NT2000iX™ Radiofrequency Generator

RFG-NT-2000

Instructions for Use

NeuroTherm

Contents

Indications for Use

The NT2000iX™ generator is intended for lesioning neural tissue. The NT2000iX™ generator is intended to be used for pain management. The NT2000iX™ generator is to be used only with separately cleared/approved lesion/temperature probes (NeuroTherm™ radiofrequency probes and SPINECATH™ and ACUTHERM™ catheters). The NT2000iX™ generator is indicated for use in the peripheral nervous system.

Procedural Overview

Clinician Requirements:

This device is only to be operated by a medical doctor trained in pain management.

Diagnosis:

The patient's pain is located using various diagnostic techniques. The clinician should use the results of these tests, as well as experience and training, to determine whether radiofrequency (RF) lesions of identified neural tissue will improve the patient's symptoms. Published guidelines are available to assist the clinician in determining when neural ablation is indicated, and in selecting the appropriate ablation technique and application. [1, 2, 3, 4, 5]

Patient preparation/electrode placement:

The patient is positioned on an appropriate treatment table and is prepped using standard techniques. Fluoroscopic guidance or some other type of anatomical localization technique is used to place the treatment cannula/electrode. Before the commencement of treatment, treatment settings are selected and the patient information can optionally be entered. For in depth descriptions on electrode connections, lesion sizes, and basic operation procedures refer to Testing, Electrode Connections, Lesion Sizes and Basic Procedures (page 55).

Nerve localization:

Sensory and motor stimulation are used to further fine tune electrode placement for many procedures. Published studies provide further guidance on these techniques. [6, 7] Both sensory and motor stimulation frequencies are available with the NT2000iX™ RF generator. Typically, low threshold responses are pursued for sensory stimulation, while high threshold responses are desired for motor stimulation. This implies proximity to the sensory nerves, while assuring distance from the motor nerves. Stimulation cannot be performed during the RF treatment process, and only one output channel can deliver stimulation pulses at any one time**.**

RF treatment:

RF energy is delivered to the target nerves during treatment, thus causing the tissue to heat to a selected set temperature under feedback control. Energy can be delivered in Monopolar Mode using 1, 2, 3, or 4 electrodes, in Dual Mode between electrodes 1-2, 3-4, or 1-2 and 3-4, or in Simplicity Mode. Parameters such as temperature, voltage, current, and impedance are continuously displayed during energy delivery. Treatment time is selectable. RF energy can be delivered in continuous output mode, pulsed output mode, or pulsed dose output mode, depending on desired treatment. In continuous output mode, the RF is delivered in an uninterrupted fashion. In pulsed and pulsed dose modes, the RF is delivered in short bursts of energy. In general, continuous output mode is used when a thermally destructive lesion is desired and pulsed or pulsed dosed modes are used when stronger electric fields are desired with or without destructive heating. See sections 1 of Stimulation Procedures (page 31) to Simplicity II and Simplicity III (page 44), and all of Testing, Electrode Connections, Lesion Sizes and Basic Procedures (page 55) , for detailed descriptions of each of these techniques.

Accessories

Table 1. NeuroTherm™ Accessories Model List

Model Number	Description
AC-BI-P	Adapter Cable-Bi Polar to NeuroTherm™ Generator
AC-BP-TC2	Adapter Cable
AC-CN-R	Adapter Cable-NT Generator to RFK Connector
AC-CN-S	Adapter Cable-NT Generator to SMK Connector
AC-IDET-4	IDET 4 Pin Connector
AC-IDET-8	IDET 8 Pin Connector
AC-NT-B	Adapter Cable-NT Generator to Baylis Medical [8] Reusable Electrode
AC-NT-COS	Adapter Cable-NT Generator to Cosman [9] Reusable Electrode
AC-NT-SN	Adapter Cable-NT Generator to S&N Reusable Electrode

[1] Bogduk, N. Percutaneous radiofrequency lumbar medial branch neurotomy. In Practice Guidelines for Spinal Diagnostic and Treatment Procedures; Bogduk, N., Ed. International Spine Intervention Society (ISIS): San Francisco, 2004a: 188-218

[2] Bogduk, N. Percutaneous radiofrequency cervical medial branch neurotomy. In Practice Guidelines for Spinal Diagnostic and Treatment Procedures; Bogduk, N., Ed. International Spine Intervention Society (ISIS): San Francisco, 2004b: 249-284.

[3] Schwarzer AC, Aprill CN, Bogduk N. The sacroiliac joint in chronic low back pain. Spine 1995; 20: 31-37.

[4] Fortin JD, Dwyer AP, West S, Pier J. Sacroiliac joint: Pain referral maps upon applying a new injection – arthrography technique. Part I: Asymptomatic volunteers. Spine 1994; 19:1475-1482.

[5] Ferrante FM, King LF, Roche EA, Kim PS, Aranda M, et al. Radiofrequency sacroiliac joint denervation for sacroiliac syndrome. Regional Anesthesia and Pain Medicine 2001; 26 (2) 137-142.

[6] Kapural L, Mekhail N. Radiofrequency ablation for chronic pain control. Curr Pain Headache Rep. 2001; 5(6): 517-525.

[7] Yin W, et al Sensory stimulation guided Sacroiliac Joint Radiofrequency Neurotomy: Technique Based on Neuroanatomy of the Dorsal Sacral Plexus. Spine Vol 28, No. 20, pp 2419-2425

[8] Baylis Medical is a trademark of Baylis Medical Company, Inc.

[9] Cosman is a trademark of Chenes LLC.

Table 1. NeuroTherm™ Accessories Model List

Model Number	Description
AC-NT-TC2	Adapter Cable-NT Generator to TC2 Connector
AC-POLE-NT	Adapter Cable-Pole Needle to NT Generator
AC-SI-III	Adapter Cable-Simplicity III (Molded) for NT1100™ Radiofrequency Generator
DAC-NT	Adapter Cable-NT Generator to NT Disposable Electrode, US
DACUK-NT	Adapter Cable-NT Generator to NT Disposable Electrode, UK
DACUK-NT-L	Adapter Cable-NT Generator to NT Disposable Electrode, UK (Long)
NRFE-10	Nitinol RF Reusable Electrode, 10cm
NRFE-15	Nitinol RF Reusable Electrode, 15cm
NRFE-5	Nitinol RF Reusable Electrode, 5cm
RF-DGP-S	RF Disposable Reference Pad
RF-NE-5	Reusable Nitinol RF Electrode
RF-NE-10	Reusable Nitinol RF Electrode
RF-NE-15	Reusable Nitinol RF Electrode
RF-NE-20	Reusable Nitinol RF Electrode
RF-NE-5-CE	Reusable Nitinol RF Electrode
RF-NE-10-CE	Reusable Nitinol RF Electrode
RF-NE-15-CE	Reusable Nitinol RF Electrode
RF-NE-20-CE	Reusable Nitinol RF Electrode
RF-SE-5	Reusable Stainless Steel RF Electrode
RF-SE-10	Reusable Stainless Steel RF Electrode
RF-SE-15	Reusable Stainless Steel RF Electrode
RF-SE-20	Reusable Stainless Steel RF Electrode
RF-SE-5-CE	Reusable Stainless Steel RF Electrode
RF-SE-10-CE	Reusable Stainless Steel RF Electrode
RF-SE-15-CE	Reusable Stainless Steel RF Electrode
RF-SE-20-CE	Reusable Stainless Steel RF Electrode
RFDE-10	RF Disposable Electrode, 10cm, US
RFDE-15	RF Disposable Electrode, 15cm, US
RFDE-20	RF Disposable Electrode, 20cm, US
RFDE-5	RF Disposable Electrode, 5cm, US
RFDE-SI	Simplicity III Electrode
RFDEUK-10	RF Disposable Electrode, 10cm, UK
RFDEUK-15	RF Disposable Electrode, 15cm, UK
RFDEUK-20	RF Disposable Electrode, 20cm, UK
RFDEUK-5	RF Disposable Electrode, 5cm, UK
RFE-10	RF Reusable Electrode, 10cm
RFE-10-L	RF Reusable Electrode, 10cm Long
RFE-10-RFK	RF Reusable Electrode - RFK, 10cm
RFE-15	RF Reusable Electrode, 15cm
RFE-15-D	RF Reusable Electrode, 15mm
RFE-15-RFK	RF Reusable Electrode-RFK, 15cm
RFE-20	RF Reusable Electrode, 20cm
RFE-5	RF Reusable Electrode, 5cm
STIM-KIT	Stimulation Test Kit
PWR-US	RF Generator Power Cord - USA
PWR-UK	RF Generator Power Cord - UK
PWR-AMS	RF Generator Power Cord - AMSTERDAM
Various	Compatible NeuroTherm™ Radiofrequency Needles

NOTES:

- The NT2000iX™ RF generator is the only repairable device of the generator system and can only be serviced by a NeuroTherm™ company qualified technician. None of the accessories listed above are repairable.
- Do not use accessories that are not listed above or accessories from competitors, as this could compromise safety and void warranty.
- Refer to accessory Instructions for Use (IFU) for additional accessory information.

Warnings

- Read the Instructions for Use before operating the NT2000iX™ RF generator.
- HAZARDOUS ELECTRICAL OUTPUT – The equipment is for use only by qualified medical personnel.
- ELECTRIC SHOCK HAZARD – Do not under any circumstances perform any testing or maintenance on the equipment while it is being used on a patient.
- FIRE HAZARD – DO NOT use extension cords or adapters of any type. The power cord and plug must be intact and undamaged.
- ELECTRIC SHOCK HAZARD – A failure of the equipment could result in unintended increase of output power. If unexpected readings of parameters are observed that do not correspond to the preset values, the procedure should be halted immediately by pressing the STOP button on the front panel. Do not operate the equipment again until a determination of the source of the problem has been identified and corrected.
- ELECTRIC SHOCK HAZARD – Should the power cord or plug become cracked, frayed, broken, or otherwise damaged, it must be replaced immediately.
- ELECTRIC SHOCK HAZARD – Unplug the power cord before cleaning or service.
- ELECTRIC SHOCK HAZARD – The operator should not perform any servicing of the equipment. Any servicing should only be carried out by qualified personnel.
- EXPLOSION HAZARD – This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- ELECTRIC SHOCK HAZARD – Always turn the equipment off before cleaning and do not allow any fluid to enter the ventilation holes or sockets.
- ELECTRIC SHOCK HAZARD – Do not touch any exposed wiring or conductive surface while cover is off and the equipment is energized. The voltage present when the electric power is connected to the equipment can cause injury or death. Never wear a grounding wrist strap when working on energized equipment.
- ELECTRIC SHOCK HAZARD – Do not remove the top cover of the NT2000iX™ RF generator, as it will expose voltage which can cause injury or death.
- FIRE HAZARD – Use non-flammable agents for cleaning and disinfection wherever possible.
- FIRE HAZARD – Flammable agents for cleaning, disinfecting, or as solvents of adhesives shall be allowed to evaporate before application of RF surgery.
- POOLING HAZARD – There is a risk of pooling of flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina.
- POOLING HAZARD – Fluids pooled in the body depressions and cavities should be mopped up before the NT2000iX™ RF generator is used.
- IGNITION HAZARD – Attention is called to the danger of ignition of endogenous gasses (e.g., cotton and gauze saturated with oxygen may be ignited by sparks produced during normal use of the NT2000iX™ RF generator).
- FUSE REPLACEMENT – For continued protection against fire hazard, replace only with same type and rating of fuse as displayed on the rear Serial Number Plate.
- RISK OF RF BURNS TO PATIENT – Ensure patient does not come into contact with metal parts of the table and its accessories – antistatic sheeting is recommended.
- RISK OF RF BURNS TO PATIENT – Avoid skin-to-skin contact between different parts of patient's body (for example between the arms and the body of the patient) – use dry gauze if necessary.
- RISK OF RF BURNS TO PATIENT – Avoid using physiological monitoring equipment during a procedure – if monitoring is required, monitoring electrodes should be placed as far as possible from the NeuroTherm™ cannula. Monitoring devices which use needle electrodes are not recommended.
- RISK OF RF BURNS TO PATIENT – Position all cables to the NeuroTherm™ cannula and grounding pad (also known as dispersive pad or reference pad) in such a way to avoid contact with the patient or other leads.
- RISK OF RF BURNS TO PATIENT – Place temporarily unused electrodes connected to the generator in a container or area that is electrically isolated from the patient. Never place a generator-connected electrode that is not being used in contact with the patient.
- RISK OF RF BURNS TO PATIENT – If unexpected readings of parameters are observed that do not correspond to the preset values, the procedure should be halted immediately by pressing the STOP button on the front panel. Do not operate the equipment again until a determination of the source of the problem has been identified and corrected.
- RISK OF RF BURNS TO PATIENT – If patient is sedated, place your hand on the backside of the grounding pad, while still leaving it attached to the patient, and STOP the procedure if the grounding pad gets unreasonably hot (a temperature greater than 46°C).
- RISK OF RF BURNS TO PATIENT – When positioning grounding pad, select a well-vascularized muscular site with proximity to the procedure.
- RISK OF RF BURNS TO PATIENT – Only use grounding pads listed in the Accessories (page 1).
- RISK OF RF BURNS TO PATIENT – Entire area of grounding pad should be reliably attached to a suitably prepared and appropriate area of the patient's body as defined by the Grounding Pad IFU.
- INTERFERENCE WITH ACTIVE INPLANTS – Check whether the patient has a cardiac pacemaker or other active implant. A possible hazard exists because interference with the action of the pacemaker may occur or the pacemaker may be damaged. In case of doubt, obtain qualified advice.

- INTERFERENCE WITH OTHER EQUIPMENT – During RF lesioning procedures, the radiated electrical fields may interfere with other electrical medical equipment. (See Minimizing Electromagnetic Interference (page 10).)
- RISK OF PATIENT INJURY – DO NOT USE ENDOSCOPICALLY- The accessories are not appropriate for endoscopic use.
- RISK OF RF BURNS TO PATIENT – In Manual Lesion Mode, select the lowest possible power for intended purpose.
- RISK OF RF BURNS TO PATIENT – Check the grounding pad before applying power to the patient.
- RISK OF RF BURNS TO PATIENT – If patient complains of heating at the grounding pad, stop the procedure and remove the grounding pad from patient.
- PROBES – Use only NeuroTherm™, SPINCATH™, or ACUTHERM™ probes or other probes cleared/approved by NeuroTherm listed in Accessories (page 1).
- Data log only can hold a certain number of files. Check log number before using to make sure no previous data will be over written.

Cautions

CAUTION indicates a condition that may lead to equipment damage or malfunction.

- Do not activate the output of the NT2000iX™ RF generator until the probe is properly positioned in the patient.
- GENERAL CONSIDERATIONS – Regularly inspect the accessories of the generator. In particular, electrode cables should be checked for possible damage to the insulation.
- GENERAL CONSIDERATIONS – If the equipment has in any way suffered mechanical damage, it should be returned to the supplier for inspection and test before further use.
- IMPROPER LINE VOLTAGE – The voltage selector on the mains input socket is factory-set and should not be changed by the user. The serial number plate shows the correct mains input voltage for the machine and the rating of the fuses to be used in the mains input unit fuse holder. An incorrect voltage setting may result in generator malfunction and potential damage.
- USE OF FLUIDS – Ensure that, if fluids (saline etc.) are being used during a procedure, they are positioned away from the generator.
- DISPERSIVE CONNECTIONS – In monopolar applications, ensure that the grounding or return electrode is connected to the patient and to the Generator.
- CLEANING – When cleaning the outer casing touch panel or screen of the equipment; do not use abrasive agents or solvents.
- CONNECTION OF EQUIPMENT TO REAR OF MACHINE – Any equipment connected to the rear socket must comply with IEC 60950 and IEC 60601-1.
- EMERGENCY STOP – For safety, always have someone positioned next to the STOP button during operation. If at any time the device is behaving erratically, press the red STOP button, which will return the device to a safe state. An example would include if the displayed temperature and graph do not match the desired set temperature.

Procedural Guidance

- No modification of this equipment is allowed.
- Ensure that the electrode length and cannula length match prior to cannula placement.
- Always visibly inspect electrodes for kinks and wear.
- Be sure the electrode is fully inserted into the cannula. Failure to do so will result in potentially erroneous temperature readings.
- Avoid positioning the cannula in a blood vessel or with the active tip on a bone, which may act as thermal heat sinks and insulators.
- Use of Bipolar techniques may be desirable in order to avoid unwanted tissue damage for surgical procedures where RF current could flow through relatively small cross-sectional area of body.
- In Monopolar Mode, do not place multiple electrodes closer than 20 mm apart. If electrodes are to be used closer than this distance, use Dual Electrode Mode.
- Always ensure that, when a temperature monitoring probe is inserted into the body, it reads body temperature ± 3°C before beginning treatment.
- When using NeuroTherm™ accessories, please refer to the IFU for those accessories.
- When using SPINECATH™ or ACUTHERM™ catheters, please refer to the IFU for those devices.
- It is strongly recommended that motor stimulation be performed to ensure no motor nerves are in the vicinity of the active cannula tip.
- When positioning grounding pad, select a well-vascularized muscular site with proximity to the procedure.
- Do not place the grounding pad on a fatty area such as the buttocks.
- Immediately stop the treatment if patient complains of any warmth or heat at the pad site.
- The device was designed for use in a procedure room or office environment. The device is not for outdoor use.

Technical Data

Specification

Size

Width	370 mm (14.5")
Height	320 mm (12.6")

Depth	430 mm (17.0")
Weight	12 kg (26.4 lb)

Electrical

Voltage Input

Europe	230 Volt	50Hz/60Hz	Fused 1 Amp on live and neutral
USA/Canada	120 Volt	50Hz/60Hz	Fused 2 Amp on live and neutral

Power Supply and Grounding

Power Consumption	240 VA
Operating frequency range	2.402–2.480 GHz
Output power (EIRP*)	+6 dBM maximum

*EIRP = equivalent isotropically radiated power

The power supply is built to Class 2 Standard. The mains transformer and all mains-related parts are double insulated from the main enclosure. The mains transformer has separate isolated bobbins for mains and low voltage windings. Poly switches are fitted into all primary and secondary windings.

The enclosure and exposed parts are not connected to mains ground (class 2).

Standards

This machine complies with:

IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
IEC 60601-1:1988 + A1:1991 + A2:1995
IEC 60601-1-4: 1996 (First Ed.) + Am.1: 1999 (Consolidated 1.1 Ed.) for use with IEC 60601-1 (1988), Amts 1 (1991) and 2 (1995)
IEC 60601-1-6:2010
IEC 60601-1-6: 2004
IEC 60601-2-2: 2009
IEC 60601-2-2:2006

With respect to electrical shock, fire, and mechanical hazards only in accordance with UL 60601-1, IEC 60601-1, CAN/CSA C22.2 No. 601.1 and IEC 60601-2-2.

Impedance

Measuring Frequency	460 KHz (± 3 %)
Measuring Power	Less than 200 mW
Measurement Display	0-2000 Ω (1 Ω resolution)
Accuracy	50-199 Ω ± 20%; 200-799 Ω ± 10%; 800-2000 Ω ± 20%
Features	Internal 200 Ω Test Resistor
	Impedance in all Lesion Modes and in Stimulation Standby Mode
	Audible tone available in Cordotomy Stimulation Mode where frequency varies with impedance over full impedance range (50-2500 Ω). Audible tone is adjustable and mutable.

Stimulation Mode

Signal Shape	Biphasic square wave with negative edge leading. This wave is available in a variety of frequencies and widths.
Output Range Voltage	0-5 V ± 5%
Stimulation Load Regulation	± 5% into 50-2000 Ω
Pulse Rates	Motor 2 or 5 Hz (default 2Hz)
	Sensory 10, 20, 50, 75, 100, 150, 180, 200 Hz (default 50 Hz)
Pulse Rate Accuracy	± 3%
Pulse Widths	0.1, 0.2, 0.5, and 1.0 mS (default 1.0 mS)
Pulse Width Accuracy	± 15%

Stimulate Features

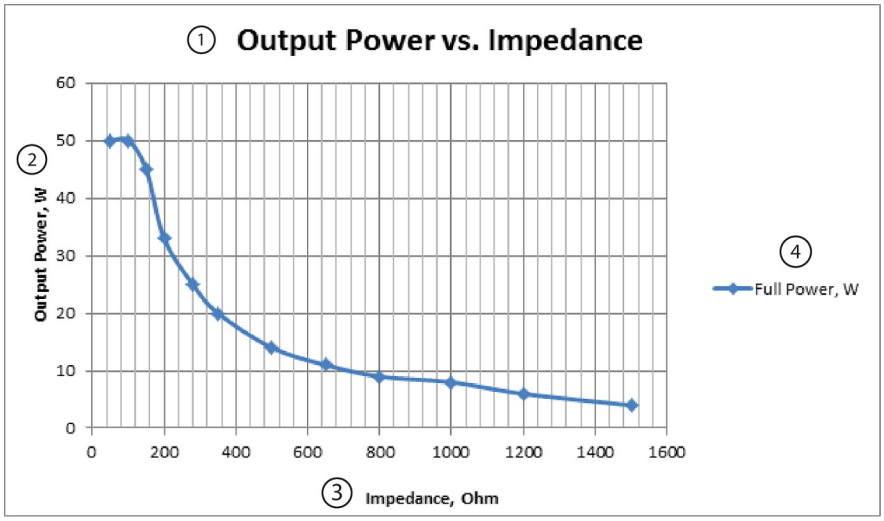
- Hardware and software lockout if voltage / current not initially set to zero.
- Warning on screen if stimulation control is not initially at zero.
- Flashing LED on front panel indicates machine is delivering stimulation pulses.

- Stimulation test socket is provided on front of machine to interface with the standard stimulation test kit.
- Various screen displays for displaying amplitude of each stimulation procedure.

Lesion Mode

RF Waveform	460 KHz ± 3% sinusoidal
Power Output (1-4 Electrodes)	Continuously variable. Maximum power output 50 W into 100 Ω.
Maximum Power Output Limit	Maximum total power output (the sum of all the RF power entering the patient from all active electrodes) is hardware and software-limited to 50 W total. This power is distributed as necessary to raise the electrodes to the desired set temperature. Depending on physiological conditions, different electrodes can have different power delivered to them. The only constraint is that the total power never exceeds 50W.
Voltage Display on Screen	0-80 RF V (RMS) ± 20%
Current Display on Screen	0-625 RF mA (RMS) ± 20%
Self Test	200 Ω internal load resistor built into machine
LED Indicator	LED flashes when Lesion Power is being delivered
Temperature Range	Selectable 50 – 90°C ±3°C for Thermal Lesion (default 80°C) and selectable in 5°C steps in initial screen setups. Selectable in 1°C steps when in Lesion Mode, using 'Temp Up' and 'Temp Down' buttons. (Output is disabled if temperature is above 98°C.)
Timer	Selectable 1-600 seconds (default 60 seconds) Selectable in 30-second steps in initial screen set-ups Selectable in 1-second steps when in Lesion Mode using 'Time Up' and 'Time Down' buttons
Special Temperature Profiles	One preset profile – Default – is programmed into the generator. The user can also program nine custom profiles
Lesion Start	Lesion timer starts as soon as temperature is within 5°C of desired temperature.
Auto Mode	With lesion power control off, the procedure can be carried out under automatic control by pressing the 'Auto' button. The temperature will ramp up and time will start when the measured temperature is within 5°C of desired temperature. The lesion can be stopped at any time by pressing the touch screen "**Stop**" button or the red emergency "**STOP**" button.
Display	Temperature/Time/Voltage/Current are displayed simultaneously.
Audible Indicator	An audible alarm tone will indicate the end of the procedure.

Figure 1. Power Curve



1. Output Power vs. Impedance
2. Output Power, W
3. Impedance, Ohm
4. Full Power, W

Pulsed RF Mode (1-4 electrodes)

Pulsed Waveform	Sinusoidal RF waves
Pulse Widths	5ms, 8ms, 20ms, 50 ms (default 20 ms)
Pulse Rates	1Hz, 2Hz, 5Hz, 10 Hz, (default 2 Hz)
Temperature Limit	Selectable 42-90°C range ±3°C (default 42°C)
Time	Selectable 0 to 30 minutes (default 2 minutes)
Set Voltage Range	Pulsed RF can be carried out in Auto Mode at fixed voltages. Voltage range 30-75 V (default 45 V).

Custom Profile

One Custom Profile and nine Programmable Profiles

Pulsed Dose Mode (1-4 electrodes)

In Pulsed Dose Mode, the numbers of pulses of RF are counted until the full quantity of pulses have been delivered to the patient. Pulsed Dose Procedures are carried out in Auto Mode.

Temperature Range	42-90 °C ± 3°C (Default 42°C)
Pulse Counts	120-960 count (Default 240 counts)
Pulse Rates	1Hz, 2Hz, 5Hz, 10Hz, (default 2Hz)
Pulse Widths	5ms, 8 ms, 20 ms, 50 ms (default 20 ms)
Set Voltage Range	Pulsed Dose RF can be carried out in Auto Mode at fixed voltages. Voltage range 30-75 Volts (default 45 Volts).

NOTE: When the electrode reaches set temperature, the RF power is switched off and the count is stopped. When the temperature is below the set temperature, the counter will start and the RF power is switched on. This will ensure only full RF pulse bursts are delivered to the patient. The procedure will end when the total selected number of pulses is reached.

Simplicity II and Simplicity III

This algorithm is used with a two or three-electrode probe and can be used in radiofrequency lesion treatment to shape lesion sizes.

For **Simplicity II**, the lesion sequence consists of a dual electrode lesion between electrodes 1 and 2, a monopolar lesion between electrode 1 and the grounding pad, and a monopolar lesion between electrode 2 and the grounding pad. There is a short time delay between the dual lesion to allow for a reduction in temperature in the lesion area.

For **Simplicity III**, the lesion sequence consists of a dual electrode lesion between electrodes 1 and 2, a dual electrode lesion between electrodes 2 and 3, a monopolar lesion between electrode 1 and the grounding pad, a monopolar lesion between electrode 2 and the grounding pad, and lastly a monopolar lesion between electrode 3 and the grounding pad. There is a short time delay between the dual lesions to allow for a reduction in temperature in the lesion area.

NOTE: The generator will automatically disconnect the grounding pad from the patient during the dual electrode section of this procedure.

Multiple Probes

The NT2000iX™ RF generator can be operated with 1, 2, 3, or 4 probes. When in Stimulation Mode, each probe is selected by the operator for Stimulation. In RF Lesion, Pulse RF, or Pulsed Dose Mode, the generator energizes all connected probes with a control circuit to limit the total RF output to a maximum of 50 Watts. In multiple probe operation, all pulse rates are available.

