NEUROTHERM RADIO FREQUENCY LESION GENERATOR

MODEL NT1000

OPERATORS MANUAL

TABLE OF CONTENTS

1 GENERAL INTRODUCTION

The Neurotherm Radio Frequency Lesion Generator Model NT1000 has been designed to offer the full range of features required by all levels of practitioners for pain relief clinic work.

The front panel of the generator which has a series of touch buttons and two rotary potentiometers is used to provide the clinician with direct manipulation of the stimulation and lesioning functions. An automatic mode is also provided for various lesioning procedures. The Generator also has an LCD screen with an integral touch screen. The screen is used to initially select the parameters for treatment and input information regarding the doctor, patient and other key information, this information is stored within the generator and can be printed out on the patient record. During treatment the touch screen becomes inactive and all control of the Neurotherm is by the front panel. The screen displays all key parameters and any treatment profiles.

The generator is designed for safe use in a low light x-ray theatre environment; a remote LCD screen can be attached via a Neurotherm Video Unit (NT-VD). This video unit is an optically isolated device which must be used to avoid any risk to the patient.

At the end of a patient session a patient record is printed out on the Neurotherm printer. This printer is not electrically connected to the Neurotherm, but gets its information via a 'Bluetooth' wireless link. Each printer is matched to a particular Neurotherm.

The Neurotherm stores patient records and treatment profiles and holds a large number of the most recent records in its memory. Records can be downloaded to a Neurotherm memory Stick (NT-USB) at any time.

There are a number of safety features in both the hardware and software of the machine to minimise any risk to the patient. The Neurotherm has full electronic interlocking to prevent accidental switching to lesion power or stimulation voltage.

The internal settings of the machine have been factory set and should not be adjusted except by approved technicians authorised by the company.

The machine is designed for use only with Neurotherm Thermocouple Probes or probes or catheters that have been tested for compatibility with the NT1000. A list of compatible probes is on page 2-2. The use of unapproved probes from other manufacturers could give serious errors in temperature reading which might compromise the safety of the patient, and would negate the warranty.

Before operating the machine observe the various Warnings and Cautions as detailed in Section 2.

1.1 General Considerations

Regularly inspect the accessories of the Neurotherm, in particular electrode cables should be checked for possible damage to the insulation.

The accessories are not appropriate for endoscopic use.

2 WARNINGS AND CAUTIONS

2.1 Warnings

A warning indicates a potentially harmful situation to yourself or others.

Ensure you read this Operators Manual before operating the Neurotherm.

HAZARDOUS ELECTRICAL OUTPUT - The equipment is for use ONLY by qualified medical personnel.

DO NOT under any circumstances perform any Testing or Maintenance on the equipment while it is being used on a patient.

DO NOT use extension cords or adaptors of any type. The power cord and plug must be intact and undamaged.

Should the power cord or plug become cracked, frayed, broken or otherwise damaged, it must be replaced immediately.

If the equipment has in any way suffered mechanical damage, it should be returned to the Supplier for Inspection and Test before further use.

Unplug the power cord before cleaning or service.

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 anaesthetic 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 energised. 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 energised equipment.

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.

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 Neurotherm malfunction and potential damage.

When carrying out treatment take care to avoid the following risks:-

RISK OF RF BURNS TO PATIENT - Ensure patient does not come into contact with metal parts of the table and its accessories – antistatic sheeting 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 dispersive plate in such a way to avoid contact with the patient or other leads.

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 Section 3.4 to Minimise Electromagnetic Interference)

GENERAL CONSIDERATIONS: - Regularly inspect the accessories of the Neurotherm, in particular electrode cables should be checked for possible damage to the insulation.

DO NOT USE ENDOSCOPE: - The accessories are not appropriate for endoscopic use.

USE OF FLUIDS: - Ensure that if fluids (saline etc.) are being used during a procedure they should be positioned away from the Neurotherm.

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 Dispersive (Neutral) Lead and the Dispersive Pad before applying power to the patient.

PROBES:- Use only Neurotherm™ , Radionics Disc Trode™, Spinecath™, or ACUTHERM™ probes.

2.2 Cautions

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

Do not activate the output of the Neurotherm until the probe is properly positioned in the patient.

In monopolar applications, ensure that the Dispersive or return electrode is connected to the patient and to the Neurotherm.

Do not remove the top cover of the Neurotherm, as it will expose voltage which can cause injury or death.

Servicing of the equipment in accordance with the appropriate service manual should never be undertaken in the absence of proper tools, test equipment and the most recent revision of the service manual which is clearly and thoroughly understood.

To reduce risk of electrical shock do not remove the back panel of the Neurotherm. Refer servicing to qualified personnel.

When cleaning the outer casing touch panel or screen of the equipment do NOT use abrasive agents or solvents.

If erratic readings of voltage, current or impedance or temperature are observed, the procedure should be halted until a determination of the source is identified.

If at any time the device is behaving erratically, press the “Auto Stop” button which will return the device to a safe state.

3 TECHNICAL DATA

3.1 Specification

SIZE

Width	400 mm (15 ¾")
Height	300 mm (11 ¾")
Depth	415 mm (16 ½")

WEIGHT

12.5 Kg. (28 lbs)

ELECTRICAL

Europe	230 Volt	50 Hz	Fused 1 Amp on live and neutral
USA/Canada	110 Volt	60 Hz	Fused 2 Amp on live and neutral

Voltage change via rear connector

Power Consumption 150 watt

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. Thermal fuses (rated to fail at 125° C) are fitted into all primary and secondary windings.

The machine is not connected to mains earth (class 2).

STANDARDS

This machine complies with:

EN 60601-1 : 1997
IEC 60601-1-2 : 1993
IEC 60601-2-2 : 1998
IEC 60601-2-10 : with Canadian deviations

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	53 KHz (± 3KHz)
Measuring Source Voltage	Less than 500 mV AC
Measurement Display	50-2000 ohms (one ohm resolution)
Accuracy	± 5%
Features	(a) Internal 500 ohm Test Resistor (b) Impedance in all Lesion Modes and in Stimulation Mode when stimulation is off (c) Audible Tone available where frequency varies with impedance over full impedance range (50-2000 ohms). Audible tone is adjustable and mutable (d) Warning on screen if impedance is less than 50 ohms or greater than 2000 ohms

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	0-5v ± 3% for motor frequencies (2Hz and 5 Hz) 0-3v ± 5% (Default) for all other frequencies 0-0.5v ± 10% for all other frequencies
	Current	0-10mA ± 5% 50-2000 ohms 0-6mA ± 5% 50-2000 ohms 0-1mA ± 5% 50-2000 ohms
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		± 5% for 0.2, 0.5 and 1.0 mS ± 15 % for 0.1 mS

Features	(a) Hardware and Software lockout if voltage / current control not initially set to zero (b) Warning on screen if stimulation control is not initially at zero. (c) Flashing LED on front panel indicates machine is delivering stimulation pulses (d) Stimulation Test Socket is provided on front of machine to interface with the standard stimulation test kit. (e) Various screen displays for displaying amplitude of each stimulation procedure.

LESION MODE

RF Waveform	480 KHz ± 5% Sinusoidal
Power Output	Continuously variable. Maximum power output 30 watts ± 5% into 200 ohms. Power is displayed in certain Lesion Modes.
Voltage Display on screen	0-99RF volts (RMS)
Current Display on screen	0-999RF milliamps (RMS)
Self Test	150 ohm dummy load resistor built into machine
Lamp Indicator	LED flashes when Lesion Power is being delivered
Temperature Range	Selectable 50 – 90° C for Thermal Lesion (Default 80°C) Selectable in 5°C steps in initial screen set ups Selectable in 1°C steps when in Lesion Mode using 'Temp up and Temp down' buttons
Time	Selectable 0:30 to 10:00 mins (Default 1:00 minute) Selectable in 30 seconds 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	A series of fixed temperature/time profiles are programmed into the generator: P1, P2, P3. The user can also program a custom profile with the following characteristics: Start Temperature 50-60°C (Default 50°C) Step Time 00:10 to 3:00 mins (Default 2 mins) Step Rise 1°C or 5°C (Default 5°C) Final Temperature 65° - 90° C (Default 65°C)

	Final Dwell Time 1:00 – 10:00 Minutes (Default 4.00 mins)
Lesion Start	Lesion starts as soon as temperature is within 5° of desired temperature
Auto Mode	With Lesion Power Control Off, the procedure can be carried out under Automatic control by pressing the 'Auto start' button. The temperature will ramp up at 8°C per second and time will start when the measured temperature is within 5°C of desired temperature. The lesioning can be stopped at any time by pressing the 'Auto Stop' Button
Display	Temperature is displayed against time as a curve on the screen together with a display of "Measured temperature" and "Time to completion of lesion". RF Lesion power (or voltage and current) together with impedance are also displayed.
Audible Indicator	An alarm tone (with a volume adjustment) will indicate the end of the procedure.

PULSE RF MODE

In pulsed mode the waveform is pulsed rather than continuous.

Pulse Widths	5ms, 10ms, 20ms, 50ms (default 20 ms)
Pulse Frequencies	1Hz, 2Hz, 5Hz, 10Hz, (default 2Hz)
Temperature Range	Selectable in 42-65°C range, (default 42°C)
Time	Selectable 00:30 to 20:00 minutes (default 2:00 mins)
Set Volts / Current	Pulsed RF can be carried out in Auto Mode at fixed voltages or current. Voltage range 30-70 Volts (default 45 Volts) Current range 50-350 mA

PULSE DOSE MODE

In Pulse Dose Mode the number of Pulses of Pulsed RF are counted. Pulse Dose Procedures are carried out in Auto Mode

Set Temperature	42°C

Pulse Counts	120-1200 count (Default 240 counts)
Rate	2Hz
Width	20 mS
Set Voltage Range	30-70V (Default 45V)
Set Current Range	50-350 mA

MULTIPLE PROBES

The Neurotherm can be operated with 1,2 or 3 probes. When in Stimulation Mode each probe is selected by the operator for Stimulation. In RF Lesion, Pulse RF or Pulse Dose Mode the generator energises all connected probes in a time interlacing method. In multiple probe operation not all pulse rates are available.

Features

(a) Hardware and Software lockout if RF Power Control not initially set to zero.
(b) Warning on screen if RF Control is not initially set to zero or if Auto is selected and RF control is not off.
(c) LED Flashes on front panel to indicate machine is delivering power.
(d) Three output sockets to accept a variety of probes, (including cordotomy (optional extra)) and enable multiple probe operation.
(e) Hardware lockout if temperature exceeds 95°C.

MAJOR FEATURES

Touch Screen Operation – User interface set up and software control via TP 400 processor .

Windows CE4.2.NET Operating System.

12.1” LCD Screen with Back lighting and wide antiglare visibility.

Printer Support	Via Bluetooth adaptor internally fitted.
Remote Mimic Screen	Optically isolated running over CAT5 Cable to External TFT screen up to 300 metres.
Storage Device	USB Memory Stick for downloading log files.
Service Ports	Only accessible by service engineers for keyboard + mouse

Any equipment connected to rear sockets must comply with IEC60950 and IEC60601-1

Use only parts supplied by Neurotherm Ltd. Any other parts will void the warranty and may cause danger to the patient.

3.2 Earth 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

3.3 Environmental Conditions

7	Transport	Temperature Humidity Pressure	-10°C to 70°C 0-95% RH 140-760mmHg	Non-Condensing (0-12,200 metres) (0-40,000ft)
8	Storage	Temperature Humidity Pressure	10°C to 60°C 10 to 80% RH 520-760mmHg	(0-3000 metres) (0-10,000ft)
9	Operating	Temperature Humidity	10°C to 40°C 10 to 80% RH	

3.4 Minimsing Electromagnetic Interference

Although the Neurotherm NT1000 meets the EMC requirements for a device of this type, it is good practice to follow certain guidelines to minimise the risk of interference between the Neurotherm and other devices.

1 Do not twist the cable of the Neurotherm with those of other devices

2 Avoid putting the Neurotherm on top of other operating equipment or other operating equipment on top of the Neurotherm

3 The Neurotherm generates 480 KHz at up to 30 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 the 200 ohm Test Box into the machine, turn to full power in RF Lesion Mode and observe any reading changes or interference on other equipment.

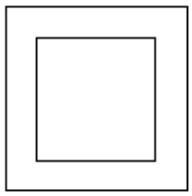
To minimise any interference, position the Neurotherm as far away as possible from the device being interfered with.

3.5 Symbols

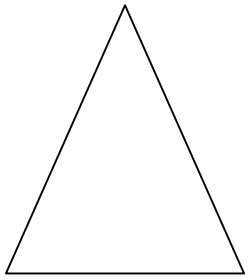
The following symbols are displayed on the machine and the meaning of them is shown below

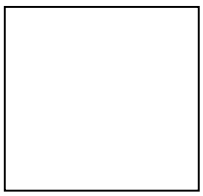
With respect to electrical shock fire and mechanical hazards only in accordance with UL60601-1, IEC60601-1, CAN/CSA C22.2 No 601.1 and IEC60601-2-2

TYPE BF EQUIPMENT



CLASS II EQUIPMENT





4 UNPACKING AND ACCEPTANCE TESTING

On receipt, the machine should be unpacked and inspected for any physical damage.

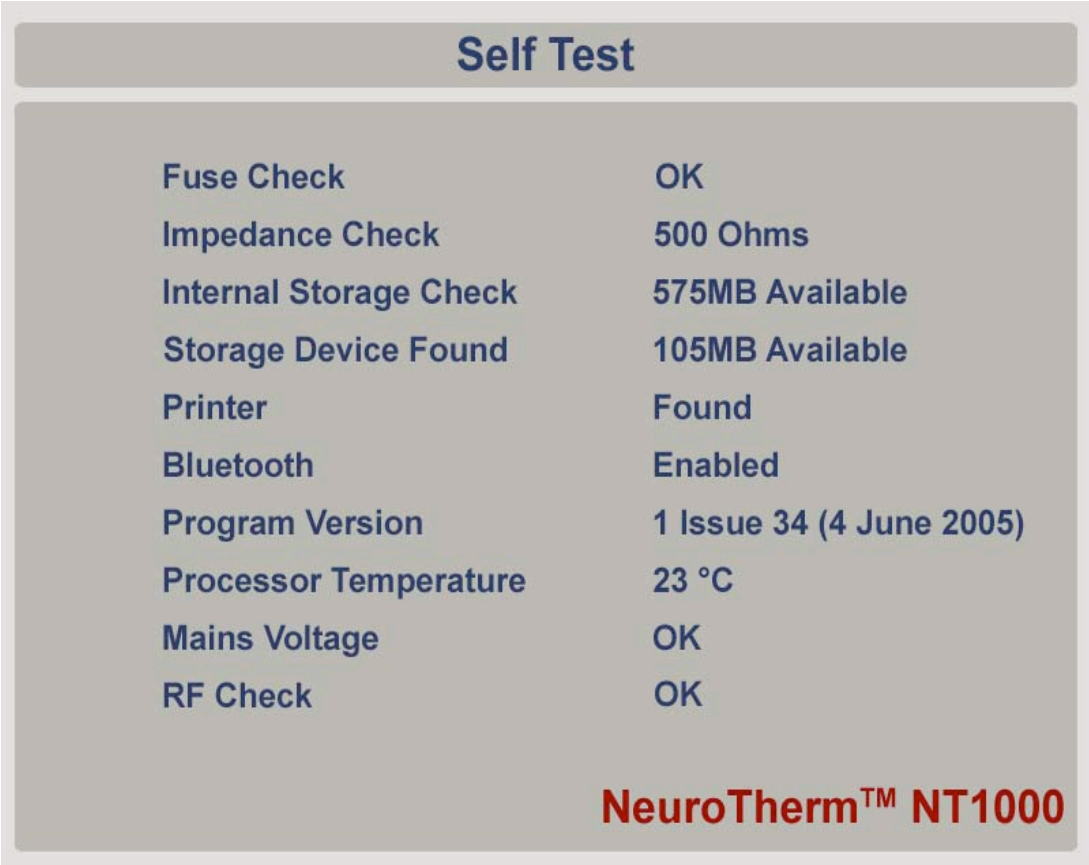
Check that the voltage shown on the rear Serial Number Plate matches the local supply, if not, contact your local distributor. On no account attempt to alter the voltage selector on the rear of the machine. This is for factory setting only.

Place the Neurotherm 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

b) After a few seconds the screen of the machine will show the word “Neurotherm”

c) After a few seconds (during which the computer within the Neurotherm is going through a boot sequence) the machine will display the “Self Test” Screen and go into a self test routine. As each test is completed the results will be shown on screen. Upon the completion of all internal tests the Self Test Screen will display its results for a few seconds.



d) The Neurotherm will then switch on its “Welcome” Screen

The Neurotherm is now ready for use.
Refer to Section 6 on Getting Started

4.1 Electrical Safety Testing

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

Machine Class: Class II Type BF

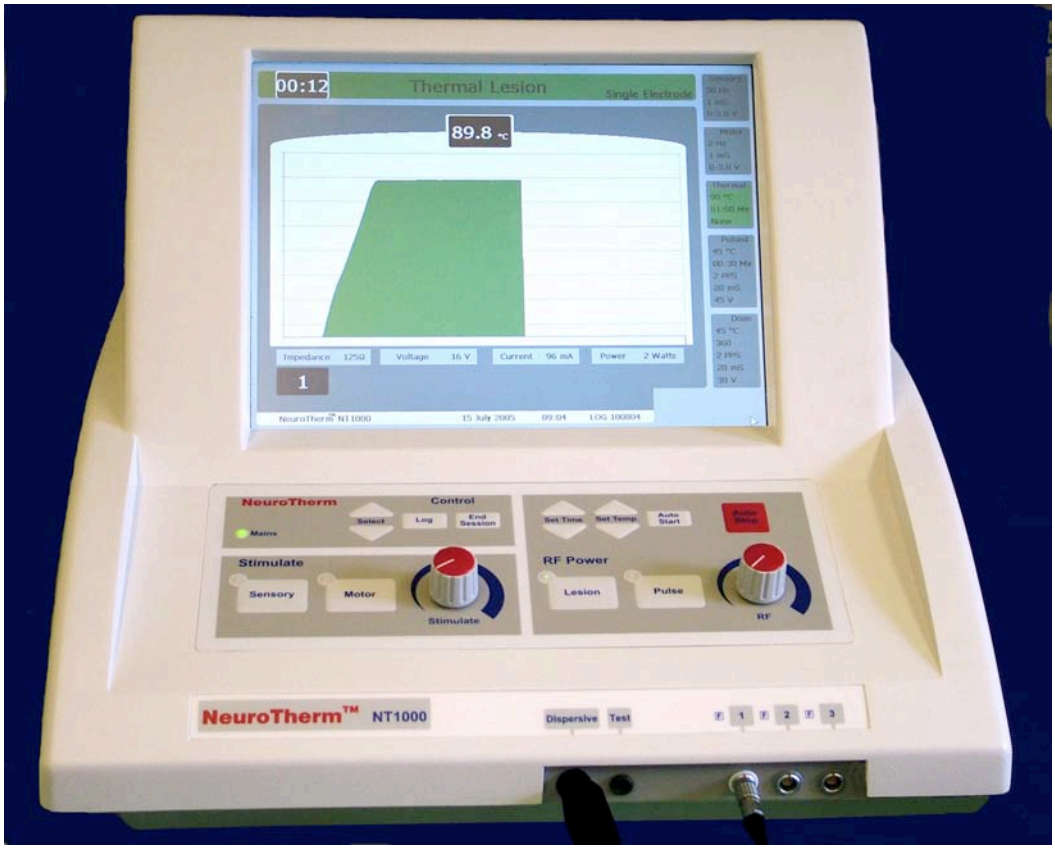
To test the various leads of the output, use the following plugs:

Dispersive plug (4mm Safety Socket)
One of the active Plugs (Lemo 4 pin)

There is no specified EARTH REFERENCE POINT as the output is floating and could possibly induce operational errors. If an earthing point is needed, attach onto any of the four allen cap bolts on the rear of the machine.

