

Lungpacer

Diaphragm Pacing Therapy System

Instructions For Use

Rx Only

This Diaphragmatic Pacing Stimulator has not been FDA cleared or approved.

This Diaphragmatic Pacing Stimulator has been authorized by FDA under an Emergency Use Authorization (EUA).

This Diaphragmatic Pacing Stimulator is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Diaphragmatic Pacing Stimulator Systems under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

CAUTION:

The Lungpacer DPTS has not been evaluated for safety when used with cardiac pacemakers or defibrillators.

Remove the LIVE Catheter prior to Magnetic Resonance (MR) imaging. The Lungpacer DPTS has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the LIVE Catheter in the MR environment is unknown. Scanning a patient who has this device may result in MR image artifact or patient injury due to heating or migration of the device.

Do not place the LIVE Catheter (or allow it to remain) in the right atrium or right ventricle.

Manufacturer:

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Warnings and Precautions

- Read all package insert warnings, cautions and, instructions prior to use. Failure to do so may result in severe patient injury or death.
- Practitioners must be aware of complications associated with central venous catheters including but not limited to:
 - Adverse tissue response
 - Allergic reaction
 - Arrhythmia (including, but not limited to ventricular fibrillation, ventricular tachycardia, atrial fibrillation, atrial fibrillation/flutter, pulseless electrical activity, asystole)
 - Atrial or ventricular perforation
 - Bleeding / Hemorrhage
 - Bradycardia
 - Bruising or swelling at insertion site
 - Cardiac tamponade
 - Central Line-associated Blood Stream Infection (CLABSI)
 - Cerebrovascular event
 - Diaphragm injury
 - Embolism (device, air, or thrombus)
 - Hematoma
 - Hemothorax
 - Hypertension
 - Hypotension
 - Inadvertent arterial puncture
 - Lung injury (e.g., pleural effusion)
 - Mediastinal injury
 - Pain or discomfort during stimulation
 - Pain, tenderness, discomfort at access site
 - Phrenic nerve damage or injury
 - Pneumohematoma
 - Pneumomediastinum
 - Pneumothorax
 - Pseudo aneurysm at access site
 - Sepsis
 - Skin irritation
 - Syncope
 - Thoracic duct laceration
 - Tissue damage
 - Vessel occlusion
 - Vessel wall damage / perforation
 - Wound infection
- Select the appropriate length LIVE Catheter (Lungpacer IntraVenous Electrode Catheter) for the patient's anatomical dimensions. Refer to the LIVE Catheter Kit IFU for instructions on selecting catheter length.
- Do not place the LIVE Catheter into or allow it to remain in the right atrium or right ventricle. X-ray, or other method in compliance with hospital/institutional practices or current guidelines, must confirm appropriate catheter placement and absence of pneumothorax or hemothorax. The LIVE Catheter tip must be located in 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. Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it.

Improper advancement of the guidewire into the heart has been implicated in causing cardiac perforation and tamponade.

- Ensure the LIVE Catheter tip has not entered the heart by performing an X-ray exam or other method in compliance with hospital/institutional practices or current guidelines. If catheter position has changed, immediately re-evaluate.
- Practitioners must be aware of the potential for entrapment of the guidewire by any implanted device in the circulatory system (i.e., vena cava filters, stents). Review the patient's history before the catheterization procedure to assess for possible implants. Care should be taken regarding the length of the guidewire inserted. It is recommended that if the patient has a circulatory system implant then the catheterization procedure should be performed under direct visualization to minimize the risk of guidewire entrapment.
- The LIVE Catheter tip must be located in the central circulation when administering >10% glucose solution, total parenteral nutrition, continuous vesicant therapy, infusates with an osmolality above 600 mOsm/L, or any medication known to be irritating to vessels proximal to the vena cava.
- Do not leave open needles or uncapped/unclamped catheters in the central venous puncture site. Air embolism can occur with these practices.
- Use only securely tightened luer-lock connections to guard against any inadvertent disconnection.
- Use luer-lock connectors to help guard against air embolism and blood loss.
- Pulsatile flow is usually an indicator of inadvertent arterial puncture.
- Implanted parts of the LIVE Catheter should not be exposed to therapeutic levels of ultrasound energy, as the device may inadvertently concentrate the ultrasound field and cause harm.
- The DPTS has not been evaluated for safety and compatibility to be used with any implanted stimulators, diathermy, electrocautery, and electrosurgical equipment.
- If the patient is subsequently given any medical treatment in which an electrical current is passed through his/her body from an external source, the Lungpacer DPTS (Diaphragm Pacing Therapy System) should first be deactivated by disconnecting the Intermediate Cable from the LIVE Catheter.
- Remove the LIVE Catheter prior to Magnetic Resonance (MR) imaging. The LIVE Catheter has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the LIVE Catheter in the MR environment is unknown. Scanning a patient who has this device may result in MR image artifact or patient injury due to heating or migration of the device. .
- The DPTS has not been evaluated for possible interaction with all other items of medical equipment in all operating conditions. Practitioners must be aware of the possibility of interaction between the DPTS and other medical equipment.

Cautions

- Do not expose the DPTS or any of its components to excessive heat.
- Do not use the DPTS in an oxygen-rich environment.
- The LIVE Catheter and accessories provided in the LIVE Catheter Kit are designed for single use only.
- Do not re-sterilize or reuse the sterile components. Reuse or re-sterilization of the single-use components may impair the structural integrity and/or performance of the system.
- Use of a non-sterile LIVE Catheter poses the risk of infection.
- Failure to adhere to aseptic catheter insertion technique may result in infection.
- Improper vein access technique may result in vessel wall damage or perforation.
- Improper handling of the LIVE Catheter extension line and/or the insertion site may result in infection.
- Use of the LIVE Catheter beyond its recommended use period may result in infection.
- Reuse of LIVE Catheter Kit components intended for single use may result in infection.
- Improper cleaning of the Intermediate Cable, Lungpacer Control Unit or Handheld Controller may result in infection. Follow all cleaning instructions for the Intermediate Cable, Lungpacer Control Unit and Handheld Controller.
- Inappropriate electrical connections may pose serious risk of adverse health consequences or death.
- Do not use the Lungpacer DPTS or any of its components if they appear altered or damaged.
- Do not use the Lungpacer DPTS or any of its components if they appear compromised by fluid ingress.
- The use of the Lungpacer DPTS incurs the following risks: lung injury, vessel wall damage, phrenic nerve damage, diaphragm injury, and diaphragmatic failure.
- Placement of the LIVE Catheter's stimulation electrodes in the atrium may result in cardiac arrhythmia.
- Placement of the LIVE Catheter's stimulation electrodes too close to the heart may result in cardiac arrhythmia.
- Delivery of electrical stimulation via the LIVE Catheter's electrodes may result in cardiac arrhythmia.
- Delivery of electrical stimulation via the LIVE Catheter's electrodes may result in bradycardia.
- Touching the contacts of the Primary Cable component of the LIVE Catheter may result in cardiac arrhythmia in the patient.

- Touching the contacts of the Intermediate Cable connector while it is connected to the LIVE Catheter may result in cardiac arrhythmia in the patient.
- Movement of the LIVE Catheter after placement and mapping may result in overstimulation of the diaphragm, which may result in diaphragm injury.
- Use of incorrect stimulation parameters during therapy may result in overstimulation of the diaphragm, which may result in diaphragm injury.
- Damage to the LIVE Catheter or occlusion of the lumen may pose the risk of embolism.
- Use of the LIVE Catheter may result in an adverse tissue response.
- Ensure that the LIVE Catheter is connected to the LCU via the Intermediate Cable as described in the Diaphragm Pacing Therapy System Instructions For Use prior to initiating therapy.
- After LIVE Catheter placement, remove any guidewire prior to electrical stimulation.
- Excessive bending, torqueing or kinking of the LIVE Catheter may cause damage to the device including damage to the internal wires.
- Ensure LIVE Catheter connector pin(s) does not contact with operator or other active or ground surface.
- Ensure Intermediate Cable connector pin(s) does not contact with operator or other active or ground surface when connected to the LIVE Catheter.
- Do not use the LCU if the enclosure or the power cord has exposed wires, or if it appears damaged.
- Do not use the LCU if the enclosure is warm to the touch.
- Connect the LCU power only to mains outlets that are properly grounded.
- Do not cover the cooling vents on the LCU enclosure.
- Avoid exposing the DPTS to excessive moisture. If fluid spills onto the DPTS, disconnect the Intermediate Cable from the LIVE Catheter, and wipe off the components of the DPTS with a cloth.
- Do not attempt to open the LCU enclosure.
- Connect the LCU power only to mains outlets compatible with the ratings printed on the LCU label.
- After use, the LIVE Catheter may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws.
- If defibrillation is necessary, disconnect the Intermediate Cable from the LIVE Catheter prior to defibrillation. If a defibrillation event occurred with the LIVE Catheter connected to the LCU, contact Lungpacer before subsequent use of the DPTS.

Introduction

The Lungpacer Diaphragm Pacing Therapy System (DPTS) has been authorized for emergency use in healthcare settings for treatment of patients on invasive mechanical ventilation who are at high risk of weaning failure, including COVID-19 patients, during the COVID-19 pandemic. The purpose of the device is to stimulate the phrenic nerves and activate the diaphragm in adult patients who have been mechanically ventilated and are unable to sustainably breathe without assistance from the mechanical ventilator.

Intended Use

The Lungpacer Diaphragm Pacing Therapy System (DPTS) is a temporary, percutaneously-placed, transvenous, phrenic nerve-stimulating device intended to stimulate the diaphragm in conjunction with a mechanical ventilator. Treatment is for a maximum of 30 days.

The Lungpacer DPTS is for treatment of patients on invasive mechanical ventilation who are at high risk of weaning failure, including COVID-19 patients, over the duration of the emergency use authorization. The Lungpacer DPTS may improve inspiratory muscle strength and weaning success in patients ages 18 years or older who have failed to wean from mechanical ventilation.

The Lungpacer Diaphragm Pacing Therapy System (DPTS) is intended for use in hospitals and hospital-type facilities by qualified, trained personnel under the direction of a physician.

Contraindications

No known contraindications have been identified at this time.

Device Classification

The DPTS has the following classifications:

- Class I Medical Electrical System
- IPX1 protected equipment
- Non-continuous operation
- Type BF applied part. The applied part is the LIVE Catheter.

Overview

The Lungpacer DPTS consists of the following components:

- LIVE (Lungpacer IntraVenous Electrode) Catheter,
- Intermediate Cable, and
- Lungpacer Control Unit (LCU), including a Handheld Controller.

The DPTS is illustrated in the figure below:

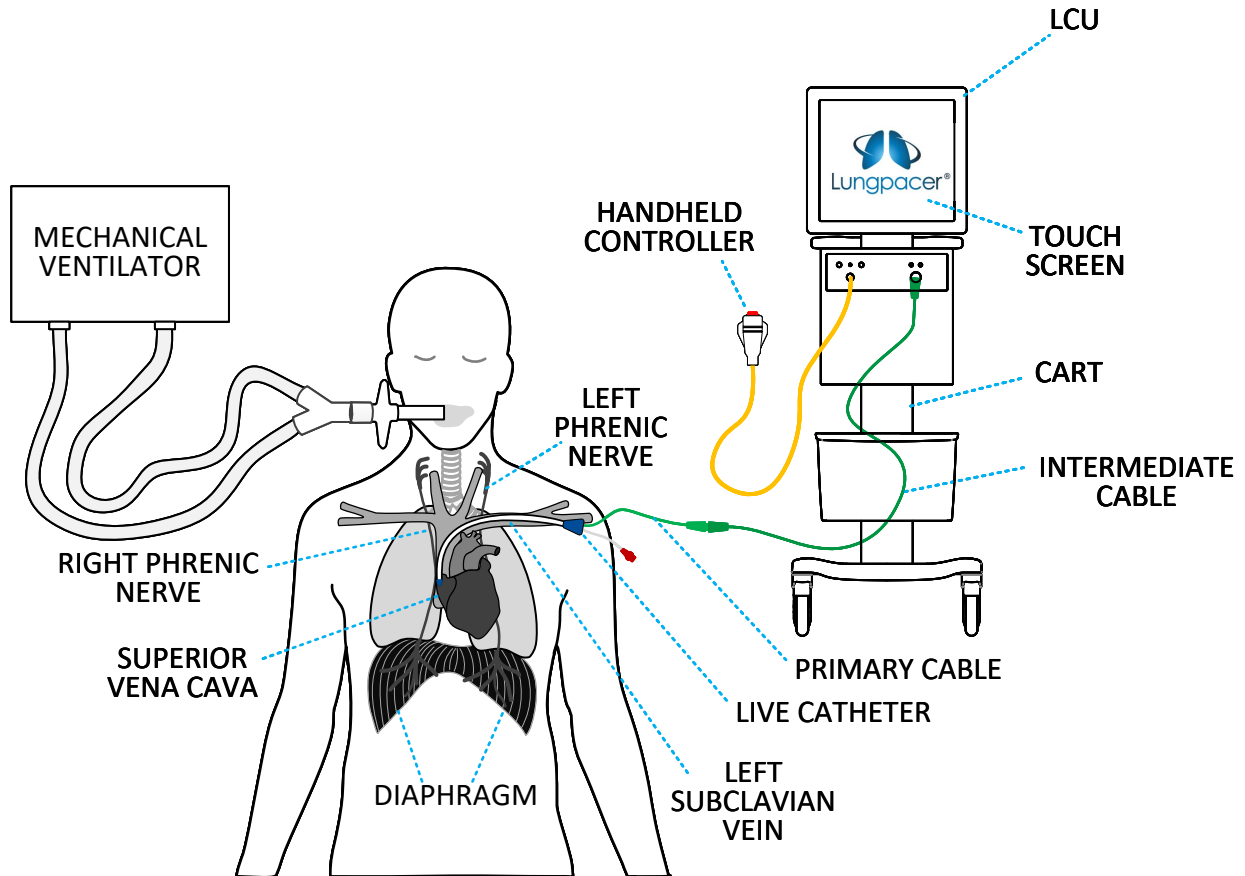





Illustration of the Lungpacer DPTS, in relation to a patient who is connected to a mechanical ventilator

The DPTS components are described in the following table:

Component Name	Lungpacer Part/Model Number	Description
LIVE Catheter Kit	000-0007 000-0008 000-0009	CVC-style catheter with a single fluid-delivery lumen and accessories to aid catheter insertion. The LIVE Catheter has two electrode arrays on its surface, which allow stimulation energy to be delivered to the patient's left and right phrenic nerves. The LIVE Catheter is available in three lengths, to accommodate variations in patient anatomy. LIVE Catheter Kit, 19 cm LIVE Catheter Kit, 21 cm LIVE Catheter Kit, 23 cm
Intermediate Cable	000-0015	Multi-contact connection cable. The Intermediate Cable connects the electrodes on the LIVE Catheter to the Lungpacer Control Unit (LCU).
Lungpacer Control Unit (LCU)	000-0026	Electrical pulse generation system. The LCU is connected to the electrodes on the LIVE Catheter via the Intermediate Cable, in order to deliver stimulation pulses to the patient's left and right phrenic nerves. The LCU consists of a touchscreen monitor, stimulation electronics, a hook and a basket, mounted on a wheeled cart. The LCU touchscreen provides a graphical user interface, by which the user can select the LCU's functional mode, modify its operating parameters, initiate stimulation pulses, and provide feedback to the LCU as part of the normal workflow. The LCU stimulation electronics deliver stimulation pulses in response to user input. The LCU stimulation electronics also perform safety-monitoring functions. The front panel of the LCU stimulation electronics enclosure includes a push-button with a QUICK-STOP function, if needed.
Handheld Controller	000-0013	Handheld push-button controller. The Handheld Controller connects to the LCU. The Handheld Controller can be used to initiate delivery of stimulation pulses to the electrodes on the LIVE Catheter.

 **Warning:** Refer to the LIVE Catheter Instructions For Use (IFU) for instructions regarding the insertion of the LIVE Catheter.

 **Warning:** Refer to the LIVE Catheter Instructions For Use (IFU) for instructions regarding care and maintenance of the LIVE Catheter while it is inserted in the patient.

 **Warning:** Refer to the LIVE Catheter Instructions For Use (IFU) for instructions regarding the removal and disposal of the LIVE Catheter.



Warning: Do not connect the LIVE Catheter to the LCU or to the Intermediate Cable while inserting the LIVE Catheter.



Warning: Do not connect the LIVE Catheter to the LCU or to the Intermediate Cable while performing X-ray confirmation of placement of the LIVE Catheter.

Pictures



LIVE Catheter



Intermediate Cable



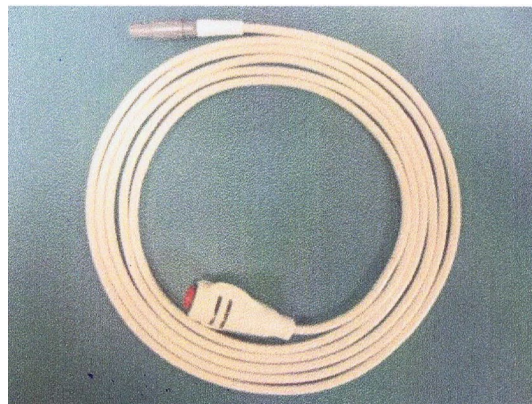
Lungpacer Control Unit (LCU)



LCU Front Panel



LCU Power Receptacle (on the underside of the LCU)



Handheld Controller

Connecting to AC Power



Warning: To avoid the risk of electrical shock, the DPTS power cord must be only connected to a supply mains with protective earth.



Warning: Always connect the DPTS to a “Hospital Only” or “Hospital Grade” AC receptacle to ensure proper grounding.



Warning: The power cord is the only means for mains disconnection. Locate the DPTS in a position where the AC receptacle is easily accessible.

The DPTS is an AC mains powered system. Connect the DPTS to a grounded receptacle that supplies AC power of 100 to 120 V, 60 Hz. The potential equalization stud is located on the left-hand side of the LCU Electronics. Connecting a potential equalization cable from this stud to an appropriate plug offers additional grounding of the LCU.

Expected Positions


The DPTS has been designed to allow it to be placed on either side of the patient bedside, with the operator on either side of the bed.


Workflows


After the LIVE Catheter has been inserted according to its Instructions For Use, the Lungpacer DPTS can be used for two workflows:

- i. LIVE Catheter Placement, and,
- ii. Mapping and Therapy.

LIVE Catheter Insertion and Placement

 **Warning:** Refer to the LIVE Catheter Instructions For Use (IFU) for instructions regarding the insertion of the LIVE Catheter.

 **Warning:** Do not connect the LIVE Catheter to the LCU or to the Intermediate Cable while inserting the LIVE Catheter.

 **Warning:** Do not connect the LIVE Catheter to the LCU or to the Intermediate Cable while performing X-ray confirmation of placement of the LIVE Catheter.

Step	Brief Description	How the Operator uses the DPTS
Placement	This is a quick sequence of stimulation pulses on the patient's left side only, to confirm placement of the LIVE Catheter. Performing Placement on the LCU is not a substitute for Catheter Placement Evaluation.	The LCU is connected to the LIVE Catheter via the Intermediate Cable during Placement. The LCU Placement mode guides the user through a sequence of evaluation steps, to determine whether diaphragm recruitment is possible (on the left side only) with the LIVE Catheter, in its current placement position. Recruitment is determined by palpation, and/or by observation of the ventilator pressure waveform.
Catheter Placement Evaluation	Standard X-ray evaluation, or other evaluation method in compliance with hospital/institutional practices or current guidelines, of LIVE Catheter placement, to confirm correct location of catheter tip.	The LCU is not connected to the LIVE Catheter during this evaluation. The Intermediate Cable is not connected to the LIVE Catheter during this evaluation.

Mapping and Therapy



Warning:

Confirm correct placement of the LIVE Catheter by X-ray evaluation, or other evaluation method in compliance with hospital/institutional practices or current guidelines, before performing Mapping for the first time.

