NerveSpa

User’s manual

I- NSP-EN Rev10.0 0826

IMPORTANT INFORMATION

FOREWORD

Read this manual carefully before using the device. The manufacturer strongly recommends carefully reading the “Warnings and Cautions”, and subsequent chapters of this manual.

WARNINGS AND CAUTIONS

Contraindications:

1. Do not use the device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
2. Do not use the device on patients whose pain syndromes are undiagnosed.

WARNINGS

1. Do not apply stimulation over the patient’s neck because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure;
2. Do not apply stimulation across the patient’s chest, because the introduction of electrical current into the chest may cause rhythm disturbances to the patient’s heart, which could be dangerous;
3. Do not apply stimulation directly on the eyes, covering

the mouth, on the front of the neck (especially the carotid sinus), or from electrodes placed on the upper back or crossing over the heart;

4. Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins);
5. Do not apply stimulation over, or in proximity to, cancerous lesions;
6. Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use;
7. Do not apply stimulation when the patient is in the bath or shower;
8. Do not apply stimulation while the patient is sleeping;
9. Do not apply stimulation while the patient is driving, operating machinery, or during any activity in which electrical stimulation can put the patient at risk of injury.
10. Apply stimulation only to normal, intact, clean, healthy skin.
11. Do not use the device on children, if it has not been evaluated for pediatric use.
12. No modification of this equipment is allowed.
13. Do not put the lead wire on or wrapped around the neck.
14. Do not inhale or swallow small parts.
15. Replacement by inadequately trained personnel could result in a hazard.

16. Parts of the ME equipment that are not serviced or maintained while in use with the patient.

PRECAUTIONS

1. Not effective for pain of central origin, including headache or stomach ache;
2. Not a substitute for other pain management therapies;
3. NOT is a symptomatic treatment and, as such, suppresses the sensation of pain that could otherwise serve as a protective mechanism;
4. Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients;
5. Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head;
6. The safety of electrical stimulation during pregnancy has not been established;
7. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrically conductive medium;
8. Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians;
9. Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.
10. Use caution when the patient has a tendency to bleed internally, such as following an injury or fracture;

11. Use caution following recent surgical procedures when stimulation may disrupt the patient's healing process;
12. Use caution if stimulation is applied over areas of skin that lack normal sensation.
13. Keep The device out of the reach of children, pets and pests;
14. Use the device only with the leads, electrodes, and accessories recommended by the manufacturer; and
15. Use the device only under the continued supervision of a licensed practitioner.
16. Interconnection of the device to other equipment not described in the instructions for use could be unsafe.
17. Potential hazard from simultaneous connection of a patient to a high frequency surgical ME equipment and the device that may result in burns and possible damage to the device.
18. Operation in close proximity (e.g., 1 m) to a shortwave or microwave therapy equipment may produce instability in the stimulator output.

ADVERSE REACTIONS

- Patients may experience skin irritation and burns beneath the stimulation applied to the skin;
- Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face;

· Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device or redness on the skin that doesn't go away after treatment.

GENERAL WARNINGS

1. Do not immerse the device in water.
2. Do not place the device close to excessive heat.
3. Use only the specified battery: 3.7V, 900mAH polymer battery (Model: 703048). Using of any other battery could damage the unit.
4. Use the device only with accessories recommended by the manufacturer. Use other parts materials supplied by other manufacturer can degrade minimum safety.
5. If you notice any adverse reactions or burning feeling, discontinue use immediately.
6. Do not use the device while asleep.
7. Please note that stimulus delivered by the device may be sufficient to cause electrocution if used improperly.
8. Keep the device away from sources of high magnetic fields such as TV'S, microwave ovens and hi-fi speakers, as these may affect the LCD screen.
9. Keep the device away from a fireplace or radiant heater, as the heat may affect the device.
10. Keep the device away from nebulizer or steam kettle, as the moisture may affect the device.
11. Keep the device away from sunlight, as long-term exposure to sunlight may affect the rubber become

less elastic and cracked.