5 DESCRIPTION OF THE CONTROLS

The Neurotherm NT1000 viewed from the front is shown below

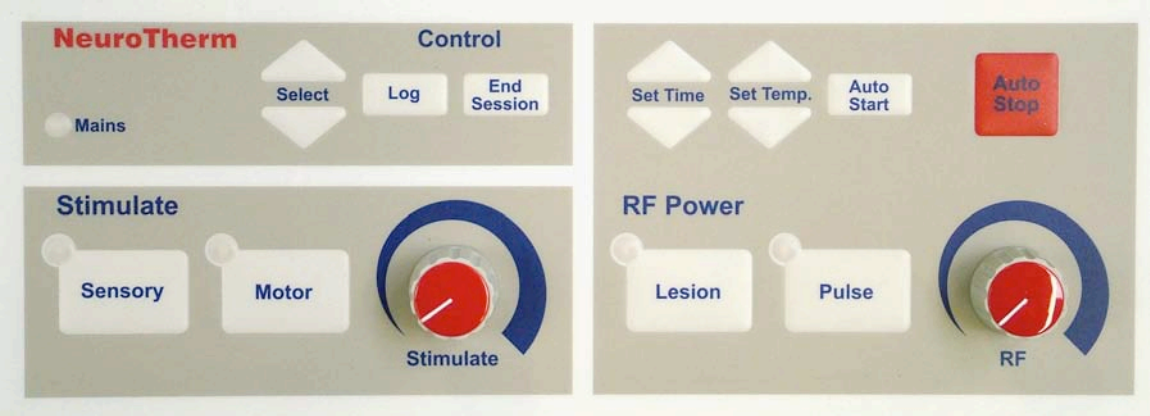


In operation, control of the generator is via a Front Panel Keyboard and the screen will show the current settings of the machine, what is being delivered to the patient and any error or warning messages.

In set up mode when the generator is not connected to the patient the screen is transformed into a touch screen, and a whole series of conditions can be set up including parameters for treatment, 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.

When the screen is in touch screen mode the Front Panel Keyboard is inactive and when the screen is in display mode the Front Panel Keyboard is active.

5.1 Front Panel Keyboard Layout



The keyboard is divided into 3 segments:

Stimulate
RF Power
Control

5.1.1 Stimulate Section

This section consists of:-

2 buttons- ‘Sensory’ and ‘Motor’ each of which contains an integral green LED
1 Rotary control-Stimulate Output Control

Pressing either of the buttons selects that function and a green LED within the button indicates that either ‘Sensory’ or ‘Motor’ function has been selected.

The Stimulate Output Control knob is used to adjust the Stimulation amplitude.

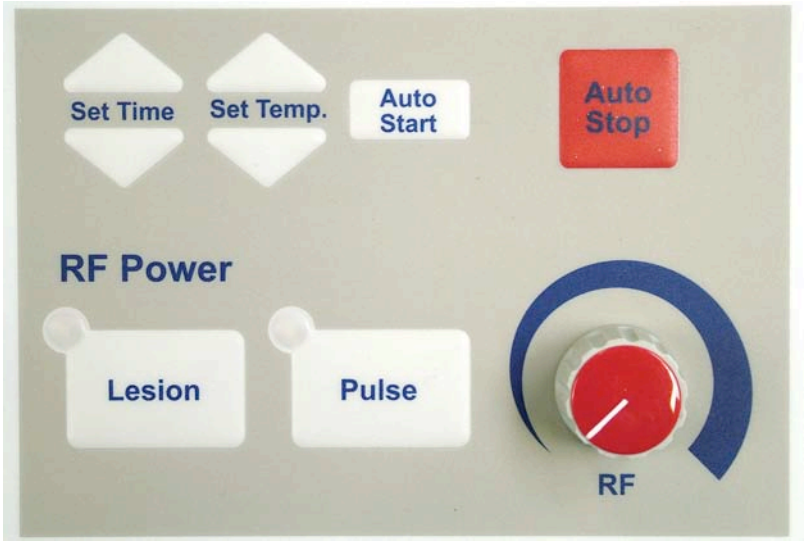
If when either of these functions is selected and the Stimulate Output Control is not in its OFF position, no stimulation output will be supplied to the probe and a warning message will appear on the display. The Stimulate Output Control needs to be turned to the OFF position (fully anticlockwise) before power can be applied.

The green LED within the button will flash when power is being applied.

The frequency, voltage or current range are selected in the original setup of the machine for both sensory and motor functions and these will be indicated on the display together with the actual amplitude of the stimulation being delivered to the patient.

In order to check that a probe is not faulty, a test facility is provided so that when the thermocouple probe is touched on the Test Block a sounder will indicate that output is present.

5.1.2 RF Power Section



This section consists of:-

2 large buttons- ‘Lesion’ and ‘Pulse’ each of which contains an integral green LED
1 Rotary Control- RF Output Control
2 pairs of up/down buttons for ‘Time/Count’ and ‘Set Temp’
2 other buttons-‘Auto Start’ and ‘Auto Stop’ (Red)

Pressing either of the large buttons selects that function and the green LED within the button indicates that either ‘Lesion’ or ‘Pulse’ function has been selected. To select Pulse Dose Mode the Pulse Button is pressed twice.

The RF Output Control knob is used to adjust the RF Power Output. If when either of these functions is selected and the RF Output Control is not in its OFF position, no RF Output will be delivered to the probe and a warning message will appear on the display. The RF Output Control needs to be turned to the OFF position (fully anticlockwise) before RF power can be applied. The green LED within the button will flash when power is being applied.

In the ‘Lesion’ function the temperature and time for a Lesion are selected from the original values set up in the machine, but both these values can be modified up or down using the relevant up/down buttons.

The generator can also be operated in the Auto Mode whereby with the RF Output Control in the OFF position, the 'Auto Start' switch is pressed and the temperature will ramp up at 8°C per second and the time will start when the measured temperature is within 5ºC of the desired temperature. (In Pulse or Pulse Dose Mode the Time starts when the Auto Start button is pressed or RF power is applied to the patient.)

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.

Similarly in the 'Lesion' Function the generator can perform profile heating to give disc heating procedures and these are performed in the Auto Mode.

When the 'Pulse' function is selected the generator gives out pulses whose width and frequency is selected from the original value set in the machine. Temperature and time for the procedure are also selected from the original values set in the machine, but both of these values can be modified using the relevant up/down buttons.

If it is required to carry out Pulsed RF at a fixed voltage or current or if a Pulse Dose procedure is required then these have to be carried out in Auto Mode (i.e. leaving the RF Output Control in the 'OFF' position and starting the procedure using the Auto Start Button.)

The output of the generator is displayed on the screen with a curve showing Temperature against Time and all relevant Temperature/Impedance/Voltage/Current/Power/Counts are also displayed for information.

The red Auto Stop button turns off the RF Output of the generator to the patient whatever state the machine is in and acts very much like an Emergency Stop button.

5.1.3 Control Section

This section consists of:

1 pair of 'Select' buttons
2 other buttons 'Log' and 'End Session'
1 Mains LED

The Up/Down Select Buttons are used under certain stimulation modes to select options that appear on the Display Screen.

If a single probe is being used, using the Select Buttons can select one of three sites. If multiple probes are being used the Select Buttons are used to select the probe to which the stimulation signal is being sent. If a Cordotomy Procedure is being undertaken, an audible tone (whose frequency is proportional to impedance) sounds and the Select Buttons can be used to change the volume of the tone.

The 'Log' button is used to highlight an event. In the stimulate mode when a stimulation signal is being delivered to a patient, a coloured bar (orange for 'Sensory', yellow for 'Motor') is drawn on the screen, the height of the bar being a measure of the output. If a stimulation level needs to be recorded, pressing the 'Log' Button fixes that bar on the screen.

In other modes of the machine (RF Lesion or RF Pulse) if it is required to note an event pressing the 'log' button put a 'highlighted' line in the stored memory of the session. If details of the session are later downloaded to the memory stick, then the position of these lines can be seen.

The 'End Session' button is used when a treatment or set of treatments has been completed. Pressing the button returns the Display Screen to a set up condition and sends a summary of the session to the printer. At the same time a delineator is put on the memory so that individual sessions can be downloaded later.

5.2 Connector Panel Layout

Dispersive Socket
This 4mm socket is for the lead of the Dispersive Patient Plate which should be at least 200 sq cm (21 square inches)

Test Socket
This 2mm socket is used to connect the Test Block for use in testing the thermocouple probes in the Stimulate Mode

Probe Socket No1
This 4 pin socket is used to connect single electrodes for standard RF Lesion and Pulsed RF Lesion Procedures

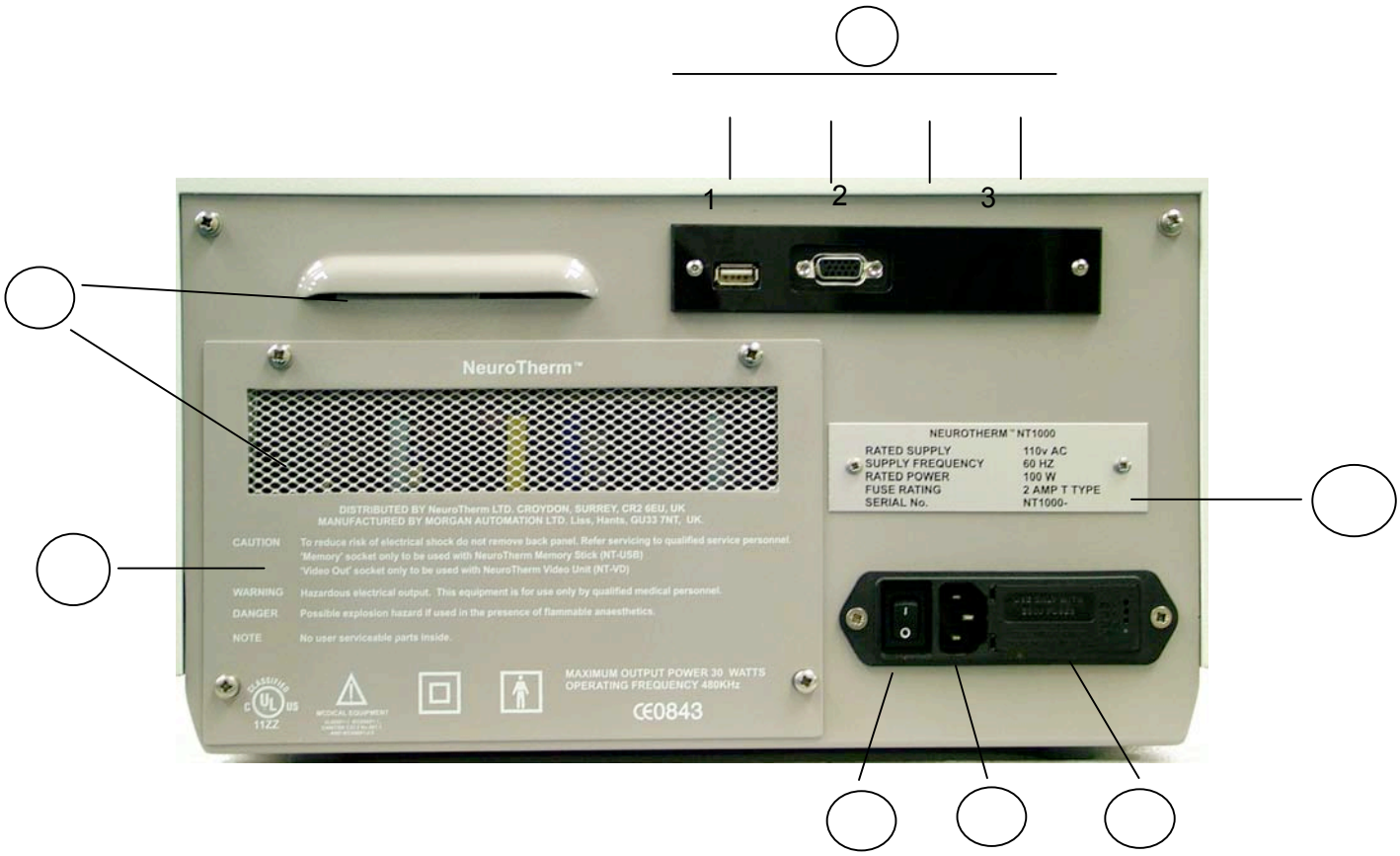
Probe Socket No2
This 4 pin Socket is used to connect electrodes used for 'special' procedures (If the machine has been adapted to carry out Cordotomy procedures, this socket will have 7 pins)

Probe Socket No3
This 4 pin socket is used to connect electrodes used for 'special' procedures.

[Special procedures include two and three electrode procedures, dual electrode procedures, bipolar electrode procedures]

6

5.3 Back Panel Layout



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

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 earth pin.

3. Fuses and Voltage Changes
   The Neurotherm 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 20mm Anti-Surge to BS 4265. 1 amp for 230v supply, 2 amps for 115v supply. To access the fuse holder lift 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]

4. Serial Plate
This plate gives information on Rated Supply, Rated Power, Fuse Ratings and the Machine Serial Number.

5. Rear Connector
Depending on the options chosen, there are a series of connectors on the rear of the generator, some which are available to the operator and some which are covered over with a protective cover.

Connector A- Memory socket available on all machines for use **only** with Neurotherm Memory Stick (NT-USB). DO NOT CONNECT ANY OTHER DEVICE TO THIS SOCKET AS IT WILL COMPROMISE THE SAFETY OF THE PATIENT

Connector B- 'Video Out' socket- available on some machines for use only with Neurotherm Video Unit (NT-VD) - this unit provides opto-isolated connection to a remote display. DO NOT CONNECT ANY OTHER DEVICE TO THIS SOCKET AS IT WILL COMPROMISE THE SAFETY OF THE PATIENT

Connector C- Remote keyboard- this connector is covered over and is a keyboard connection for service engineers only.

Connector D- Remote Mouse- this connector is covered over and is a mouse connection for service engineers only.

6. Contact Address
If the Neurotherm requires a routine service or in the unlikely event of the machine malfunctioning, the contact address of Neurotherm Ltd is shown on the back plate. The full address, telephone and contact details are shown in Section 11.

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

6 GETTING STARTED

The Neurotherm NT1000 is a Generator which is set up by its touch screen and operated by its Membrane Front Control Panel.

In set up mode the Doctor can select the parameters they want to use, for the treatment of a patient, which are then stored by the machine. Up to six doctors or potential users of the machine can also select their own favourite parameters.

Each time the machine is switched on it will revert to the default parameters, but any doctor can reselect their parameters by selecting their name on the “Doctor” Screen from the dropdown list.

Once the machine is set up the actual treatment of a patient is controlled via the Front Control Panel and the screen displays the treatment being administered to the patient together with a display of all key measurements.

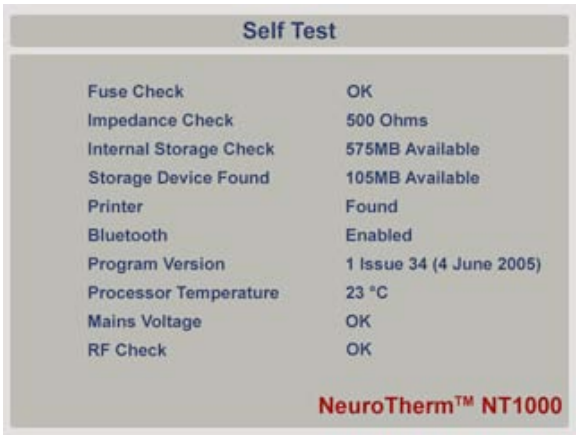
6.1 General Description of Screen Displays

6.1.1 Boot Screen

When the machine is turned and the operating system is loading on the user is greeted with the NeuroThem logo.

6.1.2 Self Test Screen

The NeuroTherm NT1000 features a self test procedure, which operates after the operating system has loaded when the machine is turned on. This checks hardware condition, data storage capacity and looks for any external devices such as the Bluetooth printer.

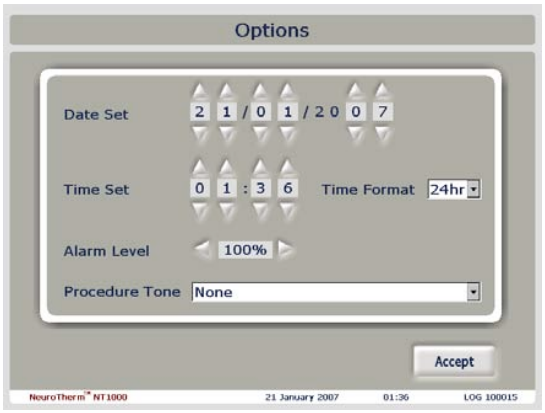


If the machine indicates an error on the test screen, contact your distributor or phone NeuroTherm Ltd (contact details shown in section 11)

6.1.3 Touch Screens & System Navigation

The Neurotherm NT1000 uses a touch screen to allow the user to navigate through menus, input data and setup key options parameters.

During an active or clinical state touch screen becomes disabled and the front panel is solely used to control the procedure.



6.1.4 Machine Options Setup

To set the date and time via the touchscreen, use the up and down arrows above and below the relevant digit. The time format can be switched between 12 and 24 hour clocks.

Return Key

The alarm level is the audio level the loudspeaker inside the unit set as a percentage, navigation is performed by using the left and right arrows between the selections 25%, 50%, 75% and 100%.

The procedure tone is a selection of when the loudspeaker will produce a tone proportional to impedance during a procedure. This can be set as None, Cordotomy or all. The tone will be heard when Sensory Stimulation Mode has been selected and the Stimulation Output control is turned fully anti-clockwise (Off position).

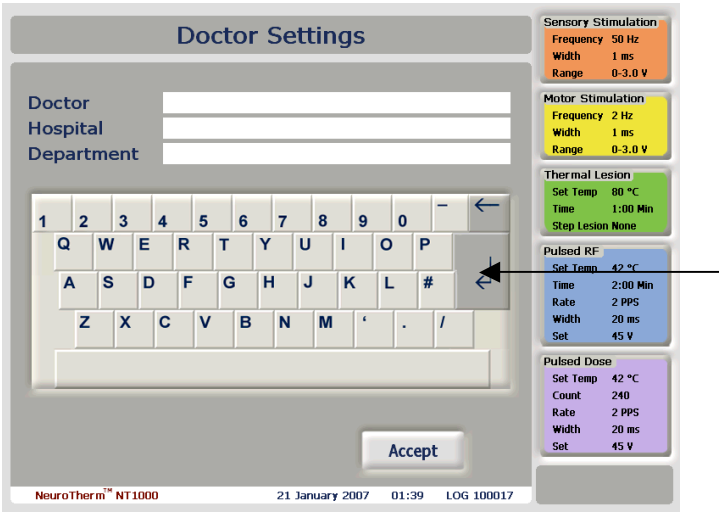
6.1.5 Log Bar

At the bottom of all screens there is a long white bar, which shows information of the doctor name, patient name, date, time and log number.

The log number is a unique number which is automatically created by the NT1000 for every session.

6.1.6 Entering & Storing Doctor Details

The NT1000 has the capability to record and store doctor details and setup parameters. The benefit of this system is that a physician can quickly and easily retrieve their preferred settings.



To input doctor details, use the keyboard by touching the screen over the relevant keys to input the Name, Department, Hospital and any Additional Details.

To move between fields use the return key or press the touchscreen screen at the relevant point.

The next time the machine restarts the default profile parameters are recalled automatically.

To recall a stored doctor profile use the drop down menu to select your name, or create a new doctor profile using the ‘add’ selection.

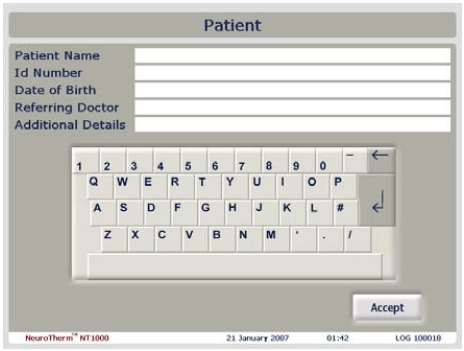
The machine has storage capacity for six individual doctor profiles. If there is already six doctors saved onto the machine you must overwrite a profile, by deleting the doctor's name and inputting your own. Parameters must then be customised for the new doctor.