Step	Brief Description	How the Operator uses the DPTS
Mapping	<p>This is a sequence of stimulation pulses to identify potential electrode combinations on the patient's left and right sides, and to determine the stimulation thresholds for those electrode combinations.</p>	<p>The LCU is connected to the LIVE Catheter via the Intermediate Cable during Mapping. The LCU Mapping mode guides the user through a sequence of evaluation steps, to determine whether diaphragm recruitment occurs when delivering stimulation pulses to different electrode combinations over a range of stimulation intensities. Delivery of the stimulation pulses is initiated by the user. Recruitment is determined by palpation, and/or by observation of the ventilator pressure waveform.</p>
Therapy	<p>This consists of the delivery of groups of stimulation pulses, intended to generate diaphragm contractions.</p> <p><i>Note:</i> Therapy cannot be delivered until Mapping has been successfully completed.</p>	<p>The LCU Therapy mode allows the user to set up and deliver a Therapy sequence. The LCU remains connected to the LIVE Catheter via the Intermediate Cable during Therapy. The therapy sequence uses the electrode combinations and thresholds identified during Mapping. Delivery of the groups of stimulation pulses is initiated by the user.</p>

Connections



LCU Power Receptacle –
 underside of LCU
 stimulation electronics
 enclosure



Handheld Controller
 Connection – LCU stimulation
 electronics enclosure front
 panel



Intermediate Cable Connection – LCU
 stimulation electronics enclosure front
 panel

Note: This is a push-pull
 connector; do not twist.

Note: This is a push-pull connector; do
 not twist.



Catheter / Intermediate Cable Connection

Note: This is a push-pull connector; do not twist.

Refer to the Technical Mode section for additional connectors.

Hardware Buttons



POWER Push-Button –
LCU stimulation electronics enclosure front panel



QUICK-STOP Push-Button –
LCU stimulation electronics enclosure front panel

Note: If you stop stimulation by pressing this button, you will have to restart the LCU before you can continue the stimulation session.



Stimulate/ Stimulate Next Button –
Handheld Controller

Touchscreen Buttons and Icons



Placement
 Touchscreen icon.
 Press this icon to navigate to the **Placement** screen.



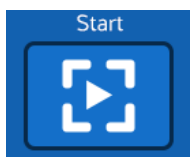
Mapping
 Touchscreen icon.
 Press this icon to navigate to the **Mapping** screen.



Therapy
 Touchscreen icon.
 Available when at least one side is mapped. Press this icon to navigate to the **Therapy** screen.



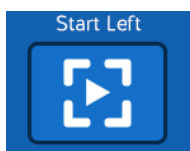
Enable
 Touchscreen button.
 Press this button to enable stimulation pulses to be delivered. Once this button has been pressed, it is replaced by the *Disable* button.



Start
 Touchscreen button.
 Press this button to start the Placement sequence from the beginning.



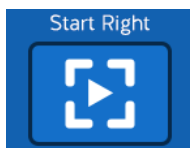
Stop
 Touchscreen button.
 Press this button to stop the Placement sequence.



Start Left
 Touchscreen button.
 Press this button to start the Left side Mapping sequence from the beginning.



Stop Left
 Touchscreen button.
 Press this button to stop the Left side Mapping sequence.



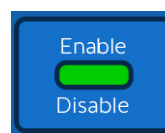
Start Right
 Touchscreen button.
 Press this button to start the Right side Mapping sequence from the beginning.



Stop Right
 Touchscreen button.
 Press this button to stop the Right side Mapping sequence.



Stimulate/Stimulate Next
 Touchscreen button.
 Press this button to start stimulation.
 Pressing the push-button on the Handheld Controller has the same effect.



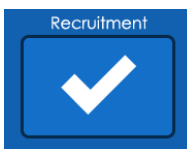
Disable
 Touchscreen button.
 Press this button to immediately stop stimulation pulses when stimulation is active in Mapping or Placement, and to disable the *Stimulate* button on the screen and the push-button on the Handheld Controller.



Stimulate Next is used only during Placement and Mapping.



Retry
 Touchscreen button.
 Press this button to repeat the previous evaluation settings. Used during Placement and Mapping. The button is highlighted in yellow when it has been selected.



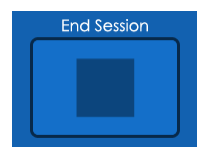
Recruitment
 Touchscreen button.
 Press this button to register that you detected recruitment at the last evaluation settings. Used during Placement and Mapping. The button is highlighted in green when it has been selected.



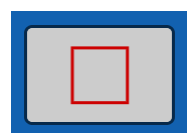
Complete
 Touchscreen button.
 Press this button to complete Mapping or Placement. Pressing the push-button on the Handheld Controller has the same effect. *Complete* is used only during Placement and Mapping.



Halt
 Touchscreen button.
 Press this button to immediately stop stimulation pulses when stimulation is active in Therapy, and to disable the *Stimulate* button on the screen and the push-button on the Handheld Controller.



End Session
 Touchscreen button.
 Press this button when you have completed all the stimulation you want to deliver in the session.



End Session (active)
 Touchscreen button.
 This is what the *End Session* button looks like after you have pressed it.

Setting Up the DPTS

Place the LCU near the patient, while remaining out of the patient's reach. Position the LCU so that a user can access the touchscreen and the **QUICK-STOP** button. If you intend to use the DPTS for Placement following LIVE Catheter Insertion, position the LCU to make sure it remains outside the sterile field. Ensure the wheels on the LCU are locked.

Connect the LCU power cord to the LCU power receptacle. Connect the LCU power cord to line power.

Connect the Handheld Controller to the receptacle labeled **CONTROLLER** on the LCU front panel.





Connect the Intermediate Cable to the receptacle labeled **INTERMEDIATE CABLE** on the LCU front panel.



Warning: Refer to the LIVE Catheter Instructions For Use (IFU) for instructions regarding the insertion of the LIVE Catheter.



Warning: Do not connect the LIVE Catheter to the LCU or to the Intermediate Cable while inserting the LIVE Catheter.

- 
Warning: Do not connect the LIVE Catheter to the LCU or to the Intermediate Cable while performing X-ray confirmation of placement of the LIVE Catheter.
- 
Warning: Confirm correct placement of the LIVE Catheter by X-ray evaluation, or other method in compliance with hospital/institutional practices or current guidelines, before performing Mapping for the first time.
- 
Warning: Wipe down the Intermediate Cable, Lungpacer Control Unit, and Handheld Controller before first use and between patients.
- 
Warning: Improper cleaning of the Intermediate Cable, Lungpacer Control Unit or Handheld Controller may result in infection. Follow all cleaning instructions for the Intermediate Cable, Lungpacer Control Unit and Handheld Controller.

When you are ready to start a session (a Placement session, and/or a Mapping and Therapy session) turn on the LCU by pressing the **POWER** button on the LCU front panel. The green light next to the **POWER** button should illuminate. Once the LCU’s power-on sequence has completed, the **Start** screen will appear on the LCU touchscreen. The LCU is now ready for you to start a session.

Lungpacer DPTS Procedure Steps

Patients should be monitored during delivery of Therapy for patient safety and effective delivery of stimulations. Refer to Patient Monitoring.

Procedure Step	Notes and Instructions
Ventilator Settings and Inspiration Duration	<ul style="list-style-type: none"> The Lungpacer DPTS can be used with any form of Continuous or Spontaneous Ventilation, meaning any ventilation mode that allows for the patient to take spontaneous breaths. If the patient is on Continuous <i>Mandatory</i> Ventilation, the stimulations should be conducted in synchrony with mechanical ventilation. Adjust the ventilation settings, if clinically possible, to allow Stim Duration on the Lungpacer LCU to be 1.2 seconds. This sets the duration of diaphragm contraction due to electrical stimulation during Therapy to approximately 1.2 seconds. <p><u>Suggestions:</u></p> <ul style="list-style-type: none"> Use Pressure Support or Volume Control. Select a ventilation mode that allows for the patient to take spontaneous breaths of longer inspiration duration. <p>NOTE: Ventilator modes where pressure is maintained constant by allowing flow to be constantly changing can lead to higher volumes due to negative pressure induced by the Lungpacer DPT.</p>



Procedure Step	Notes and Instructions
Mapping and Threshold (Stim Intensity)	<ul style="list-style-type: none"> • Mapping must be conducted at the start of <i>every session</i> because the LIVE Catheter position within the vein may change between sessions, altering the positioning of the electrodes relative to the phrenic nerves. • Mapping instructions are in the section “Mapping Screen”. • Deliver Mapping Stims during the end-expiratory period, if clinically possible, to facilitate detection of diaphragm contractions by palpation. • Only once Mapping has been successfully completed can the Therapy mode be accessed on the LCU. <p>NOTE: Mapping identifies electrode combinations for left and right phrenic nerves and the associated threshold Stim Intensities for those electrode combinations. Threshold Stim Intensity is the minimum intensity that causes diaphragm muscle contraction as observed by palpation or change in ventilator waveform at that particular session. This starting threshold Stim Intensity determined during Mapping corresponds to Stim Intensity 100% in Therapy mode.</p>
Therapy Stimulation Set	<ul style="list-style-type: none"> • During a Therapy session, <i>the objective is to deliver stimulation at the highest Intensity and longest Stim Duration</i> that is safe and tolerable for the patient, and that is suitable for the ventilator settings. • Describe to the patient the treatment sequence (use a verbal countdown to the Stim such as “1, 2, Stim”) and that Stims are intended to “work” the diaphragm muscle to improve strength as conducted for other muscle training. • Adjust the ventilation settings, if clinically possible, to allow Stim Duration on the Lungpacer LCU to be 1.2 seconds. This sets the duration of diaphragm contraction due to electrical stimulation during Therapy to the maximum duration. • Before delivering the first Stim, set the Stim Intensity to 100% (this corresponds to the initial threshold Stim Intensity) for each of the Left and Right side. Try to achieve a Stim Duration of 1.2 seconds. • If the ventilator is set to Continuous <i>Spontaneous</i> Ventilation. A breath can be initiated by delivering a Stim (i.e., electrically stimulated breath) and the ventilator will trigger a breath when the Stim causes the diaphragm to contract. • If the ventilator is set to Continuous <i>Mandatory</i> Ventilation, allow the ventilator to initiate a breath. Once the breath has been initiated by the ventilator, a Stim (i.e. electrically stimulated breath), can be triggered. Once the breath is initiated, deliver the stimulation as quickly as possible during the inspiration period. • Palpate the diaphragm to confirm that Stims cause diaphragm contractions; if not, repeat Mapping. • Assess patient tolerance. • Adjust Stim Intensity upward or downward by one or more steps during or between each set of Stims, depending on clinical judgement of patient tolerance. • Continue stepwise adjustments until the maximum tolerable Stim Intensity is reached or until Stim Intensity is at its <u>maximum</u> setting available for that session.
Therapy Session	<ul style="list-style-type: none"> • After 10 Stims, pause, if needed, to allow the patient to rest before the next set of 10 Stims. • The Therapy Session is complete when 6 sets of 10 Stims are successfully delivered.

Start screen

When you turn on the Lungpacer Control Unit, the **Start** screen will appear, as illustrated in the following figure.

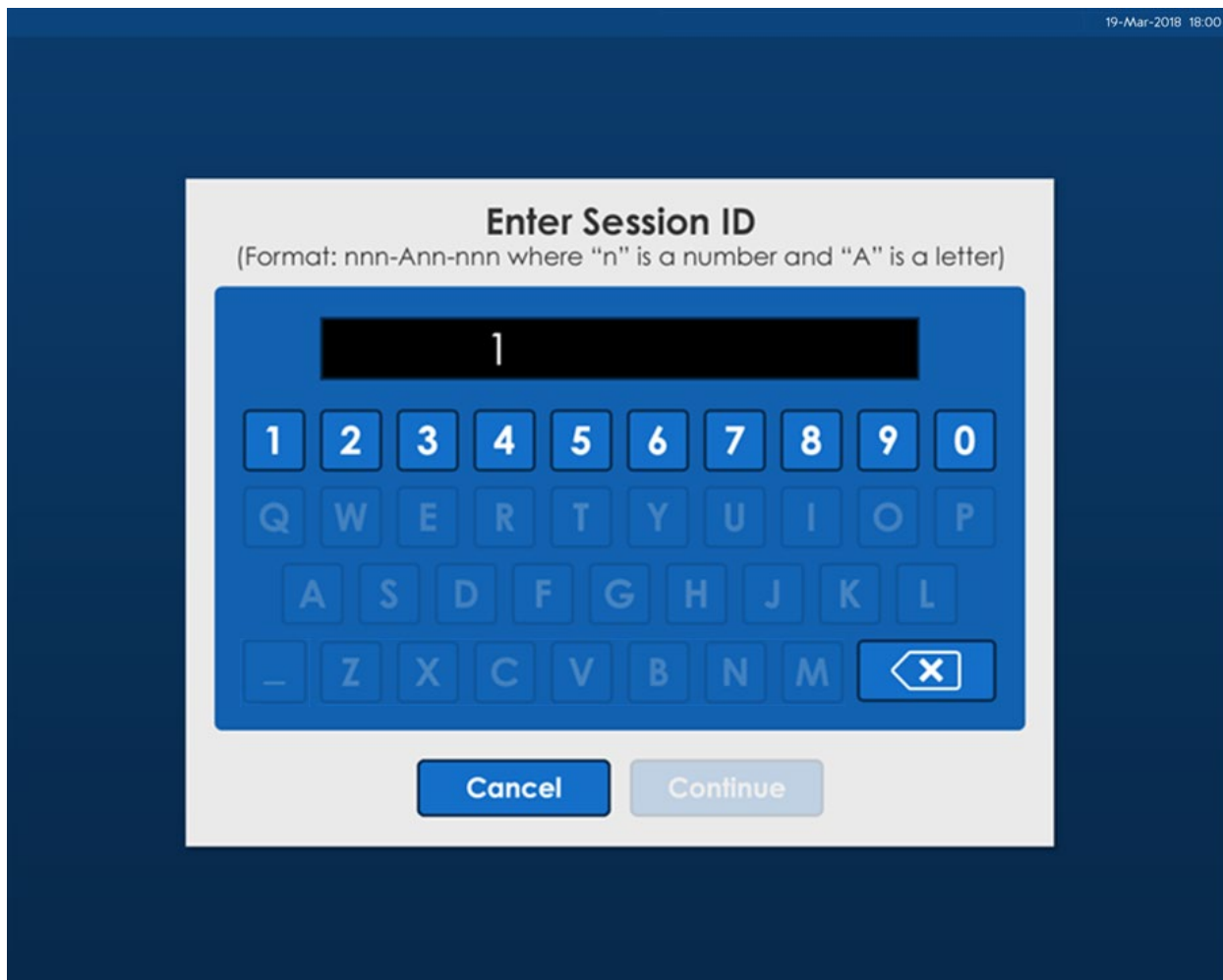


To begin a patient session, press *Start Session*. Pressing *Start Session* navigates you to the **Session ID** screen.


To perform general system setup functions, press *Tech Mode*. Pressing *Tech Mode* navigates you to the **Technical Mode** screen, which allows you to perform setup functions and download logs. This mode is not used for individual patient session setup.

Session ID screen

When you press the *Start Session* button on the **Start** screen, the **Session ID** screen is displayed, as illustrated in the following figure. This screen includes a touchscreen keyboard for entering the Session ID. The format of the Session ID is **nnn-Ann-nnn**, where **n** is a number, and **A** is a letter.




Press *Cancel* at any time to return to the **Start** screen.

Use the keys on the touchscreen keyboard to enter the Session ID in the prescribed format. The dashes (“-”) are added automatically. Use the delete key () to correct errors.

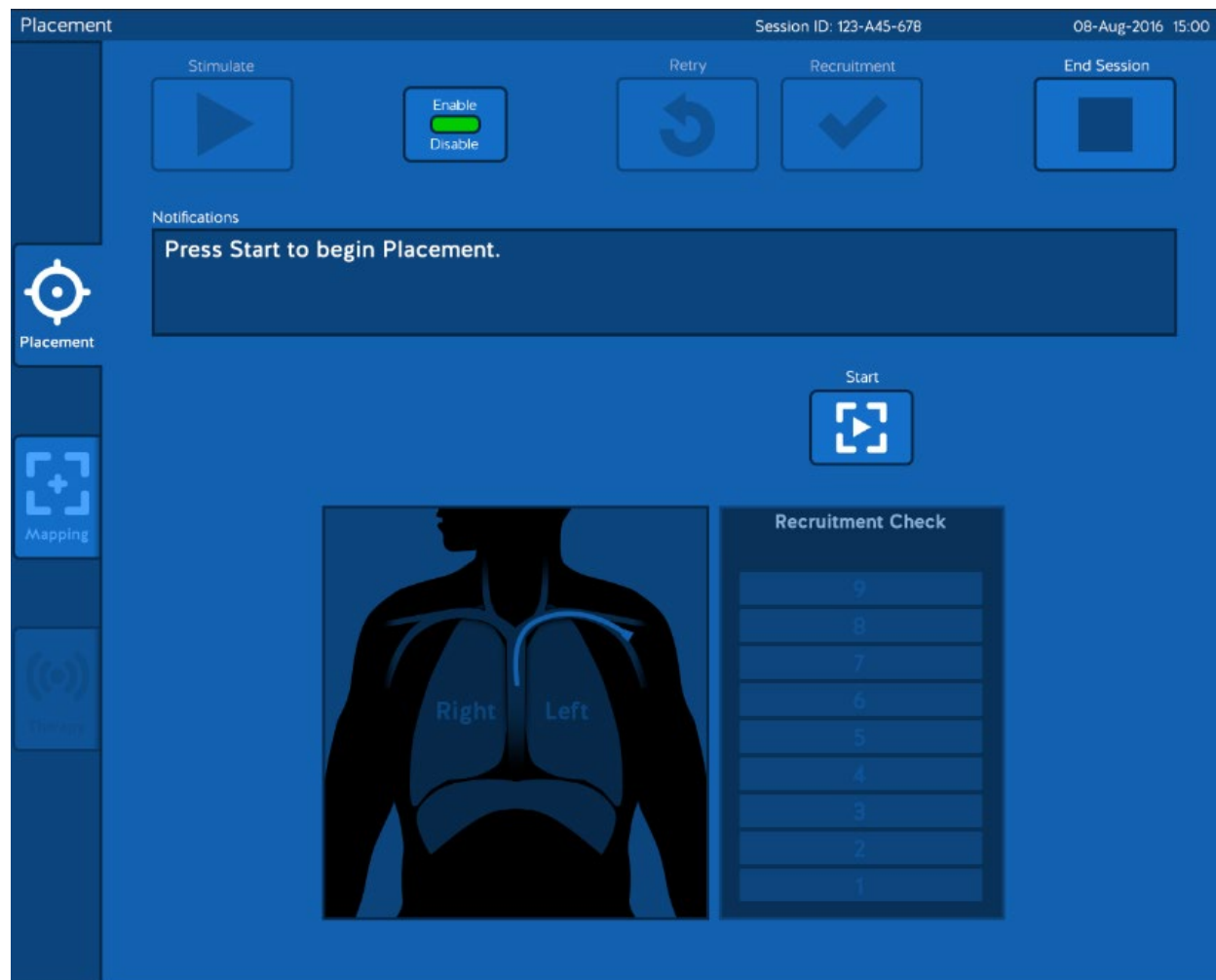
Once the Session ID has been entered, press *Continue*. You will be navigated to a prompt, which will ask you whether Placement needs to be performed. If you answer yes in this prompt, you will be navigated to the **Placement** screen. If you answer no in this prompt, you will be navigated to the **Mapping** screen.

Placement screen

Once a session has been initiated, the **Placement** screen can be accessed by pressing the *Placement* icon

() in the upper left of the screen. This icon is available only during a session, after you have entered a Session ID. Pressing the Placement icon on the **Mapping** screen or on the **Therapy** screen will navigate you to the **Placement** screen.

The initial **Placement** screen is illustrated in the figure below.





Note:

The Notifications box, in the upper portion of the **Placement** screen, provides information to help you decide what to do next.

You can perform Placement after the LIVE Catheter has first been placed, prior to confirmation of proper catheter placement. The Placement sequence allows quick verification that the LIVE Catheter is placed at the correct depth.

