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CAUTION: Investigational Device. Limited by US Federal (or United States) Law to investigational use. Exclusively for clinical investigations.

CAUTION: Instrument de recherche.
Réservé uniquement à l'usage de chercheurs compétents.

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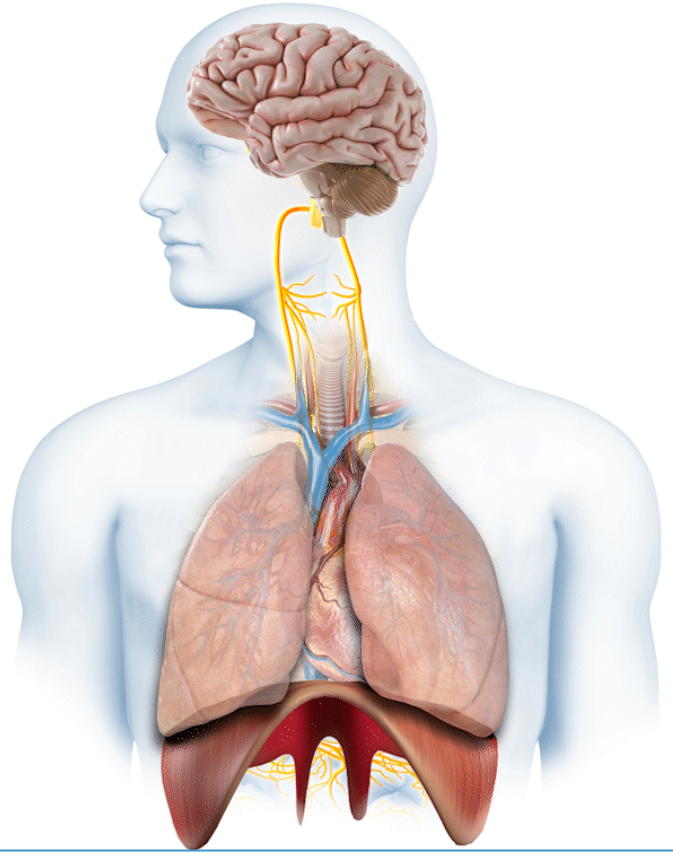
Unmet Clinical Need

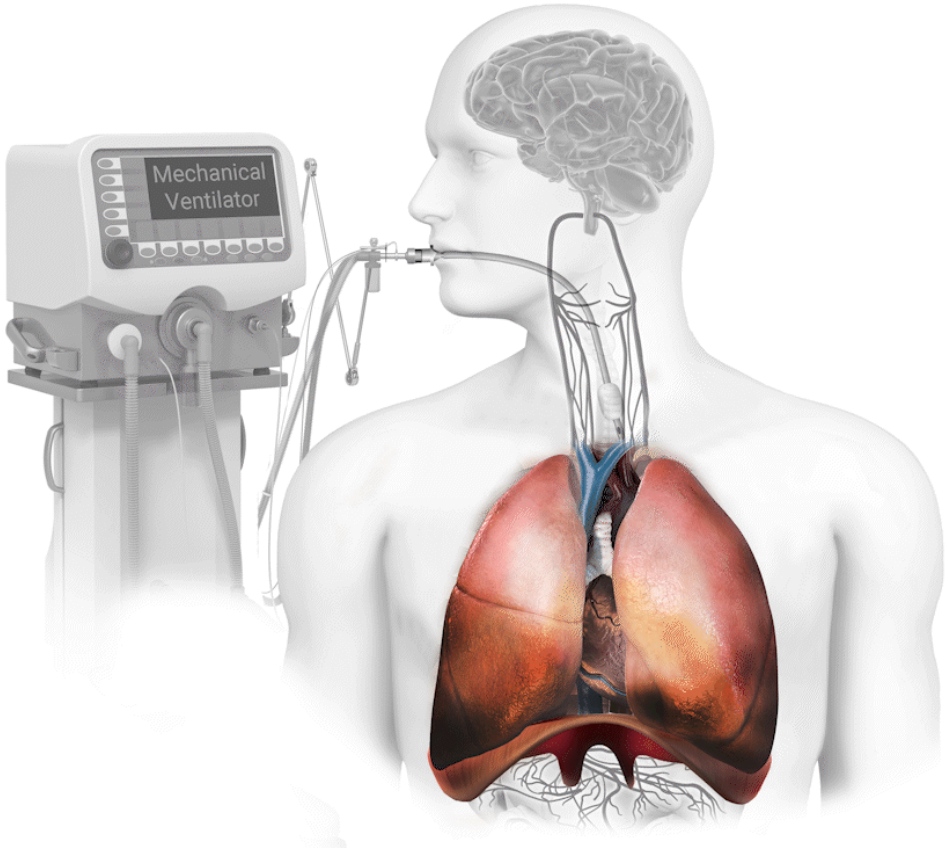
- AeroNova System
- Neurostimulation Catheter Insertion, ECG, and Placement
- AeroNova Therapy (Protection and Rehabilitation)
- Therapy Controls
- MRI Safety and Additional Information

Ventilators Fill the Lungs Differently Than a Natural Breath

Negative pressure vs Positive pressure



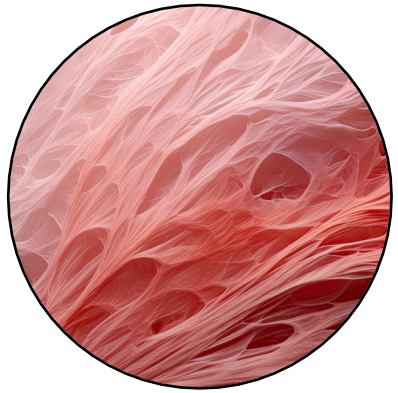
When breathing naturally, the **diaphragm muscle contracts to create negative pressure** that inflates the lungs naturally.



Mechanical Ventilation uses **positive pressure to fill the lung** and may cause upper lung overinflation (barotrauma) and lower lung collapse (atelectasis).

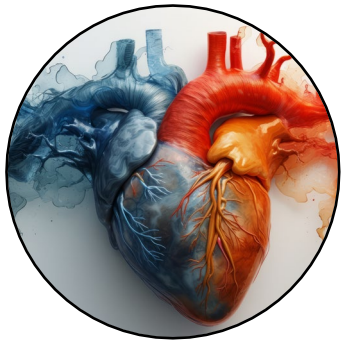
ICU Patients Experience High Risk of Additional Trauma

MV, in particular, leads to diaphragm, lung, cognitive and cardiovascular impairment



Diaphragm muscle weakness, dysfunction, and atrophy leading to **difficulty weaning**

Increased **lung injury, stress, strain,** and **tissue deterioration extending ventilation time**



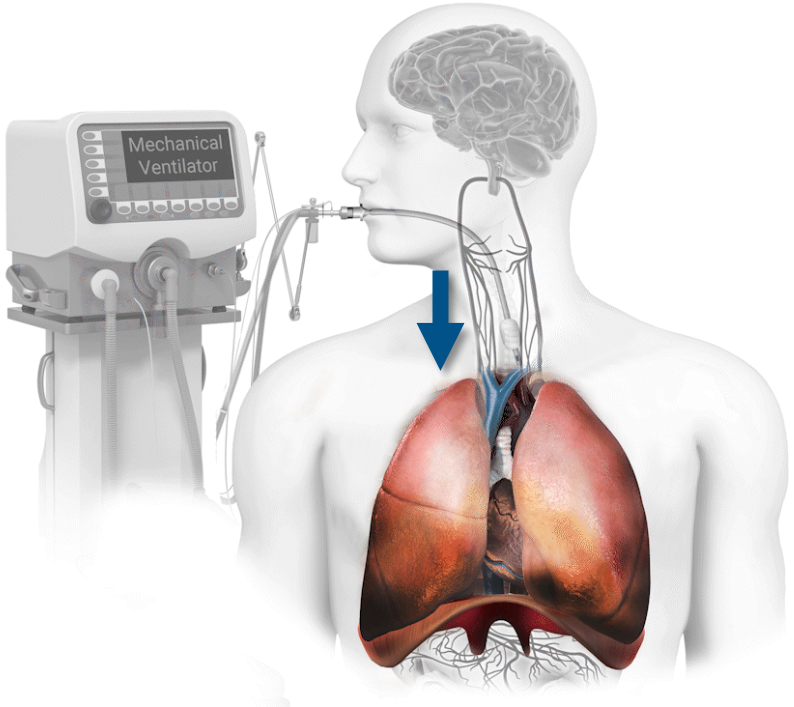
Reduced cardiac output and decreased heart rate variability raise stress on the heart

Neuroinflammation and apoptosis, Lead to delirium and prolonged cognitive injury

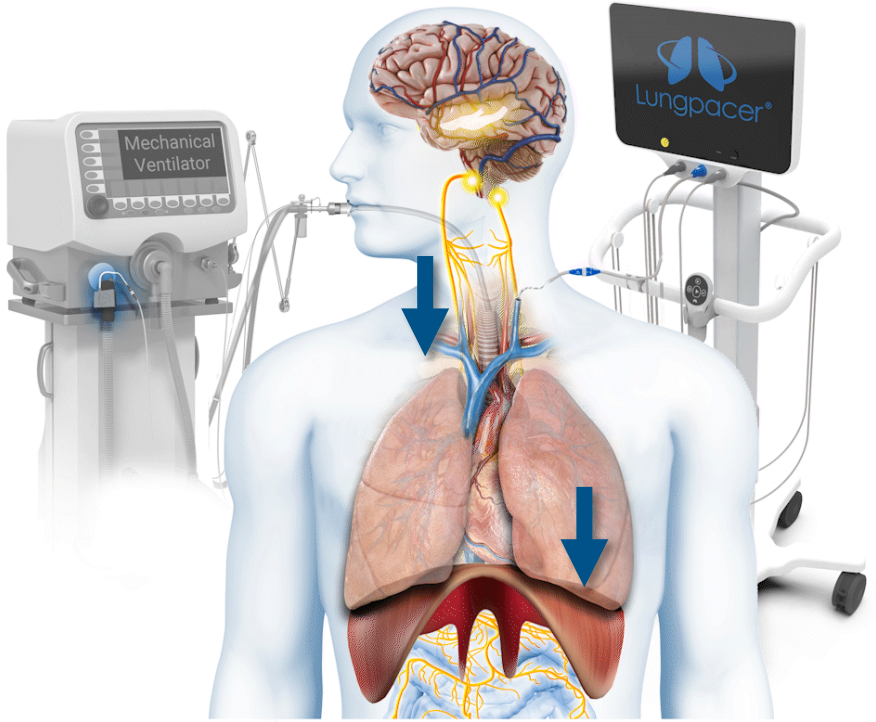
Respiratory infections, increases hospital length of stay and **mortality**

AeroNova Therapy

Maintains diaphragm function and reduces MV positive pressure



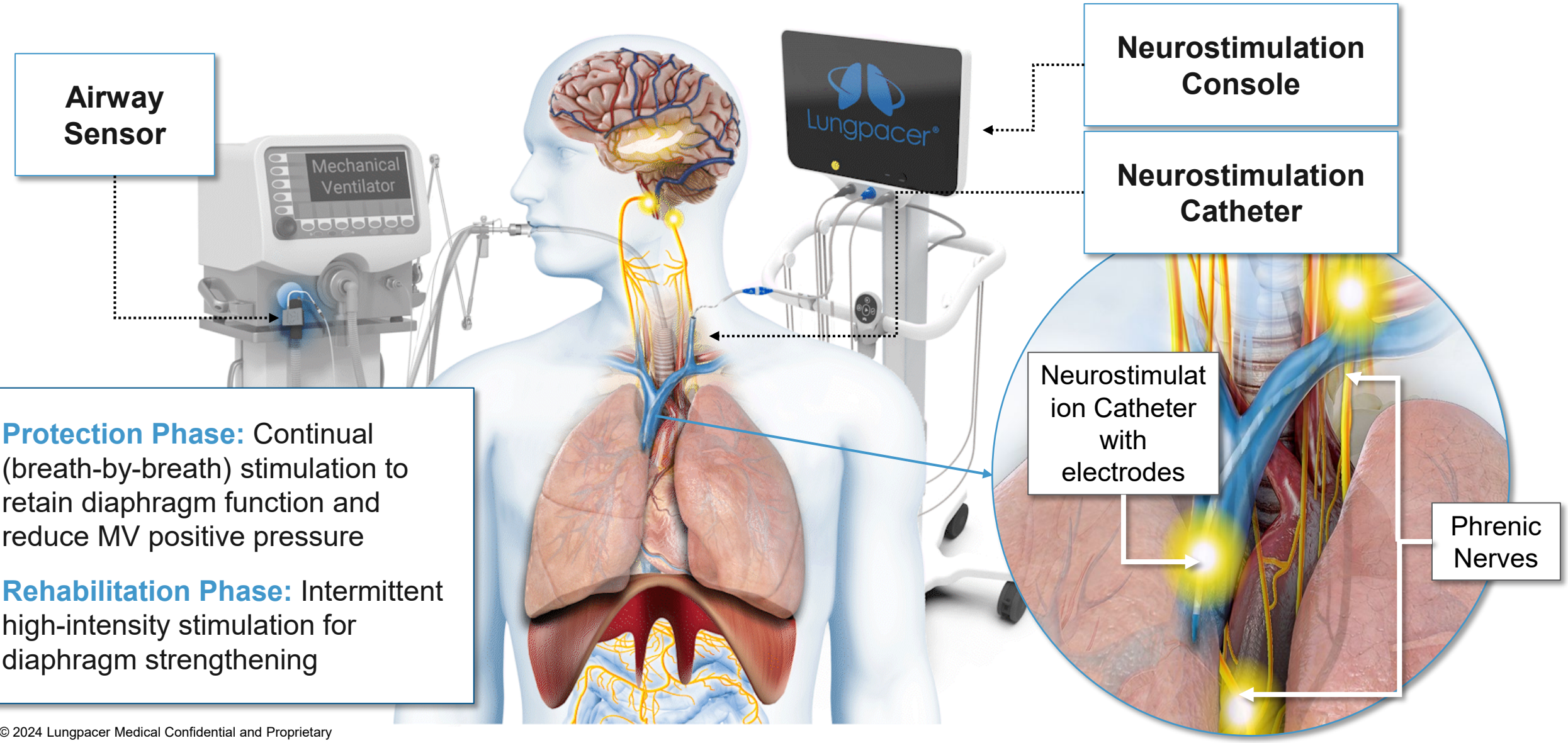
A mechanical ventilator used on its own does **all the work of breathing**, using positive pressure through the airways.



When the ventilator is used in combination with **AeroNova Continual Therapy**, the **work of breathing is shared** with an adjustable contribution of negative pressure from the diaphragm, as it contracts with each stimulation. This diaphragmatic contribution is known as the "**Diaphragm Activation Level**" or "**DAL**."

AeroNova System Delivers Therapy Adjunctively with MV

Two Phases: Protection and Rehabilitation



Protection Phase: Continual (breath-by-breath) stimulation to retain diaphragm function and reduce MV positive pressure

Rehabilitation Phase: Intermittent high-intensity stimulation for diaphragm strengthening

AeroNova Therapy's Two Phases of Care: Protection and Rehabilitation

Protection (Continual) and Rehabilitation (Intermittent, High-Intensity)

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Protection: Continual Therapy

The protection phase of AeroNova Therapy involves the **continual delivery of stimulations** adjunctively with mechanical ventilator breaths to retain diaphragm function and reduce MV positive pressure.

Diaphragm contractions elicited by the AeroNova System generate **negative-pressure** that can be titrated to reduce MV positive pressure. This level of negative pressure is called the **"Diaphragm Activation Level" or "DAL."**

User-selectable **low and high DAL notifications, as well as a high stop limit** ensure the strength of diaphragm contractions can be retained within the desired range.

Rehabilitation: Intermittent High-Intensity Therapy

The rehabilitation phase of AeroNova the **intermittent delivery of high-intensity stimulations** after the subject begins to breathe spontaneously, to increase diaphragm strength and facilitate weaning from MV.

The AeroNova System is configured to **maximize the intensity of diaphragm stimulations twice daily** for up to 30 days or until the subject is weaned.

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AeroNova System

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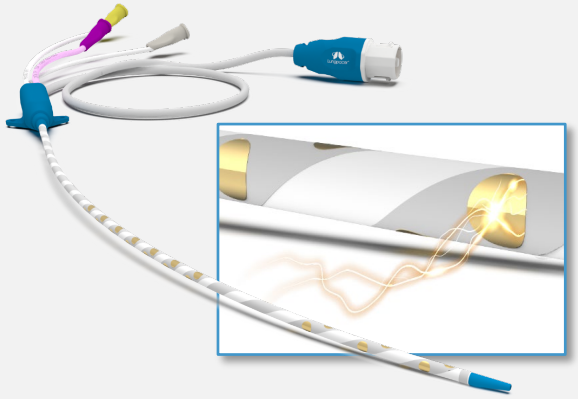
The AeroNova System

Three main components integrate system and ventilator

Neurostimulation Catheter

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



Neurostimulation Console

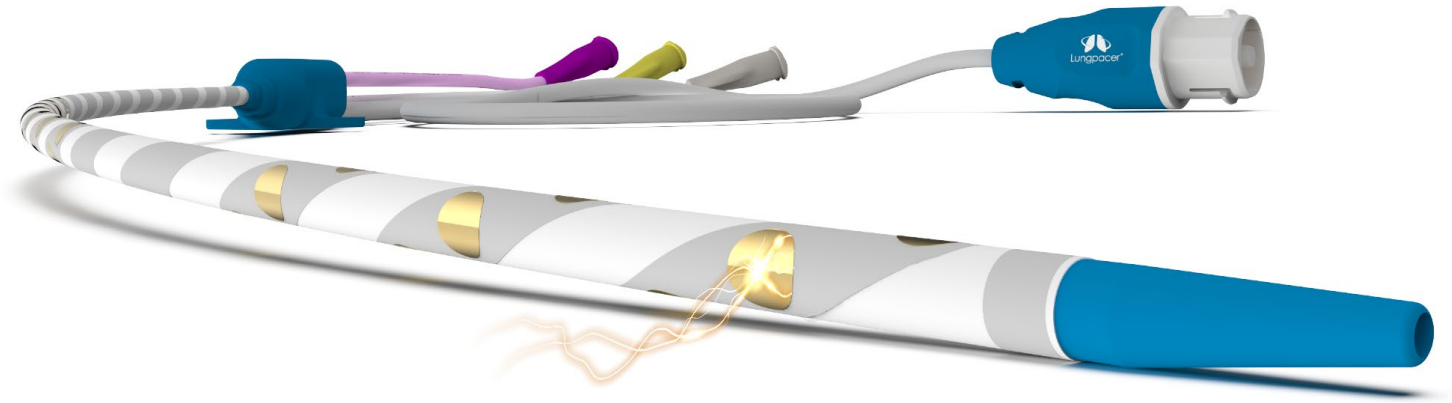
Controls **adjustable stimulation parameters** to provide two stages of therapy (protective and rehabilitation) for diaphragm activation adjunctively with mechanical ventilation.

Airway Sensor

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

Neurostimulation Catheter Specifications

Includes typical CVC functionality, plus specialized electrodes



- **30 neurostimulation electrodes** arranged in two arrays for left-side and right-side phrenic nerve stimulation
- Size: **8.5 Fr, 23 cm**
- **Triple lumen**. Distal (purple): used for guidewire insertion and high-pressure injection 5 mL/sec and flow rate of 42mL/min. Medial (yellow) and Proximal (white): flow rate of 17 mL/min
- When properly placed in central circulation, the Neurostimulation Catheter may be used for **TPN, fluid, and medication delivery**. Infusions may continue during Therapy delivery
- Sterile, designed for single-use for up to 30 days. Follow institutional guidelines for care and maintenance of CVCs
- See Neurostimulation Catheter Kit Instructions for Use for additional information

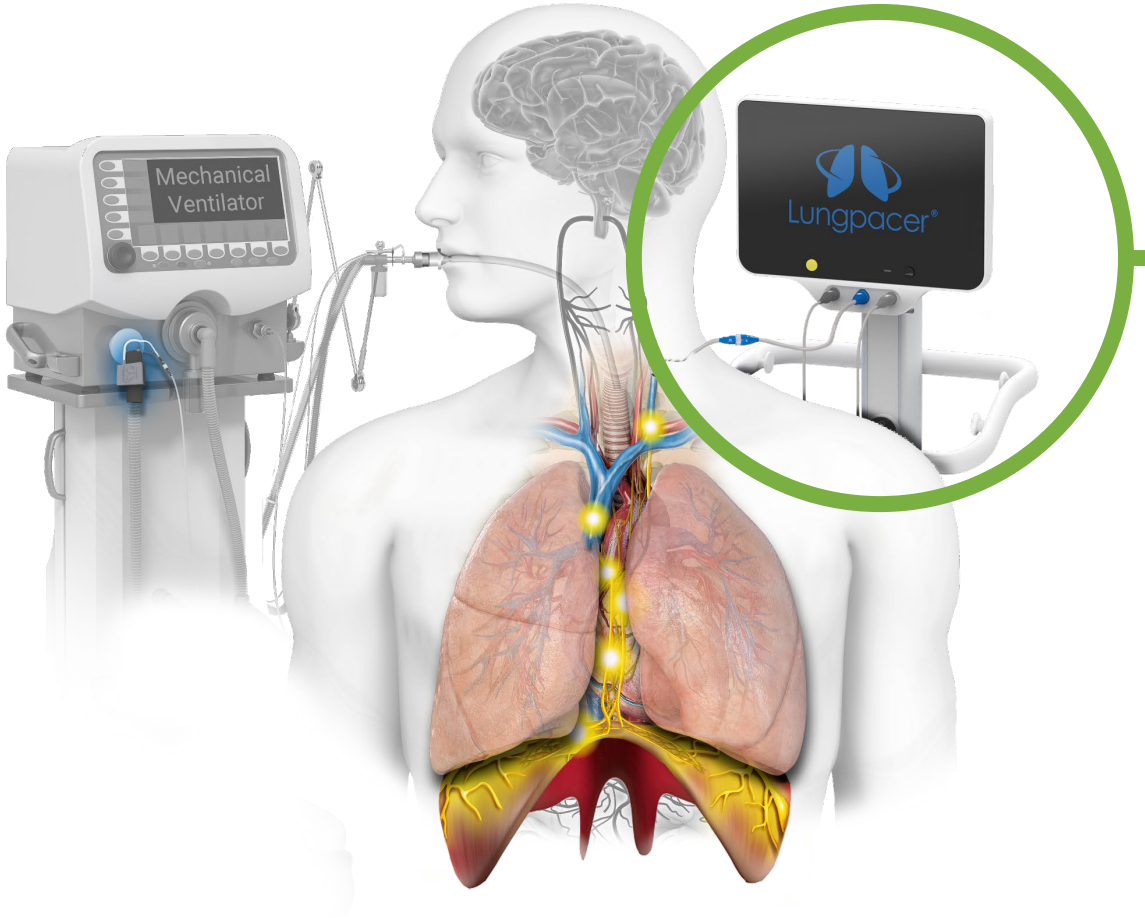
Neurostimulation Catheter Kit Contents

Includes most single-use accessories needed to insert CVC using Seldinger technique

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

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

AeroNova Neurostimulation Console
Cable Connections

1. **Airway Sensor Cable**
   - The cable with dark gray connectors electrically connects the Airway Sensor to the Console.
2. **Catheter Cable**
   - The cable with blue connectors electrically connects the Neurostimulation Catheter to the Console when in use.
3. **Handheld Controller**
   - The Handheld Controller has a light gray connector.