Features:

- Hardware and Software lockout if RF Power Control not initially set to zero during **Manual** Mode
- LED Flashes on front panel to indicate machine is delivering power
- Four output sockets to accept a variety of probes
- Hardware lockout if temperature exceeds 98°C
- Operation of the "Stop" button sets the generator to a safe state

NOTE: Independent procedure settings are not settable on individual channels.

Ground Leakage

		Typical	Maximum Allowable
1	Enclosure Leakage Current		
	Normal	40 microamps	100 microamps
	Reverse	40 microamps	100 microamps
	Single Fault Condition		
	Normal	40 microamps	500 microamps
	Reverse	40 microamps	500 microamps
2	Patient Leakage Current		
	Normal (AC)	5 microamps	100 microamps
	Reverse (AC)	4 microamps	100 microamps
	Single Fault Condition		
	Normal (AC)	7 microamps	500 microamps
	Reverse (AC)	7 microamps	500 microamps
3	Patient Leakage Current		
	Normal (DC)	4 microamps	10 microamps
	Reverse (DC)	4 microamps	10 microamps
	Single Fault Condition		
	Normal (DC)	4 microamps	50 microamps
	Reverse (DC)	4 microamps	50 microamps
4	Patient Auxiliary Leakage Current		
	Normal (AC)	4 microamps	100 microamps

	Reverse (AC)	4 microamps	100 microamps
	Single Fault Condition		
	Normal (AC)	6 microamps	500 microamps
	Reverse (AC)	6 microamps	500 microamps
5	Patient Auxiliary Leakage Current		
	Normal (DC)	4 microamps	10 microamps
	Reverse (DC)	4 microamps	10 microamps
	Single Fault Condition		
	Normal (DC)	4 microamps	50 microamps
	Reverse (DC)	4 microamps	50 microamps
6	Patient Leakage Floating Type		
	Normal	27 microamps	5000 microamps
	Reverse	27 microamps	5000 microamps
	Single Fault Condition		
	Normal	36 microamps	5000 microamps
	Reverse	35 microamps	5000 microamps

NOTE: Leakage measurements must be made as is appropriate for Class II design. See Electrode Connections (page 57) for more information referring to how leakage measurements were attained.

Environmental Conditions

1	Transport and Storage	Temperature	-10°C to 70°C	
		Humidity	10-95% RH	Non-Condensing
		Pressure	140-760 mm Hg	0-12,200 m (0-40,000 ft)
2	Operating	Temperature	10°C to 35°C	
		Humidity	10 to 80% RH	
		Pressure	520-760 mm Hg	0-3000 m (0-10,000 ft)

Electromagnetic Compatibility

Electromagnetic Emissions Declaration

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy for its internal and system interface functions. 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 device is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the device or shielding the location.**
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity Declaration I

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) EN61000-4-2 (IEC 1000-4-2)	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30%.
Electrical fast transient/burst EN61000-4-4 (IEC 1000-4-4)	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN61000-4-5	±1 kV differential mode	±1 kV	Mains power quality should be that of a typical commercial or hospital environment.

(IEC 1000-4-5)	±2 kV common mode	±2 kV	
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5 % U_T >95 % dip in U_T for 0.5 cycle 40 % U_T 60 % dip in U_T for 5 cycles 70 % U_T 30 % dip in U_T for 25 cycles <5 % U_T >95 % dip in U_T for 5 sec	>95 % dip in VNOM for 0.5 line cycle 60 % dip in VNOM for 5 line cycles 30 % dip in VNOM for 25 line cycles >95 % of VNOM for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Electromagnetic Immunity Declaration II

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the device including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms [V_1 = 3]	$d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [1.2]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m [E_1 = 3]	$d = [1.2]\sqrt{P}$ $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz $d = [2.3]\sqrt{P}$
			where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] 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. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from			

structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the device.

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	.117	.117	.233
.10	.369	.369	.737
1	1.167	1.167	2.33
10	3.69	3.69	7.37
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Minimizing Electromagnetic Interference

Although the NT2000iX™ RF generator meets the EMC requirements for a device of this type, it is good practice to follow certain guidelines to minimize the risk of interference between the generator and other devices.

1. Do not twist the cable of the generator with those of other devices.
2. Avoid putting the generator on top of other operating equipment or putting other operating equipment on top of the generator.
3. The generator generates 460 KHz at up to 50 watts during the RF Lesion Treatment phase. If any interference occurs to other equipment, it will be most noticeable under this condition.

To check this, connect a high-wattage 200 Ω Test Box to the machine, turn to full power in RF Lesion Mode and observe any reading changes or interference on other equipment.

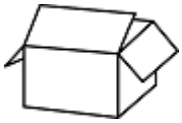
To minimize any interference, position the generator as far away as possible from the device with which it might interfere.

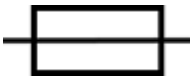
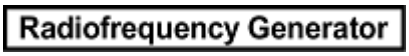
Symbols

The following symbols may be found on the product or product label:

Symbol	Description
	Type BF equipment

Symbol	Description
	Class II equipment
	ETL Mark
	General Warning Sign
	Floating Output (Not Connected to Ground)
	Follow the instructions for use
	Emergency Stop
CE 0086	European conformity, affixed according to the relevant provisions of MD directives 93/42/EEC and 2011/65/EU, and RE directive 2014/53/EU Annex II. Hereby, St. Jude Medical declares that this device complies with the essential requirements and other relevant provisions of these directives. The full text of the European Union RE directive 2014/53/EU declaration of conformity is available at the following internet address: www.sjmglobal.com/euconformity.
	Consult instructions for use
	Manufacturer
	Manufacturing Facility
REF	Reorder number
SN	Serial number

Symbol	Description
	Finished good
	Keep dry
	Caution
	Prescription only
	Authorized Representative in the European Community
	Date of Manufacture
	Lot number
	Do not use if package is damaged
	Dispose of hardware in accordance with local law
	
	Quantity
	Temperature limitations
	Humidity limitation
	Cable

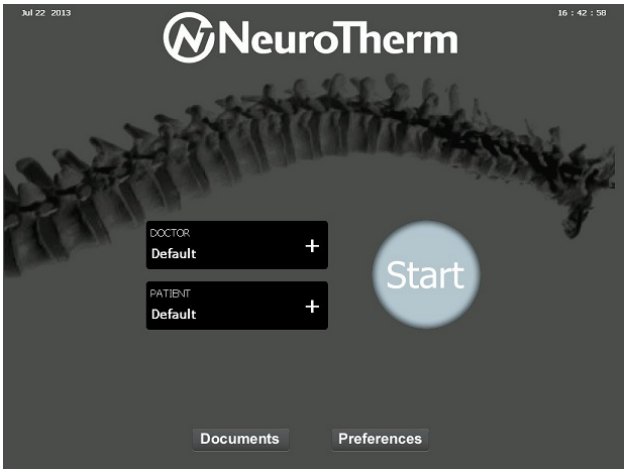
Symbol	Description
	Fuse
	Power Cord Kit
	Radiofrequency Generator
	Medical Electrical Equipment
	Australian Sponsor
	Software

Unpacking and Acceptance Testing

1. Upon receipt, the machine should be unpacked and inspected for any physical damage.
2. Check that the voltage shown on the rear serial number plate matches the local supply. If not, contact your local distributor. **Do not attempt to alter the voltage selector on the rear of the machine**. This is for factory setting only.
3. Place the NT2000iX™ RF generator on a flat surface, connect the machine into the mains and switch ON using the ON/OFF switch on the rear of the machine. The following will be observed:
    a. The mains LED will light and the Red/Green LEDs for the probes will sequence showing the machine is booting up

After displaying a splash screen, the generator will then switch to its **Welcome** screen.

Figure 2.



The generator is now ready for use.

Electrical Safety Testing

If an Automatic or Manual Electrical Safety Analyzer is used, the following settings must be used:

- Machine Class: Class II Type BF

To test the various leads of the output, use the following plugs:

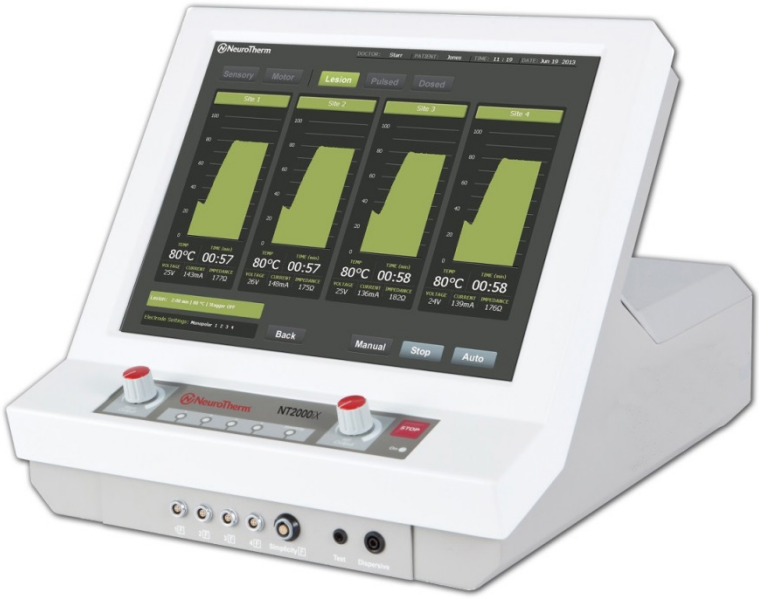
- Dispersive plug (4mm Safety Socket)
- Four of the active Plugs (Lemo 4 pin) and 10 Pin Simplicity Connector

There is no specified GROUND POINT, as the output is floating and could possibly induce operational errors. If a ground point is needed, attach onto any of the three bolts on the rear of the machine. Refer to Ground Leakage (page 7) for appropriate leakage limits.

Description of the Controls

The NT2000iX™ RF generator viewed from the front is shown below.

Figure 3.



In operation, control of the generator is via the touch screen. The screen will show the current settings of the machine, what is being delivered to the patient, and any error or warning messages. The touch screen is also used to set up a whole series of conditions including parameters for the treatment as well as the Doctor and Patient details. This information then forms part of the patient treatment record which can be printed out (and downloaded to a memory stick) at the end of a treatment session.

The control of the stimulation voltage and RF power is by the two rotary controls on the front of the unit. The "Stop" button is situated close to the controls on the front panel.

Front Panel

Figure 4.

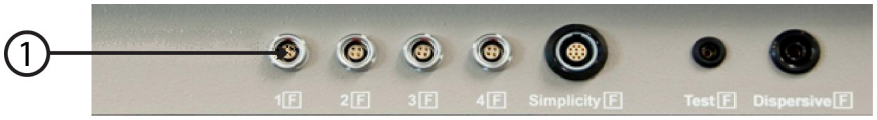
1. Stimulate Control
2. RF Lesion Control
3. Stop Button

The Front Panel contains the following controls and indicators:

Stimulate Control	For manually setting stimulate voltage
RF Lesion Control	For setting RF Output in Manual Mode
Stop Button	For stopping a procedure in an emergency
Mains ON LED	To indicate all internal fuses are OK
LED's located above the input sockets	These will sequence during start up to show the computer is booting up. In the procedure screens, they will: 1. Show RED when a probe is selected but NOT detected 2. Show GREEN when a probe is selected and detected 3. Flash when power is being delivered.

Connector Panel Layout

Figure 5.



1. Input Connectors

Dispersive Socket

This 4mm socket is for the lead of a NeuroTherm™ Generator compatible dispersive grounding pad.

Test Socket

This 2mm socket is used to connect the test block for use in testing the thermocouple probes in the Stimulate Mode.

Probe Sockets 1-4

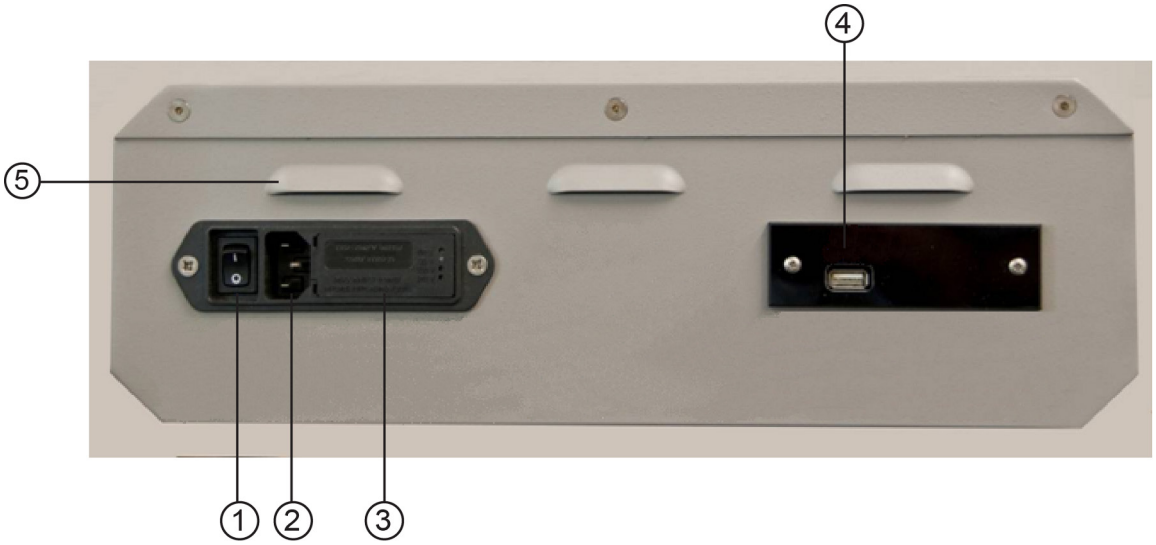
These 6-pin sockets are used to connect electrodes for standard RF Lesion, Pulsed RF, Lesion Pulsed Dose, and Cordotomy procedures.

Probe Socket 5

10-pin Socket is used for Simplicity II and Simplicity III procedures.

Back Panel Layout

Figure 6.



1. **Mains On/Off Switch**

   This is a rocker-type switch, combined with an I.E.C. connector socket with twin 'in-line' anti-surge fuses in a single unit to IEC 950. This switch is used to turn the unit both **On and Off.** When positioning the device, make sure that the mains On/Off switch is easily accessible to the doctor and/or doctor's assistant.

2. **Mains IEC Connector**

   The three-pin plug of the mains must be pushed into this socket. This cannot be done incorrectly, i.e., with the live and neutral reversed, because of the orientation of the unused ground pin.

3. **Fuses and Voltage Changes**

   The NT2000iX™ RF generator is protected by two in-line fuses, one on the live line and one on the neutral line. These fuses are located to the right-hand side of the IEC socket. The fuses are 2x 20mm T2AH250V for a 120V rated supply and 2x 20mm T1AH250V for a 230V rated supply. To access the fuse holder, lift the protective lid from the right hand edge and hinge back. The fuse carrier can then be removed. The mains input unit also contains a small printed circuit card which allows the mains input voltage to be changed.

   Note: This is for factory setting only and should not be altered.

   This device is not user serviceable. Maintenance should only be carried out by authorized personnel. Qualified companies and technicians can refer to the NT2000iX™ Service and Support Manual for more information.

4. **Rear Connector (Located in the black plastic plate)**

   The Connector is a USB Memory socket available on all machines for use **only** with the NeuroTherm™ Memory Stick (NT-USB). **DO NOT CONNECT ANY OTHER DEVICE TO THIS SOCKET**.

5. **Ventilation Apertures**

These apertures are to ensure the correct air circulation within the generator and should not be blocked or obstructed.

Procedure Configuration Matrix

Procedure Type	Number of Electrodes	Output 1	Output 2	Output 3	Output 4	Grounding Pad Connector	Figure Number
Monopolar procedure configurations: Current passes between each electrode and the common grounding pad.							
Probe 1 monopolar	1	X				X	79
Probe 2 monopolar	1		X			X	79
Probe 3 monopolar	1			X		X	79
Probe 4 monopolar	1				X	X	79
Probe 1,2 monopolar	2	X	X			X	80
Probe 1,3 monopolar	2	X		X		X	80
Probe 1,4 monopolar	2	X			X	X	80
Probe 2,3 monopolar	2		X	X		X	80
Probe 2,4 monopolar	2		X		X	X	80
Probe 3,4 monopolar	2			X	X	X	80
Probe 1,2,3 monopolar	3	X	X	X		X	81
Probe 1,2,4 monopolar	3	X	X		X	X	81
Probe 1,3,4 monopolar	3	X		X	X	X	81
Probe 2,3,4 monopolar	3		X	X	X	X	81
Probe 1,2,3,4 monopolar	4	X	X	X	X	X	82
Dual procedure configurations: Current passes between two monopolar electrodes. The generator monitors both electrode temperatures and controls the higher of the two electrode temperatures. Both temperatures are displayed on the screen.							
Probe 1-2 Dual*	2	X	X			X*	83
Probe 3-4 Dual*	2			X	X	X*	83
Probe 1-2, 3-4 Dual*	4	X	X	X	X	X*	83
Simplicity combines both dual and monopolar to make large uniform lesions							
Simplicity II	2	X	X			X	84
Simplicity III	3	X	X	X		X	84

* In Dual Lesion mode, a grounding pad is only needed, if doing stimulation.

NOTES:

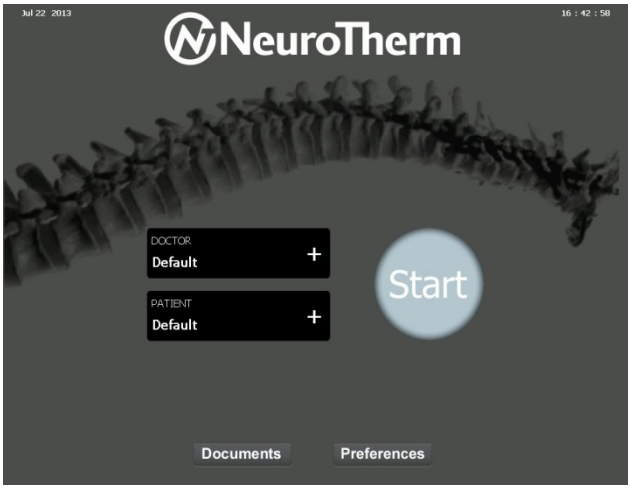
- The multi-lesion capability allows the generator to lesion tissue using multiple electrodes simultaneously. The total maximum power output is 50 W for all modes.
- The NT2000iX™ RF generator **does not** allow stimulation on more than one channel at a time. Voltages for stimulation may only be applied to **one** electrode at a time.
- Simplicity II and III electrode configuration is determined during set-up.

Description of Displays

Welcome Screen

This is the main entry screen. Upon entry, the current date, time (updated every second), and the name of the last doctor and patient selected are displayed.

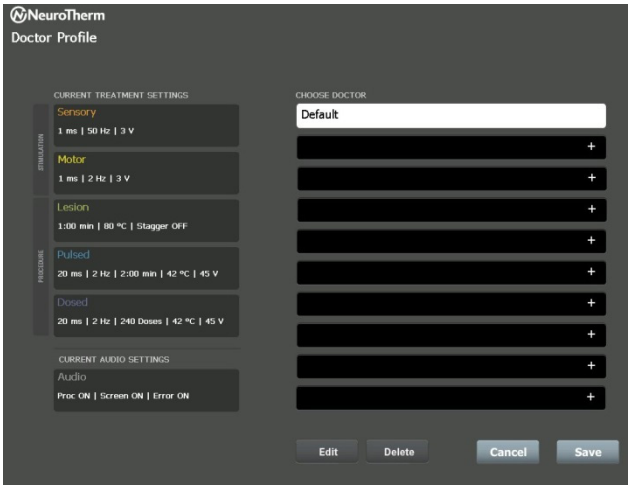
Figure 7.



Doctor

From the **Welcome** screen touch "**Doctor +**", and the **Doctor Profile** screen will appear. The screen displays the last name of Doctors configured in the system and has one default Doctor profile which cannot be edited and allows for the creation of nine additional Doctor profiles. Doctor Names, Sensory Treatment Settings, Motor Treatment Settings, Lesion Treatment Settings, Pulsed Treatment Settings, Dosed Treatment Settings, and Current Audio settings are all dynamic content and display based upon the Doctor selected.

Figure 8. Doctor Profile Screen



To delete an existing Doctor profile, select the profile to be deleted, touch "**Delete**" and "**Yes"** on the Confirm Doctor Deletion message.

To add a new Doctor profile, press the "**+**" button in any blank Doctor field. Additionally, details of existing Doctors may be edited by selecting the Doctor to be updated and then the "**Edit**" button. In both instances, the screen will change and display the **Doctor Profile Edit/Add** screen.

Figure 9. New Doctor Profile Screen

To add a new Doctor profile, enter the Doctor's Name and details via the touch screen keypad. Once the details have been entered or edited, press "**Save**" on the touch screen to return to the **Doctor Profile** screen. From the **Doctor Profile** screen, select the new Doctor name. The name being currently edited will be highlighted.

By selecting "**Cancel**", any changes made on this screen are not saved and the screen reverts to the **Doctor Profile** screen.

Treatment and Current Audio Settings (Accessible from Doctor Profile Screen)

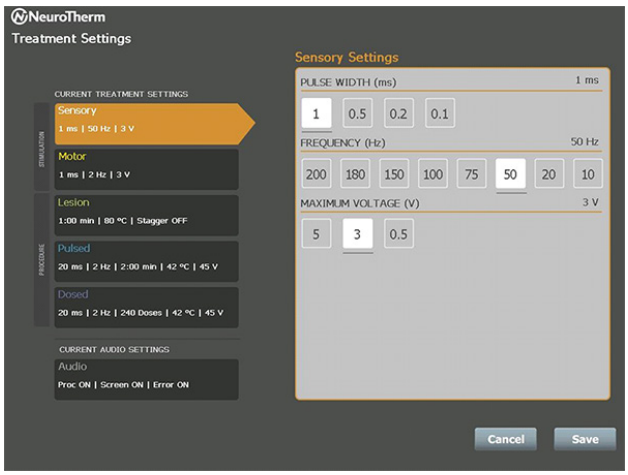
The **Treatment Settings** screens are accessible via the **Doctor Profile** and **Treatment** screens while the **Current Audio Settings** screen is available only through the **Doctors Profile** screen.

From the **Doctor Profile** screen, press the desired **Current Treatment Settings** button to display the preferred **Treatment Settings** screen. Pressing the **Current Audio Settings** button displays the **Current Audio Settings** screen. The chosen parameters are linked to the Doctor's Name and are stored by the NT2000iX™ RF generator for future use by pressing "**Save**".

Pressing the settings button on any **Treatment** screen also displays the desired **Settings** screen. Pressing "**Save**" temporarily saves the changes until the next power cycle.

Pressing "**Cancel**" or "**Save**" returns to the previous screen.

Figure 10. Sensory Settings Screen

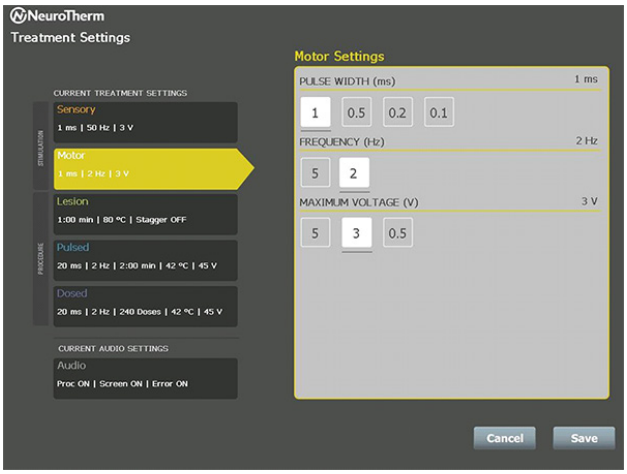


The **Sensory Treatment** screen displays the treatment settings for the currently selected Doctor.

The Sensory Settings is programmable with the default values set as:

- Pulse Width: 1
- Frequency (Hz): 50
- Maximum Voltage (V): 3

Figure 11. Motor Settings Screen

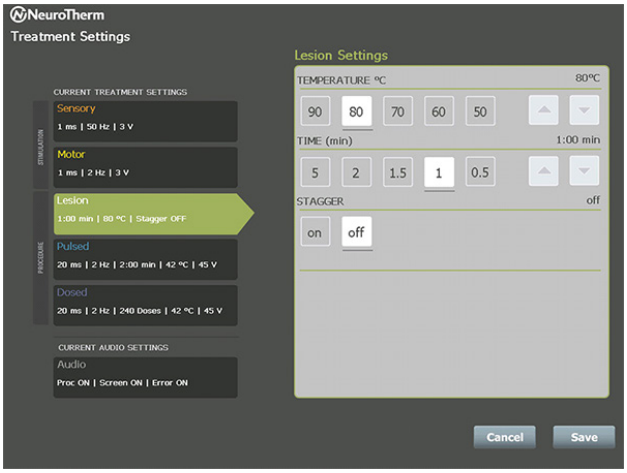


The **Motor Treatment** screen displays the treatment settings for the currently selected Doctor.

The Motor Settings is programmable with the default values set as:

- Pulse Width: 1
- Frequency (Hz): 2
- Maximum Voltage (V): 3

Figure 12. Lesion Settings Screen - Stagger Off



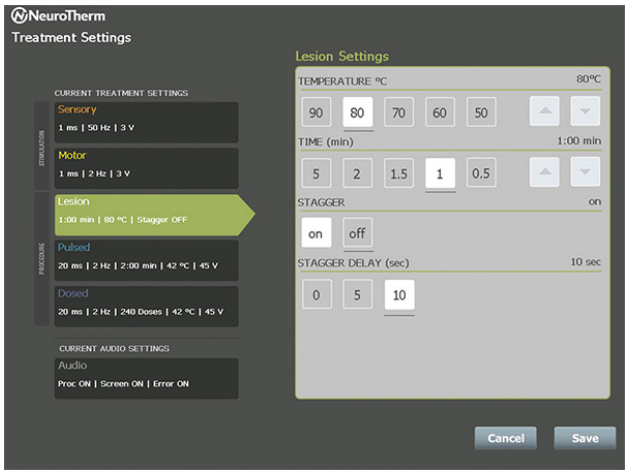
The **Lesion Treatment** screen has a Stagger Off and Stagger On option and it also displays the treatment settings for the currently selected Doctor.

The Lesion Settings for Stagger Off is programmable with the default values set as:

- Temperature: 80°C
- Time (min): 1
- Stagger: Off

The temperature and time increment by 1°C and 1 second using the up and down arrows. For both settings, once the minimum or maximum value is reached, the value is highlighted.

