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1 GENERAL INTRODUCTION WITH WARNINGS AND CAUTIONS

The NT-500 has been designed to offer the full range of features required to perform Radiofrequency denervation.

The front panel has been ergonomically designed and allows the clinician direct manipulation of the controls. Each functional effect of the device is defined within its own discrete area.

It is designed for safe use in a doctor's office, surgery centre or hospital environment.

Linear Bar Displays are used to facilitate immediate visual interpretation of temperature, RF current and RF voltage, and digital displays are used for impedance, stimulate voltage and lesion time.

The NT-500 has full electronic interlocking to prevent accidental switching to lesion power and 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 with NT-500 Thermocouple Probes only. The use of probes from other manufacturers could give serious errors in the temperature reading and may compromise the safety of the patient, and would negate the warranty.

Regularly inspect the accessories of the NT-500, in particular electrode cables should be checked for possible damage to the insulation.

The accessories are not appropriate for endoscopic use.

Warnings

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

Ensure you read this Operators Manual before operating the NT-500.

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 adapters 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.

The power cord should always be unplugged before cleaning or service.

The operator should not perform any servicing of the equipment. Any servicing should only be performed by qualified personnel.

EXPLOSION HAZARD: - This equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide.

EXPLOSION 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.

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

RISK OF RF BURNS TO PATIENT:- Ensure the 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, or between legs) – 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 NT-500 cannula. Monitoring devices which use needle electrodes are not recommended.

RISK OF RF BURNS TO PATIENT: - Position all cables to the NT-500 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 any 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 Treatment procedures the radiated electrical fields may interfere with other electrical medical equipment. (See Section 2.5 to Minimise Electromagnetic Interference)

USE OF FLUIDS: - Ensure that if fluids (saline etc.) are being used during a procedure they should be positioned away from the NT-500.

RISK OF RF BURNS TO PATIENT; - In 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 “NT-500 “probes.

Cautions

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

DO NOT Activate the output of the NT-500 until the probe is properly positioned in the patient.

DO NOT Remove the top cover of the NT-500, as it will expose voltage which can cause injury or death.

Servicing of the equipment in accordance with the appropriate service manual. This process 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 NT-500. Refer servicing to qualified personnel.

When cleaning the outer casing of front panel 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, turn the RF Power off.

2 TECHNICAL DATA

2.1 SPECIFICATION

SIZE

Width 12” (300mm)
Height 6 ½“ (160mm)
Depth 14½” (365mm)

WEIGHT

15.20 lbs (6.90kg)

ELECTRICAL

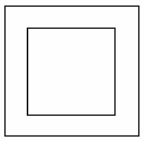
USA 110 volt 60Hz Fused 2 Ampere on live and neutral

UK 230 volt 50Hz Fused 1 Ampere on live and neutral

Rated Power Consumption 100 Watts

The power supply is built to Class II standard. The instrument is not connected to mains earth. (Class II BF).

TYPE BF EQUIPMENT



CLASS II EQUIPMENT

Medical Equipment — 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

CE 0473 — CE mark

Attention: Consult accompanying documents

STANDARDS This instrument complies with
EN 60601-1: 2003
IEC 60601-1-2: 2001
IEC 60601-2-2: 1998
IEC 60601-1-4:

IMPEDANCE

Measuring frequency	53 KHz approx
Digital Display	0-2000 Ohms (in 1 ohm steps)
Accuracy	± 5% ± 10 Ohms
Digital Display Reading	Digital display reads biological impedance

STIMULATION

Voltage Amplitude	Continuously variable between 0 - 3 volts ±10%. The voltage supplied is displayed on the Digital Meter in 0.01 Volt steps.
Accuracy	± 10 %
Pulse Rates	2 (Motor) (pulses per second) 50 or 100 (Sensory) (Default 110v units 50Hz and 100 Hz for 230 V units)
Pulse Rate Accuracy	± 5 %
Pulse Width	1mSec ± 10 %
Waveform	Biphasic pulses. Negative pulse leading
Lamp Indicator	Green LED flashes at pulse rate according to the switch which has been selected (Motor or Sens) Indicator only lights when output is present.
Safety Interlock	When stimulate Mode is selected Stimulation Voltage cannot be delivered unless the Stimulate Output Voltage Control is first set to the “Off” position (fully anticlockwise). A buzzer will sound if this is attempted.