Note: *The Airway Sensor Cable and Catheter Cable are both* ***reusable.***

AeroNova Neurostimulation Console
User Interface Buttons

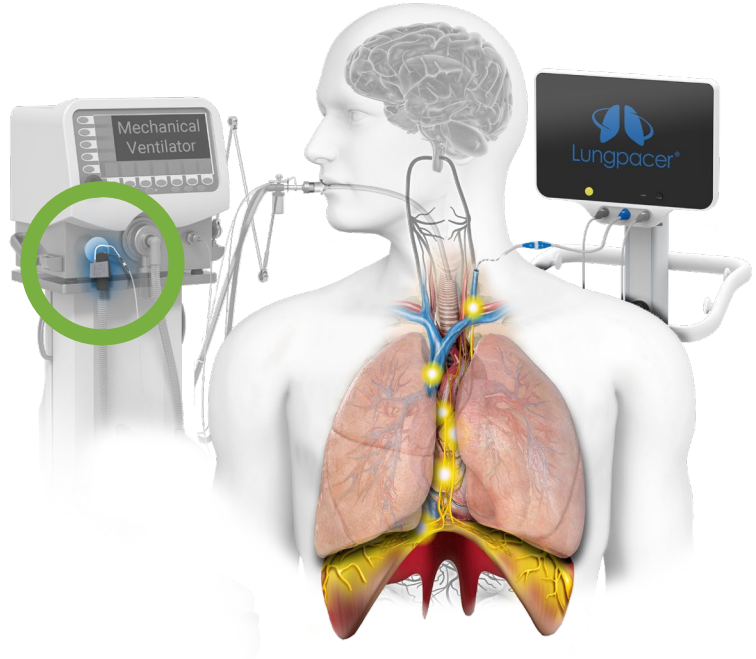
1. **Power Button**
   - Powers the Console on and off.
2. **Yellow Stop Button**
   - Pressing this button will quickly stop stimulations and prompt the user to power off the System.

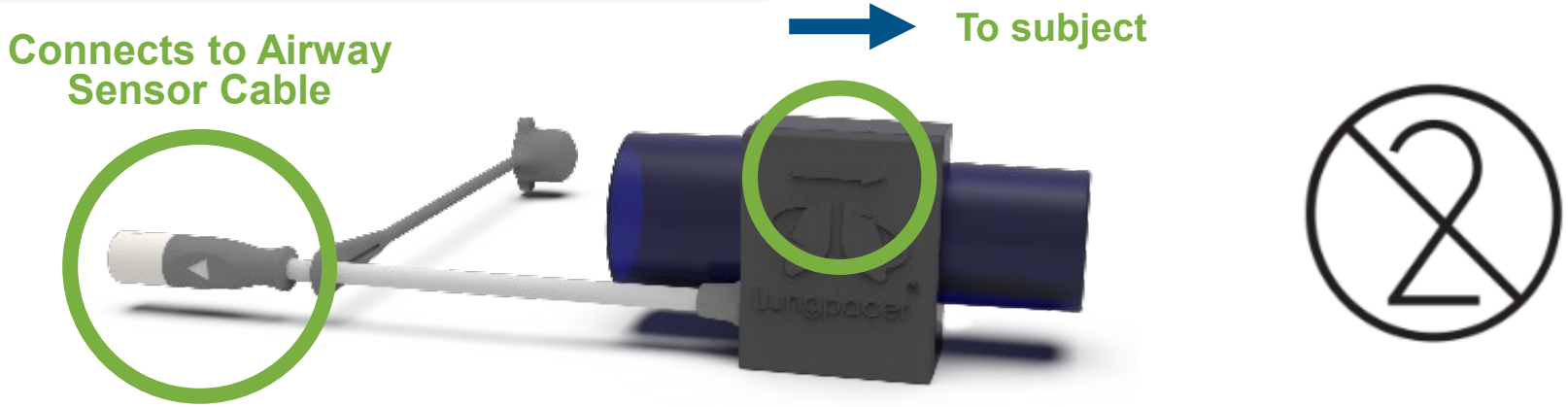
     Note: *The Console must be powered off after pressing this button. During stimulations, a blue stop button is also available on-screen, which will stop stimulations without requiring a System reboot.*

Airway Sensor
Connects to ventilator circuit and Console

The Airway Sensor is:

- **Connected before setting up the sterile field** to insert the Neurostimulation Catheter
- Designed to connect to the **inspiratory limb** of the ventilator
- Pneumatically connected to the breathing circuit so the **arrow on the sensor points toward the subject,** and **electrically connected to the Console**
- **Single-patient use** for up to **30 days**

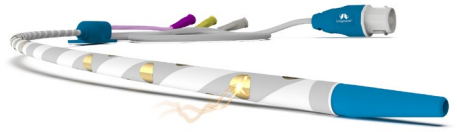




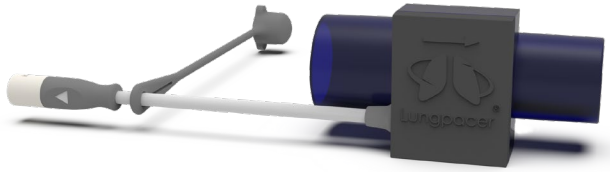
Neurostimulation Catheter Electrode Selection via Airway Sensor Data

Placement Confirmation and Mapping for Diaphragm Activation

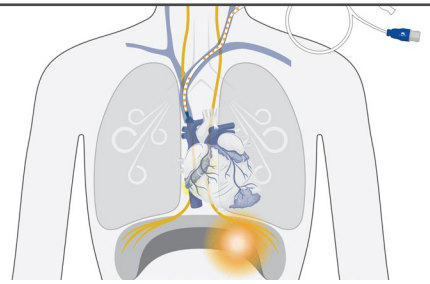
When stimulations are sent from the Neurostimulation Catheter electrodes…

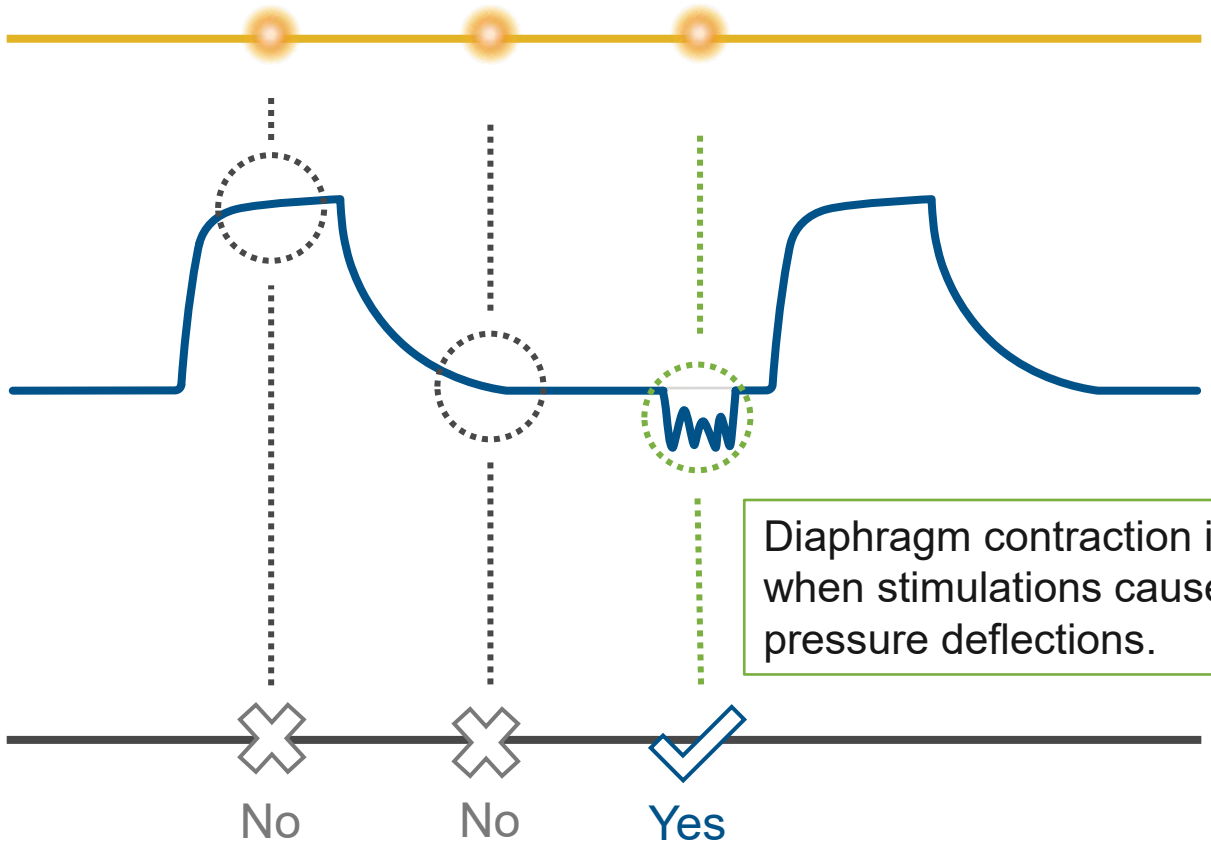


….the Airway Sensor monitors breathing circuit pressure…



…deflections in pressure indicate diaphragm contraction.

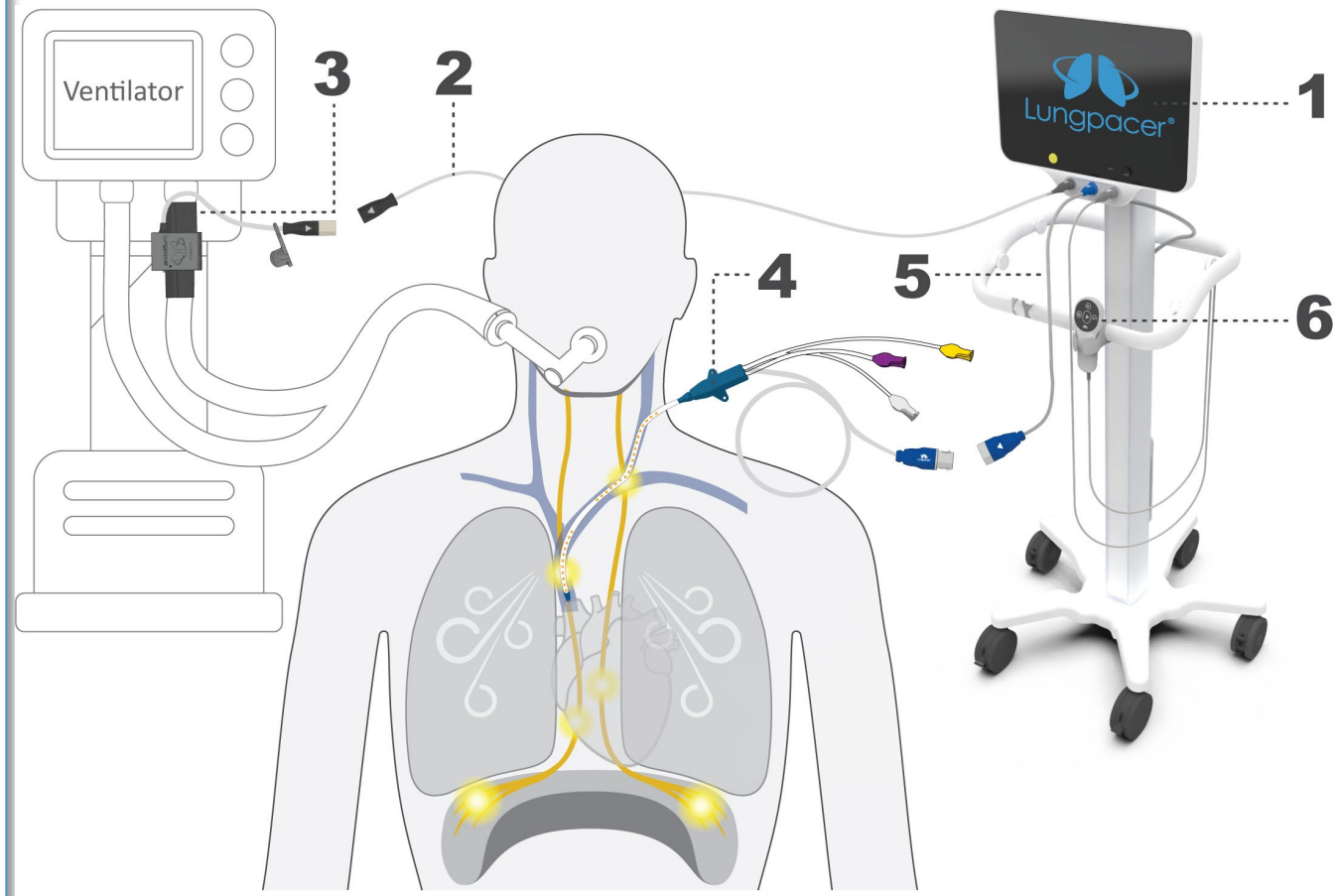




Diaphragm contraction is detected when stimulations cause airway pressure deflections.

AeroNova System Setup
Electrical and pneumatic connections

1. **AeroNova Neurostimulation Console** | Controls the delivery of stimulations that contract the diaphragm via the user interface. Typically positioned on the left side of the subject, toward the head of the bed.
2. **Airway Sensor Cable** | Electrically connects the Airway Sensor to the Console.
3. **Airway Sensor** | Pneumatically connects in the ventilator circuit at the inspiratory limb, with the arrow oriented toward the subject. Detects and communicates pressure deflections to the Console to synchronize therapy with ventilator breaths.
4. **Neurostimulation Catheter** | CVC containing electrodes. Inserted into the subject's left subclavian vein or left jugular vein, with the distal tip positioned at the SVC.
5. **Catheter Cable** | Electrically connects the Neurostimulation Catheter to the Console's middle blue connector.
6. **Handheld Controller** | Optionally used to perform basic Console functions at a distance from the Console.



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Pop Quiz

AeroNova System Setup

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- Unmet Clinical Need
- AeroNova System

Neurostimulation Catheter Insertion, ECG, and Placement

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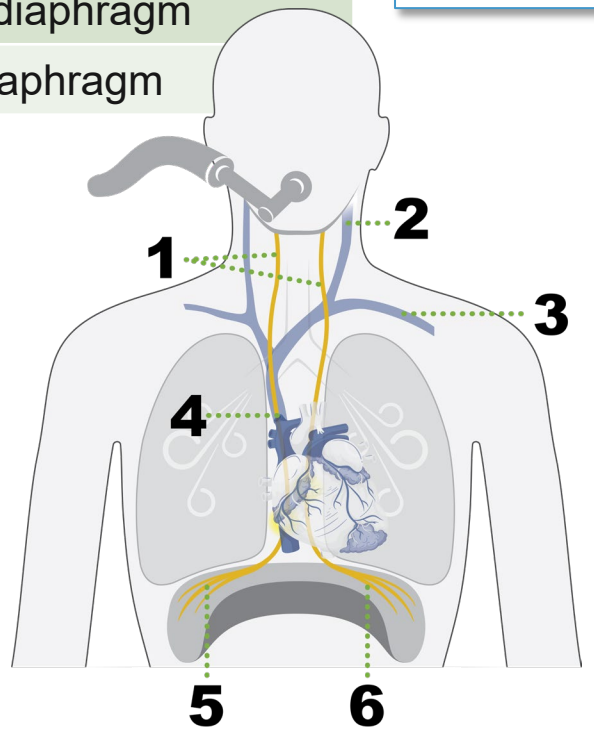
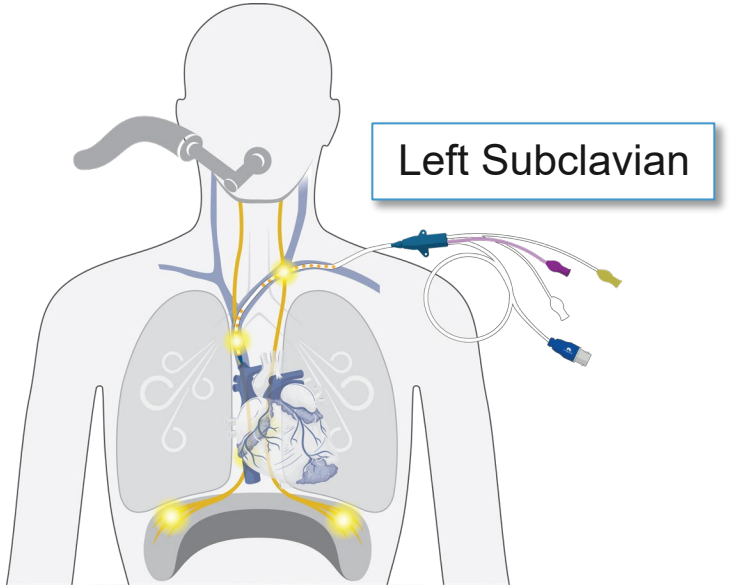
Choosing a Neurostimulation Catheter Insertion Location

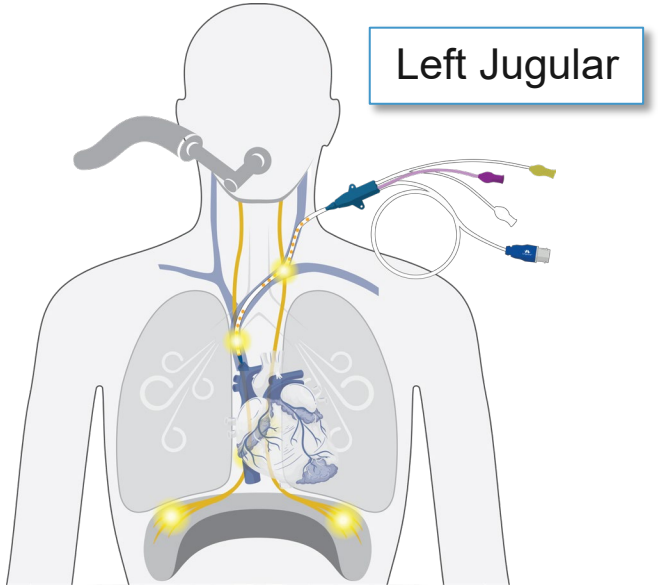
Left subclavian or left jugular vein

#	Anatomy
1	Phrenic Nerves
2	Left Jugular Vein
3	Left Subclavian Vein
4	Superior Vena Cava (SVC)
5	Right Hemidiaphragm
6	Left Hemidiaphragm

- 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**.







Proper Neurostimulation Catheter Tip Positioning

Should be deep enough to stimulate the phrenic nerves, but not too close to the heart

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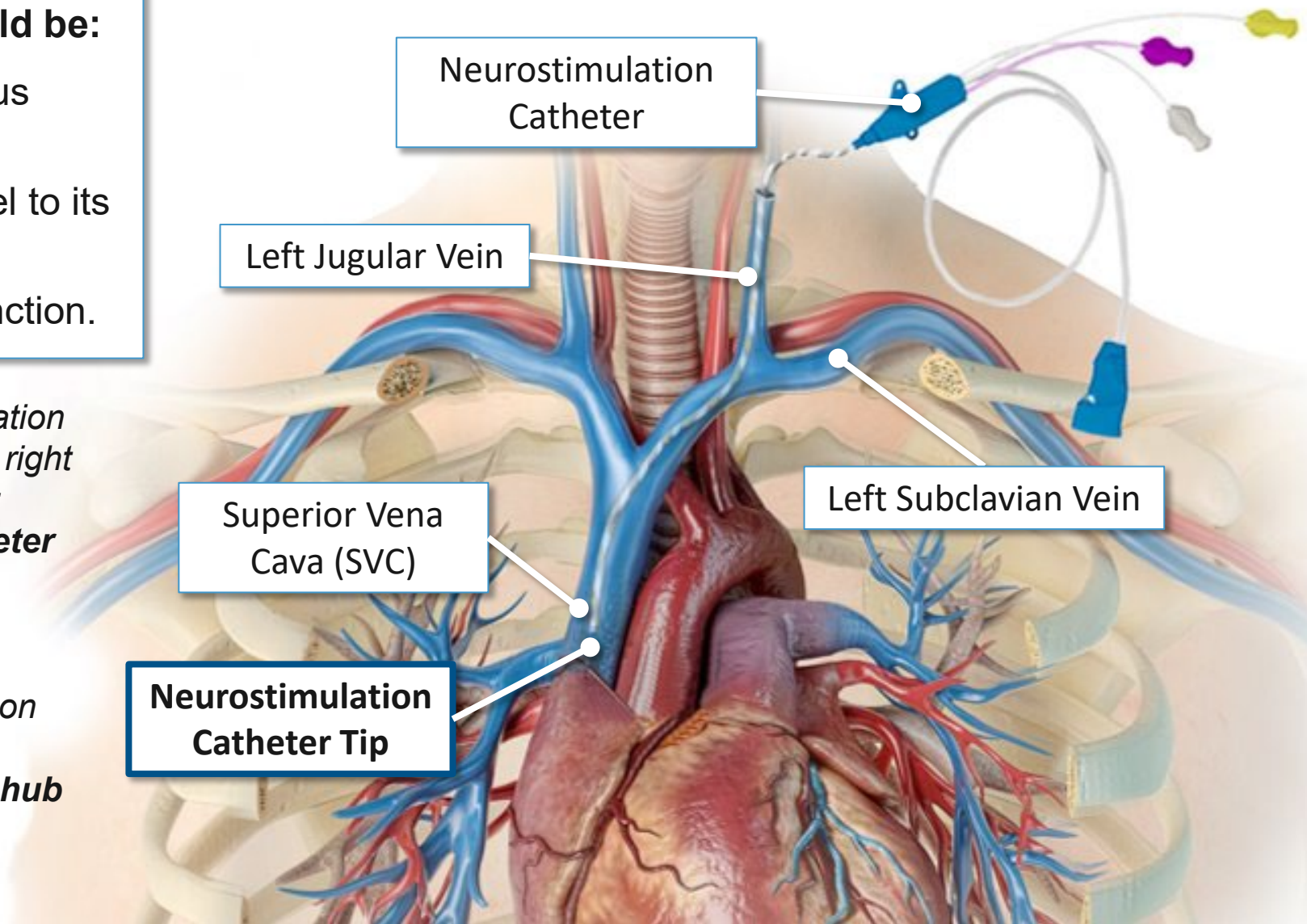
Neurostimulation Catheter tip should be:

- ✓ 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 >23cm. It is ***not intended to be inserted all the way to the hub in most subjects.***



ECG-Guided Insertion

Signal amplitude and morphology changes indicate Neurostimulation Catheter depth

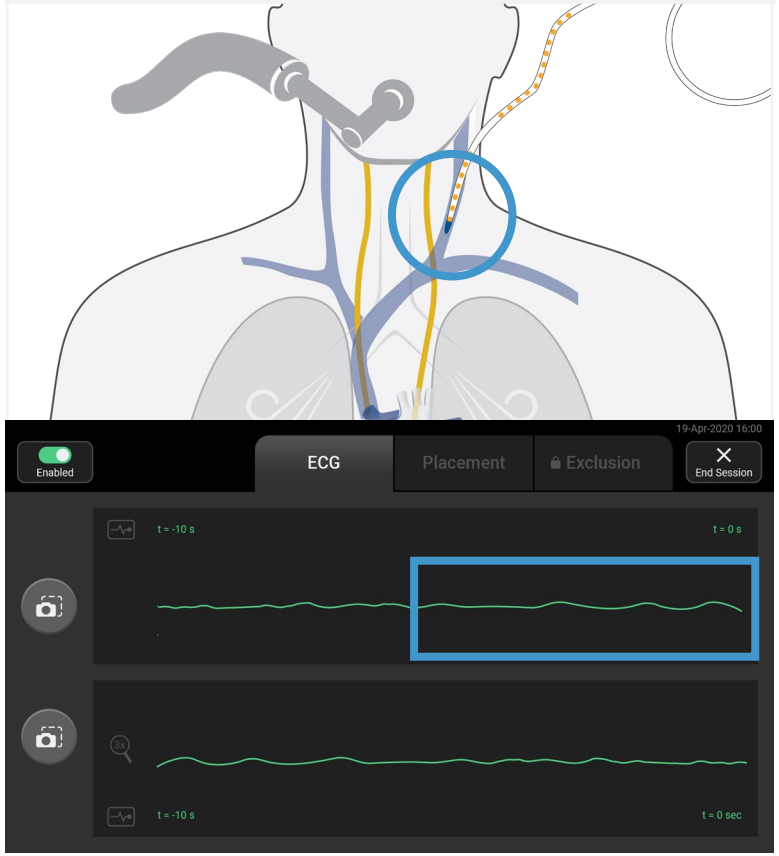
The **ECG** feature serves as a guide to Neurostimulation Catheter insertion. Changes in signal amplitude and morphology indicate that the Neurostimulation Catheter tip is near its intended position in the SVC.

