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AeroPace® Neurostimulation Therapy System Overview

MKT-0061 Rev A 22-Oct-2025

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Difficulty Weaning: Diaphragm Atrophy Occurs Rapidly

Extending time on ventilation and increasing mortality

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- ✕ Ventilation weakens diaphragm muscle by more than **50% in less than one day**[1,2]
- ✕ Weakened muscles make it difficult to regain independent breathing, meaning **extended weaning times** and **reduced weaning rates**[1]
- ✕ **Increased likelihood of reintubation**[3] (with a 5-fold increased risk of mortality), **tracheostomy**, and their associated costs[4]
- ✕ **Longer ICU/hospital stays**[3]
- ✕ Leads to increases in respiratory **complications** and **mortality**[3]

1. Dres, M. (2017) *Am J Respir Crit Care Med.*; 195(1): 57-66. doi: 10.1164/rccm.201602-0367OC; 2. Levine, S. (2008) *NEJM*; 358(13): 1327-1355. doi: 10.1056/NEJMoa070447; 3. Zilberberg, M. (2020) *Crit Care Med.*; 48(11): 1587-1594. doi: 10.1097/ccm.0000000000004525; 4. Menon, N. (2012) *Respir Care*; 57(10): 1555-1563. doi: 10.4187/respcare.01617.

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AeroPace vs Standard of Care[1,2]

RESCUE 3 RCT performed across diverse, challenging patient population

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UP TO 3.2

Fewer Days on MV in the ICU

Reduction in ICU Ventilator Time

UP TO 43%

More Likely to Wean by Day 30

Improved Weaning Success

UP TO 50%

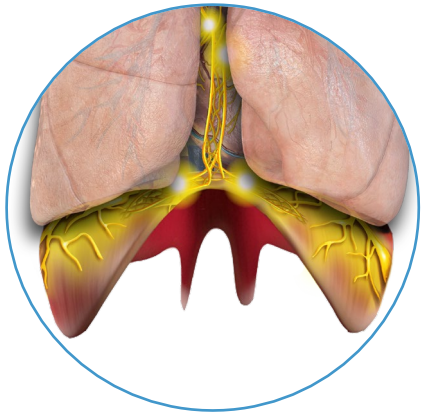
Lower Risk of Reintubation* and Tracheostomy

*Includes return-to-MV for tracheostomy patients

Fewer Additional Procedures

UP TO 74%

Stronger Diaphragm



Increased Strength

1. Data on file, RESCUE-3; 2. Dres, M. (2025) *Am J Resp Crit Care Med.*; online ahead of print. doi: 10.1164/rccm.202505-1056OC.

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The AeroPace Neurostimulation Therapy System

- Patient Selection
- Components and Setup
- Neurostimulation Catheter Insertion and Placement
- Mapping and Therapy Sessions
- Super-users: Cleaning, Storage, and MR Compatibility
- Super-users: Troubleshooting (Manual mode and Exclusion)

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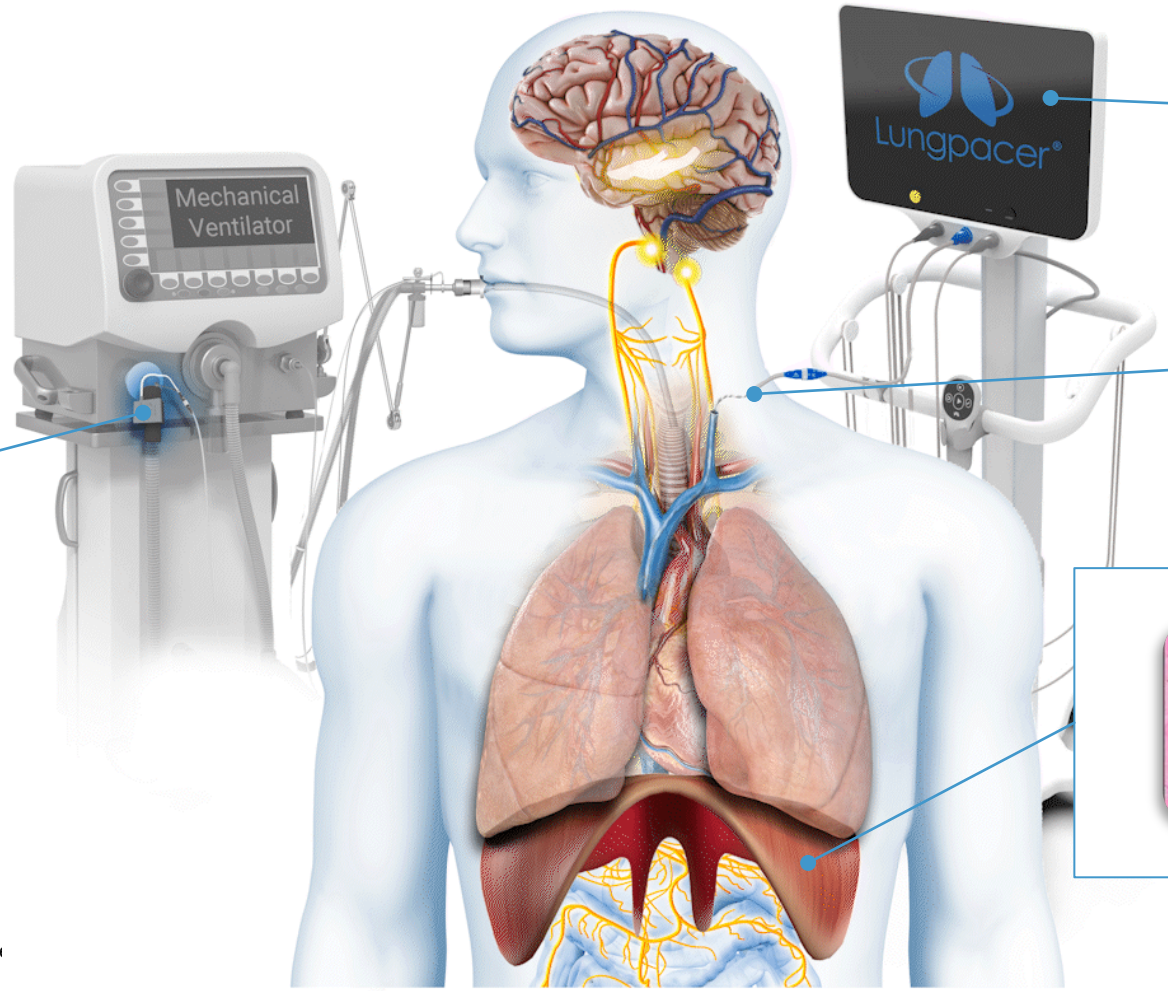
AeroPace Therapy: Neurostimulations Delivered through Specialized CVC
Exercises and Rehabilitates the Diaphragm

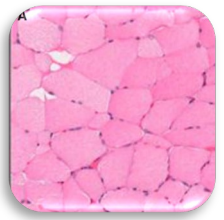
Mechanical ventilation causes diaphragm atrophy, leading to difficulty weaning. AeroPace stimulations contract the patient diaphragm, **strengthening the muscle** and **helping the patient wean** off the ventilator.



Airway Sensor

Neurostimulation Console

Neurostimulation Catheter



Activates and exercises diaphragm, increasing strength to increase the likelihood of weaning success

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AeroPace® System Safety and Effectiveness Information

Indications and Contraindications for Use

Intended Use

The AeroPace System is intended for temporary stimulation of the phrenic nerve(s) to increase diaphragmatic strength.

The AeroPace System is intended for use in hospitals and hospital-type facilities which provide care for patients requiring mechanical ventilation. The device is intended to be used by appropriately trained personnel under the direction of a physician.

Indication for Use

The AeroPace System is indicated to improve weaning success – increase weaning, reduce ventilator days, and reduce reintubation – in patients ages 18 years or older on mechanical ventilation ≥ 96 hours and who have not weaned.

Contraindications

Do not use the AeroPace System with active implanted cardiac pacemakers, defibrillators, or other implantable electronics within proximity to the AeroPace Neurostimulation Catheter. The AeroPace System has not been clinically evaluated for safety with these implantable electronic devices.

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- The AeroPace Neurostimulation Therapy System

Patient Selection

- AeroPace System Components and Setup
- Neurostimulation Catheter Insertion and Placement
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- Super-users: Troubleshooting (Manual mode and Exclusion)

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AeroPace Therapy Patient Selection

For patients with difficulty weaning from mechanical ventilation

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Potential Patients to Consider

- **ARDS**
- **COPD**
- **Pneumonia**
- **Surgical**
- **Trauma** (including Neuro)

↓

Patients (18 yr +) on Mechanical Ventilation ≥96 hours
(including Endotracheal and Tracheostomy patients)

↓

High Clinical Suspicion for Difficulty Weaning

e.g., Failed Spontaneous Breathing Trial

↓

Defibrillator and ICD patients contraindicated

Consider Lungpacer AeroPace Therapy

- Up to **74% Stronger Diaphragm** *Increased Strength*
- Up to **43% More Likely To Wean by day 30** *Improved Weaning Success*
- Up to **3.2 Fewer Days on MV in the ICU** *Reduction in ICU Ventilator Time*
- Up to **50% Lower Risk of Reintubation* and Tracheostomy** *Fewer Additional Procedures*
  **Includes return-to-MV for tracheostomy patients*

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- The AeroPace Neurostimulation Therapy System
- Patient Selection

Components and Setup

- Neurostimulation Catheter Insertion and Placement
- Mapping and Therapy Sessions
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- Super-users: Troubleshooting (Manual mode and Exclusion)

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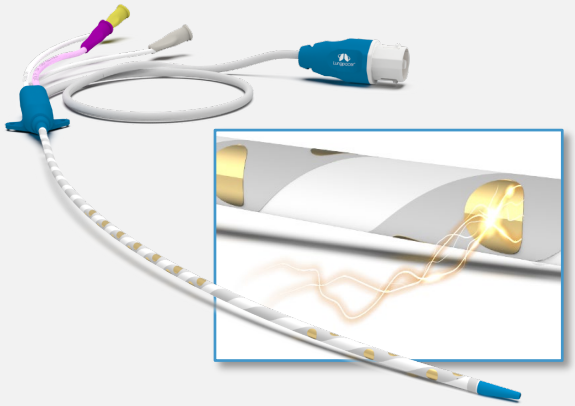
The AeroPace System

Three main components integrate system and ventilator

Neurostimulation Catheter

A temporary, transvenous neurostimulation device with **CVC functionality, plus specialized electrodes** that stimulate the phrenic nerves and activate the diaphragm.



Neurostimulation Console

Controls **adjustable stimulation parameters** that rebuild diaphragm muscle strength and help patients wean from mechanical ventilation.

Airway Sensor

Compatible with any ventilator for single-patient use to deliver AeroPace Therapy with ventilator breaths.

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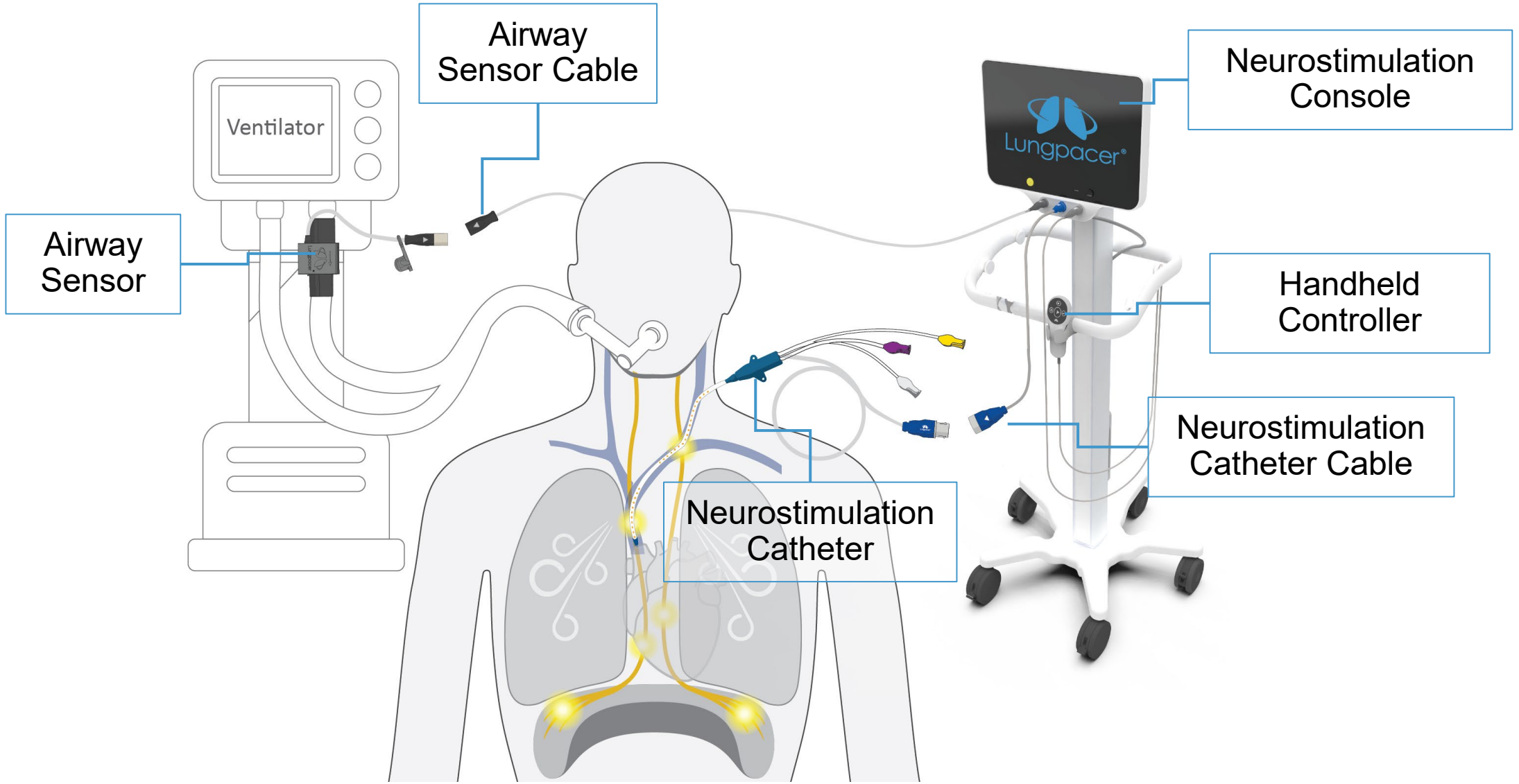
AeroPace System Setup and Overview



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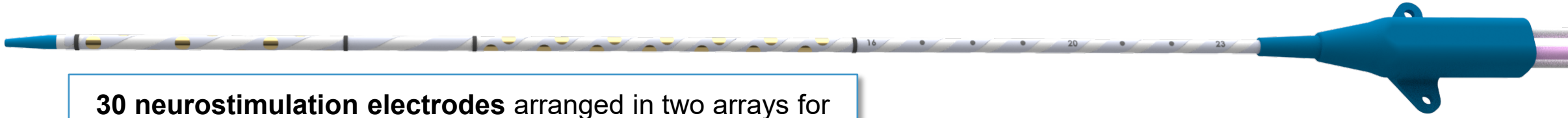
AeroPace Neurostimulation Catheter Specifications

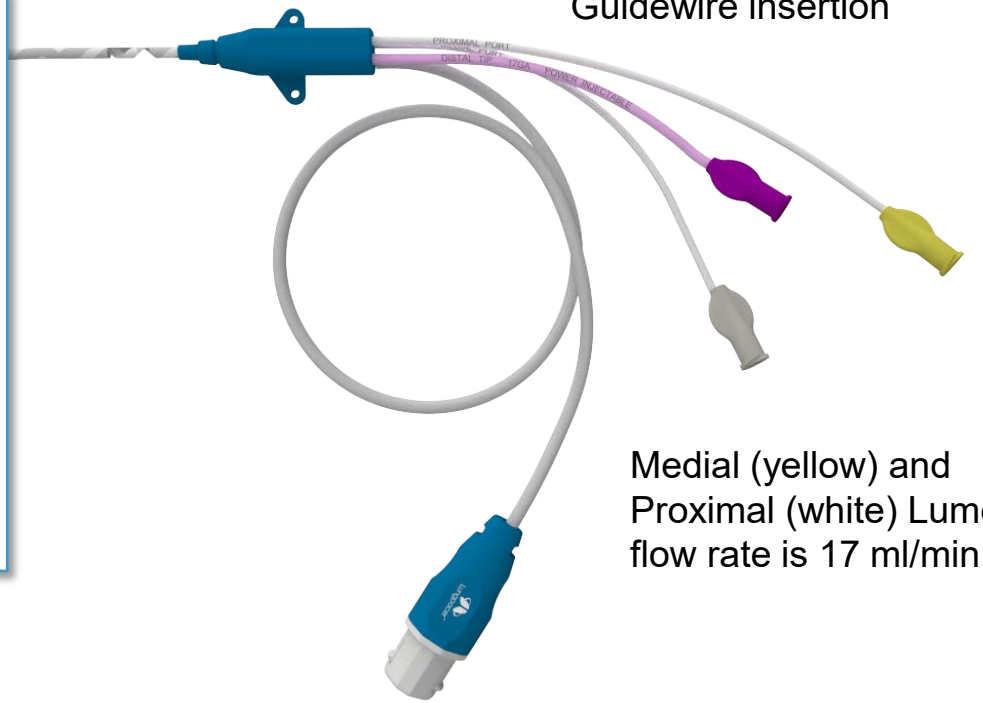
Includes standard CVC functionality, plus specialized electrodes



30 neurostimulation electrodes arranged in two arrays for left and right side phrenic nerve stimulation

- **23cm, 8.5 Fr diameter** fits easily within vein; standard left jugular or left subclavian vein insertion using Seldinger technique
- **Sterile, designed for single-use for up to 30 days**. Follow institutional guidelines for care and maintenance of CVCs.
- When properly placed in central circulation, the Neurostimulation Catheter may be used for **TPN, fluid, and medication delivery**. Infusions may continue during Therapy delivery.
- See Neurostimulation Catheter Kit Instructions for Use for additional information.

