carried out.
Details given in this document are believed to be correct at the time of going to press. Whilst proper care has been taken in the preparation of this document, no liability for injury or damage

BOC, Priestley Road, Worsley, Manchester M28 2UT 0645 645 555

BOC

Safety Data Sheet

Product : Compressed gas: Asphyxiant (NO<0.2%)

MSDS Nr :300-10-000480C Version : 1 Date : 22 / 08 / 199

resulting from its use can be accepted.

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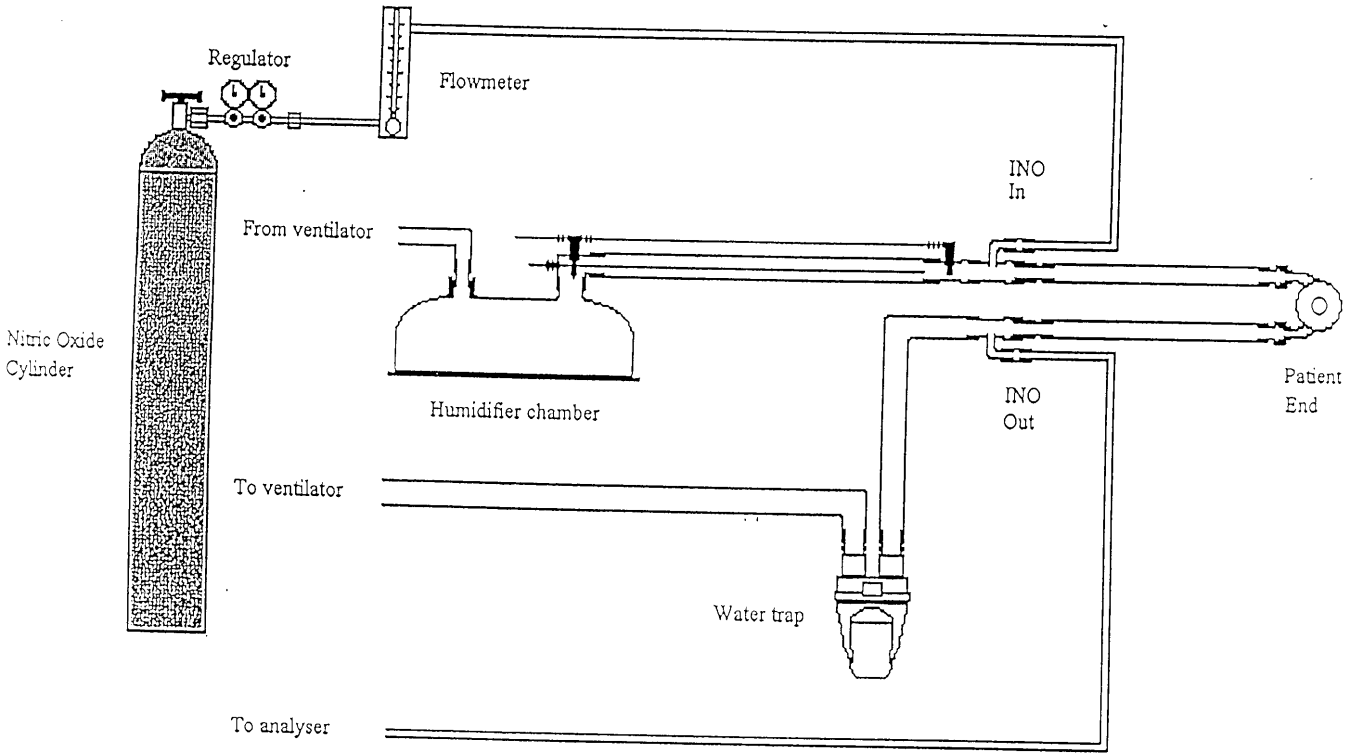
Number of pages : 3

Diagram 1

Basic Nitric Oxide Delivery Circuit



Diagrams 2

Sensormedics 3100A H.F.O.V

Nitric Oxide Administration

Flexible Patient Circuit Pt.no. 771374

with 38 inch heater wire

1.) Connection of gas delivery tube.

