

Carriage and storage of Entonox by Midwives

Issue Date	Review Date	Version
March 2019	March 2023	V1

Purpose

To provide information regarding usage, handling and storage and transportation of Entonox.

Who should read this document?

All midwifery staff that are required to transport Entonox cylinders in their vehicle for women requesting the use of Entonox analgesia in the home setting.

Key Messages

To comply with the rules and regulations regarding handling, storage and transportation, particularly with regard to the use of portable cylinders by midwives attending homebirths. To achieve safe administration of Entonox.

The Operating Policy should be read in conjunction with:

- Trust Policy – Operational Policy for Medical Gases
- HTM 02 – 01 Medical Gas Pipeline Systems

Core accountabilities

Owner	Melissa Tucker
Review	Obstetric Risk Review Governance meeting
Ratification	Director of Midwifery
Dissemination (Raising Awareness)	Obstetric and Maternity Staff
Compliance	Director of Midwifery

Links to other policies and procedures

Trust Policy – Operational Policy for Medical Gases

HTM 02 – 01 Medical Gas Pipeline Systems

Trust COSHH Policy

Trust COSHH Risk Assessment and Standard Operating Procedure

Hospital Infection Control Manual and Memoranda

Hospital Fire Procedures

Permit to work system

Hospital Environmental Health and Safety Guidance, including Hospital Manual Handling Policy

MEMS Medical Equipment Users Guide

The Management and Use of Medical Devices Policy

Plant history records and maintenance log books

Test equipment calibration certificates

Training records of all Competent Persons

Written Scheme of Examination for medical gas systems

Insurance and inspection certificates for compressed air plant, PSVs

Details of ownership and insurance liability for BOC VIE systems

Medicines Management Policy

Version History

V1	2018	New SOP for Maternity Service. Approved by Clinical Effectiveness Committee
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The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on Trust Documents on Staff NET. Larger text, Braille and Audio versions can be made available upon request.

Standard Operating Procedures are designed to promote consistency in delivery, to the required quality standards, across the Trust. They should be regarded as a key element of the training provision for staff to help them to deliver their roles and responsibilities.

Section	Description	Page
1	Introduction	4
2	Definitions	4
3	Regulatory Background	4
4	Key Duties	5
5	Procedure to Follow	8-9
6	Document Ratification Process	9
7	Dissemination and Implementation	10
8	Monitoring and Assurance	10
9	Reference Material	10 -11
Appendices		
	Medical Gas Data Sheets	12
	Risk Assessment	

Standard Operating Procedure (SOP) Storage and Carriage of Entonox within Maternity.

1 Introduction

The purpose of this Standard Operating Procedure is to provide practical safety advice in respect of Trust employed staff handling and transporting medical gas cylinders. To achieve the safe administration of Entonox. To comply with the rules and regulations regarding the storage and transportation, particularly with regard to the use of portable Entonox cylinders used by Midwives.

2 Definitions

Entonox is a homogeneous gas mixture containing 50% nitrous oxide and 50% oxygen. It is stored in cylinders at 137 bar. The pressurised mixture remains gaseous at temperatures above -6 degrees.

Nitrous oxide is a colourless sweet smelling gas with powerful analgesic properties. Pulmonary transfer of nitrous oxide is rapid, with onset of effect in seconds and full analgesia within one to two minutes. Likewise, it is rapidly eliminated from the blood, via the lungs, when inhalation ceases. Entonox combines the analgesic effect of the nitrous oxide with the anti-hypoxic effect of 50% oxygen.

3 Regulatory Background

Everyone carrying gas cylinders in the course of their work must follow basic safety requirements. These are documented in full within the Trusts Operational Policy for Medical Gases and HTM 02 – 01 Medical Gas Pipeline Systems which should be read in conjunction with this Standard Operating Procedure.

Midwives can discuss pain relief available to women. NICE guidance 'Intrapartum Care for healthy women and their babies' CG 190 and 'Inducing Labour' CG 70.

