IBRAMED

QUESTÃO DE RESPEITO

Instruction Manual

NEURODYN
PORTABLE TENS FES

Manufactured by Ibramed

Indústria Brasileira de Equipamentos Médicos EIRELI - Made in Brazil

ANVISA Nº10360310012

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SYMBOL DEFINITIONS

BELOW ARE THE DEFINITIONS OF THE SYMBOLS USED ON THE EQUIPMENT AND THROUGHOUT THE INSTRUCTIONS FOUND IN THIS MANUAL. UNDERSTAND THESE SYMBOLS AND THEIR DEFINITIONS BEFORE OPERATING THIS EQUIPMENT

Caution! Refer to user manual.

TYPE BF Electrical equipment.

Dangerous voltage.

CLASS II Electrical equipment .

IPXO

Not protected against the harmful effects of water penetration.

Sensitivity against electrostatic discharge.

Off switch.

On switch.

V~

Voltage in AC (Alternating Current).

~ line

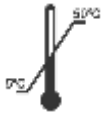
Electrical Network in AC (Alternating Current).

SYMBOL DEFINITIONS

CARTON


Fragile.


This side up.


Limits of temperature for storage and packaging in °C (Celsius Degrees).


Keep away from the rain.


Stacking up.


Do not use if the packaging is damaged.


Refer to operating instructions for correct product use.


Manufacturer’s name and address.

ABREVIATIONS GLOSSARY

Hz	Hertz (pulses per second)
mA	Milliampere
VA	Volt Ampere
TENS	Transcutaneous Electrical Nerve Stimulation
BURST	Modulation of Frequency
TENS BURST	TENS modulated
TENS AC	TENS Acupuncture
TENS VIF	TENS with Variation/Phase Duration Frequency
TENS VF	TENS with Variation Frequency
FES	Functional Electrical Stimulation
FES SYNC	Functional Electrical Stimulation Synchronous
FES REC	Functional Electrical Stimulation Reciprocal
F	Frequency
T	Phase Duration
RISE	Time of Increase Gradient
T ON	Time of Muscular Contraction
DECAY	Time of Decrease Gradient
T OFF	Time of Muscular Relaxation
M.STIM	Manual Stimulation

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FOREWORD

This user manual allows the user to efficiently use the **NEURODYN PORTABLE TENS FES** Electro Stimulator.

Consult other resources for additional information regarding the uses of electrotherapy before attempting any treatment on a patient. Users must read, understand and follow the information in this manual for each mode of treatment available, as well as the indications, contra indications, warnings and precautions.

The specifications and instructions in this manual are in effect at the time of its publication. These instructions may be updated at any time at the manufacturer's discretion. Visit our web site for updates.

PRODUCT DESCRIPTION

NEURODYN PORTABLE TENS FES transcutaneous neuromuscular stimulator is a two-channel stimulator with independent controls for current therapies used in: **TENS** (Transcutaneous Electrical Nerve Stimulation) and **FES** (Functional Electrical Stimulation).

Treatment should be administered only under the direct supervision of a health care professional.

PRECAUTIONARY DEFINITIONS

The precautionary instructions found in this section and throughout this manual are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment prior to therapy session.

Text with a "CAUTION" indicator refers to potential safety infractions that could cause minor to moderate injury or damage to equipment.

Text with a "WARNING" indicator refers to potential safety infractions that could cause serious injury and equipment damage.

Text with a "DANGER" indicator refers to potential safety infractions that represent immediately life threatening situations that would result in death or serious injury.

- Read, understand, and practice the precautionary and operating instructions. Know the limitations and hazards associated with the use of any electrical stimulation. Note the precautionary and operational labels placed on the unit.
- DO NOT operate this unit in an environment where other devices intentionally radiate electromagnetic energy in an unshielded manner.
- Check cables and associated connectors before each use.
- The **NEURODYN PORTABLE TENS FES** Electro Stimulator is not designed to prevent the infiltration of water or other liquids. The infiltration of water or other liquids could cause malfunction of internal components of the system and therefore create a risk of injury to the patient.
- Disconnect the power plug from the outlet when left unused for long periods of time.

• Be sure the unit is grounded by connecting it to a grounded electrical outlet compliant with the applicable national and local electrical codes.
• Powered muscle stimulators should be used only with the lead wires and electrodes recommended for use by the manufacturer.
• Prior to patient treatment become familiar with the operating procedures for each mode of treatment available, as well as the indications, contra indications, warnings and precautions. Consult other resources for additional information regarding the applications of Electrotherapy.
• To prevent electrical shock, disconnect the unit from the power source before performing any maintenance task.
• Keep electrodes separated during treatment. Electrodes in contact with each other could result in improper stimulation or skin burns.
• Stimulation should not be applied over the anterior neck or mouth.
• Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause breathing difficulties.
• Stimulation should not be applied transthoracically to avoid the introduction of electrical current into the heart which may cause cardiac arrhythmia.
• Stimulation should not be applied over swollen, infected, and inflamed areas or skin eruptions such as phlebitis, thrombophlebitis, varicose veins, etc.
• Stimulation should not be applied on or near cancerous lesions.
• Output current density depends on the electrode size. Improper application may result in patient injury. For any question related to the correct electrode size, consult a licensed practitioner prior to therapy session.

• Patients with an implanted neurostimulation device must not be treated with or be in close range of any shortwave diathermy, microwave diathermy, therapeutic ultrasound diathermy or laser diathermy anywhere on their body. Energy from diathermy (shortwave, microwave, ultrasound and laser) can be transferred through the implanted neurostimulation system, can cause tissue damage, and can result in severe injury or death. Injury, damage or death can occur during diathermy therapy even if the implanted neurostimulation system is powered “off.”
• Equipment not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR, OXYGEN or NITROUS OXIDE. Equipment is not the AP or APG category.

INDICATIONS FOR USE

Indications for FES waveform:

- Prevention or treatment of disuse atrophy.
- Increase local blood circulation.
- muscle reeducation.
- Maintaining or increasing range of motion.
- Relaxation of muscle spasm.

Indications for TENS waveform:

- Symptomatic relief and management of chronic pain.
- Increase local blood circulation.
- Post-traumatic acute pain.
- Post-surgical acute pain.

