# Acacium Group

# Phrenic Nerve Pacing

**Procedure Reference | SOP VENT 22**

**Version | V4.1**

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| **Procedure Name** | Phrenic Nerve Pacing |
| **Purpose of Document** | To ensure that the correct preparation, procedure and outcome are achieved by implementing a consistent, and systematic, approach to phrenic nerve pacing |
| **Target Audience** | All nurses and appropriately trained carers |
| **Version** | V4.1 |
| **Author** | Sharon Jolley |
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| **Review Frequency** | 2 yearly, or when clinical or operation guidelines change |
| **Last Reviewed** | June 2024 |
| **Next Review Date** | June 2026 |
| **Equality Impact Assessment (EIA) Form** | Acacium Group is committed to Equality, Diversity and Inclusion and in line with our values, we strive to ensure that everyone that is part of the Acacium community is not disadvantaged or discriminated against given their individual need or characteristics. To support this, an Equality Impact Assessment has been undertaken on this policy/procedure. This information is held centrally and can be requested from the Clinical Governance Team. |
| **About Acacium Group** | Details of all Acacium Group trading companies that this policy applies to are detailed within Appendix A |

| Document History | | | |
|---|---|---|---|
| **Version** | **Date** | **Changes made/comments** | **By whom** |
| V1 | Dec 2016 | Implementation of document history page. | KNF/VM |
| V1 | Jan 2018 | Review. | KMS/VM |
| V1.1 | Jan 2020 | Updated to new Template | CC |
| V2 | Jul 2020 | 2 yearly review | Clinical Advisory Group |
| V2.1 | Oct 2020 | Updated re rebrand | CC |
| V3 | Jul 2022 | 2 Yearly Review | Clinical Advisory Group |
| V4 | Jan 2024 | Rebrand | Clinical Advisory Group |
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## 1. Introduction

Mechanical ventilation has been the standard treatment for respiratory device dependent spinal cord injury clients (NHSCB/D13/P/a). Air is forced into the lungs under positive pressure to enable lung function, but mechanical ventilation can also impair the ability to cough and can limit speech.

The phrenic nerve, which originates in the cervical spine from the C3, 4 and 5 roots, is the nerve that controls diaphragmatic movements. The diaphragm is responsible for the majority of the movement of air during normal breathing.

Some clients with damage to the cervical spine will have an intact phrenic nerve. Implanted phrenic nerve stimulation applies regular electrical pulses direct to the nerve. This causes the diaphragm to contract, resulting in the intake of air, akin to natural breathing. Intact phrenic nerves and functioning diaphragm muscles are essential for this intervention.

Phrenic nerve stimulation involves direct stimulation of the nerve. The implanted phrenic nerve stimulator deploys a low amplitude current to the phrenic nerve to achieve diaphragm muscle contraction, as opposed to the direct diaphragm stimulator.

## 2. Aim

To assemble and implement phrenic nerve pacing equipment / devices correctly and effectively whilst minimising the risk of infection to the client, maintaining adequate ventilation and client safety.

## 3. Who needs to be aware of this procedure

All Acacium Group workers that provide direct care to clients as long as they have been trained in this procedure, assessed as competent, and are able to demonstrate understanding of the risks and limitations. All workers must follow this Acacium Group Standard operating procedure (SOP).

## 4. Consent

Please read Acacium Group Consent Policy thoroughly and ensure that valid consent has been gained.

## 5. Client and relatives / carers involvement

Carers and relatives may wish to be taught how to undertake this procedure. Where Commissioned and staff are appropriately trained, this should be facilitated where possible and appropriate.

## 6. Client information

As part of obtaining valid consent the risks, benefits and alternatives to treatment will have been discussed. The procedure must be explained fully in order to gain full cooperation with the procedure.

## 7. Assessment of outcomes

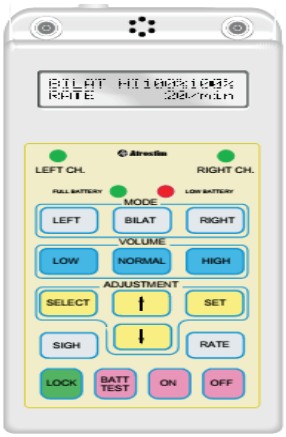
- clinical observation of improvement
- client's subjective response to therapy.

