Lungpacer®

AeroNova™ System

User Guide

CAUTION: Investigational device. Exclusively for clinical investigations.
To be used by qualified investigators only.
Instrument de recherche. Réservé uniquement à l'usage de chercheurs compétents.

AeroNova®

Rx Only
For use only with Lungpacer System components.

Contents

Introduction

Mechanical ventilation can be a life-saving intervention for patients suffering respiratory difficulty. However, it can also lead to ventilator-induced lung injury and diaphragm dysfunction, reduced cardiac output, and neuroinflammation resulting in difficulty weaning and/or other complications.

Intended Use

The AeroNova System is a temporary, percutaneously placed, transvenous, phrenic nerve-stimulating device intended to activate the diaphragm to maintain diaphragmatic effort adjunctively with mechanical ventilation. The AeroNova System is intended for use in hospitals, hospital-type facilities and rehabilitation facilities that provide medical care for patients on mechanical ventilation (MV). The device is intended to be used by qualified, trained personnel under the direction of a physician.

Trademarks

Lungpacer® Medical has the following trademarks associated with its AeroNova™ System. The name in parentheses is used throughout this User Guide to refer to the item.

NOTE: The AeroNova Neurostimulation Console connects to the AeroPace Cart, Catheter Kit, Catheter Cable, Airway Sensor, Airway Sensor Cable, and Handheld Controller.

- AeroNova™ System ("System"), which includes:
  - AeroNova™ Neurostimulation Console ("Console")
  - AeroPace™ Cart ("Cart"),
  - AeroPace™ Catheter Kit ("Catheter Kit"),
  - AeroPace™ Catheter ("Catheter"),
  - AeroPace™ Catheter Cable ("Catheter Cable"),
  - AeroPace™ Airway Sensor ("Airway Sensor"),
  - AeroPace™ Airway Sensor Cable ("Airway Sensor Cable"), and
  - AeroPace™ Handheld Controller ("Handheld Controller")

Indication for Use

The AeroNova System maintains diaphragm function during mechanical ventilation in adult patients aged 18 years or older.

Contraindications

No known contraindications have been identified at this time.

Warnings

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

System Setup Warnings:

- Connect the Console power cord (the only means for mains disconnection) to an easily accessible “Hospital Only” or “Hospital Grade” AC mains outlet that is properly grounded with protective earth, and is compatible with the ratings printed on the Console label. Connecting the Console to an incompatible power source may result in fire or electrical shock.
- Do not modify the AeroNova System. Do not use or connect any devices to the AeroNova System or its components that are not described in this User Guide.
- 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.
- Do not use the AeroNova System with implanted cardiac pacemakers, defibrillators, or other implantable electronics. The AeroNova System has not been clinically evaluated for safety with implantable devices.
- The Use of accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity.

Catheter Insertion and Placement Warnings:

- Do not position the 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 Catheter may result in cardiac injury, arrhythmia, or cardiac tamponade.
- The AeroNova ECG feature is intended to function as an assistive aid in the placement of the Catheter. Do not use the AeroNova ECG feature to diagnose cardiac events or diseases.

Mapping and Therapy Warnings:

- Ventilator settings should be configured appropriately for the patient according to institutional guidelines. Observe the patient during System use to ensure that the ventilator settings and the AeroNova System settings are compatible. Failure to do so may result in inadequate ventilation, ventilator dyssynchrony, inappropriate Therapy delivery, or lung or diaphragm injury. See *"Providing AeroNova Therapy" on page 27* 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 *"Using Exclusion to Disable Electrodes" on page 32* for details.

- The Catheter is MR Conditional, but the Neurostimulation Console is MR Unsafe. Conditions under which the Catheter is MR compatible and may be scanned safely are described in the Catheter Kit Instructions for Use. Always disconnect the Catheter from the Neurostimulation Console before conducting MRI, and keep the Console away from MR equipment.

Maintenance and Cleaning Warnings:

- To reduce the risk of electrical shock, disconnect mains power from the Console before cleaning.

EMC Warnings:

- Only accessories specified or provided by the manufacturer should be used with the AeroNova System. Use of accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the AeroNova System. Otherwise, degradation of the performance of the AeroNova System may occur, which may include the system safely entering a state where stimulation is not delivered.
- The AeroNova System should not be used while stacked or placed adjacent to other equipment, as this could result in improper operation of the AeroNova System or other equipment.

System Cautions

CAUTION:

- If external defibrillation or any medical treatment in which electrical current is passed through the patient's body from an external source is necessary, disconnect the Catheter from the Catheter Cable first. Failure to disconnect the Catheter before exposure to electrical current may result in non-effective defibrillation, and/or irreparable damage to the System. If a defibrillation event occurs with the Catheter connected to the Console, contact Lungpacer before subsequent use of the System.
- Do not expose the AeroNova Console, Catheter Cable, Sensor Cable, Handheld Controller, Sensor electrical connector or Catheter electrical connector to excessive moisture. In case of fluid ingress, disconnect the Catheter Cable from the Catheter, turn off the Console, unplug the power cord, dry the exterior of the components of the AeroNova System with a cloth, and wait for them to dry completely. Do not use the AeroNova System or any of its components if they appear compromised by fluid ingress. Fluid ingress into the System may cause device malfunction and may result in fire or electrical shock.
- Do not use the AeroNova System in an oxygen-rich environment such as a hyperbaric chamber. Doing so may result in fire.
- Do not use the Console if the enclosure is warm to the touch. Touching an overheated Console may cause injury.

Potential Complications

The potential complications associated with central venous catheters are:

- Adverse tissue response
- Allergic reaction
- Arrhythmia
- Bleeding / Hemorrhage
- Bradycardia
- Bruising, swelling or seroma at insertion site
- Cardiac structure damage
- Central line-associated blood stream infection
- Cerebrovascular event
- Discomfort
- Embolism
- Hematoma
- Hemothorax
- Hypertension / hypotension
- Inadvertent arterial or venous puncture
- Infection
- Lung injury
- Lymphatic / thoracic duct injury
- Mediastinal injury
- Nerve injury
- Pain, tenderness, swelling, discomfort at access site
- Pneumohematoma
- Pneumomediastinum
- Pneumothorax
- Procedural complications
- Pseudo aneurysm or AV fistula at access site
- Sepsis
- Seroma
- Skin irritation
- Syncope
- Thrombosis / stenosis
- Tissue inflammation, fibrosis or damage
- Vessel occlusion
- Vessel wall damage / perforation
- Wound healing issues
- Wound infection / phlebitis

The potential complications associated with diaphragm or phrenic nerve stimulation are:

- Arrhythmia
- Bradycardia
- Diaphragm injury
- Discomfort
- Hypercapnia / hypocapnia
- Hypoxia
- Liberation of lung mucus plugs/secretions
- Muscle fatigue or discomfort
- Nerve injury
- Pain or discomfort during stimulation
- Inappropriate stimulation
- Pain or discomfort during stimulation
- Phrenic nerve damage or injury
- Syncope

AeroNova System Setup

The AeroNova System must be operated under clinician supervision. The AeroNova System consists of the AeroNova Neurostimulation Console and the following AeroNova components: the Catheter, Catheter Cable, Airway Sensor, Airway Sensor Cable, and Handheld Controller. This chapter contains detailed information about settings up the AeroNova System.

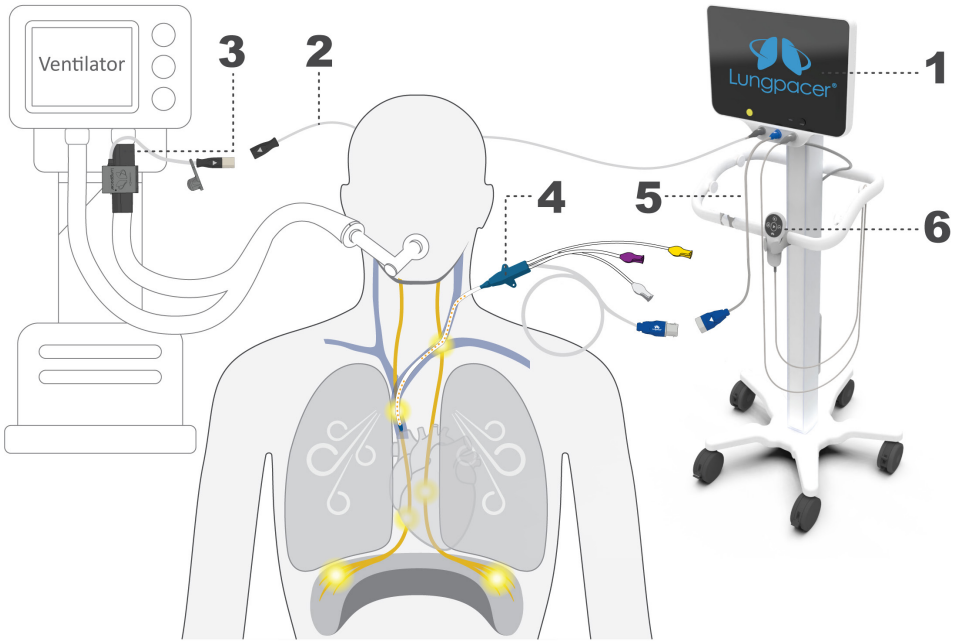
WARNING:

- Connect the Console power cord (the only means for mains disconnection) to an easily accessible “Hospital Only” or “Hospital Grade” AC mains outlet that is properly grounded with protective earth and is compatible with the ratings printed on the Console label. Connecting the Console to an incompatible power source may result in fire or electrical shock.
- Do not modify the AeroNova System. Do not use or connect any devices to the AeroNova System or its components that are not described in this User Guide.
- 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.
- Do not use the AeroNova System with implanted cardiac pacemakers, defibrillators, or other implantable electronics. The AeroNova System has not been clinically evaluated for safety with implantable devices.
- Use of accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity.

CAUTION:

- Do not use or connect any devices to the AeroNova System or its components that are not described in these instructions.
- Do not use the AeroNova System or any of its components if they appear altered or damaged, or have exposed wires. Using damaged components may result in electrical shock.
- Do not expose the AeroNova System or any of its components to excessive moisture. In case of fluid ingress, disconnect the Catheter Cable from the Catheter, turn off the Console, unplug the power cord, dry the exterior of the components of the AeroNova System with a cloth, and wait for them to dry completely. Use of a System compromised by fluid ingress may result in fire or electrical shock.
- Do not use the AeroNova System or any of its components if they appear compromised by fluid ingress. Fluid ingress into the System may cause device malfunction and severe injury or death.
- Do not use the AeroNova System in an oxygen-rich environment such as a hyperbaric chamber. Doing so may result in fire.
- Do not use the Console if the enclosure is warm to the touch. Touching an overheated Console may cause injury.

The diagram below provides a high-level overview of AeroNova System setup.:



1. Position the **Console**, typically on the same side of the patient as the 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** between the inspiratory limb of the patient's ventilator circuit and the ventilator.

4. The **Catheter** is inserted into the patient's left subclavian vein, or left jugular vein. See *"Catheter Insertion and Placement" on page 13* for details.

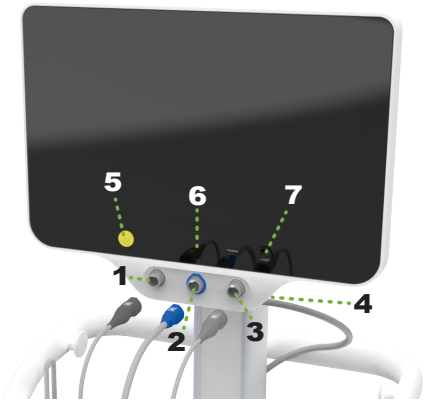
5. Use the **Catheter Cable** with blue connectors to connect the patient's Catheter to the Console.

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

Neurostimulation Console

The AeroNova Neurostimulation Console generates stimulations that are delivered to the electrodes on the Catheter and result in contraction of the diaphragm. The Console has a touchscreen user interface mounted on the upper portion of the System.

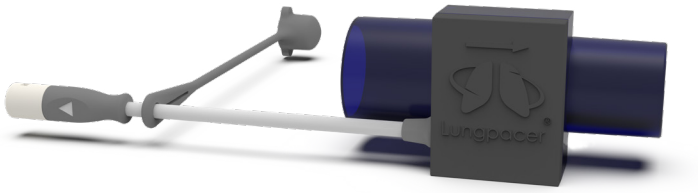
#	Item
1	Airway Sensor Cable connector (dark gray)
2	Catheter Cable connector (blue)
3	Handheld Controller connector (light gray)
4	Power cord connection (underneath the display)
5	Stop button: Forces an immediate shutdown of the Console (yellow)
6	Power indicator (illuminated blue when the Console is connected to power)
7	Power button (black)

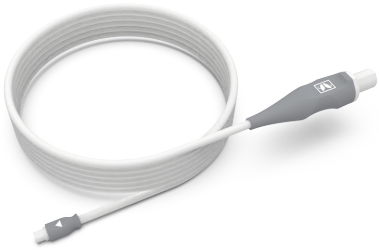


Airway Sensor and Cable

The Airway Sensor connects to the breathing circuit to provide input about airway pressure, flow, and the patient's breathing cycle to the Console. This information allows the AeroNova System to deliver stimulations in synchrony with breaths from any mechanical ventilator.

