angiodynamics

Solero

Microwave Tissue Ablation System

Generator Operator's Manual

16750970-21 REVE - English
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SECTION 1 | INTRODUCTION

1.1 System Description

The *Solero** Microwave Tissue Ablation (MTA) System is a software-controlled, microwave generator with an integrated pump that surgically ablates soft tissue through sterile applicators. The system may be used during intraoperative, laparoscopic, and percutaneous procedures.

The Solero generator is distributed with a mains power cable and a footswitch which may be used as an alternate means of controlling microwave activation. Power is delivered through the disposable Solero Microwave Applicators, which are provided separately.

A chilled coolant source, chilled sterile saline, is required to maintain the Solero applicators at an appropriate temperature. Figure 1 below shows the components of the Solero system.

Figure 1. System Diagram of the Solero System Components and Accessories

The user may adjust microwave power output from 60 W to 140 W for up to 6 minutes. When the Solero system microwave energy is activated by the button on the generator front panel or by the footswitch, microwave energy (2.45 GHz ± 50 MHz) is radiated from the tip of the Solero applicator. Soft tissue surrounding the applicator tip is then ablated as identified in the instruction for use accompanying the applicator. Track ablations may also be performed during withdrawal of the applicator.

1.2 Indications for Use

The Solero Microwave Tissue Ablation (MTA) System and Accessories are indicated for the ablation of soft tissue* during open, laparoscopic, or percutaneous procedures. The Solero MTA System is not intended for cardiac use.

*Note Canada Only: Throughout this document any reference to “soft tissue” means the following tissue types: Liver, Kidney, and Lung (early stage non-small cell lung cancer (NSCLC) and inoperable pulmonary malignancies).

1.3 Contraindications

The applicators are contraindicated in patients with heart pacemakers and other electronic device implants.

1.4 Intended User

The Solero Microwave Tissue Ablation System is designed to be used by physicians who are trained in the use and application of:

- Image-guided ablation procedures
- Intraoperative ultrasound and/or CT guided needle placement

1.5 Intended Use Environment

The Solero Microwave Tissue Ablation System is intended for use in control environments such as those found within surgical suites and emergency rooms. The exact details for environmental conditions and operating parameters may be found in **Section 8.2.**

1.6 Warnings and Cautions

1.6.1 General Warnings

- Read the Operator's Manual and Directions for Use for the Solero system and accessories prior to use. Safe tissue ablation is dependent upon operation of the equipment in accordance with the operating instructions.
- The system is for use by qualified clinical personnel who have been trained in the correct use of the equipment in accordance with the operating instructions. Use of the Solero system by untrained operator could pose a safety risk to patients and users.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains electric outlet with protective earth.
- When ablating close to vascular structures to be spared, be aware that use of the Pringle maneuver will inhibit blood flow in the vessel and reduce the ability of the vessel to protect itself from thermal damage.
- Do not obstruct or block air inlet or outlet fans. Ensure a clearance distance of 100 millimeters at the rear of the generator or the generator may not be cooled as designed.
- Microwave energy should not be applied to persons wearing metallic jewelry or clothing containing metallic material (for example metallic buttons, clips or thread).
- Parts of the body of the patient containing metallic implants (for example a medullary nail) should not be treated unless specialized medical advice is obtained.
- Patients with implanted electronic devices and/or electrodes should be excluded from treatment with microwaves and from areas where the equipment is operated.
- Hearing aids should be removed.
- This Solero system requires an uninterruptable power supply (UPS) in order to ensure continuous operation in the event that the main input power supply is interrupted.
- The Solero applicators do not require the use of neutral electrodes.
- Ensure that the generator is within the proper environmental operating conditions before turning it on.
- The generator must be within two meters of the sterile field. Longer distances may result in excess tension applied to the applicator.

1.6.2 Use Warnings

- If the tubing set becomes occluded, improper or unpredictable lesion size may occur.
- Do not attach anything (i.e., clamps, etc.) to the device. This may damage the insulation, which could contribute to patient injury.
- Solero applicators are intended for single patient use only.
- Contamination of the Solero applicator may lead to injury, illness or death of the patient.
- Reprocessing the Solero applicator may compromise its integrity and lead to device failure.
- The Solero system has not been tested for MRI compatibility and should therefore not be used in conjunction with MRI image guidance.
- Avoid placing lateral forces on the applicator tip as this may damage the device.
- Do not transport the unit by gripping the pump housing or pump clip holder as damage to the device may result.

- Do not use the applicators if the expiration date provided on the packaging has expired, or if the seal is broken.
- Use only chilled saline solution for the coolant source.
- Do not defibrillate a patient with an applicator inserted. Completely remove the applicator from the patient before defibrillation.
- Use caution when treating close to critical structures. Microwave energy penetrates 2 cm around the emitting tip of the device into tissue. Structures to be spared should be at least 2 cm away from the emitting antennae.
- Always use the lowest power and shortest time necessary to achieve the targeted ablation.
- Do not bend the applicator as this may impair the function of the cooling system and may damage the microwave feed line inside the applicator.
- When using percutaneously, the tip of the antenna may be used to puncture the skin at the point of insertion. Use the minimum force necessary to achieve this and take care not to over advance the applicator. Refer to the shaft depth markings to monitor placement depth.
- If used laparoscopically the device can be placed directly through the abdomen. It is not recommended to place the device through a laparoscopic port as this may result in a loss of abdominal insufflation.
- Do not energize the applicator unless the active region of the applicator is fully inserted into target tissue. If the applicator is not properly located into the selected tissue, an unintended thermal injury may occur.
- After each ablation, inspect the applicator for any damage. If any damage is observed, the applicator should be discarded and replaced with a new applicator.
- Do not initiate the procedure/anesthesia until the applicator has been connected, primed, and the generator status bar indicates “Ready.”

1.6.3 Generator Care

- Do not immerse or otherwise allow liquids to saturate or leak inside the generator.
- The Solero generator is designed to be durable medical equipment. Physical damage caused by dropping, bumping or striking the generator may result in improper operation of the equipment and may lead to patient or operator injury. If the generator is damaged, discontinue use and contact AngioDynamics.
- No modification of this equipment is allowed. Do not attempt to repair or alter any of the system components. Do not remove the cover of the generator. Refer all service to AngioDynamics. There are no user-serviceable parts inside the generator. The warranty will be voided if the unit is opened.
- Do not sterilize the generator.
- Use only the Solero generator, Solero applicators, mains power cable, footswitch, and parts supplied by AngioDynamics.
- Clean and maintain the generator in accordance with the operating instructions.

1.6.4 Flammable Gasses

- Do not use the system in the presence of flammable anesthetics. The use of flammable anesthetics or oxidizing gases such as nitrous oxide and oxygen should be avoided if procedure is being conducted in the region of the thorax or head, unless these agents are suctioned away.
- There is a minimal risk of the ignition of endogenous gases when the system is operating.
- This system is not for use in an oxygen-rich environment.

1.7 Cautions

- Federal US law restricts this device to sale by or on the order of a physician.

SECTION 2 | SYSTEM OVERVIEW

2.1 Generator

The Solero generator is supplied with the following components:

Description	Quantity
Solero Operator's Manual	1
Solero Generator with Integrated Pump	1
Mains Power Cable	1
Footswitch	1

The Solero generator consists of a 2.45 GHz microwave source. The generator is specifically designed for use with Solero applicators. It has user-selectable controls on the front panel and displays microwave power output and time. It also has an input for an optional footswitch to control microwave activation.