High Pressure Lumen (5 ml/sec and flow rate of 42 ml/min) and Guidewire insertion



Medial (yellow) and Proximal (white) Lumen flow rate is 17 ml/min

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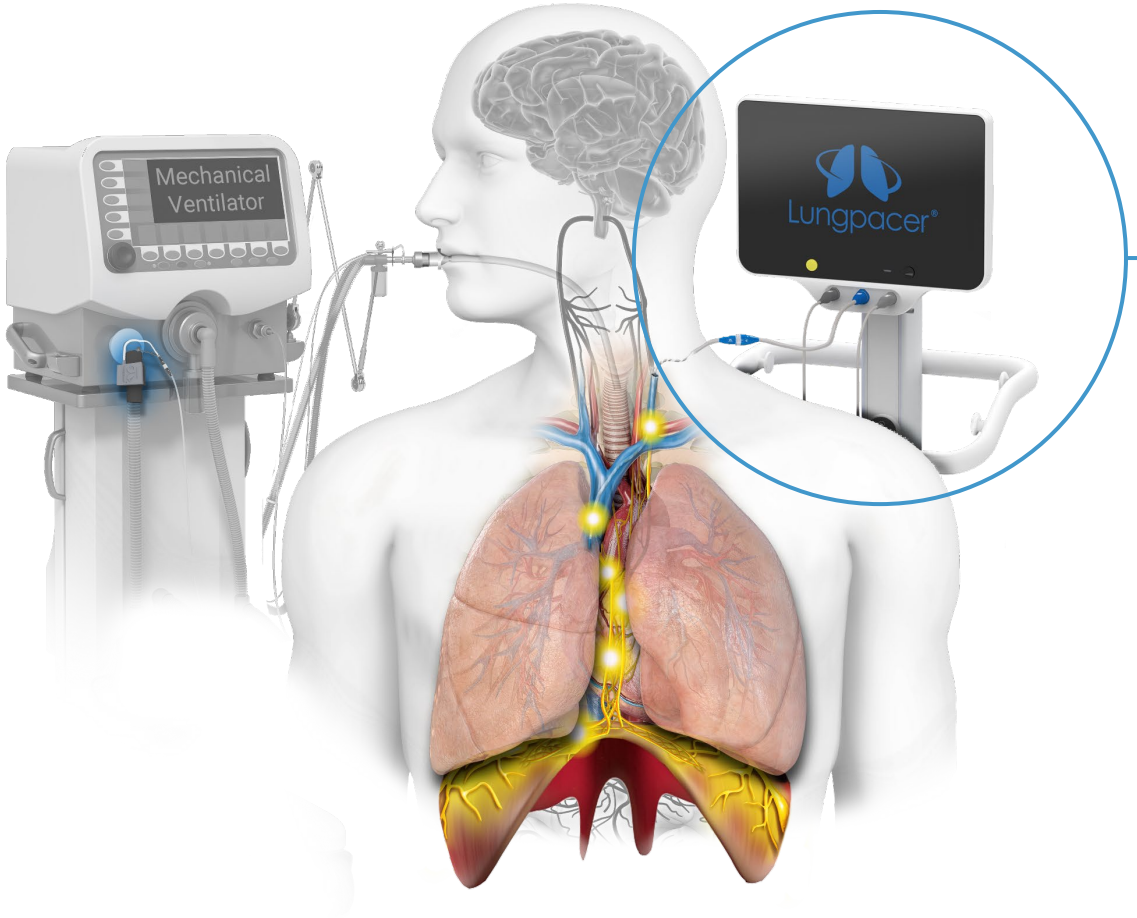
AeroPace Neurostimulation Console

Generates stimulations that activate the phrenic nerves



Features of the **Neurostimulation Console** include:

- ✓ **Touchscreen** User Interface
- ✓ **ECG**-guided Catheter insertion
- ✓ Neurostimulation Catheter **Placement** verification
- ✓ **Mapping** to select effective electrodes
- ✓ User-adjustable **Therapy** parameters and notifications for diaphragm activation

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AeroPace Neurostimulation Console
Buttons and Cables

Yellow Stop Button: Pressing this button will quickly stop stimulations. The Console must be powered off after pressing this button.

Catheter Cable: The cable with blue connectors electrically connects the AeroPace Neurostimulation Catheter to the Console when in use.

Airway Sensor Cable: The cable with dark gray connectors electrically connects the Airway Sensor to the Console.

Power Button: Powers the Console on and off.

Handheld Controller: The Handheld Controller has a light gray connector. It is used to perform System functions at a distance from the Console.

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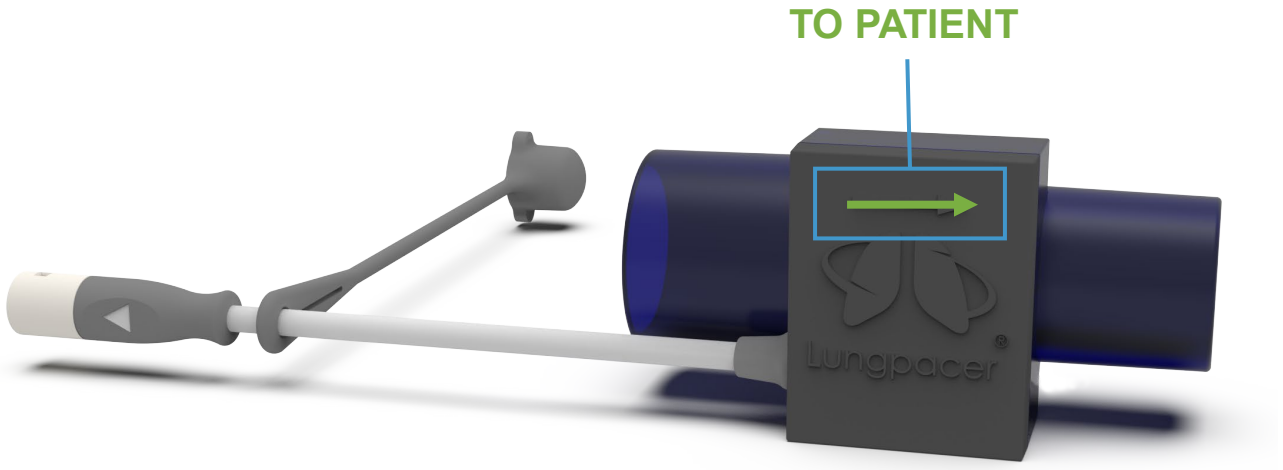
AeroPace Airway Sensor

Use

- Connect the Airway Sensor to the breathing circuit **before setting up the sterile field** to insert the Neurostimulation Catheter.
- The Airway Sensor connects to the mechanical ventilator at the inspiratory limb of the breathing circuit.
  - *Note: Alternatively, if needed, the Airway Sensor may be placed between the Y-piece and the patient's tracheostomy or endotracheal tube.*
- The **arrow** on the sensor should point toward the patient.
- Is designed to remain connected to the patient's breathing circuit.
- Single-patient use for up to 30 days.

Cleaning

- Gently **suction** secretions to remove them.
- Water could damage the sensor's electronics; do not rinse it under running water.



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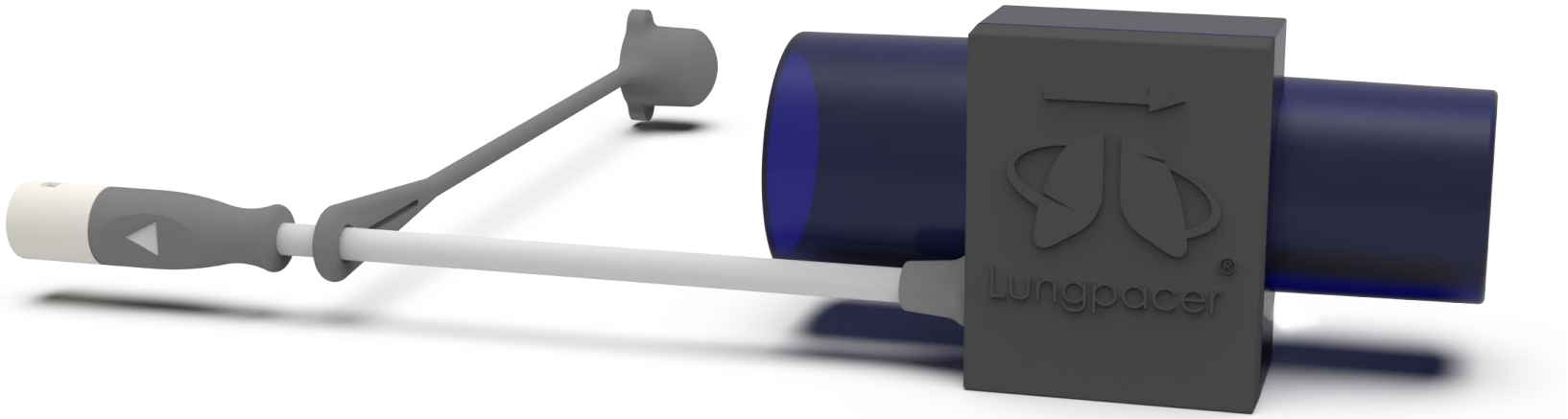
AeroPace Airway Sensor
Required for System Use in Auto mode

How it Works

- The Airway Sensor connects to and measures changes in the patient's **breathing circuit pressure.**
- Using **pressure** waveform, the Airway Sensor detects the beginning of ventilator breaths and diaphragm contraction.



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- The AeroPace Neurostimulation Therapy System
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Neurostimulation Catheter Insertion and Placement

- Mapping and Therapy Sessions
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AeroPace Neurostimulation Catheter Kit

Insert Neurostimulation Catheter before expiration date printed on the kit

- **Neurostimulation Catheter Kit <u>includes</u>:** sterile Neurostimulation Catheter and single-use accessories commonly used to insert a CVC using the Seldinger technique.
- **Does <u>not</u> include:** Ancillary medical supplies such as sterile saline flushes, **local anesthetic**, **skin preparation materials,** sterile gloves, gown, or sterile ultrasound probe cover.

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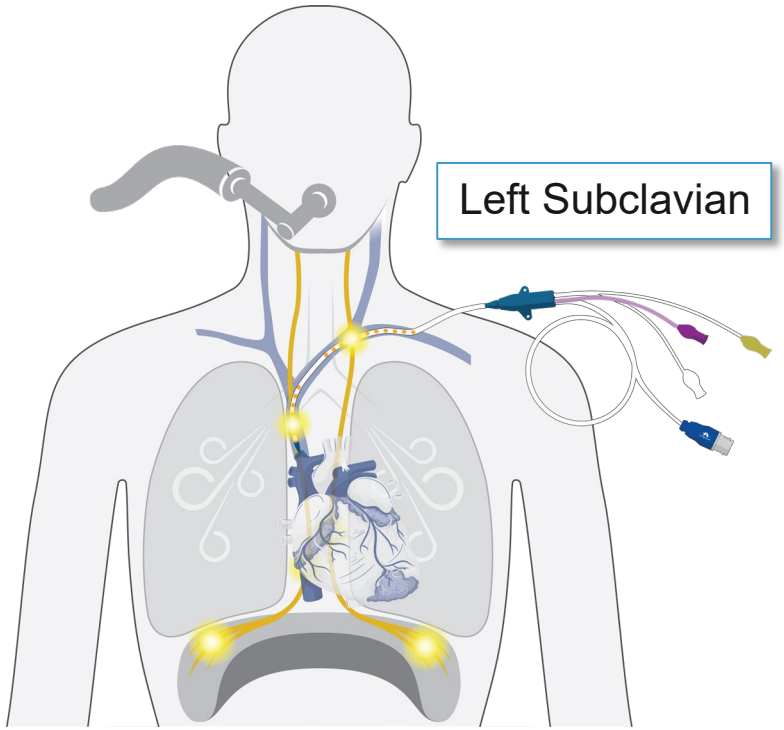
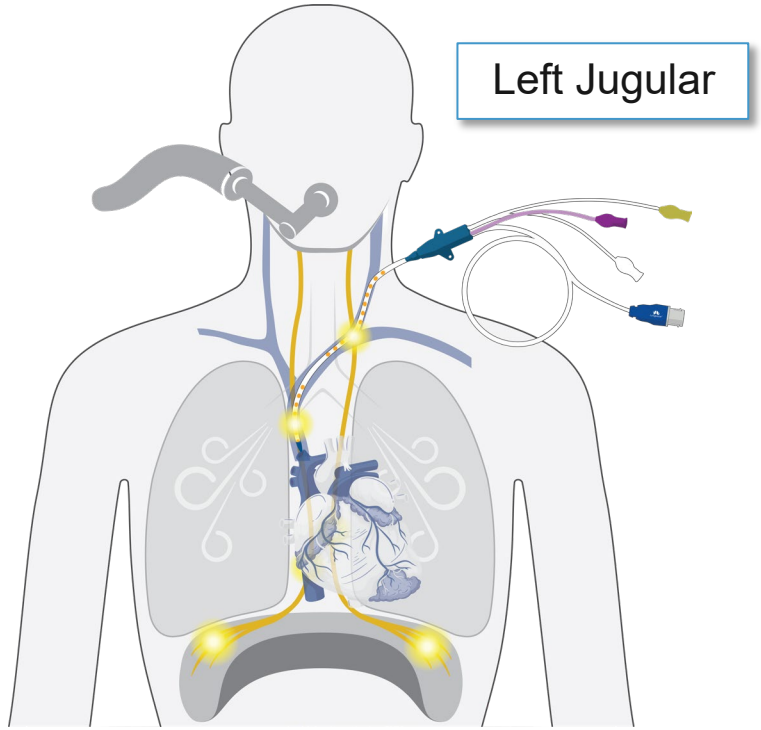
Insertion Location

- The Neurostimulation Catheter should be inserted into the **left subclavian** or **left jugular** vein.
- Prepare for insertion following the Neurostimulation Catheter Kit **Instructions for Use**, as well as institutional guidelines for the insertion of CVCs using the **Seldinger technique**.





Precaution: The US Center for Disease Control and Prevention (CDC) recommends a subclavian catheter placement to minimize the risk of infection.

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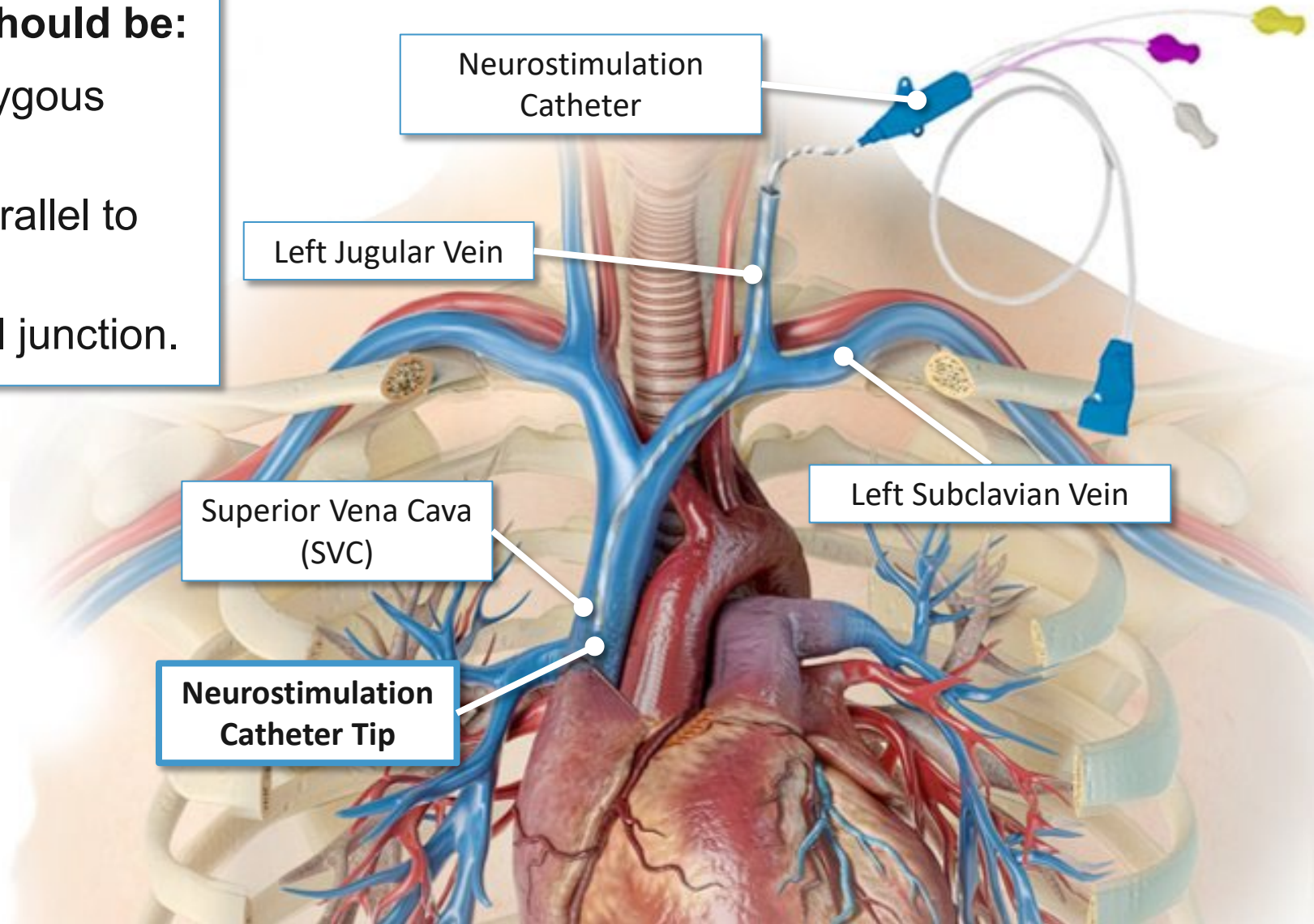
Proper Distal Tip Position

Neurostimulation Catheter tip should be:

- ✓ A few centimeters above the azygous vein or the carina or trachea.
- ✓ In distal third of the SVC and parallel to its wall.
- ✓ About 1 cm above the cavoatrial junction.