The Airway Sensor connects pneumatically to the patient's ventilator circuit between the inspiration limb of the circuit and the ventilator connection. Alternatively, it may be placed between the Y-piece and the patient's endotracheal or tracheostomy tube using an airway adapter. It connects to the Console electrically by way of the Airway Sensor Cable.





Connect a new Airway Sensor to the patient's ventilator airway circuit prior to setting up the sterile field for the Catheter insertion procedure. To connect an Airway Sensor to the patient's ventilator circuit:

1. Inspect the Airway Sensor packaging before opening it, and then remove and inspect the Airway Sensor. Only use the Airway Sensor if it and its packaging are intact, clean, and undamaged.
2. Before breaking the patient's ventilator circuit, position the Airway Sensor so that the arrow points toward the patient.
3. Position the Airway Sensor between the inspiration limb of the circuit and the ventilator connection.

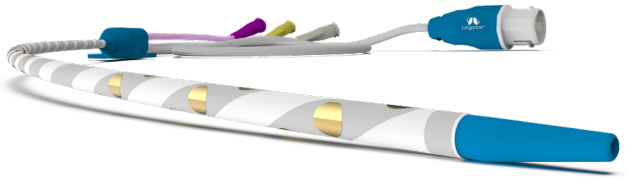
Note: The Airway Sensor may also be positioned between the Y-piece and the patient's endotracheal or tracheostomy tube using an airway adapter (e.g., HMEF). If positioned at the Y-piece, the Airway Sensor will add approximately 13 ml of dead space to the airway circuit.

4. Disconnect the patient's ventilator circuit at the location the Airway Sensor will be installed, and then quickly connect the Airway Sensor and reconnect the circuit.
5. When the ventilator circuit is reestablished, ensure that the patient's breathing returns to a stable pattern.

Note: The Airway Sensor is designed to remain connected to the patient's ventilator circuit throughout Therapy, for a maximum of 30 days.

Catheter and Catheter Cable

The AeroPace Catheter is intended for use with the AeroNova System for temporary transvenous diaphragm activation, and for short-term (up to 30 days) central venous access for administering IV fluids, blood products, medications, and parenteral nutrition solutions, as well as blood withdrawal, central venous pressure monitoring, and power injection of contrast media.



The Catheter Cable connects the Catheter to the AeroNova Neurostimulation Console, and conducts stimulations to the Catheter's electrodes.

For more information on the Catheter, refer to *"Catheter Insertion and Placement" on page 13*, and the Instructions for Use provided with the Catheter Kit.

Optional Handheld Controller

When connected to the Console, the Handheld Controller allows the clinician to activate specific functions remotely, beyond arm's reach of the Console's touchscreen. During use, the Lungpacer logo illuminates to indicate that the Handheld Controller is connected to the powered Console.

Powering the System

Position the Console based on room setup, typically on the same side of the patient as the Catheter insertion point (patient's left side), toward the head of the bed. Ensure there is access to a hospital-grade AC receptacle that meets local requirements.

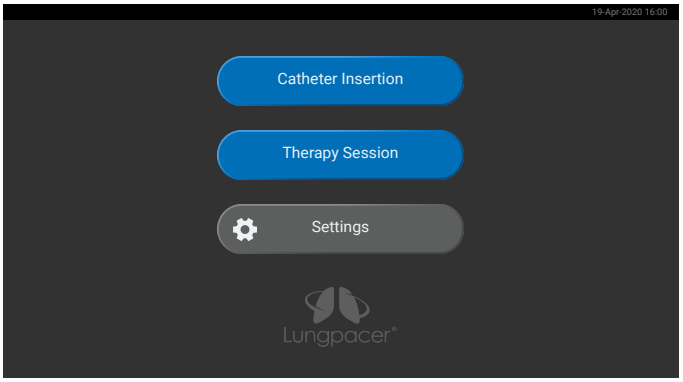
WARNING: Connect the AeroNova Neurostimulation Console power cord (the only means for mains disconnection) to an easily accessible "Hospital Only" or "Hospital Grade" AC mains outlet. Ensure the outlet is properly grounded with protective earth, and is compatible with the ratings printed on the AeroNova Neurostimulation Console label. Connecting the Console to an incompatible power source may result in fire or electrical shock.

Press the **Power** button once to power the System on. The Lungpacer logo will display as the System starts.

Touchscreen Navigation

The Home screen will appear after powering on the Console, with three options:

- **Catheter Insertion** is typically only used once per patient, during and immediately after the Catheter insertion procedure.
- **Therapy Session** is used to perform Mapping and deliver Therapy to the patient.
- **Settings** is used to adjust System parameters, such as the date and time (displayed in the upper right-hand corner of the Home screen).



Catheter Insertion and Placement

The Catheter is intended for use only with Lungpacer Systems, to provide temporary transvenous diaphragm activation, as well as short-term (up to 30 days) central venous access for administering IV fluids, blood products, medications, and parenteral nutrition solutions, as well as blood withdrawal, central venous pressure monitoring, and power injection of contrast media.

The single-use Catheter is an 8.5Fr, 23cm triple-lumen catheter with 30 electrodes arranged in two arrays on its outer surface. The distal array of 9 electrodes is designed to capture the right phrenic nerve, and the proximal array of 21 electrodes is designed to capture the left phrenic nerve. The Catheter is inserted percutaneously over a guidewire used to facilitate access to the central venous system and can be placed via the left subclavian vein or left jugular vein.

The Catheter is provided sterile and is packaged in the Catheter Kit along with some of the other single-use accessories required to complete the Catheter insertion procedure using the Seldinger technique. The items included in the kit are listed in the Catheter Kit Instructions for Use. Note that ancillary medical supplies such as saline flushes, local anesthetic, skin preparation materials, or sterile gloves are not included in the kit.

Note: The Catheter is not made with natural rubber latex.

WARNING:

- Do not position the 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 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 Catheter. Do not use the AeroNova ECG feature to diagnose cardiac events or diseases.

CAUTION:

- Refer to the Catheter Kit Instructions for Use for warnings, cautions, and instructions regarding the insertion, removal, use, maintenance, and disposal of the Catheter.
- When disconnected, ensure all Catheter and Catheter Cable connector pins are not in contact with the operator, or with any other active or electrically grounded surface. Touching or electrically grounding the contacts of the Catheter's electrical connector (including the contacts of the Catheter Cable connector while connected to the Catheter) may result in cardiac arrhythmia.
- Improper handling of the Catheter extension lines and/or the insertion site, use of a non-sterile Catheter, use of the Catheter beyond its recommended use period (30 days), and/or failure to adhere to aseptic catheter insertion technique may result in infection.

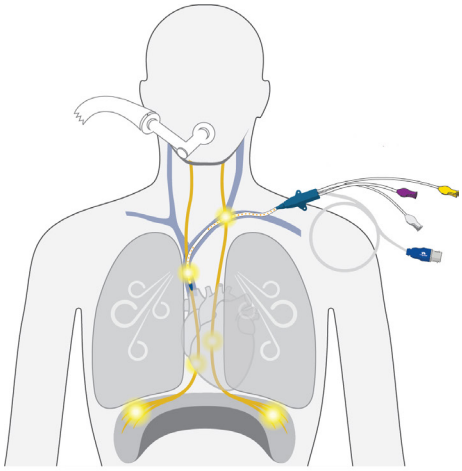
- Multiple replacements of the Catheter increase the risk of vessel wall damage and perforation.
- Excessive bending, torquing, or kinking of the Catheter may cause damage to the device including its electrical conductors.
- Damage to the Catheter or occlusion of any of its lumens may increase the risk of embolism.

Planning the Insertion

Prepare the patient for Catheter insertion according to your institutional guidelines, just as you would for insertion of a typical central venous catheter.

1 The Catheter must be placed via the **left subclavian** vein or **left jugular** vein using the Seldinger technique. Judge the vein access point based on patient anatomy: To provide effective Therapy, the Catheter tip must be located on the right side of the mediastinum in the superior vena cava (SVC) above its junction with the right atrium and parallel to the vessel wall, and its distal tip positioned at a level above either the azygous vein or the carina of the trachea, whichever is better visualized.

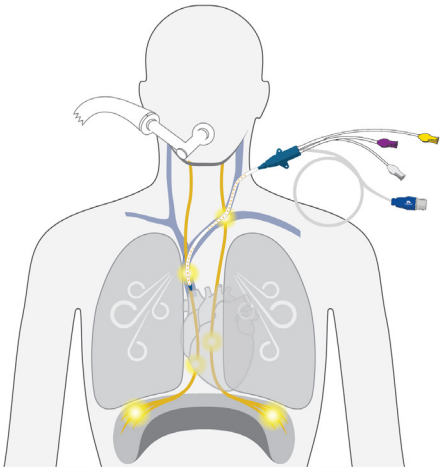
⚠ **CAUTION:** The US Centers for Disease Control and Prevention recommends Catheter placement using a subclavian site rather than a jugular site in adult patients to minimize infection risk.



Subclavian Catheter Insertion

2 Gather items needed at the patient's bedside at the time of the Catheter insertion procedure, including:

- The Airway Sensor connected to the patient circuit
- The Neurostimulation Console, connected to the Airway Sensor and its Cable, and the Catheter Cable
- You may also choose to connect the Handheld Controller
- A Catheter Kit
- Any ancillary supplies not provided in the Catheter Kit, such as saline flushes, local anesthetic, skin preparation materials, sterile gown and gloves, and others
- Clinical assistance to operate the Console outside of the sterile field



Jugular Catheter Insertion

3 Prepare the Console for use during and immediately after the Catheter insertion process by positioning it properly (typically on the left side of the patient, near the Catheter insertion point, toward the head of the bed). Plug the Console in to hospital-grade AC receptacle that meets local requirements, and lock the Cart's wheels.

⚠ **CAUTION:** Inspect the Catheter Kit expiration date before use. Use of expired product may lead to injury.

Inserting the Catheter

Insert the Catheter via the left subclavian vein or left jugular vein using the Seldinger technique, following your institution's guidelines, as well as all instructions in the Catheter Kit Instructions for Use. Advance and retract the Catheter as needed so that its tip is in the distal SVC.

⚠ **CAUTION:**

- Improper vein access technique may result in vessel wall damage or perforation.
- Observe the patient closely for unwanted effects during the Catheter insertion and Placement process. Incorrect positioning of the Catheter's electrodes may result in pain or discomfort from stimulation of unintended nerves or tissue.

1. Follow all instructions in the Catheter Kit Instructions for Use to insert the Catheter using the Seldinger Technique.
2. Follow your institutional guidelines for maintaining the sterile field and sterility of the Catheter, and have a clinical assistant connect the Catheter's electrical connector to the Catheter Cable.
3. Power on the Console by pressing the **Power** button, and then select **Catheter Insertion**.
4. To use the ECG function to assist in the assessment of the catheter tip's depth relative to the heart, select the **ECG** tab on the Console and then follow the instructions on the next page.

⚠ **CAUTION:** Ensure that the heart rhythm is not affected when the Catheter is being advanced. If an atrial arrhythmia is detected that could be produced by the Catheter tip having entered the atrium, retract the Catheter tip back into the SVC.

⚠ **WARNING:** The AeroNova ECG feature is intended to function as an assistive aid in the placement of the Catheter. Do not use the AeroNova ECG feature to diagnose cardiac events or diseases.

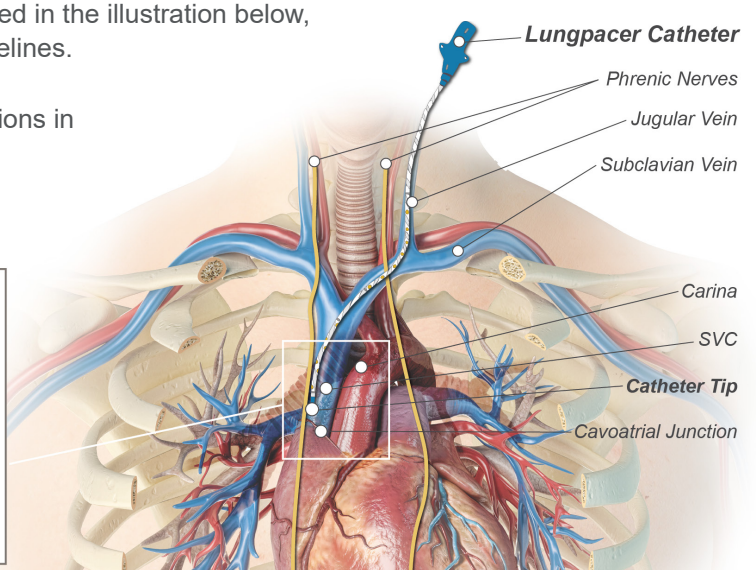
5. Once the Catheter is properly positioned as depicted in the illustration below, confirm its location following your institutional guidelines.
6. Select the **Placement** tab and follow the instructions in *"Performing Placement" on page 16* to confirm the Catheter is positioned correctly and is able to provide effective Therapy to the patient.

