Overview & Update

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May 3, 2011

Agenda

- What is Nanoknife?
- The system
- Peri-Operative Considerations
- Nanoknife Treatment Planning
- Software Planning
- Procedure, Tips & Tricks
- Clinical Update

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WHAT IS NANOKNIFE?

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NanoKnife® Therapy: *What is It?*

- The NanoKnife® System is indicated for the surgical ablation of soft tissue.
- An ablation procedure that uses low energy electrical pulses to create defects in cell membranes.
- Uses high voltage, but low energy direct current (LEDC) – does not rely on heat to ablate tissue.
- The process with which LEDC ablates soft tissue is known as electroporation or irreversible electroporation (IRE).
- Well-suited for patients who have non-resectable soft tissue disease near critical structures.

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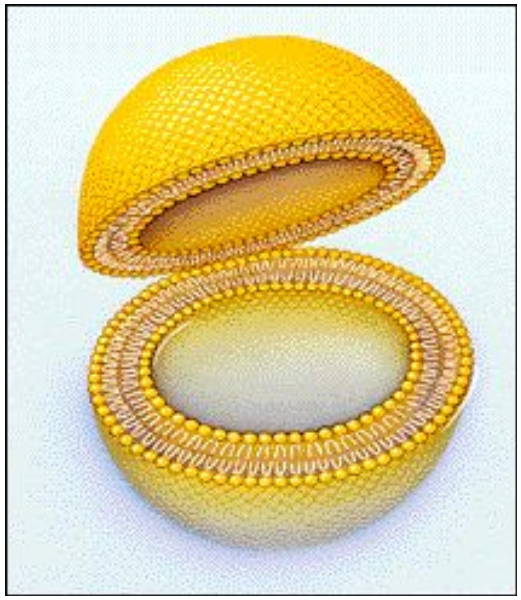
How NanoKnife® Technology Works



The function of a cell membrane is to separate the intracellular and extracellular milieu and to control the transport processes between the interior and the exterior of the cell according to the cell needs.

Electroporation is a way to increase cell membrane permeability by subjecting it to an electrical field.

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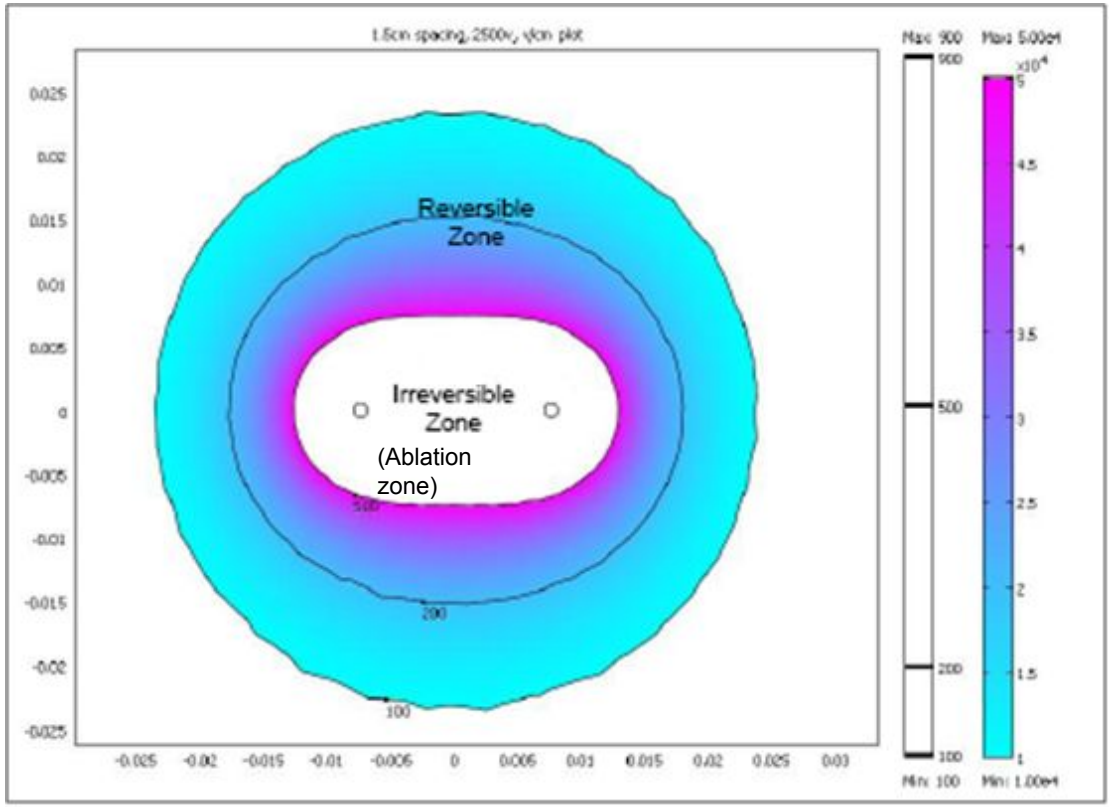
How The NanoKnife® System Works



Notes:

- *White area represents irreversible electroporation (i.e. ablation zone).*
- *Diagram developed from a mathematical model.*

- Rapid series of short, electrical pulses
- Low energy direct current (LEDC)
- High voltage, but low energy
- Does not rely on heat to ablate tissue
- Defects (“pores”) created in cell membrane
- Cell death occurs in the ablation zone

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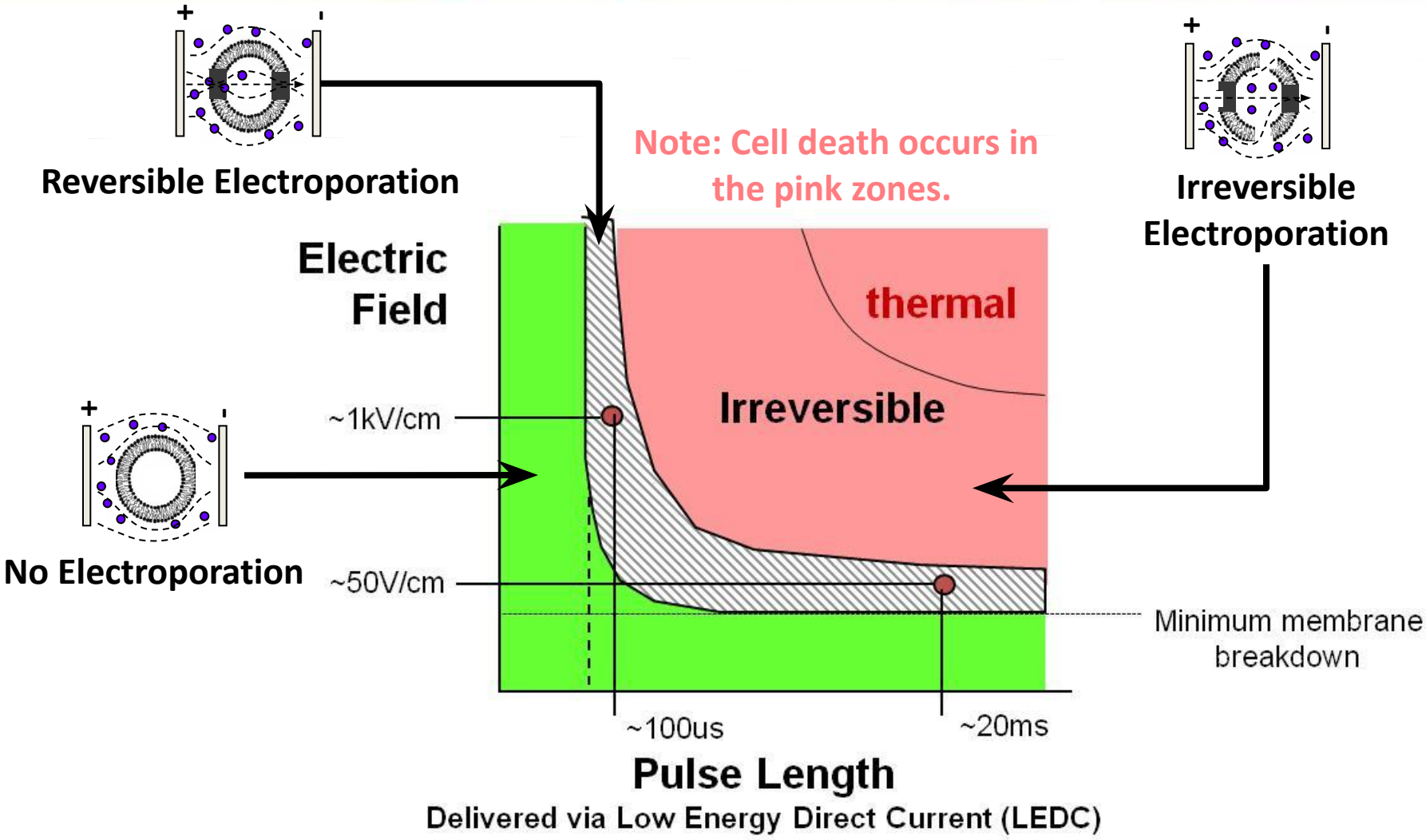
Electroporation



Dev, D. Rabussay, D. Widera, G. Hoffman, **IEEE Trans. Plasma Sci**, 2000

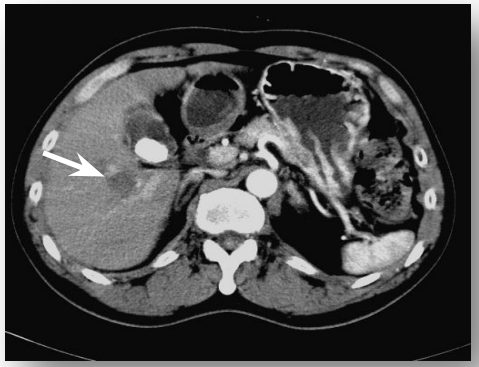
NanoKnife® System
Clinical Advantages

- **Uses high voltage, low energy electrical pulses to achieve tissue effect**
- **Does not rely on heat to ablate tissue**
- **Poses no heat sink issues**
- **Provides predictable zone of ablation**
- **Allows real-time CT/US imaging of ablated zones**
- **Provides ability to ablate soft tissue at or near critical structures (e.g., blood vessels, bile ducts, other tissues containing collagen/elastin)**
- **Provides potential to spare critical structures – *vasculature and ducts remain intact***
- **Ablated tissue removed by the body's natural processes within weeks** (mimics natural cell death)
- **Patients report experiencing minimal to no post-procedural pain**

NanoKnife® System
Clinical Advantages

Pre IRE CT scan

1 Month Follow Up



24 Hours Post Op

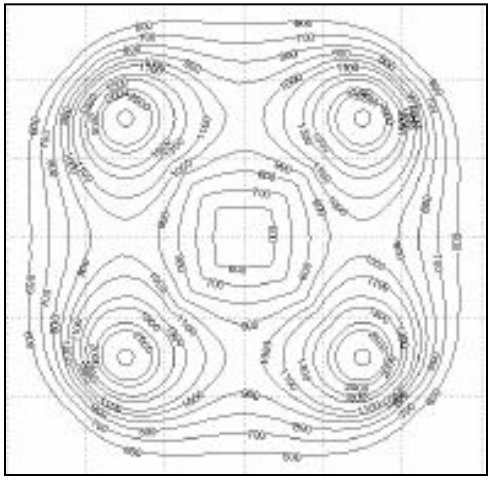
6 Months Follow Up

Images courtesy of Dr. G. Narayanan,
University of Miami – Miller School of Medicine

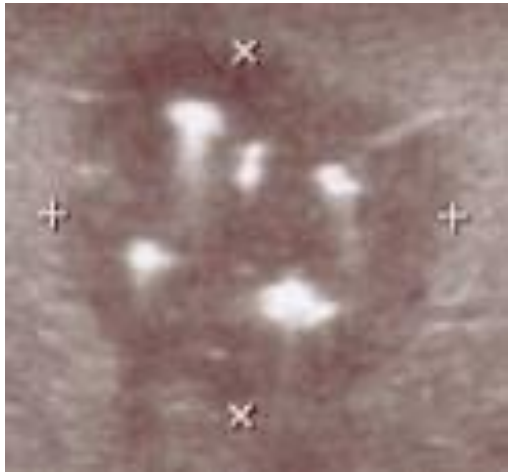
Predictable Zone of Ablation

NanoKnife lends itself very well to ablation planning

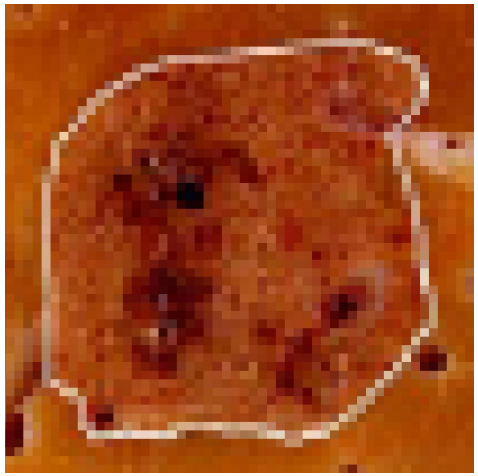
The mathematical model calculates the programmed ablation zone which correlates to the hypo echoic image immediately post-ablation and to gross pathology.



Mathematical model of ablation zone



Ultrasound post-ablation



Gross pathology of ablation

Image Source: B Rubinsky et al, Technology in Cancer Research and Treatment, 2007

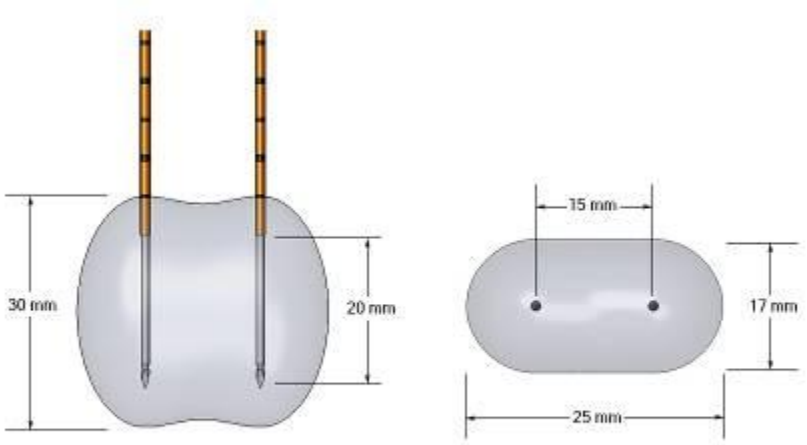
Predictable and Reproducible Ablation

1.5cm Probe Spacing

Two Electrodes, 15 mm space, 2500 volt

Generator Settings:

Probe +	Probe -	Voltage	Pulse Length	N. Pulses
1	2	2500	100	90



1.6cm by 2.6cm

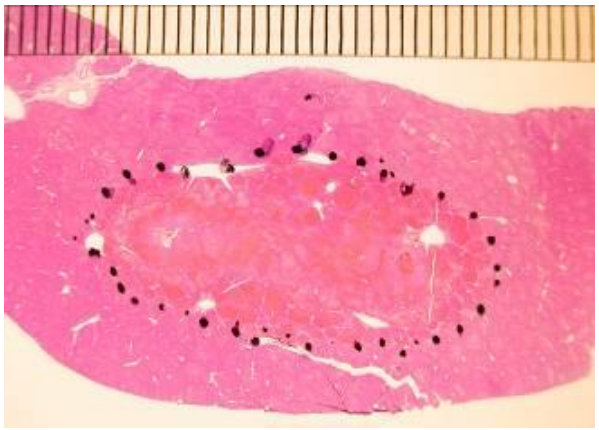


Image Source: AngioDynamics pre-clinical research porcine liver post-ablation.

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Visualized Under Ultrasound

Immediately Post-Ablation

Image Source: AngioDynamics pre-clinical research porcine liver post-ablation.

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THE NANOKNIFE SYSTEM

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NanoKnife® System

- FDA 510(k) clearance for the **surgical ablation of soft tissue.**
  - It has not received clearance for the therapy or treatment of any specific disease or condition.
- The NanoKnife System consists of the generator (pictured at right), footswitch, power cord, and a line of single-use disposable electrodes. System has:
  - Up to 6 outputs with programmable, automatic switching between each output.
  - USB port to download patient data.
- System also carries the CE mark.

NanoKnife® System: the electrodes

Monopolar Electrode

- **Single Electrode**
- **Disposable**
- **15 cm length**
- **25 cm length**
  - In the event insufflation is used
  - Obese patients

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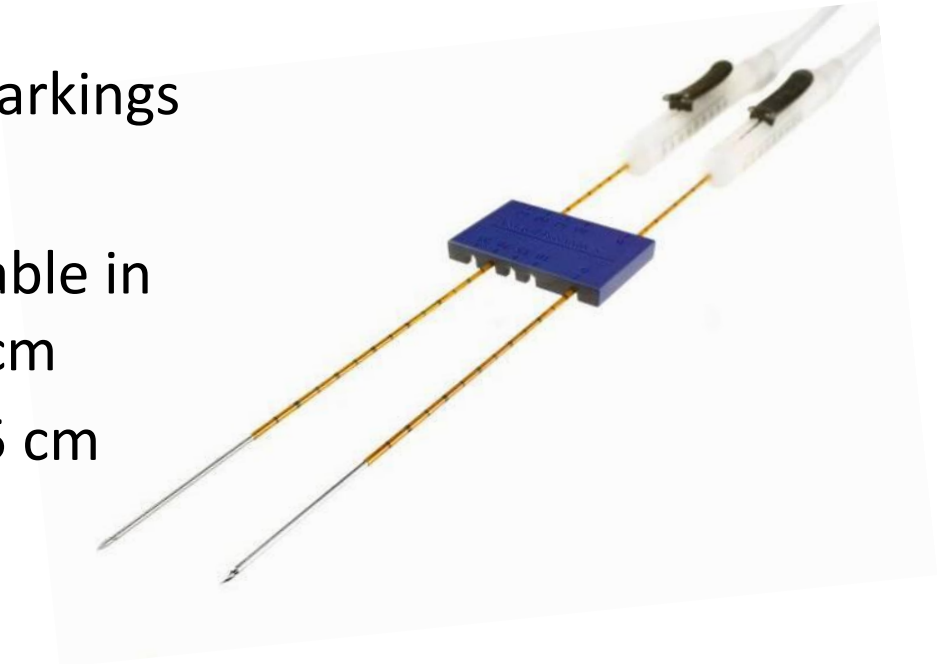
NanoKnife® System

Monopolar Electrode

Key Features

- 19 gauge needle with depth markings
- Echogenic needle surface
- Active electrode length adjustable in 0.5 cm increments from 0 – 4 cm
- Maximum insertion depth – 15 cm
- 8 foot connection cable



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Activation Probe

Figure 1: Probe configurations

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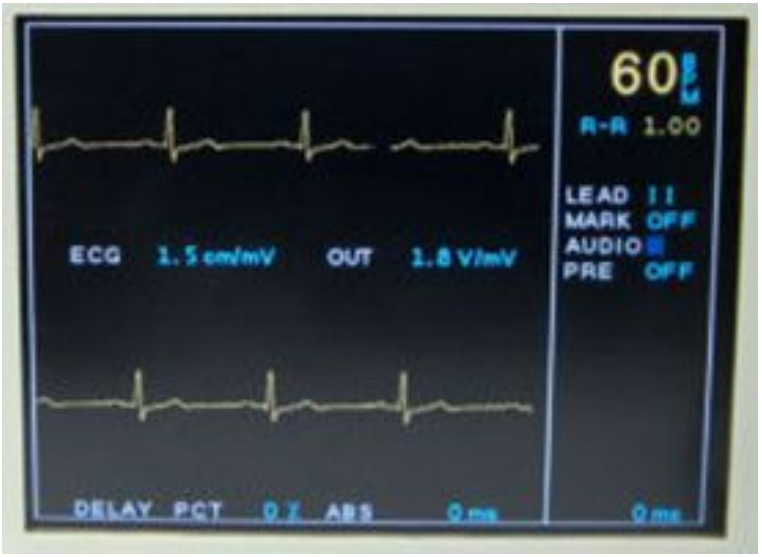
NanoKnife® System: Accusync

- External synchronization device.
- The *ECG Trigger Monitor* automatically detects the R Wave (when energy is delivered) with precision and reliability per its manufacturer.
- A synchronization system that is compatible with NanoKnife is provided with each generator.



Energy Delivery

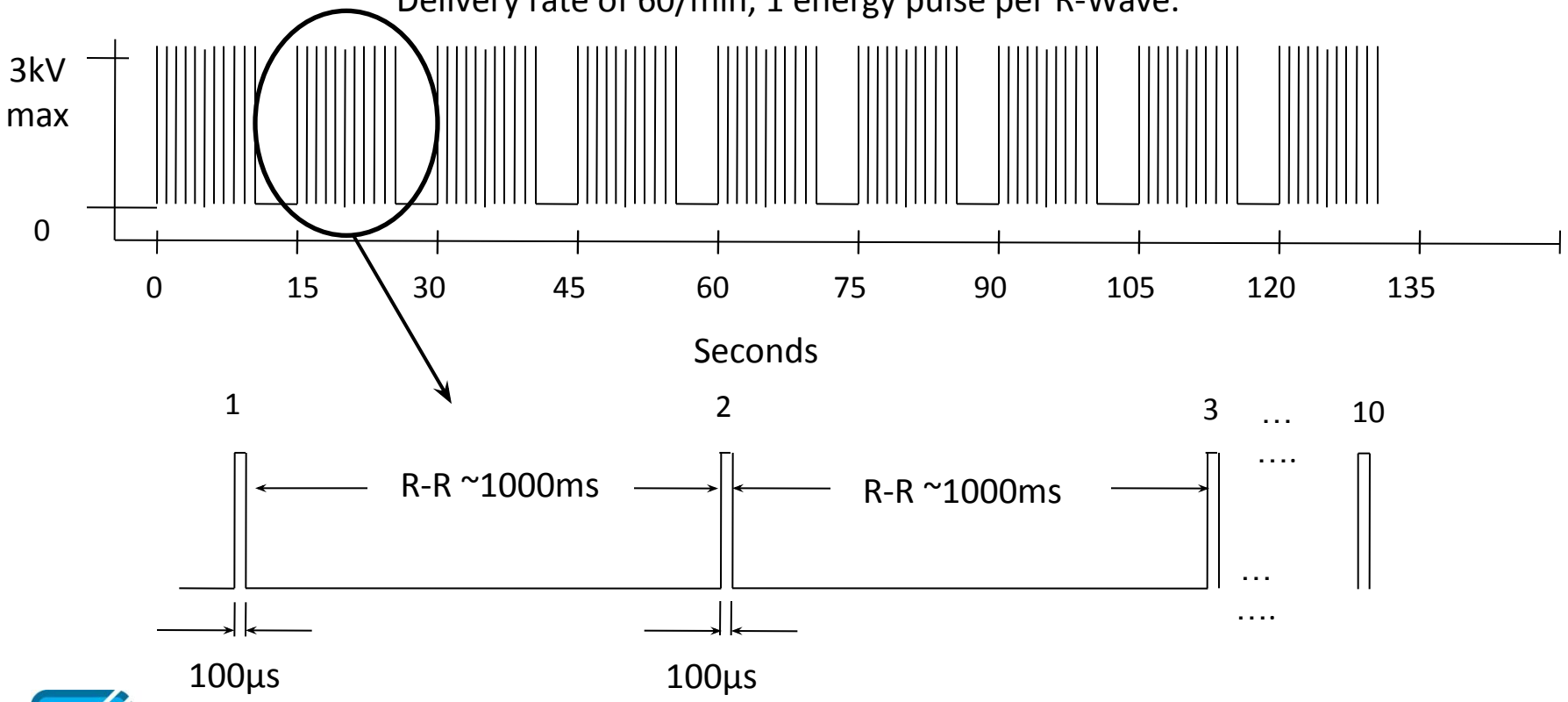
Synchronized (assume HR=60BPM)

90 pulses per ablation sequence – delivered in trains of 10 pulses.

100µS per pulse, ~1000 ms between pulses, 3500ms between trains.

Pulse amplitudes up to 3 kV @ 50 Amperes.

Delivery rate of 60/min, 1 energy pulse per R-Wave.



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Why NanoKnife® Therapy?

- ***Differentiate your institution from competing hospitals***
- ***On the cutting edge of defining new treatments and applications to expand patient care***
  - Yet another reason why patients should come to your hospital
  - Leading efforts to integrate the NanoKnife procedure into clinical practice
  - Early adopter – will have more experience than others
  - Opportunity to speak and publish on the NanoKnife procedure – will continue to build the institution's reputation
- ***Market leadership in NanoKnife therapy to referral and patient communities***
  - Drive patient referrals to your institution
  - Patients seek out physicians who are published, speak, and have the most experience with a particular therapy/procedure

University of Louisville

PERI-OPERATIVE CONSIDERATIONS

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Objectives

- NanoKnife Components
- Room Set Up
- Patient Set Up
- Anesthesia Considerations
- Treatment Planning
- Procedural Overview

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NanoKnife® System

- NanoKnife System consists of the

Generator

Monopolar Electrodes

AccuSync 72 Trigger Monitor

NANOKNIFE ROOM PREPARATION

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Room Preparation

- General anesthesia cart
  - All monitoring & resuscitation equipment required for general anesthesia per ASA guidelines
  - This includes defibrillator
- NanoKnife generator & electrodes
  - Position generator for optimal access to patient and visibility of monitor to physician
- AccuSync system in place – hand leads to anesthesia
- For O.R. - Confirm availability of sterile ultra sound transducer

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Patient Set up

- Position patient for optimal access
  - Consider type of access; percutaneous, laparoscopic, open
  - Consider gantry clearance
  - Supine, prone, head first/feet first into gantry, etc
- Place AccuSync leads *before* draping
  - Confirm R trigger indicators, compatible HR
  - Compare to anesthesia's ECG monitor
- Defib pads recommended

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Patient Set Up (Cont'd)

- Physician to discuss with anesthesiologist
  - Muscle blockade required during energy delivery
  - Alert anesthesia 10 min before test pulse
  - 0 to 1 twitches is optimal
  - High energy pulses will interfere with ECG monitor
  - BP and HR can be monitored during pulse generation by fast pulse oximeter or arterial line
- Consider Foley – initial cases may last ≥ 3 hours

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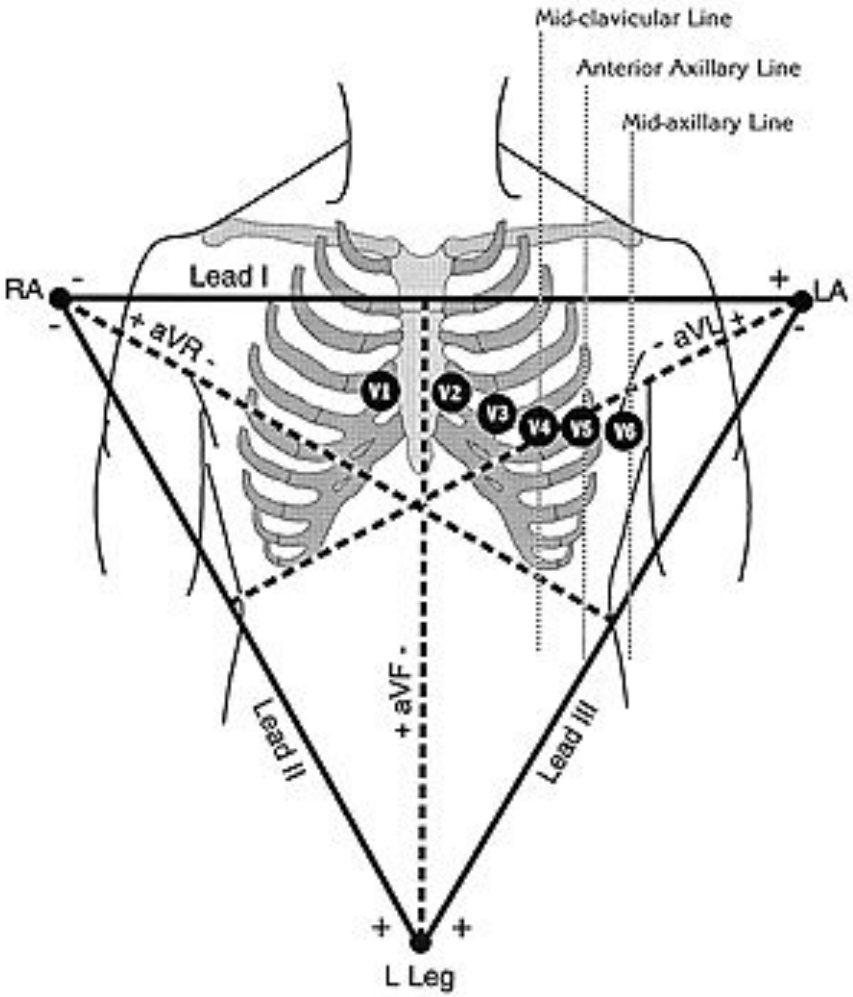
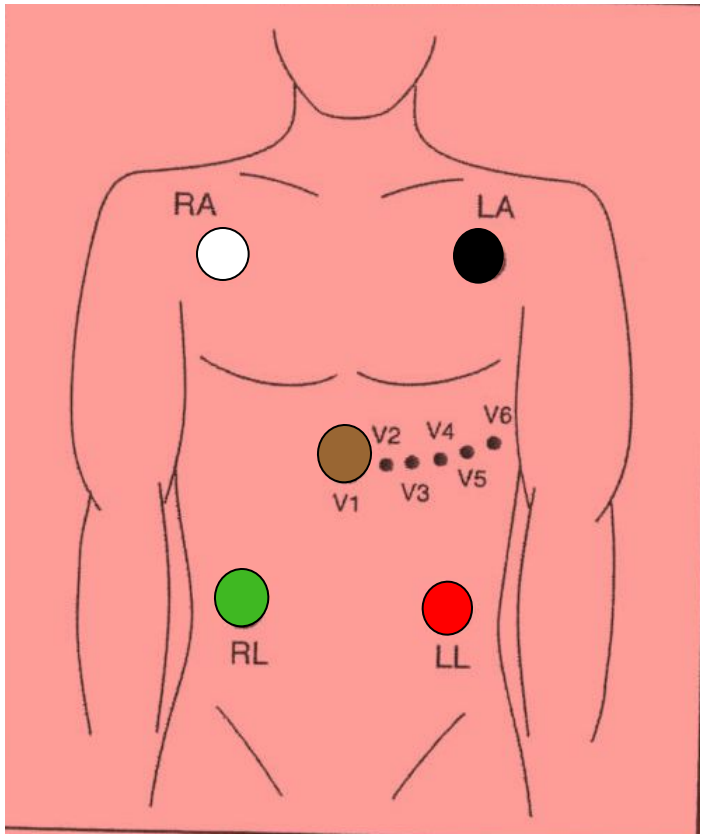
ECG Sync Device – Patient Lead Set Up





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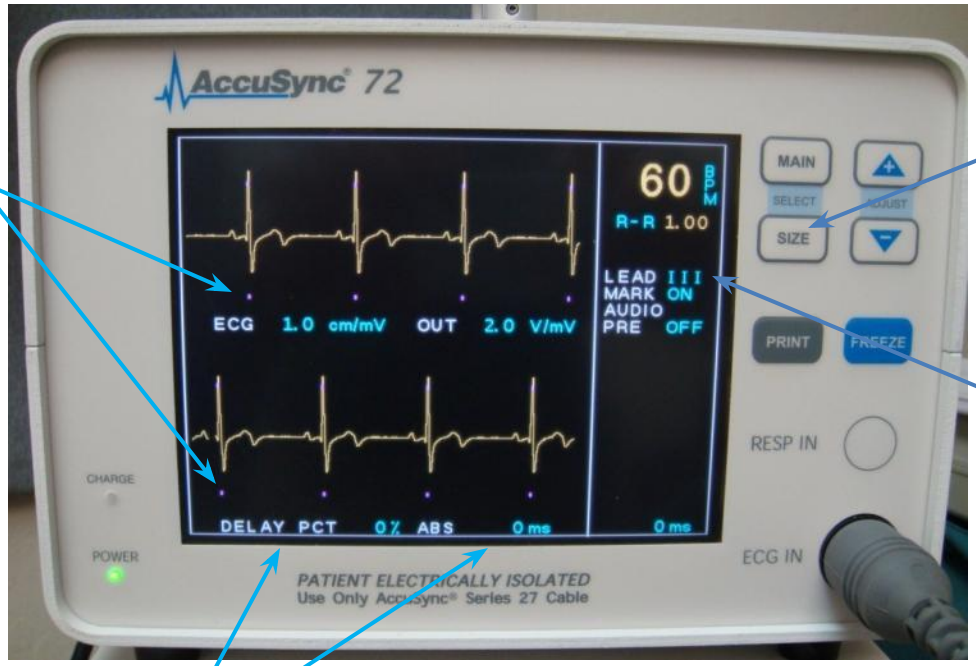
AccuSync Set Up

Pink dots indicate R-wave output.