Alternatively if parameters are not required to be stored the doctor can select the default profile, this recalls the standard factory parameters, and any selections are not saved to the machine.

CAUTION:- Review the current default settings under the chosen doctors name to ensure they have not been modified accidentally

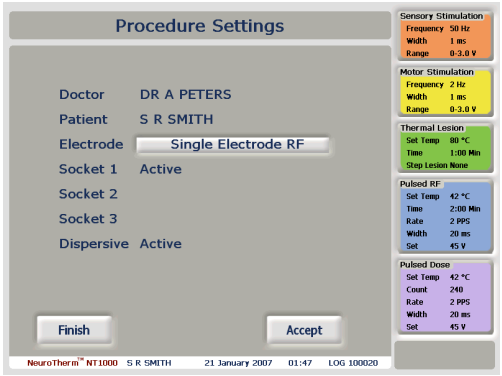
6.1.7 Entering Patient Detail

Patient details can be inputted. Any information is stored by the machine for use with the CSV files and are printed on the procedure report.



Navigation of the patient screen is similar to that of entering the doctor profile details. Use the keyboard to enter data into the Patient Name, ID Number, Date of Birth, Referring Doctor and Additional Details fields.

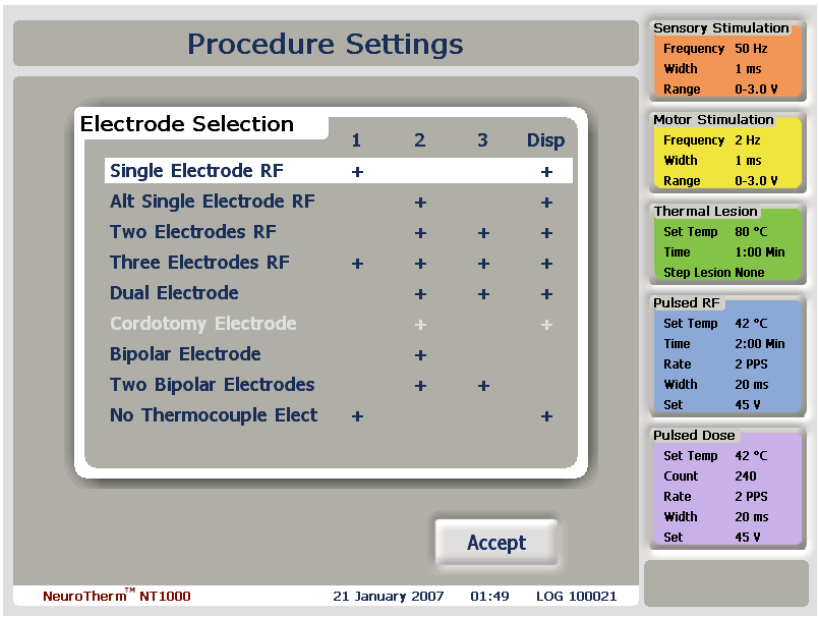
6.1.8 Setup Confirmation



Setup Confirmation gives the user an overview of the information they have entered for the session, and the option to change any operational parameters.

At the top of the screen the Doctor and Patient are detailed. If it is necessary to make any amendments to doctor or patient details select the Finish Button.

The NT1000 will then require the user to select the electrode they would like to use for a procedure. By touching the drop down box, the following menu will be displayed



6.1.9 Electrode Selection Screen

The Electrode selection screen gives the user the choice to select from a list of seven options. The left hand side of the table shows the electrode mode choices, the right hand shows the output sockets that will be used in a given mode.

A corresponding cross in the column indicates that the socket will be active in that mode. If more than one cross appears in a row the option indicates a multiple electrode procedure.

To make an electrode selection use the touchscreen to highlight the choice and press the next button. This will return the user back to the setup confirmation menu.

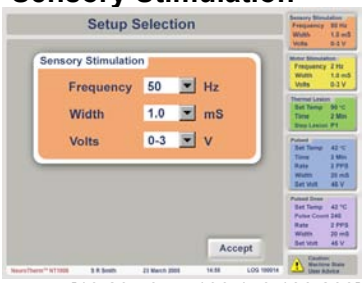
6.1.10 Setting Operating Parameters

The right hand side of the screen shows a series of five coloured boxes, each representing the different operational states, Sensory Stimulation, Motor Stimulation, Thermal Lesion, Pulsed RF and Pulsed Dose.

To enter each of the operational state menus, touch the relevant coloured box using the touch screen. This will then prompt the user with a set of menus, from where key parameters are entered and stored under the doctor profile.

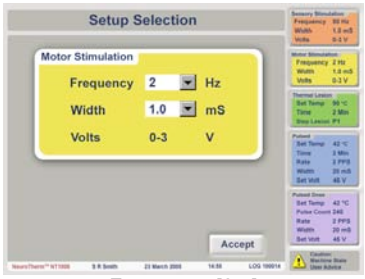
Operating Parameters – [Defaults shown in bold]

Sensory Stimulation



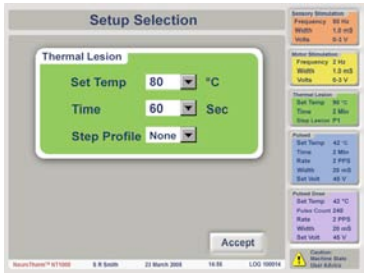
Frequency [10,20,**50**,75,100,150,180,200]
Width [0.1,0.2,0.5,**1.0**]
Volts/Current [0-0.5V, **0-3.0V**,0.5.0V. 0-1.0mA,0-6.0mA, 0-10.0mA]

Motor Stimulation



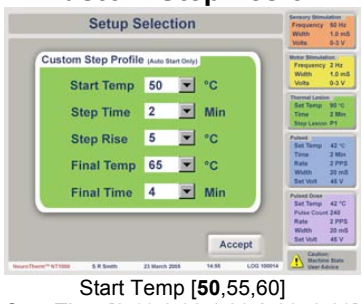
Frequency [**2**,5]
Width [0.1,0.2,0.5,**1.0**]
Volts/Current [0-0.5V, **0-3.0V**,0.5.0V. 0-1.0mA,0-6.0mA, 0-10.0mA]

Thermal Lesion



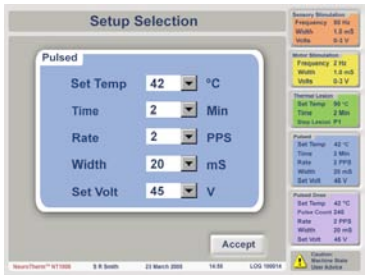
Set Temp [50,55,60,65,70,75,**80**,85,90]
Time[0:30,**1:00**,1:30,2:00,3:00,4:00,5:00,6:00,7:00,8:00,9:00,10.00]
Step Profile [**None**,IDET P1, IDET P2 IDET P3,custom]

Custom Step Lesion



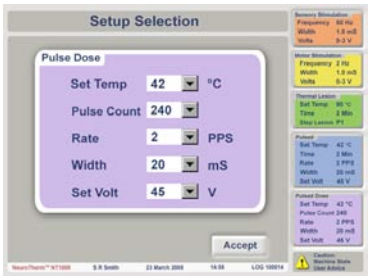
Start Temp [**50**,55,60]
Step Time [0:10,0:30,1:00,**2:00**, 3:00]
Step Rise [1,**5**]
Final Temp [**65**,70,75,80,85,90]
Final
Time[1:00,2:00,**4:00**,6:00.8:00,10:00]

Pulsed RF



Set Temp [**42**,45,50,55,60,65]
Time
[0:30,1:00,1:30,**2:00**,3:00,4:00,5:00,6:00,7:00,8:00,9:00,10:00,20:00]
Rate [1,**2,** 5,10]
Width [5,10,**20**,50]
Set Volt/Current [30v,35v,40v,**45v**,50v,60v,65v,70v,50mA, 100mA, 150mA, 200mA, 250mA, 300mA, 350mA,]

Pulsed Dose



Set Temp [**42**]
Count [no
set,120,**240**,360,480,600,1200]
Rate [**2**]
Width [**20**]
Set Volt/Current
[30v,35v,40v,**45v**,50v,60v,65v,70v,50mA, 100mA, 150mA, 200mA, 250mA, 300mA, 350mA,]

Users can set up the parameters for each sub menu in any order. At any stage if 'Accept' is pressed, settings will be stored, and the user will return to the previous screen they were viewing.

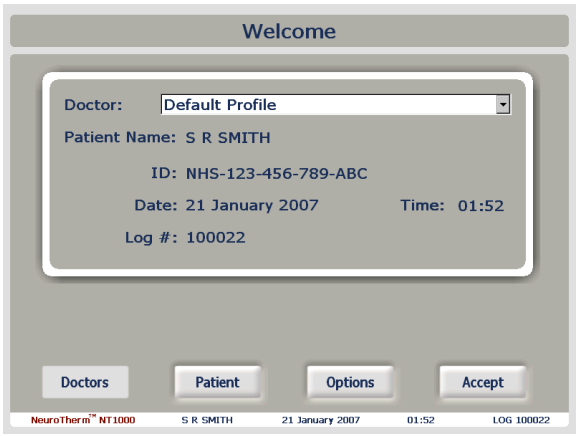
Instructions for more Advanced Use Custom Profiles and using multiple probes) are detailed in Section 7

6.2 Setting up the machine for the first time

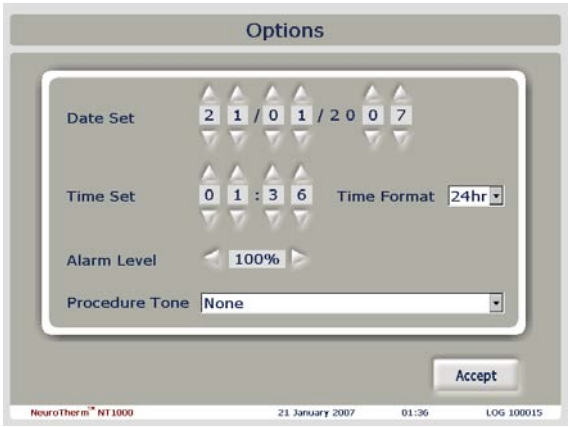
1. Turn the NT1000 on using the power switch on the rear of the unit

2. The machine will boot, showing the NeuroTherm logo, before proceeding to the self test screen, where all of the hardware is initialised and diagnostic tests are performed.

3. The NT1000 will then show the following screen:



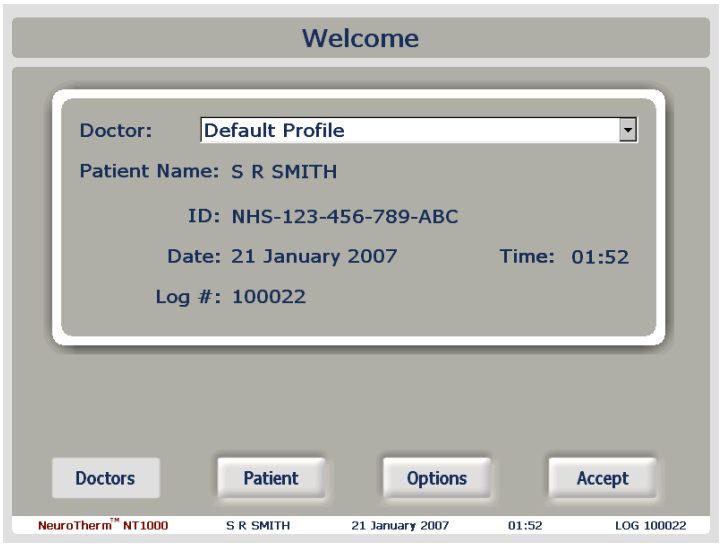
4. The date and time should then be set up. Using the touchscreen, select ‘options’



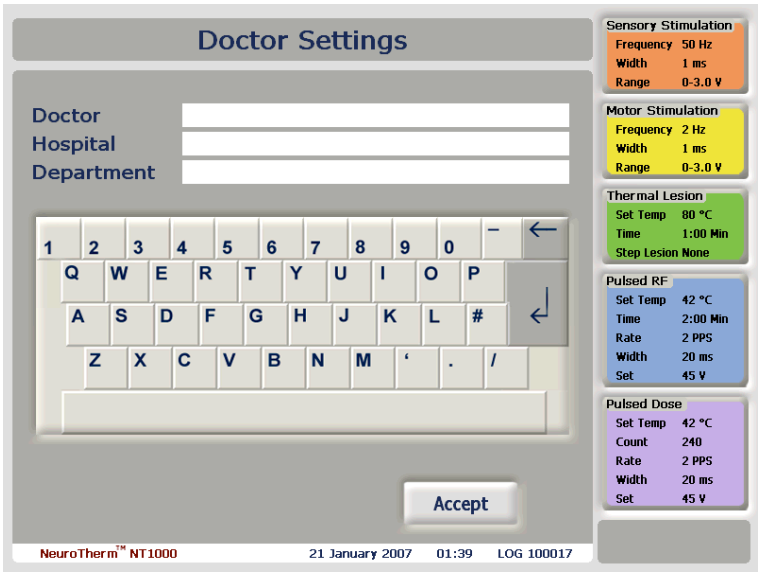
The options screen will then show. To set the date, use the up and down arrows next to ‘Date Set’ (DD/MM/YYYY format) The time is set in a similar way , by using the up and down arrows next to ‘Time Set’ (HH:MM format). The time format is selected using the dropdown

box; either 12 hour or 24 hour clock can be selected. Once completed press 'accept' to return to the welcome screen.

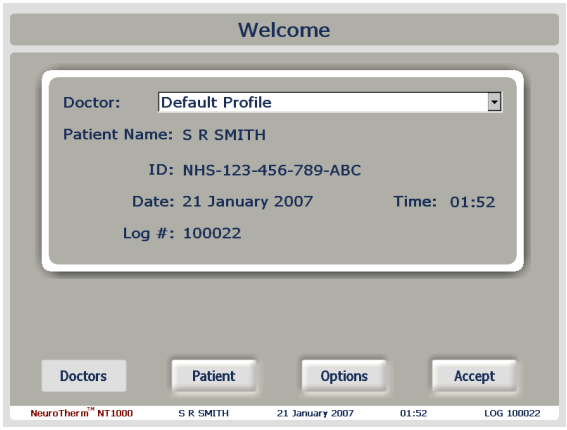
5. The NT1000 has the capacity to store up to six doctors, each with their own user profile, which stores all preferred operating parameters. As standard the default profile is selected. To set up a doctor profile for the first time press the drop down box next to 'Doctor' and select the 'add' option.



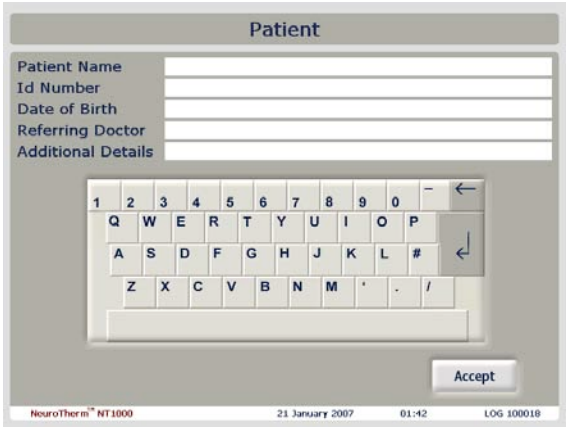
6. The 'Doctor' screen will then appear. Type the doctor's name into the 'Name' Box by touching the letters on the keyboard. If a mistake is made use the delete button. Continue to fill out all fields, using the return button or touching the relevant box on the screen to switch to the 'Department', 'Hospital' and 'Additional Details'. Once completed, press the 'Accept' button on the screen.



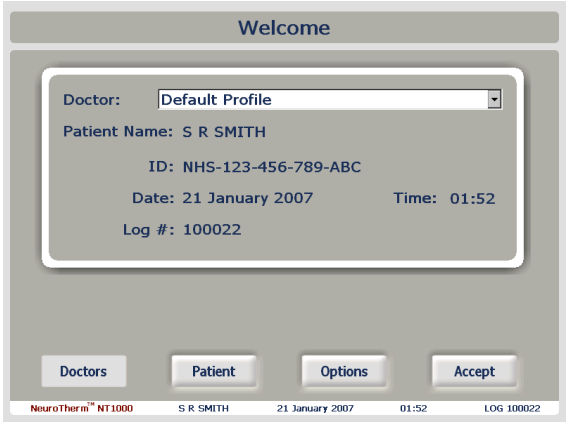
7. The name of the doctor will be filled out in the ‘Doctor’ Box. If editing of any stored parameters is required, press the ‘Doctor’ button. The next step is to press the ‘Patient’ button on the screen.



8. Fill in the patient details using the keyboard on the screen. Using return to progress onto the next field. Once completed press the ‘accept’ button to return to the welcome screen.

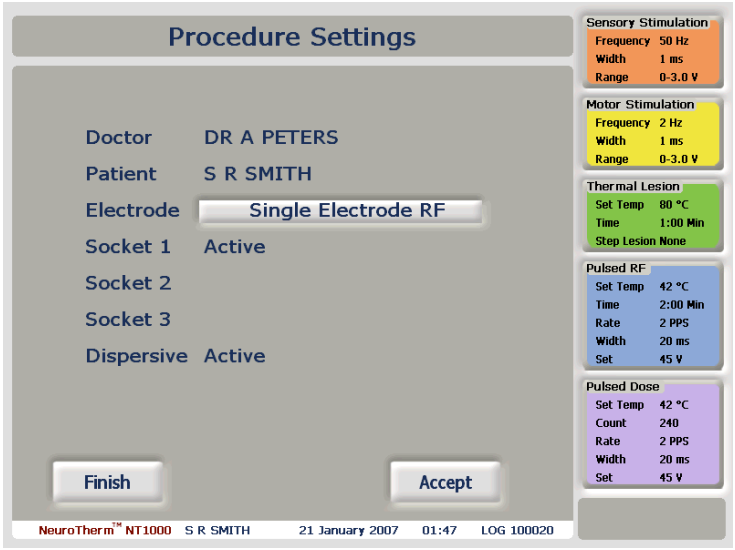


9. The NT1000 now has all of the information to proceed to setup the procedure. Press the ‘accept’ button.

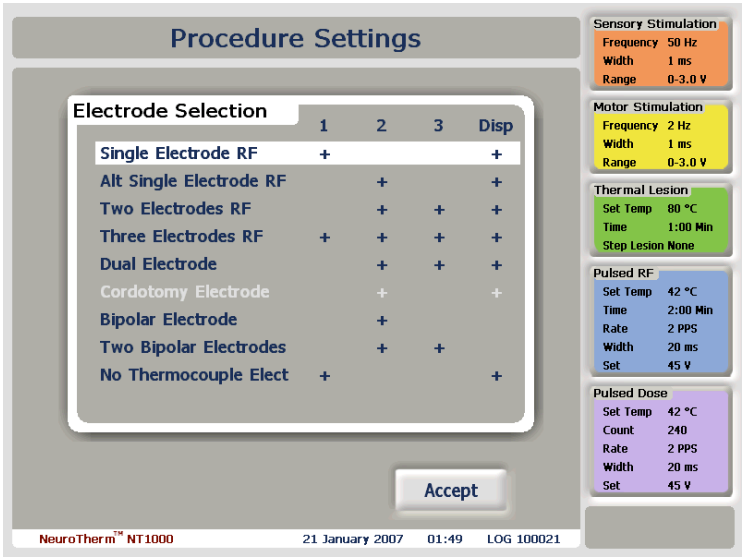


SELECTING A PROCEDURE

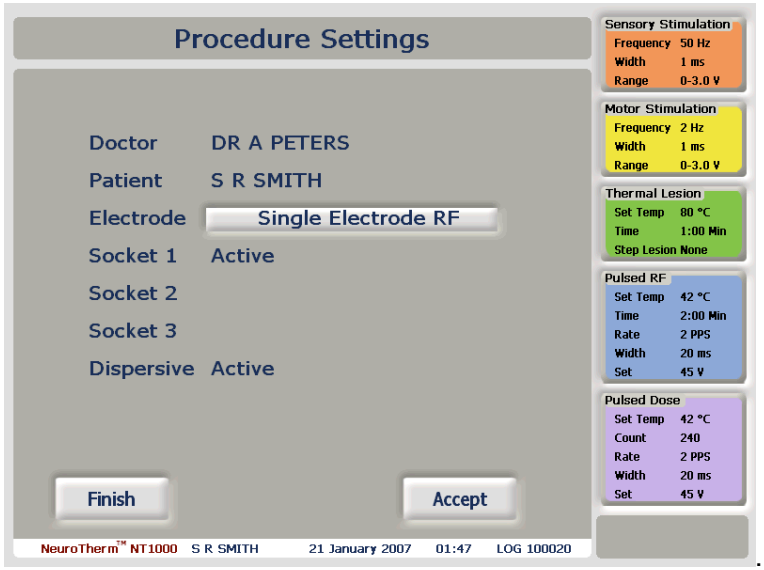
10. The setup confirmation screen will be updated to show the data entered via the welcome screen. The doctor name and patient name will be shown in the relevant fields. The electrode selection must then be made by touching the drop down box next to 'Electrode' on the screen.