## 8. Equipment: Astrostim Phrenic Nerve Pacing Components

- portable stimulus controller unit
- programming unit
- energy transfer coils and cables
- 9 & 12 volt batteries
- 2 battery chargers.

**Controller unit consists of:**

- left and right channels for both hemi-diaphragms
- volume is set at either 'Low', 'Normal' or 'High' depending on the client's level of activity
- Clients care plans will detail the client's specific requirements, the prescription should not be altered or adjusted by any staff not specifically and appropriately trained to do so.

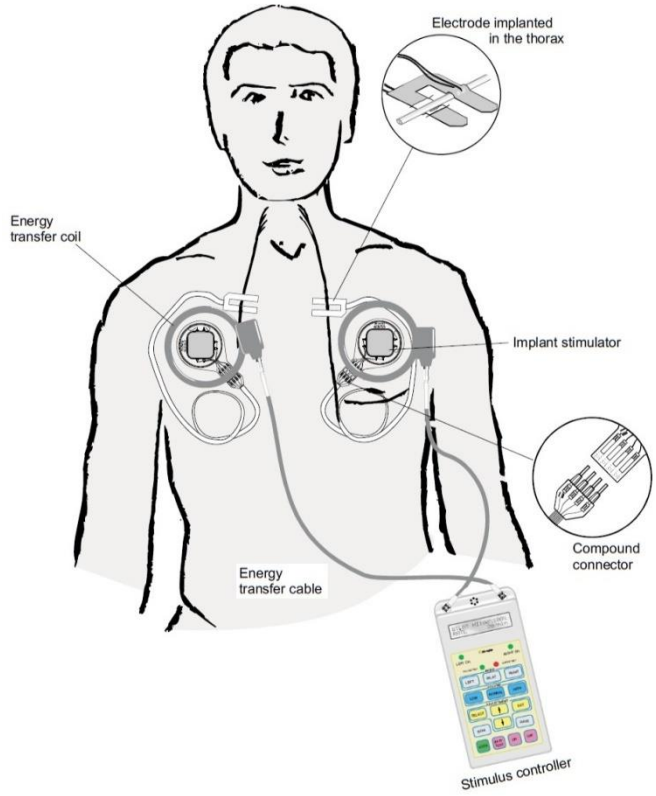


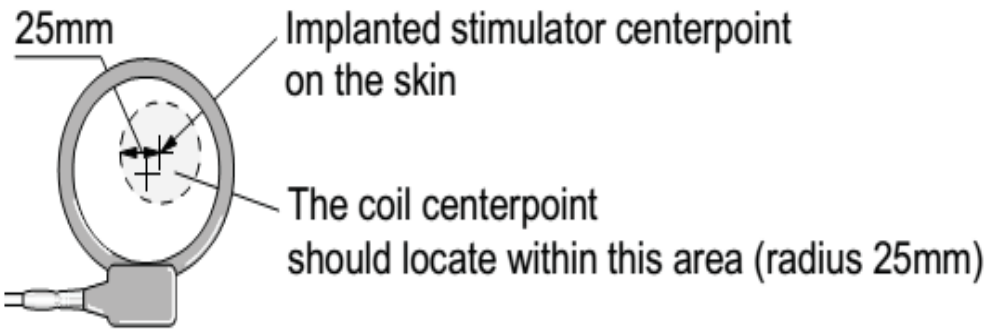

- Breathing volume, this can be easily adjusted to cope with the metabolic need of a client detailed within their care plan and in line with their requirements
- the device has three pre-adjusted levels available for breathing volumes, i.e. for supine and sitting position, and for temporary increased need.

Additionally, the device has a manual 'sigh' function for continuous training of the whole muscle mass and for assisting coughing.