ECG-Guided Insertion

Use clinical assistance to maintain sterile field while operating the Console

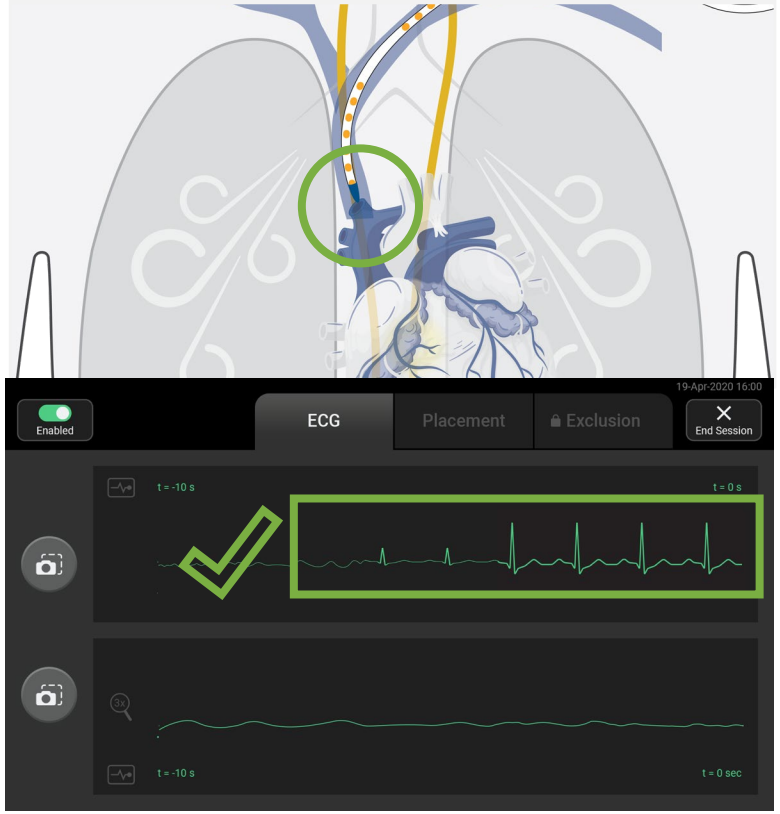
Insert the Neurostimulation Catheter

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



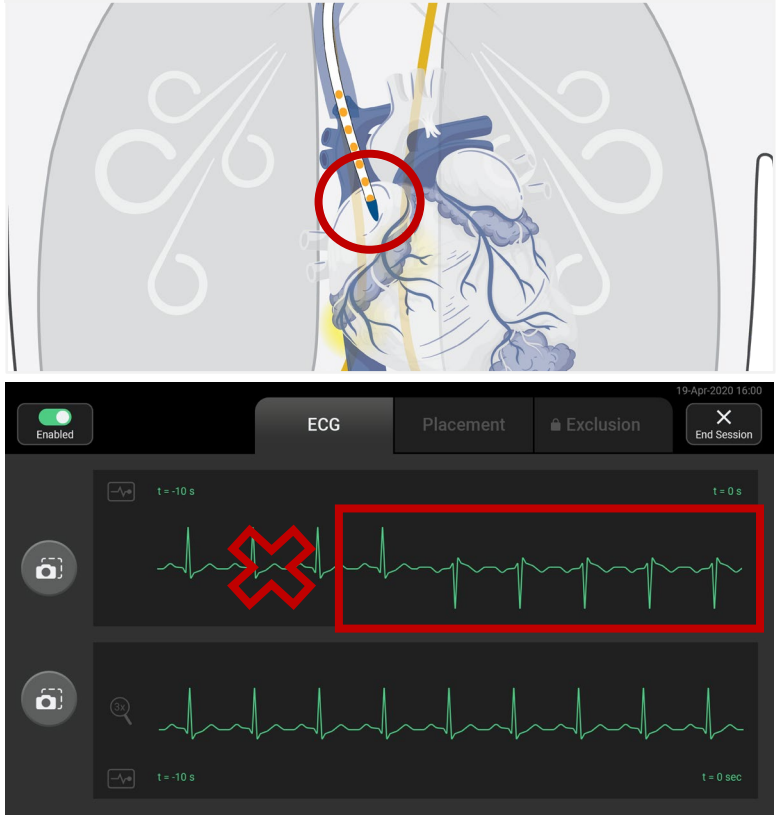
Look for clear signal while advancing

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



Do not over-advance (inverted signal)

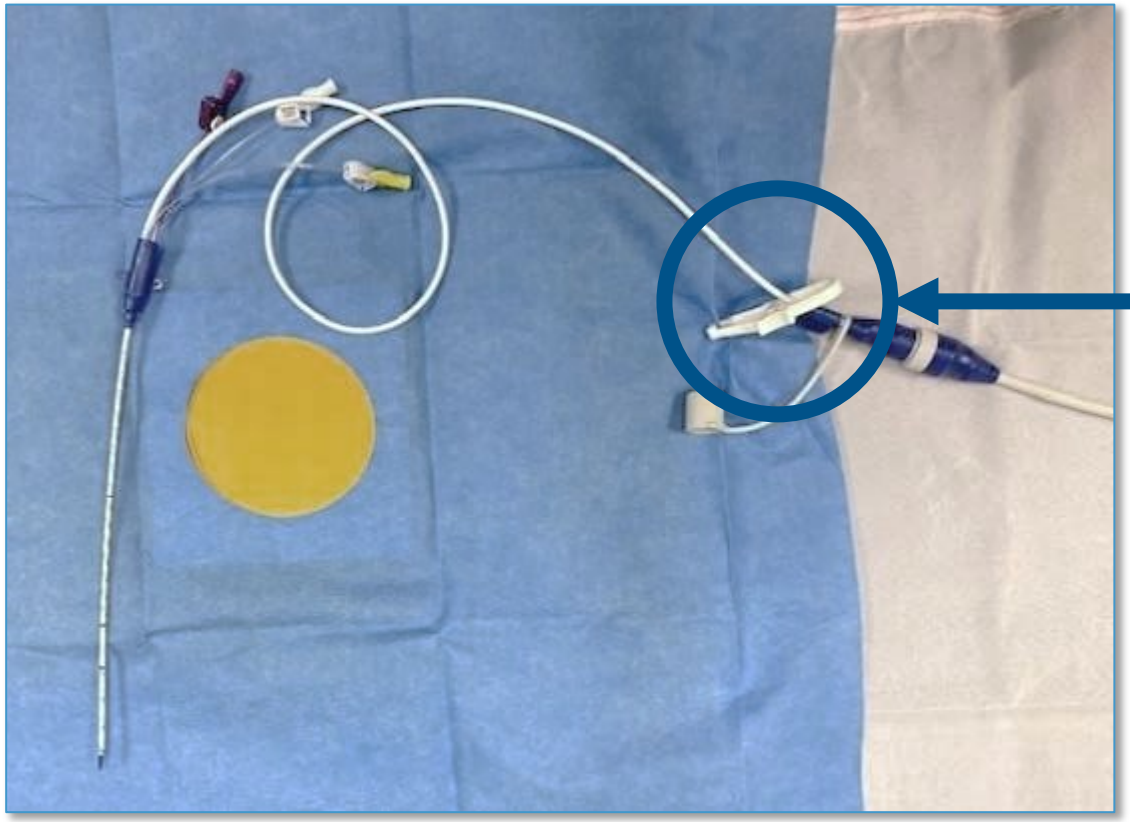
An inverted/flipped signal morphology indicates that the Neurostimulation Catheter has been **advanced too far** and may be in the atrium, and the Catheter should be retracted slowly.

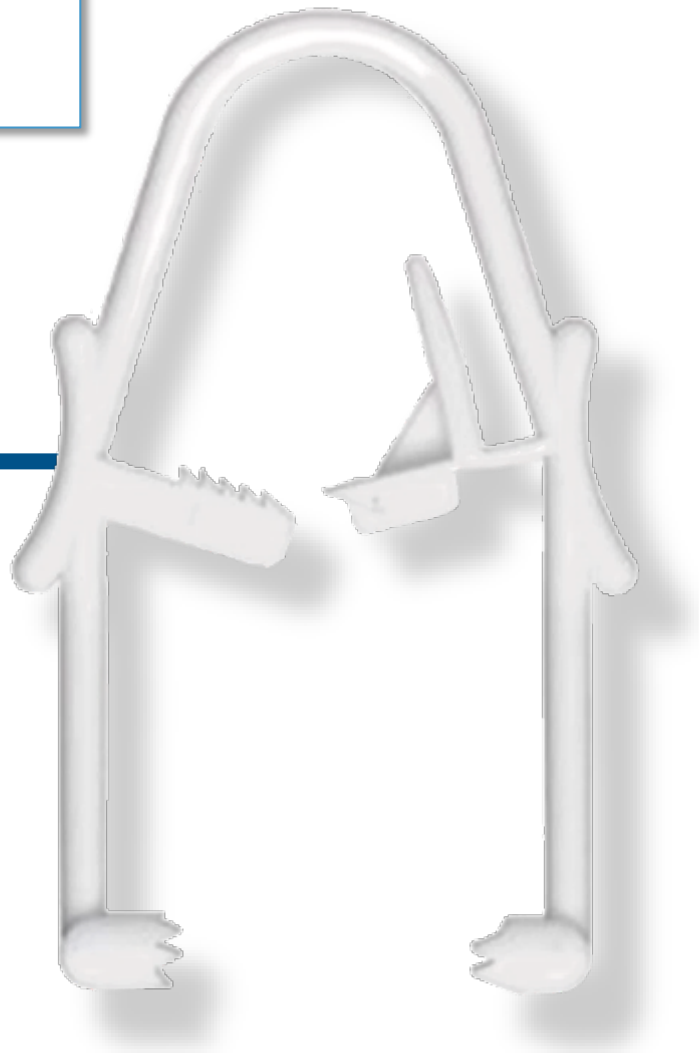


Neurostimulation Catheter Cable Clamp

Maintain the sterile field during placement

When the Neurostimulation Catheter seems to be in good position, use the Cable Clamp provided in the Neurostimulation Catheter Kit to help ensure that the sterile portion of the **Neurostimulation Catheter remains in place and in the sterile field** while the Placement procedure is performed using the Console.

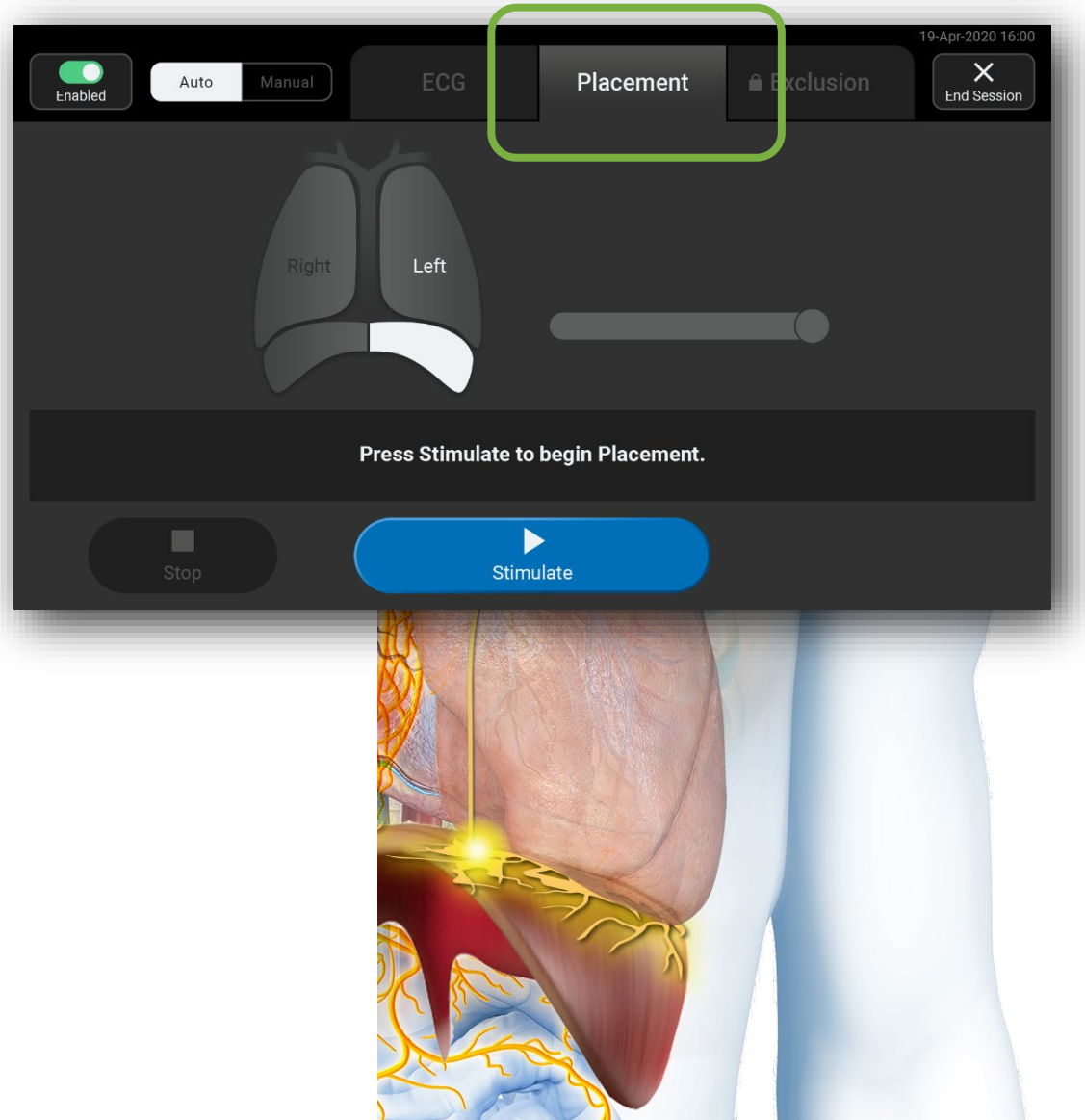




Placement

Verifies the position of the Neurostimulation Catheter's left array of electrodes

Placement verifies that from its current position, the Neurostimulation Catheter's electrodes can recruit the **left** phrenic nerve and cause the diaphragm to contract.

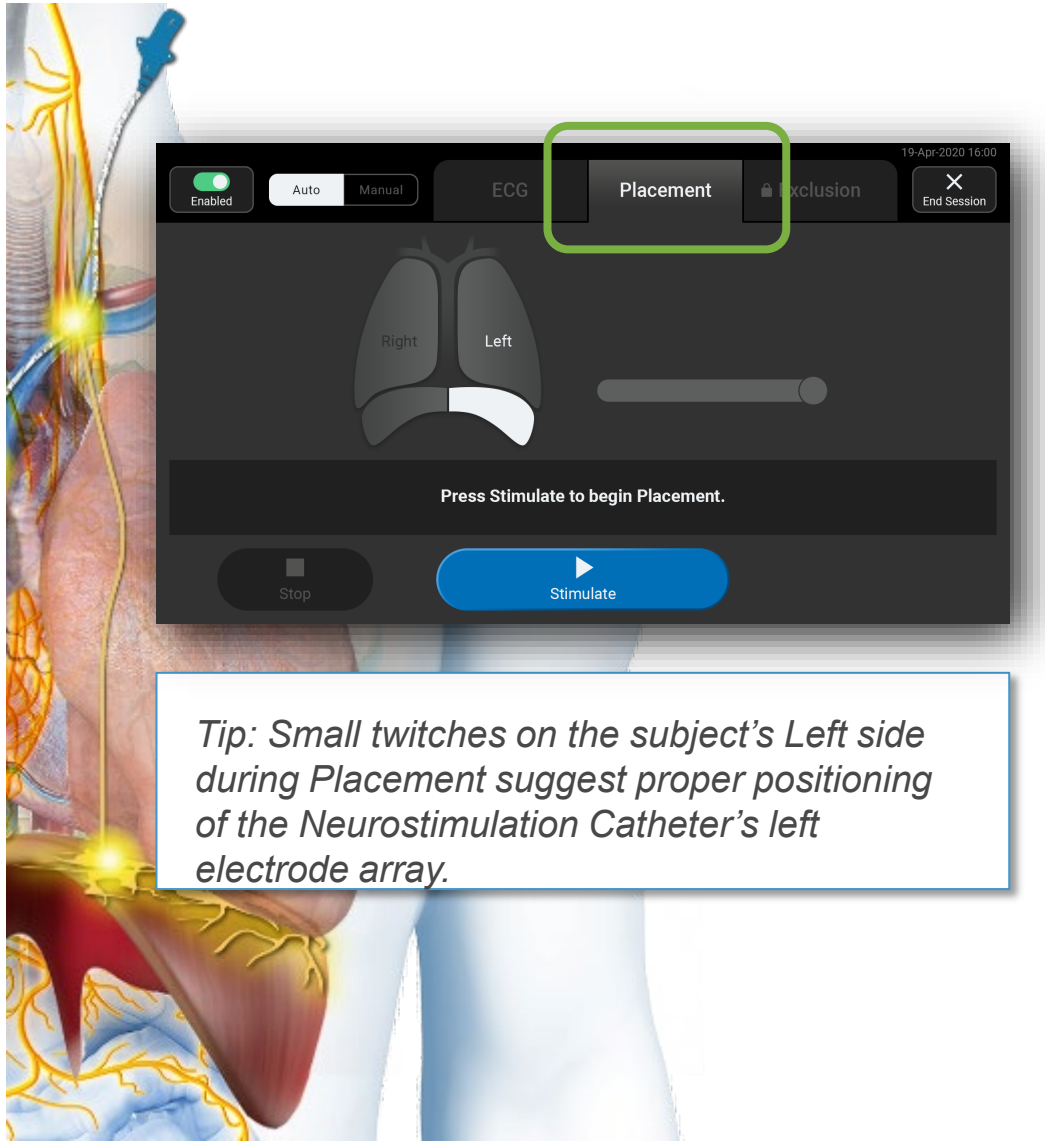


Placement: Overview

Verify the position of the Neurostimulation Catheter's left array of electrodes

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.

Why Placement is Important:
Placement confirms that ***before*** suturing the Neurostimulation Catheter in place, the Neurostimulation Catheter is positioned so that its electrodes are able to recruit the left phrenic nerve and cause the diaphragm to contract.



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

Performing Placement

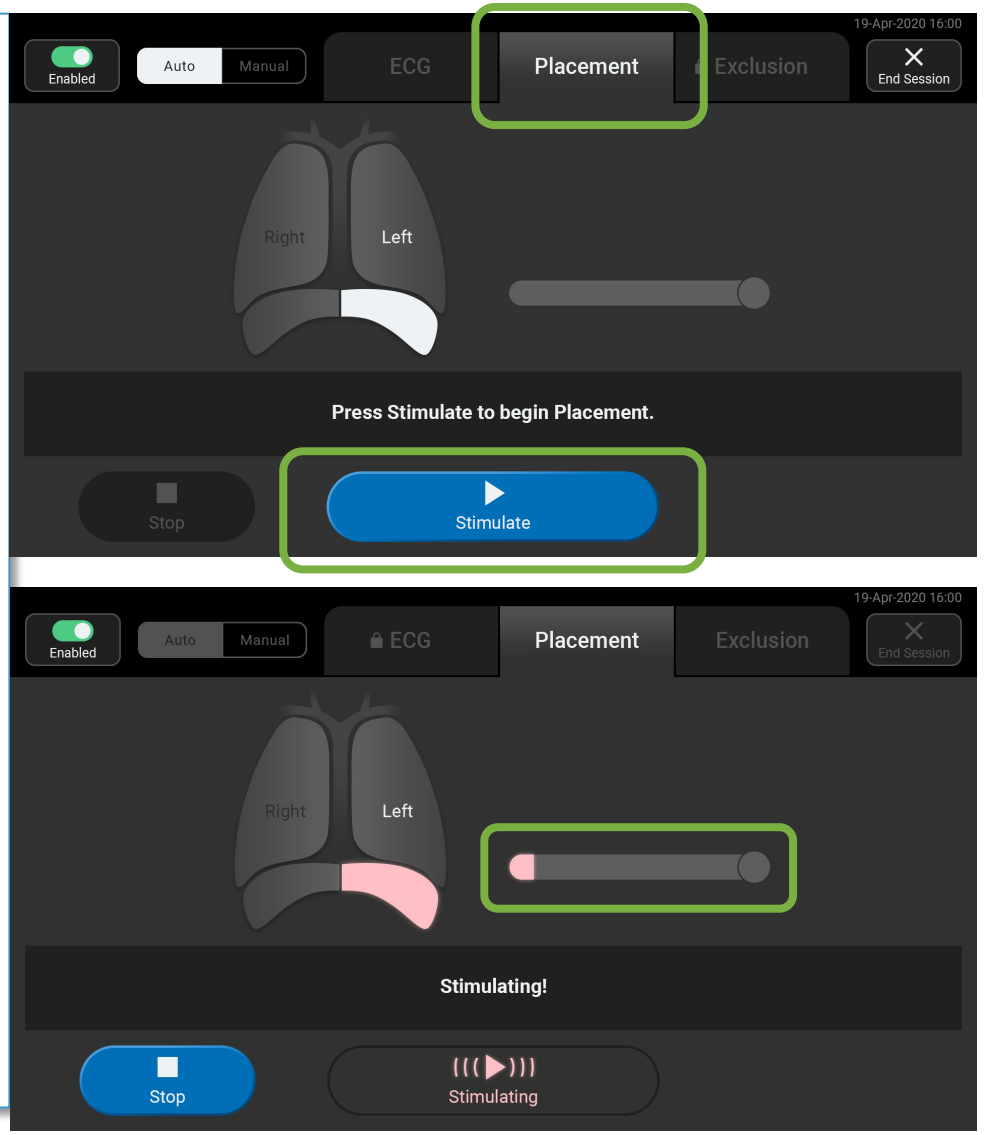
In Auto mode, Placement proceeds and completes automatically

Placement Instructions

1. Once the Neurostimulation Catheter's distal tip is thought to be in the correct position, press the **Placement** tab on the Console.
2. Press **Stimulate**.
3. In Auto mode, Placement **proceeds automatically**. It typically completes in a few minutes (or less).
2. Once complete, follow institutional guidelines to confirm Neurostimulation Catheter tip location (e.g., x-ray).

Placement Troubleshooting

- ❑ If Placement is unsuccessful, repeat Auto Placement. Consider repositioning the subject.
- ❑ If unwanted effects occur, use the Stop button.
- ❑ Try Manual mode if Auto mode is persistently unsuccessful or results in unwanted effects. See the System User Guide for details.