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*



ECG-Guided Assessment of Catheter Positioning

While maintaining the sterile field, insert the Catheter. As the Catheter tip is advanced into the superior vena cava (SVC), the intravascular electrogram signal will change in amplitude and morphology. Observe and monitor the displayed signal as an indicator of Catheter position relative to the heart. An increase in signal amplitude indicates the Catheter tip is nearing the heart. An inverted electrogram morphology may indicate that the Catheter is over-inserted and has entered the right atrium. If so, retract the Catheter slowly until the electrogram's previous morphology is restored.

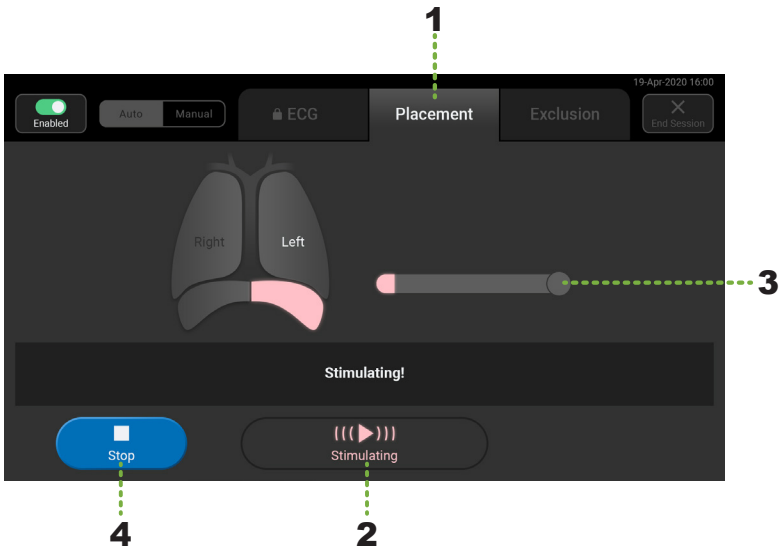
WARNING: The AeroNova ECG feature is intended to function as an assistive aid in the placement of the Catheter. Do not use the AeroNova ECG feature to diagnose cardiac events or diseases.

Note: It may be useful to compare the electrogram of the Catheter inserted at two different depths. The strip on the upper portion of the screen will display the real-time electrogram at a 1x magnification, and the lower strip will display the same electrogram at a 3x magnification. The real-time data in either magnification can be captured by pressing the **Snapshot** button to the left of the relevant strip. The visible data will freeze and display on the opposite strip, while electrogram continues to display real-time data. By comparing the real-time electrogram with the frozen snapshot, the electrogram morphology at two different Catheter positions can be assessed and compared. Press the **Go Live** button at any time to release the captured electrogram snapshot and view the electrogram at two different magnifications in real-time again.

Performing Placement

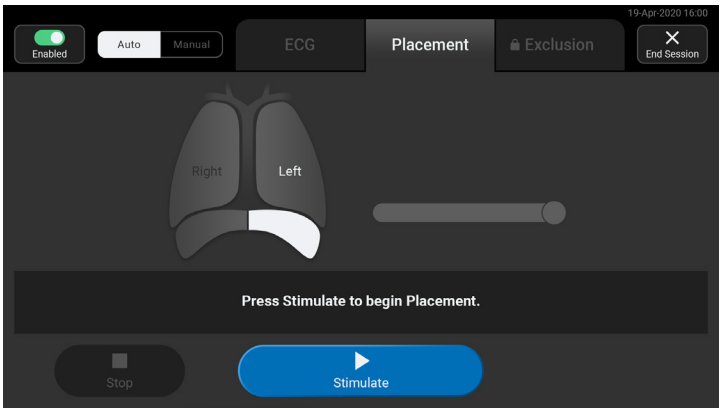
The Placement procedure verifies that the Catheter's electrodes are able to successfully stimulate the patient's left phrenic nerve. The Placement screen includes the following features:

#	Item	Description
1	Navigation Tabs	Navigates to the optional intravascular electrogram (ECG) or Exclusion features.
2	Stimulate	When blue, begins the stimulation delivery process. This button will also indicate status during and between stimulations.
3	Progress Bar	Provides a visual estimate of process progression. It illuminates in different colors to indicate status: Analyzed (blue), Active (white), Stimulating (pink), Unsure (teal), Confirm (light green), and Complete (dark green).
4	Stop	Stops active stimulation series.



Auto Placement

In Auto mode, the AeroNova System will use data from the Airway Sensor to confirm the Catheter's electrodes are able to successfully stimulate the patient's left phrenic nerve. To perform placement in Auto mode:



1. If needed, select the **Placement** tab along the top of the screen.
2. Once the System is ready and the **Stimulate** button turns blue, press it.
3. Placement will proceed automatically, as indicated by the progress bar on the screen.
4. If needed, press the **Stop** button to stop the stimulation process at any time.

Note: If Placement cannot be completed because of unwanted patient effects, the Exclusion tab can be used to identify and exclude specific electrodes. See *"Using Exclusion to Disable Electrodes" on page 32* for details.

5. After Placement verification completes successfully, lightly secure the Catheter using a clamp or other temporary means. This will prevent Catheter dislodgement or movement before its position is confirmed in the next step.

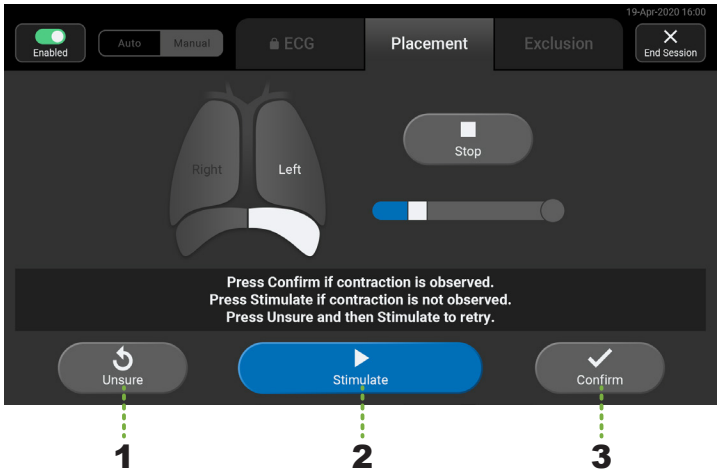
Note: If Placement verification is unsuccessful, you may try again in Auto mode, or try completing the procedure using Manual mode, instead. See *"Manual Placement" on page 18* for details.

6. Press **End Session** and disconnect the electrical cable connectors at the Catheter and Airway Sensor before pressing the **Power** button to turn off the Console.
7. Follow institutional guidelines to confirm the Catheter tip is positioned in the SVC. Once confirmed, secure the Catheter manifold to the patient's skin according to your institution's guidelines.

⚠ **CAUTION:** Secure the Catheter to prevent movement after Placement has completed successfully. Movement of the Catheter during Therapy may result in inappropriate Therapy or overstimulation and injury of the diaphragm.

Manual Placement

During manual Placement, the clinician palpates the left hemidiaphragm and/or observes the ventilator for deflections on the pressure and flow waveforms, and provides input to the Console about whether a diaphragm contraction occurred as a result of stimulations from Catheter electrode combinations. After the Catheter is inserted, two clinicians are needed to perform manual Placement: One inside the sterile field to observe and palpate the patient, and one outside it to operate the Console.



Manual mode requires that the clinician provide feedback to the Console using the three buttons on the bottom portion of the screen:

#	Item	Description
1	Unsure	Use the Unsure button to indicate uncertainty about whether diaphragm contraction occurred during a stimulation. It will prompt the Console to program a stimulation with the same electrode combination and intensity again.
2	Stimulate	When blue, press the Stimulate button to deliver stimulations. This button will also indicate status during stimulations.
3	Confirm	Use the Confirm button to indicate that a diaphragm contraction was observed during a stimulation.

To perform manual Placement:

1. Select **Catheter Insertion** from the Console's Home Screen, ensure the **Placement** tab is selected, and then toggle to **Manual** mode.

2. Have a clinician inside the sterile field prepare to observe diaphragm contractions by placing one hand on the patient's lower ribcage to palpate the diaphragm and/or by observing the pressure and flow waveforms on the mechanical ventilator.

3. Have an assistant outside the sterile field press **Stimulate** at end-expiration, while the clinician inside the sterile field palpates the patient's left hemidiaphragm and/or observes the ventilator's waveforms.

Note: Contractions are typically easiest to observe when stimulations are delivered during the end-expiration period of the patient's respiratory cycle. Because contractions will only be observed for the electrode combinations nearest to the phrenic nerve, it is normal to not detect a contraction from some stimulations during this process.

4 After the stimulation is complete, provide feedback to the Console by indicating whether a diaphragm contraction was observed:

- If uncertain whether an unwanted effect occurred, select **Unsure** to select the same electrodes again.
- If contractions occurred, select **Confirm**.
- If there was no contraction, do not select either button. It is normal and an expected part of the process to not detect a contraction during a stimulation, and move on to the next electrode and intensity combination by pressing **Stimulate**.

5 Repeat steps 3 and 4, following the instructions in the Notification Box, until all electrodes and intensities have been evaluated. Then, press **Complete**.

Note: If no contractions are observed during the Placement verification process, it will be considered unsuccessful. If this occurs persistently, the Catheter may need to be repositioned. Refer to the Catheter Kit Instructions for Use for details. Once the Catheter is repositioned, try Placement again.

6 Press **End Session** and disconnect the electrical cable connectors at the Catheter and Airway Sensor before pressing the **Power** button to turn off the Console.

7 Follow institutional guidelines to confirm the Catheter tip is positioned in the SVC. Once confirmed, secure the Catheter manifold to the patient's skin according to your institution's guidelines.

⚠ **CAUTION:** Secure the Catheter to prevent movement after Placement has completed successfully. Movement of the Catheter during Therapy may result in inappropriate Therapy or overstimulation and injury of the diaphragm.

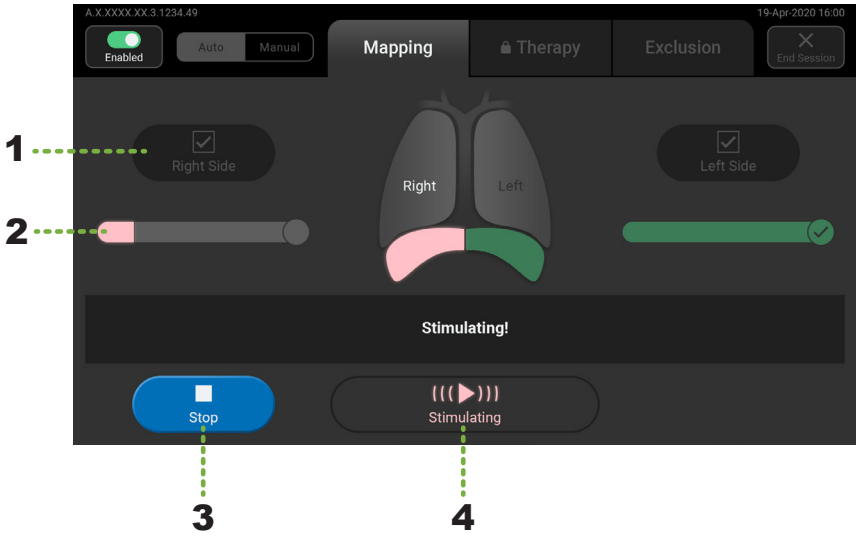
Mapping: Selecting Electrodes that Contract the Diaphragm

Mapping identifies which of the Catheter's 30 electrodes are suitable for use during Therapy, and at what baseline Therapy Levels. These Therapy Levels differ from patient to patient, and may also differ for the same patient over time. For this reason, Mapping must be performed before every Therapy session. It may also occasionally be useful to re-run mapping on occasion during an extended Therapy session. Each phrenic nerve and connected hemidiaphragm (left and right) is mapped individually, so that Therapy can be optimized on each side.

Performing Mapping

To perform Mapping, begin by preparing the System and patient. Ensure the Console is properly positioned and set up, with the Airway Sensor and Catheter connected.

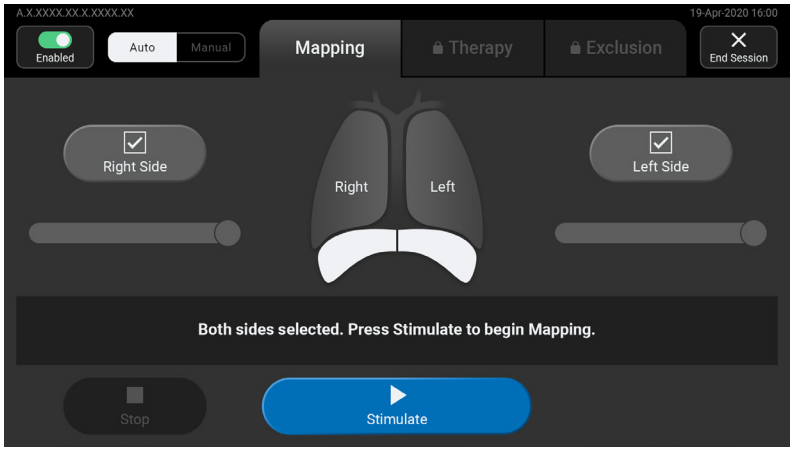
Mapping is typically performed on both hemidiaphragm sides (left and right), but if the patient's anatomy precludes that, it may also be performed on a single side. Therapy may only be delivered on sides that are successfully mapped.