**PPE to be worn in line with current guidance**

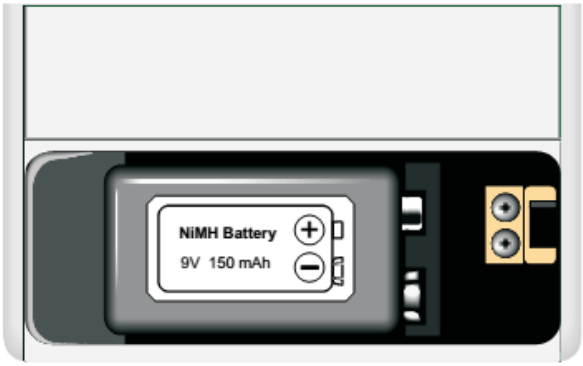
**Positioning of the Astrostim Phrenic Nerve Pacer cables, battery packs and controller**





**12v with charger**




**9V in controller unit**

Clients individual care plan will note the frequency that the equipment should be tested, frequency the battery will require changing and escalation process/trouble shooting process; however, generally;

- 12 volt battery x2 (one in use, one on charge) fully charged can last about 1 week
- 9 volt battery, in unit constantly trickle charging and spares
- 9 volt takes over when changing 12 volt
- test battery every at start of shift then 4 hourly
- RED light = low battery, manufacturer guidelines state change 12v within 2 hours (why wait?)
- RED light & bleep = change 12v battery immediately - **DO NOT WAIT.**

**Connecting the battery cable**

***Must not be forced into position***. Red dots line up to ensure accurate connection.

Failing to do this can result in damaged connections and can result in the need for additional equipment being sourced or the potential for the client being placed back onto the ventilator having a massive impact for them.

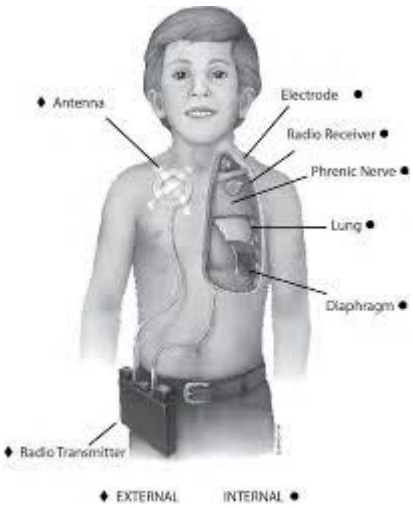
**Cable Care**

***DO NOT:***

- pull on the cables
- wrap cables around the transmitter
- hang the transmitter on the cable
- tie knots in the cable
- touch connections with metal

- stick pins in the cable
- get the connections wet.

**The Mark IV Equipment**



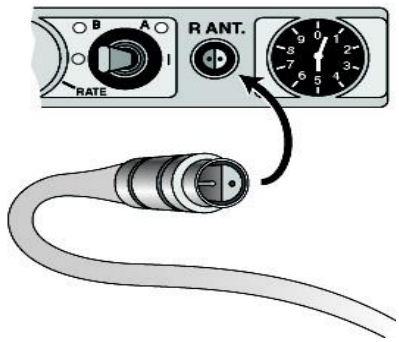

- external transmitter
- transmits radiofrequency (RF) energy to implanted receiver via antenna
- uses two independent channels for improved client safety over mechanical ventilators and earlier designs
- operates off standard 9-volt batteries, which are readily available worldwide
- made with discrete military-grade electronic components for superior operation and long-term reliability
- light weight (~1 lb.) and small size (6” x 5” x 1”) for easy portability.

**Antenna**

Antennas are used to transcutaneously transfer the RF energy from the external transmitter to the implanted receiver and electrode. Antennas can be held in place with adhesive tape, gas-permeable dressings (such as Tegaderm or Op-Site), and elastic netting or dressings.

- external Antenna
- transmits RF energy from Mark IV to the implanted receiver.
- affixed directly over the implanted receiver by tape or other dressing.
- available in a double-length version for those clients involved in water therapy or other activity where extra length is desirable.

**Antenna Connection**

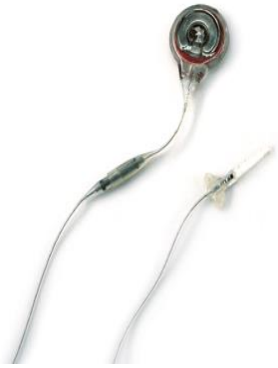



The semi-circular guide in the antenna connector has a corresponding guide in the transmitter. When aligned properly, the guides will form a whole circle.

