NanoKnife®

User Manual

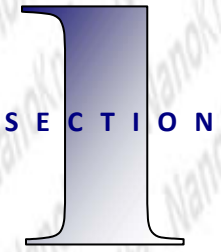
United States Edition

AngioDynamics®

NanoKnife®
User Manual

CONTENTS

INTRODUCTION



1.1 Overview

The NanoKnife System transmits non-thermal energy from the NanoKnife Generator to electrodes placed in a target area. The electrodes work in a two-pole operating mode, and up to six electrodes can be placed at a fixed distance apart in soft tissue to create several two-pole electrode configurations.

Intended Use: The NanoKnife System with six outputs is indicated for surgical ablation of soft tissue.

Components

The NanoKnife System includes multiple components. The first component of the system is the *Generator*. The Generator operates outside of the sterile field. The second component of the NanoKnife System is a *Footswitch* for the Generator. The footswitch connects to the Generator and also operates outside the sterile field. The last component of the NanoKnife System is the single-use, disposable *Electrode*. The electrodes operate in the sterile field and are packaged and shipped sterile. The NanoKnife System has six probe outputs, which allow Users to connect up to six electrodes at one time. Only one pair can be operated at a time. See Section 5.1 "System Operation" for more details.

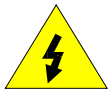
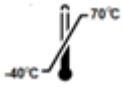
Sections

The NanoKnife User Manual contains *Sections* that are progressive. Read this User Manual thoroughly before operating the system. Do not hesitate to contact your local supplier or the manufacturer in case of doubt on the correct usage of the system.

1.2 Symbols

As with any custom software, the NanoKnife System uses specific symbols and icons. The following is a list of the standard symbols and icons used in this manual. All of the symbols used on the NanoKnife System are in conformity with CEI 62-5 Directives.

1.2.1 Standard Symbols

Symbol	Meaning	Location
	BF Applied Parts (Output separated from earth)	Printed on the data plate, on Generator's back panel.
	Protection Ground Outlet	Marks protection ground. Check inside the device.
	Dangerous High Voltage	Marks every part inside the Generator where a dangerous High-Voltage potential difference might be present, except main voltage.
	Caution: Indicates that the User should read the accompanying documentation in order to understand and/or correctly use the part marked by the symbol.	On the LCD display and data plate
	Open: When a main switch is pressed in the position marked by this symbol, the Generator is switched OFF.	Printed on the main switch
I	Closed: When a main switch is pressed in the position marked by this symbol, the Generator is switched ON.	Printed on the main switch
	Alternating Current: Indicates the kind of current required to be supplied.	Printed on the data plate
	Generator and all its parts should be disposed of according to local regulation for disposal of electronic devices.	Printed on the data plate
	Manufactured By	Printed on the data plate
	Keep Dry	Printed on the crate label
	Transport and Storage Temperature	Printed on the crate label

Symbol	Meaning	Location
	Defibrillator Proof (Body protected)	Printed on the front of the Generator in between the probe connectors
	Federal Communications Commission	Printed on the data plate
	European Conformity Marking with notified body identification number	Printed on the data plate

1.2.2 Specific Part Symbols

Symbol	Meaning	Location
	USB Port Connector, for USB storage device (e.g., USB Flash Drive). It is not recommended to connect any other kind of device.	On the side of the console
	Console Power ON Indicator It is lit when the Console is turned ON.	Above console's keyboard
	Caps Lock Keyboard Indicator If lighted, the keyboard writes in capital letters.	Above console's keyboard
HDD	Hard Disk Driver Status Indicator It is intermittently lighted when the Hard Disk Driver is operating.	Above console's keyboard

1.2.3 Icons

Icons are image files that are meant to resemble the task you wish to complete and will launch that task when "clicked" or are graphical User interface elements that provide options.

Icon	Function	Description
	Generator	User login icon
	Radio or Option Button	Various procedure screens on the console allow the User to choose only one of a predefined set of options. When the User selects a radio button, any previously selected button in the same group becomes deselected.

SAFETY INSTRUCTIONS

2.1 Overview

The Generator must be operated by trained personnel only.

The Safety Instructions included in this manual are divided into "Warnings" and "Precautions":

Warnings are safety instructions that, if neglected, might lead to serious adverse events involving the patient, User, any other person or the environment.

Precautions are safety instructions that, if neglected, might lead to undesired events, of marginal or negligible severity, that might involve the patient, User, any other person, or might lead to a failure of the device.

Federal or USA law restricts the use of the system by or on the order of a physician.

Intended Use: The NanoKnife System with its six outputs is indicated for the surgical ablation of soft tissue.

2.2 Safety Features of the Generator

The Generator incorporates the following safety features to assist the User in delivering a safe application:

a. Output Current Restriction

When the Generator senses that the current between the electrodes exceeds the operating parameters, the pulses are aborted. This safety feature protects against applying output energy that exceeds maximum current settings.

b. Double Trigger Foot Pedal

The system incorporates a double trigger foot pedal system that prevents accidental delivery of procedure pulses. The foot pedals require the User to first arm the system by depressing the "Arm" foot pedal, and then sequentially, depressing the "Pulse" foot pedal within 10 seconds of arming to deliver energy to the patient.

c. Test Pulse

After electrodes are placed and prior to the procedure, the Generator sends a low-energy test pulse to the ablation site to confirm the tissue impedance is within an acceptable range. This prevents initiating a procedure if the probes are too far apart or too close together.

2.3 Contraindications

Procedures based on high-voltage pulses are not recommended in the following cases:

- Ablation of lesions in the vicinity of implanted electronic devices or implanted devices with metal parts.
- Ablation of lesions of the eyes, including the eyelids.
- Patient history of Epilepsy
- Recent history of Myocardial Infarction.

2.4 Warnings

2.4.1 Arrhythmia Risk

- Patients with Q-T intervals greater than 550 ms (milliseconds) are at an increased risk for inappropriate energy delivery and arrhythmia. Verification of proper function of a synchronization device before initiating energy delivery is essential in these patients.
- Asynchronous energy delivery (240 PPM (Pulses Per Minute) or 90 PPM modes) might trigger atrial or ventricular fibrillation, especially in patients with established arrhythmias or structural heart disease. Ensure that interventions (defibrillator, etc.) and appropriately trained personnel are readily available for dealing with cardiac arrhythmias.
- Using QRS synchronization devices whose output is not compatible with the specifications listed in this manual may result in ventricular fibrillation.

- Patients with established arrhythmias (i.e., Atrial Fibrillation, PVC's) should be carefully monitored for proper synchronization during energy delivery.
- Adequate precautions should be taken for patients with implantable electrical devices.

2.4.2 Electrodes

- To avoid risks of infection for the patient and for the operators, always maintain the electrodes' protective packaging (cap, tubes, etc.) when the electrodes are not placed in the patient.
- To preserve the electrode's sterility do not remove the electrodes from the packaging until the User is ready to apply the electrode to the patient.
- Do not use the electrodes after the expiration date printed on their packaging. Observe the electrodes manufacturer's specific instructions (e.g., printed on the electrodes' packaging).
- Only use AngioDynamics electrode probes with the NanoKnife System Generator (BF Applied Parts Classification).
- Maintain electrical separation of the electrodes from safety ground by doing the following:
    a. Disconnect any electrode from the Generator that is not applied to the patient.
    b. Avoid any clamping of the electrode's cable, unless explicitly instructed or authorized by the electrode's manufacturer.
    c. Do not connect any devices (e.g., measurement) to the electrodes unless they have been supplied by and specifically indicated for such a use by the manufacturer.

2.4.3 Electrocution Hazard

- Electrocution Hazard! The Generator internally produces voltages that are dangerous and may be fatal. The Generator does not contain parts serviceable by the User, and should not be opened.
- Do not use the Generator in the presence of flammable or explosive gas mixtures.
- For electrical safety, the Generator needs grounding. Use only medical level main power supply cords, e.g., those supplied by the manufacturer.
- The Generator should be used by trained personnel only.
- Before plugging the Generator to the main, ensure that the main power cords are not damaged. Replace them if any damage is noticed—main cords *cannot* be repaired.
- Do not connect or disconnect the *Generator* from the main power cord with wet hands.
- Confirm that the main power cord will be connected to a properly grounded electrical outlet.

- Whenever necessary, replace Generator fuses only with spare fuses specified in this manual, see Section.
- Maintenance should be carried out only by trained personnel. The Generator must undergo periodic preventative maintenance as specified in the Maintenance and Service section.
- The NanoKnife User Manual is a fundamental part of the Generator and should always accompany it. Users must refer to this manual for correct and complete information on the use of the Generator.

2.5 Precautions

- Electrodes that are not parallel to each other may result in an incomplete ablation.
- Inappropriately positioned electrodes or metal implants in the field may distort the desired IRE ablation field.
- Read this User Manual thoroughly before operating the Generator. Do not hesitate to contact your local supplier or the manufacturer in case of doubt on the correct usage of the Generator.
- Electrodes are subjected to potentially harmful electric energy. Do not touch the metal part of the electrodes while a procedure is in progress.
- The effects of IRE on a fetus are not known. Procedure on pregnant women should be contemplated only after ensuring that the procedure benefits outweigh the risks.
- Procedure safety and efficacy may be affected if electrodes other than those supplied by AngioDynamics or by an authorized distributor are used.
- Unless there is a reasonable doubt that a site has been ablated ineffectively, repeating an ablation on the same site is not advisable, since it is not believed to increase procedure efficacy.
- Avoid unnecessarily high voltage or excessive number of pulses.
- Use of operator-defined parameters increases the risk of ineffective procedures or post-procedure complications, with respect to validated standard procedures.
- Avoid short-circuiting the electrodes when delivering pulses. Electrode to electrode contact or electrode to electrode spacing less than 5 mm (millimeters) may result in short circuiting during energy delivery resulting in incomplete ablation.
- Ensure the Generator is connected to the proper main power supply value (see Section 9.4 and that the main power supply outlet is able to supply the required power.
- Do not use the Generator if a malfunction is suspected. Contact the manufacturer or the local authorized supplier.
- Avoid intentional or accidental spilling of liquids on the Generator. In particular, do not keep containers of liquids on the Generator. Do not handle the equipment with wet hands.

- Store the Generator away from direct sunlight, heat sources, and dust; in particular, do not expose the LCD display to direct sunlight for long periods of time.
- Respect environmental operating and storing conditions, as specified in Section 10.4. Ensure that nothing obstructs the ventilation grids, which are on the rear panel of the Generator and also under the console, in order to allow the correct ventilation of the internal circuits.
- Avoid moving the device when powered ON. Avoid jarring the equipment during transport.
- Avoid scratching the LCD display.
- Before carrying out any cleaning of the device, power it OFF and disconnect the main cord from the Generator.
- Turn OFF the Generator before connecting external devices.
- Connect only devices complying with relevant regulations.

2.5.1 Side Effects

Side effects of procedures based on the administration of high-voltage pulses are reported in literature. These include involuntary muscle contraction at the time of the electric pulse, which stops at the end of the pulse.

SYSTEM COMPONENTS

SECTION 3

3.1 Overview

The NanoKnife System Generator utilizes single-use disposable electrode probes to transmit energy from the Generator to a target ablation area.

The Generator Trolley in

Figure 3-1 includes the following:

- LCD Display
- Console and Keyboard
- Power Unit and Power Cord
- Double Footswitch/Foot Pedal

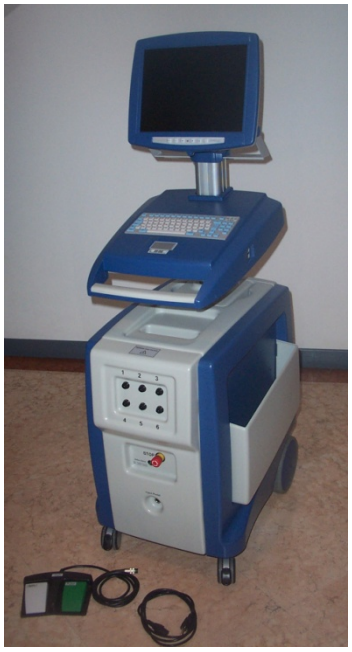


Figure 3-1: Generator Trolley

3.2 Generator Description

The User's interaction with the Generator is similar to utilizing a personal computer; the User operates the Generator through the console and LCD display. The console includes a conventional keyboard with *Power-On*, *Caps Lock* and *Hard Disk Drive* function light indicators, a touch pad with two buttons, and two USB ports located on the right side panel.

The details of the Generator front/right sides, including the console are shown in Figure 3-2 while the names of the Generator elements are listed in Table *3-1*.

3.2.1 Generator Front/Right Side Elements

Table 3-1: Generator Front/Right Side Elements

Figure 3-2	Component	Description
1	LCD Display	Displays a graphic User interface
2	Display Control Button	Adjusts the display settings
3	Keyboard	Serves to input data and interact with generator
4	Indicators	Show current status of the generator
5	Tray	Provides a place for needed equipment
6	Side Pockets	Designed as a container for the pedal, electrodes and other accessories, such as the manual
7	Front Wheel Brakes	Each front wheel is supplied with a lever to stop the wheel; a lowered lever stops the wheel, a raised lever frees the wheel

Figure 3-2: Generator Front/Right Side Elements

3.2.2 Generator Front/Lower Panel Elements

There are four front/lower panel elements of the Generator as shown in Figure 3-3 and described in Table 3-2.

Figure 3-3: Generator Front/Lower Panel Elements

Table 3-2: Generator Front/Lower Elements

Refer to Figure 3-3	Component	Description
1	Six Electrode Connectors	Plug-in for electrodes
2	Red Stop Button identified by the label "STOP"	When pressed, internally disconnects the electrode connectors. Allows interruption of procedure without removing electrodes from the patient. Accumulated energy in the power component is discharged. Rotate clockwise to release.
3	Stop Button status indicator	When lighted indicates that Stop button is released and procedure can commence. If NOT lighted, the Stop button is engaged and unit is in safety mode. Stop button must be released to proceed with procedure.
4	Pedal Connector, identified by the label "Input Pedal"	Connection for the double trigger foot pedal

3.2.3 Generator Power Unit's Back/Lower Panel Elements

The power unit of the Generator performs all procedure activity for ablation delivery and measurement. The operator interacts with the power unit through the double foot pedal that starts the procedure. Figure 3-4 and Table 3-3 provide details on the Generator's back view features. The back panel of the Generator's power unit incorporates the power supply switch and connectors for the power supply unit and external synchronization of the ablation.

Figure 3-4: Generator Power Unit's Back/Lower Panel Elements

Table 3-3*: Generator Power Unit's Back/Lower Panel Elements*

Refer to Figure 3-4	Component	Description
1	Power Supply Group	Groups the main switch, cord connector and protection fuses slide
2	Protection Fuses Slide	Insertion site for protection fuses; allows selection of the main voltage
3	Main Switch	Turns the Generator ON/OFF
4	Cord Connector	Connects the main power supply cord
5	Appliance Data Plate	Indicates the unit name, model, serial number, manufacturer, power supply specifications, and power fuse specifications
6	External Sync Connector	Connects an external synchronization device e.g., QRS detection device

3.2.4 Generator Back Handle

Back Handle – Assists when moving the Generator. The Generator can be lifted from the handle to move it over an obstacle. It is also suitable for winding the Main Power Supply Cord around, see Figure 3-5.

Figure 3-5: Generator Back Handle

3.2.5 Equipment and Supplied Components

Table 3-4 lists the Generator components and supplied quantities.

Table 3-4*: Equipment and Supplied Components*

Quantity	Component
1	Generator
1	Double Foot Pedal
1	Power Cord
Optional	Electrodes (Purchased separately)

NOTE: The Double Foot Pedal is an essential part of the NanoKnife. It is graded IPX-8. It is recommended to use only genuine parts supplied by the NanoKnife's manufacturer or authorized distributor.

3.2.6 LCD Display Controls Description

Each of the seven display control buttons are shown in Figure 3-6 and described in Table 3-5.

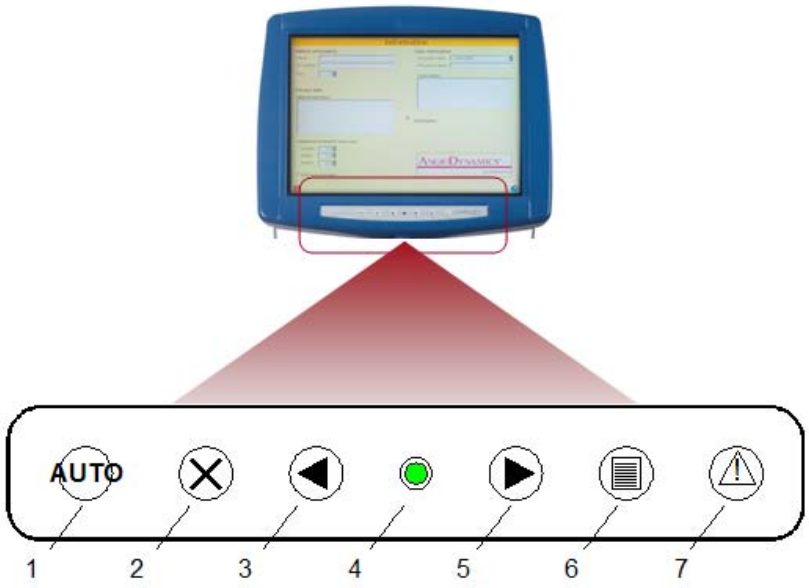


Figure 3-6: LCD Display Control Buttons

Table 3-5: LCD Display Controls Description

Refer to Figure 3-6	Symbol	Function	Description
1	AUTO	Auto Configuration	Press and the monitor will automatically optimize the display position, clock and phase of the display.
2	⊗	Exit/Back	Press to exit the On-Screen Display (OSD) or to return to previous level.
3	◀	Minus	If OSD is active, press to select or adjust OSD options.
4	●	LCD Power ON Indicator	Light displays Green when power is ON.
5	▶	Plus	If OSD is active, press to select or adjust OSD options.
6	▤	OSD Manual	Press to view OSD and select an option.
7	⏻	Power	Power ON/OFF the LCD display. User should not use this button unless the LCD display does not automatically turn on when the Generator is powered up.

3.2.7 LCD Display Settings

The viewing angle of the LCD display ranges from 45° forward to 90° backward. The display is supplied with control buttons to adjust its settings (see Table 3-6 for details.)

Table 3-6: LCD Display Settings

Refer to Figure 3-6	LCD Setting Instructions
1	Press the ▣ button to open the On-Screen Display (OSD) menu.
2	Use the buttons marked ◀ or ▶, to highlight a control, then press the ▣ button to enter.
3	Use the buttons marked ◀ or ▶, to adjust the control to the desired level.
4	Use the ⊗ button to return to previous level.
5	Once finished making all settings, press the ⊗ button to exit the OSD. **NOTE:** The OSD will clear if left idle for a given time (default is 20 seconds). Previous adjustments are retained.
6	At start-up, allow approximately 10 seconds for the video signal to appear.

3.2.8 Console Components

There are six console components on the Generator that are shown in Figure 3-7 and described in Table 3-7.

Figure 3-7: Console Components

Table 3-7: Console Component Description

Refer to Figure 3-7	Component	Description
1	Console Power-ON indicator identified by the symbol	When lighted indicates that the system is switched ON.
2	Caps Lock Indicator identified by the symbol	When lighted indicates that the keyboard's letter keys are in uppercase.
3	Hard Disk Function Light indicator identified by the HDD symbol	When lighted indicates whether the hard disk is currently working.
4	USB Ports Identified by the symbol	Each port is capable of connecting to a printer or other USB device.
5	Touch Pad with two buttons	Moves the screen pointer across the screen to interact with application; two buttons replace conventional right and left mouse buttons.
6	Front Handle	Assists in moving the device.

