NanoKnife

# NanoKnife System

## User Manual
## Version 3.5




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# NanoKnife System
## User Manual

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# SECTION 1: INTRODUCTION

## 1.1 Overview

A *NanoKnife** Procedure is an ablation procedure that involves the delivery of a series of high voltage direct current electrical pulses between two electrodes placed within or around a targeted ablation area. The electrical pulses produce an electric field which induces electroporation on cells within the targeted ablation area. Electroporation is a technique in which an electrical field is applied to cells in order to increase the permeability of the cell membranes through the formation of nanoscale defects in the lipid bilayer. After delivering a sufficient number of high voltage pulses, the cells surrounding and between the electrodes will be irreversibly damaged. This mechanism which causes permanent cell damage is referred to as Irreversible Electroporation (IRE).

Due to the body's natural reflex to high voltage electrical pulses (500-3,000 Volts), patients must be administered a neuromuscular blockade (paralytic) to minimize patient movement during pulse delivery; therefore, all NanoKnife procedures are required to be performed under general anesthesia. Furthermore, to reduce the risk of arrhythmia, NanoKnife procedures performed within a patient's abdominal or thoracic cavity require pulse delivery to be synchronized with the patient's heart rhythm which is achieved using a compatible external cardiac gating device connected to the NanoKnife Generator. The NanoKnife Generator is designed to deliver one high voltage pulse per heartbeat, within the refractory period (i.e., 50ms after the patient's R-wave is detected by the cardiac gating device).

## 1.2 Intended Purpose / Indication for Use

### 1.2.1 Intended Purpose

Ablation of tissue by cell membrane electroporation.

### 1.2.2 Indication For Use

The NanoKnife System is indicated for the ablation of soft tissue and tumors of the pancreas, kidney, liver, or prostate, including intermediate risk prostate cancer.

## 1.3 Intended User Profile

The users of the NanoKnife System will include Physicians (surgeons, interventional radiologists) and Clinical Team Members (nurses, nurse practitioner, physician's assistant, surgical fellow, surgical/radiology technicians). The primary and extended users may operate the user interface to control the NanoKnife Generator and associated peripherals, including physical procedure setup (which may include maneuvering equipment and devices, connecting electrodes, ECG connections, connecting to power supply, etc.), establishing procedure protocols, monitoring procedure progress, and stopping procedures under the supervision and direction of the primary treating physician.

## 1.4 Components

The NanoKnife System includes three components: (1) the NanoKnife Generator, which operates outside of the sterile field. (2) a Double Pedal Footswitch which connects to the NanoKnife Generator and also operates outside the sterile field, and (3) Single Electrode Probes which operate within the sterile field. The Single Electrode Probes are single-patient-use, disposable, and are packaged and shipped sterile. The NanoKnife Generator has six probe outputs, which allow a User to connect up to six Single Electrode Probes at one time. Only one electrode probe pair can be operated at a time. See Section 5, "System Operation" for more details.

## 1.5 Sections

The NanoKnife Generator 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. The instructions for use are available electronically at ifu.angiodynamics.com.



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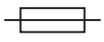
## 1.6 Symbols

The NanoKnife Generator device and labeling contain symbols. Table 1.6.1 below contains a list of the symbols, the symbol's meaning, and the location of each symbol found on the NanoKnife Generator device and labeling. A symbols glossary is provided in Section 16: of this manual.

**Table 1.6.1: NanoKnife Generator Symbols**

| Symbol | Meaning | Location |
|---|---|---|
|  | 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. |
|  | Open: When a mains power switch is pressed in the position marked by this symbol, the Generator is switched OFF. | Printed on the mains power switch |
|  | Closed: When a mains power switch is pressed in the position marked by this symbol, the Generator is switched ON. | Printed on the mains power switch |
|  | Temperature Limits | Printed on the crate label |
|  | Humidity Limits | Printed on the crate label |
|  | Atmospheric Pressure Limits | Printed on the crate label |
|  | Probe Connector 1 | Printed on the front of the Generator |
|  | Probe Connector 2 | Printed on the front of the Generator |
|  | Probe Connector 3 | Printed on the front of the Generator |
|  | Probe Connector 4 | Printed on the front of the Generator |
|  | Probe Connector 5 | Printed on the front of the Generator |
|  | Probe Connector 6 | Printed on the front of the Generator |

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| Symbol | Meaning | Location |
|---|---|---|
|  | Type BF Applied Part | Printed on the front of the Generator in between the probe connectors |
|  | Dangerous Voltage | Printed on the front of the Generator in between the probe connectors |
|  | Emergency Stop | Printed on the front of the Generator |
|  | Emergency Stop Button | Printed on the front of the Generator |
|  | Emergency Stop Button Status Indicator | Printed on the front of the Generator |
|  | Pedal connector | Printed on the front of the Generator |
|  | ECG Synchronization Signal Input | Printed on the back of the Generator above the Female BNC Connector. |
|  | Equipotentiality | Printed on the back of the Generator below the Equipotential Plug Connector |
|  | CAUTION: Indicates that the User should read the accompanying documentation in order to understand and/or correctly use the part marked by the symbol. | Printed on the data plate |
|  | Dangerous High Voltage | Printed on the data plate |
|  | Alternating Current: Indicates the kind of current required to be supplied. | Printed on the data plate |
|  | Fuse Rating | 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 |
|  | Legal Manufacturer | Printed on the data plate |
|  | Manufacturing Date | Printed on the data plate |

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| Symbol | Meaning | Location |
|---|---|---|
|  | Magnetic Resonance Unsafe | Printed on the data plate |
|  | Mass; Weight | Printed on the data plate |
|  | Catalog Number | Printed on the data plate |
|  | Serial Number | Printed on the data plate |
|  | European Authorized Representative | Printed on the data plate |
|  | Prescription Only, For provision and use only at a licensed physician's direction and under medical supervision | Printed on the data plate |
|  | Federal Communications Commission mark certifies the product is compliant to FCC Part 15 rules regarding intentional transmitting devices | Printed on the data plate |
|  | This test mark is proof of product compliance to North American electrical safety standards | Printed on the data plate |
|  | Device meets the requirements of the Medical Device Regulations and appropriate Quality System standards. | Printed on the data plate |
|  | This device emits radiofrequency transmissions | Printed on the data plate |

## 1.7 Specific Part Symbols

**Table 1.7.1: Specific Part Symbols**

| Symbol | Meaning | Location |
|---|---|---|
|  | 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 |
|  | Hard Disk Drive Status Indicator It is intermittently lighted when the Hard Disk Drive is operating. | Above console's keyboard |

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# SECTION 2: SAFETY INSTRUCTIONS

## 2.1 Overview

The Generator must be operated by properly qualified personnel only.

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

This product conforms to the requirements of Council Directive 93/42/EEC of the Council of European Communities (Medical Device Directive). Affixing the 'CE Mark' to the instrument indicates conformity to this directive.

CE 2797

The Safety Instructions included in this manual are divided into the following sections:

**Safety Features of the Generator** – identifies the safety features available on the product to assist safe use.

**Contraindications** – conditions under which the NanoKnife* System should not be used.

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

**Precautions** – 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.

**Potential Adverse Effects** – a listing of conditions that may result from an ablation.

## 2.2 Safety Features of the Generator

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

- **ECG Synchronization:**
  The NanoKnife Generator has ECG Synchronization set as the default pulse delivery mode setting. ECG synchronization must be employed in all ablations in the thorax and abdomen to avoid potential risks described further below.
- **Double Pedal Footswitch:**
  The NanoKnife Generator incorporates a double pedal footswitch that prevents accidental delivery of procedure pulses. The foot pedals require the User to first arm the system by depressing the Left (ARM) Footswitch Pedal, and then sequentially, depressing the Right (Pulse) Footswitch Pedal within 10 seconds of arming to deliver energy to the patient.
- **Output Current Restriction:**
  When the Generator senses that the current between any electrode pair exceeds the operating parameters, the remaining pulses within the current set of 10 pulses are stopped. This safety feature protects against applying output energy that exceeds maximum current settings.
- **Conductivity Test:**
  After electrode probes are placed and prior to pulse delivery, the Generator sends one low-energy pulse between each active probe pair through the targeted ablation area to confirm the tissue impedance is within an acceptable range.

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## 2.3 Contraindications

Ablation procedures using the NanoKnife System are contraindicated in the following cases:

- Ablation of lesions in the thoracic area in the presence of implanted cardiac pacemakers or defibrillators
- 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 or Cardiac Arrhythmia
- Recent history of Myocardial Infarction.

## 2.4 Warnings

### 2.4.1 Clinical Issues (including Arrhythmia, Hypertension, and Thrombus Risks)

- The NanoKnife device has been evaluated for the ablation of prostate tissue in patients with intermediate risk prostate cancer. The use of this device in other organs for other disease states has not been fully evaluated.
- Patients with Q-T intervals greater than 500 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 (90 PPM (Pulses Per Minute)) might trigger atrial or ventricular fibrillation, especially in patients with structural heart disease. Ensure that proper interventions (e.g. defibrillator) and appropriately trained personnel are readily available for dealing with potential cardiac arrhythmias (see Section 6.6).
- Using QRS synchronization devices whose output is not compatible with the specifications listed in this manual may result in arrhythmias including ventricular fibrillation.
- Adequate precautions should be taken for patients with implantable electrical devices. Note the contraindication in certain patients.
- There are potential risks associated with the location of the ablation: near the pericardium (tachycardia), or near the vagus nerve (bradycardia).
- Additional patients may be at risk with insufficient muscle blockade or anesthetic analgesia (reflex tachycardia and reflex hypertension); patients with abnormal sinus rhythm prior to an ablation (arrhythmia); patients with a history of hypertension (hypertension); or patients with partial portal venous thrombosis, low central venous pressure (CVP), and a prothrombotic condition (venous thrombosis).

### 2.4.2 Use of Electrodes

- Avoid repeated vascular insult during electrode placement.
- As anticipated with a needle-related procedure, repeated vascular insult due to multiple insertions into a vessel by an electrode during electrode placement may cause thrombus.
- Ensure continuous image guidance during the needle placements. Failure to do so can lead to traumatic injury to surrounding structures.
- Care should be taken during electrode placement in areas that require tissue be separated or retracted to avoid surrounding tissue damage.
- To avoid risks of infection, always maintain the electrodes' protective packaging (cap, tubes, etc.) when the electrodes are not placed in the patient.
- Only electrode probes with intact electrical insulation must be used. Any electrodes with damaged electrical insulation must be discarded immediately and not connected to the NanoKnife Generator.

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- 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.
- Maintain electrical separation of the electrodes from safety ground by doing the following
    - Disconnect any electrode from the Generator that is not applied to the patient.
    - Avoid any clamping of the electrode's cable, unless explicitly instructed or authorized by the electrode's manufacturer.
    - 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 Use of Generator (including Electrocution Hazard)

**WARNING:** No modification of this equipment is allowed.

**WARNING:** To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

- 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.
- Do not use the Generator in the presence of flammable anesthetics or agents.
- This Generator is not for use in an oxygen-rich environment.
- For electrical safety, the Generator needs grounding. Use only medical grade main power supply cords, e.g., those supplied by the manufacturer.
- 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 fuses specified in this manual, see Section 14.3.
- Maintenance should be carried out only by trained personnel. The Generator must undergo periodic preventative maintenance as specified in the Maintenance and Service see Section 13.2.
- 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 ablation field.
- The position of the electrodes should be monitored during pulse delivery to assure that the probe depth is not changing due to tissue reaction.
- A distance of at least 65 cm should be maintained between the front panel of the Generator and other medical devices susceptible to RF interference such as, but not limited to pacemakers and implantable cardiac defibrillators.

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- 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 the NanoKnife procedure 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.
- Intra-operative hypertension can be an indication of insufficient anesthesia administration which possibly includes insufficient narcotic administration. Conditions in which muscle stimulation is occurring require immediate pharmacologic correction. All anesthesia administration must follow ASA (American Society of Anesthesiology) or equivalent guidelines.
- Energy delivery attempts must be terminated after a high current warning during an ablation in anatomical locations in which there are abutting lumens or other critical structures. Continuous attempts to deliver energy during repeated high current warnings during ablations such as these, may result in fistula formation, especially in patients who have had prior radiation therapy or surgery in the immediate zone of ablation.
- Use of operator-defined instead of default parameters increases the risk of ineffective procedures or post-procedure complications.
- 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 mains power supply (see Section 14.2) and that the mains power supply outlet can 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. 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; Do not expose the Touchscreen LCD Display to direct sunlight for long periods of time.
- Respect environmental operating and storing conditions, as specified in Section 14.4. Ensure that nothing obstructs the ventilation grids, which are on the rear panel of the Generator and under the console, 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 Touchscreen LCD Display to preserve the image quality.
- Before cleaning 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 (IEC 60601-1).
- Do not position Medical Electrical (ME) Equipment in such a way that it is difficult to unplug the device in the event of an emergency.
- To isolate the Medical Electrical (ME) Equipment from the supply mains, unplug the device from the wall socket or power source.

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## 2.6 Potential Adverse Effects

Adverse effects that may be associated with the use of the NanoKnife System include, but are not limited to the following:

- Arrhythmia
  - Atrial fibrillation or flutter
  - Bigeminy
  - Bradycardia
  - Heart block or atrioventricular block
  - Paroxysmal supraventricular tachycardia
  - Tachycardia
    - Reflex tachycardia
    - Ventricular tachycardia
  - Ventricular fibrillation
- Damage to critical anatomical structure (nerve, vessel, and/or duct)
- Fistula formation
- Hematoma
- Hemorrhage
- Hemothorax
- Infection
- Inflammation
- Tissue Damage / Dysfunction
- Pneumothorax
- Reflex Hypertension
- Unintended mechanical perforation
- Vagal Stimulation, asystole
- Venous Thrombosis

**Notice for European Union Only:** Any serious incident which has occurred with the use of this device should be reported to AngioDynamics at complaints@angiodynamics.com and to the National Competent Authority. Refer to the following web address for contact information for the Competent Authorities. https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_vigilance_contact_points.pdf

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# SECTION 3: GENERATOR COMPONENTS

## 3.1 Overview

The NanoKnife Generator utilizes single-patient-use disposable Single Electrode Probes to transmit energy from the Generator to a targeted ablation area.

The NanoKnife Generator in Figure 3.1.1 includes the following:

1. Touchscreen LCD Display
2. Console and Keyboard
3. Power Unit and Power Cord
4. Double Pedal Footswitch




**Figure 3.1.1: NanoKnife Generator – Main Components**



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## 3.2 NanoKnife 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 Touchscreen LCD Display. The console includes a conventional keyboard with Power-On, Caps Lock and Hard Disk Drive function light indicators, a touchpad with two buttons, and two USB ports located on the right side panel.

The details of the Generator front/right side components, including the console are shown in Figure 3.2.1, while the names of the Generator elements are listed in Table 3.2.1.




**Figure 3.2.1: NanoKnife Generator – Front Right Components**

**Table 3.2.1: NanoKnife Generator – Front Right Components**

| Refer to Figure 3.2.1 | Component | Description |
|---|---|---|
| **1** | Touchscreen LCD Display | Displays a graphic User interface |
| **2** | LCD Display Label | Contains NanoKnife Logo |
| **3** | Keyboard | Serves to input data and interact with the Generator |
| **4** | USB Ports | USB Ports to connect USB Storage Devices |
| **5** | Tray | Provides a place for external Cardiac Gating Device. |
| **6** | Side Pockets | Designed as a container for the pedal, electrodes and other accessories, such as the User 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 |

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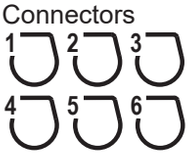
## 3.3 NanoKnife Generator – Lower Front Components

There are five front/lower panel elements of the Generator as shown in Figure 3.3.1 and described in Table 3.3.1.




**Figure 3.3.1: NanoKnife Generator – Lower Front Components**

**Table 3.3.1: NanoKnife Generator – Lower Front Components**

| Refer to Figure 3.3.1 | Component | Description |
|---|---|---|
| 1 | Six Electrode Probe Connectors   | Plug-in for electrodes |
| 2 | 7th Antenna | The 7th antenna is only for service procedures, etc. It is not used in clinical procedures. |
| 3 | **Red Stop** Button identified by the symbol  | 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. |
| 4 | **Red STOP** Button status Indicator  | When lighted indicates that **Red STOP** button is released and procedure can commence. If NOT lighted, the **Red STOP** button is engaged and unit is in safety mode. **Red STOP** button must be released to proceed with procedure. |
| 5 | Pedal Connector, identified by the symbol  | Connection site for the Double Pedal Footswitch |





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## 3.4 NanoKnife Generator Power Unit - Lower Back Components

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 Pedal Footswitch that starts the procedure. Figure 3.4.1 and Table 3.4.1 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 ECG synchronization of the ablation.




**Figure 3.4.1: NanoKnife Generator Power Unit – Lower Back Components**

**Table 3.4.1: NanoKnife Generator Power Unit – Lower Back Components**

| Refer to Figure 3.4.1 | Component | Description |
|---|---|---|
| **1** | Power Supply Group | Groups the mains power switch, cord connector and protection fuses slide |
| **2** | Protection Fuses Slide | Insertion site for protection fuses; allows selection of the mains voltage |
| **3** | Mains Power Switch | Turns the Generator ON/OFF |
| **4** | Cord Connector | Connects the mains power supply cord |
| **5** | External Sync Connector | Connects a cardiac gating device, e.g., QRS detection |
| **6** | Data Plate | Indicates the unit name, model, serial number, manufacturer, power supply specifications, and power fuse specifications |
| **7** | Equipotential Plug Connector | Provides connection for potential equalization. |

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## 3.5 NanoKnife Generator Back Handle

The back handle assists with moving the Generator. The Generator should only be lifted from the handle to move it over an obstacle. It is also suitable for winding the Main Power Supply Cord around when not in use, see Figure 3.5.1.

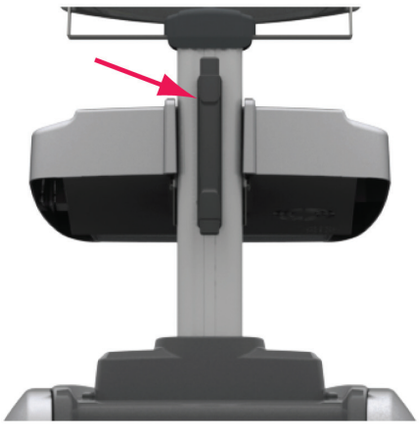


**Figure 3.5.1: NanoKnife Generator Back Handle**

## 3.6 Equipment and Supplied Components

Table 3.6.1 lists the Generator components and supplied quantities.

**Table 3.6.1: Equipment and Supplied Components**

| Quantity | Component |
|---|---|
| **1** | Generator |
| **1** | Double Pedal Footswitch |
| **1** | Power Cord |
| **Optional** | Electrodes (Purchased separately) |

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

## 3.7 Touchscreen LCD Display

The viewing angle of the LCD display ranges from 45° forward to 90° backward, Figure 3.7.1.




**Figure 3.7.1: NanoKnife Generator Touchscreen LCD Display**



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## 3.8 Console Components

There are six console components on the Generator that are shown in Figure 3.8.1 and described in Table 3.8.1.




**Figure 3.8.1: NanoKnife Generator Console Components**

**Table 3.8.1: Console Component Descriptions**

| Refer to Figure 3.8.1 | Component | Description |
|---|---|---|
| 1 | Touchpad with left and right buttons | Moves the screen pointer across the screen to interact with application; two buttons replace conventional right and left mouse buttons. |
| 2 | Front Handle | Assists in moving the device. |
| 3 | Hard Disk Function Light indicator identified by the **HDD** symbol | When lighted indicates whether the hard disk is currently working. |
| 4 | Caps Lock Indicator identified by the ⇪ symbol | When lighted indicates that the keyboard's letter keys are in uppercase. |
| 5 | Console Power-ON indicator identified by the ⏻ symbol | When lighted indicates that the console is switched ON. |
| 6 | USB Ports | USB Ports to connect USB Storage Devices |

## 3.9 Electrode Probe Components

Electrode Probes are available from AngioDynamics for use with the NanoKnife Generator.

Single Electrode Probes are available in 15 cm and 25 cm lengths. A minimum of two probes is required for a procedure. Depending on the size of the 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 target area.

A Single Electrode Probe Spacer is available as an optional accessory to aid in spacing the probes at a fixed distance and aiding in keeping the probes parallel.

Please refer to Single Electrode Probe IFU (Instructions For Use) for detailed electrode probe component information.

Check with your AngioDynamics sales representative or authorized distributor for more information on available electrodes.



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# SECTION 4: INSTALLATION AND START-UP

## 4.1 Location and Installation

The Generator must be installed and operated in an environment that conforms to the operating conditions specified in Section 14.4.

The Generator must be installed on rigid surfaces suitable to withstand its weight as specified in Section 14.6.1.

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.

### 4.1.1 Installation Instructions

- Connect the Mains Power Supply Cord (supplied by the manufacturer) to the cord connector located on the back panel.
- Connect the plug to a mains outlet with protective ground.
- Turn ON the Generator via the Mains Power Switch of the Power Supply Group, located on the power unit's back panel. The system is ON when the mains power switch is pressed in "I" position. When the switch is pressed in the "O" position, the device is OFF.

## 4.2 NanoKnife Generator Start-Up Self Test

To start up the NanoKnife Generator proceed as described below:

1. Move the Mains power switch located at the back panel of the power unit to position "I". The Green Power ON Indicator on console lights up while the console starts loading the operating system. If the generator does not turn on refer to Section 12, Troubleshooting.
2. Allow about 10 seconds for the video signal to appear on the LCD display.
3. Check that the **Red STOP** button status Indicator, on the Generator's front panel, is lit Green. If not lit, rotate the **Red STOP** button knob clockwise, as indicated on the knob to release the **Red STOP** button.
4. The NanoKnife Generator will begin a start-up self test. It will run through a series of tests before the User gains access to the NanoKnife Software:
    - Initializing Device
    - Checking Device Status
    - Checking Connections
    - Testing Charge

A status bar displays the progress of the start-up self test, Figure 4.2.1 and Figure 4.2.2.




**Figure 4.2.1: Start-Up Screen in Progress**





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**Figure 4.2.2: Start-Up Screen Successfully Passed All Self Tests**

If one of the Generator's self-test checks fails, an error message will be displayed. Figure 4.2.3 is an example of an error message. The User must then click the Proceed ✓ button, which will shut down the Generator, so that it can be restarted.

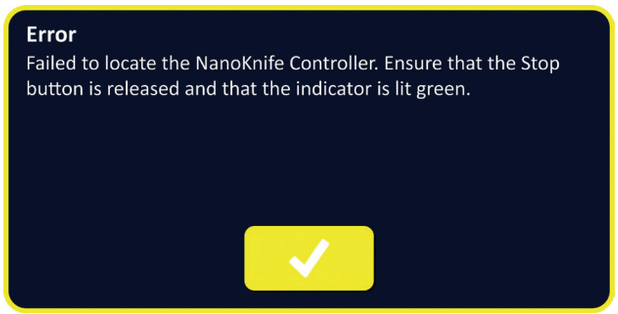



**Figure 4.2.3: Start-up Self Test Error Popup**

Refer to Section 12.3 for a complete list of start-up self test error messages.

If all self-tests are successful, the Procedure Setup screen will appear on the Touchscreen LCD Display (see Figure 6.1.1). If the generator repeatedly fails the self test, call AngioDynamics Hardware Service.

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# SECTION 5: SYSTEM OPERATION

## 5.1 Procedure Overview

An overview of a typical NanoKnife ablation procedure is listed below. Refer to subsequent sections of this user manual for detail usage instruction on operation of the NanoKnife Generator.

### 5.1.1 Procedure Setup (before patient enters procedure room):

1. Plug in the NanoKnife Generator and cardiac gating device into a grounded power outlet within the procedure room.
2. Power on the NanoKnife Generator. The NanoKnife Generator will initiate and complete a Power-On Self-Test (POST).
3. Attach the Double Pedal Footswitch to the NanoKnife Generator.

### 5.1.2 Patient Preparation

4. Prepare patient for general anesthesia.
5. Position patient into appropriate position for anticipated NanoKnife Single Electrode Probe insertion (e.g., supine, prone, lateral, lithotomy).
6. Power on the cardiac gating device.
7. Place the cardiac gating device patient leads onto patient with standard ECG sticker electrodes.

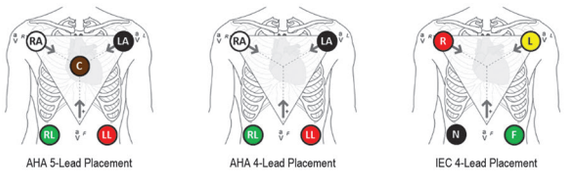



**Figure 5.1.1: Cardiac Gating Device Lead Placement**

8. Connect the other end of the cardiac gating device lead cable to cardiac gating device.
9. Attach one end of the cardiac gating device BNC cable to the cardiac gating device connector mount labeled ‘Synchronized Output’. Connect the other end of the BNC cable to the NanoKnife Generator connector mount labeled .
10. Confirm ECG signal visually on cardiac gating device monitor and select one or more appropriate lead pair waveforms (i.e., selecting a lead pair that displays a tall R-wave and small T-wave, synch indicators aligned with R-wave, absent of electrical interference or noise).

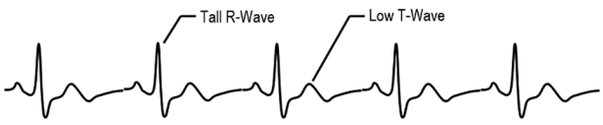



**Figure 5.1.2: Appropriate Lead Pair Waveform Example**

11. Prepare patient for sterile procedure.
12. ***OPTIONAL***: Make a surgical incision (e.g., for NanoKnife procedures performed via laparotomy i.e., open surgery).
13. ***OPTIONAL***: Perform other intended procedures on patient (e.g., metal stent removal, biopsy, lysis of adhesions, etc.).



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### 5.1.3 Procedure Planning

14. Enter patient ID into the NanoKnife Software Procedure Setup screen.
15. Optional: Enter procedure information and case notes into NanoKnife Software.
16. Use imaging equipment to visualize target area(s) and surrounding tissues.
17. Measure X, Y, and Z dimensions of targeted ablation area using imaging equipment measurement tools.
18. Select the desired Probe array type on the Probe Selection screen.
19. Click the Next ➔ button to advance to the Procedure Planning screen.
20. Enter the target area X, Y, and Z dimensions into the NanoKnife Software.
21. Use imaging equipment to determine the Single Electrode Probe placement approach and angle of insertion that avoids tissue obstacles (e.g. bone) and avoids placing any of the Single Electrode Probes into or through critical structures (e.g. blood vessels, bile ducts). The exposed electrodes of each Single Electrode Probe should be placed such that they bracket the targeted ablation area while maintaining Probe Pair Distances between 1.0 cm and 2.0cm. Refer to Section 5.3 Procedure Parameter Settings for more information on probe spacing and probe exposure.

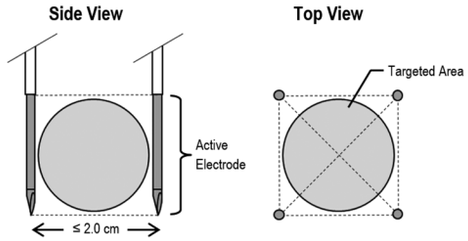



**Figure 5.1.3: Single Electrode Probes Bracketing the Targeted Area**

22. Enter the Probe Placement Plan into the Probe Placement Grid.
23. Click the Back ➔ button to return to the Procedure Setup screen.

### 5.1.4 Procedure Setup

**Note:** Refer to the Single Electrode Probe Instructions for Use included with each product for additional procedure instruction.

**Note:** The NanoKnife Generator requires the use of Activation Probes, which have a blue handle.

24. Using sterile technique, open and remove each Single Electrode Probe from its packaging. Remove and dispose of the protective shipping sheath covering the needle.
25. Place each Single Electrode Probe onto the sterile field table.
26. Uniquely number each Single Electrode Probe (1 thru 6) at both ends of the Single Electrode Probe cabling using pre-numbered tags supplied with probes or a sterile marker and Steri-Strip.




**Figure 5.1.4: Single Electrode Probes Uniquely Numbered**





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27. Pass off each Single Electrode Probe to treating physician within the sterile field.
28. Pass off Single Electrode Probe cable connectors to the NanoKnife Generator User, located outside the sterile field.
29. Connect each Single Electrode Probe cable connector to the corresponding numbered Probe Connector of the NanoKnife Generator.
30. Click the Next ➔ button to advance to the Procedure planning screen
31. Adjust the exposed electrode region of the Single Electrode Probe, referred to as the Probe Exposure Setting, using the thumb slide, pressing down on the proximal raised end to unlock.

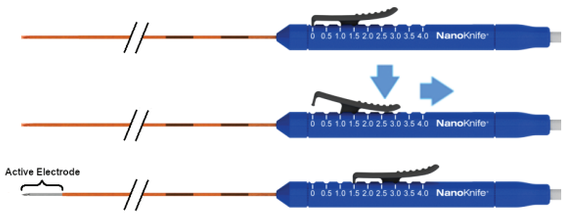



**Figure 5.1.5: Electrode Exposure Region Adjustment**

### 5.1.5 Probe Placement

32. Verify entry point and trajectory of each Single Electrode Probe prior to insertion using imaging equipment.
33. ***Optional***: Use one or more NanoKnife Single Electrode Probe Spacers to help place the Single Electrode Probes parallel to each other and at a set distance apart.
34. Place each Single Electrode Probe carefully and systematically, using imaging equipment under continual image guidance while avoiding tissue obstacles and critical structures.
35. Use imaging equipment to verify Single Electrode Probe placement is consistent with the intended probe placement plan.
36. Measure and record all the inter-electrode distances using imaging equipment measurement tools.

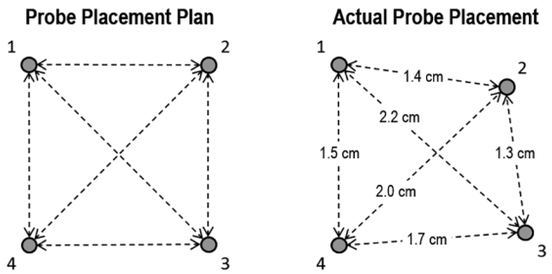



**Figure 5.1.6: Inter-Probe Distance Measurements**

37. Update the Probe Placement Grid to reflect changes made to the initial Probe Placement Plan.
38. Review the pulse parameters table to ensure all intended active probe pairs are included and all intended inactive probe pairs are excluded.
39. **Optional**: Use clinical judgement to either accept or modify the default pulse parameters. Refer to Section 5.3 Procedure Parameter Settings for more information.



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### 5.1.6 Pulse Generation

40. Click the Next ➔ button to advance to the Pulse Generation screen. The NanoKnife Generator will charge to the conductivity test voltage (≈ 400 volts). Also refer to Section 12 Troubleshooting if high current is encountered during the conductivity test.
41. Confirm adequate level of paralysis of patient using a twitch monitor (i.e. 0/4 twitches).
42. Confirm 'ECG Synchronization' status on Pulse Generation screen.
43. Initiate the conductivity test using the Double Pedal Footswitch. The NanoKnife Generator will deliver conductivity test pulses.
44. Click the Proceed ✔ button after successfully completing the conductivity test. The NanoKnife Generator will charge to maximum voltage set in the Pulse Parameters table (e.g. 3,000 volts).
45. Initiate pulse delivery using the Double Pedal Footswitch. The NanoKnife Generator will start pulse delivery. Refer to Section 12 Troubleshooting if difficulties (including high or low current notices) are encountered during pulse delivery

**CAUTION:** Monitor the pulse delivery process for any warning during the process.

46. After pulse delivery completes, review the voltage and current graphs to ensure all intended pulses were delivered.
47. Assess the ablation area using imaging equipment to ensure efficacy and preservation of critical structures.
48. ***Optional***: Assess the current changes displayed in the Pulse Parameters Table for each Active Probe Pair and determine if additional pulses are needed for any probe pair using clinical judgement.
49. ***Optional***: The NanoKnife Single Electrode Probes may be re-positioned after pulse delivery to ablate a larger area utilizing an overlapping and/or pullback ablation technique.

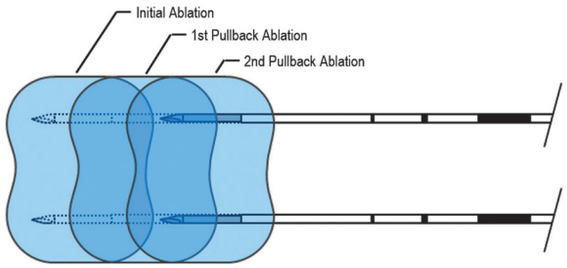



**Figure 5.1.7: Pullback Ablation Technique**

### 5.1.7 Probe Removal and Disposal

50. Use the thumb slide to change the Probe Exposure Setting to 0 cm for each Single Electrode Probe, thereby covering the exposed electrode region and the sharp tip.
51. Remove each Single Electrode Probe from the patient.
52. Place Single Electrode Probe onto sterile prep area.
53. ***Optional***: Place pressure on NanoKnife Single Electrode Probe puncture site until hemostasis is obtained; alternatively, a cautery device may be used if required.
54. Disconnect all Single Electrode Probe cable connectors from the NanoKnife Generator.
55. ***Optional***: Perform other intended procedures on patient if required and suture surgical incision if required.
56. Single Electrode Probes are sharp devices. Used or unused devices and should be disposed of in accordance with hospital, administrative and/or local government policy for such items.



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Uncontaminated device packaging should be recycled if applicable, or disposed of as common waste in accordance with hospital, administrative and/or local government policy for such items.

### 5.1.8 Ending Procedure

57. Remove cardiac gating device lead wires from patient.
58. Check patient paralysis level using a twitch monitor until effects of paralytic have worn off.
59. After patient has woken from general anesthesia, transport patient for post-operative recovery and monitored care.

### 5.1.9 Equipment Shut-Down, Cleaning, and Storage

60. ***Optional***: Click the Export button and export procedure files from NanoKnife Generator using an external USB storage device.
61. Click the Exit button on navigation bar and wait for the NanoKnife Generator to complete the shutdown sequence.
62. Power off, unplug and clean the NanoKnife Generator, Double Pedal Footswitch, and cardiac gating device. Refer to Section 13.3 for detailed cleaning instruction.
63. Wrap NanoKnife Generator power cable neatly around back handle of the NanoKnife Generator.
64. Unplug and clean cardiac gating device cable and lead wires. Neatly coil cables and wires and store in side pocket of NanoKnife Generator.
65. Neatly coil Double Pedal Footswitch cord and store in side pocket of NanoKnife Generator.
66. Carefully transport NanoKnife Generator and cardiac gating device to appropriate area designated for medical equipment storage.

## 5.2 Procedural Guidelines and Recommendations

- The NanoKnife System requires deep muscle blockade and general anesthesia (0/4 twitches on the Train of Four Test).
- ASA guidelines require a defibrillator be readily available for general anesthesia (defibrillator pads are recommended).
- ECG Leads for the Cardiac Gating Device should be placed at the appropriate location on the patient prior to preparing the sterile field.
- Anesthesia EKG monitors may display artifacts on the EKG waveform during pulse delivery; however, the peripheral capillary oxygen saturation (SpO2) and arterial line tracings should not display artifacts during pulse delivery.
- Patients are to be positioned to best facilitate access to the targeted lesion (per treating physician's clinical judgment and experience).
- To reduce the frequency of over current conditions (i.e. pulse delivery stops due to high current detected above 50 amps), the predicted current draw following the conductivity test should not exceed 35 amps.

**CAUTION:** Amperage draw will typically rise during pulse delivery.

- Metallic implants (e.g. covered or bare metal stents) positioned within 1cm of the targeted ablation area should be removed prior to pulse delivery to reduce the risk of incomplete ablation.
- A pullback ablation technique, defined as sequential ablations performed after pulling back all Single Electrode Probes a set distance, may be used to ablate larger targeted ablation areas. To ensure adequate ablation overlap, the pullback distance should not exceed the probe exposure setting. For example, if each probe has a probe exposure setting of 1.5 cm, the pullback distance of each probe should be less than 1.5 cm (e.g. 1.3 cm).



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- To ablate larger targeted ablation areas, (> 4.0cm) an overlapping ablation technique may be used, defined as sequential ablations performed after repositioning one or more Single Electrode Probes.

**CAUTION:** Single Electrode Probe visibility under ultrasound may be reduced after initial ablation. The hyperechoic zone seen immediately post ablation on ultrasound may impede the ability to take probe pair distance measurements and to avoid damaging vital/critical structures after repositioning the Single Electrode Probes.

- An overlapping ablation technique using the two probe array is not recommended as an alternative to using an adequate number of Single Electrode Probes to bracket the entire target ablation area.
- To reduce risk of tumor seeding, it is recommended to set the Probe Exposure Setting to 0 cm for each Single Electrode Probe before removing the probe from the patient.
- To reduce the risk of mechanical perforation during pulse delivery and subsequent thrombosis, probes should be placed parallel to blood vessels, ducts, or other critical structures.
- Due to NanoKnife ablation's protracted method of cell death, follow up imaging via positron emission tomography (PET) conducted less than 3 months following the NanoKnife procedure may detect the natural immune response post ablation as a positive indication for metabolic activity.

## 5.3 Procedure Parameter Settings

Any references made to 'typical' settings in Table 5.3.1 do not guarantee improved, enhanced, or favorable outcomes. It is the sole responsibility of the treating physician to determine appropriate device settings using their best clinical judgement.