4 Key Duties

Entonox is the brand name for a product containing 50% nitrous oxide and 50% oxygen. It is an inert, colourless gas that is non-flammable, but supports combustion above 450 degrees centigrade. It is used for its sedative or analgesic effects. Entonox is often referred to as "gas and air".

Entonox can be administered via a cylinder, or via piped apparatus. Entonox is designed to be self-administered by the patient, under medical supervision. Midwives

should not hold the mouth piece for the patient during use due to the risk of anaesthetising the patient.

If a patient receives more gas than necessary, they will become drowsy causing them to drop the mouthpiece. As the patient breathes ambient air, the Entonox effects rapidly wear off and the patient will regain consciousness.

Inhalation tubing is fixed to the cylinder, or to the piped apparatus, via a demand valve system. A hand piece (with a purge button) is connected to the tubing and a single use, disposable mouthpiece are attached to the hand piece. By the patient breathing normally through the mouthpiece the demand valve is opened and the gas is delivered. The gas is absorbed through the lungs. The valve closes when the patient stops inhaling.

The analgesic effect is seen almost immediately after four to five breaths and reaches its maximum effect within two to three minutes. Inhalation should commence shortly before the desired analgesic effect is required, for example, at the beginning of a contraction. It should continue throughout the painful aspect of the contraction or procedure or for as long as the analgesic effect is desired. The effects wear off within a few minutes. When administration has ended the patient should be allowed to recover under calm and controlled conditions – until the patient's degree of consciousness has recovered satisfactorily.

Safety of Health Care Professionals administering Entonox.

Warning notices prohibiting smoking or naked lights must be clearly posted. In the homebirth environment women and their birth partners must be informed that no smoking is permitted within the room the Entonox is stored and no open fires or candles are to be in use.

There is evidence that the following are potential risks to those health professionals administering Entonox:

- Chronic exposure to nitrous oxide can cause impairment of vitamin B12 – dependent enzyme, which in turn results in bone marrow depression, megaloblastic changes and neurological dysfunction.
- Prolonged occupational exposure to nitrous oxide may affect a patient's ability to become pregnant.
- May have an adverse effect on the developing fetus as determined by the Health and Safety Executive in its setting of the Occupational Exposure Standard (OSE) developmental toxicity.
- Effective ventilation and/or scavenging systems should reduce waste gas levels in the ambient air or treatment rooms to acceptable levels. Levels in these areas should be tested to ensure they are below the workplace exposure limits as listed in the HSE publication.

Care and storage of Entonox

Delivery systems must be stored away from public view; in a designated place.

A maximum of 4 Entonox cylinders to be stored in the theatre storage room, used cylinders are to be replenished from here.

All cylinders must be stored inside the cupboard with appropriate signage, not left in the outer room – photo to follow

Entonox carry bags to be kept in the storage room on CDS with the Homebirth kits.

The Risk assessment for the storage of Entonox is laminated and displayed in theatre.

Precautions should be taken to protect cylinders from theft.

- Cylinders should be kept out of the reach of children.
- Cylinders should be handles with care and not knocked violently or allowed to fall.
- F size cylinders and larger should be stored vertically with the valve uppermost. Cylinders should only be moved with the appropriate size and type of trolley.
- Entonox cylinders must be stored separately in a safe place, in a temperature above 10 degrees centigrade. Nitrous oxide begins to separate out from Entonox if the temperature falls below -6 degrees centigrade.
- Entonox equipment must be serviced on a yearly basis as per manufacturer's recommendations.
- Delivery systems must be consistent with Trust requirements.



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ENTONOX (web)_tcm

Transport of cylinders

When ENTONOX cylinders are required to be transported, ensure that the cylinders are:

- located in a compartment separated from the driver
- adequately restrained
- not leaking and have their valves closed.

The vehicle must be adequately ventilated. Ensure the driver is aware of the potential hazards of the load and knows what to do in the event of an accident or an emergency. It is advisable to provide the driver with written instructions that detail the actions to be taken in the event of an accident or emergency. Cylinders should be removed from the vehicle as soon as possible.

