ElectroMedic™

Portable, compact, easy-to-use devices that effectively respond to an even broader range of perineal and pelvic rehabilitation care, thanks to our close and constant collaboration with health care professionals and their patients.

USER MANUAL IN ENGLISH

INSTRUCTIONS BEFORE OPERATING

NMES TENS

STIMULATES and RELIEVES
a readaption at arms reach

EVA

5 YEAR WARRANTY

All Electro-Medic devices come with a 5 (five) year warranty that starts on the date of purchase.

THE ELECTRO-MEDIC WARRANTY applies only to the device, does not cover any accessories (wires, batteries, charger), which are covered by a 3 (three) month warranty.

Collaboration

BEFORE USING THE STIMULATOR

INTRODUCTION

ELECTRO-MEDIC,
In partnership with
Service d'électro-Thérapie (**SET**)
Expert in Electrotherapy using
TENS and **NMES**, presents its
new muscle stimulator designed
for women's pelvic and perineal
health, the **EVA**

1.1

Thank you for choosing Electro-Medic, a proud Canadian manufacturer of muscle stimulators (NMES) and transcutaneous electrical nerve stimulators (TENS), offering you high-end devices and accessories on the cutting edge of technology.

Portable, compact, easy-to-use devices that effectively respond to an even broader range of physical rehabilitation care, and particularly for perineal and pelvic rehabilitation.

Thanks to our close and constant collaboration with health care professionals and their patients.

An electrotherapy culture meticulously designed for women's needs in relation to perineal and pelvic rehabilitation and pain management for these areas.

A medically recognized therapy technique used both by health care professionals in a clinical setting and by patients at home to ensure that the gains made in the clinic are maintained.

NERVE STIMULATION
Its uses and benefits
Medical Context

1.2
NMES
TENS

NMES

Transcontinuous neuromuscular stimulation is applied to normally innervated pelvic floor muscles.

The muscle fibres are not directly stimulated; rather, the stimulation is done through the nerve endings.

The electrodes or probe are applied to the muscles to be worked in such a way that the current stimulates the motor nerves and induces a muscle contraction. For external use, one of the electrodes will ideally be positioned on a motor point (the area that can most easily be excited by the current). For internal use, the vaginal or anal probe will be inserted and will be in contact with the pelvic floor muscles.

To be effective, neuromuscular electrical stimulation requires precise adjustment of several parameters, such as: adjusted pulse shape, sufficient and comfortable current intensity, and adequate frequency. It is important, therefore, to use it under medical supervision, as recommended by a qualified health care professional.

TENS

Transcutaneous electrical nerve stimulation – TENS – involves depolarizing peripheral nerve fibres, using a current transmitted by means of electrodes placed on the skin or internally by a probe.

TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION APPLIED AT A SENSORY LEVEL

The purpose of this stimulation is to enhance the effectiveness of the natural pain control mechanisms. The current causes a tingling sensation which will then trigger a natural analgesic reaction in the nervous system.

ACCESSIBLE TO ALL

The option of choosing a TENS program that is appropriate for one's type of pain makes it a highly effective non-surgical, non-drug therapy solution. TENS can be used to manage pain both during activity and at rest, both in the clinic and at home.

In order to optimize the results of TENS nerve stimulation, we recommend that you be under the care of a qualified health care professional.

* For safe and proper use of the TENS, please follow the recommendations of your qualified health care professional.

1.3 SAFETY MEASURES

INDICATIONS, CONTRAINDICATIONS, PRECAUTIONS, WARNINGS, ADVERSE EFFECTS

NMES INDICATIONS

Neuromuscular electrical stimulation (NMES), particularly effective for facilitating strengthening and rehabilitation of muscles generally, but also used widely in perineal and pelvic rehabilitation.

- Stress urinary incontinence
- Urge urinary incontinence
- Mixed urinary incontinence
- Fecal incontinence
- Pelvic floor weakness:
  - Post-partum
  - Chronic lower back pain
  - Pelvic organ prolapse
- Hypertonic pelvic floor

TENS INDICATIONS

A safe, medically recognized therapy technique for pain control with no side effects.

PAIN IN CHILDBIRTH AND POST-PARTUM PAIN

- Pain related to childbirth
- Pain related to Post-partum uterine contraction
- Postural pain (musculoskeletal) related to infant care

CHRONIC PELVIC PAIN SYNDROME

- Chronic vulvar pain syndrome (vulvodynia) and vestibulodynia
- Painful bladder syndrome (Interstitial cystitis)
- Endometriosis-related pain syndrome
- Dysmenorrhea related pain
- Deep dyspareunia

OVERACTIVE BLADDER

CONTRAINDICATIONS (C-I)

- Malignancy/neoplasia: risk of spreading metastases. Risk of increasing tumour growth. Cancer (or suspected cancer) is a local contraindication to electrotherapy currents; they may therefore be used away from the affected site. In the case of metastases, use of electric current is generally contraindicated. Patients who have already had cancer are recommended to wait until the remission period is completed before restarting use of TENS or NMES on the affected site. However, under certain conditions (e.g. palliative care), with informed consent provided by the patient and by the interdisciplinary team, use of TENS or NMES is possible.
- Cardiac pacemaker: absolute or local contraindication. Risk of interference with the normal function of the cardiac pacemaker. A cardiologist's permission is needed.

LOCAL CONTRAINDICATIONS

DO NOT APPLY TO THESE REGIONS

- Transcranial: risks of applying the electrodes transcranially are unknown.
- Eyes: the risks of treating this part of the body are unknown.
- Anterior cervical region/carotid sinus: risk of stimulating the vagus nerve, phrenic nerve, pharyngeal muscles or carotid sinus.
- Infection: the infection may spread.
- Skin weakened by radiation therapy: could stimulate the growth of remaining malignant cells.
- Damaged or delicate skin: resistance is decreased, which increases the risk of burns.
- Do not apply stimulation to open wounds, erythema or rashes, or to swollen, red, infected or inflamed areas.
- Undiagnosed persistent pain.

