

Use of Entonox

Key Points

- This document provides guidance for midwives collaborating with women using Entonox in labour. The aim is to enable midwives to provide safe, appropriate and evidence-based practice to ensure both their own safety and the safety of the women.
- The guideline gives clear instructions on
 - who can use Entonox,
 - how Entonox can be used safely,
 - and additional equipment needed to minimise exposure risk.

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Abbreviations

COSHH	Control of Substances Hazardous to Health
LEV	Local extract ventilation
MDU	Mobile Destruction Units
NMC	Nursing and Midwifery Council
TNA	Training Needs Analysis

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1. Purpose of the guideline

This guideline sets out the standards and recommendations for practice at Frimley Health NHS Foundation trust to ensure that healthcare professional are compliant with local and national guidance on the safe use of Entonox within maternity services during labour and childbirth. The purpose of this guideline is to provide written guidance for staff who are caring for and managing individuals using Entonox within Maternity services.

Midwives can administer Entonox during labour under the terms of the exemption of medicines act, midwives' rules and the Nursing and Midwifery Council (NMC 2009) Standards of proficiency for the pre-registration midwifery education.

This guideline is only for use within maternity and does not cover the use of Entonox in any clinical setting outside maternity services.

2. What is Entonox?

Entonox (N_2O) is a gaseous mixture of 50% oxygen and 50% nitrous oxide which acts as an analgesic agent when inhaled. It has a noticeably short half-life and can wear off within 2-5 minutes. It has a rapid onset of analgesic effect and is exclusively used for the relief of severe pain.

Entonox is supplied to the maternity departments within Frimley Health directly piped into the labour wards and birth centre. Gas cylinders are also available for use in both the clinical setting and home environment and are identifiable by the blue and white band. Women report extremely high levels of satisfaction with it as a pain relief choice. It also promotes physiological childbirth in that it is self-administered, can be used simultaneously with water immersion, and supports women to be mobile during labour.

Entonox is administered through a mouthpiece/ facemask which is connected to an Entonox supply through a demand valve system. The valve is worked by the act of inhalation and closes when the individual ceases to inhale. In all cases Entonox is self-administered under the direct supervision of a registered practitioner, with demand apparatus safeguarding the user from overdose from nitrous oxide. When the patient becomes drowsy, the mouthpiece/ facemask drops away from the face and the flow of gas ceases.

3. Definitions

'Administer' is a term used throughout this guideline document to describe the practitioner's role in supplying and supervising a patient's self-administration of this drug.

For the purpose of this guideline document, Entonox is the combined, compressed gases 50% Nitrous Oxide and 50% Oxygen.

A 'healthcare professional' as used in this guideline constitutes a Doctor or Registered Midwife.

4. Organisational Arrangements: risk assessment and mitigation

The Trust will have an up to date clinically led Control of Substances Hazardous to Health (COSHH) risk assessment for each space in which Entonox is administered to assess the risk to staff. Each Midwifery Matron is responsible for ensuring they have an up-to-date risk assessment for their area of responsibility. Risk assessments should be reviewed and updated as yearly as a minimum requirement. The following mitigations will be used in line with local risk assessments as appropriate:

- environmental ventilation
- local extract ventilation (LEV)
- rebreather facemasks with gas scavenging (mobile destruction units)
- staff positioning relative to exhaust N₂O and the direction of ventilation flow.
- awareness of the COSHH risk assessment and its controls
- training in the administration of Entonox
- adherence to the mitigations
- awareness and review of monitoring results.
- appropriate prioritisation of optimal rooms usage

The efficacy of these mitigations must be demonstrated by monitoring exposure to Entonox in line with the following regulations:

- [Control of Substances Hazardous to Health \(COSHH\) Regulations 2002](#)
- [HSG 173 Monitoring strategies for toxic substances 2006](#)
- [EH40/2005 Workplace exposure limits, fourth edition \(2020\)](#)
- [HTM03-01 Specialised ventilation for healthcare premises Part A: Design and validation \(2021\).](#)

5. Monitoring and Assurance

The maternity clinical governance team will monitor any incidents about Entonox, and these will be discussed by exception at the fortnightly Maternity Patient Safety and Quality meeting. In the event a clinical risk to staff is shown, a referral to occupational health will be made by the staff member's line manager.