Entonox being used by Midwives attending homebirths.

Green hazardous gas Entonox sticker must be displayed on the rear windscreen of the midwives car when Entonox cylinders are being transported.

Midwives using their own cars for transporting Entonox must ensure they inform their car insurance company of this fact.

Entonox portable cylinders should be stored in the cases provided. Secure and not knocking each other.

The cylinders should not be subjected to extremes of heat or cold. Midwives storing cylinders in the car should take extra care overnight during freezing weather. Cylinders should be stored under cover, preferably inside, kept dry and clean.

When transporting the cylinders they should be turned off. E size cylinders and smaller should be stored horizontally. Ensure the cylinder valve is properly closed, that the tubing is disconnected and that the equipment is carried securely in the cases provided, in the vehicle.

Midwives should ensure they attend training days, typically held during Mandatory Training, on the transportation of Entonox as per the Management of Health and Safety at Work Regulations.

Medical Gas Data sheets

BOC provide medical gas safety sheets for their products. The data sheets provide safety information and should be read and understood. Medical Gas Data sheets for both Entonox and Oxygen can be downloaded <http://www.bochealthcare.co.uk>



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5 Procedure to Follow

Uses of Entonox

- Pain relief in labour
- Short term pain relief during painful clinical procedures, such as suturing

Adverse side effects

- Dry mouth
- Light headedness
- Inactive vitamin B12
- Vomiting

Entonox should not be used with any condition where air is entrapped within the bod and where its expansion might be dangerous such as:

- Artificial, traumatic or spontaneous pneumothorax, head injuries with impairment of consciousness
- Air embolism
- Decompression sickness

- Following a recent dive
- Following air encephalography
- Severe emphysema
- During myringoplasty
- Gross abdominal distension
- Maxillofacial injuries
- Compromised respiratory function

Entonox should not be used for more than 24 hours without monitoring peripheral blood for megaloblastic anaemia and leucopaenia.

It is recommended that driving and use of machinery should not be undertaken until 12 hours have elapsed since administration of Entonox.

Administration of Entonox

Entonox must be administered in conjunction with the terms and conditions of the following documents:

- NMC Standards for medicines management
- NMC Midwives Rules and Standards
- BOC Gases Medical data sheet for use of Entonox
- BOC Educational online material

Entonox may be administered by qualified Midwives registered with the NMC, who have received appropriate training. A patient should be continuously monitored whilst using Entonox to ensure there are no adverse effects.

Under no circumstances may a patient be given Entonox to use in their own transport. If a patient's needs to use Entonox she must be transferred by ambulance, where she can be monitored by the ambulance crew or a midwife escort.

Method of Administration

Cylinder – check if there is gas in the cylinder, by turning on, and examining the gauge. Ensure that the cylinder is not frosted.

Piped Entonox – check the flow of Entonox by pressing the purge button.

Check there are no contra-indications prior to administration.

Ascertain how much the woman knows about Entonox. Explain the use of the inhalational gas and how to use the apparatus effectively.

Encourage the patient to start using the Entonox at the beginning of a contraction and throughout the duration of the pain.

Observe the effects (both desired and adverse) on the patient and ensure she is using the equipment correctly.

Entonox can be used in conjunction with other forms of pain relief.

The filter and mouthpiece are single use only and should be disposed of when finished.

6 Document Ratification Process

The design and process of review and revision of this procedural document will comply with The Development and Management of Formal Documents.

The review period for this document is set as default of five years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed by the Guideline Committee and ratified by the Director of Midwifery.

Non-significant amendments to this document may be made, under delegated authority from the Director of Midwifery, by the nominated author. These must be ratified by the Director and should be reported, retrospectively, to the Clinical Effectiveness Committee.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes.

7 Dissemination and Implementation

Following approval and ratification, this procedural document will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document author(s) will be responsible for agreeing the training requirements associated with the newly ratified document with the Director of Midwifery and for working with the Trust's training function, if required, to arrange for the required training to be

delivered.