#	Item	Description
1	Hemidiaphragm Selector	Selects the sides (left and/or right) that will be Mapped.
2	Progress Bar	Provides a visual estimate of process progression. Illuminates in different colors to indicate status: Analyzed (blue), Active (white), Stimulating (pink), Unsure (teal), Confirm (light green), and Complete (dark green).
3	Stop	Stops the series of stimulations that are in progress.
4	Stimulate	When blue, begins delivery of stimulations. This button will also indicate status during and between stimulations.

Auto Mapping

In Auto mode, the AeroNova System will use data from the Airway Sensor to identify and select electrodes that are suitable for Therapy.



1. If it is not already powered on, press the Console's black **Power** button.
2. Select **Therapy Session** from the Home screen, and then select the **Mapping** tab.

> Note: If you completed a Catheter Insertion and Placement session immediately prior to beginning Therapy, the Mapping tab will already be active.

3. Ensure Right Side and Left Side are both checked, unless clinical conditions do not allow Therapy to be delivered to both hemidiaphragms. To omit a side from Mapping and Therapy, deselect it by clicking on the corresponding hemidiaphragm's checkmark.

> Note: At least one side must be successfully Mapped before the Therapy tab is unlocked for use.

4. Press **Stimulate**. The progress bar(s) and notification box will show the status of the Mapping process.

> Note: If needed, stop the delivery of stimulations at any time by pressing the blue Stop button on the touchscreen or Handheld Controller.

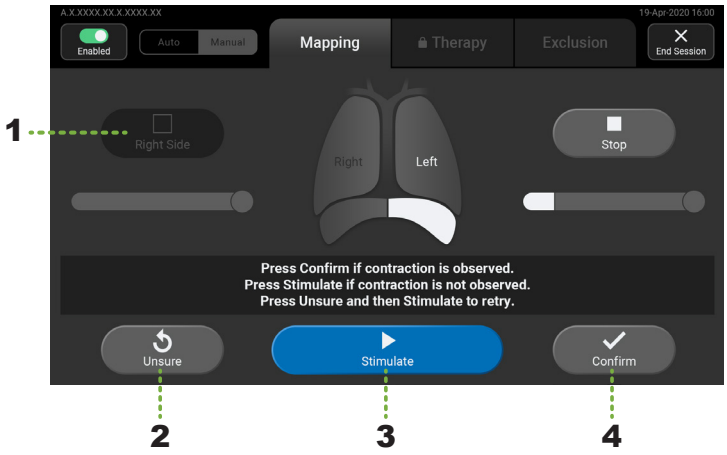
5. When Mapping is successful for the selected side(s), the 'lock' icon on the Therapy tab will disappear. Press **Continue** to proceed with Therapy.

> Note: If Mapping is unsuccessful on one or both sides, press **Continue**. The Mapping tab will remain active, where you can try auto Mapping again, or press the **Manual** toggle to troubleshoot further by performing Mapping manually. See *"Manual Mapping" on page 22* for details. Therapy will only be delivered to successfully mapped side(s).

Manual Mapping

If Auto Mapping is unsuccessful after several attempts, or there is another clinical reason to do so, Manual Mapping may be used to locate and verify sufficient stimulation of the patient's phrenic nerves and contraction of the diaphragm.

To perform Mapping manually, the clinician presses the Stimulate button while palpating each hemidiaphragm individually and/or observes the ventilator for deflections on the pressure and flow waveforms. Each time Stimulate is pressed, the Console delivers stimulations to different sets of electrodes on the Catheter. The clinician provides input to the Console about whether a diaphragm contraction resulted from the stimulation from each electrode combination. In this way, electrodes that successfully recruit the patient's diaphragm can be identified and used during Therapy.



Manual Mapping requires that the clinician select which hemidiaphragm to map, and then provide feedback to the Console using the three buttons on the bottom portion of the screen:

#	Item	Description
1	Hemidiaphragm Selector	The hemidiaphragm buttons select the side (left or right) that will be Mapped.
2	Unsure	Use the Unsure button to indicate uncertainty about whether diaphragm contraction occurred during a stimulation. It will prompt the Console to program a stimulation with the same electrode combination and intensity again.
3	Stimulate	When blue, press to deliver a stimulation. This button will also indicate status during stimulations.
4	Confirm	Use the Confirm button to indicate that a diaphragm contraction was observed during a stimulation.

To perform manual Mapping:

1. Select **Therapy Session** from the Console's Home Screen, ensure the **Mapping** tab is selected, and toggle to **Manual** mode.

2. Leave Left Side checked to map the left hemidiaphragm, or check Right Side to map the right hemidiaphragm. Note that when Mapping in Manual mode, only one hemidiaphragm can be mapped at a time.

3. Have an assistant outside the sterile field press **Stimulate** at end-expiration, while the clinician inside the sterile field palpates the appropriate hemidiaphragm and/or observes the ventilator's waveforms.

Note: Contractions are typically easiest to observe when stimulations are delivered during the end-expiration period of the patient's respiratory cycle. Because contractions will only be observed for the electrode combinations nearest to the phrenic nerve, it is normal to not detect a contraction from some stimulations during this process.

4 After the stimulation is complete, provide feedback to the Console by indicating whether a diaphragm contraction was observed:

- If uncertain whether an unwanted effect occurred, select **Unsure** to select the same electrodes again.
- If contractions occurred, select **Confirm**.
- If there was no contraction, do not select either button. It is normal and an expected part of the process to not detect a contraction during a stimulation, and move on to the next electrode and intensity combination by pressing **Stimulate**.

5 Repeat steps 3 and 4, following the instructions in the Notification Box, until all electrodes and intensities have been evaluated. Then, press **Complete**.

Note: If no contractions are observed during the Mapping process, it will be considered unsuccessful. If this occurs persistently, the Catheter may need to be repositioned. Refer to the Catheter Kit Instructions for Use for details. Once the Catheter is repositioned, complete Placement and then try Mapping again.

AeroNova Therapy

Therapy from the AeroNova System is intended for delivery with every breath, in conjunction with positive-pressure respiratory support from a mechanical ventilator. The strength of the negative-pressure generating contractions can be titrated to provide the respiratory contribution from the patient's diaphragm for adequate ventilation while preserving diaphragm muscle strength. User-selectable low and high diaphragmatic activation notifications, as well as a high stop limit ensure the strength of the patient's diaphragm contractions remain within the desired range.

The desired contribution (Diaphragm Activation Level, or "DAL") of each hemidiaphragm can be titrated using the plus (+) and (-) buttons on the right portion of the screen. The baseline therapeutic levels identified during the Mapping process are marked on the screen with white bars; these represent the minimum stimulation levels required to successfully contract the diaphragm.

In **Auto mode**, the AeroNova System detects breaths initiated by the mechanical ventilator, and delivers stimulations in time with patient inspiration. In **Manual mode**, the AeroNova System will deliver stimulations at the set Stim Rate, and trigger the ventilator to initiate breaths. In other words, in Auto mode, breaths from the ventilator trigger stimulations, and in Manual mode, stimulations from the AeroNova System trigger ventilator breaths.

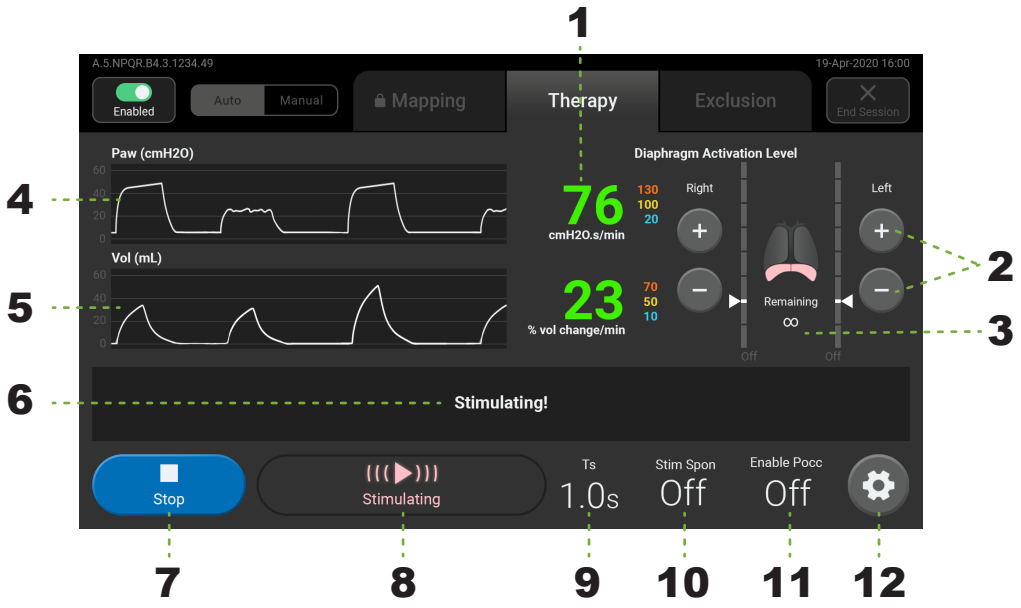
Familiarize yourself with the screen and settings before beginning Therapy. For more information on DAL readings, see *"Understanding Diaphragm Activation Levels (DAL)" on page 31.*

WARNING:

- Ventilator settings should be configured appropriately for the patient according to institutional guidelines. Observe the patient during System use to ensure that the ventilator settings and the AeroNova System settings are compatible. Failure to do so may result in inadequate ventilation, ventilator dyssynchrony, inappropriate Therapy delivery, or lung or diaphragm injury. See *"Providing AeroNova Therapy" on page 27* 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 *"Using Exclusion to Disable Electrodes" on page 32* for details.
- The Catheter is MR Conditional, but the Neurostimulation Console is MR Unsafe. Conditions under which the Catheter is MR compatible and may be scanned safely are described in the Catheter Kit Instructions for Use. Always disconnect the Catheter from the Neurostimulation Console before conducting MRI, and keep the Console away from MR equipment.
- For the safety of the patient, disconnect the Catheter from the Console before defibrillating or cardioverting. If the Catheter remains connected to the Console, electrical defibrillation current may flow through the AeroNova System and reduce the intended defibrillation energy delivered to the patient or cause myocardial damage.

CAUTION:

- Ensure Therapy is provided with the regularity and settings appropriate for the patient and their condition, and that the High (Stop) Limit is set appropriately for the patient's clinical condition. Overstimulation of the diaphragm may result in diaphragm injury.
- Therapy delivered from the AeroNova 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.



#	Item	Description
1	Diaphragm Activation Level (Indicator and Limits)	Displays the patient's estimated average Diaphragm Activation Level over the last minute, in cmH_2O•s/min and/or % vol change/min, as well as the currently set notification and stop limits. See *"Understanding Diaphragm Activation Levels (DAL)" on page 31* and *"Diaphragm Activation Level (DAL) Notifications and Limits" on page 29* for more information.
2	Therapy Level Controls (Right and Left)	The plus (+) and minus (-) buttons adjust strength of stimulations on each hemidiaphragm side (right and left). Stronger stimulations mean more contribution from the patient's diaphragm with each stimulated breath. The white squares on the vertical bars indicate the baseline levels established for each side during Mapping. Note that setting the DAL too far below these baselines may deliver stimulations at a sub-therapeutic levels.
3	Stimulations	Number or Duration of stimulations programmed or remaining in a Therapy Session. Configurable using the Settings button while Therapy is stopped.
4	Paw[1]	Waveform displaying patient airway pressure data.
5	Vol[1] (Inspiratory)	Waveform displaying inspiratory tidal volume data.
6	Notification Box	Displays information about system status and other contextually relevant information.
7	Stop	Stops the current active Therapy session. The Number or Duration of stimulations will reset to the configured value.
8	Stimulate	The Stimulate button is used to begin a Therapy session, and then displays stimulation status (Stimulating or Waiting) during an active Therapy session.
9	Ts (Stim Duration)	The duration of each stimulation during the active Therapy session, configurable by pressing this area of the screen. The System will automatically detect the patient's Inspiratory Time, and then calculate a Predicted Stim Duration that is shorter than that value. If desired, increase or decrease the offset to shorten or lengthen the total stimulation duration. Alternatively, check Fixed Stim Duration to manually configure a static duration.
10	Stim Spon	When set to On, the System will deliver stimulations during all detected breaths, including spontaneous ventilator breaths. To skip stimulations for spontaneous breaths, uncheck the box. In Auto mode, additionally set the Spontaneous Breath Detection Sensitivity. Increase the sensitivity to detect (and thus skip) more spontaneous ventilator breaths. Decrease the sensitivity to detect (and thus skip) less spontaneous breaths.
11	Enable Pocc (Auto mode only)	Enables (On) or Disables (Off) the ability to press the Stimulate button and deliver a stim between breaths while performing an expiratory hold on the ventilator to measure the occlusion pressure generated by Therapy stimulations. Enable Pocc reverts back to its default setting (Off) after two minutes of no user interactions with the System.
12	Settings	The Settings button provides access to additional Therapy controls. See *"Therapy Settings" on page 28* for details.