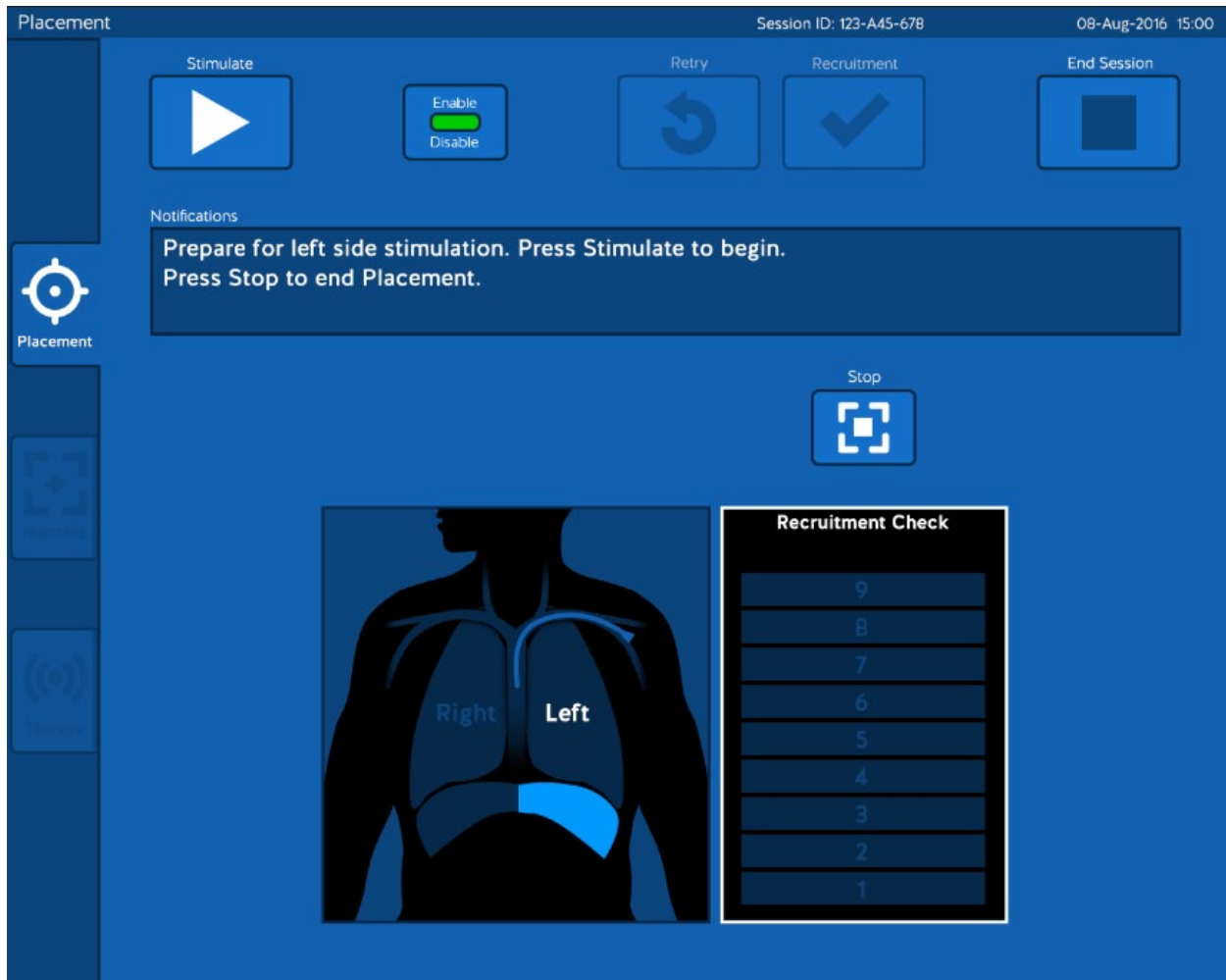
You may also choose to perform Placement if there is reason to believe that the LIVE Catheter may have been repositioned (*e.g.* if the catheter has been pulled on since the last session).

Connect the LIVE Catheter to the Intermediate Cable.


Press the *Start* button () to unlock and enable the control buttons on the **Placement** screen, and to unlock and enable the push-button on the Handheld Controller ().


After you press the *Start* button, the *Stimulate* () buttons becomes active, as illustrated in the figure below.




Note: Whenever the *Stimulate* button is active, the push-button on the Controller is also active; pressing either will have the same effect.



The Placement sequence will deliver up to nine different series of pulses to combinations of electrodes on the LIVE Catheter. Each series of stimulation pulses is delivered using a unique combination of electrodes and stimulating energy levels. The Placement sequence can now be performed, as described below.

 **Warning:** Delivery of electrical stimulation via the LIVE Catheter’s electrodes may result in cardiac arrhythmia.













 **Warning:** Delivery of electrical stimulation via the LIVE Catheter’s electrodes may result in bradycardia.

- Place one hand on the patient's lower left ribcage, to palpate for diaphragm recruitment.
- Observe the pressure waveform on the ventilator's display.
- When you are ready, press the *Stimulate/Stimulate Next* ( or ) button on the touchscreen, or press the push-button on the Handheld Controller ().

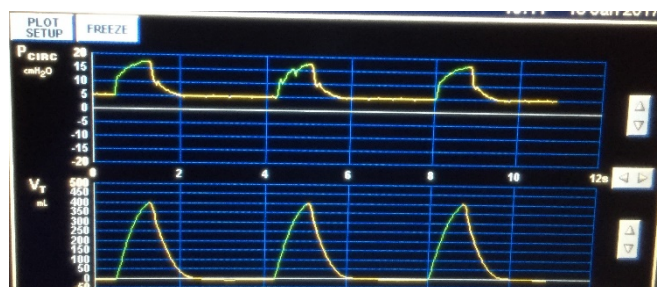
- This starts the delivery of a series of stimulation pulses delivered to the electrodes on the patient's left side. The series of stimulation pulses will finish in about a second.
- When the series of stimulation pulses finishes, the LCU will emit a brief audible tone.

Note: The *Stimulate/Stimulate Next* button can be pressed at any time during the patient's breathing cycle. You may find it easier to palpate for recruitment, and to observe perturbations of the pressure waveform on the ventilator's display, if you deliver the series of stimulation pulses during the end-expiratory period.


- Decide whether you detected recruitment (by palpation and/or by observing a perturbation on the ventilator pressure waveform); you have three options, as listed below:

<p>Recruitment not detected:</p> <p>If you detected no recruitment, do not select <i>Recruitment</i> (leave the <i>Recruitment</i> button looking like this ) and do not select <i>Retry</i> (leave the <i>Retry</i> button looking like this ).</p> <p>If you did not select either <i>Recruitment</i> or <i>Retry</i>, then pressing the <i>Stimulate Next</i> () button or the push-button on the Handheld Controller () will cause the next series of pulses to be delivered to the next group of electrodes on the LIVE Catheter.</p>	<p>Unsure:</p> <p>If you are unsure whether recruitment occurred, and you want to try the same settings again, select <i>Retry</i> (press the  button; when selected, it appears highlighted like this ).</p> <p>If you selected <i>Retry</i>, then pressing the <i>Stimulate</i> () button or the push-button on the Handheld Controller () will deliver the same series of pulses to the same electrodes on the LIVE Catheter.</p>	<p>Recruitment detected:</p> <p>If you detected recruitment, select <i>Recruitment</i> (press the  button; when selected, it appears highlighted like this ).</p> <p>If you selected <i>Recruitment</i>, this indicates that Placement is successful. To continue, press the <i>Complete</i> () button, or press the push-button on the Handheld Controller ().</p>
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Recruitment typically causes a perturbation on the ventilator pressure waveform, as illustrated below.

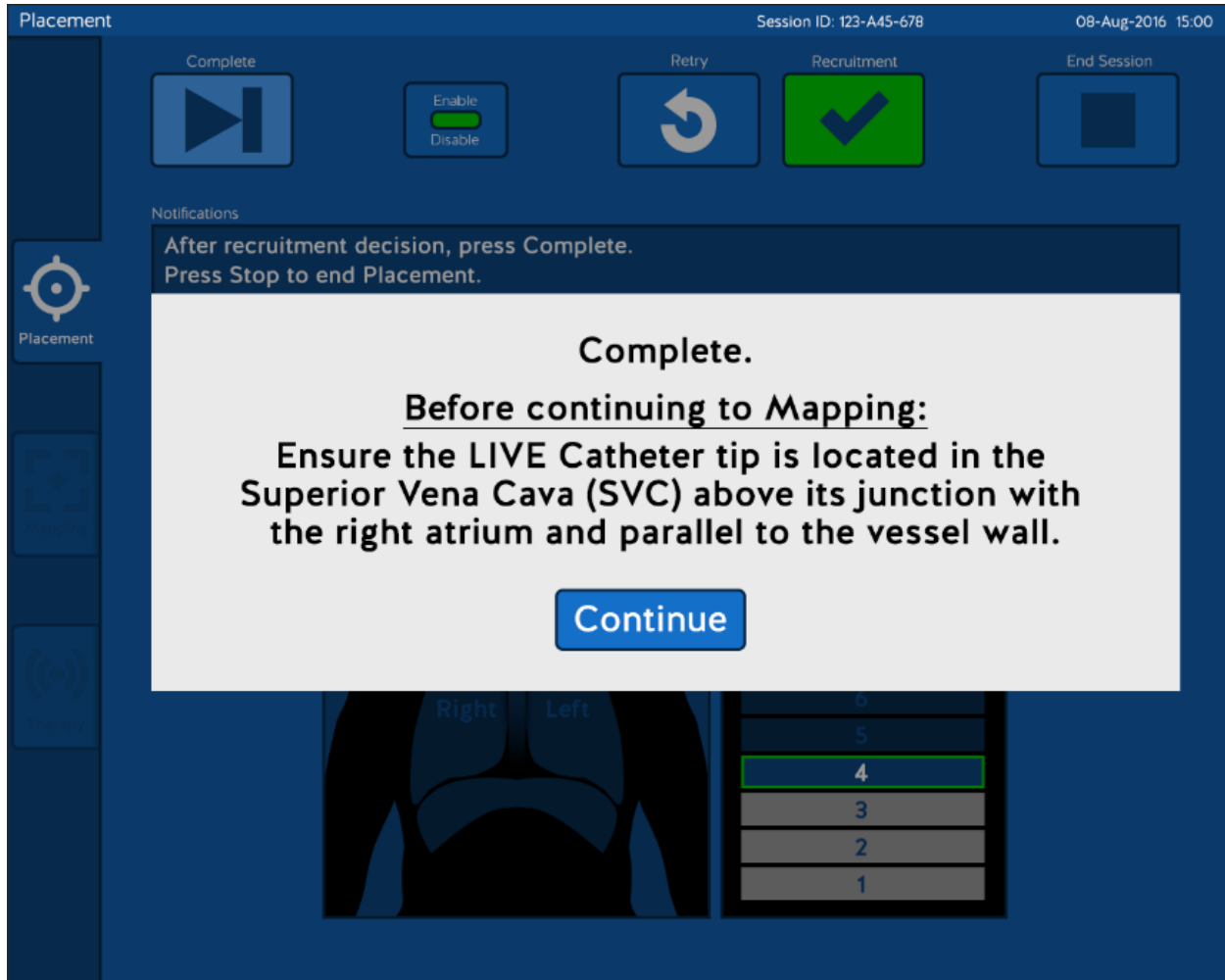


Note: *Recruitment* can be de-selected if it was selected by accident (press it again to make it look like this ).


Note: *Retry* can be de-selected if it was selected by accident (press it again to make it look like this ).

5. Repeat steps 1- 4, as instructed by the text in the *Notifications* box on the screen.


Placement success is achieved when recruitment is detected on the patient's left side. After you select *Recruitment* (), you must press the *Complete* () button on the touchscreen, or press the push-button on the Handheld Controller () to continue; you will be prompted to continue to Mapping, as illustrated in the figure below.



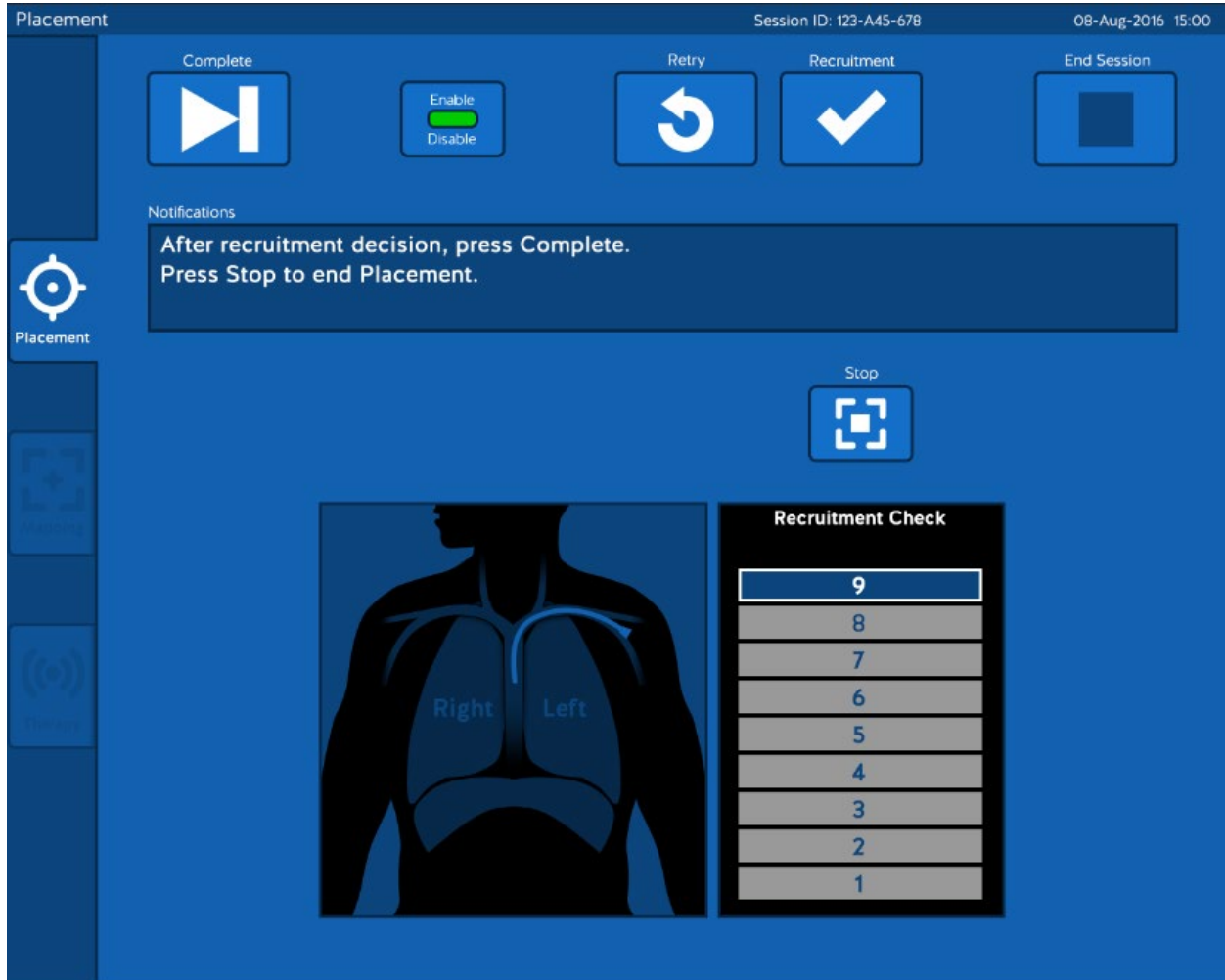
Press *Continue* to conclude Placement; you will be navigated to the **Mapping** screen.



Press the *End Session* () button at any time to end the Placement session.

Disconnect the LIVE Catheter from the Intermediate Cable before performing evaluation of proper placement of the LIVE Catheter.

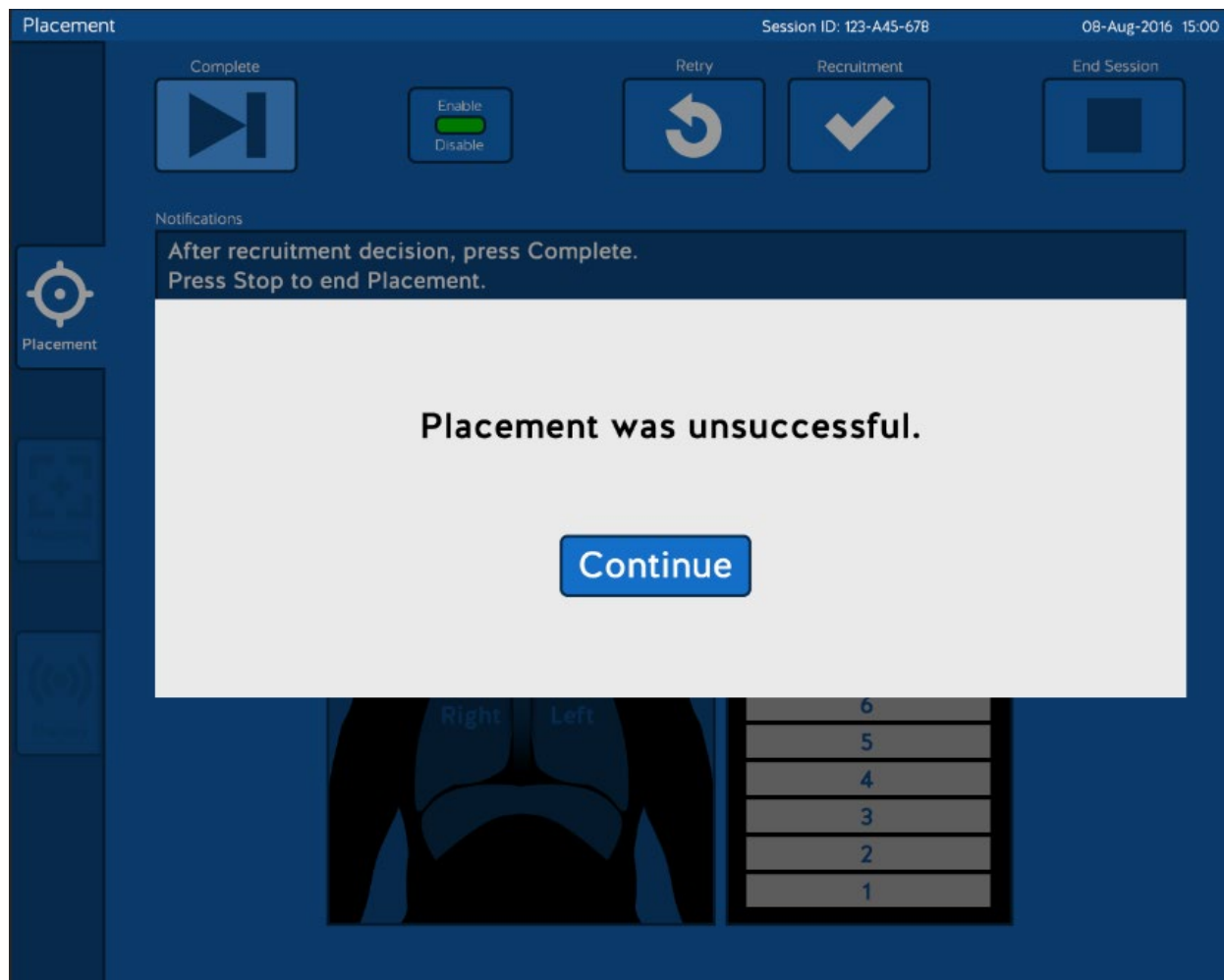
	Warning: Do not connect the LIVE Catheter to the LCU or to the Intermediate Cable while performing X-ray confirmation of placement of the LIVE Catheter.
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If recruitment is not detected for any of the series of pulses delivered, Placement is unsuccessful. After delivering a series of stimulation pulses to the LIVE Catheter at the highest level (level 9), the **Placement** screen appears as illustrated in the figure below.



If you do not select either *Retry* or *Recruitment*, and you then press the *Complete* () button on the touchscreen, or the push-button on the Handheld Controller (), this indicates that recruitment was not detected for any of the series of pulse sequences.

If Placement was unsuccessful, a notification appears, as illustrated in the figure below.



Press *Continue* and then the *Start* button () to start the Placement sequence from the beginning.

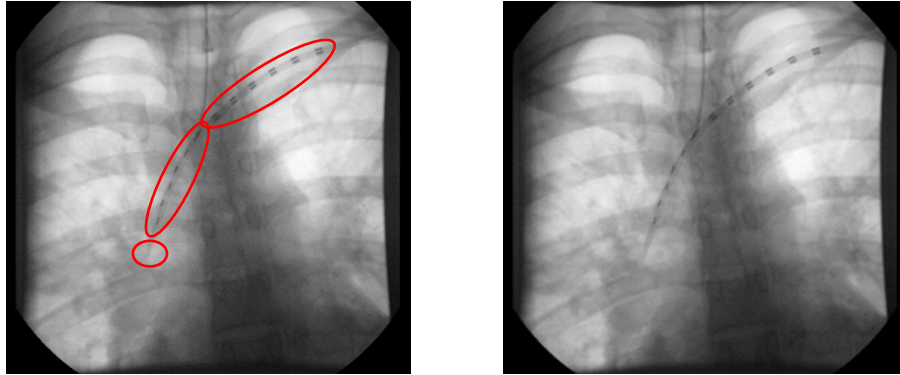
Press *Continue* and then the *End Session* button () to end the session.