3.2.9 Electrode Probe Components

The electronic probe components shown in Figure 3-8 are comprised of the following:

1. Active electrode, length adjustable in 0.5 cm increments from 0 – 4 cm via the thumbslide
2. Thumbslide
3. Insulation sleeve
4. 19-gauge needle with depth markers and echogenic needle tip
5. 10-foot connection cable

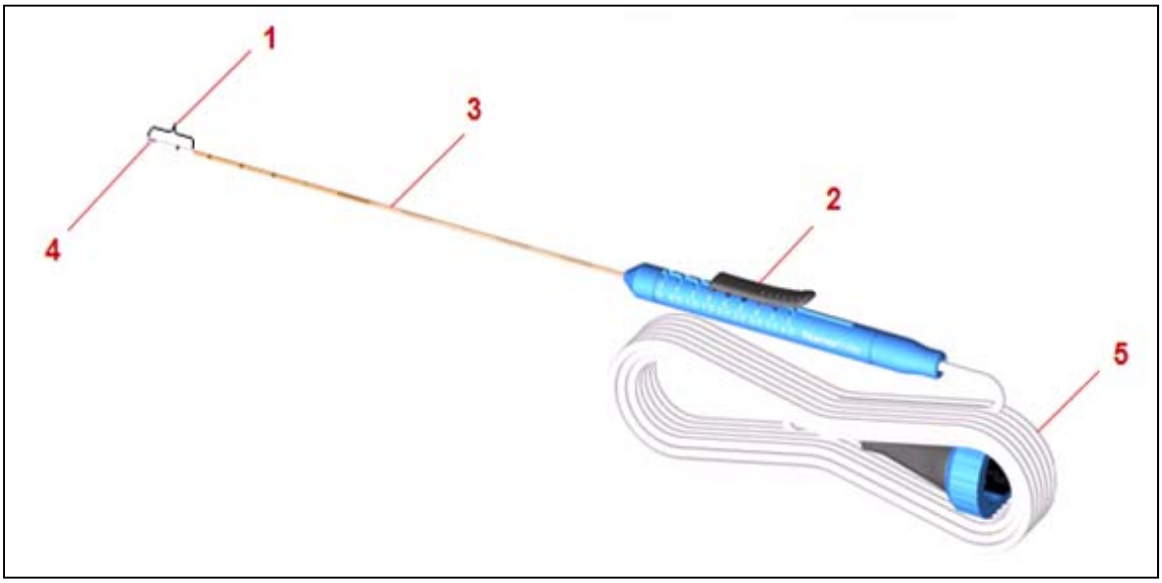


Figure 3-8: Electrode Probe Components

The Single Electrode Activation Probe is Blue, while the standard Single Electrode Probe is White. Both are available in 15 cm and 25 cm lengths. The Blue Single Electrode Activation Probe is required to activate the generator, which will allow other standard Single Electrode Probes to function with it. Only one Single Electrode Activation Probe is required to activate the generator but a minimum of two probes (Blue and White) are required for a procedure to be executed. Depending on the size of the soft tissue area to be ablated, a maximum of six probes can be used in a procedure. Probes may be repositioned after each procedure to cover a larger area, as guided by the generator software.

The Single Electrode Probe and Single Electrode Activation Probe are intended for surgical ablation of soft tissue. Please refer to product IFU (Instructions for Use) for detailed electrode probe component information.

INSTALLATION AND START-UP

SECTION 4

4.1 System Location

The Generator must be installed and operated in an environment that conforms to the operating conditions specified in Section 10.4.

The Generator must be installed on rigid surfaces suitable to withstand its weight.

In addition, the Generator must be installed in a way that any surface parallel to the Power Unit's rear panel and in relationship to its ventilation grids, remain at least 5 cm (centimeters) away.

Care must be taken to avoid items (e.g., dust covers) that can occlude the ventilation grids.

WARNING!

The Generator must be connected to the safety ground of the main. The *Main Power Supply Cord* can ensure proper grounding only if connected to properly grounded main system, through suitable main sockets.

WARNING!

The Generator must not be used in the presence of flammable mixtures.

Installation Instructions

- Connect the *Main Power Supply Cord* (supplied by the manufacturer) to the cord connector located on the back panel.

- Connect the plug to a main outlet with protective ground.
- Turn ON the Generator via the *Main switch* of the *Power Supply Group*, located on the power unit's back panel. The system is ON when the main switch is pressed in "I" position. When the switch is pressed in the "O" position, the device is OFF.

4.2 Generator Start-Up and Warm-Up

To start up the system proceed as described below:

a. Move the *Main* switch located at the back panel of the power unit to position "I". The Green *Power-ON* indicator on the front panel lights up, while the console starts loading the operating system.

b. Allow about 10 seconds for the video signal to appear on the LCD display.

c. Check that the *STOP* button status Indicator, on the Generator's front panel, is lit Green. If not lit, rotate the Stop button knob clockwise, as indicated on the knob to release the *Stop* button.

d. The operating system will automatically begin its start-up process and self checks. It will run through the following self checks before the User is able to begin the procedure process:

- Initializing Device
- Checking Connections
- Checking Status
- Checking Memory
- Device Setup
- Testing Charge
- Test Delivery

A screen will display each check's progress until the Generator completes the Start-up self test and all checks pass successfully, see Figure 4-1 and Figure 4-2.

Figure 4-1: Start-Up Screen in Progress

Figure 4-2: Start-Up Screen Successfully Passed All Check Points

If one of the Generator's self tests fails, an error message will be displayed. Figure 4-3 is an example of an error message. The User must then click OK, which will shut down the generator, so that it can be restarted.

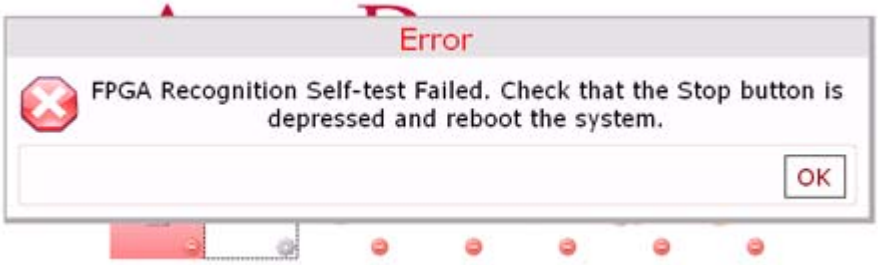


Figure 4-3: Example of Error Message If a Self Test Fails

If all self tests are successful, the *Information* screen (see Figure 5-1) then appears next on the LCD display.

SYSTEM OPERATION

5.1 Overview

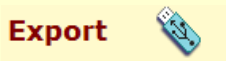
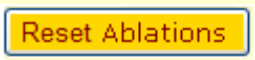
Procedure Main Steps

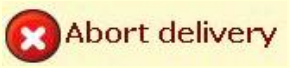
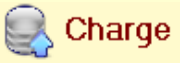
An overview of the ablation procedure process is listed below:

1. Enter patient information.
2. Enter lesion and target size.
3. Connect probes to the Generator by means of the electrode connectors. At least one activation probe is required.
4. Make probe selection/configuration.
5. Define ablation area.
6. Place probes at targeted ablation site.
7. Confirm or specify procedure pulse settings.
8. Deliver test pulse button on the console.
9. Start the procedure by using the double foot pedal.

The details are explained in following paragraphs starting with a description of what each icon symbol represents that appear in the screens (see 5.1.1 Table of Buttons), and then followed by the Information Screen (see Figure 5-1).

5.1.1 Table of Buttons

	*Exit* button on the Information screen quits the application and shuts down the generator.
	*About* button on all screens opens the About dialog box, which provides contact information, software, generator firmware, and RFID firmware versions, and TPM serial information.
	*Next* button on all screens takes you to the next screen.
	*Back* button takes you to the previous screen.
	*Settings* button on the Information, Probe Selection and Probe Placement Process screen opens the Settings dialog box, which displays the selected language and Pulse Timing control setting.
	*Export* button on the Information and Pulse Generation screens opens an Export dialog box, which allows the User to save procedure data to a USB Flash drive.
	*Add Row* button on the Probe Placement Process screen allows the User to add a new probe pair pulse sequence to the procedure. When a ***probe pair pulse sequence*** is added, a new line with default parameters is displayed in the table.
	*Delete Row* button on the Probe Placement Process screen allows the User to remove a probe pair pulse sequence from the ablation pulse configuration.
	*Edit* button on Procedure Spreadsheet of the Probe Placement Process screen allows the following: ▪ Activate the +/- buttons to add/remove probe pair pulse sequence. ▪ Allows the editing of the white cells in the procedure spreadsheet.
	*Apply* button on Procedure Spreadsheet of the Probe Placement Process screen allows the User to save the updated settings in the spreadsheet.
	*Autoset Probes* button on the Probe Placement Process screen resets the placement of the probes on the grid to their default settings.
	*Save Ablation* button on the Probe Placement Process screen allows the User to save an ablation marked on the grid.
	*Clear Ablations* button on the Probe Placement Process screen will erase any ablations marked on the grid.
	*Clear Ablations* button on the Probe Placement Process screen will erase any ablations marked on the grid after a procedure has been started.
	*Zoom In* on the Probe Placement Process screen button increase the magnification of the grid view.

	*Zoom Out* button on the Probe Placement Process screen decreases the magnification of the grid view.
	*Adjust Distance* button on the Probe Placement Process screen opens the **Probe Distance Adjuster** – A solver that allows the User to enter probe distances and have them automatically placed on the grid with the smallest, least squares error.
	*Deliver Test Pulse* button on the Pulse Generation screen allows the User to start the delivery of test pulses.
	*Abort Delivery* button on the Pulse Generation screen allows the User to stop the delivery of pulses at any time.
	*New Patient* button on the Pulse Generation screen allows the User to go to the ***Information*** screen to start a new procedure on a different patient.
	*New Probe Selection* button on the Pulse Generation screen allows the User to go to the ***Probe Selection*** screen to do another procedure on the same patient with different settings.
	*Charge* button on the Pulse Generation screen allows the User to charge the generator after the generate discharges to timeout.

5.1.2 Information Screen

The **Information** screen (Figure 5-1) is the first screen displayed when the Generator is powered on and the automatic self-checks are successfully completed. It includes the following four sections: ***Patient Information, Case Information***, ***Clinical Data***, and an ***Institution*** section that are described in following paragraphs.

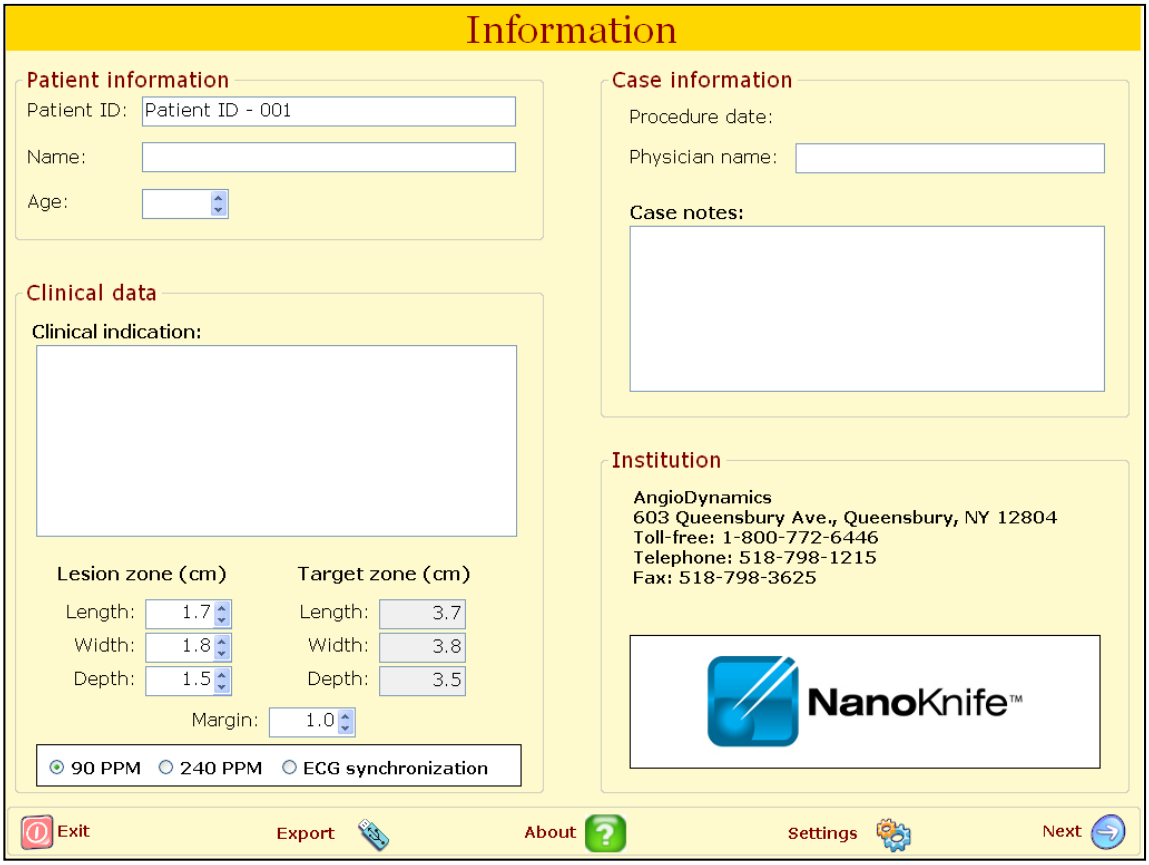


Figure 5-1: Information Screen

NOTE: Information may be inputted through the keyboard, touchpad, and touch screen on the generator to input information. From now on, Select will refer to a click, either via a mouse or the touch pad buttons or by physically touching the screen.

The **Patient Information** section allows the User to specify the following patient data which can be entered by typing text in the appropriate fields.

- The Patient ID number – Is the only "mandatory" field to be filled. The system does not allow the User to proceed if the field is not filled in.
- Patient Name – Optional
- Age (in years) – Optional, can be entered by typing or with the Up/Down arrows.

The **Case Information** section allows the User to enter the following information about the ablation, and can be entered by typing in the appropriate fields.

- Procedure Date – The *Procedure Date and Time* are automatically set by the system.
- Physician Name – Optional
- Case Notes – Optional

The **Clinical Data** section allows the User to type clinical information and tissue specifications in the appropriate fields.

- Clinical Indication Notes – Optional
- Lesion Zone (cm) – (Length, Width and Depth) – Optional, can be entered by typing or with the Up/Down arrows.
- Margin – Optional, can be entered by typing or with the Up/Down arrows.
- Target Zone (cm) – (Length, Width and Depth) cannot be modified by typing and is based on Lesion Zone value plus two times what the value is of the Margin Zone.

The Pulse Timing Control, Figure 5-2, consists of three radio buttons that allow the User to select 90 PPM, 240 PPM, or ECG synchronization (default setting) to set the timing of the pulses.

Figure 5-2: Pulse Timing Control

NOTE: 90 PPM should be selected for soft tissue procedures below the waist and 240 PPM for prostate procedures, otherwise ECG Synchronization (default setting) should be used. A pop-up warning window will appear if User setting is 240 PPM, Figure 5-3.

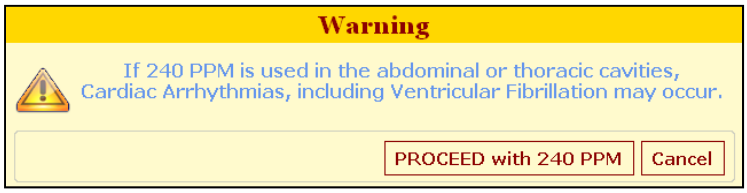


Figure 5-3: Pop-Up Warning Window

The **Institution** section shows the name and contact information of the institution who purchased the system. Only an authorized AngioDynamics Hardware service representative can update this information, Figure 5-4.

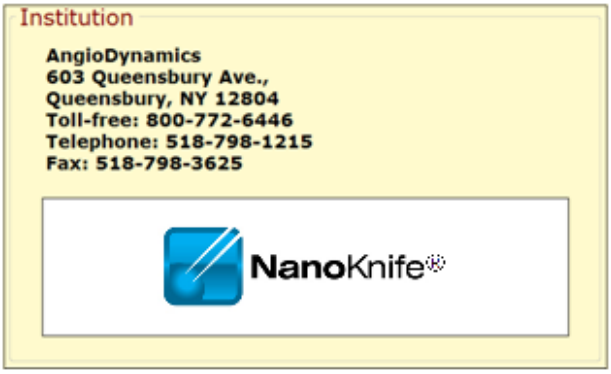


Figure 5-4: Institution Section

To complete the Information screen and progress to the Probe Selection Screen, the User will need to enter the necessary information in the Information screen as described below.

The Patient Information section − Enter Patient ID number which is a required field using any numbering system that the User chooses. Name and Age are not required fields, Figure 5-5.

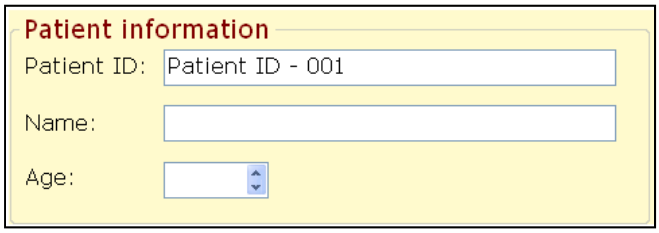


Figure 5-5: Patient Information Screen

If User forgets to enter the Patient ID number and tries to progress to the next screen, a pop-up window appear as illustrated in Figure 5-6. OK must be selected to send the User back to the screen to enter the information. The User cannot proceed until the Patient's ID number entered into the system.

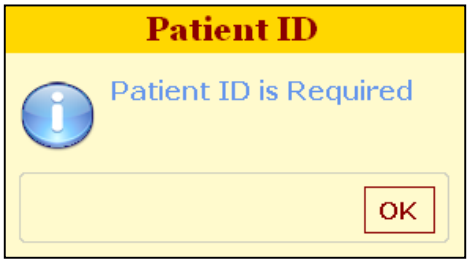


Figure 5-6: Patient ID Number Warning

The Clinical Data section − Clinical indication is an optional field and is used to capture clinical information. The Lesion zone, Margin and Pulse Timing Control are the three areas that will need to be completed in the Information screen by selecting the desired configurations, Figure 5-7.

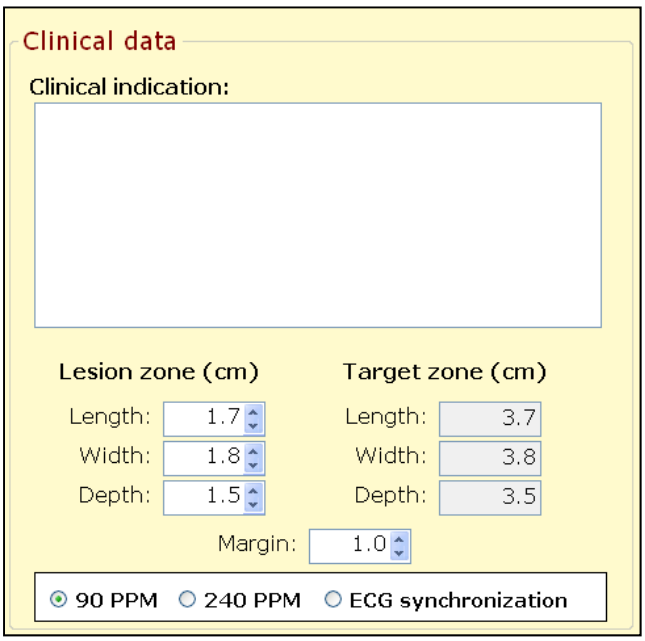


Figure 5-7: Clinical Data Screen

The Lesion Zone (cm) popups allow the User to set the configuration for Length, Width and Depth of the lesion. Standard default settings are at 1.0 cm for each of the three zones as indicated below, Figure 5-8.