RF LESION POWER

RF frequency	480 KHz (±10%) sine wave

Power Output	Continuously variable. Maximum power output 25 Watts into 200 Ohms.
Voltage Indication	Bar Graph 0 -80 Volts RF
Current Indication	Bar Graph 0-800mA RF
Lamp Indicator	Amber Lesion Power LED Flashes when Lesion Power is being delivered
Audible Tone	When Lesion is complete an audible tone will sound until the RF Output control is turned off (fully anticlockwise)

Pulsed / Pulse Dose **(Optional When ordering unit)**
RF bursts of 20mS at a frequency of 2.0 Hz

Pulse Temp limit	42º C **(option of no limit when ordering)**
Pulse Dose Limit	42º C

Pulsed RF Option **(optional when ordering unit)**

If the unit has the option to perform a procedure using **Pulsed RF** the concept is the same as conventional RF lesions, except that the Physician selects the pulsed option by pressing the "**Pulsed"** button.

In Pulsed RF Mode the unit will deliver a Burst of RF 20mS long at a frequency of 2 pulses per second. The default temperature limit is set to 42ºC **(or no limit as ordered with unit)**

And the default time is set to 120 seconds. The physician can select other time options from the "**Time** / **Count"** button these are 120, 240, 30, 60, and 90 seconds

The sensory and motor stimulation should be carried out to ensure the correct placement of the electrodes. When the physician is satisfied that the electrode is in the correct position. Select the RF Output button and rotate the Control anticlockwise until the RF Voltage indicator reads 45 volts

It should be noted that this is not performing a Thermal Lesion in pulsed RF Mode, and it is quite normal for the Temperature to not reach the 42ºC setting. The perfect treatment delivers 45 volt pulses for the full duration of the treatment. If the 42ºC limit is reached the NT-500 will reduce the width of the RF Burst until the temperature is below 42ºC. Below 42ºC the pulse will return to 20 mS full width pulses.

Pulse Dose Option **(optional when ordering unit)**

Pulse Dose delivers a pre determined number of full 20mS bursts of RF. Set the RF output to 45 volts on the RF Voltage indicator.
If the unit temperature reaches 42ºC then the counter will stop and no further Pulses will be delivered, until the temperature falls below 42ºC at this point the count will continue until the counter reaches the set limit. As only full pulses are being delivered the physician can set the number of pulses from 240 (Default) 360, 480, or 120. This removes the variables of other Pulse applications and ensures repeatable results.

To Use Pulse Dose (optional when ordering unit)

Set up the NT-500 to enable the electrode to be placed as for a conventional lesion. Carry out the sensory and motor stimulation tests until the Physician is satisfied with the placement of the electrode. Make an X-Ray record for the patient file and prepare the patient for the procedure.
Press the Pulsed button and if required change the number of pulses by pressing the Time/Count button.
The count will cycle through the option of count numbers release the button when the count number is reached. Select RF Output and rotate the RF Output control anticlockwise until the RF volt indicator reads 45 volts and press the Start button. The counter will count down to zero, if the temperature goes above 42ºC, the count will stop until the temperature is below 42ºC. The count will resume at this point until the process is complete.
At the end of the procedure the power will be switched off and a tone will sound. To stop the tone set the RF Output to the off position

LESION TIMER

Time Start	The timer will start after the Timer start button is pressed, At the end of the procedure an alarm tone will sound and RF power is removed from the output. The timer resets to the default setting. The Alarm tone can be stopped by turning the RF output Control off. (Fully anticlockwise)
Time Indicator	Clock indicates the amount of time remaining for lesioning.
Lesion Time	Defalt is 60 Seconds
Timer/Count	Time set button cycles 30, 60, 90, 120 and 240 seconds **(Pulsed RF Version)** default 120 Seconds
Count Pulse Dose	Count set cycles 120, 240, 360, and 480 counts **(Pulse dose Version)** default 240 Seconds
Audible Indicator	A one second “tick” indicates the clock is operating.