WARNINGS

- Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions such as phlebitis, thrombophlebitis, varicose veins.
- Do not apply stimulation over, or in proximity to, cancerous lesions.
- 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.
- Do not apply stimulation when the patient is in the bath or shower.
- Do not apply stimulation while the patient is sleeping.
- 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.
- Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
- Consult with the patient's physician before using this device, because the device may cause lethal rhythm disturbances to the heart insusceptible individuals.
- Apply stimulation only to normal, intact, clean, healthy skin.

PRECAUTIONS

• The safety of electrical stimulation during pregnancy has not been established.
• Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.
• Use caution when the patient has a tendency to bleed internally, such as following an injury or fracture;
• Use caution following recent surgical procedures when stimulation may disrupt the patient's healing process;
• Use caution if stimulation is applied over the menstruating or pregnant uterus.
• Use caution if stimulation is applied over areas of skin that lack normal sensation.
Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
• The long-term effects of electrical stimulation are unknown;
• Keep this device out of the reach of children;
• Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.

CONTRA INDICATIONS

• Do not use this 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.
• Do not user this device on patients whose pain syndromes are undiagnosed.

ADVERSE REACTIONS

• Patients may experience skin irritation and burns beneath the stimulation electrodes 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; and
• Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

PATIENT POPULATION

• Patients over 12 years old, under this age only by medical prescription or physiotherapeutic indication;
• Patients over 35 kg, under this weight only by medical prescription or physiotherapeutic indication;
• There are no restrictions as of nationality;
• Patients with preserved level of conscience and sensitivity.

CONDITIONS OF USE

• There are no requisites about a maximum level of education for the intended use.
• Regarding the minimum level of knowledge of the user, it is necessary that the user knows the electro physical agents and their therapeutical effects. The user must know physiology, anatomy, and the basic sciences: chemistry, physics, and biology. The user is supposed to have studied or be presently studying physiology and anatomy;
• A maximum level of knowledge is not required from the user;
• The instructions of use are available in Portuguese, Spanish and English;
• Regarding the minimum level of experience of the user, it is necessary that the instructions of use are read carefully and all the instructions are understood before the use of the device;
• There are no admissible deficiencies for the use of the equipment;
• Regarding the frequency of use, this device is used according to clinical needs, up to several times a day and is reusable;
• Regarding mobility, this device is considered a portable device.

RESPONSIBILITY FOR USE ELECTROMEDICAL EQUIPMENT

The use of electromedical equipment is restricted to a physician or under his command, the physical therapists or health professionals properly licensed. The professional will be responsible for properly licensed use and operation of the equipment. IBRAMED makes no representations regarding laws and federal, state or local laws that may apply to the use and operation of any electromedical equipment.

The physician or under his command, also the physical therapist or other professional health care licensed assumes total and full commitment to contact the local certifying agencies to determine any credential required by law for clinical use and operation of this equipment.

The use of electromedical equipment must comply with the local, state and federal country.

SHIPPING DAMAGE

Your **NEURODYN PORTABLE TENS FES** Electro Stimulator is shipped complete in one carton. Upon receipt, inspect carton and unit for visible and hidden damage. In case of damage, keep all shipping materials including carton and contact the shipping agent responsible for the delivery of the unit. All claims relating to damage during transport should be filed directly with them. The manufacturer will not be liable for any damage during shipping, nor allow for adjustments unless proper formal claim has been filed by the receiver against the carrier. The carton in which your **NEURODYN PORTABLE TENS FES** Electro Stimulator was received is specially designed to protect the unit during shipping. Please keep all shipping materials in case you need to return your unit for servicing.

INSTALLATION, CARE AND CLEANING

Installation Instructions

1. Connect the line cord to the back of the **NEURODYN PORTABLE TENS FES** Electro Stimulator.

2. Plug the line cord into a grounded wall outlet (100-240V ~ 50/60 Hz).

3. Plug the electrode cables into the electrode cable connections.

4. Switch on your equipment.

Care Instructions with the equipment

- Avoid areas subject to vibrations.
- Install the equipment on a firm and level surface.
- Do not block ventilation.
- Avoid humid, hot and dusty environments.
- Make sure the area around the network cable is free.
- Do not insert objects into device holes.

CAUTION

CORRECT EQUIPMENT INSTALLATION PREVENTS SECURITY RISKS.

Cleaning the NEURODYN PORTABLE TENS FES

- Disconnect the system from the power source, wipe with a clean, lint free cloth moistened with water and mild antibacterial soap. If a more sterile cleaning is needed, use a cloth moistened with an antimicrobial cleaner. Do not place the system in liquids.

ENVIRONMENTAL PROTECTION

The **NEURODYN PORTABLE TENS FES** is an electronic device and has heavy metals such as lead. Thus, there are risks of contamination to the environment associated with the disposal of this equipment and its accessories at the end of their useful lives. The **NEURODYN PORTABLE TENS FES**, parts and accessories must be disposed of as waste. Contact your local distributor for information on rules and laws regarding the disposal of waste electrical, electronic equipment and accessories.

ELECTRICAL FEED

NEURODYN PORTABLE TENS FES is monophasic equipment, and it may be connected to mains voltage in the range of 100 to 240v ~ 50/60 Hz. Just connect the equipment to the power supply line and it will perform the of selection mains voltage automatically. The connecting cable to the power line is detachable. The equipment uses a mains plug as a resource to electrically separate its circuits in relation to the mains power in all the poles.

NEURODYN PORTABLE TENS FES does not need any type of current stabilizer. Never use power stabilizers.

Before turning on **NEURODYN PORTABLE TENS FES**, make sure:

- The tension and frequency of the local mains voltage is equal to the one described on the label of power line and tension characteristics located in the rear part of the equipment.
- To prevent electrical shock, do not use the plug in the equipment as an extension cable, or other types of plugs except the terminals fit completely in the receptacle.
- Cleansing and disinfection must be performed with the power plug disconnected from the mains voltage.
- Maintenance and technical assistance of **NEURODYN PORTABLE TENS FES** must always be performed at an authorized technical service only by qualified technicians.

CAUTION

There are dangerous tensions inside the equipment. Never open the equipment.

Electromagnetic Compatibility Guidance

CAUTION

Medical Electrical Devices require special attention regarding Electromagnetic Compatibility (EMC) and must be installed and put into service according to the EMC information provided in the following tables.

Portable and Mobile Radio Frequency (RF) communications equipment can affect Medical Electrical Devices.

