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Introduction

These Guidelines are intended for clinician use only.

Please always refer to the User Manual before using the NIPPY Clearway for the first time.

Indications for use of the NIPPY Clearway

The NIPPY Clearway is typically used in neuromuscular disease, including the following patient groups;

- Motor Neurone Disease
- Post-Polio Syndrome
- Spinal Cord Injuries
- Muscular Dystrophy
- Spinal Muscular Atrophy

Contraindications for use of the NIPPY Clearway

The NIPPY Clearway has the following contraindications; please consider these carefully before initiating treatment:

- Patients with a history or risk of bullous emphysema
- Patients with a history or are susceptible to pneumothorax or pneumo-mediastinum
- Patients with cardiovascular instability
- Patients with tracheoesophageal fistula
- Recent or existing barotrauma
- Spinal instability
- Acute pulmonary oedema
- Active, untreated tuberculosis
- Recent esophageal surgery
- Increased intracranial pressure
- Acute lung injury
- Facial Trauma
- Patients with bulbar insufficiency may be treated using MI-E but, caution should be taken and a risk assessment carried out prior to use
- Frank haemoptysis and haemoptysis
**Considerations before using the NIPPY Clearway**

1. Are there any contraindications to using this treatment?
2. Are you competent to use the device and have you received training?
3. Where indicated, do you have cardiovascular monitoring available?
4. Is there a suction facility available?
5. With any airway clearance technique, including MI-E, there is the potential to mobilise a large amount of secretions and therefore it is important to ensure that the appropriate emergency equipment (e.g. resuscitation bag and suction) is available in case of mobilising a large mucus plug into a central airway.
6. Do you have the correct circuit and interface for use for your patient?
7. Is oxygen required? You may entrain up to 15 litres of low-pressure oxygen
8. Ensure that an anti-bacterial filter is used to protect the patient and machine

**Guidelines for use: Titration & preparation for adults**

1. For the initial titration session, we recommend that you monitor the patient’s heart rate and oxygen saturations.
2. Ensure that the appropriate emergency equipment (e.g. resuscitation bag and suction) is available in case of mobilising a large mucus plug into a central airway.
3. Ask the patient to cough with the mask and tubing on. With your settings, you are aiming to increase the audibility of your patient’s cough. i.e. the louder the cough the stronger the cough.
4. Select “Manual” mode via the Mode button
5. Set the device to 10-15cm Insufflation and 15-25cm Exsufflation in “Manual” mode according to your patient’s clinical history, lung pathology and lung compliance, as well as psychological needs.

6. Using the manual controller, stand with your patient and hold the mask to your patient’s mouth and nose or connect the tubing to the tracheostomy tube. Initiate the therapy.

7. The manual controller is designed to follow your command i.e. you control the insufflation and exsufflation times by holding the manual switch in the up or down position. Insufflation pressure should be used for 1-3 seconds, for 1-6 breaths, then immediately move to Exsufflation, for 3-4 seconds, then pause for 2-3 seconds. The breath ratio and patient’s natural rate should be considered here when determining the times for Insufflation and Exsufflation.

8. It is worth noting that some patients will like a simple sequence of insufflations-exsufflation-pause. Other patients will prefer cycles of repeated insufflation before exsufflation and then pause. The latter example may be preferential in patients whose secretions are not quite high enough to cough and clear.

9. When using the manual mode, always instruct the patient about what is happening so that they can co-ordinate with the device.

10. Repeat this for 2-6 cycles, depending on your patient’s clinical requirements, tolerance and fatigue.
11. Proportionally increase the treatment pressures during the cycles. Typical treatment parameters are +20 to 40 cm Insufflation pressure and -25 to -60 cm Exsufflation pressure. Pressure settings should be titrated for each patient based on clinical history, lung and chest wall compliance, and psychological acceptance. The NIPPY Clearway measures pressure at the patient end so it is very accurate. You are aiming for a good inspiratory tidal volume (80% of predicted total lung capacity) to ensure a deep breath in. Exsufflation pressures should be titrated to patient comfort but, for an effective cough, a greater negative than positive pressure is required.

12. It is possible to use the black switch at the front of the NIPPY Clearway to control the device in “Manual” mode if desired.

13. Whilst using the NIPPY Clearway your patient should be continually re-examined and secretions clearance monitored.

14. Where a patient cannot expel their own mucous, secretions should be removed using an external suction device via the mouth or trache tube.

15. Use the NIV mode post-therapy to allow your patient to rest, reduce their work of breathing and re-recruit if required.
Guidelines for use: Setting the NIPPY Clearway for long-term use in adults

1. Now that you have established the most effective pressures and timing for your patient (as defined in Guidelines for Use: Titration & Preparation for Adults) you may consider more advanced settings.