11. The Electrode selection screen will then give the user a list of all of the electrode modes supported by the NT1000. For this example we will be performing a thermal lesion using a single electrode only. To make this choice, touch the line on the screen labelled 'Single Electrode RF' and press the 'Next' button.



12. You will then be returned to the setup confirmation screen. ‘Single Electrode RF’ will be selected in the electrode box. Under the electrode box there is a table illustrating which sockets require an electrode to be used for the given procedure. For single electrode RF socket 1 and the dispersive lead are labelled ‘active’, this shows that they are to be used



On the right hand side of the screen are all of the operating parameters for the various modes on the NT1000. At this stage we will use the default parameters.

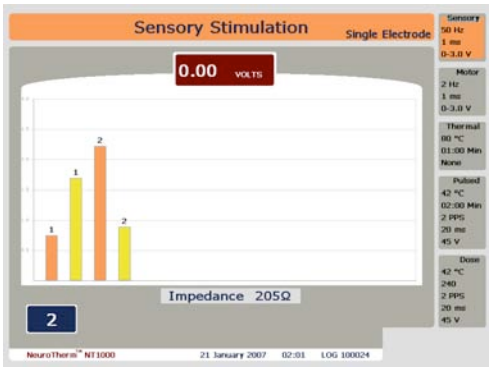
13. You may now plug in a dispersive lead into the far left socket on the front of the unit labelled ‘Dispersive’ and plug in an electrode into Socket 1.

The machine is now ready to progress to an active state. Press ‘Accept’ to continue.

6.3 Undertaking Simple Procedures

6.3.1 Motor and Sensory Stimulation

1. The NT1000 will now have progressed to the Sensory stimulation screen. As the machine is now in an active state the touch screen is no longer active. All control is now performed by the control panel.

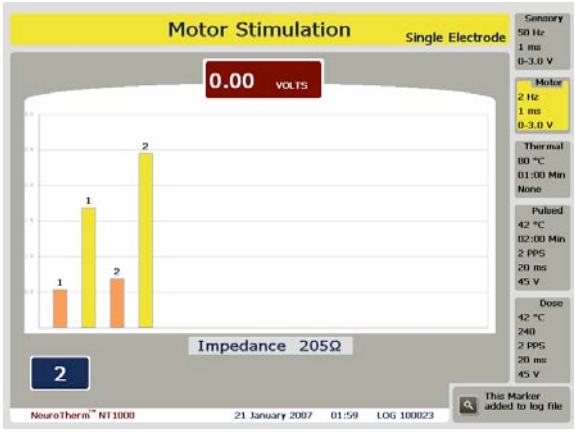


2. Position the electrode and looking at the screen slowly turn the stimulate pot on the front panel clockwise until the patient feels the stimulation. The graph will show an orange colour coded bar which will rise showing the voltage current applied to the patient. The voltage current will also be shown as a numerical reading at the top of the screen. When the level of sensory stimulation is achieved, press the log button Log. The bar will remain showing the level of stimulation logged. Turn the stimulation pot off by turning anti clockwise.

3. To switch to motor stimulation press the ‘Motor’ Button Motor

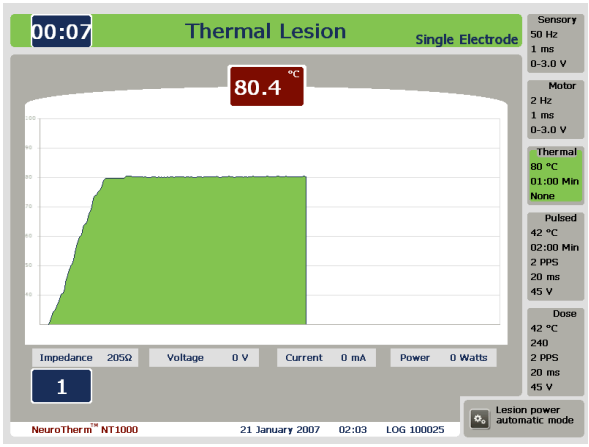
   The motor stimulation screen is in the same format as sensory stimulation. You will see the orange bar showing the logged value of the sensory stimulation that was just set in step 2

   Slowly turn the stimulate pot clockwise to the required level. The graph will now show a yellow bar which will rise showing the motor stimulation voltage current applied to the patient. When the level that has an effect on the motor nerves of the patient is achieved, Press the log button Log.



6.3.2 Performing a Lesion

1. To switch the unit to lesion mode, press the Lesion button. The lesion screen will appear. For this quick start example we will perform an automatic thermal lesion.



2. The NT1000 is now ready to apply power through the electrode in socket 1. To begin press the 'Auto Start' Auto Start button on the front control panel.

   The automatic mode will perform a thermal lesion for the selected duration, in this case, 60 seconds. At the top of the graph there is a numeric reading of the temperature at the tip of the electrode, measured in degrees c. As the power applied to the electrode is increased, this value will steadily rise to the selected set temperature, in this case, the default value of 80 °C. The clock will start to count down when the achieved temperature is within 5 °C of the set limit temperature.

   The graph will show the temperature during the duration of the lesion procedure. Once 60 seconds has passed at the set temperature, the alarm will sound, and power to the patient will be switched off. The lesion is now complete.

7 MORE ADVANCED USE

7.1 General terminology, logging, messages and simple operation

7.1.1 Active States

An active state is defined as a condition where the machine is in a mode where it can supply power to the patient.

When an active state is entered the NT1000 deactivates the touchscreen, and reverts to using only the front control panel for all user control. The screen is used as a display tool during all procedures. It will show the user data and graphical outputs of the procedure.

7.1.2 Entering Active Procedure Screens

To proceed to an active state the user can press ‘accept’ at the setup confirmation screen. The machines will emit a tone to inform the user that the machine is entering an active state.

By default the machine will initially enter the sensory stimulation mode. If the operator wishes to switch between any of the modes they can do so using the ‘Sensory’, ‘Motor’, ‘Lesion’ and ‘Pulse’ Buttons. On the front panel. Note, to enter Pulse Dose mode, press ‘Pulse’ twice.

7.1.3 Single and Multiple Electrodes

The NT1000 has the capability to operate on a patient simultaneously using up to three separate ‘multiple’ electrodes. During a lesion procedure power is supplied to all electrodes at the same time.

The unit also has the capacity for logging up to three sites using a single electrode. Each site must then be operated on separately.

7.1.4 Single electrode Stimulation Modes - Sites

For each active session, the user can chose to use 3 separate sites for which to operate on using a single electrode. The doctor can switch between sites using the up and down arrows on the control panel. This must be performed after the stimulate control is turned off

7.1.5 Colour coding

The NT1000 utilises a colour coding system throughout all of its menu systems, graphs and buttons. The colours are as follows:

Sensory Stimulation:	Orange
Motor Stimulation:	Yellow
Thermal Lesion:	Green
Pulsed RF:	Blue
Pulsed Dose:	Purple

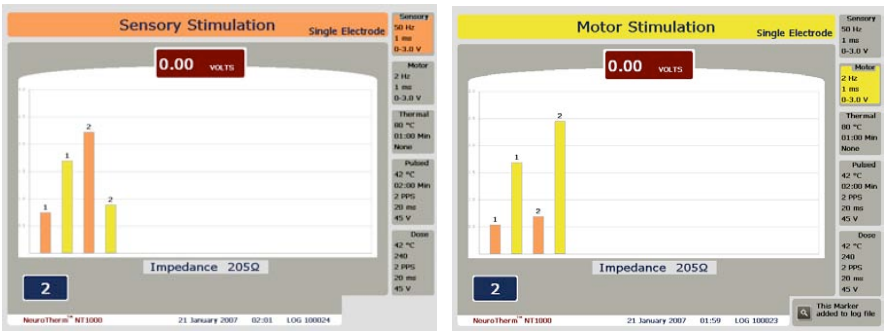
7.1.6 Motor and sensory modes

The layout of the screens for these modes is very similar. At the top of the screen there is a large readout of the voltage or current which is being applied to the patient. Below is a large graph area.

Each time the stimulation pot is turned on in Motor and Sensory modes the NT1000 creates a colour –coded vertical line (see above for colour table). Above this line is a single digit which represents the active site.

The user can switch between sensory and motor modes at any time using the 'motor' and 'sensory' buttons on the front control panel. The graph will update showing the relevant data using the same scale.

At the bottom of the screen is a reading of impedance at the active site. The box at the foot of the grey area shows the active site. It must be noted that during stimulation of a patient, the NT1000 will not read Impedance.



7.1.7 Data Logging during a procedure

The NT1000 has the capability to log and store all data from a procedure on a second by second basis. By pressing the 'log' button, the NT1000 saves all data simultaneously which can be printed or saved to the Neurotherm USB memory Stick (Part #: NT-USB) at the end of the procedure.

7.1.8 Printing Records

The Neurotherm NT1000 uses an internal Bluetooth adaptor to communicate using a wireless connection to a Printer.

Note: In order for the printer to be used it must be turned on BEFORE the NT1000 performs its self test boot sequence. During the self test the Bluetooth adaptor searches for its printer and creates a virtual link to the device. It is not possible to recreate this link at any other time.

The report is automatically printed when the user presses the 'end session button'. The report is a text based document, summarising the procedure and giving information on any logged data.

7.1.9 Advice Messages

If the NT1000 detects a fault or condition that the user should be advised of, it will automatically generate a message on the screen.

There are 4 classifications of message, based on the severity of the operating condition:

Level 1 – User Advice
This will give the user a message in the bottom right 'advice box '. If there are multiple advice messages, they will scroll in sequence every few seconds.

Level 2 – System Status
Gives information on the status of integrated devices used in the NT1000

Level 3 – User Warning
User warnings are recoverable. They alert the user with a central message box, which will overlay any graphs, menus or active screens. The user will have to acknowledge the warning on screen or will have to rectify the issue by adjusting the controls to continue. Whilst the message is displayed, the system will be in a safe state*

Level 4 - Critical Fault
This is the most severe classification. During regular operation, this state should never be witnessed by the user. A critical fault may require the user to turn off the power. The critical fault will be full screen, and will give the user guidance on how to proceed. Whilst the screen is displayed, the system will be in a safe state*

*During a safe state, the machine does not output any power to the patient.

A full list of messages under each Level is shown in Section 8

7.1.10 Saving Data to the USB Memory Stick

The USB Memory stick plugs into the back of the machine. The NT1000 automatically logs data during all active procedures.

This data can be copied and used on any Microsoft windows compatible computer, and viewed using Microsoft Excel. For reference the files are saved as .csv (comma separated value) text files. The log files are named by the log number. For example:- 100047.csv, is the log data file for procedure 100047.

To open the files in excel, use the file>open command, locate the USB memory stick (which may be labelled by windows as a removable disk), select the log file and press 'ok'. The import wizard will then assist with formatting the data into columns.

CAUTION:- Incomplete logs due to environmental error or power failure will result in a log not being stored.

CAUTION:- Rigorous procedures should be adopted to ensure backups of user logs are made and stored safely.

CAUTION:- Operator should review the data in the data file to confirm consistency.

7.1.11 Stopping a Procedure

If at any point during a procedure it is necessary to end the procedure, either in the event of an emergency or not, press the Auto Stop button.

This will put the machine into a safe state immediately, instantly stopping any power being transferred to the patient. NOTE. After pressing 'Stop', the procedure will restart from the beginning and not from the point where the 'Stop' button was pressed.

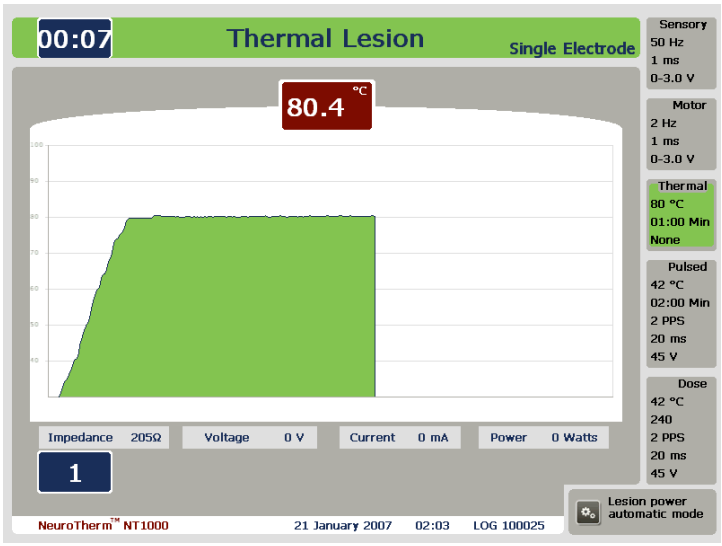
7.1.12 Ending a Session

Once the NT1000 enters an active state it enters what is known as a 'session'. A session can be made up of a series of individual tasks, albeit a combination of stimulation and lesion tasks, the activity of which, being automatically logged.

To end a session press the End Session button on the control panel.

Note: Before ending a session any procedures should either have not started or have been completed and the NT1000 should not be delivering any power to the patient and both Stimulate and RF Controls should be turned fully anticlockwise.

7.1.13 Thermal Lesion

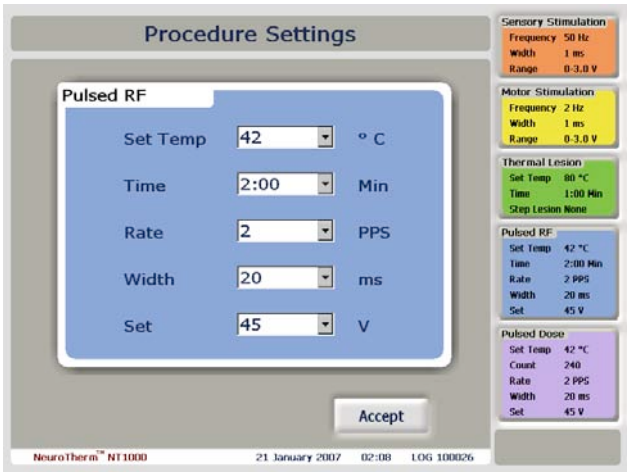


The thermal lesion screen is very similar in style to those of the motor and sensory stimulation screens. It features a central graphical interface. On the left hand corner of the screen there is a box which gives the operator the time remaining for the lesion to complete.

The vertical axis of the graph gives a reading of temperature in degrees (Scale 30-90°). The horizontal axis is time in seconds.

7.2 RF Pulse Mode

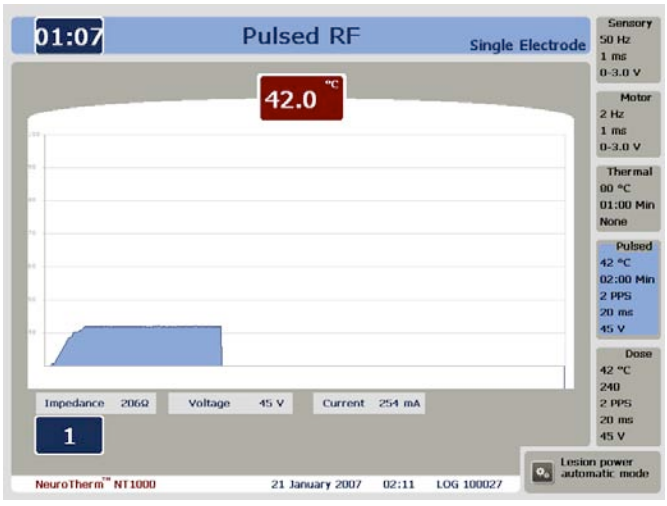
1. To access the Pulse RF parameter setup Menu press the the blue 'Pulse RF' box on the right hand side of the display in the 'Doctor' or 'Setup Confirmation' Screen.



2. Once all parameters are set press the 'Accept' Button. To progress to an active state press the Accept' button at the setup confirmation screen.

3. To switch the unit to RF Pulse mode, press the 

button. The Pulsed RF screen will appear.



The functionally of the NT1000 is the same in Pulsed RF mode as in thermal lesion (see section 6.3.2).

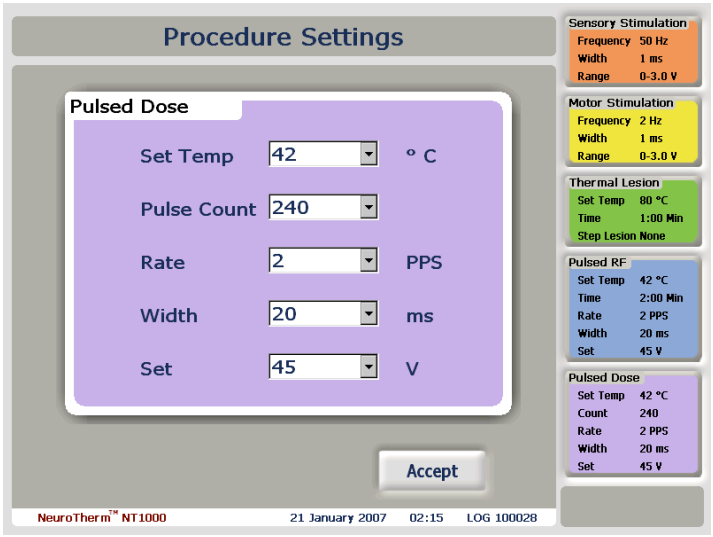
For Pulsed RF in manual mode, turn the RF pot clockwise to increase the output power. For Automatic mode the RF Control needs to be fully anticlockwise and then press the 'Auto Start' 

button.

4. Once 2.00 minutes has passed at the set temperature, the alarm will sound. The lesion is now complete.

7.3 Pulse Dose

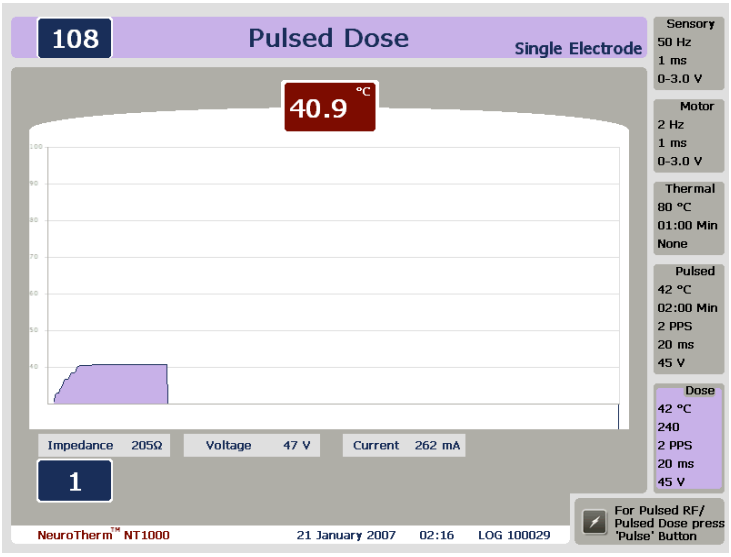
1. To access the Pulse Dose RF parameter setup Menu press the Purple 'Pulsed Dose' box on the right hand side of the display in the 'Doctor' or 'Setup Confirmation' Screen.



