



# TransAeris™ System User Manual

**CAUTION:** Investigational device. Limited by Federal (or United States) law to investigational use.



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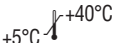
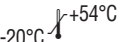



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# 1 Overview

## 1.1 ABOUT THIS MANUAL

This manual describes the features and functions of the Synapse Biomedical TransAeris™ System.

## 1.2 SYMBOLS

Explanation of symbols	
	The <i>Warning</i> symbol precedes warning information that mitigates a risk that is not obvious to the operator. Indicates that a potentially hazardous situation which, if not avoided, could result in harm to the operator or patient.  Powered equipment - indicates physiological effects not obvious to the user that can cause harm.
	The <i>Caution</i> symbol appears next to precautionary information when the intention is solely to inform. Indicates that a potentially hazardous situation which, if not avoided, may result in minor or moderate personal injury or property damage. This word is used to also alert against unsafe practices.
	The <i>Manufacturer</i> symbol appears next to the manufacturer's name and address.
	The <i>Reference</i> symbol appears preceding the part number for the device. The part number is a unique numeric identifier for the device.
	The <i>Lot</i> symbol appears preceding the lot number for a device. Devices manufactured at the same time using identical material and parts will share a common lot number.
	The <i>Serial Number</i> symbol appears on devices that require unique identification.
	The <i>Use Until</i> symbol appears on devices that have an indication of the date by which the device should be used. The date is expressed as the year and month, with the month referring to the end of the month.
	The <i>Manufactured Date</i> symbol appears on devices as an indication of the date of manufacture. The date is expressed as the year and month.
	The <i>Temperature Limits</i> symbol appears on actual devices as an indication of the operational temperature limits.
	The <i>Temperature Limits</i> symbol appears on packages of devices as an indication of the storage and transit temperature limits.
	The <i>Keep Dry</i> symbol appears on all packages of devices requiring to protect the packaging from potential damage.
	The <i>Don't Use If Packing Damaged</i> symbol appears on all packages of devices requiring to dispose of the device if the packaging has suffered damage.
	The <i>Accompanying Documents</i> symbol appears on all packages of devices indicating that instructions for use are available for additional information.

	The <i>Regulatory Marking of Conformity</i> symbol indicates that the device meets Medical Device Directive 93/42/EEC. This has been certified by notified body number 0086.
	The <i>European Community Representative</i> symbol indicates the identification of the authorized representative for the distribution of devices into the European community.
	The <i>Type BF Applied Part</i> symbol appears on powered equipment that connects directly to a patient. It is an indication of the degree of protection provided against electric shock, patient leakage current and patient auxiliary current.
	The <i>On/Off</i> symbol on powered equipment indicates push-button ON/OFF power control of the device.
	The <i>Consult Accompanying Documents</i> symbol appears on powered equipment indicating that instructions for use must be consulted for safety.
	The <i>Ingress Protection (IP)</i> Classification symbol appears on powered equipment indicating that the device is protected from water jets.
	Non-ionizing electromagnetic radiation.
	MR Unsafe. A device that is known to pose hazards in all MR environments.
	Notice of proper disposal.
	During NORMAL operation, the check mark will be displayed on the corresponding stimulating channels indicating stimulus delivered.
	During NORMAL operation, the exclamation mark will be displayed on the corresponding channels requiring attention to check lead connections.
	The HOME button used in conjunction with the Unlock button will temporarily stop stimulation and return the stimulator to Self-test mode.
	The UNLOCK button is an interlock button that requires to be pressed and held for any other function button to operate.
	The INCREASE button used in conjunction with the Unlock button allows the user to increase the selected parameter.
	The DECREASE button used in conjunction with the Unlock button allows the user to decrease the selected parameter.
	The channel pointer is displayed below the channels indicating that the channel has been selected for modification.
	ESD sensitive device.

## 1.3 GENERAL DESCRIPTION

TransAeris™ is a percutaneous intramuscular diaphragm stimulator for temporary use in the hospital setting. The system consists of implantable stimulating TransLoc® electrode leads, disposable/single-use FrictionLoc™ connectors, and a disposable/single-use portable external stimulator.

- The system has four stimulating, intramuscular TransLoc electrodes to be implanted into the diaphragm for motor point diaphragm stimulation.
- Two stimulating TransLoc electrodes shall be placed into each hemi-diaphragm.
- TransLoc electrodes are tunneled to two percutaneous exit sites on the respective lateral chest region.
- A single left and right FrictionLoc connector will provide an electrical interface from the TransLoc electrodes to a patient cable.
- The patient cable with left (blue) and right (green) identifiers is integrated into the TransAeris stimulator.
- TransAeris stimulator has a user interface for clinical control.

### 1.3.1 Safety Features

The TransAeris includes the following safety features:

- Self-test function
- Battery life indicator
- The display will indicate by counting down the number of days left that the TransAeris will function
- At the end of 30 days, the TransAeris will shut down immediately
- Lock feature to prevent accidental change of parameters
- Safe, two-step operation to turn off the TransAeris to avoid unintended shutdown
- Electrostatic protection
- Minimized susceptibility to electromagnetic and magnetic interference

### **1.3.2 Operating Features**

The TransAeris stimulator includes the following operating features:

- Easy-to-view parameter settings.
- Low battery indicator – indicates stimulator battery life.
- Four-channel operation – independent channels allow independent parameter settings and can be enabled/disabled.
- Unlock button – safeguards against unintentional parameter changes.
- Home screen – allows the stimulator to return to the self-test screen and disable stimulation.
- Intensity setting – allows the Stimulus parameters of Intensity to be programmed.
- Frequency setting – allows the Stimulus parameters of Frequency to be programmed.
- Cycle Rate setting – allows the Respiratory parameter (CPM) to be programmed.
- Cycle Time setting – allows the Respiratory parameter to be programmed.
- Burst setting – allows the Burst function to be enabled or disabled.

### **1.4 INTENDED USE**

TransAeris is a percutaneous intramuscular diaphragm stimulator intended for patients at risk of or on prolonged positive pressure mechanical ventilation. TransAeris is indicated for use in the prevention and treatment of ventilator-induced diaphragm dysfunction (VIDD).

### **1.5 PACKAGE CONTENTS**



The TransAeris Patient Kit is supplied with the following items:


- (1) One TransAeris Stimulator with Patient cable
- (2) Two FrictionLoc connectors
- (2) Pair Surface Patch Electrodes (4 total surface patches)

### **1.6 CONTRAINDICATIONS**

- None

## 2 Warnings

- 2.1 Use only under the direction of a physician. The TransAeris stimulator is electrically powered and may produce tissue damage or electrical hazard if improperly used.
- The device has accessible controls for clinical staff and NO patient-accessible controls.
  - Do NOT attempt to open the TransAeris stimulator case or attempt any unintended modifications as this will cause a failure in the TransAeris stimulator functionality.
- 2.2 Use of TransAeris could interfere with some medical equipment. Some medical equipment could interfere with the use of TransAeris. Consult the this User Manual before having any of the following:
- **Implanted cardiac pacemaker or defibrillator.** Use of the TransAeris stimulator may interfere with these devices.
  - **Surgery.** Use of high-frequency surgical equipment may cause burns where the electrode leads pass through the skin. Such equipment may damage the TransAeris stimulator. Disconnect the TransAeris stimulator when high-frequency surgical equipment is in use.
  - **Magnetic Resonance Imaging (MRI) test.**  The TransLoc electrode is MR unsafe. Do not perform a MRI test while implanted with the TransLoc electrodes or remove the TransLoc electrodes from the patient before a MRI test.
  - **Magnetic Resonance Imaging (MRI) test.**  The TransAeris stimulator, FrictionLoc connector, and surface electrode are MRI Unsafe. Remove these components from the patient before a MRI test.
  - **Use of external electrical stimulation such as transcutaneous electrical nerve stimulation (TENS)** should not be done in the chest area near the electrode leads. Unwanted diaphragm contraction could occur.
- 2.3 Clinicians should avoid accidental contact between connected but unused applied parts (cable or leads) and other conductive parts including those connected to earth ground or any device with the ground symbol.

- 2.4 Safety has not been established for the use of the device during pregnancy.
- 2.5 Safety has not been established for the use in patients with epilepsy.
- 2.6 **Cardiac interference.** Before conditioning, test interference with cardiac rhythm. Monitor electrocardiogram (ECG) while stimulating at maximal settings. If interference is observed, decrease stimulation settings below level of interaction, turn off identified electrodes, or remove identified electrodes.
- 2.7 Do NOT come in contact with TransLoc electrodes during emergency defibrillation. It may lead to electric shock to caregivers.
- 2.8 **ELECTROMAGNETIC INTERFERENCE WARNING:** Some electrically powered equipment gives off electromagnetic waves which could interfere with TransAeris systems. When using your TransAeris system around electrical equipment, check the TransAeris stimulator screen to make sure the TransAeris system is working.
- 2.9 Do follow the electromagnetic compatibility (EMC) information provided. The TransAeris stimulator needs special precautions regarding EMC. To reduce the possibility of interference on the TransAeris stimulator from other electrical equipment or the TransAeris stimulator effecting other electrical equipment, do not use cables or accessories with the TransAeris stimulator other than those specified.
- 2.10 **RF COMMUNICATION WARNING:** Portable and mobile RF communication equipment may affect medical electrical equipment. Ensure proper function of TransAeris when using around such equipment.
- 2.11 **ELECTRO-STATIC DISCHARGE (ESD):**  After the TransLoc electrode has been implanted but not connected to the FrictionLoc connector, use caution when handling the electrode leads. Before touching the electrode leads, touch the patient to equalize the electrostatic potential.
- 2.12 **FLAMMABILITY WARNING:** Do NOT use TransAeris system in an oxygen enriched environment, such as a hyperbaric oxygen chamber, or near a flammable anesthetic mixture with air, oxygen, or nitrous oxide. This could cause a fire or explosion.