Figure 13. Lesion Settings Screen - Stagger On

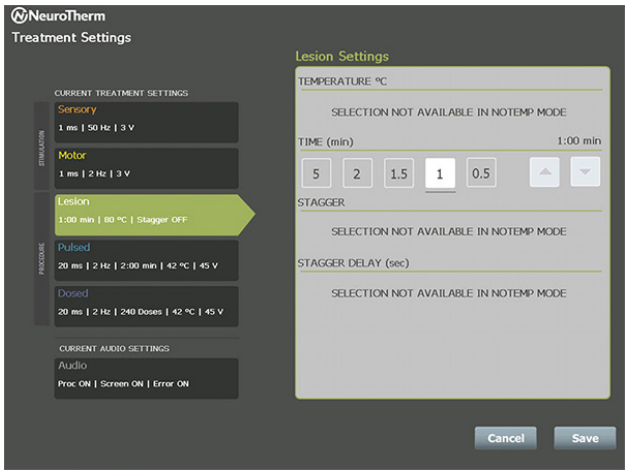


The Lesion Settings for the Stagger On option is programmable with the default values set as:

- Temperature: 80°C
- Time (min): 1
- Stagger Delay: 10

The temperature and time increment by 1°C and 1 second using the up and down arrows. For both settings, once the minimum or maximum value is reached, the value is highlighted.

Figure 14. Lesion Settings Screen – No Temp Mode



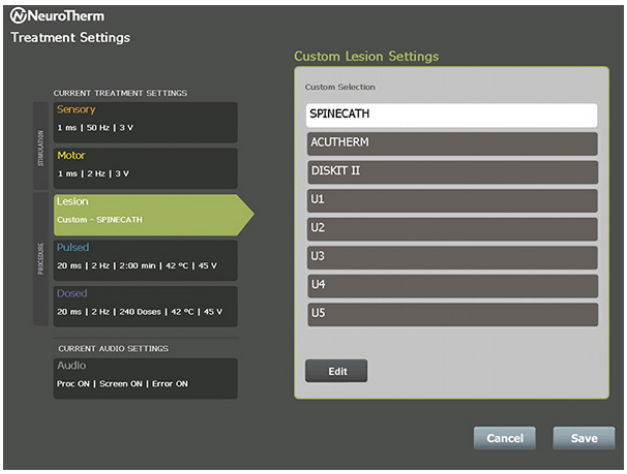
The Lesion Settings for the No Temp Mode Time setting is programmable with the default value set as:

- Time (min): 1

The time increments by 1 second using the up and down arrows. Once the minimum or maximum value is reached, it is highlighted.

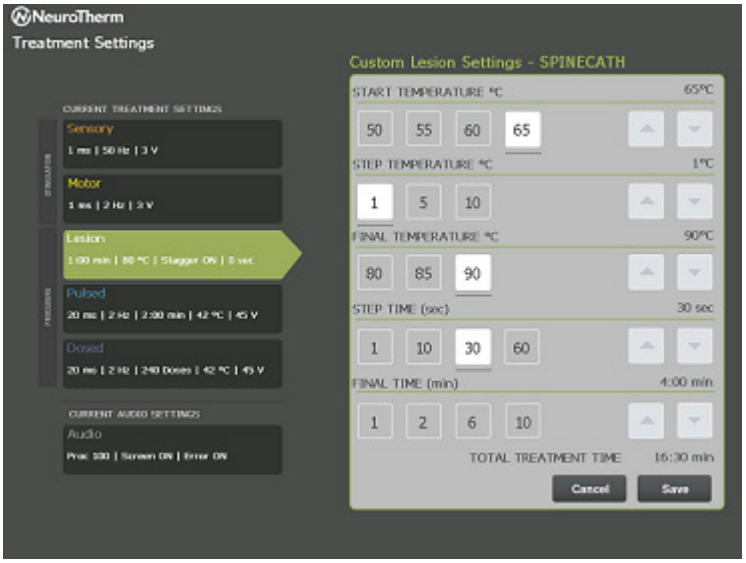
NOTE: This screen is accessed from the **No Temp Mode Procedure** screen

Figure 15. Custom Lesion Settings Screen



There are 8 Custom Lesion Settings available. Pressing "Edit" displays the Custom Lesion Settings screen for the highlighted selection.

Figure 16. Custom Lesion Settings Screen – SPINECATH



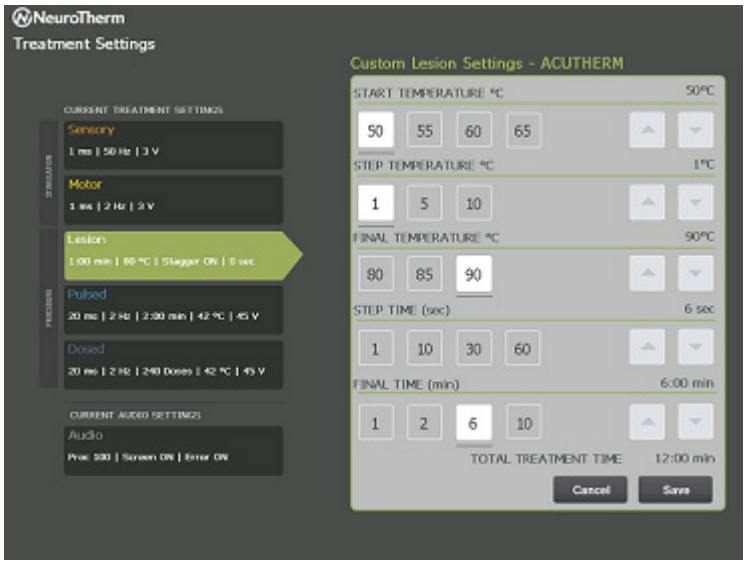
The Custom Lesion Settings screen is programmable with the default values set as:

- Start Temperature: 65°C
- Step Temperature 1 degree/step time
- Final Temperature: 90°C
- Step Time 30 seconds
- Final Time 4 minutes
- Total Treatment Time 16.5 minutes

Pressing "**Rename**" displays the **Custom Profile Name** screen discussed below.

NOTE: Pressing "**Save**" saves the settings until the next power cycle when entering from both **Doctor Profile** and **Treatment Settings** screens.

Figure 17. Custom Lesion Settings Screen – ACUTHERM



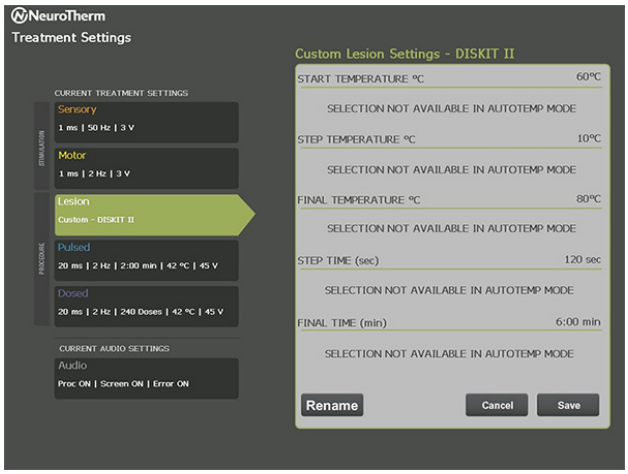
The Custom Lesion Settings screen is programmable with the default values set as:

- Start Temperature: 50°C
- Step Temperature 1 degree/step time
- Final Temperature: 90°C
- Step Time 6 seconds
- Final Time 6 minutes
- Total Treatment Time 12 minutes

Pressing "**Rename**" displays the **Custom Profile Name** screen discussed below.

NOTE: Pressing "**Save**" saves the settings until the next power cycle when entering from both **Doctor Profile** and **Treatment Settings** screens.

Figure 18. Custom Lesion Settings Screen – DISKIT II



The Custom Lesion Settings screen is programmable with the default values set as:

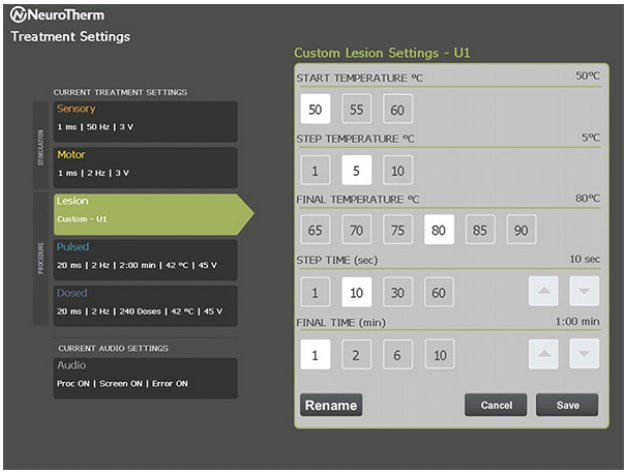
- Start Temperature: 60°C
- Step Temperature: 10°C
- Final Temperature: 80°C
- Step Time: 120 seconds
- Final Time: 6 minutes

The step time and final time increment and decrement by 1 second and 5 seconds respectively using the up and down arrows. For both settings, once the minimum or maximum value is reached, the value is highlighted.

Pressing "Rename" displays the Custom Profile Name screen discussed below.

NOTE: Pressing "**Save**" saves the settings until the next power cycle when entering from both **Doctor Profile** and **Treatment Settings** screens.

Figure 19. Custom Lesion Settings Screen – U1, U2, U3, U4, U5



The Custom Lesion Settings U1, U2, U3, U4, and U5 screens are programmable with the default values set as:

- Start Temperature: 50°C
- Step Temperature: 5°C
- Final Temperature: 80°C
- Step Time: 10 seconds
- Final Time: 1 minute

The step time and final time increment and decrement by 1 second and 5 seconds respectively using the up and down arrows. For both settings, once the minimum or maximum value is reached, the value is highlighted.

Pressing "**Rename**" displays the **Custom Profile Name** screen discussed below.

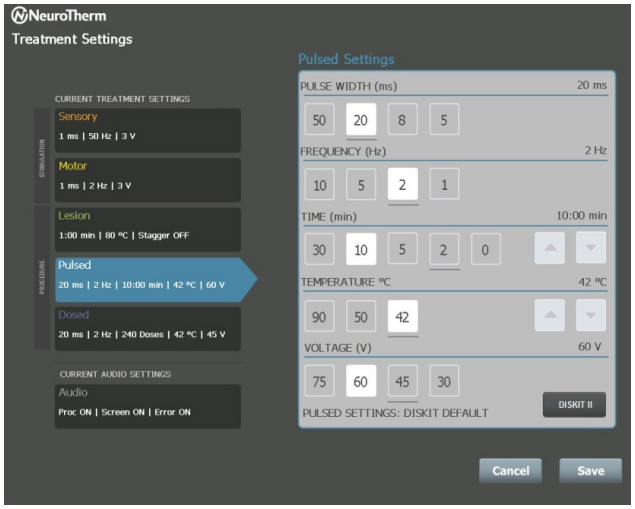
NOTE: Pressing "**Save**" permanently saves the settings independent of the currently selected Doctor when entering from both **Doctor Profile** and **Treatment Settings** screens.

Figure 20. Custom Profile Name Screen

The Custom Profile Name screen displays when "Rename" is pressed on any of the Custom Lesion Setting screens.

The Profile Name accepts any characters on the touch screen keypad with a minimum of 1 and maximum of 10 characters. Pressing "Save" saves the Profile Name to the currently active Custom Lesion Setting screen.

Figure 21. Pulsed/DISKIT II Setting Screen

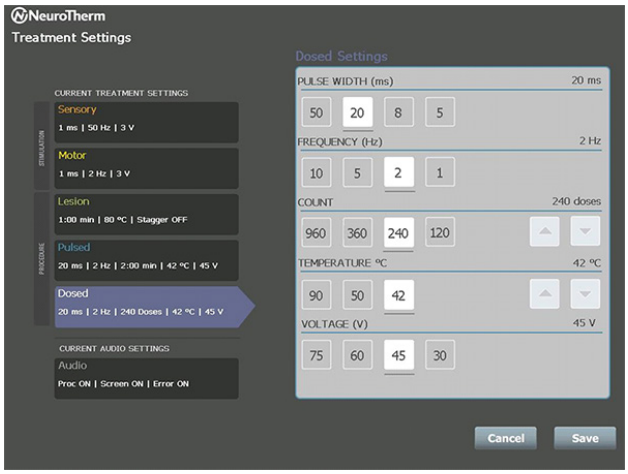


The Pulsed Settings screen is programmable with the default values set as:

- Pulsed Width: 20 ms
- Frequency: 2 Hz
- Time: 2 min (10 min DISKIT II mode)
- Temperature: 42°C
- Voltage: 45 V (60 V for DISKIT II setting)

The time increments and decrements by 1 second using the up and down arrows. The temperature increments and decrements by 1°C using the up and down arrows. For both settings, once the minimum or maximum value is reached, the value is highlighted.

Figure 22. Dosed Settings Screen

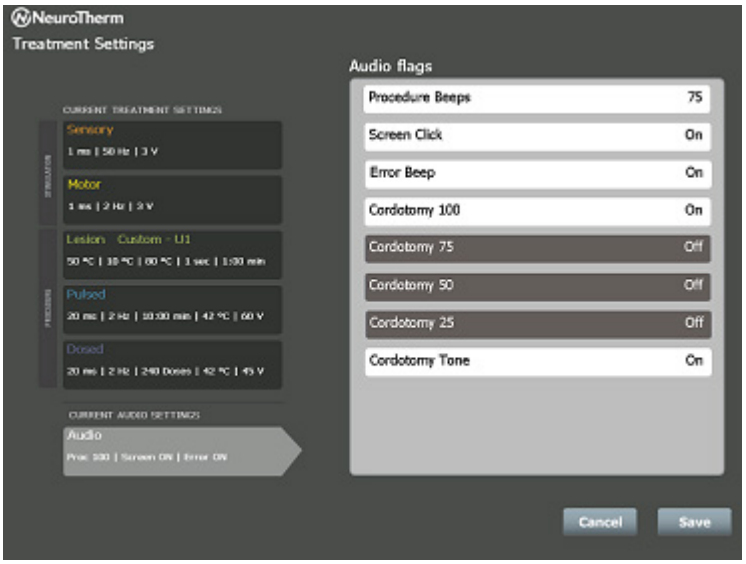


The Dosed Lesion Settings screen is programmable with the default values set as:

- Pulsed Width: 20 ms
- Frequency: 2 Hz
- Count: 240 doses
- Temperature: 42°C
- Voltage: 45 V

The count increments and decrements by 120 doses using the up and down arrows. The Temperature increments and decrements by 1°C using the up and down arrows. For both settings, once the minimum or maximum value is reached, the value is highlighted.

Figure 23. Current Audio Settings Screen



The Current Audio Settings screen is programmable with the default values set as:

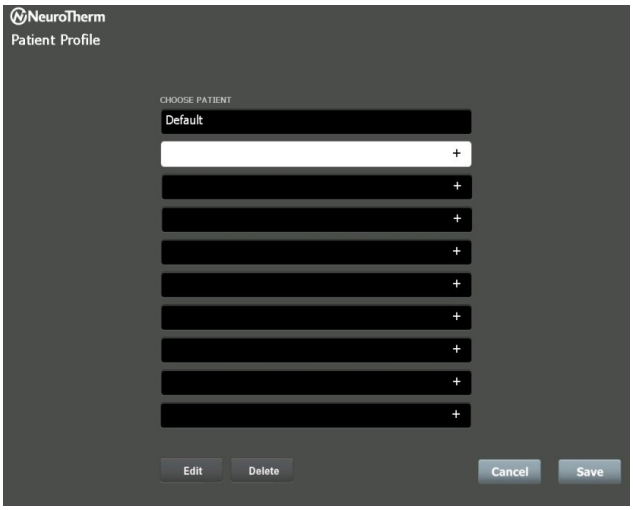
- Procedure Beeps Toggle: (100/75/50/25/Off): 100
- Screen Click Toggle (On/Off): On
- Error Beep Toggle (On/Off): On
- Cordotomy 100 Toggle (On/Off): On
- Cordotomy 75 Toggle (On/Off): Off
- Cordotomy 50 Toggle (On/Off): Off
- Cordotomy 25 Toggle (On/Off): Off
- Cordotomy Tone Toggle (On/Off): On

NOTE: In Lesion Settings, there is a stagger start option. With stagger start enabled, successive channels are activated when the previous channel is within 5 ° C of set temp. With stagger start disabled, all channels activate simultaneously.

Patient

From the **Welcome** screen, touch "**Patient +**" to setup the patient name. The screen displays the last names of the Patients configured in the system, features one default Patient profile which cannot be edited and allows for the creation of nine additional Patient profiles.

Figure 24. Patient Profile Screen



To delete an existing Patient profile, select the profile to be deleted, touch "Delete" and touch "Yes" on the Confirm Patient deletion message.

To add a new Patient profile, press the "**+**" button in any blank Patient field. Additionally, details of existing Patients may be edited by selecting the Patient to be updated and then the "**Edit**" button. In both instances, the screen will change and display the **Patient Profile Edit/Add** screen.

Figure 25. New Patient Profile Screen

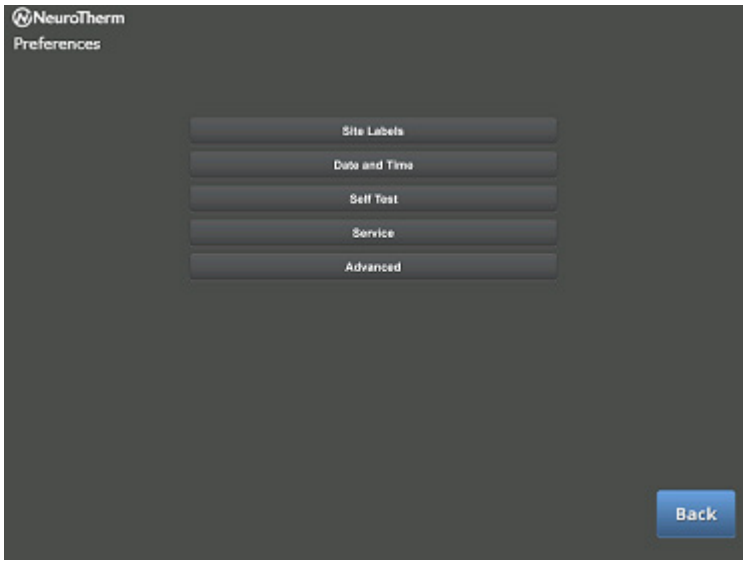
To add a new Patient profile, enter the Patient's Name and details via the touch screen keypad. Once the details have been entered or edited, press "**Save**" on the touch screen to return to the **Patient Profile** screen. Make sure the correct patient information is entered, as this is what will be displayed on the patient record.

By selecting "**Cancel**", any changes made on this screen are not saved and the screen reverts to the **Patient Profile** screen.

Preferences Screen

Touch "**Preferences**" on the **Welcome** screen to display the **Preferences** screen. The following Preferences are accessed from this screen: Site Labels, Data and Time, Self Test, Service, and Advanced.

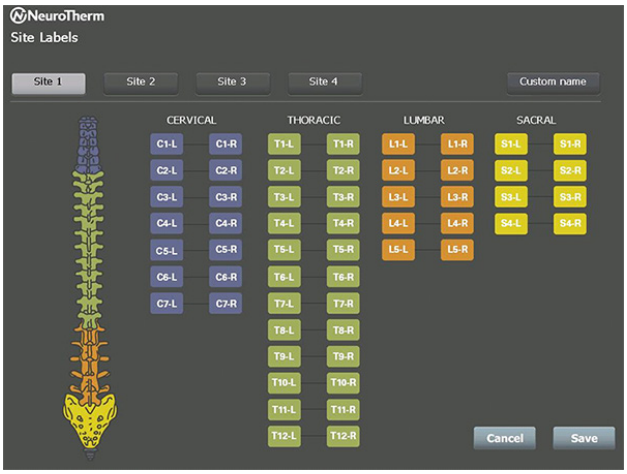
Figure 26. Preferences Screen



Site Labels

Touch "Site Labels" to display the Site Labels screen.

Figure 27. Site Labels Screen

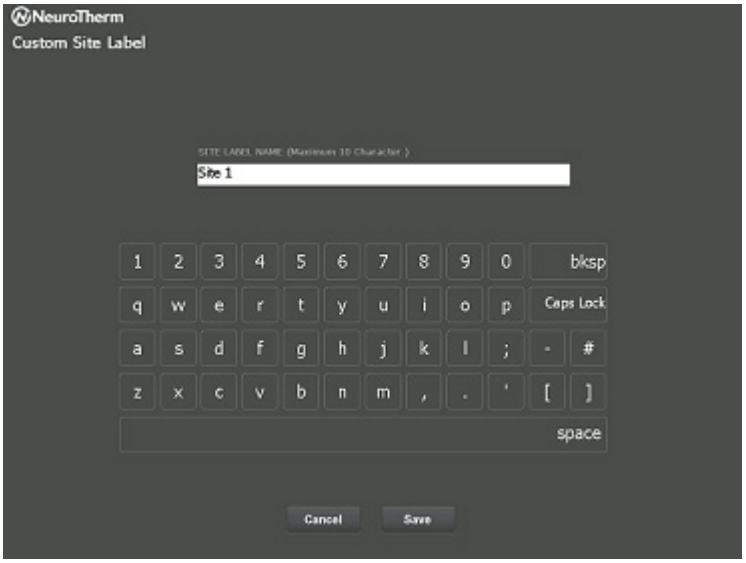


Touching "**Site 1**","**2**", "**3**", or "**4**" will allow the user to label the sites to be lesioned. Additionally, pressing one of the **Cervical**, **Thoracic**, **Lumbar**, or **Sacra**l buttons renames the selected site label to the name of the item pressed. For example, if Site 1 is selected and C3-L is pressed, Site 1 will be renamed C3-L. The site labels will appear on all generated documentation.

> **NOTE**: Site labels can be changed when a site label is pressed on any treatment screen (Sensory, Motor, Lesion, Pulsed, and Dosed).

Touching "**Custom Site Label**" displays the **Custom Site Label** screen. The site label name accepts any characters on the touch screen keypad with a minimum of 1 and maximum of 10 characters. Pressing "**Save**" saves the site label name to the currently active site label.

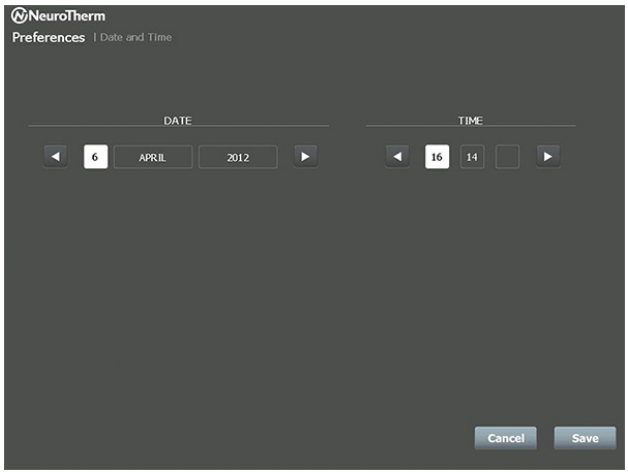
Figure 28. Custom Site Label Screen



Date and Time

Touching "**Date and Time**" displays the **Date and Time** screen.

Figure 29.



The date is set by individually pressing the DATE "day", "month", and/or "year" and using the left and right arrows to increment the respective day, month, and/or year units to the desired date.

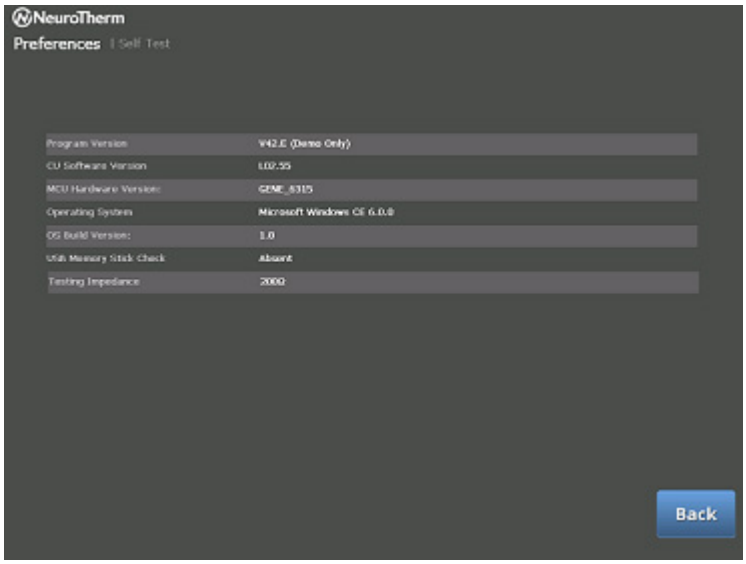
The Time is set by individually pressing the TIME "hours", "minutes", and/or "seconds" and using the left and right arrows to increment the respective hour, minute and/or seconds to the desired time.

Touch "**Save**" to save the changes to the Date and/or Time and return to the **Preferences** screen. By selecting "**Cancel"** any changes made on this screen are not saved and the screen reverts to the **Preferences** screen.

Self Test

The **Self Test** screen displays when "**Self Test**" is pressed on the **Preferences** screen.

Figure 30.



The system checks the fuses, impedance circuit (200 ohms), the presence of the USB memory stick, and displays the results. If a function fails the test, the unit will stop and warn the user of the fail condition. **If this cannot be rectified, contact NeuroTherm.**

Touching "**Back**" reverts to the **Preferences** screen.

Service

Touching "Service" displays the Service screen.

Figure 31.

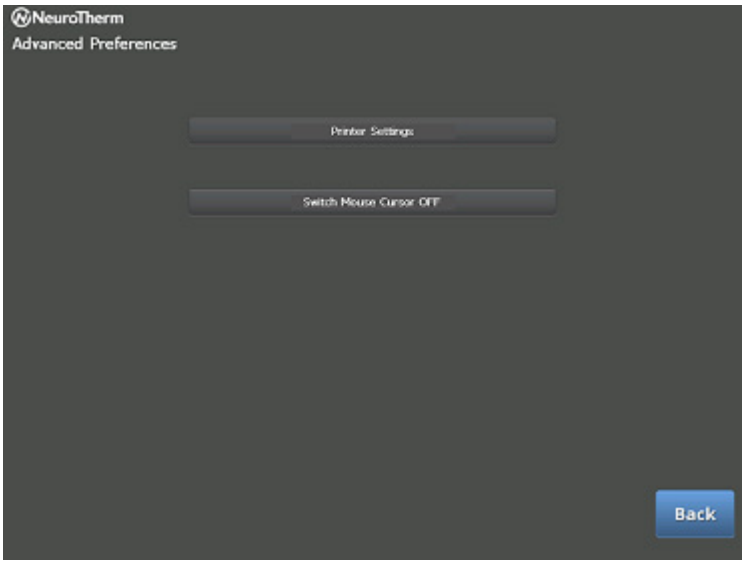
Access to the Service functions is for the use of approved personnel only by entering a password that is generated from the challenge number at the bottom of the screen.