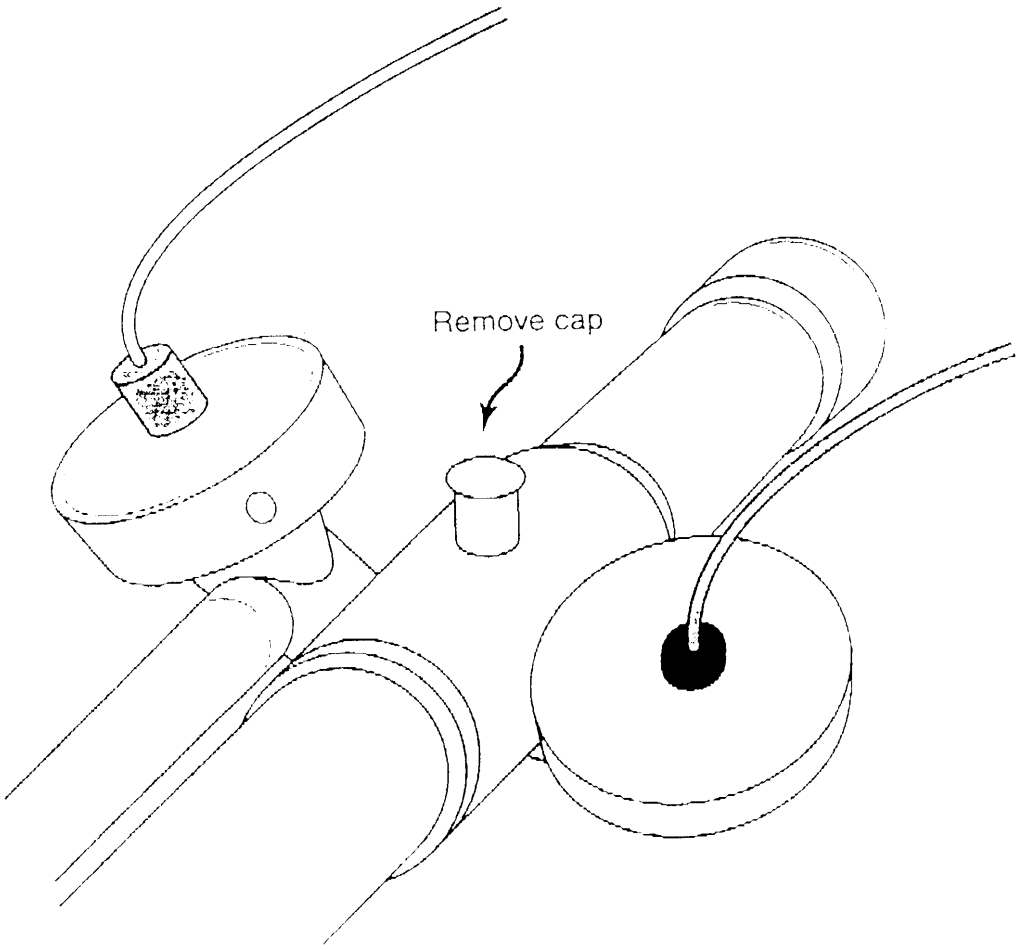
2.) Connection of measurement System

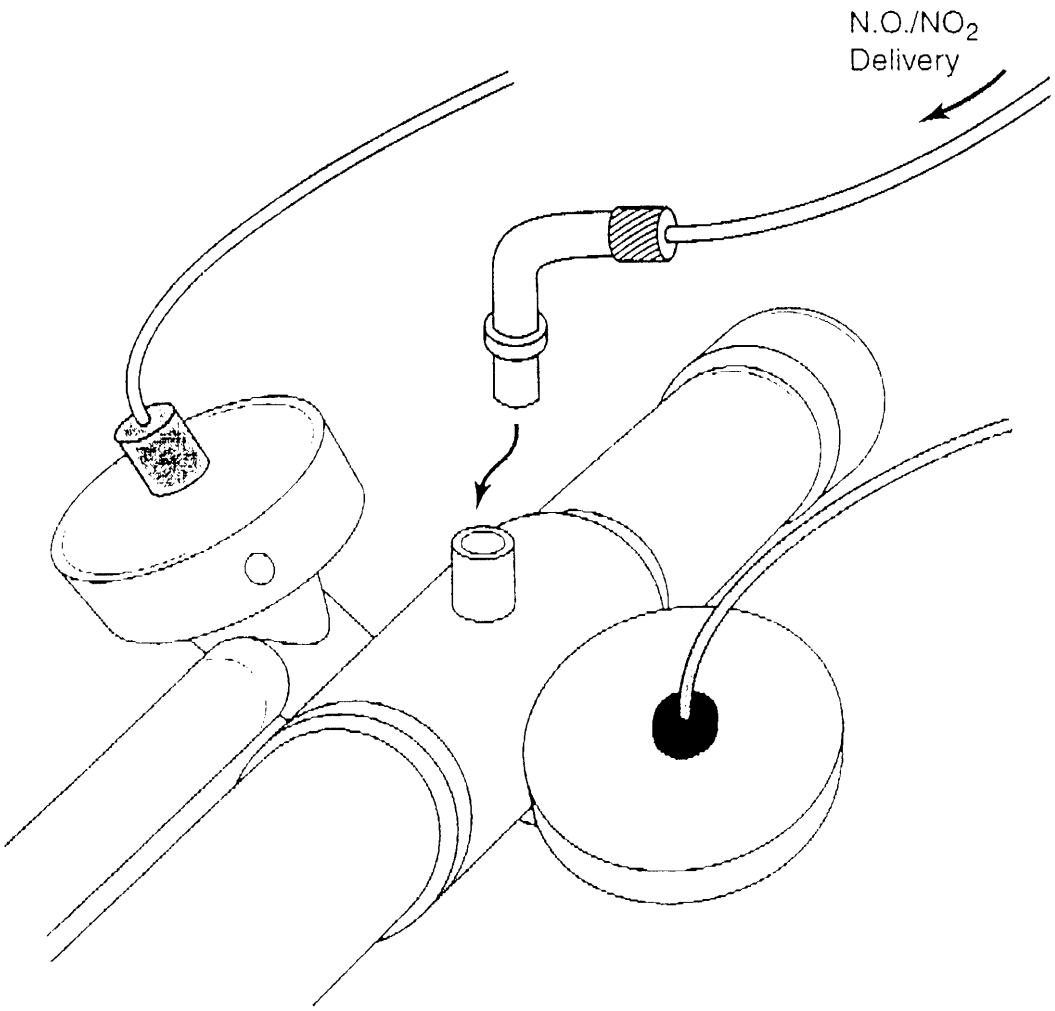