Confirming the Position of the Neurostimulation Catheter's Distal Tip

Follow institutional guidelines

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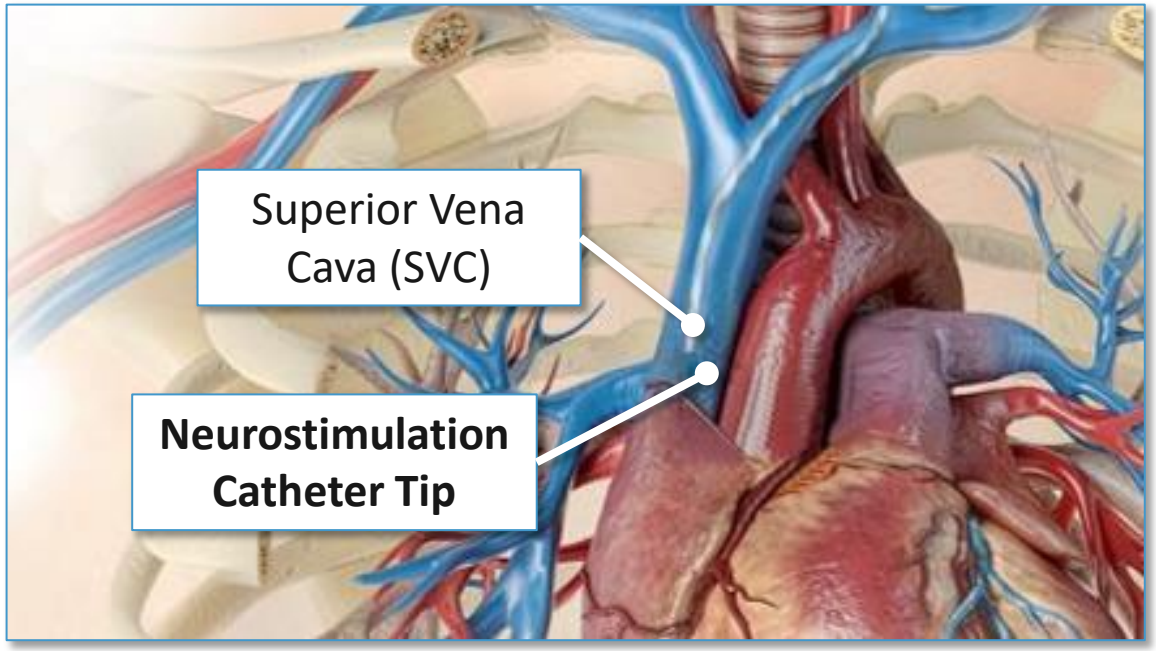
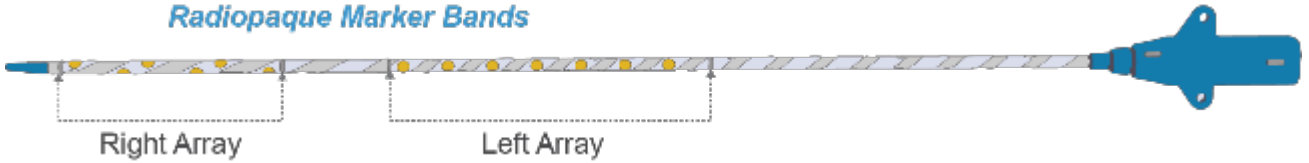
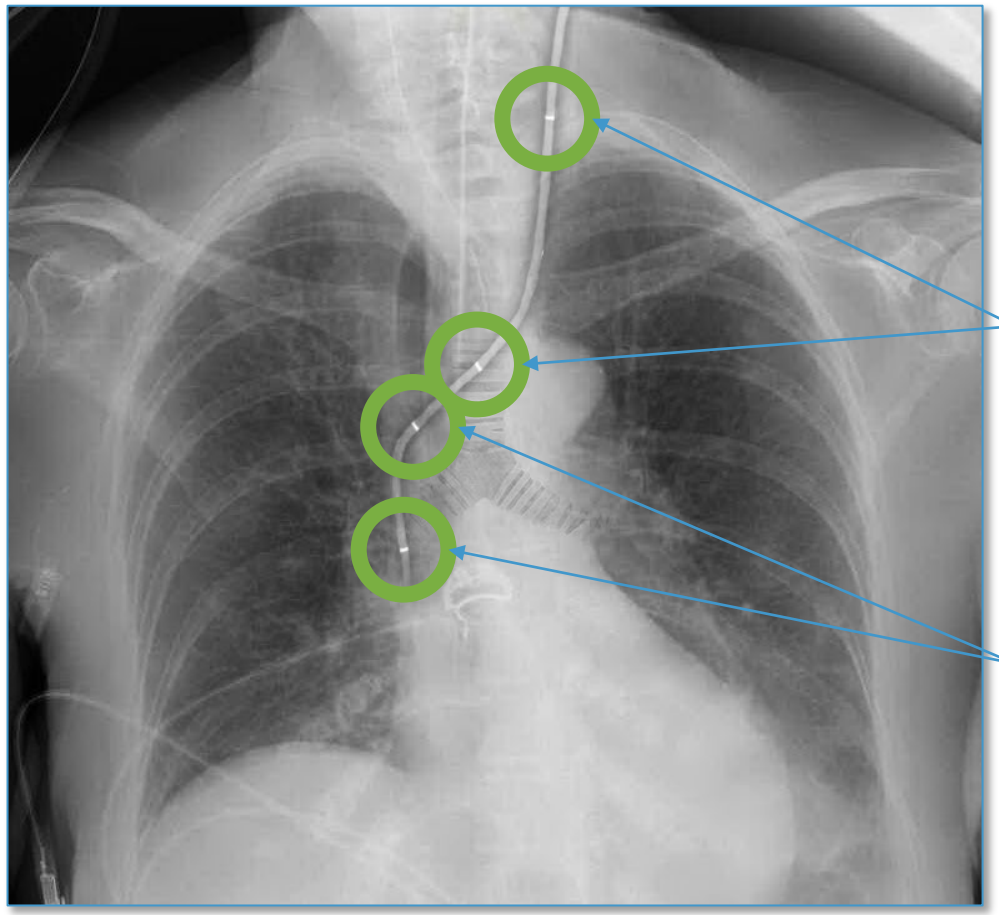
Locating the Neurostimulation Catheter's **radiopaque marker bands** on an x-ray helps ensure **both of the Neurostimulation Catheter's electrode arrays are positioned** appropriately to recruit the subject's phrenic nerves.







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.

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:

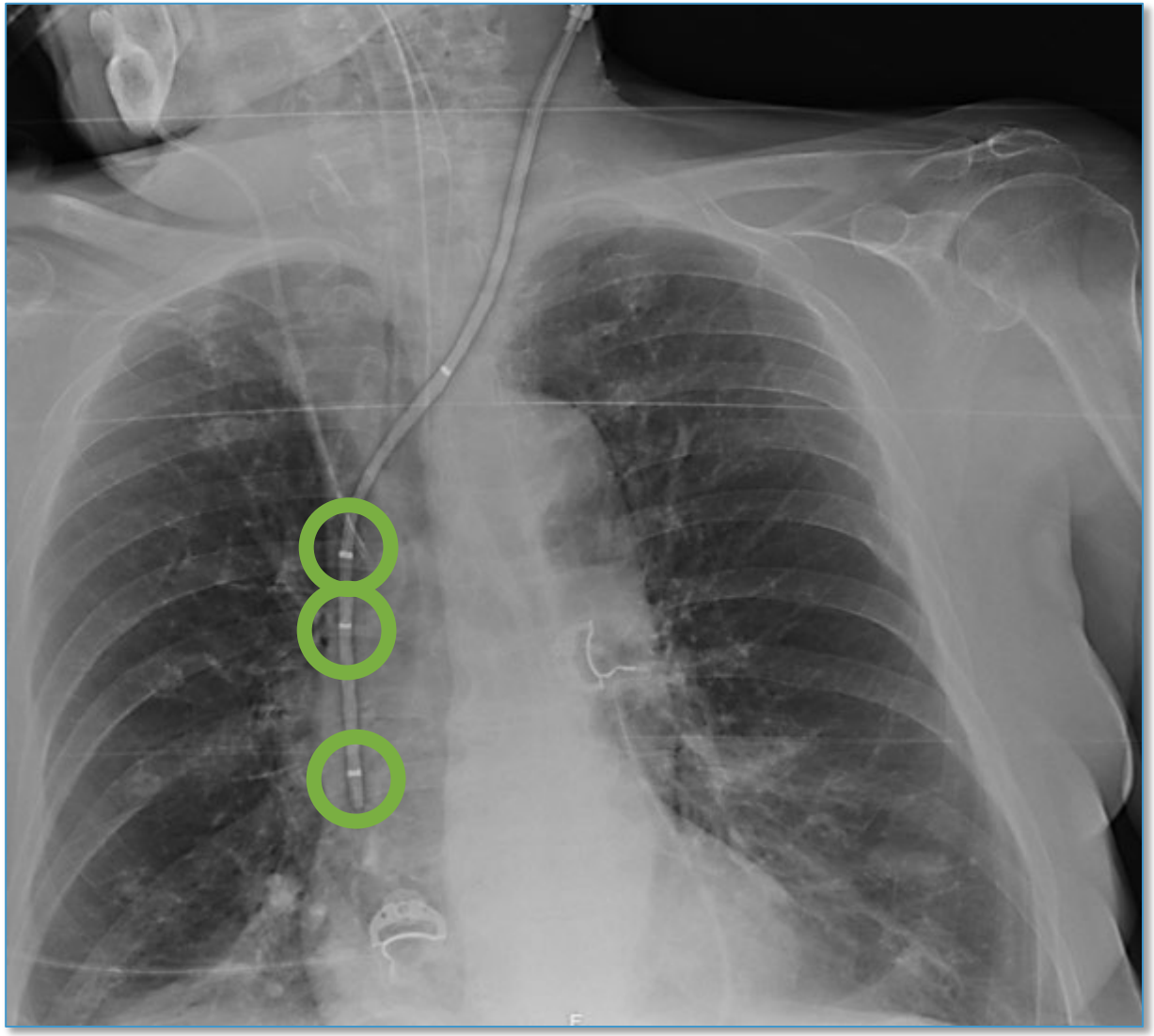
- Three marker bands are visible on the right side of the mediastinum.

Why it matters:

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

What to do:

- Neurostimulation Catheter should be retracted approximately 5 cm.



Neurostimulation Catheter Insertion too Shallow

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

Indication the tip is too shallow:

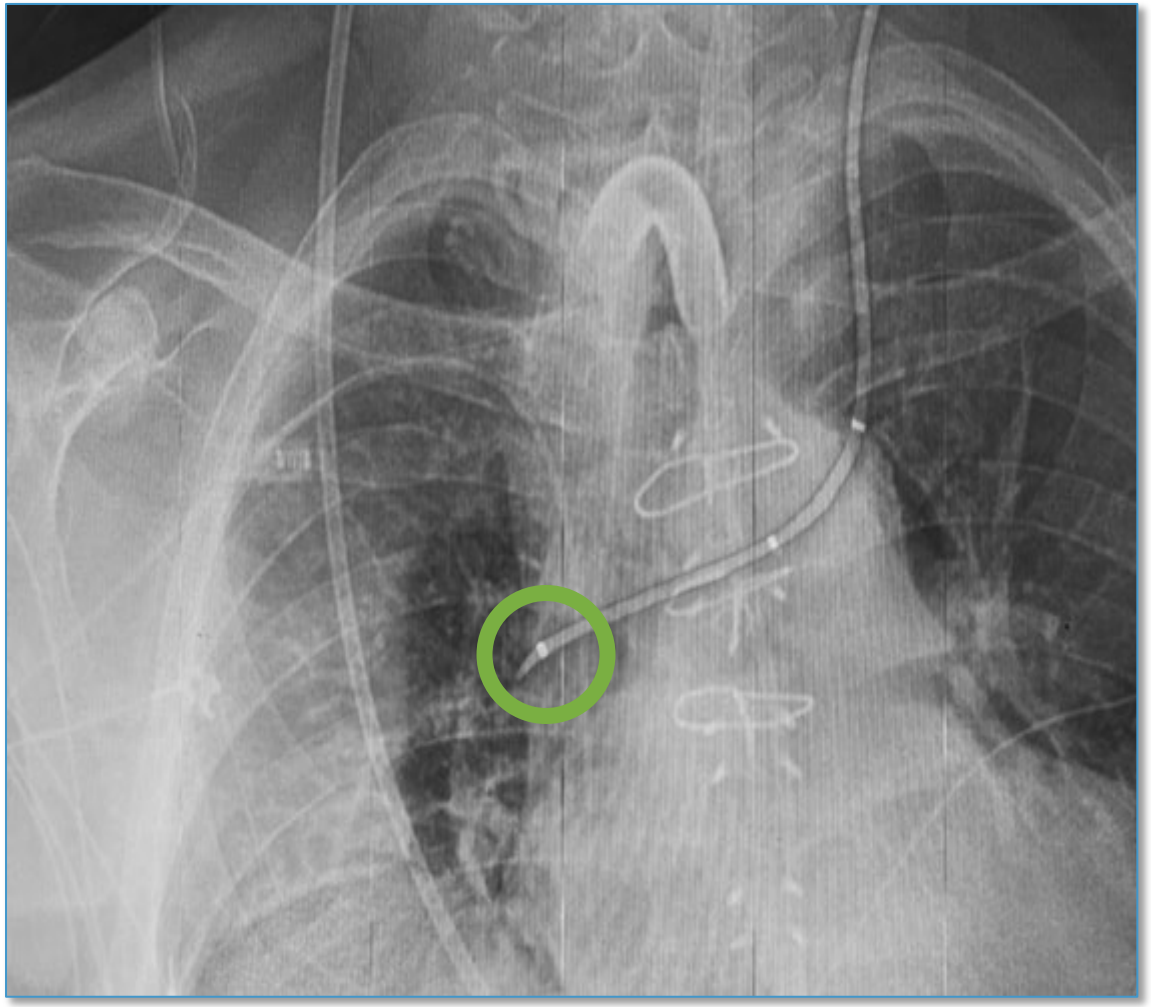
- May be in the brachiocephalic vein.
- Tip angled ~90° to the vertical of the SVC wall: Left sided CVCs, including the Neurostimulation Catheter, should have a tip angle less than <40° to the vertical in order to avoid abutting the vessel wall.*

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.



* *Stonelake, P. (2006) The carina as a radiological landmark for central venous Neurostimulation Catheter tip position. British Journal of Anaesthesia.; 96 (3): 335–40.*

Neurostimulation Catheter Suturing

Suture the hub, and add a secondary clamp as needed for insertions ≤20cm

20-23 cm
Suture **hub**

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.

≤20cm
Suture **hub + secondary clamp** at insertion point (see next slide)

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

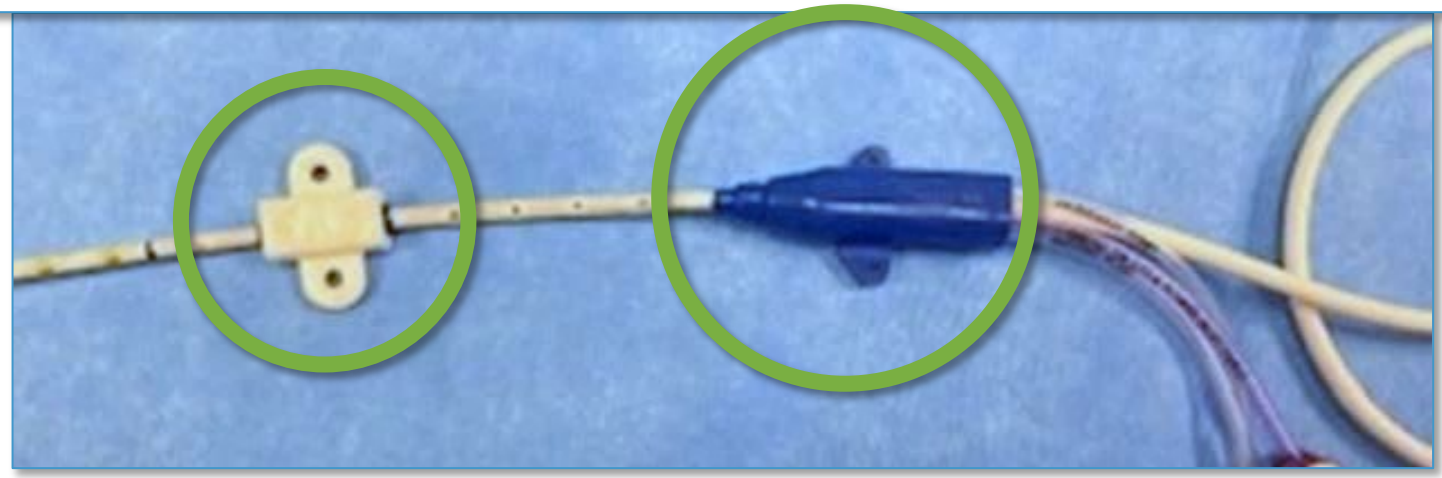
Using the Secondary Clamp

Needed for Neurostimulation Catheter insertions ≤20cm only

Assembled Secondary Clamp

To use the secondary clamp:

1. **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 subject's skin using its holes. *Never directly suture into the Neurostimulation Catheter shaft.*
4. **Suture the blue Neurostimulation Catheter hub** to the subject's skin using its holes.



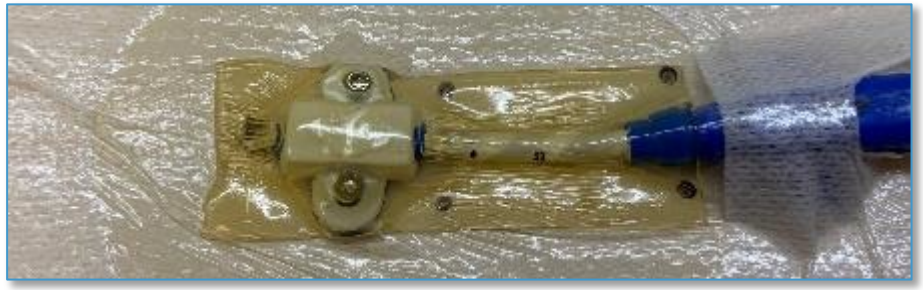
Note: Always follow your institutional guidelines for infection prevention and dressing of the Neurostimulation Catheter insertion site.

Neurostimulation Catheter Suture Dressing

Cover sutures with a gel pad to minimize Neurostimulation Catheter bends

After suturing the Neurostimulation Catheter in place, secure it using a **transparent dressing with chlorohexidine gel pad*** to minimize bends at the hub.

Position the gel pad over the insertion site and hub where it meets the Neurostimulation Catheter.



Suggested dressing size is 10 x 15.5 cm with a 3 x 7 cm chlorohexidine gel pad. Use a plain transparent dressing if it is not possible to use one containing the gel pad.

Neurostimulation Catheter Care After Insertion

Follow institutional guidelines and handle with care

- The Neurostimulation Catheter is designed for **single insertion and use**.
- Follow Lungpacer Instructions for Use and 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.

Lungpacer®
STARI Study
AeroNova Training

Pop Quiz

Neurostimulation Catheter Insertion

Scan the QR code with your phone to begin.

Lungpacer®
STARI Study
AeroNova Training

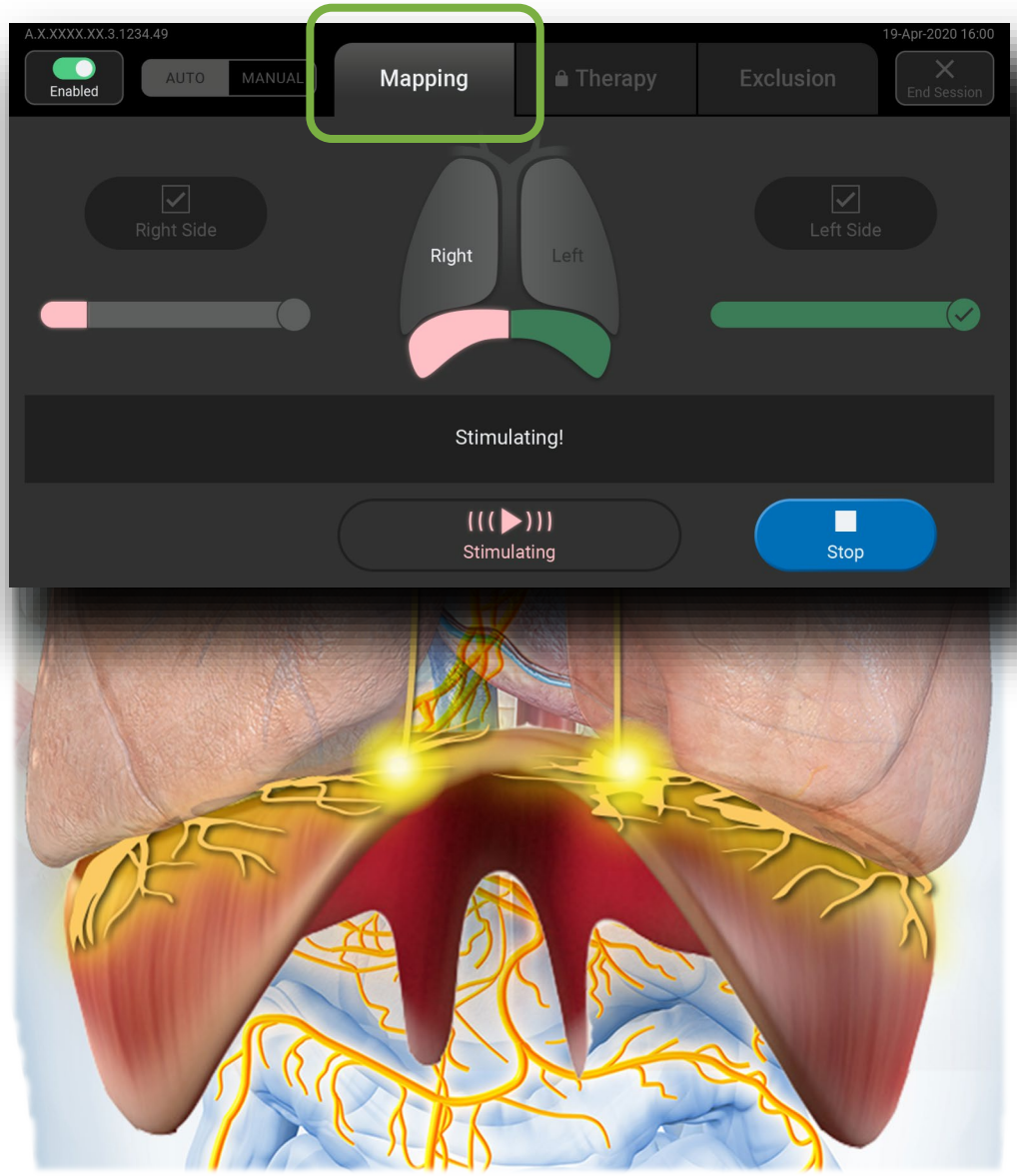
- Unmet Clinical Need
- AeroNova System

AeroNova Therapy (Protection and Rehabilitation)

- Therapy Controls
- MRI Safety and Additional Information

Mapping
Selects electrodes that effectively contract the diaphragm

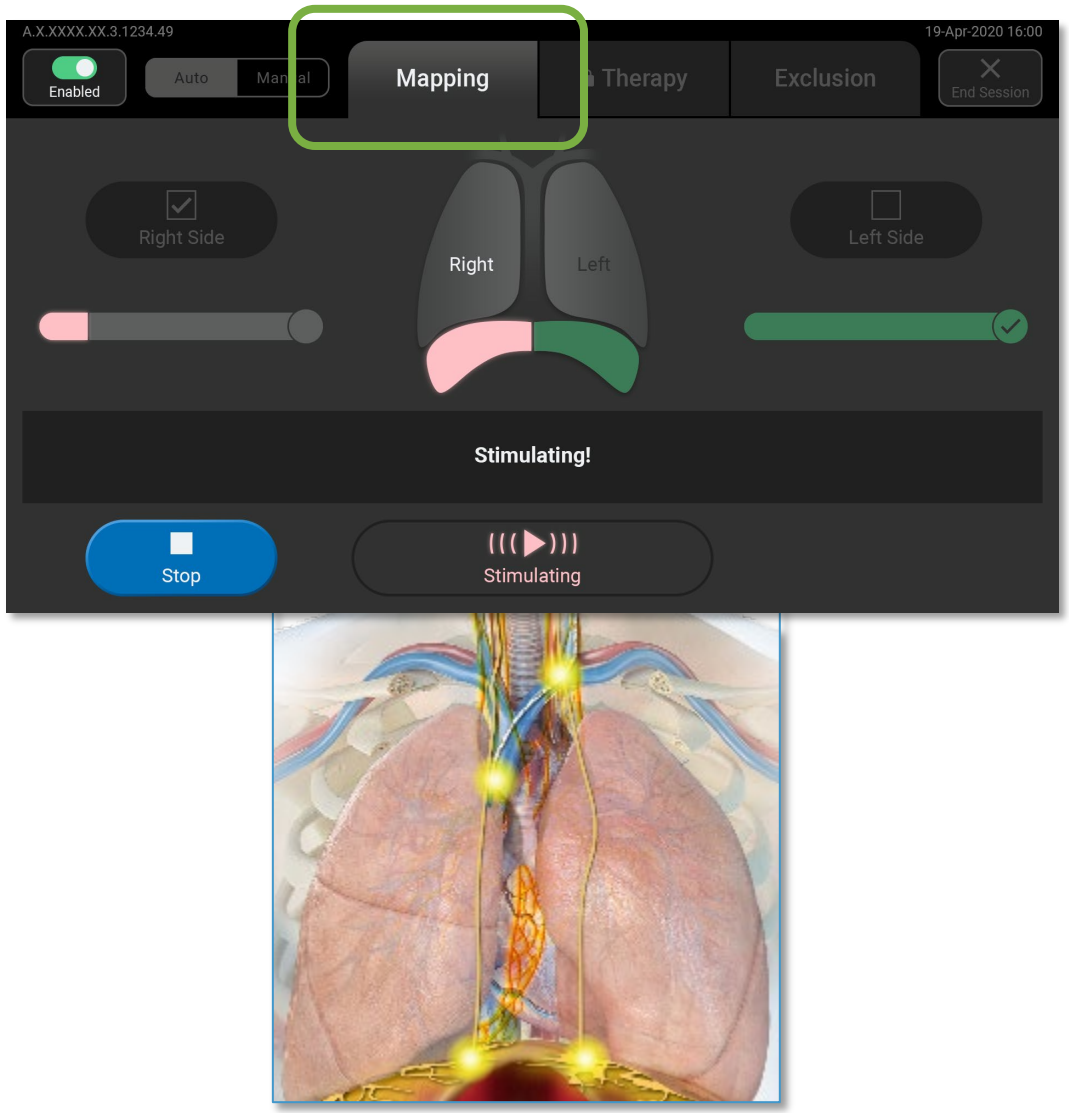
Mapping identifies and selects Neurostimulation Catheter electrodes that are positioned to effectively contract the diaphragm on both sides, and determines the minimum electrical charge required for diaphragm contraction.