The efficacy of the ventilation system should be tested annually and validated in line with HTM03-01 guidance above. This should be audited by the authorising engineer (AE) for Ventilation and reported to the ventilation safety committee. A copy of this report should be provided to the maternity department following review by the ventilation safety committee.

The efficacy of the gas scavenging systems should be tested and validated in line with the manufacturer's instructions and operated in line with the medical gases HTM 02-01: Medical gas pipeline systems Part B: Operational management (2006). This should be audited by the AE for Ventilation and reported to the ventilation safety committee.

The Medical Gas Committee will provide oversight of the Trust's monitoring and assurance process, chaired by the trust chief pharmacist.

The efficacy of the equipment, environment, clinical practices, training of staff and all other mitigations should be tested at least annually and validated by Entonox time-weighted occupational exposure sampling measures in adherence with EH40/2005 Workplace exposure

limits, fourth edition (2020) and in line with Control of Substances Hazardous to Health (COSHH) Regulations 2002. The results should be reported to:

- Clinical leadership (Matron, labour ward lead, specialty lead and Head of Midwifery) via Cross site Clinical Governance and Care Governance Committee
- Health and safety committee, who report to the trust board.
- Medical gas committee, who should in turn consult with the ventilation safety committee.

6. Healthcare Professional Responsibilities

The healthcare professional is responsible for:

- Assessing the individual's suitability for receiving Entonox as a form of analgesia.
- Ensuring informed consent is sought prior to administering Entonox, which must be documented within the records.

It is the responsibility of the healthcare professional to ensure they are up to date with training and that if there are concerns about compliance with the COSHH standards that they escalate these to their line manager, shift leader or area matron. In case of an adverse incident, the healthcare professional must ensure that an incident report is completed.

7. Staff education

At the point of registration midwives are required to have adequate knowledge of general medical knowledge (biological functions, anatomy and physiology) and of pharmacology in the field of obstetrics, the fetus and of the newly born (NMC pre reg standards). Midwives will have been deemed competent to select, acquire and administer safely a range of permitted drugs consistent with the Human Medicines Regulations [Practising as a midwife \(nmc.org.uk\)](https://www.nmc.org.uk).

Staff should be trained and competent in the use of a Mobile Destruction Unit (MDU). The training of staff will be overseen by the practice development team and included in the maternity service Training Needs Analysis (TNA). A training video has been emailed to all existing staff to watch and compliance is checked within the department by the practice development team. New midwifery staff will undertake this as part of their induction to the trust/department. Training compliance should be reviewed monthly and reported to the Maternity departmental board meeting. Local Training compliance should be kept above 85%.

8. Contraindications to Entonox

Entonox should not be used in any condition where gas is entrapped within a body and where its expansion might be dangerous such as:

- Artificial, traumatic or spontaneous pneumothorax
- Air embolism
- Decompression sickness
- Following a recent dive
- Following air encephalography
- Severe bullous emphysema
- Use during myringoplasty.
- In patients having received recent intraocular injection of gas

Entonox should not be used by patients with:

- Head injury, impaired consciousness or heavily sedated
- Suspected or known increased pressure on the brain.
- Maxillofacial injuries
- Acute psychiatric disturbance
- Early pregnancy (less than 16 weeks)
- Exposure to agents which are toxic to the lungs such as Paraquat (a type of weedkiller)
- Intestinal obstruction
- Middle ear occlusion
- Known hypersensitivity to nitrous oxide.
- Previous use of Entonox® within the last 4 days

9. Caution for Entonox use

Entonox can be used during the early postnatal period but should not be used during breast-feeding itself. Breast-feeding can be resumed as soon as the mother has recovered sufficiently.

Patients with complex multiple pathologies, polypharmacy or multiple allergies.

Patients with a known vitamin B12 deficiency, those with a diet low in animal products, e.g., vegetarians or vegans, or patients with poor nutritional status, or those with a history of anaemia. In patients with undiagnosed vitamin B12 deficiency, neurological toxicity has occurred after single exposures to nitrous oxide during general anaesthesia. Consider assessment of plasma vitamin B12 concentration.

10. Prescribing and Administration of Entonox

Midwives can supply all general sale list (GSL) and pharmacy (P) medicines in accordance with their scope of practice and subject to local policies.