Advanced Preferences

Touching "Advanced" displays the Advanced Preferences screen.

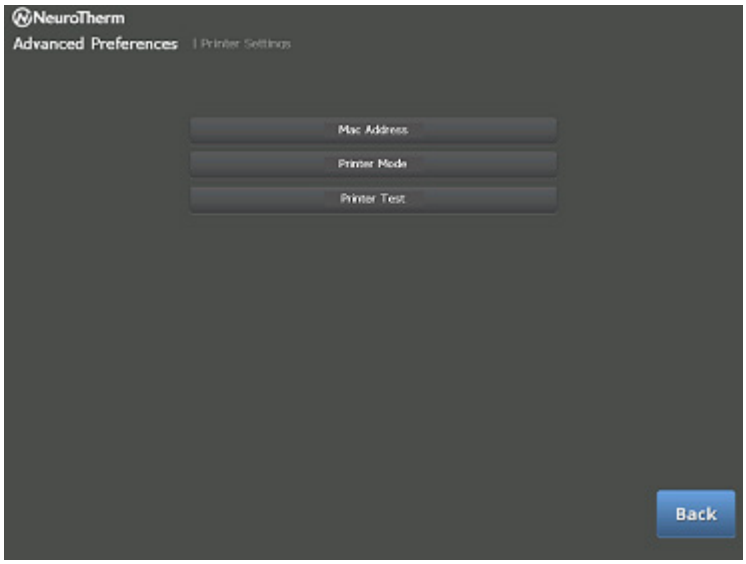
Pressing the "**Switch Mouse Cursor**" button toggles the switch between "On" and "Off".

Figure 32.



Touching "**Printer Settings**" displays the **Printer Setting** screens, from which a number of printer settings can be configured.

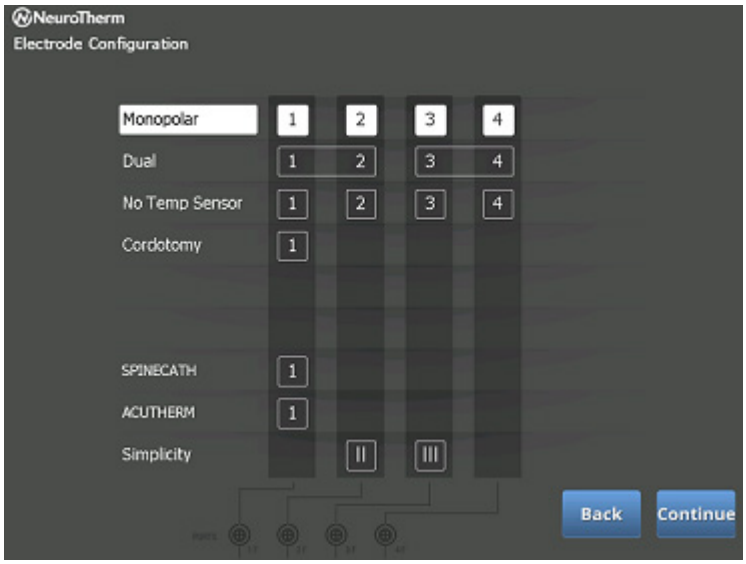
Figure 33.



Electrode Selection

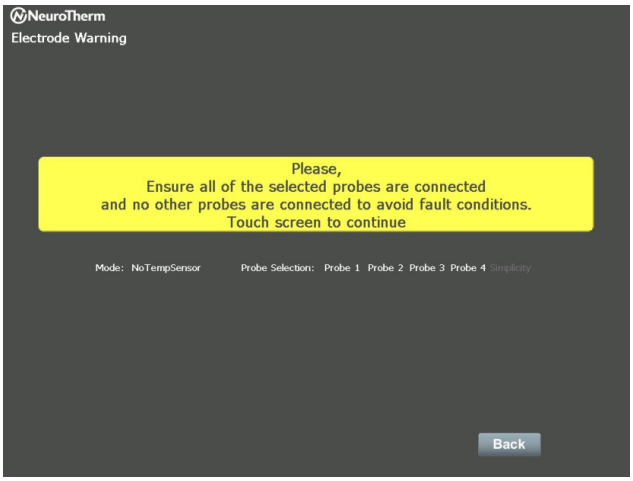
Touching "**Start**" on the **Welcome** screen displays the **Electrode Configuration** screen. The screen is also accessed by pressing "**Back**" on the **Choose Treatment** screen.

Figure 34.



From this screen, select the configuration and number of electrodes required for the treatment. Pressing "**Continue**" displays the **Electrode Warning** screen.

Figure 35.



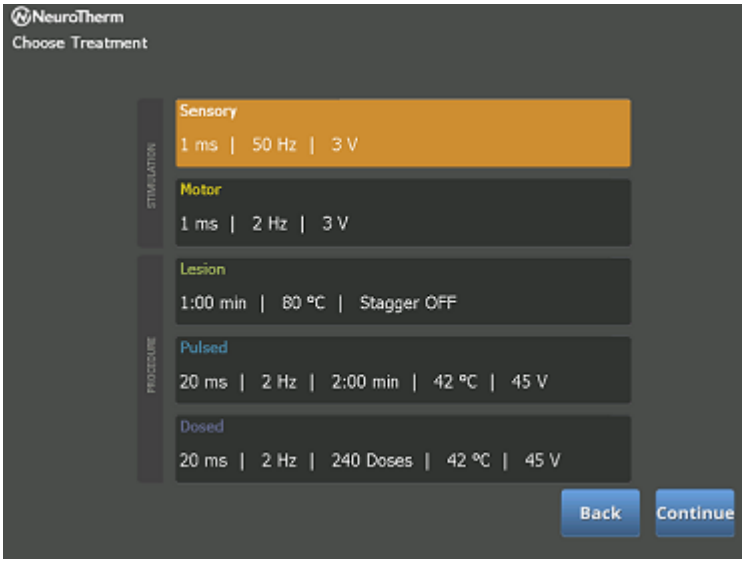
Pressing "**Back**" reverts to the **Electrode Configuration** screen, while touching anywhere else on the screen displays the **Choose Treatment** screen.

Stimulation Procedures

Stimulation Design and Operation Rationale

Nerve stimulation is widely used in medicine for the treatment of pain and for nerve localization. References to published papers on the use of stimulation techniques are identified at the end of Section Procedural Overview (page 1). In the NT2000iX™ RF generator, stimulation is commonly used for the localization of nerves prior to treatment. By delivering biphasic square wave pulses to a nerve, a response can be elicited. When the frequency of the pulses is in the range of 10Hz-200Hz, the response is a sensory type – the patient reports a tingling type sensation if the probe is in the proximity of a sensory nerve. In the 2Hz-5Hz range, the response is a motor type – there is involuntary physical movement if the probe is in the proximity of a motor nerve.

Figure 36.



The generator offers a range of frequencies and pulse widths that are consistent with other devices used to ablate nerves. Several different output ranges are available as well. In the generator, only one electrode can be active for stimulation at any one time. Stimulation can be performed before lesioning as well as after lesioning (though the latter is not usually done, since local anesthetic has been injected before the lesioning process making stimulation ineffective), but the generator does not allow stimulation to be used during the lesioning process.

In practice, stimulation is performed after electrode placement has been made, in order to confirm that the placement is optimal. The generator is first set to a sensory frequency (commonly 50 Hz, 1 ms pulse width). The pulse amplitude is slowly raised and the patient is asked to respond at the first sign of a tingling sensation. Typical response levels indicating close proximity to the nerve occur at 0.1 to 0.5 V. If a response cannot be elicited, the probe is repositioned and the test is repeated. Upon achieving satisfactory sensory response, the stimulator is set to a motor frequency (typically 2 Hz, 1 ms pulse width). The pulsed amplitude is slowly raised

and no motor response (involuntary movement) should be observed. Typically, the amplitude is raised to a level of 2-3V. If a motor response is observed at this voltage, the electrode should be repositioned and the sensory and motor tests repeated.

NOTES:

- For electrode connections and configurations, please refer to Testing, Electrode Connections, Lesion Sizes and Basic Procedures (page 55).
- RF energy and voltages for stimulation are never supplied concurrently. Voltages applied for stimulation may only be applied to one electrode at a time.

CAUTION: Always increase stimulation slowly to minimize patient discomfort and to get an accurate threshold response.

Treatment Screen

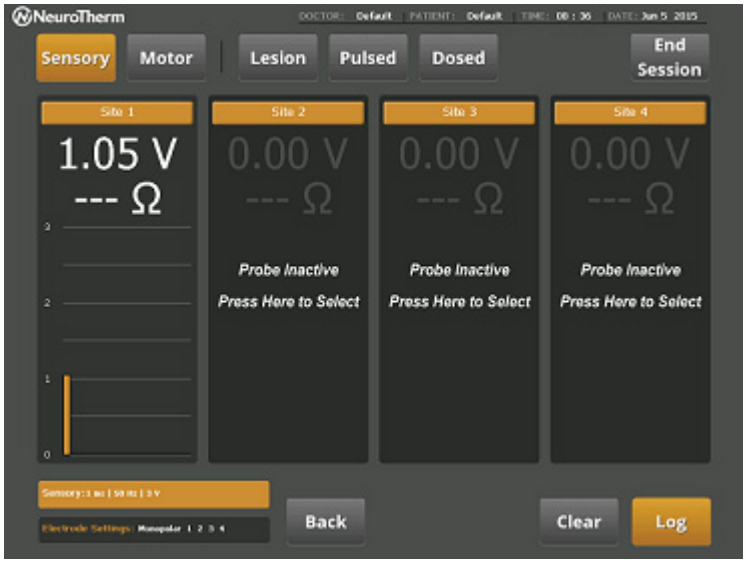
From the **Welcome** screen, select "**Continue**" to go to the **Electrode Selection** screen.

Set the electrodes to the required configuration and then press "**Continue**" to enter the **Treatment** screen.

Always check the operational settings before each procedure.

Sensory Stimulation

Figure 37.

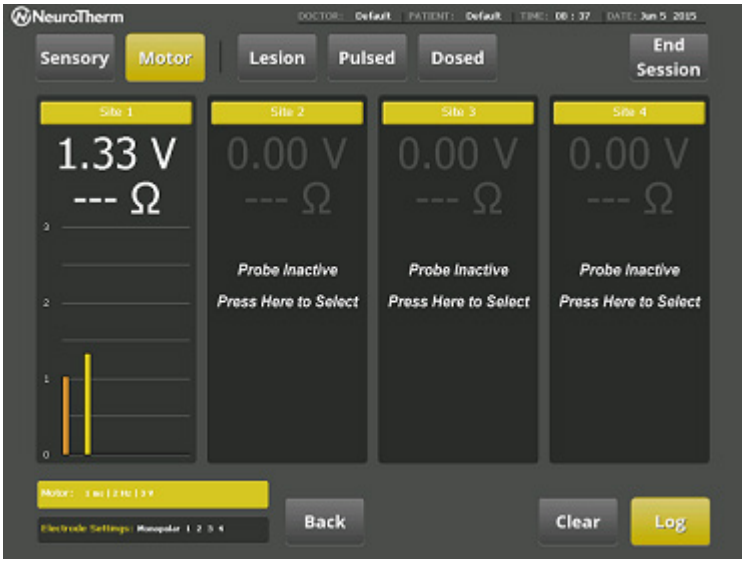


On the **Treatment** screen, select the "**Sensory"** function button.

As the stimulation voltage is applied by rotating the stimulate control slowly clockwise, the output LED will flash to indicate power is being delivered for the stimulate test. The stimulation voltage will be displayed on the screen. Pressing the "**Log**" button will store the threshold voltage on the screen and patient documentation.

Motor Stimulation

Figure 38.



On the **Treatment** screen, select the "**Motor**" function button.

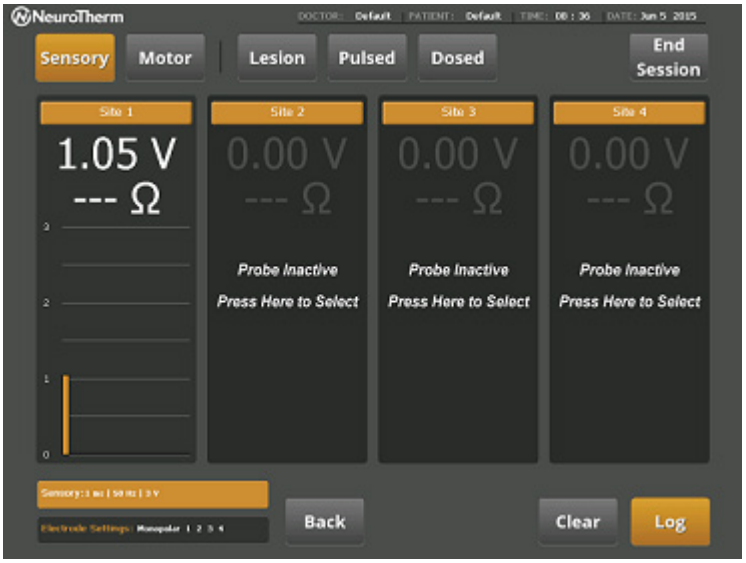
As the stimulation voltage is applied by rotating the stimulate control slowly clockwise, the output LED will flash to indicate power is being delivered for the stimulate test. The stimulation voltage will be displayed on the screen. Pressing the "**Log**" button will store the threshold voltage on the screen and patient documentation.

NOTES:

- In order to check that a probe is not faulty, a test facility is provided with the test block connected to the test socket. When the thermocouple probe is touched on the Test Block, a warning tone will indicate that a Sensory/Motor voltage is present.
- Stimulation cannot be used simultaneously with any other treatment mode.
- Only one channel can have active stimulus at one time.

Multiple Electrode Stimulation

Figure 39.

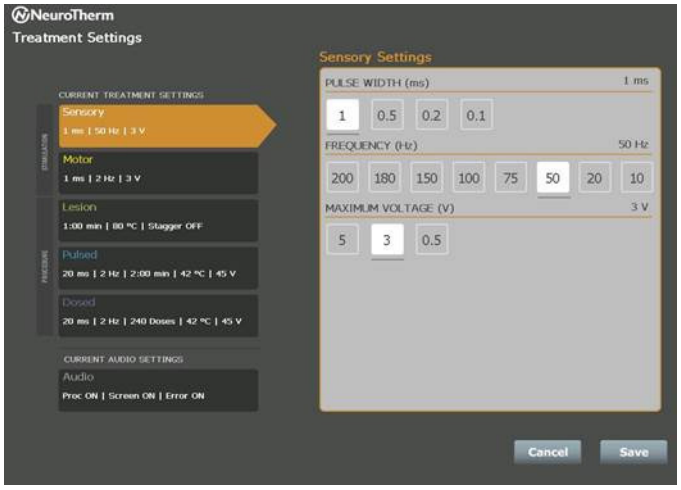


When performing multiple electrode stimulation, only one site is highlighted and active at a time. To change sites, touch anywhere in the desired site's active area.

Switch between Sensory and Motor stimulation screens by touching the appropriate areas in the top left-hand corner of the screen.

Stimulation Settings

Figure 40.



By pressing the "**Settings**" area in the bottom left part of the **Sensory** or **Motor** screen, stimulation settings in the resulting **Stimulation Settings** screen can be changed during use.

> **NOTE**: The Stimulate Output Control needs to be turned to the OFF position (fully counter-clockwise) before accessing the sensory or motor procedure screen. If power is attempted to be delivered with the knob off zero, a warning will be displayed.

Lesion Treatment Procedures

Lesion Design and Operation Rationale

RF lesioning has been used for decades to ablate nerves. Several references to the general application of RF techniques to pain management have been provided in Procedural Overview (page 1), and a detailed discussion of RF lesioning practice and principles is presented in Testing, Electrode Connections, Lesion Sizes And Basic Procedures (page 55). Another reference on the placement and treatment parameters for performing RF techniques is "Manual of RF Techniques", 2nd Edition, by Dr. Charles Gauci[10].

The NT2000iX™ RF generator provides all the standard treatment parameters in a settable and storable format. It also provides the capability to perform multiple lesions (up to four simultaneously) allowing four levels to be stimulated individually, anesthetized, and then lesioned simultaneously. If three or fewer levels are treated simultaneously, the remaining levels may be numbed from the previous anesthesia injections, which would preclude the use of stimulation.

The generator also provides a custom temperature-time profile mode. This mode can be used to program Intradiscal Electrothermal Therapy (IDET) procedures as well as allowing programmable temperature ramp times for any procedure.

This mode will typically be used when discreet monopolar lesions are desired. The insulated cannula is placed under fluoroscopic control, and stimulation is usually performed to further locate the sensory nerves and also to ensure that the cannula is not in proximity to any motor nerves. An RF lesion will then be performed at these sites.

RF lesion size is determined fundamentally by three parameters: electrode geometry, electrode tip temperature, and time. Time, however, becomes unimportant after a few minutes, since this is an equilibrium process and lesion size no longer significantly increases beyond a certain point in time. Testing, Electrode Connections, Lesion Sizes And Basic Procedures (page 55) provides a comprehensive discussion of these processes.

The lesion screen is designed to allow the clear display of these parameters, and also to allow the clinician to make changes to the default settings based on his clinical judgment.

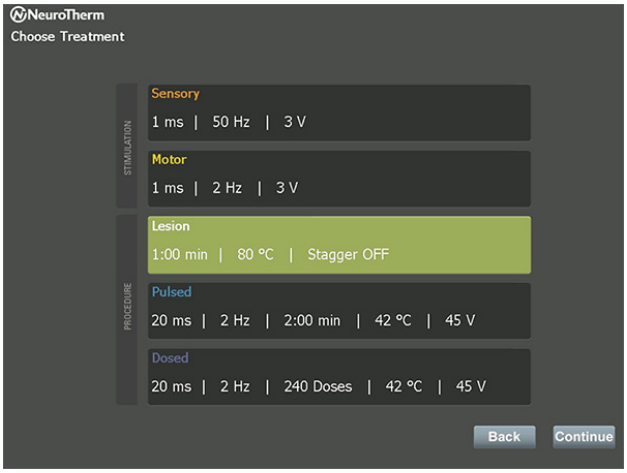
For each active output, the electrode tip temperature is displayed below a graph of lesion temperature vs. time. Please see Lesion Size Graphs (page 59) for an example. Below this graph is a digital indicator of elapsed time. A site label window allows the user to label each treatment site. By providing a graphical display, the operator can detect any rapid fluctuations in temperature, while the digital indicators report quantitative absolute values. Secondary parameters of voltage, current and impedance are also displayed in smaller indicator boxes at the base of the graphical display. A box in the lower left of the screen displays all relevant settings. Touching this box allows these settings to be modified if necessary.

> **NOTE**: For electrode connections and configurations, please refer to Testing, Electrode Connections, Lesion Sizes And Basic Procedures (page 55).

[10] Gauci CA. "Manual of RF Techniques" (2nd ed.); Flivo Press, Amsterdam, Netherlands. ISBN: 3-909441-03-3.

Treatment Screen

Figure 41.



Always check operational settings before each procedure.

When entering any Lesion screen and before starting a procedure, check that the displayed temperature indicates body temperature.

Single Lesion

Figure 42.

On the **Treatment** touch screen, select the "**Lesion**" function button. Pressing the "**Auto**" button will cause the temperature to ramp up and the time will start when the measured temperature is within 5ºC of the desired set temperature.

Pressing the "**Manual**" button enables the Rotary RF Lesion Power control. In both Auto and Manual Mode, when the time set for the procedure has elapsed, a warning tone is heard and RF Power is turned off.

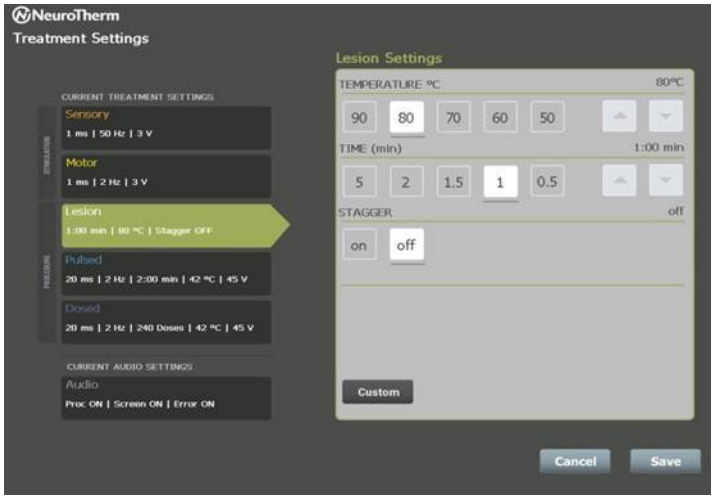
Temperature, time, voltage, current, and impedance are displayed.

NOTES:

- The red "**Stop**" button on the front panel stops all RF functions and sets the unit to safe mode.
- The RF Output Control needs to be turned to the OFF position (fully counter clockwise) before Manual RF power can be applied. Failure to do so will result in a warning message

Lesion Settings

Figure 43.



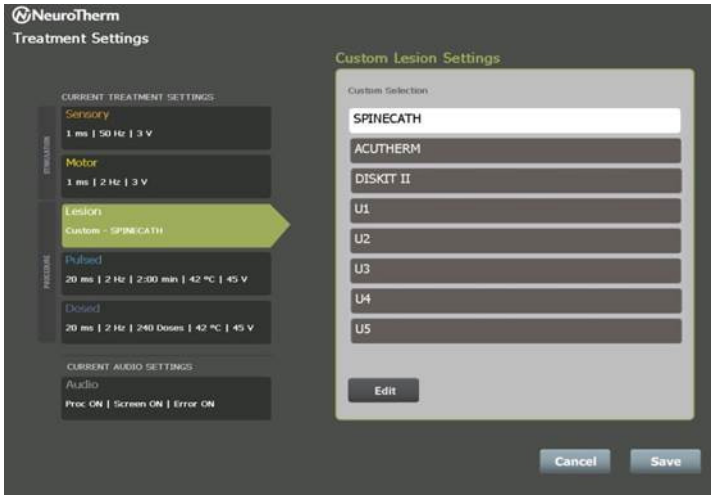
By pressing the "**Settings**" area in the lower left part of the screen, lesion settings can be changed. The **Lesion Settings** screen will then be available to change settings for the procedure.

Custom Mode

Custom Profiles

Custom profiles can be accessed from the **Lesion Settings** screen.

Figure 44.



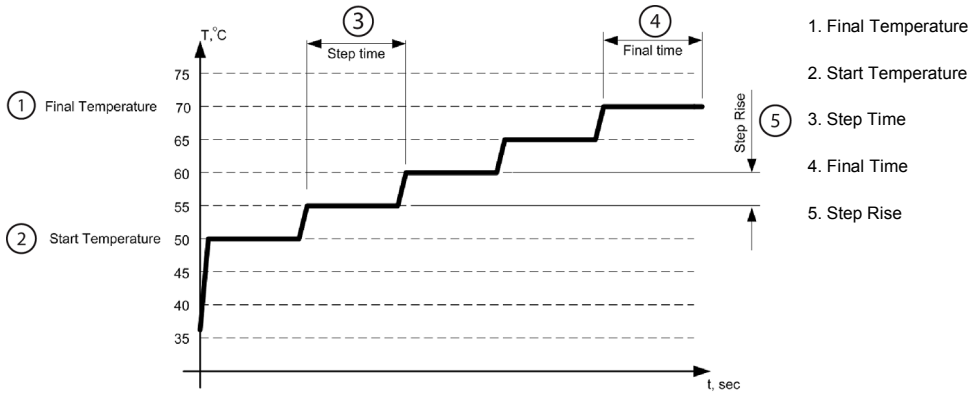
Performing an IntraDiscal Lesion Procedure

Refer to the appropriate instructions for the SPINECATH™ Intradiscal Catheter or the ACUTHERM™ Intradiscal Catheter. Connect the NeuroTherm™ AC-IDET-8 adapter cable to the NT2000iX™ RF generator and the chosen catheter. When on the **Single Electrode Lesion Procedure** screen, press on the "**Settings**" button on the bottom left of the screen. Then select "**Custom**" to access the **Custom Lesion Setting** screen. If using the SPINECATH™ catheter, select the SPINECATH profile on the Custom Lesion Settings screen. If using the ACUTHERM™ catheter, select the ACUTHERM profile on the **Custom Lesion Settings** screen. These profiles can be edited.

The generator defines a step profile using the following variables:

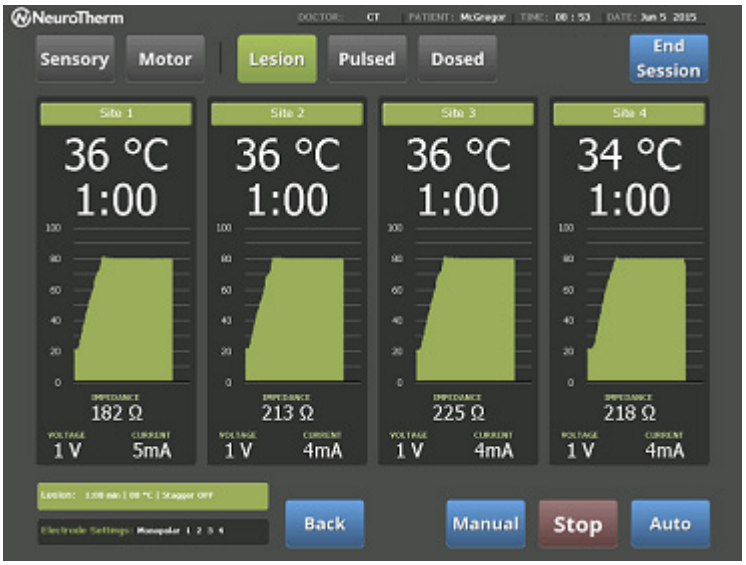
Start Temp:	The initial temperature before the making the first step rise.
Step Time:	The time in seconds at each step temperature.
Step Temp:	The increase in temperature in of each step.
Final Temp:	The maximum desired temperature of the profile.
Final Time:	The time in minutes at final temperature.

Figure 45.



Multiple Lesions

Figure 46.



By choosing more than one electrode in the **Electrode Selection** screen, multiple electrode lesioning can be performed. This can only be done in automatic mode and is initiated by pressing the "**Auto**" button.

Time for each site will start when the temperature at that site is within 5ºC of the set temperature. All electrodes will have the full time at lesion temperature.

Manual Mode can be performed, but only one electrode at a time is active. This mode is useful for determining which electrode may be responsible if discomfort is reported during the treatment process.