12. Keep the device away from lint and dust, as long-term exposure to lint or dust may affect the plug/ sockets or connector become bad contact.
13. Environmental Condition:

    Operation temperature and humidity requirements:

    Temperature range: +5℃ to + 40℃

    Humidity: 15%to 90% RH non-condensing

    Atmospheric pressure: 700hPa to 1060hPa

    Storage and transportation temperature and humidity requirements:

    Temperature range: -25℃ to + 60℃

    Humidity: 15% to 90% RH non-condensing

    Atmospheric pressure: 700hPa to 1060hPa

CONTENTS

INTENDED USE

This is a portable device and also a pain-relieving stimulator.

The device is designed to provide symptomatic pain relief for chronic, acute or post operative pain of the hands or feet through aquatic submersion that cover the hands or feet with circumferential electrotherapy stimulation.

HOW DOES THE DEVICE WORK

The device works by stimulating your body's own natural defenses against pain and peripheral Neuropathy.

The device produces a gentle stimulus that helps the body to produce natural pain relievers called endorphins. Some people feel immediate benefit; however, some may only achieve benefit after repeated treatment sessions and over an extended period of time.

When you first try electrotherapy keep it to short term treatment sessions, and check your skin periodically. Since you may have circulatory conditions or other compromising ailments, it is best to be conservative in your treatment sessions and watchful of any adverse reactions or additional pains...

CONTENT IN THE PACK

The device pack should contain the following:

- 1 × Device
- 1 × Lead wire
- 1 × Pair of carbon rubber electrode pads (2 X 2 inch)
- 1 × Charging Adapter
- 1 × Charging cord
- 1 × Foot bath
- 1 × Epsom salt
- 1 × Instruction Booklet (which you are reading)

Additional Items

- Effervescent tablet tubes

Having checked all the contents are correct please proceed to assemble the unit.

HOW TO ASSEMBLE YOUR UNIT

Assembly of the device is very simple and requires only five steps.

STEP 1 BATTERY

Charge the battery by plugging the charging cord into the device.

STEP 2 LEADS

Insert the lead wire plugs into the bottom of the device

– this is a single channel device.

NOTE: This system includes custom lead wires. When you need to replace your lead wires, only use manufacturer lead wires.

STEP 3 PADS

Connect the pin side of the lead wire to the 2” rd carbon rubber electrodes (the black pin into one, and the red pin into the other)

STEP 4 FOOT BATH

Fill the foot bath with warm water. Add a tablespoon of salt to each bay of the foot bath to increase conductivity. Next, drop one of the 2” rd carbon rubber electrodes into the left bay and the other into the right bay of the foot bath. They do not need to touch the feet but can. Just make sure they are submerged in the water.

STEP 5 READING

Read the section on “Operation of the device”, and decide how you want to set your settings before you use the unit for the treatment.

When setting the technical specifications of the device, adjust the intensity only to the level of minimum sensation. The condition of skin and cutaneous nerve endings can be delicate, especially in seniors or those with compromising health conditions.

NOTE: AFTER USE

Always ensure that the unit is switched OFF before removing the pads.

CHARGING THE BATTERY

The device is powered by a built in rechargeable polymer battery. Separate power adaptor and Charging cable are included in the kit.

When the battery is running low, the battery symbol on the top right of the screen is empty and keep flashing. It is time to charge the battery. Connect the charging cable to the adaptor and the device to start charging.

When charging is in progress, the battery indicator bar cycles from zero to the max. When the battery charging has completed, the bar stops cycling and remains at maximum to indicate full capacity. Remove the charging cable and adapter from the device when charging is completed.

Although the display fades as the battery run down, the strength of the output does not change until the warning is shown.

