

AeroNova™ System

Quick Reference Guide

Rx Only

CAUTION: Investigational device. Limited by United States law to investigational use. Exclusively for clinical investigations.

This Quick Reference Guide provides an overview of AeroNova System setup and use. For detailed instructions on Neurostimulation Catheter insertion and use of the System, including troubleshooting steps, see the **Neurostimulation Catheter Kit Instructions for Use** and the **AeroNova System User Guide**. These documents can be accessed by scanning this QR Code.



CAUTION: Do not use or connect any devices to the AeroNova System or its components that are not described in these instructions. Use of unauthorized devices may result in severe injury or death.

Patient Setup and System Overview

1 Position the **Console**, typically on the same side of the patient as the Neurostimulation Catheter insertion point (patient's left side), toward the head of the bed. Plug the console into hospital-grade wall power and lock its wheels prior to use.

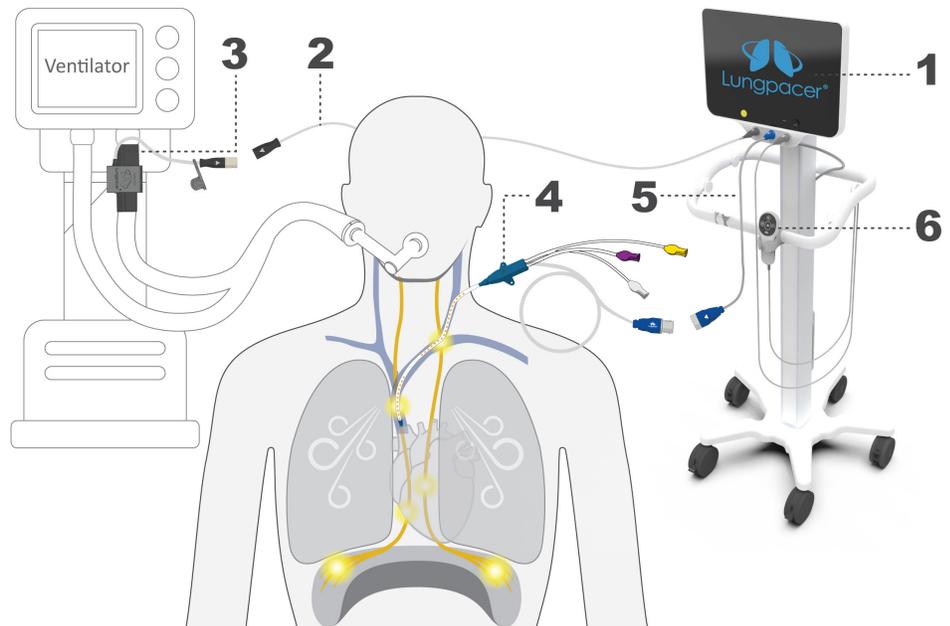
2 Use the **Airway Sensor Cable** with light gray connectors to electrically connect the Airway Sensor to the Console.

3 Pneumatically connect the **Airway Sensor** between inspiratory limb of the patient's ventilator circuit and the ventilator. The arrow on the Airway Sensor should point toward the patient.

4 The **Neurostimulation Catheter** is inserted into the patient's left subclavian vein, or left jugular vein.

5 Use the **Catheter Cable** with blue connectors to connect the patient's Neurostimulation Catheter to the Console.

6 The **Handheld Controller** connects to the Console's right-most, dark gray port.



Neurostimulation Catheter Insertion

WARNING:

- Do not position the Neurostimulation Catheter (or allow it to remain) in the right atrium, right ventricle, or in a position that may induce cardiac arrhythmia. Incorrect positioning of the Neurostimulation Catheter may result in cardiac injury, arrhythmia, or cardiac tamponade leading to severe injury or death.
- The AeroNova ECG feature is intended to function as an assistive aid in the placement of the Neurostimulation Catheter. Do not use the AeroNova ECG feature to diagnose cardiac events or diseases.