If Placement was unsuccessful, the positioning and rotation of the LIVE Catheter may need to be evaluated, and catheter repositioning should be considered. See figures below and refer to the LIVE Catheter Kit IFU. If the LIVE Catheter is repositioned, you can repeat the Placement sequence on the LCU.

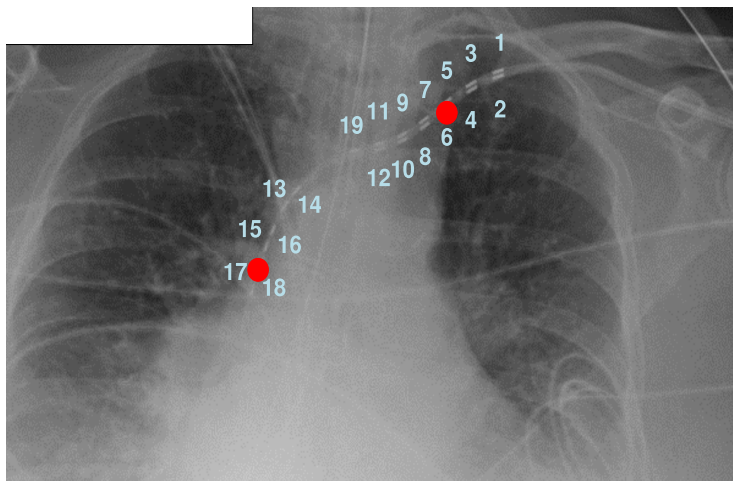
The figure below, with and without annotation, show target placement of LIVE Catheter distal tip and proper rotational orientation of the LIVE Catheter:

- The LIVE Catheter tip must be located in 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.


- The left array of electrodes appears as six sets of distinct electrode pairs; the right array appears as a line of six individual electrodes. This indicates proper rotational orientation of the LIVE Catheter.

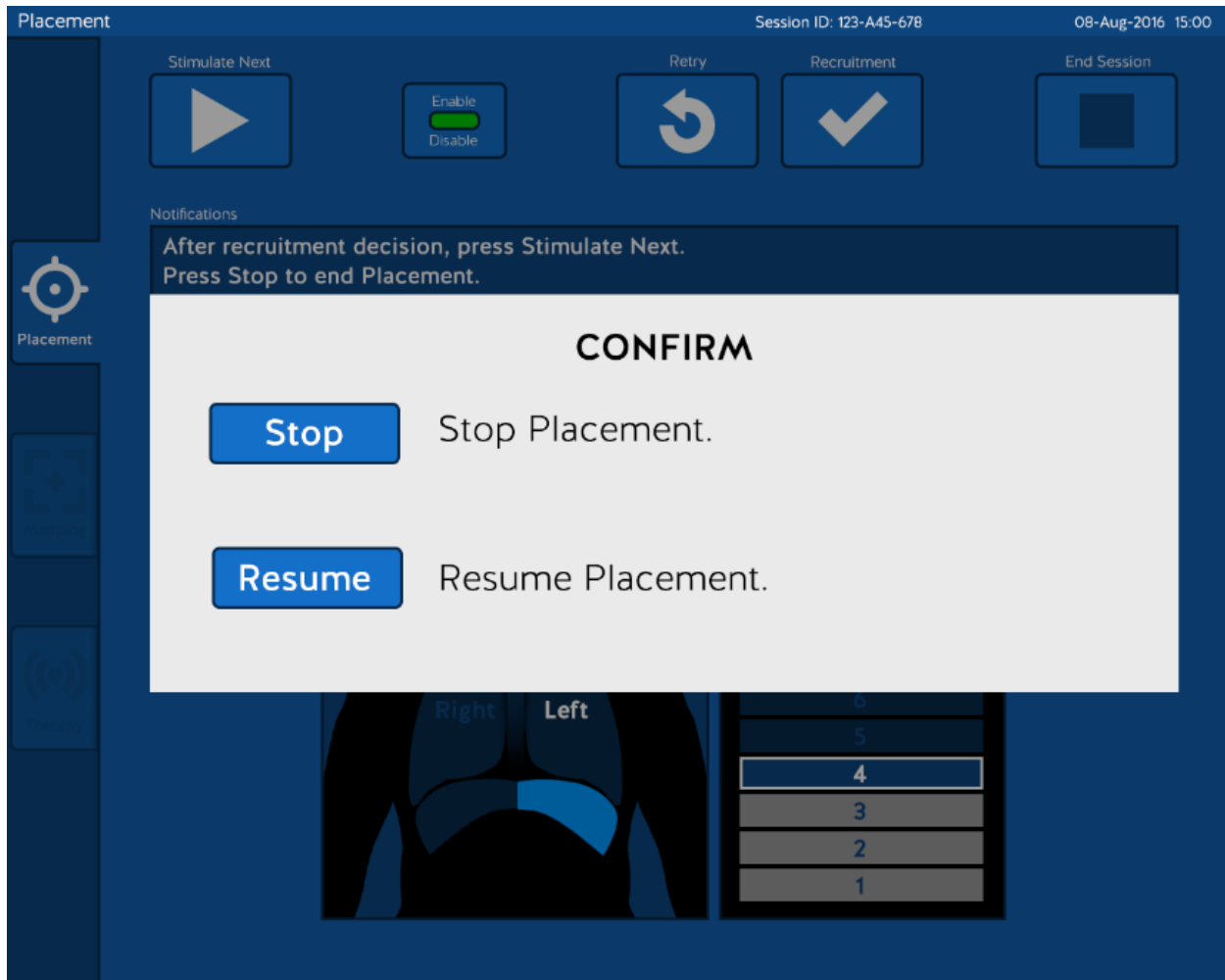


The annotated figure below shows proper LIVE Catheter placement depth and rotational orientation. The red dots represent the electrodes on the LIVE Catheter that were identified by mapping to have stimulated the left and right phrenic nerves.





At any time during Placement, if you want to start over, press the *Stop* button (). A confirmation box will appear, as illustrated in the figure below.




Press *Resume* if you do not want to restart Placement.

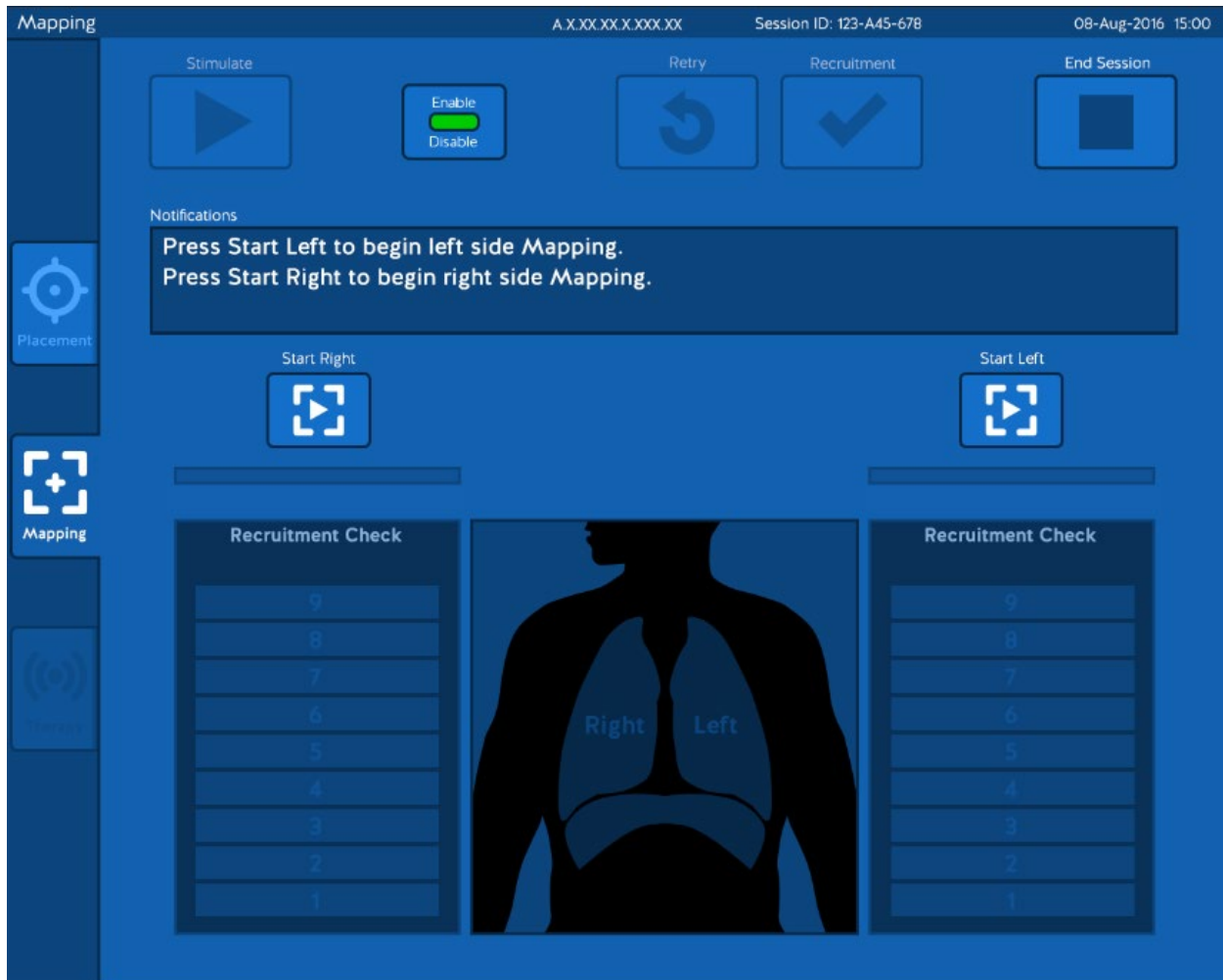
Press *Stop* and then *Start* to start the Placement sequence from the beginning.

Mapping screen

Once a session has been initiated, the **Mapping** screen can be accessed by pressing the *Mapping* icon

() on the left of the screen. This icon is available only during a session, after you have entered a Session ID. The Mapping icon is available on the **Placement** screen and on the **Therapy** screen. Pressing the Mapping icon while on the **Mapping** screen will not have any effect.


The initial **Mapping** screen is illustrated in the figure below.




Note: The Notifications box, in the upper portion of the **Mapping** screen, provides information to help you decide what to do next.




You must perform Mapping before Therapy can be delivered during a session. The Mapping sequence identifies the electrode combinations to be used for Therapy, and quantifies the stimulation thresholds for Therapy on the left and right sides. If an electrode combination is identified on only one side, Therapy will only be delivered on that side.


You may also choose to perform Mapping if there is reason to believe that the LIVE Catheter may have shifted (*e.g.* if the patient moved significantly during Therapy).

 **Warning:** Confirm correct placement of the LIVE Catheter by X-ray evaluation, or other method in compliance with hospital/institutional practices or current guidelines, before performing Mapping for the first time.

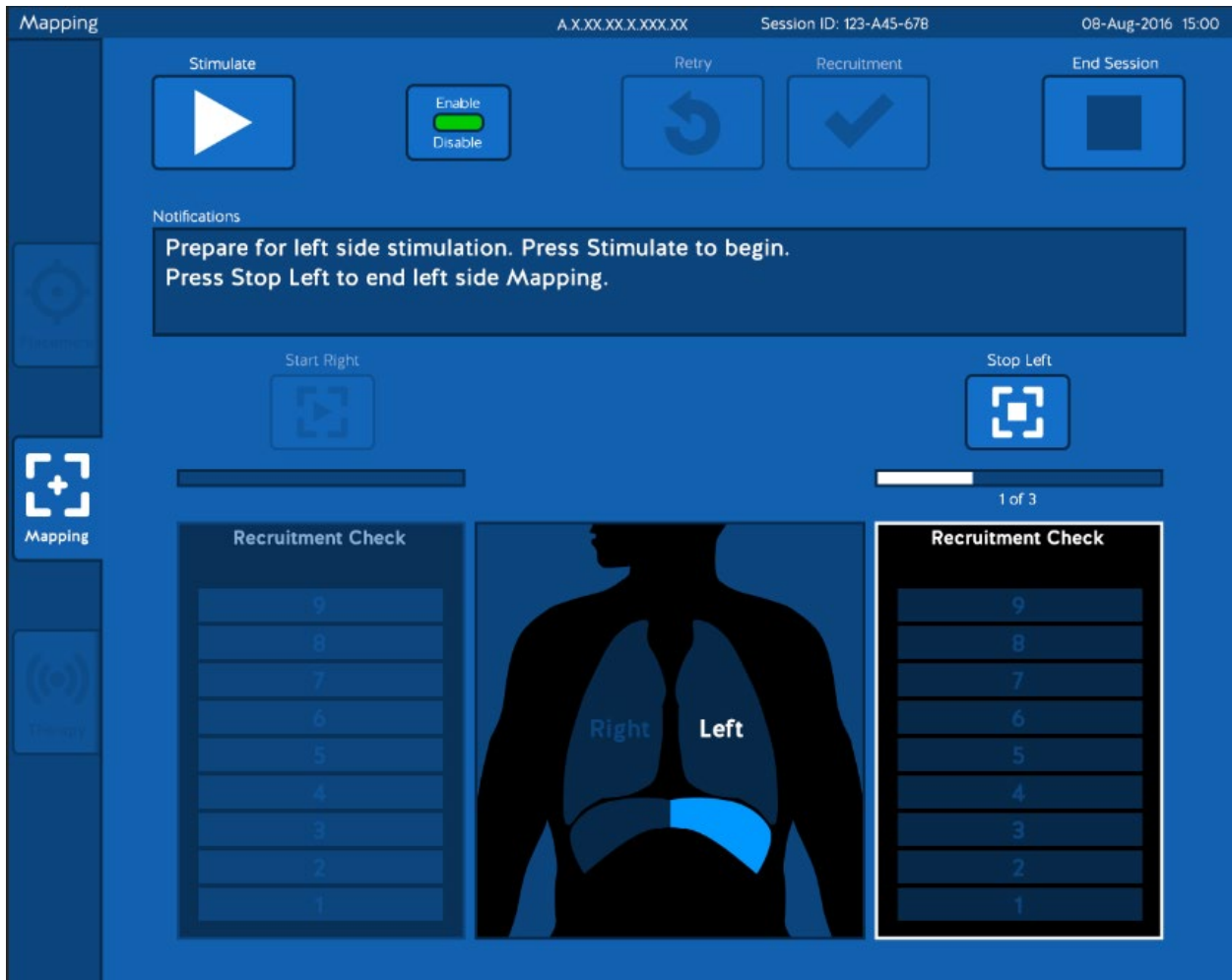
 **Warning:** Do not perform Mapping if you think the tip of the LIVE Catheter is placed in the atrium.

Connect the LIVE Catheter to the Intermediate Cable.

Press the *Start Left* button () or *Start Right* () button to unlock and enable the control buttons on the **Mapping** screen, and to unlock and enable the push-button on the Handheld Controller (). You may decide whether to Map the Left side or Right side first.

After you press the *Start Left* button or *Start Right* button, the *Stimulate* () button becomes active, as illustrated for the Left side in the figure below.

Note: Whenever the *Stimulate* button is active, the push-button on the Controller is also active; pressing either will have the same effect.



The Mapping sequence can now be performed, as described below.

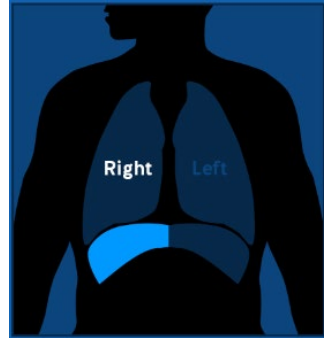
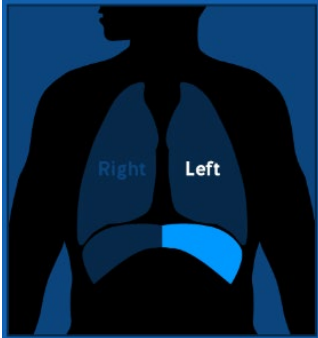


Warning: Delivery of electrical stimulation via the LIVE Catheter's electrodes may result in cardiac arrhythmia.






Warning: Delivery of electrical stimulation via the LIVE Catheter's electrodes may result in bradycardia.

1. Place one hand on the patient's lower left or lower right ribcage to palpate for diaphragm recruitment. The graphic on the display indicates which side to palpate, as shown below.



2. Observe the pressure waveform on the ventilator's display.

3. When you are ready, press the *Stimulate/Stimulate Next* ( or ) button on the touchscreen, or press the push-button on the Handheld Controller ().

- This starts the delivery of a series of stimulation pulses delivered to some of the electrodes on the patient's left or right side (depending on which side you chose to map and as indicated on the display). The series of stimulation pulses will finish in about a second.
- When the series of stimulation pulses finishes, the LCU will emit a brief audible tone.














Note:

Make sure your palpating hand is placed on the correct side of the patient, as indicated by the graphic on the screen.

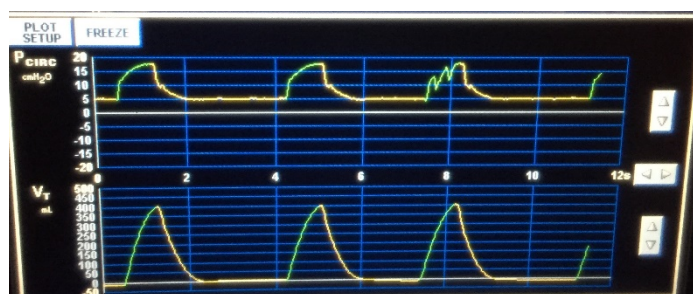
Note:


The *Stimulate/Stimulate Next* button can be pressed at any time during the patient's breathing cycle. You may find it easier to palpate for recruitment, and to observe perturbations of the pressure waveform on the ventilator's display, if you deliver the series of stimulation pulses during the end-expiration period.


4. Decide whether you detected recruitment (by palpation and/or by observing a perturbation on the ventilator pressure waveform); you have three options, as listed below:

<p>Recruitment not detected:</p> <p>If you detected no recruitment, do not select <i>Recruitment</i> (leave the <i>Recruitment</i> button looking like this ) and do not select <i>Retry</i> (leave the <i>Retry</i> button looking like this ).</p> <p>If you did not select either <i>Recruitment</i> or <i>Retry</i>, then pressing the <i>Stimulate Next</i> () button or the push-button on the Handheld Controller () will cause the next series of pulses to be delivered to the next group of electrodes on the LIVE Catheter.</p>	<p>Unsure:</p> <p>If you are unsure whether recruitment occurred, and you want to try the same settings again, select <i>Retry</i> (press the  button; when selected, it appears highlighted like this ).</p> <p>If you selected <i>Retry</i>, then pressing the <i>Stimulate</i> () button or the push-button on the Handheld Controller () will deliver the same series of pulses to the same electrodes on the LIVE Catheter.</p>	<p>Recruitment detected:</p> <p>If you detected recruitment, select <i>Recruitment</i> (press the  button; when selected, it appears highlighted like this ).</p> <p>If you selected <i>Recruitment</i>, this indicates that one or more of the electrode combinations being evaluated may be suitable for Therapy.</p> <p>If you selected <i>Recruitment</i> (), then pressing the <i>Stimulate Next</i> () button or the push-button on the Handheld Controller () will cause the next series of evaluation pulses to be delivered to the electrodes on the LIVE Catheter.</p>
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Recruitment typically causes a perturbation on the ventilator pressure waveform, as illustrated below.

