### SOP 30. Management of Penthrox

#### Change Log

<table>
<thead>
<tr>
<th>Version</th>
<th>Review Date and Person</th>
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</tr>
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<tbody>
<tr>
<td>1</td>
<td>20.7.2020 A McEnaney</td>
<td>New SOP</td>
<td>Feb 2021</td>
</tr>
<tr>
<td>2</td>
<td>12.10.2020 A McEnaney</td>
<td>Previous SOP 19 ‘Disposal of Penthrox’ added to current SOP 30.</td>
<td>Feb 2021</td>
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<tr>
<td>3</td>
<td>24.11.2020 A McEnaney</td>
<td>Addition IEC. Addition requirements to contact Trauma Resus on delivery, to update central register.</td>
<td>Feb 2021</td>
</tr>
<tr>
<td>4</td>
<td>18.01.2021 A. McEnaney</td>
<td>Removal of ‘ordering of Penthrox’ from this SOP as this is client and medical director specific. (Now SOP 30a.)</td>
<td>Jun 2021</td>
</tr>
<tr>
<td>5</td>
<td>15.3.2021 A McEnaney</td>
<td>Additions/corrections made following MD Review</td>
<td>Jun 2021</td>
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Standard

To provide guidance and information on all aspects of Methoxyflurane (Penthrox) provision through Trauma Resus’ Clinical Governance Framework.

This SOP covers:

1. Penthrox - Use (With detail to assist Instructors)
2. Penthrox - Storage
3. Penthrox - Disposal

Procedure

1. Penthrox – Use

Background

Methoxyflurane (Penthrox) is an inhaled medication that is used to manage moderate to severe pain in its ‘Green Whistle’ form.

Each Penthrox Combination Pack contains:

- 3ml vial containing Penthrox 99.9% in a bottle with a tear-off tamper-evident seal
- One ‘green whistle’ inhaler and one Activated Carbon (AC) chamber (the chamber comes attached to the inhaler).
- An information leaflet in relation to Penthrox.
- A ‘Patient Alert Card’ to be provided to the patient after each dose as detailed below.

As Penthrox is an inhaled medication, it is not restricted by the Human Medicines Regulations, 2012, to use only by medical professionals. The Medicines and Healthcare Products Regulatory Agency (MRHA) have agreed that Penthrox can be used by non-healthcare professionals if they are working under a Clinical Governance structure, as per Trauma Resus’ Clinical Governance Framework, detailed below in this document.

Clinical Governance Requirement

The Royal College of Surgeons of Edinburgh - Faculty of Pre-Hospital Care sees the Clinical Governance requirement as follows:

- The drug must be legally supplied.
- There exists a Standard Operating Procedure (This SOP) for its use.
- The ‘non-healthcare professional’ practitioner has received appropriate training by a qualified instructor.

SOP 30. Management of Penthrox
• The practitioner will be working under a robust Clinical Governance framework which is led by a Medical/Clinical Director who is both an Independent Prescriber and holds a registration with either General Medical Council, Nursing and Midwifery Council or Health Care Professionals' Council.
• Each administration is recorded on appropriate documentation
• Each administration is review by the medical/clinical director
• There is an audit process for its use within an organisation
• The Faculty of Pre-Hospital Care guidance states that the non-healthcare professional’s clinical competency should be matched at the Pre-Hospital Emergency Medicine Competency Framework – ‘Level C’, as a minimum of knowledge.

Personnel who may administer Penthrox

With consideration of the above, only EURIECA or IEC qualified practitioners are to administer Penthrox, and only whilst undertaking their duties in an organisation that is clinically governed by Trauma Resus.

Through auditing, the Maintenance of Skills (MOS) training of these qualified personnel will also be monitored, and clinical governance support removed, if skills and knowledge are not being maintained through the MOS programme.

The decision to administer Penthrox

A ‘Penthrox Checklist’ provided by Trauma Resus, with an example found at Appendix 1, should be used to assist EURIECA or IEC-qualified rescuers when considering Penthrox.

Indications (reasons why Penthrox is given)

• Patient is an adult.
• Moderate to severe pain management.
• To be used only after patient has been fully assessed by EURIECA or IEC qualified personnel.

