

AeroPace® System

Quick Reference Guide

Rx Only



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This Quick Reference Guide provides an overview of AeroPace System setup and use. For detailed instructions on AeroPace Neurostimulation Catheter insertion and use of the System, including indications, contraindications, warnings, cautions, and troubleshooting steps, see the **AeroPace Neurostimulation Catheter Kit Instructions for Use** and the **AeroPace System User Guide**.



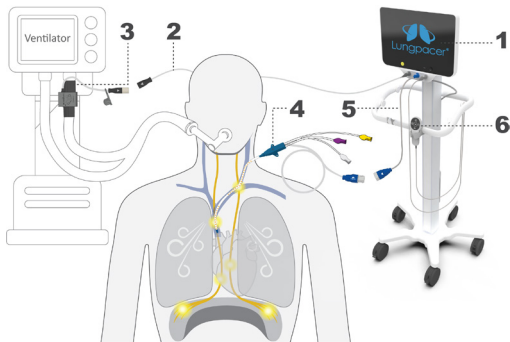
WARNING: Read all AeroPace System warnings, cautions, and instructions prior to use. Failure to observe warnings for the AeroPace System may result in severe injury or death.



CAUTION: Do not use or connect any devices to the AeroPace System or its components that are not described in these instructions.

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 dark gray connectors to electrically connect the Airway Sensor to the Console.
- 3 Pneumatically connect the **Airway Sensor** at the inspiratory limb of the mechanical 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. Follow all instructions in the Neurostimulation Catheter Kit Instructions for Use.
- 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, light gray port.



Neurostimulation Catheter Insertion

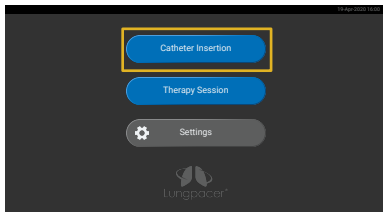


WARNING: Do not position the Neurostimulation Catheter (or allow it to remain) in the right atrium, right ventricle, or in a position that may induce cardiac arrhythmia. Incorrect positioning of the Neurostimulation Catheter may result in cardiac injury, arrhythmia, or cardiac tamponade.

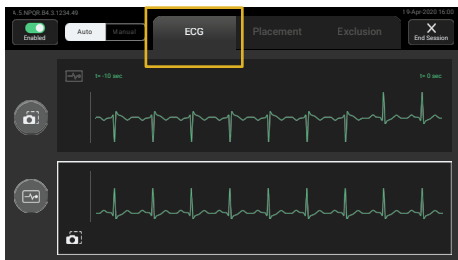


CAUTION: Refer to the AeroPace Neurostimulation Catheter Kit Instructions for Use for warnings, precautions, and instructions regarding the insertion, removal, use, maintenance, and disposal of the Neurostimulation Catheter. Failure to follow instructions for use of the Neurostimulation Catheter may result in severe injury or death. Inspect the Neurostimulation Catheter Kit expiration date before use. Use of expired product may lead to injury.

- 1 Prepare to insert the Neurostimulation Catheter, following all instructions in the AeroPace Neurostimulation Catheter Kit Instructions for Use.
- 2 Ensure the AeroPace System is set up and ready to use, as described in the previous section.
- 3 Power on the Console, and then select **Catheter Insertion** from the Home screen.

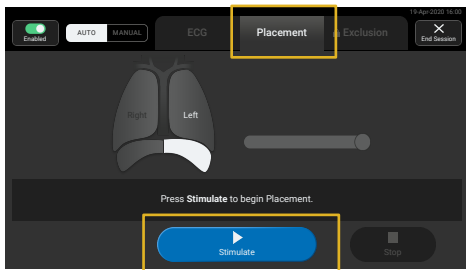


- 4 If desired, press the **ECG** tab. As the Neurostimulation Catheter nears the superior vena cava (SVC), the intravascular electrogram signal will change in amplitude and morphology. If you choose to use this optional feature to help guide insertion, observe and monitor the displayed signal as an indicator of Neurostimulation Catheter position. Inverted electrogram morphology may indicate that the Neurostimulation Catheter is over-inserted and has entered the right atrium.