3.) Connection of gas scavenging system

ALWAYS DISCONNECT THE VENTILATOR FROM THE PATIENT

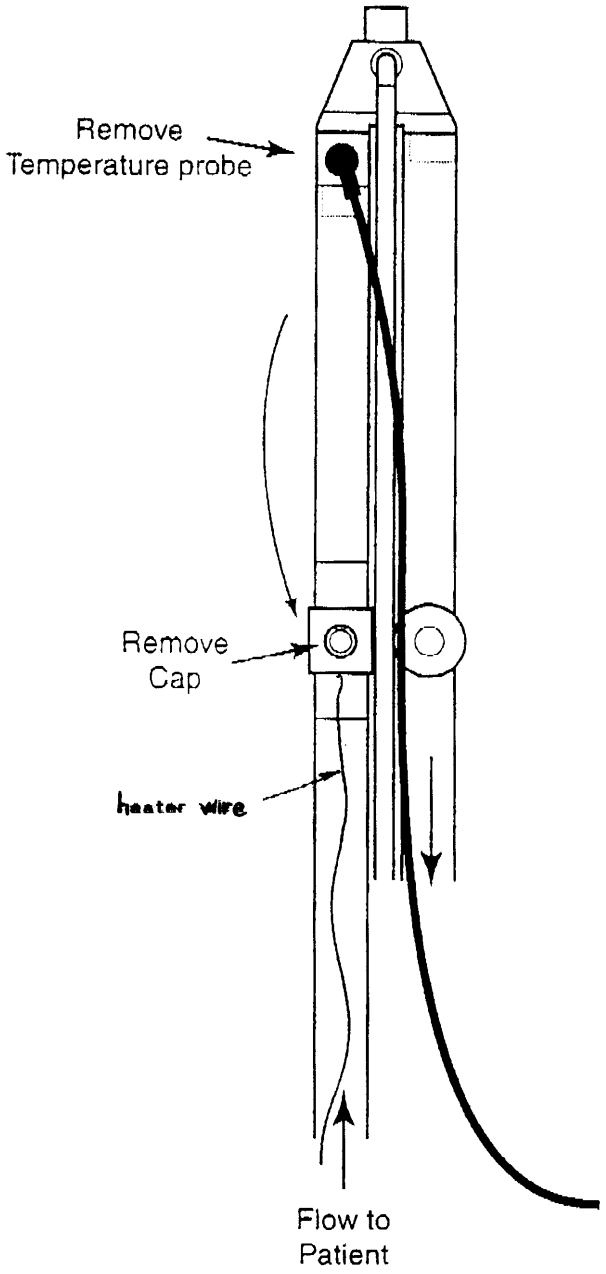