2. The parameters are set in the same way to those of all other modes – select the options from the dropdown menus and press 'Accept'. The user will be returned to the welcome screen.

3. In an active state, to access the pulsed dose function , press the 

button twice. The Pulse RF Dose screen will appear.

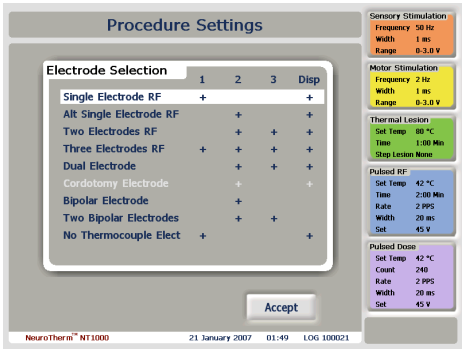


Pulse dose mode is only operational in Auto mode. To start the procedure press the 'Auto Start' Auto Start button.

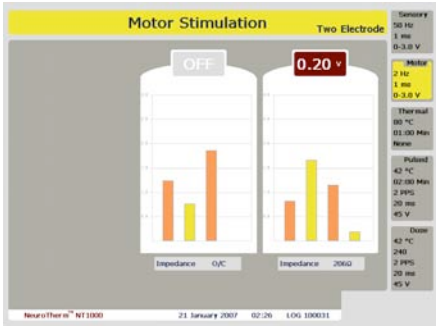
4. In the centre of the screen there is a graph similar to the other RF modes, showing temperature plotted against time. At the top left of the screen a counter shows the number of pulses left in the procedure. This will count down until all of the pulses have been supplied to the patient, the alarm will sound. The procedure is now complete. Press "end session" to return to the procedure selection screen.

7.4 Two Electrodes Operation

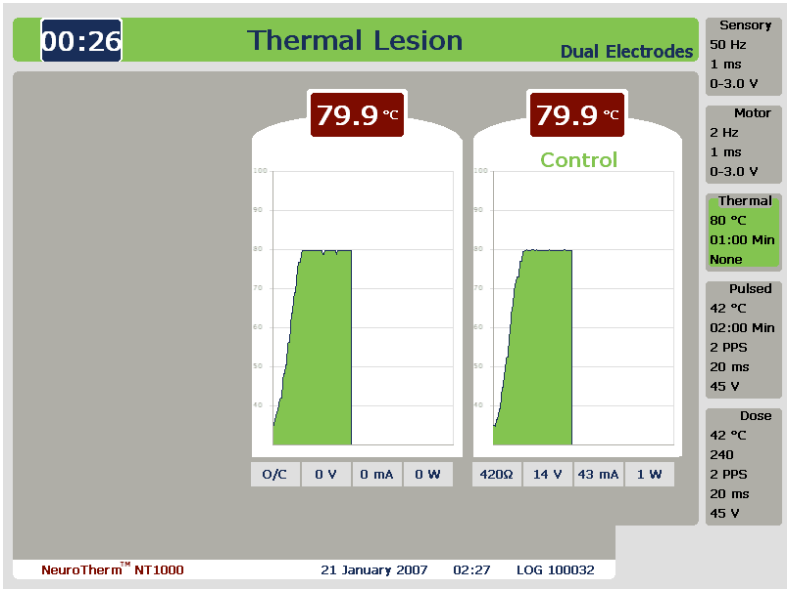
1. Two electrodes RF is only available in Auto mode. It is selected at the electrode selection menu. Highlight the choice and press 'Accept'



2. After proceeding from the procedure selection screen the NT1000 will automatically be set to the Two Electrodes RF Mode. The first step is the motor and sensory stimulation. Each electrode has its own graphical area. Electrode 1 on the left, with electrode 2 on the right. Use the Select and Select buttons to swap between electrode 1 and electrode 2. The logging functionality is the same as that of a single electrode mode.



3. In Two Electrode RF mode, the NT1000 will only function using Auto mode. Once ready to perform the procedure, press the Lesion or Pulse button. Press the 'Auto Start' Auto Start button to begin the procedure.

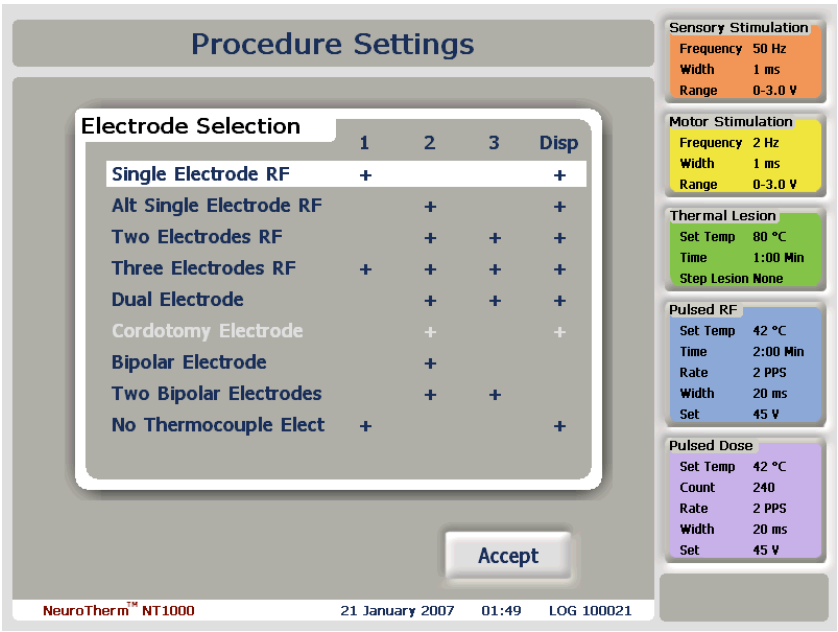


4. Each graph shows the temperature of each electrode. The NT1000 will control the temperature of each probe automatically. At the top left of the screen there is a readout of time remaining until the end of the procedure. When the lesion is complete a tone will sound.

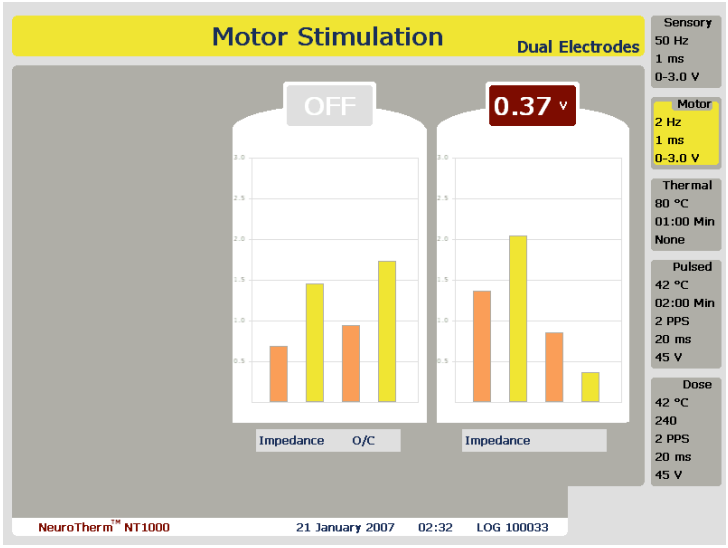
7.5 Dual Electrode Operation

(A Dual Lesion is one that is created between two separate electrodes)

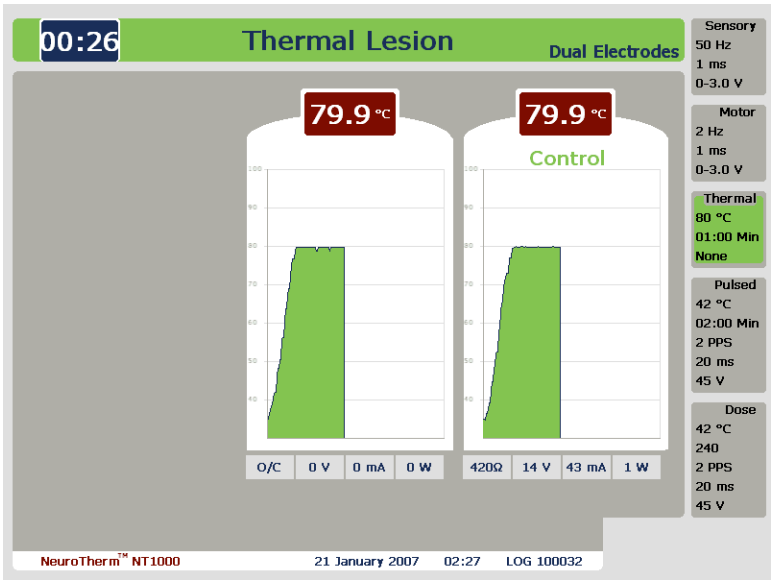
1. Dual electrodes RF is also only controlled in Auto mode. It is selected at the electrode selection menu. “Highlight Dual Electrode” and press ‘Accept’



2. Sensory, Motor and Lesion modes function in exactly the same way as in Two Electrode Operation. For operating instructions see section 7.4.



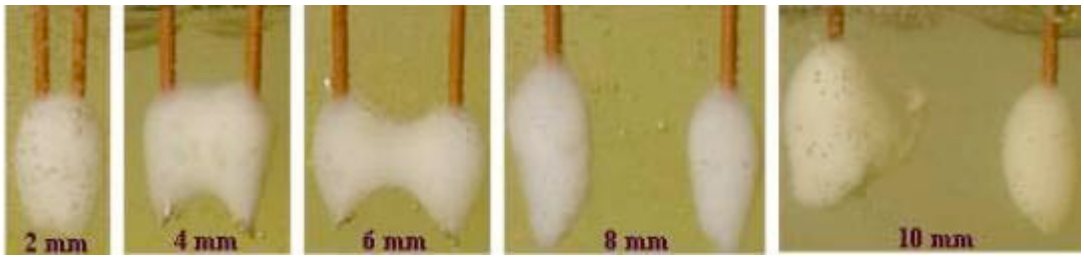
3. As the lesion is created between the two electrodes it is necessary to remove the reference plate from the patient before a lesion procedure is started. In the Lesion screen the controlling electrode is shown on the graph by having the label 'Control' under the electrode name. Once the Auto Start button is pressed the NT1000 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 Imp./ V&I / W.



7.6 Caution

When using dual electrode mode, the operator must insure that the two electrodes are not touching, as this will prevent any heating and thus will not heat 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 NT 1000 is short circuit protected and cannot be damaged by shorting the outputs.

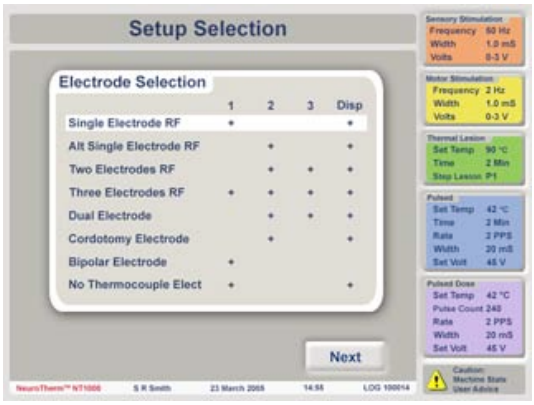
Additionally, it is important to realize the relative lesion shapes that are obtained at different electrode spacings. Typical shapes are shown in the pictures below-



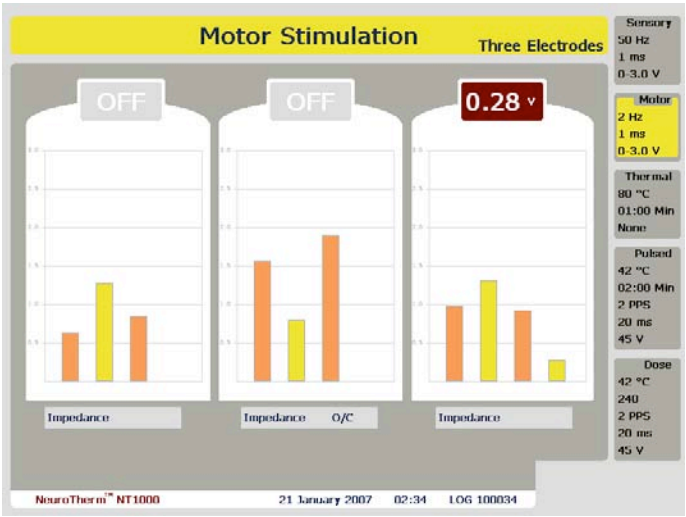
These lesions were made at 80 C for 90 seconds. Notice that at 2 mm spacing, the lesion is essentially the same shape as a single electrode lesion, only larger. The lesions take on more of a dumbbell shape at 6 mm. At 8 mm and 10 mm the lesions are essentially the same size and shape as two independent lesions.

7.7 Three Electrodes Operation

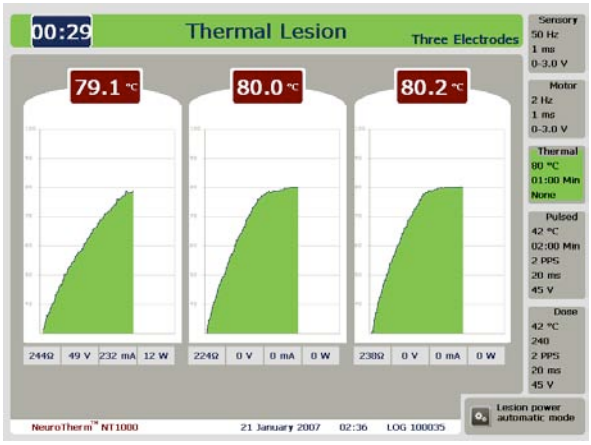
1. As with Two electrodes RF, Three electrodes RF is also only available in Auto mode. It is selected at the electrode selection menu. Highlight the choice ‘Three electrodes ‘ and press ‘Accept’



2. Proceed from the procedure selection screen by pressing ‘Accept’. The first step is the motor and sensory stimulation. Each electrode has its own graphical area. Electrode 1 on the left, with electrode 2 in the centre, with electrode 3 on the right. As with the two electrodes RF mode, navigate between the electrodes using the Select and Select buttons



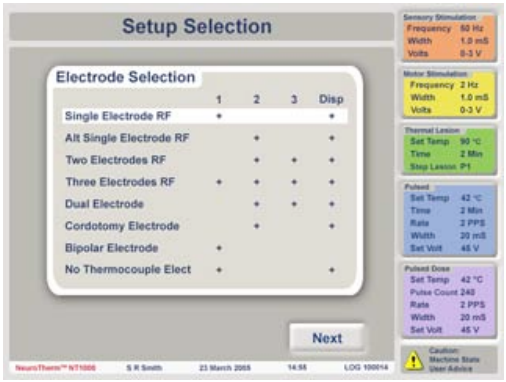
3. In Three Electrode RF mode, the NT1000 will only function using Auto mode. Once ready to perform the lesion, press the Lesion button. Press the 'Auto Start' Auto Start button to begin the lesion.



4. The graphical interface of the lesion screens is also similar to that of the two electrodes mode. The temperature of electrodes 1 to 3 is shown above each graph, with the impedance, voltage, current and power shown underneath each graph. When the lesion is complete a tone will sound.

7.8 Cordotomy, Bipolar & "No Thermocouple" Operation

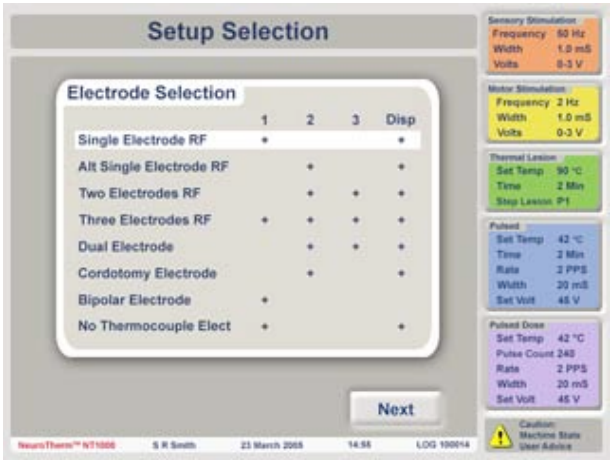
1. As with all other electrode selections, Highlight the required choice in the electrode selection menu and 'Accept'



2. Control during all active modes is identical to that during the single electrode RF modes, for information see section 6.3.2.

Two Bipolar

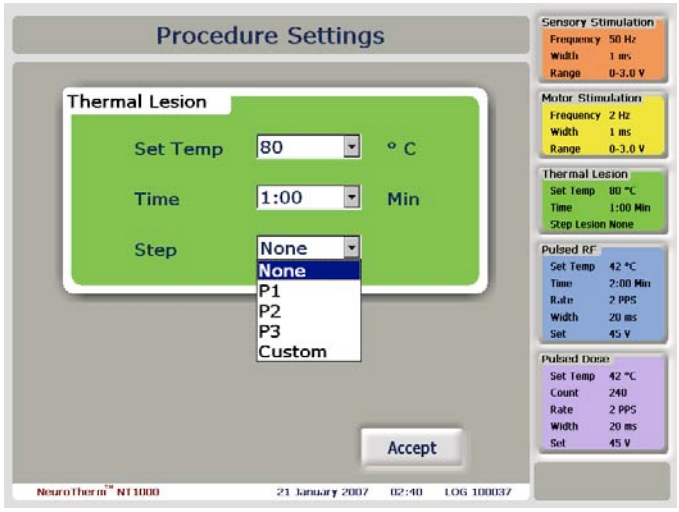
3. To select this mode at the electrode selection screen highlight the "Two Bipolar Electrode" and press 'Accept' via the touch screen.



4. Control during all active modes is identical to that during the two electrode RF, and is only available in Auto mode. For information see section 7.4.

7.9 Preset Step Profiles

1. To access the Preset Step Profiles P1/P2/P3 first access the Thermal Lesion by pressing the green Thermal Lesion box on the right hand side of the display in the 'Doctor' or 'Setup Confirmation' Screen. Under the drop down for 'Step Profile' select the requested profile and press 'Accept'.



2. The P1/P2/P3 preset step profile are only operational is automatic mode. Once in an active state, press the Lesion button. Press the 'Auto Start' Auto Start button to begin the lesion.

3. The NT1000 will automatically control the procedure, displaying the temperature and time on the graph. When the procedure completes the tone will sound.

7.10 Custom Step Profiles

The custom step profile facility gives the user the ability to create their own lesion profile. Custom step profiles are only supported by single electrode modes. The NT1000 defines a step profile using the following variables:

Start Temperature: The initial temperature in degrees centigrade that the profile should hold before the making the first step rise.

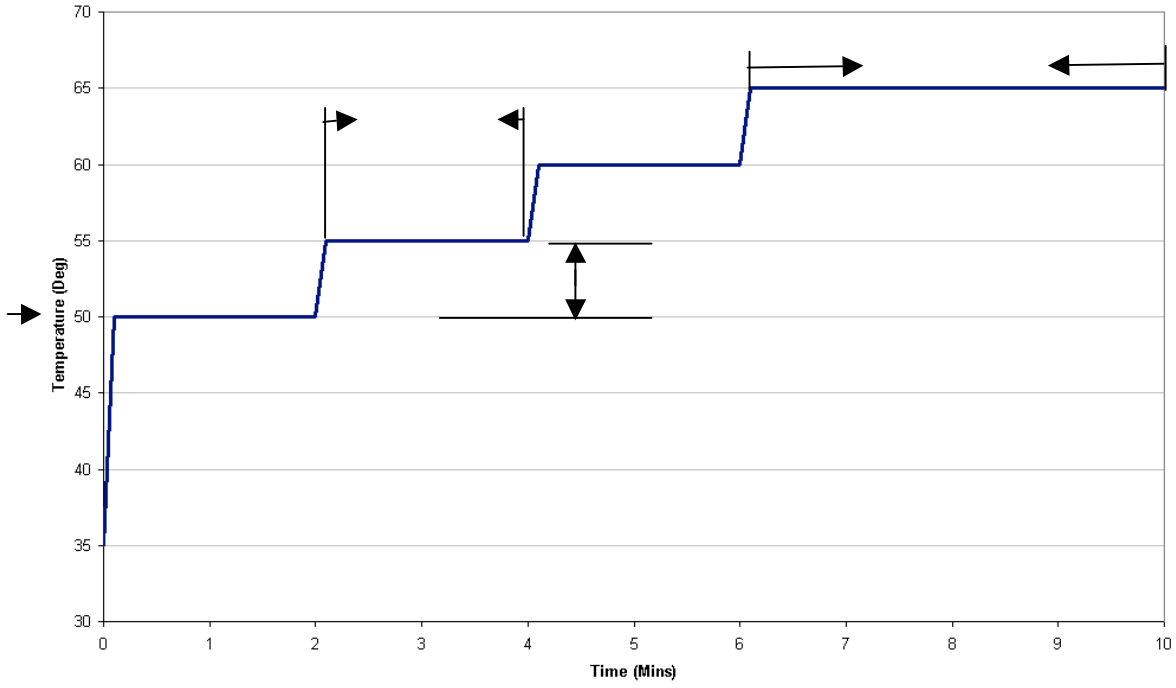
Step Time: The time in minutes the profile should hold at each step temperature.