WARNING: *Do not position the Neurostimulation Catheter (or allow it to remain) in the atrium, right ventricle, or too close to the heart.* ***Incorrect positioning of the Neurostimulation Catheter may result in cardiac arrhythmia or tamponade.***

Note: The entire length of the Neurostimulation Catheter from tip to hub is 23 cm. It is ***not intended to be inserted all the way to the hub*** *in most patients.*

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Neurostimulation Catheter Insertion

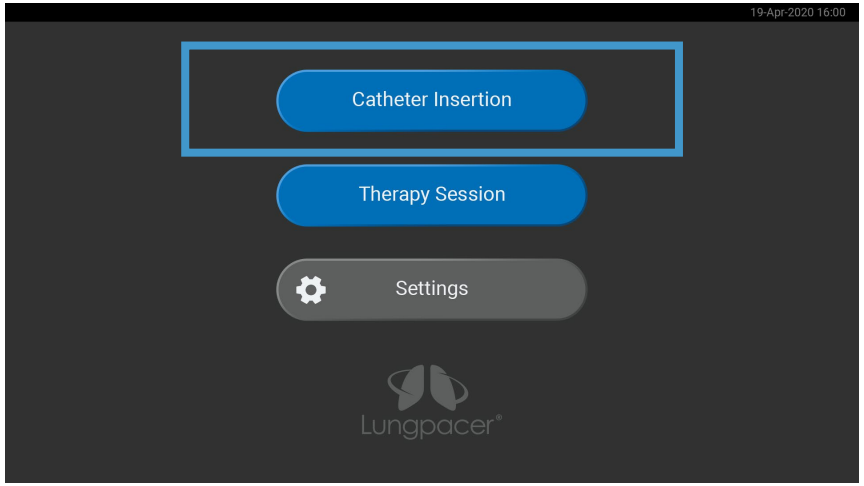
Have a non-sterile assistant available to operate Console

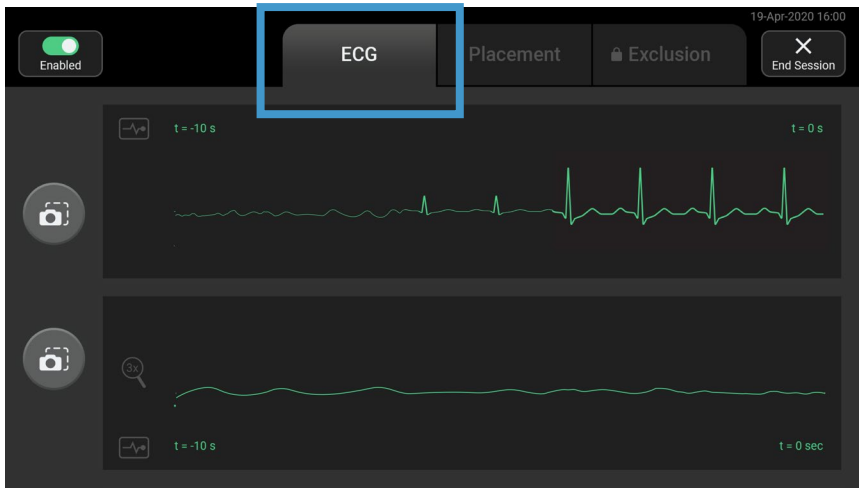
1. Have the non-sterile assistant power on the AeroPace System and select **Catheter Insertion.** You then have the **option to use the ECG** feature as an aid in the Catheter insertion process.

2. If you are using the ECG feature, the sterile clinician will slowly insert the Neurostimulation Catheter using the **Seldinger technique** while watching the screen for signal morphology changes.

   - **Avoid bending, twisting, or torquing the Neurostimulation Catheter** during insertion.

   - ***Caution:*** *Follow all instructions in the Neurostimulation Catheter Kit Instructions for Use.*





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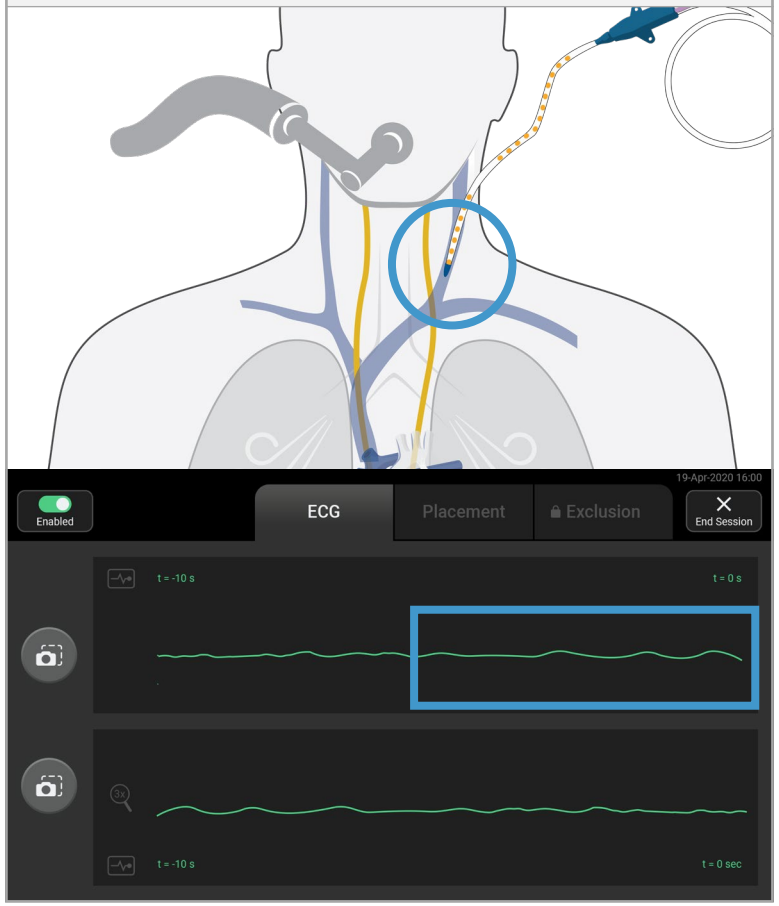
ECG-Guided Insertion (Optional)

Use clinical assistance to maintain sterile field while operating the Console

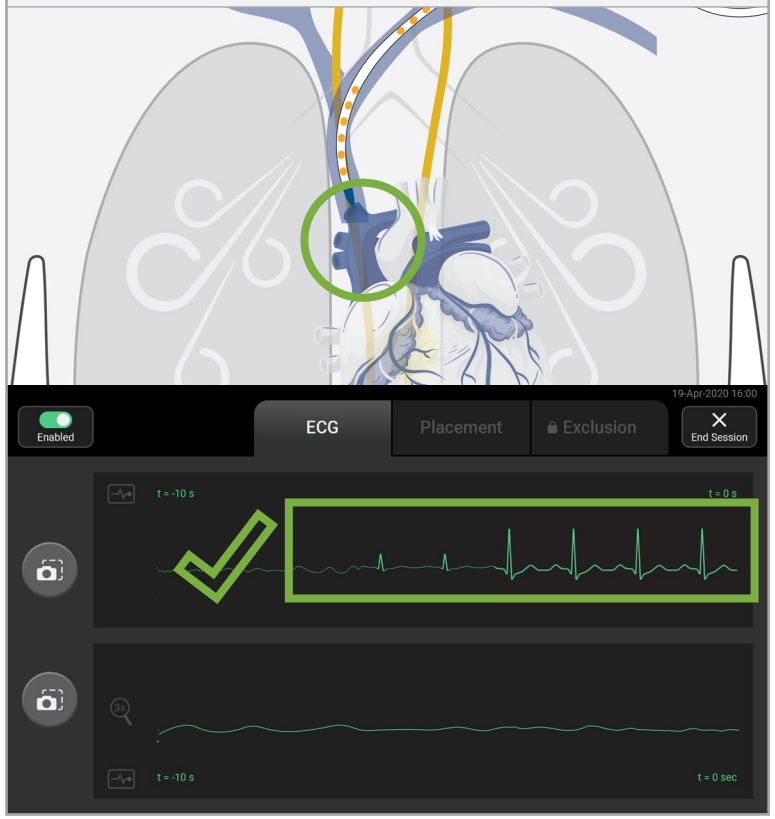
Insert the Neurostimulation Catheter

As the Neurostimulation Catheter first enters the vein over the guidewire, the electrogram will appear flat.



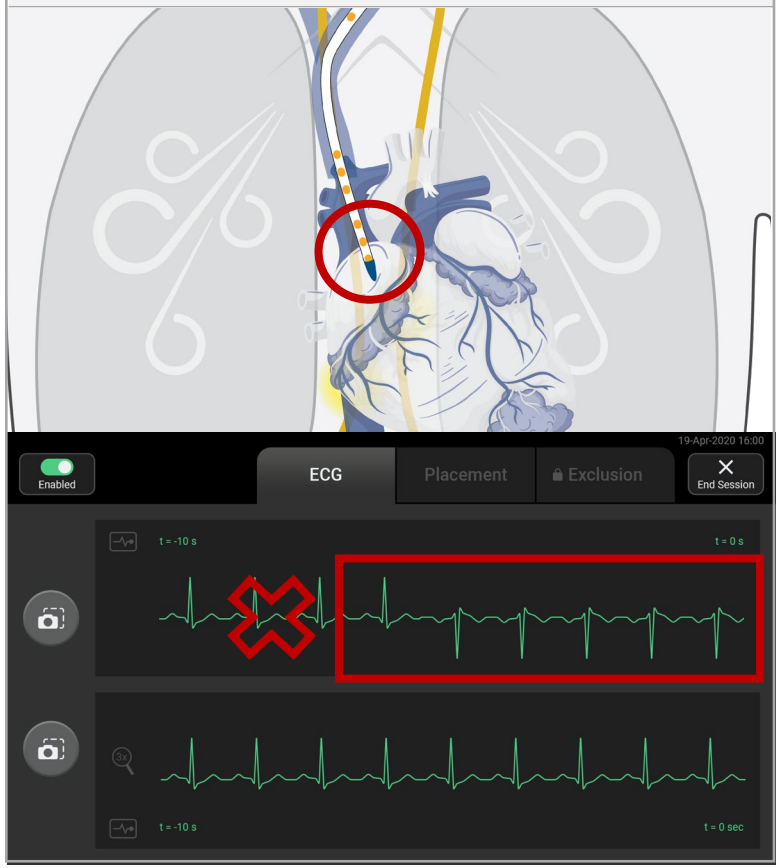
Look for clear signal while advancing

Advance the Neurostimulation Catheter **slowly,** looking for increased amplitude in the signal. **Stop advancing** upon seeing good definition of the intravascular electrogram. **Retract the guidewire.**



Do not over-advance (inverted signal)

An inverted/flipped signal morphology indicates that the Neurostimulation Catheter has been **advanced too far** and may be in the atrium; retract the Catheter slowly.



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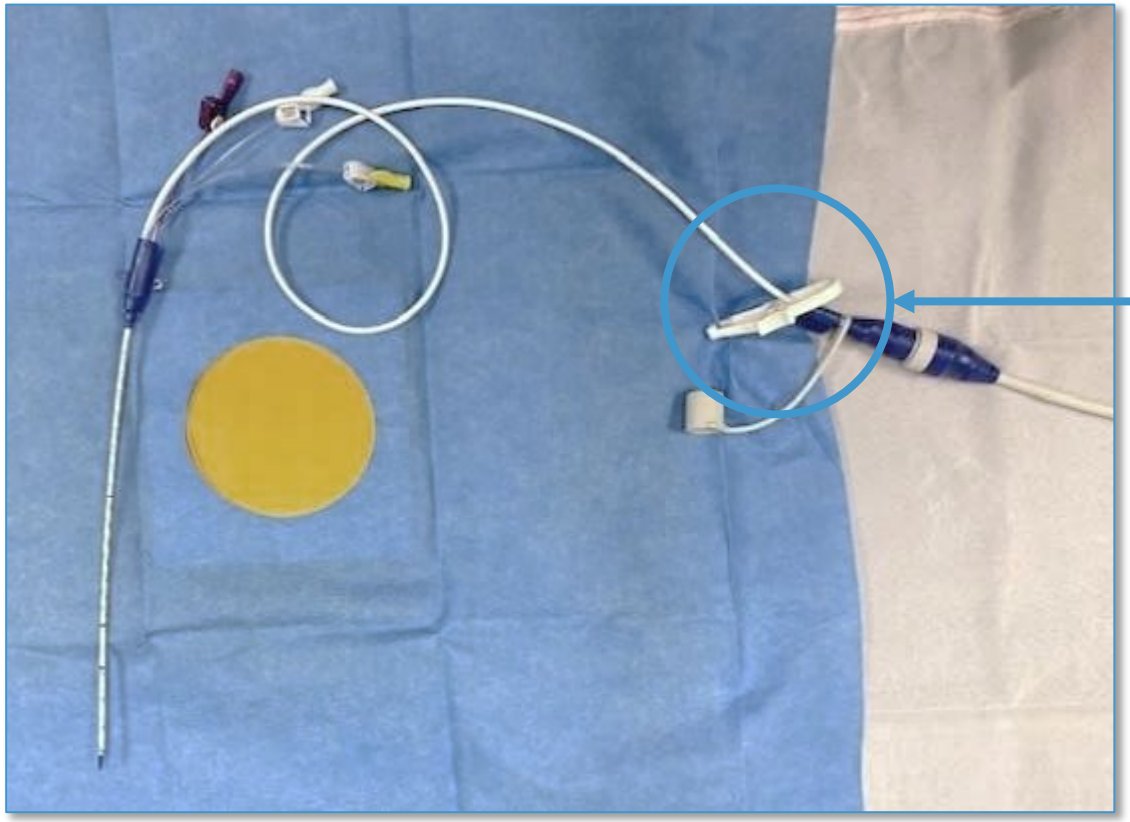
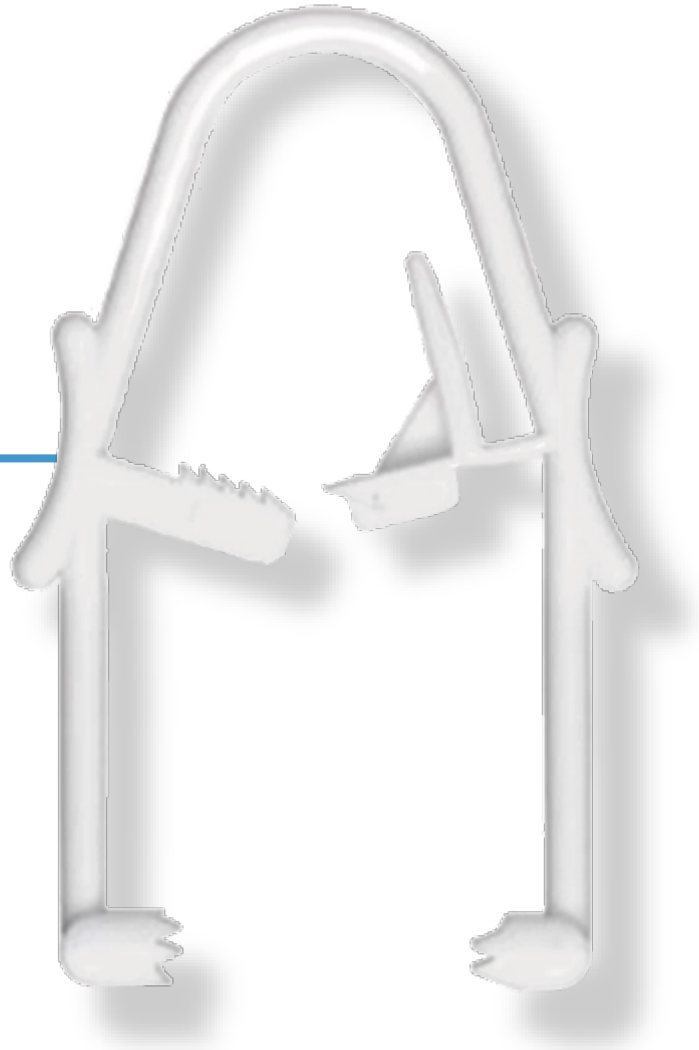
Cable Clamp

When the Neurostimulation Catheter seems to be in good position, use the **Cable Clamp** to help ensure that the **sterile portion** of the Neurostimulation Catheter remains in place as you prepare to perform the **Placement** procedure using the Console.





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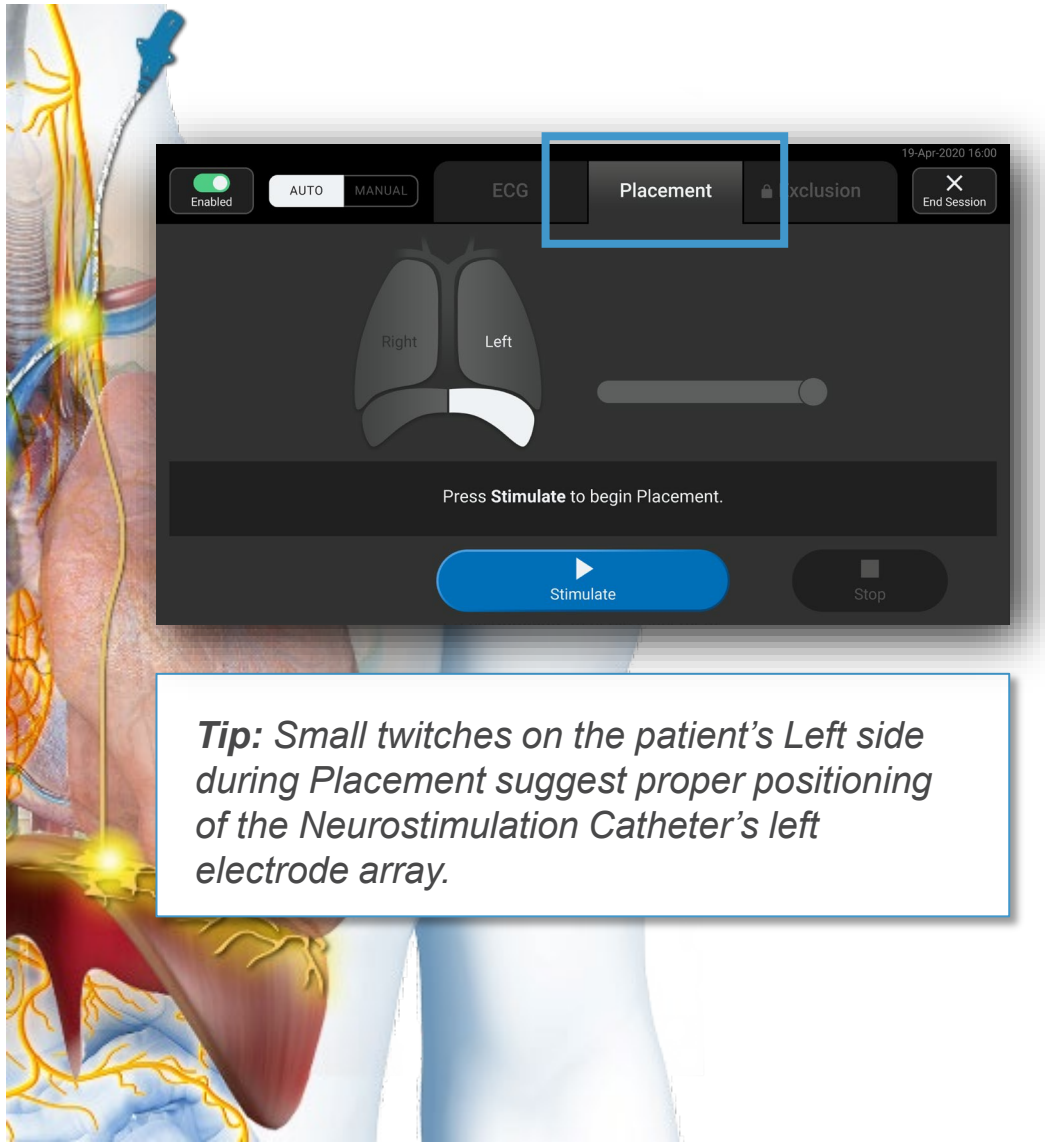
Placement

After inserting the Catheter, but before suturing it in place, perform Placement on the Console.