WARNING

The use of accessories, other than those listed, except when supplied or sold by Ibramed Indústria Brasileira de Equipamentos Médicos EIRELI as replacement parts for internal or external components, may result in increased emission or decreased immunity of the **NEURODYN PORTABLE TENS FES** Electro Stimulator.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The **NEURODYN PORTABLE TENS FES** is intended for use in the electromagnetic environment specified below. The customer or the user of the **NEURODYN PORTABLE TENS FES** should ensure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic environment - Guidance**
RF Emissions CISPR 11	Group 1	The **NEURODYN PORTABLE TENS FES** must emit electromagnetic energy in order to perform it's intend function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class A	The **NEURODYN PORTABLE TENS FES** is suitable for use in all establishments other than domestic those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class A	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The **NEURODYN PORTABLE TENS FES** is intended for use in the electromagnetic environment specified below. The customer or the user of the **NEURODYN PORTABLE TENS FES** should assure 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 by contact ± 8 kV by air	± 6 kV by contact ± 8 kV by 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 Transitories/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	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV diferencial mode ± 2 kV common mode	± 1 kV diferencial mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The **NEURODYN PORTABLE TENS FES** is intended for use in the electromagnetic environment specified below. The customer or the user of the **NEURODYN PORTABLE TENS FES** should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Voltage dips, short interruptions and voltage variations in power input lines IEC 61000-4-11	< 5% U_T (> 95% voltage drops in U_T) 0.5 by cycle 40% U_T voltage drops in (60% U_T) by 5 cycles 70% U_T (30% voltage drops in U_T) by 25 cycles < 5% U_T (> 95% voltage drops in U_T) by 5 seconds	< 5% U_T (> 95% voltage drops in U_T)by 0.5 cycle 40% U_T (60% de voltage drops in U_T)by 5 cycles 70% U_T (30% voltage drops in U_T) by 25 cycles < 5% U_T (> 95% voltage drops in U_T) by 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **NEURODYN PORTABLE TENS FES** requires continued operation during power mains interruptions, it is needed that the **NEURODYN PORTABLE TENS FES** be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to applications of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The **NEURODYN PORTABLE TENS FES** is intended for use in the electromagnetic environment specified below. The customer or the user of the **NEURODYN PORTABLE TENS FES** should assure 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2.5 GHz	3 V 10 V/m	Portable and mobile RF communication equipment should not be used no closer to any part of **NEURODYN PORTABLE TENS FES**, including cable than be separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz $d = 0.7 \sqrt{P}$ 800 MHz to 2.5 GHz Where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The **NEURODYN PORTABLE TENS FES** is intended for use in the electromagnetic environment specified below. The customer or the user of the **NEURODYN PORTABLE TENS FES** should assure 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	3 V	Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	

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 set by fixed transmitters, such as radio base stations, telephone (cellular/cordless) telephones and land mobile radios, amateur radio, AM / 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 at the location in which the **NEURODYN PORTABLE TENS FES** is used exceeds the applicable RF compliance level above, the **NEURODYN PORTABLE TENS FES** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorientation or relocating the **NEURODYN PORTABLE TENS FES**.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between the mobile RF communication equipment and NEURODYN PORTABLE TENS FES

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

Rated maximum power output of transmitter **w**	**Separation distance according to frequency of transmitter m**		
	150 KHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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: 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.

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

Equipment:
Serial number:
ANVISA Registration (M.S.):

Manufacturing date:

Expiration date: 5 years

Senior engineeer: Maicon Stringhetta

CREA - 5062850975

CONTROLS, INDICATORS AND CONNECTIONS

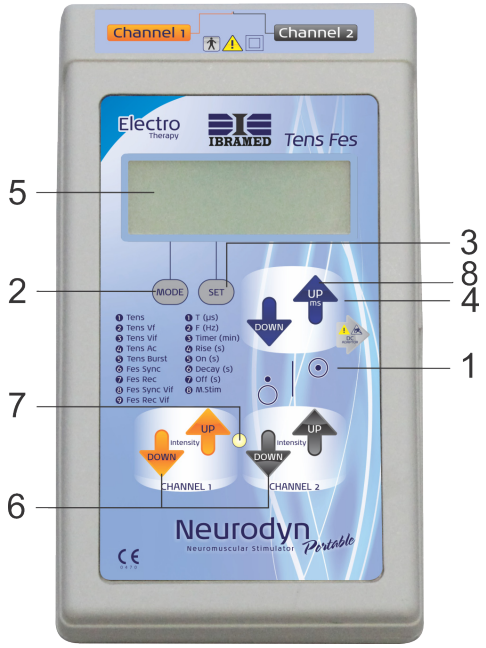


Figure 1. Upper Access Panel.

Figure 2. Rear Access Panel.

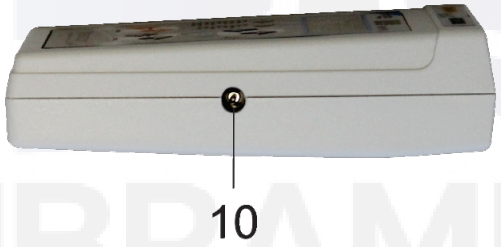


Figure 3. Lateral Access Panel.

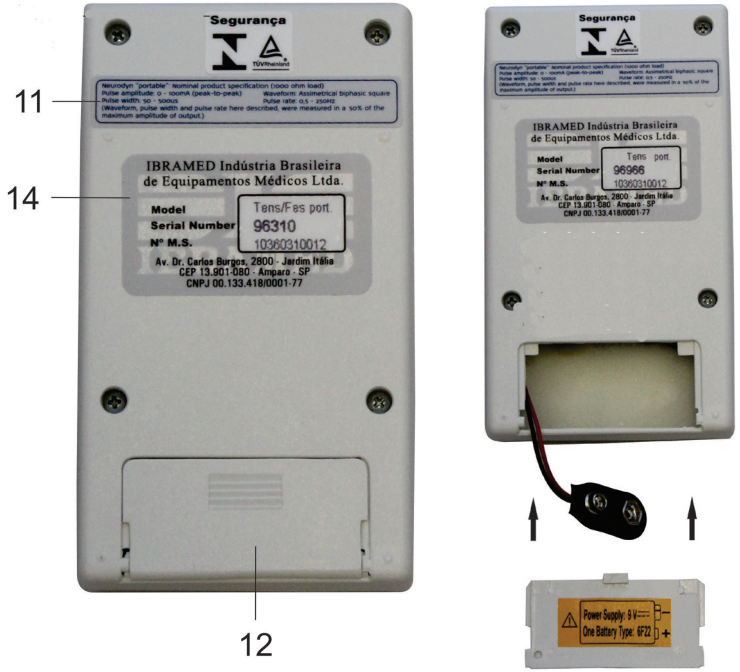


Figure 4. Lower Access Panel.