Hold “Size” button for 3 sec to get filter menu.

Lead III is selected in this example

Set delay to zero.

Connect BNC cable to BOTTOM jack labeled “R-Trig”

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PROCEDURAL OVERVIEW

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Procedure Steps – Part I

- Set-up AccuSync - select best lead vector
- Determine lesion size and location
- Determine number of electrodes and configuration
- Number the electrodes (1-6) *sterile marker, labels
- Determine and set electrode exposure
- Probes are placed under image guidance (CT/US)
- Confirm electrode spacing measurements

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Procedure Steps – Part II

- Update treatment planning software with actual inter-probe measurements
  - Re-position & Re-measure electrodes as needed
- Connect numbered electrodes to numbered generator outputs
- Review treatment parameters to ensure accuracy
  - Very important! Especially if changing the pre-set electrode numbering schema
- Confirm 0 to 1 twitches
- Physician delivers IRE energy
- Monitor AccuSync display
- Following completion of the procedure, review Pulse Generation Treatment Parameters and Results Graph

SOFTWARE PLANNING

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Getting Started

- Confirm the updated software is in place during start up

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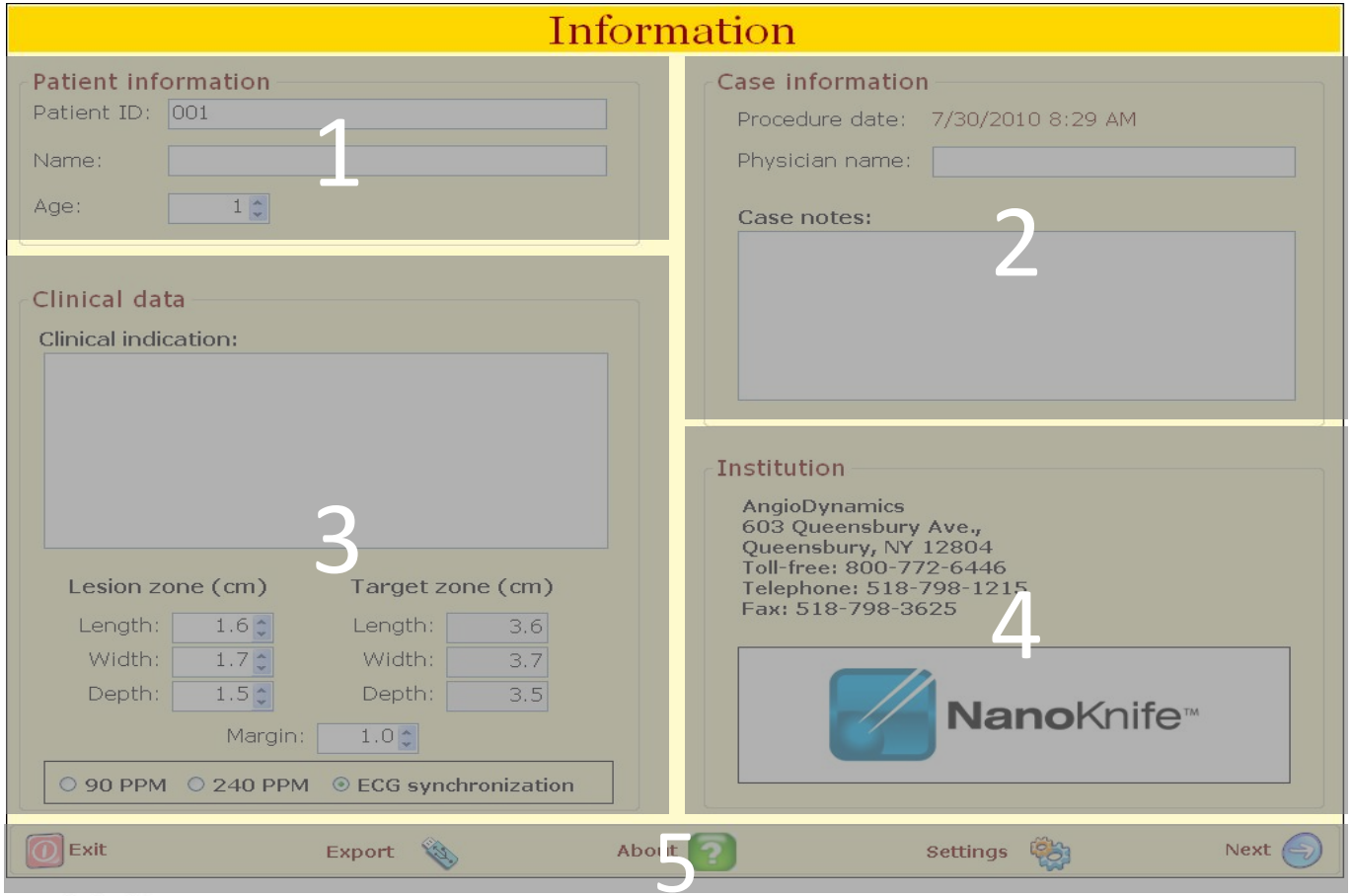
Information Screen

- There are five sections in the Information screen



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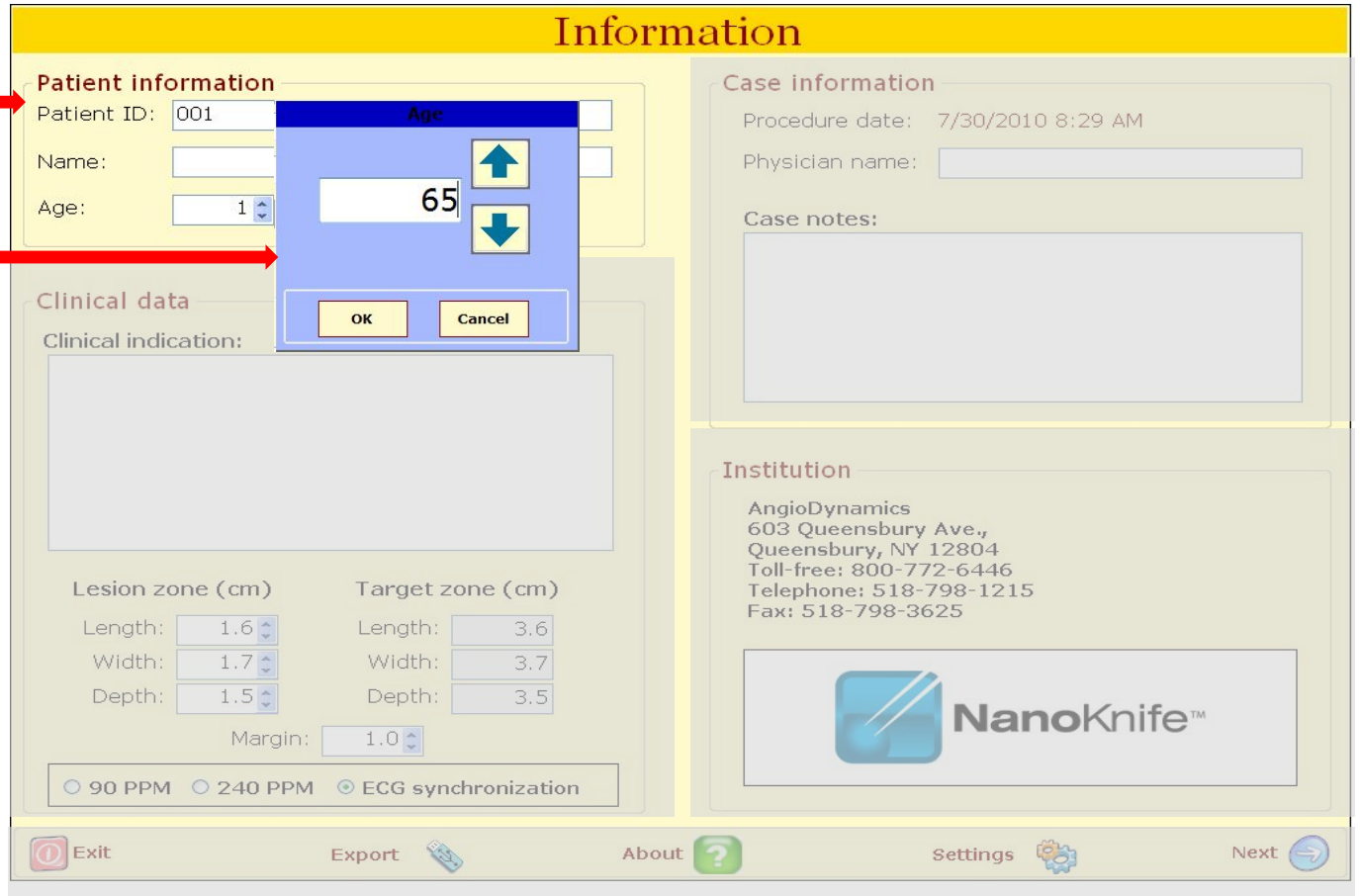
Patient Information

Mandatory information

Pop-up Window



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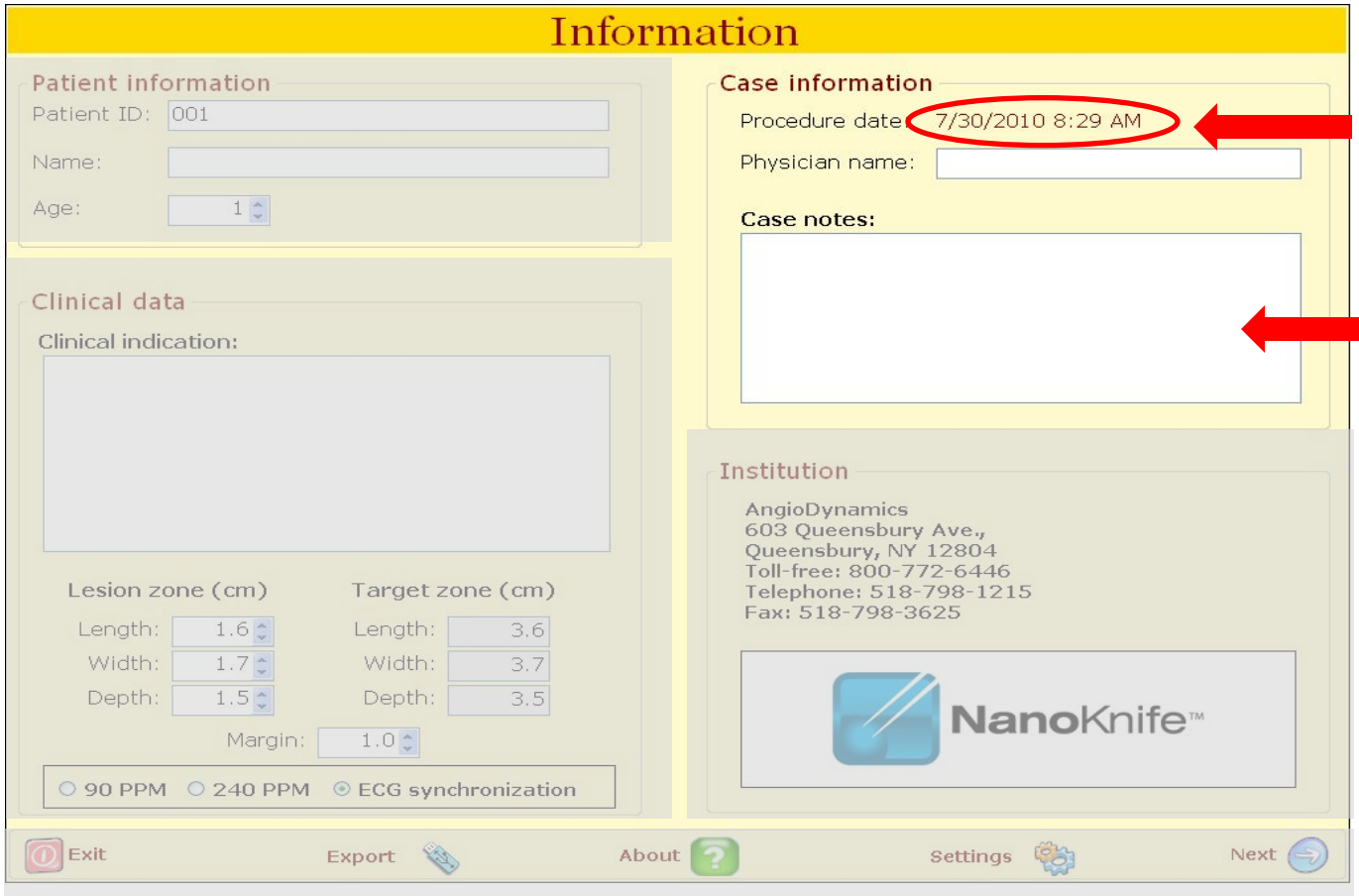
Case Information



Auto populates date

Key information about the case (e.g. type of chemotherapy they completed etc.)

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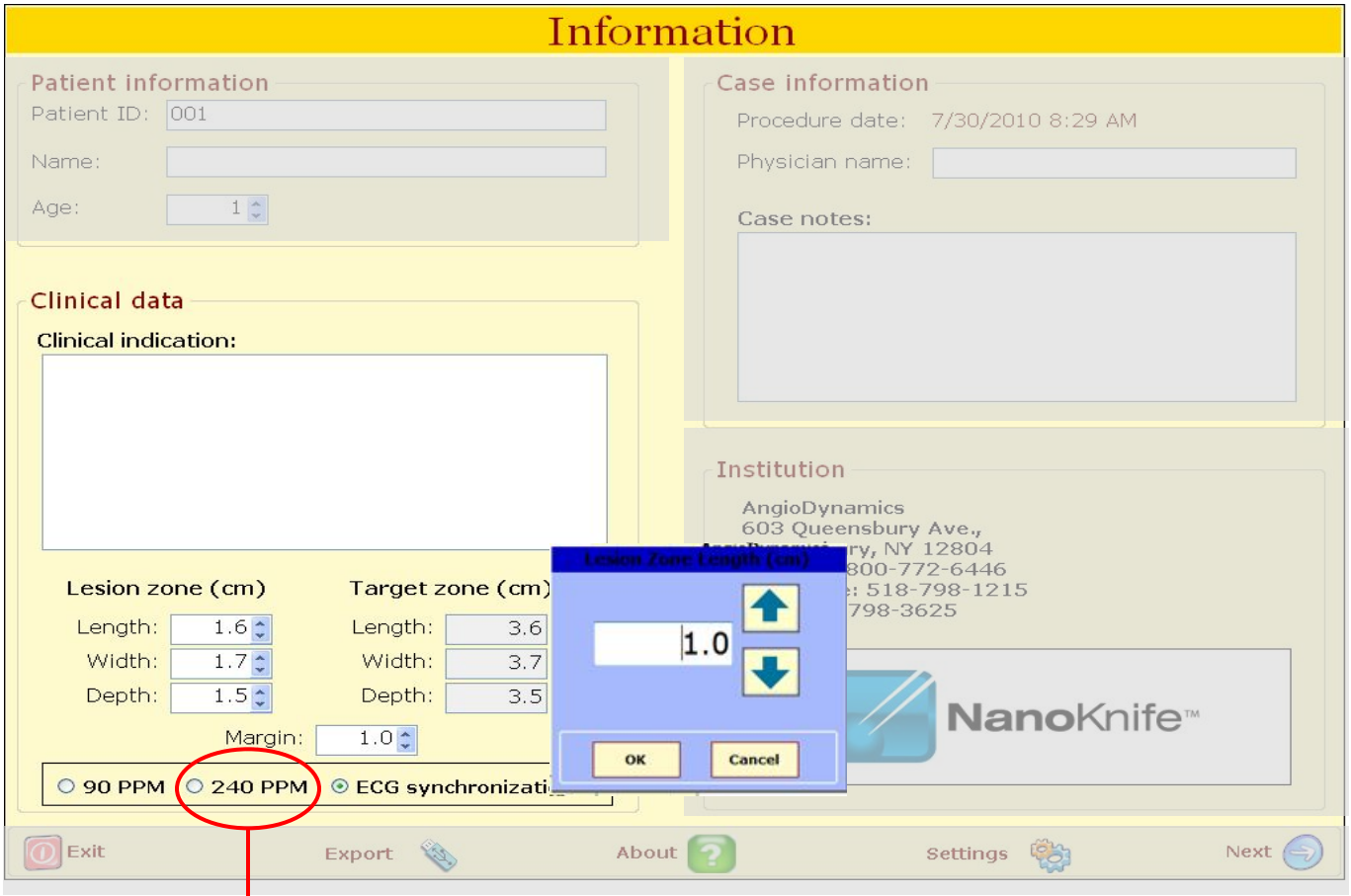
Clinical Data

Enter lesion type

Enter dimensions



Select if the organ is prostate

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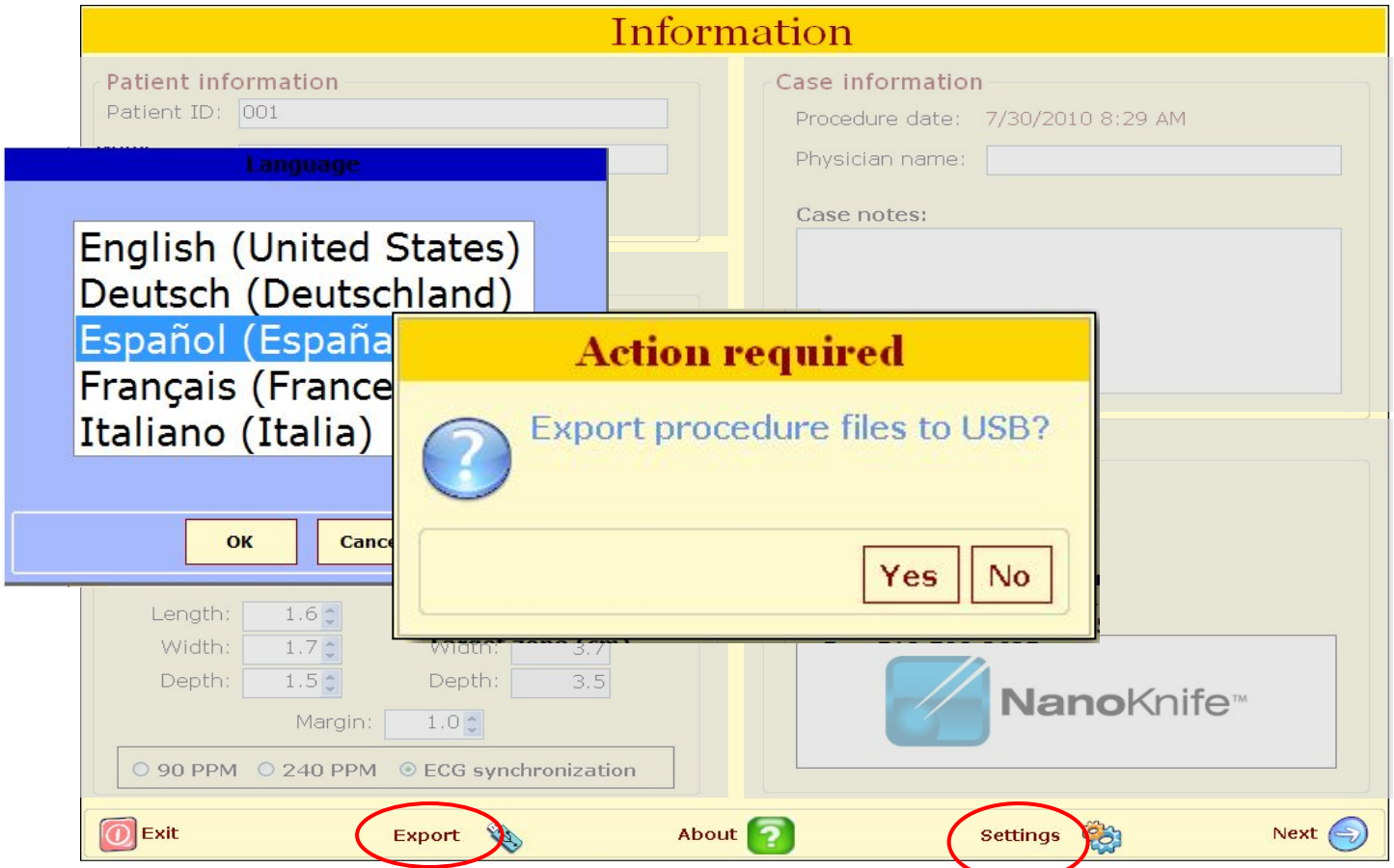
Tool Bar

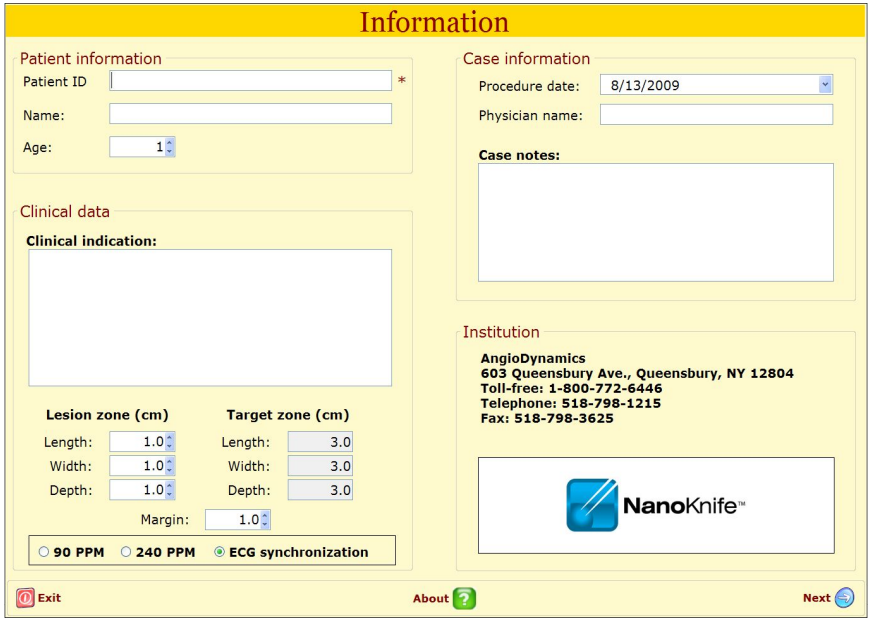


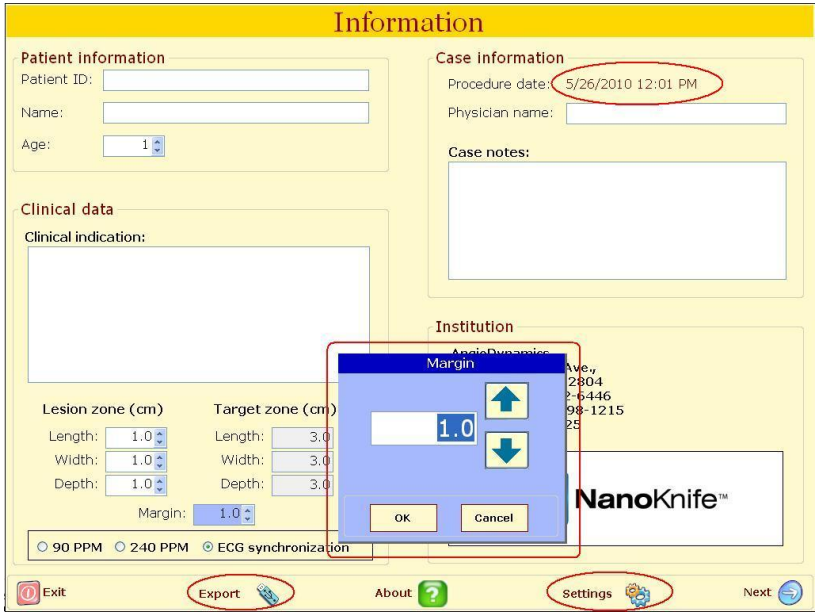
Export Data

Change Language

2.1.0 versus 2.2.0

Information Screen





- New pop-up window when selecting age, lesion zone and margin
- New settings and export options on the tool bar
- Auto populated procedure date

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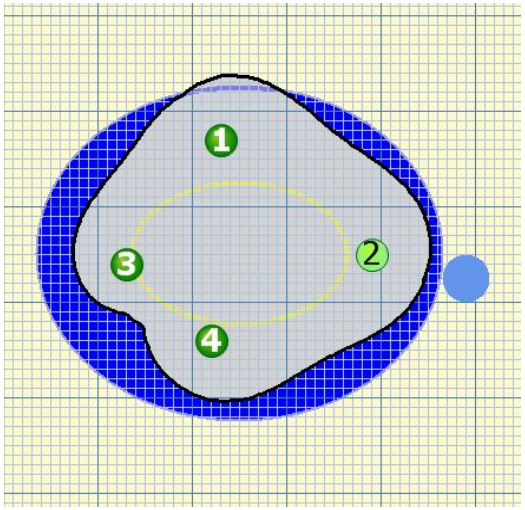
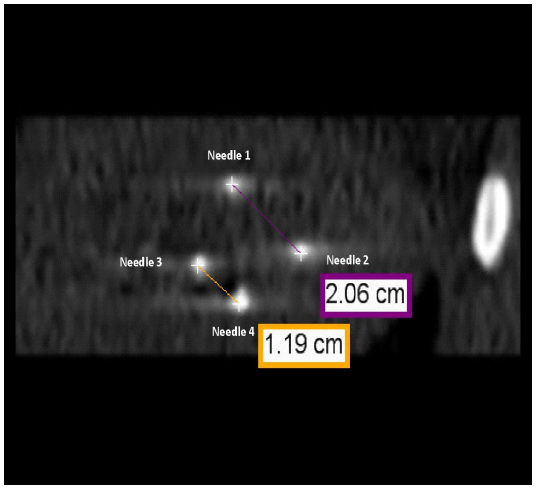
Objective:
Accurately Correlate 3 Phases

Probes in Tissue



Probes on Grid Plot



Probes in Cross Sectional Image

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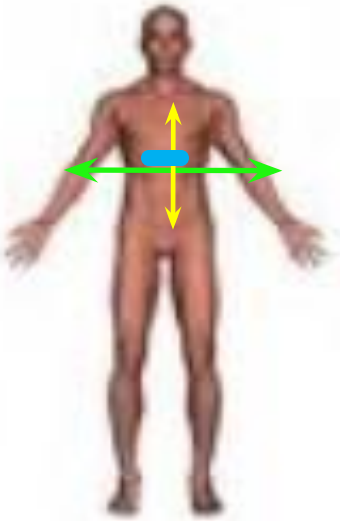
Labeling Length, Width, Depth

Width and Depth Orientation Change with Anatomical Approach



1.5 x 3.0 x 1.5 cm lesion in segment VIII
With long axis running axial (green line)

Length Craniocaudal—Yellow line	
Depth	**Width**
Corresponds to probe orientation; probe axis	
Lateral Probe Placement: D= Axial plane (green)	If D= Axial then W= AP
Anterior Probe Placement: D= AP axis (red)	IF D= AP then W= Axial

NanoKnife Treatment Planning

Estimate Number of Probes...