Note: For the default settings, range, resolution, accuracy of System controls and monitors, see *"Monitor Range, Resolution, and Accuracy" on page 42* and *"Control Range, Resolution, and Defaults" on page 42.*

1 The pressure and volume waveforms displayed on the screen are for display purposes only. This information should not be used for making any clinical decisions. Please use the pressure and volume information provided by mechanical ventilator for decisions related to patient care.

Providing AeroNova 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. To provide Therapy in Manual mode, you must additionally and precisely set the Stim Rate so that stimulations from the AeroNova System trigger ventilator breaths at a rate appropriate for the patient.

To provide Therapy:

1. Press the **Settings** button in the lower-right corner of the screen to configure the **Number** or **Duration of Stimulations**, **Skip Breaths** (Auto mode only), and stimulation **Frequency** for the Therapy session.

Note: If the System is set to **Manual** mode (using the toggle in the upper-left corner of the screen), the Skip Breaths control will be replaced with the **Stim Rate** control. Set this parameter carefully so that stimulations delivered at this rate will trigger the initiation of breaths from the ventilator, without creating asynchrony.

2. Configure **Ts** (Stim Duration) and **Stim Spon** by pressing the displayed setting on the main Therapy screen.

3. Confirm all Therapy settings, and then 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.

Note: At high settings, DAL increments have the potential to become more intense. Increase the DAL slowly within in the upper two sections of the setting for each side.

5. Set the **High** and **Low Notification Limits** — and most importantly 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. See *"Setting Diaphragm Activation Level Limits" on page 30* for detailed instructions.

6. While providing Therapy, continue to monitor the patient as appropriate for their condition, and perform the following actions if needed:
   - If DAL values fall outside the desired range, press **Settings** and then **Reassess Baseline**. If a recalculation of the baseline DAL does not address the issue, adjust the **Therapy Levels** and any other parameters as needed to optimize therapy as a second step.
   - Whenever ventilator settings are changed, use the **Reassess Baseline** button in the Therapy Settings pop-up to recalculate the patient's baseline DAL and ensure the displayed DAL values are accurate.
   - Take **Pocc** measurements as needed to titrate the Diaphragm Activation Level settings and/or assess the patient.
   - If needed, stop the delivery of stimulations at any time by pressing the blue **Stop** button on the touchscreen or Handheld Controller. If unwanted patient effects occur that prevent setting an effective Therapy Level, see *"Using Exclusion to Disable Electrodes" on page 32.*

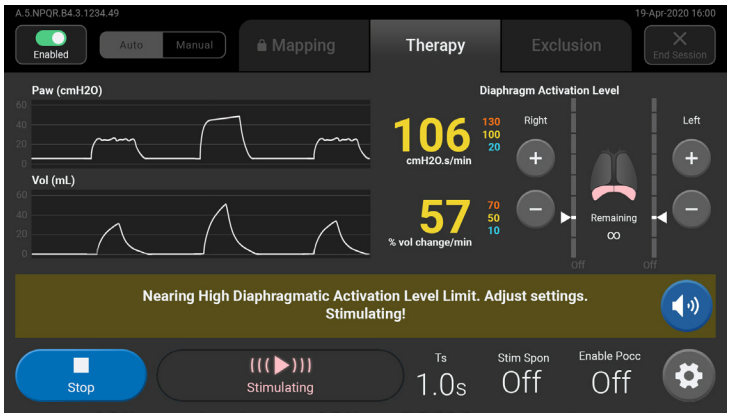
Therapy Settings

To adjust Therapy settings, press the gray Settings button on the lower right of the Therapy screen. A pop-up will appear that provides access to adjustments for the following parameters:

Item	Description
Stimulations	Use the radio buttons at the top of the control to select whether you would like to deliver a number of stimulations (including infinite), or stimulate for a set a duration. Then, use the plus and minus buttons to set the number or duration of stimulations that will be delivered each time the Stimulate button is pressed.
Skip Breaths (Auto mode only)	Sets the number of detected breaths that are skipped between each stimulation in Auto mode.
Stim Rate (Manual mode only)	Sets the rate at which stimulations are delivered, triggering ventilator breaths in Manual mode.
Frequency	Sets the stimulation pulse frequency.
Reassess Baseline	When pressed, the System will reassess the baseline DAL used for calculating the estimated patient Diaphragm Activation Level displayed on the screen. Press the Reassess Baseline button whenever the patient ventilator setup or settings are changed.
View Trends	Press this button to display 24-hour and breath-by-breath Trends related to the delivered Therapy. See *"Therapy Trends" on page 30* for more information.

Diaphragm Activation Level (DAL) Notifications and Limits

The AeroNova System provides the operator with the ability to set low and high notification thresholds, as well as a high (stop) limit to ensure the patient's diaphragmatic effort remains within the desired range.



When a set notification limit is exceeded, the Therapy screen will display a message, the notification box will display the color associated with the exceeded limit, and an audible tone will sound every 30 seconds. When the set stop limit is exceeded, a notification will display for 30 seconds, and if the DAL does not decrease below the stop limit, stimulations will stop to prevent overactivation of the diaphragm.

If desired, press the blue **Audio Pause** button in the notification box to silence the audible portion of the notification for three minutes. Each time the button is pressed, the three-minute silence timer will reset.

Item	Description
Ventilator Mode Selector	Allows the user to select whether the mechanical ventilator is in Volume-targeted or Pressure-targeted mode of operation, so that notifications and limits can be set appropriately.
High (Stop) Limit (Orange)	Sets the DAL value at which stimulations will stop to prevent overactivation of the diaphragm. The High Diaphragm Activation Level limit exceeded message will display, and if not resolved within 30 seconds, Therapy will stop.
High Notification (Yellow)	Sets the DAL value at which the system will provide a High DAL notification. Stimulations will continue.
Low Notification (Blue)	Sets the DAL value at which the system will provide a Low DAL notification. Stimulations will continue.

Setting Diaphragm Activation Level Limits

1. Press the area of the Therapy screen where the numeric Diaphragm Activation Level values are displayed. Pressing the **cmH$_2$O•s/min** and/or **% vol change/min** area will display limit settings for the corresponding value.
2. Check the **Volume-Targeted** or **Pressure-Targeted** box to match the mode of mechanical ventilation.

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.

3. You must determine and then set the **High (Stop) Limit** value appropriately for the patient's clinical condition to prevent over-activation of the diaphragm. Some methods of determining the appropriate upper limit for diaphragm activation include:
   - Using Pocc measurements
   - Slowly increasing Therapy Levels while observing the patient
4. Use the plus **(+)** and minus **(-)** buttons to set the High (Stop) Limit value, the High Notification, and the Low Notification, then press the blue check button to accept and apply the settings.

Therapy Trends

Pressing the **Trends** button in the **Settings** pop-up will replace the pressure and inspiratory volume waveforms on the main Therapy screen with graphs that show how the Diaphragm Activation Level has changed over time.

Press the page forward **(>)** and page backward **(<)** buttons to scroll through the following trended data:

- 24h Trends: % Breaths Stimulated
- 24h Trends: cmH$_2$O•s/min
- 24h Trends: % vol change/min
- 1m Trends: cmH$_2$O•s/min
- 1m Trends: % vol change/min

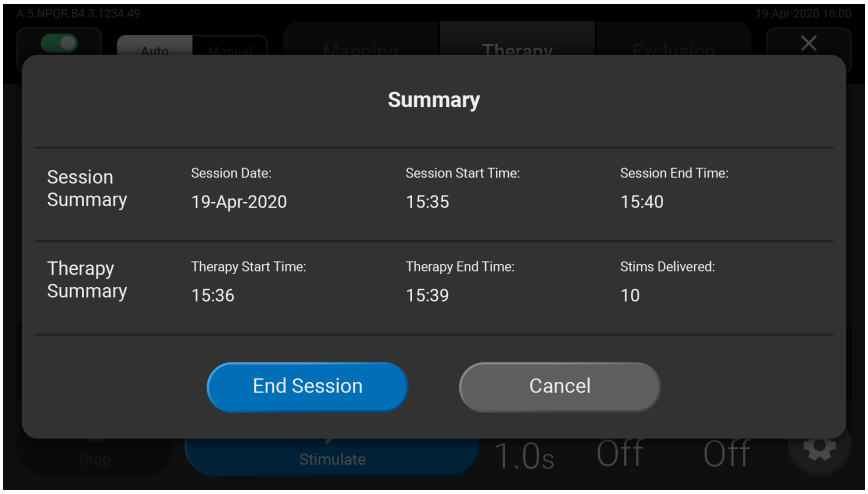
Press the **Exit** button at the bottom of the Trends section at any time to return to the Paw and Vol waveforms.

Ending Therapy

1. Press the **End Session** button in the upper-right corner of the screen to end the active Therapy Session and display a summary screen.

1. Always disconnect the electrical cable connectors at the Catheter and Airway Sensor after use. The cables may remain connected to the Console.

2. Press the **Power** button to turn off the Console.



Understanding Diaphragm Activation Levels (DAL)

The AeroNova System provides an estimated measurement of the patient's diaphragmatic contribution, or "activation" as stimulations contract their diaphragm. A mechanical ventilator used on its own does all the work of breathing for a patient, using positive pressure through the airway. When the ventilator is used in combination with the AeroNova System, the work of breathing is shared with an adjustable contribution of negative pressure from the patient's diaphragm, as it contracts with each delivered stimulation.

Diaphragm Activation Levels are displayed as an average reduction in Pressure-Time Product (or "PTP," displayed in cmH_2O•s/min) or increase in volume (% vol change/min) achieved **over a full minute of breathing**.

When used with a mechanical ventilator in **Volume-targeted** modes of operation, each stimulation will contribute negative pressure from the patient's diaphragm, reducing the amount of positive pressure required to provide the same volume of air to the patient during each breath. The estimated Diaphragm Activation Level and notification limits will be displayed in **cmH_2O•s/min**, providing an estimate of the reduction in the Pressure-Time Product (without reducing volume) achieved over one minute of breathing.

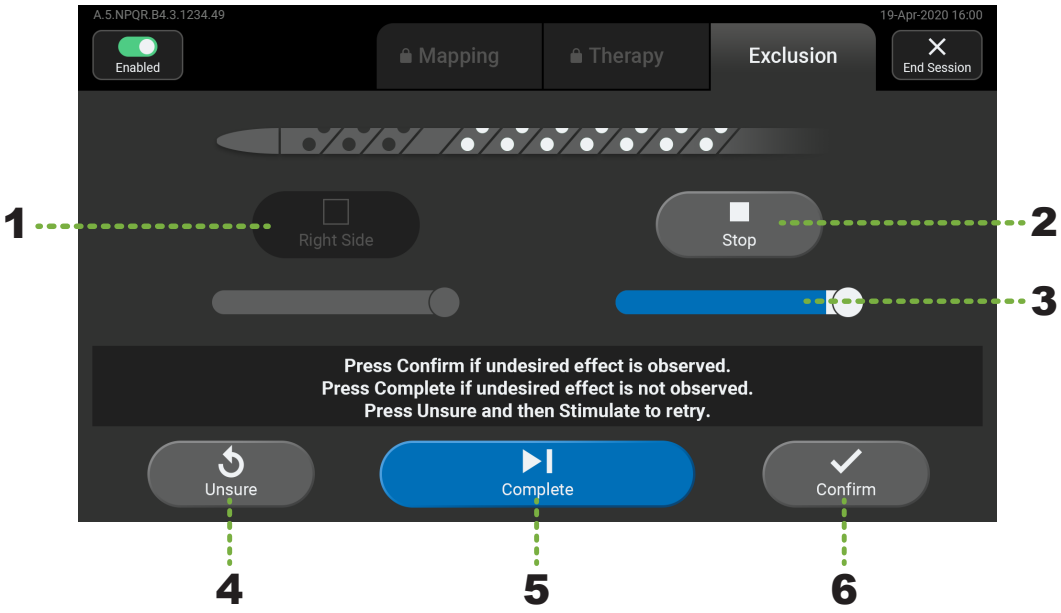
When used with a mechanical ventilator in **Pressure-targeted** modes of operation, each stimulation will generate negative pressure that increases the volume of air delivered to the patient, without increasing the peak pressure. The estimated Diaphragm Activation Level and notification limits will be displayed in **% vol change/min**, providing an estimate of the average increase in volume (without increasing pressure) achieved over a minute of breathing.

Troubleshooting

Using Exclusion to Disable Electrodes

In some cases, the Catheter's electrodes may cause bothersome or uncomfortable effects for the patient when set to an effective therapy level. Depending on the positioning of the electrodes, these may include stimulation of nerves or tissues other than those intended. If this occurs during Placement, Mapping, or Therapy, the Exclusion tab can be used to identify and then temporarily disable (exclude) the specific Catheter electrodes causing the unwanted effects.