BEFORE CONNECTING NITRIC OXIDE RELATED EQUIPMENT

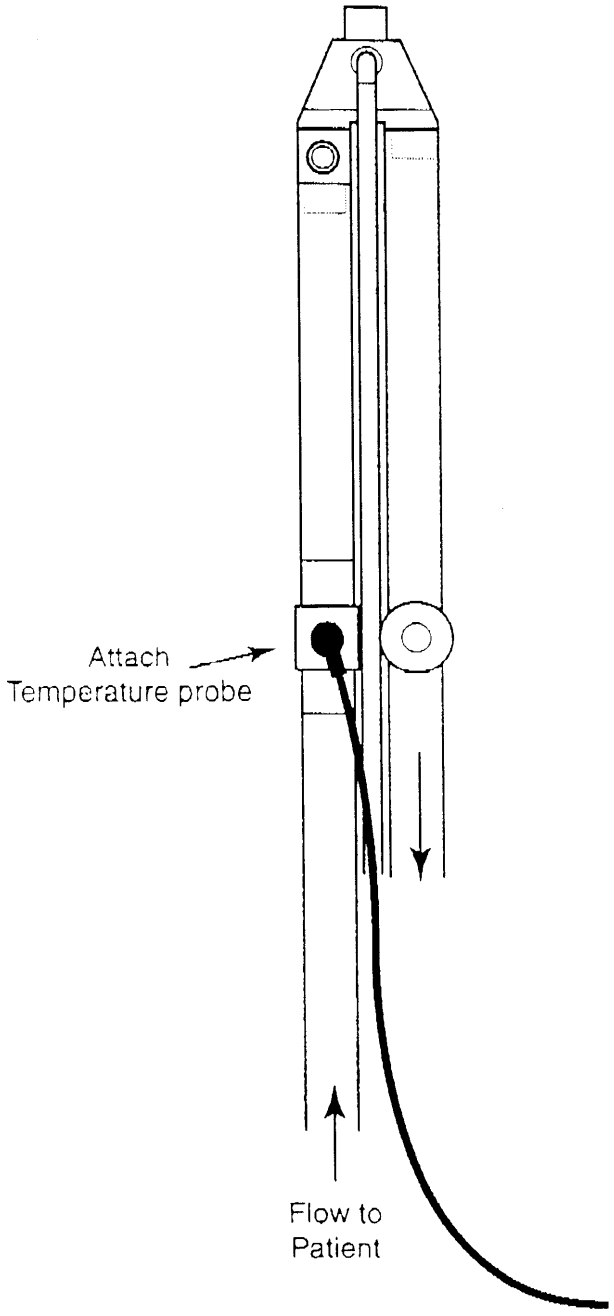
1.) Connection of Nitric Oxide Delivery Tube