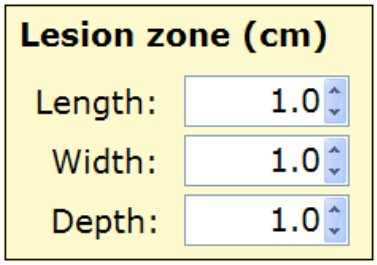
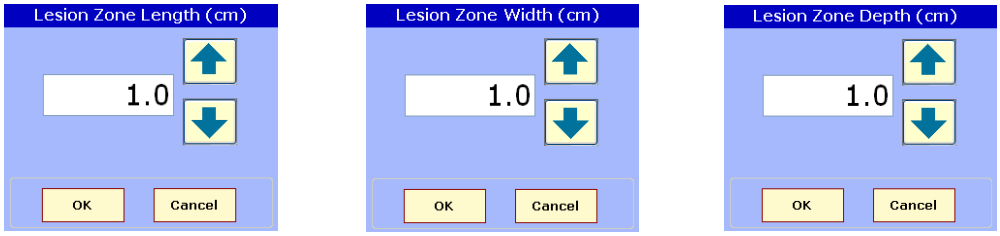


Figure 5-8: Lesion Zone Drop-Down Menu

To change the lesion settings, start with the Length field and change the value by typing entering a new one through the keyboard, using the Up or Down arrow keys on the keyboard, or using the Up and Down arrow keys on the popup. Repeat the process for the Width and Depth fields. The pop-up windows shown below will display a setting for each measurement. Select OK to save the selected dimension or Cancel to return to the previous value, Figure 5-9.



Lesion Zone Length | Lesion Zone Width | Lesion Zone Depth

Figure 5-9: Lesion Zone Settings

- When the Lesion zone is configured and saved, the system automatically sets the Target zone dimensions based upon the margin, Figure 5-10.

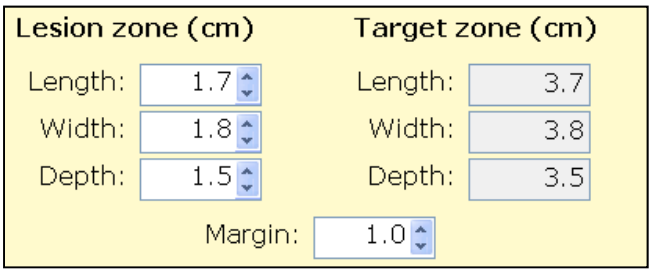


Figure 5-10: Lesion Zone Configured

- The Margin zone is the distance between the lesion zone and the target zone. Its value can be changed through the same methods described in changing the values of the lesion zone fields. Select OK to save the change or Cancel to return to the previous value, Figure 5-11.

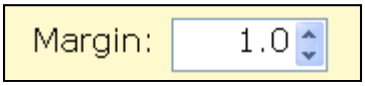


Figure 5-11: Margin Zone

The User can change the Pulse Timing Control setting selection from the default ECG synchronization by selecting on a different radio button, Figure 5-12.

Figure 5-12: Pulse Timing Control Setting

The Case Information section contains the Procedure date and time, which is automatically set. Physician name and Case notes are optional areas to complete, Figure 5-13.

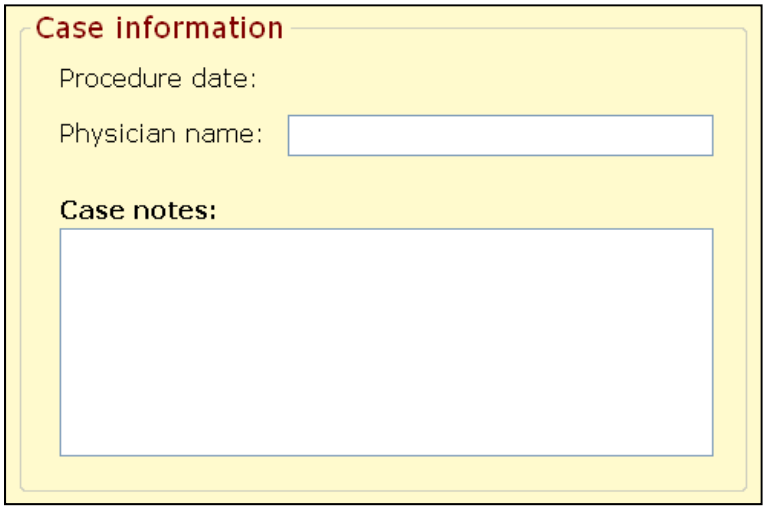


Figure 5-13: Case Information Screen

After completing the Information section, select the next button (Figure 5-14) to proceed to the *Probe Selection screen* to select the probe type configuration for ablation.

Figure 5-14: Radio Buttons

5.1.3 Probe Selection Screen

The Probe Selection screen allows the User to select the number and the configuration of the ablation probes. The screen consists of three sections: Probe Type, Probe Type Side and Top Views, and a Probes Connection Status section Figure 5-15.

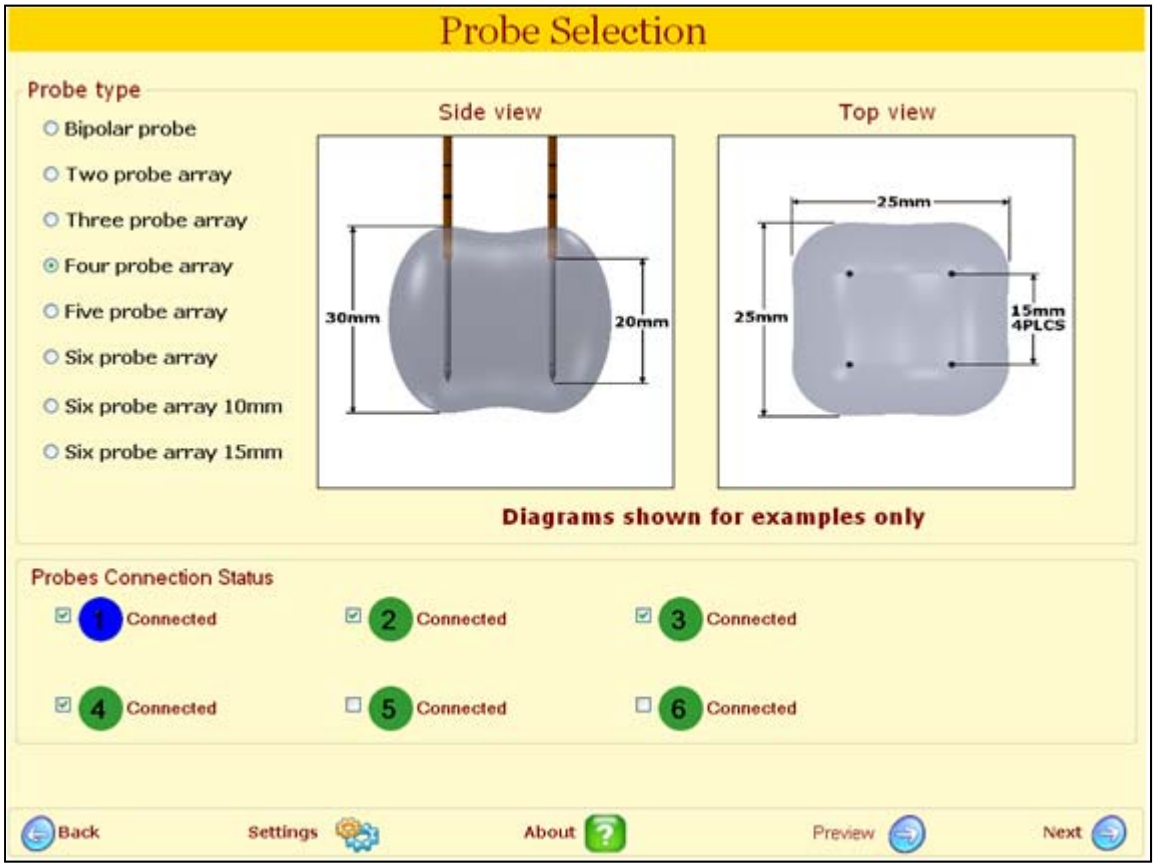


Figure 5-15: Probe Selection Screen
NOTE: Diagram shown for example only; four probe array.

There are eight different options to choose from in this screen as shown in the following pages. Each radio button selection shows a diagram of a side view and top view of the probe placement and estimated ablation size. The User is required to specify one of the probe type configurations for ablation according to the extent of the desired ablation zone, by selecting on the adjacent radio button.

The User is not allowed to select a probe configuration that contains more probes than number of valid probes connected to the generator to progress to the Probe Placement Process Screen (see Section **Error! Reference source not found.**). However, if the User desires to plan a procedure and does not have an exact procedure configuration planned, the User may select the preview button to go to the Probe Placement Process Screen, which will be displayed in a preview mode. (NOTE: The preview button will only be available if there are no probes connected to the generator.)

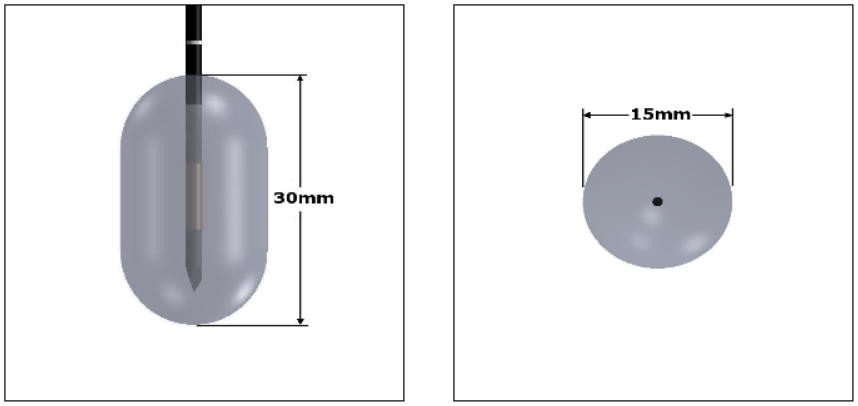
When the User plans a procedure configuration in the preview mode, the User may save the ablation configuration and return to the Probe Selection Screen or the User may return to the Probe Selection Screen to select a different probe array. Also, in preview mode, the system will not allow the user to move to the Pulse Generation screen. The user will have to return to the Probe Selection screen, connect the desired amount of probes, and then proceed to the Probe Placement Process screen via the Next button. Detailed instructions for the Probe Placement Process Screen are in Section **Error! Reference source not found.**.

The **Probe Type** section includes the following eight probe type configurations: Bipolar, Two probe array, Three probe array, Four probe array, Five probe array, Six probe array, Six probe array 10 mm and Six probe array 15 mm. (NOTE: Bipolar probe type is not commercially available. If Bipolar is requested, AngioDynamics must be notified and authorization given from Clinical Sales.)

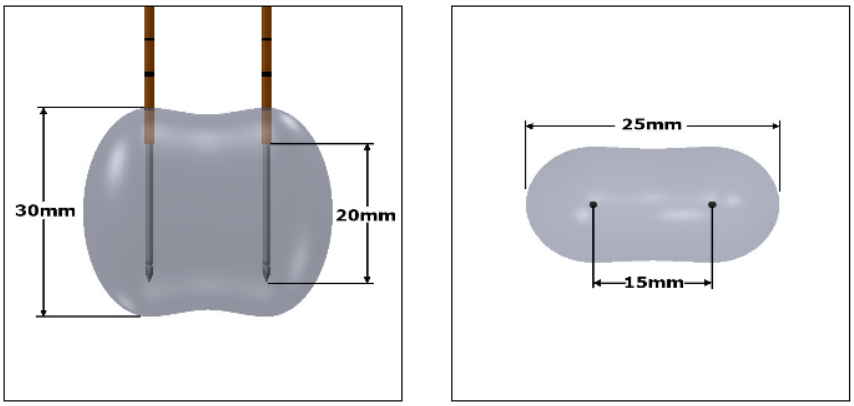
The **Probe Side and Top Views** provide a horizontal and vertical cross-sectional representation of the ablation zone that will be affected by the probe(s) configuration.

Listed below are the eight Probe type options to choose from in the Probe Selection screen Figure 5-15. The User is only allowed to select a probe type that corresponds to the number of valid probes connected to the generator.

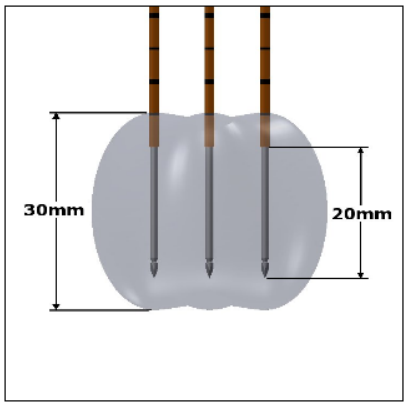
Bipolar Probe

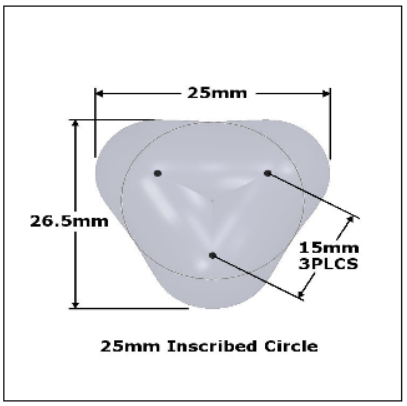


Two Probe Array

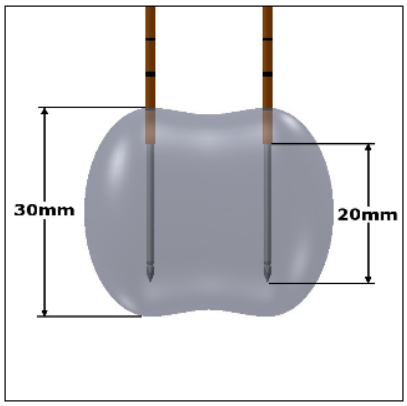


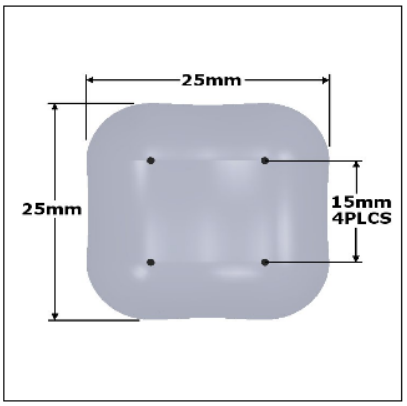
Three Probe Array



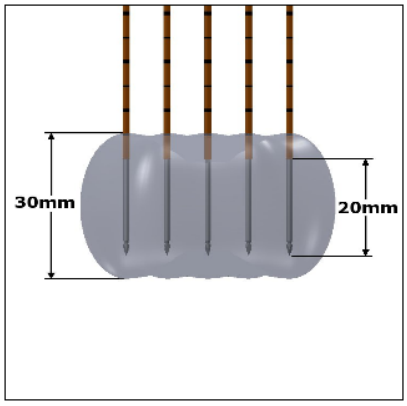


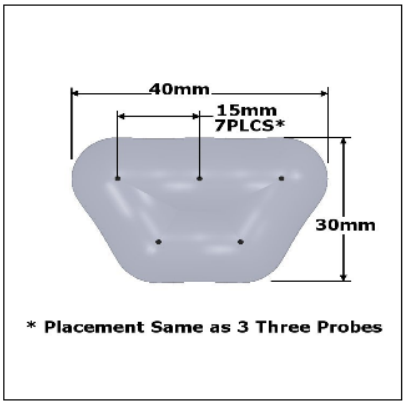
Four Probe Array



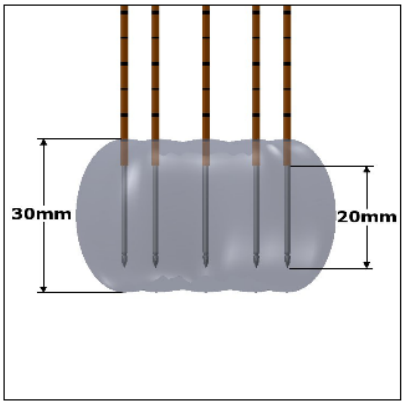


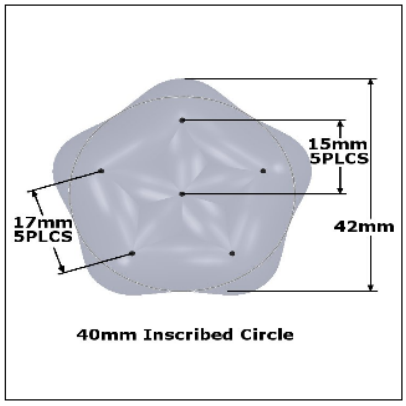
Five Probe Array



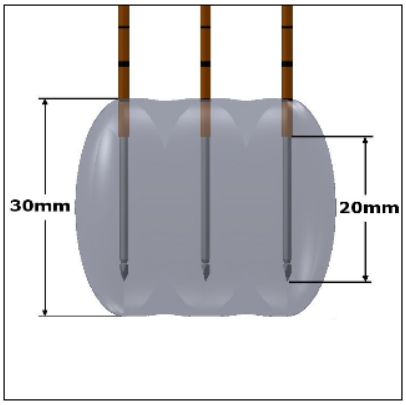


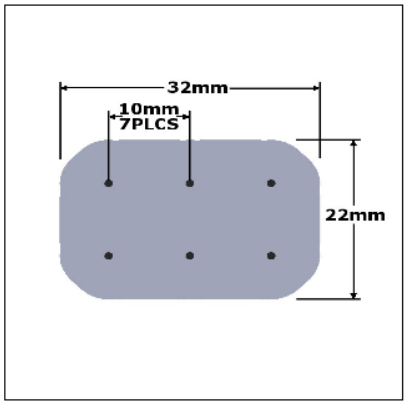
Six Probe Array



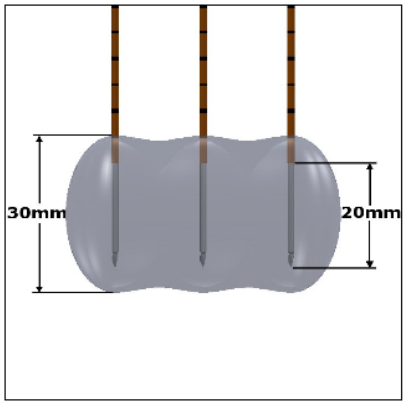


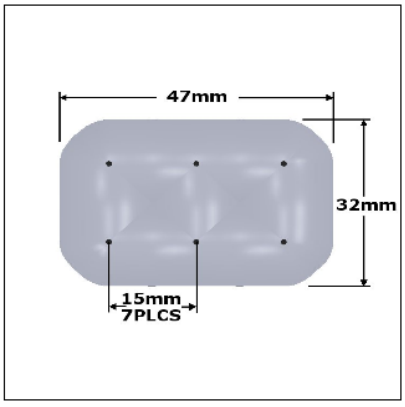
Six Probe Array 10 mm





Six Probe Array 15 mm





The **Probes Connection Status** indicates the location and number of probes connected to the generator. The generator will determine if the probes are valid and are available for a procedure. The User may select the specific probes to be used for the procedure by selecting on the probe number. The probe numbers correspond to the ports on the front panel of the Generator (see Figure 5-15).