8 Monitoring and Assurance

Heads of Departments are responsible for providing evidence, at least annually, that the concentrations of pollutants in all areas at risk from medical gas pollution comply with COSHH regulations. Please see COSHH Policy for further detail.

All midwifery staff must attend yearly mandatory training which includes skills and drills training. A record should be kept of all those who have been taught.

All midwifery staff should ensure that their knowledge and skills are up-to-date and complete the Entonox e-learning package.

Any non-compliance with this Standard Operating Procedure should be recorded on the Trust Incident reporting package and a Datix should be raised.

Key findings and learning points will be submitted to the Clinical Effectiveness Committee. Any key findings will be disseminated to relevant staff.

9 Reference Material

Regulatory legislation and applicable guidelines

A list of appropriate regulatory legislation is detailed below. (This list is not exhaustive):

Health and Safety at Work Act, 1974

Management of Health and Safety at Work Regulations, 1999

Control of Substances Hazardous to Health (COSHH) Regulations 2002

Work Place (Health, Safety and Welfare) Regulations, 1999

Provision and Use of Work Equipment Regulations, 1998

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations, 1995

Pressure Equipment Regulations, 1999

Dangerous Substances and Explosive Atmosphere, 2002

Manual Handling Operation Regulations, 1992

Personal Protective Equipment at Work Regulations, 1992 (1998)

NICE guidance 'Intrapartum Care for healthy women and their babies' CG 190

NICE guidance 'Inducing Labour' CG 70.

University Hospital Plymouth Trusts Operational Policy for Medical Gases

HTM 02 – 01 Medical Gas Pipeline Systems

Other Guidance Applicable to Medical Gas Pipeline systems:

Health Technical Memorandum (HTM) 02 – 01 “Medical Gas Pipeline Systems” 2006

- Part A – Design, Installation, Validation and Verification
- Part B – Operational Management

Health Technical Memorandum (HTM) 03 – 01 “Specialised ventilation for healthcare premises” 2007

- Part A – Design and Validation
- Part B – Operational Management and performance verification

National Health Service Model Engineering Specification, C11, “ Medical Gases” 1995

Medical Gas Data sheets

BOC provide medical gas safety sheets for their products. The data sheets provide safety information and should be read and understood. Medical Gas Data sheets for both Entonox and Oxygen can be downloaded <http://www.bochealthcare.co.uk>



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(HEALTH AND SAFETY) RISK ASSESSMENT (AND SAFE SYSTEM OF WORK / SOP)

For help in completing this form please contact the Health & Safety Team on plh-tr.Health-SafetyTeam@nhs.net

To be used for the Assessment of risks in line with the Risk Management Policy, DATIX User Guides, Health & Safety Policy and Trust wide Policies and Procedures. All manual handling risks should be referred to manual handling key worker or Manual Handling team

Care Group	Women's Services	Risk Assessor	Anna Dodd
Service Line	Maternity	Approving Manager	Sheralyn Neasham
Location	CDS / Maternity Theatres	Specialist Advisor	Steve Mitchell
Location exact	Gasses Store Room, Maternity Theatres		
Date of Assessment	07/01/2019		