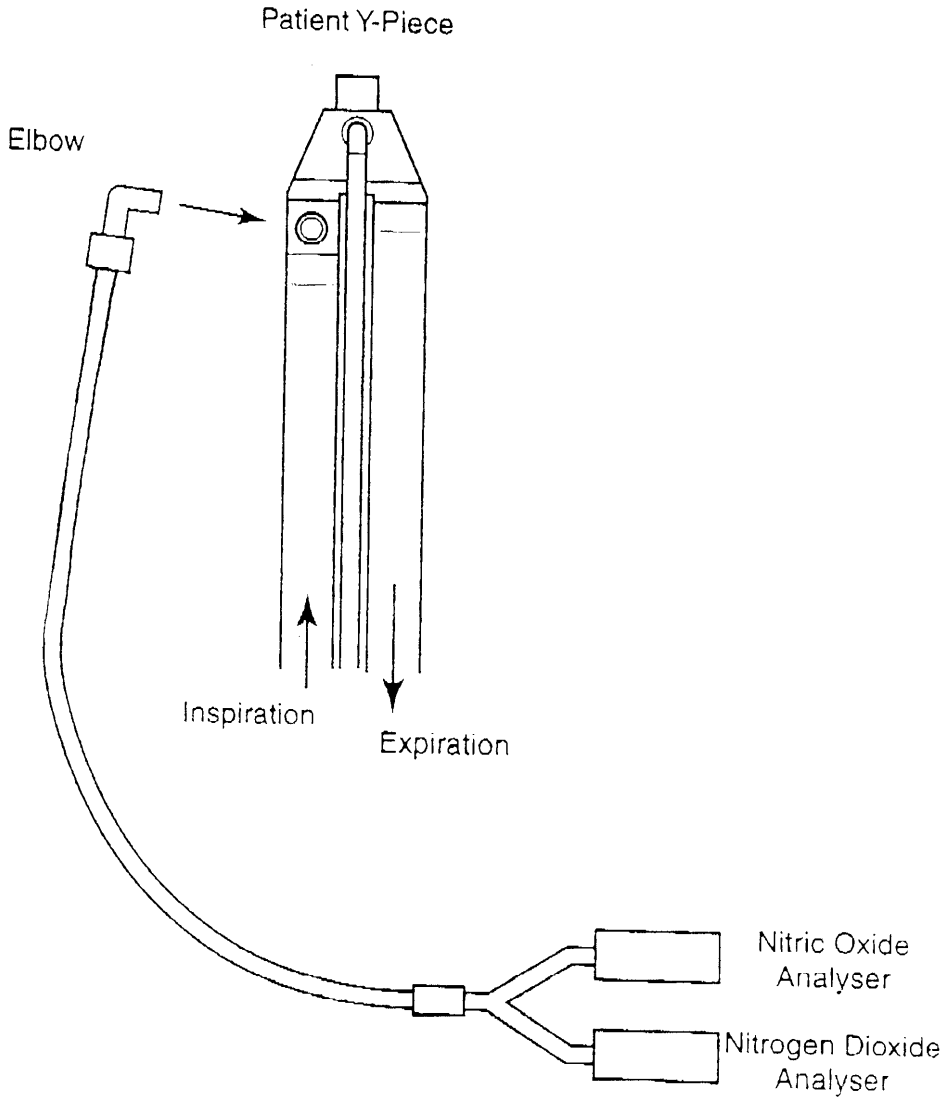



N.O./NO2
Delivery