Based on longest axis of lesion

- 3 probe array : 1- 1.2 cm lesion + 1 cm margin
- 4 probe array: 1.3-1.7 cm lesion + 1 cm margin
- 4 probe array: 1.8-2.0 cm lesion + (<1cm margin)
- 5 probe array: 1.8-2.0 cm lesion + 1cm margin
- 6 probe pentagonal array: 2.0- 2.5 cm lesion (0.9 margin)
- 6 probe rectangular array or “chevron” shaped array

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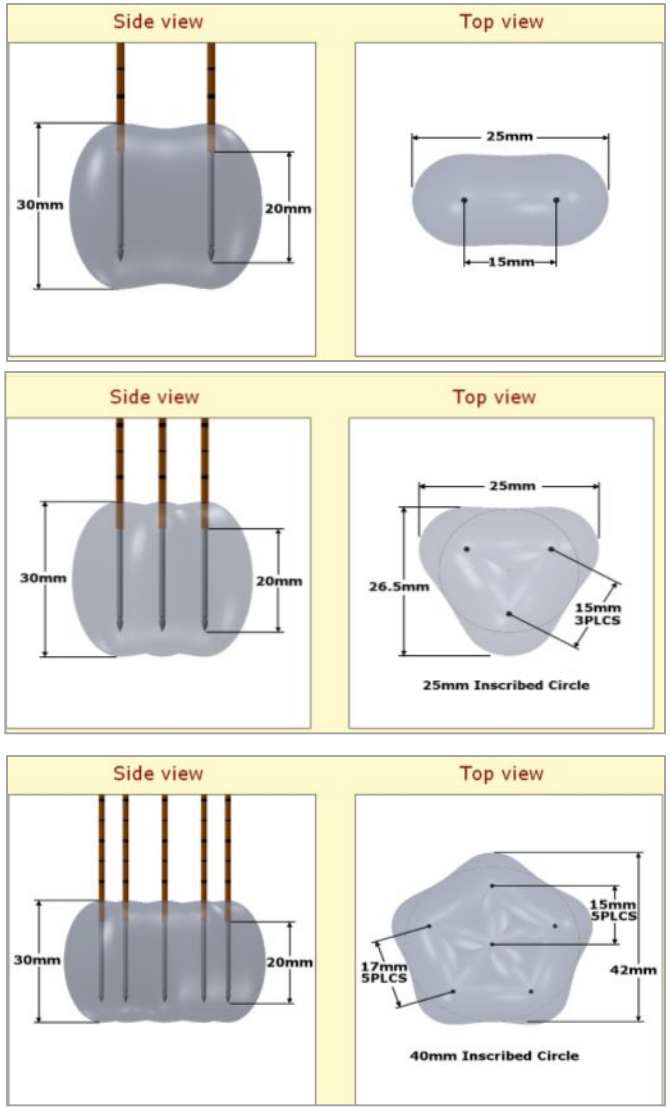
NanoKnife® Example Configurations

- Electrode Positioning
  - Flexible – customize to lesion size using 2 to 6 electrodes
  - 0.5 to 2.0 cm spacing between electrodes
  - 0.5 to 4.0 cm electrode exposure
  - Energy delivered between electrode pairs
  - 2, 3, and 6 probe configurations – examples shown at right



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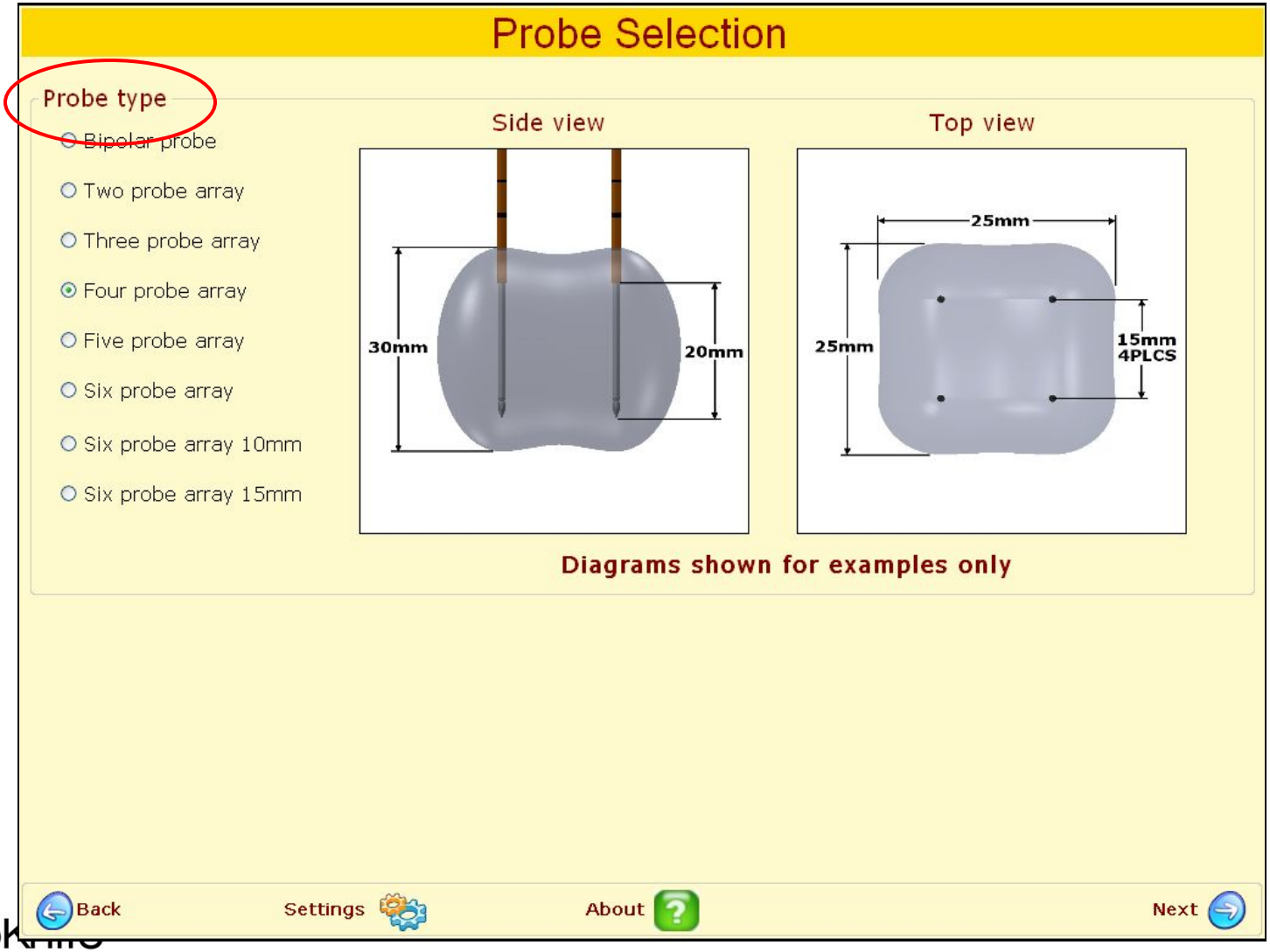
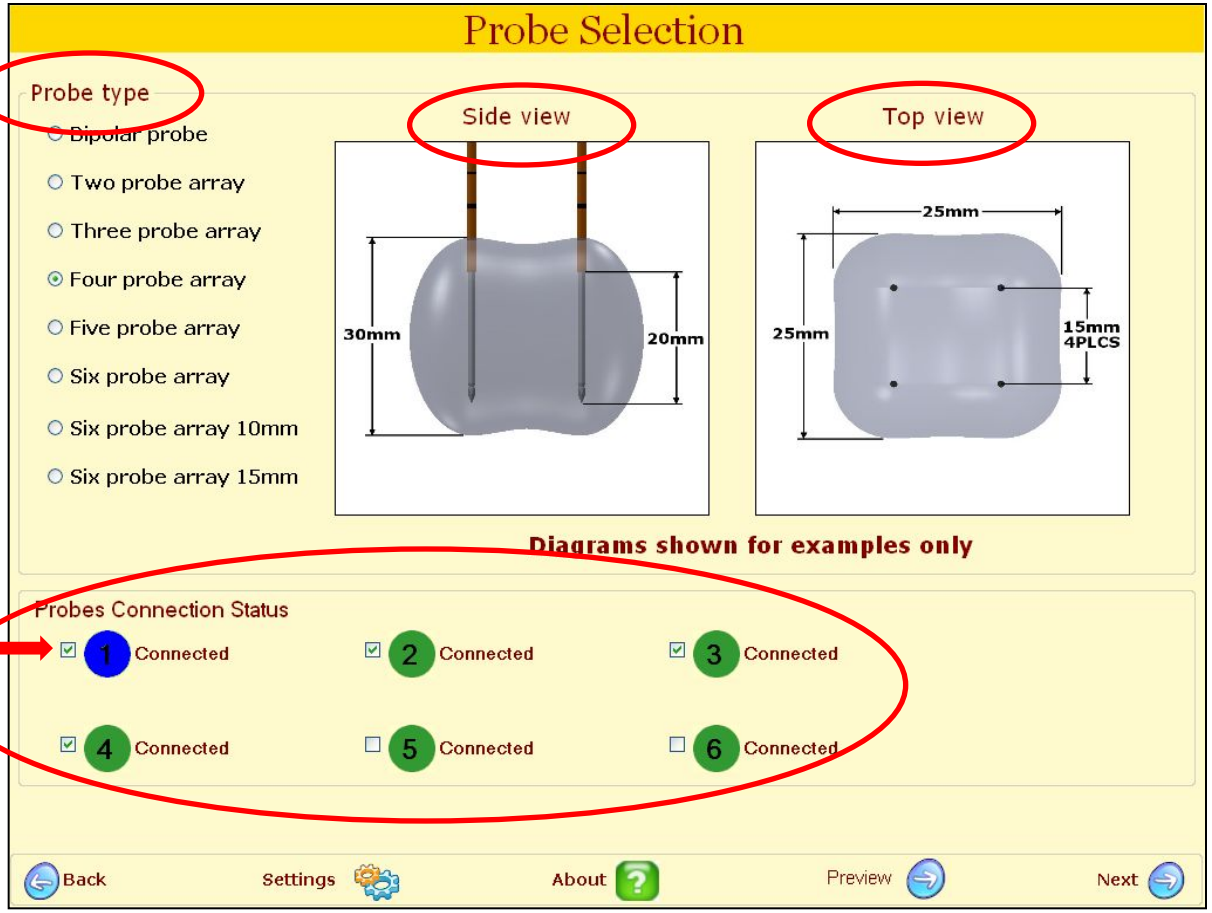
Probe Selection Screen



Probe Selection Screen

Activator probe



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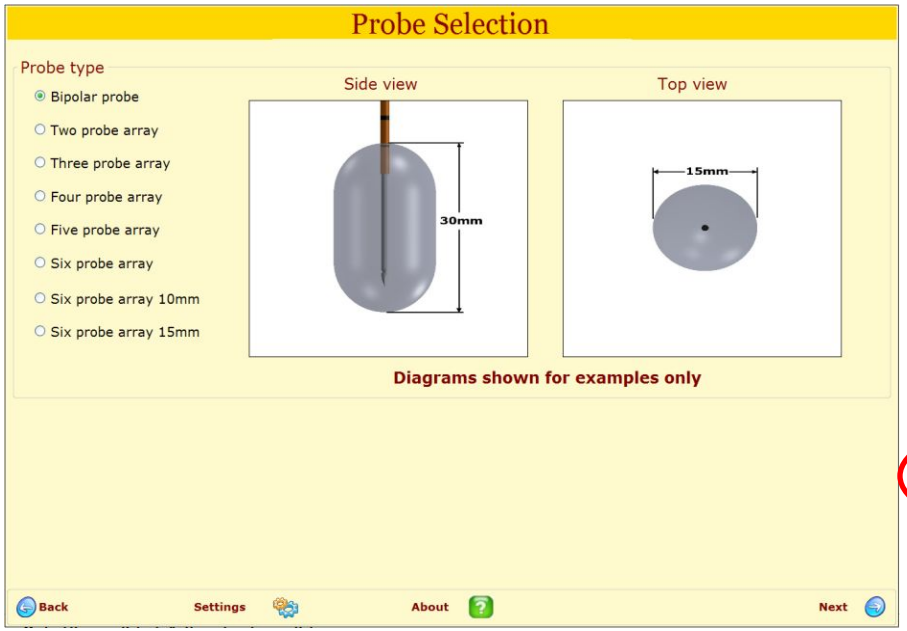
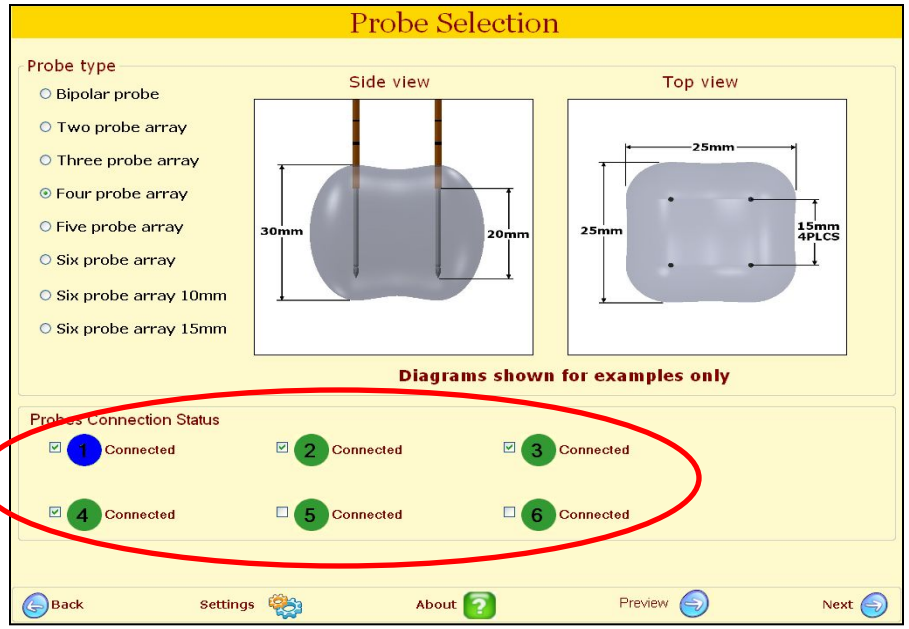
2.1.0 versus 2.2.0

Probe Selection Screen





- RFID probes identified
- Activator probe is indicated as blue
- Standard probes are indicated as green

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Probe Placement Grid

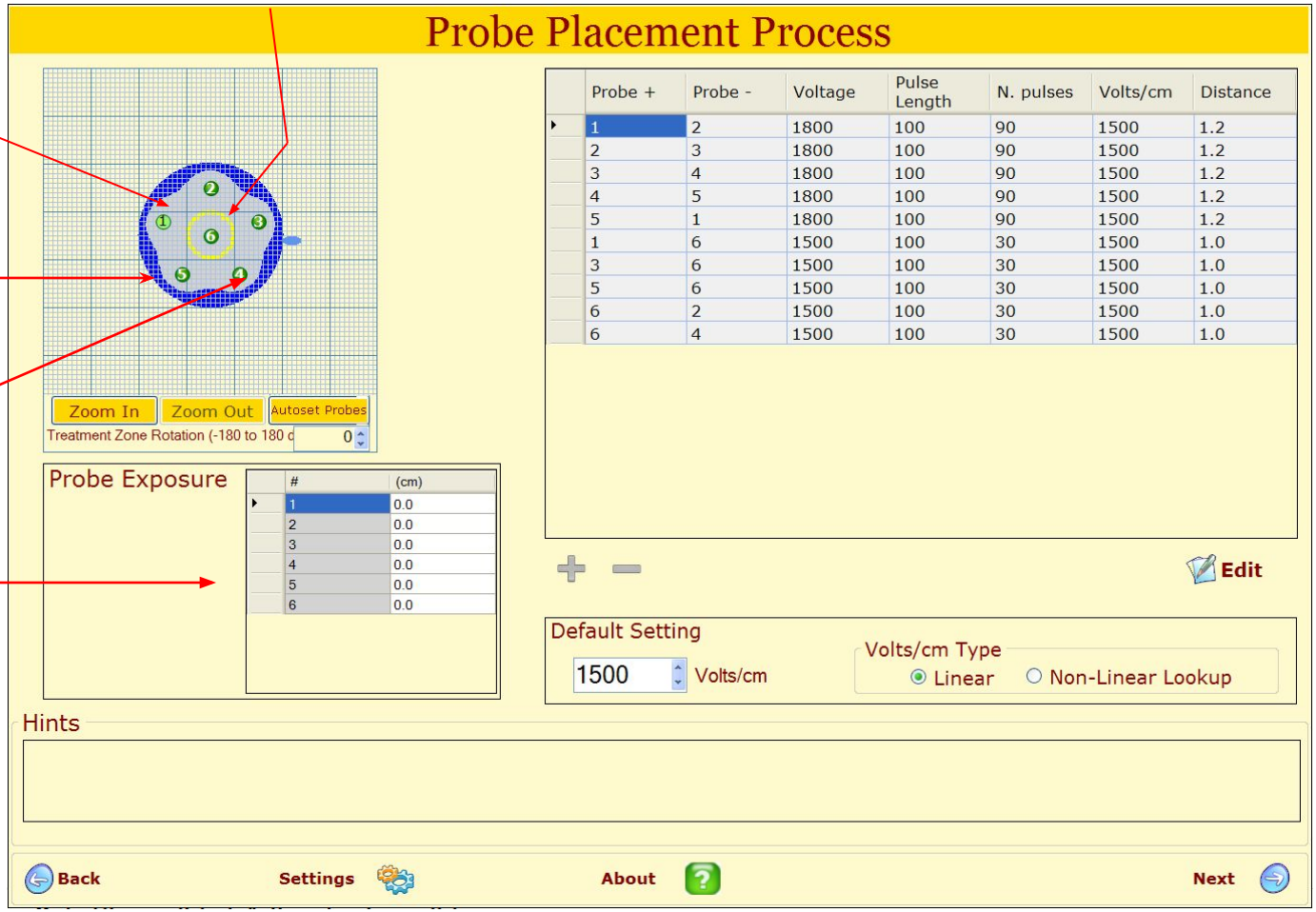
Target tissue

Ablation area

Margin

Probe icons

Probe Exposure *notated* here



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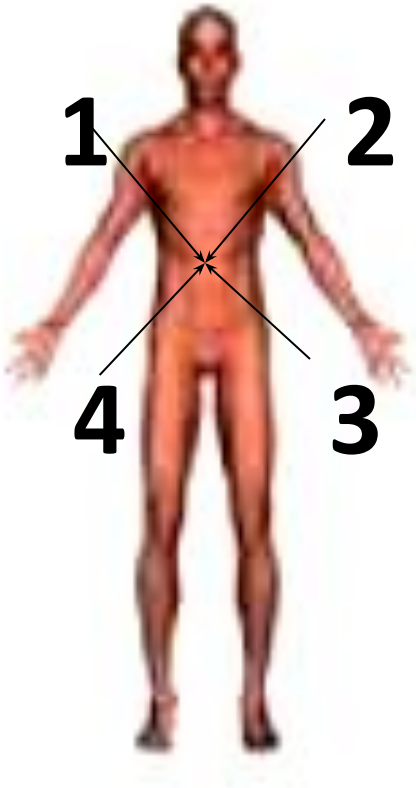
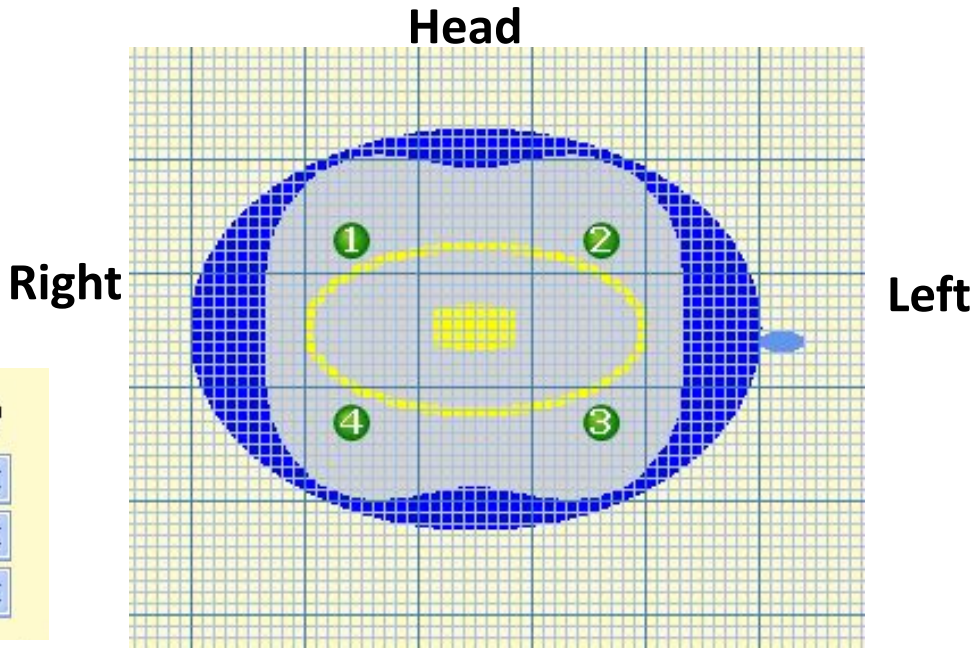
Orient Grid to Anatomical Approach

Anterior Probe Placement into 1.5 x 3.0 x 1.5 lesion



Lesion zone (cm)

Length:	1.5
Width:	3.0
Depth:	1.5



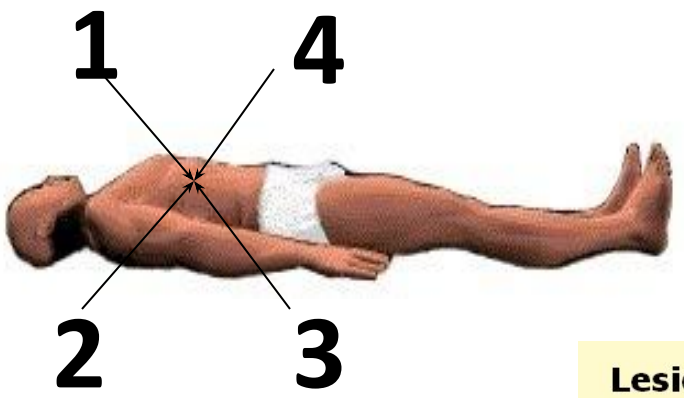
Depth = AP axis (front to back)

•Not an active value in grid model; only notated as “probe exposure”

<u>Ablation with 4 electrodes in this orientation has local miss.</u>

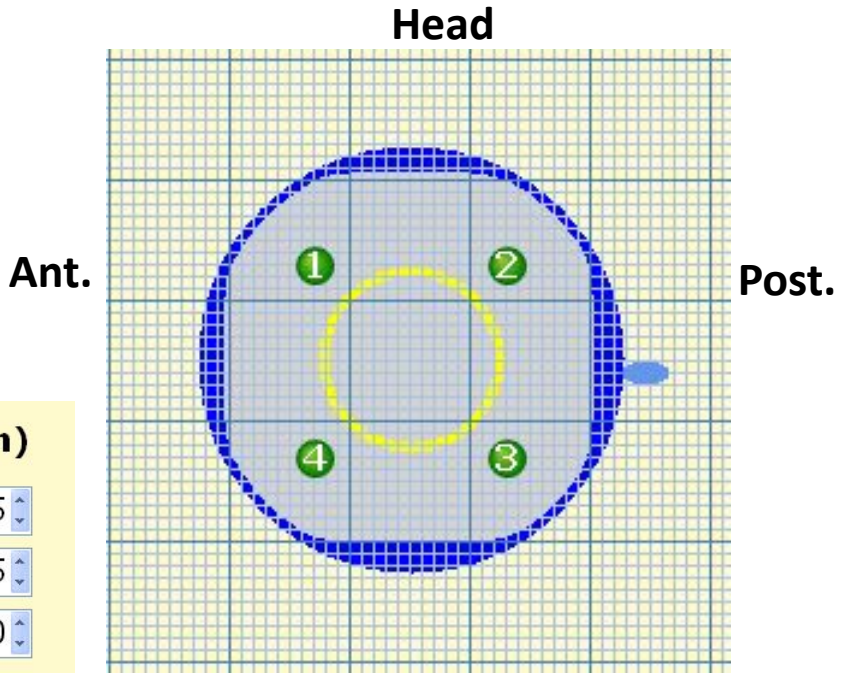
Orient Grid to Anatomical Approach

Lateral Probe Placement 1.5 x 3.0 x 1.5 lesion



Lesion zone (cm)