Pulsed RF

Pulsed RF Design and Operation Rationale

Pulsed RF has been used for over a decade to create either strong electric field low temperature or high temperature exposure to the target nerves. A complete treatise on pulse RF can be found in "Radiofrequency" Parts 1 and 2 by Prof. Menno Sluijter[11]. Pulsed RF is typically used on nerve roots that cause radicular pain. Low temperature is used in this case, since the sensory and motor fibers are in close proximity and it is difficult to position the electrode for ablation of the sensory nerve without affecting the motor nerve. Pulsed RF is also used in the case of mixed (sensory and motor) nerves often found in the peripheral nervous system.

The technique used for this procedure is analogous to the one used to create a thermal lesion. The insulated cannula is placed under fluoroscopic control and stimulation is usually performed to further locate the sensory nerves. A pulsed RF treatment is then performed.

The NT2000iX™ RF generator provides clinically common pulse frequencies rates and pulse widths used for Pulsed Radiofrequency. Lower pulse rates and shorter pulse widths will produce lower temperatures at the electrode tip. This will also expose the nerves to higher instantaneous electric fields. Higher pulse rates and longer pulse widths are used when the clinician

[11] Sluijter ME. "Radiofrequency. Part 1" and "Radiofrequency. Part 2". Flivo Press, Amsterdam. ISBN: 3-909-441-00-9 and 3-909-441-02-5.

desires a higher temperature at the electrode tip but also stronger electric fields than would be present during continuous RF heating. Temperature is settable and operated under feedback control, as in lesion modes. The generator also provides the capability to perform multiple lesions (up to four simultaneously), which allows four levels to be stimulated individually, anesthetized, and then lesioned simultaneously. If three or fewer levels are treated simultaneously, the remaining levels may be numbed from the previous anesthesia injections, which would preclude the use of stimulation.

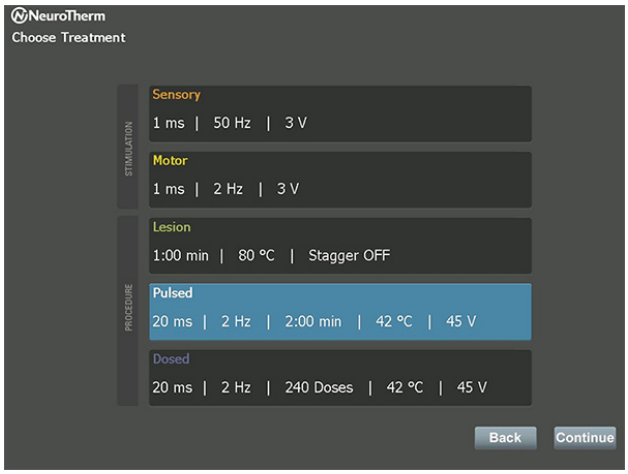
The pulsed RF screen is very similar to the lesion screen, and all treatment screens have a common format.

For each active output, the electrode tip temperature is displayed above a graph of pulsed RF temperature vs. time. Below this graph is a digital indicator of elapsed time. A site label window allows the user to label each treatment site. By providing a graphical display, the operator can detect any rapid fluctuations in temperature, while the digital indicators report quantitative absolute values. Secondary parameters of voltage, current and impedance are also displayed in smaller indicator boxes at the base of the graphical display. A box in the lower left of the screen displays all relevant settings. Touching this box allows these settings to be modified if necessary.

> **NOTE**: For electrode connections and configurations, please refer to Testing, Electrode Connections, Lesion Sizes And Basic Procedures (page 55).

Treatment Screen

Figure 47.

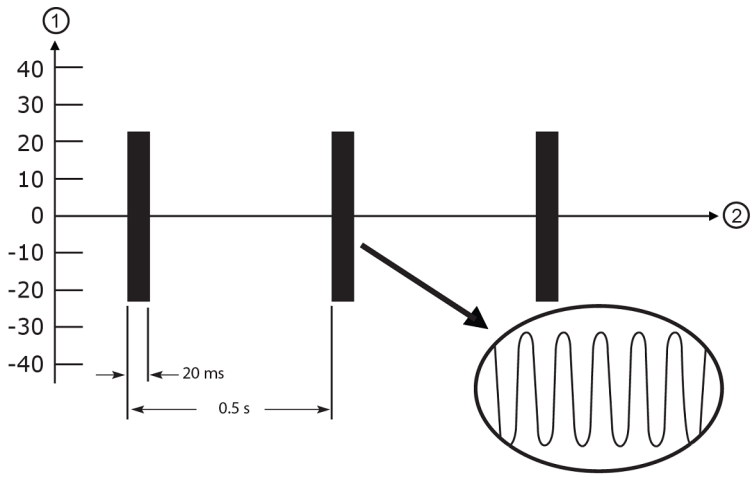


On the **Treatment** touch screen, select the "**Pulsed**" function button.

When the Pulsed function is selected the generator emits pulses whose width and frequency is selected from the **Settings** screen. Temperature and time for the procedure are also selected.

When the set temperature is reached, the pulse width is reduced to prevent exceeding the set temperature. This is pulse-width modulation.

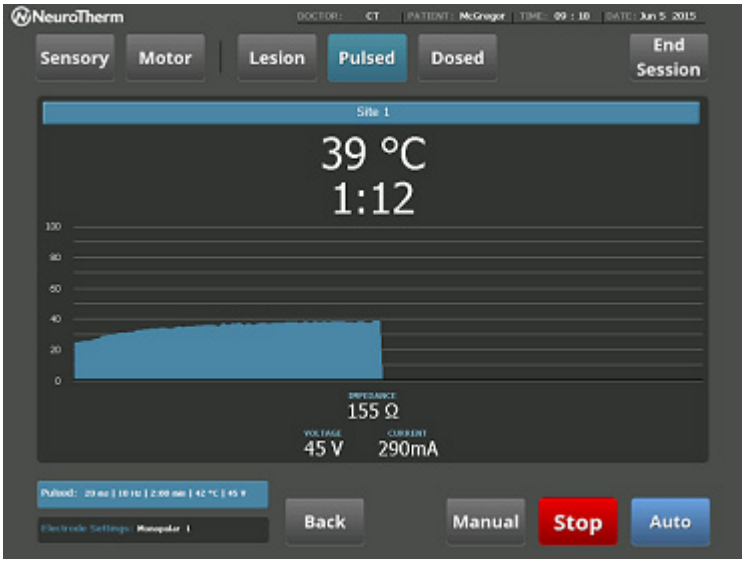
Figure 48.



1. V (Volts)
2. Time (Seconds)

Single Electrode Pulsed RF

Figure 49.



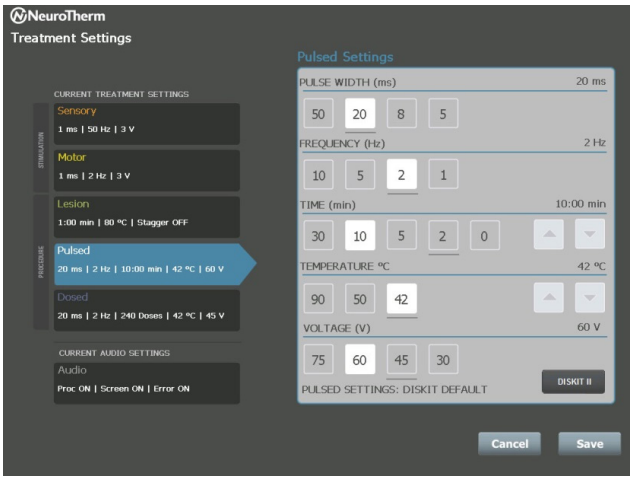
Pressing the "Auto" button will cause the voltage to ramp up and the time will start immediately.

Pressing the "Manual" button enables the Rotary RF Lesion Power control.

In both Auto and Manual Mode, when the time set for the procedure has elapsed, a warning tone is heard and RF Power is turned off.

Pulsed Settings

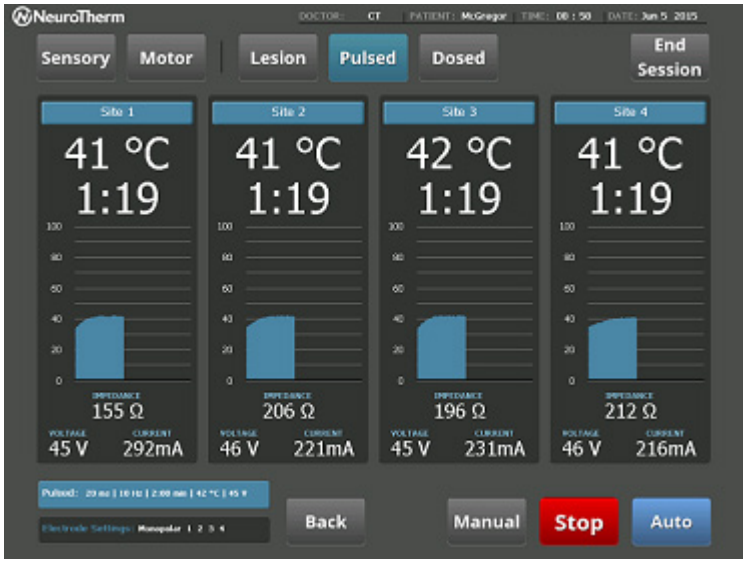
Figure 50.



By pressing the "**Settings**" area in the lower left part of the **Pulsed** screen, pulsed settings can be changed. The **Pulsed Settings** screen will then be available to change settings for the procedure.

Multiple Electrode Pulsed RF

Figure 51.



By choosing more than one electrode in the **Electrode Selection** screen, multiple electrode pulsed can be performed. This can only be done in automatic mode and is initiated by pressing the "**Auto**" button.

The timer will start immediately. When the timer reaches zero, a tone will sound and the patient will be disconnected.

Pulsed Dose

Pulsed Dose Design and Operation Rationale

Pulsed Dose RF is basically pulsed RF where the amplitude of the pulses is kept constant, and the temperature feedback control is achieved by frequency modulation rather than amplitude modulation. Pulsed Dose is a pulsed RF mode where each pulse is delivered at a preset full width and amplitude. This means that the instantaneous electric field is the same during each pulse, thereby providing treatment uniformity. Since temperature regulation is achieved by pulse inhibition, the treatment time of the procedure can vary. Therefore, the clinician will set the total number of desired treatment pulses rather than set a treatment time. This mode would be used to set consistent pulse treatment from patient to patient, and from treatment to treatment.

Pulsed Dose RF is typically used on nerve roots that cause radicular pain. Low temperature is used in this case, since the sensory and motor fibers are in close proximity and it is difficult to position the electrode for ablation of the sensory nerve without affecting the motor nerve. Pulsed Dose RF is also used in the case of mixed (sensory and motor) nerves often found in the peripheral nervous system.

The technique used for this procedure is analogous to the one used to create a thermal lesion. The insulated cannula is placed under fluoroscopic control, and stimulation will usually be performed to further locate the sensory nerves. A pulsed Dose RF treatment is then performed.

The NT2000iX™ RF generator provides clinically common pulse frequencies rates and pulse widths used for Pulsed Dose Radiofrequency. Lower pulse rates and shorter pulse widths will produce lower temperatures at the electrode tip. This will also expose the nerves to higher instantaneous electric fields. Higher pulse rates and longer pulse widths are used when the clinician desires a higher temperature at the electrode tip but also stronger electric fields than would be present during continuous RF heating. Temperature is settable and operated under feedback control, as in lesion modes. It also provides the capability to perform multiple lesions (up to four simultaneously), which allows four levels to be stimulated individually, anesthetized, and then lesioned simultaneously. If three or fewer levels are treated simultaneously, the remaining levels may be numbed from the previous anesthesia injections, which would preclude the use of stimulation.

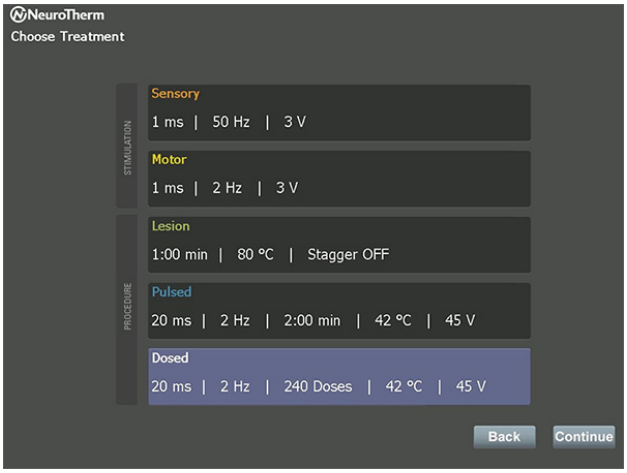
The pulsed dose RF screen is very similar to the lesion screen, and all treatment screens have a common format.

For each active output, the electrode tip temperature is displayed above a graph of pulsed RF temperature vs. time. Below this graph is a digital indicator of the number of pulses delivered. A site label window allows the user to label each treatment site. By providing a graphical display, the operator can easily detect any rapid fluctuations in temperature, while the digital indicators report quantitative absolute values. Secondary parameters of voltage, current and impedance are also displayed in smaller indicator boxes at the base of the graphics display. The upper right hand corner of the screen displays all relevant settings. Touching this window allows these settings to be quickly modified if necessary.

> **NOTE**: For electrode connections and configurations, please refer to Testing, Electrode Connections, Lesion Sizes And Basic Procedures (page 55).

Treatment Screen

Figure 52.



On the **Treatment** touch screen, select the "**Dosed**" function button.

"**Dosed**" delivers full size pulses only. If the set temperature is reached, no further pulses are delivered until the temperature drops below the set temperature. The pulsed doses are thus frequency modulated, and a pulse count is shown on the screen.

Single Electrode Dosed

Figure 53.

Pressing the "**Auto**" button will cause the voltage to ramp up and the time will start immediately.

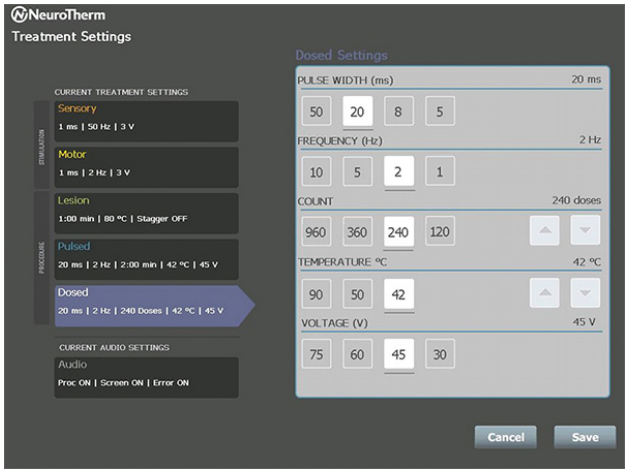
Pressing the "**Manua**l" button enables the Rotary RF Lesion Power control.

In both Auto and Manual Mode, when the time set for the procedure has elapsed, a warning tone is heard and RF Power is turned off.

> **NOTE**: In Pulsed Dose Mode, the NT2000iX™ RF generator will deliver full pulses of the preset voltage and pulse width. Should the temperature exceed the preset value the pulse will not be delivered and the counter will stop until the temperature returns to below the preset value. The count will resume at this point, ensuring the correct amount of energy is delivered.

Pulsed Dose Settings

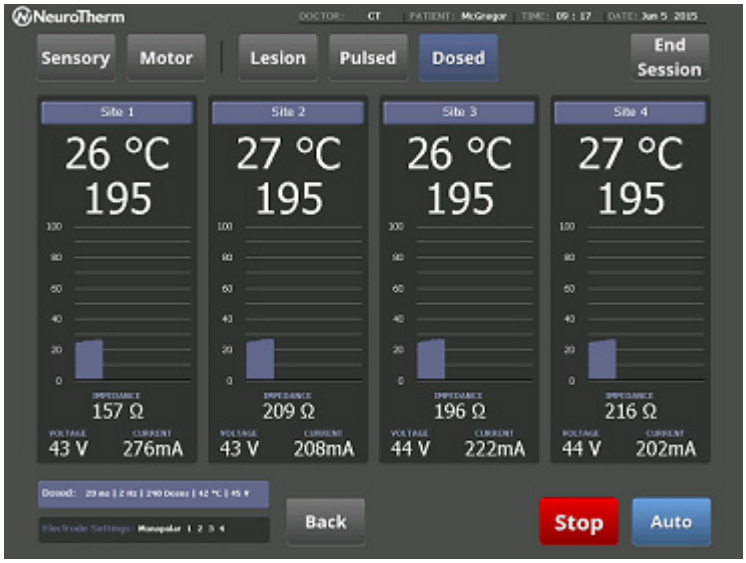
Figure 54.



By pressing the "**Settings**" area in the lower left part of the **Dosed** screen, Pulsed Dose settings can be changed. The **Dosed Settings** screen will be available to change settings for the procedure.

Multiple Electrode Pulsed Dose

Figure 55.



By choosing more than one electrode in the **Electrode Selection** screen, multiple electrode Pulsed Doses can be performed. This can only be done in automatic mode and is initiated by pressing the "**Auto**" button.

Time will start immediately. When the timer reaches zero, a tone will sound and the patient will be disconnected.

Dual Electrode Lesion

Dual Electrode Design and Operation Rationale

Dual lesioning has been used for decades to lesion nerves. It refers to the passing of RF between two temperature monitoring electrodes rather than between an electrode and grounding pad. In essence, one of the electrodes functions as the grounding pad. Since the surface area associated with the electrode is much smaller than the surface area of the grounding pad, heating results at both electrodes, and hence lesion volumes are created around both electrode tips. It is therefore important that the NT2000iX™ RF generator monitors the temperature at both electrode tips.

The technique used for this procedure is analogous to the one used to create a thermal lesion. Both insulated cannulas are placed under fluoroscopic control, and stimulation is usually performed to further locate the sensory nerves and also ensure that the cannulas are not in proximity to any motor nerves. A Dual RF treatment is then performed.

Dual electrode lesioning is often used when a contiguous lesion, rather than two discrete lesions, is desired between two electrodes. Since all the RF current is concentrated between the electrodes, this allows the electrodes to be placed further apart and still result in a complete lesion between the electrodes, compared to the two monopolar lesions obtained with a pair of electrodes referenced to a grounding pad. This may be used for lesioning of large areas or performing a large medial branch lesion on a single nerve in a single treatment. Please refer to Sections When To Use Dual Lesion (page 43) and Typical Lesion Geometries Based On Probe Spacing (page 44), and to Testing, Electrode Connections, Lesion Sizes And Basic Procedures (page 55), for additional information, including the three references cited in When to Use Dual Lesion.

In the generator, all the standard settings available for a monopolar lesion are also available in Dual electrode mode. Temperature is monitored at both electrodes, and feedback control is used to maintain the set temperature.

In Dual mode, the electrode tip temperatures are displayed above graphs of lesion temperature vs. time. Below these graphs is a digital indicator of elapsed time. A site label window allows the user to label each treatment site. By providing a graphical display, the operator can detect any rapid fluctuations in temperature, while the digital indicators report quantitative absolute values. Secondary parameters of voltage, current, and impedance are also displayed in a smaller indicator box at the base of the graphical display. The upper right hand corner of the screen displays all relevant settings. Touching this window allows these settings to be modified if necessary.

> **NOTE**: For electrode connections and configurations, please refer to Testing, Electrode Connections, Lesion Sizes And Basic Procedures (page 55).

Dual Electrode Operation

A Dual Lesion is one that is created between two separate electrodes. When performing a Dual Lesion procedure, a grounding pad is necessary for sensory and motor stimulation. The sensory and motor stimulation is carried out with respect to the grounding pad connection. Switching between the grounding pad connection and the dual electrode connection is automatic.

Figure 56.

Once the "**Auto**" button is pressed, the generator will automatically set the control electrode and the lesion will continue until the set time is reached. Once the procedure has finished the tone will sound. (During the lesion the machine will monitor the temperature at each electrode, and control the temperature on the electrode that indicates the highest temperature.) As power is passed between one probe and the other, there is only one central reading for impedance/ volts/current.

> **NOTE**: A dual electrode lesion can be made between electrodes 1-2, 3-4, or 1-2, and 3-4 simultaneously. Dual electrode treatments can be done in Lesion, Pulsed and Pulsed Dose modes.

When To Use Dual Lesion

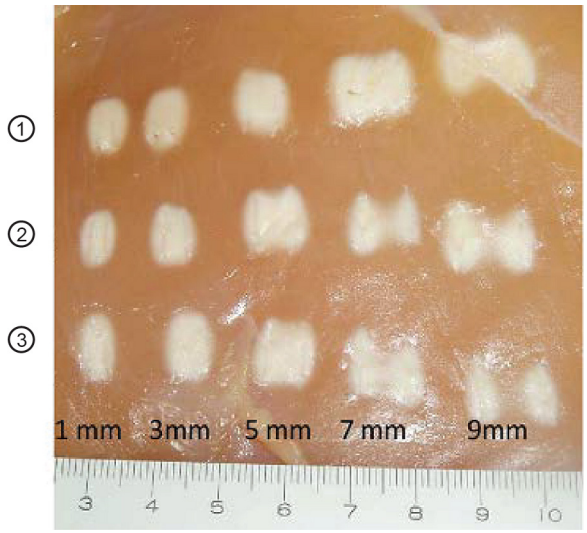
Dual lesion is typically used when a connected lesion in the form of a short strip is to be made between two electrodes.

Care must be taken not to allow the electrodes to be too far apart, as this will create two discrete lesions. More detailed information on the dual lesion technique is to be found in the published literature. [12], [13], [14]

[12] Pino CA, Hoeft MA, Hofsess C, Rathmell JP. Morphologic analysis of bipolar radiofrequency lesions: implications for treatment of the sacroiliac joint. Reg Anesth Pain Med. 2005; 30(4): 335-338.
[13] Derby R, Lee Chang-Hyung. The efficacy of a two needle electrode technique in percutaneous radiofrequency Rhizotomy: An investigational laboratory study in an animal model. Pain Physician 2006; 9: 207-214.
[14] Cosman ER, Gonzalez CD Bipolar radiofrequency lesion geometry: Implications for the palisade treatment of Sacroiliac Joint pain. Pain Practice 5 JUL 2010. (Published online in advance of print. See: http://onlinelibrary.wiley.com/doi/10.1111/j.1533-2500.2010.00400.x/abstract).

Typical Lesion Geometries Based On Probe Spacing

Figure 57.



1. Test 1
2. Test 2
3. Test 3

Sample data for dual lesioning shows the lesion separates as the needles are placed further away from each other.

Medium: Un-perfused Chicken breast

Needle size: 20G 10mm tip

Temperature 90 C

Time 120 seconds

Refer to typical dual lesion size chart in Documentation (page 53).

> **CAUTION: When using Dual Electrode Mode, the operator must insure that the two electrodes are not touching, as this will prevent any heating of the tissue. If the electrodes are in physical contact at their exposed tips, the impedance will read 0 ohms, and a "Warning - Short Circuit" will be displayed. (The NT2000iX™ RF generator is short circuit-protected and cannot be damaged by shorting the outputs). It is recommended not to place the probes closer than 9 mm apart if two discreet lesions are desired. It is also recommended to use a single monopolar electrode rather than dual mode for spacing closer than 3mm, as a single monopolar lesion will produce similar results. For spacing between 3 mm and 9 mm in Dual Electrode Mode, please use the photo above as a reference. Also refer to the typical lesion size charts in Testing, Electrode Connections, Lesion Sizes And Basic Procedures (page 55).**

Simplicity II and Simplicity III

Simplicity Design and Operation Rationale

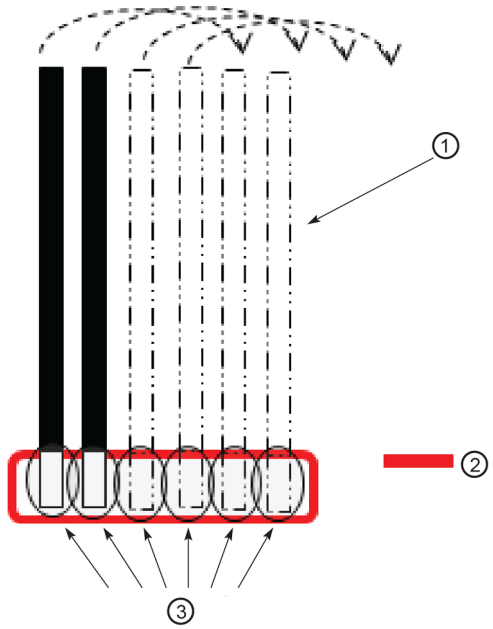
The Simplicity system combines a probe containing two (Simplicity II) or three (Simplicity III) independent active areas with an algorithm that automatically performs sequential nerve destruction between the active areas. The first phase in the sequence is a dual lesion between the distal and medial areas. The second phase is a cooling phase. The next phase is a dual lesion between the medial and proximal areas. The remaining phases are monopolar lesions performed in the distal, medial, and proximal areas, respectively.

The Simplicity Mode is used when large lesion volumes are desired. Typical lesion volumes can be found at the end of Testing, Electrode Connections, Lesion Sizes and Basic Procedures (page 55). Additional information can also be found in Typical Lesion Geometries Based On Probe Spacing (page 44). The Simplicity Mode should not be used when the lesion size can be achieved with a single lesion mode probe.

For example, in the absence of a Simplicity system, sacral nerves are often lesioned by creating a strip lesion using a "leap frog" approach. Refer to references 10, 11, and 12 of When To Use Dual Lesion (page 43) for more detail on this technique.

A traditional "leap frog" lesion is normally used to perform a series of sequential dual lesions (lesions between multiple pairs of probes), resulting in a long, sausage-shaped lesion.

Figure 58.

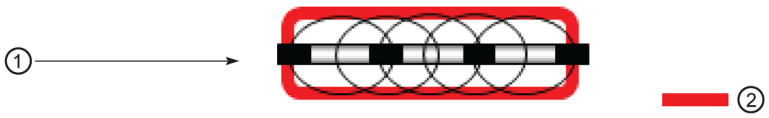


1. Probes being leap-frogged
2. Effective lesion size

This procedure may require more than an hour to complete. If the electrodes are not close enough to ensure complete lesioning between them, it is also possible to leave gaps of untreated nerve tissue.

The Simplicity probe achieves the same volume shape by conducting the lesion sequence described above, but with a single probe.

Figure 59.



1. Simplicity Probe
2. Effective lesion size

Since each of the active probe areas of the Simplicity is electrically independent, it is possible to perform both sensory and motor stimulation on each individual probe area.

The resulting lesion volume may be created to be the same as that obtained using the leap frog approach, but, in this case, it is impossible to inadvertently leave gaps of unlesioned tissue.

> **NOTE**: For electrode connections and configurations, please refer to Testing, Electrode Connections, Lesion Sizes and Basic Procedures (page 55).