TEMPERATURE MONITOR

Meter Range	30ºC to 100º C Bar Display The Bar Display has 3 colour segments 30ºC - 42ºC Amber 42ºC - 95ºC Green 95ºC - 100ºC Red
Temperature set Modes	The lesion Temperature can be selected from the front panel buttons 70, 80, and 90ºC (Default setting 80ºC)
Probes	Use only NT-500 probes - no individual adjustment necessary.
Thermocouple Indicator	LED shows Green when probe is connectedor Red when disconnected or faulty.

SAFETY FEATURES

Safety Cut Out Power	RF Power is automatically reduced if temperature reaches set limit as determined by Maximum Temperature Control, (either 70ºC, 80ºC or 90ºC). RF will automatically proceed again once the temperature of the tip of the probe drops1ºC.
Safety Interlock	a) RF Power cannot be delivered unless the RF Power Control is first set to the OFF position, this prevents any accidental application of the RF power. If the lesion power is selected and power control is on, a warning tone is given out and no RF Power is provided to the probe. b) The Lesion Power will also be cut off if any of the conditions listed below occur. a) Measured temperature goes above 95ºC b) RF Power Oscillator detects a short circuit or low patient impedance.

2.2 EARTH LEAKAGE DATA

Tests carried out as per IEC 601-1

		Typical	Max Allowable
1	**Enclosure leakage current**		
	Normal	40 microamps	100 microamps
	Reverse	40 microamps	40 microamps
	Single Fault condition		
	Normal	40 microamps	500 microamps
	Reverse	40 microamps	500 microamps
2	**Patient Leakage Current**		
	Normal (AC)	4 microamps	100 microamps
	Reverse (AC)	4 microamps	100 microamps
	Single Fault condition		
	Normal (AC)	4 microamps	500 microamps
	Reverse (AC)	4 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**		
	Normal (AC)	4 microamps	100 microamps
	Reverse (AC)	4 microamps	100 microamps
	Single Fault condition		
	Normal (AC)	4 microamps	500 microamps
	Reverse (AC)	4 microamps	500 microamps
5	**Patient Auxiliary Leakage**		
	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	25 microamps	5000 microamps
	Reverse	25 microamps	5000 microamps
	Single Fault condition		
	Normal	25 microamps	5000 microamps
	Reverse	25 microamps	5000 microamps

2.3 ENVIRONMENTAL CONDITIONS

Transport

Temperature	-10ºC to 70ºC	
Humidity	0 to 95% RH Non condensing	
Pressure	140-760mmHg	(0 to 12,200 metres) (0 to 40,000 ft)

Storage

Temperature	10ºC to + 60ºC	
Humidity	10 to 80% RH	
Pressure	520-760mmHg	(0 - 3000 metres) (0 -10,000 ft)

Operating

Temperature	10ºC to 40ºC
Humidity	10 to 80% RH

2.4 ACCESSORIES SUPPLIED

1	Mains Lead
1	Dispersive Plate Lead
8	Fuses
1	Operators Manual
1	Basic Operating Procedures.

A range of Temperature Monitoring Probes, Cannula and Dispersive Plates are available from Neurotherm Inc – address given in section 7.

Note

When ordering the NT-500 the customer should specify the options required for the unit, These are:-

1) Pulsed RF With fixed 42ºC limit

2) Pulsed RF With no temperature limit

Or the option of Pulse Dose

3) Pulse Dose

2.5 MINIMISING ELECTROMAGNETIC INTERFERENCE

Although the NT-500 meets the EMC requirement for a device of this type, it is good practice to follow certain guidelines to minimise the risk of interference between the NT-500 and other devices.

1 Do not twist the cables from the NT-500 with those of other devices.

2 Unless absolutely necessary, avoid putting the NT-500 on top of other operating equipment or other operating equipment on top of the NT-500.

3 The NT-500 generates 480 KHz at up to 25 watts during the RF Lesion Treatment phase. If any interference occurs to other equipment, it will be most noticeable under this condition.