Placement will confirm that the Neurostimulation Catheter is in a position that can stimulate the patient's left phrenic nerve.

How it works: the System delivers small electrical pulses to electrodes in the Neurostimulation Catheter's **left array** while evaluating data from the Airway Sensor to detect pressure changes that indicate diaphragm contraction.



Tip: *Small twitches on the patient's Left side during Placement suggest proper positioning of the Neurostimulation Catheter's left electrode array.*

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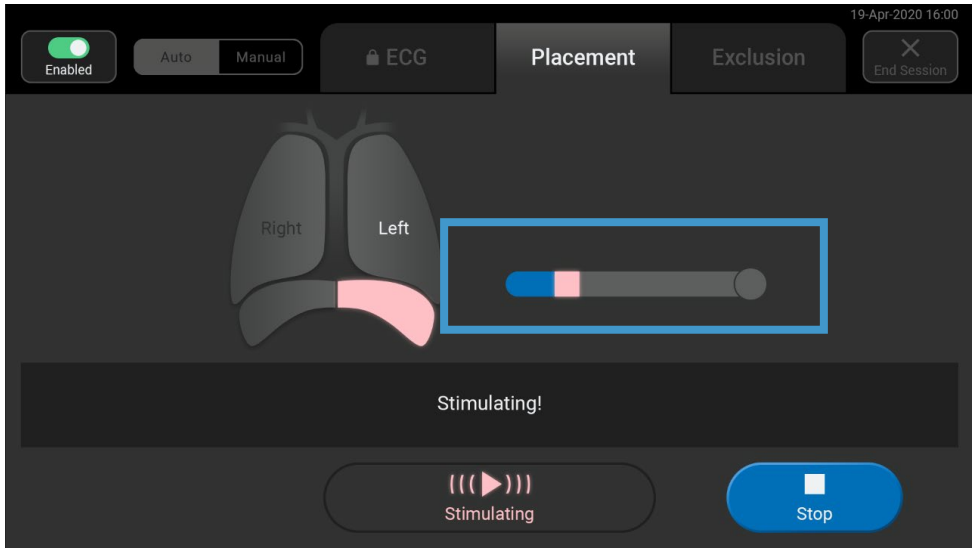
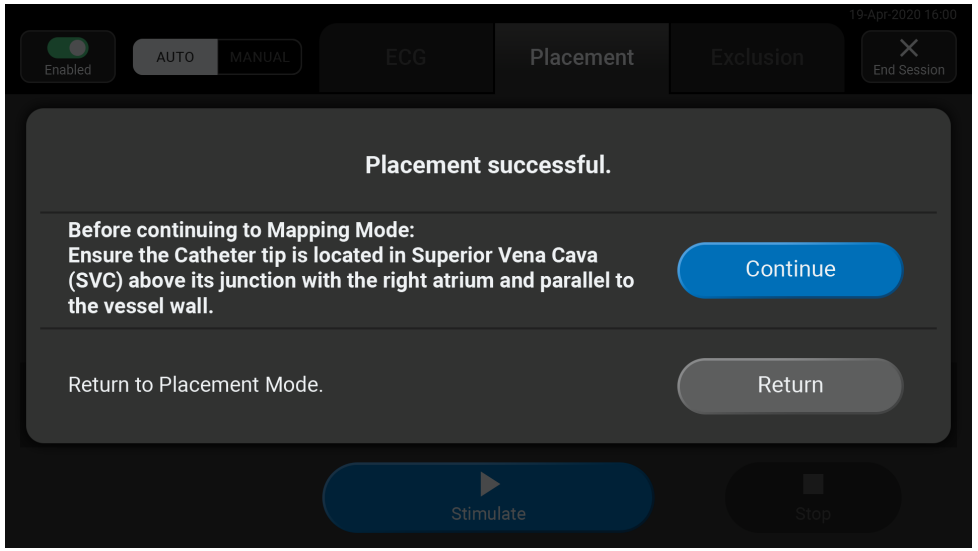
Performing Placement

Use assistance to maintain the sterile field

Placement Instructions

1. Press the **Placement** tab on the Console.
2. Press **Stimulate**.
3. Placement **proceeds automatically**. It typically completes in a few minutes (or less).
4. The System will inform you whether Placement was successful. (If it is unsuccessful, repeat it and/or follow troubleshooting steps as needed.)
5. Once you see the completion screen, follow institutional guidelines to confirm Neurostimulation Catheter tip location (e.g., x-ray).





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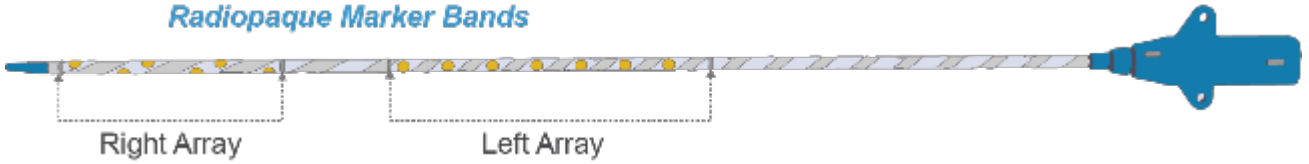
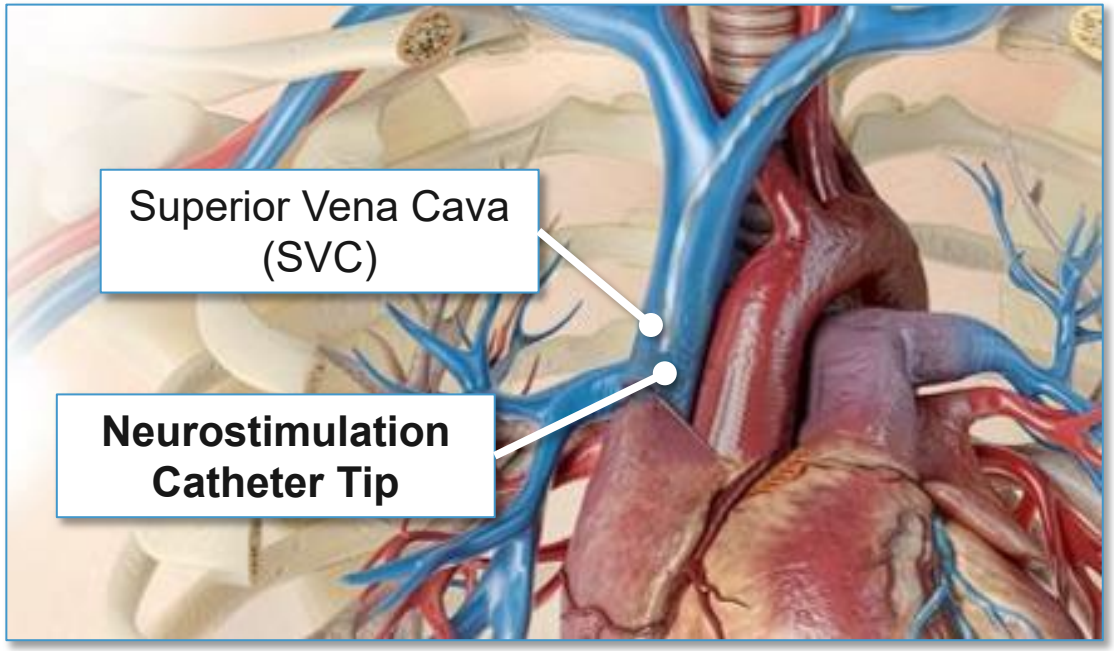
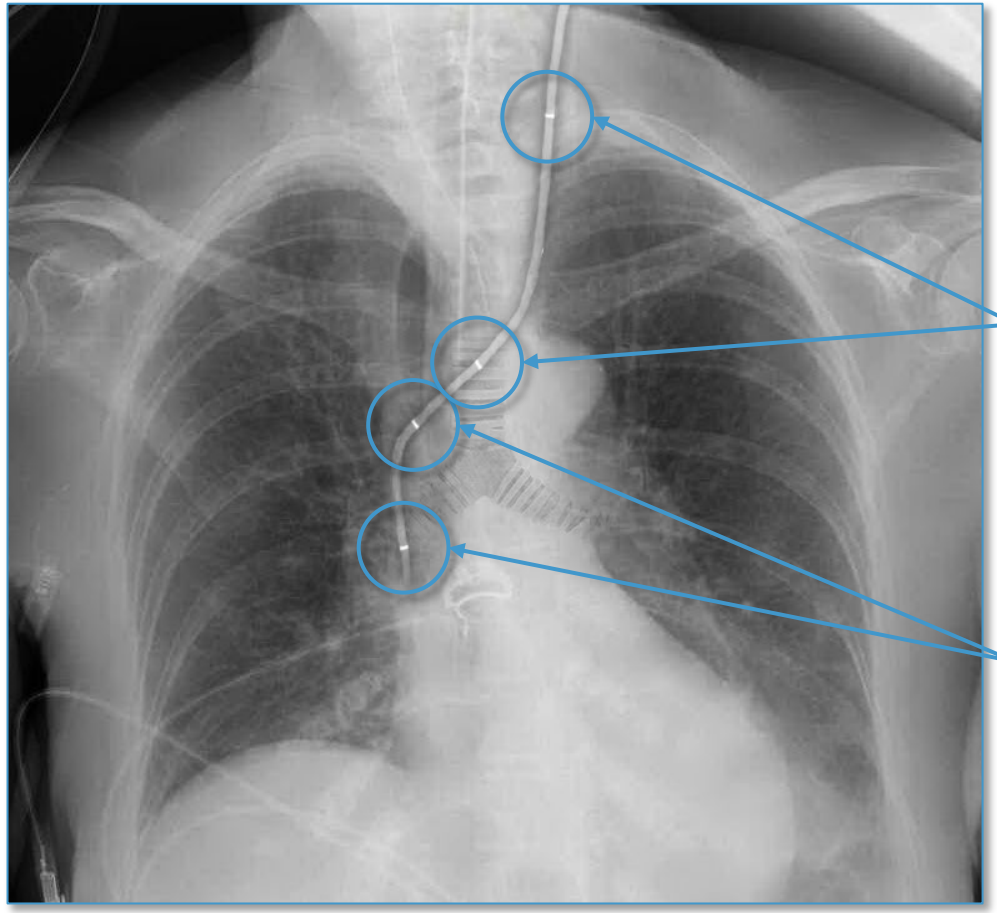
Confirming Position of Distal Tip

Locating the Neurostimulation Catheter's **radiopaque marker bands** on an x-ray helps ensure both of the Neurostimulation Catheter's **electrode arrays are positioned appropriately** to recruit the patient's phrenic nerves.







Both Left Array Marker Bands should be left of the **mediastinum**

Both Right Array Marker Bands should be right of the **mediastinum**

Note: X-ray images shown in this presentation have been edited to emphasize Neurostimulation Catheter and Marker Band location. Neurostimulation Catheter location in actual x-rays may be more subtle.

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Neurostimulation Catheter Too Deep

If the Neurostimulation Catheter tip is too close to the heart, it should be retracted

Indication the tip is too deep:

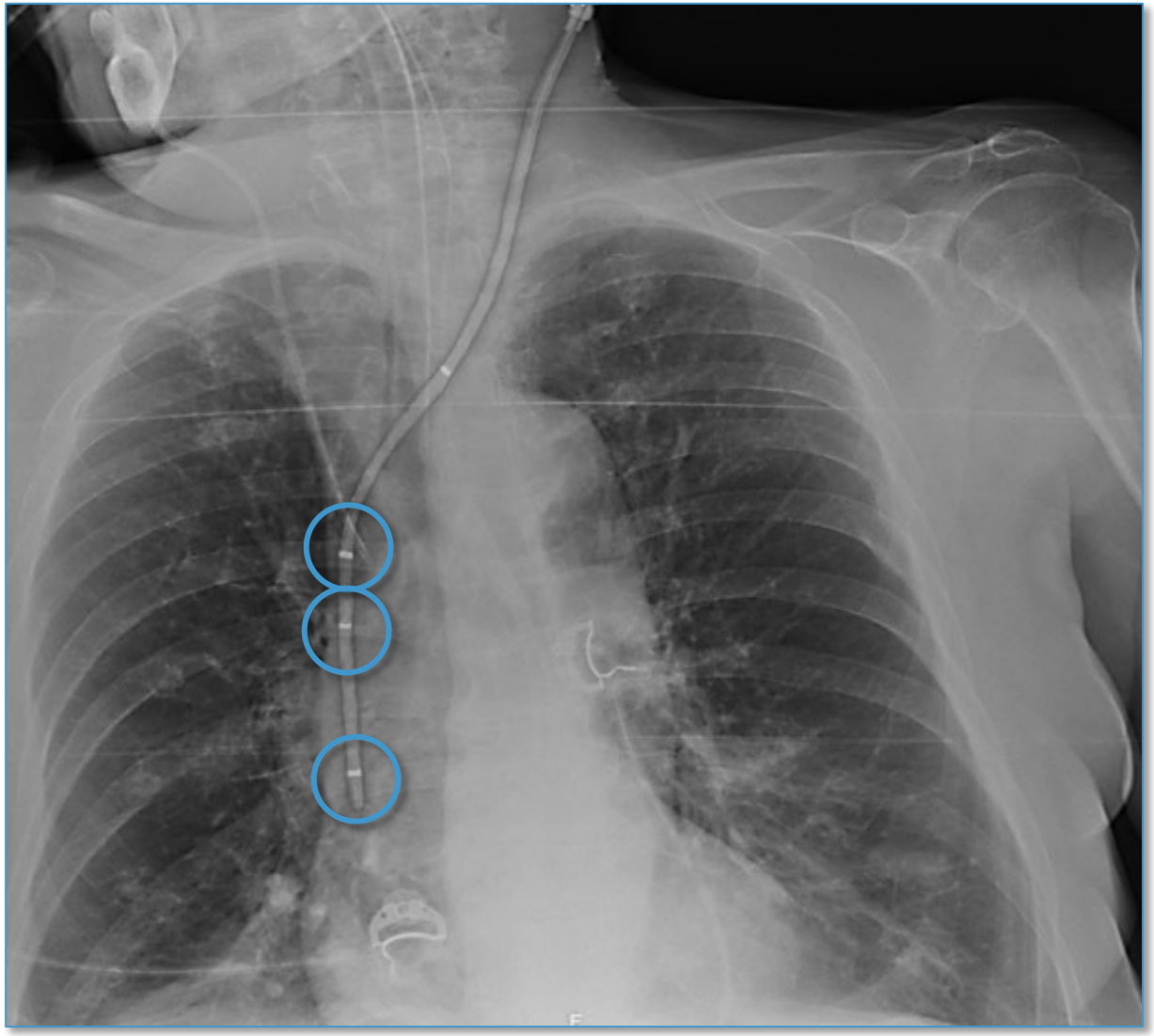
- Three marker bands are visible on the right side of the mediastinum.

Why it matters:

- Neurostimulation Catheter tip may be too close to the heart and cause unwanted cardiac stimulation
- Both electrode arrays might stimulate the right phrenic nerve.

What to do:

- Neurostimulation Catheter should be retracted approximately 5 cm.



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Neurostimulation Catheter Insertion too Shallow

If the Neurostimulation Catheter is not inserted deep enough, consider replacing it

Indication the tip is too shallow:

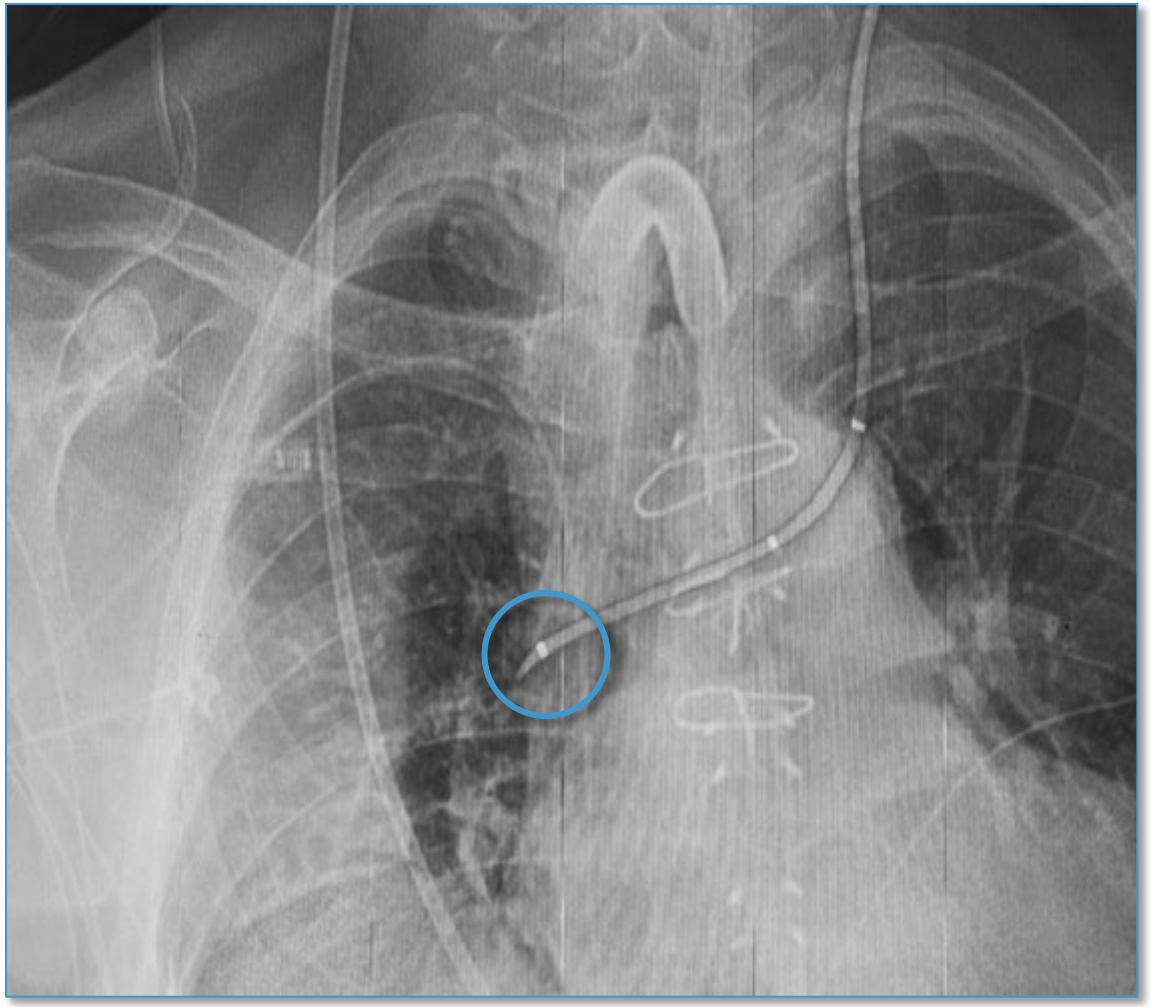
- May be in the brachiocephalic vein.
- Tip angled ~90° to the vertical of the SVC wall: Left sided CVCs, including the Neurostimulation Catheter, should have a tip angle less than <40° to the vertical in order to avoid abutting the vessel wall.[1]

Why it matters:

- May not be able to stimulate the right phrenic nerve.
- Risk of vessel wall damage or perforation.