## 3 Precautions

The TransAeris stimulator has been carefully designed and tested to ensure reliability during normal use. However, electronic devices are susceptible to stresses. To avoid damage to the TransAeris stimulator, observe the following precautions:

### 3.1 RANDOM FAILURES –

The physician should be aware that operational failure of the TransAeris stimulator can occur as the result of battery depletion, mishandling, or random component failure.

Possible operational failures of the TransAeris stimulator can include the following:

- No output or erratic output
- No sensing or erratic sensing (e.g. during self-testing)
- False indicator signals
- Inappropriate variance of rate and output intensity
- Loss of control of rate, output, intensity, or power

If loss of control of rate, output, intensity, or power occurs, and it is not due to a low battery, disconnect the TransAeris stimulator from the patient, contact Synapse Biomedical Customer Service to return it for evaluation.

- 3.2** Service condition – Before each use, evaluate the TransAeris stimulator for damage and observable defects. Do not use the TransAeris stimulator if the case is cracked, the controls are not functioning, the displays are not working, or if the controls, displays, or connectors are broken.
- 3.3** The TransAeris stimulus artifact may be seen on monitored bio-potential signals such as continuous ECG monitoring.
- 3.4** The TransAeris stimulator is designed for single-patient use. Dispose of the device when finished using on a patient. Do NOT reuse. Reuse may lead to transmission of infection.
- 3.5** TransLoc leads, FrictionLoc™ connectors, and cables – Improper connection or fracture of leads or cables may result in failure of the TransAeris stimulator. Inspect exiting electrode leads and cables for damage before use.
- 3.6** To avoid patient entanglement with the cable, keep TransAeris close to the patient at all times when in use.
- 3.7** If you think the device is not providing enough stimulation, then consult this manual or call Synapse Biomedical Customer Service. This could mean that the TransAeris may not cause the patient's diaphragm to contract.

## 4 Environmental Precautions

The TransAeris stimulator has been carefully designed and tested to ensure reliability during normal use. However, electronic devices are susceptible to many environmental stresses. To avoid damage to the TransAeris stimulator, observe the following precautions:

- 4.1 Do not expose the stimulator to excessive moisture, heat or severe mechanical shock. If display indicates system failure or device exposed to excessive moisture, heat or shock, disconnect the TransAeris stimulator and contact Synapse Biomedical Customer Service.
- 4.2 To protect the TransAeris against damage due to mechanical shock. Do NOT drop the TransAeris. The TransAeris may break and not be available for use when needed. The TransAeris stimulator should remain in the plastic packaging until needed.
- 4.3 To protect the TransAeris against damage due to moisture, Do NOT submerge the TransAeris in liquid. The TransAeris may quit working and not able to use when needed.
- 4.4 Avoid contaminating the patient cable connections with blood or other body fluids.
- 4.5 Do not attempt to open the TransAeris. The TransAeris is sealed at the factory and opening the TransAeris will damage the device and void the warranty.

Other environmental factors may impact proper performance of the TransAeris in the hospital setting. Use of appropriate environmental health and safety practices will help prevent environmental damage to the TransAeris.



## 5 Possible Adverse Effects

Possible adverse effects from the use of TransAeris system may include:

- Cardiac interaction
- Lead breakage
- Unretrieved device fragment
- Electrode dislodgement
- Skin infection
- Skin sensitivity due to adhesive
- Pain or discomfort due to stimulation

## 6 First Time TransAeris Startup

The TransAeris stimulator will operate for 30 days of consecutive use commencing from when stimulation first starts. The initiation starts by pressing and holding the unlock button and pressing “1” on the Self-Test screen the **first** time turned on.

- 6.1 When the TransAeris system has been received and opened from the shipping tray, the power can be turned on by pressing and holding the  Unlock button and pressing the  power button.
- 6.2 The startup screen will be displayed and the user is prompted with the option to proceed to enable the consecutive day counter.

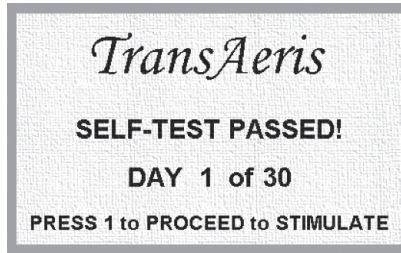


Figure 1 – TransAeris Initial Startup Screen

- 6.3 The user can power off the TransAeris stimulator and not start the 30 day consecutive counter or press and hold the Unlock button and press “1” to continue.

**NOTE:** Enabling the consecutive-day counter will enable the TransAeris stimulator operation not to exceed 30 consecutive days of use and it is **IRREVERSIBLE**.

- 6.4 Once the consecutive day counter operation is initiated, the following is displayed showing the day number in the 30 day cycle.

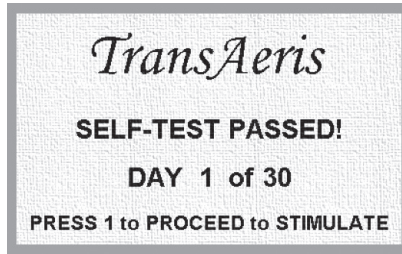


Figure 2 – TransAeris Startup screen after 30 day counter initiated

- 6.5 When the user proceeds, the TransAeris will display the stimulus status display and allow the user to program the parameters (Refer to Section 9).
- 6.6 Upon completion of the 30-day operating interval. The stimulator displays to dispose of the device properly.

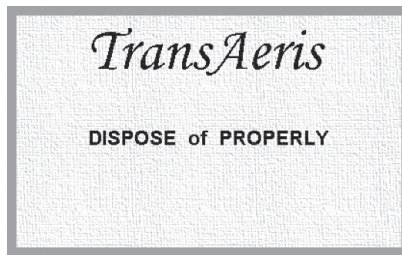


Figure 3 – TransAeris Operation Expired display (Dispose of Properly)

- 6.7 Once the operation has expired, please dispose the device per hospital solid waste disposal procedures.

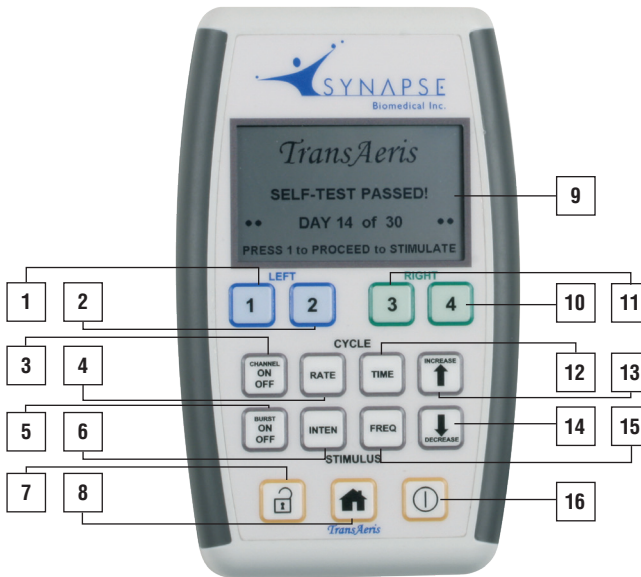
# 7 Controls and Displays

## 7.1 CONTROL BUTTONS

The buttons used to control the functions and parameter settings of the TransAeris stimulator are described in this section.

### 7.1.1 TransAeris Stimulator Controls

The TransAeris stimulator control buttons are easy to use and conveniently located to program the parameters for each patient's requirements.



1	Channel 1	9	Display
2	Channel 2	10	Channel 4
3	Channel On/Off	11	Channel 3
4	Cycle Rate	12	Cycle Time
5	Burst On/Off	13	Increase
6	Stimulus Intensity	14	Decrease
7	Unlock Button	15	Frequency
8	Home Button	16	Power On/Off

Figure 4 – Control Buttons for TransAeris

### 7.1.2 Unlock Button

This button is the interlock function for any other button to function. This button must be pressed and held to allow access to any other function.



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### 7.1.3 Power ON/OFF button

In conjunction with the Unlock Button, this button allows the power to be turned on and off.



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### 7.1.4 Channel 1 Button (color coded blue)

In conjunction with the Unlock Button, this button allows Channel 1 selection for the Intensity parameter and for enable/disable of channel.



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### 7.1.5 Channel 2 Button (color coded blue)

In conjunction with the Unlock Button, this button allows Channel 2 selection for the Intensity parameter and for enable/disable of channel.



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### 7.1.6 Channel 3 Button (Color coded green)

In conjunction with the Unlock Button, this button allows Channel 3 selection for the Intensity parameter and for enable/disable of channel.



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### 7.1.7 Channel 4 Button (Color coded green)

In conjunction with the Unlock Button, this button allows Channel 4 selection for the Intensity parameter and for enable/disable of channel.



---

### 7.1.8 Cycle Buttons

In conjunction with the Unlock Button, these buttons allow the Cycle Rate parameters and Cycle Time parameters to be modified.



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### 7.1.9 Stimulus Buttons

In conjunction with the Unlock Button, these buttons allow the Stimulus parameters of Intensity and Frequency to be modified.



### 7.1.10 Parameter Adjustment Buttons

In conjunction with the Unlock Button, these buttons allow the chosen parameters to be increased or decreased.