Refer to Risk Management Policy for further guidance

(1) Description or location The description of the task or activity being assessed	Safe storage for small entonox cylinders for community use. (Requiring immediate 24 hour availability.) Currently stored in designated Gas Store in Maternity Theatres with appropriate signage
(2) Hazard(s) Identified A hazard is anything that may cause harm	Safe storage of entonox / oxygen and air cylinders. Assessment of other hazardous chemicals nearby. Presence of combustible material nearby. (COSHH cupboard in outer part of room)
(3) Identified Risk Decide who might be harmed and how	Theatre and maternity staff. Combustible material in gas room. Avoid overstocking.
(4) Control Measures The precautions are control measures put into place to remove a hazard or control the remaining risk(s) from a hazard. Record your findings and implement them (at the time of the assessment)	<ol style="list-style-type: none"> 1) Maximum of 4 small entonox cylinders to be stored at any one time. 2) Reduce number of 'E' air & O2 cylinders to two. Others to be stored in main gas store. 3) All cylinders to be stored in inner cupboard with doors closed. 4) Advise removing COSHH cupboard with contents to alternative room. 5) Currently storage racks vertical. Small entonox cylinders should be stored horizontally.
(5) What issues are not addressed by these controls? Actions required reducing risk to an acceptable level. <i>(Review your risk assessment and update if necessary)</i>	<ol style="list-style-type: none"> 1) Liaise with theatre matron for alternative position for COSHH cupboard store. 2) Seek clarification from H&S lead as to importance of storing cylinders horizontally. 3) Liaise with porters to reduce the number of O2 & Air cylinders from 4 to 2 of each.

Refer to attached Matrix for further guidance [tick relevant box(es)]

For each risk complete following information

Risk No. 1

Adequacy of Controls in Place	Tick
Controlled (Risk is controlled as much as reasonably practicable)	√
Partially Controlled (There are controls in place but more needs to be done)	
Uncontrolled (There are no controls in place to prevent this risk from being realized)	
Likelihood Score for each identified risk	Score Tick
Almost Never - highly unlikely, but may occur in exceptional circumstances. It could happen but probably never will	1 √
Unlikely - Not expected but there's a slight possibility it may occur at some time.	2
Likely - The event might occur at some time as there is a history of casual occurrence at the Trust or within the NHS	3
Highly Likely – There is a strong possibility the event will occur as there is a history of frequent occurrence at the Trust or within the NHS	4
Almost Certain – The event is expected to occur in most circumstances as there is a history of regular occurrence at the Trust or within the NHS	5

Impact Score	Score	Risk to Patients	Risk to Staff	Risk to Business	Risk of Harm
Catastrophic, Death	5				
Severe, Permanent harm	4				
Moderate harm	3				
Minor harm	2				
Insignificant minimal Harm	1	√	√	√	√

Risk score = Likelihood x Impact (highest recorded impact)

1

Risk No. 2 (delete if not required)

Adequacy of Controls in Place	Tick
Controlled (Risk is controlled as much as reasonably practicable)	
Partially Controlled (There are controls in place but more needs to be done)	√
Uncontrolled (There are no controls in place to prevent this risk from being realized)	

Likelihood Score for each identified risk	Score	Tick
Almost Never - highly unlikely, but may occur in exceptional circumstances. It could happen but probably never will	1	
Unlikely - Not expected but there's a slight possibility it may occur at some time.	2	√
Likely - The event might occur at some time as there is a history of casual occurrence at the Trust or within the NHS	3	
Highly Likely – There is a strong possibility the event will occur as there is a history of frequent occurrence at the Trust or within the NHS	4	
Almost Certain – The event is expected to occur in most circumstances as there is a history of regular occurrence at the Trust or within the NHS	5	

Impact Score	Score	Risk to Patients	Risk to Staff	Risk to Business	Risk of Harm
Catastrophic, Death	5				
Severe, Permanent harm	4				
Moderate harm	3				
Minor harm	2				
Insignificant minimal Harm	1	√			

Risk score = Likelihood x Impact (highest recorded impact)	2
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Add additional risks as required (add as necessary)

For all above risks that cannot be addressed immediately by Care Group/Service Line these should be recorded on DATIX (see Risk Management Policy)