2. You can simply cycle from insufflation to exsufflation and then pause, using “Basic Auto” or you can use more sophisticated treatment modes.

3. For more than one insufflation prior to exsufflation, with the option to repeat the cycle, select “Programmed Timed Mode.” If you would like your patient to trigger the insufflation, consider using “Programmed Triggered Mode.” Using more than one insufflation may assist with secretion mobilisation.


5. Go to the Menu -> 3. Settings & Options -> 3. Mode Select Options

6. Select the modes you have chosen for this patient i.e. 3. “Programmed Timed Auto” ON and “NIV” mode to ON. Turn all other modes not required to OFF.
7. In the treatment modes, the default for ‘2 post exsufflation breaths’ is set to ‘OFF’.
   If you wish to turn this ‘ON’, go to the Menu -> 3. Settings & Options -> 2. Advanced Settings. Then set ‘+2 Post Positive Breaths’ to ON. Alternatively you could perform re-recruitment breaths manually via the controller.

8. Using the settings determined in the titration phase, set the NIPPY Clearway treatment parameters in each selected mode. NB - any additional settings e.g. +2 Post Exs Breaths ON, need to be set for each mode you have chosen.

9. Connect the NIPPY Clearway to the patient via the circuit and mask/mouthpiece/catheter mount.

10. Start machine in “NIV” mode for pre-Clearway therapy if required to increase tidal volume and oxygen saturations prior to treatment.

11. Use the Mode button to select the desired treatment mode i.e. “Programmed Timed/Programmed Auto” as previously selected.

12. Press START

13. At any time during therapy you can use the manual control to over-ride the “Auto” cycle if clinically indicated. This allows you to change the treatment cycle from what is being delivered via the programmed mode to manual control of insufflations and exsufflations.

14. Whilst using the NIPPY Clearway, your patient should be continually re-examined and secretion clearance monitored. Where a patient cannot expel their own mucous, secretions should be removed using an external suction device via the mouth or trache tube.

15. You may use “NIV” mode post-therapy to allow your patient to rest, reduce their work of breathing and re-recruit if required.
Manual usage of the NIPPY Clearway: The acute setting

1. Select “Mode Manual” via the Mode button
2. Set the device to 10-15cm Insufflation and 15-25cm Exsufflation in the “Manual” mode
3. Using the manual controller, stand with your patient and, holding the mask to your patient’s mouth and nose/ or connecting the tubing to the tracheostomy tube, initiate the therapy. The manual controller is designed to follow you i.e. you control the insufflation and Exsufflation times by holding the manual switch in up or down position. Insufflation pressure should be used for 2-3 seconds, for up to 3 breaths, then immediately move to Exsufflation, for 3-4 seconds, then pause for 2-3 seconds.
4. Repeat cycling between insufflation, exsufflation and pause for 2-6 cycles, depending on your patient’s needs
5. Proportionally increase the treatment pressures during the cycles. Typical treatment parameters are +20 to 40 cm Insufflation pressure and -25 to -60cm Exsufflation pressure.
6. Unlike the chronic setting, where you have time to titrate your settings, you will need to increase the pressures quickly in order to improve cough strength and to clear the retained secretions effectively.
7. Pressure settings should be titrated for each patient based on clinical history, lung and chest wall compliance. The NIPPY Clearway measures pressure at the patient end so it is very accurate. Cough strength should be audibly superior whilst using the device.
8. It is possible to use the button at the front of the NIPPY Clearway to control the device in “Manual” mode if desired. It has been observed that using the manual controller, improves patient synchrony and acceptance.
9.Whilst using the NIPPY Clearway your patient should be continually re-examined and secretion clearance monitored. Where a patient cannot expel their own mucous, secretions should be removed using an external suction device via the mouth or trache tube.
10. Use “NIV” mode post-therapy to allow your patient to rest, reduce their work of breathing and re-recruit if required.
### Considerations for the paediatric patient

