Intensive Care Unit - Nitric Oxide
This document applies to the Intensive Care Unit (ICU) at St George Hospital (SGH) only.

Cross references
(including NSW Health/ SESIAHS policy directives)
Nitric Oxide Workplace Instruction (inclusive Operator manual)
INOmaxDS® Operation Manual Rev -05 2012-03
NIOSH Recommendations for Occupational Safety and Health Standard
St Vincent’s Public Hospital ICU Clinical Practice Manual Procedure N4

1. What it is
This document describes a standardized guide to the management of patients receiving inhaled Nitric Oxide (iNO) in ICU at SGH.

2. Employees it applies to
All Intensive Care Staff Specialists (ICSS), other medical staff and nursing staff involved in administration of NO must be specifically credentialed for its use.

3. When to use it
When prescribed by the ICSS as indicated by the patient condition.

4. Why the rule is necessary
Patients in the ICU who require NO shall receive this treatment in an optimal and safe manner.
Staff that care for patients receiving NO therapy shall do so in safe work environment.

5. Who is responsible
Director of ICU
ICSS

6. Process

1.0 INTRODUCTION

2.0 INDICATIONS

3.0 CONTRAINDICATIONS

4.0 DOSE

5.0 MONITORING

6.0 DOCUMENTATION AND PRESCRIPTION

7.0 EQUIPMENT

8.0 WEANING

9.0 EXPOSURE & SAFETY ISSUES

9.1 Environment

9.2 Staff

9.3 Storage and handling

9.4 Scaevenging

9.5 Large NO leak and exposure

9.6 OH &S Effects of a major exposure to NO and treatment options

9.7 Material safety data sheet ( MSDS )
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>TRAINING &amp; COMPETENCY</td>
</tr>
<tr>
<td>10.1</td>
<td>Strategies for training</td>
</tr>
<tr>
<td>10.2</td>
<td>Key elements /troubleshooting</td>
</tr>
<tr>
<td>10.3</td>
<td>Record of training</td>
</tr>
<tr>
<td>11</td>
<td>MAINTENANCE</td>
</tr>
</tbody>
</table>

Approved by: Clinical Governance Documents Committee Date: May 2013
1. INTRODUCTION

1.1 DESCRIPTION
- NO is a colourless and odourless, gas. It spontaneously combines with oxygen to form Nitrogen Dioxide (NO₂), a reddish brown gas at temperatures >21°C.
- In air NO and NO₂ exist in equilibrium; thus mixtures are often referred to collectively. Both gases are considered atmospheric pollutants. Outdoors, the main source of this pollution is combustion of fossil fuels by industries and motor vehicles. It also occurs in cigarette smoke (at 400 – 1000ppm).

1.2 ACTION
- NO is a continually produced endogenous vascular dilator. It relaxes vascular smooth muscle by increasing intracellular levels of cyclic guanosine 3',5'-monophosphate (cGMP). A protein kinase, activated by cGMP decreases the sensitivity of myosin to calcium-induced contraction and lowers the intracellular calcium concentration inhibiting the release of calcium from the sarcoplasmic reticulum. These changes cause smooth muscle cells to relax. NO has been previously referred to as endothelial-derived relaxing factor (EDRF).
- NO is able to penetrate cell membranes to deliver a signal to nearby smooth muscles to relax. As the muscles relax, and arterial vasodilatation ensues, resistance to flow diminishes and blood flow increases, helping the heart and lungs to process more oxygen and deliver more oxygenated blood to the body.
- NO has several important physiological roles, including involvement in smooth muscle relaxation, neurotransmission, host defence responses and platelet function.
- Circulating NO has a high affinity to haemoglobin (Hb) and is rapidly inactivated by a reaction with circulating Hb, thus it has a half life of only 3 – 5 seconds. NO binds to Haemoglobin and forms methaemoglobin with potential for excessive and dangerous levels of methaemoglobinaemia.
- Metabolites of NO are generally eliminated from the body within forty-eight hours after being reduced to ammonia, converted to urea and excreted in the urine, whilst some nitrates are evacuated with faeces and others are converted by oral flora and expelled through salivary glands.