Antennas should be pressed into the transmitter socket until it clicks into place. Do not turn or twist the connector.

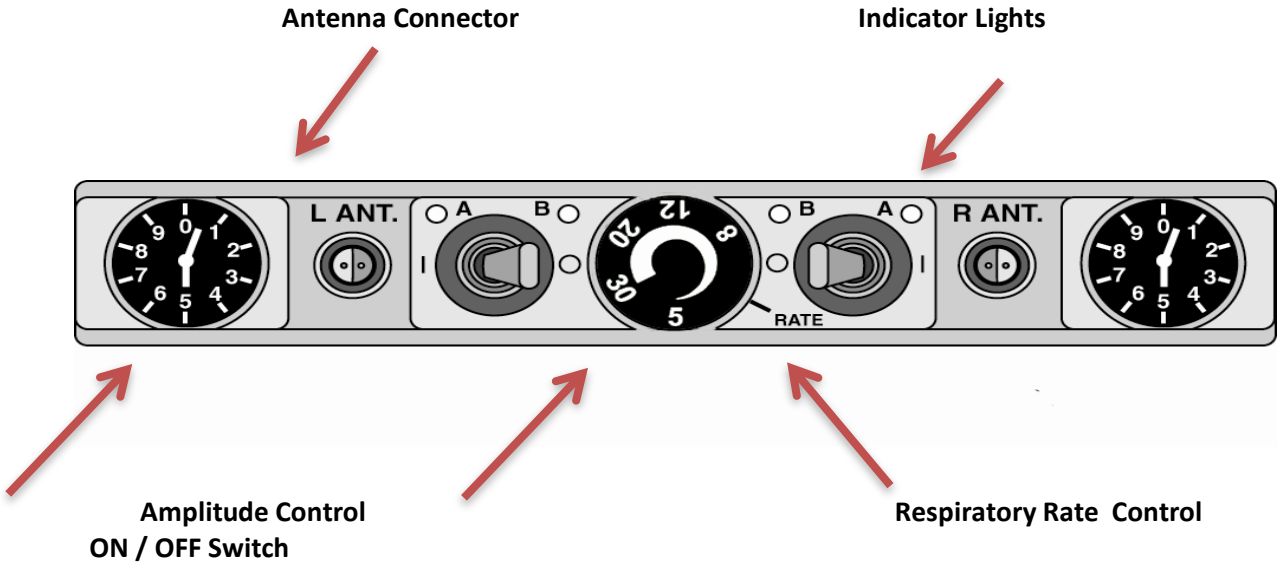
Antennas should be removed by pulling up on the textured collar of the connector, not the wire or it's covering.

**Receivers and Electrodes**



- implanted receivers and electrodes
- electrode is surgically placed around phrenic nerve
- electrode design has proven exceedingly reliable in over 30 years of use
- receiver is placed in subcutaneous pocket for easy locating by the client and / or caregivers
- receiver design is kept simple for dramatic improvement in life expectancy over earlier designs
- bipolar versions available for those clients with other implanted devices.

**Mark IV Transmitter**




The external transmitter is a battery-powered device which generates the stimulus patterns. It delivers them to the phrenic nerves via external antennas to the implanted receivers and electrodes.

Each side of the device is independent on the other but linked by a respiratory rate control so that they operate simultaneously.

- **ON/OFF Switch**
  - Each side of the transmitter has an independent switch for stimulus output
- **AMPLITUDE Controls**
  - Set level of stimulus output for each side, ranges from 0.0 to 10.0
  - Correlates to client's unilateral tidal volume
  - Amplitudes may need to be periodically adjusted to maintain tidal volume
- **RESPIRATORY RATE Control**
  - Sets the rate of bilateral breaths per minute
- **'A' INDICATOR**
  - Verifies stimulus output and antenna integrity
  - Allows for troubleshooting of antenna
- **'B' INDICATOR**
  - Verifies power circuit and battery wire integrity
  - Battery should be replaced if indicator is not lit. (not applicable when the battery is being changed)

***In normal operation, all four indicator lights are flashing in conjunction with each breath. If the client's normal amplitude settings are low (~ 1.0) the 'A' indicators may not operate.***

**Mark IV Transmitter - Batteries**

Each side of the Mark IV transmitter operates of its own alkaline 9-volt battery.