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### 7.1.11 Channel ON/OFF Button

In conjunction with the Unlock Button, this button allows the user to enable and disable individual channels.



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### 7.1.12 Burst ON/OFF Button

In conjunction with the Unlock Button, this button allows the Burst function to be enabled or disabled. Pulse Burst stimulation may be used to overcome a patient's reported stimulation discomfort when other adjustments have proven unsuccessful.



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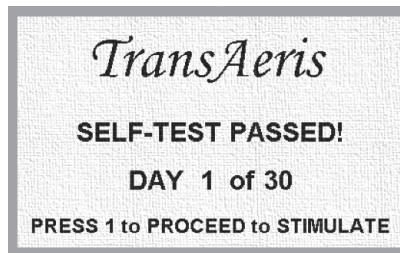
### 7.1.13 Home Button

In conjunction with the Unlock Button, this button allows the display to return to the self-test screen and disable stimulation.



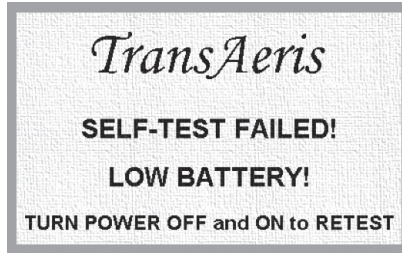
## 7.2 DISPLAY

When the TransAeris stimulator turns on, the following occurs: a self-test is initiated to test the battery, test the status of the control buttons and for data errors. When the self-test completes successfully, the following will be displayed.



If the self-test is not successful, the TransAeris will display any of three error displays. Re-cycle the power to clear the errors. If the errors do not clear, call Synapse Biomedical Customer Service for assistance.

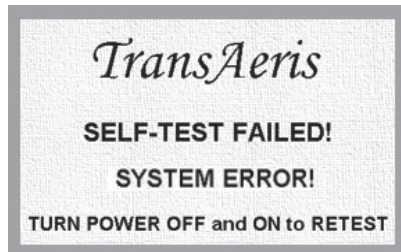
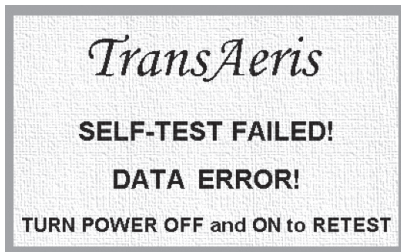
“**LOW BATTERY**” indicating the TransAeris is approaching the end of its service life.



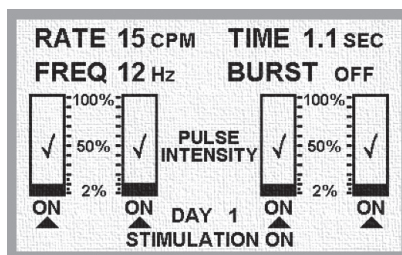
“**KEYPAD ERROR**” indicating a failure when the control buttons are non-responsive.



“**DATA ERROR!**” and “**SYSTEM ERROR!**” indicating a failure with the programmed data or firmware.



After the self-test completes successfully, press the Unlock button and “1”, then the TransAeris will display stimulus status.



# 8 Preparation for Use

## 8.1 CHECKS PRIOR TO USE

### 8.1.1 Service Condition

Visually inspect the TransAeris and FrictionLoc connectors before each use for a patient to verify that there are no observable defects. Do not use the TransAeris and FrictionLoc connectors if there are any observable defects. Verify that the TransAeris controls function each time before connecting to a patient.

**Caution:** Before each use, evaluate the TransAeris for damage and observable defects. Do not use the TransAeris if the case is cracked, the controls are not functioning, the display is not working, or if the controls, displays, or connectors are broken.

## 8.2 PHYSICAL FEATURES

### 8.2.1 Battery Powered

Battery life – The battery life is a maximum of 30 days of consecutive use.

### 8.2.2 Patient Cable

The patient cable is integral to the TransAeris and terminates in color coded keyed connectors (Left side of patient = Blue and Right side of patient = Green) that connect to the FrictionLoc color coded keyed connectors.

### 8.2.3 FrictionLoc Connector

The FrictionLoc connector is the interface between the percutaneous electrodes and the patient cable. The FrictionLoc connector cables are color coded and keyed. (Left side of patient = Blue and Right side of patient = Green). The percutaneous electrodes can be connected and disconnected with the release button.

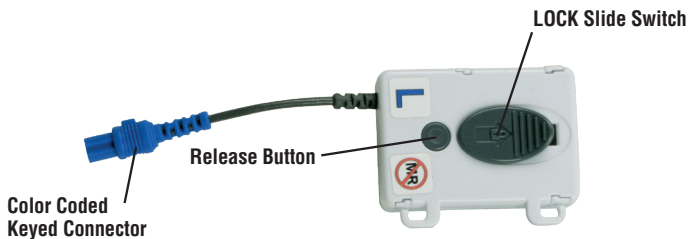


Figure 5 – FrictionLoc connector (Left side of patient = Blue connector, Right side of patient = Green connector)

## 8.2.4 Surface Electrode



Figure 6 – TransAeris Surface Electrode

### Application

- Clean and dry the skin at the prescribed area thoroughly prior to application of surface electrodes.
- The surface electrodes shall be snapped to the FrictionLoc connectors then removed from the protective liner then firmly applied to the patient. Store the protective liner in the surface electrode package.

### Removal

- When removal is required, lift the edge of surface electrode and peel towards the surface electrode.
- To reuse the surface electrode, place the surface electrode back onto the protective liner's "ON" side.

### Care and Storage

- Between uses, store the surface electrodes in the surface electrode package in a cool dry place.
- It may be helpful to improve repeated application by spreading a few drops of water over the adhesive and turn the surface up to air dry. Over saturation with water will reduce the adhesive properties.

### Very Important!

- Do not apply to broken skin.
- The surface electrodes should be discarded when they are no longer adhering.
- The surface electrodes are intended for single patient use only.

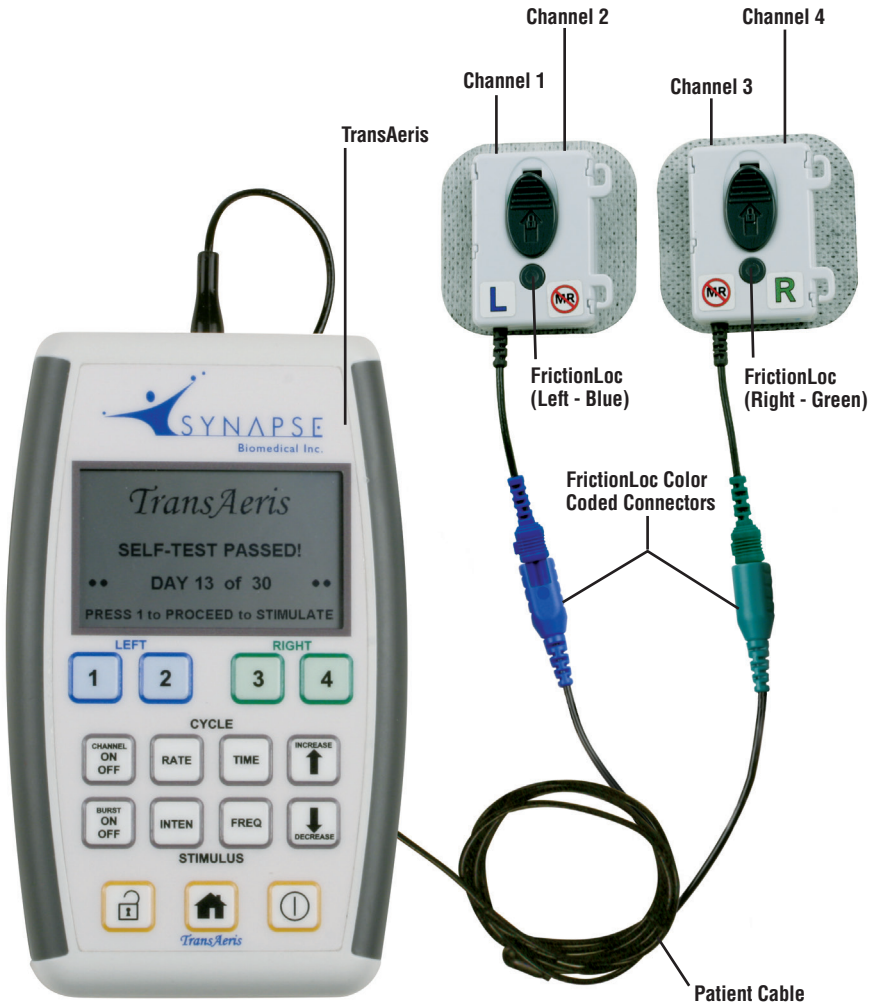


Figure 7 – TransAeris Patient cable FrictionLoc connection with Channel Designators

## 8.2.5 TransLoc Electrode

### TransLoc Electrode Preparation (Surgical)

- After the TransLoc electrodes have been implanted into the diaphragm and tunneled through the skin, the proximal end of the electrode requires preparation before it can be connected to the FrictionLoc connector.
- The suture between the tunneling needle and the conductive pin must be cut.