1.3 THERAPEUTIC USE OF INHALED NO (iNO)
- Inhaled nitric oxide, (iNO) causes relaxation of the smooth muscle cells in the pulmonary vasculature with a resultant decrease in the Pulmonary Vascular Resistance (PVR).
- iNO is a selective pulmonary vasodilator due to the extremely short half-life.
- The right ventricle (RV) is extremely sensitive to afterload, if RV function is impaired it may respond favourably to the decreased afterload, and in the absence of left ventricular failure, improve cardiac output.
- iNO was intensively used and investigated for many years in a setting of ARDS. It was shown to improve oxygenation in responder-groups but failed to demonstrate improvements in survival rates.
- There is clinical and research evidence that iNO can be beneficial to patients with acute reversible right ventricular failure. iNO has been approved for use in SGH ICU and CICU for patients in this group only.
2. INDICATIONS

1. Right Sided Cardiac Failure (RSCF)\textsuperscript{15,16,17,18} – acute and reversible right ventricular dysfunction associated with pulmonary hypertension (Mean Pulmonary Artery Pressure (MPAP) > 24 mmHg, and/or Transpulmonary Gradient (TPG) > 15 mmHg (mPAP – PAWP) and/or Pulmonary Vascular Resistance (PVR) > 400 dynes/sec/cm\textsuperscript{5}.

3. CONTRAINDICATIONS

3.1 Absolute contraindications
- Severe Left Ventricular Failure (LVF)
  - In patients with pre-existing LV dysfunction iNO may decrease pulmonary vascular resistance with resulting increase in right ventricular output. Existing LVF in such situation could lead to inability of the left ventricle to accommodate increased blood flow, in turn leading to increase in LVEDP, LAP, pulmonary capillary wedge pressure and eventually leading to pulmonary oedema.
- Methaemoglobin reductase deficiency, acquired or congenital\textsuperscript{6}

3.2 Relative contraindications
- Bleeding disorders\textsuperscript{6}
  - iNO is known to effect platelet function and bleeding time
  - Pulmonary Oedema or acute pulmonary infection is a potential problem with nitric oxide inhalation, primarily due to formation of nitrogen dioxide; nitrogen dioxide concentrations in inspired gas should be monitored and kept at least below 3 parts per million (ppm) (optimally, 1 ppm)\textsuperscript{9}
  - Dependence on right to left blood shunting significant left to right blood shunting\textsuperscript{4}
  - Paraquat induced lung injury\textsuperscript{7}
  - Intracranial Haemorrhage\textsuperscript{6}

4.0 DOSE
- The starting dose of iNO is 2 ppm (parts per million) of inhaled gas. The dose may be gradually increased with titration up to 40 ppm if the lower dose has not provided sufficient clinical effects. Such titration should be done with incremental increase of iNO concentration by 2 ppm every 5-10 minutes. The lowest effective dose should be administered and the dose should be weaned down whenever possible to 1-2 ppm provided that the pulmonary artery pressure and systemic arterial oxygenation remain adequate at this lower dose.
- Most responders to administration of iNO demonstrate good pulmonary vasodilation effect with doses below 10 ppm. Only occasionally, higher doses may be required.
- The effects of inhaled NO are rapid, decrease in pulmonary artery pressure and improved oxygenation are seen within 5-20 minutes. It may take longer until improvements are seen in RV performance, as impaired RV may require longer recovery time.
- Consideration should be given to discontinuation of treatment if no beneficial physiological effects are apparent after a 30-60 minute trial of therapy and higher doses of iNO bringing no desired beneficial results.
- Literature suggests that treatment may be initiated at any time point in the peri-operative
course to lower pulmonary pressure. In clinical studies treatment was often initiated before separation from Cardio Pulmonary Bypass. Inhaled NO has been given for time periods up to 7 days in the peri-operative setting, but common treatment times are 24-48 hours.

Please note SGH new applications committee limited administration of iNO to the ICU and did not extend administration of iNO to the operating room at this stage.

NOTE:
- Treatment with inhaled nitric oxide might aggravate cardiac insufficiency in a situation with left-to-right shunting. This is due to pulmonary vasodilation caused by inhaled nitric oxide, resulting in a further increase of already existing pulmonary hyperperfusion thus potentially giving rise to forward or backward failure. It, therefore, is recommended that prior to the administration of nitric oxide, pulmonary artery catheterisation or echocardiographic examination of central haemodynamics be performed.
- Inhaled nitric oxide should be used with caution in patients with complex heart defect, where high pressure in the pulmonary artery is of importance for maintaining circulation.
- Inhaled nitric oxide should also be used with caution in patients with compromised left ventricular function and elevated baseline pulmonary capillary pressure (PCWP) as they may be at an increased risk of developing cardiac failure (e.g. pulmonary oedema).
- Doses above 40ppm may result in increased NO2 and methamoglobin. The beneficial effects of high dose iNO (10ppm) may be lost between twenty four and ninety six hours.