Operating time is dependent on the settings but should be at least 400 hours for most clients.

When battery voltage reaches about 7 volts, 'B' indicators will no longer light and batteries should be changed as soon as possible. Transmitter will continue to operate until battery voltage reaches about 5 volts, which is approximately 24 - 36 hours of operation for most clients.

**Warnings:**

Turn the transmitter OFF while changing batteries. Failure to do so could damage the transmitter and result in a loss of output.

Transmitter does not work while batteries are being changed.

## 9. Setting up and starting

**Preparation**

1. Insert batteries into transmitter, turn both sides 'OFF'.
2. Set amplitude dials to 0.0 on both sides.
3. Secure antennas over implanted receivers and connect to transmitter.
4. Preoxygenate client if necessary.

**(Refer to care plan to determine correct settings and thresholds for client)**
**Each hemi diaphragm is initially evaluated independently of the other.**

- discontinue alternate method of ventilation if applicable
- turn first side 'ON' and slowly increase amplitude control until threshold is reached.

**Pacing procedure**

- threshold is the lowest stimulus amplitude which results in a diaphragmatic response
- threshold can be observed by: visual observation, manual palpation or client sensation
- gradually increase amplitude until adding amplitude no longer increases tidal volume or diaphragm reaches maximum deflection
- process should be repeated for the 2nd side, allowing the client to rest on alternative ventilation as necessary
- once unilateral amplitudes are determined both sides should be turned 'ON' and a bilateral tidal volume measured. Note; tidal volumes on the right are often larger than volumes on the left.
- respiratory rate should then be set in line with the client's care plan
- thresholds can vary up to 20% so adjustments may be needed of amplitudes throughout the shift.

**Reconditioning**

- clients should be allowed to pace until indications of diaphragm fatigue occur. This can be observed by a 50% decrease in tidal volume, decreasing oxygen saturation or increasing CO2 retention
- pacing should be resumed daily until 24-hour pacing (or desired amount) is achieved
- the client's ventilator should be available in case of fatigue or complete failure of the pacing system.

**Procedure**

| | Action | Rationale |
|---|---|---|
| 1. | Explain procedure and Gain Consent, prior to any actions taken | To ensure co-operation, reduce stress and anxiety.<br>In line with legal requirements and Codes of Conduct. |

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| 2. | Establish the requirement for pacing, equipment required, and the need / frequency required to change consumables. This will be indicated in the client care plan. | To ensure the task needs to be undertaken. |
| 3. | Establish whether this task requires 1 or 2 people, this will depend on the client dependency on the equipment and frequency of use. This will be documented in the client care plan. | To ensure the safety of the client throughout the procedure. |
| 4. | At the start of every shift all safety equipment checks should be completed with both the client's client/family member as detailed within the clients care plan. This should be recorded in the client daily records/weekly pack with any concerns reported to the office and the client for further guidance. | To ensure the functionality of all equipment and maintain safety and adequate ventilation of the client. |
| 5. | Batteries are to be tested at the start of each shift. Spares should be charged at the start of each shift and then tested every four hours or as detailed within the clients care plan and staff are to document that this has been completed and that there are no concerns. | To ensure there is a fully functioning battery and an emergency / replacement power supply, if required. |
| 6. | Ensure that the energy transfer cables are checked and kept dry and that they are taped to clean, dry skin. | To ensure adequate contact to enable effective pacing, reduce damage to the contacts and to maintain skin integrity. |
| 7. | Ensure sufficient monitoring and observation of the client during the procedure. Rate and depth of breathing needs to be monitored. | To detect signs of oxygen de-saturation and deterioration and documented in the care plan and reported to the office. |
| 8. | Staff are to ensure that they communicate with the client at all times by asking them how they are feeling and to observe for signs that the client is becoming unwell. | To reassure the client that their condition is being closely monitored and any changes immediately reported and acted upon. |
| 9. | Wash hands thoroughly | To minimise the risk of cross infection. |
| 10. | Apply alcohol gel to hands leave to dry. Then apply appropriate PPE in line with current guidelines before touching equipment. | To reduce risk of infection. |
| 11. | Ensure all equipment is available as detailed and included in this SOP and within the clients care plan. | To enable the task to be completed. |
| 12. | Explain the procedure to the client and family if applicable. | To provide reassurance, gain cooperation and consent. |
| 13. | Protect all endings and avoid contamination (minimal handling of ends). | To minimise risk of infection, maintain integrity and prevent contamination. |
| 14. | Connect the system to the controller. | To ensure correct assembly of equipment. |
| 15. | Switch pacing unit on and check prescribed setting. These can be found in the client's care plan. | To ensure the pacing is working and the prescribed pressures are being achieved. |
| 16. | Attach the cables and correctly position them on the client and ensure client is comfortable.<br>Check the client has equal chest expansion during the procedure, check their colour and | To enable client to rest and maintain adequate breathing. |