**Table 5.3.1: Procedure Parameter Settings**

| Procedure Parameter | Setting |
|---|---|
| **Probe Spacing:** | |
| Minimum recommended spacing | 1.0 cm |
| Maximum recommended spacing | 2.3 cm |
| Typical range used | 1.5 – 2.0 cm |
| **Probe Exposure Length** | |
| Minimum recommended probe exposure | 1.0 cm |
| Maximum recommended probe exposure | 2.5 cm |
| Recommended starting point for most soft tissue | 1.5 cm |
| Recommended starting point for high conductivity tissue (e.g. muscle) | 1.0 cm |
| Recommended maximum probe exposure for high conductivity tissue | 1.5 cm |
| **Pulse Length:** | |
| Default system setting | 90 µsec |
| Minimum recommended setting | 70 µsec |
| Maximum system setting | 100 µsec |
| Typical range used | 70 – 90 µsec |
| **Number of Pulses per probe pair:** | |
| Default system setting | 70 pulses |
| Maximum system setting | 100 pulses |
| Typical range used for this setting | 70 - 90 pulses |
| Typical number of total pulses per probe pair (after multiple rounds) | 140 – 270 pulses |



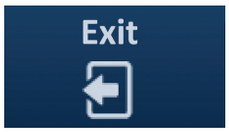
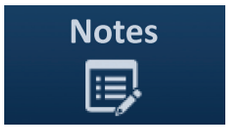
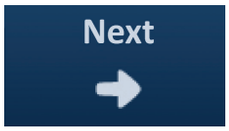
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| Volts/cm: | |
|---|---|
| Default System Setting | 1500 volts/cm |
| Typical range used | 1400 – 2000 volts/cm |
| **Volts:** | |
| Default System Setting | The value for the default volts setting is based upon probe spacing, to achieve 1500 volts/cm |
| Minimum system setting | 500 volts[1] |
| Maximum system setting | 3000 volts |
| **Probe pair current range** | |
| Maximum current system will allow | 50 amps |
| Typical current range target at conductivity test | 20-35 amps[2] |
| **Notes:** | |
| 1. During the conductivity test the system will deliver one pulse of approximately 400 volts.<br>2. The current normally rises as pulses are delivered, refer to section 8.2.6 for more information. | |

## 5.4 Table of Buttons

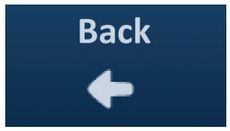
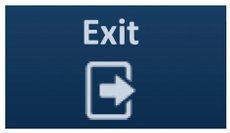
Refer to Table 5.4.1 below for a list of buttons and icons that appear in the NanoKnife Software and their functionality.

**Table 5.4.1: Buttons and their Function**

| Button | Function |
|---|---|
|  | Exit button on the Procedure Setup screen quits the application and shuts down the Generator. |
|  | New Patient button on all screens allows the User to go to the Procedure Setup screen to start a new procedure on a different patient. |
|  | Export button on all screens opens an Export dialog box, which allows the User to save procedure data to a USB Flash drive. |
|  | Notes button on all screens opens the Case Notes dialog box, which displays existing case notes and allows the User to enter in new case notes. |
|  | Settings button on all screens opens the Settings dialog box, which displays available language and Pulse Delivery Mode settings. |
|  | Next button on the Procedure Setup and Procedure Planning screens takes you to the next screen. |

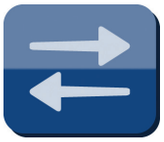
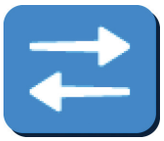


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| Button | Function |
|---|---|
|   | Back button on the Procedure Planning and Pulse Generation screens takes you to the previous screen. |
|   | Exit button on the Pulse Generation screen quits the application and shuts down the Generator. |
|  | Blue Accept Button located on various settings and parameter dialog boxes allow the user to accept the operation as listed in the dialog box. |
|  | Blue Reject Button located on various settings and parameter dialog boxes allow the user to reject the operation as listed in the dialog box. |
|  | Orange Accept Button located on various warning and attention dialog boxes allow the user to accept the operation as listed in the dialog box. |
|  | Orange Reject Button located on various warning and attention dialog boxes allow the user to reject the operation as listed in the dialog box. |
|  | Yellow Accept button located on various failure dialog boxes allow the user to proceed with exiting the software and shutting down the Generator. |
|  | Up Arrow button located on various pulse parameter settings dialog boxes allow the User to increase pulse parameters by a specific increment as listed in Table 7.5.2. Press and hold button to quickly increase the parameter value. |
|  | Down Arrow button located on various pulse parameter settings dialog boxes allow the User to decrease pulse parameters by a specific increment as listed in Table 7.5.2. Press and hold button to quickly decrease the parameter value. |
|  | Add Folder button on the Export dialog box allows the User to add the selected folder of procedure data from the 'Choose folder to save' box to the 'Folders to be saved' box. |
|  | Remove Folder button on the Export dialog box allows the User to remove the selected folder of procedure data from the 'Folders to be saved' box. |



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| Button | Function |
|---|---|
|  | Deactivate Probe Pair button on the Probe Pair Options dialog box, accessed on the Pulse Generation Screen, allows the user to deactivate the selected probe pair in the pulse parameters table. **NOTE**: The Generator will not attempt to deliver pulses between a probe pair that has been deactivated. |
|  | Activate Probe Pair button on the Probe Pair Options dialog box, accessed on the Pulse Generation Screen, allows the user to reactivate the selected probe pair in the pulse parameters table. |
|  | Add Row button on the Procedure Planning screen allows the User to add a new probe pair to the pulse parameters table. When a probe pair pulse sequence is added, a new line with default parameters is displayed in the pulse parameters table. |
|  | Delete Row button on the Procedure Planning screen allows the User to remove a probe pair from the pulse parameters table. |
|  | Distance Solver button on the Procedure Planning screen opens the Distance Solver dialog box, which allows the User to enter inter-probe pair distances and have them automatically arranged the probe placement grid with the smallest, least squares error. |
|  | Restore Default Settings button on the Procedure Planning screen returns the Probe Placement Grid and Pulse Parameters Table to default values. |
|  | Stop Pulse Delivery button on the Pulse Generation screen allows the User to stop the delivery of pulses at any time. |
|  | Skip Probe Pair button on the Pulse Generation screen allows the User to skip the remaining pulses to be delivered for the active probe pair and advance to the next probe pair listed in the pulse generation table. |
|  | Reverse All Pairs button on the Polarity Tab re-assigns the polarity of all probe pairs. |
|  | Reverse Polarity Button located on the Modify Probe Pair popup reverses the polarity of the Active Probe Pair. |



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| Button | Function |
|---|---|
|  | Revert to Grid button on the Distance Popup re-enables the Probe Placement Grid and allows the user to enter probe pair distances for Active Probe Pairs using the Grid Icons. |
|  | Charge button on the Pulse Generation screen allows the User to charge the capacitors after pulse delivery or if the Generator discharges. |
|  | Discharge button on the Pulse Generation screen allows the User to discharge the capacitors. |
|  | Repeat Conductivity Test button on the Conductivity Test Complete dialog box allows the User to repeat the conductivity test using the Double Pedal Footswitch. |
|  | Proceed button on the Conductivity Test Complete dialog box allows the User to charge the Generator to the maximum voltage listed in the pulse parameters table. |
|  | Resume Pulse Delivery button on the Incomplete Pulse Delivery Charge Options dialog box allows the User to attempt completing the remaining pulses that have either been skipped by the User or have been stopped due to over current conditions. |
|  | Restart Pulse Delivery button on the Completed Pulse Delivery Charge Options dialog box allows the User to restart pulse delivery and access the Pulse Data Options dialog box. |
|  | Cancel Charge button, located on the Incomplete Pulse Delivery Charge Options dialog box, Completed Pulse Delivery Charge Options dialog box, and Pulse Data Options dialog box, allows the User to close the current dialog box and NOT charge the Generator. |
|  | The Keep Pulse Data button on the Pulse Data Options dialog box allows the User to KEEP the initial current, max current, current change, and pulses delivered values and CLEAR the results graph. |
|  | The Reset Pulse Data button on the Pulse Data Options dialog box allows the User to CLEAR the initial current, max current, current change, and pulses delivered values and CLEAR the results graph. **NOTE**: a warning dialog box will appear to confirm Users intended selection. |

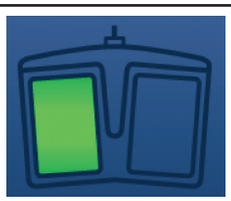


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## 5.5 Table of Status Symbols

Refer to Table 5.5.1 below for a list of status symbols that appear in the NanoKnife software and their definition.

**Table 5.5.1: Status Icons and their Definition**

| Status Icon | Definition |
|---|---|
|  | Electrode Probe not connected or not recognized |
|  | Probe connected and valid |
|  | Electrode Probe connected and expired or invalid |
|  | No Single Electrode Probes connected or the number of probes connected is less than the User's probe selection choice. |
|  | A valid number of probes has been connected and matches the User's probe selection choice. |
|  | Invalid probe or number of probes. |
|  | Probe not connected or not recognized |
|  | Probe connected and valid |
|  | Probe connected and expired or invalid |
|  | System ready to be armed. Press Left (ARM) Footswitch Pedal to arm the NanoKnife Generator for pulse delivery. |
|   | System ready to deliver pulses. Press Right (PULSE) Footswitch Pedal to initiate pulse delivery. **NOTE**: Press the Right (PULSE) Footswitch Pedal before the countdown has completed. If the Right (PULSE) Footswitch Pedal is not pressed within the 10-second countdown, the NanoKnife Generator will disarm. |



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| Status Icon | Definition |
|---|---|
|   | “ECG Disabled” if 90 PPM is 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 Lost” if ECG synchronization is selected and signal is too slow or not present. |



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# SECTION 6: PROCEDURE SETUP

## 6.1 Procedure Setup Screen Overview

The Procedure Setup screen displays after the NanoKnife Generator has been powered on and the automatic self-checks have successfully completed. The screen includes the following four panels: Patient Information, Case Information, Probe Selection, and Probe Connection Status which are each described in following subsections, Figure 6.1.1.

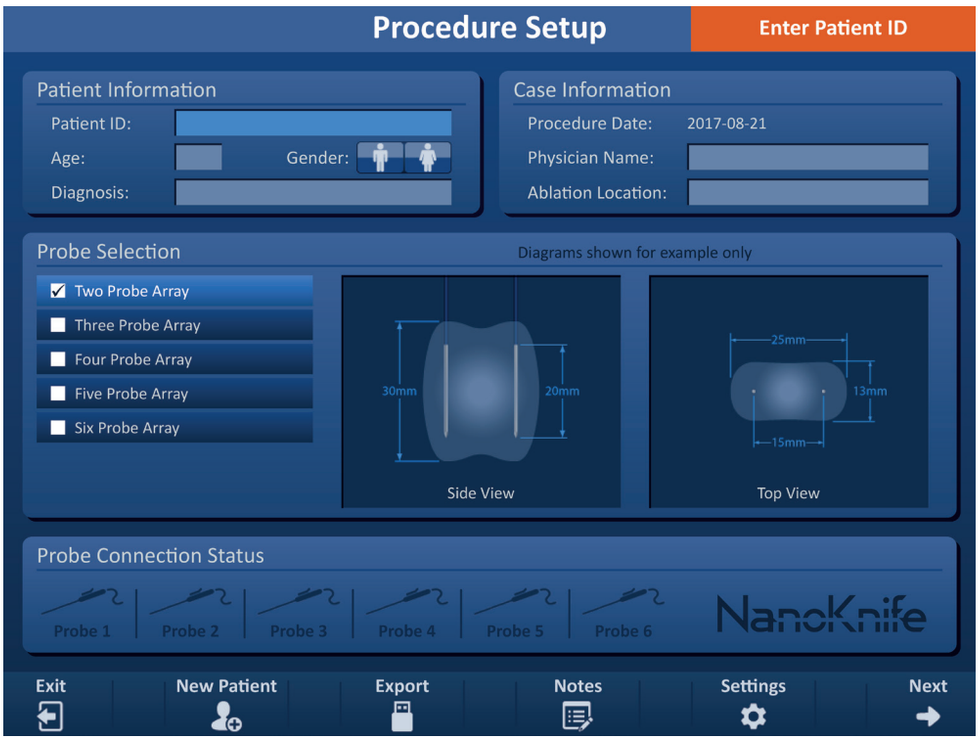



**Figure 6.1.1: Procedure Setup Screen**

**NOTE:** The User interfaces with the NanoKnife software using a combination of keyboard entries, touchpad clicks, and touchscreen touches. Throughout the remainder of this document, the terms “Select” and/or “Click” will refer to a User-made selection, delivered via either a keyboard or the touchpad buttons or by physically touching the screen.

The **Patient Information** panel allows the User to enter or specify patient information:

- The Patient ID – Required, text entered using keyboard. User must enter Patient ID to proceed to next screen.
- Age (in years) – Optional, adjusted using the ▲/▼ buttons on the popup.
- Gender – Optional, entered by clicking the button or button.
- Diagnosis – Optional, text entered using keyboard.

The **Case Information** panel allows the User to enter procedure information:

- Procedure Date – Automatically set.
- Physician Name – Optional, text entered using keyboard.
- Ablation Location – Optional, text entered using keyboard.



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The **Probe Selection** panel allows the User to select a number of probes, referred to as the Selected Probe Array. A side and top view of the Selected Probe Array will display to the right.

The Probe Selection panel includes a list of the number of probes and two image panes. This allows the User to select the number of probes, view the side and top views of the ablation zone shape and size. The following number of probes are available to choose from:

- Two Probe Array – An oval shaped probe-array consisting of two (2) Single Electrode Probes
- Three Probe Array – A triangle shaped probe array consisting of three (3) Single Electrode Probes
- Four Probe Array – A square shaped probe array consisting of four (4) Single Electrode Probes
- Five Probe Array – A trapezoid shaped probe array consisting of five (5) Single Electrode Probes
- Six Probe Array – A rectangle shaped probe array consisting of six (6) Single Electrode Probes

**CAUTION:** Only the rectangular six probe array configuration is supported for this NanoKnife Generator. The star shaped six probe array (with a center probe) option previously offered with the NanoKnife 2.2 Generator is not available. Selecting a six probe array will not provide a configuration that includes a center probe.

The **Probes Connection** Status panel includes probe icons and the NanoKnife Logo and indicates the number of probes connected to the NanoKnife Generator. The six probe icons represent the six Probe Connectors located on the front panel of the NanoKnife Generator. The NanoKnife Software checks the expiration and authenticity of each probe connected.

Detailed instructions on how to utilize the Procedure Setup screen are described in the following subsections.

## 6.2 Patient Information

The Patient Information panel includes the Patient ID text box, Age text box, Gender switch, and Diagnosis text box, Figure 6.2.1. A Patient ID is required to proceed to the Procedure Planning screen. The Age, Gender, and Diagnosis are not required to be entered.

Enter patient's ID into the Patient ID text box using the keyboard. The Patient ID may contain numbers and/or letters.

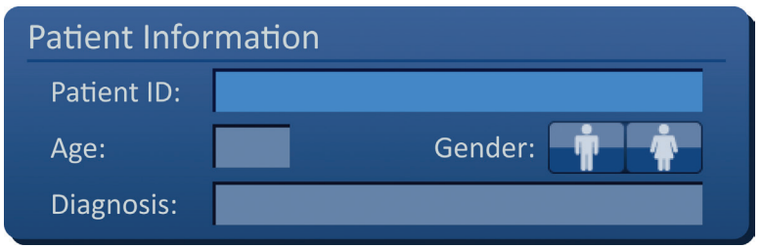



**Figure 6.2.1: Patient Information Panel**



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If the User leaves the Patient ID text box empty and attempts to advance to the next screen, a popup will appear, Figure 6.2.2. Click the ✓ button to close the popup. The User must enter the Patient ID before advancing to the next screen.

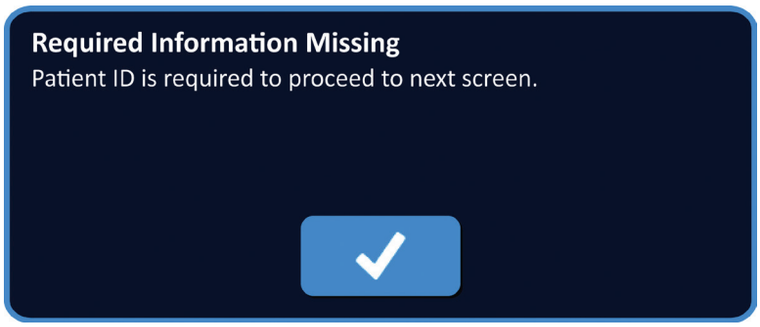



**Figure 6.2.2: Required Information Missing Popup – Patient ID Required**

To enter patient's age, click the Age text box which displays the Age popup, Figure 6.2.3. Use the ▲/▼ buttons on the popup to enter patient's age in years. Click the ✓ button to store the value and close the popup. Clicking the ✕ button will discard the value and close the popup.

**NOTE:** Click and hold down the ▲/▼ buttons to quickly adjust the value.

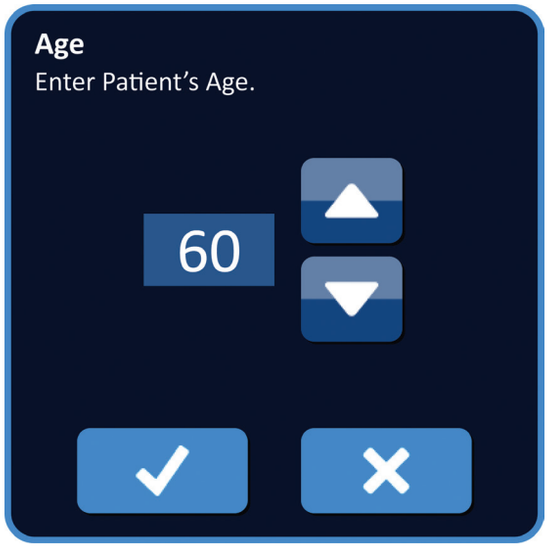



**Figure 6.2.3: Age Popup**

To enter patient's gender, click the 🚹 button or 🚺 button that matches the patient's gender, Table 6.2.1.

**Table 6.2.1: Gender Switch Buttons**

| Gender | Meaning |
|---|---|
|  | Default – no gender selected |
|  | Male selected |
|  | Female selected |

To enter patient's diagnosis, click the Diagnosis text box and enter patient's diagnosis using the keyboard.





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## 6.3 Case Information

The Case Information panel contains the Procedure Date, Physician Name text box, and Ablation Location text box, Figure 6.3.1. The Procedure Date is automatically set. The Physician Name and Ablation Location are not required to be entered.

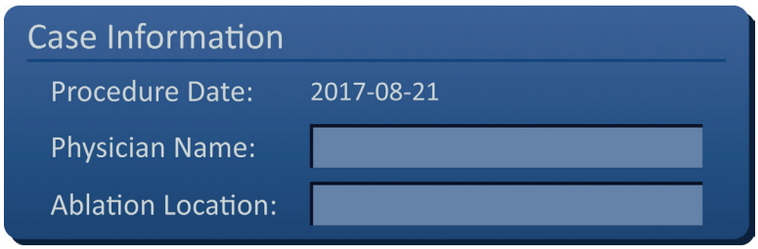



**Figure 6.3.1: Case Information Section**

To enter physician name, click the Physician Name text box and enter physician name using the keyboard.

To enter ablation location, click the Ablation Location text box and enter ablation location using the keyboard.

## 6.4 Probe Selection

The Probe Selection panel includes a list of the number of probes and two image panes, Figure 6.4.1. The Probe Selection panel allows the User to select a number of probes, referred to as the Selected Probe Array. A side and top view of the Selected Probe Array will display to the right.

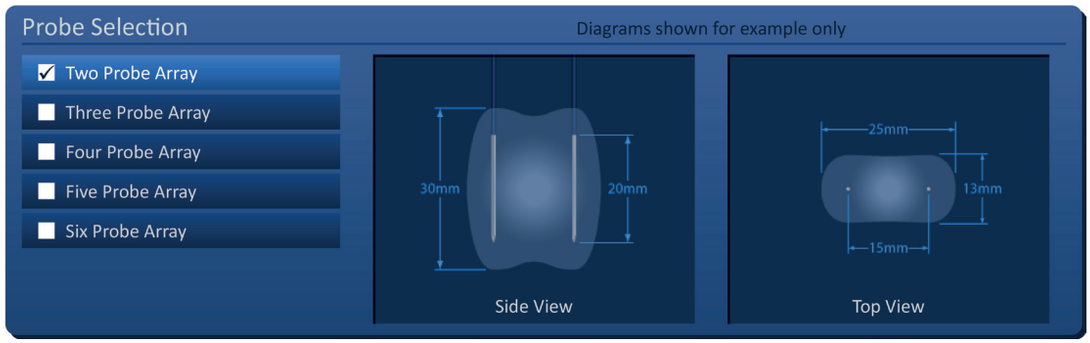



**Figure 6.4.1: Probe Selection**

The User should select a number of probes based on the targeted ablation area size and shape. All ablation procedures using the NanoKnife System should be based on imaging measurements and using clinical judgment.

The Probe Selection panel includes a list of the number of probes: Two Probe Array, Three Probe Array, Four Probe Array, Five Probe Array, and Six Probe Array.

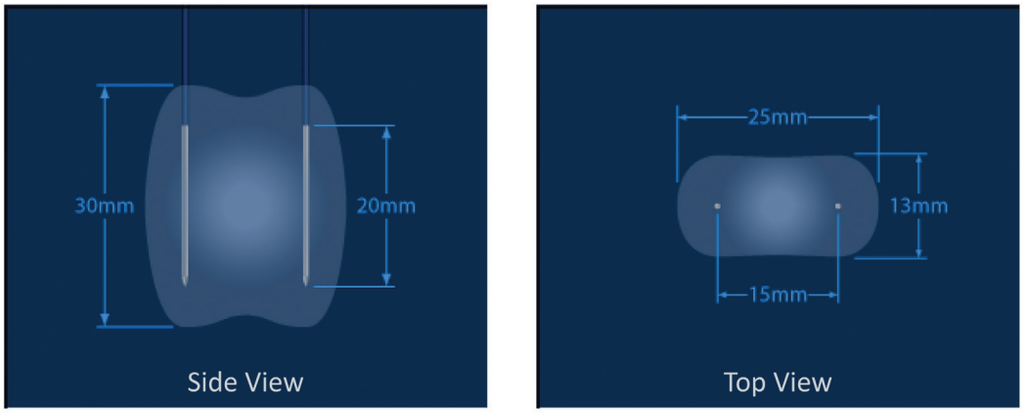
To select a number of probes, click the number of probes. A ✔ will appear in the check box to the left of the Selected Probe Array.



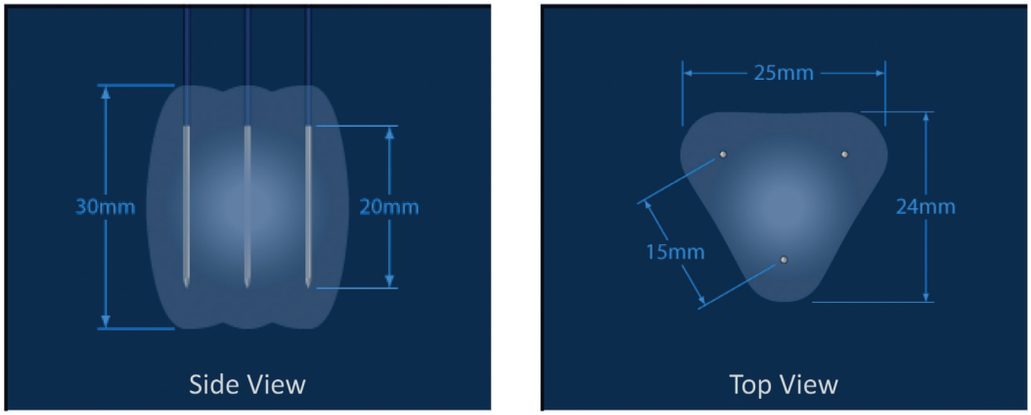
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The available probes arrays to choose from in the Probe Selection panel are listed in Figure 6.4.2.

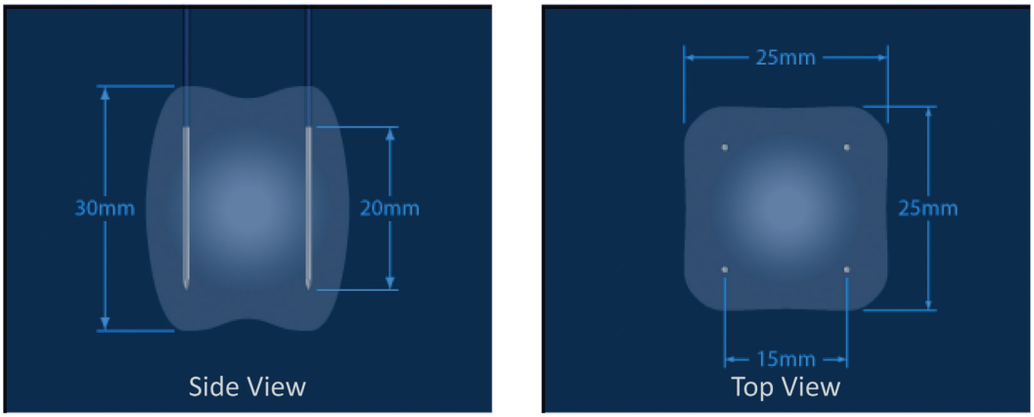
**Two Probe Array**




**Three Probe Array**



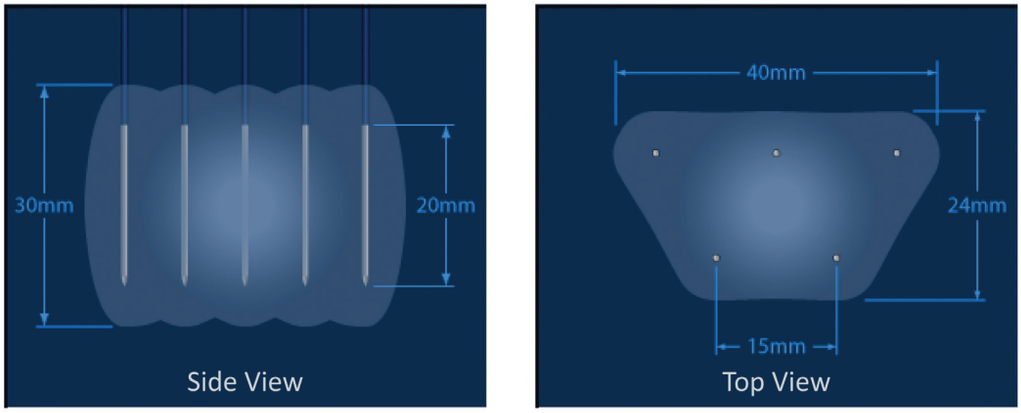

**Four Probe Array**






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**Five Probe Array**




**Six Probe Array**

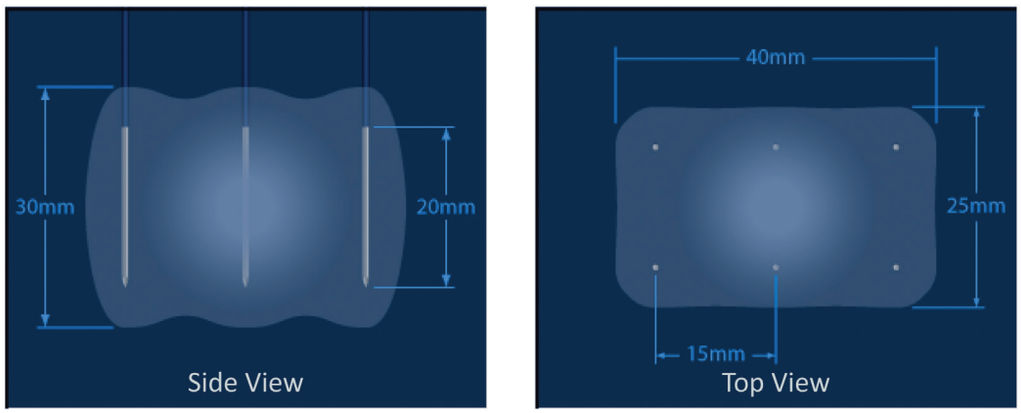



**Figure 6.4.2: Number of Probes**

## 6.5 Probe Connection Status

The Probe Connection Status panel includes probe icons and the NanoKnife Logo and indicates the number of probes connected to the NanoKnife Generator. The six probe icons represent the six Probe Connectors located on the front panel of the NanoKnife Generator, Figure 6.5.1. The NanoKnife Software checks the expiration and authenticity of each probe connected.




**Figure 6.5.1: Probe Connection Status**



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Each Single Electrode status is uniquely identified by the NanoKnife Software, Table 6.5.1.

**Table 6.5.1: Probe Connection Status – Probe Icon**

| Connection Status | Meaning |
|---|---|
|  | Probe not connected or not recognized |
|  | Probe connected and valid |
|  | Probe connected and expired or invalid |

The NanoKnife Software may take up to 10 seconds to determine the probe connection status of each probe that has been connected. Once a probe is connected, the probe icon will change color to indicate a Probe has been connected.

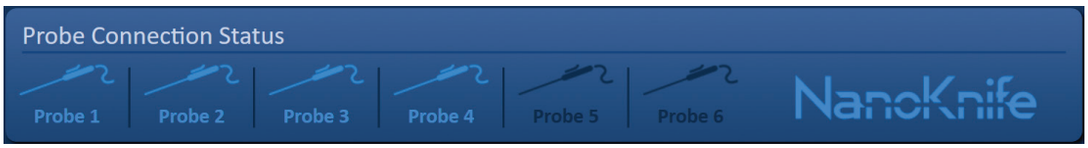



**Figure 6.5.2: Probe Connection Status – Validated Probes**

An orange probe icon indicates the connected probe is expired or invalid. Each Single Electrode Probe has a working time of eight hours which starts once the NanoKnife Software recognizes the probe has been connected. At the end of the eight-hour working time the probes will become expired, Figure 6.5.3.




**Figure 6.5.3: Probe Connection Status – Expired Probes**

**NOTE:** Expired and Invalid Probes must be replaced prior to continuing.

The following probe connection requirements must be met in order to access the Pulse Generation screen.

1. The number of probes connected to the NanoKnife Generator match the Selected Probe Array in the Probe Selection panel.
2. The probes connected to the NanoKnife Generator are not expired or invalid.
3. The probes are connected in sequential order (e.g. four probes are connected to probe connector 1, 2, 3, and 4).



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The NanoKnife Logo will change color to identify if the probe connection requirements have been met, Table 6.5.2.

**Table 6.5.2: Probe Connection Status – NanoKnife Logo**

| Status | Meaning |
|---|---|
| NanoKnife | No probes connected or the number of probes connected is less than the Selected Probe Array. |
| NanoKnife | The number of probes connected matches the Selected Probe Array and probe connection conditions have been met. |
| NanoKnife | The number of probes connected exceeds the Selected Probe Array and/or probe connection conditions have not been met. |

**NOTE:** The User may still access the Procedure Planning screen to enter patient and case information without a valid number of probes.

If the User does not meet the probe connection requirements and attempts to advance to the Pulse Generation screen a popup will appear, Figure 6.5.4. Click the ✔ button to close the popup. The User must meet the probe connection requirements before advancing to the Pulse Generation screen. Return to the Procedure Setup screen and check probe connection status.

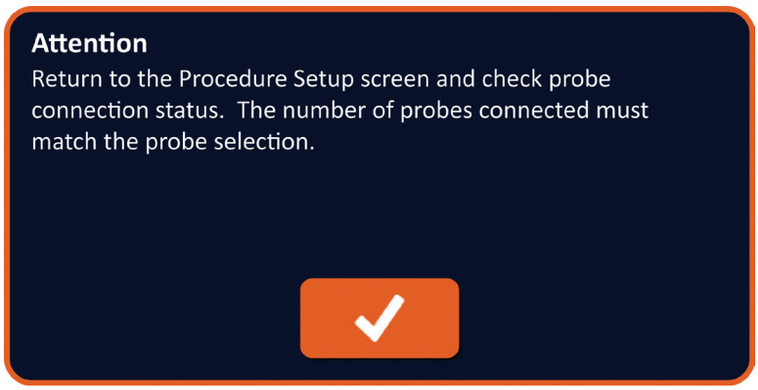



**Figure 6.5.4: Check Probe Connection Status Popup**



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If the number of probes connected exceeds the Selected Probe Array, the NanoKnife Logo will turn orange, Figure 6.5.5. Remove the Single Electrode Probe from Probe Connector 5 to satisfy the probe connection requirements.

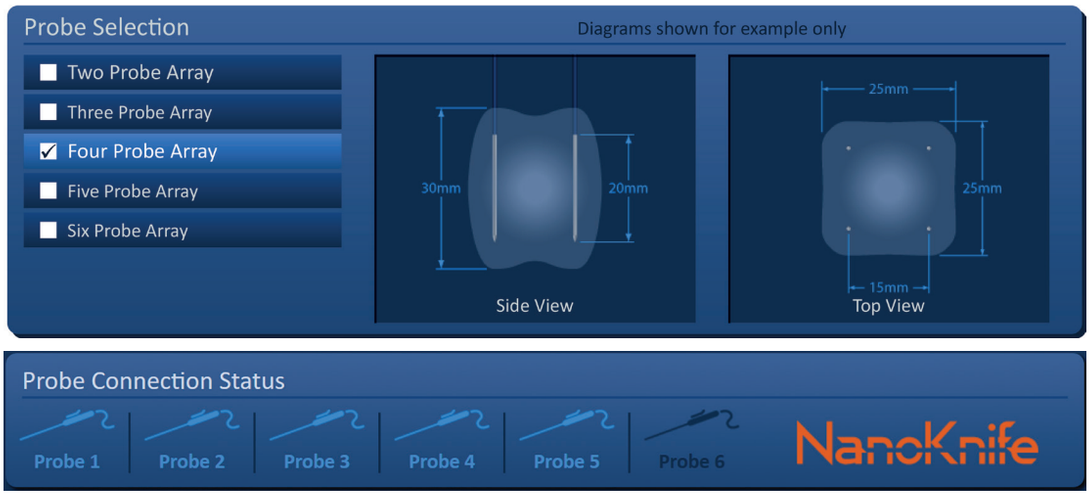



**Figure 6.5.5: Invalid Probe Connection– Too Many Probes Connected**

**NOTE:** The User may return to the Procedure Setup screen to choose a different number of probes at any point during the procedure.

If the probes are not connected in sequential order the NanoKnife Logo will turn orange, Figure 6.5.6. Reposition the Single Electrode Probe from Probe Connector 5 to Probe Connector 4 to satisfy the probe connection requirements.

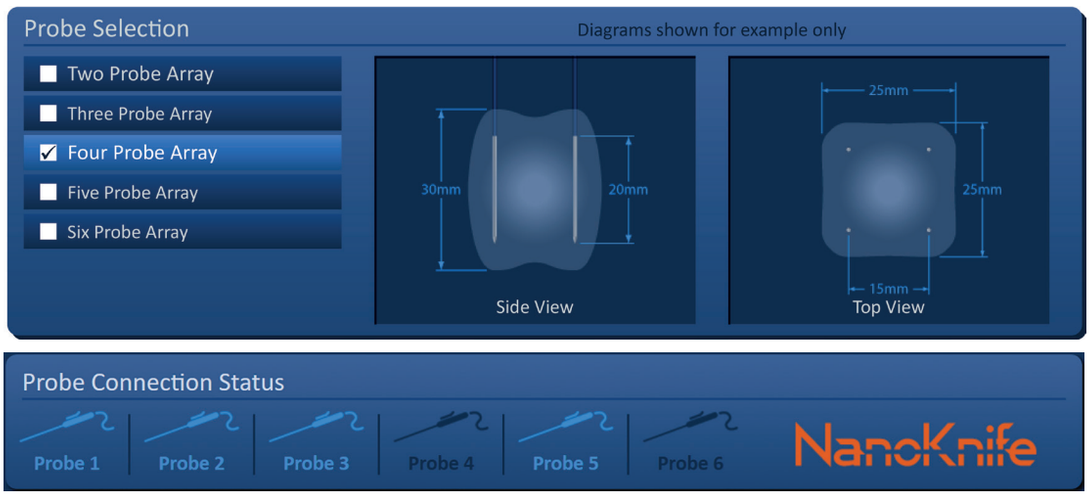



**Figure 6.5.6: Invalid Probe Connection – Probes Not Connected Sequentially**

**NOTE:** A probe may be used with a different NanoKnife Generator; however, the eight-hour working time will not change. The probe expires eight hours after the probe has been connected and recognized by the first NanoKnife Generator.



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## 6.6 Pulse Delivery Mode Setting

The User can change the Pulse Delivery Mode within the Settings dialog box. Click the Settings button located on the navigation bar in all screens to access the Settings dialog box, Figure 6.6.1




**Figure 6.6.1: Navigation Bar – Settings Button**

The Settings dialog box consists of two Pulse Delivery Modes, 1) ECG Synchronized and 2) 90 Pulses Per Minute. ECG Synchronized is the default setting.

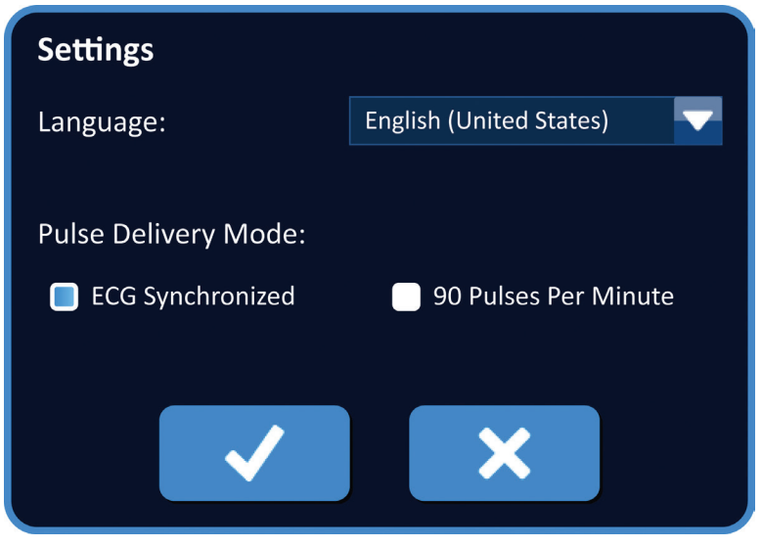



**Figure 6.6.2: Settings Dialog Box – ECG Synchronized Mode**

**WARNING:** ECG Synchronized is the preferred setting if the Targeted Ablation Area is in the abdominal and thoracic cavities. The 90 Pulses Per Minute mode should not be used if the targeted ablation area is in the abdominal or thoracic cavity as it is associated with a significant increase in arrhythmia risk.