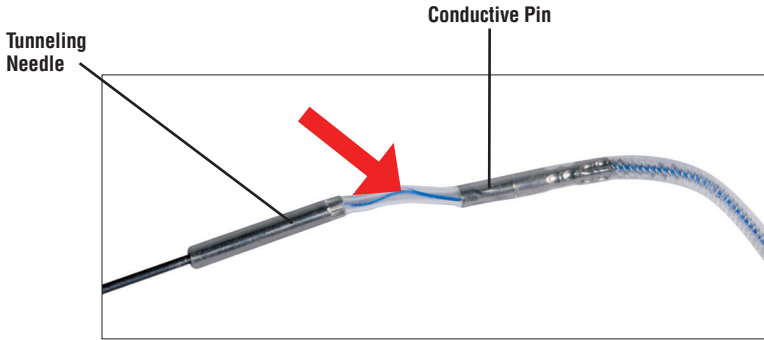


Figure 8 – TransLoc Proximal End with Tunneling Needle

- Cut the suture approximately half way between the tunneling needle and the conductive pin, leaving the silicon protective tube covering the conductive pin.
- The silicon protective tube will remain on the conductive pin until it is ready to use in the ICU.

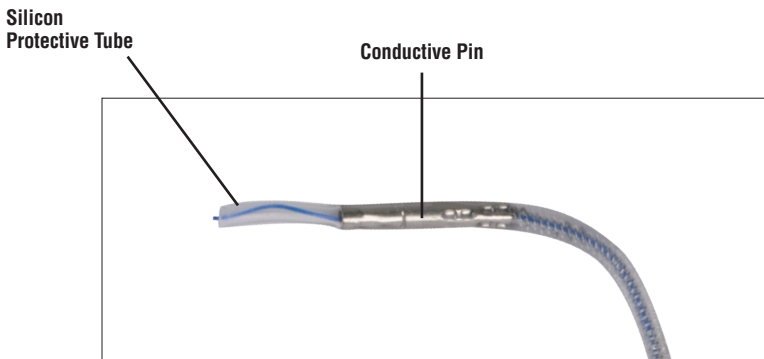


Figure 9 – TransLoc Proximal End Conductive Pin with Silicon Protective Tube

## 8.3 SYSTEM CONNECTION

**WARNING:** Confirm that the power is OFF on the TransAeris before connecting the patient cable and FrictionLoc connectors.

The following is the recommended procedure to connect the TransAeris system:

### 8.3.1 TransLoc electrode connection preparation (Intensive Care Unit)

Confirm that proximal end of the TransLoc electrode is similar to Figure 10.

- The silicon protective tube should remain on the conductive pin until it is ready to use in the ICU.
- If the silicon protective tube has been removed and the suture has been trimmed from the conductive pin, proceed to section **8.3.2**.

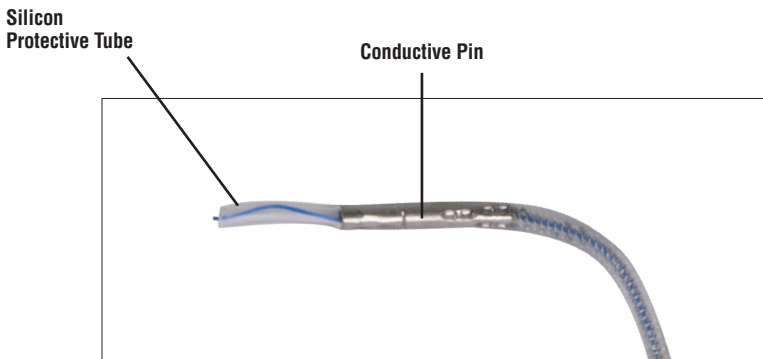


Figure 10 – TransLoc Proximal End Conductive Pin with Silicon Protective Tube

- When the TransLoc electrode is ready to be inserted into the FrictionLoc connector, remove the silicon protective tube.
- The conductive pin will now be exposed.

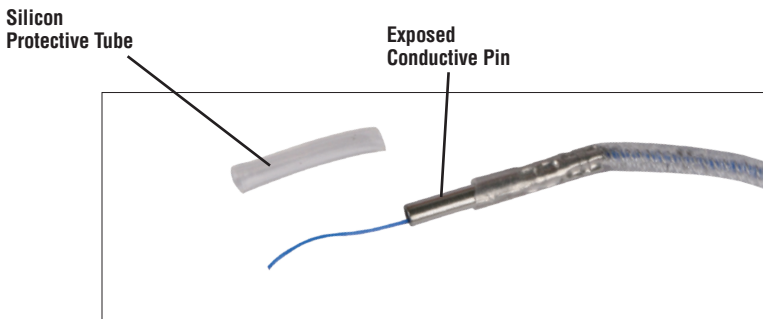


Figure 11 – TransLoc Proximal End Conductive Pin Exposed

- The suture must be trimmed to fit properly into the FrictionLoc connector.
- Cut the suture as flush as possible to the end of the conductive pin.

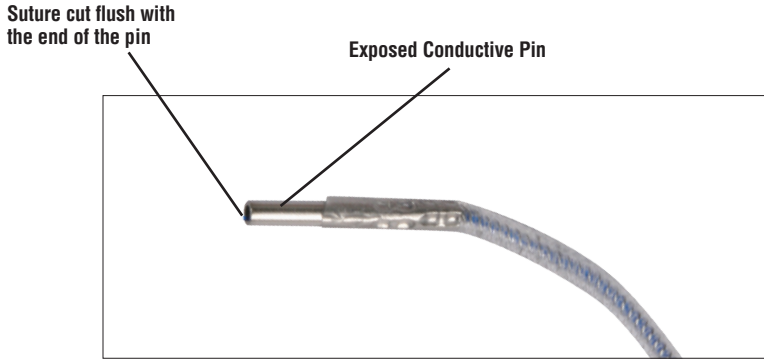


Figure 12 – TransLoc Proximal End Ready to Use

The TransLoc electrode is ready to be inserted into the FrictionLoc connector.

### 8.3.2 FrictionLoc Location on the Patient

Place the FrictionLoc connectors in close proximity to the TransLoc electrode exit site.

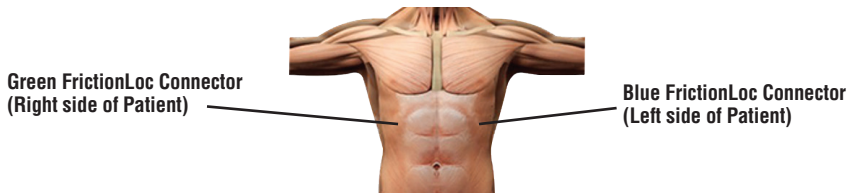


Figure 13 – Position of FrictionLoc connector with surface electrode

### 8.3.3 FrictionLoc Connector and Percutaneous TransLoc Electrodes

To connect the percutaneous TransLoc electrodes to the FrictionLoc connector, do the following:

- Remove the FrictionLoc connectors from the packaging.
- Remove two (2) surface electrodes from the packaging.
- Snap the surface electrodes to the FrictionLoc connectors.

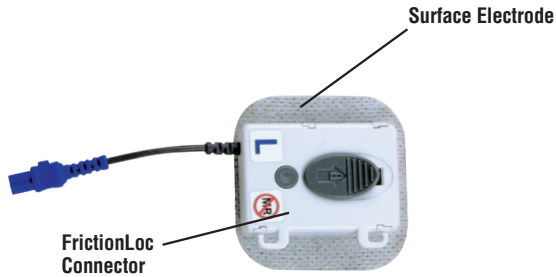


Figure 14 - FrictionLoc Connector with Surface Electrode

- (The blue connector will be placed on the LEFT side of the patient and the green connector will be placed on the RIGHT side of the patient.)
- Confirm that the LOCK slide switch to the left, as shown in Figure 16 to the Unlock position.



Figure 15 - FrictionLoc Connector

Insert each of the two electrodes into each of the two electrode inputs in the FrictionLoc connector until it stops.



Figure 16 – Electrode Insertion

- Slide the LOCK switch to the right, as shown in Figure 17 until it clicks.
- Excess electrode length may be looped in a figure 8 pattern around FrictionLoc hooks.

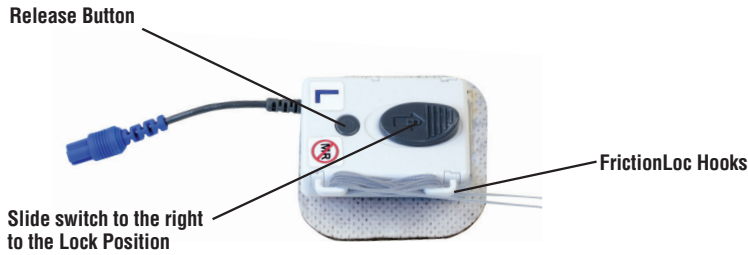


Figure 17 - FrictionLoc connector

- Gently pull on the electrodes to confirm they are locked into the connector.
- If an electrode pulls out, press the release button behind the slide switch and slide the switch back to the unlock position and repeat the process.
- Remove the adhesive backing of the surface electrode and place it on the patient in close proximity to the percutaneous electrode exit side. (Blue = Left side of the patient, Green = Right side of the patient)

### 8.3.4 Patient Cable and FrictionLoc Connector

To connect the patient cable to the FrictionLoc connector, do the following:

- Remove the TransAeris stimulator with integral patient cable from the packaging.
- Connect the color coded keyed connectors from the patient cable to the color coded mating keyed connector from the FrictionLoc connectors.

### 8.3.5 Disconnecting the TransAeris System

To disconnect the cables from the TransAeris stimulator, do the following:

- Confirm that the power is OFF on the TransAeris.
- Disconnect the color coded keyed connectors from the patient cable and FrictionLoc connectors.
- If the patient will not be using the TransAeris system anymore, dispose the TransAeris system. DO NOT reuse.
- If the patient will be using the TransAeris system again, place the TransAeris stimulator in a safe place where it will not be dropped or damaged.
- If the patient will be having a medical procedure that requires the FrictionLoc connectors to be removed, press the release button and slide the switch back to the unlock position.
- Remove the surface electrodes from the patient.
- Dress the TransLoc electrodes appropriately for the medical procedure.