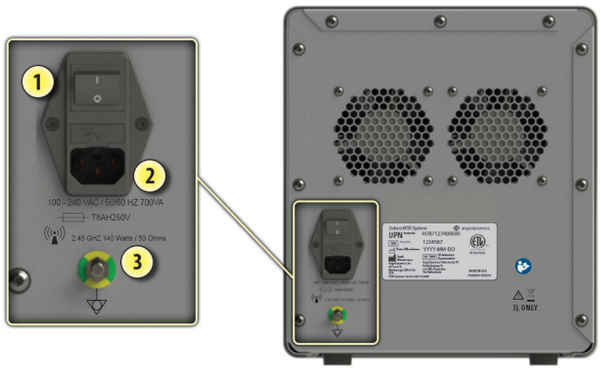
2.2 Front Panel Display, Connections, and Control Features

The following features are located on the front panel of the generator. For details of use see **Section 5** for procedure set up and implementation.

Number	Name	Description
1	Touchscreen	Allows the user to input the settings and displays the ablation and system states.
2	Microwave Power Button	Allows the user to turn on and off microwave energy delivery.
2	Status Indicator	A light in the Microwave Power Button that indicates the system's state.
3	Pump Clip Holder	Retains the pump clip on the tubing set.
4	Pump	Delivers saline to cool the attached applicator through the tubing set.
5	Applicator Connector	Allows the applicator cartridge to be connected to the system.

Number	Name	Description
6	Probe 1 Input	Not currently available.
7	Probe 2 Input	Not currently available.
8	Footswitch Input	Allows the optional footswitch to be connected to the system.

2.3 Back Panel



Number	Name	Description
1	Mains Power Switch	Turns the generator on and off.
2	Mains Power Receptacle	Provides connection for the mains power cable.
3	Equipotential Terminal and Electrical Information	Provides external grounding connection, and electrical compliance information.

2.4 Screen Regions

The following regions are for general description only. Throughout a procedure, variations of this screen will be displayed and are fully explained in **Section 5 and 6** for set up and implementation.

ID	Name	Description
A	Status Bar	Displays an indication of the current system's state and provides user prompts.
B	Time Module	Allows the ablation duration to be set and the time remaining to be monitored.
C	Power Module	Allows the ablation power level to be set and the power output to be monitored.
D	Accessory Status Bar	Allows the user to monitor the applicator connection status and turn the pump on and off.
1	Track Button	Turns on and off Track Ablation Mode.
2	Time Setpoint	Displays the user-modifiable ablation duration.
3	Time Remaining	Displays the time remaining during an ablation.
4	Time Remaining Indicator	Graphical display of the remaining ablation time.
5	Set Time Buttons	User controls to set the desired ablation duration.
6	Power Setpoint	Displays the user-modifiable power setting that will be delivered during the ablation.
7	Power Output	Displays the current microwave power output during an ablation.
8	Power Status Bar	Displays the ratio of current power output power to the maximum power output of 140 W during an ablation.
9	Set Power Buttons	User controls to set the desired power output setting.
10	Probe 1 Status	Not currently available.
11	Probe 2 Status	Not currently available.
12	Pump Button	User control to turn on and off the pump.
13	Applicator Status	Displays the connection status of the applicator.

SECTION 3 | DISPOSABLES/ACCESSORIES

3.1 Solero Applicators

The following applicators are available for use with the Solero generator. To obtain more specific information, refer to the Directions for Use of the specific applicators.

Part Number	Description
H7877001060010	Solero 14 cm Applicator
H7877001060020	Solero 19 cm Applicator
H7877001060030	Solero 29 cm Applicator

3.2 Accessories

The following accessories are supplied for use with the Solero generator as replacement parts. To obtain more specific information, refer to the Directions for Use of the specific applicators.

- **Mains Power Cable**: A regionally-appropriate power cable is supplied which allows the unit to be plugged in to the local mains power.
- **Footswitch**: A footswitch is supplied and may be used as an alternative to the Microwave Power Button to control microwave activation.

SECTION 4 | SYSTEM SET UP AND PREPARATION

4.1 Receipt

- Remove the Solero generator and Operator's Manual from the shipping container.
- Visually inspect the generator for damage during shipment.
- Thoroughly read the Operator's Manual.

4.2 Installation

- Place the generator on top of a medical grade cart or table.
- Attach the female end of the mains power cable into the AC mains power receptacle on the back of the Solero generator.
- Position the generator such that access to the mains power cable is not blocked.
- After reading, store the operator's manual in an area close to the generator where it will be easy to find.

4.3 Transportation

- To transport the system within the hospital, first ensure the power cord is disconnected from the supply mains electrical outlet.
- Grip the generator by the bottom of the unit chassis, and avoid handling the unit by the pump housing, pump clip holder, or applicator while transporting the device.

4.4 Training

- Physicians are required to read the Solero Generator Operator's Manual and the Solero Microwave Tissue Ablation System Applicator Directions for Use (DFU) prior to clinical use of the system.
- Failure to fully understand the operation of the system to include warnings and precautions may lead to patient injury.
- It is recommended that physicians and clinical support staff also attend in-service training provided by AngioDynamics prior to clinical use of the Solero MTA System.
- In-service training material includes general operating principals of the Solero MTA System but does not include all prescribing information. Please review Operator's Manual and Directions for Use for full prescribing information.

SECTION 5 | OPERATING INSTRUCTIONS

5.1 Turning the Generator On

- Ensure that the generator has been installed as described in **Section 4** of this document.
- Inspect the generator and cables for damaged parts before use.
- Plug the generator into the supply mains electrical outlet.
- Turn on the generator using the mains power switch on the back of the generator.
- The touchscreen will illuminate after several seconds and display the screen shown below. Below the AngioDynamics logo, the text “System Loading” is displayed in various languages. The languages displayed will change twice as the loading progresses.

- When the system is loaded, the languages are removed, and a bar is displayed which indicates the progress of system initialization, as shown by (1) below. Do not unplug or interrupt the initialization process as the system is performing necessary self-tests.

- While the system is initializing, a button is displayed in the lower right corner that will allow the user to change the language in which the user interface is presented. After pressing the button indicated by (2) above and the completion of the initialization process, the system will display the language selection screen.
- **The option to change the display language is only available during this initialization process.**
- Pressing the language selection button a second time will cancel the language selection process.
- Upon successful initialization, the system will advance to the Standby screen, or the language selection screen.

5.2 Language Selection

- When the language button has been pressed, and the initialization process has completed successfully, the language selection screen shown below will be displayed.

- Press the up (1) or down (2) arrows to scroll through the list of available languages.
- Press the button for the desired language. The entire panel surrounding the language text is a button.
- The selected language will be denoted by a check box beside the language and the button will be highlighted as shown in (3). English is the default language.
- The selected language may be changed at any time by pressing another language button.
- After selecting the desired language, press the confirmation button (4) to accept the language change and progress to the standby screen.
- Press the cancel button (5) to exit the language selection screen without changing the language. Regardless of what language button is currently pressed, pressing cancel will revert the display to the language in use prior to this session.
- **Once selected, the system will continue to boot up in the chosen language until it is changed again.**

5.3 Standby Screen: Connecting the Applicator

- After the system has successfully completed initialization (and possibly language selection) it will transition to the standby screen as seen below.
- Inspect all devices and packaging for damage prior to use. Do not use any devices that are damaged or if the sterile barrier is breached. Do not use the Solero generator if it has been dropped or damaged.
- Using sterile technique, open the Solero applicator packaging and carefully remove the device. Remove and dispose of all packaging materials.
- Inspect the applicator's tubing set prior to use. Do not use the device if the tubing set has any evidence of damage (e.g. kinks, cracks, etc.).
- The system will give instructions in the notification region (1) for the applicator to be connected. The applicator display is gray (2) indicating that the applicator is not connected, and the pump control is displayed as disabled (3).