### 6.6.1 How to change Pulse Delivery Mode to 90 PPM

Click the Settings button located on the navigation bar to access the Settings dialog box. Click the 90 Pulses Per Minute radio button. A warning popup will appear, Figure 6.6.3.

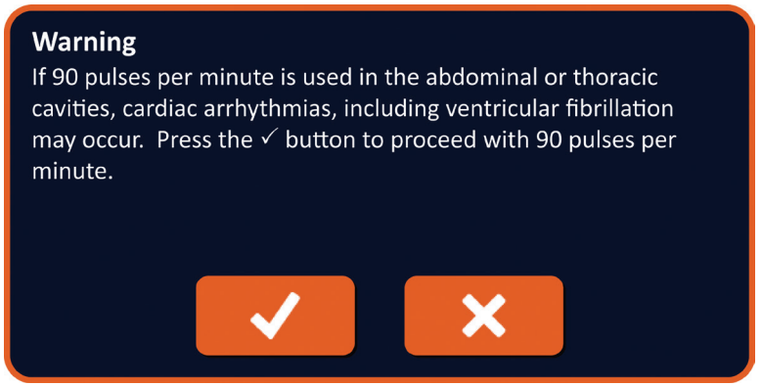



**Figure 6.6.3: Pulse Timing Warning Popup**





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Click the ✔ button to change the Pulse Delivery Mode to 90 Pulses Per Minute and close the warning popup. Clicking the ✖ button will not change the Pulse Delivery Mode and close the popup.

Click the ✔ button on the Settings dialog box to confirm changing the Pulse Delivery Mode and close the Settings dialog box, Figure 6.6.4. Click the ✖ button to not change the Pulse Delivery Mode and close the Settings dialog box.

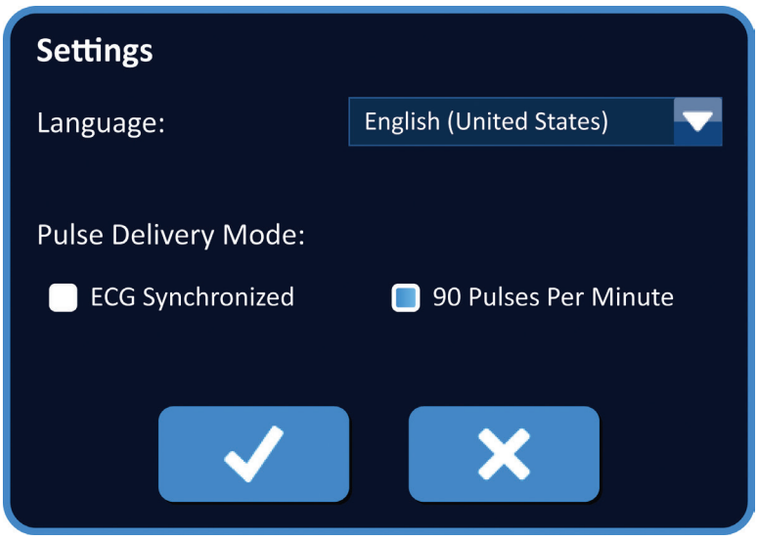



**Figure 6.6.4: Settings Dialog Box – 90 Pulses Per Minute Mode**

### 6.6.2 How to Change Pulse Delivery Mode to ECG Synchronized

Click the Settings ⚙ button located on the navigation bar to access the Settings dialog box. Click the ECG Synchronized radio button.

Click the ✔ button on the Settings dialog box to confirm changing the Pulse Delivery Mode to ECG Synchronized and close the Settings dialog box.

## 6.7 Case Notes

The User can log case notes during the procedure using the Case Notes dialog box. Click the Notes button located on the navigation bar in all screens to access the Case Notes dialog box, Figure 6.7.1.




**Figure 6.7.1: Navigation Bar – Notes Button**

The Case Notes dialog box contains two text boxes, Figure 6.7.2. The dark blue text box located on the top of the dialog box displays a time-stamped record of case notes that have previously been entered into the case notes log. The light blue text box located on the bottom of the dialog box is where new case notes are entered.



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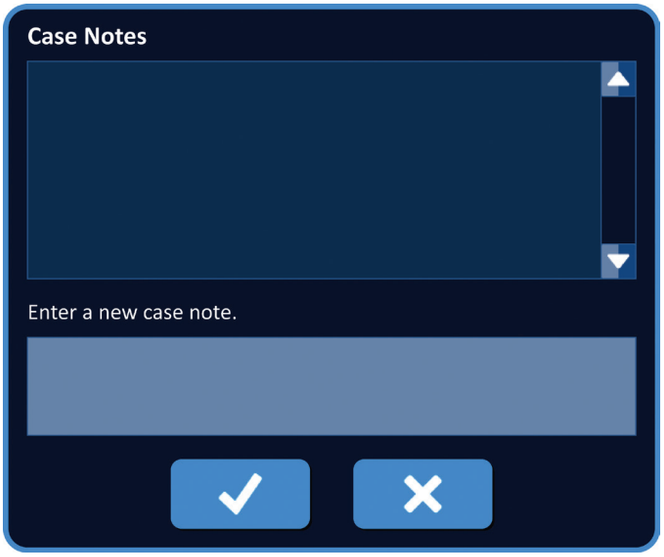



**Figure 6.7.2: Case Notes Dialog Box**

### 6.7.1 How to Enter Case Notes

Click the Notes button to display the Case Notes button dialog box. Enter in a new note into the light blue text box labelled 'Enter a new case note', Figure 6.7.3.

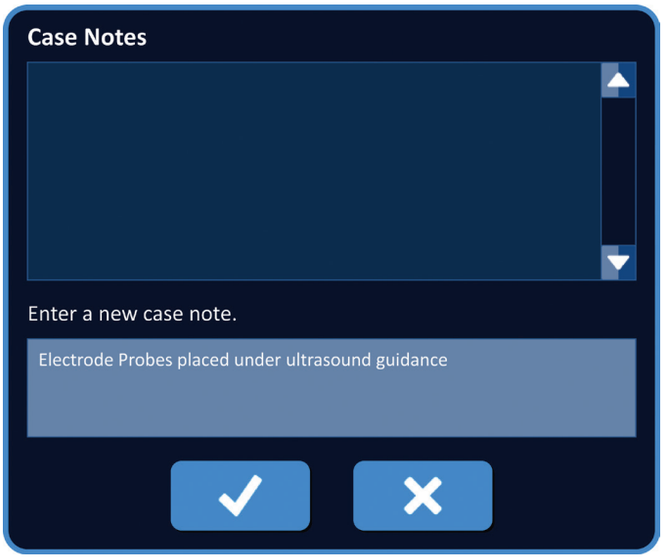



**Figure 6.7.3: Case Notes Dialog Box – New Case Note**

Click the ✓ button to record the note and close the Case Notes dialog box. Clicking the ✗ button would discard the new note and close the Case Notes dialog box.



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To record additional case notes or to verify that the previous case note was recorded, click the Notes button to display the Case Notes dialog box. Previously entered case notes are displayed in the dark blue text box along with a date and time stamp indicating when the case note was added to the case notes log, Figure 6.7.4.

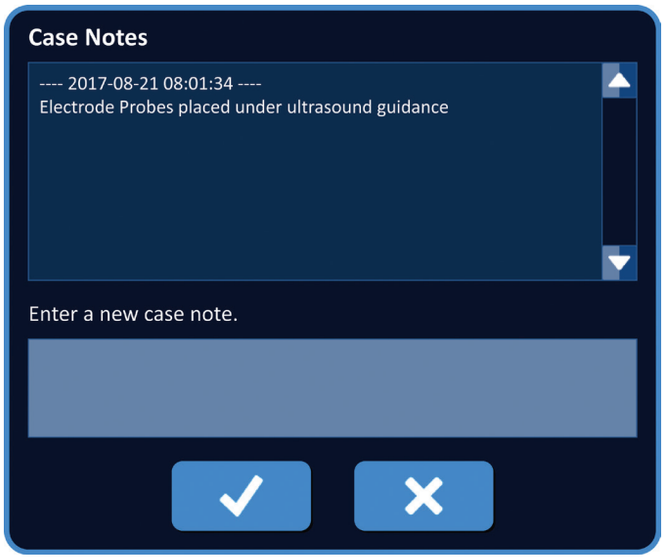



**Figure 6.7.4: Case Notes Dialog Box – Time Stamped Notes**

## 6.8 Proceed to Next Screen

After completing the Information sections, click the Next button ➜ to proceed to the Procedure Planning screen.




**Figure 6.8.1: Navigation Bar – Next Button**



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# SECTION 7: PROCEDURE PLANNING

## 7.1 Procedure Planning Screen

The Procedure Planning screen is where probe placement is planned and entered and pulse parameters are defined. The screen includes the Probe Placement Grid, Targeted Ablation Area Settings, and the Parameters and Options tabs, Figure 7.1.1.




**Figure 7.1.1: Procedure Planning Screen**

The **Probe Placement Grid** is an 8 x 8 cm grid that displays the Selected Probe Array bracketing a Targeted Ablation Area. The Selected Probe Array is displayed as set of Grid icons. There is the same number of Grid icons on the Probe Placement Grid as probes in the Selected Probe Array. Grid icons may be moved within the Probe Placement Grid to enter Probe Pair Distances measured using imaging equipment.

The **Targeted Ablation Area Settings** contain the Lesion Zone, Margin, and Target Zone dimension text boxes. The Lesion Zone and Margin dimensions may be adjusted using the ▲/▼ buttons on the popup. The Target Zone dimensions are calculated based on the Lesion and Margin values.

The **Parameters and Options** tabs allow the User to modify pulse parameters and turn on or off probe placement grid features. The Parameters and Options panel includes the following four tabs: Table, Quick Adjust, Polarity, and Options.

- Table – Displays the detailed pulse parameters.
- Quick Adjust– Easily adjust pulse parameters for all probe pairs.
- Polarity – Easily adjust polarity of a probe pair or all probe pairs.
- Options – Turn on or off Probe Placement Grid features.

Detailed instructions on how to utilize the Procedure Planning screen are described in the following subsections.

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## 7.2 Probe Placement Grid

The **Probe Placement Grid** is an 8 x 8 cm grid that displays the Selected Probe Array bracketing a targeted ablation area, Figure 7.2.1.

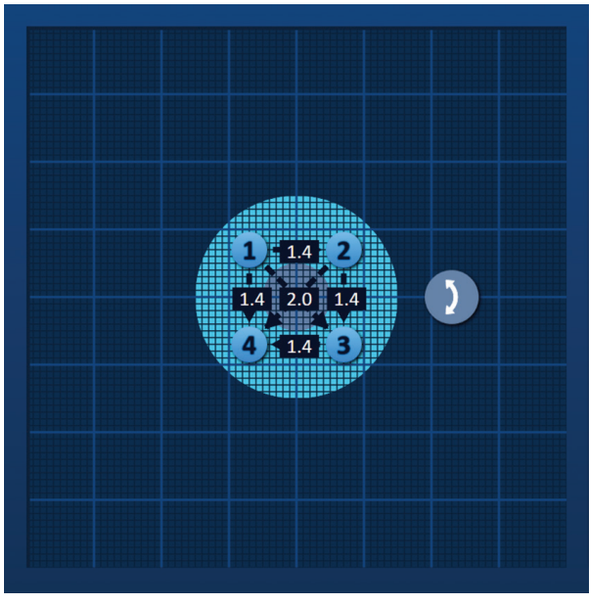



**Figure 7.2.1: Probe Placement Grid**

The Major Grid Lines are blue lines spaced 1 cm apart. The Minor Grid Lines are dark blue lines are spaced 1 mm apart. Beneath the grid lines is a two-dimensional Targeted Ablation Area. The dark grey circle in the center of the Probe Placement Grid is the Lesion Zone. The Target Zone surrounds the Lesion Zone a set distance referred to as Margin. Detailed instructions on modifying the Targeted Ablation Area Settings are described in Section 7.3.

Each circular icon with a number, referred to as a Grid Icon, represents a probe of the Selected Probe Array. The default Grid Icons are centered on the Probe Placement Grid and bracket the Targeted Ablation Area. There is the same number of Grid icons on the Probe Placement Grid as probes in the Selected Probe Array. Each Grid icon is colored and numbered to represent the Probe Connection Status, Table 7.2.1.

**Table 7.2.1: Probe Placement Grid – Grid Icons**

| Grid Icon | Meaning |
|---|---|
|  | Probe not connected or not recognized |
|  | Probe connected and valid |
|  | Probe connected and expired or invalid |



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Dashed lines that connect Grid icons represent Active Probe Pairs. Active Probe Pairs are included in the Pulse Parameters Table. Each Active Probe Pair displays a Probe Pair Distance value in centimeters, rounded to the nearest tenth. The dashed line arrow heads are pointed towards the negative probe (P-) to represent the polarity of the Active Probe Pair, Figure 7.2.2.

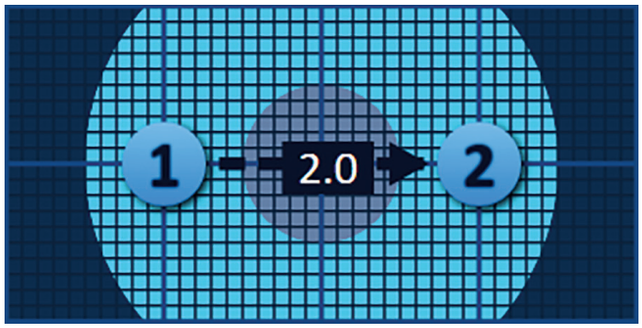



**Figure 7.2.2: Probe Placement Grid – Polarity Arrow**

Grid icons may be moved within the Probe Placement Grid to enter Probe Pair Distances measured using imaging equipment. Click and drag any Grid Icon to select and move it. The Grid Icon number will change to bright green indicating that it has been selected and may be moved. The Grid Icon can be deselected by clicking it again.

**NOTE:** The grid icons can be moved in 1 mm increments using the keyboard arrow keys.

Multiple Grid Icons may be selected and moved at the same time. Hold the Ctrl key on the keyboard and click each Grid Icon to be moved. Use the keyboard arrow keys to move the selected Grid Icons as a group, Figure 7.2.3.

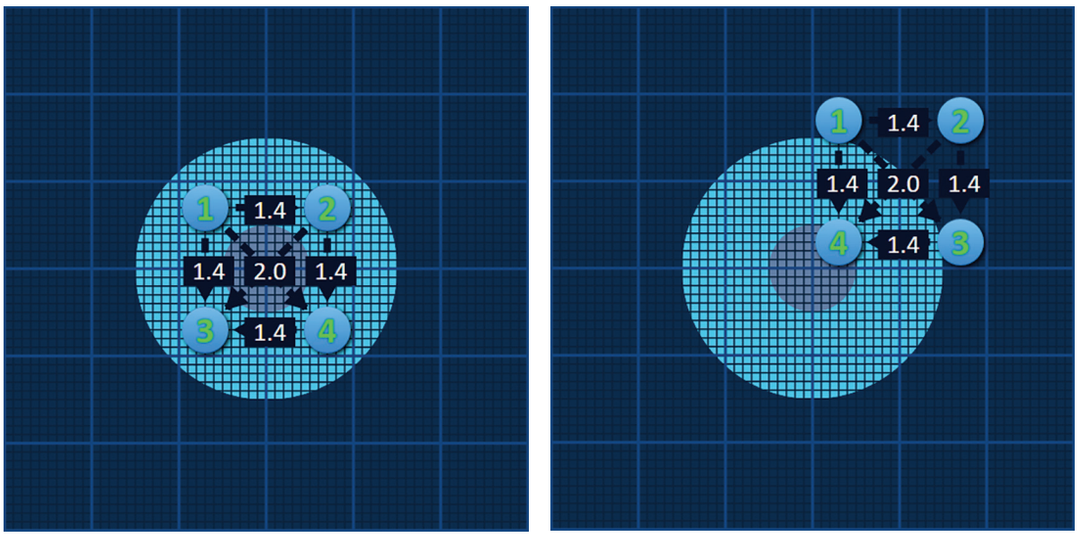



**Figure 7.2.3: Probe Placement Grid – Selecting and Moving Multiple Grid Icons**

**NOTE:** Clicking the Restore Default Settings button will return the Probe Placement Grid and Pulse Parameters Table to default values.



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## 7.3 Targeted Ablation Area Settings

The Targeted Ablation Area Settings is located directly below the Probe Placement Grid and contains the Lesion Zone, Margin, and Target Zone dimension text boxes, Figure 7.3.1.

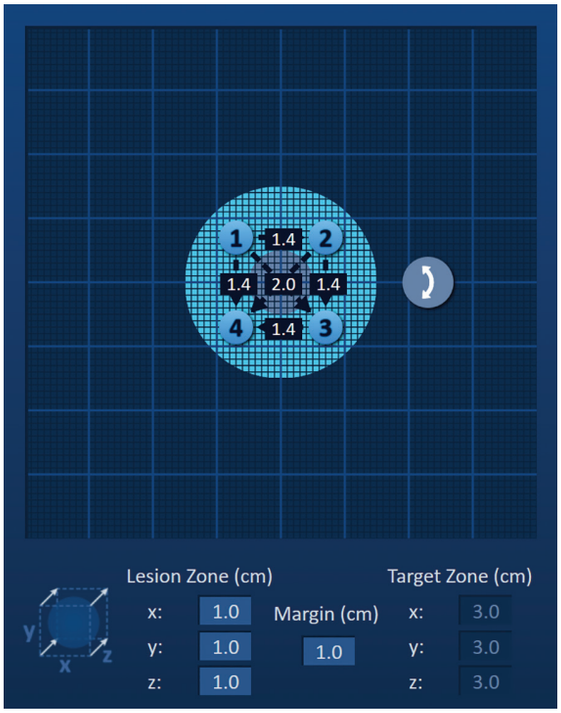



**Figure 7.3.1: Targeted Ablation Area Settings and Probe Placement Grid**

The Lesion Zone is represented as a dark grey circle located in the center of the Probe Placement Grid. The Target Zone surrounds the Lesion Zone a set distance referred to as Margin. The default Lesion Zone dimensions are 1.0 cm x 1.0 cm x 1.0 cm, Figure 7.3.2. The default Margin is set to 1.0cm. The Target Zone is calculated using the Lesion Zone and Margin settings.

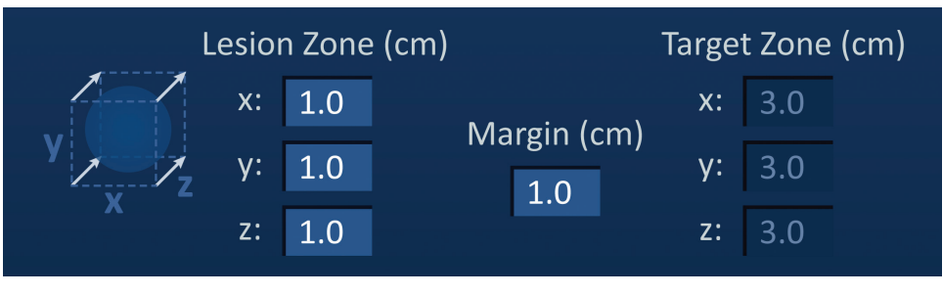



**Figure 7.3.2: Targeted Ablation Zone Settings – Default Values**

**NOTE:** Modifications to the Targeted Ablation Area Settings are optional and do not change any of the Pulse Delivery Parameters.

There are three Lesion Zone settings text boxes which represent the 3 diameters of the targeted lesion in the X, Y, and Z axis. The X and Y Lesion Zone values are the targeted lesion's width and height diameters which are perpendicular to the anticipated probe placement trajectory. The Z Lesion Zone value is the targeted lesion's diameter that runs along the anticipated probe placement trajectory. The Procedure Planning Cube on the left of the Lesion Zone settings is a graphical representation of four probes bracketing a lesion to help the User determine the targeted lesion and probe placement orientation.






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To modify the Lesion Zone width, click the text box labelled 'x:' to display the Lesion Zone popup, Figure 7.3.3. Use the ▲/▼ buttons on the popup to enter the Lesion Zone width in centimeters. Click the ✓ button to store the value and close the popup. Clicking the ✕ button will discard the value and close the popup. Adjust the Lesion Zone height and depth using the same method.

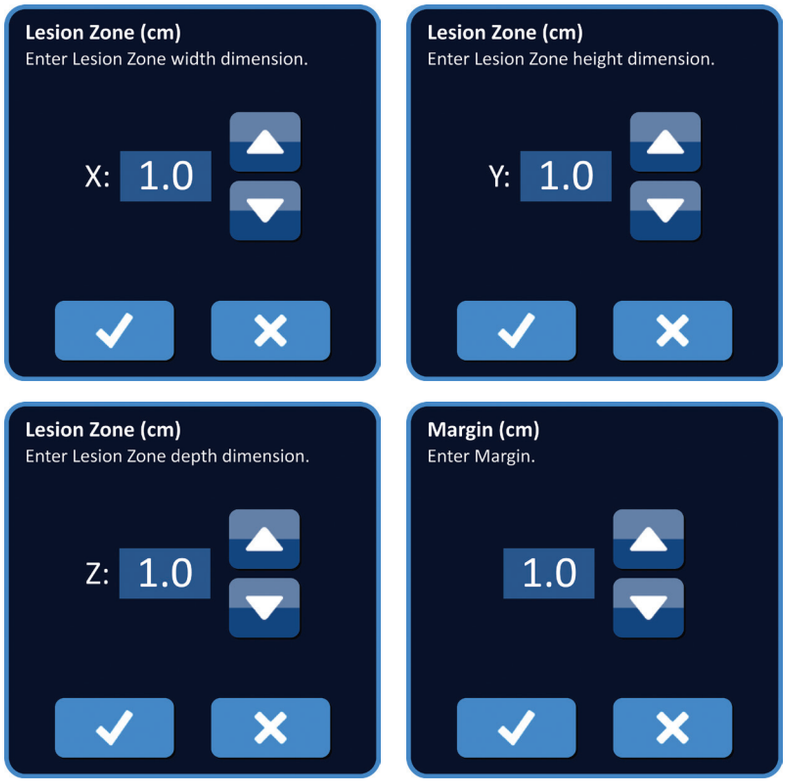



**Figure 7.3.3: Lesion Zone and Margin Settings Popups**

When the Lesion zone or Margin settings are modified, the NanoKnife Software automatically updates the Target zone dimensions, Figure 7.3.4.

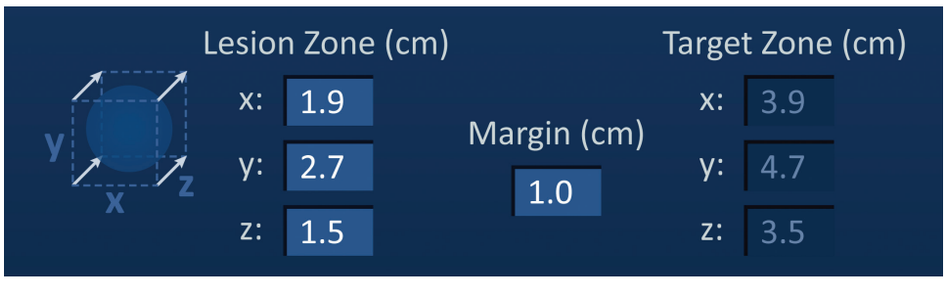



**Figure 7.3.4: Modified Lesion Zone Settings**

The Margin is the distance between the Lesion Zone and the Target Zone.

**ATTENTION:** Modification of the Margin setting should be based on clinical determination by the treating physician.



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To modify the Margin setting, click the text box below 'Margin (cm)' to display the Margin popup, Figure 7.3.3. Use the ▲/▼ buttons on the popup to enter the Margin in centimeters. Click the ✓ button to store the value and close the popup. Clicking the ✕ button will discard the value and close the popup. The Probe Placement Grid will update to reflect the change, Figure 7.3.5.

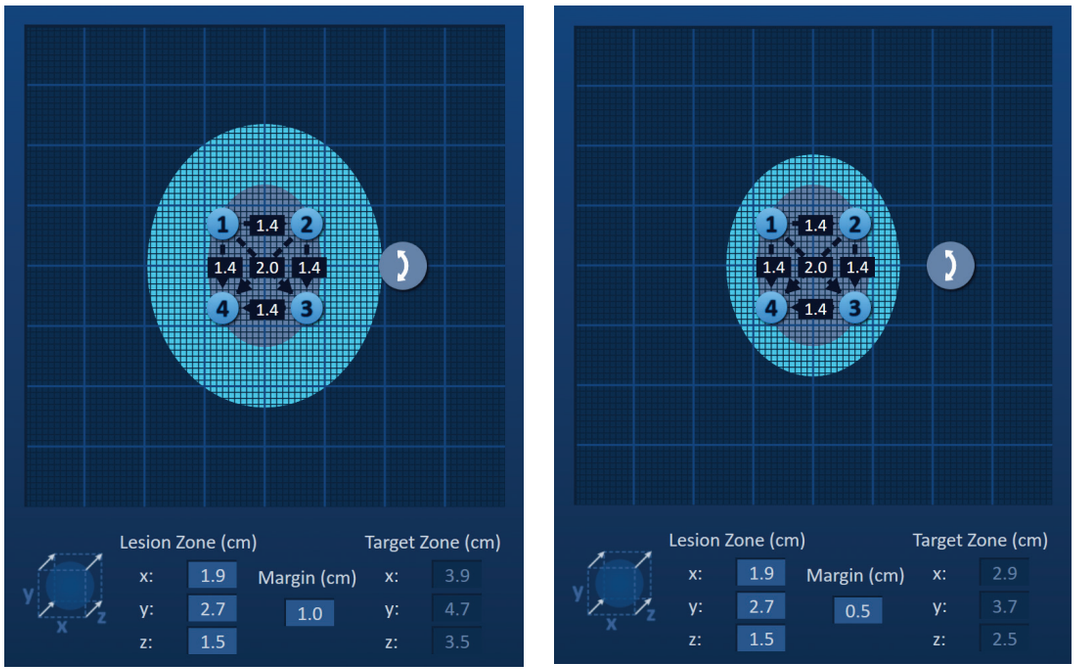



**Figure 7.3.5: Modifying the Margin Setting**

## 7.4 Target Zone Rotation Handle

When the Target Zone Rotation Handle, displays the ↻ symbol, it is in Rotation Mode. The User may rotate the Lesion and Target Zone Area up to 360 degrees, clockwise or counter-clockwise using a click and drag technique. The Targeted Ablation Area will rotate about the center point of the Lesion Zone in the same direction as the User's click and drag motion, Figure 7.4.1.

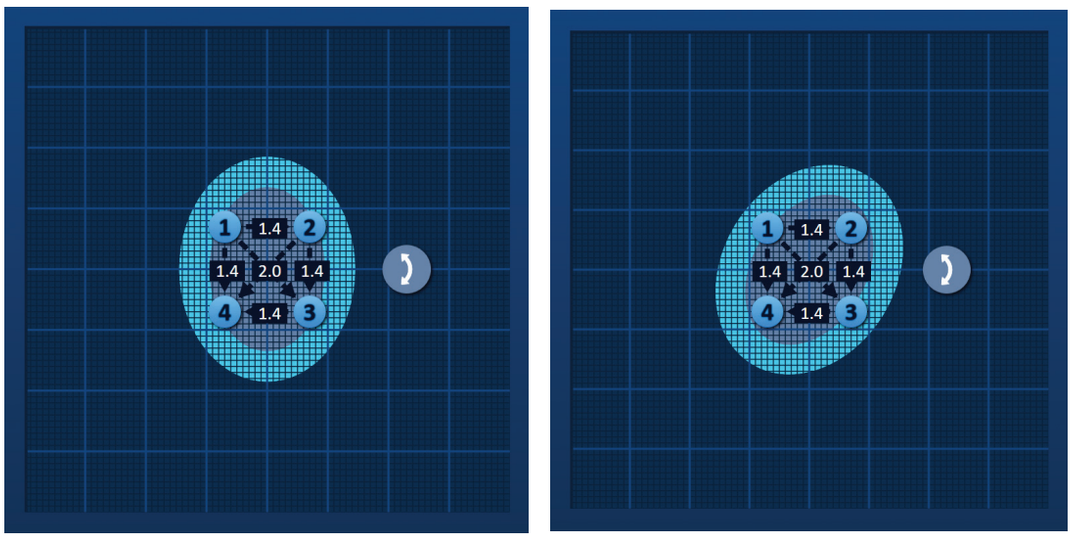



**Figure 7.4.1: Procedure Zone Rotator – Rotation Mode**





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**NOTE:** The Target Zone Rotation Handle will not move from its current position when operating in Rotation Mode.

Right-click the Target Zone Rotation Handle to enable Translation Mode. The Target Zone Rotation Handle icon will change from to , indicating Translation Mode has been enabled. The User may move (i.e. translate) the Targeted Ablation Area to a different location within the Probe Placement Grid using click and drag technique, Figure 7.4.2.

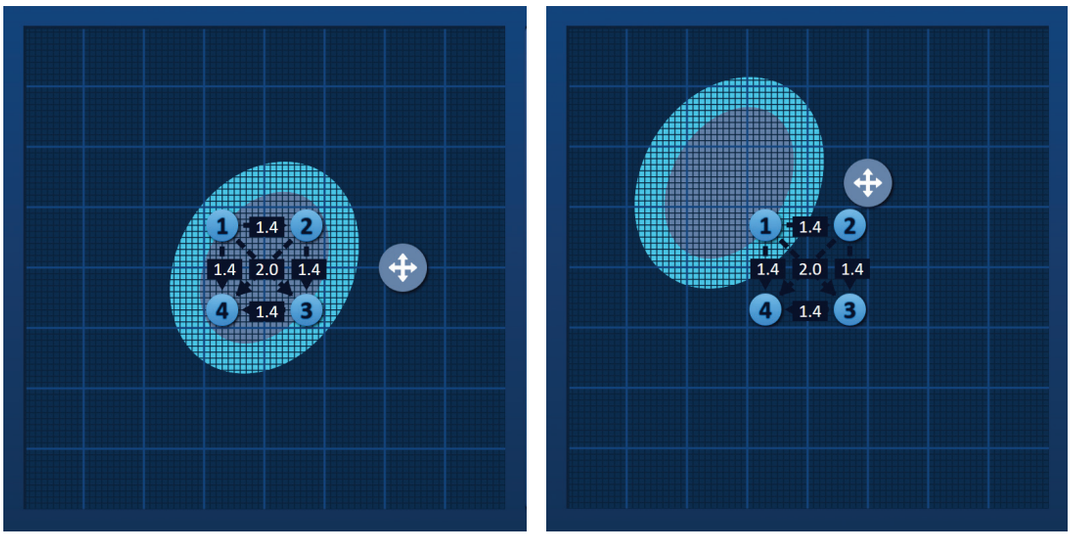



**Figure 7.4.2: Procedure Zone Rotator – Translation Mode**

**NOTE:** The Target Zone Rotation Handle will move from its current position when operating in Translation Mode and is confined by the outer edges of the Probe Placement Grid.

The User can return the Target Zone Rotation Handle back to Rotation Mode by right-clicking the Target Zone Rotation Handle. The Target Zone Rotation Handle icon will change from to , indicating Rotation Mode has been enabled.

**NOTE:** Clicking the Restore Default Settings button will return the Probe Placement Grid and Pulse Parameters Table to default values.

## 7.5 Pulse Parameters Table

The Pulse Parameters Table is located on the Table tab and displays the default pulse parameters for the Selected Probe Array, Figure 7.5.1. To achieve an ablation effect, the NanoKnife Generator delivers a series of short high voltage electrical pulses between a pair of Single Electrode Probes, referred to as an Active Probe Pair. Each row of the Pulse Parameters Table represents an Active Probe Pair.

**NOTE:** The Active Probe Pairs included in the Pulse Parameters Table are listed in sequential order. Active Probe Pairs will be reordered from highest to lowest voltage on the Pulse Generation screen.



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**Figure 7.5.1: Pulse Parameters Table**

The Pulse Parameters table includes: P+, P-, Voltage, Pulse Length, Num Pulses, V/cm, and Distance Columns. Below the table are the Add Row, Delete Row, and Distance Solver buttons. Each pulse parameter is defined in Table 7.5.1.

**Table 7.5.1: Pulse Parameters and Definitions**

| Pulse Parameter | Definition |
|---|---|
| P+ | Positive Probe of the Active Probe Pair. |
| P- | Negative Probe of the Active Probe Pair. |
| Voltage | Maximum Voltage of each pulse delivered between the Active Probe Pair with units in Volts (V). |
| Pulse Length | Time duration of each delivered pulse with units in microseconds (µsec). |
| Num Pulses | Intended Number of pulses to be delivered between the Active Probe Pair. |
| V/cm | Volts per centimeter – a factor multiplied by the Probe Pair Distance to calculate Voltage of the Active Probe Pair with units in Volts/cm. |
| Distance | Distance between the positive and negative probes of an Active Probe Pair with units in centimeters (cm). |



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### 7.5.1 Pulse Parameter Constraints

Constraints for each of the pulse parameter values are displayed in Table 7.5.2.

**Table 7.5.2: Pulse Parameter Constraints**

| Pulse Parameter | Minimum Value | Maximum Value | Incremental Step |
|---|---|---|---|
| P+<br>(Positive Probe) | 1<br>(Must be different from Probe -) | 6<br>(Must be different from Probe -) | 1 |
| P-<br>(Negative Probe) | 1<br>(Must be different from Probe +) | 6<br>(Must be different from Probe +) | 1 |
| Voltage | 500 Volts | 3000 Volts | 50 Volts<br>**NOTE**: Calculates and updates automatically as probe pair distances are adjusted or Volts/cm parameter is adjusted. |
| Pulse Length | 20µsec | 100 µsec | 10 µsec |
| Num Pulses<br>(Number of Pulses) | 10 | 100 | 10 |
| V/cm (Volts/cm) | 500 Volts/cm | 3000 Volts/cm | 50 Volts/cm<br>**NOTE**: Calculates and updates automatically when Voltage parameter is modified. |
| Distance<br>(Probe Pair Distance) | 0 cm<br>(with probe placement grid enabled)<br>0.1cm<br>(with probe placement grid disabled) | 11.3 cm<br>(with probe placement grid enabled)<br>5.0cm<br>(with probe placement grid disabled) | 0.1 cm |



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### 7.5.2 How to Modify Pulse Parameters

**ATTENTION:** Modification of pulse parameters should be based on clinical determination by the treating physician.

To modify a Voltage, Pulse Length, Num Pulses, or V/cm pulse parameter, click the cell containing the pulse parameter to display a popup.

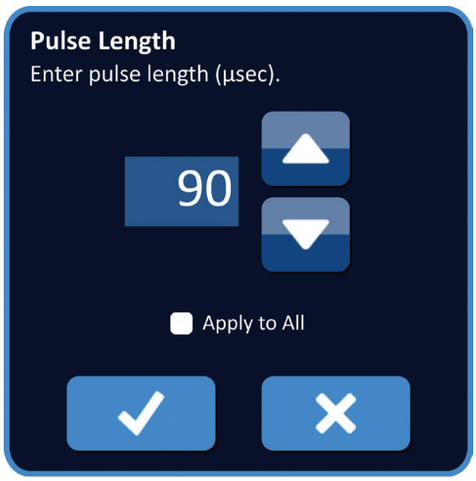



**Figure 7.5.2: Example of Pulse Parameter Popup**

Use the ▲/▼ buttons on the popup to adjust the pulse parameter. Click the ✓ button to store the value and close the popup. Clicking the ✕ button will discard the value and close the popup. The Pulse Parameters Table will update to reflect the change.

The Pulse Parameter cell's color will change to yellow indicating the pulse parameter has been modified by the User. Pulse parameter cells that are orange indicate a parameter is at the maximum or minimum setting. The pulse parameter cell backfill colors and meaning are displayed in Table 7.5.3.

**Table 7.5.3: Pulse Parameters Table Cell Colors and Meaning**

| Cell Color | Meaning |
|---|---|
| 1500 | The dark grey cell backfill indicates a pulse parameter that is currently set to the default value. |
| 1200 | The yellow cell backfill indicates a pulse parameter is either above or below the default value. |
| 3000<br>500 | The orange cell backfill indicates the parameter is set at the maximum or minimum value. |

**NOTE:** Clicking the Restore Default Settings ↺ button will return the Probe Placement Grid and Pulse Parameters Table to default values.



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### 7.5.3 How to Modify Pulse Parameters for All Active Probe Pairs

**ATTENTION:** Modification of pulse parameters should be based on clinical determination by the treating physician.

To modify a Voltage, Pulse Length, Num Pulses, or V/cm pulse parameter for all Active Probe Pairs, click any cell containing the pulse parameter to display a popup. Use the ▲/▼ buttons on the popup to adjust the pulse parameter. Click the Apply to All radio button. Click the ✓ button to store the value and close the popup. Clicking the ✕ button will discard the value and close the popup. The Pulse Parameters Table will update to reflect the change, Figure 7.5.3.




**Figure 7.5.3: Pulse Parameter – Apply to All**

### 7.5.4 How to Re-assign P+ and P- Parameters

**ATTENTION:** Modification of pulse parameters should be based on clinical determination by the treating physician.

To re-assign P+ and P- Parameters for Active Probe Pairs, click any cell in either the P+ or P- column that contains the parameter to display the Modify Probe Pair popup, Figure 7.5.4.

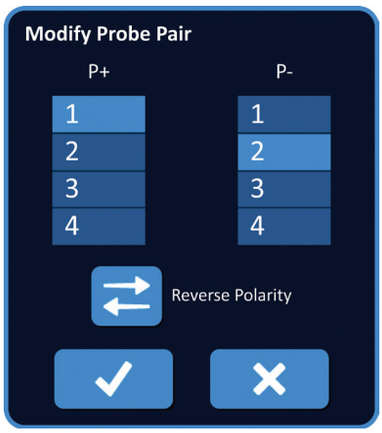



**Figure 7.5.4: Modify Probe Pair Popup**

Click another P+ or P- value to change the parameter. Click the ✓ button to store the values and close the popup. Clicking the ✕ button will discard the values and close the popup. The Pulse Parameters Table will update to reflect the change.