1- Power **ON**/**OFF** Switch.

2- MODE Button.

3- SET Button.

4- UP/**DOWN** Buttons.

5- LCD Display.

6- UP/**DOWN** Intensity Buttons - Channels **1** and **2**.

7- Channel indicator LEDs.

8- Manual Stimulation Button.

9- Channel Lead Wire Connector.

10- Line Cord Connection.

11- General Technical Information.

12- Battery Placement.

13- Battery Input 9 V.

14- Serial Number.

Read and Understand these symbols and their definitions before operating this equipment.

Figure 5. NEURODYN PORTABLE TENS FES LCD.

Current Mode: Tens, Tens Vf, Tens Vif, Tens Ac, Burst, Fes Sync, Fes Rec, Fes Sync Vif, Fes Rec Vif.

Select the parameters: Phase Duration (T), Frequency (F), Time, Rise, On, Decay, Off and Manual Stimulation (M.Stim).

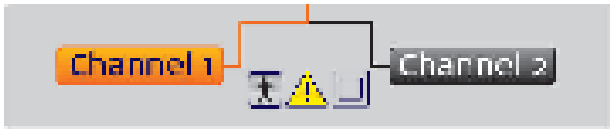
Button used to start or stop the treatment.

On switch.

Off switch.

1 Tens	1 T(us)
2 Tens Vf	2 F(Hz)
3 Tens Vif	3 Time(Min)
4 Tens Ac	4 Rise(s)
5 Burst	5 On(s)
6 Fes Sync	6 Decay(s)
7 Fes Rec	7 Off(s)
8 Fes Sync Vif	8 M.Stim
9 Fes Rec Vif	

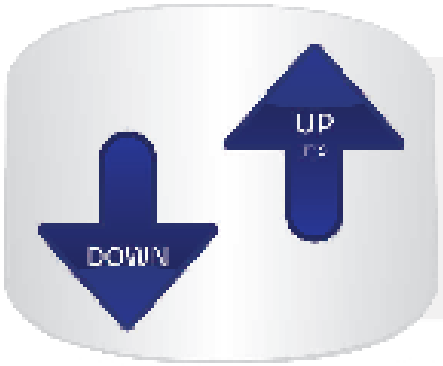
Caption with the waveforms and parameters.



Channel Lead Wire Connectors. Channels 1 and 2.

Parameters increase

Parameters decrease



Up or Down Intensity: Channels 1 and 2.
Observe the colors related to channels.

SYSTEM SPECIFICATIONS

Dimensions

Width: 3.0 in (7.8 cm)
Depth: 5.8 in (14.8 cm)
Height: 1.9 in (5 cm)
Standard Weight (without accessories): 0.240 kg

Power

Input: 100 - 240V~ 50/60 Hz
Input Power: 15 VA
Fuses: 5A 250V~ (20AG)
Electrical Class: CLASS II
Electrotherapy: TYPE BF

Regulatory Compliance

IEC/EN 60601-1
IEC/EN 60601-1-2
IEC 60601-2-10
IEC 60601-1-4

Temperature Range During Transport and Storage:
5 - 50°C/ 41 - 122°F.

Environment operating temperature range:
5 - 45 °C / 41- 113 °F.

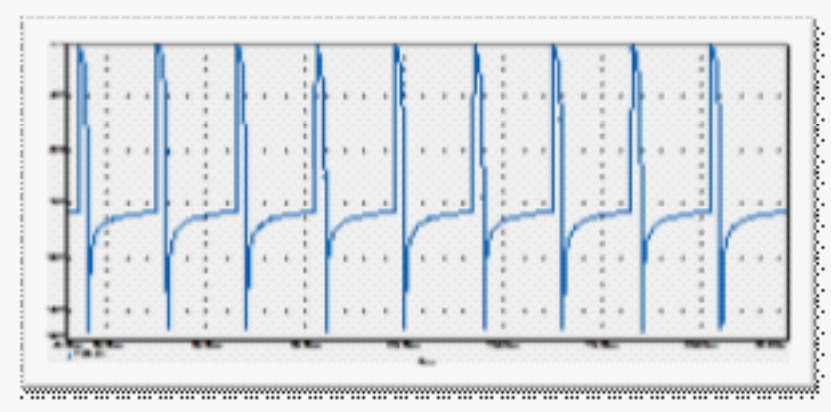
CAUTION

The device and its consumable parts must be disposed of, at end of life, according to the applicable federal and/or state and /or local regulations.

WAVEFORM SPECIFICATIONS

TENS - Transcutaneous Electrical Nerve Stimulation

The Asymmetrical Biphasic waveform has short pulse duration and is capable of strong stimulation of nerve fibers in the skin and in muscle. Because of its short pulse duration, the patient typically tolerates the current well, even at relatively high intensities.



Output Mode: Electrodes

Output Intensity: 0-100 mA

Frequency (F): 0.5-250 Hz

Phase Duration (T): 50-500 µs

Burst Frequency: 2 Hz

Modulation of Burst Frequency: 250 Hz

VF Frequency: 7-65 Hz

VIF Frequency: 7-65 Hz

VIF Phase Duration: 50-225 µs

Current Mode:

Normal (Continuous): Tens (**F** 0.5-250 Hz; **T** 50-500 µs)

Burst Modulation: Burst (**F** 250 Hz; **T** 50-500 µs)

Acupuncture: Tens Ac (**F** 8-25 Hz;**T** 175-275 µs)

Frequency/Phase Duration Variation:
Tens Vif (**F** 7-65 Hz; **T** 50-225 µs)

Frequency Variation: Tens Vf (**F** 7-65 Hz; **T** 50-500 µs)

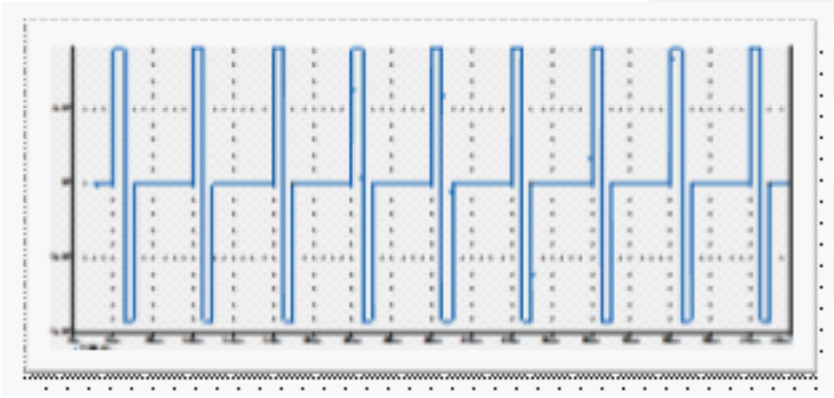
Set Intensity: Individual Channel Intensity Setting

Available on channels: 1 or 2

Timer: 1-60 min

FES - Function Electrical Stimulation

Functional Electrical Stimulation (FES) uses low levels of electrical current to stimulate physical or bodily functions lost through nervous system impairment. **FES** is applied to peripheral nerves that control specific muscles or muscle groups.