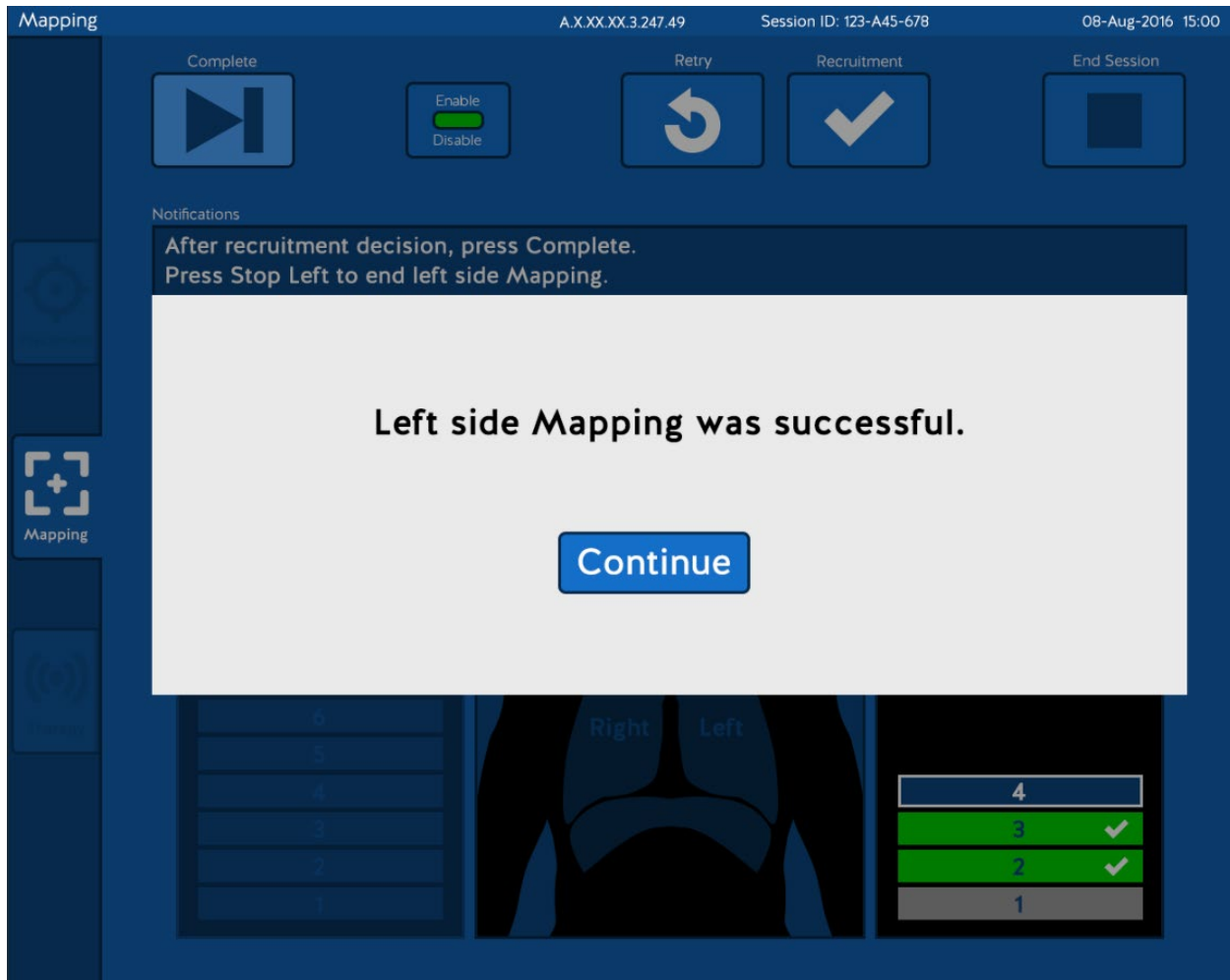


Note: *Recruitment* can be de-selected if it was selected by accident (press it again to make it look like this ).

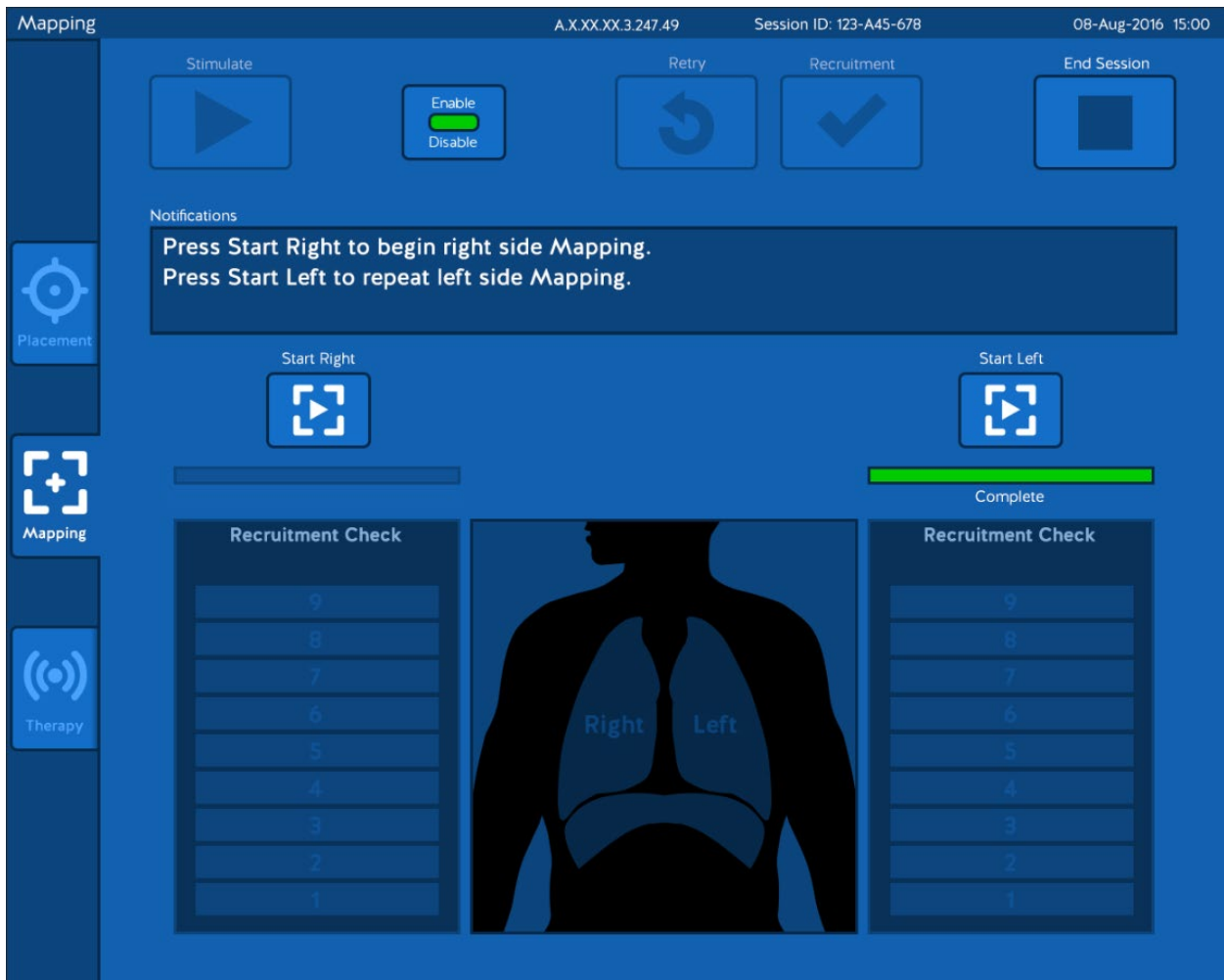
Note: *Retry* can be de-selected if it was selected by accident (press it again to make it look like this ).

5. Repeat steps 1- 4, as instructed by the text in the *Notifications* box on the screen.



When the entire Mapping sequence is completed successfully, and recruitment was detected on either the left side or the right side, the **Mapping** screen indicates this, as illustrated for the Left side in the figure below.




Press *Continue* to confirm completion of the Mapping sequence. You will be navigated to the **Mapping** screen where you can press *Start Left* or *Start Right* to map the other side, as illustrated in the figure below.



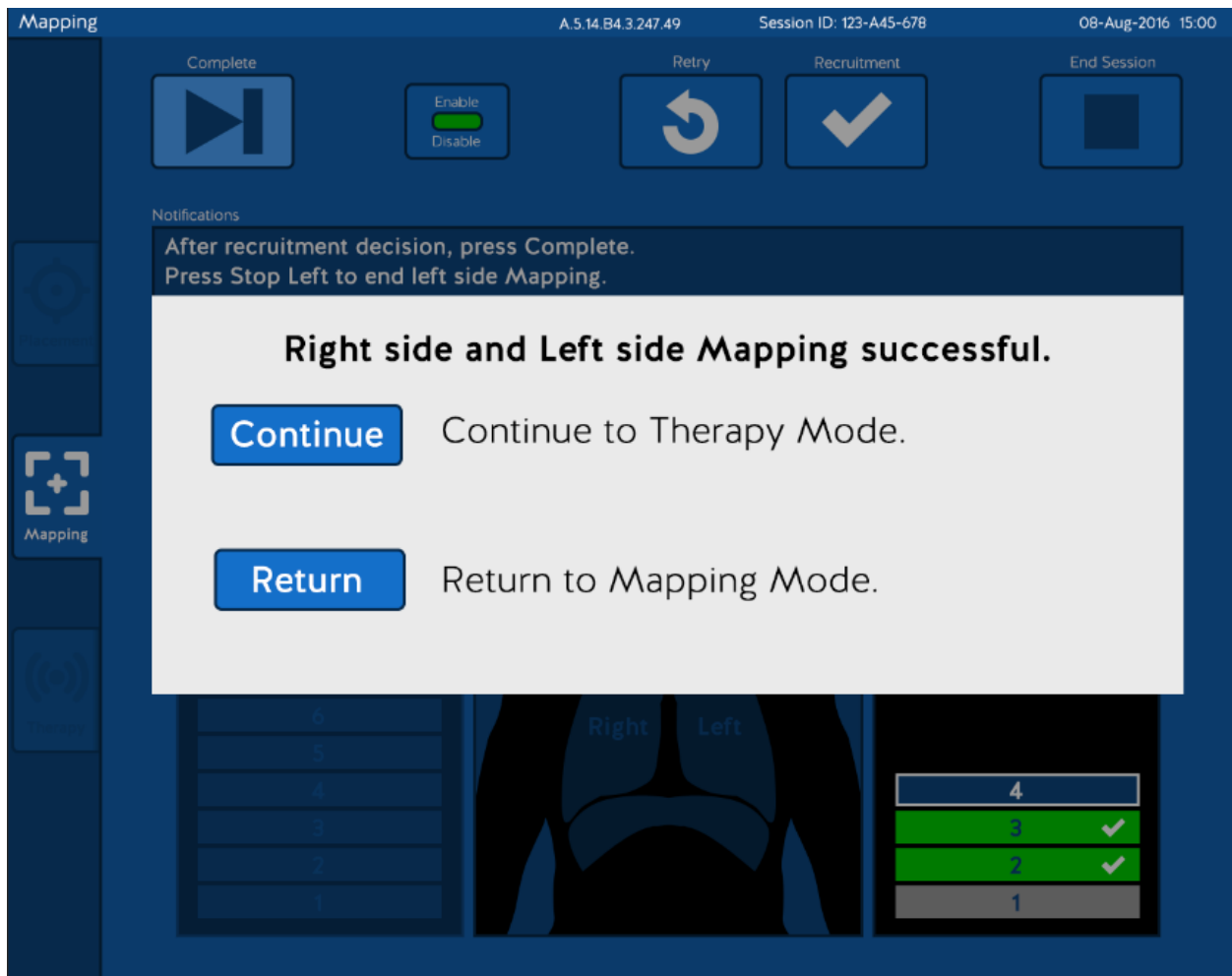
The progress bar indicates the mapping status of each side.

From the **Mapping** screen press the *Start Left* button () or *Start Right* () to perform Mapping on the side that has not yet been mapped.

It is recommended that both the left and right side should be mapped.

If necessary, once one side is mapped, the **Therapy** screen can be accessed by pressing the *Therapy* icon () on the left of the screen. In this case, Therapy will be delivered only on the side that is mapped.

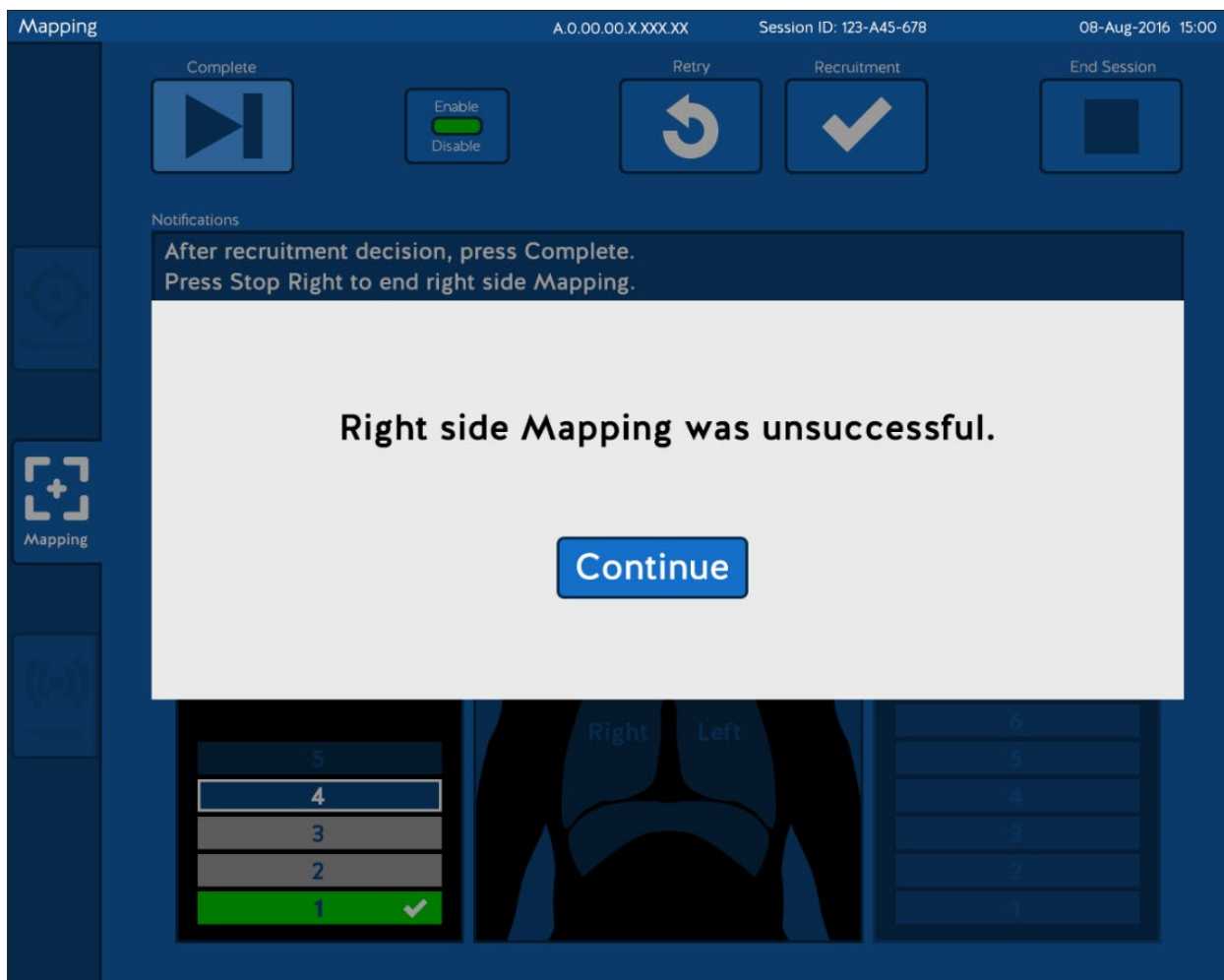
When the entire Mapping sequence is completed successfully, and recruitment has been detected on both the left side and the right side, the **Mapping** screen indicates this, as illustrated in the figure below.





Press *Continue* to confirm completion of the Mapping sequence and navigate to the **Therapy** screen.

Pressing *Return* will confirm completion of the Mapping sequence and return to the **Mapping** screen where the right or left side can be remapped.

During Mapping, it is possible that no successful electrode combination and threshold were identified on either side. This is illustrated for the Right side in the figure below.






Press *Continue* to return to the **Mapping** screen. From this screen you can start the mapping process on either side by pressing the *Start Left* button () or *Start Right* () button.

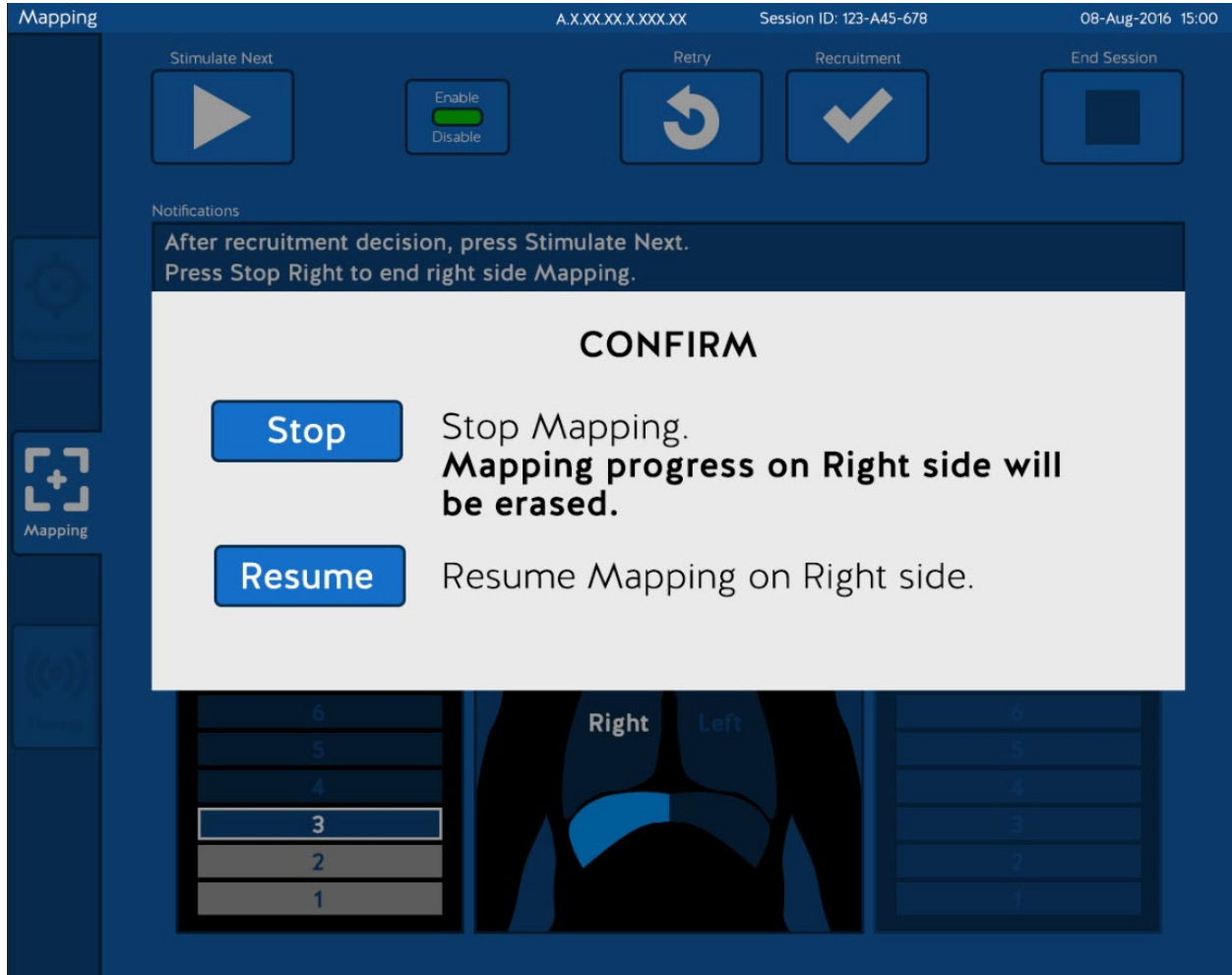
If Mapping was unsuccessful for one side, and the other side has not been successfully mapped, Therapy cannot be delivered during this session.

If Mapping was unsuccessful for one side, and the other side has been successfully mapped, Therapy can be delivered unilaterally on the side that is successfully mapped.



If Mapping was unsuccessful, the positioning and rotation of the LIVE Catheter may need to be evaluated, and catheter repositioning should be considered. If the LIVE Catheter is repositioned, you can repeat Placement.

 **Warning:** Do not connect the LIVE Catheter to the LCU or to the Intermediate Cable while performing X-ray confirmation of placement of the LIVE Catheter.

At any time during Mapping, if you want to start over, press the *Stop Left* button () or *Stop Right* button (). A confirmation box will appear, as illustrated for the Right side in the figure below.




Press *Resume* if you do not want to stop Mapping.