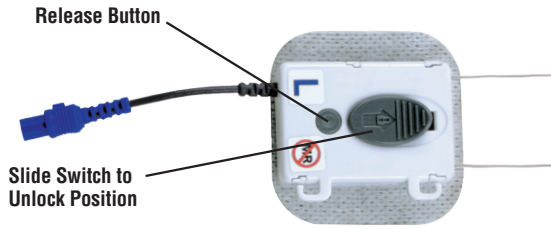


Figure 18 - Unlock FrictionLoc connector

- Remove the percutaneous electrodes from the FrictionLoc connector.
- Remove the FrictionLoc connector from the surface electrode.
- Dress the percutaneous electrodes appropriately. Coil the electrodes, cover the exposed leads and keep them close to the body so they do not get caught on anything.

## 8.4 PLACEMENT DURING USE

When the TransAeris is in use, place it in an area that reduces potential unauthorized access from patient interaction or tampering by non-medical personnel.

- Verify that the stimulator is directly observable by medical staff.

### 8.4.1 Cleaning Prior to Use

During normal use, the TransAeris stimulator and cables may become soiled with blood or body fluids. Verify that the TransAeris stays clean during use per hospital facility procedure. Please refer to section 14.1 of this manual for cleaning instructions.

## 9 Instructions for Use

The TransAeris system is indicated for use in the prevention and treatment of ventilator-induced diaphragm dysfunction (VIDD). The clinician should adjust intensity and/or frequency parameters until sufficient to cause diaphragm contraction for both left and right hemi-diaphragms.

### Default Settings

The TransAeris Stimulator will have a default setting from the factory. Please adjust the setting per patient requirements.

Stimulus Intensity	2%
Stimulus Frequency	12 Hz
Cycle Time	1.1 Seconds
Cycle Rate	15 Cycles per minute (CPM)
Burst	Off
Channels Enabled	All 4 channels enabled
Channel Selector Indicator	All 4 channels pre-selected for modification

During Normal operation when the TransAeris is stimulating, the status bar will display “STIMULATION ON”. When the TransAeris is not stimulating, it will display the number of days remaining in its service life.

### 9.1 BASIC OPERATION

The  Unlock button must be pressed and held for any other function buttons to operate.

#### 9.1.1 Turning On or Turning Off the TransAeris Stimulator

To turn on the TransAeris stimulator:

- **Press and hold** the Unlock button then press the Power button until the display turns on.



When the TransAeris turns on, the following occurs: a self-test is initiated to test for the presence of the electrodes, test the battery and status of the control buttons.

- When the self-test completes successfully, it will display “SELF TEST PASSED”.
- **Press and hold** the Unlock button then press the “1” button to continue to the TransAeris electrode status.

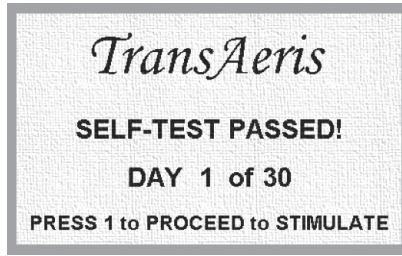


Figure 19 – TransAeris Stimulator power on

To turn off the TransAeris stimulator:

- **Press and hold** the Unlock button then press the Power button until the display turns off.

### 9.1.2 Channel Select

To select any channels to turn on/off or make parameter adjustments:

- **Press and hold** the Unlock button then press the channel number desired to turn on/off or make parameter adjustments.
- When the channel is selected, a triangle ▲ will appear below the channel:

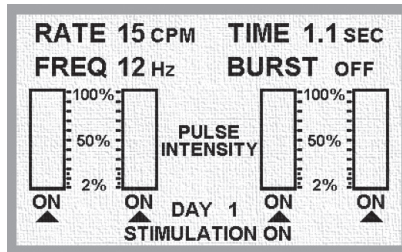


Figure 20 – TransAeris Channel Select

### 9.1.3 INTENsity Function

To adjust or modify the stimulus intensity:

- **Press and hold** the Unlock button then press the 1, 2, 3, or 4 button to choose one or more channels to modify.
- **Press and hold** the Unlock button then press the INTEN button; “PULSE INTENSITY” will be underlined to show it is enabled.
- **Press and hold** the Unlock button then press the increase or decrease to the desired setting.

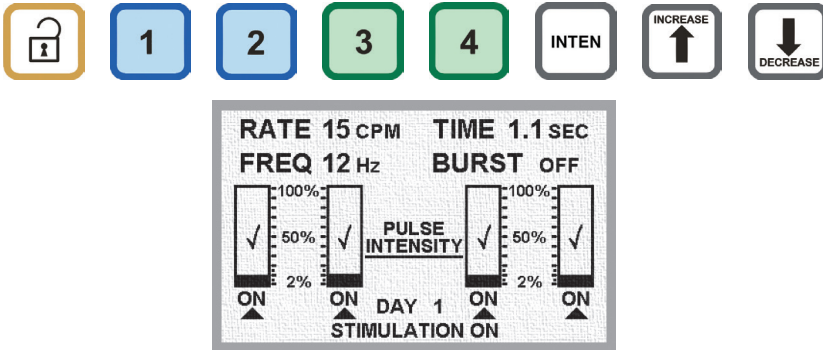


Figure 21 – TransAeris Intensity Function

### 9.1.4 FREQuency Function

To adjust or modify the stimulus frequency of the output of the stimulator:

- **Press and hold** the Unlock button then press the FREQ button; “FREQ” will be underlined to show it is enabled.
- **Press and hold** the Unlock button then press the increase or decrease to the desired setting.

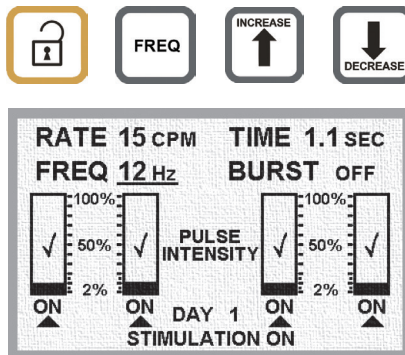


Figure 22 – TransAeris Frequency Function

### 9.1.5 Cycle TIME Function

To adjust or modify the cycle time that stimulation is on to the diaphragm:

- **Press and hold** the Unlock button then press the TIME button; “TIME” will be underlined to show it is enabled.
- **Press and hold** the Unlock button then press the increase or decrease to the desired setting.

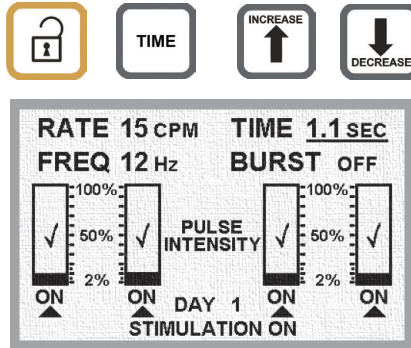


Figure 23 – TransAeris Time Function

### 9.1.6 Cycle RATE Function

To adjust or modify the cycle rate that the stimulation is presented to the diaphragm:

- **Press and hold** the Unlock button then press the RATE button; “RATE” will be underlined to show it is enabled.
- **Press and hold** the Unlock button then press the increase or decrease to the desired setting.

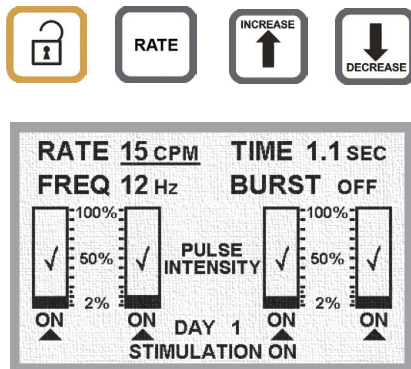


Figure 24 – TransAeris Rate Function

### 9.1.7 CHANNEL ON/OFF Function

To enable or disable the Channels:

- **Press and hold** the Unlock button then press the CHANNEL ON/OFF button.



### 9.1.8 BURST ON/OFF Function

To enable or disable the Burst Mode: (effective for all channels not individual channels)

- **Press and hold** the Unlock button then press the BURST ON/OFF button.



### 9.1.9 HOME Function

To disable stimulation:

- **Press and hold** the Unlock button then press the HOME button.
- This will stop stimulation and go back to the SELF TEST display.

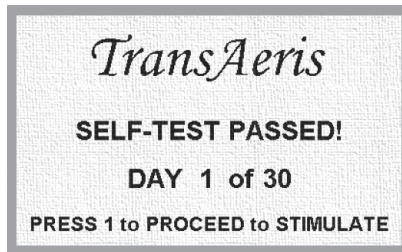


Figure 25 – TransAeris HOME Function

For any questions or concerns regarding program settings or modifications, please contact the Synapse Biomedical representative at the number provided.