LOCAL CONTRAINDICATIONS

OR USE UNDER MEDICAL OR INTERDISCIPLINARY SUPERVISION

- Do not apply stimulation to the patient's torso because the passage of an electrical current through the chest can cause life-threatening heart rhythm disturbances.
- Electronic implant: risk of interference with normal implant function.
- Heart disease: risk that the heart will have difficulty keeping up with the high metabolic demand. Patients with a suspected or diagnosed cardiomyopathy should follow the recommendations of their doctor.
- Pregnancy: endogenous opiates released during muscle contractions induced by electrical stimulation may stimulate myometrial contractions. Electrical muscle stimulation of large muscle groups should therefore be avoided during pregnancy (NMES). Risk of affecting the development and growth of the foetus. Risk of triggering premature uterine contractions. The effects of the use in the perineal area during pregnancy are unknown (TENS and NMES).
- Recent surgery, unstable fracture, osteoporosis: muscle contractions could cause a muscle tear or even a displacement of the fracture.
- Epilepsy: local C-I on the head and neck. Precautions on the trunk and extremities. Electrical stimulation could trigger a seizure.
- Sensory disorder: risk that the patient does not feel the current adequately, which increases the risk of burns or skin irritation. (Loss of sensation. Proceed with caution if stimulation is applied to areas of the skin with a lower than normal level of sensation).
- DVT/blood clot/embolism: a blood clot could move into the bloodstream.
- Tuberculosis: there is a risk of spreading infection.
- Bleeding (or risk of bleeding): risk of promoting bleeding.

PRECAUTIONS

- Circulatory disorder: stimulation increases the metabolic demand and this demand can exceed the oxygen supply, thus increasing the pain. It can also lead to ischemia or necrosis in the tissue.
- Impaired cognition or communication: increased risk of injury to the patient. The patient's opinion, judgement and behaviour must be known in order to use the device safely. (Do not apply stimulation to patients who are unable to express themselves).
- Skin disease (e.g. eczema): resistance is decreased, which increases the risk of burns.
- Active epiphyseal plate: risk of impairing bone growth.
- Chest: risk of affecting normal heart function.
- Lower abdomen: high-intensity stimulation carries a risk of increasing gastrointestinal motility.
- Abundant fat tissue: risk of ineffective treatment; the current does not reach the target tissue (muscle) because the fat tissue increases electrical impedance, which limits the penetration of the current (NMES).

SPECIFIC CONTRAINDICATIONS AND PRECAUTIONS FOR INTERNAL USE

LOCAL CONTRAINDICATIONS

- Urethral pathology: stenosis, urethral stricture, irradiated or scarred urethra
- Presence or suspicion of a vaginal, urinary or anal infection or yeast infection
- Fistula, vulvar lichen sclerosus

PRECAUTIONS UNDER THE SUPERVISION OF A QUALIFIED HEALTH CARE PROFESSIONAL:

- Systemic locomotor disorders
- Spinal conditions
- Post-partum: wait for 6 to 8 weeks before starting any neuromuscular electrical stimulation
- Pelvic or abdominal surgery in the last 6 months
- Pelvic organ prolapse
- Acute urinary retention

* This device is not indicated for stimulating denervated pelvic floor muscles.

WARNINGS

- Consult a qualified health care professional before using the device, because the device may cause lethal heart rhythm disturbances in some susceptible individuals.
- Use this device only as recommended by a qualified health care professional. (positioning of electrodes or probe, adjusting settings).
- Never begin a first stimulation session on a person who is standing up. The first five (5) minutes of stimulation should be performed while sitting or lying down. In rare cases, nervous individuals may suffer a vasovagal reaction. This reaction is related to a fear of muscle stimulation and shock at experiencing the unintentional muscle contraction. A vasovagal reaction can cause the heart to slow down and blood pressure to drop, which can lead to weakness and syncope. If this happens, stop stimulation. The patient should lie down with his or her legs elevated until the feeling of weakness goes away (5 to 10 minutes).
- Long-term effects: we are unaware of any long-term effects of NMES.
- Do not apply stimulation near any metal items. Remove all jewelry, piercings, belt buckles or any other metal objects or devices in the area of stimulation.
- Abrupt changes in temperature can cause condensation to build up inside the stimulator. To avoid this, allow the device to come back to room temperature before using it.
- During stimulation sessions, never disconnect a stimulation wire while the stimulator is switched on. The stimulator should be turned off first.
- During sessions, the stimulator should always be turned off before moving or removing the electrodes.
- Apply NMES only on normal, intact, clean and healthy skin.
- Do not use electrodes with an active area of less than 2.54 cm in diameter; otherwise, skin burns may occur. Proceed with caution if the electric current density is higher than 2 mA/cm^2.
- Always use conductive gel with carbon electrodes or the probe to avoid risk of skin damage.
- The stimulator should be used only with electrodes or a probe that are intended for stimulating nerves and muscles. Muscle pain may occur after stimulation but generally disappears within a week.
- Inspect the electrodes before each use. Change the electrodes when they begin to wear out or lose adhesiveness. Poor contact between the electrodes and the patient's skin increases the risk of irritation or burns on the skin. Apply the electrodes so that their entire surface is in contact with the skin.
- Do not share electrodes with other patients. Each user should have a packet of electrodes and a probe in order to avoid any adverse skin reactions or disease transmissions.
- The manufacturer denies all liability in cases where electrodes are positioned in ways other than as recommended.

ADVERSE EFFECTS

- Patients may feel irritation and skin burns under the stimulation electrodes applied to the skin.
- Patients may experience headaches and other painful sensations during or after the application of electrical stimulation near the eyes, on the head or the face.
- Patients should stop using the device and consult a doctor if they experience an adverse reaction.
- Some patients may experience extra sensitivity or skin irritation due to the electrical stimulation or the electrical conductor (Gel). Irritation may be alleviated by using a different conductor or by placing the electrodes differently.
- Some patients may experience redness under the electrodes after the session. This redness generally disappears within a few hours. If skin redness persists after a few hours, the patient should consult a doctor. Do not begin another stimulation session on the same area if redness is still visible. Do not scratch red areas.

SAFETY MEASURES

- Keep out of the reach of children.
- Risk of electric shock.
- Near other equipment. Do not use the device when it is placed near to or above other equipment. If it is necessary to use it in such a situation, make sure that ALL THE PERIPHERAL EQUIPMENT IS OPERATING CORRECTLY under these conditions.
- Do not use the device at the same time as monitoring equipment (e.g. ECG equipment) that uses electrodes. The signals generated by the device could interfere with those of the monitoring equipment.
- Accessories. Use this device only with manufacturer-recommended electrodes, probes and accessories. Using other accessories may harm the performance of the device, increase electromagnetic emissions or reduce the electromagnetic immunity of the device.
- Do not modify. No modifications to the equipment are authorized.
- Battery or stimulator heating up. Under extreme use conditions, some parts of the casing may reach 43°C (109°F). Handle the battery and hold the device carefully immediately after use. This temperature may cause an unpleasant sensation but does not pose a particular health risk.
- Strangulation. Never wrap the wires around the patient's neck and always keep out of the reach of children. Tangled wires may lead to strangulation.
- Falls. Pay attention to wires on the ground to prevent falls.
- Damaged device or accessories. Never use the device or accessories if damaged (casing, wires, etc.) or if the battery compartment is open because there is a risk of electric shock. Carefully inspect the wires and connectors before each use.
- Foreign body. Do not allow any type of foreign body (dirt, water, metal, etc.) to get into the device or the battery compartment.
- LI-ION BATTERY. Do not carry the battery in a pocket, wallet or any other place in which the terminals could cause a short-circuit. This may generate intense heat and cause injury. Never open the battery compartment cover during stimulation due to the risk of electric shock. Remove the battery from the device if you do not plan to use it for a long period, i.e., more than three (3) months. Leaving the battery in the device for a long period may damage the battery and the device.
- To avoid damage to the wires, it is best to leave them connected to the stimulator between two (2) sessions. Do not shake the wires and connectors.
- Equipment with internal power supply, type BF applied parts are not suitable for:
  - Use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide.
  - Continuous use