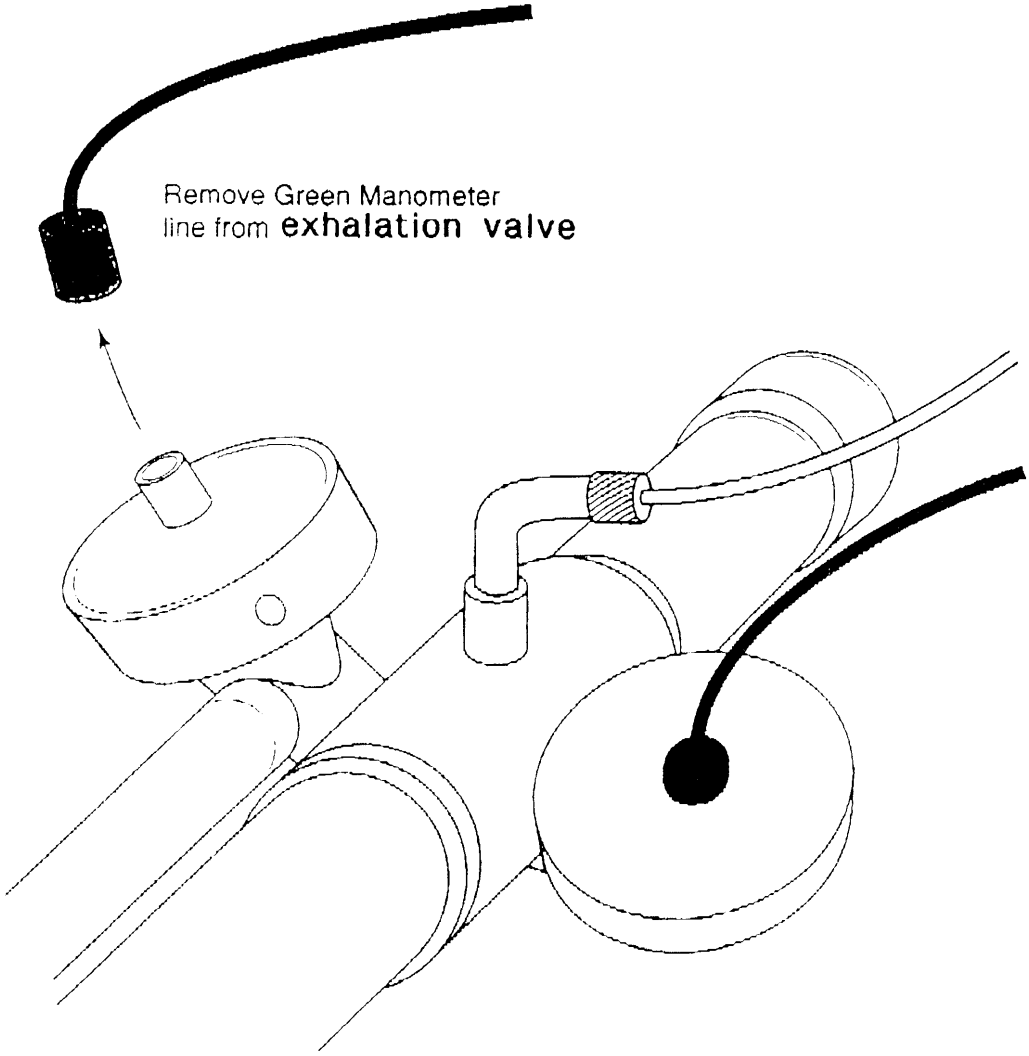
2.) Connection of Measurement System for N_2O/N_2O_2 Gas



