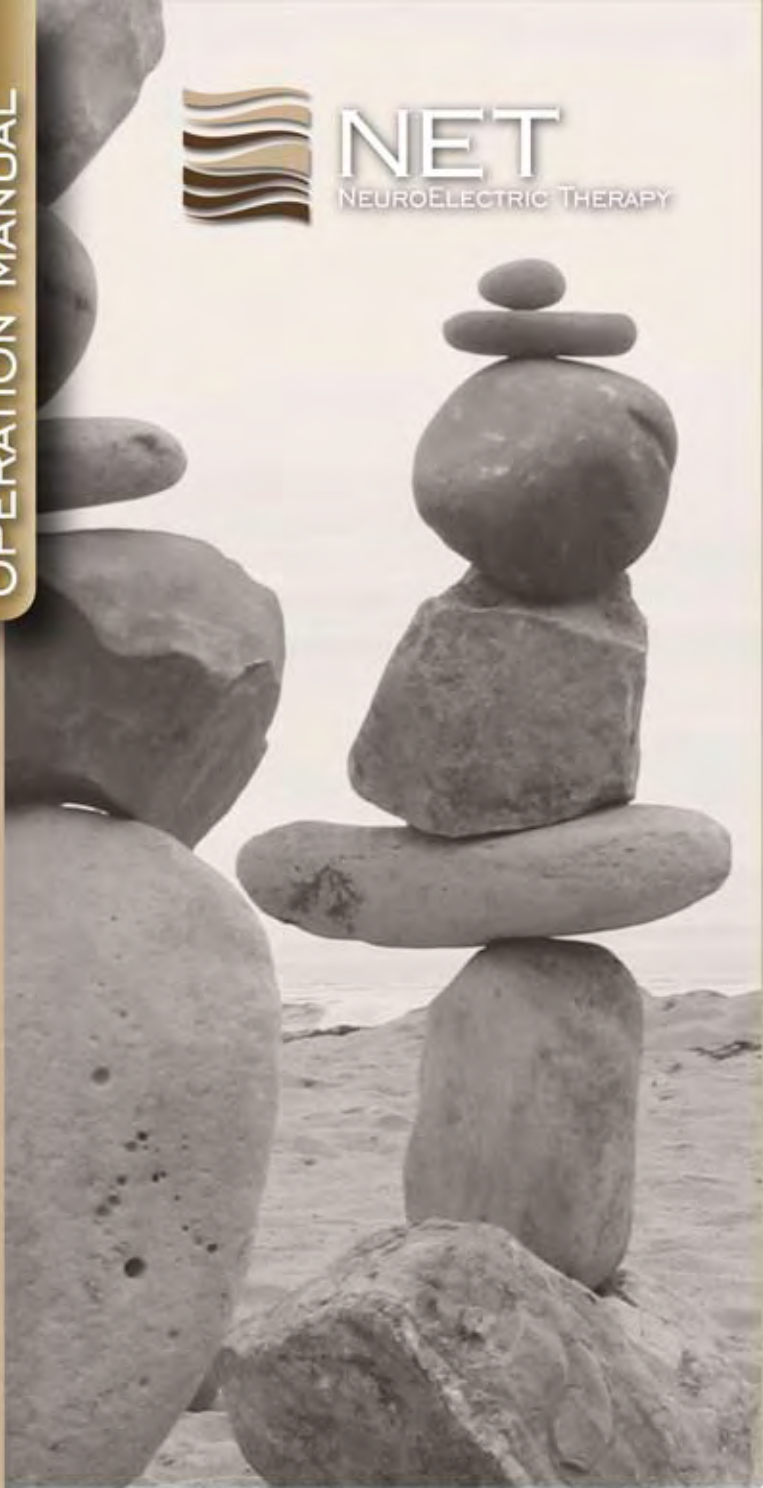


MODEL 901

OPERATION MANUAL



NET
NEUROELECTRIC THERAPY



OPERATION MANUAL

NET MODEL 901

EN.02.20.00 Release 002, February-04-2009

REFERENCE

Intended Purpose: Detoxification from and amelioration of the symptoms of acute and chronic withdrawal from licit and illicit addictive substances.