Added to Risk register	N	Date	07/01/2019	Datix Risk ID	
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2	<p>Hazard(s) Identified</p> <p>A hazard is anything that may cause harm</p>	<ul style="list-style-type: none"> • Consider Task/Procedure (what could cause harm) • Ask competent colleagues for their view • Walk around your workplace look for significant hazards • Look at datix incident records if necessary • Think long term (manual handling, PPE etc) as well as immediate • List identified hazards in Risk assessment
3	<p>Identified Risk</p> <p>Decide who might be harmed and how</p>	<ul style="list-style-type: none"> • Staff, patients, visitors and others • Do this for each identified hazard • Consider for example: patients, visitors, people working in area, clinical staff, cleaning staff, porters, persons with particular requirements e.g. new & young people, people with disabilities
4	<p>Control Measures</p> <p>The precautions are control measures put into place to remove a hazard or control the remaining risk(s) from a hazard. Record your findings and implement them (at the time of the assessment)</p>	<p>Having spotted the hazards, you then have to decide what to do about them. The law requires you to do everything 'reasonably practicable' to protect people from harm</p> <p>You can work this out for yourself, but the easiest way is to compare what you are doing with good practice</p> <p>Consider what you are already doing, what controls do you have in place? Is there more you can do:</p> <ul style="list-style-type: none"> • Can you remove the hazard altogether? • If not, how can you control the risks so that harm is unlikely? <p>Apply controls in the following order:</p> <ul style="list-style-type: none"> • Eliminate the hazard. Stop the procedure • Substitute i.e. change use of chemical, or process • Physical separation of person from hazard • Use competent trained staff and provide information, instruction and training to undertake task safely • Record giving of information/instruction/training • Written standard operating procedure – or permits to work • Appropriate warning signs • Appropriate personal protective equipment
5	<p>What issues are not addressed by these controls?</p> <p>Actions required reducing risk to an acceptable level. <i>(Review your risk assessment and update if necessary)</i></p>	<ul style="list-style-type: none"> • Record on the Risk Assessment • Keep it simple! <p>e.g. Hazard - tripping over rubbish</p> <p>Control measures - bins provided, staff instructed, weekly checks</p> <ul style="list-style-type: none"> • Make sure staff have seen the risk assessments • Prioritise – tackle the most important things first <p>Set a date for the next review, but don't forget that the environment might change in the meantime.</p> <p>For example:</p> <ul style="list-style-type: none"> • Further Actions Required to Reduce Risk to an Acceptable Level • When you introduce new equipment, new staff, new substances or procedures <p>When an incident occurs, staff member's idea or technological development might indicate a better control</p>

		Impact				
		Insignificant	Minor	Moderate	Severe	Catastrophic
		<p>Minimal impact on patients or staff.</p> <p>Day-to-day operational challenges.</p> <p>Minimal injury requiring no/minimal intervention or treatment. No time off work</p>	<p>Minor injury or harm to patient(s) or staff requiring minimal clinical intervention and/or requiring less than 7 days off work</p> <p>Temporary staffing issues resulting in increased pressure on staff and challenges in maintaining service quality.</p> <p>Temporary restriction to service delivery with limited impact on stakeholder confidence.</p>	<p>Moderate injury or harm to patient(s) or staff requiring clinical or other professional intervention and/or requiring time off work for 7-14 days. RIDDOR reportable incident</p> <p>Short-term staffing issues resulting in low staff morale or restrictions to service quality.</p> <p>Short-term failure to deliver key objectives with temporary term adverse local publicity</p>	<p>Serious permanent harm to patient(s) or staff leading to long-term incapacity/disability requiring time off work for more than 14 days. RIDDOR reportable incident</p> <p>Medium-term staffing issues resulting in very low morale or significant reduction in service quality</p> <p>Medium-term failure to deliver key objectives with ongoing adverse publicity or negative impact on stakeholder confidence.</p>	<p>Incident resulting in avoidable death, multiple permanent injuries or irreversible health effects of patient(s) or staff. RIDDOR reportable incident</p> <p>Long-term staffing issues resulting in poor morale, staff welfare issues or fundamental reduction in service quality.</p> <p>Continued failure to deliver key objectives with long-term adverse publicity or fundamental loss of stakeholder confidence.</p>
Likelihood	Almost Never	1	2	3	4	5
	Unlikely	2	4	6	8	10
	Likely	3	6	9	12	15
	Highly Likely	4	8	12	16	20

	or circumstance.					
	Almost Certain Very likely to happen/recur; possibly frequently.	5	10	15	20	25