What do to:

- Consider replacing the Neurostimulation Catheter over the wire, placing the tip deeper.



1. Stonelake, P. (2006) *British Journal of Anaesthesia.;* 96 (3): 335–40.

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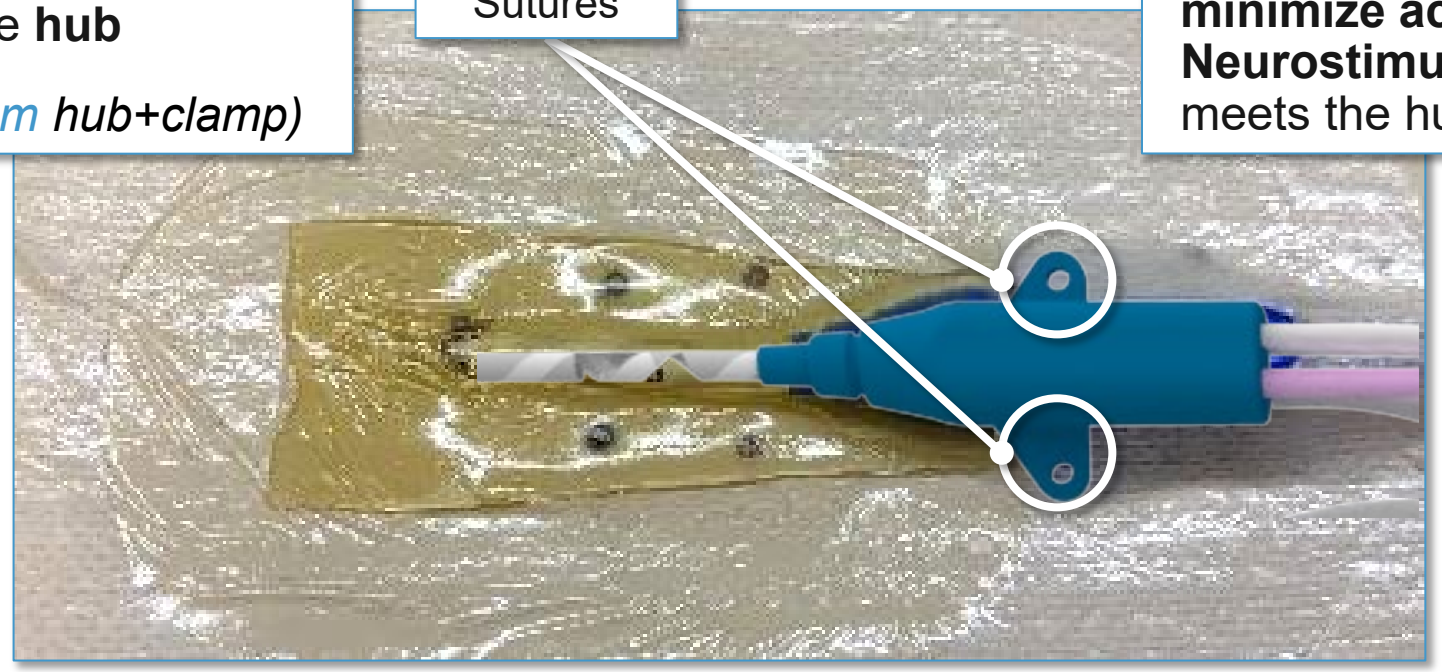
Suturing: 20-23cm Depth

20-23cm
Suture **hub**

(≤20cm hub+clamp)



Fully secure the Neurostimulation Catheter (with or without the secondary clamp, depending on its depth) taking care to **minimize acute bends in the Neurostimulation Catheter** where it meets the hub.

Note: Images shown are of simulated bench model.
Note: Always follow institutional guidelines for infection prevention and dressing of the Neurostimulation Catheter insertion site.

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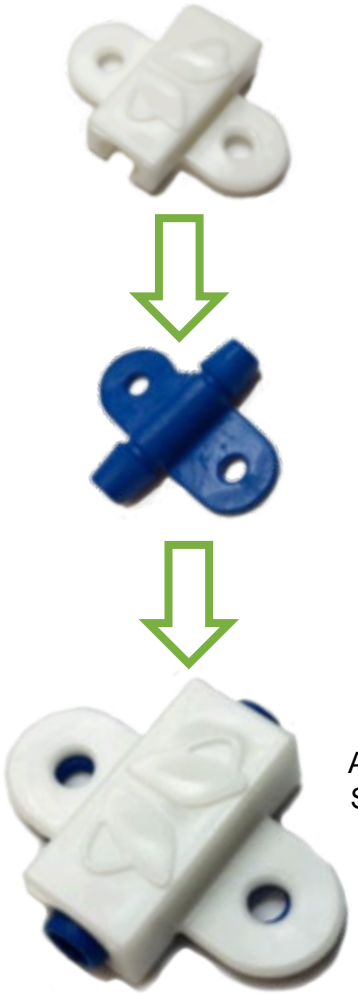
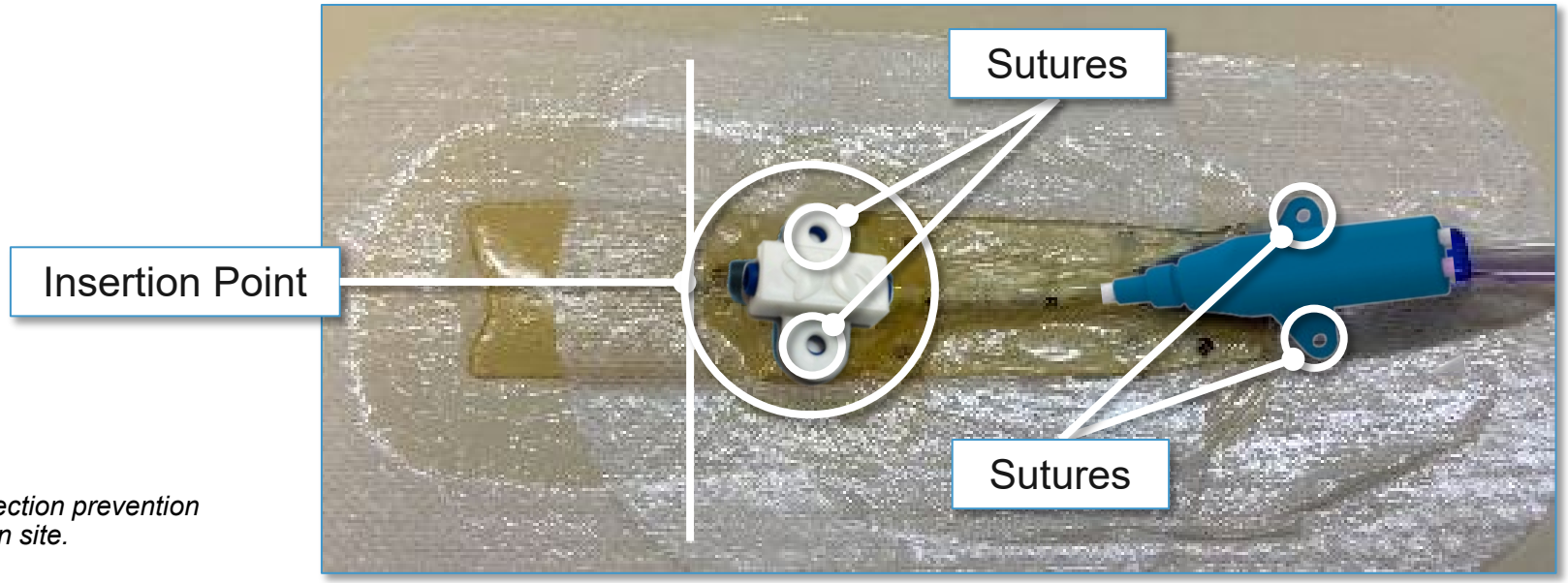
Suturing: ≤20cm Depth



Assembled Secondary Clamp

1. For insertions ≤20cm only, **fit the blue Neurostimulation Catheter clamp onto the shaft of the Neurostimulation Catheter** as close to the Neurostimulation Catheter's insertion point as possible.
2. **Press the white fastener** over the blue clamp.
3. **Suture the clamp assembly** to the patient's skin using its holes. *Never directly suture into the Neurostimulation Catheter shaft.*
4. **Suture the blue Neurostimulation Catheter hub** to the patient's skin using its holes.



Note: Always follow your institutional guidelines for infection prevention and dressing of the Neurostimulation Catheter insertion site.

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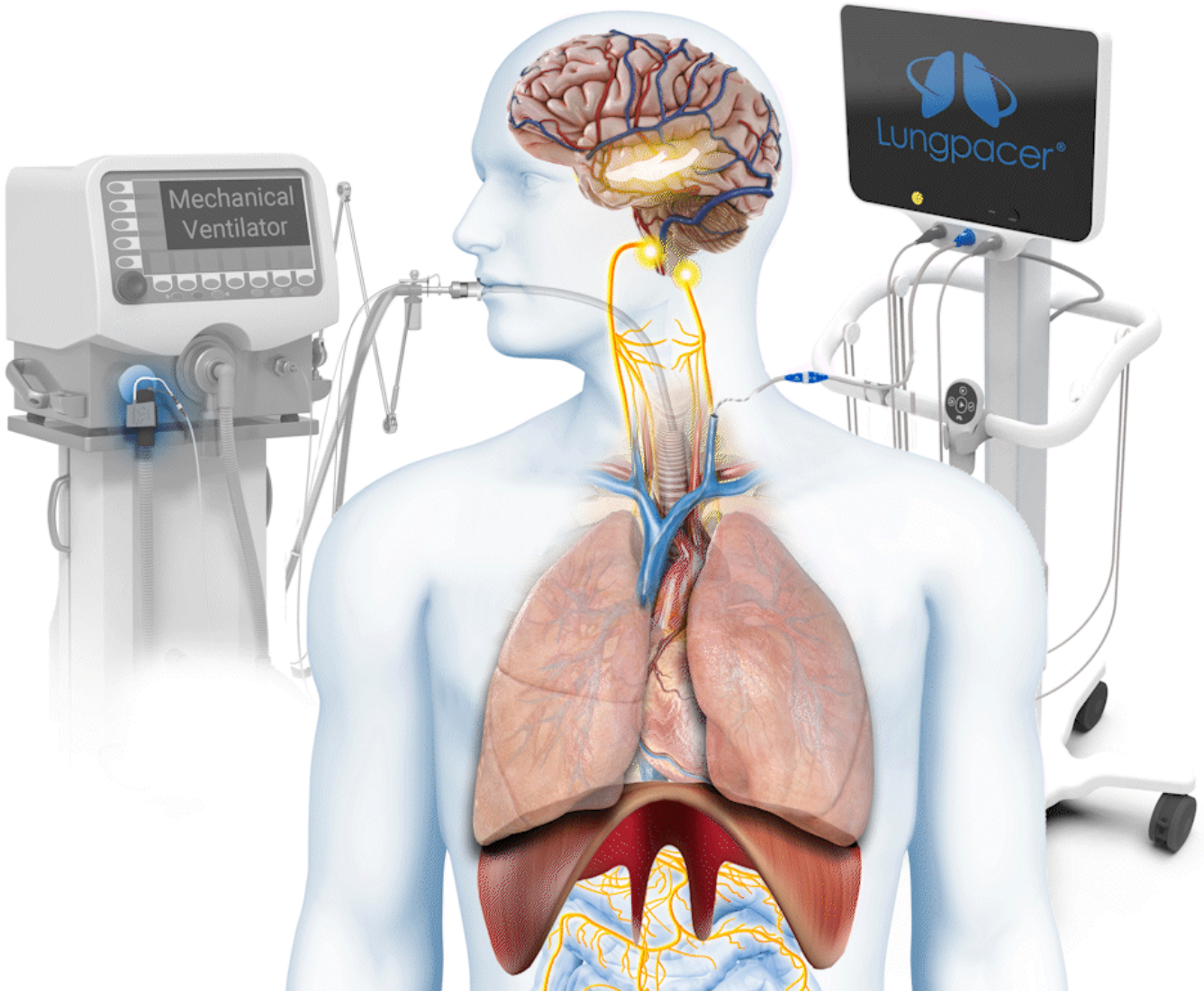
Care After Insertion

- The Neurostimulation Catheter is designed for **single insertion and use**.
- Follow institutional guidelines for care and maintenance of CVCs.
- The Neurostimulation Catheter incorporates electrical neurostimulation capabilities and must be handled with care. **Avoid bending, twisting, or torquing the Neurostimulation Catheter**, including during dressing changes.



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- The AeroPace Neurostimulation Therapy System
- Patient Selection
- Components and Setup
- Neurostimulation Catheter Insertion and Placement

Mapping and Therapy Sessions

- Super-users: Cleaning, Storage, and MR Compatibility
- Super-users: Troubleshooting (Manual mode and Exclusion)

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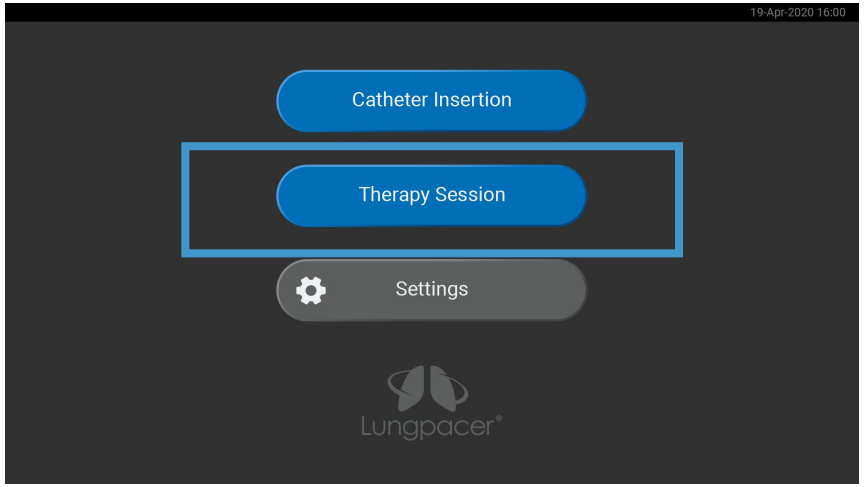
AeroPace Therapy
60 stimulations twice daily

AeroPace Therapy Overview

- Power on the Console and Select **Therapy Session.**
- **The Console will prompt you to perform Mapping** before of each Therapy session, to select suitable electrodes.
- One Therapy session is **60 stimulations**, titrated up to the **maximum intensity** possible while ensuring patient comfort.
- Therapy is provided **twice daily**.



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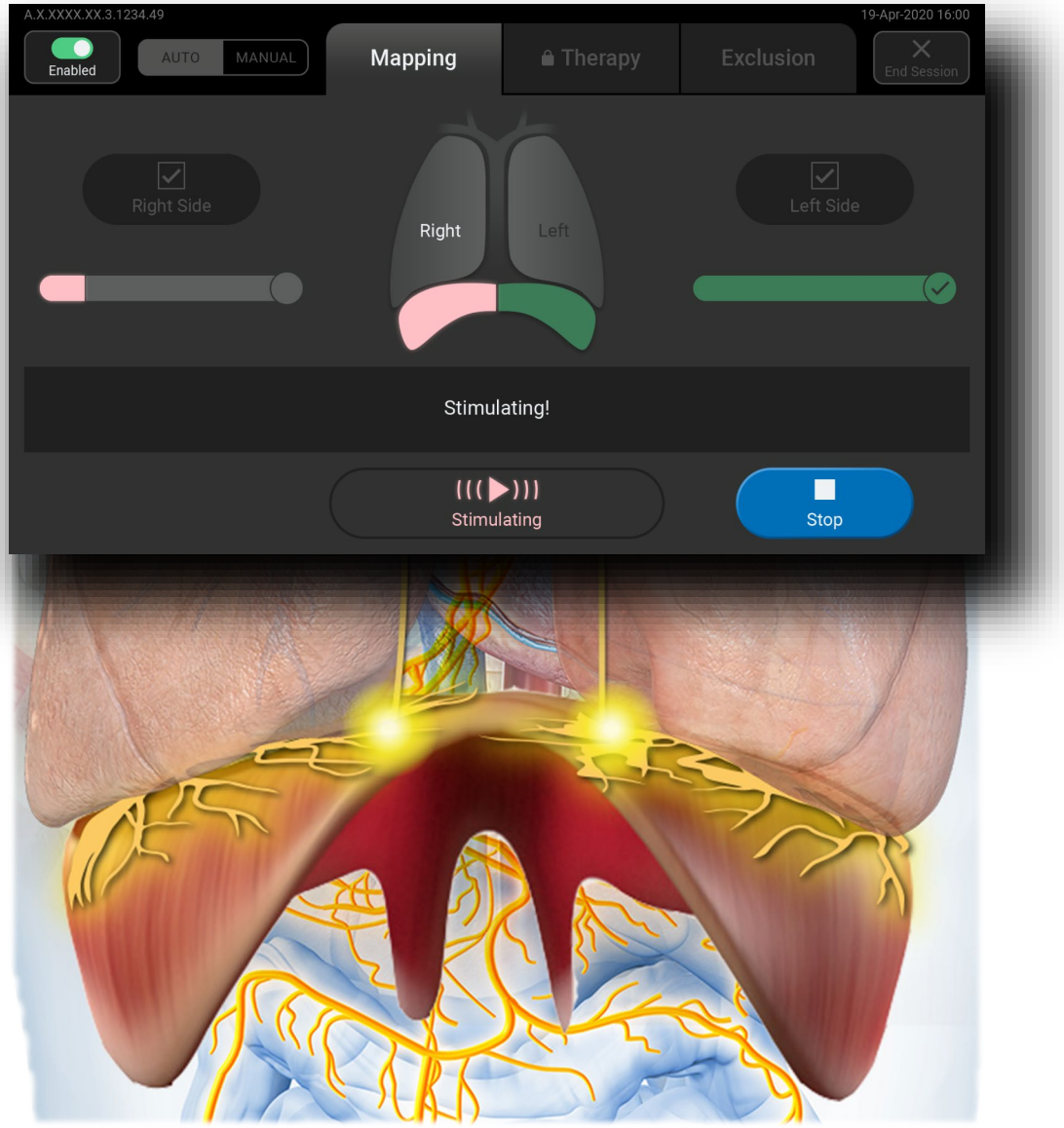
Mapping
Selects electrodes that effectively contract the diaphragm

Before each Therapy session, you will perform Mapping.