CAUTION: DO NOT REDUCE OR STOP THE CONCENTRATION OF iNO ABRUPTLY OR SEVERE PULMONARY HYPERTENSION AND/OR HYPOXEMIA MAY OCCUR

DO NOT REDUCE OR STOP THE CONCENTRATION OF iNO ABRUPTLY OR SEVERE PULMONARY HYPERTENSION AND/OR HYPOXEMIA MAY OCCUR.
- Abrupt discontinuation of iNO administration is likely to result in profound right ventricular failure and therefore should never be done.
- Please refer to Nitric Oxide Workplace Instructions (WPI) for use of back up iNO blender in the case of power loss to ventilator and/or failure of iNO delivery unit.
- In the event of delivery mode failure Prostacyclin therapy may be required (as per ICU Consultant instructions).
- It is important to have Prostacyclin readily available.


4.1 Delivery Modes

- The iNOmaxDSIR enables constant gas monitoring thus there is no need to calculate
different iNO flows for monitors for changing minute ventilation see figure 1

- The iNOmaxDS\textsubscript{IR} is compatible with:
  - Servo I – Maquet Ventilator
  - Drager Evita & Evita XL
  - HFOV Sensormedics 3100B Standard and filter circuits (see HFOV workplace instructions)

⚠️ **IN THE EVENT OF A POWER FAILURE**

- **iNO blender**\textsuperscript{13} use will be required for manual ventilation if there is electrical failure of mechanical ventilation. (See workplace instructions and competency for use).

  **NOTE:** The manual bag should be squeezed continuously (breath rate as per previous settings on ventilator) to avoid NO\textsubscript{2} building up in the bag. If the bag is not squeezed continuously (i.e. adjustment to ETT) while delivering NO the bag should be removed from the patient and the purge procedure performed before continuing.

- **Adjunct nebuliser therapy** for bronchodilators if required should not be pneumatically driven, the use of the Aerogen nebuliser system is recommended for closed system reducing the disconnections of the ventilation system

- **Suctioning**
  - Use a closed suction system. Abrupt interruption of iNO delivery to the patient may result in rebound hypoxeamia and pulmonary hypertension.

- **Transporting patient on the iNOmaxDS\textsubscript{IR}**
  - Transporting the patient on iNO therapy is not advised and only on the advice of the ICU Consultant.
  - Where possible anticipate the need for diagnostics prior to introducing iNO therapy
  - iNO therapy cannot be abruptly ceased for transporting.
5.0 MONITORING

- **INHALED NO and NO\textsubscript{2} MONITORING**
  - Inhaled NO and NO\textsubscript{2} is continuously monitored on the inspiratory limb of the ventilation circuit. The iNOmaxDS\textsubscript{IR} \textregistered delivery system continuously monitors inspiratory NO, NO\textsubscript{2} and O\textsubscript{2} levels.
  - Inhaled NO\textsubscript{2} should not exceed 3ppm\textsuperscript{6}. The ICU Consultant should be notified should the level reach 2ppm.
  - Interventions to reduce NO\textsubscript{2} formation include:
    - Decreasing the flow of NO (Consultant must be aware)
    - Decrease the concentration of oxygen and ensuring there is constant flow of air and oxygen through the inspiratory limb of the circuit. (e.g. If ventilator is turned off during bagging, but the NO continues to be delivered)

**NOTE:** NO\textsubscript{2} rapidly forms in gas mixtures containing nitric oxide and O\textsubscript{2}, and nitric oxide may in this way cause airway inflammation and damage. It should be considered to reduce the dose of nitric oxide if the concentration of nitrogen dioxide exceeds 1 ppm.\textsuperscript{4}
5.1 PATIENT MONITORING
All patients considered for administration of iNO should preferably undergo echocardiographic assessment, prior to the initiation of iNO to obtain the baseline.