2 INTRODUCING THE DEVICE

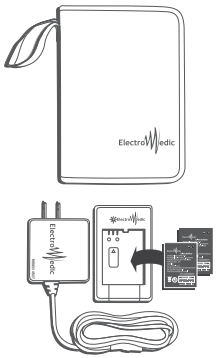
2.1 EQUIPMENT AND ACCESSORIES | MODEL: EVA

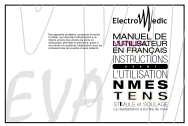
THE EVA PORTABLE MUSCLE STIMULATOR COMES WITH MANY ACCESSORIES INCLUDING

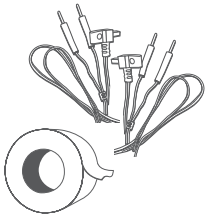
• 1 case • 1 EVA NMES • 1 quick-start guide • 1 charger and 2 Li-ion batteries • 2 wires and 1 set of carbon electrodes • 1 250 ml tube of gel • 1 roll of adhesive tape • 1 manual controller • 1 protective silicone sleeve which can be used with • 1 belt clip and • 1 elastic band for attaching to an extremity for greater comfort and mobility • 1 neck strap for easily wearing the NMES device

ATTENTION

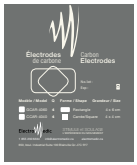
Carefully read the instructions about using the electrodes as explained on their packaging.

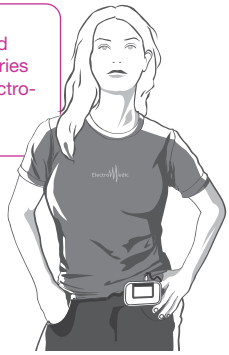


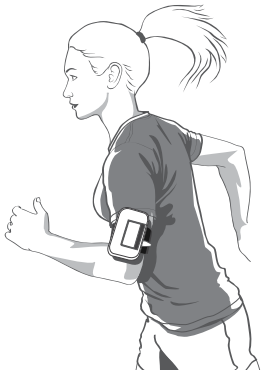




It is recommended that only accessories authorized by Electro-Medic be used.







2.2 TECHNICAL FEATURES

A muscle stimulator designed for women's pelvic and perineal health, the Electro-Medic EVA stimulator has two channels, designed for physical rehabilitation and particularly for pelvic and perineal rehabilitation (NMES) and pain relief (TENS). The stimulator has 19 programs, including 7 that can be customized. Electrical stimulation therapy requires a stimulation current capable of penetrating the resistance of the skin and the electrode, i.e. approximately 1500 ohms.

The Electro-Medic muscle stimulator can penetrate this resistance and maintain a current intensity of up to 100 mA. A change in load from 100 to 1500 ohms results in less than 10% variation in stimulation current from the set value.

The Electro-Medic muscle stimulator works with a rechargeable, 3.7V/600mAh Li-ion battery with a separate charger.

ELECTRICAL SPECIFICATIONS

• Number of channels	2 non-independent in NMES mode 2 independent in TENS mode 1 manual controller
• Constant current	Up to a resistance of 1500 ohms (an increase in load may reduce the maximum current)
• Stimulation current/channel	From 0 to 100mA (maximum load: 40µ C)
• Form of pulse	Symmetrical biphasic pulse, 100% compensated
• Number of preset programs	12
• Number of customizable programs	7
• Form of stimulation	Continuous stimulation Intermittent stimulation Conventional (Continuous) Burst Pulse duration/modulated frequency
• Maximum pulse width	40-400 µs
• Maximum frequency	1-150 Hz
• Timer	From 1-60 min/Continuous (C)
• Power supply	1 rechargeable lithium-ion battery, 3.7 volts/600 mAh
• Use	+5°C to +40°C, 15% and 90 % R.H.: 700 hPa and 1060 hPa
• Storage and transportation	-10°C to +60°C, 15% and 75% R.H.: 700 hPa and 1060 hPa
• External dimensions	110 mm (L), 64 mm (W), 17 mm (D)
• Weight with battery	Approx. 114 g
• Weight without battery	Approx. 90 g

2.3 CHOICE OF PRESET PROGRAMS

NMES

- Stress incontinence
- Urinary incontinence
- Mixed incontinence
- Stimulation of posterior tibial nerve
- Dysmenorrhea
- Muscle relaxant

TENS

- Conventional
- Burst
- Modulated pulse duration (MW)
- Massage

1 ON/OFF BUTTON

In addition to turning the device on and off, allows stimulation to be stopped at any time.

2 3 FUNCTIONS

△ 1 INCREASE

Allows the intensity of the left or right channel to be increased.
*Increases the intensity carefully, as prescribed.

△ 2 CUSTOMIZABLE PROGRAMS

3 TIMER

△ Also allows the timer to be adjusted.

3 4 FUNCTIONS

▽ 1 DECREASE

Allows the intensity of the left or right channel to be reduced.

▽ 2 LOCK

Also deactivates the lock.

▽ 3 CUSTOMIZABLE PROGRAMS

Also allows you to switch from one program to another.

▽ 4 TIMER

Also allows the timer to be adjusted.

4 PROGRAMS

PR Choice of 12 preset programs and 7 custom programs for safe and effective customized treatment.

5 SELECTION

S Hold the button down for 3 seconds to access program customization mode.
Confirm, save the selection of the current program.

6 DIGITAL SCREEN

7 TIMER

Activates the timer, allows you to set the length of treatment.
Options: 1=60 min. timer or timer on continuous mode **C** depending on your needs and the recommendations of your health care provider.