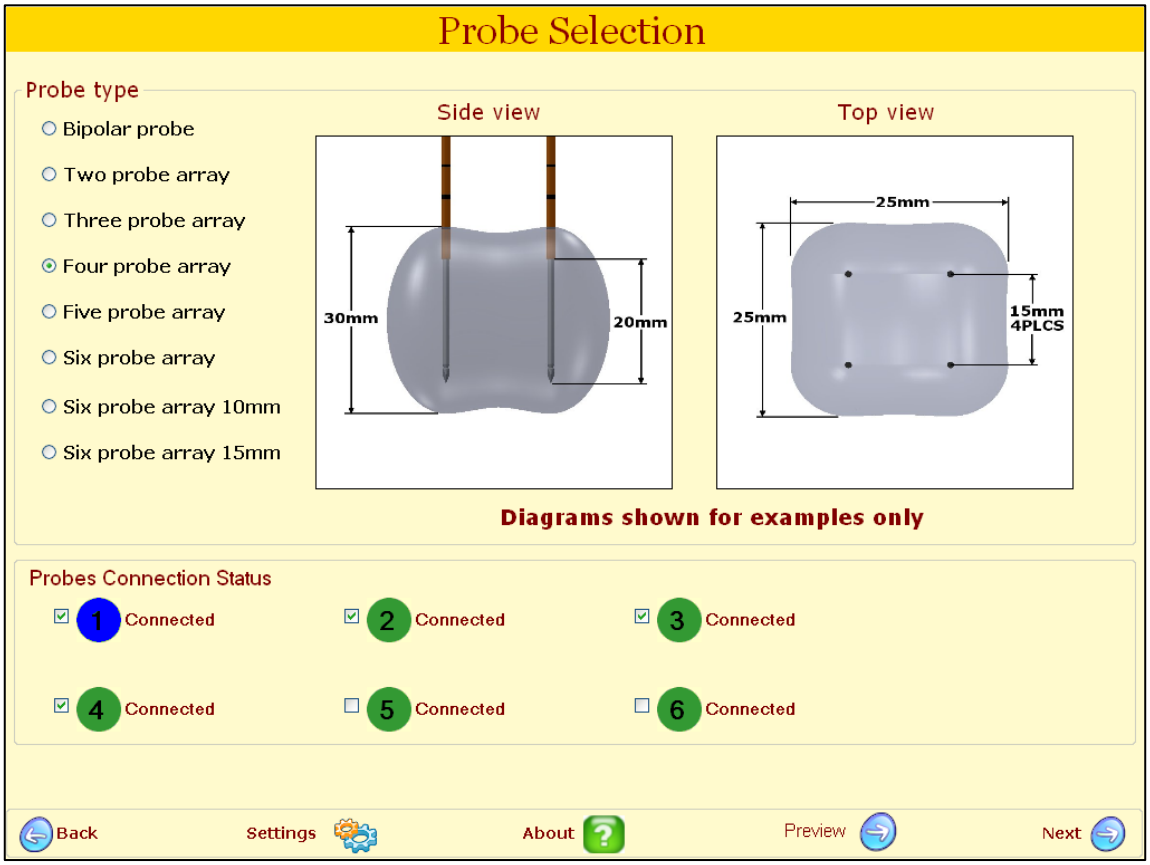


Figure 5-15: Probe Selection Screen
NOTE: Diagram shown for example only; four probe array.

There are two Probe types, Activation Probe or Standard Probe, as shown below in Figure 5-16.

Figure 5-16: Probe Types

At least one of the valid probes selected must be an Activation probe or the User will not be able to progress to the next screen. Once connected, the system will take up to five seconds to determine probe validation. If the probe is valid it will have a working time of eight (8) hours, at which time they will become invalid. Once activated a probe cannot be used on another system even if there is still working time left.

The circle indicated in **Blue** shows that the Activation probe is connected and valid. The circle indicated in **Green** shows that the standard probe is connected and valid, Figure 5-16. The **Red** circle indicates that the probe is invalid or expired and the Grey circle indicates that the probe is not connected to the Generator, Figure 5-17.

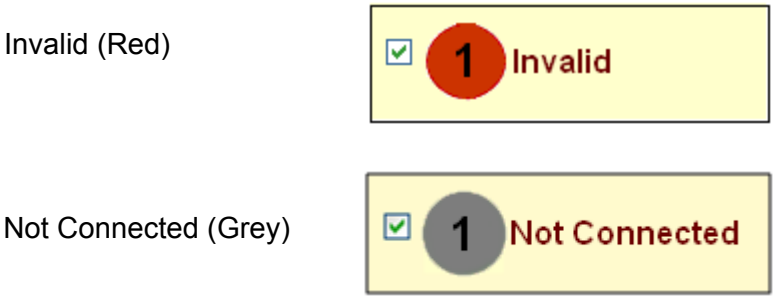


Figure 5-17: Invalid & Not Connected Probes

NOTE: The User cannot progress to the next screen without at least one valid Activation probe connected to the Generator.

Once the desired probe configuration is determined and the corresponding number of probes matches the configuration and an activation probe is connected, select the *Next button* to advance to the Probe Placement Process Screen. If the User tries to advance to the next screen without an activation probe connected, a pop-up warning window (see Figure 5-18) will appear that reads "**Probes Selecting Error − No activation Probe selected."** Connect a valid activation probe (blue handle) to proceed to the next screen.

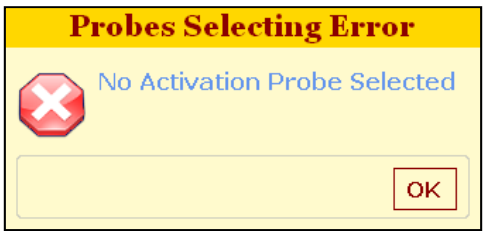


Figure 5-18: Probe Placement Process screen Error Message

NOTE 1: More than one Activation probe may be connected.

NOTE 2: The User may connect more probes than the number of probes selected. In this case, the User must select which probes to use by activating the check box to the left of the probe circle.

5.1.4 Probe Placement Process Screen

The ***Probe Placement Process*** screen is where ablation parameters are defined and ablation Pulse Settings are set. It consists of the ***Probe Placement Grid, Procedure Spreadsheet, Voltage Default Setting Box***, ***Probe Dock/Undock and Exposure Table,*** and the ***Hints Text Box,*** Figure 5-19.

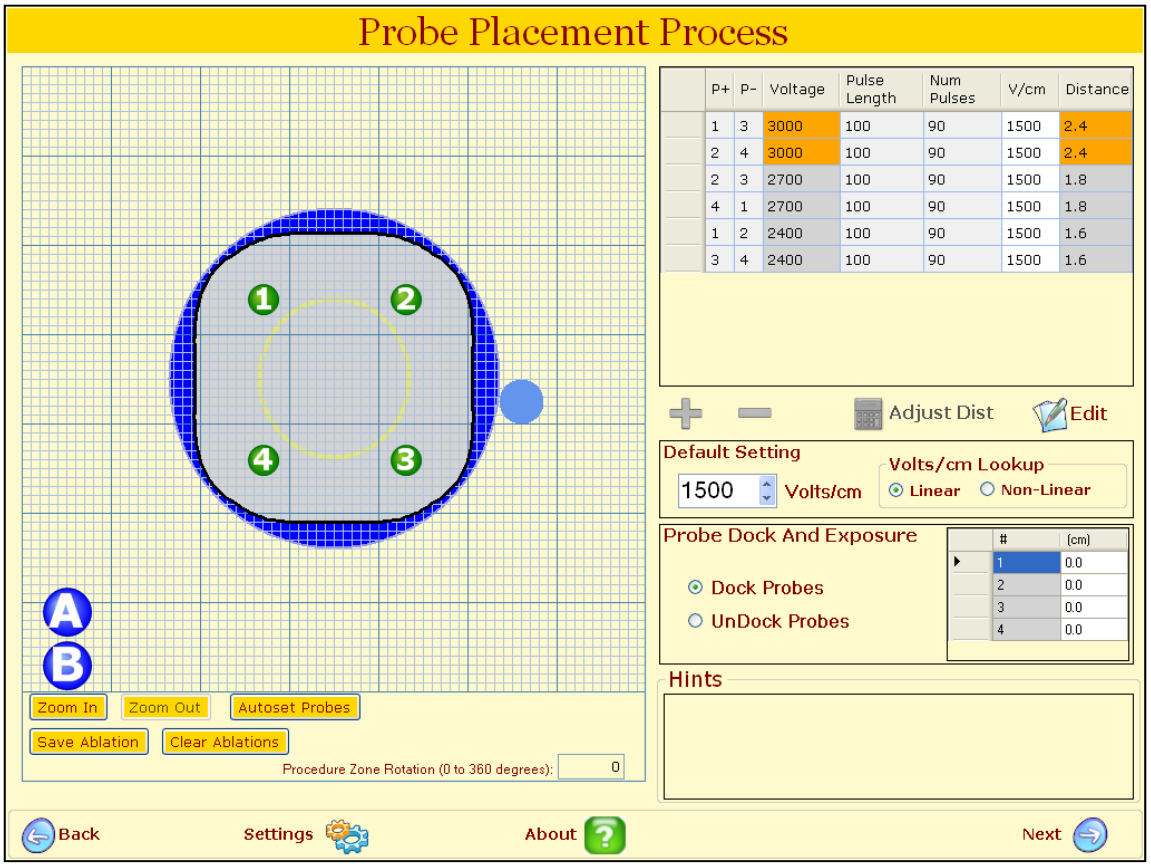


Figure 5-19: Probe Placement Process Screen

NOTE: Example of four probe array.

Examples of each of the eight standard Probe type options are shown in Figure 5-20 below that the User can choose based on the size of the ablation and the number of probes required to treat the area in the ***Probe Placement Process*** screen.

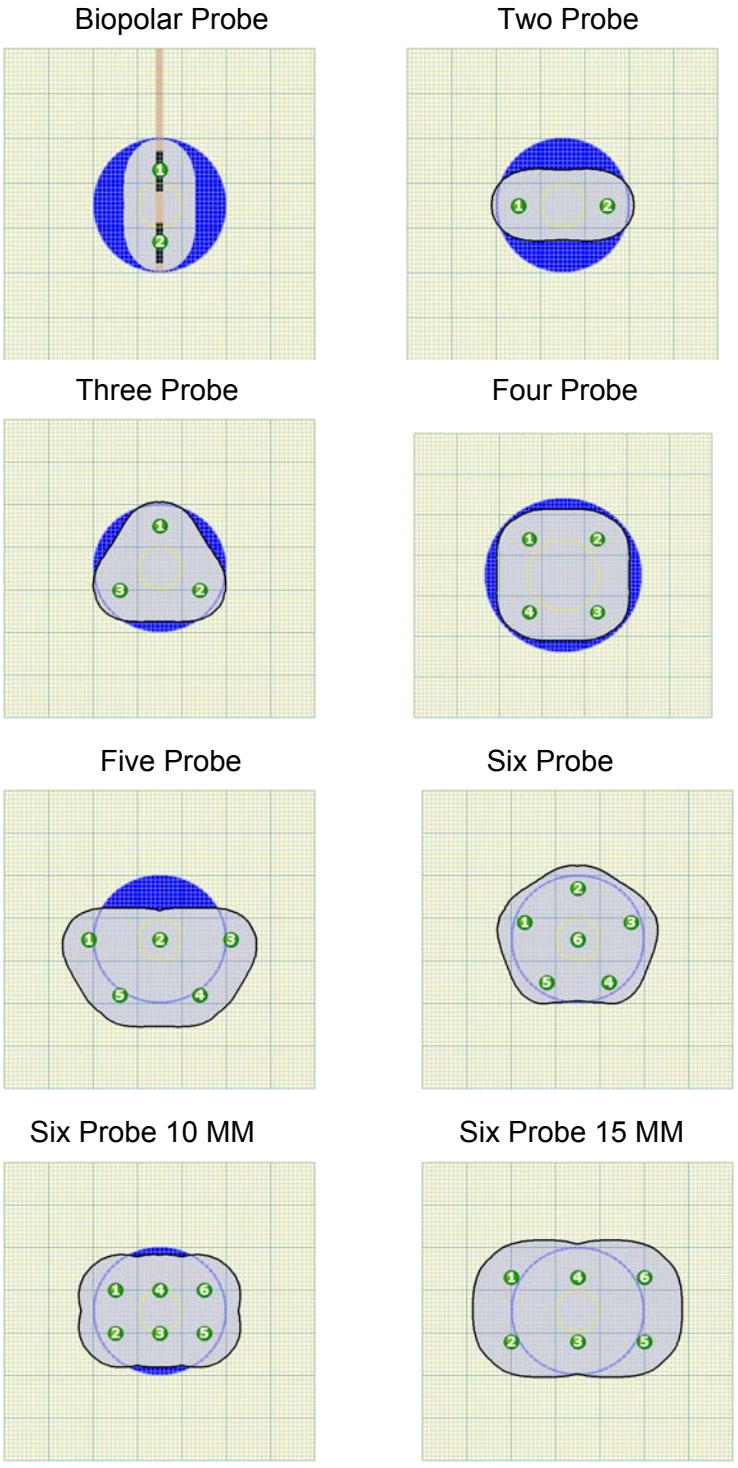


Figure 5-20: Examples of Eight Standard Probe Type Options

The **Probe Placement Grid** is a 7 x 7 cm grid that is displayed on the upper left corner of the Probe Placement Process screen as shown in Figure 5-21. This screen allows the User to move the probes, see the ablation zone, and plan the procedure. The Light Blue oval as shown by the red arrow is the Procedure Zone Rotator rotating the lesion up to 360 degrees.

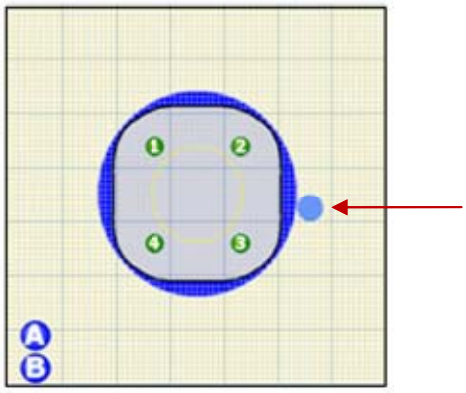


Figure 5-21: Probe Placement Grid and Oval Procedure Zone Rotator

By right clicking on this button or anywhere on the grid, a pop-up window shown below in Figure 5-22 will appear giving the User options to Hide Procedure Zone Rotator. To unhide the Procedure Zone Rotator, repeat the steps and choose Show Procedure Zone Rotator.

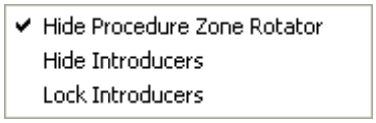


Figure 5-22: Show or Hide Rotator or Introducers

The two Dark Blue circles labeled "A" and "B" are fiduciary markers. They are objects that are used for a point of reference or a measure. The Fiduciary markers may represent known anatomical structures within a subject, such as a rib or organ. To move the fiducials, select and drag or use the Up, Down, Left, and Right arrow buttons on the keyboard to move to the desired location in 1 mm increments.

If the User wants to lock the fiducials in place, right click on the grid and when the pop-up window appears, click on Lock introducers. Once the fiducials are locked, they will turn from Dark Blue to Grey. To unhide the fiducials, repeat the steps and choose Unlock Introducers. If you try to lock the fiducials by clicking on them directly, the pop-up box will not appear and you will not be able to lock them.

The User may want to see the distances between the fiducials, probes, and lesion. To show the distances, right click on the grid and when the pop-up window appears, see Figure 5-23, click on Show Distances when Dragging or Always Show Distances.

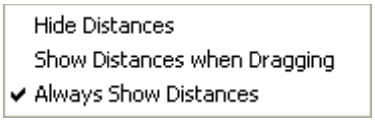


Figure 5-23: Show or Hide Distances

The Show Distances feature allows the User to switch the reference point to a specific fiducial or probe. To set the reference point, click on a fiducial or probe. When the reference point is set, the Probe will turn Green or the Fiducial will have Black text.

In the following example, the distance between Probe 1 and Probe 2 is 1.6 cm and it shown with a white box with a Black text. The distance between Probe 1 and the lesion is 0.3 cm is shown in a Black box with white text and marked with a thick Black line that will touch the Yellow Lesion Zone. Figure 5-24 shows how the **Probe Placement Grid** will change when the User switches the reference point from Probe 1 to Fiducial A.

Reference Point: Probe 1

Reference Point: Fiducial A

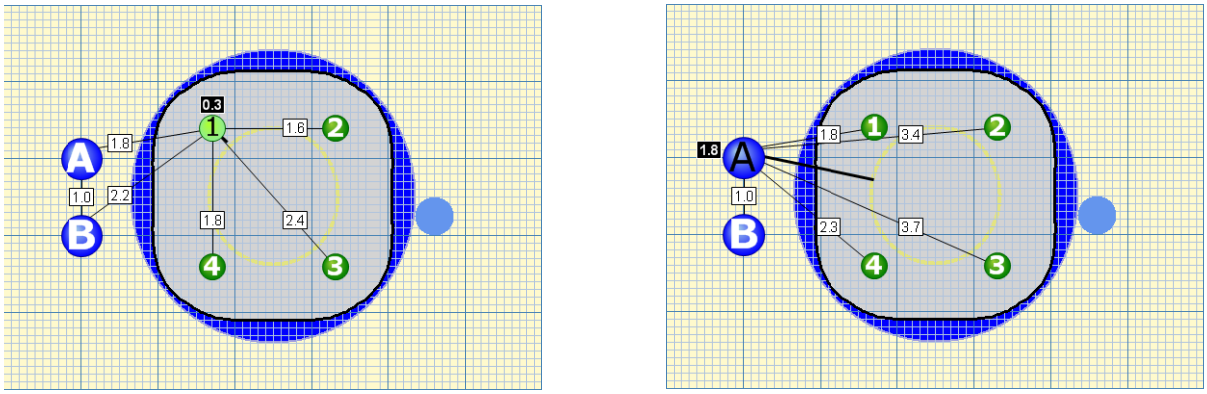


Figure 5-24: Reference Points

The tools and functions that aid the User are as follows:

Lesion Zone: The shape of the *lesion zone* is shown in "Yellow." If the lesion zone is inside the procedure zone, it is outlined with a dashed Yellow line.

Ablation Zone: The Black outline and Grey area showing the summation of all the pair procedure listed in the *Procedure Spreadsheet*.

Target Zone: The target zone within the Dark Blue area represents the desired margin as set in the Information screen Margin setting.

Selected Probe: The Green with Black number probe. Only one probe can be selected at a time. It is the probe that will adjust when the up, down, right and left arrow keys are pressed.

Non-Selected Probe: The Green with White number probe. These probes do NOT move when the up, down, right and left arrow keys are pressed.

Ablation Zone Voids: The Black outline inside the ablation zone. Depending on the location of the probes and the voltage selected, the void may be large or small (see Figure 5-25). In some cases, the void may be a single Black dot within the **Ablation Zone.** Move the probes or increase the voltage to fill in ablation zone voids.

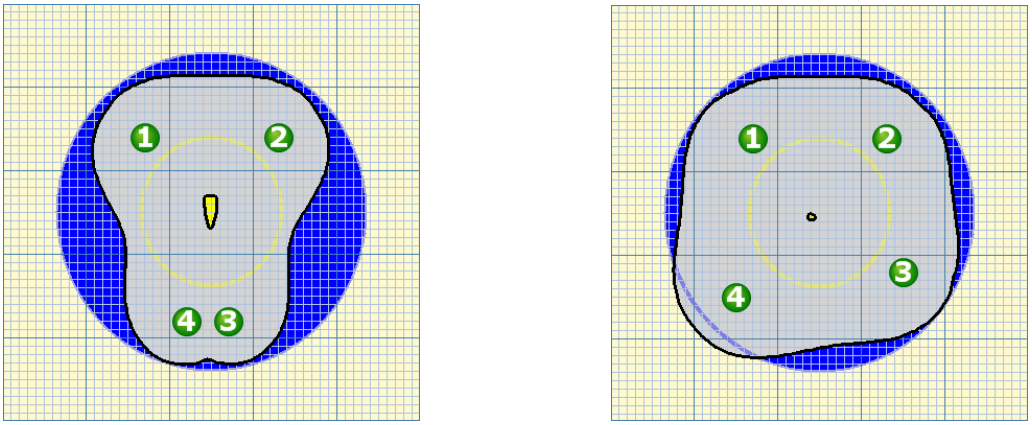


Figure 5-25: Ablation Zone Void Examples

The numbered Green circles are the Probes. The numbers correspond to the probes' connection port on the Generator. The User may click on a probe to display probe location relative to other probes and the ablation. The Probe location can be changed by dragging and dropping each probe. Ablation size and shape will be automatically updated to the Procedure Spreadsheet. Once selected, probes can be moved in 1 mm increments by using the Up, Down, Left, and Right arrow buttons on the keyboard.