# 10 Cardiac Interaction Monitoring

## 10.1 PRIOR TO START OF CONDITIONING, CARDIAC INTERACTION Monitoring must be Available.

- Be sure that the patient is connected to a cardiac monitor prior to commencing stimulation or whenever stimulus intensity changes are made
- As stimulus intensity is increased observe the cardiac rhythm for any interaction
- If cardiac interaction is noted, reduce the stimulus intensity on the channels that are causing the interaction until the interaction is eliminated or disable the channel if necessary
- Record the interaction as an adverse event on the case report form

# 11 Errors During Normal USE

## 11.1 ERROR DISPLAYS

**Low Battery** - This error displays a low battery error during operation.

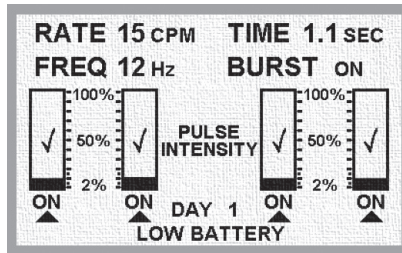


Figure 26 – TransAeris LOW BATTERY Error

**Electrode Error** - This error displays the TransLoc electrode is in need of attention during operation. The continuity is broken in one or more TransLoc electrodes or the surface electrode is detached.

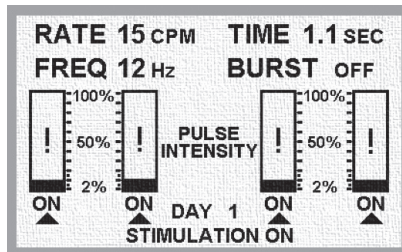


Figure 27 – TransAeris TransLoc Electrode Error

## 12 Caution During Normal USE

### 12.1 CAUTION DISPLAYS

- All stimulus channels off - This display indicates when all the channels are turned OFF supplying no stimulation.

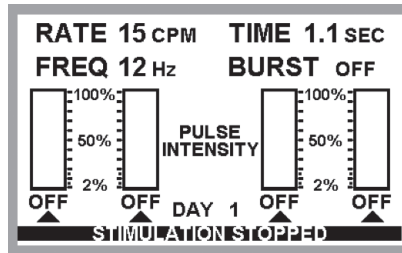


Figure 28 – TransAeris – All stimulus channels off

## 13 Post Treatment

### 13.1 TRANSLOC ELECTRODE EXTRACTION

- After the conditioning treatment has been completed and prior to discharge from the ICU, the TransLoc electrodes will be removed. Removal will be performed by the clinical staff by pulling electrodes from the percutaneous entry point. This is done in a similar fashion as a temporary cardiac pacing wire with a slow steady pull in a straight non oblique line.
- To facilitate extraction, cut the TransLoc electrode at the pin and allow the coiled wires to unravel (straighten) as you pull. This will provide a smooth path and release any adhesions at the skin interface.

## 14 Cleaning

### 14.1 CLEANING THE TRANSAERIS STIMULATOR

#### Cautions:

- Clean the TransAeris stimulator when required.
- Do not immerse the TransAeris stimulator in water or cleaning agents. Severe damage to the device may occur.

**Cleaning** – Follow Hospital facility procedures for all cleaning of the TransAeris.

**Note:** Do not expose the TransAeris to ethers, acetone, or chlorinated solvents. These solvents may damage the case, labels, or metal components.

## 14.2 Safety Checks

Perform safety checks on the TransAeris if the device has been dropped or damage is suspected.

### 14.2.1 Visual Inspection

Perform the following visual inspections each time the TransAeris is used:

- Check that there is no mechanical or physical damage to the device.
- Confirm that the device will power up and all controls buttons function.

### 14.2.2 Functional Inspection

Perform the following functional inspections each time the TransAeris is used:

- Verify that the device passes the self-test at power-up.
- Verify that the control buttons and displays function and work properly.
- Inspect all connections and cables. Verify that the patient cables properly connect to the FrictionLoc connectors and are not damaged.

**Caution:** Do not attempt to open the TransAeris. The TransAeris is sealed at the factory and opening the TransAeris will damage the device and void the warranty.

## 14.3 Service

The TransAeris stimulator is non-serviceable. If the device fails prematurely, contact Synapse Biomedical customer Customer Service to return for evaluation.

A serial number identifying each individual TransAeris is printed on the back label of the device. Reference the device serial number in any correspondence.

# 15 Product Warranty

The shelf life of the TransAeris is one (1) year and the unconditional product warranty is 30 days of consecutive calendar use. If the TransAeris is within the 1 year shelf life and fails in less than 30 days of consecutive calendar use, contact the contact Synapse Biomedical Customer Service for warranty questions.

## 16 Replacement Parts

The following replacement parts may be ordered from an authorized supplier.

Item	Part Number	Service Life	Order Quantity
TransAeris Stimulator Kit	20-1002	30 days	1 Each
FrictionLoc Kit (Blue and Green)	22-1005	30 days	1 Each
TransAeris Multi-Pack (Five 20-1002)	20-1003	30 days	1 Each
Surface Electrode Kit (5 Pair (10 total))	20-1007	30 days	1 Each
TransLoc Electrode Kit (20 electrodes)	20-1004	30 days*	1 Each

\*30 days per TransLoc electrode

### Storage of Replacement Parts:

1. Store patient kits vertically 1 high or horizontally 5 high.

### DISPOSAL of Replacement Parts:

1. TransAeris stimulator disposal – solid waste disposal per hospital policies.
2. All other replacement parts with potentially bio-hazardous contamination – please follow hospital policies for proper method of disposal.

## 17 Customer Service

For questions concerning the TransAeris System, please contact the Synapse Biomedical Customer Service at +33 (0) 1 34 16 49 11.

For Technical questions and training concerns, please contact:  
+33 (0) 9 60 12 44 98.

## 18 Troubleshooting

Use the following troubleshooting guide to help solve problems with your TransAeris System:

	Problem	Action
1	Stimulation stops.	<ul style="list-style-type: none"> <li>• Check the display for battery condition.</li> <li>• Check the connection of the patient cable to the FrictionLoc connector.</li> <li>• Try different FrictionLoc connectors.</li> <li>• Inspect the connections of the electrode leads to the FrictionLoc connector for non-connection or breakage of the electrode.</li> <li>• If the problem continues, call Synapse Biomedical Customer Service for assistance.</li> </ul>
2	The TransAeris does not power up.	<ul style="list-style-type: none"> <li>• Inspect for mechanical failures on the case due to being dropped.</li> <li>• Call Synapse Biomedical Customer Service for assistance.</li> </ul>
3	Patient is not receiving adequate stimulation for conditioning.	<ul style="list-style-type: none"> <li>• Qualified hospital staff modify the settings of the stimulator.</li> </ul>
4	Discomfort while pacing.	<ul style="list-style-type: none"> <li>• Qualified hospital staff to evaluate.</li> <li>• STOP use of the TransAeris until setting can be evaluated and/or modified.</li> </ul>
5	Bleeding, bruising, or infection where the electrode leads pass through the skin.	<ul style="list-style-type: none"> <li>• Qualified hospital staff to evaluate.</li> </ul>
6	Skin irritation from surface electrode	<ul style="list-style-type: none"> <li>• Qualified hospital staff to evaluate.</li> </ul>
7	One or multiple “!”s appear on the TransAeris stimulator display.	<ul style="list-style-type: none"> <li>• Inspect the connections of the electrode leads to the FrictionLoc connector for non-connection or breakage of the electrode.</li> <li>• Change surface patch electrode.</li> <li>• Change FrictionLoc connectors.</li> <li>• If the problem continues, call Synapse Biomedical Customer Service for assistance.</li> </ul>
8	The TransAeris stimulator is submerged in water or fluid.	<ul style="list-style-type: none"> <li>• STOP use of the TransAeris.</li> <li>• Replace with new TransAeris stimulator.</li> </ul>
9	The TransAeris is dropped.	<ul style="list-style-type: none"> <li>• Visually inspect the TransAeris for physical damage.</li> <li>• Confirm the device power, controls buttons and display are functioning.</li> <li>• If device is broken, STOP use of the device and replace with new TransAeris stimulator.</li> </ul>

# 19 Specifications

## 19.1 DEVICE SPECIFICATIONS

**Table 1. TransAeris – Temporary powered muscle stimulator specifications**

Stimulator Specifications	
<b>Device Name</b>	TransAeris Stimulator
<b>Model</b>	REF 23-1000
<b>Manufacturer</b>	Synapse Biomedical, Inc.
<b>Power Source(s)</b>	Built-in: non-replaceable Batteries (Stimulator disposed of after 30 days)
Number of batteries	8
Battery type	Alkaline
Battery size	8 x AA 1.5v Alkaline (Duracell QU1500)
<b>Operating Temperature</b>	+5°C to 40°C
<b>Storage/Transport Temperature</b>	-20°C to 54°C
<b>Relative Humidity</b>	15% to 93%, non-condensing
<b>Atmospheric Pressure</b>	700 hPa to 1060 hPa
<b>Method of Line Current Isolation</b>	N/A – Internally powered only.
<b>Number of Output Modes</b>	2 – Idle or Continuous Pulse Trains
<b>Dimensions (in.) [W x H x D]</b>	5.8" x 3.6" x 1.0"
<b>Weight</b>	390g
<b>Housing Materials and Construction</b>	ABS
<b>Ingress Protection</b>	IP55
<b>Accessories</b>	None
<b>Procedure for setting up stimulation parameters</b>	TransAeris User Manual (REF 77-1000)
<b>Number of Output Channels</b>	4
<b>Regulated Current</b>	Cathodic Pulse
<b>Microprocessor Control</b>	PEMS
<b>User Display</b>	LCD graphic
Individual Output Status	On, Off, Overload
Status Condition Indication (Low Battery, Keypad, or Data)	Visual indicator
Output Intensity Level	2% to 100% (0.1 $\mu$ C to 5 $\mu$ C)
Output Frequency	6 to 20 Hz
Cycle Rate	5 to 30 Cycles per Minute (CPM)
Cycle Time	0.5 to 1.5 sec
Days Remaining	Count up to 30 days