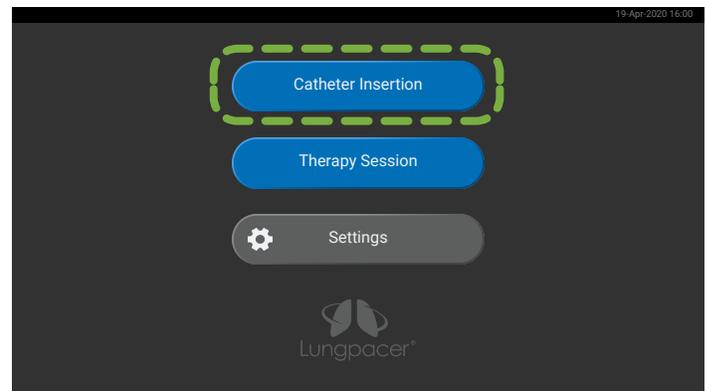
 **CAUTION:** Refer to the Neurostimulation Neurostimulation Catheter Kit Instructions for Use for warnings, precautions, and instructions regarding the insertion, removal, use, maintenance, and disposal of the Neurostimulation Catheter. Failure to follow instructions for use of the Neurostimulation Catheter may result in severe injury or death.

1 Prepare to insert the Neurostimulation Catheter, following all instructions in the Neurostimulation Catheter Kit Instructions for Use.

2 Ensure the AeroNova System is set up and ready to use, as described on the previous page.

3 Power on the Console, and then select **Catheter Insertion** from the Home screen.

4 Press the **ECG** tab. As the Neurostimulation Catheter tip is advanced into the superior vena cava (SVC), the intravascular electrogram signal will change in amplitude and morphology. **Avoid bending, twisting, or torquing the Neurostimulation Catheter during insertion.** Observe and monitor the displayed signal as an indicator of Neurostimulation Catheter position relative to the heart. An increase in signal amplitude indicates the Neurostimulation Catheter tip is nearing the heart. An inverted electrogram morphology may indicate that the Neurostimulation Catheter is over-inserted and has entered the right atrium.



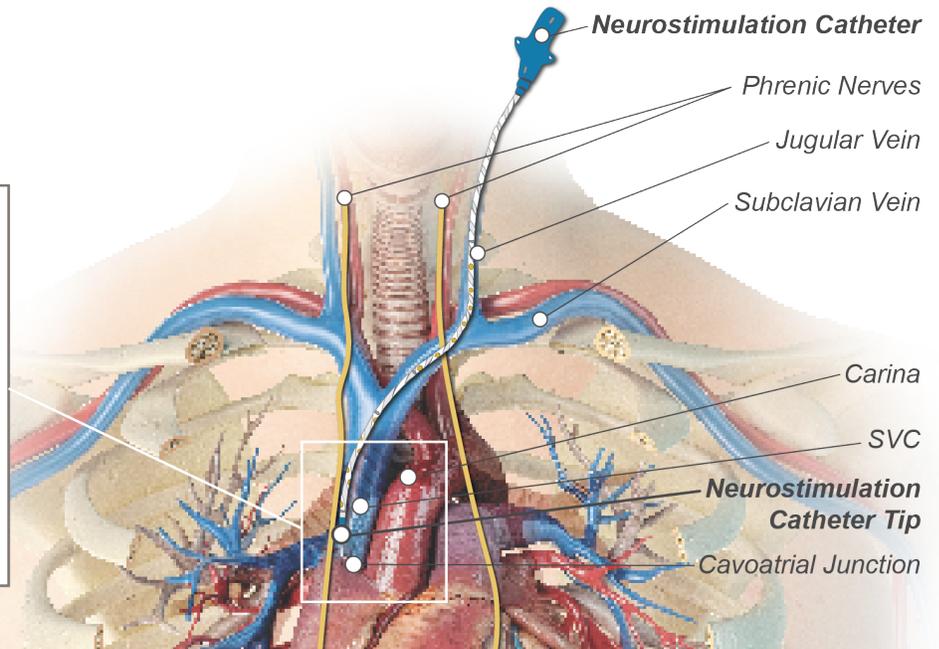
5 The correct placement of the Catheter Tip is depicted in the illustration below.

Catheter tip should be:

- ✓ Several centimeters below the carina
- ✓ In distal third of the SVC
- ✓ ~1 cm above the cavoatrial junction

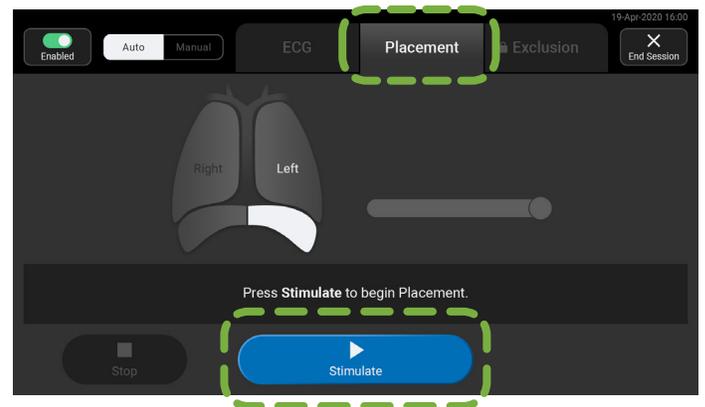
Long axis of Catheter should be:

- ✓ Parallel to SVC wall

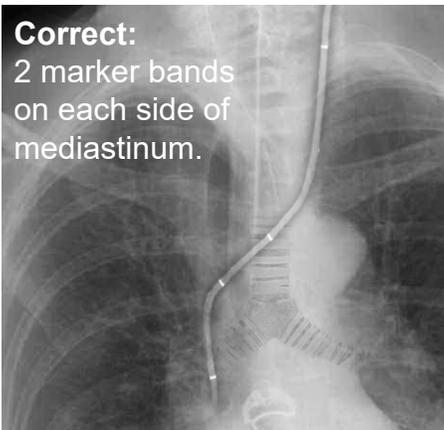


6 Once the Neurostimulation Catheter's distal tip is in the correct position, press the **Placement** tab, and then press **Stimulate**. Placement will proceed and complete automatically.

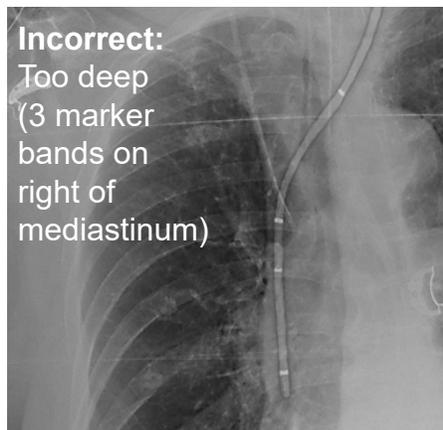
7 Follow your institutional guidelines to confirm Neurostimulation Catheter position. The images below show examples of correct and incorrect Neurostimulation Catheter placements shown under x-ray.



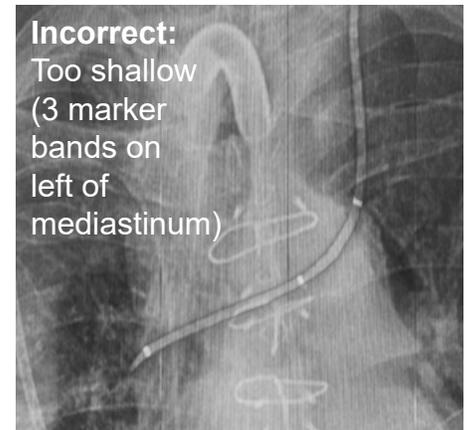
Correct:
2 marker bands on each side of mediastinum.



Incorrect:
Too deep (3 marker bands on right of mediastinum)



Incorrect:
Too shallow (3 marker bands on left of mediastinum)



8 Once its position is confirmed, secure the Neurostimulation Catheter using its suturing holes.

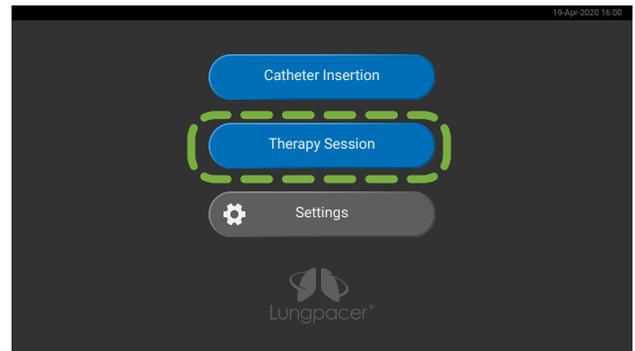
Providing Therapy

By default, AeroNova Therapy is provided in Auto mode. In Auto mode, the AeroNova System detects breaths initiated by the ventilator, and delivers stimulations in time with inspiration at the configured duration and intensity.

 Note: If needed, use the on-screen blue **Stop** button to halt stimulations at any time.

Power on System

- 1** Ensure the AeroNova System is set up and ready to use, as described on the first page of this document.
- 2** Power on the Console and then press **Therapy Session** on the Home screen.



Mapping

- 3** Keep both the Right and Left sides selected to automatically map both hemidiaphragms. (Alternatively, if needed, each side can be mapped individually.)
- 4** Press **Stimulate** and observe the patient. Mapping will complete automatically in Auto mode.
- 5** Press **Continue** to proceed to the Therapy tab.