- Connect the applicator's cartridge to the generator's connector on the front panel. Verify that the pins of the connector and plug are not bent before continuing.

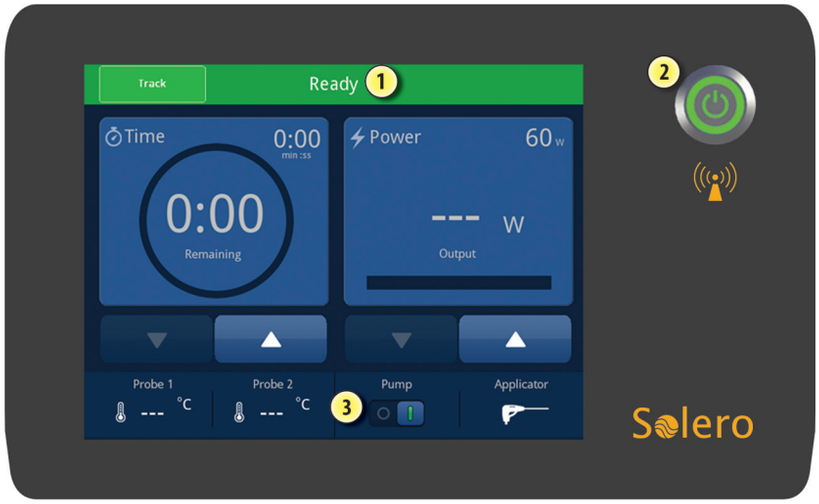
CAUTION: The cartridge connections can only mate to the generator in one direction and require minimal force to ensure proper attachment. If force is required, remove the cartridge, inspect the pins for damage, and ensure that the correct orientation is being used. Replace the applicator if it appears damaged. Otherwise, try reseating the cartridge in the connector.

- When a good connection is made, the applicator indicator will light up (1), and the pump activation button will become enabled (2). The system will remain in Standby and the notification will indicate that the pump should be turned on next (3).

- Obtain a minimum of 1000 mL of sterile chilled saline. The saline will heat up as an ablation progresses and may eventually become too hot at which point the system will inhibit operation. Using larger volumes of chilled saline (up to 3000 mL) may increase the amount of time before the cooling reservoir needs to be replaced.
- Remove the cap on tubing set spike and insert spike, item (1) shown below, in the saline source, being careful not to puncture through the saline source.
- To insure proper fluid movement, place the saline source higher than the generator, such as on an IV pole.
- Open the pump housing cover (2), and load the applicator tubing set under the pump rollers as shown below. Ensure that the tubing is not twisted. It should lie flat and be inline with the cartridge and pump clip holder and completely under the pump rollers. Do not close the pump housing cover.
- Pull the pump clip over the holder and seat it there firmly as shown by (3). Again, ensure that the tubing is flat and inline between the holder and the cartridge. Remove the clip from the holder and redo if necessary.

- Close the pump housing cover.
- Ensure that the cartridge is still firmly attached to the connector (4) and that the applicator connection indicator (5) confirms proper connection by being displayed in white, not gray.
- To start the pump, press the pump button (6) on the main screen.
- The system may indicate an error when the pump is started and the tubing set is not properly loaded. For detail see the error conditions and indicators. **Section 6**.

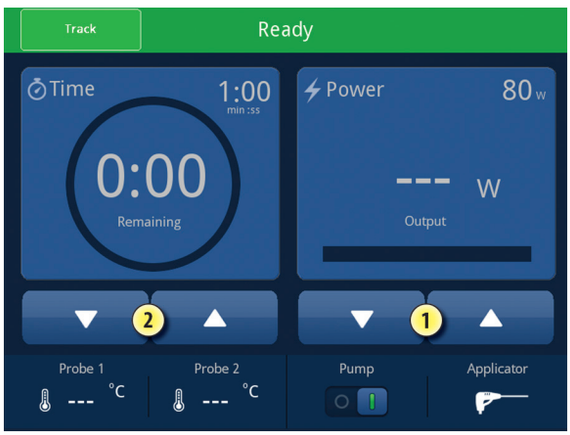
- The system will transition to the Ready screen (1) as seen below and illuminate the green indicator light on the front panel (2). The pump indicator button will change as seen in (3) to indicate that the pump is now rotating and circulating coolant.



- Inspect the tubing set and saline bag for bubbles or leaking fluid. If leaking is observed, replace the applicator and coolant source.

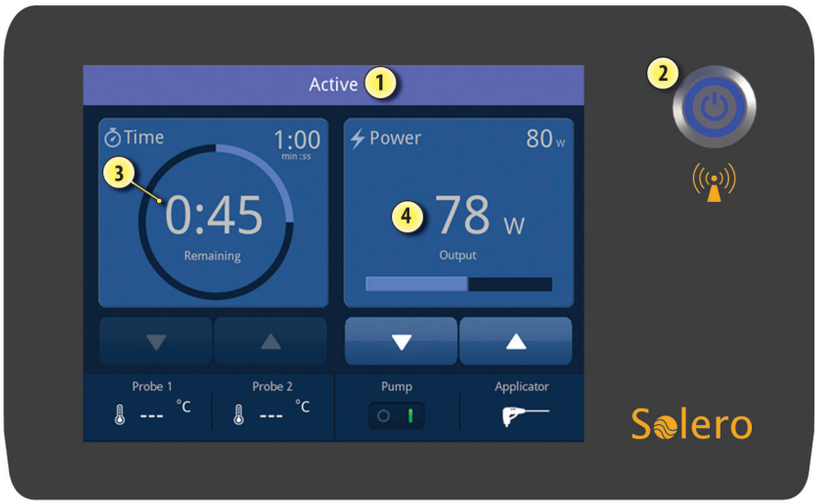
5.4 Setting Power and Time

- The generator will default to a power setting of 60 watts and a time setting of 0:00 after initialization. The system will maintain the previous settings for subsequent ablations.
- Set the desired ablation power by pressing the respective Set Power Buttons (1) as shown below. Power is set in increments of 20 watts from 60 watts to 140 watts. Always set the lowest power required to achieve the desired ablation. Refer to the directions for use for the relevant applicator for detailed guidance.
- Set the desired ablation time by pressing the respective Set Time Buttons (2) as shown below. Time is set in 10 second increments from 0:00 to 6:00. Always set the shortest time period required to achieve the desired ablation. Refer to the directions for use for the relevant applicator for detailed guidance.



5.5 Beginning Ablation

- Use imaging techniques to confirm the proper placement of the applicator. Refer to the Directions for Use for the relevant applicator for detailed guidance.
- Confirm that the screen shows the correct settings as selected from the applicator Direction for Use, and indicates “Ready.” If it does not, follow the relevant on-screen instructions to prepare the system.
- To begin an ablation, press the Microwave Power Button on the front panel of the generator.
- The optional footswitch may be used as an alternative means of starting and stopping ablations. In all cases, whenever instructed to use the Microwave Power Button, the footswitch may be used instead.
- The system will transition to the Active state as shown below (1).



- The indicator light on the front panel will illuminate blue (2). The timer will begin to count down (3) from the Time Setpoint, and the power output will begin to rise toward the Power Setpoint (4) as displayed above.

CAUTION: Under normal system operation, the output power may not reach the Power Setpoint due to tissue desiccation and the subsequent increase in reflected power. The Power Output (4) displays the “actual power” which is the difference between the instantaneous forward power and the instantaneous reflected power. As the ablation progresses, the forward power will remain nominally constant around the setpoint, but the reflected power will gradually increase. So, for a typical ablation, the Power Output display will initially be close to the setpoint, but decrease as the tissue desiccates.