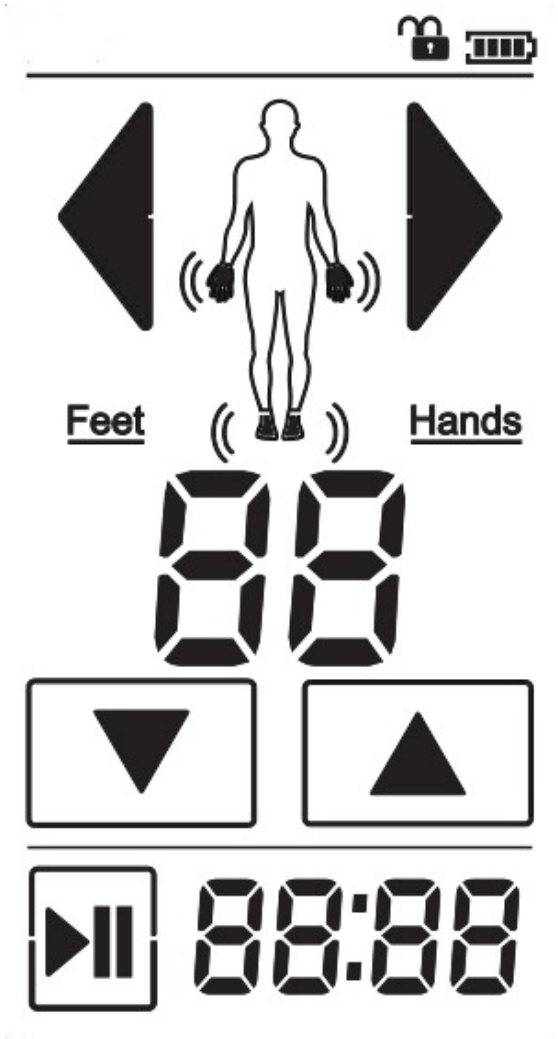
NOTE

1. When the battery is running low, it has to be charged with the power adaptor.
2. Use only the provided power supply adapter that certified to IEC 60601-1 and IEC 60601-1-11.
3. Only factory provided cords are approved for use.

USE OF OTHER ACCESSORIES OR OTHTER TYPE OF CHARGER COULD BE HAZARDOUS

OPERATION OF THE DEVICE

The device is easy to operate by touching the screen as following diagram.



WHAT DOES EACH KEY DO

The ON/OFF key - It allows switching the unit ON and OFF. Press and hold this key for **3 seconds**, the LCD display will light up. There will be no feeling from either leads at this point as the intensity always start at zero. Press and hold this key for **3 seconds** again and the unit will switch OFF.

 Press these keys to adjust the intensity of channel. When the intensity is over zero, the corresponding LED light located at the bottom of the device will light up. Pressing the up intensity key  will start the program.

 Press this key to pause the unit. When the unit is paused, the intensity level goes down to zero, and the pause key symbol will change to be  . To continue it, press this key again, once the unit is released from paused, it starts from the point where it was paused, and the pause key symbol will return to be  . If the paused time is over 5 minutes, the unit will be shut off automatically.

 Press this key to lock the unit. When the unit is locked, the lock symbol will change to be  . To unlock the unit, press the lock key again or press this key  . The lock symbol will return to be  when the unit is unlocked.

 Press these keys to select the body parts (hands or feet). When the touch screen is unlocked, select the hands or feet alternately with each press. A human body icon on LCD displays corresponding parts selected.

SPECIFICATION

Model: NS Advanced Neuropathy Stimulator
Channel: Single
Output: Maximum 65V (peak value)
across 500 Ohm load
Power density: <0.25W/cm2
Waveform: Symetrical Biphasic Rectangular
Monophasic Spike
Treatment Timer: 30mins
Mode: 2 modes
There are 2 programs that cycle as follows:

1-11min is program A
12-16 min is program B
17-30 min is program A

The unit will automatically shut off when complete.

Program A	
Pulse Width	0.5ms
Frequency	7.83Hz
Waveform	Monophasic Spike

Program B	
Pulse Width	5ms
Frequency	7.83Hz
Waveform	Symetrical Biphasic Rectangular

OTHER FEATURES

1. When the unit intensity level is Zero (0), and it has not been in use for 5 minutes, the unit will be shut off automatically.
2. To show the accumulated time: press “min” and “ON/OFF” for 3 seconds at the same time when starting up, LCD displays cumulative use time. To return to the main screen, repeat the same operation again.
3. To clear the cumulative use time: when the unit is starting up, press button ▼ and ON/OFF button at the same time for 3 seconds to clear the cumulative use time, and the LCD displays 0.

ELECTRODES PLACEMENT WITH FOOT BATH

Each bay should have one carbon rubber pad. And the lead wires should be hooked such that the pads do not touch during your treatment.

WARNINGS

● When using the foot bath make sure your feet have no open sores, cuts or existing infections

● When using the foot bath make sure to check your feet periodically to make sure there are no adverse reactions.

● If you notice ANY adverse reaction while using the garments or the foot bath, discontinue use and contact your supplier.