Output Mode: Electrodes

Output Intensity: 0-100 mA

Frequency (F): 0.5-250 Hz

Phase Duration (T): Adjustable 50-500 µs

VIF Phase duration: 50-225 µs

VIF Frequency: 7-65 Hz

Current Mode:

Synchronous: Fes Sync (1 & 2 channel)

Reciprocal: Fes Rec (1 & 2 channel)

Frequency/Phase Duration Variation: Vif (**F** 7-65 Hz; **T** 50-225 µs)

Ramp:

Rise (Time of Increase Gradient): 1-9 s

On (Time of Muscular Contraction): 1-30 s

Decay (Time of Decrease Gradient): 1-9 s

Off (Time of Muscular Relaxation): 1-30 s

Set Intensity: Individual Channel Intensity Setting

Available on Channels: 1 or 2

Timer: 1-60 min

TENS or **FES:** pin connector cables with banana ends (2 mm) and rubber conductive electrodes (Figure 6).

A.

B.

Figure 6. A. Pin cables with banana ends (2 mm) and **B.** Conductive rubber electrodes and neutral gel.

CAUTION

The connector screws must be firmly affixed to your connection on the back panel of the device.
To remove the banana pins self-adhesive electrodes, pull them by their protective cover, never pull the cord.

Prepare Device

The **NEURODYN PORTABLE TENS FES** can be used with power cable or with battery.

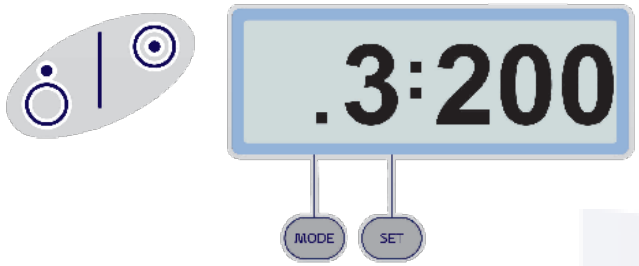
In case the use of battery, the IEC 6F22 type - use 9 volt battery as accessory to the equipment; battery not include.

Replace battery

Remove the protection packing and connect the battery to the connector within the compartment. Close the compartment cover. The battery connector within the compartment is special and does not allow incorrect placement (Figure 7).

Figure 7. Type of battery used with device: IEC 6F22 - 9 Volts battery.

Turn on the power switch. The LCD will display the default screen with the parameters used at the last treatment, for example:



Note that the LCD displays the number **3** that indicates **Tens Vif**.

Select Waveform

Press **MODE** to select the waveform you want to use for the treatment: **1** (Tens), **2** (Tens Vf), **3** (Tens Vif), **4** (Tens Ac), **5** (Burst), **6** (Fes Sync), **7** (Fes Rec), **8** (Fes Sync Vif) and **9** (Fes Rec Vif). Note that a point to the left of the first number will be flashing indicating that the **MODE** function is ready for programming. The numbers related to the waveforms are identified in the caption and should be adjusted via the **MODE** key, for example change number **3** (Tens Vif) to number **1** (Tens) (Figure 8).

A.

B.

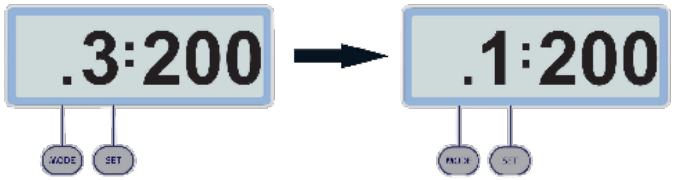


Figure 8. A. MODE switch and caption with the waveforms and parameters; **B.** Number **3** (Tens Vif) changing to number **1** (Tens).

Edit Waveform Parameters

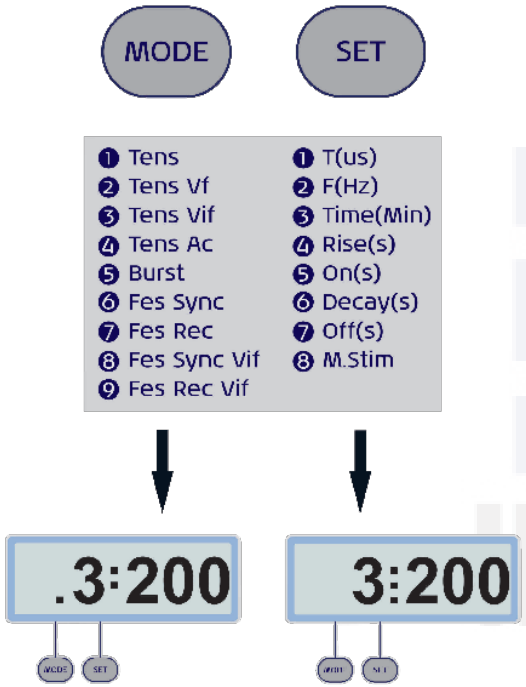
The **SET** button allows the selection of the parameters required for the treatment: **1** T (µs); **2** F (Hz), **3** Time (min), **4** Rise (s), **5** On (s), **6** Decay (s), **7** Off (s) and **8** MStim. Press **SET** and note that the point now will be flashing indicating that the **SET** function is now ready for programming. Observe that this time the flashing point is located to the right of the first number, giving access to choose the parameters (Figure 9).

A.

B.

Figure 9. A. SET switch; **B.** Display showing the flashing point.

The figure below shows an example of waveform and parameter adjustment, according to the text above:



The **UP/DOWN** buttons allow the selection of the values of each parameter required for the treatment.
Press the **UP** button to increase the value of the parameter.
Press the **DOWN** button to move back to the previous setting (Figure 10).