- MI-E can be used in small children, depending on the age and condition of the child. There are reports of clinical use in infants as young as 3 months old. One needs to be aware that infants have limited collateral ventilation and are nearer to their physiological closing volume (1-5).
- Pressures should start low and be titrated up until chest and abdominal wall movement indicate a deep breath in. Then set the exsufflation pressure an extra 5-10 cmH2O more negative (1-5).
- Physiologically, children do not breathe in as long or out as long as adults (6). The length of their cough will also be reduced; therefore, you will need to adjust your insufflation and exsufflation time accordingly. (A good place to start is 0.8 to 1.0 seconds).
- Care needs to be applied with MI-E in infants, where the chest wall is very compliant and the closing volume of the lung is high as this can induce atelectasis, especially with long exsufflation times (7).
- Infants and severely weak children may find MI-E uncomfortable if you have taken them below their closing volume and not helped them re-recruit (7). An insufflation after exsufflation can help prevent this or the NIPPY Clearway can be used in “NIV” mode.
- With any airway clearance technique, including MI-E, there is the potential to mobilise a large amount of secretions and therefore it is important to ensure that the appropriate emergency equipment (e.g. resuscitation bag and suction) is available in case of mobilising a large mucus plug into a central airway.
- Oximetry should be monitored in infants during treatment and is recommended in all children who are severely weak during an acute hospital admission. A sudden drop in oxygen saturation from baseline is highly likely to indicate that a large amount of secretions has been moved and oral or NP suction is warranted. If oxygen saturations do not improve immediately and secretions are no longer an issue, and if on assessment there are decreased air breath sounds, potential complication of a pneumothorax should be considered and the medical team should be alerted (1-5).
- The resting energy of sick children is high and transient periods of oxygen therapy may be warranted during airway clearance (6).
- Unlike other devices, the NIPPY Clearway can be used in conjunction with oxygen therapy.
• Infants and children are often unable to co-ordinate or synchronise with complex programmes. Therefore you may find optimal synchronisation using simple cycling between insufflation and exsufflation with a short pause. This can help move the secretions up towards the mouth when a simultaneous cough may occur, further assisting clearance. Continually reminding the child that a deep breath is coming in followed by a cough also improves synchronisation.

• For community use of MI-E, a programmed setting enables treatment of the infant or child by one person.

• NB community use of MI-E, modes not required to ‘off’ in the menu to ensure the correct modes only are available for use.

Considerations for the spinal patient

• In high cervical spine injuries (C1 to C4), pneumonia is the primary complication, followed by atelectasis. In lower cervical spine injuries (C5 to C8), atelectasis remains a problem and pneumonia is a problem but to a lesser degree (8).

• When using the NIPPY Clearway for the first time with a patient with SCI, it is crucial to monitor them cardiovascularly. Autonomic dysreflexia (AD) is a complex symptom that arises from a noxious or intense stimulus below the level of injury that leads to an unopposed discharge of the sympathetic nervous system. This sympathetic discharge cannot be modulated from higher cerebral centres and often results in hypertension. A reflex bradycardia is classically observed in many cases as a compensatory response because the carotid baroreceptors stimulate an increase in vagal tone, however tachycardia may also be seen (9). As mechanical insufflation-exsufflation will cause changes in the patient’s intrathoracic pressure which may stimulate AD and the patient may be unaware of their symptoms, it is prudent to cardiovascularly monitor SCI patients when initiating MI-E treatment. Patients with acute cervical spine injury can experience bronchospasm, even in individuals without a prior history of asthma, because of autonomic changes seen in acute injury (10). MI-E can exacerbate bronchospasm.

• Patients with acute cervical spine injury can experience bronchospasm, even in individuals without a prior history of asthma, because of autonomic changes seen in acute injury (10). MI-E can exacerbate bronchospasm.
• Optimum positioning for the spinal cord patient will be supine. Tidal volume and forced vital capacity are significantly higher in the supine position compared with the sitting position. When sitting, the abdominal contents push up on the diaphragm and place them in a less efficient position (11-13). The use of MI-E in supine may be the position of choice to produce the greatest improvements in the patient’s cough strength.

• Some patients are managed acutely with tracheostomy. Research has identified that they find suction painful, irritating and uncomfortable. In one study, SCI patients preferred use of MI-E to suction as part of their airway clearance regime when compared to suction alone. They reported that it was less painful, more comfortable and less tiring than suction (14).

• Assisted coughing is also used to duplicate a normal cough. Contraindications to manual-assisted cough or “quad” coughing include: unstable spine in traction, internal abdominal complications, chest trauma such as fractured ribs, and a recently placed vena cava filter. Mechanical insufflation–exsufflation devices alone are therefore indicated in this situation and can be used when there is an unstable spine.
Using an IPPB circuit

When using the NIPPY Clearway for IPPB for prolonged periods, it is possible that the patients’ exhaled air remains in the breathing circuit. This exhaled air could potentially be re-breathed by the patient. This is because the exhalation port (hole) in the leak circuit may not provide sufficient carbon dioxide (CO₂) washout, as there is no EPAP delivered to wash the exhaled air from the circuit.

It is therefore beneficial and safer to use a dedicated IPPB circuit with patients where they use the NIPPY Clearway as a method of delivering IPPB treatment.

The dedicated IPPB circuit has an active exhalation valve. This circuit allows the patient to exhale, at (zero) atmospheric pressure, into the atmosphere via the active exhalation valve. This valve helps to prevent air being exhaled back into the breathing circuit.