Contra-indications (reasons not to give Penthrox)

Patients is/has:

• Allergy - As with any drug, patients can be allergic to Penthrox (methoxyflurane) and administration could lead to anaphylaxis. The biggest risk is a condition called malignant hyperthermia (MH) which, although rare, is a risk with all anaesthesia. It leads to the patient
having muscle rigidity, high fever and high heart rate and can be fatal if not managed. Practitioners must ask the patient if they or relatives have previously had a reaction to general anaesthesia (as MH can be hereditary), therefore the patient may be more at risk.

- **Antibiotics** - The use of Penthrox for a patient currently on antibiotics can lead to nephrotoxicity (severe damage of the kidneys). Although this does not apply to all antibiotics, people often do not know the name or dose of antibiotics they are using, therefore for caution, the checklist includes ANY antibiotic.

- **Breathing (difficulty)** - If the patient has either an altered respiratory rate or reduced oxygen saturations (SpO2), that may be related to hypoxia, 100% oxygen should be administered to manage this as it is life-threatening. Managing cABCDE is more important than pain management.

- **Circulation (poor)** - Penthrox, by its nature, increases the risk of hypotension (low blood pressure) in patients. If the patient is showing signs of shock, their blood pressure may be low as a result of trauma, therefore Penthrox should not be given, as it will worsen the shock condition.

- **Consciousness** - Penthrox must be self-administered (i.e. the patient should hold it to their own lips). This is to limit the risk of Penthrox having an anaesthetic effect, as the patient will drop the device prior to becoming fully unconscious. A reduced level of consciousness from any cause is a contra-indication.

- **Renal or hepatic impairment** - Previous prolonged use of methoxyflurane, as an anaesthetic agent, was noted to have a negative effect on patients’ liver and kidney function. If they currently undergo regular investigation into their kidney or liver function, they are not to have Penthrox as it may worsen their underlying condition.

- **Previous use** - If they **HAVE** had Penthrox within the last 3 months, national guidance is to give them no further Penthrox. If they have **NOT** had Penthrox in the last 3 months, they can have up to **2 x 3ml doses**. Their pain score is to be monitored with the corresponding time and level to be written on the ‘Penthrox Checklist’ and the document signed. This is important for clinical governance.

### Undesired effects of Penthrox

As with all drugs, Penthrox itself has side effects which rescuers should be aware of. These are not contra-indications but should be managed as necessary.

The most common is Central Nervous System depression, seen through altered mood, drowsiness, memory loss, feeling abnormal and muscle relaxation. As such, patients should not drive or operate machinery after use of Penthrox.
Other common side effects include cough, dry mouth, difficulty with speech, drop in blood pressure, nausea, and altered taste.

Uncommon side effects are anxiety, increased appetite, chills, depression, fatigue, flushing, increased sweating, oral discomfort, vision disorders, and paraesthesia and peripheral neuropathy (numbness/ pins & needles to peripheral limbs).

Using Penthrox

- Each Penthrox container is labelled with an illustrated diagram as per Appendix 2. for use during emergencies.
- One 3 ml bottle of Penthrox provides approximately 20-25 minutes of pain relief when inhaled continuously.
- Where appropriate and clinically indicated, a second 3 ml bottle of Penthrox can be used to extend the period of pain relief.
- Intermittent inhalation with effective patient counselling of slow, deep breathing will increase the effectiveness and duration of analgesic effect.
- Patient is to inhale and exhale through the device to limit occupational exposure of rescuers by forcing exhalation through the charcoal filter.
- Patients are to hold the device themselves with no assistance, to reduce risk of overdose.
- After use, place the Penthrox Inhaler and used bottle in the plastic bag provided, seal and dispose of as clinical waste.
- Patients are to be provided the included Penthrox ‘Patient Alert Card’ for each Penthrox application.
- Any Penthrox packs opened but not used, should be destroyed.
- Any use should be documented on the Penthrox Checklist and Patient Report Form (PRF) as appropriate.
- As with any patient interaction, use of Penthrox should be reported to Trauma Resus through sending the ‘redacted’ copy of the PRF to the clinical governance lead for the client organisation via the below email addresses. The ‘redacted’ copy does not show the patient’s name or address.
2. **Penthrox - Storage**

- No special temperature storage conditions required.