- 5 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.

- 6 Follow your institutional guidelines to confirm Neurostimulation Catheter position and secure it.



AeroPace System Reminders and FAQs



WARNING:

- Ventilator settings should be configured appropriately for the patient according to institutional guidelines. Observe the patient closely during System use to ensure that the ventilator settings and the AeroPace System settings are compatible. Failure to do so may result in inadequate ventilation, ventilator dyssynchrony, inappropriate Therapy delivery, or lung or diaphragm injury. See The AeroPace System User Guide for details.
- Delivery of electrical stimulation in the right atrium, right ventricle, or other positions may result in cardiac arrhythmia. If unwanted patient effects (such as an arrhythmia) occur during Mapping or Therapy, stop stimulation immediately. If needed, perform Exclusion before restarting Mapping or Therapy. See the AeroPace System User Guide or details.



CAUTION: Therapy delivered from the AeroPace System may result in the liberation of 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: 5 mL/sec (rated for high-pressure injection). Flow rate: 42 mL/min. Used for over-the-wire insertion of Neurostimulation Catheter.

Medial and **Proximal:** 17 mL/min.

Can I Perform MRI with the Neurostimulation Catheter?

The AeroPace Neurostimulation Catheter is **MR Conditional**, but the Neurostimulation Console is MR Unsafe. Refer to the AeroPace 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 gently suctioning out the secretions. If Auto mode still isn't working, you may also try using the System in Manual mode by following the instructions in the AeroPace 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 setting effective Therapy Levels. See the AeroPace System User Guide for more information.

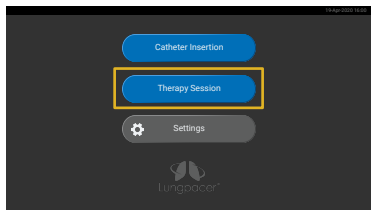
Daily Therapy Sessions

Daily therapy is delivered in two sessions, spaced at least three hours apart. Each session consists of 60 stimulations (Stims), for a total of 120 stimulations each day. Optimizing Therapy entails delivering the target number of Stims at the maximum Therapy Level possible based on patient comfort during both daily Therapy sessions. To maximize Therapy, do not skip Therapy Sessions.



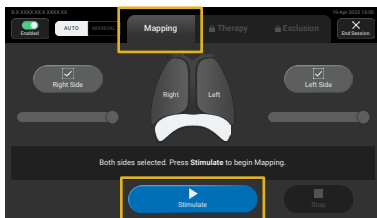
Note: **Mapping** must be performed each time the Console is powered on, before each **Therapy** session. **Auto** mode will be enabled automatically. To use the system in **Manual** mode, follow the instructions in the AeroPace System User Guide. If needed, use the on-screen blue **Stop** button to halt stimulations at any time.

- 1 Ensure the AeroPace 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 tab

- 3 Keep both the Right and Left sides selected to automatically map both hemidiaphragms. (If needed, each side can be mapped individually.)



- Press **Stimulate**. Mapping will complete automatically.
- Press **Continue** to proceed to the Therapy tab.

Therapy tab

- Set the **Stim Duration** as long as possible while also matching the patient's Inspiration Time on the ventilator, and other parameters as appropriate for the patient.
- Press **Stimulate** and observe the patient for diaphragm contraction and signs of discomfort.
- Observe the patient and increase the **Therapy Level** (right and left) to be as high as possible while still ensuring patient comfort.
- Once the parameters are optimized, press **Settings** to increase the **Stims Programmed**, and then continue to press **Stimulate** until the **Total Stims** counter reaches 60.
- Press **End Session**.
- Disconnect the Airway Sensor and Catheter from their cables, and then power off the Console.
- As needed, follow your institutional guidelines to clean the Console, Airway Sensor Cable, Catheter Cable, and Handheld controller using an approved disinfectant. See the AeroPace System User Guide for details.