During Exclusion, the Console sends stimulations to one electrode combination at a time. The clinician must observe the patient closely to determine whether the selected electrode combination caused an unwanted effect, and then provide observational feedback to the Console. In this way, the electrodes that cause unwanted effects are identified and disabled.



#	Item	Description
1	Side Selector	Selects which grouping of Catheter electrodes (left or right) will be included in the Exclusion process.
2	Stop	Stops the series of stimulations that are in progress.
3	Progress Bar	The Progress Bar provides a visual estimate of process progression. It illuminates in different colors to indicate status: Analyzed (blue), Active (white), Stimulating (pink), Unsure (teal), Confirm (light green), and Complete (dark green).
4	Unsure	Use the Unsure button to indicate uncertainty about whether an unwanted effect occurred during a stimulation. It will prompt the Console to program a stimulation with the same electrode combination and intensity again.
5	Stimulate	When blue, press the Stimulate button to deliver stimulations. This button will also indicate status during stimulations.
6	Confirm	Use the Confirm button to indicate that an unwanted effect was observed during a stimulation. The Console will use this information to identify the specific electrodes causing the unwanted effect.

To exclude electrodes:

1. Press the **Exclusion** tab on the Placement, Mapping, or Therapy screen.
2. Press **Stimulate** and observe the patient closely for unwanted effects.

> ⚠ **WARNING:** Delivery of electrical stimulation in the right atrium, right ventricle, or other positions may result in cardiac arrhythmia.

> Note: If needed, stop the delivery of stimulations at any time by pressing the blue **Stop** button on the touchscreen or Handheld Controller.

3. After the stimulation is complete, provide feedback to the Console by indicating whether or not an unwanted effect was observed:
   - If uncertain whether an unwanted effect occurred, select **Unsure** to select the same electrodes again.
   - If the unwanted effect occurred, select **Confirm**.
   - If there were no unwanted effects, do not select either button. It is normal and an expected part of the process to not detect an unwanted effect during a stimulation, and move on to the next electrode combination by pressing **Stimulate**.
4. Repeat steps 2 and 3, following the instructions in the Notification Box, until all electrodes awaiting assessment in the array (right or left) have been evaluated, and then press **Complete**.
5. If needed, repeat steps 2 and 3 for the other side (right or left) array, and then press **Complete** again.
6. Press the **Placement**, **Mapping**, or **Therapy** tab; the procedure or session in progress will now continue with the excluded electrodes disabled.

> Note: If desired, press **Clear** to undo the completed Exclusion process and turn all electrodes back on. If unwanted effects remain or return, the Exclusion process will need to be repeated.

> Note: Excluded electrodes remain disabled for the remainder of the Placement or Therapy session, unless **Clear** is selected.

Manual Placement and Mapping

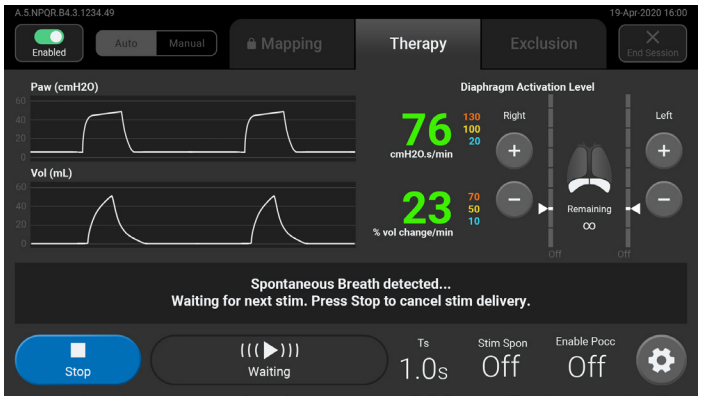
In some cases, Manual mode may be useful in troubleshooting the Placement or Mapping procedures. Instead of using data from the Airway Sensor, the System relies on the clinician to carefully observe the patient and ventilator waveforms during each Placement or Mapping stimulation, and then provide feedback to the Console. Contractions can be detected through palpation of the appropriate hemidiaphragm and deflections on the ventilator waveforms. See *"Manual Placement" on page 18* and *"Manual Mapping" on page 22* for details.

Understanding System Messages

The Console will provide on-screen updates about the status of the AeroNova System, and its interaction with the patient. The notification bar and Stimulate button will display relevant information contextually, and provide information about how to proceed with use of the system.

Notifications

Notifications appear in the notification box above the Stimulate button, and provide additional information about System status. If appropriate, more than one message may be displayed at the same time.



- **Airway Sensor used more than 60 days**: Indicates that the Airway Sensor needs to be replaced with a new one before continuing System use.
- **Airway Sensor error detected. Resetting**: Indicates the System detected an error with the Airway Sensor. If resetting the Airway Sensor resolves the issue, the message will clear. If not, the System will stop stimulations.
- **Airway Sensor errors detected. Check Airway Sensor**: Indicates the System was unable to resolve the detected error with the Airway Sensor by resetting it. Verify the Airway Sensor is connected correctly and if needed, replace it to continue Therapy.
- **Baseline data could not be gathered**: Indicates that the Console was unable to gather a baseline DAL. If needed, adjust settings and then start stimulation. If the message persists during stimulation, press the blue Stop button to stop the stimulation sequence, verify that the ventilator and System settings and setup are correct, and then restart stimulations.
- **Baseline Pressure out of range***: Indicates that the baseline pressure measured by the Airway Sensor is out of the expected range. Verify that the Airway Sensor is pneumatically connected correctly to the patient's ventilator circuit, and verify the patient's ventilator parameters. The notification will go away if the baseline pressure returns to the expected range after the pause period.
- **Catheter used more than 60 days**: Indicates that the Catheter needs to be replaced with a new one before continuing System use.
- **Early Breath Detected**: Indicates that the Console detected a breath earlier than expected. The stimulation sequence will continue, though stimulation will not be delivered on an early breath. Shortening the Stim Duration, adjusting ventilator settings, and/or delivering Therapy in Manual mode all may help resolve frequent Early Breath Detected notifications.

- **Flow out of range***: Indicates that the flow measured from the Airway Sensor is out of the expected range. Verify that the Airway Sensor is pneumatically connected correctly to the patient's ventilator circuit, and verify the patient's ventilator parameters. The notification will go away if the flow returns to the expected range after the pause period.
- **Gathering Baseline DAL Data**: Displays after pressing the Reassess Baseline button in the Settings pop-up, or when the System detects that the Console needs more data from the Airway Sensor before the next stimulation can be delivered. Wait while the Airway Sensor continues to gather information about the patient's breathing. If needed, press the blue Stop button to stop the stimulation sequence.
- **Respiratory Rate out of range***: Indicates that the Console detected a breath rate that is too high. The System will pause stimulations if the detected breath rate is above 60 breaths per minute. The notification will go away if the breath rate returns to the expected range after the pause period.
- **High Diaphragm Activation Level**: Indicates that the calculated DAL has risen above the user-set High Notification Limit (yellow).
- **High Diaphragm Activation Limit Exceeded**: Indicates that the calculated DAL has exceeded the High Stop Limit (orange). If the DAL remains higher than the set limit for more than 30 seconds, stimulations will stop, and will not resume until an operator restarts them.
- **Low Diaphragm Activation Level**: Indicates that the calculated Diaphragm Activation Level (DAL) has fallen below the user-set Low Notification limit (light blue).
- **Pressure out of range***: Indicates that the pressure measured from the Airway Sensor is out of the expected range. Verify that the Airway Sensor is pneumatically connected correctly to the patient's ventilator circuit, and verify the patient's ventilator parameters. The notification will go away if the pressure returns to the expected range after the pause period.
- **Reassessing Baseline Pressure**: Indicates that the System detects the pressure baseline is inconsistent and is being recalculated. While this notification is active, the Console will not deliver stimulations, unless the Stimulate button is pressed when Enable Pocc is set to On. Verify that the Airway Sensor is pneumatically connected correctly to the patient's ventilator circuit, and verify the patient's ventilator parameters. The notification will go away if the baseline pressure returns to the expected range.
- **Spontaneous Breath Detected**: Indicates that the Console detected a spontaneous breath and did not stimulate. This only occurs when Stim Spon is set to Off. Stimulations will continue during ventilator-initiated breaths that are not calculated to be spontaneous based on the Stim Spon Sensitivity setting.
- **Stimulations Paused**: Indicates that stimulations have paused while the AeroNova System continues to monitor data from the Airway Sensor. Stimulations will automatically resume if the issue is resolved after the pause period.
- **Stimulations Stopped**: Indicates that stimulations have stopped. Adjust ventilator and/or AeroNova System settings as necessary, and then press the Stimulate button to restart Therapy. The Notification box will turn orange when stimulations are stopped.

* When these messages display, the System will pause stimulations and then reanalyze status in three-minute increments. At three minutes and at six minutes, stimulations will resume if the condition has been resolved, or remain paused if the condition is still detected. At 9 minutes, stimulations will resume if the condition has been resolved, or stop if the condition remains. If stimulations stop, they must be restarted by pressing the Stimulate button.

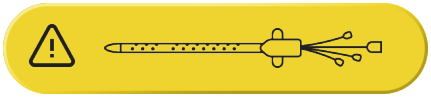
Error Messages

Error messages indicate that something is preventing the AeroNova System from providing Therapy to the patient. Take the steps below to resolve the issue and resume Therapy.

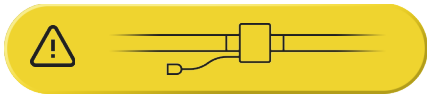
Component Connection Error Messages

Component connection errors appear as a yellow button on the bottom of the screen (in place of the Stimulate button).

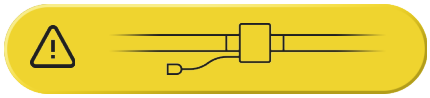
- **Catheter Cable Connection:** Indicates that the Catheter Cable may not be connected to the Catheter, or to the Console. Verify the that the patient's Catheter is securely connected to the Catheter Cable, and that the Catheter Cable is securely connected to the Console.



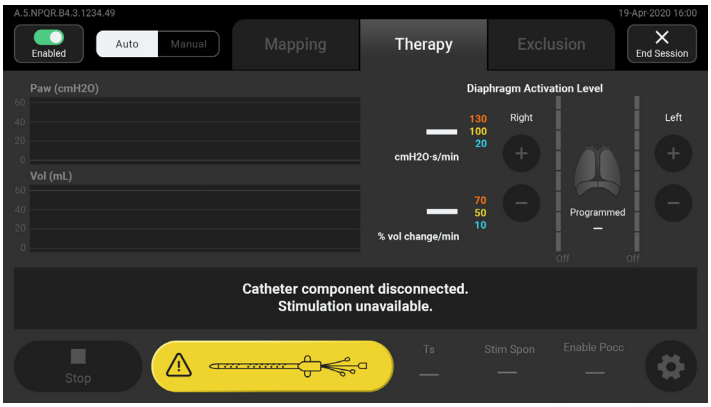
- **Airway Sensor Cable Connection**: Indicates that the Airway Sensor Cable may not be connected to the Airway Sensor, or to the Console. Verify that the patient's Airway Sensor is securely connected to the Airway Sensor Cable, and that the Airway Sensor Cable is securely connected to the Console.

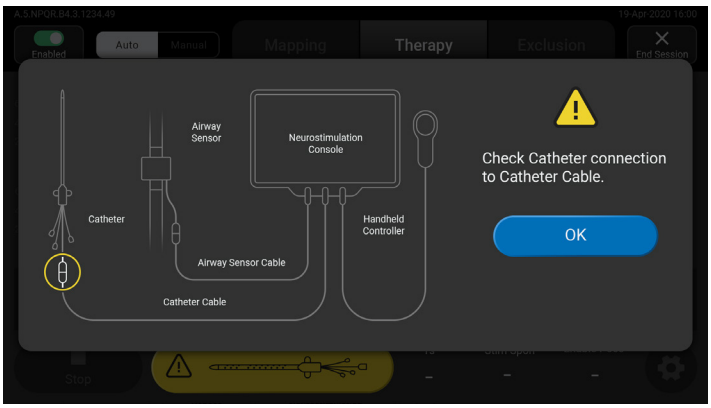


- **Airway Sensor Connection to Patient**: Indicates that the Airway Sensor may not be connected to the patient's ventilator circuit. Verify that the patient's Airway Sensor is correctly connected to the patient's ventilator airway circuit at the inspiratory limb or Y-piece. The arrow on the front of the sensor should be oriented toward the patient.

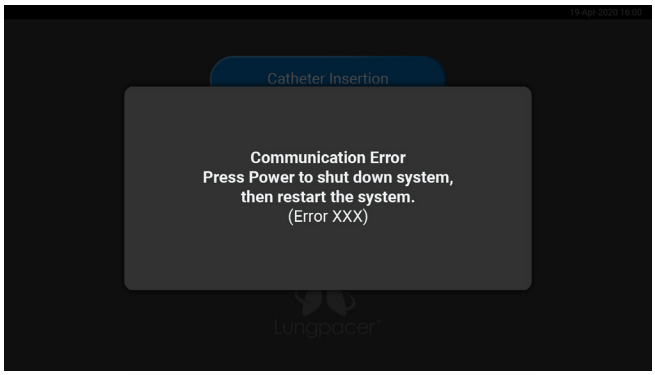


Press the yellow warning button to view more information about the warning, including a graphic that helps explain where the component connection error has been detected.