Press *Stop* to stop the Mapping sequence and return to the **Mapping** screen. From this screen, you can start the mapping process on either side by pressing the *Start Left* button () or *Start Right* () button.

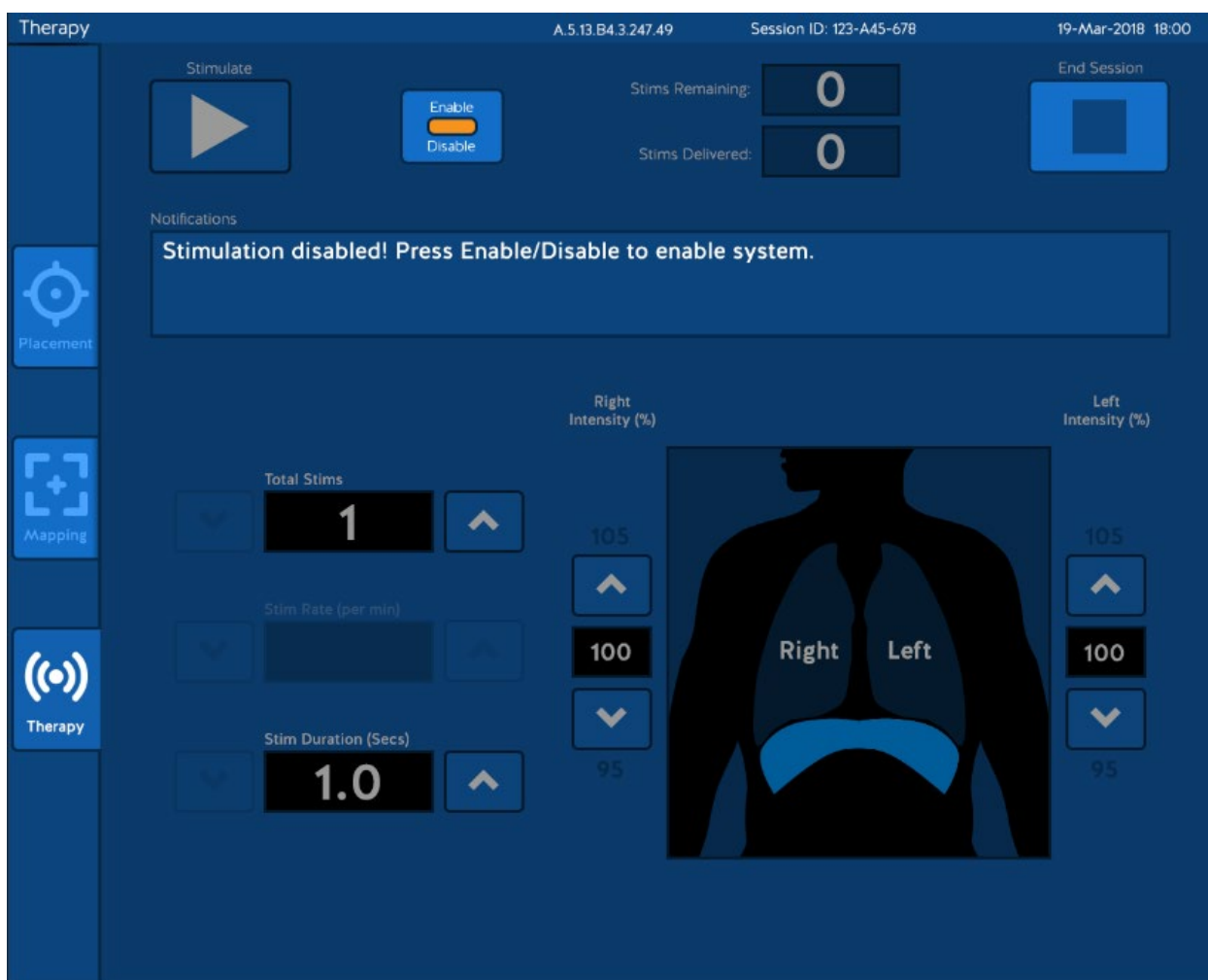
Therapy screen

The **Therapy** screen appears automatically after successfully Mapping both the Left and Right side, indicating that therapy can now be initiated.




The *Therapy* () icon is highlighted on the **Therapy** screen. If you navigate to the **Placement** screen from the **Therapy** screen, you must complete a Mapping sequence to return to the **Therapy** screen. If you navigate to the **Mapping** screen from the **Therapy** screen, you may return to the **Therapy** screen as long as at least one side remains mapped.



The initial **Therapy** screen is illustrated in the figure below.



Note:

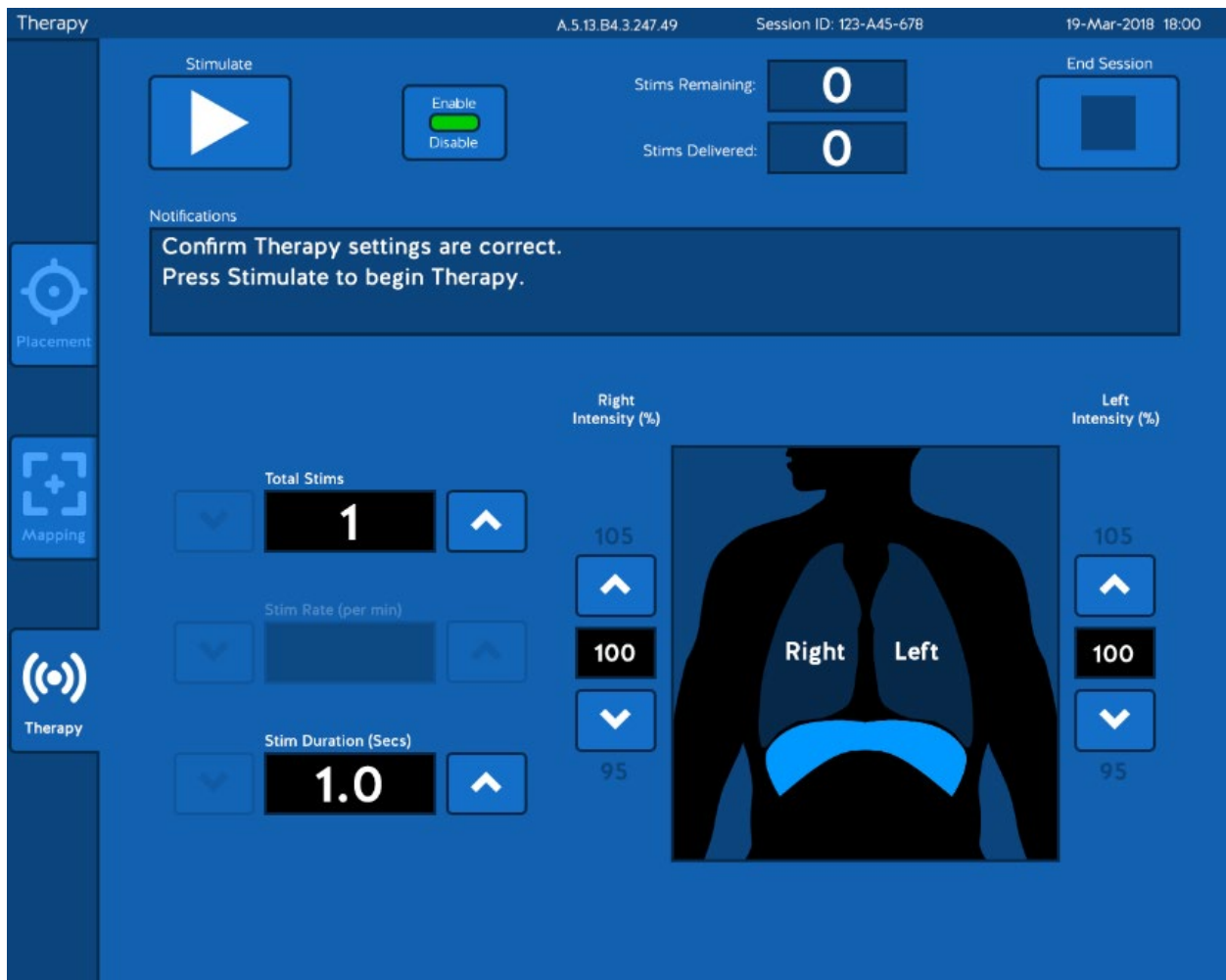
The Notifications box, in the upper portion of the **Therapy** screen, provides information to help you decide what to do next.

You must enable the screen by pressing the *Enable* button () before you can adjust Therapy parameters on this screen.

After you press the *Enable* button (), the *Stimulate* () and parameter control buttons become active, as illustrated in the figures below.

Note: Whenever the *Stimulate* button is active, the push-button on the Controller is also active; pressing either will have the same effect.

Note: Therapy parameters can be further adjusted from this screen, if necessary.



Note: The Notifications box, in the upper portion of the **Therapy** screen, provides information to help you decide what to do next.

There are five parameters that you can adjust on the **Therapy** screen:

Parameter	Minimum Value	Maximum Value	Notes
Total Stims ¹	1	10	Total number of stimulation repetitions (Stims) in the sequence
Stim Rate (per min) ²	8	15	Repetition rate at which the stimulation repetitions (Stims) will be delivered
Stim Duration (secs)	0.1	1.2	Duration of each stimulation repetition (Stim)
Right Intensity (%) ^{3,4}	50	1000	Stimulation intensity level, expressed as a percentage of threshold
Left Intensity (%) ^{3,5}	50	1000	Stimulation intensity level, expressed as a percentage of threshold

There are two ways the parameters can be configured on the **Therapy** screen:

1. Single Stim
2. Multiple Stim

Single Stim

In this configuration, the **Total Stims** parameter is set to 1.

The **Stim Rate** parameter is not available in this configuration.

You initiate each Stim by pressing the Stimulate (



) button or the push-button on the

Handheld Controller ().

Set the **Total Stims** parameter to 1 if you want to evaluate a combination of **Stim Duration**, **Right Intensity** and **Left Intensity** to observe the functional effect, or to see how the settings interact with the mechanical ventilator settings. You may also choose to set the **Total Stims** parameter to 1 if you want to be able to control when each Stim is delivered.

Multiple Stim


In this configuration, the **Total Stims** parameter is set to a value between 2 and 10.

The **Stim Rate** parameter is available in this configuration, and you must set it to synchronize appropriately with the mechanical ventilator settings and with the patient's intrinsic breathing patterns.

You initiate a sequence of Stims at the selected



parameters by pressing the Stimulate () button or the push-button on the Handheld

Controller ().

Use this configuration after you have evaluated the selected combination of **Stim Duration**, **Right Intensity** and **Left Intensity** in Single Stim configuration.





¹ When **Total Stims** is set to 1, a single Stim will be delivered when the *Stimulate* button is pressed.

² When **Total Stims** is set to 1, the **Stim Rate** parameter is not available.

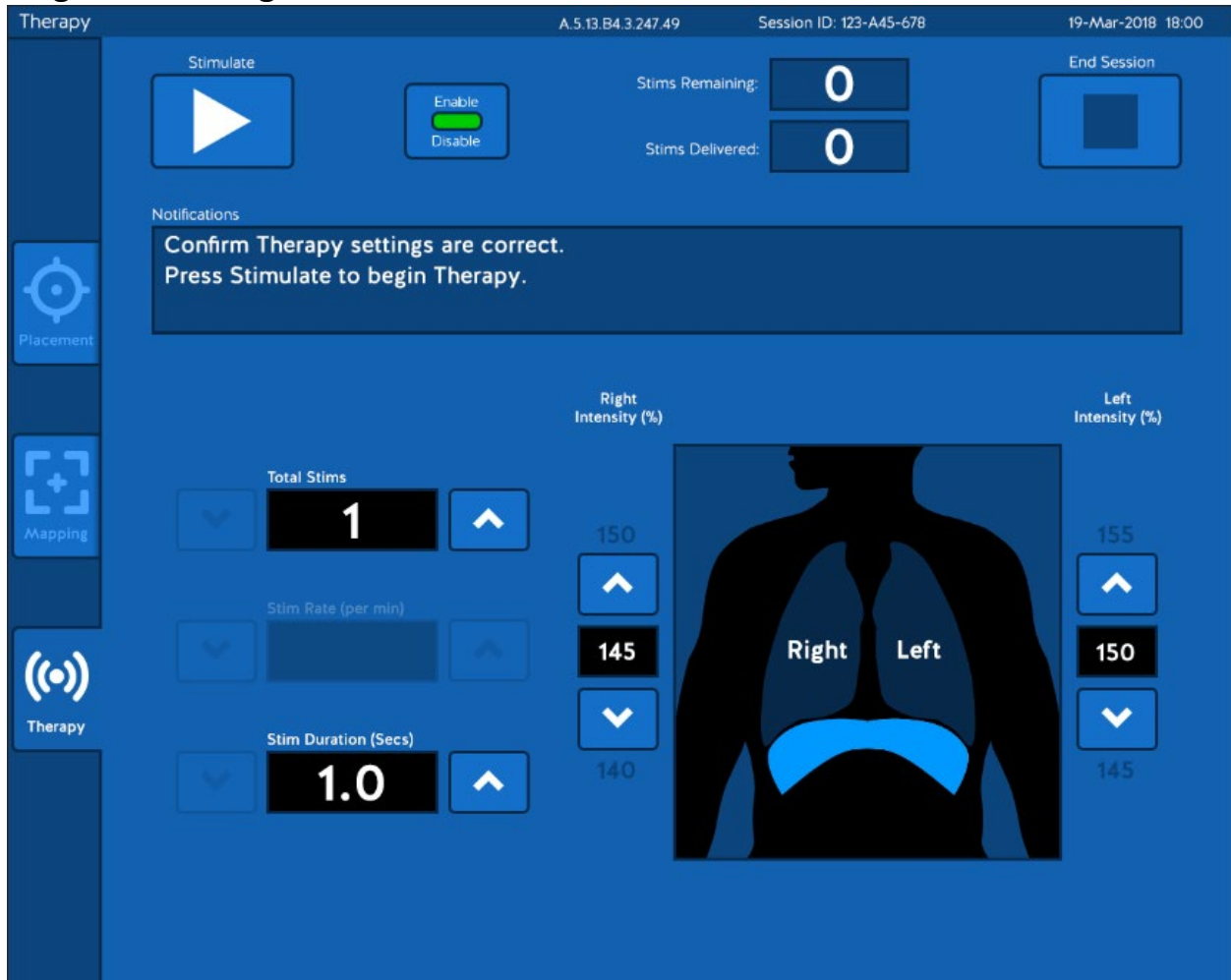
³ Not all values for **Right Intensity** and **Left Intensity** will always be available; maximum values are limited by the maximum output capability of the Lungpacer Control Unit; some increments may not be available, due to the resolution limits of the output circuitry or based on the thresholds.

⁴ **Right Intensity** will not be available if Mapping was unsuccessful on the right side.

⁵ **Left Intensity** will not be available if Mapping was unsuccessful on the left side.

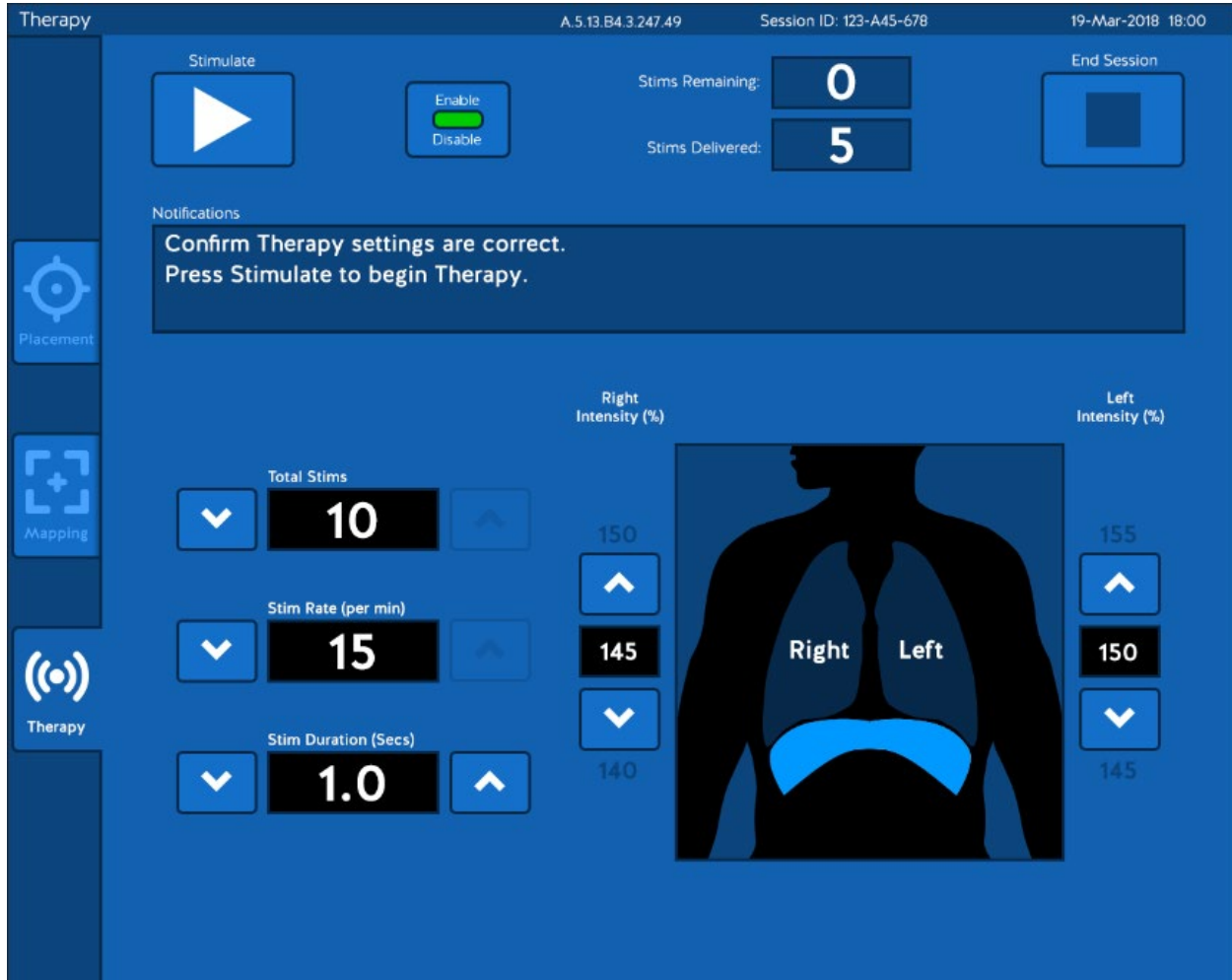
-  **Warning:** Delivery of electrical stimulation via the LIVE Catheter’s electrodes may result in cardiac arrhythmia.
-  **Warning:** Delivery of electrical stimulation via the LIVE Catheter’s electrodes may result in bradycardia.
-  **Warning:** Overstimulation of the diaphragm may result in diaphragm injury.
-  **Warning:** Ensure the mechanical ventilator settings are compatible with the LCU Therapy parameter settings. Failure to do so may result in lung injury.

Single Stim configuration



The screenshot shows the 'Therapy' configuration screen. At the top, it displays 'Therapy', 'A.5.13.B4.3.247.49', 'Session ID: 123-A45-678', and '19-Mar-2018 18:00'. The main interface includes a 'Stimulate' button with a play icon, an 'Enable' toggle (currently on), and 'Stims Remaining' and 'Stims Delivered' counters, both showing '0'. An 'End Session' button is also present. A notification box states: 'Confirm Therapy settings are correct. Press Stimulate to begin Therapy.' Below this, there are three main settings: 'Total Stims' set to 1, 'Stim Rate (per min)' set to 145, and 'Stim Duration (Secs)' set to 1.0. On the right, a silhouette of a human torso shows the diaphragm area with 'Right' and 'Left' labels. The 'Right Intensity (%)' is set to 145 (range 140-150) and the 'Left Intensity (%)' is set to 150 (range 145-155). A vertical sidebar on the left contains icons for 'Placement', 'Mapping', and 'Therapy'.

Multiple Stim configuration





The screenshot shows the 'Therapy' screen with the following elements:



- Stimulate:** A play button icon and an 'Enable' toggle switch (currently on).
- Stims Remaining:** 0
- Stims Delivered:** 5
- End Session:** A square button icon.
- Notifications:** A box containing the text: "Confirm Therapy settings are correct. Press Stimulate to begin Therapy."
- Configuration Settings:**
 - Total Stims:** 10
 - Stim Rate (per min):** 15
 - Stim Duration (Secs):** 1.0
- Intensity Settings:**
 - Right Intensity (%):** 145 (range 140-150)
 - Left Intensity (%):** 150 (range 145-155)
- Diagram:** A silhouette of a human torso with the diaphragm highlighted in blue, labeled 'Right' and 'Left'.
- Navigation:** A vertical sidebar on the left with icons for 'Placement', 'Mapping', and 'Therapy'.