Overlapping Ablation Zone: The system allows the User to save an ablation so that if a part of the lesion was missed, User can go back to the Probe Placement Process screen to see where the procedure was completed. After the first ablation, click on the back button to go back to the ***Probe Placement Process*** screen to see the completed **Ablation Zone**. This will be the grey area with the red hash marks. The User can then move the probes to completely cover the lesion. See the following examples showing overlapping ablation zones in Figure 5-26 and Figure 5-27, noting the treated area and area missed.

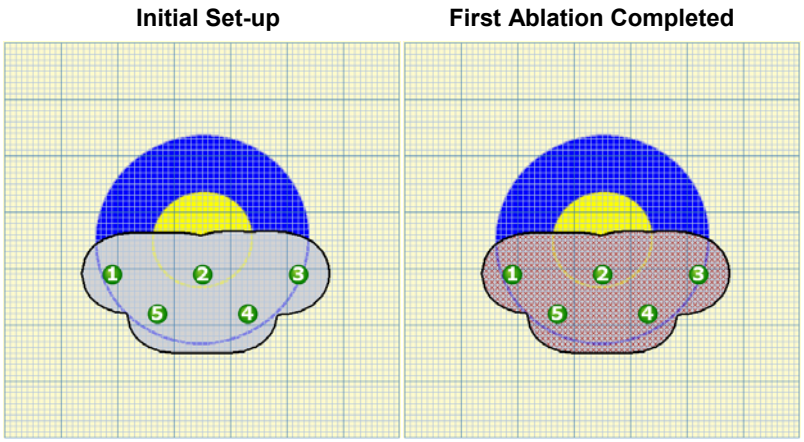


Figure 5-26: Example of Overlapping Ablation Procedure Using a Five Probe Array

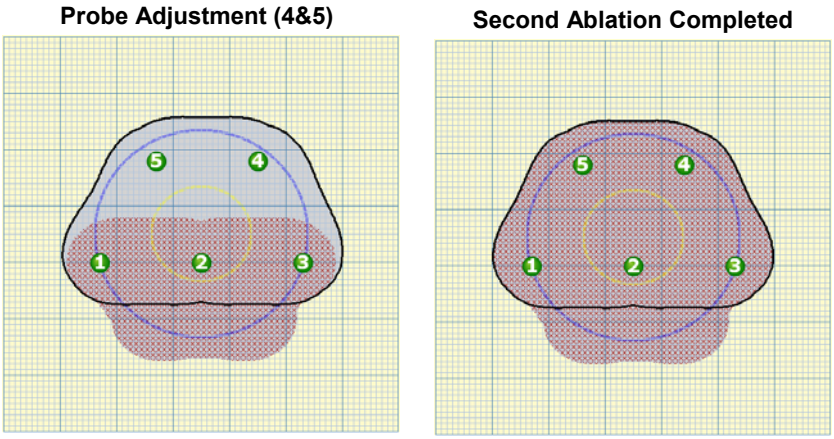


Figure 5-27: Moving Probes 4 and 5 to cover the Lesion Zone

Buttons are **in the screen under** the placement grid as shown in Figure 5-28.

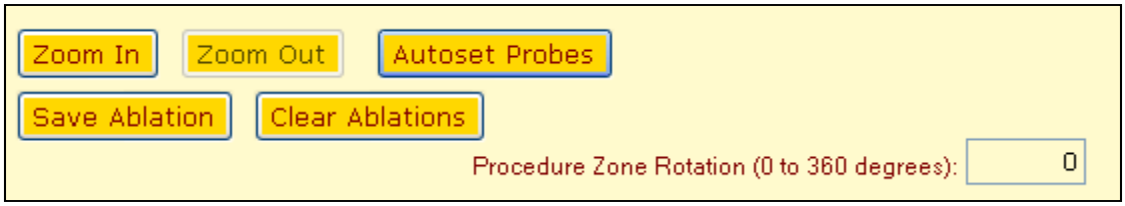


Figure 5-28: Screen Buttons

The *Zoom In and Zoom Out* buttons enlarge or decrease views of grid, to display a 7 x 7 view or a 5 x 5 view.

Autoset Probes *button* with pop-up confirmation screen,

Figure 5-29 allows the User to return the probes to their default settings

Figure 5-29: Autoset Probe Pop-Up Window

Save ablation button is use with “Overlapping Ablations” to save the current ablation zone so that it can be referenced with other ablation zones as shown in Figure 5-30

Figure 5-30: Save Ablation or Do Not Save Ablation

Clear ablation button will remove all the save ablation zones.

Procedure Zone Rotation allows the User to rotate the ablation zone by Selecting on the blue oval and dragging the oval around the target zone, selecting 0 to 360 degree angles.

Procedure Spreadsheet shows the ablation parameters for the selected array configuration and allows the User to define the specific ablation parameters. An ablation consists of a series of sequences of electrical pulses delivered between two probes. Each line of the *Procedure Spreadsheet* represents the settings of a single probe pair. The Generator automatically sets the default ablation parameter settings that are displayed in the spreadsheet. The User can change these settings. Procedure Spreadsheet values may only be changed when the screen is in edit mode by Selecting on the Edit button.

Cells can be accessed by selecting on the cell to change the appropriate setting. The "Grey" cells are calculated values and are not editable (when in non-edit mode, all cells will be grayed out). Cells can be changed by clicking or using the touch screen to select a cell, which will bring up a dialog box. In the dialog box the user may type to enter a new value through the keyboard, use the Up/Down arrows keys, or select the Up/Down buttons on the dialog box, Figure 5-31.

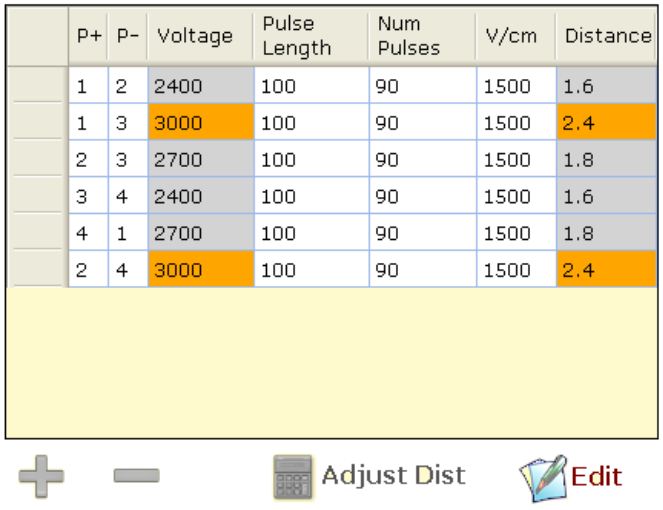


Figure 5-31: Procedure Spreadsheet

The Orange cell indicates the Generator is at the maximum output voltage, 3000 V or the distance between probes is greater or equal to 2 cm.

3000

The **Light Blue** cell indicates the Generator is at the minimum output voltage, 500 V.

500

The **White** cell indicates values that can be changed.

1500

For details about the constraints for the input parameter, see Table 5-1 below:

Table 5-1*: Procedure Spreadsheet Constraints*

Parameter	Minimum Value	Maximum Value	Increment Step
Probe +	1 (Must be different from Probe -)	6 (Must be different from Probe -)	1
Probe -	1 (Must be different from Probe +)	6 (Must be different from Probe +)	1
Voltage	500 V	3000 V	100 V
Pulse Length	20 µs	100 µs	10 µs
Number of Pulses	10	100	10
Volts/cm	500	3000	50
Probe Distance	0 cm	9.3 cm	0.1 cm

Probe Distance Adjuster – A solver that allows the User to enter probe distances and have them automatically placed on the grid. This allows the User to enter distances from an image device versus using the mouse or touch screen to manually move probes on the grid.

Note 1, the solver does not accept values that are greater than 6 cm.

Note 2, solutions and probes are placed on discrete 1 mm (x,y) grid boundaries.

Note 3, if inconsistent data is entered, inconsistent results will occur.
This tool is shown in Figure 5-32.

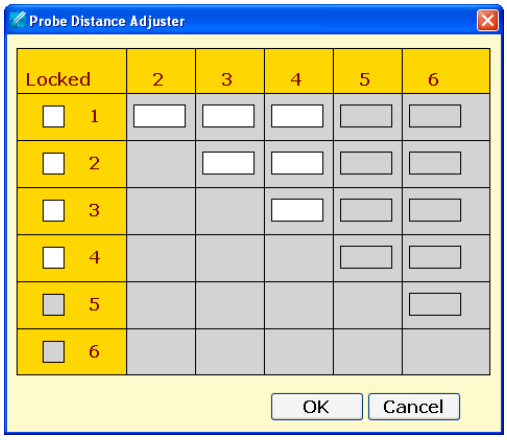


Figure 5-32: Probe Distance Adjuster

1. Select the Edit Button below the ***Procedure Spreadsheet***. 

2. Select the Adjust Dist button. When the Adjust Dist button actuated, the Probe Distance Adjuster will appear. 

3. Input the desired distances between probes, see Figure 5-33, into the white boxes of the Probe Distance Adjuster. In the example below, the spreadsheet distance between Probe 1 and Probe 3 is 2.4 cm. If the User desires to reduce the distance between Probe 1 and Probe 3 to 2.0 cm, click on the 1-3 text box in the Probe Distance Adjuster and input 2.0.

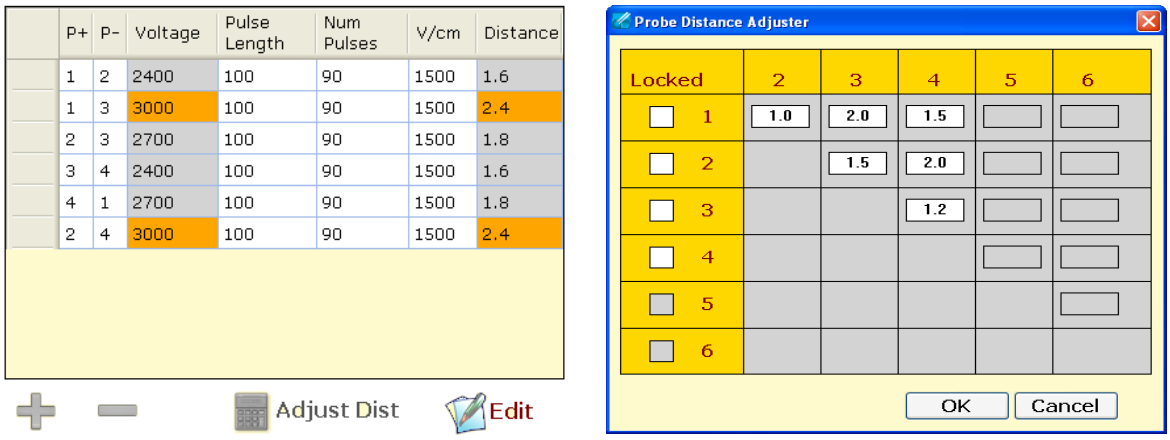
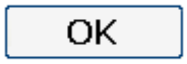


Figure 5-33: Procedure Spreadsheet & Adjuster

4. After making the desired changes, select the OK Button to close the Probe Placement Adjuster and return to the ***Procedure Spreadsheet***. 

5. The probes will automatically move in the ***Probe Placement Grid*** to reflect the changes inputted in ***Procedure Spreadsheet*** via the Probe Distance Adjuster, Figure 5-34.

Before Changes **After Changes**

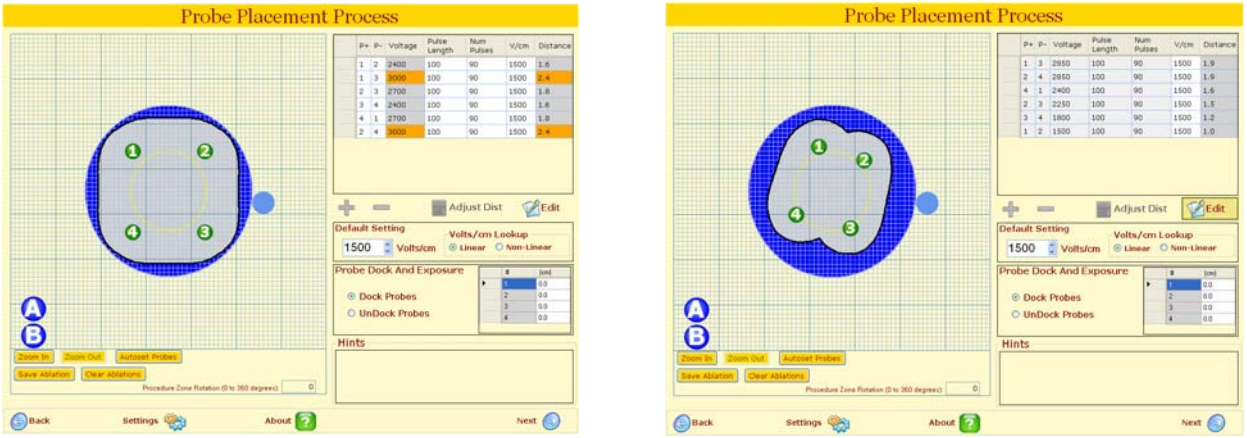


Figure 5-34: Before and After Using Probe Distance Adjuster

6. Click the Apply button when completed with edits. 

NOTE :If the User tries to proceed to another screen without selecting the “Apply” button the below error box will appear as shown in **Error! Reference source not found.**5. Select OK and then select on the Apply Button.

Figure 5-35: Error Box

Add or Delete Rows allows the User to add or delete Rows in the ***Procedure Spreadsheet***. For example, if the User determines that the procedure Probe 1 – Probe 2 is unnecessary, the following is a step-by-step process to use this tool as shown in Figure 5-36.

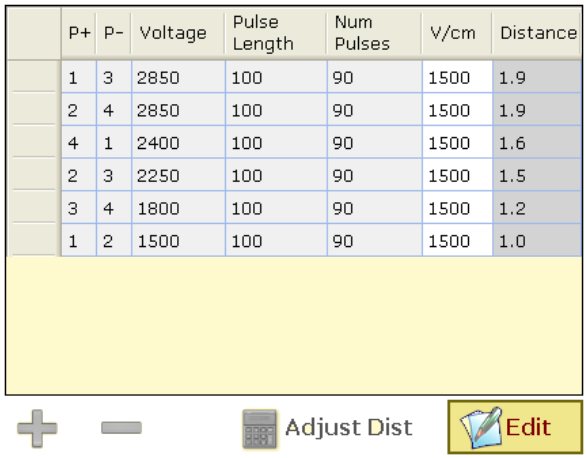
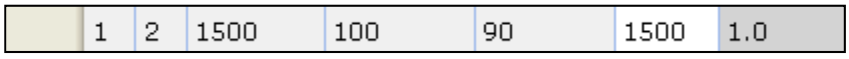


Figure 5-36: Procedure Spreadsheet

1. If displayed, select the Edit Button below the ***Procedure Spreadsheet***. 

2. Click on the row and it will change from a Grey background to a Blue background, Figure 5-37.

Before



After

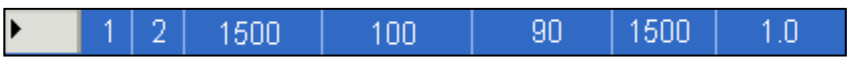


Figure 5-37: Background Color Change

3. Select the minus button to delete the Row. 

4. Confirm deletion by clicking the Yes button, Figure 5-38.

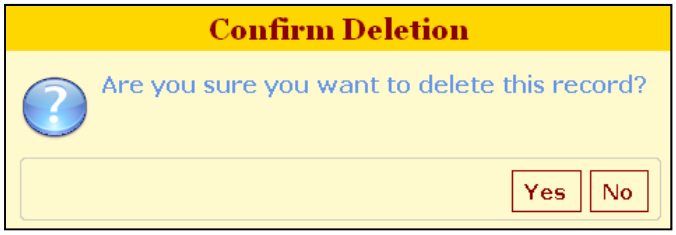


Figure 5-38: Deletion Confirmation Box

5. Click Apply when finished

NOTE #2: When a Row is deleted, the procedure may not be sufficient to fully cover the lesion. Please check the **Probe Placement Grid** for any Ablation Zone Voids: The Black outline inside the ablation zone. Depending on the location of the probes and the voltage selected, the void may be large or small (see Figure 5-25). In some cases, the void may be a single Black dot within the Ablation Zone. Move the probes or increase the voltage to fill in ablation zone voids.

Conversely, if the User wants to add a Row in the ***Procedure Spreadsheet***, the User would follow the same steps as they did to delete a Row except the User will replace the minus button with the plus button. 

1. Click the edit button on the ***Procedure Spreadsheet***.
2. Click the plus button.
3. (Optional) Edit the new row values. (e.g. Change P+ and/or P- probe pair combination etc.)
4. Click Apply when finished.

NOTE: The process of adding a Row is limited by the probe configuration selected in the **Probe Selection** screen. In this example, a Four-probe configuration was selected. If the User tries to add a Row that exceeds the combinations of a Four-probe configuration, a warning box will appear as shown in Figure 5-39.

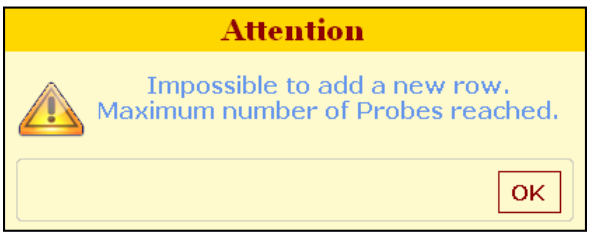


Figure 5-39: Maximum Probe Reached Attention Box

Voltage Default Setting Box allows the User to change the Volts/cm setting with the Up/Down arrows to the desired volts/cm, Figure 5-40.

Figure 5-40: Voltage Default Setting Box

The Volts/cm Type allows the User to select either "Linear" process or "Non-Linear Lookup," depending on the type of tissue being treated, by selecting the adjacent radio buttons. Observe changes to ablation zone and Pulse Configuration table when changing from Linear to Non-Linear modes. The Default setting for selecting Linear is 1500 Volts/cm.

- *Linear* uses the equations *Distances* x *Volts/cm* = procedure *Voltage*. This setting is for soft tissue procedures.

- *Non-Linear Lookup*, uses a table to look up *Voltage* based on *Distances*. It is primarily used with *Six probe array 10 mm* and *Six probe array 15 mm* Probe types. This setting is for a prostate procedure.

The Probe Dock/UnDock ExposureTable is shown in Figure 5-41. The Dock and UnDock Probes radio buttons are used to disconnect and reconnect the probes from the Generator. Click UnDock Probes to remove the probes from the Generator.

The exposed length of each probe can be entered from 0 to 4 cm.

Selecting the cell brings up a dialog box. Use the keyboard to manually change the value or to use Up/Down arrows keys, or select the Up or Down arrow buttons on the dialog box. Select OK when complete.

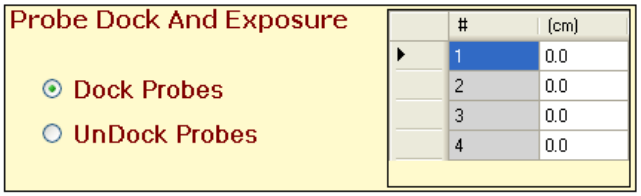


Figure 5-41: Probe Dock/Undock Exposure Table

The following are the main steps for probe placement:

- Image the ablation zone either by standard imaging technologies or direct visualization.
- Prior to placing the probes, set the probe exposure to the required depth of ablation zone. Be sure to insert all probes to the ablation zone tissue depth.
- Apply the probes to the ablation zone, reproducing the probe configuration on the grid.
- Verify that the probe placement is consistent with the probe configuration on the grid.
- Edit the recommended probe layout to match the actual probe layout. Observe the predicted ablation zone.
- Connect probes to the corresponding electrode connector on the front panel of the Generator. Verify that the connections are correct.
- Select the UnDock Probes ratio button to remove probes from the Generator. This feature will allow User to remove probes from the Generator without receiving an error. If a Probe becomes unconnected when the Dock Probes radio button, the system will send the User back to the Probe Selection Screen.

