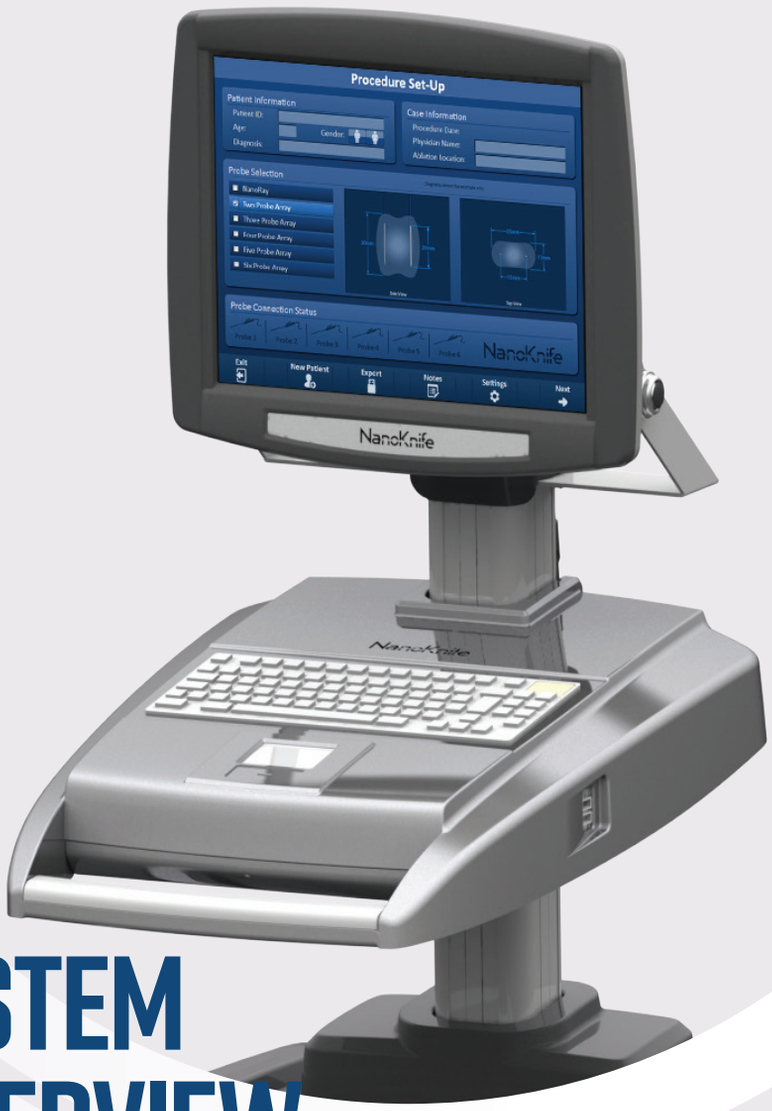
angiodynamics



NANOKNIFE SYSTEM PROCEDURE OVERVIEW QUICK REFERENCE GUIDE

SOFTWARE VERSION 3.0

NanoKnife 3.0
Irreversible Electroporation (IRE)

Aquilant
A HC2I Group Company
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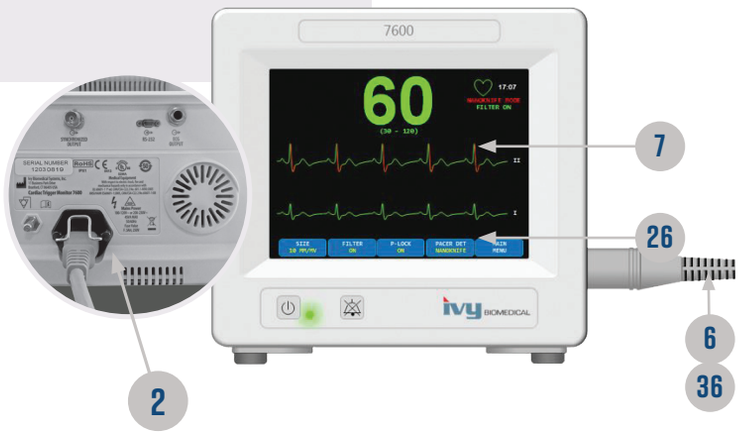
NANOKNIFE USER:

- Anesthesia Team
- Physician
- Nurse/Tech

BOLD NUMBERS:

Corresponds with a specific part of an image



Before the Patient Enters the Room

1 Gather NanoKnife Probes & NanoKnife Probe Spacers (Optional)

2 Plug in & Power ON the NanoKnife System & External Synchronization Device

3 Enter Procedure Setup information

Note: Complete NanoKnife System Self-Test prior to entering the information

4 With Physician, in-service Anesthesia Team on NanoKnife procedure guidelines referenced in the User Manual

After Intubation/Prior to Sterile Draping

5 Attach External Synchronization Device ECG leads to patient

6 Plug ECG cable into External Synchronization Device

7 Identify & select lead pair displaying the best ECG waveform

After Sterile Draping

8 Measure target tissue dimensions under image guidance and determine probe length and number of probes needed

9 Select the desired probe array

10 Using sterile techniques, open & pass off NanoKnife Probes and Spacers (optional) to sterile field

11 Adhere the provided sterile number labels to both ends of the cable attached to each NanoKnife Probe

12 Uncoil NanoKnife Probe cables & pass off to Nurse/Tech

13 Connect each NanoKnife Probe connector to the NanoKnife System's corresponding numbered output

14 Advance to Procedure Planning screen & enter the soft tissue dimensions in the Lesion Zone section

15 Select Probe Tip exposure & place

16 Measure inter-probe distance(s) using image guidance

17 Update the Probe Placement Grid with the Physician's inter-probe distance measurements

18 Modify default settings in Table as needed & enter Probe Exposure values with the Physician's preferences

NanoKnife Pulse Delivery

19 IMPORTANT: Check with Anesthesia Team to ensure adequate paralysis (0/4 twitches)

20 Use the twitch monitor to ensure adequate paralysis (0/4 twitches)

21 Advance to Pulse Generation screen & place double foot pedal in a location for the Physician to access

Note: Please be prepared for significant changes in blood pressure

22 Physician to deliver tissue conductivity test sequence

23 Inform the Physician of the conductivity test results

24 Under Physician instruction, select the Proceed button

25 Activate NanoKnife pulse delivery using double foot pedal sequence (Arm then Pulse)

26 Monitor External Synchronization Device & NanoKnife System to ensure proper synchronization, change lead pairs as needed

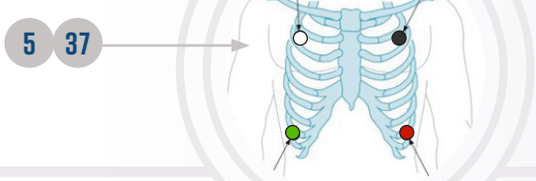
27 Monitor target ablation zone site & NanoKnife Probe placements under direct visualization

28 Inform the Physician and NanoKnife User of any significant BP or HR changes

29 During and after completion of pulse delivery, view Current Results graph

30 Analyze Results graphs, evaluate ablation site using image guidance, & remove from target ablation zone

31 Export procedure files to USB storage device (optional)



End of Nanoknife Procedure

32 Disconnect all NanoKnife Probes from the NanoKnife System and dispose of accordingly

33 Click the Exit button from the Navigation Bar on the Pulse Generation or Procedure Setup screens

34 Wait for System to finish the shutdown sequence, then power OFF & unplug the NanoKnife System and External Synchronization Device