| | | |
|---|---|---|
| | oxygen levels are within the normal limits, as documented in the care plan. | |
| 17. | Staff are to make themselves familiar with any alarm that may sound as this will indicate that the phrenic nerve pacer is failing and will need emergency support. | To respond immediately and seek assistance. |
| 18. | Clean the controller, battery and coils according to the manufacturer's guidelines, or discard disposables used in accordance to the waste disposal policy (this will be documented in the client's care plan).<br><br>NB: Ensure that you have removed all waste so that it does not compromise the client's safety. | To ensure the system is ready for next change.<br>To ensure the disposables are disposed of safely and in line with Acacium Group Waste Disposal Policy. |
| 19. | Record procedure in record of respiratory management or the client's weekly packs, as appropriate. | To ensure continuity of care and ensure events are recorded and documented. |
| 20. | All staff will be supported with their clinical training and competencies in order for them to safely support each client. | To ensure client safety and comply with medical device training requirements in line with the Safe Use of Medical Devices Policy. |

**Respiratory rate should be set in the client's care plan.**
**This should be checked but NOT changed.**

**Volume** should only be changed by staff if detailed in the care plan and prescribed by the specialist; an example of possible changes dependant on the clients position would be;(for example):

- **high -** when getting out of bed
- **normal -** when sat in chair (or normal activity)
- **low -** when asleep.

**Simulation modes**

- **left unilateral –** left hemi-diaphragm
- **bilateral –** right and left hemi-diaphragm
- **right unilateral –** right hemi-diaphragm.

**Energy transfer cables**

- positioned over implant
- affixed with tape to clean, dry skin
- always check position after movement
- avoid moisture on connections
- no chest physiotherapy where receiver is positioned.

IN THE EVENT OF THE PHRENIC NERVE PACER FAILING EMERGENCY MANUAL VENTILATORY SUPPORT WILL BE REQUIRED. ALARMS WILL SOUND. STAFF ARE TO ENSURE THAT THEY ARE POSITIONED SO THAT THEY CAN HEAR ANY ALARM AND RESPOND IMMEDIATELY.

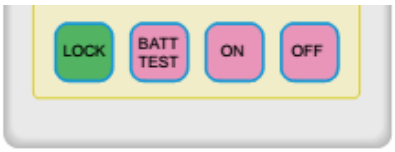
## 10. Programming module

- the programming module should not be changed by staff
- it is important to have the control module nearby in case of system error and requirement for 're-boot'

- this should only be completed by an experienced appropriately trained and designated individual.

## 11. Starting procedure

1. Place a fully charged 9v battery into the control module. Then connect the 12v battery ensuring the red dots are correctly aligned.
2. Place the energy transfer coils (aerials) accurately over the implant stimulators and secure with adhesive tape.
3. Plug both right and left hand cables into their respective connections being careful not to damage or 'CROSS CONNECT' the aerials.
4. To start stimulation press 'LOCK' and 'ON' keys simultaneously. Follow the green channel LEDs in the front panel as they should blink on inspiration.
5. Monitor the client's breathing – rate, equal chest rise, depth, noises, and oxygen saturation (if care plan stated).