Note: The Notifications box, in the upper portion of the **Therapy** screen, provides information to help you decide what to do next.

Once you have confirmed that the Therapy parameters are correct, Therapy stimulation can be delivered, as described here:

1. Prepare the patient for Therapy stimulation.
2. Observe the pressure waveform on the ventilator, and monitor the patient's status.
3. Initiate Therapy stimulation by pressing the *Stimulate* () button, or by pressing the push-button on the Handheld Controller ().

Single Stim



If you set the **Total Stims** parameter to 1, then pressing the *Stimulate* () button, or pressing the push-button on the Controller () , will initiate a single Stim with the selected parameters.

If the Stim had the desired effect, you may initiate another Stim by pressing the *Stimulate* () button, or by pressing the push-button on the Controller () , again.

Initiate single Stims until the desired amount of Therapy stimulation has been delivered.

Note: In Single Stim configuration, the rate at which Stims are delivered is determined by how frequently you press the *Stimulate* button, or the push-button on the Controller.

Multiple Stim

If you set the **Total Stims** parameter to a value between 2 and 10, then pressing the *Stimulate* () button, or pressing the push-button on the Controller () , will initiate a series of Stims with the selected parameters.

Once Therapy stimulation has been initiated, wait for the series of Stims to complete. The **Therapy** screen has a counter showing the number of Stims remaining; after each Stim is delivered it counts down by one:

- With six Stims remaining, it looks like this




- When all Stims have been delivered, it looks



like this

In Multiple Stim configuration, the rate at which Stims are delivered is determined by the value you selected for **Stim Rate**. Pressing the *Stimulate* button, or the push-button on the Controller while a series of Stims are in progress will have no effect.

Note:

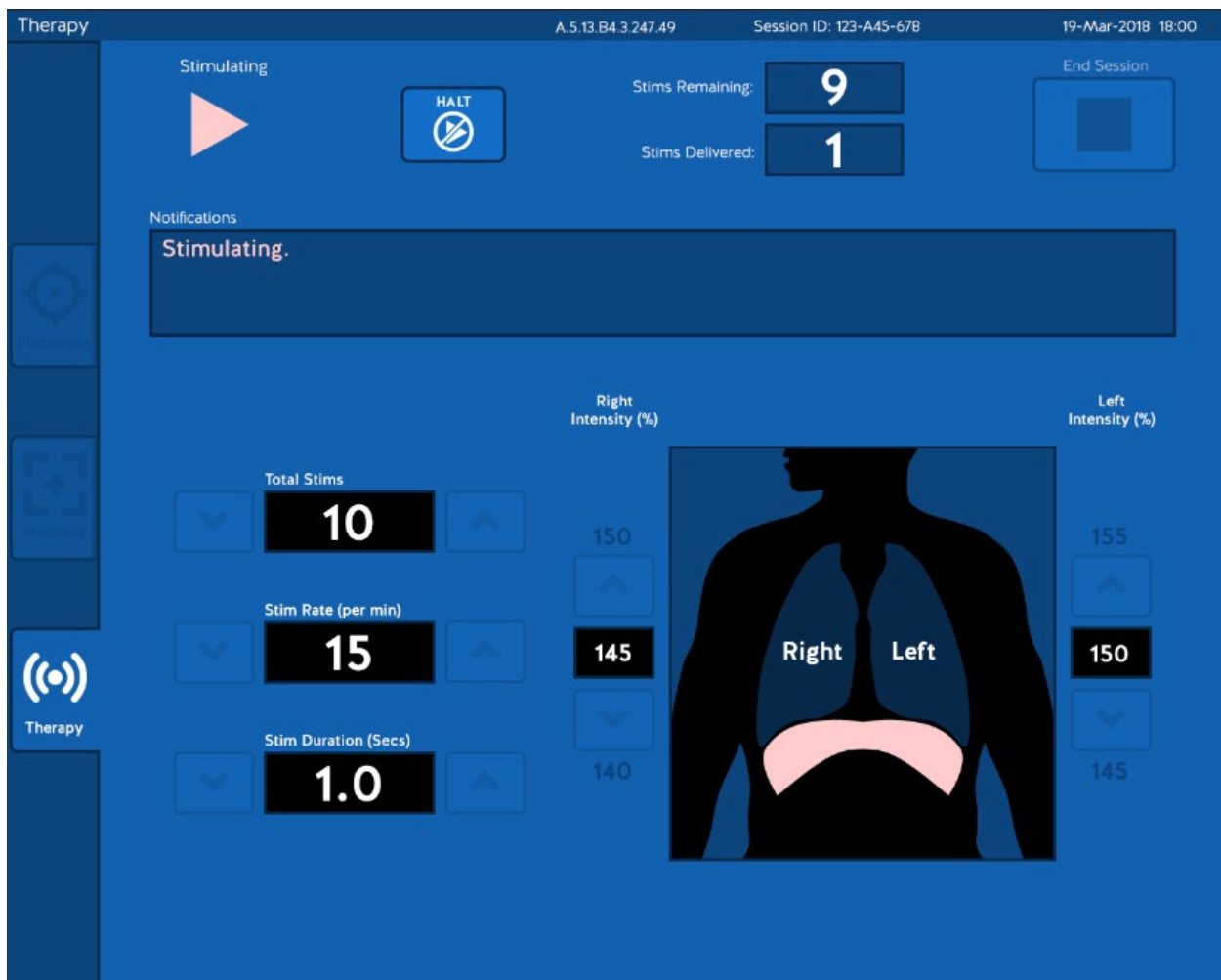
You can stop stimulation at any time by pressing the *Halt* button ().

The **Therapy** screen has a counter showing the number of Stims delivered in a Therapy Session; after each Stim is delivered it counts up by one. This counter will only be reset when the Therapy Session is ended.

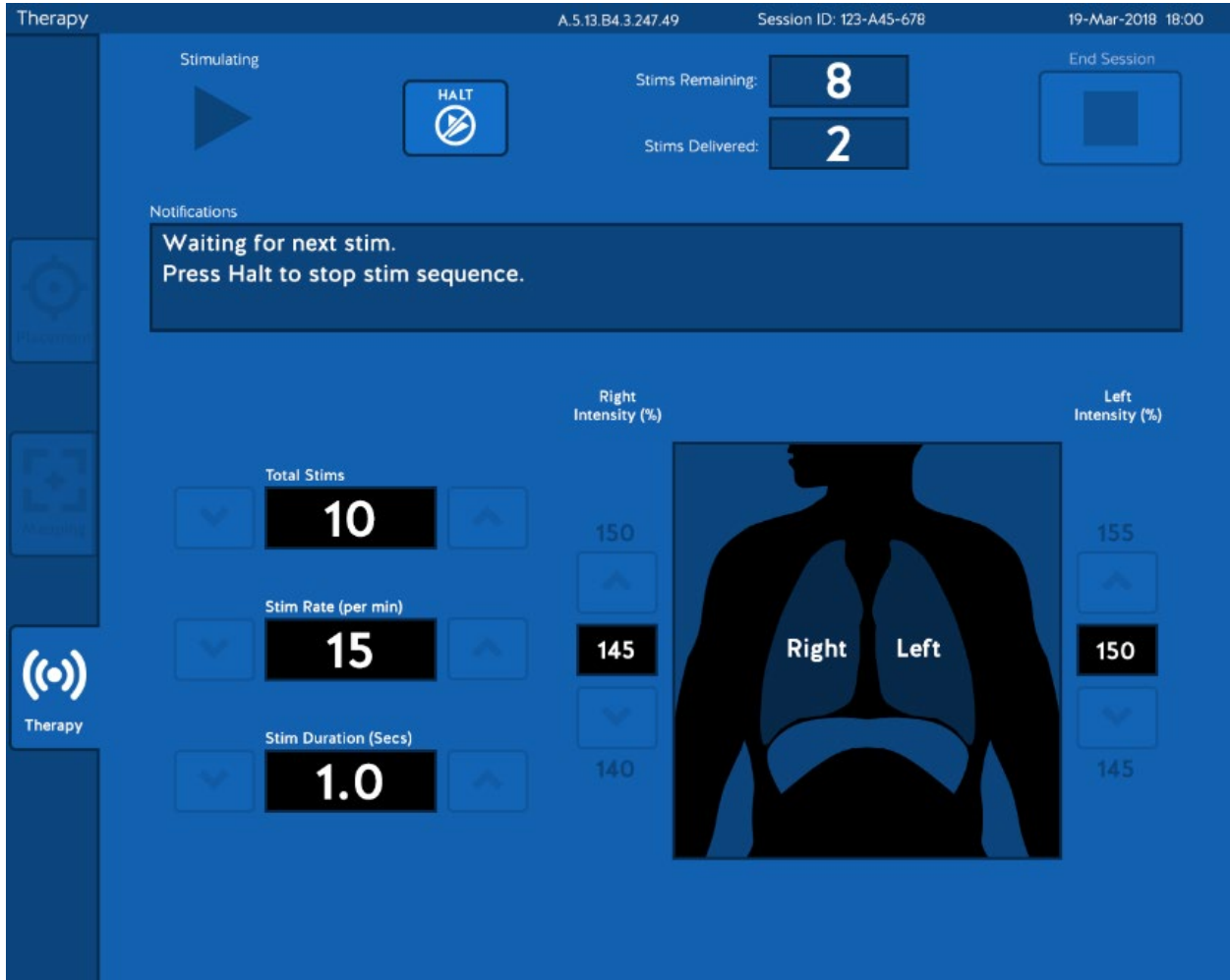
- With eight Stims delivered, it looks like this



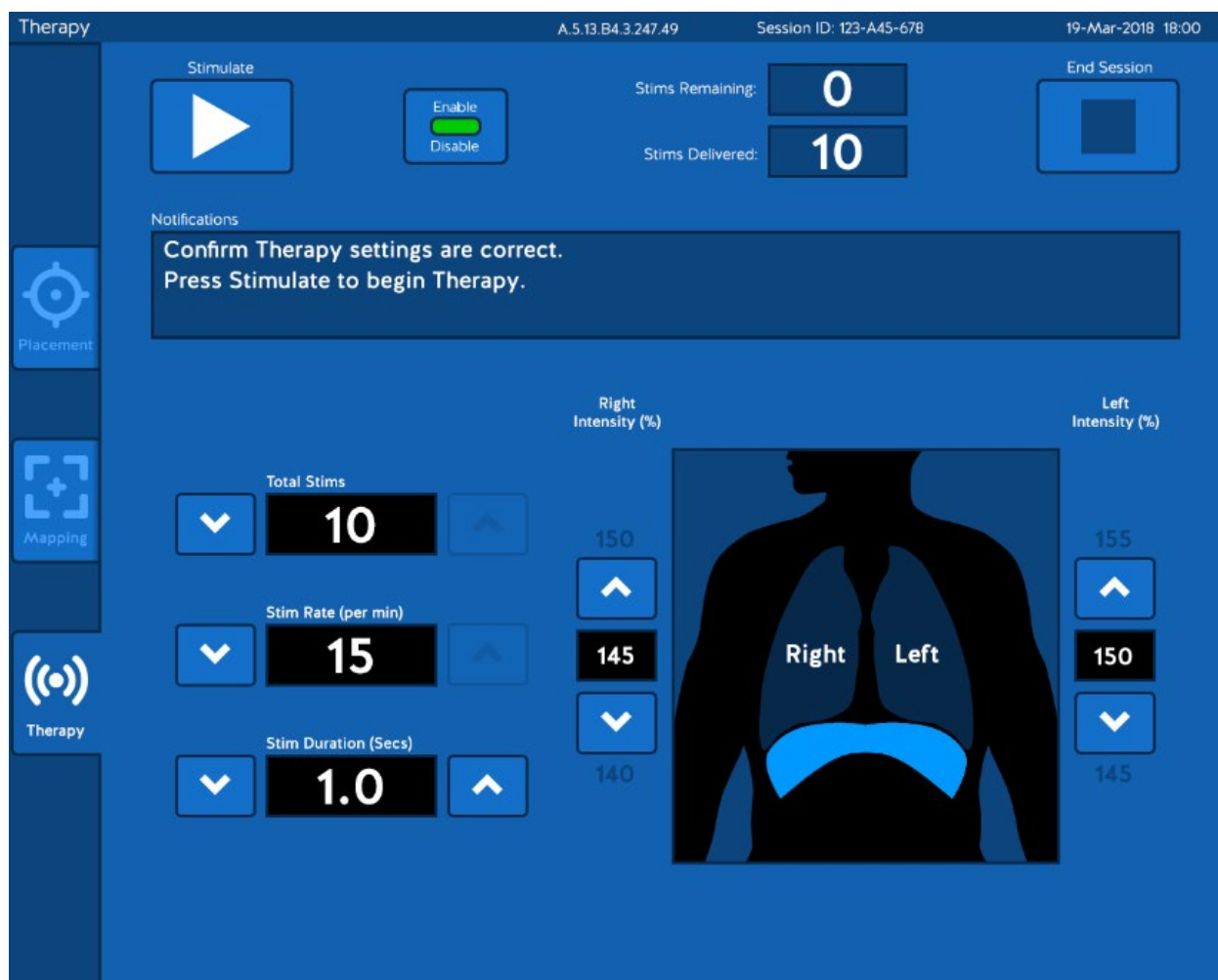
While each Stim is in progress, the **Therapy** screen looks like this:





In Multiple Stim configuration, between the end of one Stim and the start of the next Stim, the **Therapy** screen looks like this:




After the selected number of Stims have been delivered, the **Therapy** screen looks like this:




You can initiate another Stim (Single Stim) or sequence of Stims (Multiple Stim) by pressing the *Stimulate* () button, or by pressing the push-button on the Handheld Controller (), again.

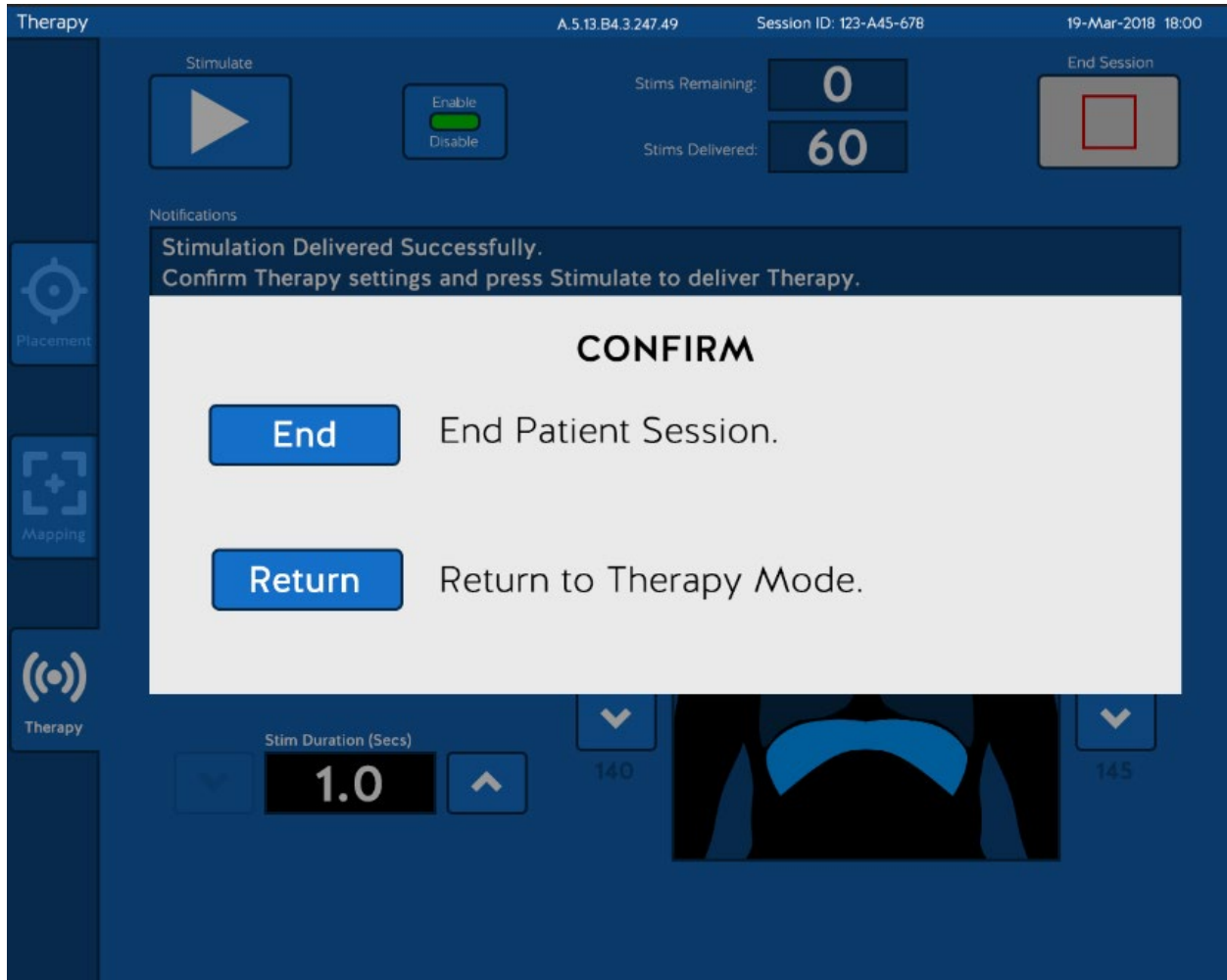
Note: Do not deliver another Therapy sequence until the appropriate rest period has expired.

You can adjust Therapy parameters, if desired, before starting another Therapy sequence.

Note: You cannot adjust Therapy parameters while a Therapy sequence is in progress. To adjust Therapy parameters, wait until the Therapy sequence is complete, or stop stimulation at any time by pressing the *Halt* button ().

Once the desired amount of Therapy stimulation has been delivered, wait for the duration of the rest period, and repeat steps 1-3 if another Therapy stimulation sequence is desired. The Stims Delivered counter will keep track of how many stims have been delivered in the session.

Once all Therapy stimulation sequences for the session have been delivered, you can end the session by pressing the *End Session* () button. The screen will appear as illustrated in the figure below.



Press *End* to end the session.

Press *Return* if you want to return to the session.

Patient Monitoring

- During Therapy delivery, palpate the diaphragm or observe the mechanical ventilator waveform to confirm that Stims cause diaphragm contractions; if not, repeat Mapping.
- During Therapy delivery, monitor for interactions of diaphragmatic stimulation with the mechanical ventilator operations.

Note:

The Lungpacer DPTS can be used with any form of Continuous or Spontaneous Ventilation, i.e., any ventilation mode that allows the patient to take spontaneous breaths.

Select a ventilation mode that allows for the patient to take spontaneous breaths of longer inspiration duration.

Deliver stimulation as quickly as possible during the inspiration period.

- During Therapy delivery monitor for patient tolerance.

Note:

Adjust Stim Intensity upward or downward by one or more steps during or between each set of Stims, depending on clinical judgement of patient tolerance.

When Stim Intensity adjusted is downward, repeat Mapping if unable to confirm that Stims cause diaphragm contractions.

- During Therapy delivery monitor for cardiac arrhythmias. Stop Therapy delivery if cardiac arrhythmia is observed.

Note:

If cardiac arrhythmia is detected that could be produced by the LIVE Catheter tip having entered the atrium, retract the catheter tip back into the SVC.

Shut down


When you are ready to shut down the DPTS, end the session and then turn off the LCU by pressing the **POWER** button on the LCU front panel. The green light next to the **POWER** button should turn off.


Recruitment Troubleshooting Guide

How to use this guide:

The information is separated into three columns, one column for each of the three situations in which non-recruitment might be seen.

1. If you are seeing no recruitment during **Placement (Left Side Only)**, follow the sequence of troubleshooting steps in the **left-hand column**.
2. If you are seeing no recruitment during **Left Side Mapping**, follow the sequence of troubleshooting steps in the **middle column**.
3. If you are seeing no recruitment during **Right Side Mapping**, follow the sequence of troubleshooting steps in the **right-hand column**.