- The Penthrox combination pack should be kept in a locked cabinet and not be left on an open shelf.

- Access to the secure Penthrox cabinet should be restricted to a minimum number of staff, with a list of staff members with access being maintained alongside the Drug Register for the organisation.

- The quantity and expiry dates of Penthrox stored in the Penthrox cabinet must be checked and the check documented by two people on a monthly basis.

- Methoxyflurane (Penthrox) combination packs removed for storage in a trauma / first aid kit must be stored in a security sealed pouch within a security sealed bag. All security seals must have a unique identifying number that is documented.

- Do not use after the expiry date shown on the package label and the carton.

- Contact Trauma Resus for advice on disposal of expired stock.

- Under terms of Clinical Governance, Trauma Resus require the client to maintain a formal drug register, which will be monitored during the audit process.

- The drug register must clearly document the following:
  
  a. Number of Penthrox combination packs in total circulation
  b. Number of Penthrox combination packs stored in base location
  c. Number of Penthrox combination packs allocated to trauma / first aid bags
  d. Batch number and expiry date of each Penthrox combination pack
  e. Security tag number of each Penthrox pouch
  f. The name and signature of the person conducting the monthly check
  g. The name and PRF number of any casualty who has been administered Penthrox
  h. The details of any Penthrox combination packs that have expired and been disposed of.

- The drug register should be kept securely in a central location.

- Agreed Stock Level – At each issue of prescription a maximum agreed number would be agreed with each client site. This can be altered if need arises but must be after a formal discussion with, and authorisation from, the Trauma Resus Clinical Team.
3. **Penthrox - Disposal**

**Removal from stock:**

- Expired Penthrox is removed from live kit and recorded on the Penthrox log, signed for and then witnessed and countersigned by a 2nd person.
- The 3ml vial is to be separated from the rest of the combination pack.
- The only item to be disposed of is the medicine itself (3ml vial). The ‘green whistle’ inhaler can be kept for training.
- The cardboard box can be kept for training but must be clearly marked as ‘out of date stock’ or ‘training stock’.

**Sending stock to Trauma Resus:**

- EURIECA or IEC-trained team members disposing of stock must complete the Penthrox disposal form in full (available at Appendix 3)
- Expired vials of Penthrox are to be placed in zip-lock plastic bags and placed in appropriate padded packaging i.e. Jiffy type bag/envelope. Trauma Resus Penthrox Disposal form to be placed inside package
- Package to be sent by recorded delivery for the attention of:
  
  Head of Clinical Services  
  Trauma Resus Ltd  
  Tannery Court  
  Tanners Lane  
  Warrington  
  WA2 7NA

**Actions on Receipt of vials at Trauma Resus:**

- Package to be opened by Head of Clinical Services.
- Contents to be checked against supplied Penthrox disposal form.
- Once contents are reconciled against Penthrox disposal form, Trauma Resus will forward receipt of vials to responsible person.
- Trauma Resus disposal actions:
  - 2 x registered health care professionals will dispose of the Penthrox into a clinical waste container with a purple lid.
  - Both health care professionals will sign to declare the Penthrox as disposed of correctly.
  - Hazardous Waste container will be stored within a locked ventilated space.
  - Trauma Resus will use a licensed hazardous waste disposal contractor to provide final disposal. A final disposal record will be retained by Trauma Resus for a minimum of 10 years.
SOP Review Arrangements

Trauma Resus Ltd will review this SOP in accordance with the Internal Audit Plan as part of its self-evaluation arrangements and continuous improvement activities. The company may also revise it earlier than scheduled in response to client and course participant feedback, changes in practices, actions from the regulatory authorities or external agencies or changes in legislation.
# Penthrox checklist