## 12. Client monitoring

1. Monitor and record the rate and depth of breathing.
2. Monitor and record the oxygen saturations as detailed in the client's care plan.
3. Observe the client - are they able to talk in sentences, colour of skin, equal breathing pattern (client will have abdominal rise and fall).
4. Ask the client how they feel and offer reassurance at all times.
5. Monitor for any added symptoms e.g. secretions etc., is there a requirement for client suctioning?

## 13. Care plan

- if there is a discrepancy between what is documented in the care plan and what is programmed on the pacer? Inform the branch immediately and switch the client to the ventilator, if applicable
- always follow the care plan
- follow emergency procedures and protocol
- maintain documentation at all times.

## 14. Complications: Diaphragmatic fatigue

Diaphragmatic fatigue is a condition which may develop due to an improper combination of chosen stimulus pulse interval and adjusted or selected stimulus currents. Lowest stimulation currents should therefore always be used, where possible. This will be determined by a professional and dictated in the client's care plan:

- lowest stimulation currents should be chosen, where possible
- examples include high humidity, excess heat, poor air quality and body position
- allow sufficient and appropriate rest period before resuming stimulation.

## 15. Troubleshooting

- check settings for each shift against the care plan
- check setting is correct for position i.e. *LOW* if sleeping
- check connections regularly, are they loose, trapped, corroded, kinks etc.
- ensure channels are not crossed (due to different threshold for left and right lungs)
- check the battery is charged
- if the unit fails to start after ***'lock & on'*** are pressed simultaneously, switch off, check battery and restart
- clients often require increased amplitudes in the presence of any systemic infection or illness. This increase is transient and will resolve once the condition abates
- changes in medications or dosing of medications, particular drugs which affect the anterior horn cells (eg, Baclofen) can affect amplitude settings
- weight gain increases tissue depth over the receiver and results in the need for additional amplitude. Contact technical support regarding possible parameter adjustment but surgical intervention to relocate the receivers may be required in extreme cases.
- If transmitter and Antennas check out as fully functional, but pacing is not possible check for signs of infection. Evidence has shown that diaphragm pacing may become ineffective when the client has any type of infection in any location.

**It is strongly recommended that the client always has a spare set of known, good antennas and spare 9-volt batteries readily available at all times.**

## 16. Cautions

1. Magnetic Resonance Imaging (MRI), shockwave lithotripsy, and therapeutic diathermy are contraindicated for clients implanted with diaphragm pacemakers.
2. Use of a defibrillator may damage the implanted receiver and or phrenic nerve.
3. Exposure to therapeutic dosages of ionizing radiation may damage implanted components or interfere with the operation of the device.
4. Exposure of the implanted components to therapeutic levels of ultrasound energy may inadvertently concentrate the ultrasound field and cause harm.
5. Exposure to a powerful radio transmitter, such as those used for navigational or maritime communications, may interfere with the operation of the device.
6. Staff are not to:
    - pull on the cables
    - wrap the cables round the transmitter
    - tie knots in the cable
    - touch the connectors with metal
    - stick pins in the cable
    - get the connections wet.