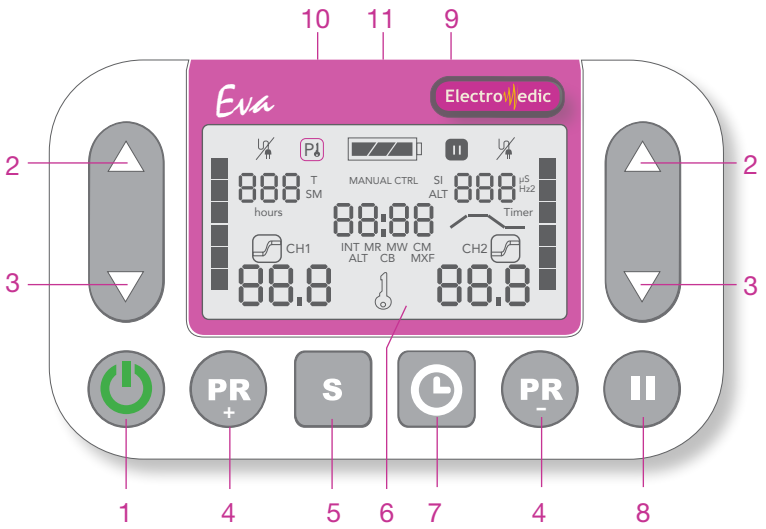
8 PAUSE

Puts the device in standby mode, brings the intensity down to zero. The intensity will then resume gradually when you press the pause button. The timer stops when the device is in pause mode.

9 CHANNEL #2 OUTPUT

10 CHANNEL #1 OUTPUT

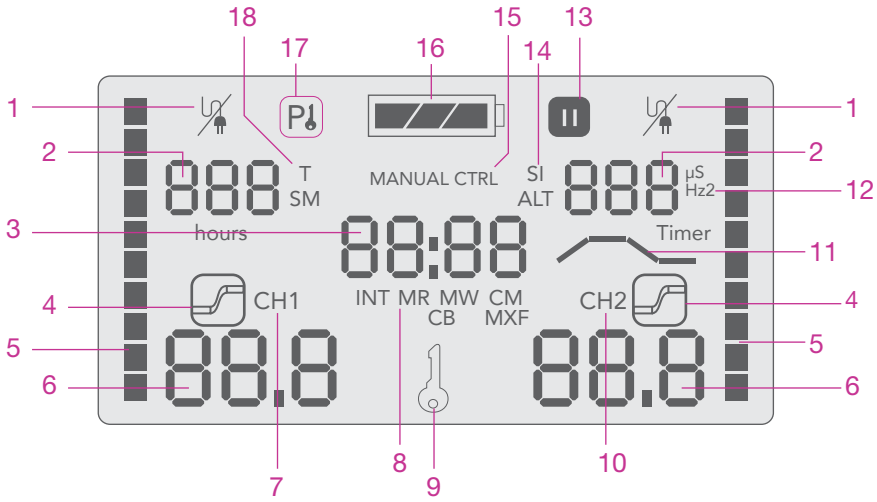
11 MANUAL CONTROLLER CONNECTOR



CONTROL BUTTONS

2.4

SCREEN DISPLAY 2.5



1 OPEN CIRCUIT
- Electrode or probe disconnected
- Poor contact of electrode or probe
- Wire breakage
- Impedance too high
- Other likely issue

2 PROGRAM
Displays the selected program.
- The left side displays the number of the channel 1 program
- The right side displays the number of the channel 2 program

3 TIMER
Displays the remaining time.

4 WORK/REST
- Work/rest indicator for intermittent stimulation programs.
- The upper part of the symbol blinks in work phase.
- The lower part blinks in rest phase.

5 INTENSITY
Intensity of the channel in graduated scale.

6 PULSE INTENSITY
Intensity of the channel represented in numbers.

7 CHANNEL 1

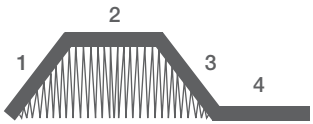
8 INDICATES THE STIMULATION MODE

9 LOCK
Indicates whether the program is locked.

10 CHANNEL 2

11 INTERMITTENT STIMULATION PHASE
This symbol shows the 4 intermittent stimulation phases. It will be displayed with customized programs that require a rest period between muscle contractions.

THERE ARE 4 PHASES:
- 1 - Ramp-up phase
- 2 - Work phase
- 3 - Ramp-down phase
- 4 - Rest phase



12 µS OR Hz DISPLAY
In selection mode, indicates whether the numerical value is in µs or Hz.

13 DEVICE IN PAUSE MODE

14 SI/ALT
- Symbol present during NMES muscle stimulation only (SM mode)
- SI: Indicates that the 2 channels are working simultaneously
- ALT: Indicates alternating between 2 channels

15 MANUAL CONTROLLER (MANUAL CTRL)
- Indicates that the stimulator is in manual mode and controlled by the manual controller.
- When the manual controller is inserted into the device, the symbol automatically appears.

16 BATTERY STATUS
Indicates the battery level in thirds (1/3 - 2/3 - 3/3)

17 LOCKED PROGRAM
Program cannot be modified.

18 T or SM
Indicates which mode the device is in:
- TENS (T)
- NMES MUSCLE STIMULATOR (SM)

3 3.1

DEVICE SETUP

FOR THE PATIENT

INSTRUCTIONS

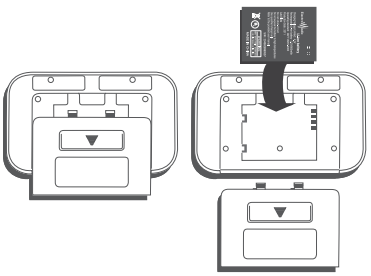
The Electro-Medic EVA stimulator gives you the option of choosing the treatment mode that best suits your needs: treatment by NMES or TENS. In addition, since it has 2 separate outputs, it allows you to treat several parts of the body at once in different modes with different intensities; some programs and parameters can be modified under the supervision of a qualified health care professional.

Do not place the device in a position where it will be difficult to quickly reach the main power source to cut it off if needed.

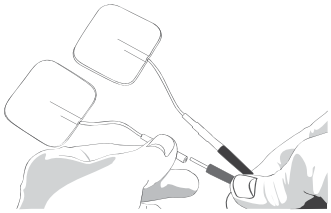
For optimal and completely safe use, only use accessories provided by Electro-Medic. In addition, setting the device to the appropriate intensity and only increasing the level gradually will provide the comfort, improvement and relief you seek. Increasing levels too quickly is not recommended.