Length:	1.5
Width:	1.5
Depth:	3.0

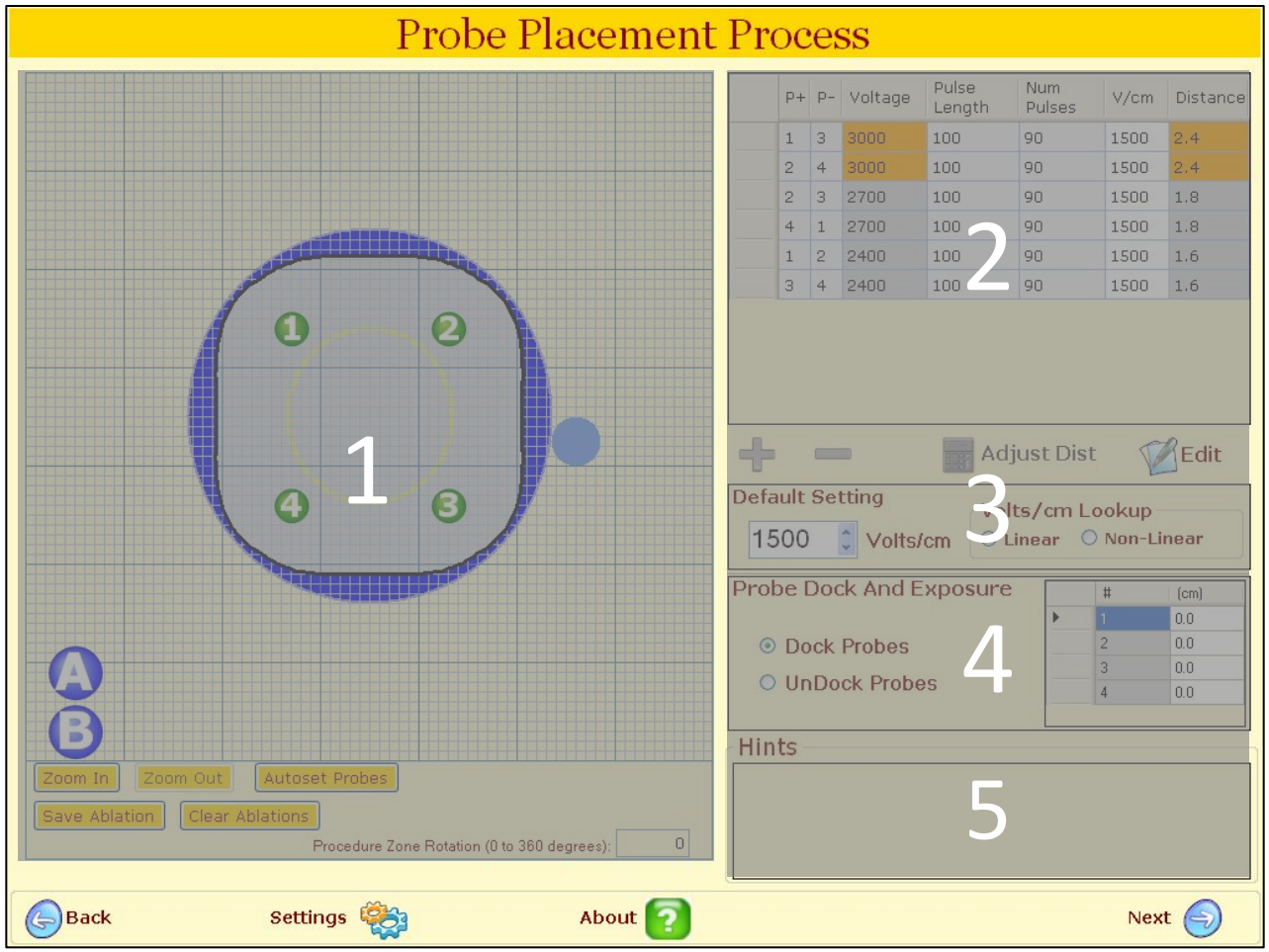


Depth = Axial (Pt's right to left/side to side)

- Not an active value in grid model; only notated as "probe exposure"
- Probe exposure and pull backs address this dimension

<u>4 electrodes ablates the lesion in 2 steps with 1 pull back.</u>

Probe Placement Process Screen



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Probe Placement Grid

Target tissue *(yellow)*

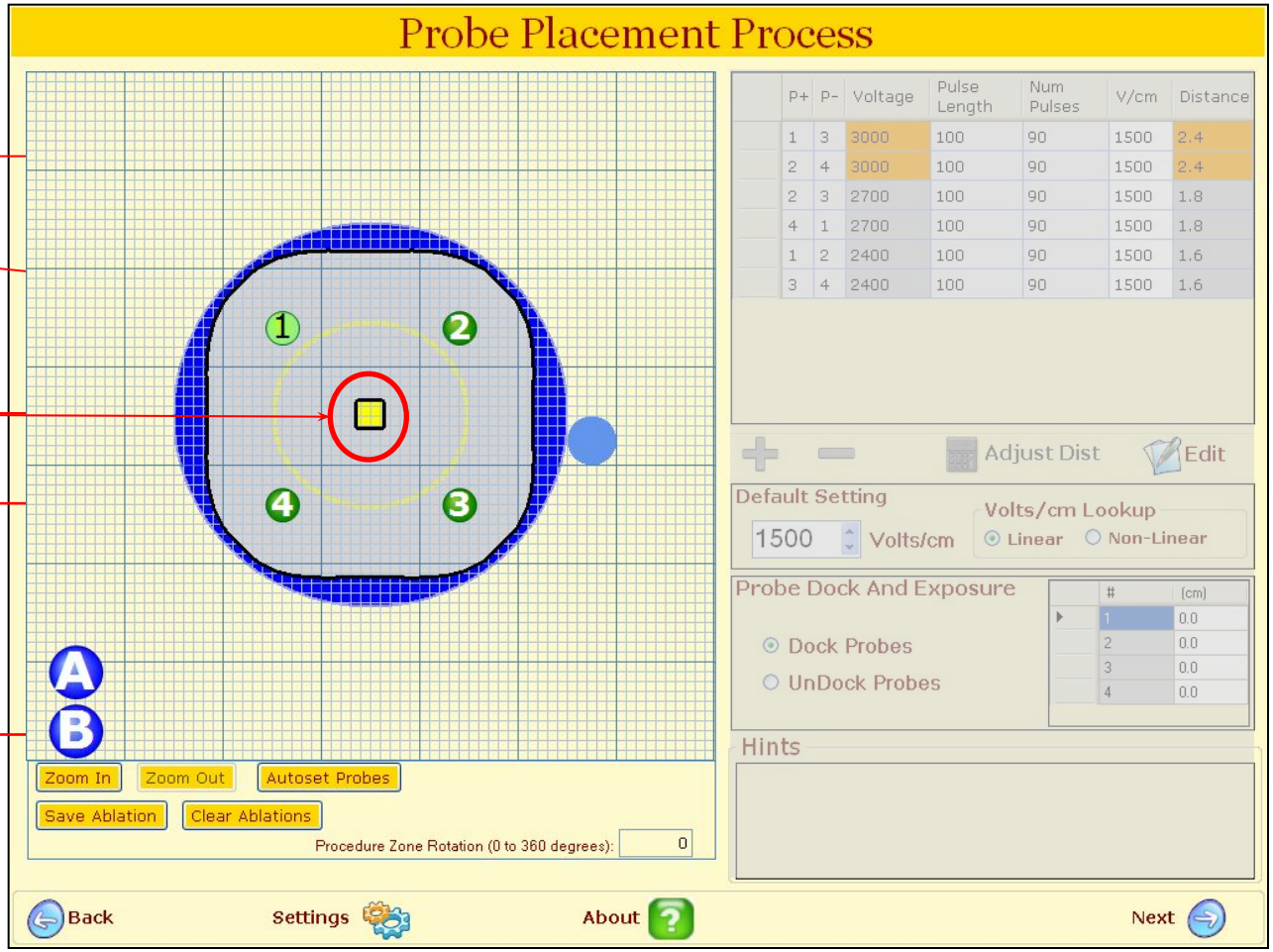
Ablation area *(gray)*

Margin *(blue)*

Skipped Ablation

Probes

Fiducials



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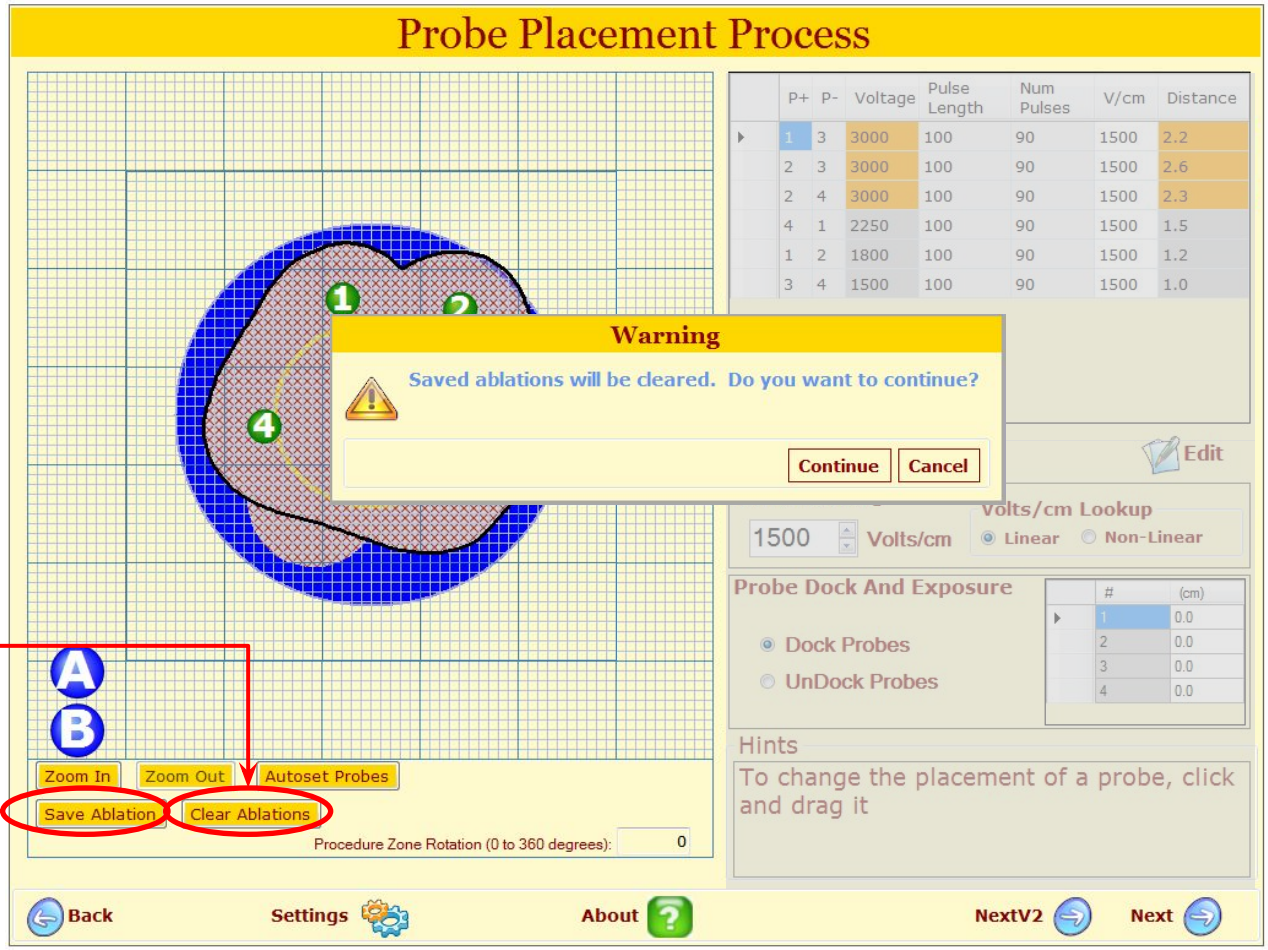
Probe Placement Grid



Clear ablations

Save initial set up

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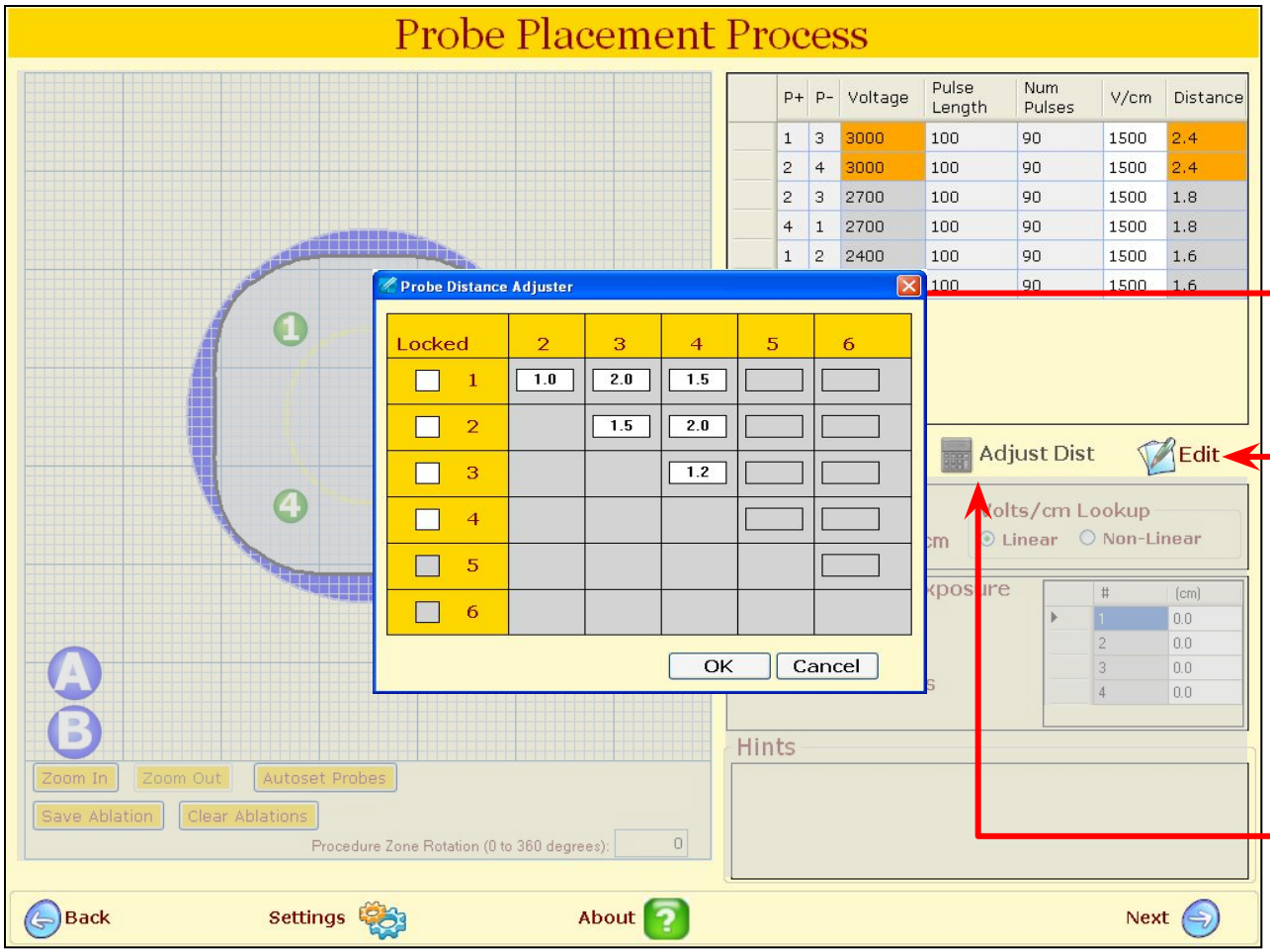
Ablation Spreadsheet



Allows the user to add/remove pulse sequence

Values may be changed

Enter probe distances and have them automatically placed on the grid

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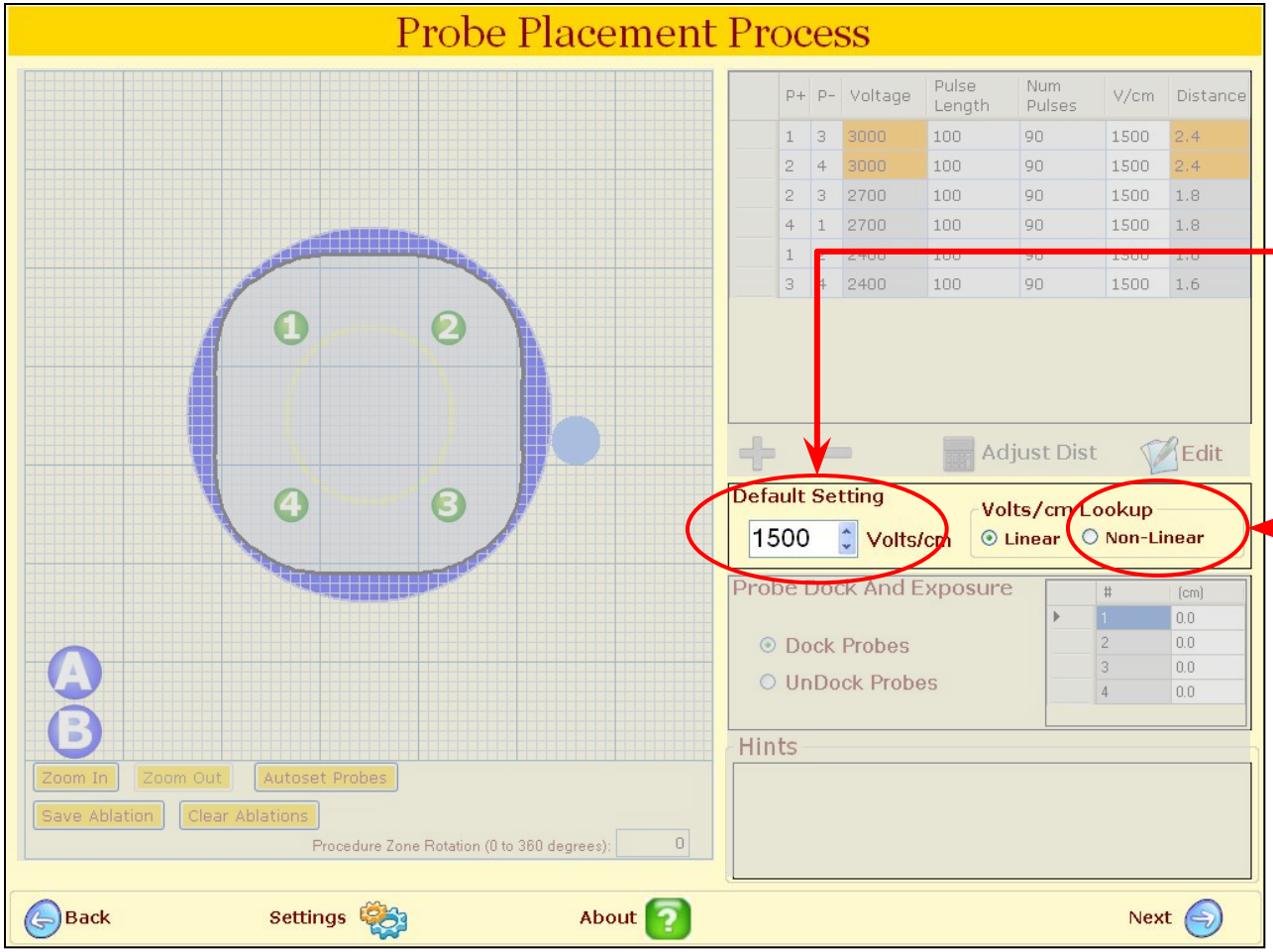
Adjusting Voltage



Change setting to obtain required Volts/cm

Select if organ is prostate

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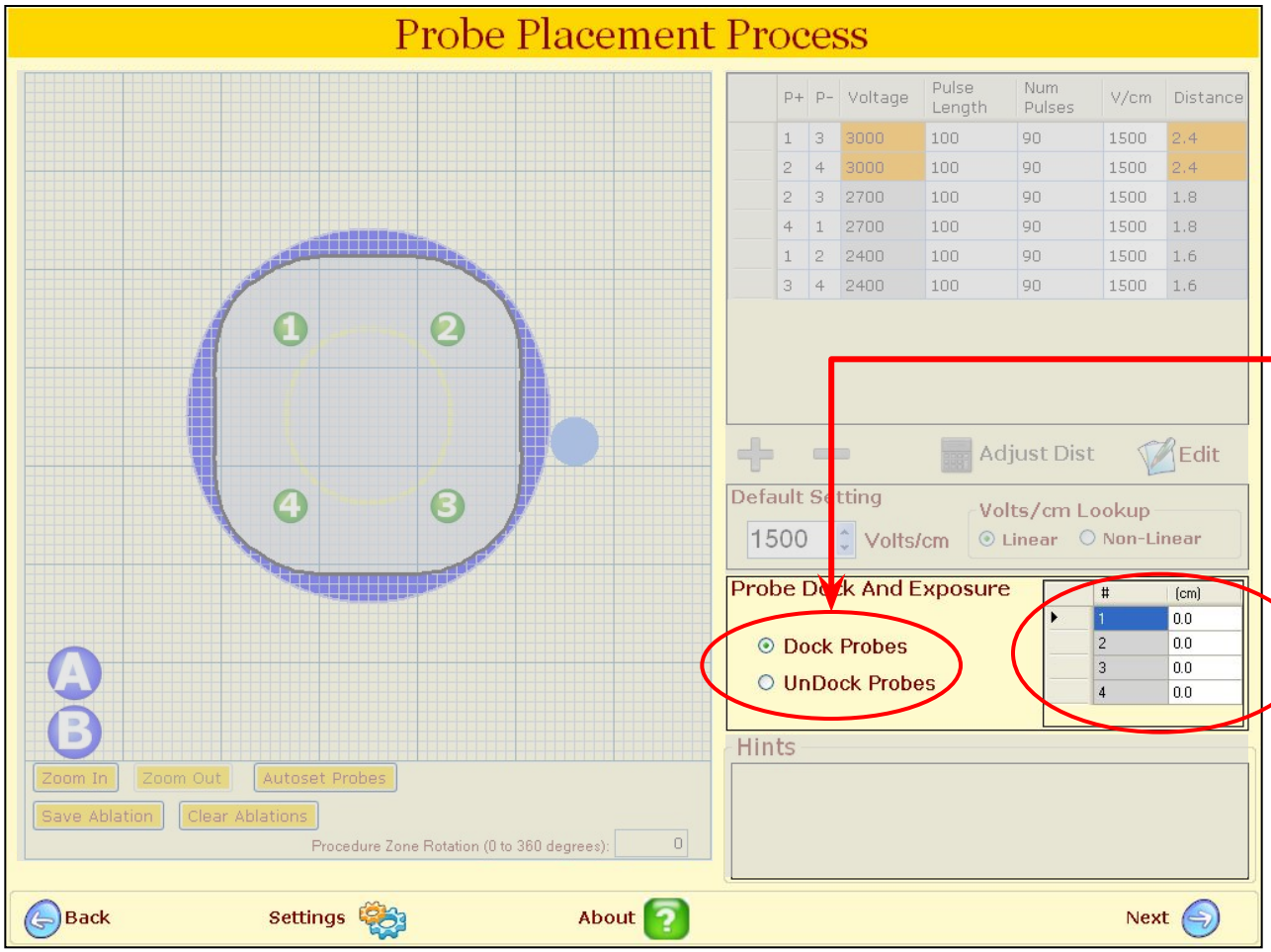
Probe Dock and Exposure Table



Disconnect / reconnect the probes from the Generator

Probe exposure

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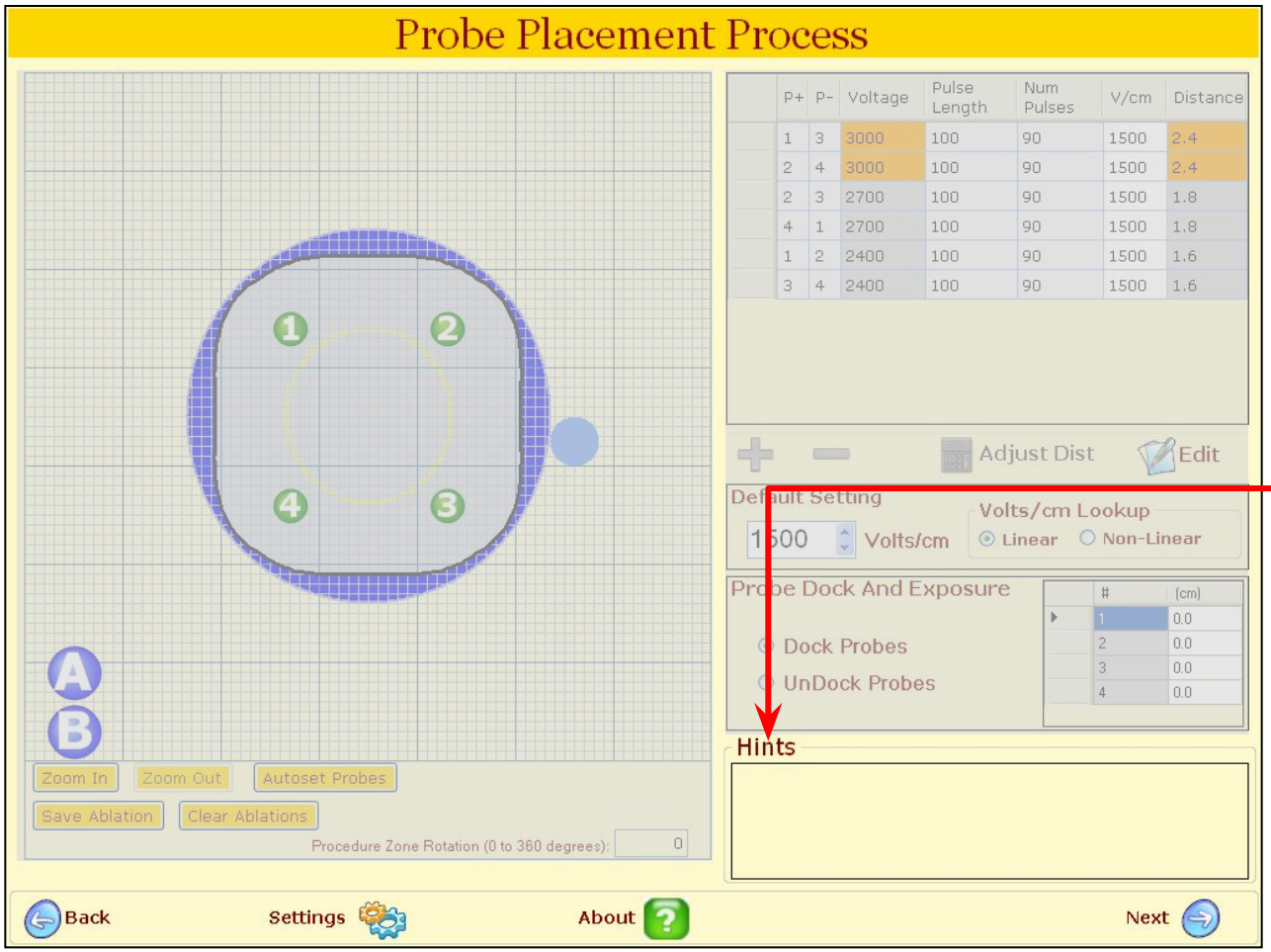
Hint Box



Hints box provides additional instructions

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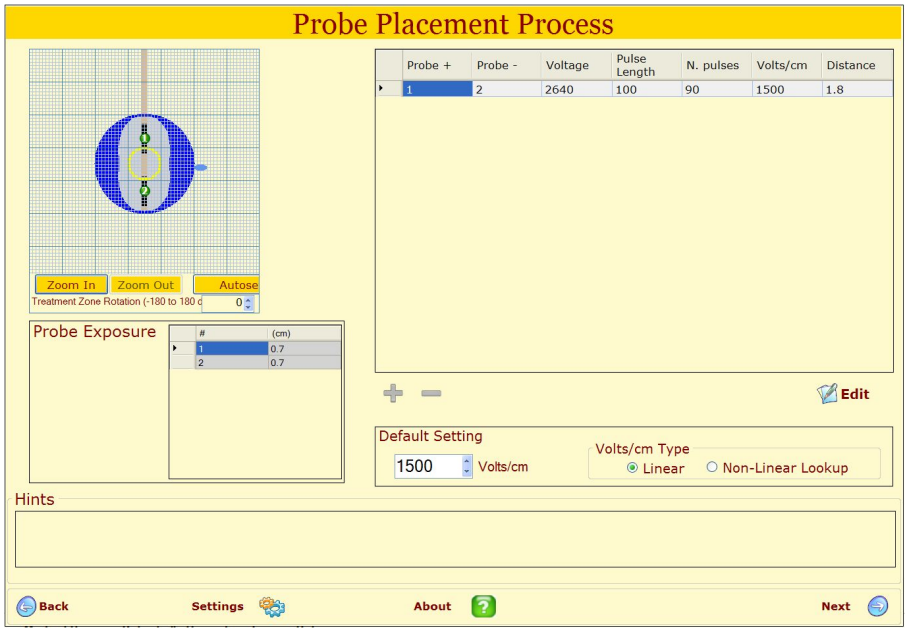
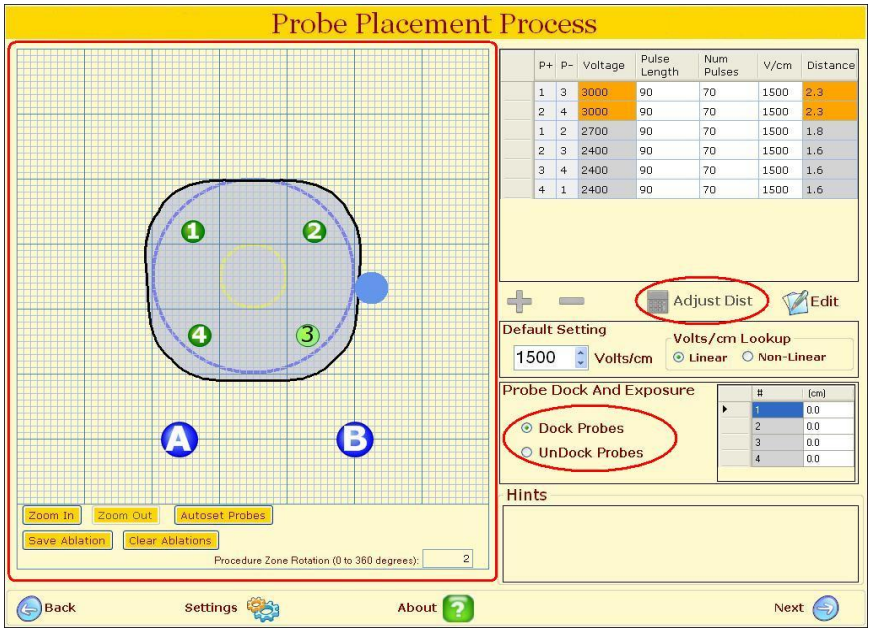
2.1.0 versus 2.2.0