Mapping identifies and selects Neurostimulation Catheter electrodes that are positioned to effectively contract the diaphragm on both sides, and determines the minimum electrical charge required for diaphragm contraction.



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Mapping

Tiny pressure deflections or “twitches” detected by the Airway Sensor during Mapping allow the System to **identify suitable electrodes** for Therapy, and determine the **baseline Therapy Levels** needed.

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Mapping Screen

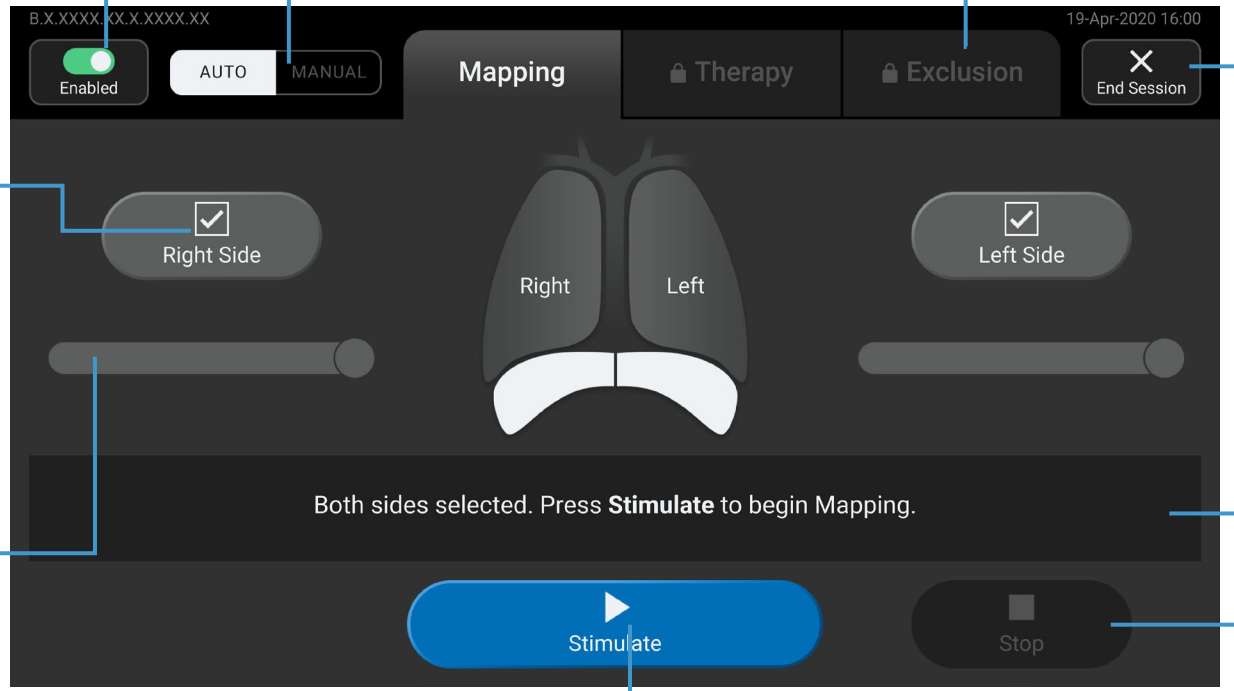
Selects electrodes that effectively contract the diaphragm

Enable/Disable
Enables or disables entire screen

Auto/Manual
(See Troubleshooting section)

Exclusion
(See Troubleshooting section)

Hemidiaphragm Selectors
Selects which side(s) to Map. The default setting is to Map both sides



End Session
Return to main menu

Progress Bars
Shows the progression of Mapping process on each side

Notification Box
Displays contextual System and Mapping process information

Stop Button
Stops the delivery of stimulations if needed

Stimulate Button
Press to begin Mapping

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Performing Mapping
Mapping proceeds and completes automatically

Mapping Instructions

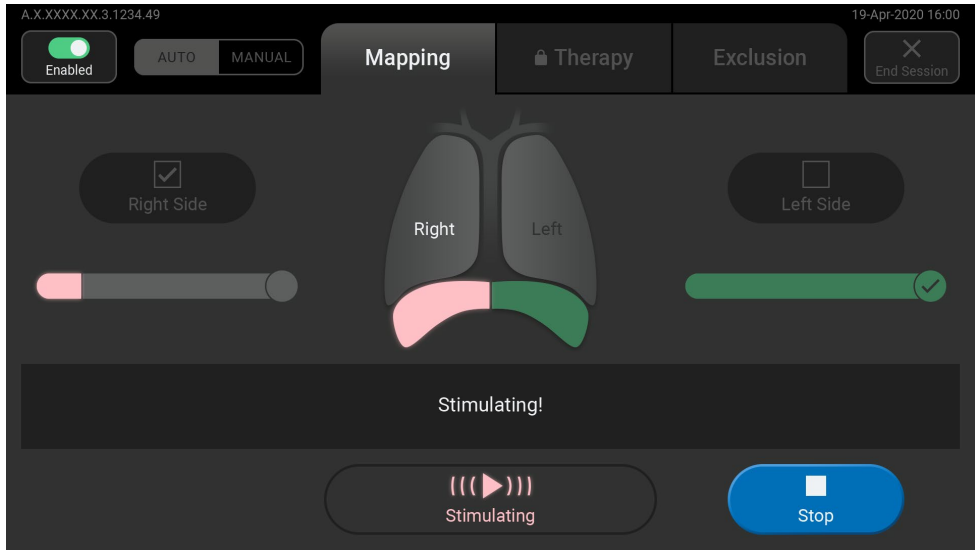
1. After Placement completes successfully, the **Mapping** tab automatically displays.

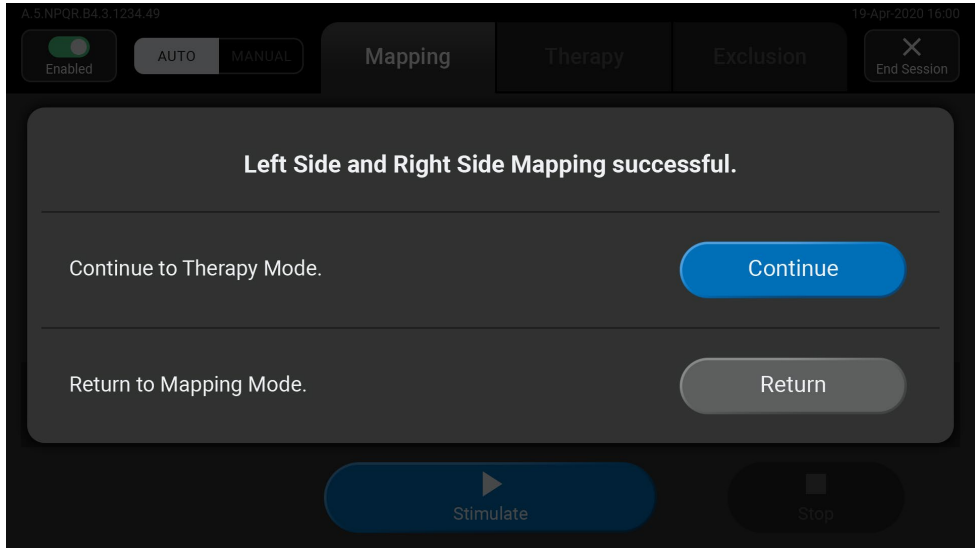
   *Note: If performing Mapping after powering on the Console, select **Therapy Session** from the main menu to navigate directly to the Mapping tab.*

2. If anatomical restrictions limit Therapy to only one side, deselect the relevant side.

3. Press **Stimulate** to begin.

4. **Mapping completes automatically** on the selected side(s). It typically completes in a few minutes (or less). **The System will inform you whether Mapping was successful.** (If it is unsuccessful, repeat it and/or follow troubleshooting steps as needed.)





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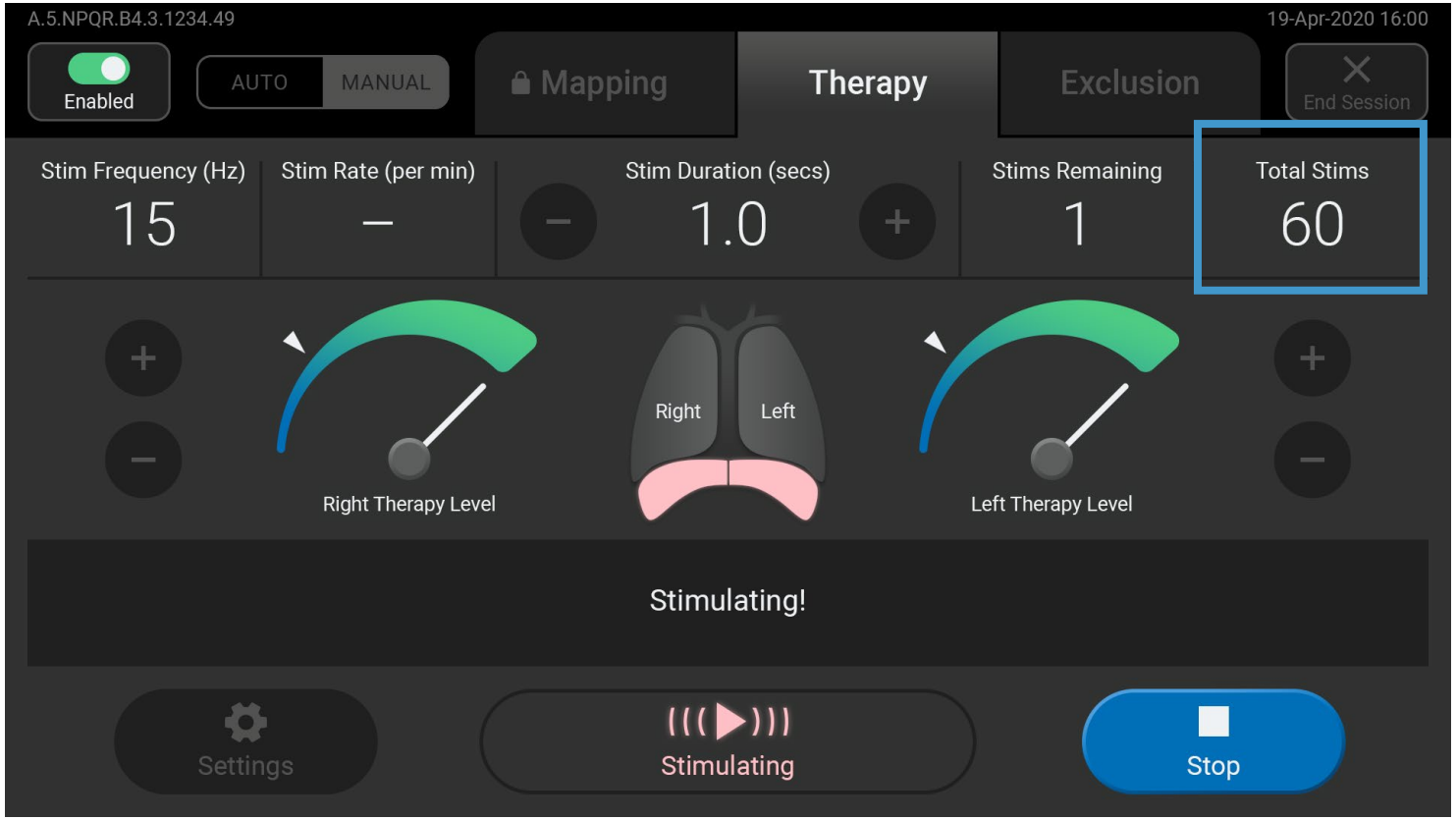
Therapy Overview

Once Mapping is complete, you are ready to begin **Therapy**.

The goal of Therapy is to deliver **60 stimulations** at the **maximum Therapy Levels** possible while still ensuring patient comfort.



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Therapy Screen: Stimulation Controls

Stim Frequency
The rate of electrical pulses within a stimulation. ***This should not be changed***

Skip Breaths
The number of ventilator breaths between each stimulation

Stim Duration
Set as long as possible to match ventilator Inspiratory Time

Stims Programmed
The number of stimulations (0-10) delivered with each press of the Stimulate button

Total Stims
The number of stimulations delivered during the Therapy session so far

Therapy Levels (Left and Right)
Increase (+) or decrease (-) as needed on each side to optimize Therapy

Settings
Access a pop-up where Therapy session settings can be modified

Stop Button
Stops the delivery of stimulations if needed

Stimulate Button
Press to deliver the set number of Stims Programmed

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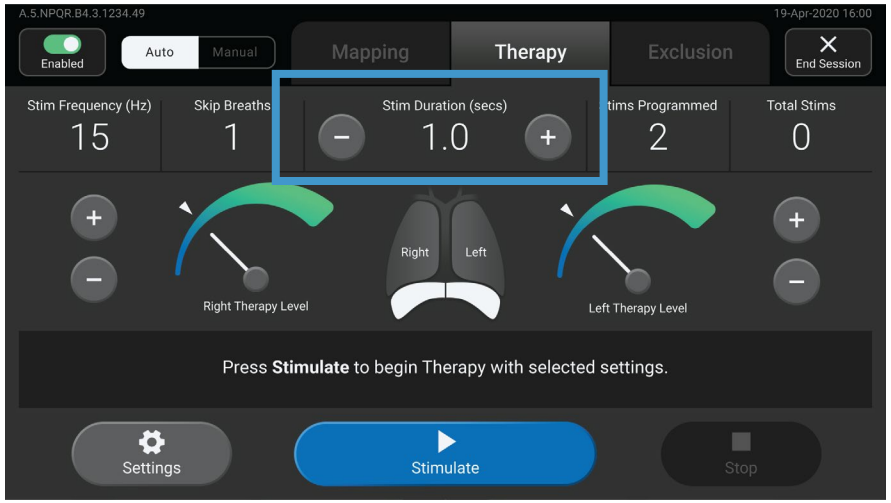
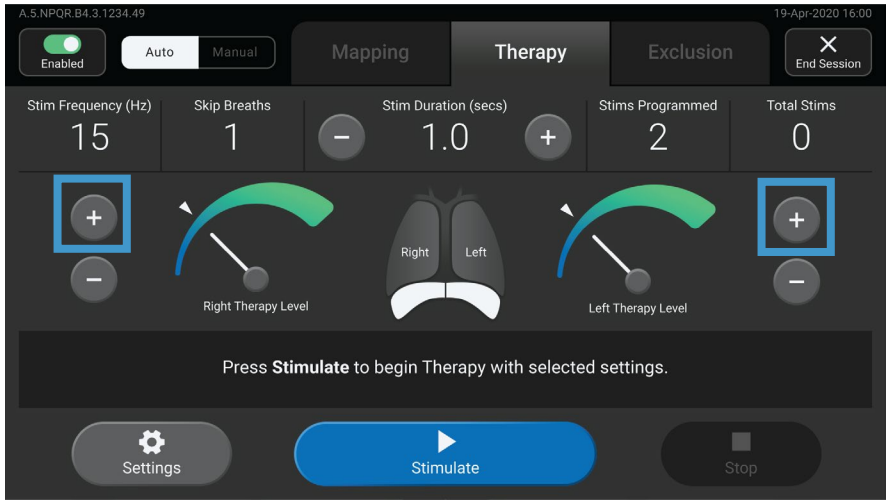
Therapy





To begin and titrate Therapy:

1. Set **Stim Duration** as long as possible while matching patient's **Inspiration Time** on ventilator.
2. Begin to titrate Therapy by pressing **Stimulate** to deliver initial stimulations.
3. Observe patient, and **increase the Therapy Level** on both the left and right side if possible, by pressing the **plus (+) buttons on each side several times**.
4. Press **Stimulate** to deliver another stimulation (or two) and observe the patient.
5. Continue this process until reaching the maximum possible Therapy Level on each side that can be delivered to the patient comfortably.

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Therapy

To complete Therapy:

1. Continue to deliver stimulations until the **Total Stims** counter in the upper right-hand corner of the screen reaches 60.

   *Note: You may press Settings and increase **Stims Programmed** to any value from **1 to 10** as you approach 60 stimulations.*

2. Once **60 stimulations** are delivered, press **End Session** to display session data.

- **Power off the System, and disconnect the Catheter and Airway Sensor** until the next Therapy session. The cables may remain attached to the Console, neatly arranged on the handle.