- It is necessary to monitor the effects of iNO on the patient. Monitoring should include:
  - PaO2
  - PaCO2
  - SvO2
  - SaO2
  - SpO2** See 6.2 Methaemoglobin levels
  - PAP
  - PVR
  - And recorded on the CIS minimum 1/24
  - Repeat and/or dynamic echocardiographic assessment

6.0 DOCUMENTATION & PRESCRIPTION

6.1.1 Medical Prescription & documentation
- iNO therapy cannot be commenced until appropriately prescribed in the patient’s notes/CIS using the template available
- The iNO therapy template can be found on the CIS under “Templates” in the green ‘Resp’ tab.
- iNO therapy must be reviewed and prescribed daily or with any change in settings by the Senior ICU Registrar/ICU Consultant
- A daily methaemoglobin level must be cited and documented by the ICU team

6.1.2 Nursing documentation
- The iNO documentation can be found on the CIS under “Resp”
- It involves recording 1/24 or increased in frequency as per patient condition:
  - Standard ventilation & respiratory observations
  - NO ppm
  - NO2 ppm Inform ICU Consultant at 1 ppm. Alert ICU Consultant at 2ppm
  - O2 %

6.2 METHAEMAGLOBIN LEVELS

iNO binds with haem to form methaemoglobin. An increase in the level of methaemoglobin by 5% can lead to the inability of Hb to transport O2 to the tissues. Methaemoglobin levels should remain < 1%.

- Methaemoglobin levels should be checked prior to commencement of iNO therapy and one hour to 6 hours after commencement.
- Once methaemoglobin levels are stable they can be repeated daily or with an increase in iNO dose.
- Methaemoglobin levels are provided by the arterial blood gas analyser with co-oximeter.** Regular pulse oximeters without co-oximeter capabilities are unable to differentiate methaemoglobin and may provide false high readings for oxyhaemoglobin.
- Symptomatic methaemoglobin is marked by signs that are associated with cyanosis and includes grey coloured skin, headache, CNS depression, tachycardia, and acidosis.
- If the fraction of methaemoglobin rises to a level that potentially compromises adequate oxygen delivery, the INOmax dose should be decreased and the administration of reducing medicinal products such as methylene blue, Vitamin C and exchange blood
transfusion, based on the clinical situation may be considered. The most frequent therapy for excessive methaemoglobinemia is intravenous infusion of methylene blue (refer to MIMS).

- Caution should be used when administering INOMAX with other drugs that can cause methemoglobinemia regardless of their route of administration, i.e. nitroprusside.

### 6.3 INTERACTION WITH OTHER DRUGS:

- Caution should be exercised when administering iNO with other vasodilators (nitroglycerin infusion, phosphodiesterase inhibitors etc.)
- Major caution must be exercised in administration of iNO simultaneously with other methaemoglobin-forming medication.
7.0 EQUIPMENT

Drager Ventilator with water base humidification circuit
- In – Line suction catheter
- iNOmaxDSIR® machine
- Bacterial filter for inspiratory limb prior to injector module
- Injector module
- Injector module cable
- Injector module tubing
- Sample line (luer lock)
- White 22mm/15F connectors x 2
- Blue 22mm connector x 2
- Laerdal resuscitator bag with PEEP if required attached to iNO blender
- Water separator cartridge
- Water trap bottle
- 2 size 88 NO cylinders (see section 9.3 figure 3) and regulators
- PPE equipment

Please refer to workplace instruction & Operator Manual for step by step guide to set up.

8.0 WEANING – Under direction of the ICU Consultant

- Weaning occurs under the direction of the ICSS since patients’ responses to weaning need to be individualised and since it is possible that long term exposure to iNO (e.g. for four or more days) may increase the patient’s responsiveness to lower dose iNO (e.g. 1ppm) whereas the same patient may remain unresponsive to higher doses of iNO (e.g. 10ppm)\(^1\)
- Attempts to wean INOmax should be made after the ventilator support and cardiovascular support (inotropes) is substantially decreased. Treatment with iNO should be routinely reassessed after 96 hours of therapy\(^9\)
- Weaning should be attempted at least every 12 hours when the patient is stable on a low
dose of INOmax.