Entonox is classified as a pharmacy (P) medicine and therefore midwives are able to administer Entonox as a midwifery exemption. [Practising as a midwife \(nmc.org.uk\)](https://www.nmc.org.uk)
Student midwives can administer the drugs included within the midwives' exceptions under the direct supervision of a midwife. Student midwives are not allowed to start a person on Entonox without a midwife being physically present.

Entonox is self-administered via the individual using a demand valve. All users of Entonox must be supervised.

11. Duration of treatment

Maximum of 24 hours of inhalation, not repeated more often than every 4 days.

Where Entonox is used for more than a total of 6 hours but less than a total of 24 hours, within a 4-day period, it should be used with caution.

Staff should make themselves familiar with the risk assessments for each area in maternity to ensure they are aware of any time limitations on Entonox use for specific rooms or areas which have been made based on room size and effectiveness of ventilation.

12. Side effects

Most side effects associated with the correct use of Entonox for short term use are minimal and wear off quickly.

- **Effect on vitamin synthesis**

The nitrous oxide part of Entonox can affect vitamin B12 synthesis by inhibiting the enzyme methionine synthetase. This effect is of importance if the therapeutic exposure to Entonox exceeds a total of 24 hours, or more often than every four days.

Nitrous Oxide can interfere with folate metabolism and DNA synthesis, which can impair bone marrow function.

- **Mild Nausea**

Studies show a very low level of nausea and vomiting during Entonox use. Dizziness, euphoria and mild nausea are sometimes experienced but rapidly subside following withdrawal of gas.

The use of the Yellow Card System (the adverse drug reaction reporting system found in the back of every British National Formulary), should be used for any adverse response to Entonox and an incident form completed.

All adverse reactions must be recorded in the patient's nursing/medical notes and reported to pharmacy.

13. Patient education

- Individuals should be provided with comprehensive guidance on how to use the equipment. This may need to be reiterated repeatedly.
- Individuals should be informed that they need to inhale and exhale through the mask/mouthpiece. This may need to be reiterated repeatedly.
- Entonox is a patient-controlled analgesic and therefore must only be administered by the individual. It has a demand valve system that shuts off the supply if the person stops inhaling, becomes sedated and / or confused.
- The individual must be able to use the equipment without help and be supervised when they are using it.

14. Equipment for Entonox

The Entonox cylinder has a blue and a white band on the shoulder. When in use, the demand valve and tubing should be attached to disposable filter which is then attached to either a face mask or mouthpiece. Individuals should be encouraged to use a mask rather than a mouthpiece to reduce the level of Entonox being exhaled into the environment. Initial evidence shows that using a mask is 10% more effective at reducing environmental exposure levels.

The filter, mask and mouthpieces are for single patient use and when the patient is finished using this equipment, they should be discarded.

Ward staff are responsible for ensuring that the demand valve and attached tubing are serviced and maintained at the proper safety standard.

Clinical areas that use Entonox should buy their own administration sets and order cylinders from the porters.

15. Setting up of Entonox

The proposed use of Entonox should be discussed with the patient prior to setting it up. The benefits and possible side-effects should be explained to allay any fears/anxieties.

Entonox can be used in any normally ventilated area such as a ward bay. If using in a confined space such as a side room or labour room where mechanical ventilation is not present a window should be opened. Where possible Entonox should be used in rooms with mechanical ventilation that have the design criteria for air flow movement and extraction. Criteria such as closing the doors, closing the windows and relocating the patient to ensure air flow is not disturbed from head to toe is important. This optimises Entonox extraction. Staff should be mindful of the air breathing discharge and try to avoid being in the direct path of exhalation where possible.

Assessment of environment and ventilation in the home environment should be completed and windows opened where possible.

Trained staff are responsible for Entonox commencement. Equipment should only be set up by staff if they have had the correct training.

16. Entonox cylinders

Entonox is generally administered in the maternity setting via piped Entonox. Entonox is mainly used within the labour ward and birth centre environments. In certain circumstances and in maternity areas outside of the Labour Ward and Birth Centre's, Entonox is administered from cylinders. Entonox cylinders should be:

- Stored separately from industrial and other non-medical cylinders.
- Stored to keep separation between full and empty cylinders.
- Not stored near stocks of combustible materials
- Not subjected to extremes of heat or cold
- Stored separately from other medical cylinders.
- 'F' size cylinders and larger should be stored vertically. 'D' size cylinders and smaller may be stored horizontally.
- Be secured and out of a walkway and always placed securely.