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**NOTE:** If the user attempts to enter identical P+ and P- values an Attention popup will appear, Figure 7.5.5.

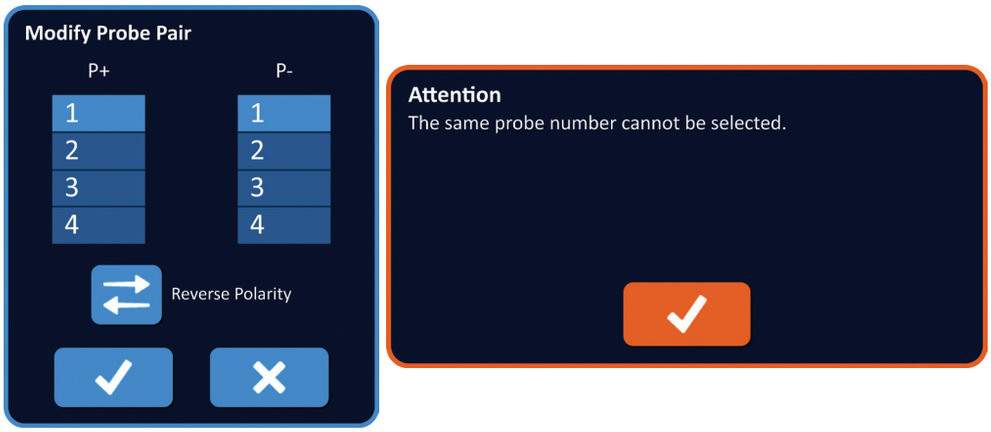



**Figure 7.5.5: Attention Popup – Identical Probe Value**

Click the ✔ button to close the Attention popup. The P+ and P- values will return back to the original values.

**NOTE:** If the user attempts to enter a probe pair that is already listed within the Pulse Parameters Table a warning popup will appear, Figure 7.5.6.




**Figure 7.5.6: Attention Popup – Identical Probe Pair**

Click the ✔ button to close the Attention popup. The P+ and P- values will return back to the original values.



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### 7.5.5 How to Reverse Polarity of Active Probe Pairs

To reverse the polarity of an Active Probe Pair, click any cell in either the P+ or P- column for the Active Probe Pair to display the Modify Probe Pair popup, Figure 7.5.4. Click the Reverse Polarity ⇄ button, Figure 7.5.7.

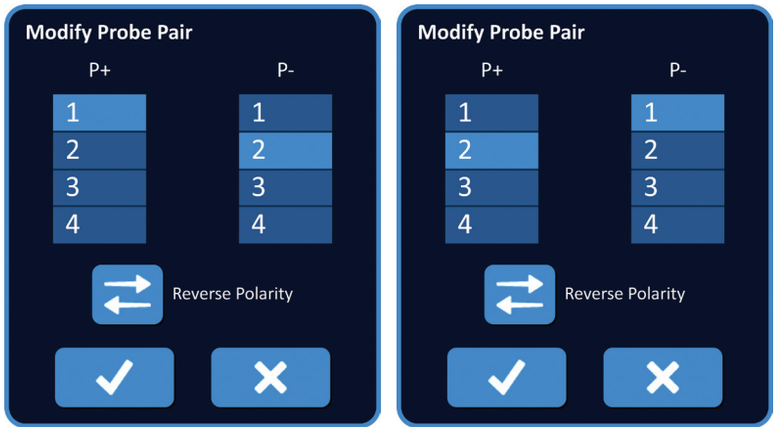



**Figure 7.5.7: Reverse Polarity of Probe Pair**

Click the ✓ button to store the values and close the popup. Clicking the ✗ button will discard the values and close the popup. The Pulse Parameters Table will update to reflect the change.

**NOTE:** Clicking the Restore Default Settings ⟲ button will return the Probe Placement Grid and Pulse Parameters Table to default values.

### 7.5.6 How to Enter Probe Pair Distances Manually

Probe Pair distances are typically entered by moving the Grid Icons around the Probe Placement Grid. The NanoKnife Software allows the User to override the Probe Placement Grid and enter Probe Pair Distances manually into the Pulse Parameters Table. To override the Probe Placement Grid and enter probe pair distances for Active Probe Pairs, click the cell in the Distance column that contains the value to display an Attention popup Figure 7.5.8.




**Figure 7.5.8: Attention Popup – Disable Probe Placement Grid**



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Click the ✔ button to disable the Probe Placement Grid and close the Attention popup and display the Distance popup, Figure 7.5.9. Clicking the ✖ button will cancel and close the Attention popup.

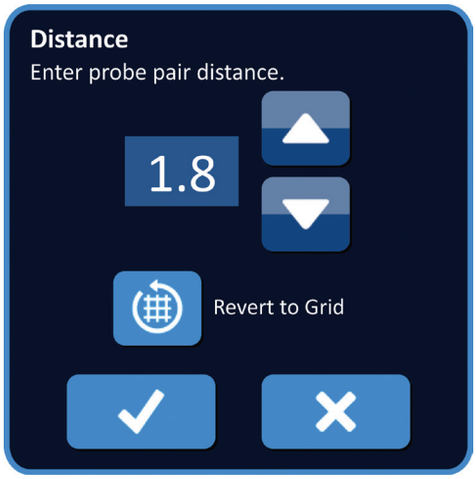



**Figure 7.5.9: Distance Popup**

Use the ▲/▼ buttons on the Distance popup to adjust the distance value. Click the ✔ button to store the value and close the popup. Clicking the ✖ button will discard the value and close the popup. The Pulse Parameters Table will update to reflect the change and the Probe Placement Grid will be disabled, Figure 7.5.10.

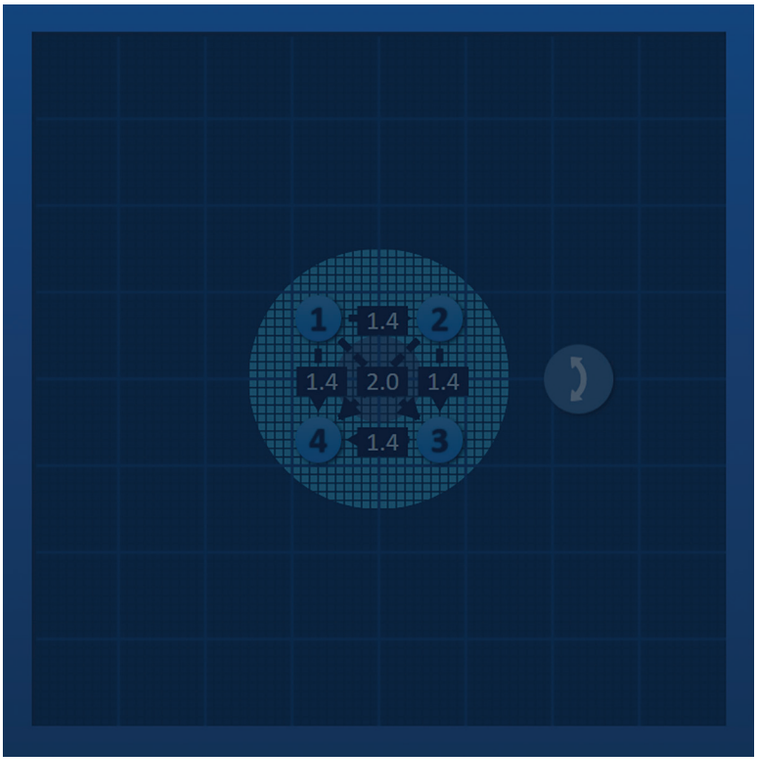



**Figure 7.5.10: Probe Placement Grid – Disabled**

**NOTE:** Clicking the Restore Default Settings button will re-enable the Probe Placement Grid and return the Probe Placement Grid and Pulse Parameters Table to default values.





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### 7.5.7 How to Re-Enable the Probe Placement Grid

To re-enable the Probe Placement Grid and enter probe pair distances for Active Probe Pairs using the Grid Icons, click the cell in the Distance column to display the Distance popup, Figure 7.5.9. Click the Revert to Grid button to display an Attention popup, Figure 7.5.11.

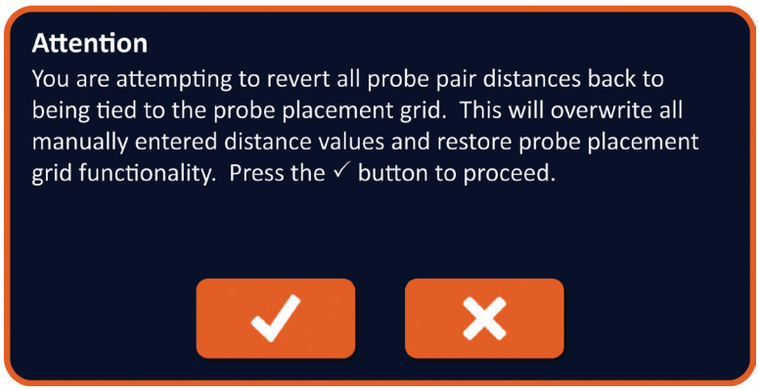



**Figure 7.5.11: Attention Popup – Revert to Grid**

Click the ✓ button reset the distance values as defined by the Probe Placement Grid and close the popup. Clicking the ✕ button will cancel and close the popup.

## 7.6 Add and Delete Row Buttons

Add Row and Delete Row buttons allow the User to add and delete Active Probe Pairs from the Pulse Parameters Table. For example, if the User determines that delivering pulses between Probe 1 and Probe 2 is unnecessary, the User can use the Delete Row button to delete the Active Probe Pair from the Pulse Parameters Table. If the User wants to deliver pulses between a probe pair that is not currently listed within the Pulse Parameters Table, the User can use the Add Row button to add the probe pair to the Pulse Parameters Table.

### 7.6.1 How to Delete Probe Pairs from Pulse Parameters Table

**ATTENTION:** Adding or Deleting probe pairs should be based on clinical determination by the treating physician.

Click the light grey cell in the first column of the row that is to be deleted. A triangle will appear in the light grey cell in the first column and the selected row backfill color will change from a dark grey to bright blue, Figure 7.6.1.




**Figure 7.6.1: Background Color Change**





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Click the button to display an Attention popup, Figure 7.6.2.




**Figure 7.6.2: Deletion Confirmation Box**

Click the ✓ button to remove the selected probe pair from the Pulse Parameters Table and close the popup. Clicking the ✗ button will cancel and close the popup.

**NOTE:** Clicking the Restore Default Settings button will return the Probe Placement Grid and Pulse Parameters Table to default values.

## 7.6.2 How to Add Probe Pairs to the Pulse Parameters Table

**ATTENTION:** Adding or Deleting probe pairs should be based on clinical determination by the treating physician.

Click the button to add a new probe pair to the Pulse Parameters Table. The new probe pair row will be selected and have a bright blue backfill color, Figure 7.6.3.




**Figure 7.6.3: Add Row to Pulse Parameters Table**

**NOTE:** Clicking the Restore Default Settings button will return the Probe Placement Grid and Pulse Parameters Table to default values.



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## 7.7 Distance Solver

The Distance Solver is a utility that allows the User to enter probe distances and have them automatically arranged on the grid. This allows the User to enter actual probe pair distances measured from an imaging device rather than using the touchpad or touchscreen to manually move probes on the grid, Figure 7.7.1.

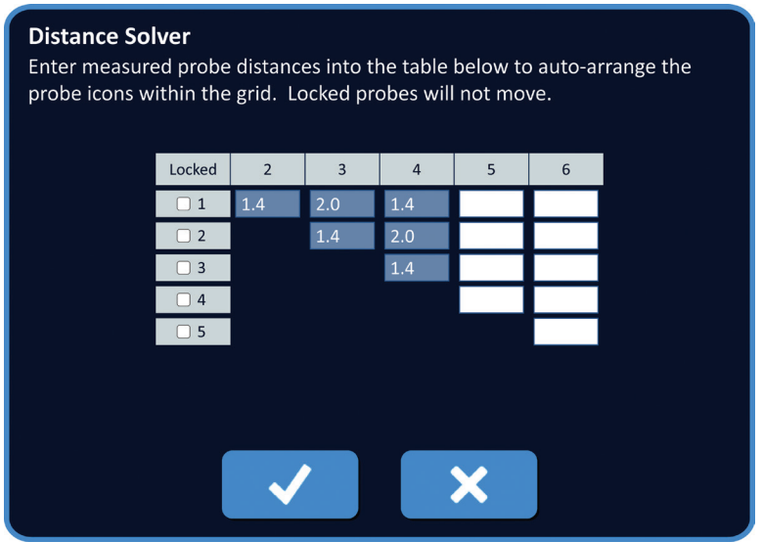



**Figure 7.7.1: Probe Distance Adjuster**

### 7.7.1 How to use the Distance Solver

**NOTE:** The Distance Solver does not accept values greater than 5 cm.

**NOTE:** The Distance Solver accepts input values with a resolution of 0.1cm.

**NOTE:** Inaccurate data entered into the Distance Solver will yield inaccurate results.

**NOTE:** The Distance Solver might not reach a solution if incorrect input values are entered.

Click the Distance Solver button to display the Distance Solver dialog box. Input the desired distances between probes into the dark grey boxes of the Distance Solver dialog box, Figure 7.7.2.

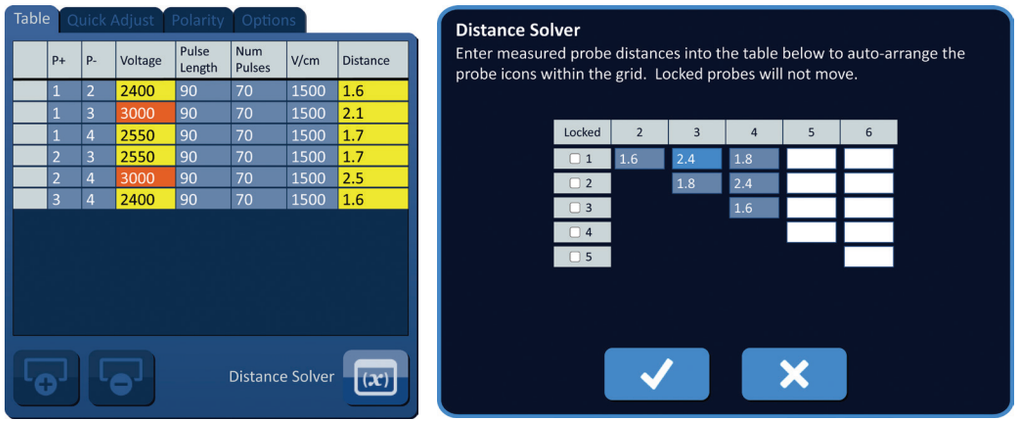



**Figure 7.7.2: Pulse Parameters Table & Adjuster**



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For example, if the Probe Pair Distance between Probe 1 and Probe 3 is currently 2.4 cm and the User determines the Probe Pair Distance between Probe 1 and Probe 3 should be 2.0 cm, the User would click on the Row 1/ Column 3 text box of the Distance Solver dialog box to display the Distance popup. Use the ▲/▼ buttons on the Distance popup to enter a value of 2.0, Figure 7.7.3.

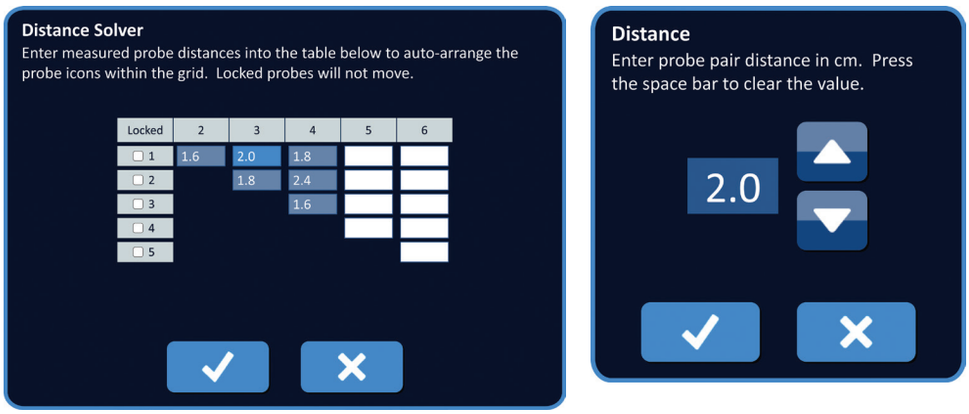



**Figure 7.7.3: Distance Solver – Probe Pair Distance Popup**

***Optional***: Click the radio button in the Locked column to prevent specific Grid Icons from repositioning within the Probe Placement Grid.

Click the ✔ button to store the value and close the Distance popup. Clicking the ✖ button will discard the values and close the popup. The Distance Solver dialog box will update to reflect the change.

After making all desired changes, click the ✔ button to close the Distance Solver dialog box and display the Distance Solver Results dialog box.

**NOTE:** The Distance Solver Status popup may display while a solution is calculated, Figure 7.7.4.

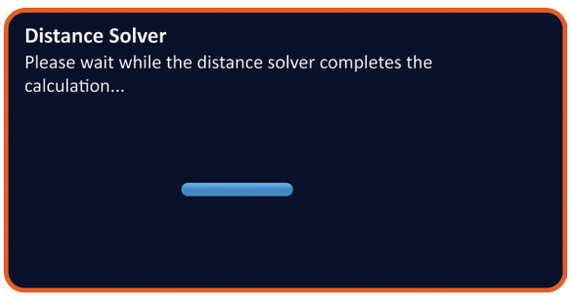



**Figure 7.7.4: Distance Solver Status popup**



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After the Distance Solver completes the calculation, a Distance Solver Results dialog box will display the User input distance, solver output distance, and deviation between the two values, Figure 7.7.5.

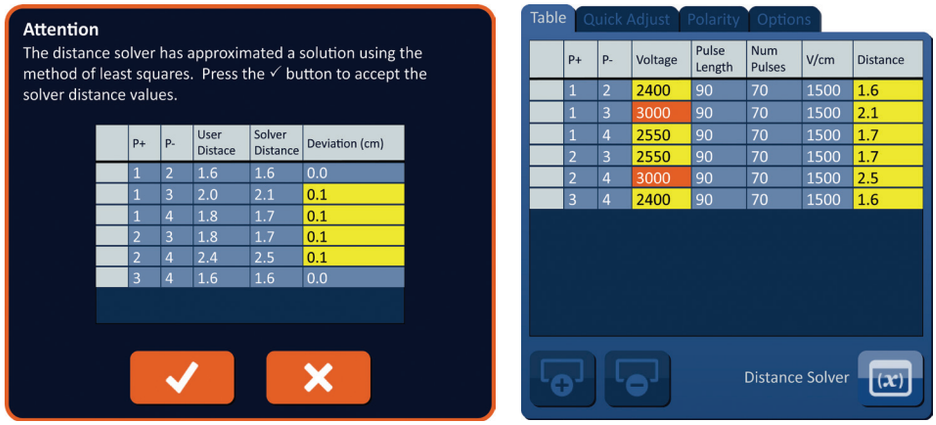



**Figure 7.7.5: Distance Solver Results & Pulse Parameters Table**

Yellow colored cells in the Deviation column indicate deviations exists between the entered value and calculated value. Clicking the ✖ button will reject the Distance Solver Results, close the Distance Solver Results dialog box, and return to the Distance Solver dialog box to make further modifications.

Click the ✔ button to accept the Distance Solver Results, close the Distance Solver Results dialog box, and update the Pulse Parameters Table. The Grid Icons will automatically reposition within the Probe Placement Grid to reflect the changes made by the Distance Solver calculation.

**NOTE:** Clicking the Restore Default Settings button will return the Probe Placement Grid and Pulse Parameters Table to default values.

## 7.8 Quick Adjust Tab

The Quick Adjust tab displays a set of controls that allows the User to quickly add or remove probe pairs, modify pulse parameters for all Active Probe Pairs, and enter in Probe Exposure settings, Figure 7.8.1.

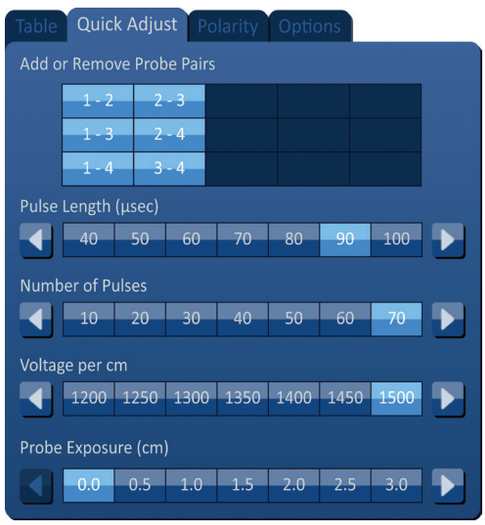



**Figure 7.8.1: Quick Adjust Tab**



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**ATTENTION:** Modification of pulse parameters should be based on clinical determination by the treating physician.

**NOTE:** Clicking the Restore Default Settings button will return the Probe Placement Grid and Pulse Parameters Table to default values.

### 7.8.1 How to Quickly Add or Remove Probe Pairs

Click the Quick Adjust tab to display the Quick Adjust controls. Each bright blue cell in the table labeled 'Add or Remove Probe Pairs' represents an Active Probe Pair; dull blue cells in the table represent inactive Probe Pairs. Clicking a bright blue cell will turn the cell color to dull blue and remove it from the Pulse Parameters Table. Clicking a dull blue cell will turn the color to bright blue and add it to the Pulse Parameters table.

**NOTE:** At least one probe pair must be active. If the user attempts to deactivate all probe pairs a warning popup will appear, Figure 7.8.2.

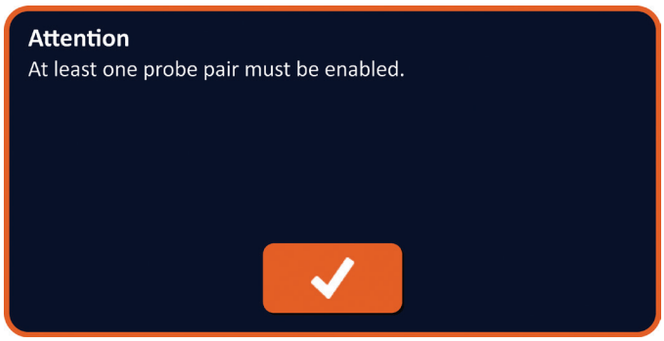



**Figure 7.8.2: Attention Popup – Remove Probe Pair**

Click the ✔ button to close the close the Attention popup. The Probe Pair will be left Active.

### 7.8.2 How to Quickly Modify Pulse Length for All Probe Pairs

Click the Quick Adjust tab to display the Quick Adjust controls. Each bright blue cell in the table below the label 'Pulse Length (µsec)' represents the current parameter setting; dull blue cells in the table represent available parameters to choose from. Click a dull blue cell to quickly modify the parameter for all probe pairs. The cell will become bright blue indicating the parameter has changed.

**NOTE:** Not all parameters options are displayed. Use the ◀/▶ buttons to modify the parameter and access pulse parameters above or below what is displayed. A ◀ or ▶ button that turns midnight blue indicates the parameter is set to either the minimum or maximum value.

### 7.8.3 How to Quickly Modify Number of Pulses for All Probe Pairs

Click the Quick Adjust tab to display the Quick Adjust controls. Each bright blue cell in the table below the label 'Number of Pulses' represents the current parameter setting; dull blue cells in the table represent available parameters to choose from. Click a dull blue cell to quickly modify the parameter for all probe pairs. The cell will become bright blue indicating the parameter has changed.

**NOTE:** Not all parameters options are displayed. Use the ◀/▶ buttons to modify the parameter and access pulse parameters above or below what is displayed. A ◀ or ▶ button that turns midnight blue indicates the parameter is set to either the minimum or maximum value.





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### 7.8.4 How to Quickly Modify Voltage Setting for All Probe Pairs

Click the Quick Adjust tab to display the Quick Adjust controls. Each bright blue cell in the table below the label 'Voltage per cm' represents the current parameter setting; dull blue cells in the table represent available parameters to choose from. Click a dull blue cell to quickly modify the parameter for all probe pairs. The cell will become bright blue indicating the parameter has changed.

**NOTE:** Not all parameters options are displayed. Use the ◀/▶ buttons to modify the parameter and access pulse parameters above or below what is displayed. A ◀ or ▶ button that turns midnight blue indicates the parameter is set to either the minimum or maximum value.

### 7.8.5 How to Enter Probe Exposure for All Probe Pairs

Click the Quick Adjust tab to display the Quick Adjust controls. Each bright blue cell in the table below the label 'Probe Exposure (cm)' represents the current parameter setting; dull blue cells in the table represent available parameters to choose from. The default probe exposure setting is 0.0 cm. Click a dull blue cell to quickly modify the parameter for all probe pairs. The cell will become bright blue indicating the parameter has changed.

**NOTE:** Not all parameters options are displayed. Use the ◀/▶ buttons to modify the parameter and access pulse parameters above or below what is displayed. A ◀ or ▶ button that turns midnight blue indicates the parameter is set to either the minimum or maximum value.

**NOTE:** Entering in the Probe Exposure Setting is optional and does not change any of the Pulse Delivery Parameters.

The Help Text box provides additional information. To open the help screen select the **?** symbol in the upper right of the Procedure Planning Screen.

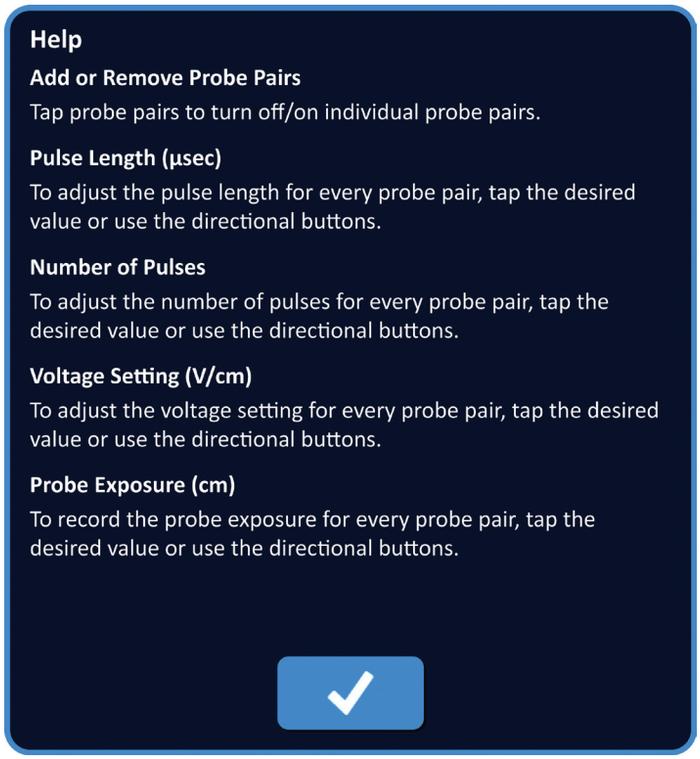



**Figure 7.8.3: Quick Adjust Parameters Tab – Help Popup**



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## 7.9 Polarity Tab

The Polarity tab displays a set of controls that allows the User to quickly re-assign the polarity of each probe pair individually or all probe pairs simultaneously, Figure 7.9.1.

**ATTENTION:** Modification of pulse parameters should be based on clinical determination by the treating physician.

**NOTE:** Clicking the Restore Default Settings button will return the Probe Placement Grid and Pulse Parameters Table to default values.

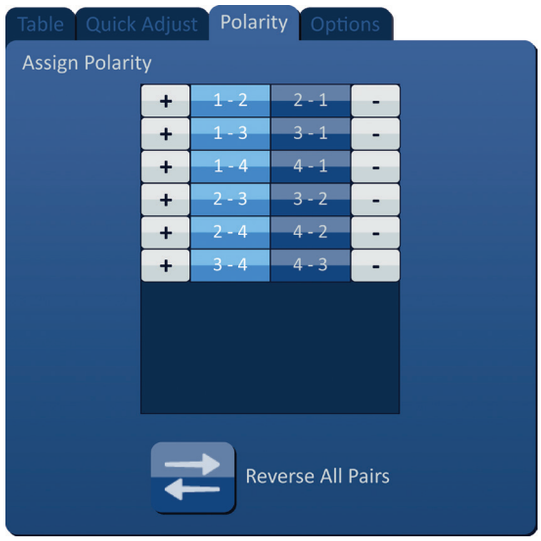



**Figure 7.9.1: Polarity Tab**

### 7.9.1 How to Re-Assign Polarity of a Probe Pair

Click the Polarity tab to display the Assign Polarity controls. Each row represented in the table represents an Active Probe Pair. The current polarity assignment is indicated by the bright blue backfill color. Click either the blue cell containing the reversed numbers or use the + or – buttons to re-assign the polarity of a probe pair.

### 7.9.2 How to Re-Assign Polarity of All Probe Pairs

Click the Reverse All Pairs button to re-assign the polarity of all probe pairs.



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## 7.10 Options Tab

The Options tab displays a set of controls that allows the User to modify visual elements within the Probe Placement Grid, Figure 7.10.1.

**NOTE:** Clicking the Restore Default Settings button will return the Probe Placement Grid and Pulse Parameters Table to default values.




**Figure 7.10.1: Procedure Planning Screen Options Tab**

### 7.10.1 Probe Placement Grid Options

Descriptions of each option are displayed in Table 7.10.1.

**Table 7.10.1 Probe Placement Grid Options**

| Option | Description |
|---|---|
| Target Zone Rotation Handle | Hide (OFF) or display (ON) the Target Zone Rotation Handle. |
| Probe Pair Distances | Hide (OFF) or display (ON) the inter-probe pair distances between active probe pairs. |
| Polarity Arrows | Hide (OFF) or display (ON) the dotted and arrowed lines between active probe pairs. |
| Minor Grid Lines | Hide (OFF) or display (ON) the millimeter grid lines. |
| Major Grid Lines | Hide (OFF) or display (ON) the centimeter grid lines. |



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### 7.10.2 How to Modify Probe Placement Grid Options

Click the ON/OFF button next to an option to toggle on or off a visual element, Figure 7.10.2.

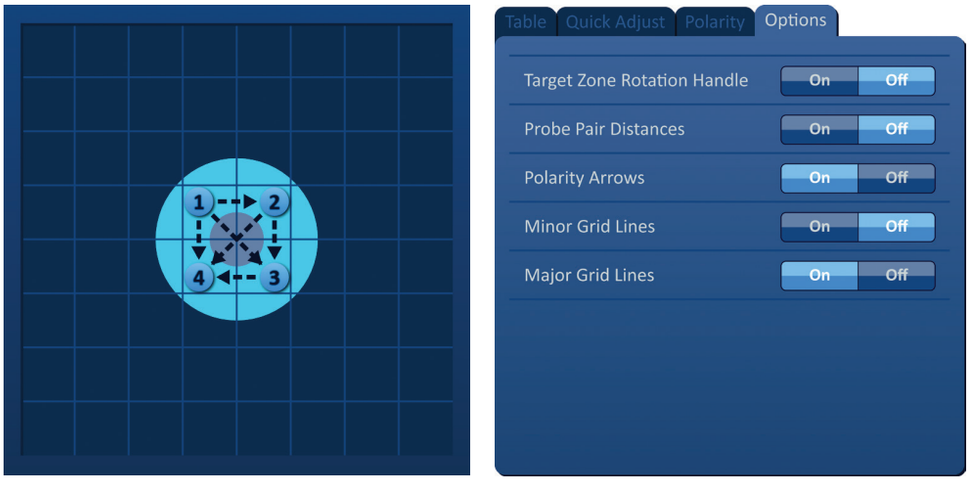



**Figure 7.10.2: Probe Placement Grid Options**

## 7.11 Restore Default Settings

The Restore Default Settings button brings up an Attention popup that allows the User to return the probes to their default procedure settings, positioned around the center of the lesion dimension entered by the treating physician. Clicking the Restore Default button will return the Probe Placement Grid and Pulse Parameters Table to default values; including the Targeted Ablation Area Settings, Grid Icon locations, Probe Polarity, and Probe Placement Grid Options.




**Figure 7.11.1: Restore Default Settings Popup**



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## 7.12 Proceed to Next Screen

After entering the probe placement plan into the Procedure Planning screen, click the Next button ➜ to proceed to the Pulse Generation screen, Figure 7.12.1.




**Figure 7.12.1: Navigation Bar – Next Button**

**WARNING:** 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.

**CAUTION:** Ensure the probes are properly connected to the Generator and placed into the target tissue prior to pulse delivery. Attempting to proceed to the Pulse Generation screen without the correct number of probes connected to the generator will bring up an Attention popup, Figure 7.12.2.

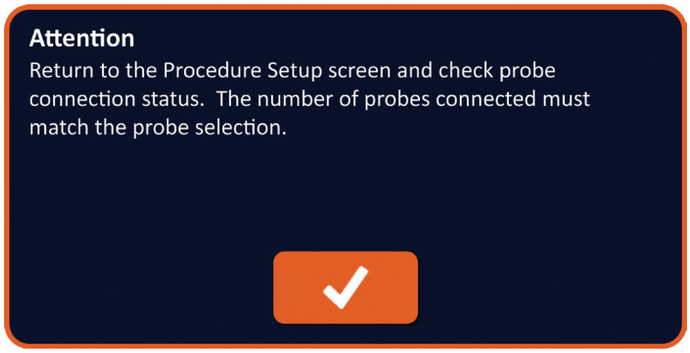



**Figure 7.12.2: Check Probe Connection Status Popup**



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# SECTION 8: PULSE GENERATION

## 8.1 Pulse Generation Screen

The Pulse Generation screen is where pulse delivery is controlled and monitored. The screen includes the Pulse Generation Table, Probe Pair Status Grid, Electrical Results Chart, Voltage Gauge, and Pulse Delivery Control panel, Figure 8.1.1.




**Figure 8.1.1: Pulse Generation Screen**

The **Pulse Generation Table** is where the pulse parameters, current measurements, and pulse delivery statuses are displayed. The pulse parameters displayed in the table are the same parameters displayed in the Pulse Parameters table found on the Procedure Planning screen; however, they are sorted by voltage, from highest to lowest. The user can modify pulse parameters and activate or deactivate probe pairs before and after pulse delivery. Predicted current measurements for each probe pair are displayed in the Pulse Generation Table following completion of a tissue conductivity test. The predicted current measurements will be replaced with initial current measurements following initiation of pulse delivery. Maximum current and change in current values for each probe pair will be updated throughout pulse delivery. The total number of pulses delivered for each probe pair along with a Status Bar is also displayed.

The **Probe Pair Status Grid** is a pictorial representation of the Probe Placement Grid displayed on the Probe Placement screen. Two probe icon labels will slowly change color between dark blue and green indicating the probe pair that is active during pulse delivery.

The **Electrical Results Chart** allows the User to toggle between the Voltage, Current, and Resistance charts during and after pulse delivery. The charts update after each pulse is delivered during pulse delivery.

The **Voltage Gauge** displays the real-time voltage present on the capacitors before, during, and after pulse delivery.

The **Pulse Delivery Control** panel is where the User can stop pulse delivery, skip a probe pair during pulse delivery, and charge or discharge the capacitors. The panel also contains an ECG Synchronization status indicator and message window. The message window displays helpful information during and after pulse delivery.

Detailed instructions on how to utilize the Pulse Generation screen are described in the following subsections.



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## 8.2 Pulse Generation Table

The Pulse Generation Table is where the pulse parameters, current measurements, and pulse delivery statuses are displayed, Figure 8.2.1.

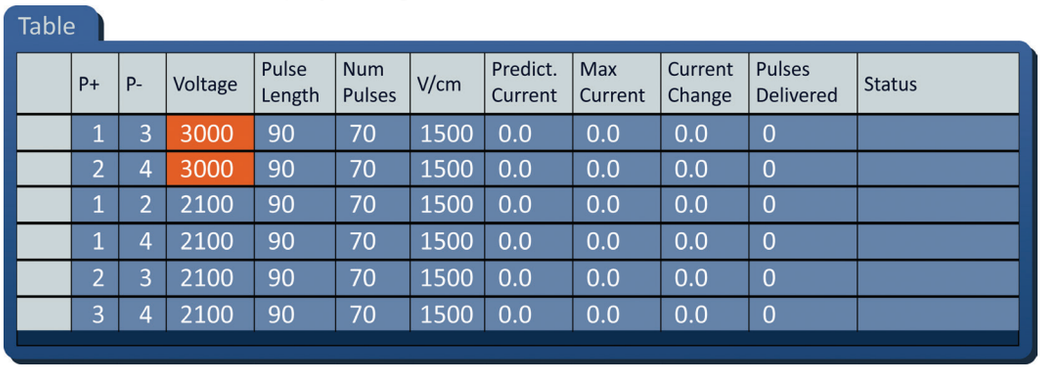



**Figure 8.2.1: Pulse Generation Table**

The Pulse Generation Table includes P+, P-, Voltage, Pulse Length, Num Pulses, V/cm, Predict. Current, Initial Current, Max Current, Current Change, Pulses Delivered, and Status columns. Each parameter is defined in Table 8.2.1.

**Table 8.2.1: Pulse Generation Table Parameters and Definitions**

| Pulse Parameter | Definition |
|---|---|
| P+ | Positive Probe of the Probe Pair. |
| P- | Negative Probe of the Probe Pair. |
| Voltage | Maximum Voltage of each pulse delivered between the Probe Pair with units in Volts (V). |
| Pulse Length | Time duration of each delivered pulse with units in microseconds (µsec). |
| Num Pulses | Intended Number of pulses to be delivered between the Probe Pair. |
| V/cm | Volts per centimeter – a factor multiplied by the Probe Pair Distance to calculate Voltage of the Probe Pair with units in Volts/cm. |
| Predict. Current | Predicted current draw between the Probe Pair following completion of a tissue conductivity test with units in Amps. Column replaced with Initial Current after initiation of pulse delivery. |
| Initial Current | Initial current draw between the Probe Pair during pulse delivery with units in Amps. Column replaces Predict. Current after initiation of pulse delivery. |
| Max Current | Maximum current draw between the Probe Pair during pulse delivery. |
| Current Change | The calculated difference between Max Current and Initial Current values with units in Amps. |
| Pulses Delivered | Total number of pulses delivered for the Probe Pair.<br>**NOTE**: Pulses are counted in groups of 10 following successful completion of each pulse train. |
| Status | Percentage of pulses successfully delivered during pulse delivery for the probe pair. The status is 100% if all intended pulses are delivered. If pulse delivery is stopped or the User skips the remaining pulses for a probe pair, the Status indicates only the successfully completed pulse trains. |

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### 8.2.1 How to Modify Pulse Parameters

**ATTENTION:** Modification of pulse parameters should be based on clinical determination by the treating physician.

The user can modify pulse parameters and activate or deactivate probe pairs before and after pulse delivery. To modify a Voltage, Pulse Length, Num Pulses, or V/cm pulse parameter, click the cell containing the pulse parameter to display a popup, Figure 8.2.2.