Probe Placement Screen





- Probe Placement Grid is larger
- Skipped lesions identified
- Overlapping Ablation saved
- Probe Distance Adjuster included

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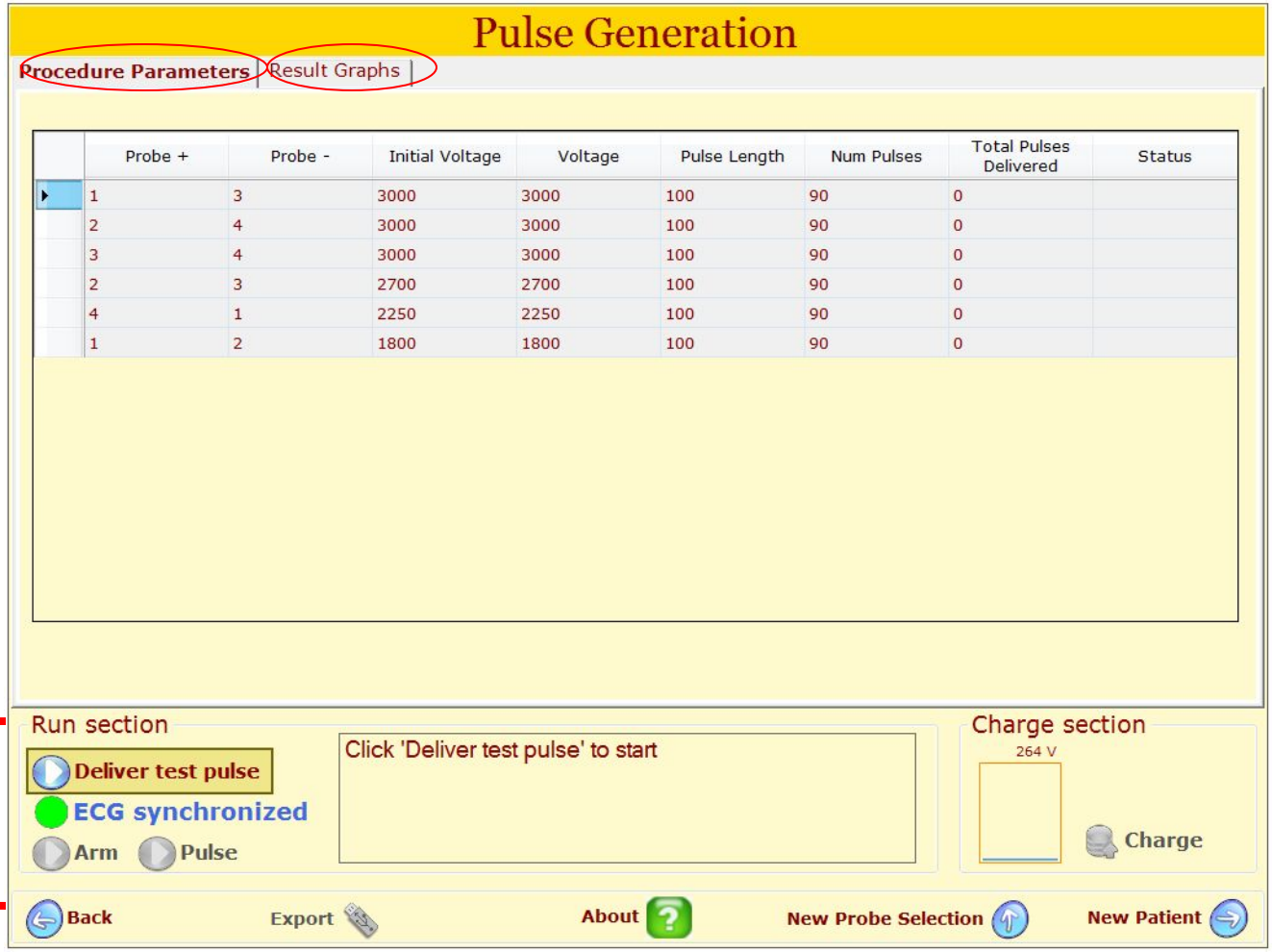
Pulse Generation Screen

- Where the ablation is delivered



Prepares, controls, and runs the ablation delivery.

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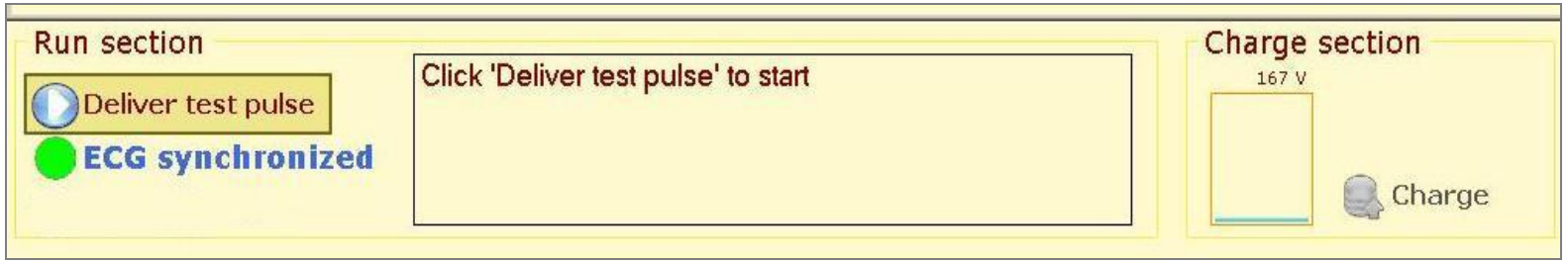
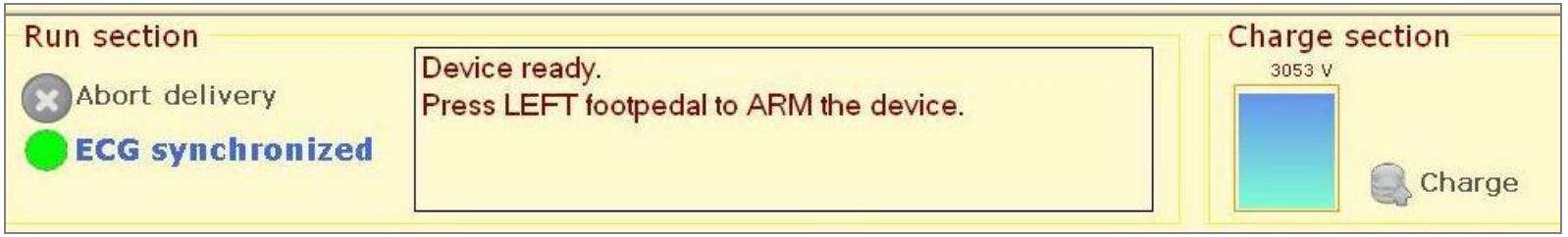
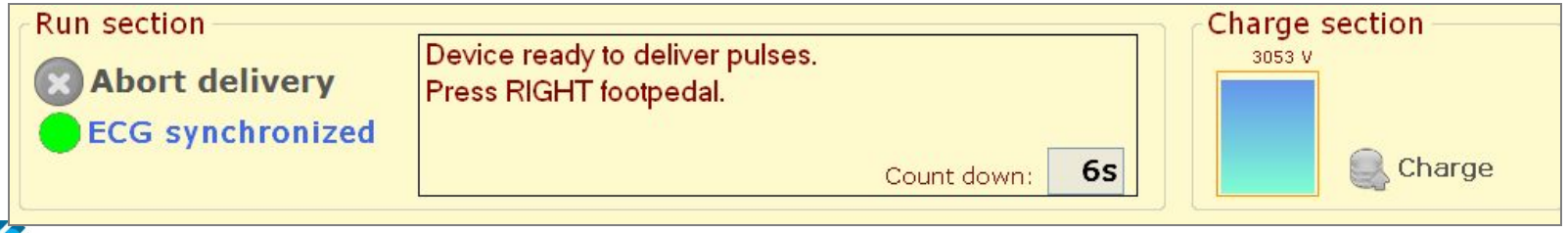
Run Section



If **unsuccessful**, the system will guide the user to check the probe connections to ensure they are connected.





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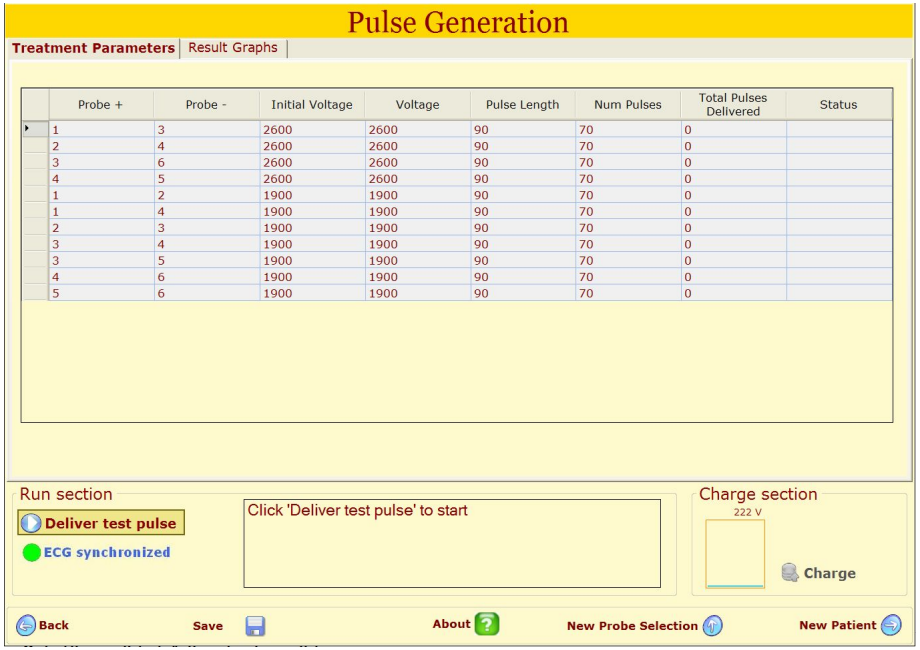
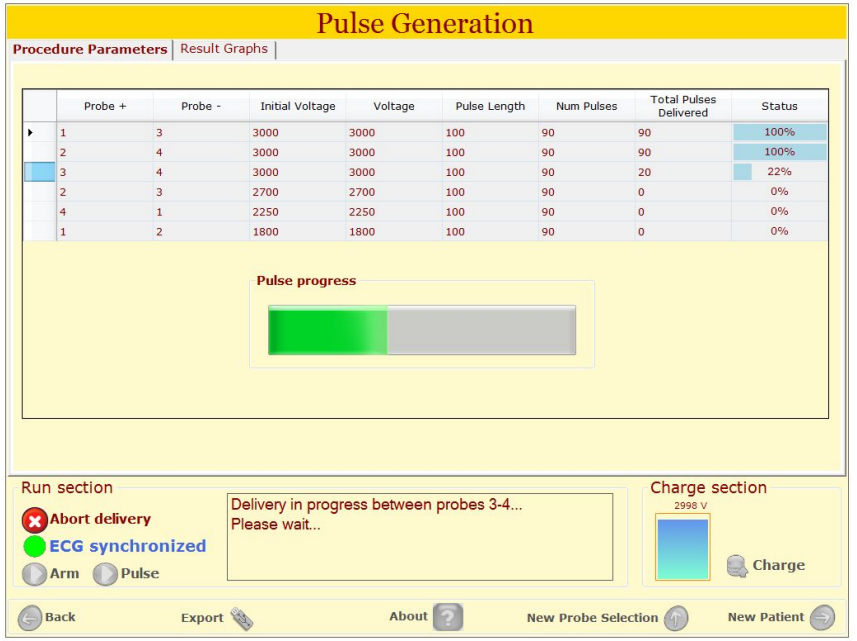
2.1.0 versus 2.2.0

Pulse Generation Screen





- Different progress bar
- Export button available

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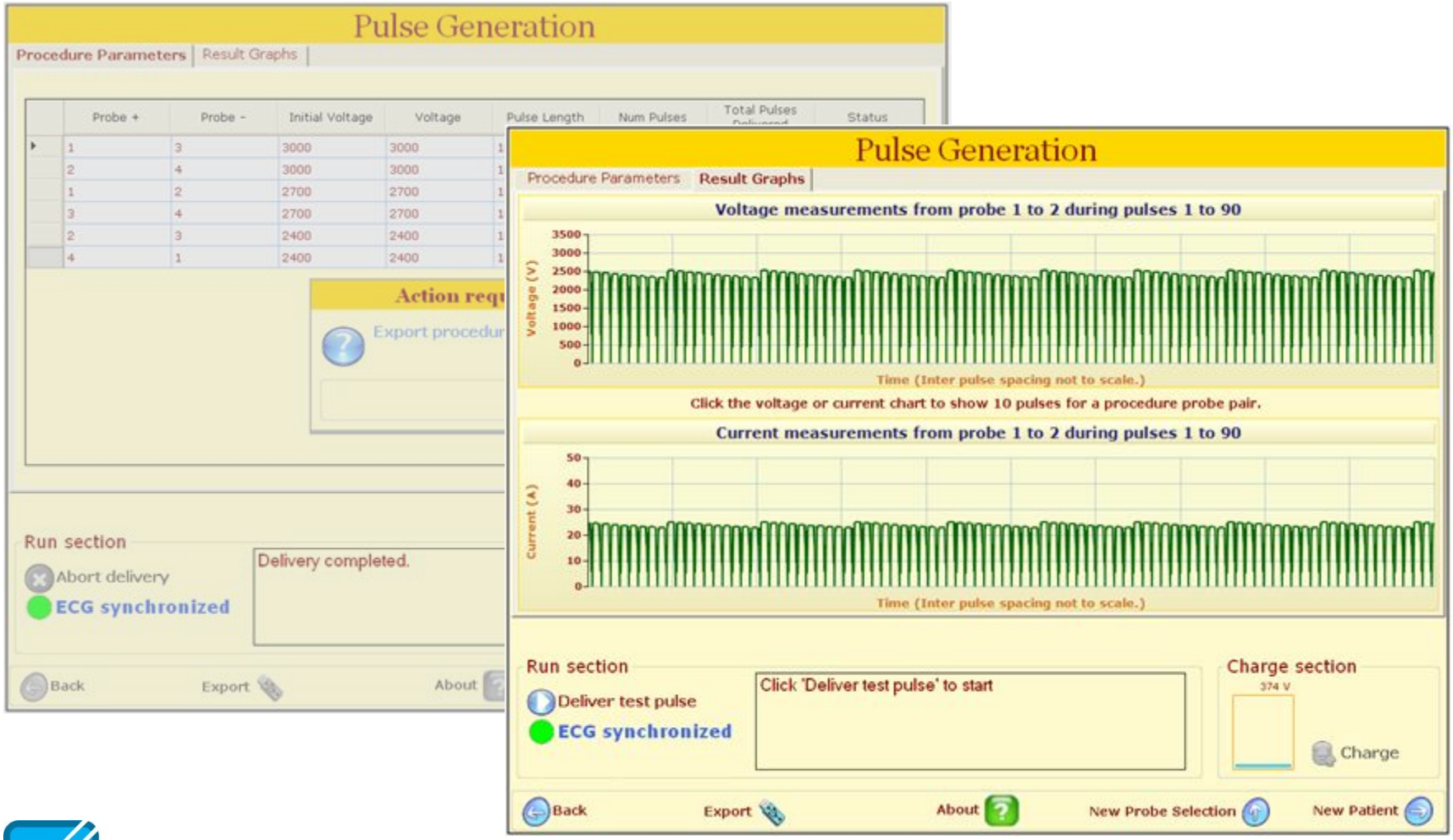
Ablation Delivery Completed



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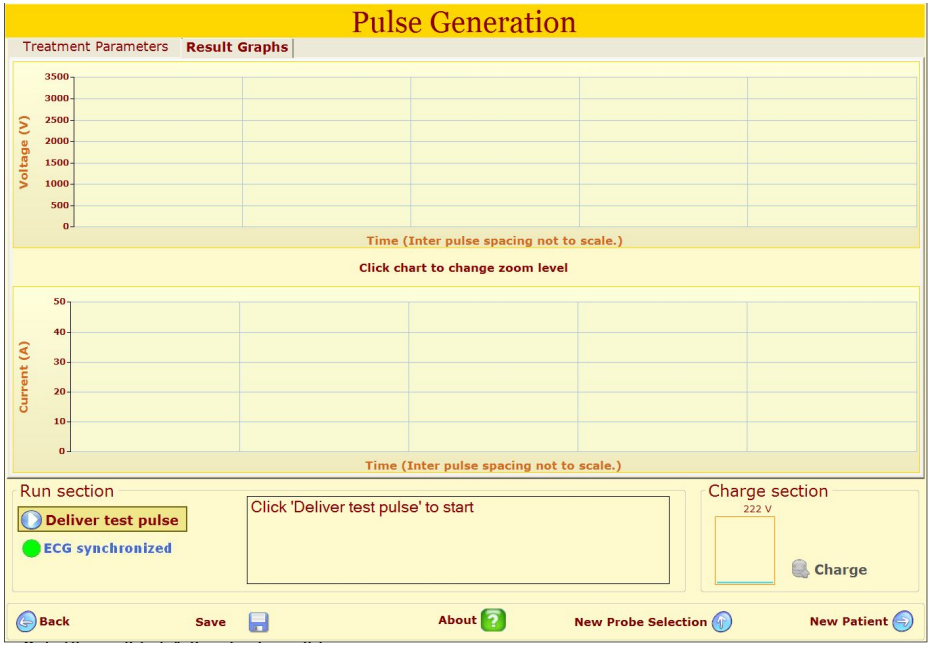
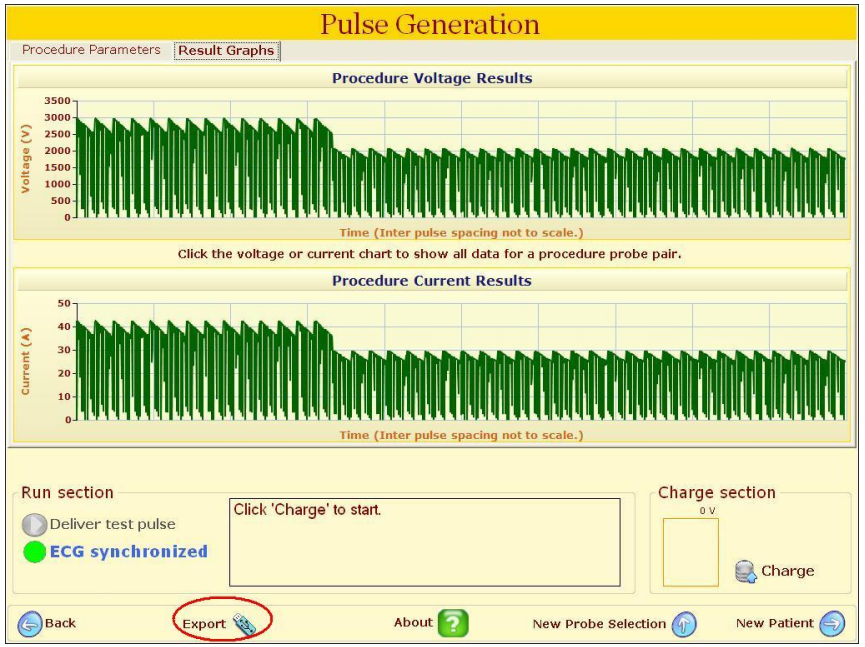
2.1.0 versus 2.2.0

Pulse Generation Completed Ablation and Graph Screen





- Export button available

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Pulse Generation screen

Confirm level of neuromuscular blockade now

Prepares, controls, runs the ablation delivery.

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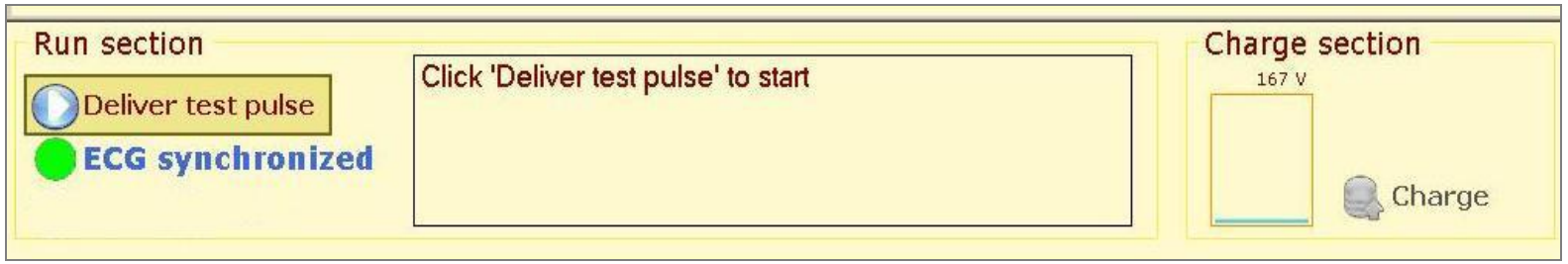
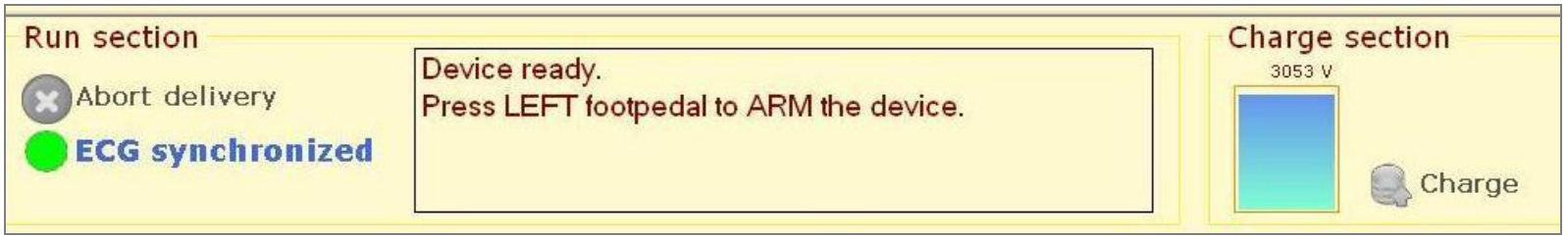
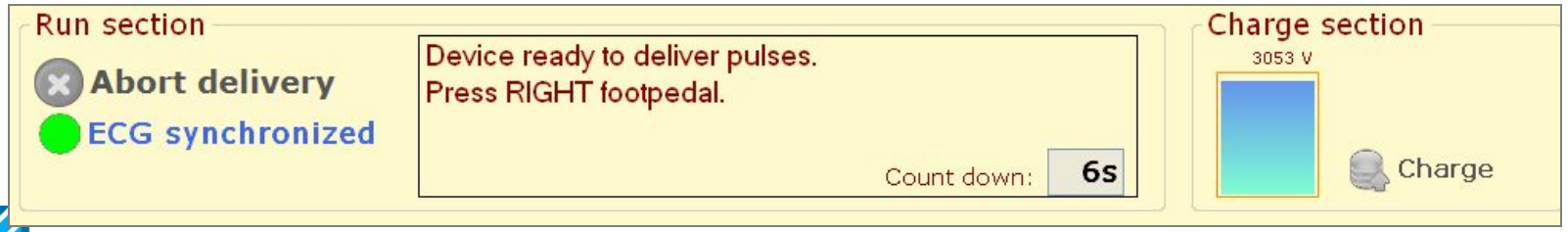
Run Section



If unsuccessful, the system will guide the user to check the probe connections to ensure they are connected.





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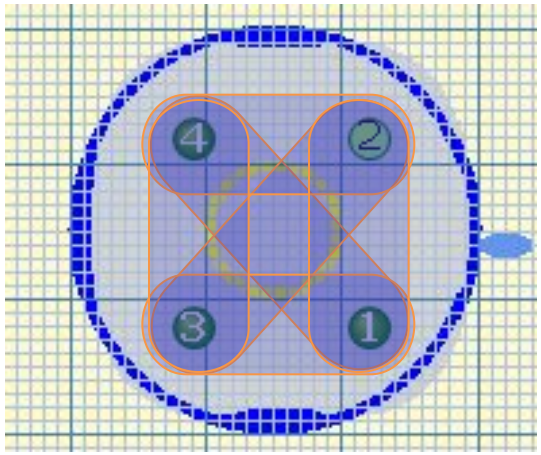
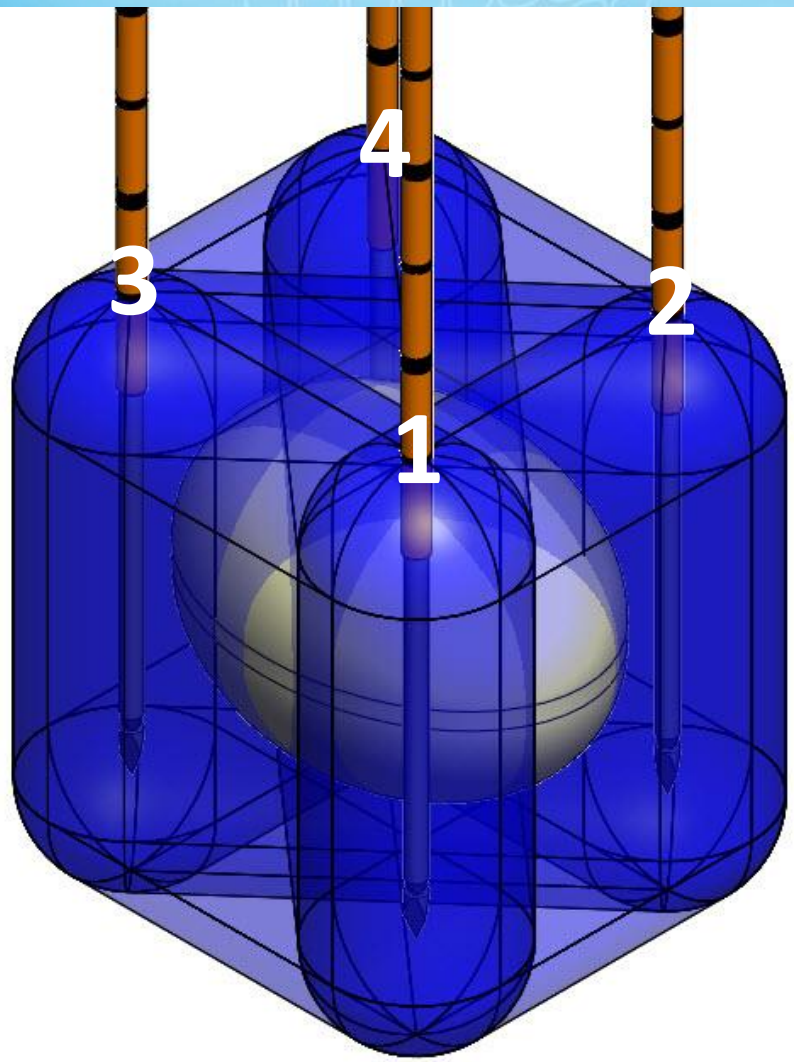
r Probe Ablation Sequence

Probe (+)	Probe (-)	Voltage	Pulse Length	N. Pulses	V/cm	Distance
1	4	3000	100	90	1500	2.2
2	3	3000	100	90	1500	2.2
2	4	2550	100	90	1500	1.7
3	1	2550	100	90	1500	1.7
3	4	2250	100	90	1500	1.5
1	2	2250	100	90	1500	1.5