NOTE: It is very important that the probe number corresponds to the number indicated on the Generator, so that its connector is plugged in so that the procedure performed meets the planned procedure.

The **Hints Text Box** provides additional instructions as shown in Figure 5-42; i.e., "Use the Dock Probes/UnDock Probes radio buttons to disconnect and re-attach probe(s)."

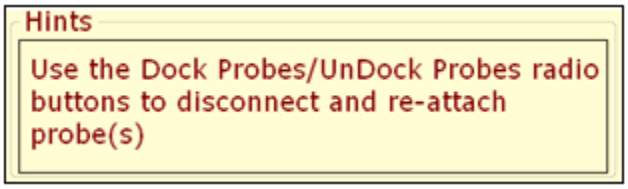


Figure 5-42: Hints Text Box

5.1.5 Pulse Generation Screen

The **Pulse Generation** screen (see Figure 5-43) is the screen where the ablation is delivered. It consists of two sub-screens, the *Procedure Parameters* screen, which is the default screen, and the *Result Graphs* screen (see tabs in the upper left of the screen). The lower sections of the screen do not change when moving from the Procedure Parameters screen to the Result Graphics screen. An ablation procedure can be started and aborted from either screen. The User can move between the screens during the ablation procedure.

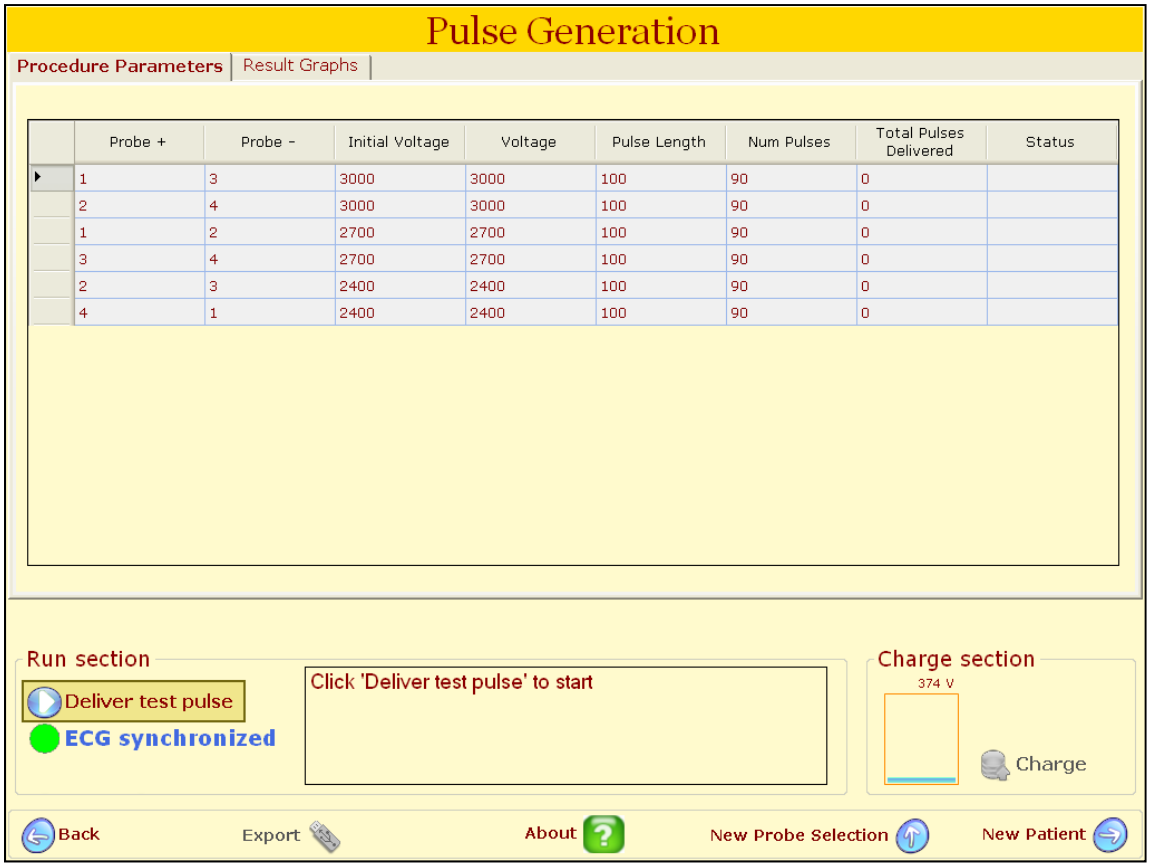


Figure 5-43: Pulse Generation Screen

The **Run Section** prepares, controls, and runs the ablation delivery. It displays several controls and messages according to the status of the ablation progress.

Deliver Test Pulse button launches a low-voltage test pulse to the ablation site to confirm that the electrical pathway between the electrodes is within the operating ranges for impedance. Once the probe test is completed, control of the ablation is switched to the Double Foot Pedal.

ECG Synchronized status indicator is for Pulse Timing Status listed below:

- "ECG disabled" if 90 PPM or 240 PPM are selected.
- "ECG synchronized" if ECG synchronization is selected and the signal is synchronized.
- "ECG noisy" if ECG synchronization is selected and signal is too fast.
- "ECG no signal" if ECG synchronization is selected and signal is too slow or not present.

The ***Status Panel/Message Box*** displays status messages and instructions for the User.

The **Charge Section** controls the voltage on the capacitors and displays the accumulated energy for ablation. The Capacitor Status Indictor displays the level of the capacitor charge and shows, in Volts the voltage present on capacitors.

5.1.6 Ablation Delivery

After the probes have been placed and ablation parameters have been set, the User can initiate an ablation.

NOTE: The User should observe and review messages displayed in the *Status Panel/Message Box* for instructions.

To deliver ablation, the User must first press the *"Deliver Test Pulse"* button.

The Generator prepares for the test pulse as soon as the *Pulse Generation* screen is accessed. When the Generator's capacitors have accumulated the energy required for the test pulse, the following message appears in the status panel:

"Click 'Deliver test pulse' to start."

Click the ***Deliver Test Pulse*** button and the Generator will deliver the test pulse, Figure 5-44.

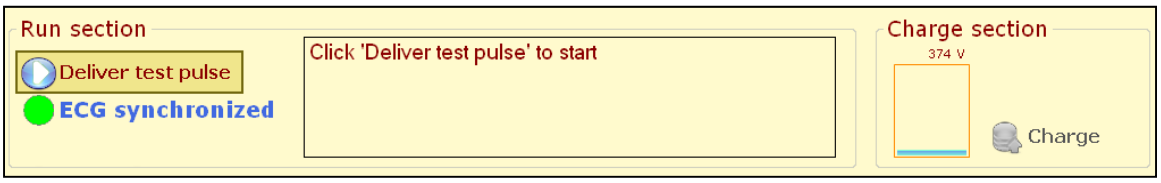


Figure 5-44: Deliver Test Pulse

Successful Test Pulse – If the test pulse is successful, the Generator automatically charges the capacitors to the required voltage. The *Charge* section indicates the status of the *Voltage* on the capacitors by progressively filling the bar Blue, from bottom to top. This might require up to 30-40 seconds. When the capacitors are fully charged the status panel displays "Device ready. Click arm button to ARM the device."

Unsuccessful Test Pulse – If the test pulse is unsuccessful, the system will indicate a fault condition. The fault condition will guide the User to check the probe connections to ensure that the probes are connected to the Generator.

If the fault condition indicates impedance is too low, the User will be instructed to check the probe placement in the tissue to ensure that the probes are placed appropriately and that the probes are not touching.

Once the energy for the ablation has been accumulated, the following message appears in the status panel in Figure 5-45:

"Device ready. Click arm pedal to ARM the device."

Press the ***LEFT foot pedal*** to complete this action.

Figure 5-45: Device Ready/Arm Device

The system will arm and the message box prompt will show that the system is ready to deliver pulses. The Pulse RIGHT foot pedal is now enabled and the ablation will start as soon as the User presses it. The following message appears in the status panel in Figure 5-46:

"Device ready. Click pulse pedal to start procedure."

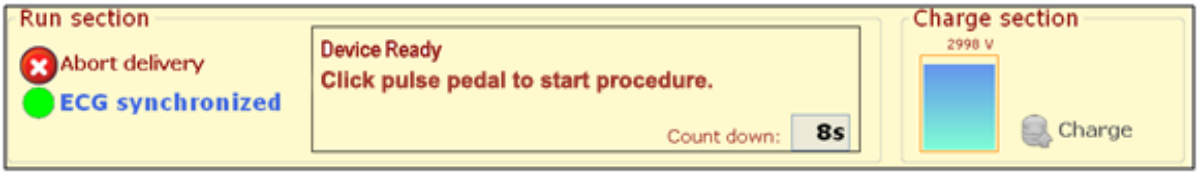


Figure 5-46: Device Ready/Start Procedure

A 10-second countdown starts in the status panel. Press the ***RIGHT foot pedal*** before the countdown is completed to deliver the procedure. As the procedure starts, an audible long beep is produced. While the procedure is in process there are audible double beeps for each group of pulses. When the procedure completes an audible double long beep is produced.

The **Procedure Parameters** screen displays the probe parameters selected on the Probe Configuration table. When the "Pulse" pedal is pushed, the procedure starts for each pair listed in the Procedure Parameters table. See Figure 5-47:

Total Pulses Delivered – The number of pulses delivered during the ablation sequence.

Status – Displays the percentage of pulses completed during the procedure sequence for each pair treated. When the sequence is successfully completed, it displays 100%. If the procedure is aborted, it will indicate the completed sequences and the aborted sequences.

Pulse Progress – A pop-up screen with bar indicator is displayed. The Pulse progress screen is also available in the Result Graphs screen.

The **Abort button is active** so the User can stop the procedure at any time.

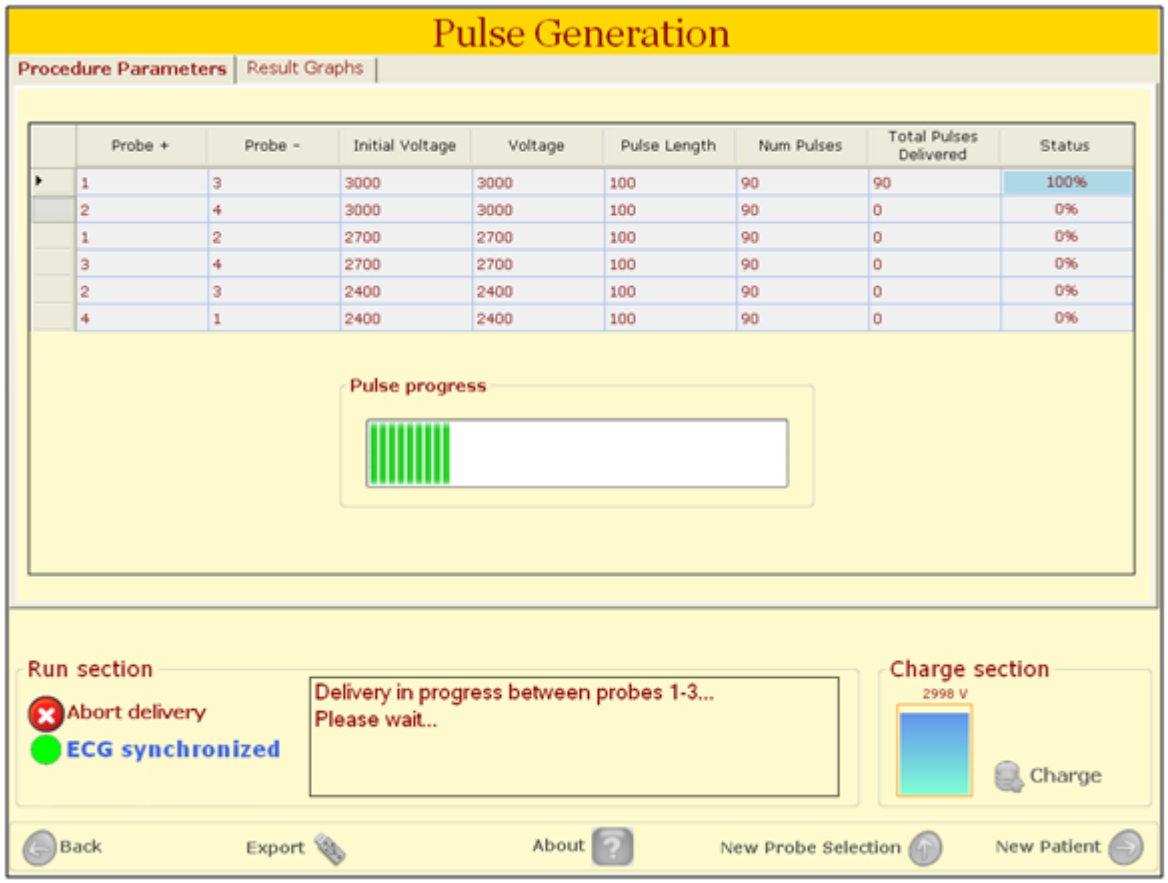


Figure 5-47: Procedure Delivery in Progress

If the User presses "Abort" the procedure will stop (Figure 5-48). The complete and incomplete pairs will show in the status column. The User has a choice to "Continue Procedure" which will continue where the procedure left off, or "Stop Procedure" which will end the procedure.

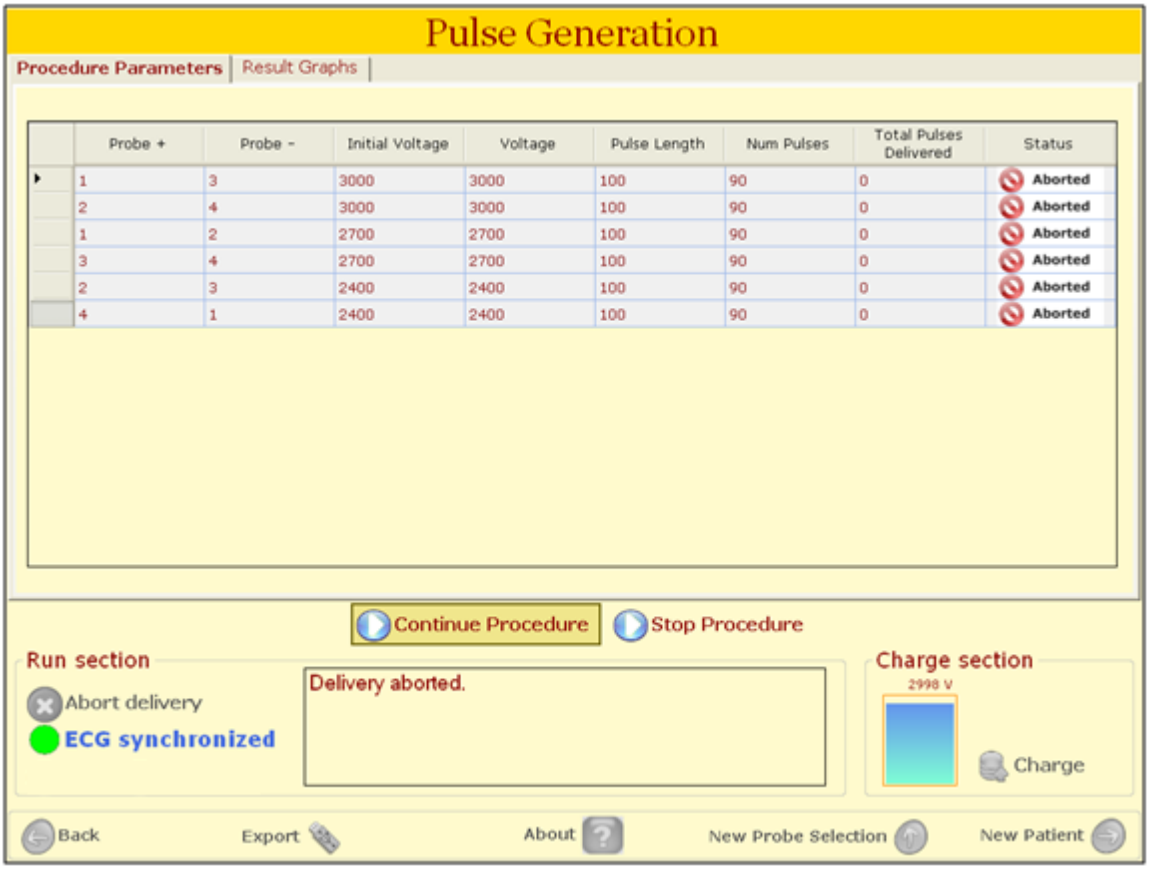


Figure 5-48: Procedure Delivery Aborted

When the User chooses to "Continue Procedure," the procedure will complete.

During the procedure, an audible indication is produced: double beep for each group of pulses.

If ECG synchronization was selected, and the ECG signal is noisy, low, or not present during the procedure, the system will indicate by displaying the "Pulse Timing" status. Energy delivery will not be allowed to continue until the signal is synchronized or the procedure can be restarted if the User returns to one of the screens that has an active *Settings* button to access the *Pulse Timing Control* screen, and selects either 90 PPM or 240 PPM. This is explained further in section 5.1.2, Information screen: Clinical Data.

When a procedure is completed, an audible indication is produced: double long beeps.

Then the following message appears in the status panel, indicating that the procedure is completed (Figure 5-49):

"Delivery completed."

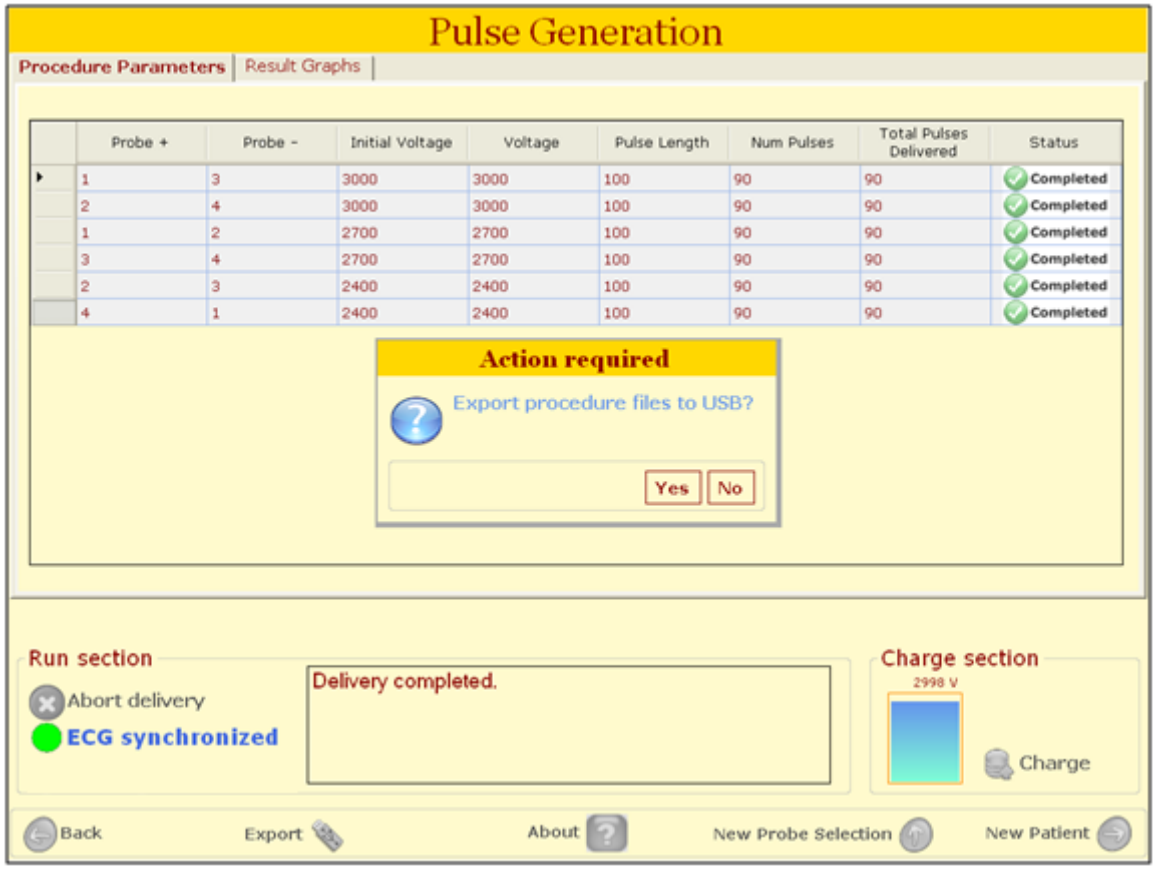


Figure 5-49: Delivery Completed Screen

Next, an Action Required pop-up screen will be displayed with the following message Figure 5-50:

Export procedure files to USB?