It may not be necessary to use the dedicated IPPB circuit if, for instance, the patient is using a mouthpiece and choses to open their mouth and exhale into the room, rather than back into the circuit.

It may not be required to use this type of circuit if the patient only has a few breaths delivered at a time. Do not use the IPPB circuit when using the device in an MI-E mode, as the exhalation valve prevents the delivery of negative pressure.

As with everything you issue to patients we recommend that you asses the risk for that individual and issue equipment appropriately and educate accordingly. We hope that the introduction of this new circuit will provide you with greater options for the NIPPY Clearway, thus gaining the best clinical results for your patients.
Using oxygen with the NIPPY Clearway

If required, supplementary oxygen may be entrained into the breathing circuit up to a maximum of 15 L/minute.

- When adding oxygen, fit an entrainment port at the mask / tracheotomy end of the circuit.
- Switch on the Clearway before the oxygen.
- When treatment is complete, switch off and disconnect the oxygen supply, switch off the Clearway and disconnect the breathing circuit. Store the breathing circuit in a clean bag or other suitable container.
• DO NOT leave the oxygen connected when not in use. This can cause a build-up of oxygen in, or around the machine
• DO NOT block the end of the breathing circuit with oxygen connected.
• DO NOT expose oxygen to naked flames.
• DO NOT smoke in the vicinity
• DO NOT use a gas cooker in the vicinity
• DO NOT use a gas, oil or solid fuel heater in the vicinity

Precaution: always follow user instructions when entraining Oxygen.

Potential side-effects of MI-E

Manual Insufflation-Exsufflation is a widely-used therapy. However, there are some minimal but reported side-effects to be aware of when using MI-E.

1. Pneumothorax

It is a relative contraindication for patients who are known to be susceptible to pneumothoraces to be treated with MI-E (15).

It is a considered recommendation that ventilator users who are also using MI-E, and who have increasing dyspnea or who require increasing positive inspiratory pressures with regard to their ventilation, should be evaluated for pneumothorax (15).

2. Bloating

There have been reports of nausea and abdominal distension/bloating when using MI-E in a few cases (16). This may cause patients to discontinue with therapy.

However, MI-E is considered to be a safe and effective treatment which is well-tolerated by the majority of patient groups (16).
Frequently asked questions

• Can the same mechanical insufflator–exsufflator be used with different patients?

The device will need to be cleaned between patients and each patient should have a single-use circuit and filter; settings should be checked prior to commencement of treatment. A high-efficiency bacterial filter should be placed between patient circuit and device. If you are treating a patient with suspected H1N1, a filter should be placed at the device end and also at the distal end of the circuit before the interface to double-filter and protect the device.

The device should not be taken from dirty to clean areas as defined by local infection control policy.

• How often does the tubing need replacing?

Manufacturers’ recommendations are that tubing can be used for up to 7 days. However, in the community setting, for single-patient use, local infection control policies may be adopted.

• Can we use AB filters that are different?

Yes, but the resistance of the filter should be checked to ensure that the device and the patient are protected and that the performance is not affected. Filters should be within resistance levels of 0.4 mbar at 30LPM and 0.7 mbar at 60LPM.

• How can I be sure that my patient is getting the settings I have set?

The NIPPY Clearway is an extremely effective and accurate device. Digital settings ensure accurate titration and setting of pressures. The device also measures and monitors pressure at the patient end via the external pressure line.

• How many times a day should MI-E be used?

MI–E can be used as many times during a 24-hour period as required to clear your patient’s secretions. However, it is important to remember that prolonged coughing does induce fatigue, so ensure that you allow adequate rest periods.

• Does MI-E negate the need for suctioning?

Using MI–E does not necessarily negate the need for suctioning to clear secretions, especially when initially using the technique, due to the success of the therapy. Suction equipment must always be available when treating patients with MI-E.

• Should the NIPPY Clearway be used if there are no secretions present?

If it is considered that there is an area of collapse and/or consolidation on chest x-ray, combined with a patient who has an ineffective cough, MI-E can be indicated. Patients who have a device at home can use it daily to ensure that there are no secretions present. Additionally, the Nippy Clearway can be used to provide a stretch to the chest wall and used as a method of IPPB.
• Considerations for community use and training?

It may be advisable within the community to have a programmed mode to enable use by only one carer. The settings can be titrated and set and then locked before discharging the patient, ensuring safe and accurate treatment within the community setting. There are competency documents available for carers and clinicians.

• What information should my patient go home with?

The patient and carers should be trained as per the competency guidelines. The patient should always have a written or photocopied document of their settings. The patient or carer can then check the settings against the record. You may want to give the patient some indication of the changes in settings that they may require for when they are unwell.
References


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