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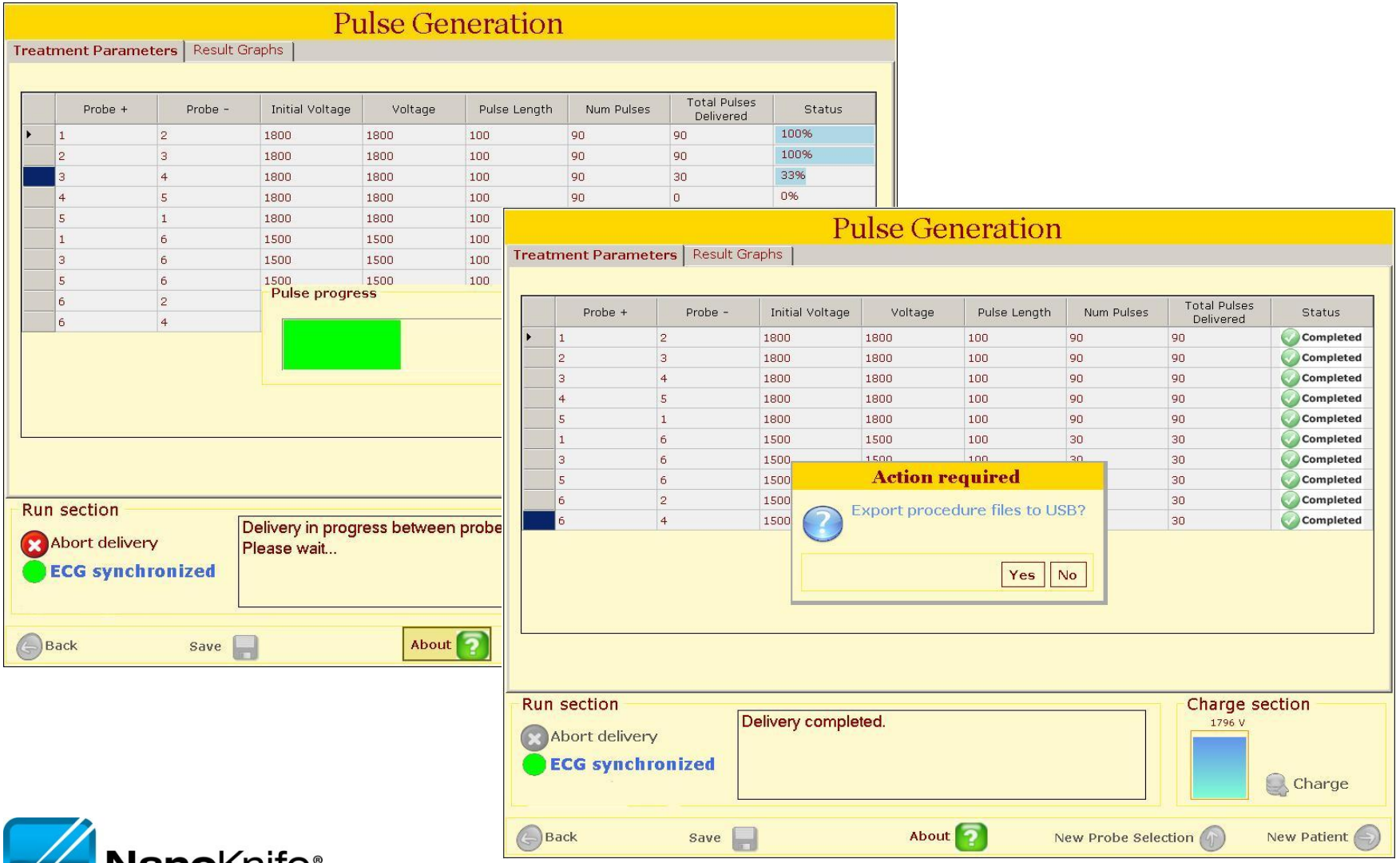
e Generation Completed



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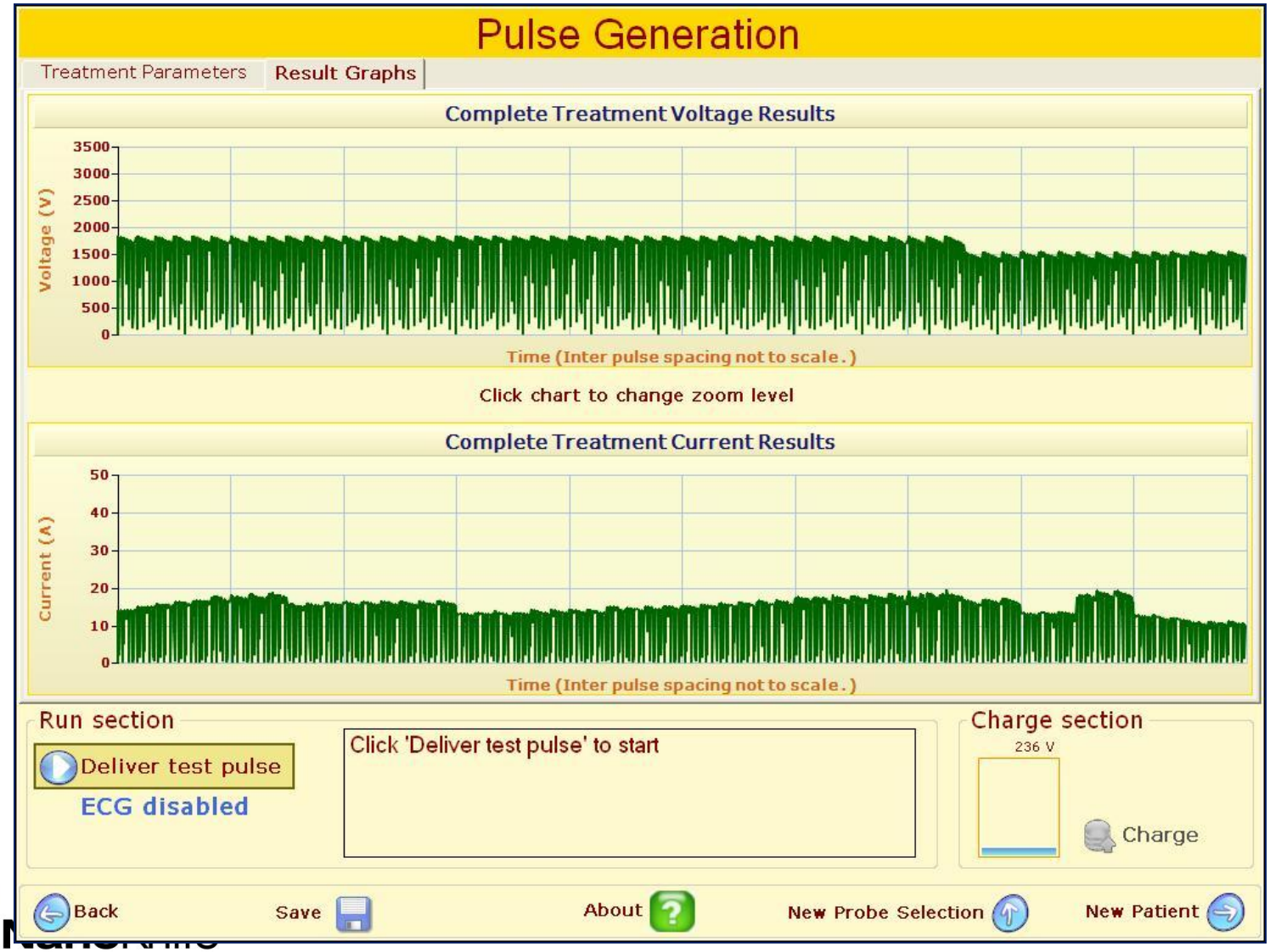
View Results Graph



NanoKnife™
Irreversible Electroporation

NANOKNIFE TREATMENT PLANNING – PRACTICAL CONSIDERATIONS

USING 2.1.0 LESION ESTIMATOR

The Start

Target organs

- Liver
- Pancreas
- Lung
- Kidney

Manageable starting points

Endophytic lesions ≤ 2cm

Single probe groupings initially

Possibility to overlap later as user becomes established

NanoKnife Treatment Planning

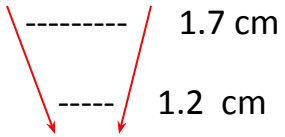
Estimate Number of Probes...

Based on longest axis of lesion

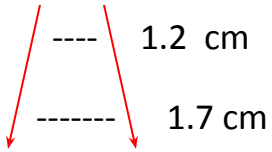
- 3 probe array : 1- 1.2 cm lesion + 1 cm margin
- 4 probe array: 1.3-1.7 cm lesion + 1 cm margin
- 4 probe array: 1. 8-2.0 cm lesion + (<1cm margin)
- 5 probe array: 1.8-2.0 cm lesion + 1cm margin
- 6 probe pentagonal array: 2.0- 2.5 cm lesion (0.9 margin)
- 6 probe rectangular array or “chevron” shaped array
  - Primarily used for prostate

Optimum Electrode Placement

- Keep electrodes parallel
- Avoid convergence
  - Tips are closer together



- Avoid divergence
  - Tips are further apart



- Equal penetration depth
  - Probe handles should be at same level
  - Can adjust exposure while in tissue
- 1-2 mm from critical structures

Optimum Placement Parameters

Value	Optimal
Inter-probe distance (5- 20 mm range)	15-17 mm
Probe exposure (0-4cm range)	1.5 - 2.5 cm (pancreas maximum 1.5 to 2 cm)
Penetration depth	Equivalent among all probes
Vertical orientation	Probes parallel to each other
Distance from critical structures	1-2 mm avoid mechanical damage

Treatment Planning Parameters

Value	Lower Limit	Upper Limit	Optimal	Increment	Use Default
Inter-probe distance	5 mm	20 mm	15-17 mm	1 mm	
*Probe exposure	0 cm	4 cm	2 cm	0.5 cm	
Current (Amps)	5A	50A	< 45 A	1	
Voltage (Volts)	500 V	3000 V	<3000	100	
V/cm	500	3000	1500-1900	50	
# of pulses	10	100	90	10	X
Pulse length	20 µs	100 µs	100 µs	10	X

*vertical spread is 5mm in both directions; ablation depth = probe exposure+ 1cm

Pairs are re-ordered automatically from highest to lowest voltage

Relative Indicators of Electroporation

How can you tell if you got an effective treatment?

Short answer: There are no *certain* indicators other than pathology.

There are relative indicators

- Hypo echoic image (immediately)
- Hyperchoic image after 24 hours
- During treatment, tissue density changes; “softens”
- Current outputs increase as tissue becomes electroporated
- Saw tooth current output graph trends up from left to right
- Contrast enhanced CT immediately after
- At least 80 pulses completed

High Current and Popping

- Hydrolysis is the dissociation of water molecules
  - A ‘muffled’ sound during pulses is common and benign
  - Loud popping may require adjustment
    - Probes may be arcing or outside organ capsule
    - Common in cystic, fluid-filled areas i.e. kidney
    - High current and possibly heating
- Recommended adjustments
  - Reposition probe tips within organ capsule
  - Decrease exposed electrode
  - Retract probe(s) to a shallower penetration depth
  - Decrease amplitude V/cm

Trouble shooting- first line assessment

It’s always a good idea to…

RE-IMAGE when probe placement, inter-probe distance or relative ablation zone is in question.

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Organ-Specific Considerations

- **Liver**
  - Good starting place
  - Possibility for combined treatment on larger lesions (IRE at/near critical structures + thermal, embolic or chemical)
  - 2.5 cm max electrode exposure
  - Bile very conductive; high current

- **Pancreas**
  - Risk to benefit ratio favors IRE
  - Pancreatitis is probable but manageable
  - Limit punctures when possible

Organ-Specific Considerations

- **Kidney**
  - Very conductive (draws 20-23 Amps)
  - 2-2.5 max probe exposure
  - Pulses into adrenal gland can cause elevated BP > 200
  - Circuits across collecting system create high current, smaller than expected ablation
  - Dbl -J stents have been placed (by Thompson, Pech) to maintain ureteral patency
- **Lung**
  - Poor conductivity in normal lung
  - CT imaging preferred
  - Place probes *into* (solid) lesion at peripheral edges for best conductivity
  - Pneumothorax is common
  - Multiple punctures increase pneumo risk
  - Atelectatic lung more conductive than aerated lung

Procedure Tips, Tricks, and Troubleshooting

September 16, 2010

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Learning Objectives

- NanoKnife Set-Up
- AccuSync 72 Set-Up
- ECG Synchronized Pulse Delivery
- Proper Sync Function
- ECG Sync Device Lead Set-Up
- Signs of Saturation
- Other ECG Sync Problems
- Trouble Shooting
- Physics (Voltage/Current/Resistance)
- Optimal Parameters

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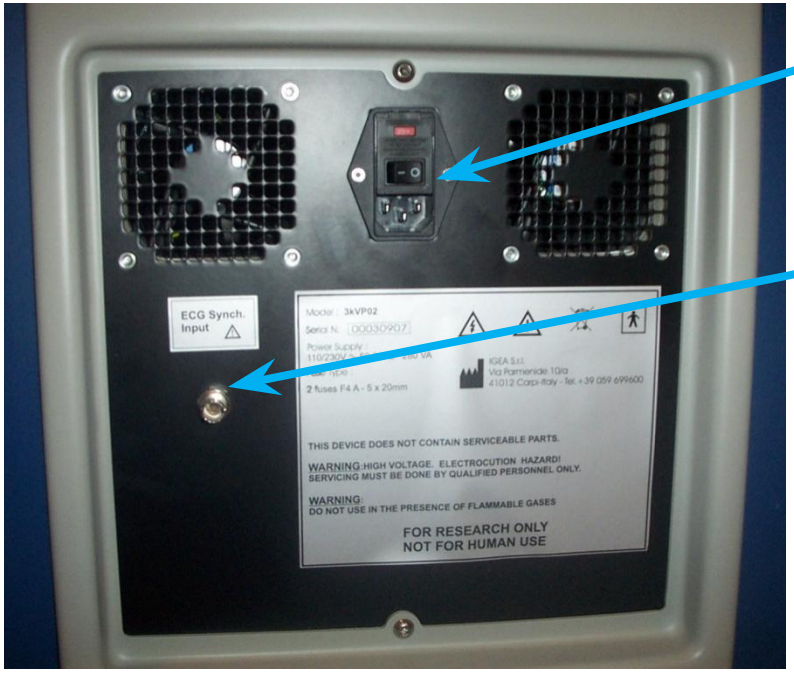
NanoKnife Set-Up

The power button is located on the back panel of the generator. This is also where the AccuSync cable gets plugged into. The foot pedal screws into the front of the system.



Back Panel of NanoKnife Generator

Power Switch

AccuSync Cable Attaches Here

Foot Pedal Attaches Here

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Demo Mode

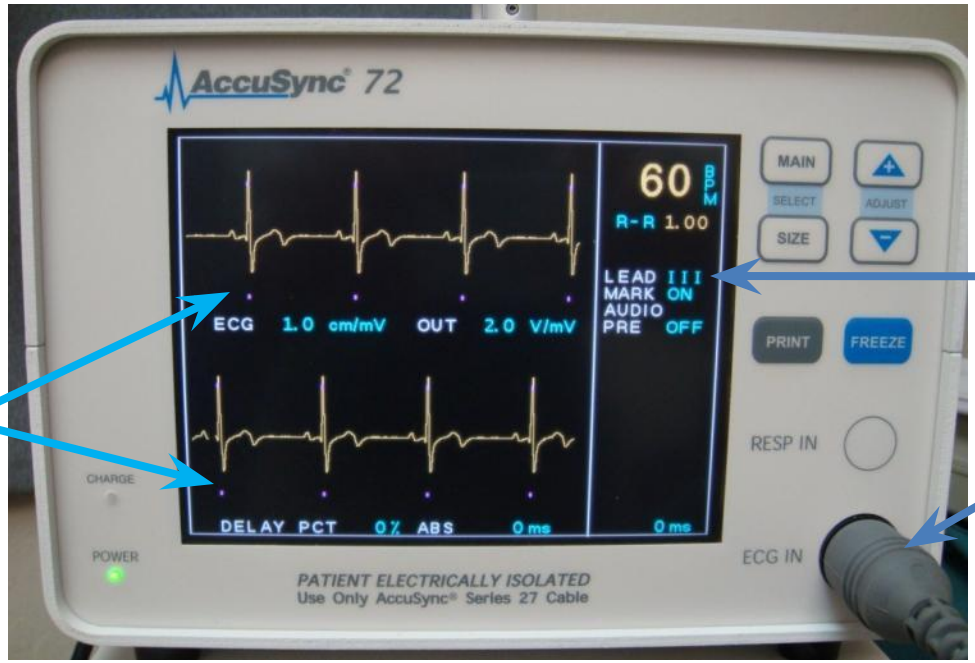
In the event the system boots in demo mode, check to make sure the STOP button is not depressed. The “Button Status” light should be on (Green)

AccuSync Set-Up

Cable Connected to BOTTOM jack labeled **“R-Trig”**

Power Switch

Power Cord



Lead Pair

Sync Marks

Patient Leads

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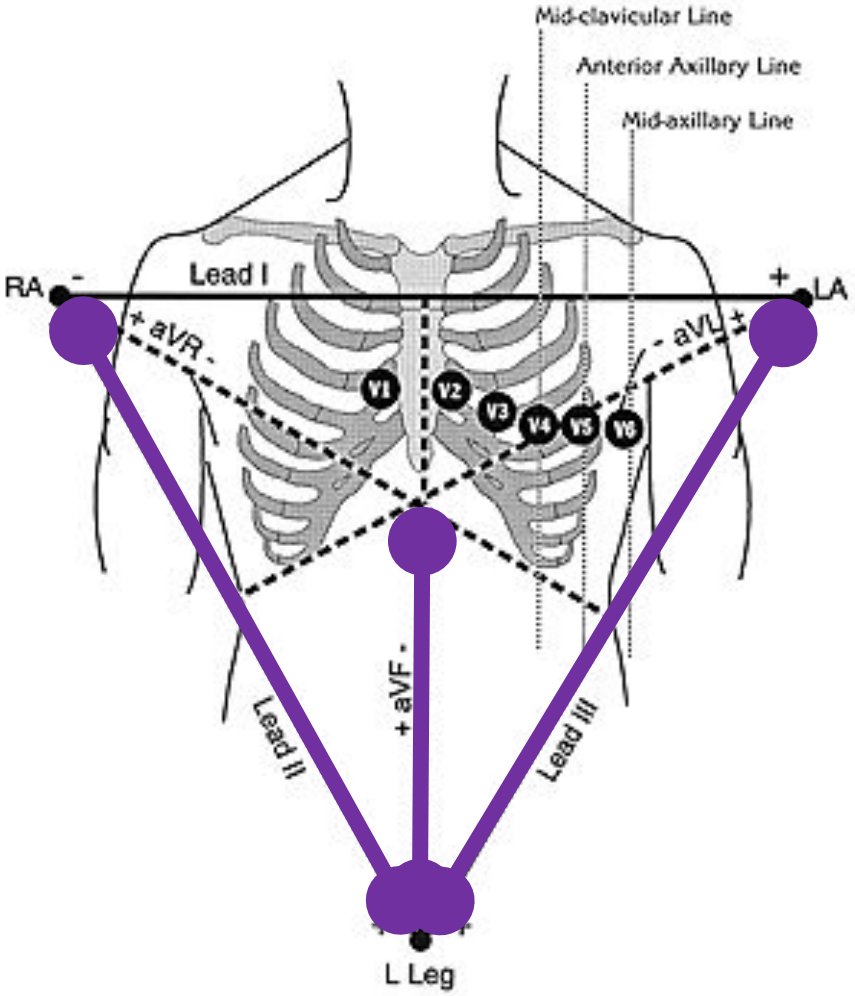
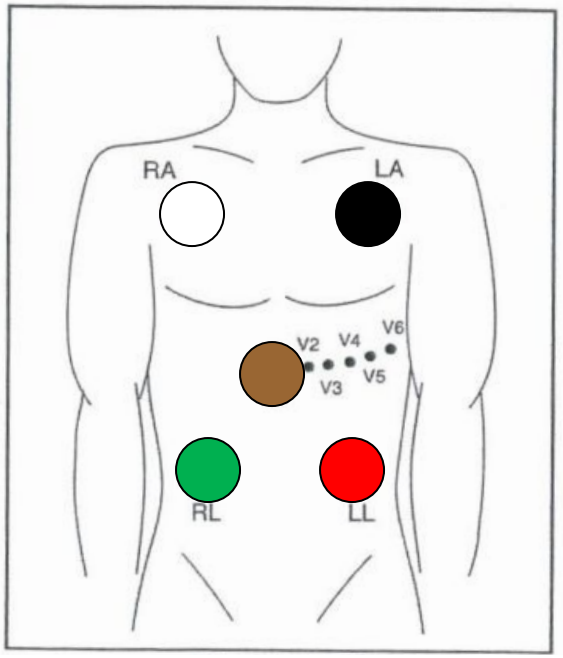
AccuSync Set Up



Recommend attaching AccuSync Leads before preparing sterile field



AccuSync Pad Placement Diagram

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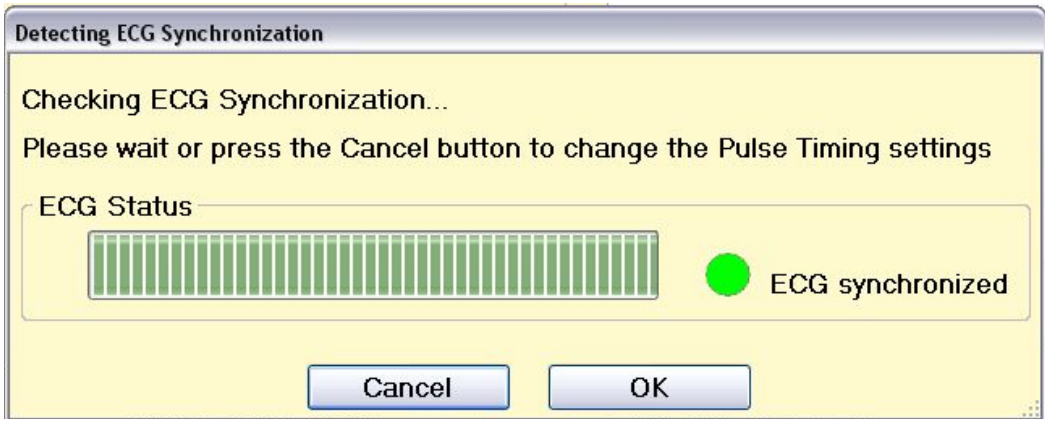
Software with AccuSync

- The generator will start in ECG Synchronization mode (default setting)

- You won't be able to leave the patient screen until the sync signal is connected and consistent



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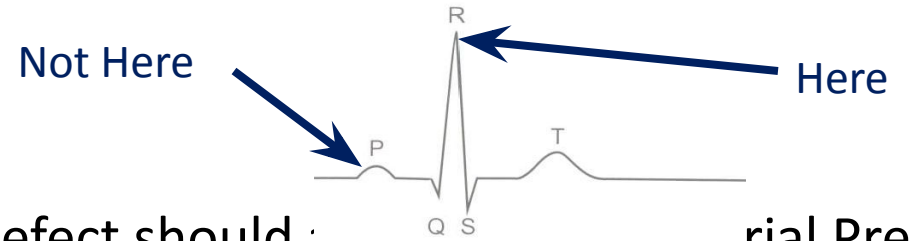
AccuSync Tips

- Select **2-3** leads with the Biggest R wave and smallest T wave

- Tip: Use same lead as anesthesiologist (I, II, III, aVF, aVL, aVR, or C)
  - They will most likely choose the best waveform.

- Right before Test Pulse, Verify that the:
  - Sync pulses are on R wave—not the p-wave



- Tip: No Defect should appear in the Arterial Pressure

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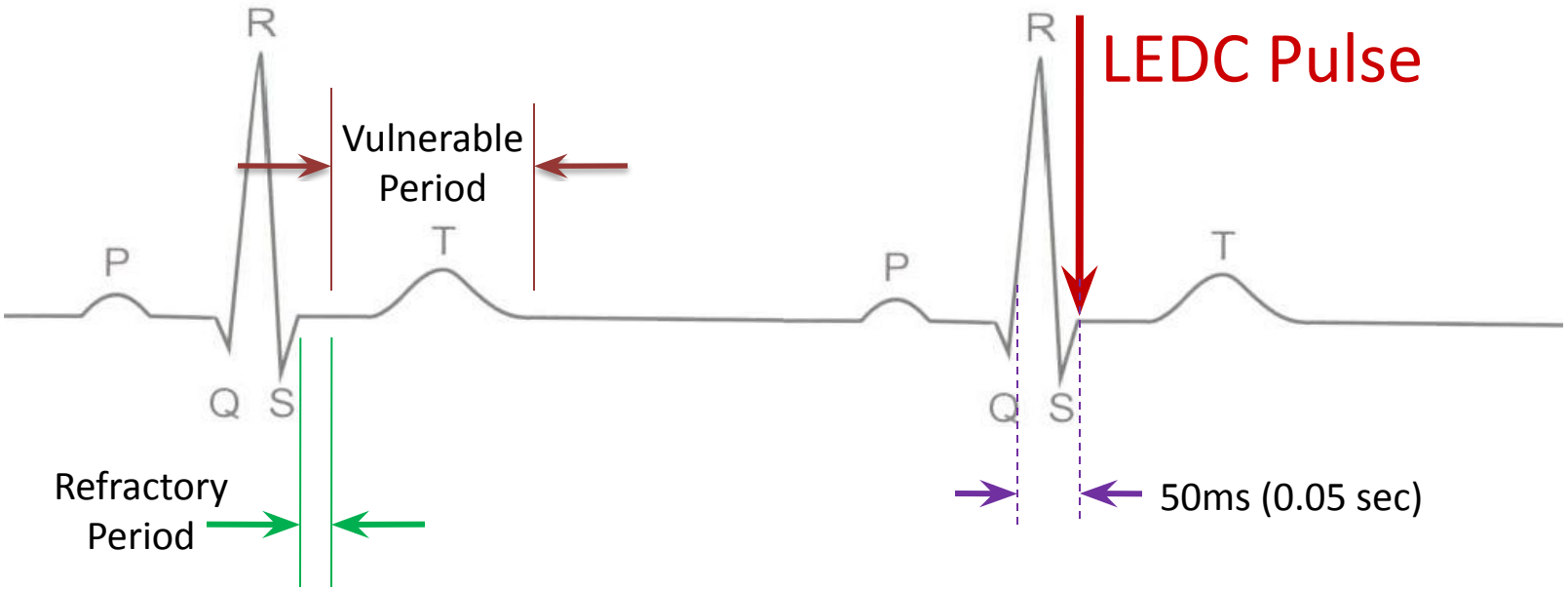
ECG Synchronized Pulse Delivery



Sync device (e.g. AccuSync 72) senses the rising slope of the R-wave, and sends a signal to the NanoKnife. The NanoKnife waits 50 milliseconds (.05 sec) and delivers 1 LEDC pulse. The LEDC pulse is delivered during (or just before) the refractory period.