Mapping: Overview

Selecting electrodes that effectively contract the diaphragm

Why Mapping is Important: Mapping must be performed before each Therapy session, so that the System can identify and select effective electrodes for Therapy. Mapping should be repeated if the subject position is changed, or during long Therapy sessions to ensure consistently effective nerve capture.



Performing Mapping

In Auto mode, Mapping proceeds and completes automatically

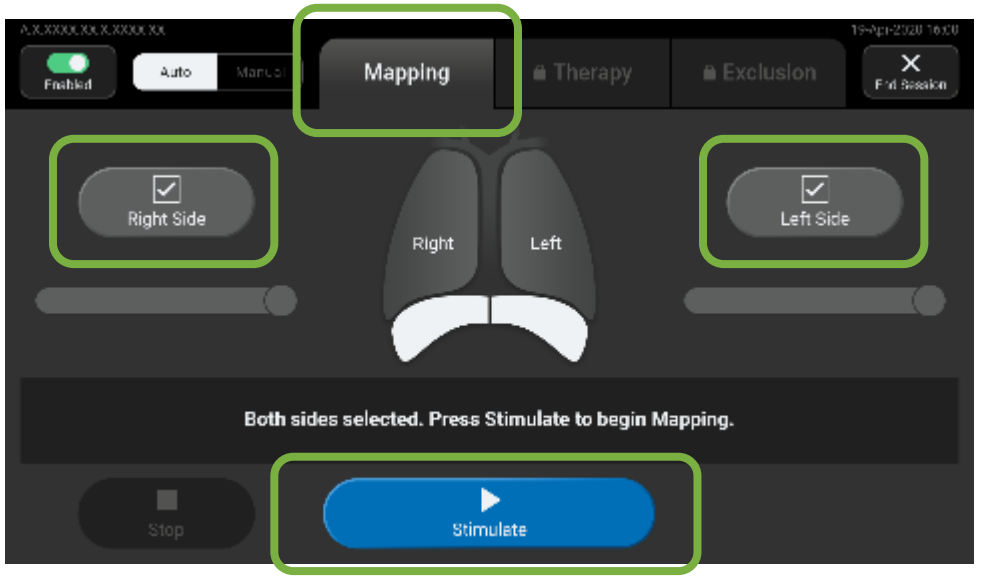
Mapping Instructions

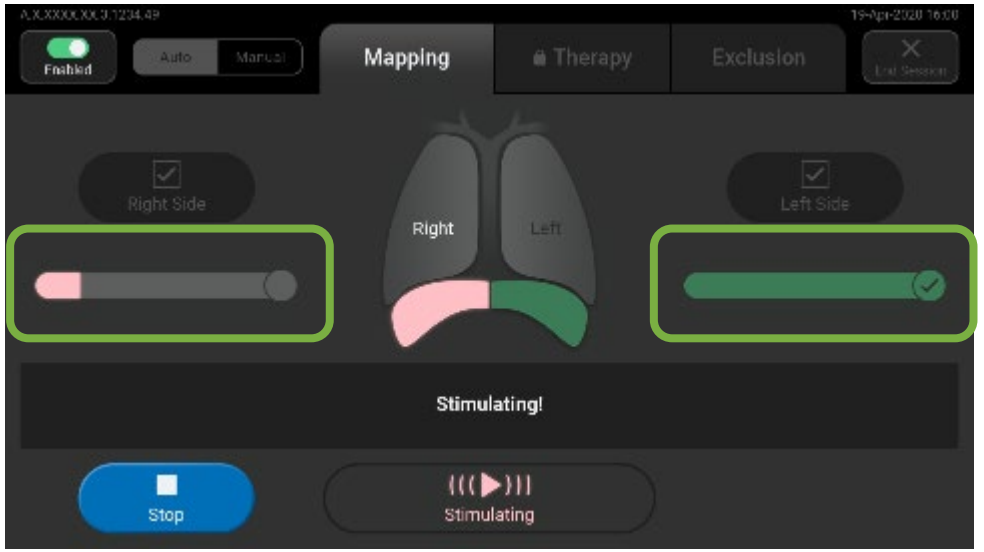
1. After Placement completes successfully, the **Mapping** tab automatically displays.

   *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. In Auto mode, **Mapping completes automatically** on the selected side(s). It typically completes in a few minutes (or less).

Mapping Troubleshooting

- ❑ If Auto Mapping is unsuccessful, repeat it. Consider repositioning the subject.
- ❑ If unwanted effects occur, use the Stop button.
- ❑ Try Manual mode if Auto Mapping is persistently unsuccessful or results in unwanted effects. See the System User Guide for details.





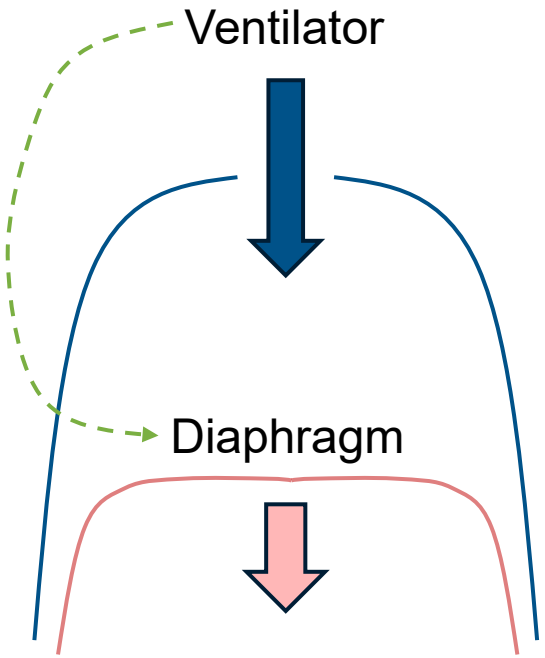
Continual AeroNova Therapy

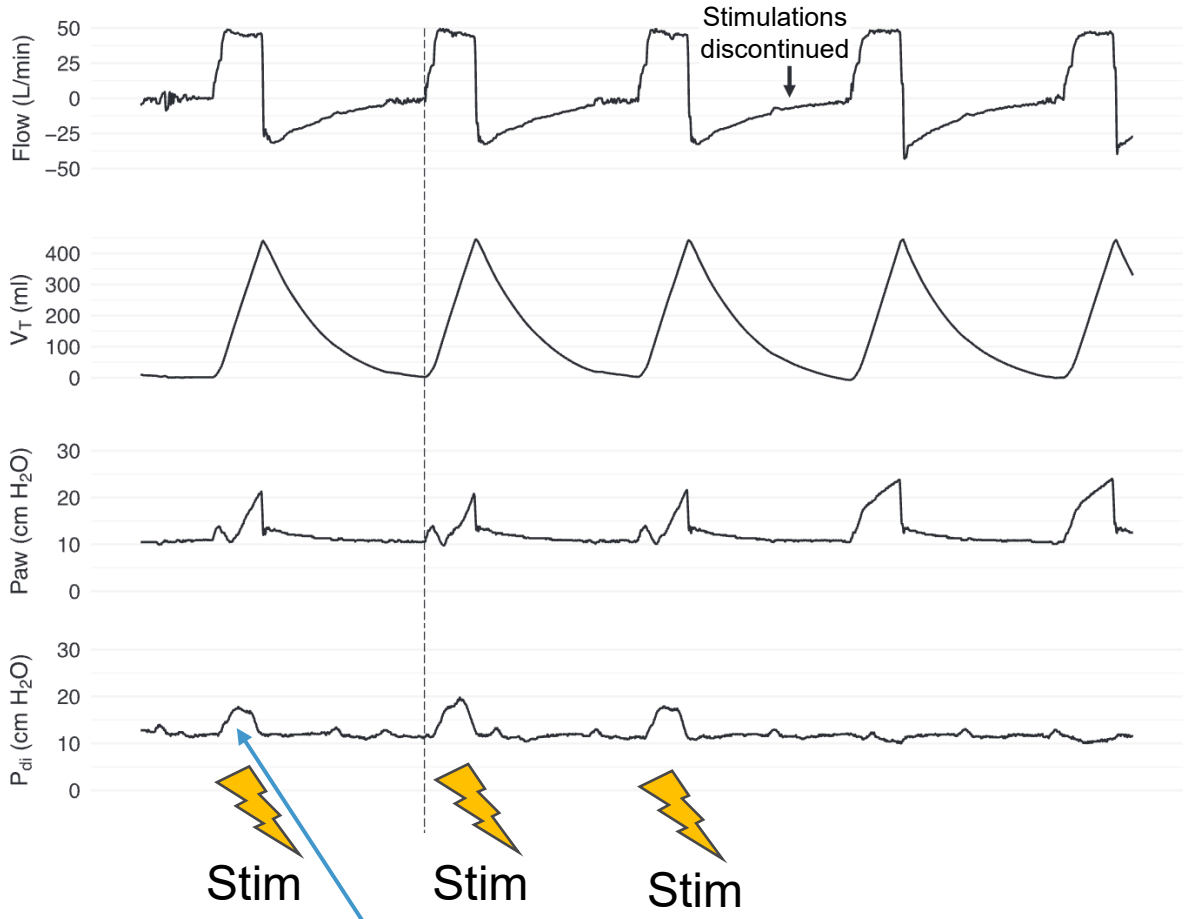
Stimulations maintain diaphragm function and reduce MV positive pressure

The **protection phase** of AeroNova Therapy is delivered adjunctively with MV **continuously** for patients reliant on MV.

Continual AeroNova Therapy and Ventilator Diaphragm Interaction

Waveforms during the protection phase of AeroNova Therapy



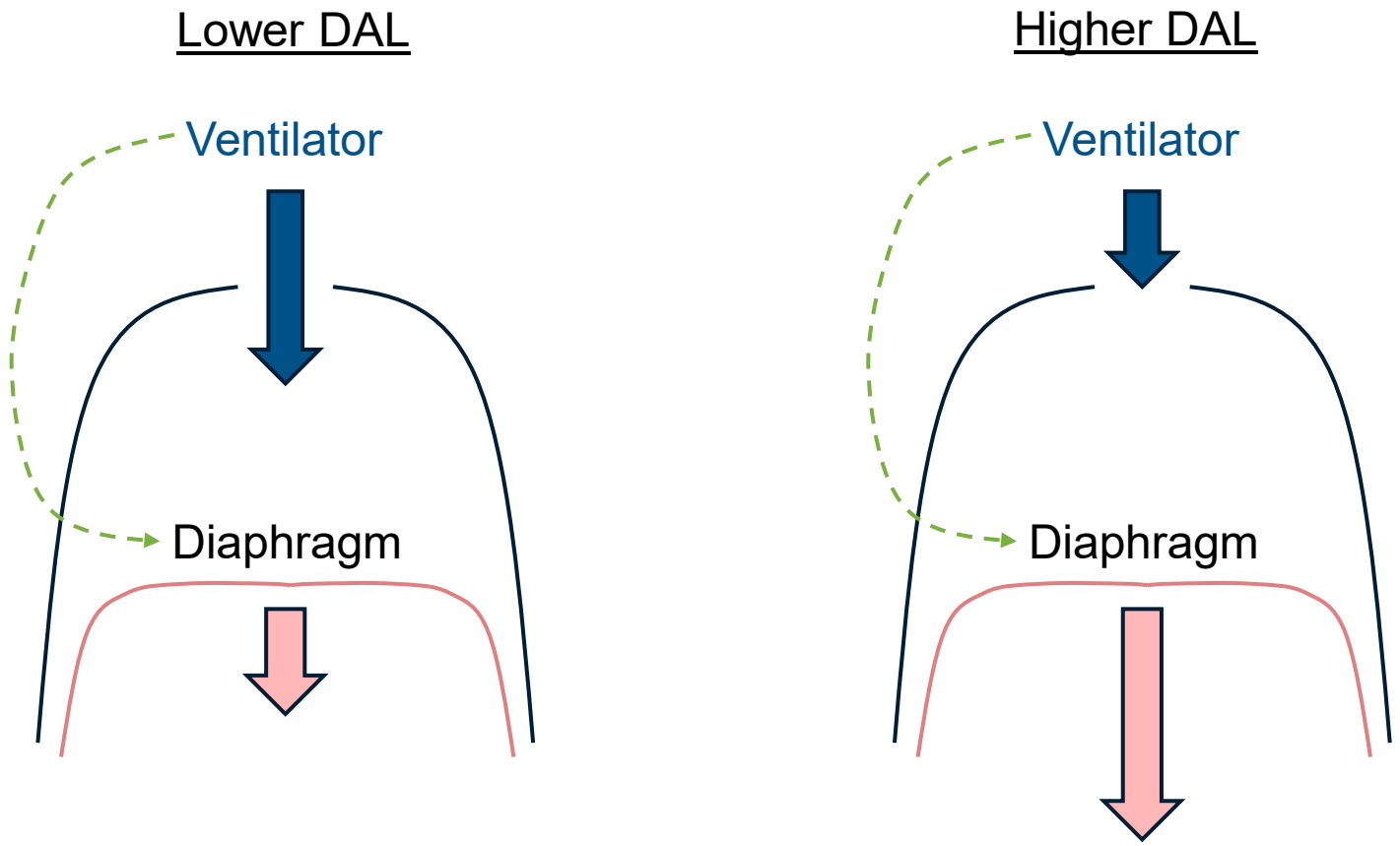


Area under curve = PTP (Pressure-Time Product) = diaphragm effort

From Morris et al. *AJRCCM* 2023

Continual AeroNova Therapy & ACVC Ventilation Modes

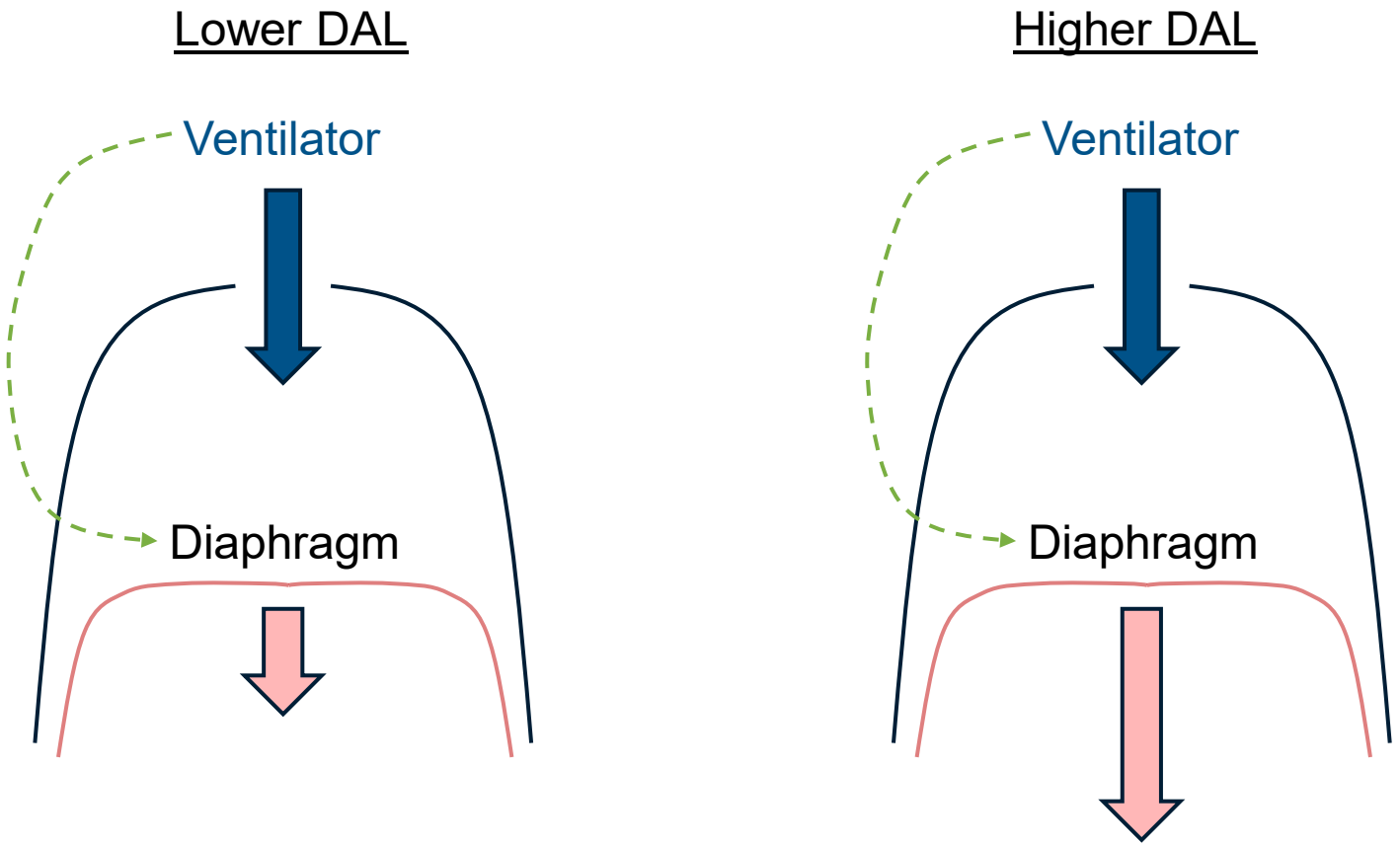
Assist Control Volume Control Ventilator and Diaphragm Interaction



In ACVC, when DAL increases, ventilator contribution decreases, total tidal volume does not change
Therefore, assess **diaphragm activation level** by measuring decrease in ventilator-delivered pressure

Continual AeroNova Therapy & PCV Ventilation Modes

Pressure Control Ventilation and Diaphragm Interaction



In PCV, ventilator contribution does not change; total tidal volume increases as DAL increases
Therefore, assess **diaphragm activation level** by measuring relative increase in tidal volume

DAL Readings

Estimating diaphragmatic contraction intensity and contribution to breathing

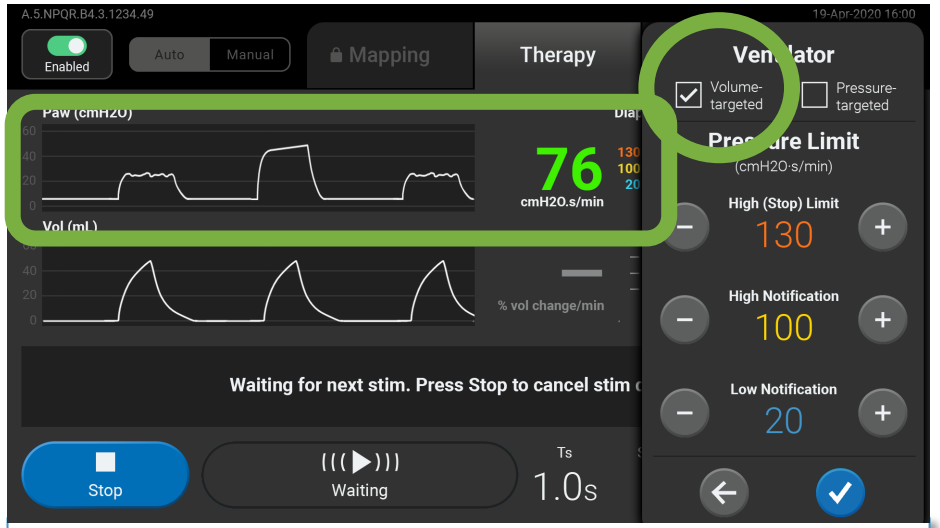
Diaphragm Activation Levels represent the diaphragm's contribution to the work of breathing, **averaged over one minute**. They are displayed on the Therapy screen in two measurements:

1. **cmH_2O•s/min**:
   Reduction in pressure during **Volume ventilation**

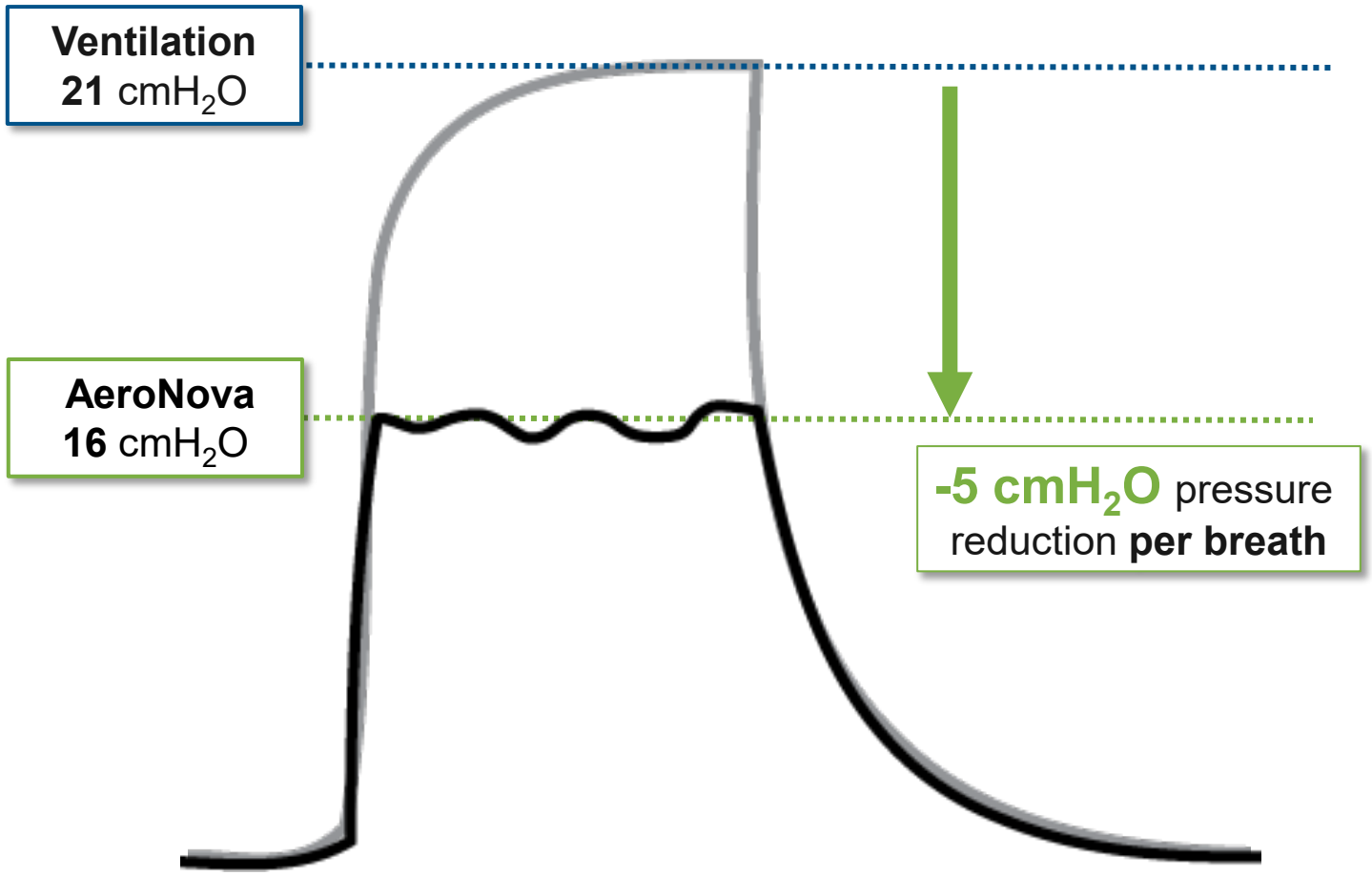
2. **% vol change/min**:
   Increase in volume during **Pressure ventilation**

Volume Ventilation Modes = Pressure Reduction

AeroNova reduces peak pressure while providing same volume



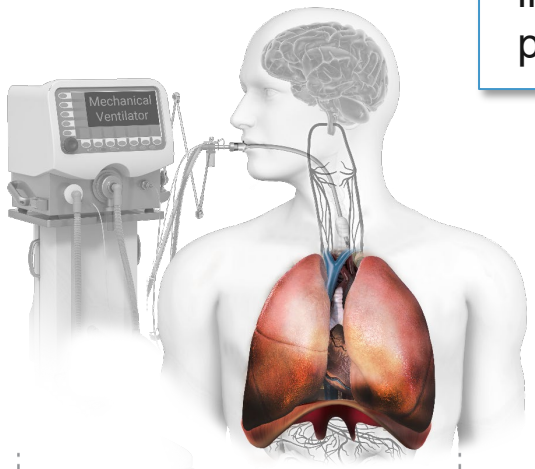
When used with a ventilator in “**Volume-targeted**” modes, AeroNova will generate negative pressure that **reduces the peak pressure delivered without reducing tidal volume.**



Volume Ventilation | DAL = $cmH_2O.s/min$ (pressure reduction)

DALs are calculated as an average over one minute of breathing

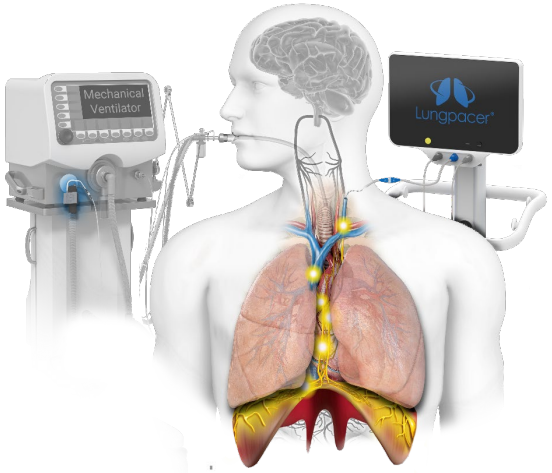
During Volume ventilation, the DAL and notification limits are displayed in **cmH_2O•s/min**, providing an estimate of the average reduction in peak pressures achieved over **one full minute** of breathing.