Step Rise: The increase in Temperature in degrees centigrade of each step.

Final Temperature: The temperature in degrees centigrade that the profile should hold at after the last step rise.

Final Time: The time in minutes that final temperature is held at before the end of the lesion.

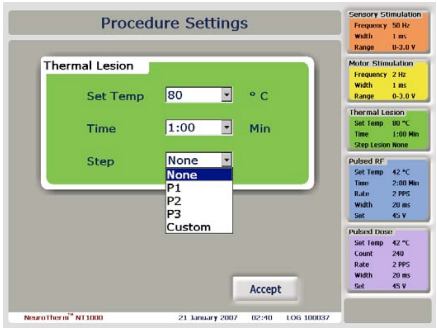
For this example we will create a custom step profile of the following:



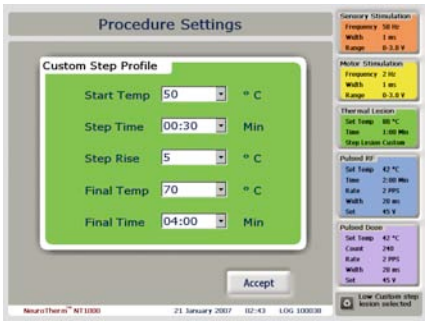
From the graph, the key profile variables are identified as:

Start Temperature: 50°C
Step Time: 2 Mins
Step Rise: 5°C
Final Temperature: 65°C
Final Time: 4 Mins

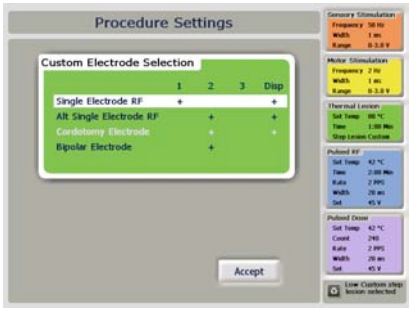
1. To access the custom step lesion firstly access the Thermal Lesion by pressing the green Thermal Lesion box on the right hand side of the display in the 'Doctor' or 'Setup Confirmation' Screen. Under the drop down for 'Step Profile' select 'Custom'.



2. This will give the user a menu for custom step profile for the Thermal lesion menu. Use the dropdown boxes to enter the profile variables (Start Temperature: 50°C, Step Time: 2 Mins, Step Rise: 5°C, Final Temperature: 65°C, Final Time: 4 Mins). When completed press 'Accept'

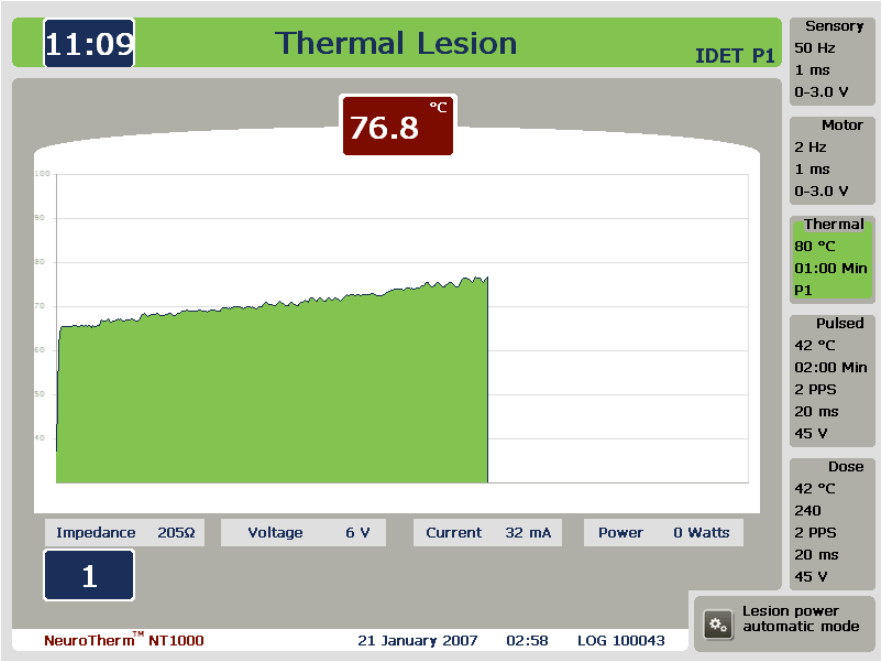


3. The user will then be given a menu which requires a selection of the electrodes For this example we will select ' Single Electrode RF', and press 'Accept'



4. The user will then be returned to the Setup confirmation screen. To then progress to an active state press ‘Accept’.

5. Once ready to perform the lesion, press the Lesion button. Press the ‘Auto Start’ Auto Start button to begin the lesion.



At the top centre of the screen the current temperature is shown. There is readout at the top left showing the time remaining for the custom profile to complete the lesion. When the lesion is complete a tone will sound.

Hierarchy of Screens

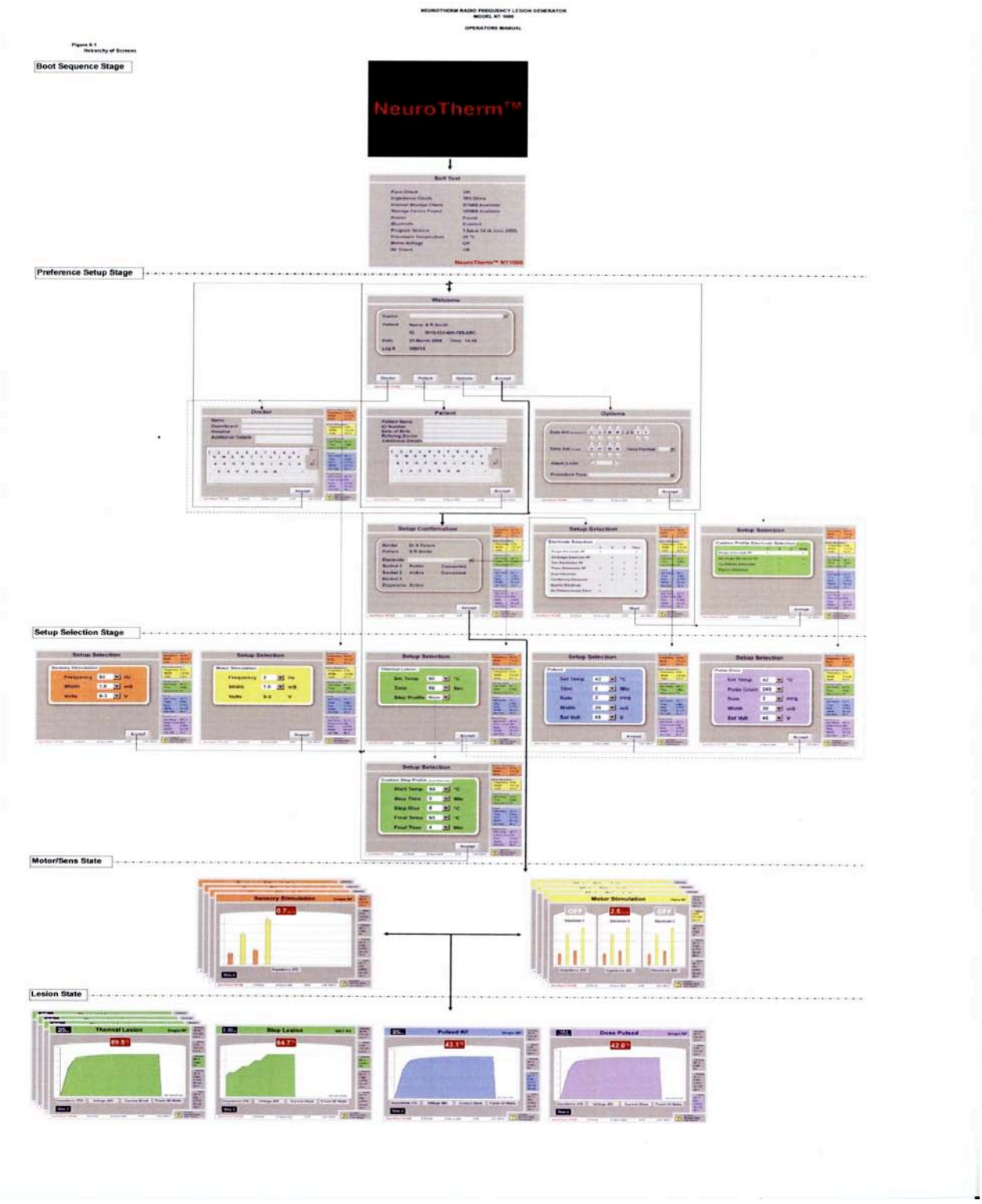


Figure 7.1

8 ERROR / FAULT MESSAGES

If the NT1000 detects a fault or condition that the user should be advised of, it will automatically generate a message on the screen.

There are 4 classifications of message, based on the severity of the operating condition:

Level 1 – User Advice
This will give the user a message in the bottom right 'advice box '. If there are multiple advice messages, they will scroll in sequence every few seconds.

Level 2 – System Status
Gives information on the status of integrated devices used in the NT1000

Level 3 – User Warning
User warnings are recoverable. They alert the user with a central message box, which will overlay any graphs, menus or active screens. The user will have to acknowledge the warning on screen or will have to rectify the issue by adjusting the controls to continue. Whilst the message is displayed, the system will be in a safe state*

Level 4 - Critical Fault
This is the most sever classification. During regular operation, this state should never be witnessed by the user. A critical fault may require the user to turn off the power. The critical fault will be full screen, and will give the user guidance on how to proceed. Whilst the screen is displayed, the system will be in a safe state*

*During a safe state, the machine does not output any power to the patient.

Level 1 - User Advice

Message Scenario	Message Text	Message code
When setting defaults in doctor setup screen	These setting will be saved as defaults	1-001
When the user presses the log button	Marker added to log file	1-002
Impedance goes open circuit when the output is switched off	Impedance open circuit - check continuity of circuit	1-003
In motor or sensory stimulation setup screen, when a voltage is selected in the sensory stimulation setup	Stimulation set to constant voltage	1-004
In motor stimulation or sensory setup screen, when a current is selected in the sensory stimulation setup	Stimulation set to constant current	1-005
In pulsed dose procedure screen	Estimated time left: mm:ss	1-006
In Pulsed Dose/Pulse rf procedure screen, before the procedure is actually started.	For Pulsed RF/Pulsed Dose press 'Pulse' Button	1-007
In pulsed RF/Pulse Dose setup screen, when a temperature higher than 45 degrees is selected	Selected temperature above 45 degrees	1-009
In Pulsed RF/Pulse Dose setup screen, when a voltage higher than 45 volts is selected	Voltage above 45 V	1-010
In custom step lesion setup screen	Procedure time: mm:ss	1-011
When the auto start function is used to switch on the lesion power *This message will stay there until the timer runs out*	Lesion power automatic mode	1-013
when the lesion power is started manually *This message will stay there until the timer runs out*	Lesion power manual mode	1-014
Impedance of 2000 ohms or more with the output switched off	High Impedance - check probe and leads	1-033
Impedance of less than 50 ohms with the output switched off	Low impedance - check probe and leads	1-015
When timer runs out and the power was wsitched on manually	End of time - Switch off RF power control	1-017
When the accept button is pressed in the setup confirmation screen with any mode selected, but there is no probe or a faulty probe connected to socket 1	No probe detected Output 1	1-018
When the accept button is pressed in the setup confirmation screen with any mode selected , but there is no probe or a faulty probe connected to socket 2	No probe detected Output 2	1-019

When the accept button is pressed in the setup confirmation screen with any mode selected, but there is no probe or a faulty probe connected to socket 3	No probe detected Output 3	1-020
When two electrodes, three electrodes, dual electrode or two bipolar electrodes is selected and you are in the procedure screen for RF lesion, pulsed RF or pulse dose with the output switched off	Auto start only	1-028
When custom step lesion has been set up and you are in any setup or procedure screen	Custom step lesion selected	1-029
When P1 is selected and you are in any setup or procedure screen	P1 selected	1-030
When P2 is selected and you are in any setup or procedure screen	P2 selected	1-031
When P3 is selected and you are in any setup or procedure screen	P3 selected	1-032

Level 2 - System status

Message Scenario	Message Text	Message code
When the NT1000 is printing the procedure details for the patient file *message will disappear after printing is finished*	Printing patient record	2-001
When the NT1000 is writing the log file to the USB memory stick *message will disappear after data transfer is finished*	Writing LOG file to USB device Time left mm:ss	2-002
When the NT1000 finished writing the log file to the USB memory stick *Message will disappear after 5 sec.*	LOG file transferred to USB device USB device xx% full	2-003
When the accept button is pressed in the doctor setup screen *message will disappear after 5 sec.*	Saving doctor details and defaults	2-004
When the accept button is pressed in the options screen *message will disappear after 5 sec.*	Saving options	2-005
When the accept button is pressed in the patient details screen *message will disappear after 5 sec.*	Saving patient details	2-006
When the accept button is pressed in the setup confirmation screen *message will disappear after 10 sec.*	Setting up hardware according to software settings	2-007
When the auto stop button is pressed during a procedure *Message will appear for 5 sec.*	Auto stop pressed Machine in Safe State	2-008

Level 3 - User warning

Message Scenario	Message Text	Message code
When trying to print, but there is an error with the printer. E.g. out of paper / out of ink / paper jam	Printing error - check printer Fix problem, press <retry> or press <cancel> to abort the print.	3-001
When trying to switch into sensory/motor stim with the stimulation pot switched on	Turn off stimulation control before continuing	3-003
When trying to switch into lesion/pulse mode with the RF power control switched on	Turn off RF power control before continuing	3-004
When the accept button is pressed in the setup confirmation screen with No thermocouple elect selected	No thermocouple elect selected. Be aware that there will be no temperature monitoring during the procedure.	3-005
Open circuit condition on Probe 1 with stimulate control turned on	Unable to stimulate probe 1 Impedance probe 1 open circuit. Turn off stimulate control and check probe and reference plate.	3-006
Open circuit condition on Probe 2 with stimulate control turned on	Unable to stimulate probe 2 Impedance probe 2 open circuit. Turn off stimulate control and check probe and reference plate.	3-007
Open circuit condition on Probe 3 with stimulate control turned on	Unable to stimulate probe 3 Impedance probe 3 open circuit. Turn off stimulate control and check probe and reference plate.	3-008
Impedance lower than 50 Ohm condition on Probe 1 with stimulate control turned on	Unable to stimulate probe 1 Impedance probe 1 too low (<50 ohms) Turn off stimulate control, check probe placement and leads.	3-009
Impedance lower than 50 Ohm condition on Probe 2 with stimulate control turned on	Unable to stimulate probe 2 Impedance probe 2 too low (<50 ohms) Turn off stimulate control, check probe placement and leads.	3-010
Impedance lower than 50 Ohm condition on Probe 3 with stimulate control turned on	Unable to stimulate probe 3 Impedance probe 3 too low (<50 ohms) Turn off stimulate control, check probe placement and leads.	3-011

When the temperature goes over 95 degrees while you are in any of the procedure screens	High temperature shutdown Machine set to safe state	3-122
When the auto stop button is pressed while in motor or sensory stimulation with the stimulation output switched on	Emergency stop pressed Motor stimulation cancelled and machine set to safe state Turn off Stimulate control to go back to procedure screen	3-123
When the auto stop button is pressed while in any lesion or pulse mode with the RF output switched on manually	Emergency stop pressed RF output cancelled and machine set to safe state Turn off RF control to go back to procedure screen	3-125
When the auto stop button is pressed while in lesion or pulse mode with the RF output switched on with the auto start function	Emergency stop pressed RF output cancelled and machine set to safe state Press lesion to go back to procedure screen	3-126
When manually starting the RF output in any mode with the impedance of probe 1 open circuit	Unable to deliver RF power Impedance open circuit on probe 1. Turn off RF power control, check probe and connection of the reference plate and restart procedure.	3-128
When manually starting the RF output in any mode with the impedance of probe 2 open circuit	Unable to deliver RF power Impedance open circuit on probe 3. Turn off RF power control, check probe and connection of the reference plate and restart procedure.	3-129
When manually starting the RF output in any mode with the impedance of probe 3 open circuit	Unable to deliver RF power Impedance open circuit on probe 3. Turn off RF power control, check probe and connection of the reference plate and restart procedure.	3-130
When automatically starting the RF output in lesion mode with the impedance of probe 1 open circuit.	Unable to deliver RF power Impedance open circuit on probe 1. Check probe and connection of the reference plate and restart procedure. Press lesion to go back to procedure screen	3-131

When automatically starting the RF output in lesion mode with the impedance of probe 2 open circuit.	Unable to deliver RF power Impedance open circuit on probe 1. Check probe and connection of the reference plate and restart procedure. Press lesion to go back to procedure screen	3-132
When automatically starting the RF output in lesion mode with the impedance of probe 3 open circuit.	Unable to deliver RF power Impedance open circuit on probe 1. Check probe and connection of the reference plate and restart procedure. Press lesion to go back to procedure screen	3-133
When automatically starting the RF output in pulse mode with the impedance of probe 1 open circuit.	Unable to deliver RF power Impedance open circuit on probe 1. Check probe and connection of the reference plate and restart procedure. Press pulse to go back to procedure screen	3-134
When automatically starting the RF output in pulse mode with the impedance of probe 2 open circuit.	Unable to deliver RF power Impedance open circuit on probe 2. Check probe and connection of the reference plate and restart procedure. Press pulse to go back to procedure screen	3-135
When automatically starting the RF output in pulse mode with the impedance of probe 3 open circuit.	Unable to deliver RF power Impedance open circuit on probe 3. Check probe and connection of the reference plate and restart procedure. Press pulse to go back to procedure screen	3-136
When manually starting the RF output in any mode with the impedance of probe 1 less than 50 Ohms	Unable to deliver RF power Impedance is lower than 50 Ohms on probe 1. Turn off RF power control, check probe and connection of the reference plate and restart procedure.	3-137
When manually starting the RF output in any mode with the impedance of probe 2 less than 50 Ohms	Unable to deliver RF power Impedance is lower than 50 Ohms on probe 2. Turn off RF power control, check probe and connection of the reference plate and restart procedure.	3-138