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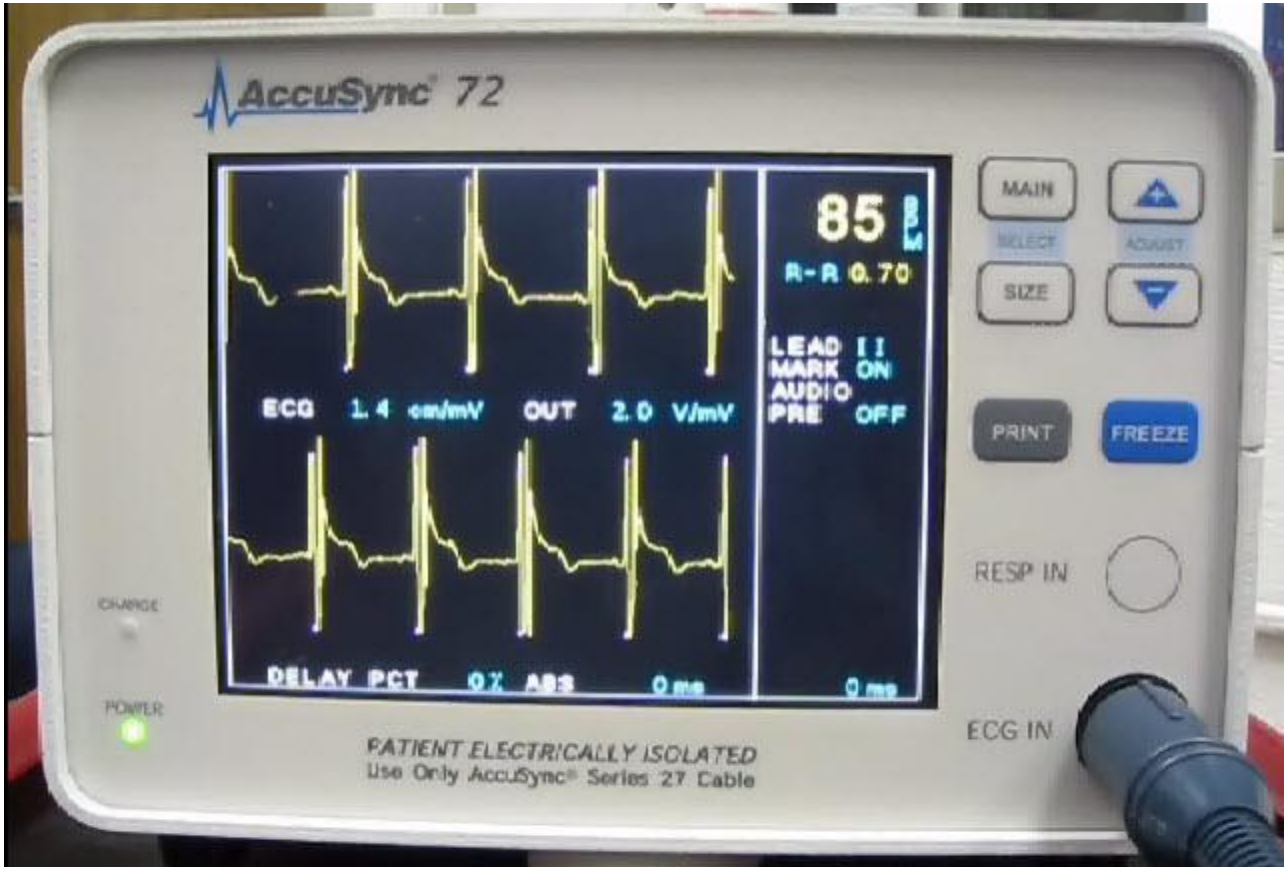
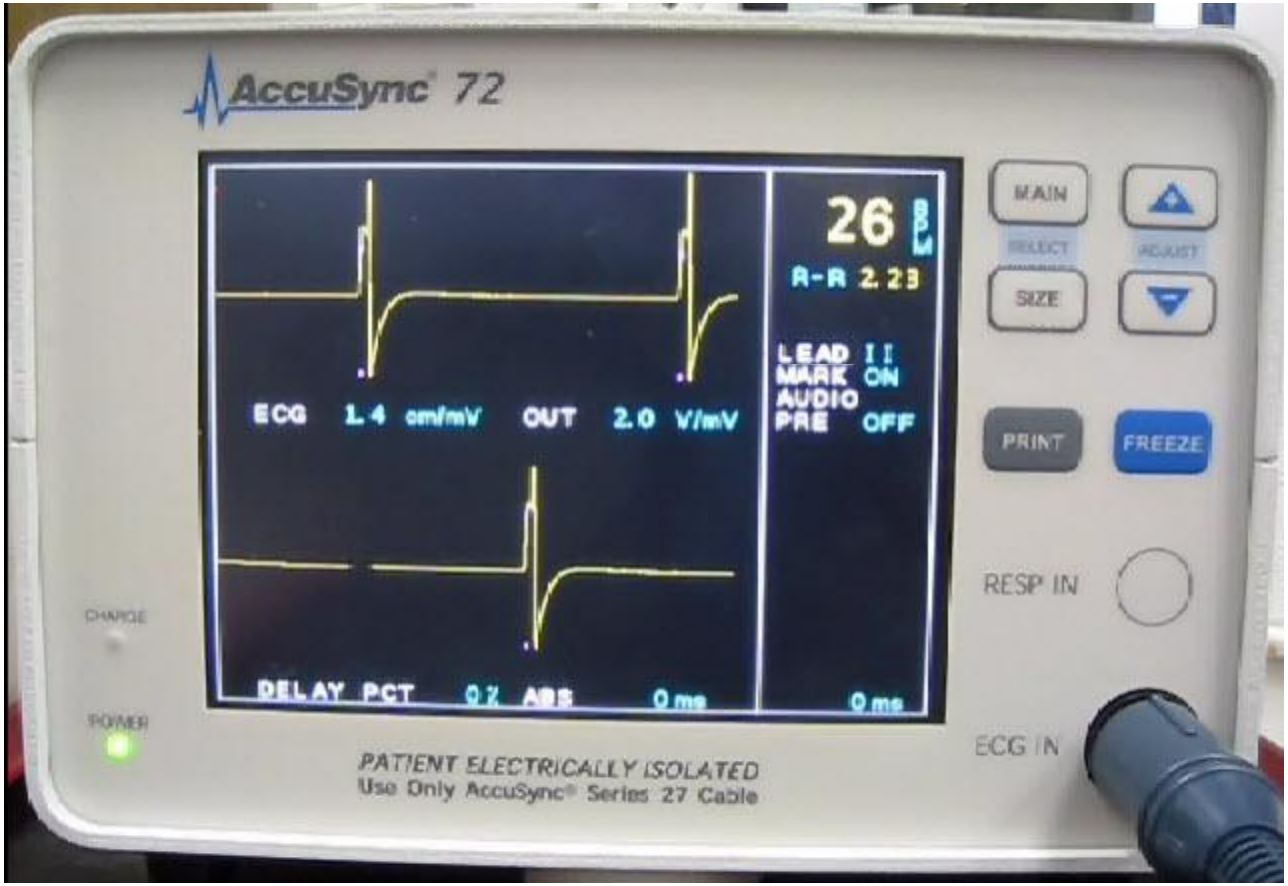
No Saturation



Heavy Saturation

Recommend changing lead pair to resolve saturation



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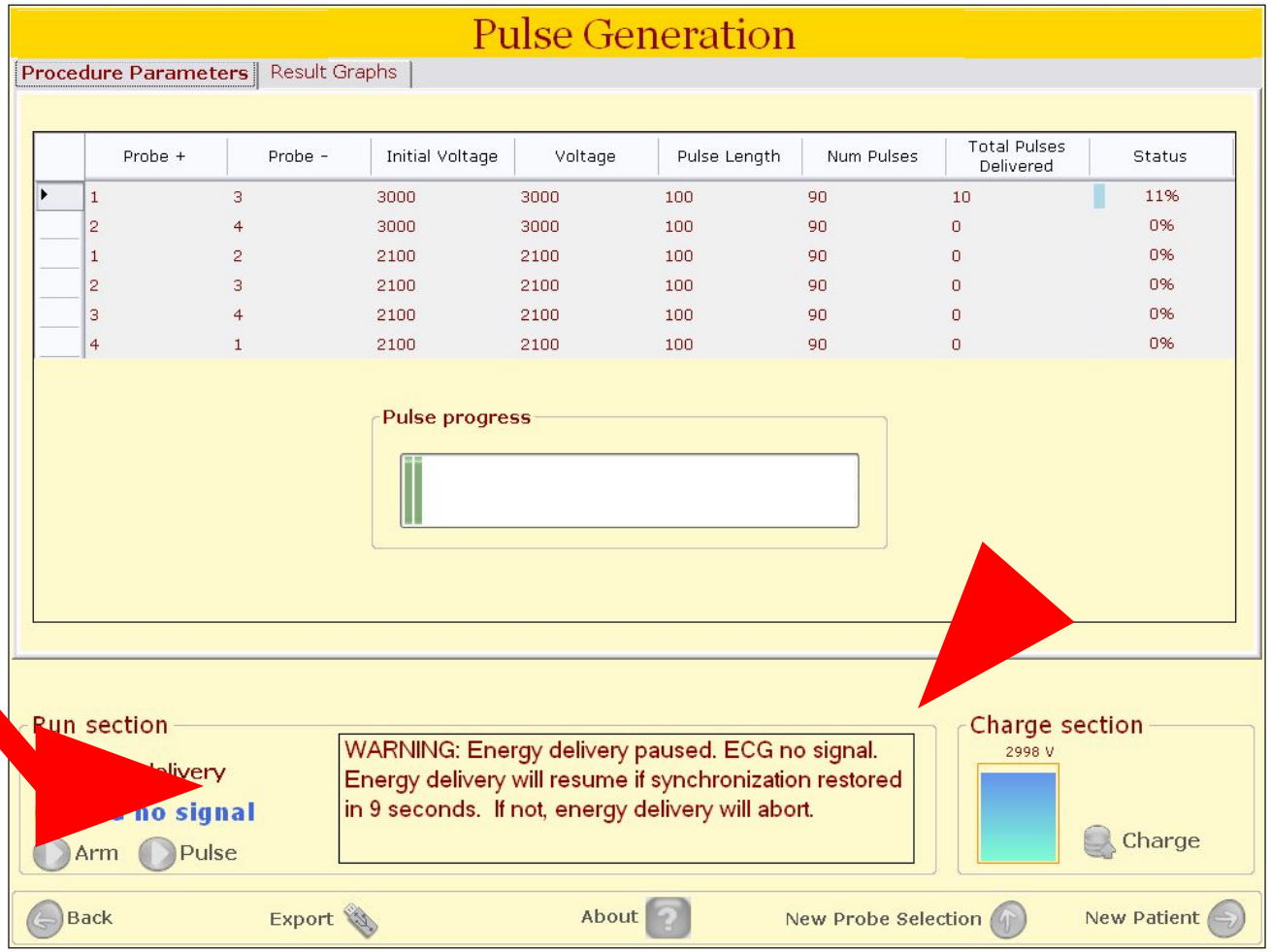
Trouble Shooting Saturation

Remove the BNC Cable from the back of the AccuSync Box

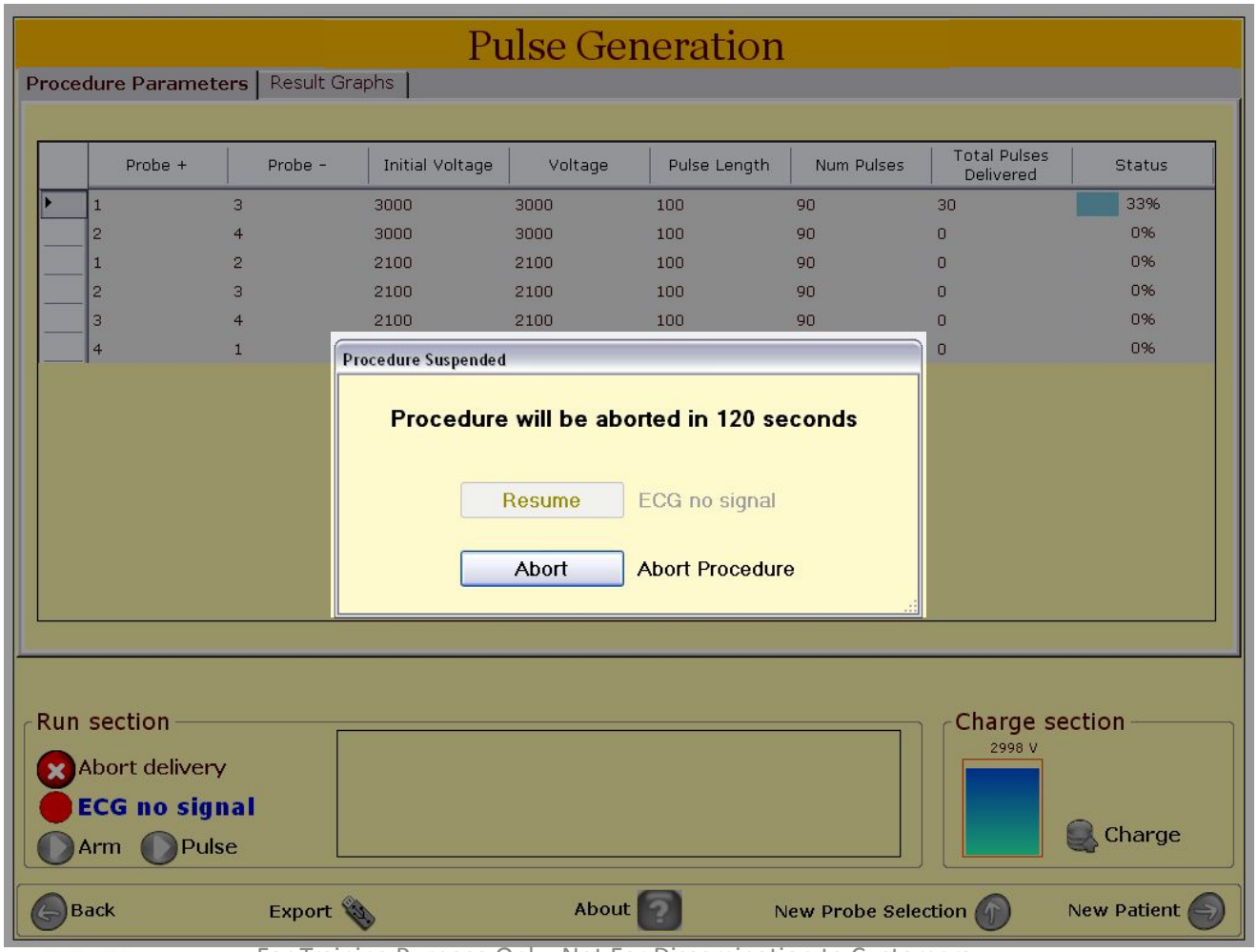
Trouble Shooting Saturation

Warning Message will Appear on Generator Screen



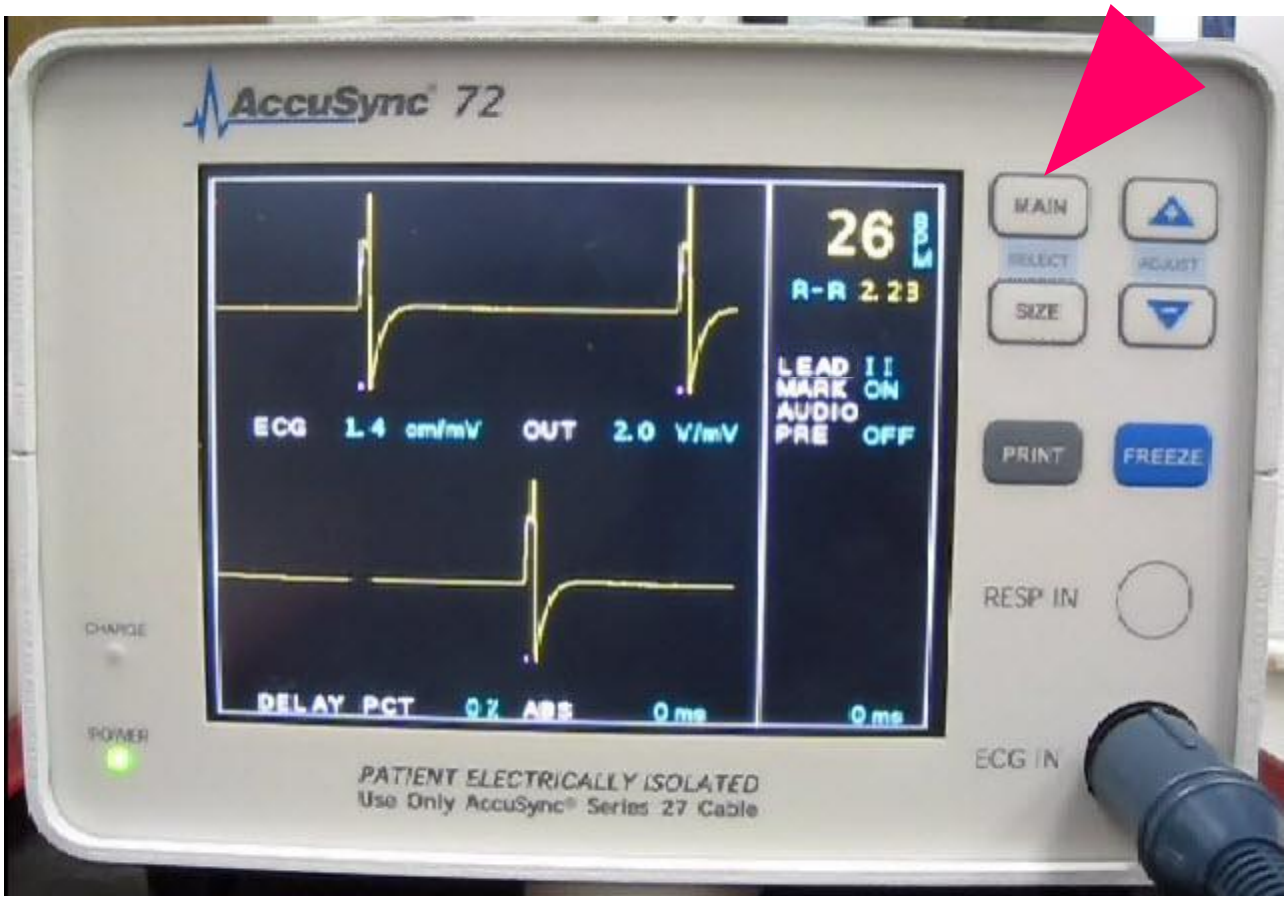
Trouble Shooting Saturation

After 15 seconds, a new window appears giving you 120 seconds before the procedure self aborts



Trouble Shooting Saturation

Press the “MAIN” button. (just tap it, don’t hold it down)



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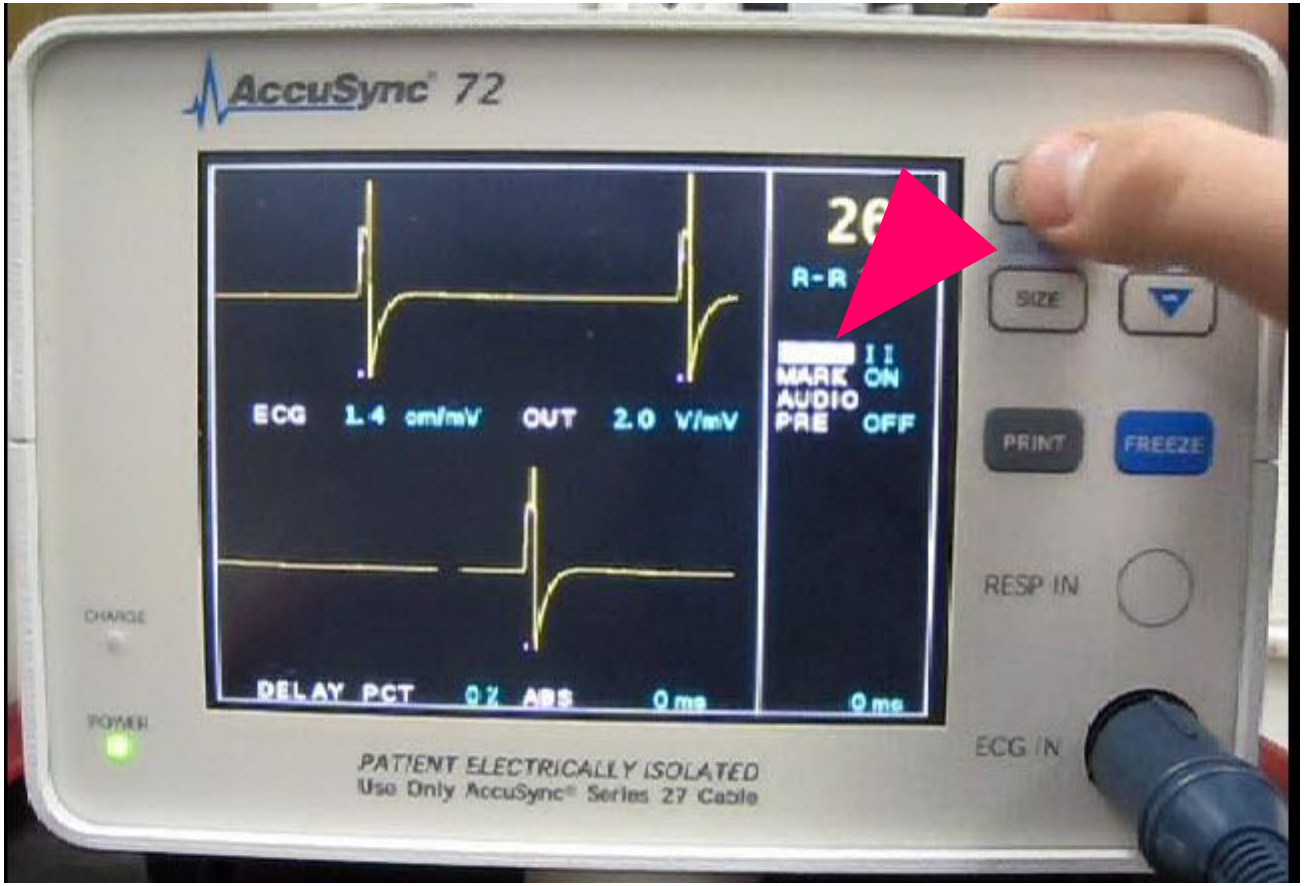
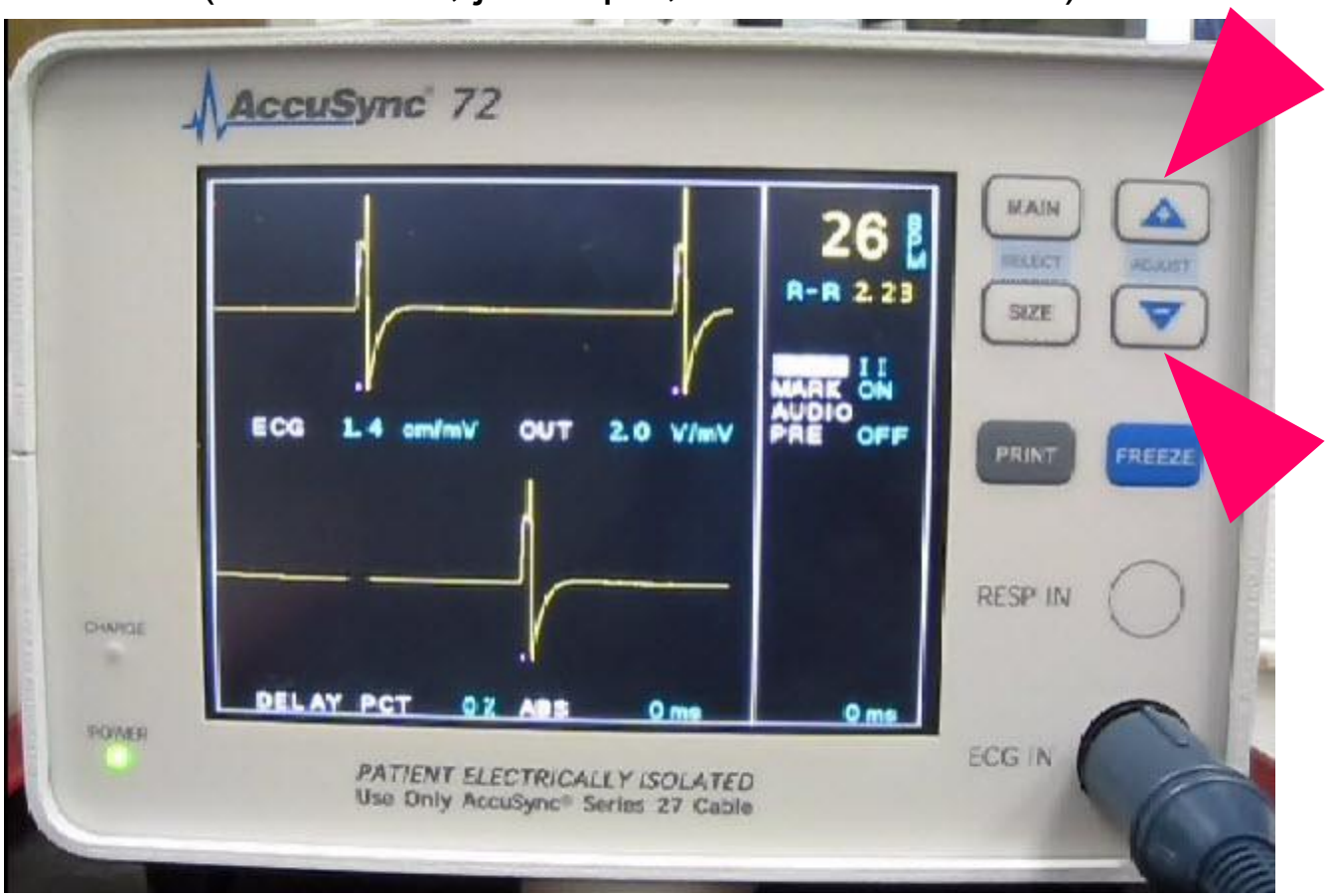
Trouble Shooting Saturation

You will see the “LEAD” field highlighted, if it’s not, keep pressing main until you see “LEAD” highlighted.



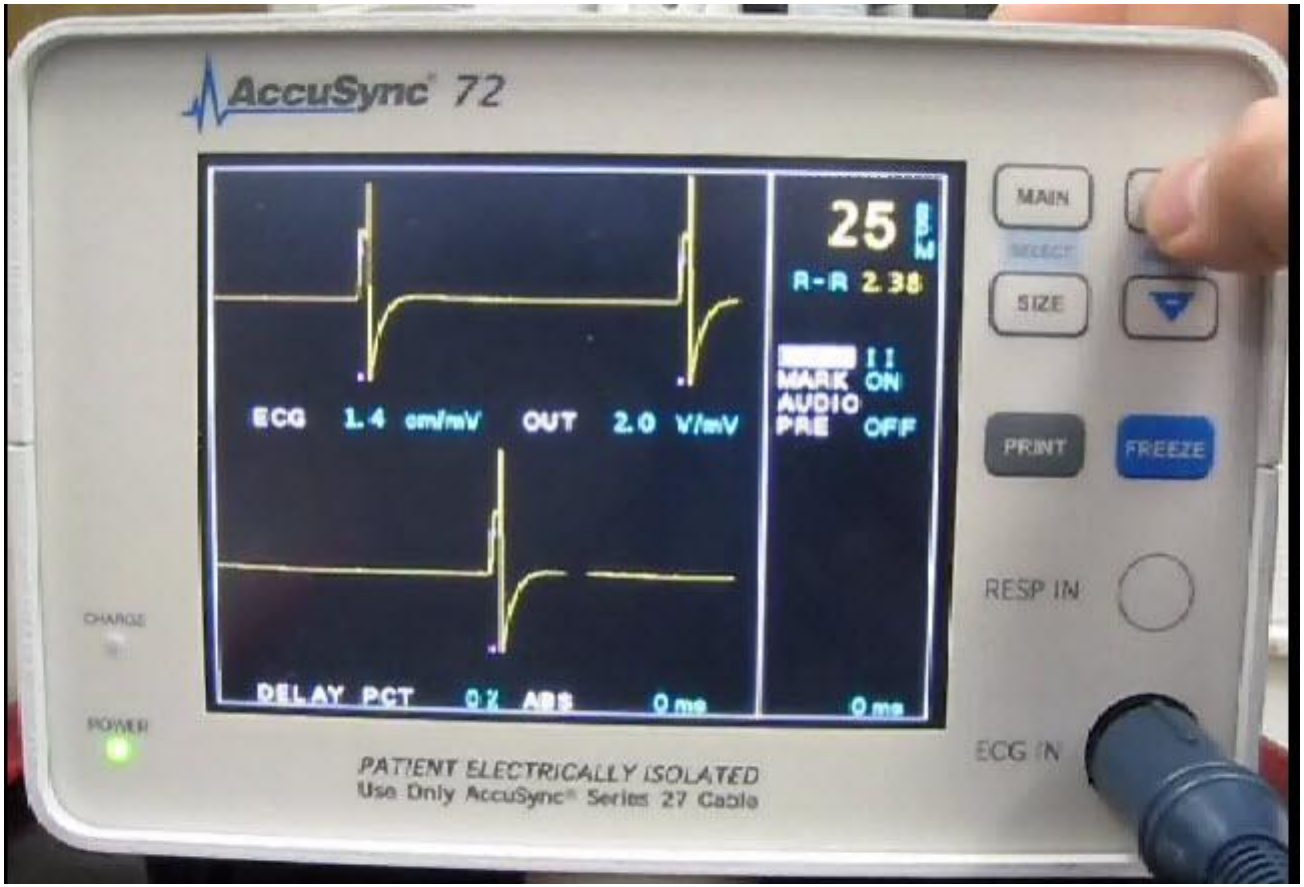
Trouble Shooting Saturation

Then press the “+” or “-” arrow to change the lead pair.
(Remember, just tap it, don’t hold it down)