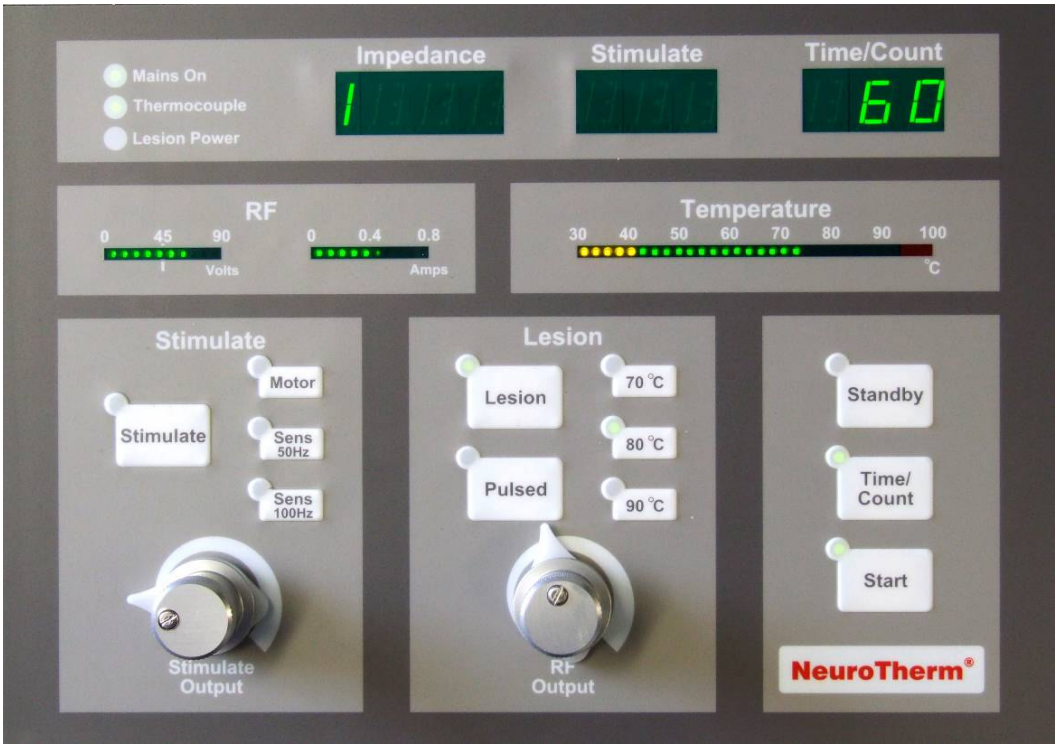
To check this, connect a NT-500 Test Box, (set at 200 ohms) into the machine, turn to full power and observe any reading changes or interference on other equipment.

To minimise any interference, position the machine as far apart as the source and the device being interfered with.

3 DESCRIPTION OF CONTROLS

3.1 OPERATING PANEL LAYOUT

The front panel of the NT-500 machine is segmented into four main panels.

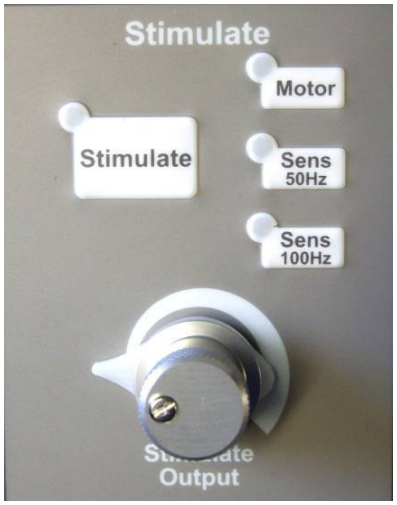


1. Standby Mode
2. Stimulate Mode
3. Lesion Mode
4. Displays

3.1.1 STANDBY MODE

STANDBY	On switching on the NT-500 the machine goes into 'STANDBY' MODE and the LED on STANDBY Button is lit. In this mode the machine can read the Impedance of the patient.
TIME/COUNT	The time/count button is used to set the the time for the Lesion or Pulsed RF. For a Pulse Dose unit unit the time/count button, sets the Count number of full RF pulse bursts
START	The 'TIMER START' Button is only active when the NT-500 is switched to 'LESION MODE' and is used to start the timer.