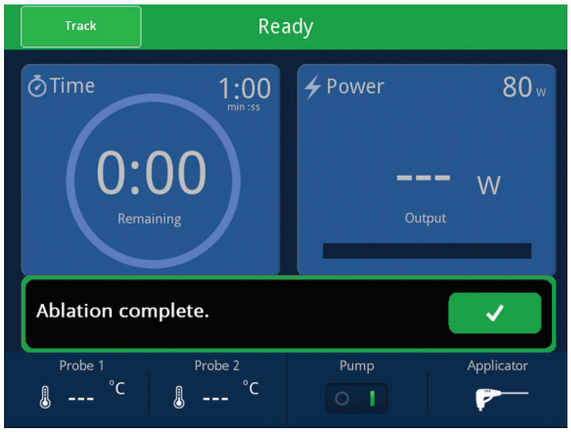
- An audible indicator will sound every 5 seconds during the delivery of microwave energy.

5.6 During an Ablation

- Confirm delivery of microwave energy via the following indicators: A beep will sound every 5 seconds. The screen will read “Active.” The indicator light on the front panel will stay illuminated blue. The Time Remaining will be counting down, and the Power Output will be close to the Power Setpoint.
- Other system notifications will appear in the top right corner of the screen if necessary. These messages will prompt the end user for appropriate action. Refer to the system notifications in this section and **Section 6** for a complete list of possible actions.
- An ablation may be stopped at any time by pressing Microwave Power Button.
- Pressing the Microwave Power Button again will restart the ablation using the current Time and Power Setpoints, not the Time Remaining.

CAUTION: The system will always use the Time and Power Setpoints at the start of an ablation. If an ablation is aborted by the user or by the system and then restarted, the Time Remaining will begin counting down from the existing Time Setpoint, not the time that was remaining when the ablation was aborted. In order to preserve the original duration, the Time Setpoint will need to be adjusted down to the appropriate remaining time before restarting the ablation.

5.7 Ending an Ablation



- Microwave energy delivery will terminate automatically after the set time has elapsed. A short then long tone will sound to alert the clinician that the procedure has ended and the screen below will be displayed.
- Any dialogue box with the checkmark may be cleared from the screen by pressing the button with the checkmark.
- While an ablation is underway, pressing the Microwave Power Button will terminate microwave energy delivery.
- The generator power switch on the back of the equipment may also be used for emergency termination of microwave energy delivery.

5.8 Track Ablation

- Track ablation may be used after an ablation is completed. The mode may be entered when the “Standby” or “Ready” screen is displayed.
- Press the “Track” button located in the upper left corner of the screen as shown below (1) to enter track ablation mode. The button will darken to indicate it has been pressed.

- In Track Ablation Mode the wattage is preset to 100 watts.
- Set the desired track ablation power by pressing the respective Set Power Buttons (2) as shown above. Power is set in increments of 20 watts from 60 watts to 140 watts. Always set the lowest power required to achieve the desired ablation. Refer to the Directions for Use for the relevant applicator for detailed guidance.
- Set the desired track ablation time by pressing the respective Set Time Buttons (3) as shown above. Time is set in 5 second increments from 0:00 to 1:30 while in track ablation mode. Refer to the Directions for Use for the relevant applicator for detailed guidance.
- Press the Microwave Power Button on the generator to start energy delivery.
- Microwave energy delivery will terminate automatically after the set time has elapsed. Pressing the Microwave Power Button again will also terminate energy delivery.
- Take care to stop energy delivery once the applicator reaches the minimum insertion depth.

5.9 Ending the Procedure / Shut Down

- Ensure microwave energy delivery has stopped and the ablation is complete by observing that the screen has returned to the Ready screen.
- To disconnect the applicator, first remove the applicator from the patient. Take care to avoid touching the tip which may retain latent ablation heat and is sharp.
- Press the Pump Button on the screen to turn the pump off.
- Turn off the generator using the mains power switch on the back of the unit.
- Open the pump housing cover and remove the pump tubing from the pump bed.
- Remove the saline bag from the IV hook. Invert the coolant reservoir and remove the spike connector.
- Disconnect the applicator cartridge by depressing the locking clips to disengage it and pulling firmly.
- Dispose of the applicator according to hospital policy or state and local regulations for the safe handling of sharps and bio hazardous materials.
- Clean the generator per **Section 7.1** of this Operator’s Manual.

5.10 Storage

- The generator should be stored according to specified storage conditions. See **Section 8.2** for specifics.

SECTION 6 | SYSTEM NOTIFICATIONS / WARNINGS / ERRORS

6.1. Notifications

Persistent notifications are displayed in the upper right-hand corner of the Status Bar in an orange-colored panel. These notifications relate to conditions that may persist until action is taken by the user and they represent suggested actions to help facilitate ease of use, but do not represent hazardous scenarios or system errors. System notifications happen for a variety of reasons as listed below.

The notification orange-colored panel is not a button. It only provides context-relevant user information.

Transient notifications are green-bordered dialog boxes that indicate that an ablation has completed. They block further activity until they are acknowledged.

6.1.1 Connect Applicator

The system will display a notification when an applicator is not detected as shown. This notification may also be accompanied by a dialog box as shown in **Section 6.2.1**.

The Power and Time Setpoints may be adjusted in this state, but ablations may not be started.

6.1.2 Turn on Pump

The system will display a notification when an applicator is connected, the pump housing cover is closed, and the pump is not running as shown. Ensure the pump tubing is properly loaded and the pump clip is in place before activating the pump.

The Power and Time Setpoints may be adjusted in this state, but ablations may not be started.

6.1.3 Close Pump Cover

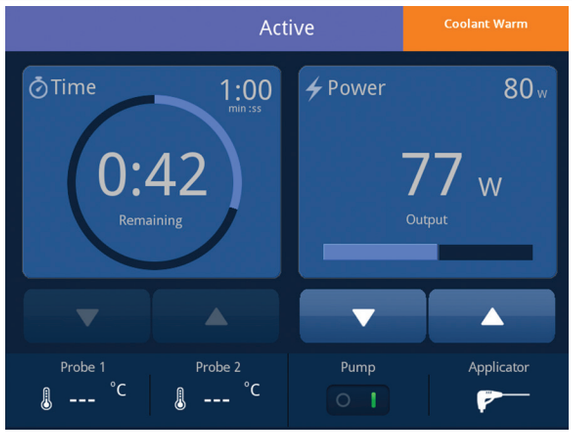
The system will display a notification to close the pump cover when the pump housing cover is opened and an applicator is connected. If the pump is running when the cover is opened, the system will stop it. The pump may not be restarted while the cover is open as indicated by the pump control being disabled.

The Power and Time Setpoints may be adjusted in this state, but ablations may not be started.

6.1.4 Coolant Warm

The system will display a notification if the applicator temperature sensor detects the coolant to be hotter than 38 °C as shown. The coolant source should be replaced as soon as is convenient to ensure uninterrupted performance.

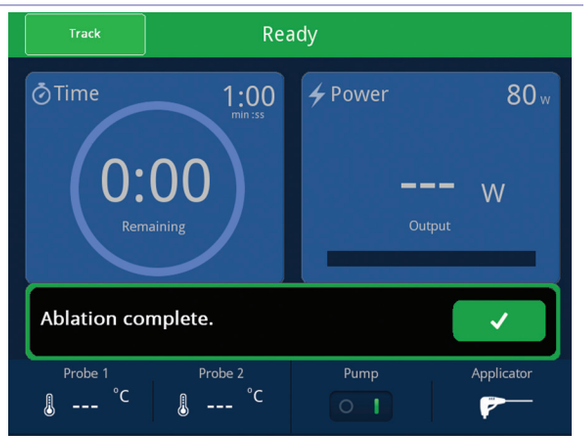
While this notification does not present a risk to the patient or end user, if the temperature rises above 48 °C, the system will abort an ablation that is in progress. This notification may occur during long ablations, or during treatment of patients with multiple lesions.