Electrode Selection

The Simplicity II Procedure is accessible from several screens if the Electrode Configuration is Simplicity II:

- The **Simplicity II Lesion** screen is accessible by selecting the treatment on the **Choose Treatment** screen and pressing "**Continue**".
- The **Simplicity II Lesion** screen is accessible by pressing "**Lesion**" on the **Dual Channel Sensory Stim Procedure** screen.

The Simplicity II Lesion screen is accessible by pressing "Lesion" on the Dual Channel Motor Stim Procedure screen.

Pressing either the "Sensory" or "Motor" buttons displays the associated Dual Channel Sensory Stim or Motor Stim Procedure screen. Pressing "Lesion" displays the Treatment Settings screen with the Lesion highlighted. The Site Labels screen is displayed when the "Site Label Bar" is pressed.

Pressing "Auto" starts the procedure on both sets of probes, with the probe temperatures graphed as they change over time and stopping when the timer reaches 0 for both probes. The procedure is stopped by pressing the "Stop" button.

To perform a Simplicity II Lesion, press the "Auto" button. The procedure will perform the following functions:

A dual electrode lesion between electrode 1 and 2 for the time/ temperature selected in the **Set Up** screen, with no grounding connection.

Figure 60.

Figure 61.

Figure 62.

A single electrode lesion between electrode 1 and the grounding pad for the time/ temperature selected in the **Set Up** screen.

Figure 63.

A single electrode lesion between electrode 2 and the grounding pad for the time/ temperature selected in the **Set Up** screen.

Similar to the Simplicity II procedure, the Simplicity III procedure is accessible from several screens if the Electrode Configuration is Simplicity III:

- The **Simplicity III Lesion** screen is accessible by selecting the treatment on the **Choose Treatment** screen and pressing "**Continue**".
- The **Simplicity III Lesion** screen is accessible by pressing "**Lesion**" on the **Triple Channel Sensory Stim Procedure** screen.
- The **Simplicity III Lesion** screen is accessible by pressing "**Lesion**" on the **Triple Channel Motor Stim Procedure** screen.

Pressing either the "**Sensory**" or "**Motor**" buttons displays the associated **Triple Channel Sensory Stim** or **Motor Stim Procedure** screen. Pressing "**Lesion**" displays the **Treatment Settings** screen with the Lesion highlighted. The **Site Labels** screen is displayed when the "**Site Label Bar**" is pressed.

Pressing "**Auto**" starts the procedure on the probes, with the probe temperatures graphed as they change over time stopping when the timer reaches 0. The procedure is stopped by pressing the "**Stop**" button.

To perform a Simplicity III Lesion, press the "**Auto**" button. The procedure will perform the following functions:

Figure 64.

A Dual electrode lesion between electrode 1 and 2 for the time/ temperature selected in the **Set Up** screen, with no grounding connection.

Figure 65.

Figure 66.

A Dual electrode lesion between electrode 2 and 3 for the time/ temperature selected in the **Set Up** screen, with no grounding connection.

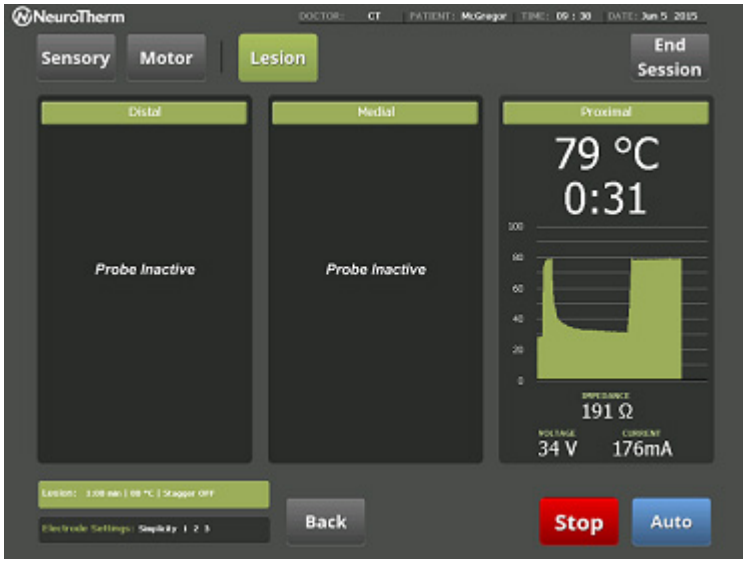
Figure 67.

A single electrode lesion between electrode 1 and the grounding pad for the time/ temperature selected in the Set Up screen.

Figure 68.

A single electrode lesion between electrode 2 and the grounding pad for the time/ temperature selected in the **Set Up** screen.

Figure 69.

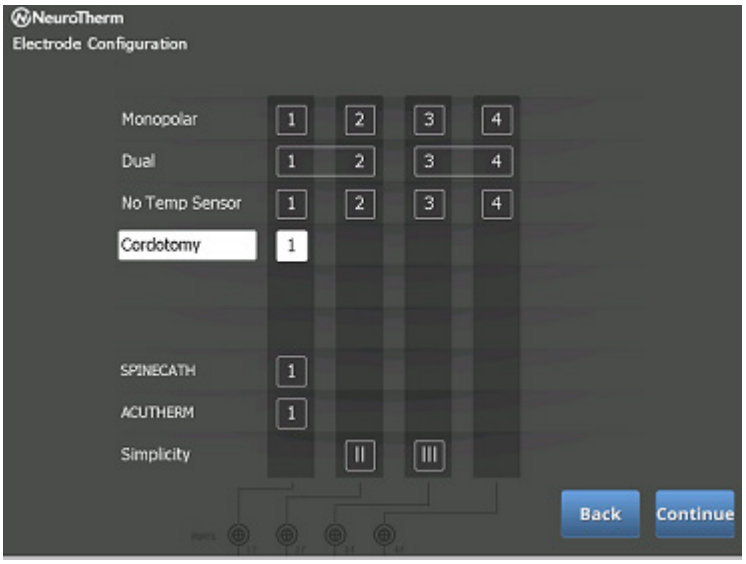


A single electrode lesion between electrode 3 and the grounding pad for the time/ temperature is selected the **Set Up** screen.

Cordotomy Mode

Electrode Selection

Figure 70.



In Cordotomy mode of operation, the NT2000iX™ RF generator is modified to give a reduced power.
In stimulate standby, the generator will generate an audio tone that changes with the Impedance at the probe tip.
The user may select up to a 95ºC limit for this procedure only.

Cordotomy Lesion

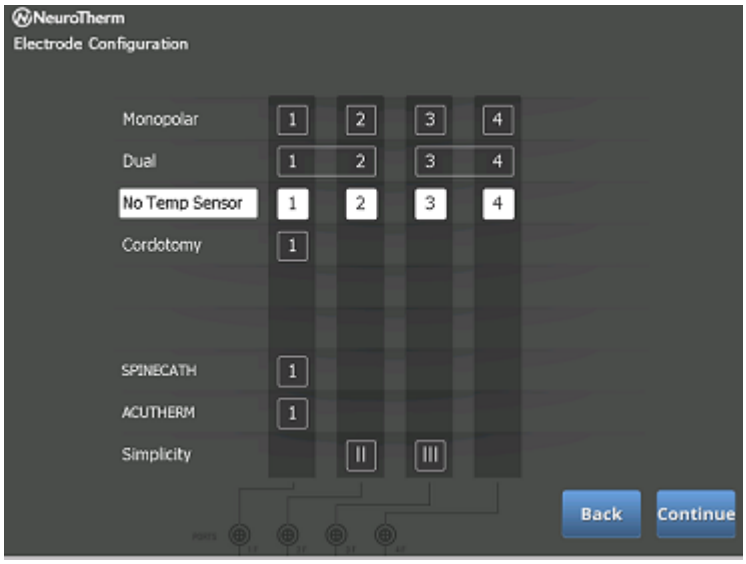
Figure 71.

In Cordotomy Mode, only electrode one is active. In this mode, automatic control is not available. Manual Mode must be used.
Control the RF power is achieved by rotating the RF Power Control clockwise.
Cordotomy is only available in Lesion Mode.

No Temperature Sensor Mode

Electrode Selection

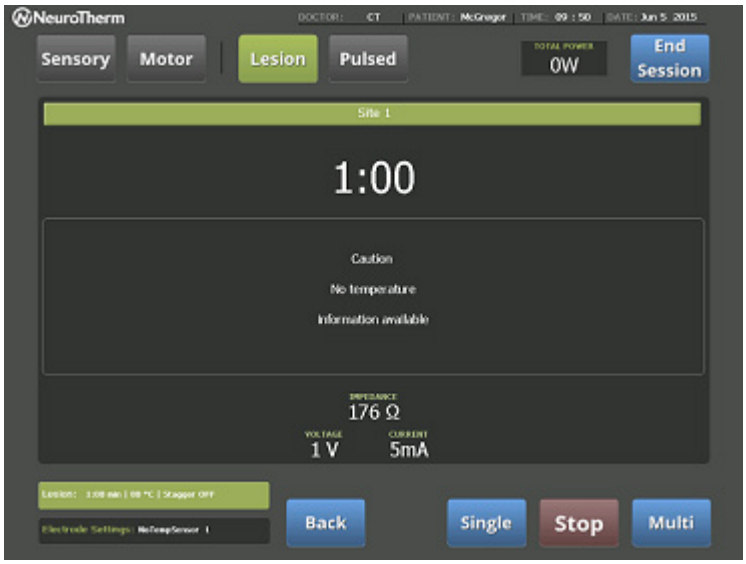
Figure 72.



No Temp Sensor Mode allows the user to apply a voltage to an electrode that does not have a temperature sensor.

Single Electrode No Temperature Sensor

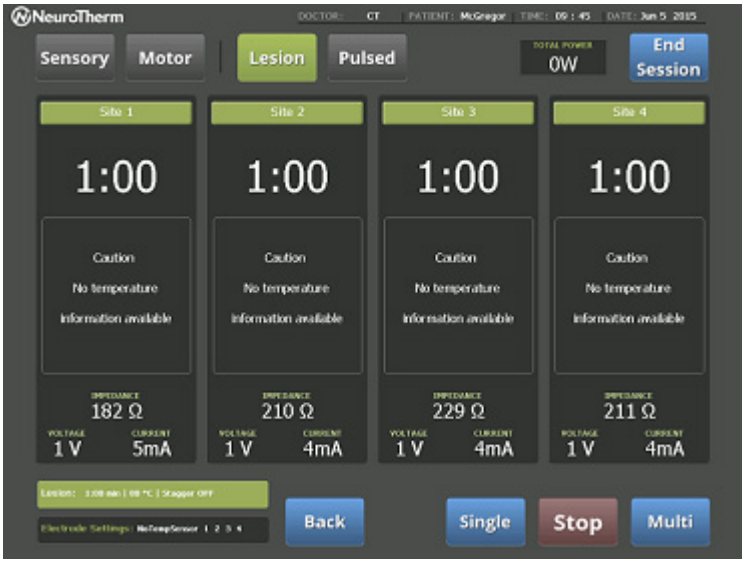
Figure 73.



No Temp Sensor only operates in manual mode.
It is recommended that temperature monitoring is used whenever possible.
No Temp Sensor only operates in **Lesion** mode in the USA. Outside USA, it also operates in **Pulsed** mode.

Multiple Electrode No Temperature Sensor

Figure 74.



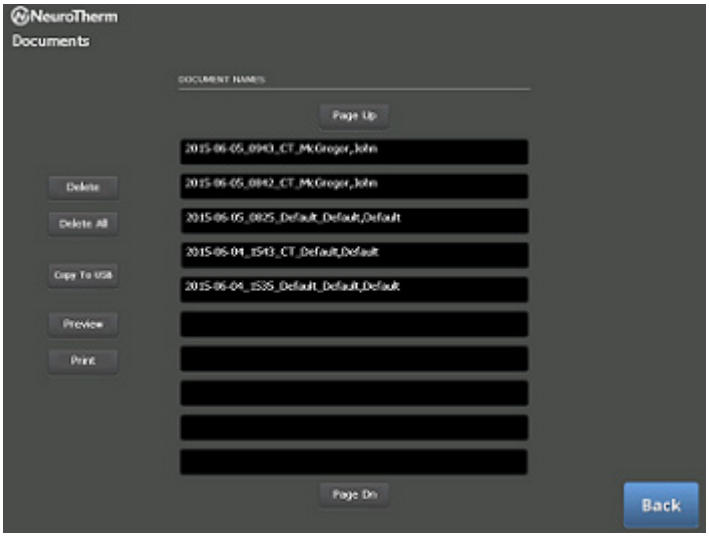
The NT2000iX™ RF generator supports multiple No Temp Sensor in Multiple Electrode Mode. It is supported in Lesion and Pulsed Modes, but only under manual control. If "**Multiple**" is selected, all active channels are simultaneously controlled by the RF rotary knob. If "**Single**" is selected, then only one electrode can be operated at a time. Electrode selection occurs by touching the desired electrode graph area.

Documentation

Documents Screen

Access the **Documents** screen by touching "**Documents**" in the **Welcome** screen. The NT2000iX™ RF generator logs and stores all data from every procedure on a second-by-second basis. The **Documents** screen allows one to show summary files, preview files, delete files, print files, or copy files to a memory stick. It is good practice to avoid having more than 100 log files – if necessary, download onto USB memory stick and then delete files.

Figure 75.



Saving Data to the USB Memory Stick

The USB memory stick plugs into the back of the machine.

Data can be copied and used on any Microsoft [15] Windows-compatible computer, and viewed using Microsoft Excel. For reference the files are saved as .CSV (Comma Separated Value) text files, using log number and names for the log files. The log number correspond to the log file name, example: 100047.csv is the log data file for procedure 100047.

Detailed CSV files can be viewed with any spreadsheet program, and summary patient files can be viewed with any text editor.

NOTES:

- Rigorous procedures should be adopted to ensure backups of user logs are made frequently and stored safely.
- Operator should review the data in the data file to confirm consistency.

Viewing Reports

By pressing "**Preview**" in the **Documents** screen, the currently selected report is displayed. Once reviewed, it can be printed using the "**Print**" button (found on the **Documents** screen).

Figure 76.

Messages

Table 2. Fault Messages

Message	Action
An Error has occurred. *Patient is no longer connected to the machine.* *Disconnect all electrodes, and restart machine, using the power switch, to continue.*	Disconnect electrodes, and restart the machine, using the power switch, to continue.
Amplifier fault	Contact NeuroTherm.
Fuse blown	Contact NeuroTherm.
Probe # over 98ºC, Press Back	Press "Back" and wait for electrode to cool to 40°C before continuing.
No thermocouple on probe 1, 2, 3, 4	Check probe connection to machine. If probe is connected, test thermocouple.
Check connector and probe *Press OK to continue*	Check probe connection to machine. If probe is connected, test thermocouple.

Table 3. Warning Messages

Message	Action
Not all channels reached the target voltage in time allotted. *Reduce the target voltage or reduce the number of active electrodes.* *(Press here to acknowledge)*	Press the message box to continue.
Not all channels reached the target temperature in time allotted.	Press "Yes" or "No" to continue. "Yes" will initiate single channel

[15] Microsoft, Excel, and Windows are trademarks of Microsoft Corporation.

Would you like to initiate single channel RF lesion procedures for all stalled probes?	RF lesion mode and "No" will bring up Target Temperature message screen below.
Not all channels reached the target temperature in time allotted. Re-position electrode(s) and try monopolar RF lesion procedure for all stalled probes. *(Press here to acknowledge)*	Press the message box to continue.
Emergency stop has been pressed. *Patient is no longer connected to the machine.* *Disconnect all electrodes, and restart machine, using the power switch, to continue.*	Disconnect electrodes, and restart the machine, using the power switch, to continue.

Cleaning Procedures

Cleaning Procedure for the NT2000iX™ RF Generator

Wipe with a cloth dampened with a mild soap-water solution. Do not use solvents or bleach on any part of the machine. For extreme contamination, isopropyl alcohol can be used, but it may smear the touch screen and should be followed by wiping with a cloth dampened with mild soap-water solution. **Do not use too much water.**

Cleaning should take place if the system has been contaminated or on 6-month intervals.

Cleaning Procedure for NT2000iX™ Accessories / Equipment

Needles and single use disposable probes are supplied sterilized, and for single patient use.

It is recommended that single use disposable electrodes should be used for added safety of the patient and members of the hospital staff.

If reusable electrodes, test leads, and stimulation test block are used, refer to the "Instructions for Use" documentation of the equipment for information on autoclave settings and sterilization procedures.

Testing, Electrode Connections, Lesion Sizes and Basic Procedures

Using The NeuroTherm™ Stimulation Test Kit

Introduction

There are times when the cannula and electrodes look to be properly positioned in the patient but the patient does not feel any stimulation.

The Stimulation Test Kit (STIM-KIT) provides a positive test that the electrode and NT2000iX™ RF generator are operating correctly. This test can be performed within the sterile field.

Preparation

Ensure that the Stimulator Test Kit is kept sterile and is always available.

Figure 77.

Figure 78.

Table 4. Stimulation Test Kit Contents

Part #	Description
STIM-TBL	Black Cable
STIM-TB	Circular Test Block

Sterilization Instructions

After use, the Stimulation Test Kit cable and test block should be washed with a mild soap solution and damp cloth then rinsed thoroughly. After rinsing, sterilize by autoclave but not exceeding a maximum temperature of 140°C.

Check Electrode

When the electrode is plugged into the generator, the red LED above the electrode input will turn green. When inserted into the cannula located in the patient, the temperature reading on the generator in Test or in Lesion mode will read between 35°C and 38°C.

Check the Grounding Pad

Ensure that the grounding pad is properly connected. With the electrode and cannula in place in the patient, check the impedance.

Check the Stimulation – Test to be carried out with sterile electrode away from the patient.

Plug the black test lead into the generator and the other end into the round test block. Place the test block on the sterile trolley.

Remove the electrode from the patient, the cannula can stay in place and touch the end of the electrode onto the sterile block.

Switch the generator into Stimulation Mode, set to 100Hz or 2Hz, turn up the amplitude, and note the meter increases up to 10V.

With the amplitude turned up, a buzz (100Hz) or a tick (2Hz) will be heard.

This is proof that the stimulation voltage is actually being delivered to the tip of the cannula.

Repositioning the Electrode

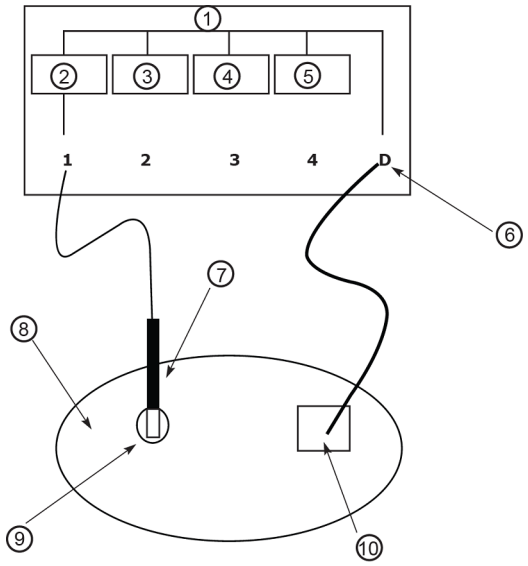
If all is correct with the machine and electrodes, then the position of the cannula is suspect. Continue to reposition until the patient feels the stimulation.

If a satisfactory threshold cannot be found, turn up the stimulation voltage to 0.5V (or 1V) and keep the stimulation on while the needle is slowly moved around. Ensure an assistant is ready to turn the amplitude down or off as soon as stimulation is felt, as it can be painful for the patient. When stimulation is felt properly, test for the sensory threshold by turning up from 0V.

Electrode Connections

Monopolar Single Electrode Mode

Figure 79.



1. Common Ground
2. Oscillator One
3. Oscillator Two
4. Oscillator Three
5. Oscillator Four
6. Dispersive Connection
7. Electrode
8. Patient
9. Treatment area
10. Grounding pad

Charge polarity: sinusoidally oscillating

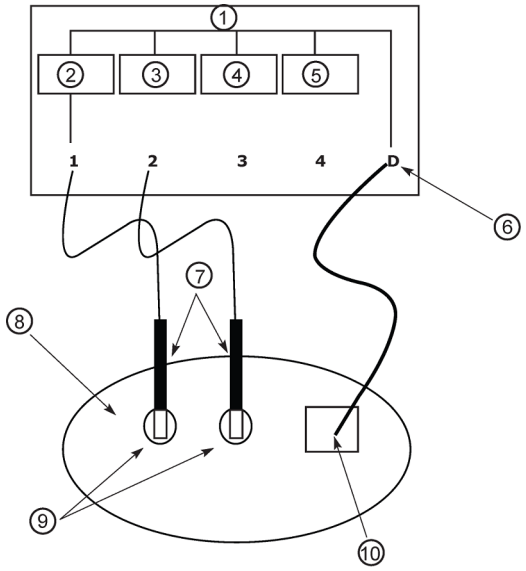
Current path: Oscillator 1 through electrode, patient tissue, and dispersive pad to dispersive connection

Temp monitoring: at probe tip

NOTE: Output 2, 3, or 4 may alternatively be selected.

Monopolar Double Electrode Mode

Figure 80.



1. Common Ground
2. Oscillator One
3. Oscillator Two
4. Oscillator Three
5. Oscillator Four
6. Dispersive Connection
7. Electrodes
8. Patient
9. Treatment area
10. Grounding pad

Charge polarity: sinusoidally oscillating

Current path: Oscillators 1 and 2 simultaneously through corresponding electrodes, patient tissue, and dispersive pad to dispersive connection.

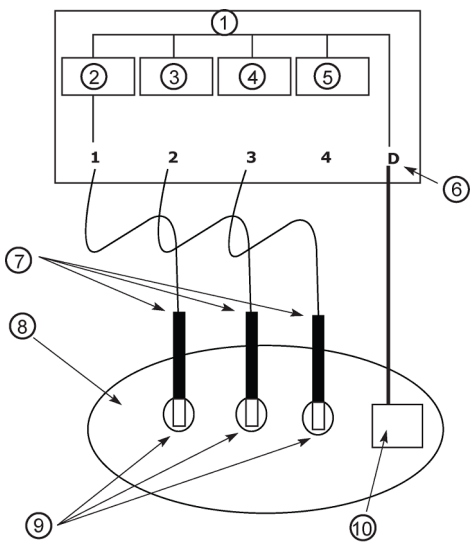
If the two electrodes are at different voltages, current may also pass through the tissue between the two electrodes

Temp monitoring: at both probe tips

NOTE: Any other output combination of two electrodes may also be selected.

Monopolar Triple Electrode Mode

Figure 81.



1. Common Ground
2. Oscillator One
3. Oscillator Two
4. Oscillator Three
5. Oscillator Four
6. Dispersive Connection
7. Electrodes
8. Patient
9. Treatment area
10. Grounding pad

Charge polarity: sinusoidally oscillating

Current path: Oscillators 1, 2 and 3 simultaneously through corresponding electrodes, patient tissue, and dispersive pad to dispersive connection

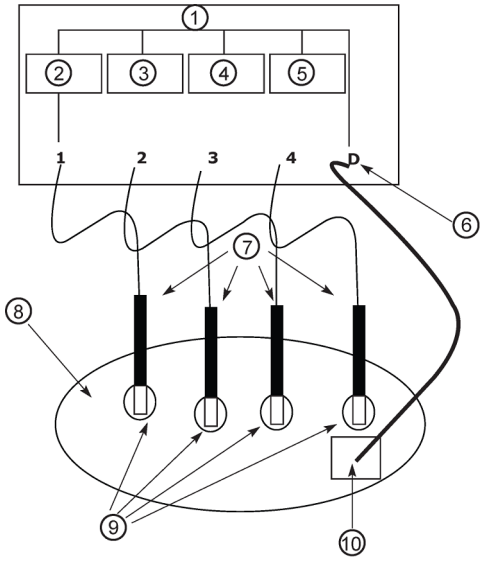
If any of the three electrodes are at different voltages with respect to one another, current may also pass through the tissue between the electrodes

Temp monitoring: at all three probe tips

NOTE: Any other combination of three outputs may also be selected.

Monopolar Quadruple Electrode Mode

Figure 82.



1. Common Ground
2. Oscillator One
3. Oscillator Two
4. Oscillator Three
5. Oscillator Four
6. Dispersive Connection
7. Electrodes
8. Patient
9. Treatment area
10. Grounding pad

Charge polarity: sinusoidally oscillating

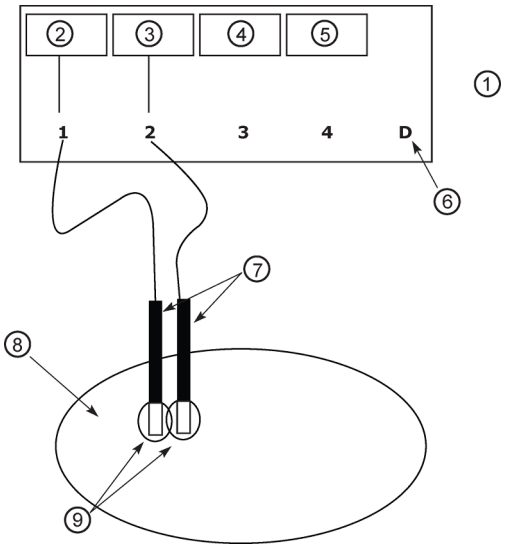
Current path: Oscillators 1, 2, 3 and 4 simultaneously through corresponding electrodes, patient tissue, and dispersive pad to dispersive connection

If any of the four electrodes are at different voltages with respect to any of the others, current may also pass through the tissue between these electrodes.

Temp monitoring: at all four probe tips

Dual Electrode

Figure 83.



1. Dual Electrode mode
2. Oscillator One
3. Oscillator Two
4. Oscillator Three
5. Oscillator Four
6. Dispersive Connection
7. Electrodes
8. Patient
9. Treatment area

Charge polarity: sinusoidally oscillating

Current path: Oscillator 1 through first electrode and patient tissue to second electrode and then oscillator 2

Temp monitoring: at both probe tips

NOTE: It is also possible to do a Dual between outputs 3-4.

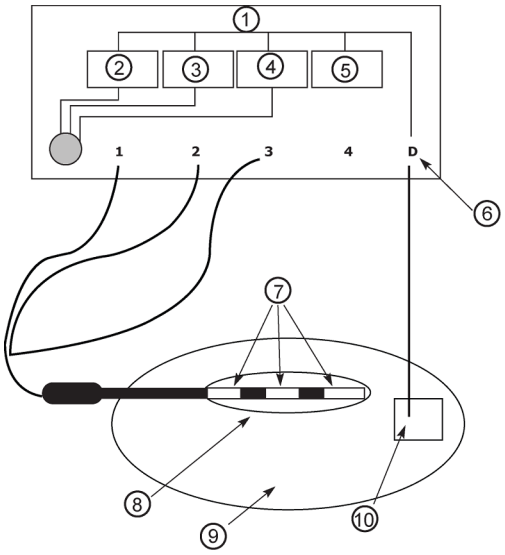
NOTE: It is also possible to perform a Dual electrode lesion between electrodes 1-2 and 3-4 simultaneously using the NT2000iX™ RF generator. The results are simply a duplication of the results of a 1-2 lesion at the site of the 3-4 electrodes.