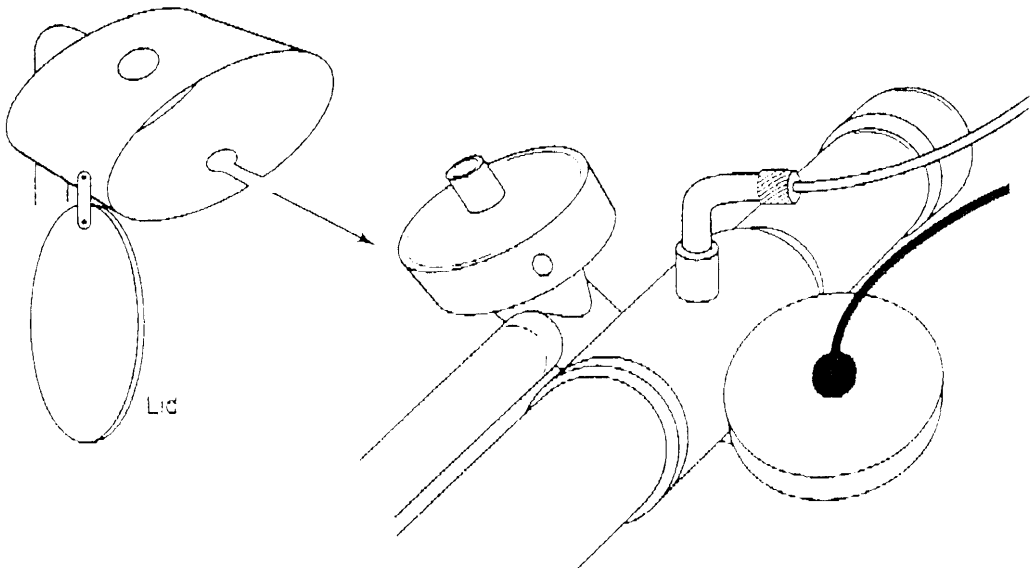

Attach
Temperature probe
Flow to
Patient

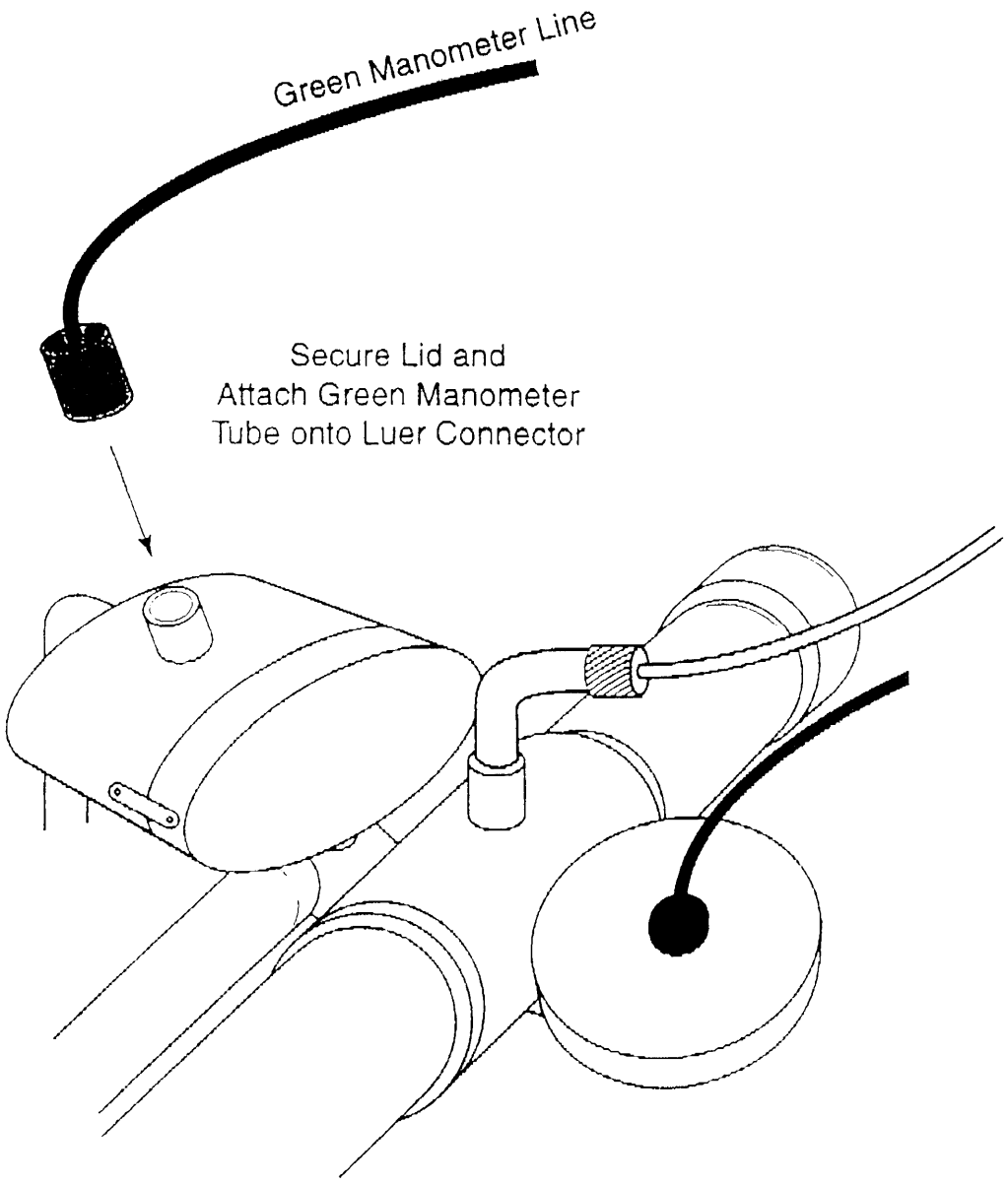

Patient Y-Piece
Elbow
Inspiration
Expiration
Nitric Oxide Analyser
Nitrogen Dioxide Analyser