6.1.5 Ablation Complete

The system will display a prompt indicating that the ablation has completed when the Time Remaining reaches “0:00” as shown.

Further progress is blocked until the dialog is acknowledged by pressing the checkmark button on the right side of the prompt.

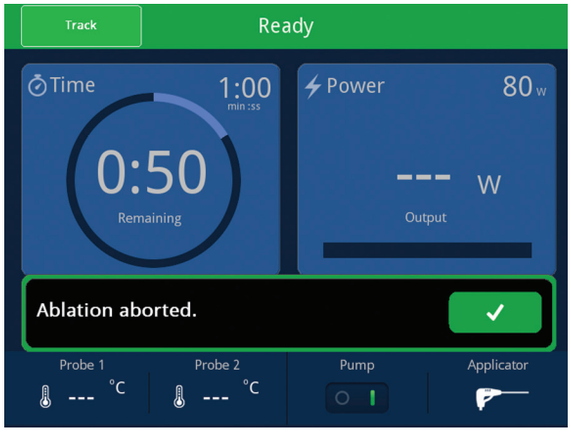


6.1.6 Ablation Aborted

The system will stop an ablation and display a dialog when the user manually terminates an ablation by pressing the Microwave Power Button as shown.

Further progress is blocked until the dialog is acknowledged by pressing the checkmark button on the right side of the prompt.

If it is desired to complete the interrupted ablation, the user must change the Time Setpoint to the appropriate value before resuming. In the example shown, the user should set the time to “0:50” before resuming the ablation.



6.2 Warnings

The system will display an orange-bordered warning dialog when conditions exist that inhibit microwave activation. Progress may not continue until the dialog is acknowledged and the underlying anomalous condition is corrected.

6.2.1 Applicator not Detected

The system will display a warning when the applicator is not detected as shown. An applicator must be connected and the prompt acknowledged by pressing the checkmark on the right side of the prompt to continue with the procedure.

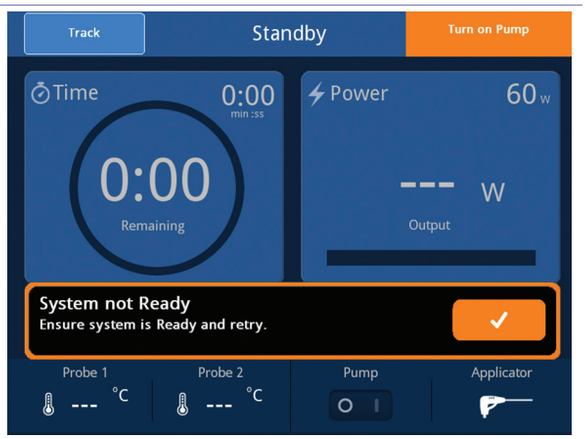
After the warning is acknowledged, the “Connect Applicator” notification will remain until an applicator is connected.

If an applicator is properly connected but the warning or notification persists, it may be necessary to replace the applicator.

6.2.2 System not Ready

The system will display a warning when the user presses the Microwave Power Button when the system is in the Standby state as shown. The warning must be acknowledged and the subsequent notifications followed to continue with the procedure.

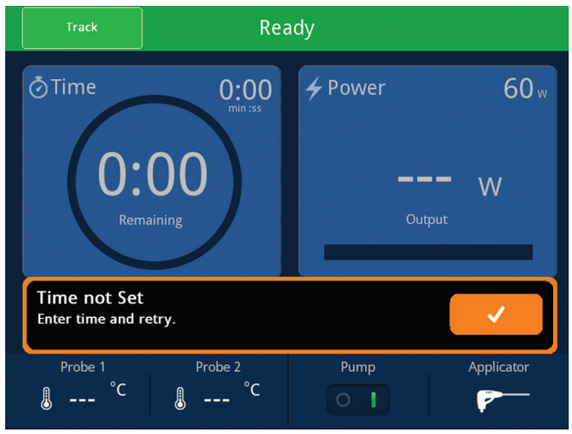
It is necessary to have both the applicator attached and the pump started to enter the Ready state to begin an ablation.



6.2.3 Time not Set

The system will display a warning when the Microwave Power Button is pressed while in the Ready state and the Time Setpoint is “0:00” as shown. The system will not activate until the warning is acknowledged by pressing the checkmark button on the right side of the prompt and a non-zero Time Setpoint is entered.

Use the Set Time Buttons to set an appropriate Time Setpoint before attempting to start an ablation.



6.2.4 Coolant Tempurature >48°C

The system will display a warning when the applicator temperature sensor detects the coolant to be hotter than 48°C as shown. If an ablation is in progress when this occurs, the system will abort and return to Standby.

This will likely occur if ablations are continued after the “Coolant Warm” notification (described in **Section 6.1.4**) is displayed and the warm source is not replaced.

The warning must be acknowledged by pressing the checkmark button on the right side of the prompt and the coolant source replaced before the ablation can be restarted. Replace the coolant source and start the pump to cool the applicator. The “Coolant Hot” notification will be displayed and the system will stay in Standby while the temperature remains high.

The system will transition to Ready and the “Coolant Warm” notification may be displayed when the temperature falls below the threshold. Ablations may resume when in the Ready state even if “Coolant Warm” is still displayed.

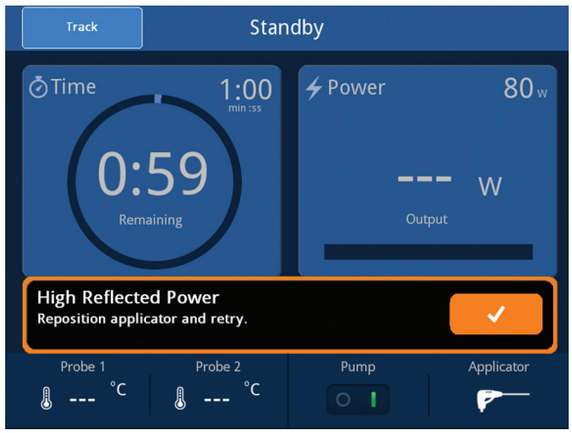
6.2.5 High Reflected Power

The system will display a warning when the reflected power exceeds a preset threshold as shown, and abort the ablation.

If this occurs, microwave energy is unable to be effectively transferred from the applicator tip into the targeted tissue due to desiccation.

Further progress is blocked until the warning is acknowledged.

If a “High Reflected Power” condition is indicated, several sources are possible and warning message will be displayed as shown.



The following are several possible sources leading to the “High Reflected Power” condition:

- The applicators active region may not be fully inserted into the tissue or a transient gas pocket may have formed around the applicator tip. Adjust the positioning of the applicator. Adjust time as necessary. Press Start/Stop button to restart the ablation.
- Connection to the generator may have been lost. Check the connection to the generator. Adjust time as necessary. Press the Start/Stop button to restart the ablation.
- The applicator may be defective. Replace the applicator with a new one.
- If the problem persists, contact AngioDynamics Inc. for technical support.

6.2.6 Invalid Pump Speed

The system will display a warning when the pump speed is outside a preset tolerance as shown, and will abort an ablation if one is in progress.