Entonox strongly supports combustion and will cause substances to burn vigorously, including some materials that do not normally burn in air due to the high concentration of oxygen within the mixture. It is highly dangerous in the presence of oils, greases, tarry substances and many plastics due to the risk of spontaneous combustion in the presence of oxygen in relatively high concentrations.

To ensure that the gas is suitable for immediate use, Entonox cylinders should be kept at a temperature above 10°C for at least 24 hours before use.

Warning notices prohibiting smoking and naked lights must be posted clearly in the cylinder storage area and the emergency services should be advised of the location of the cylinder store. Precautions should be taken to protect cylinders from theft and care is needed when handling and using Entonox cylinders.

The cylinder has a demand valve system attached that shuts off the supply when the patient stops inhaling. The patient must be able to use this technique unaided and should be supervised at all times.

17. Transportation of Entonox in the Community

Transportation of Entonox is subject to national regulation. Community midwives transport Entonox for use in homebirth situations. Entonox should not be used in the community outside of a homebirth setting.

Healthcare workers do not need to follow the requirement of ADR 8.1.4 to carry a fire extinguisher when, as part of their duties, they are transporting the following medical gases that have been set up to administer to patients:

- UN 1072 (compressed oxygen)
- UN 1070 (nitrous oxide)
- UN 3156 compressed gas, oxidising, n.o.s (Entonox)
- UN 3538 (articles containing non-flammable, non-toxic gas)

This is subject to the following conditions:

- medical gases are contained in a cylinder(s), as part of a set that includes a regulator, hose and mask with a total maximum number of 6 cylinders per vehicle.
- measures have been taken to prevent any leakage of contents in normal conditions of carriage.
- healthcare workers are appropriately health and safety trained.
- a risk assessment has been carried out for the carriage.

<https://www.gov.uk/government/publications/the-carriage-of-dangerous-goods-approved-derogations-and-transitional-provisions/carriage-of-dangerous-goods-approved-derogations-and-transitional-provisions>

The community matrons are responsible for completing a yearly risk assessment relating to the transportation of Entonox.

18. Mobile Destruction Units (MDU)

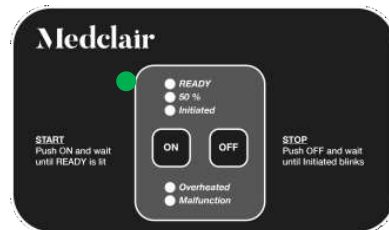
MDU's can only be used within the hospital setting and are not suitable for use during homebirths.

MDU's are designed to break down exhaled Entonox into nitrogen and oxygen in order to reduce the amount of residual Entonox within the environment where staff are working, thus reducing the risk of inhalation by staff. In order to help manage levels of exhaled Entonox within the birthing rooms, Entonox must be administered via an MDU. In order for the MDU to be effective, the Entonox user must ensure that all exhaled Entonox is exhaled into the MDU. If the user does not use the MDU correctly, this may result in residual Entonox being dispersed into the air. The healthcare professional supervising the Entonox user must ensure that they are using the equipment correctly.

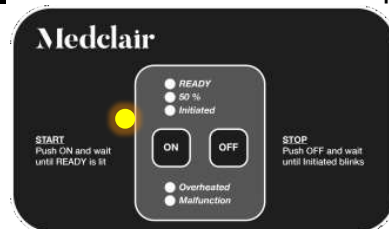
There are two types of inhalation/exhalation apparatus: mouthpieces and facemasks. Mouthpieces are known to be around 70% effective in removing exhaled Entonox, and the facemasks around 80% effective (Implementing nitrous oxide cracking technology in the labour ward to reduce occupational exposure and environmental emissions, 2022).