3.1.2 STIMULATE MODE



STIMULATE — The 'STIMULATE' Button is used to select the STIMULATE Mode. When this mode is active the LED on the button is lit.

SENS 50Hz — When the Stimulate Mode is selected, the SENS mode is also selected- this mode gives a stimulation frequency of 50 pulses/second When this mode is active the LED on the button is lit.

SENS 100Hz — To select 100Hz press 100 Hz button When this mode is active the LED on the button is lit.

MOTOR — When the NT-500 is in Stimulate Mode the Motor Mode can be selected and gives a stimulation frequency of 2 pulses/second.

STIMULATE OUTPUT CONTROL

The Stimulate Output controls can be used to adjust the Stimulation Output. Up to 3.0 volts can be applied. The voltage supplied is displayed on the Stimulate Display.If when the Stimulate Function is selected and Stimulate Output Control is not in its OFF position no Stimulate voltage will be supplied to the probe. The Stimulate Output Control needs to be turned to OFF position before power can be applied.

When a Stimulate Rate has been selected the LED will flash at appropriate rate in the selected button.

3.1.3 LESION MODE

Lesion	The 'LESION' Button is used to select the LESION Mode. When this mode is active the LED on the button is lit.
70ºC	When the NT-500 is in lesion mode the 70ºC can be selected This mode will limit the temperature at which treatment is given to 70ºC.
80ºC	When the Lesion Mode is selected the 80ºC Mode is also selected – this mode will limit the temperature at which treatment is given to 80 ºC.
90ºC	When the NT-500 is in Lesion Mode the 90ºC Mode can be selected- this mode will limit the temperature at which treatment is given to 90ºC.
Pulsed	Selects Pulsed RF or Pulse Dose depending on the units Specified Mode of operation (See ordering options)
RF Output Control	The RF Output Control controls the supply of radio frequency power to the lesioning probe. The power is variable from 0 - 25 watts. The RF Output Control must initially be in the OFF position (fully anticlockwise) otherwise no lesion power can be delivered and an alarm will sound. When power is being delivered, the Lesion Power Amber LED will flash and the RF Current and Voltage meters will indicate the amount of RF Current and Voltage being delivered.

When carrying out a Treatment, the RF Output Control is slowly turned up, and the power delivered will produce a temperature rise at the treatment site – this will be seen on the temperature display.Once the site temperature is near the selected treatment temperature (70ºC, 80ºC or 90ºC) as selected by the buttons, the Timer Start button is pressed and the timer counts down to zero at which point the RF Power is removed and an alarm sounds.The RF Output Control needs to be turned off (fully anticlockwise) to silence the alarm.

NOTE: - WHEN CARRYING OUT A TREATMENT THE 70ºC, 80ºC AND 90ºC TEMPERATURE LIMITS ARE SAFETY LIMITS AND SHOULD NOT BE USED TO CONTROL THE TEMPERATURE OF THE LESION EXCEPT WHEN BEING CONTINUOUSLY OBSERVED BY THE OPERATOR.

3.1.4 DISPLAYS

The Displays occupy the top section of the Front Panel and comprise.

RF Voltage and Current Displays

These 10 segment bar meters show the amount of electrical voltage and current being delivered to the lesion site. (These displays are only active on the Lesion Mode)

Temperature Display	This 30 segment bar meter shows the Temperature at the Lesion site. It is a three colour display. 30º C - 42ºC Amber 42º C - 95º C Green 95º C - 100º C Red (This Display is only active in the Lesion Mode)
Impedance Display	This 3½ digit display shows the impedance measurement between the tip of the probe and the dispersive plate. The readout is in ohms. It should be noted that this measurement is of biological impedance. (This Display is only active in the Standby Mode)
Stimulate Display	This 3 digit display shows the Stimulate Output Voltages in a range of 0- 3.0 volts. (This display is only active in the Stimulate Mode)
Time/Count	Displays the time set for the Lesion or Pulsed RF For a Pulse Dose unit the number of pulse counts will be displayed.