Simplicity II and Simplicity III

This configuration (Simplicity III) uses a cable that plugs into outputs one, two, and three of the generator. The three cables are labeled.

NOTE: Simplicity II uses outputs one and two only.

Figure 84.



1. Common Ground
2. Oscillator One
3. Oscillator Two
4. Oscillator Three
5. Oscillator Four
6. Dispersive Connection
7. Electrodes
8. Treatment area
9. Patient
10. Grounding pad

Lesion Size Graphs

This section provides user guidance on what typical lesion dimensions might be expected in a clinical setting. The modeling was done using finite element analysis of the bioheat equation for various common configurations of electrode lengths, electrode tip

exposures, and operational modes using parameters consistent with human tissue, electrode insulation, and stainless electrodes. The model was two dimensional with axial symmetry, and the initial temperature was taken to be 37°C. Confirmation of the model was done by comparing results to in vitro lesions in boneless chicken breast.

The physical parameters used for the modeling are as follows:

Table 5. Physical Parameters

Material	Quantity	Value	Units
Human tissue	CP, heat capacity	3400	J/Kg°C
	P, density	1000	Kg/M3
	σ, electrical conductivity	.29	S/m
	ϵ, relative permittivity	2000	----
	K, thermal conductivity	1.2	W/m°C
	Wb, blood perfusion	10	Kg/m3s
Electrode insulation	CP, heat capacity	3400	J/Kg°C
	P, density	800	Kg/M3
	σ, electrical conductivity	0	S/m
	ϵ, relative permittivity	2.7	----
	K, thermal conductivity	.01	W/m°C
Stainless steel	CP, heat capacity	500	J/Kg°C
	P, density	7900	Kg/M3
	K, thermal conductivity	15	W/m°C

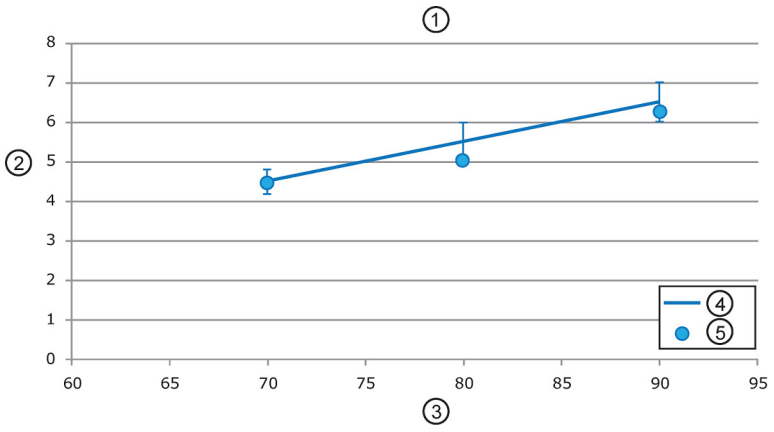
* Cosman ER Jr, Cosman ER Sr. Electric and thermal field effects in tissue around radiofrequency electrodes. Pain Med. 2005; 6(6): 405-424.

NOTES:

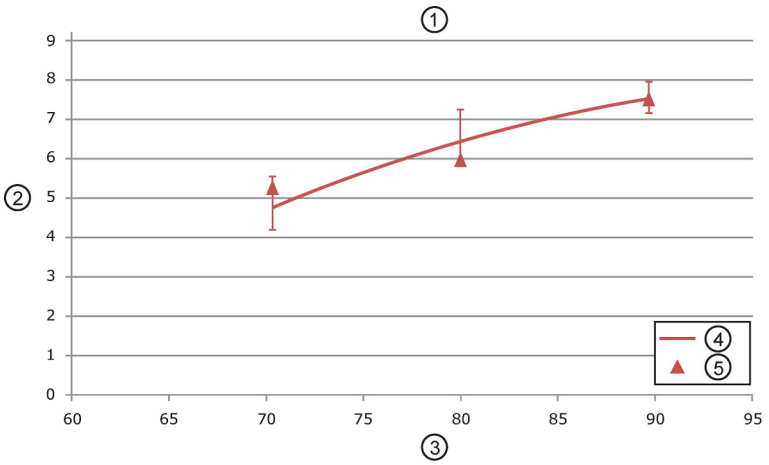
- Given the low resistivity of chicken and the fact that the breasts were not perfused, the results are likely overestimates of the lesion diameter compared to what would be achieved in clinical practice.
- These dimensions represent 60°C isotherms. Other boundary temperature definitions will result in different results.
- The error bars on the following graphs represent size differences resulting from temperature variations of ±2°C.
- The points represented at 70, 80 and 90°C are actual chicken data values.

WARNING: These results are for reference only. Actual lesion volumes created in human patients will depend on many factors such as tissue resistivity, proximity to bone, and proximity to vascular structures.

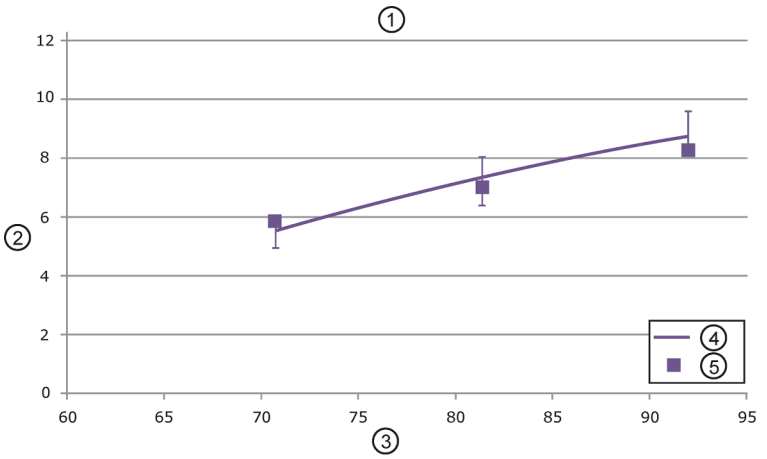
Monopolar Lesions



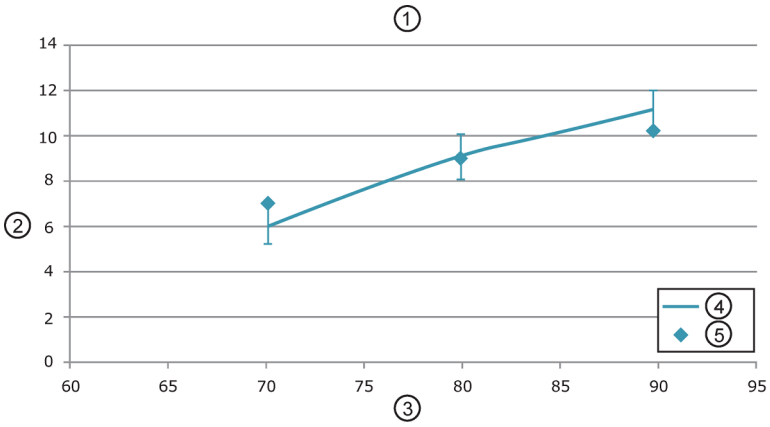
1. Width as a Function of Temperature 18 Gauge 10mm Tip
2. Width, mm
3. Temperature, ºC
4. 30 Seconds Simulation
5. 30 Seconds Actual



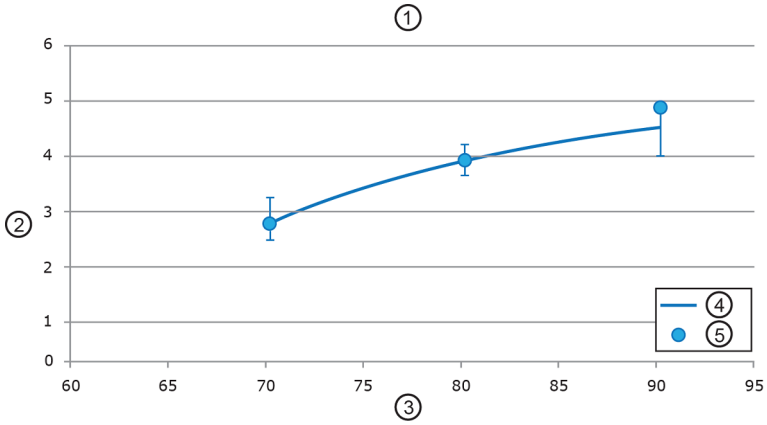
1. Width as a Function of Temperature 18 Gauge 10mm Tip
2. Width, mm
3. Temperature, ℃
4. 60 Seconds Simulation
5. 60 Seconds Actual



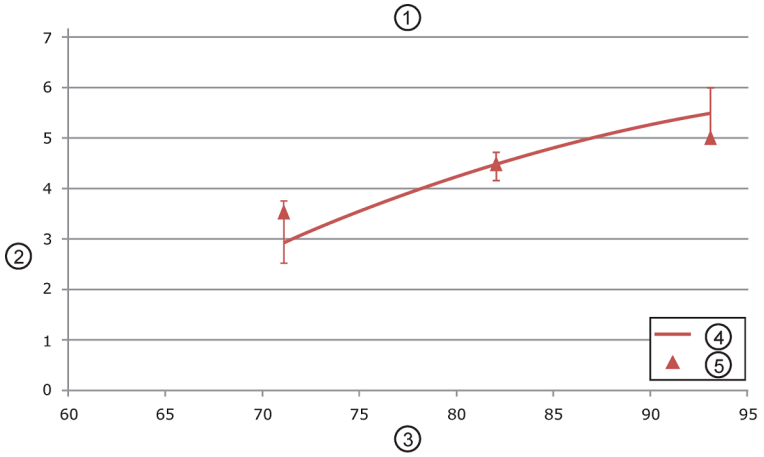
1. Width as a Function of Temperature 18 Gauge 10mm Tip
2. Width, mm
3. Temperature, ℃
4. 120 Seconds Simulation
5. 120 Seconds Actual



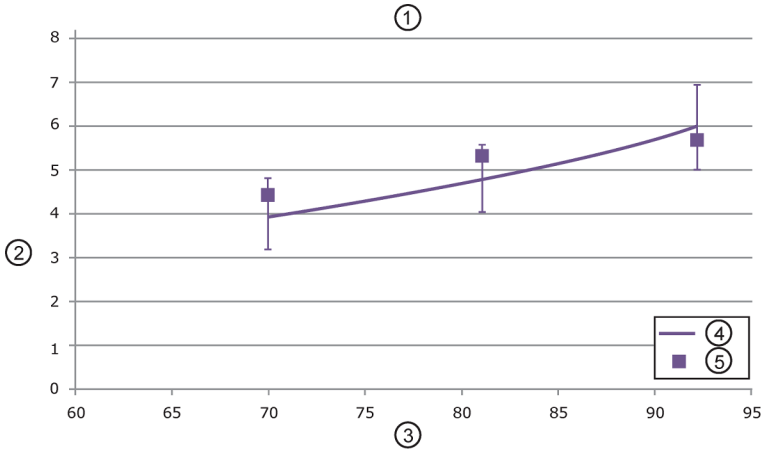
1. Width as a Function of Temperature 18 Gauge 10mm Tip
2. Width, mm
3. Temperature, ℃
4. 360 Seconds Simulation
5. 360 Seconds Actual



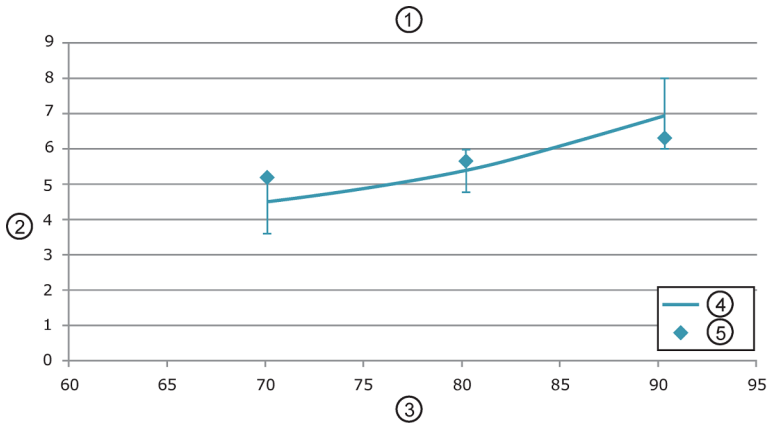
1. Width as a Function of Temperature 22 Gauge 5mm Tip
2. Width, mm
3. Temperature, ºC
4. 30 Seconds Simulation
5. 30 Seconds Actual



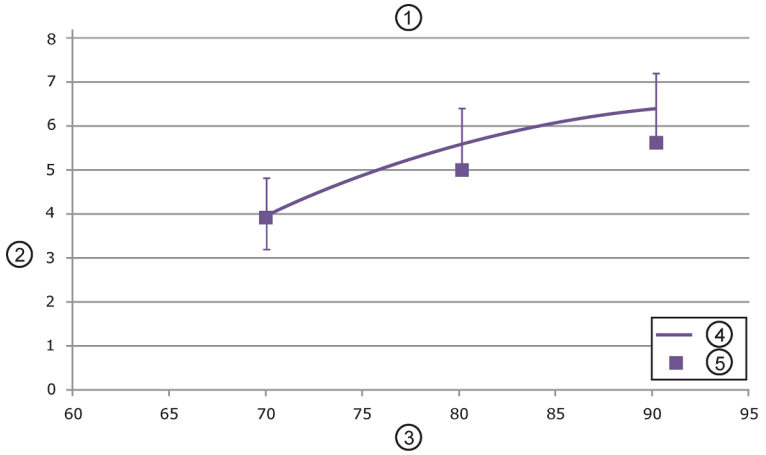
1. Width as a Function of Temperature 22 Gauge 5mm Tip
2. Width, mm
3. Temperature, ºC
4. 60 Seconds Simulation
5. 60 Seconds Actual



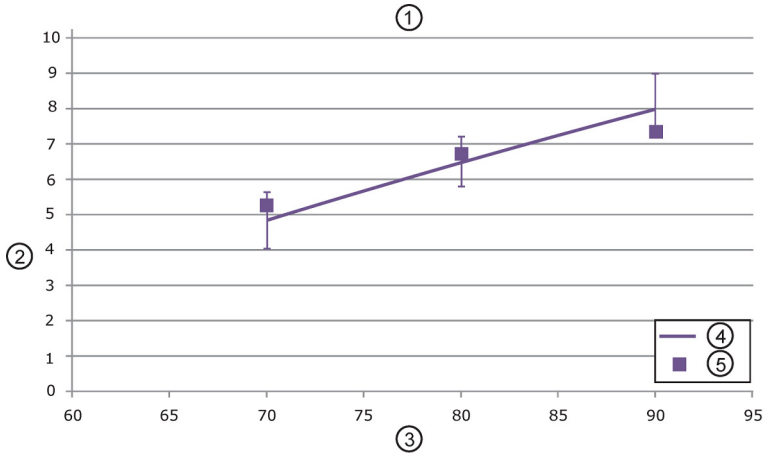
1. Width as a Function of Temperature 22 Gauge 5mm Tip
2. Width, mm
3. Temperature, ºC
4. 120 Seconds Simulation
5. 120 Seconds Actual



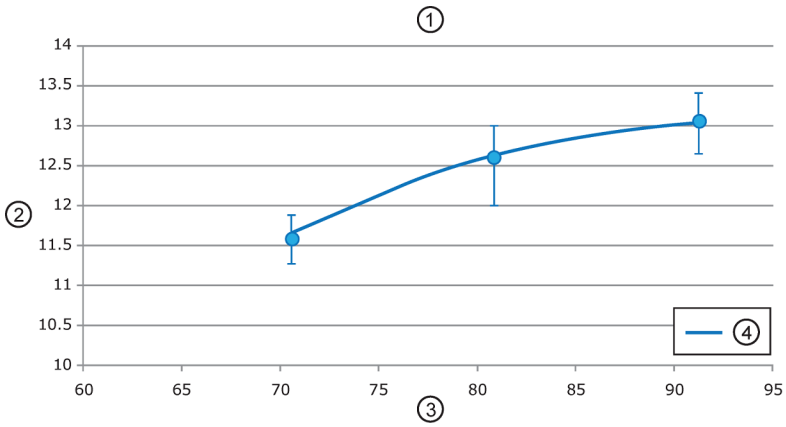
1. Width as a Function of Temperature 22 Gauge 5mm Tip
2. Width, mm
3. Temperature, ºC
4. 360 Seconds Simulation
5. 360 Seconds Actual



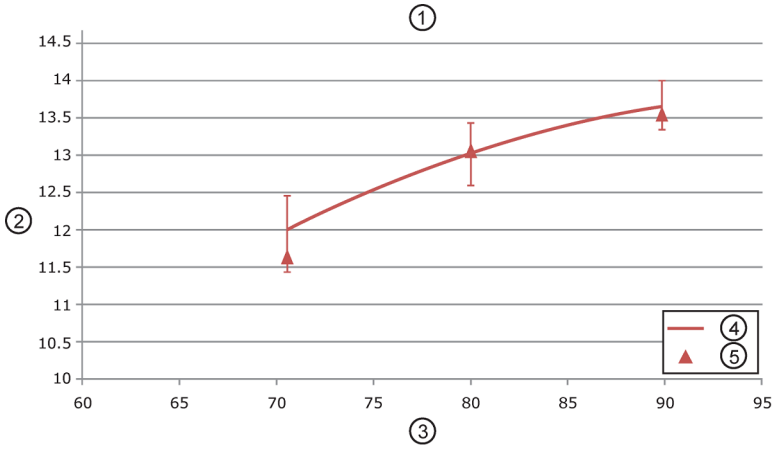
1. Width as a Function of Temperature 20 Gauge 5mm Tip
2. Width, mm
3. Temperature, ºC
4. 120 Seconds Simulation
5. 120 Seconds Actual



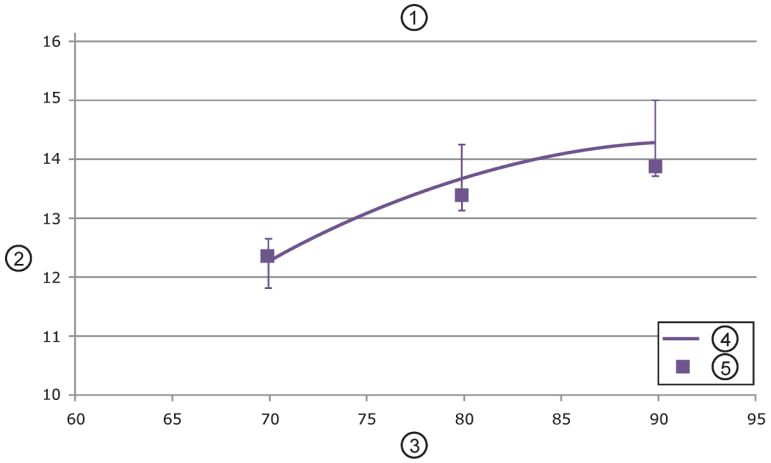
1. Width as a Function of Temperature 20 Gauge 10mm Tip
2. Width, mm
3. Temperature, ºC
4. 120 Seconds Simulation
5. 120 Seconds Actual



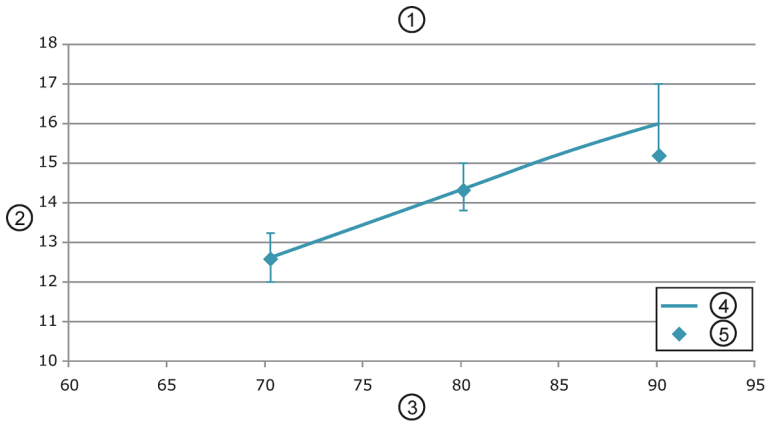
1. Length as a Function of Temperature 18 Gauge 10mm Tip
2. Length, mm
3. Temperature, ℃
4. 30 Seconds Simulation



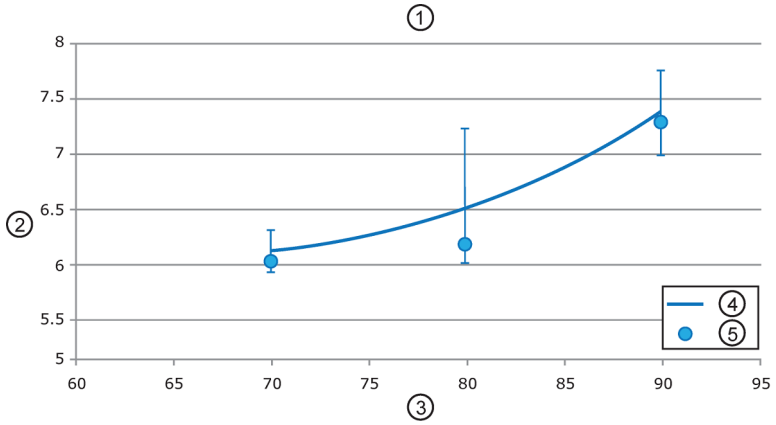
1. Length as a Function of Temperature 18 Gauge 10mm Tip
2. Length, mm
3. Temperature, ℃
4. 60 Seconds Simulation
5. 60 Seconds Actual



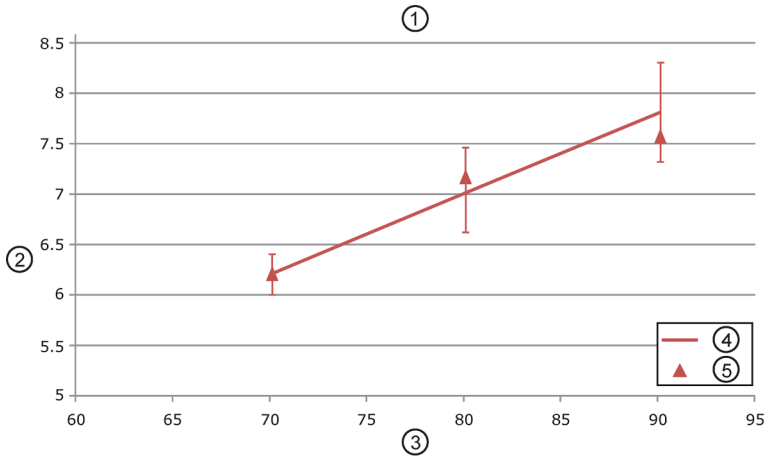
1. Length as a Function of Temperature 18 Gauge 10mm Tip
2. Length, mm
3. Temperature, ℃
4. 120 Seconds Simulation
5. 120 Seconds Actual



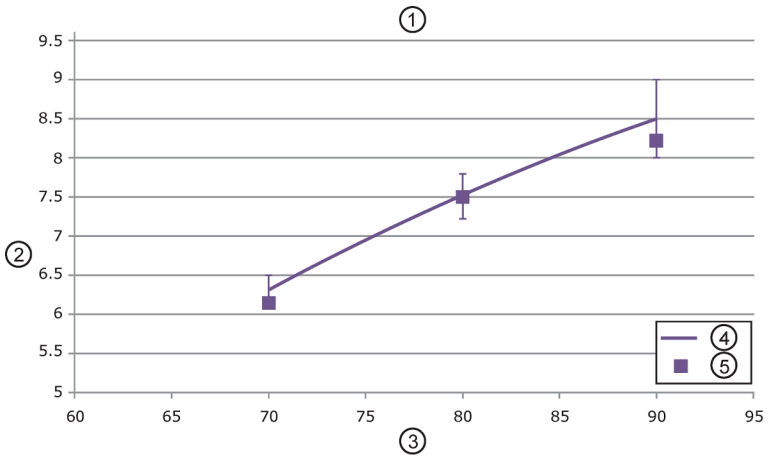
1. Length as a Function of Temperature 18 Gauge 10mm Tip
2. Length, mm
3. Temperature, ℃
4. 360 Seconds Simulation
5. 360 Seconds Actual



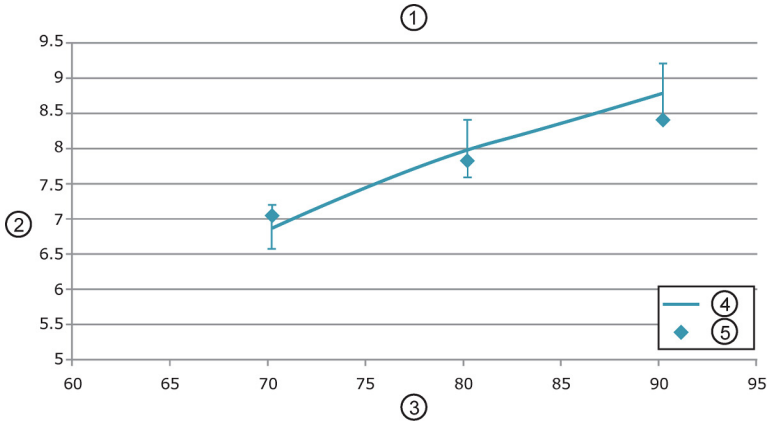
1. Length as a Function of Temperature 22 Gauge 5mm Tip
2. Length, mm
3. Temperature, ℃
4. 30 Seconds Simulation
5. 30 Seconds Actual



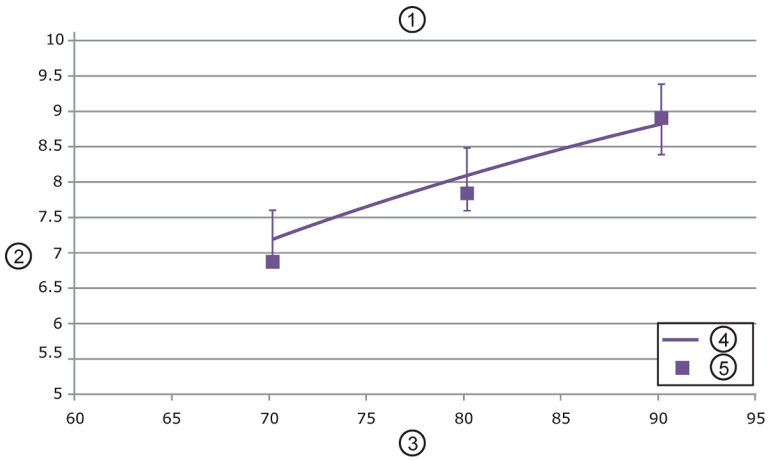
1. Length as a Function of Temperature 22Gauge 5mm Tip
2. Length, mm
3. Temperature, ℃
4. 60 Seconds Simulation
5. 60 Seconds Actual



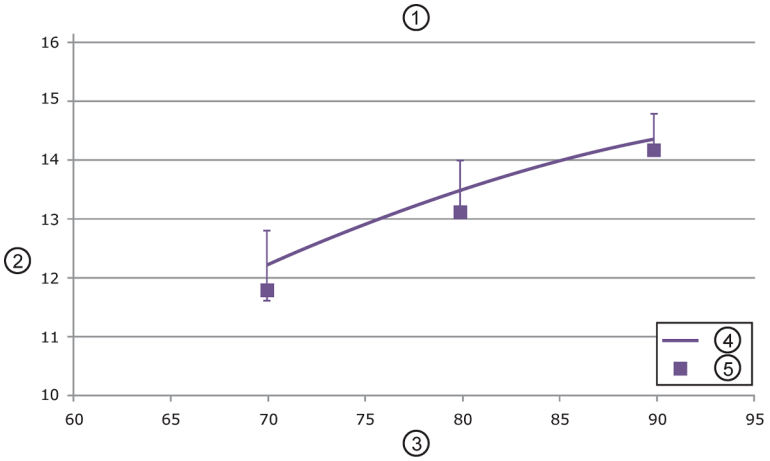
1. Length as a Function of Temperature 22 Gauge 5mm Tip
2. Length, mm
3. Temperature, ºC
4. 120 Seconds Simulation
5. 120 Seconds Actual



1. Length as a Function of Temperature 22 Gauge 5mm Tip
2. Length, mm
3. Temperature, ºC
4. 360 Seconds Simulation
5. 360 Seconds Actual



1. Length as a Function of Temperature 20 Gauge 5mm Tip
2. Length, mm
3. Temperature, ºC
4. 120 Seconds Simulation
5. 120 Seconds Actual



1. Length as a Function of Temperature 20 Gauge 10mm Tip
2. Length, mm
3. Temperature, ºC
4. 120 Seconds Simulation
5. 120 Seconds Actual

Lesion Size Tables

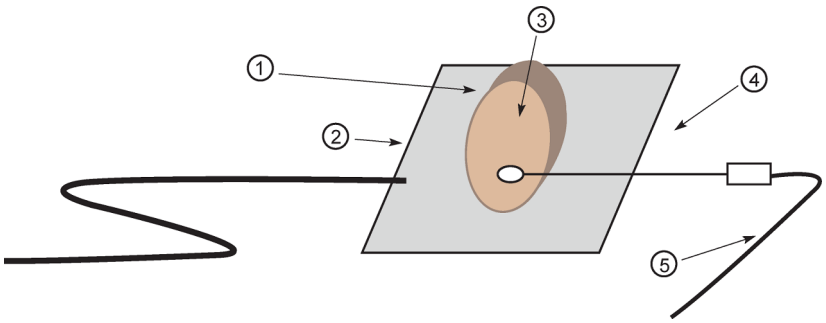
This section provides user guidance on what typical lesion dimensions might qualitatively be expected in a clinical setting. The modeling was done for various common configurations of electrode lengths, electrode tip exposures, and operational modes in non-perfused chicken breast that began at an initial temperature of 37°C. Three ablations were made and the numbers represent the mean size in black with the standard deviation in parenthesis ( ), in the tables under Monopolar Lesions (page 68). Given the low resistivity of chicken and the fact that the breasts were not perfused, the results are likely overestimates of the lesion diameter compared to what would be achieved in clinical practice.