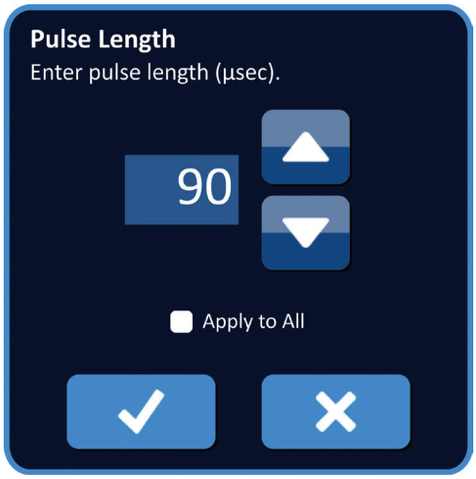



**Figure 8.2.2: Example of Pulse Parameter Popup**

Use the ▲/▼ buttons on the popup to adjust the pulse parameter. Click the ✓ button to store the value and close the popup. Clicking the ✕ button will discard the value and close the popup. The Pulse Generation Table will update to reflect the change.

The Pulse Parameter cell's color will change to yellow indicating the pulse parameter has been modified by the User. Pulse parameter cells that are orange indicate a parameter is at the maximum or minimum setting. The pulse parameter cell backfill colors and meaning are displayed in Table 8.2.2.

**Table 8.2.2: Pulse Parameters Table Cell Colors and Meaning**

| Cell Color | Meaning |
|---|---|
| 1500 | The dark grey cell backfill indicates a pulse parameter that is currently set to the default value. |
| 1200 | The yellow cell backfill indicates a pulse parameter is either above or below the default value. |
| 3000<br>500 | The orange cell backfill indicates the parameter is set at the maximum or minimum value. |



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### 8.2.2 How to Modify Pulse Parameters for All Probe Pairs

**ATTENTION:** Modification of pulse parameters should be based on clinical determination by the treating physician.

To modify a Voltage, Pulse Length, Num Pulses, and V/cm pulse parameter for all Probe Pairs, click any cell containing the pulse generation parameter to display a popup. Use the ▲/▼ buttons on the popup to adjust the pulse parameter. Click the Apply to All radio button. Click the ✓ button to store the value and close the popup. Clicking the ✕ button will discard the value and close the popup. The Pulse Generation Table will update to reflect the change, Figure 8.2.3.

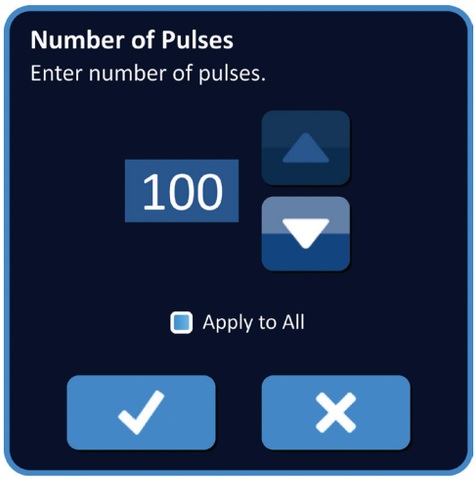



**Figure 8.2.3: Pulse Parameter – Apply to All**

### 8.2.3 How to Reverse Polarity of Active Probe Pairs

To reverse the polarity of an Active Probe Pair, click any cell in either the P+ or P- column for the Active Probe Pair to display the Modify Probe Pair popup, Figure 8.2.4. Click the Reverse Polarity ⇄ button, Figure 8.2.4

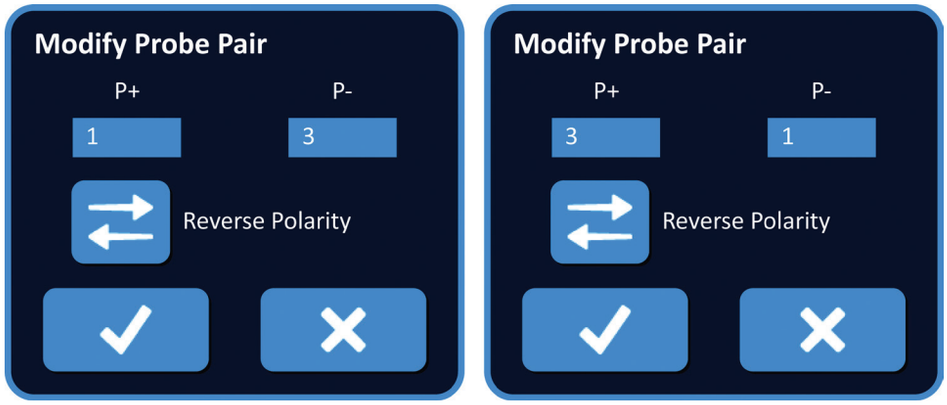



**Figure 8.2.4: Reverse Polarity of Probe Pair**

Click the ✓ button to store the values and close the popup. Clicking the ✕ button will discard the values and close the popup. The Pulse Generation Table will update to reflect the change.



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### 8.2.4 How to Deactivate Probe Pairs

**ATTENTION:** Activating and deactivating probe pairs should be based on clinical determination by the treating physician.

Click the light grey cell in the first column of the row that is to be deleted. A triangle will appear in the light grey cell of the first column and the selected row backfill color will change from a dark grey to bright blue, Figure 8.2.5.

Table

| | P+ | P- | Voltage | Pulse Length | Num Pulses | V/cm | Predict. Current | Max Current | Current Change | Pulses Delivered | Status |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 3 | 3000 | 90 | 70 | 1500 | 0.0 | 0.0 | 0.0 | 0 | |
| ▶ | 2 | 4 | 3000 | 90 | 70 | 1500 | 0.0 | 0.0 | 0.0 | 0 | |
| | 1 | 2 | 2100 | 90 | 70 | 1500 | 0.0 | 0.0 | 0.0 | 0 | |
| | 1 | 4 | 2100 | 90 | 70 | 1500 | 0.0 | 0.0 | 0.0 | 0 | |
| | 2 | 3 | 2100 | 90 | 70 | 1500 | 0.0 | 0.0 | 0.0 | 0 | |
| | 3 | 4 | 2100 | 90 | 70 | 1500 | 0.0 | 0.0 | 0.0 | 0 | |

**Figure 8.2.5: Background Color Change**

The Probe Pair Options popup will display, Figure 8.2.6.




**Figure 8.2.6: Probe Pair Options Popup – Deactivate Probe Pair**

Click the ⊖ button to deactivate the selected probe pair in the Pulse Generation Table. Click the ✔ button to confirm deactivating the probe pair and close the popup. Clicking the ✖ button will discard the changes and close the popup. The Pulse Generation Table will update to reflect the change, Figure 8.2.7.

Table

| | P+ | P- | Voltage | Pulse Length | Num Pulses | V/cm | Predict. Current | Max Current | Current Change | Pulses Delivered | Status |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 3 | 3000 | 90 | 70 | 1500 | 0.0 | 0.0 | 0.0 | 0 | |
| ✖ | 2 | 4 | 3000 | 90 | 70 | 1500 | 0.0 | 0.0 | 0.0 | 0 | |
| | 1 | 2 | 2100 | 90 | 70 | 1500 | 0.0 | 0.0 | 0.0 | 0 | |
| | 1 | 4 | 2100 | 90 | 70 | 1500 | 0.0 | 0.0 | 0.0 | 0 | |
| | 2 | 3 | 2100 | 90 | 70 | 1500 | 0.0 | 0.0 | 0.0 | 0 | |
| | 3 | 4 | 2100 | 90 | 70 | 1500 | 0.0 | 0.0 | 0.0 | 0 | |

**Figure 8.2.7: Deactivated Probe Pair**





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### 8.2.5 How to Activate Probe Pairs

**ATTENTION:** Activating and deactivating probe pairs should be based on clinical determination by the treating physician.

Click the light grey cell in the first column of the row that contains the ✕ symbol. The selected row backfill color will change from a dark blue to bright blue and the Probe Pair Options popup will display, Figure 8.2.8.




**Figure 8.2.8: Probe Pair Options Popup – Activate Probe Pair**

Click the ⊕ button to activate the selected probe pair in the Pulse Generation Table. Click the ✓ button to confirm activating the probe pair and close the popup. Clicking the ✕ button will discard the changes and close the popup. The Pulse Generation Table will update to reflect the change.

### 8.2.6 How Current Measurements are Calculated

Predicted current measurements for each probe pair are displayed in the Pulse Generation Table following successful completion of a tissue conductivity test. The predicted current measurements will be replaced with initial current measurements following initiation of pulse delivery. Maximum current measurement values and change in current values for each probe pair will be updated throughout pulse delivery. The current change value for each probe pair is calculated by subtracting the maximum current value by the initial current value as shown in Figure 8.2.9.

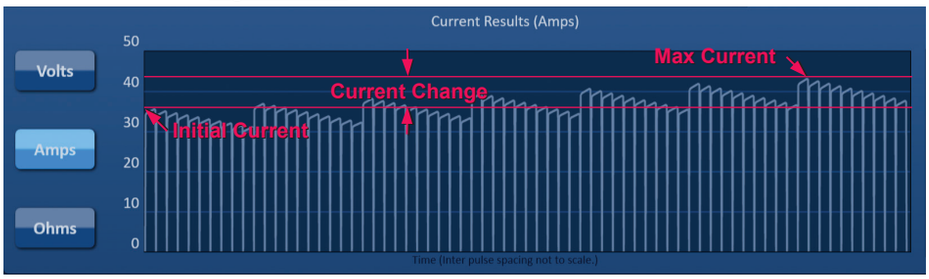



**Figure 8.2.9: Initial, Max, and Change in Current**



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### 8.2.7 How to Evaluate Pulses Delivered and Status

The total number of pulses delivered for each probe pair along with a Status Bar is displayed during and after pulse delivery. The Pulses Delivered and Status columns of the Pulse Generation Parameters Table updates as each group of 10 pulses is delivered, Figure 8.2.10.

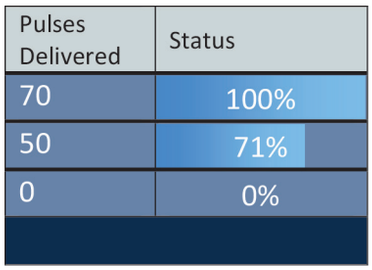



**Figure 8.2.10: Pulses Delivered and Status Columns during Pulse Delivery**

**NOTE:** Pulses delivered successfully within the same pulse train, group of 10 pulses, leading up to an over current condition will not be counted in the pulses delivered column.

The Status Bar is located below the Electrical Results Chart and indicates the overall progress through pulse delivery and percentage complete, Figure 8.2.11.

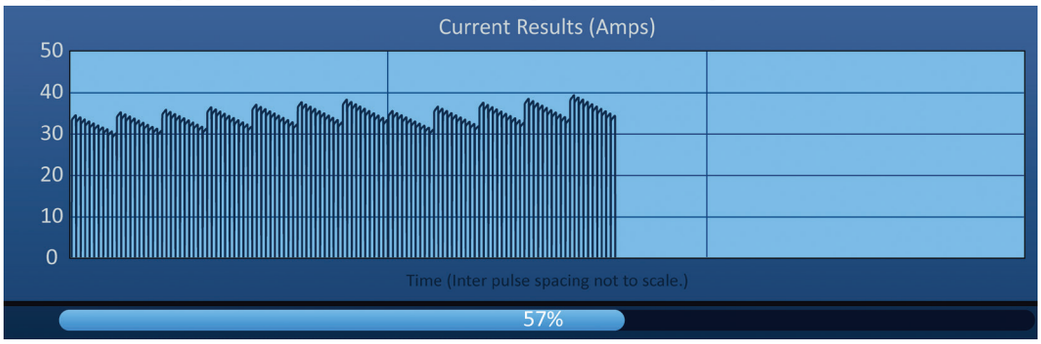



**Figure 8.2.11: Status Bar during Pulse Delivery**

The Status Bar is synchronized to the Electrical Results Chart. The Status Bar will update after each pulse is delivered.



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## 8.3 Probe Pair Status Grid

The Probe Pair Status Grid is a pictorial representation of the Probe Placement Grid displayed on the Probe Placement screen. Two probe icon labels will slowly change color between dark blue and green indicating the probe pair that is active during pulse delivery, Figure 8.3.1. The positive probe will change color from dark blue to green prior to the negative probe indicating polarity of the probe pair.

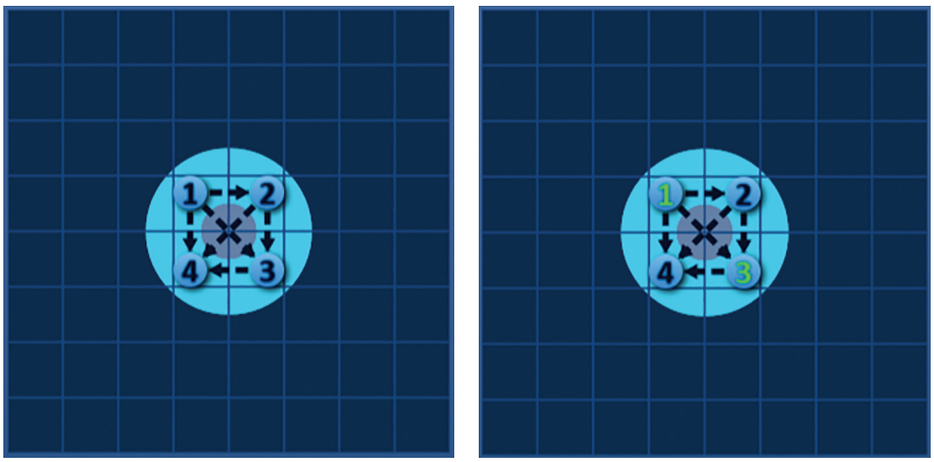



**Figure 8.3.1: Probe Pair Status Grid**

## 8.4 Electrical Results Chart

The Electrical Results Chart allows the User to toggle between the Voltage, Current, and Resistance charts during and after pulse delivery. Refer to Table 8.4.1 below for a list of buttons that appear next to the Electrical Results Chart and their functionality.

**Table 8.4.1: Electrical Results Chart Buttons and Meaning**

| Button | Function |
|---|---|
| Volts | Volts button toggles the Electrical Results Chart to display voltage readings between 0 and 3,000 volts. |
| Amps | Amps button toggles the Electrical Results Chart to display current readings between 0 and 50 amps. |
| Ohms | Ohms button toggles the Electrical Results Chart to display resistance readings between 0 and 250 ohms. |

The Electrical Results Charts include vertical grid lines which represent transitions between each probe pairs listed within the Pulse Generation Table, Figure 8.4.1.

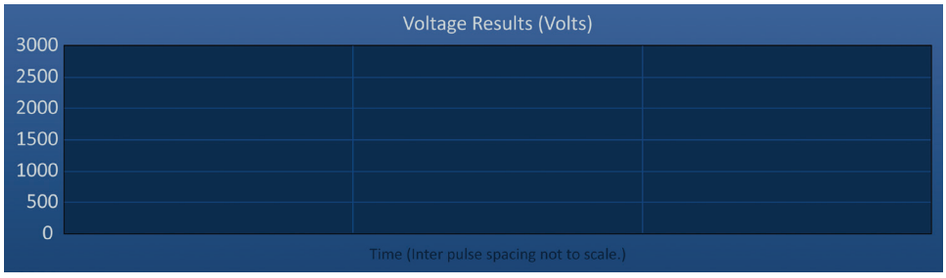



**Figure 8.4.1: Voltage Results Graphs with Vertical Grid Lines**



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### 8.4.1 How to Toggle between Electrical Results Charts

The Electrical Results Chart may be toggled between Voltage, Current, and Resistance before, during, and after pulse delivery. Click the Volts button to view the Voltage Results chart. Click the Amps button to view the Current Results chart. Click the Ohms button to view the Resistance Results chart. The button color will change to bright blue when clicked, Figure 8.4.2.

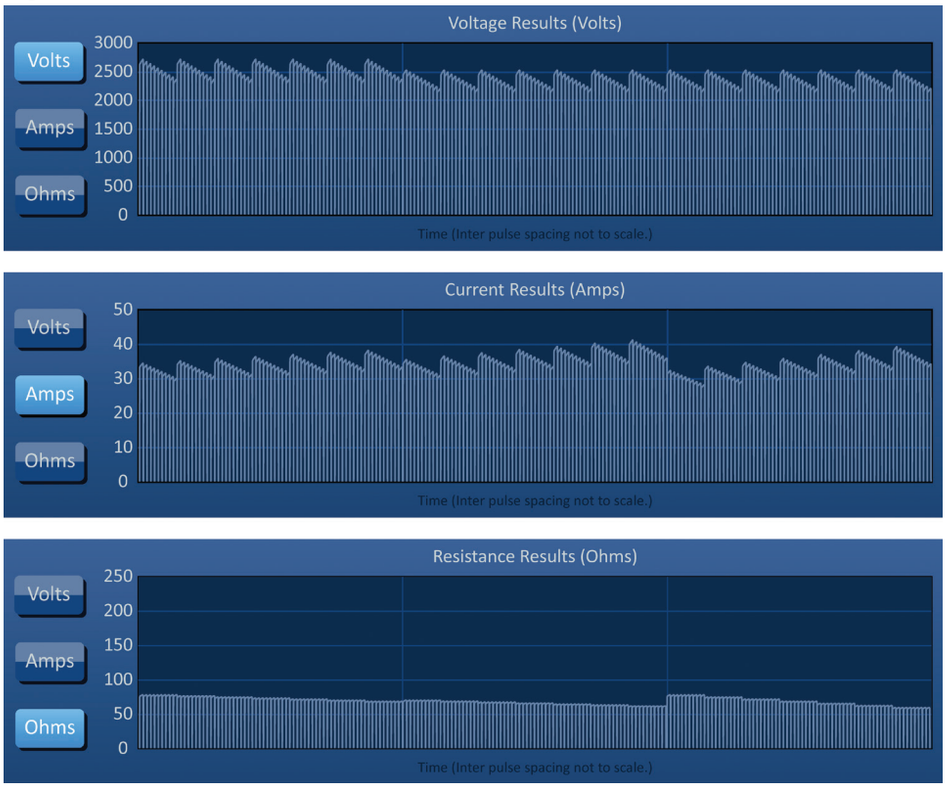



**Figure 8.4.2: Electrical Results Charts**

### 8.4.2 Electrical Results Chart during Pulse Delivery

The Electrical Results Chart's color scheme will change during pulse delivery. The background color will change to light blue and the pulse data will change to dark blue. A synchronized Status Bar positioned below the Electrical Results Chart indicates the overall pulse delivery progress, Figure 8.4.3.

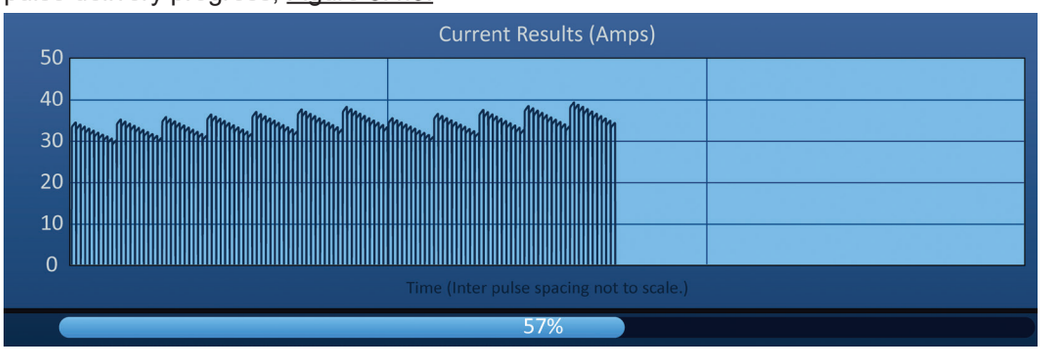



**Figure 8.4.3: Current Results Chart during Pulse Delivery**



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The Electrical Results Chart will update after each pulse is delivered providing an electrical measurement to the User. The User may choose to stop pulse delivery if the current measurements are approaching the 50 Amp limit and avoid a high current condition.

**ATTENTION:** High current conditions may result in ineffective ablation or excessive energy delivered. Refer to Section 8.7.11 for more information on high current conditions.

### 8.4.3 Electrical Results Chart after Pulse Delivery

The Electrical Results Charts will continue to display the electrical measurements after pulse delivery has completed and after pulse delivery has stopped by the User, Figure 8.4.4.

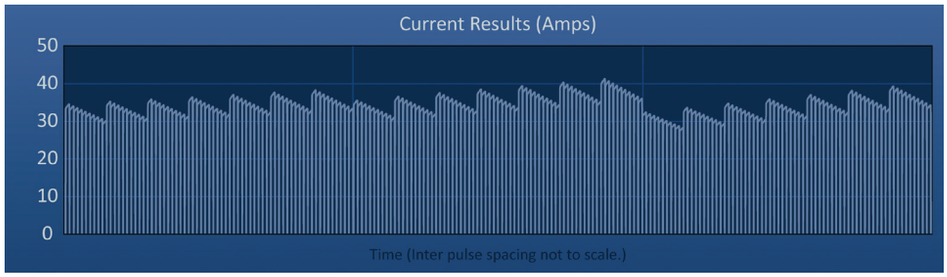



**Figure 8.4.4: Electrical Results Chart – All Probe Pairs**

The User may zoom in on a specific probe pair by clicking the area within the chart that corresponds to the probe pair. The Electrical Results Chart title will change indicating which probe pair is displayed, Figure 8.4.5.

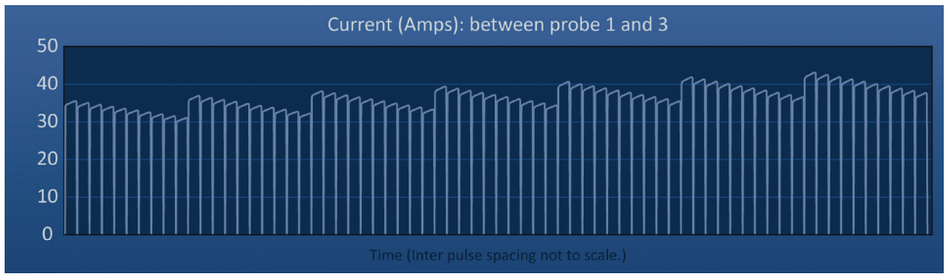



**Figure 8.4.5: Electrical Results Chart – One Probe Pair**

The User may zoom in further on a specific pulse train of 10 pulses by clicking the area within the chart that corresponds to the pulse train. The Electrical Results Chart title will change indicating which probe pair and pulse train is displayed, Figure 8.4.6.

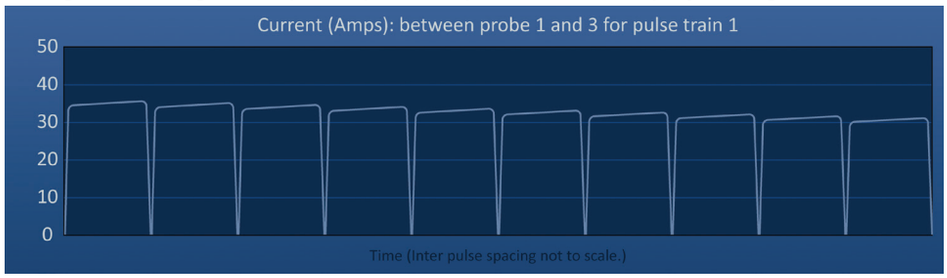



**Figure 8.4.6: Electrical Results Chart – One Pulse Train**

The User may zoom out to view the electrical measurements for all probe pairs by clicking anywhere within the chart area.

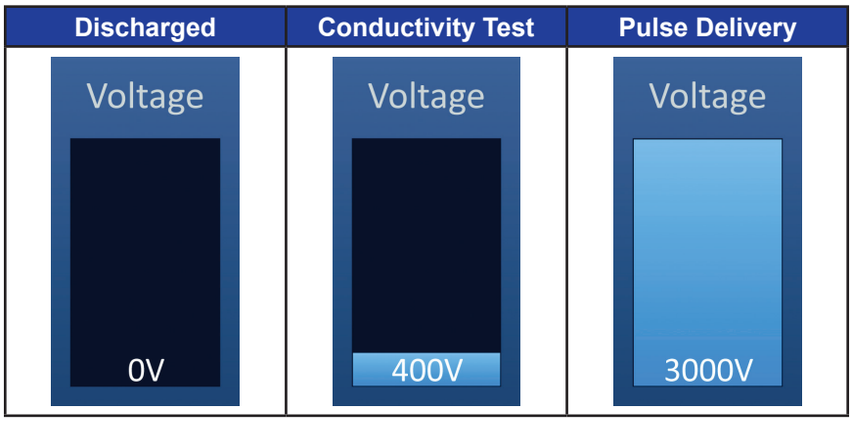


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## 8.5 Voltage Gauge and Charge Options

The Voltage Gauge displays the real-time voltage present on the capacitors before, during, and after pulse delivery. The various Voltage Gauge states are shown in Table 8.5.1.

**Table 8.5.1: Voltage Gauge States**




**NOTE:** The capacitors will discharge if the NanoKnife System is left idle on the Pulse Generation Screen for 5 minutes.

### 8.5.1 How to Discharge Capacitors

Click the button to discharge the capacitors. The message window will display text as shown below in Figure 8.5.1.

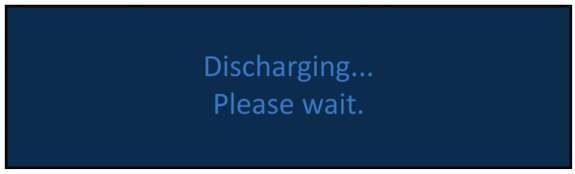



**Figure 8.5.1: Message Window while Discharging**

A light blue flag indicator will also appear in the top right corner of the screen as shown in Figure 8.5.2.




**Figure 8.5.2: Discharging Status Flag**

### 8.5.2 How to Charge Capacitors

When the capacitors are discharged, the message window will instruct the user to press the charge button to start, Figure 8.5.3.

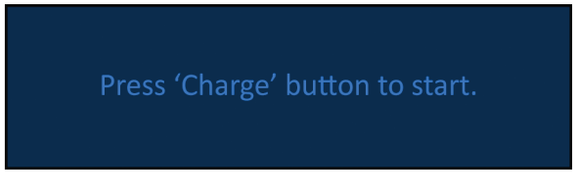



**Figure 8.5.3: Message Window when Capacitors are Discharged**



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Click the button to charge the capacitors. The message window will display text as shown below in Figure 8.5.4.

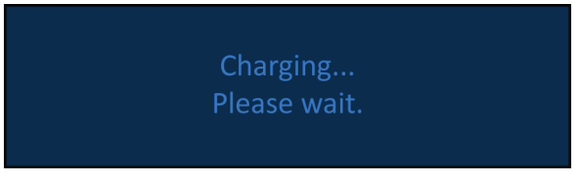



**Figure 8.5.4: Message Window while Charging**

A light blue flag indicator will also appear in the top right corner of the screen as shown in Figure 8.5.5.




**Figure 8.5.5: Charging Status Flag**

## 8.6 Audible Indications During Pulse Delivery

The Generator produces four different audible indications. Refer to Table 8.6.1 below for a list of audible tones and their meaning.

**Table 8.6.1: Audible Indications**

| Audible Indication | Description |
|---|---|
| One Long Beep | Pulse delivery started |
| Two Short Beeps | Conductivity test pulse delivered or Pulse train delivered |
| Four Short Beeps | High current condition or low-current condition detected within pulse train |
| Two Long Beeps | Pulse delivery complete |

## 8.7 Pulse Delivery Control Panel

The Pulse Delivery Control panel is where the User can stop pulse delivery, skip a probe pair during pulse delivery, and charge or discharge the capacitors, Figure 8.7.1.

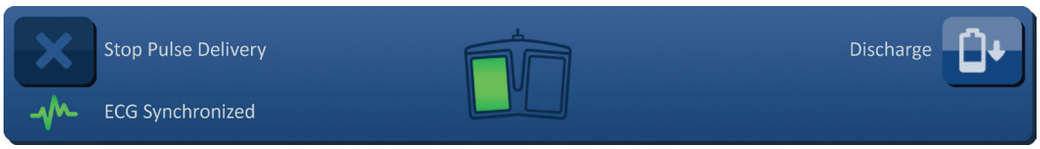



**Figure 8.7.1: Pulse Delivery Control Panel**



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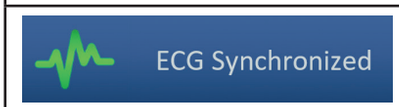
Refer to Table 8.7.1 below for a list of buttons that appear on the Pulse Delivery Control panel and their functionality.

**Table 8.7.1: Pulse Delivery Control Panel Buttons and Functionality**

| Button | Function |
|---|---|
|  | Stop Pulse Delivery button allows the User to stop the delivery of pulses during the conductivity test and pulse delivery. |
|  | Skip Probe Pair button allows the User to skip the remaining pulses to be delivered for the active probe pair and advance to the next probe pair listed in the Pulse Generation table. |
|  | Charge button allows the User to charge the Generator after pulse delivery or after the Generator discharges due to timeout. |
|  | Discharge button allows the User to discharge the Generator. |

The panel also contains an ECG Synchronization status indicator. Refer to Table 8.7.2 below for a list of ECG Synchronization status indicators that appear on the Pulse Delivery Control panel and their meaning.

**Table 8.7.2: ECG Synchronization Status**

| ECG Status | Description |
|---|---|
|  | “ECG Disabled” if 90 PPM is 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 (i.e. above 120 bpm). |
|  | “ECG Lost” if ECG synchronization is selected and signal is too slow or not present. |



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The Pulse Delivery Control Panel will display an icon of the Double Pedal Footswitch instructing the User to press either the left (ARM) or Right (PULSE) footswitch pedal. Refer to Table 8.7.3 below for a list of Double Pedal Footswitch Icons that appear on the Pulse Delivery Control panel and their meaning.

**Table 8.7.3: Double Pedal Footswitch Icons and Description**

| Icon | Description |
|---|---|
|  | System ready to be armed. Press Left (ARM) Footswitch Pedal to arm the NanoKnife Generator for pulse delivery. |
|  | System ready to deliver pulses. Press Right (PULSE) Footswitch Pedal to initiate pulse delivery. |

A message window will appear in place of the Double Footswitch Pedal Icon when the system is not in a Ready state. The message window displays text to inform or instruct the User.

### 8.7.1 How to Start the Conductivity Test

The Conductivity Test involves delivering one low-energy pulse between each active probe pair through the targeted ablation area to confirm the tissue impedance is within an acceptable range. The Conductivity Test voltage is approximately 400 Volts. Delivery of the Conductivity Test is started using the Double Pedal Footswitch.

The Generator charges for the Conductivity Test when the User advances to the Pulse Generation screen. When the capacitors charge to 400 Volts, the Pulse Delivery Control Panel will display the Double Pedal Footswitch icon with the left pedal illuminated green, Figure 8.7.2.




**Figure 8.7.2: Double Pedal Footswitch Icon - Left Pedal Illuminated**

A green flag indicator will also appear in the top right corner of the screen as shown in Figure 8.7.3.




**Figure 8.7.3: Device Ready Status Flag**

Press the Left (ARM) Footswitch Pedal to arm the Generator. The Pulse Delivery Control Panel will display the Double Pedal Footswitch icon with the right pedal illuminated green with a 10-second countdown, Figure 8.7.4.

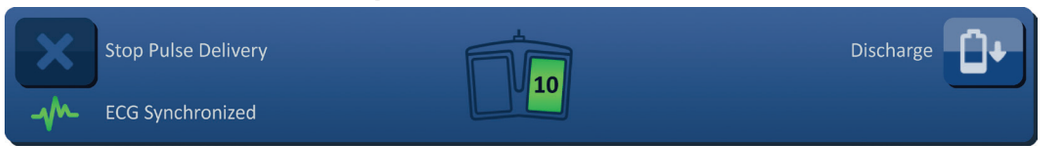



**Figure 8.7.4: Double Pedal Footswitch Icon - Right Pedal Illuminated**



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Press the Right (PULSE) Footswitch Pedal before the countdown has completed to start the Conductivity Test.

**NOTE:** If the Right (PULSE) Footswitch Pedal is not pressed within the 10-second countdown, the NanoKnife Generator will disarm.

**NOTE:** Pressing the Right (PULSE) Footswitch Pedal without the Generator armed has no effect.

After the Conductivity Test begins, the message window will appear and display text as shown below in Figure 8.7.5.




**Figure 8.7.5: Message Window while Conductivity Test in Progress**

Two short audible beeps are produced after each probe pair is tested.

**NOTE:** The User may stop the conductivity test by pressing the Stop Pulse Delivery button any time during pulse delivery.

During the Conductivity Test, The Predict. Current column of the Pulse Generation Table updates with predicted current measurements, Figure 8.7.6.

| Predict. Current | Max Current | Current Change |
|---|---|---|
| 25.4 | 0.0 | 0.0 |
| 26.3 | 0.0 | 0.0 |
| 24.1 | 0.0 | 0.0 |

**Figure 8.7.6: Pulse Generation Table – Predicted Current Values**

**ATTENTION:** The User should consider changing pulse parameters or probe exposure settings if the predicted current values are greater than 35 Amps to prevent over-current conditions during pulse delivery. Refer to Section 12 for additional instruction on troubleshooting high current conditions.

The Status Bar will indicate the progress through the conductivity test and percentage complete. After the Conductivity Test is complete, the message window will display text as shown below in Figure 8.7.7.




**Figure 8.7.7: Message Window while Conductivity Test is Complete**



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If the Conductivity Test is successful, an Attention popup will display that allows the User to repeat the conductivity test or proceed to pulse delivery, Figure 8.7.8.

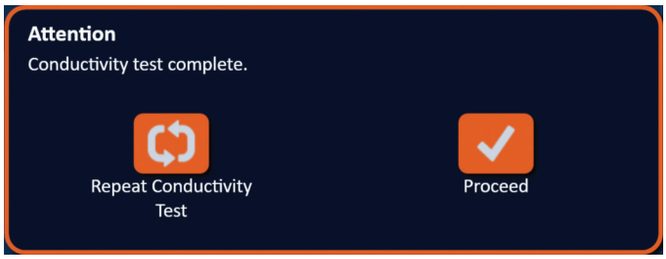



**Figure 8.7.8: Conductivity Test Complete Popup**

Press the ✔ button to proceed and prepare for pulse delivery. Pressing the ↻ button will ready the system to repeat the conductivity test.

**NOTE:** The User will still be required to use the Double Pedal Footswitch to start the conductivity test after pressing the Repeat Conductivity Test button.

After pressing the ✔ button, the Generator will charge the capacitors and the message window will display text as shown in Figure 8.5.4 and a light blue flag indicator will also appear in the top right corner of the screen as shown in Figure 8.5.5. The Voltage Gauge will progressively fill from bottom to top and display the real-time voltage present on the capacitors. Charging typically takes 30 seconds to complete.

### 8.7.2 High Current Detected during the Conductivity Test

If the Conductivity Test is unsuccessful, a popup will appear indicating the reason. If the reason is due to high current detected, an Attention popup will appear and instruct the user to check probe connections and measurements, Figure 8.7.9.

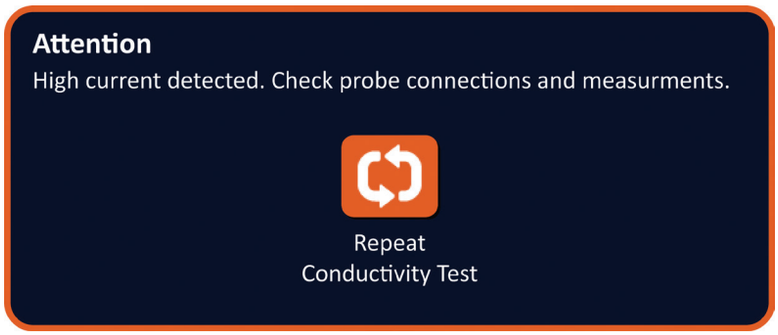



**Figure 8.7.9: Conductivity Test - High Current Detected Popup**

The Predict. Current column of the Pulse Generation Table updates with predicted current measurements during the Conductivity Test. The Predict. Current cell's color will change to orange indicating the predicted current is greater than 45 Amps, Figure 8.7.10.

| Predict. Current | Max Current | Current Change |
|---|---|---|
| 100.0 | 0.0 | 0.0 |
| 100.0 | 0.0 | 0.0 |
| 100.0 | 0.0 | 0.0 |

**Figure 8.7.10: Pulse Generation Table – Conductivity Test – High Current Detected**



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Press the ↻ button to ready the system to repeat the conductivity test.

**ATTENTION:** The User must change pulse parameters or probe exposure settings and repeat the conductivity test to proceed to pulse delivery. Refer to Section 8.7.11 for additional instruction on troubleshooting high current conditions.

### 8.7.3 Low Current Detected during the Conductivity Test

If the Conductivity Test is unsuccessful, a popup will appear indicating the reason. If the reason for the Conductivity Test to be unsuccessful is due to low current detected, an Attention popup will appear and instruct the user to check probe connections, Figure 8.7.11. Also refer to Section 12 Troubleshooting if low current is encountered during the conductivity test.