If this occurs, acknowledge the dialog, open the pump housing cover, and inspect the tubing. Ensure that it is properly loaded as described in **Section 5.3** and retry.

6.3 Errors

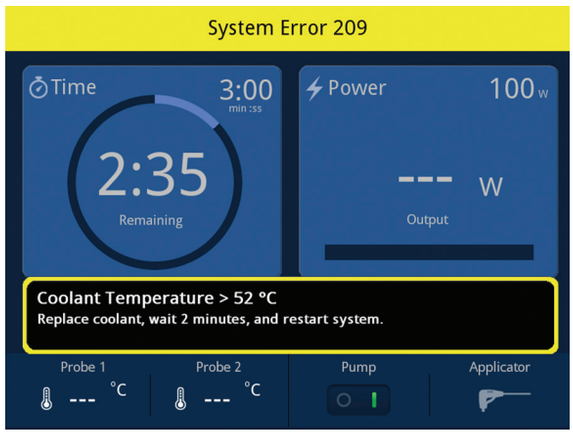
Errors are non-recoverable system failures which require the end user to reboot the system. System errors may be the result of a failure that the end user in general has no ability to correct. System errors will be reported with unique error numbers which must be provided to AngioDynamics to facilitate troubleshooting. In the event of a system error please make note of the events leading up to the error, record the error number, and follow the on-screen instructions.

If such an error occurs, the Solero unit will turn off and disable the microwave source, so there is no risk of immediate harm to the end user or the patient.

6.3.1 Coolant Temperature >52°C (System Error 209)

The system will display an error when the applicator temperature sensor detects the coolant to be hotter than 52 °C as shown. If an ablation is in progress when this occurs, the system will abort and enter the System Error state.

This may occur if the temperature at the applicator tip spikes, or if the coolant flow is restricted or stopped.



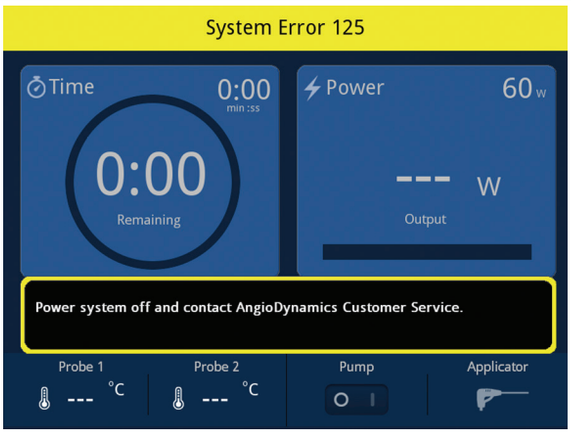
If the pump is stopped due to an error or if the pump housing cover is opened during an ablation, the hot tissue surrounding the tip will cause a sudden spike in temperature because there is no coolant flow. In this case, replace the coolant, and wait two minutes to allow the tissue to cool and then restart the system. If the error immediately recurs, it may be necessary to reposition the tip into cooler tissue or replace the applicator completely.

If the error occurs but the pump continues to run, the coolant should be replaced even though the pump is running, and allowed to circulate for two minutes to reduce the temperature, after which the system should be restarted.

In either case, an ablation may not be resumed until the system has been rebooted and the temperature of the coolant in the tip is below 38°C.

6.3.2 Unrecoverable System Errors

Any System Error other than the Coolant Fault will be the result of an underlying problem with the system that the user will be unable to correct. In this case, the system will display an error similar to the one shown (Example System Error 125).



The only differentiation will be the error number reported in the Status Bar. In this event, the user should note the conditions leading up to the error, record the error number, and report this information to the complaint handling department of AngioDynamics. See **Section 12** for contact information.

System errors are unrecoverable and the system should be shut down. It is not recommended that the system be restarted for further procedures until cleared by AngioDynamics.

SECTION 7 | CARE AND MAINTENANCE

7.1 Cleaning

- Turn the generator off using the Mains Power Switch and disconnect the power cord from the Mains Power Receptacle before cleaning.
- Clean the generator by wiping down all accessible surfaces with a clean cloth that is slightly dampened with 70% isopropyl alcohol cleaning solution.
- The cleaning solution should be allowed to evaporate before the generator is switched on.
- Take care to keep moisture out of connectors and fan openings.

7.2 Maintenance

The generator is not user serviceable. If there is a problem, see the troubleshooting guide in **Section 13.** If the problem persists, contact AngioDynamics for assistance. See **Section 12** for contact information.

7.3 Generator End of Life

Dispose of the generator through standard hospital procedures for electronic devices, or return the Solero Generator to AngioDynamics for safe disposal.

SECTION 8 | SPECIFICATIONS AND STANDARDS

8.1 Essential Performance

The essential performance of the Solero microwave system is maintained during normal use (as defined by the Operator's Manual and the Directions for Use) and during electrical safety and electromagnetic compatibility testing (as defined by EN 60601-1), IEC 60601-1-2, and other relevant collateral standards. For each procedure cycle the system must deliver the energy selected by the user at the start of each treatment cycle. The essential performance is defined as follows:

- The system must delivery energy within stated wattage tolerance of ± 20 % of the user request output power.
- The system must delivery energy within stated time tolerance of ± 1 second of the user request output time.
- The system may only deliver energy with specific user input.
- The prevention of the display of incorrect numerical values associated with the therapy to be performed (IEC 60601-2-6 201.4.3.101).

8.2 Specifications

Item	Specification
AC input Voltage	100-240VAC, 50/60 Hz, auto-sensing
AC input Fusing	AC Input Fuse: T8AH250V
AC input VA	700 VA
Rated Currents	6A max at 100V, 3A max at 240V
Protection	Protectively earthed, Class I A separate earth terminal is provided for installations with floating supply mains
Earth Leakage Current	500 microamperes at 240VAC
Microwave output	2.45 GHz ± 50 MHz 140 W @ 50 Ω
Microwave output power	Adjustable from 60 – 140 in 20 watt increments
Power Tolerance	Power displayed ± 20 %
Output time setting	Adjustable in 10 second increments up to 6 minutes
Time Tolerance	Time displayed ± 1 second
Patient isolation / classification	The generator and applicator are considered type BF applied parts
Duty cycle	Continuous
Dimensions	18.5" (470mm) X W11.4" (290mm) X H13.0" (331mm)
Weight	30 ± 2 lbs
Installation and Use	Portable/Mobile
Transport conditions	Transport the Solero System in environmental temperatures between -29°C (-20°F) and 60°C (140°F), between 10% and 85% relative humidity (non-condensing), and between 50 and 106 kPa
Storage conditions	Store the Solero System in environmental temperatures between 10°C (50°F) and 40°C (104°F), between 30% and 75% relative humidity (non-condensing), and between 70 and 106 kPa
Operating conditions	Operate the Solero System in environmental temperatures between 13°C (55°F) and 27°C (80°F), and between 30% and 75% relative humidity (non-condensing), and between 70-106 kPa

Item	Specification
Mains Power Cable Specifications Domestic (US):	115 VAC Length - 3.05 m Voltage Rating - 125 VAC Current Rating - 10 amps Connector Type - IEC 60320 C13 CE Marking - Yes
Mains Power Cable Specifications International (outside US):	Length - 2.50 m Voltage Rating - 250 VAC Current Rating - 10 amps Connector Type - IEC 60320 C13 CE Marking - Yes
Expected Service Life	The Solero Generator is expected to function normally for 5 years
Medical Electrical Specifications	Type of protection against Electric Shock: Class 1
Suitability for use in oxygen rich environments:	Equipment not suitable for use in the presence of flammable mixtures
Software Revisions	Software revision level is controlled by AngioDynamics Inc. Current revision level is displayed on the instrument's screen during initialization and also can be obtained by contacting AngioDynamics with the serial number listed on the machine