Mains on LED	This Green LED is illuminated if all the power supplies in the NT-500 are correct. If this LED fails to light check the internal fuses by removing the rear panel and checking the LEDs on the Fuse Board.
Thermocouple LED	This LED shows the status of the Probe. If it shows: Green – the thermocouple is connected and operational. Red – the thermocouple is either disconnected or faulty.
Lesion Power LED	This Amber LED will flash when RF Power is being delivered to the patient.

3.2 FRONT PANEL LAYOUT

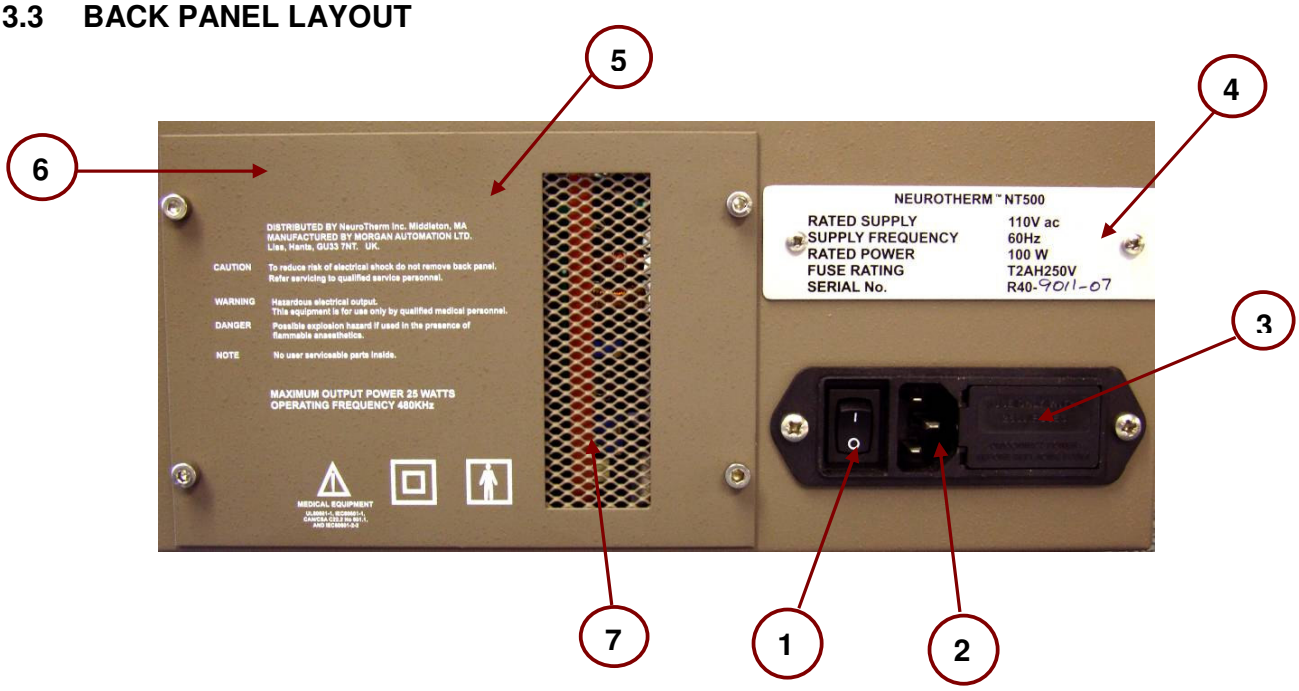
1. LEFT HAND 4MM SOCKET

This socket is for the lead of the Dispersive Patient Plate, which should be of at least 200 square centimetres (21 square inches).

2. RIGHT HAND 4 WAY PROBE CONNECTOR

This socket is for the connection of the probe to the NT-500 and for carrying the thermocouple signal.

3.3 BACK PANEL LAYOUT



1. Mains ON/OFF SWITCH
This is a rocker type switch combined with an IEC Connector Socket with twin in-line anti - surge fuses in a single unit to BS4265.

2. MAINS IEC CONNECTOR
The three pin plug of the mains lead must be pushed into this socket. This cannot be done incorrectly with the live and neutral reversed because of the orientation of the unused earth pin.