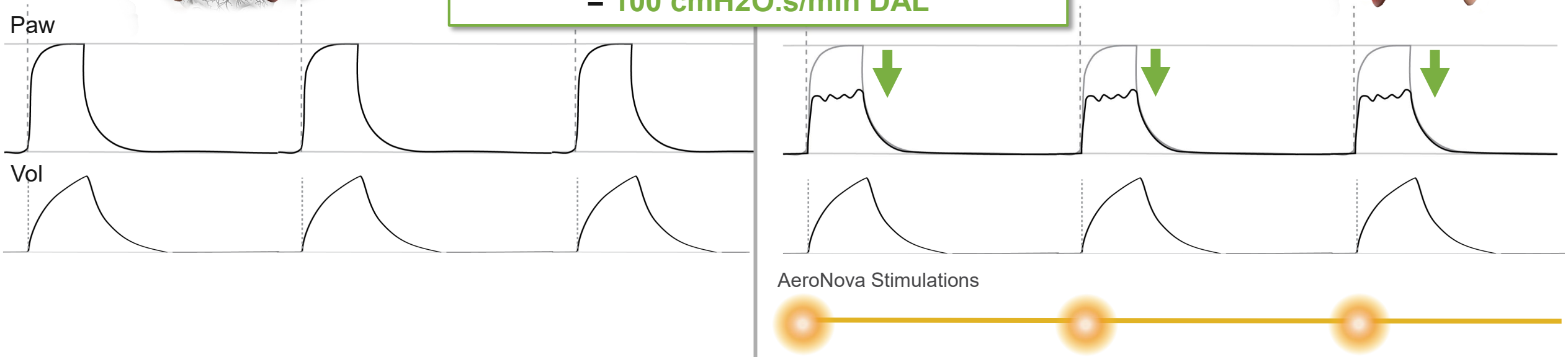


Ventilator
21 cmH_2O per breath

AeroNova
16 cmH_2O per breath

DAL Calculation
21 cmH_2O (Ventilator) **- 16** cmH_2O (AeroNova)
= -5 cmH_2O per breath x **1.0** s Ts x **20** breaths/min
= 100 cmH2O.s/min DAL

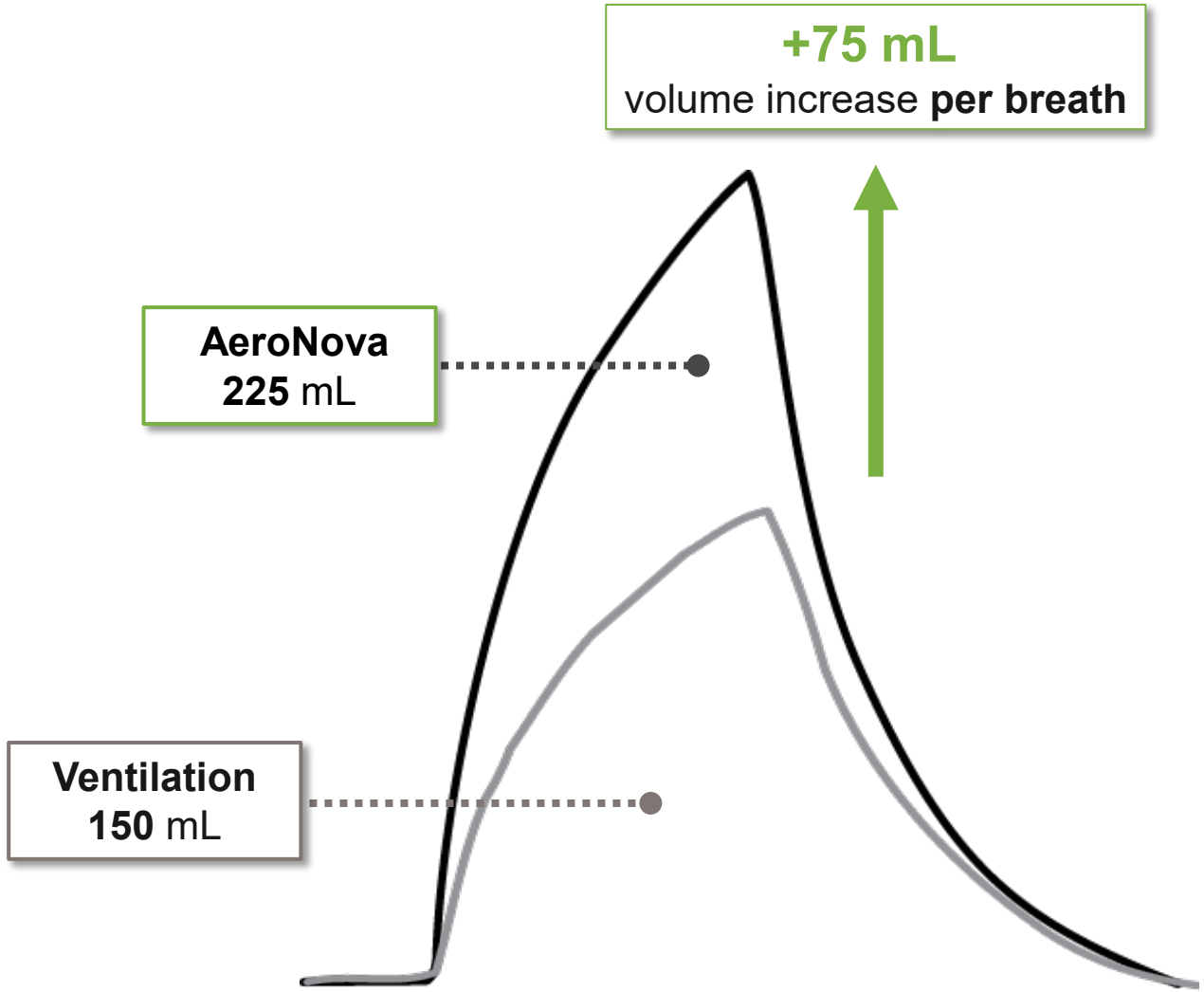




Pressure Ventilation Modes = Volume Increase

AeroNova increases volume while providing same pressure

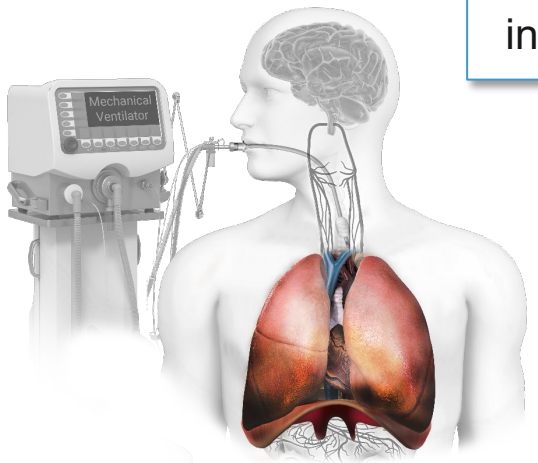
When used with a ventilator in “**Pressure-targeted**” modes, AeroNova will generate negative pressure that **increases the volume of air delivered without increasing the peak pressure.**



Pressure Ventilation | DAL = % vol change/min (vol increase)

During pressure ventilation, AeroNova will increase tidal volumes

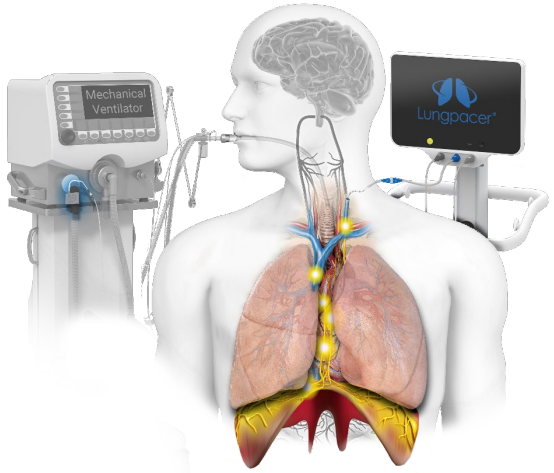
During Pressure ventilation, the DAL and notification limits are displayed in **% vol change/min**, providing an estimate of the average volume increase percentage achieved over **one full minute** of breathing.

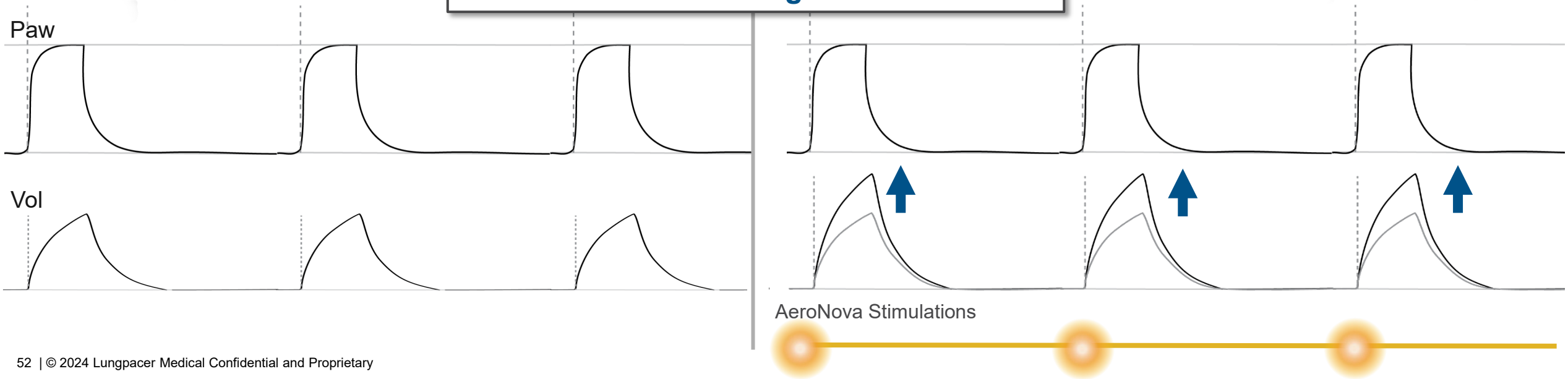


Ventilator
150 mL per breath

AeroNova
225 mL per breath

DAL Calculation
225 mL (AeroNova) **- 150** mL (Ventilator)
= +75 mL per breath
= 50 % vol change/min DAL





Protection Phase: Starting Continual AeroNova Therapy

Begin with default values, then titrate DALs and set limits

1. The AeroNova System default settings are preconfigured to begin Continual Therapy. **Press Stimulate to begin**.

   Note: *Before beginning Continual Therapy, adjust settings only as needed depending on the specific needs of the study protocol and/or subject.*

2. The AeroNova System will perform a few calculations (such as refining the stimulation current and calculating the baseline DAL) before beginning stimulations. **As stimulations begin, observe the subject** to confirm the diaphragm contracts, and look for signs of discomfort.

Setting the Ventilation Mode

Ensure AeroNova System settings are compatible with the ventilator mode

1. **Press the DAL area** of the Therapy screen.
2. **Check the Volume-Targeted or Pressure-Targeted box** to match the mode of mechanical ventilation.
3. **The DAL on-screen will display in either cmH$_2$O.s/min *or* % vol change/min** as appropriate for the selected ventilation mode.

   Note: *If the configurable limits in the pop-up become disabled (display "--"), press the blue check button, and then select the other, active DAL area of the Therapy screen to set the limits associated with the selected ventilation mode.*

Setting DAL Notification Limits for Continual Therapy

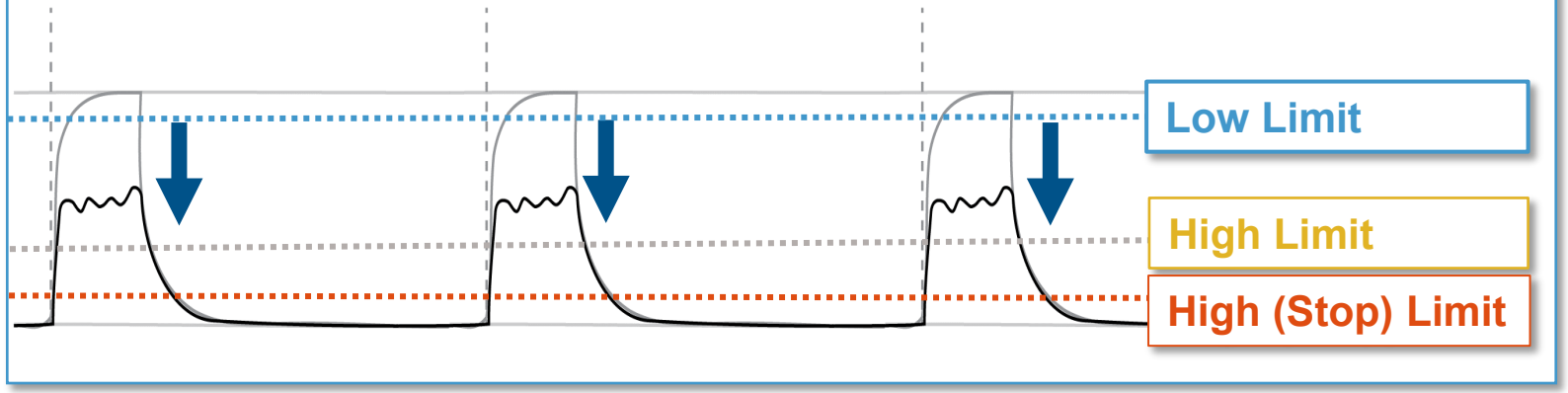
Ensuring the subject's DAL can be retained within the desired range

1. **Set the High (Stop) Limit** value.
2. **Set the High Notification** and **Low Notification** limits.

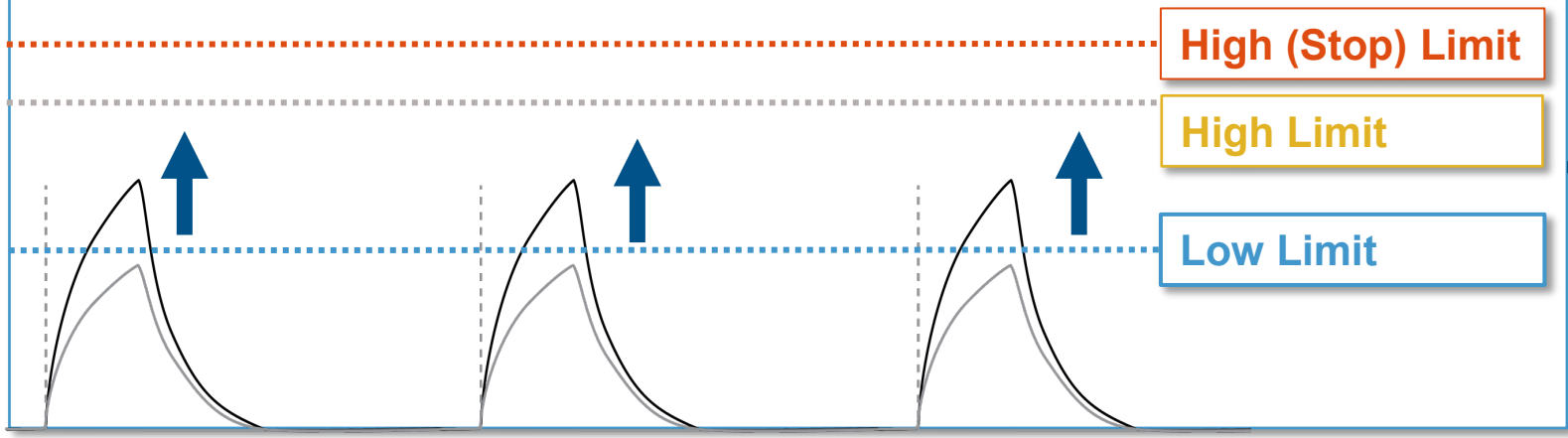
DAL Notifications and Limits

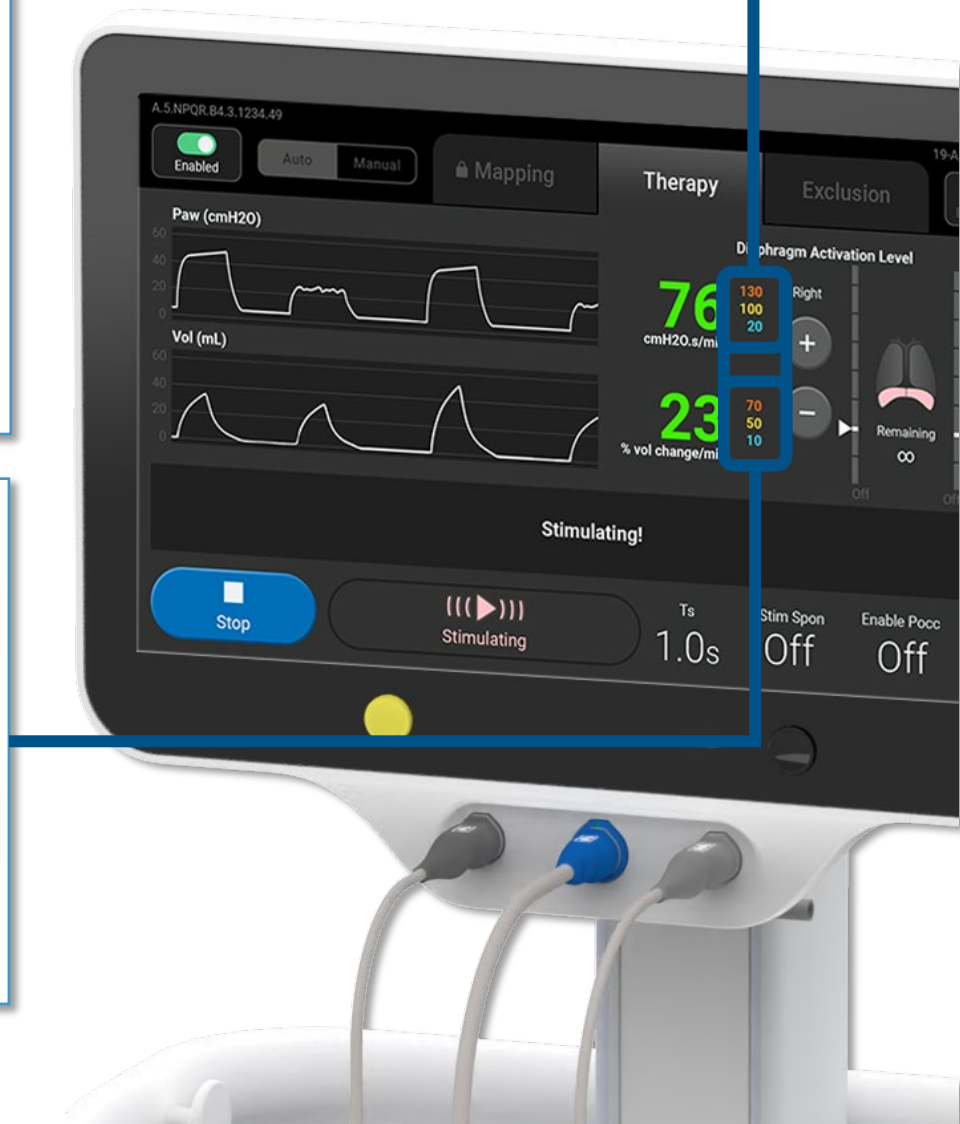
User-configurable constraints for diaphragm activation

$cmH_2O.s/min$ (limiting pressure reduction during volume ventilation)



% vol change/min (limiting volume increase during pressure ventilation)





On-Screen DAL Notifications

Visual and auditory indications that the DAL is outside the desired range

The **Diaphragm Activation Level notifications and Therapy stop limit** are user-configurable. They allow the user to generate a notification - automatically stop stimulations - if the diaphragm activation level is outside the desired range.

During Continual AeroNova Therapy

Keep DALs in the desired range

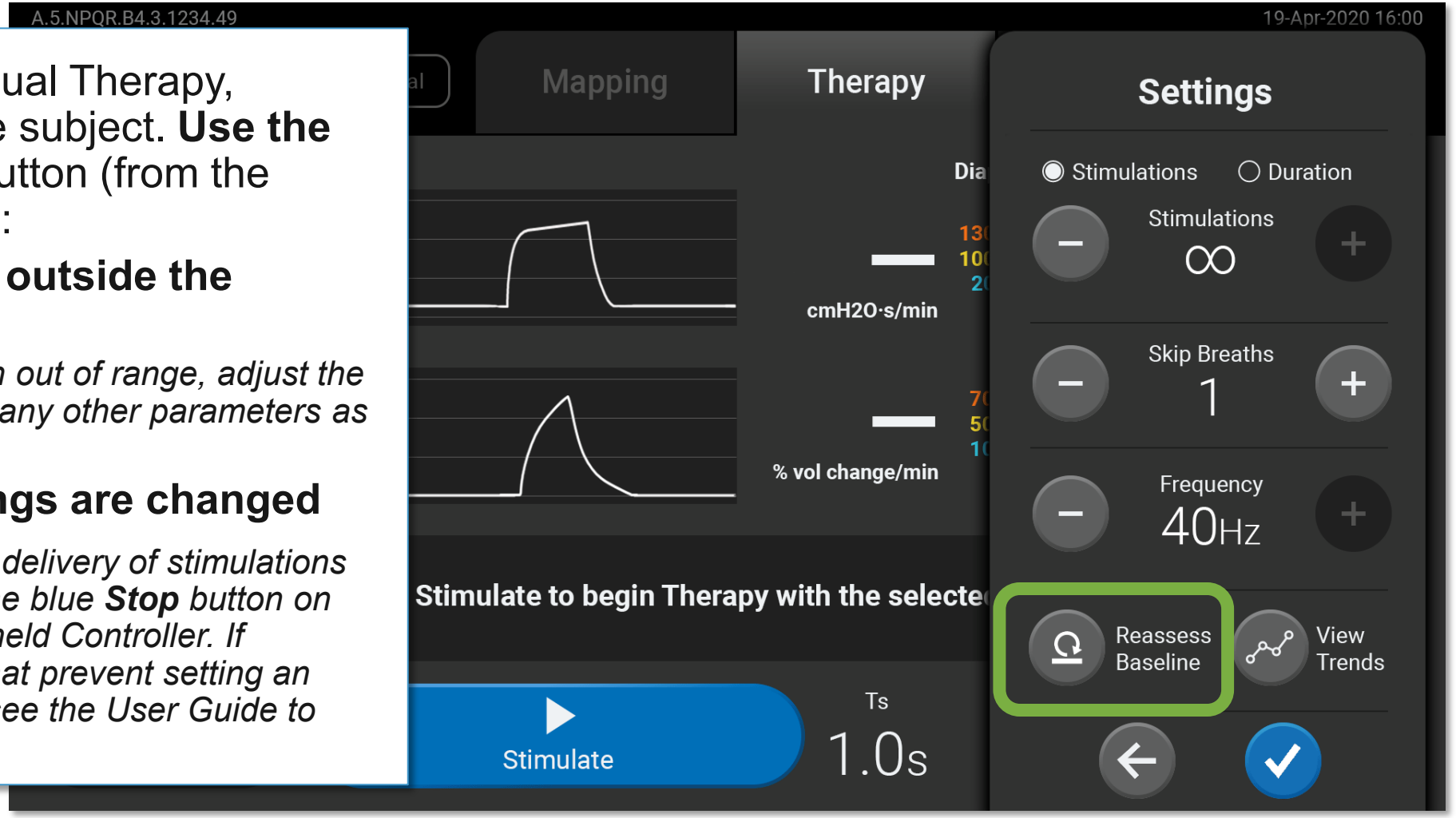
While providing Continual Therapy, continue to monitor the subject. **Use the Reassess Baseline** button (from the Settings pop-up) when:

- **DAL values fall outside the desired range**

  Note: If DALs remain out of range, adjust the Therapy Levels and any other parameters as needed.