When manually starting the RF output in any mode with the impedance of probe 3 less than 50 Ohms	Unable to deliver RF power Impedance is lower than 50 Ohms on probe 3. Turn off RF power control, check probe and connection of the reference plate and restart procedure.	3-139
When automatically starting the RF output in lesion mode with the impedance of probe 1 less than 50 Ohms	Unable to deliver RF power Impedance is lower than 50 Ohms on probe 1. Check probe and connection of the reference plate and restart procedure. Press lesion to go back to procedure screen	3-140
When automatically starting the RF output in lesion mode with the impedance of probe 2 less than 50 Ohms	Unable to deliver RF power Impedance is lower than 50 Ohms on probe 2. Check probe and connection of the reference plate and restart procedure. Press lesion to go back to procedure screen	3-141
When automatically starting the RF output in lesion mode with the impedance of probe 3 less than 50 Ohms	Unable to deliver RF power Impedance is lower than 50 Ohms on probe 3. Check probe and connection of the reference plate and restart procedure. Press lesion to go back to procedure screen	3-142
When automatically starting the RF output in Pulse mode with the impedance of probe 1 less than 50 Ohms	Unable to deliver RF power Impedance is lower than 50 Ohms on probe 1. Check probe and connection of the reference plate and restart procedure. Press pulse to go back to procedure screen	3-143
When automatically starting the RF output in Pulse mode with the impedance of probe 2 less than 50 Ohms	Unable to deliver RF power Impedance is lower than 50 Ohms on probe 2. Check probe and connection of the reference plate and restart procedure. Press pulse to go back to procedure screen	3-144
When automatically starting the RF output in Pulse mode with the impedance of probe 3 less than 50 Ohms	Unable to deliver RF power Impedance is lower than 50 Ohms on probe 3. Check probe and connection of the reference plate and restart procedure. Press pulse to go back to procedure screen	3-145

Probe 1 reached temperature fault with stimulate control turned on in any mode	Unable to deliver stimulation Probe 1 has been disconnected or may have a fault. Turn off stimulation control, check probe and restart procedure	3-146
Probe 2 reached temperature fault with stimulate control turned on in any mode	Unable to deliver stimulation Probe 2 has been disconnected or may have a fault. Turn off stimulation control, check probe and restart procedure	3-147
Probe 3 reached temperature fault with stimulate control turned on in any mode	Unable to deliver stimulation Probe 3 has been disconnected or may have a fault. Turn off stimulation control, check probe and restart procedure	3-148
Probe 1 reached temperature fault with RF control turned on in any mode	Unable to deliver RF Power Probe 1 has been disconnected or may have a fault. Turn off RF power, check probe and restart procedure	3-149
Probe 2 reached temperature fault with RF control turned on in any mode	Unable to deliver RF Power Probe 3 has been disconnected or may have a fault. Turn off RF power, check probe and restart procedure	3-150
Probe 3 reached temperature fault with RF control turned on in any mode	Unable to deliver RF Power Probe 3 has been disconnected or may have a fault. Turn off RF power, check probe and restart procedure	3-151

Level 4 - Critical fault

Message Scenario	Message Text	Message code
	An unrecognised error has occurred	#900000
	Fuse error - A fuse has failed	#100001
	Impedance error. Impedance measurement is out of tolerance.	#100002
	RF check failed	#100003
	File access error. Internal data storage has been corrupted.	#200001
	RF amplifier fault detected during sensory stimulation	#300001
	Fuse failure during sensory stimulation	#300004
	Sensory stimulation output detected with stimulate board switched off	#300005
	Invalid parameters passed to sensory stimulation	#300006
	Invalid state reached during sensory stimulation	#300007
	Sensory stimulation unrecognised error	#300008
	RF amplifier fault detected during motor stimulation	#400001
	Fuse failure during motor stimulation	#400004
	Motor stimulation output detected with stimulate board switched off	#400005
	Invalid parameters passed to motor stimulation	#400006
	Invalid state reached during motor stimulation	#400007
	Motor stimulation unrecognised error	#400008
	Invalid parameters passed to lesion	#500001
	Invalid substate entered	#500002
	RF amplifier fault detected during lesion	#500003
	Fuse failed during lesion state	#500006
	Lesion unrecognised error	#500007

	Lesion automatic interlock failed to trigger, hardware set safe	#500008
	Invalid parameters passed to pulsed RF state	#600001
	Invalid substate entered	#600002
	Invalid parameters passed to Pulsed dose state	#700001
	Invalid substate entered	#700002

9 STERILISATION PROCEDURES

Needles and disposable probes are supplied sterilised, double wrapped and for single patient use.

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

If re-usable electrodes, Test Leads and Stimulation Test Block are used they must be sterilised by autoclaving to the instructions provided by the manufacturer.

9.1 Cleaning Procedure for the Neurotherm NT1000

Wipe with a soapy 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 a wipe of soapy water.

Cleaning frequency will be determined by hospital procedures- these are normally ‘clean if contaminated’ or at 6 monthly intervals.

10 PRINCIPLES OF LESIONING, TYPICAL LESION SIZES AND BASIC PROCEDURES

10.1 Principles of Lesioning

10.1.1 The basic physical principles of radiofrequency ablation

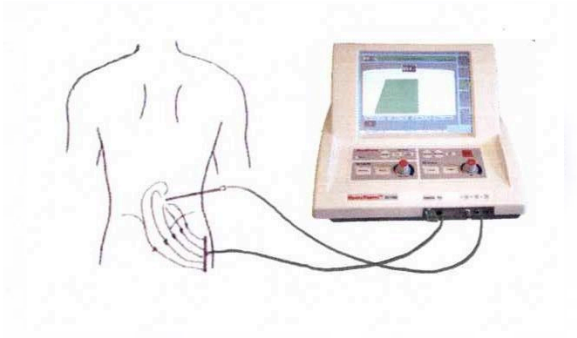


Figure 10.1 shows the fundamental radiofrequency circuit. The RF lesion generator or power source provides a source of RF. It is connected by wires to 2 electrodes: one inserted into the body, referred to as the active electrode; another in contact with the surface of the body, referred to as the dispersive electrode. This is the so-called monopolar configuration. The RF voltage causes current to flow through the wires, through the electrodes, and to the patients body. The patient's body is a conductive electrolytic media, and thus the patient's body becomes part of the RF circuit. This current spreads out from the electrodes and flows through the electrolytic tissue medium of the body. The active and dispersive electrodes have a similar physical role in delivering and receiving the current, but functionally, because of their differing areas, they have very different effects with regard to the RF heating process.

The active electrode with its smaller surface area has much higher field densities in the tissue adjacent to it. This higher field density causes significant heating near the active electrode surface. The dispersive electrode has a much larger area, and, as a consequence, the field density is much lower in the tissue adjacent to it. This results in a lower radiofrequency heating effect, and thus if the dispersive electrode is large enough no appreciable heating will occur near it. In fact, a large area surface plate to join to the skin with a conductive gel for good conductivity will not heat appreciably even though this same radiofrequency current will cause intense heating near the much smaller active electrode. It is recommended for most radiofrequency procedures that the dispersive electrode, therefore, should have an area of greater than 150 square centimeters to be safe from any significant heat elevation when RF lesions delivering 50 watts or less are used.

The mechanism for radiofrequency heating is shown in figure 10.2. The electric field lines emanate from the active electrode tip and are created by the voltage impressed upon it by the radiofrequency generator. This electric field creates an electric force on the charged ions within the electrolytic medium of the tissue. According to the physics laws this force produces a motion, and the motion is oscillatory at the frequency of the RF current. It is this radiofrequency motion which causes

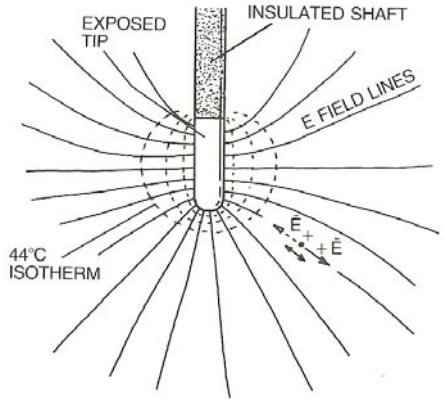


Figure 10.2

the ions to rub against the surrounding fluid medium, causing friction which results in the tissue heating. The temperature at any point is controlled by the frictionally induced power dissipation at that point, mediated by thermal diffusion and thermal convection. The thermal diffusion and convection are typically caused by blood circulation.

The temperature distribution around the electrode tip can be calculated by making certain simplifying assumptions. One of the assumptions is that the medium is homogeneous and that the factors of thermal diffusion and circulation are also uniform. Under these circumstances one can calculate the isotherms (surfaces of constant temperature) surrounding the electrode tip for a given impressed radiofrequency voltage. These isothermal surfaces are critical to determining the lesion size. As it is known that living tissue will be permanently destroyed for sustained temperatures of approximately 45 C, the 45 degree isotherm can be considered to be the outer border of the lesion since tissue within this volume will be thermally destroyed and tissue outside of this volume will experience lower temperatures than are necessary for cellular destruction. Isothermal surfaces are indicated by the -- lines in **figure 10.2**.

It is important to understand that the radiofrequency field, and thus power dissipation in the tissue actually heats the tissue as opposed to the electrode itself. The heated tissue in turn raises the temperature of the electrode tip and thus heats the tip. Therefore, it is not to the electrode tip which heats the tissue, but rather the tissue which heats the electrode tip. If the electrode is properly designed so as not to sink away too much of the thermal energy, the electrode will give an accurate representation of the tissue temperature at it's surface. It is for this reason that thermal monitoring of the radiofrequency tip is a good indication of the hottest portion of the lesion volumes, namely the isotherm that lies closest to the surface of the electrode. With the simplifying assumptions of a homogeneous medium, the lesion size represented by the 45 degree isotherm increases with increasing tip temperature and also increases with increasing tip dimension particularly the radius of the electrode tip.

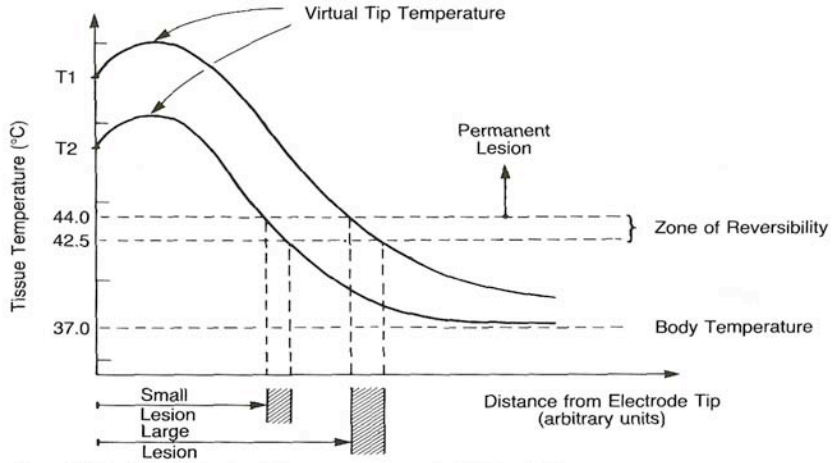


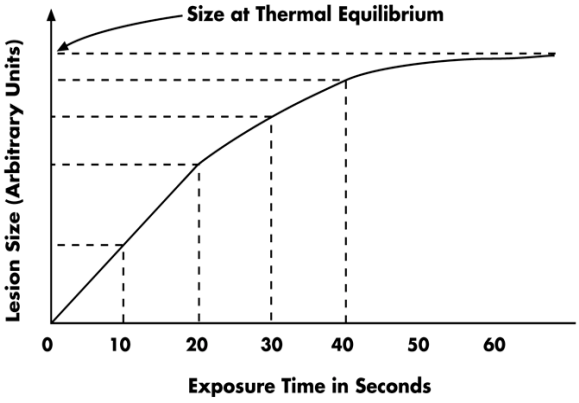
Figure 337-5 The distribution of tissue temperature as a function of distance away from the active electrode tip. The actual function depends on the shape of the tip and the point on the tip from which one takes the distance. (From Cosman and Cosman.[3])

Figure 10.3

Figure 10.3 shows a schematic diagram of the temperature of the tissue as a function of distance from the electrode tip. It should be noted that the temperature is not isotropic for a non-spherical electrode, and thus these curves may differ at different orientations on a non-spherical electrode tip. The temperature at the surface of the electrode, such as T2, measures very nearly the hottest tissue nearby, and the tissue at greater distances falls off until it asymptotically approaches body temperature at large distances from the electrode tip. By raising the radiofrequency voltage, one will increase the temperature to T1 near the electrode tip, and thus the distances to the 45 C isotherm will increase accordingly. With knowledge of these characteristics and the temperature vs.distance curve, one can therefore judged the size of the lesion volumes by choosing the appropriate tip temperature for a given tip geometry. This is the reason temperature measurement has been historically essential to produce consistent and quantified lesion volumes. (See section 10.2 for typical Lesion sizes).

Measurement of the tip temperature has another very important benefit. By avoiding tip temperatures near 100 C (the temperature at which water boils), one avoids the undesired effects of charring, sticking or the formation of a haemorrhage or explosive gas which may be also be accompanied by sparking. In the early days of neurosurgical lesions, before reliable tip temperature measurement was possible, neurosurgeons would establish the end point of their lesion making by listening for the “popping” lesion. The popping was caused by the tip temperature exceeding 100 C and the subsequent gas formation at the tip to the electrode. This obviously was not a controlled lesion technique and led to unpredictable and dangerous destructive conditions.

In pain management there are now well-established prescriptions for appropriate electrode size and tip temperature to achieve desired lesion volumes. It has been historically clear that prescriptions which involve power and current did not have lasting value, but rather prescriptions that involve temperature, electrode size and accounting for the heat washout caused by blood flow. The importance of temperature control was not always recognized. For instance, in the early days of percutaneous cervical cordotomy, elaborate prescriptions of current, power and time for making RF lesions were established. The subsequent clinical results were not consistent in the early days of cordotomies, and it was only when temperature was measured at the tip of the cordotomy electrode that consistency and reproducibility was finally achieved.



Another important aspect of controlled radiofrequency lesion making is illustrated in **Figure 10.4**. This shows experimental data of the increase in lesion size for a fixed electrode geometry and a fixed tip temperature. The lesion size in this situation is defined as the width of the prolate ellipsoidal width of the prolate ellipsoidal lesion volume. The graph clearly shows that for constant tip temperature the lesion size grows and asymptotically reaches a maximum value in a time between 30 and 60 seconds. The 45C isothermal surface can then be referred to as the equilibrium.

Lesion size. Leaving the radiofrequency power turned on indefinitely beyond 60 seconds will not increase the equilibrium lesion size. In the past, so-called time-dependent lesions were made in which a certain power was held by the radiofrequency generator for 10-20 seconds.. This too led to inconsistent results, and resulted in the acknowledgment of the equilibrium lesion size as being the optimum methodology.

It is noteworthy that impedance monitoring has a great value in assessing the progress of a heat lesion. The impedance seen by the electrode tip depends on tissue interfaces and this property has been used very effectively to distinguish between the interface of electrolytic fluids and tissue. For example this has been used with percutaneous cordotomy electrodes to clearly tell when the electrode has traversed from the cerebral spinal fluid to a position of contact with the spinal cord. Impedance monitoring has also been used to identify when an advancing electrode has progressed from the annulus of the disk into the nucleus pulposus. The change of impedance during the heating process is dramatic. It is been shown as the tissue or medium heats up, the impedance will drop. This is very much related to the phenomena that the engine oil in an automobile will become less viscous as the temperature of the engine increases. There is a point, however, as the temperature at the lesion tip approaches 100 C, when the impedance will cease to decrease and, in fact, will rise precipitously as the temperature approaches the boiling point. The reason for this is that the protein coagulation has a rapid onset in this temperature range causing a decrease in Ionic mobility. Near the boiling point, gas suddenly forms around the electrode tip, acting as an electrically insulating barrier thus sending the impedance to very high levels. At the onset of boiling, the impedance rises very rapidly. In summary, it is clear that the monitoring of temperature and impedance are both of great significance.

10.1.2 Pulsed radiofrequency

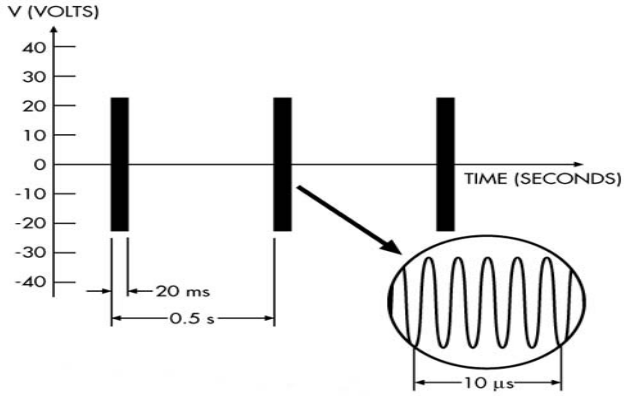
Historically, radiofrequency was neuroablation. This was true for percutaneous cordotomy, the treatment of trigeminal neuralgia, and the destruction of the medial branch nerve for facet pain. Mysteries remained however. It was not understood why RF lesions were so often followed by long periods of discomfort before any beneficial clinical effect appeared. In the 1990s, additional unanswered questions were added. The mode of action of RF lesions of the lumbar sympathetic change (other than for vascular disease) was not understood since there were acceptable success rates, though the results did not correlate with the degree of sympathetic block.

This led to the hypothesis by Sluijter that heat might not be the element causing the clinical effect of an RF lesion. The next obvious steps were to define a method to apply radiofrequency at high intensity without allowing the tip temperature to rise to neurodestructive levels. The method that was chosen by Sluijter was placing the output setting of the RF generator in the same range as was customary for making heat lesions but interrupting the output, thus allowing for sufficient time for the generated heat to be washed away by thermoconductivity and circulation.

2 4 6 8 10 12 Frequency Hz

This method has been commonly referred to as pulsed radiofrequency (PRF). Pulsed radiofrequency is a relatively new technique that applies short pulses of radiofrequency (20 ms) at a high voltage of 45 to 60 volts to neural tissue. **Figure 10.5** shows the currently accepted paradigm of 20 milliseconds of RF followed by 480 milliseconds of off time. In this way high intensity radiofrequency is delivered but with a short enough on time so as not to cause heating above 42 C.

Figure 10.6



It is a natural reaction to think of pulsed radiofrequency as being analogous to the neural modulation effects achieved using spinal cord stimulators or TENS units. However, these two modalities are very different. In neural modulation the therapeutic effect is achieved by applying low frequency (< 1000 Hz) rectangular pulses.

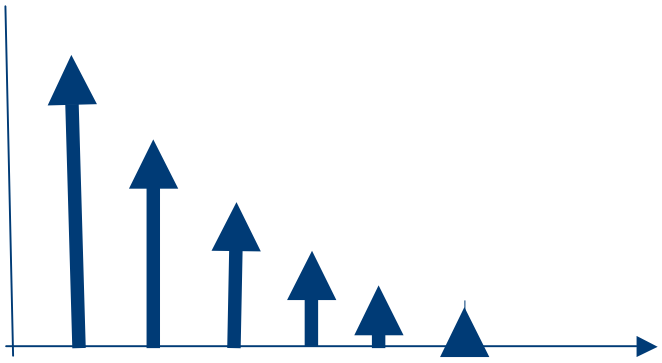


Figure 10.6 shows the frequency spectrum of a two Hz rectangular pulse. As can be seen from the figure, the major frequency component is at two Hz and falls off as the frequency increases. At frequencies above 1000 Hz, the amplitude of the frequency component is getting very small. There is a very different situation with pulsed radiofrequency. In this case, the rectangular pulses have radiofrequency inside of them. This changes the frequency spectrum entirely. As can be seen from **figure 10.7**, the major frequency component is now 500 kHz and decreases at higher and lower frequencies. At frequencies below 1000 Hz, the contribution can be shown to be negligible .

In conclusion, the frequency spectrums of pulsed radiofrequency are entirely different than the frequency spectrums of low frequency stimulators.