<b>Stimulator Specifications</b>	
<b>Compliance with Voluntary Standards</b>	IEC 60601-1:2006 +A1:2013 IEC 60601-1-2:2007 IEC 60601-1-6:2010 21 CFR 898
<b>Essential Performance Requirements</b>	<ul style="list-style-type: none"> <li>• The output of the device will measure the same as programmed.</li> <li>• The programmed parameter values will not change.</li> <li>• The output of the device will measure within specification.</li> </ul>
<b>Waveform Shape</b>	Biphasic: Rectangular cathodic current pulse followed by anodic capacitive discharge.
<b>Maximum Output Current</b>	
@ 200 $\Omega$	25mA
@ 500 $\Omega$	25mA
@ 1 k $\Omega$	25mA
<b>Maximum Output Voltage @ Maximum Output Current</b>	
@ 200 $\Omega$	5V
@ 500 $\Omega$	12.5V
@ 1 k $\Omega$	25V
<b>Pulse Width Range</b>	Cathodic: 25 $\mu$ sec to 200 $\mu$ sec Impedance Limited Anodic Discharge: ~1msec at 1K $\Omega$
<b>Non-Burst Amplitude Range</b>	4 mA to 25 mA
<b>Burst Amplitude Range</b>	1 mA to 6.25 mA
Net Charge ( $\mu$ C per pulse) @ 500 $\Omega$	0 $\mu$ C, Capacitively-Coupled Outputs

<b>Intensity Table</b>													
Display (%)	100	90	80	70	60	50	40	30	20	15	10	5	2
Charge ( $\mu$ C)	5.00	4.50	4.00	3.50	3.00	2.50	2.00	1.50	1.00	0.75	0.50	0.25	0.10

## 20 Electro-Magnetic Compatibility

- ⚠ • **ELECTROMAGNETIC INTERFERENCE WARNING:** Some electrically powered equipment gives off electromagnetic waves which could interfere with the TransAeris stimulator. When using the TransAeris stimulator around electrical equipment, check the TransAeris screen to make sure the device is working.
- ⚠ • Do follow the EMC information provided. The TransAeris needs special precautions regarding electromagnetic compatibility (EMC). To reduce the possibility of interference on the TransAeris from other electrical equipment or the TransAeris effecting other electrical equipment, do NOT use cables or accessories with your TransAeris other than those specified.
- ⚠ • **RF COMMUNICATION WARNING:** Portable and mobile RF communication equipment can effect medical electrical equipment.
- ⚠ • The TransAeris should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the TransAeris should be observed to verify normal operation in the configuration in which it is used.

### Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The TransAeris stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the TransAeris stimulator should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The TransAeris stimulator 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 B	The TransAeris stimulator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	


### Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The TransAeris stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the TransAeris stimulator 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 ± 15 kV air	± 8 kV contact ± 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%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not Applicable	The TransAeris stimulator is battery operated equipment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not Applicable	
Voltage dips, short interruptions and voltage variations input lines IEC 61000-4-11	<5 % $U_T$ (>95 % dip in $U_T$ ) for 0,5 cycle  40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles  <5 % $U_T$ (>95 % dip in $U_T$ ) for 5 s	Not Applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	
Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment.			
NOTE $U_T$ is the a.c. mains voltage prior to application of the test level.			

## Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The TransAeris stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the TransAeris stimulator should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands <sup>a</sup>	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the TransAeris stimulator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b>  $d = 1.2\sqrt{P}$  $d = 1.2\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands <sup>a</sup>	10 Vrms	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz  Where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in metres (m). <sup>b</sup>  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>c</sup> should be less than the compliance level in each frequency range. <sup>d</sup>  Interference may occur in the vicinity of equipment marked with the following symbol:  

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>a</sup> The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

<sup>b</sup> The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

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

<sup>d</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.


**Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and The TransAeris Stimulator**

The TransAeris stimulator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TransAeris stimulator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TransAeris stimulator as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.				
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.				
NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.				
NOTE 3 An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.				
NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

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 300 Artino Street  
Oberlin, Ohio 44074  
U.S.A.  
[www.synapsebiomedical.com](http://www.synapsebiomedical.com)


Tel: + 1-888-767-3770 extension 137  
+ 1-440-774-2488 extension 137  
Fax: + 1-440-774-2572

 Synapse Biomedical - Europe  
7 Rue de la Libération  
95880 Enghien Les Bains, France

France and other Countries  
Tel: +33 (0) 1 34 16 49 11  
Fax: +33 (0) 1 74 18 08 19  
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 77-1006 Rev 2

# Surgical Procedures for Implantation of TransLoc<sup>®</sup> Electrodes (for TransAeris<sup>™</sup> System)

**CAUTION:** Investigational device. Limited by Federal (or United States) law to investigational use.



 300 Artino Street  
Oberlin, Ohio 44074  
U.S.A.  
www.synapsebiomedical.com

Tel: + 1-888-767-3770 extension 137  
+ 1-440-774-2488 extension 137  
Fax: + 1-440-774-2572



Synapse Biomedical - Europe  
7 Rue de la Libération  
95880 Enghien Les Bains, France

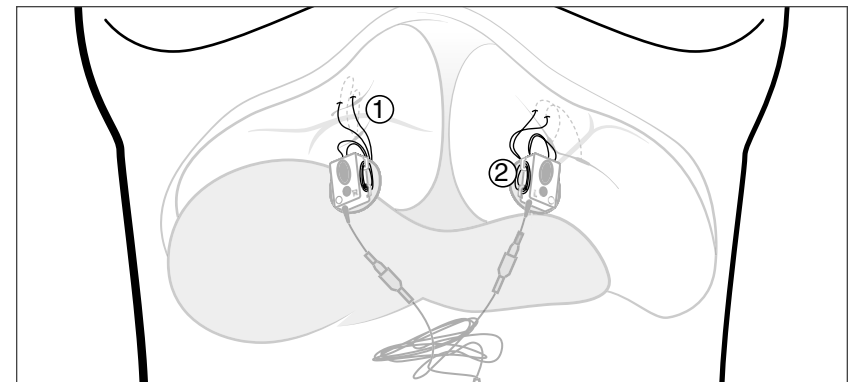
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 77-1007 (REV 1)

 0086



## TransAeris System

- ① TransLoc Electrode Kit
- ② TransAeris Patient Kit (FrictionLoc)
- ③ TransAeris Patient Kit (TransAeris Stimulator)



## About This Manual

This manual describes the surgical procedures for implantation of TransLoc Electrodes.

TransAeris™ is a percutaneous intramuscular diaphragm stimulator for temporary use in the hospital setting. The system consists of implantable stimulating TransLoc® electrode leads, disposable/single-use FrictionLoc™ connectors (20-1002 Patient Kit), and a disposable/single-use portable external stimulator (20-1002 Patient Kit).

- When done prophylactically with another procedure, the implant approach to the diaphragm may be from either the inferior (abdominal) or superior (chest) aspect of the diaphragm surface.
- The system has four stimulating intramuscular TransLoc electrodes to be implanted into the diaphragm for motor point diaphragm stimulation.
- Two stimulating TransLoc electrodes shall be placed into each hemi-diaphragm.
- TransLoc electrodes are tunneled through two percutaneous exit sites on the respective lateral chest region.
- A single left and right FrictionLoc connector (Patient Kit) will provide an electrical interface from the TransLoc electrodes to a patient cable.
- The patient cable with left (blue) and right (green) identifiers (Patient Kit) is integrated into the TransAeris stimulator (Patient Kit).
- TransAeris stimulator has a user interface for clinical control.

## Intended Use

TransAeris is a percutaneous intramuscular diaphragm stimulator intended for patients at risk of or on prolonged positive pressure mechanical ventilation.

TransAeris is indicated for use in the prevention and treatment of ventilator-induced diaphragm dysfunction (VIDD).

## Contraindications

- None

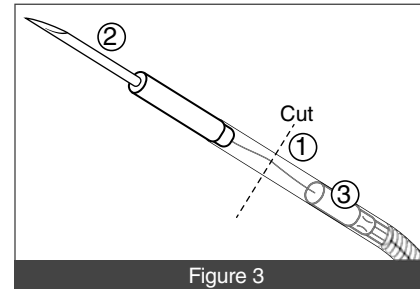


Figure 3

After the TransLoc electrodes have been implanted into the diaphragm and tunneled through the skin, the external end of the electrodes requires preparation before it can be connected to the FrictionLoc connector. The suture (1) between the tunneling needle (2) and the conductive pin (3) must be cut.

Cut the suture approximately halfway between the tunneling needle and the conductive pin, leaving the silicon protective tube covering the conductive pin.

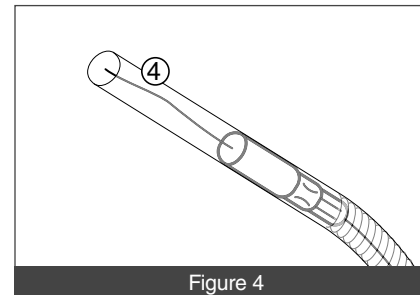


Figure 4

The silicon protective tube (4) will remain on the conductive pin until it is ready to use in the ICU.