- **Ventilator settings are changed**

- ***Note:** If needed, stop the delivery of stimulations at any time by pressing the blue **Stop** button on the touchscreen or Handheld Controller. If unwanted effects occur that prevent setting an effective Therapy Level, see the User Guide to perform Exclusion.*



Rehabilitation Phase: Intermittent High-Intensity Therapy

Stimulations to build diaphragm strength

AeroNova High-Intensity Therapy is delivered intermittently for patients beginning to breathe spontaneously. Sets of high-intensity stimulations are delivered to increase the subject's diaphragm strength and **facilitate weaning** from mechanical ventilation.

 |

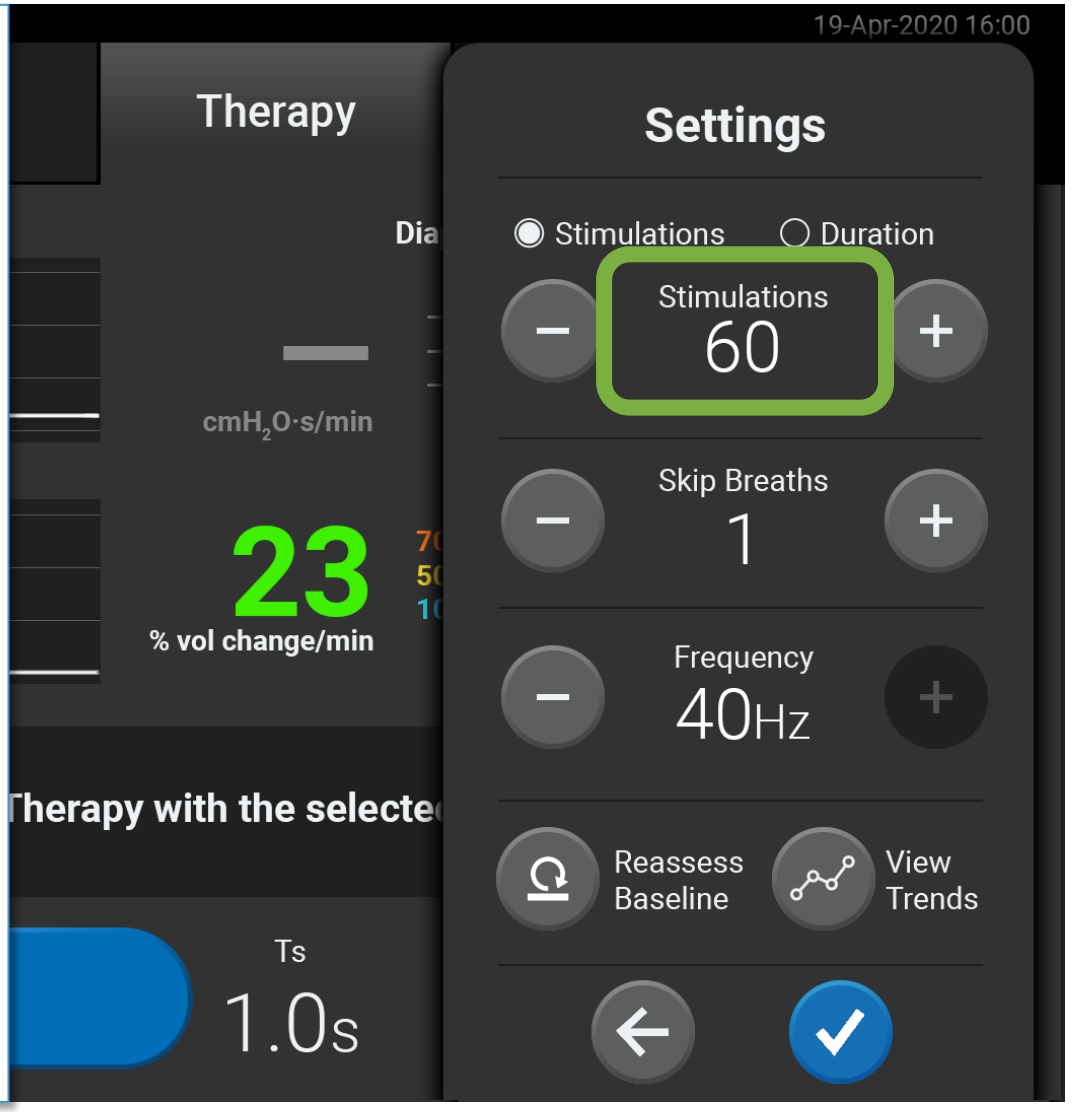
Starting Intermittent High-Intensity Therapy

60 stimulations in 2 sets each day in spontaneously breathing subjects

Rehabilitation – Intermittent High-Intensity Therapy

Once the subject begins breathing spontaneously, the patient transitions off Continual Therapy, and instead, a set of 60 stimulations are delivered twice each day at maximum intensity:

1. Press the DAL section of the screen and set the **Ventilation Mode** to **Pressure-Targeted.**
2. Press the Settings button and set the number of **Stimulations** to the desired value.
3. Press the plus (+) buttons to **maximize the Diaphragm Activation Level** on each side.
4. Press **Stimulate** to deliver a Therapy session



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Pop Quiz

AeroNova Therapy: Protective and Rehabilitation Phases

Scan the QR code with your phone to begin.

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STARI Study

AeroNova Training

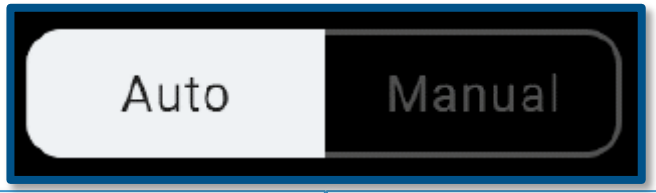
- Unmet Clinical Need
- AeroNova System
- Neurostimulation Catheter Insertion, ECG, and Placement
- AeroNova Therapy (Protection and Rehabilitation)

Therapy Controls

- MRI Safety and Additional Information

Auto mode and Manual mode
Breath Rate led by Ventilator or Console

- In **Auto mode**, the AeroNova System uses data from the Airway Sensor to deliver **stimulations in time with breaths triggered by the ventilator.**
- In **Manual mode**, the AeroNova System delivers stimulations at a set rate. These **stimulations trigger ventilator breaths** at the Stim Rate configured on the Console. Refer to the AeroNova System User Guide for detailed instructions on the use of Manual mode.



Auto: Ventilator controls breath timing

Manual: AeroNova System controls breath timing

System Displays: Waveforms and Notifications
Therapy Controls

Paw: Waveform displaying subject airway pressure.

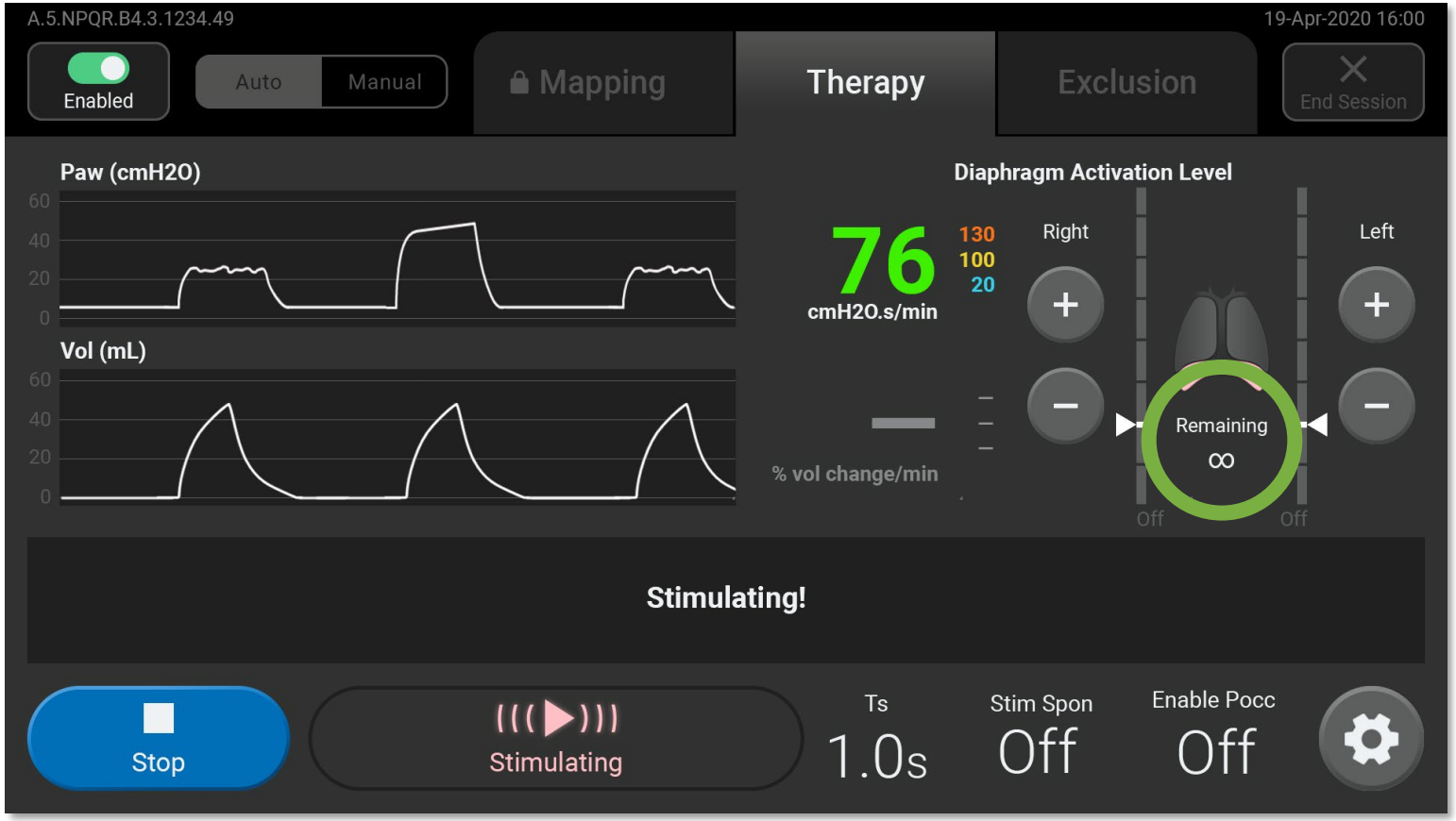
Vol: Waveform displaying inspiratory tidal volume.

Notification box: Displays system status or instructions.

Stimulations: Number or Duration

Stimulations Programmed & Remaining

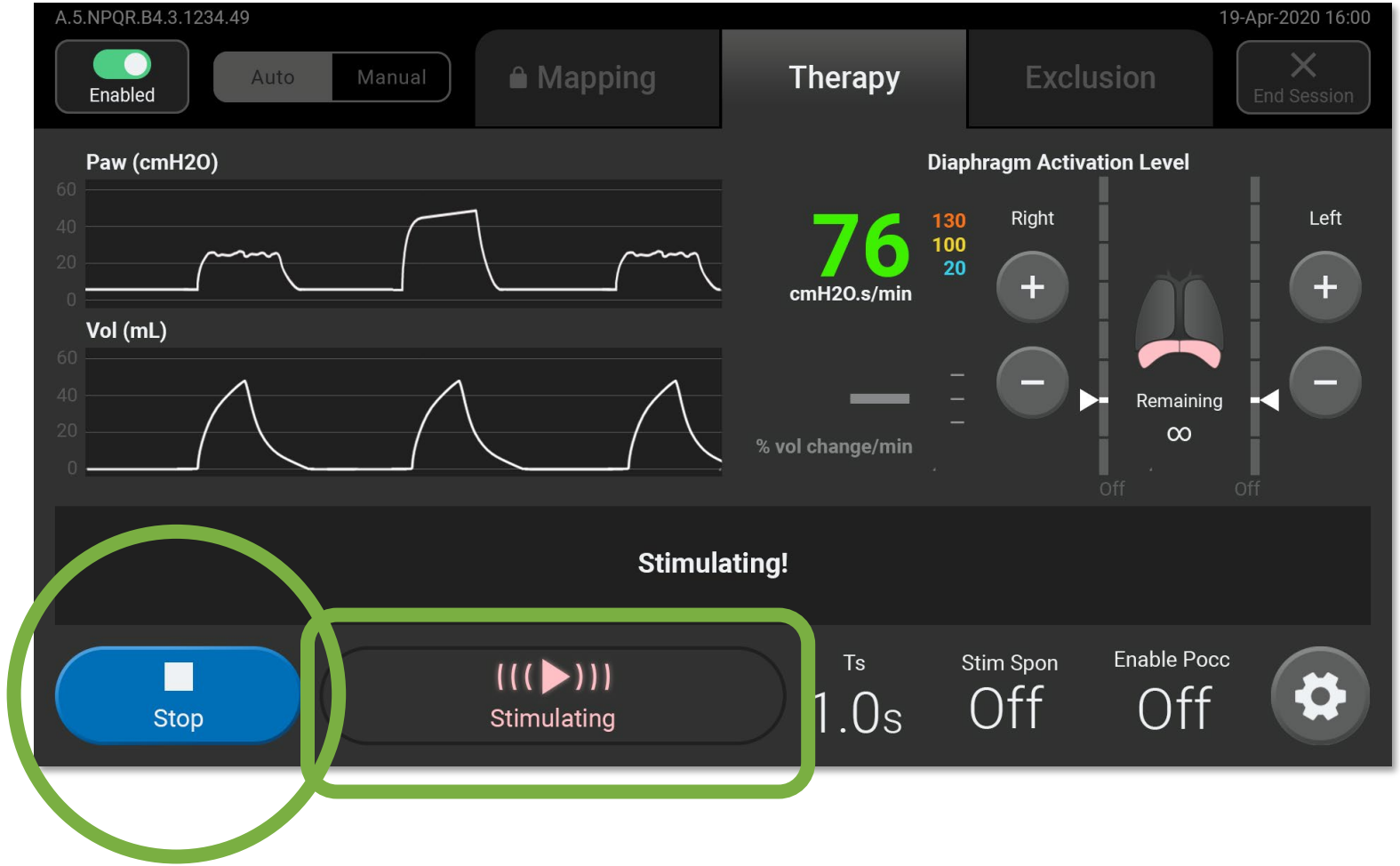
Stimulations: Number or Duration (including infinite) of stimulations programmed or remaining in the Therapy Session. Configurable using the Settings button while Therapy is stopped.



Stop and Stimulate Button
Therapy Controls

Stop: Stops the Therapy session. The Number or Duration of stimulations will reset to the configured value.

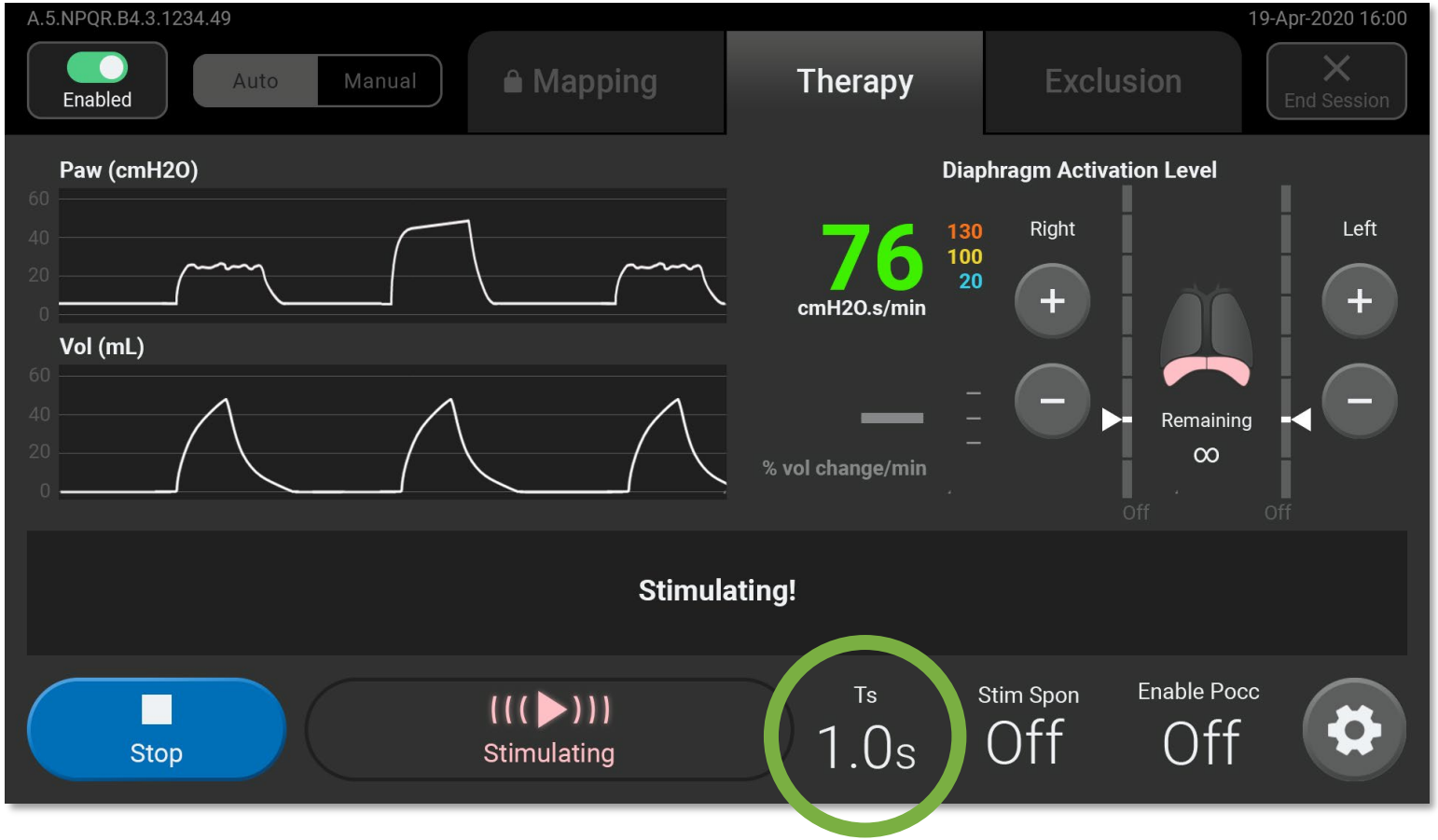
Stimulate: The Stimulate button is used to begin a Therapy session, and then displays stimulation status (Stimulating or Waiting) during a Therapy session.



Ts (Stim Duration)
Therapy Controls

Ts (Stim Duration): The duration of each stimulation during the Therapy session, configurable by pressing this area of the screen. The System automatically detects the Inspiratory Time, and then calculates a Predicted Stim Duration, slightly less than that value. If desired, Ts can be increased or decreased using the Offset button or set as a fixed value using the Fixed Stim Duration checkbox.

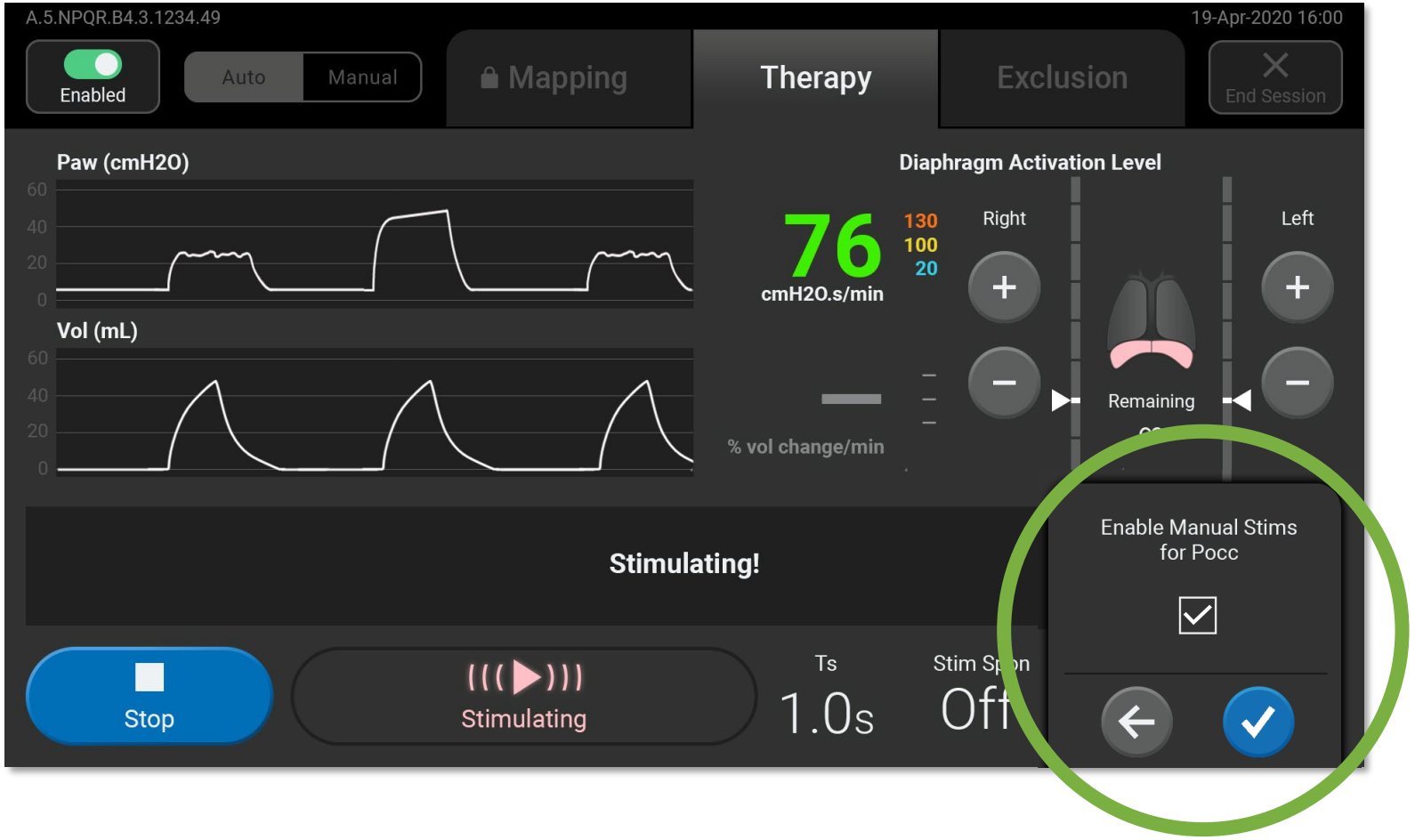
Stim Spon: *Used for spontaneous breathing and not used for subject management.*



Enable Pocc
Therapy Controls

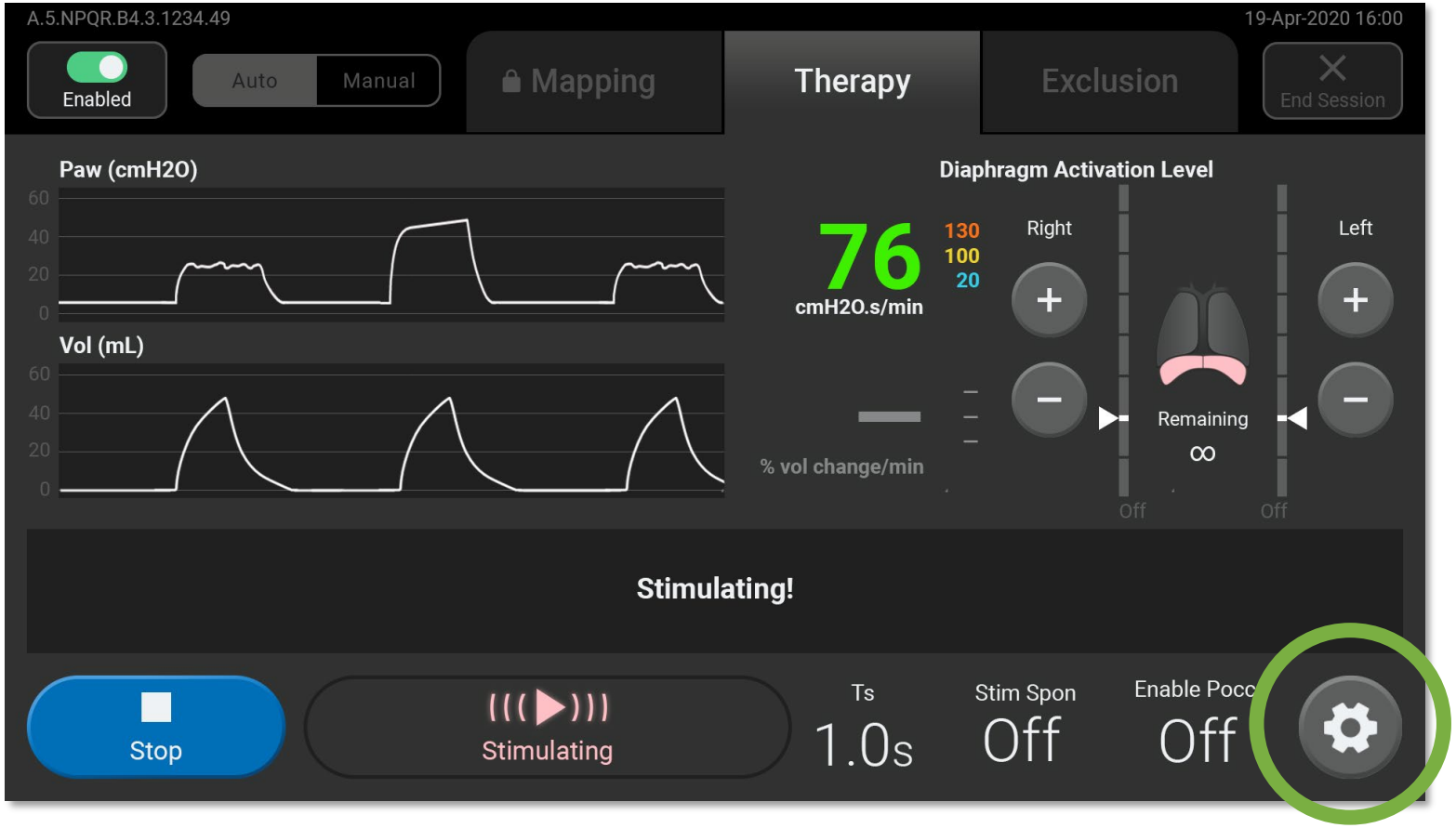
Enable P_{Occ} (Auto mode only): Enables (On) or Disables (Off) the availability of the Stimulate button between Therapy stimulations. Pressing the stimulate button while performing an expiratory hold on the ventilator allows the user to measure the occlusion pressure (P_{Occ}) generated by Therapy stimulations.