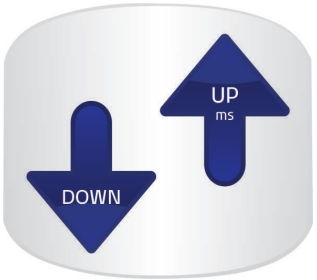
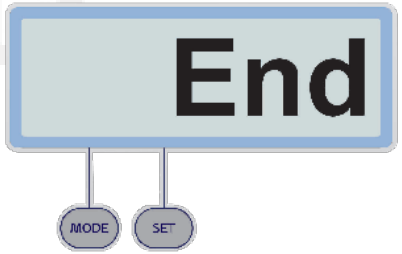


Figure 10. UP/DOWN switch.

Time Parameters

At the end of the scheduled application time, the yellow luminous indicator of the presence of output current intensity will be turned off, indicating the end of the treatment. The current intensity will be stopped. The LCD will display:



Prepare and Install Patient Electrodes

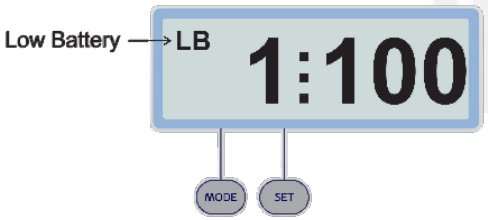
Prepare the patient for therapy as described and read about the use of electrodes.

Waveform Intensity

The Waveform Intensity may be increased or decreased at any time during the session. Press the **INTENSITY** button up or down.

Low Battery

The equipment has a protection against safety risks if the battery is low. When the conditions to the battery are unsatisfactory (low) the LCD of the **NEURODYN PORTABLE TENS FES** will display the low battery message (**LB**). Even with battery low, the equipment will operate for an additional time and disconnect automatically when the battery is empty. At this time the LCD will display the message:



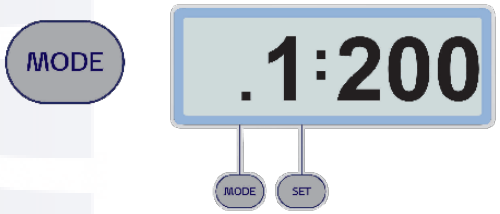
WARNING

Remove the 9 volt battery if the equipment is not used for a long period of the time.

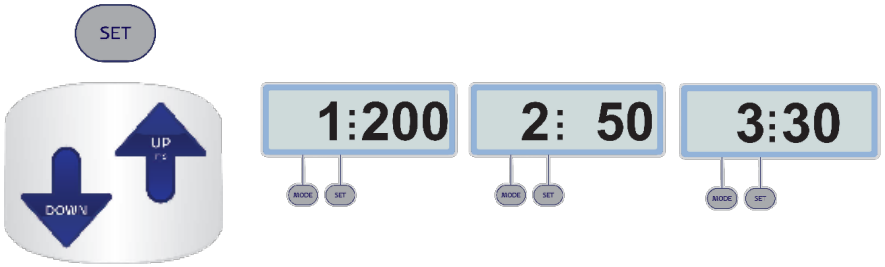
Example 1: Suppose that to treat a specific pathology, you need to select the following parameters:

Mode: **1** (Tens)
Frequency (**F**): 50 Hz
Phase Duration (**T**): 200 µs
Time: 30 min

1. Press the **MODE** button until number **1 (Tens)** displays, as shown below:



2. Using the **SET** button select number **2** and number **3** and with **UP/DOWN** buttons, scroll through the other parameters and select the value shown in the example: **(1)** Phase Duration (T) = 200 µs, **(2)** Frequency (F) = 50 Hz and **(3)** Time = 30 min.



3. Now adjust the **INTENSITY** channel in use to select the amount of current needed for the treatment, increasing slowly, using the **UP/DOWN** intensity button.

ELECTROTHERAPY PATIENT PREPARATION

• Electrode Placement can be achieved using the Bipolar or Monopolar Techniques. Proper positioning and contact will insure treatment comfort and efficiency.

• Examine the skin for any wounds and clean the treatment area by rubbing the skin with medical grade alcohol.

• Before placing the electrodes, clean the area with soft soap and water to remove oil and possible skin fragments, thus reducing the resistance to the passage of the electrical current. Rinse and dry the area well before placing the electrodes.

• Distribute the conductive gel onto the surface of the rubber which will be in contact with the skin.

• When using the self-adhesive electrode, remove it from the protective backing and apply it on the treatment area as prescribed.

• Ensure the entire electrode surface is in contact with patient skin by pressing into place.

• Check the electrode contact regularly during treatment.

• Examine the skin again after the treatment.

ELECTRODE POSITIONING

Bipolar Electrode Placement Technique

Bipolar Electrode Placement Techniques should be used to provide stimulation to larger muscle groups, such as the quadriceps or the hamstrings. Equal size electrodes are placed at each end of the muscle or muscle group. For another application are used equal size electrodes placed at each painful area with this area between the electrodes. This is used for control pain. The symmetrical waveforms of the Biphasic and Low Frequency are usually applied to the body using the Bipolar Technique. The **NEURODYN PORTABLE TENS FES** Electro Stimulator offers waveforms of the Functional Electrical Stimulation (FES) and Nervous Transcutaneous Electrical Stimulation (TENS).

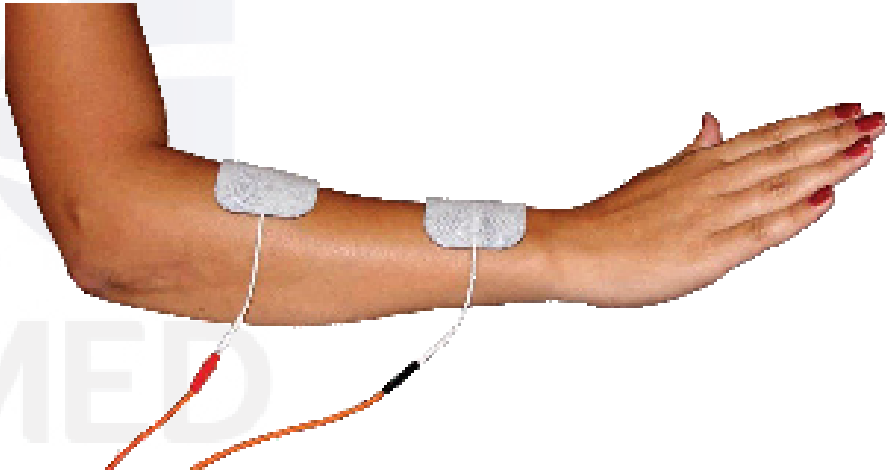


Figure 11. Bipolar Electrode Placement Technique.