- When the decision is made to discontinue inhaled nitric oxide therapy, the dose should be incrementally reduced every 30 minutes to one hour.\(^9\)
- When patients remain on iNO therapy for a prolonged time, they may be highly susceptible to a total withdrawal of iNO and therefore may require small doses of iNO support for extended periods. If there is no change in oxygenation during administration of INOmax at 1 ppm the FiO\(_2\) should be increased by 10%, the INOmax is discontinued\(^9\).
- Monitor closely for signs of hypoxaemia. If oxygenation falls greater than 20%, INOmax therapy should be resumed at 5 ppm and discontinuation of INOmax therapy should be reconsidered after 12 to 24 hours.
- Patients who cannot be weaned off INOmax by 4 days should undergo careful diagnostic work up for other diseases.
- Monitor and maintain acceptable pulmonary and haemodynamic variables prescribed by the ICU team.
- During weaning, pulmonary pressures and other haemodynamics as well as oxygenation and ventilation parameters are monitored for signs of intolerance to weaning. E.g should PAP and PVR increase or hypoxaemia develop the weaning should pause whilst acceptable parameters are obtained and titrated to the lowest effective dose of iNO. Clinical signs of deteriorating right ventricular function should be monitored.
- Attempts to wean INOmax should be commenced as soon as the hemodynamics have stabilised in conjunction to weaning from ventilator and inotropic support.
- Too rapid weaning from inhaled nitric oxide therapy carries the risk of a re-bound increase in pulmonary artery pressure with subsequent circulatory instability.

9. EXPOSURE & SAFETY ISSUES

9.1 Environment

- When the ICU Consultant confirms the use of iNO in the ICU the air handling system for side rooms and main room must be switched to the “Spill Air Mode”. This is when the flow of Return Air is fully exhausted & the system is supplied with 100% fresh air
  - In hours – Call Air- conditioning technician
  - Out of hours – Out of hours – AHSNM to instruct O/C technician/engineer (NOT Biomedical ) to control from remote
- Ideally room A,B or C should be used for a patient requiring iNO therapy
- If unable to use side room it is recommended to position the patients in bed spaces 11 or 12 of the main room.
- When not in use the two (2) iNOmaxDS\(_{im}\) machines will be stored with two (2) iNO cylinders attached to each machine in the engineering gas room.
- For the ability to access the two machines with iNO cylinders attached call:
  - In hours – Call Engineering
  - Out of hours –AHSNM and Security (have keys to blue cage in the “Gas room"

See workplace instructions for machine and cylinder retrieval.
Both machines will need to be placed through the Pre – Use Checkout procedure (see workplace instruction/Operator manual). The machine to be used is priority for this procedure. The Pre Use Checkout can take approx 10 – 15 minutes to carry out.

The spare iNOmaxDS IR machine will be placed in the procedure room in preparation for emergency use.

In the event of 2 patients simultaneously requiring iNO therapy a spare iNO cylinder will be stored in the equipment room secured to the O2 storage cage.

9.2 Staff

- Staff should not be at risk of harm from exposure to these gases, however safety precaution should be maximised.
- At the doses prescribed, in a well ventilated room, staff should not be at risk of exposure to NO or NO₂.
- The environmental monitor must be worn by the primary RN who is at the bedside of the patient receiving iNO.

![NO and NO₂ portable environmental monitor](image)

- Staff who have a condition that may be impacted upon exposure to NO or NO₂ should be reviewed by the ICU Nurse Manager prior to fulfilling the primary care role.
- Pregnant members of staff must not fulfil the primary care role.
- Eye goggles and nitrile (purple) gloves must be worn when cylinders are changed.
- A risk assessment has been attended and can be accessed from the Nurse Manager system\\ Critical Care and Surgery\intensive care unit

9.3 Storage and handling

- Inhaled NO (size 88 canister 800ppm) is mixed with nitrogen in a teal coloured bottle (IKARIA – INOmax Material Safety Data Sheet –July 2009).
Do not drag, slide or roll cylinders. Use a suitable trolley for movement.

NO reacts in air to form Nitrogen Dioxide. The mixture is an asphyxiant if directly inhaled. It has no liquid phase and is non-flammable. It is a brown coloured gas.

High pressure, heat above 50°C, fire or impact damage may cause the cylinder to rupture.

Cylinders should be stored upright in a dry area away from traffic in a well ventilated area. They will be stored in the Engineering Dept (see Section 9.1).

In the event of 2 patients simultaneously requiring iNO therapy the spare cylinder will be stored in the equipment room secured to the O2 storage cage.