Trouble Shooting Saturation

This will change the lead pair. Pressing “+”/UP arrow goes to lead III



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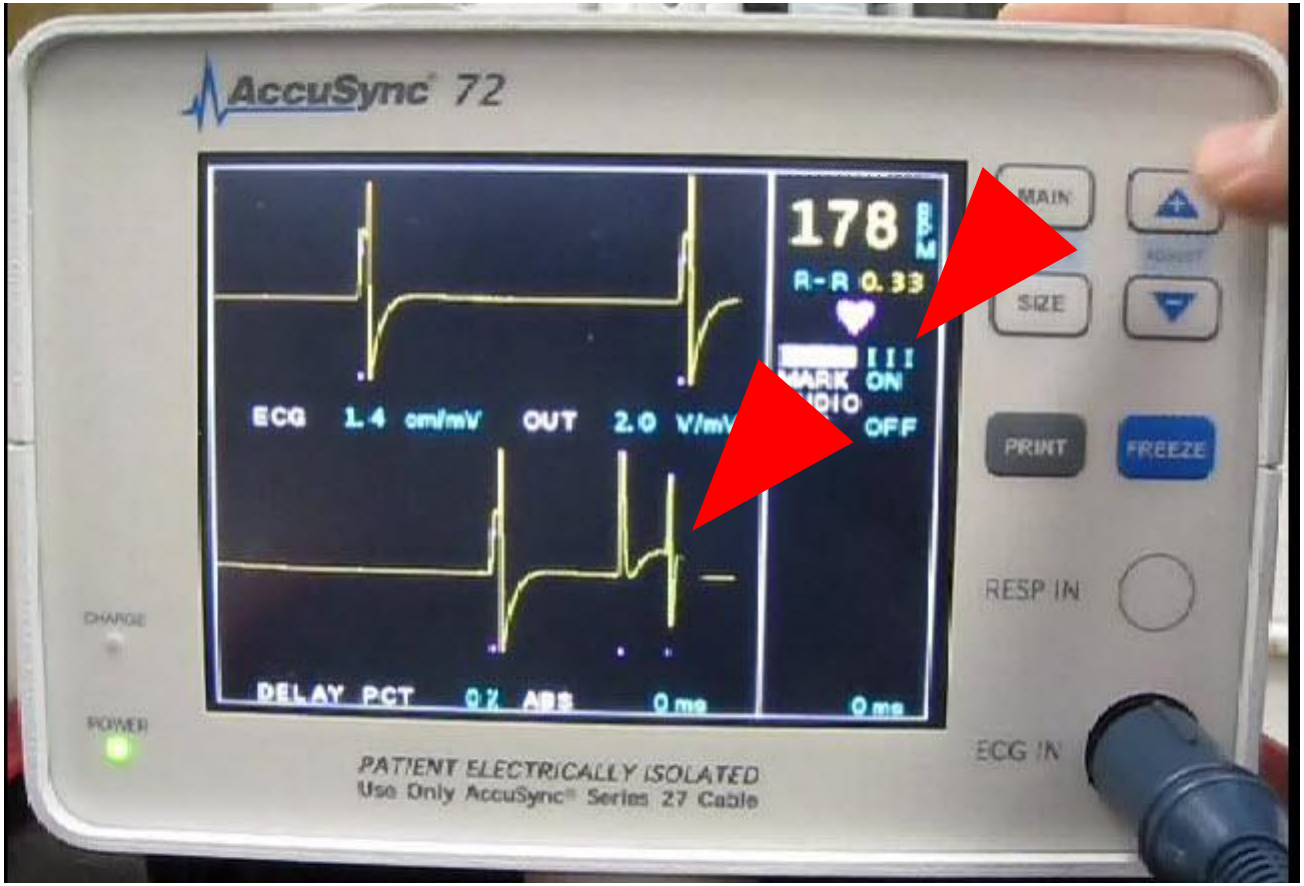
Trouble Shooting Saturation

After a second or two, you can start to see nice waveform



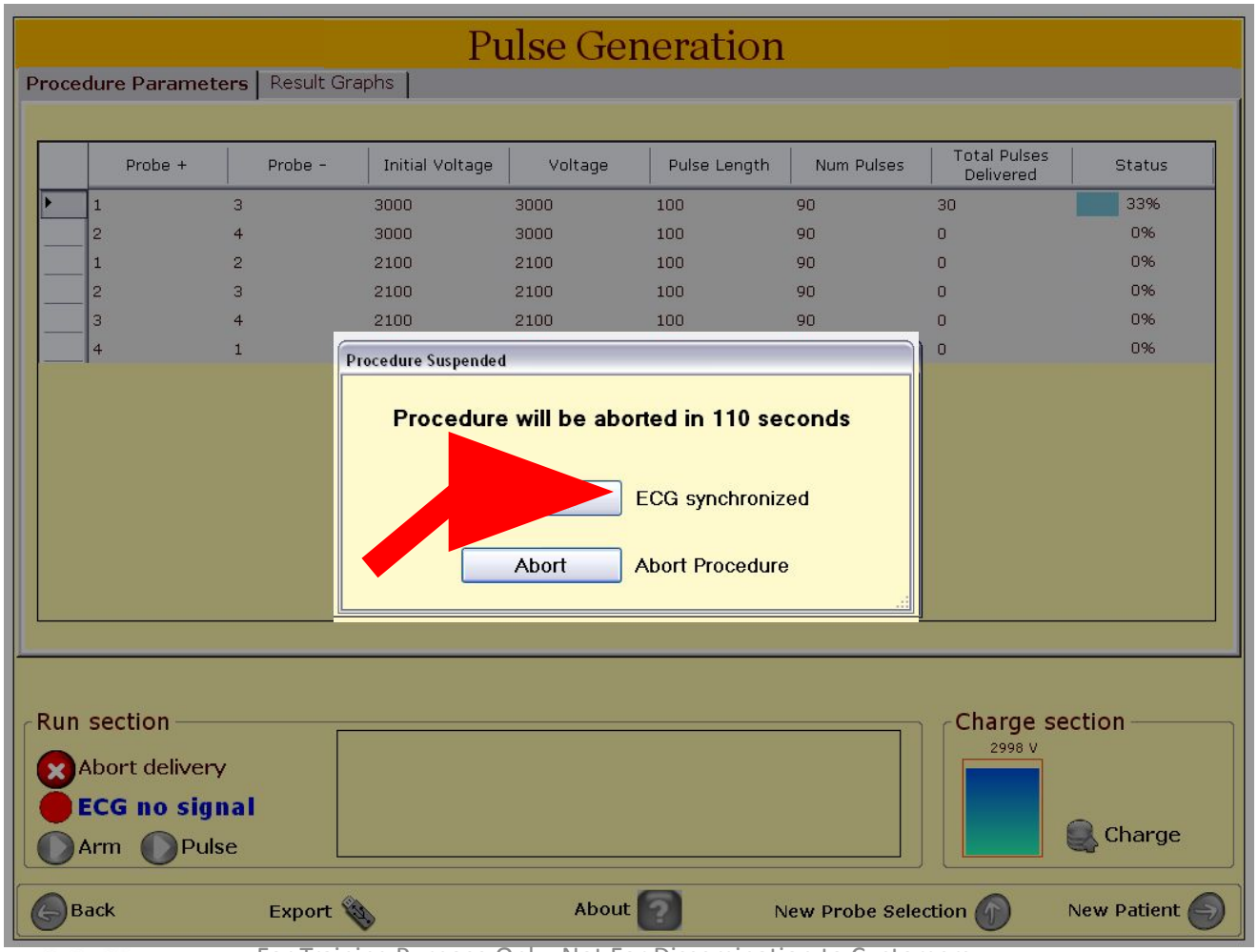
Trouble Shooting Saturation

Reattach the BNC Cable to the back of the AccuSync Box
After verifying proper waveform

NanoKnife®

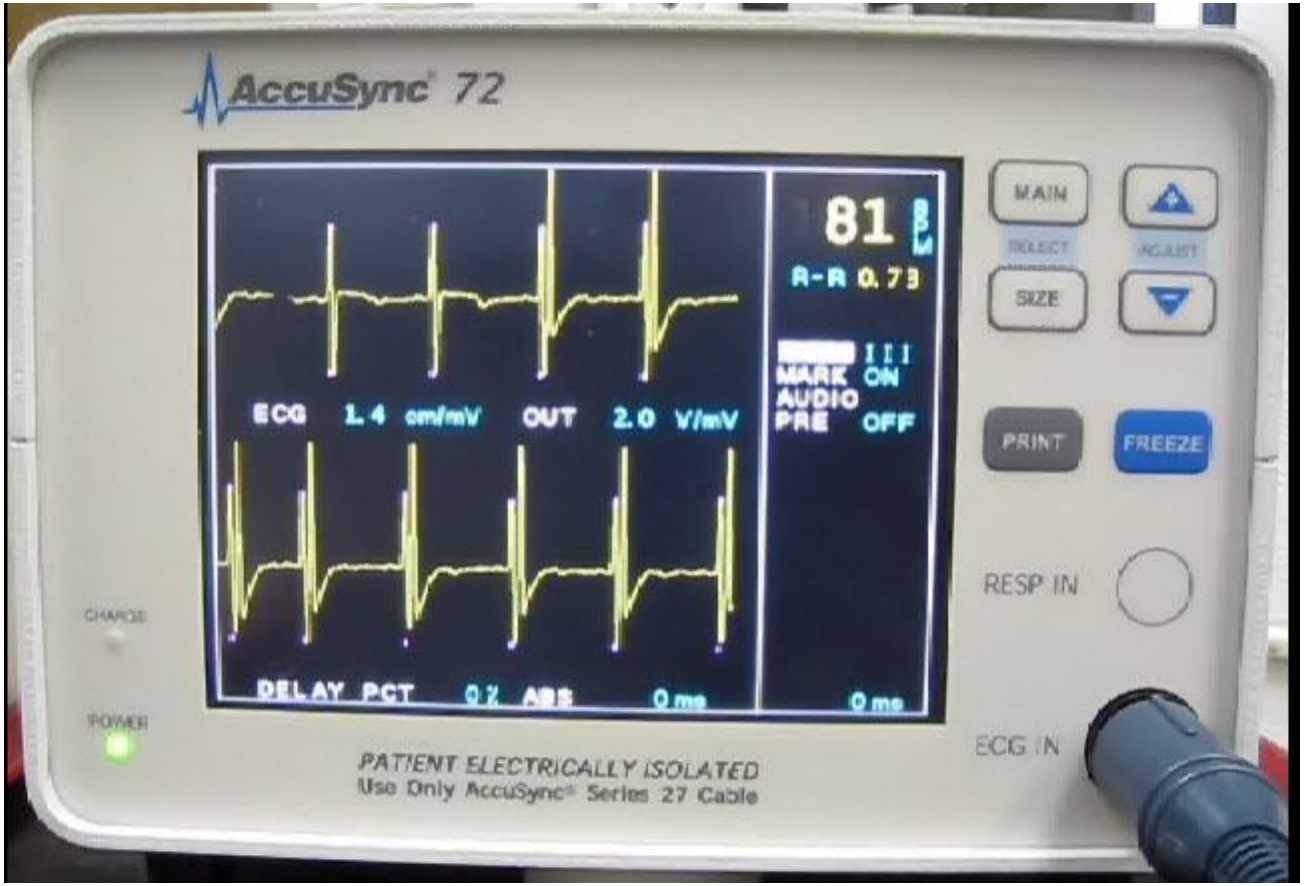
Trouble Shooting Saturation

Clicking Resume will continue the treatment from where it left off.



Trouble Shooting Saturation

Now your treatment time will decrease!



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AccuSync Troubleshooting

Problem	Solution
NanoKnife does not see sync signals during setup. ("Sync Lost" alarm)	•Check that the BNC cable on the back of the AccuSync is connected to "R-Trig" (and not 'ECG out'). •Is the cable connected to the NanoKnife?
"Sync Lost" alarm during treatment	•Did an ECG lead fall off? ("lead off" on sync device display) •Sync device missing R-waves after LEDC pulse. Switch leads.
"Noisy ECG"	•High HR > 120 bpm •Move AccuSync Cables away from Generator Panel Mount •Move bovie pencil away from patient. •Switch leads on AccuSync (II, III, and aVf seem to work best). •Plug NanoKnife into a different circuit. •Check AccuSync filter is set to 60Hz (hold size button 3 sec)
AccuSync saturates	•Change lead setting. •Move ECG buttons further from treatment area. •Use different button locations.
Anesthesia Monitor ECG interference	Monitor arterial pressure wave or monitor fast response SPO2 wave. Recommend Stopping pulse delivery if BP drops.
Can't get aVF, aVR, or aVL	Check connections on RL and V1 leads. These 2 can locate anywhere on the body (including siamesed w/ RA, LA, or LL).

NanoKnife Troubleshooting

Problem	Solution
Starts up in Demo Mode	•Reset red Emergency Stop button on front of console. •Green light indicates Emergency Button is Reset
NanoKnife Does not turn on (plugged in).	•Replace BOTH Fuses. Quick 'Off/On' cycling can blow the fuses. 'Off / Wait ~5 sec / On' prevents blown fuses. Carry spare fuses!
Can not leave the patient info screen	•Must enter a patient ID Number (Upper left of screen).
Can not arm, or can not activate	•Is the foot pedal plugged in? Wiggle cord at connector. Possible faulty foot pedal.
"Failure to Charge / Discharge"	•Go back to probe layout screen, forward to delivery screen. If that does not work, then shut down and restart.
USBFPGA communication error	•Shut down and restart. Unit will prompt shutdown.

Procedure Troubleshooting

Problem	Solution
Loud popping during pulse delivery; may also have over-current alarm.	** Stop ablation** •Reduce exposed electrode and treat at 2 depths. •Reduce treatment voltage. Try Reducing Electrode Exposure First •Is the entire exposed electrode INSIDE the target tissue?
Current too low	•Are electrodes plugged into the generator and in the right number socket? •Low current may be normal if low voltage (<1500V) and short probe exposure (<1.5 cm). •Normal in lung.
Current too high	Reduce probe exposure, perform duplicate treatment at 2 depths, re-position probes further apart, shorten pulse to 70usec.
Treatment aborted due to high current	Repeat aborted pulse trains at a lower voltage; OR Reduce probe exposure, repeat aborted trains at 2 depths. Repeat pulse delivery until 70-90 pulses have been delivered.
Patient movement	Suggest muscle blockade similar to that used for a thoracotomy. Paralytic half life is usually 20 min. Additional dose may be needed prior to LEDC pulse delivery

Procedure Troubleshooting

Problem	Solution
Probes are migrating out during pulse delivery	** Stop ablation** •Check to ensure cables are clamped to sterile drape to reduce weight
Probes are migrating inwards during pulse delivery	•Is the patient fully paralyzed? 0-1 twitches? •Use a tuohy borst adapter or steri-strip flag to prevent probe migration
Missing ablations in lesion estimation software	Verify the treatment table is accurate, pulses will be delivered according to table, not image. You can select different probe icons to visualize the missing lesion, usually this makes another pair disappear.
Charge “flutters” prior to test pulse	Press back, then forward. If this does not work, change configuration to include 1 extra probe, add treatment pair including extra probe, set spacing > 2cm from other probes, reduce pulse for that one pair to 10, it will result in low current warning, proceed with treatment.
Narrow pulse widths on output graph	IGBT2 Calibration Error, Service Required. Operate in low current range to get through case (i.e. reduce probe exposure).
Pulse delivery stalls mid-treatment	Must abort treatment, treat like any other high current condition. (e.g. reduce electrode exposure, reduce pulse width, reduce voltage)

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Procedure Troubleshooting

Problem	Solution
Software Lags	Shut down and restart system. Do this between patients to prevent this issue. Usually caused from performing too many treatments.
Screen Freeze Mid-Treatment	No option but to hard reset system using switch on back panel of generator. Treat like any other high current condition. (e.g. reduce electrode exposure, reduce pulse width, reduce voltage)
Long Delays between pulses with ECG synchronization	Caused by low amplitude R-Waves, select different lead with higher R-Wave amplitude. Could be caused by variations in the patient's R-R intervals.
Memory Error	No option but to shut down. Restart system and re-enter patient and treatment information. This is caused by a memory leak in the current 2.1.0 software and can be prevented by shutting down machine in-between patients.
Multiple low current warnings after Test Pulse	If all share common probe number, e.g. 2, then output 2 is most likely faulty. This can be caused from loose cabling or a defective switching board. For example, if a four probe array was being used, set up the treatment as a five probe configuration, set probe 2 aside, and put probe 5 in its place, connect probe labeled 2 in the generator output labeled 5 and ensure all the treatment pairs accurately use 5 instead of 2.

Ohms Law V=IR

- V= Voltage (Volts) – “The Input”
- R = Resistance (Ohms) - “Tissue Dependent”
- I = Current (Amps) – “The Output”
- Lung has **HIGHER** resistance
- Conn
- Urine
- Electr

High Resistance (Insulator/Dielectric)	Low Resistance (Conductive)
Air	Metals (Copper/Gold)
Plastics (Polyimide/Silicone)	Water (Saline)
Non-Metals	Bile
Elastin & Collagen	Urine

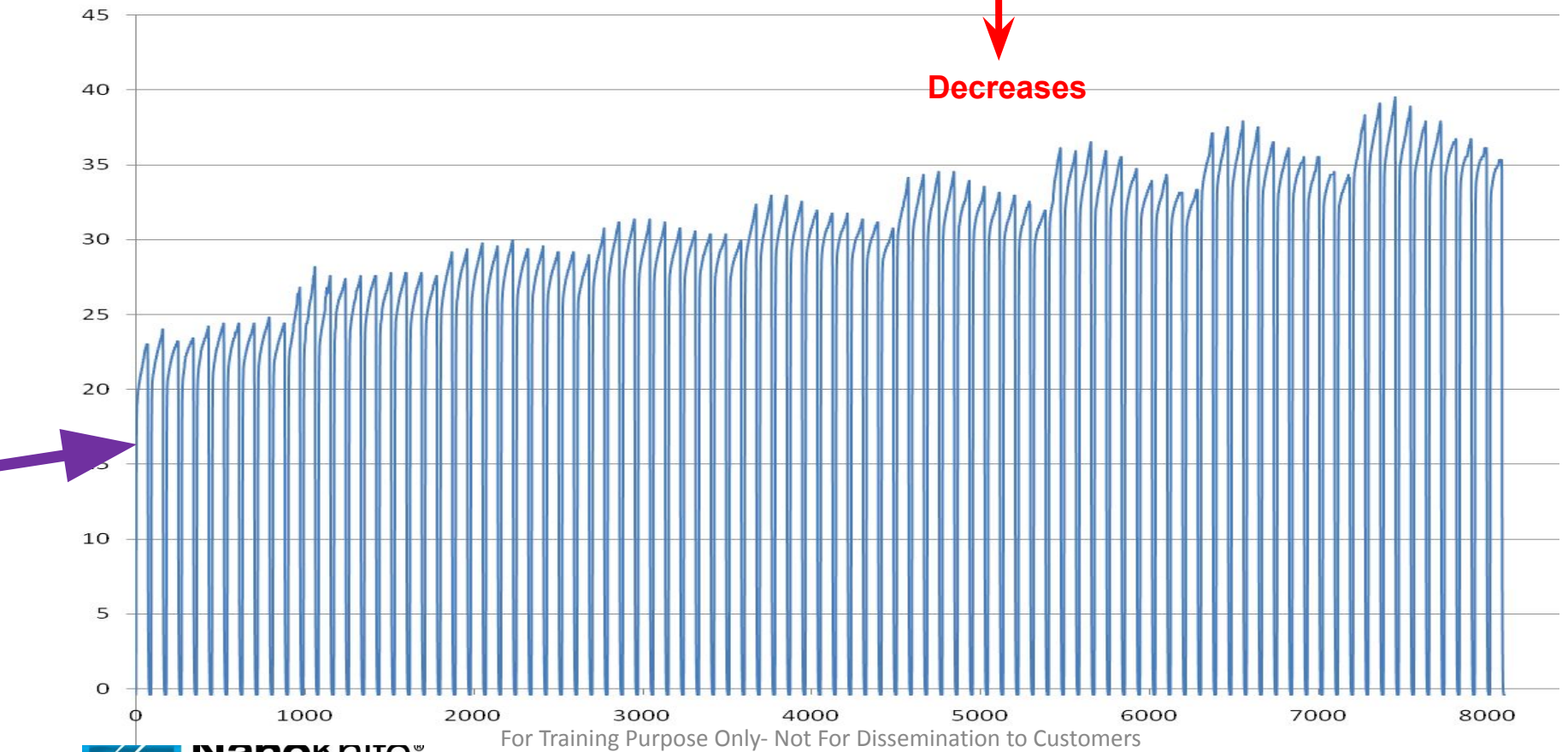
LOWER

Current Output

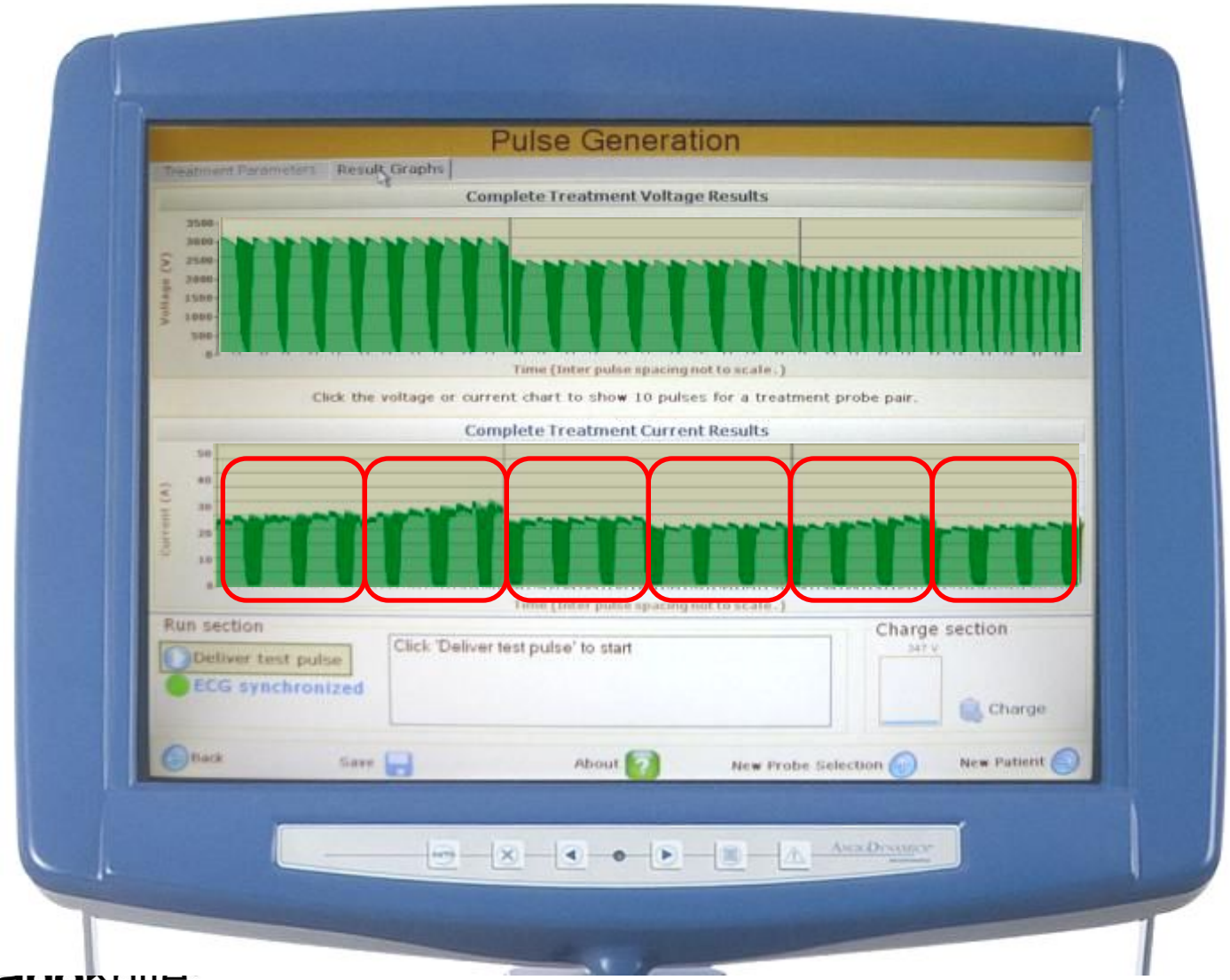
Increases

Stays the Same → V = I x R

Decreases

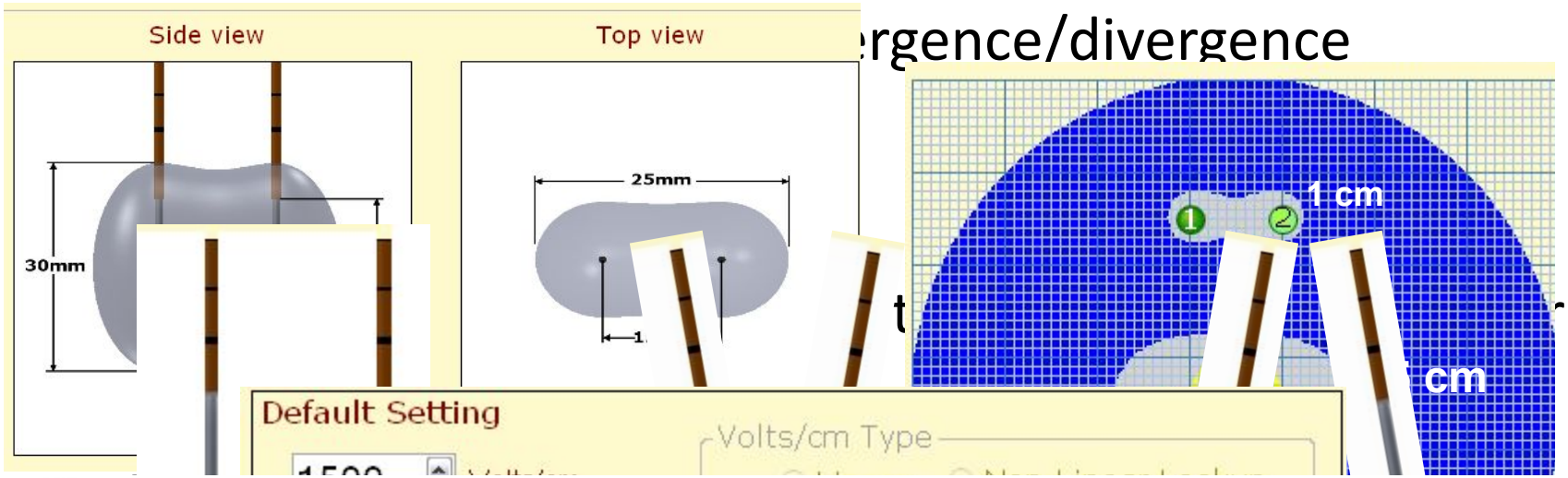


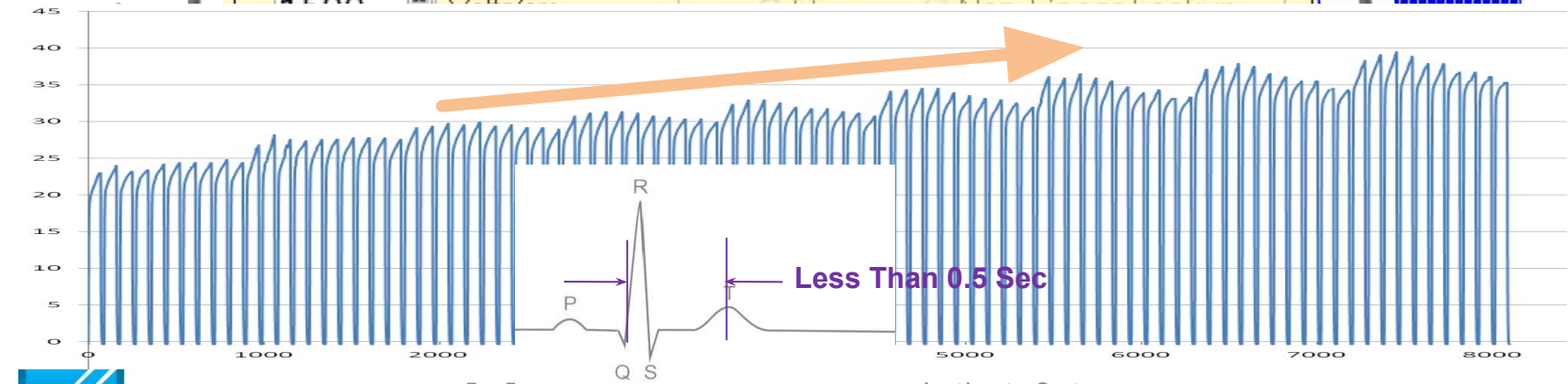
Current Output



Optimal Values

- Probe distance – less than 2.0cm and greater than 0.5cm
  - Physician should aim for 1.5 – 1.75cm between probes





Review Questions

1. **What options are available to solve an over-current condition?**

   Reduce Probe Exposure / Reduce Pulse Length (70 µsec) / Reduce Voltage

2. **How do you solve AccuSync saturation?**

   Change Lead Pair (a.k.a. Vector) / Move Buttons Further from Treatment Area

3. **What do you check if the NanoKnife does not recognize a sync signal?**

   BNC Cable is connected to "R-Trig" / HR below 120 bpm / Change Lead Pair

4. **How can you tell if AccuSync is sending signals?**

   Triggering is indicated by pink marks on AccuSync Display Monitor

5. **What can cause low current errors?**

   Probes too far apart / Short Electrode Exposure / Low Input Voltage / Probe Not Connected

Highlights

- **Make sure:**
  - BNC Cable is Attached to “R Trig”
  - Pink Marks Indicates Proper Sync Output
  - The Generator has ECG Sync Enabled (default setting)
- **Select lead with the Biggest R wave and smallest T wave**
- **Recommend attaching AccuSync Leads before preparing sterile field**
- **Saturation can be corrected:**
  - Change lead setting.
  - Move ECG buttons further from treatment area.
  - Use different button locations.
- **V = I x R**
- **Trouble Shooting**
- **Optimal Parameters**

Thank you