Monopolar Electrode Placement Technique

The Monopolar Electrode Placement Technique has been found to be especially useful for muscle stimulation of the upper extremities and small muscle groups. The smaller electrode is placed over the muscle motor point and the larger electrode is placed over the painful area. Monopolar Techniques may be used with the waveforms symmetrical Biphasic and Low Frequency.

The **NEURODYN PORTABLE TENS FES** Electro Stimulator offers waveforms of the Functional Electrical Stimulation (**FES**).

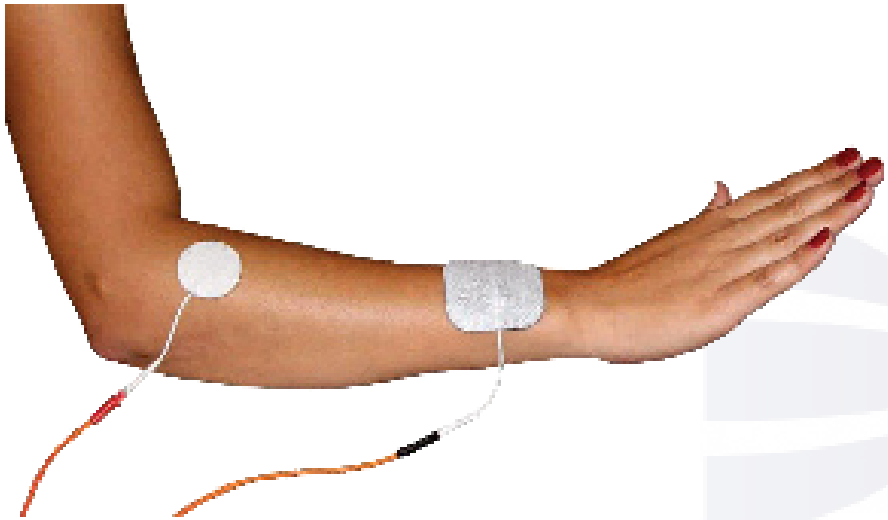


Figure 12. Monopolar Electrode Placement Technique.

Electrode Sizes and Current Density

The size of the electrodes and the energy density used during therapy must comply with IEC 60601-2-10, i.e., the current density per area of electrode should not exceed 2 mA/cm^2.

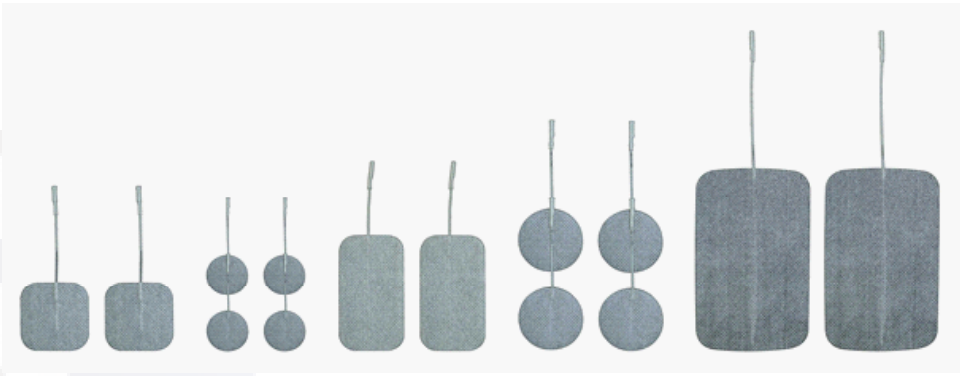


Figure 13. Electrode sizes and current density.

WARNING

Placement of the electrodes near the chest may increase the risk of cardiac fibrillation.

PROGRAMMING USER MANUAL STIMULATION

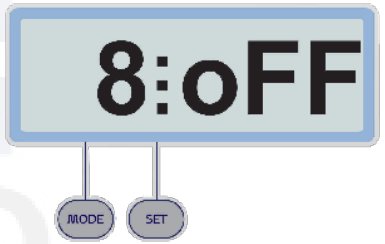
Manual Stimulation (MS) is a switch that allows for the stimulation to be manually performed by the user. When this switch is activated, the equipment will execute the rise, on, decay and stop gradients, this means that it will remain in **off** for the period that the operator considers necessary. Each time this switch is activated, **NEURODYN PORTABLE TENS FES** will perform the stimulation following the rise, on and decay gradients, programmed for FES current types: Fes Sync (Synchronized Fes), Fes Sync VIF (Synchronized Fes with Vif), Fes Rec (Reciprocal Fes) or Fes Rec Vif (Reciprocal Fes with Vif).

It is necessary to program the parameters in the LCD of the **NEURODYN PORTABLE TENS FES** so that the **MS** key works as a manual stimulation (Figure 14).

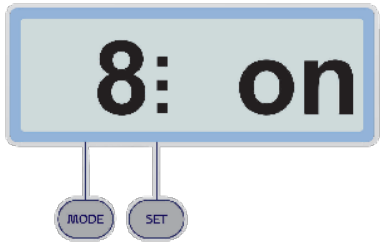
Figure 14. UP switch for manual stimulation (MS).

To use the **MS** switch select the function number **6** (Fes Sync), **7** (Fes Rec), **8** (Fes Sync Vif) or **9** (Fes Rec Vif) using the **MODE** switch. After that using the **SET** switch, select function **8** (M.Stim) **ON** and select the others parameters: **4** (Rise), **5** (On), **6** (Decay) and **7** (Off) using the **UP/ DOWN** switch.

The LCD will display the following message:



Now press the **UP** switch and the **MS** function will be activated and the display will show **ON**:



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ST Pierre D, Taylor AW, Lavoie M. et al. Effects of 2500-Hz sinusoidal current on fibre area and strength of quadriceps femoris. J Sports Med Phys Fitness. 1986; 26(1):60-66.

NEURODYN PORTABLE TENS FES contains accessories designed to meet the requirements of electromagnetic comparability accessories (03049001, 03049008 and 03049009).