NOTE: These dimensions represent 60°C isotherms. Other boundary temperature definitions will result in different results.

WARNING: These results are for reference only. Actual lesion volumes created in human patients will depend on many factors such as tissue resistivity, proximity to bone, and proximity to vascular structures.

The basic setup is illustrated below:

Figure 85.



1. Chicken Breast
2. Grounding Pad
3. Lesion
4. Cannula
5. Electrode

Using the NT2000iX™ RF generator, NeuroTherm™ electrodes, cannula, grounding pad, and chicken breasts, lesions were created for the following combinations of time, temperature, tip exposure, and needle gauge:

Table 6. Combination Settings

Time, seconds	Temperature, °C	Tip Exposure, mm	Needle Gauge
30	70	5	18
60	80	10	20
120	90	-	22
360	-	-	-

Each combination was repeated three times for single, double, and quadruple lesions for a total of 1,512 data points. Triple lesion testing was determined to be unnecessary, as both two lesion and four lesion was performed. The measurements from single, double, and quadruple will provide enough data to calculate average lesion size. After the lesion was created, the width and length at the largest section was recorded. Given the material properties of chicken (low resistivity), as well as no wash out due to blood flow, the lesions created in chicken breasts will be larger than those created in humans. Care was taken to place the probes near the center of the chicken rather than the ends, and spacing was chosen to be what would typically be encountered clinically (2.5 cm).

The average and standard deviation measurement were calculated and compared between the lesioning modes. Standard deviation is in parenthesis ( ), in the tables under Monopolar Lesions (page 68).

Monopolar Lesions

Table 7. Cannula Size: 18 Gauge 5 mm Tip

		Average Length (mm)				Average Width (mm)			
Temp	Time	Single Lesion Avg(SD)	Double Lesion Avg(SD)	Triple Lesion Avg(SD)	Quad Lesion Avg(SD)	Single Lesion Avg(SD)	Double Lesion Avg(SD)	Triple Lesion Avg(SD)	Quad Lesion Avg(SD)
70°	30 Sec	5.67(1.2)	5.12(.06)	4.96(.4)	4.66(1.7)	3.91(1.6)	3.99(1.4)	3.74(1.9)	3.34(.4)
	60 Sec	5.87(1.5)	5.34 (1.7)	5.23(1.2)	5.21(1.5)	4.18(1.4)	4.72(1.5)	4.35(1.7)	3.53(1.9)
	120 Sec	6.62(1.4)	5.43(.06)	5.62(1.6)	5.38(1.4)	4.69(1.6)	5.34(1.4)	4.23(1.6)	3.66 (1.5)
	360 Sec	6.89(1.5)	6.2 (1.7)	6.21(1.2)	6.10(.06)	5.86(1.5)	5.60(1.9)	5.23(1.5)	4.04(1.7)
80°	30 Sec	6.46(1.4)	5.82(1.7)	4.66(1.9)	5.27(1.7)	4.48(.4)	5.32(1.7)	4.74(1.9)	4.08(1.4)
	60 Sec	6.29(.06)	5.87(1.5)	5.45(1.4)	5.46(1.4)	4.80(1.7)	5.78(1.4)	4.85(.06)	4.25(1.5)
	120 Sec	6.75(.4)	6.93(1.7)	6.34(.06)	7.03(1.7)	5.63(1.4)	6.57(.4)	5.33(1.4)	5.20(1.7)
	360 Sec	7.75(1.7)	7.34(1.6)	7.11(1.7)	7.25(1.4)	6.09(1.5)	8.2 (1.7)	5.83(1.4)	5.55(1.5)
90°	30 Sec	6.66(.06)	6.34(.4)	6.26	6.13(1.7)	4.50(1.9)	6.36(1.2)	5.74(.06)	4.26(1.9)
	60 Sec	6.86(1.7)	5.60(1.2)	5.34(.06)	5.67(1.4)	5.27(.4)	6.84(1.4)	5.35(1.9)	5.00(1.2)
	120 Sec	7.58(1.7)	7.32(1.7)	7.03(1.9)	7.14(1.7)	5.95(1.9)	7.56(1.7)	5.23(.06)	5.55(1.2)
	360 Sec	7.96(.06)	7.88(1.5)	7.38(1.9)	7.82(.06)	6.43(1.7)	8.02(1.5)	5.45(1.9)	6.24(1.6)

Table 8. Cannula Size: 18 Gauge 10 mm Tip

		Average Length (mm)				Average Width (mm)			
Temp	Time	Single Lesion	Double Lesion	Triple Lesion	Quad Lesion	Single Lesion	Double Lesion	Triple Lesion	Quad Lesion
70°	30 Sec	9.89(1.2)	9.37(1.7)	9.54(2.0)	9.46(1.5)	4.48(1.6)	4.01(1.4)	4.45(1.2)	5.26(1.2)
	60 Sec	11.13(1.1)	9.68(1.9)	9.98(1.9)	10.81(1.6)	5.31(1.5)	4.66(1.5)	4.86(1.9)	5.21(1.9)
	120 Sec	12.00(1.6)	10.12(1.2)	10.56(1.2)	10.28(2.0)	6.85(1.7)	4.83(1.9)	5.34(1.2)	5.18(2.0)
	360 Sec	11.77(1.2)	10.87(1.7)	10.15(1.9)	11.90(1.6)	6.89(1.1)	6.29(1.6)	6.56(1.9)	6.70(1.2)
80°	30 Sec	11.02(1.2)	11.02(1.5)	11.12(1.9)	11.37(1.7)	5.02(1.9)	5.25(1.2)	5.15(1.7)	5.2 (1.7)
	60 Sec	11.60(1.7)	11.05(1.2)	11.32(1.6)	11.34(1.6)	6.00(1.4)	5.55(1.9)	5.56(1.6)	5.74(1.9)
	120 Sec	12.61(1.2)	11.74(1.7)	11.65(1.4)	11.93(1.9)	6.92(2.0)	7.03(1.9)	6.87(1.7)	6.4 (1.7)
	360 Sec	13.90(1.2)	12.08(1.1)	12.08(1.2)	12.15(1.2)	8.92(1.7)	8.38(1.5)	7.45(1.7)	6.85(1.6)
90°	30 Sec	11.94(1.2)	11.56(1.4)	11.45(1.7)	11.13(1.2)	6.26(1.6)	6.21(2.0)	6.43(1.5)	6.75(1.7)
	60 Sec	12.31(1.6)	11.63(1.9)	11.56(1.6)	11.67(1.6)	7.58(1.4)	7.02(1.4)	7.15(1.6)	6.84(1.6)
	120 Sec	12.45(1.2)	12.21(1.4)	12.24(1.6)	12.01(1.5)	8.15(1.9)	8.35(1.6)	8.23(1.5)	7.46(1.7)
	360 Sec	13.77(1.1)	13.78(1.6)	13.67(1.6)	13.72(1.2)	10.09(1.9)	9.75(1.9)	9.14(1.2)	8.25(1.7)

Table 9. Cannula Size: 20 Gauge 5 mm Tip

		Average Length (mm)				Average Width (mm)			
Temp	Time	Single Lesion	Double Lesion	Triple Lesion	Quad Lesion	Single Lesion	Double Lesion	Triple Lesion	Quad Lesion
70°	30 Sec	5.78(.4)	5.96(1.4)	5.82(1.4)	5.84(1)	3.36(1.3)	3.55(1)	3.43(1.5)	3.50(1.8)
	60 Sec	5.91(.8)	5.66(1.0)	5.72(1.5)	5.54(1.0)	3.55(1.3)	3.90(.4)	3.86(1.0)	4.06(1.0)
	120 Sec	6.04(1.5)	5.99(1.4)	5.95(1.4)	5.84(1.8)	3.86(1)	4.24(1.8)	3.94(1.8)	4.60(1.3)
	360 Sec	5.97(1.5)	6.45(1.3)	6.24(.7)	5.87(.7)	4.04(1.5)	4.42(.8)	4.62(1.5)	5.04(.7)
80°	30 Sec	5.5(.4)	5.75(1.7)	5.62(.4)	5.24(1.5)	3.64(1.3)	3.60(1.7)	3.52(1.7)	3.43(1.3)
	60 Sec	5.75(1)	6.31(.8)	6.18(1.4)	6.32(.8)	4.22(1.8)	4.29(.8)	4.54(1)	5.06(1.3)
	120 Sec	6.09(1.3)	6.67(.8)	6.43(.8)	6.23(1.0)	4.39(.4)	4.68(1.5)	4.82(.4)	5.48(.7)
	360 Sec	6.49(1.4)	8.52 (1.9)	7.67(1.5)	7.34(.8)	4.41(1.7)	6.39(1.7)	6.13(1.7)	6.99(1.4)

90°	30 Sec	6.20(1.9)	7.20(.4)	6.75(1)	5.95(1.9)	4.65(.4)	4.70(.7)	4.68(1.0)	4.89(1.5)
	60 Sec	6.55(1.4)	7.33 (1.9)	6.56(.8)	6.23(1)	4.69(1.8)	5.20(.4)	5.34(1.5)	5.41(1.3)
	120 Sec	6.57(1.4)	7.86(.8)	7.03(1.5)	6.95(1.5)	5.04(1.5)	5.88(.8)	5.61(1)	5.61(1.4)
	360 Sec	7.65(.4)	8.21 (1.9)	7.49(.8)	7.86(1.9)	5.96(1.4)	6.17 (1.9)	6.82(1.5)	6.64(.8)

Table 10. Cannula Size: 20 Gauge 10 mm Tip

		Average Length (mm)				Average Width (mm)			
Temp	Time	Single Lesion	Double Lesion	Triple Lesion	Quad Lesion	Single Lesion	Double Lesion	Triple Lesion	Quad Lesion
70°	30 Sec	10.38(.08)	11.26(1.4)	10.34(1.1)	10.10(1.6)	3.35(1.8)	4.98(1.9)	3.72(.4)	3.19(.5)
	60 Sec	10.62(1.6)	11.37(1.4)	10.67(1.3)	10.85(.08)	4.23(.05)	6.43(1.1)	4.23(1.3)	3.39(1.4)
	120 Sec	11.24(.08)	12.51(1.7)	11.23(.8)	11.45(1.9)	4.60(.05)	5.03(1.4)	5.43(1.1)	4.24(.4)
	360 Sec	11.14(1.4)	12.23(1.9)	12.06(1.6)	12.43(.8)	5.43(1.4)	5.86(.05)	5.62(.4)	4.89(2.1)
80°	30 Sec	11.03(1.3)	10.73(.8)	10.76(1.3)	11.56(.8)	4.41(.08)	5.54(1.4)	4.56(.8)	3.87(1)
	60 Sec	11.17(.08)	11.31(1.4)	11.65(.8)	11.87 (1.3)	4.60(1.4)	6.31(1.1)	5.34(.5)	5.54(1.4)
	120 Sec	11.17(1.1)	10.76(.8)	10.83(1)	10.98(2.1)	5.60(1.4)	5.94(1.4)	5.39(1.8)	5.19(1.4)
	360 Sec	12.11(1.3)	11.11(1.1)	11.67(1.3)	11.67(2.1)	6.94(.08)	6.24(.4)	6.39(1.8)	6.14(.5)
90°	30 Sec	11.19(.08)	10.44(1.3)	10.65(1.3)	10.95(1.1)	5.02(1.8)	5.32(1.8)	5.10(1.3)	4.23(1.4)
	60 Sec	11.39(.08)	11.35(.8)	11.54(1)	11.90(1)	5.69(1.3)	6.15(1.1)	5.80(1)	6.05(1.1)
	120 Sec	11.62(1.1)	11.77(1.3)	11.82(1.4)	12.03(1.3)	6.29(1.1)	7.70(1)	7.54 (1.3)	7.16(1.4)
	360 Sec	11.86(1.3)	11.78(1)	11.91(1.3)	12.23(1)	6.76(1.3)	7.54(.8)	7.23 (1.6)	7.66(.4)

Table 11. Cannula Size: 22 Gauge 5 mm Tip

		Average Length (mm)				Average Width (mm)			
Temp	Time	Single Lesion	Double Lesion	Triple Lesion	Quad Lesion	Single Lesion	Double Lesion	Triple Lesion	Quad Lesion
70°	30 Sec	5.00(.08)	5.86(.08)	5.12(1)	4.88(1.3)	2.00(1.6)	4.37(.8)	3.52(1.9)	3.07(.4)
	60 Sec	5.18(1.6)	6.33 (1.9)	5.45(1.7)	5.49(1.1)	2.92(.05)	4.10(1.4)	3.78(1.4)	3.44(1.7)
	120 Sec	5.85(1)	6.87(1.6)	5.89(1.9)	5.64(.4)	3.14(1.9)	4.24(.8)	3.16(1)	3.63(1.7)
	360 Sec	6.50(.8)	6.90(.08)	6.29(1)	5.90(1)	4.04(1.7)	5.43(.08)	4.45(.4)	3.88(1.4)
80°	30 Sec	5.78(.08)	6.43(1.6)	5.82(1.3)	5.54(1.4)	3.33(.05)	4.14(.4)	3.81(1.7)	3.02(1)
	60 Sec	6.27(1.4)	7.13(1)	6.72(1.6)	5.80(1.7)	3.66(.4)	5.04(1.9)	4.23(1.4)	3.43(1.7)
	120 Sec	6.31(1.7)	7.63(.05)	6.26(1.3)	5.57(1.4)	4.37(1.4)	5.42(.05)	3.91(1.3)	4.09(1)
	360 Sec	6.69(1.3)	8.24(1)	6.54(1.7)	6.17(1)	4.92(.08)	6.57(1.4)	4.89(1.6)	4.05(1.4)
90°	30 Sec	6.59(1.4)	6.78(1.7)	6.27(1.7)	5.63(1.7)	4.13(1.4)	4.39(1.7)	4.34(1.4)	3.63(1)
	60 Sec	6.45(.08)	7.80(.05)	6.81(1)	6.12(1.4)	4.27(.08)	5.47(1.4)	4.91(1.3)	4.31(1.4)
	120 Sec	6.88(1.7)	8.01(1.3)	6.62(1)	6.45(1.4)	4.79(1)	6.21(1.7)	5.23(.05)	4.47(1.6)
	360 Sec	7.27(1.6)	9.40(1.1)	7.20(.8)	6.82(1.3)	5.51(1.4)	7.55(1.1)	6.34(.4)	5.21(1.7)

Table 12. Cannula Size: 22 Gauge 10 mm Tip

		Average Length (mm)				Average Width (mm)			
Temp	Time	Single Lesion	Double Lesion	Triple Lesion	Quad Lesion	Single Lesion	Double Lesion	Triple Lesion	Quad Lesion
70°	30 Sec	8.69(1.7)	10.36(1.0)	8.67(.8)	9.14(1.3)	2.51(1.3)	3.50(1.9)	3.23(1.3)	3.12(1.9)
	60 Sec	8.41(1)	10.55(1.1)	9.46(1.2)	9.39(1.4)	2.99(1.3)	4.28(1.2)	3.67(1.9)	3.57(.4)
	120 Sec	8.92(1.9)	10.54(1.3)	9.26(1.5)	9.52(1)	2.73(1.2)	4.74(.8)	3.98(1.3)	4.60(.4)
	360 Sec	8.73(1.0)	10.35(1.0)	8.97(.8)	9.07(1.1)	3.58(1.5)	5.34(1.9)	4.12(1.7)	4.71(1.3)
80°	30 Sec	10.04(1.1)	9.67(1.9)	9.45 (1.5)	9.79(.8)	3.26(1.9)	3.99(.4)	3.56(1.5)	3.49(1.3)
	60 Sec	9.79(1.3)	9.56(1.3)	9.67(1.9)	9.56(1)	3.67(1.5)	4.48(1.3)	4.23(1.5)	4.50(1.2)
	120 Sec	9.75(.8)	11.23(1.9)	9.98(1.7)	10.12(1.5)	4.26(1.9)	5.65(1.5)	4.78(1.3)	4.49(1.7)
	360 Sec	9.79(1.3)	11.71(1)	10.18(1.5)	11.30(1.4)	6.08(.4)	7.47(1.6)	6.76(1.6)	5.48(1.3)

90°	30 Sec	10.37(1.1)	10.60(1.0)	10.34(1.4)	9.92(1.5)	4.07(1.7)	4.92 (1.9)	4.62(1.2)	4.12(1.5)
	60 Sec	10.17(1.4)	10.79(1.0)	10.45(1.9)	10.37(1.7)	4.57(1)	5.10(1.1)	5.27(1.5)	5.43(1.2)
	120 Sec	11.16(1.0)	10.66(1.9)	10.89(1.1)	10.95(1)	5.25(1.3)	5.39(.4)	5.32(1.2)	5.27(.8)
	360 Sec	11.76(1.9)	12.32(1.0)	11.23(1.2)	11.15(1.2)	6.16(1.7)	8.42(1.2)	6.67(.8)	6.26(1.6)

Dual Lesion

90°C 120 Sec 10 mm tip	Length (mm)					Width (mm)				
	1 mm apart	3 mm apart	5 mm apart	7 mm apart	9 mm apart	1 mm apart	3 mm apart	5 mm apart	7 mm apart	9 mm apart
22 gauge	10.50 (1)	11.06 (1.4)	11.04 (1.9)	10.13 (1)	10.77 (1.4)	5.55 (1.6)	7.85 (.4)	9.78 (1.2)	12.40 (1.6)	5.08 (.4)
20 gauge	10.51 (1.9)	10.98 (.8)	11.62 (1.4)	10.99 (1)	11.79 (.4)	6.16 (1.6)	7.14 (1)	10.77 (1.6)	11.58 (.8)	14.88 (1)
18 gauge	11.28 (1.6)	12.12 (1.9)	12.27 (1.1)	12.25 (1.2)	11.64 (1.4)	6.72 (1.9)	8.24 (.8)	9.13 (1.2)	14.43 (1.6)	15.65 (1.1)

Simplicity

Simplicity III				
	Length, mm		Width, mm	
Time/Temp	80°C	90°C	80°C	90°C
60 sec	67.94(2.1)	70.21(1.2)	13.67(1.2)	14.37(1.9)
360 sec	69.10(1.2)	71.64(2.1)	13.76(1.6)	14.40(1.2)

Simplicity II				
	Length, mm		Width, mm	
Time/Temp	80°C	90°C	80°C	90°C
60 sec	47.2(1.2)	49.7(1.9)	11.0(1.2)	11.99(1.6)
360 sec	49.69(2.1)	53.2(1.6)	14.39(1.1)	15.72(1.6)

Troubleshooting

Electrode(s) Stop Working

In the event that an electrode(s) stops working properly and the patient is not at risk, try these recommended recovery techniques.

- Check to make sure all electrode(s) connections are securely connected to their respective NT2000iX™ RF generator port(s).
- If available, try using electrode(s) on a different port of the generator.
- If the procedure was a multiple electrode procedure and you are unable to get all the electrodes/ports necessary to work at once, carry out the procedure one electrode at a time.
- If you are unable to get the electrode(s) to work on any port, try using a different electrode(s).
- If the problem still persists after trying all of the above techniques, contact NeuroTherm for additional help.

Electrode(s) Not Getting Up To Temperature

In the event that an electrode(s) is not getting up to temperature and the patient is not put at risk, try these recommended recovery techniques.

- Check to make sure all electrode(s) connections are securely connected to their respective NT2000iX™ RF generator port(s).
- If available, try using electrode(s) on a different port of the generator.
- If the procedure was a multiple electrode procedure, try to carry out the procedure using Stagger Mode.
- If the procedure was a multiple electrode procedure and you are unable to get all the electrodes/ports necessary to work at once, carry out the procedure one electrode at a time.
- If you are unable to get the electrode(s) to work on any port, try using a different electrode(s).
- If the problem still persists after trying all of the above techniques, contact NeuroTherm for additional help.

No Stimulation To Patient

In the event that you are unable to get stimulation from the patient and the patient is not at risk, try these recommended recovery techniques.

- Check to make sure all electrode(s) connections are securely connected to their respective NT2000iX™ RF generator port(s).
- If available, try using electrode(s) on a different port of the generator.
- Use the Stimulation Test Kit as described in Using The NeuroTherm™ Stimulation Test Kit (page 55), to test if the electrode(s) is working properly.

- If you are unable to get the electrode(s) working on any port, try using another electrode(s).
- If the problem still persists after trying all of the above techniques, contact NeuroTherm for additional help.

Patient Complains of Heating at the Grounding Pad

In the event that a patient complains of heating at the reference pad and the patient is not at risk, try these recommended recovery techniques.

- Check to make sure grounding pad connection is securely connected to the dispersive port on the front panel of the NT2000iX™ RF generator.
- Check that the grounding pad is making maximum surface area contact with the patient.
- Check to make sure grounding pad is placed in a well-vascularized muscular site in proximity to the procedure.
- Check to make sure the grounding pad is NOT placed over scars, bony prominences, prosthesis, hair, or EKG electrodes.
- Check to make sure impedance is not greater than 800 ohms.
- Check to make sure the grounding pad is NOT located in a location where fluids may pool.
- If the problem still persists after trying all of the above techniques, contact NeuroTherm for additional help.

Disposal

The Instructions for Use is recyclable. Dispose of all packaging materials as appropriate. Dispose of products and accessories per standard solid biohazard waste procedures.

Unit Disposal

Dispose of unit in accordance with state and federal laws regarding the disposal of electronic equipment. Proper disposal techniques may be based on the amount of hazardous waste generated by facility. Consult local agencies for recycling and disposal options.

Be sure to remove all patient information from device prior to device disposal.

Accessory Disposal

Electrodes and grounding pads should be disposed of using sharp bin and/or local biohazard protocol.

Maintenance

General

Each time the NT2000iX™ RF generator is switched on, the computer within it carries out a number of self tests. These tests not only check the operation of the machine, but also the performance of the Impedance and RF functions. Should any of these fail, the generator is automatically disabled from use.

In the event of a Self Test failure or any other malfunction, you should immediately call your local distributor.

WARNING: No modification of this equipment is allowed.

This device is not user serviceable. Maintenance should only be carried out by authorized personnel. For qualified companies and approved technicians refer to the NT2000iX™ Service and Support Manual for more information including schematics, fuse and battery replacement, and troubleshooting. A full service on an annual basis is recommended. The NT2000iX™ Service and Support Manual is available upon request for use by qualified company approved technicians. Contact the manufacturer for qualified service technicians.

Basic Battery and Fuse Information

The NT2000iX™ RF generator contains a single CR2032 lithium battery. The battery holder is designed to ensure correct polarity upon installation and is not possible to install backwards. The battery should only be replaced by a company approved technician.

Table 13. Fuse Information

120V			230V		
Qty.	**Part #**	**Location**	**Qty.**	**Part #**	**Location**
2	T2AH250V	Back Panel Mains	2	T1AH250V	Back Panel Mains
4	T2AL250V	Supply Board	4	T2AL250V	Supply Board
1	T1AL250V	Supply Board	1	T1AL250V	Supply Board

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