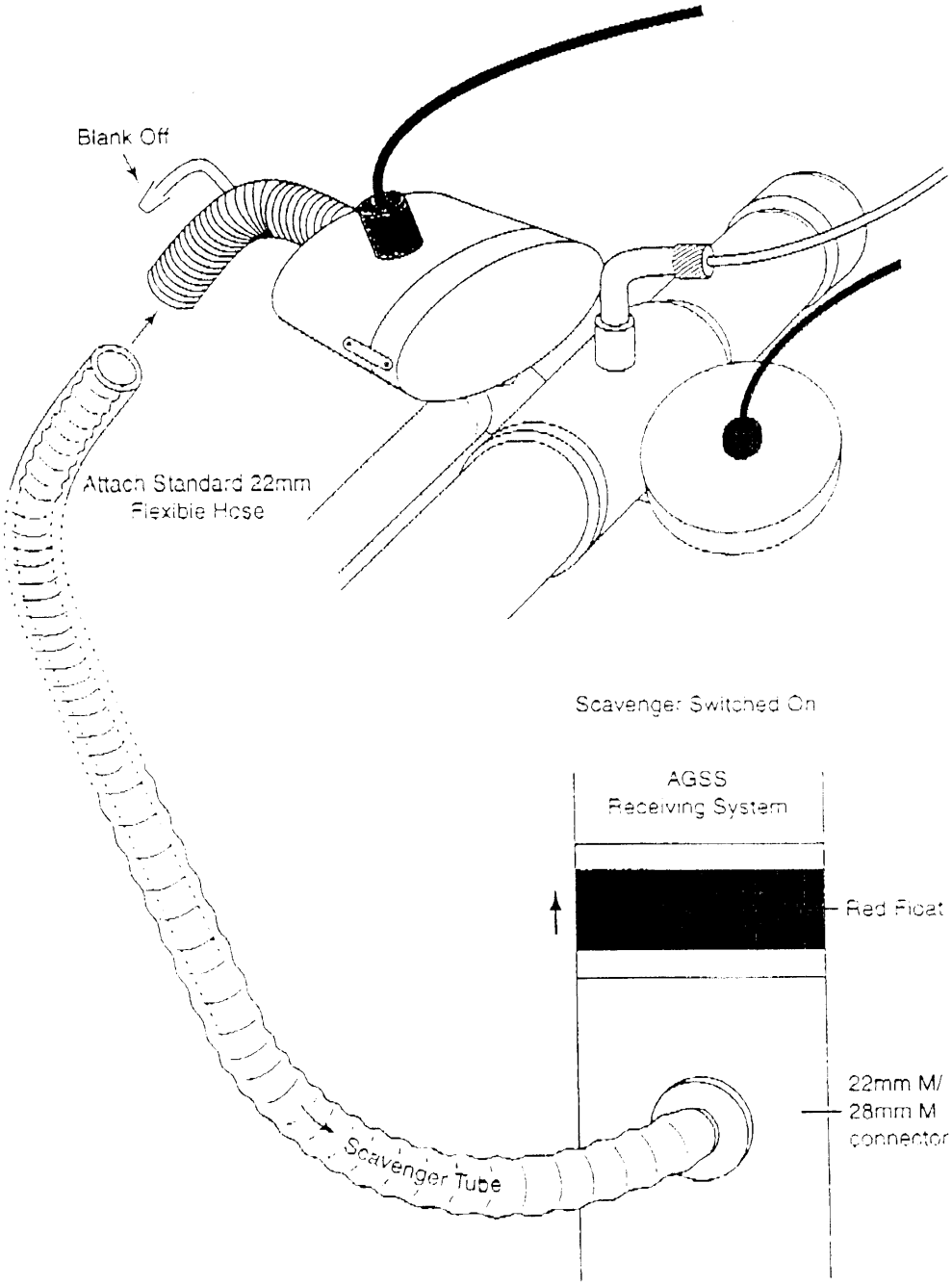
3.) Connection of Gas Scavenging System



Attach Sensormedic Scavenger Adapter
onto Exhalation Valve Housing p/n 770150




Green Manometer Line
Secure Lid and
Attach Green Manometer
Tube onto Luer Connector


Blank Off
Attach Standard 22mm
Flexible Hose
Scavenger Switched On
AGSS
Receiving System
Red Float
22mm M/
28mm M
connector
Scavenger Tube

Administration of Nitric Oxide using a Laerdal Resuscitator

This information applies only to users of the SLE 2000 ventilator and SLE H.F.O. ventilator, which operate with a bias flow of 5 L/min.

It is important to maintain the same nitric oxide concentration as measured in the ventilator circuit, therefore use 5 L/min of fresh air/02 mixture administered from the SLE flow meter.

Simply remove the NO/N2 supply manometer tube from the ventilator inlet elbow and attach to the Y-piece adapter. (see illustration). Attach your air/02 tube to the other branch of the Y-piece and finally attach onto your Laerdal adapter. Hand ventilate using 5 L/min of your desired Air/02 mixture.

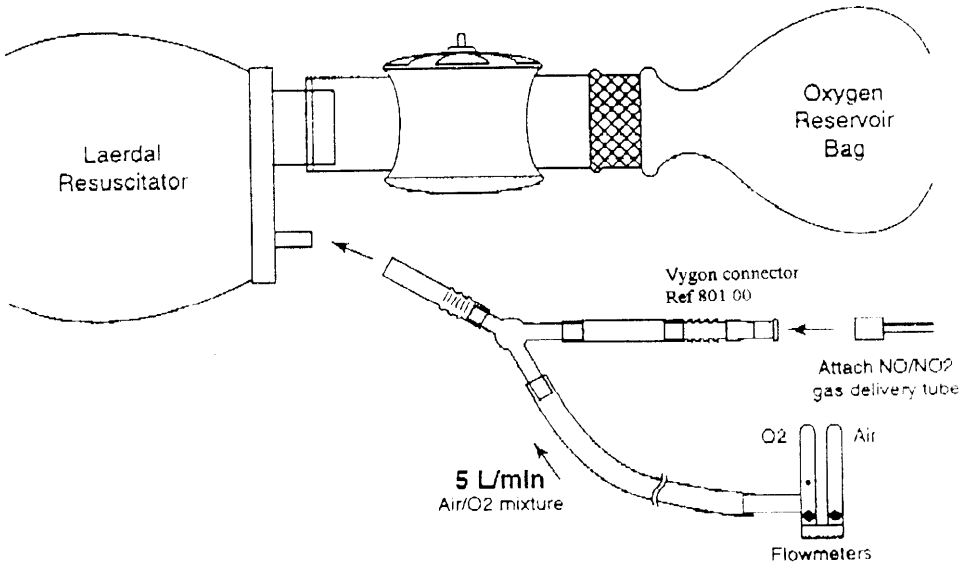


Diagram 3

Hand Ventilation Circuit