Device Name: NET Model 901

Device Part Number: REF 11000004

Manufacturer: NET Device Corp
100 Technology Way
Mt. Laurel, NJ 08054 USA
www.netdevice.net

European Authorized Representative: EC REP
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Priory View
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Type BF
Equipment



Consult
Operating
Instructions



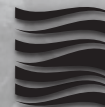
9V Battery
Powered



CE Marking

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NET DEVICE CORP
NEUROELECTRIC THERAPY

NET MODEL 901


DEL 901

WARNINGS

- *Always turn intensity off before changing battery.*
- *Do not place over carotid sinus (upper part of the neck), inside mouth, or across the heart area.*
- *Do not use with an implanted electronic device (for example, a cardiac pacemaker).*
- *Do not use in pregnancy, heart disease, or epilepsy.*
- *Keep out of the reach of children.*
- *Remove unit while bathing.*
- *Use under the supervision of a physician.*
- *Do not use with h.f. surgical equipment.*
- *Operation in close proximity (e.g. 1m) to shortwave or microwave therapy equipment may produce instability in the NET Model 901 output.*
- *Current density for any electrode exceeding 2mA r.m.s/cm² may require special attention by the user. If electrodes become partially detached, the current density may increase; reduce the intensity setting to relieve any discomfort, and refer to the NET Treatment Manual for proper re-application of the electrodes.*

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T*his Operation Manual describes the
NET Model 901 device and provides
instructions for its correct operation.*

*Please read the entire manual carefully
prior to use. Should any questions arise
during the course of treatment that
are not covered in this manual,
please contact your physician.*

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FEATURES

The NET Model 901 has the following features:

1. Intensity Control Knob
2. Electrode Leads Socket
3. "ON" Indicator
4. "BATTERY LOW" Indicator
5. 9 Volt Battery Compartment
6. Serial Number
7. USB Connector

Top



Front



Back



Bottom



3

LOADING A TREATMENT PROGRAM

The NET Model 901 is capable of delivering a number of different treatment programs. For the unit to function, a treatment program must be loaded using the NET Vue™ application running on a USB attached PC.

Refer to the NET Vue™ manual (accessible from within the NET Vue™ application) for instructions on loading a treatment into the NET Model 901.

To attach electrodes to the NET Model 901:

1. Always turn the Intensity Control Knob to the “OFF” position (fully counter-clockwise) before attaching or removing electrodes from your body.
2. Attach the electrodes and electrode leads to your body as described in the NET Treatment Manual.

Use 1cm x 2cm adhesive silver impregnated TENS-type electrodes with pigtails and 2mm diameter sockets, available from NET Device Corp at www.netdevice.com. Use part number 90980001 (pre-cut, 1cm x 2cm) or 90980000 (uncut, 2 inch diameter).

Use electrode leads part number 11210008.

3. Insert the electrode leads plug into the Electrode Leads Socket at the top of the unit.
4. Turn the NET Model 901 “ON” by rotating the Intensity Control Knob clockwise just until it clicks.
5. Wait for the treatment to begin (the “ON” indicator will blink continuously).
6. The intensity may now be increased by turning the Intensity Control Knob as described in the NET Treatment Manual.

ALWAYS TURN THE INTENSITY CONTROL KNOB TO THE "OFF" POSITION (FULLY COUNTER-CLOCKWISE) WHEN ATTACHING OR REMOVING ELECTRODES FROM YOUR BODY.

As long as the treatment program is running, the "ON" indicator will display a heartbeat. When the treatment program is completed, the "ON" LED will stop blinking and stay on.

At this time, you should...

1. Turn the Intensity Control Knob down counter-clock wise to its minimum setting until it clicks into the "OFF" position.
2. Disconnect the electrode leads from the unit.
3. Disconnect the electrodes from the body.





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INSTALLING THE BATTERY

The NET Model 901 will function with almost any standard size 9-volt battery. Alkaline batteries are recommended, as a single battery typically provides enough power to span a complete treatment. Rechargeable 9 volt batteries may also be used.

To install a battery:

1. Open the battery compartment at the back of the unit by pressing firmly with your thumb and pulling back on the cover door. Insert a 9V battery in the orientation indicated by the internal label and replace the cover.
2. When the battery is installed, the unit will perform a diagnostic self-test. Both LED indicators will flash briefly as part of this test.
3. If no treatment program is loaded when the battery is installed, the “ON” indicator will remain lit following the diagnostic self-test.
OR...
If a treatment program is in progress when the battery is installed or changed, the “ON” indicator will blink continuously and the treatment program will resume.
OR...
If the unit detects an error during its diagnostic self-test, the “ON” and “BATTERY LOW” indicators will flash in unison. Please refer to section 9, “Error Indications”.

When the NET Model 901 detects that the output of the 9-volt battery has dropped below a useful level, it will light the yellow “LOW BATTERY” indicator and shut itself down.

Please replace the battery as described in section 6, “Installing The Battery”. Following battery replacement, the treatment program will resume. Note that the unit’s internal clock stops when it is shut down

for low battery and when there is no battery installed. This means that if 1 hour passes before the battery is replaced, the unit’s internal clock will be 1 hour behind. If a significant time elapses without power and you wish to reset the clock, reload the treatment program as discussed in section 3, “Loading A Treatment Program”.