Staff are responsible for the following:

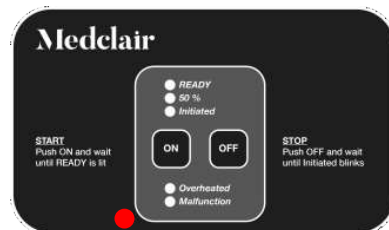
- The MDU is to be plugged in 24/7 in the red plug which will supply constant power in case of a power outage.
- The MDU will take 40 minutes to 'warm up'. Entonox is **NOT** to be used before the MDU 'Ready' button is green. Once ready, a steady green light will appear as per the below:



- If the MDU needs to be moved, before moving the MDU, the following steps **MUST** be taken:
 1. Press the 'OFF' button. The unit will start to cool down and 'READY' will flash for one minute.
 2. The MDU can **ONLY** be disconnected from the power supply once 'INITIATED' is flashing.



- If the MDU is disconnected before these steps are completed, the machine will fail and may require a full reset from the manufacturer.
- If there is a fault with the machine, the 'MALFUNCTION' light will illuminate red:



- In case of this occurring, or any other fault occurring with the MDU, please escalate to the Labour Ward shift leader or Manager on Call who will contact the manufacturer and arrange for the MDU to be fixed.

19. Cleaning Equipment

The equipment should be cleaned as per manufacturer's instructions and according to hospital infection control policy.

The MDU machine should be removed from the birthing room during the cleaning process and for 20 minutes after room cleaning has occurred.

The mouthpiece, filter and facemask are single patient use only and should be discarded when no longer required by that patient.

Testing of the equipment will be on a yearly basis however if there are any doubts in the operation of performance EME Clinical Engineering must be contacted to first line validate and deal with any identified issues.

20. Staff exposure to Entonox

Midwives and professionals working in intrapartum environments may have regular and prolonged exposure to this gas whilst caring for women using it. There is increasing concern about the effects of this exposure on health professionals.

There is a lack of large, high-quality trials to be certain of the risks to staff with long term, repeated exposure to Entonox in the work. However, this does not mean these risks do not exist, just that there is a lack of high-quality evidence to support or refute the notion. Due to the severity of the health implications that have been noted in small scale trials, and the more conclusive evidence seen in rat populations (particularly in relation to fertility), it is imperative and sensible that proper mitigation is in place to minimise these suggested associated risks.

Staff safety is incredibly important, and processes have been put in place to reduce the risk of long-term exposure on vitamin synthesis to staff caring for those using Entonox.

It is the responsibility of the staff member administering Entonox to ensure they help minimise their exposure, this includes ensuring they use the MDUs and follow advice relating to rooms set ups and mechanical ventilation support to ventilate the rooms.

Staff risk assessments are encouraged. Completed risk assessments should be sent to the occupational health department for follow up. Blood tests may be offered to staff members to check for B12 and folate deficiency depending on risk assessment outcomes.

As research around staff exposure is inconclusive Frimley Health maternity have offered that all staff members who are undergoing fertility investigations or are in early pregnancy up to 13 weeks gestation can request to be moved to an area where Entonox is used more infrequently.

Monitoring of staff exposure to Entonox will be undertaken yearly within the department.

21. Equality Impact Assessment

The users of this guideline will take into account their statutory duty to promote equality and human rights and act lawfully within current equality legislation and guidance.

This guideline has been equality impact assessed and has been shown to have no adverse impact on any equality group.

The Trust will continue to monitor its effect and will assess again if negative impact is found or at the review date.

References

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Useful websites

- BOC (2024) Available at: <https://www.bocpnlne.co.uk/en/industries/healthcare/index.html> (Accessed 03 April 2024)
- British Pain Society (2024) Available at <https://www.britishpainsociety.org/> (Accessed 03 April 2024)
- Royal College of Anaesthetists (2024) Available at <http://www.rcoa.ac.uk> (Accessed 03 April 2024)

Full version control record

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This guideline has been registered with the trust. However, clinical guidelines are guidelines only. The interpretation and application of clinical guidelines will remain the responsibility of the individual clinician. If in doubt, contact a senior colleague or expert. Caution is advised when using guidelines after the review date. This guideline is for use in Frimley Health Trust hospitals only. Any use outside this location will not be supported by the Trust and will be at the risk of the individual using it.

Version Control Sheet

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1.0	March 2024	Danielle Eghobamien	Final	Cross Site Obstetrics Clinical Governance Meeting 27.03.2024

Related Documents

None