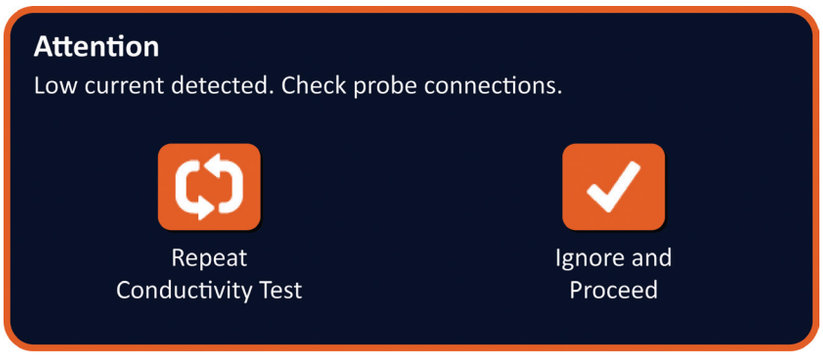



**Figure 8.7.11: Conductivity Test - Low Current Detected Popup**

The Predict. Current column of the Pulse Generation Table updates with predicted current measurements during the Conductivity Test. The Predict. Current cell's color will change to orange indicating the predicted current is less than 0.75 Amps, Figure 8.7.12.

| Predict. Current | Max Current | Current Change |
|---|---|---|
| 0.0 | 0.0 | 0.0 |
| 0.0 | 0.0 | 0.0 |
| 0.0 | 0.0 | 0.0 |

**Figure 8.7.12: Pulse Generation Table – Conductivity Test – Low Current Detected**

Press the ↻ button to ready the system to repeat the conductivity test. Pressing the ✓ button will ignore the low current warning and proceed and prepare for pulse delivery.

**ATTENTION:** Low current measurements may be expected based on the impedance of the targeted tissue. Use clinical judgement to ignore the conductivity results and proceed.



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### 8.7.4 How to Modify Pulse Parameters After the Conductivity Test

**ATTENTION:** Modification of pulse parameters should be based on clinical determination by the treating physician.

The user can modify pulse parameters and activate or deactivate probe pairs after the conductivity test is complete and before pulse delivery. To modify a Voltage, Pulse Length, Num Pulses, or V/cm pulse parameter, click the cell containing the pulse parameter to display a popup, Figure 8.2.2.

Use the ▲/▼ buttons on the popup to adjust the pulse parameter. Click the ✔ button to store the value and close the popup. Clicking the ✖ button will discard the value and close the popup. The Pulse Generation Table will update to reflect the change.

The Pulse Parameter cell's color will change to yellow indicating the pulse parameter has been modified by the User. Pulse parameter cells that are orange indicate a parameter is at the maximum or minimum setting. The pulse parameter cell backfill colors and meaning are displayed in Table 8.2.2.

When a pulse parameter has been changed following the conductivity test, the capacitors will discharge, the message window will display text as shown in Figure 8.5.1.

When the capacitors are discharged, the message window will instruct the user to press the charge button to start, Figure 8.5.3. Click the button to charge the capacitors. The message window will display text as shown below in Figure 8.5.4.

When the capacitors reach full charge, the Pulse Delivery Control Panel will display the Double Pedal Footswitch icon with the left pedal illuminated green, Figure 8.7.13 and a green flag indicator will also appear in the top right corner of the screen as shown in Figure 8.7.14.

**NOTE:** To repeat the conductivity test at the new pulse parameters, click the Back button ← on the Navigation Bar to display the Procedure Planning screen. Click the Next button → to proceed to the Pulse Generation screen. A conductivity test will be required prior to proceeding to pulse delivery.

### 8.7.5 How to Start Pulse Delivery

Pulse Delivery involves delivering multiple high voltage pulses between each active probe pair included in the Pulse Generation table. Only one probe pair will be active during pulse delivery. Pulse delivery between probe pairs occurs sequentially as listed in the Pulse Generation table from top to bottom

The Generator will recharge after each group of 10 pulses is delivered. A group of 10 pulses is referred to as a pulse train. Pulse Delivery voltages range between 500 and 3,000 Volts. Pulse Delivery is started using the Double Pedal Footswitch.

The Generator charges for Pulse Delivery after successful completion of the Conductivity Test. When the capacitors reach full charge, the Pulse Delivery Control Panel will display the Double Pedal Footswitch icon with the left pedal illuminated green, Figure 8.7.13.

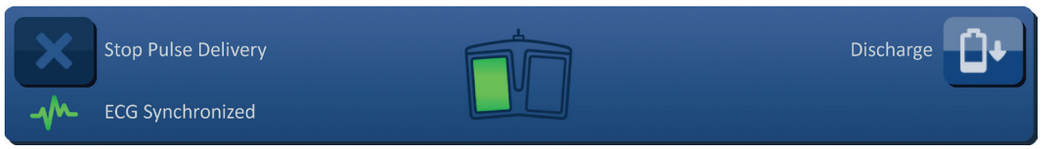



**Figure 8.7.13: Double Pedal Footswitch Icon - Left Pedal Illuminated**

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A green flag indicator will also appear in the top right corner of the screen as shown in Figure 8.7.14.




**Figure 8.7.14: Device Ready Status Flag**

Press the Left (ARM) Footswitch Pedal to arm the Generator. The Pulse Delivery Control Panel will display the Double Pedal Footswitch icon with the right pedal illuminated green with a 10-second countdown, Figure 8.7.15.




**Figure 8.7.15: Double Pedal Footswitch Icon - Right Pedal Illuminated**

Press the Right (PULSE) Footswitch Pedal before the countdown has completed to start Pulse Delivery.

**NOTE:** If the Right (PULSE) Footswitch Pedal is not pressed within the 10-second countdown, the NanoKnife Generator will disarm.

**NOTE:** Pressing the Right (PULSE) Footswitch Pedal without the Generator armed has no effect.

After the Pulse Delivery begins, a long audible beep is produced and the message window will appear and display text as shown below in Figure 8.7.16.

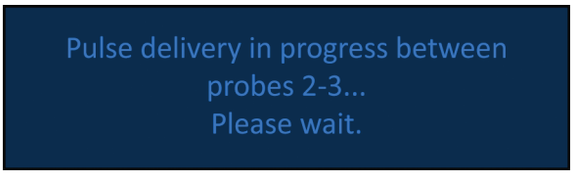



**Figure 8.7.16: Message Window while Pulse Delivery in Progress**

**ATTENTION:** The User should observe and review messages displayed in the message window for notifications during pulse delivery. Overlooking errors may result in ineffective ablation or excessive energy delivered.

**NOTE:** The User may stop pulse delivery by pressing the Stop Pulse Delivery button any time during pulse delivery.

**ATTENTION:** If loud popping noises are heard during pulse delivery, it is recommended to stop pulse delivery using the Stop Pulse Delivery button. Verify that the electrodes are placed entirely within the targeted tissue, the probes are connected to the proper Generator Probe Connector, and the distances between the probes have been accurately entered into the Probe Placement Grid. Refer to Section 12 for additional troubleshooting information.



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After starting Pulse Delivery, The Predict. Current column of the Pulse Generation Table will be replaced with an Initial Current column and updates with initial current measurements during pulse delivery. The Max Current and Current Change columns update as well during pulse delivery, Figure 8.7.17.

| Initial Current | Max Current | Current Change |
|---|---|---|
| 25.4 | 35.2 | 9.8 |
| 26.3 | 36.4 | 10.1 |
| 24.1 | 33.8 | 9.7 |

**Figure 8.7.17: Pulse Generation Table – Initial Current Values**

**ATTENTION:** The User should consider stopping pulse delivery if the maximum current values are approaching 50 Amps to prevent high current conditions during pulse delivery. Refer to Sections 8.7.11 and 12 for additional instruction on troubleshooting high current conditions.

Two probe icon labels within the Probe Pair Status Grid slowly change color between dark blue and green indicating the probe pair that is active during pulse delivery. The Electrical Results Chart updates after each pulse is delivered providing an electrical measurement to the User. After each pulse train is successfully delivered, two short audible beeps are produced. The Status Bar indicates the overall progress through pulse delivery and percentage complete. The Pulses Delivered and Status columns update as each group of 10 pulses is delivered, Figure 8.7.18.

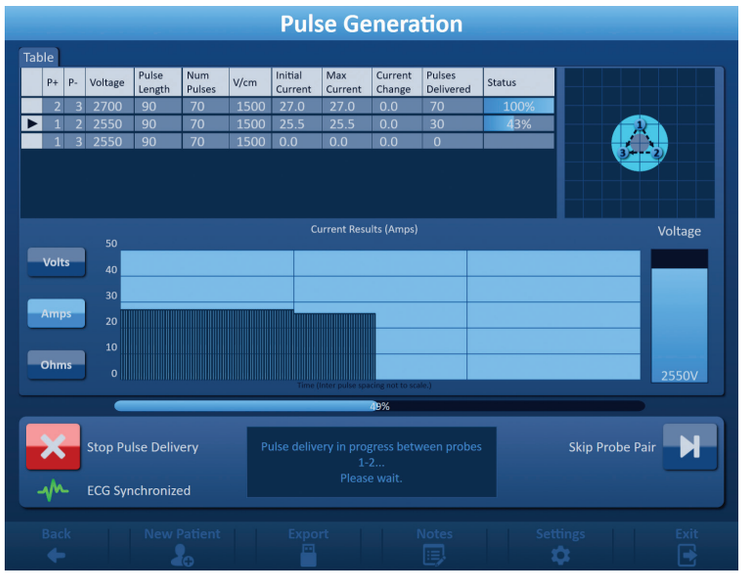



**Figure 8.7.18: Pulse Generation Screen during Pulse Delivery**

**NOTE:** If ECG Synchronization was selected and the ECG signal is Noisy or Lost during pulse delivery, the ECG Synchronization status indicator will update to reflect the status. Refer to Table 8.7.2 for list of ECG Synchronization status indicators that appear on the Pulse Delivery Control panel and their meaning. Pulse delivery will stop until the ECG Synchronization signal is restored. Refer to Section 10: for more information on ECG Synchronized Pulse Delivery.



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After the Pulse Delivery is complete, an audible double long beep is produced and the Capacitors will discharge and the message window will display text as shown below in Figure 8.7.19.

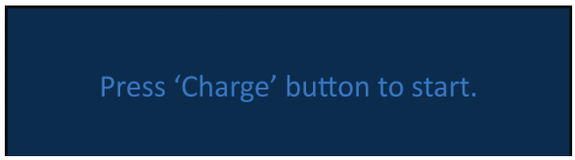



**Figure 8.7.19: Message Window when Pulse Delivery is Complete**

Refer to Sections 8.7.12, 8.7.13, and 8.7.14 for instruction on resetting the generator for additional rounds of pulse delivery.

### 8.7.6 How to Stop Pulse Delivery

At any point during pulse delivery, the User can stop pulse delivery by pressing the Stop Pulse Delivery button, Figure 8.7.20.

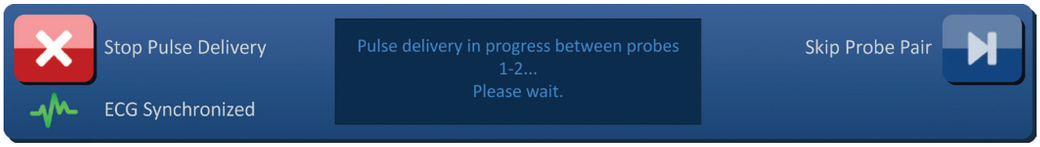



**Figure 8.7.20: Pulse Delivery Control Panel – Stop Pulse Delivery Button**

After the Pulse Delivery has stopped, the Capacitors will discharge and the message window will display text as shown below in Figure 8.7.21.

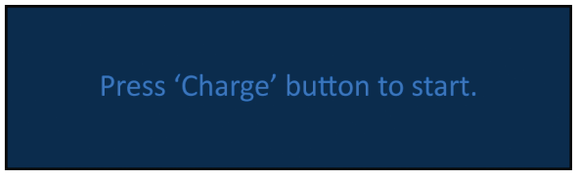



**Figure 8.7.21: Message Window after Stopping Pulse Delivery**

Refer to Section 8.7.7 for instruction on resuming pulse delivery.

### 8.7.7 How to Resume Pulse Delivery

To resume pulse delivery, click the button to display the charge options popup as shown below in Figure 8.7.22.

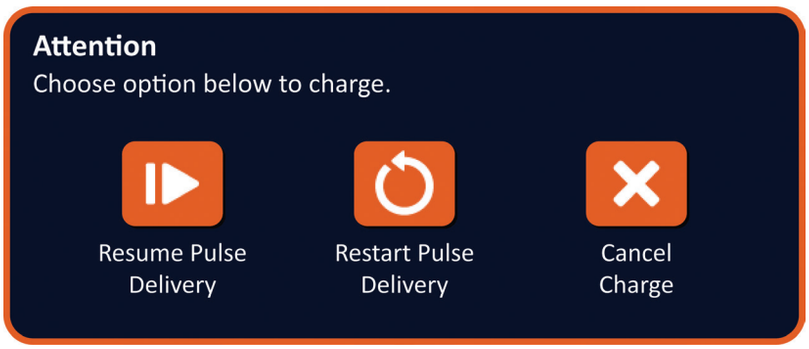



**Figure 8.7.22: Charge Options Popup – Mid Pulse Delivery**

Click the button to charge the capacitors and ready the system for pulse delivery to continue where pulse delivery was stopped. Clicking the button will restart pulse delivery. Clicking the button will close the popup and not charge the capacitors.

Refer to Section 8.7.8 for information on restarting pulse delivery.





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### 8.7.8 How to Reset Pulse Delivery Mid Pulse Delivery

To reset pulse delivery, press the Stop Pulse Delivery button to stop pulse delivery. Click the button to display the charge options popup as shown in Figure 8.7.22.

Click the button to display the Pulse Data Options popup as shown below in Figure 8.7.23.

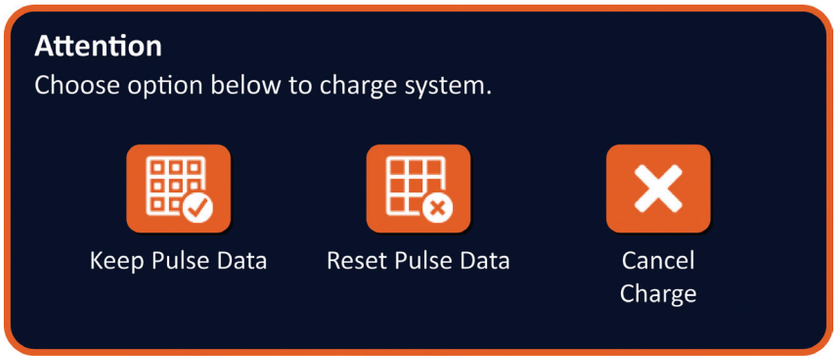



**Figure 8.7.23: Pulse Data Options Popup – Mid Pulse Delivery**

To keep the initial current, max current, current change, and pulses delivered values displayed in the Pulse Generation table, click the button to keep pulse data. The Generator will charge the capacitors for pulse delivery.

To reset the initial current, max current, current change, and pulses delivered values displayed in the Pulse Generation table, click the button to reset pulse data. A warning popup will appear, Figure 8.7.24.

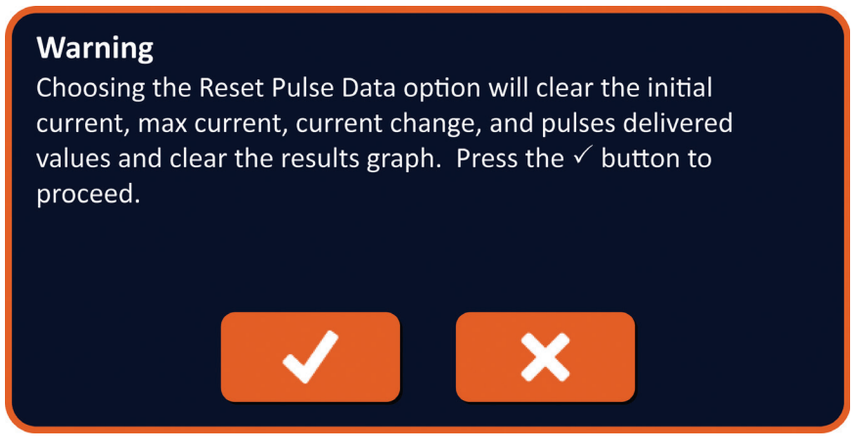



**Figure 8.7.24: Reset Pulse Data Warning Popup**

Click the ✓ button to reset the pulse data, close the warning popup, and charge the capacitors for pulse delivery. Clicking the ✗ button will not reset the pulse data, close the popup, and return to the Pulse Data Options popup, Figure 8.7.23.

### 8.7.9 How to Skip Probe Pairs during Pulse Delivery

At any point during pulse delivery, the User can skip the remaining pulses to be delivered for the Active Probe Pair by pressing the Skip Probe Pair button, Figure 8.7.25.

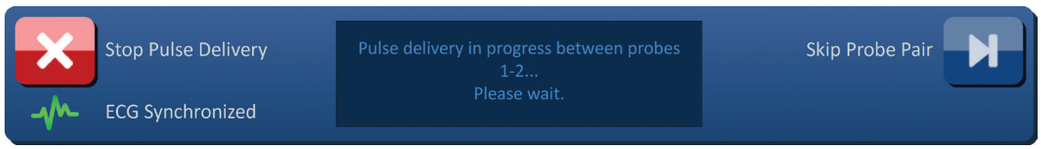



**Figure 8.7.25: Pulse Delivery Control Panel – Skip Probe Pair Button**



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After clicking the Skip Probe Pair button, the message window will display text as shown below in Figure 8.7.26.

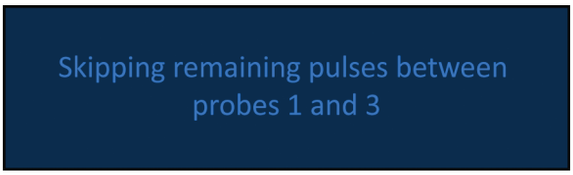



**Figure 8.7.26: Message Window after Skipping Probe Pair**

Pulse delivery will resume after approximately 5 seconds at the beginning of the next Active Probe Pair listed in the Pulse Generation Table. The Electrical Results chart will display a gap representing the skipped pulses, Figure 8.7.27.

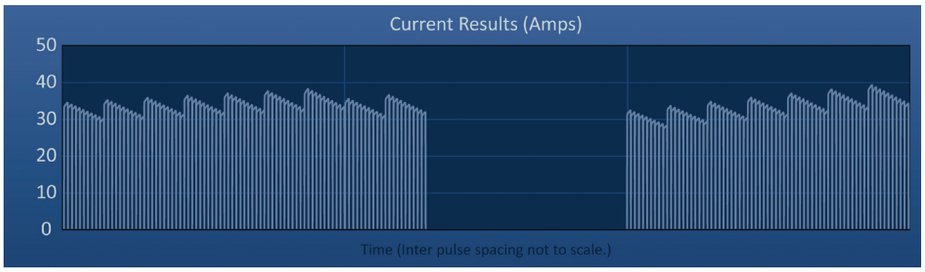



**Figure 8.7.27: Current Results Chart after Skipping Probe Pair**

The Pulses Delivered and Status columns will display the total number of pulses delivered and percentage complete, Figure 8.7.28.

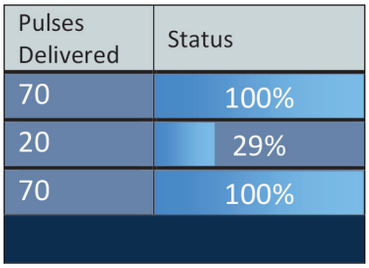



**Figure 8.7.28: Current Results Chart after Skipping Probe Pair**

**CAUTION:** If the User stops and resumes pulse delivery after previously using the skip probe pair button, the Generator will attempt to deliver pulses that have previously been skipped.

### 8.7.10 Low Current Conditions during Pulse Delivery

If the Generator detects pulses with a current measurement of less than 0.75 Amps, the Generator will prevent the remaining pulses within the same pulse train from being delivered. This is referred to as a Low Current Condition. After a short amount of time, the Generator will attempt to deliver another pulse train at the same pulse parameters. The Generator attempts to deliver all intended pulses unless the Stop Pulse Delivery button is pressed.

If low current is detected during Pulse Delivery, the message window will display text as shown below in Figure 8.7.29. Refer to Section 12, Troubleshooting for additional information regarding low current detected during pulse delivery.




**Figure 8.7.29: Message Window - Low Current Detected during Pulse Delivery**





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**CAUTION:** Use clinical judgment to Stop Pulse Delivery if multiple Low Current Conditions occur during Pulse Delivery.

**CAUTION:** All 10 pulses, within a pulse train, must be delivered over the minimum current settings to be added to the Total Pulses Delivered column. For example, if a Low Current Condition occurs during the 6th pulse delivered, the remaining 4 pulses will not be delivered and no pulses will be added to the Total Pulses Delivered column. The pulses delivered will still however be displayed in the Electrical Result Graphs.

The Electrical Results chart will display a gap representing the low current pulses, Figure 8.7.30.

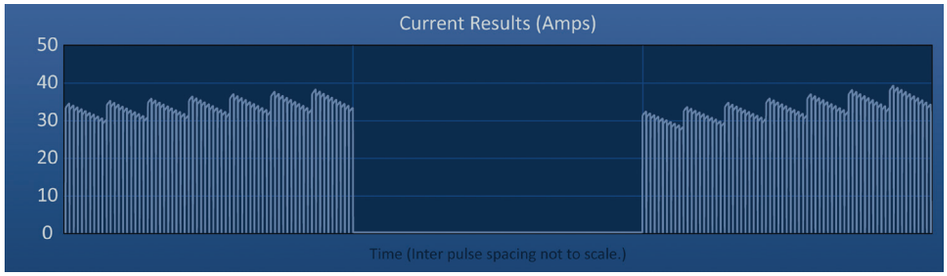



**Figure 8.7.30: Current Results Chart after Low Current Detected**

Possible causes of low current measurements include:

- Probes are disconnected from the generator
- Inter-probe spacing distances incorrectly measured
- Inter-probe spacing distances incorrectly entered into the probe placement grid
- Exposed electrodes regions are exposed to air
- Distance between probes exceeds guidelines
- Voltage too low for targeted tissue
- Insufficient exposed electrode region

Confirm probe connections, placement and pulse parameters. It is recommended to identify the cause and repeat any pulses skipped due to low current pulses. Refer to Section 12, Troubleshooting for additional information regarding low current detected during pulse delivery.

**CAUTION:** If the User chooses to resume pulse delivery after experiencing low current conditions, the Generator will attempt to delivery any pulses that were skipped due to low current.

Refer to Section 8.7.7 for instruction on resuming pulse delivery

### 8.7.11 High Current Conditions during Pulse Delivery

If the Generator detects pulses that exceed the maximum current setting, 50 Amps, the Generator will end the pulse train short and prevent the remaining pulses within the same pulse train from being delivered. This is referred to as an Over Current Condition. After a short amount of time, the Generator will attempt to deliver another pulse train at the same pulse parameters. The Generator attempts to deliver all intended pulses unless the Stop Pulse Delivery button is pressed.



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If high current is detected during Pulse Delivery, audible 4 short beeps are produced and the message window will display text as shown below in Figure 8.7.31.




**Figure 8.7.31: Message Window -
High Current Detected during Pulse Delivery**

**ATTENTION:** Use clinical judgment to Stop Pulse Delivery if multiple Over Current Conditions occur during Pulse Delivery.

**NOTE:** All 10 pulses, within a pulse train, must be delivered under the maximum current settings to be added to the Total Pulses Delivered column. For example, if an Over Current Condition occurs during the 6th pulse delivered, the remaining 4 pulses will not be delivered and no pulses will be added to the Total Pulses Delivered column. The pulses delivered will still however be displayed in the Electrical Result Graphs.

The Electrical Results chart will display a gap with an orange line drawn along the horizontal axis to represent the high current condition, Figure 8.7.32.

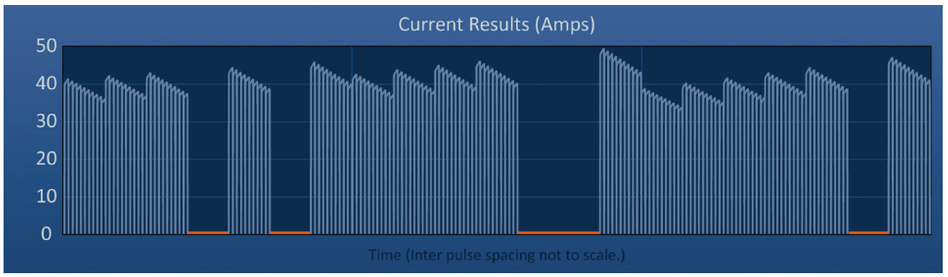



**Figure 8.7.32: Current Results Chart after High Current Detected**

Possible causes of high current conditions include:

- Probes are converging or electrode tips are touching
- Electrode exposure setting is too large for targeted tissue
- Inter-probe spacing distances incorrectly measured
- Inter-probe spacing distances incorrectly entered into the probe placement grid
- Voltage too high for targeted tissue
- Pulse length too large for targeted tissue

Confirm probe placement and pulse parameters. It is recommended to identify the cause and repeat any pulses skipped due to high current pulses. Refer to Section 12, Troubleshooting for additional information regarding high current detected during pulse delivery.

**CAUTION:** If the User chooses to resume pulse delivery after experiencing over current conditions, the Generator will attempt to deliver any pulses that skipped due to high current.

**CAUTION:** Using shorter probe exposures will significantly reduce current draw during pulse delivery. To minimize the occurrence of High Current and Over Current Conditions, use shorter probe exposures.

Refer to Section 8.7.7 for instruction on resuming pulse delivery.



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### 8.7.12 How to Deliver Additional Pulses

**ATTENTION:** Use clinical judgement to determine if additional pulses are needed.

After successfully completing pulse delivery, click the button to display the Pulse Data Options popup as shown below in Figure 8.7.33.

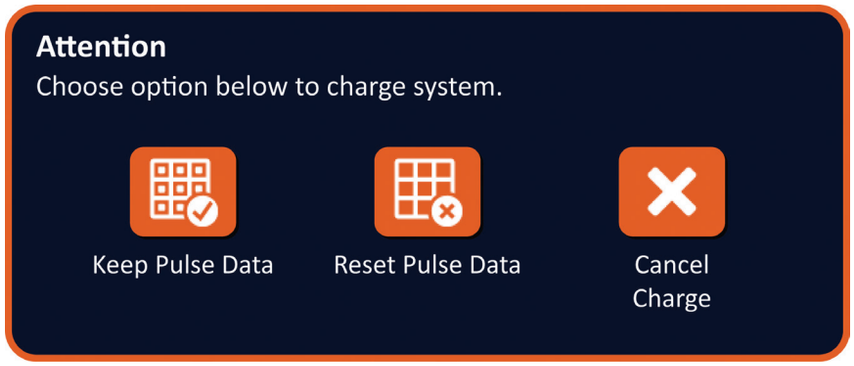



**Figure 8.7.33: Pulse Data Options Popup – After Pulse Delivery**

To keep the initial current, max current, current change, and pulses delivered values displayed in the Pulse Generation table, click the button to keep pulse data. The Generator will charge the capacitors for pulse delivery.

### 8.7.13 How to Reset Pulse Delivery for a Pullback Ablation

A pullback ablation technique, defined as sequential ablations performed after pulling back all Single Electrode Probes a set distance, may be used to ablate larger targeted ablation areas. To ensure adequate ablation overlap, the pullback distance should not exceed the probe exposure setting. For example, if each probe has a probe exposure setting of 1.5 cm, the pullback distance of each probe should be less than 1.5 cm (e.g. 1.3 cm).

After successfully completing pulse delivery at the initial probe insertion depth, pullback each NanoKnife Single Electrode the same distance using image guidance. Click the button to display the Pulse Data Options popup as shown below in Figure 8.7.34.

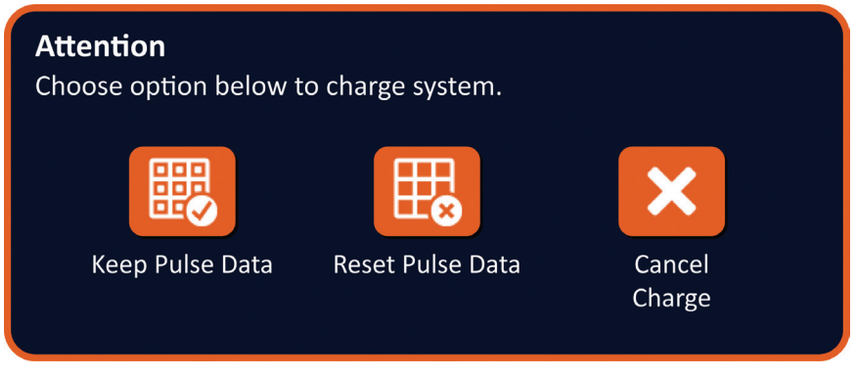



**Figure 8.7.34: Pulse Data Options Popup – After Pulse Delivery**

To reset the initial current, max current, current change, and pulses delivered values displayed in the Pulse Generation table, click the button to reset pulse data. A warning popup will appear, Figure 8.7.24.

Click the ✔ button to reset the pulse data, close the warning popup, and charge the capacitors for pulse delivery.

**NOTE:** Anytime the pulse data is reset, the conductivity test must be repeated before proceeding to pulse delivery



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### 8.7.14 How to Reset Pulse Delivery for an Overlapping Ablation

To ablate larger targeted ablation areas, an overlapping ablation technique may be used, defined as sequential ablations performed after repositioning one or more Single Electrode Probes.

**ATTENTION:** Single Electrode Probe visibility under ultrasound may be reduced after initial ablation. The hyperechoic zone seen immediately post ablation on ultrasound may impede the ability to take probe pair distance measurements after repositioning the Single Electrode Probes.

**ATTENTION:** An overlapping ablation technique using the two probe array is not recommended as an alternative to using an adequate number of Single Electrode Probes to bracket the entire target ablation area.

After successfully completing pulse delivery at the initial probe configuration, click the Back button ← on the Navigation Bar to display the Procedure Planning screen.

Reposition NanoKnife Single Electrode probes and update the probe placement plan into the Procedure Planning screen. Click the Next button → to proceed to the Pulse Generation screen. A conductivity test must be performed prior to proceeding to pulse delivery.

### 8.7.15 How to Use the Red STOP Button

The preferred method of stopping pulse delivery is to use the Stop Pulse Delivery button. Refer to Section 8.7.6 for more information on using the Stop Pulse Delivery button.

An alternative to using the Stop Pulse Delivery button is pressing the **Red STOP** button located on the front panel of the Generator as shown in Figure 3.3.1.

After pressing the **Red STOP** button, the Generator internally disconnects the energy load and automatically discharges the energy accumulated on the capacitors. The Hardware / Communication Failure popup displays, Figure 8.7.35.

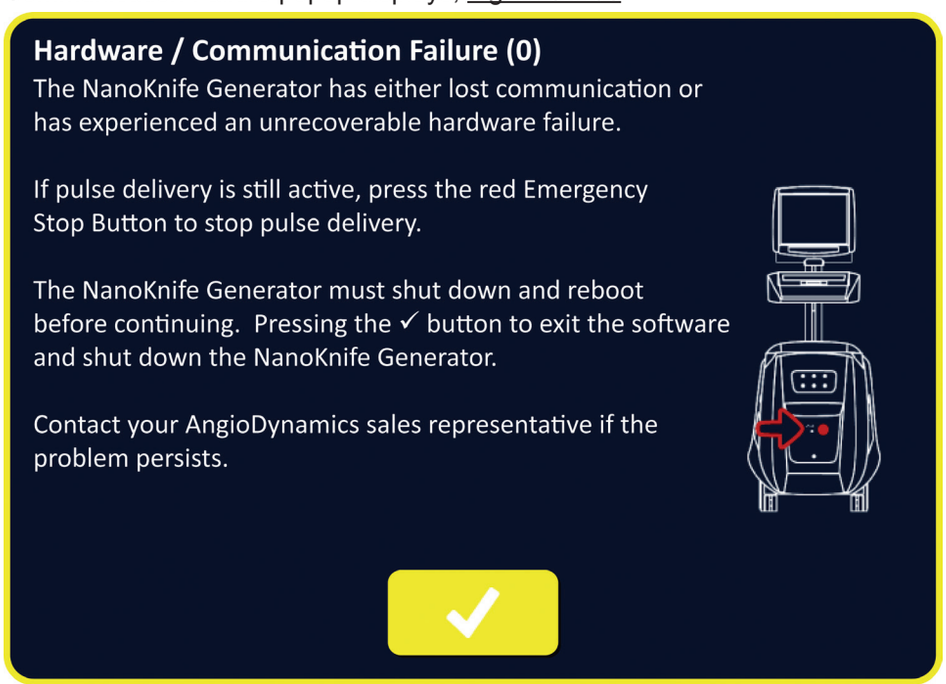



**Figure 8.7.35: Hardware / Communication Failure Popup**



AngioDynamics, Master Manual Template 8.5 in 11in, 15678511 Rev/Ver. A, Manual, Nanoknife System User Manual Ver 3.5, 16795935-21A_English

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

- Click the ✔ button to close the Hardware / Communication Failure popup, exit the NanoKnife Application, and shut down the Windows operating system.
    - After the Touchscreen LCD Display goes black, turn the mains power switch located on the back panel to the OFF position.
    - Release the **Red STOP** button, by rotating it clockwise, as the arrows on button indicate.
    - Turn the power ON at the mains power switch on the back panel of the Generator and wait for the Generator to reboot.

### 8.7.16 Storage of Pulse Parameters and Electrical Results Charts

The NanoKnife Software stores procedure information, case notes, pulse parameters and electrical results charts for each procedure completed. The procedure information can be exported to a USB storage device as a zipped folder labeled as the procedure date in “YYYY-MM-DD” format. Each zipped folder contains a PDF file and an XML file for each patient. The PDF and XML file names are comprised of procedure date in “YYYY-MM-DD” format and the ablate start time in “HH.MM-SS” in 24 hours format. The PDF file is referred to as the NanoKnife Procedure Report, Figure 8.7.36.

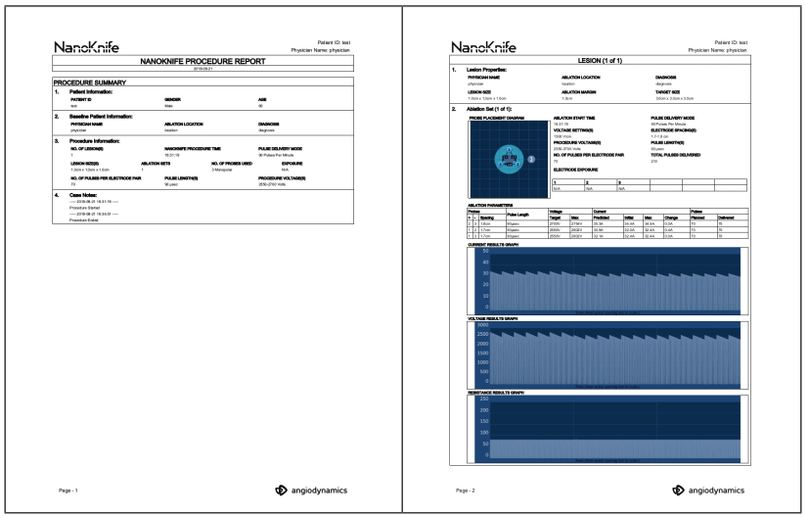



**Figure 8.7.36: NanoKnife Procedure Report PDF**

AngioDynamics, Master Manual Template 8.5 in 11in, 156T8511 Rev/Ver. A, Manual, Nanoknife System User Manual Ver 3.5, 16795935-21A_English

Each PDF file contains:

- Patient ID, Gender, Age and Diagnosis
- Physician Name
- Ablation Location
- Number of Lesions
- Lesion Size
- Ablation Sets per Lesion
- Number of Probes Used
- Electrode Spacings (inter-probe spacing distances)
- Electrode Exposures (probe exposure length)
- Pulse Lengths
- Voltage Settings
- Procedure Voltages
- Number of Pulses Per Electrode Pair
- Total Pulses Delivered
- Pulse Delivery Mode
- Ablation Start and End Times
- Number of Over Current Conditions (determined from Chart Images and Case Notes)
- Probe Placement Grid Image
- Current Results Chart Image
- Voltage Results Chart Image
- Resistance Results Chart Image
- Case Notes

In addition to the information found in the PDF file, each XML file contains:

- Detailed Voltage Measurements
- Detailed Current Measurements

**NOTE:** An XML file can be opened in commercial applications like *Microsoft Excel 2003 or newer, Open Office spreadsheet, Notepad, etc.

Refer to Section 9.1.1 for more information on how to export procedure files.



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# SECTION 9: END OF PROCEDURE

## 9.1 Export Procedure Files

Procedure files can be exported from the NanoKnife Generator using a USB storage device (e.g. USB Flash Drive) plugged into one of the USB ports located on the side of the console. Click the Export button on the Navigation Bar to display the Export dialog box.




**Figure 9.1.1: Navigation Bar – Export Button**

### 9.1.1 How to export procedure files:

Click the Export button on the Navigation Bar to display the Export dialog box, Figure 9.1.2.

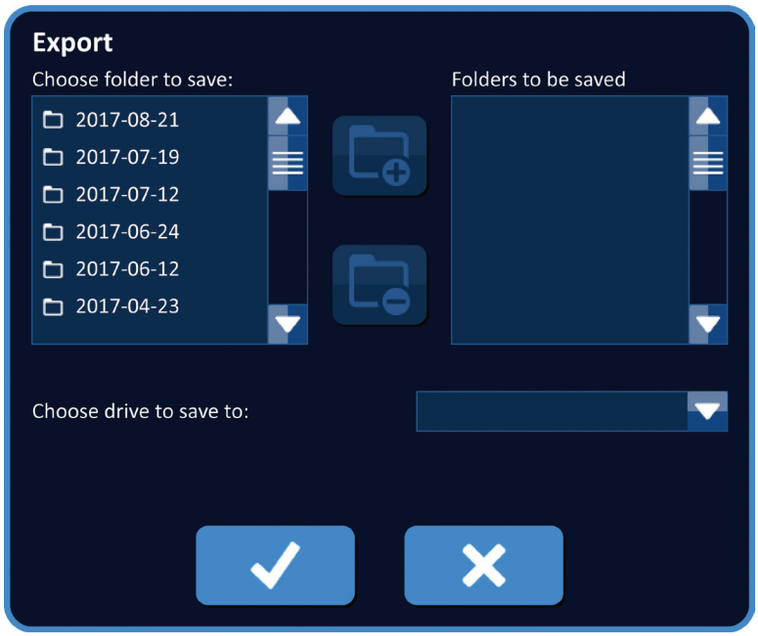



**Figure 9.1.2: Export Dialog Box**

Insert a USB storage device (e.g. USB Flash Drive) into one of the USB ports located on the side of the NanoKnife Generator console. Please wait 10 seconds for the NanoKnife Software to detect the USB Flash Drive.