3. FUSES
The NT-500 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 mains ON/OFF Switch. The fuses are 20 mm Anti Surge to BS4265 2 amp rating. (110 volt) or 1Amp 230 v machines.

4. SERIAL PLATE
This plate shows the Serial Number of the Machine together with its Supply Voltage and Rated Power.

5. CONTACT ADDRESS
If the NT-500 requires a routine service or in the unlikely event of the machine malfunctioning, the contact address is shown on the rear of the machine and the telephone, fax and email information is given in Section 7 of this manual.

6. REAR PLATE

This plate which is secured by 4 bolts gives access to some of the circuit boards of the NT-500. This includes the Fuseboard which contains the fuses of the internal supplies.

This unit has no user serviceable parts
And should only be serviced by qualified personell
Contact NeuroTherm for service support

7. VENTILATION APERTURE

This is to ensure air circulation within the NT-500 and correct cooling of the RF Power Amplifier and should not be blocked.

4 CHECK AND TEST PROCEDURES

These should be carried out before each session

CHECK

1 The Mains Switch is OFF	This switch is located at the rear of the NT-500
2 A Dispersive Lead, Dispersive Pad and Probe are available for treatment.	Make sure the accessories are all available for the treatment session.

TEST

3 Connect the Mains Power lead to the NT-500	
4 Turn Mains Switch ON	The Mains Green LED on the front Panel will light up. (If the Mains Green LED fails to light check the fuses- fuses are located in the Mains Inlet Module and behind the rear panel of the machine on the Fuse Board). The Standby LED will be lit and the impedance Display will indicate.
5 Connect the Probe to the right hand Front Panel Socket	The Thermocouple LED will change from Red to Green showing the Probe is connected and operating.
6 Press the Lesion Button on the Front Panel	The Lesion Button LED will light together with 80ºC Button LED and the Time Start LED. The temperature display will be active and will show if temperature is above 30ºC.
7 Turn the RF Power Control clockwise	The Time Display should display 60 seconds. The RF Voltage Display shows Voltage being present (if the display fails to show check the 75V Fuse on the Fuse Board.) The Amber Lesion Power LED will flash.

8 Press the Timer Start Button	The Time Start LED should flash, the machine will count down in 1 second increments from 60 seconds shown in Timer Display . When the timer reaches 0 the Voltage Display should turn off and an alarm will sound.
9 Turn the RF Power Control fully counter - clockwise	The alarm will cease.
10 Check the Stimulate Mode by pressing the Stimulate Button	The Stimulate and Sensory Button LEDs will light and the Stimulate Display should indicate Voltage.
11 Turn the Stimulate Control Clockwise	The Stimulate Voltage should display up to 3.0 volts and Sensory Button LED should flash at 50Hz.or 100Hz (When Motor is selected the flash rate is 2Hz)
12 Turn the Stimulate Control Fully Anticlockwise	The Stimulate Display should read 0.0 volts and any flashing should cease.
13 Press the Standby Button	Testing of the NT-500 is now complete and machine is ready for use.

5 STERILISATION PROCEDURES

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

The probes, leads and plugs must be sterilised by autoclaving before re-use.
Use Sterilization procedure as recomended on the Electrode documentation supplied by the manufacturer.

Cleaning Procedure for the NT-500
Wipe with a weak bleach solution or isopropyl alcohol.
The cleaning frequency will be determined by local or hospital procedures – these are normally 'clean if contaminated' or at 6 monthly intervals.

6 LESION PROCEDURES

Apply a suitable dispersive electrode to the patient and connect this to the left hand socket on the NT-500.

The left hand 4mm protected socket is located on the very front of the NT-500. Ensure that a dispersive electrode of the right surface area (not less than 16 sq inches) is correctly applied to the chosen site. Check that the clip on the lead that connects the dispersive plate to the NT-500 does not come into contact with the patient.

Turn the Mains Switch **ON** and leave for two minutes to stabilise.

THE PROCEDURE CAN NOW BE STARTED. FROM NOW ON YOU ARE IN STERILE MODE

Plug the sterile Thermocouple lead into the Lemo socket on the front panel.