TROUBLESHOOTING

If your machine is not working properly please check the following:

Problem	Causes	Solution
Symbol of battery is flashing	Battery power is low	Charging the device
No display	Battery run out	Charging the device
No impulse output from pads	Poor contact of pads or pads defect	1. Check the contact of leads and electrodes; 2. Check the electrodes adhesive quality. If they lose the adhesive quality, please apply fine spray of water to reactivate the adhesiveness. 3. Lead or electrodes defect, please contact local agent.

If the above review has failed to resolve your problem, or to report unexpected operation or events, call local agent for advice.

CLEANING

Clean the case and lead wires at least once a week by wiping with a damp cloth and a solution of mild soap and water. Wipe dry.

Do not immerse the device in water.

Do not use any other cleaning solution than soap and water.

SEVICE LIFE

1) The expected service life of the device is 5 years.
2) The expected shelf life of battery is 5 years.
3) The expected shelf life of electrodes is 2 years.

SERVICE AND MAINTENANCE

- The patient is an intended operator.
- Do not service and maintain the device while in use with a patient.
- Maintenance and all repairs should only be carried out by an authorized agency. The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.
- The user must not attempt any repairs to the device or accessories. Please contact the retailer for repair.
- Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.
- Charging the battery is the simply maintenance that the patient can perform.

WARNING: Do not modify the device without authorization of the manufacturer.

SYMBOLS USED

TYPE BF EQUIPMENT: Equipment providing a degree of protection against electric shock, with isolated applied part Indicates that the device has conductive contact with the end user.

This symbol on the unit means “Refer to User Manual”.

Serial Number: indicates the manufacturer’s serial number so that a specific medical device can be identified.

Do not dispose in household waste. It is compliance with WEEE

Manufacturer

The first number 2: Protected against access to hazardous parts with a finger, and the jointed test finger of 12mmø, 80mm length, shall have adequate clearance from hazardous parts and protected against solid foreign objects of 12.5mmø and greater.

The second number 2: Protected against vertically falling water drops when enclosure is tilted up to 15˚. Vertically falling drops shall have no harmful effects when the enclosure is tilted at any angle up to 15˚ on either side of the vertical.

EMC PRECAUTIONS

Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d = 3,3 m away from the equipment.

(Note. As indicated in Table 6 of IEC 60601-1-2 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields d = 3,3 m at an IMMUNITY LEVEL of 3 V/m).

1* WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally."

2* WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

3* WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

Table 1

declaration - electromagnetic emission	
Emissions test	Compliance

RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Clause 5

Table 2

declaration - electromagnetic immunity		
Immunity test	IEC 60601test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycleAt 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycleand 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	0 % UT; 0.5 cycleAt 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycleand 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

Table 3

declaration - electromagnetic immunity		
Immunity test	IEC 60601test level	Compliance level

Conducted RF IEC 61000-4-6	3V 0.15 MHz to 80MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	3V 0.15 MHz to 80 MHz 6 V in ISM bandsbetween 0.15 MHz and 80 MHz
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m

Table 4

declaration - IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF	385 MHz	**Pulse Modulation: 18Hz	1.8W	27V/m	27 V/m

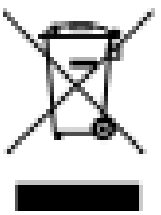
IEC 61000-4-3	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m

	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m

Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.

Disposal of Waste Electrical And Electronic Products (WEEE)



One of the provisions of the European Directive 2002 / 96 / CE is that anything electrical or electronic should not be treated as domestic waste and simply thrown away. New products are now being marked with the symbol to remind you. Your local council or retailer will be able to tell you where your nearest facility is. The collection facilities will send items for treatment, recovery and recycling, so by using them you'll help to save resources and minimize the effects on the environment.

WARRANTY

In addition to your statutory rights, the Manufacturer agrees that if any defect in materials or workmanship appears in this product within one year after the original date of consumer purchase, it will repair or at its option replace the product in question free of charge. This applies only if the product has been used for domestic purposes and has not been damaged through misuse, accident or neglect and has not been modified or repaired by anyone other than the Manufacturer or its authorized agents.
If a defect appears, please check that the article is being used in accordance with instructions, if so, return it with this warranty and the Certificate of Purchase or some other proof of purchase to your supplier.
Note: only our authorized service agents should carry out repairs to the device. For the technical documents please contact the manufacturer.
Batteries, electrodes and lead wires are not included within this warranty.