Select the "YES" or "NO" button. "YES" will forward the User to a My Computer window to select a file and USB port location and "No" will close the pop-up window and discharge the capacitors.

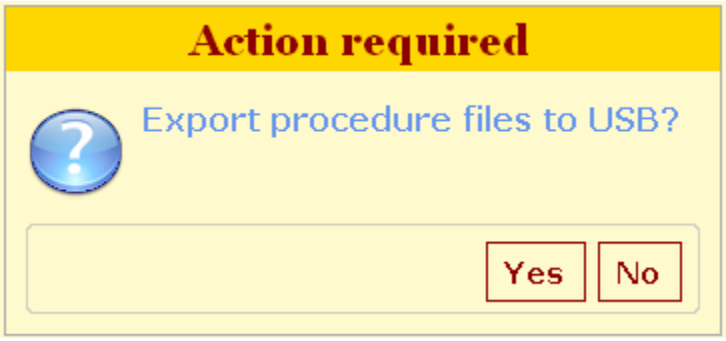


Figure 5-50: Export to USB

At the end of the procedure, a pop-up panel may appear on the screen, showing events that may have occurred during the procedure. In particular, the following error messages may appear:

An error message indicating that the procedure between specified electrode probes has been interrupted due to excessive current.

An error message indicating that the current measured during the procedure between the specified electrodes was very low. In this case, verify whether the electrode probes are correctly connected to the Generator, i.e., each electrode probe to the proper output connector on the front panel of the Generator.

For a complete list, go to Section 8.3 Generator Error Messages.

NOTE: Overlooking the above errors may result in ineffective ablation.

To view the **Result Graphs** screen, select the "Result Graphs" tab in the upper left corner of the screen (Figure 5-51). The Result Graphs screen consists of the *Complete Procedure Voltage Results graphs* and *Complete Procedure Current Results graphs* for all pulses of the procedure. The lower sections of the screen do not change when moving from the Procedure Parameters screen to the Result Graphs screen.

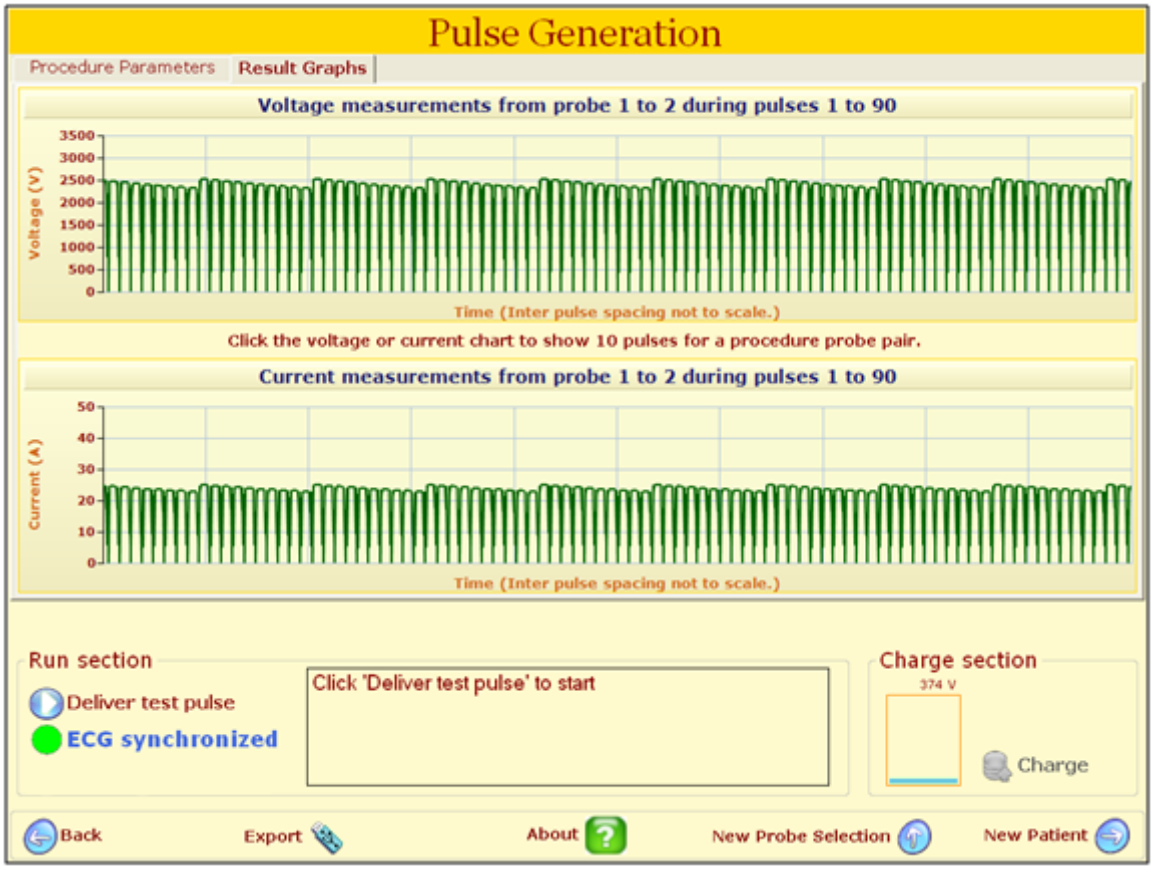


Figure 5-51: Pulse Generation Screen with Result Graphs Sub-Screen Shown

The Graphs on the Pulse Generation screen display the measured voltage and current waveforms of all the pulses delivered during the procedure.

The **Voltage** graph displays the voltage waveforms measured during each pulse of the procedure as shown in Figure 5-52.

The **Current** graph displays the current waveforms measured during each pulse of the procedure as shown in Figure 5-52.

If the cursor is placed over either graph and moved slowly across the graph, a pop-up box will display the associated sequence of pulses. A single left click on any location of the graph allows the User to zoom in on the pulses corresponding to the position of the pointer.

When the User makes a selection on either the voltage or the current graph shown in Figure 5-52, both graphs are changed correspondingly as shown in the following figures.

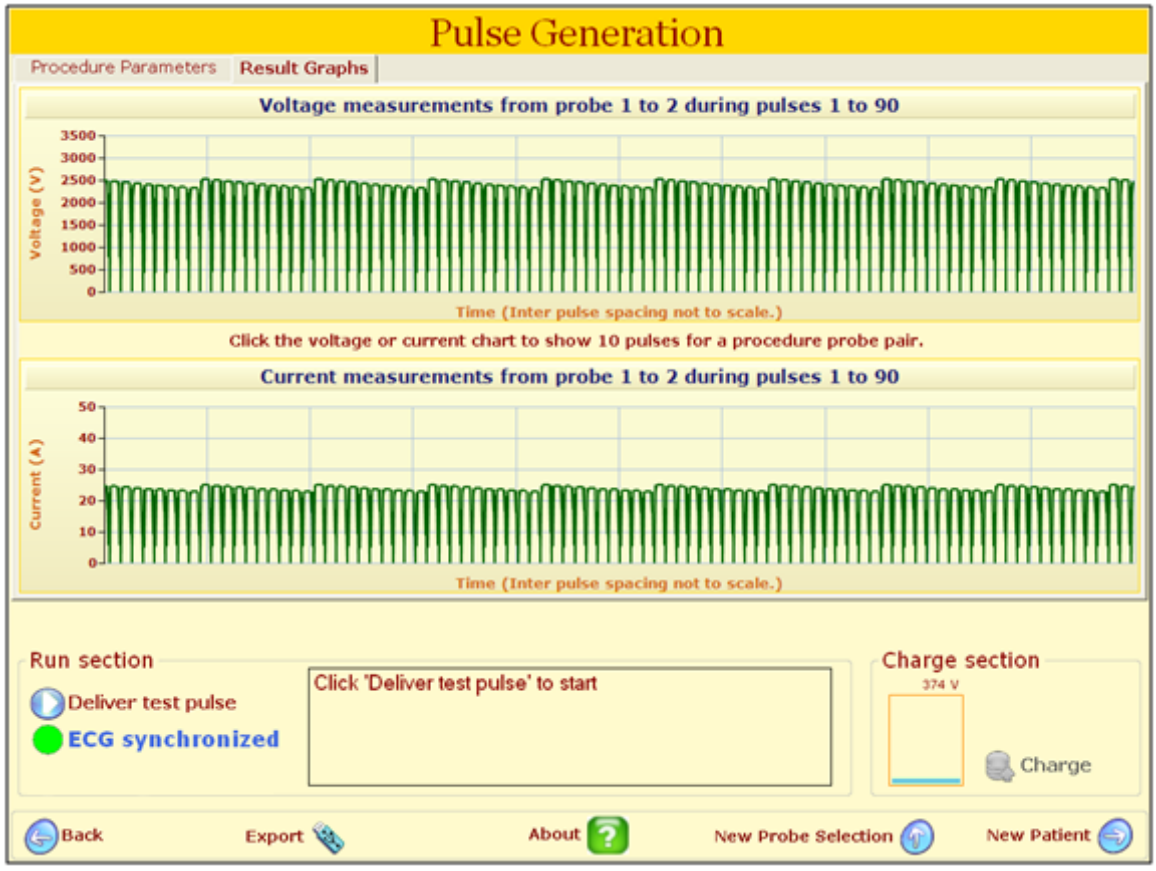


Figure 5-52: Pulse Generation Screen Showing Voltage Waveforms Measured

An additional left click on the either the voltage or current waveforms measured during the procedure allows the User to zoom in on the pulses corresponding to the position of the pointer. From the Result Graphs or Procedure Paramters screen, the User can directly access the Probe Placement Process screen to set a new procedure for the same patient by selecting the **Back** button, or go to the Probe Selection screen by selecting the **New Probe** button. The User can also directly access the Information screen to start a new procedure on another patient by selecting the **New Patient** button. The ***Export*** button, when active, allows the User to access the *Action Required* pop-up screen to export procedure files to a USB.

5.1.7 Additional information

If five (5) minutes elapse without pulse delivery, the capacitors will automatically discharge. To initiate the procedure, select the Charge button in the Charge section to charge the capacitors.

NOTE: Pressing the ARM foot pedal, before the message "*Device ready*" appears, has no effect.

5.1.7.1 Emergency Procedure Interruption

To interrupt or stop a procedure, it is *sufficient to use* the *Abort Delivery* button on the *Pulse Generation* screen. When the *Abort Delivery* button is selected, the generator will stop the procedure and will be able to resume the procedure where it was stopped.

As an alternative to interrupting a procedure, press the *Red STOP* button located on the front panel of the Generator as shown in Figure 5-53.

Figure 5-53: Stop Button

When pressing the *Red STOP* button, the Generator internally disconnects the energy load and automatically discharges the energy accumulated on the capacitors.

After engaging the *Red STOP* button to stop delivery of a procedure, it is necessary to do the following:

Release the *Red STOP* button, by rotating it clockwise, as the arrows on button indicate.

Turn the power OFF at the main switch on the back panel of the Generator and then re-start.

5.1.7.2 Audible Indications

The Generator produces three different audible indications: 1) before delivering a procedure (long beep), 2) during the procedure (double beep for each group of pulses), and 3) when the procedure is complete (double long beep).

5.1.7.3 Storage of Procedure Parameters and Waveforms

The Generator automatically stores procedure parameters and waveform results of each procedure in an appropriate file.

Each procedure file contains:

Institution data
Patient data
Clinical data, if any specified in the *Information* screen
Case Information data, if any specified in the *Information* screen
Lesion Zone data, if specified in the *Information* screen
Procedure Parameters
Applied Voltage measured samples
Applied Current measured samples

Files are stored in XML format and can be opened/viewed with commercial applications like MS Excel 2003 or newer, Open Office spreadsheet, etc.

The name of each procedure file is composed of procedure date, hour and patient ID number, and is unique.

5.1.7.4 Exporting Files

Files can be exported from the console using a USB storage device (e.g., USB Flash Drive) plugged into one of the USB ports.

To export the procedure files:

1. Insert a memory stick/USB storage device into one of the USB ports located on the side of the console, wait 10 seconds.
2. Select the Export button.
3. Select "*Yes."*
4. Select the file(s) to be exported. The file name is a date code, which contains information on all procedures performed on that day.
5. Select the *Add folder* button, and then the *Save* button and the files will be copied to the USB storage device. Once the files have been exported, the Application software will shut down.

Select "*No"* to skip exporting procedure files and the Application software will shut down. The software application closes and Windows shuts down.

5.1.7.5 System Shut Down

To shut down the system select the Exit button on the Information screen, and select Yes on the popup. When the Application software closes, the Windows operating system will shut down as well. When the Windows operating system completes its shut down, turn OFF the Generator at the main switch located on the back panel.

EXTERNAL ECG SYNCHRONIZATION

6.1 Overview

The Generator starts in the ECG Synchronous mode (default setting). When working in this mode, the Generator has to be connected to an external R-wave detector.

6.2 External R-Wave Detector

The external R-wave detector must have the following specifications:

- Be FDA approved or CE marked medical grade device.
- Generate an output signal that is TTL/CMOS compatible signal with an output that is a 5 V positive logic pulse starting when the R-wave is detected and with a length of at least 1 ms.
- Deliver an output at least 15 mA.
- The connection cable should be an RGU 174/U cable with a length up to 90 cm.
- Since the Generator will deliver a pulse after 50 ms from the R-wave trigger signal, it is required that the delay between the R-wave and the trigger signal output is less than 10 ms.
- The R-wave detector should reject erratic pulses and ECG artifacts to assure that the triggering signal always corresponds to an R-wave.
- It is recommended that the Generator's outputs be protected against defibrillator discharge.
- The *External Sync Connector* is a female BNC connector located on the Generator's back panel labeled "ECG Synch. Input"

The Generator will deliver one IRE Pulse 50 ms after the rising edge of the triggering signal, provided that the triggering interval is greater than 500 ms.

There are three conditions the ECG triggering signal may be in: *ECG synchronized, ECG noisy*, and *ECG no signal*. The last two conditions will prevent energy delivery from starting or continuing (if already started). On the Pulse Generation screen, the following will be shown depending on the status of ECG synchronization.

When first entering the **Pulse Generation** screen (Figure 6-1), the system requires 3.5 seconds to verify the status of the ECG signal. After the 3.5 seconds and BEFORE delivering a test pulse, if the ECG signal is *synchronized*, the button for *Deliver test pulse* will be active and the Run section of the screen will display:

Click 'Deliver test pulse' to start.

Figure 6-1: Test Pulse of Run Section with ECG Synchronized on the Pulse Generation Screen

After the 3.5 seconds and BEFORE delivering a test pulse, if the ECG signal is slow or not present, the button *Deliver test pulse* will be inactive and the Run section of the screen in Figure 6-2 will display:

"External ECG trigger not present. Please check the connection."

Figure 6-2: Run section with ECG No Signal on Pulse Generation Screen Before Test Pulse

Possible solutions "ECG no signal":

- Verify that ECG cables are firmly connected to buttons.
- Check the display of the synchronization device—is it generating a synchronization signal on each R-wave? Toggle different lead combinations on the synchronization device until a satisfactory synchronization signal is found.
- Relocate ECG buttons on patient and try lead combinations again.

After the 3.5 seconds and BEFORE delivering a test pulse, if the ECG signal is fast, the button for *Deliver test pulse* will be inactive and the Run section of the screen in Figure 6-3 will display:

"External ECG trigger noisy. Please check the connection."

Figure 6-3: Run Section with ECG Noisy on Pulse Generation Screen Before Test Pulse

Possible Solutions for "ECG Noisy."

- Check for ECG double counting. Select a different lead on the synchronization device.
- Check for a noisy ECG signal. Verify cable connections and buttons are secure. Noise may come from RF energy devices connected to the patient (e.g., electrocautery) or from high-energy devices (x-ray equipment, etc.) on the same circuit.

If the ECG signal is synchronized DURING delivery of the test pulse, the Run section of the screen in Figure 6-4 will display:

"Test in progress."

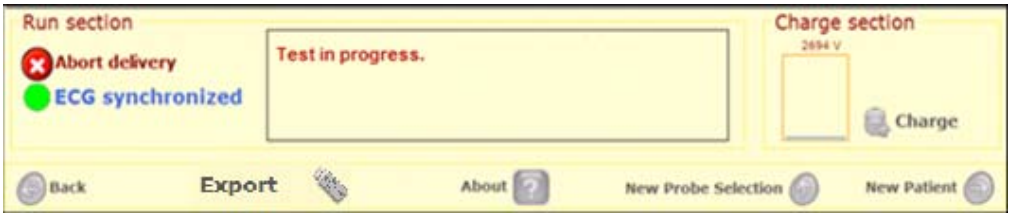


Figure 6-4: Run Section with ECG Synchronized on Pulse Generation Screen During Test Pulse

If the ECG signal is synchronized DURING energy delivery, energy delivery will occur and the screen in Figure 6-5 will display:

"Delivery in progress between probes 3-4…Please wait…"

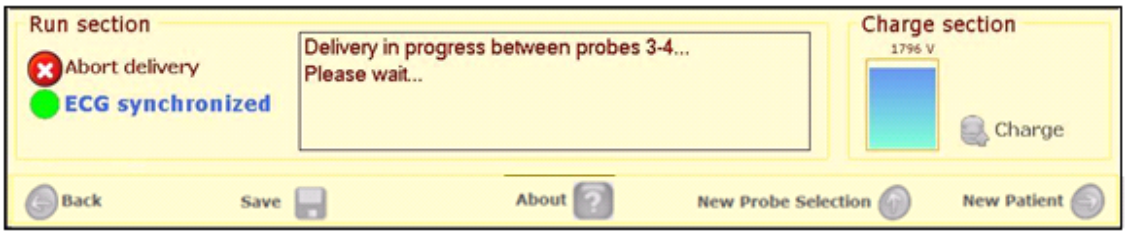


Figure 6-5: ECG Synchronized on Pulse Generation Screen During Energy Delivery

If the ECG signal is slow or not present DURING the test pulse or energy delivery, the test pulse or energy delivery will stop and a 15-second countdown will begin. If synchronization is resumed within the 15 second countdown, the test pulse or energy delivery will automatically resume. The only difference between the screens is that for the test pulse, the capacitors will have a low charge and for the energy delivery, the capacitors will have a full charge. Below is an example of the screen during energy delivery. When paused, a warning screen in Figure 6-6 will display:

"WARNING: Energy delivery paused. ECG no signal. Energy delivery will resume if synchronization restored in 5 seconds. If not, energy delivery will abort."

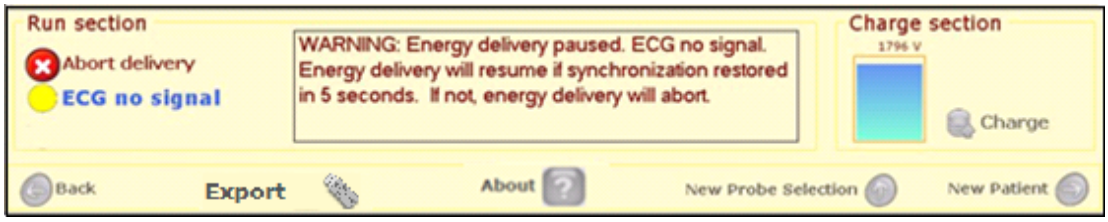


Figure 6-6: ECG No Signal on Pulse Generation Screen During Energy Delivery

If the ECG signal is fast DURING the test pulse or energy delivery, the test pulse or energy delivery will stop and a 15 second countdown will begin. If synchronization is resumed within the 15-second countdown, the test pulse or energy delivery will automatically resume. The only difference between the screens is that for the test pulse, the capacitors will have a low charge and for the energy delivery, the capacitors will have a full charge. Below is an example of the screen during energy delivery. If the energy delivery is paused, a warning screen in Figure 6-7 will display:

"WARNING: Energy delivery paused. ECG Noisy. Energy delivery will resume if synchronization restored in 9 seconds. If not, energy delivery will abort."