Protection Phase of Therapy

The protection phase of AeroNova Therapy involves the continual delivery of stimulations adjunctively with mechanical ventilator breaths to maintain diaphragm function and reduce MV positive pressure. AeroNova will not deliver stimulations for patient-initiated breaths.

- 1** Press the Diaphragm Activation Level area of the screen, and select whether the patient is receiving mechanical ventilation in **Volume** or **Pressure** mode.
- 2** The AeroNova System default settings are pre-configured to begin Continual Therapy. Confirm all Therapy settings, including Number or Duration of **Stimulations**, **Skip Breaths**, **Frequency**, **Ts** (Stim Duration) and **Stim Spon**.



- 3** Press **Stimulate** to begin Therapy. 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 patient to confirm the diaphragm contracts, and look for signs of discomfort.
- 4** Titrate the **Diaphragm Activation Levels** on the main Therapy screen as needed using the plus (+) and minus (-) buttons until the strength of contractions is within the desired range.
- 5** Set the **High and Low Notification Limits** — and the **High (Stop) Limit** — appropriately for the patient's clinical condition to prevent under- and over-activation of the diaphragm. Press the numeric value displayed in the Diaphragm Activation Level area of the screen to access these settings. If the patient DAL exceeds these limits, a notification will display on the screen.

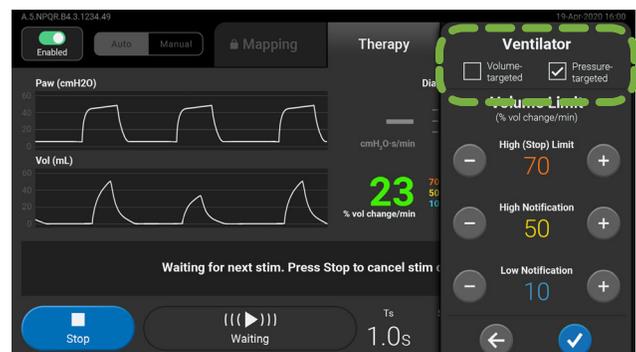


Rehabilitation Phase of Therapy

The rehabilitation phase of AeroNova is 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.

Once the subject begins breathing spontaneously, high-intensity stimulations may be added. High-intensity stimulations will be delivered in a set of 60 stimulations twice each day at the maximum intensity tolerable by the patient:

- 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



AeroNova System Reminders and FAQs

! WARNING:

- The AeroNova System has not been evaluated for its interaction with all possible medical equipment under all operating conditions. Do not use the AeroNova System with equipment likely to interact adversely with neurostimulation devices or central venous catheters. Assess all potential interactions before using the AeroNova System in conjunction with other medical equipment.
- Delivery of electrical stimulation in the atrium or too close to the heart may result in cardiac arrhythmia.



CAUTION: Therapy delivered from the AeroNova System may result in the liberation of patient mucus and/or secretions. Monitor airway secretions and suction as needed during and after Therapy to help avoid airway occlusion.

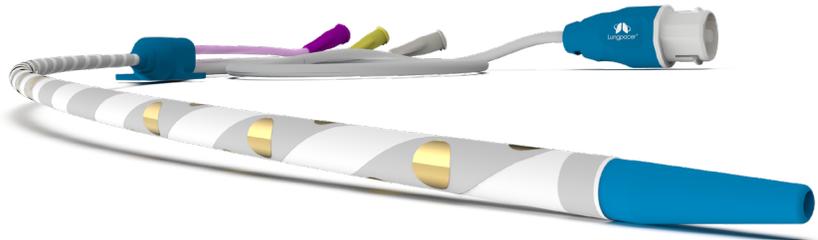
What are the Neurostimulation Catheter's lumen flow rates?

Distal Lumen:

- 42 ml/min maximum.
- Pressure injection maximum 5 ml/s.

Medial and Proximal Lumens:

- 17 ml/min maximum.
- Not rated for high pressure power infection.



Can I Perform an MRI with the Neurostimulation Catheter?

The Neurostimulation Catheter is **MR Conditional**. The rest of the System is MR Unsafe. Refer to the Neurostimulation Catheter Kit Instructions for Use for details regarding the safe use of the Neurostimulation Catheter with MR equipment.

What should I do if Placement, Mapping, or Therapy isn't working in Auto mode?

First, check the Airway Sensor for secretions. If needed, clean it by using gentle suction. If Auto mode still isn't working, you may also try using the System in Manual mode by carefully following the instructions in the AeroNova System User Guide.



What is the Exclusion tab for?

Exclusion can be used to temporarily disable specific electrodes if there is patient discomfort that prevents you from setting effective Therapy Levels. See the AeroNova User Guide for more information.