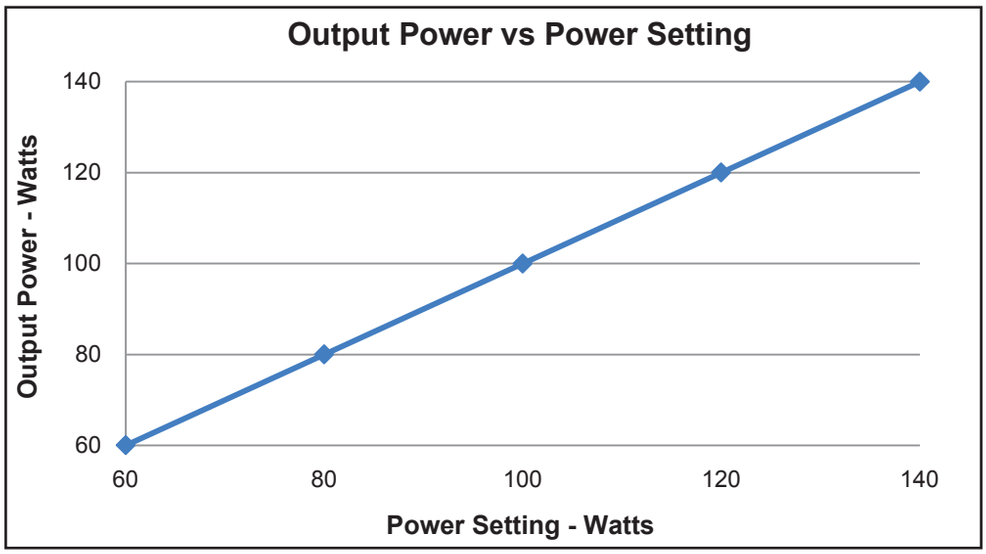


Figure 2: Output Power vs Power Setting into Matched 50Ω Load.[1]

1. The power output in the chart was obtained using Bird Technologies 7020 power sensor, 8201 Thermaline 50 Ω load and compatible cabling.

SECTION 9 | ELECTROMAGNETIC COMPATIBILITY (EMC)

9.1 Background

The Solero Microwave Generator has been tested and complies with relevant directives for electromagnetic compatibility of medical electrical equipment in accordance to IEC 60601-1-2 4th edition,

- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If the equipment is used in a residential environment (for which class B is normally required), this equipment might not offer adequate protection to radio frequency communication. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Medical Electrical Equipment requires special precautions regarding EMC and must be installed and put into service according to the EMC information provided below. The Solero system must only be used with the applicators listed in **Section 3**. Failure to do so may result in increased emissions or decreased immunity of the system.
- Portable and Mobile RF Communications can affect Medical Electrical equipment.

The system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary the system should be observed to verify normal operation in the configuration in which it will be used.

9.2 Guidelines for Avoiding, Identifying and Resolving Electromagnetic Effects

This equipment can radiate radio frequency (RF) energy. If it is not installed and used in accordance with the instructions it may affect or be affected by other equipment. While the Solero System has been designed to comply with required standards, there is no guarantee that interference will not occur in a particular installation.

Since the system intentionally applies Microwave energy for procedures, nearby electronic equipment may be affected. If interference is suspected, this can be confirmed by switching the relevant equipment off and on.

Suggested methods of correcting the interference are:

- Increase the separation between the two items of equipment.
- Rearrange the cables to increase the separation between them.
- Connect the equipment into outlets on different circuits.

9.3 Electromagnetic Emissions

The Solero MTA System has been tested and complies with relevant directives for electromagnetic compatibility of medical equipment in accordance to IEC 60601-1-2 4th edition.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions		
The system is intended for use in a Professional Healthcare facility for the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Guidance on Electromagnetic Environment**
RF emissions CISPR 11	Group 2	The system must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected, in particular at 2.45 GHz.
RF emissions CISPR 11	Class A	The system is suitable for use in all establishments other than domestic 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	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliant	

9.4 Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The **Solero MTA System** is intended for use in a Professional Healthcare facility electromagnetic environment specified below. The customer or the user of the **Solero MTA System** 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 100 KHz repetition frequency	+/-2 kV for power supply lines[a] +/-1 kV for input/output lines[a] 100 KHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.[b]
Surge IEC 61000-4-5	+/-1 kV differential mode +/-2 kV common mode	+/-1 kV differential mode +/-2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0.5 cycles @ 0°, 45°, 90°,135°, 180°, 225°, 270°, and 315°. 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase @ 0°. 0% U_T; 250/300 cycles	0% U_T; 0.5 cycles @ 0°, 45°, 90°,135°, 180°, 225°, 270°, and 315°. 0% U_T*; 1 cycle and 70% U_T*; 25/30 cycles[c] 0% U_T*; 250/300 cycles[c]	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Solero MTA System requires continued operation during mains interruptions, it is recommended that the Solero MTA System be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

a The System may produce an error and stop the delivery of microwave power before this level is reached.
b If mains power quality is suspected to be poor, it is recommended to use a filter on AC power input
c The system may shut down during these conditions and automatically recycle the power to the start-up menu.

Guidance and manufacturer's declaration – electromagnetic immunity			
The **Solero MTA System** is intended for use in a Professional Healthcare environment in the electromagnetic environment specified below. The customer or user of the **Solero MTA System** should assure that is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80 MHz 6 Vrms in ISM bands between 150 kHz to 80 MHz 80% AM at 1 kHz	[V1] = 3 Vrms [V1] = 6 Vrms in ISB bands	Portable and mobile communications equipment should be separated from the Solero MTA System by no less than distances calculated below. d= 3.5/V1 √P 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	[E1] = 3V/m	d= 3.5/E1 √P 80 MHz to 800 MHz d= 7/E1 √P 800 MHz to 2.7 GHz where P is max power in watts and d is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance levels V1 and E1 in each frequency range.[b] Interference may occur in the vicinity of equipment containing a transmitter.
NOTE 1: At 80 MHz to 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.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, Amateur radio, AM and FM, radio broadcasts an TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters an electromagnetic site survey should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Solero MTA System. b Over the frequency range from 80 MHz to 2.7 GHz, field strengths should be less than [E1] V/m.			

9.5 Recommended Separation

Recommended separation distances between portable and mobile RF communications and the Solero Microwave MTA System.

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

Maximum Power of Trans Rated maximum output power of transmitter W mitter (W)	**Separation distance according to frequency of transmitter m Separation**		
	150kHz to 80 MHz d = [3.5/V1] √P	**80MHz to 800MHz d = [3.5/E1] √P**	**800 MHz to 2,7 GHz d = [7/E1] √P**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated 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: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- Recommended separation distances between the system and mobile RF communications equipment should be strictly respected for proper functioning of the equipment. If another electrical medical device must be placed on or near the equipment, check correct operation of the device prior to use.
- The equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment as recommended above, according to the maximum output power of the communications equipment.
- For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated 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.
- Recommended separation distance
  - d = [3.5/V1] √–P
  - d = [3.5/E1] √–P 80 MHz to 800 MHz
  - d = [7/E1] √–P 800 MHz to 2.7 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 meters (m).