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SPECIFICATIONS

The NET Model 901 is powered by a single 9-volt battery and outputs a series of low-current bi-phasic electrical waveforms having a frequency varying between 4Hz and 3000Hz and a pulse width varying between 7 microseconds and 1024 microseconds.

The output has no net DC component.

The maximum amount of current delivered is 3.2 mAmps (peak) into a 15K load (and up to 44 volts peak-to-peak). This is enough current to provide effective treatment but not enough to cause any harm.

Power:	DC 9V
Operating Temperature:	-10°C to +50°C (+14°F to +122°F)
Operating Relative Humidity:	10% to 95% RH non-condensing
Operating Atmospheric Pressure Range:	50hPa to 1060hPa
Storage Temperature:	-10°C to +50°C (+14°F to +122°F)
Storage Relative Humidity:	10% to 95% RH non-condensing
Storage Atmospheric Pressure Range:	50hPa to 1060hPa

Table 1: Error Indications

Green “ON” Indicator	Yellow “LOW BATTERY” Indicator	Error	Action Required
	ON	Low battery	Replace Battery
FLASHING	FLASHING	* Device failure	Return unit to seller

* When a treatment is running the green “ON” indicator will blink, and the Yellow “LOW BATTERY” indicator will be either on or off, depending on the battery charge. This is normal and does not indicate an error. In the event of a device failure the “ON” and “LOW BATTERY” indicators with both flash in unison.



- Medical electrical equipment needs special precautions regarding EMC (electromagnetic compatibility). The NET Model 901 needs to be installed and put into service according to the EMC information provided in this section.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- The NET Model 901 complies with the EMC requirements indicated in this section when used with the NET Lead Wires (NET Device Corp Part Number 11210008). The use of other cables (excluding cables sold by NET Device Corp as replacement parts) may result in increased emissions or decreased immunity of the NET Model 901.
- The NET Model 901 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the NET Model 901 should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration – electromagnetic emissions

The NET Model 901 is intended for use in the electromagnetic environment specified below. The customer or the user of the NET Model 901 should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The NET Model 901 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The NET Model 901 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity


The NET Model 901 is intended for use in the electromagnetic environment specified below. The customer or the user of the NET Model 901 should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable	
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not Applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Not Applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not Applicable	

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The NET Model 901 is intended for use in the electromagnetic environment specified below. The customer or the user of the NET Model 901 should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	<p>Portable and mobile RF communications equipment should be used no closer to any part of the NET Model 901, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>Not applicable</p>
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	<p>$d = 0.35 \sqrt{P}$ (80 MHz to 800 MHz)</p> <p>$d = 0.70 \sqrt{P}$ (800 MHz to 2.5 GHz)</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NET Model 901 is used exceeds the applicable RF compliance level above, the NET Model 901 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the NET Model 901.

Recommended separation distances between portable and mobile RF communications equipment and the NET Model 901

The NET Model 901 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NET Model 901 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NET Model 901 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz Not Applicable	80 MHz to 800 MHz $d=0.35 \sqrt{P}$	800 MHz to 2.5 GHz $d=0.70 \sqrt{P}$
0.01	Not Applicable	0.035	0.070
0.1	Not Applicable	0.11	0.22
1	Not Applicable	0.35	0.70
10	Not Applicable	1.1	2.2
100	Not Applicable	3.5	7.0

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

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

Classification according to clause 5 of IEC 60601-1

The NET Model 901 is classified as follows:

1. Type of protection against electric shock: Internally powered equipment.
2. Degree of protection against electric shock: Type BF Equipment.



3. Degree of protection against harmful ingress of water:
Ordinary equipment. (enclosed equipment without protection against ingress of water) IPX0.
4. **Not** suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide (Not AP or APG).
5. Mode of operation: Continuous operation.

1. No regularly scheduled periodic maintenance or inspection is required.
2. The NET Model 901 may be cleaned with a clean, dry cloth as needed.
3. The battery should be removed when the unit is not in use.
4. Do not dispose of the NET Model 901 or its electrode lead wires in general purpose waste collection facilities. Inform yourself about the local separate collection system for electrical and electronic products. Dispose of the complete product (including lead wires) in the designated WEEE (Waste Electrical and Electronic Equipment directive) collection facilities.
5. Electrodes may be disposed of in general purpose waste collection facilities.
6. The Net Model 901 may be disinfected by wiping with a clean cloth to which disinfectant has been applied. The cloth should be moistened (not dripping). Moisture should not be allowed to drip onto, drip into, or collect upon the NET Model 901.



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NeuroElectric Therapy

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