The following is a guide to demonstrate the duration of use of a size 88 cylinder at different flow rates in order to guide when cylinder availability and retrieval from Engineering room should be sought.

### Duration Chart

**INOMAX® Cylinder 88-Size**

For an 88 Size 800 ppm Cylinder Concentration

(Enumerative Only)

<table>
<thead>
<tr>
<th>INOMAX® Dose (ppm)</th>
<th>5 L/min</th>
<th>10 L/min</th>
<th>20 L/min</th>
<th>40 L/min</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 ppm</td>
<td>43.3 Days</td>
<td>21.7 Days</td>
<td>10.8 Days</td>
<td>5.4 Days</td>
</tr>
<tr>
<td>10 ppm</td>
<td>21.5 Days</td>
<td>10.7 Days</td>
<td>5.4 Days</td>
<td>2.7 Days</td>
</tr>
<tr>
<td>20 ppm</td>
<td>10.0 Days</td>
<td>5.3 Days</td>
<td>2.6 Days</td>
<td>1.5 Hours</td>
</tr>
<tr>
<td>40 ppm</td>
<td>5.2 Days</td>
<td>2.6 Days</td>
<td>1.5 Hours</td>
<td>7 Hours</td>
</tr>
<tr>
<td>80 ppm</td>
<td>2.4 Days</td>
<td>2.6 Days</td>
<td>1.4 Hours</td>
<td>7 Hours</td>
</tr>
</tbody>
</table>

### 9.4 Scavenging –

- In a well ventilated room there is no need for scavenging of exhaled gases, especially at delivery doses of iNO less than 40ppm
- See risk assessment
9.5 Large NO leak and exposure

- The procedure for a leak during the Pre Use checkout – High Pressure leak test must be followed and is available on page 104 of the Operators Manual – Workplace Instruction. (Diagram attached to machine)
- A large or uncontrollable leak of NO (as demonstrated by hissing noise or environmental monitoring) may occur with accidental damage to the cylinder or one of its main connections
- Risks to health are by inhalation.
- It may result in severe irritation and burns of eyes, skin, mucous membranes, and any other exposed tissue. If high concentrations of this gas mixture are inhaled, delayed pulmonary damage and breathing difficulty may occur.
- If a large, uncontrollable leak or cylinder rupture occur, an internal emergency code must be followed (Code Yellow)
- Evacuate personnel/relatives/ and non ventilated patients from the vicinity/room
- Call a “Code Yellow” by dialling 777 and report a Nitric Oxide leak, the vicinity and number of people affected.
- If non-ventilated patients cannot be removed from the immediate vicinity of a large leak, protect their eyes – don goggles and apply O2– Hudson mask
- An environmental monitor/iNO delivery system can monitor the levels of NO₂ and NO in the environment if any levels of NO or NO₂ are anticipated.
- The environmental monitor must be used to determine safe levels of NO and NO₂ prior to the safe return of staff to the bed area.
- The Control of Substances Hazardous to Health (COSHH) and National Institute for Occupational Safety (NIOSH) guidelines suggest that environmental NO levels should not exceed a time weighted average (TWA) of 25 ppm over 8 hours. NO₂ levels should not exceed a TWA of 3 ppm over 8 hours or ceiling limit of 1 ppm.

9.6 OH &S Effects of a major exposure to NO and treatment options

- A major exposure to NO refers to the exposure that may occur with a large leak as described in section 9.5 and involves levels of 100ppm
- The following responses may be noted and actions taken
  - Eyes – Discomfort and pain resulting in severe conjunctivitis
    **Action:**
    - Report to the Emergency Department (ED) immediately
    - The eyes should be opened and irrigated with saline or water solution for 20 minutes.
    - Do not rub eyes, or tightly shut or use hot tepid water. Do not use lubricants or ointments until medical advice obtained.
  - Skin – Chemical burns can result from contact with the skin
    **Action:**
    - Report to the ED
    - Shower or flush skin with large amounts of water
    - Remove contaminated clothing
Lungs – Inhalation of high concentration of NO may cause respiratory discomfort. A major exposure can result in progressive inflammation of the lungs.

Action:
- Report to ED for assessment and follow up
- Report incident of leak through the IIMS reporting database.

9.7 Material safety data sheet (MSDS)
- iNOmax MSDS to be kept in MSDS folder in the unit
- In the event of exposure section 9.6 to be followed.