<table>
<thead>
<tr>
<th>Title</th>
<th>Question</th>
<th>Response</th>
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<tbody>
<tr>
<td>Allergy</td>
<td>Is the casualty allergic to Penthrox / methoxyflurane or have they or a family member ever had a reaction to any anaesthetic?</td>
<td>Yes/No</td>
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<tr>
<td>Adult</td>
<td>Is the casualty a child? (less than 18 years)</td>
<td></td>
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<tr>
<td>Antibiotics</td>
<td>Is the casualty currently taking any antibiotics?</td>
<td></td>
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<tr>
<td>Breathing</td>
<td>Is the casualty having difficulty in breathing, unable to talk in sentences or has oxygen saturations of less than 94%?</td>
<td></td>
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<tr>
<td>Circulation</td>
<td>Is the casualty showing any signs of shock, complaining of chest pain or have a history of heart problems? (heart rate &lt;60 or &gt;120, CRT &gt;2seconds or no palpable pulse)</td>
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<tr>
<td>Conscious</td>
<td>Is the casualty unconscious or semiconscious or unable to answer questions effectively</td>
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<tr>
<td>Renal</td>
<td>Does the casualty have a history of kidney or liver problems that have required hospital or regular GP visits?</td>
<td></td>
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<tr>
<td>Previous Use</td>
<td>Has the casualty had Penthrox in the last 3 months?</td>
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</tbody>
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**If the answer to all safety questions is NO then it is safe to offer Penthrox to the casualty**

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## Pain Score Assessment tool

<table>
<thead>
<tr>
<th></th>
<th>NO PAIN</th>
<th>MODERATE PAIN</th>
<th>WORST PAIN</th>
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<tbody>
<tr>
<td>Pain Score-Assessment tool</td>
<td>Time</td>
<td>Initial Pain Score</td>
<td>5mins Pain Score</td>
</tr>
<tr>
<td>Initial Pain Score</td>
<td>Time</td>
<td>Initial Pain Score</td>
<td>5mins Pain Score</td>
</tr>
<tr>
<td>1st dose administered</td>
<td>Time</td>
<td>Initial Pain Score</td>
<td>5mins Pain Score</td>
</tr>
<tr>
<td>2nd dose administered</td>
<td>Time</td>
<td>Initial Pain Score</td>
<td>5mins Pain Score</td>
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**Administered by:**

| Name: | Signed: | Date: | Time: |

**Checked by:**

| Name: | Signed: | Date: | Time: |

**Disposal Method:**

[www.traumaresus.com](http://www.traumaresus.com)
Appendix 2. Assembling the ‘Green Whistle’

1. Ensure the Activated Carbon (AC) Chamber is inserted into the dilutor hole on the top of the PENTHROX Inhaler.

2. Remove the cap of the bottle by hand. Alternatively, use the base of the PENTHROX Inhaler to loosen the cap with a ½ turn. Separate the Inhaler from the bottle and remove the cap by hand.

3. Tilt the PENTHROX Inhaler to a 45° angle and pour the total contents of one PENTHROX bottle into the base of the Inhaler whilst rotating.

4. Place wrist loop over patient's wrist. Patient inhales and exhales PENTHROX through the mouthpiece to obtain analgesia. First few breaths should be gentle and then breathe normally through Inhaler.

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Patient exhales into the PENTHROX Inhaler. The exhaled vapour passes through the AC Chamber to adsorb any exhaled methoxyflurane.

If stronger analgesia is required, patient can cover dilutor hole on the AC chamber with finger during use.

If further pain relief is required, after the first bottle has been used use a second bottle if available. Alternatively use a second bottle from a new combination pack. Use in the same way as the first bottle in step 2 and 3. No need to remove the AC Chamber. Put used bottle into the plastic bag provided.

Patient should be instructed to inhale intermittently to achieve adequate analgesia. Continuous inhalation will reduce duration of use. Minimum dose to achieve analgesia should be administered.
Replace cap onto PENTHROX bottle. Place used PENTHROX Inhaler and used bottle in sealed plastic bag and dispose of responsibly (see section 6.6).
Appendix 3 – Penthrox Disposal Form

Penthrox (Methoxyflurane) Disposal Form

<table>
<thead>
<tr>
<th>Organisation Name:</th>
<th>Site:</th>
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<tr>
<th>Batch No</th>
<th>Expiry Date</th>
<th>Returned to TRS date</th>
<th>Print Name</th>
<th>Signature</th>
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<tbody>
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<td>1.</td>
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Received at TRS By: _______________________________ Date _______________________________

Checked and Confirmed: TRS HCP 1 _______________________________ TRS HCP 2 _______________________________

Sent to approved waste contractor: Date _______________________________

Penthrox Disposal Form
Trauma Resuscitation Services limited
This record and disposal receipt to be retained by TRS for 10 years from disposal date