A INSERTING THE LI-ION BATTERY INTO THE DEVICE

(Please refer to the section: REPLACING THE BATTERY 3.7 for more information)



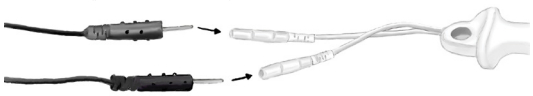
B.1 CONNECTING THE ELECTRODES TO THE WIRES



Be careful when handling the wires to avoid damaging them. The electrodes used with this device must never be smaller than 2.54 cm in size. Be aware that the smaller the electrodes are, the more intense the stimulation will be at the site of the electrodes.

B.2 CONNECTING THE PROBE TO THE WIRES

(probe not included)



Be careful when handling the wires to avoid damaging them. Please make sure that the probe is clean before use.

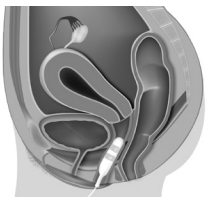
C.1 APPLY THE ELECTRODES

Apply to non-irritated skin that has been washed and dried, for the best adherence and optimal electrode performance.

C.2 INSERT THE PROBE

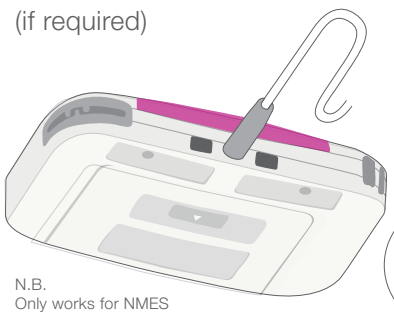
(probe not included)

Insert the probe, using the gel (recommended for maximum performance). Do not insert the probe too deeply. For more detailed information, please consult your qualified health care professional.



D CONNECT THE WIRES TO THE UNIT – NMES – AT THE INPUT FOR EACH CHANNEL

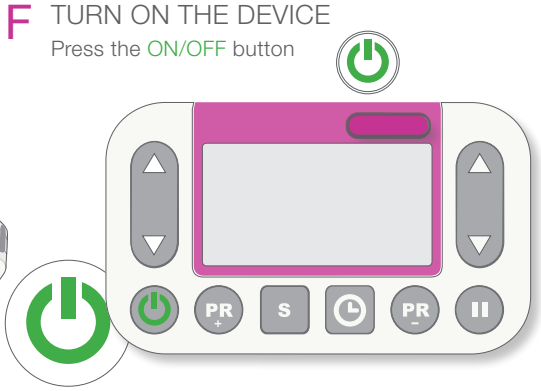
E CONNECT THE MANUAL CONTROL CONTROLLER (if required)



N.B.
Only works for NMES programs

F TURN ON THE DEVICE

Press the ON/OFF button



G SELECT A PROGRAM
(P1 to P19)

To select a program, as recommended by your qualified health care professional for your diagnosed medical condition,

press the PR button PR + or PR PR - until the desired program is displayed in region 2 on the screen or press the arrow to start treatment.

For more detailed information on the programs available, refer to section 4: PROGRAMS.

I STOP STIMULATION

STOP To stop stimulation, reduce the intensity with the down arrow until the intensity returns to 0.00 or press the On/Off button.

H START STIMULATION

Press the INCREASE button ▲ for each channel until you reach the preferred level of stimulation. Press the button and hold it down to increase the intensity continuously.
N.B. Always increase amplitude carefully.

For the following cases, refer to section 3.2:
SPECIAL INSTRUCTIONS

- Intermittent stimulation + manual controller

LOCK The safety lock symbol indicates that the key lock is activated. It will appear after 10 seconds once the intensity setting is selected. So if you would like to increase the intensity, first press the down arrow to deactivate the safety lock. You can then adjust the intensity level by pressing on the up ▲ or down ▼ arrows

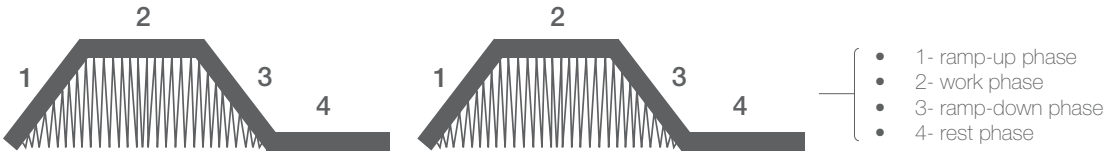
Treatment length is preset but can be changed by using the TIMER function

3.2 SPECIAL INSTRUCTIONS

Intermittent stimulation (P1 - P2 - P5 - P6 - P7 - P12)

The programs indicated above include rest periods between muscle contractions (work phase) as illustrated below.

+ manual controller (P11)



- 1- ramp-up phase
- 2- work phase
- 3- ramp-down phase
- 4- rest phase

OPERATION

The contraction increases progressively during the ramp-up phase and reaches its maximum during the work phase. During the ramp-down phase, the stimulation reduces progressively until the start of the rest phase.

During intermittent stimulation programs, the work/rest symbol  is displayed on the screen. The upper part of the symbol blinks in work phase while the lower part blinks in rest phase.

For program 11, the manual controller is used to change intensity quickly during childbirth. There are two intensity settings for this program, one for the contraction phase and one for when the contraction has finished. Once the two intensity levels have been set, you only need to press the button to toggle between them.

AMPLITUDE SETTING FOR CONTRACTIONS (work phase)

When the upper part of the work/rest symbol  is blinking, increase the intensity gradually until you achieve painless muscle contractions.

3.3 LOCK/UNLOCK A PROGRAM

To lock or unlock a program, simultaneously press the down arrow of program 2 and the **PR** button of program 2 for 10 seconds.
You will see the lock symbol, illustrated above, in the section to the left.

- To change the lock status: use the down arrows ▼ to confirm the operation.
- If the lock symbol appears: program locked, cannot be changed.
- If the lock symbol does not appear: program unlocked; the user can change the program.
  *Perform the same operation to unlock the program

3.4 TIMER

CHANGE THE LENGTH OF TREATMENT 0-60 MINUTES

- Press the Timer button and the timer will blink.
- The device will count down the elapsed time and will automatically stop once the time has run out
- For the continuous treatment option, without interruption, keep pressing until the signal **C** appears. You will need to stop the device yourself when you think the treatment has been long enough. Confirm the option selected by pressing the **S** button to save, or press the arrow ▲ to start the treatment

3.5 STOP/PAUSE AN ONGOING PROGRAM

STOP — To stop the stimulation, reduce the intensity using the down arrow until the intensity returns to 0.00 or press the On/Off button.

PAUSE — At any time during treatment, you can pause for 5 minutes.