1. Placement (Left Side Only)	2. Mapping (Left Side)	3. Mapping (Right Side)
1.1 Confirm that the LIVE Catheter is connected correctly to the LCU	2.1 Confirm that the LIVE Catheter is connected correctly to the LCU	3.1 Confirm that the LIVE Catheter is connected correctly to the LCU
<p>If there is a poor connection between the LCU and the electrodes in the LIVE Catheter, the LCU reports it by showing an exclamation point in a yellow circle , and the message "System unable to deliver desired current (maximum output reached)" in the Notifications field on the touchscreen.</p> <p>Check the connection from the Intermediate Cable to the LCU, and ensure the Intermediate Cable is fully engaged with the connector on the LCU.</p> <p>Check the connection from the Intermediate Cable to the LIVE Catheter, and ensure the Intermediate Cable is fully engaged with the connector on the LIVE Catheter.</p>		

1. Placement (Left Side Only)	2. Mapping (Left Side)	3. Mapping (Right Side)
1.2 Determine (without X-ray) whether the LIVE Catheter is correctly rotated	2.2 Determine (without X-ray) whether the LIVE Catheter is correctly rotated	3.2 Determine (without X-ray) whether the LIVE Catheter is correctly rotated
<p>Ensure that the Orientation Stripe is visible on top (180° from skin), and that the catheter hub (when it is not secured in place) is oriented to lie flat on the skin with the Lungpacer logo visible on top (see figure below).</p>  <p><i>LIVE Catheter Orientation Stripe and Hub with Lungpacer logo</i></p> <p>If the Orientation Stripe is not visible on top, you may choose to rotate the LIVE Catheter.</p> <p>Document the depth of the Catheter before manipulation to allow later determination whether it has been moved/pulled out/etc.</p>		
<p>To rotate the LIVE Catheter during the placement process, IF the sterile zone has not been compromised, and ONLY IF sterility can be maintained:</p> <p>Pull the catheter out over the guidewire, and advance the LIVE Catheter ensuring that the Orientation Stripe is visible on top during the entire Catheter insertion sequence. If the catheter is not pulled out sufficiently before re-inserting, rotation may not be effective. Incorrect positioning of the LIVE Catheter carries risks, which are detailed in the IFU and Clinical Protocol.</p>	<p>To rotate the LIVE Catheter when the sterile zone is no longer in place:</p> <p>Rotate the LIVE Catheter in the desired direction, making sure to NOT further advance the catheter. This will increase the risk of infection as sterility cannot be maintained.</p> <p>After rotation, the orientation stripe should be visible on top (180° from skin), and lie flat before the catheter has been secured in place.</p>	
<p>Document the depth of the Catheter after manipulation to allow later determination whether it has been moved/pulled out/etc.</p> <p>After catheter manipulation, placement should be re-assessed, in compliance with hospital/institutional practices or current guidelines.</p> <p>Placement assessment, in compliance with hospital/institutional practices or current guidelines, must show the LIVE Catheter tip located in 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. Incorrect positioning of the LIVE Catheter carries risks, which are detailed in the IFU and Clinical Protocol.</p>		




1. Placement (Left Side Only)	2. Mapping (Left Side)	3. Mapping (Right Side)
<p>1.3 Determine (without X-ray) whether the LIVE Catheter is inserted to the correct depth</p> <p>Confirm that, during the insertion process, the tip of the LIVE Catheter has been placed as deep as possible in the SVC without entering the right atrium.</p> <p>To change the insertion depth of the LIVE Catheter during the placement process, IF the sterile zone has not been compromised, and ONLY IF sterility can be maintained: advance or retract the catheter over the guidewire.</p> <p>Incorrect positioning of the LIVE Catheter carries risks, which are detailed in the IFU and Clinical Protocol.</p> <p>Document the depth of the Catheter after manipulation.</p>		
	<p>2.4 If Mapping or Placement has been successfully completed at least once before on the Left Side, or if recruitment was achieved during Placement: It is possible that the LIVE Catheter has shifted relative to the left phrenic nerve, subsequent to a previous session where recruitment was achieved</p>	<p>3.4 If Mapping has been successfully completed at least once before on the Right Side: It is possible that the LIVE Catheter has shifted relative to the right phrenic nerve, subsequent to a previous session where recruitment was achieved</p>
	<p>Determine whether the insertion depth of the LIVE Catheter has changed, by reviewing the insertion depth markings on the catheter shaft. If the LIVE Catheter has moved out, placement of the LIVE Catheter tip should be re-assessed, in compliance with hospital/institutional practices or current guidelines.</p>	



1. Placement (Left Side Only)	2. Mapping (Left Side)	3. Mapping (Right Side)
	<p>Placement assessment, in compliance with hospital/institutional practices or current guidelines, must show the catheter tip located in 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.</p> <p>If the LIVE Catheter tip is in the atrium, retract the Catheter so that the tip is no longer in the atrium.</p> <p>Document the depth of the Catheter before and after manipulation.</p> <p>Placement should be re-assessed, in compliance with hospital/institutional practices or current guidelines.</p> <p>Placement assessment, in compliance with hospital/institutional practices or current guidelines, must show the catheter tip located in 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.</p> <p>If the LIVE Catheter tip is placed in the upper SVC, consider removing the Catheter.</p> <p>If placement assessment shows that the LIVE Catheter tip is placed correctly, and if electrodes are rotated correctly and in proximity to the phrenic nerves, do not manipulate the catheter.</p>	



1. Placement (Left Side Only)	2. Mapping (Left Side)	3. Mapping (Right Side)
	2.5 If Mapping has been successfully completed at least once before on the Left Side, or if recruitment was achieved during Placement: Determine whether the patient is in the same position and posture as previous sessions where recruitment was achieved.	3.5 If Mapping has been successfully completed at least once before on the Right Side: Determine whether the patient is in the same position and posture as previous sessions where recruitment was achieved.
	Adjust the patient's position (posture, incline of the bed, pillow under a shoulder, make sure the patient is pulled up to the top of the bed so there is no bend in the torso, etc.) to be as similar as possible as previous sessions where recruitment was achieved.	

1. Placement (Left Side Only)	2. Mapping (Left Side)	3. Mapping (Right Side)
1.6 Determine whether the LIVE Catheter is placed correctly	2.6 Determine whether the LIVE Catheter is placed correctly	3.6 Determine whether the LIVE Catheter is placed correctly
<p>Placement assessment, in compliance with hospital/institutional practices or current guidelines, must show the LIVE Catheter tip located in 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. Incorrect positioning of the LIVE Catheter carries risks, which are detailed in the IFU and Clinical Protocol.</p> <p>Ideal placement should show the electrodes of the left array as six distinct pairs of rectangles. The electrodes of the left array should span across the left phrenic nerve, as illustrated in the figure below.</p> <p>Ideal placement should show the electrodes of the right array as a series of individual rectangles in a straight, dotted line. The electrodes of the right array should run parallel to the right phrenic nerve, along the wall of the SVC, as illustrated in the figure below.</p> 		



1. Placement (Left Side Only)	2. Mapping (Left Side)	3. Mapping (Right Side)
<p>1.6.1 If Catheter placement assessment shows that the LIVE Catheter tip is not fully advanced into the distal portion of the SVC</p>	<p>2.6.1 If the LIVE Catheter tip is not fully advanced into the distal portion of the SVC</p>	<p>3.6.1 If the LIVE Catheter tip is not fully advanced into the distal portion of the SVC</p>
<p>You may choose to advance the LIVE Catheter further. When considering whether to advance the LIVE Catheter further, to ensure the catheter tip is in the distal SVC lying parallel to the SVC vessel wall, remember that sterility must be maintained. If further advancement of the LIVE Catheter would compromise sterility, DO NOT advance the catheter.</p> <p>When advancing the LIVE Catheter, ensure that it is advanced over the wire to minimize the vessel wall abrasion.</p> <p>Ensure that the heart rate is not affected when the catheter is being advanced. If an atrial arrhythmia is detected that could be produced by the LIVE Catheter tip having entered the atrium, retract the catheter tip back into the SVC.</p> <p>Do not place the LIVE Catheter into or allow it to remain in the right atrium or right ventricle.</p> <p>Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it.</p> <p>Placement assessment must show the LIVE Catheter tip located in the right side of the mediastinum in the Superior Vena Cava (SVC) above its junction with the right atrium and <u>parallel to the vessel wall</u>, and its distal tip positioned at a level above either the azygous vein or the carina of the trachea, whichever is better visualized. Incorrect positioning of the LIVE Catheter carries risks, which are detailed in the IFU and Clinical Protocol.</p> <p>Consider removing the LIVE Catheter and replacing it over a wire with a different size LIVE Catheter unless there are anatomical reasons this cannot be done.</p>		



1. Placement (Left Side Only)	2. Mapping (Left Side)	3. Mapping (Right Side)
<p>Placement of the LIVE Catheter's electrodes in the atrium may result in cardiac arrhythmia.</p> <p>Placement of the LIVE Catheter's electrodes too close to the heart may result in cardiac arrhythmia.</p> <p>Document the depth of the Catheter before and after manipulation.</p> <p>Placement should be re-assessed, in compliance with hospital/institutional practices or current guidelines.</p>		



1. Placement (Left Side Only)	2. Mapping (Left Side)	3. Mapping (Right Side)
1.6.2 If the LIVE Catheter tip is advanced beyond the distal portion of the SVC	2.6.2 If the LIVE Catheter tip is advanced beyond the distal portion of the SVC	3.6.2 If the LIVE Catheter tip is advanced beyond the distal portion of the SVC
<p>Do not place the LIVE Catheter into or allow it to remain in the right atrium or right ventricle. Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it. Placement of the LIVE Catheter’s electrodes in the atrium may result in cardiac arrhythmia. Placement of the LIVE Catheter’s electrodes too close to the heart may result in cardiac arrhythmia. Retract the LIVE Catheter so that the catheter tip is not in the right atrium or the right ventricle. Document the depth of the Catheter before and after manipulation. Placement should be re-assessed, in compliance with hospital/institutional practices or current guidelines.</p>		



1. Placement (Left Side Only)	2. Mapping (Left Side)	3. Mapping (Right Side)
<p>1.6.3 If placement assessment shows non-ideal rotation of the electrodes of the left array: Rotate the LIVE Catheter to obtain ideal placement of the electrodes of the left array</p>	<p>2.6.3 If placement assessment shows non-ideal rotation of the electrodes of the left array: Rotate the LIVE Catheter to obtain ideal placement of the electrodes of the left array</p>	<p>3.6.3 If placement assessment shows non-ideal rotation of the electrodes of the right array: Rotate the LIVE Catheter to obtain ideal placement of the electrodes of the right array</p>
<p>Document the depth of the Catheter before manipulation to allow later determination whether it has been moved/pulled out/etc.</p>		
<p>To rotate the LIVE Catheter during the placement process, IF the sterile zone has not been compromised, and ONLY IF sterility can be maintained: Pull the catheter out over the guidewire, and advance it in the right orientation (Orientation Stripe visible on top). Incorrect positioning of the LIVE Catheter carries risks, which are detailed in the IFU and Clinical Protocol.</p>	<p>To rotate the LIVE Catheter when the sterile zone is no longer in place: Rotate the LIVE Catheter, making sure to NOT further advance the catheter. This will increase the risk of infection as sterility cannot be maintained. After rotation, the orientation stripe should be visible on top (180° from skin), and lie flat before the catheter has been secured in place.</p>	
<p>Document the depth of the Catheter after manipulation to allow later determination whether it has been moved/pulled out/etc. After catheter manipulation, placement should be re-assessed, in compliance with hospital/institutional practices or current guidelines. Placement assessment, in compliance with hospital/institutional practices or current guidelines, must show the LIVE Catheter tip located in 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. Incorrect positioning of the LIVE Catheter carries risks, which are detailed in the IFU and Clinical Protocol.</p>		



1. Placement (Left Side Only)	2. Mapping (Left Side)	3. Mapping (Right Side)
<p data-bbox="107 289 646 354">1.7 Determine whether the LIVE Catheter is inserted correctly at the access point</p> <p data-bbox="107 375 646 618">If the initial catheter insertion point is such that the LIVE Catheter enters the left subclavian vessel at a location that is not lateral to the left phrenic nerve, the electrodes of the left array may not be in the vein where the vein crosses the left phrenic nerve.</p> <p data-bbox="107 634 646 699">Recruitment on the right side may still be possible and pacing may be done unilaterally.</p>		



1. Placement (Left Side Only)	2. Mapping (Left Side)	3. Mapping (Right Side)
1.8 Determine whether the patient has anatomical abnormalities	2.8 Determine whether the patient has anatomical abnormalities⁶	3.8 Determine whether the patient has anatomical abnormalities¹
<p>The patient may have an abnormality of the anatomy (e.g. lung resection) or vasculature or left phrenic nerve that causes the electrodes of the left array to not be near the left phrenic nerve.</p> <p>Consider proceeding without the ability to obtain recruitment on the left. Unilateral right-sided therapy may still be possible.</p>	<p>The patient may have an abnormality of the anatomy (e.g. lung resection) or vasculature or left phrenic nerve that causes the electrodes of the left array to not be near the left phrenic nerve.</p> <p>Consider proceeding without the ability to obtain recruitment on the left. Unilateral right-sided therapy may still be possible.</p>	<p>The patient may have an abnormality of the anatomy (e.g. lung resection) or vasculature (e.g. left sided SVC) or right phrenic nerve that causes the electrodes of the right array to not be near the right phrenic nerve.</p> <p>Consider proceeding without the ability to obtain recruitment on the right. Unilateral left-sided therapy may still be possible.</p>

⁶ If the preceding troubleshooting steps have not resolved the observation of non-recruitment: **DO NOT** remove the LIVE Catheter unless the catheter tip is in the upper SVC; **DO NOT** retract the LIVE Catheter unless the tip is in the atrium or the ventricle. Contact Lungpacer for further troubleshooting assistance.



1. Placement (Left Side Only)	2. Mapping (Left Side)	3. Mapping (Right Side)
	2.9 If Mapping or Placement has been successfully completed at least once before on the Left Side.	3.9 If Mapping has been successfully completed at least once before on the Right Side.
	Reposition the patient and if still unsuccessful, consider performing a non-invasive EMG or nerve conduction study after all other possibilities have been evaluated.	Reposition the patient and if still unsuccessful, consider performing a non-invasive EMG or nerve conduction study after all other possibilities have been evaluated.

Tech Mode



Warning: Tech Mode is for authorized Lungpacer Medical personnel only!



Tech mode is accessible from the Start Screen. This mode is for authorized Lungpacer personnel only.

USB Receptacle



USB Receptacle (closed) –
LCU stimulation electronics enclosure right side



USB Receptacle (open) –
LCU stimulation electronics enclosure right side

Note: The USB Receptacle is for data export only




Warning: Do not attach any USB device to the DPTS other than a USB flash drive.

The USB Receptacle is used to data export to a USB flash drive via the Technical Mode Screen. The recommended size for the USB flash drive is at least 4GB.

When the USB Receptacle is not in use, close the USB Receptacle.

Notifications

The following notifications may appear during use.

Icon	Notification Text	Explanation
	System unable to deliver desired current (maximum output reached)	If this icon and message appear during Placement, Mapping, or Therapy, the LCU cannot deliver the intended stimulation current to the LIVE Catheter electrodes.

Message in Popup Box	Notification Text	Explanation
System Error - Shut Down System. Communication Error	Stimulation disabled. Shut Down System.	An internal error has occurred. To continue the session, you will have to shut down the LCU and restart it.
System Error - Shut Down System. Stimulation Output Error	Stimulation disabled. Shut Down System.	An internal error has occurred. To continue the session, you will have to shut down the LCU and restart it.
System Error - Shut Down System. Logging Error	Log write error. Shut Down System.	An internal error has occurred. To continue the session, you will have to shut down the LCU and restart it.
System Error - Shut Down System. Quick stop button pressed	Stimulation disabled. Shut Down System.	The quick stop button was pressed. To continue the session, you will have to shut down the LCU and restart it.
Controller Error – Replace Handheld Controller and Restart System	N/A	An error was detected on the handheld controller. To continue the session, you will have to replace the handheld controller and shut down the LCU, then restart it.

Maintenance

Disinfection Instructions

Before first use, and between patients, disinfect the Intermediate Cable, Lungpacer Control Unit, and Handheld Controller as follows:

Wipe down the Intermediate Cable, Lungpacer Control Unit (except the touchscreen), and Handheld Controller with a clean, soft, and lint free cloth. Only the following agents may be used:

- Virox*
- Cidex
- Alcohol*
- CaviWipes*

*Listed in the EPA-registered list of disinfectants for use against coronavirus, COVID-19. To view the list of EPA-registered disinfectant products, visit <https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>.

Wipe down the Lungpacer Control Unit touchscreen with a clean, soft, and lint free cloth. Only the following agents may be used:

- Window/glass cleaner



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



Warning: Do not disinfect, sterilize, or reuse single-patient use or disposable components.

Sterilized Parts

Refer to the LIVE Catheter Instructions For Use (IFU) for information on sterilization processes used on the LIVE Catheter and the steps to take in the event of damage to the sterile packaging.

Disposal

Refer to the LIVE Catheter Instructions For Use (IFU) for instructions regarding the removal and disposal of the LIVE Catheter.

The Intermediate Cable, Handheld Controller and Lungpacer Control Unit are to be returned to Lungpacer Medical Inc. after the duration of the emergency use authorization. Contact Lungpacer Medical Inc. using the contact details on the front page of this document.
























Installation and Service Procedures

Lungpacer recommends only qualified personnel perform DPTS installation, service, and maintenance procedures. Contact Lungpacer Medical Inc. using the contact details on the front page of this document for additional information.



Warning: Do not service the DTPS while the device is in use.

Symbol Glossary

	Caution		Serial number
	Warning		Batch code
	Consult instructions for use		Use by
	Keep dry		Do not re-use
	Keep away from sunlight		Sterilized using ethylene oxide
	Do not use if package is damaged		Do not re-sterilize
	Prescription only		Mass
	Type BF applied part		Fuse
	Manufacturer		Alternating current
	Date of manufacture		Equipotentiality
	Catalogue number		Protected against vertically falling water drops
			MR Unsafe

Specifications

Environmental Requirements

Temperature	Operating: 15 to 30 °C (59 to 86 °F) Storage: -20 to 60 °C (-4 to 140 °F)
Relative humidity	Operating: 30% to 90%, non-condensing Storage: 10% to 90%, non-condensing
Altitude	Up to 8000 ft (2438 m) above sea level.

Technical Data

Parameter	Specification
Power Input Rating	Voltage Range: 100 to 240 VAC Power Frequency: 50 to 60 Hz Max Current: 1.5 Amps
Water resistance	IPX1 Classification (some water drops that are falling vertically)

Output Characteristics

Output Characteristic	Device Output
Waveform Type	Charge balanced biphasic asymmetrical
Pulse Delivery Mode	Mapping: 1 burst of 3-24 pulses delivered on 1 to 12 electrode sets. Determined by algorithm. Therapy: 1 to 10 bursts of 1-18 pulses delivered on 1 electrode set per side. Determined by operator.
Pulse Durations	200 μ s – 300 μ s
Pulse Repetition Frequencies	Mapping: 4Hz frequency on the same electrode set for Mapping. Multiple electrode sets on the same side may be interleaved by algorithm. Therapy: 15 Hz for each side
Maximum Voltage	Current regulated 33V maximum
Maximum Current	13.5mA +/- 5% at 600 Ω (minimum impedance range) 6.5mA +/- 5% at 4000 Ω (typical impedance range) 3.0mA +/- 5% at 9000 Ω (maximum impedance range)
Net DC Current (mA) at maximum pulse rate	<100nA

Manufacturer's Declaration – Electromagnetic Compatibility (EMC)

The following accessories were used with the Lungpacer Control Unit (000-0026) in the evaluation of the Lungpacer DPTS:

Part Number	Description
000-0007	LIVE Catheter Kit, 19cm
000-0008	LIVE Catheter Kit, 21cm
000-0009	LIVE Catheter Kit, 23cm
000-0015	Intermediate Cable
000-0013	Handheld Controller

Use of other accessories may result in increased emissions or decreased immunity.

The Lungpacer DPTS should not be stacked with other equipment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Lungpacer DPTS is intended for use in the electromagnetic environment specified below. The customer or the user of the Lungpacer DPTS should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Lungpacer DPTS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	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.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Lungpacer DPTS is intended for use in the electromagnetic environment specified below. The customer or the user of the Lungpacer DPTS should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

WARNING: This equipment has not been tested for radiated RF immunity and use of nearby emitters at other frequencies could result in improper operation.