Note: System will ask to confirm shutdown through two pop-ups

35 Wrap NanoKnife System power cable neatly around back handle

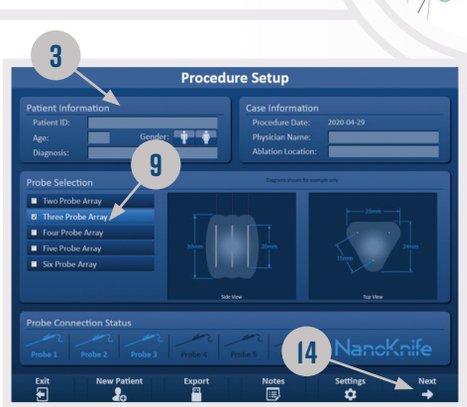
36 Unplug ECG cable from External Synchronization Device

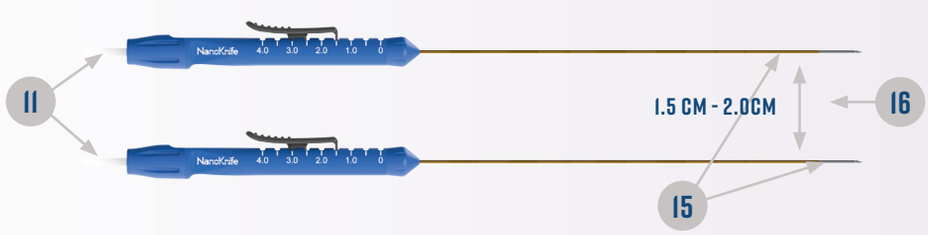
37 Detach External Synchronization Device ECG leads from patient; **DO NOT THROW AWAY ECG CABLE/LEADS**

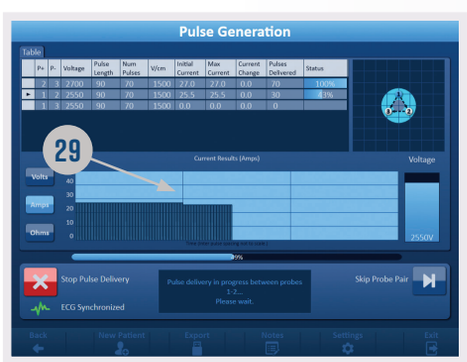
38 Clean ECG cable/leads with disinfectant wipes, neatly coil leads, & wrap around the back handle of the NanoKnife System

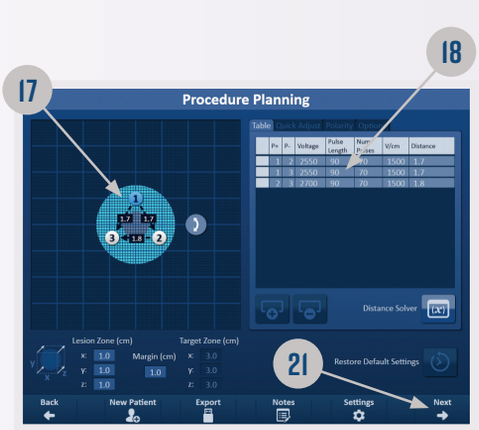
39 Neatly coil double foot pedal cable and store in side pocket of NanoKnife System

40 Carefully transport NanoKnife System to proper storage location









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Important Risk Information

Indication For Use

US: The NanoKnife System with six outputs is indicated for surgical ablation of soft tissue.
CE: The NanoKnife System is a medical device for cell membrane electroporation. Electroporation is a phenomenon that occurs in cell membranes as cells are exposed to an electrical field of sufficiently high intensity. The electric field acts as a physical stimulus, bringing about alterations in cell membranes that result in increased permeability.

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

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 o Reflex tachycardia o Ventricular tachycardia • Ventricular fibrillation • Damage to critical anatomical structure (nerve, vessel, and/or duct) • Fistula formation • Hematoma • Hemorrhage • Hemothorax • Infection • Pneumothorax • Reflex Hypertension • Unintended mechanical perforation • Vagal Stimulation, asystole • Venous Thrombosis

Refer to Directions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects, and Contraindications. Observe all instructions for use prior to use. Failure to do so may result in patient complications. CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

NanoKnife.com

NOTE: These instructions are not comprehensive. Refer to the User Manual and Instructions for Use for detailed instructions, warnings, precautions, and possible adverse effects.