- If the device is locked, unlock it by pressing the down arrow then pressing Pause
- The timer will stop while paused as desired
- To resume treatment, press Pause again

3.6 MANUAL CONTROLLER (MANUAL Ctrl) FOR **NMES** ONLY

- To use the manual controller, connect the wire on top of your stimulator.
  The message (MANUAL Ctrl) will appear on your screen.
- By pressing the button, you will be able to manually control your muscle contractions.
  (Work Phase/Rest Phase)

For program 11 (pain relief in childbirth), the manual controller is used to change intensity quickly during childbirth. There are two intensity settings for this program, one for the contraction phase and one for when the contraction has finished. Once the two intensity levels have been set, you only need to press the button to toggle between them.

For the other programs, the manual controller will be used to toggle between the contraction work phase and rest phase.

LI-ION BATTERY 3.7

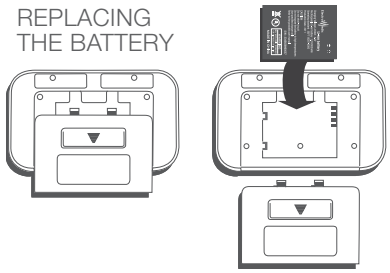
You can always check your battery level by checking the following symbol:

BATTERY STATUS As displayed: 1/3 battery 2/3 battery 3/3 battery

You may continue treatment as long as the stimulator is operating normally. When the effect of stimulation diminishes or the stimulator turns off, it is time to recharge the battery. If you are not using the stimulator for a period of time (approximately three months), it is preferable to remove the stimulator battery.

The stimulator only works with an Electro-Medic 4.2V lithium-ion battery.

REPLACING THE BATTERY



BATTERY LIFE EXPECTANCY

The typical life of a lithium-ion battery is approximately:

- Three (3) years
  or
- 300 charge cycles
  a charge cycle refers to a complete discharge followed by a complete recharge of the battery.

N.B. ONLY USE AN ELECTRO-MEDIC LI-ION BATTERY FOR THE STIMULATOR AND THE ELECTROMEDIC CHARGER TO RECHARGE THE BATTERY.

LI-ION BATTERY CHARGER

LED INDICATOR LIGHT FEATURES

- Adaptor (Model: JKY36-MDA534627)EN
- Input: 100 V-240 V~, 50/60 HZ, 150 mA
- Output: 4.2 V , 650 mA
- Red light: recharging
- Yellow light: recharging
- Green light: no battery in charger or battery fully charged

CHARGER

- Input: 4.2V input
- Output: 4.2V output
- Green light: fully charged
- Green light: device plugged in without battery

THE PATIENT IS THE DESIGNATED OPERATOR

The patient can operate the buttons and change the battery under normal conditions and can maintain the device and its accessories according to the user guide

ATTENTION!

- Use only Electro-Medic rechargeable Li-ion batteries
- NEVER reverse the (+) and (-) terminals when connecting them or let the batteries come into contact with metal objects (necklaces, hairpins, etc.)
- NEVER charge Li-ion batteries for longer than 72 hours
- The battery charger must comply with IEC 60601-1 standards

SAFETY MEASURES

- Do not expose the equipment to fire, direct sunlight or other heat sources, which may cause a fire or explosion, or generate toxic gases
- Do not store or transport the device with metal objects
- Do not disassemble or modify the device components
- Avoid all contact with water or any other liquid

INSTRUCTIONS FOR USING THE CHARGER

- Insert a Li-ion battery. Align the connection terminals (+) and (-) correctly
- Plug the charger into a standard wall outlet
- A red or yellow LED indicates charging
- When fully charged, the LED turns green. Unplug the charger and remove the battery

CHARGING TIME

- A Li-ion battery takes about 3.5 hours to charge.

LI-ION BATTERY

- Limited voltage: 4.2 V
- Rechargeable Li-ion battery: 3.7 V/600 mAh

ADAPTOR

- 100-240 v 50-60 Hz, 1.2A

The adaptor is a 2MOPP piece of equipment under IEC 60601-1-1. Approval of the equipment is valid if used in combination with the adaptor provided with this equipment.

ATTENTION

- This equipment must never be connected with an adaptor other than the adaptor provided with the Electro-Medic equipment.

SAFETY MEASURES

- Do not cause a short-circuit
- Do not expose the device to high temperatures
- Use the charger only as specifically recommended

Colours of indicator lights and their meaning

red	The operator must respond immediately
yellow	The operator must respond quickly
green	Ready to use
Other	Other meaning

SAFETY CLASSIFICATION OF ELECTRO-MEDIC EQUIPMENT

Protection from electric shock	Internally powered Electro-Medic device
Applied part	Type BF applied part: Electrodes
Electrical equipment protected against harmful ingress of water or particulate matter.	IP22
Operating mode	Continuous operation

Note: Not intended to be sterilized. Not for use in an oxygen-rich environment.

Do not position the device in a way that would make it difficult to reach the main power source and that might prevent the device being switched off rapidly if needed.

4

	Program	Title	Frequency (Hz)	Pulse duration (µs)	PHASE (IN SECONDS)				Timer	Modifiable program
					Ramp-up	Work	Ramp-down	Rest		
PRESET PROGRAMS	1	Stress incontinence 1 (Strength)	50 Hz	250	1	5	1	10	20	no
	2	Stress incontinence 2 (Strength)	75 Hz	250	1.5	4	1.5	12	20	no
	3	Urge urinary incontinence 1	8 Hz	180	-	-	-	-	30	no
	4	Urge urinary incontinence 2	5 Hz	180	-	-	-	-	30	no
	5	Stress incontinence 3 (Strength)	20 Hz	250	2	30	2	30	20	no
	6	Mixed incontinence 1	Strength 75 Hz Endurance 5 Hz	250	1.5	(Strength 75 Hz) 4	1.5	(Endurance 5 Hz) 23 secs	30	no
	7	Mixed incontinence 2	Strength 50 Hz Endurance 5 Hz	250	1.5	(Strength 50 Hz) 10	1.5	(Endurance 5 Hz) 30 secs	30	no
	8	Stimulation of posterior tibial nerve	5 Hz	200	-	-	-	-	30	no
	9	Dysmenorrhea/Endometriosis	85 Hz	150	-	-	-	-	-	no
	10	Muscle relaxant	5 Hz	80-150	-	-	-	-	30	no
	11*	Pain relief in childbirth	80 Hz	150	0	HIGH FREQUENCY, with manual controller: 2 settings for the 2 phases, when there is a contraction and when there is no contraction			C	no
	12	Muscle strengthening (Strength)	50 Hz	400	4	10	2	30	10	no
TENS	13	Conventional	80 Hz	150	-	-	-	-	30	yes
	14	Modulated pulse duration	80 Hz	80-150	-	-	-	-	30	yes
	15	Burst	2 Hz	250	-	-	-	-	20	yes
	16	Massage	7-15 Hz	250	-	-	-	-	30	yes
CUSTOMIZABLE PROGRAMS	17	NMES/TENS	1-150 Hz	40-400	-	-	-	-	30	yes
	18	NMES/TENS	1-150 Hz	40-400	-	-	-	-	30	yes
	19	NMES/TENS	1-150 Hz	40-400	-	-	-	-	30	yes

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CUSTOMIZABLE PROGRAMS

CUSTOMIZATION

With the Electro-Medic Stimulator, you can customize and save three custom programs (P17 to P19) for patient-specific treatment.