If the NanoKnife Software does not automatically select the USB storage device or if multiple USB storage devices are connected to the console, click the drop down menu to select the desired USB storage device to export the procedure files to.

1. Select the folder(s) to be exported from the 'Choose folder to save' text box. The folder name correlates to the procedure date code in YYYY-MM-DD format. Each folder contains a set of procedure files for all procedures performed on that date.

2. Click the Add Folder button to add the selected folder to the 'Folders to be saved' text box, Figure 9.1.3.

AngioDynamics, Master Manual Template 8.5 in 11in, 15678511 Rev/Ver. A, Manual, Nanoknife System User Manual Ver 3.5, 16795935-21A_English

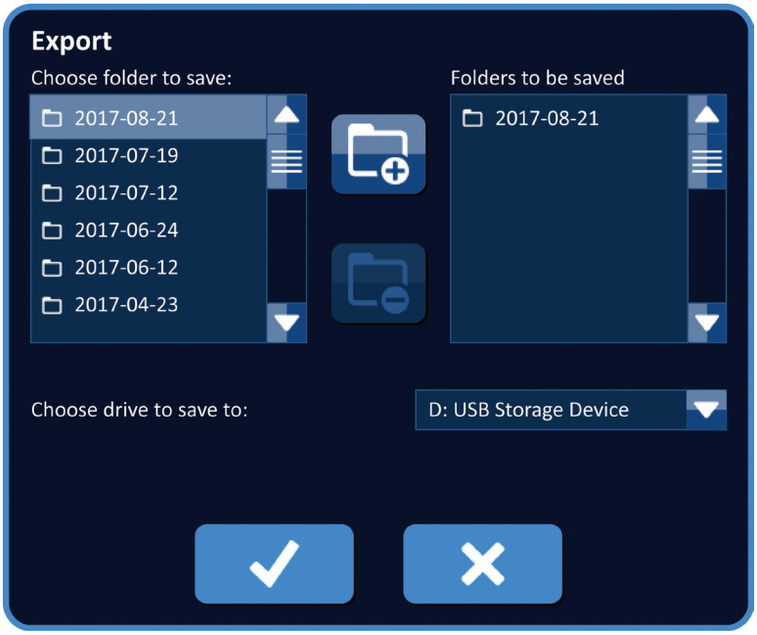



**Figure 9.1.3: Export Dialog Box – Add Folder**

3. Optional: To remove a folder from the 'Folders to be saved' text box, select the folder(s) 🗀 to be removed from the 'Folders to be saved' text box and click the Remove Folder 🗀 button.
4. Click the ✔ button to save a copy of the procedure files to the USB storage device and close the Export dialog box. Once the files have been exported, an Attention popup is displayed, Figure 9.1.4 and the USB storage device can safely be removed.

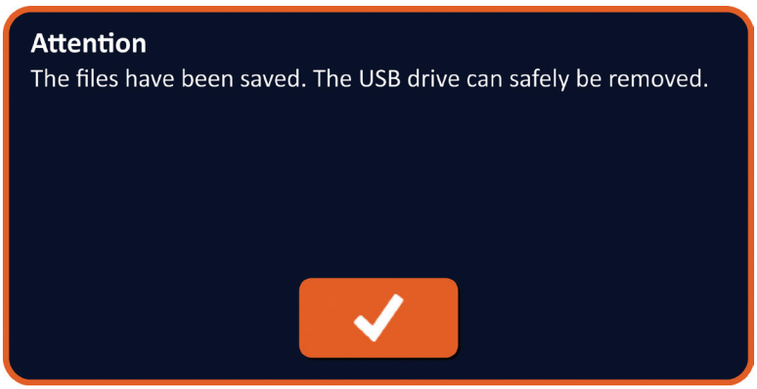



**Figure 9.1.4: Procedure Files Saved Popup**

5. Remove the USB storage device from the NanoKnife Generator.

**NOTE:** Exporting procedure files to a USB storage device does not remove the files from the NanoKnife Generator.



AngioDynamics, Master Manual Template 8.5 in 11in, 15678511 Rev/Ver. A, Manual, Nanoknife System User Manual Ver 3.5, 16795935-21A_English

## 9.2 Disconnect Electrode Probes

Disconnect each Single Electrode Probe from the NanoKnife Generator Probe Connectors by rotating and holding the Electrode Probe cable connector collar clockwise, then pull the cable connector away from the NanoKnife Generator. The Electrode Probes are single-patient-use only and should be properly discarded after each procedure.

## 9.3 Reset the NanoKnife Software for a New Patient

Click the New Patient button located on the navigation bar, Figure 9.3.1.




**Figure 9.3.1: Navigation Bar – New Patient Button**

A Warning popup will display, Figure 9.3.2.

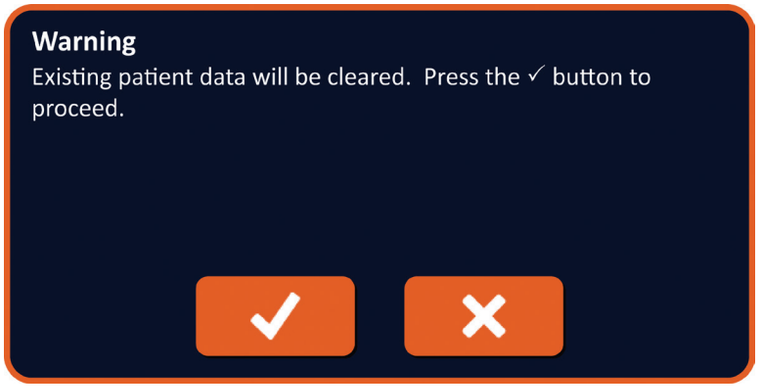



**Figure 9.3.2: Warning Popup – New Patient Button**

Click the ✓ button to clear existing patient data and return to the Procedure Setup screen. Clicking the ✗ button will close the popup and not clear patient data.

## 9.4 Shut Down the NanoKnife Generator

Click the Exit button located on either the navigation bar of the Procedure Setup or Pulse Generation screens, Figure 9.4.1.




**Figure 9.4.1: Navigation Bar – Exit Button**



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A Confirm Exit popup will display, Figure 9.4.2.

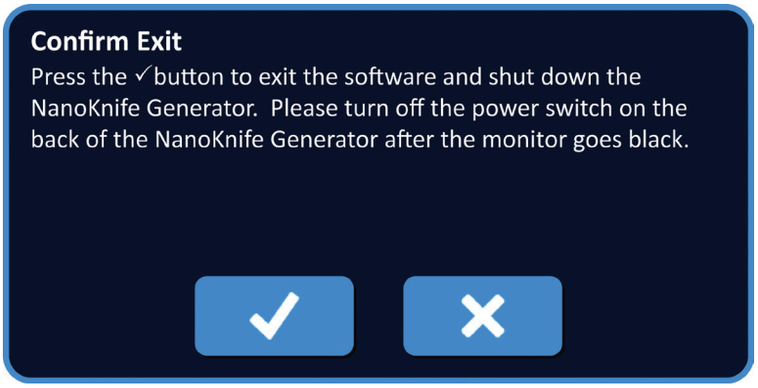



**Figure 9.4.2: Confirm Exit Popup**

Click the ✓ button on the Confirm Exit popup. Clicking the ✗ button will close the popup and not shut down the NanoKnife Generator.

When the NanoKnife Application closes, the Windows operating system will shut down. After the Touchscreen LCD Display goes black, a long beep will be produced indicating it is safe to turn the main power switch located on the back panel to the OFF position.

**ATTENTION:** Turning the main power switch to the OFF location before hearing the audible beep may damage the NanoKnife Generator.



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# SECTION 10: ECG SYNCHRONIZATION

## 10.1 Overview

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

## 10.2 External R-Wave Detector / Cardiac Gating Device

The external R-wave detector must be an IVY Model 7600 device, AngioDynamics part number 3303-30-15

- The External Sync Connector is a female BNC connector mount located on the Generator's back panel labeled with the symbol .

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

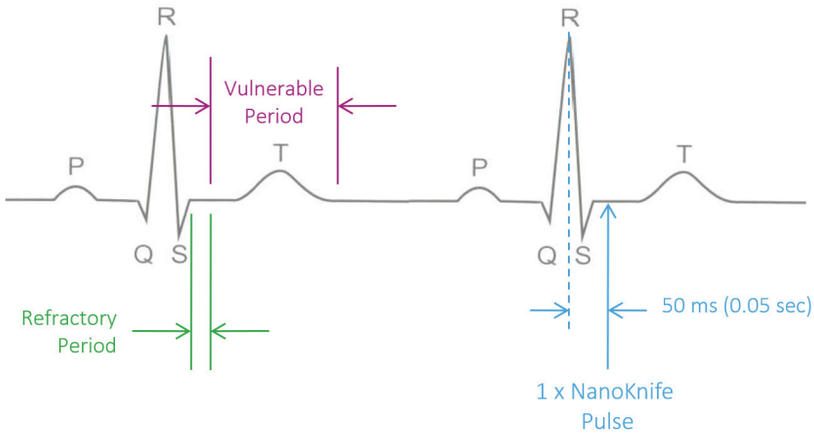



**Figure 10.2.1: ECG Synchronized Pulse Delivery**

## 10.3 ECG Synchronization

There are three conditions the ECG triggering signal may be in:

1. ECG Synchronized
2. ECG Noisy
3. ECG Lost

The last two conditions will prevent energy delivery from starting or continuing (if already started). The following sections include a short description of these three conditions for various states of the Pulse Generation screen.

## 10.4 Before the Conductivity Test

### 10.4.1 ECG Synchronized

ECG Synchronization is verified by the NanoKnife Software when the user navigates to the Pulse Generation screen. On this screen, The Pulse Delivery Control panel displays an ECG Synchronization status indicator. If the signal is within acceptable range then the ECG Synchronization status indicator will display as shown in Figure 10.4.1.

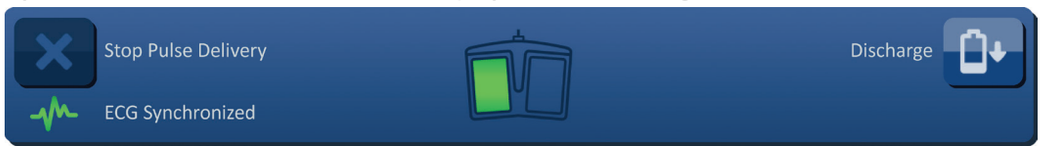



**Figure 10.4.1: ECG Synchronized before the Conductivity Test**



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### 10.4.2 ECG Lost

If the ECG signal is slow or not present, the Generator will not allow the User to start the conductivity test. A message window will appear in place of the Double Footswitch Pedal Icon. The message window will appear and display text as shown below in Figure 10.4.2.

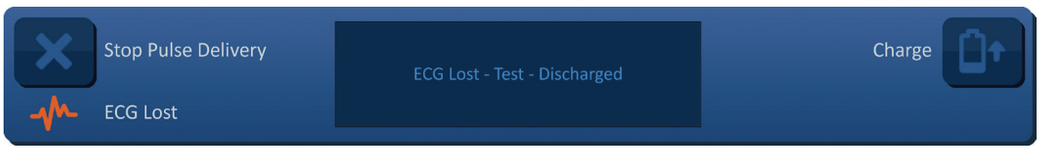



**Figure 10.4.2: ECG Lost before the Conductivity Test**

Possible Causes Of ECG Lost Include:

- ECG cable has detached from ECG Sticker Electrode.
- Cardiac gating device isn't generating a synchronization signal on R-wave.
- Cardiac gating device lead pair has low amplitude R-wave.
- ECG Sticker Electrodes have become unattached to patient.
- ECG Sticker Electrodes are in wrong location.
- Cardiac Gating Device ECG cable is disconnected
- BNC cable between Cardiac Gating Device and Generator is disconnected
- Patient heart rate is below 17 bpm (beats per minute).

### 10.4.3 ECG Noisy

If the ECG signal is too fast, the Generator will not allow the User to start the conductivity test. A message window will appear in place of the Double Footswitch Pedal Icon. The message window will appear and display text as shown below in Figure 10.4.3.

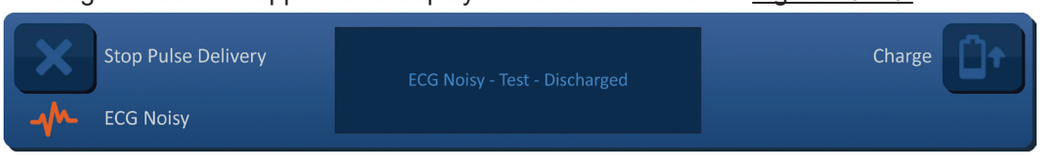



**Figure 10.4.3: ECG Noisy before the Conductivity Test**

Possible causes of ECG noisy include:

- Patient heart rate is above 120 bpm (beats per minute).
- Electrical interference displaying on Cardiac Gating Device monitor
- ECG cable crossing an electrical device wire (e.g. electrocautery device)
- Cardiac gating device generating a synchronization signal on R-wave and T-Wave.
- Cardiac gating device lead pair has high amplitude P-wave.

## 10.5 During the Conductivity Test

### 10.5.1 ECG Synchronized

If the ECG signal stays within the acceptable range during the Conductivity Test then the ECG Synchronization status indicator will display as shown in Figure 10.5.1.

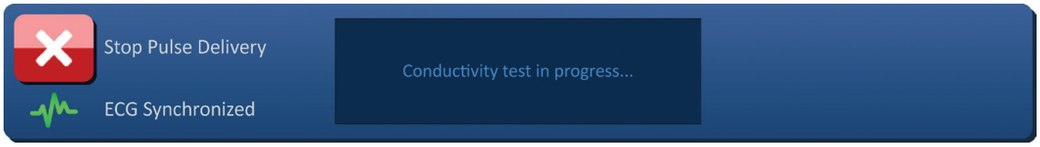



**Figure 10.5.1: ECG Synchronized during the Conductivity Test**





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### 10.5.2 ECG Lost

If the ECG signal is slow or not present during the Conductivity Test, then the Conductivity Test will stop and a 10-second countdown will begin. The message window will appear and display text as shown below in Figure 10.5.2.

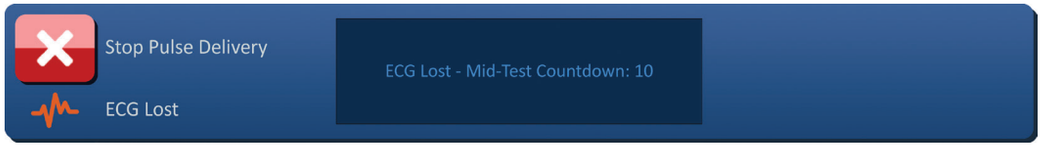



**Figure 10.5.2: ECG Lost during the Conductivity Test**

If the ECG signal is restored within the 10-second countdown, the Conductivity Test will automatically resume.

If the ECG signal is not restored during the 10-second countdown, the capacitors will discharge. After the ECG Signal has been restored, the Charge button will appear as shown in Figure 10.5.3.

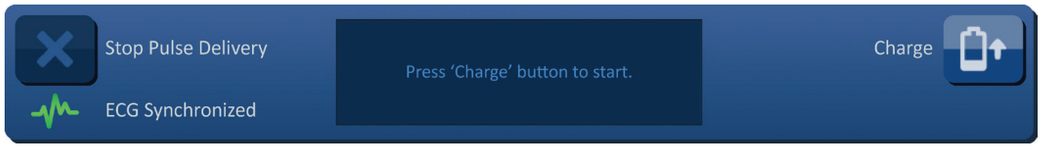



**Figure 10.5.3: ECG Signal Restored during the Conductivity Test**

Click the button to charge the capacitors to the Conductivity Test Voltage. The Generator is ready to restart the Conductivity Test. Refer to Section 8.7.1 for more instruction on Starting the Conductivity Test.

### 10.5.3 ECG Noisy

If the ECG signal is too fast during the Conductivity Test, then the Conductivity Test will stop and a 10-second countdown will begin. The message window will appear and display text as shown below in Figure 10.5.4.

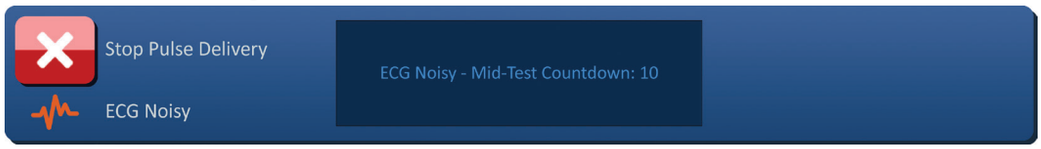



**Figure 10.5.4: ECG Signal Noisy during the Conductivity Test**

If the ECG signal is restored within the 10-second countdown, the conductivity test will automatically resume.

If the ECG signal is not restored during the 10-second countdown, the capacitors will discharge. After the ECG Signal has been restored, the Charge button will appear as shown in Figure 10.5.5

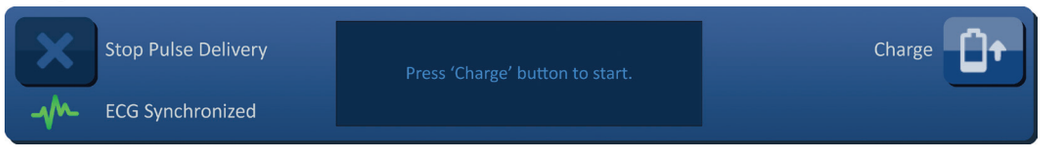



**Figure 10.5.5: ECG Signal Restored during the Conductivity Test**

Click the button to charge the capacitors to the Conductivity Test Voltage. The Generator is ready to restart the Conductivity Test. Refer to Section 8.7.1 for more instruction on Starting the Conductivity Test.

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## 10.6 During Pulse Delivery

### 10.6.1 ECG Synchronized

If the ECG signal stays within the acceptable range during Pulse Delivery then the ECG Synchronization status indicator will display as shown in Figure 10.6.1.

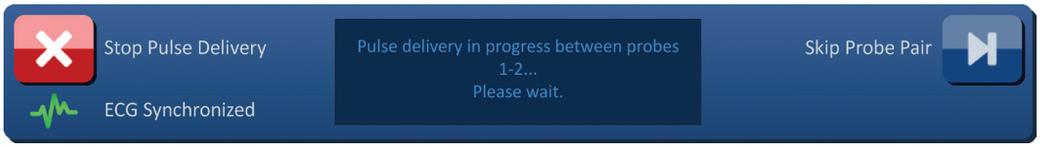



**Figure 10.6.1: ECG Synchronized during Pulse Delivery**

### 10.6.2 ECG Lost

If the ECG signal is slow or not present during Pulse Delivery, then Pulse Delivery will stop and a 10-second countdown will begin. The message window will appear and display text as shown below in Figure 10.6.2.

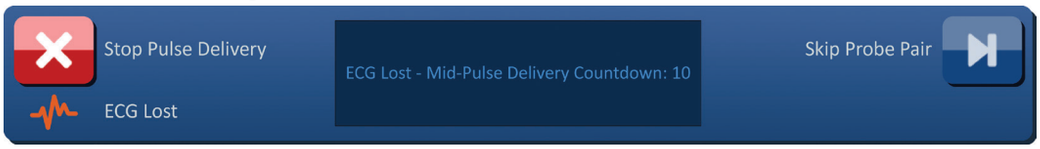



**Figure 10.6.2: ECG Lost during Pulse Delivery**

If the ECG signal is restored within the 10-second countdown, Pulse Delivery will automatically resume.

If the ECG signal is not restored during the 10-second countdown, the capacitors will discharge and the message window will display text as shown below in Figure 10.6.3.

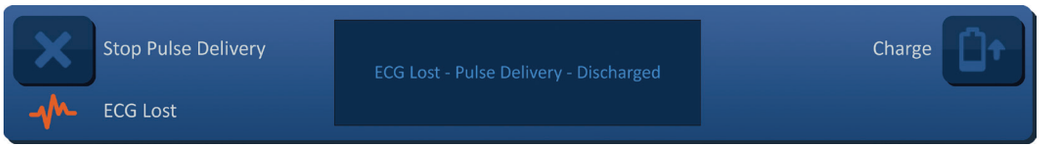



**Figure 10.6.3: ECG Lost during Pulse Delivery - Discharged**

After the ECG Signal has been restored, the Charge button will appear as shown in Figure 10.6.4.

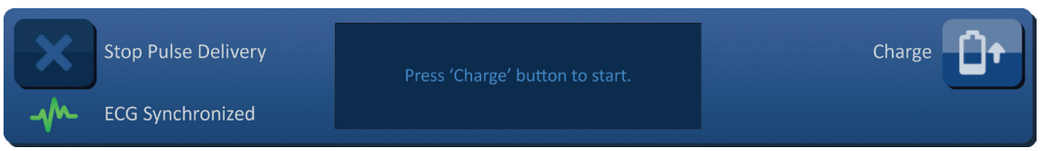



**Figure 10.6.4: ECG Signal Restored during Pulse Delivery**



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To resume pulse delivery, click the button to display the charge options popup as shown below in Figure 10.6.5.

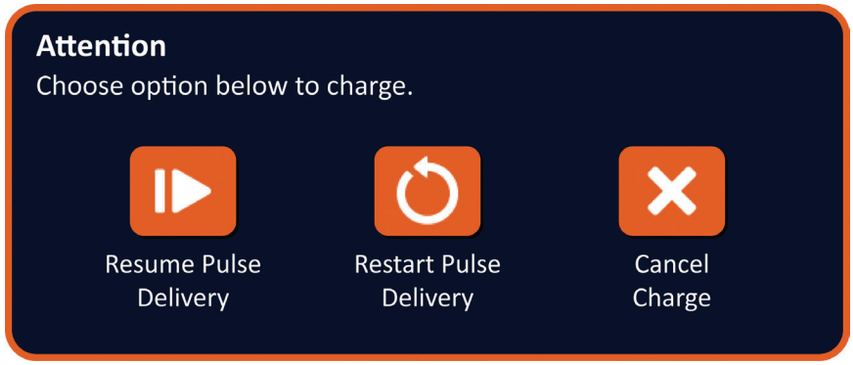



**Figure 10.6.5: Charge Options Popup – Mid Pulse Delivery**

Click the button to charge the capacitors and ready the system for pulse delivery to continue where pulse delivery was stopped. Refer to Section 8.7.7 for more instruction on Resuming Pulse Delivery.

### 10.6.3 ECG Noisy

If the ECG signal is too fast during Pulse Delivery, then Pulse Delivery will stop and a 10-second countdown will begin. The message window will appear and display text as shown below in Figure 10.6.6.

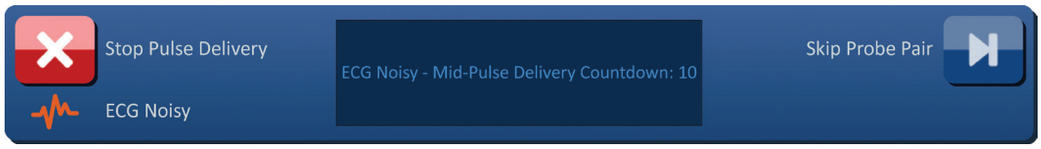



**Figure 10.6.6: ECG Noisy during Pulse Delivery**

If the ECG signal is restored within the 10-second countdown, Pulse Delivery will automatically resume.

If the ECG signal is not restored during the 10-second countdown, the capacitors will discharge and the message window will display text as shown below in Figure 10.6.7.

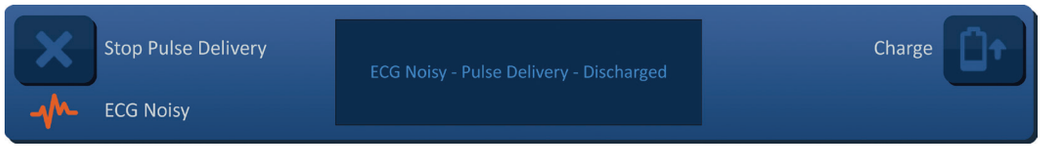



**Figure 10.6.7: ECG Noisy during Pulse Delivery - Discharged**

After the ECG Signal has been restored, the Charge button will appear as shown in Figure 10.6.8.

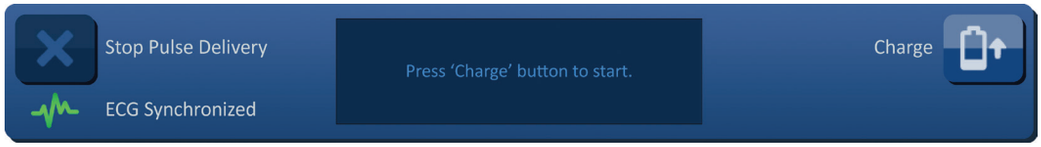



**Figure 10.6.8: ECG Signal Restored during Pulse Delivery**

To resume pulse delivery, click the button to display the charge options popup as shown below in Figure 10.6.9.

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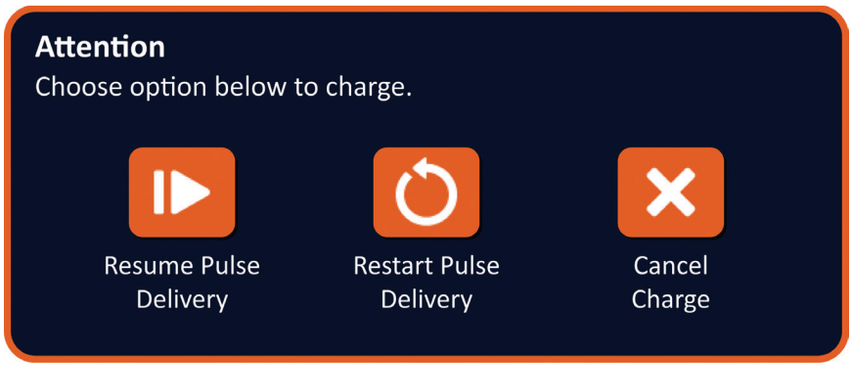



**Figure 10.6.9: Charge Options Popup – Mid Pulse Delivery**

Click the ▮▶ button to charge the capacitors and ready the system for pulse delivery to continue where pulse deliver was stopped. Refer to Section 8.7.7 for more instruction on Resuming Pulse Delivery.

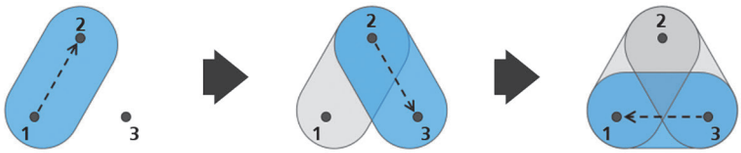


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# SECTION 11: ELECTRODE PROBES

## 11.1 NanoKnife Single Electrode Probes

NanoKnife Single Electrode Probes are monopolar, meaning they can only act as either an anode or cathode; therefore, a minimum of two NanoKnife Single Electrode Probes must be used to perform a NanoKnife procedure. NanoKnife Single Electrode Probes are placed within a target area of tissue using a bracketing approach. The NanoKnife Generator has built in pre-programmed pulse algorithms that can accommodate up to six NanoKnife Single Electrode Probes in a procedure. The number of NanoKnife Single Electrode Probes required for a procedure is dependent on the size and shape of the target area of tissue. The NanoKnife Generator is designed to only deliver energy between one electrode pair at a time. For NanoKnife procedures that involve three or more NanoKnife Single Electrode Probes, pulse delivery is segmented into sequential probe pairings, alternating polarity between each probe pairing, Figure 11.1.1.




Probe Pair 1→2 Probe Pair 2→3 Probe Pair3→1

**Figure 11.1.1: NanoKnife Procedure Using Single Electrode Probes**

During pulse delivery, the NanoKnife Generator monitors the current delivered between the active NanoKnife Single Electrode Probes. Pulse delivery is suspended if current values reach 50 amps. Active probe exposure length, pulse length, and voltage parameters may be modified to ensure pulse delivery remains within normal operating range.

In use, multiple NanoKnife Single Electrode Probes are placed around a target area of tissue such that the active electrode exposure brackets the target area, using a percutaneous, laparoscopic, or laparotomy (i.e., open surgical) approach. NanoKnife Single Electrode Probe placement is directed under image guidance via CT, fluoroscopy, or ultrasound. Once the NanoKnife Single Electrode Probes has been maneuvered into position, pulse delivery is initiated using a dual foot pedal sequence. After pulse delivery is complete, the probes are removed and the resulting target area of tissue is visualized using imaging equipment.

**CAUTION:** Monitor probe position during pulse delivery to assure that the probe depth is not changing due to tissue reaction. If necessary, pause pulse delivery and reposition probes.

The NanoKnife Single Electrode Probe for use with the NanoKnife Generator has a blue colored handle and is available in 15 cm and 25 cm lengths. A minimum of two NanoKnife Single Electrode Probes are required to complete a procedure. Depending on the size of the targeted area, up to six NanoKnife Single Electrode Probes can be used for any one procedure. Probes may be re-positioned after successful pulse delivery to cover a larger area utilizing an overlapping and/ or pullback ablation technique.

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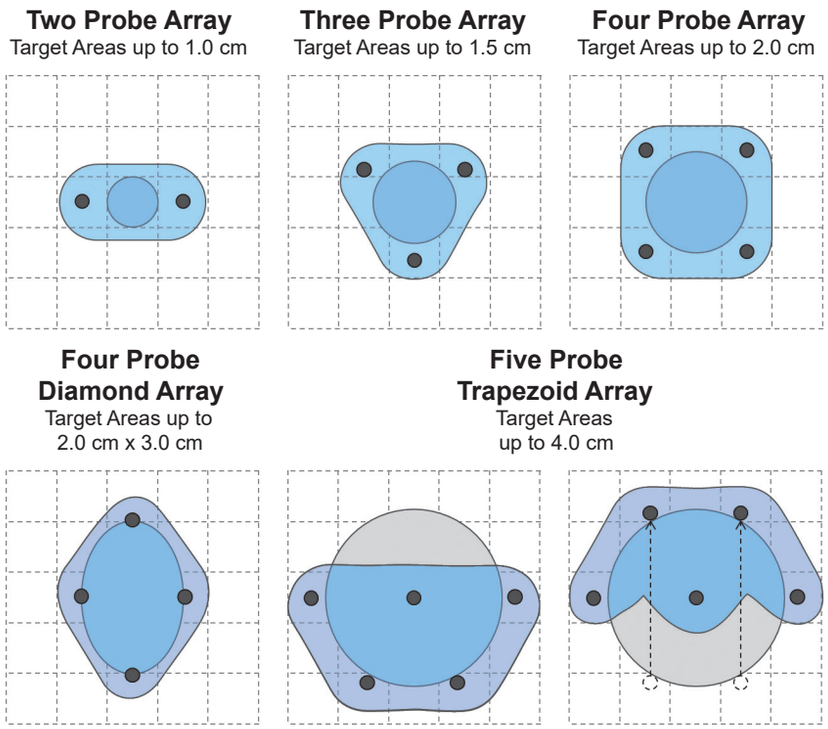



**Figure 11.1.2: NanoKnife Single Electrode Probe Configuration Examples**

The NanoKnife Generator is only to be used with Electrode Probes supplied by AngioDynamics, Inc. that are specified for use with the NanoKnife Generator, with most currently available software.



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# SECTION 12: TROUBLESHOOTING

## 12.1 Overview

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

## 12.2 Documented Problems and Solutions

**Table 12.2.1: Documented Problems and Solutions**

| **Malfunction:** Generator does not turn ON. | |
|---|---|
| **Possible Reasons** | **Actions** |
| Generator unplugged from the mains or mains outlet not powered. | Check that the mains power supply cord is connected to cord connector on the power unit back panel and that it is connected to a suitable mains outlet. (Reference Section 14.2) Check that mains outlet is powered. |
| Blown power unit main protection fuses. | Replace power unit main protection fuses. (Reference Section 13.4)<br>**ATTENTION!** Replace only with fuses with identical specifications, as indicated on the data plate. |

| **Malfunction:** Generator fails self-test. | |
|---|---|
| **Possible Reasons** | **Actions** |
| **Red STOP** button pushed in (activated). | Check that the **Red STOP** button status Indicator, on the Generator's front panel, is lit Green. If not lit, rotate the **Red STOP** button knob clockwise, as indicated on the knob to release the **Red STOP** button. Click the Proceed button, which will shut down the Generator. Restart the Generator. If the problem persists, call AngioDynamics Hardware Service. |

| **Malfunction:** Touchpad not working or not working correctly. | |
|---|---|
| **Possible Reasons** | **Actions** |
| Damaged or faulty component. | Use the touchscreen in place of the touchpad. User can temporarily use a mouse connected to the USB port, to complete procedure. In general, it is not recommended to use a mouse. Call AngioDynamics Hardware Service. |

| **Malfunction:** Cannot arm or activate conductivity test or pulse delivery. | |
|---|---|
| **Possible Reasons** | **Actions** |
| Double Pedal Footswitch not properly attached to Generator. | Check Double Pedal Footswitch cable connections. |
| The 10 seconds countdown between the pressing the Left (ARM) Footswitch Pedal and the Right (PULSE) Footswitch Pedal has expired. | Press the Left (ARM) Footswitch Pedal again to re-arm the NanoKnife Generator. Then Press the Right (PULSE) Footswitch Pedal within 10 seconds to start pulse delivery. |
| Double Pedal Footswitch is defective. | Call AngioDynamics Hardware Service. |

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| **Malfunction:** High current detected after conductivity test. | |
|---|---|
| **Possible Reasons** | **Actions** |
| Probes are converging or electrode tips are touching. | Check to ensure probes are placed parallel to one another and not converging. Reposition probes as needed. |
| Electrode Exposure Setting is too large for targeted tissue. | Decrease the probe exposure by 5mm and perform subsequent pullback ablation as needed to achieve desired ablation height. |
| Inter-probe spacing distances incorrectly measured. | Check that measurements were taken and entered correctly. |
| Inter-probe spacing distances incorrectly entered into the Probe Placement Grid. | Check that measurements were taken and entered correctly. |
| Voltage too high for targeted tissue. | Decrease the voltage setting by 100 V/cm for affected probe pair. |
| Pulse Length too large for targeted tissue. | Decrease the pulse length by 10µsec for affected probe pair.<br>**ATTENTION**: Using a pulse length below 70 µsec may result in an incomplete ablation. |
| Probes connected to wrong Electrode Probe Connectors. | Verify probes are connected to the proper Electrode Probe Connectors. |

| **Malfunction:** High current detected during pulse delivery. | |
|---|---|
| **Possible Reasons** | **Actions** |
| Electrode Exposure Setting is too large for targeted tissue. | Stop pulse delivery. Decrease the probe exposure by 5mm and perform subsequent pullback ablation as needed to achieve desired ablation height. Resume pulse delivery and complete any undelivered pulses. |
| Inter-probe spacing distances incorrectly measured | Stop pulse delivery. Check that measurements were taken and entered correctly. Resume pulse delivery and complete any undelivered pulses. |
| Inter-probe spacing distances incorrectly entered into the Probe Placement Grid | Stop pulse delivery. Check that measurements were taken and entered correctly. Resume pulse delivery and complete any undelivered pulses. |
| Voltage too high for targeted tissue. | Stop pulse delivery. Decrease the voltage setting by 100 V/cm for affected probe pair. Resume pulse delivery and complete any undelivered pulses. |
| Probes connected to wrong Electrode Probe Connectors. | Stop pulse delivery. Verify probes are connected to the proper Electrode Probe Connectors. Resume pulse delivery and complete any undelivered pulses. |



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| **Malfunction:** Loud popping noises during pulse delivery. | |
|---|---|
| **Possible Reasons** | **Actions** |
| Electrodes are not placed entirely into targeted tissue. | Stop pulse delivery. Check to ensure electrodes are placed completely into the targeted tissue and not exposed to air. Reposition probes as needed. Resume pulse delivery and complete any undelivered pulses. |
| Probes connected to wrong Electrode Probe Connectors. | Stop pulse delivery. Verify probes are connected to the proper Electrode Probe Connectors. Resume pulse delivery and complete any undelivered pulses. |
| Inter-probe spacing distances incorrectly measured | Stop pulse delivery. Check that measurements were taken and entered correctly. Resume pulse delivery and complete any undelivered pulses. |
| Inter-probe spacing distances incorrectly entered into the Probe Placement Grid | Stop pulse delivery. Check that measurements were taken and entered correctly. Resume pulse delivery and complete any undelivered pulses. |
| Voltage too high for targeted tissue. | Stop pulse delivery. Decrease the voltage setting by 100 V/cm for affected probe pair. Resume pulse delivery and complete any undelivered pulses. |

| **Malfunction:** Low current detected after conductivity test. | |
|---|---|
| **Possible Reasons** | **Actions** |
| Probes are disconnected from the Generator. | Verify probes are connected to the proper Electrode Probe Connectors. Repeat the Conductivity Test. |
| Probes connected to wrong Electrode Probe Connectors. | Verify probes are connected to the proper Electrode Probe Connectors. Repeat the Conductivity Test. |
| Inter-probe spacing distances incorrectly measured. | Check that measurements were taken and entered correctly. Repeat the Conductivity Test. |
| Inter-probe spacing distances incorrectly entered into the Probe Placement Grid. | Check that measurements were taken and entered correctly. Repeat the Conductivity Test. |
| Electrodes are not placed entirely into targeted tissue. | Check to ensure electrodes are placed completely into the targeted tissue and not exposed to air. Reposition probes as needed. Repeat the Conductivity Test. |
| Inter-probe spacing exceeds guidelines (i.e. 1.5cm – 2.0cm). | Check inter-probe spacing measurements and reposition probes as needed. Repeat the Conductivity Test. |
| Voltage too low for targeted tissue. | Increase the voltage setting by 100 V/cm for affected probe pair. Repeat the Conductivity Test. |
| Targeted tissue has low conductivity or high impedance. | Low current measurements may be expected based on the impedance of the targeted tissue. Use clinical judgement to ignore the conductivity results and proceed. |
| Electrode Exposure Setting is too small for targeted tissue. | Low current measurements may be expected based on the impedance of the targeted tissue. Use clinical judgement to ignore the conductivity results and proceed or increase the probe exposure by 5mm and Repeat the Conductivity Test. |
| Probe has bent cable connector pin. | Inspect each cable connector for a bent pin. Replace defective probe. Repeat the Conductivity Test. |