PART NUMBER	QUANTITY	ITEM DESCRIPTION
03049001	**01**	POWER CABLE KIT NEURODYN PORTABLE
03049009	**01**	ELECTROSTIMULATION 2 WAY CABLE ORANGE (03/13)
03049008	**01**	ELECTROSTIMULATION 2 WAY CABLE BLACK (03/13)
03026042	**01**	PLASTIC BAG SMALL – BLUE/ CRYSTAL (RC-EL 155M)
03041002	**01**	9 V BATTERY
03026024	**04**	CONDUCTIVE RUBBER ELECTRODES 5 CM X 3 CM
03040004	**01**	CD USER MANUAL
03044001	**01**	GEL TUBE (CAP. 100 GRAMS) (REGISTERED ANVISA Nº 80122200001)

REPLACEMENT ACCESSORIES

This list of replacement accessories are designed for use with the **NEURODYN PORTABLE TENS FES** Electro Stimulator. When ordering, provide the respective part numbers, description, and quantity desired.

The use of accessories, cables and electrodes other than those intended for this specific equipment may significantly degrade the performance of the emissions and immunity. DO NOT USE accessories, cables and electrodes from **NEURODYN PORTABLE TENS FES** equipment on other equipment or medical electro systems.

TROUBLESHOOTING

What may initially look like a problem is rarely a defect. Before calling customer support, please check the items described below:

PROBLEMS	SOLUTIONS
The equipment does not turn on 1.	• Is the power cable properly connected? If not, connect it. Also check the wall socket.
The equipment does not turn on 2.	• Have you checked the safety fuse? Check if there is a bad contact. Check if the value is correct as stated in the instructions.
The equipment is turned on but does not emit current to patient 1.	• Have you followed the recommendations for correct use the equipment as mentioned in the instructions? Check and repeat the steps in the controllers, indications and operation section.
The equipment is turned on but does not emit current to patient 2.	• Have you checked the electrodes and the connecting cables to the patient? Check if the cable plug is adequately inserted in the equipment. Check if the electrodes are adequately placed on the patient's body.
The equipment does not turn on and/or work properly.	• Check the condition of the 9 volt battery.

MAINTENANCE

For safe use of the equipment, it is recommended to have it inspected and undergo preventive maintenance at IBRAMED or an authorized technical center every 12 months. The manufacturer IBRAMED only assumes liability for the technical features and equipment safety provided the unit is used according to the instructions for use contained in the manual, when maintenance, repairs and modifications are undertaken solely by the factory or authorized agents, and in the event of a breakdown when the components that can cause a security risk to the appliance are replaced by original spare parts. If requested, IBRAMED will provide technical documentation (circuit diagrams, lists of parts and components etc) necessary for the repair of any equipment. We assume no responsibility for repairs without prior explicit written permission from IBRAMED.

WARRANTY

IBRAMED, Indústria Brasileira de Equipamentos Médicos EIRELI, here identified to the consumer through the following address and telephone number: Av. Dr. Carlos Burgos, 2800, Jd Itália, Amparo/SP; Tel.: +55 19 3817 9633 provides product-warranty for eighteen (18) months insofar as the conditions set for warranty terms are followed by the user as mentioned below.

WARRANTY TERMS

1) IBRAMED warrants that this product is free of manufacturing defects for eighteen (18) continuous months, provided the set terms presented in these instructions for use are followed.

2) The warranty period takes effect from the date of purchase and applies to the original purchaser only, even in the event of a product being transferred to a third party. The warranty covers the replacement of component parts and labor required to repair defects whenever the presence of such manufacturing defects can be determined.

3) Customer Service during the warranty period will be provided exclusively at IBRAMED sale points by IBRAMED itself or another agent designated by the manufacturer.

4) The warranty does not cover damage caused to the product resulting from:

a) Failure to follow the specifications and recommendations detailed in these instructions for use during installation or use of the product.

b) Accidents or acts of God, connections to electrical system with inappropriate voltage and/or subjected to excessive fluctuation or overcharge.

c) Misuse, lack of reasonable care, product

alterations, modifications or repairs undertaken by individuals or entities not authorized by IBRAMED.

d) Removal or adulteration of the equipment serial number.

e) Damage during Transport.

5) The legal warranty does not cover: expenses incurred during product installation or transport to the plant or sale point, labor, materials, parts and adjustments necessary to the readiness of the premises in view of the installation of the device, such as but not limited to electric net, masonry, hydraulic network, grounding system, as well as their requirements.

6) The warranty does not cover parts subjected to natural wear, such as but not limited to control buttons, control keys, handles and moving parts, radiofrequency applicators, cooling applicator, cables, connectors, device cabinets, pedal, infrared thermometer.

7) The selling points are neither authorized to alter the conditions mentioned in this document nor take any commitment on behalf of IBRAMED.

TECHNICAL ASSISTANCE

If you have any doubts or problems related to the operation of your equipment please contact our technical department. Call: **+55 19 3817.9633**.

Do not alter this equipment. Any unauthorized modification can affect the safety of this equipment.

Never make unauthorized repairs.

CEFAI – IBRAMED CENTER FOR EDUCATION AND ADVANCED TRAINING

IBRAMED Equipment goes beyond technology. It also provides knowledge! Science constitutes our differential value and we effectively take advantage of its benefits in order to ensure patient safety and thereby maximize results.

IBRAMED develops products with scientific support of the most recent medical studies published in major scientific journals in the areas of biological, health and exact.

Access to the knowledge database is guaranteed by CEFAI (IBRAMED Center for Education and Advanced Training) whose goal is to provide technical and scientific support as well as current literature on therapies and their applicability while our treatment choices are always thoroughly selected according to the best and latest clinical criteria. CEFAI takes into account the personal and professional development of all its partners and customers.

CEFAI invites both students and professionals in the fields of Physical Rehabilitation, Esthetics, Physiotherapy, Dermatology and Esthetic Medicine to take part in free courses, workshops, and the best Postgraduate Lato Sensu courses in the areas of physical rehabilitation and esthetics.

Special attention is also given to those interested in visiting our structure. Whatever your professional development needs, we'll be right by your side to provide you with unconditional support.

We are happy to assist you!

Contact – **cefai@conexaocefai.com.br**
www.conexaocefai.com.br
+55 19 3808. 2348

Thanks,

IBRAMED – A matter of respect!

CEFAI
CENTRO DE ESTUDOS E FORMAÇÃO AVANÇADA IBRAMED

IBRAMED

QUESTÃO DE RESPEITO

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