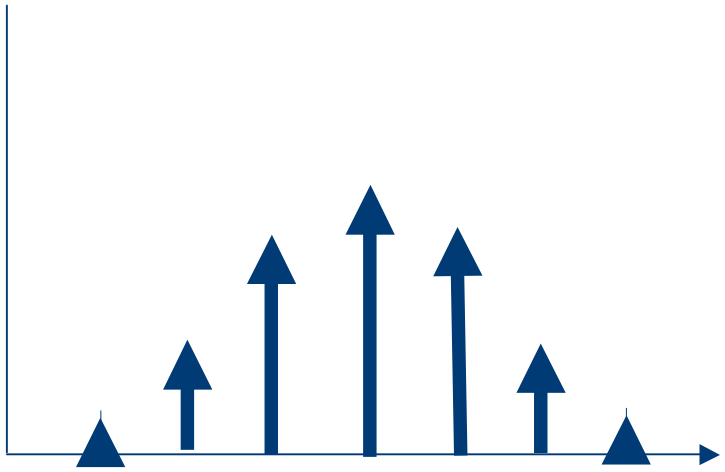


Figure 10.7

There is very little conclusive research to date on the mode of action of PRF. A few preliminary studies have shown that a modification of CFOS and DNA expression has been observed in cells of rat DRG after exposure to PRF. However, additional basic research needs to be done to come to any good scientific conclusion as to the mechanism of action of PRF. References for the available research today are contained at the end of this chapter.

In this era of evidence based medicine, pulsed radiofrequency has not yet been validated. Several retrospective studies and audits have been conducted and the initial results are positive. Because of a lack of uniform treatment guidelines, the anecdotal results for pulsed have ranged from magnificent to abysmal. It is this author's belief that standardization of many of the PRF parameters will at worst result in uniform treatment for all patients and at best significantly improve the clinical outcomes. In any case, controlled clinical studies are long overdue for this potentially promising modality.

When the study of PRF began, the parameters were arbitrary. For the voltage, a value is taken that was within the range of the voltage during the initial heating phase of an RF heat lesion. The values of 20 milliseconds on time and 480 milliseconds off time were chosen because they were thought to provide good conditions for preventing heating above 42 degrees Centigrade. The initial choice of 120 second duration of the procedure was completely arbitrary, and it was just taken as a starting point. With no scientific basis, these parameters have been arbitrarily modified by clinicians and thus there is no consensus as to what the optimum parameters are.

One of the major variables in pulsed radiofrequency treatment is the voltage level when the pulses are “on”. This arises from the desire to keep the temperature below 42 degrees C. if 42 degrees C. is reached, it is necessary to either manually or automatically reduce the pulsed amplitude or the pulsed duration in order to ensure the temperature does not exceed 42 degrees. Using the pulsed dose method, every pulsed is insured to be of the same amplitude and duration. It is explained in detail in the following paragraph

10.1.3 The Pulse Dose Concept.

Whenever Pulsed RF is used, if your selected temperature limit is reached, the pulse must be modified in some way to prevent the selected temperature limit from being exceeded.

1. Modify the pulse **amplitude** of the pulses- i.e. if a 45 volt amplitude was set, and if the temperature limit was set to 42 degrees and was reached, the next pulses will be reduced to prevent the temperature from increasing above the 42 C temperature limit.

2. Modify the pulse **width** whenever the temperature limit was reached, thus insuring that each pulse delivered was the full set voltage amplitude.

In **Pulse dose** one and two above is no longer done. You **ALWAYS** give a **FULL** pulse, i.e. if your settings is 45 volts amplitude for 20 milliseconds, you will always deliver this pulse amplitude and duration. If the set temperature limit is reached, the generator will wait until the temperature drops below the set temperature limit, and then again will give a **FULL** amplitude and duration pulse.

Because you are delivering only full pulses, in this mode you set the number of pulses that is desired for the procedure as opposed to procedure time, since procedure time can vary depending on whether the set temperature limit was reached.

The following diagrams depict the different modes-

Figure 10.8 shows Historical Pulsed RF-amplitude control-

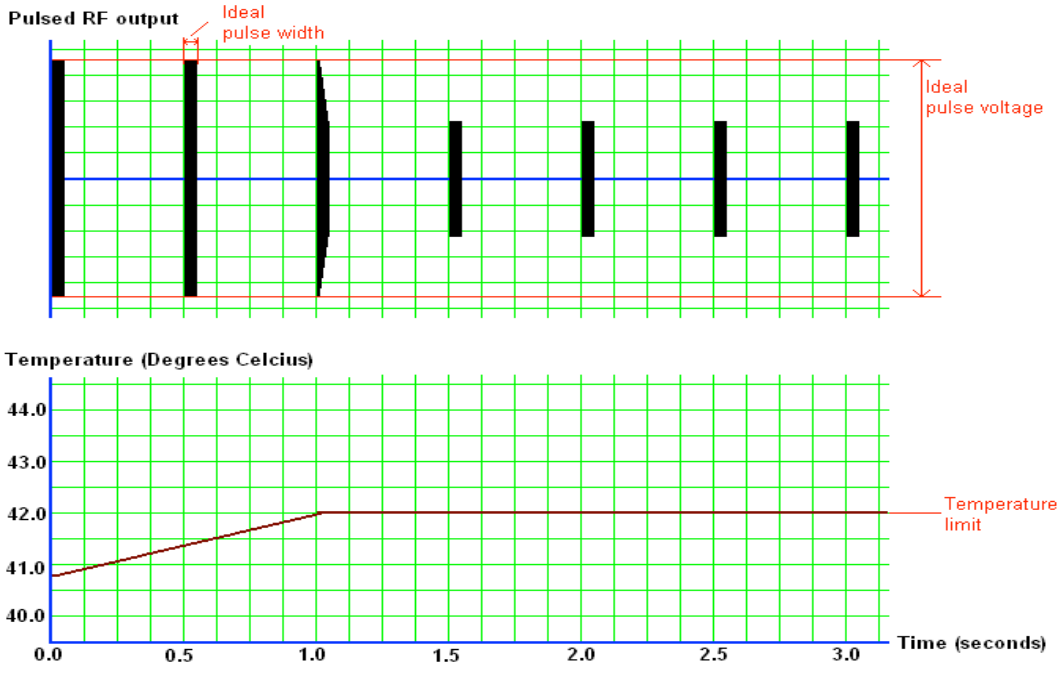


Figure 10.8

The beginning pulses are the desired pulses of 45 volts amplitude and 20 ms duration. Note that the moment the set temperature limit is reached the voltage is changed (reduced) in order to keep the temperature below this limit. (Note that this implies that every patient gets an unpredictable and variable pulse amplitude which is undesirable)

Figure 10.9 shows Historical Pulsed RF- pulse width control

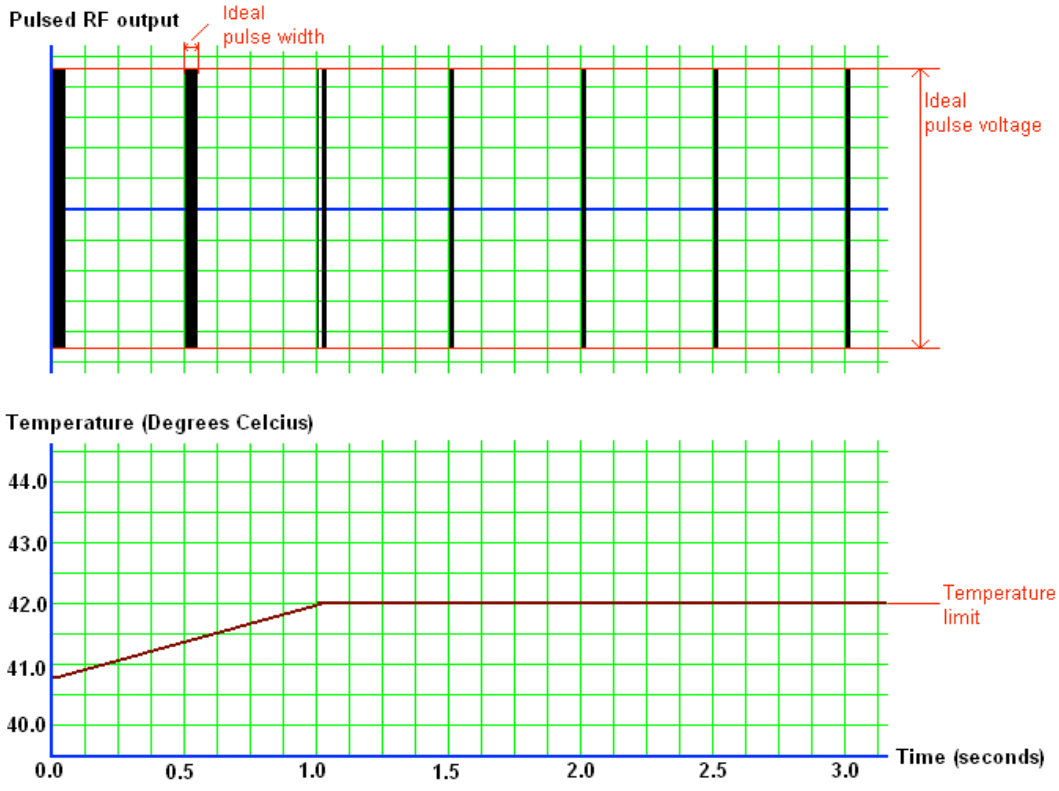


Figure 10.9

When the temperature limit is reached the pulse width is changed as opposed to the pulse amplitude. Note that the pulse width is changed the moment the temperature limit is reached, the width is varied to keep the temperature below the temperature limit. Though this is better than amplitude control, it still implies that treatments will not be consistent and uniform between patients.

Figure 10.10 Pulse Dose- a new more consistent approach

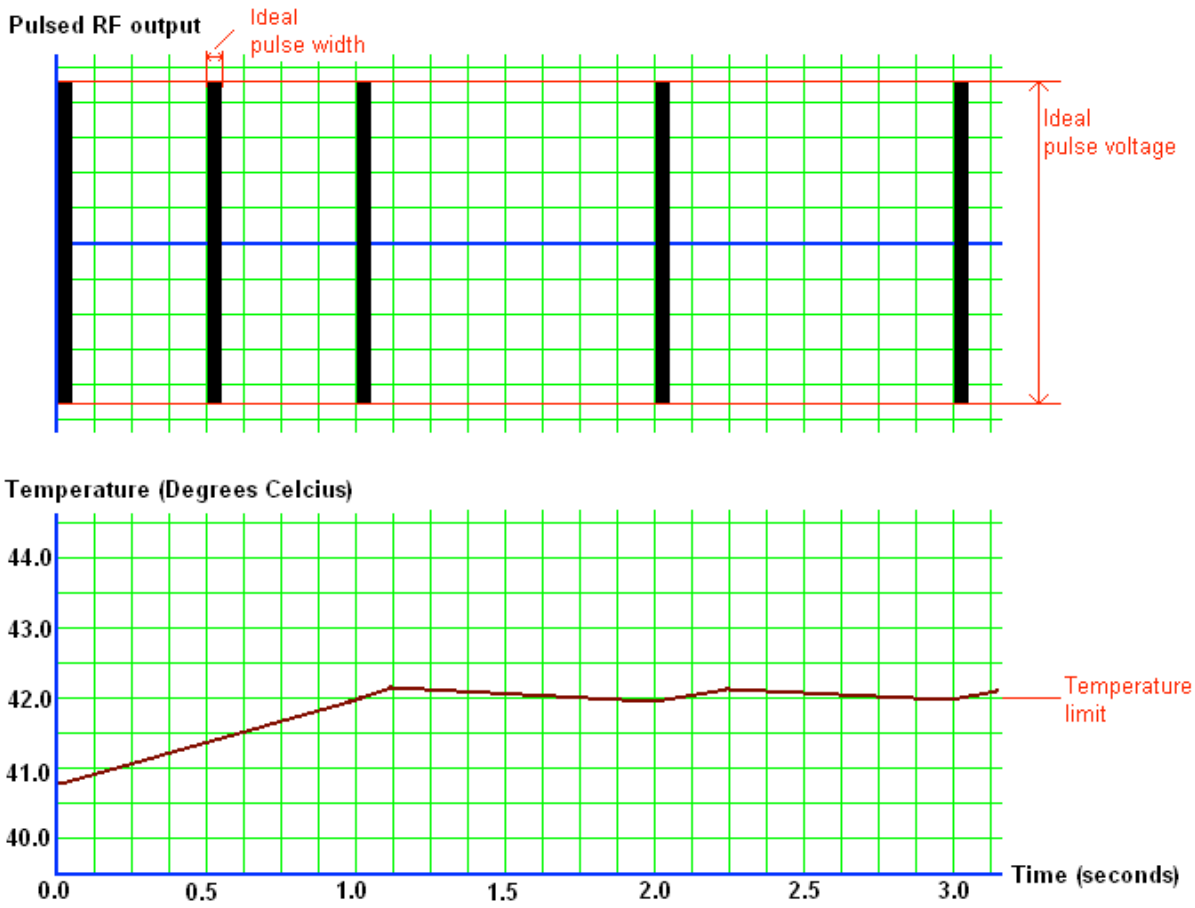


Figure 10.10

In the pulse dose mode, only amplitudes that are the full set voltages and widths that are the full set pulse width are delivered. If the temperature limit is reached, generator stops giving output until the temperature falls below the temperature limit. This guarantees that every treatment delivers the full set amplitude and pulse width. The number of pulses or “doses” are set by the operator as opposed to time, thus ensuring that every treatment is consistent patient to patient.

Here is why pulsed dose is superior to the other methods. Imagine doing medial branch heat lesions and every patient is treated at a different temperature, i.e. one at 80 º C, one at 70 º C, another at 60 º C. Would you be surprised if this resulted in variable patient outcomes? Pulsed dose standardizes pulsed RF, just as always using the same temperature standardizes heat RF.

10.2 Typical heat lesion sizes

Typical lesion sizes are categorized below in figures 10.11, 10.12, and 10.13, for different tip temperatures, tip exposures and needle gauges. Though lesion size can vary considerably depending on tissue electrical and thermal conductivity, presence of heat sinking by blood, and thermal insulation such as the presence of bone, some qualitative observations can be made. It is clear that the lesion shape is that of prolate spheroid where the major axis is always along the needle shaft, and whose length is virtually the length of the tip exposure. Note that the lesion extends very little beyond the electrode tip thus indicating that a tangential approach to the target is warranted. The minor axis becomes larger with increasing temperatures and electrode diameters. Typical sizes for common needles and temperatures are given below. It is worth noting that these sizes represent equilibrium volumes (greater than 60 second treatment). After this time the lesion volume ceases to increase.

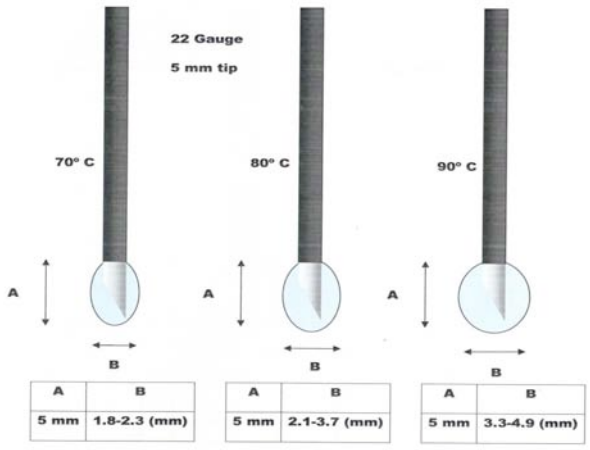


Figure 10.11

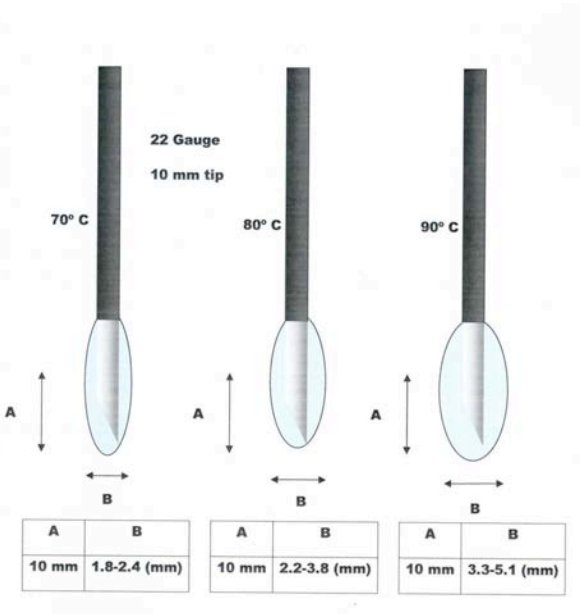


Figure 10.12

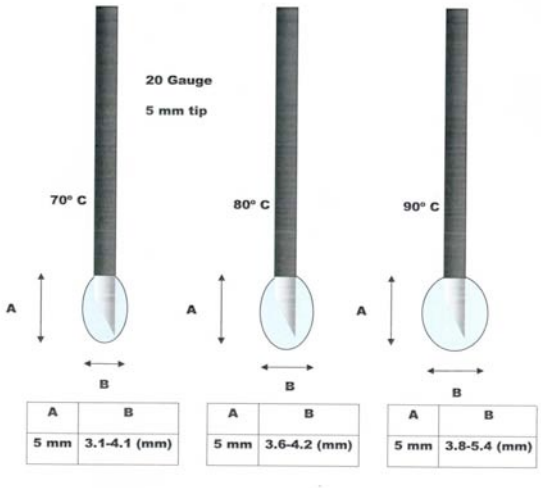


Figure 10.13

10.3 Basic Procedures for Stimulation and Lesion

10.3.1 Auto Test Procedure – Basic Check

1) The Mains Power switch is OFF (Located at the rear of the generator)
2) Connect the Mains Power Lead to the machine
3) Switch the mains power ON (The Mains light will illuminate Green)
4) The Unit will display (The Neurotherm Logo while Loading)
5) The Unit will carry out an auto test (If all procedure functions are operating the display will change to the Welcome Screen)
6) From the Welcome Screen the user can continue to use the system using the default settings or optimising the settings to their requirements.
7) For a standard default procedure the electrode would be a single electrode in socket 1.
8) To use the basic default settings follow the “Seven Steps Procedure”

10.3.2 Seven Steps Stimulation and Lesion Procedure

Step 1 Switch on power to the NT1000 (wait for self test)

Step 2 “Accept” Default Profile (ensure the settings are correct for the procedure)

Step 3 “Accept” procedure settings

The control of the procedure is now transferred to the active panel with the touch screen being disabled.

Step 4 Perform “Sensory” stimulation

Step 5 Select “Motor” Stimulation and perform Stimulation

Step 6 Select “Lesion” and press “Auto-Start”

Step 7 After completion of lesion, select “End Session”

The Procedure is now completed and a record has been saved

11 MAINTENANCE

Each time the Neurotherm NT1000 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 Neurotherm is automatically disabled from use.

In the event of a Self Test Failure or any other malfunctioning you should immediately call your local distributor.

Maintenance should only be carried out by authorised personnel. A periodic full service on an annual basis is recommended.

Main Distributor

Neurotherm Ltd
429 Brighton Road
Croydon
Surrey CR2 6EU
U.K.

Tel: 0208-660-4374 International: +44 208 660 4374
Fax: 0208-660-9417 International Fax: +44 208 660 9417
Email: admin@rdgmedical.com

12 EC DECLARATION OF CONFORMITY

Morgan
The Intelligent Application of Technology

E.C DECLARATION OF CONFORMITY

Morgan Automation Limited declares that the apparatus known as

Neurotherm Model NT 1000 Series

is a Class IIB Machine according to Directive 93/42/EEC, Annex IX, Rule 9
and is in conformity with the following Standards and Requirements

BS EN 60601-1-2:2002
UL60601-1:2003
CAN/CSA C22.2 No.601.1-M90(R1997)
CAN/CSA C22.2 No.601.1S1-94
CAN/CSA C22.2 No.601.1B-98 (National Differences for Canada)
IEC60601-2-2:1998
IEC60601-2-10:1988
Directive 93/42/EEC as amended and transposed into the national legislation of member states.

Signed ..... Date 20 -10 -2005

Name : H M Clarke (Technical Director)

Document 107-00 Issue 02

Morgan Automation Ltd
Rake Heath House London Road Hillbrow Liss Hampshire GU33 7NT
Telephone: +44 (0) 1730 895900 Facsimile: +44 (0) 1730 895922
E-mail: info@morgan-automation.com
Registered in England & Wales No. 2174066. Registered Office: as above
VAT Reg. No. 474 3267 34

Morgan Automation Ltd
A11806 ISO 13485