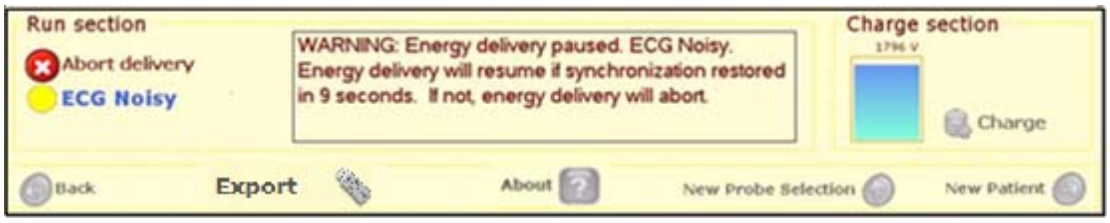


Figure 6-7: ECG Noisy on Pulse Generation Screen During Energy Delivery

If the ECG signal is not synchronized within the 15-second countdown, a 120-second countdown will begin. If the signal becomes synchronized during the 120-second countdown, the User will have the option to resume or abort the procedure. The following screen in Figure 6-8 will be displayed:

Figure 6-8: ECG Synchronized on Pulse Generation Screen During 120-Second Countdown

If the ECG signal is not synchronized within the 15-second countdown, a 120-second countdown will begin. If the signal remains low or not present for the 120 seconds, the following screen in Figure 6-9 will be displayed:

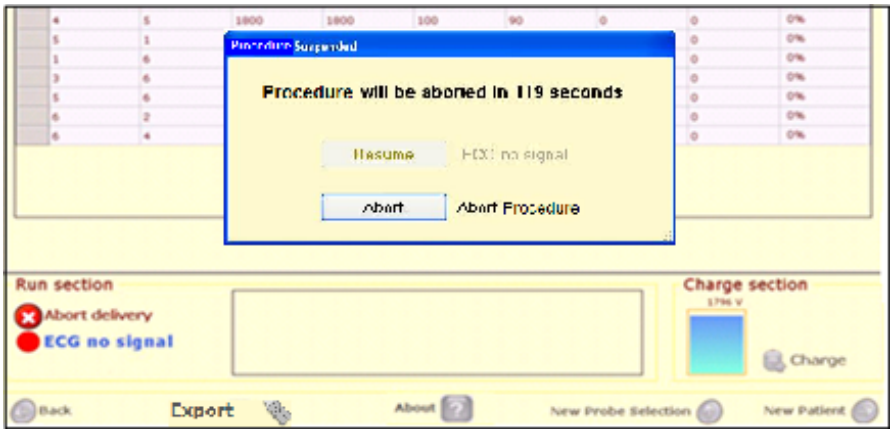


Figure 6-9: ECG No Signal on Pulse Generation Screen During 120-Second Countdown

If the ECG signal is not synchronized within the 15-second countdown, a 120-second countdown will begin. If the signal remains fast for the 120 seconds, the following screen in Figure 6-10 will be displayed:

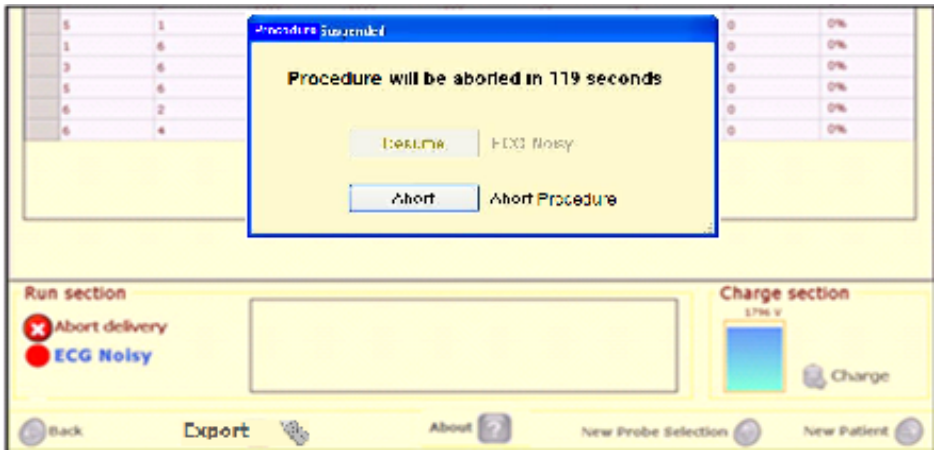


Figure 6-10: ECG Noisy on Pulse Generation Screen During 120-Second Countdown

If the ECG signal is not synchronized during the 120-second countdown or if it is synchronized and the User does not select the *Resume* button, the procedure will automatically abort.

WARNING! The triggering signal should always correspond to an R-wave. If the ablation is applied in the thoracic area, any erratic triggering signal may cause cardiac depolarization or arrhythmia.

WARNING! Should the Generator be connected to a medical device used for cardiac application (which therefore has CF applied parts), it is necessary to ascertain that the medical device continues to comply with the relevant requirements for electrical safety, prescribed by the standards (e.g., the enclosure leakage current remains lower than 100 µA and the patient leakage current remains lower than 10 µA, as prescribed by UL 60601-1).

PROBES AND ABLATION AREA

7.1 Electrode Probes

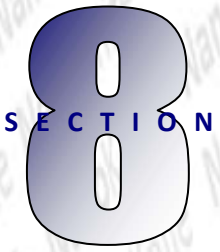
Electrode probes are required to transmit the ablation energy from the Generator to the target ablation area. The Generator works in two-pole operating mode, one probe is positive and one probe is negative. Up to six single probes can be placed at a fixed distance apart in the tissue to create several two-pole electrode configurations.

The Generator is only to be used with electrode probes supplied by AngioDynamics, Inc.

7.2 Ablation Area

Refer to the Ablation Zone, reference Section 5.1.4 Probe Placement Process Screen.

TROUBLE SHOOTING



8.1 Overview

The following tables delineate some of the process problems and error messages of the NanoKnife System and how to address them.

8.2 Documented Problems and Solutions

Table 8-2*: Problems and Solutions*

Malfunction	Possible Reasons	Actions
Generator does not turn ON	Generator unplugged from the main or main outlet not powered.	Check that the main power supply cord is connected to cord connector on the power unit back panel and that it is connected to a suitable main outlet. (Reference Section 4.2.) Check that main outlet is actually powered.
	Blown power unit main protection fuses.	Replace power unit main protection fuses (section 9.4.2). **ATTENTION!** Replace only with fuses having identical specifications, as indicated on *Appliance Data Plate*.
LCD Display does not turn ON	LCD display is OFF	Press the right-most Display Control button labeled with ⚠ symbol. (Reference Figure 3-6 in Table 3-5.)
No Current during the pulse sequence	Probe disconnected	Check that all probes are connected to the Generator.
System not able to charge/discharge	*STOP* button latched	Twist the stop button clockwise, to release it. NOTE: When the *STOP* button is latched, the *STOP button Status Indicator* is OFF.
Touchpad not working or not working correctly	Faulty component	User can temporarily use a mouse connected to the USB port, to complete patient's procedure. In general, it is not recommended to use a mouse.

8.3 Error Messages

Table 8-3: Generator Error Messages

Message	Possible Reasons	Actions
Current measured between probes {X}-{Y} exceeds limits. Check the probes and the values.	During the test pulse, the system detected excessive current between two probes.	Reposition the probes, reduce the voltage, or reduce the exposure. If error message persists, decrease the voltage between the probes.
Current Too Low between probes: {X}-{Y}. Verify probes connection and proceed to ablation.	During the test pulse, the system detected a too-low current between two probes.	Check the probes connection or the probes placement. Reposition the probes.
ECG Noisy	ECG synchronization is selected and signal is too fast.	Check the ECG system, leads, connections, buttons, and cables.
ECG No Signal	ECG synchronization is selected and signal is too slow.	Check the ECG system, leads, connections, buttons, and cables.
	ECG synchronization is selected on Patient Information screen	IF unsynchronized procedure is desired, select 90 or 240 PPM on patient Information screen.
	High-Voltage IRE delivered asymmetrically relative to ECG buttons can cause ECG saturation.	Switch ECG leads used. Relocate ECG buttons.
Error while uploading procedure parameters	The system had a problem during transfer of ablation parameters	Enter the procedure parameters again. Reboot the device to let the auto-test check the system.
Hardware Failure	The system detected excessive current and failed.	Turn OFF the system and call AngioDynamics Hardware Service.
Reading Error from USB3FPGA	Communication problem with the console and power unit.	Reboot the system to let the auto-test check the system. Repeat any portions of ablation that were not delivered. If the auto-test fails, call AngioDynamics Hardware Service.
Time Expired	The 10 seconds timeout between the activation of the ARM foot pedal and the PULSE foot pedal is elapsed.	Press the ARM foot pedal again to restart a new ablation sequence.

Message	Possible Reasons	Actions
Unable to Deliver a Correct Pulse	The system detected a pulse that is too long.	Reboot the system to let the auto-test check the system. If the auto-test fails, call AngioDynamics Hardware Service.
Unable to Complete Ablation: Charge Failure	The system detected a charge fail during the ablation.	Reboot the system to let the auto-test check the system. If the auto-test fails, call AngioDynamics Hardware Service.
Unable to Charge/Discharge	The system detected a problem during the charge or discharge of the capacitors.	Confirm that the STOP button is not engaged. If "New Probe Selection" button is active, click, then return to "Pulse Generation screen" to reinitialize and return to the Pulse Generation screen to start the ablation over. If the "Continue Procedure" and "Stop Procedure" buttons are active, Click, "Stop Procedure," and do not save. Then follow the steps above. If the system is not able to recharge or discharge the capacitors, please call AngioDynamics Hardware Service.
Warning! Low Current between probes {X}-{Y}	During the ablation a low current has been detected between two probes.	Confirm probe connections, placement and procedure parameters. It is recommended to repeat the ablation between the probes in question.
Warning! Ablation Aborted between probes {X}-{Y} due to high current.	During the ablation, excessive current was detected between two probes. The system stopped the pulse delivery only between the selected probes.	When there is high current, the system gives the User at the end of ablation, the option to "Continue Procedure" or "Stop Procedure" for the missing pulses. If the User chooses "Continue Procedure," then the User has the following options: 1. Reduce pulse length 2. Reduce voltage 3. Reduce probe exposure and treat at 2 levels 4. Increase probe spacing (NOTE: when changing probe spacing, return to the *Probe Placement Process* screen to reset ablation parameters per the new spacing).

MAINTENANCE AND SERVICE

9.1 Overview

This section describes the recommended periodical checks and preventive maintenance that the User should complete to ensure that the NanoKnife System will satisfactorily perform its intended function.

There are no User-serviceable parts inside the Generator. The warranty will be voided if the unit is opened and/or the warranty seal is broken.

9.2 Preventive Maintenance and Periodical Verifications

The following Table 9-1 indicates the recommended periodical checks and preventative maintenance.

Table 9-1: Generator Periodical Checks

Test/Service	Time Interval	Rationale
Annual Service	12 Months	Maintenance calibration required every 12 months by an authorized service agent.

9.3 Cleaning

- To periodically clean the device, use a soft, lint-free cloth, dry or slightly dampened with water. **Do not pour water or any other liquid** directly on the device. **Do not use alcohol or solvents or other aggressive products** to clean the device! The use of aggressive detergent products can discolor or damage the paint.
- The dirt remaining between the keys of the keyboard can be removed with a small vacuum cleaner (reduced power).
- Console's screen can be cleaned with a soft cloth dampened with water. Do not use spray or aerosol products on the screen, to avoid the liquid from penetrating inside the console and damaging the components.

9.4 Replacing Main Fuses

The device has the capability to select the main power for use in the US (115 V) or in Europe (230 V). The main selector is located inside the **Power Supply Group** and is a unique part of the fuse-holder in Figure 9-1.

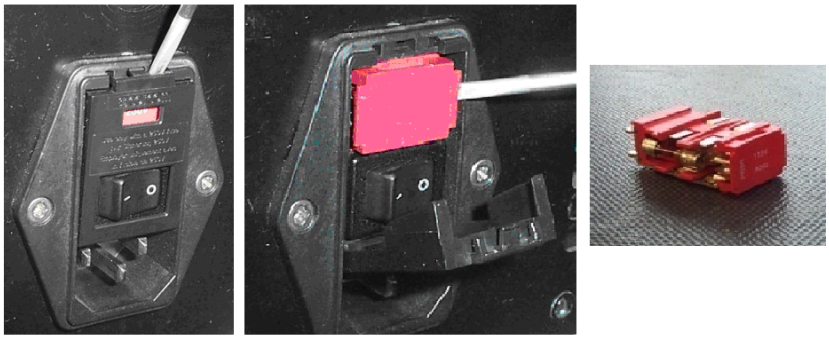


Figure 9-1: Power Supply Group Hosting the Main Selector

The device has protection fuses on the main power supply. The fuses are seated inside the** Power Supply Group**, i.e., close to the** Main Switch**.

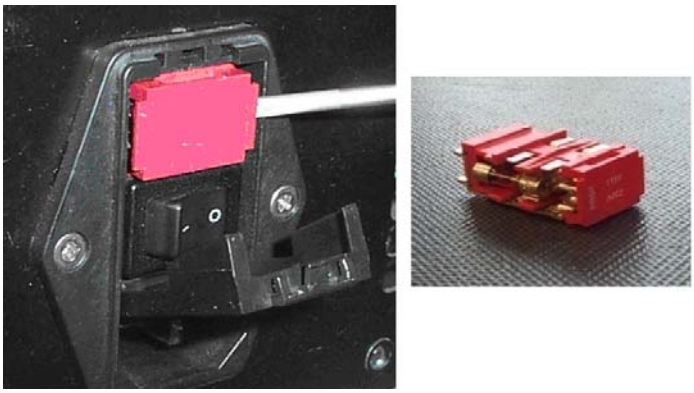


Figure 9-2: Power Supply Group Hosting Main Fuses

To replace the main fuses, perform the following steps:

1. Make sure that the **Main** switch is on "O" position, i.e., switch-OFF position.
2. Disconnect the **Main Power Supply Cord** from the Generator.
3. Open the cover of the main selector using a flat-bladed screwdriver as illustrated in Figure 9-3.
4. Pull out the “Red” fuse-holder using a flat-bladed screwdriver, as illustrated in **Figure 9-2: Power Supply Group Hosting Main Fuses**.
5. Replace the two fuses contained in the fuse-holder with new fuses, Type T 4A L 250V – 5 x 20 mm (whenever necessary).
6. Place the fuse-holder back into the Power Supply Group and close the cover.
7. Reconnect the main power cord.

CAUTION!

This operation must be carried out by qualified technical personnel.

WARNING!

Use exclusively protection fuses of the type, current and voltage values specified by the manufacturer and indicated on the **Device Plate Label**.

Do not proceed if the Generator does not charge or discharge Capacitors correctly when acting on the *Charge or Discharge* button.

After the *Discharge* button is pressed, the voltage indicated by the *High-Voltage Capacitors digital* indicator must be lower than 70 V.

TECHNICAL DATA

SECTION 10

The technical data defined in this section contain the overall system and functional specifications of the NanoKnife Generator.

10.1 General Information

Generator Model: HVP01

Manufacturer of HVP01 (NanoKnife System)
AngioDynamics, Inc.
14 Plaza Drive
Latham, NY 12110
USA

Hardware Service: 1 800 772 6446
Technical Support: 1 877 704 NANO (6266)
Fax: 1 518 798 1360

12.1 Power Supply Specifications

Main Voltage:	100 to 240 VAC
Main Frequency:	50/60 Hz
Maximum Input Power:	280 VA

12.2 Fuse Type Specifications

NanoKnife Fuse Type T 4A L 250V
Supplier: Digi-Key
Description: Axial Lead Fuse
Kigi-Key P/N: F2666-ND (Littelfuse, Inc. P/N: 0215005.HXP)
Dimensions: 5 x 20 mm
Meets IEC 60127-2
RoHS Compliant
5 Amp Rating
250 V Rating
Fuse blow occurs @ 55-65 Arms after> 10 ms

10.3.1 Inspection

Vendor to provide part description with Certificate or Conformance OR Packing List

10.4 Environmental Conditions

10.4.1 Operating Conditions

Room Temperature:	10° C to 40° C
Relative Humidity:	30% to 75%
Atmospheric Pressure:	700 to 1060 hPa

10.4.2 Transport and Storing Conditions

Current Room Temperature: -40° C to +70° C
(Note: Temperature must be from -20° to +60° C because the Non-Operating temperature range for a new ATX Power Supply is from -20°C to +80° C and the Storage Temperature of the NanoKnife Touch-Screen Monitor is specified as -20° C to +60° C.)

Relative Humidity:	10% to 90%
Atmospheric Pressure:	500 to 1060 hPa

10.5 Classifications

10.5.1 EN 60601-1 Classification

Protection Against Electric Shock: Class I

10.5.2 Protection Against Electric Shock

BF Applied Part

10.5.3 Ingress of Liquids

IPX0 – No Special Protection

Footswitch: IPX8

10.5.4 Safety Level

The Generator is NOT SUITABLE to be employed within the regions where flammable anesthetic mixtures may be present, specified by EN 60601-1.

10.5.5 EEC 93/42 Classification

Hazard Class: Class IIb

10.5.6 FDA Classification

Class II

10.6 Use Conditions

The Generator is suitable for continuous operation. It is recommended that the User shut down the device at the end of each procedure.

10.6.1 Physical Specifications (Without Packaging)

Dimensions (Width x Length x Height):	56 cm x 68 cm x 149 cm
Weight:	66 kg

10.7 Technical Specifications

Table 10-1: Technical Specifications

Component	Description
Number of Probe Outputs	1 - 6
Number of Pulses*	10 to 100
Pulse Amplitude	500 to 3000 V
Pulse Length	20 - 100 μs
Pulse Interval, Un-sync	240 PPM, 250 ms/3.5 s every 10^{th} pulse 90 PPM, 670 ms/3.5 s every 10^{th} pulse
Pulse Interval, Sync	ECG, interval varies depending on heart rate
Maximum Energy per Pulse (Nominal)	15 J
Energy Storage**	100 μF minimum
Pulse Amplitude Precision	±5%
Pulse Length Precision	±2 μs or 2% (Whichever is larger)
Maximum Current	50 A

**Number of pulses for each pair of electrodes.*
***Between recharges*

10.8 Radio Frequency Identification

FCC ID: YHS-600-104443

The RFID card with its FCC ID label is located inside the NanoKnife generator. The RFID antennas are located around the probe connectors on the front panel of the device.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment..

WARRANTY AND ELECTRO-MAGNETIC COMPATIBILITY

SECTION 11

11.1 Warranty

The NanoKnife System Generator is warranted to be free from defects of materials and workmanship under normal and proper use for a period of twelve months. Full details of this limited warranty are described in the 12-Month Limited Warranty & Extended Care Plans booklet supplied with each product.

There are no User-serviceable parts inside the Generator. **Warranty will be voided if the unit is opened and/or the warranty seal is broken.**

11.2 Electromagnetic Compatibility

The Generator has been tested and complies with relevant directives for electromagnetic compatibility of medical equipment (IEC 60601-1-2).

The Generator can be used nearby or along with other electrical or electronic equipment without the risk of hampering their normal working by electromagnetic interference.

The Generator's functionality is not affected by electromagnetic interference caused by the concurrent operation of other electrical or electronic devices, provided that they comply with relevant mandatory regulations.