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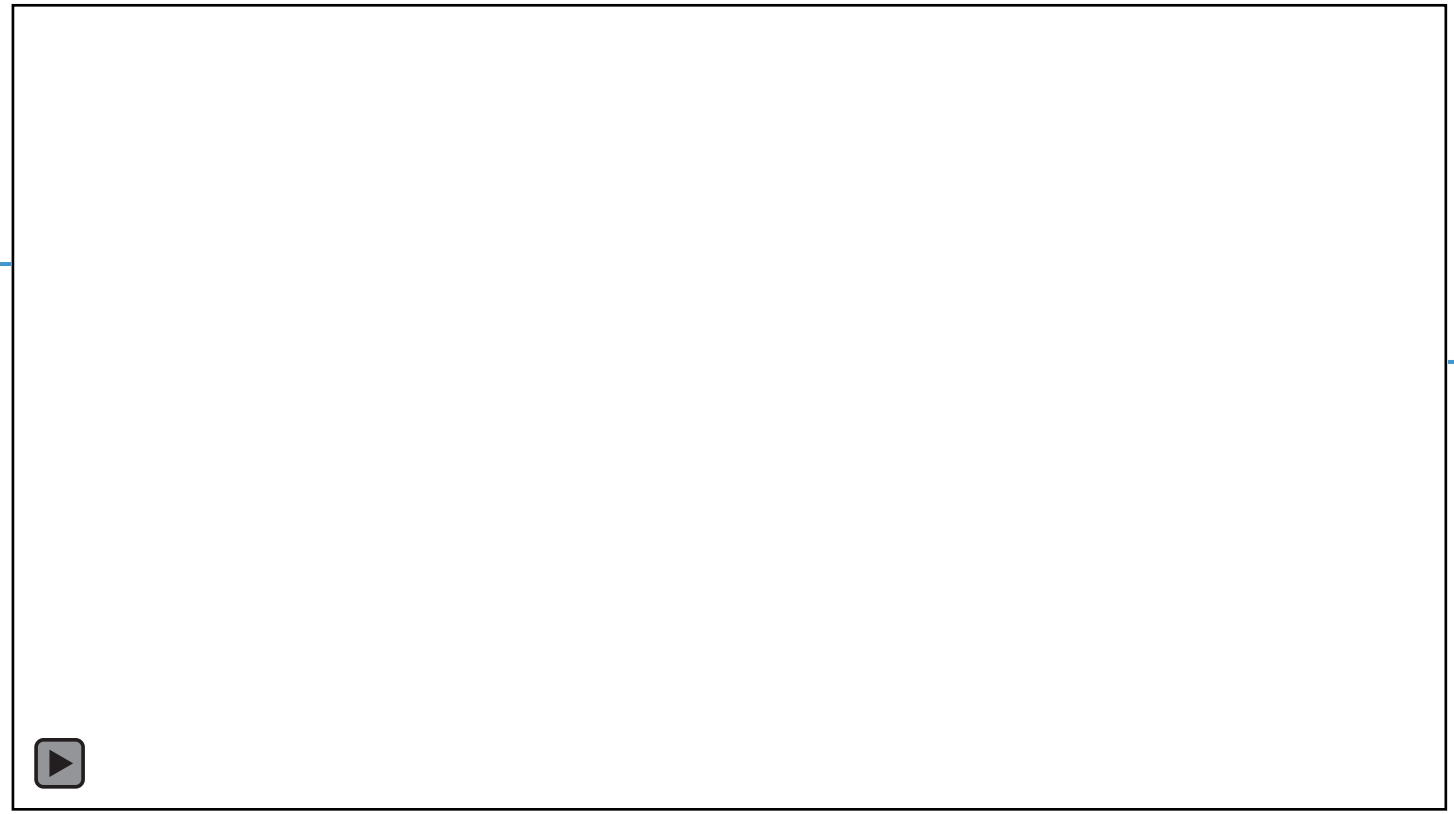
Therapy

Large pressure deflections during breaths indicate AeroPace stimulations are contracting the patient diaphragm to exercise it, and generating negative pressure.



Incrementally increase the Therapy Levels on each side to reach the maximum possible while maintaining patient comfort, to deliver **60 stimulations**.

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AeroPace Therapy Patient Selection

For patients with difficulty weaning from mechanical ventilation

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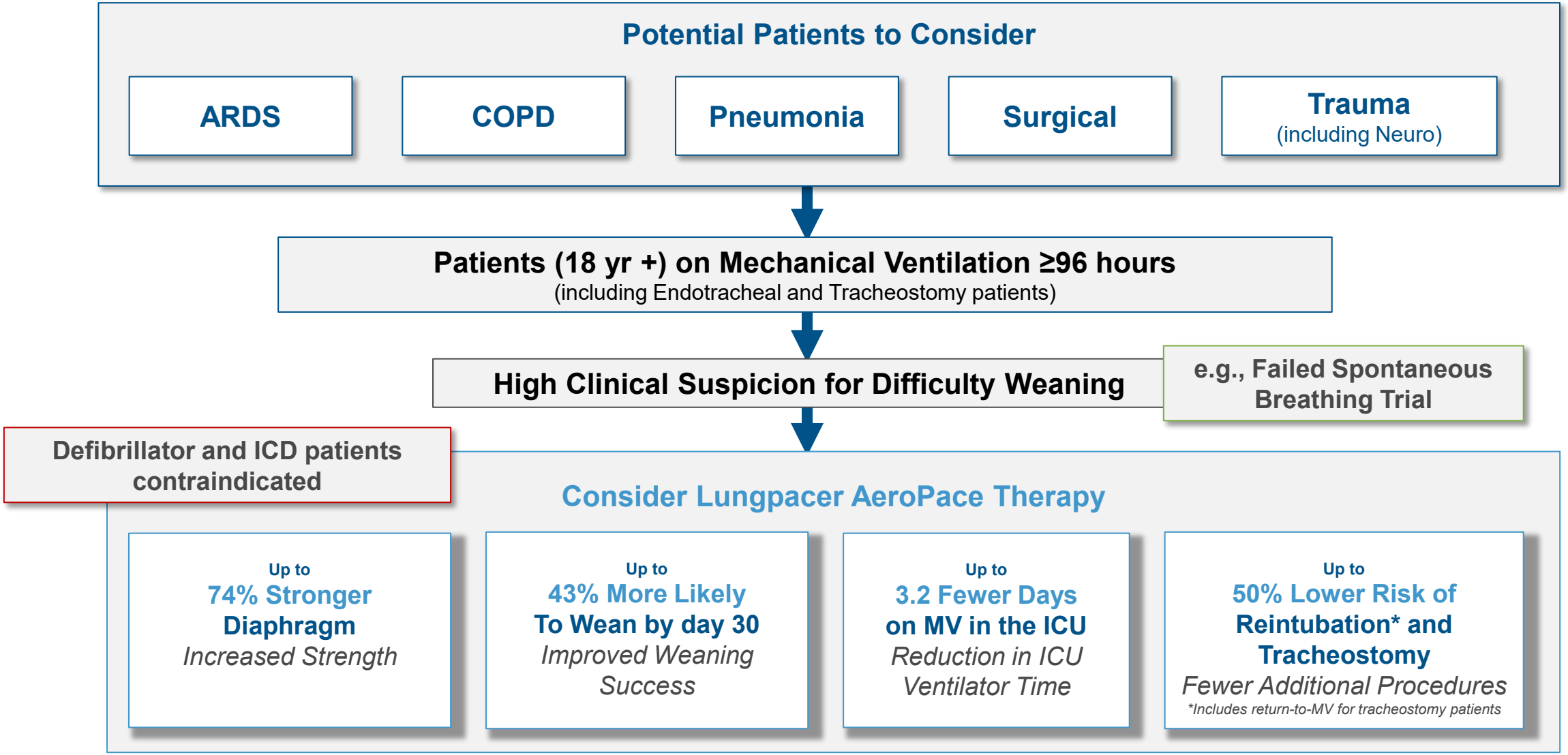

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Knowledge Check

AeroPace System

Scan the QR code with your phone to begin.

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- The AeroPace Neurostimulation Therapy System
- Patient Selection
- Components and Setup
- Neurostimulation Catheter Insertion and Placement
- Mapping and Therapy Sessions

Super-users: Cleaning, Storage, and MR Compatibility

- Super-users: Troubleshooting (Manual mode and Exclusion)

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Cleaning

Clean the Console, Airway Sensor Cable, Catheter Cable, and Handheld Controller using Virox, Cidex, or CaviWipes, following your institutional policy for cleaning bedside equipment.

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Storage

To store the AeroPace System:

- Disconnect cables
- Ensure the System is stored within the following environmental conditions:
  - Console and Cables Temperature Range: -10 to 60 ˚C (14 to 140 ˚F)
  - Console and Cables Relative Humidity Range: 15% to 90%, non-condensing
  - Console and Cables System Altitude: Up to 8000 ft (2438 m) above sea level
  - Neurostimulation Catheter Temperature Range: 18 to 28 ˚C (64.5 to 82.4 ˚F)

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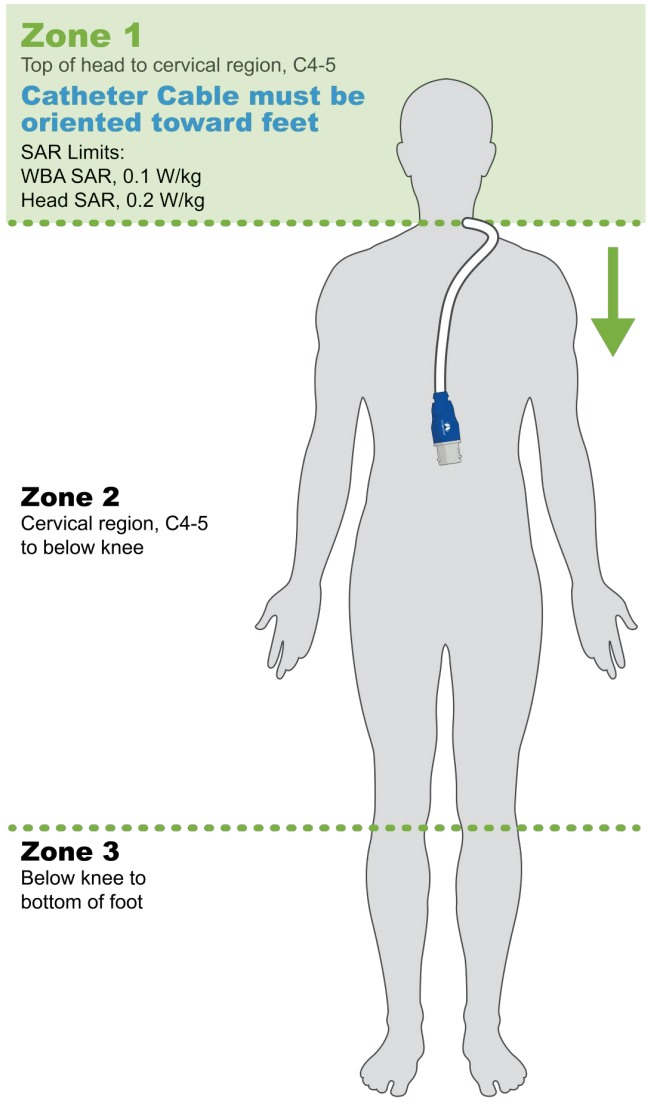
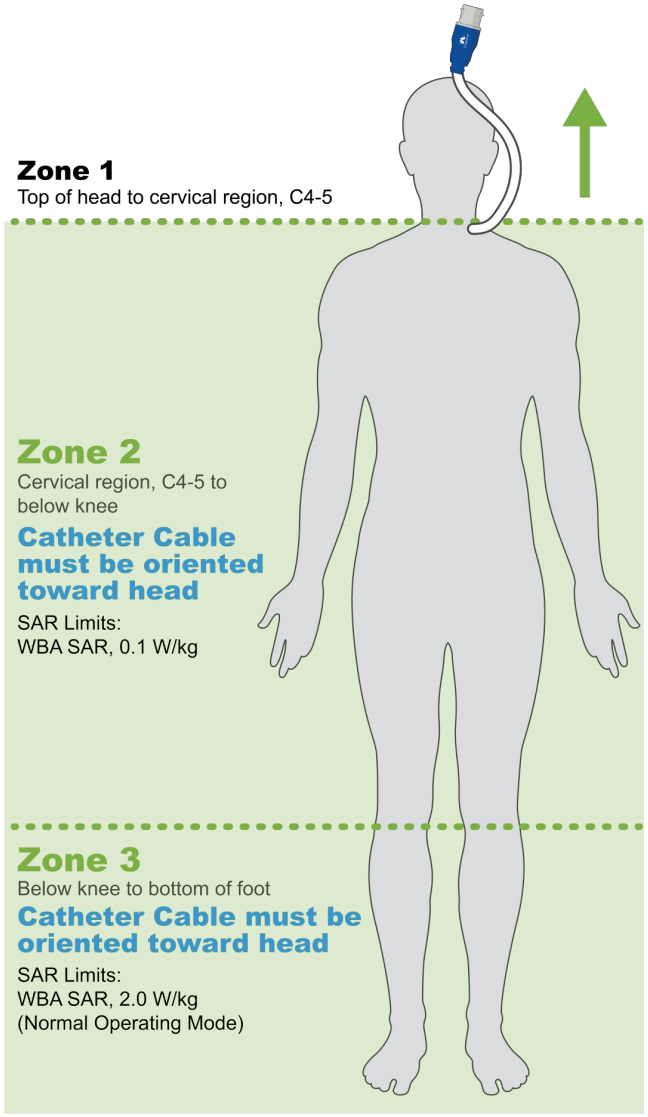
MR Safety Information





- **The AeroPace Neurostimulation Catheter is MR Conditional.** A patient may be safely scanned under conditions listed in the Instructions for Use and with the Neurostimulation Catheter oriented as shown.
- **Warning:** The AeroPace Neurostimulation Catheter is MR Conditional, but the Neurostimulation Console and Cables are MR Unsafe. Always disconnect the Catheter from the Neurostimulation Console before conducting MRI, and keep the Console away from MR equipment.

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- The AeroPace Neurostimulation Therapy System
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➢ Super-users: Troubleshooting (Manual mode and Exclusion)

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Auto and Manual Modes

	Auto Mode	Manual Mode
Placement and Mapping	Diaphragm contractions detected by **Airway Sensor**	Diaphragm contractions detected by **clinician palpating patient** (and then providing feedback to Console).
Therapy	Stimulations delivered when **Airway Sensor** detects patient breaths	Stimulations delivered at end-expiration at set **Stim Rate**, which must be set to match ventilator breath rate to avoid dyssychrony.

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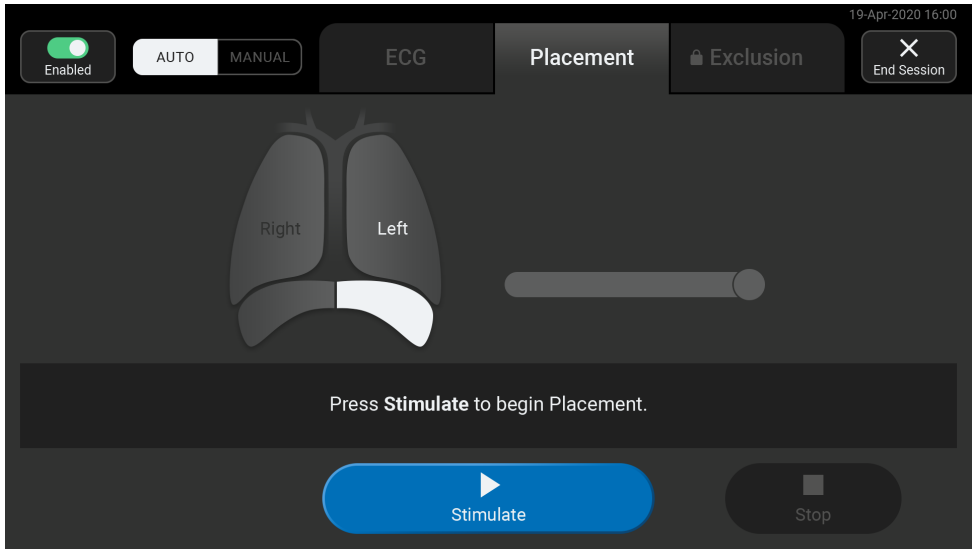
Placement Troubleshooting

Placement Troubleshooting

- ❑ If Placement is unsuccessful, repeat Placement in Auto mode.
- ❑ Consider repositioning the patient.
- ❑ Assess the Neurostimulation Catheter's location and consider repositioning it.
- ❑ If unwanted effects occur, use the Stop button. Use the electrode Exclusion function if unwanted effects continue.
- ❑ Try Manual mode if Auto mode is persistently unsuccessful or results in unwanted effects.



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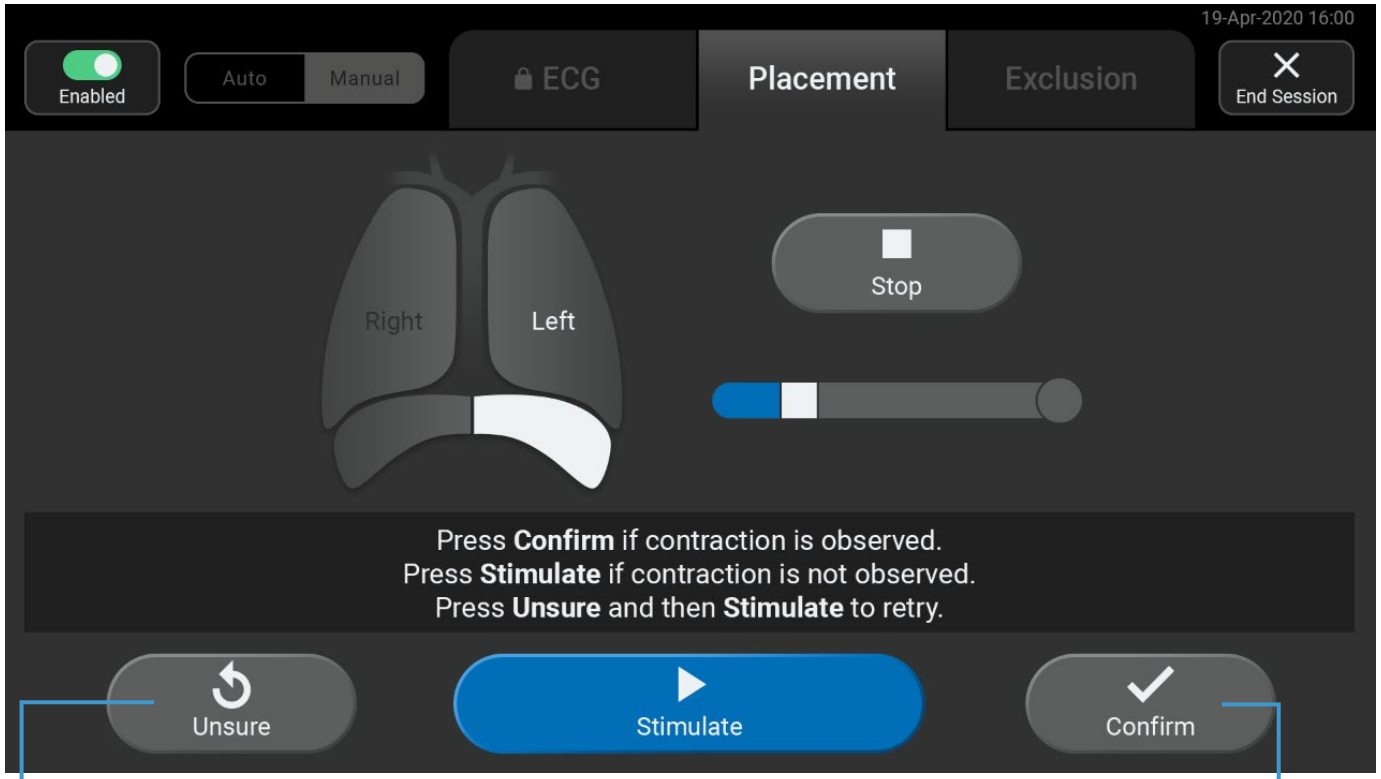
Manual Placement

To perform manual Placement, press Stimulate while you **palpate the patient to feel for diaphragm contractions**, and then provide feedback to Console using the on-screen buttons or Handheld Controller.