To create a custom program, follow the programming procedure below.

5.1 PROGRAMMING MUSCLE STIMULATOR **NMES** (SM)

Press the ON/OFF button.

Press the PROGRAM button PR + OR PR - to go to the next program or return to the previous program until the program is at P17-P19.

Press the **S** (SELECT) button S and hold it down for 3 seconds in order to enter programming mode.
(Please refer to the programming chart (6.0) for the next steps.)

1 STEP 1

The first step is to choose between:

SM: NMES Muscle Stimulator

or T: TENS

Press the INCREASE (or DECREASE) button ▲▼ to go from SM to T and vice versa.
Confirm your selection by pressing the **S** (SELECT) button S

2 STEP 2

For this step, you will be directed to make the following 2 selections:

- Simultaneous stimulation (SI)
- Alternating stimulation (ALT)

Press the INCREASE (or DECREASE) button ▲▼ to go from SI to ALT and vice versa.
Confirm your selection by pressing the **S** (SELECT) button S

3 STEP 3

The available types of stimulations at this level depend on your previous selections.

Press the INCREASE (or DECREASE) button ▲▼ to display the different types of stimulations available on the screen.
The programming chart (6.0) indicates the different settings that are possible for each type of stimulation.
Confirm your selection at each step by pressing the **S** (SELECT) button S

5.2 PROGRAMMING TENS (T) INDEPENDENT CHANNELS

Press the ON/OFF button.

Press the PROGRAM button PR+ OR PR- to go to the next program or return to the previous program until the program is at P17-P19.

Press the **S** (SELECT) button S and hold it down for 3 seconds in order to enter programming mode.
(Please refer to the programming chart for the next steps.)

1

STEP 1
CHANNEL #1

The first step is to choose between:

SM: NMES Muscle Stimulator

or **T**: TENS

Press the INCREASE (or DECREASE) button ▲▼ to go from **SM** to **T** and vice versa.

Confirm your selection by pressing the **S** (SELECT) button S

2

STEP 2

Press the INCREASE (or DECREASE) button ▲▼ to display the different types of stimulations available on the screen.

The programming chart (6.0) indicates the different settings that are possible for each type of stimulation.

Confirm your selection at each step by pressing the **S** (SELECT) button S

Types of stimulation for the TENS mode

- Conventional (**C**)
- Burst (**B**)
- Pulse duration modulation (**MW**)
- Pulse frequency modulation (**MR**)

3

STEP 3
CHANNEL #2

- Repeat the previous steps for channel #2
- Confirm your selection at each step by pressing the **S** (SELECT) S

6 PROGRAMMING CHART

MAINTAINING AND CLEANING THE DEVICE

Maintaining and cleaning the device are relatively

simple

- Always store the stimulator and its accessories in the case provided.
- No maintenance is required for the stimulator. The lifespan of the device may vary depending on the conditions of use, but it is generally around 5 years (5-year warranty on the devices); the accessories may need to be changed beforehand depending on how the device is used
- Never tamper with the device while in use.
- Never expose the stimulator to water. Wipe the device with a damp cloth as needed.
- Use the silicone pouch to protect your stimulator at all times.
- Disconnect wires and fittings carefully and properly.
- You may leave the wires plugged into your stimulator between treatments.
- Battery
  To maintain the battery amperage at its optimum level, the battery should be removed from the unit when not in use for an extended period (approx. 3 months).
- If you use carbon electrodes, use a large amount of conductive gel and prevent them from drying out by applying an adhesive tape (supplied in the kit). Rinse the carbon electrodes and your skin after use. Never use detergent to clean carbon electrodes
- For self-adhesive electrodes, you can moisten them with a little water after treatment to restore their adhesiveness. Keep them in an airtight place (such as a plastic bag). It also is important to cover them with their protective film after use and when they are not in use.
- Probe (not included)
  Clean the probe using soapy water or in accordance with the manufacturer's instructions.
- Contact the manufacturer for help with installing and using or maintaining the equipment or to report any unusual events.

STORAGE AND WAREHOUSING CONDITIONS

- The device should be transported and stored within a temperature range of -10°C to 60°C, at a barometric pressure of 700 hPa to 1060 hPa and a relative humidity of 15 to 75%.

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TROUBLESHOOTING

8

PROBLEM	POTENTIAL SOLUTION	ACTION
Broken screen	None	Contact your distributor
Display problem	None	Contact your distributor
Detached part	None	Contact your distributor
The device does not light up at all	Is the battery correctly inserted?	• Try changing the battery • Charge the battery
Symbol appears Intensity increases, but no current	Check the condition of the wires	• Try changing the wire • Try the other channel with the same wire
Symbol appears Intensity stays at 1 and does not increase	Check the condition of the wires	• Try changing the wire • Try the other channel with the same wire • Check the wire for twisting • Check the connector for damage
Symbol appears	• Are the electrodes on your skin? • Are the electrodes at the end of their life? • Is the contact with your skin good? • Check the condition of the wires • Resistance too high between the electrode and the skin	• Try with the carbon electrodes • Change the self-adhesive electrodes • Try the other channel
Symbol appears	• Is the probe inserted correctly? • Is the probe connected correctly? • Is the probe lubricated correctly?	• Remove the probe and reposition • Remove the probe, check the connection with the wires • Add some conductive gel to the probe
The device switches on and off	Check the battery Or the battery compartment	• Try changing the battery • Check that the battery is properly secure in the compartment
The current is unstable	• Does the program allow you to really feel the current? • Is the wire tangled? • Is the electrode correctly stuck to the skin?	• Test with P13 (Conventional) • Try the other channel • Try with carbon electrodes
The effect of stimulation is weak or nonexistent	• Check the status of the battery • Check the program you are using • Try on a healthy muscle (NMES)	• If the problem persists, consult your qualified health care professional
Stimulation does not produce the usual sensation	• Check the setting parameters • Slightly change the position of your electrodes	• If the problem persists, consult your qualified health care professional
Stimulation causes discomfort	• There is skin irritation • There is not sufficient contact between the electrode and your skin • The self-adhesive electrodes are worn out • There is not enough conductive gel on the carbon electrodes • The positioning of the electrodes is not optimal	• If the problem persists, consult your qualified health care professional

NB: To reduce risks to the patient and avoid damage to the stimulator, never increase the intensity (amplitude) above 20 mA when testing for a possible wire breakage. For more information, do not hesitate to contact your point of sale or authorized distributor.