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| **Malfunction:** Low current detected during pulse delivery. | |
|---|---|
| **Possible Reasons** | **Actions** |
| Probes are disconnected from the Generator. | Stop pulse delivery. Verify probes are connected to the proper Electrode Probe Connectors. Resume pulse delivery and complete any undelivered pulses. |
| Probes connected to wrong Electrode Probe Connectors. | Stop pulse delivery. Verify probes are connected to the proper Electrode Probe Connectors. Resume pulse delivery and complete any undelivered pulses. |
| Inter-probe spacing distances incorrectly measured. | Stop pulse delivery. Check that measurements were taken and entered correctly. Resume pulse delivery and complete any undelivered pulses. |
| Inter-probe spacing distances incorrectly entered into the Probe Placement Grid. | Stop pulse delivery. Check that measurements were taken and entered correctly. Resume pulse delivery and complete any undelivered pulses. |
| Electrodes are not placed entirely into targeted tissue. | Stop pulse delivery. Check to ensure electrodes are placed completely into the targeted tissue and not exposed to air. Reposition probes as needed. Resume pulse delivery and complete any undelivered pulses. |
| Inter-probe spacing exceeds guidelines (i.e. 1.5cm – 2.0cm). | Stop pulse delivery. Check inter-probe spacing measurements and reposition probes as needed. Resume pulse delivery and complete any undelivered pulses. |
| Voltage too low for targeted tissue. | Stop pulse delivery. Increase the voltage setting by 100 V/cm for affected probe pair. Resume pulse delivery and complete any undelivered pulses. |
| Targeted tissue has low conductivity or high impedance. | Low current warnings may be expected based on the impedance of the targeted tissue. Use clinical judgement to ignore the low current warnings and continue pulse delivery. |

## 12.3 Error Messages

**Table 12.3.1: Error Messages**

| **Message:** Error: Failed to locate the NanoKnife Controller. Ensure that the Stop button is released and that the indicator is lit green. | |
|---|---|
| **Possible Reasons** | **Actions** |
| The NanoKnife Generator start-up self test has failed because the **Red STOP** button pushed in (activated). | Check that the **Red STOP** button status Indicator, on the Generator's front panel, is lit Green. If not lit, rotate the **Red STOP** button knob clockwise, as indicated on the knob to release the **Red STOP** button. Click the Proceed button, which will shut down the Generator. Restart the Generator. |
| The NanoKnife Generator start-up self test has failed because of a communication failure between the NanoKnife Software and the NanoKnife Generator Controller. | Click the Proceed button, which will shut down the Generator. Restart the Generator. |
| The NanoKnife Generator start-up self test has failed because of a damaged or faulty component. | Call AngioDynamics Hardware Service. |





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| **Message:** Error: Failed to locate RFID controller. | |
|---|---|
| **Possible Reasons** | **Actions** |
| The NanoKnife Generator was improperly powered down. | Click the Proceed button, which will shut down the Generator. Restart the Generator. |
| The NanoKnife Generator start-up self test has failed because of a damaged or faulty component. | Call AngioDynamics Hardware Service. |

| **Message:** Error: Device status test failed (#). | |
|---|---|
| **Possible Reasons** | **Actions** |
| The NanoKnife Generator was improperly powered down. | Click the Proceed button, which will shut down the Generator. Restart the Generator. |
| The NanoKnife Generator start-up self test has failed because of a damaged or faulty component. | Note the number listed in parenthesis in the title of the popup. Call AngioDynamics Hardware Service. |

| **Message:** Error: Device charge test failed. | |
|---|---|
| **Possible Reasons** | **Actions** |
| The NanoKnife Generator was improperly powered down. | Click the Proceed button, which will shut down the Generator. Restart the Generator. |
| The NanoKnife Generator start-up self test has failed because of a damaged or faulty component. | Call AngioDynamics Hardware Service. |

| **Message:** Attention: High current detected. Check probe connections and measurements. | |
|---|---|
| **Possible Reasons** | **Actions** |
| Probes are converging or electrode tips are touching. | Check to ensure probes are placed parallel to one another and not converging. Reposition probes as needed. |
| Electrode Exposure Setting is too large for targeted tissue. | Decrease the probe exposure by 5mm and perform subsequent pullback ablation as needed to achieve desired ablation height. |
| Inter-probe spacing distances incorrectly measured. | Check that measurements were taken and entered correctly. |
| Inter-probe spacing distances incorrectly entered into the Probe Placement Grid. | Check that measurements were taken and entered correctly. |
| Voltage too high for targeted tissue. | Decrease the voltage setting by 100 V/cm for affected probe pair. |
| Pulse Length too large for targeted tissue. | Decrease the pulse length by 10µsec for affected probe pair. **ATTENTION**: Using a pulse length below 70 µsec may result in an incomplete ablation. |
| Probes connected to wrong Electrode Probe Connectors. | Verify probes are connected to the proper Electrode Probe Connectors. |

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| **Message:** Attention: Low current detected. Check probe connections. | |
|---|---|
| **Possible Reasons** | **Actions** |
| Probes are disconnected from the Generator. | Verify probes are connected to the proper Electrode Probe Connectors. Repeat the Conductivity Test. |
| Probes connected to wrong Electrode Probe Connectors. | Verify probes are connected to the proper Electrode Probe Connectors. Repeat the Conductivity Test. |
| Inter-probe spacing distances incorrectly measured. | Check that measurements were taken and entered correctly. Repeat the Conductivity Test. |
| Inter-probe spacing distances incorrectly entered into the Probe Placement Grid. | Check that measurements were taken and entered correctly. Repeat the Conductivity Test. |
| Electrodes are not placed entirely into targeted tissue. | Check to ensure electrodes are placed completely into the targeted tissue and not exposed to air. Reposition probes as needed. Repeat the Conductivity Test. |
| Inter-probe spacing exceeds guidelines (i.e. 1.5cm – 2.0cm). | Check inter-probe spacing measurements and reposition probes as needed. Repeat the Conductivity Test. |
| Voltage too low for targeted tissue. | Increase the voltage setting by 100 V/cm for affected probe pair. Repeat the Conductivity Test. |
| Targeted tissue has low conductivity or high impedance. | Low current measurements may be expected based on the impedance of the targeted tissue. Use clinical judgement to ignore the conductivity results and proceed. |
| Electrode Exposure Setting is too small for targeted tissue. | Low current measurements may be expected based on the impedance of the targeted tissue. Use clinical judgement to ignore the conductivity results and proceed or to increase the probe exposure by 5mm and Repeat the Conductivity Test. |
| Probe has bent cable connector pin. | Inspect each cable connector for a bent pin. Replace defective probe. Repeat the Conductivity Test. |

| **Message:** ECG Noisy | |
|---|---|
| **Possible Reasons** | **Actions** |
| Patient heart rate is above 120 bpm (beats per minute). | The heart rate of the patient must be above 17 bpm and below 120 bpm to resume pulse delivery. Check Anesthesia monitors to confirm patient heart rate is above 120 bpm. If the heart rate displayed on the Cardiac Gating Device is inaccurate, select a different ECG lead pair. Refer to Section 5.1.2 for instruction on selecting an appropriate lead pair. |
| Electrical interference displaying on Cardiac Gating Device monitor. | Check each ECG Cable relative to other electrical device wires. Reposition other electrical device wires or turn off other electrical devices as needed. |
| ECG cable crossing an electrical device wire (e.g., electrocautery device). | Check each ECG Cable relative to other electrical device wires. Reposition other electrical device wires or turn off other electrical devices as needed. |
| Cardiac gating device generating a synchronization signal on R-wave and T-Wave. | Select a different ECG lead pair. Refer to Section 5.1.2 for instruction on selecting an appropriate lead pair. |
| Cardiac gating device lead pair has high amplitude P-wave. | Select a different ECG lead pair. Refer to Section 5.1.2 for instruction on selecting an appropriate lead pair. |





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| **Message:** ECG Lost | |
|---|---|
| **Possible Reasons** | **Actions** |
| ECG cable has detached from ECG Sticker Electrode. | Check each ECG Cable to ECG Sticker Electrode connections. Reattach the ECG Cable to the corresponding ECG Sticker electrode as needed. |
| Cardiac gating device isn't generating a synchronization signal on R-wave. | Select a different ECG lead pair. Refer to Section 5.1.2 for instruction on selecting an appropriate lead pair. |
| Cardiac gating device lead pair has low amplitude R-wave. | Select a different ECG lead pair. Refer to Section 5.1.2 for instruction on selecting an appropriate lead pair. |
| ECG Sticker Electrodes have become unattached to patient. | Check each ECG Sticker Electrode. Replace or reattach the ECG Sticker Electrode as needed. |
| ECG Sticker Electrodes are in wrong location. | Check each ECG Sticker Electrode placement. Replace or reattach the ECG Sticker Electrode in the proper placement as needed. Refer to Section 5.1.2. |
| Patient heart rate is below 17 bpm (beats per minute). | The heart rate of the patient must be above 17 bpm and below 120 bpm to resume pulse delivery. Check Anesthesia monitors to confirm patient heart rate is below 17 bpm. If the heart rate displayed on the Cardiac Gating Device is inaccurate, select a different ECG lead pair. Refer to Section 5.1.2 for instruction on selecting an appropriate lead pair. |
| Cardiac Gating Device ECG cable is disconnected. | Check connection between Cardiac Gating Device and ECG cable. Reattach cable if needed. |
| BNC cable between Cardiac Gating Device and Generator is disconnected. | Check BNC cable connection between Cardiac Gating Device and NanoKnife Generator. Ensure BNC cable is connected to the Cardiac Gating Device connector mount labeled 'Synchronized Output'. Reattach cable if needed. Refer to Section 5.1.2. |

| **Message:** Warning An error has occurred. | |
|---|---|
| **Possible Reasons** | **Actions** |
| The system detected a problem while charging or discharging the capacitors. | Click the Proceed button, which will close the popup. Click the Charge button. The NanoKnife Generator should charge the capacitors. If the system is not able to charge or discharge the capacitors, call AngioDynamics Hardware Service. |

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| **Message:** Hardware / Communication Failure (#) | |
|---|---|
| **Possible Reasons** | **Actions** |
| **Red STOP** button pushed in (activated). | Check that the **Red STOP** button status Indicator, on the Generator's front panel, is lit Green. If not lit, rotate the **Red STOP** button knob clockwise, as indicated on the knob to release the **Red STOP** button. Click the Proceed button, which will shut down the Generator. Restart the Generator. |
| Communication failure between the NanoKnife Software and the NanoKnife Generator Controller. | Click the Proceed button, which will shut down the Generator. Restart the Generator. |
| Damaged or faulty component. | Note the number listed in parenthesis in the title of the popup. Call AngioDynamics Hardware Service. |

| **Message:** Warning! Low Current detected between probes {X}-{Y} | |
|---|---|
| **Possible Reasons** | **Actions** |
| Probes are disconnected from the Generator. | Stop pulse delivery. Verify probes are connected to the proper Electrode Probe Connectors. Resume pulse delivery and complete any undelivered pulses. |
| Probes connected to wrong Electrode Probe Connectors. | Stop pulse delivery. Verify probes are connected to the proper Electrode Probe Connectors. Resume pulse delivery and complete any undelivered pulses. |
| Inter-probe spacing distances incorrectly measured. | Stop pulse delivery. Check that measurements were taken and entered correctly. Resume pulse delivery and complete any undelivered pulses. |
| Inter-probe spacing distances incorrectly entered into the Probe Placement Grid. | Stop pulse delivery. Check that measurements were taken and entered correctly. Resume pulse delivery and complete any undelivered pulses. |
| Electrodes are not placed entirely into targeted tissue. | Stop pulse delivery. Check to ensure electrodes are placed completely into the targeted tissue and not exposed to air. Reposition probes as needed. Resume pulse delivery and complete any undelivered pulses. |
| Inter-probe spacing exceeds guidelines (i.e. 1.5cm – 2.0cm). | Stop pulse delivery. Check inter-probe spacing measurements and reposition probes as needed. Resume pulse delivery and complete any undelivered pulses. |
| Voltage too low for targeted tissue. | Stop pulse delivery. Increase the voltage setting by 100 V/cm for affected probe pair. Resume pulse delivery and complete any undelivered pulses. |
| Targeted tissue has low conductivity or high impedance. | Low current warnings may be expected based on the impedance of the targeted tissue. Use clinical judgement to ignore the low current warnings and continue pulse delivery. |



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| **Message:** Warning! Pulse delivery skipped between probes {X}-{Y} due to high current. | |
|---|---|
| **Possible Reasons** | **Actions** |
| Electrode Exposure Setting is too large for targeted tissue. | Stop pulse delivery. Decrease the probe exposure by 5mm and perform subsequent pullback ablation as needed to achieve desired ablation height. Resume pulse delivery and complete any undelivered pulses. |
| Inter-probe spacing distances incorrectly measured | Stop pulse delivery. Check that measurements were taken and entered correctly. Resume pulse delivery and complete any undelivered pulses. |
| Inter-probe spacing distances incorrectly entered into the Probe Placement Grid | Stop pulse delivery. Check that measurements were taken and entered correctly. Resume pulse delivery and complete any undelivered pulses. |
| Voltage too high for targeted tissue. | Stop pulse delivery. Decrease the voltage setting by 100 V/cm for affected probe pair. Resume pulse delivery and complete any undelivered pulses. |
| Probes connected to wrong Electrode Probe Connectors. | Stop pulse delivery. Verify probes are connected to the proper Electrode Probe Connectors. Resume pulse delivery and complete any undelivered pulses. |

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# SECTION 13: MAINTENANCE & SERVICE

## 13.1 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.

For all service or maintenance support, please contact your local distributor or AngioDynamics directly:

USA
Telephone: 1-866-883-8820
Fax: 1-518-932-0660
Email: service@angiodynamics.com

## 13.2 Preventative Maintenance and Periodical Verifications

The following Table 13.2.1 indicates the recommended periodical checks and preventative maintenance.

**Table 13.2.1: Preventative Maintenance Schedule**

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

## 13.3 Cleaning

- To periodically clean the device, use a soft, lint-free cloth, dry or slightly dampened with 70% isopropyl alcohol cleaning solution.
- Do not pour water or any other liquid directly on the device.
- Do not use 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.

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## 13.4 Replacing Main Fuses

**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.

The fuses are located in the fuse-holder inside the Power Entry/Switch/Fuse Module located in the back of the Generator. See Figure 13.4.1 below.

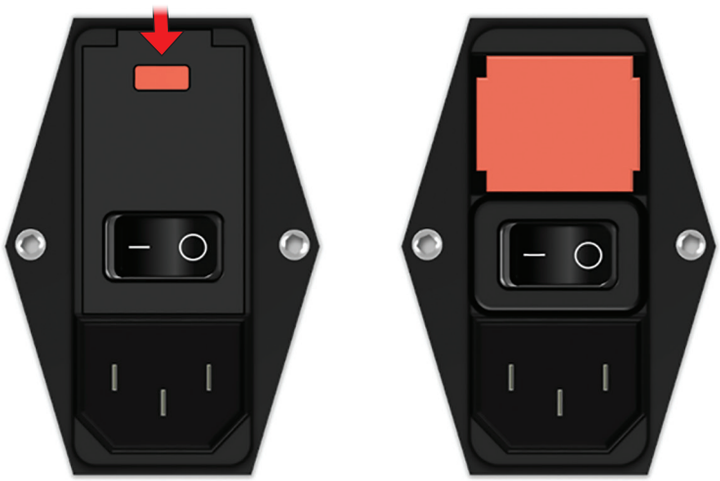


**Figure 13.4.1: Power Entry/Switch Fuse Module for Fuse Replacement**

The fuses are seated inside the red-colored fuse-holder.

To replace the main fuses, perform the following steps:

1. Make sure that the Mains power switch is on “O” position, i.e., OFF position.
2. Disconnect the Main Power Supply Cord from the Generator.
3. Open the cover of the Power Entry/Switch/Fuse Module using a flat-bladed screwdriver in the top slots to pry open the cover as illustrated in Figure 13.4.1.
4. Pull out the “Red” fuse-holder using a flat-bladed screwdriver.
5. Replace the two fuses contained in the fuse-holder with new fuses as indicated on the Device Plate Label.
6. Place the fuse-holder back into the Power Supply Group and close the cover.
7. Reconnect the main power cord.

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# SECTION 14: TECHNICAL DATA

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

## 14.1 General Information

| | |
|---|---|
| NanoKnife Generator Part Number: | H787203003510 |
| Manufacturer of NanoKnife Generator: | AngioDynamics, Inc.<br>603 Queensbury Ave.<br>Queensbury, NY 12804 USA<br><br>Toll Free (USA Only): 1-800-772-6446<br>Telephone: 1-518-798-1215<br>Fax: 1-518-798-1360 |
| Authorized European Representative | AngioDynamics Netherlands BV<br>Siriusdreef 17-27<br>Hoofddorp, 2132 WT<br>The Netherlands<br><br>Telephone: +31(0)20 753 2949<br>Fax: +31(0)20 753 2939 |

## 14.2 Power Supply Specifications

| | |
|---|---|
| Mains Voltage: | 100 to 230 VAC |
| Mains Frequency: | 50-60 Hz |
| Maximum Input Power: | 250 VA |

## 14.3 Fuse Type Specifications

| | |
|---|---|
| Electrical Description: | Time Lag 3.15A, 250V |
| Physical Description: | Axial Lead Fuse |
| Dimensions: | 5 x 20 mm |
| Other: | Meets IEC 60127-2 Sheet 5 Specification<br>RoHS Compliant |

## 14.4 Environmental Conditions

### 14.4.1 Operating Conditions

| | |
|---|---|
| Room Temperature: | 10° C to 40° C |
| Relative Humidity: | 30% to 75% |
| Atmospheric Pressure: | 70 to 106 Kpa |

### 14.4.2 Transport and Storing Conditions

| | |
|---|---|
| Temperature: | -20° C to +60° C |
| Relative Humidity: | 10% to 90% |
| Atmospheric Pressure: | 70 to 106 Kpa |

## 14.5 Classifications

### 14.5.1 EN 60601-1 Classification

Protection Against Electric Shock: Class I

CISPR 11 Class A (EMC)



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### 14.5.2 Protection Against Electric Shock

BF Applied Part

### 14.5.3 Ingress of Liquids

IPX0 – No Special Protection

Double Pedal Footswitch: IPX8

### 14.5.4 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.

### 14.5.5 Council Directive 93/42/EEC Concerning Medical Devices

Class II b

### 14.5.6 FDA Classification

Class II

### 14.5.7 Applied Parts

The NanoKnife Generator does not contain any applied parts. All applied parts are contained in the single-patient-use disposable Single Electrode Probes.

## 14.6 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.

### 14.6.1 Physical Specifications (Without Packaging)

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

Weight: 66 kg

## 14.7 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 | 90 PPM, 670 ms/3.5 s every 10th 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

## 14.8 Essential Performance

The System must deliver energy within stated voltage tolerance of ± 15% of the user requested pulse voltage.

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The System must deliver pulses of length indicated with a tolerance of ± 2 µs of the user requested pulse length.

The System must deliver square wave pulses with rise and fall times < 10 µs.

The System must not deliver pulses when the ECG Synchronization status is Noisy or Lost.

## 14.9 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.

The RFID is used to wirelessly identify and authenticate disposable NanoKnife probes. An RFID tag is integrated into each NanoKnife probe's connector. The tags contain an integrated circuit and an antenna which are used to transmit encrypted data. The information is then decoded and read by an RFID reader which stores the information collected from the tags into a database for further analysis. The RFID operates at frequency of 13.56MHz and has an operating distance range of 0.58 ± 0.15 inches (1.47 cm ± 0.38 cm).

For Quality of Service (QoS), the detection, reading, and writing of a tag at a specific antenna has 99% reliability. In the case that two tags are detected in range of the same antenna, they will be ignored until only one tag is detected.

For security, the NanoKnife System utilizes encrypted tags with secure RFID reader. The tag communications are encrypted using 128bit AES overlaying 3-DES. The File Key stored on the tag is encrypted, as is all the data stored on the tag. Likewise, the RFID reader device itself, all keys are encrypted using 128-bit AES.

The NanoKnife System may take up to 10 seconds to process. Should there be a communication issue and the system is unable to read the tag, or is not valid or recognized, the system will inform the user of the probe status, and will not allow the user to progress to the next step. The user should try to reconnect the probe to the NanoKnife Generator. If that does not work, then the user should try a new probe. If neither of these solution s work, then the user should contact customer service.

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.

## 14.10 Summary of Application Specification

### 14.10.1 Intended Medical Conditions

The NanoKnife System is intended to kill the cells within targeted regions of tissue including cancerous prostatic tissue. The targeted regions and pathologies for procedure are determined by the clinician on a patient-specific basis. The device can be inserted to deliver the therapy percutaneously, laparoscopically, or via laparotomy (open surgical approaches).

### 14.10.2 Intended Patient Population

The NanoKnife System intended patient population may include a broad range of ages, weights, race, nationality, general health, and medical conditions. Patients must be deemed candidates for general anesthesia per ASA (American Society of Anesthesiologists) or equivalent guidelines.

### 14.10.3 Intended Part of the Body

The system will be used to treat various tissues within the body. This includes organs within the peritoneal cavity and limbs, as well as other cavities and locations through the body that exhibit aberrant tissues targeted for addressing with NanoKnife.

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### 14.10.4 Intended User Profile

The users of the NanoKnife System will include surgeons, interventional radiologists, nurses, residents, radiology technicians, clinical specialists (depending on hospital guidelines), and other general clinical assistants. The primary and extended users may operate the user interface to control the NanoKnife Generator and associated peripherals, including physical procedure setup (which may include maneuvering equipment and devices, connecting electrodes, ECG connections, connecting to power supply, etc.), establishing procedure protocols, monitoring procedure progress, and stopping procedures under the supervision and direction of the primary treating physician.

### 14.10.5 Intended Conditions of Use

- Environmental Conditions: The NanoKnife System will operate in standard hospital environmental temperature, moisture, and lighting conditions. The device will operate in proximity to standard anesthetic, radiologic, and surgical operating equipment.
- Hygienic Requirements: NanoKnife System should be in clean and operable condition.
- Frequency of Use: The NanoKnife System is a multiple use device.
- Location: The NanoKnife System is intended to be used within an operating or radiological suite, depending on placement guidance method intended (open or laparoscopic placement, versus image-guided percutaneous placement).
- Mobility: The NanoKnife System may be moved between rooms within a hospital. It is to remain within the hospital, but may be transported between rooms and wards as needed for varying procedure approaches and storage.
- Identification of other devices/equipment: The NanoKnife System is intended to interact with the Monopolar NanoKnife Probes.
- Identify fluids that the device will be exposed or contact: The generator may inadvertently come into contact with water, saline, bodily fluids, and other physiologic solutions (LRS, modified Krebs solution, etc.). The System may be exposed to various cleaning solutions as well. All contact should be with the exterior of the device only.

### 14.10.6 Operating Principle

Following electrode placement and making the necessary connections to the devices outside the sterile field, the user operates the NanoKnife (NK) Generator via a graphical user interface (GUI) to input the relevant patient data for documentation. The clinician proceeds and selects the NK desired number of probe(s) option. The clinician establishes the separation distances between the probes. Following probe selection and parameter settings, the patient is administered paralytic (a.k.a. muscle blockade), and the user then proceeds to the pulse generation screen on the GUI. After confirming paralysis (a.k.a. muscle relaxation), a low-voltage test pulse (a.k.a. conductivity test) is delivered to ensure correct electrical connections and check whether there is a significant chance of arcing (a.k.a. high current warning) when using selected parameters. The NanoKnife Generator then charges to the determined voltage, is armed via foot pedal operated by the user, and is then set to deliver the therapeutic electric pulses via foot pedal operated by the user. All test and therapeutic pulses are delivered within the saturated excitation period 50 milliseconds following the R-wave, where the pulse timing relative to patient's cardiac rhythm is determined using an external accessory Cardiac Gating device. The NanoKnife System delivers the pulses according to the predetermined protocol, but can be stopped or interrupted by the user, or automatically by the system in the instance of an arc. For the Monopolar NK Probes, following high current conditions, the user may adjust the procedure parameters manually in response to the arc conditions. Following delivery of the final pulse, the NanoKnife Generator discharges and the NanoKnife Probes are removed from the targeted site. The patient is then closed according to standard clinical practice, and awoken from anesthesia.

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# SECTION 15: WARRANTY AND ELECTROMAGNETIC COMPATIBILITY

## 15.1 Warranty

The NanoKnife 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 Warranty 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.

## 15.2 Electromagnetic Compatibility

The Generator has been tested and complies with relevant directives for electromagnetic compatibility of medical equipment (IEC 60601-1-2 4th edition).

- The emissions characteristic of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this section.
- Electromagnetic interference from portable and mobile RF communications equipment, or 5G network infrastructure, can affect medical electrical equipment.

**WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NanoKnife Generator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

**WARNING:** Use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the NanoKnife Generator as replacement parts for internal components may result in increased emissions or decreased immunity of the NanoKnife Generator.

**WARNING:** The NanoKnife Generator should not be used adjacent to or stacked with other equipment not designed to be used with the NanoKnife System and that if adjacent or stacked use in necessary, the NanoKnife Generator should be observed to verify normal operation in the configuration in which it will be used. The Cardiac Gating device supplied by AngioDynamics has been tested for stacked configuration and does not impact the operation of the NanoKnife System.

- This product includes an FCC Certified loop antenna RF transmitter that operates at 13.56 MHz. The RF transmitter utilizes ASK(amplitude shift key) modulation to communicate with a close proximity device embedded into an accessory device. Maximum emissions levels were measured per FCC Part 15.225 standards and were measured to be 24.1 dB (µV/m) at the fundamental frequency, which is within the FCC limit of 84.0 dB (µV/m).

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| Test Specifications on NanoKnife System for Immunity to RF Wireless Communication Carriers | | | | | | |
|---|---|---|---|---|---|---|
| Test Frequency (MHz) | Band(a) (MHz) | Service(a) | Modulation(b) | Max Power (W) | Distance (m) | Immunity Test Level (V/m) |
| 385 | 380-390 | TETRA | Pulse(b) Modulation (18 Hz) | 1.8 | 0.3 | 27 |
| 450 | 430-470 | GMRS 460(c) FRS 460 | FM(c) ± 5KHz deviation 1KHz sine | 2 | 0.3 | 28 |
| 710 | 704-787 | LTE Band 13 17 | Pulse(b) Modulation 217 Hz | 0.2 | 0.3 | 9 |
| 745 | | | | | | |
| 780 | | | | | | |
| 810 | 800-960 | GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5 | Pulse(b) Modulation (18 Hz) | 2 | 0.3 | 28 |
| 870 | | | | | | |
| 930 | | | | | | |
| 1720 | 1700-1990 | GSM 1800 CDMA 1900 GSM 1900 DECT TE Band 1,3,4,25; UMTS | Pulse(b) Modulation (217) Hz | 2 | 0.3 | 28 |
| 1845 | | | | | | |
| 1970 | | | | | | |
| 2450 | 2400-2570 | Bluetooth\| WLAN 802.11 b/g/n RFID 2450 LTE Band 7 | Pulse(b) Modulation (217) Hz | 2 | 0.3 | 28 |
| 5240 | 5100-5800 | WLAN 802.11 a/n | Pulse(b) Modulation (217) Hz | 0.2 | 0.3 | 9 |
| 5500 | | | | | | |
| 5785 | | | | | | |
| **NOTE:** If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3. | | | | | | |
| [a] For some services, only the uplink frequencies are included.<br>[b] The carrier shall be modulated using a 50% duty cycle square wave signal.<br>[c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. | | | | | | |

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| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The **NanoKnife Generator** is intended for use in a Professional Healthcare facility electromagnetic environment specified below. The customer or the user of the **NanoKnife Generator** should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | +/-8 kV contact<br>+/-2 kV, +/-4 kV, +/-8 kV, +/-15 kV air | +/-8 kV contact<br>+/-2 kV, +/-4 kV, +/-8 kV, +/-15 kV air | |
| Electrical fast transient / burst IEC 61000-4-4 | +/-2 kV<br>100 KHz repetition frequency | +/-2 kV<br>100 KHz repetition frequency | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | +/-1 kV differential mode<br>+/-2 kV common mode | +/-1 kV differential mode<br>+/-2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | 0% *UT*; 0.5 cycles @ 0°, 45°, 90°,135°, 180°, 225°, 270°, and 315°.<br>0% *UT*; 1 cycle and 70% UT; 25/30 cycles<br>Single phase @ 0°. 0% *UT*; 250/300 cycles | 0% *UT*; 0.5 cycles @ 0°, 45°, 90°,135°, 180°, 225°, 270°, and 315°.<br>0% *UT*; 1 cycle and 70% UT; 25/30 cycles<br>Single phase @ 0°. 0% *UT*; 250/300 cycles | Mains power quality should be that of a typical commercial or hospital environment. If the user of the NanoKnife Generator requires continued operation during mains interruptions, it is recommended that the NanoKnife Generator be powered from an uninterruptible power supply or battery. |
| Power frequency (50/60 Hz) IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Proximity magnetic fields IEC 61000-4-39 | 65 A/m<br>134.2 kHz<br>7.5 A/m<br>13.56 MHz | 65 A/m<br>134.2 kHz<br>7.5 A/m<br>13.56 MHz | |
| **NOTE** *UT* is the AC mains voltage prior to application of the test level. | | | |

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| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The **NanoKnife Generator** is intended for use in an electromagnetic environment specified below. The customer or the user of the **NanoKnife Generator** should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz<br><br>6V in ISM bands between 150 kHz and 80 MHz 80% AM @ 1 kHz | 3 Vrms 150 kHz to 80 MHz<br><br>6V in ISM bands between 150 kHz and 80 MHz 80% AM @ 1 kHz | Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the **NanoKnife Generator**, including cables specified by the manufacturer.<br><br>Field strengths from fixed RF transmitters as determined by an electronic site survey, [A] should be less than the compliance level in each frequency range. [B] |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.7 GHz | 3 V/m 80 MHz to 2.7 GHz | Interference may occur in the vicinity of equipment marked with the following symbol:  |
| **NOTE 1** At 80 MHz and 800 MHz, the higher frequency range applies.<br>**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |
| **A:** Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephone and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **NanoKnife Generator** is used exceeds the applicable RF compliance level above, the **NanoKnife Generator** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **NanoKnife Generator.**<br>**B**: Over the frequency range 150 kHz to 800 MHz, field strengths should be less than 3 V/m. | | | |

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| Guidance and manufacturer's declaration – electromagnetic emissions | | |
|---|---|---|
| The **NanoKnife Generator** is intended for use in the electromagnetic environment specified below. The customer or user of the **NanoKnife Generator** should ensure it is used in such an environment. | | |
| **Emissions test** | **Compliance** | **Electromagnetic emissions – guidance** |
| RF emissions CISPR 11 | Group 1 | The **NanoKnife Generator** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class A | The **NanoKnife Generator** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations / flicker emissions IEC 61000-3-3 | Complies | |

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# SECTION 16: SYMBOLS GLOSSARY

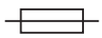
In compliance with the requirements of 21 CFR Part 801.15, below is a glossary of symbols which appear without accompanying text within the labeling of the NanoKnife Generator, the disposable probes, and other system accessories.

| Symbol | Reference Number | Title of Symbol | Meaning of Symbol |
|---|---|---|---|
|  | 5.1.1 | Manufacturer | Indicates the medical device manufacturer.[b] |
|  | 5.1.2 | Authorized representative in the European Community/ European Union | Indicates the authorized representative in the European Community/European Union.[b] |
|  | 5.1.3 | Date of manufacture | Indicates the date when the medical device was manufactured.[b] |
|  | 5.1.4 | Use-by date | Indicates the date after which the medical device is not to be used.[b] |
|  | 5.1.5 | Batch code | Indicates the manufacturer's batch code so that the batch or lot can be identified.[b] |
|  | 5.1.6 | Catalog number | Indicates the manufacturer's catalog number so that the medical device can be identified.[b] |
|  | 5.1.7 | Serial number | Indicates the manufacturer's serial number so that the medical device can be identified.[b] |
|  | 5.1.8 | Importer | Indicates the entity importing the medical device into the locale.[b] |
|  | 5.2.3 | Sterilized using ethylene oxide | Indicates the medical device has been sterilized using ethylene oxide.[b] |
|  | 5.2.6 | Do not resterilize | Indicates a medical device that is not to be resterilized.[b] |
|  | 5.2.8 | Do not use if package is damaged and consult instructions for use | Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.[b] |
|  | 5.2.11 | Single sterile barrier system | Indicates a single sterile barrier system.[b] |
|  | 5.3.1 | Fragile, handle with care | Indicates a medical device that can be broken or damaged if not handled carefully.[b] |
|  | 5.3.2 | Keep away from sunlight | Indicates a medical device that needs protection from light sources.[b] |
|  | 5.3.4 | Keep dry | Indicates a medical device that needs to be protected from moisture.[b] |
|  | 5.3.6 | Upper limit of temperature | Indicates the upper limit of temperature to which the medical device can be safely exposed.[b] |

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| Symbol | Reference Number | Title of Symbol | Meaning of Symbol |
|---|---|---|---|
|  | 5.3.7 | Temperature limit | Indicates the temperature limits to which the medical device can be safely exposed.[b] |
|  | 5.3.8 | Humidity limitation | Indicates the range of humidity to which the medical device can be safely exposed.[b] |
|  | 5.3.9 | Atmospheric pressure limitation | Indicates the range of atmospheric pressure to which the medical device can be safely exposed.[b] |
|  | 5.4.2 | Do not re-use | Indicates a medical device that is intended for one single use only, or for use on a single patient during a single procedure.[b] |
|  | 5.4.3 | Consult instructions for use or consult electronic instructions for use ifu.angiodynamics.com | Indicates the need for the user to consult the instruction for use.[b] |
| MD | 5.7.7 | Medical device | Indicates the items is a medical device.[b] |
| UDI | 5.7.10 | Unique Device Identifier | Indicates a carrier that contains unique device identifier information.[b] |
| ℞ ONLY | NA | Rx only | Caution: (US) Federal law restricts this device to sale by or on the order of a licensed practitioner.[a] |
| UPN | NA | Universal Product Number | A Universal Product Number (UPN) code represents the manufacturer's number for an item. |
|  | NA | Quantity in package | To indicate that the adjacent number reflects the number of units contained in the package. |
| CE 2797 | NA | CE Mark | Manufacturer's declaration of conformity to the Medical Device Regulation EU 2017/745.[i] |
|  | NA | Magnetic Resonance (MR) unsafe | Keep away from magnetic resonance imaging (MRI) equipment.[f] |
| | | | |

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| Symbol | Reference Number | Title of Symbol | Meaning of Symbol |
|---|---|---|---|
|  | 5.4.4<br>0434A | Caution | Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot for a variety of reasons be presented on the medical device itself.[b] |
|  | 5.4.4<br>0434B | Caution | To indicate that caution is necessary when operating the device or control close to where the symbol is placed.[c] |
|  | 6042 | Caution, risk of electric shock | To identify equipment that has risk of electric shock.[d] |
|  | NA | Follow instructions for use<br>ifu.angiodynamics.com | Refer to instruction manual.[e] |
|  | 5140 | Non-ionizing electromagnetic radiation | To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.[d] |
|  | 3079 | Open here | To identify the location where the package can be opened and to indicate the method of opening it.[c] |
|  | 5016 | Fuse | Identifies the rating of the fuses used in the equipment.[c] |
|  | 5021 | Equipotentiality | To identify the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding.[d] |
|  | 1135 | Recyclable Package | Recyclable Package.[c, k] |
|  | NA | Wheelie bin | Separate collection for Waste Electrical and Electronic Equipment (do not place in trash).[g] |
|  | NA | FCC Declaration of Conformity | Certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission.[h] |
|  | 1321A | Mass, weight | To indicate mass.[c] |
|  | 0621 | Fragile, handle with care | Contents of the distribution packages are fragile therefore it shall be handled with care.[c, j] |

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| Symbol | Reference Number | Title of Symbol | Meaning of Symbol |
|---|---|---|---|
|  | 0623 | This way up | This is the correct upright position of the distribution packages for transport and/or storage.[c, j] |
|  | 0626 | Keep dry | Distribution packages shall be kept away from rain and be kept in dry conditions. [c, j] |
|  | 0632 | Temperature limit | Distribution packages shall be stored, transported, and handled within temperature limits indicated.[c, j] |
|  | 2402 | Do not stack | Stacking of the distribution packages is not allowed and no load shall be placed on the distribution packages.[c, j] |

a. 21 CFR 801.109 - Code of Federal Regulations.
b. EN ISO 15223-1 - Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied.
c. ISO 7000 - Graphical symbols for use on equipment – Registered symbols.
d. IEC 60417 - Graphical symbols for use on equipment.
e. IEC 60601-1 Table D2, symbol 19 - Medical electrical equipment – Part 12: General requirements for basic safety and essential performance.
f. ASTM F2503-13 - Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.
g. EC Directive 2012/19/EU - Waste Electrical and Electronic Equipment Directive (WEEE Directive).
h. 47 CFR part 15 - US Code of Federal Regulations Title 47: Telecommunication PART 15—RADIO FREQUENCY DEVICES.
i. EU 2017/745 Medical Device Regulations published 5 May 2017
j. ISO 780 Distribution packaging - Graphical symbols for handling and storage of packages
k. EN ISO 14021 Environmental labels and declarations. Self-declared environmental claims (Type II environmental labeling)

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