Select **Unsure** if you're not sure if you felt a contraction or not.

Press **Stimulate** if you did not feel anything.

Select **Confirm** if you felt a diaphragm contraction.

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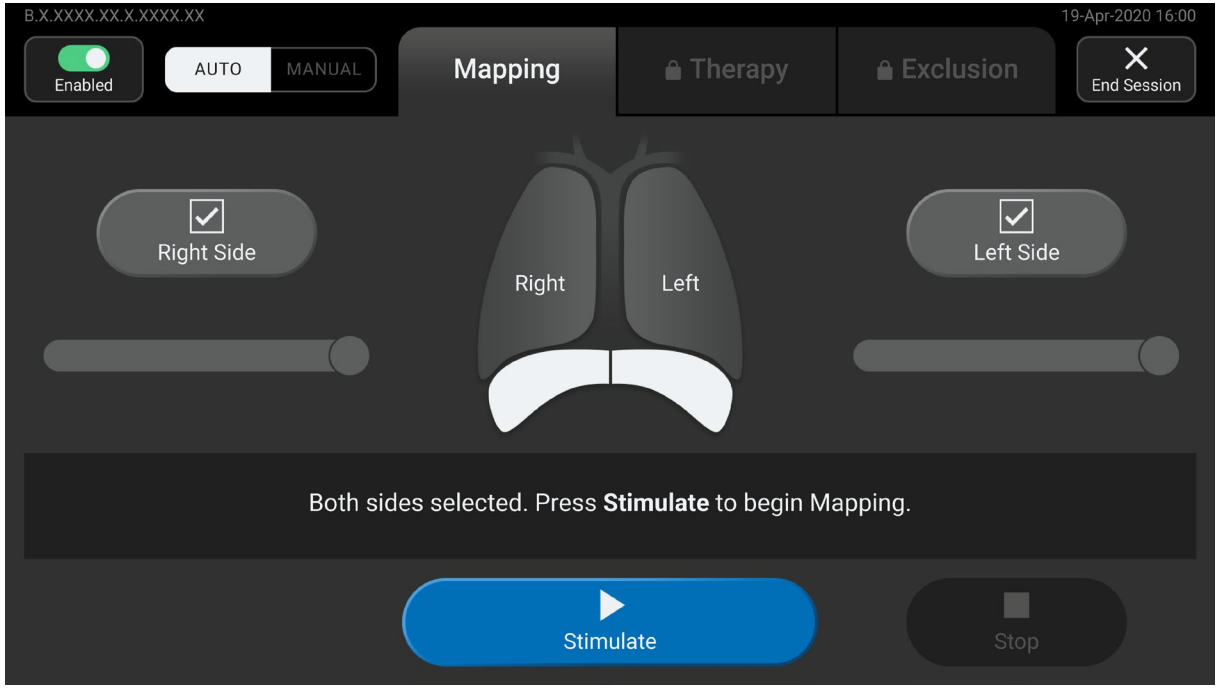
Mapping Troubleshooting

Mapping Troubleshooting

- ❑ If Auto Mapping is unsuccessful, repeat it.
- ❑ Consider repositioning the patient.
- ❑ Try Manual mode if Auto Mapping is persistently unsuccessful. See the System User Guide for details.
- ❑ If unwanted effects occur, use the Stop button. Use the electrode Exclusion function if unwanted effects continue.



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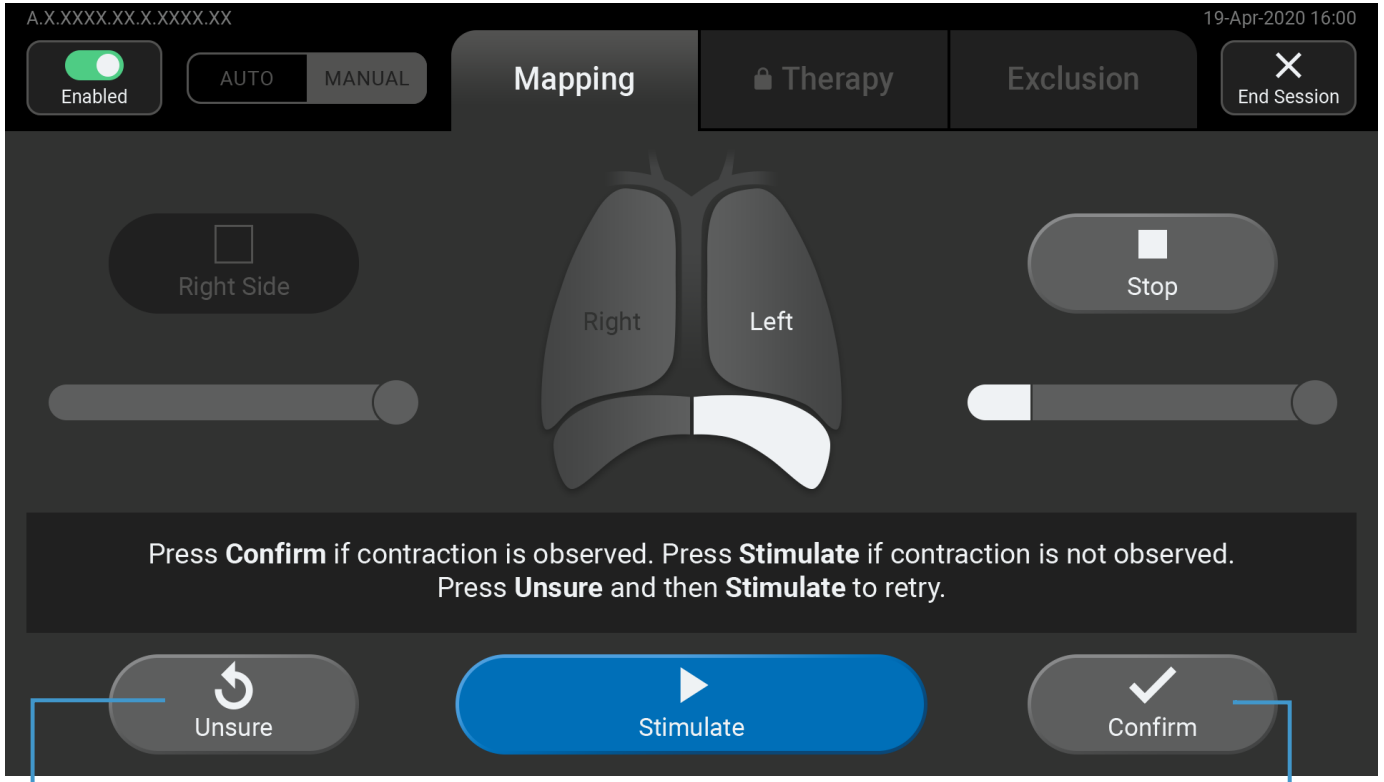
Manual Mapping

To perform manual Mapping, press Stimulate while you **palpate the patient to feel for diaphragm contractions**, and then provide feedback to Console using the on-screen buttons or Handheld Controller.



Select **Unsure** if you're not sure if you felt a contraction or not.

Press **Stimulate** if you did not feel anything.

Select **Confirm** if you felt a diaphragm contraction.

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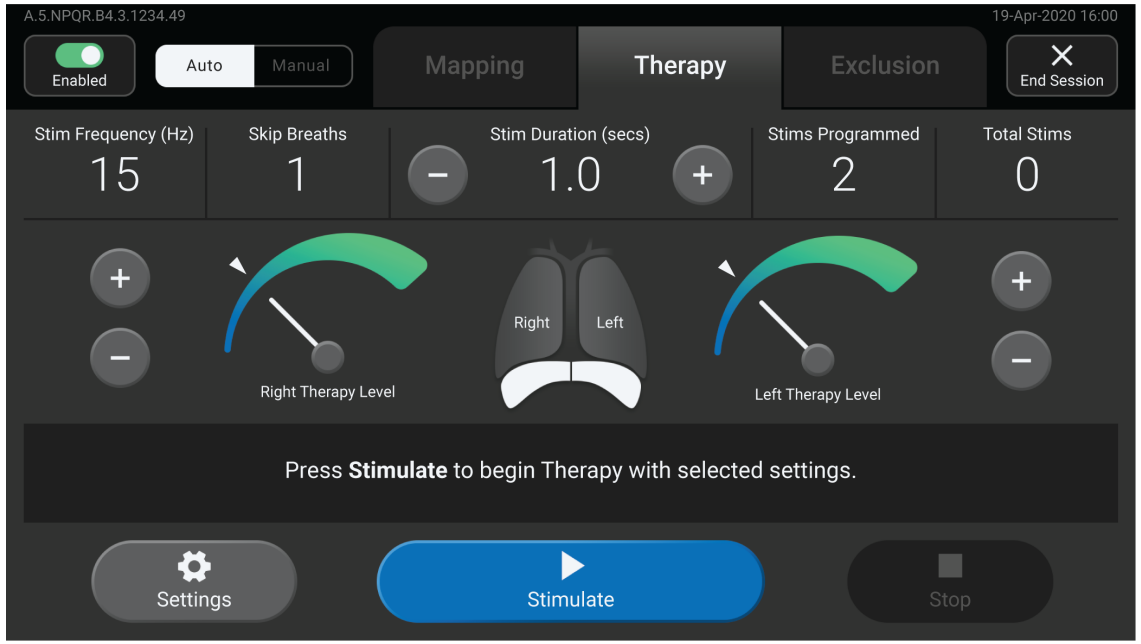
Therapy Troubleshooting

Therapy Troubleshooting

- ❑ If patient discomfort, muscle twitching, or other unwanted effects occur:
  - ❑ Use the **Stop** button to quickly stop stimulations if needed.
  - ❑ Incrementally decrease the **Therapy Level** on affected side.
  - ❑ Use electrode **Exclusion** only if needed.
- ❑ If a persistent **Double Trigger Warning** occurs: Increase number of Skip Breaths and/or reduce the Stim Duration if clinically possible.



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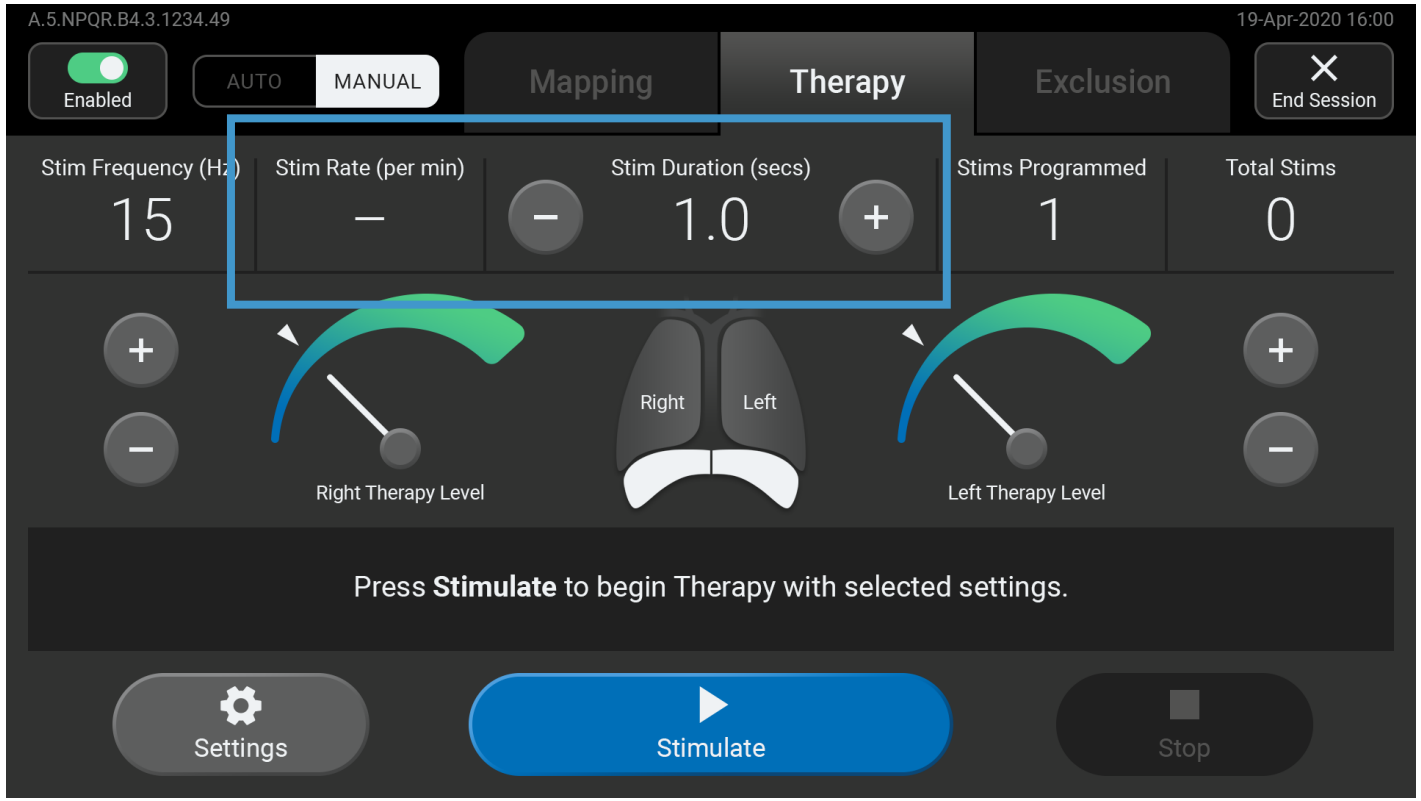
Manual Therapy

During manual Therapy, Stimulations are delivered at the set Stim Rate, which must be configured to match the ventilator breath rate. Additionally, the Stimulate button must be pressed at end-expiration of the patient's breathing cycle to avoid ventilator dyssynchrony.

To provide Manual Therapy:

1. Adjust the Therapy Levels to optimize Therapy.
2. Set the **Stim Rate** and **Stim Duration** carefully to match the patient's ventilator settings, and press **Stimulate at end-expiration**,
3. Continue to assess the patient during Therapy.
4. Deliver 60 total stimulations (2x/day).



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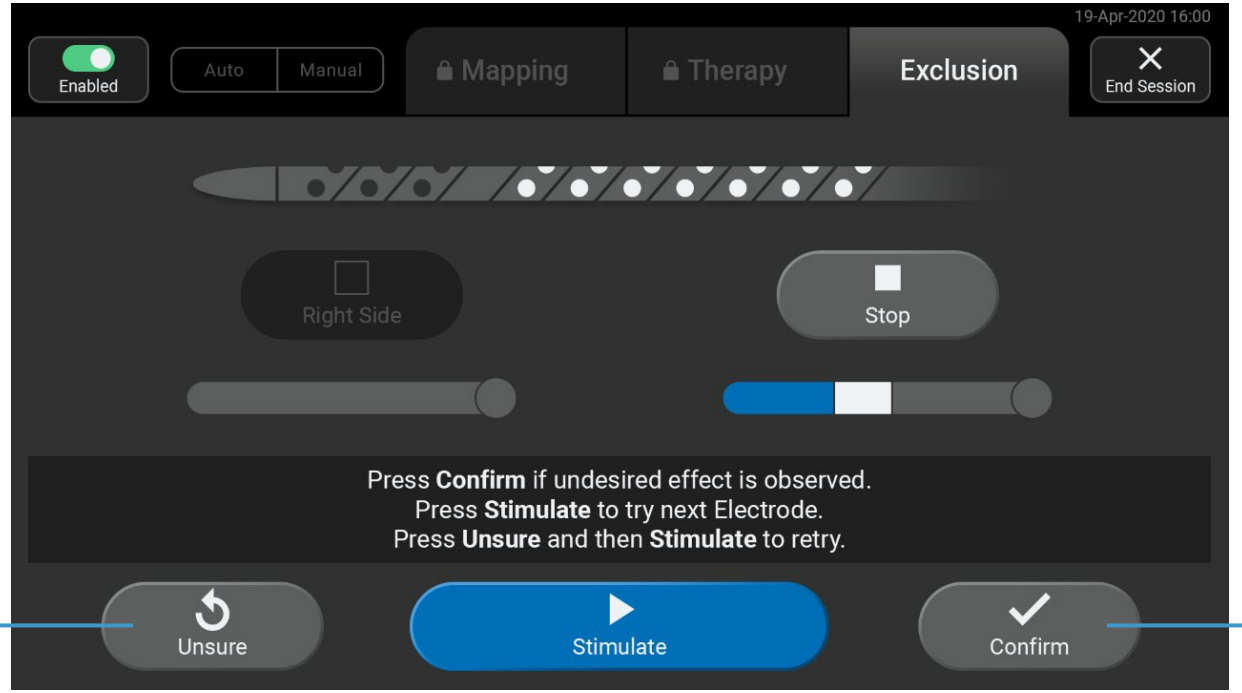
Exclusion

Use the Exclusion tab to identify and then temporarily disable (exclude) the specific Catheter electrodes that cause unwanted effects. Exclusion can be performed as part of Placement, Mapping, or Therapy.

Press Stimulate while you **observe the patient to watch for unwanted effects**, and then provide feedback to Console using the on-screen buttons or Handheld Controller.



Select **Unsure** if you're not sure if you saw an unwanted effect.

Press **Stimulate** if you did not observe anything of note.

Select **Confirm** if you observed an unwanted effect.

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