10. TRAINING & COMPETENCY - Training in administration

10.1 Strategies for training
- On line learning – simulation
- In-service
- Clinical Practice Assessment
- Workplace Instruction manual
- Clinical Business Rule

10.2 Key elements
- The key elements that need to be covered in training hospital personnel are as follows:
  - Correct set-up and connections
  - Connections to the gas cylinder and to the ventilator patient breathing circuit
  - Operation
  - Pre-use check out procedure (a series of steps required immediately prior to each patient initiation to ensure that the system is working properly and that the system is purged of NO$_2$)
  - Setting the device for the correct concentration of nitric oxide to be administered
  - Setting the NO, NO$_2$, and O$_2$ monitors for high and low alarm limits
  - Using the manual backup delivery system
  - Procedures for correctly switching gas cylinders and purging system
  - Troubleshooting alarms
  - Troubleshooting equipment failure
  - NO, NO$_2$, and O$_2$ monitor calibration
  - Monthly system performance check-up procedures

10.3 Record of training
- Training logs will be maintained through:
  - In-service record LMS database
  - Competency standards (see Clinical Practice Assessment record)
11 MAINTENANCE

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Maintenance</th>
</tr>
</thead>
</table>
| Daily           | • Check the INOMAX® cylinder pressure: a cylinder with less than 200 psig should be replaced.  
                  • Perform the low range calibration.  
                  • Empty the water trap bottle as needed. |
| Start of each patient | Must perform the Pre-Use Procedure.                                      |
| Between each patient | • Sterilize and/or disinfect the Injector Module.                  
                     • Clean water trap bottle.                                      
                     • Replace the single patient use items.                           
                     • Make sure that the delivery system power cord is always plugged into an emergency-power-backed electrical outlet.  
                     • Make sure the connectors, hoses, and cables are in good condition. |
| Monthly         | • Do the high range calibration of NO, NO2, and O2.                    |
| Yearly in Service agreement with IKARIA | • O2, NO and NO2 sensors                                             |

- After use clean the iNOmaxDSIR machine take off from electrical source
- Clean the outer surface of the INOmax DSIR with a soft cloth dampened in a mild soap and water solution, isopropyl alcohol (70%).
- Remove electrical injector cable from injector module. Clean electrical cable with the above solution and leave with the machine
- Send the Injector housing module to CSSD.
- If alcohol is used to clean water trap bottle, make sure alcohol is completely evaporated before placing back onto sample block
- Patient circuit adapters, sample line, Injector Module tubing and water separator cartridge are single-patient use items. Do not sterilize them. Dispose of all single-patient use items in accordance with Universal Precautions for contamination.
7. Compliance evaluation

<table>
<thead>
<tr>
<th>Q1: Where are the iNO machine and Nitric Oxide cylinders located when not in use?</th>
</tr>
</thead>
<tbody>
<tr>
<td>A: Engineering</td>
</tr>
<tr>
<td>Q2: What is the guideline and limit for the time weighted average of NO and NO2 levels in the environment?</td>
</tr>
<tr>
<td>A: NO levels should not exceed a time weighted average (TWA) of 25 ppm over 8 hours. NO2 levels should not exceed a TWA of 3 ppm over 8 hours or ceiling limit of 1 ppm.</td>
</tr>
<tr>
<td>Q3: What is the reason for weaning iNO and not stopping iNO abruptly?</td>
</tr>
<tr>
<td>A: If iNO is ceased abruptly, even from the smallest dose, acute pulmonary hypertension and hypoxemia could occur</td>
</tr>
<tr>
<td>Other: eg: Audit Plan</td>
</tr>
</tbody>
</table>

8. Keywords

Nitric Oxide, Nitrogen Dioxide

9. External references

4. INOmax® (nitric oxide) for inhalation. Full prescribing information 7/2011
13 INOmaxDS® Operation Manual Rev -05 2012-03

I, Dawn Fowler Clinical Group Manager Medicine and Critical Care SGSHHS attest that this business rule is not in contravention of any legislation, industrial award or policy directive.

### Revision and approval history

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision number</th>
<th>Contact Officer (Position)</th>
<th>Date for revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/12/2012</td>
<td>0</td>
<td>Dr Konstantin Yastrebov ICU Staff Specialist Sarah Jones CNC ICU</td>
<td></td>
</tr>
</tbody>
</table>