  Field strengths V1 and E1 from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Immunity to Proximity Fields from RF Wireless Communication Equipment						
Test Frequency (MHz)	**Band[a] (MHz)**	**Service[a]**	**Modulation[b]**	**Max Power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380-390	TETRA	Pulse[b] Modulation (18 Hz)	1.8	0.3	27
450	430-470	GMRS 460[c] FRS 460	FM[c] ± 5KHz deviation 1KHz sine	2	0.3	28
710	704-787	LTE Band 13 17	Pulse[b] Modulation 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse[b] Modulation (18 Hz)	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800 CDMA 1900 GSM 1900 DECT TE Band 1,3,4,25; UMTS	Pulse[b] Modulation (217) Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse[b] Modulation (217) Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse[b] Modulation (217) Hz	0.2	0.3	9
5500						
5785						

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a For some services, only the uplink frequencies are included.
b The carrier shall be modulated using a 50% duty cycle square wave signal.
c As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

SECTION 10 | WARRANTY AND CONTACT INFORMATION

10.1 Warranty Statement

LIMITED WARRANTY FOR AngioDynamics PRODUCTS

(This warranty applies to all AngioDynamics, Inc. Products including its Solero Generators and Accessories. “Purchaser” as used herein refers to any individual or entity that purchases any AngioDynamics, Inc. Product from AngioDynamics, Inc. or its authorized representative.)

1) AngioDynamics, Inc. agrees to repair or replace (at AngioDynamics, Inc.’s sole discretion) any AngioDynamics Product it sells that is proven to have a material defect in material or workmanship and of which AngioDynamics, Inc. is notified in writing prior to its expiration date, if applicable, or prior to the date indicated on the warranty card accompanying the Product. If the Product does not have an expiration date or if no warranty card is available, AngioDynamics, Inc.’s obligation to repair or replace the Product shall not exceed 12 months from the receipt of such Product by the individual or entity originally purchasing such Product from AngioDynamics, Inc. directly. Purchaser’s sole and exclusive remedy against AngioDynamics, Inc., and AngioDynamics, Inc.’s sole and exclusive liability, shall be the repair or replacement of the AngioDynamics, Inc. Product in accordance with this limited warranty.
2) AngioDynamics, Inc. Products contain no user-serviceable parts. If servicing is required the products must be returned to AngioDynamics, Inc. and may only be returned with the prior written approval of AngioDynamics, Inc. Any such approval shall reference a Service Order number issued by AngioDynamics, Inc. Customer Service. Shipping and transportation costs, if any, incurred in connection with the return of defective Product to AngioDynamics, Inc. shall be the responsibility of the Purchaser. If the AngioDynamics, Inc. Product is determined, in AngioDynamics, Inc.’s sole discretion, to be defective, shipping and transportation costs will be reimbursed by AngioDynamics, Inc. to the Purchaser.
3) Except for the express limited warranties set forth in Section 1 above, AngioDynamics, Inc. grants no warranties for AngioDynamics, Inc. Products, express or implied, either in fact or by operation of law, by statute or otherwise, and AngioDynamics, Inc. specifically disclaims any implied warranty of quality, warranty of merchantability, warranty of fitness for a particular purpose or warranty of non-infringement.
4) AngioDynamics, Inc.’s liability under these warranties shall be limited to a refund of the Purchaser’s purchase price or repair or replacement of the Product. In no event shall AngioDynamics, Inc. be liable for the cost of procurement of substitute goods by the Purchaser or for any special, consequential or incidental, damages for breach of warranty.
5) AngioDynamics, Inc. shall not be liable, expressly or implied, for:
    a) Repairs or modifications performed other than by AngioDynamics, Inc. or an AngioDynamics Inc. authorized repair facility.
    b) Use in any manner or medical procedure, other than that for which it is designed. Either of which shall void this warranty.

SECTION 11 | SYMBOLOGY

11.1 Explanation of Symbols

Symbol	Description
	Consult accompanying instructions.
	Protective Earth Ground
	On (Power switch, Pump)
	Off (Power switch, Pump)
	Time (screen)
	Power (screen)
	On/Off button (generator)
	Type BF equipment
	Caution
	Identifies the Equipotential Connection (Power Unit)
	Separate Collection
	Fuse
	Non-ionizing radiation
	Footswitch
	Temperature Probe
	Applicator

Symbol	Description
℞ ONLY	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
UPN	Product Number
REF	Catalog Number
X number	Quantity of the Contents
	Legal Manufacturer
	Keep Dry
	Temperature Limitation
	Humidity Limitation
	Atmospheric Pressure Limitation
	Fragile, handle with care
	This way up
	Stacking limit by Mass
	Date of Manufacture
SN	Serial Number
	Recyclable Packaging
CE 2797	A mandatory mark for products approved for sale in the European Union accompanied by the notified body registration number
EC REP	EU Authorized Representative

V	A	Hz	KHz	MHz	GHz	W	°C
Volts	AMPS	Hertz	Kilohertz	Megahertz	Gigahertz	Watts	Celsius

SECTION 12 | INFORMATION AND REGISTRATIONS

AngioDynamics, Inc.
26 Forest Street.
Marlborough, MA 01752
United States

Telephone: 1-508-698-7990
Fax: 1-508-658-7981

Hardware Services:
+ 1-866-883-8820
H.S. Fax: + 1-518-932-0660

EC REP AngioDynamics
Netherlands BV
Haaksbergweg 75
1101 BR Amsterdam
The Netherlands

Telephone: +31(0)20 753 2949
Fax: +31(0)20 753 2939

CE 2797

Intertek Medical Electrical Equipment & Devices	ETL listed mark is proof of product compliance to North American electrical safety standards.
Conforms to:	IEC 60601-1 Edition 3.1, General requirements for safety – Section 1: Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-2 Edition 4.0, General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests IEC 60601-2-6 particular requirement for safety – specification for microwave therapy equipment IEC 60601-1-6 Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability IEC 62366 Medical Devices - Application of Usability Engineering to Medical Devices IEC 62304 MEDICAL DEVICE SOFTWARE -SOFTWARE LIFE CYCLE PROCESSES CSA C22.2#60601-1 3rd Edition Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

SECTION 13 | APPENDIX A: TROUBLESHOOTING

13.1 Troubleshooting

Typical Generator use issues are discussed in **Section 6**. See the troubleshooting information below for cases not covered by **Section 6**.

Problem	Troubleshooting
Nothing happens when the power switch turns on	Wait 60 seconds for the screen to turn on. If the fan is not audibly running, check the mains power cable, the electrical outlet to which it is connected, and all fuses. If the system will still not turn on, then contact AngioDynamics for technical support.
System is on, but the screen is blank	Switch the power off, wait five seconds, then switch it back on again. If the display remains blank, then contact AngioDynamics for technical support.
Standby screen is displayed, but the screen buttons are unresponsive	Switch the power off, wait five seconds, then switch it back on again. If the buttons continue to be unresponsive, then contact AngioDynamics for technical support.
System does not progress to Standby screen	If the system does not move beyond the initialization screens described in **Section 5.1**, disconnect the applicator if it is attached, and switch the power off, wait five seconds, then switch it back on again. If the system does not progress to the Standby screen again, then contact AngioDynamics for technical support.
Language-change selection defaults back to English	If after following the instructions in **Section 5.3**, the language display remains in English, switch the power off, wait five seconds, then switch it back on again, and try to change the language again. If the problem persists, then contact AngioDynamics for technical support.
Tone sounds continuously	Switch the power off, wait five seconds, then switch it back on again. If the condition recurs then contact AngioDynamics for technical support.
There is no system function (the system is non responsive) and no system error message appears	Switch the power off and then contact AngioDynamics for technical support.
Fluid leak	Check for a line rip or tear in the disposable portion of the system. Replace the disposable with a new sterile device as outlined in **Section 5**.
Fuse is triggered	Contact AngioDynamics for technical support. The generator is not user-serviceable.