9 WARRANTY

The manufacturer, Electro-Medic, affirms that Electro-Medic muscle stimulators are free from material and manufacturing defects at the time of delivery.

All Electro-Medic devices come with a 5-year warranty that starts on the date of purchase

THE ELECTRO-MEDIC WARRANTY applies only to the device and does not cover any accessories (wires, batteries, charger), which are covered by a 3-month warranty.

The warranty can be claimed only by the purchaser of a new product upon presentation of proof of purchase.

Electro-Medic, after verifying that the device is defective, will replace the product if it is still under warranty.

Any modification, misuse, improper use or accidental damage, and any repair made by a third party will cancel this warranty.

In case of a problem and for warranty purposes, the defective device will be shipped to the point of sale during the warranty period and the point of sale will follow up on your request with the manufacturer as soon as possible.

10 FAQ

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IS NEUROMUSCULAR ELECTRICAL STIMULATION FOR THE PELVIC AND PERINEAL REGION ACCESSIBLE TO EVERYONE?

People who have no contraindications or precautions can use the muscle stimulator. Please read the Indications, Contraindications and Precautions section of your user manual carefully.

To ensure safe and efficient use, the supervision of a heath care professional is recommended the first time you use the muscle stimulator in order to receive appropriate training and instructions on how to position the electrodes and configure the stimulator.

WHAT ARE THE ADVANTAGES OF USING THE MANUAL CONTROLLER?

The manual controller is used to change intensity quickly during childbirth. In program 11 (pain relief in childbirth), there are two intensity settings for this program, one for the contraction phase and one for when the contraction has finished. Once the two intensity levels have been set, you only need to press the button to toggle between them.

N.B. The preset length of the work phase may be shortened but not lengthened.

It is therefore preferable to use a program with longer work phase when you are using the manual controller.

N.B. The manual controller does not work with alternating stimulation.

HOW DO I FIND OPTIMAL ELECTRODE POSITIONS FOR NMES EXTERNAL TREATMENT?

Follow the recommendations of your qualified health care professional for optimal electrode positioning.

To start, we recommend using the carbon electrodes and gel in order to find the right contraction. The optimal electrode position is the place where you get the strongest motor response.

HOW MANY TIMES CAN SELF-ADHESIVE ELECTRODES BE USED?

Self-adhesive electrodes can be used between 15 and 20

times. How long they can be used depends, however, on following maintenance and cleaning instructions and on the patient's skin type.

HOW LONG SHOULD A STIMULATION SESSION LAST?

NMES: depending on the condition of the patient's muscles and the patient's progress in the rehabilitation process, treatment may last from 5 to 30 minutes. Always follow the recommendations of your qualified health care professional.

N.B. Patients may experience some soreness following NMES treatment.

TENS (high frequency): 30 to 60 minutes per session. Repeat as needed, with no limit on the number of sessions per day.

TENS (low frequency): 20 minutes per session and a maximum of three times per day.

N.B. Patients may experience some soreness following low-frequency treatment.

WHY CAN'T I FEEL THE CONTRACTION?

- The intensity may not be high enough; increase the intensity gradually without reaching a point where you feel pain.
- The electrodes may not be in an optimal position (motor point). Try moving the electrodes on the muscle to be stimulated, consult your qualified health care professional.
- The settings may not be optimal for your condition. Consult your qualified health care professional to check the settings.
- If you have a significant muscular atrophy, the smaller number of muscle fibres may not be able to generate visible muscle contractions. Consult your qualified health care professional to confirm.
- In some people, a visible contraction is very difficult to obtain even on healthy muscles. Compare by stimulating the same muscle on the healthy side. If there is a significant difference, consult your qualified health care professional.

CAN A MUSCLE STIMULATION SESSION REPLACE ACTIVE EXERCISE FOR STRENGTHENING?

No. Muscle stimulation can:

- Help to improve the quality of contractions in addition to exercise.
- Maintain muscle function or prevent atrophy when active exercise is not possible or not optimal.
- Contribute to motor learning.

INTERNAL USE

HOW DO I KNOW WHETHER MY VAGINAL OR ANAL PROBE IS POSITIONED CORRECTLY?

There should not be any discomfort when the probe is positioned correctly. For any other questions on probe location, please consult your qualified health care professional.

WHY CAN'T I FEEL THE CURRENT, DESPITE A HIGH LEVEL INTENSITY SETTING?

- The vaginal walls are not properly contact with the metal part of the probe. Please consult your qualified health care professional to find an alternative solution.
- Hyposensitivity in the tissues of the vagina. Please consult your qualified health care professional to find an alternative solution.

IS THE STIMULATION PAINFUL?

No. You may experience some discomfort if the intensity is too high, if there is any irritation of the mucous membranes or if you are not using sufficient gel or lubrication.

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DOCUMENT HISTORY

DESIGNED BY ELECTRO-MEDIC

650 Boul. Industriel suite 100 Blainville Qc Canada J7C 5Y7
1 855 230 6334
info@electromedic.ca / www.electromedic.ca

IN COLLABORATION WITH

Service d'Électro-Thérapie (SET)
1 800 761-1183
canadaset.com

For information about how to use your Electro-Medic muscle stimulator, please contact your authorized distributor.

INFORMATION ABOUT ELECTROMAGNETIC COMPATIBILITY

Tested and approved according to safety standards
IEC 60601-1 / IEC 60601-1-2 / IEC 60601-2-10

Wireless communication devices such as wireless home appliances, cell phones, cordless telephones and their bases, and walkie-talkies may affect the operation of the equipment and should be kept at least 3.3 metres away. (Note: as indicated in table 6 of IEC 60601-1-2: 2007 for Electro-Medic equipment, a typical cell phone with an output of 2W d=3.3m with an immunity level of 3 V/m)

Complete EMC tables are available from TENSCARE upon request.

The Electro-Medic EVA stimulator is designed to withstand foreseeable interference caused by electrostatic discharges (ESD), magnetic fields from mains power, and radio-frequency transceivers such as cell phones.

12 LEGEND


Read the instruction manual before using the stimulator


Type BF Equipment - Type BF Isolated Part (floating)


Dispose of the device, batteries and accessories according to applicable recycling standards


Class II equipment


AC

DC

Protection index

Barcode

Serial number


Manufacturer

Manual version 1.0

Software version 1.0