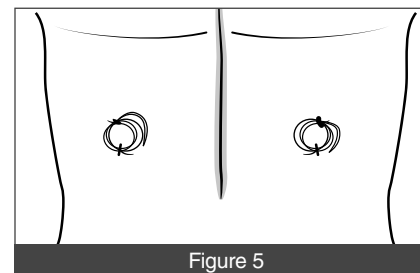


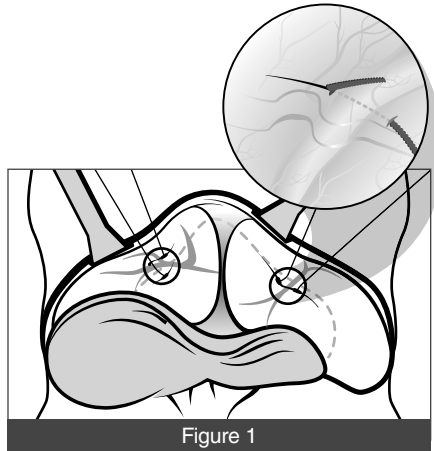
Figure 5

The external wires are fixated on the skin by looping them and suturing them.

# Surgical Instructions

## INFERIOR IMPLANT

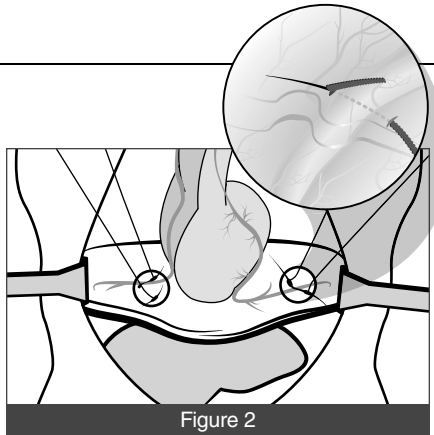
During a laparotomy with a midline incision for patients such as Liver Transplant, Esophagectomy, Gastrectomy, or Exploratory Laparotomy from Trauma. Hold a retractor up on the abdominal wall to see the left and right diaphragm. Place two electrodes into the right hemi diaphragm lateral to the central tendon. The blue polypropylene sutures are then cut to remove the curved needles from the distal end of the electrodes. The electrodes are externalized by pushing the percutaneous access needles through the abdominal wall through the right upper quadrant. Adequate electrode length remains near the diaphragm so that there is not any tension on the lead during contraction. On the patient's left diaphragm two electrodes are placed lateral to the edge of the pericardium, where you can see the heart is beating as the phrenic nerve comes in laterally on the left diaphragm.



The blue polypropylene sutures are then cut to remove the curved needles from the distal end of the electrodes. The two electrodes are externalized by pushing the percutaneous access needles through the lateral aspect of the left upper abdomen below the costal margin. Adequate electrode length remains near the diaphragm so that there is not any tension on the lead during contraction.

## SUPERIOR IMPLANT

During an open median sternotomy two electrodes are implanted on the right hemi diaphragm and two electrodes on the left hemi diaphragm. They are implanted just lateral to where the phrenic nerve comes into the central tendon. The blue polypropylene sutures are then cut to remove the curved needles from the distal end of the electrodes. Each electrode is externalized so that it exits the chest in as direct a path as possible to the percutaneous exit site to allow for eventual easier removal. This is done by using the percutaneous access needle to bring the lead out through the skin in the desired location. For procedures with temporary cardiac pacing, two electrodes exit on each side above and lateral to the temporary



cardiac pacing wires. Adequate electrode length remains near the diaphragm so that there is not any tension on the lead during contraction.

## ⚠ Warnings

Use only under the direction of a physician. The TransAeris stimulator is electrically powered and may produce tissue damage or electrical hazard if improperly used.

- The device has accessible controls for clinical staff and NO patient-accessible controls.
- Do NOT attempt to open the TransAeris stimulator case or attempt any unintended modifications as this will cause a failure in the TransAeris stimulator functionality.

Use of TransAeris could interfere with some medical equipment. Some medical equipment could interfere with the use of TransAeris. Consult the User Manual before having any of the following:

- **Implanted cardiac pacemaker or defibrillator.** Use of the TransAeris stimulator may interfere with these devices.
- **Surgery.** Use of high-frequency surgical equipment may cause burns where the electrode leads pass through the skin. Such equipment may damage the TransAeris stimulator. Disconnect the TransAeris stimulator when high-frequency surgical equipment is in use.
- **Magnetic Resonance Imaging (MRI) test.** The TransLoc electrode is MR unsafe. Do not perform a MRI test while implanted with the TransLoc electrodes or remove the TransLoc electrodes from the patient before a MRI test.
- **Magnetic Resonance Imaging (MRI) test.** The TransAeris stimulator, FrictionLoc connector, and surface electrode are MRI Unsafe. Remove these components from the patient before a MRI test.
- **Use of external electrical stimulation such as transcutaneous electrical nerve stimulation (TENS)** should not be done in the chest area near the electrode leads. Unwanted diaphragm contraction could occur.

Clinicians should avoid accidental contact between connected but unused applied parts (cable or leads) and other conductive parts including those connected to earth ground or any device with the ground symbol.

Safety has not been established for the use of the device during pregnancy.

It should not be used in patients with epilepsy.

**CARDIAC INTERFERENCE.** Before conditioning, test interference with cardiac rhythm. Monitor electrocardiogram (ECG) while stimulating at maximal settings. If interference is observed, decrease stimulation settings below level of interaction, turn off identified electrodes, or remove identified electrodes.

Do NOT come in contact with TransLoc electrodes during emergency defibrillation. It may lead to electric shock to caregivers.

**ELECTROMAGNETIC INTERFERENCE WARNING:** Some electrically powered equipment gives off electromagnetic waves which could interfere with TransAeris systems. When using your TransAeris system around electrical equipment, check the TransAeris stimulator screen to make sure the TransAeris system is working.

Do follow the electromagnetic compatibility (EMC) information provided. The TransAeris stimulator needs special precautions regarding EMC. To reduce the possibility of interference on the TransAeris stimulator from other electrical equipment or the TransAeris stimulator effecting other electrical equipment, do not use cables or accessories with the TransAeris stimulator other than those specified.

**RF COMMUNICATION WARNING:** Portable and mobile RF communication equipment may affect medical electrical equipment. Ensure proper function of TransAeris when using around such equipment.

## ⚠ Warnings Continued

### ⚠ ELECTRO-STATIC DISCHARGE (ESD):

After the TransLoc electrode has been implanted but not connected to the FrictionLoc connector, use caution when handling the electrode leads. Before touching the electrode leads, touch the patient to equalize the electrostatic potential.

**FLAMMABILITY WARNING:** Do NOT use TransAeris system in an oxygen enriched environment, such as a hyperbaric oxygen chamber, or near a flammable anesthetic mixture with air, oxygen, or nitrous oxide. This could cause a fire or explosion.

## ⚠ Precautions

The TransLoc electrodes have been carefully designed and tested to ensure reliability during normal use. To avoid damage to the TransLoc electrodes, observe the following precautions.










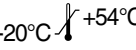






- The TransAeris system is designed for single-patient use. Dispose of the device and all components when finished using on a patient. Do NOT reuse. Reuse may lead to transmission of infection.
- TransLoc leads, improper connection, or fracture of leads may result in failure of the TransAeris stimulator. Inspect exiting electrode leads for damage before use.

## Possible Adverse Effects

Possible adverse effects from the use of TransAeris system may include:

- Cardiac interaction
- Lead breakage
- Unretrieved device fragment
- Electrode dislodgement
- Skin infection
- Skin sensitivity due to adhesive
- Pain or discomfort due to stimulation

## Symbols

Explanation of symbols	
	The <b>Warning</b> symbol precedes warning information that mitigates a risk that is not obvious to the operator. Indicates that a potentially hazardous situation which, if not avoided, could result in harm to the operator or patient. Powered equipment indicates physiological effects not obvious to the user that can cause harm.
	The <b>Caution</b> symbol appears next to precautionary information when the intention is solely to inform. Indicates that a potentially hazardous situation which, if not avoided, may result in minor or moderate personal injury or property damage. This word is used to also alert against unsafe practices.
	The <b>Manufacturer</b> symbol appears next to the manufacturer's name and address.
	The <b>Reference</b> symbol appears preceding the part number for the device. The part number is a unique numeric identifier for the device.
	The <b>Lot</b> symbol appears preceding the lot number for a device. Devices manufactured at the same time using identical material and parts will share a common lot number.
	The <b>Use Until</b> symbol appears on devices that have an indication of the date by which the device should be used. The date is expressed as the year and month, with the month referring to the end of the month.
	The <b>Sterile</b> symbol and the EO method of sterilization symbol appear on devices that have undergone an ethylene-oxide gas sterilization process and are provided sterile
	The <b>Do not Re-sterilize</b> symbol appears on devices that are supplied sterile to indicate that the device may not be re-sterilized.
	The <b>Do not Re-use</b> symbol appears on devices that are supplied sterile to indicate that the device is for single-use and may not be used again.
	The <b>Temperature Limits</b> symbol appears on packages of devices as an indication of the storage and transit temperature limits.
	The <b>Keep Dry</b> symbol appears on all packages of devices requiring to protect the packaging from potential damage.
	The <b>Don't Use If Packing Damaged</b> symbol appears on all packages of devices requiring to dispose of the device if the packaging has suffered damage.
	The <b>Regulatory Marking of Conformity</b> symbol indicates that the device meets Medical Device Directive 93/42/EEC. This has been certified by notified body number 0086.
	The <b>European Community Representative</b> symbol indicates the identification of the authorized representative for the distribution of devices into the European community.
	<b>MR Unsafe.</b> A device that is known to pose hazards in all MR environments.
	<b>ESD sensitive device.</b>