## 17. Maintenance and checks

ATROTECH OY
02/2012 EN

ATROSTIM Phrenic Nerve Stimulator

System Version V2.0

**Recommended Maintenance and Service Measures**

| Subject of Maintenance and Service Measure | Description of Measure | Permormed by | Check Interval and Documentation |
|---|---|---|---|
| Entire stimulation system | Technical inspection of system components and checking of system functionality (parameter check, ventilatory measurements) according to test protocol.<br>Checking the status of back-up ventilation and ventilation monitoring. (Refer to Manual, pp. 4-5) | Device supplier and doctor in charge | Annually<br>Test Report<br>Parameter Form (Form3.xls) |
| Energy Transfer Cable PCL 80 | Checking of connectors and cables (according to checklist in the Manual, pp. 33-35) | User | Weekly |
| | Changing a new cable | User's organisation/Hospital | Every 2 years |
| Energy Transfer Coil TCL 27 | Cleaning and inspection of the cable (according to checklist in the Manual, pp. 33-35) | User | Weekly |
| | Changing a new coil | User's organisation/Hospital | Every 2 years |
| Battery N12V | Charging | User | Weekly |
| | Changing a new battery | User's organisation/Hospital | 2 to 4 years |
| Internal Battery 9V | Changing a new battery | User's organisation/Hospital | Need for a change checked during annual inspection |
| Stimulus Controller PX 244 L | Status and function of the display, keyboard, alarm indicators and receptacles (according to checklist in the Manual, pp. 33-35) | User | Every 6 months<br>Possible dysfunction to be reported |

Reference: User's Manual (February 2012), pages 4 - 5 and 33 - 35

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## 18. Final points

- Staff should understand the basic principles of threshold and amplitude settings from the care plan
- Staff should know the pacing schedule within the care plan as established by the client's specialist
- Staff should understand the clinical indications when the client has reached the point of diaphragmatic fatigue which indicate that the pacing session should be discontinued
- training and 'competency' in phrenic nerve pacing will be determined by the RCL/CNM

## 19. Associated Policies / SOPs

**Policies**

CLIN 02 Assisted Ventilation Policy
CLIN 06 Consent Policy
CLIN 12 Safe Use of Medical Devices Policy.

**SOPs**

SOP VENT 01 Tracheostomy Dressing Change (Adult & Child)
SOP VENT 02 Tracheostomy Care General Guidelines
SOP VENT 03 Humidification of a Client's Tracheostomy
SOP VENT 04 Tracheal Suctioning (Adult & Child)
SOP VENT 05 Tracheostomy Tube Care (Adult)
SOP VENT 06 Tracheostomy Tube Change (Adult)
SOP VENT 07 Tracheostomy Tube Change (Child)
SOP VENT 08 Administration of a Nebuliser through a Ventilator Circuit
SOP VENT 09 Assembling a Ventilator Circuit
SOP VENT 10 Cleaning the Ventilator Equipment

SOP VENT 11 Safe Management of a Ventilated Client During Outings
SOP VENT 12 Safe Management of a Ventilated Client During Power Cuts
SOP VENT 13 Safe Use of Battery Packs
SOP VENT 14 Assisted Airway Maintenance and Cough (Adult)
SOP VENT 15 BiPAP
SOP VENT 16 Oral and Nasal Suctioning
SOP VENT 18 CPAP
SOP VENT 19 Mechanical Cough Assist
SOP VENT 20 Changing Tracheostomy Cotton Ties (Child)
SOP VENT 21 Changing Tracheostomy Velcro Tapes (Child)
SOP VENT 23 Laryngectomy Care General Guidelines
SOP VENT 24 Emergency Tracheostomy Tube Change (Adult)
SOP VENT 25 Emergency Tracheostomy Tube Change (Child)
SOP VENT 26 Nasopharyngeal Airway Management (Adult & Child)
SOP VENT 27 Nebuliser Therapy

## 20. References


- Clinical Commissioning Policy: Phrenic Nerve Pacing Following Spinal Cord Injury April 2013 - Prepared by the NHS Commissioning Board Clinical.
  [Accessed 25th June 2010].
- Diaphragm Pacing by Phrenic Nerve Stimulation - Am J Respir Crit Care Med Vol. 193, P13-P14, 2016
- Clinical Commissioning Policy: Phrenic Nerve Pacing Following Spinal Cord Injury - April 2013 Reference: NHSCB/D13/P/a

## Appendix A: About Acacium Group

Acacium Group consists of a number of trading companies, each providing services within core niche areas of the health and social care industries. Therefore, as this document is a Group Policy, the Policy herein applies to all trading companies detailed below:

| | |
|---|---|
| pulse<br>Part of Acacium Group | Thornbury Nursing Services<br>Part of Acacium Group |
| Thornbury Community Services<br>Part of Acacium Group | Scottish Nursing Guild<br>Part of Acacium Group |