Console Error Messages



Console error messages will appear as pop-ups that cover most of the screen. If these error messages occur, **restart the System by pressing the Power button**, waiting a few seconds, and then pressing the Power button again to turn the System on. If error messages cannot be cleared by restarting the System, make note of the error code at the end of the message, and contact Lungpacer. Example error messages include:

- **Yellow Stop Button Pressed**: Indicates that the yellow Stop button on the front of the Console was pressed, quickly halting all stimulation output.
- **Communication Error**: Indicates that the Console had difficulty communicating internally or with other System components. This message may appear, for example, if there are loose or damaged electrical connections within the Console, between the Console and other System components (such as the Catheter, Airway Sensor, or Handheld Controller), or if other electrical supply or software issues occur.
- **Stimulation Output Error**: Indicates that the Console detected unexpected pulse characteristics such as timing, count, voltage, current, problems with the power supply, or failed an internal integrity check.
- **Logging Error**: Indicates the Console had difficulty writing, exporting, or deleting logs.

System Care and Maintenance

WARNING: To reduce the risk of electrical shock, disconnect mains power from the Console before cleaning.

CAUTION:

- Do not disinfect, re-sterilize, or reuse single-patient use or sterile components. Reuse or re-sterilization of sterile components may impair the structural integrity and/or performance of the AeroNova System and may cause injury or infection.
- Do not attempt to open the Console enclosure. Opening the Console may result in electrical shock.
- Follow all cleaning instructions for the System. Improper cleaning of System components may result in infection.
- After use, the Catheter, Catheter Kit Components, and/or Airway Sensor may be a potential biohazard. Handle and dispose of them in accordance with accepted medical practice and applicable local, state, and federal laws for biohazardous waste.

Duration of Use

The Catheter is sterile for single-use and may be used for a maximum of 30 days.

Note: Refer to the Catheter Kit Instructions for Use for information about sterilization processes used on the Catheter and the steps to take in the event of damage to the sterile packaging.

The Airway Sensor is single-patient use for a maximum of 30 days.

Cleaning Instructions

Before use, follow institutional policies regarding cleaning of bedside equipment.

To clean the Airway Sensor, suction the secretions from it, or gently wipe them away using a damp, sterile cloth. Do not rinse the Airway Sensor or its electrical connector under running water, as fluid ingress may permanently damage its electronics and cause it to stop functioning.

Wipe down the Console, Catheter Cable, Airway Sensor and Cable, and Handheld Controller with a clean, soft, and lint-free cloth using one of the following cleaning agents:

- Virox
- Cidex
- Alcohol
- CaviWipes

Disposal

When the Console, Catheter Cable, Airway Sensor Cable, or Handheld Controller are removed from service, adhere to regulations and local guidelines for recycling and disposal of electrical and electronic equipment. To dispose of the Airway Sensor, additionally adhere to local regulations for the disposal of biohazardous waste.

Refer to the Catheter Kit Instructions For Use for instructions regarding the removal and disposal of the Catheter.

Service Procedures

Only qualified personnel may perform AeroNova System service and maintenance procedures. Contact Lungpacer Medical Inc. using the contact details on the last page of this document for additional information.

System Specifications

Device Classification

The AeroNova System has the following classifications:

- Class III medical device
- Class I Medical Electrical Equipment
- IPX1 protected equipment
- Type BF applied parts. The applied parts are the Catheter and the Airway Sensor.

Power Input Rating

Parameter	Specification
Voltage Range	100 to 240 VAC
Power Frequency	50 to 60 Hz
Max Current	1.5 Amps

Note: The AeroNova System is an AC mains-powered system. Connect the Console to a grounded receptacle that supplies AC power of 100 to 240 V, 50 to 60 Hz. A potential-equalization stud for additional grounding is located on the left-hand side of the Console. To use, connect a potential-equalization cable from this stud to an appropriate plug to obtain the additional grounding, if needed.

Operating Conditions

Parameter	Specification
Temperature Range	10 to 40 ˚C (50 to 104 ˚F)
Relative Humidity Range	30 to 90% non-condensing
Altitude	Up to 8000 ft (2438 m) above sea level

Storage Conditions

Parameter	Specification
System (excluding Catheter) Temperature Range	-10 to 60 ˚C (14 to 140 ˚F)
Catheter Kit Temperature Range	18 to 28 ˚C (64.5 to 82.4 ˚F)
System Relative Humidity Range	15% to 90%, non-condensing
System Altitude	Up to 8000 ft (2438 m) above sea level

Transportation Conditions

Parameter	Specification
System Temperature Range	-18 to 60 ˚C (-0.4 to 140 ˚F)
System Relative Humidity Range	15% to 90%, non-condensing

Output Characteristics

Parameter	Specification
Waveform Type	Charge-balanced biphasic asymmetrical
Pulse Delivery Mode	Constant current stimulation pulses
Pulse Durations	100 µs ± 10% to 300 µs ± 10%
Pulse Repetition Frequencies	15 Hz, 20 Hz, 25 Hz, 30 Hz, and 40Hz (default) options in Therapy for each channel. Typically, 4 Hz in Mapping & Placement. Tolerance: ± 5%
Maximum Voltage	Current regulated 33V maximum
Maximum Current	27.0 mA ± 5% at 300 Ω 27.0 mA ± 5% at 500 Ω 27.0 mA ± 5% at 1000 Ω (typical impedance) 13.0 mA ± 5% at 2000 Ω 6.0 mA ± 5% at 4500 Ω
Net DC Current (nA) at maximum pulse rate	≤ 100 nA

Monitor Range, Resolution, and Accuracy

Monitor	Range	Resolution	Accuracy
Diaphragm Activation Level (DAL)	-99 to 200 cmH_2O•s/min -99 to 100 % vol change/min:	1 cmH_2O•s/min, or 1 %/min	n/a
Stimulations Remaining	Stimulations: 1 to 300, ∞ (Infinite) Duration: 0h 1m to 24h 0m	1 stimulation, or 1 minute	n/a
Paw[1] Waveform	-100 to 100 cmH_2O	0.1 cmH_2O (minimum)[2]	± 3.5 cmH_20
Vol[1] (Inspiratory) Waveform	0 to 2000 mL	2.5 mL (minimum)[2]	Accuracy has not been quantified and is not guaranteed

Control Range, Resolution, and Defaults

Control	Range	Resolution	Default
Therapy Level Controls (Right and Left)	Min – Max	n/a	Baseline Therapy Levels
Stimulations Control	Stimulations, Duration	n/a	Stimulations
Stimulations (Number)	1 to 300, ∞ (Infinite)	1	∞ (Infinite)
Stimulations (Duration)	0h 1m to 24h 0m	1 m	1h 0m
Skip Breaths (Auto mode only)	0 to 5	1	0
Stim Rate (Manual mode only)	8 to 36/min	1/min	10/min
Frequency	15, 20, 25, 30, 40Hz	n/a	40Hz
Enable Pocc (Auto mode only)	On, Off	n/a	Off
Stim Spon	On, Off	1	Off
Stim Spon Sensitivity (Auto mode only, when Stim Spon is set to Off)	1-16	1	8
Ts (Stim Duration)	Predicted + Offset: -1.9 to 1.9, depending on calculated inspiratory time Fixed: 0.0 to 2.0s	0.1s	Predicted + 0.0s Offset
DAL Limits Ventilator Mode	Volume-Targeted, Pressure-Targeted	n/a	Neither selected
DAL High (Stop) Limit (Orange)	-99 to 200 cmH_2O•s/min, and/or -99 to 100 % vol change/min, and ≥High Notification Setting	1 cmH_2O•s/min or 1 %/min	130 cmH_2O•s/min and/or 70 % vol change/min
DAL High Notification Limit (Yellow)	-99 to 200 cmH_2O•s/min, and/or -99 to 100 % vol change/min, and ≤High (Stop) Limit Setting, and >Low Notification Setting	1 cmH_2O•s/min or 1 %/min	100 cmH_2O•s/min and/or 20 % vol change/min
DAL Low Notification Limit(Blue)	-100 to 199 cmH_2O•s/min and/or % vol change/min and <High Notification Setting	1 cmH_2O•s/min or 1 %/min	50 cmH_2O•s/min and/or 10 % vol change/min

1 The pressure and inspiratory volume waveforms displayed on the screen are for display purposes only. This information should not be used for making any clinical decisions. Please use the pressure and volume information provided by mechanical ventilator for decisions related to patient care.

2 The pressure and inspiratory volume waveforms displayed on the screen auto-scale, with units of measure displayed on the left. At large pressure and inspiratory volume ranges, the resolution may also become larger.

Manufacturer's Declaration – Electromagnetic Compatibility (EMC)

The following accessories were used with the AeroPace Neurostimulation Console (000-0055) in the evaluation of the AeroNova System:

NOTE: The AeroNova Neurostimulation Console (000-0070, 000-0071, and 000-0072) is equivalent to the AeroPace Neurostimulation Console (000-0055) in regard to electromagnetic compatibility.

Part Number	Description	Cable Length
000-0057	Neurostimulation Console Cart	N/A
100-0025	Catheter contained within the Catheter Kit (000-0036)	0.8 m
000-0041	Airway Sensor	0.2 m
000-0045	Airway Sensor Cable	3.2 m
000-0043	Catheter Cable	3.2 m
000-0039	Handheld Controller	3.2 m

WARNING:

- Only accessories specified or provided by the manufacturer should be used with the AeroNova System. Use of accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the AeroNova System. Otherwise, degradation of the performance of the AeroNova System may occur, which may include the system safely entering a state where stimulation is not delivered.
- The AeroNova System should not be used while stacked or placed adjacent to other equipment, as this could result in improper operation of the AeroNova System or other equipment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The AeroNova System is intended to electrically stimulate the phrenic nerves resulting in activation of the diaphragm while maintaining essential performance, which consists of limiting charge density and stimulation frequency to specified levels. The AeroNova System is intended for use in the electromagnetic environment specified below. The customer or the user of the AeroNova System should assure that it is used in such an environment. Otherwise, degradation of the AeroNova System may occur, which may include the system safely entering a state where stimulation is not delivered.		
Emissions Test	Compliance	Electromagnetic environment - guidance
Radiated RF Emissions CISPR 11	Group 1 Class A	The AeroNova System generates RF energy for its internal function. Interference to nearby electronic equipment is possible.
Conducted Emissions CISPR 11		The AeroNova System is intended for the professional healthcare environment and may not be suitable for connection to the public mains network supplying domestic establishments where CISPR 11 Class B limits are required.[3]
Power Frequency Harmonics IEC 61000-3-2	Class A	The AeroNova System is intended for the professional healthcare environment and may not be suitable for connection to the public mains network supplying domestic establishments.
Voltage Fluctuation/Flicker IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The AeroNova System is intended for use in the electromagnetic environment specified below. The customer or the user of the AeroNova System should assure that it is used in such an environment.			
Immunity Test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment - guidance
ESD IEC 61000-4-2	±2 kV, ±4 kV, ±8 kV Contact	±2 kV, ±4 kV, ±8 kV Contact	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±2 kV, ±4 kV, ±8 kV, ±15 kV Air	±2 kV, ±4 kV, ±8 kV, ±15 kV Air	
Radiated Immunity IEC 61000-4-3	80 MHz to 1000 MHz 3 V/m Modulation 80%, 1 kHz 1.0 GHz to 2.7 GHz 3 V/m Modulation 80%, 1 kHz	80 MHz to 1000 MHz 3 V/m Modulation 80%, 1 kHz 1.0 GHz to 2.7 GHz 3 V/m Modulation 80%, 1 kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.[4]
Proximity field from RF wireless communication equipment	IEC-60601-1-2	See table "Immunity to proximity fields for RF wireless communications equipment"	N/A