The Thermocouple LED should change from RED to GREEN.

When the needle position is satisfactory, switch the NT-500 to Standby Mode, insert the probe into the needle and measure the impedance.

A reading of 200 to 1000 ohms is correct. If the reading is greater than 1500 ohms check the probe, lead and dispersive plate connections. If the reading is 100 ohms change the probe.

Pulsed RF	
When the needle position is satisfactory switch the NT-500 to Standby Mode, insert the probe into the needle and measure the impedance	Select Pulsed RF button (This will activate pulsed RF if this has been specified)
The default time will be 120 seconds	To change the time, select the required time from the Time/Count button
Rotate the RF Output control anticlockwise until the correct voltage 45 V is reached on the Voltage display. (Other Voltages can be used if the unit has the no limit Specified).	Press the start button to start the timer counting down
When the counter reaches Zero the pulsed RF will switch off and a tone will sound.	To stop the tone turn the RF Output control to the off position

Pulse Dose	

When the needle position is satisfactory switch the NT-500 to Standby Mode, insert the probe into the needle and measure the impedance	Select Pulsed RF button (This will activate pulse dose if this has been specified)
The Default count is 240 bursts of RF	To change the count number, select the count required from the Time/count button
Rotate the RF Output control anticlockwise until the correct voltage 45 V is reached on the Voltage display	Press the start button to start the counting down (note that if the temperature reaches 42ºC the count will stop until the temperature is below 42ºC, then the count will Resume)
When the count reaches zero the RF will switch off and a tone will sound.	To stop the tone turn the RF Output control to the off position
Pulse Dose will deliver only full 45 volt bursts of RF at 2 pulses per second	The Physician the can be confident the dose applied to to the patient

STIMULATE

Set Stimulate Voltage to zero

Select Stimulate Mode

Select “Sens” Rate and then “Motor” Rate and note responses and differentials.

If the Physician is satisfied that the needle is in the correct position, and the patient responds satisfactory to the stimulation - inject local analgesic or administer light General Anaesthetic as appropriate. The patient is now ready for lesioning.

LESION

Select Lesion Mode	If the RF Output control has been accidently left on an alarm will sound and no power will be delivered. In this case the RF Output control must be turned anticlockwise to the Off position then the Lesioning procedure can recommence.
Select the Lesioning Temperature by selecting 70ºC, 80ºC or 90ºC.	
Turn the RF Output Control slowly clockwise.	The Lesion Power LED will flash.
When Lesion Temperature is reached press	The timer will start counting down from 60

the Timer Start button.

seconds until it reaches zero, at which point Lesion power will be switched off and the timer will reset to 60 seconds. An alarm will sound.

When the alarm sounds indicating the Lesion has been completed turn the RF Output Control fully anticlockwise to the off position.

This will silence the alarm.

If no further lesion power is required, select Standby Mode and then switch the NT-500 OFF.

7 MAINTENANCE

The CHECK AND TEST PROCEDURE described in Section 4 should be routinely performed each time the NT-500 is used. A periodic full service on an annual basis is recommended.

Maintenance should only be carried out by authorised personnel.

In the event of the NT-500 malfunctioning, you should immediately contact.

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8 UNPACKING AND ACCEPTANCE TESTING

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

Place the NT-500 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 should be observed when the NT-500 is switched on:

NT-500

Mains on Green LED will be lit
The Standby Switch LED will be lit
The Impedance meter will be reading the impedance seen by the probe.
The Thermocouple LED will be showing either Green – Probe Connected
or
Red - Probe faulty or not connected.

Electrical Safety Analyser

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 two plugs namely :-

1 Dispersive plug (4mm socket)
2 Active Plug 4 pin Lemo connector

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 bolts on the rear of the machine.

9 EC Declaration of Conformity

Morgan
The Intelligent Application of Technology

EC DECLARATION OF CONFORMITY

Morgan Automation Ltd. as the manufacturer of the apparatus known as :

NT500

are 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)
IEC 60601-2-2:1998

Directive 93/42/EEC as amended and transposed into the national legislation of member states.

Signed ..... Date 22-8-07

Name H.M. Clarke (Technical Director)

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