Enable P_{Occ} reverts back to the default setting (Off) after two minutes of no user interactions with the System.



Settings Button
Accessing additional Therapy Controls

Settings: Provides access to additional Therapy controls. (See the next slide for details)



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Settings Pop-Up
Additional stimulation and System controls

Stimulations: Radio buttons at the top of the Settings pop-up select whether stimulations are counted as a number of (including infinite) or duration (in seconds).

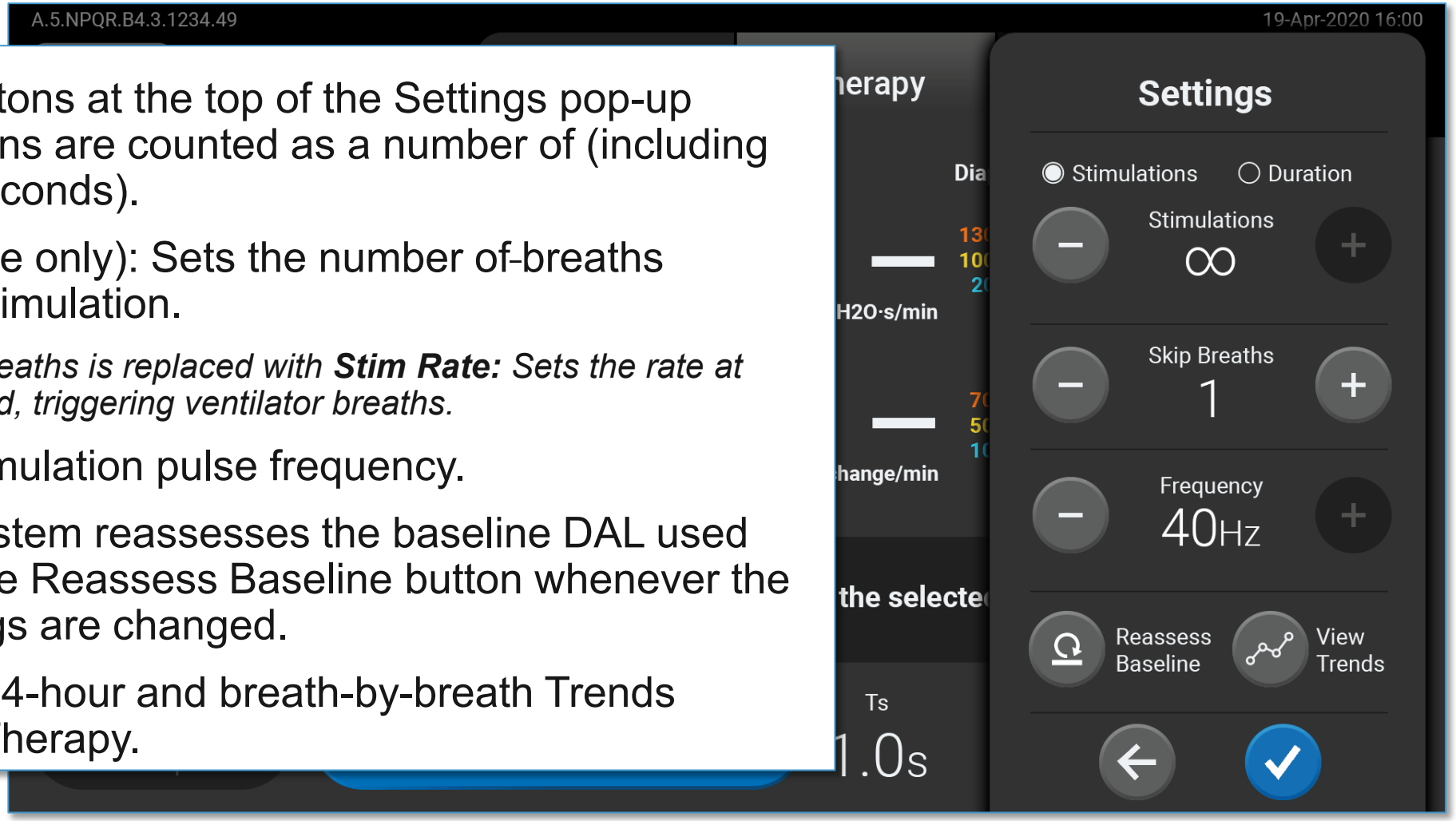
Skip Breaths (Auto mode only): Sets the number of-breaths skipped between each stimulation.

*Note: In Manual Mode, Skip Breaths is replaced with **Stim Rate:** Sets the rate at which stimulations are delivered, triggering ventilator breaths.*

Frequency: Sets the stimulation pulse frequency.

Reassess Baseline: System reassesses the baseline DAL used for calculations. Press the Reassess Baseline button whenever the ventilator setup or settings are changed.

View Trends: Displays 24-hour and breath-by-breath Trends related to the delivered Therapy.



Diaphragm Activation Level Controls

Titrating the Therapy intensity

Therapy Level Controls: The plus (+) and minus (-) buttons adjust intensity of stimulations on each hemidiaphragm side (right and left). Stronger stimulations mean more contribution from the diaphragm with each stimulated breath. The white squares on the vertical bars indicate the baseline levels established for each side during Mapping. Setting the DAL too far below the baselines may deliver stimulations at sub-therapeutic levels.

Titration to Increase DAL

Increasing the diaphragmatic contribution to breaths

To increase the subject DAL:

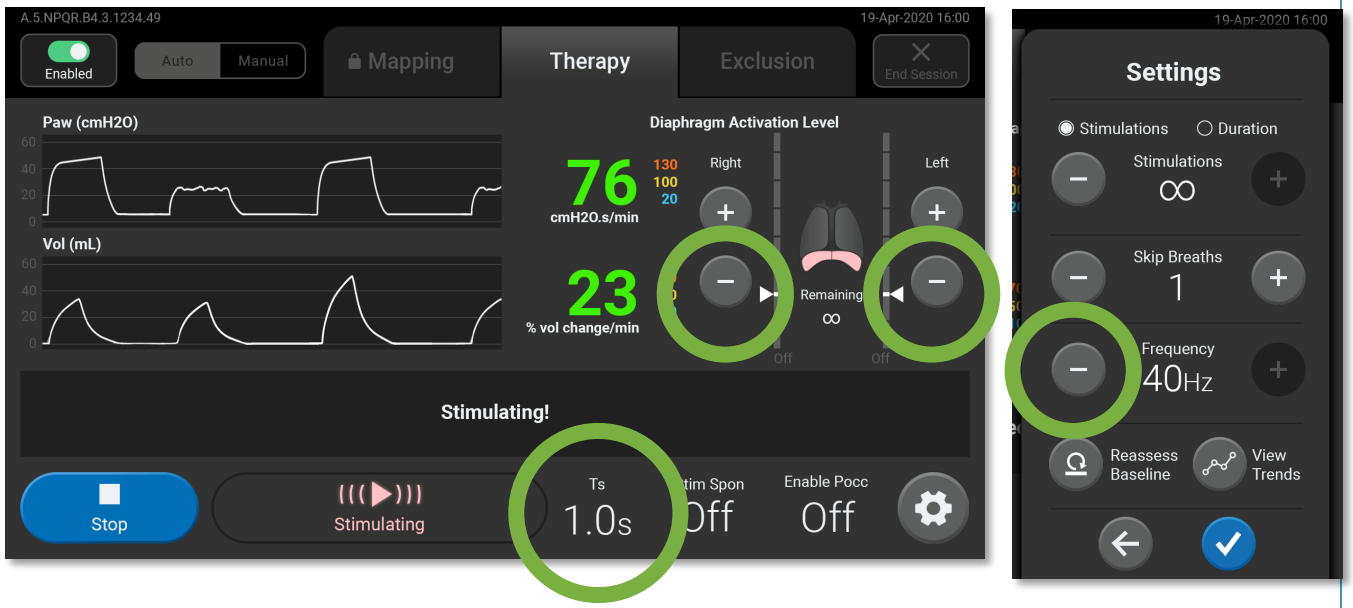
1. First, **Increase (+) DAL with equal clicks on both sides** until reaching the desired diaphragm contribution, or until the maximum value is set.

   Note: *If only one side is needed to achieve the target, increase only the Left DAL.*

2. If DAL is still low, **increase (+) Ts** (Stim Duration), ensuring interaction with ventilator inspiratory time is not affected.

Titration to Decrease DAL

Decreasing the diaphragmatic contribution to breaths



To reduce subject DAL:

1. First, **reduce (-) DAL with equal clicks on both sides** until reaching the desired range of diaphragm contribution, or until lowest value without losing phrenic nerve capture is set.

   Note: *If only one side is needed to achieve the target, reduce only the Right DAL.*

2. If DAL is still high, **reduce (-) Frequency** one increment at a time until reaching the desired range of diaphragm contribution, or until the lowest value (15 Hz) is set.

3. If DAL is still high, **reduce (-) Ts** (Stim Duration), ensuring interaction with ventilator inspiratory time is not affected.

Lungpacer®

STARI Study

AeroNova Training

- Unmet Clinical Need
- AeroNova System
- Neurostimulation Catheter Insertion, ECG, and Placement
- AeroNova Therapy (Protection and Rehabilitation)
- Therapy Controls

MRI Safety and Additional Information

MRI Safety Information

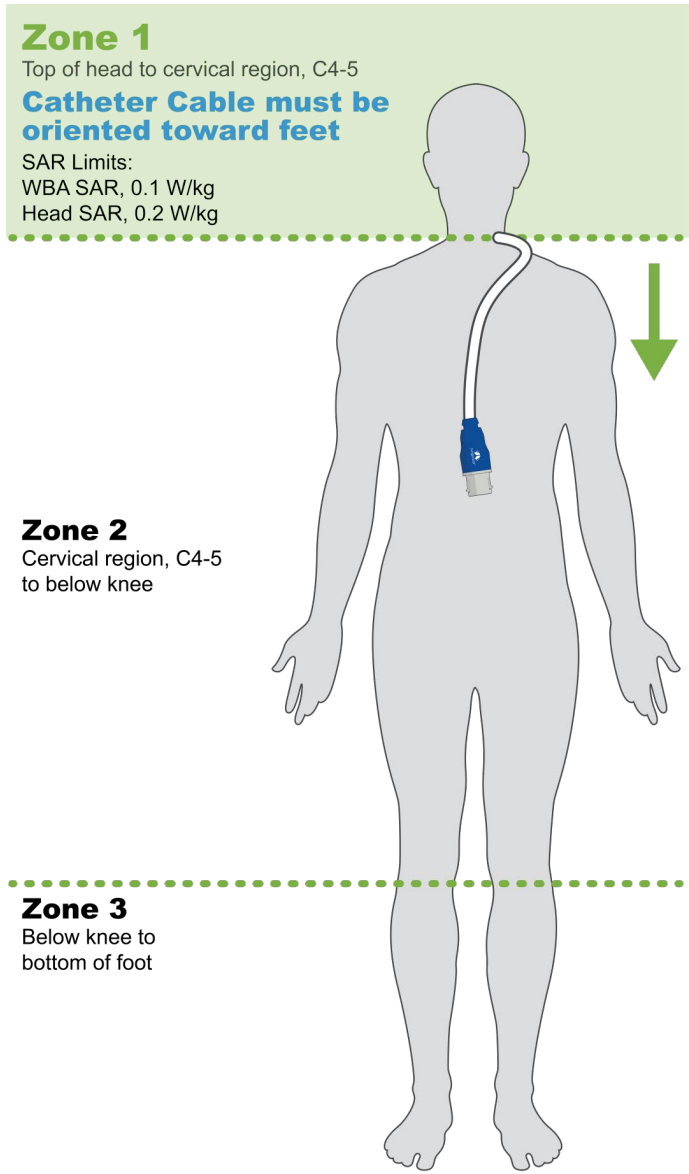
The Neurostimulation Catheter is MR Conditional.

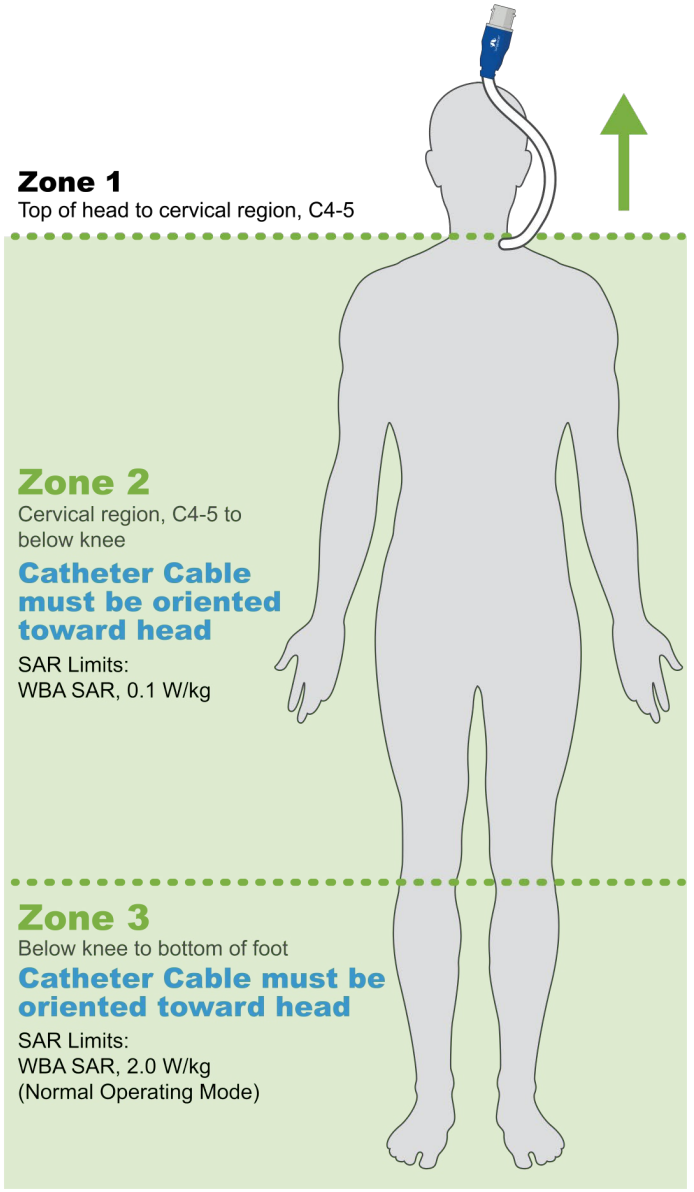
A subject with the Neurostimulation Catheter may be safely scanned under the conditions here and in the Neurostimulation Catheter Kit Instructions for Use. Always Instructions for Use documentation for safety information. The Neurostimulation Catheter but must always be disconnected from the Console and cable before entering an MR environment. Failure to follow these conditions may result in injury to the subject.

Nominal Values of Static Magnetic Field (T)	1.5 T
Type of Nuclei	Hydrogen
MR Scanner Type	Cylindrical
Direction of Static Magnetic Field	Horizontal.
Maximum Spatial Field Gradient (T/m and gauss/cm)	40 T/m (4,000 gauss/cm).
Type of RF Excitation	Circularly Polarized (CP) (i.e., quadrature-driven).
Operating Mode of MR System	Normal Operating Mode*. *Note: Certain conditions require reducing the whole-body averaged and head SAR to values lower than the Normal Operating Mode. Refer to the information above and in Figures on next slide.
RF Conditions	1.5 T/64 MHz. See information in Figures on next slide.
Maximum Head SAR	Certain conditions require reducing the head SAR to a value lower than the Normal Operating Mode. Refer to the information in Figures on next slide. For the use of the transmit/received RF head coil, the maximum head SAR is 3.2 W/kg) as long as the Neurostimulation Catheter is not positioned inside of the T/R RF head coil.

Scan Regions	Depending on the type of MRI examination to be performed, careful consideration must be given to the particular scan region (i.e., zone) and the positioning of the Neurostimulation Catheter in order to ensure patient safety. The WBA SAR or head SAR must not be exceeded. Refer to Figures on next slide.
Limits on Scan Duration	Maximum whole body averaged SAR of 0.2 W/kg for 30 minutes of continuous RF exposure with a 30-minute cooling period. Under the scan conditions defined, the Neurostimulation Catheter is expected to produce a maximum rise of 6°C after 15 minutes of continuous scanning.
MR Image Artifact	The presence of the Neurostimulation Catheter produces an imaging artifact. Therefore, carefully select pulse sequence parameters to minimize artifacts if the Neurostimulation Catheter is located in the area of interest. In non-clinical testing, the image artifact caused by the Neurostimulation Catheter extends approximately 6 mm from this device when imaged using a gradient echo pulse sequence and a 1.5 T MR system.

MRI Safety Information





Additional Information

Electrode Exclusion

- In Exclusion, electrodes persistently causing unwanted effects are identified and temporarily disabled.
- After Exclusion, Mapping must be performed again.

Ending a Therapy Session

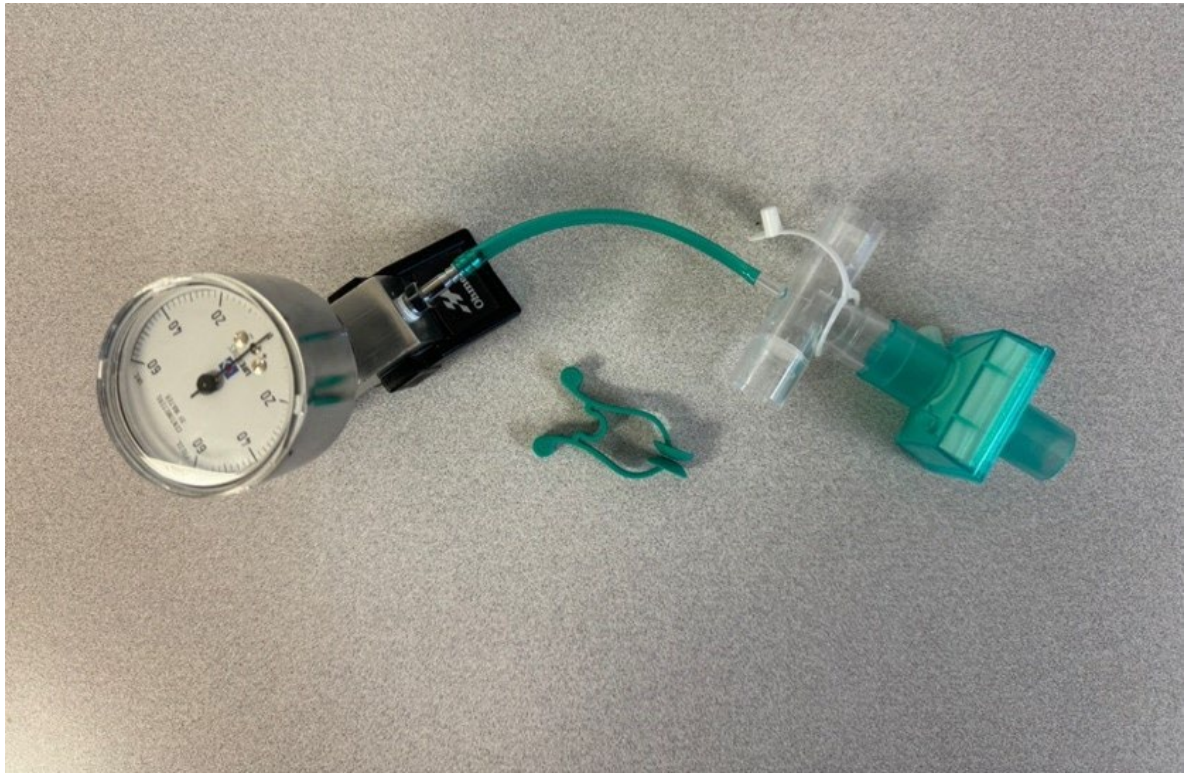
- When a Therapy session is complete, press “End Session” in the upper-right corner of the screen to view summary information about the session. This information may be useful for your records.
- Power off the System after use.

Cleaning the System

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

Additional Information
MIP (Maximal Inspiratory Pressure)

- An **MIP** will be performed at time of the **first spontaneous breathing trial** (SBT) using equipment and supplies provided by Lungpacer
- **MIP will be collected 3 times.** All 3 measurements should be recorded on the source document. The highest value of the 3 attempts will be recorded in the EDC.



MIP Manometer
(analog manometer, green tubing, NIF-tee, and filter)

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AeroNova Training

Pop Quiz

MRI and Additional Information

Scan the QR code with your phone to begin.

Questions?


Enabled
Auto
Manual
Mapping
Therapy
Exclusion
End Session
Paw (cmH2O)
Vol (mL)
Diaphragm Activation Level
76
cmH2O.s/min
Right
Left
% vol change/min
Remaining
Stimulating!
Stop
Stimulating
Ts
1.0s
Stim Spon
Off
Enable Pocc
Off

260 Sierra Drive, #116
Exton, PA 19341

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