3 The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

4 Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AeroNova System is used exceeds the applicable RF compliance levels shown above, the AeroNova System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AeroNova System.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Proximity field from Common Electromagnetic Emitters	N/A[5]	See table "Immunity to proximity fields for Common Electromagnetic Emitters"	N/A
Electrical Fast Transient / Burst IEC 61000-4-4	AC Mains ±0.5 kV, ±1.0 kV, ±2.0 kV 100 kHz repetition frequency I/O ±0.25 kV, ±0.5 kV, ±1.0 kV 100 kHz repetition frequency	AC Mains ±0.5 kV, ±1.0 kV, ±2.0 kV 100 kHz repetition frequency I/O ±0.25 kV, ±0.5 kV, ±1.0 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or professional healthcare environment.
Surge IEC 61000-4-5	Line to Line (Differential Mode) ±0.5 kV, ±1.0 kV Line to Ground (Common Mode) ±0.5 kV, ±1.0 kV, ±2.0 kV	Line to Line (Differential Mode) ±0.5 kV, ±1.0 kV Line to Ground (Common Mode) ±0.5 kV, ±1.0 kV, ±2.0 kV	Mains power quality should be that of a typical commercial or professional healthcare environment.
Conducted Immunity IEC 61000-4-6	AC Mains, I/O 0.15 MHz to 80 MHz 3 V RMS Modulation: 80% AM, 1 kHz 6.765 MHz to 6.795 MHz 13.553 MHz to 13.567 MHz 26.957 MHz to 27.283 MHz 40.660 MHz to 40.700 MHz 6 V RMS Modulation: 80% AM, 1 kHz	AC Mains, I/O 0.15 MHz to 80 MHz 3 V RMS Modulation: 80% AM, 1 kHz 6.765 MHz to 6.795 MHz 13.553 MHz to 13.567 MHz 26.957 MHz to 27.283 MHz 40.660 MHz to 40.700 MHz 6 V RMS Modulation: 80% AM, 1 kHz	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the AeroNova System otherwise degradation of the performance of the AeroNova System may occur, which may include the system safely entering a state where stimulation is not delivered.
Magnetic Immunity IEC 61000-4-8	50 Hz, 60 Hz 30 A/m	50 Hz, 60 Hz 30 A/m	Power frequency fields should be that of a typical commercial or professional healthcare environment.
Voltage Dips / Interruptions IEC 61000-4-11	Dips 100 VAC 60 Hz, 240 VAC 60 Hz UT = 0%; 0.5 cycle (0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°) UT = 0%; 1 cycle (0°) UT = 70%; 30 cycles (0°) Interruptions 100 VAC 60 Hz, 240 VAC 60 Hz UT = 0%; 300 cycles (0°) UT is the AC Mains voltage prior to application of test level.	Dips 100 VAC 60 Hz, 240 VAC 60 Hz UT = 0%; 0.5 cycle (0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°) UT = 0%; 1 cycle (0°) UT = 70%; 30 cycles (0°) Interruptions 100 VAC 60 Hz, 240 VAC 60 Hz UT = 0%; 300 cycles (0°) UT is the AC Mains voltage prior to application of test level.	Mains power should be that of a typical commercial or professional healthcare environment. If the operator of the AeroNova System requires continuous operation during power mains interruptions, it is recommended that the AeroNova System be powered from an uninterruptable power supply.

5 Certain electromagnetic emitters commonly found within the AeroNova System's intended use environment are not adequately addressed by consensus standards. Specific immunity testing was performed for each of these emitters to demonstrate that using the AeroNova System is safe with regard to each identified emitter in the table: "Immunity to proximity fields for Common Electromagnetic Emitters."

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
RFID Immunity AIM 7351731	RFID Fields ISO/IEC 14223 134.2 kHz, 65 A/m ISO/IEC 14443-3 (Type A) 13.56 MHz, 7.5 A/m ISO/IEC 14443-4 (Type B) 13.56 MHz, 7.5 A/m ISO/IEC 15693 (ISO/IEC 18000-3 (Mode 1)) 13.56 MHz, 5 A/m ISO/IEC 18000-3 (Mode 3) 13.56 MHz, 12 A/m ISO/IEC 18000-7 433.92 MHz, 3 V/m ISO/IEC 18000-63 (Type C) 860 MHz to 960 MHz, 54 V/m ISO/IEC 18000-4 (Mode 1) 2.4 GHz, 54 V/m	RFID Fields ISO/IEC 14223 134.2 kHz, 65 A/m ISO/IEC 14443-3 (Type A) 13.56 MHz, 7.5 A/m ISO/IEC 14443-4 (Type B) 13.56 MHz, 7.5 A/m ISO/IEC 15693 (ISO/IEC 18000-3 (Mode 1)) 13.56 MHz, 5 A/m ISO/IEC 18000-3 (Mode 3) 13.56 MHz, 12 A/m ISO/IEC 18000-7 433.92 MHz, 3 V/m ISO/IEC 18000-63 (Type C) 860 MHz to 960 MHz, 54 V/m ISO/IEC 18000-4 (Mode 1) 2.4 GHz, 54 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Immunity to proximity fields RF wireless communications equipment				
Test Frequency (MHz)	**Band[6] (MHz)**	**Service[7]**	**Modulation**	**Level (V/m)**
385	380 to 390	Tetra 400	Pulse 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM 1 kHz sine, ±5 kHz deviation	28
710	704 to 787	LTE Band 13, 17	Pulse 217 Hz, 50% DC	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse 18 Hz, 50% DC	28
870				
930				
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; L TE Band 1, 3, 4, 25; UMTS	Pulse 217 Hz, 50% DC	28
1845				
1970				
2450	2400 to 2570	Bluetooth, WLAN, 802. 11 b/g/n, RFID 2450, LTE Band 7	Pulse 217 Hz, 50% DC	28
5240	5100 to 5800	WLAN 802. 11 a/n	Pulse 217 Hz, 50% DC	9
5500				
5785				

6 Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AeroNova System is used exceeds the applicable RF compliance levels shown above, the AeroNova System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AeroNova System.

7 For some services, only the uplink frequencies are included.

Immunity to proximity fields for Common Electromagnetic Emitters		
Equipment Type / Immunity Test	**Test Frequency**	**Compliance Level**
Diathermy with specific modulation	1.7 MHz to 2.3 MHz	50 V/m
Electrosurgical Cut with protection	1.7 MHz	500 V/m Pulsed
Electrosurgical Coagulate with protection	1.7 MHz	400 V/m Pulsed
X-ray with modulation and protection	30kHz	10 V/m
NFC with multiple modulations	13.56 MHz	81.5 dBuA/m
Wireless Power Transfers (WPT)	Multiple frequencies and modulations	35 dBuA/m
5G Cellular	FR1 Band (with specific modulation)	30 dBm
5G Cellular	FR2 Band (with specific modulation)	15-30 dBm
Metal Detectors	19 different frequencies (mixed modulations)	Up to 400 A/m
Electronic Article Surveillance (EAS)	15 different EAS frequency and modulation combinations	Various uT and A/m power settings

AeroNova System's Essential Performance Requirements

Per IEC 60601-1, Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance, the AeroNova System's essential performance is defined by the two following requirements:

- The maximum charge density delivered by the system shall be 0.24 mC/cm^2 with an electrode with a gold external surface area.
- The maximum stimulation pulse rate delivered by the System shall be 45 Hz (pulses per second) per side, or less.

The AeroNova System includes an internal subsystem dedicated to constantly monitoring the output characteristics sent from the internal electronics out to the catheter's implanted patient electrodes. These output characteristics are continuously examined to be within the limits of the essential performance requirements listed above. If the internal monitor detects a violation of the essential performance requirements or cannot maintain its operation for any reason, the operator should expect to experience the following:

- Patient stimulation will cease and an error will be displayed on the screen giving context as to why stimulation was stopped.
- In rare circumstances, the Console may cease stimulation and power down without displaying an on-screen error.

List of Software Anomalies and Risk Analysis

Description	Risk Assessment
During bilateral mapping it is possible that the right-side progress bar moves slower than the left-side progress bar.	This issue only occurs when right side mapping identifies more than one possible electrode set that elicits recruitment. While this may appear on the screen as a delay, mapping will still complete as intended. This issue therefore does not cause harm or impact risk to the patient, user, or user environment.
It is possible that the Console doesn't start-up after the first button press, if home screen doesn't appear press power button again to restart system.	This issue only occurs when starting up the Console. To continue using the device, the user needs to start the system again. This is a user inconvenience. Since therapy has not started, the issue does not cause harm or impact risk to the patient, user, or user environment.
It is possible, if pressing the Stimulate button immediately after pressing the Stop button, the system may present an Error on the screen. If this occurs, press the Power button to turn the system off, then restart the system to clear the error.	The functional effect of this issue is that stimulation can no longer be delivered. The Console requires a restart to restore correct functionality. This issue is an inconvenience but does not cause harm or impact risk to the patient, user, or user environment.
If the lowest Therapy Level is identified for both left and right-side during Mapping, the DAL notifications may appear earlier than expected.	This issue will only occur in the rare case that the right and left side both map to 0.1 mA. The functional effect of this issue is advisories may occur or stimulation may stop if associated limits are exceeded after only 30 seconds rather than 60 seconds. If stimulation is stopped, the user can restart stimulation. This issue is a user inconvenience but does not cause harm or impact risk to the patient, user, or user environment.
If there is a communication error with the Airway Sensor, the system may appear frozen. If this occurs, disconnect and reconnect the Sensor Cable to the Console.	The functional effect of this issue is that Auto Mapping and Auto/Manual Therapy will not work. Auto Mapping will appear stuck after one stimulation. Manual Mapping will work. This is a user annoyance and can be corrected by reconnecting or replacing the airway sensor. Since auto stimulation cannot be delivered past one stimulation, no harm or impact risk to the patient, user, or user environment can occur.
It is possible that right-side Auto Mapping isn't successful due to Baseline Pressure being out of range. If this occurs, the user may perform right-side mapping in manual mode.	The Baseline Pressures do not have an effect on Placement or Manual Mapping. Baseline Pressures only possibly affect Auto Mapping when right-side Mapping identifies more than one possible electrode set that elicits recruitment. If Baseline Pressure being out of range causes right-side mapping to fail, there is no harm. The user could perform Manual Mapping on the right. If there are issues with the Baseline Pressure, the System will not allow stimulation to start in Therapy Mode. This does not cause harm or impact risk to the patient, user, or user environment.

Description	Risk Assessment
Occasionally, if the system is displaying a pop-up, the Stim Button on the Multi-button controller can turn blue as if it's in an active state. Pressing the blue Stim button on the Multi-Button Controller (MBC) while the pop-up is shown will not result in stimulation. The Multi-Button Controller will continue in the correct state once the user interacts with the pop-up.	While the MBC LEDs are not in sync with the GUI on the Console, the system is already in a stopped state. The Console buttons all still function as intended, and pressing stimulate on the MBC does not trigger stimulation. Since the System is not stimulating and the Console buttons are working correctly, there is no impact on the safety of the patient. This issue is an inconvenience but does not cause harm or impact risk to the patient, user, or user environment.
In Manual Therapy, with Stim Spon off, if Reassess Baseline is pressed when there is an early breath detected notification, the system will stimulate 1 to 2 more times before gathering baseline DAL.	This issue causes a delay in the re-baselining process. The additional stimulations being sent are sent at the same intensity as the previous programmed stimulations. This issue causes user annoyance and does not cause harm or impact risk to the patient, user, or user environment.
If a Therapy Session has been active for more than 24 hours, an error may be displayed after pressing End Session. If this occurs, restart the system and wait 5 minutes before starting a new Therapy Session to avoid subsequent errors.	Issue can be resolved by restarting system and waiting about 5 minutes* before starting a new Therapy Session. No logs are lost if this issue occurs. This issue is a user annoyance and does not cause harm or impact risk to the patient, user, or user environment. *Note: estimated based on a 28-day Therapy Session with >59bpm
Errors may occur more often than expected due to conservative current measurements. If this occurs, press the Power button to turn the system off, then restart the system to clear the error.	This calculation difference causes error handling on measured currents to be more conservative. This issue therefore does not cause harm or impact risk to the patient, user, or user environment.
Errors may occur more often than expected. If this occurs, press the Power button to turn the system off, then restart the system to clear the error.	The functional effect of this issue is that Stimulation can no longer be delivered. The Console requires a restart to restore correct functionality. This issue is an inconvenience but does not cause harm or impact risk to the patient, user, or user environment.
An Error may occur if the system is left running for over 49 days. If this occurs, press the Power button to turn the system off, then restart the system to clear the error.	This error will only occur when the system has been on for 49 straight days which is not normal usage. The Console requires a restart to restore correct functionality. This issue is an inconvenience but does not cause harm or impact risk to the patient, user, or user environment.
Errors may occur more often than expected when running at high breathing rates. If this occurs, press the Power button to turn the system off, then restart the system to clear the error.	The functional effect of this issue is that Stimulation can no longer be delivered. The Console requires a restart to restore correct functionality. This issue is an inconvenience but does not cause harm or impact risk to the patient, user, or user environment.

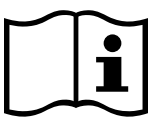
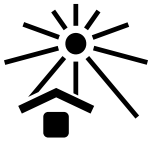
Glossary of Symbols

Symbol	Meaning	Symbol	Meaning
	Caution		Use by
	Warning		Do not re-use
	Consult instructions for use		Sterilized using ethylene oxide
	Keep dry		Do not re-sterilize
	Keep away from sunlight		Mass
	Do not use if package is damaged		Fuse
Rx Only	Prescription only		Waste Electrical and Electronic Equipment
	Type BF applied part		Equipotentiality
	Manufacturer	IPX1	Protected against vertically falling water drops
	Date of manufacture		Temperature limit
REF	Catalogue number	MD	Medical device
SN	Serial number		Open here
LOT	Batch code		

Lungpacer®

AeroNova®

Lungpacer Medical, Inc.
130 – 601 W Cordova Street
Vancouver, BC V6B 1G1
Canada
+1 (778) 655-2100
www.lungpacer.com

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